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Original Article

Paediatrics Section

Glycaemic Control of Type 1 Diabetes Mellitus Paediatric Patients before and after the Use of Telephonic Reinforcement: A Prospective Interventional Study at a Tertiary Care Hospital, Western India

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ABSTRACT

Introduction: Type 1 Diabetes Mellitus (T1DM) is one of the most common paediatric endocrine illnesses. It is a chronic condition that involves regular administration of insulin, meal planning, strict adherence to physical activity and home-based sugar monitoring. Regular follow-up is essential to prevent short-term and long-term complications. Telemedicine has been extensively used in the management of multiple chronic conditions in adults. However, there are limited studies showing the impact of telemedicine in T1DM in paediatric patients in the Indian population.

Aim: To compare the glycaemic control in paediatric T1DM patients, before and after the use of telephonic reinforcement.

Materials and Methods: A prospective, interventional study was conducted at Shree Krishna Hospital, Karamsad, Gujarat, India, with no sub-specialty clinic. The duration of the study was one year and five months, from November 2017 to April 2019. Paediatric patients upto the age of 18 years, diagnosed with T1DM (by paediatricians/physicians) were included in the study. The records of 64 patients were traced, 27 were enrolled prospectively for the study (who could be contacted and consented to the present study). The baseline data like weight, height, age, duration of T1DM, insulin dosage and baseline Glycosylated Haemoglobin (HbA1c) were recorded. After receiving due consent, the patients/parents were provided telephonic reinforcement by a paediatrician to ensure regular sugar monitoring, solve queries of parents and to ensure regular follow-up. The clinical profile and parameters were repeated at three monthly intervals and compared. A paired t-test was used with a p-value <0.05 as a cut-off to compare data before and after intervention.

Results: The mean and median ages of the study participants at diagnosis were found to be 8.9 years and 10.5 years, respectively. Average duration of T1DM was six years. On telephone, three things were reinforced: 1) To take insulin regularly as advised; 2) To come for follow-up regularly and 3) If any difficulties faced by them while taking insulin or coming for follow-up then to contact us. The patients were followed-up as per routine, diabetic care protocol every three months and value of HbA1c was reduced significantly during follow-up. The (p-value <0.001) showed a significant difference after telephonic reinforcement.

Conclusion: Telephonic reinforcement improves control of T1DM, by improving laboratory parameters and compliance with regular follow-up.

Keywords: Adherence, Blood glucose, Compliance, Endocrine illness, Glycosylated haemoglobin

INTRODUCTION

The Type 1 Diabetes Mellitus (T1DM) is one of the most common paediatric endocrine illness. India has the highest number of children diagnosed with T1DM in the South-East Asian region. According to the 6th edition of the International Diabetes Federation (IDF) diabetes atlas, India has an incidence rate of three new cases of T1DM per 100,000 children aged 0 to 14 years [1]. T1DM is usually caused by an autoimmune reaction, where the body immune system attacks the insulin-producing beta cells in the islets of the pancreas gland. T1DM being a chronic life-long disorder, requires a multidisciplinary approach involving the child, parents, the treating physician, as well as, a nurse educator.

The standard management of the disease involves four main pillars-lifelong daily insulin injections, self-monitoring of blood sugar, meal planning and regular physical activity. Compliance with regular follow-ups with the Diabetologist/Physician is essential for better glycaemic control and prevention of chronic and acute complications. The management of T1DM requires innovative strategies to improve glycaemic control [2]. The study of telemedicine follow-up of T1DM included population from rural as well as urban areas. In the current era, the use of telemedicine has been on a rise, to improve the management of chronic conditions, particularly Diabetes Mellitus (DM). There have been multiple studies including meta-analyses and review articles for use of telemedicine in Type 2 Diabetes Mellitus (T2DM) in the adult population [2-4]. However, the use of telemedicine in the T1DM paediatric population is scarcely studied in India.

In a developing country like India, T1DM children face multiple challenges including a lack of free supply of insulin, syringes, glucose measuring devices and strips, a lack of structured diabetes education and counselling, and inadequately trained healthcare professionals [5]. In this scenario, telemedicine using landlines/mobile phones can act as a boon to patients residing in rural areas. The present study was conducted at a tertiary healthcare facility in a rural town that caters to the majority of patients from rural areas. The aim of the present study was to assess the impact of telemedicine interventions (telephonic reinforcement) combined with usual care with primary objective of comparison of HbA1c in T1DM paediatric patients. Secondary objective of the present study was to know their baseline profile and factors hindering regular follow-up.

MATERIALS AND METHODS

A prospective interventional study was conducted at Shree Krishna Hospital, Karamsad, Gujarat, India. The duration of the study was one year and five months, from November 2017 to April 2019. The study was approved by the Institutional Ethics Committee letter no. (IEC/HMPCMCE/87/FACULTY/13/13/18). The study was in the, central part of Gujarat, which caters to a large number of patients from rural areas, and it does not have paediatric endocrinology subspeciality.

Inclusion criteria: Patients who were diagnosed with T1DM by Paediatrician/physician and those patients or parents, who were willing to give consent were included in the study.

Exclusion criteria: Patients who were >18 years of age, patients/parents who did not gave consent and those with other co-morbidities (uncontrolled hypothyroidism, celiac disease, syndromic patients) were excluded from the study.

Sample size size calculation: Being a retrospective and database search, sample size calculation is not applicable. Whatever information of such diagnosis was found, we tried to contact but all were not traceable. The patients were enrolled prospectively for six months with latest follow-up at 9 months after enrollment.

Study Procedure

A computer database of 2.5 lac patients were actively searched and 65 paediatric patients (one month to 18 years) were found with a diagnosis of T1DM. However, 38 patients were excluded as they could not be contacted and the remaining 27 T1DM patients were studied once consented to participate in the study. The demographic details like age, sex, residence, age of diagnosis, duration of treatment of diabetes, insulin dosage, compliance, height, weight, Body Mass Index (BMI), socio-economic status and baseline HbA1c were noted [6,7]. HbA1c was measured by High-Performance Liquid Chromatography (HPLC) method at this Institute's Biochemical Laboratory.

These patients were then followed-up with a telephonic conversation and counseling every week for the initial three months and then monthly till nine months. During this telephonic intervention done by a trained Paediatrician, the parents were asked about the well-being of the child, and any episodes of hyperglycaemia or hypoglycaemia, counselled about regular insulin administration and provided a reminder for the follow-up dates. The patients were regularly followed-up at the outpatient clinic every three months, as per standard diabetic care for one year. During the outpatient visit, the anthropometric parameters were rechecked and HbA1c was repeated as per the diabetes protocol. All these visits and investigations were a part of routine diabetic care. All efforts were made to ensure regular follow-up of the enrolled subjects, a minimum of three for the study period.

STATISTICAL ANALYSIS

Descriptive statistics were used for all variables. A paired t-test was performed with a p-value <0.05 as a cut-off to compare data, before and after the intervention by using Statistics and Data (STATA) software version 14.2.

RESULTS

The demographic data of the enrolled 27 paediatric T1DM patients shown in [Table/Fig-1]. It was noted down when patient enrolled in the study and agreed to follow-up. The data noted during their personal visit and by phone calls in a few of them. Out of total 27 patients, 14 were males and 13 were females. The mean and median age at diagnosis of T1DM was 8.9 and 10.5 years, respectively. At the time of the first presentation, clinical symptoms were polyuria 19 (70.3%), polydipsia 18 (66.66%), vomiting 12 (44.44%), abdominal pain 09 (33.33%), rapid breathing 08 (29.6%), altered sensorium 08 (29.6%) and weight loss 05 (18.5%). Eighteen patients were diagnosed following an episode of diabetic ketoacidosis. Out of 27 enrolled patients, five had a duration of the disease less than three months, 13 had one to three years duration whereas, nine had a duration of more than five years.

Demographic data	
Sex distribution	
Males	14
Females	13
Average age of study subjects (in years)	10.2
Average duration from diagnosis of T1DM (in years)	6
Socioeconomic class	
Lower SE	24
Lower middle SE	3

[Table/Fig-1]: Demographic data of T1DM paediatric patients.

The anthropometric details and HbA1c was noted at baseline and follow-up. HbA1c mean values±SD at baseline was 12.24±1.24. After three months follow-up, it was 11.54±1.32 (p-value=0.047), after six months follow-up, it was 11.34±1.5 (p-value=0.017), and after nine months, it was 9.65±1.6 (p-value <0.001). And comparison of mean HbA1c at baseline three, six and nine months follow-up was shown in [Table/Fig-2].

Laboratory parameter (n=27)	Follow-up (in months)	Mean±SD	p-value*
HbA1c	Baseline	12.24±1.24	
	3	11.54±1.32	0.047
	6	11.34±1.5	0.017
	9	9.65±1.6	<0.001

[Table/Fig-2]: Comparison of mean HbA1c at baseline three, six and 9 months follow-up.
*Paired t-test was used for comparison of baseline mean with three, six, 9 months follow-up

There was a significant reduction in HbA1c after telephonic counseling/reinforcement, with a p-value of 0.047 as compared to the baseline. Various factors affecting compliance in T1DM patients were also identified among the study participants. The education of parents in 3 (11.11%) and regular outpatient visit 11 (40.7%) positively impacted the glycaemic control whereas, lower socio-economic class (as per revised Kuppuswami) 22 (81.4%), uneducated parents 12 (44.4%), large family size 06 (22.2%) and economic constraints 22 (81.4%) negatively impacted glycaemic control of T1DM paediatric patients in the present study as shown in [Table/Fig-3].

Positive factors	n (%)	Limiting factors	n (%)
Regular OPD visits	11 (40.7)	Economic constraints	22 (81.4)
		Uneducated parents	12 (44.4)
Well-educated parents	3 (11.11)	Lower socio-economic class	22 (81.4)
		Large family size	06 (22.2)

[Table/Fig-3]: The possible factors affecting compliance with T1DM treatment.
OPD: Outpatient department

DISCUSSION

The incidence of DM has been on a rise worldwide. T1DM is also on the increase, albeit not in the same proportion as T2DM, but still with a 3%-5% increase/year [8,9]. India, infamously considered as "The Diabetes Capital" of the world, accounts for most of the children with T1DM in South-East Asia [10]. The prevalence of diabetes in India, varies across different regions. According to available data, the rates of diabetes in children are reported as follows: 17.93 cases per 100,000 children in Karnataka, 3.2 cases per 100,000 children in Chennai, and 10.2 cases per 100,000 children in Karnal (Haryana) [11-13]. The increasing incidence of T1DM in India, can have serious implications for the national health infrastructure. Rising prevalence, shortage of trained diabetologists,

and complexity of treatment translate to poor health outcomes and failure to reach desired therapeutic targets [14]. However, the current study does not include the incidence or prevalence. The incidence rate of T1DM increases as age advances and peaks between ages of 10-14 years during puberty [15,16]. In current study, the mean and median age of T1DM was 8.9 and 10.5 years, respectively. In the current study, the disease had no sex predilection. Majority of patients were diagnosed after an episode of diabetic ketoacidosis. Most patients (88.9%) belonged to the lower socio-economic class with poor parental education. Secrest AM et al., suggested that lower socio-economic class T1DM patients may have poorer self-management and thus, more diabetes complications [17].

T1DM management requires strict compliance with insulin therapy and regular follow-up. The enrolled study participants were followed-up with telephonic reinforcement with an aim to achieve better glycaemic control. Numerous studies have examined the practicality and effectiveness of telemedicine approaches in the management of individuals with diabetes. While several studies have demonstrated its feasibility, the findings vary across different research investigations, leading to inconsistent results. Various studies have been done in T1DM and T2DM with varied modes of telecommunication including telephones, smartphones and online applications for improving the glycaemic control of patients [8,18-27]. With advancing technology, telephonic calls are replaced by mobile-based application systems for regular glucose monitoring and feedback from healthcare professionals. The present study was conducted at a tertiary centre in a resource-limited setting, with the majority of the participants belonging to the lower socio-economic group and hence, the use of conventional telephone/mobile phones for reinforcement was the appropriate mode of intervention.

In current study, HbA1c was used as an indicator of improved compliance and glycaemic control. It is recognised as a valuable indicator of glycaemic control in T1DM patients, as it reflects average glycaemia over several months and is strongly correlated with diabetes complications [28]. In the present study, HbA1c was measured at baseline and at every three months of interval and it showed significant improvement in the mean values from the baseline values. In one of the meta-analyses, it was seen that compared with usual care, the addition of telemedicine appeared to improve HbA1c significantly in people with T1DM [3,27]. This is in contrast to Randomised Control Trials (RCT) of telecare intervention, where HbA1c of patients managed with telecare interventions was not reduced during trials [8]. A published systematic review (which included 13 studies, 4207 patients) conducted by Marcolino MS et al., indicated that in diabetes patients, telemedicine strategies concomitant to the usual care are associated with a mean HbA1c decline of -0.44% (-4.8 mmol/mol) when compared to the usual care alone [3]. Many of these studies used telecommunication to aid in the daily monitoring of blood glucose levels by changing insulin dosages. However, in the present study, advise on the treatment of insulin therapy on teleconsultation was not provided. In such cases, patients were called for in-person consultation.

A similar Indian study by Pramanik BK et al., was done to examine the effectiveness of a motivational smartphone application to improve their glycaemic control [18]. Adolescents aged between 11 to 18, who had T1DM for atleast one year and exhibited poor glycaemic control (with a mean HbA1c of 8.5% or higher in the previous 9 months), were enrolled in the study. An application installed on their smartphones was programmed to deliver three reminders per day related to insulin administration, meals, and physical exercise. After a period of three months, the participants' HbA1c levels were measured. Out of the 28 participants, 22 demonstrated a decrease in HbA1c levels following the installation of the application.

The researchers analysed the extent of change in HbA1c levels during the three months period before and after application usage. A statistically significant difference was observed between the mean HbA1c levels before and after usage: +0.28 (2.06) vs -0.914 (1.52); p-value=0.019. This suggests that, the utilisation of the smartphone application as a motivational intervention in adolescents with T1DM resulted in a significant reduction in HbA1c levels after three months [18]. Many factors have been associated with adherence to diabetes treatment and glycaemic control such as economic status, local healthcare infrastructure, family support, social and peer pressures and transition to adolescence [14]. In the present study, an attempt was made to identify the factors affecting compliance. Few of positive factors were identified among study subjects such as better education of parents and regular healthcare visits. Various limiting factors were identified such as economic constraints, poor education, social stigma, and large family size as per [Table/Fig-3]. These factors can help target interventions for future interventions. Telephonic reinforcement and counselling were used to overcome the above limiting factors commonly encountered in T1DM patients, especially in a country like India.

There are very limited prospective interventional studies in India, involving T1DM paediatric patients. The current study represents a rural population of T1DM paediatric patients, that remains under-served. Regular telephonic reinforcement has been shown to improve glycaemic control in the present study. This can be used for better outcomes of T1DM paediatric patients in a larger population.

Limitation(s)

A major limitation of the present study was small sample size and no control group was present to compare the effectiveness of the telephonic reinforcement. The prevalence and incidence of the disease burden was not estimated.

CONCLUSION(S)

Telephonic reinforcement improves control of T1DM by improving laboratory parameters and compliance with regular follow-up. Further studies with a larger sample size estimating the prevalence and incidence of disease burden can be conducted.

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