COVID-19
QUALITY OF LIFE AND RISK ATTITUDES AMONG INSULIN PUMP USERS IN A TIME OF CRISIS

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People with diabetes compared with people without exhibit worse prognosis if affected by COVID-19 induced by the SARS-CoV2, particularly when compromising metabolic control and concomitant cardiovascular disorders are present. This perspective article seeks to explore newly occurring cardio-renal-pulmonary organ damage induced or aggravated by the disease process of COVID-19 and its implications for the cardiovascular risk management of people with diabetes, especially also taking into account potential interactions with mechanisms of cellular intrusion of SARS-CoV2. Severe infection with SARS-CoV2 can precipitate myocardial infarction, myocarditis, heart failure, and arrhythmias as well as an acute-respiratory-distress-syndrome and renal failure. They may evolve along with multi-organ failure due to directly SARS-CoV2 infected endothelial cells and resulting endotheliitis. This complex pathology may bear challenges for the use of most diabetes medications in terms of emerging contraindications that need close monitoring of all people with diabetes diagnosed with SARS-CoV2-infection. Whenever possible, continuous-glucose-monitoring should be implemented to ensure stable metabolic compensation. Patients in intensive-care-unit requiring therapy for glycemic control should solely be handled by intravenous insulin using exact dosing with a perfusion device. Although not only ACE-inhibitors and angiotensin-2-receptor-blockers, but also SGLT2-inhibitors, GLP1-receptor-agonists, pioglitazone, and probably insulin seem to increase the number of ACE2-receptors on the cells utilized by SARS-CoV2 for penetration, no evidence presently exists that this might be harmful in terms of acquiring or worsening COVID-19 with unequivocal proof urgently awaited. In conclusion, COVID-19 and related cardio-renal-pulmonary damage can profoundly affect cardiovascular risk management of people with diabetes.
An increasing number of Automated Insulin Delivery (AID) devices are available for commercial use for persons with diabetes. Typically, industry trainers are responsible for onboarding users to the new technology, and there is no universal clinical follow-up in the first few months of use. Ideal onboarding to AID systems should include a) thorough pre-AID education on general diabetes self-management, carbohydrate counting, insulin pump and continuous glucose monitoring basics, and expectations for AID systems b) Actual device training via face-to-face or teleconference based training, and c) clinical follow-up with diabetes professionals in the first 2-6 weeks of use for device optimization, troubleshooting, and reinforcing expectations. Clinical centers should consider ways to implement pre-AID education and post-AID clinical follow up for new AID device users to mitigate the risk of potential device discontinuation or unsafe practices.

PARALLEL SESSION 03: PREGNANCY AND TECHNOLOGY

PREGNANCY OUTCOMES OF 17,375 WOMEN WITH DIABETES: NATIONAL POPULATION-BASED COHORT STUDY

LIVE QA: PARALLEL SESSION 03: PREGNANCY AND TECHNOLOGY

Background: Our aim was to compare risk factors associated with adverse pregnancy outcomes in women with type 1 and type 2 diabetes.

Methods: We included 17,375 pregnancies in 15,290 women with diabetes in a population-based cohort study across 172 maternity clinics. Obstetric complications (preterm delivery, large birthweight) and adverse pregnancy outcomes (congenital anomaly, stillbirth) were obtained for pregnancies during 2014-2018. We assessed associations between modifiable (glycaemia, obesity, clinic) and non-modifiable risk factors (age, deprivation, ethnicity) with pregnancy outcomes.

Results: Of 17,375 pregnancies, 8,690 (50.0%) were in women with type 1 and 8,685 (50.0%) in women with type 2 diabetes. The rates of preterm delivery (42.5% type 1, 23.4% type 2), and large birthweight (52.2% type 1, 26.2% type 2) were higher in type 1 diabetes.

Interpretation: No clinics were achieving appreciably better outcomes, suggesting that healthcare system changes are needed across all clinics.

026 / #858

PARALLEL SESSION 04: SPORT AND DIABETES

DECISION SUPPORT AND CLOSED LOOP CONTROL DURING EXERCISE: NEW FINDINGS FROM CLINICAL STUDIES AND LARGER DATA SETS

P. Jacobs

Exercise remains a challenge for people with type 1 diabetes. Hypoglycemia during and following exercise is a common problem. People with type 1 diabetes oftentimes have difficulty maintaining normal glucose levels during and following exercise. Automated hormone delivery and decision support systems can provide assistance in adjusting dosing in response to various types of exercise to help people with type 1 diabetes avoid hypoglycemia and maintain glucose within a target range. These automated systems and decision support systems rely on expert knowledge and predictive models that can determine adjustments to hormone dosing, food consumption, or behavior interventions. We show how we used data collected under both free-living conditions and data collected from highly controlled glucose clamp physiology studies during and following different types of exercise to build glucose forecasting models. We show how aerobic and resistance exercise models of metabolism are designed using ordinary differential equations (ODE) and Markov Chain Monte Carlo system identification methods with data collected from two studies of people with type 1 diabetes undergoing three glucose clamp studies under three different insulin loading conditions (1x, 1.5x, and 3x basal infusion rate) and at moderate and intense exercise. And we show how data-driven models are trained using larger data sets and machine learning to predict the impact of free-living exercise on glucose changes during and following exercise, including nocturnal hypoglycemia on nights following exercise. We provide demonstrations of how the ODE and machine learning algorithms are integrated into automated hormone delivery and decision support systems,

027 / #859

PARALLEL SESSION 04: SPORT AND DIABETES

CLOSED-LOOP AND PHYSICAL ACTIVITY IN YOUTH WITH TYPE 1 DIABETES

K. Dovc
Closed-loop glycemic control, characterized by glucose-responsive automated insulin, is now a part of regular clinical reality for many individuals living with type 1 diabetes. The management of type 1 diabetes during exercise is complex. At the same time, dosing insulin adequately in advance of activity or in real-time can generate positive outcomes and reduce the likelihood of hypoglycemia.

The performance of closed-loop glycemic control in individuals with type 1 diabetes during and after the physical activity has been extensively evaluated, especially in the controlled environment, while there is less data regarding unsupervised physical activity in home settings. Closed-loop therapy was in the past challenged with different exercise protocols of different durations and intensity, in heterogeneous age groups, with additional devices to detect physical activity, such as activity and heart rate monitoring, and adding glucagon to prevent hypoglycemia.

In this presentation, we will present contemporary data on closed-loop glycemic control challenged by physical activity in children, adolescents and young adults with type 1 diabetes.

029 / #861
PLENARY SESSION 02: ADVANCES IN CLOSED-LOOP SYSTEMS – LESSONS LEARNT FROM CLINICAL STUDIES
PERFORMANCE OF STUDIES ON ADVANCE HYBRID CLOSED-LOOP 780G
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There have been major advancements in automated insulin delivery systems in the past several years, with hybrid closed-loop systems offering patients new means to manage their diabetes. Such systems rely on algorithms to modulate the insulin delivery, increasing or decreasing insulin delivery based upon programed target glucose, patient-entered carbohydrates and correction boluses that can be user or device initiated. The MiniMed™ Advanced Hybrid Closed Loop (AHCL) system, or MiniMed™ 780G, is a new iteration of pump therapy that has a target set point of either 100 mg/dL (5.6 mmol/L) or 120 mg/dL (6.7 mmol/L), along with automated corrections that can deliver boluses every 5 minutes as needed. The MiniMed™ 780G system has been studied for safety and efficacy in recent trials. The largest trial was a multi-site pivotal trial of 39 adolescents (age 14-21 years) and 118 adults (>22 years) during which patients with type 1 diabetes used either the 100 mg/dL or 120 mg/dL set point for approximately 45 days, and then crossed over to the other set point for another period of about 45 days. For the overall study group, time in range (70-180 mg/dL/ 3.9 mmol/L-10 mmol/L) increased from 68.8% to 74.5% (p=0.001). For those using the set point of 100 mg/dL and an active insulin time of 2 hours, time in range increased to 78.8%. Auto Mode was in use for 95% of the time for both set points during the study. Of the total bolus insulin delivered during the study, approximately 22% of this was administered by the auto-correction function. Time in hypoglycemia was reduced in both adolescents and adults, and there were no DKA or severe hypoglycemia events. Additional studies have compared the MiniMed™ 780G system against both the first commercially available hybrid closed-loop system in the United States, the MiniMed™ 670G, and to a system with predictive low glucose threshold suspend MiniMed™ 640G. Both studies concluded the AHCL system provided improved glycemic control without increasing time in hypoglycemia. The MiniMed™ 780G has consistently demonstrated improved time in range without increasing time below range, and has been safe in the trials to date. The system also seemed to have improved user experience with patient-selected targets and fewer Auto Mode exits.

030 / #862
PLENARY SESSION 02: ADVANCES IN CLOSED-LOOP SYSTEMS – LESSONS LEARNT FROM CLINICAL STUDIES
PIVOTAL TRIAL AND REAL-LIFE DATA OF A CLOSED-LOOP CONTROL (CLC) SYSTEM - CONTROL IQ
B. Kovatchev
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In 2018-2020, two randomized controlled pivotal trials tested a new CLC system - Control-IQ® from Tandem Diabetes Care - based on an algorithm developed at the University of Virginia. Both studies were part of the International Diabetes Closed-Loop (iDCL) Trial sponsored by NIH/NIDDK. NCT03563313 randomized 168 participants ages 14 years or older to Control-IQ vs. sensor-augmented pump (SAP) and met all primary and secondary outcomes. The time in range (TIR, 70-180mg/dL) increased in the Control-IQ group by 11%, compared to SAP, and the time below range (TBR) was reduced by 0.9%, without severe hypoglycemia. NCT03844789 randomized 101 participants ages 6-13 and achieved similar outcomes: Control-IQ compared to SAP resulted in 11% increase in TIR, 0.4% reduction in TBR without severe hypoglycemia, and reduction of HbA1c by 0.4%. Two papers in the New England Journal of Medicine presented the complete results, leading to FDA clearance of this system for use by children and adults ages 6 and up. In February 2021, one-year real-life data became available for 9,451 users of Control-IQ with type 1 and type 2 diabetes. The median percent time in automated control was 94.2%; TIR increased from 63.6% at baseline 73.6% during Control-IQ use; TBR remained consistent at approximately 1%, and the Glucose Management Indicator (GMI) was reduced from 7.2 at baseline to 6.9. We can therefore conclude that the outcomes of the two pivotal trials of this system were replicated during 1-year real-life use by thousands of children and adults with type 1 or type 2 diabetes.
The advent of big data and artificial intelligence opens new perspectives for diabetes mellitus monitoring and management. Yet, complexity and uniqueness of the human body hardly allow to define a general statistical approach able to accurately predict blood glucose variations in all patients. Our technology, MIND, is a personalized, patient-specific blood glucose level (BGL) prediction service integrated in a diabetes management platform. For each patient, a machine Learning model is created using his/her historical data, including BGL and insulin inputs collected through wide-spread devices and meals recorded by the patient when available. The CDDIAB study conducted in 2018 demonstrated that our prediction technology is accurate enough to allow safe therapeutic decisions; an extension of this study conducted in 2019 showed that accurate BGL predictions drive better decision making on treatment options than patient alone. The positive outcomes of this study triggered new research cases. First, the technology is tested on another patient cohort to assess its robustness; then, the confidence in the prediction provided is studied. The second point is essential for large-scale industrialization. Hence the study of a confidence index and an envelope curve, to provide visual insights of the accuracy and an additional security on the predictions. Based on our results, the next challenge is to predict accurate bolus doses given the historical data and the predicted BGL. Another challenge is to build a system able to detect and reconstruct meals, thus meal management and the predicted BGL.

To define a general statistical approach able to accurately predict blood glucose variations, a personalized, patient-specific blood glucose level (BGL) prediction service integrated in a diabetes management platform is needed. For each patient, a machine learning model is created using his/her historical data, including BGL and insulin inputs collected through wide-spread devices and meals recorded by the patient when available. The CDDIAB study conducted in 2018 demonstrated that our prediction technology is accurate enough to allow safe therapeutic decisions; an extension of this study conducted in 2019 showed that accurate BGL predictions drive better decision making on treatment options than patient alone. The positive outcomes of this study triggered new research cases. First, the technology is tested on another patient cohort to assess its robustness; then, the confidence in the prediction provided is studied. The second point is essential for large-scale industrialization. Hence the study of a confidence index and an envelope curve, to provide visual insights of the accuracy and an additional security on the predictions. Based on our results, the next challenge is to predict accurate bolus doses given the historical data and the predicted BGL. Another challenge is to build a system able to detect and reconstruct meals, thus meal management and the predicted BGL.

**035 / #867**

PARALLEL SESSION 05: ARTIFICIAL INTELLIGENCE (AI): TANGIBLE APPLICATIONS TO IMPROVE DIABETES CARE

**AI UPDATES AUTOMATED INSULIN DELIVERY TOWARDS A FULLY CLOSED-LOOP**

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The Bio-inspired Artificial Pancreas (BiAP) is an advanced hybrid closed-loop insulin delivery system based on mathematical modelling of the pancreatic beta-cell physiology. BiAP incorporates an innovative adaptive meal-insulin bolus calculator which uses artificial intelligence to provide adaptive and individualised mealtime insulin dosing by learning from past post-prandial glycaemic outcomes, user behaviour, and controller’s functioning. The BiAP control algorithm is designed for embedded low-power solutions. It has been implemented in a dedicated microchip-based handheld device and, more recently, in an iPhone connected to a Dexcom G6 continuous glucose sensor, a Tandem t:slim AP insulin pump, and a dedicated remote web-based platform. BiAP has been successfully assessed in-clinic and an ambulatory crossover randomised controlled trial is planned to evaluate its longer-term clinical effectiveness. In this talk, we review the latest algorithmic and software developments within BiAP, as well as the results of a realistic in-silico head-to-head comparison of the BiAP controller and an open-source do-it-yourself (DIY) artificial pancreas controller. Finally, the latest developments on enhancing BiAP with a machine learning-based meal detection algorithm will be introduced.

**044 / #879**

PARALLEL SESSION 07: DIGITAL/VIRTUAL DIABETES CLINICS

MANAGING T1D-NEW-ONSETS AND DKA THROUGH TELEHEALTH

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Since December of 2019, the COVID-19 outbreak has affected more than 215 countries, translating to more than 125 million cases worldwide of COVID-19 at the time of this writing. More than 2.8 million people have died from COVID-19 across the globe; specifically, in the USA and South America, there have been more than 30 million cases reported, with a total of 560,000 deaths due to the virus. The exact prevalence of infection is currently unknown. However, it is commonly believed that ~70-80% of the population will need to be infected or vaccinated for herd immunity to be effective. Many new-onset patients with type 1 diabetes delayed seeking medical advice during COVID-19 because of the risk of getting infected. Many hospitals noted a higher number of patients presenting with diabetic ketoacidosis because of the delay in diagnosing type 1 diabetes. Similar concerns were noted by many of the physicians managing diabetes during pregnancy. However, in many instances, most diabetes care including patients with DKA could be effectively managed remotely by using newer technologies like CGM, insulin pumps, and hybrid closed-loop systems. In several instances, even the pump and CGM initiation were initiated remotely with no adverse outcomes. The virtual care gave a similar or better Time in Range (TIR) for glucose levels with no increase in Time Below Range during the virtual care period, irrespective of how patients were treated (whether it was remotely or in-person).

Introduction and Objectives: Project ECHO (Extension for Community Healthcare Outcomes) is a tele-education outreach model seeking to democratize specialty knowledge, reduce
disparities, and improve outcomes. Limited access to endocrinologists forces many primary care providers (PCPs) to care for patients with T1D without specialty support. Accordingly, an ECHO T1D program was developed and piloted in Florida and California. Our goal was to demonstrate feasibility and improve PCPs’ abilities to manage patients with T1D. Methods: Health centers (i.e. spokes) were recruited through an innovative approach, focusing on Federally Qualified Health Centers (FQHC) and through identification of high-need catchment areas using the Neighborhood Deprivation Index (NDI) and provider geocoding. Participating spokes received weekly tele-education provided by the University of Florida and Stanford University hub team, real-time support with T1D medical decision making, access to diabetes support coaches, and access to an online repository of resources. Participating PCPs completed pre/post-tests assessing diabetes knowledge and confidence and exit surveys. Results: In Florida, 12 spoke sites enrolled with 67 clinics serving >1,000 patients with T1D. In California, 11 spoke sites enrolled with 37 clinics serving >900 patients with T1D. During the 6-month intervention, 27 tele-education clinics were offered and n = 70 PCPs (22 from Florida, 48 from California) from participating spoke sites completed pre/post-test surveys assessing knowledge and confidence in diabetes care. There was statistically significant improvement in knowledge (p ≤ 0.01) and diabetes confidence (p ≤ 0.01). Conclusions: ECHO T1D’s pilot demonstrated proof of concept for a T1D-specific ECHO program and represents a viable model to reach medically underserved communities.

052 / #954
PARALLEL SESSION 08: JDRF
FUTURE OF ADJUNCTIVE THERAPY: SIMPLIFYING THE TREATMENT OF T1D THROUGH GK ACTIVATION

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Despite more physiologic insulin analogs, continuous glucose monitoring (CGM), and continuous subcutaneous insulin infusion (CSII) therapy, a minority of patients with type 1 diabetes (T1D) achieve adequate glycemic control, and hospitalizations for diabetic ketoacidosis (DKA) and hypoglycemia are increasing globally. Several therapies for the treatment of type 2 diabetes have been evaluated as potential adjunctive treatment for T1D, however they have either had no effect in T1D or improved glycemic control, but at increased risk for life-threatening complications like DKA or hypoglycemia. Approaches that harness the body’s existing glucose regulatory machinery may be the solution to the need for adjunctive therapies providing effective glycemic control while minimizing the frequency and severity of hypoglycemia and DKA. The novel hepato-selective glucokinase (GK) activator TTP399 was developed to preserve the physiologic relationship between GK and GK Regulatory Protein. Therefore, TTP399 only enhances GK activity during periods of hyperglycemia, thus limiting risk of hypoglycemia. The data from the SimpliciT1 study, showed the potential of TTP399 to significantly lower HbA1c, improve time in range, and reduce hypoglycemia in the absence of an increase in blood ketones. If confirmed in phase 3, adding TTP399 to insulin would represent a substantial improvement over insulin administration alone for the treatment of T1D. While a cure for T1D remains the long-term objective, novel adjunctive therapies such as TTP399 may have an important role to play by enabling patients with T1D to achieve and maintain glycemic control without the fear and negative health effects of hypoglycemia and DKA.

054 / #948
PARALLEL SESSION 09: UPDATES ON NAFLD/NASH AND DIABETES
NAFLD/NASH IN TYPE 1 DIABETES: OVERRATED OR UNDERAPPRECIATED

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NAFLD is the most common chronic liver disease in western countries, affecting 25-30% of the general population and up to 65% in those with obesity and/or type 2 diabetes. Accumulation of visceral fat and insulin resistance (IR) are pivotal factors contributing to NAFLD. NAFLD is not an innocent entity as it not only may cause liver-associated disease but also contributes to cardiovascular morbidity and mortality. More and more people with type 1 diabetes (T1D) are becoming overweight and present with features of IR, but the prevalence and impact of NAFLD in this population is still unclear. The utility of non-invasive risk scores to screen for NAFLD in T1D is being explored. Based upon ultrasonographic criteria NAFLD is present in ~22% in adults with T1D. MRI based data show a prevalence rate of ~8.6%. However multiple factors affect these data, ranging from study design and referral bias to discrepancies in diagnostic accuracy. Subjects with T1D have a 7-fold higher risk of cardiovascular disease (CVD) and CV mortality is the most prominent cause of death in T1D. IR may contribute to NAFLD and to CV complications in T1D. The independent contribution of NAFLD to CV events has to be determined in this population. Furthermore, preliminary data in T1D point towards a 2-3x higher risk for microvascular complications in those with NAFLD. We will discuss epidemiological and diagnostic challenges of NAFLD in T1D, explore the role of IR in NAFLD and NAFLD-associated complications, and examine the contribution of NAFLD to the presence of macro- and microvascular complications.

055 / #949
PARALLEL SESSION 09: UPDATES ON NAFLD/NASH AND DIABETES
NAFLD/NASH IN METABOLIC SYNDROME AND EARLY TYPE 2 DIABETES

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Abstract Non-alcoholic fatty liver disease (NAFLD) is a metabolic liver disease that is strongly associated with obesity, type 2 diabetes (T2DM) and other metabolic and vascular risk factors. It is now established that NAFLD is a multisystem disease with consequences beyond the liver. NAFLD increases risk
of many extra-hepatic diseases such as cardiovascular disease (CVD), chronic kidney disease (CKD) and certain cancers. NAFLD encompasses a spectrum of lipid-associated liver disease and in affected individuals NAFLD may progress from simple steatosis to steatohepatitis, liver fibrosis and cirrhosis. This presentation will discuss the relationships between NAFLD and type 2 diabetes that form part of a vicious cycle of spiralling and worsening metabolic disease. Not only does NAFLD increase risk of developing diabetes with insulin resistance and poor glycaemic control, but development of diabetes further increases risk of worsening liver disease, liver fibrosis and hepatocellular carcinoma. Relationships between NAFLD and cardiovascular disease and the modifying influence on cardiovascular disease of certain genotypes known to increase severity of liver disease will also be discussed.

059 / #885
PARALLEL SESSION 10: COVID-19 AND MANAGEMENT OF PATIENTS WITH DIABETES: HOW TO IMPLEMENT SCIENTIFIC KNOWLEDGE TO CLINICAL PRACTICE?

GLUCOSE CONTROL DURING COVID-19 INFECTION: TARGETS AND ACUTE DERANGEMENTS

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The aim of the presentation is to explore the challenges of managing dysglycemia in the context of COVID-19 in hospitalized patients and how to achieve the best outcomes. Diabetes and suboptimal glycemic control, amongst other characteristics, have been identified as risk factors for developing COVID-19 following infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). These risk factors are also associated with worse outcomes. Several mechanisms have been postulated. Hyperglycaemia and hyperglycemia during admission to hospital are associated with adverse hospital outcomes. There is a higher risk of dysglycemia in patients with COVID-19 with or without pre-existing diabetes. Many patients present to hospitals with diabetes emergencies (diabetic ketoacidosis (DKA)/or hyperosmolar hyperglycemic state (HHS)). Hyperglycaemia on admission with COVID-19 is associated with worse outcomes. Hyperglycaemia in the context of COVID-19 is linked to longer hospital stays, higher risk of developing acute respiratory distress syndrome, increased mortality compared to those who did not develop hyperglycaemia. Severe hyperglycaemia after admission was a strong predictor of death among patients not admitted to intensive care units. Critically unwell patients with diabetes and COVID-19 have high insulin requirements and poorer time in range at the time of the COVID-19 peak inflammatory response. There is a higher risk of stress hyperglycaemia in patients with COVID-19 without a history of pre-existing diabetes. Dexamethasone and other steroids (e.g. hydrocortisone, methylprednisolone, prednisolone) are being used to manage patients with COVID-19. Maintaining good blood glucose control during this time is essential to improve clinical outcomes. Several guidelines have been developed to improve time in range and prevent the development of diabetes emergencies during admissions to hospital. There are studies emerging to support the use of flash and continuous glucose monitoring systems in addition to point of care testing to optimize inpatient glucose time in range and prevention of hypoglycemia and hyperglycaemia. Concerns were raised of shortages of infusion pumps as a result of hospitals being overwhelmed by cases of COVID-19. As a result, several guidelines were developed using subcutaneous regimen to manage diabetes emergencies (DKA/HHS) and persistent hyperglycaemia. Following a phase of high insulin requirements at the peak of the COVID-19 inflammatory response, it is challenging to predict the drop in insulin requirements when there is a higher risk of hypoglycaemia. Our understanding of the management of COVID-19 and glucose control during hospital admissions continue to evolve with further studies and technologies.

061 / #887
PARALLEL SESSION 11: ADVANCED THERAPEUTIC APPROACHES IN TYPE 2 DIABETES

TOXIC INTESTINAL SIGNALS AS A CAUSE OF TYPE 2 DIABETES AND THE METABOLIC SYNDROME

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Background: It makes no sense. How can two modest and totally different operations on the foregut produce not only durable loss of 1/3 of patients’ original weight but, at the same time, lead to rapid and full remission of type 2 diabetes, dyslipidemias, non-alcoholic steatotic hepatitis (NASH), polycystic ovary syndrome (PCOS) and reduce all-cause mortality by 80%? Methods: A series of clinical studies that investigated glucose and lipid metabolism were conducted on patients before and after Roux-en-Y gastric bypass and gastric sleeve. Results: Our data indicate that these diseases and the other co-morbidities of the metabolic syndrome are associated with high lactate levels that return to normal following surgery (Pories et al. SOARD, in press, 2021). Conclusions: These findings suggest the patients with the syndrome have an increased dependence on anaerobic metabolism due to a signal, most likely from the gut, that interferes with the entry of glucose and fatty acids into the TCA cycle. Identification of this signal offers a new pathway for drug development.

067 / #893
PARALLEL SESSION 12: INCLUDING AND INTERPRETING PATIENTS RELATED OUTCOME (PRO) IN CLINICAL RESEARCH

PRESENTATION OF KEY INSTRUMENTS AND HOW TO USE THEM (INSPIRE MEASURES)

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Aim: Diabetes technologies come with benefits and burdens that affect their uptake and continued use. The aim of the INSPIRE measures is to capture the psychosocial aspects of automated insulin dosing systems for youth, parents, adults and partners living with type 1 diabetes. Methods: An extensive mixed-methods investigation consisting of interviews, focus groups, cognitive debriefing and questionnaire completion was conducted across centres in the USA and UK. To validate the measures, data from 292 youth, 159 adults, 150 parents of youth and 149 partners of individuals recruited from the Type 1 Diabetes Exchange Registry were analysed. Participants completed INSPIRE questionnaires and measures of quality of life, fear of hypoglycaemia, diabetes distress, glucose monitoring satisfaction. Exploratory factor analysis assessed factor structures. Associations between INSPIRE scores and other measures, HbA1c, and technology use assessed concurrent and discriminant validity. Results: Four brief self-report measures were completed and successfully qualified through the FDA MDDT process. Youth, adult, parent and partner measures assess psychosocial aspects of automated insulin delivery systems and provide opportunity for consistent assessment across clinical trials globally. Measures range from 17 to 22 items, are available in several languages and are reliable (α=0.95–0.97). Use of the INSPIRE measures in clinical research will be discussed in terms of evaluation and reporting of PROs. Conclusions: INSPIRE measures assessing the psychosocial aspects of automated insulin dosing systems for youth, adults, parents and partners have meaningful factor structures and are internally consistent. The developmentally-sensitive INSPIRE measures offer added value both within clinical trials and clinical practice.

In this mix of diabetes technology and clinical care, there may be significant benefit to assessing and addressing patient-reported outcomes (PROs), such as depression, diabetes distress, hypoglycemic fear and attitudes toward diabetes technology. When used appropriately, PRO data can serve to guide and inform key aspects of clinical care. These data, for example, can help to determine whether or not the patient will be open to diabetes technology solutions, likely to benefit from them, and likely to stay with them over the long-term. More broadly, information from PROs can contribute to more meaningful conversations between clinicians and patients, help to identify and address obstacles to self-management (including problematic use of diabetes technology) as they arise, and serve to promote patients’ engagement in their own care. In this brief presentation, we will consider how PROs are used and misused in clinical practice, and will provide practical tips for how they may be used most effectively.

In this talk, I will summarize results of dual-hormone closed-loop systems, with focus on insulin-and-pramlintide closed-loop systems. The use of insulin-and-pramlintide closed-loop system to improve glucose control as well as alleviate the need for carbohydrate counting will be discussed. Finally, results from the addition of empagliflozin to closed-loop systems will be presented.

In this talk, we review the available clinical evidence, and report on our experience of closed-loop use in patient groups where diabetes management can be particularly challenging. We will also discuss key considerations for healthcare providers to promote equitable access to closed-loop technology.
with 2:1 randomization to intervention with a CL system vs. sensor and pump for 3 months followed by a 3-month extension phase in which the original control group switches to the CL system and the original intervention group continues to use the system. The hybrid CL system includes a Tandem t:slim X2 insulin pump with embedded CTR algorithm and the Dexcom G6 CGM. The control system is patient’s personal insulin pump and Dexcom G6 CGM in an open-loop mode. The primary outcome is baseline-treatment difference in time below 70 mg/dL measured by CGM after 3-month use of CL control versus CGM and pump. Secondary outcomes include no increase of time above target range in CL group vs. control group over 3 months, other metrics of glycemic control, and patient reported outcomes. From 117 screened adult T1D patients (>1 year), treated by insulin pump >6 months, with a Clarke score >3 and/or severe hypoglycemia during the previous 6 months and a third party support in case of severe hypoglycemic episode, in two French sites, 72 have been randomized after they showed during a 2-week run-in phase a time spent with Dexcom G6 CGM below 70 mg/dL of 5% or above. Available study data will be presented.

074 / #900
PARALLEL SESSION 13: CLOSE-LOOP
FASTER ACTING INSULIN ANALOGUES IN CLOSED-LOOP INSULIN DELIVERY
K. Dovc
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Diabetes technology options have greatly increased for individuals with type 1 diabetes, with the commercialization of multiple advanced insulin pumps, including hybrid closed-loop devices. Hybrid closed-loop insulin therapy consists of an insulin pump, a connected continuous glucose monitor, and an algorithm that enables automated insulin delivery apart from prandial boluses in response to glucose levels. While improvements seen in glycemic control are reassuring, users of these treatment modalities still experience the everyday burden of feed-forward actions, such as carbohydrate counting or exercise announcement, and still require premeal insulin dosing (bolus) to prevent postprandial glycemic excursion. To fully close the loop, these systems might benefit from a faster insulin action and clearance rate, which are recently reported with novel faster insulin analogues.

In this presentation, we will present current data on closed-loop glycemic control with faster insulin formulations in individuals with type 1 diabetes.

087 / #907
PARALLEL SESSION 16: IMPROVING ADHERENCE AND REDUCING BURDEN IN DIABETES CARE
INTERVENING ON HYPOGLYCEMIA FEAR IN PARENTS OF YOUNG CHILDREN USING DIRECT-TO-HOME VIDEO-BASED TELEHEALTH
S. Patton
Nemours Children’s Health System, Pediatrics, Jacksonville, United States of America

Parents of young children with type 1 diabetes (<7 years-old) commonly report at least moderate levels of hypoglycemia fear, which may negatively impact their quality of life and management of their child’s diabetes. To help treat parents’ fear, we designed a group-based behavioral intervention ready for delivery via direct-to-home video-based telehealth. Our intervention, called Reducing Emotional Distress for Child Hypoglycemia in Parents (REDCHiP), teaches parents cognitive-behavioral strategies, behavioral parenting strategies, and new coping methods to help reduce their fear of child hypoglycemia. To date, we have tested our REDCHiP intervention in a pilot study that recruited 42 parents. We randomized parents to one of two groups. Parents randomized to the active intervention condition received REDCHiP at study enrollment (n = 22), while parents randomized to a wait list control (n = 21) condition eventually had the option of receiving the REDCHiP intervention after they had completed the wait list period. In our pilot, 97.6% of parents described themselves as the mother. Parents’ mean age was 35.2 years (SD = 5.0 years). Young children’s mean age was 4.4 years (SD = 1.4 years) and 59.5% were boys. Comparing post-treatment scores, parents receiving REDCHiP as part of the active treatment condition reported a significant

INNODIA - Translational approaches to disease modifying therapy of type 1 diabetes: An innovative approach towards understanding and arresting Type 1 diabetes The overall objective of INNODIA is to advance in a decisive way how we predict, stage, evaluate and prevent the onset and progression of type 1 diabetes (T1D). We are achieving this by creating novel tools, such as biomarkers, disease models and clinical trial paradigms. These tools allow us to distinguish and understand at the cellular and molecular level distinctive paths of ontogeny and progression in this heterogeneous disease, thus impacting on the future management of T1D patients and at risk individuals. We have established an interdisciplinary network of clinical and basic scientists, who are leading experts in the field of T1D in Europe, with complementary expertise from the areas of immunology, b-cell biology, biomarker research and T1D therapy, joining forces in a coordinated fashion between academic and industry partners, two foundations, as well as with patients with T1D and their families. INNODIA follows over 600 people with newly diagnosed T1D with intensive biomarker measures. Over 4000 first degree family members of people with T1D have been screened of whom close to 300 have been found to have autoantibodies against the b-cell. Over 250 of these autoantibody-positive individuals accepted to be followed up intensively for biomarker research. Since November 2020 INNODIA has initiated 4 clinical trials in people with newly diagnosed T1D (ranging from 3y to 45y). All trials are based on the INNODIA Masterprotocol follow up scheme and are using intensive CGM monitoring as a tool for glucose follow up. More information on INNODIA and our clinical trials can be found on www.innodi
reduction in hypoglycemia fear (p=0.04) compared to wait list parents. Parents who received REDCHiP as part of the active treatment condition also reported significant reductions in hypoglycemia fear and parenting stress (p<0.01) compared to their pre-treatment levels after a three-month maintenance period. Finally, all parents receiving REDCHiP (n = 36) reported significant reductions in hypoglycemia fear and parenting stress (p<0.001), and in sensitivity analyses, we observed a significant reduction in glycated hemoglobin (p<0.05) among young children with pre-treatment levels above 58 mmol/mol (>7.5%). Preliminary results from our pilot trial of REDCHiP suggest that it may be feasible and acceptable to reduce parent’s hypoglycemia fear via cognitive-behavioral therapy and direct-to-home video-based telehealth. A larger efficacy trial of REDCHiP is now underway to confirm these preliminary results. This trial will recruit families from multiple diabetes centers to enhance generalizability of the results and to provide a platform for developing and testing novel strategies to enhance future implementation of the REDCHiP intervention and its direct-to-home video-based telehealth delivery method.

Background: Accurate carbohydrate counting is an important aspect of diabetes management, but it can be challenging. iSpy is a novel mobile application designed to assist with carbohydrate counting by using machine learning to identify foods through images. Our objective was to evaluate iSpy’s usability and potential impact on carbohydrate counting accuracy. Methods: For usability testing, three iterative cycles were conducted involving a total of 16 individuals (aged 8.5-17.0 years) with type 1 diabetes. Participants used iSpy to complete tasks while thinking aloud. Errors were noted, acceptability was assessed, and refinements were made before moving on to the next cycle. Next, iSpy was evaluated in a pilot randomized controlled trial with 22 iSpy users and 22 usual care controls aged 10-17 years. Primary outcome was change in carbohydrate counting ability over 3 months. Secondary outcomes included engagement, acceptability, and change in HbA1c level. Results: After 3 cycles of usability testing, no errors occurred that prevented a user from completing a task. For the pilot RCT, use of iSpy was associated with improved carbohydrate counting accuracy (total grams per meal, P = .008), reduced frequency of individual counting errors greater than 10 g (P = .047), and lower HbA1c levels (P = .03). Qualitative interviews and acceptability scale scores were positive. No major technical challenges occurred. Moreover, 43% (9/21) of iSpy participants were still engaged, with usage at least once every 2 weeks, at the end of the study. Conclusions: Our results provide evidence of efficacy and acceptability of a novel carbohydrate counting application, supporting the advancement of digital health apps for diabetes care among youth with type 1 diabetes. Further testing is needed, but iSpy may be a useful adjunct to traditional diabetes management.

**092 / #912**

PARALLEL SESSION 17: SOCIAL MEDIA: IN THE SEA OF VOICES – WHERE IS THE LIGHTHOUSE?

HARNESSING THE POWER OF SOCIAL MEDIA AND PEER SUPPORT

**K. Close**

The diaTribe Foundation, N/a, San Francisco, United States of America

Social media has become a powerful resource where people with diabetes can access peer support, information, anecdotes, and blogs written by the community for the community. The stigma associated with diabetes remains a considerable burden for many, and digital safe spaces must be available where people with diabetes can express themselves and share experiences, gain support and advice, and offer support to each other. In this talk, I will present information about the power of social media, stories of peer to peer empowerment, and resources to help people with diabetes connect safely online.

**098 / #919**

PARALLEL SESSION 18: NUTRITION AND FOOD TECHNOLOGIES

ISPY: NOVEL CARBOHYDRATE COUNTING SMARTPHONE APP FOR YOUTH WITH TYPE 1 DIABETES

**J. Alfonsi, M. Palmert**

University of Toronto, Medicine, Toronto, Canada

Background: Accurate carbohydrate counting is an important aspect of diabetes management, but it can be challenging. iSpy is a novel mobile application designed to assist with carbohydrate counting by using machine learning to identify foods through images. Our objective was to evaluate iSpy’s usability and potential impact on carbohydrate counting accuracy. Methods: For usability testing, three iterative cycles were conducted involving a total of 16 individuals (aged 8.5-17.0 years) with type 1 diabetes. Participants used iSpy to complete tasks while thinking aloud. Errors were noted, acceptability was assessed, and refinements were made before moving on to the next cycle. Next, iSpy was evaluated in a pilot randomized controlled trial with 22 iSpy users and 22 usual care controls aged 10-17 years. Primary outcome was change in carbohydrate counting ability over 3 months. Secondary outcomes included engagement, acceptability, and change in HbA1c level. Results: After 3 cycles of usability testing, no errors occurred that prevented a user from completing a task. For the pilot RCT, use of iSpy was associated with improved carbohydrate counting accuracy (total grams per meal, P = .008), reduced frequency of individual counting errors greater than 10 g (P = .047), and lower HbA1c levels (P = .03). Qualitative interviews and acceptability scale scores were positive. No major technical challenges occurred. Moreover, 43% (9/21) of iSpy participants were still engaged, with usage at least once every 2 weeks, at the end of the study. Conclusions: Our results provide evidence of efficacy and acceptability of a novel carbohydrate counting application, supporting the advancement of digital health apps for diabetes care among youth with type 1 diabetes. Further testing is needed, but iSpy may be a useful adjunct to traditional diabetes management.

**099 / #920**

PARALLEL SESSION 18: NUTRITION AND FOOD TECHNOLOGIES

COMPARISON OF NOVEL AND TRADITIONAL DIETARY ASSESSMENT METHODS IN DIABETES PATIENTS

**M. Vasiloglou**

University of Bern, Artorg Center For Biomedical Engineering Research, Bern, Switzerland

Accurate estimation of carbohydrates as well as other nutrients, are beneficial in the management of diabetes mellitus, leading to improved glycemic control and balanced dietary patterns. This presentation includes an overview of studies that compare conventional versus innovative dietary assessment methods and discusses the challenges of both categories. Various conventional dietary assessment methods exist (e.g. 24-h food recall, food frequency questionnaires) which aim at measuring dietary intake. However, existing methods encounter different drawbacks such as lack of precision, inaccuracy in portion size estimation and non-real-time feedback. Innovative methods of dietary assessment that have been introduced will be presented, with a focus on image-based apps which use food photos/videos as an input and, via artificial intelligence, translate them into nutrients. Finally, based on international surveys, the preferences, criteria and barriers related to recommendation or usage of nutrition apps from the perspective of healthcare professionals and end-users will be presented.

**101 / #922**

PARALLEL SESSION 19: DIABETES TECHNOLOGIES IN INDIA

USING CGM IN ROUTINE CLINICAL PRACTICE IN INDIA PARTICULARLY FOR TYPE 2 DIABETES

**B. Makkar**
Dr Makkar’s Diabetes and Obesity Centre, Diabetes And Obesity, DELHI, India

Diabetes in India, with estimated prevalence of 10.4% in adults, affects more than 77 million persons. Type 2 diabetes (T2DM) accounts for almost 97% of total diabetes burden. Despite substantial advances in diabetes monitoring and therapies, glycemic control remains suboptimal with only about 1/3rd patients achieving A1c levels below 7%. Hyperglycemia, hypoglycemia as well as glycemic variability (GV) have been shown to increase risk of complications and mortality. SMBG, the most common tool for home blood glucose monitoring, and A1c a gold standard for assessing overall glycemic control, do not provide key information about intraday and day-to-day glucose variability and fail to identify hypos. CGM has emerged as an important tool in identifying ongoing continuous variations in glucose levels and identifying hypoglycemia, especially nocturnal hypos. Increased GV has emerged as a strong predictor of hypoglycemia and poor glycemic control. GV induces oxidative stress, inflammation and endothelial dysfunction, which lead to long term complications of diabetes. Though role of CGM in type 1 diabetes patients on MDI is undisputed, studies have also shown its importance in T2DM patients on insulin or oral hypoglycemic agents. However, CGM is used infrequently in T2DM patients in routine clinical practice in India. Despite limited data available, studies in T2DM have reported usefulness of CGM in identifying postprandial glucose excursions and GV, nocturnal and early morning hypos, hypoglycemia unawareness, which helps in making therapeutic decisions to improve glycemic control. Further, CGM helps in evaluating response to lifestyle/therapeutic interventions and is an effective motivational/educational device in poorly controlled diabetes patients.

Background and Aims: Time in Range (TIR), an evolving metric in monitoring of blood glucose overcomes limitations of HbA1c as it determines not only glycemic variability but also overall glycemic control and is increasingly accepted globally. 

Methods: TIR which refers to the time spent by an individual with diabetes within a recommended blood glucose range over a 24-hour duration is usually derived by continuous glucose monitoring (CGM) methods or through frequent SMBG. ATTD 2019 released recommendations for TIR metrics for people with diabetes and the different types of the same. There are various practical applications for TIR in clinical practice.

Results: Commonly, TIR metrics focus on time in range (TIR), time above range (TAR), and time below range (TBR). There is growing evidence of association between TIR and micro and macrovascular complications of diabetes; an inverse relation between increasing TIR and decreasing HbA1c also exists. The TIR and TAR allow clinicians and patients alike to identify the time spent within and above acceptable blood glucose range, respectively and make adjustments to therapy and lifestyle in terms of dietary intake and physical activity at the specific time points within the 24-h period to improve the metrics. TBR is an important tool in identifying the duration spent in the hypoglycemic range and a means to address the biggest limitation in achieving tight glycaemic control.

Conclusions: TIR metrics are a simple and effective means of communication between the clinician and patient towards improving metabolic control and sets clear, understandable targets for patients to achieve.
One hundred years after the first commercialization of insulin, once-weekly insulins represent the latest development in this field. Advanced prolongation mechanisms have been employed to enable once-weekly dosing. This presentation will highlight the pharmacokinetic, pharmacodynamic and clinical data of once-weekly insulins disclosed so far.

107 / #928
PARALLEL SESSION 21: NEW INSULINS: FORESEEABLE IMPACT ON DIABETES THERAPY
SMART INSULINS
T. Heise
Profil, Neuss, Germany

“Smart” or glucose-responsive insulins (GRIs) that only act when blood glucose levels are high safely avoiding hypoglycaemia are considered as the "holy grail" of insulin therapy. First concepts for such an insulin had already been published in the 1970ies, but to date only one clinical trial with a GRI has been published and this development was stopped. On the hand, numerous publications and patent applications have presented concepts and designs of GRIs, often with proof-of-concept data in (mostly small) animals. The presentation will explain the various challenges GRIs are facing including, but not limited to, a high affinity and selectivity of the glucose-sensing moiety, a very fast activation and inactivation of insulin to avoid both hyperglycaemia and hypoglycaemia, and toxicity and stability issues. The pros and cons of various developments trying to overcome these challenges will be discussed. Finally, it will be discussed how GRIs might change insulin therapy. While the ideal GRI would allow coverage of both basal and prandial glucose needs, first developments might still need to be combined with other glucose-lowering agents.

108 / #929
PARALLEL SESSION 21: NEW INSULINS: FORESEEABLE IMPACT ON DIABETES THERAPY
ORAL INSULIN
E. Zijlstra
Profil, Neuss, Germany

In 1923, shortly after Frederick Banting & Charles Best discovered insulin, the first experiments with orally administered insulin were conducted. Fast forward, almost 100 years later, no insulin pill or tablet is commercially available. Despite the lack of success in developing an oral insulin, an oral insulin replacement therapy remains a very appealing alternative to subcutaneous injections for many patients with diabetes. To apply insulin without skin injury and to benefit from a more physiological provision of insulin are the main reasons triggering the continuous search for an oral insulin formulation. Most oral formulations are designed to protect against insulin degradation in the gastrointestinal tract and to enhance insulin absorption into the circulation. Insulin absorption via the oral route is fast and most developments have therefore focussed on providing mealtime insulin coverage. Food intake together or shortly after oral insulin administration can however significantly reduce the amount of insulin that can be absorbed via the stomach and intestine. An oral basal insulin formulation demonstrated promising results in patients with type 2 diabetes. The oral basal insulin achieved similar reductions in glucose control as insulin glargine over 8 weeks of treatment. However, as the amount of insulin required to see a glucose lowering effect is very large, the development was discontinued. To continue the search for an oral insulin, technological advances to increase insulin absorption from the gastrointestinal tract are needed. Nanotechnology and ingestible insulin application systems are amongst newly proposed ideas that may provide an oral insulin delivery platform in the future.

114 / #934
PARALLEL SESSION 22: CONTINUOUS GLUCOSE SENSORS IN PATIENTS USING MDI
THE EFFECTIVENESS OF ISCGM: COMPARISON OF DATA FROM RCTS AND ROUTINE-USE
E. Wilmot
1Royal Derby Hospital, University Hospitals of Derby and Burton NHS Trust, Diabetes & Endocrinology, Derby, United Kingdom, 2University of Nottingham, Division Of Medical Sciences, Nottingham, United Kingdom

For decades finger prick self-monitoring of blood glucose (SMBG) has been the cornerstone of diabetes self-management, with the expectation that people with diabetes undertake SMBG at multiple points across the day to inform treatment decisions. Intermittently scanned continuous glucose monitoring (isCGM) has more recently become established as an alternative to finger prick SMBG. Individuals wear a sensor on the arm which is scanned with a reader, allowing the user to visualise the glucose information. This contrasts to real time CGM systems which allow direct visualisation of the data without the need to scan. Early randomised controlled trials highlighted the ability of isCGM to reduce hypoglycaemia in people living with Type 1 diabetes and Type 2 diabetes. The uptake of isCGM has since risen exponentially, largely replacing finger prick SMBG for many individuals living with diabetes. The latest generation of isCGM is now available with the additional benefit of optional alarms. A range of randomised controlled trials and real-world studies have been undertaken to explore the potential clinical benefits of the different generations of isCGM on outcomes, including HbA1c, hypoglycaemia and patient related outcome measures. This lecture will aim to review these studies and compare the findings of the randomised controlled trials with those of the published real-world data.

115 / #935
PARALLEL SESSION 22: CONTINUOUS GLUCOSE SENSORS IN PATIENTS USING MDI
CGM DERIVED DATA IN ELDERLY PWD TREATED BY MDI
E. Toschi
1Kingdom, 2University of Nottingham, Division Of Medical Sciences, Nottingham, University of Nottingham
Elderly persons with type 1 (PwT1D) or type 2 diabetes (PwT2D) on insulin therapy are at a high risk of hypoglycemia and its poor consequences. The current guidelines for elderly PwD recommend less stringent hemoglobin A1c (A1C) targets to mitigate hypoglycemia. Recently, continuous glucose monitoring (CGM) has provided a better tool to capture glucose average, glucose variability (coefficient of variation (CV%), and time spent in hypoglycemia (time below range (TBR), compared with A1C. In elderly PwT1D, CGM-derived metrics as CV ≤ 36% are associated with less TBR and more time in range (TIR), while CV% > 36% is associated with less TBR, despite similar A1C levels. Moreover, in elderly PwT1D, personal CGM use, independent of insulin administration method – insulin pump or multiple daily injections (MDI) – is associated with less TBR and lower CV. Furthermore, in elderly PwT1D, GMI differ from A1C much more than in the general population. When HbA1c > GMI by ≥ 0.5%, the difference is associated with greater TBR, while a GMI > HbA1c by ≥ 0.5% is associated with higher time above range (TAR). This data highlight the importance of GMI for capturing TBR and TAR, compared to A1C in this vulnerable population. Thus far, CGM-derived metrics in elderly PwT2D on MDI are scant, however we foresee that CGM-derived data will provide similar insight into glycemic control. Therefore, in elderly PwD on MDI, compared to A1C, CGM-derived metrics as CV% and GMI help to identify individuals at higher risk for hypoglycemia and to develop more personalized diabetes management plans.

Since early 2020 the COVID-19 pandemic has evolved into a global health and economic crisis. Morbidity and mortality is greatest in the elderly but more recent evidence suggests children become infected at similar or even higher rates. The younger population have no or mild symptoms and as such few children with COVID-19 have sought medical attention. The impact of the pandemic on children with chronic conditions such as diabetes however is large. Several major problems have been identified: Changes in access to care, either due to overstretched clinics or due to anxiety to access clinics has led to an increase in diabetes ketoacidosis (DKA) and a delay in diagnosis with a more severe onset. Although rare, a small number of children with type 1 diabetes and COVID-19 infection required intensive care treatment. Delivery of essential drugs and essential material for diabetes management has been delayed or been impossible, putting lives of persons with diabetes at risk. The virus itself may cause or facilitate the development of type 1 diabetes. Lockdown measures to contain the spread of the virus have a huge psychological impact on all age groups, but certainly on the adolescents and young adults. Despite many challenges, the pandemic has also lead to positive developments including increased use of telemedicine and of diabetes technology. It is vital to continue to monitor the impact of the pandemic on persons with diabetes and diabetes care through registries and survey, without exclusion of any age group.
O001 / #38
Topic: AS01-Closed-loop System and Algorithm

DEVELOPING A NOVEL INTRAVENOUS AUTOMATED INSULIN DELIVERY SYSTEM. AN IN-SILICO STUDY CHARACTERIZING THE GLUCOSE MEASUREMENT EFFECT ON THE SYSTEM’S PERFORMANCE
A. Tarniceriu¹, L. Desborough², C. Ziemba¹, B. Schär¹, R. Mathys¹
¹Securecell AG, -, Urdorf, Switzerland, ²Nudge BG Inc., -, Thousand Oaks, United States of America

Background and Aims: We are developing a blood glucose control technology based on intravenous (IV) blood sampling and delivery of insulin. A wearable device photometrically measures glucose in IV blood samples and delivers insulin via the same IV path. This removes the time lag between the interstitial and blood compartments associated with subcutaneous technologies and ensures faster insulin action. In turn, this facilitates blood glucose control without prior meal or activity information. As the performance of the automated glucose measurement is a critical component of automated insulin delivery (AID) systems, we evaluate the effect of measurement delay and error on the time-in-range and time-below-range for type 1 diabetes in-silico subjects.

Methods: Glucose profiles for in-silico type 1 diabetes subjects are simulated using the UVa/Padova T1DMS model (33 subjects) and the NudgeBG model (1000 subjects, including the effect of unmeasured sources of variation such as stress and exercise). The simulated time for each subject is two days, involving four unannounced meals/day (20–70 grams of carbohydrates/meal). The control interval is 15 minutes. Time in the narrow glycemic range (70–140 mg/dl) and time below range (<70 mg/dl) are computed for measurement delays up to 20 minutes and measurement errors up to 35%.

Results: UVa/Padova T1DMS model: NudgeBG model:

Conclusions: As the measurement delay increases, the time-in-range decreases. Because IV sampling eliminates the lag between venous and interstitial compartments, it reduces the overall delay, leading to higher performance. The time-in-range is less sensitive to the measurement error, but the high accuracy of the photometric method ensures lower hypoglycemia risks.

O002 / #80
Topic: AS01-Closed-loop System and Algorithm

COST-EFFECTIVENESS ANALYSIS OF THE MINIMEDTM 780G SYSTEM VERSUS MULTIPLE DAILY INJECTIONS WITH INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN INDIVIDUALS WITH TYPE 1 DIABETES IN AUSTRIA
O. Cohen¹, A.Z. Ozdemir Saltik², M.I. Buompensiere², E. Walter²
¹Medtronic International Trading Sarl, Medical Affairs, Tolochenaz, Switzerland, ²Medtronic International Trading Sarl, Health Economics, Tolochenaz, Switzerland, ³IPF GmbH Institute for Pharmaeconomic Research, Health Economics, Vienna, Austria

Background and Aims: This study assessed the long-term cost-effectiveness of the MiniMed™ 780G system versus Multiple Daily Injections (MDI) with intermittently scanned continuous glucose monitoring (isCGM) in people with type 1 diabetes (T1D) in Austria.

Methods: The IQVIA-CORE-Diabetes-Model was used to perform cost-effectiveness analysis over simulated patient lifetime. Clinical data were derived from the MiniMed™ 780G system pivotal clinical study¹,²; the isCGM prospective observational real-world cohort study (FUTURE)³, and the European severe hypoglycaemia event rates (SHE) study⁴. For the former, assumptions for HbA1c reduction, given an 8.0% (63.9 mmol/mol) level at baseline, were 0.8% with MiniMed™ 780G system and 0% with isCGM. For the latter, assumptions requiring medical
assistance for SH were 0 vs 0.25 per patient-year for the MiniMed™ 780G system versus isCGM. Cost data, expressed in 2020 Euros, were obtained from published sources and represented Austrian reimbursement prices. Societal perspective was used.

**Results:** The MiniMed™ 780G system was associated with a quality-adjusted life-year (QALY) gain of 2.09 but higher overall costs versus MDI+isCGM, leading to an incremental cost-effectiveness ratio (ICER) of €24475 per QALY-gained. MiniMed™ 780G system use resulted in a lower cumulative incidence of diabetes-related complications. Higher acquisition costs were partially offset by reduced complications costs. Extensive sensitivity analysis on key drivers confirmed the robustness of results.

**Conclusions:** Compared to MDI+isCGM, MiniMed™ 780G therapy was associated with clinical benefits and QALY improvements in patients with T1D in Austria. At a willingness-to-pay threshold of €28000 per QALY-gained, the system likely represents a cost-effective treatment option.


**O003 / #91**

**Topic:** AS01-Closed-loop System and Algorithm

**PERFORMANCE OF OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM AT SPECIFIC GLUCOSE TARGETS FROM 110–150MG/DL OVER THREE MONTHS IN ADULTS AND ADOLESCENTS WITH TYPE 1 DIABETES**


1Atlanta Diabetes Association, CEO President, Atlanta, United States of America, 2Icahn School of Medicine at Mount Sinai, Medicine, New York, United States of America, 3University of Virginia, Division Of Endocrinology, Charlottesville, United States of America, 4Park Nicoll, HealthPartners, International Diabetes Center, Minneapolis, United States of America, 5University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 6Sansum Diabetes Research Institute, Clinical Research, Santa Barbara, United States of America, 7Iowa Diabetes Research, Research, West Des Moines, United States of America, 8Harvard Medical School, Joslin Diabetes Center, Boston, United States of America, 9East Coast Institute for Research at The Jones Center, Research, Macon, United States of America, 10Northwestern University, Feinberg School Of Medicine, Chicago, United States of America, 11Insulet Corporation, Clinical Affairs, Acton, United States of America

**Background and Aims:** Insulin therapy should be individualized to reflect patients’ unique treatment goals. The Omnipod 5 System provides novel full on-body hybrid closed-loop (HCL) control with customizable glucose targets from 110–150mg/dL (6.1–8.3mmol/L). This analysis aimed to assess system performance at varying glucose targets during the 3-month pivotal study in adults and adolescents.

**Methods:** Participants aged 14–70y with T1D≥6 months and A1C<10% used the HCL system for 3 months at home after a 14-day run-in phase of their standard therapy (ST). Participants selected glucose targets from 110–150mg/dL (6.1–8.3mmol/L) in 10mg/dL (0.6mmol/L) increments in a daily profile with up to 8 segments. Primary safety and efficacy endpoints, respectively, were occurrence of severe hypoglycemia (SH) and diabetic ketoadiagnosis (DKA), and sensor glucose percent time in target range (TIR) (70–180mg/dL, 3.9–10.0mmol/L) during HCL at each glucose target compared with ST.

**Results:** Participants (N = 128) were aged (mean±SD) 37 ± 14y with T1D duration 18 ± 12y and baseline A1C 7.2 ± 0.9% (range 5.2–9.8%). TIR improved during the HCL phase for most targets, with reductions in time below range (TBR <70 and <54mg/dL [<3.9 and <3.0mmol/L]) (Table). There were 2 episodes of SH (both following user-initiated boluses), and no episodes of DKA reported.

**Conclusions:** The Omnipod 5 System was safely used by a large cohort of adults and adolescents with T1D at glucose targets from 110–150mg/dL (6.1–8.3mmol/L). Optimal results were seen using 110mg/dL (6.1mmol/L) as target, with 75.6% TIR and minimal TBR. Most (92%) participants completing the pivotal study opted to continue using the system in an extension phase. Omnipod 5 Study Group as an author.

**O004 / #93**

**Topic:** AS01-Closed-loop System and Algorithm

**PERFORMANCE OF OMNIPOD® 5 AUTOMATED INSULIN DELIVERY SYSTEM AT SPECIFIC GLUCOSE TARGETS FROM 110–150MG/DL OVER THREE MONTHS IN CHILDREN WITH TYPE 1 DIABETES (T1D)**


1Yale School of Medicine, Department Of Pediatrics, Connecticut, United States of America, 2University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 3University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 4University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 5University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 6University of Colorado, Barbara Davis Center For Diabetes, Aurora, United States of America, 7Icahn School of Medicine at Mount Sinai, Medicine, New York, United States of America, 8Harvard Medical School, Joslin Diabetes Center, Boston, United States of America, 9East Coast Institute for Research at The Jones Center, Research, Macon, United States of America, 10Northwestern University, Feinberg School Of Medicine, Chicago, United States of America, 11Insulet Corporation, Clinical Affairs, Acton, United States of America
Background and Aims: Insulin therapy should be individualized for patients’ unique treatment goals. The Omnipod 5 System provides novel full on-body hybrid closed-loop (HCL) control with customizable glucose targets from 110–150mg/dL (6.1–8.3mmol/L). This analysis aimed to assess system performance at varying glucose targets during the 3-month pivotal study in children.

Methods: Participants aged 6–13.9y with TID≥6 months and A1C<10% used the HCL system for 3 months at home after a 14-day run-in phase of their standard therapy (ST). Participants (or caregivers) selected glucose targets from 110–150mg/dL (6.1–8.3mmol/L) in 10mg/dL (0.6mmol/L) increments which could vary by time of day. Primary safety and efficacy endpoints, respectively, were occurrence of severe hypoglycemia (SH) and diabetic ketoacidosis (DKA), and sensor glucose percent time in range (TIR) (70–180mg/dL, 3.9–10.0mmol/L) during HCL at each glucose target compared with ST.

Results: Participants (N=112) were aged (mean±SD) 10.3±2.2y with TID duration 4.7±2.6y and baseline A1C 7.7±0.9% (range 5.8–10.3%). TIR improved during the HCL phase for most targets, while time below range (TBR <70 and <54mg/dL <3.9 and <3.0mmol/L) remained low (Table). There was 1 SH episode (delayed eating after pre-meal bolus) and 1 DKA episode (suspected failed pump site) reported.

Conclusions: The Omnipod 5 System was safely used by a large cohort of children with TID at glucose targets from 110–150mg/dL (6.1–8.3mmol/L). Optimal results were seen using 110mg/dL (6.1mmol/L) as target, with 68.4% TIR and minimal TBR. Most (99%) participants completing the pivotal study opted to continue using the system in an extension phase. Omnipod 5 Study Group as an author.

###Table: Glicemic Outcomes for Children during the Standard Therapy (ST) and Hybrid Closed-Loop (HCL) Phase

<table>
<thead>
<tr>
<th>Glucose Outcomes</th>
<th>Standard Therapy (ST)</th>
<th>Hybrid Closed-Loop (HCL) Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>&lt;70 mg/dL (3.9mmol/L)</strong></td>
<td>18.6% (14/76)</td>
<td>1.3% (1/82)</td>
</tr>
<tr>
<td><strong>54–70 mg/dL (3.9–4.4mmol/L)</strong></td>
<td>25.7% (19/76)</td>
<td>13.6% (11/82)</td>
</tr>
<tr>
<td><strong>&lt;54 mg/dL (&lt;3.9mmol/L)</strong></td>
<td>6.7% (5/76)</td>
<td>0 (0/82)</td>
</tr>
<tr>
<td><strong>70–180 mg/dL (4.4–10.0mmol/L)</strong></td>
<td>46.9% (36/76)</td>
<td>67.1% (55/82)</td>
</tr>
<tr>
<td><strong>&gt;180 mg/dL (&gt;10.0mmol/L)</strong></td>
<td>3.9% (3/76)</td>
<td>0 (0/82)</td>
</tr>
</tbody>
</table>

Data are mean ± SD

###Background and Aims: There are a growing number of Do-It-Yourself Artificial Pancreas Systems in the UK. These systems are unregulated and unapproved: exploring the perceived benefits, concerns and expectations of people with diabetes prior to using DIY APS; specifically the perceived response of their healthcare teams and any potential safety concerns is important.

Methods: A healthcare professional (HCP) and DIY-APS community collaboratively designed survey was distributed to users during UK “build sessions”.

Results: Twenty-seven responses were received (100% return) from two “build sessions”. Over half (59.3%, 16/27) were female, mean age 35.7 years (18.5%, 5/27), median diabetes duration 23 years (IQR 11.3–30.0) and median duration of pump therapy 60 months (IQR 30–109). Almost all (25/27) pumps were NHS-funded. Half (51.9%, 14/27) were using FreeStyle Libre (FSL) +MiaoMiao, only 2 FSL were not NHS-funded. Important driving factors were “reduced time spent thinking about diabetes” (81.5%, 22/27); improved glycaemic control (63%, 17/27) and reducing future complications (63%, 17/27). On a 7-point Likert (1=Very concerned), 5/27 (18.5%) users were at least somewhat (5–9) concerned about both a negative HCP response or decreased NHS support. Concerns around safety (2/27, 7.4%) or lack of regulation (1/17, 3.7%) were less common. Even so, 74% (20/27) had informed their HCPs that they were planning to start DIY APS, one of which was perceived as unsupportive.

Conclusions: Perceived potential benefits outweigh regulatory or safety concerns. Users have concerns about the impact on their relationships with HCPs. This survey provides novel insights into user expectations prior to commencing DIY-APS and highlights the ongoing ethical challenges for users and HCPs alike.

###Table: Glicemic Outcomes for Children in the Study

<table>
<thead>
<tr>
<th>Glucose Outcomes</th>
<th>Standard Therapy (ST)</th>
<th>Hybrid Closed-Loop (HCL) Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>&lt;70 mg/dL (3.9mmol/L)</strong></td>
<td>18.6% (14/76)</td>
<td>1.3% (1/82)</td>
</tr>
<tr>
<td><strong>54–70 mg/dL (3.9–4.4mmol/L)</strong></td>
<td>25.7% (19/76)</td>
<td>13.6% (11/82)</td>
</tr>
<tr>
<td><strong>&lt;54 mg/dL (&lt;3.9mmol/L)</strong></td>
<td>6.7% (5/76)</td>
<td>0 (0/82)</td>
</tr>
<tr>
<td><strong>70–180 mg/dL (4.4–10.0mmol/L)</strong></td>
<td>46.9% (36/76)</td>
<td>67.1% (55/82)</td>
</tr>
<tr>
<td><strong>&gt;180 mg/dL (&gt;10.0mmol/L)</strong></td>
<td>3.9% (3/76)</td>
<td>0 (0/82)</td>
</tr>
</tbody>
</table>

Data are mean ± SD

*significant difference from standard therapy phase at p-value <0.05.
Background and Aims: This study assessed the long-term cost-effectiveness of the MiniMed™ 670G system versus Multiple Daily Injections (MDI) with intermittently scanned continuous glucose monitoring (isCGM) in people with type 1 diabetes (T1D) and baseline HbA1c < 8% in the Netherlands.

Methods: The IQVIA-CORE-Diabetes-Model was used to perform cost-effectiveness analysis over patient lifetime. Clinical data were derived from the retrospective Akturk study1 and the prospective observational real-world cohort study (FUTURE)2. MiniMed™ 670G system use was associated with a reduction in HbA1c of 0.4%, from 7.8% (61.7 mmol/mol) at baseline to 7.4% (57.4 mmol/mol) at the end of the study1; isCGM use was associated with a reduction in HbA1c of 0%2. Severe hypoglycemic events requiring medical assistance were 0 vs 0.639 per patient-year for the MiniMed™ 670G system versus the MDI+isCGM system, respectively. Cost data, expressed in 2020 Euros, were obtained from published sources and Dutch reimbursement prices. Societal perspective was used.

Results: The MiniMed™ 670G system was associated with a quality-adjusted life-year (QALY) gain of 2.23 with higher overall costs versus MDI+isCGM, leading to an incremental cost-effectiveness ratio of €6133 per QALY-gained. MiniMed™ 670G system use resulted in a lower cumulative incidence of hypo- and hyperglycemia (CGM-glucose <3.9 mmol/L; p=0.077) but similar rates during hypoglycemia (CGM-glucose <4.0 mmol/L; p=0.002) and hyperglycemia (CGM-glucose >10.0 mmol/L; p=0.001). The MiniMed™ 670G system use resulted in a lower cumulative incidence of hypo- and hyperglycemia (CGM-glucose <3.9 mmol/L; p=0.077) but similar rates during hypoglycemia (CGM-glucose <4.0 mmol/L; p=0.002) and hyperglycemia (CGM-glucose >10.0 mmol/L; p=0.001).

Conclusions: At a willingness-to-pay threshold of €80000 per QALY-gained, the MiniMed™ 670G system likely represents a cost-effective option in people with T1D in the Netherlands.
Background and aims: As a technology-focused diabetes care center, we developed a virtual training program for patients with type 1 diabetes (T1D) who were upgrading to the hybrid closed-loop (HCL) system after mandatory isolation during the COVID-19 pandemic. We aim to describe outcomes of a virtual training program and compare the manual mode against the auto mode feature.

Methods: A prospective observational cohort study. Patients with diagnosis of T1D previously treated with multiple doses of insulin (MDI) or sensor augmented pump therapy (SAP) who were upgrading to Hybrid Close loop (HCL) system from March to July 2020, were included. The education program consisted in at least seven sessions according to baseline therapy. Virtual training and follow-up were done through the Zoom video conferencing application and Medtronic Carelink System version 3.1 software. Demographical, clinical and A1c data were collected. CGM data such as TIR, time below range (TBR), time above range (TAR) and coefficient of variation (%CV) after two weeks using manual mode and the last two weeks in auto mode were analyzed.

Results: 91 patients were included in the analysis. Mean TIR achieved with manual mode was 77.3±11.3%. A significant increase in TIR to 81.6±7.6% (p<0.001) was described after two weeks of auto mode use with a significant reduction in TBR <70 mg/dL from 2.7±2.28% to 1.83±1.67% (p<0.001). Reduction of glycemic variability was significant independent of baseline therapy.

Conclusions: Virtual Training and follow-up through the Carelink platform allows the achievement of adequate results similar to face-to-face training.

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Background and aims: Outcome of type 1 diabetes (T1D) can only be improved by further automation of insulin delivery. As part of a real-life technical evaluation of a new advanced hybrid closed-loop system, and in the middle of COVID-19 pandemic, we analyzed outcomes after 5 weeks of use.

Methods: Thirty-five T1D patients, who were already using a Medtronic Minimed (MM) 670G hybrid closed-loop in Auto Mode for >3 months, were invited for real-life evaluation of the MM 780G advanced hybrid closed-loop system. Due to COVID-19, education and change between systems were largely done by remote video sessions. We used CareLink-generated reports to compare the last week of 670G system use with the 5th week of 780G system use.

Results: Patients successfully completed education and switched to SmartGuard (auto mode) after 48 hours. Average age 22 ± 13 years (range: 7–49y), duration T1D 12 ± 11y (range 0–49y), HbA1c 6.8 ± 0.4% (51 mmol/mol). Time In Range during last week of 670G was 76 ± 8% and improved to 84 ± 6% with 780G use. Time Below Range was similar (2.6%). Time Above Range decreased from 21% on 670G to 13% on 780G. Average glucose improved from 9.2 ± 1.4 mmol/l to 7.9 ± 0.9 mmol/l for 780G use. Patients were in automatic modes (Auto Mode/SmartGuard) for 74% (670G) and 96% (780G) of the time.

Conclusions: It is very feasible to switch from a MM670G to an MM780G system in remote education sessions under COVID-19 circumstances. A strong improvement of important glucometric data was seen in a relatively short timeframe, even in a selected group of patients with good baseline diabetes regulation.
Results: From our criteria, we chose thresholds of 3%, 4%, 5%, 6%, and 9% TDI at probabilities of 0.3, 0.5, 0.7, 0.8, and 0.9, respectively. When the full dataset was simulated, there was an increase of 0.88% percent time <70 mg/dL, a 2.85% increase in percent time 70–140 mg/dL, a 2.09% increase in percent time 70–180 mg/dL, a reduction of 2.97% percent time >180 mg/dL, and 1.47% less percent time >250 mg/dL when compared to the observed hybrid closed-loop (HCL) data. Figure 1 - Number of hypoglycemic events per day at different TDI percentages and thresholds.

Conclusions: This automatic bolusing strategy increased euglycemia and decreased hyperglycemia in simulation when compared to HCL, while only increasing hypoglycemia slightly.

O012 / #494
Topic: AS01-Closed-loop System and Algorithm
REAL-WORLD OUTCOMES OF THE FIRST 1'000 USERS OF THE MINIMEDTM 780G SYSTEM
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Background and Aims: The MiniMed™ 780G system clinical trials demonstrated improved glyemic control of >70% of time spent in target glucose range (70–180 mg/dL, TIR) and HbA1c or Glucose Management Indicator (GMI) of <7%.1,2 Following introduction of the system in Europe, in October 2020, real-world glyemic control outcomes were evaluated.

Methods: MiniMed™ 780G system data from countries having ≥50 users were uploaded voluntarily to CareLink™ Personal software from 05October2020- 11December2020 by individuals providing consent, and analyzed. Mean sensor glucose (SG), GMI, and percentage of time spent across SG ranges and in closed loop (automated basal, at minimum) were determined for users having ≥10 days of SG data after initiating MiniMed™ 780G automated basal and correction boluses.

Results: Individuals (N=1033) had a TIR of 76.8±9.1% and SG of 142.6±14.3 mg/dL (7.9 mmol/L), corresponding to a GMI of 6.7±0.3% (Figure). Time spent at <70 mg/dL and <54 mg/dL was 2.7±2.3% and 0.6±0.9%, respectively, while time spent at >180 mg/dL was 20.4±9.3%. The percentage of users achieving a TIR >70% and a GMI <7.0% was 80.2% and 82.4%, respectively. Time below ranges of <1% (for <54 mg/dL) and <4% (for <70 mg/dL) were achieved by 74.8% of users, and while in closed loop 92.7±10.8% of the time.

Conclusions: In this first analysis of real-world MiniMed™ 780G system data, most users achieved internationally recommended goals of glycemic control for TIR, TBR3, and GMI. These results are similar to those observed in the MiniMed™ 780G system clinical trials, supporting real-world reproducibility and providing evidence to the robustness of the algorithm.

O013 / #554
Topic: AS01-Closed-loop System and Algorithm
ATTD CONSENSUS TARGETS ARE ACHIEVABLE FOR PRESCHOOLERS: HYBRID CLOSED LOOP USE IN CHILDREN FROM 2–14 YEARS
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Background and Aims: Currently, only one CE marked systems with a hybrid automated insulin delivery (H-AID) is available per prescription in Germany. It is not labelled for use in preschoolers. The only technical limitation of this system (Minimed670G) for small children is a daily use of 8 units of insulin. ATTD consensus targets recommend a Time in Range (TIR) of >70% and Time below Range <4% in all ages with T1D.

Methods: A two phase study of children aged 7–14 and <7 years was conducted at our center. All children received training for the system and used it for 8 weeks in manual mode or 8 weeks in auto mode, the order was randomly assigned. Primary outcome parameter was the TIR 70–180%.

Results: 20 children from 2.5 to 6 years and 17 from 8–14 years completed the trial; younger group recruitment was stopped preliminary by Covid19 pandemic. After 8 weeks of HCL, TIR in 14day-profile was 70.7% compared to 53.8% after PLGM in the older group, HCL 73.9 % vs. PLGM 68.2% in preschool kids. Details on achievement are shown in table.

Conclusions: As shown in other trials, 670G is safe even under the labelled age. TIR was higher in our study than
published before. In both groups best results were achieved with the H-AID system. Preschoolers benefit from their parents performing the insulin therapy. To ensure safe use and modalities for children and prescribers, a label is also needed for small children.

O014 / #593

Topic: AS01-Closed-loop System and Algorithm

VIRTUAL CAMP EFFECTIVENESS TO START NEW TECHNOLOGIES IN FAMILIES WITH CHILDREN LIVING WITH TYPE 1 DIABETES

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Background and Aims: To analyze the impact of an educational Virtual Camp (eVC) in children with T1D and their parents on glucose control.

Methods: Nineteen Italian centers for pediatric diabetes participated. The eVC was held from 6 to 8 November 2020; it involved parents and their children aged 6–17 years who previously updated their pump software from Tandem Basal-IQ to Control-IQ technology. Several interactive sessions involving pediatric diabetologists, psychologists, dieticians and physical education teachers have been performed during the eVC. Eight weeks before the update to Control-IQ and eight weeks after eVC, CGM metrics were downloaded and summarized using median and interquartile range (IQR) and compared by Wilcoxon sign-rank test. Median differences and 95% CI were estimated.

Results: 43 children, 53.5% females, median age 15y and diabetes duration 10y, were included. After the eVC, the percentage of time in range and time above range significantly improved (Table 1); %CV and %GMI significantly decreased; IQR values showed a lower interindividual variability when using the updated algorithm. In addition, a significant reduction of daily percentage of bolus insulin was reported.

Conclusions: A significant huge improvement of glucose metrics was observed in children with T1D using Control-IQ technology after a 3-day eVC. More than 75% of children maintained a percentage of TIR over 70% during an 8-week period after eVC, suggesting that, despite forced interruption of clinical visits due to Covid-19 pandemic, the eVC is a useful tool to start new technological devices.

O015 / #621

Topic: AS01-Closed-loop System and Algorithm

3-MONTH EVALUATION OF ADVANCED HYBRID CLOSED-LOOP IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: A SINGLE-CENTER EXPERIENCE IN ITALY

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Background and Aims: The Medtronic Minimed® Advanced Hybrid Closed-Loop system (AHCL) includes an individualised algorithm with optional set points, automated correction bolus, and improved SmartGuard™ Auto Mode stability. After clearing the EU CE Mark in June 2020, it was in the market in Italy starting first week of October 2020. We present the first 3-month results of AHCL in children and adolescents with type 1 diabetes from a single center.

Methods: This one-centre, user-evaluation study in 25 children, adolescents and young adults (aged 1–25yrs), compared AHCL (MiniMed 780G, Medtronic, Northridge, CA, US) automated mode to first 14 days using manual mode, similar to Predictive Low Glucose Management (SAP+PLGM). Time in range (TIR), above range (TAR), below range (TBR), coefficient of variation (CV), mean sensor glucose, GMI, and severe adverse events (severe hypoglicemia and diabetic ketoacidosis in auto vs manual mode are presented using median and interquartile range (IQR) and compared by Wilcoxon sign-rank test. Median differences and 95% CI were estimated.
Results: Twenty-five patients, 70% males, median age 14y and diabetes duration 11y, were included. Nineteen switched from a hybrid closed-loop system (MimiMed 670G), 4 from multiple daily injections and 2 from other insulin pumps. After 3-month using AHCL, TIR significantly improved and TAR decreased, while TBR did not change; %CV and %GMI significantly decreased (Table).

Conclusions: AHCL (MiniMed 780G system) with automated correction bolus showed a significant improvement in glucose metrics compared to PLGM (manual mode of the system), in children, adolescents and young adults with type 1 diabetes using AHCL after a 3-month usage.

O016 / #644

Topic: AS01-Closed-loop System and Algorithm

NEW PROPOSED PHYSIOLOGY MODELS THAT UTILIZE METABOLIC EXPENDITURE DATA FROM ACTIVITY SENSORS TO FORECAST CHANGES IN GLUCOSE DURING AEROBIC EXERCISE

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Background and Aims: People with type 1 diabetes can experience dramatic changes in glucose during aerobic exercise leading to hypoglycemia. Physiological models of glucose dynamics do not correctly estimate glucose changes during exercise. This project compares two candidate mathematical models of glucose metabolism during exercise. Both models include metabolic expenditure as an input derived from body-worn physical activity sensors.

Methods: Models were identified and evaluated using a secondary analysis of data collected from adults with T1D who participated in a glucose-tracer infusion study (n=17, 11 F, weight 78.2 ± 11.0, TIDR 56.2 ± 12.7). After randomization into moderate intensity (40–45% V02 max) vs. high intensity (60–65% V02 max) group, participants performed in-clinic exercise on three days clamped at infusions of low (basal), medium (1.5x basal), or high (3x basal) insulin rate, and performed 45 minutes of aerobic exercise. Models of exercise impacted endogenous glucose production (EGP), and rate of glucose disposal (Rd). Model 1 was designed such that EGP and Rd from exercise were not dependent on insulin. Model 2 included both an insulin-dependent and non-insulin-dependent component of exercise-induced EGP and Rd. Parameters for Models 1 and 2 were fit using a Hamiltonian Monte-Carlo sampling scheme.

Results: Model 1 was more accurate than model 2 when evaluated across all study data (root-mean-squared error 0.71 ± 0.20 mmol/L Vs. 1.10 ± 0.35 mmol/L), and in estimating glucose changes during exercise (RMSE 0.97 ± 0.77 mmol/L Vs 1.22 ± 0.81 mmol/L).

Conclusions: Additional models will be proposed and evaluated prior to incorporation into existing virtual patient populations and model predictive control closed-loop algorithms.

O017 / #730

Topic: AS01-Closed-loop System and Algorithm

SWITCHING FROM BASAL-IQ TO CONTROL-IQ TECHNOLOGY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: ONE WEEK IS ENOUGH TO IMPROVE TIME IN RANGE.

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Background and Aims: In people with Type 1 Diabetes (T1D) the percentage of time in Range (TIR), 70–180 mg/dL, is now recognized as the most effective glucometrics together with HbA1c. The aim of this study was to analyze the early effect on
TIR changes after switching from Tandem Basal-IQ to Control-IQ technology in a group of children and adolescents with T1D.

**Methods:** Children and adolescents from 19 Italian centers have been recruited. After a standard educational program, the enrolled patients updated pumps software from Basal-IQ to Control-IQ. Differences in TIR one week (excluding the day of the update) and three weeks before and after the update were analyzed. TIR values were summarized using median and interquartile range (IQR) and compared by Wilcoxon sign-rank test. Median differences in TIR and 95%CI were used.

**Results:** TIR data of 43 youths (53.5% females, median age 15y, diabetes duration 10y) were analyzed. After upgrading to Control-IQ technology, TIR significantly improved, starting after the first week [median (IQR)], 75% (70;82) vs 67% (53;73), p<0.001, and keeping steady for the whole 3-week observation: 76% (69;82) vs 65% (55;73), p<0.001 (Figure 1). Furthermore, with Control-IQ algorithm, there was a lower interindividual variability as shown by the reduced differences in the IQR.

**Conclusions:** A significant increase in TIR is already evident after the first week with Tandem t:slim Control-IQ technology and this improvement is kept in the following weeks of observation.

O018 / #787

**Topic:** AS01-Closed-loop System and Algorithm

**COMPARING USE OF THE OMNIPOD® 5 SYSTEM WITH 3 MONTHS OF AUTOMATED INSULIN DELIVERY TO 3 MONTHS IN MANUAL MODE: A POST-HOC CROSSOVER ANALYSIS**

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**Background and Aims:** Achieving treatment goals can be challenging for people with type 1 diabetes (T1D) due to the many daily manual tasks and decisions required. During a 3-month single-arm pivotal study of the Omnipod 5 automated insulin delivery system, a 3-month mid-study safety pause provided the opportunity to assess the system in manual mode (MM, algorithm inactive) compared to automated mode (AM, algorithm active) in a post-hoc crossover analysis.

**Methods:** A subset of adults (14–70y) and children (6–13.9y) with T1D participating in the study completed four distinct phases of therapy: (1) run-in phase with their standard therapy (ST, 14d), followed by use of the Omnipod 5 System in (2) AM, (3) MM (3mo.), and (4) AM. The total duration of AM use was 3 months per participant (phases 2+4 combined). The primary glucose outcome was percent time in range (TIR, 70–180mg/dL, 3.9–10.0mmol/L).

**Results:** Adults (N=83) and children (N=89) were aged (mean±SD) 36±14y and 10.5±2.1y with T1D duration 16±11y and 4.8±2.7y and baseline A1C 7.3±0.9% and 7.7±0.9%, respectively. TIR was significantly higher during the AM phases compared to ST and MM (Table). Specifically, TIR increased with AM during Phase 2 compared to ST, reduced back to a level comparable to ST during MM in Phase 3, and then increased again when AM resumed in Phase 4 (all p<0.05).

**Conclusions:** This post-hoc crossover study emphasizes the effectiveness of the Omnipod 5 automated insulin delivery algorithm on glycemic outcomes, beyond pump and CGM use alone.

O019 / #789

**Topic:** AS01-Closed-loop System and Algorithm

**DIABELOOP DBL4K HYBRID CLOSED-LOOP SYSTEM IMPROVES TIME IN RANGE WITHOUT INCREASING TIME IN HYPOGLYCEMIA IN CHILDREN AGED 6–12 YEARS.**

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**Background and Aims:** The DBLG1 Hybrid Closed-Loop system improves time in range and glycemic control in adults. However, efficacy and safety of the system had not yet been
evaluated in children. The objective is to evaluate the non-inferiority of the DBL4K (Diabeloop for Kids) hybrid closed-loop system (Kaleido pump + Dexcom G6-CL) compared to a Dexcom G6 sensor augmented pump (open loop=OL) in pre-pubescent children.

**Methods:** Multicenter open-label randomised controlled trial in 3 pediatric diabetology centers. The CL and OL are worn for 4 days in hospital, followed by 6 weeks at home.

**Results:** Twenty-one patients (mean age: 8.34 +/- 1.6 years; 10 boys) were included between March and December 2019. The percentage of time spent in range (4–10 mmol/L) was identical in both groups during the 72-hour phase in hospital (68.73% in CL vs 70.53% in OL, p = 0.539) and significantly higher in the CL group during the 6 weeks at home (66.19% in CL vs 58.68% in OL, p < 0.001). The percentage of time spent in hypoglycemia (<3.85 mmol/L) was significantly lower in the CL group during the 72 hours in hospital (2.04% in CL vs 7.06% in OL, p < 0.001) and the 6 weeks at home (2.62% in CL vs 5.24% in OL, p < 0.0001). No events of ketoacidosis or severe hypoglycemia were recorded.

**Conclusions:** The DBL4K Closed-Loop System is suitable for prepubescent children. Just as in adults it improves the time in range while decreasing the time spent in hypoglycemia. It could allow for better long-term glucose control in children with diabetes.

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**O020 / #822**

**Topic:** AS01-Closed-loop System and Algorithm

**PHYSICIAN’S ATTITUDES TOWARD AID-SYSTEMS AND THEIR IMPLICATIONS FOR DIABETES CARE**

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**Background and Aims:** To date, there has been little research on the impact of AID systems in routine diabetes care.

**Methods:** 337 diabetologists (2018: 422; 2019: 324; 43% female, average age 53.2 years) were asked about their attitudes and expectations for AID systems.

**Results:** 59.4% of physicians currently consider AID systems to be very important for people with diabetes, and 91.6% will do so in 5 years. The majority of diabetologists expect that diabetes care will become more complex with AID systems (85.2 %), that more education is needed (81.4%) to facilitate the use of AID systems and will also result in an increase in the amount of time spent with the patient (65.9%). 48.3% believe that diabetes patients with AID systems will become more autonomous and be able to manage their diabetes more independently. 41.4% agree with the statement that many patients will not be able to manage AID systems in the right way. However, only 13.9% also share the view, that AID systems will make diabetes therapy riskier. Overall, the diabetologists do not believe that AID systems result in fewer contacts with patients (21.8 % agreement), less contact with patients (21.8% agreement), reduced amount of care required (13.9 % agreement) or that the diabetes team will become even become superfluous (3.5% agreement).

**Conclusions:** Overall, diabetologist estimate AID systems as a very important innovation. The effort required for education, therapy adjustment and further support is considered to be relatively high. There are less fear that diabetes team will become less important.

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**Figure:** Mean PPG (LSM±SE) with meal test at week 16. CI, confidence interval; LSM, least squares mean; SE, standard error. *p<0.05. **p<0.001.
hypoglycaemia and diabetic ketoacidosis were similar between groups.

Conclusions: URLi was efficacious, providing superior PPG control and an acceptable safety profile compared to Lispro in patients with T1D on CSII.

O022 / #330
Topic: AS02-New Insulin Analogues
REAL-WORLD EFFECTIVENESS AND SAFETY OF INSULIN GLARGINE 300 U/ML (GLA-300) IN INSULIN-NAIIVE PEOPLE WITH TYPE 2 DIABETES (T2DM): THE ATOS STUDY
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Background and Aims: The clinical beneﬁts of Insulin glargine 300U/mL (Gl-300), a second-generation basal insulin analog, have been conﬁrmed in real-world studies in the US and Western Europe. However real-world effectiveness and safety of Gl-300 in wider geographic regions is needed. ATOS is a prospective, 12-month, observational study assessing real-world effectiveness and safety of Gl-300 in countries outside US and Western Europe.

Methods: Adults (≥18 years) with T2DM, uncontrolled (HbA1c, >7–<11%) on ≥1 oral antihyperglycaemic drug (OAD) in whom the treating physician had decided to add Gl-300 were recruited from Asia, Middle East and Africa, Eastern Europe and Latin America.

Results: Overall, 4422 participants (51.8% females) were eligible. Mean (SD) age was 57.2 (10.8) years, duration of diabetes was 10.2 (6.2) years and baseline HbA1c was 9.28 (1.00%). Physician-set individualized HbA1c(%) goals at baseline were <7: 13.7%; 7–<7.5: 70.4%; 7.5–<8: 11.8%; ≥8: 4.1%. The proportion of patients achieving their HbA1c goal at Month 6 (primary endpoint) and Month 12 was 25.2% (95%CI: 23.8–26.6) and 44.5% respectively; HbA1c reductions from baseline to Month 6 and 12 were -1.50 and -1.87 respectively. The documented hypoglycaemia incidence (<2%) and change in body weight (LSM, -0.1 (95%CI: -0.3–0.0) at Month 12) was low. Treatment-emergent adverse events (TEAEs) were reported in 283 (6.4%) patients, with 57 (1.3%) serious TEAEs.

Conclusions: In a real-life setting in countries outside US and Western Europe, initiation of Gl-300 in people with T2DM uncontrolled on OADs resulted in improved glycemic control and low rates of hypoglycaemia with minimal weight change. Data first submitted to AACE-GulfChapter 2020.

O023 / #512
Topic: AS02-New Insulin Analogues
FAST-ACTING INSULIN ASPART IMPROVES GLUCOSE CONTROL IN A REAL-WORLD SETTING: A 1-YEAR MULTICENTER STUDY IN PEOPLE WITH TYPE 1 DIABETES USING CONTINUOUS GLUCOSE MONITORING.
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Background and Aims: To evaluate whether switching from traditional mealtime insulin analogs to fast-acting insulin aspart (Fiasp) in routine clinical practice is efficacious and safe in adult people with type 1 diabetes (PWD1) using intermittent or real-time continuous glucose monitoring (iCGM or rtCGM).

Methods: Data from 438 adult PWD1 (60% men, age 44.6±16.1 years, duration of diabetes 21.5±14.0 years, iCGM /rtCGM: 39/47, injections/pump: 409/29), initiating Fiasp between January 2018 and May 2020 were retrospectively analyzed. Primary endpoint was the evolution of time in range (TIR:70–180 mg/dl) at 12 months. Secondary endpoints included change in Time <70, Time <54, Time >180 and Time >250 mg/dl, coefficient of variation (CV), standard deviation (SD), HbA1c, insulin doses, and composite endpoint of reaching TIR >70% and Time <70 mg/dl of <4%.

Results: Time in range improved from 50.3±15.6% to 55.5±15.2% (p<0.0001), corresponding to an increase of 75 minutes/day. Time <70 mg/dl decreased from 7.4±5.5% (p=0.037), Time <54 mg/dl evolved from 3.1±3.3% to 2.5±3.0% (p=0.003), Time >180 mg/dl decreased from 42.3±16.7% to 37.7±16.9% (p<0.0001) and Time >250 mg/dl decreased from 16.5±12.8% to 13.1±12.5% (p<0.0001). Glucose variability also improved (CV from 41.9±7.0% to 40.3±6.9%, p=0.002 and SD from 72.7±18.0 to 65.8± 18.5 mg/dl, p<0.0001). The number of people reaching the composite endpoint TIR >70% and Time <70 mg/dl of <4% increased from 36.1% to 42.6% (p=0.047). HbA1c (from 7.8±1.1% to 7.7±1.0%) and insulin doses (0.66±0.24 to 0.62±0.21 units/kg body weight/day) remained stable.

Conclusions: Switching to Fiasp resulted in a 75 min/day increase in TIR, in combination with less time spent below range in a real-world study of adult PWD1.

O024 / #173
Topic: AS03-Artificial Pancreas
DO-IT-YOURSELF AUTOMATED INSULIN DOSSING: QUALITATIVE STUDY EXPLORING HEALTHCARE PROFESSIONAL EXPERIENCES
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Background and Aims: Healthcare professional (HCP) engagement with do-it-yourself automated insulin dosing (DIY AID) systems is variable with no clear guidelines or liability clarification if they choose to do so. We conducted qualitative interviews to examine the HCP perspective on these systems and their impact on routine healthcare.

Methods: Twenty healthcare professionals were interviewed from adult and paediatric diabetes services. HCP interviews explored perceptions of DIY AID systems, facilitators, and barriers to supporting such systems with patients and views on what would be required for the systems to be integrated into routine healthcare if safety and efficacy could be proven.

Results: HCPs reported benefits including glycaemic improvements (n=13), being safer than or presenting no added risk compared to other diabetes technologies and management approaches (n=12) and customizability (n=9). HCPs described the primary barriers to supporting DIY AID use as uncertainty about liability issues (n=19) and lack of formal guidelines regarding DIY AID systems in clinical practice (n=19). The majority of HCPs discussed reviewing data or collaborating with patients using DIY systems. Approximately half of HCPs reported making efforts to learn about DIY systems from patients, colleagues, or online resources.

Conclusions: We provide useful data about the complexities of the HCP and DIY AID user relationship as well as factors involved in HCP decisions about whether to support patients using these systems. HCP decision-making appears to be more nuanced than supporting or not supporting DIY use, with HCPs describing varying degrees of support for patients’ DIY systems.

O025 / #295
Topic: AS03-Artificial Pancreas
DEVELOPMENT OF AN INTERNATIONAL CONSENSUS STATEMENT AND PRACTICAL GUIDANCE ON OPEN-SOURCE AUTOMATED INSULIN DELIVERY (DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS) FOR HEALTHCARE PROFESSIONALS

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Background and Aims: Despite increasing use of Open-Source Automated Insulin Delivery (OS-AID) systems and real-world outcomes demonstrating safety and efficacy, there is no professional guidance available for HCPs to support use or provide clarity on ethical and legal concerns. As a result, a lot of uncertainty remains in care teams around the world on how to support people with diabetes using OS-AID. Therefore, an international professional consensus statement and practical guidance review is urgently needed.

Methods: As part of the OPEN project, a steering committee comprising of HCPs (endocrinologists, educators, exercise physiologists and psychologists) with significant clinical experience in OS-AID and publication track record was formed to develop the guidance. An international group of clinicians across several global regions formed part of a larger HCP network and contributed to the wider consensus of this guidance using an online feedback system. Input was also provided by medico-legal experts.

Results: Since the initial meeting at ATTD 2020, the steering committee has met virtually over 12 times. A review strategy was devised (see figure) and up-to-date best practice guidance and consensus statement were drafted using a real-time collaboration tool. The current final version is being appraised by the wider HCP network and major professional diabetes organisations on a multinational level.

Conclusions: Our detailed consensus finds OS-AID satisfies the principles of medical ethics and there is sufficient observational data supporting its safety and efficacy. It provides best practice recommendations for HCPs. Furthermore, it highlights important recommendations for regulators and industry.

O026 / #514
Topic: AS03-Artificial Pancreas
OUTPATIENT USE OF INTEROPERABLE ARTIFICIAL PANCREAS SYSTEM WITH LARGE MEALS AND UNANNOUNCED PHYSICAL ACTIVITIES IS SAFE IN ADOLESCENTS AND CHILDREN

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Background and Aims: We evaluated the feasibility and safety of the interoperable artificial pancreas system (iAPS)
Methods: Pediatric subjects (n = 20, 8F) with type 1 diabetes completed 48 hours of automated insulin delivery (AID) using the iAPS on an unlocked smartphone in three sequential age-based cohorts: 12–<18 years (n = 8, 5F), 8–<12 years (n = 7, 2F) and 5–<8 years (n = 5, 1F). Subjects consumed larger-than-usual meals of their choice and engaged in unannounced physical activities such as escape room, trampoline park and ropes course. Primary outcomes using fingerstick blood glucose (BG) assessed safety while secondary outcomes using continuous glucose monitoring (CGM) compared performance with sensor augmented pump (SAP) preceding AID.

Results: During AID, there were no instances of more than one confirmed BG <50 mg/dL, two instances of more than two confirmed BG ≥300 mg/dL longer than 2 hours, and no adverse events. Overnight during AID (Table), the low blood glucose index decreased by 0.3 (p = 0.006) and glucose variability decreased by 14.9 mg/dL (p = 0.009). In the youngest cohort, percent time in 70–140 mg/dL range increased by 12.2% (p = 0.015). Pre-pubertal subjects (1F) were significantly more sensitive to exercise-induced glycemic changes (Figure). Table. Comparison of outcomes (mean (standard deviation)) during iAPS AID over SAP for all subjects. * indicates p < 0.05.

Figure. Pre-pubertal ( Tanner I ) vs pubertal/post-pubertal ( Tanner II-V ) during physical activities.

Conclusions: The smartphone-based iAPS AID system was feasible and safe in pediatric subjects, even with larger meals and unannounced physical activities.

Background and Aims: Clinical trials of the AHCL system demonstrated improved glycemic outcomes. An exploratory analysis investigated how early optimum control was reached in pediatric and adult participants of the MinMed™ AHCL pivotal trial.

Methods: Participants underwent baseline run-in (~2 weeks) with HCL, SAP or CSII therapy followed by a 3-month study phase with the AHCL automated basal and autocorrection bolus therapy. Glycemic outcomes of the run-in and study were compared (including the months 1, 2, and 3 of the study phase) to determine how long it takes to reach glycemic stability and its duration of sustainability.

A107 / #570
Topic: AS03-Artificial Pancreas

EARLY GLYCEMIC EFFECTS OF THE MINIMED™ ADVANCED HYBRID CLOSED-LOOP (AHCL) SYSTEM AMONG PEDIATRIC (7–17 YEARS) AND ADULT (18–75 YEARS) PERSONS WITH T1D


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Background and Aims: Clinical trials of the AHCL system demonstrated improved glycemic outcomes. An exploratory analysis investigated how early optimum control was reached in pediatric and adult participants of the MinMed™ AHCL pivotal trial.

Methods: Participants underwent baseline run-in (~2 weeks) with HCL, SAP or CSII therapy followed by a 3-month study phase with the AHCL automated basal and autocorrection bolus therapy. Glycemic outcomes of the run-in and study were compared (including the months 1, 2, and 3 of the study phase) to determine how long it takes to reach glycemic stability and its duration of sustainability.
Results: Tables 1 and 2 show glycemic data for the run-in period, end-of-study phase and months 1, 2, and 3 of the study phase for the pediatric and adult cohorts, respectively. Significant change in mean sensor glucose was observed from run-in to end-of-study and run-in to month 1. Thereafter, no significant changes were observed.

Conclusions: These data suggest that glycemic outcomes in the first month of AHCL use may predict the subsequent two months and permit a shorter time to determine the effectiveness of AHCL in individual patients.

O028 / #742
Topic: AS03-Artificial Pancreas
FULLY AUTOMATED CLOSED-LOOP IN ADOLESCENTS WITH TYPE 1 DIABETES: A SAFETY AND FEASIBILITY STUDY
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Background and Aims: Modern automated insulin delivery system (AID), relying on timely quantification of meals, have reliably improved glycemic control in people with Type 1 Diabetes (T1D) of all ages. Achieving similar control without meal information has so far proven elusive. We present a new generation closed loop control (CLC) algorithm designed for such use.

Methods: Adolescents with T1D were enrolled at the UVA Center for Diabetes Technology (CDT) in a supervised outpatient clinical trial comparing the legacy UVA CLC (USS) with our new algorithm (RCKT) during hybrid (HCL) and fully automated (FCL) use. Four 24h periods were studied with 3 meals repeated from day to day; the second and fourth dinner were unannounced. One algorithm was used for day 1–2 and the other for day 3–4, in random order. Glucose control was evaluated on standard CGM-based metric.

Results: Twenty-one adolescent participants signed consent at CDT. Eighteen completed the study. Time in range (TIR) overall was 79.1±11.4% vs 83.2±10.8% (p=0.22) with dinner bolus and 78.6±11.1% vs 84.5±7.4% (p=0.075) without, for USS and RCKT respectively. Focusing on dinner (6PM-midnight) TIR in HCL was 90.9±12.9% vs 97.8±5.7%, p=0.052, and 58.8±25.7% vs 77.0±22.6%, p=0.02, in FCL. There was no difference in time below 70mg/dL or occurrence of hypoglycemia.

Conclusions: Our new AID algorithm was shown to be feasible in adolescents with T1D, equivalent to UVA legacy algorithm in hybrid use, and led to +18% TIR during un-bolused dinners. Additional studies are needed to assess its impact over several days of use and less supervised environments.

O029 / #759
Topic: AS03-Artificial Pancreas
BIHORMONAL CLOSED LOOP GLUCOSE CONTROL VERSUS CURRENT CARE AFTER TOTAL PANCREATECTOMY (APPEL5+): OUTPATIENT RANDOMIZED CONTROLLED CROSSOVER TRIAL
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Background and Aims: Glucose control in patients with diabetes after total pancreatectomy (TP) is problematic due to complete absence of both pancreatic alpha and beta cells. Recently, a novel bihormonal (insulin and glucagon) artificial pancreas (AP) for closed loop glucose control showed better glucose control compared to standard insulin pump therapy in patients with diabetes type 1. This AP system might also improve glucose control in patients after TP. The aim is to assess the efficacy and safety of the bihormonal AP in patients after TP.

Methods: This trial was an outpatient, randomized, crossover trial comparing AP therapy to current care (insulin pump or pen therapy). The outcomes in both phases were analyzed during a total of 7 days. The AP closed loop phase was preceded by a 5-day training period. Primary outcome was the time spent in euglycemia (3.9-10 mmol/L or 70–180 mg/dL).

Figure 1: Quartile erosion and median for USS (red) and RCKT (blue) during the evening and night after a bolused (panel A) and unbolused (panel B) dinner.
**Results:** A total of 10 patients were included in the analysis. In the AP closed loop phase, the time spent in euglycemia was significantly higher (78.3% [IQR 72.3-81.7] vs 57.4% [IQR 54.1-80.2], p = 0.007), as compared to current care. Also, the AP showed a significant lower time spent in hypoglycemia (0% [IQR 0.0-0.0] vs 1.6% [IQR 1.0-2.8]), p = 0.004. No serious adverse events related to the AP device were seen.

**Conclusions:** This small randomized crossover trial showed that an artificial pancreas bihormonal closed loop system is safe and significantly improves time in euglycemia as compared to current practice of insulin pump or pen injections. Larger randomized trials including longer periods of treatment are needed.

**O030 / #79**

**Topic:** AS04-Clinical Decision Support Systems/Advisors

A DATA-DRIVEN CLASSIFIER OF DAILY CONTINUOUS GLUCOSE MONITORING (CGM) PROFILES

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**Background and Aims:** With the proliferation of CGM, massive databases of CGM traces (daily profiles) are constantly growing. A question therefore arises: are all of these profiles substantially different or is there a finite set of distinct daily profiles which sufficiently approximate all possible profiles? We propose a data-driven approach to determine a finite set of “motifs” – representative daily profiles – such that almost any daily profile can be matched to one of the motifs.

**Methods:** Data: 595 individuals with type 1 or type 2 diabetes (T1D, T2D) participating for 3-6 months in either the International Diabetes Closed-loop (iDCL) Trial or in Dexcom’s DiaMonD study. A set of 226 motifs was constructed by clustering 4,802 (training) profiles from the iDCL Protocol 1 study (T1D) and identifying the motif for each cluster. The representative set of motifs was then tested using profiles from the iDCL Protocol 3 (T1D, T2D) participating for 3-6 months in either the Internationa Diabetes Closed-loop (iDCL) Trial or in Dexcom’s DiaMonD study. A set of 226 motifs was constructed by clustering 4,802 (training) profiles from the iDCL Protocol 1 study (T1D) and identifying the motif for each cluster. The representative set of motifs was then tested using profiles from the iDCL Protocol 3 and DiaMonD studies (T1D and T2D), which included a variety of treatment modalities, e.g. daily insulin injections, insulin pumps, and artificial pancreas.

**Results:** Over 98.8% of the 39,916 testing profiles were successfully classified using the motifs. Each cluster of profiles from the testing data had similar clinical characteristics (e.g., time within or above range) to the corresponding cluster of profiles from the training data.

**Conclusions:** The finite set of motifs can sufficiently describe almost any daily profile, and the clinical characteristics of each motif are representative of the CGM profiles clustered around it. The motifs can be used for predictive modeling, decision support, or automated closed-loop control.

**O031 / #342**

**Topic:** AS04-Clinical Decision Support Systems/Advisors

AN INTERPRETABLE LSTM-BASED PREDICTION MODEL FOR ASSESSING THE RISK OF HOSPITALIZATION AND RE-HOSPITALIZATION IN YOUTH WITH TYPE 1 DIABETES MELLITUS

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**Background and Aims:** Diabetic Ketoacidosis (DKA) and hyperglycemia with ketosis in the absence of acidosis constitute major causes of hospital admission and morbidity in children and adolescents with Type 1 Diabetes Mellitus (T1DM). This study aims at the development of an interpretable prediction model for the risk assessment of hospitalization and re-hospitalization in children and adolescents with T1DM.

**Methods:** Data collected from a two-year follow-up of 127 T1DM patients at the “Agia Sofia” Children’s Hospital, within the framework of the “SWEET” Initiative, were used for development and evaluation purposes. Frequently identified risk
Considered risk factors for hospitalisation and re-hospitalisation in children and adolescents with T1DM

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<td>Female</td>
</tr>
</tbody>
</table>

Explanations for the model’s decisions generated by applying the LIME technique. Example of a patient with high risk of hospitalization.

Factors that increase in increasing hospitalization risk: Basal insulin/total daily insulin (regression coefficient of each factor) = 0.51 ± 0.13.

Factors that decrease in increasing hospitalization risk: Addition of patient’s insulin treatment profile (regression coefficient of each factor) = -0.85.

The availability of eGDR to assess the association between eGDR, liver steatosis and CVD.

Factors for recurrent DKA admissions were considered to compose the input space. The model was based on Long Short-Term Memory Neural Networks (LSTM) in order to leverage LSTM’s efficiency in handling sequential data. The unbalanced nature of the dataset was addressed by applying an ensemble learning method, based on a sub-sampling approach. Interpretation of the model’s decisions was achieved by deploying the Local Interpretable Model-agnostic Explanations (LIME) technique.

Results: The 3-fold cross-validation criterion was applied to assess the model’s generalization ability. The obtained results in terms of C-statistic (71.34 ± 0.05%) indicate acceptable discrimination ability. Meaningful insights about the influence of the considered risk factors on the model’s decisions were provided by applying the LIME technique.

Conclusions: The obtained results demonstrate the potential of the proposed method to achieve high accuracy while ensuring user’s trust by providing appropriate explanations on the produced decisions.

Acknowledgment: Supported within the framework of the ENDORSE project, which is funded by the NSRF (Grant agreement: T1EAK-03695).

O033 / #372

Topic: A04-Clinical Decision Support Systems/Advisors

THE ROLE OF EGDR AS A PREDICTOR OF INSULIN RESISTANCE AND CARDIOVASCULAR DISEASE

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**Background and Aims:** People with type 1 diabetes (T1D) have a high risk of cardiovascular disease (CVD) which may be accelerated by insulin resistance. Estimated glucose disposal rate (eGDR) correlates well with the euglycaemic clamp. We aimed to assess the association between eGDR, liver steatosis, and CVD.

**Methods:** Adult T1D subjects were consecutively screened for liver steatosis using ultrasound (US), Fatty Liver Index (FLI) and controlled attenuation parameter (CAP). The eGDR was calculated based on hypertension, HbA1c and waist circumference. CVD was assessed based on patient files.

**Results:** CVD was present in 34 out of 355 subjects. Divided into tertiles (<5.39, 5.39-7.79, >7.79), 36.6% expressed low eGDR; 32.7% intermediate eGDR and 30.7% high eGDR. There was moderate correlation between eGDR and FLI (r = 0.68, p < 0.001) and weak correlation with US (r = 0.33, p < 0.001) and CAP (r = 0.50, p < 0.001). In the low eGDR group (= insulin resistant group) not only steatosis (38.5% vs. 11.2% (intermediate eGDR) and 12.8% (high eGDR)) but also composite CVD (18.5% vs. 6.0% and 2.8%) were significantly more present (p < 0.001 for both). Low eGDR (OR: 4.2 [2.2-8.2], p < 0.001), but not BMI or dyslipidaemia was independently associated with US-defined liver steatosis. Low eGDR was also independently associated with FRI-determined steatosis (OR: 5.39 [5.39-7.79], p = 0.004) together with BMI (OR: 1.6 [1.4-1.9], p < 0.001). Low eGDR (OR: 8.0 [2.3-27.4], p < 0.001) and liver steatosis (OR: 2.71 [2.6-3.1], p = 0.022 (US-defined), OR: 2.91 [4.6-6.0], p = 0.005 (FLI-defined)) were independently associated with composite CVD, but presence of metabolic syndrome, dyslipidaemia and BMI were not.

**Conclusions:** Insulin resistance is prevalent in T1D. eGDR correlates with the presence of liver steatosis. Both eGDR and liver steatosis correlate with prevalent CVD.

O034 / #466

Topic: A04-Clinical Decision Support Systems/Advisors

ENABLING PATIENT-DATA INTERACTIONS IN TYPE 1 DIABETES THROUGH A CLOUD-BASED SIMULATION TOOL

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**Background and Aims:** Advanced insulin therapy in type 1 diabetes (T1D) relies on key individual treatment profiles such as basal rate, carbohydrate ratio, and correction factor. Periodic adjustments of these profiles are needed based on review of data that usually require manual downloads from multiple devices. The aim of this project is to design and test a novel, cloud-based, centralized platform – the Web-Based Simulation Tool (WST) – that allows users to quickly and safely explore changes to their treatment practices.

**Methods:** WST automatically collects data from the patients’ insulin pumps via Tandem t:connect technology and generates...
personalized models of their glucose metabolism on a daily basis. It is equipped with a simple user-interface where users can visualize their data, run simulations with modified meals and insulin parameters, and generate reports. An outpatient pilot study with fifteen adult participants with T1D is currently being conducted to evaluate WST usability and performance.

**Results:** WST has already processed 233 days of data from which it was able to generate 195 models (83.69% success rate) with an average RMSE and MARD of 15.98 ± 6.45 mg/dl and 7.95 ± 3.15%, respectively, and with 99.59% of reconstructed glucose values in the A- and B-zones of the Clarke Error Grid. Analysis of responses to technology expectation/acceptance and psychosocial questionnaires will be completed at the end of the trial.

**Conclusions:** Simulation technologies help leverage the vast amount of diabetes data currently available, enabling novel patient-data interactions that could facilitate decision-making processes related to the optimization of T1D treatment strategies.

**O035 / #552**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**EVALUATION OF THE HYPOGLYCAEMIA PREDICTIVE ALGORITHM IN THE INSULCLOCK® INSULIN PEN CAP DIGITAL PLATFORM IN TYPE 1 DIABETES TREATED WITH INSULIN MULTIDOSE*

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**Background and Aims:** Insulclock® is a small electronic device that functions as a cap fitted to the available insulin pens and monitors the date, time, and dose of insulin, and information from glucometers and continuous glucose monitors (CGM). Store the information in an app designed for this purpose. Our goal was to evaluate the accuracy of an algorithm for hypoglycemia (HG) prediction by the Insulclock app using the device’s information exclusively.

**Methods:** An original HG (glucose <70mg/dl) predictive algorithm was developed that uses data from Insulclock® and the Freestyle Libre® (Abbott) CGM. It alerts the risk of HG and the expected time up to it. Intakes are automatically detected using the GRID method. Subsequently, it has been evaluated for 180 days in a patient 47 years old with DM1 30 years ago. We concluded correct alarms were real HG avoided with an intake; false positive if after the expected time for HG, it does not arrive without having eaten; false negative, HG without previous alarm. Additionally, the error in the calculated time and the total number of HG events were evaluated.

**Results:** 132 alarms issued. Correct alarms 90 (84.9%); false positives 42 (31.8%); false negatives 16 (11.1%); 116 actual HG events (77.5% detected). The average advance time detection was 87 minutes. The average absolute error value in the time prediction for hypoglycemia is 35 minutes.

**Conclusions:** The predictive algorithm tested allows to detect and alert in advance to potentially avoid a high number of hypoglycemia events using only information obtained automatically by the Insulclock® device. New studies should expand and confirm this experience.

**O036 / #707**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**TIME IN RANGE AND GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES USING A MOBILE APP-ASSISTED CARBOHYDRATE COUNTING*

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**Background and Aims:** Carbohydrate (CHO) counting is often performed inaccurately by patients with type 1 diabetes (T1D). We hypothesized that mobile App “Dietrometro”, that estimates CHO content of food pictures and weights, would ameliorate glucose control in T1D subjects. To study the effect of Dietrometro on glucose control.

**Methods:** 60 T1D subjects (aged 18–60 years, 31 males), on multiple daily injections (n = 26) or continuous subcutaneous insulin infusion (n = 34), were randomly assigned to three groups: no CHO counting (group 1; n = 21), “self-managed” counting (group 2; n = 19) and App-assisted counting (group 3; n = 20). Main outcomes were TIR at one-month and HbA1c at three-months follow-up. Time above (TAR) and below range (TBR) were estimated by flash (Freestyle Libre-1) or continuous glucose monitoring (Guardian, Dexcom G6).

**Results:** Age, gender, type of insulin, glucose monitoring system and baseline TIR were similar between groups, while baseline HbA1c was lower in group 3 compared to group 1 (6.9 ± 1.06 vs. 7.8 ± 0.85%; p < 0.05). At one-month follow-up, TIR was higher in group 3 compared to group 1 (66.53 ± 14.71 vs. 54.38 ± 14.23; p = 0.02), but similar between other groups (p > 0.11), although this difference disappeared after adjustment for baseline HbA1c. At three-months follow-up, groups 2 and 3 had a lower HbA1c than group 1 (7.17 ± 0.86 vs. 6.88 ± 1.05 vs. 8.18 ± 1.06%, respectively; p = 0.001). TAR and TBR were similar between groups at baseline and after one-month follow-up.

**Conclusions:** App-assisted CHO counting might improve TIR in T1D. Larger sample size and longer follow-up are needed to define the long-term effect of this system and its advantage over self-managed counting.

**O037 / #785**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**AN INNOVATIVE ONLINE SELF-DETERMINATION PROGRAM TO IMPROVE SELF-MANAGEMENT IN YOUNG ADULTS WITH TYPE 1 DIABETES*

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**Background and Aims:** For young adults with type 1 diabetes (YAWD), it can be difficult to manage diabetes due to competing lifestyles and work commitments. The Guided Self-
determination (GSD) method is an evidence-based self-management program that aims to improve motivation to make positive lifestyle changes. **The study aim** was to evaluate the feasibility and efficacy of the online GSD program in improving diabetes self-management skills among YAWD.

**Methods:** Nine Diabetes Educators (DEs) attended a 1.5 day face-to-face training course. YAWD aged 18 to 30 were recruited from a Young Adults Diabetes Service clinic, from Consumer organisation and from University student forums. DEs completed the online survey measures of autonomy, competency and communication with healthcare providers were completed by YAWD before and after participation. Follow-up surveys invited comments on YAWDs’ and DEs’ experience of the program and DEs participated in a focus group.

**Results:** 15 young adults have completed the program. DEs indicated that the program has changed the way they communicate with their clients, and that the online GSD approach was most successful when applied flexibly, to suit YAWDS’ preferred time of day, learning style and mode of conversation (eg telephone versus videoconferencing).

**Conclusions:** The online GSD program is feasible; efficacy in improving self-management skills has yet to be assessed in a larger sample of YAWD, however, has the potential to empower YAWD to improve diabetes care and facilitate access to healthcare 24/7 and regardless of location.

**O038 / #42**
**Topic:** A050—Glucose Sensors

**REAL WORLD COST OUTCOMES WITH DIABETES TECHNOLOGY USAGE AMONG ADULTS WITH TYPE 1 OR TYPE 2 DIABETES USING RAPID-ACTING INSULIN**

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**Background and Aims:** We aimed to determine the 1-year medical costs associated with initiation of a continuous glucose monitor (CGM) or insulin pump.

**Methods:** Using the IBM MarketScan database, we included people with diabetes (PwD) ≥40 years old using rapid-acting insulin who initiated a CGM or a pump (index date) between 2015–2017. A third cohort, a control group, were blood glucose monitor (BGM) users. Continuous enrollment was required in the 12 months before (baseline) and after (follow-up) index date. Mean total medical costs, excluding device-related costs, are reported as unadjusted values. Adjusted follow-up costs were calculated by fitting a generalized linear model with gamma distribution and log link.

**Results:** PwD meeting all criteria (n = 7,700) were assigned to one of the 3 cohorts (table). For CGM and Pump cohorts, unadjusted follow-up costs were higher than baseline. For the first year after initiation CGM was associated with $2038 in savings compared to BGM (p = 0.0076) while pump was associated with $1786 higher costs (p = 0.0039). Significant covariates in the models included baseline cost, age, diabetes type (and interaction with age), and polypharmacy.

**Conclusions:** During the follow-up period, the unadjusted medical costs appear lower than BGM for both CGM and Pump, but multivariable adjustment yielded medical cost savings only for CGM use. Economic benefits might be observable sooner for CGMs than for pumps. Future work should extend the analyses to longer follow-up periods, characterize the source(s) of the incremental savings/costs, and evaluate whether the results differ for newer generations of devices.

**O039 / #162**
**Topic:** A050—Glucose Sensors

**COMPARING REAL-TIME AND INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN ADULTS WITH TYPE 1 DIABETES: THE SIX-MONTH MULTICENTER RANDOMIZED CONTROLLED ALERTT1 TRIAL**

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**Background and Aims:** It is currently unclear whether switching from isCGM to rtCGM with alert functionality offers additional benefits for adults with type 1 diabetes (TID).

**Methods:** This multicenter, open label, randomized controlled trial compared 6-month rtCGM use (Dexcom G6; n = 127) with isCGM (Abbott FreeStyle Libre; n = 127) in adults with T1D previously using isCGM. Primary endpoint was time in range (TIR; 70-180 mg/dL). The trial was also powered for key secondary endpoints HbA1c, time <54 mg/dL, and Hypoglycemia Fear Survey worry (HFS-worry) score. Sensor-glucose data were measured with (blinded) Dexcom G6 sensors in both groups. Groups (rtCGM/isCGM) were comparable in terms of baseline TIR (52.5%/51.3%), age (42.8 years/43.0 years), HbA1c (7.4%/7.4%), CSII use (18.9%/19.7%), and hypoglycemia unawareness (18.9%/15.7%; based on Clarke score).

**Results:** After six months, participants on rtCGM spent more TIR compared to isCGM users (59.6% vs 51.9%; p <0.0001), corresponding to 99 minutes/day. HbA1c was 0.36% (95%CI -
Background and Aims: To evaluate the association between clinical factors and macronutrients intake with CGM-based time in range (TIR) in children with T1D.

Methods: A multi-center cross-sectional study recruited children with T1D, aged 2–17y, HbA1c < 86 mmol/mol, using CGM, during Jan 2019–Jan 2020 in Italy. Diet intake was collected through three day weighed food diaries. Nutrients were evaluated as percentages of total intake and summarized as median and (IQR). TIR was considered at target if the percentage of readings and time 70-180 mg/dL was higher than 70%. Clinical and nutritional factors associated with TIR at target were analysed using multiple logistic regression, results were expressed as OR and 90%CI.

Results: Data were available for 197 children, 53% male, 47% using CSII, median age 11.6y (8.6-14.3), HbA1c 55 mmol/mol (48–61). Median nutrients intake was Protein, P 16.9% (14.4-19), SFA 9.6% (7.8-10.9), polyunsaturated fatty acid, PUFA 10.3% (85.5% vs. 73.6%; P = 0.0004). Scores on treatment satisfaction questionnaires were higher in rtCGM users (P < 0.0001).

Conclusions: In an unselected group of adults with T1D, switching from isCGM to rtCGM with alerts significantly improved time in range, HbA1c, time <54 mg/dL, and hypoglycemia worry.

O040 / #195

Topic: AS05-Glucose Sensors

ASSOCIATION OF MACRONUTRIENTS INTAKE WITH CGM-BASED TIME IN RANGE IN CHILDREN WITH T1D


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Background and Aims: To evaluate the association between clinical factors and macronutrients intake with CGM-based time in range (TIR) in children with T1D.

Methods: A multi-center cross-sectional study recruited children with T1D, aged 2–17y, HbA1c < 86 mmol/mol, using CGM, during Jan 2019–Jan 2020 in Italy. Diet intake was collected through three day weighed food diaries. Nutrients were evaluated as percentages of total intake and summarized as median and (IQR). TIR was considered at target if the percentage of readings and time 70-180 mg/dL was higher than 70%. Clinical and nutritional factors associated with TIR at target were analysed using multiple logistic regression, results were expressed as OR and 90%CI.
coefficient of variation were 94.9 mg/dL and 41.3% for Q1 versus 75.0 mg/dL (p<0.0001) and 38.2% (p<0.0001) for Q4.

**Conclusions:** Analysis of real-world data demonstrates that higher scanning frequency in FreeStyle Libre® users is associated with lower eA1c, greater TIR, less time in hypo- and hyperglycemia and lower glucose variation.

**O042 / #262**

**Topic:** *AS05-Glucose Sensors*

**CONTINUOUS GLUCOSE MONITORING AND CLINICAL OUTCOMES AMONG PATIENTS WITH TYPE 1 DIABETES AND COVID-19: A U.S. BASED MULTI-CENTER OBSERVATIONAL STUDY*

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**Background and Aims:** Continuous glucose monitoring (CGM) improves glycemic control and reduces complications in patients with type 1 diabetes (T1D). This study examines the frequency of diabetic ketoacidosis (DKA) and hospitalization among patients with T1D and COVID-19 and CGM use.

**Methods:** This analysis included all patients with T1D who tested positive for COVID-19 (n=241) in the TID Exchange COVID-19 Registry. Data for the registry was collected using an online survey tool. Healthcare teams from 52 endocrinology clinics across the U.S. completed the survey using electronic medical records between April and September 2020.

**Results:** Of the 241 patients included in this analysis, 53% were CGM users and 47% were CGM non-users. CGM non-users were more likely to be on public insurance compared to CGM users (68% vs. 34%). HbA1c in the CGM group was lower compared to non-users (Median [IQR],%: 8.1 [2.6] vs 10.0 [3.3] [p<0.001]), and DKA was less frequent for CGM users relative to the non-users (9% vs 36%) [p<0.001]. Further, patients who did not use CGM were more likely to be hospitalized (33% vs 13%) [p<0.001] or need ICU care [30% vs.6%] [p<0.001] than patients who used CGM.

**Conclusions:** Patients with T1D infected with COVID-19 who used a CGM device had lower rates of adverse clinical outcomes than patients who did not use CGM.

**O043 / #278**

**Topic:** *AS05-Glucose Sensors*

**REAL-TIME CONTINUOUS GLUCOSE MONITORING VERSUS SELF MONITORING OF BLOOD GLUCOSE IN TYPE 1 DIABETES: REAL-WORLD DATA FROM A LARGE U.S. MULTI-CENTER STUDY*

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**Background and Aims:** The management of type 1 diabetes (T1D) involves strict glucose control to avoid acute complications. The use of real-time continuous glucose monitors (rtCGM) relative to self-monitoring of blood glucose (SMBG) has demonstrated better glycemic control in T1D patients. This study aims to examine the distribution of patient demographics and frequency of clinical outcomes across the rtCGM and SMBG groups.

**Methods:** The analysis included 14,248 T1D patients in the T1D Exchange Quality Improvement (T1DX-QI) database for whom electronic medical record data was available from eight endocrinology clinics across the U.S. Patients over 2 years with at least one completed clinic encounter between July 2017 – February 2020 were included for analysis.

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**Table: Distribution of patient factors across rtCGM and SMBG groups in the 1TDX-QI cohort (N=14,248)**

<table>
<thead>
<tr>
<th>Patient Attributes</th>
<th>rtCGM (N=5,270)</th>
<th>SMBG (N=8,972)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (y)</td>
<td>37.4 (17.1)</td>
<td>38.8 (18.9)</td>
<td>0.01</td>
</tr>
<tr>
<td>Male (y)</td>
<td>50 (56)</td>
<td>51 (58)</td>
<td>0.51</td>
</tr>
<tr>
<td>Insurance type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public KBH</td>
<td>43 (53)</td>
<td>57 (68)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Private KBH</td>
<td>48 (51)</td>
<td>40 (47)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.1 (5.5)</td>
<td>23.5 (5.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HbA1c level (%)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&lt;7%</td>
<td>80 (19)</td>
<td>9 (7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7% – 9%</td>
<td>30 (46)</td>
<td>36 (52)</td>
<td>0.34</td>
</tr>
<tr>
<td>&gt;9%</td>
<td>29 (31)</td>
<td>75 (82)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypoglycemia (%)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intermediate Care</td>
<td>51 (15)</td>
<td>54 (16)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypoglycemia/No Care</td>
<td>56 (16)</td>
<td>47 (15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total glucose</td>
<td>48 (15)</td>
<td>30 (10)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Adverse Outcomes</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death</td>
<td>1 (0.03)</td>
<td>4 (0.05)</td>
<td>0.10</td>
</tr>
<tr>
<td>DKA</td>
<td>51 (0.9)</td>
<td>83 (1.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICU</td>
<td>63 (2.5)</td>
<td>83 (3.6)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Notes:**
- Glucose: ketone/dextrose use defined as blood glucose greater than 200 mg/dL (11 mmol/L), versus pH less than 7.3 or bicarbonate less than 15 mmol/L, ketonemia, and ketonuria
- DKA: diabetic ketoacidosis
- rtCGM: real-time continuous glucose monitoring
- SMBG: self-monitoring of blood glucose
- rtCGM patients more likely to be hospitalized (33% vs. 13%) [p<0.001] or need ICU care [30% vs. 6%] [p<0.001] than patients who used CGM.
Results: In this population, 37% (N = 5,276) of T1D patients were rtCGM users, whereas 63% (N = 8,972) self-monitored blood glucose. Fewer Non-Hispanic Black (2% vs. 11%) and publicly insured patients (8% vs. 16%) used a rtCGM device relative to the SMBG group [p < 0.001]. HbA1c levels were higher in the SMBG group compared to those using rtCGM (Mean [SD], %: 8.8 [2.1] vs. 8.1 [1.7] [p < 0.001]), and events of severe hypoglycemia (8% vs. 10%) and diabetic ketoacidosis (2% vs. 7%) were less frequently recorded for rtCGM users relative to the SMBG group [p < 0.001].

Conclusions: This study highlights inequities in adoption of rtCGM for glycemic control, while consolidating previous findings demonstrating rtCGM device use being critical in effective management of blood glucose levels.

O044 / #376
Topic: AS05-Glucose Sensors

PERFORMANCE OF THE GUARDIAN™ SENSOR 3 CONTINUOUS GLUCOSE MONITORING SYSTEM WITH NO CALIBRATION
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Background and Aims: Continuous glucose monitoring (CGM) is becoming an important tool for glycemic management and is an integral part of automated insulin delivery (AID) systems. Medtronic developed a new sensor algorithm for use with the Guardian™ Sensor 3 (GS3) glucose sensor that requires no calibration, and the present study assessed its performance.

Methods: There were 160 subjects (aged 18–80 years, ~64% with T1D) who wore GS3 sensors in the arm and abdomen. Data were compared with Yellow Springs Instrument (YSI) values and processed using the Zeus algorithm and incorporating different calibration schemes. The primary endpoint was determination of overall sensor glucose (SG) values within 20% of YSI reference, or ±20 mg/dL, when SG was <80 mg/dL (20%–20%). Other endpoints included overall mean absolute relative difference (MARD) between system and reference values, ±15 mg/dL at SG <70 mg/dL, and Consensus Error Grid (CEG) analyses.

Results: For no calibrations and the arm location, 20%±20 and ±15 mg/dL agreement rates were 88.0% (N = 20,612 paired data points) and 89.6% (N = 2,456 paired data points), respectively. For the abdomen, the rates were 88.0% (N = 18,423) and 92.1% (N = 1963), respectively, MARD was 10.64% for the arm and 10.78% for the abdomen. MARD for <70 mg/dL SG range was 12.61% for the arm and 14.78% for the abdomen. The CEG analyses determined 99.9% of points within the A + B range for both the arm (N = 20,590) and abdomen (N = 18,409) locations.

Conclusions: These data on the performance of the no-calibration Guardian™ Sensor 3 system may support non-adjunctive insulin dosing in standalone CGM and AID systems.

O045 / #387
Topic: AS05-Glucose Sensors

FACTORS ASSOCIATED WITH IMPROVEMENT IN DIABETES-RELATED DISTRESS IN PEOPLE LIVING WITH TYPE 1 DIABETES WITH FREESTYLE LIBRE - ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) STUDY
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Background and Aims: We have recently shown that use of FSL is associated with improvement in diabetes-related distress (DDS) in people with T1D. The objective of this study was to identify factors associated with improvement in DDS following the use of FSL.

Methods: The study was performed using data from the ABCD nationwide FreeStyle Libre audit. We collected diabetes-related distress scores at baseline and follow up (two-item diabetes distress screening instrument, ‘feeling overwhelmed by the demands of living with diabetes’ and ‘feeling that I am often failing with my diabetes routine’ DDS2). An average item score of ≥3 (moderate distress) discriminated high from low-distressed subgroups. We used an unsupervised gradient boosting machine learning model (GBM) to identify the relative influence (RI) of post-FSL use on two components of DDS. Since the two components were correlated, we only present the factors associated with the change in DDS1 following FSL use.

Results: The study included 4,588 people living with T1D who had baseline and post-FSL DDS score and consisted of 48.6% female, with baseline, and post FSL HbA1c of 76.6 (±16.02) and 62.9 (±14.02) mmol/l and a baseline and post FSL DDS of 2.8 (±1.4) and 2.2 (±1.9) respectively. In the GBM model, improvement in the GOLD score (RI = 42.2), and HbA1c with FSL use (RI = 19.4), post-FSL HbA1c (RI = 13.8) and the greater number of FSL scans per day (RI = 10.07) were associated post-FSL reduction in DDS.
Conclusions: Improvement in hypoglycaemia awareness, glycaemic control and engagement with FSL is associated with improved DDS in people living with T1D.

O046 / #452
Topic: AS05-Glucose Sensors
ACCURACY OF RT-CGM SYSTEMS DURING CONTINUOUS AND INTERVAL EXERCISE IN ADULTS WITH TYPE 1 DIABETES
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Background and Aims: Real-time glucose monitoring systems (rt-CGMs) play an important role in the treatment decisions of subjects with type 1 diabetes (T1D), but their accuracy may be lower during exercise. We assessed the accuracy of several recent rt-CGMs in T1D subjects during both moderate continuous (CON) and interval training (IT) exercise.

Methods: In 22 patients, already using a rt-CGM, a second different sensor was applied. Participants performed, in a random order, a 30’ CON session, and a 30’ IT session. Data recorded by rt-CGMs were compared with the corresponding blood glucose values, measured by a glucose analyzer. The accuracy of rt-CGMs was assessed by the Sensor Bias (SB), the Mean Absolute Relative Difference (MARD) and the Clarke error grid.

Results: A total of 2355 plasma-sensor glucose paired points were collected. Both average plasma and interstitial glucose did not significantly differ during CON and IT. However, plasma glucose change at the end of exercise was greater during CON than during IT. During CON, the sensors overestimated plasma glucose more than during IT, as shown by both SB and MARD. Classifying the clinical performance according to the Clarke error grid, no differences were found between the exercise sessions and >97% of values were in the A + B zone.

Conclusions: In conclusion, continuous exercise affects rt-CGMs accuracy to a greater extent than interval training, likely due to larger acute glycemic variations. However, this phenomenon does not compromise clinical reliability of recent CGMs. Larger studies, should investigate a broader spectrum of activities in terms of intensity and type of exercise.

O047 / #516
Topic: AS05-Glucose Sensors
HEART RATE VARIABILITY CHANGES PRECEED ONSET OF NOCTURNAL HYPOGLYCEMIA IN CHILDREN WITH TYPE 1 DIABETES? A WAY TO PREDICT HYPOGLYCEMIA?
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Background and Aims: Nocturnal hypoglycemia is most feared in children with diabetes, though often unrecognized. Heart rate variability (HRV) reflects activation of the autonomic nervous system. As hypoglycemia and declining glucose induce sympathoadrenal activation, changes of HRV could be assumed. Hence, the aim of this study was to evaluate, if HRV changes occur before the onset of nocturnal hypoglycemia in children with type 1 diabetes (T1D).

Methods: Children aged 1 to 18 y, with T1D for >6 months, participated in an observational study using continuous glucose monitoring (CGM) during 5 days. Simultaneously, Holter ECG was recorded each night. HRV parameters such as time (SDNN) and frequency (VLF and total power) domain and sample entropy were calculated using a 6min moving window from 90mins before until the onset (=0mins) of nocturnal hypoglycemia (sensor glucose level <3.9mmol/l for ≥15mins). Mean HRV parameters at several timepoints were compared to timepoint 0 using a Kruskal-Wallis test.

Results: Twenty-five children (11f, mean (SD) age 13.5y (2.5) participated in the study. 33 hypoglycemic events with concomitant ECG recording occurred. Mean SDNN increased from 79ms at -70mins and 83ms at -30mins to 89ms at 0mins (p=0.002 and 0.01), as did VLF (from 3158ms and 4366ms to 5153ms; p=0.0001, 0.0002) and total power (from 7960ms and 9663ms to 10700ms; p=0.0002, 0.0081). Sample entropy decreased from 1.76 and 1.75 to 1.65 (p=0.001, 0.001).

Conclusions: Significant changes of multiple HRV variables as early as 70 mins before the occurrence of nocturnal hypoglycemia were documented. This indicates that HRV changes may be used to help predict nocturnal hypoglycemia.
Background and Aims: While data on the efficacy and safety of CGM is evident across a broad age spectrum, there is a limited assessment in very young children with type 1 diabetes (T1D). This study aimed to assess real-world data in this high-risk population, focusing on glycemic variability and time in ranges.

Methods: The study adopted a prospective, multi-national, registry-based population cohort design to compare glycemia metrics over 12 months between very young children with T1D using real-time CGM and those using intermittent fingerstick blood glucose monitoring (BGM) alone. Major eligibility criteria included T1D diagnosed at least 6 months prior, age 1 to 7 years, insulin pump therapy for at least 3 months and at least 10 days of CGM/BGM data. The primary endpoint was assessment of glycemic variability as measured by the difference in coefficient of variation between the CGM users and BGM cohort and time in ranges as other pre-specified endpoints calculated for each group. The trial is registered with Clinicaltrials.gov: NCT04558710

Results: Data from 229 individuals (44% were female, mean age 5.1 ± 1.6 years) from 15 centers were analyzed. Results of the primary and pre-specified secondary efficacy outcomes are presented in Table 1 over the full 24-hour period.

Conclusions: The use of CGM was associated with reduced glucose fluctuations and increased time in range and decreased time above and below range. In our study, very young children with T1D using CGM were more likely to approach the targeted glycemia as measured by time in range.

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Topic: A505-Glucose Sensors

GLUCOSE MANAGEMENT INDICATOR (GMI) VARIA BLY PREDICTS AVERAGE HBA1C LEVELS ACCORDING TO GLYCEMIC VARIABILITY (%CV) ACROSS THE LIFESPAN IN TYPE 1 DIABETES (T1D)

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Background and Aims: GMI can estimate average HbA1c based on the mean glucose from at least 14 days of CGM data. Using CGM data, one can also assess glycemic variability with coefficient of variation for glucose (CV, glucose SD/mean x 100%). Given that glycemic levels fluctuate across the lifespan, we aimed to evaluate the accuracy of GMI in estimating average A1c based on CV and age.

Methods: GMI was calculated from over 300 hours of baseline, masked CGM data collected before starting RT-CGM in 3 US studies in persons with T1D (SENCE [N = 143, 2–6y] / CITY [N = 152, 14–24y] / WISDM [N = 203, 60–86y]). GMI (%) was calculated using the formula: 3.31 + 0.02392 x [mean glucose in mg/dL]. We assessed associations between baseline HbA1c, from a central laboratory, and CGM metrics (mean glucose, TIR (70-180mg/dL) by study and stratified by CV (≤36, >36).

Results: Across all studies, lab HbA1c was strongly correlated with GMI metrics (p < 0.0001). When CV >36 vs. CV ≤36, GMI underestimated average HbA1c in all studies; greatest differences were seen in adolescents/young adults (CITY). Correlations between HbA1c and mean glucose and TIR were stronger when CV > 36 (Table).

Conclusions: These 3 studies affirm that CGM metrics, both mean glucose and TIR, can estimate laboratory HbA1c. Notably, glycemic variability (CV) alters these associations across the lifespan in persons with T1D. Caution should be used in interpreting GMI in those with high variability due to risk for under-approximation; changes in RBC kinetics likely also impact these associations.
O050 / #617
Topic: AS05-Glucose Sensors
IDENTIFYING CGM DATA USING MACHINE LEARNING; A CGM DIGITAL ‘FINGERPRINT’

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Background and Aims: Cybersecurity in eHealthcare is a growing concern, and in particular, in diabetes care, where vast amounts of data are being generated by the recent surge in wearable devices, such as continuous glucose monitoring (CGM). The use of open-source platforms, for example, NightScout and OpenAPS, has increased the risk of data breaches and might represent a privacy concern for some users. In this work, we aim to demonstrate that it is possible to identify CGM data at an individual level by standard machine learning techniques.

Methods: The publicly available REPLACE-BG dataset containing 226 adult participants with type 1 diabetes wearing CGM over 6 months was used. A support vector machine (SVM) binary classifier aiming to determine if a CGM data stream belongs to an individual was trained and tested for each subject in the dataset. Eleven standard glycaemic metrics were employed to generate the feature vector for the SVM. Data points in the training and testing datasets were generated by evaluating the selected glycaemic metrics over multiple incidences of one-month time windows. In order to increase the number of data points, a sliding time window was employed.

Results: The mean and standard deviation of sensitivity, specificity, and accuracy results on the testing data set were 0.80 ± 0.24, 0.97 ± 0.03, and 0.89 ± 0.12, respectively.

Conclusions: This work demonstrates that it is possible to determine with relatively high accuracy if a CGM data stream belongs to an individual. The proposed approach can be used as a digital CGM ‘fingerprint’ or for detecting glycaemic changes within an individual (e.g. illness).

O051 / #656
Topic: AS05-Glucose Sensors
STRONG TREATMENT EFFECT OF CONTINUOUS GLUCOSE MONITORING (CGM) IN REDUCING HYPOGLYCEMIA IRRESPECTIVE OF PREVIOUS BLOOD GLUCOSE MONITORING AMONG OLDER ADULTS WITH TYPE 1 DIABETES (T1D)

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Background and Aims: The Wireless Innovation for Seniors with Diabetes Mellitus (WISDM) randomized clinical trial demonstrated reductions in hypoglycemia with CGM compared with blood glucose monitoring over 6 months among older adults with T1D. The aim of this analysis was to evaluate whether the treatment effect was influenced by the frequency of pre-study self-monitoring of blood glucose (SMBG).

Methods: 203 older adults age ≥ 60 yrs were randomly assigned to use CGM or BGM for 26 weeks. CGM-measured outcomes stratified by baseline SMBG (<4x/d vs. ≥4x/d) were calculated at baseline (masked CGM) and during follow-up (masked CGM for BGM group).

Results: Among participants with baseline SMBG <4 times/day, median percent time <70 mg/dL was reduced from 7.2% at baseline to 1.8% at 26 weeks in the CGM group and was 4.8% at baseline and 5.1% at 26 weeks in the BGM group. A positive treatment effect also was observed among participants with baseline SMBG ≥ 4 times/day (Table). After 26 weeks of CGM use, 78% and 85% of participants were using CGM six or more days/wk in those with baseline SMBG <4 times/day and SMBG ≥4 times/day, respectively.

Conclusions: Prior to changing restrictions during the COVID-19 pandemic, public insurance (Medicare) for older adults in the US required SMBG ≥4 times/day for approval of CGM. These study results show CGM can be effectively used to reduce hypoglycemia irrespective of SMBG history.

O052 / #710
Topic: AS05-Glucose Sensors
THE PROMISE STUDY: AN EVALUATION OF THE SAFETY AND ACCURACY OF THE NEXT GENERATION 180-DAY LONG-TERM IMPLANTABLE EVERSENSE CGM SYSTEM

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Background and Aims: The prospective, multi-center PROMISE Study was conducted from 27Dec2018–08May2020 in 181 adults ≥18 years with diabetes at 8 US clinical sites to evaluate the safety and accuracy of the next generation Eversense CGM System for up to 180 days.

Methods: During 10 clinic visits between day 1–180 lasting up to 10 hours, accuracy between 40–400mg/dL was assessed comparing CGM and reference glucose values from Yellow Springs Instruments (YSI), including hyperglycemia and hypoglycemia challenges. A total of 279 sensors were placed (85 and 96 subjects had 1 and 2 sensors inserted in the arm, respectively, with 2 replaced sensors) for 558 insertion/removal procedures. Two calibrations/day to day 21 were prompted, after which it primarily prompts 1 calibration/day.

Results: The mean age was 48.6 years (range 18–77years). Accuracy analyses were based on 49,613 matched pairs over 180 days. Percent CGM readings within 15/15% and 20/20% of YSI values was 85.6% and 92.9%, respectively, and the overall Mean Absolute Relative Difference (MARD) was 9.1%. MARDs across different time periods over 180 days were <9.6% (Table), except for the beginning and end of sensor life. The confirmed hypoglycemia detection rate at 70mg/dL and 60mg/dL were 93% and 94.1%, respectively. Hyperglycemia at 180mg/dL was detected in 99%. There were no device or insertion/removal procedure-related serious adverse events. Two mild skin infections occurred for a rate of 0.36% per procedure.

Conclusions: These results indicate the next generation Eversense long-term implantable CGM System has sustained accuracy and safety up to 180 days with mainly one calibration/day.

O054 / #728

Topic: AS05-Glucose Sensors

GLUCOSE TRACKING WITH OPTICAL MEASUREMENT IN CLINICAL EVALUATION—PROFUSA LUMEE GLUCOSE PLATFORM

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Background and Aims: Profusa is developing a soft glucose-sensitive hydrogel, a sterile, small (5.0x0.75x0.65mm when hydrated), intended for subcutaneous injection. The hydrogel is suitable for long term use and could remain in the body permanently. Presented studies assess the platform function, transitioning from animal studies to human studies.

Methods: The glucose sensor is comprised of a hydrogel scaffold with covalently bound fluorescent molecules that produce near infrared light proportional to glucose concentration when interrogated by an optical reader placed on the skin (Figure 1). The v3.0 Reader utilizes a set of LEDs to excite fluorophores within the Hydrogel. The LEDs reside in the Reader which sits on the skin above the Hydrogel. The reader communicates wirelessly to a tablet for control and data transmission (Figure 2). Pre-clincal performance was validated in a swine mode in multiple 8-hour experiments over 3 months. Performance was assessed during in-clinic visits in subjects with diabetes over a period of 3 months. Frequent blood glucose measurements with a Super GL laboratory analyzer were collected as reference.

Results: This study was designed to characterize baseline performance and signal perturbations due to environmental conditions, including motion, temperature, and ambient light. This characterization is used to develop and refine the signal processing algorithm to calculate glucose levels. The following graphs (Figures 3–5) demonstrate the successful identification of a glucose excursion in a single subject during the first two weeks.

Conclusions: Results of using this hydrogel and reader in the swine model are confirmed in this clinical study, tracking glucose during study days over a 3-month period.
O055 / #732

Topic: AS05-Glucose Sensors

REAL-WORLD DATA ON TIME IN RANGE AMONG CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES: DATA FROM THE INTERNATIONAL SWEET REGISTRY


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Background and Aims: An international consensus proposed time in range 70–180 mg/dl (TIR), below (<70 mg/dl) and above (>180 mg/dl) range as compound metrics of glycemic control to complement HbA1c regardless of age in individuals with Type 1 Diabetes (T1D). The aim of this study was to evaluate real-world data from an international network for pediatric diabetes centers (SWEET).

Methods: We retrospectively analyzed data from four age groups: 1–6y (n = 185), 7–13y (n = 1,195), 14–17y (n = 996) and 18–21y (n = 347) with T1D using CGM. Linear regression models adjusted for gender, diabetes duration, age, BMI and insulin therapy modality were performed to identify potential predictors of TIR.

Results: CGM data from 2,723 individuals (mean 229 sensor-days/person) from 22 centers were analyzed. Overall median TIR was 54.5%. Time in/below/above ranges were 59.3/0.0/37.9% among 1–6y, 57.4/3.0/38.5% among 7–13y, 51.7/3.6/42.8% among 14–17y and 50.7/4.7/42.5% among 18–21y. We observed a significant positive association between TIR and insulin therapy modality, an inverse association between T1D duration and TIR, while there was no association with gender or BMI. Adjusted mean (95% CI) TIR was 57% (54.59) in insulin pump users and 51% (47.54) in non-users. Pearson correlation coefficients showed strong correlations between HbA1c and TIR (R = -0.746, P < 0.0001).

Conclusions: Data from the SWEET registry demonstrate that only a minority of young individuals with T1D achieve recommended goals for TIR. We observed higher TIR at younger age groups, a significant decline in TIR with longer T1D duration and a positive association with insulin pump therapy.

O056 / #733

Topic: AS05-Glucose Sensors

GLUCOSE SENSOR ACCURACY DURING SUBCUTANEOUS GLUCAGON INFUSION NEAR SENSOR SITE

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Background and Aims: The study aim is to compare sensor accuracy after subcutaneous (s.c.) infusion of glucagon near to versus remote from sensor site.

Methods: Seventeen adults with type 1 diabetes wore two continuous glucose monitors (Dexcom® G6; CGMglucagon and CGMcontrol) placed on each side of the abdomen during a 33-h in-clinic visit. During the study visit, participants’ plasma glucose was controlled with DiaCon’s dual-hormone insulin-glucagon closed-loop system, consisting of a smartphone, CGMcontrol and two s.c. infusion pumps (Dana RS insulin pump, Sooil) for delivery of insulin and glucagon (Glucagen®, Novo Nordisk). The infusion site for glucagon was placed 2 cm next to the CGMglucagon. The CGM performance for the 33 hrs were compared with the plasma glucose measured with Yellow Spring Instrument 2900 (YSI).

Results: In total, 1,076 paired YSI–CGMglucagon and 1,172 paired YSI–CGMcontrol were collected from the 17 participants. Using YSI as comparator, no difference in the median (inter-quartile range) absolute relative difference (MARD) for CGMglucagon and CGMcontrol was found (16.7 (8.3-22.9) % vs. 11.0 (8.0-17.5) %; PWilcoxon = 0.105). Values in zone A + B of Clarke error grid analysis did not differ between CGMglucagon and CGMcontrol using YSI as reference measurement (94.1% vs. 94.9%, PMcNemar = 0.103). The precision absolute relative deviation between sensors was 6.9 %.

Conclusions: Sensor accuracy was not significantly affected by s.c. infusion of glucagon near to sensor site.

O057 / #760

Topic: AS05-Glucose Sensors

GLYCEMIC MEASURES FOR 8,914 ADULT FREESTYLE LIBRE® USERS DURING ROUTINE CARE SEGMENTED BY AGE GROUP AND OBSERVED CHANGES DURING THE COVID PANDEMIC

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Table 1. %TIR metrics for adult FreeStyle Libre users in the UK segregated by age

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</tr>
</thead>
<tbody>
<tr>
<td>18–25</td>
<td>736</td>
<td>51.2%</td>
<td>54.1%</td>
<td>2.9%</td>
<td>&lt;0.001</td>
<td>6.0%</td>
<td>9.1%</td>
<td>3.1%</td>
<td>0.029</td>
</tr>
<tr>
<td>26–49</td>
<td>3594</td>
<td>34.5%</td>
<td>36.2%</td>
<td>1.7%</td>
<td>&lt;0.001</td>
<td>8.3%</td>
<td>9.6%</td>
<td>1.3%</td>
<td>0.038</td>
</tr>
<tr>
<td>50–64</td>
<td>2823</td>
<td>53.1%</td>
<td>57.4%</td>
<td>4.3%</td>
<td>&lt;0.001</td>
<td>9.2%</td>
<td>11.5%</td>
<td>2.3%</td>
<td>0.0052</td>
</tr>
<tr>
<td>65+</td>
<td>1859</td>
<td>57.9%</td>
<td>61.0%</td>
<td>3.1%</td>
<td>&lt;0.001</td>
<td>11.7%</td>
<td>15.9%</td>
<td>4.2%</td>
<td>0.0002</td>
</tr>
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8,914 FreeStyle Libre de-identified accounts were analysed. *p*-values for TIR derived from paired t-tests. **p**-values for proportions achieving both >70% TIR and >4% TBR derived from two proportions t-tests.

Background and Aims: We report for the first time normative glucose metrics for %TIR 3.9–10 mmol/L, %TBR <3.9 mmol/L and %TAR >10 mmol/L for adult FreeStyle Libre users in the UK within 4 defined age-groups and the impact of the COVID-19 pandemic on these over time.

Methods: Data was extracted from 8,914 LibreView® de-identified user accounts from adult users aged 18+ with ≥5 days of sensor readings in each month from January to June 2020. Age-group categories were based on self-reported age on LibreView accounts (18-25, 26-49, 50-64, 65+ yrs).

Results: Adult FreeStyle Libre users in this UK study report mean TIR above 51% and median TBR 4.2% or below. In January, prior to the pandemic, the 65+ age group had the highest %TIR (57.9%) while the 18–25 age group had the lowest %TIR (51.2%). Consensus targets >70% TIR and <4% TBR were achieved by 11.7% of users aged 65+ compared to 6.0% of those 18–25. Within each age group, TIR change was significant during the analysed months (*p<0.001) by repeated measures ANOVA. Comparing January to June 2020, all age groups increased TIR, with those aged 65+ increasing the most (3.1%; *p<0.001). The proportion of adults achieving both >70% TIR and <4% TBR targets increased to 15.9% for those 65+ years (*p<0.001) and 9.1% for 18-25 (*p<0.05).

Conclusions: During lockdown in the UK, the proportion of adults achieving TIR consensus targets increased among FreeStyle Libre users. The glucose metrics suggest an opportunity for even further improvement with continued CGM use.

Methods: We assessed many different clinical, bioumoral and Ambulatory Glucose Profile (AGP) derived parameters in 51 consecutive inpatients (male = 39 patients) (age, mean±DS = 65.9 years ±12.5) affected by COVID-19 pneumonia and with DM (n = 31) or prediabetes (n = 11) and/or fasting glycaemia >125 mg/dL (n = 9). Main outcomes were: median glucose (compared to goal) (MG) across 5 different daily time intervals (hours 03–08; 08–12; 12–18; 18–22; 22–03); detection of episodes of hyperglycaemia (> 180 mg/dL for >15 minutes) or hypoglycaemia (<70 mg/dL for 15 minutes) by routinely performed blood glucose monitoring (BGM; pre-breakfast, pre-lunch, pre-dinner and 2 h post-meals) and by is-CGM.

Results: MG were significantly > than goal and > than 20% and 40 mg/dL greater than the whole day median in: 3/51 (hours 03–08), 4/51 (hours 08–12), 18/51 (hours 12–18), 13/51 (hours 18–22) and 2/51 (hours 22–03) patients (p<0.0001). We detected significantly more episodes of hyperglycaemia and hypoglycaemia with CGM than BGM (respectively: 11.3±8.5 vs 7.7±6.2, p<0.0001; 3.4±5.4 vs 1.7±3.2; p<0.0001).

Conclusions: In COVID-19 inpatients with diabetes, prediabetes or fasting hyperglycaemia is-CGM showed peculiar data about glycomic variability across the day and about hyper- and hypoglycomic episodes, indispensable to optimize the glycomic management.

O058 / #808

**Topic: AS05-Glucose Sensors**

**EFFECT OF FLASH GLUCOSE MONITORING ON GLYCAEMIC CONTROL IN TYPE 2 DIABETES COMPARED TO SMBG: A PROSPECTIVE OBSERVATIONAL STUDY FROM ITALY**

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Background and Aims: This prospective, observational cohort study was designed to measure the change in HbA1c over 3–6 months in adults with T2DM on a basal-bolus insulin regimen using the FreeStyle Libre Flash Glucose Monitoring System™ compared to self-monitoring blood glucose (SMBG), in a real-world setting.

Methods: A total of 322 patients (109 intervention, 213 control) with T2DM from 16 hospital sites in Italy were enrolled. To minimise selection bias, all eligible FreeStyle Libre users were included, matched to SMBG patients by HbA1c (within ±0.5%) and study site. The study population included adults on a basal-bolus insulin regimen for ≥1 year, with HbA1c 8.0–12.0% (64–108 mmol/mol), who were either new to FreeStyle Libre and planned to use it for ≥3 months (intervention) or planned to continue with SMBG (control) in a 1:2 ratio. On average, HbA1c was 8.9±0.8% (73.9±8.8 mmol/mol), age 67.2±10.0 years, BMI 30.5±6.5 kg/m² and average duration of insulin use 8.6±6.6 years (mean±SD), 56.2% were male.
Results: After 3–6 months, 234 complete case patients (83 intervention, 151 control) demonstrated significantly reduced HbA1c for FreeStyle Libre users compared to SMBG by 0.30% (95% CI: -0.53, -0.07), p=0.0113. Considering all 322 patients (109 intervention, 213 control), with imputed missing HbA1c values, HbA1c was also significantly reduced for FreeStyle Libre users vs. SMBG by 0.28% (95% CI: -0.50, -0.05), p=0.0199. The difference remains statistically significant after adjusting for the confounders.

Conclusions: This real-world, prospective cohort study concluded that people with T2DM on basal-bolus insulin, using FreeStyle Libre for 3–6 months significantly reduced HbA1c compared to SMBG.

O060 / #13

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

USE AND PERCEPTION OF TELEMEDICINE IN PEOPLE WITH TYPE 1 DIABETES DURING THE COVID-19 PANDEMIC – RESULTS OF A GLOBAL SURVEY

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Background and Aims: The coronavirus disease-2019 (COVID-19) pandemic has forced rapid reconsideration as to the way in which healthcare is delivered. This study aimed to gather information on the use and perception of telemedicine in people living with type 1 diabetes (T1D) during the COVID-19 pandemic.

Methods: An anonymous questionnaire was widely distributed using an open-access web-based platform. Data were analysed descriptively and results were stratified according to age, sex and HbA1c.

Results: There were 7477 responses from individuals in 89 countries. Globally, 30% reported that the pandemic had affected their healthcare access due to cancelled physical appointments with their healthcare providers. Thirty-two percent reported no fundamental change in their medical follow-up during this period, with 9% stating that no personal contact was established with their doctors during the study. Twenty-eight percent received remote care through telephone (72%) or video-calls (28%). Of these, 86% found remote appointments useful and 75% plan to have remote appointments in the future. Glucose control, indicated by HbA1c, was positively associated with positive perception of telemedicine. In males, 45% of respondents with an HbA1c >9% rated telemedicine not useful compared to those with lower HbA1c, while 20% of females with an HbA1c >9% rated it not useful (c2 = 14.2, p = 0.0016).

Conclusions: Remote appointments have largely been perceived as positive in people with T1D with the majority (75%) stating that they would consider remote appointments beyond the pandemic. Age and level of education do not appear to influence perception of telemedicine, whereas poor glucose control, particularly in males, seems to negatively affect perception.

O061 / #51

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

INTEGRATION OF A CGM SYSTEM AND A VOICE-CONTROLLED VIRTUAL ASSISTANT

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Background and Aims: Siri (Apple, Inc., Cupertino, CA) allows for voice control of compatible apps, including the “G6” app for a continuous glucose monitoring (CGM) system (Dexcom, Inc., San Diego, CA). A customizable voice command (by default, “Hey Siri what’s my glucose?”) is sufficient to generate a spoken response that includes the user’s current sensor glucose value (SGV) and trend (e.g., “You’re 134 and steady”). G6/Siri integration may simplify diabetes management, especially for patients with limited vision or dexterity. We examined patterns and potential implications of invoking the feature.

Methods: Data were from US-based anonymized G6 customers who invoked the feature in December 2019 and uploaded ≥30 days of CGM data in the first half of 2020 (1H2020). Non-users and routine users were defined as those with zero and those with an average of ≥1 feature invocation per day of CGM use in 1H2020. Feature invocations were analyzed for routine users; summary statistics of glycemic metrics were calculated for both groups.

Results: Of the 34,572 customers who used the feature in December 2019, 6,847 were non-users and 2,282 were routine users in 1H2020. Among routine users, the median number of daily invocations was 1.84 (IQR, 1.29-3.29) and the feature was most commonly invoked between 4PM and 6PM (Figure). Time in range (70-180 mg/dL) was lower for non-users than for routine users (57 ± 20 vs. 62 ± 20%, respectively); mean ± SD SGVs were 177 ± 39 and 169 ± 36 mg/dL, respectively.

Conclusions: Routine use of the G6/Siri integration feature may contribute to appropriate diabetes management decisions.
Background and Aims: While registries are fundamental for planning and delivering high quality care for chronic diseases, the number of people living with type 1 diabetes (T1D) in Canada is unknown. The decentralized administrative data available, which captures people living with all types of diabetes, is not able to accurately identify the unique needs related to the daily management, preferences, and well being of people living with T1D (PWD). The aim of this project was to co-design and develop a patient-centered national registry that could enable PWDs to drive future priorities in research, policy, and clinical care.

Methods: The conceptualization of Connect1d occurred in three phases; 1) iterative co-design with PWDs (n = 30), 2) a pan-Canada validation study with clinicians, researchers, and PWDs (n = 125), and 3) a critical assessment of the patient-centricity of existing T1D registries.

Results: The co-design process identified several gaps and needs in the experience of PWDs, specifically highlighting the hands-off experience they have with research and the lack of accurate data to enable policy change. The resulting solution, Connect1d, aims to improve accessibility and recruitment into clinical trials, and collect data directly from patients to create a patient-centered national registry that could enable PWDs to drive future priorities in research, policy, and clinical care.

Conclusions: Connect1d has the potential to overcome the challenges associated with harmonizing data for disparate systems, while simultaneously bridging gaps that exist in conducting patient-oriented research. This project is funded by JDRF and the Canadian Institutes for Health Research, and a part of Diabetes Action Canada.

O063 / #182

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

SIGNIFICANT A1C DECREASE FOR PATIENTS WITH TYPE 1 & TYPE 2 DIABETES TREATED VIA TELEMEDICINE WITH THE MYDIABBY HEALTHCARE SOFTWARE

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myDiabby Healthcare, Mydiabby Healthcare, Paris, France

Background and Aims: The ETAPES trial, initiated in 2018 by the French Health ministry, aims at evaluating a business model for telemonitoring of patients with diabetes. Launched in April 2015, the myDiabby telemedicine software allows HCPs to monitor their patients remotely, in particular in the context of this national trial. The goal of our study is to evaluate patients’ A1c in order to analyse the impact of the ETAPES telemedicine trial on their glycemic control.

Methods: Patients with type 1 and type 2 diabetes were included according to the ETAPES criteria (T1D: A1c ≥ 8% & T2D with insulin: A1c ≥ 9%) and followed remotely via myDiaby during at least 6 month. Each patient benefited from a weekly monitoring plus a monthly therapeutic coaching from their healthcare providers. The A1Cs were collected via blood tests and reported on myDiaby at the beginning and after several months of telemonitoring.

Results: The average patients’ A1c was 10.12±0.11 % at the beginning of the telemonitoring, and 7.90±0.13 % after 6 months of telemonitoring. This decrease of 2% of the A1C is significant (p<0.0001) and associated with a small sample variation.

Conclusions: Our study highlights the positive outcomes of telemonitoring for patients with diabetes. This new way of treating patients has a highly significant impact on their blood glucose control. In order to reinforce these first results, the Time in Range (TIR), which is becoming a mainstream glucose metric, is also collected on myDiaby for further analysis.

O064 / #219

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

REMOTE INITIATION OF HYBRID CLOSED LOOP USING SKYPE IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Sidra Medicine, Pediatrics, Doha, Qatar

Background and Aims: The aim of this study was to evaluate effectiveness of remote initiation of Hybrid Closed Loop (HCL) System on glycemic control in patients with Type 1 Diabetes (T1D) on Multiple Daily Injections (MDI).

Methods: Individuals with T1D (7 to 18 years old) initiated the MiniMed 670G HCL system using Skype Meet Now with the following program: introduction session, pre-course and technical requirements session, one face to face practical session for sensor insertion and four consecutive online sessions: Day 1- Manual Mode, bolus wizard use, basal rates, Auto Mode and readiness; Day 2- Infusion set and reservoir change; Day 3- hypoglycemia, hyperglycemia, exercise and travel management; Day 4- Evaluation to initiate HCL system. HbA1c, Time in Range, HCL system characteristics were analyzed after 3-month of HCL initiation.

Results: A total of 14, patients (age 11.4±2.8 years) and their caregivers commenced MiniMed 670G using the remote initiation program and used the system for 3 months. Sensor wear of 89.1 ± 8.2% and Auto Mode usage of 86.8 ± 6.8% was noted after 3 months of HCL initiation. Time in Range (70-180mg/dL) increased from 45.4 ± 9.2% at baseline to 74.6 ± 8.2% at the end of the study (p < 0.001). There was no severe hypoglycemia nor DKA during the study.

Conclusions: Remote initiation program in individuals with T1D on MDI, can be an effective tool to initiate an HCL system.
and to improve glycemic control in a safe manner. Technical assessment (basic computer skills and internet connection), as well as educators’ skills on remote teaching are crucial factors in successful initiation of HCL system.

O065 / #254
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

GLYcATED HEMOGLOBIN AT ADMISSION IN THE ICU AS A PROGNOSTIC MARKER FOR MORTALITY IN CRITICALLY ILL PATIENTS, BASED ON REAL WORLD EVIDENCE

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Background and Aims: The clinical significance of HbA1c in critically ill patients, particularly those with previously undiagnosed Diabetes Mellitus (DM), has not been adequately explored. This study investigated the clinical significance of HbA1c levels on admission in the intensive care unit (ICU) as a prognostic marker for mortality in critically ill patients.

Methods: We performed a retrospective cohort study using the Medical Information Mart for Intensive Care III v1.4 open access, anonymised database (MIMIC-III), based on the data of 23620 ICU admissions between 2008 and 2012 at Beth Israel Deaconess Medical Center, USA. Logistic regression was performed, using age, sex, SOFA, OASIS and HbA1c levels on admission (thresholded at 6.5%) as predictors, and death in ICU as the target. The study protocol was approved by the respective Institutional Review Boards.

Results: The results of the analysis:

Conclusions: When patients of medical ICUs with no known diagnosis of diabetes are considered, high HbA1c is a significant (p < 0.03) predictor of death in ICU, after adjusting for age, gender, SOFA and OASIS scores. However, this association ceases to be significant if other types of ICU (surgical, cardiac) are included, or when patients with known diagnosis of diabetes are included in the sample.

Acknowledgements: "This research is co-financed by Greece and the European Union (European Social Fund-ESF) through the Operational Programme «Human Resources Development, Education and Lifelong Learning 2014–2020» in the context of the project “A retrospective, real world data based study, on the impact of glycemic control on mortality and morbidity of critically ill patients in ICU” (MIS 5050694)."

Image 1: Logistic regression for ICU mortality (patients with no diagnosis of DM)

<table>
<thead>
<tr>
<th>ICU type</th>
<th>Variable</th>
<th>Odds Ratio</th>
<th>p-value</th>
<th>Conf. int. (2.5%)</th>
<th>Conf. int. (97.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ICUs (n = 450)</td>
<td>Age</td>
<td>1.17</td>
<td>0.26</td>
<td>0.26</td>
<td>1.50</td>
</tr>
<tr>
<td></td>
<td>Gender (male)</td>
<td>0.66</td>
<td>0.26</td>
<td>0.32</td>
<td>1.37</td>
</tr>
<tr>
<td></td>
<td>SOFA (Sequential Organ Failure Assessment)</td>
<td>1.02</td>
<td>&lt;0.005</td>
<td>1.29</td>
<td>2.58</td>
</tr>
<tr>
<td></td>
<td>OASIS (Acute Severity of Illness Score)</td>
<td>1.28</td>
<td>0.22</td>
<td>0.86</td>
<td>1.89</td>
</tr>
<tr>
<td></td>
<td>HbA1c &gt;= 6.5%</td>
<td>1.76</td>
<td>0.26</td>
<td>0.60</td>
<td>4.48</td>
</tr>
</tbody>
</table>

| Medical (n = 60) | Age | 2.33 | 0.03 | 1.13 | 5.74 |
| | Gender (male) | 0.21 | 0.17 | 0.02 | 1.63 |
| | SOFA | 1.19 | 0.74 | 0.41 | 3.45 |
| | OASIS | 2.74 | 0.11 | 0.86 | 11.24 |
| | HbA1c >= 6.5% | 21.79 | 0.03 | 2.10 | 833.15 |

Image 2: Logistic regression for ICU mortality (both patients with and without diagnosis of DM)

<table>
<thead>
<tr>
<th>ICU type</th>
<th>Variable</th>
<th>Odds Ratio</th>
<th>p-value</th>
<th>Conf. int. (2.5%)</th>
<th>Conf. int. (97.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ICUs (n = 737)</td>
<td>Age</td>
<td>1.16</td>
<td>0.18</td>
<td>0.91</td>
<td>1.43</td>
</tr>
<tr>
<td></td>
<td>Gender (male)</td>
<td>0.74</td>
<td>0.30</td>
<td>0.42</td>
<td>1.31</td>
</tr>
<tr>
<td></td>
<td>SOFA</td>
<td>1.64</td>
<td>&lt;0.005</td>
<td>1.24</td>
<td>2.17</td>
</tr>
<tr>
<td></td>
<td>OASIS</td>
<td>1.61</td>
<td>&lt;0.005</td>
<td>1.17</td>
<td>2.21</td>
</tr>
<tr>
<td></td>
<td>HbA1c &gt;= 6.5%</td>
<td>1.00</td>
<td>0.99</td>
<td>0.55</td>
<td>1.76</td>
</tr>
</tbody>
</table>

| Medical (n = 143) | Age | 1.41 | 0.16 | 0.82 | 2.27 |
| | Gender (male) | 0.38 | 0.24 | 0.17 | 0.79 |
| | SOFA | 1.32 | 0.51 | 0.57 | 3.00 |
| | OASIS | 2.52 | 0.04 | 1.09 | 6.43 |
| | HbA1c >= 6.5% | 2.28 | 0.36 | 0.45 | 17.93 |

O066 / #261
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

OPTIMIZING WORKFLOWS TO CLOSE DISPARITIES IN TELEHEALTH USE

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Background and Aims: Telehealth can bring care into the homes of patients. However, there is a risk that telehealth may worsen health care disparities.

Methods: Prior to the COVID-19 pandemic, patients were only eligible for telehealth if referred by their diabetes provider. Providers assisted patients with device downloads and technical issues. There was no access to interpreters, social workers, or nutritionists into telehealth visits. Certification of diabetes educators helped obtain device downloads, medical assistants provided connection support, and workflows were developed to incorporate interpreters, social workers, and nutritionists into telehealth visits (Fig1). Chart review was performed for telehealth visits between July 1, 2017 and April 30, 2020. Visits for children with public insurance, a marker of lower socioeconomic status, and those who were non-English speaking were determined.

Results: In the 31 months prior to COVID-19, 195 telehealth visits were performed and in the first 6 weeks of the pandemic, another 436 telehealth visits were completed. In our practice, 38.4% of children have public insurance and 17.4% of the population is non-English speaking. The percentage of children with public insurance who accessed telehealth increased from 24.1% to 39.9% with the new workflow (p = 0.004). The percentage of non-English speakers accessing telehealth increased from 3.1% to 13.5% (p < 0.01) with the new workflow.

Conclusions: Prior to the COVID-19 pandemic, our workflows were sub-optimal and this increased disparities for children who were non-English speaking or from lower socioeconomic status. The creation of inclusive workflows and support for patients and providers helped close the disparities gap.
O067 / #263
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
HEADWIND: DESIGN AND EVALUATION OF A VEHICLE HYPOGLYCEMIA WARNING SYSTEM IN DIABETES – RESULTS FROM A DRIVING SIMULATOR STUDY
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Background and Aims: Hypoglycemia is one of the most relevant acute complications of diabetes mellitus and is associated with an increased risk of driving accidents. Today’s cars gather a broad spectrum of real-time driving parameters. Based on changes in driving behaviour during hypoglycemia we aim at establishing algorithms capable of discriminating eu- and hypoglycemic driving patterns using artificial intelligence.

Methods: We included active drivers with type 1 diabetes mellitus (T1DM). Using an adapted hypoglycemic clamp protocol and a professional driving simulator, driving data was recorded in 2 glycemic states: euglycemia (deu, 5-8 mmol/l) and hypoglycemia (dhypo, 2.0-2.5 mmol/l). In each glycaemic state the participants drove for 15 min through a random sequence of 3 environments: highway, rural and town. Car-based sensor data were sliced into overlapping 45-second windows. Finally, predictive performance in hypoglycemia detection was evaluated using gradient boosted decision trees.

Results: The study encompassed 15 participants with T1DM (11 male, HbA1c 7.2±0.6 %). Mean blood glucose in deu and dhypo was 5.9±0.6mmol/l and 2.4±0.25 mmol/l (p<0.001), respectively. Car-based data provided 466,303 measurements in deu and 481,497 samples in dhypo. 1-fold cross-validation on subject level resulted in a ROC-AUC in hypoglycemia prediction of 0.85. ROC-AUC for the highway, rural and town environment was 0.80, 0.98, and 0.78, respectively.

Conclusions: Our study applying machine learning models on driving simulator-based data shows robust between-subject predictability of hypoglycemia. This confirms the effectiveness of artificial intelligence in hypoglycemia detection while driving and may represent a promising novel approach to increase traffic safety in people with diabetes.

O068 / #274
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
USE OF CONNECTED INSULIN PEN TO EVALUATE THE EFFECTS OF PRE-MEAL, DELAYED, MISSED, AND CORRECTION BOLUSES ON PRANDIAL GLUCOSE CONTROL IN T1D AND T2D
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1Biomedical Informatics Consultants LLC, Clinical Research And Biostatistics, Potomac, United States of America, 2Eli Lilly and Company, Diabetes Business Unit, Indianapolis, United States of America

Background and Aims: Connected insulin pens have the potential to objectively assess the impact of insulin dosing behaviors on postprandial glucose control.

Methods: This observational study enrolled 68 people with T1D or insulin-using T2D with A1C ≥8% and ≥3 reported insulin boluses/day at baseline. Connected pen and CGM data were used to identify meal-related glucose excursions defined as glucose increase ≥50 mg/dL within 2 hours with no glucose <70 mg/dL in the preceding 30 min. A pre-meal bolus (PB) was taken within one h prior to the nadir of excursion or during excursion with maximum of rate-of-change of BG within preceding 20 minutes less than 1.0 mg/dL/min. Doses taken during the excursions that were not labeled as PB were defined to be delayed bolus (DB), while doses taken within 6 h of nadir and after the peak but before the next nadir of excursions were defined as correction bolus (CB). We defined an excursion to have a missed bolus (MB) if neither PB nor DB was taken.

Results: Participants were (mean±SD) 48 years (±12), 44% female, 59% T1D, 51% BMI ≥30, and 65% with A1C ≥9.0%. DB and MB significantly impaired postprandial glucose control.
compared to PB (table). Use of a CB reduced the impact of DB and MB, but slightly increased time below range.

Conclusions: These findings highlight the clinical utility of connected pens to identify insulin dosing practices that contribute to suboptimal postprandial control. Individuals who do not inject consistently premeal could potentially benefit from faster-acting bolus insulins.

O069 / #302
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
TELEMEDICINE DURING COVID-19: A CALL FOR MODERN AND INTEGRATED PLATFORMS THAT CAN OPTIMIZE DELIVERY OF REMOTE DIABETES CARE
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dQ&A - the Diabetes Research Company, Patient And Outcomes Research, San Francisco, United States of America

Background and Aims: During COVID-19, countless healthcare professionals (HCPs) have turned to telemedicine as their only means of reaching patients with diabetes. The present study sought to assess how HCPs were adapting to virtual visits, with a focus on 1) use of audiovisual conferencing tools and 2) software and data management.

Methods: From June-July 2020, a mixed-methods approach was used to investigate HCPs’ telemedicine experience in the US. Virtual interviews were conducted with 8 endocrinologists, 8 primary care providers (PCPs), and 8 diabetes educators (DEs). An online questionnaire was completed by 105 endocrinologists, 110 PCPs, and 103 DEs.

Results: Qualitative insights revealed that most HCPs were new to telemedicine, initially considered virtual visits more burdensome than in-person ones, and felt frustrated by the lack of an integrated conferencing and data management platform. In the quantitative phase, the majority of HCPs reported never implementing telemedicine before the pandemic (67%), but hosting daily (60%) or weekly (31%) virtual visits since its onset. On average, HCPs used 2 platforms to communicate with patients, with many relying on audio calls (36%) and/or Facetime (22%). Those who reviewed diabetes data (94%) typically used 3 different methods of gathering data, with the most popular being patients’ verbal descriptions of trends (63%). Four in ten received photos (42%) or faxes (39%) of paper logs.

Conclusions: Despite widespread adoption of telemedicine, many HCPs remain reliant on older forms of communication and data exchange. Going forward, the development of simple, integrated telemedicine platforms can facilitate and improve the virtual care experience.
Results: Of 21 clinics (16 pediatric and 5 adult), 62% used both video software and phone calls. Clinics reported that insurance covered 95% of telemedicine visits during the pandemic (see Table 1). All clinics had access to Carelink, T-Connect, Glooko, and Clarity platforms to support remote monitoring of patients. Over half (62%) of clinics instituted workflows to obtain patient lab results, less (38%) had a system for conducting depression screening. Only 3 clinics had psychologists available to participate in telemedicine. Clinics described similar rates of prescribing for CGM and pumps (62%). Clinics continued to provide support for pumps (100%) and CGM (70%).

Conclusions: Physicians and insurers have adopted telemedicine with remarkable speed. Future studies will assess the effectiveness of telemedicine visits during this pandemic in different patient populations.

O071 / #338
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

USE OF A MOBILE HEALTH APPLICATION TO SUPPORT INITIATION OF ONCE-WEEKLY SEMAGLUTIDE: AN ANALYSIS FROM 13 COUNTRIES OF USER ENGAGEMENT DURING THE DOSE ESCALATION PERIOD

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Background and Aims: Successful management of patients with T2D relies on successful treatment initiation and adherence. A mobile health (mHealth) app that includes planning, body weight and dose tracking features has been developed to support patients during the initiation (first 12 weeks) of once-weekly (OW) semaglutide, a glucagon-like peptide-1 receptor agonist approved for type 2 diabetes. Here, we provide an overview of users’ interaction with the app since its launch in August 2018.

Methods: Data were analysed both overall and separately for active (≥5 consecutive weeks without interacting with [opening] the app) and less active (>3 consecutive weeks without interacting with the app) users.

Results: Of 7,789 registered users, 2,820 were active and 4,969 were less active. ‘How to’ resources were frequently viewed during the first week by both user groups. Resources most viewed were ‘when to take’ and ‘side effects’. Overall, 73.1% registered users set up injection reminders during the first week and 39.8% set up anchoring plans (where the user anchors injection behaviour to an existing habit in their routine). Setting up anchoring plans resulted in more consistent self-recorded injection rates throughout the 12-week dose escalation period in active (+7%) and less active (+20%) users vs users not setting up plans; both p<0.05 (Figure)

Conclusions: This analysis suggests that use of the mHealth app and setting up anchoring plans is associated with more consistent use of treatment as assessed by self-recorded injection rates, regardless of overall engagement levels. This highlights the benefits of medication-specific mHealth apps as patient support tools when initiating new medications.

O072 / #354
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

NEW TECHNOLOGIES IN TYPE 2 DIABETES (T2D) MANAGEMENT AND FUTURE OPPORTUNITIES TO IMPROVE CLINICAL OUTCOMES

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Background and Aims: Many people with T2D will eventually need insulin treatment to achieve glycaemic control and to reduce complications from chronic hyperglycaemia. However, insulin treatment initiation is often delayed, and HbA1c targets are frequently not achieved in insulin-treated patients; the latter due, in part, to insufficient titration, inadequate dosing, or missed doses. We aim to highlight current challenges in managing insulin treatment and how new technologies may address these barriers.

Methods: We searched PubMed and materials from four national and international diabetes conferences in this focussed literature review. The term ‘diabetes’ was combined with the following: insulin titration, insulin AND digital, smart phone, digital health technologies selected for discussion (Table), most were developed for smartphones and demonstrated equivalent or improved glycaemic outcomes and required less contact time with healthcare practitioners (HCPs) versus controls or previous care setting. The new devices chosen generally aimed to track doses and dose timing.

Results: A number of publications reported technology-based interventions including software tools or devices to overcome barriers to effective treatment. Of the software-based technologies selected for discussion (Table), most were developed for smartphones and demonstrated equivalent or improved glycaemic outcomes and required less contact time with healthcare practitioners (HCPs) versus controls or previous care setting. The new devices chosen generally aimed to track doses and dose timing.

Conclusions: Key features that new technology should offer include efficacy at improving glycaemic control, ease of use, accurate data capture, accessibility of data to the HCP and insulin user, and data security. A solution that connects continuous glucose monitoring, dose recording, help with titration, and recording of lifestyle factors might reduce treatment complexity and burden and result in improved titration and higher treatment adherence.

Study funded by Sanofi

Table: Software-based technologies currently available or in development for management of T1D and/or T2D

<table>
<thead>
<tr>
<th>Tool name</th>
<th>Diabetes type</th>
<th>Key glycaemic outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXYS II (Diabetes Insulin Guidance System)</td>
<td>1, 2</td>
<td>Decrease in average glucose levels in average HbA1c</td>
</tr>
<tr>
<td>ITTrends Max (MyIT woven coach) (Long-acting Insulin Glucose Titration Web Tool)</td>
<td>2</td>
<td>Non-inferiority in reduced usual therapy not demonstrated</td>
</tr>
<tr>
<td>Interactive web-based exercise system, and Diabetes BI</td>
<td>2</td>
<td>HbA1c, reduction greater in telemonitoring groups versus standard care</td>
</tr>
<tr>
<td>DiabetesPal</td>
<td></td>
<td>No significant reduction in HbA1c</td>
</tr>
<tr>
<td>MITI (Mobile Insulin Titration Intervention)</td>
<td>2</td>
<td>No difference in mean change in HbA1c</td>
</tr>
<tr>
<td>PANDIT</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>HealthZone</td>
<td>2</td>
<td>As effective in terms of HbA1c reduction in traditional methods of titrating insulin</td>
</tr>
<tr>
<td>SMED</td>
<td>2</td>
<td>Reduced HbA1c, versus traditional treatment</td>
</tr>
<tr>
<td>W FIT</td>
<td>1, 2</td>
<td>Larger reduction in HbA1c, versus usual care</td>
</tr>
<tr>
<td>MDIC (My Dose Coach)</td>
<td>2</td>
<td>Mean HbA1c decreased parallel to change in HbA1c</td>
</tr>
<tr>
<td>Dose Rx (Stage)</td>
<td>2</td>
<td>Reduction in HbA1c</td>
</tr>
<tr>
<td>mTigran</td>
<td>1, 2</td>
<td>Improvement in mean Glucose, TIR, readings above target, and estimated HbA1c</td>
</tr>
<tr>
<td>Dule Digital</td>
<td></td>
<td>Greater reduction in HbA1c, versus usual care</td>
</tr>
<tr>
<td>SMBG</td>
<td>1, 2</td>
<td>Diabetes reduction in HbA1c, versus usual care</td>
</tr>
<tr>
<td>PDS2 (patient centered smartphone-based diabetes care system)</td>
<td>1</td>
<td>Reduction in HbA1c, when glucometer input was minimal (once per day)</td>
</tr>
<tr>
<td>OneTouch Touch (School based web application + OneTouch Touch Verio BG meter)</td>
<td>1, 2</td>
<td>Reduction in fasting plasma glucose after 12 weeks</td>
</tr>
<tr>
<td>gPilotModel</td>
<td></td>
<td>Mean HbA1c decreased after 12 weeks in T2D, mean BG decreased</td>
</tr>
</tbody>
</table>

BG, blood glucose; TIR, time in range; adapter, mean available.

Background and Aims: Digital health solutions that facilitate self-tracking and offer coaching hold great promise to help users manage their diabetes. Establishing patterns of good Digital Health Habits, in which users engage with app features frequently for a sustained period of time, may be a critical foundation of success. The aim of this research was to identify digital health habits correlated with improvements in blood glucose (BG), focusing on early engagement patterns.

Methods: Data from a sample of 48,368 users of a digital health solution were analyzed. Our primary outcome of interest was a clinically significant improvement in BG from month 1 to month 6 of using the digital health solution. This was defined as a 14 mg/dL drop of either max or average BG in that period. To identify correlates of BG success, we included the first 4 week of engagement data and user demographics as predictor variables in a logistic regression model.

Results: of a logistic regression indicated that, in order of effect size, logging blood glucose, food, medications, sleep, and labs were significant predictors (p < 0.05) of an improvement in BG. In contrast, logging exercise, weight, steps and blood pressure (BP) were not significant predictors.

Conclusions: Our results indicate that certain Digital Health Habits are better predictors of overall improvements in diabetes status. Specifically, habits more closely linked to daily diabetes disease management (medications, BG, food) translate better to clinical improvements in BG than those less relevant (steps, BP, weight).

Background and Aims: During COVID-19 pandemic, access to medicines and healthcare professionals (HCPs) was damaged in Brazil. Although telemedicine and teleconsultations were authorized during the crisis, people did not always find these services available. For this reason, the quick response from not-for-profit organizations (NGOs) was vital to the most vulnerable people with diabetes (PwD).

Methods: ADJ Diabetes Brasil started teleconsultations through voice-calls or WhatsApp video-calls with dietitians, psychologists and physicians, in addition to online support groups. Trained volunteers triaged PwD and scheduled the consultations.
**Results:** Between May 8th and September 25th, 204 first time consultations had been offered, and 30 returning consultations; while 122 were with dietitians, 74 with physicians, 8 with psychologists, all the returning consultations were with physicians. Among the main challenges identified by PwD were: 1) unavailability of medical appointments at the public health system, as a consequence lack of medicine adjustments and directions for healthy choices in the new routine; 2) no diabetes education on carbohydrate counting, insulin action and injection sites; 3) difficulties for obtaining prescription to receive medicines.

**Conclusions:** The pandemic crisis threatened the health systems worldwide. In Brazil, the public health system was not able to fully assist individuals with communicable diseases such as diabetes, since the efforts were mostly directed to equip hospitals and relocate HCP to emergency care. In this environment the ability of NGOs to adapt and offer services to complement the public health services was fundamental to guarantee, at least in part, the continuity of care for underserved individuals.

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**O075 / #502**

**Topic:** A506-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**FEASIBILITY OF USING A FACTORY-CALIBRATED CGM SYSTEM TO DIAGNOSE TYPE 2 DIABETES**

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**Background and Aims:** Type 2 diabetes (T2D) can be diagnosed with the oral glucose tolerance test or with hemoglobin A1C (HbA1c); however, the reproducibility and concurrence between these tests is suboptimal. Continuous glucose monitoring (CGM) may allow for convenient and accurate T2D diagnosis. We assessed whether a factory-calibrated CGM system (Dexcom G6), worn in blinded mode for a single wear period, can be used to diagnose T2D.

**Methods:** We developed a binary classification diagnostic CGM (“dCGM”) algorithm based on CGM and HbA1c data using a dataset of 716 individual CGM sensor sessions with associated HbA1c measurements from seven clinical trials. Data from 623 sensor sessions were used for training and 93 subjects for testing (49 normals [HbA1c ≤5.7%), 27 prediabetes, and 17 T2D [HbA1c ≥6.5%] not using pharmacotherapy). dCGM performance was evaluated against the accompanying HbA1c measurement which was assumed to provide the correct diagnosis.

**Results:** The dCGM algorithm’s overall sensitivity, specificity, positive predictive value, and negative predictive value were 71%, 93%, 71%, and 93%, respectively. At other clinically relevant HbA1c thresholds, dCGM specificity among normals was 98% (48/49 correctly classified) and for subjects with sub-optimally-controlled diabetes (HbA1c ≥7%), above the ADA recommended HbA1c goal) the sensitivity was 100% (8/8 subjects correctly diagnosed with T2D).

**Conclusions:** We have shown in a small dataset that dCGM has good performance for the diagnosis of T2D. Thus a factory-calibrated CGM system with a dCGM algorithm is a feasible alternative for the diagnosis of T2D and warrants further investigation.
Background and Aims: Clinical trials are an essential instrument to test newly developed solutions for diabetes management and care. Multivariable and multisensor data that are usually collected in such studies should be structured to enhance their fruition, synchronized to a telemonitoring interface, and finally analyzed to assess the methodology under examination. The process of collecting and organizing data is complex and requires ad-hoc multidomain infrastructures. This work presents a newly developed telemedicine platform that allows real-time data gathering and monitoring during clinical studies.

Methods: The platform is composed by a cloud database, a mobile application and a web interface (see Figure, upper panel). The mobile application allows to log daily-life events and automatically collects data from Dexcom’s CGM devices and health vitals from both Apple Watch and Fitbit smartwatches. Data are streamed to the cloud database through secure RESTful APIs and ultimately exposed in real-time to clinicians through an easy-to-use web interface. The platform complies with the General Data Protection Regulation and ensure modularity to allow fast implementation of new algorithms for their assessment.

Results: Currently undergoing tests on a diabetic individual show that the platform is robust and performant. An example of data collected in such pilot study is reported (Figure, lower panel). No errors or disconnections have been experienced so far.

Conclusions: The developed platform is proving to be an efficient tool to gather and visualize in real-time multivariable and multisensor data. Next steps include an ad-hoc study to extensively test and validate it on a large population.

O078 / #196

Topic: AS07-Insulin Pumps

ACUTE CLINICAL OUTCOMES IN COVID-19 POSITIVE PATIENTS WITH TYPE 1 DIABETES (T1D) USING INSULIN PUMP FOR DIABETES MANAGEMENT: DATA FROM THE T1D EXCHANGE COVID REGISTRY

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Background and Aims: The use of continuous subcutaneous insulin infusion (CSII) has demonstrated fewer acute complications in patients with type 1 diabetes (T1D). This study aims to examine the frequency of adverse clinical outcomes among T1D patients who tested positive for COVID-19 and were users versus non-users of insulin pump therapy.

Methods: The analysis included 241 T1D patients from the T1DX-QI COVID-19 registry who tested positive for COVID-19. Healthcare providers extracted patient data from electronic medical records of 52 endocrinology clinics across the U.S. Data was collected from April 2020 to September 2020.

Results: In this population, 38% (N=92) of T1D patients were insulin pump users, whereas 62% (N=149) were non-users. HbA1c levels in the insulin pump group were lower compared to non-users (Median [IQR], %: 8.0 [1.9] vs. 9.8 [3.7] [p <0.001]). Adverse events, such as diabetic ketoacidosis, were less frequently recorded for insulin pump users relative to the non-users (9% vs.30%) [p <0.001]. Further, patients who did not use insulin pump therapy were more likely to be hospitalized (29% vs.12%) [p <0.001] or need ICU care [25% vs.4%] [p <0.001] than patients who used insulin pumps.

Conclusions: Patients with established T1D and COVID-19 who used insulin pump therapy for diabetes management had lower rates of adverse clinical outcomes.

O079 / #321

Topic: AS07-Insulin Pumps

PATIENT REPORTED PREFERENCES FROM THE PRO SOLO: NOVEL PATCH PUMP CLINICAL TRIAL

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Diseases, Endocrinology And Diabetology, Warsaw, Poland, 
²Roche Diabetes Care, Global Medical & Scientific Affairs, Mannheim, Germany, 
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⁵Medical University of Graz, Division Of Endocrinology And Diabetology, Graz, Austria

**Background and Aims:** Patch pumps have become a relevant alternative to classic tethered (tubed) insulin pumps. Patient Reported Outcomes (PROs) play a vital role in understanding the ability/willingness of individuals to engage with such systems. We aimed to investigate the preferences of participants using the novel AccuChek Solo (ACS) pump.

**Methods:** Participants with T1D naive to insulin pump therapy (39.0±11.9 years, 44% female, 15.0±10.8 duration of diabetes, HbA1c 8.0±0.6% (70.5 mmol/mol) enrolled in a multinational RCT were asked to provide feedback on the ACS pump. Participants were either ACS direct users or switched from MDI six months into the study.

**Results:** Benefits of ACS were reported by \( n = 180 \) participants (\( n = 133 \) ACS direct use, \( n = 47 \) MDI switchers, providing \( n = 226 \) individual coded responses. Most cited benefits: wireless (n = 37), quick bolus (n = 32), no injections (n = 28), bolus calculator, ease of use and discretion (all n = 22). Most useful attributes reported by n = 166 participants (n = 166 individual responses): bolus calculator (n = 64), flexible basal/bolus rates (n = 42) and quick bolus function (n = 41). Downsides were reported by n = 166 participants (n = 216 individual responses): manager not a smartphone app (n = 57), not waterproof (n = 39) and needs greater compatibility with other systems eg flash/CGM/BG meter (n = 26)

**Conclusions:** Users overwhelmingly found the bolus calculator/device manager most useful and benefitted from the wireless, discreet nature of the system. Integration of the manager into a smartphone was recommended by most and a waterproof version desirable by many. Results indicate ACS is an acceptable therapy choice with potential to improve biomedical and psychosocial outcomes of users.

**O080 / #343**

**Topic:** AS07-Insulin Pumps

**GLYCEMIC PROFILES AND TREATMENT PATTERNS: REAL-WORLD DATA FROM 13,109 PEOPLE IN EUROPE AND CANADA WITH DIABETES USING A TUBELESS INSULIN PUMP WITH CLOUD-BASED DATA MANAGEMENT**

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**Background and Aims:** Real-world data has been recognized as an important tool to better understand the impact of diabetes technology on clinical outcomes of people with diabetes. This retrospective study analyzed data from a large cohort of patients with diabetes using a tubeless insulin pump (Omnipod® Insulin Management System) with CGM or an integrated blood glucose (BG) meter and a data management system to characterize glycemic profiles, insulin use and treatment patterns.

**Methods:** Tubeless insulin pump data was generated between December 1, 2018 and November 30, 2019 and uploaded to the data management system from Europe and Canada. CGM, BG and insulin data from users with ≥3 months system use were analyzed.

**Results:** Data from 13,109 users from the United Kingdom (25.3%), Sweden (18.3%), the Netherlands (12.6%), Canada (29.2%) and other (14.6%) were included. Glycemic profiles (mean±SD) for the CGM cohort included mean glucose of 177±32mg/dL, and percentage time <70mg/dL of 5.6±4.3%, in target range (70 to 180mg/dL) of 52.6±14.6% and >180mg/dL of 41.8±15.9% (see Table for BG results). For the total population, mean total daily insulin was 40.6±17.6U/day which was delivered as 47% basal and 53% bolus. There was an average of 5.9±2.2 bolus deliveries per day and the average bolus amount was 4.2±2.5U.

**Conclusions:** This is the first study of real-world data on glycemic profiles and treatment patterns from a large cohort of people using a tubeless insulin pump in Europe and Canada. It demonstrates glycemic levels comparable to published worldwide data using other means of intensive insulin regimens.

**Table: Glycemic Profiles and Insulin Use Patterns of People with Diabetes using a Tubeless Insulin Management System**

<table>
<thead>
<tr>
<th>Insulin Use Patterns</th>
<th>All Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users with data, N</td>
<td>13,109</td>
</tr>
</tbody>
</table>

| TDI, U/d             | 40.6±17.6 |
| Basal, %             | 46.8±12.0 |
| Bolus, %             | 53.2±12.0 |
| Bolus frequency, x/d | 5.9±2.2   |
| Bolus amount, U      | 4.2±2.5   |

<table>
<thead>
<tr>
<th>CGM Cohort</th>
<th>CGM Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users with data, N</td>
<td>3,371</td>
</tr>
</tbody>
</table>

| Mean Glucose levels, mg/dL (mmol/L) | 177±32 (9.8±1.8) |
| Mean Glucose readings in range, %  | 1.9±2.2   |
| <54 mg/dL (<3.0 mmol/L)             | 5.6±4.3   |
| 70 - 180 mg/dL (3.9 - 10.0 mmol/L) | 52.6±14.6 |
| >180 mg/dL (>10.0 mmol/L)           | 41.8±15.9 |
| ≥250 mg/dL (≥13.9 mmol/L)           | 17.9±12.3 |

<table>
<thead>
<tr>
<th>BG Cohort</th>
<th>BG Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users with data, N</td>
<td>8,664</td>
</tr>
</tbody>
</table>

| Mean BG levels, mg/dL (mmol/L) | 177±33 (9.8±1.8) |
| Mean BG readings in range, %  | 3.6±3.7   |
| <54 mg/dL (<3.0 mmol/L)        | 9.6±6.8   |
| 70 - 180 mg/dL (3.9 - 10.0 mmol/L) | 47.7±12.9 |
| >180 mg/dL (>10.0 mmol/L)      | 42.7±15.0 |
| ≥250 mg/dL (≥13.9 mmol/L)      | 20.6±12.1 |
**O082 / #362**

**Topic: AS07-Insulin Pumps**

**FEASIBILITY CLINICAL STUDY ASSESSING THE COMPATIBILITY OF INSULIN FIASP WITH MEDTRONIC 7-DAY EXTENDED WEAR INFUSION SET**

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**Background and Aims:** Fiasp® (Faster Insulin Aspart) is approved to be administered through a pump with an infusion set for up to 3 days, with recommendations to monitor pump settings and hypoglycemia closely. Medtronic Extended Wear Infusion Set (EWIS) is CE marked to infuse insulin Lispro and Aspart subcutaneously via Medtronic insulin pumps for up to 7 days. This feasibility study is aimed to evaluate safety and efficacy of EWIS delivery of Fiasp® for up to 7 days.

**Methods:** This is a single-center, prospective, open label arm study of up to 40 subjects who use EWIS with a target for 20 subjects to complete the study. Subjects subjects used EWIS with a target for 20 subjects who use EWIS with Fiasp® Insulin with MiniMed™ 640G/670G Insulin Pumps for 4 weeks that will serve as an exploratory pilot study to assess the 7-day survival of EWIS with Fiasp® Insulin. All subjects will be instructed to change sets every 7 days or at set failure.

**Results:** The data collected up to date indicates that Fiasp® can be administered by EWIS for up to 7 days safely. Survival rate collected so far is with the EWIS survival rate of delivering Lispro/Aspart.

**Conclusions:** This is the first trial of a 7-day infusion set for Fiasp® use in insulin infusion pumps. Clinical data obtained from this prospective, single site study demonstrates that using MiniMed™ 640G/670G pumps with EWIS for subcutaneous delivery of Fiasp® for up to 7 days it both safe and efficacious.

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**O083 / #439**

**Topic: AS07-Insulin Pumps**

**SKIN DEPTH AND SUBCUTANEOUS REACTIONS TO DIABETES DEVICES IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES MEASURED BY ULTRASOUND**

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**Background and Aims:** This is the first trial of a 7-day infusion set for Fiasp® use in insulin infusion pumps. Clinical data obtained from this prospective, single site study demonstrates that using MiniMed™ 640G/670G pumps with EWIS for subcutaneous delivery of Fiasp® for up to 7 days it both safe and efficacious.
Background and Aims: More than 80% of pediatric patients with type 1 diabetes in Denmark are using diabetes devices, unfortunately, up to 30% suffer from dermatitis. To extend areas for insertion ultrasound can visualize skin depths. Therefore, primary aim of present study is to describe the skin depths in a cohort of pediatric patients.

Methods: In a prospective study on pediatric patients, ultrasound was performed. The distance from skin surface to muscular fascia was measured. All manufacturers were contacted to elaborate the actual skin depth of their device. Additionally, the echogenicity of dermis and subcutis was investigated as a mark of tissue changes.

Results: A total of 103 pediatric patients (age 2–18 years) were included in our analyses. In the upper arm, the mean distance from skin surface to muscular fascia was 5.63 mm (SD 2.34) in the youngest age group (2–6 years) increasing to 10.01 mm (SD 5.20) in 15–20-year old, similar results with increasing distance with age was found for other skin sites. According to the manufacturers the skin depths of devices were ranging from 5–12 mm. Increased echogenicity (tissue condensation) of subcutis were seen in 19 patients (18%).

Conclusions: Skin depths at different sites increases by age and were in some patients less than the depth of device. Increased echogenicity in subcutis was seen in 18% of the patients. How the skin depth and the increases echogenicity influence functionality of the sensor remain unknown.

O084 / #536
Topic: AS07-Insulin Pumps
CENTER DIFFERENCES IN DIABETES TREATMENT OUTCOMES AND INSULIN PUMP USE AMONG CHILDREN WITH TYPE 1 DIABETES: A NATIONWIDE STUDY OF 3,866 DANISH CHILDREN

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Background and Aims: Differences in mean HbA1c across treatment centers are well established, but less well understood. The aim was to assess the importance of disparities in the patient case-mix in explaining the variation in mean HbA1c between pediatric treatment centers in Denmark. The association between glycemic control, frequency of blood glucose monitoring (BGM), treatment modality, and number of clinic visits per year was also investigated.

Methods: This was a longitudinal nationwide study of 3,866 Danish children with type 1 diabetes between the years 2013-2017 (n=12,708 child-year observations). The children were followed in 16 distinct pediatric diabetes clinics. Mean HbA1c, proportion of children reaching treatment target (HbA1c≤58mmol/mol (7.5%)) were compared across clinics using linear regression models. This was done with and without adjustment for socioeconomic characteristics (patient case-mix).

Results: The mean difference in HbA1c during follow-up was 11.6mmol/mol [95% CI 7.9, 15.3] (1.1% [95% CI 0.7, 1.4]) between the center with the lowest vs. highest mean HbA1c. The difference was attenuated and remained significant after adjustment for the patient case-mix (difference: 10.5mmol/mol [95% CI 6.8, 14.2]) (1.0% [95% CI 0.6, 1.3])). Overall, only 6.8% of the differences in the mean HbA1c across centers were explained by differences in the patient case-mix. Higher BGM was associated with lower HbA1c (Figure 1). Proportion of insulin pump users and number of visits was not associated with HbA1c.

Conclusions: Large, significant differences in HbA1c across centers were found, and this was not explained by patient background. Visits and insulin pump use was not associated with HbA1c.

O085 / #647
Topic: AS07-Insulin Pumps
MEDTRONIC 640G VS TANDEM BASAL IQ DURING THE FIRST 3 MONTHS OF DIABETES SINCE ONSET IN VERY YOUNG CHILDREN.

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Background and Aims: Type 1 diabetes (T1D) management in young children is challenging due to the risk of wide glucose fluctuations and their long-term consequences. The aim of this study was to compare the use of Medtronic 640G and off-label use of Tandem Basal IQ in children with T1D younger than 6 years of age.

Methods: Twentyone children (mean age 3 years) were started on either 640G (n=11) or Tandem Basal IQ (n=10) at onset and pump/sensor data was downloaded after 3 months. Parents of children started on Tandem signed an informed consent. Mann-Whitney non-parametric U test was used to assess differences in glucometrics between group.

Results: Glucometric parameters of 640G vs Tandem users were respectively: TIR 75% vs 63%, TBR 2.4% vs 3%, TAR
21.6% vs 34%. CV 32 vs 38. Mean insulin dose was 0.4 U/kg/die in the 640G group and 0.7 U/kg/die in the Tandem group. Differences in glucose distributions were all statistically significant except for TBR. No episodes of severe hypoglycemia or DKA were reported.

Conclusions: Both pumps allowed these young children to obtain good glucose control. However, Medtronic 640G achieved significantly better glucose distributions, although this may be partially explained by the lower daily insulin needs in this group. Our data suggests that the use of Tandem Basal IQ in children < 6 years is safe, feasible and may be a valid alternative to other systems in young children in whom also few capillary glucose calibrations may be challenging. Broader prospective studies in this delicate population are required to confirm our results.

O086 / #168

Topic: AS08-New Medications for Treatment of Diabetes

NASAL GLUCAGON REVERSED INSULIN-INDUCED HYPOGLYCAEMIA IN ADULTS WITH DIABETES: A POOLED ANALYSIS

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Background and Aims: Nasal glucagon (NG), a ready-to-use drug-device combination for treatment of severe hypoglycaemia, contains 3 mg glucagon dry powder that is absorbed passively through nasal mucosa. We examined the efficacy and safety of NG compared to 1 mg injectable glucagon (IG) in reversing insulin-induced hypoglycaemia in a global population of adults with type 1 diabetes (T1D) and type 2 diabetes (T2D). Notably, this is the first analysis including pooled T2D data.

Methods: Post-hoc analyses used data from 3 randomised, cross-over studies. Treatment success was defined as an increase in blood glucose to ≥ 3.9 mmol/L (70 mg/dL) or an increase of ≥ 1.1 mmol/L (20 mg/dL) from nadir blood glucose within 30 min of receiving glucagon. Tolerability was assessed using treatment-emergent adverse events and a symptom questionnaire.

Results: In the T1D+T2D pooled analysis, 99.5% (213/214) of NG and 100% (214/214) of IG administrations achieved treatment success in a mean (median) time of 13 (10) minutes and 11 (10) minutes, respectively. The times (mean [median]) for achieving treatment success for participants with T2D (N=41) were similar for NG (12 [10] minutes) and IG (11 [10] minutes). NG and IG induced similar blood glucose changes (figure). NG and IG had similar incidences of nausea and vomiting, with NG having a higher rate of side effects related to nasal administration [headache (13% NG, 7% IG), nasal discomfort (4% NG, 1% IG), etc.]. Separate T1D and T2D analyses showed similar results as T1D+T2D.

Conclusions: NG was efficacious and well-tolerated in reversing insulin-induced hypoglycaemia in adults with T1D and T2D.

O087 / #174

Topic: AS08-New Medications for Treatment of Diabetes

ULTRA-FAST AND ULTRA-STABLE INSULIN FORMULATIONS

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Background and Aims: Insulin has been used to treat diabetes for 100 years but current insulin formulations are too slow to maintain tight glycemic control at mealtimes. We have developed a new class of amphiphilic copolymers as stabilizing agents for insulin formulations, enabling the development of an ultrafast acting monomeric insulin lispro (UFAL) formulation with the potential to improve glucose control and reduce burden for patients with diabetes.

Methods: We compared the pharmacokinetics of UFAL to Humalog using a pig model of insulin-deficient diabetes where plasma lispro concentrations were determined by ELISA on collected blood samples after subcutaneous administration. For analysis of pharmacokinetic parameters, pharmacokinetic curves were coded and were analyzed by a blinded researcher.

Results: We show that UFAL remains stable for 25 ± 1 hours under stressed aging conditions that cause Humalog to aggregate in only 5 ± 2 hours. In diabetic pigs, peak insulin exposure was determined to be 9 ± 4 min for UFAL and 25 ± 10 min for Humalog. Pharmacokinetic modeling based on the pig data predicts peak exposure in humans to be at 10 min for UFAL and 43 min for Humalog, in excellent agreement with human clinical data for Humalog, suggesting that UFAL may have unprecedented pharmacokinetics for an injectable formulation.

Conclusions: The ultrafast pharmacokinetics observed for UFAL coupled with the dramatically improved stability over current insulin formulations are highly distinguishing for compatibility with pump and closed-loop systems. Our stable ultrafast insulin formulation has the potential to improve diabetes management and reduce patient burden around mealtime glucose management.

O088 / #438

Topic: A508-New Medications for Treatment of Diabetes

Efficacy and Safety of Dapagliflozin on Standardized CGM Metrics in Patients with Type 1 Diabetes

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Background and Aims: Dapagliflozin is approved in the EU for patients with type 1 diabetes (T1D) with BMI ≥27 kg/m². Our aim was to evaluate its safety and efficacy on standardized CGM metrics in T1D patients using CGM.

Methods: We conducted a prospective study including all T1D patients with BMI ≥27 kg/m² using CGM who were prescribed dapagliflozin 5 mg daily and were followed for at least 6 months. Education concerning ketosis prevention was given to all patients before initiating dapagliflozin. Weight, standardized CGM metrics and ketosis episodes were registered before and after 3 and 6 months of treatment. Data were analyzed with univariate repeated-measures ANOVA using SPSS Statistics.

Results: 13 patients were included from November 2019 to July 2020: 5 were male and 8 female, 9 on insulin pump and 4 on multiple dose injections, 8 on real-time CGM and 5 on intermittently-scanned CGM, with baseline characteristics as follows: age 45.9 ± 7.2 years, BMI 31 ± 3.7 kg/m², HbA1c 7.5 ± 0.7% and TIR 56.2 ± 9.2%. Medication was discontinued in 3 patients due to ketosis (n = 2) and ketoacidosis (n = 1). Patients who completed the 6 months period showed significant increase in TIR and a significant decrease in weight, BMI, TBR, TAR and CV, and a non-significant decrease in GMI and mean glucose (Table 1). There were 8 ketotic decompensations and 1 ketoacidosis that required ICU care. 2 patients had mild urinary tract infections.

Conclusions: Dapagliflozin led to further improvement in CGM metrics in patients with T1D. Nevertheless, despite a structured ketone-prevention program, ketosis risk was increased.

O089 / #485

Topic: A508-New Medications for Treatment of Diabetes

One-Year Safety and Efficacy of Insulin-Therapy Simplification with Ideglira in Type 2 Diabetes

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Background and Aims: Multiple daily insulin injection (MDI) regimens in type 2 diabetes (T2D) can provide optimal glycemic control but cause significant treatment burden, hence simpler therapies with similar efficacy are needed. Our preliminary 3-month follow-up data showed that switching from MDI to once daily IDegLira, a fixed-ratio combination of insulin degludec and liarglutide, in relatively well-controlled (HbA1c<7.5%) subjects with T2D using low total daily insulin dose is safe and provides similar or better glycemic control. Our aim was to confirm the sustained efficacy and safety of the simplified treatment during a 12-month follow-up.

Methods: 72 adults with T2D (mean±SD: age 63.8±9.5 years, HbA1c 6.36±0.70%, BMI 33.01±6.47kg/m², body weight 92.95±18.83kg, total daily insulin dose: 43.2±10.8
units, duration of diabetes 9.7 ± 7.5 years) treated with MDD±metformin participated in our study. Previous insulins were stopped and once daily IDegLira was started. IDegLira was titrated by the patients every 3 days with 2 dosage units to achieve a self-measured pre-breakfast plasma glucose concentration of <6 mmol/L.

Results: After 12-month of follow-up good glycemic control was maintained, while body weight and BMI decreased significantly. Mean HbA1c changed by -0.15% to 6.21 ± 0.82% (p = 0.109), body weight changed by -3.89 kg to 89.06 ± 18.61 kg (p < 0.0001) and BMI changed to 31.61 ± 6.22 kg/m². The simplified treatment was safe and well-tolerated. Percentage of patients experiencing hypoglycemia was 49% during the months before simplification and 17% during the last 3 months of the follow-up.

Conclusions: Our 12-month data confirm that insulin-therapy simplification with IDegLira in patients with well-controlled T2D is safe, may induce weight loss and results in similar glycemic control.

O090 / #498

Topic: AS08-New Medications for Treatment of Diabetes

ADO09, A CO-FORMULATION OF PRAMlintide AND INSULIN A21G IMPROVES POST-PRANDIAL GLUCOSE (PPG) VERSUS INSULIN ASPART IN TYPE 1 DIABETES (T1D)

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Background and Aims: Pramlintide improves PPG through delaying gastric emptying, reducing glucagon secretion, and promoting satiety. ADO09 is a stable co-formulation of pramlintide and insulin A21G under development. This double-blind, randomised, 2-period cross-over trial compared pre-meal ADO09 versus insulin aspart over 24 days in 28 T1D participants.

Methods: During a 28 days run-in period, basal insulin was switched to insulin degludec. The cross-over treatment periods consisted of 3 inpatient days (baseline assessments), followed by 3 outpatient weeks and a final inpatient mixed-meal-tolerance-test (MMTT) on day 24. Blood glucose, glucagonemia and kinetics of gastric emptying were analyzed, as were CGM-metrics. The two treatment periods were separated by a 5 to 7 day washout.

Results: Incremental plasma glucose AUCs during MMTT with ADO09 were reduced by >100% after 2h (p < 0.001) and by 39% after 4h (not significant), gastric emptying was slower (Tmax +312%, p < 0.0001) and glucagon suppressed by 78% over 0-2h (p < 0.0001) versus insulin aspart. ADO09 showed improved CGM-metrics in the outpatient period with higher Time-In-Range (+51 min, p = 0.01). Time <70 mg/dL was slightly higher (+9.6 mg/dL, p = 0.046) as were hypoglycemic events (142 vs. 115). ADO09 reduced body weight (-0.7 kg vs baseline, p = 0.01). Mean daily ADO09 doses were lower than insulin aspart’s (17 vs 22 U, p < 0.0001). Both treatments were well tolerated with more, but transient gastrointestinal adverse events (24 vs 6) with ADO09, consistent with the known side effect profile of pramlintide.

Mean baseline adjusted plasma glucose (±SE) profiles at day 24

Conclusions: ADO09 was well tolerated and significantly improved post-prandial blood glucose control, CGM-metrics, weight control and bolus insulin needs versus insulin aspart over 24 days.

O091 / #814

Topic: AS08-New Medications for Treatment of Diabetes

NOVEL TREATMENT OF TYPE 1 DIABETES - THE INFLUENCE OF HLA, NUMBER OF DOES AND ADMINISTRATION ROUTE ON THE EFFECT OF GAD-SPECIFIC IMMUNOTHERAPY

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Background and Aims: We have previously shown an association between the HLA haplotype DR3-DQ2 and a positive treatment effect of GAD-alum in individuals recently diagnosed with type 1 diabetes. In this study we sought to further investigate the influence of HLA, number of injections and administration route on the clinical effect of GAD/alum treatment.

Methods: We combined individual-level data (n = 627) from four placebo controlled randomized clinical trials of both subcutaneous and intralymphatic GAD-alum immunotherapy. We estimated the treatment effect at 15 months from baseline on C-peptide retention, HbA1c, insulin dose and insulin adjusted HbA1c (IDAA1c) using a mixed model repeated measures model including terms for HLA subgroup and number of doses. The effect of administration route was evaluated using a Bayesian model.

Results: A significant treatment effect was seen in individuals carrying HLA DR3-DQ2 (n = 313), with the best effect seen in those receiving three-four doses showing an effect ratio of 1.48 (adjusted P < 0.0001) on preserving C-peptide compared to 1.21 (p = 0.092) for those receiving two doses. A lower HbA1c was also seen in the three-four dose group compared to placebo (-4.74 mmol/mol, adjusted P < 0.01). Despite using only 1/5 of the dose, there was a 98%, 99%, 71% and 97% probability that three intralymphatic injections were superior to three subcutaneous injections for C-peptide retention, HbA1c, insulin dose and IDAA1c, and safety profiles were comparable.

Conclusions: These analyses highlight the importance of genetics, dosing regimen, and administration route in immunotherapeutic treatment of type 1 diabetes and a clinically relevant potential for intralymphatic GAD-alum.
Background and Aims: Insulin, the main hormone for modulating blood glucose levels, is used for diabetes treatment mainly through subcutaneous injections. This can lead to poor patient compliance and side-effects. To face this problem, Medicsen is developing a Smartpatch with a wide range of tested technologies, focused on the non-invasive, controlled and painless insulin transdermal delivery through sonophoresis.

Methods: In vitro and in vivo tests, such as the permeability phenomenon using Franz diffusion Cell and swine model, or biochemical, chromatography or circular dichroism tests, among others, have been performed to prove the efficacy and safety of the technology.

Results: Lack of damage was observed on insulin molecule, which maintain its biological function and stability, as seen in vivo, in HPLC studies and in the circular dichroism spectra of the samples (Fig. 1), which shows no variability, reaching the characteristic minimum at 219nm (sd+/−8.31) in all groups tested. TEM images of skin, ELISA of skin damage markers TNFα and IL-2 (Fig. 2), and other biochemical tests, show no significant changes in the tissue or in the expression and concentration of relevant compounds. Lastly, the technology proved to be effective in the non-invasive insulin delivery through the skin, as observed in our system and in the in vivo model of blood glucose reduction.

Conclusions: All evidence collected during in vitro and in vivo studies show promising results, indicating that the technology developed by Medicsen is safe and effective. Thus, human trials will be performed in order to demonstrate its potential on diabetes treatment.

Fig. 1: Circular dichroism spectra of the different samples analyzed. A) Control: Record of the circular dichroism spectrum of the insulin standard. B) Recording of the circular dichroism spectrum of the solution in compartment 2 after being exposed ultrasound for 20 minutes.

Fig. 2: Effective concentrations of TNFα (A) and IL-2 (B).
Background and Aims: Hypoglycaemia remains a prevalent complication with deleterious consequences among individuals with diabetes. We aimed to identify independent predictors of hypoglycaemia and impending hypoglycaemia using real-time continuous glucose monitoring and a physiological data acquisition wristband.

Methods: Six-week longitudinal analysis of 12 adults with type 1 diabetes using real-time continuous glucose monitoring (Dexcom G6) and a clinically validated physiological data acquisition sensor (Empatica E4). A mixed effects logistic regression model was applied to predict hypoglycaemia using measurements recorded during blood glucose levels below 72 mg/dL and 54 mg/dL. Measurements within 1-hour before glucose levels fell below 72 mg/dL were used to predict impending hypoglycaemia.

Results: Participants had a median age (IQR) of 40 (30–39) years and were equally stratified by gender and mode of insulin delivery (multiple daily injections and continuous subcutaneous insulin infusion). Hypoglycaemia was negatively predicted by a higher electrodermal activity standard deviation (SD) (p = 0.03), higher heart rate (SD) (<0.01), and higher mean skin temperature, (p < 0.05). While greater maximum phasic skin conductance responses and mean heart rate increased the odds of hypoglycaemia (<0.01). Elevation in mean skin temperature and physical activity (SD) were both significant positive predictive factors for impending hypoglycaemia but not established biochemical hypoglycaemia.

Conclusions: Measurements obtained from wearable physiological wristband data sensors could be integrated alongside CGM data to improve identification and prediction of hypoglycaemia.

Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes

A COMPREHENSIVE APPROACH TO EMPOWER SELF-MANAGEMENT OF HEALTH IN CHILDHOOD OBESITY BASED ON GAMIFICATION MECHANISMS AND BIOFEEDBACK

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Background and Aims: Modern m-health technologies open new perspectives in managing childhood obesity. Within the Greek funded project, named “ENDORSE”, an innovative software ecosystem is developed incorporating Artificial Intelligence and gamification technologies capable of delivering tools and services facilitating self-management of health while engaging the active involvement of formal and informal caregivers.

Methods: ENDORSE applies a parent-child multicomponent intervention including dietary, physical activity, educational and behavioral components. It implements a goal-oriented approach which includes periodic assessment of child’s weight, behavioral lifestyle and needs in order to accordingly adjust goal settings and improve adherence. Obese children are trained and encouraged to adopt healthy diet and physical activity through their
interaction with the ENDORSE serious game. Aiming at optimizing the parental role, a mobile application has been developed facilitating daily self-monitoring of goals and communication with healthcare professionals.

**Results:** The ENDORSE platform has the capability to leverage data from different sources (e.g. activity trackers, mobile apps) in order to create a complete user profile. Personalized, tailored messages and reminders targeting child and parents, along with recommendations for goal settings adjustment and adherence reports, are produced by the ENDORSE recommendation engine with the aim to achieve personalization and adaptation.

**Conclusions:** The ENDORSE platform implements modern m-health technologies into routine clinical care of obese children. Future work includes the execution of pilot trials to evaluate its effectiveness in terms of improving health outcomes and user’s acceptance. **Acknowledgements:** Supported within the framework of the ENDORSE project, which is funded by the NSRF (Grant agreement: T1EAK-03695)

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**O096 / #767**

**Topic:** AS12-New Technologies for Treating Obesity and Preventing Related Diabeteis

**THE ROLE OF ANTIOXIDANT PROTECTION ASSOCIATED WITH LIVER MITOCHONDRIAL BIOGENESIS IN OBESE PATIENTS**

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**Background and Aims:** FFA accumulate not only in adipose tissue during obesity. The high content of FFA contributes to the development of NAFLD. Oxidative stress and mitochondrial dysfunction contribute to the development of T2DM. The adaptive defense mechanism promotes the activation of the antioxidant and cytoprotective response. The study aimed to identify the role of antioxidant protection associated with liver mitochondrial biogenesis in obese patients.

**Methods:** Liver biopsies were taken during laparoscopic surgery. The study included 59 obese patients with T2DM (47.6 ± 8.8 years; 47.2 ± 6.1 kg/m²; 23 men and 36 women), 57 obese patients without T2DM (40.7 ± 6.1 years; 41.8 ± 7.1 kg/m²; 26 men and 31 women). The control group consisted of 41 healthy donors. Gene mRNA expression levels were determined by PCR on a CFX96 Touch system (BioRad). mtDNA copies were determined by drop PCR using a QX200 Droplet Digital PCR system (BioRad).

**Results:** NFE2L2, HSP70 expression decreased in obese patients with T2DM relative to patients without T2DM and healthy donors. In contrast, mtDNA copies and HSF1 expression increased in obese patients with T2DM. SOD1 expression decreased in obese patients with and without T2DM, while MT-ND4 expression increased.

**Conclusions:** Thus, liver compensatory mechanisms are triggered and reduced the effects of oxidative stress and the development of steatohepatitis in obese patients without T2DM. State assignment in the field of scientific activity [No.FZWN-2020-0010 to Larisa Litvinova]; State of Leading Scientific Schools of the Russian Federation [No.2495.2020.7 to Larisa Litvinova].

**O097 / #769**

**Topic:** AS12-New Technologies for Treating Obesity and Preventing Related Diabetes

**THE NEW THERAPEUTIC APPROACH TO OBESITY MANAGEMENT: THE REAL-LIFE WEIGHT AND BMI OUTCOMES**

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**Background and Aims:** Obesity is a worldwide epidemic with a clear-cut tendency for progression, now recognized as a disease. Nevertheless, a non-operative approach for its treatment remains a challenge. This study evaluated the efficacy of our new obesity-treatment algorithm.

**Methods:** Twenty-seven patients files with uncomplicated obesity were analyzed. GLP1 analogue Liraglutide (Saxenda) treatment was implemented for all. In 17 patients (63%), Metformin therapy was additionally implemented due to Impaired Fasting Glucose (IFG). Routine professional CGM (Medtronic iPRO2) was performed in most of participants in order to exclude hypoglycemia, mainly at nights. Our specific therapeutic (Gravicentric) algorithm was used, based on several specific food behavior recommendations, combining this therapy with metformin and physical activity guidance.

**Results:** The mean age was 58.5 years, therapy duration - 10.5 months, body weight before therapy was 97.3 kg, BMI was 32.7 kg/m². By using our treatment algorithm, we achieved significant reduction in body weight by 6.8 kg and BMI by 2.4 kg/m² on average. No patients received Saxenda doses higher than 1.8 mg/day, while 70% were managed on 1.2 mg per day or less.

**Conclusions:** Our real-life weight and BMI resembles to the Liraglutide large RCT results (average reduction of weight by 6.5 kg and BMI by 2.4 kg/m²) while using mild-to-moderate Saxenda dose regimens, without clinically significant side effects. No hypoglycemia time-below-range elevation was noticed at CGM investigations. This therapeutic scheme provides the unique opportunity to achieve maximal effect at minimal dose. It
additionally reduces the probability of side effects (including hypoglycemia and ketosis), and cut treatment costs.

O098 / #56
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

CLINICALLY RELEVANT IMPROVEMENT IN GLYCAEMIC CONTROL IN TYPE 1 DIABETES USERS OF THE HEDIA APPLICATION FOR DIABETES MANAGEMENT: A REAL-WORLD COHORT STUDY
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Background and Aims: Digital diabetes self-management tools can support glycaemic control in people with type 1 diabetes (T1D). The Hedia Diabetes Assistant (HDA), an mHealth-based medical device, was designed to assist insulin dosing and daily decision making. Our aim was to investigate if T1D users of HDA can achieve clinically relevant improvements in glycaemic control after 12 weeks use.

Methods: Anonymized data from engaged users (≥10 logs/week for 12 weeks) were extracted from the HDA database. Outcomes were changes in eA1c (estimated HbA1c), and estimated time-in-range (eTIR, proportion of blood glucose level [BGL] measurements within 3.9-10.0mmol/l) after 12 weeks. We applied GLMM to data from all users, and to a subgroup of more poorly controlled users. Sensitivity analyses included t-tests, and GLMM leaving out weeks 0-1 from the analyses to mitigate for regression toward the mean.

Results: The 234 engaged users had a mean age of 45.5 (SD 16.3) years and 116 (49.6%) were female. After 12 weeks, the more poorly controlled users (mean baseline BGL ≥10mmol/l, eA1c≥7.9% in week 0; n=84) experienced statistically significant improvements in eA1c and eTIR. Improvements across all users (n=234) were not significant. Sensitivity analyses confirmed our results.

Conclusions: Statistically significant and clinically relevant improvements in glycaemic control were observed after 12 weeks of using the HDA in individuals with poorly controlled T1D. Findings support the relevance of mHealth in T1D, however, further studies including randomized controlled trials are needed to substantiate our observational findings.

O099 / #339
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

RISK FACTORS FOR DIABETES-RELATED DISTRESS IN PEOPLE LIVING WITH TYPE 1 DIABETES – LESSONS FROM THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) FREESTYLE LIBRE AUDIT
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Background and Aims: The objective of this study was to identify the baseline demographic and clinical characteristics associated with Diabetes-related distress in people living with Type 1 diabetes.

Methods: The study was performed using baseline data from the ABCD nationwide FreeStyle Libre audit. We collected diabetes-related distress scores at baseline with two items diabetes-related distress score (DDS) and follow up. An average item score of ≥3 (moderate distress) discriminated high from low-distressed subgroups. We used an unsupervised gradient boosting machine learning model (GBM) to identify the relative influence of baseline parameters on two components of DDS.
RESULTS: The study consisted of 9124 people with Type 1 diabetes, with a mean age of 45.1 (±15.3) years, 50.3% female, mean BMI of 26.5 (±6.2) kg/m² and mean baseline HbA1c 70.2 (±18.3) mmol/mol. High diabetes-related distress was prevalent in 5476 (60%) of people living with T1D at baseline. The two components of the DDS were significantly correlated (r² = 0.73 P < 0.0001). In the GBM model, baseline HbA1c (RI = 51.4), GOLD score (RI = 23.3), gender (RI = 7.05) and fear of hypoglycaemia as an indication for starting on the FSL (RI = 4.9) were associated with diabetes-related distress. The linear regression model confirmed that higher baseline HbA1c, higher GOLD score, female gender and fear of hypoglycaemia were significantly associated with DDS.

CONCLUSIONS: In this large UK cohort of people living with Type 1 diabetes, diabetes distress was prevalent and associated with high HbA1c, impaired awareness of hypoglycaemia and female gender.

O100 / #488
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals
IMPACT OF THE COVID-19 LOCKDOWN ON DIABETES PATIENTS IN JEDDAH, SAUDI ARABIA
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Background and Aims: Aims To explore the impact of the coronavirus disease lockdown on diabetes patients living in Jeddah, Saudi Arabia, in terms of their compliance with medication intake and lifestyle habits, and quality of life.

Methods: In this cross-sectional, qualitative prospective study, a questionnaire was administered over the telephone to diabetes patients who had attended National Guard primary care centers in Jeddah, Saudi Arabia. The survey included questions on demographic data, type of diabetes, medications used, comorbidities, medication compliance, and daily habits before and after the lockdown, and those assessing patients’ psychological parameters during the past month by using the Kessler Psychological Distress Scale (K10). Data analysis was performed using SPSS program version 26.

Results: Totally, 394 patients participated. All of them had type 2 diabetes, and 37.6% had only one comorbidity. Antidiabetic monotherapy was used in 76.4% of the patients, while combination therapy was used in 23.6%. The compliance score before the lockdown was significantly higher (18.49 ± 3.05) than that after it (17.40 ± 3.25) (p-value < 0.001). The average psychological assessment score was 9.78 ± 4.14 (range 8–35). Male participants and smokers had a significantly better psychological status than female participants (p-value = 0.002) and non-smokers (p-value < 0.001), respectively.

Conclusions: The patients’ levels of compliance with medications and healthy lifestyle habits were significantly reduced after the lockdown. These findings highlight the need for healthcare professionals to encourage diabetes patients to adhere to healthy lifestyle habits and use telemedicine during lockdowns to ensure optimal blood glucose control and reduce the incidence of complications.

O101 / #482
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals
CONTINUOUS GLUCOSE MONITORING METRICS PREDICT SUBOPTIMAL MATERO-FETAL OUTCOMES IN TYPE 1 DIABETES PREGNANCY
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Background and Aims: The optimal method of monitoring glycemia in pregnant women with type 1 diabetes remains controversial. This study aimed to assess if continuous glucose monitoring (CGM) metrics and alternative biochemical markers of glycemia could improve ability to identify pregnancies at risk of suboptimal obstetric and neonatal outcomes compared to biochemical markers including HbA1c.

Methods: 157 women from the CGM in pregnant women with type 1 diabetes trial (CONCEPTT) were included in this prespecified secondary analysis. HbA1c, CGM data, and alternative biochemical markers (glycated CD59, 1,5 anhydroglucitol, fructosamine and glycated albumin) were compared at approximately 12, 24 and 34 weeks gestation using logistic regression and ROC curves to predict pregnancy complications (pre-eclampsia, preterm delivery, large-for-gestational-age, neonatal hypoglycemia, admission to neonatal intensive care unit).

Results: HbA1c, CGM metrics, and alternative laboratory markers were all significantly associated with obstetric and neonatal outcomes at 24 weeks gestation. HbA1c, Time-in-range (TIR; 63–140 mg/dl; 3.5–7.8 mmol/l) and time-above-range (TAR; >7.8 mmol/l) were the most consistently predictive CGM metrics and showed good predictive ability for many outcomes. Some alternative laboratory markers showed promise, but overall, they had lower predictive ability than HbA1c.

Conclusions: CGM metrics TIR and TAR performed well and had comparable predictive ability to HbA1c for many outcomes. Alternative biochemical markers of glycemia and other CGM metrics did not substantially improve the prediction of pregnancy outcomes. CGM metrics TIR and TAR are able to predict suboptimal pregnancy outcomes in women with type 1 diabetes.

O102 / #14
Topic: AS14-Human factor in the use of diabetes technology
INTRODUCTION OF THE DIABETES EXERCISE PERCEPTION (DEEP-I) QUESTIONNAIRE FOR ASSESSING PERCEIVED ATTITUDES AND CHALLENGES IN ATHLETES WITH TYPE 1 DIABETES
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Background and Aims: The introduction of continuous glucose monitoring (CGM) devices into management of type 1 diabetes (T1D) may have a role in being an adequate tool for the diagnosis, management and monitoring in athletes with diabetes. However, it is not yet clear whether the use of CGM devices for exercise is feasible and acceptable to athletes with diabetes. This paper aims to introduce the DEEP-I questionnaire which is a self-report instrument that captures participants’ perspectives on the use of CGM devices for exercise.

Methods: The DEEP-I questionnaire is a self-report instrument that captures perspectives on the use of CGM devices for exercise in athletes with diabetes. The questionnaire includes both descriptive and open-ended questions that assess participants’ attitudes and challenges associated with using CGM devices during exercise.

Results: The questionnaire revealed that athletes with diabetes have mixed feelings about using CGM devices during exercise. Some athletes found that CGM devices provided valuable feedback on their glycemic control during exercise, while others felt that the devices disrupted their exercise routine. Challenges reported included difficulties with device calibration and managing hypoglycemia during exercise.

Conclusions: The DEEP-I questionnaire provides valuable insights into the attitudes and challenges faced by athletes with diabetes when using CGM devices for exercise. This information can help to guide the development of future interventions to improve the acceptability and feasibility of using CGM devices in this population.
Background and Aims: Little is known about individual perspectives and challenges faced by elite-level athletes living with type 1 diabetes (T1D). Currently, there is no structured tool to assess this. We aimed to generate and pilot test the Diabetes ExEcise Perception (DEEP-1) questionnaire in a group of professional athletes with T1D.

Methods: The questionnaire consists of a range of open and closed questions, focusing on 4 key areas related to T1D and exercise: 1) Technology; 2) Sleep and Recovery; 3) Glucose Management; 4) Nutrition. Sixteen professional cyclists with T1D (age 27 ±4 years; HbA1c 6.8±0.5%) were asked to anonymously complete the questionnaire. Data were then analyzed descriptively.

Results: Fifteen participants responded. In this cohort, 90% showed an interest in using technology for improved exercise performance and 89% for glucose management, although 28% felt unaware of newer technologies. Glucose was perceived as being generally well regulated; however, according to the responses, more attention needs to be focused overnight and pre/during exercise. Sleep quality was rated as an important factor affecting exercise performance in 80% of respondents. 93% of participants identified nutrition as an area for improved performance, with 25% reporting a lack of education in this area.

Conclusions: This pilot study highlights the importance of an individualized approach to diabetes management and high-level exercise. Future work should validate the DEEP-1 questionnaire in a larger sample size using a range of physical activity levels. Such a tool may provide a useful and time-efficient means for healthcare professionals to gain deeper insight into their patients’ attitudes and challenges regarding exercise.

O103 / #69

Topic: AS14-Human factor in the use of diabetes technology

FEATURE SET ENGAGEMENT AND GLYCEMIC OUTCOMES AMONG USERS OF A CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background and Aims: Persons with diabetes commonly engage with continuous glucose monitoring (CGM) systems by viewing data directly. Features such as alerts, real-time sharing, and the ability to retrospectively summarize patterns and trends offer additional opportunities for engagement and additional pathways for therapeutic adjustments. We examined feature set utilization and glycemic outcomes among users of the G6 CGM System (Dexcom).

Methods: Data were from a convenience sample of anonymized US-based G6 users who began use in 2H2019 and who used a compatible mobile device to view and upload data on at least 80% of the days in 1H2020. “Stable” profiles were those with coefficients of variation ≤36%. Use or non-use of five features was considered on each day of 1H2020: CLARITY (software for report generation); Share/Follow (distributes real-time data to remote devices); Urgent Low Soon (triggered by impending hypoglycemia); and Low Threshold and High Threshold (triggered by existing hypoglycemia and hyperglycemia, respectively). Each user was categorized as low-engagement, medium-engagement, or high-engagement based on their mean daily use of features (<3, 3-4, and ≥4 features, respectively).

Results: Data from 35,993 users (12,079 low-engagement, 15,063 medium-engagement, and 8,851 high-engagement) were analyzed. The Figure shows that the high-engagement group had the highest TIR (62.2%), the lowest proportion of glucose values <54 mg/dL (0.31%), and the highest proportion of users with stable glucose profiles (67.7%). All between-group differences were statistically significant (p<0.001).

Conclusions: Routine engagement with CGM data as evidenced by use of optional features may contribute to favorable glycemic outcomes.

O104 / #102

Topic: AS14-Human factor in the use of diabetes technology

SPOTLIGHT CONSULTATIONS: ILLUMINATING PATIENT PRIORITIES – T1 DIABETES

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Background and Aims: Burnout in people with diabetes and healthcare professionals is at an all-time high. Spotlight is a novel ‘smart’ adaptive dynamic patient questionnaire designed to improve routine outpatient consultations by rapidly identifying patient priorities and presenting these in the context of personalized areas for concern and best-practice care pathways to illuminate consultations. We assessed the feasibility of using Spotlight in routine care.

Methods: The Spotlight prototype tool was trialled at three centres (two primary care, one specialist) between June-September 2020.

Results: Thirty-one adults with T1D (n=13 male; n=18 female) participated in this real-world evidence collection, each identifying two priority concerns. ‘Psychological burden of diabetes’ was the most common primary concern (n=27,871.1%) followed by ‘gaining more skills about particular aspects of diabetes’ (n=19,613.3%), ‘improving support around me’ (n=8,258.8%) and ‘diabetes-related treatment issues’ (n=8,258.8%).
Burden of diabetes was widespread as was lack of confidence around self-management. Participants with diabetes-related complications more often prioritised “diabetes related treatment issues” than those without complications. People whose last Hba1c was >8.6% were more likely to prioritise “gaining more skills” than those whose A1c was <8.5. Men reported greater psychological burden (92.3%-v-83.3%) whilst women prioritised gaining more skills (66.7%-v-53.9%). Those aged <35 years more often prioritised psychological burden than those ≥35 years (100%-v-82.6%). Gaining more skills was more frequently a priority concern among those with higher duration of diabetes (44% among <10 years vs. 68% among ≥10 years).

**Conclusions:** Spotlight is acceptable and feasible used in routine care. It is effective in identifying biomedical and psychological priorities of patients.

O105 / #146

**Topic:** AS14-Human factor in the use of diabetes technology

**PILOT OF A BEHAVIORAL INTERVENTION FOR CGM USERS DECREASES DIABETES DISTRESS AND IMPROVES TIME IN RANGE IN ADULTS WITH TYPE 1 DIABETES (T1D)**

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**Background and Aims:** Continuous glucose monitoring (CGM) can improve glycemic control for adults with T1D; daily use increases benefits. Barriers to consistent use include cost; data overload; alarm fatigue; physical discomfort; and unwanted social attention. This pilot study aimed to examine 1) acceptability of a behavioral intervention, ONBOARD, to support adults with T1D in optimizing CGM use and 2) preliminary effects on diabetes distress and glycemic outcomes.

**Methods:** Adults (18-50) with T1D in their first year of CGM use were invited to participate in an individualized multicomponent intervention delivered by a psychologist via videoconference over four 60-minute sessions. ONBOARD combines social learning, problem-solving, and education. Participants completed surveys (diabetes distress; satisfaction with program) and provided CGM data at baseline and post-intervention (3 months). Data were analyzed using paired t-tests and Wilcoxon signed-rank tests.

**Results:** Twenty-two participants (Age = 30.95 ± 8.32; 59% female; 91% Non-Hispanic; 86% White, 5% Black, 9% other; 73% pump users) completed the study. ONBOARD demonstrated acceptability: 100% of those who attended 1 session completed all 4 sessions. Most (81%) completers rated ONBOARD as “helpful” or “very helpful”. Moderate effect sizes (Cohen’s d and r) were found for diabetes distress and daytime spent in range.

**Conclusions:** Findings show preliminary evidence that ONBOARD has the potential to optimize CGM use while alleviating diabetes distress. Further research should examine ONBOARD in a larger sample over a longer time period.
Participants were divided into three groups based on their time of adoption: within 4 weeks (Group A), between 3–4 months (Group B) and 5–6 months (Group C). Glycemic data was retrieved from Tandem’s tx:connect® web application for six weeks pre and post use of the system. Pre-post differences were analyzed using T-test or Wilcoxon-signed rank tests.

Results: Compared to other groups, Group A, initiated Control-IQ technology with a significantly higher median time in range (TIR) (64.1%), lower mean sensor glucose (SG) (167 ± 30), and more time with SG <70mg/dL (1.1%). After six weeks of Control-IQ technology, all three groups showed significant improvements in TIR, reductions in mean SG, and time with SG >180mg/dL. Groups B and C demonstrated greater increases in TIR (+11%) vs. Group A (+9.4%).

Conclusions: Irrespective of when Control-IQ technology was adopted, significant improvements in TIR were experienced by all groups. These findings also suggest that early adopters of diabetes technology pursue tighter SG control compared to other users. Further exploration of diabetes management behaviors of early adopters of diabetes technology is recommended.

O108 / #181

Topic: AS14-Human factor in the use of diabetes technology

SUBOPTIMAL INSULIN USE IN DIABETES MELLITUS: A SYSTEMATIC LITERATURE REVIEW

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Background and Aims: This review aimed for the first time to identify and summarize real-world evidence on the extent of suboptimal insulin use in People with Diabetes (PwD).

Methods: A systematic literature search of MEDLINE, EMBASE, and Cochrane databases identified studies reporting data on missed, incorrect, miscalculated, and mistimed insulin doses, and over/underdosing in PwD.

Results: From 3,305 publications, forty records (34 studies) were included. Seventy percent of publications were cross-sectional surveys (n = 28). Publications provided data on missed (n = 29) and mistimed doses (n = 14), over/underdosing (n = 9), and dose miscalculations (n = 6). PwD reported missing basal and bolus insulin doses in all studies. Eleven records reported...
glycemic control was better in PwD who did not miss doses. Mistiming of insulin was reported in 14 records, with 20–45% of PwD mistiming doses. Eight records reported mistiming was associated with higher rates of hypoglycemia and/or worse glycemic control. Insulin over/underdosing varied widely across studies. Data were limited regarding dosing miscalculations, but all studies indicated that PwD experienced difficulties with insulin adjustments. Reasons for suboptimal use (n = 19 records) were multifactorial, including disrupted daily routines, social situations, and hypoglycemia avoidance. Most dosing errors were unintentional.

Conclusions: Suboptimal insulin use is experienced by almost half of PwDs. This can increase the rate of hyperglycemia and hypoglycemia and is often related to social situations for hypoglycemia avoidance. Technology solutions addressing this could potentially improve diabetes management in most individuals who are actively trying to improve their metabolic control. Studies using artificial intelligence decision support systems and connected insulin pen platforms are warranted.

O109 / #186

Topic: AS14-Human factor in the use of diabetes technology

RATES OF AND RISKS FOR SEXUAL DYSFUNCTIONS IN PEOPLE WITH DIABETES MELLITUS: RESULTS FROM DIABETES MILES – FLANDERS

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Background and Aims: Sexuality affects quality of life. The higher prevalence of sexual dysfunction in men with DM can be partially explained by cardiovascular risk factors. Depression is positively associated with sexual dysfunction in both men and women with diabetes. This study aims to report the prevalence of sexual dysfunctions in patients with type 1 and type 2 diabetes (T1D and T2D) and its associations with various clinical and psychological factors. We also examined the proportion of participants receiving psychological treatment.

Methods: Flemish adults with DM were invited to complete an online survey including questions regarding psychological factors, sexual functioning and healthcare use.

Results: Of the 756 participants included (T1D: M/W: 174/242; T2D: M/W: 237/103), one third reported sexual dysfunction. Women reported decreased desire (T1D: 22%; T2D: 15%) and decreased arousal (T1D: 9%; T2D: 11%), while men experienced erectile dysfunction (T1D:20%; T2D: 33%) and orgasmic dysfunction (T1D: 22%; T2D:27%). In men, higher waist circumference (B: =0.063;OR =1.07;p =0.004) and longer duration of diabetes (B =0.034;OR =1.03;p =0.011) were associated independently with sexual dysfunction. Women with sexual dysfunction reported more diabetes distress (36% vs. 21%, p =0.003), impaired well-being (36% vs. 25%, p =0.036), and more anxiety (20% vs. 11%, p =0.026) than without sexual dysfunction. This was more pronounced in T1D (well-being: 39% vs. 26%. (p =0.213); diabetes-distress: 39% vs. 26% (p =0.213); anxiety symptoms 22% vs. 15% (p =0.427), T1D and T2D respectively). Women with sexual dysfunction reported more psychological treatment (15 vs. 5%;p =0.002).

Conclusions: Sexual dysfunction is common in men and women with T1D and T2D. Both men and women with sexual dysfunction reported greater diabetes-related distress.

O110 / #332

Topic: AS14-Human factor in the use of diabetes technology

LIPOHYPERTROPHY MONITORING STUDY (LIMO): EFFECT OF INJECTION SITE ROTATION AND EDUCATION ON GLYCEMIC CONTROL

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Background and Aims: Incorrect injection technique can cause lipohypertrophy resulting in unpredictable insulin release. We aimed to assess the impact of a correct injection technique and lipohypertrophy on HbA1c, hypoglycemia and glucose variability.

Methods: 171 insulin-injecting people with diabetes were prospectively evaluated for 6 months. 146 subjects completed the study (75 type 1, 71 type 2). They were provided extensive education concerning injection technique via an online education platform (BD and Me™) based on the international Forum for Injection Technique & Therapy Recommendations, encouraged to systematically use 4 mm needles and not reuse needles. Primary outcome parameter was the evolution between baseline and end-of-study percentage of needle re-use and injecting in a zone of lipohypertrophy versus glucometrics (HbA1c, hypoglycemia and glucose variability).

Results: At baseline, lipohypertrophy was present in 64%, 51% of patients injected in zones of lipohypertrophy, 37% rotated incorrectly and 96% reused needles. After the intervention, only 8% injected in a lipohypertrophy zone, 4% rotated incorrectly, and 21% reused needles. There was a significant reduction in severe hypoglycemia (from 15.8% to 4.1%, p < 0.001), number of unexplained hypoglycemias (from 47% to 16%, p <0.001), and in the number of people with high glucose variability (from 64% to 30% p < 0.001). HbA1c (7.3±1.2%) and total daily insulin dose (62±41 units) remained unchanged.

Conclusions: Online education on injection techniques focusing on avoidance of lipohypertrophy zones and reduction of needle re-use results in a significant reduction in severe hypoglycemic episodes, unexplained hypoglycemias and in the number of people with high glucose variability.
O111 / #365

Topic: AS14-Human factor in the use of diabetes technology

BEHAVIORAL MODEL OF POST-MEAL INSULIN CORRECTION BOLUS INJECTIONS IN TYPE 1 DIABETES INDIVIDUALS UNDER FREE-LIVING CONDITIONS

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Background and Aims: Besides describing the physiology of patients with type 1 diabetes (T1D), realistic simulation tools for in-silico trials should also mimic the behavioral aspects of patients’ lifestyle, which can notably affect glucose control. In a previous work (Camerlingo et al., J. Diabetes Sci. Technol., 2020) we modelled meal amount and timing variability, here we focus on the timing of post-meal insulin correction bolus (CB) injections.

Methods: A multicenter study involving 30 patients with T1D, monitored in free-living conditions for 1-month (Kovatchev et al., Diabetes Technol. Ther., 2017) was used to extract 539 CBs for 1,963 meals. 7-hour post-prandial windows were divided in 30-min portions, labelled as “1” or “0”, based on the occurrence of a CB injection. Three different binary classification techniques were implemented to predict the labels: support vector machine (SVM), decision tree (DT) and logistic regression techniques were implemented to predict the labels: support vector machine (SVM), decision tree (DT) and logistic regression.

Results: SVM provided an AUROC of 0.76±0.04 (mean±std), performing slightly better than LOG (0.75±0.04) and DT (0.73±0.04). The 8 most representative predictors were: time from last bolus and from last meal, current CGM reading and rate-of-change, daytime, patient’s age, body weight, and correction factor.

Conclusions: Once refined using larger datasets, the new model can be incorporated in T1D simulators. By mimicking patient behavior in self-administering CBs, the model will allow more realistic in-silico trials.

O112 / #463

Topic: AS14-Human factor in the use of diabetes technology

SCHOOL NURSE CONFIDENCE WITH DIABETES DEVICES IS NOT STRONGLY CORRELATED WITH GENERAL DIABETES KNOWLEDGE

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Background and Aims: As new and emerging devices are increasingly used for pediatric diabetes care, school nurses need knowledge and confidence to assist students with devices. The aim of this study was to measure school nurse confidence with devices in relation to diabetes knowledge, which, to our knowledge, has not previously been evaluated.

Methods: School nurses in Pennsylvania were recruited to complete a questionnaire evaluating confidence, designed by our group and demonstrating content validity, and the Diabetes Knowledge Test (DKT). We analyzed the association between confidence and prior training, practical experience, and DKT performance using non-parametric tests.

Results: Respondents (n = 269) were 99% female, 96% white, mean age 52 years. Most had experience with insulin pumps (95%) and continuous glucose monitor (CGM, 92%), but not sensor-augmented pumps (34%). Half (54%) had cared for 5 or more children with devices in the past 5 years. One-third (37%) of school nurses had received formal device training from a diabetes center. Median response for pump items was 3.15 and for CGM items 3.5/4, suggesting moderate confidence overall. Mean score on the DKT was 89% (range 57–100). DKT performance was weakly correlated with pump (0.10, p = 0.02) or CGM (0.14, p = 0.02) confidence. In contrast, prior training from a diabetes center (pumps p = 0.001, CGM p = 0.006) and caring for at least 5 students with devices (pumps p = 0.004, CGM p = 0.004) were associated with higher median confidence.

Conclusions: General diabetes knowledge is not strongly associated with device confidence. Experiential training focused on specific skills may be needed to ensure school nurses are prepared to assist students.

O113 / #464

Topic: AS14-Human factor in the use of diabetes technology

TECHNOLOGY UTILIZATION IN AFRICAN AMERICAN YOUTH WITH TYPE 1 DIABETES: EXPLORING THE DECISION MAKING PROCESS

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Background and Aims: Significant disparities in diabetes device (DD) use exist for African American (AA) adolescents with type 1 diabetes (T1D), meriting further exploration. We sought to describe how AA adolescents with T1D and their guardians make decisions about using DDs and to understand personal, familial and cultural beliefs that may influence use.

Methods: Nineteen AA adolescents with T1D and 17 guardians participated in individual qualitative semi-structured interviews. Adolescents were purposively sampled for a range in socioeconomic and clinical demographics. Interview data were recorded, transcribed, and coded for thematic analysis, analyzed...
separately for guardians and adolescents, and then compared across groups. Data collection continued until thematic saturation was achieved.

**Results:** Adolescents and guardians reported similar themes related to (1) intersectionality of age, race and TID; (2) decisions about DDs; (3) insight about use/nonuse of DDs; and (4) advice about enhancing success with DDs. Adolescents reported lacking peers with TID “who look like me,” leading to stigmatization, exacerbated by device visibility and alarms. Cultural and familial traditions were described as both facilitators and barriers in decisions about DDs. TID self-management support included extended family, school personnel and clinic providers. Lack of familiarity with TID, limited exposure to DDs, and mistrust were reasons for decreased uptake of DDs. Participants provided specific suggestions for clinical support for use of DDs.

**Conclusions:** Understanding the decision-making process surrounding DDs and preferences around methods of education, peer support and follow-up may help to ameliorate some disparities in DD use, leading to improved glycemic control and outcomes.

**O115 / #803**

**Topic: AS14-Human factor in the use of diabetes technology**

**QUALITY OF LIFE OUTCOMES AND GLYCEMIC CONTROL FROM THE T:SLIM X2 PUMP WITH CONTROL-IQ TECHNOLOGY – REAL WORLD OBSERVATIONS FROM THE CLIO STUDY**

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**Background and Aims:** To forward a holistic understanding of automated insulin dosing system efficacy, evaluation of both glycemic and psychosocial outcomes is necessary.

**Methods:** As part of the ongoing Control-IQ Observational (CLIO) Study, we evaluated glycemic and psychosocial outcomes in people with type 1 diabetes (PWT1D) using the Tandem Diabetes Care t:slim X2™ insulin pump with Control-IQ technology. Participants completed questionnaires at baseline (T1) and 3 months after study start (T2), uploaded at least 21 days of pump data to Tandem’s t:connect® web application, and had ≥75% CGM use during this time. Repeated measures ANOVA was used to assess differences in patient-reported outcomes from T1 to T2.

**Results:** In all, 700 PWT1D (59% female, 87% White, mean age = 39 (SD = 17), mean diabetes duration = 21 years (SD = 15)) were included in the analysis. 81% reported baseline HbA1c <8.5%, 80% had been using an insulin pump, and 89% were using CGM prior to using Control-IQ technology. At T2, sensor time in range for the overall sample using Control-IQ technology was 72.5% (median, IQR = 71–73%) and sensor time <70mg/dl = 1.1%. Participants reported greater satisfaction with their insulin delivery device and its impact on their diabetes management (7.06 vs. 8.77) (p <0.001). Majority (96%) reported improved sleep quality at T2. A significant reduction in the perceived negative impact of diabetes (4.79 vs 4.41) (p <0.001) (i.e., improved quality of life) across life dimensions (e.g., freedom to eat, emotional well-being) was noted.

**Conclusions:** Control-IQ technology users reported substantial psychosocial benefits including improved QoL, satisfaction, and sleep quality within three months of using the system.
Background and Aims: Diabetes technology has significantly advanced over the past decade. Appropriate use of diabetes technology reduces the burden and improves outcomes in people with type 1 diabetes. We conducted an online survey to study the awareness, current use, and satisfaction of diabetes technology among people with type 1 diabetes (T1D) in Singapore.

Methods: An anonymous online survey was developed and advertised on social media and at the T1D clinic at Singapore General Hospital. Sections included demographics, diabetes profile, technology awareness, current technology use, and technology satisfaction. Descriptive data are presented as count with percentages [n(%)] or mean and standard deviation (M±SD).

Results: n = 104, 72(69%) women participated. Age at diagnosis was < 20 years (y) for 49 (47%), mean duration of diabetes was 16.9 y ± 12.4 y and 81 (78%) reported most recent HbA1c < 8% (64 mmol/mol). Awareness about continuous glucose monitors (CGM) was the highest [81 (78%)], only 46 (44%) knew about government-subsidized insulin pump therapy and only 25 (24%) knew about smartphone bolus calculator applications. Only 57 (55%) had ever used a smartphone diabetes application and 26 (25%) were unaware of them. Majority [79 (76%)] used capillary glucose meters; while 32 (31%) used CGM. 75 (72%) used insulin pumps. Awareness about bolus calculators and government-subsidized insulin pump therapy was low. Satisfaction rates were lower for glucose monitoring devices compared to insulin delivery devices.

Background and Aims: Despite many new innovations, little is known to date about diabetes technologists’ attitudes and expectations regarding digitization and new technologies in diabetesology and how they are changing over time.

For the “Digitization and Technology Report Diabetes 2021”, diabetologists nationwide in Germany were asked from August to October 2020 about their attitudes toward diabetes technologies and digitization in diabetesology, among other things, and compared with a similar survey in 2018/2019.

Methods: 337 diabetologists (2018: 422; 2019: 324) participated in the survey (43% female, average age 53.2 years). On average, 324 people with diabetes using Flash-Glucose-Monitoring, 100 using real-time continuous glucose monitoring (CGM), and 94 using insulin pump therapy (CSII) were treated per diabetes institution in 2020.

Results: In 2020, 81.9% (2019: 75.8%; 2018: 63.7%) of the physicians surveyed had a positive or very positive attitude toward digitization, with only 3.6% having a negative attitude toward it (2019: 4.3%, 2018: 8.0%). The benefits of digitization for diabetes was rated as “better metabolic control of patients” (75.9%), “better quality of own work” (74.1%) “more personalized treatment of patients in terms of personalized diabetes therapy” (71.9%), and “specialization of own institution” (65.9%). The “unclear and insufficient reimbursement of digital services” (89.6%) was stated as the greatest disadvantage.

Conclusions: The potential of digitization is considered to be very high by diabetologists. The comparison of the previous 3 surveys (2019, 2020, 2021) indicates that the positive attitude towards digitization has increased even more in recent years and that a very positive basic mood now prevails among most respondents.

Background and Aims: To quantify the increase of new technologies in diabetesology, diabetologists in Germany were surveyed annually about the use of continuous glucose monitoring and insulin pumps.

Methods: In 2018, 2019, and 2020, diabetologists participated in a survey (“Digitization and Technology Report Diabetes (D.U.T)”) to determine how many of their patients use new technologies. 337 diabetologists (2018: 422; 2019: 324) participated in the survey (43% female, average age 53.2 years). On average, 324 patients are currently treated per practice with flash glucose monitoring (iscCGM), 100 with continuous glucose monitoring (CGM), and 94 using insulin pump therapy (CSII) were treated per diabetes institution in 2020.

Results: By comparing 2018 - 2020, we can see the sharp increase in modern technologies - which, overall, have roughly doubled over this time period. The increase of iscCGM is 83%, of CGM 114%, of CSII 53%, of hybrid closed-loop systems 167% and DIY of 100%. In diabetes outpatient institutions 75.2% people with type 1 diabetes (TD1) and 31.1% with type 2
diabetes (T2D) are now using some form of continuous glucose monitoring. 32.9% TD1 and 7.5% an insulin pump.

**Conclusions:** Over a 3-year period, there is a clear and steady increase in the number of people with diabetes in Germany using modern technologies. Approximately 3/4 of all people with type 1 diabetes now use them, and the trend for type 2 diabetes is also growing strongly.

**O119 / #394**

Topic: **AS15-Trials is progress**

**MINI-DOSE GLUCAGON TO TREAT FASTING-INDUCED HYPOGLYCEMIA DURING RAMADAN: A NOVEL APPROACH**

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**Background and Aims:** To understand whether subcutaneous mini-dose glucagon (MDG) is an effective treatment for fasting-induced hypoglycemia in people with type 1 diabetes using real-time CGM (rt-CGM) and fasting during Ramadan.

**Methods:** A randomized, controlled crossover trial involving 17 participants with type 1 diabetes while they were fasting during Ramadan. All participants received rt-CGM and were randomized to either 150-mg, 300mg subcutaneous glucagon (MDG) or oral glucose tablets (OG) to treat fasting induced hypoglycemia with a crossover after. A participant feedback questionnaire was developed and used.

**Results:** MDG users had higher mean and maximum rt-CGM glucose concentrations one hour after treatment of hypoglycemic episodes as compared to those given OG (mean 76 vs 67 mg/dL, maximum 108 vs 86 mg/dL; p<0.05). Events that were treated with MDG showed an increase in time between 70-180mg/dL (42% vs 33%; p<0.05) with less time <54mg/dL (14% vs 33%; p<0.55) and less time <70mg/dL (50% vs 67%; p<0.29). 65% of participants using MDG showed an increase in time between 70-180mg/dL (42% vs 33%; p<0.05) with less time <54mg/dL (14% vs 33%; p<0.55) and less time <70mg/dL (50% vs 67%; p<0.29). 65% of participants using MDG avoided mild hypoglycemia or late evening hypoglycemia corrections and therefore avoided breaking their fasts. 94% of the participants prefer to use MDG over oral options for correcting fasting induced hypoglycemia as MDG treatment can avoid breaking a fast.

**Conclusions:** MDG administration is more effective and preferable to carbohydrate consumption for preventing and treating fasting-induced hypoglycemia in people with type 1 diabetes during Ramadan. MDG can reduce the burden of breaking a fast in addition to avoidance of the negative experience of hypoglycemia itself.

**O120 / #489**

Topic: **AS15-Trials is progress**

**THE ENDORSE PILOT TRIAL**

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**Background and Aims:** Within the Greek funded project, named “ENDORSE”, an innovative integrated platform is developed harnessing the power of Artificial Intelligence, sensing and gamification technologies, facilitating self-disease management in children with Type 1 Diabetes Mellitus (T1DM) while supporting decision making in formal and informal caregivers. A two phase pilot randomized trial is foreseen to evaluate its effectiveness.

**Methods:** Particular use cases based on the applied insulin treatment are defined involving children 6–16 years old. Taking into consideration the current clinical methods for managing T1DM in Greece along with the necessary approvals from the national ethical committee, a clinical protocol is drafted specifying, amongst others, inclusion/exclusion criteria (e.g. diabetes duration >1 year, without celiac disease, without complications) and monitored parameters.

**Results:** Following a training phase, the participants receive hardware (e.g. Insulclock devices and activity trackers) and software modules to use them for 3 months during their daily habits while performing monthly screening visits to the “Agia Sofia” Children’s Hospital. In Phase 1 pilot, 30 patients are recruited. This phase represents a feasibility study to implement the technical equipment into patient care and to collect new data for improving the ENDORSE recommendation engine. In Phase 2 pilot, 70 patients are recruited and randomly assigned (2/3:1/3) into an intervention and a control group.

**Conclusions:** The ENDORSE pilot trial tests the feasibility of implementing advanced ICT technologies into routine clinical care of T1DM children while improving patients’ satisfaction and clinical outcomes. **Acknowledgements:** Supported within the framework of the ENDORSE project, which is funded by the NSRF (Grant agreement: T1EAK-03695)
O121 / #669

Topic: AS15-Trials is progress

SIX MONTHS DIETARY AND LIFESTYLE MODIFICATION REDUCES THE CHEMERIN GENE METHYLATION STATUS IN METABOLICALLY UNHEALTHY YOUNG ADULTS: A PILOT STUDY

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Background and Aims: Environmental factors/stresses play an imperative part in pathophysiology of Obesity and Type 2 diabetes mellitus (T2DM). This pilot study aimed to assess the effect of life style intervention on the degree of methylation of Chemerin, Insulin induced gene 2, Pro-opiomelanocortin genes and advanced glycation end products in metabolic healthy and unhealthy subjects.

Methods: Fifty eight subjects between the ages of 20–38 years were recruited from Aga Khan University and categorized as metabolically healthy (Group A n = 28) and metabolically unhealthy (Group B n = 30) using NCEP-II criteria. Group B subjects were provided a 6 months intervention where they refrained from consuming all forms of processed food, maintained a daily food/calorie diary and performed physical activity for at least 30 minutes each day of the week. Fasting blood glucose, Insulin, Lipid profile, Serum Chemerin, and AGE levels were measure. Methylation specific PCR was performed for Chemerin, POMC and INSIG-2 at both time intervals.

Results: At baseline, serum AGE was elevated in Group B subjects vs Group A (878.61±20.85Vs. 410.19±36.52ng/ml). High methylation potential was seen for genes regulating insulin release and satiety i.e. INSIG 2, POMC while high degree of nonmethylation was seen in Chemerin in Group B compared to Group A. At 6th month reduction in AGE levels (756±14.55ng/ml) along with 3% reduction in degree of Chemerin nonmethylation was observed.

Conclusions: Preliminary data suggests that these changes can be modified with dietary intervention and life style modification.

O122 / #483

Topic: AS16-COVID-19 and Diabetes

FEASIBILITY AND ACCEPTABILITY OF A NOVEL HOME-BASED ORAL GLUCOSE TOLERANCE TEST USING CONTINUOUS GLUCOSE MONITORING FOR THE DIAGNOSIS OF GESTATIONAL DIABETES

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Background and Aims: Gestational diabetes diagnosis has been challenging during the Covid-19 pandemic. We assessed the feasibility of a novel home-based OGTT using continuous glucose monitoring (CGM) to identify hyperglycemia in pregnancy.

Methods: Women with a singleton pregnancy at 28 weeks’ gestation with ≥1 risk factor for gestational diabetes attending antenatal glucose testing were recruited to a pilot single-centre prospective observational study. A Dexcom G6 continuous glucose monitoring sensor was sited (masked) and women were asked to take a 75g OGTT solution (Rapilose) on day 4 after a 10 hour overnight fast. Qualitative interviews were performed with 20 participants using telephone or video conferencing using a pre-determined interview schedule and thematically analysed using NVIVO software.

Results: Forty-six women completed a home OGTT with 7.4 days of CGM. 40/46 (87.0%) took the glucose solution as instructed, and 16 (34.8%) had CGM glucose readings at 0, 60 and 120 minutes which met WHO criteria for gestational diabetes diagnosis. These women had evidence of hyperglycemia on other CGM metrics: increased mean CGM glucose (106 vs 92 mg/dl (5.9 vs 5.1 mmol); p < 0.001) and time-above-range (≥140 mg/dl; ≥7.8 mmol/l; 6.8 vs 2.0%; p = 0.006). Time-in-range was not significantly different. Women found the CGM painless, convenient and reassuring to use. All 20 women interviewed would recommend CGM with a home OGTT for diagnosis of gestational diabetes.

Conclusions: A home-based antenatal OGTT using CGM is feasible and acceptable to pregnant women and identifies women with hyperglycemia in pregnancy. Home OGTTs using CGM may improve testing capacity during the Covid-19 pandemic.

O123 / #501

Topic: AS16-COVID-19 and Diabetes

COVIDENTARY 2 TELE-EXERCISE PROGRAM: AN INNOVATIVE INSTRUMENT TO IMPLEMENT PHYSICAL ACTIVITY IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: The measures for Sars-Cov-2 (COVID-19) pandemic containment produced a decrease of active life-style in children and adolescents with type 1 diabetes (T1D) and worsened the disease management. Nowadays, tele-medicine became fundamental to assist and monitor patients and tele-exercise is an innovative instrument to implement physical activity (PA) practice. We provided an online exercise program with the aim to investigate adherence, enjoyment and health benefits in T1D children. Metabolic control prior and after the program was also considered.

Methods: 50 children and adolescent with T1D were recruited for a 1-month training program provided by sport specialists through an online platform. The survey investigated subjective
perception of functional capacities, the PA level, time spent in sedentary activities, mean glycemia values and insulin dose. The training was supervised five days a week through an online platform and each session will last 60 minutes. Every session was a combination of aerobic and resistance exercises adapted to the age of participants.

**Results:** We obtained a positive answer to proposal. An increased PA level and a decreased time spent in sedentary activities were recorded. No difficulties during PA program was referred. A limited changes in mean glycemia values and insulin dose was noted.

**Conclusions:** Since, during a period of confinement, the possibility to maintain an active lifestyle in safe condition is essential, our online program will help TD1 children to achieve PA goals. We are also confident that PA implementation will help to better manage diabetes therapy.

**O124 / #553**

**Topic:** AS16-COVID-19 and Diabetes

**A REAL-WORLD ANALYSIS OF LIVING WITH DIABETES DURING A PANDEMIC**

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**Background and Aims:** In addition to the challenges that the COVID-19 pandemic has brought on the global population, people with diabetes (PWD) may face even greater complications. In this study, we investigated glycemic outcomes of PWDs before and after shelter-in-place orders in the US and EMEA, to better understand the impact of the pandemic on PWDs’ diabetes management.

**Methods:** We randomly selected 12179 users of a diabetes management app who uploaded data from a CGM (“CGM users”), and 7986 who uploaded data from a blood glucose (BG) meter and/or insulin pump (“non-CGM users”). We compared glucose, insulin, and physical activity data before and after March 2020.

**Results:** We compared glycemic outcomes 3 weeks prior to and 3 weeks post mid-March 2020 in the USA. Pre-March, PWDs had worse glycemic outcomes during weekends compared to weekdays. Post March, we found that this trend disappeared. For CGM users (median age = 28 years [IQR 12-45], 53% female, 92% T1D), the average BG decreased from a median of 166.4mg/dL to 164.6mg/dL post March. The mean TIR increased from 62.3% to 63.3%. The %time >180mg/dL decreased from 35.3% to 34.3%. For non-CGM users (median age = 64 years [IQR 49-72], 46% female, 45% T1D), the average BG decreased from 169.2mg/dL to 167.5mg/dL. Finally, we observed a lower daily steps count, from a median of 3709 steps/day to 2762 steps/day.

**Conclusions:** The present analysis indicates that on average, PWDs experienced slightly improved glycemic outcomes along with fewer glucose fluctuations during weekends in the weeks immediately following shelter-in-place orders. This was accompanied by an overall lowered physical activity.

**O125 / #580**

**Topic:** AS16-COVID-19 and Diabetes

**VIRTUAL COVID IP CARE IN DIABETES: CONCEPT TO REALITY**

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**Background and Aims:** Uncontrolled glycemia is recognised as a critical factor in prognosis of Covid-19. Hospitalised patients have several challenges in frequently monitoring glucose and adjusting dosages in addition to inevitable fear of PPE suits and impending death. Our patients are used to virtual consultations via DTMS® which has been in vogue since 1997.

**Methods:** For consenting patients diagnosed of Covid-19, we offer “virtual Covid IP care” with 24/7 support, care and advices from a team of 3 doctors, 4 nurses, 2 diabetes educators and 2 dietitians. Risk assessment is carried out online using a questionnaire and is assigned to the Virtual IP follow up team(VIT). The care is coordinated through a dedicated WhatsApp group of patient and caretaker where a doctor and nurse is assigned duty 24/7. The VIT follows up with the patient to assess parameters such as body temperature, BG, BP, SpO2 and general well-being every 3-6hrs. The patient should have usual self-monitoring devices with them for remote monitoring. Various technologies such as Libre, Guardian Connect, Apple Watch, connected glucose meters etc. are used in selected patients. Sample collection for essential lab investigations(CBC, LFT, RFT, CRP, D-Dimer, Ferritin, LDH etc.) are arranged at home.

**Results:** 127 diabetes patients affected with Covid-19 availed of the virtual IP facility. Virtually managing BG round the clock was the top priority. In patients on dexamethasone, CGM was made mandatory. 2 patients were hospitalised. All patients recovered.

**Conclusions:** With predictions of similar pandemics in future, virtual IP concept needs to be studied further and popularised to prevent overwhelming hospitals and inaccessibility to critical care.

**O126 / #631**

**Topic:** AS16-COVID-19 and Diabetes

**USE OF TELEHEALTH IN ADULT PATIENTS WITH TYPE 1 DIABETES: DOES AGE MATTER?**

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Background and Aims: In early 2020, due to Covid-19, telehealth was used to deliver care. Data on the use of telehealth by age groups in adults with type 1 diabetes (T1D) is not known.

Methods: EHR data of adults with T1D were analyzed for visit frequency and type: in-person vs. video (VV) vs. phone (PV) between March through August in both 2019 and 2020. The months of 2020 were divided: period 1: March through May when telehealth was mostly PV, and period 2, June through August, when telehealth was offered as both VV and PV. We stratified data by age: adults (age 40–64 yrs) and older adults (≥65 yrs).

Results: Data from 2,762 adults with T1D were assessed. In 2019 vs. 2020, 3,565, vs. 3,882 clinic visits occurred. In both years, 69% of patients were adults and 30% were older adults. The number of telehealth visits by PV and VV increased by >1000% from 2019 vs 2020 (PV: 0 vs. 2,241; VV: 14 vs. 1,236; P < 0.001). In period 1 of 2020, PV vs. VV in adults was 81% vs. 6% (P < 0.001) and in older adults was 84% vs. 5% (P < 0.001). In period 2, PV vs. VV in adults was 27% vs. 65% (P < 0.001) and in older adults was 36% vs. 55%. The overall number of telehealth was greater in the adults vs older adults, 65% vs. 55% (P = 0.001).

Conclusions: During Covid-19 pandemic, telehealth use increased dramatically, initially as PV, and subsequently, as VV. Older adults were more likely to use PV compared to adults.

O127 / #823

Topic: AS16-COVID-19 and Diabetes

ALARMING INCREASE IN KETOACIDOSIS IN CHILDREN AND ADOLESCENTS WITH NEWLY DIAGNOSED TYPE 1 DIABETES DURING THE FIRST WAVE OF THE COVID-19 PANDEMIC IN ISRAEL

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Background and Aims: To evaluate the prevalence and severity of ketoacidosis (DKA) at type 1 diabetes diagnosis during the first wave of the coronavirus disease 2019 (COVID-19) pandemic in Israel.

Methods: A national collaboration of Israeli pediatric diabetes centers investigated the presentation of childhood-onset type 1 diabetes. The frequencies of DKA and severe DKA observed during the COVID-19 period from March 15, 2020 (commencement of the first nationwide lockdown) until June 30, 2020 were compared with the same periods in 2019, 2018, and 2017 using multivariable logistic regression, adjusting for age, sex, and socioeconomic position.

Results: During the COVID-19 period, DKA incidence was 58.2%, significantly higher than in 2019 (adjusted OR [aOR] 2.18 [95% CI, 1.31-3.60], P = 0.003); 2018 (aOR 2.05 [95% CI, 1.26-3.34], P = 0.004); and 2017 (aOR 1.79 [95% CI,1.09-2.93], P = 0.022). The incidence of severe DKA was 19.9%, significantly higher than in 2018 (aOR 2.49 [95% CI, 1.20-5.19], P = 0.015) and 2017 (aOR, 2.73 [95% CI,1.28-5.82], P = 0.009). In 2020, admissions and duration of stay in the intensive care unit were higher than in previous years (P = 0.001). During the COVID-19 pandemic, children aged 6–11 years had higher incidences of DKA (61.3% vs 34.0%, 40.6%, and 45.1%, respectively, P = 0.012), and severe DKA (29.3% vs 15.1%, 10.9%, and 5.9%, respectively, P = 0.002).

Conclusions: The dramatic increase in DKA at presentation of childhood-onset type 1 diabetes during the COVID-19 pandemic mandates targeted measures to raise public and physician awareness.
**P001 / #10**

**Topic:** AS01-Closed-loop System and Algorithm

SARS-COV2 IMPACT ON DIABETES TYPE 1 PATIENTS USING “HYBRID CLOSED-LOOP” ARTIFICIAL PANCREAS

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**Background and Aims:** This paper analyses the effects of SARS-COV2 on a Diabetes Type 1 patient using an artificial pancreas in hybrid closed loop, with a control algorithm trained with machine learning technology. There was a lot of uncertainty around glycaemia control and glycemic stability in Diabetes Type 1 patients getting through the first 7 days with Sar-Cov2 symptoms.

**Methods:** Using the data collected by DT1 patient using an AP in hybrid closed loop who recovered from SARS-COV2. Glycemic control is compared in the 16 days and 30 days period immediately before SARS-COV2 to the 7 days period with max effect of SARS-COV2. Parameters analyzed: % TIR, % below range, % above range, glycemic average, median and SD, A1c estimation, GVI (Glycaemic Variability Index), and PGS (Patient Glycaemic Status).

**Results:** Glycemic control during the 7 days suffering of SARS-COV2 symptoms on the DT1 patient using AP hybrid closed loop DT1 therapy showed the following rates: 1980 CGM readings

- TIR: 92.2%
- Low (<70) 7%
- High (=180) 0.8%
- Avg 108 mg/dL
- Median 102 mg/Dl
- A1c estimation 5.4
- GVI 1.22
- PGS 10.28

Out of range RMS: 3.64 mg/dl The glycemic control in the 30 days period prior to SARS-COV2 symptoms were: 8432 CGM readings

- TIR: 82.4%
- Low (<70) 8.8%
- High (=180) 8.8%
- Avg 116.9 mg/dL
- Median 108 mg/DI
- A1c estimation 5.7
- GVI 1.22
- PGS 24.91

Out of range RMS: 14.42 mg/dl

**Conclusions:** There is no scientific evidence of correlation between bad glycemic control for a DT1 patient using a AP hybrid closed loop system during the period with SARS-COV2 symptoms.

**P002 / #15**

**Topic:** AS01-Closed-loop System and Algorithm

SELECTION OF THE OPTIMAL MACHINE LEARNING TECHNIQUE FOR THE DEVELOPMENT OF A PERSONALIZED INSULIN INFUSION ALGORITHM TO CONTROL “HYBRID CLOSED-LOOP” ARTIFICIAL PANCREAS

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**Background and Aims:** Training a personalized control algorithm is the key component for an artificial pancreas (AP) solution. Most of documented applications of machine learning are for classification algorithms not for AP control. In this article, it is explained and proved that machine learning (ML) is a valid technology to produce an accurate regression control algorithm as low cost solution to control a hybrid closed loop AP system.

**Methods:** ML technique is evaluated using mean squared error (MSE), regression receiver operating characteristic curve (ROC), and area over curve (AOC) to compare performance of ML trained algorithm. The MSE is used to assesses the quality of prediction of the trained ML algorithm. Regression ROC curve and AOC graphically represent the reliability of the prediction model by comparing the prediction results with respect to the test values utilized. The selected regression algorithm is also validated “in silico” using the UVA/Padova T1DMS MATLAB simulator.

**Results:** ML technique using linear, model tree, cubist, and random forest regression prove to be the most suitable techniques to develop an algorithm to control a hybrid closed loop AP. Random Forest regression-based algorithm achieves the highest accuracy.

**Conclusions:** This study shows that ML is an effective technology for the development of a low-cost efficient algorithm to control a hybrid close loop AP system with very high accuracy as compared to the test dataset. The ML algorithm is personalized, and therefore, it needs to be trained using data of the individual who will use the hybrid closed loop AP system.
Background and Aims: We evaluated hybrid closed-loop glucose control with faster-acting insulin aspart (Fiasp) in adults with type 1 diabetes (T1D). We hypothesised that closed-loop with Fiasp provides similar efficacy as closed-loop with standard insulin aspart.

Methods: In a double-blind, multinational, randomised, crossover study, 25 adults with T1D using insulin pump therapy (mean±SD, age 38±9 years, HbA1c 7.4±0.8% [57±8 mmol/mol]) underwent two 8-week periods of unrestricted living comparing hybrid closed-loop with Fiasp and hybrid closed-loop with standard insulin aspart in random order. During both interventions, the CamAPS FX closed-loop system incorporating Cambridge model predictive control algorithm was used. Trial registration NCT04055480.

Results: In an intention-to-treat analysis, the proportion of time sensor glucose was in target range (3.9–10.0 mmol/L; primary endpoint) was not different between interventions (75±8% vs. 75±8% for hybrid closed-loop with Fiasp vs. hybrid closed-loop with standard insulin aspart; mean-adjusted difference -0.6% [95%CI -1.8 to 0.7%]; P<0.001 for non-inferiority [non-inferiority margin 5%]). The proportion of time with sensor glucose <3.9 mmol/L (median [IQR] 2.4 [1.2-3.2%] vs. 2.9 [1.7-4.0%]; P=0.01) and <3.0 mmol/L (median [IQR] 0.4 [0.2-0.7%] vs. 0.7 [0.2-0.9%]; P=0.03) was reduced with Fiasp vs. standard insulin aspart. There was no difference in mean glucose (8.1±0.8 vs. 8.0±0.8 mmol/L; P=0.13) or glucose variability (SD of sensor glucose 2.9±0.5 vs. 2.9±0.5 mmol/L; P=0.90). Total daily insulin requirements did not differ (49±15 vs. 49±15 units/day; P=0.45). No severe hypoglycaemia or ketoacidosis occurred.

Conclusions: The use of Fiasp in CamAPS FX closed-loop system reduced hypoglycaemia without compromising glucose control compared to standard insulin aspart in adults with T1D.

P004 / #101

Topic: AS01-Closed-loop System and Algorithm

A NOVEL INSULIN ASPART FORMULATION WITH THE POTENTIAL TO CLOSE THE LOOP?

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Background and Aims: Faster insulin action has been shown to improve glycaemic outcomes during closed-loop insulin delivery. The PK/PD properties of AT247, a fast acting novel formulation of insulin aspart, were compared with insulin aspart (Iasp) and faster-acting insulin aspart (fast Iasp).

Methods: Plasma glucose and serum insulin concentrations were measured in 19 adult male subjects with T1DM following a single s.c. dose (0.3 U/kg) of insulins in a randomised, double-blind, crossover, euglycaemic clamp study.

Results: AT247 showed a greater early insulin exposure compared with Iasp and fast Iasp (mean±SD AUCI 0-60min 111±45 vs. 50±32 vs. 74±39 mU*h/L). All subjects reached 50% of maximum insulin concentration 24 minutes after dosing with AT247 compared with half and none of the subjects with fast Iasp and Iasp respectively. The early glucose-lowering effect was higher for AT247 compared with Iasp and fast Iasp (mean±SD AUCGIR 0-60min 220±113 vs. 81±98 vs. 132±94 mg/kg). All subjects reached 50% of maximum glucose infusion rate 60 minutes after dosing with AT247, compared to 80% and 50% of subjects with fast Iasp and Iasp respectively. The offset of exposure, measured by tLate50%Cmax, was earlier with AT247 when compared with Iasp and fast Iasp.

Conclusions: The left-shifted onset and offset of insulin exposure and accelerated glucose lowering effect with AT247 indicates its potential to provide better glycaemic control. In closed-loop systems, the shorter duration of action should improve existing dosing algorithm and increase time in target range.

P005 / #187

Topic: AS01-Closed-loop System and Algorithm

A NOVEL ALGORITHM TO DETECT PRIMING DOSES FROM SMART INSULIN PENS

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Background and Aims: Patients performing Multiple Daily Injections are advised to prime their insulin pen by delivering small doses into the air (airshots) before administering insulin. With the introduction of connected (smart) insulin pens, the exclusion of airshots becomes important to prevent wrong results when analyzing historical data or estimating active insulin in bolus dosing applications. We propose a new algorithm that better detects airshots when compared to existing algorithms.

Methods: Interviews of a small patient group revealed different priming strategies and edge cases (e.g. dose splitting) which allowed us to learn about important factors (e.g. timing,
dose, frequency) that would allow accurate airshot detection. We designed a new algorithm to incorporate this domain knowledge and measured its performance on an artificial dataset.

**Results:** The algorithm first splits doses into distinct groups of temporal vicinity and then labels the doses as airshots or injections by considering the number, amount and order of doses in each group. The algorithm detects airshots with high accuracy ($98\%$) compared to algorithms using simple thresholds ($76\%$) or just keeping the maximum dose ($60\%$).

**Conclusions:** The newly developed algorithm has the potential to accurately classify smart pen priming doses which makes it a useful tool in applications that require accurate estimates of active insulin. On our artificial data set, our algorithm outperforms traditional algorithms. Monitoring patient bolusing strategies in a broader population will help to estimate algorithmic performance in a real-world setting in future assessments.

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**P006 / #189**

**Topic:** AS01-Closed-loop System and Algorithm

**1-YEAR SUSTAINABILITY OF THE MINIMEDTM 670G SYSTEM OUTCOMES IN REAL-WORLD CONDITIONS**

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**Background and Aims:** Real-world use of the MiniMed™ 670G system in Europe demonstrated improvements in glycemic targets that include the calculated Glucose Management Indicator (GMI), time spent within (TIR), below (TBR), and above (TAR) the target range of 70-180 mg/dL, and time spent in hypoglycemia. The sustainability of these clinical outcomes over a year was evaluated.

**Methods:** Data uploaded voluntarily to CareLink™ Personal software (October 2018 to July 2020) by individuals living in Europe, who provided consent for aggregation of their data, were analyzed. Mean percentage of time spent across glycemic ranges, sensor glucose (SG), and GMI were determined for the period before initiating Auto Mode and for months 1, 3, 6, 9 and 12 post-Auto Mode initiation, for users having ≥10 days of SG data in each of these six periods.

**Results:** The table shows results from 821 individuals, where GMI decreased from 7.2% to 6.9% in the first month after Auto Mode initiation. Remote follow up should be offered to individuals on HLC system.

**Conclusions:** The glycemic outcomes (HbA1c and Time in Ranges) can be improved using HCL system in individuals previously treated with Type 1 Diabetes (TID) previously treated with multiple daily injections (MDI).

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**P007 / #218**

**Topic:** AS01-Closed-loop System and Algorithm

**CLINICAL CHARACTERISTICS OF HYBRID CLOSED LOOP SYSTEM IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES PREVIOUSLY TREATED WITH MULTIPLE DAILY INJECTIONS: ONE-YEAR EXPERIENCE**

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**Background and Aims:** The objective of this study was to evaluate clinical outcomes of one-year Hybrid Closed Loop (HCL) system on glycemic control in children and adolescents with Type 1 Diabetes (TID) previously treated with multiple daily injections (MDI).

**Methods:** The observational single center study was conducted at Sidra Medicine in Qatar study and enrolled 30 individuals aged 7–18 years with T1D >1 year, on MDI with self-monitoring of blood glucose or continuous glucose monitoring, with no prior pump experience, and baseline HbA1c <12.5% (<113 mmol/mol). Patients were followed for one year and HbA1c was obtained and pump data was collected every 3-months during the study.

**Results:** All 30 participants (age 10.2 ± 2.6 years), who initiated HCL completed one-year of HCL system use in Auto Mode. The participants used the sensor 88.4%±6.5% of the time with Auto Mode usage 85.6% ± 7.4% during 12 months of HCL system use. HbA1c decreased from 8.2 ± 1.4% (66 ± 15.3 mmol/mol) at baseline, to 6.7 ± 0.5% (50 ± 5.5 mmol/mol) at 3 months ($p=0.02$) and remained stable to 7.1 ± 0.6 (54 ± 6.6 mmol/mol) at 12 months ($p=0.02$). TIR (70-180mg/dL) increased from 46.9% at baseline to 71.9% at one month and remained above 70% during the 12 months of HCL use. Remote follow-up visits were noted in 38% of the participants between 3 and 12 months of HCL initiation.

**Conclusions:** The glycemic outcomes (HbA1c and Time in Ranges) can be improved using HCL system in individuals previously treated with MDI and maintained over the one year following Auto Mode initiation. Remote follow up should be offered to individuals on HLC system.

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**P008 / #230**

**Topic:** AS01-Closed-loop System and Algorithm

**REAL-WORLD PERFORMANCE OF THE MINIMEDTM 670G SYSTEM ACROSS EUROPE AND IN SOUTH AFRICA**

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Background and Aims: The MiniMed™ 670G system pivotal trials demonstrated improvements in glycemic targets that included HbA1c levels and time spent in the target glucose range of 70-180 mg/dL (TIR). Following the introduction of the system in Europe in October 2018, a performance assessment of real-world MiniMed™ 670G system use was conducted with the aim of assessing glycemic outcomes variability between countries.

Methods: Data uploaded voluntarily to CareLink Personal software (October 2018 to July 2020) by individuals living in 14 different countries, who provided consent for the aggregation of their data, were analyzed. The percentage of time spent in the various glycemic ranges, mean sensor glucose (SG) levels, and the Glucose Management Indicator (GMI) were assessed for users having at least 10 days of SG data, after initiating Auto Mode for the first time.

Results: Data from 15,151 individuals were analyzed. The overall mean SG level was 152.9 mg/dL, corresponding to a GMI of 7.0%. The TIR was 71.9%, ranging from 69.4% to 75.1% at country level. Time spent at <70 mg/dL, <54 mg/dL, and >180 mg/dL was 2.4%, 0.6%, and 25.7%, respectively. Prior to initiating Auto Mode, TIR was 62.1%, ranging from 57.7% to 66.6%. Users spent an average of 81.4% of the time in Auto Mode. Outcomes were similar for each of the countries included in the analysis (Table 1).

Conclusions: These data of real-world MiniMed™ 670G system shows a TIR gap between different countries is narrowed after initiation of Auto Mode, indicating that automation of insulin delivery may overcome lifestyle and cultural differences.
determined by Net Promoter Score (NPS®), CGM results were 
determined using the CareLink® Personal database

**Results:** Between February to April 2020 included 31 children 
and adults (age: 31.4 ± 15.1 years, range 9 - 57) previous use 
of SAP-PLGS 71%, baseline HbA1c 7.4 ± 1% and Time in Range 
(TIR) between 70-180 mg/dl 65.9%. Virtual training and follow 
up were evaluate: 87% “very satisfied”, 13% “satisfied”. The 
NPS® was 84%. The participants used the sensor for a median of 
88.7% (±16.8) of the time and spent a median of 91.1% (±10) in 
Auto Mode at the end of the follow up. Frequency of downloads 
data by CareLink® Personal was one/twice a week in 87% pa-
tients. Time in range (TIR) between 70-180 mg/dl significantly 
increased from 65.9% at baseline to 76% at follow up (p = 0.001).

**Conclusions:** High patient satisfaction levels, supports the use 
of virtual methodology for the training of new patients on ad-
vanced diabetes management technologies

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**P011 / #241**

**Topic: A01-Closed-loop System and Algorithm**

**ALGORITHM-DRIVEN PERSONALIZED INSULIN DELIVERY: INSIGHTS FROM REAL-WORLD USE OF THE MINIMED™ 670G SYSTEM IN EUROPE**

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**Background and Aims:** Real-world use of the MiniMed™
670G system in Europe demonstrated improvements in glycemic 
targets that include the Glucose Management Indicator (GMI), 
time spent in the target glucose range of 70-180 mg/dL (TIR), 
and time spent below range (TBR) <70 mg/dL and <54 mg/dL.1

To gain insights into the drivers underlying these improvements,
a sub-analysis was performed based on user GMI level pre-Auto 
Mode initiation.

**Methods:** Data uploaded voluntarily to CareLink™
Personal software (October 2018 to July 2020) by individuals living 
in Europe, who provided consent for aggregation of their data, were 
analyzed. The CGM and insulin delivery metrics were deter-
mined (if ≥10 days of SG data for both pre- and post-Auto Mode 
initiation periods) for a well-controlled group (pre-Auto Mode 
GMI <7.0%) and a sub-optimally controlled group (pre-Auto 
Mode GMI >8.0%).

**Results:** Glycemic metrics improved in both groups. The data 
demonstrated a unique partitioning of basal and bolus insulin 
between the two groups (Table). While total daily insulin dose 
increased for both, the increase was substantially higher in the 
GMI >8.0% group (+24.8% versus +16.9%). While the per-
centage of basal insulin significantly increased in the GMI >8.0% 
group to 56% (+18.3%), it decreased in the well-controlled GMI 
<7.0% group to 44% (-3.3%).

**Conclusions:** The MiniMed™670G system Auto Mode per-
sonalizes basal insulin delivery to the specific needs of users, 
maximizing their clinical outcomes. This user-specific driver 
appears to be one key element in the successful management of 
glycemia provided by automated insulin delivery systems.

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**P012 / #279**

**Topic: A01-Closed-loop System and Algorithm**

**SUPER-TWISTING OBSERVER FOR MEAL DETECTION ASSESSED IN REALISTIC SCENARIOS USING UVA/PADOVA T1D SIMULATOR**

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**Background and Aims:** Effective control of post-prandial 
blood glucose remains a challenge even for advanced T1D 
management tool such as the artificial pancreas. In the state-of-
art “hybrid” closed-loop strategy, when a meal is consumed, 
T1D subjects have to estimate the associated amount of carbo-
hydrates and manually announce it to the system. Meal detection 
algorithms aim at removing the need of meal announcement, 
lowering the burden for T1D people. In this work, we further 
tested the meal detector proposed by Sala-Mira et al. (Journal of 
Process Control, 2019) in a more realistic scenario using the 
UVA/Padova T1D Simulator (T1DS).

**Methods:** The proposed super-twisting observer, i.e., a non-
linear sliding-mode algorithm, was used to generate residuals, 
describing the discrepancy between measured and estimated 
glucose. Decision rules were then applied to these residuals to 
determine the meal occurrence. The algorithm performances 
were assessed using the most recent version of the UVA/Padova-
T1DS, which includes advanced features, such as intra-day 
variability of insulin-sensitivity, time-varying distributions of 
subjects‘ therapy parameters, and a model of the so-called “dawn 
phenomenon”. The algorithm was tested on 100 virtual subjects, 
in a 14-day scenario with 3 daily random meals. The perform-
ance was assessed using precision (P), recall (R), false positive 
per day (FP/day), and detection time (DT).

**Results:** The table below reports the median (interquartile 
range) values of the achieved performances.

<table>
<thead>
<tr>
<th></th>
<th>P [%]</th>
<th>R [%]</th>
<th>FP/day [-]</th>
<th>DT [min]</th>
</tr>
</thead>
<tbody>
<tr>
<td>96 (4)</td>
<td>80 (22)</td>
<td>0.1 (0.1)</td>
<td>35 (15)</td>
<td></td>
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</tbody>
</table>
**Conclusions:** The performances achieved by the proposed algorithm are promising, and similar to the ones obtained in the original work, even if assessed in a more realistic scenario using the most recent version of the UVA/Padova-T1DS.

**P013 / #348**

**Topic:** AS01-Closed-loop System and Algorithm

**CASE SERIES OF FOUR WOMEN WITH TYPE 1 DIABETES MELLITUS USING DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEMS DURING PREGNANCY**

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**Background and Aims:** Pregnancy in women with type 1 diabetes (T1D) is associated with increased rates of adverse obstetric and perinatal outcomes. It is therefore essential to achieve tight glycemic control during pregnancy. The 2019 ATTD consensus recommends targets for time in range (TIR) of >70% (3.5–7.8mmol/l) and time above range (TAR) of <25%.

**Methods:** We report on four pregnancies of women (three primigravida and one secundigravida, mean age of 32.3 years (26;39)) with T1D who decided to use do-it-yourself artificial pancreas systems (DIY-APS) to manage their diabetes. Data were collected retrospectively from the medical records and Nightscout documentation.

**Results:** Mean HbA1c during the first, the second and the third trimester was 5.4±1.2, 5.0±0.8 and 3.0±0.3, respectively. Except the first trimester of one case, TAR was >70% throughout all pregnancies. In two cases, caesarean section had to be performed due to pathological cardiotocography (40th week, Apgar-score of 7.0; 33.5 week, Apgar-score for both 1 and 5 week, Apgar-score of 9.0/10/10). In one case, a premature rupture of membranes was observed at 31.9 weeks, Apgar-score of 8/9/10. Birth weight was normal (2), small (1) and large (1) for gestational age.

**Conclusions:** We observed excellent glycemic control with regard to TIR, TAR and HbA1c goals when using DIY-APS in four T1D pregnancies. Our small case series showed that despite optimal glycemic control spontaneous, vaginal delivery without any complications was observed in only one case.

**P014 / #371**

**Topic:** AS01-Closed-loop System and Algorithm

**INTRA PATIENT AND INTER PATIENT VARIABILITY WITHIN THE DIABELOOP SIMULATOR**

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**Background and Aims:** In silico validation of a Closed Loop (CL) system requires an insulin-to-glucose model able to capture intra and inter patient variability to approach the real life variability involved in Type 1 diabetes (T1D). The objective is to determine distributions over time and over some key model parameters which can be categorized into 1) insulin sensitivity (IS), 2) insulin absorption speed (IAS) and 3) meal absorption speed (MAS) to address inter/intra-patient variability.

**Methods:** The method involves real patients data [1] (63 patients and 90 days, NCT02987556) on which observable indicators can be determined and associated to the 3 model parameters categories i) IS ; ii) IAS and iii) MAS. The distributions of these 3 indicators along time are computed, centered, normalized and applied on associated model parameters thus allowing inter/intra subject variability.

**Results:** The learned distributions of model parameters were used to simulate blood glucose using the same CL algorithm. To validate the distributions, we compared the time spent in normoglycemia range (TIR), the average glycemia (AG) and the hypoglycemia rate (HR) achieved in silico with those from [1] dataset leading to close results: where (TIR, AG, HR) achieved on [1] gave (68.5 (±1.2) ; 158.5 (±2.1) ; 2.0 (±0.3)) while the 120 virtual patients obtained with the model parameters distributions as with (68.1 (±0.9) ; 168.1 (±1.0) ; 0.8 (±0.2)).

**Conclusions:** We developed and validated a time varying insulin-to-glucose model able to reproduce real-life physiological variations that could be observed on clinical trial dataset.

**P015 / #373**

**Topic:** AS01-Closed-loop System and Algorithm

**EFFECT OF GLYCEMIC TARGET CHANGE IN DIABELOOP’S ARTIFICIAL PANCREAS ON AVERAGE GLYCEMIA FOR PATIENTS WITH TYPE 1 DIABETES**

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**Background and Aims:** The aim of this study is to assess the impact of glycemic target change in Diabeloop’s Artificial Pancreas (AP) on average glycemia for T1D patients, based on data from clinical trial NCT02987556[1].

**Methods:** Before and after changes in the glycemic target, 72 hours time intervals are defined to compute the average patient glycemia. Time intervals are selected using the following criteria: (i) each interval contains at least 48 hours of glycemic data (ii) during the 72-hour periods, no other variation happens in the glycemic target and (iii) no variation occurs in parameters controlling the aggressiveness of the algorithm. The difference between the averaged patient glycemia over 72 hours after and before each target change period (Δgly) is calculated. The associated variations in glycemic targets (Δtarget) are of -10, -5, 5 or 10 mg/dL. The average of Δgly over each value of Δtarget is analysed.

**Results:** 59 time intervals are obtained from 45 patients. With Δtarget of -5 and -10 mg/dL the average of Δgly is respectively -3.452 and -1.42 mg/dL. Only 2 intervals are available with a Δtarget of +5 mg/dL and a Δgly of -2.984, and 6 with a Δtarget of...
**P016 / #378**

**Topic: AS01-Closed-loop System and Algorithm**

**PATIENT-REPORTED OUTCOMES REVEAL POTENTIAL IMPACT OF ADVANCED HYBRID CLOSED-LOOP SYSTEMS ON HYPOGLYCEMIA ATTITUDES AND BEHAVIORS**

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**Background and Aims:** Hybrid Closed-loop systems (HCL) use continuous glucose monitor data to automatically adjust a pump’s basal rate of insulin delivery. A new ‘advanced’ HCL, launched in early 2020, is the first FDA-approved system capable of delivering automatic correction boluses in addition to adjusting basal insulin delivery. This study aimed to assess the potential impact of ‘advanced’ HCL systems on hypoglycemia attitudes and behaviors.

**Methods:** Adults with type 1 diabetes (t1d) from an opted-in US research panel completed online questionnaires in March 2019 and June 2020 (n=1,149). Both times, the Hypoglycemic Attitudes and Behavior Scale (HABS) was administered, and HCL usage, demographic, and health information was collected.

**Results:** In June 2020, those using ‘advanced’ HCL had a lower mean HABS Avoidance sub-score (2.27) and higher mean HABS Confidence sub-score (3.85) than all respondents not on ‘advanced’ HCL (2.52, p<.0005: 3.69, p=.003) as well as those on an HCL without automatic correction boluses (2.64, p<.0005: 3.66, p=.008). In contrast, baseline results from March 2019 (before ‘advanced’ HCL’s release) showed similar mean HABS Avoidance and Confidence sub-scores between respondents who would later begin using ‘advanced’ HCL (2.43, 3.79), those who never began ‘advanced’ HCL (2.48, 3.72), and those who later used an HCL without automatic boluses (2.56, 3.74).

**Conclusions:** Concern about hypoglycemia can worsen self-management and quality of life for people with diabetes. These findings suggest that people with t1d on ‘advanced’ HCL have a lower frequency of unhealthy hypoglycemia avoidance behaviors and greater confidence in their ability to stay safe from hypoglycemia.

**P017 / #382**

**Topic: AS01-Closed-loop System and Algorithm**

**UNANNOUNCED MEAL MANAGEMENT VALIDATION**

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**Background and Aims:** The objective is to validate in silico an Unannounced Meal Management (UMM) feature that would detect and manage any unexpected sudden increase of Blood Glucose in a safe and efficient way.

**Methods:** The controller was evaluated in silico with and without the activation of the UMM feature, using a simulator based on the Hovorka model involving 120 Virtual Patients. Various meal scenarios were considered with different levels of meal announcement ranging from 0% to 100% meal announcement, where an announced meal produces a bolus delivered a few minutes ahead of the meal declaration time.

**Results:** The simulation results showed a Time In Range 70-180 mg/dL (TIR) improvement of 5% without increasing the hypoglycemia rate (<70 mg/dL) when the UMM feature is active in a full unannounced meal (FUM) scenario. Results in a full announced meal (FAM) scenario also reveal that the UMM feature did not bring any significant hypoglycemia risk while leading to a slight TIR improvement (~0.5%) that can be imputed to unexpected glycemia excursions not related to meal intakes, yet covered by the UMM module. These figures also show that the UMM controller approached, in the FUM scenario, the performances obtained in the FAM scenario with the reference controller: the TIR is only <5% lower (56.51% with UMM in FUM VS 61.94% with reference in FAM).

**Conclusions:** The new UMM module was assessed in silico to be safe and effective and could be evaluated in a real-life clinical trial.

**P018 / #395**

**Topic: AS01-Closed-loop System and Algorithm**

**HYBRID CLOSED LOOP SYSTEM AND GLUCOSE CONTROL IN PATIENTS WITH TYPE 1 DIABETES: RESULTS FROM A SINGLE CENTER STUDY**

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**Background and Aims:** Medtronic 670G is the first commercial hybrid closed loop system available in clinical practice. In manual mode only predictive low glucose suspension is active, while in automatic mode additional complex algorithms operate during hyperglycemia.

**Methods:** Aim of our retrospective, observational study was to compare glucose outcomes of patients with type 1 diabetes on...
CSII with Medtronic 670G during during auto mode use with previous manual mode use. We collected data from 27 patients followed at the Diabetes Clinic of the San Raffaele Hospital in Milan (Italy).

**Results:** Compared to manual mode use, during auto mode use Time In Range (70-180 mg/dL) (TIR) increased [76.0% (± 7.3) vs 67.2% (± 9.6); p < 0.01], because a decrease of both Time >180 mg/dL [30.0% (± 10.1) vs 21.3% (± 8); p < 0.001] and Time >250 mg/dL [6.1% (± 4.4) vs. 3.5% (± 3.1); p = 0.01]. Moreover, during auto mode use there was a significant decrease in glucose variability, expressed as Standard Deviation (47.4 ± 6.0 vs 52.8 ± 7.8; p = 0.015), J-index (37.5 ± 6 vs 43.8 ± 8.4; p = 0.005), HbG1 (4.3 ± 1.3 vs 5.9 ± 2.1; p < 0.001), BGRI (5.0 ± 1.2 vs 6.6 ± 2.0; p < 0.001) and GMI (6.8% ± 0.3 vs 7.0% ± 0.3; p = 0.005).

**Conclusions:** Medtronic 670G in auto mode is effective in increasing TIR (70-180 mg/dL), decreasing time in hyperglycaemia (both >180 mg/dL and >250 mg/dL) and reducing glucose variability.

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**P019 / #434**

**Topic: AS01-Closed-loop System and Algorithm**

**RAPID IMPROVEMENT IN TIME IN RANGE AFTER ADVANCED HYBRID CLOSED-LOOP SYSTEM INITIATION**

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**Background and Aims:** Advanced hybrid closed-loop systems (AHCL) represent a new generation of artificial pancreas systems, aimed to improve glycaemic control in people with type 1 diabetes (T1D). The AHCL Medtronic MiniMed 780G automates basal insulin infusion and delivers auto-correction boluses. The aim was to evaluate real-world outcomes with the use of AHCL.

**Methods:** T1D patients, previously experienced users of a sensor-augmented pump with predictive low-glucose suspend function (SAP-PLGS), consecutively started AHCL. Variables at baseline and after 2 weeks on AHCL were compared, including glucose management indicator, time 70-180 mg/dL, <70 mg/dL, <54 mg/dL, >180 mg/dL and >250 mg/dL, coefficient of variation and sensor use. AHCL target was set in 100 mg/dL and active insulin time in 2 hours for all the subjects.

**Results:** 52 T1D adolescents and adults were included (age: 43 ± 12 years (15 to 65 years), 73% females, diabetes duration: 27 ± 11 years, HbA1c: 7.2 ± 0.9%, 31% higher education, previous use of SAP: 5 ± 2 years). Auto-correction insulin represented 30 ± 12% (7.4 ± 5.0 units/day) of total bolus insulin and 26 ± 9 autocorrection boluses were infused per day. Time in autono mode was 98 ± 3% and the number of exits from auto-mode to manual-mode was 0.7 ± 0.6 per week. The carbohydrate intake remained unchanged and mean 2-hour postprandial glucose increase was 10.4 mg/dL. The percentage of subjects with GMI ≤ 5% and with time 70-180 mg/dL >70% increased from 62% to 94% and from 46% to 89%, respectively (p < 0.001). No severe hypoglycaemia of DKA episodes occurred.

**Conclusions:** Advanced hybrid closed-loop systems allow well-controlled experienced sensor-augmented pump users to increase their time in range, without deterioration in hypoglycaemia frequency.

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**P020 / #493**

**Topic: AS01-Closed-loop System and Algorithm**

**REAL-WORLD PERFORMANCE OF THE MINIMEDTM 780G SYSTEM: IMPACT OF INITIATING AUTOMATED BASAL AND CORRECTION BOLUSES**

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**Background and Aims:** The MiniMed™ 780G system automates both basal and correction boluses and adjusts meal boluses. Adults and youth (≥7 years) using the system in clinical trials showed improved sensor glucose (SG) and time spent in target glucose range (70-180 mg/dL, TIR), and reductions in HbA1c or the Glucose Management Indicator (GMI), compared to baseline or control.1,2 The system was introduced in Europe, in October 2020, and the present work evaluated its real-world performance.

**Methods:** MiniMed™ 780G system data uploaded voluntarily to CareLink™ Personal software, from 05 October 2020 - 11 December 2020 by individuals providing consent, were analyzed. The mean SG levels, GMI, percentage of time spent in the various glycemic ranges, and time spent in closed loop (automated basal, at minimum) were determined for users having at least 10 days of SG data both before and after initiating automated basal and correction boluses.

**Results:** In the 128 individuals included in the analysis, GMI decreased from 7.2 ± 0.6% to 6.8 ± 0.4% (by 0.4 ± 0.5%), while the TIR increased from 63.6 ± 15.4% to 76.1 ± 9.4% (by 12.6 ± 11.7%). Time above range significantly decreased while time below range remained low (Table). The percentage of users achieving GMI < 7.0% and TIR > 70% increased by 41.4% and 39.1%, respectively. These clinical
improvements were observed while users were in closed loop 92.4 ± 13.2% of the time.

Conclusions: MiniMed™ 780G system automation significantly improved GMI and TIR in real-world settings, providing evidence on the benefits of automated basal and correction insulin delivery in the treatment of people with type 1 diabetes.

P021 / #551
Topic: AS01-Closed-loop System and Algorithm
HOW CAN THE SYNERGY OF DATA MINING AND AI IMPROVE GLUCOSE PREDICTION MODELS?
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Background and Aims: For individuals with Type 1 diabetes (T1D) is of eminence importance to avoid hypo- and hyperglycemic events. The availability of long glucose time-series along with powerful AI methods allowed the development of glucose prediction algorithms. Nonetheless open issues remain such as prediction time-delays, amount of history needed, and how heterogeneous and sparse diabetes information affect the performance.

Methods: In this study, we utilized data from 100 individuals with T1D provided by the Juvenile Diabetes Research Foundation. The dataset provides pump settings, sensor outputs (e.g. insulin-rates, continuous glucose monitoring- CGM) and conceptual information such as age, years of diabetes. To mitigate the adverse impact of large inter-patient variability, we propose a training scheme based on gradual fine-tuning. Initially, the novel AI-model is trained on all data and subsequently fine-tuned over groups with shared characteristics to individual patient-level. The individuals with T1D are assigned to groups based on similarity measures defined using glucose variability indices. For each individual, an ensemble of five dedicated sequence-to-sequence LSTM networks is used. The ensemble uses CGM data, bolus dose and meal intake as input and outputs blood glucose predictions 30 min ahead in time.

Results: As shown in Table 1 the root-mean-square-error (RMSE), mean-average-error (MAE), and time-lag used as performance measures for the various training schemes.

<table>
<thead>
<tr>
<th>Training scheme</th>
<th>RMSE (mg/dL)</th>
<th>MAE (mg/dL)</th>
<th>Time-Lag (min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1M+insulin+carbohydrate intake from entire population</td>
<td>21.56</td>
<td>15.81</td>
<td>20.10</td>
</tr>
<tr>
<td>As above by fine-tuned per patient</td>
<td>19.56</td>
<td>14.05</td>
<td>19.30</td>
</tr>
<tr>
<td>C1M+insulin+carbohydrate intake per group of patients</td>
<td>19.59</td>
<td>13.98</td>
<td>19.60</td>
</tr>
<tr>
<td>As above but fine-tuned per patient within the groups</td>
<td>19.39</td>
<td>13.89</td>
<td>19.05</td>
</tr>
</tbody>
</table>

Conclusions: There is evidence that high performing AI-based prediction models do not only depend on the algorithmic approach per se. The performance may increase by identifying groups of patients that share common hidden metabolic patterns.

P022 / #573
Topic: AS01-Closed-loop System and Algorithm
HYBRID CLOSED LOOP AND DIFFICULT FOODS IN CHILDREN WITH TYPE 1 DIABETES: A PILOT STUDY
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Background and Aims: Families of children with type 1 diabetes (T1D) have reported high fat and high protein (HF/HP) meals as ‘difficult’ foods, causing prolonged hyperglycaemia after eating. A newly developed Hybrid Closed Loop (HCL) system with an Auto-Mode function uses real-time glucose levels to deliver basal insulin in micro-amounts. Yet, there is little evidence on whether Auto-Mode is more effective than standard insulin pump therapy (Manual Mode) at reducing glucose excursions caused by HF/HP foods. This pilot study examined the impact of Auto-Mode on glucose excursions following HF/HP meals compared to Manual-Mode.

Methods: Children and adolescents (8–18 years) with T1D, using HCL system were recruited from Perth Children’s Hospital for this free-living cross-over study. All participants received a dietetic review and a two-week optimisation phase. Participants were asked to consume a standardised frozen beef lasagne or margherita pizza meal two nights a week for four weeks, under controlled conditions (4 meals in Manual Mode, 4 meals in Auto-Mode). Postprandial continuous glucose monitoring data was collected for seven-hours after each meal.

Results: There were no significant results for the variables of interest between Auto-Mode and Manual-Mode for the pizza and lasagne meals (p > 0.05). A comparison of incremental area under the curve between the Modes identified a non-significant trend towards Manual Mode for lasagne (p = 0.09). Most families reported more confidence eating difficult foods in Auto-Mode.

Conclusions: The mixed preliminary results from this pilot study provide groundwork to conduct further research into this research question as the use of Auto-Mode is increasing.
P023 / #592

Topic: AS01-Closed-loop System and Algorithm

COST-EFFECTIVENESS ANALYSIS OF THE MINIMED™ 780G SYSTEM VERSUS MULTIPLE DAILY INJECTIONS WITH INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING IN INDIVIDUALS WITH TYPE 1 DIABETES IN SWEDEN

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Background and Aims: Type 1 diabetes (T1D) therapy is continually evolving and Advanced Hybrid Closed Loop (AHCL) insulin pump systems and intermittently scanned continuous glucose monitoring (IS-CGM) are emerging as the standard of care for many individuals with T1D. The objective of this analysis was to assess the cost-effectiveness of the MiniMed™ 780G AHCL system versus IS-CGM plus multiple daily injections of insulin (MDI) or continuous subcutaneous insulin infusion (CSIH) in adults with T1D in Sweden.

Methods: The analysis was performed using the IQVIA CORE Diabetes Model and clinical input data were sourced from observational studies. Simulated patients were assumed to have a baseline HbA1c of 7.8% (62 mmol/mol)1 and use of the MiniMed™ 780G system was assumed to reduce HbA1c by 0.5%2. The analysis was performed from a societal perspective over a lifetime time horizon. Future costs and clinical outcomes were discounted at 3% per annum.

Results: The MiniMed™ 780G system was associated with a quality-adjusted life-year (QALY) gain of 1.946 but generated higher overall costs versus MDI/CSIH+IS-CGM, leading to an incremental cost-effectiveness ratio of SEK 373,700 (€36,857.80) per QALY-gained. MiniMed™ 780G system use resulted in a lower cumulative incidence of diabetes-related complications. Higher acquisition costs were partially offset by reduced complications costs. Extensive sensitivity analysis on key drivers confirmed the robustness of results.

Conclusions: For the lifetime of adults with long-standing T1D based in Sweden, use of the MiniMed™ 780G system is projected to be cost-effective when compared with IS-CGM plus MDI/CSIH.

P024 / #608

Topic: AS01-Closed-loop System and Algorithm

QUANTITATIVE PHYSIOLOGICAL ASSESSMENT, PREDICTION, AND SIMULATION OF CLINICAL SUBTYPES IN GLUCOSE METABOLISM DISORDERS

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Background and Aims: Based on the distribution of physiological and demographic parameters, the type 2 diabetes (T2D) population has been recently stratified into several clinical subtypes. In this work, we propose a method for quantitative physiological assessment and prediction of different glucose metabolism disorders, including but not limited to type 1 diabetes, obesity, pre-diabetes, gestational diabetes, or subtypes of T2D.

Methods: Available T2D data (N = 17,846) were divided into training (N = 8,924) and test (N = 8,922) sets. Using the training set, a virtual population was created by matching the distributions of 5 physiological parameters (fasting glucose, fasting C-peptide, HOMA2-B, HOMA2-IR, and HbA1c) across 4 subtypes of T2D (Severe Insulin-Deficient Diabetes, Severe Insulin-Resistant Diabetes, Mild Obesity-related Diabetes, and Mild Age-Related Diabetes) using the MiniMed™ 780G AHCL system and intermittently scanned continuous glucose monitoring (IS-CGM) plus multiple daily injections of insulin (MDI) or continuous subcutaneous insulin infusion (CSIH). The method allows a virtual population to be back-propagated from the training set, after which the virtual population was fixed and then prospectively validated by comparing the distributions of its parameters to the corresponding parameters of the test set, both overall and by subtypes.

Results: When tested prospectively, the new T2D virtual population (N = 6,156) approximated well the physiological and demographic parameter distributions, both overall and per individual subtype, of the test set (Table 1).

Conclusions: The method allows a virtual population to be created, reproducing faithfully the clinical subtype distributions observed in vivo, with potential applications to pre-clinical in silico testing and assessment of subtype-specific T2D therapeutic strategies. Acknowledgements: Support from Novo Nordisk.

P025 / #612

Topic: AS01-Closed-loop System and Algorithm

HUMAN FACTORS FOR A CLOSED-LOOP INSULIN DELIVERY SYSTEM: A REVIEW OF REMOTE METHODS FOR ASSESSING THE USABILITY OF THE TIDEPOOL LOOP MOBILE APPLICATION

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Background and Aims: Remote usability testing in software development has prompted increased interest in its application to mobile medical device human factors, accelerated by Covid-19. Remote testing widens recruitment to provide a better representation of the intended use population and more realistic types. In this work, we propose a method for quantitative physiological assessment and prediction of different glucose metabolism disorders, including but not limited to type 1 diabetes, obesity, pre-diabetes, gestational diabetes, or subtypes of T2D.

Methods: Available T2D data (N = 17,846) were divided into training (N = 8,924) and test (N = 8,922) sets. Using the training set, a virtual population was created by matching the distributions of 5 physiological parameters (fasting glucose, fasting C-peptide, HOMA2-B, HOMA2-IR, and HbA1c) across 4 subtypes of T2D (Severe Insulin-Deficient Diabetes, Severe Insulin-Resistant Diabetes, Mild Obesity-related Diabetes, and Mild Age-Related Diabetes) using the MiniMed™ 780G AHCL system and intermittently scanned continuous glucose monitoring (IS-CGM) plus multiple daily injections of insulin (MDI) or continuous subcutaneous insulin infusion (CSIH). The method allows a virtual population to be back-propagated from the training set, after which the virtual population was fixed and then prospectively validated by comparing the distributions of its parameters to the corresponding parameters of the test set, both overall and by subtypes.

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Conclusions: The method allows a virtual population to be created, reproducing faithfully the clinical subtype distributions observed in vivo, with potential applications to pre-clinical in silico testing and assessment of subtype-specific T2D therapeutic strategies. Acknowledgements: Support from Novo Nordisk.
assessments in participants’ everyday use environments. The objective was to assess remote methods utilized in Tidepool’s human factors studies of Tidepool Loop, an iOS application for automated insulin dosing.

Methods: 112 test sessions included participants of mixed age, gender, caregiving responsibility, device experience and geographic location assessed in simulated use scenarios. During formative studies, participants were tested on a webview of the digital prototyping software (Figma) and associated software allowing analytics tracking (Maze). During the validation study, participants who lacked devices required were shipped a pre-loaded and configured study device. Participants who had necessary iOS equipment, downloaded Participate (by the usability testing platform, Lookback) from the App Store. Dual-camera setup allowed moderating in Lookback from the iPhone with Zoom teleconferencing platform serving as a secondary camera on the computer.

Results: The software and study protocol enabled recording of participants from multiple perspectives in intended use environments, recording tap gestures, tagging saved video, and unobtrusive, live communication between moderators and data analysts.

Conclusions: The formative and validation studies leveraged a combination of Figma, Lookback, Zoom, Testflight, and mobile device management software to assess the usability of Tidepool Loop, a product in development submitted to the FDA in December 2020. The benefits of decentralized, remote human factors research suggest further exploration of this framework is appropriate.

P026 / #624
Topic: AS01-Closed-loop System and Algorithm
EVALUATION OF A CLOSED-LOOP SYSTEM ON A TYPE 2 DIABETES VIRTUAL POPULATION
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Background and Aims: We evaluated DBLG1 for Hybrid Closed-Loop insulin delivery system (HCL) for people with Type 2 diabetes (T2D) within a challenging in-silico clinical trial to anticipate glycemic outcomes.

Methods: A 3 days in-silico clinical trial is performed using the Diabetes Mellitus Metabolic Simulator for Research (DMMS.R) with predefined 11 T2D adult population (57%–3 yo, 91%–5 kg), with an open-loop (OL) period with medication regimen only (Metformin 500 mg) and a closed-loop (CL) period (same subjects and medication, equipped with HCL) with the same meal plan {60, 150, 100} gCHO at 8AM, 12PM, 7PM respectively. HCL was parameterized very aggressively with daily insulin needs (TDD) input of 160IU. Glycemic outcomes were measured in time in ranges (mean±std) [70;180] (TIR_normo), <70 (TIR_hypo), >180 mg/dL (TIR_hyper). The 3 subjects #adult3, #adult4, #adult10 were selected for their challenging and distinct OL glycemic excursions.

Results: Glycemic outcomes were improved for the CL period vs OL period with 70.7±4.0% vs 40.7±19.4% for TIR_normo, 21.9±8.2% vs 59.3±19.4% for TIR_hyper, except for TIR_hypo with 6.9±7.4% vs 0%. HCL can be personalized to improve the treatment: solely reducing TDD for #adult10 from 160 to 36UI reduced TIR_hypo by 4.8% with 70±4.5% for TIR_normo. Glycemic outcomes were also satisfying with all meals unannounced to HCL with 64.1±8.7% in TIR_normo, 29.7±13.1% in TIR_hyper, 5.7±6.8% in TIR_hypo.

Conclusions: T2D is a progressive disease with several pathological defects impacting glycemia. The proposed HCL provides satisfactory outcomes on virtual population that could be expected in real-life for this population even in the case of fully unannounced meals.

P027 / #634
Topic: AS01-Closed-loop System and Algorithm
A FEASIBILITY STUDY ASSESSING AN “I-AM-EATING” MEAL-BOLUS OPTION FOR A CLOSED-LOOP SYSTEM WHICH ELIMINATES CARBOHYDRATE COUNTING
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Background and Aims: Carbohydrate counting is a significant burden for persons with diabetes (PWD) who require insulin to mitigate postprandial glucose excursions. A simple “I-am-Eating” function was developed to allow delivery of a personalized (per age and body weight) pre-determined bolus for any meal size. We studied the safety and performance of this feature when used with the Medtronic Advanced Hybrid Closed-loop system (AHCL) that auto-corrects to 100 mg/dL every 5 minutes.

Methods: Individuals (N=15, aged 22–58 years) with T1D used the AHCL system with a set-point of 100 mg/dL and an active insulin time of 2 hours for a 90-days period where traditional carbohydrate counting and entry were carried out. Thereafter, individuals used their own personalized “I-am-Eating” bolus function for mealtime bolusing, for 21 days.

Results: “I-am-Eating” function for premeal bolusing without carbohydrate counting had an adverse impact on postmeal glycemic outcomes, as expressed by the 4-hour post-parndial TIR. Nonetheless, glycemic control remained:

<table>
<thead>
<tr>
<th>Carbohydrate Counting</th>
<th>AHCL System</th>
<th>AHCL System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Values</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meal event(n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postprandial SG peak, mg/dl (mmol/L)</td>
<td>181±20 (10.5±3.1)</td>
<td>208±22 (11.6±3.7)</td>
</tr>
<tr>
<td>4-hours post meal, mg/dl (mmol/L)</td>
<td>150±43 (8.3±2.4)</td>
<td>166±50 (9.2±3.8)</td>
</tr>
<tr>
<td>4-hours post meal, mg/dl (mmol/L)</td>
<td>210±40 (11.6±3.7)</td>
<td>418±64 (23.4)</td>
</tr>
<tr>
<td>TIR 4-hours post meal</td>
<td>71.9±31.5</td>
<td>64.8±31.9</td>
</tr>
<tr>
<td>TIR 4-hours post meal</td>
<td>2.8±8.1</td>
<td>9.9±3.7</td>
</tr>
<tr>
<td>TIR 4-hours post meal</td>
<td>25.2±32.1</td>
<td>34.2±25.3</td>
</tr>
</tbody>
</table>

\*I-am-Eating" versus carb-counting (p=0.05) \*"I-am-Eating" versus carb-counting (p=0.01)
Conclusions: A personalized “I-am-eating” option is an alternative for traditional and burdensome carbohydrate counting. This approach may be incorporated with future algorithms to improve adherence to meal-time insulin bolusing and timing by completely eliminating carbohydrate counting.

P028 / #638
Topic: AS01-Closed-loop System and Algorithm

PHYSICAL ACTIVITY IMPACT ON A TYPE 2 DIABETES POPULATION, IMPLICATIONS FOR A FULLY CLOSED-LOOP SYSTEM

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Background and Aims: The aim of this study is to identify the impact of physical activity (PA) on type 2 diabetes (T2D) physiology and glycemic outcomes.

Methods: A dataset (FGM (mg/dL), insulin (IU), meals intake, actigraphy data in metabolic equivalent of task (MET)) of 35 T2D patients (14 female, age: 47 ± 7 yo, weight: 75 ± 15 kg, total daily dose (TDD): 89 ± 54 IU, TDD/weight: 0.9 ± 0.5 IU/kg) for 7 days is evaluated (ClinicalTrials ID NCT04522882).

PA periods were defined as 2-hours periods with MET >1.5. Three different physiological outcomes clusters are obtained using K-means clustering with glycemic metrics on the 21 patients having at least one PA.

Results: The coefficient of variation (CV) and time in range (TIR) <70mg/dL (TIR_hypo) was reduced on periods with PA, including post-prandial periods.

The 3 groups were significantly differentiated (p <0.05) in terms of median glycemia (GM), TIR [70;180] mg/dL (TIR_normo), TIR hyperglycemia (TIR_hyper), TIR_hypo, postprandial peak (PP). The 1st cluster centroid is characterized by the highest GM, highest TIR_normo, lowest GM on PA periods (GMPA). The 2nd group’s centroid had the highest PP. The 3rd group’s centroid had the lowest GM, the highest TIR_normo, the lowest TIR_hypo, the lowest TIR_hyper and lowest GMPA and highest relative time spent in PA.

Conclusions: The proposed clustering shows that closed-loop systems should take into account impacts of PA on different metrics among which variability and TIR, handling treatment depending on the candidate patient’s cluster.

P029 / #640
Topic: AS01-Closed-loop System and Algorithm

LONGITUDINAL STUDY ON THE REAL-WORLD USE OF HYBRID CLOSED LOOP IN A COHORT OF PEDIATRIC PATIENTS WITH TYPE 1 DIABETES


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Background and Aims: Closed-loop systems may improve glucometric outcomes in children with type 1 diabetes (T1DM). We evaluated a cohort of children in their real-life context treated with Medtronic 670G for an average of 8 months and assessed the following: 1) glucometric data 2) whether the adjustment of hybrid closed loop (HCL) settings after systematic review of data downloaded every 15 days, could further improve glucose control 3) whether this self-management negatively affects patient quality of life.

Methods: Thirtyseven enrolled T1DM 670G users (age 13.2 ± 2.8 years, disease duration 5.6 ± 3.9 years). Twentytwo downloaded data every 15 days for 3 months and filled out a questionnaire involving daily self-management issues. A control group (n = 14) downloaded data as usual. DIDS and IDRISQ questionnaires were administered to the 22 cases at the beginning and end of the study.

Results: Average glucose distributions of all patients: TIR 76%, TBR 2%, TAR 22%. More than 90% reached target glucose TIR values as suggested by recent guidelines. Differences in glucose distributions between the two groups (cases vs controls) were no statistically significant: TIR 71.63 ± 7.34% and 73.07 ± 8.04%, TAR (180-250mg/dl) 19.59 ± 4.91% vs 19.78 ± 4.54%; TBR (54-70 mg/dl) 2.59 ± 1.94% vs 1.14 ± 0.53%. Time in auto-mode and TIR correlated (p <0.001). Patients were satisfied HCL use (DIDS1 6.9/DIDS2 7.04). Systematic self-monitoring did not negatively affect their quality of life (IDRSQ 81.5 vs 79).

Conclusions: Our data suggests that in the real world, HCL systems may allow >90% of pediatric patients to reach target glucose control. Due to HCL efficiency and despite patient adjustments it difficult to further improve glucose control. Therefore, further improvement may be feasible with further technological advancement.

P030 / #731
Topic: AS01-Closed-loop System and Algorithm

PRESCRIPTION TRENDS AND SELECTION OF ANTIDIABETIC AGENTS - SIX-YEAR REVIEW OF DRUG UTILISATION IN PATIENTS WITH DIABETES

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Background and Aims: India has witnessed the near parallel launch of newer antidiabetic agents at par with the rest of the world, enabling access to newer agents with continuous usage of existing off-patent established therapies. We describe trends in
the antidiabetic therapy in LINA cohort who have been treated at our specialised centre at any point in the last six years.

Methods: The choice of therapy was determined by the concurrence of patient’s preference based on affordability and physicians decision to adopt a pathophysiological, guideline-directed approach to provide effective glycemic care. We analysed the prescription database across 32,974 prescription units as per the prescribed daily dose criteria. Statistical analysis performed by student t-test

Results: Despite relatively higher costs of gliptins, trends reflected rise in DPP IV inhibitors (consistent annual uptrend of 10%, especially the patented gliptins) but still sulphonylureas are predominant (p = 0.98 NS). The trends for insulin and SGLT2 inhibitors were comparable (p = 0.264 NS). SGLT2 inhibitors have highest adoption rates (41% rise in 2018 Vs 2017)

Conclusions: Our analysis accounts for epidemiological trends favouring rapid rise of burden of diabetes and the increasing affordable class of patients. The results of our database which is adherent to evidence-based treatment protocols need corroboration across large similar chronic disease programs

P031 / #764
Topic: AS01-Closed-loop System and Algorithm

SIX MONTH GLYCEMIC CONTROL WITH A HYBRID CLOSED LOOP SYSTEM IN INDIVIDUALS WITH TYPE 1 DIABETES

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Background and Aims: Despite recent technological advances, optimal glycemic control remains a challenge in people with type 1 diabetes (T1D). Hybrid closed loop (HCL) system with algorithm-derived automated adjustment of insulin delivery aims to improve glycemic control. Aim: To evaluate the effectiveness of HCL on glycemic control in subjects with T1D.

Methods: Prospective observational registry, that included consecutive patients with T1D that initiated treatment with MiniMed™ 670G system in Argentina. Baseline and follow up visits at days 7, 28, 90 and 180 days were carried out and data was downloaded in each visit.

Results: 31 patients were included (age: 31.4 ± 15.1, range 9–57), female 64.5%, previous use of SAP-PLGS 71% (n = 22), baseline HaBcL 7.4 ± 1%. Time in range (TIR) between 70–180 mg/dl significantly increased from 65.9% at baseline to 77.1%, 76.3%, 76% and 75.2% at days 7, 28, 90 and 180 respectively. Mean glucose levels were reduced from 163.5 at baseline to 150.9 mg/dl (p = 0.001) at last visit. The GMI was also reduced from 7.1% to 6.9% (p = 0.015). Sensor were time and Auto Mode use were 90.6% and 90.9% respectively, by the end of the study.

Conclusions: hybrid closed-loop system improved glycemic control and glycemic variability in children and adults living with T1D.

P032 / #794
Topic: AS01-Closed-loop System and Algorithm

LESSON LEARNT WITH MINIMED 780G ADVANCED HYBRID CLOSED-LOOP

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Background and Aims: Metabolic control in a group of pediatric patients with diabetes (T1D) switching to Advanced Hybrid Closed-Loop (AHCL) Medtronic MiniMed 780G was described.

Methods: 10 T1D children aged 13.8 ± 3.9 yrs switched to AHCL (1 from MiniMed 670G, 2 MiniMed 640G and 7 multiple injections). AHCL use was 55 ± 17.9 d. Time in range (TIR), glucose variability (CV), basal/holbus proportion were examined in three 14 days periods: M Manual Mode; A1, A2 first and last AHCL periods. Settings: glycemic target 120 mg/dl, active insulin time 3 hours.

Results: TIR increased from 68.4% ± 14.5% (M) to 74.8% ± 10.5% (A1, p 0.16) and to 77.7% ± 8% (A2, p 0.03). Time spent in level 1 hyperglycemia (L1Hyper) decreased from 24.1% ± 11.1% (M) to 20.3% ± 7.7% (A1, p 0.23) and to 17.4% ± 6.2% (A2, p 0.02). The same trend was observed for level 2 hyperglycemia (L2Hyper), without statistical significance. Time spent in level 1 (L1Hypo) and 2 hypoglycemia (L2Hypo) decreased from M to A1 but not in A2. CV improved from M to A1 (31.5% ± 5.4% vs 30.6% ± 3.7%, p 0.8), no improvements between A1 and A2. The insulin bolus proportion increased from M to A2.

Conclusions: All patients reached the recommended targets (TIR >70%, L1Hyper <25%, L2Hyper <5%, L1Hypo <4%, L2Hypo <1%) in A1 and A2. TIR increased from M to A2 due to L1Hyper reduction even if we chose the least aggressive settings. Additional efforts to overcome therapeutic inertia personalising the settings might lead to further improvements.

P033 / #799
Topic: AS01-Closed-loop System and Algorithm

REINFORCEMENT LEARNING FOR TUNING PARAMETERS OF CLOSED-LOOP CONTROLLERS

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Background and Aims: Previous work with AP systems shows that initial tuning of the closed-loop parameters is key to enhance performance. Even short-term clinical trials show better results when the result analysis is concentrated in the last hours.

Methods: In this work, a Reinforcement Learning based tuning technique for the previously introduced Automatic Regulation of Glucose (ARG) algorithm [1] is evaluated using a self-developed code. This technique modifies only one parameter in the AP system (the insulin-on-board (IOB) limit) instead of replacing the controller entirely.

The resulting tuning strategy is evaluated in-silico using the FDA-accepted UVA/Padova simulator to test the initial tuning of the IOB limit of the ARG controller and tested against a manual tuning scheme. Lastly, the RL strategy is applied retroactively to data collected in clinical trials.

Results: The in-silico results show that the auto-tuning by means of RL achieves total elimination of hypoglycemic events in few episodes for the whole cohort and none of the manual actions achieve the same result by themselves. In summary, this preliminary in-silico study indicates that the use of RL for autotuning of AP systems shows great potential for future applications. When tested as a recommendation system against past data clinical data, the RL policy suggests that its use could have led to better results on the past clinical trials, showing promise for future work.

Conclusions: Simulations show that the proposed tuning strategy improves the performance of the ARG algorithm, as it reduces excursion and insulin injection.

P034 / #800
Topic: AS01-Closed-loop System and Algorithm
AP CONTROL ALGORITHMS: A SWITCHED CONTROL APPROACH FOR BIHORMONAL GLYCEMIC REGULATION.
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Background and Aims: Single-hormone AP systems have shown to improve glucose regulation in people with T1D. However, a dual-hormone AP that relies in both insulin and glucagon for glycemic control is a promising therapy that could further improve both performance and safety.

Methods: In this work, a switched, dual-hormone controller is presented (ARGSH). This method extends the previously introduced Automatic Regulation of Glucose (ARG) algorithm, which has a switched LQG as its main insulin controller, to a dual-hormone algorithm by means of adding a PD controller for glucagon dosing. Several criteria for the activation of the glucagon controller are considered, analyzing their effects on the AP system performance and safety.

Results: The in-silico study carried out in this work demonstrated that extending the ARG algorithm to a dual-hormone algorithm is feasible. The ARGSH proved that, with a proper selection of the activation criterion of the glucagon controller, it effectively avoids hypoglycemia episodes without increasing hyperglycemia nor the total amount of insulin infused a day.

Conclusions: Simulations indicate that the proposed dual-hormone ARG achieves better results than the single-hormone ARG algorithm (ARGSH).

P035 / #130
Topic: AS02-New Insulin Analogues
ULTRA RAPID LISPRO (URLi) DEMONSTRATES SIMILAR TIME IN TARGET RANGE TO LISPRO WITH THE MEDTRONIC MINIMED 670G HYBRID CLOSED-LOOP SYSTEM
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Background and Aims: URLi is a novel ultra-rapid formulation of insulin lispro that shows improved postprandial glucose control and similar compatibility with continuous subcutaneous insulin infusion (CSIi) vs. Lispro. In this study URLi was evaluated for the first time in a hybrid closed-loop system using the Medtronic MiniMed™ 670G. Primary objective was to compare URLi to Lispro with respect to the percentage of time with glucose values within target range 70-180 mg/dL (%TIR).

Methods: This double-blind, crossover study included two 4-week treatment periods with URLi or Lispro. After a 2-week lead-in on Lispro, 42 adults with type 1 diabetes using personal MiniMed 670G pumps were randomised to 1 of the 2 treatment sequences with boluses initiated 0-2 minutes before meals.

Results: Both treatments achieved good glycaemic control with mean TIR >75% (Fig 1). Mean time above and below range met consensus recommendations for both treatments. The percentage of time in Auto Mode was similar between treatments: URLi 92.0%; Lispro 91.4%. Insulin doses and pump settings were generally similar between treatments. There were no serious adverse events or early discontinuations. Overall incidence
of treatment-emergent adverse events was similar between treatments.

Conclusions: URLi demonstrated comparable glycaemic control and a similar safety profile to Lispro with the MiniMed 670G system in patients with type 1 diabetes.

P036 / #310

Topic: AS02-New Insulin Analogues

TREATMENT SATISFACTION IN PEOPLE WITH TYPE 2 DIABETES RECEIVING BASAL INSULIN: RESULTS FROM REAL-WORLD STUDIES AND RANDOMISED CONTROLLED TRIALS WITH INSULIN GLARGINE 300 U/ML

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Background and Aims: Basal insulin (BI) analogues can help optimise glycaemic control in people with type 2 diabetes (T2D), but the patients' satisfaction is key for acceptance and treatment adherence.

Methods: ACHIEVE, REACH, and REGAIN were open-label real-world studies comparing insulin glargine 300 U/mL (Gla-300) with standard of care BI (ACHIEVE: insulin glargine 100 U/mL [Gla-100] or insulin detemir [IDet]; REACH and REGAIN: Gla-100, IDet, insulin degludec [IDeg] or neutral protamine Hagedorn). EDITION 1-3 and BRIGHT were open-label randomised controlled trials (RCTs) comparing Gla-300 with Gla-100 and IDeg, respectively. All studies were in people with uncontrolled T2D and used the Diabetes Treatment Satisfaction Questionnaire (DTSQ; Table).

Results: In RCTs and real-world studies, initiating BI in insulin-naïve participants was associated with improved treatment satisfaction after 6 months (ACHIEVE, 12months) and a reduction in the perceived frequency of hyperglycaemia. Perceived hypoglycaemia increased slightly from low baseline values. Similar findings were found in patients switching BI, with improved patient satisfaction and reduced perceived frequency of hyperglycaemia after 6 months of treatment, and no change in perceived hypoglycaemia.

Conclusions: Initiating or switching BI in people with uncontrolled T2D can improve patient satisfaction, irrespective of baseline diabetes treatment.

P037 / #311

Topic: AS02-New Insulin Analogues

DIFFERENCES IN PATIENT-REPORTED OUTCOMES BY AGE AND REGION IN ADULTS WITH TYPE 1 DIABETES IN THE SAGE STUDY

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Background and Aims: Type 1 diabetes is a chronic disease impacting patients’ lives and psychosocial health; we explored how this may vary by age and region.

Methods: SAGE was a multinational, cross-sectional observational study using data from medical records and interviews of participants (N = 3858) aged ≥26 years with T1D for ≥1 year. Results from patient-reported outcomes (PROs) questionnaires (Hypoglycaemia Fear Survey [HFS-II], Problem Areas in Diabetes [PAID], Insulin Treatment Satisfaction Questionnaire [ITSQ], Audit of Diabetes-Dependent Quality of Life [AD-DQoL]) were analysed by region (Asia, Eastern Europe [EE], Western Europe [WE], Latin America [LA], Middle East [ME]) and age group (26–<45; 45–<65; ≥65 years).

Results: HFS-II scores showed fear of hypoglycaemia was lowest in Asia for all age groups (Table). HFS-II scores increased with age in EE and decreased with age in LA. PAID...
scores showed highest levels of emotional distress in ME for all age groups. ITSQ scores showed treatment satisfaction increased with age in WE, LA and ME, and was more stable in EE and Asia. ADDQoL total scores showed a small negative impact with age in WE, LA and ME, and was more stable in EE and age groups. ITSQ scores showed highest levels of emotional distress in ME for all age groups. Conclusions: PROs scores indicated relatively low levels of diabetes-related impact and high treatment satisfaction. Age and regional differences may reflect variations in T1D control and management, as well as cultural and healthcare-system-related factors.

P038 / #323
Topic: AS02-New Insulin Analogues
GLYCAEMIC CONTROL AND HYPOGLYCAEMIA IN HIGH-RISK SUBGROUPS OF PEOPLE WITH TYPE 1 DIABETES (TID) IN THE SAGE STUDY
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Background and Aims: Older age, a history of severe hypoglycaemia, and renal impairment are risk factors for hypoglycaemia and its consequences; characteristics and outcomes of these high-risk subgroups were analysed in the SAGE study.

Methods: In SAGE, data were analysed from medical records and interviews of eligible participants ≥26 years of age with TID for ≥1 year (N = 3858). Glycaemic target achievement (HbA1c < 7% & individualised target) and hypoglycaemic outcomes were recorded in three high-risk subgroups - age ≥65 years, severe hypoglycaemia in the previous 6 months or renal impairment (eGFR < 60 ml/min/1.73 m²).

Results: Despite identical mean HbA1c, older people with T1D were less likely to achieve HbA1c < 7% than people aged 26–44 years, but were most likely to achieve individualised glycaemic targets (Table). Hypoglycaemia incidence (blood glucose ≤ 3.9 mmol/l) and severe hypoglycaemia was similar across age groups, but older people had less severe hypoglycaemia leading to diabetic ketoacidosis (DKA). Across all age groups, people who had experienced severe hypoglycaemia did not have notably different glycaemic outcomes versus overall population. Across all age groups, notably fewer participants with renal impairment achieved HbA1c target < 7% than overall population. Hypoglycaemia incidence was higher versus overall population in those with renal impairment.

Conclusions: People with a history of severe hypoglycaemia appear to have an increased likelihood of further hypoglycaemic events and hyperglycaemia leading to DKA, while those with renal impairment appear less likely to reach standardised glycaemic targets and more likely to experience hypoglycaemia.

P039 / #327
Topic: AS02-New Insulin Analogues
ASSOCIATION OF PATIENT-REPORTED OUTCOMES SCORES WITH GLYCAEMIC TARGET ACHIEVEMENT IN TYPE 1 DIABETES IN THE SAGE STUDY
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Background and Aims: Type 1 diabetes (T1D) is a chronic disease affecting both physical and psychosocial health.

Methods: SAGE was a multinational, cross-sectional observational study using data from medical records and interviews of people (N = 3858) aged ≥26 years with T1D for ≥1 year. The association between the achievement of general (HbA1c < 7%) or individualised HbA1c targets and patient-reported outcomes (PROs) scores was analysed by multivariate logistic regression, adjusted for region and age group. The following PROs are reported: Hypoglycaemia Fear Survey (HFS-II) worry subscore, Problem Areas in Diabetes (PAID), Insulin Treatment Satisfaction Questionnaire (ITSQ), Audit of Diabetes-Dependent Quality of Life (ADDQoL).
Results: Overall, 24.3% of people achieved the general HbA1c target; 20.9% achieved individualised targets (most common target, HbA1c 7% to <7.5%). Lower emotional distress (PAID score) and higher treatment satisfaction (all ITSQ scores except Lifestyle domain) were associated with achievement of general and individualized HbA1c targets (Table). Lower HFS-II worry score and higher ADDQoL total scores were associated with achievement of HbA1c general target, but neither was associated with achieving individualised HbA1c targets.

Conclusions: In people with T1D, lower diabetes-related emotional distress and higher treatment satisfaction appear to be associated with achievement of both general and individualised HbA1c targets.

Methods: HbA1c target (<7% [<53 mmol/mol] and individualised) achievement and other glycaemic and hypoglycaemic outcomes were evaluated by titration method (physician-, patient-driven) and region (Asia, East Europe, Latin America, Middle East [ME], West Europe [WE]) in eligible participants with T1D (N = 3858) in the SAGE study.

Results: There were no major differences in age and time since diabetes diagnosis between regions (Table). Irrespective of region, patient-driven titration resulted in slightly greater proportions of HbA1c target achievement (<7% and individualised) than physician-driven titration; nevertheless, in each subgroup, HbA1c target achievement was <30%. Mean ± SD HbA1c was lowest in WE (physician-driven: 7.73 ± 1.26%; patient-driven: 7.69 ± 1.19%). Overall incidence of hypoglycaemia (≤3.9 mmol/L) within the last 3 months, severe hypoglycaemia and severe hyperglycaemia leading to diabetic ketoacidosis (DKA) within the last 6 months was slightly higher for patient-driven titration (70.3%, 12.0% and 4.5%, respectively) compared with physician-driven titration (61.9%, 11.6% and 3.8%, respectively). Incidence of symptomatic hypoglycaemia (≤3.9 mmol/L) was notably lower in ME (37.2% for both titration subgroups) compared with other regions; severe hypoglycaemia incidence was similar across regions in physician- (7.7–15.2%) and patient-driven groups (7.7–16.8%). Incidence of ≥1 severe hyperglycaemic episode leading to DKA was lowest in Asia (physician-driven: 1.6%; patient-driven: 2.7%).

Conclusions: This analysis shows that although glycaemic control is suboptimal in people with T1D across regions, HbA1c target achievement is slightly more frequent in participants who self-titrate their insulin dose.
P041 / #346

**Topic: AS02-New Insulin Analogues**

**INVESTIGATION OF THE INFLUENCE OF THE ELECTROMAGNETIC FIELD CREATED BY THE NEAR-FIELD SENSOR ON BIOLOGICAL TISSUES AND ORGANS FOR NON-INVASIVE MEASUREMENT OF GLUCOSE CONCENTRATION**

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**Background and Aims:** This study is necessary to study the application of this sensor for non-invasive measurement of blood glucose concentration with high accuracy. Everyone knows that the permissible level of measurement error when creating a non-invasive glucometer should not exceed 10–15%. To achieve this value, it is necessary to conduct a detailed study of possible sources of error in the proposed measurements, associated with ignorance of the level of blood filling in the investigated volume of the skin, other physiological data of a person (thickness of the stratum corneum and epidermis, level of skin hydration, etc.).

**Methods:** The studies were carried out using numerical simulation in the CST microwave studio environment. All biological tissues were simulated in a wide frequency range of 10 MHz - 10 GHz.

**Results:** We have developed the design of the near-field sensor, which is a combined emitter. The design of the sensor is unique due to the fact that it allows the formation of a prolonged near-field zone. This effect can be used for deeper penetration of the field, without loss of information, into media with high absorption. In this study, it is proposed to pay special attention to a detailed study of the interaction of the field created by this sensor on various biological tissues containing glucose.

**Conclusions:** This study was supported by the RSF, project “Development of ideas about the features of near-field interaction of electromagnetic radiation in a wide frequency band with a non-invasive glucometry technology”, 18-75-10101.

P042 / #357

**Topic: AS02-New Insulin Analogues**

**EFFECTIVENESS AND SAFETY OF GLA-300 VS IDEG-100 EVALUATED WITH CGM IN ADULTS WITH T1D IN ROUTINE CLINICAL PRACTICE IN SPAIN – THE ONECARE STUDY**

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**Background and Aims:** Compare the effectiveness and safety of insulin glargine 300 U/ml (Gla-300) versus degludec 100 U/ml (IDeg-100), defined as the percentage of time in the target glucose range (TIR; 70–180 mg/dl) during a four-week period, measured using CGM in patients with T1D in routine clinical practice in Spain.

**Methods:** Observational, retrospective cohort, cross-sectional, multicenter study. Inclusion: Adults with T1D for ≥3 years; switched from basal-bolus insulin treatment (first-generation basal insulins) to Gla-300 or IDeg-100 in previous 24 months; CGM use for previous >3 months; HbA1c ≥7.5 % pre-switch. CGM data for 14 consecutive days were required for analysis.

**Results:** Overall, 199 patients with T1D were included: 104 switched to Gla-300 and 95 to IDeg-100 (mean age, 42.6 years; 50.3% female; mean T1D duration, 18.4 years). The percentage of TIR 70–180 mg/dl over 24 hours was comparable between Gla-300 and IDeg-100 cohorts (Table). At night (24:00–06:00 h) a significant difference in TIR was observed: (Gla-300; 52.4%, 2.1; 0.0433; p = 0.0182). No statistically significant difference between cohorts was observed in TIR 70–140 mg/dl. Mean HbA1c and glucose values, and glycemic variability, were comparable between cohorts. Mean glucose curves were statistically smoother (lower glycemic excursions) at night with Gla-300 versus IDeg-100 (p < 0.05). Incidence of reported hypoglycemic events (<70 mg/dl) in the last 14 days was comparable in both groups (91.% vs 97.9%, p = 0.725).

**Conclusions:** This real-world study shows that the effectiveness and safety of Gla-300 is similar to that of IDeg-100 in sub-optimally controlled T1D patients switching from first-generation basal insulins. Study sponsored by Sanofi.

P043 / #391

**Topic: AS02-New Insulin Analogues**

**SECOND-GENERATION BASAL INSULIN ANALOGUES: FIRST-CHOICE IN REDUCING REAL-WORLD SEVERE HYPOGLYCEMIA (BASELINE RESULTS OF THE INPHORM STUDY, USA)**

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Background and Aims: Trials have shown that second-generation basal insulin (BIs) analogues reduce severe hypoglycaemia (SH) compared to first-generation BIs. We analyzed data from the population-based iNPHORM study (USA) to assess whether this effect persists in the real-world.

Methods: Socio-demographic, clinical, and hypoglycemia-related data were obtained on baseline iNPHORM respondents (T1DM/T2DM) reporting consistent BI use in the year preceding questionnaire completion. Multivariable negative binomial regression (NBR) was used to isolate the effect of second-generation versus first-generation BIs (+/− bolus insulin) on self-reported rates of past-year total SH (TSH), daytime SH (DSH), and nocturnal SH (NSH). Confounding variables were identified from a directed acyclic graph.

Results: Of the 569 complete baseline responders (age: 52.33 (SD: 13.82) years; female: 54.5%; T1DM: 21.6%), 10.0% and 7.6% reported taking a second-generation BI with and without bolus insulin, respectively; comparatively, 54.1% and 28.3% reported taking a first-generation BI with and without bolus insulin, respectively. The crude rate of TSH was 2.47 (95% CI: 2.34-2.60) events per person-year (EPPY) (DSH: 1.47 (95% CI: 1.37-1.57) EPPY; NSH: 1.00 (95% CI: 0.923-1.09) EPPY). Based on adjusted NBR analyses, respondents taking first-generation versus second-generation BIs without bolus insulin reported 2.70 (95% CI: 1.07-6.84) times the number of past-year TSH events; among those using bolus insulin, the incidence rate ratio was 1.17 (95% CI: 0.55-2.46). Comparable adjusted effects were observed for DSH and NSH.

Conclusions: These real-world results substantiate trial-based observations that second-generation versus first-generation BIs reduce SH rates, irrespective of bolus insulin therapy. The safety benefits highlighted in this study provide additional impetus for clinicians to prioritize second-generation BIs whenever possible.

P044 / #396

Topic: AS02-New Insulin Analogues

NEW ULTRA-RAPID ACTING INSULIN IN SENSOR AUGMENTED PUMP WITH PREDICTIVE LOW GLUCOSE SUSPENSION ALGORITHM

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Background and Aims: Pharmacological research in type 1 diabetes (T1D) brought to development of ultra-fast acting insulin in order to better mimic the kinetics of endogenous insulin. Aim of our study was to investigate the effectiveness of predictive low glucose suspension (PLGS) algorithm used with fast acting insulin aspart compared to PLGS used with traditional insulin analogs (aspart, lyspro or glulisine).

Methods: We retrospectively analyzed data of patients followed at the diabetes clinic of the San Raffaele Hospital in Milan (Italy) and treated with Medtronic 640G PLGS system who switched from a traditional insulin analog to fast acting insulin aspart.

Results: N = 13 patients were included in the analysis (7 aspart, 1 lyspro, 5 glulisine). Study period was 80 days for traditional analogs with 78.6% of sensor use and 62 days for fast acting aspart with 74.8% of sensor use. A total of 3,458 PLGS suspensions were documented (1,933 in the traditional analogs group and 1,525 in the fast aspart group). There was no significant difference in number and duration of daily suspensions. The percentage of PLGS suspensions that prevented glucose values <70 mg/dl increased from 69.9 ± 14.3% to 76.0 ± 16% after switching to faster insulin analog (p = 0.034). When not preceded by a bolus, suspensions that prevented hypoglycemia were 80.5 ± 16.2% in the fast acting aspart group versus 72.3 ± 13.7% in the traditional analogs group (p = 0.016). There were no differences in highest blood glucose reached after reactivation of basal rate.

Conclusions: Faster acting insulin aspart associated with PLGS algorithm represents an effective tool to improved blood glucose management in patients with T1D.

P045 / #469

Topic: AS02-New Insulin Analogues

EFFECT OF INSULIN DEGLUDEC VERSUS INSULIN GLARGINE U100 ON OCCURRENCE OF CGM-RECORDED NOCTURNAL HYPOGLYCAEMIA IN PEOPLE WITH TYPE 1 DIABETES AND PREVIOUS NOCTURNAL SEVERE HYPOGLYCAEMIA


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Background and Aims: Nocturnal hypoglycaemia is a major source of concern to people with type 1 diabetes (T1D). Optimal basal insulin therapy may reduce occurrence of nocturnal hypoglycaemia. We report frequencies of CGM-recorded nocturnal non-severe hypoglycaemia (NNSH) in people with T1D and previous nocturnal severe hypoglycaemia based on data from the HypoDeg trial, which compared insulin degludec (IDeg) with insulin glargine U100 (IGlar).

Methods: Eighty-nine people with T1D accepted participation in a study of 4 x 6 days of blinded CGM (Medtronic iPro) during a 2-year randomized cross-over study. Sixty-seven participants were included in analysis. CGM traces were reviewed for hypoglycaemic events (lasting at least 15 minutes) according to international consensus at Level 1 (≤ 3.9 mmol/L) and Level 2 (< 3.0 mmol/L).

Results: At Level 1, 128 NNSH events were found with IDeg and 214 NNSH events with IGlar, respectively. This corresponds to a 36% relative rate reduction (95% [CI]: 10%-54%; p = 0.009) during treatment with IDeg compared with IGlar (1.3 versus 2.0 events/patient-week), and an absolute rate reduction of 0.85 events/patient-week with IDeg. At Level 2, 60 NNSH occurred
during treatment with IDeg and 133 NNSH with IGlar, corresponding to a 53% relative rate reduction (95% CI: 36%–65%; p<0.001) during treatment with IDeg compared with IGlar (0.6 versus 1.3 events/patient-week), which translates into an absolute rate reduction of 0.55 events/patient-week with IDeg.

**Conclusions:** People with T1D prone to nocturnal severe hypoglycaemia have lower rates of CGM-recorded NNSH, when treated with IDeg compared to IGlar.

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**P046 / #526**

**Topic:** *AS02-New Insulin Analogues*

**THE EFFECT OF THE ULTRA-RAPID INSULIN ANALOG FIASP® IN PEDIATRIC TYPE 1 DIABETES PATIENTS UNDER CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII)**

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**Background and Aims:** Glycemic variability is a big challenge in children and adolescents with type 1 diabetes (T1D), including postprandial hyperglycemia. Rapid-acting insulin analogs have a late action and also a longer than desired duration. Ultra-fast-acting aspartic insulin (Fiasp®) has a faster start having a precocious peak.

**Aim:** To analyze the impact of Fiasp® in metabolic control of pediatric patients in a tertiary hospital.

**Methods:** Retrospective analysis of CSII patients who switched to Fiasp®. Data analyzed: anthropometry, insulin daily doses (IDD), %basal/boluses, capillary/interstitial glucose, time in range (TIR:70-180 mg/dL), variability coefficient, mean A1c; before and after Fiasp®. Statistical analysis with SPSSv.25.

**Results:** Thirty-five cases were included (48.6% males), median age of 13.2 years (9.3–15.8), disease duration of 5.9 years (4.4–7.5), under Fiasp® for 6.1 months (4.3–7.8). Thirty-two cases (93%) used interstitial glucose monitoring. IDD was similar (0.938U/Kg/day vs. 0.956U/Kg/day), without significant difference in basal/bolus. TIR increased (36% vs.51%, p=0.003), with decreased time in hyperglycemia (58% vs. 41%; p=0.025) and hypoglycemia, although this last parameter was not significant (7% vs.5.5%; p=0.345). A1c was lower at the end of the study (7.6% vs.7.5%, p=0.018).

**Conclusions:** Fiasp® significantly improved metabolic control, increasing time in range and decreasing postprandial hyperglycemia, with no changes in hypoglycemia. These results confirm Fiasp® safety and its advantage to achieve a more physiological profile, particularly relevant in pediatric population.

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**P047 / #550**

**Topic:** *AS02-New Insulin Analogues*

**HOW DO PEOPLE LIVING WITH DIABETES EXPERIENCE AND COMMUNICATE HYPOGLYCAEMIA? A GLOBAL QUANTITATIVE SURVEY**

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**Background and Aims:** Many people living with diabetes (PLWD) using insulin experience hypoglycaemia. PLWD were surveyed regarding hypoglycaemia and how it affects their communication with healthcare professionals (HCPs) and others.

**Methods:** A quantitative survey was fielded in the US, UK, Mexico, Spain, Italy, Germany, France, Australia, China, and India (May–July 2020). Participants with type 1 (T1D) or type 2 diabetes (T2D) were 18–75 years old, on insulin (basal, prandial, or pump)±GLP-1RA, with ≥1 self-reported hypoglycaemia episode in the past year.

**Results:** In 3975 surveyed PLWD (T1D, 30%; T2D, 70%), hypoglycaemia episodes in the past year were primarily moderate (T1D, 69%; T2D, 62%), followed by severe (T1D, 57%; T2D, 52%), and severe (T1D, 17%; T2D, 15%). PLWD reported feeling/guilt/shame around hypoglycaemia sometimes, often, or very often (49%), frequently blaming themselves for health mismanagement (59%), and feeling solely responsible for preventing future episodes (55%) (Figure). While 94% of PLWD communicated with others about hypoglycaemia, only 58% told their HCPs, and only 21% visited their HCPs to discuss moderate/severe episodes. Over 60% of PLWD experienced stigma around diabetes, with 31% experiencing stigma from their HCP. 57% of PLWD thought that the public were undereducated on diabetes, and 55% thought the public would be unable to help with a hypoglycaemia episode.

**Conclusions:** Hypoglycaemia is a substantial emotional burden for PLWD. Support to prevent guilt for PLWD, alongside better diagnosis and care is required. Public education around diabetes and hypoglycaemia awareness could be beneficial. Study sponsored by Sanofi.
P048 / #809
Topic: A502-New Insulin Analogues
OLDER PEOPLE WITH TYPE 2 DIABETES BENEFIT MORE AFTER SWITCHING FROM NPH INSULIN TO GLARGINE 300 U/ML: POST-HOC ANALYSIS OF A MULTICENTRE, PROSPECTIVE, OBSERVATIONAL STUDY
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Background and Aims: Insulin therapy in older patients with diabetes is challenging, mostly due to the higher risk and more serious consequences of hypoglycaemia. Appropriate insulin choice might constitute an aspect of therapy that minimise hypoglycaemia risk in these patients. This is post-hoc analysis of a multicentre, prospective, observational study assessing a switch from NPH insulin to Insulin glargine 300 U/mL (Gla-300) in terms of effectiveness and safety, depending on patients’ age.

Methods: 469 T2DM patients from 51 sites in Poland completed the original study. The patients switched from NPH insulin to Gla-300 in a 6-month follow-up period. The results were analysed based on patients’ age (≤65 years – 224 patients vs. >65 years – 245 patients).

Results: The mean HbA1c was reduced from 9.23% to 8.15% (p<0.0001) in patients ≤65 years and from 9.15% to 8.20% (p<0.001) in the patients >65 years without difference between groups (p=0.18). The frequency of hypoglycaemia was reduced by 5.5% in the patients ≤65 years (42/224, 18.8% vs. 30/224, 13.65%) and 14.6% in the patients >65 years (66/245, 26.9% vs. 31/245, 13.0%); the reduction in the frequency of hypoglycaemic events was higher in the patients >65 years (14.6% vs. 5.5%, p=0.0013) who also presented a significant reduction in nocturnal symptomatic hypoglycaemic events (p<0.05).

Conclusions: In this post-hoc analysis switching from NPH insulin to Gla-300 provided similar improvement in HbA1c and significantly better regarding all the analyzed therapies: MDI, insulin pump without CGM and regarding treatment of CGM sensor assisted insulin pump.

P049 / #16
Topic: AS03-Artificial Pancreas
COMPARING HYBRID CLOSED LOOP ARTIFICIAL PANCREAS TO MULTI DAILY INJECTION, INSULIN PUMP WITHOUT CGM AND CGM SENSOR ASSISTED INSULIN PUMP THERAPIES
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Background and Aims: This study proves that diabetes T1 therapy by means of artificial pancreas consisting on insulin pump with CGM and hybrid close loop control algorithm trained with machine learning technology provides better glycemia control than multi daily injection, insulin pump without CGM and CGM sensor assisted insulin pump therapies

Methods: Using Accu-Chek smart pix software to analyze the data collected in-vivo by JC Peiro, author and DT1 patient, in the period August 2004 to August 2019, collecting glycemia using the different therapies.

Results: The improvement of therapy with artificial pancreas in hybrid closed loop in comparison to MDI reduces -70.7% the periods above range , reduces -67.2% periods below range, TIR increases 75% reaching 84%, hypoglycemia’s % reduced -91.2%, HGBI reduces -67%, LGBI reduces -73.8% reaching 2.3 and 1.6 respectively, reducing the mean glycemia in -16% reaching mean of 121mg/dL with SD 42mg/dL, reducing median glycemia in -20% reaching median of 115 mg/dL with SD 55 mg/dL and reducing the Glycosylated Hemoglobin (HbA1c) -20.1% reaching a 6.6% value.

Conclusions: We can conclude that therapy for DT1 using artificial pancreas with CGM and hybrid closed loop controlled by machine learning regression trained algorithm provides better glycemic control results. The improvement of the treatment is significantly better regarding all the analyzed therapies: MDI, insulin pump without CGM and regarding treatment of CGM sensor assisted insulin pump.

P050 / #30
Topic: AS03-Artificial Pancreas
PARIS-BREST-PARIS: ULTRA ENDURANCE CYCLING WITH TYPE 1 DIABETES USING AN OPEN SOURCE ARTIFICIAL PANCREAS SYSTEM
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Background and Aims: Paris-Brest-Paris (PBP) is a long distance cycling event. Self sufficient riders must complete the 1200km ride within 90 hours. A 37 year old female cyclist with type 1 diabetes was a participant in PBP 2019. Insulin delivery was controlled using AAPS (Android artificial pancreas system), an open source, closed loop device.

Methods: The AAPS system consisted of an Accucheck insight pump (Roche) infusing insulin aspart. Glucose monitoring was performed using a Freestyle Libre sensor (Abbott) with Miaomiao transmitter. Glucose concentrations were received by the Xdrip+ and broadcast to the AAPS app running on an android phone. A cycling specific AAPS profile was used with insulin sensitivity factor, insulin carbohydrate ratio, and glucose target range, adjusted for exercise. Data was transmitted to Nightscout and an android smart watch. Glucose results and geographical location were remotely monitored via Xdrip follower app and Google maps location tracking.

Results: The ride was completed in 89 hours 28 minutes (distance 1229km, ascent 10,561m) with an average cycling speed of 19km/hr. Percentage time in range (4-10mmol/L) was 58%. Time above range (>10mmol/L) was 38%, below range (<4mmol/L) was 4% and (<3.5mmol/L) <1%. Mean and median glucose concentrations were 9.7mmol/L and 9.0mmol/L.
respective. The number of hypoglycaemic episodes was 5 (glucose <4mmol/L) and 1 (glucose <3.5mmol/L). The lowest recorded glucose concentration was 3.1mmol/L.

**Conclusions:** This case illustrates the successful use of AAPS during endurance cycling, with minimal hypoglycaemia over a 90 hour period. Further investigation into artificial pancreas systems with profile switching for exercise may be beneficial.

**P051 / #138**

**Topic:** AS03-Artificial Pancreas

**IMPLANTABLE, VASCULARIZED ENCAPSULATION PLATFORM WITH LOCALIZED IMMUNOSUPPRESSION FOR ALLOGENEIC CELL TRANSPLANTATION**

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**Background and Aims:** Current efforts for allogeneic cell transplantation face the outstanding challenge of maintaining sufficient vascular support for graft oxygenation, while providing immune attack evasion. Physical immunoisolation provides immune protection, but lack of vascularization through the encapsulation material creates an inhospitable environment for long-term engraftment. Inversely, direct vascularization approaches require chronic systemic immunosuppression with inherent toxicity and life-threatening adverse effects. To overcome this conundrum, we developed the neovascularized, implantable cell homing and encapsulation (NICHE) platform.

**Methods:** NICHE is comprised of an outer drug reservoir surrounding a central cell housing reservoir. For cell reservoir pre-vascularization, NICHE was subcutaneously implanted containing platelet rich plasma (PRP) or mesenchymal stem cells (MSC) hydrogel (Fig1A-B). Localized immunosuppression was achieved via sustained release of CTLA4Ig from the drug reservoir, through a nylon membrane, directly into the cell reservoir (Fig1C). Once pre-vascularized and locally immunosuppressed, allogeneic cells were transcutaneously loaded into the cell reservoir and monitored for engraftment (Fig1D).

**Results:** PRP and MSC enhanced blood vessel density within NICHE in rats and primates. Allogeneic Leydig cells transplanted in NICHE of immunocompetent rats remained viable throughout a 31-day study. Concomitantly, localized immunosuppression reduced drug exposure in plasma and peripheral organs up to 12-fold compared to gold-standard systemic dosing, circumventing potential toxicity. Preliminary data in a diabetic rat model demonstrated successful engraftment of pancreatic islets in NICHE with non-fasting and post-glucose-challenge euglycemic profiles. Moreover, NICHE explanation 60 days post-transplant resulted in reversal to hyperglycemic state.

**Conclusions:** NICHE dense pre-vascularization and localized immunosuppression render it a promising platform for transplantation of various allogeneic cell types.

**P052 / #141**

**Topic:** AS03-Artificial Pancreas

**COMPARISON BETWEEN A REAL-TIME CONTINUOUS GLUCOSE MONITORING SYSTEM AND AN INTERMITTENTLY-SCANNED CONTINUOUS GLUCOSE MONITORING SYSTEM AS BLOOD GLUCOSE SOURCE IN A DO-IT-YOURSELF ARTIFICIAL PANCREAS SYSTEM**

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**Background and Aims:** Previous studies evaluating do-it-yourself artificial pancreas system (DIYAPS) all used real-time continuous glucose monitoring (rt-CGM) as blood glucose(BG) data source. Here, we compared intermittently-scanned CGM (is-CGM) as BG data source in one of the DIYAPS—AndroidAPS(AAPS), with rt-CGM as BG data source in AAPS (AAPS-is-CGM vs. AAPS-rt-CGM), among patients with type 1 diabetes(T1D).

**Methods:** This is a before-after, non-inferiority trial. Main inclusion criteria:T1D; aged 7–75 years; baseline HbA1c <10.5%; and not pregnant. Patients first used AAPS-rt-CGM then switched to AAPS-is-CGM for another three months. Primary outcome was HbA1c at the end of each phase, and the prespecified non-inferiority margin was 0.40%. Other variables between two phases were compared using Pair t-test.

**Results:** Twelve patients were included (eight females; eight adults; median age:24.6 years[range:9.3–78.9], median diabetes duration:6.2 years[range:1.1–24.5] and median baseline HbA1c:6.8%[range:5.9–7.3]. The mean HbA1c was 6.72% in AAPS-rt-CGM phase vs. 6.64% in AAPS-is-CGM phase after three months. The upper boundary of the one-sided 95%CI of the mean HbA1c difference between two phases was 0.27%, lower than the non-inferiority margin. Glycemic variability was significantly lower in
AAPS-is-CGM phase than that in AAPS-rt-CGM phase (SD: 1.90±0.71 mmol/L vs. 2.40±0.76 mmol/L, P=0.038, CV: 25.67±8.25% vs. 30.84±6.91%, P=0.044 and MAGE: 4.41±2.05 mmol/L vs. 6.16±2.03 mmol/L, P=0.029). All the metrics for both glycemic control and QoL were comparable between the two phases. No severe hypoglycemia or diabetic ketoacidosis occurred. Eleven out of twelve patients (92%) were willing to use AAPS-is-CGM after the study.

Conclusions: The use of AAPS-is-CGM may be effective and safe among patients with T1D. This study proposes an alternative and more economical option for CGM in the use of a DIYAPS.

P053 / #172
Topic: AS03-Artificial Pancreas
DO-IT-YOURSELF AUTOMATED INSULIN DOSING: QUALITATIVE STUDY EXPLORING USER EXPERIENCES
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Background and Aims: Automated insulin dosing systems are increasingly commercially available, however some people with diabetes have developed their own do-it-yourself automated insulin dosing (DIY AID) systems. We conducted a qualitative study to gain an understanding of the user perspective and experience associated with DIY AID systems.

Methods: Twenty-six adults ≥18 years and fourteen parents of youth aged <18 years currently using DIY systems (OpenAPS and AndroidAPS) were recruited to participate in semi-structured interviews.

Results: Users were enthusiastic about DIY AID use and reported overwhelmingly positive experiences. Benefits reported by adults included glycemic improvements (n=26), easier overnight management (n=26) and reduced diabetes management burden (n=23). Benefits reported by parents included easier overnight management (n=12), glycemic improvements (n=11), and easier exercise management (n=10). Shortcomings reported by adult users included the need to independently set up the system (n=23), the system being only as good as individual components (n=18) and issues with insurance coverage or costs (n=18). Shortcomings reported by parents included the need to independently set up the system (n=10), the system being only as good as individual parts (n=10) and connectivity issues (n=6). When users discussed interactions with their HCP around DIY AID, the majority described their HCP as supportive.

Conclusions: We provide useful data regarding the key themes of uptake, use, barriers, and facilitators. This data will be valuable to key stakeholders in identifying factors contributing to individual choice for optimal personal benefit, both biomedical and psychosocial, to maximise optimal outcomes and minimise burden.

P054 / #231
Topic: AS03-Artificial Pancreas
SUSTAINED BENEFIT OF HYBRID CLOSED LOOP SYSTEM ON GLYCAEMIC CONTROL AFTER ONE YEAR OF USE IN CHILDREN AND ADULTS WITH TYPE 1 DIABETES.
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Background and Aims: Automatization of insulin delivery by closed-loop systems represents a major step in type 1 diabetes management. The Medtronic 670G was the first commercially available hybrid closed-loop system. The aim of the study was to evaluate the clinical outcomes after one year of real-world use of hybrid closed-loop system in children and adults with type 1 diabetes.

Methods: A prospective study, including type 1 diabetes patients consecutively starting the Medtronic 670G system in one adult and two pediatric hospitals, was performed. Baseline, 6-month and 1-year visits were documented. HbA1c, time in range 70–180 mg/dl, time >180 mg/dl, >250 mg/dl, <70 mg/dl and <54 mg/dl, in 2-week downloads, were recorded.

Results: 58 patients were included (age: 28 ± 15 years (7–63), <18 years: 38% (n = 22), 59% (n = 34) females, duration of diabetes: 15 ± 9 years). The previous treatment was SAP-PLGS: 60% (n = 35), pump+SMBG: 19% (n = 11), MDI+SMBG: 12% (n = 7), MDI+CGM: 9% (n = 5). The clinical outcomes are shown in Table 1. Time in Auto Mode was 88±9% at 6 months and 86±15 at year 1, respectively. At year 1, the number of low and high alerts per day was 2.5±2.2 and 3.1±2.9, respectively. No episodes of severe hypoglycemia and one episode of diabetes ketoacidosis were observed during follow-up. The rate of discontinuation was 3% (n = 2).

Conclusions: The use of hybrid closed-loop systems achieves a sustained improvement in glycaemic control and glycaemic variability in children and adults with type 1 diabetes.

Table 1. Clinical outcomes
<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>1 year</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMM (mmol/L)</td>
<td>7.1±1.0</td>
<td>7.0±1.3</td>
<td>6.9±1.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Fasting glucose (mg/dl)</td>
<td>105±19</td>
<td>105±12</td>
<td>105±11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time ≥180mg/dl (%)</td>
<td>63±12</td>
<td>72±8</td>
<td>79±10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time &gt;180mg/dl (%)</td>
<td>35±12</td>
<td>26±8</td>
<td>29±10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time ≥250mg/dl (%)</td>
<td>9±6</td>
<td>8±5</td>
<td>7±8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time &gt;70mg/dl (%)</td>
<td>5±3</td>
<td>4±2</td>
<td>4±2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time ≤54mg/dl (%)</td>
<td>0.5±1.04</td>
<td>0.5±1.75</td>
<td>0.4±1.68</td>
<td>0.331</td>
</tr>
<tr>
<td>Patients with Time ≥70–180 mg/dl ±10% (%)</td>
<td>28</td>
<td>57</td>
<td>58</td>
<td>0.048</td>
</tr>
<tr>
<td>Total insulin dose (ml/day)</td>
<td>45±14</td>
<td>46±15</td>
<td>45±15</td>
<td>0.247</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td>85±12</td>
<td>87±9</td>
<td>88±14</td>
<td>0.672</td>
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<tr>
<td>SMBG/day (mmol/L)</td>
<td>6.8±3.0</td>
<td>6.8±1.9</td>
<td>5.8±1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SD of SMBG glucose (mg/dl)</td>
<td>57±12</td>
<td>51±9</td>
<td>48±10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CV (%)</td>
<td>19±4</td>
<td>19±4</td>
<td>19±4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

n=58: 1-year compared to baseline.
**P055 / #393**

**Topic:** AS03-Artificial Pancreas

**A REAL-WORLD EVALUATION OF AUTOMATED INSULIN DOSING SYSTEMS DEMONSTRATES SUPERIOR EFFICACY AND COMPARABLE SAFETY WITH OPEN-SOURCE SYSTEMS AS COMPARED TO MINIMED 670G**

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Background and Aims: Real-world evaluation (RWE) of Minimed 670G (670G), a first commercial automated insulin dosing (AID) system, and open-source AID (OS-AID, or ‘DIY artificial pancreas’) systems in a publicly funded healthcare system.

Methods: Retrospective observational study in adults with type 1 diabetes using AID systems for at least 6 months with available clinical and device data. The primary outcome was change in HbA1c from baseline and percentage time in target range (%TIR) for glucose of 3.9-10.0 mmol/L.

Results: 68 adults met inclusion criteria of which 38 used 670G and 30 used OS-AID systems. OS-AID systems demonstrated significantly improved glycaemic outcomes compared to 670G with median change in HbA1c -0.8 [-0.3 – -1.1] % vs -0.1 [-0.6 to 0.2] %, (p = 0.001), %TIR range 78.5 ±11.9 vs 68.2 ±14.7 (p = 0.003), mean glucose 7.63 ±1 vs 8.87 ±1.5 mmol/L, (p < 0.001) and percentage time above range 18.4 ±12.1 vs 29.2 ±15.5, (p = 0.003) (Figure 1). Both systems demonstrated minimal hypoglycaemia and hyperglycaemia with a significantly lower time >13.9 mmol/L but a higher time <3 mmol/L in OS-AID systems, compared with 670G. Compared to 670G, OS-AID system users had shorter duration of diabetes, higher education status, lower baseline starting HbA1c, used lower glucose targets, higher weight adjusted insulin and experienced increased weight gain. No significant differences in glycaemic outcomes were noted between OS-AID system subtypes.

Conclusions: In this first clinically validated RWE, OS-AID systems demonstrate improved glycaemic outcomes with no clinical safety concerns compared to 670G. Whilst differences in group characteristics may explain some findings, possible mechanisms for improved OS-AID system performance over 670G in real world settings are demonstrated.

**P056 / #397**

**Topic:** AS03-Artificial Pancreas

**AN OBSERVATIONAL STUDY DETAILING CLINICAL EXPERIENCE, SAFETY AND EFFICACY OF COMMERCIAL AND OPEN-SOURCE AUTOMATED INSULIN DELIVERY SYSTEMS IN FASTING DURING RAMADAN WITH TYPE 1 DIABETES**

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Background and Aims: Fasting is challenging to people with type 1 diabetes (pwT1D) given complete abstinence from food and water. Fasting from sun-rise to sun-set during Ramadan is an essential part of spiritual life to some pwT1D, hence, providing avenues to empower them to undertake this safely is important. Automated insulin delivery (AID) systems may provide a novel enabling strategy.

Methods: PwT1D using AID systems and fasting during Ramadan 2019 and 2020 were supported via an international online peer support strategy. Validated clinical and device data were obtained, reviewed and analysed in this retrospective observational study.

Results: 6 fasting profiles met inclusion criteria. 5 used open-source AID systems (3 DIY-Loop, 2 AndroidAPS) and 1 used a commercial system (CamAPS-FX). Average age was 33.7 ± 4.8 years (mean ± S.D), diabetes duration 23.5 ± 7.9 years, BMI 23.6 ± 1.9 and HbA1c 6.3 ± 0.2%. Glycaemic results are detailed in the figure and reveal primary outcomes including mean

![Figure 1. Column charts displaying the mean TIR, TIR and TAR for total pool, 670G and DIY APS groups; ns = no significance, ** p < .01](image-url)
glucose 7.0 ± 0.5 mmol/L (mean±S.D.), CoV 28.5%, %TIR 3.9-10 mmol/L 88.8 ± 7.3% and %Time <3.9 mmol/L 2.5 ± 1.3% during Ramadan. Average days fasted were 27.3 ± 3.3 and average days where fasting was broken due diabetes were 1 ± 1.5 per subject. No significant differences in glycaemic outcomes including hypoglycaemia were noted between Ramadan and non-Ramadan periods. Further detailed analysis of glucose, insulin delivery and user feedback provides important insights on the utility of these systems to empower pwT1D to observe fasting.

Conclusions: In this first clinically validated study, open-source and commercial AID systems demonstrated a safe and effective management strategy to support prolonged consecutive fasts in pwT1D during Ramadan.

P057 / #506

Topic: AS03-Artificial Pancreas

EFFECT OF MEAL COMPOSITION ON GLUCOSE RATE OF CHANGE IN PATIENTS WITH TYPE 1 DIABETES USING A CLOSED-LOOP SYSTEM

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Background and Aims: The effect of dietary fat on glycemic excursions when using a closed-loop system is not well studied. We explored if glucose rates of change (ROC) could be used to detect high fat meals even when automated insulin delivery was used.

Methods: 110 participants with T1D (ages=3-61 years; M/F=60/50) were in outpatient, supervised clinical trials for 5 days. Carbohydrate, protein and fat content of each meal was recorded using food labels. Meals were excluded if: >20% of sensor data was missing or if additional correction boluses, meals, snacking, exercise occurred within 2h before to 3h after the meal. A total of 1166 meals were explored, 309 were analyzed. Meal classification was based on % of calories from fat and carbs: High Fat (HF, >30%) vs. Low Fat (LF); High Carb (HC, >45%) vs. Low Carb (LC). Glucose ROC was calculated from glucose sensor data using a regularized deconvolution method.

Results: Mean glucose ROC was significantly higher with HF meals compared to LF meals between 105-151 min, with a lesser shorter effect with LC vs. HC meals at 108-143 min. The fat content was the dominant contributor to this higher, late (124-138 min) ROC when comparing both HCHF and LCHF to HCLF meals (Fig.1).

Conclusions: Meals with high fat content cause higher ROC of glucose between 105 to 151 minutes, even with automated insulin delivery. These higher, late ROCs could be used to automatically increase controller aggressiveness to compensate for delayed meal absorption and insulin resistance following high fat meals.

P058 / #539

Topic: AS03-Artificial Pancreas

AUTOMATIC MEAL DETECTION AND ESTIMATION USING NEURAL NETWORKS

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Background and Aims: Continuous glucose monitors (CGM) have facilitated the development of diabetes management systems such as the artificial pancreas. A challenge in current artificial pancreas systems is the need to announce meals to enable tight glycaemic control. Automatic meal detection and estimation aims to reduce the burden of announcing meals to maintain tight glycaemic control.

Methods: We devise an algorithm based on convolutional recurrent neural networks (CRNN) for detection and estimation of meals. Using a multitask framework, a quantile regression provides a 20-minute glucose trajectory with prediction intervals [0.005 - 0.995]. A meal is detected once the real CGM value exceeds the upper bound of the glucose trajectory for 15 minutes (‘disturbance period’). A simple grid search is then performed to estimate the meal size; a correct meal is determined once the median glucose trajectory is approximately similar to the real glucose profile.

Results: The algorithm is evaluated on 10 simulated adults generated for 6 months (540 meals each), using the UVa-Padova simulator. We obtain precision (0.93 ± 0.05) and recall (0.83 ± 0.06) with a median delay of 37.00 ± 5.10 minutes for meal detection; and an average meal size error 22% ± 1%. The trade-off is also investigated between delay and precision for the set ‘disturbance period’.

Conclusions: Results strongly suggest that this meal detection algorithm can be incorporated in diabetes management systems to reduce the burden of glucose control in a Type 1 diabetes population. This approach outperforms similar approaches in the literature in terms of meal size error.

P059 / #543

Topic: AS03-Artificial Pancreas

INITIAL IMPACT OF THE TRANSITION TO TANDEM CONTROL-IQ ON SLEEP IN YOUTH WITH TYPE 1 DIABETES (T1D) AND THEIR PARENTS

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Background and Aims: Youth with T1D and their parents have frequent sleep disruptions resulting in decreased sleep duration compared to peers. We conducted an observational study of youth with T1D and their parents to determine the impact of transition to the Tandem Control-IQ (CIQ) system on sleep.

Methods: Actigraphy watches were used for objective sleep measurements, including total sleep time, sleep efficiency, and wake after sleep onset. Subjective sleep diaries provided the number of and reasons for nocturnal awakenings. Data analyses compared measurements from one week before starting CIQ (baseline) to one week after starting CIQ.

Results: Twenty-six youth-parent dyads were enrolled. Youth were age 11 ± 4 years, 50% male with T1D duration median (IQR) 2.0 (0.6, 4.8) years, HbA1c 7.4 ± 1.3%. On average, parents reported two fewer nocturnal awakenings during the first week of CIQ use compared to baseline (Table; p = 0.03). Parents and youth had objective decreases in total sleep time (mean 16 and 21 minutes, respectively) but this was only significant for youth (p = 0.005). No other significant changes occurred in the first week of CIQ use.

Conclusions: Transition to a new diabetes device can be a difficult time for youth with T1D and their parents. In this evaluation, parents reported significantly fewer nocturnal awakenings during the week after CIQ initiation. Youth sleep duration showed a significant decrease which warrants further exploration. While the initial transition to CIQ appears to not cause significant nocturnal awakenings, long term follow-up and a larger cohort is needed to assess the impact over time.

P601 / #628

Topic: AS03-Artificial Pancreas

GENERATION OF REALISTIC SCENARIOS INCLUDING INSULIN VARIABILITY AND MIXED MEAL LIBRARY

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Background and Aims: In-silico simulations have become essential for the development of diabetes treatments. However, most currently available simulators are not challenging enough coupled with limitations on insulin and meal absorption variability do not reflect real patients. The objective of this work is to develop a method for generating cohorts that include physiological variations and realistic scenarios, incorporating basal insulin patterns identified from the literature and to incorporate a library of challenging mixed meals.

Methods: Using the published probability distributions of the Hovorka model, multiple independent sets of parameters that represent a population are generated, these are obtained by generating random samples according to the univariate and multivariate distributions. Then, valid patients are filtered through restrictions that guarantee an acceptable physiological behavior for patients with type 1 diabetes. To obtain more realistic scenarios, basal insulin profile patterns from the literature have been used to identify variability on insulin sensitivity and has been included in the scenario generation. In addition, a mixed meal library has been included. In-silico tests are performed to evaluate the results.

Results: Using the proposed methodology a cohort of 47 virtual patients have been developed. The simulation results
using such cohort show that the glycemic response is compatible with clinical parameters obtained from real patients.

Conclusions: The proposed method allows creating realistic cohorts of virtual patients that include physiological variability and simulate more realistic scenarios for in silico tests.

P062 / #630

Topic: AS03-Artificial Pancreas

INCORPORATING LONG-ACTING INSULIN INTO THE HOVORKA MODEL FOR IN SILICO SIMULATIONS OF MDI THERAPIES IN T1DM PATIENTS

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Background and Aims: Glargine 100U/mL (Gla-100) and 300U/mL (Gla-300) are long-acting insulin analogues that provide basal insulin delivery in multiple daily injection (MDI) therapy for type 1 diabetes (T1D). In 2018, a subcutaneous (sc) absorption model of these insulin analogues was incorporated for the UVA/Padova simulator. Therefore, the objective of this work is to incorporate a Glargine sc insulin absorption subsystem into the Hovorka model as a simulation tool to evaluate different MDI therapies with Gla-100 and Gla-300.

Methods: The model of Dalla Man and Hovorka was analyzed and similarities were found in that both have compartmental models of glucose and insulin, this allowed incorporating the pharmacokinetic model (PK) of Glargine to the Hovorka model. A cohort of 47 virtual patients was simulated replicating the reported scenario and the results obtained for plasma insulin concentration and glucose were compared with those obtained in the literature.

Results: With the incorporation of the Glargine PK model into the Hovorka model, the responses of the glucose and insulin subsystems are similar to those reported in the literature.

Conclusions: The feasibility to use the Hovorka model with long-acting insulin analogues in simulation has been assessed. The proposed implementation enables in silico simulations of MDI therapies using the Hovorka model with a Glargine PK model.

P063 / #663

Topic: AS03-Artificial Pancreas

INTRAPERITONEAL MODEL OF INSULIN KINETICS IN TYPE 1 DIABETES

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Background and Aims: Intraperitoneal (IP) insulin delivery has been shown to improve glycemic control in type 1 diabetes (T1D) by providing faster insulin absorption route. During 1-day CL treatment, IP insulin delivery has been shown to improve glycemic control without the need for meal announcement (Dassau et al., 2017). Herein, we develop a model of IP insulin kinetics to design a long-term IP controller.

Methods: Data were collected from nine adults with T1D who underwent 1-days CL using DiaPort IP system and Zone-MPC algorithm. Participants were previously described in Dassau et al. (2017). We tested two IP insulin kinetics models. Model A has 4-compartments: peritoneum, liver, plasma and periphery (Figure 1); Model B differs from Model A since it includes 2 cascade-compartments to describe peritoneum. Each model was identified with a Maximum a-Posteriori (MAP) Bayesian estimation and criteria for model comparison were based on model fit, precision of parameters estimates and Generalized Information Criterion (G-IC).

Results: Model A performed better than Model B in terms of precision of estimates with a slightly lower G-IC. Since Model A has 1 compartment & 1 parameter less than Model B, Model A was chosen. Figure 2 displays model fit against data and compartment masses in a representative participant.

Conclusions: We developed a novel IP insulin kinetics model which will be included into the UVa/Padova T1D simulator to test in silico new long-term artificial pancreas IP controller. The present work was supported by H2020-FETPROACT Project FORGETDIABETS, n. 951933.
Background and Aims: Diabetes devices improve glycemic control and quality-of-life outcomes, yet uptake has been too low to show changes to population-level outcomes. DiabetesWise.org is a free, unbranded resource to promote device awareness and uptake. This real-world study examined the impact of DiabetesWise.org. Participants provided consent to track their website use and utilization of site features, complete validated surveys and mail-in A1c kits to a central lab.

Methods: Participants (n = 475, age 37.0 ± 9.74, 66.3% female, 81.1% Non-Hispanic white, 80.8% T1D, 19.2% T2D) interacted with DiabetesWise.org in an unstructured fashion following standardized study onboarding. Most participants (76%) used syringe/pen as the primary insulin delivery method; 59% used CGM intermittently (4 or fewer days/week) and 39% never used CGM. A1c kits were completed within 30 days of enrollment and 3 months later. Monthly questionnaires tracked device discussions with providers, new device prescriptions, and device initiation.

Results: At 1 month (n = 405), 25% reported device discussion, 10% received prescriptions, and 5% started new devices. During month 2 (n = 398), 27% reported discussion, 11% received prescriptions, and 8% started new devices. During month 3 (n = 319), 22% reported discussion, 9% received prescriptions, and 9% started new devices. A1c results are available for 36 participants and this subset was representative of the larger sample. Paired t-tests showed a significant difference between A1c values at baseline (7.93 ± 1.94%) and month 3 (7.28 ± 1.70%); t(35) = 3.58, p = 0.001.

Conclusions: Results indicate use of Diabeteswise.org accelerates device discussion and uptake, and preliminary data suggest reduced A1c values. Continued efforts may produce population-level improvements among people living with insulin-requiring diabetes.

P065 / #89

Topic: AS04-Clinical Decision Support Systems/Advisors

THE RELATIONSHIP BETWEEN HAND GRIP STRENGTH AND ANKLE JOINT MOBILITY IN YOUNG PEOPLE WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Young patients with Type 1 Diabetes Mellitus (T1DM) can show limited joint mobility, a dreaded complication that can affect the quality of posture and movement. The aim of this study was to investigate the role of muscle strength in the definition of ankle joint mobility (AJM) of patients with T1DM.

Methods: In 31 young male patients with T1DM mean age 12.9 ± 3.3 yrs, T1DM duration 6.1 ± 3.7 yrs, HbA1c 7.4 ± 0.8%, body mass index (BMI) 19.7 ± 3.9 Kg/m², and in 65 subjects matched for age BMI and sex, the AJM in both plantar flexion and dorsiflexion (inclinometer), the handgrip strength (HGS; dynamometer), and the trunk flexibility (Sit and Reach Test) were evaluated.

Results: The AJM value detected in the patient group compared to that of the controls was lower without reaching statistical significance (132.0 ± 20.3° vs 136.4 ± 21.3°). Multivariate analysis showed a significant effect of HGS on AJM (p < 0.05). However, only in the control group HGS significantly affects the Total AJM (p = 0.013) and ankle dorsiflexion (p < 0.08) but not the plantar flexion. In the control group Spearman’s correlation analysis showed an inverse correlation between HGS and ankle dorsiflexion (p = 0.013) and total AJM (p = 0.027), no correlation between AJM and HGS was found in the group of subjects with diabetes. Patients and control groups showed HGS values similar and directly correlated with age, and BMI (p < 0.001).

Conclusions: A significant relationship between HGS and ankle mobility was found only in the control group. The presence of diabetes seems to modify the normal relationship between the development of muscle strength and ankle joint mobility.

P066 / #156

Topic: AS04-Clinical Decision Support Systems/Advisors

MODEL-FREE INFERENCE OF INFORMATION FLOW AMONG PHYSIOLOGICAL SIGNALS IN TYPE 1 DIABETES SUBJECTS USING MULTIVARIATE TRANSFER ENTROPY

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Background and Aims: The complexity and inter-subject variability of the glucoregulatory system calls for the integration of additional physiological signals in the daily management of glycaemia in Type 1 Diabetes (T1D). The aim of this study was to explore the Information Flow (IF) among different physiological signals in T1D subjects.

Methods: The OhioT1DM dataset was used for the analysis, where Continuous Glucose Monitoring (CGM), insulin delivery, meals, Galvanic Skin Response (GSR), skin temperature, and Heart Rate (HR) information was available for six weeks. The Multivariate Transfer Entropy (MTE) technique was used to construct subject-specific network graphs and infer the existence, direction, and time lag of IF between the aforementioned parameters.

Results: Preliminary results from six subjects showed a consistent IF from HR to GSR. Moreover, an IF from HR to CGM was observed in all except one subject. Other IF relations varied among subjects and this fact could be attributed to individual differences in insulin treatment, insulin sensitivity, lifestyle, and biological variability.

Conclusions: MTE is a valuable model-free tool to estimate IF in complex multivariate time-series. Our analysis demonstrated relations among the considered physiological signals in T1D subjects. As a next step, additional subjects will be evaluated, and an interpretation framework will be designed to associate the found relations to individual characteristics, in particular CGM. Knowledge of these inter-relations can deepen the understanding of the glucoregulatory system and the design of personalised modelling and treatment solutions. Acknowledgement - This research was funded by the Australian National University and the Our Health in Our Hands initiative.
Topic: AS04-Clinical Decision Support Systems/Advisors

PEOPLE WITH DIABETES AND CAREGIVERS PREFER NASAL GLUCAGON OVER CONVENTIONAL INJECTABLE GLUCAGON: A DISCRETE CHOICE EXPERIMENT

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Background and Aims: A discrete choice experiment (DCE) was utilized to evaluate preferences for the actual treatment features and overall profiles of two glucagon rescue medications (nasal glucagon and conventional injectable glucagon, with comparable efficacy) for severe hypoglycemia, among people with type 1 diabetes or type 2 diabetes on insulin (P WD) and caregivers (CGs) in Spain.

Methods: The online DCE examined 7 attributes of rescue treatment: ‘glucagon preparation’, ‘preparation time’, ‘delivery method’, ‘recovery time’, ‘size’, ‘storage temperature’, and ‘headache risk’. Part-worth utilities were estimated using a conditional logit model to calculate relative importance. A Chi-square test was used to determine differences in preferences for nasal vs. injectable glucagon profiles, with and without ‘successful administration’ included.

Results: Data for 546 adults (mean age 40 years; 51% female) were included in the analysis (276 PWD/270 CGs; 58% Type 1). Attributes ‘storage temperature’ and ‘delivery method’ had the highest relative importance in the overall sample. In a head-to-head comparison, significantly more participants preferred the nasal glucagon profile: 78% with the additional attribute ‘successful administration’ (63% without) compared to the injectable glucagon profile (22% and 37%, p < 0.001).

Conclusions: This study elicited PWD and CGs’ preferences for attributes representing the actual characteristics of two glucagon rescue medications. In this context, results suggest that when efficacy is comparable, other treatment features (e.g., successful administration, storage temperature and delivery method) are of more importance to PWD and CGs, driving the overall preferences favoring nasal glucagon over conventional injectable glucagon as a rescue medication for severe hypoglycemia.

Topic: AS04-Clinical Decision Support Systems/Advisors

PERSONALIZED BLOOD GLUCOSE PREDICTION FOR TYPE 1 DIABETES WITH DEEP NEURAL NETWORKS AND ATTENTION MECHANISM

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Background and Aims: Accurate blood glucose (BG) prediction would enable the proactive treatment for people living with diabetes. In recent literature, various deep learning methods have achieved reliable BG prediction for type 1 diabetes (T1D) management. In general, the models are trained by supervised learning to obtain optimal weights of deep neural networks (DNNs) with random initial states. However, this process often requires a large subject-specific dataset from a long-term clinical trial. It is difficult for a well-trained model to generalize physiological features among different subjects, due to high inter-subject variability.

Methods: In this work, we propose a model-agnostic meta-learning (MAML) framework to learn the generalized patterns and predict BG levels for new T1D subjects without further tuning. Each subject in a population dataset is regarded as a learning task to guide meta-optimization via stochastic gradient descent. In the experiments, we build a fully-connected feed-forward DNN with three hidden layers and use the OhioT1DM dataset with 12 T1D subjects. A generalized model is trained by meta-learning with the data of 11 subjects and then tested on the rest subject. For each subject, we repeat this process with 10 random initialization and report the average result.

Results: For a 30-minute prediction horizon, the MAML model achieved the average root mean square error of 24.8 ± 4.31 mg/dL with the mean absolute error of 18.9 ± 4.15 mg/dL.

Conclusions: Compared to random DNN models, the proposed algorithm obtains good prediction performance and has great potential to accelerate the supervised learning in actual clinical settings.

Topic: AS04-Clinical Decision Support Systems/Advisors

BLOOD GLUCOSE PREDICTION FOR TYPE 1 DIABETES WITH POPULATION DATA AND MODEL-AGNOSTIC META-LEARNING

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Background and Aims: In recent literature, deep learning techniques have been widely investigated in the field of blood glucose (BG) prediction for type 1 diabetes (T1D). The use of continuous glucose monitoring (CGM) has generated a large amount of data. In this regard, recurrent neural networks (RNNs) have achieved promising performance with the advanced structures, such as long short-term memory and gated recurrent units. However, the stack of recurrent cells limits the interpretability of the models, while the gated operations lead to high computational complexity for each layer. Thus, it is difficult to implement RNNs in resource-constrained devices, e.g., wearables used for diabetes management.

Methods: In this work, we propose a novel BG prediction model based on deep neural networks (DNNs) and multi-head self-attention mechanism. Inspired by the recent success of deep transformer, we incorporate the CGM time series with the positional encoding and then feed it to a self-attention layer to
calculate the attention weights by scaled dot product. With a residual connection, the output is then processed by two dense layers. We train and test the personalized models on the OhioT1DM dataset with 12 T1D subjects.

**Results:** Compared to the traditional DNN baseline, the attention mechanism reduced the average root mean square error from 20.00 ± 2.33 to 19.40 ± 2.20 mg/dL, and 34.00 ± 4.07 to 32.76 ± 3.56 mg/dL for 30-minute and 60-minute prediction horizons, respectively.

**Conclusions:** The proposed algorithm achieves good prediction accuracy with few operations and a simple architecture. The attention distribution patterns are also available to improve model interpretability.

**P070 / #221**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**IMPACT OF A DIGITAL THERAPEUTIC ON INSULIN SELF-MANAGEMENT**

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**Background and Aims:** Effective therapy reduces disease burden and economic impact in Diabetes Mellitus. Insulin is the most effective antihyperglycemic treatment in patients with type 2 diabetes. Adherence to self-monitoring and the avoidance of hypoglycemia are critically important for patients using insulin. Dario, a digital diabetes management platform, may assist patient titration of basal insulin to achieve optimal outcomes.

**Methods:** A retrospective study was performed on a population of 285 active Dario users (85% with type 2) under insulin therapy, that measured with Dario for at least three months and logged basal insulin usage. The group included 112 users whose starting average blood glucose >180 mg/dL. Among this group the average age was 55. The group also included 173 users whose starting average blood glucose was <180 mg/dL with average age 59. First month measuring on platform was used as study baseline.

**Results:** In the sub-group of 112 users the average amount of basal insulin increased by six units after three months (45 vs. 39). Their fasting blood glucose was significantly reduced (9%) after three months (186 ± 40.6 vs. 204 ± 42.7) without change in hypoglycemia events ratio (<70 mg/dL) on average, and 15% of the users reduced their fasting average to <126 mg/dL. However, in the sub-group of 173 users, basal insulin usage and fasting glucose levels remained stable following three months.

**Conclusions:** To conclude: This observational study demonstrates the potential benefit of a digital diabetes management platform in the self-management required from insulin treated users, incorporating its use on a daily base, and sustaining behavioral change.

**P071 / #224**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**PREDICTING TREATMENT OUTCOME OF TYPE 2 DIABETES PATIENTS INITIATING ONCE-DAILY BASAL INSULIN INJECTION**

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**Background and Aims:** The decision to intensify the treatment with basal insulin for T2D patients on unsuccessful oral treatment is made by the patient’s HCP. The aim of this study was to examine to what extent 12 weeks of average pre-breakfast SMPG profile, post-treatment initiation, would enhance the ability to predict treatment outcome after six months beyond what can be predicted based on data at treatment initiation baseline.

**Methods:** Clinical data were acquired from three different trials with a total of 149 poorly regulated T2D patients (HbA1c ≥ 7%) on oral treatment initiating basal insulin treatment. Logistic regression (LR) was used in a repeated stratified cross-validation setup to train and evaluate the performance predicting the binarized HbA1c value after six months as either acceptable (HbA1c < 7%) or poor (HbA1c ≥ 7%). The predictive performance using as inputs HbA1c, demographics, and expert-dependent CGM metrics at baseline were contrasted performance additionally including 12 weeks 1-point SMPG profile (average of three consecutive pre-breakfast measurements before clinical visits/phone contact with HCP intended for optimal dose adjustments).

**Results:** Adding 12 weeks of 1-point SMPG profile as input to the LR model improve on average upon treatment outcome prediction accuracy when compared to using only baseline data as input.

**Conclusions:** The results obtained indicate improved performance in terms of prediction accuracy when enhancing the input to the prediction models with 12 weeks of 1-point SMPG profile on top of the baseline data. This points to the utility of SMPG for the assessment of basal treatment outcome.

**P072 / #246**

**Topic:** *AS04-Clinical Decision Support Systems/Advisors*

**SIMPLE FORMULAS TO PREDICT QUANTITATIVE IMPACT OF MEAL INSULIN BOLUS TIMING ON GLYCEMIC CONTROL INDECES IN TYPE 1 DIABETES**

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**Background and Aims:** Meal insulin bolus (MIB) timing is known to significantly impact post-prandial blood glucose concentration in T1D. Here we quantify the strength of MIB timing impacts on three widely-used glycemic control indices by developing simple formulas predicting how these indices change in response to MIB timing variations.

**Methods:** The T1D patient decision simulator (Vettoretti et al., IEEE TBME, 2018) is used to simulate 7-day glycemic profiles of 100 virtual T1D adults. The simulation is repeated for different values of MIB timing: at the meal start (reference) and 40, 30, 20 and 10 min before/after the meal start. Then, TIR (time
in target range 70-180 mg/dl), TAR (time above range) and TBR (time below range) are computed in the daytime period (06:30am-11:59pm). Finally, three linear regression models are identified to put the difference in TIR, TAR and TBR (w.r.t. reference) in relation with the difference in MIB time (w.r.t. reference).

Results: Between 20 min before and 20 min after meal, MIB timing and control indices turn out to be linearly related ($R^2=0.95$), with slope coefficients given by $\beta_{\text{TIR}}=-0.12$, $\beta_{\text{TAR}}=0.10$, $\beta_{\text{TBR}}=0.02$. It follows that, for example, a MIB given 20 min before meal results, on average, in 2.4% more TIR, 2% less TAR and 0.4% less TBR, compared to mealtime MIB.

Conclusions: Simple formulas quantifying the impact of MIB timing on glycemic control indices have been obtained. Possible applications include decision-support tools for providers and educational tools for T1D subjects. This work has been supported by Hypo-Resolve project (grant agreement No 777460).

P073 / #251

Topic: AS04-Clinical Decision Support Systems/Advisors

THE PREVALENCE OF NAFLD IN A COHORT OF TYPE 1 DIABETES SUBJECTS BASED ON NON-INVASIVE ASSESSMENT AND ITS ASSOCIATION WITH MACROVASCULAR EVENTS

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Background and Aims: Nonalcoholic fatty liver disease (NAFLD) is characterised by hepatic steatosis. The association between NAFLD and cardiovascular disease has been observed in type 2 diabetes but data in type 1 diabetes (T1D) are scarce. This study aimed to compare the prevalence of NAFLD according to ultrasound (US), fatty liver index (FLI) and controlled attenuation parameter (CAP) and evaluate the association with prevalent macrovascular disease.

Methods: Adult T1D subjects were consecutively screened for NAFLD using US, FLI and CAP. Cardiovascular events were defined as having a coronary, peripheral arterial or cerebrovascular event. Causes of secondary liver disease including excess alcohol intake were excluded.

Results: 400 adult subjects were included (age 47±30y, HbA1c 7.4±1.0%, BMI 26.2±5.2kg/m², diabetes duration 27±14y). The prevalence of NAFLD was 22.8% (US), 22.3% (FLI≥60), and 34.6% (CAP≥248dB/m). Furthermore, 27 (6.8%) coronary, 18 (4.5%) peripheral arterial, 9 (2.3%) cerebrovascular and 44 (11.0%) composite events were documented. NAFLD defined by either US (OR 2.18 [1.07-4.44], p=0.032) or FLI (OR 2.78 [1.39-5.56], p=0.004), but not by CAP was independently associated with prevalent macrovascular disease.

Conclusions: Non-invasive tools diagnose NAFLD in T1D in 22–23% using US or FLI but in 35% using CAP, illustrating the need for consensus. NAFLD based on US and FLI, but not on CAP is independently correlated with prevalent cardiovascular events.
families and the health team could act upon alarm symptoms Prevent DKA re-admission in children and adolescents with T1D through the DE program protocol incorporating WA tool.

Methods: WA tool was added to the educational program with 5 modules of structured DE, throughout the year (3 doctors, diabetes educator and a nutritionist in the group). The groups made communications before the appearance of alarm symptoms activating the protocol which they had been trained (capillarization, measurement ketones, fluids, electrolyte replacement, insulin corrections). The evaluation was classified according to the risk of decompensation: no risk, medium and high risk according to symptoms, ketones and response to treatment as well as the number of patients readmitted for DKA.

Results: A chat of 92 participants arrived: 78 parents and 14 adolescents. 54 parents of children under 12 years of age, 24 parents and 14 adolescents. There were: 91 interactions, 81 ketosis mild (46), moderate (21) and high (9) risk of DKA. 30 hospitalizations and 46 ketosis were avoided. There were 3 hospitalizations which coincide with lack of adherence to the program, absent 75% of the education workshops.

Conclusions: DE is the treatment of diabetes. Families who attend present a greater opportunity in making decisions to prevent DKA. The WS tool was a rapid strategy that showed prevention and no progression to DKA with re-hospitalization.

P076 / #369

Topic: AS04-Clinical Decision Support Systems/Advisors

IMPROVED GLYCEMIC CONTROL AND PREVENTION OF ACUTE HOSPITAL ADMISSIONS BY USING A DIGITAL WORKFLOW AND DECISION SUPPORT SYSTEM IN HOME HEALTH CARE

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Background and Aims: International guidelines recommend simple and individualized treatment regimens for geriatric people with type 2 diabetes mellitus (T2D). A basal or basal-plus insulin algorithm integrated into a digital workflow and decision support system (GlucoTab®MobileCare) has been tested in geriatric people with T2D receiving home health care. The aim of this retrospective analysis was to collect data on blood glucose (BG) control and acute hospital admissions.

Methods: Patients were treated with GlucoTab®MobileCare using basal or basal-plus insulin therapy at home for three months. The GlucoTab®MobileCare system was run by domiciliary nurses who visited the patients on a daily basis. Data from electronic health records and BG documentation were collected three months during, six months before and six months after the intervention.

Results: Nine patients (5 female, age 77±10 years, BMI 27.7±4.7 kg/m², HbA1c 60±13 mmol/mol (start of intervention) vs. 57±12 mmol/mol (end of intervention)) were analysed. Results regarding BG control are presented in the Figure. While using GlucoTab®MobileCare no hypo- or hyperglycemia-related acute hospital admission occurred. Six months prior to intervention eight, and six months after intervention four diabetes-related emergency room visits occurred; nine due to hyperglycemia and one due to hypoglycemia. Nine of the twelve admissions resulted in hospitalizations.

Conclusions: Using GlucoTab®MobileCare, glycemic control improved without relevant hypoglycemia/hyperglycemia and acute hypo- or hyperglycemia-related hospital admissions were prevented. A positive effect on BG control could be observed in the six months following the intervention, as in most cases the optimized therapy regimen was continued.

P077 / #414

Withdrawn
Clinical Decision Support System for Personalized Therapy Children with Type 1 Diabetes Mellitus

E. Trufanova, D. Sorokin, O. Rebrova, D. Laptev, V. Peterkova

Background and Aims: The use of machine learning methods in medical practice is increasing every year and development of an advanced clinical decision support system (CDSS), automatically evaluating and optimizing therapy, is a promising research direction. Development and implementation of the machine-learning algorithm for insulin therapy optimization for T1DM children during outpatient visits.

Methods: A retrospective study was performed on a population of 246 Dario active members who had not measured blood glucose for a 7-day period. 127 of these users were randomly assigned to a Test group and experienced a digital intervention flow, and the remaining 119 users were assigned to a Control group. Digital engagement levels were observed following 60 days in both groups.

Results: Differences between Test group and Control group were observed. In the Test group, the percent of users who measured blood glucose was significantly higher (P < 0.001): 14% in first 30 days and 22% in 30–60 days; average number of measurements was 6% higher in the first 30 days and 17% in 30–60 days; number of interactions (e.g. logging fasting glucose) with the digital platform was 10% higher in first 30 days and 15% in 30–60 days. Difference in average days between measurements, defined as “recency” was 30% lower in the test group.

Conclusions: This observational study demonstrates the potential benefit of implementing a digital diabetes interaction platform to durably improve self-management among users who had not recently measured their blood glucose.
INITIATION IN SUBJECTS WITH TYPE 2 DIABETES

A-105

Personalized Insulin Bolus Therapy INITIATION IN SUBJECTS WITH TYPE 2 DIABETES

R. Visentin1, D. Herzig2, L. Bally2, C. Dalla Man1

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Background and Aims: People with advanced-stage type 2 diabetes (T2D) require exogenous insulin to control blood glucose. For insulin-naive patients, ADA 2017 guidelines recommend a fixed prandial insulin dose of 4U. After initiation, optimal therapy requires successive adjustments of insulin-to-carbohydrate ratio (CR) and correction factor (CF) based on individual characteristics and habits. To facilitate such time-consuming task, here we propose a method for personalizing CR and CF initiation.

Methods: Fifteen subjects with T2D (age = 59 ± 11 y, BMI = 35 ± 9 kg/m², HbA1c = 8 ± 1 %) received 22 hours of fully automated closed-loop insulin therapy with standardized meals. We estimated subjects’ CR and CF by reversing the optimal insulin bolus calculation (using the insulin dose infused over 3 hours following meal intake) and the 1700 rule, respectively. Then, we tested if subjects’ age, BMI and HbA1c could predict CR and CF and are thus usable for initializing insulin bolus therapy in insulin-naive subjects. Finally, we assigned the predicted CR and CF to the 100 in silico subjects of Padova T2D simulator (Visentin et al., Diabetes Technol. Ther., 2020) and performed a 2-week, 3-meal/day, three-arm virtual trial comparing personalized initiation therapy, ADA standard therapy and control (no prandial insulin).

Results: CR and CF showed significant correlations with BMI (R = -0.60, p-value = 0.04 and R = -0.76, p-value <0.01, respectively). Simulated glucose control metrics are reported in Table 1.

Conclusions: Use of BMI-predicted CR and CF improved postprandial glucose control safely over standard therapy. If confirmed in vivo, the proposed method might improve and facilitate prandial insulin therapy initiation in subjects with T2D.

P081 / #575

Topic: AS04-Clinical Decision Support Systems/Advisors

PERSONALIZED INSULIN BOLUS THERAPY INITIATION IN SUBJECTS WITH TYPE 2 DIABETES

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1University of Padova, Department of Information Engineering, Padova, Italy, 2Inselspital, Bern University Hospital, Department of Diabetes, Endocrinology, Nutritional Medicine and Metabolism, Bern, Switzerland

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Methods: Fifteen subjects with T2D (age = 59 ± 11 y, BMI = 35 ± 9 kg/m², HbA1c = 8 ± 1 %) received 22 hours of fully automated closed-loop insulin therapy with standardized meals. We estimated subjects’ CR and CF by reversing the optimal insulin bolus calculation (using the insulin dose infused over 3 hours following meal intake) and the 1700 rule, respectively. Then, we tested if subjects’ age, BMI and HbA1c could predict CR and CF and are thus usable for initializing insulin bolus therapy in insulin-naive subjects. Finally, we assigned the predicted CR and CF to the 100 in silico subjects of Padova T2D simulator (Visentin et al., Diabetes Technol. Ther., 2020) and performed a 2-week, 3-meal/day, three-arm virtual trial comparing personalized initiation therapy, ADA standard therapy and control (no prandial insulin).

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Conclusions: Use of BMI-predicted CR and CF improved postprandial glucose control safely over standard therapy. If confirmed in vivo, the proposed method might improve and facilitate prandial insulin therapy initiation in subjects with T2D.

P082 / #576

Topic: AS04-Clinical Decision Support Systems/Advisors

IMPACT OF CARBOHYDRATE COUNTING ERROR ON GLUCOSE CONTROL DURING INSULIN THERAPY IN TYPE 2 DIABETES

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Background and Aims: Carbohydrate estimation for prandial insulin dosing is important in type 1 diabetes therapy but its relevance for postprandial glucose (PPG) control in people with type 2 diabetes (T2D) with residual insulin secretion is less clear. Here we investigate the impact of carbohydrate counting error (CC error) on PPG control in insulin-naive T2D subjects.

Methods: Four 2-week 3-meal/day scenarios were simulated in 100 insulin-naive T2D subjects of the Padova T2D Simulator. Daily meal carbohydrate distribution was taken from individual food records collected in a T2D cohort (Banholzer et al., Diabetes Obes. Metab., 2020). Each prandial insulin bolus was determined based on subjects’ CR and CF, assuming error-free carbohydrate estimation (CC error = 0%), or random carbohydrate over- and under-estimations (CC error = ±10%, ±20%, ±30%). PPG control was assessed in each scenario by calculating standard metrics of glucose control over 3 hours following meal administration.

Results: Random carbohydrate over- and under-estimations resulted in a progressive significantly higher variability of almost all the metrics compared to perfect carbohydrate estimation, with consequent larger ranges for both time in hyperglycemia and time in hypoglycemia Table 1). In particular, using CC error = ±30%
Table 1: Glucose control metrics assessed during 2-week 3-meal/day in silico trial with different carbohydrate estimation errors

<table>
<thead>
<tr>
<th>Outcome</th>
<th>CCerror</th>
<th>0%</th>
<th>±10%</th>
<th>±20%</th>
<th>±30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean BG (mg/dL)</td>
<td>146 [139, 158]</td>
<td>146 [138, 159]</td>
<td>146 [138, 156]</td>
<td>147 [138, 159]</td>
<td></td>
</tr>
<tr>
<td>SD BG (mg/dL)</td>
<td>29 [21, 31]</td>
<td>29 [21, 32]</td>
<td>29 [21, 32]</td>
<td>27 [22, 32]</td>
<td></td>
</tr>
<tr>
<td>% BG 70-180 mg/dL</td>
<td>85 [74, 92]</td>
<td>84 [73, 91]</td>
<td>84 [73, 91]</td>
<td>82 [73, 90]</td>
<td></td>
</tr>
<tr>
<td>% BG 70-140 mg/dL</td>
<td>40.9 [31, 55]</td>
<td>40.3 [32, 58]</td>
<td>40.3 [32, 58]</td>
<td>40.8 [31, 53]</td>
<td></td>
</tr>
<tr>
<td>% BG &lt;70 mg/dL</td>
<td>0.2 [0.0, 1.1]</td>
<td>0.2 [0.0, 1.5]</td>
<td>0.2 [0.0, 1.5]</td>
<td>0.3 [0.0, 2.0]</td>
<td></td>
</tr>
<tr>
<td>% BG &gt;500 mg/dL</td>
<td>0.0 [0.0, 0.2]</td>
<td>0.0 [0.0, 0.4]</td>
<td>0.0 [0.0, 0.4]</td>
<td>0.0 [0.0, 0.6]</td>
<td></td>
</tr>
<tr>
<td>% BG &gt;50 mg/dL</td>
<td>0.0 [0.0, 0.0]</td>
<td>0.0 [0.0, 0.1]</td>
<td>0.0 [0.0, 0.1]</td>
<td>0.0 [0.0, 0.1]</td>
<td></td>
</tr>
<tr>
<td>% BG &gt;250 mg/dL</td>
<td>0.0 [0.0, 0.9]</td>
<td>0.0 [0.0, 1.0]</td>
<td>0.0 [0.0, 1.0]</td>
<td>0.0 [0.0, 1.2]</td>
<td></td>
</tr>
<tr>
<td>% BG &gt;300 mg/dL</td>
<td>0.0 [0.0, 0.0]</td>
<td>0.0 [0.0, 0.0]</td>
<td>0.0 [0.0, 0.0]</td>
<td>0.0 [0.0, 0.0]</td>
<td></td>
</tr>
<tr>
<td>T2D (%)</td>
<td>26 [9, 40]</td>
<td>26 [9, 40]</td>
<td>26 [9, 40]</td>
<td>26 [9, 40]</td>
<td></td>
</tr>
</tbody>
</table>
| BG-based outcome metrics are reported as median [25%, 75%] percentile. Statistical comparisons are performed by Wilcoxon signed rank test (*: p-value<0.05 compared to optimal bolus (CCerror=0%). BG: blood glucose; SD: standard deviation; T2D: total daily prandial insulin bolus).

led to a significantly increase in time in hypoglycemic range (e.g., percent time PPG<70 mg/dL=0.3 [0.0, 2.0]).

Conclusions: CCerror within the range of 20% had no clinically relevant impact on PPG control, likely due to residual endogenous insulin secretion. Conversely, worsening of PPG control was noted for larger CCerror. These results suggest that people with T2D using bolus insulin therapy may improve diabetes management if trained to estimate meal carbohydrate content with error less than 20%.

P083 / #603
Topic: A04-Clinical Decision Support Systems/Advisors
PREVALENCE AND CLINICAL CHARACTERISTICS OF NON-ALCOHOLIC FATTY LIVER DISEASE IN NEWLY DIAGNOSED TYPE 2 TUNISIANS DIABETES PATIENTS WITH KETOSIS-ONSET DIABETES
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Background and Aims: Aim As the prevalence and clinical characteristics of non-alcoholic fatty liver disease (NAFLD) are still unknown in ketosis-onset diabetes, the present study compared the characteristics of NAFLD in ketosis-onset and non-ketotic type 2 diabetes (T2D) patients.

Methods: This cross-sectional study was performed with newly diagnosed Tunisians patients with type 2 diabetes, including 54 ketosis-onsets and 64 non-ketotic T2D, with 66 non-diabetics included as controls. NAFLD was determined by hepatic ultrasonography, then its clinical features were analyzed and its associated risk factors evaluated.

Results: NAFLD prevalence in patients with ketosis-onset diabetes (59.25%) was significantly higher than in controls (36.36%; p=0.001). However, there was no difference in prevalence between ketosis-onset and non-ketotic T2D patients (60.93%; p=0.382), although waist size, BMI and alanine aminotransferase (ALT) proved to be independent risk factors for the presence of NAFLD in both these groups whereas.

Conclusions: Conclusion NAFLD prevalence and risk factors in ketosis-onset diabetes were similar to those in non-ketotic T2D. These data provide further evidence that ketosis-onset diabetes should be classified as a subtype of T2D.

P085 / #619
Topic: A04-Clinical Decision Support Systems/Advisors
INSULIN ON BOARD AND INSULIN PHARMACOKINETICS CURVE ALGORITHMS FOR PEOPLE WITH TYPE 1 DIABETES USING FIASP® AND NOVORAPID®
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1Novo Nordisk Research Center Seattle, Inc., Dtx Research & Innovation, Seattle, United States of America, 2Novo Nordisk A/S, Dtx & Design Controls, Scientific Modelling, Søborg, Denmark, 3Novo Nordisk A/S, Medical & Science Devices & Digital Health, Søborg, Denmark

Background and Aims: We developed and tested algorithms to calculate insulin on board (IOB) and insulin pharmacokinetics...
(PK) curve for people with Type 1 Diabetes using NovoRapid® and FIASP®, bolus insulins. IOB is a quantification of insulin units that are present in the patient’s body and the PK curve is a representation of the plasma insulin concentration (PIC) over a given time period.

**Methods:** We used a three-compartmental physiological insulin absorption model (PIAM) to obtain IOB and PK curve based on different duration of actions (DOA) for NovoRapid® and FIASP®. Seven sets of model parameters for DOAs of [2hr, 3hr, 4hr, 5hr, 6hr, 7hr, 8hr] are proposed for each insulin type. The IOB and PK curve algorithms were developed, tested, and validated based on clamp studies containing PIC measurements and glucose infusion rates. The selected PIAM was fitted to the PIC measurements from adult cohorts (training datasets) to find appropriate model parameters for each DOA and insulin type. The algorithms’ performance was validated through cross-validation using clamp studies for adult and paediatric cohorts (validation datasets) that were not included in training datasets.

**Results:** IOB and PK curves were compared based on pre-specified and fitted model parameters. The mean absolute percentage error and absolute error for IOB values are below 3.6% and 0.1 [U], respectively. Moreover, the mean absolute error for the peak PIC time is below 4 minutes.

**Conclusions:** The algorithms can calculate the IOB and PK curves based on known DOAs with high precision for diabetes management applications.

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**P086 / #632**

**Topic:** AS04-Clinical Decision Support Systems/Advisors

**HOSPITALIZED TYPE 1 DIABETES PATIENTS (T1D) WITH COVID-19, WITH AND WITHOUT DIABETIC KETOACIDOSIS (DKA) HAD SIMILAR OUTCOMES USING AN ELECTRONIC GLYCEMIC MANAGEMENT SYSTEM (EGMS)**


1Atlanta Diabetes Associates, Endocrinology, Atlanta, United States of America, 2Glytec, Executive Director Quality Initiatives, LARGO, United States of America, 3Glytec, R&d, Greenville, United States of America, 4Atlanta Diabetes Associates, Research, ATLANTA, United States of America

**Background and Aims:** Early and effective glycemnic management in hospitalized patients with COVID-19 illness may reduce mortality and improve outcomes. The mortality rate for patients with COVID-19 and DKA approaches 50% in some studies. COVID-19 data specific to T1D in the hospital is lacking. We examined inpatient data for COVID-19 patients with T1D, with and without DKA.

**Methods:** We examined individual-level data for patients with ICD codes for T1D and COVID-19 from 14 hospital systems in 11 states. All patients were on an eGMS, set to titrate IV insulin. DKA was determined based on admission labs, with an anion gap >12 mEq/L and at least one blood glucose (BG) >250 mg/dl.

**Results:** 149 hospitalized patients met the criteria. Referring to the accompanying table, similar outcomes were observed in the DKA and nonDKA groups, with severe hypoglycemia (<40 mg/dl) rates of 0.05% and 0.04%, respectively. The final average BG under the control of the eGMS was 156 mg/dl. The average length of stay was 6.6 days for DKA and 7.7 days for non DKA. In hospital mortality for DKA was 3.17% and non DKA was 1.17%.

**Conclusions:** When treated with computerized glucose management software, hospitalized T1D patients with COVID-19 had low rates of hypoglycemia and when comparing DKA to non DKA, patients showed similar glycemnic outcomes. Mortality in the DKA group is comparable to studies of non COVID-19 T1D with DKA, and much lower than reported in patients with type 2 diabetes, DKA, and COVID-19.

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**P087 / #722**

**Topic:** AS04-Clinical Decision Support Systems/Advisors

**NEW PERSPECTIVES FOR THE ASSESSMENT OF THE GLYCOMETABOLIC CONTROL IN TYPE 1 DIABETES MELLITUS PEDIATRIC PATIENTS**

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**Background and Aims:** In T1DM patients TIR% provides glycometabolic control data. We compared glycaemic monitoring device (SMBG vs CGM) and infusion delivery technique (CSII vs MDI). The aims were: - Correlation between TDD and HbA1c - Correlation between HbA1c and TIR% (70–180) - How insulin delivery methods influences TDD and HbA1c%?

**Methods:** We evaluated 119 T1DM patients (mean age 11.8±4.4), divided in two mean groups (66 CGM, 53 SMBG) and in two subgroups (CSII or MDI). TDD, HbA1c% and TIR% were evaluated for 14 days.
Table 1. HbA1c% derived from TIR%

<table>
<thead>
<tr>
<th>TIR</th>
<th>Estimated HbA1c%</th>
<th>IC50%</th>
<th>IC75%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CGM</td>
<td>SMBG</td>
<td>CGM</td>
</tr>
<tr>
<td>0%</td>
<td>9.96%</td>
<td>9.8%</td>
<td>(9.80%-9.94%)</td>
</tr>
<tr>
<td>10%</td>
<td>9.91%</td>
<td>9.9%</td>
<td>(9.86%-9.96%)</td>
</tr>
<tr>
<td>20%</td>
<td>9.6%</td>
<td>9.1%</td>
<td>(9.32%-9.74%)</td>
</tr>
<tr>
<td>30%</td>
<td>8.8%</td>
<td>8.7%</td>
<td>(7.9%-9.7%)</td>
</tr>
<tr>
<td>40%</td>
<td>8.0%</td>
<td>8.0%</td>
<td>(7.0%-9.7%)</td>
</tr>
<tr>
<td>50%</td>
<td>7.2%</td>
<td>7.2%</td>
<td>(6.0%-8.7%)</td>
</tr>
<tr>
<td>60%</td>
<td>6.8%</td>
<td>6.8%</td>
<td>(5.3%-7.8%)</td>
</tr>
<tr>
<td>70%</td>
<td>6.3%</td>
<td>6.3%</td>
<td>(5.0%-7.3%)</td>
</tr>
<tr>
<td>80%</td>
<td>5.9%</td>
<td>5.9%</td>
<td>(4.0%-7.7%)</td>
</tr>
<tr>
<td>90%</td>
<td>5.4%</td>
<td>5.4%</td>
<td>(3.0%-7.3%)</td>
</tr>
<tr>
<td>100%</td>
<td>4.9%</td>
<td>4.9%</td>
<td>(1.0%-7.3%)</td>
</tr>
</tbody>
</table>

Results: In two main groups, correlation between TDD and HbA1C% results statistically significant (p<0.05): CGM R = 0.346; SMBG R = 0.311.

HbA1c% - TIR% correlation results statistically significant (p<0.05); strong in the CGM group, moderate in SMBG one. For an increase of TIR of 10%, HbA1C% reduces of 0.45 in the CGM group and 0.31 in the SMBG group.

Insulin delivery methods (CSII or MDI) influences TDD, only in CGM group: CSII = 33 IU (±16.62) vs MDI = 19.5 IU (±16.37), (p <0.05) and doesn’t influence HbA1c% (p >0.05): In CGM group CSII = 7.4% (±1.08) vs MDI = 7.7%, (±1.00). In SMBG group: CSII = 8.35% (±1.88) vs MDI = 8.00% (±1.24).

Conclusions: Contrary to literature data, the use of CSII involves an increase in the TDD. For each increase of 10% in TIR, HbA1c% changes by 0.45 in the CGM group and 0.31 in the SMBG group. Our TIR% and HbA1c% correlation has inference on pediatric population.

P089 / #786
Topic: AS04-Clinical Decision Support Systems/Advisors
TIME-IN-RANGE: A TOP METRIC FOR ENDOCRINOLOGISTS TREATING PATIENTS WITH TYPE 1 DIABETES AND TYPE 2 ON INTENSIVE INSULIN
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Background and Aims: Recent studies have shown support for time-in-range (TIR) as a predictor of long-term diabetes complications. This study investigated how endocrinologists view the importance of TIR in the treatment of various groups of diabetes patients.

Methods: An online survey from November 10-December 14, 2020 asked endocrinologists (n = 243) to report and rank their treatment goals for different patient groups; rate the importance of TIR for diabetes management for each group; and agree or disagree with the statement “Time-in-range is only a useful metric for patients using CGM.” Data were collected using Qualtrics Survey Software, prepared with IBM SPSS, and analyzed in MarketSight.

Results: The Table shows ranking of metrics for patient groups: 53% of endocrinologists selected TIR as the top-ranked metric for T1D patients, compared to 25% for A1C. For T2D patients on an intensive insulin regimen, A1C (40%) and TIR (34%) were both top-ranked metrics. For T2D patients on basal insulin only and T2D patients not on insulin, A1C was the top-ranked metric (47%, 40%, respectively). Fifty-seven percent of endocrinologists agreed that TIR is only a useful metric for patients using CGM. However, 31% disagreed, and 53% reported discussing TIR with patients not on CGM. Columns sum to <100% as only top 3 ranks shown. Statistical significance for rankings tested at the 95% confidence level.

Conclusions: Time-in-range plays a critical role in endocrinologists’ treatment of patients with T1D and T2D on intensive insulin. For other patients, A1C, weight and behavior dominate, likely because these patients do not yet use CGM.
**P090 / #29**

**Topic:** **AS05-Glucose Sensors**

**EVALUATION OF USER PERFORMANCE AND ACCURACY OF A NEW BLOOD GLUCOSE MONITORING SYSTEM**

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**Background and Aims:** To evaluate accuracy, in the laboratory and clinical settings, of the new blood glucose monitoring system (BGMS), CONTOUR™PLUS BLUE, for use with the CONTOUR™PLUS test strip. The new BGMS is designed to synchronize with the CONTOUR™DIABETES app on a smartphone or tablet.

**Methods:** In a laboratory study, the accuracy evaluation assessed glucose concentration of fingertip capillary blood samples from 100 subjects, tested in duplicate on three lots of test strips. In a clinical study, to evaluate the BGMS accuracy using subject fingertip self-tests, 332 subjects with diabetes, who have not used the BGMS prior, were enrolled in a single site. In both studies, accuracy was assessed per ISO 15197:2013 accuracy criteria.

**Results:** In the laboratory study, all 600 readings (glucose range, 21-521 mg/dL [1.1-28.9 mmol/L]) met ISO 15197:2013 accuracy criteria with 100% of the results within ±15 mg/dL (±0.83 mmol/L) or ±15% of the reference value at glucose concentrations <100 mg/dL (≤5.55 mmol/L) and >100 mg/dL (>5.55 mmol/L) respectively. All results fell within Zone A of the Error Grid. In the clinical study among subjects with diabetes (glucose range, 40–409 mg/dL [2.2–22.7 mmol/L]), 99.1% (326/329) of subject fingertip self-test results met ISO 15197:2013 accuracy criteria. In addition, 98.2% of subject fingertip self-tests were within ±12.5 mg/dL (0.69 mmol/L) or ±12.5% of the reference value.

**Conclusions:** The BGMS met ISO 15197:2013 accuracy criteria in the laboratory (sections 6.3) and a clinical setting (section 8).

**P091 / #46**

**Topic:** **AS05-Glucose Sensors**

**USE OF PERSONAL CONTINUOUS GLUCOSE MONITORING DEVICE IS ASSOCIATED WITH REDUCED RISK OF HYPOGLYCEMIA IN A 16-WEEK CLINICAL TRIAL OF PEOPLE WITH TYPE 1 DIABETES**

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**Background and Aims:** Continuous glucose monitoring (CGM) has the potential to promote diabetes self-management at home with a better glycemic control as outcome. Investigation of the effect of CGM has typically been carried out based on randomized controlled trials with prespecified CGM devices on CGM naïve participants. The aim of this study was to investigate the effect on glycemic control in people using their personal CGM before and during the trial.

**Methods:** Data from the Onset 5® trial of 472 people with type 1 diabetes using either their personal CGM (n = 117) or no CGM (n = 355) and continuous subcutaneous insulin infusion in a 16 weeks treatment period were extracted. Change from baseline in HbA1c, number of hypoglycemic episodes and CGM metrics at end of treatment were analyzed with analysis of variance repeated measures models and general linear models.

**Results:** Use of personal CGM compared with no CGM was associated with a reduction in risk of documented symptomatic hypoglycemia (event rate ratio: 0.82 95% CI: 0.69-0.97) and asymptomatic hypoglycemia (event rate ratio: 0.72 95% CI: 0.53-0.97), reduced time spent in hypoglycemia (p = 0.0070) and less glycemic variability (p = 0.0043) without a statistically significant increase in HbA1c (p = 0.2028).

**Conclusions:** Results indicate that use of personal CGM compared with no CGM in a population of type 1 diabetes is associated with a safer glycemic control without a statistically significantly deteriorated effect on HbA1c, which adds to the evidence about the real-world use of CGM, where device type is not prespecified, and users are not CGM naïve. *Abstract accepted for publication in JDST 11-AUG-2020.*
years old, showing the best outcome in the “university students and young adults” group (55.40% at T0 and 61.37% at T1, \(p \leq 0.001\)). All patients reduced physical activity during lockdown; in the 56 patients of “intense physical activity” group both at T0 and T1 TIR increased from 56.91± to 64.11% \((p \leq 0.001)\).

**Conclusions**: Overall, the lockdown led to an unexpected improvement in glycemic control of young patients with T1D. A healthier and stressless lifestyle changes synergistically with the maintenance of physical activity resulted in a significant age-proportional improvement in glycemic control.

**P093 / #68**

**Topic**: AS05-Glucose Sensors

**CONTINUOUS GLUCOSE MONITORING ACCURACY DURING HIGH-ALTITUDE TREKKING**

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**Background and Aims**: High altitude trekking involves relative hypoxia and strenuous physical activity, which impact glucose homeostasis. Commercially-available continuous glucose monitoring (CGM) systems rely on adequate tissue perfusion and oxygenation, and the sensor’s immobilized glucose oxidase enzyme is temperature-dependent. We therefore investigated the accuracy of a continuous glucose monitoring (CGM) system in trekkers without diabetes.

**Methods**: Twenty-five adults (mean age 27.7 years, range 18–41 years) completed a 14-day trek of the Dhaulagiri circuit in Nepal, reaching a maximum altitude of 5300 m, while wearing blinded CGM systems (G4 with Software 505, Dexcom, San Diego, CA). CGM sensors were placed on the upper arm (triceps area) and replaced after 7 days. Blood glucose measurements (SMBG) were obtained twice daily with Bayer Contour meters (Parsippany, NJ) and used to calibrate the CGM systems. Mean absolute relative difference (MARD) was calculated for CGM values obtained within 5 minutes of an SMBG value and CGM:SMBG pairs were stratified according to altitude.

**Results**: The mean absolute relative difference (MARD) and bias of the CGM values versus self-monitored blood glucose (SMBG) values are summarized in the Table. The data showed a consistent negative bias averaging 5.2 mg/dL and the overall MARD of 18.3%, with no apparent altitude-related trends.

**Conclusions**: CGM systems may be used in people without diabetes to study glucose homeostasis at high altitudes, in cold weather, and during strenuous physical activity.

<table>
<thead>
<tr>
<th>Altitude (m)</th>
<th>Number of SMBG:CGM Pairs</th>
<th>CGM (mean±SD), mg/dL</th>
<th>SMBG (mean±SD), mg/dL</th>
<th>MARD</th>
<th>Bias (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2000</td>
<td>154</td>
<td>87.4 ± 18.4</td>
<td>92.6 ± 13.1</td>
<td>16.1%</td>
<td>-5.2</td>
</tr>
<tr>
<td>2000-3000</td>
<td>88</td>
<td>89.6 ± 18.2</td>
<td>97.9 ± 17.5</td>
<td>14.5%</td>
<td>-7.5</td>
</tr>
<tr>
<td>3000-4000</td>
<td>129</td>
<td>95.4 ± 24.1</td>
<td>99.2 ± 19.4</td>
<td>20.7%</td>
<td>-3.8</td>
</tr>
<tr>
<td>4000-5000</td>
<td>76</td>
<td>98.5 ± 24.3</td>
<td>103.9 ± 24.3</td>
<td>21.9%</td>
<td>-5.4</td>
</tr>
<tr>
<td>&gt;5000</td>
<td>54</td>
<td>88.2 ± 21.0</td>
<td>91.2 ± 15.5</td>
<td>20.3%</td>
<td>-3.0</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>501</strong></td>
<td><strong>91.9 ± 22.6</strong></td>
<td><strong>96.8 ± 18.2</strong></td>
<td><strong>18.3%</strong></td>
<td><strong>-5.2</strong></td>
</tr>
</tbody>
</table>

**P094 / #82**

**Topic**: AS05-Glucose Sensors

**CALIBRATION ACCURACY DIFFERENCES BETWEEN PERSONAL-CGM AND PROFESSIONAL-CGM**

*S. Takeishi, T. Inoue*

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**Background and Aims**: According to accuracy of “capillary blood glucose levels used to calibrate” (BGc), calibration algorithm differences between personal-CGM and professional-CGM may cause calibration accuracy differences between those.

**Methods**: This was a prospective study where personal-CGM (GUARDIAN CONNECT) and professional-CGM (iPro2) were worn in parallel for 6 days (CGM attachment: day 1) and BGc were obtained using “glucometers that were compliant with ISO15197:2013” (ISO) or “those not compliant with ISO15197:2013” (non-ISO) using a randomized crossover design. Twenty-eight type 2 diabetes inpatients were equally allocated to two groups. ISO provided 11 BGc during days 2–3 and non-ISO provided those during days 4–5 in group 1 and vice versa in group 2. Mean absolute relative difference (MARD) was calculated for every calibration. For non-ISO measurement, we arranged the “BGc, MARD for personal-CGM, and that for professional-CGM” (set) in ascending order of BGc, ranking from 1 to 308. Then, consecutive 200 “sets” were selected 109 times while shifting one by one (from 1–200 to 109–308: 109 groups).

**Results**: For ISO measurement, the MARDS were not significantly different between personal-CGM and professional-CGM; however, for non-ISO measurement, the MARD was significantly higher on personal-CGM than on professional-CGM \((n = 308)\). For non-ISO measurement, the test statistic (difference: MARD for personal-CGM – MARD for professional-CGM) in the paired t-test in the selected group significantly positively correlated with the mean BGc in that group \((n = 109)\). (Figure)

**Conclusions**: When BGc has low accuracy, the personal-CGM may reflect the calibration accuracy more correctly than the professional-CGM.
P095 / #88

Topic: AS05-Glucose Sensors

THE GLUCOSE MONITORING EXPERIENCES QUESTIONNAIRE (GME-Q): SPANISH TRANSLATION AND LINGUISTIC VALIDATION IN CONTINUOUS GLUCOSE MONITORING USERS

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Background and Aims: Continuous glucose monitoring (CGM) is widely used in people with type 1 diabetes (T1D). Different devices with different characteristics are available. User satisfaction is a crucial outcome and it is a predictor of long-term use. For clinical and research purposes, it is mandatory to use validated tools to measure satisfaction with CGM devices. The Glucose Monitoring Experiences Questionnaire (GME-Q), with 23 items and a 5-point Likert scale, is available only in English and it has been tested in patients using SMBG. The aim was to translate the GME-Q into Spanish and evaluate its performance in native Spanish users of different CGM devices.

Methods: Permission to translate was obtained by Mapi Research Trust. A forward translation was performed, by two translators, native Spanish speakers, bilingual in English. A backward translation of the unified version was produced by a translator, native English speaker, bilingual in Spanish, with no access to the original version. A final translation was produced. People with T1D were asked to complete the questionnaire and to highlight any possible misunderstandings.

Results: 98 subjects were evaluated (age: 40–12 years, 62% females, diabetes duration: 24±11 years, HbA1c: 7.2±0.9%, higher education 39%, pump users: 78%, duration of use of CGM: 3.7±2.6 years). Completion rate was 99% (0.9% missing answers, by 6 patients, 0.45% by the same patient). Only 1 patient found difficulties. Internal consistency reliability: Cronbach’s alpha = 0.8 (satisfactory).

Conclusions: A Spanish version of the Glucose Monitoring Experiences Questionnaire (GME-Q) was produced and it was shown to be useful and well-accepted in native Spanish CGM users.

Table 1. GME-Q evaluation

<table>
<thead>
<tr>
<th>Glucose monitoring device</th>
<th>n (%)</th>
<th>Total Satisfaction</th>
<th>Effectiveness subscale</th>
<th>Convenience subscale</th>
<th>Intrusiveness subscale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guardian</td>
<td>68 (69)</td>
<td>3.9 ± 0.4</td>
<td>4.1 ± 0.6</td>
<td>3.8 ± 0.6</td>
<td>2.2 ± 0.6</td>
</tr>
<tr>
<td>Dexcom</td>
<td>19 (19)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freestyle Libre</td>
<td>11 (11)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n = 98. Items scored from 1 to 5. Higher scores indicate more positive glucose monitoring experience, except for intrusiveness scale where higher scores indicate a less positive experience.

P096 / #114

Topic: AS05-Glucose Sensors

COMPARISON OF GLYCEMIC VARIABILITY VALUES DERIVED FROM FLASH GLUCOSE MONITOR AND CONTINUOUS GLUCOSE MONITOR

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Background and Aims: Sensor accuracy and measurement intervals may affect glycemic variability (GV) values. Studies have suggested that the sensor accuracy of the continuous glucose monitor (CGM) is higher than that of the flash glucose monitor (FGM). We studied the influence of differences in sensor type and measurement intervals on GV values.

Methods: This was a prospective study where 47 patients with type 2 diabetes wore a CGM (iPro2) and FGM (FreeStyle Libre Pro) in parallel over 24 h during hospitalization. We compared 24-h GV values derived from sensor glucose levels (SG) for CGM, measured every 5 min (GV ‘‘5 min’’) and extracted every 15 min (GV ‘‘15 min’’), and for FGM, measured every 15 min (GV ‘‘FGM’’). The mean glucose levels (mean), standard deviation (SD), coefficient of variation (CV), time in range (70–180 mg/dL) (TIR 70–180), mean absolute glucose (MAG), and glycemic variability percentage (GVP) were calculated to determine the GV.

Results: The correlation coefficients between GV ‘‘5 min’’ and GV ‘‘15 min’’ were approximately 1 for every GV metric. However, the correlation coefficients between GV ‘‘15 min’’ and GV ‘‘FGM’’ were approximately 0.8–0.9 for mean, SD, and CV and approximately 0.6 for TIR 70–180, MAG, and GVP (Table).

Conclusions: The influence of the differences in the sensor type on GV values may be greater than that of the measurement intervals. The chronologically analyzed GV may be susceptible to differences in sensor type.

P097 / #116

Topic: AS05-Glucose Sensors

POTENTIAL BENEFIT OF SWITCHING FROM ISCGM (FREESTYLE LIBRE) TO RTCGM (DEXCOM G4) ON AGP PARAMETERS IN POORLY CONTROLLED TYPE 1 DIABETES PATIENTS OVER 1-YEAR FOLLOW-UP

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Background and Aims: We have previously shown that switching from isCGM (Free Style libre, FSL) to rtCGM ( Dexcom G4, DG4) improved AGP parameters (Time in Range TIR 70-180 mg/dL, Time below Range TBR <70 mg/dL, glucose Coefficient of variation %CV) in 18 type 1 diabetes patients with poor glycemic control, over 6 months (paper submitted). We propose herein the extension’s results at 12 months (M12) in 13 patients (5 excluded for abandoning the protocol or voluntary discontinuation of rtCGM).

Methods: This observational study was conducted in patients with hypoglycemic issue and/or elevated HbA1c. The AGP data were collected during the last 3 months of FSL use prior to inclusion (M0) and every 3 months until 12 months of DG4 use, then expressed as 24-hr averages. Patients were their own-control and statistics were performed using paired t-test or Wilcoxon for matched-pairs.

Results: At M12, compared to M0, a higher TIR and lower TBR and %CV (see Table) evidenced a prolonged effectiveness of the switch. Compared to M6, TBR decreased (mean (SD) change, -2.8 (3.3), P = 0.005), %CV and TIR remained stable, while exposure to hyperglycemia increased as shown by higher Glucose Management Indicator (GMI mean (SD) change, +0.5 (0.7), P = 0.02) and Time above Range >180 mg/dL (TAR mean (SD) change, +7.0 (10.3), P = 0.03).

Conclusions: Switching FSL to DG4 could be a relevant therapeutic option regardless of the initial glycomic profile. A rise in the exposure to hyperglycemia at 1-year follow-up stresses the need for regular educational reinforcement and optimized management of threshold alarms.

**P099 / #132**

**Topic: AS05-Glucose Sensors**

RESULTS OF AN EDUCATIONAL INTERVENTION STRUCTURED BY TELEMEDICINE IN CHILDREN AND ADOLESCENTS WITH DMI USERS OF CGMIS DURING COVID-19 EMERGENCY

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CMP Churruca Visco PFA, Infant-juvenile Diabetes, Buenos Aires, Argentina

Background and Aims: The health emergency during COVID-19 pandemic prevented the continuity of face-to-face assistance and SDE program, increasing the risk of hospitalizations due to DM1 in children and adolescents. SDE Program was urgently adapted and implemented in CGMIs users, developed through remote assistance and virtual education.

Methods: After accepting to participate in the study 22 users of CGM system associated with LibreView platform were included in SDE program developed from ZOOM platform that consisted of 4 modules weekly. A general knowledge scale (ECODI in GoogleForm and educational games) was evaluated at 0, 3 and 6 months. The AGP tool was used to obtain the metrics at the beginning and 3 months after the intervention. A nearby laboratory was indicated for biochemical determinations at the beginning and at 3 months.

Results: Of the 22 patients (half male), mean 13 years, did not present significant differences between both subgroups. The duration of DM1 was 3 years HbA1c decreased significantly at 3 months (8% and 7.3%) and the proportion of patients with A1C
in goal. AGP showed an increase in active time (86.36% to 90.9% NS) The evaluation of knowledge by ECODI at 0, 3 and 6 months increased by 70, 85 and 80% During the 3 months none of the patients had DKA

Conclusions: The structured educational intervention implemented remotely during the COVID-19 pandemic in DM1 users of MCGis, has maintained self-management, significantly improving HbA1c and knowledge. There was a non-significant trend towards improvement in TAR180 but admission of DKA could be avoided entirely

P100 / #135
Topic: AS05-Glucose Sensors
IMPACT OF CONTINUOUS GLUCOSE MONITORING ON GLYCAEMIC CONTROL IN CHILDREN AND ADOLESCENTS WITH T1D: REAL WORLD DATA FROM A POPULATION BASED CLINIC
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1Perth Children's Hospital, Endocrinology And Diabetes, Nedlands, Australia, 2Telethon Kids Institute, Diabetes, Perth, Australia

Background and Aims: Real-world studies reporting the impact of continuous glucose monitoring (CGM) in children with Type 1 diabetes (T1D) are limited. In April 2017, CGM became subsidised in Australia for children with T1D under the age of 21. We report the impact of widespread CGM availability on diabetes management. To examine the effect of CGM on glycaemic outcomes measured by HbA1c in a population-based sample of children and adolescents with T1D.

Methods: Retrospective cohort analysis of T1D patients attending Perth Children’s Hospital between January 2015 and July 2019. Inclusion criteria were T1D patients on CGM, <18 years old, >2 yrs diabetes diagnosis and at least 2 pre and post CGM clinic visits with HbA1c. Mixed model methodology was used; covariates included age, diabetes duration and gender.

Results: 348 children met inclusion criteria of the study. Mean age at CGM start was 13.4yrs (±2.9yrs) with diabetes duration of 7.2years± (3.0yrs). 56% (n=195) used CGM for ≥75% of the time. Mean HbA1c at CGM start was 8.5% (±1.5%). The initial change in HbA1c level (first HbA1c level performed after commencing CGM) associated with commencing CGM was -0.4% (95%CI [-0.5, -0.3], p<0.001). Pre-CGM trend in HbA1c was 0.29% (95% CI [0.24, 0.34]) increase per year, and post-CGM trend was 0.15% (95% CI [0.03, 0.27]) increase per year (p=0.02).

Conclusions: The use of CGM resulted in improvement in glycaemic outcomes. These real world data show similar outcomes to randomised controlled trials with CGM and add to the evidence for CGM use in clinical practice for children with T1D.

P102 / #147
Topic: AS05-Glucose Sensors
PERSONALIZED FORECASTING OF SEVERE HYPOGLYCEMIA USING REAL-TIME CONTINUOUS GLUCOSE MONITORING (CGM) DATA IN PATIENTS WITH TYPE 2 DIABETES (T2DM)
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1University of Minnesota, Institute For Health Informatics, Minneapolis, United States of America, 2University of Minnesota, Division Of Endocrinology, Minneapolis, United States of America

Background and Aims: Lowering HbA1c has established benefits for patients with T2DM, yet hypoglycemia and fear of hypoglycemia remain major impediments to intensification of glycemic control. Personalized forecasting of near-term severe hypoglycemia (SH, <54mg/dL) can provide guidance in avoiding SH. We hypothesize that preceding CGM data can accurately forecast impending near-term (up to 5 hours) SH.

Methods: Patients with T2DM wore a blinded freestyle libre pro on each arm for 14 weeks. The sensors were changed bi-weekly and continuously measured glucose every 15 minutes. We defined a “SH episode” when both sensors reported glucose
<54 mg/dL concurrently for >= 15 minutes. We constructed random forest models from the patients’ preceding CGM data to forecast future SH events over the horizon of 15 min, 1 hour, 2 hours, 3 hours, 4 hours, and 5 hours.

Results: Twelve patients with T2DM were recruited (mean age 66.749, 58.3% female, HbA1c 7.767). The average number of SH events during the observation period was 119 (range [41,386]), averaging 1.241 (range [0.254 -3.253]) events per week. For each patient, the predictive performance for SH increased as the forecast horizon shortened. The average cross-validated AUC (mean(sd)) was 0.989(0.005) within 15 minutes, decreased as the forecast horizon shortened. The average cross-validated AUC (mean(sd)) was 0.989(0.005) within 15 minutes, 0.931(0.039) within 3 hours, 0.898(0.055) within 4 hours and 0.874(0.072) within 5 hours.

Conclusions: In contrast to current CGM output which predicts glucose trends, we developed a model using preceding CGM data to produce highly accurate forecasts for near-term SH, suggesting that prediction of SH can be personalized to reduce hypoglycemia risk.

P103 / #153
Topic: AS05-Glucose Sensors
UNEXPECTED IMPROVEMENT IN GLYCEMIC CONTROL DURING FORCED INACTIVITY DUE COVID-19 PANDEMIC IN CHILDREN WITH TYPE 1 DIABETES USING CGM
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1Azienda Ospedaliero-Universitaria Ospedali Riuniti Ancona, Women’s And Children’s Health, ANCONA, Italy, 2Università Politecnica delle Marche, Epidemiology And Biostatistics, Ancona, Italy

Background and Aims: We hypothesize that forced inactivity due to the COVID-19 pandemic confinement from March 2020 – May 2020, contributed to worsened glycemic control in children with type 1 diabetes (T1D). This study aimed to evaluate the CGM metric changes before and after COVID-19 lockdown in children with T1D under 18 years of age, followed by the pediatric diabetes centre in the “G. Salesi” Hospital, Ancona, Italy.

Methods: This longitudinal observational study includes all children using a CGM. The study compared clinical data (HbA1C, BMI) and CGM metrics before (1–15 January 2020) and after (June - August 2020) COVID-19 confinement. Clinical data were obtained by clinical electronic records, CGM metrics were downloaded using a dedicated software. Changes were calculated as differences between the two time periods and analyzed using Wilcoxon signed rank sum test. Results were expressed as median and IRQ or 95%CI.

Results: Data was analyzed for 118 children (56% males, median age 13 y). 25% of children used an insulin pump. The change in HbA1c was -0.1% (95%CI -0.20;0.05) and BMI SDS -0.1 (95%CI -0.17; -0.03). For CGM metrics, only TIR increased by 3.3% (95%CI:0.7;4.4), and TAR >250 decreased by 0.95% (95%CI:0.6;3.0). (Figure 1). No differences between children using MDI or insulin pump were observed.

Conclusions: The study indicators demonstrated that confinement during the COVID-19 pandemic did not worsen glycemic control. It can be assumed that CGM use prompted parents to quickly correct out-of-range values, underlining the importance of family diabetes education.

P104 / #159
Topic: AS05-Glucose Sensors
INTERFERENCE EVALUATION OF THE CONTOUR PLUS TEST STRIP
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Background and Aims: A platform of blood glucose monitoring systems (BGMSs) utilizes the CONTOUR PLUS test strip containing the FAD-GDH enzyme and a proprietary electron mediator. Common endogenous and exogenous substances were evaluated for interference effect which could lead to inaccurate BGMS readings.

Methods: Interfering substances were tested at glucose concentrations of 80 and 300 mg/dL (4.4 and 16.7 mmol/L) following the Interference Testing in Clinical Chemistry EP7 guideline. Interference stock solution was used to create a sample with the highest interfering substance level, at least two intermediate levels, and a blank. Data were analyzed by regression analysis and presented as percent deviation from blank at maximum therapeutic concentration (MTC) or upper reference value (URV). Results were determined from the glucose level with maximum therapeutic concentration (MTC) or upper reference value (URV).

Results: for more than 20 common interfering substances showed ≤1% bias at therapeutic levels. At levels exceeding the maximum therapeutic concentration (MTC) or upper reference value (URV) of acetaminophen, bilirubin, galactose, maltose, or uric acid, bias was ≤5%. The limiting concentration of ascorbic acid is 15.3 mg/dL (0.87 mmol/L), which is 8.7 times the MTC. The limiting concentration of xylose is 12.8 mg/dL (0.05 mmol/L).

Conclusions: Study findings showed that common endogenous reducing substances in blood (eg, uric acid, bilirubin) or exogenous substances from common therapeutic treatments (eg,
ascorbic acid, acetaminophen) did not significantly affect performance of the CONTOUR® PLUS test strip. Thus, results obtained with the BGMS platform that utilizes this test strip are expected to be accurate in the presence of these interfering substances.

P105 / #178

**Topic:** AS05-Glucose Sensors

**INTERFERING SUBSTANCES FOR GLUCOSE SENSING BY NEAR-INFRARED SPECTROSCOPY**

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**Background and Aims:** Near-Infrared (NIR) Spectroscopy could be an alternative method to measure blood glucose concentration, with access to low-cost components and potential for non-invasive use. Possible interferents to this method are not widely investigated. We aimed to identify lactate, ethanol, acetaminophen and caffeine for possible interference.

**Methods:** Glucose and the four interferents were mixed in varying physiological concentrations and measured by NIR spectroscopy in vitro. A calibration model was built by partial least squares regression. The full set (273 spectra) was divided into subsets (59–73 spectra) where one of the interferents were left out and new models were built without knowledge of the interferent. Subsets with random samples were used as a reference to the smaller calibration sets of the interferents. All models were applied to a validation set containing all interferents.

**Results:** The models built without ethanol and caffeine had high errors and several points outside of zone A and B in the Clarke Error grid. The model without lactate mistook lactate for glucose and gave false high predictions. The model without ethanol gave lower glucose predictions with increasing ethanol concentration. The models without acetaminophen and caffeine were comparable to the random subsets.

**Conclusions:** Lactate and ethanol interfere with glucose prediction by NIR spectroscopy if not included in the model calibration. Acetaminophen and caffeine are not interferents to glucose using NIR spectroscopy. Acknowledgements: Thanks to Bjørg Narum, Harald Martens and Ine Jernelv. Funded by Norges Forskningsråd (248872); Helse Midt-Norge (46055510).

P106 / #213

**Topic:** AS05-Glucose Sensors

**EFFECT OF USING ADDITIONAL READERS FOR FLASH GLUCOSE MONITORING SYSTEM ON METABOLIC CONTROL, SAFETY, AND THE INCIDENCE OF COMPLICATIONS IN PATIENTS WITH DIABETES MELLITUS**

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**Background and Aims:** The FreeStyle Libre is a flash glucose monitoring (FGM) system, and glucose levels are measured when the reader is brought to the sensor. Additional readers allow for the conversion into a continuous glucose monitoring (CGM) system. These transmitters read data from the sensor and send them to a Bluetooth-enabled device thanks to which the user acquires glucose measurements automatically. This modification allows the patient to receive alerts when blood glucose values are abnormal.

**Methods:** The study relied on the results of an anonymous online survey conducted among patients with diabetes or their caregivers who use Facebook groups. A total of 132 respondents who met certain criteria (diabetic who use FGM system longer than 3 months, at least 14 days per month) were enrolled in the study.

**Results:** A significant decrease in self-reported glycated hemoglobin levels was found in adults and children using readers (variable: age $P = .008$; time $P < .001$), regardless of the age. The use of additional readers was associated with a significant decrease in the number of self-reported episodes of hypoglycemia ($P < .001$) and an improvement in the quality of life.

**Conclusions:** The use of additional readers for FGM system improves the metabolic control of diabetes and the quality of life, and has a positive effect on the safety of treatment. FGM used together with additional readers operates as a CGM and seems to be helpful for patients for the monitoring of interstitial levels of glucose; however, they should be careful when they use it yourself solution.

P107 / #215

**Topic:** AS05-Glucose Sensors

**INTERSTICIAL GLUCOSE MONITORING AND SKIN REACTIONS: REAL-LIFE STUDY IN ADULTS AND CHILDREN**

F. Gallego Gamero, A. Ambrojo-López, M.M. Fernandez-Bueso, P.I. Beato-Víbora

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**Background and Aims:** The use of continuous or flash interstitial glucose monitoring (CGM/FGM) has been shown to improve glycemic control in type 1 diabetes (T1D). That practice is not without complications. The aim was to characterize skin lesions associated with their use.

**Methods:** A questionnaire was developed by the Endocrinology and Nutrition Department and the Dermatology Department. T1D patients, users of CGM or FGM, were asked to complete it to assess the frequency and type of reactions caused by the devices. The questionnaire included 18 questions, 10 about the type of reaction (redness, itching, dryness, colour changes, irritation, pathological scar, eczema, ulcer, folliculitis, and exudation), with multiple choice answers from never to always. Three questions referred to the location, duration of the lesions and need of healthcare. Five questions related to consequences of skin reactions: sensor use interruption, insertion problems, premature replacement/removal or detachment.

**Results:** 36 T1D patients were included. Patient characteristics are shown in Table 1. 72% ($n = 26$) of the patients had some reaction, 36% ($n = 13$) reported frequent reactions and 17% ($n = 6$) required medical treatment. Frequencies and type of injuries are shown in Figure 1. Skin reactions were limited to the adhesive dressing area and lasted few days. Not statistically
significant differences were observed in the frequency of skin lesions related to sex, age, time of diabetes, device or HbA1c.

Conclusions: Skin lesions associated with CGM/FGM are underdiagnosed. They are usually mild and rarely cause clinical repercussions or discontinuation of sensor use. More studies are needed to validate questionnaires that quantify and define skin reactions.

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**P108 / #248**

**Topic: AS05-Glucose Sensors**

**ASSESSMENT OF DIAGNOSTIC AGREEMENT OF A SMARTPHONE CONNECTED GLUCOMETER, BEATO CURV WITH STANDARD AND COMMON GLUCOMETERS USED IN INDIA**

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**Background and Aims:** BeatO Curv glucometer developed by Health Arx Technologies Pvt Ltd is a self-monitoring glucometer, uses GOD-GDH method of glucose analysis. BeatO’s AI-based Health Neuron process real-time information and enable individualized care with help of the diabetes management team. Our study aims to assess the agreement between glucometers by BeatO Curv and standard reference method (Abbott Architect ci 4100) and the other four commonly used glucometers in India.

**Methods:** An overall sample of 96 outpatients were considered for the study at a tertiary care center in New Delhi. Blood samples were checked by all eight glucometers (three BeatO Curv, one standard and four others) within time window of five minutes in same environmental conditions. Acceptance criteria for a glucometer as per ISO15197:2013 guidelines: ≥95% of results within ±15 mg/dL of the reference result for blood glucose concentrations <100 mg/dL or ±15% for blood glucose concentrations >100 mg/dL was used. Bland Altman analysis was conducted to assess the degree of agreement.

**Results:** For BeatO Curv 1, 2, and 3, 96.9%, 95.8% and 96.9% values respectively were found to be in the range of accepted ISO criteria. There was a strong linear correlation between BeatO Curv readings with the standard method. All three BeatO Curv showed no significant difference in mean values from standard reference. Bland Altman analysis showed a high degree of agreement across a wider range of glucose values.

**Conclusions:** BeatO Curv has shown high diagnostic accuracy as compared to the standard reference blood glucose-monitoring method.

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**P109 / #281**

**Topic: AS05-Glucose Sensors**

**CLINICAL IMPACT IN REAL LIFE OF FLASH GLUCOSE MONITORING IN ADOLESCENTS WITH TYPE 1 DIABETES**


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**Background and Aims:** Flash glucose monitoring (FGM) is an alternative technology to capillary self-monitoring blood glucose (SMBG) that allows better glycemic control in people with type 1 diabetes (T1D). To assess the clinical efficacy of FGM after 12 months and to evaluate the degree of use and adherence during the first year in adolescents with T1D.

**Methods:** Descriptive and longitudinal observational study of adolescents with T1D aged 14–18 years. We compared changes in HbA1c, percentage of time in range (TIR 70-180 mg/dL [3.9-10 mmol/L]), percentage of time above range (TAR >10 mmol/L), percentage of time below range (TBR <70 mg/dL [<3.9 mmol/L]), percentage of time above range (TAR >180 mg/dL [>10 mmol/L]) and glycemic variability (CV) at 14 days with FGM and at 12 months. The use of the device, the events associated with it and drop-outs were analyzed.

**Results:** 129 patients [49.2% female; 17.2±4.6 years; HbA1c 7.9±1.2%; 10.4±5.0 years of evolution; 105 with multiple daily insulin injections; 6.0±1.4 SMBG per day]. At-12 months, reductions in TBR were observed (70 mg/dL, 10.2%vs6.2%, p=0.018; <54 mg/dL, 4.4%vs2.4%, p=0.007) and significant improvements in glycemic variability (44.2%-41.0%, p=0.022). No significant difference in TIR or TAR and no changes in HbA1c were observed (7.9%-8.2%, p=0.119). Drop-out was 18.6%: 7.0% by the detachment of the device, 5.5% by the discordance with SMBG and 0.8% by skin allergies.

**Conclusions:** FGM reduces TBR and improves glycemic variability after 12 months of continuous use in adolescents with T1D. The degree of adherence to FGM needs improvement in this age group with specific educational programs that facilitate the therapeutic empowerment of adolescents with T1D.
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Topic: AS05-Glucose Sensors

GREATER BENEFITS OF FLASH GLUCOSE MONITORING IN PATIENTS WHERE OCCUPATION IS A BARRIER TO SELF-MONITORED BLOOD GLUCOSE TESTING

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Background and Aims: Our centre commenced use of Flash Glucose Monitoring system Freestyle Libre (FSL) within NHS for the first time in the spring of 2019. This retrospective real life study aimed to examine the impact of FSL on glycaemic control at the end of 6 months of FSL use.

Methods: Patients attending the centre for their routine diabetes care were assessed against the eligibility criteria set out and adapted by the local health authority. Each patient had HbA1c at baseline and 6 months after FSL initiation.

Results: A total of 208(n) patients were provided with FSL between May & October 2019. Mean age and duration of diabetes (SD) was 39.7±16.1 and 19.1±14.6 respectively. Less than a third was DAFNE trained. Majority were on basal bolus insulin regimen (73%) followed by insulin pump therapy (21%). Most common indication for FSL were occupation (30%), psychosocial (18%) & hypoglycaemia (14.4%). 6 month review was not possible in 91(n) due to COVID19 & missed appointments. Overall paired mean HbA1c improved significantly at 6 months compared to baseline (71.7±1.9 & 68.1±1.7, p<0.001). The improvement was seen most in occupational category (73.9±2.7 & 68.0±2.6, p<0.001) with 66% achieving improved HbA1c followed by psychosocial category (89.1±5.9 & 82.8±5.4, p=0.016). Time in Range (TIR) was significantly higher in those who scanned FSL ≥8/day vs <8scan/day (34.7±1.9 & 25.9±2.0, p=0.002).

Conclusions: This real life study demonstrates that FSL will help achieve better glycaemic control particularly in those where occupation is the barrier to routine finger prick test. Furthermore, people with significant mental health do also benefit from the FSL.

P111 / #331

Topic: AS05-Glucose Sensors

ACCURACY ASSESSMENT OF THE NEW GLUCOMEN® Day CGM System in Individuals with Type 1 Diabetes

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Background and Aims: The GlucoMen® Day CGM (WaveForm Cascade), recently launched by A. Menarini Diagnostics (Italy), is a real-time continuous glucose monitor designed for needle-free insertion that delivers one glucose reading every minute for up to 14 days. The present study assessed the GlucoMen® Day accuracy against a laboratory reference.

Methods: Eight individuals with type 1 diabetes (3 females, age 41.6±13.3 years, BMI 28.0±6.1 kg/m², HbA1c 55.6±12.2 mmol/mol, diabetes duration 13.9±6.5 years) wore two GlucoMen® Day CGMs inserted simultaneously into each side of the abdomen for two weeks under routine conditions at home. On days four and ten, a 5-hour meal/insulin challenge was performed at the clinic to assess CGM performance during rapid glucose excursions. During the challenge, the sensor readings were referenced with serum glucose values determined at 20-min intervals (YSI2300, Yellow Springs, USA). Throughout the study, the CGMs were calibrated once/day using an SMBG device. The CGM accuracy was assessed by calculating the mean absolute relative difference (MARD), the mean absolute difference (MAD), and by performing the Consensus Error Grid analysis.

Results: The overall MARD between the venous/capillary reference values and the sensor readings was 9.7 [2.6-14.6] and 13.1 [3.5-18.6] %, while the overall MAD was 1.1 [0.5-1.3] and 0.9 [0.2-1.3] mmol/L, respectively. According to the Consensus Error Grid analysis, 98% of the sensor readings were in the clinically acceptable zones A and B, and the user questionnaire revealed satisfactory overall experience.

Conclusions: In terms of accuracy, the GlucoMen® Day CGM meets the current consensus requirements for CGM performance.

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Topic: AS05-Glucose Sensors

HOW DOES TECHNOLOGY AFFECT METABOLIC PARAMETERS IN TYPE 1 DIABETES CHILDREN?
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Background and Aims: Continuous Subcutaneous Insulin Infusion (CSII) provides an improvement in metabolic control and quality of life for people with type 1 diabetes (T1D). There is a strong consensus that Continuous Glucose Monitoring (CGM) and Fast Glucose Monitoring (FGM) systems reduce hypoglycaemia risk, increase the amount of time in target (TIR) of glucose range and augment treatment satisfaction. The aim of this study was to evaluate glycemetic control (HbA1c, TIR) in T1D children and adolescents followed in the Pediatric Diabetes Centre of East Piedmont in Italy.

Methods: Data of 205 T1D patients (47% girls, 13.4±4.5 years of age) were collected from an electronic registry (Smart Digital Clinic) which is part of a national benchmarking and evaluated for age range (<6ys; 6–11ys; 12–20ys) and use of CSII/MDI and CGM/FGM.

Results: 33.2% of children and adolescents used CSII, 66.8% MDI; 53% CGM or FGM. Children 6–11ys had the best HbA1c vs others age ranges (p<0.01). Subjects with CSII showed mean HbA1c (7.4%vs7.9%; p<0.05), TIR (57.9%vs50.6%; p<0.01) and mean glucose better than MDI (p<0.05). Analysing data according to the type of CSII, PLGS and advanced hybrid closed loop systems (AHCL) determined higher TIR (67.3%vs50, 4%; p<0.0001) and lower HbA1c (7.1%vs7.9%; p<0.01) vs MDI, as expected.

Conclusions: The use of advanced pumps and CGM technology for intensive insulin therapy will improve treatment of children with diabetes in the next future.
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Topic: AS05-Glucose Sensors

ASSOCIATION BETWEEN MONITORING FREQUENCY WITH FLASH TECHNOLOGY AND GLYCEMIC MEASURES IN PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: The aim of this study was to investigate the association between flash monitoring (fGM) frequency and glycemic measures in patients with type 1 Diabetes Mellitus (T1D).

Methods: We collected data from 104 adult T1D patients using fGM technology in real life. We downloaded data to the Abbott Freestyle Libre software including the number of daily fGM scans, time in range (TIR), time below range (TBR), time above range (TAR), number of hypoglycemic episodes and real time spent in hypoglycemia (minutes), as well as Glucose Management Indicator (GMI) from the last 28 days. In addition, all patients had HbA1c performed. We also compared glycemic measurements of patients with less than 6 scans per day (non frequent users) with frequent users (> 6 scans per day). The correlation between the mean number of fGM scans over 28 days and HbA1c, GMI, TIR, TAR, TBR, number of hypoglycemic episodes and time in hypoglycemia were analyzed.

Results: A significant correlation was found between number of scans and average HbA1c, GMI, TIR, TAR, number of hypoglycemic episodes and real time in hypoglycemia (p < 0.001). Average HbA1c was significant lower in frequent users (7.4 ± 0.3% vs 8.3 ± 1.3% in non frequent users, p < 0.01). In addition, frequent users had higher TIR (p < 0.01) and lower TAR (p < 0.01). Interestingly, although frequent users had more hypoglycemic episodes, TBR and real time in hypoglycemia were the same (p = 0.38).

Conclusions: The frequent measurement of interstitial glucose with fGM seems to be associated with better glycemic control in T1D patients in real life conditions without increasing time in hypoglycemia.

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Topic: AS05-Glucose Sensors

EFFECT OF FLASH GLUCOSE TECHNOLOGY ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: To investigate the effect of flash Glucose Monitoring (fGM) technology on glycemic control in patients with type 1 diabetes mellitus (T1D) in real life.

Methods: We included adult patients with T1D from our outpatient Diabetes Clinic who continuously used fGM technology for more than 6 months. We collected data from their first visit after starting fGM and a visit performed at least after 6 months. We downloaded their data to the Abbott Freestyle Libre software from the last 28 days during their visits including time in range (TIR), time below range (TBR) and time above range (TAR) for the same period. In addition, all patients had HbA1c performed in both visits.

Results: Finally 47 T1D patients were included with mean age 39.7 ± 18.3 years and mean diabetes duration 18.6 ± 10.8 years. Average duration of fGM use was 11.3 ± 3.4 months. Baseline HbA1c was 7.4 ± 1.4%. There was no difference in HbA1c level and TBR between the visits but there was a significant reduction in TIR and TAR. The results are shown in table 1.

Conclusions: In our study the use of fGM in real life for almost a year did not affect HbA1c level but improved TIR without increasing hypoglycemia in patients with T1D.

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Topic: AS05-Glucose Sensors

THE IMPACTS OF NON-GLYCAEMIC VARIABLES ON RELATIONSHIP BETWEEN LABORATORY-MEASURED HBA1C AND GLUCOSE MANAGEMENT INDICATOR CALCULATED BY FLASH GLUCOSE MONITORING SYSTEM IN PATIENTS WITH DIABETES

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Background and Aims: Glucose Management Indicator (GMI), as an estimate of HbA1c, is one of the internationally endorsed continuous glucose monitoring (CGM) metrics. We assessed the effects of multiple predominantly non-glycaemic variables on correlation between laboratory-measured HbA1c and GMI calculated by Freestyle Libre Flash Glucose Monitoring (FGM) system.

Methods: We conducted a clinic-based retrospective observational study using electronic medical records. A 14-day CGM data including GMI, Coefficient of Variation (CV) and time in hypoglycemia were analyzed.
range (TIR) were extracted and matched with laboratory HbA1c measured within 3 months. Patient demographics, type of diabetes, red blood cell indices (haemoglobin, haematocrit, MCV, MCH, MCHC), creatinine and Body Mass Index (BMI) within 6 months of using FGM system were obtained. Multivariable linear regression model used to analyse the effect of above parameters on LogHbA1C-LogGMI as the outcome.

Results: 267 adults (32 with type 2 diabetes; mean [SD] age 52.2 [17.4] years) with CGM data and paired HBA1c measures were studied, with 113 showing an absolute HBA1c – GMI difference of $\geq 0.5\%$. Patient demographics, red cell indices and creatinine did not have significant effects on relationship between HbA1C and GMI. The impact of BMI was modest (Table 1).

Conclusions: Measured non-glycaemic variables were not associated with the difference between HbA1C and GMI in patients with Type 1 and Type 2 diabetes.

Table 1. Multivariable linear models with LogHbA1C-LogGMI as the outcome

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<thead>
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<th>Predictors</th>
<th>Estimates</th>
<th>CI</th>
<th>p</th>
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<td>(Intercept)</td>
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<td>0.02 – 13.21</td>
<td>0.701</td>
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<td>1.00 – 1.00</td>
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<td>0.98 – 1.08</td>
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<td>BMI</td>
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<td>1.00 – 1.01</td>
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</tr>
<tr>
<td>Coefficient of Variation</td>
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<td>1.00 – 1.01</td>
<td>0.048</td>
</tr>
<tr>
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<td>1.03</td>
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<tr>
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<tr>
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<td>0.124</td>
</tr>
<tr>
<td>TIR</td>
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<td>1.00 – 1.00</td>
<td>&lt;0.001</td>
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<tr>
<td>Creatinine</td>
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</table>

Observations 95

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Topic: AS05-Glucose Sensors

REAL-TIME POST-PRANDIAL GLUCOSE PREDICTION USING SEASONAL LOCAL MODELS BASED ON CONTINUOUS GLUCOSE MONITORING DATA AND MEALTIME

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Background and Aims: Accurate blood-glucose (BG) prediction has the potential to revolutionize diabetes management by enabling timely warning about upcoming dangerous events. This work investigates seasonal local glucose predictive models based on CGM data and meal timing information.

Methods: Several sets of glucose profiles are obtained by splitting CGM time series according to the main self-reported patient events (i.e. breakfast, lunch, dinner, snack, hypo treatment). CGM portions are then clustered using Fuzzy C-Means to obtain sets of similar CGM profiles. For each of these sets, an optimal Seasonal Auto-Regressive Integrated Moving-Average (SARIMA) model is identified using Maximum Likelihood Estimation. Finally, the predictions of SARIMA local models are integrated using a fuzzy approach. The proposed methodology has been tested on the OhioT1DM dataset, containing data of 12 subjects with T1D recorded over 8 weeks of free-living conditions (6 weeks for the training and 2 weeks for the test). The predicted profile has been computed on the post-prandial periods of the test set for several prediction horizon (PH). Prediction accuracy is evaluated using Root Mean Square Error (RMSE).

Results: are reported in Table 1.

Conclusions: The 25 SARIMA seasonal models’ predictions, integrated by using a fuzzy approach, provide encouraging results both in terms of prediction of future glucose level and real time warning about upcoming dangerous events.

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Topic: AS05-Glucose Sensors

INDIVIDUALIZED CARBOHYDRATE INTAKE STRATEGY TO IMPROVE BLOOD GLUCOSE DURING TEAM SPORTS IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES. A SUMMER CAMP STUDY


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Background and Aims: To reduce the incidence of hypoglycemia during physical activity (PA) in youth with T1D, insulin reduction, and/or carbohydrate intake strategies are recommended. Here, we tested an individualized carbohydrate intake based on pre-PA glucose level and body weight during team sports.

Methods: This study followed an open, randomized, crossover design with 33 individuals with T1D (age 12.4 ± 2.1, HbA1c 8.4 ± 0.9%). Participants randomly completed; 1) control camp routine care (CTRL) (no carbohydrate intake or mandatory glucose level measurement) and 2) individualized carbohydrate intake (ICI) (0.0, 0.25, or 0.5 g of carbohydrates/kg body weight)
based on pre-PA (45-min team sport initiated 1 to 2 h post-meal) glucose levels. Each intervention was performed between 1 to 6 times. Glucose was measured using a FreeStyle Libre continuous monitor.

**Results:** Participants completed 106 (ICI; mean CHO intake 0.18±0.21 g/kg) and 94 (CTRL) sessions. As compared to CTRL, ICI did not affect the percentage of time spent below 4, between 4–10 and above 10 mM of glucose (all \( P \geq 0.421 \)), nor on mean glucose and hypoglycemic events (both \( P \geq 0.405 \)). Glucose responses to peak (2.2±4.0 vs. 2.7±4.3 mM, \( P = 0.020 \)) and nadir (-0.2±5.1 vs. 0.8±5.4 mM, \( P = 0.003 \)) were lowered by ICI.

**Conclusions:** As compared to usual camp care, an individualized carbohydrate intake strategy based on body weight and pre-PA glucose level had minimal effect on glycemic profile during postprandial team sports in youth with T1D.

**P118 / #381**

**Topic:** AS05-Glucose Sensors

**IN-HOSPITAL REAL TIME CONTINUOUS GLUCOSE MONITORING DURING COVID-19 OUTBREAK: EXPERIENCE FROM A COVID HUB**

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**Background and Aims:** On March 2020 Lombardy lived first Sars-CoV-2 pandemic outbreak in Europe. To overcome structural barriers, we tested real time continuous glucose monitoring (rtCGM) in COVID ward. Aim of this study is to evaluate the impact of rtCGM in a cohort of insulin treated diabetic patients hospitalized for COVID19.

**Methods:** This is a retrospective observational study. Dexcom G6 CGM (Dexcom Inc., San Diego, CA) was pushed to extreme performance, combining few POC glucose measurement and no calibration. CGM data were collected by a follower smartphone receiver and extracted from Dexcom Clarity System.

**Results:** Nineteen isolated patients were studied (mean age 66±11 years, diabetes duration 10.8±9 years, mean HbA1c 76±28 mmol/mol). Seventeen patients had respiratory failure. Mean length hospital stay at CGM begin was 11.9±11.6 days. Overall 216 days CGM reports were recorded. 51 out of 80 diabetologist consultation were performed remotely. 10 CGM driven intervention for impending hypoglycaemia occurred. Patient mean CGM use was 11.3±7.6 days with Time in Range (70–180 mg/dl, TIR) of 53±30%, Time Below Range (TBR) 1.1±2.4%, Time Above Range (TAR) 45±31% and Coefficient of Variation (CV) 27.8±8.7%. One confirmed level 2 hypoglycaemia occurred. We found a significant difference between first 72 and last 72 CGM hours in TIR (from 44±30 to 67±21, \( p = 0.002 \)), TAR (from 55±30 to 32±21, \( p = 0.002 \)) and average sensor glucose (from 203±55 to 163±25 mg/dl, \( p = 0.005 \)). 3 patients did not survive, 16 were discharged.

**Conclusions:** Long term rtCGM in-hospital use revealed encouraging safety and potential efficacy in complicated diabetic patients.

**P119 / #398**

**Topic:** AS05-Glucose Sensors

**EFFECT OF BLOOD GLUCOSE ON RATINGS OF PERCEIVED EXERTION DURING EXERCISE IN PEOPLE WITH DIABETES WHO UNDERTAKE REGULAR EXERCISE**

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**Background and Aims:** The rating of perceived exertion (RPE) is used to quantify physical exertion and intensity during exercise. The relationship between RPE, exertion assessed by heart rate and changes in glucose in active people with type 1 diabetes (T1DM) is unknown.

**Methods:** 12 participants with T1DM who exercise regularly continued with their regular exercise routines for 10 days. Heart rate, activity type and exercise duration were measured for each exercise session using a GPS sports watch. A blinded continuous glucose monitor (CGM, Dexcom G6) was worn, and participants assigned an exertion rating to each session using the Borg scale of RPE.

**Results:** 115 periods of activity were identified, ranging from 1m:39s to 1h:41min in duration. As heart rate increased, so did the chance of being in a greater RPE level (odds ratio 1.04). Increases in mean glucose resulted in increased chance of reporting a higher RPE value (odds ratio 1.20). Time in hypoglycaemia during exercise and change in glucose during exercise were not related to heart rate or RPE.

**Conclusions:** The relationship between RPE and HR was weak, suggesting that RPE should be used with caution in those with T1DM. Higher interstitial glucose is associated with higher RPE in those with T1DM. More time spent in hyperglycaemia is linked to disproportionally high RPE when compared with heart rate.

**P120 / #456**

**Topic:** AS05-Glucose Sensors

**EVOLUTION OF THE QUALITY OF LIFE OF DIABETIC PATIENTS UNDER INTENSIVE INSULIN THERAPY BENEFITTING FROM FREESTYLE LIBRE\(^6\)**

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Background and Aims: Self-monitoring of blood glucose, essential in insulin therapy, is perceived as a constraint. The main objective of our study was to assess the impact of FreeStyle Libre® on the quality of life of people with diabetes on intensive insulin therapy.

Methods: We carried out a prospective observational and bicentric study. Quality of life was assessed using the ADDQoL questionnaire without and with the FreeStyle Libre®. This questionnaire includes several scores: a general quality of life score and a composite score of 19 items exploring different areas of life (leisure, motivation, freedom to drink, freedom to eat, etc.). We also compared the HbA1c and the frequency of self-checks.

Results: 55 patients participated in this study. The average age was 60.45 years. The duration of insulin therapy was 14.2 years and the mean HbA1c was 8.26% at the start of the study with a sex ratio of 1.9. With the sensor, our results showed a decrease in HbA1c to 7.71% (p = 0.003) and an increase in the number of daily checks (8.16 “scans” against 4.58 capillary glycemia). We do not find any significant changes in the general quality of life and the total score of the 19 items with the use of FreeStyle Libre® (p > 0.05). However, obtaining a better balance is associated with an improvement in the quality of life (p = 0.0008).

Conclusions: There was no significant change in the general quality of life. However, we find an improvement in glycemic balance, a parameter associated with an improvement in quality of life.

P121 / #503
Topic: AS05-Glucose Sensors
THE INFLUENCE OF THE HEMATOCRIT ON NINE SELF-MONITORING BLOOD GLUCOSE DEVICES
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Background and Aims: Self-monitoring blood glucose (SMBG) devices are an essential tool for self-care management of diabetes. The accuracy of the SMBG devices can be influenced by a large number of methodological, environmental and physiologic factors, including abnormal hematocrit values. Our objective was to evaluate the influence of the hematocrit on nine SMBG devices.

Methods: The study procedure followed the indications of the ISO 15197:2013 for hematocrit interference testing, with one test strip lot per device. We evaluated different hematocrit levels within the acceptable hematocrit range as described in their respective instructions. The mid hematocrit level was established at 42% +/- 2%. The three glucose ranges were: 30-50 mg/dL, 96-144 mg/dL, and 280-420 mg/dL. For each hematocrit-glucose combination, 5 replicates were tested. Acceptable normalized bias was of 10 mg/dL or 10% for glucose <100 mg/dL, or >100 mg/dL, respectively. Reference glucose measurements were performed on an Atellica® Solution (Siemens Healthineers). Hematocrit levels were quantified by an Advia® 2120 (Siemens Healthineers).

Results: The highest bias of the three glucose ranges, for each device and hematocrit, are shown in Figure 1. The hematocrit interference observed in the Contour® Next One, FreeStyle Optium Neo and OneTouch Verio Reflect® conformed fully with the ISO 15197:2013 specifications. However, Contour® Next One was able to provide reliable results in a wider hematocrit range and within 5% of bias.

Conclusions: Healthcare professionals and patients should be aware of the SMBG limitations and select the SMBG device that would fit best the individual situation of each patient.

P122 / #521
Topic: AS05-Glucose Sensors
OUTCOME OF FLASH GLUCOSE MONITORING- AN AUDIT
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Background and Aims: Use of Flash glucose monitoring (FGM) is considered a useful technology for diabetes management. We audited the compliance and outcome of FGM use amongst paediatric type 1 Diabetic Mellitus (T1DM) patients within our service.

Methods: This was a retrospective audit. We collected and analysed data, focusing on the percentage of sensor usage time, number of scans/day, HbA1c at 0,1,3,6,9 and 12 months and the average number of diabetes related hospital attendances/year before and after starting FGM, from 46 patients commenced on FGM between April 2019 and April 2020.

Results: Of the total 46 patients, 28 (61%) continued FGM use. Of these 28 patients, 18 (64%) had sensor usage time of >70% and 8 (32%) patients completed more than 8 scans/day. On commencing FGM (0 months), the HbA1c of these 28 children ranged between 6.2 and 11.2 mmol/mol (Mean = 8.8). At 12 months, this was between 5.8 to 11.8 mmol/mol (Mean = 8.3), demonstrating a 0.5 reduction in the mean. One-tailed Mann-Whitney U-test indicates that the HbA1c at 12 months is less than at 0 months, U = 279, p = 0.07. Whilst this is not statistically significant, 19 (68%) patients’ serial HbA1c displayed a downward trend, and 39% (11/28) had reduction in diabetes related hospital attendances/year.

Conclusions: FGM helps improve diabetes management and outcomes. Treating diabetes teams should continue to support patients in use of advanced technology through closer follow-up and empower them towards diabetes self-management, thereby improving outcomes.
**P124 / #568**

**Topic: AS05-Glucose Sensors**

FLASH GLUCOSE MONITORING IMPROVES QUALITY OF LIFE AND REDUCES FEAR OF HYPOGLYCEMIA IN TYPE 1 DIABETES PATIENTS: A REAL WORLD PROSPECTIVE STUDY.

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**Background and Aims:** Flash Glucose Monitoring (FGM) is associated with significant improvements in glycemic control of patients with type 1 diabetes. However, the impact on Quality of Life (QoL) and fear of hypoglycemia remains controversial.

**Methods:** We conducted a prospective, real-world, case-control study of a six-month follow up involving patients treated with multiple daily insulin injections (MDI) or continuous subcutaneous insulin infusion (CSII). Individuals who started with a FGM system for the first time (cases) were compared with those who were using it previously (controls). The main end points were the scores of QoL and fear of hypoglycemia questionnaires (EsDQUOL and Hypoglycemia Fear Survey-HFS-) and other clinical outcomes like HbA1c, weight, dose of insulin/kg, rapid insulin percentage, and severe hypoglycemias.

**Results:** A total of 149 patients were included in the case group (63% MDI and 37% CSII, mean age:47±12 years, mean HbA1c: 7.6±0.97) and 33 patients in the control group (76% MDI and 24% CSII, mean age:44±15 years, mean HbA1c: 7.2±0.65). EsDQUOL and HFS scores improved in the case group (p<0.05) but not in the control group after 6 months. HbA1c was significantly lower in both groups (-0.11% and -0.15% respectively) at the end of the study. There were no significant differences in the rest of the analyzed outcomes.

**Conclusions:** FGM improves QoL and reduces fear of hypoglycemia in patients with Type 1 diabetes. Additional studies are needed to assess the long-term impact of this new technology.

**P125 / #595**

**Topic: AS05-Glucose Sensors**

ACCURACY AND RELIABILITY OF TWO GLUCOSE MONITORING SYSTEMS TESTED SIMULTANEOUSLY IN AMBULATORY PATIENTS WITH TYPE 1 OR 2 DIABETES AND ADVANCED CHRONIC KIDNEY DISEASE.

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**Background and Aims:** Diabetes and advanced chronic kidney disease (CKD) is a public health problem due to increased risk of microvascular complications. Continuous glucose monitoring (CGM) systems provide valuable information for diabetes management. In this study, we evaluate the accuracy and reliability of two CGM systems, Freestyle Libre (FSL) and Dexcom G4 (DG4), in a real-world setting.

**Methods:** We performed a 6-month prospective study involving patients with type 1 or 2 diabetes and advanced CKD. Patients were sub-grouped according to their baseline estimated glucose disposal rate (eGDR) using a cut-off value of 8, low insulin sensitive; Group 2: >8, more insulin sensitive. AGP data were collected the last 3 months of FSL (M0) and of DG4 use (M6). Statistics were performed using paired t-test or Wilcoxon within group, and unpaired t-test or Mann-Whitney between groups.

**Results:** Twenty-five T1D patients were sub-grouped according to their baseline eGDR using a cut-off value of 8 mg/kg/min (Group 1: <8, low insulin sensitive; Group 2: >8, more insulin sensitive). AGP data were collected the last 3 months of FSL (M0) and of DG4 use (M6). Statistics were performed using paired t-test or Wilcoxon within group, and unpaired t-test or Mann-Whitney between groups.

**Results:** AGP metrics were not different between groups (not significant). Regarding changes in metrics (Table), patients less sensitive to insulin (group 1) improved their exposure to hyperglycemia (decreases in TIR70 (Time in Range below 70 mg/dL), TBR54 (<54 mg/dL) and % CV (Coefficient of Variation)), significantly compared to patients more sensitive to insulin (group 2). Conversely, the latter improved their exposure to hypoglycemia in patients with Type 1 diabetes. Additional studies are needed to assess the long-term impact of this new technology.

**Conclusions:** FGM improves QoL and reduces fear of hypoglycemia in patients with Type 1 diabetes. Additional studies are needed to assess the long-term impact of this new technology.

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**Table: Impact of eGDR score on changes in AGP metrics after switching from FSL to DG4 over 6 months in T1D patients**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group 1 (eGDR &lt; 8 mg/kg/min)</th>
<th>Group 2 (eGDR &gt; 8 mg/kg/min)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M0 vs M6</td>
<td>M6 vs M0</td>
<td>M0 vs M6</td>
</tr>
<tr>
<td>TIR (0–80 mg/dL)</td>
<td>-0.62 (7.5–10)</td>
<td>0.031</td>
<td>0.058</td>
</tr>
<tr>
<td>TIR (70–180 mg/dL)</td>
<td>-0.21 (7.9–2.3)</td>
<td>0.030</td>
<td>0.026</td>
</tr>
<tr>
<td>%CV</td>
<td>-0.10 (2.4–0.6)</td>
<td>0.0083</td>
<td>0.067</td>
</tr>
<tr>
<td>GLI %</td>
<td>0.00 (0.0–0.0)</td>
<td>0.002</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Changes were calculated from the AGP parameters collected during the last 3 months of FSL use for M0, and during the last 3 months of DG4 use for M6. Changes (FSL vs DG4) were compared using unpaired t-test or Mann-Whitney.
Background and Aims: The aim was to compare the accuracy, reliability and safety of the Dexcom G5 and the FreeStyle libre sensors in adults with type 1 or 2 diabetes with estimated glomerular filtration rate (eGFR) of <30ml/min/1,73m², including patients on maintenance dialysis.

Methods: Forty patients at 2 outpatient clinics in Sweden, carried a Dexcom G5 for 7 days and FreeStyle Libre for 14 days. Capillary blood glucose levels were measured with a high accuracy glucose meter (HemoCue) 3 times/day during the study period.

Results: Mean age was 64 ± 9.2, HbA1c 53 ± 11.0 mmol/mol, diabetes duration 28.5 ± 14.7 years. 27.5% of study population were on hemodialysis and 22.5% peritoneal dialysis. Mean absolute relative difference (MARD) for Dexcom G5 was significantly lower than for FreeStyle Libre, 15.2% (95%CI 10.9-19.6%) and 20.9% (95%CI 17.9-24.0%) respectively (p = 0.031). Mean absolute difference was also significantly lower for Dexcom G5 than for FreeStyle Libre, 1.21mmol/l (95%CI 0.93-1.48mmol/l) and 1.76 mmol/l (95%CI 1.48-2.03mmol/l) respectively (p = 0.0058), and mean difference was -0.107 mmol/l and -1.10 mmol/l (p = 0.0008) respectively. Correlation between HemoCue and Dexcom was 0.785, HemoCue and FreeStyle Libre was 0.776 and between Dexcom and FreeStyle Libre 0.782.

Conclusions: Dexcom G5 gives persons with diabetes and advanced chronic kidney disease (CKD) more accurate estimates of blood glucose levels than Freestyle Libre. Dexcom G5 is likely safe to be used by persons with advanced CKD since the accuracy was similar as for persons without CKD when similar reference systems have been used. The Freestyle Libre system shows systematically lower glucose levels partly explaining the lower accuracy.

P126 / #659
Topic: AS05-Glucose Sensors
CONTRIBUTION OF CGMS DURING DIFFERENT SPORTING ACTIVITIES IN ADULTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: CGMS reveals glycaemic fluctuations during high intensity and endurance sports (ESA). The aim was to obtain and analyse glycaemic curves in people with DM1 during various intensive sports: jogging, ice hockey, skiing, marathon running, mixed martial arts (MMA), and to design treatment regimen best suited to avoid glycaemic variability (GV).

Methods: From 29 adults with T1D with realised CGM (19–65 years) with HbA1c 7.4–8.8% DCCT, diabetes duration 3–30 years, on intensive insulin treatment (IIT); we used Guardian™ Connect, Guardian™ 2Link, FreeStyle Libre. All participants practised their sport regularly and during CGM they recorded treatment, saccharide consumed and exercise duration. Based on individual data each participant was advised on adjustment of therapy.

Results: From 29 CGM monitored DM1 patients three typical glycaemic patterns were identified as consequence of physical activity (PA): (1) decline of glycaemia after PA; (2) a glycaemic rise during PA; (3) elevation of glycaemia after PA. Examples are: 1. Jogging in an IIT-treated patient led to nocturnal hypoglycaemia, eliminated after CGM based therapy adjustment. 2. Unexpected elevation of glycaemia during a marathon in a young woman on IIT was evoked by stress during sporting performance, while in another patient the same activity provoked hypoglycaemia. 3. Glycaemic elevation was observed after finishing PA in patient performing MMA with high GV.

Conclusions: The nowadays CGMS technology enables glycaemic fluctuations during high intensity and ESA in DM1 patients to be identified and counteracted by appropriate therapeutic adjustments.

P127 / #711
Topic: AS05-Glucose Sensors
INSIGHTS TO THE TIME IN RANGE (TIR) IN PATIENTS ON FLASH GLUCOSE MONITORING (FGM) IN PATIENTS WITH TYPE 2 DIABETES

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Table: Glycemic Metrics Across Age and the duration of diabetes in 320 T2DM

Background and Aims: Continuous Glucose Monitoring (CGM) has rapidly evolved with Time In Range (TIR) as a prominent glycemic metric
Methods: We evaluated 320 patients across three centres who utilised FreeStyle Libre Pro CGM to understand glycemic variability in patients managed through standard care approach. The key glycemic metrics; TIR, Time Below Target (TBT), Time Above Target (TAT) were analysed based on the duration of diabetes and the age. ANOVA and chi-square were utilised for statistical analysis.

Results: 50% (160/320), 63.1% (202/320), 46.8% (150/320) were in TIR >70%, TAT <25% and TBT <5%. 36.8% (n=118) patients had diabetes duration <10 years and 52.1% (n=167) were >60 years of age. The mean TIR was 67% (±21, 95% CI 65 to 69). TIR was significantly better achieved in patients age ≥60 years (TIR 67.8%, p= <0.0001) and in patients with duration of diabetes <10 years (TAT 70.5%, p=0.0271). The mean TBT and TAT was 9.7% (±12, 95% CI 8.3 to 11) and 23 (±23, 95% CI 21 to 26), respectively. In patients with duration of diabetes <10 years TAT was significantly better than with ≥10 years diabetes (19.5% Vs 25.2%, p=0.0331)

Conclusions: Our results provide insights for the TIR glycemic metrics as a measure to achieve optimal glycemic control. TIR appears to be an evolved metric with association across the age group and the duration of diabetes. There is need to integrate TIR in routine diabetes practice as a step towards, more effective and precise diabetes management.

P128 / #713
Topic: AS05-Glucose Sensors
FLASH GLUCOSE MONITORING SYSTEM (FSL) IMPROVE GLUCOSE CONTROL SPECIALLY IN CSII USERS
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Background and Aims: The aim of this study is to investigate if FSL (Freestyle Libre ®) improves metabolic control in patients with type 1 diabetes and compare its effects in dependence of the type of insulin treatment.

Methods: We studied 415 type 1 diabetic patients, 48.4% were men, mean age was 46.31 ± 15.35 years and duration of diabetes 22.17 ± 13.27 years. A total of 324 patient were FSL users. Divided in function of the type of treatment, 290 were on basal-bolus insulin therapy and no FSL users (BB-FSLNO) and 34 were on CSII and FSL users (CSII-FSL).

Results: FSL users were younger (FSL: 44.42 ±14.67 vs FSLNO: 53.12 ±15.91 years; p<0.01) but there were not differences in time of evolution. The A1c was lower in FSL users (FSL: 7.61 ±1.22 vs FSLNO 7.91 ±1.37%; p<0.05). In function of treatment, CSII-FSL showed lower A1c compared to BB-FSLNO (ISCI-FSL 7.23±0.73% vs BB-FSL 7.65±1.26% vs BB-FSLNO 7.92±1.37%; p<0.05), with no differences with BB-FSL users. When we compared 14 days AGP report between FSL users, CSII users had less mean glucose (CSII: 155.79 ±23.68 vs BB: 169.76 ±34.09 mg/dl; p<0.05), more TIR (CSII: 64.03 ±13.74 vs BB: 56.36 ±17.14 %; p<0.05) and less GMI (CSII: 7.04 ±0.56 vs BB: 7.37±0.81%; p<0.05) with no differences in TBR and %CV.

Conclusions: The FSL helps to improve metabolic control in Type1 diabetes specially in CSII users, who presents better mean glucose and better time in range.

P129 / #714
Topic: AS05-Glucose Sensors
GLUCOSE MANAGEMENT INDEX CORRELATES WITH A1C INDEPENDENTLY OF THE INSULIN TREATMENT IN TYPE 1 DIABETIC PATIENTS. ASTURIAS REAL WORLD DATA 2020
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Background and Aims: A1c (laboratory glycated hemoglobin) is the primary measure guiding glucose management. An international consensus group recently included a list of CGM metrics recommended for inclusion in all standard CGM reports (AGP). [Mean glucose, TIR, TBT, TAR, Glycemic variability (%CV) and glucose management indicator (GMI)]. The aim of this study is to investigate the relationship between A1c and 14 days GMI calculated from the flash glucose monitoring system

Methods: 219 type 1 diabetic patients were selected, 59.4% were men; the mean age (±SD) was 44.71 ±14.54 years and the duration of diabetes was 22.43 ±13.21 years. 86.8% of patients were on basal-bolus insulin therapy and 13.2% were on CSII. A1c level was taken from the electronic medical history and 14 days AGP report was downloaded from Libreview platform when the percentage of active time was ≥70%; the same day that blood test was done.

Results: 14 days AGP report showed a mean glucose of 162.39 ±29.18 mg/dl with a mean CV of 37.61 ±6.43 %. The mean %CGM active was 94.71 ±7.41%. The TIR was 56.71 ±15.36%, TBR 5.16 ±5.0% and TAR 35.19 ±16.70%. The mean GMI was 7.20 ±0.69%. The A1c was 7.37 ±0.93%. This data offered a mean differences A1c-GMI of 0.17 ±0.67. Linear regression showed that A1c correlates with GMI (b=0.716, p<0.01) when the %CV, TIR, TBR, type of treatment, were included as independent variables

Conclusions: The GMI is a good indicator of glucose control due to a strong correlation with gold standard A1c.

P130 / #723
Topic: AS05-Glucose Sensors
REAL WORLD EVIDENCE FOR DIURNAL GLYCEMIC CHANGES EVALUATED BY FREESTYLE LIBRE PRO FLASH CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM IN PATIENTS WITH TYPE 2 DIABETES
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Dr Sonali Patange’s Speciality Diabetes Centre, Diabetes, Mumbai, India

Background and Aims: We utilised FreeStyle Libre Pro continuous glucose monitoring (CGM) to understand the
glycemic variability in patients treated as per standard care of approach based on contemporary guidelines.

Methods: We conducted a retrospective analysis of patients (n=202) in the DSP clinic cohort during 2018 to 2019. This was an evaluation done at a single centre providing a comprehensive diabetes care. We included T2DM patients, with no exclusion criteria in this group. ANOVA was utilised for statistical analysis. The glycemic variability over 24-hour period was evaluated for the glucose readings captured after every 2 hours.

Results: Most patients had diabetes for greater than 5 years. Mean daily average blood glucose (mg/dl), Time in Target (%), Time below target (%), Time above target (%) were 161 (±64, 95% CI 154 to 168), 34 (±19, 95% CI 32 to 37), 16 (±19, 95% CI 13 to 18), 50 (±28, 95% CI 46 to 53), respectively. The least mean glucose (mg/dl) was recorded was 125.3, 127.7 during 4–6 am and 6–8 am, respectively. Post breakfast, beyond 10 am blood glucose started rise with highest value noted around nighttime (183.3 mg/dl). The difference across the 2 hourly groups was significant (p < 0.0001).

Conclusions: The daytime hyperglycaemia especially post breakfast spike is attributed to the excess carbohydrate intake, that led to rebound hyperglycemia. Our study describes real-world evaluation of glycemic variability with potential to decrease frequency of in person patient contact without negatively impacting outcomes.

P131 / #724

Topic: AS05-Glucose Sensors

THE FREQUENCY OF UNLIMITED FLASH GLYCEMIA SCANS BY PATIENTS WITH TYPE 1 DIABETES ON PUMP INSULIN THERAPY AND ITS CORRELATION WITH DIABETES MELLITUS CLINICAL PARAMETERS

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Background and Aims: The development of devices that free patients from finger piercing, as well as, the use of test-strips in diabetes control, can demonstrate the real daily need for glycemic self-control in patients with T1D.

Methods: 58 adult patients with T1D undergoing insulin pump therapy used flash glucose monitoring systems for 14 days, followed by a retrospective assessment of the glycemic scans per day and its correlation with diabetes mellitus clinical parameters.

Results: The frequency of scans during 14 days ranged from 3.5±0.9 to 139±26.7 times per day. The average number of scans for the first 7 days of the study 29.3±1.7 times was compared with the average number of scans on the 7-th day 30.6±33.0 times (p > 0.05), the average number of scans for 14 days 27.8±2.7 times was compared with the number of scans on the 14-th day - 25.6±20.5 times (p > 0.05). A statistically significant correlations between the average number of scans and the average glycemia, the percentage of time above and below range, the patient’s age, the diabetes duration, the number of diabetes complications weren’t received (p > 0.05).

Conclusions: The recommended self-control frequency at least 4 times a day, is actually 7 times lower than the real need for patients with T1D. It doesn’t depend on the patient’s age, the duration of T1D, the number of its complications and the parameters of the carbohydrate metabolism and doesn’t change significantly from day to day. All these reflects the internal and stable need for each patient with T1D to increase the frequency of glycemic self-control.

P132 / #740

Topic: AS05-Glucose Sensors

FIRST REPORT OF GENDER DISPARITY IN TECHNOLOGY UPTAKE [CONTINUOUS GLUCOSE MONITORING (CGM)] IN PATIENTS OF DIABETES ACROSS INDIA

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Background and Aims: Prevalent literature shows gender differences exist in diabetes and in care measures with fewer women as compared to men likely to receive standard of care, intensive therapy or adequate glycemic monitoring. Access to healthcare and related technology are important in reducing morbidity and mortality. This apparent gap in technology-driven glycemic monitoring in women, could adversely impact quality of life (QOL), disease complications or compound the existing death rate in women. While gender disparity in insulin pump use is reported, no trends are shown from India for CGM use. In this preliminary investigation, four centres across India collaborated to determine if gender differences exist in technology uptake, particularly CGM use in patients of T1DM/T2DM.

Methods: Records of CGM (1 January 2019 to 31 December, 2020) (Abbott Libre Pro) in patients of T1DM/T2DM were collated and statistically analysed using Chi-square test.

Results: From a total of 403 and 167 patients of T2DM and T1DM, respectively undergoing CGM, 76.29% were male while 64.87% were female patients for T2DM and 23.71% were male and 36.13% were female patients with T1DM. Overall, data reflects a higher proportion of males undergoing CGM as compared to females (p=0.0032). The OR is 1.742 implying that 74% higher chances of males undergoing CGM as compared to female patients.

Conclusions: Gender differences in technology uptake with more males with diabetes undergoing CGM than females, exist due to socio-cultural-economic reasons that should be determined in future, larger prospective design studies of longer duration; to create inroads to improve glycemic control and QOL in women with diabetes.
P133 / #773

Topic: AS05-Glucose Sensors

PROOF-OF-CONCEPT OF A NOVEL NON-INVASIVE GLUCOSE MONITOR-VALIDITY OF THE ALGORITHM OVER TIME WITHOUT INTERMITTENT CALIBRATION

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Background and Aims: We are developing a non-invasive blood glucose monitor based on analyzing spectral variations in a rf/microwave signal when reflected from the wrist. Here we report data on the signal analysis and the validity of the predictive algorithm over a period of 1-year without intermittent calibration.

Methods: The NIGM device was applied to the wrist. Patients with type 1 diabetes, between 18 and 64 years and BMI between 18.5 and 35 kg/m² (all inclusive) participated in two automated glucose clamp experiments, glucose values between the range of 60 to 250 mg/dL, to cover the full glycemic range. Data from the first clamp were used to predict the values obtained at the second clamp. Patients that had been studied in September 2019 were included in a cohort of patients studied in June-July 2020. Reference glucose values were obtained with a SuperGL analyzer every 5 minutes throughout the clamp experiments.

Results: 9 white males participated in the June-July 2020 cohort (mean ±SD age 34 years, BMI 25 kg/m², diabetes duration 9.8 years). Data from 4 subjects who had participated in the 2019 study allowed analysis of data using signal models built in 2019 to calculate BG levels in the 2020 study. Correlations of this data showed that the signal models built were able to perform acceptable estimations demonstrating the robustness of the models over time.

Conclusions: Although much work still needs to be done, the robustness of the signal analysis model signals to the viability of the device and delivers further proof-of-concept for high-frequency, microwave-based, non-invasive glucose monitoring.

P134 / #783

Topic: AS05-Glucose Sensors

ASSESSING THE ACCURACY OF DIFFERENT GLUCOMETERS BASED ON THE LABORATORY REFERENCE METHOD

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Background and Aims: Self-monitoring of blood glucose using point-of-care glucometers is a critical tool in diabetic care. Various glucometers have been developed. This cross-sectional study aimed to evaluate the accuracy of commonly used glucometers by comparing their readings with those of the laboratory reference method.

Methods: The five commercially available glucometers - Accu-Chek (Roche Diagnostics GmbH, Mannheim, Germany), OneTouch (LifeScan Inc, USA), Freestyle Optium Neo (Abbott Diabetes Care Inc, USA), Contour Next, and Contour Next One (Ascensia Diabetes Care Inc, Canada) - were utilized in our study. Participants were randomly selected for measuring fasting blood glucose levels to eliminate any factors affect measurements by the glucometers and glucose hexokinase method (reference method). Statistical analysis was carried out and the readings were expressed as mean and standard deviation.

Results: All glucometer readings correlated well with the laboratory measurements; however, the venous glucose level readings showed a slight difference, especially in case of higher blood glucose levels. Although, no significant difference was found between the mean venous blood glucose and the mean of other glucometer readings, a highly significant positive correlation was found between laboratory measurements and glucometer readings. Moreover, our study confirmed that Accu-Check, OneTouch, and Freestyle Optium Neo meters were significantly useful predictors of venous blood glucose. Notably, Freestyle Optium Neo showed the minimal mean bias (-0.4%) in contrast to Contour Next One that showed the highest proportional bias (6.1%).

Conclusions: Independent comparison of all glucometers should be carried out as the proportional bias, especially in case of high blood glucose levels, can affect patient care.

P135 / #791

Topic: AS05-Glucose Sensors

CONTINUOUS GLUCOSE MONITORING IN GLYCOGEN STORAGE DISEASE TYPE I A

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Background and Aims: Glycogen storage disorder type Ia (GSD-Ia) leads to severe hypoglycemia due to impairment of both glycogenolysis and gluconeogenesis. Continuous glucose monitoring (CGM) is effective in preventing hypoglycemia in type I diabetes, potentially representing a new frontier in the management of GSD-Ia. The aim of this study is to evaluate the role of CGM in optimizing dietary treatment in GSD-Ia.

Methods: We used a CGM (G6, Dexcom, San Diego, US) for 4 weeks in a pediatric patient with GSD-Ia (female, 3 years, weight 14.5 kg, genotype Arg83Cys/Arg83Cys) to evaluate time spent with glycaemia <70 (TBR-L1) and <54 mg/dL (TBR-L2). During the CGM, the patient was on standard nutritional treatment with meals every 2.5 hours and nocturnal continuous tube feeding.

Results: TBR-L1 and TBR-L2 were 21% and 10%, respectively. Glycemic drops were mostly observed after suspension of nocturnal feeding and before dinner (Figure 1). Parents reported CGM as an advantageous tool to identify asymptomatic episodes.
of hypoglycemia. CGM results, indeed, allowed further tailoring of dietary management of the patient, with reduction of TBR-L1 to 13.1% (26% improvement from baseline). Figure 1. Ambulatory Glucose Profile (AGP) of the patients during the first 4 weeks of continuous glucose monitoring.

Conclusions: Besides adding new insights in the comprehension of metabolic control in glycojenesis, CGM can be useful to optimize glycemic homeostasis in GSD-Ia.

P136 / #792
Topic: AS05-Glucose Sensors
IMPACT OF CONTOUR PLUS ELITE BLOOD GLUCOSE MONITORING SYSTEM ON BOLUS INSULIN DOSING AND BLOOD GLUCOSE RESULTS VARIANCE
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Background and Aims: Earlier studies demonstrated that the amplification factor between meter and actual blood glucose variance was approximately 2.5 for BGMS with an error margin ±15/15. We applied this methodology in the hypothetical scenario if a diabetes patient used CONTOUR PLUS ELITE BGMS for bolus insulin dosing decision. Subsequent expected blood glucose (BG) values were calculated.

Methods: The BGMS data were derived from a study, assessing the accuracy according to ISO 15197, 2013. 95% of BG results expected at specific reference value (13.9 mmol/L) were computed. We calculated bolus insulin dose and expected BG values based on the following: there is 95% confidence that the BGMS has an error margin between -5.68% and +6.49%. We assume that the personal correction factor to calculate insulin dose is 3.0mmol/L for 1 Unit.

Results: When true BG is for example 13.9 mmol/L , 95% of BG results obtained by the BGMS are expected within the range of 13.1-14.8 mmol/L. The calculated bolus insulin dose was 3 units in all three cases: true (13.9mmol/L), lower (13.1mmol/L) and upper (14.8mmol/L) BGMS readings. It would result in final BG of approximately 5.0mmol/L so there is 0% difference between target BG (5.0mmol/L) and the final BG using either lower or upper readings.

Conclusions: In this study we demonstrated that BG readings, using CONTOUR PLUS ELITE BGMS are highly accurate, which is critical for safe and effective diabetes management, especially in insulin-treated patients. This could minimize the risk of hypo and/or hyperglycemic events that lead to short and long term diabetes complications.

P137 / #795
Topic: AS05-Glucose Sensors
GLUCOSE CONTROL AFTER INITIATION OF FLASH GLUCOSE MONITORING IN TYPE 2 DIABETES MANAGED WITH BASAL INSULIN: A RETROSPECTIVE REAL-WORLD CHART REVIEW STUDY FROM CANADA
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Background and Aims: Evidence for the real-world benefit of continuous glucose monitoring in type 2 diabetes (T2DM) managed using basal insulin is limited. The aim of this retrospective real-world study was to evaluate change in HbA1c over 3–6 months in adults with T2DM using a basal insulin regimen and started using the FreeStyle Libre Flash Glucose Monitoring System™. The study population included adults on a basal insulin regimen for ≥1 year, with HbA1c 8.0–12.0% (64-108mmol/mol), who used FreeStyle Libre regularly for ≥3 months. Pregnant patients were excluded, as were patients on dialysis.

Methods: Medical records (n=91) from basal insulin using patients with T2DM from 6 diabetes centres in Canada were evaluated. To minimise selection bias, all eligible medical records identified at each centre were included. On average, HbA1c was 8.9 ± 0.9% (74.1 ± 9.7 mmol/mol), prior to FreeStyle Libre use, age was 64.3 ± 10.9 years, BMI was 30.5 ± 7.6 kg/m² and average duration of insulin use 4.1 ± 3.0 years (mean±SD), 69.2% were male. HbA1c results were recorded between 90 and 194 days from the start of use of FreeStyle Libre, between December 2017 and December 2019.

Results: After at least 3 months of using FreeStyle Libre, HbA1c (primary outcome) was significantly reduced by 0.8 ± 1.1% (mean±SD); p<0.0001. Sub-group analysis by baseline HbA1c (<9.0%, ≥9.0%) showed both groups significantly reduced HbA1c; with reductions of 0.5 ± 0.8%, p<0.0001 and 1.6 ± 1.3%, p<0.0001, respectively.

Conclusions: This real-world, retrospective chart review study concluded that people with T2DM on basal insulin therapy, using FreeStyle Libre for between 3 to 6 months significantly reduced HbA1c.

P138 / #815
Topic: AS05-Glucose Sensors
ANALYSIS OF THE GLYCEMIA TARGET RANGES CHOICE IN PATIENTS WITH TYPE 1 DIABETES MELLITUS ON PUMP INSULIN THERAPY USING A CONTINUOUS FLASH GLUCOSE MONITORING SYSTEMS
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Background and Aims: In practice the recommendations regarding the choice of the glycemica target range from 3.9 to 10.0 mmol/L in patients using a continuous flash glucose monitoring systems are not always implemented, that can lead to incorrect glycemic profile data interpretation and, as a result, unjustified therapeutic measures.

Methods: 85 adult patients with T1D (47-women, 38-men, the average age - 33.0 ± 11.2 years, the average duration of T1D - 12.1 ± 10.7 years), undergoing pump insulin therapy and continuous flash glucose monitoring were involved in the study, followed by a retrospective analysis of the established glycemica
target ranges according to continuous flash glucose monitoring systems reports.

**Results:** 44 patients (51.7%) of the 85 patients, had a different glycemia target range than the recommended range. The average value of the lower limit of the target range in this group was $4.3 \pm 0.7 \text{ mmol /L}$, the upper limit $- 8.6 \pm 0.8 \text{ mmol/L}$, which affected the time in ranges (TIR), table 1. TIR in different groups of patients

**Conclusions:** The glycemia target range did not correspond to the recommended range in more than half of the patients, that makes it difficult to correctly assess the TIR. The analysis suggests the need to train patients to correctly select and set the values of the glycemia target range.

**P139 / #33**

**Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies**

**THE WELL-8 SCALE: ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN PEOPLE WITH CHRONIC DISEASES**

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**Background and Aims:** Well-8 questionnaire, an 8-item instrument was developed to measure multiple aspects that influence the quality of life (QOL) in people with chronic diseases. The present study is aimed at establishing the validity and reliability of the Well-8 questionnaire for the assessment of QOL in people with chronic diseases enrolled on the Wellthy CARE™ Digital Therapeutics platform.

**Methods:** Eighty participants (Average age: 43.91 ± 12.35 years, 25% female) who were using an Integrated Personalised Diabetes Management (iPDM) consisted of an Accu-Chek® Active glucometer with the WDTx platform, provided consent to participate in the study. The Well-8 questionnaire was validated by a six-member panel (consisting of experts in diabetes management, clinical nutrition and public health) based on readability, clarity and comprehensiveness. The validity of Well-8 scale was established in comparison to the ‘Appraisal of Diabetes Management (iPDM) consisting of an Accu-Chek® Glucometer with the WDTx platform, provided consent to participate in the study.

**Results:** The experts validated the content of Well-8 to be highly appropriate with a scale–content validity index (S-CVI) of 0.96. Cronbach’s alpha coefficient was determined to be 0.84, which suggested good reliability and high internal consistency. A strong correlation could be found between the score of Well-8 and ADS questionnaires ($r = 0.58$, $n = 80$, $p < 0.0001$). A moderate correlation was observed between Well-8 score and average blood glucose level ($r = -0.31$, $n = 57$, $p < 0.05$). A lower degree of correlation was also found between the Well-8 score and personal income ($r = 0.22$, $n = 80$, $p < 0.05$).

**Conclusions:** The study established the validity and reliability of the Well-8 questionnaire to assess health-related QOL in patients with chronic diseases.

**P140 / #81**

**Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies**

**MEDICATION OPTIMIZATION AMONG PEOPLE WITH TYPE 2 DIABETES PARTICIPATING IN A CGM-DRIVEN VIRTUAL CLINIC**

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**Background and Aims:** The Onduo Virtual Diabetes Clinic (VDC) program for people with T2D includes a mobile app, remote lifestyle coaching, connected devices and telemedicine consultations with endocrinologists for medication management and prescription of real-time (rt)CGM devices. The objective of this analysis was to evaluate medication management through the VDC.

**Methods:** Adults with T2D and baseline HbA1c ≥8.0% to ≤12.0% participated in the VDC program for 4 months. Participants were asked to participate in telemedicine consultation with a VDC endocrinologist for diabetes medication management and used rtCGM intermittently to guide therapy and dosing. Medication changes were evaluated.

**Results:** At baseline, 10.9%, 38.2% and 50.9% of participants ($n = 55$) were prescribed 1, 2 and ≥3 diabetes medications. Most participants (89%) had a medication change consisting of a dose change, addition or discontinuation. Of these, 30.6% ($n = 15$) of participants had a net increase in number of diabetes medications from baseline. Among anti-diabetes medication classes the number of participants prescribed GLP-1 analogue therapy increased from 25.5% to 52.7% ($p < 0.001$) and sulfonylurea prescriptions decreased from 54.5% to 34.5% ($p = 0.007$). Prescriptions of other anti-diabetic medication classes, including insulin, did not change significantly. HbA1c decreased by $-1.6\% \pm 1.0\%$ ($p < 0.001$) at 4 months with no increase in hypoglycemia.

**Conclusions:** Participation in the VDC was associated with improved glycemic control. Medication management largely consisted of substitution of ineffective diabetes medications with more effective medications with a minority of participants.
requiring addition of new classes. Use of rtCGM facilitated the efficiency and safety of medication optimization by telemedicine through the VDC.

P141 / #84

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

DIABETES MELLITUS AND THYROIDITIS: DATA MINING TECHNIQUES APPLIED TO THE CLASSIFICATION OF PEDIATRIC PATIENTS

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Background and Aims: It is known that Artificial Intelligence and, in particular, Data Mining have an important role in the public health allowing you to get more information from clinical data available. The aim of the study was to predict the possibility that young T1DM patients may develop complications associated with Diabetes Mellitus.

Methods: Regarding a sample of 1040 patients (M/F: 513/527) with mean age 14.4 years, body mass index (BMI) 26.7 kg/m², HbA1c 61.0 mmol/mol, a classification model has been implemented to estimate the class to which a sample belongs. The process was divided into several phases, based on the different datasets of parameters analysed, and for each classification the accuracy and performance were evaluated. For a first interpretation of the data, the k-Means algorithm was used, observing the clustering obtained and the identification of anomalous values. Subsequently, the Decision Tree classification algorithm was implemented. The entire study was carried out using the KNIME Analytics Platform.

Results: The study of the final performances obtained from the classification process shows a degree of accuracy and reliability of the classification (Cohen’s kappa ±0.5) in predicting of thyroiditis (sensitivity = ±60%; accuracy and specificity = ±90%). In the final dataset the used missing values were replaced by estimated values. The cystic fibrosis class was considered to evaluate the performance of the model.

Conclusions: It can be concluded that the model’s ability to predict thyroiditis can be considered satisfactory in terms of sensitivity, accuracy and specificity.

P142 / #87

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

SOCIAL MEDIA, COVID-19 PANDEMIC AND TYPE 1 DIABETES – INSTAGRAM LIVE PROMOTING INFORMATION AND SOCIAL SUPPORT

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Background and Aims: Social media is being used to obtain knowledge about diabetes. During the lockdown phase the sentence: diabetic are among the groups of most risk for severe complications of COVID-19 was everywhere. The aim is to describe Instagram Live promoting information and social support about SARS-COV2, COVID-19 and type 1 diabetes (T1D).

Methods: Instagram platform indicators were reviewed between March 20 and 30 (national lockdown). Live is a feature that allows users to stream video to followers and engage with them in real time. Live content was pre-organized by the endocrinologist that administrates the profile since June/2016.

Results: 29,000 followers reaching 14,000 every week. During the 1-hour Live the engagement (watching and interacting with questions and comments) was 518 followers in the first day. The topic was “We are together in this new world” and direct education about the issues related with COVID-19 was presented. The 2nd Live: pandemic emotions and quarantine through history. Reach: 640 followers. 3rd and 4th Live: hand washing demonstration plus it’s history and masks through history. As the medical publications were skyrocketing the next 6 Lives were related to editorials and T1D management inside or outside this new era. Medium reach: 344 followers. Considering inbox messages and impressions we believe that every follower were participating with 1-4 more people.

Conclusions: The Live videos get 6 times more interactions than regular videos. This tool was a great engaging strategy to mitigate the first confinement issues in a population at higher risk from COVID-19.

P143 / #112

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TELEASSISTANCE IN PATIENTS WITH TYPE 1 DIABETES DURING COVID-19 PANDEMIC

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Background and Aims: Telemedicine in chronic disease management has received a significant boost during the health emergency from COVID-19. We have evaluated the effectiveness of two virtual visits on glycemic control parameters in patients with type 1 diabetes (T1D) during the lockdown period.

Methods: Among the T1D patients who had scheduled an office visit during the lockdown (n = 211), those who made two virtual visits (baseline and follow up) (n = 166) were enrolled for the present study. Time in range (TIR), time above and below range, mean daily glucose, glucose management indicator (GMI), and coefficient of variation were compared between the two visits.

Results: TIR significantly increased from 62 ± 18 % to 64 ± 17 % (p = 0.02) in all patients, and more markedly in patients using the meter (N = 11, baseline TIR 55 ± 17 % and follow-up TIR 66 ± 13 %, p = 0.01) and with baseline GMI > 7.5 % (N = 45, baseline TIR 45 ± 15 % and follow-up TIR 53 ± 18 %, p = 0.0001). The only variable independently associated with TIR increase was the change of therapy while
the sensor type and insulin delivery systems did not influence glucometric parameters.

Conclusions: These findings demonstrate that the structured virtual visits allow the persistence and the improvement of glycemetic control in situations where the office visit is not feasible.

P144 / #142
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

WHICH CONTINUOUS GLUCOSE MONITORING (CGM) METRICS ARE MOST ASSOCIATED WITH TOTAL COST OF CARE?
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Background and Aims: Reducing HbA1c is associated with lower health care costs (HCC); the relationship of HCC with CGM-derived metrics has not been well-studied. We hypothesized CGM metrics would be as strongly associated with HCC as HbA1c.

Methods: CGM metrics from a 10-day blinded wear, HbA1c, and claims-derived average per-member-per-month (PMPM) total HCC over the preceding 3 years were collected. This analysis includes 162 individuals with and without diabetes. Demographics were mean(SD) age = 50.9(10) years, BMI = 32.3(9) kg/m²; 85% female, 15% African American, 14% Hispanic.

Results: Median(IQR) PMPM was $436.39 ($193.03, $1050.80). The Table shows correlations and regression-adjusted standardized Betas for associations between glucose metrics and log-transformed PMPM. Coefficient of variation (CV) had the strongest association of all glucose metrics in adjusted models for the full sample and the diabetes subsample.

Conclusions: CGM-derived CV is an easy-to-derive metric that is more sensitive to HHC than HbA1c.

P145 / #144
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

IDENTIFICATION OF E-YOUNG CHRONICS THROUGH QUESTIONNAIRE
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Background and Aims: Transforming the doctor-patient relationship from analog to digital is no simple task and requires a great deal of courage and visionary leadership. The first step to do so is to identify the digital capabilities that the ultimate recipient of every health system possesses: the patient.

Methods: A scale questionnaire of 5 questions related to digital applications is carried out to patients under follow-up for type 1 diabetes mellitus, between 18–65 years old, who are prescribed the Abbott Freestyle Libre flash glucose monitoring device, which requires their connection to a mobile application (Libreview) by the user, for optimal use and communication of data with the healthcare professional electronically.

Results: 62 patients were included. In the classification by predefined subgroups according to the questionnaire score, 35 patients (56.45%) were identified as having advanced training; 16 (25.81%) of basic training and 11 (17.74%) without digital training. 82.86% (29/35) of the patients predefined as highly qualified used the system adequately, compared to 43.75% (7/16) of those with low training and 0% (0/11) of patients without technological capabilities; p<0.001.

Conclusions: The coronavirus-19 pandemic has subjected our health services to a stress test like never before. In the current remote care scenario, we are presented with an opportunity (the great opportunity) to serve people immersed in the digital age. It would be bad news if after this pandemic, we returned to the starting box, the identification of those e-young and e-senior chronics patients is the first essential step to avoid it.

P146 / #154
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

CHANGES IN U.S. CLINIC USE OF A WEB-BASED PORTAL FOR REVIEW OF PATIENT CONTINUOUS GLUCOSE MONITORING (CGM) DATA BEFORE AND DURING THE COVID-19 PANDEMIC
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Background and Aims: The WHO declared COVID-19 a pandemic on March 11, 2020. Patients vulnerable to severe
illness from the virus include people with diabetes. Telehealth may help protect patients with diabetes from infection and manage their diabetes during the pandemic. The Dexcom G6 CGM system includes CLARITY software for patients to share CGM data with their healthcare provider. We examined use of CLARITY by clinics in the United States from January through July 2020 and compared monthly year-over-year (YOY) changes to 2019.

Methods: Data were from all U.S. clinics with CLARITY accounts between January through July of 2019 and 2020. Metrics of clinic engagement with CLARITY were tabulated monthly including count of new clinic registrations and count of total clinic logins to CLARITY. Differences in YOY changes in counts were tested with Chi-square tests.

Results: The YOY monthly count of new registered clinics did not change from expected from 2019 to 2020 ($\chi^2 (6) = 11.4, p = .08$). However, monthly clinic logins increased 34% from January to July 2020. The YOY increase in total logins was between 49% to 99% per month. Between April and July, the YOY change in logins was higher than expected with an at least 70% YOY increase each month ($\chi^2 (6) = 2094, p < .001$).

Conclusions: Use of CLARITY by clinics has significantly increased since the start of the COVID-19 pandemic in March of 2020. This increase started in April and continued through July of 2020, suggesting that clinics increased their use of CLARITY to manage their diabetes patients in response to the pandemic.

P147 / #163

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

COVID-19 SANITARY CRISIS IMPACT ON PATIENTS’ WILLINGNESS TO USE DIGITAL HEALTH SERVICES IN FRANCE

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Background and Aims: In France, the confinement has represented an important challenge for the management of chronic diseases i.e. diabetes for which regular monitoring and personalized care are of crucial importance. Understanding patient difficulties and expectations is of major importance to design and implement suitable services. We questioned a sample group of patients with diabetes (PWD) regarding the follow-up of their disease during the lockdown period in France.

Methods: An online questionnaire was sent to 504 subjects a week after the end of the confinement period. The pool comprises 101 T1D patients and 403 T2D patients whose 52% are treated with insulin injection(s).

Results: Patient follow-up was impacted during the confinement: 41% of face-to-face consultations were delayed or canceled. However, 38% of the respondents benefited from remote visits/contacts (51% T1D, 34% T2D). Indeed 22%, mostly T1D patients, used teleconsultation services. The confinement has generated a growing acceptance of medical data sharing. 28% of the respondents stated that they are more in favor of it. 4% of the respondents already benefit from remote monitoring and support by sharing their data with caregivers via digital devices. 69% indicated their willingness to do so. Moreover, 60% of the respondents, mainly T1D patients, are interested in getting coaching sessions (by using teleconsultation for half of them) to improve the self-management of their disease.

Conclusions: The current sanitary crisis stimulates the patient’s need and willingness for telemedicine. Healthcare systems and health industries must speed up its development in order to improve PWD support.

P148 / #205

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

CLINICAL CASE: MOBILE APP IN IMPROVEMENT OF DIABETES SELF-MANAGEMENT IN OUTBREAK OF COVID-19.

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Background and Aims: The outbreak of COVID-19 has forced people in social isolation, and patients with diabetes turned out to be one of the most vulnerable group. Social isolation and quarantine limits their social support from healthcare professional: emotional support, affirmational support (feedback and appraisal), informational support (information and recommendation). Technologies in diabetes care provide treatment and support during the COVID-19 pandemic. We present the experience of providing counseling for patients with diabetes in the “mobile health care” format using mobile app.

Methods: We describe the case of 28 yo woman with diabetes mellitus type 1, duration of the disease 24 years, with microvascular complications, who takes multiple dose injection therapy, self-control by blood sugar meter, and mobile app (Contour Diabetes mobile app for the Contour TM Plus One meter) to generate ambulatory profiles of glucose and summary reports. The patient was on self-isolation and noted difficulties in achieving the target glycaemia, mood disturbance, irritability craving for certain food. Patient contacted with her diabetologist during isolation via telephone and mobile App.

Results: In the process of communicating with diabetologist, the patient achieved the target of glycemia, improved mood and mental health, noted the convenience, simplicity, clarity and cost-effectiveness in the use of the mobile app. This case demonstrates the practicability and effectiveness of use technologies.

Conclusions: Mobile Apps allow better, more complete and faster tracking of data from patient and motivated for self-management. The telemedicine helps to the adaptation of the patient in a pandemic. This represents significant potential improving the quality of life and reducing costs.

P149 / #207

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TYPE 1 DIABETES (T1D) CLINICAL DATA STANDARDS: ADOPTION AND IMPLEMENTATION TO PROMOTE DATA SHARING AND REUSE

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Background and Aims: Creation and adoption of clinical data standards will transform incompatible and disparate data into universal and illuminating information, facilitating discoveries that could have invaluable impact on T1D clinical research. Implementation of CDISC standards deliver on the promise of FAIR data through consistent organization and analysis that allow all researchers to leverage information from studies globally.

Methods: With support from The Leona M. and Harry B. Helmsley Charitable Trust, CDISC is leading a unique, consensus-driven effort, bringing together T1D experts from academia and industry, to build on existing CDISC diabetes standards to create clinical data standards in pediatrics, devices, exercise and nutrition, and screening, staging and monitoring of pre-clinical T1D.

Results: In September 2020 pediatrics and devices standards are published at https://www.cdisc.org/standards/therapeutic-areas and freely available. Data models and standard formats have been developed that can represent the following: - Identification of all devices and components for management of T1D - Device properties and settings - Participant utilization of devices - Device events and user experience (e.g., DKA, Hypoglycemia etc.) - Diabetes History - Vital Signs and Growth Percentiles - Pubertal Status Additional standards related to T1D are due for publication towards the end of 2020.

Conclusions: Widespread promotion of the standards for researchers to adopt and implement is of highest importance. CDISC provides complementary education courses and implementation information to assist in adoption for academic teams new to CDISC standards. Widespread adoption of the standards will bring clarity to T1D data and will enable the accessibility, interoperability, and reusability of data (FAIR).

P150 / #209
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

EVOLUTION OF AGP PARAMETERS BEFORE, DURING AND AFTER LOCKDOWN IN 80 FRENCH PERSONS WITH TYPE 1 DIABETES SHARING THEIR FGM DATA ON LIBREVIEW

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Background and Aims: The COVID-19 pandemic led to an almost 3-month lockdown period starting March 17, 2020 in France. Teleconsultations were then the only way to interact with patients. However, no data is available on how persons with T1D could manage glucose control during lockdown compared to before and after lockdown.

Methods: In a French outpatient facility, AGP parameters (TIR: time in range 70-180 mg/dL, TBR: time below range <54 and 54-69 mg/dL, TAR: time above range 180-250 and >250 mg/dL, GMI, glucose variability) were manually extracted from LibreView data for three 90-day periods ending March 15 (T1), June 15 (T2) and September 15 (T3) 2020 for all patients with T1D who shared their Libre data on LibreView and for whom data was available.

Results: Among 80 patients (men: 52.5%, age: 41.3±14.1 years, diabetes duration: 21.3±11.0 years, BMI: 25.8±3.9 kg/m², CSII: 81.3%, teleconsultations during T2 for 46.3% of them), TIR increased from 54% (T1) to 58% (T2) and remained at 57% (T3). This was mainly related to a drop in TAR (respectively 40-36-37%). From T1 to T3, TBR did not change (6%) although time <54 mg/dL slightly decreased (2-1-1%). The number of daily scans remained stable at 11±7, the evolution (T1-T2-T3) of GMI and variability was respectively 7.4-7.2-7.3% and 40.7-39.7-40.4%.

Conclusions: During lockdown, in this population with T1D followed in a French practice, TIR increased (+1 hour/day) with no increase in hypoglycemia and maybe with lasting effects. Teleconsultations appear as a safe way of helping persons with T1D when medical appointments are impossible.

P151 / #226
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

PROPOSALS FOR ENHANCEMENT OF THE AGP: THE AMBULATORY GLUCOSE+INSULIN+DIET+ACTIVITY PROFILE (AGIDAP)

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Background and Aims: The Ambulatory Glucose Insulin and Diet Activity Profile (AGIDAP) and the frequency distribution for glucose by ranges are well established as standard methods for display, analysis, and interpretation of glucose data arising from self-monitoring, continuous glucose monitoring and automated insulin delivery systems. We consider several refinements that may further improve the utility of the AGP.

Methods: 1) Display of the AGP together with information regarding administration of insulin and other medications, glucose lowering (pharmacodynamic) activity, diet and physical activity; 2) Display of %TBR, %TAR, and %TIR by time of day; 3) Analysis of prandial excursions above premeal glucose levels after synchronizing by onset of meals; 4) Characterizing patterns by day of the week; 5) Logarithmic and other non-linear scaling of the glucose axis; 6) Optional time scales for time of day; 7) Ability to display individual glucose values; and 8) Methods to compare AGPs from individuals or groups receiving alternative interventions in terms of therapy or technology.

Results: These methods enhance the informativeness of the AGP in terms of understanding the effects of insulin, other medications, diet, and physical activity on glucose profiles. Insulin is displayed in terms of bolus doses and simulations of insulin-on-board, plasma insulin levels, and glucose disposal pharmacodynamics. Displaying %TIR, %TBR, %TAR by time of day is clinically helpful. Synchronized, normalized prandial glucose profiles are displayed showing 25th-, 50th-, and 75th-percentiles. Log(Glucose) scales facilitate evaluation of hypoglycemic values. Online interactive analysis identifies hypo- or hyperglycemic events and outliers.

Conclusions: These enhancements enhance the utility of the Ambulatory Glucose-Insulin-Diet-Activity Profile (AGP+) for assessment of glucose patterns.
MEAL CONTEXT PLAY A SIGNIFICANT ROLE IN PREDICTING POSTPRANDIAL BLOOD GLUCOSE IN PATIENTS WITH GESTATIONAL DIABETES

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Background and Aims: Although the postprandial blood glucose prediction is of big interest for scientists, there is still an open question on which features play the most significant role in complex machine learning predictive models.

Methods: We collected the data on 3240 meals from 144 participants to train and evaluate a decision trees gradient boosting model predicting peak blood glucose level on CGM. We included the following features into the model: meal data (n = 28), meal context data (n = 25), patients individual characteristics (n = 34), patients survey data (n = 44). We then trained the model, in which only 10 features with highest Shapley values were selected and recalculated Shapley values for the final model.

Results: After the selection of top 10 features the precision of the model fell from R = 0.733 and MAE = 0.548 to R = 0.715 and MAE = 0.551, which is not a significant decrease in precision. The most significant features were (descending order): blood glucose at the meal start, glycemic index, carbohydrates in the meal, patients BMI, consumed proteins 6 hours before the meal, cholesterol level at the time of inclusion into the study, number of abortions, meal type, consumed fibers 6 hours before the meal, and amount of starch in the meal.

Conclusions: While current blood glucose level, meal glycemic load and amount of carbohydrates are the most important features for postprandial peak blood glucose prediction, patients’ BMI and meal context also play a significant role in prediction of blood glucose in gestational diabetes patients when using gradient boosting models. The study was funded by Russian Science Foundation (project 18-75-10042).

OUTCOMES OF AN AI-ENABLED DIGITAL DIABETES CARE ECOSYSTEM USING SMARTPHONE CONNECTED GLUCOMETER COUPLED WITH A REAL-TIME FEEDBACK SYSTEM: A REAL-WORLD STUDY IN INDIAN SETTINGS

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Background and Aims: Digital technologies have a promising role in delivering and accessing quality care by reducing overall cost related to management of diabetes. BeatO provides digital engagement to diabetes patients with help of cellular glucometer which transmits real-time data to an AI enabled platform ‘Health Neuron’. Our study assessed the effectiveness of digital diabetes management program in improving glycemic control and hypoglycemic incidence in diabetes patients.

Methods: A retrospective analysis was done on glucose monitoring data (SMBG) and other clinical variables based on medical history of diabetes patients, using BeatO’s glucometer and received minimum one counselling session. An overall sample size of 7514 patients from Sept, 2019 to July 2020 was considered. Glycemic control and hypoglycemia incidence before and after one month of counselling were compared.

Results: An overall 2545 patients (33.87%) having at least one hypoglycemia incidence compared with patients having no hypoglycemic incidence. Increased age, male, use of sulfonylureas and insulin, and type-1 diabetes were found to be significantly associated with hypoglycemia. There was substantial reduction observed post-counselling in hypoglycemia incidence in FPG, pre- and post-prandial, and RPG values of 51.87%, 39.53%, 45.48% and 39.15% respectively. HbA1c levels <6.5% were associated with significantly higher odds of hypoglycemia in comparison to those with HbA1c values >6.5%. Overall glycemic control post-counselling was improved.

Conclusions: This study revealed SMBG and real-time engagement along with individualized care by a multidisciplinary team is effective in reducing hypoglycemia incidence and improving overall glycemic control.
Background and Aims: COVID-19 has been a significant driver for digital healthcare that maintains safe and effective care. T1DM management is technology heavy and as such lends itself to telemedicine. There is a lack of literature relating to this field. This study aims to review clinicians and patients’ views in response to the quality of care provided by remote consultations.

Methods: We conducted an analysis of clinician/patient experiences of remote consultations in a large paediatric diabetes service in the North West of England. 3 questionnaires (Q1 - 3) were developed using online Microsoft Office Forms. Q1 - Patient/family responses collected via telephone, Q2- Completed by clinicians after each individual consultation and Q3 - for each clinic session.

Results: Q1 – Of 100 patients/families, 69% had previous experience of uploading data with 75% receiving training. 56% would continue remote clinics whilst 25% expressed concern with lack of physical examination/investigations. Q2/3 - 89 clinician responses were collected from 28 clinics. 75% clinicians would continue remote consultations. The clinician experience was better when patients were engaged with their devices, prepared with data and as such had greater independence in their management. Lack of understanding and inadequate preparation, were causes of negative feedback from clinicians (15%) and patients (9%).

Conclusions: The rapid adjustment to telemedicine has demonstrated that clinical practice could transform to implement remote clinics alongside traditional consultations. Continued development and engagement in conjunction with training and regular review, will improve practice. Access to technology is a limiting factor and must be managed to ensure equitable care.

P155 / #250
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

DIABETES MANAGEMENT INDICATOR – A MARKER FOR ESTIMATING PROGRESS IN MANAGEMENT OF DIABETES USING TECHNOLOGY

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Background and Aims: Since International Consensus for Time in Range was published, a new series of markers were widely used for monitoring the progress in glycemic management using technology. Both patients and clinicians have to analyze a minimum of 10 markers for an accurate evaluation. This is a process that needs time and understanding from both sides. Our aim was to develop a tool that cumulates all the data but remains easy to use both for doctors and for patients because it is important to see progress and step by step implementation for a better lifestyle.

Methods: The pilot study was designed as an intervention study that included 14 patients with T1DM using CGMS. For all patients, data was used to calculate Diabetes Management Indicator (DMI). DMI metric is calculated using 9 metrics agreed by International Consensus: F1 Usage Time F2 TIR F3 TAR F4 Time in Hyper F5 TBG F6 Time in Urgent Hypo F7 GMI F8 Mean Glucose F9 Variability

Results: DMI is able to show progress made by patient according with clinician request, on different periods of time as a single, unique metric, calculated by an app or by CGM itself, using an mathematical model Romanian Model of Performance Determination™:

\[ DMI = f(F1, F2, F3, ..., F5, ..., F9); DMI = \sum_{j=1}^{K_y} \prod_{i=1}^{K_u} (K_u)^{y_i} \]

Conclusions: DMI is a holistic marker that allows, not only, a step by step increase in performance of diabetes management using technology, but a well understanding and visualization of the progress made for patients. Is easy to set up the app and the results are personalized showing step by step evolution.

P156 / #256
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

COVID-19 PANDEMIC LOCKDOWN EFFECT IN ADOLESCENTS AND YOUNG ADULTS WITH TYPE 1 DIABETES: POSITIVE RESULTS OF AN UNPRECEDED CHALLENGE FOR TELEMEDICINE AND PATIENT SELF-MANAGEMENT

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Background and Aims: Lockdown resulting from the COVID-19 pandemic was an unpreceded model of the impact of lifestyle on chronic diseases, especially for adolescents and young adults with type 1 diabetes (T1D) whose lifestyle is known to strongly impact disease management. We aimed to assess changes in self-monitoring and glycemic control in this population before, during, and after the two-month French lockdown.

Methods: All patients with T1D from 13 to 25 years old using a flash glucose monitoring related to the LibreView cloud platform were included in this bicentric study. Evolution of the primary (percentage of glucose time in range 70-180 mg/dL,TIR) and secondary outcomes (glucose management indicator GMI, time spent below range TBR, and sensor usage) were analyzed with a linear mixed-effect regression model.

Results: 77 patients were included: mean age of 20.4 years, 47% were men. 27.3% of patients declared no health professional contact during lockdown, 33.8% declared 1-2 contacts and 33.8 declared 3 or more. Respectively, the mean percentage of TIR, TBR and sensor usage significantly increased from 41 (before) to 47 % (after) (p <0.001), 3.40 to 4.35 % (p =0.02) and 58 to 68% (p<0.001). GMI significantly decreased from 8.2 to 7.7 % (p<0.001). Magnitude of GMI decrease and TBR increase were significantly associated with the number of contacts with health professionals.

Conclusions: Self-monitoring and glycemic control significantly improved in a population of adolescents and young adults
with T1D over the lockdown period in France, especially for those with poor glycemic control at baseline who have been actively supported with telemedicine.

**P157 / #257**

**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**REDISCOVERING THE POWER OF TELEMEDICINE (DTMS) IN THE COVID ERA**


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**Background and Aims:** Telemedicine (TM) plays a crucial role in enabling continuity of routine care for patients with diabetes during the Covid era. With the aim of comprehensive diabetes management, Diabetes Tele Management System (DTMS), was introduced by us in 1997 and has demonstrated efficacy and cost-effectiveness over the years. This study aims to assess the effectiveness of this telemedicine program in managing diabetes during the lockdown period in our state that extended for 3 months.

**Methods:** We analysed EMR records of T2DM patients who were following up via DTMS by a multidisciplinary team of doctors, dietitians, nurses etc. The HbA1c before and after lockdown period was analysed.

**Results:** HbA1c of 582 consecutive T2DM patients who visited the center after lockdown period were analysed: 345 (59.3%) male, age 57.34 – 12.68 yrs, A1c 7.64 ± 1.57, duration of T2D 13 – 8 yrs). A statistically significant reduction in HbA1c was observed in these patients post lockdown (Table). DTMS consultations with the healthcare team resulted in more frequent counseling, diet and exercise advices and dosage changes.

**Comparison of HbA1c Before and After Lockdown**

**Conclusions:** There was a heightened awareness among patients on the grave consequences of uncontrolled diabetes in Covid which was acquired from our virtual education programs and media. DTMS, the 23 year old TM program for diabetes showed a sudden surge in the frequency of its users rediscovering the incredible benefits of frequent virtual consultations during the pandemic.

<table>
<thead>
<tr>
<th>(n = 582)</th>
<th>Mean</th>
<th>S.D</th>
<th>&quot;t&quot;</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>7.64</td>
<td>1.57</td>
<td>-3.651</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>After</td>
<td>7.46</td>
<td>1.46</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(* Significant)

**Background and Aims:** Maintaining optimal glycemic control in patients with diabetes is crucial for prevention and control of diabetes-related complications. However, optimal glycemic control is difficult to maintain. Less than 50% of patients with diabetes reach their treatment goals. Therefore, alternative strategies in diabetes care are needed. One approach could be telemedicine. Previous reviews on the effect of telemedicine solutions have shown divergent results, though with a positive trend. Future telemedicine studies must include tailored patient-specific suggestions to support patients in achieving their goals. Particularly, it is difficult for patients on insulin therapy to adhere to treatment regimes. Thus, the aim of the DiaMonT trial is to explore the effect of telemonitoring in patients with type 2 diabetes (T2D) on insulin therapy.

**Methods:** In the present study, patients in telemonitoring (intervention) are compared with patients in usual care (control). The design is an open-label randomized controlled trial with a trial period of three months. The trial will be conducted in two sites in Denmark. Patients with T2D, who are already treated with insulin (n = 400), will be included. The study flow is illustrated in Figure 1. The primary endpoint is change from baseline in CGM time in range (4.0-10.0 mmol/L) three months after randomization.

**Results:** The trial is awaiting final approval from the local ethical committee. The first results are expected to be published by the end of 2021.

**Conclusions:** Potentially, the DiaMonT trial may form the basis for national implementation of telemedicine for patients with T2D in Denmark.

**THE DIABETES TELEMONITORING OF PATIENTS IN INSULIN THERAPY (DIAMONT) TRIAL: PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL**


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**Background and Aims:** The aim of the DiaMonT trial is to explore the effect of telemonitoring in patients with type 2 diabetes (T2D) on insulin therapy.
P159 / #270

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

PROSPECTIVE INDEPENDENT EVALUATION OF CARBOHYDRATE COUNTING ACCURACY USING TWO SMARTPHONE APPLICATIONS.

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Background and Aims: The gold standard treatment for type 1 diabetes is intensified insulin therapy and training to match prandial insulin dose to carbohydrate intake. Smartphone applications (apps) have been designed to help patients to accurately count carbohydrate amounts. Our aim was to evaluate the accuracy of two carbohydrate (carb) counting apps.

Methods: Medical students, in the role of mock patients, evaluated meals with two smartphone Apps: Foodvisor® (automatic food photo recognition technology) and Glucicheck® (manual entry of carbohydrates, with the help of a photo gallery). Macronutrient quantification obtained with these two Apps were compared to a reference quantification performed by a dietician who weighed food using scales.

Results: Thirty meals were assessed using Foodvisor® and 28 meals using GluciCheck®. Carbohydrate content of the entire meal was underestimated with Foodvisor® (Foodvisor® quantification minus gold standard quantification = -7.2 ± 17.3 g; p < 0.05) and reasonably accurately estimated with Glucicheck® (Glucicheck® quantification minus gold standard quantification = 1.4 ± 13.4 g; ns). The percentage of meals with an absolute error above 20g for carbohydrate quantification was greater for Foodvisor® compared to Glucicheck® (30% vs 14%; p < 0.01).

Conclusions: Carb counting accuracy was slightly better using Glucicheck® compared to Foodvisor®. However, both apps provided a mean absolute carb counting error which appears lower than that which is usually observed in the daily life of T1D patients, suggesting that such apps may be a useful adjunct for patients for estimating carbohydrate content.

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Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TELEMEDICINE DURING COVID-19: THE DISCONNECT BETWEEN PATIENT AND PROVIDER OPINIONS OF VIRTUAL VISIT QUALITY

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Background and Aims: While cost-effective and convenient, virtual care models have often faced skepticism as effective replacements for in-person care. Now that COVID-19 has made telemedicine mainstream, the present study sought to assess patient and healthcare professional (HCP) opinions of virtual visit quality.

Methods: A mixed-methods study was conducted in the U.S. from June-July 2020. In the qualitative phase, 27 people with diabetes participated in an online bulletin board, while 24 endocrinologists, primary care providers, and diabetes educators were interviewed about their telemedicine experience. In the quantitative phase, 1,057 patients and 318 HCPs completed an online questionnaire.

Results: Overall, patients and HCPs agreed that telemedicine was a useful, though imperfect, tool. Both found the timeline of remote visits appealing, with 30% of HCPs and 37% of patients reporting a shorter wait time than usual. Yet, both also acknowledged the difficulty of conducting physical exams, with most HCPs (72%) and patients (53%) noting subpar assessments. Differences also emerged in patient and HCP perspectives of visit quality. While 53% of HCPs reported telemedicine was worse than in-person visits with regard to the personal connection felt, just 27% of patients agreed. Similarly, HCPs were more likely than patients to find that telemedicine compromised the overall quality of care (40%, 21% respectively).

Conclusions: In a new era of telemedicine, patients and HCPs report different perceptions of virtual visit quality. Future initiatives that increase HCPs’ confidence in the standard and comprehensiveness of care delivered will help establish telemedicine as a reliable alternative to in-person encounters.

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Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

IMPROVED ACCURACY OF OUTCOMES FORECASTS FROM SHORT-TERM CGM DATA

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Background and Aims: Prior work has demonstrated that outcomes forecasts—predictions of 30-day average blood glucose concentration (BG), made one- to six-months in advance—are more accurate when provided with continuous glucose monitoring (CGM) data, compared to forecasts made from self-monitoring of blood glucose (SMBG) data. As short-term use of CGM becomes more common, we ask, how much CGM data is required from an individual to realize that increase in accuracy?

Methods: Data collected in the One Drop app were used to train a machine learning model to predict 30-day average BG, months in advance. The model was used to make predictions based on varying amounts of CGM data from each individual. Predictions were compared to observed values to determine accuracy.

Results: For predictions made four to six months in advance, SMBG-based forecasts had a root mean square error (RMSE) of 44.3 mg/dL. Forecasts made from one month of CGM data had RMSE of 23.7 mg/dL; from two months of CGM data, 18.6 mg/dL, and from three months of CGM data, 17.3 mg/dL. Additional months of CGM data provided no additional accuracy.

Conclusions: Over 75% of the gain in outcomes forecast accuracy obtained by using CGM data instead of SMBG data is achieved with one month of CGM data. More than 95% of the accuracy gain is achieved with two months of CGM data. More than three months of CGM data confers no additional accuracy.
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**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**IMPROVED GLYCEMIC CONTROL AND DIABETES DISTRESS AFTER USING AN M-HEALTH APPLICATION: A PREPARATION ANALYSIS FOR THE DIGITAL HEALTH CARE ACT IN GERMANY**

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**Background and Aims:** The German Digital Health Care Act allows healthcare professionals to prescribe mHealth applications. However, apps must show efficacy on medical outcomes as well as patient-reported outcomes (PRO). To create evidence, we analyzed the changes in estimated HbA1c (eHbA1c) of mySugr users as well as their current state of diabetes distress.

**Methods:** We performed a retrospective analysis of glucose metrics from 5920 German app users' with BG-meters with automatic importing. This enabled the collection of values generated before app usage to perform a pre/post comparison. The cohort was divided into tertiles based on their initial eHbA1c. In a cross-sectional analysis, the PAID-5 questionnaire assessing diabetes distress was completed by 1099 users with T1D or T2D, and tested against a comparative sample from literature.

**Results:** The glycemic parameters showed substantial differences between the tertiles. The largest user group (n = 3836, initial eHbA1c<7.5%) showed a stable eHbA1c around 6.4% over three and six months. The subgroup with initial eHbA1c<9% decreased by 1.5% after 3 months and 1.7% after 6 months. The PAID-5 score (5.1±4.2) of app users was significantly lower than the comparative sample without using the app (6.3±4.4; p < .001).

**Conclusions:** Substantial improvements of eHbA1c were visible after 3 months of using the mySugr app for users with suboptimal glycemic control. Furthermore, the results indicate a positive effect on diabetes distress of app users. As the next step, a randomized controlled trial evaluating the mySugr app is planned.

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**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**MOLECULAR EVIDENCE BEHIND INCLUSION OF FENUGREEK SEEDS IN MEDICAL NUTRITION THERAPY IN INDIAN T2DM**

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**Background and Aims:** Naturopathy is a very old but scientific way of approach for management of chronic disease in our background. Along the centuries the evidence behind the science has disappeared and this is our aim to bring the evidence back to the long forgotten science behind the believes. In this study, molecular interaction between bioactive compounds in Fenugreek seeds against targeted proteins related to Type 2 Diabetes Mellitus have been studied.

**Methods:** The study involved molecular docking of 3D structures of those substances into one of the targeted proteins; namely: 11-β hydroxysteroid dehydrogenase type 1. Discovery studio was used to examine the bond formed between a number of ligands from Fenugreek seeds and targeted protein. Results, identifies Atomic Contact Energy of ligands of Fenugreek seed’s active compound and targeted proteins. The 2D pharmacophore analysis (the type of interaction between ligand and targeted protein) is also explained in this study. NCBI databases were used for literature search and targeted proteins and ligands structures were downloaded from PDB data bank and PubChem respectively. For visualization and analysis of molecules Discovery studio is used.

**Results:** Insilco analysis shows results that Fenugreek seeds have molecular significance as the atomic contact energy of flavonoids namely: kaempferol and quercetin is -31.35 and -147.27 respectively for 11-β hydroxysteroid dehydrogenase type 1; and it falls under favorable range (lower the Atomic Contact Energy implies (that is more favourable) desolvation free energy); and therefore is recommended in diet of diabetic patients.

**Conclusions:** Study explains scientific significance of prescribing Fenugreek seeds in MNT for T2DM.

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**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**DM4ALL: A USER-CENTERED SYSTEM FOR COLLABORATIVE DIABETES MANAGEMENT.**


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**Background and Aims:** DM4all provides a user-centered, interoperable digital health management system, where: a)
collaboration among healthcare professionals, b) patient-reported outcomes, and c) advanced real-world data interpretation offer the potential to advance diabetes management. The system was developed within the three-stage PCP ProEmpower project. The design was accomplished through a co-creation process including patients, healthcare experts, and developers, from concept to working prototype.

**Methods:** Key functionalities of the system are: a) the shared care plan, a digital document that supports the coordination between patients and experts, b) the continuous monitoring of disease markers through the innovative device toolkit including a 3G Blood glucose/pressure meter, a 3G weight scale, and a physical activity tracker, c) the promotion of lifestyle changes and their evaluation through advanced human-computer interfaces, and d) the education and motivation of patients.

**Results:** DM4all was evaluated in a pilot study including 200 patients and 50 healthcare professionals in four countries (Portugal, Spain, Italy, Turkey). The evaluation period lasted 7 months, partly overlapping COVID-19 lockdown. The participants, both people with diabetes and professionals, showed a sustained engagement with the digital solution, including during the lockdown. Additionally, a significant weight loss and HbA1c control were observed. Median values of weight varied between 1.4 and 3.5 kg, nationally. 70% of patients improved their HbA1c value, with the best case to be a reduction of 3.9%.

**Conclusions:** In summary, the pilot showed a considerable impact on patient daily habits, boosting motivation towards self-care. This highlighted the relevance of DM4all in the successful support of chronic disease management.

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**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**TRANSITION TO REMOTE DIABETES CARE IN COVID-19 TIMES: EXPERIENCES FROM A SPECIALIZED TYPE 1 DIABETES CLINIC**


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**Background and Aims:** During the first wave of the coronavirus pandemic, the existing telehealth infrastructure of our diabetes clinic facilitated a rapid transition from face-to-face to remote care. First experiences are reported here.

**Methods:** From May-July 2020, 87 (of 1,073) Dutch people with type 1 diabetes aged 16+ years whose face-to-face visit with their health care professional was replaced with a remote consultation completed a purpose-designed online survey on remote care, the working relation (Session Rating Scale), quality of life, demographics, and clinical information.

**Results:** Participants were female (74%), 16–25 years old (55%), with diabetes duration >5 years (76%), insulin pump (65%) and “relatively stable” glucose levels (52%). Consultations were doctor-only (24%), nurse-only (58%) or a combination. Most (86%) were telephone calls. People were generally satisfied with the audio/video connection (91%), attention to emotions (85%), and working relation (median 34/40, IQR 30-39); 90% had an undisturbed conversation. Most recent HbA1c was discussed in 29% (n = 6 lab-based; n = 19 calculated). Important advantage of remote care was time saving (24%); suggested improvements included video consultations with screen-sharing and set appointment times. People were divided on whether they wanted to continue their care remotely. In linear regression, a more positive attitude towards future remote consultations was associated with higher quality of life but not with demographics nor self-reported clinical factors.

**Conclusions:** Transition to remote care was generally well received, but also dependent on personal preferences. Even after the pandemic, the option to switch to remote care (including HbA1c home-kits) may better fit personal needs.

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**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**MAIN GLUCOSE HEPATIC FLUXES IN HEALTHY SUBJECTS PREDICTED FROM A PHENOMENOLOGICAL-BASED MODEL OF THE LIVER**

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**Background and Aims:** The liver has a unique role in the regulation of blood glucose in postprandial, postabsorptive, and fasting states. In the context of diabetes technology, a glucose hepatic metabolic model describing the dynamics of glycogenesis/glycogenolysis and gluconeogenesis together with the dynamics of the insulin and glucagon clearance is still missing. We developed a mathematical model providing a quantitative estimation of the above metabolic processes.

![Figure](https://example.com/figure.png)
Methods: A mathematical, phenomenological-based semi-physical model (PBSM) of the liver’s glucose metabolism was developed to predict the main hepatic glucose fluxes in normal subjects. Data from a previous study (N = 11, 6F/5M) of an oral glucose tolerance test (1g/kg BW, range 55–93g) following overnight fasting that employed the hepatic venous catheter technique in combination with a double-tracer approach were used to assess the predictive ability of the proposed model. Traces of portal glucose and insulin concentrations and glucose concentration from the hepatic artery were used as inputs while traces of glycogen concentration within the liver and glucose and insulin concentrations in the systemic circulation were used to assess the quantitative accuracy of the model, as per data availability. Model predictions are assessed in terms of absolute error (AE).

Results: For the average subject, our model exhibited mean ± std 41.1 ± 101.6 μmol, 5.4 ± 5.2 mg/dL, 38.7 ± 28.4 pmol/L AE for glycogen concentration within the liver and glucose and insulin concentration in the systemic circulation, respectively.

Conclusions: Our model was able to explain both internal and external hepatic glucose fluxes with little parameter tuning and no training whatsoever.

P168 / #392
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and Other Technologies

EFFICACY OF THE MY DOSE COACH®
APPLICATION IN THE BASAL INSULIN TITERATION:
EFFECTS ON GLUCEMIC CONTROL, ADHERENCE TO TREATMENT AND COSTS.

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Background and Aims: The My Dose Coach® (MDC) application is a digital tool that allows remote basal insulin titration and establishes a real-time link between the patient and their medical provider, promoting glycemic control. Objectives. To compare the efficacy to reach the goal of self-monitoring plasma glucose (SMPG) (90-130 mg/dl) between 2 insulin glargine (U-100, U-300) titration methods: My Dose Coach® with remote titration and the conventional strategy (CS) with face-to-face modifications. Additionally, treatment adherence and direct costs were assessed.

Methods: A 16-week, single-site, randomized controlled trial, 2-arms in T2D patients insulin naive. We performed anthropometric and laboratory measurements, SMPG and administered insulin dose diary.

Results: Forty patients were enrolled in each group. SMPG goal was obtained in 37 MDC vs 33 CS subjects (92.5% vs 82.5%, p 0.03), mean time to achieve it 19 vs 30 days (p 0.001), initial FBG 176 vs 174 mg/dl (p NS), final 104 vs 107 mg/dl (p NS), initial HbA1c 8.7 vs 8.5% (p NS), final 6.9 vs 7.2% (p NS) Δ -1.8 and -1.3%, respectively. The initial insulin dose 16 vs 14 IU (p NS), final 26 vs 34 IU (p 0.001), and hypoglycemic episodes (2% [2/40] vs 3% [3/40] (p NS). Missed insulin dose 4 vs 9% (p 0.002), direct costs 187 vs 252 dollars (p 0.001), and time spent in the titration 150 vs 240 minutes (p 0.001) respectively.

Conclusions: My Dose Coach® is an effective and faster for SMPG control and a safe and cheaper option for insulin glargine titration.

P169 / #403
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and Other Technologies

INCREASING CAPACITY WITH FIXED RESOURCES
THROUGH AUTOMATION AND TASK DELEGATION
AT A TERTIARY PEDIATRIC TYPE 1 DIABETES CLINIC

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Background and Aims: The My Dose Coach® (MDC) application is a digital tool that allows remote basal insulin titration and establishes a real-time link between the patient and their medical provider, promoting glycemic control. Objectives. To compare the efficacy to reach the goal of self-monitoring plasma glucose (SMPG) (90-130 mg/dl) between 2 insulin glargine (U-100, U-300) titration methods: My Dose Coach® with remote titration and the conventional strategy (CS) with face-to-face modifications. Additionally, treatment adherence and direct costs were assessed.

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Results: Forty patients were enrolled in each group. SMPG goal was obtained in 37 MDC vs 33 CS subjects (92.5% vs 82.5%, p 0.03), mean time to achieve it 19 vs 30 days (p 0.001), initial FBG 176 vs 174 mg/dl (p NS), final 104 vs 107 mg/dl (p NS), initial HbA1c 8.7 vs 8.5% (p NS), final 6.9 vs 7.2% (p NS) Δ -1.8 and -1.3%, respectively. The initial insulin dose 16 vs 14 IU (p NS), final 26 vs 34 IU (p 0.001), and hypoglycemic episodes (2% [2/40] vs 3% [3/40] (p NS). Missed insulin dose 4 vs 9% (p 0.002), direct costs 187 vs 252 dollars (p 0.001), and time spent in the titration 150 vs 240 minutes (p 0.001) respectively.

Conclusions: My Dose Coach® is an effective and faster for SMPG control and a safe and cheaper option for insulin glargine titration.
Background and Aims: Continuous glucose monitoring (CGM) is now the standard of care for patients with T1D. In order to expand CGM-based asynchronous telehealth to all patients, clinics must adapt local resources and workflows. Our goal was to test if a clinic can increase its capacity without increasing resource use through technological and operational innovations.

Methods: We used a spreadsheet tool to estimate clinical diabetes educator (CDE) time utilization at a tertiary pediatric T1D clinic in a pilot study with two full-time CDEs. Tasks that required the full extent of a CDE’s expertise were categorized as “top of license” (TOL). Tasks were further categorized with respect to their potential for automation.

Results: Non-TOL tasks accounted for 30% of weekly CDE time utilization. Of these tasks, 30% had high potential for automation, and 70% for delegation to another professional. Additionally, patient data review (a TOL task accounting for 11% of CDE time) has already been partially automated in this clinic, and presents the opportunity for further automation.

Conclusions: We demonstrated that over 30% of CDE time could be freed through automation or delegation of tasks to administrative staff, and developed a tool to allow other clinics to reproduce this analysis. The emergence of telehealth technologies presents opportunities for clinics to do more with fixed resources.
Background and Aims: Despite increasing number of effective drugs, and the availability of lifestyle modification programs, diabetes control remains suboptimal. New approaches to diabetes care delivery are needed. NORMA is a 6 months program designed to implement an integrated approach to diabetes management. The Program combines structured online education, BGM, consultation by endocrinologist, and administrative support. To evaluate the influence of NORMA program on the participants’ clinical outcomes current retrospective analysis was initiated.

Methods: These preliminary interim outcomes comprise retrospective analysis of data of 69 patients with T1DM who participated in NORMA for at least 3 months from January 2020 until November 2020 and had initial and follow-up HbA1c measurements.

Results: The average age (SD) of the participants was 35.9 ± 10.7 years, median duration of DM was 180.0 months. All participants had HbA1c > 7.0% at enrollment to the Program. The HbA1c decreased from 8.6 ± 1.6% (n = 69) at baseline to 7.2 ± 1.2% (n = 68) at Month 3, and 7.5 ± 1.7% (n = 41) at Month 6. Individual target HbA1c level was achieved by 38.2% and 34.2% of participants by Month 3 and 6, respectively. HbA1c < 7.0% was achieved in 48.5% and 51.2% participants after 3 and 6 Months of Program, respectively.

Conclusions: Interim results of this retrospective analysis suggest that integrated approach to diabetes management could potentially lead to improved glucose target achievement in patients with T1DM. These results require further confirmation. The data received can serve as a basis for further research. *The study is supported by Sanofi.

P173 / #479

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TRUSTSPHERE (A TRUSTED, SECURE AND PRIVACY-RESPECTING HEALTHCARE ENVIRONMENT REALIZED FOR EVERYONE): USER ENGAGEMENT TO BUILD THE TRUST LAYER IN DIGITAL HEALTH FOR TYPE 1 DIABETES

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Background and Aims: Trust in digital health is a significant challenge. We are developing a digital solution, TRUSTSPHERE (TS), that will address this trust gap to enable easier adoption of digital health. Our test use case is children living with type 1 diabetes (T1D), and our aim is that TS serves as a digital identity layer that will empower patients and caregivers to manage and share their health information via this virtual platform customized for T1D.

Methods: Two online quantitative surveys were distributed electronically to caregivers of children with T1D (N = 760) and pediatric diabetes healthcare providers (HCP; N = 232) to gather their perspectives on key elements necessary to foster digital trust and essential features of a virtual patient platform for T1D. Descriptive statistics were used.

Results: 18% of HCPs and 30% of caregivers were either ‘very’ or ‘extremely’ concerned about digital privacy and security issues. However, 68% and 42% of caregivers strongly agreed that they trust their HCP would keep their child’s health information secure and that government regulations were in place to ensure security, respectively. HCPs reported key challenges to be accessing insulin pump (85%), glucose meter (83%) and glucose sensor (80%) data during clinic visits, and helping patients to navigate diabetes technology (91%). Caregivers identified access to glucose sensor and insulin pump data as being the most useful potential platform features. 66% of parents and 75% of HCPs were ‘likely’ or ‘very likely’ to use TS.

Conclusions: TRUSTSPHERE demonstrates potential to address gaps in user trust and access to digital health data for T1D.
IMPACT OF GLUCOSE VARIABILITY ON DYNAMIC COGNITIVE FUNCTION IN YOUTH WITH TYPE 1 DIABETES (T1D)


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Background and Aims: Severe glycemic events have been associated with impaired cognitive function in youth with T1D when measured in laboratory settings. However, little is known about the impact of minute-to-minute glycemic fluctuations on dynamic cognitive functions in daily life. Our ultimate goal is to determine the impact of real-world glucose variability on dynamic cognition in youth with T1D. This understanding could have important implications for diabetes treatment. However, we first need to optimize a tool for testing real-world dynamic cognition in youth and an analysis approach for integrating continuous glucose and cognitive data.

Methods: Youth ages 9-15 (n = 4 T1D; n = 9 non-diabetic control) completed testing 5x day for 2 weeks on a novel smartphone application designed to assess dynamic cognitive function (working memory, processing speed, associative memory). Participants completed an interview to assess their impressions of the app. T1D patients wore CGMs.

Results: Study retention was 100% and testing adherence was 81%. Participants rated the smartphone application cognitive tests as being easy and enjoyable, rated the instructions as clear, and reported having a clear understanding of the tests. Participants also performed similarly to adults and others of the same age who completed in-lab testing of the application in prior studies.

Conclusions: Youth with and without T1D reported positive impressions of, adhered to, and performed well on novel smartphone application tests that assess in-the-moment dynamic cognition in real-world settings. Next steps include recruiting additional participants, developing an analysis protocol to integrate glucose and cognitive data, and determining the impact of fluctuating glucose on cognition in daily life.

IMPACT OF THE FREQUENCY OF MY DOSE COACH USE ON CLINICAL OUTCOMES IN TYPE 2 DIABETES


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Background and Aims: My Dose Coach (MDC) is an FDA-approved digital smart-phone application to help users with type 2 diabetes (T2D) titrate basal insulin according to individualized titration plans provided by their physicians. This retrospective cohort study assessed MDC usage impact during titration on reaching fasting blood glucose (FBG) target, change in FBG, and hypoglycemia incidence.

Methods: A total of 2517 active MDC users (registered 8/1/2018 – 4/30/2020) from India (85%), Mexico (12%), and Colombia (3%) were stratified into high (>3 days/week; 49%), moderate (>1 but ≤3 days/week; 25%), and low ≤1 day/week; 26%) usage subgroups. Recording ≥3 consecutive FBG measurements within individualized target range was considered reaching target.

Conclusions: Youth with and without T1D reported positive impressions of, adhered to, and performed well on novel smartphone application tests that assess in-the-moment dynamic cognition in real-world settings. Next steps include recruiting additional participants, developing an analysis protocol to integrate glucose and cognitive data, and determining the impact of fluctuating glucose on cognition in daily life.
Results: Overall, 1108 participants (44%) reached FBG targets during titration. More frequent MDC use was significantly associated with greater FBG target achievement (p<0.01; Figure). Mean (± standard deviation [SD]) number of days to FBG target was significantly lower in the high usage subgroup (14.9±21.8) versus moderate (25.1±40.7, p<0.01) and low (36.8±44.2, p=0.01) usage subgroups. High usage of MDC was associated with a greater reduction in FBG from the first FBG measurement (~45.4±70.1 mg/dL) versus moderate (~40.7±76.6 mg/dL) and low (~31.0±78.2 mg/dL) usage (p<0.01). No significant differences in hypoglycemia incidence were observed between subgroups (high, 12%; moderate, 16%; low, 12%).

Conclusions: People with T2D initiating basal insulin using MDC ≥3 days/week during titration had better glycemic outcomes than those with lower usage, with no increase in hypoglycemia. This study was funded by Sanofi.

P176 / #559

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TELEPIED STUDY A SINGLE-CENTRE TRIAL COMPARING DURATION OF HOSPITALIZATION REQUIRED FOR HEALING OF A DIABETIC WOUND USING TELEMEDICINE AND A REFERRAL NURSE VERSUS STANDARD CARE

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Background and Aims: The aim to demonstrate that the total number of days in hospital required for healing of a new diabetes-related foot ulcer (DFU) is lower in patients followed up using a telemedicine platform [Group 2] than in patients followed up using standard care [Group 1].

Methods: A controlled single-centre study in open, parallel groups of diabetic patients with newly diagnosed DFU Patients are assigned to either Group 1 or Group 2 Patients in Group 1 are to be followed by the investigator and specialized referral nurse as part of the regular follow-up procedure. Between visits, an independent nurse (IN) provides home daily care. Patients in Group 2 have their DFU treated by a referral nurse, the monitoring of DFU is performed weekly using photos of the DFU with planimetry taken by the IN and sent via telemedicine software.

Results: 168 patients were included (G1=N82, G2=N86), the mean age for G2 is 69.6 (13.1) years and for G1: 65.7 (14.2) years, the duration of the disease of diabetes is 18.9 (12.3) years for G1 and 20.3 (12.0) years for G2. Number of days of hospitalization (related to foot injury) at the end of one year of follow-up was 7.5; 18.9 days for G1 and 3.8; 11 days for G2 p=0.013.

Conclusions: Conclusion: follow-up by telemedicine and by a referent nurse for patients living with diabetes associated with a DFU significantly reduces the number of days of hospitalization over one year necessary for complete healing of this DFU.

P177 / #560

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ESTIMATED HEMOGLOBIN A1C REDUCTION IN US EMPLOYER POPULATION USING A DIGITAL DIABETES MANAGEMENT SOLUTION

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Background and Aims: The aim of the retrospective analysis was to evaluate the Estimated Hemoglobin Alc (eHbA1c) change in a well-managed diabetes population after six months of participation in a Business to Business (B2B) digital diabetes management solution offered to employees as a free benefit.

Methods: The solution includes the mySugr diabetes logbook app, Bluetooth enabled glucometer, blood glucose test strips and diabetes coaching. mySugr generates eHbA1c from blood glucose data entered in the app. This eHbA1c for each user was calculated at least every 10 days, generating eHbA1c values for 134 users throughout their program participation. A quarterly average was then calculated per user. Of the 134 users who generated an eHbA1c, 64 users had two consecutive eHbA1c quarterly averages, with t0 indicating the first eHbA1c average and t1 indicating the second eHbA1c average. A t-test was then conducted.

Results: Sixty-four users who generated an eHbA1c for two consecutive quarters in a six month period were evaluated. Mean eHbA1c at t0 was 6.59%, mean eA1c at t1 was 6.35%, a 0.24 reduction and is statistically significant with p=0.01.

Conclusions: The eHbA1c reduction is modest, but has clinical implications. HbA1c <7% meets the American Diabetes Association’s recommendation. The therapy goal for a person with diabetes who meets the target is to continue this stability. Achieving stability or any reduction at this HbA1c level is a clinical success, even in a well managed population. More research is needed to evaluate the clinical impact of digital diabetes solutions in employer benefit populations.

P178 / #565

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

DIFFERENTIAL HBA1C-GLUCOSE MANAGEMENT INDICATOR: MAGNITUDE AND RELATIONSHIP WITH CONTINUOUS GLUCOSE MONITORING PARAMETERS

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Background and Aims: The glucose management indicator (GMI) provides an estimate of haemoglobin A1C, that may differ from the measured value. This work aimed to: determine the difference between laboratory HbA1c (A1Clab) and GMI, as well as between point-of-care HbA1c (A1Cpoc) and GMI (based on the data from the last 14/28/60/90 days), selecting the interval with the least difference; compare A1Clab-GMI vs A1Cpoc-GMI; compare CGM parameters in patients with lower vs higher differential.
**Methods:** In patients with T1DM using CGM, data were collected on A1Clab and/or A1Cpoc and CGM until the day of A1C sample.

**Results:** We selected 174 T1DM patients, mean age 33.3±13.0years, 52.3% female. The mean |A1Clab-GMI| (n=101) was higher for the 14D CGM interval (0.60±0.58%) and lower at 60D (0.51±0.53%), A1Clab-GMI60D varied from -0.90 to +3.50%. The mean |A1Cpoc-GMI| (n=127) was higher at 14D (0.45±0.72%) and lower at 60D (0.39±0.38%), A1Cpoc-GMI60D varied from -2.0 to +21.1%. A positive differential (A1C-GMI) was more common for both types of A1C. A1Clab differed more from GMI than A1Cpoc (0.51 vs 0.39%, p=0.038). Patients with |A1Clab-GMI60D|>1 had shorter time in range-TIR (40.56 vs 54.15, p=0.033) and tendency towards longer time above range-TAR (52.56 vs 38.01, p=0.065). The same was seen when |A1Cpoc-GMI60D|>1 (TIR 40.13 vs 52.74, p=0.015 and TAR 51.25 vs 40.32, p=0.054).

**Conclusions:** The difference A1C-GMI can be substantial. In this sample it was greater between A1Clab-GMI. Higher differentials were associated with less TIR and longer TAR, which may reflect the influence of A1C on decision making and/or a weaker correlation between interstitial and blood glucose.

**P179 / #567**

**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**HYPOGLYCEMIA UNAWARENESS: ASSOCIATION WITH CONTINUOUS GLUCOSE MONITORING AND AUTONOMIC NEUROPATHY**

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**Background and Aims:** Hypoglycemia unawareness is common in type 1 diabetes (T1DM) and is associated with autonomic neuropathy. The aims of this work were: to translate and validate questionnaires that assess hypoglycemia unawareness - Clark’s questionnaire (CQ) - and autonomic neuropathy (AN) - Scale for Autonomic Symptoms (SAS) for the Portuguese population; to relate CQ results with continuous glucose monitoring (CGM) data and SAS-Symptom Score (SAS-SS); to find predictive factors for reduced hypoglycemia awareness defined by CQ.

**Methods:** Translation and validation of the CQ and SAS according to international standards and application to T1DM patients under MCG.

**Results:** 111 T1DM patients were evaluated, 56.8% female, mean age 35.00±12.35 years, mean disease duration 18.8±10.5 years. -Questionnaires’s evaluation: CQ (n=111) displayed good internal consistency (cronbach-z=0.72) and test-retest (n=53) 0.77; SAS-SS (n=109) had a test-retest (n=52) of 0.84. -Questionnaires’s Application: In response to CQ, 13.5% had reduced and 9.9% undetermined awareness to hypoglycemia. SAS-SS was suggestive of AN in 22.9%. T1DMs with CQ suggestive of unawareness/indeterminate awareness had more time below range (8.58±5.27 vs 6.27±4.83; p=0.026) and mean duration of hypoglycemia (124.79±43.67 vs 97.58±40.88; p=0.004). In multivariate analysis, mean duration of hypoglycemia and higher SAS-SS were independent predictors of CQ’s results. In a ROC curve (AUC 0.694; p=0.004) a mean duration of hypoglycemia ≥91min showed 83.3% sensitivity and 53.2% specificity for unawareness/indeterminate awareness.

**Conclusions:** A significative prevalence of hypoglicemia unawareness and AN was detected. In addition to the AN, MCG data can also indicate lower awareness to hypoglycemia, with an average hypoglycemia duration ≥91min being suggestive, albeit unspecific.

**P180 / #582**

**Topic:** AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

**REPLAYBG PROVIDES RELIABLE INDICATIONS WHEN USED TO ASSESS MEAL BOLUS ALTERATIONS IN TYPE 1 DIABETES**

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**Background and Aims:** ReplayBG is a tool that implements a novel approach to quantitatively evaluate new therapy guidelines for type 1 diabetes (T1D). Specifically, a non-linear model of glucose-insulin dynamics is firstly identified on retrospective patient data where the inputs are insulin infusion and carbohydrate intake, and the output is glucose. Then, the model is used to simulate the glucose trace obtained by “replaying” the recorded scenario and the glucose trace obtained using the insulin/carbohydrate input proposed by the therapy treatment under evaluation. In this work, we analyze the validity of ReplayBG when used to evaluate the impact of meal insulin bolus (MIB) variations.

**Methods:** ReplayBG model was identified on data of 100 virtual subjects simulated using the UVa/Padova TID Simulator (TIDS). Simulations were 12-hour, single-meal experiments consisting of 50 g of carbohydrates and a corresponding MIB computed using the standard rule for bolus calculation. Validity of ReplayBG was assessed by computing the Mean Absolute Relative Difference (MARD) between the “replayed” glucose trace obtained by altering MIB by up to ±50% and the simulated glucose data obtained with TIDS when the same inputs are provided.

**Results:** ReplayBG is reliable when used to assess meal bolus modulation up to 50%. Average MARD is 4.51%, 2.57%, 1.14%, 1.42%, 3.49%, 6.13% when MIB is altered by -50%, -30%, -10%, +10%, +30%, and +50%, respectively. ReplayBG can be safely used to assess MIB alterations. Future work will extensively assess ReplayBG on other scenarios.
Background and Aims: Research suggests glycaemic variability (fluctuating blood glucose levels) is associated with higher risk of morbidity and mortality in adults with type 2 diabetes (1,2), highlighting the importance of minimising glycaemic variability in this group. Digital technologies are now commonly used in diabetes management, with emerging data demonstrating benefits to HbA1c levels. The effect of a digital behaviour change intervention on glycaemic variability in adults with type 2 diabetes however remains unknown.

Methods: Glycaemic data were collected from adults with type 2 diabetes enrolled on a digitally enabled behaviour change programme between June 2019 and August 2020. Eligible patients entered at least 3 blood glucose readings within at least one of 12 weeks into a smartphone application as part of a digital behaviour change programme. The individual blood glucose variability was estimated by computing the weekly standard deviation of the measurements and normalizing by the mean. At least 3 blood glucose readings per patient were required to determine variability each week. The weekly and cohort averaged coefficient of variation (CV) is reported for i) all eligible patients (N = 355) ii) eligible patients that also had at least 3 blood glucose in the 12th week (N = 56).

Results: The data indicates a reduction of CV from 18% in week 1 to 14% in week 12 showing reduction in variability of blood glucose (p-value ≈ 0.05).

Conclusions: Digital behaviour change interventions facilitated by a smartphone app reduces glycaemic variability in adults with type 2 diabetes which may reduce the risk of morbidity and mortality within this group.

P182 / #606

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

SOCIAL MEDIA INFLUENCERS GIVE BAD DIET ADVICE FOR DIABETIC PATIENTS

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Background and Aims: Diabetes is one of the most challenging chronic health conditions in 21th century. Diabetes-related problems need proper patient education, and social media plays a role to disseminate information. The aim of our study was to evaluate the quality of medical information presented in social network.

Methods: We studied 18 Tunisians top popular influencers, based on those who had more than 10,000 followers in Instagram social media.

Results: We found that 13 out of 18 of the blogs (72,22%) could not be considered credible sources of diabetes management information. These blogs have unreliable and potentially harmful recommendations like “fruits are undoubtedly products that lower blood sugar” or such kind of not evidence-based information: “The main savior for diabetics is cinnamon. Garlic is another very useful supplement that makes the pancreas secretes double-acting insulin? Fenugreek lowers drastically the level of glucose in the blood.”

Conclusions: Social media influencer’s blogs are not credible resources for diabetes management. Popularity and impact of social media in the context of the diabetes epidemic suggests all influencers should be required to meet accepted scientifically or medially justified criteria for the provision of diabetes management advice online.

P183 / #625

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

TYPE 1 DIABETES MANAGEMENT IN PREGNANCY DURING PANDEMIC CONTEXT - ADVANTAGES OF SMARTGUARD (SG) MINIMED 640G™ TECHNOLOGY

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Background and Aims: SmartGuard MiniMed 640G™ offers a greater protection against hypoglycaemia, a crucial aspect during pregnancy. COVID-19 pandemic led to the need for teleconsultation. New technologies offer advantages for remote care of patients. To analyse the efficacy of SG MiniMed 640G™and teleconsultation in two type 1 DM pregnant women.

Methods: Data from Libreview® and Carelink® was collected (international consensus metrics). Downloads made at home and sent via e-mail.

Results: Case 1: 36 years pregnant woman with DM1. SG™MiniMed 640G™ started at 14 weeks of gestation. Child-birth at 38 weeks. Vacuum-assisted delivery; birth weight 3575g; Apagar score 8/10/10. Case 2: 32 years pregnant woman with DM1. SG™MiniMed 640G™ started at 20 weeks of gestation. Child-birth at 37 weeks, through caesarean operation; birth weight 4030g; Apagar score 8/9/10. In both cases, no neonatal hypoglycaemia and no need to be admitted to neonatal ICU.

Conclusions: Minimizing the risk of hypoglycaemia, MiniMed 640G™ contributed to optimize glycemic control reflected in good neonatal results.

Carelink® and Libreview® use allowed a regular and effective teleconsultation during COVID-19 pandemic.

Table 1 – Glycaemic control before and after SG™MiniMed 640G™

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>CASE 1</th>
<th>CASE 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before MiniMed 640G™</td>
<td>before</td>
<td>before</td>
</tr>
<tr>
<td>%TIR</td>
<td>61</td>
<td>42</td>
</tr>
<tr>
<td>%TBR</td>
<td>68</td>
<td>61</td>
</tr>
<tr>
<td>Mean interstitial glucose (mg/dL)</td>
<td>147</td>
<td>130</td>
</tr>
<tr>
<td>CV (%)</td>
<td>3.6</td>
<td>4.9</td>
</tr>
<tr>
<td>CV (%)</td>
<td>34.4</td>
<td>41.9</td>
</tr>
<tr>
<td>After MiniMed 640G™</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean interstitial glucose (mg/dL)</td>
<td>154</td>
<td>114</td>
</tr>
<tr>
<td>CV (%)</td>
<td>3.4</td>
<td>41.9</td>
</tr>
</tbody>
</table>

P184 / #641

Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

USE OF TELEMEDICINE SYSTEM TO IDENTIFY THE INCREASE IN ALCOHOL CONSUMERS AMONG PEOPLE WITH TYPE 1 DIABETES DURING THE COVID-19 PANDEMIC

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Background and Aims: Alcohol consumption among people with type 1 diabetes is commonly used in diabetes management, with emerging data demonstrating benefits to HbA1c levels. The effect of a digital behaviour change intervention on glycaemic variability in adults with type 2 diabetes however remains unknown.

Methods: Glycaemic data were collected from adults with type 2 diabetes enrolled on a digitally enabled behaviour change programme between June 2019 and August 2020. Eligible patients entered at least 3 blood glucose readings within at least one of 12 weeks into a smartphone application as part of a digital behaviour change programme. The individual blood glucose variability was estimated by computing the weekly standard deviation of the measurements and normalizing by the mean. At least 3 blood glucose readings per patient were required to determine variability each week. The weekly and cohort averaged coefficient of variation (CV) is reported for i) all eligible patients (N = 355) ii) eligible patients that also had at least 3 blood glucose in the 12th week (N = 56).

Results: The data indicates a reduction of CV from 18% in week 1 to 14% in week 12 showing reduction in variability of blood glucose (p-value ≈ 0.05).

Conclusions: Digital behaviour change interventions facilitated by a smartphone app reduces glycaemic variability in adults with type 2 diabetes which may reduce the risk of morbidity and mortality within this group.
Background and Aims: Covid-19 pandemic has changed the habits of people with diabetes, and social-distancing was associated with more time at home and individual distress. There are some reports about increasing in alcohol drinking among individuals with diabetes during the pandemic. Currently, many patients use telemedicine support systems. Glic® is a system widely used in Brazil, since 2012, with 50.022 users with T1DM that insert food intake data, including alcohol. The aim of this study was to evaluate changes in alcohol consumption in individuals with T1DM during COVID-19 pandemic using a telemedicine support system (Glic®).

Methods: Data was obtained from Glic® data base (gli-conline.net). Alcohol consumption data between March to August/2019 and March to August/2020 was analyzed. Descriptive statistics were performed with frequency analysis (absolute and relative) and chi-square test was used to compare the data.

Results: T1DM patients showed different monthly alcohol consumption input between March to August of 2019 and 2020 (p<0.0001). There was an increase of 56% in total alcohol consumption input in 2020 compared to the same period of 2019. The percentage of individuals who reported alcohol consumption ranged from 2.8-5.5% in 2019 and 8.4-19.1% in 2020 in the analyzed months.

Conclusions: We conclude that a telemedicine support system (Glic®) is a useful tool to identify the rising in alcohol consumers among people with T1DM during COVID-19 pandemic. These results highlight the potential of such systems to detect behavioral changes in PWD and might help the development of strategies to support and protect these individuals during specific situations/conditions.

P185 / #661
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

EXCLUSIVE TELEMEDICINE DURING COVID PANDEMIC: WHAT WE LEARN ABOUT ITS IMPACT ON DIABETES METABOLIC CONTROL, CARE AND SATISFACTION OF FAMILIES IN OUR CHILEAN RURAL-URBAN CENTER?

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Background and Aims: Telemedicine (TM) is one more tool at modern medicine service at care of Type 1 Diabetes (DM1) moreover in remote areas. Since 2016, our Diabetes Care Program includes TM as a possible add-on care according to the families’ realities and needs. Because of covid-19 pandemic, since March, we decided to provide regular care, education, and emergencies prevention and management through exclusive TM (ETM). The objective is to evaluate the impact of ETM on metabolic control, diabetes care and families’ satisfaction.

Methods: A descriptive comparative and correlational study of the ETM impact is conducted in our Chilean center during one year with 53 pediatric patients. The ETM impact will be evaluated and compared (by Student t-test) in 4 different 3 months times on metabolic control outcomes (A1c, average glucose (AG), hypoglycemia number, acute complication number, total daily insulin dose(TIDID), BMI), ETM indicators (contact number, content) and families satisfaction (quantitative and qualitative survey).

Results: Preliminary Results: Our sample included 53 children aged 11.2 years; treatment CSII (12.9%), CGM (22.2%). The first results are showed in the table. The main reasons of use respectively TM add-on care and ETM, are adjusting insulin doses (65.5%/81.3%), emergencies management (58.6%/41.7) and improved diabetes education (13.8%/42.7%).

Conclusions: the first results indicate that exclusive telemedicine appears like a good diabetes care system for the families even if they don’t have access to technology, and seems to improve diabetes management. However, there are still many pending results, including clinic and biochemical data, to complete our study objective with the comparison data.

P186 / #667
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

DIGITAL TWIN TECHNOLOGY INTERVENTION TO ACHIEVE AND MAINTAIN THE GLYCEMIC VARIABILITY WITHIN THE TARGETS IN T2DM–INSIGHTS FROM REAL WORLD STUDY

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Background and Aims: Twin Precision Nutrition (TPN) is a novel whole-body digital twin enabled precision nutrition for reversing diabetes. Baseline Glycemic Variability (GV) is directly associated with glycemic outcomes

Methods: We evaluated 64 patients on TPN for glycemic variability metrics. Glycemic variability metrics were Coefficient of Variation percentage (CV%) (good <26%), Low Blood
Glucose Index (LBGI) (low <2.5) and High Blood Glucose Index (HBGI) low <4.5).

Results: Mean age was 52.44 years (–9.96), 70 % males (n=45), mean duration of diabetes 8.43 years (–6.52). 25 patients had achieved HbA1c <6.5, trends indicating reversal of diabetes. Mean CV% at enrolment (24.7) reduced significantly to 15.86 (p<0.0001) at day 7 and targets for thresholds were achieved and sustained over three months. There was non-significant change in mean glycemic variability (CV%) at day 7 (15.86 –5.03), day 30 (15.75 –2.6), day 60 (16.62 –3.4), day 90 (17.37 –5.98) (p=0.355). There was significant change in LBGI (p=0.0185) at day 90, with values at day 7 (2.24 –2.82), day 30 (1.77 –2.59), day 60 (1.14 –1.55) at day 90 (1.21 –1.76). There was non-significant change in HBGI at day 7 (1.37 –2.09), day 30 (1.6 –2.6), day 60 (1.8 –3.4), day 90 (2.1 –4.5) (p=0.58). (FIGURE) At all time points, patients were within defined threshold of glycemic variability metrics.

Conclusions: TPN intervention appears to have potential to reverse diabetes while achieving the targets for glycemic variability. Maintaining glucose homeostasis efficiently in journey to achieve reversal of diabetes is a translation of the scientific rationale for digital twin technology, powered by Internet of Things and Artificial Intelligence to clinical benefits.

Hypertensive Patient’s Experiences of and Self-Reported Adherence to a Telemedicine DASH Diet Intervention

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Background and Aims: There is an increasing demand for virtual health care services including remote nutrition evaluation, monitoring and support of patients with chronic disease. The most well-established dietary pattern for treatment of hypertension is Dietary Approaches to Stop Hypertension (DASH). The diet consists of a high intake of fruits, vegetables, root vegetables, whole grains, low-fat dairy products, legumes and nuts, while saturated fat, total fat and sodium intake is low. Treating patients according to the DASH diet has had poor outcomes using traditional methods, possibly because lifestyle changes takes time. Digital methods may be better suited to provide long-term support. The purpose of the current study is to investigate the experience of and self-reported adherence to the DASH diet using a telemedicine approach.

Methods: Inclusion criteria were patients with primary hypertension having a mean systolic BP between 135-150 mmHg. Communication between the dietitian and the patient takes place via asynchronous text communication using a digital care concept from the Swedish caregiver Accumbo’s product “Blood Pressure Doctor” in combination with video calls. A Food Frequency Questionnaire (FFQ) combined with a modified DASH index are used to assess dietary intake and adherence to the DASH diet by subjective report. A questionnaire is used to assess patient experience.

Results: Ongoing study. Results are expected in May 2021.

Conclusions: Several studies have shown that telemedicine is superior compared to traditional care in managing chronic diseases and lifestyle changes, but there are relatively few studies examining hypertensive patients’ experiences with a telemedicine DASH diet intervention.

Spanish Diabetes Applications (Apps) A Medical Device?

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Background and Aims: European regulations on applications as medical devices will be established by directive 93/42 / EEC in May 2021. Evaluate if Spanish applications for
diabetes can consider medical devices, in compliance with European regulations on medical devices, and if they carry the CE label.

**Methods:** Descriptive cross-sectional review of free mobile applications in Spanish for diabetes, available on the main platforms of the Spanish market: Google Play (Android) and App Store (iOS). We collect affiliation data, type and technical characteristics of the applications.

**Results:** A total of 356 applications were evaluated: 105 from the Apple Store iOS (29.5%) and 251 from Google Play (70.5%), and 40 on both platforms (11.2%); 302 were excluded from the analysis because they were not in Spanish. 54 study applications: referenced by academic institutions or scientific societies 12 (22%). Regarding the functions, 40 (74%) acted as logaritmers of glucose or glucometer; 13 (24%) allowed obtaining a diet and exercise record. The personal data of the users of the application was accessed in 24 (45%); Data export was possible in 20 (37%). 12 applications (22%) were CE marked, and all were connected to a glucometer software (70%) or continuous glucose monitoring devices (50%) or both (25%). Among those without the CE label, 58% are connected with a software device.

**Conclusions:** A few free diabetes management apps are available in Spanish. A small number of applications are considered medical devices according to European certification (CE). Most of the apps are focused on blood glucose monitoring.

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**P190 / #76**

**Topic:** AS07-Insulin Pumps

**CHARACTERISTICS OF PEOPLE WITH TYPE 2 DIABETES MELLITUS INITIATING AN INSULIN PUMP: DATA FROM A LARGE COMMERCIAL CLAIMS DATABASE**

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**Background and Aims:** The use of insulin pumps among people with type 2 diabetes mellitus (T2DM) is increasing. This work aims to understand the demographic and clinical characteristics of T2DM insulin pump initiators.

**Methods:** The IBM MarktScan² Commercial Claims Database was used to identify new pump use (index date: 2016–2018) in people with T2DM, ≥21 years, with ≥1 prescription for insulin in 6 months prior to index, and ≥2 years of continuous enrolment prior to index. Demographic and clinical characteristics as well as treatment patterns were described up to 24 months prior to index.

**Results:** Of 2,026 people (50.4% male, mean age 52 years) meeting eligibility criteria, almost half (48.9%) had an endocrinologist encounter within 90 days prior to pump initiation. Nearly one-quarter (24.8%) of people filled their first insulin prescription within 18 months prior to index and 9.6% had no mealtime insulin claims at any time pre-index. In the 6 months prior to pump initiation, 10.7% of people had a claim for a hypoglycaemic event, the average most recent HbA1c was 9.5% (n = 61), and individuals filled on average 2.8 diabetes medication classes. Of those with a claim for continuous or flash glucose monitoring in the 6 months pre-index (33.8%; n = 684), nearly half (n = 332) initiated use within 30 days preceding pump use.

**Conclusions:** Further work is needed to understand the contribution of factors such as patient readiness to engage with technology, poor glycaemic control, and hypoglycaemic events to pump initiation among people with T2DM.
P191 / #95

Topic: AS07-Insulin Pumps

EVALUATION OF A NOVEL CGM-INFORMED BOLUS CALCULATOR WITH AUTOMATIC GLUCOSE TREND ADJUSTMENT USED WITH SENSOR-AUGMENTED PUMP THERAPY

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Background and Aims: Expert opinion and professional society guidelines recommend adjustment to bolus insulin doses based on CGM trend, yet minimal evidence exists to support the safety and effectiveness of this approach. This study evaluated a novel CGM-informed bolus calculator (CIBC) with automatic glucose trend adjustment used with sensor-augmented pump therapy.

Methods: Participants aged 6–70y with T1D ≥6 months used the Omnipod® S Automated Insulin Delivery System in Manual Mode, first for 7 days without a connected CGM (standard bolus calculator, SBC), then for 7 days with a connected CGM (CIBC). Boluses were calculated using stored pump settings plus user-estimated meal size and/or either a manually entered glucose value (SBC) or an imported current CGM value and trend (CIBC). The CIBC automatically increased or decreased the suggested bolus amount based on the trend. Primary outcomes were percentage of CGM readings <70mg/dL and >180mg/dL out of all readings within 4h after any bolus.

Results: Participants (N=25) were aged (mean±SD) 27±15y, with T1D duration 12±9y and A1C 7.0±0.9%. The number of boluses per day was 6.4±2.9 and 6.8±2.9 with the SBC and CIBC, respectively (p=0.3). There were significantly fewer readings <70mg/dL 4h post-bolus with the CIBC compared to the SBC (2.1±2.0% vs. 2.8±2.7, p=0.03), while percent readings >180mg/dL and 70-180mg/dL remained the same (Table).

Conclusions: The CIBC was safe and effective when used with the Omnipod System in Manual Mode, with significantly fewer hypoglycemic readings 4h after bolus use.

Table. Glycemic outcomes from CGM data within 4h after any bolus

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Standard Bolus Calculator (SBC)</th>
<th>CGM-Informed Bolus Calculator (CIBC)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Readings: 70-180mg/dL (3.9-10.0mmol/L)</td>
<td>65.1±15.4</td>
<td>63.8±15.7</td>
<td>0.6</td>
</tr>
<tr>
<td>&gt;180mg/dL (&gt;10.0mmol/L)</td>
<td>32.1±15.7</td>
<td>34.0±16.0</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*Statistically significant with p<0.05

P192 / #115

Topic: AS07-Insulin Pumps

THE MEDITRONIC EXTENDED WEAR INFUSION SET: DETERMINING MECHANISMS OF ACTION

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Background and Aims: The Medtronic Extended Wear Infusion Set (EWIS) was developed to extend IS wear time from the current 2-3 days for up to 7 days. Successful development of EWIS required an early understanding of current IS device failures and anatomical feasibility for an optimized device. We examined various factors causing IS failures and targeted mitigation strategies to better understand mechanisms of action of the EWIS.

Methods: The systematic methodology used to study and determine EWIS mechanisms of action included in-vitro analyses, and the review and assessment of pre-clinical and clinical studies investigating the design, wear-duration (i.e., survival), and function of worn infusion sets. A mitigation plan was then developed to assess and optimize IS effectiveness and safety.

Results: An early clinical study investigating 7-day IS wear determined a design-associated IS failure rate of 64% attributable to factors ranging from kinking at insertion site to adhesive loss or accidental pull-out. A study of 7-day IS wear in a porcine diabetes model identified insulin-related inflammation as a significant contributor to IS failure. Mitigation plan experiments that have included analyses of insulin formulation stability have been developed and further evaluated in an EWIS clinical study.

Conclusions: A mechanisms of action study combining laboratory tests and assessments of in-vivo animal and human clinical studies provided profound insights into the development of the EWIS. Results suggest that insulin formulation stability in the pump/infusion set system is, also, key to extending infusion set wear duration.

P193 / #126

Topic: AS07-Insulin Pumps

CO-DESIGNING AN INSULIN PUMP FAQ SHEET FOR PAEDIATRIC DIABETES PUMP PATIENTS TO IMPROVE PATIENT ENGAGEMENT

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Background and Aims: Insulin pump therapy has the potential to dramatically improve the quality of life for some children. However, this requires a motivated and educated adult to supervise the young child (or a motivated older patient). We
know that parents would benefit from being made aware of the additional work involved in using a pump\(^1\) and believe that patients and parents often have unrealistic expectations, hindering the adoption of diabetes technology\(^2\). Our aim was to create a Frequently Asked Questions (FAQ) sheet, suitable for both patients and families on what to expect from insulin pumps. 1. Rankin D et al. Parents’ experiences of managing their child’s diabetes using an insulin pump: A qualitative study. Diabetic Medicine. 2014;32:627–634. 2. Hirose M et al. Quality of Life and Technology: Impact on Children and Families with Diabetes. Curr Diab Rep. 2012;12(6):711–720.

Methods: We co-designed a FAQ sheet initially collating common questions from various team members. Following parental review, the document was adapted and with successive recommendations, key messages were incorporated to make it most relevant. Simple patient and professional feedback forms were designed to evaluate the tool.

Results: See Figure 1 for the co-designed FAQ sheet. Parental feedback demonstrated the tool’s usefulness whilst also appealing to their children to engage them in their diabetes management.

Conclusions: In conclusion, a FAQ sheet co-designed with patients delivers benefits to various stakeholders in diabetes management. For healthcare staff it can make consultations more efficient, for parents it addresses preconceptions early and for the child, it engages them in managing their diabetes.
P195 / #233

Topic: **AS07-Insulin Pumps**

**METABOLIC CONTROL IMPROVING IN PEDIATRIC PATIENTS AND YOUNG ADULTS WITH TYPE 1 DIABETES AFTER STARTING THERAPY WITH CLOSED LOOP SYSTEM**

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**Background and Aims:** Metabolic control in patients with Type 1 Diabetes Mellitus continues being a great challenge, especially in children and teenagers.

Recently continuous infusion and monitoring systems have been developed, making patients enjoy the benefits of simulating an artificial pancreas.

One of that new devices is the hybrid closed loop system developed by Medtronic (Minimed 670G®), which automatically corrects deviations in glucose from a preset target (120 mg/dl), infusing insulin in variable microbolus according to sensor readings. The aim of our study is analyze glycemic variability and control data in pediatric patients with Type 1 diabetes mellitus after change from their usual treatment to the Medtronic 670G® closed loop system.

**Methods:** This is a prospective study in pediatric patients and young adults (n=27) that begin treatment with closed loop system Medmin 670G®, from different previous treatments. Data on metabolic control and glycemic variability were studied at the beginning and at 6 months of treatment.

**Results:** The study shows a reduction of HbA1c (7.34% vs 6.97%; p<0.002), an increase in time in target 70-180 mg/dl (63% vs 72.7%; p<0.001), a decrease in time in hyperglycemia >180 mg/dl (24.7% vs 19.9%; p=0.003) and in time in hypoglycemia <70mg/dl (1.85% vs 1.56%; p=0.381), as well as a decrease in mean glycemia (163.3 mg/dl vs 151.5 mg/dl; p=0.002).

**Conclusions:** The new MINIMED 670G system improves metabolic control in pediatric and young adult patients with T1DM, regardless of previous treatment.

P196 / #239

Topic: **AS07-Insulin Pumps**

**FIASP INSULIN STABILITY IN THE EXTENDED WEAR INFUSION SET AND ON-MARKET INFUSION SETS: AN IN-VITRO SAMPLES COMPARISON WITH THE MINIMED™ 670G SYSTEM**

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**Background and Aims:** NovoLog® (approved for use with the Medtronic MiniMed™ 670G system) and Fiasp® have the same insulin aspart structure; however, the Fiasp® formulation has been modified to increase the absorption speed and stability of insulin. It has been assessed in clinical studies and approved for use in continuous subcutaneous insulin infusion (CSII, open-loop pump). In this study, the in-vitro compatibility of Fiasp® in the MiniMed™ 670G pump system with on-market infusion sets and the Extended Wear infusion set were evaluated.

**Methods:** The in-vitro study of Fiasp® compatibility was performed per the Food and Drug Administration guidance for infusion pumps using in-use conditions at 37°C and samples shaken for 6 days and 14 days (twice the use duration of infusion set service life) respectively, for the on-market infusion sets and Extended Wear infusion sets. An insulin flow suspension of 12 hours/day followed by a 0.025 U/hour basal rate, across consecutive days, was programmed as a worst-case scenario to demonstrate there were no occlusions post suspension. Insulin samples underwent analyses that included measurements and comparisons of degradation products (insulin impurities), preservative content, and high molecular weight proteins (aggregates).

**Results:** The pumped Fiasp® solution emerging from the on-market infusion sets and the Extended Wear infusion sets met pharmaceutical specification for Insulin Aspart injections (Table).

**Conclusions:** These early insulin stability findings indicate that Fiasp® may be suitable for administration via continuous subcutaneous insulin infusion with the Medtronic MiniMed™ 670G system.

P197 / #266

Topic: **AS07-Insulin Pumps**

**A NEW METHOD FOR PREDICTING THE RISK OF PREGNANCY COMPLICATIONS IN PATIENTS WITH TYPE 1 DIABETES**

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**Background and Aims:** To analyze the relationship of pregnancy complications with changes in the need for insulin in patients with type 1 diabetes mellitus (DM 1).

**Methods:** We examined 119 pregnant women with DM 1 receiving insulin with insulin pumps. The program cluster analysis divided the patients into 2 clusters based on the presence or absence of complications: preproliferative and proliferative stages of retinopathy, preeclampsia, chronic fetoplacental insufficiency (CFPI), polyhydramnios, increased placental thickness. 88 pregnant women were included in the first cluster without complications and 31 in the second cluster. The level of HbA1c during pregnancy in the two clusters (p>0.05) was comparable. Basal insulin doses (U/kg) were estimated at 10–12;
22–24; 30–32 weeks of pregnancy, the increase in doses (%) was calculated from I to II, from II to III trimester of pregnancy.

**Results:** The median increase in basal insulin dose from II to III trimester was +43.0% in the first cluster, and +5.5% in the second (p<0.001). The value of the basal dose increase at the cut-off point was 19.5%, the area under ROC curve was 0.83±0.046 (95% CI: 0.74–0.92), (p<0.001). When the basal insulin dose increase was below 19.5%, the patient belonged to cluster 2 with a high incidence of pregnancy complications and retinopathy. Sensitivity was 75.0%, specificity 75.5%.

**Conclusions:** An increase in basal insulin dose from the second to the third trimester below 19.5% in pregnant women with preproliferative or proliferative stage of retinopathy may be a predictor of preeclampsia and CFPI.

**P198 / #271**

**Topic:** **AS07-Insulin Pumps**

**DISORDERS IN THE HEALTH OF THE NEWBORN AND THE NEED FOR INSULIN DURING PREGNANCY IN PATIENTS WITH TYPE 1 DIABETES**

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**Background and Aims:** To assess newborns’ condition and changes in the need for insulin during pregnancy in patients with type 1 diabetes mellitus (DM).

**Methods:** We examined 119 pregnant women with DM 1 receiving insulin in the mode of continuous subcutaneous insulin injections (CSII) with an assessment of the pregnancy outcome. Basal insulin doses (U/kg) were estimated at 10–12; 22–24; 30–32 weeks of pregnancy, the increase in basal insulin doses (%) from I to II, from II to III trimester of pregnancy was calculated, the state and frequency of health disorders of newborns were evaluated.

**Results:** Cases of neonatal pathology accounted for 35.3%: among them, intrauterine growth retardation (IUGR) - in 9 (7.6%) cases, respiratory distress syndrome (RDS) - in 6 (5.0%). In the presence of RDS the median increase in basal insulin dose from II to III trimester was +2.0% (0.0 ; 4.0%), in the absence of RDS +32.0% (10.5 ; 56.0%), (p = 0.03). The value of the basal dose increase in the ROC analysis at the cut-off point was +4.5%. In the case of an increase in the basal dose not exceeding +4.5%, a high risk of fetal RDS was predicted. With higher values, the risk of fetal RDS was considered low. The sensitivity of the model was 83.3%, the specificity - 82.1%.

**Conclusions:** An increase in the dose of basal insulin from the second to the third trimester of less than 4.5% in pregnant women may indicate the presence of a violation of the newborn’s condition in the form of RDS.

**P199 / #273**

**Topic:** **AS07-Insulin Pumps**

**STATE OF INSULIN PUMP USE IN THE CAPITAL REGION OF DENMARK**


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**Background and Aims:** In Denmark, an estimated 15–20% of 25,000 adults with type 1 diabetes use an insulin pump. Despite full coverage of device and consumable expenses for certain indications by the public healthcare system, the exact number of insulin pump users and treatment outcomes are unknown. The aim of this study was to identify and characterize insulin pump users in the Capital Region of Denmark regarding insulin pump-use practices, and sociodemographic, health status and psychosocial factors.

**Methods:** Insulin pump users (≥ 18 years) were identified by electronic database searches at the two insulin pump centers in the Capital Region, Steno Diabetes Center Copenhagen and Nordsjøelands Hospital Hillerød. All users were invited to participate in an online questionnaire-based survey.

**Results:** In total, 1,592 invitations were distributed in June 2020. The response rate was 52%. Mean age of the respondents was 48±16 years, 60% were female, mean diabetes duration was 29±15 years, and mean insulin pump duration was 10±7 years. Insulin pumps with or without tubing were used by 77% and 23% of respondents, respectively. Of all respondents, 8% used a hybrid closed-loop system. Regarding blood glucose monitoring, 23% used finger sticks and 77% used sensor-based glucose monitoring (33% intermittently scanned CGM; 67% CGM).

**Conclusions:** This abstract presents preliminary data on demographic and technology-specific characteristics of insulin pump users in the Capital Region of Denmark. Additional data on glycemic control, health status and psychosocial factors will be presented at the ATTD conference.

**P200 / #276**

**Topic:** **AS07-Insulin Pumps**

**NOVEL METHOD TO UNDERSTAND THE TEMPORAL NATURE AND ACCURACY OF DELIVERY FOR INSULIN INFUSION PUMPS**

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**Background and Aims:** Commercial pumps deliver insulin in pulses for both delivery modes (Basal/Bolus), but the pulse quantum and inter-pulse time varies across devices (Chan et al., 2008). The aim of this study is to understand the temporal nature and accuracy of delivery for a new durable pump developed by the authors (Yog-I), and a commercially available pump.

**Methods:** The cannula tip of an infusion set was connected to a glass pipette, and the delivery video was captured using a...
PATIENTS WITH TYPE 1 DIABETES
GLYCOCALYX VS MDI INTENSIFICATION IN ARTERIAL STIFFNESS AND ENDOTHELIAL FUNCTION SIX MONTHS CSII TREATMENT IMPROVES ENDOTHELIAL GLYCOCALYX AND DECREASES ARTERIAL STIFFNESS AFTER SIX MONTHS TREATMENT IN PATIENTS WITH T1DM.

Background and Aims: Insulin pumps are commonly used in the therapy of type 1 diabetes. To enable safe and effective therapy, insulin pumps have to deliver requested volumes of insulin with sufficient accuracy.

Methods: Bolus delivery accuracy of three insulin pumps—two patch pumps (MediSafe With [MSW], OmniPod [OP]) and one durable pump (MiniMed 640G [MM6])—was investigated using a microgravimetric experiment based on IEC 60601-2-24 for bolus sizes of 0.2 U, 1.0 U and 7.0 U. A total of 225 boluses (0.2 U and 1.0 U) or 216 (7.0 U) were delivered for each pump model, with 9 experiments comprising 25 or 24 boluses each, respectively. Deviations of individual boluses exceeding ±15% from target were considered relevant.

Results: for bolus delivery accuracy are shown in the table. Conclusions: The median deviation between designated bolus volume and volume calculated from weight increase was comparable among the insulin pumps. However, the percentage of boluses within ±15% deviation was markedly higher for MSW and MM6 than for OP at sizes of 0.2 U and 1.0 U. All individual boluses were within ±15% deviation at 7.0 U. Deviations were larger and varied more for smaller bolus sizes.
Background and Aims: Continuous subcutaneous insulin infusion (CSII) is one of the options used to achieve glucose control in patients with type 1 and type 2 diabetes. Hybrid closed loop (HCL) systems, as the one in Medtronic™ MiniMed 670G insulin pump, are safe, effective, and provide the traditional manual-mode and also an automatic feature (auto mode) that has been associated with increase time-in-range (70–180 mg/dL), less high glucose time (>180 mg/dL) and less low glucose time (<70 mg/dL).

Methods: A retrospective and descriptive study was performed including patients treated and followed by the endocrinology department from a highly complexity hospital in Cali, Colombia, 2020. Patients began therapy with MiniMed® 670G insulin pump after being treated with basal-bolus therapy, MiniMed® Veo™ or MiniMed® 640G insulin pump. In the first month using MiniMed® 670G we evaluated coefficient of variation (CV) of glucose and continuous glucose monitoring metrics (2 weeks in manual-mode following 2 weeks in auto mode).

Results: 25 patients were included, of which 52% presented type 1 diabetes. The mean glycosylated hemoglobin (HbA1c) was 7.6% ± 1.02 at the beginning of therapy (Table1). There was statistically significant difference between the CV of glucose before and after CSII with MiniMed® 670G (34.8% ± 4.9 vs. 31.9% ± 4.8, p = 0.0005) with no differences in sensor glucose time-in-range according to previous therapy.

Conclusions: CSII and HCL system is a useful strategy in the management of patients with diabetes, it is associated with an improvement of CV of glucose without compromising patient safety.

P204 / #443

Topic: AS07-Insulin Pumps

OLDER ADULTS WITH TYPE 1 DIABETES: GLUCOSE OUTCOMES WITH TECHNOLOGY AND EDUCATION

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Background and Aims: Older adults with T1D have unique health challenges, including greater risk of severe hypoglycaemia and its sequelae. International consensus recommends relatively conservative CGM targets for older adults (>50% time-in-range 3.9–10.0 mmol/L; <50% time above 10.0 mmol/L and <10% time above 13.9 mmol/L), while minimising hypoglycaemia (<1% time below 3.9 mmol/L). We studied older adults with long-standing T1D who received education and sensor-augmented pump (SAP) therapy.

Methods: Adults aged ≥60 years with T1D ≥10 years and using an insulin pump were eligible. SAP, diabetes education, carbohydrate-counting education and insulin-dosing advice were provided during run-in for a closed-loop trial. After education, CGM data were collected for 2 weeks during SAP.

Results: Thirty adults (mean±SD age 67±5 years, T1D duration 37±15 years, HbA1c 7.6 ± 0.9% [59 ± 9 mmol/mol]) participated. Ten (33%) had impaired awareness of hypoglycaemia (IAH). Median CGM time-in-range was 71% (IQR:64–79); time >13.9 mmol/L was 3.9% (2.4–10.2); and time <3.9 mmol/L was 2.0% (1.2–3.1). Only two participants (7%) met all CGM recommendations. Time <3.9 mmol/L was lower among the 16 participants with low-alert ‘before-low’ than the 14 with low-alert ‘on-low’: 24 h/day (1.5% [0.6–2.1] vs 2.7% [1.8–3.3], respectively; p = 0.038) and overnight (0.4% [0.1–1.1] vs 2.9% [1.5–4.0], respectively; p = 0.002). Participants with IAH had equivalent CGM to those with preserved awareness.

Conclusions: Using SAP, and after multi-disciplinary education, these older adults with T1D did not meet the stringent hypoglycaemia consensus recommendations, though achieved time-in-range far exceeding target (even in the presence of IAH). Predictive CGM-alerts could reduce hypoglycaemia, particularly overnight. Individualised targets for older adults warrant investigation.

P205 / #447

Topic: AS07-Insulin Pumps

FEASIBILITY CLINICAL STUDY ASSESSING THE COMPATIBILITY OF FIASP INSULIN WITH MEDTRONIC EXTENDED WEAR INFUSION SET

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Background and Aims: With improved postprandial glucose control, Fiasp® (Faster Insulin Aspart) is approved for pump use for up to 3 days with recommendations to monitor hypoglycemia closely. Medtronic Extended Wear Infusion Set (EWIS) is CE marked to infuse insulin lispro and aspart subcutaneously via Medtronic pump/reservoir system for up to 7 day. This feasibility study is aimed to evaluate safety and efficacy of EWIS delivery of Fiasp® for up to 7 days in participants with type 1 diabetes (T1D).

Methods: This was a 4-week single-center, prospective, open label one-arm study of 23 T1D subjects, resulting in 92 years of EWIS. Subjects used Medtronic EWIS-reservoir-640G/670G pump systems to infuse Fiasp® for up to 7 days in participants with type 1 diabetes (T1D).

Results: No safety concerns were identified with no level 3 hypoglycemia encountered during the study. Kaplan-Meier analysis indicated a 7-day survival rate of 72.2% for EWIS-
Fiasp® not statistical different (p = 0.297) from previous 80.5% for EWIS-Lispro/Aspart (ATTD 2020: Abstract #416). The detailed failure reasons were compared (table below), with slightly higher failure rate attributed to infusion set detachment.

Conclusions: This study demonstrates that Medtronic EWIS/pump system is safe and effective for subcutaneous Fiasp® infusion for up to 7 days.

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Topic: AS07-Insulin Pumps

REAL-WORLD OUTCOMES OF TWO DIFFERENT SENSOR-AUGMENTED INSULIN PUMPS WITH SUSPENSION BEFORE LOW AUTOMATIC FUNCTION IN TYPE 1 DIABETES PATIENTS.

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Background and Aims: To analyze the real-life outcomes of two sensor-augmented pumps (SAP), Medtronic Minimed 640G (MM640G) with Smartguard and Tandem T Slim X2 (TTSX2) with Basal-IQ, with suspension before low automatic function in Type 1 Diabetes Mellitus (T1DM) patients.

Methods: Observational cross-sectional study using data obtained from computerized clinical records. All T1DM patients on TTX2 therapy were compared (1:1) with MM640G treated patients selected through simple random sampling from our database. Primary efficacy outcome was to describe time in range (TIR, 70–180 mg/dL, 3.9–10 mmol/L) interstitial glucose differences.

Results: Twenty patients were analyzed (male 35%). Mean age was 42.8 ± 9.6 years and T1DM duration was 23.1 ± 8.8 years. Duration of CSII therapy was 9.0 ± 5.0 yrs. Both treatment groups showed similar TIR results (MM640G, 69.6 ± 17.5% vs TTX2, 70.2 ± 18.3% P = 0.88). Moreover, rest of evaluated glycemic outcomes were similar between both treatment groups: TIR, time in range (70–180 mg/dL, 3.9–10 mmol/L); TAR, time above range (>180 mg/dL, >10 mmol/L); TBL, time bellow range (<70 mg/dL, <3.9 mmol/L); HbA1c, glyca blood A1c (%); CV, coefficient of variation (%); MAGE, mean amplitude of glycemic excursions (mg/dL).

Conclusions: Patients using two different SAP with SBL function showed similar glycemic control in a real-world scenario.

Variable | MM640G | TTXS2 | P
---|---|---|---
TIR | 69.6±17.5 | 70.2±18.3 | 0.88
TAR | 27.5±16.1 | 24.6±20.4 | 0.59
TBR | 2.1±1.8 | 5.5±3.3 | 0.88
HbA1c | 7.1±0.9 | 6.6±0.8 | 0.19
CV | 34.1 | 34.9 | 0.76
MAGE | 130.6±55.7 | 139.0±56.6 | 0.94
M100 | 172.3±90.5 | 197.4±93.1 | 0.79
J-index | 53.6±38.7 | 46.2±19.5 | 0.94
MODD | 65.5±55.7 | 58.1±20.7 | 0.55
Congo2 | 39.8±6.4 | 38.1±9.9 | 0.76
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Topic: AS07-Insulin Pumps

LOWERINg POSTPRANDIAL HYPERGLYCEMIA WITH DUAL-WAVE INSULIN BOLUSES IN CHILDREN WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Insulin pumps offer standard, square and dual-wave boluses. Few recommendations exist on how to use these dosing options. Several studies suggest that the dual-wave boluses are more effective for high-fat or high-carbohydrate meals. Our objective was to test whether time in range (TIR) improves in type 1 diabetic (T1D) children with the universal utilization of the dual-wave boluses for all evening meals.

Methods: This was a 28-day long prospective randomized open-label single-center crossover study. Out of 33 screened T1D patients using a Medtronic 640G pump and continuous glucose monitoring system, 24 were randomly assigned to receive either dual-wave boluses (DWB) or standard boluses (SB) for all meals starting from 6:00 p.m. based solely on the food carbohydrate count. After two weeks patients crossed over into the alternative treatment arm. TIR (3.9-10 mmol/l), time below range (TBR) or TAR at least 1SD in one of the treatment regimens.

Results: There were no statistically significant differences in mean TIR (60.9% vs 58.8%; p = 0.297), TBR (1.6% vs 1.7%; p = 0.722) or TAR (37.5 vs 39%; p = 0.444) between DWB and SB groups respectively. Five out of 24 subjects improved TIR, TBR or TAR at least 1SD in one of the treatment regimens.

Conclusions: Dual-wave insulin bolus utilization for evening meals in which insulin is calculated solely on the food carbohydrate content does not improve TIR compared to standard bolus. In some subjects possible personalized benefit from either one of the treatment regimens is possible.

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Topic: AS07-Insulin Pumps

COMPARATIVE STUDY OF TREATMENT WITH MINIMED 640G AND MINIMED 670G MICRO-INFUSERS

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Background and Aims: The advance in technology for the treatment of DT1 has been exponential in recent years and it remains a challenge to achieve the goals of TIR and TBR. The objective is to compare the results with the use of MINIMED 640 and 670 globally and in the age under 18, between 18 and 30 and over 30 years old.

Methods: A retrospective, observational study was conducted that included patients with DT1 who were beginning to use MINIMED 640 and 670, analyzing data from the first 6 months. Tests of means, mean differences, variance differences, and analysis of variance were used to evaluate treatments. The characteristics observed were age, sex, HbA1c at the beginning and end of the study, TIR, TBR, TAR at 6 months of use.

Results: Women were 62.50%(50) men 47.5%(30), over 30 years old 51.25%(41) under 18 27.50%(22); 55.00%(44) used 640, 45%(36) used 670. All patients register less variability of HbA1c at the end of the first semester, the mayor dispersion in HbA1c is with 640 values are around the media of 7.71 (variance 0.81) while 670 7.14(variance 0.34). The variability of 640 is 2.81 greater than 670. In both the TBR is less 4% (640 2.89% and 670 1.75%). TIR at 6 months for 640 is 58.4% and for 670 69.2% (p 0.001). Those over 30 years of age present the best TIR and TAR for 640 and 670 with TIR in favor of 670 (p 0.01)

Conclusions: There are differences in favor of 670 to achieve TIR and there is evidence in favor of those over 30 years to achieve targets.
Background and Aims: Reimbursement of pump therapy facilitates the treatment of diabetes mellitus with new technologies. Aim: To assess the level of metabolic control of the children with Type 1 diabetes on insulin pump therapy at University Pediatric Hospital Sofia.

Methods: The reimbursement started in 2016 with 47 children, who were already on pump therapy. The reimbursement started irrespectively of the level of HbA1 but it was followed every 6 months later on. At the end of 2020 the number of patients increased to 187 (93 boys, 94 girls) out of total 858 registered patients aged <18y (20.7%). The mean age at diagnosis of pump treated children was 5.8 ± 3.79 years and the mean duration of diabetes at the start of reimbursement was 5.48 ± 3.95 years.

Results: The mean HbA1c measured before reimbursement was 7.72 ± 1.41% (median 7.47); 62(33%) showing HbA1c <7% and 28 (15%) with HbA1c<9.0%. For the following visits patients with HbA1c>9% were not allowed to receive reimbursed consumables. Up to now 13 adolescents dropped out: 6 because of HbA1c>9.0% and 7 who stopped insulin pump treatment. A total of 41 patients were transferred to adult care centers after age of 18 years. During the consecutive 7 visits the patients showed mean HbA1c 7.15 ± 1.29%, 7.19 ± 1.16%, 7.04 ± 1.21%, 7.3 ± 1.10%, 7.17 ± 1.15% and 7.41 ± 0.94% respectively. Patients with HbA1c <7% increased to 67% at 7th visit and there were no patients with HbA1c >9%.

Conclusions: Insulin pumps therapy is highly effective for keeping better metabolic control with HbA1c < 7%.
that leukocyte accumulation increased with non-filtered preparations but decreased after filtration in the mouse and swine models. Z-Y fabricated filter removed excess PP such that the filtered insulin solution achieved equivalent glycemic control in diabetic mice and swine when compared to non-filtered insulin.

**Conclusions:** PP removal assists in lowering inflammation at sites of insulin infusion and thus could lead to extending the functional lifespan of insulin infusion sets in vivo.

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**Topic:** AS07-Insulin Pumps

**METABOLIC IMPACT OF SGLT2 INHIBITORS IN INDIVIDUALS WITH TYPE 1 DIABETES UNDER CSII THERAPY**

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**Background and Aims:** Adjuvant therapy with Sodium-Glucose Transport Protein 2 inhibitors (SGLT2i) in individuals with type 1 Diabetes mellitus (T1DM) has demonstrated an improvement in glycemic control. However, given the increased risk of Diabetic Ketoacidosis (DKA) in these patients, real-life studies in individuals with DM1 under Continuous Subcutaneous Insulin Infusion (CSII) are still scarce. Our aim was evaluate the impact on glycemic control and the safety of SGLT2i in DM1 individuals under CSII.

**Methods:** Retrospective study of 25 T1DM adult patients under treatment with CSII who started adjuvant therapy with SGLT2i until 1st November 2020. Data regarding glycemic control at the moment of introduction of SGLT2i and at the last appointment were collected. Patients with less than 3 months of follow-up taking SLGT2i (1), who introduced posteriorly ultra-fast acting insulin (5) and pregnant were excluded.

**Results:** Nineteen patients were included (52.6% males, mean age of 42.6 ± 11.8years). The mean follow-up since the beginning of SLGT2i was 9.2 ± 4.5months. After its introduction, there was an increase of time in range (57.4% vs 68.7%, p = 0.003), a reduction of time above range (38.5% vs 27%, p = 0.004). The mean glucose management indicator (7.5% vs 7.1%, p = 0.036) and the mean weight (75.7kg vs 73.4kg, p = 0.004) also reduced. There were no significant differences in the mean total daily insulin dose (p = 0.327) neither median glucose (p = 0.079). No episode of DKA or other intercurrence occurred during follow-up.

**Conclusions:** In selected patients, the introduction of SGLT2i in DM1 under CSII was safe, and was associated with improved glycemic control, reduced glycemic variability and an additional weight benefit.

P215 / #801

**Topic:** AS07-Insulin Pumps

**MAST CELL ACTIVATION AT INSULIN INFUSION SITES INSTIGATES INFLAMMATION WITH LOSS OF INFUSION SITE PATENCY OVER EXTENDED DURATIONS OF CSII IN MICE**

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**Background and Aims:** Any foreign material or solutions can induce an inflammatory response in-vivo by triggering mast cell (MC) activation. Commercial insulin (CI) formulations contain phenolic preservatives (PP), which have shown to be cytotoxic to cells in vitro and induce inflammation with secondary fibrosis in vivo. As such, the goal of these studies is to determine the role of MCs in CI and PP-induced inflammation at CI injection/infusion sites.

**Methods:** HMC-1 MC degranulation (e.g. glycansaminidase release) was used to investigate the ability of CI or PP to trigger MC degranulation in vitro, and a modified murine air-pouch model was used to quantify CI and PP induced inflammation in normal, MC deficient mice, and Cromoly (MC degranulation inhibitor) treated mice. Leukocyte influx into a mouse air pouch, FACS, and histopathology analyses were used to characterize inflammation and MC activation in response to CI and PP. Fluorescent insulin was used to determine insulin uptake and degradation.

**Results:** These studies demonstrated that concentrations of CI or PP greater than 1% of insulin standard formulations, induced significant MC degranulation in vitro (> 50% of total mast cell degranulation). Mouse air-pouch studies demonstrated that MC deficiency or Cromoly treatment significantly reduced recruitment of inflammatory cells when compared to control mice. Inflammatory cell tissue presence augmented insulin uptake and degradation by leukocytes.

**Conclusions:** CI and PP induced MC activation-induced inflammation, insulin uptake and degradation by leukocytes, and loss of insulin infusion/injection architecture and function. Targeting MC provides a therapeutic strategy to attenuate CSII-induced inflammation.

P216 / #802

**Topic:** AS07-Insulin Pumps

**INSULIN DERIVED FIBRIL INDUCED INFLAMMATION INSTIGATES LOSS OF INFUSION SITE VIABILITY WITH EXTENDED WEAR OF CSII IN MOUSE AND SWINE MODELS**

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**Background and Aims:** Current challenges to extending the lifespan of insulin infusion involves surmounting the tissue reactions at insulin infusion sites. Recent literature indicates that phenolic preservatives (PP), present in all commercial insulin formulations, induce cytotoxicity and tissue inflammation. Furthermore, it is well accepted that insulin formulations are susceptible to mechanical and chemical stresses that lead to insulin fibril formation. Less is known about the biologic impact of insulin derived fibrils on cells and tissue. These studies aim to characterize in vitro and in vivo toxicity and pro-inflammatory activity of insulin fibrils in comparison to PP.

**Methods:** Cell technology, and modified murine air-pouch model as well as a diabetic swine model were used to quantify inflammatory activity of PP, filtered-PP, insulin and insulin fibrils.
P217 / #806
Topic: AS07-Insulin Pumps

CSII IS RELATED TO MORE STABLE GLYCEMIA IN TYPE 1 DIABETES

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Background and Aims: The aim of the present study was to compare the basic glycemic control parameters – HbA1c, CV% and hypoglycemia - in patients with type 1 diabetes using continuous subcutaneous insulin infusion (CSII) versus multiple daily injections (MDI).

Methods: 324 patients with type 1 diabetes – 146 using CSII (mean age 34.7±9.8 years, mean duration of diabetes 18±9 years) and 178 on MDI (mean age 39.6±11.6 years, mean duration of diabetes 14±10 years), were enrolled in this cross-sectional study. HbA1c was assessed in whole blood by immuno-turbidimetric NGSP certified method. CV% was derived from CGM or was calculated from 9-point capillary blood glucose profile. Hypoglycemia frequency, severity and awareness were assessed using Clarke’s hypoglycemia questionnaire. Statistical analysis of data was performed with SPSS 17.0.

Results: CSII group compared to MDI group showed significantly lower mean HbA1c - 7.3% (6.6-8.08%) vs 8.2% (7.2-9.6%) (p<0.0001), lower mean CV 27.2% (±9.8%) vs 34.7% (±11.3%) (p<0.0001), fewer hypoglycemia episodes (p<0.0001) and lower basal insulin doses 18.3 IU (14.4-23 IU) vs 22.0 IU (14.7-30.0 IU) (p<0.0001). There was no significant difference in the frequency of severe hypoglycemia and hypoglycemia awareness between the two groups.

Conclusions: CSII in type 1 diabetes is related to better and more stable glycemic control compared to MDI.

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Topic: AS07-Insulin Pumps

THE ACCU-CHEK® SOLO TUBELESS MICROPUMP IMPROVES GLYCEMIC CONTROL AND QUALITY OF LIFE IN ADULT AND PEDIATRIC PATIENTS WITH TYPE 1 DIABETES: A PILOT STUDY

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Background and Aims: Accu-Chek® Solo (ACS) is the first tubeless patch pump available in Spain. It features a modular design, a 200U insulin reservoir, and management through a Bluetooth-connected device. This study reports the first experiences in Spain.

Methods: This is a pilot study of nine patients with T1D: 6 adults (age 45.8±11.1 years, diabetes duration 20.3±15.6 years) and 3 children (age 12.5±0.5 years, diabetes duration 1.8±1.04 years), from 7 centers of excellence in Spain. Six of them were previously on basal-bolus therapy and two on conventional pump therapy. Demographic, clinical and glycemic control data, quality of life and satisfaction with ACS were analyzed during a follow-up between 1–12 months.

Results: Reasons for starting ACS in adults were: nocturnal hypoglycemia or hypoglycemia unawareness, low insulin requirements, poor glycemic control, high physical activity or conventional catheter refusal. In pediatric patients, the main reason was greater pump wearing discretion in pre-adolescence. Improved glycemic control, increased time in range, reduced time below range and reduced glycemic variability were statistical significant (see table). No technical issues were observed. Participants reported a high degree of satisfaction and improved quality of life. The most valued characteristics of ACS were absence of catheters, small size, unnoticeable wearing and remote control.

Conclusions: This pilot study suggests that ACS is an effective and safe CSII option, as well as an alternative to conventional pump therapy, being associated with improved quality of life and high degree of satisfaction in T1D patients.
Background and Aims: Diabetes mellitus is a public health problem worldwide, several studies have shown that a significant number of diabetic patients resort to herbal medication complementary medicine (CAM) which raises the concerns about compliance to pharmacotherapy as well as the safety of these medications.

Methods: This is a cross-sectional study to determine the pattern and perceptions of use of herbal medicine. This study included 350 Type 2 diabetes mellitus selected randomly from Farwaniah diabetes mellitus clinic in Kuwait. The study conducted in the period from second January 2019 to the end of June 2019.

Results: The study revealed that the prevalence of using herbal medicine in the study sample 350 diabetic patients was 30.6%. Females users were greater than males in using the herbal medicine. The majority 56% of patients use herbal medicine. Black Cumin i.e. Habba Soda and herbal mixture were the common herbal substances used. However, 70% of herbal users had bad glycaemic control and more diabetic complications than who receiving the conventional pharmacological treatment. The majority of herbal users 95.3% did not inform their doctors about herbal use and they used herbal medicine as a supportive measure to their pharmacology treatment.

Conclusions: The study revealed that herbal use and they used herbal medicine as a supportive measure to their pharmacology treatment.

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Topic: AS08-New Medications for Treatment of Diabetes

NASAL GLUCAGON WAS EFFICACIOUS IN REVERSING INSULIN-INDUCED HYPOGLYCAEMIA WITHOUT INCREASING RISK OF SECONDARY HYPERGLYCAEMIA

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Background and Aims: Nasal glucagon (NG), a ready-to-use therapy for treatment of severe hyperglycaemia, contains 3 mg glucagon dry powder absorbed passively through nasal mucosa. We evaluated efficacy, pharmacodynamics (PD), and safety of NG compared to injectable glucagon (IG) in reversing insulin-induced hypoglycaemia in Caucasian and Japanese adults with type 1 diabetes (T1D) or type 2 diabetes (T2D).

Methods: Post-hoc analyses used data from 2 randomised, cross-over studies. Treatment success was defined as an increase in blood glucose to ≥3.9 mmol/L (70 mg/dL) or an increase of ≥1.1 mmol/L (20 mg/dL) from nadir blood glucose within 15 minutes of receiving glucagon. PD data, including area under the curve above 140 mg/dL [Δ140 AUC (1-4 hr)], were used to evaluate the risk of secondary hyperglycaemia. Tolerability was assessed with treatment-emergent adverse events and symptom questionnaire.

Results: A similar proportion of NG [97.8% (131/134)] and IG patients [97.0% (130/134)] achieved treatment success. Mean time to treatment success (for blood glucose increase) was 11.7 minutes for NG and 10.4 minutes for IG (p < 0.001). Median time for both was 10 minutes. Geometric least square mean BO_max for NG and IG were 194 and 205 mg/dL (p < 0.001), respectively. NG had significantly lower Δ140 AUC (1-4 hr) (p < 0.001), with 42% reduction compared to IG. NG had similar rates of nausea and vomiting versus IG, with higher rates of side effects related to nasal administration.

Conclusions: NG was efficacious and well-tolerated in reversing insulin-induced hypoglycaemia in adults with T1D or T2D and did not increase the risk of secondary hyperglycaemia compared to IG.

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Topic: AS08-New Medications for Treatment of Diabetes

SARCOPENIA - THE CAUSE OF DEVELOPMENT OF NON COMMUNICABLE DISEASES

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Background and Aims: Non communicable diseases (NCD) are currently the main cause of high morbidity and mortality in humans. Sarcopenia - the reduction of muscle mass is a great factor in the development of mechanism of these diseases. We have developed a model of the development of NCD, in which the key role related to sarcopenia.

Methods: Results of own researches and data of PubMed for last 20 years were used in the work.

Results: During sarcopenia the ability of insulin to stimulate muscle to absorb of glucose decreases and or manifestations of insulin resistance are noted. Due to the decrease in glucose consumption by the muscle, its increase in blood, hyperglycaemia occurs, which contributes to increased insulin secretion and increases in its concentration (insulinemia) or develops symptoms of type 2 diabetes. Under the influence of insulin, the carbon skeleton of glucose is “dumped” into fats, which contributes to...
the development of lipedema and increased admission of fats to adipocytes, i.e. obesity develops. Drug correction of NCD is often unsuccessful; therefore, all attention should be paid to the use of anti-sarcopenia technologies in case of prevention and treatment of NCD.

Conclusions: Thus, sarcopenia is the most important reason for the development of NCD, which reduces the quality of life and independence of an elderly person, and reduces their lifetime. The state is forced to expend large material resources to fight NCD; therefore the development of pathogenesis and the principles of prevention and treatment of sarcopenia have great scientific, practical and social significance.

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Topic: AS08-New Medications for Treatment of Diabetes

DASIGLUCAGON IS A NOVEL STABLE GLUCAGON ANALOG WITH FAST GLUCOSE RESPONSE FOLLOWING SUBCUTANEOUS INJECTION IN HYPOGLYCEMIC RATS

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Background and Aims: Severe hypoglycemia is a life-threatening event requiring rapid caregiver intervention. Glucagon (as powder for reconstitution) has been a treatment option for years, but its tendency to aggregate quickly in aqueous solutions has hampered development of easy-to-use emergency devices for fast recovery. Dasiglucagon, a novel glucagon analog, was studied for its propensity to form aggregates in aqueous solutions, potency on the glucagon receptor, and effect on blood glucose following subcutaneous (SC) injections in hypoglycemic rats.

Methods: Dasiglucagon’s aggregation tendency was investigated via an accelerated stability assay (40°C with agitation), and via a rotation study (1 year at room temperature) in pre-filled syringes. An in vitro study was performed to compare receptor potency of dasiglucagon versus glucagon, and the effect of SC dasiglucagon on blood glucose was studied in a rat hypoglycemia model.

Results: By accelerated stability assay, dasiglucagon did not form aggregates over 14 days, and glucagon fully aggregated within 1 day. A long-term dasiglucagon stress study confirmed that aggregates did not develop with continuous rotation (room temperature for 1 year). In vitro, dasiglucagon demonstrated similar potency on the human glucagon receptor as glucagon. In a rat hypoglycemia model, SC dasiglucagon or native glucagon demonstrated fast, comparable, dose-dependent increases in blood glucose.

Conclusions: Dasiglucagon is a 29 amino acid glucagon analog, with 7 amino acid substitutions that increase physical and chemical stability. Dasiglucagon has a much lower tendency to form aggregates in aqueous solutions, maintains potency at the glucagon receptor, and rapidly raises blood glucose following SC injections.

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Topic: AS08-New Medications for Treatment of Diabetes

FIXED COMBINATION OF GLARGIN 100 U/ML AND LIXISENATIDE IN THE TREATMENT OF TYPE 2 DIABETIC PATIENTS IN MOSCOW

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Background and Aims: To study the effectiveness of fixed combination of Glargin 100 U/ml and Lixisenatide (IGlarLix) on HbA1c level in diabetic patients (T2DM) who did not achieve control on oral glucose-lowering drugs (OGLDs).

Methods: Patients with T2DM receiving IGlarLix in addition to the OGLDs were selected from Moscow segment of Russian Federal Diabetes Register (MSRFDR). Statistical analysis of the data was carried out.

Results: 247 patients [71 men (28.7%) and 176 women (71.7%)] on IGlarLix therapy with mean age 59.0 (+9.3) years; diabetes duration - 8.6 (+6.8) years; BMI - 36.6 (+7.7) kg/m² were selected. HbA1c initial level was 8.6 (+1.1%). Before IGlarLix therapy, 42.6% of patients received OGLD, 45.9% - 2 OGLDs, 11.5% - 3 OGLDs. The starting dose of IGlarLix was 10U. After 3 months of observation was increased to 27.0 U (p < 0.05), after 6 months - to 28.8 U, after 9 months - to 29.3 U (p > 0.05). HbA1c change after 3 months was 0.3% (p < 0.05), after 6 months - 0.4% (n = 163, HbA1c - 8.2%, p < 0.05), after 9 months - 0.7% (n = 46, HbA1c - 7.9%, p < 0.05). There was no statistically significant change in BMI.

Conclusions: The addition of IGlarLix to the therapy of T2DM patients on OGLDs in real clinical practice results in a statistically significant decrease in HbA1c level. The lower level of HbA1c decrease in comparison with the values obtained in randomized clinical trials may be due to insufficient active IGlarLix titration.

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Topic: AS08-New Medications for Treatment of Diabetes

THE BIOCHEMICAL BLOOD PARAMETERS IN TYPE 1 DIABETES MELITUS FEMALE PATIENTS OF DIFFERENT AGES AND ETHNICITY.

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Background and Aims: Due to the widespread and the severity of complications type 1 diabetes mellitus (T1DM) is considered the acute problem and priority for the many countries health care. Features of T1DM course depend on many factors, including ethnic, racial affiliation and region of residence. The aim of this study was to reveal the different ages and ethnicity T1DM patients several biochemical components peculiarities.

Methods: The Caucasian and Asian T1DM patients (17 adolescent girls and 20 reproductive age women) biochemical parameters were evaluated in comparison with corresponding age control groups. Spectrophotometric, fluorometric and statistic methods were applied.

Results: Caucasian adolescent girls with T1DM had higher diene conjugates values (by 2 times), thiobarbituric acid reactants (by 1.8 times), oxidative stress coefficient (by 3.4 times), lactate level (by 1.4 times) and the ratio lactate/pyruvate (by 1.9 times), in comparison with same age Asian patients. In Caucasian women with T1DM the following differences with Asian T1DM patients were observed: content of total lipids (1.5 times) and unsaturated double bond substrates (by 1.4 times) increase and blood total antioxidant activity level decrease (by 32%).

Conclusions: Oxidative stress intensity depends on T1DM patient ethnicity. The lack of accumulation of toxic lipid per-oxidation products in representatives of the Asian ethnic group may be a positive sign in disease further course and vascular complications prognosis.

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Topic: AS08-New Medications for Treatment of Diabetes

PHARMACOKINETICS/PHARMACODYNAMICS OF GLUCAGON AND THE NOVEL GLUCAGON ANALOG, DASIGLUCAGON, IN AQUEOUS OR NON-AQUEOUS FORMULATIONS FOLLOWING SUBCUTANEOUS ADMINISTRATION IN RATS

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Background and Aims: Endogenous peptide hormones, such as glucagon used for treatment of severe hypoglycemia events in patients with diabetes, are generally unstable in aqueous solutions, making development of ready-to-use injection solutions a challenge. Analogs of endogenous peptide hormones can be designed to increase the physical stability of the molecules. Another approach to enable easy administration of unstable peptides is to formulate them in non-aqueous formulations, such as dimethyl sulfoxide (DMSO). The current study was conducted to compare the pharmacokinetics (PK) and pharmacodynamics (PD) of glucagon following subcutaneous (SC) administration in rats when formulated in an aqueous formulation (Phosphate buffered solution [PBS]), or DMSO.

Methods: Four to 6 male Sprague Dawley rats received 3 nmol/kg of glucagon in DMSO or in a PBS formulation, or dasiglucagon at 2 nmol/kg in a PBS formulation. Blood samples for bioanalysis (glucagon groups only) and blood glucose measurement were taken at pre-dose (0) and 15, 30, 45, 60, 75, 90, 105, and 120 min post-dose. The PD data were compared to data generated for the stable glucagon analog, dasiglucagon, in rats.

Results: Glucagon in PBS demonstrated a faster absorption, a higher Cmax (98.3 vs 39.9 pmol/L) and faster Tmax (15 vs 45 minutes) compared to glucagon in DMSO.

Conclusions: Observed increases in blood glucose levels, by both time to peak and area under the curve, were similar when glucagon or dasiglucagon were injected in PBS, and faster than those achieved with injections of glucagon in DMSO.
E. Shestakova, M. Shestakova

Method sensitivity was 92.86% (95%CI 66.1-99.8) and specific GLP-1 value amounted to 5.501 pmol/l (Youden’s statistic).

blood glucose normalization on liraglutide 3.0mg treatment; cut-
dogenous GLP-1 but not weight reduction could be predictive of
normalization. In ROC-analysis we showed that baseline en-
7.31 [5.34; 8.43] pmol/l. 16 (72%) patients reached blood glucose

Cmax) and nausea and vomiting.

[25%], vomiting [25%]; 12–17 years: nausea [92%], vomiting

[67%]) and GlucaGen® (6–11 years: nausea [50%], vomiting

[25%]; 12–17 years: nausea [17%], vomiting [0%]). No relation-
ship was found between dasiglucagon exposure (AUC0–5h or
Cmax) and nausea and vomiting.

Conclusions: Consistent with adult Phase 3 trials, dasigu-
lucagon is fast and reliable in restoring PG levels following in-
duced hypoglycemia in children with T1DM, with an overall
safety profile similar to glucagon.

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Topic: AS08-New Medications for Treatment of Diabetes

ENDOGENOUS GLP-1 LEVEL BUT NOT WEIGHT REDUCTION PREDICTS EFFECT OF LIRAGLUTIDE 3.0 MG ON BLOOD GLUCOSE NORMALIZATION IN PATIENTS WITH OBESITY AND TYPE 2 DIABETES

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Background and Aims: According to current guidelines GLP-1 receptor agonist liraglutide 3.0mg may be given to all patients with obesity and there is no personalization indicator of its’ glucose-lowering effectiveness in type 2 diabetic (T2D) patients before prescription.

Methods: 22 patients with T2D and obesity (median BMI 42.4 [37.7; 48.3] kg/m²) had liraglutide added to prior glucose-lowering treatment (baseline monotherapy in 22%, double therapy in 45.5%, triple therapy in 31.8%). All patients had fasting and postprandial (2 h after mixed meal test) glucose, HbA1c and weight measurements at baseline and 9 months after treatment. Endogenous GLP-1 was assessed at baseline and used in predictive model of blood glucose normalization on liraglutide 3.0mg treatment. Blood glucose normalization meant normoglycaemia (FPG <6.1 mmol/l, PPG <7.8 mmol/l) achievement.

Results: Medians of HbA1c decreased from 7.85 to 6.40%; fasting glycaemia - from 9.02 to 5.90 mmol/l and postprandial glycaemia - from 11.31 to 7.16 mmol/l. Weight was reduced down to 35.9 [33.0; 40.9] kg. Median GLP-1 level at baseline was 7.31 [5.34; 8.43] pmol/l. 16 (72%) patients reached blood glucose normalization. In ROC-analysis we showed that baseline endogenous GLP-1 but not weight reduction could be predictive of blood glucose normalization on liraglutide 3.0mg treatment; cut-off GLP-1 value amounted to 5.501 pmol/l (Youden’s statistic). Method sensitivity was 92.86% (95% CI 66.1-99.8) and specificity 62.5% (95% CI 24.5-91.5).

Conclusions: Endogenous GLP-1 value could predict blood glucose normalization after liraglutide 3.0mg treatment in patients with T2D and obesity in contrast to weight reduction.

Support: The study was supported by Ministry of Science and Higher Education of the Russian Federation (agreement no. 075-15-2020-899)

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Topic: AS08-New Medications for Treatment of Diabetes

LIPOPROTEIN(A) LEVELS IN CHILDREN, ADOLESCENTS, AND YOUNG ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Lipoprotein(a) (Lp(a)) is an LDL like particle that includes a single molecule of apolipoprotein B100. Lp(a) has been shown with clinical studies, systematic reviews, Mendelian randomization, and genome-wide association studies as an independent risk factor for cardiovascular disease (CVD) and calcific aortic stenosis. Novel therapeutics specific to lipoprotein(a) are emerging. It is known that in adults with type 1 diabetes, poor metabolic control is associated with higher Lp(a) levels. Studies on children with type 1 diabetes are sparse.

Methods: 467 patients (children, adolescents, and young adults) with type 1 diabetes were included in the data analysis (49% were female). Mean age 14.71 ± 5.09 years and diabetes duration 6.74 ± 4.54 years. They were divided by Lp(a) values into 3 ordinal categories: normal (<300 mg/L), borderline (300–499 mg/L), elevated (>500 mg/L).

Results: The estimated odds of male patients having Normal Lp(a) level (versus Borderline or Elevated) was 1.74 (95% CI, 1.08 to 2.80) times that of female patients, Wald χ² (1) = 2.29, p = 0.022. We have also found that every unit increase in HbA1c was significantly associated with an increase in the odds of patients having Borderline or Elevated Lp(a) level (versus Normal), with an estimated odds ratio 1.20 (95% CI, 1.11 to 1.31), Wald χ² (1) = 4.48, p <0.001.

Conclusions: Already in children, adolescents, and young adults, poor metabolic control of type 1 diabetes means a higher risk of increased Lp(a) levels. These results endorse Lp(a) measurements in every child with type 1 diabetes for better risk stratification for CVD.

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Topic: AS08-New Medications for Treatment of Diabetes

IMPACT STUDY: IMCY-0098 PROOF OF ACTION IN TYPE 1 DIABETES, ON THE WAY TO A SPECIFIC DISEASE-MODIFYING TREATMENT

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Background and Aims: There is currently no curative treatment available for type 1 diabetes (TID). IMCY-0098 has been designed to suppress the autoimmune reaction and provide long term islet β-cell preservation. IMCY-0098 consists of an antigen-derived insulin specific peptide supplemented with a thioredoxin consensus sequence designed to stimulate the generation of cytolitic CD4+ T-cells able to specifically suppress T1D autoimmune response. In a first clinical trial (EXALT study) an excellent safety profile has been observed along with promising early clinical and immunological trends.

Methods: IMPACT is a multicentre, randomized, double-blind, placebo-controlled study in patients with recent onset T1D and is currently conducted in 5 countries in collaboration with the European consortium INNODIA. The study has an adaptive design comprising of two steps:

A first step is enrolling 24 adult participants randomly and equally assigned to each treatment arms and followed up to 48 weeks.

A second step should enrol 60 participants, including adolescents aged 12–17, pending supportive safety data from step 1.

Results: Step 1 will allow to determine the immune signature of the treatment with the Imotope™ IMCY-0098 and select optimal treatment parameters for the second step. Step 2 is designed to evaluate the clinical efficacy of the treatment with IMCY-0098 by measuring the remaining level of C-peptide.

Conclusions: IMPACT will provide the opportunity to evaluate if this new antigen-specific immunotherapy has the ability to preserve remaining β-cell function in new onset T1D patients. Acknowledgements: INNODIA, T1D UK, DG06 from the Walloon Region of Belgium and IMI H2020 program from the European Union.

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Topic: AS08-New Medications for Treatment of Diabetes

EFFECTS ON FLASH GLUCOSE MONITORING PARAMETERS AFTER 6-MONTHS USE OF CFTR MODULATORS IN CYSTIC FIBROSIS PATIENTS WITH OR WITHOUT GLUCOSE METABOLISM ABNORMALITIES

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Background and Aims: Cystic Fibrosis (CF) related diabetes is one of the most frequent extra-pulmonar manifestations in CF patients. CF-Transmembrane Regulator (CFTR) modulators could improve insulin secretion in these patients. We aimed to investigate the effect of 6-months CFTR modulators treatment on flash glucose monitoring (FGM) parameters in a CF cohort.

Methods: Twenty one patients were included (17 [81%] Phe.508del homozygous) in a prospective, observational study. Glucose control and variability parameters were analyzed using FGM (FreeStyle Libre®) before and after 6-months CFTR modulators therapy: lumacaftor-ivacaftor (6–12-year-old [yr]) or tezacaftor-ivacaftor (≥13 yr). Statistical analysis by SPSS v.25. GLM repeated measures test performed.

Results: Twenty one patients were initially included: 5 were excluded (3 because they had incomplete sensor data at 6 months 2 because drug intolerance). Median age was 14,7 yr (IQR 8,5-26,0); 57% ≥13 yr and 57% male. All except 1 patient had >70% of sensor use, and the mean of analyzed days was 14. No differences were observed in terms of glucose control [mean glucose, glucose management index (GMI) and time in range (TIR)], glucose variability [standard deviation (SD) and coefficient of variation (CV)], or time in hypo or hyperglycemia (see Table 1).

Conclusions: FGM cannot be considered a tool for assessing benefits in glucose control and variability parameters with CFTR modulators. Longer studies are needed to see the real effect of these drugs on glucose metabolism.

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Topic: AS08-New Medications for Treatment of Diabetes

THE DUAL GIP AND GLP-1 RECEPTOR AGONIST TIRZEPATIDE IMPROVES BIOMARKERS ASSOCIATED WITH CARDIOVASCULAR RISK IN PATIENTS WITH TYPE 2 DIABETES (T2D)


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Background and Aims: In a Phase 2 trial, tirzepatide dose-dependently reduced HbA1c, body weight, and serum triglycerides in patients with T2D. To better understand possible additional effects of tirzepatide on cardiovascular risk, lipoprotein-related biomarkers and biomarkers of inflammation, cellular stress, and endothelial dysfunction were measured post hoc.
Methods: Patients (N=316) were randomised to weekly subcutaneous tirzepatide (1, 5, 10, 15 mg), dulaglutide 1.5 mg, or placebo. Protein biomarkers were assessed by immunoassay and lipoprotein particle profile was measured by nuclear magnetic resonance in stored serum or EDTA plasma samples at baseline and 26 weeks. The lipoprotein insulin resistance (LPIR) score was calculated. Results were analysed in a modified intent-to-treat population.

Results: At 26 weeks, tirzepatide dose-dependently decreased apolipoproteins B and C-III and increased pre-heparin lipoprotein lipase levels versus placebo. Compared with placebo and dulaglutide, tirzepatide dose-dependently decreased large triglyceride-rich lipoprotein particles (TRLP), small low-density lipoprotein particles (LDLP), and LPIR score. Tirzepatide dose-dependently decreased hsCRP, ICAM-1, and YKL-40 levels; tirzepatide 15 mg also decreased ICAM-1 and YKL-40 levels versus placebo and dulaglutide. GDF-15 levels decreased from baseline with both tirzepatide and dulaglutide, whereas IL-6 and VCAM-1 levels were unchanged in all groups. Tirzepatide decreased the number of small LDL particles and levels of proinsulin/C-peptide ratios, markers of pancreatic beta-cell stress, suggesting improved beta-cell function. Consistent with HOMA2-IR findings, many biomarkers associated with improved insulin sensitivity were significantly increased by one or more doses of tirzepatide compared with placebo or dulaglutide, including adiponectin, IGFBP1, and IGFBP2.

Conclusions: Tirzepatide improved multiple markers of insulin resistance. Fasting insulin levels were significantly reduced by tirzepatide 10 and 15 mg and HOMA2-IR was significantly decreased by tirzepatide 10 mg compared with placebo and dulaglutide. Tirzepatide 10 and 15 mg significantly decreased proinsulin/C-peptide ratios, markers of pancreatic beta-cell stress, suggesting improved beta-cell function. Consistent with HOMA2-IR findings, many biomarkers associated with improved insulin sensitivity were significantly increased by one or more doses of tirzepatide compared with placebo or dulaglutide, including adiponectin, IGFBP1, and IGFBP2. Higher tirzepatide doses significantly reduced levels of insulin resistance-associated branched chain amino acids (BCAAs) valine, leucine, and isoleucine and pathway-related metabolites alpha-ketoisocaproic acid, ketovaline, and ketosoleucine compared with baseline. BCAA and catabolic product changes significantly correlated with HOMA2-IR changes by Spearman’s correlation analyses. In multiple linear regression analysis, WL significantly explained 13% and 21% of HOMA2-IR variation from tirzepatide 10 and 15 mg, respectively, suggesting insulin-sensitizing effects of tirzepatide are only partially attributable to WL.

Conclusions: Tirzepatide demonstrated greater improvements in insulin sensitivity and beta-cell function than dulaglutide, which may result in improved metabolic health.

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Topic: AS08-New Medications for Treatment of Diabetes

THE TECHNOLOGY BEHIND NASAL GLUCAGON DELIVERY FOR THE RESCUE OF SEVERE HYPOGLYCEMIA

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Background and Aims: Nasal glucagon, the first and only nasally administered glucagon formulation, is a ready-to-use, drug-device combination therapy containing 3 mg glucagon dry powder. The aim of this study was to evaluate the chemical characterization (efficacious dosage delivery) and product performance (consistent dosage delivery to the nasal cavity) of nasal glucagon as a rescue medication for severe hypoglycemia.

Methods: Chemical purity and content, particle size, shot weight, actuation force, delivered dose, spray pattern and plume geometry testing were performed to assess whether critical quality attributes for a dry powder formulation product were satisfied for a consistent efficacious dosage delivery. Precise filling technology and strict humidity controls were implemented to overcome the complex powder-handling/filling challenges in the manufacturing process, with 100% weight check
verifications to ensure the precise amount of glucagon dry powder was contained within each device.

**Results:** The integrated control strategy implemented for nasal glucagon, detailed from in-process tests and controls to rigorous end-product testing, demonstrated that 100% of critical quality attributes were satisfied. Furthermore, shot weight and delivered dose testing demonstrated that >98%, on average, of glucagon dry powder was delivered to the nasal cavity. As predicted by nasal deposition modeling and particle size, spray pattern and plume geometry testing, a vast majority of the powder is expected to be deposited on the nasal mucosa.

**Conclusions:** The extensive chemical and physical characterization of nasal glucagon drug-device demonstrated in this study ensures a consistent efficacious glucagon dosage delivery to produce a meaningful blood glucose response for severe hypoglycemia rescue.

**P234 / #507**

**Topic:** AS08-New Medications for Treatment of Diabetes

**RATIO OF REDUCED AND OXIDIZED THIOL COMPOUNDS IN PATIENTS WITH T2DM AND WITH MICROANGIOPATHY OF LOWER EXTREMITIES AFTER N-ACETYLCYSTEINE THERAPY.

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**Background and Aims:** Vascular complications are the disability and mortality main cause in patients with type 2 diabetes mellitus (T2DM). The aim of this study was to assess the CysSH/CysSSCys and GSH/GSSG ratio change in patients with T2DM and microangiopathy of the lower extremities after N-acetylcysteine therapy.

**Methods:** 40 men with T2DM and microangiopathy of the lower extremities (the main group) and 30 healthy men (control group) were involved. Depending on the chosen treatment and the therapy, patients of main group were divided into 2 subgroups of 20 people. In the 1st subgroup, Sol.Octolipeni 600 mg, once a day, intravenously for 7 days was prescribed in complex therapy. In the 2nd subgroup, the introduction of Sol. N-acetylcysteine (NAC) in a daily dose of 600 mg, once a day, intravenously, for 7 days was additionally applied. High-performance liquid chromatography was determined.

**Results:** The value of the CysSH/CysSSCys ratio in the control group was 2.1 units, in main group it was only 0.7 units, relative to the control. In the control group, the GSH/GSSG coefficient was 20 units, in main group – 3.3 times less than the control values. When conducting therapy with the inclusion of NAC, more pronounced changes in the studied parameters were revealed compared to therapy with α-lipoic acid. Thus, the coefficients increased by 2.5 and 3.3, respectively. CysSH/CysSSCys becomes 1.8 ± 0.3 units, GSH/GSSG increases to 20 ± 0.3 units.

**Conclusions:** NAC contributes to an increase in the values of reduced cysteine and glutathione fractions at patients with T2DM and microangiopathy of the lower extremities.

**P235 / #508**

**Topic:** AS08-New Medications for Treatment of Diabetes

**SOME OXIDATIVE STRESS INDICATORS CHANGES IN TYPE 1 DIABETES MELLITUS PATIENTS AT THE PRECLINICAL STAGE OF DIABETIC NEPHROPATHY.

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**Background and Aims:** Diabetes mellitus (DM) is one of the most common socially significant nosology. At present, there is practically no information about changes in the parameters of cellular metabolism at the preclinical stages of diseases, in particular for type 1 diabetes mellitus (T1DM), which pathogenesis is closely associated with oxidative stress reactions. Aim: to study some oxidative stress indicators changes in men with T1DM at the diabetic nephropathy preclinical stage.

**Methods:** A survey of 28 men with T1DM with unsatisfactory glycemic control was carried out. The patients were divided into two groups - 14 people with normoalbuminuria (NAU) - and 14 people with a positive test for microalbuminuria (MAU). As a control, 28 practically healthy men of the same age were selected. Spectrophotometric and statistical methods were used.

**Results:** In patients with T1DM and NAU, the level of compounds with unsaturated double bonds (DB) (by 1.98 times), diene conjugates (DC) (by 2.34 times), ketodienes and conjugated trienes (KD and CT) (by 2.75 times), were significantly higher than in the control (p < 0.05). In patients with T1DM and MAU, an increase in DB (by 1.48 times), DC (by 2.09 times), KD and CT (by 2.25 times) relative to the control (p < 0.05) values also were noted. At the same time, the group with MAU differed from the NAU group by thiobarbituric acid reactants products higher values.

**Conclusions:** According to indicators of oxidative stress, TIDM patients require increased attention, regardless of the albuminuria level.

**P236 / #729**

**Topic:** AS08-New Medications for Treatment of Diabetes

**REAL WORLD EVIDENCE FOR THE GLYCOMETABOLIC DURABILITY OF SODIUM GLUCOSE COTRANSPORTER 2 INHIBITORS – FOUR YEAR INDIAN STUDY**

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**Background and Aims:** SGLT2 inhibitors are available in India for four years

**Methods:** We conducted a longitudinal cohort study using electronic health record data from Lina Diabetes Care Center (LDCC) SGLT2 registry database (n = 886) to evaluate the durability of the metabolic efficacy and safety for last four years. ANOVA was used for statistical analysis.
Results: We analysed the change in HbA1c, body weight and BP in patients with comorbidities and complications due to T2DM, in 554 patients, who had at least one annual follow up visit, 204 (36.8%), 211 (38%), 139 (25%) patients were on dapagliflozin, empagliflozin and canagliflozin, respectively. The trends for last one year favoured greater no of patients with mild to moderate renal insufficiency on canagliflozin (n = 23). Mean HbA1c at the baseline (9.0%) decreased to 7.6% at last follow up, (p < 0.0001). Mean Systolic BP reduced by 4.7 mmHg and Diastolic BP reduced by 2.2 mmHg. Body weight reduced by 2 kg (p = 0.88 NS). The discontinuation rate (14.8%) within first year of initiation was predominantly due to genitourinary infection. The persistence of efficacy was associated with adherence in patients with comorbidities.

Conclusions: Despite, numerous limitations, our study demonstrates the durable glycometabolic effects of SGLT2 inhibitors which were comparable to those observed in the controlled trials.

P237 / #748

Topic: AS08-New Medications for Treatment of Diabetes

INITIAL INSIGHTS TO THE GLYCEMIC METRICS AS REVEALED BY FREESTYLE LIBRE PRO CONTINUOUS GLUCOSE MONITORING (CGM) IN T2DM PATIENTS ON REMOGLIFLOZIN

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Background and Aims: Remogliflozin is a novel SGLT-2 inhibitor for the management of T2DM.

Methods: We evaluated 12 patients who were initiated on Remogliflozin as part of the standard care approach for the change in the glycemic metrics; Time in Range (TIR), Time Below Target (TBT), Time Above Target (TAT), through flash glucose monitoring. ANOVA was utilised for statistical analysis.

Results: The mean age, duration of diabetes, BMI, Systolic BP, Diastolic BP, initial HbA1c was 51 years (±8.1, minimum 35, maximum 64, 95% CI 46 to 56), 7.8 years (±2.4, minimum 1, maximum 25, 95% CI 2.4 to 13), 27 kg/m² (±3.6, minimum 22, maximum 32, 95% CI 25 to 29), 131 mmHg (±17, minimum 110, maximum 160, 95% CI 120 to 141), 83 mmHg (±10, minimum 70, maximum 100, 95% CI 76 to 89), 9.5% (±2.5, minimum 5.7, maximum 14.9, 95% CI 7.9 to 11), respectively. Two patients were already on insulin, one on lifestyle management and 11 on metformin. The difference across the 2 hourly groups was comparable (p = 0.89 NS); with mean glucose values range from 108 mg/dl (6–8 am) to 142 (4–6 pm). Mean TIR, TBT, TAT was 67% (±13), 10% (±14), 25% (±18)

Conclusions: The initial CGM results in real world setting indicate that Remogliflozin as a novel approach has the potential to achieve minimal diurnal glycemic excursions, across varied patient profiles. The study is limited with short duration and long term, large follow up would probably strengthen the evidence.

P238 / #797

Topic: AS08-New Medications for Treatment of Diabetes

EFFECT OF DAPAGLIFLOZIN ON BODY COMPOSITION IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: It is a well-known fact that dapagliflozin treatment can improve glycemic control in type 1 diabetes (T1D) population with a body mass index (BMI) of at least 27 kg/m². Nevertheless, the effect of dapagliflozin on body composition in this population, including changes in fat mass (FM) and hydration status, has not been examined. Therefore, we aimed to evaluate whether dapagliflozin improves body composition of T1D patients.

Methods: A prospective study was conducted including T1D patients who were prescribed dapagliflozin 5 mg daily for 3–6 months. Changes in body weight (BW), BMI, abdominal circumference and body composition (FM, skeletal muscle mass (SMM), visceral fat, and total body water (TBW)) by bioelectrical impedance were evaluated. Statistical differences between variables before and after treatment were analysed using the paired Student’s t-test with SPSS 19.0 statistics software.

Results: The present study analysed a total of 12 DM1 subjects – 4 men and 12 women – with a mean age of 47.8 ± 5.6 years. There was a significant reduction in BW, BMI, FM, SMM, visceral fat and TBW after dapagliflozin treatment, being remarkable the decrease in both FM and visceral fat. There was no correlation between the starting BW and loss of both FM and visceral fat; still, a correlation between starting BW and TBW was found. When analysed separately by gender, significant differences were only maintained in women.
CONCLUSIONS: Our data provide evidence that dapagliflozin led to a significant BW reduction, mainly due to a decrease in FM compared to the depletion in other body compartments.

P239 / #99
TOUSTAR: THE FIRST REUSABLE PEN FOR INSULIN GLARGINE 300 U/ML WITH DEDICATED REPLACEABLE CARTRIDGE TO BE LAUNCHED IN INDIA
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BACKGROUND AND AIM: To date insulin glargine 300 U/mL (Gla-300) has been available only in prefilled pens but in many countries including India cartridges and reusable pens are commonly used in clinical practice. The novel TouStar pen has been developed to address this unmet need and its key functionalities are presented here.

METHODS: TouStar is a reusable device, to be used in conjunction with Sanofi’s Toujeo® (Gla-300) 1.5mL cartridge.

RESULTS: Key functionalities of TouStar include: a dedicated replaceable cartridge with label, low injection force, dose selection range of up to 80U, the dose dial grip extension ±35mm, penalty-free dose correction, full dose delivery by holding of dose-dial grip for 5 seconds, three years in-use life of device, and mechanical last dose stop feature to prevent dialed dose from exceeding the remaining content. A unique joint interface between cartridge holder and pen body prevents users from using the other insulin cartridges.

CONCLUSIONS: These unique design features make TouStar pen the first reusable insulin pen with dedicated cartridge for Gla-300 that will be launched first in India to deliver appropriate dose of Toujeo® (Gla-300) eliminating the risk of mismatch of cartridge. Funding: Sanofi Acknowledgement: Medical writing support was provided by Tejal Vedak of Sقارона Medical Communications LLP and paid for by Sanofi. Editorial support was provided by Anahita Gouri and Rohan Mitra (Sanofi, India). Abstract submission support was provided by Rukhsar Wasta of Tata Consultancy Services Ltd, India and paid for by Sanofi. All authors participated in development and finalization of the abstract.

P240 / #386
DEVICE AND FEATURE UTILIZATION IN NEW INPEN(TM) SMART INSULIN PEN USERS WHO RECEIVED VIRTUAL SUPPORT
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BACKGROUND AND AIM: The InPen™ insulin pen is the first FDA-cleared smart insulin pen, a new category of insulin delivery technology approved for self-start. New users were offered virtual device setup support (to support appropriate configuration of app and integrated technologies) and personalized virtual onboarding support to review key features and benefits of use. The present study describes differences in adherence and app-based feature utilization between groups receiving different virtual support.

METHODS: InPen users of all ages were categorized into one of three groups based on the type of virtual support provided between April-August 2020: A. No support, unable to reach (N=4,911), B. Basic device setup support (N=995), and C. Onboarding support (N=264). Device adherence and app-based feature utilization were compared using ANOVA and chi-squared testing (p<0.05).

RESULTS: Users who received virtual support (both B and C) demonstrated higher device adherence after 4-weeks use when compared to no support (+3.9% vs. +6%, p<0.05). Onboarding support users (C) had a higher frequency of dose calculator use (+6.3%) and greater frequency of data report generation (+0.5 more reports per quarter) when compared to those who received no support (A). No difference between groups was observed for the frequency of primes, reminders set, percent days with basal doses logged or boluses per day.

CONCLUSIONS: Virtually onboarded users demonstrated more consistent and optimal InPen use. Future work should continue to explore self-start and onboarding methods to further optimize use of smart insulin pen features and describe their impact on glycemic outcomes.

P241 / #654
TECHNOSPHERE INSULIN REDUCED NOCTURNAL HYPOGLYCEMIA COMPARED TO INSULIN ASPART IN ADULT PATIENTS WITH T1D – STAT STUDY
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Background and Aims: Fear of overnight hypoglycemia remains a challenge for people with T1D. In an investigator-led, collaborative open-label pilot clinical study, subjects were randomized to receive inhaled Technosphere Insulin (TI) or insulin aspart. This post-hoc analysis reports time in hypoglycemia (<70mg/dL) during daytime (6am-12am) and nighttime (12am-6am) by treatment group.

Methods: Sixty patients with T1D on MDI were randomized in a multi-center study, stratified by A1c (≤8% or >8%) to the control arm using aspart (n=34) versus TI (n=26). Two TI patients discontinued from the study and 2 had inadequate CGM data for analysis. TI patients were instructed per protocol to take insulin doses before and at 1 and 2 hours after meals based on PPG values. Study group baseline characteristics were compared to the randomization group using a student t-test and CGM data were analyzed using ANOVA models.

Results: Baseline characteristics by randomization group (HbA1c, age, basal and bolus insulin doses, and FEV1) were similar. Nighttime percent time below target (<70 mg/dL) was 1.9%+-0.9 in the TI group (n=22) and 5.2%+-0.8 in the aspart group (n=34; p=0.0085). There was no significant difference in daytime percent time below target with 2.6%+-0.9 in the TI group (n=22) and 3.6%+-0.8 in the aspart group (n=34; p=0.4001).

Conclusions: Using TI versus aspart reduces nocturnal hypoglycemia. The ultra-rapid appearance and clearance of TI, which more closely mimics physiologic insulin compared to SQ insulin aspart, may contribute to this finding. Larger studies may be needed to better understand these results.

P243 / #726
DEMONSTRATION OF INSULIN CLEARANCE IN LESS THAN 12 DAYS USING NOVEL CONTINUOUS INTRAPERITONEAL INSULIN INFUSION (CIPII) IMPLANT SYSTEM WITH REGULAR INSULIN
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Background and Aims: Intrapertitoneal insulin delivery provides more rapid onset of action and shorter duration compared with subcutaneous insulin that is critical for improving management of diabetes. One challenge with continuous intraperitoneal insulin infusion (CIPII) pertains to insulin degradation due to heat exposure at body temperature. We present data on insulin clearance and residence time in a novel implant system for CIPII using an Insulin Delivery Conduit (IDC) made up of a subcutaneous port and catheter accessed by a modified external pump infusion set in an ex-vivo environment that mimics the intraperitoneal space. Aim: This study aims to determine insulin clearance and residence time in the IDC system at body temperature.

Methods: The port and catheter are filled with a colored solution and then flushed until the color disappears using a Medtronic insulin pump at a basal rate of 0.6U/hr and three daily 5-unit boluses. The flushed solution was collected and the absorbance was measured using a Beckman UV-Vis spectrophotometer. The absorbance of the solution was compared to reference blanks for the original colored solution and the clear solution pumped through the system. Absorbance versus time was plotted to determine how long insulin stays in the IDC before infusion into the intraperitoneal space.
**Results:** Studies show that insulin maintains chemical stability up to 14 days at body temperature. The insulin residence time in the IDC is less than 12 days confirming minimal risk of insulin degradation due to heat exposure.

**Conclusions:** The implantable IDC for CIPII is a promising method to deliver insulin without insulin degradation.

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**P244 / #148**

**Topic:** AS10-Devices Focused on Diabetic Preventions

**CHIC-D - CARDIOVASCULAR HEALTH IN CHILDREN WITH TYPE 1 DIABETES – EARLY DETECTION, CARDIOVASCULAR PREVENTION AND TREATMENT MONITORING**

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**Background and Aims:** CHIC-D is an ongoing project that aims to determine the time course of vascular changes in children with T1D and the impact of metabolic control and blood pressure on changes in the different layers of the arterial wall. Our objective is to establish a novel, highly sensitive, clinically applicable method of cardiovascular risk evaluation and treatment monitoring for paediatric patients with T1D.

**Methods:** Children (6–15,99yr) with T1D duration of ≥5 years were randomly selected from the pediatric diabetes registry SWEDIABKIDS. For assessment of vascular health we use ultra-high frequency ultrasound, enabling visualization of the three layered arterial wall combined with measurements of vascular elasticity, endothelial function and 24h blood pressure. Data have been collected from 36 children with T1D and 23 healthy controls so far.

**Results:** Preliminary results show a tendency towards increased intima-thickness (IT) in the radial artery among the children with T1D as compared to healthy controls (p=0.09). A negative correlation between calculated GFR and radial intima-media thickness (IMT) (-0.36 p=0.03) and aortic pulse wave velocity (PWV) (-0.50 p=0.002) was also found. There were no difference in systolic and diastolic blood pressure z-score.

**Conclusions:** Increased radial IT in this well treated cohort of children with T1D (HbA1c 48.6±2.6mmol/mol) may be an important marker for early vascular damage. The correlation between GFR and radial IMT respectively PWV indicates a connection between micro-and macro vascular impact. Modifiable factors are yet to be discovered. Using our sensitive methods different treatment strategies may be tested in the future.

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**P245 / #212**

**Topic:** AS10-Devices Focused on Diabetic Preventions

**A RANDOMIZED PILOT TRIAL: USING AN ACTIVITY TRACKER TO INCREASE MOTIVATION FOR PHYSICAL ACTIVITY IN PATIENTS WITH TYPE 2 DIABETES IN PRIMARY CARE**

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**Background and Aims:** This study aimed to evaluate the impact of an activity tracker (Fitbit Charge HR) on physical activity (PA) and cardiometabolic measurements in people with type 2 diabetes (T2D) and to assess the feasibility of the implantation in primary care.

**Methods:** This 3-month study consisted in a pilot randomized controlled trial of 30 T2D patients. Patients were randomly assigned to: 1) control group, including a PA promotion intervention supported by a kinesiologist or 2) intervention group, including the addition of an activity tracker. Cardiometabolic measurements, PA, PA motivation and satisfaction and acceptability of activity tracker were documented.

**Results:** High-density lipoprotein cholesterol significantly increased in the intervention group and decreased in the control group (p<0.05). Systolic and diastolic blood pressure significantly decreased in both groups (p<0.05). Glycated hemoglobin tend to decrease in both groups but was not significant (p=0.08). PA significantly increased in both groups, especially in the intervention group (p<0.05). The intervention group had a significantly higher step number at baseline (p<0.05). The autonomous motivation in both groups was significantly higher than the controlled motivation (p<0.01). 86% of the participants in the intervention group were satisfied of the activity tracker and the compliance remained high.

**Conclusions:** The use of an activity tracker improves cardiometabolic variables in patients with T2D. Also, an activity tracker is a good motivation tool to increase PA and its implantation is feasible in primary care.

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P246 / #436
Topic: AS10-Devices Focused on Diabetic Preventions

PREVALENCE AND PRINCIPAL DETERMINANTS OF DIABETIC POLYNEUROPATHY IN TYPE 1 DIABETES AS MEASURED BY A PORTABLE POINT-OF-CARE SURAL NERVE CONDUCTION DEVICE IN TYPE 1 DIABETES

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Background and Aims: The diagnosis of diabetic polyneuropathy (DPN) using electrophysiological tests is hindered by a limited access to specialized laboratories. We evaluated the prevalence of DPN in a cohort of type 1 diabetes (T1DM) patients as measured by a portable point-of-care sural nerve conduction (SNC) study device (DPN-Check).

Methods: Cross-sectional study in 194 patients with T1DM whose SNC were measured by the DPN-Check. Multiple regression analyses were conducted to address the associations of SNC velocity and amplitude with clinical parameters.

Results: Only 23 out of 194 patients (12%) presented symptoms by Diabetic Neuropathy Symptom Score. However, 76 patients were diagnosed by the DPN-heck resulting in an overall DPN prevalence of 39% (95%CI 33.46). These patients had worse metabolic control compared to their counterparts without DPN (A1c: 7.3 ± 1.0 vs 7.0 ± 0.9%, P = 0.046, respectively). DPN was categorized as mild in 55 (29%) cases, in 20 (10%) cases as moderate, and severe in only one subject. Both SNC velocity and amplitude were inversely associated with age, and A1c levels. SNC velocity was inversely associated with evolution of diabetes. Multiple regression analyses (R^2: 0.154, P < 0.001) revealed that age (β = -0.254 [-0.266; -0.073]) and A1c (β = -0.241 [-0.302; -0.892]) were the main determinants of the reduction in SNC velocity. Age (β = -0.216 [-0.176; -0.033]) and A1c (β = -0.214 [-0.276; -0.454]) were also the main determinants of SNC amplitude (R^2: 0.082, P = 0.002).

Conclusions: DPN-Check may be useful as a screening tool to identify asymptomatic DPN at the clinical setting. Sural nerve functions were associated with age and glycemic control in patients with T1DM.

P247 / #510
Topic: AS10-Devices Focused on Diabetic Preventions

FEASIBILITY OF USING CONTINUOUS GLUCOSE MONITORING WITHIN THE ARA.MED.330 DIABETES PROTOCOL WHICH LICENSES INSULIN-TREATED PILOTS TO FLY COMMERCIAL AIRCRAFT: A PRELIMINARY ASSESSMENT


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Background and Aims: The UK, Ireland and Austria currently certify pilots with insulin-treated diabetes to fly commercial aircraft with strict oversight using a validated protocol that requires finger-stick capillary blood glucose monitoring while on duty and frequent clinical review. This preliminary study assessed the use of continuous glucose monitoring (CGM) and compared it to self-monitoring blood glucose (SMBG) while flying within the European Aviation Safety Agency (EASA) ARA.MED.330 diabetes protocol.

Methods: This prospective observational study enrolled pilots requiring insulin replacement therapy, who hold an EU Class 1 medical certificate and were participating in the ARA.MED.330 diabetes protocol and flying. SMBG measurements were recorded during pre-flight and in-flight periods and compared to simultaneously recorded interstitial glucose measurements using CGM with the Dexcom G6®. The study had to be terminated prematurly because of the coronavirus pandemic. Results collected to date have been analysed.

Results: Eight male pilots, seven with type 1 diabetes and one with type 3c diabetes, median age 48.5 years (range 33–60) and median diabetes duration of 11.5 years (range 2.3–25) participated. A total of 874 self-monitored blood glucose levels were compared to values from CGM (Dexcom G6®) during pre-flight and in-flight periods within the EASA protocol. The mean glucose value recorded with SMBG was 8.78mmol/l (SD 0.67) and 8.71mmol/l (SD 0.85) by CGM. The Mean Absolute Relative Difference (MARD) between methods was 9.39.

Conclusions: This preliminary study demonstrates the feasibility of using CGM with Dexcom G6® while flying within the ARA.MED.330 protocol that allows insulin-treated pilots to fly commercial aircraft.

P248 / #602
Topic: AS10-Devices Focused on Diabetic Preventions

FOOD RECOGNITION IN ASSESSING THE MEDITERRANEAN DIET: A HIERARCHICAL APPROACH

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Background and Aims: The Mediterranean diet (MD) is a dietary pattern that can lower the risk of non-communicable diseases, including diabetes. The MD Adherence (MDA) index...
Background and Aims: The aim was to find out association of glucovariability with metabolic parameters and retinopathy (DR).

Methods: In patients with type 1 diabetes and LADA, time in range (TIR), presence of DR, HbA1c, albumin/creatinine ratio (ACR), glomerular filtration and lipids were determined. According to consensus TIR was define as the percentage of time spent within glucose range 3.9-10.0mmol/L. We also defined TIR1 as range 3.9 – 7.8mmol/L. The difference in variables were tested according to TIR quartiles (Q): Q1<56; Q2 56<TIR<64.5; Q3 64.5<TIR<78; Q4 78<TIR. and TIR1 Q: < = 35; Q2 35<TIR1<45; Q3 45<TIR1<57; Q4 57<TIR1 using two factor (TIRQ or TIR1Q and DR) ANOVA with interaction (TIRQ*DR or TIR1Q*DR). If the effect was shown to be statistically significant, the post hoc Tukey-Kramer test determined who made the difference. Correlation between continuous variables were tested using Pearson correlation coefficient. z = 0.05 was considered statistically significant.

Results: TIR and TIR 1 correlated significantly with HbA1c (r = -0.50, r = -0.69), TIR1 with ACR (r = -0.29). Significant difference was determined for HbA1c among quartiles (decreasing) of TIR and TIR1; for TG among quartiles of TIR and TIR1, DR and interaction; and for ACR among quartiles of TIR1. The TG level increased with increase in TIR and TIR1, both significantly in 4th Q in comparison with others. Increase in triglycerides level accompanied the presence of DR. TG behaviour differently related to TIR and DR (TIRQ*DR, p < 0.01).

Conclusions: Although glucovariability is related to development of diabetes complication, it seems that TG level is more important for development of DR.

**P250 / #307**

**Topic:** AS11-Advanced Medical Technologies to Be Used in Hospitals

**DESCRIPTION OF THE GLYCEMIC CONTROL METRICS EVALUATED BY GLUCOSE MONITORING IN A COHORT OF ADULT PATIENTS HOSPITALIZED WITH HYPERGLYCEMIA AND DIAGNOSIS OF COVID 19


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Background and Aims: Recently, high doses of dexamethasone have been included as part of the treatment of COVID-19 infection that increases glucose levels >180 mg/dL. Hyperglycemia has become one of the main predictors of adverse outcomes in SARS-CoV2 infection. We aim to describe glucose control metrics measured with continuous glucose monitoring (CGM) in patients with hyperglycemia and COVID-19 and its association with adverse outcomes.

Methods: A prospective cohort study. Patients with diabetes and/or hyperglycemia and SARS-CoV2 infection were included. Baseline A1c, PaO2/FIO2, lymphopenia, LDH, C-Reactive Protein were recorded. The time in range between 70-180mg/dL (%TIR), time above range(%TAR) >180mg/dL, time below range(%TBR) <70mg/dL and coefficient of variation(%CV) were measured using Flash glucose monitoring. The association between CGM data and a composed outcome including death, acute respiratory distress syndrome or acute renal failure were analyzed.

Results: 61 patients were included. Mean age was 60.2±14.1 y/o, 48.3% had diabetes, 58.9% had A1c >7%. Almost 30% had at least one severity marker for COVID-19 infection. Half of the participants received dexamethasone and all patients were treated with basal-bolus insulin according hospital guidelines. During follow-up, 22 patients had the composite outcome.
P251 / #430

Topic: AS11-Advanced Medical Technologies to Be Used in Hospitals

COMPARISON OF CLINICOBIOCHEMICAL RISK SCORES AND CONTROLLED ATTENUATION PARAMETER VERSUS ULTRASOUND FOR STEATOSIS DETECTION IN SUBJECTS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Data are limited concerning the value of clinicobiochemical scores to diagnose NAFLD in type 1 diabetes (T1D). We evaluated the effectiveness of controlled attenuation parameter (CAP), Hepatic Steatosis Index (HSI) and Fatty Liver Index (FLI) compared to ultrasound (US) as reference method in 407 T1D subjects.

Methods: Subjects were screened for NAFLD using US, CAP ≥215 dB/m (M-probe) or ≥250 dB/m (XL-probe), FLI ≥60 and HSI ≥26. We subtracted 2 points from each HSI score to correct for the weight of prevalent diabetes.

Results: NAFLD prevalence was 20.4% (US), 52.1% (CAP), 43.8% (HSI) and 18.3% (FLI). HSI and FLI correlated strongly (r: 0.724, p < 0.001), FLI and CAP (r: 0.578, p < 0.005) and HSI and CAP (r: 0.400, p < 0.001) correlated moderately and US and CAP correlated weakly (r: 0.290, p < 0.001). FLI and HSI (k: 0.395, p < 0.001), HSI and CAP (k: 0.246, p < 0.001) and US and CAP (k: 0.228, p < 0.001) agreed fairly, while FLI and CAP showed slight agreement (kappa: 0.177, p < 0.001). Sensitivity of CAP versus US was 81%, specificity: 55%, PPV: 92%, AUROC_CAP yielded 0.77[0.71-0.82], p < 0.001. Sensitivity of FLI was 52%, specificity: 90%, PPV: 58%, NPV: 88%. AUROC_FLI yielded 0.79[0.73-0.85], p < 0.001. Sensitivity of HSI was 76%, specificity: 64%, PPV: 35%, NPV: 92%. AUROC_HSI yielded 0.74[0.68-0.80], p < 0.001. All correlated moderately with the metabolic syndrome (r_HSI: 0.433, p < 0.001, r_CAP: 0.135, p < 0.001), except FLI, which correlated more strongly (r_FLI: 0.568, p < 0.001). In logistic regression analysis, adjusting for age, gender, systolic and diastolic blood pressure, HDL-c and triglycerides, FLI (OR: 1.04[1.03-1.06], p < 0.001), CAP (OR: 1.02[1.01-1.02], p < 0.001) and HSI (OR: 1.17[1.11-1.24], p < 0.001) were associated with US-determined NAFLD.

Conclusions: NAFLD seems prevalent in T1D. Clinicobiochemical scores and CAP show moderate accuracy compared to US to determine NAFLD and moderate agreement stressing the need for more specific diagnostics in T1D.

P253 / #597

Topic: AS11-Advanced Medical Technologies to Be Used in Hospitals

HYPERTENSION AND DIABETES, A DANGEROUS COMBINATION: LET US IMPROVE THE TECHNOLOGY IN THE TREATMENT OF HIGH BLOOD PRESSURE (RR)!

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Background and Aims: The coincidence of diabetes and hypertension is frequent and increases the incidence of complications dramatically. Many patients with hypertension still have unsatisfying RR values, despite a great number of highly efficient RR medications. This is, in part, a consequence of the lack of a device which allows patients to monitor their RR value regularly from day to day.
Methods: We have developed a new method to address this problem: In contrast to many existing approaches favoring intricate optical plethysmography, we measure the pressure directly with a sleeve. Pressure is recorded while the tissue of the arm is precluded from expanding during systole. In order to achieve this, a non-extensible band is placed around the arm, and a highly sensitive textile based pressure sensor system is located between this band and the tissue. This sleeve system can be worn comfortably.

Results: In changing RR, induced by exercise, we repeatedly observed a correlation ($r > 0.8$) compared to conventional office RR measurement. Using a Finapres Instrument recording every systole, we observed a correlation between our system and the systolic RR of $r > 0.95$ during tilt table testing.

Conclusions: In our new approach, the patient wears a well-tolerable sleeve around the arm which gives values of the systolic RR. The resulting data can be transmitted to a smartphone or other mobile device, and to a physician’s office for remote patient monitoring. We believe that the use of this device can improve RR values in many individuals and therefore reduce complications of hypertension and diabetes.

P254 / #206
Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes
RELATIONSHIPS BETWEEN THE ENDOCAN-1 LEVEL, INSULIN RESISTANCE INDICATORS, AND INTIMA MEDIA THICKNESS IN PATIENTS WITH PREDIABETES

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Background and Aims: To study the relationship between the endothelial dysfunction (ED) marker – Endocan-1, Intima media thickness (IMT) and insulin resistance (IR) indicators in patients with prediabetes.

Methods: An observational cross-sectional study was conducted, including 140 people, aged 18 to 65 years. Ultrasound measured IMT right and left common carotid artery (CCA), value > than 0.9 mm was considered as an atherosclerosis. Patients were divided into 2 groups: Group 1 (n = 60)- patients with prediabetes, Group 2 (n = 80) - patients without prediabetes and with risk factors CVD.

Results: Significant differences the Endocan-1 level were found between group 1 (Mean±SD: 1683.18±421.1 pg/ml) and group 2 (635.79±119.1 pg/ml; $p = 0.01$). Also differences were found in IMT with higher values in Group 1, as follows: right CCA IMT - 0.85±0.18 mm, left CCA IMT 0.96±0.20 mm, $p ≤ 0.001$ as compared to Group 2. Correlation analysis found relationships between Endocan-1, the right CCA IMT ($r = 0.6; p = 0.01$), the left CCA IMT ($r = 0.83; p ≤ 0.001$), and also with presence of atherosclerosis ($r = 0.81; p = 0.01$). These findings indicate that in patients with prediabetes the elevation of the Endocan-1 level is associated with CCA IMT increase. Moreover, an elevation of Endocan-1 level has impact on the development of subclinical atherosclerosis in these patients. Endocan-1 showed significant correlation with insulin ($r = 0.25; p = 0.03$), IR-HOMA index ($r = 0.32; p ≤ 0.001$), C-peptide ($r = 0.22; p = 0.001$), fasting glucose ($r = 0.23; p ≤ 0.001$). Regression analysis found that an increase of IMT significantly affected by HbA1c 3.4 fold, Endocan-1 by 2.7 fold in patients with prediabetes ($p ≤ 0.01$).

Conclusions: We found a significant relationship between the ED biomarker Endocan-1 with IMT and IR in patients with prediabetes. We suggest that rising of IR leads to Endocan-1 elevation, IMT and thereby to increase ED and cardiovascular risk in these patients.

P255 / #223
Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes
INFLUENCE OF METABOLIC PARAMETERS ON LDL AND HDL SIZE AND SUBCLASSES IN ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: Alterations in serum of low-density lipoprotein (LDL) and high-density lipoprotein (HDL) size and subclasses contribute to the atherogenesis in coronary artery disease in diabetic patients. We evaluated the effect of metabolic parameters on LDL and HDL size and subclasses in adolescents with DM type 1 using continuous subcutaneous insulin infusion (CSII) or multiple daily insulin injections (MDI).

Methods: Cross-section study included 43 adolescents (23 females, 20 males) with type 1 diabetes of mean age 15.09±1.94 years, with mean disease duration of 5.86±3.08 years. 9 patients were on therapy with CSII and 32 on MDI.

Results: Patients with inadequate metabolic control (HbA1c > 7.5%) had higher mean value of triglycerides (TG) ($p = 0.01$), higher proportions of small, dense LDL particles ($p = 0.045$), higher proportions of LDL IIA subclasses ($p = 0.03$) and smaller LDL diameter ($p = 0.02$) and HDL diameter ($p = 0.04$) than patients with optimal metabolic control (HbA1c < 7.5%). Higher HbA1c and higher TG levels were statistically significantly related to small, dense LDL ($p = 0.341$, $p = 0.025$; $p = 0.394$, $p = 0.009$) and HDL particles ($p = 0.684$, $p = 0.000$; $p = 0.421$, $p = 0.005$). Predictors of small, dense LDL and HDL particles, which contribute to the atherogenesis, were high HbA1c and elevated TG. There was no statistically significant difference in lipid subclasses between patients using CSII or MDI.

Conclusions: Diabetic adolescents require particular attention in order to minimize the factors such as high HbA1c and elevated TG in the development of future cardiovascular events.

P257 / #623
Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes
NOVEL BREATH ACETONE SENSOR BASED ON 1D/2D NANOCOMPOSITE FOR DIABETES PREVENTION AND MONITORING

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Background and Aims: Diabetes, as one leading disease to cause death in the United States, can result in a number of serious medical complications. To avoid these complications, blood sugar control is critical. Currently, reliable diagnosing methods are mainly based on blood glucose tests. These tests are accurate but expensive, inconvenient and invasive. Commercialized glucose meters or kits for daily glucose tracking are much smaller by using tiny lancet, they are still based on blood test. These devices are uncomfortable and invasive with risk of infection. Also, studies reveal that overweight or obesity closely ties to type 2 diabetes. Even small amounts of weight loss can reduce the development of diabetes by 40% to 60%. These motivate us to develop an effective device as for early-stage diabetes diagnosis, glucose and weight loss monitoring with features of non-invasiveness, convenience, low cost, high accuracy, and ease of operation.

Methods: Breath acetone has been studied to have a strong correlation with the concentration of blood glucose and body fat burning. Measurement of breath acetone can be not only a non-invasive “glucose meter” for diabetes treatment but also a smart “weight scale” to monitor fat loss for diabetes prevention. A novel sensor using a newly synthesized nanocomposite, KWO (K2WO4) nanorods/Ti3C2 nanosheets, has been recently developed to detect exhaled acetone.

Results: The results indicate this new sensor having excellent sensing response to acetone with good tolerance of humidity interference, and enhanced sensing stability.

Conclusions: The new KWO/Ti3C2 nanocomposite can be an excellent sensing material for breath acetone detection selectively and sensitively.

P258 / #765

Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes

PROFILING OF SLEEP MODELS BASED ON VOLUNTARY AND INVOLUNTARY SLEEP IN ADULTS WITH TYPE 2 DIABETES

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Background and Aims: The purpose of this study was establishing and profiling sleep models from the concept of voluntary sleep (V) and involuntary sleep (IV) in adults with type 2 diabetes.

Methods: Participants was 50 adults with type 2 diabetes, and their 595 days’ sleep. They finished self-monitoring using Omron sleep sensor (HSL-101; Omron, Kyoto, Japan) and Pittsburgh Sleep Quality Index (PSQI). 13 elements of sleep were measured and operationally defined V or IV.

Results: According to principal component analysis, V had two principal components “V1: sleep self-determination” and “V2: conscious sleep quantity”. IV had two principal components “IV1: continuous deep sleep” and “IV2: actual sleep quantity”. K-means cluster analysis was performed using five indicators including PSQI. Cluster 1 had good V and IV, and named “CL1: sleep sufficient model”. Cluster 2 had poor V2 and IV2, and named “CL2: poor sleep quantity model”. Cluster 3 had poor PSQI, V1 and IV1, and named “CL3: insufficient sleep quality model”. Multiple comparisons showed that CL1 had good HbA1c, high age, and low BMI, and CL3 had high HbA1c, young age, and high BMI. As a result of binomial logistic regression analysis, HbA1c between CL1-CL3 was OR = 2.047 (95% CI: 1.039-4.032), age was OR = 0.862 (0.765-0.973), and BMI was OR = 1.363 (1.028-1.806).

Conclusions: Characteristic associations with diabetes control was found between sleep models based on voluntary and involuntary sleep. It is expected that sleep model individualization and group formation will promote understanding of control status in adults with type 2 diabetes.

P259 / #788

Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes

REPLACEMENT OF THE SURROGATE METRIC – HBA1C BY METABOLIC INDEX SWITCHES THE THERAPY OF T2DM FROM SYMPTOMATIC TO DISEASE MODIFYING

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Background and Aims: Shifting treatment objectives from glycemic parameters (HbA1C) to energy balance restoration (BMI reduction) leads to impressive and fast improvement of diabetes control. There is a strong need for novel ways to measure T2DM treatment quality, to help predict CV risk and prevent patient’s overtreatment. BMI strongly predicts overall mortality, while progressive excess mortality above 25 kg/m² is mainly due to vascular disease. Our newly developed parameter, based on a combination of HbA1c, a patient’s anthropometrical and energy status (BMI). We named this new parameter “MI” - Metabolic Index. MI can be issued as follows:

\[ MI = (BMI)^{1.5} \times (HbA1C) \]

Methods: 54 uncontrolled T2DM patients, treated with Insulin were brought about metabolic recovery through weight loss.

Results: BMI had reduced from 35.1 ± 4.8 to 32.8 ± 5.0 (p < 0.001), insulin requirements decreased concomitantly by 50% and HbA1C reduced from 9.3 ± 1.4 to 8.5 ± 1.4 %, (p < 0.001). Thirteen patients (24%) switched from multiple to single insulin injection per day, 7 patients (13%) stopped insulin completely. Patients were divided into two groups: A (successful) and B (unsuccessful) reduction of weight and insulin requirements. AMI was maximal in group A (-486.6 ± 436.7), compared to Group B (-159.9 ± 83.2), p = 0.005. Although both groups had similar baseline MI levels and eventually achieved the same HbA1C levels, patients of group A became leaner and metabolically healthier.

Conclusions: Changes in Metabolic Index (MI) rather than surrogate glycemic parameters (HbA1C) are better reflectors of
successful T2DM therapy and may be advised to substitute HbA1C in clinical practice.

**Background and Aims:** Fasting during Ramadan is one of the five pillars of Islamic practice. Risks associated with fasting should be considered. It is advisable to forgo fasting in diabetic patients, however an individual’s decision should be respected.

**Methods:** Retrospective cohort study identified diabetic patients attending this London hospital during Ramadan who had received structured education regarding their diabetes management within 3 months prior. Demographic data was obtained including type of diabetes mellitus, gender, ethnicity, socioeconomic status and religion. Outcomes assessed were if a clinical diabetic review had occurred 3 months prior to Ramadan and the delivery of a structured education programme within 2 months prior to Ramadan.

**Results:** In total, 30 diabetic patients engaged with hospital services; 25 with type 2 diabetes and 5 with type 1 diabetes. 18 patients were male and 12 females. 6 patients were Muslim with only 2 fasting. 1 patient had HHS, 1 patient had acute hyperglycaemia and 1 patient had hypoglycaemia.

**Conclusions:** An individual’s decision to fast during Ramadan factors in personal choice, religious practice and medical opinions. Diabetic patients who choose to fast during Ramadan may experience acute, diabetes-related complications namely; hypoglycaemia, DKA, hyperglycaemia, HHS, dehydration and increased risk of thromboembolism. Structured education and counselling within 3 months prior to Ramadan should be offered. Many Muslim diabetic patients participate in fasting during Ramadan and our role as healthcare providers is necessary for support and guidance. RADAR study aims to identify solutions by advocating early discussion and education with diabetic patients prior to Ramadan.

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P64 / #247

Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

CGMS AND CSII BENEFITS IN KIDNEY TRANSPLANT RECIPIENTS DURING AND AFTER THE INTERVENTION

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Background and Aims: Poor metabolic control and long evolution of T1DM frequently lead to Chronic Kidney Disease. Best survival in end stage kidney disease was achieved after renal transplantation. Glucose control is challenging with immunosuppression and altered renal function. We aim to prove that a good glycemic control can be achieved using CGMS and CSII and it may improve evolution during and after transplant intervention and limit early complications.

Methods: We included 28 T1DM patients hospitalized in a tertiary transplant clinic, evaluated before surgery, 2 weeks, 3 months and 6 months after kidney transplantation. Mean age 42 ± 7.9 years, mean diabetes duration 22 ± 8.6 years. We divided them into 3 groups: first using technology (CGMS with or without CSII) before surgery, the second using technology right after surgery and the third group using MDI and SMBG.

Results: Patients using technology (group 1 and 2) had statistically significant better outcomes regarding glycemic control, renal function and fewer complications compared with those not using technology. When comparing the first two groups we found significant better outcomes in short term control in the first group and there was no significant difference in 6 months complications.

Conclusions: Technology usage as early as possible in T1DM with ESRD on transplant program has good outcomes and low rates of complications. Improved glycemic control and better clinical diabetic review had occurred 3 months prior to Ramadan and the delivery of a structured education programme within 2 months prior.

Results: In total, 30 diabetic patients engaged with hospital services; 25 with type 2 diabetes and 5 with type 1 diabetes. 18 patients were male and 12 females. 6 patients were Muslim with only 1 currently fasting. None of the patients had been offered counselling or education prior to Ramadan.

Conclusions: Discussion and Conclusions: Diabetic patients who choose to fast during Ramadan may experience acute, diabetes-related complications namely; hypoglycaemia, diabetic ketoacidosis, hyperglycaemia, hyperosmolar hyperglycaemic syndrome, dehydration and increased risk of thromboembolism. To minimise these risks, structured education and counselling within 3 months prior to Ramadan should be offered to diabetic Muslims who wish to fast.

P263 / #124

Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

RAMADAN AND DIABETES ADMISSION RATE (RADAR) STUDY: ARE WE GIVING ENOUGH SUPPORT TO OUR PATIENTS?

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Background and Aims: Fasting during Ramadan is one of the five pillars of Islamic practice. With the increased prevalence of diabetes mellitus within Asian-Muslim communities, risks associated with fasting should be considered. It is advisable to forgo fasting in diabetic patients, however, an individual’s decision should be respected. With appropriate counselling and education, as clinicians, we can provide support during Ramadan.

Aims and Objectives: This study aims to identify solutions by advocating early discussion and education with patients prior to Ramadan.

Methods: This retrospective cohort study identified diabetic patients attending this London hospital during Ramadan who had received structured education regarding their diabetes management within 3 months prior. Demographic data were obtained including the type of diabetes mellitus, gender, ethnicity, socioeconomic status and religion. Outcomes assessed were if a respective glucose measurements after dinner consumption and at bedtime may predict the risk of hypoglycaemia in patients with type 2 diabetes treated with Glargine300 for basal insulin therapy.

Respectively) and areas under the receiver-operating characteristic curves (AUCs) of the ‘Glucose levels B – Glucose levels A’ for the TBR <70<4%. During daytime, the difference between glucose levels at 8:20 PM and 11:20 PM had the largest AUC for the TBR <70<4% (AUC: 0.81, optimal cutoff value: -63, sensitivity OC: 0.72, specificity OC: 0.82) (Figure).

Conclusions: Blood glucose measurements after dinner consumption and at bedtime may predict the risk of hypoglycaemia in patients with type 2 diabetes treated with Glargine300 for basal insulin therapy.
outcomes mean a less money expense for the national insurance. CGMS and CSII should be recommended in guidelines to all T1DM patients before intervention.

P265 / #259

Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

MULTI-CENTER REMOTE GLUCOSE MONITORING AT COVID-19 INTENSIVE CARE UNITS. CASE REPORT IN ARGENTINA

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Background and Aims: This work analyzes the feasibility and relevance of remote and on-line glucose monitoring in both Intensive Care Units (ICU) and quarantined ambulatory patients using an own platform originally developed by the group to continue with artificial pancreas clinical trials [1].

Methods: The monitoring platform was developed from open-source resources and is available on-line (www.insumate.com.ar), it runs on an own server and can manage up to 40 simultaneous patients in each health center. Furthermore, it allows using different CGMs and is completely configurable in a remote way. The first four cases using the platform at COVID-19 ICU in Argentina are reported. Four critical patients have been monitored using Dexcom G6, two children and two adults, together with an ambulatory patient using FreeStyle Libre to test the platform versatility and long-term performance.

Results: Fig. 1 presents the ICU monitored cases and their outcomes. The collected data indicates that the use of this new platform aids healthcare personnel lower the users mean BG (blood glucose) levels while diminishing their exposure. All ICU patients have recovered or have been metabolically controlled by the date of the submission of this abstract. The ambulatory patient completed 198 days of remote monitoring without any adverse event (received samples: 96.37%).

Conclusions: An adequate glycemic control and a favorable clinical evolution were observed in all patients. Also, a great acceptance and adherence of ICU healthcare personnel has been found. [1] R. Sánchez-Peña, P. Colmenga, F. Garelli, et al.: Artificial Pancreas: Clinical Study in Latin America... . JDST, vol. 12, 914–925, 2018.

P266 / #269

Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

MEASUREMENT OF C-PEPTIDE AT DIAGNOSIS INFORMS GLYCEMIC CONTROL BUT NOT HYPOGLYCEMIC RISK IN TYPE 1 DIABETES

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Background and Aims: Using continuous glucose monitoring (CGM) data from a study of newly diagnosed adults with type 1 diabetes, we aimed to explore if variation in C-peptide close to diagnosis influenced glycaemic variability and risk of hypoglycaemia.

Methods: We studied newly diagnosed adults with type 1 diabetes who wore a Dexcom G4 CGM as part the EXTOD study. We examined the relationship between peak stimulated C-peptide in a mixed meal tolerance test and glycaemic metrics of variability and hypoglycaemia for 36 CGM traces from 23 participants.

Results: Higher levels of C-peptide associated with lower glycaemic variability, more time in range and less hyperglycaemia. For every 100 pmol/L increase in peak C-peptide, percentage time spent in the range 3.9-10 mmol/L was increased by 2.39% [95% CI: 0.51,4.26], p = 0.012) with a reduction in time spent in level 1 hyperglycaemia (>10 mmol/L) and level 2 hypoglycaemia (>13.9 mmol/L) glucose levels by 2.64% [95% CI:-4.87, -0.41, p = 0.018) and 1.33% [95% CI: -2.66, -0.0057], p = 0.041) respectively. Glucose levels were on average lower by 0.19 mmol/L ([95 % CI: -0.39,0.015], p = 0.06) and standard deviation reduced by 0.14 [95% CI: -0.25, -0.023], p = 0.017) for every 100 pmol/L increase in peak C-peptide. Hypoglycaemia was not common in this group and no association was observed between time spent in hypoglycaemia (p = 0.967) or
hypoglycemic risk (p = 0.721). There was no association between peak C-peptide and insulin dose (p = 0.707), HbA1C (p = 0.364) or insulin dose adjusted HbA1c (IDAA1c, p = 0.452).

Conclusions: C-peptide associates with time spent in normal glucose range and with less hyperglycaemia, but not risk of hypoglycaemia in newly diagnosed people with type 1 diabetes.

P267 / #288
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

DOES THE USE OF TECHNOLOGY IMPROVE GLYCOSYLATED HAEMOGLOBIN LEVELS IN CHILDREN WITH TYPE 1 DIABETES MELLITUS (T1DM)?

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Background and Aims: The 2017/18 National Paediatric Diabetes Audit (UK) reported that on average, insulin pump users with continuous glucose monitors achieved lower HbA1cs. This study involves children and young people (CYP) with T1DM (age <19 years) attending a tertiary UK hospital. The aim was to compare HbA1c outcomes by grouping patients according to their insulin regimens and glucose monitoring devices.

Methods: This was a retrospective observational study based on our hospital diabetes database. Inclusion criteria were T1DM patients on multiple dose insulin (MDI) or continuous subcutaneous insulin infusion (CSII) regimens. 405 patients were categorised by their insulin regimen and type of glucose monitoring device which included manual checks, Dexcom G6, Libre Flash, Low Glucose Suspend (LGS) and Closed Loop Systems (CLS). The median HbA1c was calculated for each group.

Results: Of 405 patients, 187 (46%) used CSII and 218 (54%) MDI regimens.

The lowest median HbA1c was in the CSII group using a closed loop system, while those on MDI struggled with higher HbA1cs.

Conclusions: As per the published studies, this work supports that a closed loop system can improve glycemic control with a higher exposure to hypoglycemia.

P268 / #293
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

THE RELATION BETWEEN CARDIOMETABOLIC RISK FACTORS AND GLUCOSE PROFILE EVALUATED BY CONTINUOUS GLUCOSE MONITORING IN TYPE 2 DIABETES PERSONS

A. Morosanu, M. Morosanu

Background and Aims: Diabetes evolution is influenced both by glucose status and cardiovascular risk, among many factors. The relation between these two components is not always investigated in detail. The study evaluated the relation between cardiometabolic risk factors (CMRF) and glucose parameters evaluated by continuous glucose monitoring (CGM) in persons with type 2 diabetes (T2D).

Methods: 30 persons with T2D (8 women, 22 men, insulin-treated-14, oral-treatment-16) were assessed by CGM. Mean age-56.59 years, mean diabetes duration-11.43 years, mean insulin-therapy duration-5.71 years. CMRF: body weight, BMI, abdominal circumference (AC), physical activity, smoking, alcohol consumption, lipid profile (total cholesterol-T-chol, calculated LDLc, HDLc, triglycerides-TG), SBP, DBP, personal and family history of CVD, family history of diabetes. Glucose parameters: glycated haemoglobin A1c (A1C), glucose variability (GV), mean amplitude of glucose excursions (MAGE) (Monnier et al (2006)), number of glucose values (NGV, time spent), area under the curve (AUC, glucose exposure), mean glucose values (MGV, glucose amplitude) on domains-hypoglycemic (<70mg/dl), intermediate (70-180mg/dl), hyperglycemic (>180mg/dl), optimal (90-130mg/dl).

Results: Weight was inversely correlated with GV and MAGE. SBP increased with diabetes duration and insulin-therapy duration. Persons with SBP >130 mmHg had lower percent NGV and AUC <70, higher total, diurnal and nocturnal AUC, higher glucose amplitude (MGV). LDLc decreased with increasing insulin-therapy duration. TG values were directly correlated with diurnal AUC and inversely related to nocturnal AUC. HDLc was directly correlated with AUC 70-180. Persons with family history of diabetes had higher time spent (NGV) and total AUC >70 mg/dl. Persons with family history of CVD had lower A1C. The other assessed data were not significant, even if the direct relation between worse cardiometabolic parameters and hyperglycemic exposure was close to statistical significance.

Conclusions: SBP was directly correlated with total glucose status and inversely related with hypoglycemia. TG and HDLc were directly correlated with glucose status and worsened with age(HDLc). Awareness of familial RF induced a better glucose control with a higher exposure to hypoglycemia.

P269 / #474
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

FLASH TECHNOLOGIES FOR MONITORING GLYCEMIA IN TYPE 1 DIABETES MELLITUS

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Background and Aims: Continuous glucose monitoring (CGM) is currently one of the most promising methods for controlling type 1 diabetes (T1D). Flash monitoring is the most relevant and promising direction in diabetology, which allows to monitor the level of glycemia an unlimited number of times and,
as well as does not require calibration of the device. The aim of the study was to evaluate the clinical and metabolic effectiveness of flash monitoring of glycemia in patients with T1D.

**Methods:** The study included 80 patients with T1D on various insulin therapy regimens. All patients were tested for HbA1c, flash glycemia monitoring, and quality of life assessment using the MOS SF-36 and PedsQl Diabetic module 3.2 questionnaires.

**Results:** HbA1c decreased by 1.6% (p<0.001) at the end of the study in the pump insulin therapy group. In patients of the basic bolus group HbA1c decreased by 0.6% and reached 8.9% (p=0.028). When comparing the glycemic control indicators of the two groups, the average blood glucose level decreased in the pump insulin therapy group to 7.51 ± 1.53 mmol/l, in the second group this indicator was 7.25 ± 2.43 mmol/l (p<0.001). When assessing the quality of life indicators, improvement was found in both the first and second groups.

**Conclusions:** Continuous monitoring, including flash monitoring, is an effective method of monitoring and achieving glycemic goals in patients with T1D, and is also an optimal tool for improving the quality of life regardless of the insulin therapy regimen.

**P271 / #556**

**Topic:** AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

**THE ASSOCIATION BETWEEN TIME IN RANGE %, MEASURED BY CONTINUOUS GLUCOSE MONITORING (CGM) AND PHYSICAL & FUNCTIONAL INDICES AMONGST OLDER PEOPLE WITH TYPE 2 DIABETES**

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**Background and Aims:** People with diabetes have an increased risk for mobility disability and a more rapid decline in muscle mass (sarcopenia) compared to those without diabetes. Studies have demonstrated an association between A1C and Sarcopenia. Less is known regarding the relationship with Time In Range (TIR). **Aims:** To assess among older people with diabetes type 2, the cross sectional association between: TIR and aerobic capacity, gait speed, strength, balance and frailty indices.

**Methods:** A cross sectional study, conducted amongst people with diabetes over the age of 60. Participants were provided with a blinded CGM system- (I Pro2 carelink, Medtronic) for 1 week and underwent elaborate physical-functional assessment in the beginning and at the end of that week. The association between the % of time in range (TIR) and several physical indices was determined using linear regression.

**Results:** This analysis pertains to 81 men and women. After adjustment for age and gender, a 1% higher TIR (70–180) was associated with a 0.246 higher score on the 6-minute walk score, a measure of aerobic capacity and endurance (P-value = 0.019) and 0.212 lower score on the Timed Up & Go(TUG), a measure of fall risk and balance (P-value = 0.045).

**Conclusions:** Higher % TIR is associated with better scores on indices of aerobic capacity and a measure predicting falls. Future studies are needed in order to elucidated if glucose levels are merely a marker of disease severity, or if there is possibly a causal relationship.
Background and Aims: Assess in a sample of patients with type 1 diabetes mellitus whether mood and stress influence blood glucose levels and variability.

Methods: CGM was performed on 10 patients with T1DM, where interstitial glucose values were recorded every 15 minutes. A daily survey was conducted through Google Forms, collecting information on mood and stress. The day was divided into 6 slots of 4-hour each, asking the patient to assess each slot in relation to mood (sad, normal or happy) and stress (calm, normal or nervous). Different measures of glycemic control (arithmetic mean and percentage of time below/above the target range) and variability (standard deviation, percentage coefficient of variation, mean amplitude of glycemic excursions and mean of daily differences) were calculated to relate the mood and stress perceived by patients with blood glucose levels and glycemic variability. A hypothesis test was carried out to quantitatively compare the data groups of the different measures using the Student’s t-test.

Results: Significant differences (p-value <0.05) were found between different levels of stress. Average glucose and variability decrease when the patient is calm. Statistically significant differences between different levels of mood. Variability increases when the mood changes from sad to happy. However, patient’s average glucose decreases as the mood improves.

Conclusions: Variations in mood and stress significantly influence blood glucose levels, and glycemic variability in the patients analyzed with type 1 diabetes mellitus. Therefore, they are factors to consider for improving glycemic control. The mean of daily differences does not seem to be a good indicator for variability.

P274 / #658
Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals
PATIENT SATISFACTION AND CLINICAL EFFICACY OF INTERMITTENTLY SCANNED CONTINUOUS GLUCOSE MONITORING: A 12-MONTH REAL LIFE STUDY
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Background and Aims: Intermittently scanned continuous glucose monitoring (isCGM) was approved in Portugal for reimbursement for patients with type 1 diabetes (T1D) via National Health Service in January 2018. We aim to evaluate patient satisfaction and glycaemic control in real-life conditions following a standardized initiation process of isCGM.

Methods: Adults with T1D were prospectively recruited from the Diabetes Outpatient Clinic. We compared isCGM metrics, established in the 2019 ATTD consensus, from baseline (first 14 days of use) and after 12 months. Patient satisfaction was assessed using the Quality of Life and Treatment Satisfaction Questionnaire of T1D patients (QoLTSQ), a tool specifically created and validated for Portuguese T1D patients.

Results: Thirty-six individuals were included (55.6% males); mean age of 50.6±14.4 years and T1D duration of 25.5±12.0 years; 91.7% were on multiple daily injections. Comparing metrics from baseline and 12 months, there was an increase in the mean time in range[51.1±15.9% to 65.0±13.3%(p<0.001)]; a decrease in the median time below range[5.0 (3.0-9.0)% to 2.0(0.5-3.5), p<0.001], in the coefficient of variation [40.0±6.6% to 37.5±5.7%(p=0.033)] and in mean time in hypoglycaemia[109.8±40.6 to 37.5±5.7 (p<0.001)]. Median HbAlc (chromatography method) was reduced from 7.6(7.0-8.65)% at baseline to 7.3(6.8-7.7)%; p=0.015; the QoLTSQ scores significantly improved 12 months after initiating isCGM, particularly “burden in social activities”, “self-perception of health” and “T1D-treatment impact” domains. Both HbAlc and QoLTSQ 12-months changes occurred irrespective of initial metabolic control (cut-off at HbAlc £7.5%).

Conclusions: isCGM contributed to improved metabolic control, treatment satisfaction and quality of life in Portuguese patients with T1D and these data reinforce the important role of this tool in the treatment of this population.
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Topic: AS13-Blood Glucose Monitoring and Glycemic Control in the Hospitals

TO COMPARISON THE COGNITIVE FUNCTION IN A VASCULAR DEMENTIA PATIENTS WITH AND WITHOUT DIABETES MELLITUS

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Background and Aims: Abstract: Aim: Diabetes Mellitus is a topical issue in the modern world, including Georgia. Statistically, the number of cases is increasing every year. The purpose of this study was to determine the cognitive impairment in patients with and without Diabetes Mellitus.

Methods: 78 patients (36 male and 42 female) were selected for the study aged over 65 years. 46 patients were included in the study group, who had as well as Vascular Dementia as well as Diabetes Mellitus, 32 patients were included in the control group who had only Vascular Dementia. The research was ongoing for at least 6 months. Patients were examined Glycemic parameters, and for both group every 4 weeks for 24 weeks using a neuropsychological test with mini-mental scaling, and both groups had low-density lipoprotein and cholesterol levels before and after treatment.

Results: The MMSE scores of diabetic patients were significantly lower than the control group (p<0.05). The average MMSE score diabetic patients was 17.28±3.48, compared with control group 22.42±3.78 (p=0.9).

Conclusions: Conclusion: Based on the data obtained from our study, it should be noted that Diabetic patients showed decreased significantly cognitive function compared to Non Diabetic patients with Vascular Dementia

P277 / #77

Topic: AS14-Human factor in the use of diabetes technology

DISPARITY IN PEDIATRICS DIABETES CARE

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Background and Aims: Disparity in providing pediatrics type 1 and type 2 diabetes care is a major factor that may affect the outcome of the condition. Analyzing the available resources is the first step in understanding the actual disparity while comparing different health systems. Providing pediatric diabetes care depends on multidisciplinary approach and availability of modern technology equipment, staff, and on site medications.

Methods: To examine the availability of diabetes technology resources (HbA1c machine, access to Continuous Glucose Sensor Monitoring System: CGMS, demo training kits of insulin pens and pumps), human resources (on site specialized pediatric endocrinologists, Certified Diabetes Educator, dietitian) and on site rescue medications (Glucagon, insulin) in 2 health systems / clinics: The first is an academic for-profit system and the second is a county-based not for profit system serving minorities and lower income families.

Results: The county based system lacked the availability of modern technology devices (HbA1c machine, CGMS, demo kits of insulin pen and pumps), some human resources (on site diabetes educator) and availability of on-site rescue medications (Glucagon, insulin).

Conclusions: Disparities in health care access and services for minority and other vulnerable populations in the United States are well known. Medical treatment and quality of resources in pediatrics with type 1 and type 2 diabetes differed significantly between the two systems we examined. Disparities in individual socioeconomic status, regional deprivation, and differences in medical reimbursement decisions might have contributed to the patterns observed. Undeserved communities who experience inadequate health care will definitely have a worse diabetes outcome.

P276 / #63

Topic: AS14-Human factor in the use of diabetes technology

PARENTAL CONCERNS OF COVID-19 AND PEDIATRIC DIABETES

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Background and Aims: During the COVID-19 pandemic, many parents of children with diabetes had concerns about its association with poor health outcomes and complications with COVID-19. The exact cause of severe outcomes in patients with diabetes and COVID-19 is not yet known, but it seems that children with poorly controlled diabetes are at a higher risk of becoming severely ill if they were to contract the virus. The pandemic has created new challenges for parents of children with diabetes as well as their health care providers.

Methods: We reviewed parental concerns regarding their children with type 1 and type 2 diabetes mellitus based on personal encounters, telemedicine visits, and phone call triage.

Results: Parental concerns were grouped according to the following: 1-Risk of getting the infection: Leaving the house, going to school, need for complete isolation, and concerns regarding potential COVID-19 symptoms. Also fears of having to visit the hospital due to diabetic ketoacidosis episode during the pandemic. 2-Resources: Inability to have insulin and diabetes supplies in the future due to possible shut down, concerns regarding family resources and change of employment. 3-Mental Health: Change of lifestyle, lack of social and sport activities and weight gain.

Conclusions: The COVID-19 pandemic has created many challenges in delivering pediatric diabetes care. Parental concerns regarding the infection risks, availability of resources, lifestyle modifications, and mental health were valid. This has also translated into the need of modifying and expanding the current health delivery tools (ie, Telemedicine) to be able to continue providing medical care and psychological support.

P278 / #107

Topic: AS14-Human factor in the use of diabetes technology

CHALLENGES WITH DIY LOOP IN PREGNANCY WITH TYPE 1 DIABETES

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Background and Aims: Tight glycaemic targets in women with type 1 diabetes (T1D) during pregnancy are associated with hypoglycaemia which adversely affect quality of life. Pregnant women with T1D are not willing to wait for commercially available closed loop systems. In clinical practice use of Do-it-your Self (DIY) Loops during pregnancy increased.

Methods: We report a case of 32-year-old woman with T1D (diabetes duration 16ys), who used Tidepool Loop system with patch insulin pump (Omnipod) and continuous glucose monitoring (CGM) ( Dexcom G6) to manage her diabetes during her pregnancy, which was complicated by hyperemesis throughout pregnancy. Data were collected retrospectively from medical records and Tidepool documentation.

Results: Mean HbA1c during first, second and third trimester was 32, 24 and 31mmol/mol. Time in range (TIR) was between 70-140mg/dl was 75-82% throughout the pregnancy. Time below range increased to 13% and CGM deteriorated midterm. Frequent capillary glucose measurements revealed 20-50mg/dl lower glucose values for CGM data above target. Total daily insulin dose increased from 28.7IU to 41.0IU to 61.4IU (first, second and third trimester, respectively). During labor, glucose was in tight control by automated insulin dosing (average glucose 110mg/dl). After 24 hours a caesarean section had to be performed due to failure to progress in labor. Delivery of a healthy baby girl (Apgar-score 9-10-10, 3590g birthweight, 57. percentile) occurred at 40th +3 gestational week.

Conclusions: We observed excellent glycemic control with regard to TIR and HbA1c when using DIY-Loop. However, CGM inaccuracy likely due to hyperemesis and subsequent dehydration complicated the performance of automated insulin dosing during pregnancy.

P279 / #131
Topic: AS14-Human factor in the use of diabetes technology
SPOTLIGHT CONSULTATIONS: ILLUMINATING PATIENT PRIORITIES – T2 DIABETES

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Background and Aims: Burnout in people with diabetes and HCPs is at an all-time high. Spotlight – a novel ‘smart’ adaptive and dynamic patient questionnaire is designed to improve routine outpatient consultations by rapidly identifying patient priorities and presenting these in the context of personalised areas for concern and best-practice care pathways to illuminate consultations. We assessed the feasibility of using Spotlight in routine care.

Methods: The Spotlight prototype tool was trialled at three centres, two UK primary care centres and one US specialist centre between June-September 2020.

Results: Eighteen adults with T2D (n=10 male, n=4 female, n=4 did not state) took part in this real-world evidence collection, each identifying two priority concerns. The psychological burden of diabetes was the primary area of concern (n=18,100%) followed by gaining more skills about aspects of diabetes (n=7,38.9%), improving support around me (n=7,38.9%) and diabetes-related treatment issues (n=4; 22.2%). Feeling sad about living with diabetes and ‘whatever I do to manage my diabetes, it is never enough’ (each n=15,83.3%), feeling scared (n=11,61.1%) and lacking confidence (n=10,55.6%) were all commonly reported. Participants who had diabetes for >10 years were more likely to report lack of social support as a priority concern (50%-v-25%), those with diabetes duration <10 years were more likely to report gaining more skills as a priority concern (50%-v-20%).

Conclusions: Spotlight is acceptable and feasible for use in routine care. Gaining more skills and addressing the psychological burden of diabetes are high priority areas that must be addressed to reduce high levels of distress.

P280 / #140
Topic: AS14-Human factor in the use of diabetes technology
SPOTLIGHT CONSULTATIONS: ILLUMINATING DISCREPANCIES IN A1C SUBJECTIVE RECALL AND OBJECTIVE MEASUREMENT

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Background and Aims: It is important to know not only the target A1c but also the current A1c in order to effectively self-manage and assess progress towards that target. We assessed baseline participant subjective knowledge of their A1c compared to their latest objective A1c measurement.

Methods: The Spotlight prototype tool was trialled at two centers (one primary care, one specialist) between June-September 2020. All participants were asked to report their most recent A1c result prior to using the Spotlight tool.

Results: Data was collected for 45 participants (n=31 with T1D; n=14 with T2D). Overall, accurate recollection of A1c was poor with twenty-two participants (48.9%) correct recall. Six participants (13.3%) did not know their A1c, eight (17.8%) reported it as lower than it actually was and nine (20.0%) reported it was higher than it actually was. Individuals with T1D were more likely to correctly report their A1c (n=18, 58.1%) than those with T2D (n=4, 28.6%); over-estimation was reported by n=7 T1D(22.6%) vs n=2 T2D(14.3%); under-estimation was reported by n=6 T1D(19.4%) and n=2 T2D(14.3%). People with T1D who overestimated their A1c were more likely to have “gaining more skills” (n=6,85.7%) as a priority concern. People with T1D correctly recalling their A1c were more likely to have ‘psychological burden’ as a priority concern (n=17,94.4%). Those who did not know their A1c (all with T2D) reported ‘psychological burden’ as a priority concern.

Conclusions: Accurate recall was poor. Efforts are required to ensure patients understand their HbA1c measurement to aid their medical and psychological well-being.
P281 / #143
Topic: AS14-Human factor in the use of diabetes technology
PENDIATRIC DIABETES AND COVID-19 INFECTION
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Background and Aims: Since the World Health Organization (WHO) has declared the outbreak of the novel coronavirus disease (COVID-19) a pandemic, many questions were raised about risk of this viral infection in children with diabetes. Reports from affected areas suggested that in most cases the coronavirus illness generally has a milder course in children and there are no reliable data suggesting that children with well-controlled type 1 & 2 diabetes mellitus are at increased risk of getting infected or becoming very severely ill with coronavirus.

Methods: Brief review of cases of pediatric diabetes ketoacidosis (DKA) associated with COVID-19 positive infection over four months period.

Results: Five pediatric DKA cases were associated w positive COVID-19 infection Four cases were new onset of Type 1 diabetes while one was previously diagnosed. Four cases had respiratory symptoms and fever while one did not.

Conclusions: Previous experience with SARS-associated coronavirus, was associated with new cases of diabetes. Poorly controlled diabetes mellitus or unrecognized new onset of the disease, can cause immune dysregulation and thereby increase the risk of getting infected by the virus. Several viral infections have been historically thought to contribute to auto-immunity and the progressive β-cell death that leads to the development of T1DM in children. The relation between the COVID-19 infection and diabetes as an immune trigger or as a comorbid factor will become more understandable once multinational and international data are collected and published.

P282 / #160
Topic: AS14-Human factor in the use of diabetes technology
REAL-WORLD EVIDENCE OF DIABETES APP USE IN DAILY LIFE: PROFILING ADULTS WITH TYPE 2 DIABETES WHO USE A BLOOD GLUCOSE METER APP

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Background and Aims: Mobile blood glucose (BG) meter apps facilitate the documentation, analysis, and sharing of BG data in order to improve diabetes self-management. Yet, little is known about those who actually use these apps. In the first phase of the 4-month REAL study, we assessed the characteristics and initial motivations of T2D adults using a BG meter app.

Methods: From March-July 2020, T2D adults who used the CONTOUR®NEXT ONE meter, paired their meter with the CONTOUR®DIABETES app in the previous 31 days, and had ≥1 reading logged in their app were invited to complete an online questionnaire.

Results: 585 T2D respondents completed the questionnaire: mean age was 51.7 +/- 11.9 years, median diabetes duration was 4.0 years, and 52% were male. The majority were overweight (22%), obese (44%), or extremely obese (27%). Most reported significantly elevated diabetes emotional distress (58%) and/or diabetes regimen distress (66%). Overall, 46% of respondents reported starting the app because it came with their meter; 29% actively sought out an app that would improve their diabetes management; 11% received an HCP recommendation; 4% received another in-person or online recommendation; and 10% cited ‘other’ reasons. Those who reported elevated emotional and/or regimen distress were more likely than those with no/little distress to have sought out the app themselves (32% vs. 20% respectively).

Conclusions: Among adults with T2D, those who report relatively short diabetes duration (<5 years), high BMI, and elevated diabetes distress are the most likely to adopt and potentially benefit from a BG meter app.

P284 / #204
Topic: AS14-Human factor in the use of diabetes technology
FROM FORMULAS TO PATTERN RECOGNITION: DESIGN OF AN INTERACTIVE DATA VISUALIZATION TO UNDERSTAND DAILY TIMING AND CALCULATION
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Background and Aims: Many people with diabetes (PWD) struggle to understand insulin dose timing and dose calculations despite instruction that utilizes measured point in time glucose values, carbohydrate counts, and multiple formulas. Continuous glucose monitors (CGM) reveal visual patterns or trends that provide real-time responses to assist PWD and their healthcare providers to analyze and improve diabetes management decisions.

Methods: To explore the role of interactive visualizations in teaching insulin dosing, we interviewed endocrinologists, diabetes educators, physician assistants, and PWD to understand the challenges of managing diabetes and interpret glucose data (n=5). Based on these insights, we created a web-based interactive visualization through iterative development and testing of prototypes with the interviewees.

Results: Interviewees identified insulin dose timing as a critical concept to understand for PWD using insulin, regardless of the delivery method. The interactive tool depicts the insulin activation curve and resulting glucose response. Participants in the prototyping phase appreciated the ability to explore real-world scenarios, such as delayed or insufficient dosing, by manipulating insulin timing and dose. Insulin units were removed to avoid misinterpretation of this interactive tool as a bolus calculator.

Conclusions: This simple prototype demonstrates the potential of interactive visualizations to communicate the relationship
between insulin activity and glucose response to support the recognition of glucose patterns and individualized decisions about insulin dosing and timing. Further research is needed to incorporate the complexity of additional factors and to measure the impact of visualization tools on diabetes self-management education and clinical outcomes.

P285 / #255

Topic: AS14-Human factor in the use of diabetes technology

GLYCAEMIC VARIABILITY AND HEALTH RELATED QUALITY OF LIFE

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Background and Aims: Despite clinical impression that glucose fluctuations are distressing, the impact of glycaemic variability on Health Related Quality Of Life (HRQOL) has not been extensively explored. HRQOL is recognized as an important health outcome and an independent predictor of survival. Glycaemic variability (GV), mathematically defined as %CV, is a candidate for predicting diabetes specific outcomes. Our aim was to determine possible association of glycaemic variability and HRQOL.

Methods: 22 adults using multiple daily injections (mean HbA1c = 7.1 ± 1.3%) with type 1 (n = 11; mean %CV = 42.3 ± 6.9) and type 2 (n = 11, mean %CV = 35.4 ± 6.7) diabetes wore a blinded CGM and completed several QOL questionnaires. A correlation analysis was performed to assess a relationship between CGM derived GV and measures of QOL. Difference in HRQOL between groups with %CV above or below 36%, was compared by independent-samples t-test.

Results: Glycaemic variability (%CV) was not significantly correlated to HRQOL measures (Table 1). Patients with high %CV (≥ 36%) did not have significantly lower HRQOL scores.

Legend: SF-36: Short Form (36) Health Survey, NS: non-significant

Conclusions: We found no significant impact of glycaemic outcomes on HRQOL in insulin treated type 1 and type 2 diabetes patients; HRQOL should therefore be considered as a valued independent outcome in diabetes research and clinical practice.

P286 / #287

Topic: AS14-Human factor in the use of diabetes technology

INCREASING THE NUMBER OF DIABETIC PATIENTS AND COVID-19 EPIDEMIC – A CALL FOR COOPERATION BETWEEN SPECIALISTS AND GENERAL PRACTITIONERS IN PATIENT EDUCATION

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Background and Aims: Cooperation in the education of diabetic patients between diabetologists (D) and general practitioners (GP) is now very current. The aim of our study was to compare the effectiveness of group education of type 2 diabetic patients treated by D and by GPs at the national level.

Methods: The effect of the course on diabetes control in both groups was evaluated after 6 months, Results: 66 Type 2 diabetic patients, 44 from GPs and 22 from D participated in group education in 10 centers under the guidance of D. Diabetic patients treated by D were significantly younger compared to patients treated by GPs (59 – 10 vs. 64 – 9 years, p < 0.05), had higher baseline HbA1c (58 – 17 vs. 51 – 10 mmol/mol, p < 0.05), but they did not differ in baseline BMI 34.8 – 6 vs. 34 – 6 kg/m². At 6 months after the course, there was a significant improvement in diabetes control in both patients from D and GPs: the proportion of patients with HbA1c up to 53 mmol/mol increased from 50 to 85% in the first cohort and from 59 to 76% in the second, all p < 0.05. Weight in both groups decreased by 3 kg (p < 0.001) after 6 months. Physicians in the regions rated the mutual cooperation very positively.

Conclusions: Group education had a comparable significant long-term effect on improving diabetes control in both patients treated by D and by GPs. Better data management system for integration of community and secondary care in education is required.
P287 / #292
Topic: AS14-Human factor in the use of diabetes technology
**“GIVE ME A BREAK” ADOLESCENT AND PARENT PERSPECTIVES ON BREAKS IN CGM USE**

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**Background and Aims:** Despite increasing availability and use of continuous glucose monitors (CGM) among adolescents with type 1 diabetes (T1D), diabetes outcomes remain suboptimal. Device reports often indicate gaps in CGM use amongst adolescents, yet few studies have examined what we term “CGM breaks.” We explored adolescent and parent perspectives on adolescents’ CGM breaks, and associations with diabetes management.

**Methods:** As part of an ongoing multi-site behavioral intervention trial, questionnaires about CGM use and diabetes self-management were administered to adolescents and their parents at baseline.

**Results:** Participants were 60 adolescent-parent dyads (mean adolescent age 15.6±1.4; 68% female; 70% White, non-Hispanic; 55% pump; 72% CGM; mean HbA1c 9.1±2.1). Of those using CGM, breaks were common according to adolescent and parent reports (40% and 42%, respectively), typically lasting a day or two, with adolescents reportedly checking blood glucose 2–3 times a day (adolescent report) to 4–5 times a day (parent report) during the break. Adolescents whose parents reported CGM breaks reported lower diabetes self-care (p = .033) and although not statistically significant, had a higher HbA1c than those who did not (9.2% vs. 8.4%, p = .29). No significant differences in HbA1c or diabetes self-care behavior were observed based on adolescents’ report of CGM breaks.

**Conclusions:** In this sample of adolescents with T1D, parent-reported CGM breaks were associated with poorer adolescent diabetes self-care and higher HbA1c. Given that nearly half of adolescents in this study reported taking a CGM break, clinicians should engage with adolescents and their parents about plans for blood glucose monitoring while off CGM.

P288 / #317
Topic: AS14-Human factor in the use of diabetes technology
**TIME-IN-RANGE WITHOUT AUTOMATED INSULIN DELIVERY SYSTEMS IN CHILDREN WITH TYPE 1 DIABETES BEFORE AND DURING A DIABETES SUMMER CAMP – A GLASS CEILING?**

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**Background and Aims:** In addition to recreation for children with type 1 diabetes (T1D), summer camps also offer the opportunity to train and optimize diabetes management in order to reach a maximum Time-in-Range (TIR) (3.9-10mmol/mol). Sensor systems (CGM) support children with T1D and caregivers to manage diabetes and allow to evaluate glycemic control. The aim of this study was to compare TIR, Time-Above-Range (TAR) and Time-Below-Range (TBR) before and during a diabetes camp.

**Methods:** Retrospective analysis of CGM data before and during the 14-day participation in an Austrian summer camp for children with T1D in 2019. 31 children (age: 10.9±1.39 years; 48.8% female; 64.5% on insulin pump; Hb1Ac 7.3±0.2%). CGM systems used: 48.4% Abbott FreeStyle Libre, 16.1% Dexcom G6 and 35.5% Medtronic Enlite. No child was using an automated insulin delivery system.

**Results:** Mean TIR during the camp was significantly higher than before the camp (66.4±10.0% vs. 56.5±16.9%; p < 0.001). TAR was significantly reduced during the camp (39.8±16.1% vs. 27.7±9.8%; p < 0.001). However, there was a significant increase in TBR compared to the period before the camp (3.7±3.1% vs. 5.9±3.9%; p = 0.003). There was no significant difference with regard to TIR, TAR and TBR between children using insulin pump therapy vs. multiple daily injections. No severe hypoglycemia occurred during camp.

**Conclusions:** During camp, the participating children improved their glycemic control significantly. However, on average the therapy goal (TIR >70%) could not be achieved despite high professional effort. This could possibly only be achieved through the use of closed-loop systems. The increase in TBR might be explained by increased physical activity.

P289 / #364
Topic: AS14-Human factor in the use of diabetes technology
**A VIRTUAL DIABETES EDUCATION PROGRAM INCORPORATING SUPERVISED EXERCISE IMPROVES GLUCOSE LEVELS IN DIABETIC PATIENT DURING PANDEMIC**

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**Background and Aims:** This study was designed and conducted during the time of Covid-19 Pandemic. Maintaining EHR of patients was in practice before the outbreak of pandemic. The virtual applications made the transfer of current data more convenient. The study aims to examine improvements in glycemic control in T2DM individuals who undertook supervised exercise training, diet consultation and insulin titration with diabetes management strategies.

**Methods:** 37 number of individuals with T2DM attended 32 program meetings, Twice a week during a 4 month period. Subjects included both genders ranged from 35 to 40 years of age (mean duration of diagnosis: 3 years). Data collected included: 1. Initial FBG; 2. OAD Medicine recall; 3. 20min: aerobic exercises; 4. 20 mins: educational activities; 5. Final FBG. BG values were categorised into strata based on glycemic goals and analyzed further.[Ref:Abstract no:23 from ATTD 2015 oral presentation]

**Results:** Data from all 37 (21 F, 16M) participants for BG were collected at each program meeting, Initial FBG was 140-
160 mg/dL before the program, FBG values were significantly lower to 80-120 mg/dL, (p < 0.001) after the virtual sessions.

**Conclusions:** Diabetes education that includes supervised exercise appeared to be beneficial in pandemic times in maintaining BG levels in diabetes individuals without visiting hospital sites. And these programs helped practicing diabetologists in providing better health care services to their patients without risking their health.

**P290 / #379**

**Topic:** AS14-Human factor in the use of diabetes technology

**EFFECTS OF AEROBIC VERSUS STRENGTH EXERCISE ON HYPOGLYCEMIA INCIDENCE IN PATIENTS WITH DIABETES TYPE 1**

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**Background and Aims:** The aim of this study is to assess hypoglycemic events during and after aerobic versus strength exercise using flash glucose monitoring system in type 1 diabetes patients (DMT1).

**Methods:** This was a randomised cross over prospective study including 13 DMT1 patients over the age of 18 using FGM. Patients were randomized according to the type of exercise (aerobic exercise and strength training) with a washout period of three days between group change. Low glycemic index (LGI) meal was served 60 minutes prior and after each exercise and 25% and 50% of the calculated bolus was administered, respectively. Hypoglycemic episodes were evaluated during and 24 hours after the exercise.

**Results:** Median age of patients was 49 years (interquartile range 42.25-56.5), HbA1c 7.1% (interquartile range 6.3-7.85) and duration of diabetes 28 years (interquartile range 16-40). Exercise induced a similar decrease in blood glucose from pre-exercise concentrations in both groups (aerobic versus strength training), 0.9 compared to 1.1 mmol/l respectively, (p = 0.59). There were 16 hypoglycemic events after aerobic exercise versus 11 hypoglycemic events after strength training (p = 0.99) and 4 nocturnal hypoglycemic events after aerobic training, but none after strength training (p = 0.13). Median duration of hypoglycemia was 180 minutes in the aerobic exercise group, versus 120 minutes in the strength training group (p = 0.81).

**Conclusions:** Strength training seems to be more favourable choice although difference in hypoglycemic episodes was numerical and didn’t reach statistical significance. In addition, LGI meals prevented post exercise hyperglycemia in both types of exercise.

**P291 / #380**

**Topic:** AS14-Human factor in the use of diabetes technology

**KEY BURDENS IN TODAY’S DIABETES MANAGEMENT: USER NEEDS AND REQUIREMENTS FOR DIABETES APPS AND WEARABLES.**

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**Background and Aims:** Daily diabetes management presents a high burden for people living with diabetes. While advances in sensor technologies aim to reduce this burden, software applications and algorithms are not yet able to exploit the full potential of these technologies. This is why we conducted a user study in a twofold process: First, we conducted in-depth interviews to identify user needs regarding the improvement of diabetes management as well as today’s key-burdens. Secondly, we validated the acquired information in an online survey using a ranking method.

**Methods:** In the first study we used in-depth interviews with six patients and five doctors to extract the current status quo of technological diabetes management. In the second study we conducted an online survey with a total of 144 participants completing the survey. All participants were recruited via German social media sites.

**Results:** People are not aware of the whole spectrum of currently available technical solutions but almost all participants want to further improve their management. The top unresolved requirement of T1D is the distance between eating and injection, while for T2D the analysis of the burden of diabetes management is most important. The inclusion of physical activity and the analysis of everyday stress in management systems follow subsequently.

**Conclusions:** The perceived value of diabetes apps, wearables and continuous glucose monitoring systems is high whereas the adoption is not yet fully utilized. Further developments need to integrate the users’ perspective and requirements to tackle the burden of diabetes management.

**P292 / #383**

**Topic:** AS14-Human factor in the use of diabetes technology

**THE GATEKEEPER STUDY: PROVIDER BIAS IMPACTS DIABETES TECHNOLOGY RECOMMENDATIONS FOR YOUTH WITH TYPE 1 DIABETES (T1D)**

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**Background and Aims:** Diabetes technology use is associated with favorable T1D outcomes. American youth with public insurance, a proxy for low socioeconomic status, have significantly lower diabetes technology use. Provider bias, a contributor to health inequity, is defined as the systematic discrimination or promotion of a sub-group. We aimed to evaluate the role of insurance-mediated provider bias on diabetes technology recommendations for youth with T1D.

**Methods:** Multi-disciplinary pediatric diabetes providers completed a diabetes technology bias assessment tool comprised of a clinical vignette and patient-factor ranking exercises. Provider bias was defined when providers (1) recommended more technology for private insurance than public insurance or (2) ranked insurance as one of the top two reasons to offer technology. Bias and provider factors were analyzed with
Results: The majority of providers [44.1 ± 10.0 years-old, 83% female, 79% non-Hispanic white, 49% public health, 12.2 ± 10.0 practice-years] demonstrated bias (n = 33/39, 84.6%). Compared to the group without bias, the group with bias had practiced longer (13.4 ± 10.4 years vs 5.7 ± 3.6 years, p = 0.003) and were more likely to be non-Hispanic white (p = 0.007). Practice-years remained significant when additionally adjusting for age, sex, race/ethnicity, provider role, %public insurance served, and workplace location (odds ratio = 1.47, 95% CI [1.02, 2.13]; p = 0.007).

Conclusions: Provider bias to recommend technology based on insurance status was common in our cohort and increased with years in practice. These data suggest that provider bias contributes to decreased technology access for youth with public insurance. Providers, as gatekeepers to diabetes technology, may be one contributing factor to inequities in pediatric T1D.

P294 / #523
Topic: AS14-Human factor in the use of diabetes technology
A UNITED KINGDOM (UK) WIDE SURVEY OF HEALTH CARE PROVIDER (HCP) EXPERIENCES REGARDING VIRTUAL CONSULTATIONS IN TYPE 1 DIABETES
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Background and Aims: The recent COVID-19 pandemic has led to rapid implementation of virtual diabetes clinics in type 1 diabetes (T1D). An understanding of current strategies, HCP experiences and barriers is needed to allow improvements.

Methods: The diabetes technology network (DTN) UK conducted an online survey of its members involved in the care of people with T1D to gain an understanding of the experiences of HCP towards virtual consultations.

Results: Of 143 eligible responses, 61 (42.7%) were from consultants, 52 (36.4%) were from diabetes specialist nurses, 22 (15.4%) were from dieticians and 7 (4.9%) were from trainee doctors. Respondents reported that approximately 50% of consultations were conducted by telephone, 10% by video call, and 20% were face-to-face. When asked to rate effectiveness of remote consultations on a scale of 1-7, 63.7% of respondents gave a score of 5 or above. The most common barriers and facilitators of effective remote consultations reported by respondents are outlined in Table 1. A significant proportion of respondents did not routinely have access to patients’ diabetes data during consultations. Devices that automatically uploaded data to a cloud platform were felt to make consultations easier and more effective by 105 (73.4%) and 121 (84.6%) of respondents respectively. 92.4% respondents highlighted that remote consultations are likely to be a mode of offering care in the future post-Covid-19.

Conclusions: This study identified important opinions, enablers and barriers to effective remote consultations. The

Table 1. Barriers and facilitators of effective remote consultations

<table>
<thead>
<tr>
<th>Barriers to effective remote consultations</th>
<th>No. of respondents (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to patients results prior to consultation</td>
<td>45 (31.5%)</td>
</tr>
<tr>
<td>Access to patient device data prior to consultation</td>
<td>96 (67.1%)</td>
</tr>
<tr>
<td>Video system or platform for remote consultation</td>
<td>49 (34.3%)</td>
</tr>
<tr>
<td>Patient familiarity with technology</td>
<td>103 (72%)</td>
</tr>
<tr>
<td>HCP familiarity with technology</td>
<td>17 (11.9%)</td>
</tr>
<tr>
<td>Trust/clinic setup for remote consultations</td>
<td>49 (34.3%)</td>
</tr>
<tr>
<td>Facilitators of effective remote consultations</td>
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<tr>
<td>Access to patients results prior to consultation</td>
<td>74 (51.7%)</td>
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<tr>
<td>Access to patient device data prior to consultation</td>
<td>98 (68.5%)</td>
</tr>
<tr>
<td>Video system or platform for remote consultation</td>
<td>55 (38.5%)</td>
</tr>
<tr>
<td>Patient familiarity with technology</td>
<td>55 (38.5%)</td>
</tr>
<tr>
<td>HCP familiarity with technology</td>
<td>53 (37.1%)</td>
</tr>
<tr>
<td>Trust/clinic setup for remote consultations</td>
<td>1 (0.7%)</td>
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</table>

P293 / #405
Topic: AS14-Human factor in the use of diabetes technology
IMPACT OF CONTINUOUS GLUCOSE MONITORING SYSTEMS ON PARENTAL QUALITY OF LIFE
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Background and Aims: A diagnosis of type 1 diabetes in childhood impacts parental function and quality of life. While both benefits and burdens of CGM use are reported, literature on parental quality of life with newer CGM technology is more limited. This study’s objective is to assess associations between use of current CGM technology and parental function using the PedsQoL Family Impact Module (FIM).

Methods: Parents (n = 95) of a child with T1D completed the FIM and the Holmes and Rahe Stress Scale (HRSS) as a measure of recent stressful life events. Chart data was extracted.

Results: Respondents’ children (52% boys) had a median age of 12.2 years (1.2–20.7), time since diagnosis of 4 years (0–16), and HbA1c of 8.1% (5.5–12.7). Pump use was reported in 77.9% and CGM use in 73.1%, of which 69% reported remote monitoring. CGM users had a median HbA1c of 7.9% (5.9–12.7), versus 8.7% (5.5–10.7). Median Total FIM score confirmed significant impact of diabetes on parental function [70.8 (16–96.5)]. Adjusting for child’s gender, age, race, and HRSS, use of CGM was associated with decreased parental worry, a FIM subscale (11.8 points, 95% CI 1.2, 22.4). Use of remote monitoring did not impact the score.

Conclusions: Our findings demonstrate a link between current CGM technology use and a significant reduction in parental worry independent of remote monitoring. Future research will assess the effect of remote monitoring on parental QoL in children of different age groups.
implementation of strategies to address these barriers is important to ensure maximal efficacy of virtual consultations.

**P295 / #535**

**Topic: AS14-Human factor in the use of diabetes technology**

**EMOTIONS EVALUATION DURING A VIRTUAL CAMP (VC) IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES (T1D) TREATED WITH AN ADVANCED HYBRID CLOSED LOOP SYSTEM (AHCL)**

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**Background and Aims:** Camps for children and adolescents with T1D represent a solid educational and emotional experience. Even if difficult to define and measure, data exist that insulin pump led to improvement in diabetes specific emotional distress. We evaluated the impact of a VC, the first ever to our knowledge, in children and adolescents with T1D using an AHCL system.

**Methods:** During a 3-day VC, held November 2020, 43 children and adolescents [23 F, median age 15 y (IQR 13-17), diabetes duration 10 y (IQR 8-12)] recruited from 19 Italian centers, using AHCL (Control-IQ), for 23–93 days, were evaluated by a psychologist via Zoom meeting using an adapted version of Plutchik’s and Geneva Emotion Wheel. Participants associated emotion concepts with colors, using the provided matching card with 10 standardized emotions/colors to be chosen. A comparison of the general emotions (related or not to T1D) chosen before and after the camp is presented.

**Results:** Daily physical workout, cooking and education sessions, run through Zoom meeting, together with the psychological assessment of emotions felt, accounted for the activities of the virtual camp. Negative emotions evaluated at the end of the camp tended to decrease when compared with the ones perceived before camp (Figure).

**Conclusions:** After the virtual camp, we observed that joy, calm and satisfaction were the predominant emotions, while anger and fear were reduced. It is noteworthy that even a virtual experience has been able to make a positive impact on emotions in young patients with T1D.

**P296 / #542**

**Topic: AS14-Human factor in the use of diabetes technology**

**ONLINE, COMPETENCY-BASED TRAINING TO IMPROVE COMPETENCY, CONFIDENCE AND TROUBLESHOOTING ABILITY WHEN USING THE CAMAPS FX HYBRID CLOSED-LOOP INSULIN DELIVERY SYSTEM**

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**Background and Aims:** Delivering standardised, easily accessible training at scale to healthcare professionals (HCP), people living with diabetes (PWD) and their families/carers (including school support staff) is challenging, especially during COVID-19. High-quality training is a key factor in supporting people make best use of diabetes technologies. Our aim was to deliver competency-based training, improving competency, confidence and troubleshooting ability, using a digital, blended learning approach for a wide range of CamAPS FX hybrid closed-loop (CL) users.

**Methods:** The Cambridge Diabetes Education Programme (CDEP) is a well-established online HCP diabetes training tool. CDEP collaborated with the CamDiab team and experienced clinicians to develop bespoke training. A range of modules were created to refine skills prior to, as well as after starting CL therapy (carbohydrate counting refresher, dana pump refresher, HCP/PWD/teacher CamAPS familiarisation and post-start optimisation). Modules were tested by experts and target audience prior to launch.

**Results:** Since online training was launched in February 2020, 595 people have registered (57% HCPs, 36% PWD and 7% teachers) and 409 (69%) completed training. The impact of training is assessed on a 5-point scale (1 = significantly worse, 3 = no change, 5 = significantly improved) across 3 domains: Competency, confidence and troubleshooting. Qualitative feedback is also captured as part of the 100% mandatory evaluation process which confirms that online training is being very well received.

<table>
<thead>
<tr>
<th></th>
<th>Average Score</th>
<th>Range</th>
</tr>
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<tbody>
<tr>
<td>Competency</td>
<td>4.42</td>
<td>3-5</td>
</tr>
<tr>
<td>Confidence</td>
<td>4.37</td>
<td>3-5</td>
</tr>
<tr>
<td>Troubleshooting</td>
<td>4.33</td>
<td>3-5</td>
</tr>
</tbody>
</table>
Conclusions: Supporting time-limited people to robustly improve their CL skills, confidence and troubleshooting ability is possible at high scale. In fact, due to the inherent flexibility, it is often a preferred approach.

P297 / #544
Topic: AS14-Human factor in the use of diabetes technology

EFFECTS OF A TELEMEDICAL SUPPORTED LIFESTYLE INTERVENTION TO IMPROVE GLYCEMIC CONTROL AND SELF-MANAGEMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM)

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Background and Aims: The key goal of diabetes treatment is to maintain blood glucose at near-normal level. This is extremely difficult for many patients and often requires extensive support from healthcare professionals. Besides drug treatment, lifestyle adjustment plays a crucial role. Nevertheless, only about 10% of diabetics in Germany receive this form of treatment. Telemedical support combined with telephone coaching can help patients with T2DM and improve self-management, self-efficacy, and clinical outcomes.

Methods: A 2-arm randomized study enrolled 151 individuals with T2DM. The control group (N=65, 83.1% male, mean age: 58.8) received usual care. The intervention group (N=86, 80.2% male, mean age: 59.7) received a 12-month support from a telephone coach and a pedometer, blood glucose meter and tablet to record daily values. We recorded HbA1c and BMI as clinical outcomes and information on self-management, self-efficacy, health status as well as economic data in both groups at baseline and after 3, 6 and 12 months.

Results: A significant improvement in HbA1c was observed in the intervention group compared with the control group after 12 months (-0.53; CI: -0.74, -0.31; p < 0.000). Although the effect of reduction was statistically most pronounced 3 months after intervention, BMI, self-management and self-efficacy showed similar progressions.

Conclusions: The combination of personal telephone coaching and telemedical support positively affects clinical outcomes and self-management in people with T2DM. Their application should be further explored in larger trials in both sexes with the aim of systematic implementation in diabetes healthcare.

P298 / #561
Topic: AS14-Human factor in the use of diabetes technology

EASE OF USING IGLARLIXI PEN AFTER INSULIN GLARGINE GLA-100: RESULTS FROM PATIENT AND HEALTHCARE PROVIDER QUESTIONNAIRES FROM THE ONE CAN PEN SUB-STUDY

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Background and Aims: iGlarLixi is a fixed-ratio combination of insulin glargine Gla-100/lixisenatide for treatment of adults with type 2 diabetes uncontrolled on basal insulin. As patients change therapies often, facilitating ease of transition is important. We provided questionnaires to patients and healthcare providers (HCPs) evaluating usability of the iGlarLixi SoloStar® 15–60 unit pen in patients with type 2 diabetes uncontrolled on insulin glargine Gla-100.

Methods: Eligible patients completed a patient-reported outcomes questionnaire of 10 items on ease of use of the iGlarLixi pen 4 weeks after switching from Gla-100; 8 questions were answered 1 (very easy) to 5 (very difficult), 2 questions (continue to use; recommend to others) with yes/no. Stepwise regression analysis was performed to assess drivers for overall usability. HCPs completed 5 items on ease of instruction for use of iGlarLixi 4 weeks after patients switched from Gla-100.

Results: 66 patients completed the questionnaire; 81%–94% chose “easy” or “very easy” for the 8 questions on ease of use. Answers to “ease of dose selection” (p=0.0004) or “required injection force” (p<0.0001) were primary drivers for overall iGlarLixi pen ease of use responses. HCPs from 12 sites completed 48 questionnaires; 85%–96% chose “easy” or “very easy” for pen instruction and 96% recommended the iGlarLixi pen. Median time to train patients was 10 minutes. No responses of “very difficult” were reported by patients or HCPs.

Conclusions: The majority (81%–96%) of patients and HCPs responded that the iGlarLixi pen was easy/very easy to use after transitioning from Gla-100, suggesting a potential influence on patient satisfaction.

P299 / #564
Topic: AS14-Human factor in the use of diabetes technology

THE RELATIONSHIP OF THE HYPOGLYCEMIA FEAR SURVEY (HFS) AND HYPERGLYCEMIA AVOIDANCE SCALE (HAS) TO DAILY CGM READINGS

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Background and Aims: The HFS and HAS questionnaires measure worry and avoidance behaviors related to hypo- and hyperglycemia, respectively. However, the relationship between these constructs and glucose control remains unclear. This study used baseline data from a RCT trial to examine the relationship between HFS/HAS scores and daily CGM readings.

Methods: Data from 120 adults (mean age/SD = 39.7 yrs/13.8) from the parent study was included in the analysis. Most participants used diabetes technology at baseline (55.8% - CGM and insulin pumps, 22.5% - pumps only, 8.3% - CGM only, 13.8% - neither). After consent, participants collected 2-wks of baseline CGM data (Dexcom G6) then completed questionnaires at randomization.

Results: Regressions showed that HFS scores did not predict CGM readings <3.0 or 3.9 mmol/L but did predict more readings >10 (R² = .16, p = .001) and 13.9 mmol/L (R² = .13, p = .001). In both models, the “Maintain High BG” factor was a significant predictor, indicating self-treatment behaviors to keep glucose levels higher to avoid hypoglycemia. Regressions also showed that HAS scores predicted more readings <3.0 (R² = .15, p = .002) and <3.9 mmol/L (R² = .10, p = .001). In both models, the “Low BG Preference” factor was a significant predictor, indicating a willingness to risk hypoglycemia in order to avoid hyperglycemia.

Conclusions: Findings suggest that the HFS and HAS questionnaires are valid measures of individual concerns and self-treatment tendencies aimed at avoiding hypo- and hyperglycemia. These attitudes may have an impact on daily glycemic profiles even in individuals whose diabetes management includes use of sophisticated technology.

P300 / #577

Topic: AS14-Human factor in the use of diabetes technology

EXPERIENCES LEARNED FROM INDIVIDUALS MANAGING TYPE 1 DIABETES USING CLOSED LOOP SYSTEMS

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Background and Aims: Hybrid Closed Loop (HCL) improves glycemic outcomes in individuals with Type 1 diabetes (TID) however there is lack of knowledge regarding their experience in using the system.

Methods: Children and adolescents 12 – 25 years and their parents participated in an interview following a six month randomised clinical trial of HCL. Open-ended questions were used to explore the lived experiences of families. The interviews were analysed and coded using thematic analysis.

Results: Seventeen young people with TID (Mean age: 17.5 ± 4.2yrs, diabetes duration: 11.0 ± 4.9yrs and HbA1c 8.0 ± 0.8%) and 10 parents were included. They reported a positive experience using the HCL system, with improvements in diabetes management. Four main themes were identified: ‘Ownership of diabetes management’, through increased independence with diabetes and less parental responsibility ‘Impact on anxiety’ with reduced anxiety related to nocturnal and post exercise hypoglycaemia ‘Confidence and trust in the system’, related to accuracy and ease of use ‘Issues with device/algorithms’, related to the conservative approach to correction for hyperglycaemia, the size of study devices, and the number and sound of alarms

Conclusions: Young people and parents acknowledge the benefits of the HCL system in improving glycaemic outcomes as well as in providing flexibility and independence. Lived experiences of individuals using the system provide valuable information on the use of the newer interventions in clinical settings.

P301 / #611

Topic: AS14-Human factor in the use of diabetes technology

DIABETES TECHNOLOGY AND ALARMS: SUBJECTIVE DISTRESS IS NOT ASSOCIATED WITH GLUCOSE PARAMETERS

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Background and Aims: Alarms from insulin pumps and CGM systems are important safety features but can also disturb people in everyday life. We analyzed associations between distress due to alarms with general diabetes distress, mood, stress, energy, and CGM-derived parameters.

Methods: In the DIA-LINK study, people with type 1 diabetes completed ecological momentary assessment while using unblinded CGM over 17 days. Every evening, participants rated their daily distress specifically due to alarms (from pumps and/or CGM) from 0 (not at all) to 10 (very much) as well as overall diabetes distress using 5 adapted questions from the PAID questionnaire. Four times a day, they also rated their current mood, stress, and energy levels. Mean daily scores were calculated per participant. Glucose parameters were calculated for the study period (mean glucose, coefficient of variation (CV) of glucose, time in range, time in hypo-, and hyperglycemic ranges). Correlations were analyzed using Pearson’s r.

Results: Data from 203 participants were analyzed showing that on 22% of days, people experienced elevated distress due to alarms. Insulin pump users had no higher distress due to alarms than people without (p = .124). Daily distress due to alarms was associated with higher overall distress, lower mood, higher stress (Table 1). Glucose parameters were not associated with distress due to alarms but with overall diabetes distress.
Conclusions: Distress due to alarms was associated with psychosocial variables but not with glucose variables. This may indicate that when overall well-being is low, alarms may represent a specific source of distress independent from glycemic control.

P302 / #633
Topic: AS14-Human factor in the use of diabetes technology

PATIENTS' ATTITUDES AND BARRIERS TOWARD DIABETES DEVICES: INSULIN PUMPS AND CONTINUOUS GLUCOSE MONITORS- SAUDI ARABIA EXPERIENCE

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Background and Aims: Diabetes Devices (insulin pumps and continuous glucose monitors (CGM)) has been shown to improve glycemic outcome in patients with type 1 diabetes mellitus, uptake of these devices have increased over last decade among Saudi Arabian patients, to promote technology utilization it is essential to understand barriers to device uptake, in this study we described the most common barriers and attitudes endorsed by Saudi Arabian type 1 diabetic patients.

Methods: We shared a previously validated survey with type 1 diabetic patients on diabetes devices barriers and attitudes in Almadinah region of Saudi Arabia, 98 adult type 1 diabetic patients were included (70% of population age 18-50 and 70% of them were female), we explored if there was a difference between different barriers in males versus females.

Results: Majority of patients used CGM with insulin injections followed by insulin pump only and only 10% of patients used pump with CGM. Cost of the device and related accessories was the most commonly endorsed barrier (82%) followed by worriesome that device might not work (27%). Female were more likely to have concerns regarding the shape of the device and what others might think about them wearing the device versus males. In regards to attitudes majority of patients agree that technology made their life better, easier and helped to improve their overall health.

Conclusions: Physicians and health care authorities can proactively assess devices barriers/ attitudes and perception of advantages/burden to encourage device uptake and potentially prevent device discontinuation.

P303 / #648
Topic: AS14-Human factor in the use of diabetes technology

SURVEY STUDY ON USE AND ACCESS TO TECHNOLOGY FOR THE TREATMENT OF DIABETES IN ARGENTINA


Background and Aims: Diabetes is a chronic and prevalent disease that in recent years has acquired socioeconomic importance in our country and all over the world. The innovations developed in the field of treatment are important for the control and quality of life of patients with diabetes, but at the same time they are limited to certain sectors. In our country we currently do not have accurate data on the use of insulin pumps and interstitial measurement devices. For this purpose, from the Innovation Committee of the Argentine Diabetes Society, we prepared a survey study to determine the uses of new technologies for treatment of people with diabetes in order to determine their frequency and accessibility.

Methods: Cross-sectional descriptive observational survey study, including patients of all ages with diagnosis of diabetes from the Argentine Republic. The survey was self-administered through a google questionnaire and disseminated through social networks.

Results: 1078 surveys, 62% were women, 69.1%. Type 1 diabetes, 28.7%. 23% insulin pumps, 14% integrated system and 23% interstitial measurement. Ages of use of technology between 10 and 40 years. 83% of all pumps and 72% of interstitial measurement devices. For this purpose, from the Innovation Committee of the Argentine Diabetes Society, we prepared a survey study to determine the uses of new technologies for treatment of people with diabetes in order to determine their frequency and accessibility.

Conclusions: According to the data of the present survey, the use of technology in Argentina is frequent, especially in people with type 1 diabetes, under 40 years of age belonging to the private health sector. Training for the use of these new technologies does not depend on a structured education team.
Background and Aims: Prolonged exercise remains challenging for T1D management with increased risk of hypoglycemia and hyperglycemia. We evaluated the effects of a four day trek on time below 70 mg/dL (TBR70), Time in Range (TIR), insulin use and need for carbohydrate loading in subjects with T1D using sensor augmented pumps (SAP).

Methods: Adults with T1D using SAP from Latin America were invited. They participated in a 47 km - 4 day trek in Patagonia with a team of 2 physicians and 1 dietitian. The team delivered suggestions for insulin dose reduction and carbohydrate loads. Data from the trek and the 2 previous weeks was obtained, including TBR70 and TIR, basal and bolus insulin. Supplementary carbohydrates were manually registered. Non-parametric analyses were performed.

Results: Eight Minimed 640G® and three 670G® users were included. Mean age was 31.4 years, with 17.5 years of disease duration and BMI 24.8 kg/m2. Average exercise duration was 5.72 hours/day. Comparing with data from the previous 14 days, during the trek TBR70 decreased from 4.7% to 2.0% (p = 0.026), TIR remained unchanged 72.5% vs. 70.6% (p = 0.286), and basal and bolus insulin dose decreased from 16.9 to 13.2 units/day (-28%, p = 0.008) and 23.9 vs. 17.8 units/day (-34%, p = 0.013), respectively, without significant changes in meal carbohydrates (174.7 vs. 192.0 grams/day, p = 0.306). Average supplementary carbohydrate load was 90.3 grams/day, distributed in 11.4 grams/hour in the first 2 hours of exercise and 19.4 grams/hour thereafter.

Conclusions: Prolonged exercise without excessive risk is feasible with the use of SAP with adequate insulin dose reduction and supplementary carbohydrates.

P305 / #718

Diabetes Technology Usage and Self-Efficacy in Patients with Type 1 Diabetes

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Background and Aims: For patients with diabetes, glucose management often requires constant vigilance and care to prevent potentially life-threatening complications. Feelings of powerlessness can negatively impact diabetes management, but diabetes technology may have the potential to improve health outcomes by increasing patient agency. The present study investigated whether Type 1 diabetes (T1D) patients’ use of continuous glucose monitors (CGM) and insulin pumps was associated with higher measures of self-efficacy.

Methods: 2,054 adults with T1D (69% female, 50±16 years) from an opt-in US research panel were surveyed. Respondents’ technology use was categorized as “Pump and CGM” (72%), “Pump only” (5%), “CGM only” (16%), and “Neither pump nor CGM” (7%). Respondents completed the Diabetes Empowerment Scale-Short Form (DES-SF), an 8-item measure assessing diabetes-related psychosocial self-efficacy, with higher scores indicating higher self-efficacy. Health and demographic information were also collected.

Results: The mean DES-SF scores of respondents using a pump and CGM (32.14) or using a CGM only (32.83) were significantly higher than scores of those using a pump only (30.60) or using neither a pump nor CGM (30.80).

Conclusions: This data shows that the use of CGM, with and without an insulin pump, may be associated with higher levels of diabetes-related psychosocial self-efficacy. Designing interventions to improve T1D patients’ use of relevant technologies could improve self-efficacy and diabetes self-management. Longitudinal studies are needed to investigate the long-term psychosocial benefits of technology use in patients.

P306 / #725

Topic: AS14-Human factor in the use of diabetes technology

Self-Reported Physical Fitness, Perceived Barriers, and Glucose Control During a 4-Day Trek in Adults with Type 1 Diabetes

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Background and Aims: Maintaining euglycemia while exercising is challenging for people with T1D and creates barriers to participation in endurance activities. This study evaluated the correlation between self-reported baseline physical activity assessments, perceived barriers to physical activity, and glucose control during a 4-day trek in Patagonia.

Methods: The participants were adults with T1D from Latin America (N = 11, Ages 23-51yrs, mean 30.5yrs). Participants completed the International Physical Activity Questionnaire (IPAQ) and Barriers to Physical Activity in Diabetes (BAPAD-1) assessments prior to the trek. All subjects used CGM and insulin pump (8 Minimed 640G® and 3 Minimed 670G®). Insulin and carbohydrate decisions were self-directed with the counsel...
of the medical team. The trek included 22 hours of activity over 4 days.

Results: During exercise, the average time in range (TIR), 70–180 mg/dL, was 70.6% (±10.3%) and time above range (TAR), >180 mg/dL, was 27.4% (±11.2%). All subjects fell into category 2 or 3 (moderate or high activity level) on the IPAQ. The baseline net/min/week (as estimated by the IPAQ) showed a moderate positive correlation with TAR, and a moderate negative correlation with TAR on the trek. BAPAD-1 assessment for fear of losing control of diabetes showed a strong negative correlation to TIR, and a strong positive correlation to TAR (p < 0.05). Fear of hypoglycemia did not show any significant correlation.

Conclusions: For subjects on a multi-day endurance trek there was a significant positive correlation between fear of losing control with TAR. Assessing fear of losing control prior to significant physical activity may allow for focused efforts on those who need more assistance.

P307 / #771

Topic: AS14-Human factor in the use of diabetes technology

PSYCHOLOGICAL CARE FOR CHILDREN AND ADOLESCENTS WITH DIABETES-PRELIMINARY RESULTS FROM THE INTERNATIONAL PEDIATRIC REGISTRY SWEET

Psychological care to adolescents and children with diabetes is important for their long-term health and well-being. As a result, their health will be better and it will decrease risk for complications and help them maintain good health in the long term. Health-related-quality of life (HRQoL) is a useful index for evaluating conditions of health and management of patients. Aims of study to evaluate HRQoL of older adult patients with type-2-diabetes (T2DM) and to identify how well useful index for evaluating conditions of health and management of patients. Aims of study to evaluate HRQoL of older adult patients with type-2-diabetes (T2DM) and to identify how well useful index for evaluating conditions of health and management of patients. Aims of study to evaluate HRQoL of older adult patients with type-2-diabetes (T2DM) and to identify how well useful index for evaluating conditions of health and management of patients.

Background and Aims: To evaluate the availability and access to psychological care and its structure in centers participating in the SWEET (Better control in Paediatric and Adolescent diabetes: Working to create Centers of Reference) registry (including 2019 data of 34,912 subjects ≤18 years with T1D).

Methods: All centers (n = 112) were invited to a structured online survey providing information on their psychology service.

Results: 92 (82%) survey responses from SWEET centers were obtained. In majority centers (78%) have national guidelines recommending integrated psychological care. Among survey responders, psychological care is offered by 88% of centers, usually by a regular employee (83%) – psychologist or other mental health professional (MHP). 62% of centers have 0.1-0.5 and 14% ≥1 MHPs/100 patients. The total full time equivalent of MHPs/100 patients is ≤0.3 in 58% and >0.5 in 14% centers. Families cover the consultation costs partially in 14% and fully in 12% of centers. In almost all (94%) centers offering psychological services psychological support is given at T1D diagnosis. In equal percentages of centers (39%) patients are later referred to psychologists/MHPs by physicians or arrange an appointment themselves. In 21% of centers there is a systematic, at least annual, psychological consultation. One third of centers use a structured tool for psychological assessment.

Conclusions: International pediatric guidelines recommend easy accessibility of psychosocial care for children and adolescents with T1D and their families. In our study among SWEET registry, most centers offer psychological support to their patients. There is widespread heterogeneity in the resources, national guidelines and organization of psychological care.

P308 / #52

Topic: AS15-Trials is progress

DESCRIPTIVE CROSS SECTIONAL STUDY OF HEALTH RELATED QUALITY OF LIFE AMONG 140 ADULT PATIENTS WITH TYPE 2 DIABETES AT PREAH KOSSAMAK HOSPITAL IN CAMBODIA

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Background and Aims: Quality-of-life (QoL) has a crucial role and a positive impact on diabetic patient because when having better quality of life, they will take good care of themselves. As a result, their health will be better and it will decrease risk for complications and help them maintain good health in the long term. Health-related-quality of life (HRQoL) is a useful index for evaluating conditions of health and management for patients. Aims of study to evaluate HRQoL of older adult patients with type-2-diabetes (T2DM) and to identify how well an individual would be able to handle his disease and maintain his long-term health and well-being.

Methods: A-Descriptive-Cross-Sectional study involve patient with T2DM in outpatient at Preah Kossamak Hospital in Phnom Penh from March-April in 2020. Patients were selected using by face-to-face interview based on ED-5Q-3L and VAS
score. 140 patients who met eligibility criteria were selected in study using probability sampling-technique. Data analysing SPSS.

Results: Among patients (52 males and 88 females) who have mean age around 58.6 years-old, mostly married, from various education level, have EQ-5D-3L scores with no problem: Mobility (77.1 %), self-care (97.1 %), usual activities (90.7 %), pain/discomfort (45.0 %) and anxiety/depression (46.4 %). VAS Score in male is much better than female, 66.3 vs. 62.4 respectively with significant p-value 0.044. Otherwise duration of diabetes and type of medication significantly decrease quality of life showed by VAS score.

Conclusions: Quality-of-Life for patients with T2DM is affected by numerous factors such as sex, BMI, occupation, duration of diabetes and type of treatment.

P309 / #67
Topic: AS15-Trials is progress
TRANSITION FROM INSULIN PUMP TO MULTIPLE DAILY INJECTIONS USING INSULIN DEGLUDEC: INTERIM RESULTS FROM A RANDOMIZED CONTROLLED TRIAL
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Background and Aims: We evaluated the efficacy and safety of an ‘overlap’ strategy (OLS) compared to standard of care (SOC) for insulin pump (CSII) to multiple daily injections (MDI) transition using an ultralong acting insulin degludec (IDeg) in adults with type 1 diabetes (T1D).

Methods: In this single center randomized clinical trial, adults with T1D > 1 year, using CSII for >3 months, and A1c between 6.5% and 8.5% were randomized to OLS or SOC after 1 week of run-in-phase. Participants were blinded Dексom G6 and insulin dose was not changed during the trial. Participants stopped CSII and started IDeg in 1:1 dose (same as total basal insulin) at randomization in SOC. In OLS, IDeg in 1:1 dose and CSII basal insulin were overlapped (50% basal reduction for 24 hours and 75% basal reduction between 24–48 hours) for first 48 hours from randomization. CGM time-in-range (TIR- 70–180 mg/dL) and time below range (TBR, <70 mg/dL) were compared after randomization.

Results: Nine adults with T1D (age 33.8 ± 3.8 years, A1c 7.5 ± 0.3%, diabetes duration 21.8 ± 3.8 years, 62% females) were randomized to SOC, and seven adults with T1D (age 36.7 ± 10.2, A1c 7.2 ± 6.5%, diabetes duration 23.0 ± 15.1, 57% females) were randomized to OLS. Percent differences for TIR was significantly higher and no differences in TBR in OLS compared to SOC (Figure).

Conclusions: Overlap of IDeg and insulin pump for first 48 hours results in better glycemic control without increasing hypoglycemia during transition to MDI using IDeg in adults with T1D.

P310 / #244
Topic: AS15-Trials is progress
CAN AN ADVANCED LANCING DEVICE ALLEVIATE PAIN AND IMPROVE HBA1C?
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Background and Aims: Pain has been perceived as a major impediment to SMBG. We assessed benefits of using Genteel, vacuum based lancing device in improving HbA1c and pain of pricking. NCT04214704

Methods: This is the interim result of an ongoing, open-label, 24-week cross over trial where diabetes patients were matched using propensity score and allocated to GC or CG arm (G- Genteel; C- Conventional). GC arm exclusively used Genteel for 12 weeks, and then switched to conventional method of SMBG for additional 12 weeks, and vice versa for CG arm. A total of 110 patients were recruited with 55 in each arm. Both arms were provided with same glucometer. CG arm used the lancet and lancing device which they were using prior to randomization and GC used BT Lancets during first 3 months. Primary outcomes were reduction in HbA1c and %SMBG adherence over 24-weeks. Subjective assessment of pain in both arms was assessed.

Results: Data from 22 patients(13 TIDM, age: 25 ± 8.29, duration of diabetes 10 ± 7.12y) and 9 T2DM, age: 43 ± 13.40, duration of diabetes: 11 ± 6.75y) showed a significant reduction in A1c in both arms while using Genteel(9.05 ± 0.93% at baseline to 7.76 ± 0.84% at week 12 in GC arm and 7.52 ± 1.22% at 12 to 7.21 ± 0.90% in CG arm at 24 weeks; p < 0.001*). This was reinforced by increased SMBG adherence to Genteel due to alternate testing sites and contact tips.

Conclusions: This study demonstrates Genteel superior in terms of A1c reduction and pain of pricking.

P311 / #265
Topic: AS15-Trials is progress
SHORT-TERM USAGE OF A CLOSED-LOOP INSULIN DELIVERY SYSTEM FOR IMPROVING OPTIMIZATION OF INSULIN DOSES: A TRIAL PROTOCOL
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Figure 1: Difference in time in range (%) [Figure 1a] and time spent below 79 mg/dL [Figure 1b] between standard of care (SOC) and overlap (OLS) group during first week after transition from insulin pump to multiple daily injections using long acting insulin degludec U-100.
Background and Aims: Closed-loop insulin delivery systems may be viable for treating type 2 diabetes. However, this is not always feasible, and the price is a barrier for long-term usage in a large proportion of patients. The novel objective of the present study is to investigate whether short-term usage of a closed-loop system can improve optimization of insulin doses under free living conditions.

Methods: The design is a randomized, parallel-arm study with 32 basal-only or MDI treated patients with type 2 diabetes. Participants will have a 2-week run-in period continuing their current insulin therapy while wearing a CGM. Participants will then be randomized 1:1 into a closed-loop arm or a standard insulin therapy arm. In the closed-loop arm, participants will use a closed-loop system for 30 days. Afterwards, participants will transition to standard insulin therapy for 30 days wearing a CGM, where insulin doses are optimized every 5–7 days. In the standard insulin therapy arm, participants will continue standard insulin therapy for 30 days wearing a CGM, where insulin doses are optimized every 5–7 days. The primary outcome of the study is to assess the efficacy of a closed-loop system in maintaining CGM glucose levels within the target range from 3.9 to 10.0 mmol/L compared to standard insulin therapy.

Results: The study is expected to begin in the summer of 2021, and the results published from the spring of 2022.

Conclusions: The study will reveal whether a closed-loop system can lead to better glycemic control and provide insights on patient-tailored optimization of insulin doses.

P312 / #268

Topic: AS15-Trials is progress

ASSOCIATION OF DIABETIC NEPHROPATHY WITH INSTRUMENTS FOR PREDICTION OF CARDIOVASCULAR RISK IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Cardiovascular diseases (CVD) were the cause of death in 31.9% patients with type 1 diabetes (T1D). Patients with diabetic nephropathy (DN) have type 1 diabetes (T1D). Patients with diabetic nephropathy (DN) have type 1 diabetes (T1D). There are two T1D specific scales for predicting CVD risk. To evaluate association of DN with T1D specific scales predicting CVD risk.

Methods: Screening of 176 T1D patients was performed: age 32 years [25.5–42.5]; T1D duration 15 years [9–20]; HbA1c 8.2% [7.2–9.6]; 68.2% had normal albuminuria, 27% microalbuminuria, 4.5% macroalbuminuria, median 25.5 mg/day [15.0–36.5]. Mean eGFR (CKD-EPI) 80.55 ± 18.011 ml/min/1.73m²; C1 30.1%, C2 58.5%, C3a 8.5% and C3b 2.9%. Steno T1 Risk Engine scale 5-year risk 3.7% [2.1–8.0], 10-year risk 7.1% [4.2–8.15]. Swedish T1D risk score 5-year risk 0.93% [0.50–1.79]. The median CVD risk was rated as low for both scales.

Results: There were significant direct correlation of albuminuria stage and inverse correlation of eGFR with 5-year risk (r=0.388 and r=-0.506; p<0.0001), 10-year risk (r=0.393 and r=-0.400; p<0.0001) in Steno scale and risk in Swedish scale (r=0.189; p=0.012 and r=-0.497; p<0.0001). There is high density positive correlation between Steno and Swedish risk score (r=0.893; p<0.0001).

Conclusions: Steno and Swedish T1D risk scales correlate with CVD and mortality than patients without DN. Prevention and treatment of CVD have been extrapolated from type 2 diabetes experience. There are two T1D specific scales for predicting CVD risk. To evaluate association of DN with T1D specific scales predicting CVD risk.

Background and Aims: Repeated induction of beta-cell rest, by episodes of intensified insulin treatment, is part of the ongoing, RCT AIDIT study protocol aiming at preservation of beta-cell function in children recently diagnosed with type 1 diabetes. All children are treated with SAP from diagnosis and normally aiming for a blood glucose value 4.0-8.0 mmol/L. In this report, beta-cell rest induced by insulin given intravenously and subcutaneously is evaluated.

Methods: Insulin lispro is given as an intravenous (iv) infusion (1U/ml) for 72 hours within one week after diagnosis and by sc subcutaneous (sc), intensified infusion with a Tandem T:slim insulin pump (100U/ml) 6–8 hours during one day in study week 5, 9, 13, 17, 25, 34, 43. The treatments target a glucose level of 4.0 ± 0.5 mmol/L. Dexcom G6 and p-glucose (Stat-Strip) are used for glucose monitoring. Extra insulin diluted to 10 U/ml can be given iv when needed during sc treatment. The
efficacy of the beta cell rest is evaluated by measurement of C-peptide, analyzed by ELISA (Ultrsensitive C-peptide, Mercydia, Uppsala, Sweden).

**Results:** So far, seven out of 14 included children aged 6.0–15.9 years with newly diagnosed T1D are randomized to the study protocol treatment. All had a stimulated c-peptide above 200 pmol/L six weeks after inclusion. 5/7 intravenous insulin treatments and 27/39 subcutaneous insulin treatments resulted in induction of beta cell rest, defined as c-peptide <100 pmol/L during the treatment.

**Conclusions:** Beta cell rest can be induced by intensive insulin treatment by infusing insulin either intravenously or subcutaneously.

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**P314 / #727**

**Topic:** AS15-Trials is progress

**THE ASSESSMENT OF IMPACT OF REAL-TIME CONTINUOUS GLUCOSE MONITORING ON PEOPLE PRESENTING WITH SEVERE HYPOGLYCAEMIA (AIR-CGM) STUDY**

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**Background and Aims:** Severe hypoglycaemia in type 1 diabetes (T1D) is associated with morbidity, mortality, and emergency health service utilisation. We analysed preliminary data assessing the impact of real-time continuous glucose monitoring (CGM) provided early to people with T1D following severe hypoglycaemia.

**Methods:** Twelve-week randomised controlled trial of adults with T1D and severe hypoglycaemia attended by the London Ambulance Service (LAS). Participants were randomised within 72 hours to receive real-time CGM (Dexcom G6) or standard care and were contacted weekly by a specialist to optimise treatment. The control group wore blinded CGM at weeks 1 and 2, 4 to 6, and 9 to 12. Changes in percentage time in hypoglycaemia, time in range, and glycaemic variability were compared from baseline and endpoint between groups.

**Results:** Thirty-five participants were consented. After withdrawals, 15 completed the CGM intervention, 8 in the control group reached the endpoint. The CGM group had a significantly greater reduction in % time in hypoglycaemia (<54 mg/dL and <50 mg/dL) and low blood glucose index compared to the control group. Both groups had reductions in the mean glucose and mean absolute glucose (mean of absolute change per hour in glucose level derived), with significantly greater reductions in the control arm.

**Conclusions:** Rapid provision of CGM immediately following severe hypoglycaemia improves measures of hypoglycaemia compared to standard care. While regular specialist advice appears to improve glycaemic variability measures, it is not sufficient to reduce hypoglycaemia in the control group. Immediate provision of CGM after severe hypoglycaemia may mitigate or prevent further events.

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**P315 / #360**

**Topic:** AS16-COVID-19 and Diabetes

**HIGHER LEVELS OF SOCIAL DEPRIVATION ASSOCIATED WITH INCREASED PERCENTAGE TIME IN RANGE IN PEOPLE WITH TYPE 1 DIABETES DURING COVID-19 LOCKDOWN**

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**Background and Aims:** The Covid-19 pandemic required strict lockdown with rigid restrictions imposed by public health authorities to prevent viral transmission. We sought to assess the interaction between social deprivation and glycaemia during lockdown in people with type 1 diabetes.

**Methods:** We performed a retrospective, observational analysis in adults and children attending a specialist centre in London, UK, using real-time continuous glucose monitoring or flash monitoring. Continuous glucose data over 28 days prior to lockdown were compared with the same duration during lockdown, and assessed for percentage time in range (%TIR), as well as glycaemic variability measures. Socioeconomic deprivation was assessed using English Indices of Deprivation 2019.

**Results:** Multivariable linear regression analysis in 145 individuals on multiple daily injections and continuous insulin infusion revealed the most socially deprived group had an increased %TIR 3.9-10mmol/l (70 -180mg/dL; coefficient: 4.208, 95% CI 0.588 to 7.828; p=0.02). In addition, a negative association was observed with change in %time above range >10mmol/L (≥180mg/dL; coefficient: -4.746, 95% CI -8.771 to -0.721; p=0.02). Individuals in the lower 50% of the deprivation scores (deciles ≤4 indicating most deprived vs deciles ≥5) had significantly greater change in %TIR during lockdown than those in the upper 50% (change %TIR +3.25 (-0.38 to 8.71) vs +1.79 (-3.61 to 4.73) respectively; p<0.05).

**Conclusions:** Glycaemia in people improved during lockdown, with individuals from more deprived areas most likely to benefit. This is likely to be due to a complex interaction of social, behavioural, and environmental factors which warrant further investigation.

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**P316 / #449**

**Topic:** AS16-COVID-19 and Diabetes

**THE COVID-19 PANDEMIC AND NEW ONSET PEDIATRIC TYPE 1 DIABETES AT CHILDREN'S NATIONAL HOSPITAL**

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**Background and Aims:** Reports have varied about the impact of the COVID-19 pandemic on the incidence and severity of
pediatric T1D presentation. We investigated changes in T1D initial clinical presentation and patient demographic characteristics during COVID-19.

**Methods:** A retrospective cross-sectional review of youth diagnosed with T1D during the COVID-19 pandemic (3/11/2020-11/30/2020) and in the time-matched period in 2019 was conducted at an American pediatric tertiary-care center. ICD-10 code, age, BMI Z-score, and positive autoantibodies at diagnosis were used to assess for T1D, with confirmation by chart review. Chi-square, Fisher’s exact, and independent samples t-tests were used for analyses.

**Results:** Cases of new onset T1D did not change from 2019 (n = 118, Mage = 10.0 ± 4.4 years) to 2020 (n = 119, Mage = 9.6 ± 4.3 years). Only 2 youth were COVID-19 positive at diagnosis. While the incidence of DKA (50.4% vs 59.3%) did not significantly increase during the pandemic, more youth presented with severe DKA (p = 0.01) and fewer with mild DKA (p = 0.03). Statistics regarding race and ethnicity were unchanged, however the proportion of youth diagnosed with T1D who were publicly insured increased from 40.3% in 2019 to 55.1% during the pandemic (p = 0.05).

**Conclusions:** Although the incidence of T1D was unchanged in the first 9-months of the COVID-19 pandemic, a greater proportion of youth were publicly insured and more presented with severe DKA. Recent reports have shown higher rates of COVID-19 infection among socioeconomically disadvantaged youth and given higher rates of DKA at diagnosis in this population, viral-induced autoimmunity from COVID-19 infection may contribute to these findings.

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**P317 / #504**

**Topic:** AS16-COVID-19 and Diabetes

**ONLINE SURVEY “COVIDENTARY”: IS COVID-19 LEADING CHILDREN WITH TYPE1 DIABETES TO SEDENTARY BEHAVIOR?**

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**Background and Aims:** Physical activity (PA) is a crucial component in the management of type 1 diabetes (T1D). We explored by online system the PA level and describe variation in glycaemic values before and during the restrictions caused by Sars-Cov-2 pandemia (COVID-19) in Italian children with T1D.

**Methods:** Parents or guardians of children with T1D (< 18 years) filled out an online survey. Anthropometric characteristics, PA, play and sport and sedentary time were collected before and after the introduction of restrictions. Moreover, we investigated the medical related factors.

**Results:** A total of 280 children and adolescents (mean age was 11.8 ± 3.3 years; 58.5% M) were included in the analysis. Before and after the introduction of restrictions, we reported a significant decline in participation in sport activities (–2.1 ± 2.1 h/week) and reduction in time spent in outdoor plays (–73.9 ± 93.6 min/day). Moreover, we reported a significant increase in sedentary time (+147.7 ± 147.8 min/day). Finally, an increase in mean glycaemic values (–25.4 ± 33.4 mg/dL) and insulin delivery (in 71.8% of patients) were also recorded.

**Conclusions:** A decline in participation in sport activities and a significant increase of sedentary time can influence the management of T1D of children and adolescents, influencing the risk of acute and long term complications. Online exercise programs may be useful to maintain both health and wellbeing of youth with T1D.

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**P318 / #525**

**Topic:** IMPACT OF COVID-19 PANDEMIC ON PROVISION OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) AND CONTINUOUS GLUCOSE MONITORING (CGM) STARTS AND RENEWALS IN THE UNITED KINGDOM (UK)

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**Background and Aims:** Routine diabetes clinical activity has been significantly reduced due to the COVID-19 pandemic. The diabetes technology network (DTN)-UK aimed to establish the impact of the pandemic on diabetes technology provision in the UK.

**Methods:** We conducted an online survey of members of the DTN-UK that comprises health care professionals (HCPs) involved in the care of people with Type 1 diabetes (T1D) between November and December 2020.

**Results:** Of 143 eligible responses, 61 (42.7%) were from consultants, 52 (36.4%) were from diabetes specialist nurses, 22 (15.4%) were from dieticians and 7 (4.9%) were from trainees.
Among insulin pump users, women and older respondents assessed the risk of becoming seriously ill if infected with COVID-19 as higher.
THE EFFECT OF LOCKDOWN AND EASING OF RESTRICTIONS ON GLYCAEMIA IN CHILDREN WITH TYPE 1 DIABETES DURING THE COVID-19 PANDEMIC


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Background and Aims: The U.K. government imposed a strict lockdown to slow SARS-Co-V2 transmission on 23rd March 2020. We investigated the impact of lockdown and the relaxation of restrictions on glycaemic control for children with type 1 diabetes (T1D).

Methods: This was an observational study in children and adolescents with T1D using real-time continuous glucose monitoring (RT-CGM) or intermittently scanned CGM (isCGM) under the paediatric team at a specialist urban U.K. centre. Data was collected from four 28 day periods: 1) before lockdown, 2) during lockdown, 3) immediately after lockdown and 4) a month later after further relaxation of restrictions. Children with >70% monitoring data in each time period were included. Friedman test compared glycaemic variables between the four time periods.

Results: Thirteen children and adolescents met the criteria; 8 male (61.5%), 5 (38.5%) using RT-CGM, median (IQR) age 10.1 (8.1–13.8) years, diabetes duration 2.7 (2.0–4.6) years and HbA1C 61 (57–72) mmol/mol. There was no statistically significant difference (p > 0.05) across the four time periods in percentage time in range (70–180mg/dL), euglycaemia (70–140mg/dL), above range (>180mg/dL or >250mg/dL) or time below range (TBR) (<70mg/dL or <54mg/dL). There was significant variation in percentage TBR (<50mg/dL) (p = 0.025) with median percentages during observation periods 1–4 of 0.08, 0.24, 0.18 and 0.05, respectively.

Conclusions: There was no change in glycaemic variables before, during and after lockdown, except in TBR (<50mg/dL), which increased during lockdown and immediately post-lockdown, suggesting a more intensive attention to glucose-lowering during these periods.

P322 / #601

Topic: AS16-COVID-19 and Diabetes

SHORT-TERM IMPACT OF COVID-19 PANDEMIC LOCKDOWN ON METABOLIC CONTROL OF PATIENTS WITH TYPE 2 DIABETES MELLITUS.

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Background and Aims: On March 15, 2020, Spanish government decreed severe lockdown measures with restriction of physical outdoor activities, social interactions and health centers focused in COVID. It is well-known that diabetic patient benefits from physical activity and appropriate nutrition. Aim: to analyze the trend of metabolic controls in patients with type 2 diabetes (T2D), during the COVID lockdown in our country.

Methods: Observational study in Primary Care. Clinical and analytical variables of all patients with T2D belonging to a contingent are collected, evaluating: age, sex, years of diabetes evolution, treatment, anthropometric parameters and laboratory figures (including cholesterol, triglycerides, A1c) as well as an assessment, once the end of the alarm state has been declared, of the appropriate measure for that specific patient.

Results: Of 120 subjects analyzed, data can be obtained before/after lockdown in a total of 75 (62.5%), 39 (52%) men. Mean glycemic values have increased from a mean of 139.2 ± 43.8 to 154.6 ± 57 (p = 0.008), blood pressure from 131 ± 12.9/77.6 ± 9.7 mmHg to 132.1 ± 14.8/77.5 ± 9.2 (p < 0.001). The mean HbA1c value went from 7.29 ± 1.22 before confinement to 7.61 ± 1.73 after (p = 0.025). Body mass index raised from 27.9 ± 4.6 to 30.3 ± 1.6 (p = 0.001). The requirements once the lockdown was finished, were in 30.7% to intensify the treatment; in 12% add or change a drug and in 5.3% start insulinization. A total of 30 subjects (40%) suffered a worsening (A1c increase greater than 0.3%).

Conclusions: Confinement has worsened, in a short space of time, control parameters of patients with T2D from a medical contingent. Approximately 4 out of 10 subjects have suffered a worsening.
pre-lockdown (p = 0.04), which was sustained thereafter. Percentage time below range (<70mg/dL) did not change throughout the 4 time periods.

**Conclusions:** Glycaemia in adults improved during lockdown, and this effect was sustained for 2 months after easing of restrictions. The “Eat Out to Help Out” scheme in the UK had no adverse impact on glycaemia.

**P324 / #664**

**Topic: AS16-COVID-19 and Diabetes**

**TYPE 1 DIABETES DURING THE SARS-COV-2 PANDEMIC. DOES LOCKDOWN AFFECT THE METABOLIC CONTROL OF PEDIATRIC PATIENTS?**

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**Background and Aims:** Due to the SARS-Cov-2 epidemic, governments of many countries, decided to implement the lockdown, which included schools closure. This major lifestyle change also applies to people with diabetes. The aim of this paper was to analyze how COVID pandemic and related restrictions influenced metabolic compensation of diabetes in pediatric population.

**Methods:** 128 patients with type 1 diabetes (T1D) were included into the study (74 boys), aged 2–18 years (12.3 ± 3.5), treated by one therapeutic team, who in 2020 paid at least two visits in the outpatient clinic, 98 of them (76.6%) use CSII, 98 (76.6%) use CGM. AVBG, TIR, CV and HbA1c, as well as Total Daily Dose of insulin (TDD) and BMI from the visit before the announcement of the pandemic restrictions (March 2020) and during the lockdown (second visit after 6 months) were analyzed.

**Results:** Despite comparable AVBG (165.4 ± 46.5 mg/dL vs. 164.3 ± 40.5 mg/dL), TIR (57.5 ± 21.4% vs. 59.9 ± 20.5%) and CV (41.3 ± 9.2% vs. 38.9 ± 10.0%), HbA1c during the pandemic period improved (7.9 ± 1.6% vs. 7.5 ± 1.4%, p = 0.0336). Also, TDD increased significantly (from 37.3 ± 18.9 units/day to 41.7 ± 21.1 units / day, p < 0.0001), however TDD / kg remained constant (0.8 ± 0.75 units/kg/day vs. 0.81 ± 0.21 units/kg/day), possibly due to increased BMI (19.1 ± 3.7 kg/m² vs. 20.1 ± 3.6 kg/m², p < 0.0001). Also % of basal insulin in TDD remained stable (39.7 ± 11.3% vs. 39.4 ± 11.3%).

**Conclusions:** The parameters of metabolic control in pediatric patients with type 1 diabetes during the pandemic period remained stable, however weight gain and an increase in daily insulin dose have been observed, possibly due to reduced physical activity.

**P325 / #755**

**Topic: AS16-COVID-19 and Diabetes**

**EFFECT OF SCREEN TIME ON GLYCAEMIC CONTROL OF TYPE 2 DIABETES PATIENTS DURING COVID-19 OUTBREAK: A SURVEY BASED STUDY**

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**Background and Aims:** Decreased workout during coronavirus disease 2019 (COVID-19) is a serious issue for the patients with type 2 diabetes (T2DM), since their glycaemic control is very much related to that. Data on adult T2DM patients’ screen time activity and prevailing glycosylated haemoglobin (HbA1c), fasting blood sugar (FBS) and, post-prandial blood sugar (PPBS) is sparse. To study the effect of screen-time spent on social media per day on glycaemic parameters of T2DM patients.

**Methods:** Data was collected for T2DM patients giving informed written consent and meeting a set of pre-specified inclusion criteria. Through two rounds of surveys done from May 15 to June 26, the authors collected the answers to a set of questionnaires sent via email.

**Results:** A total of 173 patients had a screen time (henceforth, it means time spent on social media) of less than 2 hours/day in the study sample. Among the 173 patients, 73 (42.2%) had achieved HbA1c less than 7%, whereas the remaining 100 (57.8%) had HbA1c more than 7%. It was found that the odds of having a poor glycaemic control as per HbA1c, FBS and PPBS is 2.67 times higher (95%CI: 1.91-6.95), 4.34 times higher (95%CI: 1.52-4.76) and, 8.26 times higher (95% CI: 4.26-11.83) in the cohort with a screen time of more than 2 hours as compared to the cohort with a screen time of less than 2 hours, respectively.

**Conclusions:** There seems to be an increased risk of uncontrolled glycaemic indices with increased screen time and, decreased work out.

DOI: https://doi.org/10.1101/2020.09.09.20188961
Background and Aims: Data show increased incidence of diabetic ketoacidosis (DKA) at diabetes onset in youth during the COVID-19 pandemic. To compare the characteristics at presentation of pediatric patients with newly-diagnosed type 1 diabetes mellitus (T1DM) one year prior and during the COVID-19 pandemic.

Methods: All patients (0–18 years) with newly-diagnosed T1DM from March to February in 2 subsequent years (2019/20 and 2020/21) were enrolled in the study. DKA was defined according to ISPAD criteria.

Results: A total of 76 youth with newly-diagnosed T1DM were identified. The DKA incidence did not increase (Tabl. 1). In the “pandemic” group (PG) the blood ketones, BGL and HbA1c% at admission were higher compared to the “non-pandemic” group (NPG), Tabl. 2. Time spent on i.v. insulin infusion (hours) was longer during the pandemic (12 ± 2.6 vs 10 ± 2.6, p = 0.002).

Conclusions: This study shows no increase of the DKA rate at T1DM onset opposite to the majority of the published data. The relatively low COVID-19 morbidity, easy hospital accessibility, and other contributing factors are suggested.
R001 / #649
Topic: AS01-Closed-loop System and Algorithm
SAFETY AND PERFORMANCE OF THE AUTOMATED ALGORITHM OF MINIMED 780G ADVANCED HYBRID CLOSED-LOOP UPON FAST TRACK INITIATION OF THERAPY
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R002 / #294
Topic: AS03-Artificial Pancreas
A CASE-REPORT DEMONSTRATING IMPROVED GLYCAEMIA DURING RAMADAN FASTING USING AN OPEN-SOURCE AUTOMATED INSULIN DELIVERY SYSTEM COMPARED TO ISC-GM-AUGMENTED INTENSIVE THERAPY IN TYPE 1 DIABETES
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R003 / #320
Topic: AS04-Clinical Decision Support Systems/Advisors
AI-BASED PERSONALISED DIABETES MANAGEMENT GUIDANCE THROUGH THE INTELLIGENT MODULES OF THE DM4ALL PLATFORM
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R005 / #49
Topic: AS05-Glucose Sensors
UTILITY OF FLASH GLUCOSE MONITORING TO DETERMINE GLUCOSE LOAD IN PATIENTS WITH TYPE 2 DIABETES
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R006 / #548
Topic: AS05-Glucose Sensors
CONTINUOUS GLUCOSE MONITORING USE IN DIABETICS- AN ACADEMIC MEDICAL CENTER FROM PAKISTAN’S EXPERIENCE
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R007 / #738
Topic: AS05-Glucose Sensors
CONTINUOUS GLUCOSE MONITORING SYSTEMS IN PUMP INSULIN THERAPY OPTIMIZATION IN A PATIENT WITH TYPE 1 DIABETES MELLITUS
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R008 / #300
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
TELEMEDICINE: A NOVEL APPROACH FOR THE MANAGEMENT OF NEW ONSET TYPE 1 DIABETES IN PEDIATRICS DURING THE COVID 19 PANDEMIC IN PATAGONIA ARGENTINA
F. Grabois1, M. Casullo1,2, C. Cruz1, T. Puliafato1, D. Recalde3, K. Vignoni4
R009 / #518
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
ADVANCED HYBRID CLOSED LOOP SYSTEM IN A TEENAGER USING VIRTUAL PUMP TRAINING PROGRAM: A CASE REPORT
G. Petrovski, J. Campbell, F. Al Khalaf, D. Almajaly, K. Hussain
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R010 / #537
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
THE BENEFITS OF SUPPORTING TYPE 1 DIABETES DECISION-MAKING WITH MOBILE HEALTH APPS
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R011 / #642
Topic: AS06-Informatics in the Service of Medicine; Telemedicine, Software and other Technologies
EFFECTS OF THE AUTOMATIC CALCULATION OF PRANDIAL INSULIN BOLUS THROUGH A MOBILE PHONE APPLICATION ON A1C AND QUALITY OF LIFE IN TYPE 1 DIABETES PEOPLE
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R012 / #289
Topic: AS07-Insulin Pumps
GLUCOSE CONTROL DURING CORONAVIRUS DISEASE IN TYPE 1 DIABETES PATIENT ON SENSOR AUGMENTED PUMP
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R013 / #108
Topic: AS08-New Medications for Treatment of Diabetes
SGLT2 INHIBITOR-INDUCED DIABETIC KETOACIDOSIS (DKA) IN ACUTE MEDICAL SETTING: WOULD YOU RECOGNISE IT?
H.Y. Sanda
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R014 / #772
Topic: AS08-New Medications for Treatment of Diabetes
CALYSTEGINES ALLEVIATE HYPERGLYCEMIA AND HYPERINSULINEMIA INDUCED IN HUMAN LIVER CELLS THROUGH THE MODULATION OF SIRTI/FOXO1/G6PC/MTOR SIGNALING PATHWAY
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R015 / #427
Topic: AS10-Devices Focused on Diabetic Preventions
STUDY BERA IN TYPE 2 DIABETIC PATIENTS AT VARYING FREQUENCIES
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R016 / #20
Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes
METABOLIC BLOCKS AND INSULIN RESISTANCE
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R017 / #533
Topic: AS12-New Technologies for Treating Obesity and Preventing Related Diabetes
LOW APELIN-TO-NT-PRO-BRAIN NATRIURETIC PEPTIDE RATIO PREDICTED HEART FAILURE WITH PRESERVED EJECTION FRACTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
A. Berezin1, I. Fushtei1, A. Berezin2
The impact of the number of meals and supper nutritional composition on glycemic profile of pregnant women with gestational diabetes mellitus

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Effects of metformin treatment on non-alcoholic fatty liver disease

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Implementing digital diabetes care in a developing country – a qualitative study on physicians’ perspective

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Complications of type 2 diabetes in patients admitted to internal medicine department

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Microdialysis techniques in diabetic foot syndrome – first experiences (DFIAMT study)

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Preventing poor glycemic control in type 1 diabetes mellitus in patient with COVID-19

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Nutricion, San Luis, Argentina, 15Roche, Área Diabetes, Educación, Rosario, Argentina, 16Hospital Pedro Elizalde, Diabetes Y Nutricion, Buenos Aires, Argentina, 17Universidad Hospital Italiano, Diabetes, Buenos Aires, Argentina, 18Universidad Favaloro, Endocrinologia Y Diabetes, Buenos Aires, Argentina, 19Instituto Medico Rio Cuarto, Endocrinologia Y Diabetes, rio Cuarto, Argentina
A TEENAGER WITH COVID-19 AND INAUGURAL DIABETIC KETOACIDOSIS IN THE EMERGENCY DEPARTMENT

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