Original Article

"Puddles on the Road": Hurdles in the Pathway from Symptoms to Diagnosis and Treatment in Children with Type 1 Diabetes

Latika Rohilla, Rakesh Kumar, Priyanka Walia, Jaivinder Yadav, Devi Dayal

Endocrinology and Diabetes Unit, Advanced Pediatrics Centre, Post Graduate Institute of Medical Education and Research, Chandigarh, India

Abstract

Introduction: This study was conducted to investigate the pathway from first symptoms to initiation of insulin regimen in children with new-onset Type 1 Diabetes Mellitus (T1DM) and explore the reasons behind diabetes ketoacidosis (DKA) at onset among children with T1DM. **Materials and Methods:** An exploratory study was conducted using a pretested questionnaire, among parents of children diagnosed with T1DM within preceding 3 months. **Results:** Out of the total 105 children, 56.1% were males. The median age was 7 years. The commonest reported symptoms were polydipsia (97.8%), polyuria (75.2%), and nocturia (75.2%). The mean time taken by parents from onset of symptoms to decide to visit the physician (appraisal gap) was 7.85 ± 7.95 days. The help-seeking gap (from decision-making to visiting a physician) was 3.01 ± 8.31 days, diagnostic gap (from first visit to diagnosis) was 4.19 ± 6.72 days, and the treatment gap (from diagnosis to the start of insulin) was 2.12 ± 6.87 days. The DKA at onset (was present in 39 out of 105 children 37.1%) and was higher among children with lower per-capita income (*P*-0.017), lack of previous experience among parents (*P*-0.017), longer appraisal (*P*-0.023), and treatment gap (*P*-0.009). **Conclusion:** Increasing awareness about the diabetes among children among the public and primary healthcare workers can help prevent DKA at onset.

Keywords: Diabetic ketoacidosis, new onset diabetes, pediatrics, primary care, T1DM

Introduction

Type 1 diabetes mellitus (T1DM) occurs because of autoimmune destruction of pancreatic beta cells leading to a deficiency of insulin. According to the 2019 IDF Atlas, there is a regional difference in the prevalence of T1DM across the globe, India being home to second largest number of T1DM cases after the USA.[1] Among the South Asian region, India has a significantly larger T1DM patients than the rest of the neighborhood.[1] The regional variation exists even in India as the prevalence has been reported to be particularly more in north India as compared to south India.[2]

T1DM being a chronic disease affects all spheres of life of both the child and family[3,4] as the complex management requires self-control and responsibility on the part of both child and family.[5] Diagnosing diabetes in children is a two stage process; identification of the symptoms by the parents, followed by correct diagnosis by the healthcare professional (HCP). Presentation of the child with diabetes ketoacidosis (DKA) signifies delay in any of the two stages. Although DKA at onset has been found to be linked to insulin related autoantibodies positivity and neutral genotypes,[6] the time gap between the onset of symptoms and diagnosis (Diagnostic interval) plays a crucial role. DKA is associated with increased risk of death and long-term morbidity like cognitive deficits because of severe dehydration, cerebral edema,[7] and electrolyte derangements. Thus, delayed diagnosis indirectly leads to higher healthcare burden in terms of both direct and indirect expenses involving hospitalizations and intensive care.[8]

A previous study in North India documents need of early diagnosis and appropriate treatment.[9] Multiple HCP contact

Access this article online

Quick Response Code:

Website: www.ijem.in

DOI: 10.4103/ijem.IJEM_519_20

Address for correspondence: Dr. Rakesh Kumar, Professor, Endocrinology and Diabetes Unit, Advanced Pediatrics Centre, Post Graduate Institute of Medical Education and Research, Chandigarh, India.
Office Address: Room No. 3117, Level 3, A Block, Advanced Pediatrics Centre, Post Graduate Institute of Medical Education and Research (PGIMER), Sector 12, Chandigarh - 160 012, India.
E-mail: drrakesh.pgi@gmail.com

Submitted: 31-Aug-2020 **Revised:** 09-Oct-2020
Accepted: 19-Dec-2020 **Published:** 21-Jul-2021

How to cite this article: Rohilla L, Kumar R, Walia P, Yadav J, Dayal D. "Puddles on the road": Hurdles in the pathway from symptoms to diagnosis and treatment in children with type 1 diabetes. Indian J Endocr Metab 2021;25:23-30.

prior to diagnosis[10] and the awareness about disease among society and HCPs has been previously found to be related to presence of DKA at the time of onset.[11,12] However, there is a shortage of studies in India that identify the reasons for delays in diagnosis or the relative contribution of the parental or HCP-related factors. Studies that explore the factors that influence help-seeking behavior among parents are warranted. A better understanding of the patient pathway from symptom-onset to diagnosis is required to aptly target interventions to decrease the risk of DKA at onset.[13]

There is an increasing interest in understanding the treatment seeking behavior and the factors leading to delay in diagnosis and treatment initiation among patients with T1DM around the world.[8,10-12] In India, there is a dearth of data on treatment seeking behaviors of patients with diabetes mellitus.[14] No previous study on treatment seeking behavior among T1DM patients in India was found. So, the objectives of this study were, (1) To investigate the pathway from first symptoms to initiation of insulin regimen in children coming for treatment of T1DM, (2) To assess the level of awareness among their parents about the disease, and (3) To explore causes of delay in initiation of insulin regimen among children suffering from T1DM.

Materials and Methods

Study design

This study was conducted at the Pediatric Endocrinology unit of a tertiary care hospital in North India. The data collection was done during June 2018 to May 2019. Using total enumeration sampling technique, all children (age group 6 months to 14 years) attending Pediatric Diabetes services with new-onset T1DM (within 3 months of diagnosis) during the time frame of one calendar year, were included in this study after a written informed consent. The diagnosis of T1DM was based on American Diabetes Association (ADA)[15] criteria for diabetes along with low C-peptide and no family history of diabetes to suggest monogenic diabetes. The information was collected by interview using a structured pretested proforma/questionnaire (details given below). In case either/both of the parents were not available, the relative taking care of the child was interviewed. The previous medical records of the children were used to counter check the information provided by the parents where available.

Conceptual framework and definitions for various intervals in Pathway-to-diagnosis

The "Anderson Model of Total Patient Delay"[16] was used to develop the conceptual framework for this study. This model developed for cancer patients, can be used to explore the delay in diagnosis in children with T1DM. Accordingly, the Pathway-to-diagnosis was defined as the series of events from the onset of first symptoms to initiation of insulin regimen among children with T1DM. The pathway was further divided into four intervals. The Appraisal gap (AG) was the number of days between the onset of symptoms and parents deciding to seek medical help for them. The help-seeking gap (HG) was the number of days between the parents deciding to seek medical help and the day of visiting any medical facility. The diagnostic gap (DG) was the number of days between day of first visit to any medical facility and diagnosis of T1DM. Lastly, the treatment gap (TG) was the number of days between diagnosis of T1DM and initiation of insulin regimen.

Data collection

A questionnaire was prepared using extensive review of literature and local clinical experience. The questionnaire had five sections. First section included questions about the sociodemographic profile like their age, gender, residence, per capita income, education, and occupation of the parents. The second section enquired about previous knowledge about T1DM among the parents. The third section asked questions related to the pathway from onset of symptoms to initiation of insulin. The last section asked the parents about 10 common symptoms whether they were present in their child. If yes, then the duration and explanation for it, if any, was asked. This questionnaire was first reviewed by an expert panel including pediatric endocrinology consultants and diabetes nurse specialists. Then the questionnaire was piloted with parents of 10 children (10% of the estimated sample size of 100). The results of the pilot study were then reviewed and imbibed in the questionnaire to give it the final shape. The questionnaire was used in both Hindi and English for direct interview as per the preference of the participants.

Statistical analysis

Data was entered and analyzed in IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, N.Y., USA). The inferential results of the categorical data were analyzed using Chi-square test. As the data regarding various pathway gaps was skewed, non-parametric test, that is, Mann–Whitney U test was used to compare the median intervals of the pathway-to-diagnosis of the DKA and non DKA group. A *P* value of less than 0.05 was considered statistically significant. Post-hoc analysis of the power of the study was done using G*power version 3.1.9.4 (Germany). Given the effect size of 0.28, alpha error probability of 0.05, sample size of 105, the power came out to be 0.84.

Ethical considerations

The study protocol conformed to the ethical guidelines of the Declaration of Helsinki (2013) and was approved by the Institute Ethics Committee (Ethical Approval no. INT/IEC/2018/000630 dated 03-05-2018).

Results

A total of 105 patients (out of 260 patients visiting the centre over the study period) met the selection criteria and were included in the study. The mean age of the patients was 7.09 ± 3.39 years (Range: 6 months to 13 years). Of these, 56.1% were males. The DKA (39 out of 105 children;

37.1%) and Non-DKA groups were not different in terms of age (*P*-value = 0.166) and gender (*P*-value = 0.753). There was significant difference between the two groups, in terms of per capita income (*P*-value = 0.017) showing that DKA at onset was significantly more in children with lower per capita income. Also, DKA was significantly lower (*P*-value = 0.017) among the children whose parents had family members or friends with diabetes [Table 1].

The pathway-to-diagnosis is described in Table 2. At least one of the osmotic symptoms (polydipsia, polyphagia, or polyuria) was present among 88.6% of the children. The DKA at onset was present in 37.1%. Incidental diagnosis of T1DM was made in 13.3% of the patients, that is, they were diagnosed when they went to the physician for an ailment not directly linked to diabetes. Almost half (40.9%) of the patients were misdiagnosed before the correct diagnosis of diabetes was made. Only 48.6% of the patients were started insulin on the day of diagnosis; four daily doses of regular insulin being the most common regime (41.2%). Of the patients with DKA at onset, only 7.8% were started on appropriate DKA management before referral to higher Centre. Majority (63.8%) of the patients reaching the Centre were referred by a doctor. The common reasons for the referral were need for initiation of insulin (41.79%), better management of insulin regimen (28.35%) or acute emergency (16.2%). Regarding the expectation of parents from the tertiary centre, the most common were permanent cure (49.5%) and better management of their condition (42.9%).

The various pathway-to-diagnosis intervals and the perceived barriers related to each interval as reported by the parents are depicted in Table 3. Longest of these intervals was the AG of 7.85 ± 7.95 days and the TG was the shortest being 2.12 ± 6.87 days. The AG was not explained convincingly by most parents (96.55%). The most common explanation for delay in seeking help was household barriers like other important work at home, some other family member was too sick or hospitalized, father being out of station, guests visiting the home, etc. Most often the delay in diagnosis was because of various laboratory related issues like delay in collecting lab reports or time bound lab facilities. The TG was mostly attributed to delay in reaching the referral Centre and non-initiation of insulin by the primary care giver.

The comparison between the intervals of the pathway-to-diagnosis is depicted in Table 4. There was a significant difference among the Median values of the two groups, in terms of AG (*P*-value = 0.023) and TG (*P*-value = 0.001). This shows that DKA at onset was significantly more where the parents failed to identify the symptoms of diabetes in their child and where the insulin administration was delayed. Table 5 shows the most commonly found symptoms and the parental explanations for the same, which led them to postpone visiting the physician. The mean duration of some of the symptoms was even more than the mean appraisal gap as the parents did not report these as "chief complaints" to the physician initially, but on probing about each of the listed 10 common symptoms one by one as a part of this study, they acknowledged that they were present in their child although they never identified it as a problem. Of the

Table 1: Children and family characteristics, by DKA or non-DKA at the time of diagnosis (*n*=105)

Variable	Category	DKA (*n*=39)	Non DKA (*n*=66)	*P* (Chi-square)
Age Group	<5	14	15	0.923
	5-10	15	30	
	10-15	10	21	
Age (mean±SD)	-	6.49±3.64	7.44±3.21	0.166*
Sex	Male	22	37	0.753
	Female	17	29	
Housing	Rural	23	38	1.000
	Urban	16	28	
Highest level of parental education	Above Graduate	11	33	0.734
	Undergraduate	28	33	
Employment status of mother	Employed	4	14	0.187
	Unemployed	35	52	
Employment status of father	Employed	37	61	1.000
	Unemployed	2	5	
Per capita income	Less than 1000	10	6	0.017
	1001-1500	3	8	
	1501-2000	6	3	
	2001 and above	20	49	
Whether parents knew that diabetes can happen to children	Yes	8	19	1.000
	No	31	47	
Whether parents suspected diabetes in the child before diagnosis was made	Yes	6	13	1.000
	No	33	53	
Whether parents have Family members or friends with diabetes	Yes	17	45	0.015
	No	22	21	

**T*-test

Table 2: Description of the pathway-to-diagnosis (*n*=105)

Misdiagnosis (43 out of 105)	*n*	%	Referred to tertiary centre by: (*n*=105)	*n*	%
Malnutrition	6	13.9	Doctor	67	63.8
Pneumonia	6	13.9	Self	34	32.4
UTI	5	11.6	Friends	3	2.9
Gastritis	5	11.6	Family	1	1
Anemia	4	9.3	Patient referral by primary physician (*n*=67 out of 105)		
Depression	4	9.3	To initiate insulin	28	41.79
Fever	3	6.9	Better management of insulin regimen	19	28.35
Common Cold	3	6.9	Acute emergency	17	16.2
Infection	3	6.9	Second opinion	2	2.98
Worm infestation	2	4.6	Expectation of parents at tertiary centre (*n*=105)		
Typhoid	2	4.6	Permanent cure	52	49.5
Rx initiated (*n*=105)			Better management	45	42.9
Insulin	51	48.6	Replacement of needle pricks	3	2.9
No treatment initiated	29	27.6	To avoid 'mishappening'	3	2.9
Other medicines	22	21	Confirmation of diagnosis	2	1.9
Oral hypoglycemics	3	2.9			

Table 3: Duration of intervals of the pathway-to-diagnosis (in number of days) with perceived barriers reported by the parents

Gap	Mean±SD (range)	Median (IQR)	Gap more than 1 day: *n* (%)	Perceived barrier for the gap	*n* (%)
Appraisal gap (AG)	7.85±7.95 (0-40)	5 (1-15)	87 (82.85)	Not sure why	84 (96.55)
				Child was taking normal diet	1 (1.15)
				Checking RBS at home	1 (1.15)
				Symptoms were due to rainy season	1 (1.15)
Help seeking gap (HG)	3.01±8.31 (0-60)	0 (0-2)	41 (39.05)	Not sure why	17 (41.46)
				Household priorities	8 (19.50)
				Lack of medical facility near home	2 (4.88)
				OPD holidays	2 (4.88)
				Symptoms were due to growing age	2 (4.88)
				Workplace priorities	2 (4.88)
				Financial limitation	2 (4.88)
				Lack of faith in Govt. hospitals	1 (2.44)
				School priorities	1 (2.44)
				Preferred self-medication	1 (2.44)
				Weight loss due to unknown reason	1 (2.44)
				Came when condition was critical	1 (2.44)
				Lack of any serious symptom	1 (2.44)
Diagnostic gap (DG)	4.19±6.72 (0-30)	1 (0-6)	56 (53.34)	Not sure why	44 (78.57)
				Delay by parents in collecting reports	5 (8.93)
				Delay in diagnosis by physician	2 (3.58)
				Time bound lab facilities	2 (3.58)
				Time bound medical facilities	1 (1.78)
				Delay in reporting symptoms by parents	1 (1.78)
				Took medicine from nearest physician	1 (1.78)
Treatment gap (TG)	2.12±6.87 (0-60)	2 (1-1.5)	46 (43.81)	Delay by parents to reach physician	10 (21.75)
				Not sure why	23 (50)
				Referral without initiating any treatment	6 (13.04)
				Visiting multiple physicians to confirm	2 (4.35)
				Time bound medical facility	2 (4.35)
				Delay in lab reports	1 (2.17)
				Use of Alternative medicines	1 (2.17)
				Did not know where to go	1 (2.17)

total, 91 (86.6) parents reported symptom of polydipsia in their child but only 10 (13.3%) of them attributed it to diabetes. Others attributed it to weather change (9.7%) or because of increased urination (8%) etc.

Table 4: Intervals of the pathway-to-diagnosis, by DKA or non-DKA at the time of diagnosis

Variable	Category	DKA (*n*=39)	Non DKA (*n*=66)	*P**	Variable	DKA (*n*=39)	Non DKA (*n*=66)	*P*#
Appraisal gap	0	11	7	0.120		2 (0-10)	7 (3-15)	0.023
	1-5 days	13	23		Median (IQR)			
	6-10 days	6	16		Appraisal gap			
	More than 10 days	9	20					
Help seeking gap	0	24	40	0.746		0 (0-2)	0 (0-3)	0.740
	1-5 days	11	16		Median (IQR)			
	6-10 days	3	5		Help seeking gap			
	More than 10 days	1	5					
Diagnostic gap	0	17	32	0.392		1 (0-5)	1 (0-7)	0.602
	1-5 days	9	20		Median (IQR)			
	6-10 days	8	6		Diagnostic gap			
	More than 10 days	5	8					
Treatment gap	0	30	29	0.009		1 (0-2)	0 (0-0)	0.001
	1-5 days	8	30		Median (IQR)			
	6-10 days	0	4		Treatment gap			
	More than 10 days	1	3					

*Chi-square, #Mann Whitney *U* teast

Table 5: Parental explanations for the most common symptoms

Symptom	*n* (%)	Duration of symptom (days) (Mean±SD)	Number with explanation for the symptom	Most common explanations among those who had an explanation	*n* (%)
Polydipsia	91 (86.6)	15±16.68	75 (82.4)	Suspected diabetes	10 (13.3)
				Weather change	7 (9.7)
				Increased urination	6 (8)
Polyuria	79 (75.2)	14.86±16.71	63 (79.7)	Increased water intake	15 (23.8)
				Suspected diabetes	8 (12.7)
				Growing age	5 (7.9)
Nocturia	79 (75.2)	11.12±14.85	27 (34.1)	Increased water intake	4 (14.8)
				'Some problem'	4 (14.8)
				Cold, fever	3 (2.9)
Tiredness	65 (61.9)	7.21±13.29	33 (32)	Cold, fever	10 (30.3)
				'Some problem'	8 (24.2)
				Weakness	6 (18.2)
Enuresis	60 (57.1)	6.81±9.6	27 (45)	More urination	3 (11.1)
				Due to winters	3 (11.1)
				Increased water intake	3 (11.1)
Mood swings	60 (57.1)	10.0±15.52	20 (33.34)	'Some problem'	4 (20)
				Cold, fever	4 (20)
				Weakness	4 (20)
Unexplained Weight loss	48 (45.7)	16.86±38.16	37 (77)	'Some problem'	10 (27)
				Growing age	8 (21.6)
				Weakness	5 (13.5)
Polyphagia	37 (35.2)	9.75±15.36	30 (81)	Growing age	11 (36.7)
				Worm infestation	3 (10)
				'Some problem'	3 (10)
Urinary incontinence	24 (22.8)	3.78±8.48	11 (45.8)	Weakness	4 (36.4)
				Suspected diabetes	3 (27.3)
				Growing age	2 (18.2)

Discussion

The presence of DKA at onset was significantly more among children with lower per capita income and delayed initiation of insulin after the diagnosis was made. Also, DKA at onset was more among the children whose parents had no previous experience of diabetes among family or friends. Further, it was also found that it was difficult for the parents as well as the primary physicians to identify the symptoms otherwise considered "classical" for diabetes. Strangely, the classical

symptoms of polyuria, polydipsia, polyphagia, and weight loss were often attributed to growth spurts, change is dietary habits or even weather changes.

The mean age of the patients in this study was 7.09 ± 3.4 years which is similar to another retrospective study on clinical profile of children admitted with DKA in North India (7.4 ± 3.9 years).[17] No significant relation between the type of residential location and presence of DKA at onset was seen. Similar to this, is the result of a previous study,[8] and a systematic review,[13] which reports that three studies have shown no effect of rural or urban household in occurrence of DKA at onset among children with T1DM. Also, in this study, DKA at onset of T1DM was slightly more among males but the gender-related difference was not statistically significant. However, in a large multi-centric cohort studied in Europe, DKA was found to be significantly higher in females.[18]

In this study, DKA at onset of T1DM was seen significantly associated with lower per capita income (*P*-value = 0.017). This is in agreement to a large US population based study, which reported that DKA at onset was associated by lack of health insurance, low family income and lower parental income although they ruled out ethnicity as a predictor.[19] However, low social status has been found to be associated with DKA at onset of T1DM in another study from Dusseldorf *et al*.[20] In this study, DKA at the time of diagnosis was present among 37.1% of the patients. This is comparative to two studies from Ethiopia and America reporting 35.8%[12] and 38%[21] of the children presenting with DKA at onset, respectively. It is however lowest among similar previous studies from different parts of this country[9] and most from rest of the world, which have reported a DKA at onset incidence ranging between 39% and 93%.[6,8,9,22-26] Two similar studies reported even lower incidence of DKA at onset among children; one from New Zealand (27%)[27] and another from Poland (26%).[28] It can be said that primary healthcare in the catchment area is considerably good as lesser patients are reporting with DKA at onset. The frequency of DKA at diagnosis of T1DM has been decreasing over time world over because of increased awareness (among caregivers and health professionals) and accessibility of the hospitals. So, the older studies are likely to have higher percentage of patients presenting with DKA at diagnosis compared to more recent ones like this study. Polydipsia, polyuria, nocturia, and weight loss were most common four reported symptoms similar to previous studies. Going away from convention is the finding that the symptom of polyphagia, was neither found common in this study (35.2%) nor in other similar studies that were compared.[8,20,22,23]

Misdiagnosis raises the risk of presenting with DKA at onset by threefold.[13,28] In this study, 40.9% of the patients were misdiagnosed; most common misdiagnoses being malnutrition (13.9%), pneumonia (13.9%), UTI (11.6%), and gastroenteritis (11.6%). Such misdiagnosis have been previously reported too, where urinary symptoms were misdiagnosed as UTI, or extensive focus was given on one or more symptom rather than looking at the whole picture; preventing the apt investigations.[13] These challenges faced by the physicians are probably because of rarity of this disease and "how well the children appeared" in first few days/weeks after the onset of disease. Difficulty in collecting blood or urine sample could be another issue among the younger children.[29]

DKA at onset of T1DM is largely a sequel to delay in diagnosis and initiation of insulin therapy because of any reason.[13] Similar to this study, appraisal gap has been found to be the longest among the diagnostic intervals in earlier studies.[8,13,29,30] This can be justified as the initial symptoms are sometimes vague, it takes the parents a long period of turmoil and often a physical trigger like vomiting weight loss or breathlessness to realize that the child requires medical attention.[8] The number of visits to the health care physicians were not different among the ones who presented with DKA and those without, similar to a previous study in America.[31]

Increased awareness among parents as well as primary healthcare professionals can lead to reduction in number of children presenting with DKA at onset.[20,23,27,28,32] The finding that DKA was significantly lower (*P*-value = 0.017) among the patients whose parents' family or friends had diabetes is in notion to earlier studies who have found that previous parental experience with diabetes reduces the risk of DKA at onset.[8,11,26]

No previous study was found exploring the reasons for referral of T1DM children to a tertiary care center and the parental expectations of these children, on reaching there. It needs to be highlighted here that nearly half of the patients received were referred for the initiation of insulin; an early insulin administration might have arrested the progress of DKA in at least some of the cases. Also, the information provided at the primary level is questionable as the majority if parents reportedly visited the tertiary care center expecting a permanent cure for T1DM.

Reliance on memory-based parental reporting of initial hospitalization and treatment is considered as potential limitation of this study. However, we tried to minimize the recall and framing bias by only including the children who were diagnosed within last 3 months. Nevertheless, this is the first study in India as well as the South Asian region which has attempted to quantify the delay in diagnosis and treatment of T1DM among children in terms of actual number of days. T1DM is not preventable but DKA at onset surely is.

There is potential time, scope, and opportunity to intervene between the symptom onset and development of DKA in children. Leveraging the identified potential targets can aid in reducing the incidence of DKA. Although there was no practical difficulty in the study design, exploring the same information at the primary level can overcome the limitation of recall bias. This study also warrants the need to assess the knowledge and awareness about T1DM among the public as well as primary care providers. The appraisal gap may be reduced by increasing awareness of T1DM among the public.

Similar study can be conducted at primary care centres to identify the reasons for delay in diagnosis and treatment. Primary care providers should specifically inquire about polydipsia, polyuria, weight loss, and polyphagia in cases with vague presentations. There is a need to address the tendency to find alternate explanation to the classical symptoms of diabetes. Educational interventions aimed at the primary care physicians will benefit a small population with missed diagnosis at first encounter, overcoming barriers to point of care tests availability at primary centres will help early diagnosis of T1DM and even other emergencies of children. As a result of these findings, it is being proposed to organize a continuing education program for all the primary care providers in the catchment area of the tertiary level centre for capacity building and enhancing the skills needed for management and treatment initiation for T1DM.

Conclusion

It was found that DKA at onset among children with T1DM is significantly associated with low per capita income, no previous knowledge about the disease and delay in initiation of insulin even after the diagnosis was made. Majority of children reaching the tertiary care centre were devoid of insulin administration before the referral which could have impeded the DKA. Also, in the absence of adequate counseling at diagnosis, half of the parents expected a permanent cure on visiting the tertiary care centre.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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