E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.02.504

Research Article

Glycemic Control, Compliance and Adverse Effects Related to Subcutaneous Insulin in Pediatric Age Group (1-18 Years): A Single-Centre Observational Study in Chevella, Telangana

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Received: 09.07.26, Revised: 12.08.26, Accepted: 10.09.26

ABSTRACT

Background: Optimal glycemic control remains the cornerstone of management in children and adolescents with type 1 diabetes mellitus (T1DM). Poor adherence to insulin therapy increases the risk of acute and chronic complications, while treatment-related adverse effects may further compromise long-term disease management. Limited prospective data are available from India regarding factors influencing glycemic control and insulin adherence in pediatric patients.

Objective: To evaluate glycemic control, adherence to subcutaneous insulin therapy, and insulin-related adverse effects among children and adolescents with T1DM and to identify factors associated with poor glycemic control.

Methods: A prospective single-centre observational study was conducted among 41 children aged 1–18 years with T1DM at PMR Medical College and Research Institute, Chevella, Ranga Reddy, Telangana. Glycemic control was assessed using glycated hemoglobin (HbA1c) and random blood glucose (RBS) measurements. Treatment adherence was evaluated using the Adherence in Diabetes Questionnaire (ADQ). Demographic characteristics, disease-related variables, caregiver characteristics, physical activity, routine glucose monitoring, and insulin-related complications were recorded. Statistical analyses included descriptive statistics, paired t-test, and Chi-square test, with $p<0.05$ considered statistically significant.

Results: The mean age of participants was 12.02±3.70 years, and 53.7% were males. Poor glycemic control was observed in 56.1% of patients despite a significant reduction in mean HbA1c during follow-up (11.96±1.92 vs. 10.03±2.75; p=0.001). Better glycemic control was significantly associated with educated caregivers (p=0.013), female primary caregivers (p=0.047), higher ADQ adherence scores (p=0.001), and caregiver relationship (p=0.027). Lipohypertrophy occurred in 34.1% of patients, while pain at the injection site was reported by 48.8%.

Conclusion: More than half of pediatric patients demonstrated suboptimal glycemic control despite insulin therapy. Caregiver education, treatment adherence, and family involvement were important determinants of metabolic control. Structured diabetes education targeting both patients and caregivers may improve adherence and long-term glycemic outcomes.

Keywords: Type 1 diabetes mellitus, Glycemic control, HbA1c, Insulin adherence, Pediatric diabetes, Treatment compliance.

INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a chronic autoimmune endocrine disorder characterized by immune-mediated destruction of pancreatic β-cells, resulting in absolute insulin deficiency and lifelong dependence on exogenous insulin therapy. It represents the most common form of diabetes in children and adolescents and is associated with considerable morbidity, healthcare burden, and reduced quality of life if optimal metabolic control is not achieved. Although remarkable advances have been made in insulin formulations, glucose monitoring technologies, and diabetes education, maintaining adequate glycemic control in pediatric patients continues to be a

major clinical challenge because of growth-related physiological changes, hormonal fluctuations during puberty, psychosocial factors, and the complexity of intensive insulin therapy.(1,3)

The global incidence of T1DM has steadily increased over recent decades, with an estimated annual rise of approximately 3–5%. India contributes substantially to the burden of childhood diabetes in the South-East Asian region, where the number of newly diagnosed cases continues to increase each year. Despite this growing burden, epidemiological and clinical data from developing countries remain relatively limited compared with Western populations. Regional differences in healthcare access, socioeconomic conditions, caregiver education, and availability of diabetes support services may substantially influence treatment outcomes, emphasizing the need for locally generated evidence.(2,4)

The principal objective of diabetes management is to achieve and maintain near-normal blood glucose concentrations while minimizing the risk of hypoglycemia and preventing long-term microvascular and macrovascular complications. Persistent hyperglycemia has been strongly associated with diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease. The landmark Diabetes Control and Complications Trial (DCCT) demonstrated that intensive glycemic control significantly reduces the risk of diabetes-related complications, establishing glycated hemoglobin (HbA1c) as the most reliable indicator of long-term metabolic control. Consequently, current international guidelines recommend periodic assessment of HbA1c together with routine self-monitoring of blood glucose (SMBG) to evaluate treatment effectiveness and guide therapeutic adjustments.(5,6,7)

Achieving recommended glycemic targets in children and adolescents, however, is considerably more difficult than in adults. Puberty is associated with increased insulin resistance, accelerated somatic growth, hormonal changes, and greater psychological stress, all of which contribute to deterioration in metabolic control. Furthermore, successful diabetes management depends not only on appropriate insulin administration but also on regular blood glucose monitoring, adherence to dietary recommendations, physical activity, timely dose adjustment, and continuous caregiver supervision. Poor adherence to any of these components may lead to sustained hyperglycemia, recurrent diabetic ketoacidosis (DKA), hypoglycemia, and reduced treatment effectiveness.(8)

Family participation plays a particularly important role in pediatric diabetes care. Previous studies have demonstrated that caregiver education, parental involvement, socioeconomic status, and treatment adherence are significant predictors of glycemic control among children with T1DM. Better caregiver knowledge has consistently been associated with lower HbA1c levels, improved compliance with insulin therapy, and reduced diabetes-related complications. Conversely, inadequate diabetes education, poor adherence, and insufficient family support have been linked to poorer metabolic outcomes and increased hospitalization. These findings highlight the importance of evaluating both clinical and behavioral determinants of glycemic control in pediatric populations.(8,9)

Subcutaneous insulin therapy remains the standard treatment for T1DM but is frequently associated with local adverse effects, including lipohypertrophy, injection-site pain, and hypoglycemic episodes, all of which may negatively influence adherence to treatment. Early identification of these complications and assessment of patient compliance are therefore essential for optimizing long-term disease management. Despite increasing recognition of these issues, prospective Indian studies simultaneously evaluating glycemic control, adherence to insulin therapy, caregiver characteristics, and insulin-related adverse effects remain scarce.

Therefore, the present prospective single-centre study was undertaken to evaluate glycemic control using HbA1c and random blood glucose measurements, assess adherence to subcutaneous insulin therapy using the Adherence in Diabetes Questionnaire (ADQ), determine the frequency of insulin-related adverse effects, and identify demographic, clinical, and caregiver-related factors associated with poor glycemic control among children and adolescents with T1DM attending a tertiary care hospital in Chevella, Telangana. The findings are expected to provide clinically relevant evidence that may facilitate targeted interventions aimed at improving adherence, optimizing glycemic control, and reducing diabetes-related complications in pediatric patients.

METHODS

Study Design and Setting

A prospective single-centre observational study was conducted from February 2025 to February 2026 at PMR Medical College and Research Institute, Chevella, Ranga Reddy, Telangana.

Study Population

Children and adolescents aged 1–18 years with confirmed Type 1 diabetes mellitus (T1DM) receiving subcutaneous insulin therapy and attending regular follow-up at the participating centers were eligible for inclusion. Diagnosis of T1DM was established according to the American Diabetes Association (ADA) diagnostic criteria. Children presenting with diabetes-related complications or requiring insulin therapy were also included.

Patients younger than one year or older than 18 years, those with transient or stress-induced hyperglycemia, syndromic or monogenic diabetes, and those unwilling to participate were excluded from the study.

Sample Size

The minimum required sample size was calculated using the single population proportion formula:

$$N = \frac{(Z_{\alpha/2})^2 \times p(1-p)}{d^2}$$

using an anticipated prevalence (p) of 0.319, 90% confidence level (Z=1.6449), and absolute precision of 0.12. The calculated minimum sample size was 41 participants, all of whom were included in the final analysis.

Data Collection

Clinical information was collected using a structured proforma during scheduled follow-up visits. The following variables were recorded:

- Demographic characteristics (age, sex, residence)
- Clinical characteristics (age at diagnosis, duration of diabetes, diabetic ketoacidosis at presentation)
- Anthropometric measurements (height, weight, body mass index)
- Family history
- Primary caregiver characteristics
- Educational status of the caregiver
- Physical activity
- Routine blood glucose monitoring practices
- Insulin-related complications

All participants underwent detailed clinical examination for assessment of diabetes-related complications throughout the one-year follow-up period. Weight and height were measured using standardized techniques, and body mass index (BMI) was calculated for each participant.

Assessment of Glycemic Control

Glycemic control was evaluated using glycated hemoglobin (HbA1c) and random blood glucose (RBS) measurements.

HbA1c estimation was performed using high-performance liquid chromatography (HPLC). Glycemic control was categorized according to ADA age-specific recommendations for preschool children, school-age children, and adolescents. Random blood glucose levels were recorded during hospital admission as an additional indicator of metabolic status. Follow-up HbA1c measurements were obtained after one year to evaluate improvement in glycemic control.

Assessment of Treatment Adherence

Adherence to insulin therapy was assessed using the validated **Adherence in Diabetes Questionnaire (ADQ)** developed by the Danish Society for Diabetes in Childhood and Adolescence. The questionnaire evaluates multiple aspects of diabetes self-management, including insulin administration, dietary adherence, blood glucose monitoring, physical activity, hypoglycemia management, clinic attendance, and treatment-related behaviors. Higher ADQ scores indicated better adherence to prescribed diabetes management.

Assessment of Insulin-Related Adverse Effects

Participants were prospectively monitored for common adverse effects associated with subcutaneous insulin therapy. These included:

- Lipohypertrophy
- Pain at the injection site
- Hypoglycemic episodes
- Emergency department visits related to diabetes

Children presenting with diabetic ketoacidosis (DKA) were classified as mild, moderate, or severe according to the International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines. Short-term and long-term complications were evaluated following ADA recommendations throughout the follow-up period.

Outcome Measures

The primary outcome was glycemic control as determined by HbA1c levels. Secondary outcomes included treatment adherence

measured using the ADQ, insulin-related adverse effects, and demographic and caregiver-related factors associated with poor glycemic control.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 20. Continuous variables were summarized as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages.

Comparison of baseline and follow-up HbA1c values was performed using the paired Student's t-test. Associations between categorical variables and glycemic control were evaluated using the Chi-square test. A two-tailed p-value <0.05 was considered statistically significant.

RESULTS

Table 1. Baseline demographic and clinical characteristics of the study population (n=41)

Variable	Number of cases (%) Mean ± SD
Age (years), mean ± SD	**12.02 ± 3.70**
Age range	2–17 years
2–6 years	4 (9.8)
7–12 years	10 (24.4)
13–17 years	27 (65.9)
Male	22 (53.7)
Female	19 (46.3)
Rural residence	24 (58.5)
Urban residence	17 (41.5)
DKA at presentation	35 (85.4)
Mean random blood glucose (mg/dL)	**492.34 ± 123.98**

Table 2. Glycemic control during follow-up

Variable	Value
Baseline HbA1c (%)	11.96 ± 1.92
Follow-up HbA1c (%)	10.03 ± 2.75
Mean reduction in HbA1c (%)	1.92
p-value	0.001
Good glycemic control	18 (43.9%)
Poor glycemic control	23 (56.1%)

Table 3. Caregiver characteristics and treatment adherence

Variable	Number of cases (%)
Female primary caregiver	25 (61.0)
Mother as caregiver	21 (51.2)
Educated caregiver	19 (46.3)
Regular glucose monitoring	30 (73.1)
Regular physical activity	24 (58.5)
Good ADQ adherence	16 (39.0)
Poor ADQ adherence	25 (61.0)

Table 4. Insulin-related adverse effects

Complication	Number of cases (%)
Lipohypertrophy	14 (34.1)
No lipohypertrophy	27 (65.9)
Pain at injection site	20 (48.8)
No pain at injection site	21 (51.2)

DISCUSSION

The present prospective single-centre observational study evaluated glycemic control, treatment adherence, and adverse effects associated with subcutaneous insulin therapy among children and adolescents with Type 1 diabetes mellitus (T1DM). Despite significant improvement in HbA1c during follow-up, more than half of the participants continued to demonstrate poor glycemic control. Importantly, caregiver-related characteristics and treatment adherence emerged as stronger determinants of metabolic control than demographic or disease-related variables. These findings reinforce the importance of family-centered diabetes management in achieving optimal glycemic outcomes among pediatric patients.

The prevalence of poor glycemic control observed in the present study (56.1%) is consistent with previous reports indicating that maintaining recommended HbA1c targets remains challenging in children and adolescents with T1DM. Although mean HbA1c decreased significantly during follow-up, the majority of patients failed to achieve optimal metabolic control. Similar observations have been reported in pediatric diabetes registries from Europe and North America, where adolescence has consistently been identified as the period associated with the greatest deterioration in glycemic control because of hormonal changes, increased insulin resistance, psychological stress, and reduced adherence to treatment. These physiological and behavioral changes make glycemic management particularly difficult during puberty.(10,11,12)

The mean age of participants in the present study was 12 years, with approximately two-thirds belonging to the adolescent age group. Although age itself did not demonstrate a statistically significant association with glycemic control in the present cohort, previous multicenter studies involving large pediatric populations have shown progressively increasing HbA1c values during adolescence. Gerstl et al. reported significantly poorer metabolic control among adolescents compared with younger children, while Mortensen and colleagues demonstrated similar findings in the Hvidøre Study involving multiple international diabetes centers. Differences between our findings and these larger studies may largely be explained by the relatively small sample size and limited statistical power of the present investigation. (12,13)

Another important observation was the significant influence of caregiver characteristics on glycemic outcomes. Children cared for primarily by female caregivers, particularly mothers, demonstrated better glycemic control than those primarily responsible for self-management or cared for by other family members. Furthermore, caregiver education showed a statistically significant association with improved metabolic control. These findings agree with previous investigations showing that caregiver knowledge, parental involvement, and educational status are among the strongest predictors of treatment success in pediatric diabetes. Educated caregivers are more likely to understand insulin administration techniques, recognize early symptoms of hypo- and hyperglycemia, encourage regular blood glucose monitoring, and ensure timely follow-up visits, thereby improving overall diabetes management. (14,15)

Treatment adherence assessed using the Adherence in Diabetes Questionnaire (ADQ) demonstrated the strongest association with glycemic control in the present study. Patients with higher adherence scores achieved significantly better metabolic control than those demonstrating poor adherence. This observation is biologically plausible because successful management of T1DM requires consistent insulin administration, dietary compliance, blood glucose monitoring, and lifestyle modifications. Similar findings have been reported in a meta-analysis by Hood et al., which demonstrated a significant inverse relationship between adherence and HbA1c among children and adolescents with T1DM. Likewise, Kristensen et al., who developed and validated the ADQ instrument, reported that higher adherence scores correlated closely with improved glycemic outcomes, supporting the usefulness of ADQ as an objective tool for evaluating diabetes self-management. (14)

The present study also documented insulin-related adverse effects, with lipohypertrophy observed in approximately one-third of participants and injection-site pain reported by nearly half. Lipohypertrophy remains one of the most common complications of repeated subcutaneous insulin injections and may impair insulin absorption, resulting in increased glycemic variability and unpredictable blood glucose levels. These findings emphasize the importance of educating patients and caregivers regarding proper injection-site rotation and regular examination of injection

sites during follow-up visits. Early identification and prevention of injection-related complications may improve insulin absorption and contribute to better metabolic control.

Interestingly, sex, age at diagnosis, and duration of diabetes were not statistically associated with glycemic control in the present study. Previous studies have produced conflicting results regarding these variables. Several investigators have reported poorer metabolic control among female adolescents because of increased insulin resistance during puberty and psychosocial influences, whereas others have found disease duration to be an independent predictor of worsening HbA1c. The absence of significant associations in the present study likely reflects the modest sample size rather than the absence of true clinical relationships.

The present investigation has several strengths. It employed a prospective single-centre design, used standardized HbA1c measurements for assessment of metabolic control, incorporated a validated adherence questionnaire, and evaluated both clinical and behavioral determinants of glycemic outcomes. These features provide a comprehensive assessment of pediatric diabetes management in a real-world tertiary care setting.

However, certain limitations should be acknowledged. The study included only 41 participants, limiting statistical power for subgroup analyses and reducing the ability to identify predictors of less common complications. Follow-up duration was limited to one year, preventing evaluation of long-term microvascular and macrovascular outcomes. Furthermore, adherence data were partly based on caregiver-reported responses, introducing the possibility of recall and reporting bias. Future multicenter studies involving larger populations and longer follow-up periods are needed to validate these findings and identify additional modifiable determinants of glycemic control.

CONCLUSION

Poor glycemic control remained common among children and adolescents with Type 1 diabetes mellitus despite significant improvement in HbA1c during follow-up. Caregiver education, family involvement, and adherence to insulin therapy were the strongest predictors of favorable metabolic control, whereas demographic characteristics and disease duration were not significantly associated with glycemic outcomes in this cohort. Strengthening diabetes education, promoting treatment adherence, and encouraging active caregiver participation may improve long-term glycemic control and reduce insulin-related complications in pediatric patients.

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