204 / Abstract ID 660

INFLAMMATION AND SUBSEQUENT FIBROSIS UNDERLIES INSULIN INFUSION SET FAILURES: PROOF OF CONCEPT IN ANIMAL MODELS

E-POSTER DISCUSSION 06 (STATION 6)

U. Klueh[1], M. Hidau[1], A. Mulka[1], R. Sharafieh[2], D. Kreutzer[2]

[1]Wayne State University, Biomedical Engineering, Detroit, United States of America, [2]University of Connecticut Health Center, Surgery, Farmington, United States of America

Background and Aims: Continuous subcutaneous insulin infusion (CSII) is only FDA approved for 3 days. We believe that excipient-induced tissue reactions are responsible for the short-lived CSII functionality, skin complications and pharmacokinetic variation. The objective is to determine the role of inflammation in insulin-excipient induced tissue reaction in both murine and porcine models.

Methods: We modified the classic murine ''air pouch'' model to investigate CSII causes and mechanisms associated with compromised blood glucose control. The addition of an inline home-made filter also permits the removal of excipients prior to insulin infusion into the mouse air pouch. Tissue responses to insulin infusion, excipients, excipient-free insulin and control solutions (e.g. saline) over a 7-day period were investigated. These studies were also extended into a pre-clinical porcine animal model.

Results: Our data indicate that 1) phenol-based insulin diluents trigger infusion site inflammation in both murine and porcine models; 2) that the acute inflammation alters infusion site tissue architecture and functions and 3) the resulting fibrosis eliminates future use of the same infusion site. Pharmacokinetic evaluations demonstrated that insulin absorption is delayed and maximum plasma concentration is decreased in inflamed tissue suggesting a role of inflammatory cells in insulin absorption. In-line removal of excipients immediately prior to insulin infusion minimized the loss of insulin function as well as insulin infusion associated tissue inflammation and subsequent fibrosis at CSII infusion sites.

Conclusions: These studies directly demonstrate the toxicity of excipients in commercial insulin formulations in both murine and porcine models.

205 / Abstract ID 674

MY LIFE AS A PRACTICAL CYBORG: A T1D'S REFLECTION ON LOOP AND THE DIY BIO-HACK MOVEMENT

E-POSTER DISCUSSION 07 (STATION 1)

J. Garfinkel

University of Alberta, Mlcs (media And Cultural Studies), Edmonton, Canada

Background and Aims: In March 2017, after being a T1D for 34 years, I built the Loop app. Life on Loop has completely changed my life, marking significant improvements in diabetes care. In this paper, I wish to consider the philosophical and practical realities of life on Loop, drawing on my own experiences.

Methods: As an internationally published writer, the notion of ''returning to the patient narrative'', as advocated by philosopher Havi Carel, is appealing. With this in mind, I set out to write a ''Diabetes Diary''. For the past year, I have been writing about what it means to live as a T1D in 2019 on Loop. In my paper I will highlight and summarize results of this diary, a literary memoir project at the core of my PhD dissertation at University of Alberta.

Results: My journey has been, in many ways, a mediation and encounter with the uncanny. Borrowing from Heideigger's concept of ''unhomelikeness-in-the-world'' (1996), my experience of the 'unheimlisch' is both a response to technological changes presented by the Loop phenomena, as well as a symptom of the day-to-day illness experience.

Conclusions: I hope this paper will open conversations into how medical professionals approach T1Ds. In listening to the diabetic's story, it opens the possibility of a broader empathy, what Havi Carel calls ''the second-person perspective''. Loop also challenges our very belief in a life-story. For as I grow into my own flesh, medical technology grows into my diabetic body, and with it, the question: Where does my body begin and end?

206 / Abstract ID 750

PROSPECTIVE EVALUATION OF THE IMPACT OF HYBRID CLOSED-LOOP SYSTEM ON GLYCAEMIC CONTROL, GLYCAEMIC VARIABILITY AND PATIENT-RELATED OUTCOMES IN CHILDREN AND ADULTS IN SPAIN

E-POSTER DISCUSSION 07 (STATION 1)

P.I. Beato Víbora[1], F. Gallego-Gamero[1], L. Lázaro-Martín[1], M. Romero-Pérez[2], F. Arroyo-Díez[3]

[1]Badajoz University Hospital, Endocrinology And Nutrition, Badajoz, Spain, [2]Virgen de Macarena Hospital, Department Of Paediatrics, Sevilla, Spain, [3]Badajoz University Hospital, Department Of Paediatrics, Badajoz, Spain

Background and Aims: The aim was to evaluate the outcomes of hybrid closed-loop system in children and adults with type 1 diabetes.

Methods: Patients consecutively starting hybrid closed-loop system (MiniMed-670G) were evaluated in a prospective longitudinal design (baseline, 3-months, 6-months). HbA1c, time in range (TIR) 70–180mg/dl, time >180mg/dl, >250mg/dl, <70mg/dl and <54mg/dl in 2-week downloads were recorded. Glycaemic variability measures were calculated. Adolescents and adults completed a set of questionnaires (Gold and Clarke scores, Hypoglycemia Fear Survey [HFS], Diabetes Quality of Life [DQoL], Diabetes Treatment Satisfaction [DTS], Diabetes Distress Scale [DDS], Pittsburgh Sleep Quality Index [PSQI]).

Results: 58 patients were included, age: 28 ± 15 years (7–63), <18 years-old: 38% (n = 22), 59% (n = 34) females, diabetes duration: 15 ± 9 years, previous treatment: sensor-augmented pump with predictive low glucose suspend (SAP-PLGS): 60% (n = 35) (median time: 3.2 years [1.7–3.7]), pump+SMBG: 19% (n = 11), MDI+SMBG: 12% (n = 7), MDI+CGM: 9% (n = 5).

At 3 months, number of auto-mode exits: 4 ± 2/patient-week (0.6 ± 0.3/patient-day), time in auto-mode: 85 ± 17%, alarms: 8.5 ± 3.7/day. Improvement in TIR was not different in children compared to adults, previous pump or CGM users compared to non-users. Baseline HbA1c and baseline TIR were predictors of improvement in TIR. In patients with baseline high hypoglycaemia risk (n = 29), time in hypoglycaemia range was significantly

Table 1. Glycaemic control, glycaemic variability and questionnaire scores.

	Baseline	3 months	p
Glycaemic control			
HbA1c (%)	7.4 ± 0.9	7.0 ± 0.6	**<0.001**
Estimated HbA1c (%)	7.3 ± 0.7	6.9 ± 0.4	**<0.001**
Time 70-180 mg/dl (TIR) (%)	63 ± 11	73 ± 9	**<0.001**
Time > 180 mg/dl (%)	35 ± 12	25 ± 9	**<0.001**
Time > 250 mg/dl (%)	8.8 ± 6.4	5.1 ± 3.7	**<0.001**
Time < 70 mg/dl (%)	2.5 ± 2.4	2.0 ± 1.8	0.155
Time < 54 mg/dl (%)	0.59 ± 0.86	0.41 ± 0.70	0.159
Use of the system			
Basal insulin (%)	48 ± 11	51 ± 9	**0.042**
Insulin dose (U/kg/day)	0.7 ± 0.2	0.7 ± 0.2	0.778
Sensor use (%)	85 ± 13	86 ± 13	0.741
SMBG/day (n)	7 ± 2	7 ± 2	0.707
Glycaemic variability			
SD of glucose (mg/dl)	57 ± 11	50 ± 9	**<0.001**
CV (%)	35 ± 4	33 ± 4	**0.001**
MAGE (mg/dl)	117 ± 25	102 ± 21	**<0.001**
Patient-related outcomes*			
Hypoglycaemia unawareness (%)	37%	27%	**0.001**
Clarke Score	2.4 ± 1.8	1.9 ± 1.5	**0.023**
Hypoglycaemia Fear Survey (HFS)	41 ± 23	31 ± 18	**0.005**
HFS behaviour	16 ± 9	13 ± 8	**0.02**
HFS worry	24 ± 17	18 ± 12	**0.016**
Diabetes Quality of Life (DQoL)	87 ± 21	78 ± 17	**<0.001**
Diabetes Treatment Satisfaction (DTS)	29 ± 7	31 ± 4	**0.037**
Diabetes Distress Scale (DDS)	40 ± 19	34 ± 16	**0.002**
Pittsburgh Sleep Quality Index (PSQI) > 5 (poor sleep quality), n (%)	49%	40%	**0.004**

n = 58. Baseline: SAP-PLGS (670 Manual Mode) (2 weeks). *≥13 years-old (n = 51). Lower scores indicating less fear of hypoglycaemia (HFS), a better quality of life (DQol), less satisfaction (DTS) and less diabetes distress (DDS).

reduced. At 6 months (n = 21), HbA1c and TIR 70–180 mg/dl improved compared to baseline (HbA1c: 6.9 ± 0.4% *vs* 7.3 ± 0.7%, p = 0.003, TIR: 73 ± 8% *vs* 64 ± 11%, p < 0.001). Discontinuation rate was 3% (n = 2).

Conclusions: Real-world use of hybrid closed-loop systems improves glycaemic control, reduces glycaemic variability and ameliorates diabetes burden in children and adults with type 1 diabetes.

207 / Abstract ID 976

THE PRODUCTS EVERSENSE CGM SYSTEM AND ACCU-CHEK SOLO MICROPUMP ARE IBOA-FREE

E-POSTER DISCUSSION 07 (STATION 1)

H. Fink, N. De Barros Fernandes, J. Weissmann

Roche Diabetes Care GmbH, Tba, Mannheim, Germany

Background and Aims: The increasing offering of patch-based medical devices is accompanied by growing numbers of reported adverse skin reactions. Isobornylacrylate (IBOA) is a leachable compound found in some devices and strongly suspected for allergenic potential on skin. Therefore we investigated whether the Eversense CGM system and the Accu-Chek Solo micropump pose a risk for IBOA leaching.

Methods: The products were extracted for three days by three different methods according to ISO 10993. A worst-case extraction was performed in isopropanol and two different simulated-use extractions were made in ethanol water (5:95) and in sweat-sebum emulsion, which can be a superior solvent for use-case assessments. The extraction volume was varied between complete immersion versus immersion for only 2mm of solvent.

Solvent Product	Isopropanol Fully immersed	Ethanol-water Fully immersed	Sweat-sebum Immersed 2mm
Eversense CGM system	< 0.2 mg/L	< 0.2 mg/L	< 1.6 mg/L
Accu-Chek Solo micropump	< 0.4 mg/L	< 0.2 mg/L	< 1.6 mg/L

Results: IBOA was not found in any extraction, neither from the Eversense XL Smart Transmitter (including adhesives) nor from the Accu-Chek Solo micropump (see table below).

Conclusions: The Eversense XL CGM system and the Accu-Chek Solo micropump do not contain IBOA.

Thus these products do not pose a risk to patients of adverse skin reactions by leakage of IBOA.

208 / Abstract ID 975

A PROOF-OF-CONCEPT STUDY OF A NOVEL NON-INVASIVE GLUCOSE MONITOR

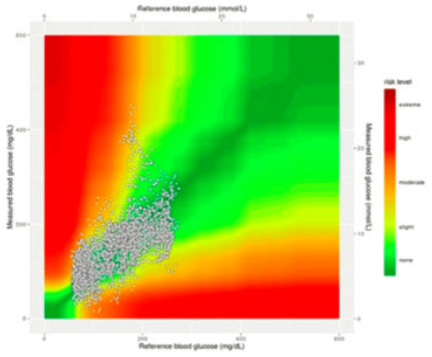
E-POSTER DISCUSSION 07 (STATION 1)

H. Devries[1], M. Rafaqat Ali Qureshi[2], E. Zijlstra[1], L. Plum-Mörschel[3], C.M. Handy[2], B. Love[4], S. Chaudhry[5]

[1]Profil Neuss, Clinical, Neuss, Germany, [2]Afon Technology Ltd, Uk Riversde Court, Beaufort Park, United Kingdom, [3]Profil Mainz, Rheinstr, Mainz, Germany, [4]Citalytics Inc, Dulaney Valley, Maryland, United Kingdom, [5]Afon Technology Ltd, Research, Chepstow, United Kingdom

Background and Aims: Non-invasive glucose monitoring (NIGM) has always proven a very elusive goal. We developed a non-invasive glucose monitor based on analysing resonance shifts from an applied signal in the super high frequency microwave spectrum. Here we report results of a proof-of-concept study.

Confidential p.3



SEG Risk Category	SEG Risk Category	Number of Pairs	Percent
0	None	1747	48.6%
1	Slight, Lower	1203	33.5%
2	Slight, Higher	468	13%
3	Moderate, Lower	161	4.5%
4	Moderate, Higher	14	0.4%
5	Severe, Lower		NA
6	Severe, Upper		NA
7	Extreme		NA

Methods: The NIGM device was applied to the wrist. Patients with type 1 diabetes, age between 18 and 64 years and BMI between 18.5 and 35 kg/m2 (all inclusive) participated in two automated glucose clamp experiments, establishing glucose values at 60, 70, 80, 130, 160, 180 and 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. Reference glucose values were obtained with a SuperGL analyzer every 5 minutes throughout the clamp experiments.

Results: 16 white male subjects (mean±SD age 31.5 ± 9.38 years, BMI 25.9 ± 2.92 kg/m2, diabetes duration 12.6 ± 9.34 years) participated. Data from 1 subject could not be analysed. Paired NIGM-reference blood glucose values were obtained (n = 3593) and are presented in the surveillance error grid (Figure and Table). Predictive MARD, using individual models from the data from first clamp to predict data obtained at the second clamp, was 21.3% (IQR 9.9–36.8).

Conclusions: Although much work still needs to be done, this study delivers proof-of-concept for high frequency microwave based non-invasive glucose monitoring.

209 / Abstract ID 226

DEVELOPMENT OF AN EXERCISE ADVISOR SMARTPHONE APPLICATION FOR PEOPLE WITH DIABETES ON INSULIN THERAPY

E-POSTER DISCUSSION 08 (STATION 2)

S. Edwards[1], H. Wolpert[1], M. Riddell[2]

[1]Eli Lilly and Company, Delivery, Device, And Connected Solutions, Cambridge, United States of America, [2]Muscle Health Research Centre, York University, Toronto, Canada

Background and Aims: Regular exercise is an important part of healthy lifestyle for people with diabetes (PWD). However, the complexities around adjusting insulin doses and food intake to maintain glucose control during exercise are major barriers. Current paper-based guidelines are difficult to apply in practice and provide limited individualisation of recommendations, and there is an unmet need for software-based clinical decision support tools. Here we describe an application (app), which we have developed, to provide personalised proactive guidance with the goal of facilitating improved glucose control around exercise.

Methods: In the software development process, the decision tree from the current international consensus guidelines (Riddell et al.) was deconstructed and expanded from 8 branches in total to 3 separate decision trees for aerobic, mixed and anaerobic exercise with 20, 20 and 6 pathways, respectively. The app provides recommendations for insulin dose adjustments throughout the day and weight-based carbohydrate supplements, as well as pre-emptive bedtime guidance to prevent nocturnal hypoglycaemia following exercise. Guidance is customised based on insulin delivery modality (pump vs injection therapy), insulin-on-board status and includes specific exercise suggestions based on current glucose levels and hypoglycaemia risk. This latter functionality, specifically recommendations for mixed or anaerobic exercise activity to minimise carbohydrate supplementation requirements, could facilitate the use of exercise to support weight management goals in PWD on insulin.

Results: Not applicable

Conclusions: This personalised exercise advisor app addresses an important therapeutic need for a tool to facilitate exercise in PWD on insulin. Reference: Riddell et al. Lancet Diabetes Endocrinol. 2017;5:377–390.

210 / Abstract ID 376

INSULIN PUMP USAGE PATTERNS AMONG PERSONS WITH DIABETES (PWD) PREDICT DETERIORATING SENSOR-BASED GLUCOSE CONTROL 2–4 WEEKS FOLLOWING CLINIC VISITS: A MACHINE LEARNING MODEL

E-POSTER DISCUSSION 08 (STATION 2)

S. Babikian[1], V. Singh[1], M. Clements[2]

[1]Glooko, Inc., Product Management, Mountain View, United States of America, [2]Glooko, Inc., Clinical Development & Research, Mountain View, United States of America

Background and Aims: We developed a machine learning algorithm that predicts risk for decreased sensor glucose time in range (TIR) following a clinic appointment, using primarily clinic-uploaded device data.

Methods: We selected 3175 PWD using pump+CGM who had 7079 clinic upload events of pump data to Glooko between 1/19/2018-6/28/2019. We trained a random forest-based algorithm to predict risk for a 10% decrease in TIR within any 14-day window in the next 30 days, relative to the average TIR 30 days pre-appointment.

We built features from insulin usage trends over the 30–90 days pre-appointment: means and standard deviations of values and counts for boluses (extended, manual, normal, without carbs, with override, with correction), basals (scheduled, suspend, temporary increase and decrease), and carbohydrate amounts. We also included average CGM active time, diabetes type, and gender.

Results: The training cohort had median age = 24 years (IQR:12–43), 56.3% female, 80.9% type 1 diabetes (T1D), average blood glucose median = 168.3mg/dL (IQR:147–191.2). We performed out-of-sample validation using 680 individuals (1516 clinic upload events). The validation cohort had median age = 23 years (IQR:11–42), 55.5% female, 78.9% T1D, average blood glucose median = 168.6mg/dL (IQR:147.4–190.7). The algorithm predicted individuals at risk of decreased TIR with a precision of 0.76 and a recall of 0.64. This correlates to sensitivity = 64%, specificity = 75%, and positive predictive value = 76%.

Conclusions: The present model indicates that it is feasible to predict future deterioration in glycemic control at clinic visits with limited data; additional datapoints may improve predictions. Predicting worsening glycemic control via machine learning may help clinicians identify their most at-risk patients for more intensive intervention.

211 / Abstract ID 388

TRENDS OF COMPLICATIONS OF DIABETES IN TYPE 1 SUBJECTS WITH DIABETIC FOOT ON INSULIN PUMP THERAPY: A 5 YEARS REGISTRY ANALYSIS

E-POSTER DISCUSSION 08 (STATION 2)

A. Scorsone, L. Spano, P. Leonardo, V. Aiello, M. Gambino, G. Saura, M. Fleres, A. Di Noto, F. Provenzano, D. Brancato, V. Provenzano

ASP Palermo - Partinico Civic Hospital, Referral Centre For Diabetes And Insulin Pumps, Partinico, Italy

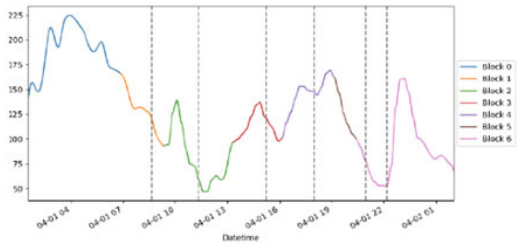
Background and Aims: The onset of a diabetic foot ulcer is a severe complication.Our aim was to study if diabetes complications are better managed in Type 1 diabetes subjects on insulin pump therapy presenting with a diabetic foot problem.

Methods: We extracted data on T1 DM, from our electronic registry during the last 5 yrs.

AIM: to study if insulin pump users had different mangement of diabetic foot.

Results: Population: 193 insulin pump users admitted to our outpatient diabetic foot clinic (23.3% first access). Mean age was 37.7 ± 6,9 (M ± SD). 90% of users (73% not users) underwent a diabetic foot screening procedure before, 70% vs 63% screened for diabetic retinopathy ($p < 0.05$). Mean HbA1c was not different (7.9 ± 1,6 vs 8.0 ± 1.7 %) . LDL was <100 mg/dl in 55% of both. Among T1 DM subjects (users vs not users) BMI was >30 in 13,3% vs 18,2%, eGFR <60 ml/min 66,7% vs 33 %, CV event in 3,3% vs 4,5%, Microalbuminuria 26,7% vs 31,3 %, diabetic retinopathy rate and blood pressure levels were not different. No maior amputation rate was registered in users 3% in non users, lesser degree amputation in 3,3% and 3.5%.

Conclusions: Insulin pump users may have a better management of diabetes related complications, apart from glucose control, due to a more intensive follow-up scheduled for them that does not overlook any action of diabetes care. This may improve the outcome of diabetic foot and diabetes-oriented databases may help us in controlling health care procedures.



Block	Carbohydrates (portions)	Rapid-acting insulin (units)	Glucose level statistics			
			Mean	Standard deviation	Maximum	Minimum
0	0	0	189.571	25.1209	224	141
1	1	1	102.458	36.1073	166	47
2	1	2	92.4583	29.342	139	47
3	1	3	130.5	23.0934	169	97
4	1	1	119.667	37.487	169	53
5	1	1	107.714	39.6612	162	52
6	1	1	86.4074	32.5886	161	52

Day summary of glucose values

- Mean of the level of glucose of the day: 116.715
- Standard deviation of the level of glucose of the previous day: 44.7084
- Maximum level of glucose of the previous day: 224
- Minimum level of glucose of the previous day: 47
- Glycemic variability (MAGE): 102.833

212 / Abstract ID 401

A WEB APPLICATION FOR THE IDENTIFICATION OF BLOOD GLUCOSE PATTERNS THROUGH CONTINUOUS GLUCOSE MONITORING AND DECISION TREES

E-POSTER DISCUSSION 08 (STATION 2)

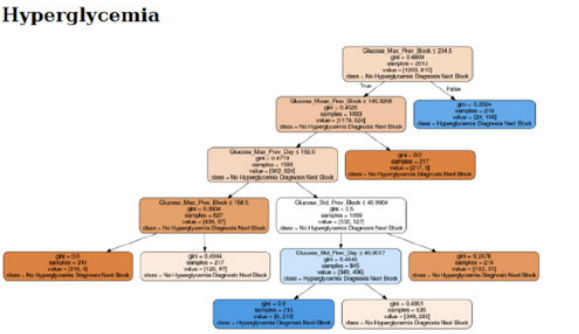
I. Hidalgo[1], *M. Botella-Serrano*[2], *F. Lozano-Serrano*[2], *E. Maqueda*[3], *J. Lanchares*[1], *R. Martínez-Rodríguez*[2], *A. Aramendi*[3], *O. Garnica*[1]

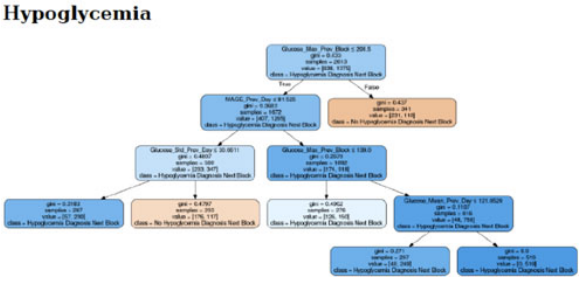
[1]*Universidad Complutense de Madrid, Computer Architecture And Automation, Madrid, Spain,* [2]*Hospital Universitario Príncipe de Asturias, Servicio De Endocrinología Y Nutrición, Alcalá de Henares, Spain,* [3]*Hospital Virgen de la Salud, Servicio De Endocrinología Y Nutrición, Toledo, Spain*

Background and Aims: This increased demand for CGM devices means an opportunity for data and computer scientists, who can contribute to the development of decision-making support systems based on the data collected from the devices. Our aim is to applied Machine Learning techniques to this data and find patterns that leads to advisory systems.

Methods: Using both the entered data and the blood glucose values collected by the device automatically, the application presented here uses decision trees to detect the patterns and entails a starting point in the creation of ensemble models with more predictive power, also based on decision trees. Furthermore, the methodology makes a segmentation of the data set in blocks, determined by the different meals done throughout the day, adding more information to the set of variables used to train the models.

Results: The application developed in this project generates a report of the patient's glucose patterns and provides a web application that allows the user to upload the data obtained from his device and download the report on his computer or smartphone.





Conclusions: As a result, the application can discover repetitive patterns in the daily life of the patient, which can help him to take early preventive measures for risk situations in a period close to the next meal. Thanks: RTI2018-095180-B-I00 and Fundación Eugenio Rodriguez Pascual

213 / Abstract ID 619

RELATIONSHIPS BETWEEN DIABETES DISTRESS, TECHNOLOGY EXPECTATIONS, TECHNOLOGY EXPERIENCE AND TECHNOLOGY USE

E-POSTER DISCUSSION 09 (STATION 3)

L. Gonder-Frederick, A. Bisio, S. Brown, M. Breton, S. Anderson, L. Kollar, J. Robic, E. Emory, M. Oliveri, C. Wakeman, B. Kovatchev

University of Virginia, Center For Diabetes Technology, Charlottesville, United States of America

Background and Aims: Adoption and use of diabetes technology may be associated with pre-existing psychosocial factors, including expectations and emotional status. This study investigated the relationships between diabetes distress and user expectations, experience, and utilization of Closed-Loop Control (CLC) and Decision Support Systems (DSS).

Methods: In Study 1, 61 T1D adults (60% F, age = 42.5 ± 11.6, T1Dyrs = 22.1 ± 12, HbA1c = 7.4 ± 1.0, regimen = insulin pump) participated in a CLC clinical trial using SAP therapy, overnight CLC (ON-CLC), and 24-hr CLC (24-CLC) over three 8-week periods. In Study 2, 57 T1D adults (59.6% F, age = 33 ± 14.1ys, T1Dyrs = 16 ± 12.6, HbA1c = 7.4 ± 1.2, regimen = MDI + CGM) used a DSS which provided insulin recommendations for meals, exercise and sleep. In both studies, participants completed the Diabetes Distress Scale (DDS), as well as Technology Expectations and Technology Experience questionnaires (Benefit and Burden subscales) at baseline and following treatment conditions.

Results: The table below shows correlations and t-test results between the questionnaires and user score. For CLC, higher Emotional DDS scores correlated with higher experienced burdens in the SAP and ON-CLC conditions, with a similar trend in 24-CLC. For DSS, participants were divided into high and low user groups based on system interactions. High user scores correlated with higher expected and experienced benefits. Lower user scores correlated with higher expected and experienced burdens. Low user scores showed trends in correlations with higher Regimen-related and Physician-related baseline distress.

Study 1					
t-test comparing Burdens scores between Low and High emotional DDS groups					
			Low Emotional DDS at Baseline	High Emotional DDS at Baseline	p-value
Experienced Burdens	SAP	Mean Score	32.00	40.20	0.024
	CLC Overnight		33.42	39.82	0.039
	CLC 24/7		31.86	39.67	0.061
Study 2					
Correlation between Questionnaires and User Score					
			r	p-value	
Baseline Regimen DD			-0.258	0.077	
Baseline Physician DD			-0.242	0.097	
Expected Benefits			0.387	0.007	
Expected Burdens			-0.348	0.015	
Experienced Benefits			0.435	0.001	
Experienced Burdens			-0.382	0.005	
t-test comparing questionnaires scores between Active and Low users					
			Active users	Low Users	p-value
Expected Benefits		Mean Score	72.13	56.01	0.006
Expected Burdens			29.54	38.96	0.062
Experienced Benefits			64.77	48.71	0.006
Experienced Burdens			32.24	44.63	0.013

Conclusions: Relationships between diabetes distress and technology expectations, experience and use should be considered for successful adoption and utilization of different types of diabetes technology.

214 / Abstract ID 55

PROPOSAL FOR ESTABLISHING A PEDIATRIC DIABETES CENTER AND ENHANCING TECHNOLOGY USE

E-POSTER DISCUSSION 09 (STATION 3)

L. Haugland[1], M. Yafi[2]

[1]Akershus University Hospital, Pediatrics, STABEKK, Norway, [2]University of Texas in Houston, Pediatric Endocrinology, Houston, Texas, United States of America

Background and Aims: Providing care for young children with type 1 diabetes requires special training and experience since the diabetes care in children is different from that in adults. Furthermore, many general pediatricians may not have the most up to- date knowledge about diabetes care. The delivery of diabetes care in an efficient way can improve the diabetes outcome in the long term.

Methods: We evaluated obstacles which can interfere in providing an optimal care focusing on different aspects: 1- Staffing and personnel 2- Rescue medications 3- Technology utilization 4- Outcome evaluation

Results: 1- Trained staff who have experience in managing pediatric diabetes should be utilized instead of referring visits and phone calls to general pediatric personnel. The team should include dietitians and certified diabetes educators to help the current pediatric endocrinologists 2- Rescue medications (insulin and glucagon) should be available in outpatient settings for immediate use 3- Immediate testing of Hemoglobin A1c (HbA1c), training to utilize insulin pumps and continuous glucose monitor systems (CGMs), and evaluating families readiness for technology use should be performed at diagnosis 4- Diabetes care outcomes should be evaluated by HbA1c levels, fluctuation of recorded glucose levels, prevention of hypoglycemia and quality of life

Conclusions: The optimal delivery of pediatric diabetes care in the society plays a major role in improving diabetes outcome for children. Early utilization of technology by dedicated well-trained staff can improve the metabolic control and allow better quality of lives, not only for children with diabetes, but also their families.

215 / Abstract ID 259

SEXUAL DYSFUNCTION IN MALE WITH TYPE 1 DIABETES MELLITUS

E-POSTER DISCUSSION 09 (STATION 3)

I. Zografou, A. Reklou, A. Binas, E. Papadopoulou, K. Christou, C. Sampanis

Hippokration General Hospital, Thessaloniki, Diabetes Centre, Thessaloniki, Greece

Background and Aims: To investigate the frequency and risk factors of sexual dysfunction (SD) in male with type 1 Diabetes Mellitus (t1DM)

Methods: We concluded patients with t1DM. The International Index of Erectile Function (IIEF) self-completed questionnaire was used to detect SD, while patients with a low score (<26 of 30) in questions regarding erectile function were considered to have erectile dysfunction (ED). Depressive symptoms were evaluated with the Zung Self-rating Depression Scale (ZDRS). The Hamilton Anxiety Rating Scale (HAM-A) was used to evaluate the severity of anxiety and the Sexual Quality of Life Questionnaire (SQOL-M) to assess the quality of sexual life. All patients had a 24-hour ambulatory blood pressure monitoring (ABPM) performed and average Blood Pressure (aBP), average Heart rate (aHR) and nighttime BP dipping (%) measured.

Results: Thirty-eight male patients 42.7±11.7 years old and with 15.6±10.4 years DM duration were included. ED was detected in 26.3% of the patients. Mean IIF score was 56.4±18.9. Depressive symptoms were found in 21% and anxiety in 47.3% of the patients. There was correlation between IIEF score with DM duration ($p < 0.005$, $r = -0.73$), the co-existence of hypertension ($p = 0.018$, $r = -0.61$), the co-existence of retinopathy ($p < 0.005$, $r = -0.79$) and the absence of nighttime BP dipping ($p = 0.041$, $r = 0.81$). Although, there was strong correlation of ED with SQOL score ($p < 0.005$, $r = 0.85$) there was no statistical significant correlation with depressive symptoms or anxiety.

Conclusions: SD seems to be frequent among male patients with t1DM and affects negatively the quality of their sexual life. Abnormal nighttime dipping status seems to be associated with ED

216 / Abstract ID 260

ENDOTHELIAL DYSFUNCTION IN PATIENTS WITH CONTROLLED AND UNCONTROLLED DIABETES MELLITUS

E-POSTER DISCUSSION 09 (STATION 3)

K. Tchaava[1], *N. Gegeshidze*[1], *M. Shavdia*[2], *N. Ninashvili*[3]

[1]*Tbilisi State Medical University, Propedeutics, Tbilisi, Georgia,* [2]*TSMU, Oncology, Tbilisi, Georgia,* [3]*TSMU, Epidemiology, Tbilisi, Georgia*

Background and Aims: To do comparative analysis of the level of asymmetrical dimetilarginin in two groups of the patients with controlled and uncontrolled diabetes mellitus.

Methods: 94 patients were divided into 2 groups. Group I – 53 patients with uncontrolled diabetes mellitus. Group II – 41 patients with controlled diabetes mellitus. Was done clinical, laboratory and instrumental methods of examination including the levels of asymmetrical dimetilarginin, creatinine in the blood and calculated glomerular filtration rate.

Results: During the comparative analysis concentration of asymmetrical dimetilarginin in patients of group I was higher, and was found significant positive correlation between the levels of asymmetrical dimetilarginin and creatinine. ($P < 0,05$). Increase of the level of asymmetrical dimetilarginin in blood was in correlation with decrease of glomerular filtration rate.

Conclusions: In both groups was found increase of the level of asymmetrical dimetilarginin, but the level of asymmetrical dimetilarginin was higher for the patients of group I. According on our findings during the uncontrolled diabetes mellitus manifestation of endothelial dysfunction was significantly visible. Positive correlation between the levels of asymmetrical dimetilarginin and glomerular filtration rate in uncontrolled diabetic patients shows possibility to use this substance as a marker of damages of target organs.

217 / Abstract ID 755

EFFECT OF YOGA ON REDUCING GLYCEMIC VARIABILITY IN INDIVIDUALS WITH TYPE 2 DIABETES: A RANDOMISED CONTROLLED TRIAL

E-POSTER DISCUSSION 10 (STATION 4)

V. Vijayakumar[1], *S. Kannan*[2]

[1]*Government Yoga and Naturopathy Medical College & Hospital, Department Of Yoga, Chennai, India,* [2]*Narayana Health City, Department Of Endocrinology, Bengaluru, India*

Background and Aims: Glycemic variability is a known risk factor for cardiovascular complications in type 2 diabetes mellitus (T2DM). Yoga is a moderate intensity physical activity and is considered to be beneficial for patients with T2DM. The objective of the current study is to understand the effect of yoga on glycemic variability.

Methods: Individuals with T2DM ($n = 60$) of both genders, 40–70 years of age, HbA1C between 7% - 8.5% were recruited from a tertiary referral centre for diabetes. Subjects were randomly assigned to either intervention (yoga) or control (brisk walking) group. During the first 7 days, baseline glycemic variability was established using Freestyle *Libre* pro flash glucose monitoring system, followed by 7 days of either one hour of yoga or walking per day. A traditional validated yoga module was taught. Data on glycemic variability was obtained on baseline, day 7 and 14.

Results: In total, 57 participants successfully completed the study. Mean reduction in daily average glucose level was higher in intervention groups than control group (23.99 ± 18.78 vs 8.69 ± 27.08 mg/dL), with no significant difference between groups ($p > 0.05$). However, significant reduction in various measures of glycemic variability was observed in intervention group (SD: 9.79 ± 7.56 vs 4.67 ± 7.13; MAGE: 17.47 ± 21.25 vs 6.15 ± 13.6; % CV: 3.33 ± 4.09 vs1.03 ± 2.98; MODD: 8.38 ± 6.18 vs 1.16 ± 8.08) when compared to the control group ($p < 0.001$).

Conclusions: Short term yoga practice has shown a statistically significant reduction in the glycemic variability in T2DM when compared to brisk walking, inspite of a similar reduction in mean blood glucose levels.

218 / Abstract ID 223

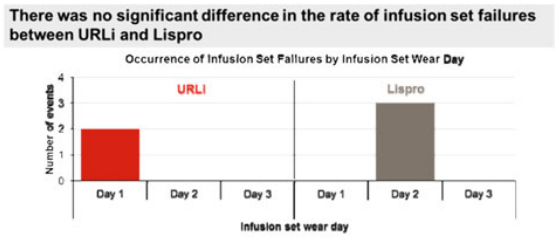
COMPATIBILITY AND SAFETY OF ULTRA RAPID LISPRO (URLI) WITH CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) IN PATIENTS WITH TYPE 1 DIABETES (T1D)

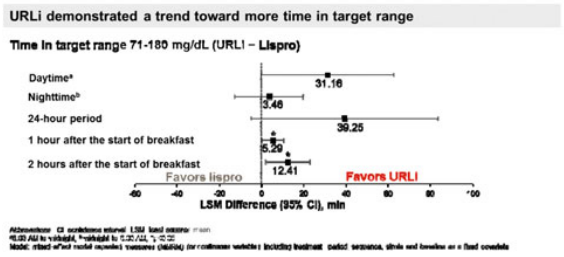
E-POSTER DISCUSSION 10 (STATION 4)

B. Bode[1], *R. Liu*[2], *T. Hardy*[2], *D. Ignaut*[2]

[1]*Atlanta Diabetes Associates, Diabetes, Atlanta, United States of America,* [2]*Eli Lilly and Company, Lilly Corporate Center, Indianapolis, United States of America*

Background and Aims: URLi is a novel insulin lispro formulation that shows accelerated absorption and improved postprandial glucose control compared to lispro. We evaluated the compatibility and safety of URLi vs. lispro in patients with T1D currently using CSII. Primary endpoint was the rate of infusion set failures due to a pump occlusion alarm, or unexplained





hyperglycemia with blood glucose >250 mg/dL (13.9 mmol/L) that did not decrease within 1 hour following a correction bolus delivered via the pump.

Methods: This Phase 3, double-blind, crossover study included 6 weeks of each treatment after a 2-week lead-in period on lispro. Forty-nine patients were randomized. Boluses were initiated 0–2 minutes prior to meals. Patients were required to - Change infusion sets every 72 ± 4 hours - Record infusion set changes and reason - Use Dexcom G5 (real-time mode)

Results: There was no significant difference in the incidence and rate of infusion set failures between URLi and Lispro (primary endpoint). URLi showed a statistically significantly higher overall premature infusion set change rate, but difference was small, translating to 1 additional infusion set change every 2–3 months. A higher incidence of treatment-emergent adverse events (TEAEs) was observed for URLi, driven by infusion site reaction and pain, which was mostly reported by one investigative site. Over 90% of these were mild severity. Incidence of all other TEAEs was low and similar between groups.

Conclusions: URLi was compatible with CSII use with a safety profile similar to lispro. URLi demonstrated a trend towards improved glycemic control in patients with T1D.

219 / Abstract ID 753

EFFICACY, SAFETY AND IMMUNOGENICITY IN PEOPLE WITH DIABETES ON MDI USING SAR341402 OR INSULIN ASPART TOGETHER WITH BASAL INSULIN GLARGINE (GLA-100): GEMELLI-1 STUDY

E-POSTER DISCUSSION 10 (STATION 4)

S. Garg[1], K. Wernicke-Panten[2], M. Wardecki[3], D. Kramer[4], F. Delalande[5], E. Franek[6,7], K. Sadeharju[8], T. Monchamp[9], V.N. Shah[1]

[1]University of Colorado Denver, Barbara Davis Center For Diabetes, Aurora, United States of America, [2]Sanofi-Aventis Deutschland GmbH, R&d Diabetes, Clinical Development, Frankfurt am Main, Germany, [3]Sanofi R&D, Operational Medical Development, Warsaw, Poland, [4]Sanofi R&D, Biomarkers And Clinical Bioanalysis, Frankfurt am Main, Germany, [5]Ividata, Statistics, Levallois-Perret, France, [6]Polish Academy of Sciences, Mossakowski Clinical Research Centre, Warsaw, Poland, [7]CSK MSWiA, Diabetology, Warsaw, Poland, [8]Terveystalo Seinäjoki, General Medicine, Seinäjoki, Finland, [9]St. Charles Medical Center, Endocrinology, Bend, United States of America

Background and Aims: SAR341402 (SAR-Asp) was developed as a biosimilar/follow-on to rapid-acting insulin NovoLog®/NovoRapid® (NN-Asp). Efficacy and safety results, including immunogenicity, for SAR-Asp and NN-Asp in patients with type 1 diabetes (T1DM) or type 2 diabetes (T2DM) are similar. Further subgroups analyses were done by baseline factors (age, ethnicity, race, BMI, duration of diabetes and HbA_{1c}).

Methods: GEMELLI-1 (NCT03211858) was a 6-month (with 6-month extension) open-label randomised phase 3 study of SAR-Asp and NN-Asp in people with T1DM or T2DM using insulin glargine 100 U/mL (Gla-100) as basal insulin. Primary endpoint was HbA_{1c} change (non-inferiority margin of 0.3 %) from baseline to Week 26.

Results: 597 participants were randomized, with similar baseline characteristics in both treatment groups. The mean change in HbA_{1c} at Week 26 was similar in both treatment groups in the total cohort as well as in subgroup analyses based on baseline BMI (≥30 vs <30 kg/m^2), duration of diabetes (≥10 or <10 years), eGFR (≥60 vs <60 mL/min/1.73 m^2), and ethnicity (**Table**). In these subgroups, the incidence of hypoglycaemia, especially severe hypoglycaemia (SAR-Asp 4.0%; NN-Asp 3.4%), was similar in participants who received SAR-Asp and NN-Asp. The immunogenicity data and TEAEs in subgroups were also consistent with the overall population (**Table**).

Conclusions: SAR341402 was as effective and well tolerated as insulin aspart in people with T1DM or T2DM regardless of the baseline characteristics.

Table: Summary of Results by Subgroups

Subgroup Treatment group	ITT	Change in HbA_{1c} (%) from baseline to Week 26 Baseline mean	Week 26 mean	LS mean change (SE)*	LS mean difference (SE) SAR-Asp vs NN-Asp (95% CI)*	Patients with at least one hypoglycaemia Any hypoglycaemia n/N (%)	Severe hypoglycaemia n/N (%)	Documented symptomatic hypoglycaemia (53.0 mmol/L (54 mg/dL)) n/N (%)	TEAEs) Patients with any TEAE n/N (%)	TEAIAs Patients with TEAIAs n/N (%)
All patients										
SAR-Asp	301	8.00	7.60	−0.38 (0.042)	−0.08 (0.059)	291/301 (96.7)	12/301 (4.0)	206/301 (68.4)	156/301 (51.8)	50/296 (16.9)
NN-Asp	296	7.94	7.62	−0.30 (0.041)	(−0.190 to 0.039)	285/296 (96.3)	10/296 (3.4)	153/296 (51.7)	146/296 (49.3)	60/292 (20.5)
Age <65 y										
SAR-Asp	254	8.00	7.62	−0.36 (0.047)	−0.10 (0.065)	247/254 (97.2)	11/254 (4.3)	183/254 (71.7)	126/254 (49.6)	45/251 (18.3)
NN-Asp	244	7.98	7.69	−0.26 (0.045)	(−0.223 to 0.032)	235/244 (96.3)	8/244 (3.3)	175/244 (71.7)	117/244 (48.0)	54/240 (22.5)
Age ≥65 to <75 y										
SAR-Asp	40	8.01	7.47	−0.52 (0.106)	−0.03 (0.152)	38/40 (95.0)	1/40 (2.5)	19/40 (47.5)	24/40 (60.0)	4/39 (10.3)
NN-Asp	45	7.72	7.27	−0.49 (0.108)	(−0.327 to 0.268)	44/45 (97.8)	2/45 (4.4)	18/45 (40.0)	24/45 (53.3)	6/45 (13.3)
Male										
SAR-Asp	179	7.96	7.57	−0.38 (0.054)	−0.04 (0.075)	174/179 (97.2)	6/179 (3.4)	117/179 (65.4)	83/179 (46.4)	33/177 (18.6)
NN-Asp	177	7.97	7.56	−0.34 (0.053)	(−0.186 to 0.108)	170/177 (96.0)	8/177 (4.5)	117/177 (66.1)	75/177 (42.4)	36/174 (20.7)
Female										
SAR-Asp	122	8.05	7.64	−0.37 (0.065)	−0.13 (0.092)	117/122 (95.9)	6/122 (4.9)	89/122 (73.0)	73/122 (59.8)	20/119 (16.8)
NN-Asp	119	8.03	7.72	−0.24 (0.066)	(−0.316 to 0.047)	115/119 (96.6)	2/119 (1.7)	76/119 (63.9)	71/119 (59.7)	24/118 (20.3)
BMI <30 kg/m²										
SAR-Asp	207	8.00	7.61	−0.38 (0.052)	−0.10 (0.071)	202/207 (97.6)	8/207 (3.9)	146/207 (70.5)	104/207 (50.2)	33/204 (16.2)
NN-Asp	209	7.94	7.66	−0.25 (0.049)	(−0.244 to 0.036)	202/209 (96.7)	8/209 (3.8)	144/209 (68.9)	100/209 (47.8)	46/205 (22.4)
BMI ≥30 kg/m²										
SAR-Asp	94	7.99	7.57	−0.42 (0.071)	−0.01 (0.103)	89/94 (94.7)	4/94 (4.3)	60/94 (63.8)	52/94 (55.3)	17/92 (18.5)
NN-Asp	87	7.93	7.52	−0.41 (0.074)	(−0.211 to 0.192)	83/87 (95.4)	2/87 (2.3)	45/87 (56.3)	46/87 (52.9)	14/87 (16.1)
Diabetes duration <10 y										
SAR-Asp	95	7.86	7.49	−0.40 (0.084)	−0.18 (0.120)	94/95 (97.0)	2/95 (3.0)	44/95 (50.7)	32/95 (48.5)	11/95 (16.7)
NN-Asp	67	7.84	7.64	−0.22 (0.086)	(−0.414 to 0.056)	63/67 (94.0)	2/67 (3.0)	42/67 (62.7)	33/67 (49.3)	16/66 (24.2)
Diabetes duration ≥10 y										
SAR-Asp	235	8.03	7.63	−0.37 (0.049)	−0.05 (0.068)	227/235 (96.6)	10/235 (4.3)	162/235 (68.9)	124/235 (52.8)	39/230 (17.0)
NN-Asp	229	7.96	7.62	−0.32 (0.047)	(−0.181 to 0.085)	222/229 (96.9)	8/229 (3.5)	151/229 (65.9)	113/229 (49.3)	44/226 (19.5)
eGFR ≥60 mL/min/1.73 m²										
SAR-Asp	273	7.97	7.61	−0.35 (0.045)	−0.07 (0.062)	265/272 (97.1)	12/272 (4.4)	153/273 (70.7)	138/273 (50.5)	46/268 (17.2)
NN-Asp	268	7.95	7.66	−0.27 (0.043)	(−0.196 to 0.046)	257/268 (95.9)	9/268 (3.4)	162/268 (67.9)	126/268 (47.0)	51/264 (21.6)
eGFR <60 mL/min/1.73 m²										
SAR-Asp	28	8.24	7.47	−0.66 (0.128)	−0.11 (0.192)	26/28 (92.9)	0/28 (0.0)	13/28 (46.4)	18/28 (64.3)	4/28 (14.3)
NN-Asp	28	7.85	7.25	−0.55 (0.142)	(−0.484 to 0.265)	28/28 (100.0)	1/28 (3.6)	11/28 (39.3)	20/28 (71.4)	3/28 (10.7)
Hispanic										
SAR-Asp	27	8.24	7.50	−0.63 (0.147)	−0.29 (0.222)	25/27 (92.6)	1/27 (3.7)	15/27 (55.6)	17/27 (63.0)	7/27 (25.9)
NN-Asp	19	8.20	7.61	−0.40 (0.166)	(−0.636 to 0.234)	18/19 (94.7)	1/19 (5.3)	10/19 (52.6)	11/19 (57.9)	1/19 (5.3)
Not hispanic										
SAR-Asp	271	7.97	7.61	−0.35 (0.044)	−0.06 (0.062)	263/271 (97.0)	11/271 (4.1)	159/271 (70.1)	137/271 (50.6)	43/266 (16.2)
NN-Asp	275	7.92	7.62	−0.30 (0.043)	(−0.178 to 0.064)	265/275 (96.4)	9/275 (3.3)	162/275 (66.2)	134/275 (48.7)	59/271 (21.4)
Type 1 diabetes										
SAR-Asp	250	7.97	7.64	−0.31 (0.045)	−0.06 (0.063)	240/250 (96.4)	12/250 (4.8)	161/250 (72.4)	120/250 (48.0)	43/247 (17.4)
NN-Asp	247	7.94	7.68	−0.25 (0.044)	(−0.187 to 0.060)	239/247 (96.4)	9/247 (3.6)	178/247 (72.1)	115/247 (46.6)	56/243 (23.0)
Type 2 diabetes										
SAR-Asp	51	8.10	7.36	−0.69 (0.102)	−0.14 (0.144)	45/51 (88.2)	0/51 (0.0)	25/51 (49.0)	36/51 (70.6)	7/49 (14.3)
NN-Asp	49	7.92	7.33	−0.55 (0.101)	(−0.422 to 0.141)	47/49 (95.9)	1/49 (2.0)	15/49 (30.6)	31/49 (63.3)	4/49 (8.2)
Screening HbA_{1c} <8.0 %										
SAR-Asp	143	7.37	7.19	−0.18 (0.062)	−0.04 (0.086)	138/143 (96.5)	7/143 (4.9)	104/143 (72.7)	75/143 (52.2)	23/141 (16.3)
NN-Asp	138	7.40	7.25	−0.15 (0.062)	(−0.204 to 0.133)	130/138 (94.2)	4/138 (2.9)	91/138 (65.9)	62/138 (44.9)	29/136 (21.3)
Screening HbA_{1c} ≥8.0 %										
SAR-Asp	158	8.56	7.95	−0.57 (0.058)	−0.15 (0.083)	153/158 (96.8)	5/158 (3.2)	102/158 (64.6)	77/158 (48.7)	27/155 (17.4)
NN-Asp	158	8.41	7.96	−0.41 (0.059)	(−0.317 to 0.008)	155/158 (98.1)	5/158 (3.8)	102/158 (64.6)	84/158 (53.2)	31/156 (19.9)

*Retrieved (tropical multiple imputations of missing changes at Week 26 (10,000 imputations using separate models for patients who prematurely discontinued or completed the main 6-month treatment period) followed by ANCOVA with treatment group (SAR-Asp, NN-Asp), the randomization strata of geographical region and type of diabetes (Europe T1DM, US T1DM, US T2DM, Japan T1DM) and prior use of NN-Asp (yes, no) as fixed categorical effects, as well as the continuous fixed covariate of baseline HbA_{1c} value. BMI, body mass index; CI, confidence interval; eGFR, estimated glomerular filtration rate; ITT, intent to treat; LS, least square; SE, standard error; T1DM, type 1 diabetes; T2DM, type 2 diabetes; TEAE, treatment-emergent adverse event; TEAIA, treatment-emergent anti-insulin antibody.

220 / Abstract ID 569

EFFICACY OF ORAL SEMAGLUTIDE ACCORDING TO BASELINE HBA1C: AN EXPLORATORY SUBGROUP ANALYSIS OF THE PIONEER TRIAL PROGRAMME

E-POSTER DISCUSSION 10 (STATION 4)

J. Meier[1], R. Bauer[2], T. Blicher[2], I. Lingvay[3], M. Treppendahl[2], B. Zinman[4], J. Rosenstock[5]

[1]St Josef Hospital, Ruhr-University Bochum, N/a, Bochum, Germany, [2]Novo Nordisk A/S, N/a, Søborg, Denmark, [3]University of Texas Southwestern Medical Center at Dallas, N/a, Dallas, United States of America, [4]Lunenfeld-Tanenbaum Research Institute, Mount Sinai Hospital, University of Toronto, N/a, Toronto, Canada, [5]Dallas Diabetes Research Center at Medical City, N/a, Dallas, United States of America

Background and Aims: This exploratory subgroup analysis of the PIONEER programme evaluated the effect of baseline HbA_{1c} on overall HbA_{1c} and bodyweight reductions achieved during each trial.

Methods: Data from patients who participated in PIONEER 1–5, 7 and 8 (n = 5657) were grouped by trial and according to baseline HbA_{1c} (≤8.0%, >8.0–≤9.0% and >9.0%). In the PIONEER trials, patients received either once daily treatment with oral semaglutide (3, 7 or 14 mg, or flexibly dosed) or a comparator (placebo, empagliflozin 25 mg, sitagliptin 100 mg or liraglutide 1.8 mg). Endpoints were change from baseline in HbA_{1c} and bodyweight at week 26 (week 52 in PIONEER 7).

Results: Reductions from baseline in HbA_{1c} and bodyweight were greater with increasing oral semaglutide dose. HbA_{1c} reductions were also greater with higher baseline HbA_{1c}, but there was no consistent relationship between change in bodyweight and baseline HbA_{1c}. Reductions in HbA_{1c} were greater with oral semaglutide 7 mg and 14 mg versus placebo and versus active comparator in all subgroups (Table). Significant interactions by baseline HbA_{1c} were observed for oral semaglutide vs comparator in PIONEER 3 (14 mg), PIONEER 4 (14 mg vs placebo), and PIONEER 8 (7 and 14 mg).

Conclusions: Oral semaglutide showed improved glycaemic control across baseline HbA_{1c} subgroups in the PIONEER trials, with greater reductions in HbA_{1c} with oral semaglutide 7 and 14 mg versus all comparators in all subgroups. Reductions in HbA_{1c} were greater with higher oral semaglutide dose and higher baseline HbA_{1c}.

Table. Change from baseline in HbA_{1c} by by baseline HbA_{1c} subgroup in 7 of the global Phase 3a PIONEER trials

Trial	HbA_{1c} (%) at baseline	Estimated mean change from baseline in HbA_{1c} (%-points)					
		Oral semaglutide				Comparator(s)	
		3 mg	7 mg	14 mg	Flex	Pbo	Active
PIONEER 1 (diet and exercise)	≤8 (n=409)	−0.5	−1.1	−1.2	-	0.0	-
	>8–≤9 (n=244)	−1.1	−1.6	−1.8	-	−0.1	-
	>9 (n=50)	−1.5	−1.8	−2.6	-	−0.6	-
PIONEER 2 (vs empagliflozin 25 mg)	≤8 (n=457)	-	-	−1.0	-	-	−0.5
	>8–≤9 (n=211)	-	-	−1.8	-	-	−1.1
	>9 (n=153)	-	-	−2.0	-	-	−1.7
PIONEER 3 (vs sitagliptin 100 mg)	≤8 (n=850)	−0.3	−0.6	−0.9	-	-	−0.5
	>8–≤9 (n=593)	−0.5	−1.1	−1.5	-	-	−0.8
	>9 (n=420)	−1.0	−1.9	−2.2	-	-	−1.4
PIONEER 4 (vs liraglutide 1.8 mg and pbo)	≤8 (n=403)	-	-	−1.0	-	−0.0	−0.8
	>8–≤9 (n=248)	-	-	−1.6	-	−0.1	−1.4
	>9 (n=60)	-	-	−2.2	-	−0.1	−2.0
PIONEER 5 (renal impairment)	≤8 (n=188)	-	-	−0.8	-	0.1	-
	>8–≤9 (n=108)	-	-	−1.5	-	−0.3	-
	>9 (n=28)	-	-	−2.1	-	−0.4	-
PIONEER 7 (flex vs sitagliptin 100 mg)	≤8 (n=201)	-	-	-	−1.0	-	−0.5
	>8–≤9 (n=246)	-	-	-	−1.5	-	−0.7
	>9 (n=57)	-	-	-	−2.0	-	−1.5
PIONEER 8 (added-on to insulin)	≤8 (n=329)	−0.3	−0.6	−1.0	-	0.2	-
	>8–≤9 (n=296)	−0.7	−1.2	−1.6	-	−0.2	-
	>9 (n=106)	−1.2	−1.8	−2.3	-	−0.1	-

Mixed model for repeated measures analysis with treatment, region, stratification factors and interaction between them, as well as baseline HbA_{1c} group and interaction between treatment and baseline HbA_{1c} groups as factors, and baseline value of dependent variable as covariate. -, not investigated in trial; flex, flexible dose adjustment; pbo, placebo

221 / Abstract ID 666

THE GLYCEMIC OUTCOMES OF THE EVERSENSE CGM SYSTEM IN AN EXPANDED COHORT OF 582 REAL-WORLD US COMMERCIAL USERS

E-POSTER DISCUSSION 11 (STATION 5)

S. Ghosh-Dastidar[1], P. Sanchez[1], K. Tweden[2], F. Kaufman[3]

[1]Senseonics Inc, Product Development, Germantown, United States of America, [2]Senseonics Inc, Clinical Sciences, Germantown, United States of America, [3]Senseonics Inc, Medical Affairs, Germantown, United States of America

Background and Aims: The first long term implantable Eversense CGM system was approved for US commercialization in 2018. Accuracy and safety have been demonstrated in multiple clinical trials and real-world studies. The first US real-world data publication reported on 205 users with a 90-day sensor wear cycle. Using the same analytic methodology, a larger user base of 582 was subsequently analyzed.

Methods: De-identified sensor glucose (SG) data from the Eversense data management system were analyzed for the first 582 patients who reached a 90-day wear period and compared to the first 205 patients previously reported. Mean SG, variability measures (SD, CV), GMI, and glucometrics were computed. Median transmitter wear time was assessed.

Results: The makeup of the 582 cohort was similar to the 205 cohort with ∼1/3 naïve CGM users and ∼80–85% T1D. Glucometric data were similar between the larger cohort and the original population (Table). The mean SG was 162 and 161 mg/dL, CV was .35, GMI was 7.18% and 7.16%, and time in range was 62 and 63% in the 205 and 582 user groups, respectively. Mean percent SG <70mg/dL approached the targeted value of <4% (4.2 and 4.0%). Median transmitter wear time was 84 and 85%.

Conclusions: These data show that the promising glycemic outcomes and system usage obtained in the first 205 users was sustained in a larger cohort of US commercial Eversense CGM system users and likely represents the real-world population outcomes to be expected when using the system as a tool for diabetes management.

	24-hour time period Mean (SD) 205 Users	24-hour time period Mean (SD) 582 Users
SG mg/dL	161.8 (33.3)	161.1 (30.6)
SD mg/dL	57.4 (14.8)	57.1 (15.1)
CV	0.35 (0.06)	0.35 (0.07)
GMI%	7.18 (0.80)	7.16 (0.73)

	% SG Mean (SD)	Time in Minutes 24-hour time period	% SG Mean (SD)	Time in Minutes 24-hour time period
<54 mg/dL	1.2 (1.8)	18.0	1.2 (1.7)	17.1
[54-70] mg/dL	2.9 (2.5)	41.8	2.8 (2.5)	40.3
<70 mg/dL	4.1 (4.1)	59.7	4.0 (4.1)	57.5
[70-180] mg/dL	62.3 (19.0)	897.7	62.8 (17.8)	904.9
>180 mg/dL	33.5 (20.3)	482.6	33.2 (18.8)	477.7
(180-250] mg/dL	21.9 (9.7)	315.8	22.4 (9.8)	323
>250 mg/dL	11.6 (12.8)	166.7	10.7 (11.4)	154.7
Median Percent Wear Time	83.6 190 Users		84.9 541 Users	

SG=sensor glucose, SD-standard deviation, CV=coefficient of variation GMI=glucose management indicator

222 / Abstract ID 751

GLUCOSE MANAGEMENT INDICATOR (GMI) BASED ON SENSOR DATA AND LABORATORY HBA1C IN PEOPLE WITH TYPE 1 DIABETES FROM THE DPV DATABASE: DIFFERENCES BY SENSOR TYPE

E-POSTER DISCUSSION 11 (STATION 5)

J. Hermann[1,2], S. Von Sengbusch[3], M. Freff[4], U. Ermer[5], P. Schlumberger[6], K. Placzek[7], T. Danne[8], E. Hammer[9], R. Holl[1]

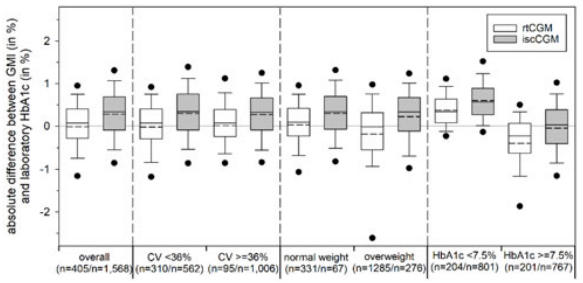
[1]German Center for Diabetes Research (DZD), German Center For Diabetes Research (dzd), München-Neuherberg, Germany, [2]Ulm University, Institute Of Epidemiology And Medical Biometry, Zibmt, Ulm, Germany, [3]1University Hospital of Schleswig-Holstein, Campus Luebeck, Dep. Of Pediatric Endocrinology And Diabetology, Lübeck, Germany, [4]Princess Margaret Children's Clinic, Diabetes Center, Darmstadt, Germany, [5]Kliniken St. Elisabeth, Abt. Kinder- Und Jugendmedizin Neonatologie, Neuburg, Germany, [6]University Hospital Marburg, Philipps University of Marburg, Pediatric Diabetology, Marburg, Germany, [7]University Hospital Halle (Saale), Martin-Luther University, Pediatric Endocrinology And Diabetology, Halle, Germany, [8]AUF DER BULT, Diabetes-center For Childeren And Adolescents, Hannover, Germany, [9]Catholic Children's Hospital Wilhelmstift, Pediatric Endocrinology And Diabetology, Hamburg, Germany

Background and Aims: The Glucose Management Indicator (GMI) was developed using data from real-time continuous glucose monitoring (rtCGM). We aimed to compare GMI and laboratory HbA1c using both rtCGM and intermittent scanning CGM (iscCGM) profiles collected during routine care in people with type 1 diabetes (T1D).

Methods: We analyzed 132,361 CGM days from N = 1,973 individuals with T1D duration ≥1 year from the German/Austrian DPV Registry. As measurement ranges of CGM devices differ, we truncated glucose values to the same range (40–400 mg/dl). GMI was calculated from a median number of 77 [IQR: 46–89] days/individual as GMI (%) = 3.31 + 0.02392*[mean glucose, mg/dL]. Differences between GMI and laboratory HbA1c were illustrated using boxplots for rtCGM vs. iscCGM stratified by glucose variability (coefficient of variation [CV] </≥36%), normal weight vs. overweight, and HbA1c </≥7.5%.

Results: Mean GMI and HbA1c were similar in rtCGM users (n = 405, 7.6 ± 0.7% vs. 7.6 ± 1.1%), whereas iscCGM users (n = 1,568) had higher mean GMI than HbA1c (7.9 ± 0.9% vs. 7.6 ± 1.2%). Overall and stratified by glucose variability or weight, differences between GMI and laboratory HbA1c were almost symmetrically distributed around 0 in rtCGM users, whereas GMI was higher than HbA1c in almost three fourth of all iscCGM users. For both sensor types, most individuals with HbA1c <7.5% had higher GMI than HbA1c, whereas three fourth of the individuals with HbA1c ≥7.5% and rtCGM had lower GMI than HbA1c (Figure).

Conclusions: As measurement ranges, distributions of glucose values, and calibration methods differ between CGM sensors, it may be necessary to use formulas specific for sensor type to calculate GMI.



223 / Abstract ID 97

A NOVEL CERUMEN GLUCOSE SELF-SAMPLING DEVICE

E-POSTER DISCUSSION 11 (STATION 5)

A. Herane-Vives[1,2]

[1]King's College London, Psychological Medicine, Denmark Hill, United Kingdom, [2]King's College London, Psychological Medicine, Denmark Hill, United Kingdom

Background and Aims: Cerumen glucose may have the potential to improve the diagnosis of diabetes. Currently, cerumen extraction has to be exclusively performed by clinicians. Its extraction is not advisable for healthy ears, although it is a common practice through the use of ''cotton buds''. Then, a novel cerumen sampling device should be safe, reliable, comfortable and usable by a patient.

Methods: Both external ears were cleaned on two occasions, one month apart, in 37 controls. A clinical method was used for cleaning both ears during a baseline visit. During a follow-up visit, one month later, a right cerumen sample was obtained using the novel self-sampling external ear device, and a left ear sample, using the clinical method. Both follow-up samples represented the same retrospective period of cerumen secretion. Vector of Sample Relative Dispersion (VRSD) analysis was performed for comparing the reliability between both extraction methods. Potential side-effects and novel device user experience were recorded.

Results: The weight of the baseline samples were not significantly different between ear sides (both $p > 0.05$). The self-extraction method removed 8 times more earwax than the clinical method ($p < 0.01$). Although no VRSD was significant, left ear cerumen samples (baseline and follow-up) showed the largest variability between them ($p = 0.15$). No side effects were reported by any method in any visit. Participants considered that the self-sampling external ear device was safer, more effective, and as comfortable as the use of ''cotton buds''.

Conclusions: The novel device may constitute a reliable, economical, comfortable and effective option for measuring glucose level.

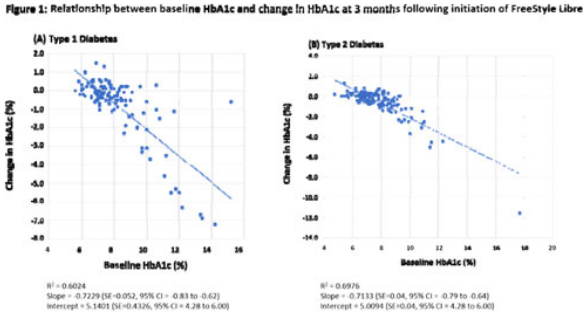
224 / Abstract ID 777

IMPROVING HBA1C CONTROL IN PEOPLE WITH TYPE 1 OR TYPE 2 DIABETES USING FLASH GLUCOSE MONITORING: A RETROSPECTIVE OBSERVATIONAL ANALYSIS IN 2 GERMAN CENTRES

E-POSTER DISCUSSION 11 (STATION 5)

G. Klausmann[1], L. Rose[2], A. Seibold[3]

[1]Praxis Drs. Klausmann, Diabetolgie, Aschaffenburg, Germany, [2]Zentrum für Diabetes und Gefäßerkrankungen Münster, Praxis, Münster, Germany, [3]Abbott Diabetes Care, Medical Affairs, Wiesbaden, Germany



Background and Aims: To evaluate change in HbA1c in patients with Type 1 (T1D) or Type 2 diabetes (T2D) following initiation of the FreeStyle Libre® flash continuous glucose monitoring system.

Methods: A retrospective observational study was undertaken on adults with T1D (n = 131) or T2D on insulin (n = 176), who were started on the FreeStyle Libre system. Chart review included patients with HbA1c recorded prior to initiation and at 3-month intervals thereafter.

Results: Mean HbA1c decreased significantly at 3 months after initiation of the FreeStyle Libre system in T1D (mean change −0.75 ± 0.15% (−8.2 ± 1.6 mmol/mol); $p < 0.001$) and in T2D (mean change −0.52 ± 0.11% (−5.7 ± 1.2 mmol/mol); $p < 0.001$). Reduction was maintained for 12 months. Change in HbA1c from 3 months to 12 months was not significant in either T1D or T2D. Subgroup analysis showed significant improvements in patients with mean baseline HbA1c >7.5 % (>58 mmol/mol). Patients with a baseline HbA1c >7.5 % (> 58 mmol/mol) showed a reduction of −1.36 ± 0.34% (−14.9 ± 3.7 mmol/mol) in T1D and a reduction of −1.16 ± 0.38% (−12.7 ± 4.2 mmol/mol) in T2D at 12 months ($p < 0.001$). Linear regression confirms that baseline HbA1c is negatively correlated with change in HbA1c, both in T1D ($p < 0.001$) and in T2D ($p < 0.001$) (Fig 1).

Conclusions: People with T1D or T2D on insulin show a reduction in HbA1c by 3 months following initiation of the FreeStyle Libre system. Fall in HbA1c at 3 months is negatively correlated with starting HbA1c and is maintained over 12 months. The most significant benefit seen in patients with a starting HbA1c >7.5% (>58 mmol/mol).

225 / Abstract ID 40

INTEGRATED CARE PROGRAM (INCAP) FOR TYPE 1 DIABETES PATIENTS WITH CONTINUOUS SUBCUTANEOUS INSULIN INFUSION SYSTEM (CSII), IMPROVED BY DIGITAL TECHNOLOGIES

E-POSTER DISCUSSION 12 (STATION 6)

P. Ros[1], B. Nuñez[2], B. Merino Barbancho[3], A. Abad[1], A. Serrano[1], I. Martinez-Badás[1], N. Lacámara[1], F. Esrail[4], S. Flipse[4], M.T. Arredondo[3], G. Fico[3]

[1]Hospital Universitario Puerta de Hierro-Majadahonda, Department Of Pediatric Endocrinology, Madrid, Spain, [2]Medtronic Ibérica, S.A, Integrated Health Solutions Department, Madrid, Spain, [3]Universidad Politécnica de Madrid, Life Supporting Technologies, Madrid, Spain, [4]Technische Universiteit Delft, Technische Universiteit Delft, Delft, Netherlands

Background and Aims: T1D is a complex chronic disease, and requires high level of self-management education to prevent long term complications. Even though there have been different telematics approaches to support diabetes management, none of them have been well integrated into the health care system to date. The aim of this work is to build INCAP solution: to develop a Remote Monitoring Support Centre (CSSR) to optimize the medical outcome of patients based on personal progression and a digital educational program to improve self-management and adherence.

Methods: The algorithm implemented in CSSR uses clustering techniques to classify the data extracted from CSII. A colour code was used for triage (emergency patients in red, alert patients in yellow and stable patients in green). Moreover, a mobile application for patients has been developed including self-management contents and professional support. We included 51 patients (28 children-CH-;23 adults-A-) with T1D treated with CSII.

Results: Preliminary results (4 months of follow-up) from CSSR deployment show a total of 164 remote follow-ups (100CH *vs* 64A), clustering 49% emergency patients (56%CH *vs* 38%A), 19% alert patients (17%CH *vs* 23%A) and 32% stable patients (27%CH *vs* 39%A). Comparing with baseline follow-up, downloads in red have decreased 12% (from 61% to 49%) and those classified in green have increased 9% (from 23% to 32%). Besides, 5 out of 28 pediatric in-office visits were cancelled or postponed.

Conclusions: The deployment and implementation of the INCAP solution points direct impact on the efficiency of in-office follow-up, as well as on the reduction of the number of unnecessary follow-ups.

226 / Abstract ID 215

COST OFFSET ANALYSIS (COA) COMPARING REAL-TIME CONTINUOUS GLUCOSE MONITORING (RT-CGM) WITH SELF-MONITORING OF BLOOD GLUCOSE (SMBG) IN PEOPLE WITH TYPE 1 DIABETES IN EIGHT COUNTRIES

E-POSTER DISCUSSION 12 (STATION 6)

M. Minshall[1], J. Isitt[2], D. Price[3], C. Graham[4], P. Lynch[2]

[1]Certara, Evidence & Access, New York, United States of America, [2]Dexcom, Global Access, San Diego, United States of America, [3]Dexcom, Medical Affairs, San Diego, United States of America, [4]Graham Advisors, LLC, Consulting, Long Beach, United States of America

Background and Aims: A COA was performed comparing clinical cost offsets for an rt-CGM system with SMBG calibration compared with SMBG alone in people with T1D (n = 2,000 per country) and uncontrolled glycemia, in eight countries over a one-year period.

Methods: Clinical effects for HbA_{1c} reduction from rt-CGM and SMBG were −1.0% and −0.4%, respectively, taken from a recently published RCT (Beck, 2017). HbA_{1c} reductions for rt-CGM and SMBG were converted into an economic benefit based on a US study (Wagner, 2001), adjusted for the Organization for Economic Cooperation and Development (OECD) healthcare purchasing power parity and 2019 exchange rates for non-US countries. Reduced hospitalization rates for severe hypoglycemia (SH; −73%) and diabetic ketoacidosis (DKA; −80%) were taken from a recent observational study in Belgium where