Late Breaking Abstracts

June 2017 | Volume 66 | Suppl. 1A | www.diabetes.org/diabetes

American Diabetes Association®

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77TH SCIENTIFIC SESSIONS
SAN DIEGO, CA • JUNE 9 - 13, 2017

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preferred algorithm 2 and 180(90.9%) preferred algorithm 3. No patients preferred other three algorithms. There were four reasons for most physicians preferred algorithm 2. First, it was recommended by several guidelines (89.5%). Second, the titrating dose and frequency were moderate (56.2%). Third, I don't know other algorithms (15.7%). Forth, it was better than other algorithms (9.0%). In contrast, there were also four reasons for most patients preferred algorithm 3. First, it was simple (97.5%). Second, titrating 1U once is safe (13.6%). Third, titrating every day reached target faster (2.5%). Forth, it does not need calculating mean FBG (1.0%).

Conclusion: Patients prefer different insulin glargine titration algorithms with physicians. We should pay more attention to 1U increased once daily algorithm.

CLINICAL THERAPEUTICS/NEW TECHNOLOGY—INSULIN DELIVERY SYSTEMS

126-LB

Maintaining Glucose Control at One+ Year of MiniMed® 670G System Home Use: Single Center Experience

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The safety and effectiveness of 3-month in-home use of the MiniMed 670G hybrid closed-loop (HCL) system has been reported. 19/24 of patients (mean±SD 28.4±14.6 yrs) continued to use the system for > 1 year at the Barbara Davis Center for Diabetes, via the Continued Access Program (CAP). To the best of our knowledge this is the first report of in-home use of the system at 1 yr.

The Table in the Figure (1a) shows mean A1c and % of sensor use and HCL control (or Auto Mode), over time. Improvements observed at 3-month (time in target, 70-180 mg/dL; hypoglycemia, ≤70 mg/dL, ≤50 mg/dL; hyperglycemia, >180 mg/dL, >300mg/dl; and CV, were maintained at 1 yr. The Figure (1b-d) also shows sensor glucose over the 24-hour day, for the 2-week run-in and combined 3-month study and 9-month CAP periods for all, adolescent and adult patients. The mean bolus insulin dose in units/day at baseline was lower than at 1 yr (24.7±12.2 vs. 26.7±10.7), while total daily insulin dose in units/day was essentially unchanged (50.0±16.8 vs. 50.3±17.4). There were no serious adverse device-related events throughout the study at our site.

At our center, use of the MiniMed 670G HCL system for up to 1 yr was safe and improvements in glycemia were maintained. Our findings suggest that long-term use of the system may benefit patients with type 1 diabetes.

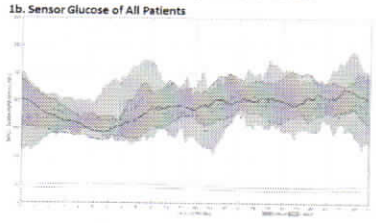
Figures.

1a.

		Baseline Mean±SD	3 Months Mean±SD	1 year Mean±SD
A1c(%)		7.7±0.9	7.0±0.5	7.3±0.9*
Sensor Usage(%)			88.2±7.0	80.5±12.4
HCL Control Usage(%)			73.8±10.7	68.2±16.4
Time in Range (%)	SG <50 mg/dL	0.8±0.8	0.6±0.5	0.6±0.5
	SG <70 mg/dL	4.7±3.8	3.2±1.5	3.5±1.7
	70< SG <180 mg/dL	63.9±11.3	70.4±7.5	68.0±9.4
	SG >180 mg/dL	31.5±13.3	26.4±7.5	28.5±9.8
	SG >300mg/dL	3.2±4.7	2.8±1.8	3.0±3.1
Coefficient of Variation-CV		34.1±4.1	31.7±3.8	32.1±2.7

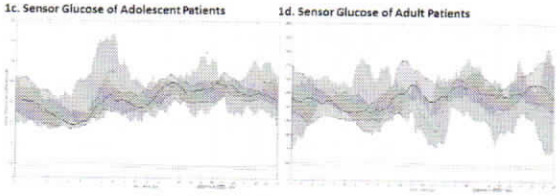
Note: Summary Baseline and 3- month data are based on 24 subjects (28.5±13.6 yrs of age). Summary 1-year data are based on: 19 subjects, except A1c at 1 year (* 13 subjects).

1b. Sensor Glucose of All Patients



1c. Sensor Glucose of Adolescent Patients

1d. Sensor Glucose of Adult Patients



The 1 year duration includes the 3-month study and 9-month CAP periods.

127-LB

Automatic Estimation of Basals, ISF, and Carb Ratio for Sensor-Augmented Pump and Hybrid Closed-Loop Therapy

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Summary: A tool for automatically tuning insulin pump basal rates, ISF, and carb ratios has been developed by patients in the open source community. Insulin dosing and carb data, glucose data from CGM, and pump profile settings are used to calculate expected blood glucose impact (BGI) for each glucose value. Each glucose value is then categorized as being most attributable to basal, ISF, or carb sensitivity factor (CSF=ISF/carb ratio), and used to calculate adjustments to basals, ISF, and CSF. For each hour, total BGI deviations and necessary adjustment in basal to bring deviations to 0 are calculated; 20% is applied to the previous 3 hours' basals. Median deviation for entire day's ISF-attributed data and necessary adjustment in ISF to bring the median deviation to 0 are calculated; 10% is applied. Total BGI deviations during observed carb absorption are calculated and compared to total carb intake to calculate new CSF; 10% is applied to the carb ratio. (n=1)*16 users reported feedback about how well this tool ("autotune") works.

Outcomes: 75% of surveyed users made changes to their insulin pump settings after running autotune. 100% of people felt basal suggestions were accurate: 83% changed their basal rates. They were less sure of carb ratio estimations (only 69% felt the estimates were accurate): 58% changed their carb ratios. 88% of people felt ISF suggestions were accurate: 67% changed their ISF. On average in the surveyed population, autotune estimated a needed 10.24% average change in hourly basal rates (net 4.54% increase overall); 29% increase needed in carb ratios; and 19% increase needed in ISF. Patients felt strongly that using data to assess changes to pump settings should be the norm rather than relying on the current methods of guessing or weight-based estimations.

Conclusion: These data show many patients are using non-optimal settings. Pump users and HCPs could benefit from using this type of tool to help make ongoing changes to ratios and basals.

128-LB

Metabolic Differences between CSII and MDI in Type 1 Diabetes Mexican Patients from the Multicentric Study RENACED

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Introduction: There is limited information regarding differences in metabolic control in patients with type 1 diabetes (T1D) treated with CSII or MDI in Mexico. RENACED, a longitudinal online system, was created to have a real-life data registry of T1D patients.

Methods: Bivariate analysis (alfa=0.05) of 464 T1D patients registered in RENACED system up to 2/22/2017.

Results: Of the 464 patients, 135 (29%) are on CSII and 329 (71%) on MDI. Patients on CSII had lower HbA1c levels (7.9%; CI 95% 7.6-8.1) than those on MDI (8.8%; CI 95% 8.6-9.1) (p<0.05). The total insulin daily dose was lower on CSII (0.58 IU/kg; CI 95% 0.52-0.64), than on MDI (0.82 IU/kg; CI 95% 0.69-0.96) (p<0.05), (Table 1). CSII was associated with higher SMBG per day (p<0.01). Almost no patients on MDI used CGM. A significantly higher event rate of mild/moderate hypoglycemia/week was observed in the CSII group 4.2 (3.0-5.3) vs. the MDI group 2.5 (2.3-2.7) (p<0.01). Patients on CSII that used CGM had lower HbA1c levels (7.7%; CI95% 7.4-8.0) than those that did not (8.0%; CI95% 7.7-8.4) (p=.22). An interesting finding is that those patients on CSII exercise more.

Conclusions: According to the literature, CSII use and higher number of SMBG/day are associated with better glycemic control. It is interesting that

those on CSII exercise more, a finding that will need to be confirmed with higher number of patients in the registry.

Table 1. Bivariate analysis of T1D patients that are on CSII or MDI therapy

	MDI (CI 95%)	CSII (CI 95%)	p
HbA1c (%)*	8.8 (8.6 - 9.1)	7.9 (7.6 – 8.1)	< 0.01
Mean daily insulin dose (kg/day)	0.82 (0.69 - 0.96)	0.58 (0.52 - 0.64)	< 0.01
Age (years)*	24.7 (23.4 - 26.1)	27.4 (25.1 - 29.8)	0.04
SMBG per day*	3.2 (3.0 - 3.4)	4.2 (3.7 - 4.6)	< 0.01
Exercise (%)*	38.9 (33.5 - 44.3)	76.2 (68.6 - 83.9)	< 0.01
Count Carbohydrates (%)*	62.6 (57.3 - 68.9)	93.2 (88.9 - 97.6)	< 0.01
Mild/Moderate hypoglycemia per week (events)*	2.5 (2.3 - 2.7)	4.2 (3.0 - 5.3)	< 0.01

*p< 0.05

129-LB

Behind Closed Doors: Technology and Intimacy in Type 1 Diabetes

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Introduction: Intimacy is an important determinant of quality of life. External technologies such as insulin pumps (CSII) and continuous glucose monitors (CGM) have the potential to impact intimacy and this may impact their uptake. We aimed to explore the association between external technologies and sexual activity.

Methods: An invitation to complete an online survey was sent to 3500 type 1 diabetes patients aged 16-60 years living in Western Australia. We used a mixed method approach with quantitative and qualitative responses.

Results: Of the 289 respondents (mean age 34.3 years, range 16-60 years, female 53%), 129 (45%) used CSII and 101 (35%) used CGM. Most respondents were sexually active (92%). Of CSII users, 48% reported that CSII interferes with sex. Common problems cited were; interrupts the moment, tangles and pulls. As a result, 75% of patients disconnect their pump to avoid this. The preferred CSII insertion site with respect to sexual activity was the abdomen, and 22% of patients reported that comfort during sex influenced the location of the site. One in four non-CSII users cited concerns about intimacy as a factor for not adopting the technology. In contrast, CGM was reported to interfere with sexual activity in only 20% of respondents, sexual activity did not commonly affect CGM placement (18%), and just one in ten non-CGM users cited intimacy as a factor for not adopting the technology. There were no differences between CSII and non-CSII respondents in body dissatisfaction using the Stunkard Figure rating scale (p=0.664) or anxiety the state-trait anxiety inventory (p=0.344).

Conclusion: CSII has a significant impact on intimacy and these concerns may significantly influence their uptake, but is less of an issue with respect to CGM. With increasing use of diabetes technologies, it is important for health care professionals to be aware of these potential concerns and address strategies to mitigate these.

Supported By: University of Western Australia

130-LB

WITHDRAWN

131-LB

Device-Supported vs. Routine Titration of Insulin Glargine 300 U/mL (Gla-300) in T2DM: Efficacy and Safety

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Insulin self-titration may help people with T2DM reach glycemic targets. MyStar DoseCoach™, a combined titration device/blood glucose meter, aids self-titration by providing automated insulin glargine dosing suggestions. AUTOMATIX, a randomized, parallel-group, multicenter treat-to-target trial, evaluated the efficacy and safety of device-supported vs. routine (investigator recommended) Gla-300 titration regimens. In total 151 participants with T2DM (insulin naïve/insulin pre-treated) were randomized 1:1 to device-supported or routine titration with Gla-300. Primary endpoint: percentage of participants reaching fasting SMPG (FSMPG) target 90-130 mg/dL at week 16 without severe hypoglycemia. Secondary endpoints included: percentage of participants reaching target FSMPG at week 16 without confirmed or severe hypoglycemia; change in mean FSMPG, HbA_{1c} and daily insulin dose (baseline to week 16). Number of participants experiencing hypoglycemia and adverse events were also reported. Although not significant, a higher proportion of participants using device-supported vs. routine titration achieved the primary endpoint (Table). Between titration arms, comparable numbers of participants experienced hypoglycemia and TEAEs/SAEs (Table). The results show that device-supported titration with Gla-300 has a good efficacy/safety profile and may aid glycemic target achievement.

Table. Outcomes from the AUTOMATIX study

	Device-supported titration (on-treatment period) (n=75)	Routine titration (on-treatment period) (n=76)
Participants[a] reaching mean FSMPG target range (90–130 mg/dL) at week 16, estimated[b] %		
Without severe hypoglycemia	45.9	36.8
Estimated weighted difference (95% CI)[c]	9.04 (-6.745 to 24.829)[d]	
Without confirmed (≤70 mg/dL) or severe hypoglycemia	34.3	14.5
Estimated weighted difference (95% CI)[c]	19.75 (6.284 to 33.227)[d]	
Change in mean FSMPG from baseline to week 16, mg/dL[a]	−45.22 (42.34)	−40.96 (41.23)
Change in mean HbA_{1c} from baseline to week 16, %[a]	−1.16 (0.84)	−1.01 (0.88)
Change in average daily Gla-300 dose from baseline to week 16, U/kg[a]	0.213 (0.189)	0.197 (0.153)
Hypoglycemia, number of participants (%)[e]		
Any time of day (24 h)		
Any event	26 (34.7)	29 (38.2)
Confirmed (≤70 mg/dL) or severe hypoglycemia	22 (29.3)	27 (35.5)
Nocturnal (00:00–05:59 h)		
Any event	8 (10.7)	11 (14.5)
Confirmed (≤70 mg/dL) or severe hypoglycemia	7 (9.3)	10 (13.2)
TEAEs, n (%)[e]	54 (85.3)	20 (38.2)
SAEs, n (%)[e]	2 (2.7)	3 (3.9)

[a]mITT population
[b]Estimated proportion of participants obtained by averaging all the imputed proportions of participants reaching the endpoint (a multiple imputation method was used to address missing values in the mITT population).
[c]Estimated difference of proportions obtained by combining the difference in percentage, weighted by the randomization stratum of previous use of insulin (insulin naive, insulin pre-treated), between titration groups of all different imputed data sets using Rubin's formula.
[d]Safety population.
[e]Not statistically significant (superiority testing).
[f]Superiority not determined.
Values are expressed as mean (SD) unless otherwise stated.
CI, confidence interval; SAE, serious adverse event; SD, standard deviation; FSMPG, fasting self-monitored plasma glucose; mITT, modified intent-to-treat; TEAE, treatment-emergent adverse event.

Supported By: Sanofi (NCT02585674)

132-LB

Safety and Feasibility of Omnipod Hybrid Closed-Loop in Children Aged 6-12 Years with Type 1 Diabetes Using a Personalized Model Predictive Control Algorithm

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Children have enhanced insulin sensitivity compared to adolescents and adults with type 1 diabetes. We investigated the performance of an automated glucose control algorithm using the Omnipod® Insulin Management System in children with type 1 diabetes. The system included a modified version of Omnipod, Dexcom® G4 sensor and a personalized model predictive control algorithm. The study consisted of a 36-hour inpatient closed-loop assessment with announced meals ranging from 30-90 g of carbohydrates and limited physical activity. Subjects aged 6-12 y and A1C between 6.0-10.0% were eligible. Endpoints included sensor glucose percentage of time <70, 70-180, >180, >250 mg/dL and mean glucose. Clinical demographics for 12 subjects included (mean±SD): age 8.9±1.6 y, diabetes duration 4.3±2.3 y, A1C 7.8±0.8% and TDD 0.8±0.1 U/kg. Glycemic outcomes are reported in the Table. The mean percentage of time in range, 70-180 mg/dL, was 69.2% overall and 82.0% overnight. The mean fasting glucose following overnight closed-loop was 136±24 mg/dL. The Omnipod automated glucose control algorithm performed well and was safe during day and night use in children with type 1 diabetes.

Table. Glycemic Outcomes during Hybrid Closed-Loop.

Glycemic outcomes	Overall	Night (23:00 - 07:00)
Mean glucose (mg/dL)	157±20	149±24
Percentage time between 70-180 mg/dL (%)	69.2±12.6	82.0±19.9
Percentage time between 70-140 mg/dL (%)	38.2±16.1	32.8±30.6
Percent time <70 mg/dL (%)	2.0±2.6	0.1±0.3
Percent time >180 mg/dL (%)	28.8±13.5	22.0±30.0
Percent time >250 mg/dL (%)	6.7±5.5	2.1±5.8

ADA-Supported Research

For author disclosure information, see page LB107.

feet checked by doctor (OR=1.54), received dilated eye exam (OR=1.32), have blood pressure checked (OR=2.49), and medical visit in past year (OR=2.45).

Conclusions: Access to care is relatively high and the QoC indicators in patients with diabetes and a diagnosis of kidney disease are being met. However, there is room for improvement in access to care in this patient population to avoid the expensive complication of end stage renal disease.

EPIDEMIOLOGY—TYPE 1 DIABETES

241-LB

Results of the Multicentric Study RENACED on Type 1 Diabetes Mexican Patients

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Introduction: Information regarding treatment, follow-up and outcomes of type 1 diabetes (T1D) Mexican patients is limited. An online system, RENACED, was created to have a longitudinal T1D registry with real-life data in Mexico.

Methods: Descriptive and bivariate analysis of 743 T1D patients registered on RENACED in 16 Mexican States (28 different medical units), until 2/22/2017.

Results: Forty percent of patients were men, with median age 21 years and median age at diagnosis 11 years old. Median diabetes duration from diagnosis was 10.5 years. Median HbA1c at diagnosis and in the last visit were 11.8% and 8.6%, respectively. Twelve percent have family history of T1D and 55% of T2D. SMBG is performed in 92%, 36% perform it ≥4 times/day. Regarding treatment, 26% are on CSII, 64% on MDI with insulin analogues, 8% on MDI with human insulin, 1.2% on premixed insulin, 1% on basal insulin only. Patients that perform SMBG ≥4 times/day, had lower HbA1c levels (8.2; CI95% 7.9-8.4) than those that monitor less (8.6; CI 95% 8.4-8.9) ($p<0.05$). Also, lower HbA1c levels ($p<0.05$) were observed in patients that used CGM (7.8; CI 95% 7.5-8.1 vs. 8.7; CI 95% 8.5-8.9), CSII (7.9; CI 95% 7.6-8.1 vs. 8.8; CI 95% 8.6-9.1), or Metformin (8.0; CI 95% 7.4-8.6 vs. 8.7; CI 95% 8.5-8.9). An HbA1c level <7% was found in 19% of patients. The presence of mild/moderate hypoglycemia is 71% and of severe hypoglycemia is 19%. Presence of retinopathy, neuropathy and nephropathy was found in 15%, 13% and 12.5%, respectively.

Conclusions: According to the literature, the percentage of patients with HbA1c at goal is lower than desired, even though many are on state-of-the-art treatment. Performing SMBG ≥4 times/day, CGM use, CSII and Metformin are associated with better glycemic control. This is the first online system for T1D registry in Mexico. A larger number of cases will lead to better national representation.

Supported By: FIND

242-LB

Maternal Obesity and the Risk of Childhood-Onset Type 1 Diabetes

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Background: A few studies have suggested that maternal pre-pregnancy obesity or excessive gestational weight gain predicts higher risk of childhood type 1 diabetes, but results are not consistent and the mechanisms are unknown. No previous study has explored the corresponding association with paternal anthropometry to evaluate whether maternal obesity could reflect shared unmeasured background characteristics.

Methods: We evaluated the associations of parental anthropometric measurements with the offspring's risk of type 1 diabetes among 132,331 children participating in the Norwegian Mother and Child Cohort Study (MoBa) and the Danish National Birth Cohort (DNBC). The associations with type 1 diabetes, as defined by national childhood diabetes registers (n=499 cases), were evaluated using Cox proportional hazards regression. Parental anthropometric measurements were self-reported.

Results: 81,630 children participated from MoBa (mean age at end of follow-up, 11.0 years) and 50,701 from DNBC (mean age at end of follow-up, 15.5 years). The incidence rate of type 1 diabetes was 32.7 cases per 100,000 person-years in MoBa and 28.5 cases per 100,000 person-years in DNBC. Both maternal pre-pregnancy obesity, HR 1.41 (95% CI: 1.06, 1.89), and paternal obesity, HR 1.51 (95% CI: 1.11, 2.04), was associated with childhood type 1 diabetes. In contrast, there was no strong evidence of an association between maternal gestational weight gain and childhood type 1 diabetes.

Conclusion: While maternal obesity predicted higher risk of childhood type 1 diabetes, the causal nature of this observation is questioned by a similar observation for paternal obesity, which might reflect unobserved confounding by shared parental lifestyle characteristics.

Supported By: National Institutes of Health; Norwegian Research Council; Medical Research Council, UK; Danish National Research Foundation; European Union

243-LB

Where Are the Missing Children? Development and Implications of Improved Type 1 Diabetes Prevalence Estimates in Less-Resourced Countries

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Aim: Current estimates of type 1 diabetes (T1D) prevalence in less-resourced countries produced by the International Diabetes Federation (IDF) have various limitations. These include an assumption of zero mortality, a developed-country age-of-onset distribution with a fixed prevalence/incidence ratio, age range restricted to <15 years (y), and no temporal incidence changes. We developed a model to address these limitations.

Methods: A discrete time Markov illness-death model with age and calendar-year-dependent transition probabilities was developed in R 3.3.1. A novel feature of the model is the inclusion of a two-fold impact of diabetes on mortality: a probability of death at onset (from misdiagnosis, or during initial ketoacidosis episode), as well as a sustained excess mortality.

Results: The model was validated against 17 y of incidence/prevalence/mortality data from Uzbekistan, with correlation of r=0.93 and marked improvement compared to estimates based on IDF Atlas assumptions; and also against 15 y of similar data from New South Wales, Australia (difference with model 1.3%).

Prevalence was modelled for various countries under varying assumptions. Data indicates that in a country such as Nigeria, the proportion of children aged 0-<15 y who die at onset and/or within 6 months of developing T1D may be 90% or more. In sub-Saharan Africa, a very conservative estimate is that there are over 2,000 deaths annually <15 y alone.

Conclusion: This model improves prediction of incidence or prevalence or mortality in young people with T1D under varying measurements/estimations of two of these parameters. Results demonstrate the need for public health and clinical interventions in many countries to prevent deaths from misdiagnosis and improve ongoing management. A further implication is that numbers will quickly rise when care improves, requiring expansion of clinical services and increased requirements of insulin and other supplies.

Supported By: The Leona M. and Harry B. Helmsley Charitable Trust

244-LB

Impact of Excessive Gestational Weight Gain and Prepregnancy BMI on Prevalence of Large-for-Gestational-Age Infants in Two Cohorts of Women with T1DM

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Background: Despite improvements in treatment modalities, prevalence of large-for-gestational age (LGA) remains high among mothers with TIDM. Higher birthweight is associated with increased risk of obesity and TIIDM among offspring. We aimed to establish the change in LGA prevalence and associations between gestational weight gain (GWG) and LGA outcomes among mothers with TIDM between periods 1978-1995 and 2002-2008.

Research Design and Methods: Analysis of mothers with TIDM enrolled in Diabetes in Pregnancy Program Project Grant (PPG), a cohort from 1978-1995 (n=333) and those enrolled in Consortium on Safe Labor (CSL), a multi-center cross-sectional study from 2002-2008 (n=358). LGA was defined as birthweight >90th percentile adjusted for gestational age, sex and race. GWG was defined according to 2009 Institute of Medicine (IOM) guidelines. Logis-