



Glucometrics and device satisfaction in children and adolescents with type 1 diabetes using different treatment modalities: A multicenter real-world observational study

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ABSTRACT

Aims: To analyze metabolic outcomes, diabetes impact and device satisfaction in children and adolescents with type 1 diabetes in Italy who used different treatment modalities for diabetes care in a real-life context.

Methods: In this multicenter, nationwide, cross-sectional study, 1464 participants were enrolled at a routine visit. The following treatment modalities were considered MDI + SMBG; MDI + CGM; Sensor Augmented Pump Therapy; predictive management of low glucose; Hybrid Closed Loop (HCL); Advanced Hybrid Closed Loop (AHCL). Health related quality of life was evaluated by the Italian version of the Diabetes Impact and Device Satisfaction Scale (DIDS) questionnaire.

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Results: Patients treated with AID systems were more likely to have $HbA1c \leq 6.5\%$, higher percentage of time with glucose levels between 70 and 180 mg/dL, lower percentage of time with glucose levels above 180 mg/dL, higher device satisfaction, and reduced impact of diabetes. All the therapeutic modalities with respect to MDI + CGM, except for MDI + SMBG, contributed to increase the device satisfaction. HCL and AHCL respect to MDI + CGM were associated with lower diabetes impact.

Conclusion: Real-life use of automated insulin delivery systems is associated with reduced type 1 diabetes impact, increased device satisfaction, and achievement of glycemic goals.

Research in context

Evidence before this study

We searched PubMed studies published between Jan 1, 2000, and Aug 31, 2023 using the terms: (“type 1 diabetes”) AND (“children”, OR “adolescent”) AND (“glucose monitoring”, OR “glucometrics”, OR “glucose targets”, OR “glycemic targets”, OR “metabolic targets”) AND (“insulin pumps”, OR “multiple daily injection therapy”, OR “Sensor Augmented Pump Therapy”, OR “automated insulin delivery system”, OR “hybrid closed-loop system”, OR “advanced hybrid closed-loop system”) AND (“quality of life”, OR “satisfaction”, OR “impact”) with no language restrictions. The previous studies detected reveal that advancements like continuous glucose monitoring (CGM) and insulin pumps (IPs) have significantly improved glycemic outcomes and quality of life in young and adult populations dealing with Type 1 diabetes. Various technologies, including sensor-augmented insulin pump therapy, Predictive Low Glucose Management, and automated insulin delivery systems, have been developed, aiding in managing blood glucose levels and reducing the distress associated with diabetes. However, there is a notable absence of comprehensive information to guide the selection of suitable therapeutic modalities for individual patients based on various factors like lifestyle habits, glycemic results, and socio-economic backgrounds.

Added value of this study

In this multicentre national study involving 1464 children and adolescents with type 1 diabetes aged 2 to 17 years we provide evidence that the real-life use of automated insulin delivery systems is associated with reduced type 1 diabetes impact, increased device satisfaction, and achievement of glycemic goals.

Implications of all the available evidence

All young individuals with type 1 diabetes deserves access to the most advanced and affordable insulin delivery technology. It's crucial that these technologies are tailored to meet their unique needs and preferences, to optimize health outcomes and enhance their quality of life. Prioritizing the availability and adaptation of such technology is essential to accommodate individual circumstances and lifestyles.

1. Introduction

Young people (17 years of age and younger) with type 1 diabetes often strive to maintain blood glucose levels close to glycemic target. However, only a small percentage manage to achieve this goal [1]. Research results, namely, systematic reviews and meta-analyses of well-designed randomized controlled trials demonstrate the efficacy and safety of new diabetes technologies for improving glycemic outcomes in children and adults with type 1 diabetes. In practice, the use of continuous glucose monitoring (CGM) and insulin pumps (IPs) by people with type 1 diabetes has increased markedly over the past two decades [2,3] changing the paradigm in diabetes care. Technology uptake has increased the most dramatically in the pediatric population [3,4]. Increasingly performing algorithms that connect CGMs and IPs allow patients to obtain glycemic targets both in children [5] and adults [6]. In developed countries, it is rare for a patient with type 1 diabetes not to use a form of technology to manage their blood glucose. There are many combinations of technology systems which may or may not use different algorithms. The number of patients using the traditional therapeutic modality with multiple daily injection therapy (MDI) and Self-

Monitoring of Blood Glucose (SMBG) is decreasing. In daily clinical practice, many still use the IP and CGM without algorithms linking to each other, the so-called sensor-augmented insulin pump (SAP) therapy. Some use the Predictive Low Glucose Management (PLGM) system, where an algorithm helps prevent hypoglycemia by reducing insulin delivery or stopping it before hypoglycemia begins. Others use automated insulin delivery (AID) systems, which include hybrid closed-loop (HCL) systems and advanced hybrid closed-loop (AHCL) systems. And finally, few patients use an open-source AID (OS-AID) system.

Beyond achieving glucose targets, the use of technology impacts on the quality of life of children and their caregivers. Widespread use of CGMs is associated with improved in quality of life (QOL), reduction of fear of hypoglycemia, of distress due to diabetes [7–9]. Benefits of using IP on QOL and treatment satisfaction were recently reported [10,11]. Automated systems have been shown to reduce stress and improve sleep quality for children and parents [12,13], as have OS-AID systems [14]. When choosing the most suitable therapeutic modality for the individual patient in clinical practice, it is very useful to have contemporary information on clinical characteristics, lifestyle habits, glycemic results, quality of life and family socio-economic background [15].

However, this information is not available to guide clinicians and patients. The aim of this study was to analyze metabolic outcomes, diabetes impact and device satisfaction in children and adolescents with type 1 diabetes in Italy who used different treatment modalities for diabetes care in a real-life context. In order to evaluate diabetes impact and device satisfaction, the Italian version of the Diabetes Impact and Device Satisfaction Scale (DIDS) [13] questionnaire was validated.

2. Subjects, materials and methods

Between 2021 and 2022 22 pediatric diabetes centers distributed throughout Italy participated in a multicenter, nationwide, cross-sectional study. Children and adolescents with type 1 diabetes aged 2 to 17 years were consecutively enrolled at a routine visit. Inclusion criteria were diagnosis of type 1 diabetes for more than six months, any diabetes treatment modality, willing to participate in the study of the parents and children over 11 years of age. Exclusion criteria were psychiatric diseases, unwilling to participate in the study and the use of an OS-AID system as it is not approved for use in Italy at the time of this study.

The Regional Marche Ethical Committee approved the study on 3rd March 2021 (Protocol n. 2020–439).

2.1. Treatment modalities

The following treatment modalities were considered: MDI + SMBG; MDI + CGM (isCGM or rtCGM); SAP (Sensor Augmented Pump Therapy); PLGM (predictive management of low glucose); HCL (Hybrid Closed Loop); AHCL (Advanced Hybrid Closed Loop). Since the isCGM used by patients in this study included Abbott Freestyle 2 and later, we considered rtCGM and isCGM together. Advanced Hybrid Closed loop systems differ from HCLs in the ability to deliver an automatic bolus to correct hyperglycemia, whereas in HCL systems, hyperglycemia correction occurs through an automatic change in basal insulin. Although HCL and AHCL may be included in the same group of AID systems, we have considered them as different modalities as they have

been marketed separately. The Italian National Healthcare System offered all treatment devices to all type 1 diabetes patients free-of-charge without discrimination based on income, gender or age.

2.2. Devices characteristics

This study included patients using all types of devices available on the Italian market. The CGM systems were Dexcom G6, Abbott Freestyle libre 2 and Enlite® or Guardian™ Connect. The insulin pumps used in SAP treatment were Omnipod or GlucoMen Day Pump. Predictive Management of Blood Glucose (PLGM) systems were Medtronic Mini-Med™ 640G or Tandem Basal-IQ, HCL system was Medtronic Mini-Med™ 670G, AHCL systems were Medtronic MiniMed™ 780G or Tandem Control-IQ.

Once the informed consent was signed by parents and children over 11 years, the demographic, clinical and anamnestic data of the clinical routine were collected.

Demographic information included indicators on the parents' socioeconomic status, such as level of education, declared gross annual income was also collected.

Metabolic outcomes for the previous 30 days were assessed at the time of visit. We considered the percentage of time that the glucose level measured by the CGM was below 54 mg/dL (3.0 mmol/L), in the range of 54 to 70 mg/dL (3.9 to 10.0 mmol/L), in the target glucose range of 70 to 180 mg/dL (3.9 to 10.0 mmol/L), in the range of 180 to 250 mg/dL (10.0 to 13.9 mmol/L), greater than 250 mg/dL (13.9 mmol/L), and the coefficient of variation of glucose (%). We also considered HbA1c, which was measured with DCA Vantage® analyzer in all participating centers.

The Italian version of the Diabetes Impact and Device Satisfaction Scale (DIDS) questionnaire, consisting of 11 items, was first validated, and then filled in anonymously and autonomously by the participants if over the age of 11 or by their parents if younger.

2.3. Questionnaire validation

The DIDS [13] questionnaire comprises 11 items, each rated using a 10-point Likert Scale. Out of these, seven items concentrate on gauging satisfaction concerning the insulin delivery device, including aspects like trust and user-friendliness. The other four items aim to evaluate the regularity of prevalent diabetes-related issues, like the disease's impact on daily life, concerns about hypoglycemia, and disruptions in sleep. In relation to the device satisfaction, a higher score on the scale indicates greater satisfaction with the insulin delivery device. Conversely, for assessing the impact of diabetes, a lower score reflects a more favourable outcome, suggesting fewer diabetes-related complications and a lesser impact on daily life. The few number of items making it quick to compile and easy to use in clinical practice.

Confirmatory factor analysis was used to evaluate the validity of the Italian version of the questionnaire by examining its two-domain structure. Goodness of fit was assessed using the Tucker Lewis Index (TLI), Comparative Fit Index (CFI), and Root Mean Square Error of Approximation (RMSEA). Acceptable fit is indicated by TLI and CFI values > 0.90, while values > 0.95 suggest a very good fit. RMSEA values < 0.05 indicate a good level of fitting, values up to 0.10 a reasonable fitting and values above 0.10 a poor level of fitting.

The validation of the DIDS questionnaire in the Italian version was based on a sample randomly extracted from the entire set of collected data. Reliability was assessed analysing internal consistency using Cronbach's α coefficients and 95 % Confidence Intervals (95 % CI). Concurrent validity was evaluated by estimating Spearman correlation coefficients and 95 % CI between each domain scores of the Insulin Delivery System Rating Questionnaire (IDSRQ [16]) and DIDS domain scores.

The ability of the questionnaire to discriminate children who could achieve with optimal glycaemic control (HbA1c values \leq 6.5 %, percentage of time with blood glucose between 70 and 180 mg/dL \geq 75) from those with sub-optimal or poor glucose control (HbA1c values \geq

7.5%, percentage of time with blood glucose between 70 and 180 mg/dL < 54) was evaluated by comparing the distribution of DIDS Satisfaction and Impact scores using the Wilcoxon rank-sum test.

Data collected from patients who had completed DIDS questionnaire twice, at baseline and after 3 months, were analysed to test reproducibility, by estimating the median of the differences in DIDS domains score and 95 % CI.

2.4. Statistical analysis

A descriptive analysis of the main characteristics of the subjects was performed using medians and interquartile ranges (IQR) to summarize the quantitative variables, as because the shape of their distribution was not normal to the Shapiro-Wilks test; absolute and percentage frequencies were used for the qualitative variables.

Demographic, socioeconomic, anamnestic, clinical, treatment satisfaction and impact of diabetes scores, and glucose metrics were evaluated according to treatment modalities; Kruskal-Wallis test or Chi-square test were used to compare groups.

The role of treatment on metabolic outcomes was analysed by means of logistic regression model, considering to be at target metabolic (HbA1c \leq 6.5 %) as dependent variable and therapeutic modalities as explicative factor, demographic, socioeconomic, anamnestic, and clinical variables as covariates.

Evaluation of the effects of different therapeutic modalities on insulin treatment satisfaction and diabetes impact was analysed through quantile regression models, considering DIDS score as dependent variables, therapeutic modalities as factors of interest, and demographic, socioeconomic, anamnestic, and clinical variables as adjusting factors.

As SMBG is currently being used in fewer children with TYPE 1 DIABETES, MDI + CGM has been used as a reference category.

All methods are summarised in Fig. S3.

3. Results

3.1. Questionnaires validation

The validation process was based on a random sample of 279 children with diabetes type 1 with a median age of 14 years, IQR 11; 16, 49.8% males, with a mean HbA1c of 7.1% (SD = 0.89), a median number of SMBG of 2 (IQR 0; 2) and 25 (0.9%) had familiarity for diabetes. Majority of patients (86.4%) used a diabetes sensor and an insulin pump (62.2%). The median percentage of Time with blood glucose between 70 and 180 mg/dL (TIR) was 66.7 % (IQR 53; 76) (Table S1). The Italian version of DIDS showed good internal consistency and validity in our sample (Tables S2-S4, Figs. S1-S2).

3.2. Results of the study

A total of 1,464 children and adolescents, 53 % males, median age 13 years, were recruited from 22 Italian paediatric diabetes centres nationwide (Table S5).

Demographic, clinical, and socio-economic characteristics of participants are reported in Table 1.

Fig. 1a shows the demographic and clinical characteristics of the subjects by therapeutic modalities. Patients treated with AHCL (n = 235) were younger than subjects treated with HCL (n = 72), MDI + SMBG (n = 65), SAP (n = 206), shorter diabetes duration was associated to MDI + CGM (n = 771) and AHCL modalities, the AHCL system was associated with the lowest distribution of HbA1c; moreover, the automated treatment modalities were associated with the highest level of device satisfaction and the lowest diabetes impact.

Glucose metrics were at their best level in subjects treated with automated systems, in AHCL was characterised by the highest values of TIR, the lowest values of percentage of time with glucose higher than 180 mg/dL (Fig. 1b). The distribution of the coefficient of variation was

Table 1
Demographic, clinical, and socio-economic characteristics of participants.

| | n | |
|--|------|-----------------|
| Age, years [median (IQR)] | 1464 | 13 (10; 16) |
| Age classes, n (%) | 1464 | |
| 2–5 years | 64 | (4.4) |
| 6–9 years | 241 | (16.5) |
| 10–13 years | 453 | (30.9) |
| 14–17 years | 706 | (48.2) |
| Gender, M [n (%)] | 1464 | 773 (52.8) |
| Diabetes duration, years [median (IQR)] | 1464 | 5 (3; 8) |
| HbA1c, % [mean (sd)] | 1259 | 7.4 (3.1) |
| mmol/mol [mean (sd)] | 1259 | 56.9 (10.8) |
| Percentage of time with glucose level below 54 mg/dL [median (IQR)] | 1351 | 0 (0; 1.0) |
| Percentage of time with glucose level between 54 and 69 mg/dL [median (IQR)] | 1366 | 2 (1; 4) |
| Percentage of time in glucose range 70–180 mg/dL [median (IQR)] | 1366 | 60.2 (48.2; 72) |
| Percentage of time with glucose level between 181 and 250 mg/dL [median (IQR)] | 1367 | 26 (19; 33) |
| Percentage of time with glucose level above 250 mg/dL [median (IQR)] | 1356 | 8.1 (3; 17) |
| Number of hypoglycemic episodes in the previous year [n, %] | 1301 | 31 (2.4) |
| Number of DKA episodes in the previous year [n, %] | 1307 | 24 (1.8) |
| Frequency of SMBG [median (IQR)] | 1368 | 1 (0; 3) |
| Physical activity, hours / week [median (IQR)] | 1399 | 2 (0; 4) |
| First-degree relative with type 1 diabetes, yes [n (%)] | 1464 | 139 (9.5) |
| Father age, years [median (IQR)] | 1409 | 48 (7) |
| Father educational level, n (%) | 1395 | |
| Low | 606 | (43.4) |
| Medium | 544 | (39.0) |
| High | 245 | (17.6) |
| Mother age, years [median (IQR)] | 1369 | 44 (6) |
| Mother educational level, n (%) | 1404 | |
| Low | 522 | (37.2) |
| Medium | 579 | (41.2) |
| High | 303 | (21.6) |
| Family gross annual income, n (%) | 1399 | |
| <15000 € | 189 | (13.5) |
| 15,000 – 25,999 € | 415 | (29.7) |
| 26000–54999 € | 516 | (36.9) |
| 55000–75000 € | 205 | (14.6) |
| >75000 € | 74 | (5.3) |

IQR: interquartile range; SMBG: Self-Monitoring of Blood Glucose

significantly lower in subjects treated with automated devices than non-automated therapies.

Table 3 report factors associated with device satisfaction and diabetes impact scores. All the therapeutic modalities with respect to MDI + CGM, except for MDI + SMBG, contributed to increase the device satisfaction. Subjects aged 12–17 years had higher level of device satisfaction than the youngest group (11 years). Among clinical factors, a higher HbA1c were associated with decreasing satisfaction score.

HCL and AHCL respect to MDI + CGM were associated with lower diabetes impact, but in presence of physical activity the diabetes impact tended to increase for patients using AHCL.

Table 2 shows factors associated with an optimal metabolic control expressed as HbA1c \leq 6.5 %. The use of IP increased the probability of having HbA1c \leq 6.5 %, in fact all the treatment modalities including IP and SGM, independently from the algorithm, were associated with optimal metabolic control. The probability of HbA1c \leq 6.5 % significantly increased for each year of patients' or mother's age added, for each hour of physical activity added, while decreased for each year of diabetes duration added.

4. Discussion

In this study, we analysed the metabolic outcomes, diabetes impact, and device satisfaction of all currently authorized therapeutic modalities

in Italy for the treatment of children with type 1 diabetes in the context of daily life. Patients treated with AID systems were more likely to have HbA1c \leq 6.5 %, higher percentage of time with glucose levels between 70 and 180 mg/dL, lower percentage of time with glucose levels above 180 mg/dL, higher device satisfaction, and reduced impact of diabetes.

In addition, the findings of this study were based on the Diabetes Impact and Device Satisfaction (DIDS) scale, which is a short, reliable, and validated questionnaire in Italian, aimed at assessing the device-specific satisfaction and impact of diabetes management. The scale is particularly useful for better understanding the human factors related to the adoption and ongoing use of diabetes-related technology.

4.1. Glycemic control

Our data showed that AHCL users were younger and had a shorter duration of diabetes than those treated with other treatment modalities. However, a short duration of diabetes was also observed in those who used CGM alone. These findings may suggest that technology is used since the onset of diabetes in Italian children. It is also interesting to note that with the most advanced technologies, not only was HbA1c lower, achieving desired glycemic goals, but variability was lower than with other treatment modalities. Most of the children treated with MDI also used a CGM and had better HbA1c values than those treated with SMBG. However, only a very small number of them, less than 25 %, managed to have HbA1c values in the desired target [17]. On the other hand, it had already been reported that using the MDI and CGM treatment modality, only 49 % of those using isCGM and 56 % of those using rtCGM achieved a percentage of time in the glucose target range 70–180 mg/dL [18].

4.2. Device satisfaction and diabetes impact

In Italy, the introduction of the insulin pump into clinical practice preceded that of the CGM. The first real-world national study showed advantages in quality of life in adolescents treated with IP compared to MDI, highlighting a positive role of technology in diabetes management [19].

Not surprisingly, in the current study, young people treated with MDI and CGM were more satisfied than those treated with MDI and SMBG. However, it is interesting to note that the simultaneous use of the insulin pump and the glucose sensor were, in all cases, associated with greater user satisfaction. On the other hand, the use of AID systems was also associated with reductions in diabetes impact compared with those using MDI and CGM therapy. These elements confirm that AID systems contributed to improve quality of life [20,21] and, thus, should have wider use in children and adolescents with type 1 diabetes.

4.3. Treatment modalities and physical activity

A separate discussion should be reserved for users of advanced technological systems during physical activity. In fact, the association between AHCL and physical exercise highlights a greater impact of diabetes in those who perform more hours of physical activity per week, suggesting that they need more information and probably personalized education.

This greater impact of diabetes may be due to the uncertainty of how to treat blood glucose changes before and after physical activity, the choice of whether or not to wear an insulin pump during exercise, and the discomfort of wearing a pump while participating in sports.

4.4. Comparison with other real-life studies

Our results are consistent with those of recent studies highlighting glycemic benefits of AID in the real world [22–24].

A recent analysis of the SWEET international registry [25] on a cohort of 4,930 young people with type 1 diabetes in 2008–2010 and 13,654 in 2016–2018 reported an increase from 21 % to 34 % in the percentage of

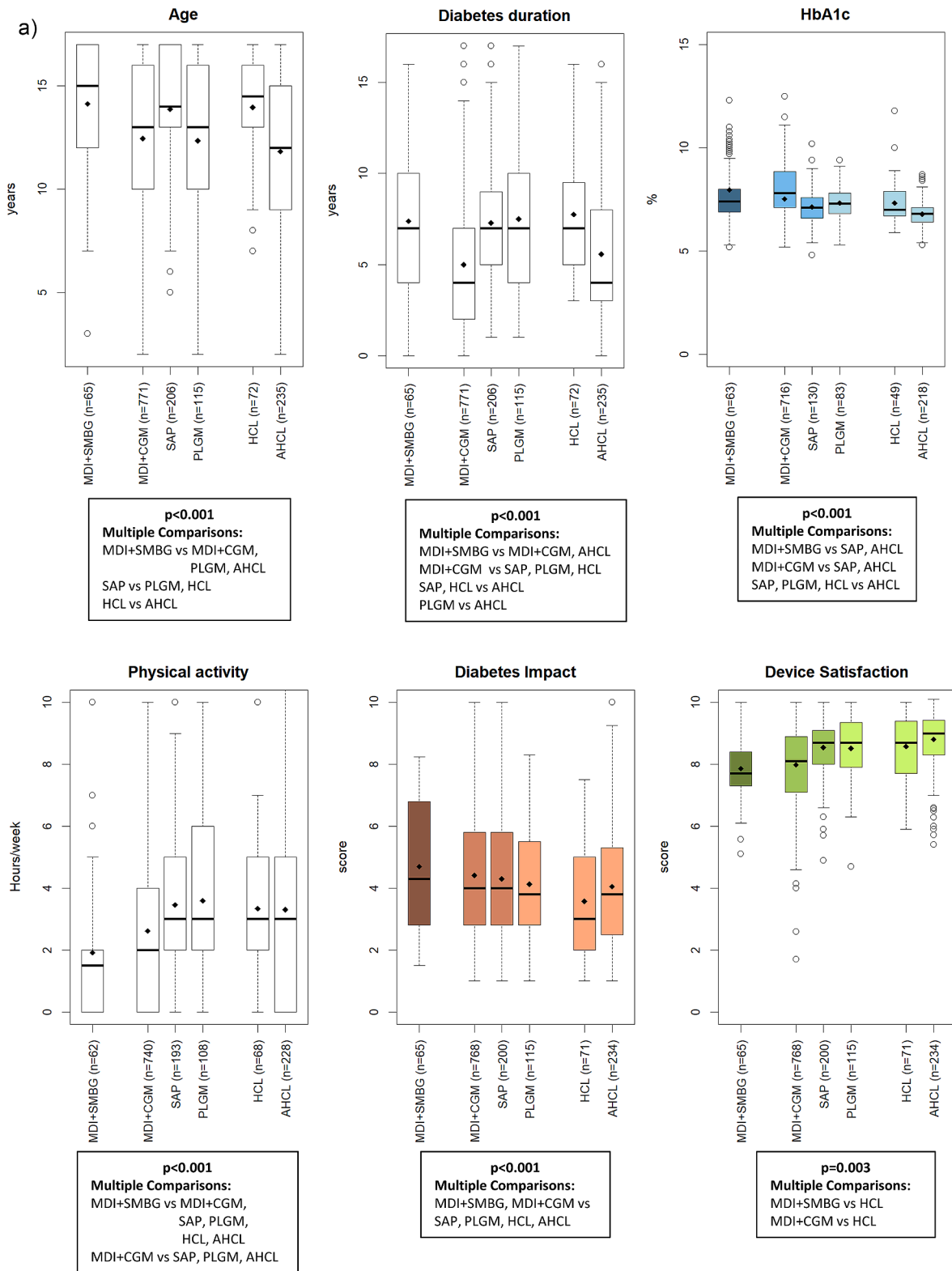


Fig. 1. Demographic, clinical characteristics and glucose metrics according to treatment strategy.

people achieving HbA1c target (<7%). This increase was associated with the growing use of diabetes technology, with glucose sensors being used by 44.6% of patients and insulin pumps by 41.8% in 2018.

The strengths include a study design based on real-world data, a large sample size obtained from 22 of the 52 Italian pediatric diabetes

centres, following fewer or more than 150 patients [26], evenly distributed across the country, thus increasing the generalizability of our results. Moreover, the participating centres are included in the ISPED study group for diabetes, sharing the same electronic medical record system and standardized clinical procedures.

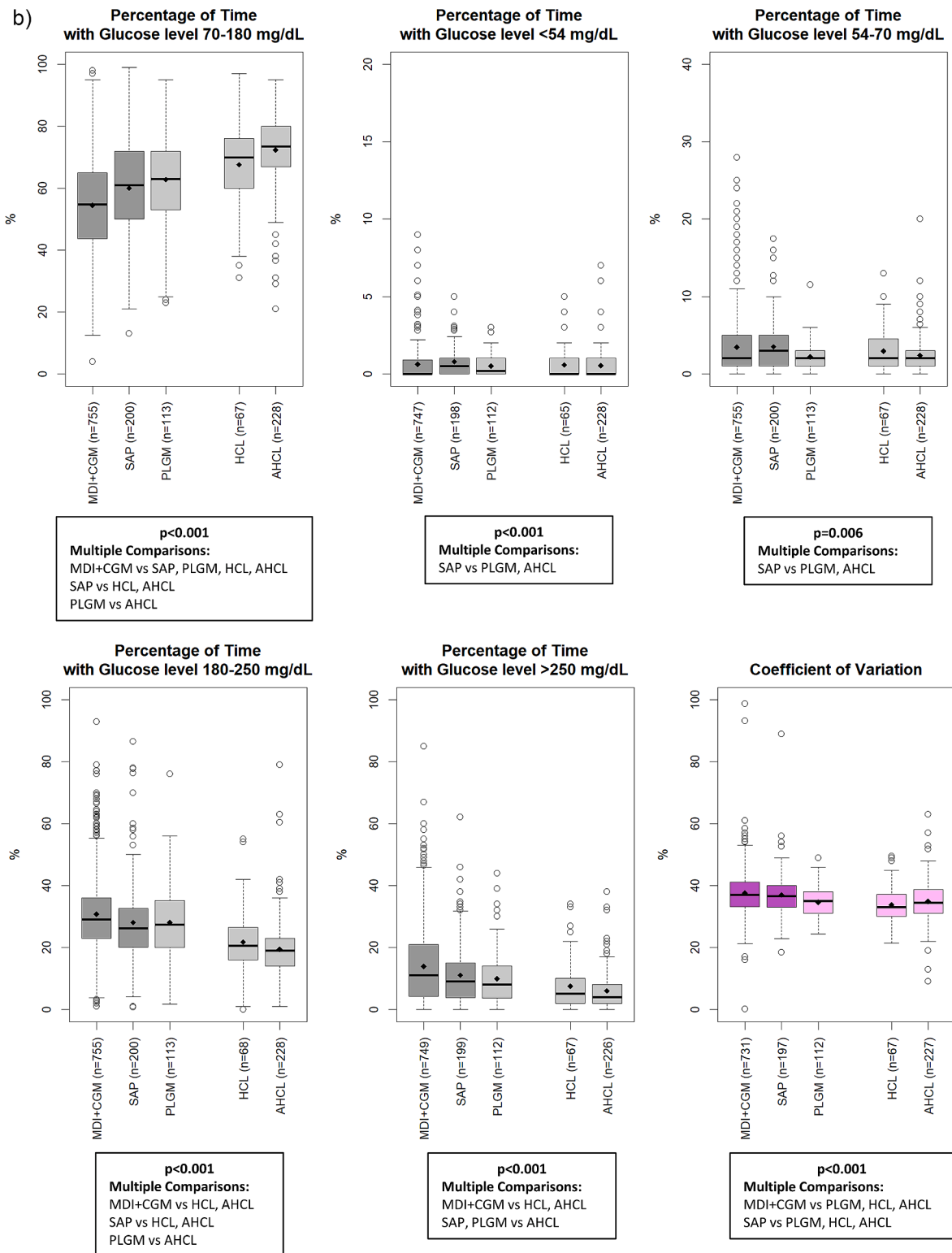


Fig. 1. (continued).

Among the limitations, less than 50 % of the centres participated in the study, perhaps because great organizational efforts were required. Furthermore, for many variables the completeness of the data did not reach 100 %, even if the highest percentage of missing was equal to 14 %.

Regardless of sensor or pump type, real-life use of automated insulin delivery systems is associated with reduced type 1 diabetes impact,

increased device satisfaction, and increased achievement of glycemic goals.

The findings of this study raise some questions that need to be answered. Why are most children with type 1 diabetes still using less effective treatment modalities? In our study more than 50 % of patients use MDI with or without CGM. What are the main barriers to using AID systems in clinical practice? Is it possible that the costs of new

Table 2

Factor associated to optimal metabolic control (HbA1c \leq 6.5 %). Results of logistic regression analysis.

| | OR | 95 %CI | p |
|---------------------------------|------|------------|--------|
| Gender (Female vs Male) | 0.96 | 0.74; 1.25 | 0.778 |
| Age (years) | 1.05 | 1.00; 1.11 | 0.036 |
| Diabetes Duration (years) | 0.95 | 0.91; 0.99 | 0.013 |
| Therapy MDI + SMBG vs MDI + CGM | 1.08 | 0.51; 2.11 | 0.830 |
| Therapy SAP vs MDI + CGM | 3.57 | 2.48; 5.16 | <0.001 |
| Therapy PLGM vs MDI + CGM | 2.59 | 1.60; 4.15 | <0.001 |
| Therapy HCL vs MDI + CGM | 3.03 | 1.74; 5.25 | <0.001 |
| Therapy AHCL vs MDI + CGM | 2.27 | 1.58; 3.25 | <0.001 |
| Physical activity (hours/week) | 1.08 | 1.03; 1.13 | 0.001 |
| Father education medium vs low | 1.31 | 0.95; 1.81 | 0.103 |
| Father education high vs low | 1.29 | 0.83; 1.98 | 0.254 |
| Mother education medium vs low | 0.97 | 0.70; 1.36 | 0.876 |
| Mother education high vs low | 1.30 | 0.85; 1.98 | 0.232 |
| Father age (years) | 1.00 | 0.97; 1.03 | 0.998 |
| Mother age (years) | 1.04 | 1.01; 1.08 | 0.011 |

Table 3

Factor associated with health-related quality of life.

| | Coefficient estimate | 95 %CI |
|--|----------------------|--------------|
| Device Satisfaction | | |
| Age group 6–11 vs 0–5 years | 0.24 | −0.03; 0.55 |
| Age group 12–17 vs 0–5 years | 0.34 | 0.01; 0.65 |
| Therapy MDI + SMBG vs MDI + CGM | −0.40 | −0.62; −0.15 |
| Therapy SAP vs MDI + CGM | 0.60 | 0.42; 0.81 |
| Therapy PLGM vs MDI + CGM | 0.46 | 0.04; 0.79 |
| Therapy HCL vs MDI + CGM | 0.70 | 0.32; 0.89 |
| Therapy AHCL vs MDI + CGM | 0.76 | 0.49; 0.86 |
| HbA1c 7.7–9% vs < 7 % | −0.24 | −0.40; −0.06 |
| HbA1c \geq 8% vs < 7 % | −0.44 | −0.60; −0.15 |
| Mother education medium vs low | −0.10 | −0.24; 0.07 |
| Mother education high vs low | −0.20 | −0.40; 0.07 |
| Mother age (years) | −0.20 | −0.33; −0.07 |
| Diabetes Impact | | |
| Age group 6–11 vs 0–5 years | −0.90 | −1.47; −0.22 |
| Age group 12–17 vs 0–5 years | −1.35 | −1.79; −0.68 |
| Therapy MDI + SMBG vs MDI + CGM | −0.13 | −0.75; 1.42 |
| Therapy SAP vs MDI + CGM | −0.25 | −1.15; 0.96 |
| Therapy PLGM vs MDI + CGM | −0.80 | −1.36; 0.10 |
| Therapy HCL vs MDI + CGM | −0.75 | −1.64; −0.03 |
| Therapy AHCL vs MDI + CGM | −0.60 | −1.30; −0.15 |
| Physical activity (hours/week) | 0.03 | −0.06; 0.07 |
| HbA1c 7.7–9% vs < 7 % | 0.20 | −0.22; 0.55 |
| HbA1c \geq 8% vs < 7 % | 0.55 | 0.05; 1.00 |
| Father education medium vs low | −0.10 | −0.48; 0.25 |
| Father education high vs low | −0.25 | −0.71; 0.26 |
| MDI + SMBG vs MDI + CGM in Physical activity | −0.06 | −0.48; 0 |
| SAP vs MDI + CGM in Physical activity | 0.10 | −0.16; 0.32 |
| PLGM vs MDI + CGM in Physical activity | 0.08 | −0.11; 0.22 |
| HCL vs MDI + CGM in Physical activity | 0.06 | −0.47; 0.48 |
| AHCL vs MDI + CGM in Physical activity | 0.13 | 0.03; 0.31 |

Results of quantile regression analysis.

technologies are too high? Can we start AID systems from the first day after diagnosis?

As a definitive cure for type 1 diabetes is not yet achievable and achieving metabolic targets is essential to reduce cardiovascular risk, all young people should be offered the most advanced insulin delivery technology available that is affordable and tailored to their individual needs and preferences.

Data sharing

Aggregated data might be made available upon reasonable request via email to the corresponding author.

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CRediT authorship contribution statement

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2024.111621>.

References

- [1] Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016–2018. *Diabetes Technol Ther* 2019;21(2):66–72.
- [2] Miller KM, Hermann J, Foster N, Hofer SE, Rickels MR, Danne T, et al. Longitudinal changes in continuous glucose monitoring use among individuals with type 1 diabetes: international comparison in the German and Austrian DPV and U.S. T1D exchange registries. *Diabetes Care* 2020;43(1):e1–2.
- [3] van den Boom L, Karges B, Auzanneau M, Rami-Merhar B, Lilienthal E, von Sengbusch S, et al. Temporal trends and contemporary use of insulin pump therapy

- and glucose monitoring among children, adolescents, and adults with type 1 diabetes between 1995 and 2017. *Diabetes Care* 2019;42(11):2050–6.
- [4] Prigge R, McKnight JA, Wild SH, Haynes A, Jones TW, Davis EA, et al. International comparison of glycaemic control in people with type 1 diabetes: an update and extension. *Diabet Med* 2022;39(5):e14766.
 - [5] Dovc K, Lanzinger S, Cardona-Hernandez R, Tauschmann M, Marigliano M, Cherubini V, et al. Association of achieving time in range clinical targets with treatment modality among youths with type 1 diabetes. *JAMA Netw Open* 2023;6(2):e230077.
 - [6] Norgaard K, Ranjan AG, Laugesen C, Tidemand KG, Green A, Selmer C, et al. Glucose monitoring metrics in individuals with type 1 diabetes using different treatment modalities: a real-world observational study. *Diabetes Care* 2023.
 - [7] Brew-Sam N, Chhabra M, Parkinson A, Hannan K, Brown E, Pedley L, et al. Experiences of young people and their caregivers of using technology to manage type 1 diabetes mellitus: systematic literature review and narrative synthesis. *JMIR Diabetes* 2021;6(1):e20973.
 - [8] Burckhardt MA, Roberts A, Smith GJ, Abraham MB, Davis EA, Jones TW. The use of continuous glucose monitoring with remote monitoring improves psychosocial measures in parents of children with type 1 diabetes: a randomized crossover trial. *Diabetes Care* 2018;41(12):2641–3.
 - [9] Marigliano M, Pertile R, Mozzillo E, Troncone A, Maffei C, Morotti E, et al. Satisfaction with continuous glucose monitoring is positively correlated with time in range in children with type 1 diabetes. *Diabetes Res Clin Pract* 2023;110895.
 - [10] Al Shaikh A, Al Zahrani AM, Qari YH, AbuAlnasr AA, Alhawsawi WK, Alshehri KA, et al. Quality of life in children with diabetes treated with insulin pump compared with multiple daily injections in tertiary care center. *Clin Med Insights Endocrinol Diabetes* 2020;13. 1179551420959077.
 - [11] Speight J, Choudhary P, Wilmot EG, Hendrieckx C, Forde H, Cheung WY, et al. Impact of glycaemic technologies on quality of life and related outcomes in adults with type 1 diabetes: a narrative review. *Diabet Med* 2023;40(1):e14944.
 - [12] Bisio A, Brown SA, McFadden R, Pajewski M, Yu PL, DeBoer M, et al. Sleep and diabetes-specific psycho-behavioral outcomes of a new automated insulin delivery system in young children with type 1 diabetes and their parents. *Pediatr Diabetes* 2021;22(3):495–502.
 - [13] Manning ML, Singh H, Stoner K, Habib S. The development and psychometric validation of the diabetes impact and device satisfaction scale for individuals with type 1 diabetes. *J Diabetes Sci Technol* 2020;14(2):309–17.
 - [14] Braune K, Gajewska KA, Thieffry A, Lewis DM, Froment T, O'Donnell S, et al. Why #WeAreNotWaiting-motivations and self-reported outcomes among users of open-source automated insulin delivery systems: multinational survey. *J Med Internet Res* 2021;23(6):e25409.
 - [15] Cherubini V, Zucchini S, Bonfanti R, Rabbone I, Scaramuzza A. Which treatment modalities are being used by Italian children and adolescents with type 1 diabetes? *Diabetes Technol Ther* 2024.
 - [16] Peyrot M, Rubin RR. Validity and reliability of an instrument for assessing health-related quality of life and treatment preferences: the insulin delivery system rating questionnaire. *Diabetes Care* 2005;28(1):53–8.
 - [17] de Bock M, Codner E, Craig ME, Huynh T, Maahs DM, Mahmud FH, et al. ISPAD clinical practice consensus guidelines 2022: glycemic targets and glucose monitoring for children, adolescents, and young people with diabetes. *Pediatr Diabetes* 2022;23(8):1270–6.
 - [18] Cherubini V, Bonfanti R, Casertano A, De Nitto E, Iannilli A, Lombardo F, et al. Time in range in children with type 1 diabetes using treatment strategies based on nonautomated insulin delivery systems in the real world. *Diabetes Technol Ther* 2020;22(7):509–15.
 - [19] Cherubini V, Gesuita R, Bonfanti R, Franzese A, Frongia AP, Iafuso D, et al. Health-related quality of life and treatment preferences in adolescents with type 1 diabetes. The VIPKIDS study *Acta Diabetol* 2014;51(1):43–51.
 - [20] Kudva YC, Laffel LM, Brown SA, Raghinaru D, Pinsker JE, Ekhlaspour L, et al. Patient-reported outcomes in a randomized trial of closed-loop control: the pivotal international diabetes closed-loop trial. *Diabetes Technol Ther* 2021;23(10):673–83.
 - [21] Wheeler BJ, Collins OJ, Meier RA, Betts ZL, Frampton C, Frewen CM, et al. Improved technology satisfaction and sleep quality with Medtronic MiniMed(R) advanced hybrid closed-loop delivery compared to predictive low glucose suspend in people with type 1 diabetes in a randomized crossover trial. *Acta Diabetol* 2022; 59(1):31–7.
 - [22] Silva JD, Lepore G, Battelino T, Arrieta A, Castaneda J, Grossman B, et al. Real-world performance of the MiniMed 780G system: first report of outcomes from 4120 users. *Diabetes Technol Ther* 2022;24(2):113–9.
 - [23] Breton MD, Kovatchev BP. One year real-world use of the control-IQ advanced hybrid closed-loop technology. *Diabetes Technol Ther* 2021;23(9):601–8.
 - [24] Akturk HK, Giordano D, Champakanath A, Brackett S, Garg S, Snell-Bergeon J. Long-term real-life glycaemic outcomes with a hybrid closed-loop system compared with sensor-augmented pump therapy in patients with type 1 diabetes. *Diabetes Obes Metab* 2020;22(4):583–9.
 - [25] Gerhardsson P, Schwandt A, Witsch M, Kordonouri O, Svensson J, Forsander G, et al. The SWEET project 10-year benchmarking in 19 countries worldwide is associated with improved HbA1c and increased use of diabetes technology in youth with type 1 diabetes. *Diabetes Technol Ther* 2021;23(7):491–9.
 - [26] de Beaufort C, Vazeou A, Sumnik Z, Cinek O, Hanas R, Danne T, et al. Harmonize care to optimize outcome in children and adolescents with diabetes mellitus: treatment recommendations in Europe. *Pediatr Diabetes* 2012;13(Suppl 16):15–9.