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Research Article

A STUDY ON CLINICAL PROFILE AND COMPLICATIONS IN CHILDREN BELOW 14 YEARS OF AGE WITH TYPE 1 DIABETES MELLITUS ADMITTED IN A TERTIARY CARE HOSPITAL IN SOUTH INDIA: A CROSS-SECTIONAL STUDY

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ABSTRACT

Objective: Type 1 diabetes mellitus (DM) is a common disease in children presenting with acute complications such as diabetic ketoacidosis (DKA). This study was undertaken to study the clinical profile, biochemical parameters, acute complications, associated comorbidities, and outcomes in children admitted with Type 1 DM in a tertiary care hospital.

Methods: This is a hospital-based cross-sectional study conducted in a tertiary hospital.

Results: A total of 38 children were included in the study. Most of the children were between 5 and 10 years (47.37%) with a slightly high female preponderance (60.53%). The mean age at diagnosis was 7.25 years, and 63.16% of children were newly diagnosed. Most of the children were from the rural population (55.26%), and the mean body mass index was 14.07. 35 children presented with DKA (92.11%), with the majority of severe type (51.43%). Mean random blood sugar was 601.75, and mean hemoglobin A1c (HbA1C) was 11.70. Mean HbA1C in males versus females was 11.48 vs. 10.44, in newly versus previously diagnosed cases was (10.29 vs. 11.94), and in children with normal versus low Vitamin D levels was (10.4 vs. 13.4). Most presenting complaints were polyuria (57.89%), fever (42.10%), and lethargy (39.47%). Other associated significant comorbidities were hypothyroidism (10.52%) and dyslipidemia (15.79%). Only 21.05% were using newer insulin analogs (glargine); 4 children (10.52%) succumbed during treatment.

Conclusion: Steps should be taken to increase awareness regarding the disease among people. The government should also ensure the availability of newer insulin analogs, which are found to be user-friendly at an affordable price.

Keywords: Type 1 diabetes mellitus, Diabetic ketoacidosis, Hyperglycemia, Insulin.

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INTRODUCTION

India is one of the leading nations in the Southeast Asian region, with a high number of children under 19 years with Type 1 diabetes mellitus (DM). As per the 10th International Diabetes Federation Atlas 2021, the number of children in the age group 0–19 years with Type 1 DM in India is around 2,29,40,001 [1]. The Indian Council of Medical Research Youth Onset Diabetes in India registry estimates that the average annual incidence of Type 1 DM (below 20 years) is 4.9 cases/1,00,000 population [2]. Lack of awareness among people regarding diabetes and its presenting symptoms in children leads to high morbidity and mortality. Most of the children present with ketoacidosis to the emergency room due to a lack of knowledge and neglect of the clinical features of this disease. Type 1 DM can lead to acute and chronic complications in children, which can be a burden to both children and families taking care of these kids. Very few studies have been done on this disease in this area of Andhra Pradesh. Hence, this study was undertaken to study the clinical profile, biochemical parameters, acute complications, associated comorbidities, and outcomes in children admitted with Type 1 DM.

METHODS

Study design

This is a hospital-based cross-sectional observation study.

Study population

Children under the age of 14 years diagnosed to have Type 1 DM and admitted to the Department of Paediatrics in a tertiary hospital, Government General Hospital, Kakinada, Andhra Pradesh, in South India.

Inclusion criteria

All children below the age of 14 years, either previously diagnosed or diagnosed for the 1st time at the time of admission over 3 years from January 2022 to December 2024, were included in the study.

Exclusion criteria

Children with other causes of hyperglycemia, such as drug-induced pancreatic disorders, were not included in the study.

Data collection

Ethics committee approval was taken before the study. Prior consent from the parents/caregivers of the children included in the study was taken. Details of the patient were taken in a predesigned proforma, which included information related to age, sex, age at diagnosis, family history, clinical features at presentation, and birth weight of the patient. Data of biochemical parameters such as HbA1C, random blood sugar (RBS), arterial blood gas analysis, serum electrolytes, Vitamin D levels, Lipid profile, and thyroid-stimulating hormone (TSH) levels were taken from the patient's laboratory reports, and usage of the type and regimen of insulin used was noted. The outcome in terms of successful discharge or death was recorded.

Sample size calculation

The estimated prevalence of Type 1 DM in Indian children based on available data is approximately 3.2–17.93/100,000 population.

Sample size was calculated by estimating the prevalence of Type 1 DM with a specified level of precision using the formula;

$$n = \frac{Z^2 \times P \times (1 - P)}{d^2}$$

Where:

n = required sample size

Z = Z-score corresponding to the desired confidence level (1.96 for 95% confidence)

P = estimated prevalence (as a decimal)

d = desired precision (margin of error)

Assumptions:

Confidence level: 95% (Z = 1.96)

Desired precision (d): 0.01 (1%)

Using a prevalence of 0.0009 (0.09%):

$$n = \frac{(1.96)^2 \times 0.0009 \times (1 - 0.001793)}{(0.01)^2} = 34.5$$

With a prevalence of 0.09%, a sample size of approximately 35 children is needed.

Data analysis

Data were entered in Excel 2017 and analyzed using the Statistical Package for the Social Sciences 21 software. Statistical analysis was done using appropriate statistical tools such as the Pearson Chi-square test.

RESULTS

A total of 38 children were included in the study (Table 1).

Most of the admitted children were between 5 and 10 years of age (47.37%), with the majority being female (60.53%) (Table 2). Aout 19 children (51%) were between 5 and 10 years of age at the time of diagnosis, and the mean age at diagnosis was 7.25 years. About 24 children (63.16%) were diagnosed for the 1st time, and 3 children (7.89%) had the disease between 5 and 10 years duration. Most of the children (55.26%) were from rural areas. The mean BMI of the children was 14.07, and most (89.47%) had normal birth weights. Only one child had a first-degree relative with Type 1 DM, and 18 children had either first or second-degree relatives with Type 2 DM.

The mean RBS at admission in the children was 601.75 mg/dL, and the mean RBS was higher in children above 5 years (511 mg/dL) than in children below 5 years (478 mg/dL) and was also higher in females (610.75 mg/dL) compared to male children (490.9 mg/dL). The mean HbA1c was 11.78. The mean HbA1c in males (11.48) was slightly higher than in female children (10.44), and it was higher in children above 5 years (12.37) compared to children below 5 years (9.26).

The primary presenting symptoms were polyuria (57.89%), fever (42.10%), lethargy (39.47%), and polydipsia (34.21%). Most of the children presented with the complication of diabetic ketoacidosis (DKA) (92.10%), which was of severe type (51.43%), mild (28.57%), and moderate (20%). Besides DKA, the other complications seen were hypoglycemia (28.95%), cerebral edema (15.79%), shock (15.79%), and acute kidney injury (7.89%). Vitamin D levels could be done in 29 out of 38 children, of whom 14 were deficient. Hypothyroidism (10.52%) and dyslipidemia (15.79%) were the major comorbidities.

Most of the children (78.95%) were either already using or were using at discharge with a mixture of insulin, and only 8 children (21.05%) used insulin analogs. Four children died (10.52%), and 34 children (89.48%) were discharged.

Group Statistics

Dx	n	Mean	Standard deviation	Standard error mean	t-test
HBA1C					
Newly diagnosed	24	11.567	3.5594	0.7266	−0.354 df 36 p=0.725
Previously diagnosed	14	11.950	2.5062	0.6698	(p>0.05)

Group statistics

Age classification	n	Mean	Standard deviation	Standard error mean	t-test
HBA1C					
<5 years	9	9.544	3.4352	1.1451	−2.495 df 36 p=0.0185
>5 years	29	12.379	2.8331	0.5261	(p<0.05)

No statistical significance was seen between HbA1C values of newly versus previously diagnosed cases of Type 1 DM (p>0.05), but significance was seen between HbA1C values of children <5 years versus children more than 5 years (p>0.05).

DISCUSSION

This is a tertiary teaching hospital that caters to children with endocrinological emergencies such as DKA. Type 1 DM was more prevalent in females (60.53%) than males (39.47%) in the present study. The Karnataka T1DM registry (3.7/1, 00,00 in males vs. 4.0/1,00,00 in females) [3], studies from Calabria region (55.2% in females vs. 44.8% in males) [4] and Kirikkale region (51.5% in females vs. 48.5% in males) also reported a higher prevalence in females compared to males [5]. A study from Karnal district and AIIMS Rishikesh had shown a higher prevalence in males [6-8].

The mean age at diagnosis was 7.25 years in this study, which is lower than in other studies. The mean age at diagnosis was 11.5±4.7 years, 8.1±3.8 years, 8.80 years, and 10.5 years in studies from Kirikkale [5], a study on Turkish children [9], AIIMS Rishikesh [7], and Praveen et al. [10]. Most of the children were between 5 and 10 years old at diagnosis (51.35%). 26.32% of children in this study were between 1 and 4 years old at diagnosis. In children with new-onset Type 1 DM, young age has been identified as a risk factor in studies in Canada, Italy, and the UK, where they reported higher rates of DKA in Type 1 DM at diagnosis in children aged 0–4 years and <2 years [11-13].

The youngest patient in this study was a 2-month-old child who presented with neonatal DM (NDM) with complications such as DKA, shock, cerebral edema, and acute renal failure requiring mechanical ventilation, inotropes, and insulin therapy, but did not survive. It is challenging to diagnose diabetes in infants as it is difficult to obtain a proper history of polydipsia, polyphagia, and polyuria. Infants with DKA are usually misdiagnosed as sepsis, bronchiolitis, and pneumonia with shock and, in due course, may receive glucocorticoids during treatment, further deteriorating the condition. Another child was 11 months old, admitted only with respiratory distress as the presenting complaint, initially considered to be a case of bronchiolitis. Due to a delay in diagnosis, infants usually have DKA at the time of diagnosis, leading to high morbidity and mortality.

HbA1C estimation in infants may not be ideal. The HbA1C in the 2-month-old child in this study was found to be 2.1. A study including five babies with NDM showed normal HbA1c levels (5.4±2.6%) despite high plasma glucose levels [14]. As HbF is the predominant hemoglobin in children <6 months of age, HbA1c cannot be used as a diagnostic indicator in these children. Alternative laboratory tests such as fructosamine or glycated albumin may be used to assess glucose control

in neonatal diabetes, which are unavailable at our hospital. Therefore, these tests were not done.

The mean BMI of the children in this study was 14.07. Most of the recent studies have shown that there has been an increase in the incidence of Type 1 DM, particularly in overweight and obese children with higher BMI, as postulated by the accelerator hypothesis [15]. However, in the present study, all the children were underweight or of normal weight. As insulin is the major anabolic hormone and Type 1 DM is due to decreased or absent production of insulin, children with Type 1 DM usually present with weight loss or being underweight. A study by Wasyl-Nawrot *et al*. on children with Type 1 DM from Lesser Poland has shown almost all children with a normal range of BMI, with very few obese (2.7%) and underweight (5.7%) children at the time of diagnosis [16].

In the present study, the mean birth weight of the children was 2.9 kg. No significant correlation was found between birth weight and the risk of Type 1 DM in these children. Genetic and environmental factors are believed to be responsible for the increasing incidence of Type 1 DM in children. As Type 1 DM can manifest very early in life, a long pre-clinical phase precedes clinically overt diabetes, which has led to the suggestion that perinatal factors may contribute to the pathogenesis of the disease. A cohort study from Chennai on infantile diabetes found low birth weight in 50% of the cases [17]. A cohort study from the UK has shown that the risk of Type 1 DM is high in children born large for gestational age or birth weight >4000 g, whereas small for gestational age or lower birth has been found to be negatively correlated with the risk of Type 1 DM [18]. According to some studies, there is a 1.7% increase in the incidence rate of Type 1 DM per 100 g increase in birth weight. However, a few smaller case-control studies have failed to show any significant correlation between birth weight and the risk of Type 1 DM.

Polyuria (56.5%), polydipsia (34.8%), polyphagia (21.7%), and weight loss (39.1%) were the most common presenting symptoms in a study by Pasi and Ravi [8]. In a study in Bhilai, Chhattisgarh, children mainly presented with polyuria (85.71%), breathlessness (42.85%), and weight loss (64.28%) [19]. In the present study, the most common presenting complaints were also polyuria (57.89%), polydipsia (34.21%), polyphagia (21.05%), and breathlessness (28.95%), similar to the above studies. Other common complaints were lethargy (39.47%), fever (42.10%), abdominal pain (28.95%), and vomiting (31.57%).

28.57%, 20%, and 51.43% of cases in this study were admitted with mild, moderate, and severe DKA. Three children who had Type 1 DM did not present with DKA. The findings were different from those of studies in China and Kuwait [20,21]. A study from China reported a higher number of mild DKA (36%) than moderate (30%) and severe DKA cases (33.9%). Mild/moderate DKA was seen in 24.8% of cases and severe DKA in 8.8% of cases in a study from Kuwait. Many severe DKA cases in the present study could be due to late presentation to the hospital due to a lack of knowledge regarding the disease and its presenting symptoms. Symptoms such as fever, abdominal pain, vomiting, and respiratory distress are often mistaken for being due to infectious causes such as urinary tract infection (UTI) and pneumonia.

HbA1c level is used to estimate glycemic control in diabetic patients. The mean HbA1c levels in this study were 11.70, with the mean in males slightly higher (11.48) than in females (10.44). The mean HbA1c was 13.5±2.8 in the study at AIIMS Rishikesh [7], and the mean HbA1c was 9.4% in a study by Annika Gronberg [22]. According to various studies, HbA1c levels can be affected by gender, age, and season [23,24]. The mean HbA1C in the newly diagnosed cases in this study was 10.29 versus 11.95 in previously diagnosed cases, with no statistical significance. Statistical significance was seen in HbA1C values in children <5 years versus children >5 years (p=0.0185).

Type 1 DM, being an autoimmune disorder, is often associated with other autoimmune disorders such as autoimmune thyroiditis (15–30%), celiac disease (3–12%), and vitiligo (1–7%), as part of a complex syndrome called autoimmune polyglandular syndrome [25]. In this study, all children were screened for thyroid disorders by estimating their TSH levels. Four children were found to have hypothyroidism and were treated with thyroxine. An 8-year-old child who was previously diagnosed with Graves' disease now presented with Type 1 DM. Hyperthyroidism is a promoter of hyperglycemia by reducing the half-life of insulin. The association between these two diseases is due to the sharing of a common genetic background of similar HLA antigens, such as DQ2 and DQ8, linked to DR3 and DR4 [26].

In this study, a 9-year-old female child diagnosed for the 1st time with Type 1 DM was found to have vitiligo when screened for other autoimmune conditions. An 8-year-old female child had clinical features suggestive of H syndrome, a rare autosomal recessive disorder. Insulin-dependent DM can be the sole presentation of H syndrome as per a study by Broshtilova *et al*. [27]. A 10-year-old female child who was previously diagnosed with immune thrombocytopenic purpura (ITP) was admitted with DKA. The association of Type 1 DM and ITP is very rare, with very few cases reported worldwide. Autoimmune disorders are more common in female children and usually present as an association with other autoimmune disorders; a high index of suspicion is needed in them.

Studies have shown that Vitamin D has a pivotal role beyond calcium and bone homeostasis, as the Vitamin D receptor is ubiquitously expressed on nucleated cells in pancreatic beta cells and in insulin-responsive tissues such as skeletal muscles, adipose tissue, and myocardium [28]. A relationship between low Vitamin D levels and the development of

Table 1: The Sociodemographic profile of the children

S. No.	Parameter	Number	Percentage
1	Age of the child		
	<1 year	2	5.26
	1–4 years	7	18.42
	5–10 years	18	47.37
	>10 years	11	28.95
2	Gender		
	Male	15	39.47
	Female	23	60.53
3	Age at diagnosis		
	<1 year	2	5.26
	1–4 years	10	26.32
	5–10 years	19	50.00
	>10 years	7	18.42
	Mean age at diagnosis	7.25 years	
4	Duration of disease		
	Newly diagnosed	24	63.16
	<5 years	11	28.95
	5–10 years	3	7.89
5	Residence		
	Urban	10	26.36
	Rural	21	55.26
	Tribal	7	18.42
6	Birth weight of the child		
	<2.5	1	2.64
	2.5–3.5	34	89.47
	>3.5	3	7.89
7	BMI of the child		
	Underweight (<18.5)	36	94.74
	Normal (18.5–24.9)	2	5.26
	Overweight (25–29.9)	nil	
	Obesity (>30)	nil	
	Mean BMI	14.07	
8	Family history		
	Negative	19	50.00
	Positive	19	50.00
	Relative to Type 1 DM	1	2.63
	Relative to Type 2 DM	18	47.37

BMI: Body mass index, DM: Diabetes mellitus

Table 2: The clinical parameters of the children

S. No.	Clinical parameter	Number/unit	Percentage
1	RBS		
	Mean RBS	601.75 mg/dL	
	Mean RBS in<5 years	478 mg/dL	
	Mean RBS in>5 years	511 mg/dL	
	Mean RBS in males	490.9 mg/dL	
	Mean RBS in females	610.75 mg/dL	
2	HbA1C		
	Mean HbA1C	11.70	
	Mean HbA1C in<5 years	9.26	
	Mean HbA1C in>5 years	12.37	
	Mean HbA1C in males	11.48	
	Mean HbA1C in females	10.44	
	Mean HbA1C in newly diagnosed cases	10.29	
	Mean HbA1C in previously diagnosed cases	11.95	
	Mean HbA1C in children with normal vitamin D levels	10.40	
	Mean HbA1C in children with deficient or insufficient vitamin D levels	13.4	
3	DKA		
	DKA present	35	92.11
	No DKA	3	7.89
4	Severity of DKA		
	Mild	10	28.57
	Moderate	7	20
	Severe	18	51.43
5	Vitamin D levels		
	Not Done	9	23.68
	Done	29	76.31
	Deficient	14	48.28
	Insufficiency	5	17.24
	Normal	10	34.48
6	Presenting symptoms		
	Polyuria	22	57.89
	Polydipsia	13	34.21
	Polyphagia	8	21.05
	Lethargy	15	39.47
	Fever	16	42.10
	Respiratory distress	11	28.95
	Vomitings	12	31.57
	Abdominal pain	11	28.95
	Altered sensorium	7	18.42
	UTI	2	5.26
	Weight Loss	5	13.16
	Vaginal itching	1	2.7
	Varicella with complicated pneumonia	1	2.7
7	Complications		
	DKA	35	92.10
	Hypoglycemia	11	28.95
	Cerebral edema	6	15.79
	Shock	6	15.79
	Acute kidney injury	3	7.89
	Hypoglycemic seizures	1	2.7
	Complicated pneumonia with effusion	1	2.7
	Respiratory failure	1	2.7
8	Associated comorbidities		
	Hypothyroidism	4	10.52
	Dyslipidemia	6	15.79
	ITP	1	2.7
	Graves disease	1	2.7
	H Syndrome	1	2.7
	Vitiligo	1	2.7
9	Type of insulin regimen used		
	Mixtard/Mixtard+Short acting	30	78.95
	Glargine+Short acting	8	21.05
10	Outcome		
	Discharged	34	89.48
	Died	4	10.52

DKA: Diabetic ketoacidosis, HbA1C: Hemoglobin A1c, UTI: Urinary tract infection, RBS: Random blood sugar, ITP: Immune thrombocytopenic purpura

autoimmune diseases such as Rheumatoid arthritis, systemic lupus erythematosus, and Multiple Sclerosis has been established. A birth cohort study in Finnish infants and a meta-analysis review of various studies have shown that Vitamin D supplementation reduced the risk of Type 1 DM through adulthood [29].

In this study, a Vitamin D assay could be done in 29 out of 37 children due to logistical issues. The majority of those whose Vitamin D levels were done were deficient (14 children), and five children had insufficient levels of Vitamin D. A study from Chandigarh found Vitamin D levels deficient in 58% of children with Diabetes compared to 32% of controls [30]. Recent reports from the literature have shown that lower Vitamin D levels are associated with high HbA1c levels and impaired glycemic control. Studies have also shown that patients with Type 1 Diabetes have better Vitamin D levels and better HbA1c levels during the summer when good sunlight is available. Hence, supplementation of Vitamin D can improve glycemic control by regulating insulin sensitivity and glucose homeostasis. Early supplementation of Vitamin D in the 1st year of life can help prevent Type 1 DM in children. Good sunlight exposure will help maintain good Vitamin D and HbA1c levels in children with Type 1 DM. In this study, the mean HbA1C in children with normal Vitamin D levels was 10.40 versus 13.4 in children with low Vitamin D levels.

Studies in Caucasian children with Type 1 DM have shown that the incidence of both Type 1 DM and Type 2 DM is higher in their families compared to the general population [31]. This could probably be due to shared susceptibility to risk factors. Familial clustering of Type 1 DM is common, with the risk being 8–15 times higher in a first-degree relative (father, mother, or siblings) and twofold higher in a second-degree relative (grandparents, uncles, aunts, or cousins) having Type 1 DM. Offspring of diabetic fathers (approximately 12%) have almost double the risk of offspring of diabetic mothers (approximately 6%). In the present study, 50% cases were sporadic, four children had a first-degree relative with Type 2 DM, 14 children had a second-degree relative (maternal or paternal grandparents) with a history of Type 2 DM, and one child had a younger sibling with Type 1 DM.

All the children in the present study were screened for lipid abnormalities, and dyslipidemia was seen in 15.79% of children. High cholesterol, triglycerides, low-density lipoprotein (LDL) levels, and low high-density lipoprotein (HDL) levels are the common lipid abnormalities seen in children with Type 1 DM. Inadequate glycemic control and associated hypothyroidism can cause significant lipid abnormalities, particularly low HDL levels over the years. Dyslipidemia increases the risk of cardiovascular diseases in children with Type 1 DM. Selvaraj *et al*. in a study in South Indian children, identified a high prevalence of increased LDL levels in children with poor glycemic control in children with Type 1 DM [32]. Hence, these children must be screened routinely every 5 years to ensure good glycemic control.

Cerebral edema and hypoglycemia as complications due to DKA are seen in 0.3–0.9% and 5–25% of pediatric cases. In the present study, cerebral edema and hypoglycemia were seen in 15.79% of cases, respectively. In the present study, mortality was 10.52%, and cerebral edema, a serious complication of DKA, was seen in all those cases. Mortality rates in pediatric DKA range from 0.15 to 0.35% in developed countries and 3.4–13.4% in developing countries such as India [33].

Insulin is the only treatment modality available to children with Type 1 DM. The majority of the children were already using or were kept on conventional insulin, such as mixtard (78%), rather than newer insulin analogs such as glargine, due to lack of affordability and non-availability in the government sector. A study from Visakhapatnam, Andhra Pradesh, South India, also showed higher usage of conventional insulins (80–85%) [34]. Hartman's study has shown that insulin analogs lead to better glycemic control because they mimic the physiological mealtime response [35]. A study by Grunberger showed that analog insulins have improved treatment adherence and satisfactory results due to user-friendly devices and flexibility [36]. Adherence to insulin therapy and strict glycemic control is essential to prevent early onset of complications such as nephropathy and neuropathy [37]. Children of older age are more prone to non-compliance with insulin therapy, hence should be carefully monitored and managed to prevent long-term complications [38]. In this study, statistical significance was seen in HbA1C values in children <5 years (mean=9.26) versus children >5 years (mean=12.37) with p=0.0185. Regular follow-up and screening for complications such as nephropathy, neuropathy, retinopathy, dyslipidemias, and hypertension are needed in these children.

CONCLUSION

Most people, including healthcare workers, lack awareness about Type 1 diabetes in children, resulting in children with Type 1 DM presenting to the hospital with severe complications such as DKA at first presentation. The common presenting symptoms in these children, such as polyuria, abdominal pain, vomiting, and breathlessness, are usually misdiagnosed as UTI, lower respiratory tract infection, acute pancreatitis, or appendicitis. Steps should be taken to increase awareness of the disease among people. The government should also ensure the availability of newer insulin analogs, which are found to be user-friendly at an affordable price.

Limitations

The study could be done on a small sample size; most were from lower and middle socioeconomic strata.

ETHICAL ISSUE

Prior approval of the ethics committee was taken.

AUTHOR'S CONTRIBUTIONS

Venkata Vijayalakshmi V: Conceptualization, Data collection, analysis, manuscript writing; Jhansi Padma K: Data collection and analysis, manuscript writing; Madhavi N: Manuscript writing and reviewing; Manikyamba D: Manuscript writing and reviewing.

CONFLICTS OF INTEREST

None.

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