The Impact of Insulin Pump Therapy on Glycemic Regulation in Children and Adolescents with Type 1 Diabetes Mellitus

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Article

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Abstract

Background/Objectives: Advanced technologies in type 1 diabetes mellitus (T1DM) management have reshaped the strategies used to achieve optimal glucose control. Continuous Subcutaneous Insulin Infusion (CSII) and Automated Insulin Delivery (AID) systems are effective alternatives to multiple daily injections (MDI). This study aims to evaluate glycemic regulation in children and adolescents transitioning from MDI to insulin pumps and to raise awareness among patients and their families regarding the benefits of these systems. **Methods:** 50 pediatric patients with T1DM (24 males, 26 females; mean age 10.76 ± 3.2 years) were evaluated. Cycle 1 established MDI metrics 3 months pre-transition. In cycle 2, patients transitioned either to an AID system (Medtronic MiniMed 780G, 78%), or a non-automated system (Omnipod DASH, 22%). Data were assessed at 3- and 6-months post-initiation. Parameters assessed were: Glycosylated hemoglobin (HbA1c), Time In Range (TIR), Time Above Range (TAR), Time Below Range (TBR), Glucose Management Indicator (GMI), Coefficient of Variation (CV). **Results**: The cohort exhibited a statistically significant increase in TIR (p=0.0038) with mean values of 70.9% at 3 months and 70.8% at 6 months. TAR significantly reduced (p=0.033) to 26.5% and 24.3% at 3 and 6 months, respectively. Sub-analysis in the AID group, revealed a marked increase in TIR (p=0.0001) alongside significant reductions in TAR (P=0.0009) and GMI (p=0.03). **Conclusion**: Transitioning from MDI to insulin pump therapy, particularly AID systems, is transforming the clinical landscape of T1DM management. The consistency of these results across age groups indicates that AID systems can successfully overcome pediatric and adolescent diabetes management challenges.

Keywords: type 1 diabetes mellitus (T1DM); Continuous Subcutaneous Insulin Infusion (CSII); Automated Insulin Delivery (AID); insulin pump; glycemic regulation

1. Introduction

Type 1 Diabetes Mellitus (T1DM) is a chronic autoimmune disease characterized by the destruction of pancreatic beta cells within the islets of Langerhans [1]. It remains one of the most prevalent chronic conditions in childhood, although it may present at any age. Despite the rising incidence of Type 2 Diabetes Mellitus (T2DM) among youth in recent years, T1DM remains the predominant form of diabetes in the pediatric population, accounting for approximately 5-10% of all diabetes cases [1–3].

Even though the exact etiology of T1DM is still unknown, it is thought to arise from interactions between genetic predisposition and environmental factors [1]. Precipitating factors include maternal

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and intrauterine influences, viral infections, diet and reduced early-life exposure to infectious agents as suggested by the "hygiene hypothesis" [2–4]. Consequently, a process that triggers the breakdown of immune self-tolerance is initiated, stimulating antigen-presenting cells to activate autoreactive T cells that progressively deplete pancreatic beta cells [2–4].

Following initial diagnosis and medical stabilization, an interprofessional medical team is responsible for providing diabetes education. This process is essential for the management of this chronic condition, empowering both the patient and the family to navigate the complexities of the disease [7]. Core educational components include understanding insulin therapy - its aim, mechanism of action, delivery methods, rotation of injection sites and dose adjustment. Furthermore, education focuses on blood glucose monitoring, including daily glucose targets and long-term glycemic control assessed by HbA1c. Additionally, it addresses the impact of diet, exercise and intercurrent illnesses on glycemic variability, alongside the management of acute situations such as hypoglycemia, hyperglycemia and ketosis [1,5,6,10].

Over the past 20 years, the introduction of advanced technologies in the management of diabetes has reshaped the strategies used to achieve optimal glucose control. Continuous glucose monitoring (CGM), sensor-integrated insulin pump therapy and hybrid closed-loop systems are examples of these innovations. They have promoted greater engagement of pediatric patients in self-management and have contributed to better quality of life apart from improving metabolic outcomes [8,9].

Continuous Subcutaneous Insulin Infusion (CSII) or insulin pump therapy has proven to be a safe and effective alternative to multiple daily injections (MDI) for a period over than fifteen years [12,13]. Unlike conventional injections, insulin pumps enable a delivery pattern that resembles physiological basal secretion, reflecting circadian fluctuations in insulin demand. Additionally, these devices allow the delivery of extremely small quantities of insulin, which is particularly important in very young children, with infusion rates capable of being titrated to levels as low as 0.01 U/h [12–14]. Although evidence from Diabetes Control and Complications Trial (DCCT) initially associated intensive insulin regimens with an elevated risk of hypoglycemia, more recent studies indicate that CSII correlates with lower rates of severe hypoglycemia – especially nocturnal- and diabetic ketoacidosis (DKA), when compared to MDI. It is also related to a diminished risk of long-term complications, including retinopathy and peripheral neuropathy [14]. Although complications due to CSII including local infections and dermatological changes are common, they do not relate to glycemic control nor lead to discontinuation of insulin pump treatment [12–14].

Further investigation of these technologies led to sensor-augmented pump therapy (SAP), a clinical combination or augmentation of a conventional insulin pump with CGM. In SAP systems, glucose values are transmitted to a dedicated reader, a smartphone, or through direct integration on the insulin pump interface. This provides the user with continuous data to act upon proactively, such as administering a correlation bolus when a high alert threshold is reached, rather than relying solely on intermittent fingerstick measurements. While SAP therapy does not yet utilize algorithmic automation for insulin dosing, it establishes the essential framework and data-driven environment upon which integrated systems are built [15].

The past 6 years have marked a shift in diabetes technology, particularly through the emergence of Automated Insulin Delivery (AID) systems, often referred to as hybrid closed-loop systems or "artificial pancreas" [11,12]. The development of this technology initially focused on sensor-augmented insulin pumps aimed at reducing hypoglycemia. Several studies have shown that suspending basal insulin delivery in response to low sensor glucose levels, leads to a reduction in hypoglycemic episodes [4,11,12,15]. Further technological advancements led to systems capable of suspending insulin delivery in anticipation of predicted hypoglycemia. However, the most significant breakthrough has been the development of "hybrid" closed-loop systems. These systems automatically adjust insulin delivery in response to both hyperglycemia and hypoglycemia, by integrating continuous glucose sensors with insulin pumps via controller algorithms, to automatically adjust insulin delivery, based on data from a CGM [11,12,14,15]. These systems are associated with increased time in the target glucose range (TIR), reduced time below range (TBR),

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improved HbA1c outcomes, better metabolic control, and a better quality of life among children and adult populations. Currently, all commercially available AID systems operate as single hormone (insulin only) systems. Dual hormone AID systems, which incorporate other hormones (glucagon, pramlintide) to replicate pancreatic physiology better, are under development [11,12,15].

While AID and CSII systems represent the highpoint of modern diabetes management, they currently still require manual inputs for prandial boluses and exercise. As these technologies become more accessible, current research is directed toward reducing user – related barriers through the development of fully automated systems that may eventually obviate the need for carbohydrate counting. By evaluating management outcomes 3 months prior to and 3 and 6 months following the uptake of these technologies, this quality improvement project seeks to determine how these theoretical benefits translate into real-world clinical improvements within a pediatric population. Simultaneously, this study aims to a) evaluate the glycemic regulation of children and adolescents with T1DM following the transition from an intensified insulin regimen to insulin pump therapy and b) raise awareness among patients and their families regarding the benefits of insulin pump use, specifically focusing on the reduction of complications and the improvement of quality of life [15].

2. Materials and Methods

2.1. Study Criteria and Standards

The clinical efficacy of transitioning from multiple daily injections (MDI) to insulin pump therapy was evaluated against the following standards, as established by the International Society for Pediatric and Adolescent Diabetes (ISPAD). Through the comparison between automated versus non-automated systems, these criteria were selected to assess if the technological intervention met the goals of improving glycemic stability and reducing hyperglycemic exposure [16,17]. The criteria are presented in the following table (Table 1).

Table 1. Study criteria and standards

Study Criteria	Clinical Standards (Targets) – ISPAD Guidelines	Rationale
Time In Range (TIR)	Increase in TIR (Target: > 70% of time within 70-180 mg/dl)	TIR is the primary metric for glycemic stability; improvements suggest successful insulin pump adjustment.
Time Above Range (TAR)	Reduction in TAR (Target: < 25% of time above 180 mg/dl, or < 5% of time above 250 mg/dl)	Reducing TAR is a key objective to prevent long-term complications.
Time Below Range (TBR)	Maintenance of TBR within safe limits (Target: < 4% of time below 70 mg/dl or < 1% of time below 54 mg/dl)	A core safety standard for insulin pump therapy is the reduction of hypoglycemic episodes.
Glycemic Management Indicator (GMI)	Reduction in GMI, particularly in automated system users (< 7%).	GMI provides a sensor-derived estimate of HbA1c; reduction indicates improved overall metabolic control.
Coefficient of Glycemic Variability (CV)	Stabilization or reduction of CV (Target: <= 36%)	Lower glycemic variability indicates more

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		predictable glucose patterns and a reduced risk of severe hypoglycemia.
HbA1c	Reduction in HbA1c (Target < 7.0 %) or a statistically significant reduction from the 3-month pre-pump baseline.	HbA1c is the primary indicator of long-term glycemic control and a predictor of microvascular complication risk.

To successfully close the study loop, the primary measure of efficacy is the achievement of statistical significance ($p<0.05$) across the established metabolic markers. Specifically, the intervention is considered successful if a measurable and significant improvement is observed in HbA1c, TIR, TAR, CV and GMI when comparing the 3-month pre-intervention baseline against the 3 and 6-month post-initiation data. This statistical threshold ensures that the observed clinical improvements in glycemic control are consistent and attributable to the transition to insulin pump technology, rather than random variation.

2.2. First Study Cycle (3 Months Prior to Intervention).

This study was conducted at the Pediatric Endocrinology Outpatient Clinic of the University General Hospital of Patras, Greece, to evaluate the clinical impact of transitioning from MDI to CSII or AID systems. During the first study cycle, baseline clinical data were established, reflecting the cohort's glycemic status while they remained on MDI therapy. Retrospective data were collected for the 3-month period prior to the intervention. A total of 50 pediatric patients with T1DM were included – 24 males and 26 females - with a mean age of 10.8 ± 3.2 years. All participants were on an intensified MDI regimen for at least 6 months prior to the study. During this 3 – month baseline phase, patients maintained active use of CGM devices to provide the necessary data for comparison against post-intervention metrics. The following data were assessed: HbA1c, TIR, TAR, TBR, GMI, and CV.

2.3. Intervention and Change Implementation

All 50 patients transitioned to insulin pump therapy and utilized CGM throughout the follow-up period.

- 39 patients (78%) transitioned to a fully AID system, the *Medtronic MiniMed 780G* (hybrid closed-loop system).
- 11 patients (22%) transitioned to a non-automated system, the *Omnipod DASH* patch pump system.

To ensure a smooth transition to pump therapy, comprehensive education was delivered through a team-based approach. Technical representatives from each manufacturer accompanied by specialized nursing staff, performed intensive training sessions for both the children and their families. This educational process was performed in close coordination with the multidisciplinary medical team to standardize the implementation protocol and optimize system settings for each patient.

2.4. Second Study Cycle (3- and 6-Months Post Insulin Pump Initiation)

To close the study loop, follow-up data were collected at 3- and 6-months post insulin pump initiation (AID system or CSII). The parameters (HbA1c, TIR, TAR, TBR, GMI, CV) were re-evaluated according to the *Study Criteria and Standards* (see Table 1). This phase allowed us to determine if the transition to insulin pump technology resulted in achieving glycemic targets.

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2.5. Statistical Analysis

Continuous variables are presented as means with standard deviations (SD). Statistical analyses were performed to identify significant changes across the three time points (the 3-month baseline and the sequential 3 – and 6 – month pump therapy intervals). For normality analysis of the continuous variables, we used the Shapiro-Wilk test. Data for measured parameters (HbA1c, TIR, TAR, TBR, GMI, CV) were analyzed using *repeated measures ANOVA* to compare mean values across the three time points, and *mixed-effects models* in case data points were missing. The *Tukey post-hoc test* was applied for multiple comparisons. All statistical analyses were carried out with either GraphPad Prism (version 8.0.2 for Windows, GraphPad Software, San Diego California, USA) or SPSS for Windows (version 16.0 SPSS Inc. Chicago II, USA). All results were considered statistically significant at a threshold of $p < 0.05$.

3. Results

During the first study cycle, the cohort of 50 pediatric patients (24 males – 26 females) was managed through an intensified MDI regimen. The metabolic profile was characterized by a mean HbA1c value of 7.03%, mean TIR of 67.50%, mean TBR of 3.20% and mean GMI of 6.97%. While these values indicate good glycemic control, a mean TAR value of 28.9% and a mean CV of 35.7%, indicate frequent hyperglycemic episodes and borderline glucose variability (Table 2).

The implementation of technological interventions through AID and CSII systems, initiated the second study cycle. 39 patients (78%) transitioned to a fully AID system, the *Medtronic MiniMed 780G* (hybrid closed-loop system), while 11 patients (22%) transitioned to a non-automated system, the *Omnipod DASH* patch pump system. Follow-up assessment 3 – and 6 – months post transition, revealed a clear trend towards improved glycemic regulation. The total patient cohort exhibited a significant increase in TIR (p=0.0038) rising to a mean value of 70.9% at 3 months and 73.2% at 6 months (Figure 1) and a reduction in TAR (p=0.033) to 26.5% and 24.3% at 3 and 6 months respectively (Figure 2). The above observations are presented in Table 2. No other glycemic parameters reached statistical significance for the group as a whole.

A critical standard of the study was the maintenance of a low incidence of hypoglycemic episodes. TBR remained consistently low across both cycles (mean value of 3.2% during the first cycle and of 2.5% for the 3- and 6-month assessments within the second cycle), staying well within the international safety TBR recommendations (< 4%). This confirms that the observed improvements in TIR and TAR were achieved without increasing the risk of hypoglycemic events (Table 2).

Table 2. Mean values of examined study parameters for the whole cohort.

Study Parameters	First Study Cycle	3 Months Post Intervention	6 Months Post Intervention	p-value (ANOVA)
TIR (%)	67.51 ± 11.85	70.90 ± 11,02	73.19 ± 9.89	0.0038
TAR (%)	28.96 ± 12.45	26.50 ± 11.61	24.30 ± 10,75	0.033
TBR (%)	3.23 ± 3.53	2.50 ± 2.67	2.55 ± 2.42	0.08
GMI (%)	6.97 ± 0.48	6.88 ± 0.35	6.83 ± 0.33	0.098
CV (%)	35.72 ± 5.74	34.31 ± 4.95	34.96 ± 3.84	0.12
HbA1c (%)	7.04 ± 0.82	6.95 ± 0.72	6.94 ± 0.74	0.74

All measurements are presented in mean ± SD.

The comparative outcomes for glycemic control across both study cycles are illustrated in Figures 1 through 5.

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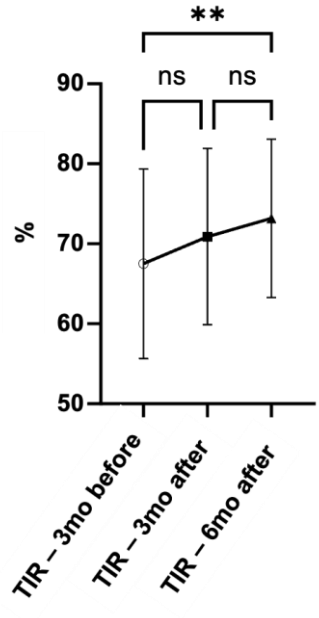

Figure 1. Total patient cohort – TIR

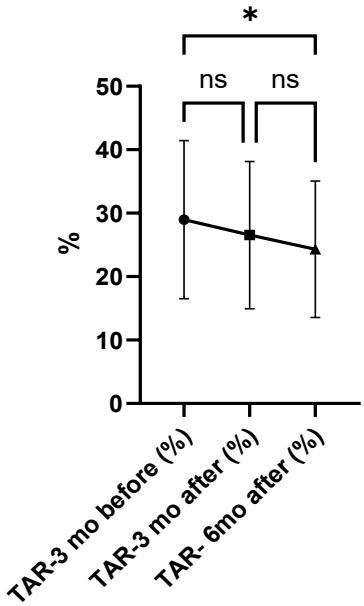

Figure 2. Total patient cohort – TAR

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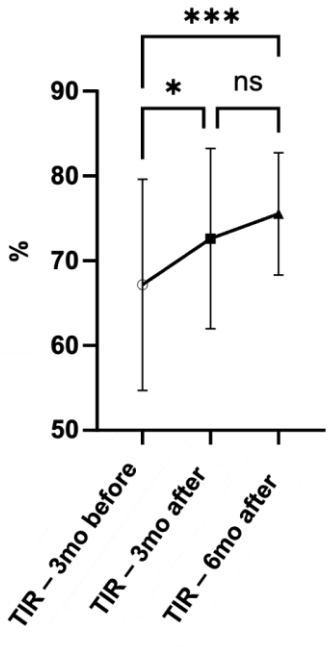

Figure 3. Patients in AID – TIR

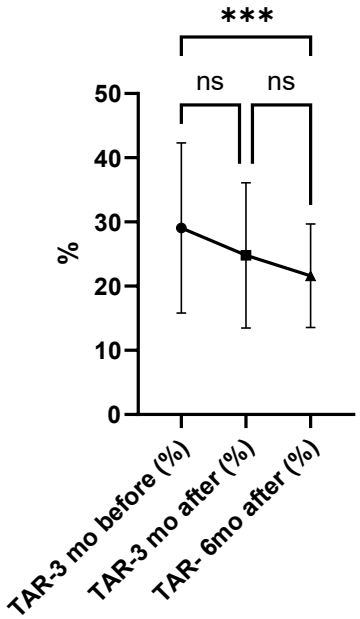

Figure 4. Patients in AID – TAR

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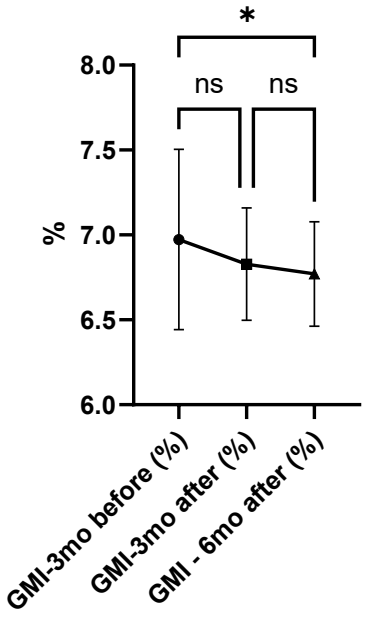

Figure 5. Patients in AID – GMI

Sub-analysis revealed that participants utilizing the Medtronic MiniMed 780G closed-loop system, achieved a highly statistically significant increase in TIR (p=0.0001; Figure 3) alongside significant reductions in both TAR (p=0.0009; Figure 4) and GMI (p=0.03; Figure 5). Additionally, patients utilizing the non-automated insulin delivery system demonstrated no statistically significant changes across any of the assessed metabolic markers. This means that the significant differences in TIR and TAR between pre- and post-initiation of an insulin pump are attributed to the automated system.

Table 3. Mean values of examined study parameters for the AID group.

Study Parameters	First Study Cycle	3 Months Post Intervention	6 Months Post Intervention	p-value (ANOVA)
TIR (%)	67.17 ± 12.44	72.61 ± 10.63	75.54 ± 7.21	0.0001
TAR (%)	29.05 ± 13.25	24.80 ± 11.31	21.62 ± 8.05	0.0009
TBR (%)	3.22 ± 3.63	2.45 ± 2.75	2.60 ± 2.47	0.14
GMI (%)	6.97 ± 0.53	6.83 ± 0.33	6.77 ± 0.30	0.03
CV (%)	35.62 ± 5.86	33.95 ± 4.43	34.56 ± 3.55	0.13
HbA1c (%)	6.98 ± 0.84	6.89 ± 0.73	6.92 ± 0.76	0.86

Also, significant difference was found in the number of patients who achieved the goal of TIR > 70% 6 months after initiation of pump therapy. Specifically, 19 patients achieved the TIR goal both pre- and post transition, 3 patients achieved the TIR goal only pre-transition, 13 patients only post transition and 12 patients never achieved the TIR goal (McNemar test: p=0.021). No significant differences were found in the number of patients who achieved the HbA1c, TAR, TBR, GMI and CV goals pre- and post transition.

4. Discussion

The results of this clinical study demonstrate that transitioning pediatric patients from MDI therapy to insulin pump technology, in particular AID systems, led to significant improvements in glycemic regulation. It also became evident that the integration of controller algorithms for the adjustment of insulin delivery in AID technology, has a clear advantage over non-automated

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systems. This was highlighted by the decline in glycemic fluctuations and hyperglycemic spikes. While the total patient cohort showed improvement in TIR and TAR values, the rest of the glycemic parameters remained relatively stable. However, the Medtronic MiniMed 780G subgroup demonstrated the most significant improvements in TIR, TAR and GMI, supporting the aspect that automated algorithms are the key factor in achieving proper glycemic regulation.

While non-automated systems provide the essential framework for integrated systems, their success depends on the proactive engagement of the patient. The user is responsible for dose calculation and basal adjustment, leaving room for human error and delayed response to glucose fluctuations [4,5].

Current clinical recommendations suggest that insulin pumps should be considered for all pediatric patients through a collaborative decision-making process between families and the multidisciplinary healthcare team [5,6]. The role of a multidisciplinary pediatric diabetes team is fundamental in delivering continuous education, nutritional guidance and psychosocial support from the time of diagnosis, while providing regular assessment of the proper transition from caregiver - led management to independent self-care [5,6]. Inadequate control may lead to acute complications, such as hypoglycemia or hyperglycemia, including DKA, as well as long-term complications, including cardiovascular disease, neuropathy, nephropathy and retinopathy [1,6]. Therefore, frequent glucose monitoring is mandatory both during the day and at night to minimize short and long-term adverse effects. In pediatric and adolescent populations, management should be guided by age-specific considerations, including fluctuations in insulin sensitivity associated with physical growth and pubertal maturation [5,6]. Furthermore, physicians should evaluate the patient's ability of self-management while being aware of the neurological vulnerability to hypoglycemia and hyperglycemia in young children and the potential adverse neurocognitive effects of DKA [5,6].

In our study, these favorable outcomes remained consistent across the entire cohort (10.76 ± 3.2 years). Age and the different developmental stages of the children involved did not limit the system's success. Adolescence in particular is a critical period of physical, social and emotional changes, which is often characterized as a period of hormonal shifts and poor T1DM adherence [5]. Despite these circumstances, our findings suggest that automated technology was not affected by the complex behavioral and hormonal challenges that often compromise glycemic management in the pediatric population.

A notable finding is the relative stability of laboratory-measured HbA1c compared to the significant changes in TIR and GMI. HbA1c reflects average glucose levels over a 3-month period but misses the daily glucose fluctuations. Since GMI uses real-time CGM data to provide the estimated HbA1c, their results may differ. Our findings suggest that sensor-augmented technologies are more sensitive indicators of clinical improvement than traditional HbA1c.

A significant point of this intervention was the maintenance of a low incidence of hypoglycemic episodes. TBR remained low throughout the study, with a mean value of 3.2% during the first cycle and 2.5% during the second cycle (at both the 3- and 6-month assessments). These figures remained well under the international safety TBR threshold of < 4%, demonstrating the safety of the intervention. In intensive insulin regimens, attempting to lower high glucose levels, often resulted in a rebound effect or an increased risk of hypoglycemia. However, AID systems automatically suspend insulin delivery as glucose approaches the lower limit, thus more effective glucose management is achieved. The success of the implementation phase can also be attributed to the collaboration between the technical representatives of the manufacturer companies as well as the multidisciplinary medical team in delivering continuous education, nutritional guidance and psychosocial support.

While this study provides valuable insights into the insulin pump efficacy in the glycemic control of children and adolescents, its limitations must be acknowledged. The relatively small sample size (n=50) and the non-randomized assignment of insulin delivery systems may limit the generalizability of the results to broader pediatric populations.

5. Conclusions

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The outcomes of the present study confirm that the transition from MDI therapy to insulin pump therapy -AID systems in particular- is transforming the clinical landscape of T1DM management. By acting as a "clinical shield" these systems significantly reduce TAR and enhance glycemic regulation. Furthermore, the study underscores the safety of these systems. With TBR remaining below the 4% safety threshold, it confirms that glycemic control was achieved without compromising patient safety. The consistency of these results across a wide age group indicates that AID systems can successfully overcome the challenges of pediatric and adolescent diabetes management. Future research should focus on the long-term sustainability and the impact of these technologies on the quality of life for both children and their families.

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Abbreviations

The following abbreviations are used in this manuscript:

T1DM	Type 1 Diabetes Mellitus
CSII	Continuous Subcutaneous Insulin Infusion
AID	Automated Insulin Delivery
MDI	Multiple Daily Injections
HbA1c	Glycosylated Hemoglobin
TIR	Time In Range
TAR	Time Above Range
TBR	Time Below Range
GMI	Glucose Management Indicator
CV	Coefficient of Variation
T2DM	Type 2 Diabetes Mellitus
CGM	Continuous Glucose Monitoring
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic Ketoacidosis
SAP	Sensor Augmented Pump
ISPAD	International Society for Pediatric and Adolescent Diabetes

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