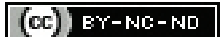


Effect of Quality Improvement Interventional Tool on Emotional, Behavioural and Self-perception Profile of Children with Type 1 Diabetes Mellitus: A Pretest, Post-test Quasi-experimental Study

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ABSTRACT

Introduction: Psychological stress associated with Type 1 Diabetes Mellitus (T1DM) in children is relatively higher in developing countries due to limited health resources. However, no data are available regarding the impact of a Quality Improvement (QI) intervention on emotional, behavioural, and self-perception in paediatric patients with T1DM.

Aim: To study the impact of a QI interventional tool on the emotional, behavioural, and self-perception profile in children with T1DM.

Materials and Methods: This pretest, post-test quasi-experimental study was conducted at PGIMS, Rohtak, Haryana, India from August 2021 to July 2022. A total of 50 children, aged between 6-14 years with T1DM, were enrolled from the paediatric outpatient department and paediatric ward for the study. Initially, baseline data were collected, and patients were followed-up for six months during which required interventions were given, including one-on-one counseling with mother and child, demonstration of insulin injection, providing them with a booklet for recording blood glucose at home, etc. After six months, data were collected again for comparison. The

Strengths and Difficulties Questionnaire (SDQ) and Self-perception Profile for Children (SPPC) questionnaires were used for the study. Data were statistically analysed using a paired t-test.

Results: In the present study, there were 27 (54%) males and 23 (46%) females with an average age of 9.64 ± 2.3 years. Positive outcomes were noted in the emotional, behavioural, and self-perception profiles of children following the intervention. HbA1C values (pre: $13.12 \pm 1.02\%$, post: $10.63 \pm 1.07\%$), hypoglycaemic episodes (pre: 2.54 ± 0.88 , post: 1.24 ± 0.43), and Diabetic Ketoacidosis (DKA) episodes (pre: 2.76 ± 0.52 , post: 1.08 ± 0.27) significantly reduced following the intervention. The SDQ score was significantly lower (pre: 16.97 ± 1.48 , post: 7.76 ± 2.14), and the SPPC score was significantly higher (pre: 76.52 ± 0.61 , post: 94.34 ± 1.06) after the intervention.

Conclusion: In the present study, it was found that psychological and behavioural interventions have a beneficial effect on children with diabetes in terms of better compliance with therapy, glycaemic control, as well as better relationships with family and peers, and improved coping capability.

Keywords: Glucose, Insulin, Psychological stress

INTRODUCTION

Diabetes mellitus is a metabolic disorder characterised by hyperglycaemia and glycosuria, resulting from pancreatic dysfunction caused by genetic and environmental factors. Most patients with diabetes can be classified as T1DM or Type 2 DM. Type 1 Diabetes (T1D), once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin. Insulin is a hormone needed to allow sugar (glucose) to enter cells to produce energy [1]. India has the highest number of children with T1DM in South-East Asia. According to the 7th edition of the International Diabetes Federation Diabetes Atlas, India, reports three new cases of T1DM per 100,000 children aged 0-14 years [2].

In a study conducted by Puri K et al., a significant association of elevated HbA1c was found with poorer emotional wellbeing. Additionally, an earlier onset (age <5 years) was associated with fewer behavioural problems and had a less negative impact on Quality of Life (QoL) [3]. Another study conducted by Khandewal S et al., found that children (6-14 years of age) with T1DM for at least one year had a significantly higher prevalence of psychosocial illness compared to the non diabetic group. The prevalence of psychosocial illness was significantly higher in T1DM patients with poorer metabolic control, poor dietary compliance, and a higher

mean HbA1c level [4]. Matziou V et al., in their study, also found a negative correlation between QoL and age, the duration of diabetes, body mass index, and co-morbidities [5].

The management of T1DM requires a lifelong therapeutic routine to mitigate both acute and chronic complications. Beyond the physical aspects, psychological factors, including family dynamics, developmental adjustments, autonomy, mental health issues, and other elements, have been identified as influencing metabolic control. It is essential to perceive these psychological factors not as a one-way causal relationship but as part of a dynamic and multidirectional system influenced by the normal developmental transitions during childhood and adolescence [6].

Despite active research, T1DM has no cure. Treatment focuses on managing blood sugar levels with insulin, diet, and lifestyle to prevent complications. Children with diabetes are at greater risk of emotional, behavioural, and self-perception problems [7]. Not much literature is available regarding QI in paediatric patients with T1DM. So far, researchers have not seen an impact on the emotional and behavioural profile by QI initiatives in T1DM patients. Hence, the present study was conducted to assess the emotional, behavioural, and self-perception difficulties faced by children with T1DM and to evaluate the utility of QI interventions in reducing these difficulties.

MATERIALS AND METHODS

This pretest, post-test quasi-experimental study was conducted in the Department of Paediatrics at Pt. B.D.S. PGIMS, Rohtak, Haryana, India from August 2021 to July 2022. The study was approved by Ethical committee. Voluntary informed consent was obtained from parents, and assent was obtained from the subjects.

Inclusion criteria: Children aged between 6-14 years with T1DM, diagnosed for at least one year, were included in the study. The diagnostic criteria for diabetes mellitus are mentioned in [Table/Fig-1] [8].

1. Classical symptoms of diabetes or hyperglycaemic crisis, with plasma glucose concentration ≥ 11.1 mmol/L (200 mg/dL) Or
2. Fasting plasma glucose ≥ 7.0 mmol/L, ≥ 126 mg/dL. Fasting is defined as no caloric intake for at least 8 h. ^a Or
3. Two-hour post load glucose ≥ 11.1 mmol/L ≥ 200 mg/dL during an OGTT. The test should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water or 1.75 g/kg of body weight to a maximum of 75 g. Or
4. HbA1c $\geq 6.5\%$ The test should be performed in a laboratory using a method that is NGSP certified and standardised to the DCCT assay.

[Table/Fig-1]: Diagnostic criteria for diabetes mellitus.
^aIn the absence of unequivocal hyperglycaemia, the diagnosis of diabetes based on these criteria should be confirmed by repeat testing; ^aA value of less than 6.5% does not exclude diabetes diagnosed using glucose tests. The role of HbA1c alone in diagnosing T1D in children is unclear. OGTT: Oral glucose tolerance test; NGSP: National glycohemoglobin standardisation program; DCCT: Diabetes control and complications trial

Exclusion criteria: Sick children with hyperosmolar coma, children with neurological illnesses, children with an IQ less than 80 (as children with lower IQ might not be able to communicate/express properly), and children on antiepileptic drugs were excluded from the study.

Sample size: A total of 50 children with T1DM who presented in the paediatric outpatient department and paediatric wards within the study duration were enrolled in the study through convenient sampling.

Data collection: Demographic details such as age, gender, residence, source of family income, and socio-economic status using the Modified Kuppuswami scale [9] updated for the year 2020 were collected. The degree of glycaemic control was assessed by previous HbA1c levels and episodes of DKA/hyperglycaemia/hypoglycaemia in the previous six months. The presence of co-morbidities was noted. Children were first subjected to demographic and clinical details as per the study proforma. Details about the age of onset, type of insulin used, its administration, and any associated diseases were noted. Participants underwent a baseline assessment, which included anthropometric measurements, medical history, and dietary history. Baseline data regarding their diet pattern, blood glucose readings, exercise pattern, and HbA1c levels were recorded. This provided baseline information on existing diet patterns, exercise routines, insulin administration, blood glucose monitoring, follow-up visits, and average blood glucose levels.

None of the participants refused enrollment in the study. Initially, their baseline data were collected, the interventional tool was applied, patients were followed-up for six months, and after six months, data were collected again for comparison. None of the participants were lost to follow-up.

The following instruments were used to assess the emotional, behavioural, and self-perception profiles in children with T1DM:

- a.

Strengths and difficulties questionnaire;
- b.

Self-Perception Profile for Children (SPPC).

All 50 children were introduced to an interventional tool with the following components:

1.

One-on-one counseling for the mother and child regarding knowledge about the disease, insulin administration including

- doses, and self-monitoring of blood glucose. This counseling would be reinforced during monthly visits.
2.

Demonstration of insulin injection administration and showing a brief video to parents and the child regarding insulin administration at home.
3.

Providing brochures/booklets regarding various aspects of T1DM.
4.

Providing a booklet for recording blood glucose levels at home.
5.

A session with a dietitian to explain the diet chart, carbohydrate counting of various food products, and the insulin-carbohydrate ratio.
6.

Psycho-behavioural sessions with a child psychologist to address psychological issues once a month for three months.
7.

Telemedicine support by providing them with doctor's phone numbers to address their queries at home. They will be reminded via phone to come for follow-up in the paediatric endocrinology clinic. During follow-up visits, their queries will be addressed, and the treatment plan will be reinforced.

The children were followed for six months, and data regarding the number of hypoglycaemic, hyperglycaemic, and DKA episodes during this period, as well as the number of hospitalisations, were collected. Data regarding their diet patterns, blood glucose readings, exercise routines, and HbA1c levels were recorded again and compared with the previous data. These children were once again subjected to the SDQ and the SPPC to assess their emotional and behavioural profiles, which were later compared and analysed.

The SDQ is a concise screening tool designed to assess emotional and behavioural aspects in children and young individuals [10,11]. It serves as a predictive measure, offering insights into the perspectives of the children themselves, as well as those of their parents and teachers. There are currently three versions of the SDQ- a short form, a longer form with an impact supplement (which assesses the impact of difficulties on the child's life), and a follow-up form. The 25 items in the SDQ comprise 5 scales of 5 items each. The scales include: 1) Emotional symptoms subscale; 2) Conduct problems subscale; 3) Hyperactivity/inattention subscale; 4) Peer relationships problem subscale; 5) Prosocial behaviour subscale. Interpretation of scores: Generally, higher scores indicate a positive outcome, i.e., a good outcome due to intervention.

The SPPC [12] is one of the most commonly used scales to measure self-concept in children. There are 36 items under six contents of the SPPC [Table/Fig-2].

Specific domains	1. Scholastic competence 2. Social competence 3. Athletic competence 4. Physical appearance 5. Behavioural contact 6. Global self-worth
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[Table/Fig-2]: Contents of self-perception profile score.

Scoring criteria: Each item on the questionnaire is assigned a score on a scale of 4, 3, 2, or 1. A score of four indicates the most appropriate or favorable self-judgment, while a score of 1 signifies the least adequate or least favorable self-judgment.

Scoring interpretation: Generally, lower scores indicate a positive outcome, i.e., a good outcome following intervention.

STATISTICAL ANALYSIS

All the measurements and data were analysed using standard statistical tools. All data were entered into Statistical Package for Social Sciences (SPSS) software version 26.0 Normally distributed variables were presented as means and standard deviations. The data were finally analysed using appropriate statistical methods such as means, standard deviations, paired t-tests, etc.

RESULTS

A total of 50 children aged 6-14 years with T1DM, diagnosed at least one year back, were enrolled from the outpatient department and paediatric ward. The mean age of the subjects was 9.64 ± 2.3 years, with a slight male preponderance (M:F=1.2:1). The majority of subjects 28 (56%) belonged to the lower-middle socioeconomic class. Half of the subjects were using long-acting and ultra-short-acting insulins, while the other half were using NPH and regular insulin as their insulin regimen. The majority of subjects were from urban areas, 41 (82%) [Table/Fig-3].

Parameters		n (%)
Gender	Males	27 (54)
	Females	23 (46)
Insulin regimen	Long acting and ultra short acting	25 (50)
	NPH and regular insulin	25 (50)
Locality of patients	Rural	9 (18)
	Urban	41 (82)
Glycaemic control	Yes	50 (100)
	No	0
Socio-economic status	Upper class	5 (10)
	Upper middle class	13 (26)
	Lower middle class	28 (56)
	Lower class	4 (8)

[Table/Fig-3]: Distribution of demographic data (n=50).
NPH: Neutral protamine hagedorn insulin

In the present study, the HbA1C level hypoglycaemic episodes and episodes of DKA values had significantly reduced after the intervention [Table/Fig-4].

Variables	Preintervention	Postintervention	p-value
HbA1c (%)	13.12 ± 1.02	10.63 ± 1.07	<0.01
No. of hypoglycaemic episodes	2.54 ± 0.88	1.24 ± 0.43	<0.01
No. of episodes of DKA	2.76 ± 0.52	1.08 ± 0.27	<0.01

[Table/Fig-4]: Comparison of pre-post HbA1c, pre-post hypoglycaemic episodes, pre-post episodes of DKA (n=50).
Paired sample t-test used to calculate p-value

Comparison of preintervention and postintervention values showed that the emotional symptoms score, conduct problem score, and hyperactivity score components of the SDQ score had more positive impact following intervention [Table/Fig-5].

SDQ score	Preintervention	Postintervention	p-value
Emotional symptoms score	5.10 ± 1.28	0.48 ± 0.91	<0.01
Conduct problem score	5.00 ± 0.00	2.82 ± 0.48	<0.01
Hyperactivity score	5.00 ± 0.00	2.80 ± 0.53	<0.01
Peer relationship problem score	0.83 ± 0.11	0.70 ± 0.13	<0.01
Prosocial behaviour score	1.04 ± 0.09	0.96 ± 0.09	<0.01
Total score	16.97 ± 1.48	7.76 ± 2.14	<0.01

[Table/Fig-5]: Comparison of pre and post SDQ components score (n=50).
Paired sample t-test used to calculate p-value

Scholastic performance, social competence, physical appearance, behavioural conduct, and global self-worth components of the SPPC score improved significantly following the intervention [Table/Fig-6].

SPP score	Preintervention	Postintervention	p-value
Scholastic performance	14.00 ± 0.00	15.08 ± 0.27	<0.001
Social competence	12.36 ± 0.52	13.36 ± 0.52	<0.001
Athletic competence	12.16 ± 0.37	12.26 ± 0.44	0.024
Physical appearance	12.00 ± 0.00	18.00 ± 0.00	<0.001
Behavioural conduct	14.00 ± 0.00	17.66 ± 0.74	<0.001

Global self-worth	12.00 ± 0.00	17.98 ± 0.14	<0.001
Total score	76.52 ± 0.61	94.34 ± 1.06	<0.001

[Table/Fig-6]: Comparison of pre and post self-perception profile components score (n=50).
Paired sample t-test used to calculate p-value

DISCUSSION

The chronic and multifaceted nature of T1DM can induce considerable stress in affected children. The need for continuous management, including multiple daily injections, regular blood glucose monitoring, adherence to dietary restrictions, and the associated risk of complications, all contribute to the overall stress experienced by these individuals. To date, not much literature is available regarding quality improvement in paediatric patients with T1DM.

The SDQ acts as a dimensional measure of "child mental health," where (except for the prosocial scale) a higher score indicates poor mental health, and a low score indicates good mental health [10]. Therefore, the children in the study have shown a favorable outcome by scoring lower after the intervention, and they have shown significant improvement in the emotional symptoms subscale, conduct problems subscale, and hyperactivity/inattention subscale after the intervention, with the most significant improvement seen in the emotional symptoms subscale.

The SPPC allows for the assessment of children's self-concept, self-esteem, or self-worth, where a higher score indicates higher self-worth (opposite to depression), and a lower score indicates poor self-esteem [12]. Therefore, the children in the study have shown a favorable outcome by scoring high after the intervention, and they have shown significant improvement in scholastic performance, athletic competence, behavioural conduct, and global self-worth, with the highest improvement seen in global self-worth. These findings are consistent with previous studies [13,14].

Terens N et al., conducted a systematic review where randomised controlled studies published between January 2005 and May 2016 were identified through a search conducted on PubMed, Embase, CINAHL, and the Cochrane Library. This review indicates that quality improvement interventions for individuals with diabetes are both feasible to implement and well-received. However, further research is essential to discern the effective components of these interventions, and there is a need for adopting an equity-oriented approach in conducting primary studies. Additionally, a broader range of socio-economic characteristics, including social capital, place of residence, occupation, education, and religion, should be considered for a more comprehensive understanding [15]. In the present study, authors have attempted to address various factors affecting glycaemic control, psychological, and behavioural issues in T1DM.

Edupuganti S et al., conducted a study where five teams developed a Quality Improvement (QI) intervention plan to improve their diabetes care, while three teams served as comparisons without intervention plans. The HbA1C value showed a change from baseline to post-intervention of +0.09 in the intervention group, while the comparison group demonstrated a higher change of +0.322. Although the QI project did not result in improved HbA1C values, it did show significant enhancements in various secondary outcomes within the intervention groups [16]. Consistent with these studies, the present study has not only shown improvement in the psychological and behavioural profile of the study subjects' lives but also a significant improvement in HbA1c values after the intervention.

Bădescu SV et al., have shown in their studies that the incidence of depression is two to three times higher in individuals with diabetes mellitus, with a significant portion of cases often going undiagnosed. They have demonstrated the connections between depression and diabetes underscore the significance of recognising depression in individuals with diabetes and exploring potential

strategies for managing both conditions. The review highlighted possible shared pathophysiological mechanisms such as stress and inflammation. Emphasis was placed on the importance of systematically screening for depression in diabetic patients. It is crucial for diabetic specialists to grasp the common origins of diabetes and depression, acknowledging the frequent co-existence of these conditions. This understanding is essential for enhancing outcomes in the management of both diseases [17].

Limitation(s)

A wide age range of 6-14 years was selected for the study, which may not be reliable as the mental status of a child drastically varies as age advances. The questionnaire was filled out only by the parents, and the analysis was solely based on their responses. However, this approach may not be accepted as the child's behaviour can differ in various settings. For example, if the teacher had filled out the questionnaire, the responses might have been different from those provided by the parents. Additionally, given that most of the subjects were from a lower-middle socioeconomic class, it may have been difficult for them to fully understand the questionnaire with just one explanation. This was a single-centre study involving a limited number of subjects.

CONCLUSION(S)

In the present study, it was found that multidisciplinary interventions have a beneficial effect on children with diabetes in terms of better compliance with therapy, glycaemic control, as well as improved relationships with family and peers, and better coping capabilities. Additionally, such interventions had a positive impact on improving the psychological and behavioural profile of these patients. In resource-limited scenarios, where T1DM is typically managed by a single physician without the support of psychologists, social workers, or diabetes counselors, present study results can help in prioritising children for behavioural monitoring and psychological evaluation. More studies are required to support the results of present study.

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