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https://doi.org/10.31925/farmacia.2025.2.14 **ORIGINAL ARTICLE**

GLYCAEMIC CONTROL IN PAEDIATRIC TYPE 1 DIABETES: THE INTERPLAY OF DIABETES ACCEPTANCE AND MEDICAL TECHNOLOGIES

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Abstract

Type 1 diabetes (T1D) is characterised by complete insulin deficiency, placing a lifelong burden of insulin replacement therapy on patients. Children and adolescents are particularly vulnerable patients who must balance physical and emotional developmental changes with strict adherence to treatment regimens. Thus, they might benefit the most from advanced diabetes management technologies (ADMT), such as Continuous Glucose Monitoring Systems (CGMS) and insulin pumps. This study aimed to: (*i*) assess how different medical devices for managing T1D impact glycaemic control in young patients, and (*ii*) evaluate diabetes acceptance levels in this population group using a structured questionnaire. A total of 97 children and adolescents with T1D were recruited from Galati County. Many diabetes complications were observed, mainly diabetic neuropathy, neuropathy and nephropathy. ADMT use was associated with significant improvements in glycaemic control. Notably, diabetes acceptance scores were significantly associated with HbA1c improvement. CGMS demonstrated high efficacy regardless of patients' knowledge and attitudes, whereas insulin pump efficacy was influenced considerably by diabetes acceptance levels. These findings highlight the importance of tailoring therapeutic interventions to the characteristics of the patient and the devices used.

Rezumat

Diabetul zaharat de tip 1 (T1D) este caracterizat de un deficit complet de insulină, impunând pacienților o povară pe viață constând în terapia de substituție cu insulină. Copiii și adolescenții sunt pacienți deosebit de vulnerabili, fiind nevoiți să echilibreze modificările fizice și emoționale ale dezvoltării cu respectarea strictă a regimurilor de tratament. Astfel, ei ar putea beneficia cel mai mult de tehnologiile avansate de gestionare a diabetului (ADMT), cum ar fi sistemele de monitorizare continuă a glicemiei (CGMS) și pompele de insulină. Acest studiu a urmărit să: (*i*) evalueze modul în care diferite dispozitive medicale pentru gestionarea T1D au un impact asupra controlului glicemic la pacienții tineri și (*ii*) evalueze nivelurile de acceptare a diabetului în acest grup de populație utilizând un chestionar structurat. Un total de 97 de copii și adolescenți cu T1D au fost recrutați din județul Galați. Au fost observate numeroase complicații ale diabetului, în principal neuropatie diabetică, neuropatie și nefropatie. Utilizarea ADMT au fost asociate cu îmbunătățiri semnificative ale controlului glicemic. În special, scorurile de acceptare a diabetului au fost asociate semnificativ cu îmbunătățirea HbA1c. CGMS au demonstrat o eficacitate ridicată indiferent de cunoștințele și atitudinile pacienților, în timp ce eficacitatea pompei de insulină a fost influențată semnificativ de nivelurile de acceptare a diabetului. Aceste constatări evidențiază importanța adaptării intervențiilor terapeutice la caracteristicile pacientului și la dispozitivele utilizate.

Keywords: type 1 diabetes, continuous glucose monitoring system (CGMS), diabetes acceptance, glycaemic control

Introduction

Type 1 diabetes (T1D) is a chronic autoimmune disorder characterised by the destruction of insulin-producing beta cells in the pancreas, resulting in complete insulin deficiency. With T1D being the third most common disease in children and adolescents [1], significant challenges appear in terms of management and patients' life quality, requiring lifelong insulin therapy, continuous glucose monitoring and lifestyle adaptations [2]. Younger populations' distinct physiological, psychological, and social demands add to the difficulty of managing T1D [3], making patient-centred treatment approaches imperative.

Achieving glycaemic control to avoid both short-term and long-term complications is the most important target in T1D management, especially in young adults [4]. Possible short-term complications due to glycaemic dysregulation include hypoglycaemia and diabetic ketoacidosis, which is more frequent among young people recently diagnosed with T1D [5]. Long-term risks include retinopathy, nephropathy, and neuropathy [6, 7].

When referring to children and adolescents, the increased rate of physical growth, hormonal changes and differing levels of adherence to the treatment plan can impede adequate therapeutic efficiency. Adolescents, in particular, might be at an even greater risk of nonadherence when compared to other paediatric age groups [3]. Younger patients face complex formative years of physical and emotional development, as well as social adaptation [8]. Tailored interventions that factor these patients' unique needs and integrate advanced medical technologies (ADMT) could ensure better adherence to the treatment plan and improved quality of life [9, 10].

According to a recent report, continuous glucose monitoring systems (CGMS) are increasing, particularly among children and young adults, and have long-term benefits in diabetes management [11]. Another study found that insulin pump use in children and adolescents has increased significantly in recent years, illustrating a trend towards advanced diabetes management technologies [12]. Integrated systems that combine CGMS and insulin pumps could provide optimal glycaemic control by automatically adjusting insulin delivery based on real-time glycaemic data. A study published in The Lancet demonstrated that these systems can significantly reduce the time spent in hypoglycaemia and hyperglycaemia [13].

Thus, the current study aimed to (*i*) assess how different medical devices for managing T1D impact glycaemic control in young patients, and (*ii*) evaluate diabetes acceptance levels in this population group using a structured questionnaire.

Materials and Methods

Study design and participants

A cross-sectional study was conducted in April 2024 over a convenience sample of 97 children and adolescents with T1D from Galați County, Romania. All the study participants signed an informed consent for their inclusion. The inclusion criteria were patients younger than 25 years old with type 1 diabetes, registered in the records of "Sfântul Ioan" Children's Emergency Hospital in Galați, with parents or tutors agreeing to participate in the survey. Exclusion criteria were refusal to participate, lack of written informed consent, presence of pathology that could interfere with the ability to respond to the questionnaire, and incomplete responses in the survey.

Clinical and demographic data collection

We used the patient's medical records to extract information regarding sociodemographic characteristics and T1D characteristics. The variables extracted were age, sex, area of residence, T1D duration, complications (neuropathy, nephropathy, retinopathy), HbA1c (initial and actual), history of diabetic ketoacidosis, self-monitoring frequency, and device use (CGMS, insulin pump or both). HbA1c levels were measured using an immunoturbidimetric assay per the manufacturer's protocol. Results were extracted from the patients' medical records, which had been recorded as part of routine clinical evaluations at the "Sfântul Ioan" Children's Emergency Hospital in Galați.

Diabetes acceptance assessment

We applied a questionnaire that consisted of 12 items related to diabetes acceptance (Q1- usability of the insulin pump; Q2-usability and acceptability of CGMS; Q3-changes in the quality of sleep associated with continuous insulin delivery and/or CGMS; Q4 -changes in stress level related to continuous insulin delivery and/or CGMS; Q5 - the level of confidence on diabetes management decision; Q6 - the level of confidence in the self-management of hyper- or hypoglycaemia; Q7 -confidence in changes in the T1D treatment; Q8- satisfaction with actual T1D treatment; Q9- confidence in the self-management of T1D in special situations (physical activity; holiday; sickness days); Q10 - knowledge of the chronic diabetes-specific complications; Q11 - perceptions on the accessibility to continuous insulin delivery and/or CGMS; Q12 - overall impact of T1D on daily activities). The second part of the questionnaire was recorded through direct interviews with the patients. The answers were provided on a Likert scale ranging from 1 - disapproval to 5 - total agreement.

Questionnaire design and validation

The Diabetes Acceptance Questionnaire was newly developed for this study based on clinical experience and expert input, aiming to capture both attitudinal and behavioural aspects related to medical device use in paediatric T1D patients. Although inspired by existing constructs from the literature, it represents a novel tool. Its internal consistency was validated in this study (Cronbach's alpha = 0.87).

Statistical analysis

Statistical analysis was performed with R Studio version 4.4.2 [14]. Descriptive statistics characterised general aspects of the socio-demographic and questionnaire variables (mean, standard deviation, 95% confidence interval, median, frequencies). The association between variables was tested using the Chi-Square and Fisher test. Binary logistic regression was employed to predict a positive change in glycaemic control (shown by the positive changes of the category of HbA1c level) using as predictors the type of self-monitoring system, type of treatment, and initial HbA1c level. Glycaemic control improvement was defined as a categorical reduction in HbA1c level, *i.e.*, a change from a higher to a lower clinically relevant HbA1c range (*e.g.*, from > 10% to 8.6-10%, or from 8.6-10% to 7.5-8.5%). This definition aligns with other clinical studies assessing diabetes interventions in paediatric populations [15, 16]. The structured questionnaire was validated using the alpha-Cronbach coefficient.

Ethical approval

All the study participants signed an informed consent for their inclusion in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of "Sfântul Ioan" Children's Emergency Hospital in Galați.

Results and Discussion

The alpha-Cronbach coefficient of 0.87 (confidence interval (CI):0.83, 0.90) showed good internal validity. The questionnaire was tested for data suitability for factor analysis (KMO = 0.85, Bartlett's Test (χ^2 = 471.83, $p < 0.001$). Factorial analysis revealed the presence of two components that explained 45% of the variance: factor 1 (MR1) - gathered tie items related to attitudes toward CGMS, aspects related to the quality of life, such as stress, sleep quality, and confidence in self-management of T1D; factor 2 (MR2) grouped the items I1- usability of the insulin pump; I8- satisfaction with actual T1D treatment; I9- confidence in the self-management of T1D in special situations reflecting attitudes toward the T1D treatment (Table I).

Although Item I10 had low loadings, it was kept in the final score of the questionnaire because it showed the general level of knowledge on diabetes-specific complications. These findings support the internal consistency of the questionnaire and the validity of the two-factor structure. Similar multidimensional tools have been used to assess treatment satisfaction and device acceptance in diabetes management, particularly in adolescents, where psychological and behavioural constructs significantly influence outcomes [8].

Table I

Items Factor Loadings

Item	MR1	MR2	h² (communality)
I1	0.21	**0.58**	0.39
I2	**0.49**	0.41	0.40
I3	**0.66**	0.42	0.62
I4	**0.54**	0.41	0.47
I5	**0.77**	0.30	0.68
I6	**0.62**	0.00	0.38
I7	**0.60**	0.48	0.60
I8	0.52	**0.63**	0.66
I9	-0.02	**0.72**	0.52
I10	**0.21**	0.02	0.05
I11	**0.48**	0.41	0.40
I12	**0.42**	0.23	0.23

The score obtained by the participants on the questionnaire ranged from 27 to 50, with a mean value of 39.9 (SD = 5.07) and a median of 40. The scores obtained on the Diabetes Acceptance Questionnaire showed a normal distribution in the participants from our sample (Shapiro-Wilk, p = 0.06).

The sample included children and adolescents with a mean age of 14.38 (SD: 5.34), ranging from 5 to 25 years old. According to data published by the International Diabetes Federation (IDF), type 1 diabetes mellitus is commonly diagnosed in childhood and adolescence, with a peak incidence between 10 and 14 years of age. The present study confirms this trend, with the highest proportion of respondents (48%) in the 12-18 age group [17].

A relatively large number of participants came from urban areas, although the difference was not statistically significant (χ^2 = 2.77, p = 0.096), and had a duration of type 1 diabetes longer than 6 years (n = 36 participants) (Table II). Device usage in most cases exceeded 1 year (53%), and an important part of participants declared self-monitoring blood glucose more than 4 times a day (47.4%). Although many children had continuous glucose monitoring systems (CGMS) (61.9%), a relatively low number of participants had continuous insulin delivery and CGMS (11.3%).

Continuous glucose monitoring devices consist of a sensor that continuously measures subcutaneous glucose while wirelessly sending data to a display device. The result is real-time, continuous blood glucose monitoring [18].

It is important to note that the prevalence of specific diabetes complications was relatively high, with 27 children having diabetic neuropathy (27.8%), 16 with nephropathy (16.5%), and 4 having diabetic retinopathy (4.1%). This high incidence is likely influenced by the recruitment strategy involving hospitalised patients. Since individuals with more severe or advanced diabetes are more likely to require hospital care, the sample may have been skewed toward those presenting complications. As a result, these findings may not accurately reflect the prevalence of complications in the general paediatric diabetic population but rather highlight the burden of diabetes-related complications among those requiring hospitalisation. Other clinic-oriented studies have reported the prevalence of neuropathy ranging from 6% to 62% [19-21]. A percentage similar to ours was observed when analysing a cohort of 1433 adolescents with T1D in Australia [22]. The high rate of CGMS usage among participants (61.9%) reflects a growing trend in paediatric diabetes care, as reported in recent literature [23]. However, despite technological advancements, the high prevalence of complications like neuropathy and nephropathy may indicate late initiation or suboptimal integration of such devices in routine care. Additionally, given that this cohort included hospitalised patients, the complication rates may be inflated due to selection bias - a phenomenon also observed in other hospital-based studies [24].

The answers to the Diabetes Acceptance Questionnaire were provided on a Likert scale ranging from 1 - disapproval to 5 - total agreement (Figure 1).

Table II

Socio-demographic characteristics

Variable	**Categ.**	**No**	**%**	**Categ.**	**No**	**%**	**Categ.**	**No**	**%**	**Categ.**	**No**	**%**
Age categories	<6	8		6-12	19		12-18	47		18-25	23	
Sex	Male	53		Female	45							
Area of residence	Urban	61	62.9	Rural	36	37.1						
Diabetes duration (years)	< 1	9	9.30	1-3	25	25.8	3-6	27.00	27.8	> 6	36	37.1
Time of device usage (months)	< 6	11	11.3	6-12	24	24.7	12-24	29.00	29.9	> 24	33	34.0
Device Type	CGMS	60	61.9	insulin pump	26	26.8	Insulin pump & CGMS	11	11.3			
Glycaemia (frequency of determination/day)	2 - 4	51	52.6	> 4	46	47.4						
Initial HbA1c	< 7.5	3	3.10	7.5 - 8.5	5	5.2	8.6 - 10	30.00	30.9	> 10	59	60.8
Actual HbA1c	< 7.5	39	40.2	7.5 - 8.5	32	33.0	8.6 - 10	17.00	17.5	> 10	9	9.3
History of diabetic Ketoacidosis	No	70	72.20%	Yes	27	27.80%						
Chronic complications	absent	50	51.5	neuropathy	27	27.8	retinopathy	4.00	4.1	nephropathy	16	16.5

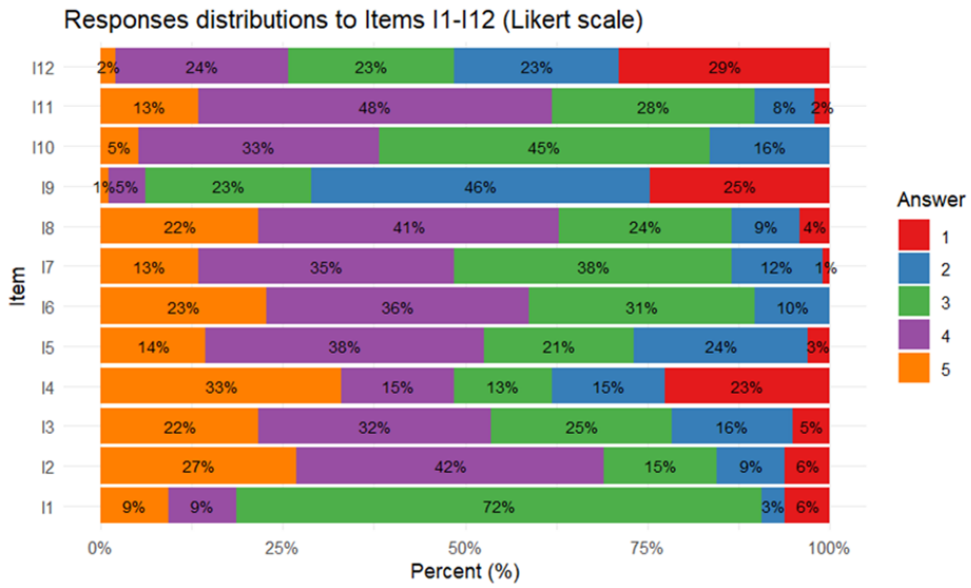

Figure 1.
Distribution of Responses to Diabetes Acceptance Questionnaire

According to the initial HbA1c level, many respondents had a HbA1c level above 8.6% (n = 89; 94.68%). However, at the moment of the study, almost half of the participants had reasonable glycaemic control (HbA1c < 7.5: n = 39; 40.2%). Only 9.3% (n = 9) and 17.5% (n = 17) children had very poor (HbA1c > 10%) and poor control, respectively (HbA1c: 8.6-10%) (Table II). The overall improvement in glycaemic control observed in the cohort, especially among patients initially presenting with poor or inferior control, aligns with data from the DIAMOND and CITY trials [15, 25]. Both trials demonstrated that structured CGMS use can lead to significant HbA1c reductions, particularly in younger populations with historically high baseline values. This effect is likely mediated by the immediacy of feedback from CGMS, allowing real-time adjustments and better glycaemic awareness. Baseline analysis of HbA1c by device type indicates a significant difference between patients who switched to the insulin pump without CGMS *versus* those who had CGMS (Fisher's Exact Test: p = 0.008) (Table III). No differences in HbA1c were observed between participants who opted for

CGMS only and those who opted for an insulin pump and CGMS (p = 0.53) and also between participants receiving only an insulin pump and those on an insulin pump and CGMS (p = 0.059) (Table III).

Table III

Initial HbA1c Category Distribution According to the Device Type

Device type	HbA1c < 7%	HbA1c 7 - 8.5%	HbA1c 8.6 - 10%	HbA1c > 10%
CGMS	2.1%	2.1%	26.8%	30.9%
Insulin pump	0%	2.1%	3.1%	21.6%
CGMS and Pump	1%	1%	1%	8.2%

The mean score for the Diabetes Acceptance Questionnaire did not differ between participants on CGMS (40.1; SD = 4.83), insulin pump (38.9; SD = 4.6), and those on CGMS and insulin pump (41.5; SD = 7.16) (ANOVA test, p = 0.347).

There was a general improvement in glycaemic control, and HbA1c in patients with poor control improved significantly. Many patients who previously had very poor control progressed to moderate control (28 patients). A significant number of patients with poor prior control progressed directly to good control (27 patients). Very few patients remained in the same category (the diagonal has low frequencies), and there were no significant shifts in the opposite direction. No deterioration of glycaemic control was observed (Figure 2).

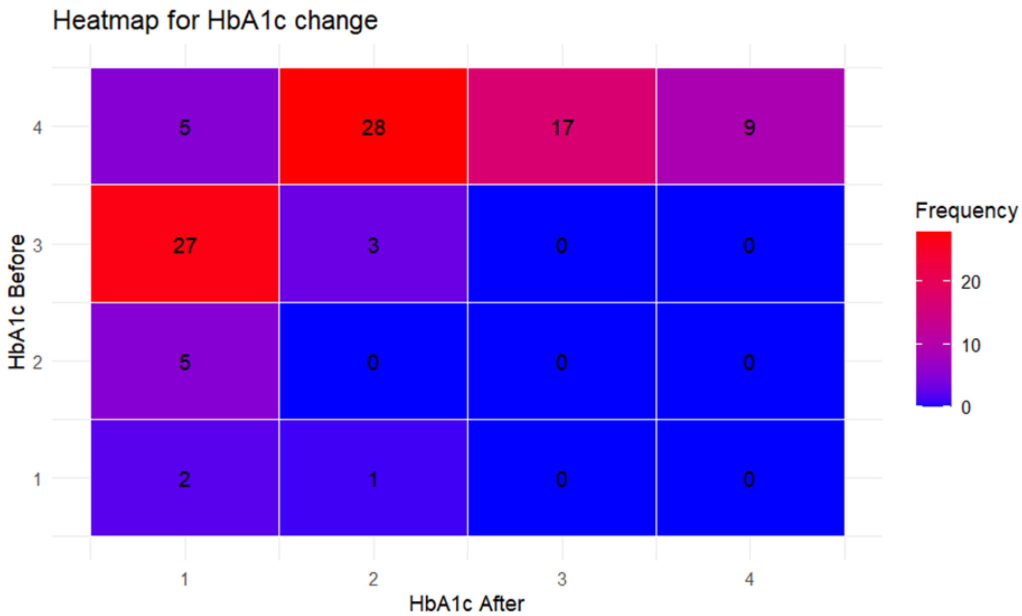

Figure 2.

Heatmap for HbA1c change

1 - HbA1c < 7.5%; 2 - HbA1c: 7.5 - 8.59%; 3 - HbA1c: 8.6-9.9%; 4 - HbA1c > 10%

A significant proportion of patients with CGMS improved their glycaemic control (57 *vs*. 3; 95%), while those receiving only an insulin pump improved their control in 7 cases (26.92%) (Fisher's Exact Test: p = 0.01). Other studies have also observed improvements in glycaemic control in young patients with type 1 diabetes [15, 16, 26]. Compared to standard blood glucose monitoring, in adolescents and young adults with T1D, improved HbA1c was associated with the use of CGMS [25]. Patients using CGMS showed the highest rate of HbA1c improvement (95%), while insulin pump-only users had significantly lower improvement rates (26.9%). This may be due to the fact that insulin pump therapy requires a higher degree of patient engagement and active decision-making. Without adequate diabetes acceptance and self-management confidence, the potential benefits of pump therapy may not be fully realised. Similar findings have been reported by Battelino *et al*., who emphasised the need for patient education and behavioural support alongside technological interventions [16].

The score obtained on the Diabetes Acceptance Questionnaire was significantly associated with improved HbA1c (OR = 1.23, 95% CI: 1.09 - 1.43, p = 0.002). Our logistic regression analysis highlighted that diabetes acceptance was a significant predictor of HbA1c improvement, particularly among insulin pump users. This suggests that the psychological dimension of treatment plays a critical role in its efficacy. Previous research indicates that high treatment satisfaction and confidence in self-management correlate with better glycaemic outcomes [3, 8]. Patients on insulin pumps only were about 86% less likely to improve their HbA1c compared to baseline. Patients who used CGMS and the pump were approximately 76% less likely to improve HbA1c than those with CGMS, but the effect was not statistically significant (OR = 0.24, CI = 0.034 - 1.98) (Table IV).

Table IV

Logistic regression for HbA1c improvement

Variable	OR	95% CI	p-value
Diabetes Acceptance Questionnaire Score	1.23	1.09 - 1.43	**0.002**
Insulin pump vs. CGMS	0.14	0.028 - 0.568	**0.024**
CGMS and Insulin pump vs. CGMS	0.24	0.034 - 1.98	0.710
Model 1 - combined effect: type of device and questionnaire			
Intercept	2.89	2.60e - 31.78	0.8233
Diabetes Acceptance Questionnaire Score	1.04	0.82-1.32	0.6930
Insulin Pump	0.13	0.02-0.64	**0.0240**
Insulin Pump and CGMS	0.02	0.001-1.66	0.5479
Questionnaire × Insulin Pump (Interaction)	1.91	1.04-3.50	**0.0366**
Questionnaire × Insulin Pump and CGMS (Interaction)	1.06	0.76-1.47	0.7109

The score obtained on the questionnaire did not directly influence the improvement of HbA1c (p = 0.6930). Patients on insulin pump only significantly decreased the chance of HbA1c improvement (p = 0.0240). The interaction between the questionnaire score and Device Type was significant (p = 0.0366, OR = 1.91) for patients on insulin pump only, where Attitudes had a stronger effect on improving HbA1c. Patients with this device need greater scores on the Diabetes Acceptance Questionnaire to have an improvement in their glycaemic control (Table IV).

Figure 3 illustrates the relationship between the Diabetes Acceptance Questionnaire Score (C) and the likelihood of improvement in glycosylated haemoglobin (HbA1c) according to three types of medical devices (1- CGMS, 2 - Insulin Pump, 3 - CGMS and Insulin Pump).

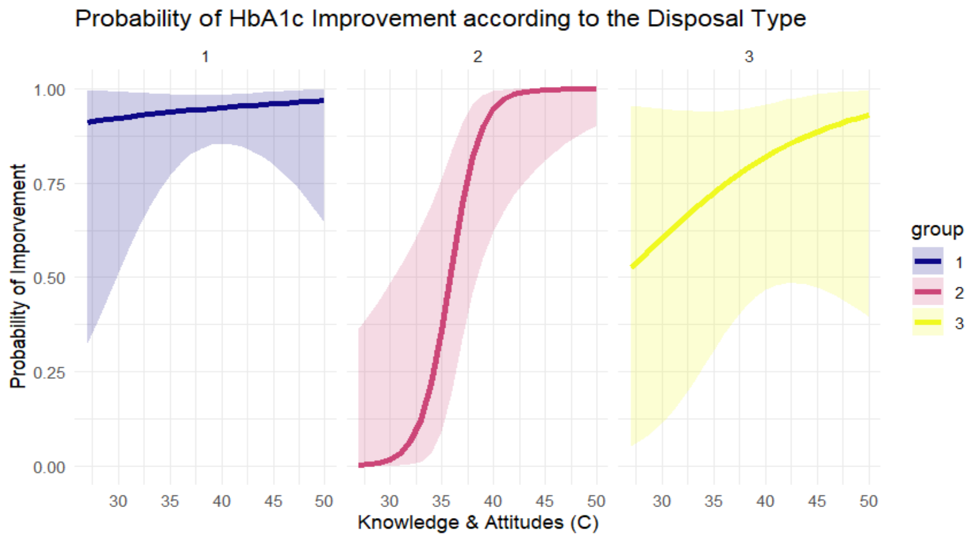

Figure 3.
Probability of HbA1c improvement according to the device type

CGMS showed high efficacy regardless of C-score level, with a consistent probability of HbA1c improvement (~80-90%). Device 2 (Insulin pump only) demonstrated a significant interaction with the Diabetes Acceptance Questionnaire, where the probability of improvement increased steeply for patients with a C score above 35-40, reaching almost 100%. Device 3 (CGMS and Insulin Pump) showed less effectiveness with a smoother curve, indicating a modest influence of Diabetes Acceptance on the likelihood of improvement. Confidence intervals suggest greater precision of estimates for Device 2 (Insulin pump only) at high Diabetes Acceptance scores, while Device 3 (CGMS and Insulin Pump) showed more significant variability. This highlights the importance of personalising therapeutic interventions according to patient characteristics and the device used.

Despite the overall improvement observed in ours and other studies [27], patients still face multifaceted difficulties when incorporating these devices into their treatment regimen. Thus, their incentive to use this technology may affect how well their chronic disease is managed [28]. Another aspect to consider is the financial burden placed on the family or caregivers of T1D paediatric patients. A study involving healthcare practitioners from the International Society for Paediatric and Adolescent Diabetes (ISPAD) showed that their decision of whether to recommend ADMT to young patients relied on the income of their family and the extent of the cost covered by the insurance [29]. An extensive comparative study involving over 56,000 patients with T1D under the age of 18 from the United States and Germany focused on the impact of socioeconomic factors in order to confirm whether patients' socioeconomic status hinders the implementation of devices in their diabetes treatment and clinical outcomes. In both cases, children from low-income families were less likely to use ADMT, which resulted in worsening glycaemic control and higher HbA1c levels [30].

Adolescent T1D is among the most difficult chronic diseases to manage from a psychological and behavioural standpoint, making it challenging. Our findings underline the need for personalised diabetes care strategies that consider both technological and psychosocial factors. While CGMS appears effective across acceptance levels, insulin pump therapy may require a higher threshold of psychological readiness to achieve optimal outcomes. One limitation of this study is the cross-sectional design and the inclusion of hospitalised patients, which may limit generalizability. Longitudinal studies are needed to assess long-term benefits and adherence dynamics.

Conclusions

This study highlights the significant role of advanced diabetes management technologies (ADMT) in improving glycaemic control among children and adolescents with type 1 diabetes (T1D). The findings demonstrate that the use of Continuous Glucose Monitoring Systems (CGMS) and insulin pumps is associated with better glycaemic outcomes. CGMS proved effective regardless of patients' knowledge and attitudes, while insulin pump efficacy was influenced by diabetes acceptance levels. Moreover, the high prevalence of diabetes-related complications underscores the urgent need for optimised management strategies in this population.

Conflict of interest

The authors declare no conflict of interest.

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