Original Article

Management of Type 1 Diabetes in a Limited Resource Context: A Study of the Diabetes Research Education and Management Trust Model in Nagpur, Central India

Caroline Sarah Zuijdwijk[1,2], Sharad Pendsey[3], James Ron[4], Kathryn A. Williams[2], Salwa Akiki[2], Seema Chalkhore[3], Graham D. Ogle[5], Alexandra Ahmet[1,2]

[1]Division of Endocrinology and Metabolism, Department of Pediatrics, Children's Hospital of Eastern Ontario, [2]Children's Hospital of Eastern Ontario Research Institute, Ottawa, ON, K1H 8L1, Canada, [3]DREAM Trust, Opp. Dhantoli Park, Nagpur, 440 012, MS, India, [4]Department of Political Science, Humphrey School of Public Affairs, University of Minnesota, Minneapolis, MN, 55455, USA, [5]International Diabetes Federation Life for a Child Programme, Sydney, NSW, 2001, Australia

Abstract

Background/Objective: Diabetes Research Education and Management (DREAM) Trust (DT) is a charitable organisation that offers free insulin and healthcare to children and youth with type 1 diabetes (T1D) in central India. We systematically describe DT's model of care and evaluate medical and sociodemographic factors influencing glycaemic control in this resource-poor setting. **Methods:** Study of DT patients diagnosed with T1D <16 years old and followed at DT ≥1 year. Participants completed an interview, retrospective chart review and prospective haemoglobin A1c (HbA1c) measurements. Uni- and multi-variate linear regressions determined factors associated with HbA1c. Percentage of underweight patients (as proxy for glycaemic control) was compared at presentation to DT versus time of interview. **Results:** A total of 102 DT patients (51% female) completed the interview and chart review. 74 had HbA1c measured. Median HbA1c was 10.4% (90.2 mmol/mol). In multivariate regression, higher HbA1c was independently associated with higher insulin dose/kg ($P < 0.001$) and holding a below the poverty line certificate ($P = 0.004$). There was no association between HbA1c and age, sex, caste, religion or experience of stigma. However, the psychosocial burden of T1D (expressed as concern about others learning about the diagnosis, and worry about the future), and experience of stigma were substantial. Percentage of patients with underweight body mass index was significantly lower at the time of study vs. presentation to DT ($P = 0.005$). **Conclusions:** The DT charitable programme overcomes social status, gender inequalities and experience of social stigma to provide life-saving treatment to children with T1D in central India. Glycaemic control remains inadequate however, with children living in extreme poverty most at risk.

Keywords: Haemoglobin A1c, insulin, poverty, stigma, type 1 diabetes mellitus

Introduction

Type 1 diabetes (T1D) is one of the most common chronic childhood diseases, with an increasing incidence of approximately 3% annually worldwide.[1-3] Although the reported incidence rates of many low- and middle-income countries are low (perhaps falsely due to inaccurate diagnosis and reporting), their T1D burden is large given their population size.[4] India's T1D incidence is only 3.0/100,000 children/year, but its absolute number of incident cases is 10,900/year (second only to the United States).[4,5]

Optimal T1D management is resource-intensive, creating significant barriers to developing-world care. The lack of affordable insulin and other essential medical supplies are the most significant problems, coupled with the dearth of accessible and knowledgeable medical personnel.[6-11] Other serious problems include the lack of refrigeration for insulin storage, social stigma, gender bias and patient education.[6-10,12]

Diabetes Research Education and Management (DREAM) Trust (DT) is a non-governmental organisation and registered

Access this article online

Quick Response Code:

Website: www.journalofdiabetology.org

DOI: 10.4103/jod.jod_3_17

Address for correspondence: Dr. Caroline Sarah Zuijdwijk, Division of Endocrinology and Metabolism, Children's Hospital of Eastern Ontario, 401 Smyth Road, Ottawa, ON, K1H 8L1, Canada. E-mail: czuijdwijk@cheo.on.ca

How to cite this article: Zuijdwijk CS, Pendsey S, Ron J, Williams KA, Akiki S, Chalkhore S, *et al*. Management of Type 1 diabetes in a limited resource context: A study of the diabetes research education and management trust model in Nagpur, Central India. J Diabetol 2017;8:37-44.

charity in the city of Nagpur, India (Maharashtra State) that offers free healthcare to underprivileged children with T1D and seeks to overcome these barriers.[13] Functioning with very limited resources, DT has adapted to provide life-saving treatment to over 1300 children since its inception in 1995.[13] DT's team includes two physicians and one diabetes educator. Patients are seen every 3 months for clinical assessment and receive a 3-month supply of insulin and syringes. Insulin storage varies, as some patients have access to refrigeration, whereas others use specialised clay pots (evaporative cooling).[14,15] Due to high cost, DT has not been able to provide regular blood glucose (BG) or haemoglobin A1c (HbA1c) testing to its patients. Therefore, insulin dose adjustments are based on symptoms of hyper- and hypoglycaemia and anthropometric parameters. The cost of treatment is $350 USD/child/year, including funding for diabetes supplies, clinic support staff and administration, laboratory tests, funding for travel to the clinic, educational scholarships, interim coverage of diabetes supplies for children on the DT waiting list, and other activities supporting the medical and psychosocial development of DT patients. Funding comes from private donors and the International Diabetes Federation's Life for a Child programme.

The purpose of this study was to systematically describe and evaluate DT's model of care and the factors (medical and sociodemographic) that influence glycaemic control in this resource-poor setting. We also assessed DT's impact on glycaemic control by evaluating weight status (as a proxy for HbA1C), pre- and post-management at DT.

Methods

We conducted a study of the DT patient population from August 2011 to December 2011. All patients followed by DT for T1D for ≥1 year and who were under 16 years of age at the time of diagnosis were eligible. All patients meeting eligibility criteria and presenting to the clinic in a 4-month period were invited to participate in the study. Study participants were followed prospectively for HbA1c measurements every 3 months for up to a year. A local pharmaceutical company, Glenmark Pharmaceuticals, funded these HbA1c measurements. All samples were measured on the Bio-Rad in2it (Hercules, USA) point of care analyser, which uses affinity chromatography.

For each participant, an interview and retrospective chart review were also completed. Data was collected for patient sociodemographic factors, details of the medical management of T1D, historical HbA1C measurements, acute diabetes complications, anthropometric data, psychosocial burden, the stigma of T1D diagnosis and cost of diabetes management. A full list of variables that were assessed can be found in Tables 1 and 2.

This study received institutional research ethics board approvals and was conducted in accordance with the Declaration of Helsinki. Informed consent (and assent as applicable) was obtained from all the participants.

Table 1: Univariate analysis of association between Diabetes Research Education and Management Trust patient medical characteristics and glycated haemoglobin

DT patient characteristics	Median (IQR) or *n* (%) (*n*=102)	Univariate association with HbA1c *P* (*n*=74)
HbA1c (%)[a]	10.4 (8.8-11.9)	-
HbA1c (mmol/mol)[a]	90.2 (72.7-106.6)	
BMI		
Underweight	20 (16)	-
Not underweight	77 (84)	-
Demographics		
Age (years)	16 (13-21)	0.738
Female	52 (51)	0.362
Diabetes management		
Duration T1D (years)	6 (3-9)	0.678
Management at DT (years)	6 (3-9)	0.494
Number of DT visits/year	4 (3-4)	0.390
Blood glucose tests/30 days	4 (2-8)	0.005
Urine glucose tests/30 days	0 (0-4)	0.774
HbA1c/year (before study)	0.5 (0.2-1.0)	<0.001
Insulin injections/day	3 (3-3)	0.053
Insulin dose (unit/kg/day)	1.1 (0.9-1.2)	<0.001
Insulin storage		
Refrigerator	65 (64)	0.043
Ceramic pot	26 (25)	
Other	3 (3)	
No storage unit	8 (8)	

[a]If more than one HbA1c was collected for a participant, the mean HbA1c was used, HbA1c: Glycated haemoglobin, BMI: Body mass index, T1D: Type 1 diabetes, DT: DREAM Trust, DREAM: Diabetes Research Education and Management, IQR: Interquartile range

Statistical analysis

Descriptive statistics were used to describe the DT patient population's medical and psychosocial characteristics using frequencies and percentages, or median and interquartile range (IQR), where appropriate. We employed univariate ordinary least squares (OLS) linear regression to determine factors associated with HbA1c at the time of the study. We used a multivariate OLS linear regression model to determine factors independently associated with HbA1c. In this model, we considered variables with a $P < 0.1$ in univariate analysis. To reduce over-fitting and consider collinearity, variables thought to be correlated were first tested together in a regression model to determine whether they still met the $P \leq 0.1$ criterion for inclusion in the multivariate model. Stepwise and backwards selection methods were used and compared for the final multivariate models. In the OLS regression models, $P < 0.05$ were considered statistically significant.

Pre- post-analysis (at presentation to DT vs. time of interview) of percentage of patients with underweight body mass index (BMI), as a proxy for glycaemic control (i.e., less likely to be underweight with adequate glycaemic control), was used to assess the overall impact of the DT model of

Table 2: Univariate analysis of association between Diabetes Research Education and Management Trust patient sociodemographic characteristics and glycated haemoglobin

DT patient characteristics	Median (IQR) or *n* (%) (*n*=102)	Univariate association with HbA1c *P* (*n*=74)
Caste		
Scheduled caste and tribes	23 (23)	0.681
Other backward caste	28 (28)	
Other caste	44 (44)	
No caste	4 (4)	
Religion		
Hindu	73 (72)	0.974
Buddhist	20 (20)	
Muslim	5 (5)	
Christian	1 (1)	
Other	2 (2)	
Below the poverty line certificate		
Yes	26 (25)	0.003
No	76 (75)	
Weekly household income (INR)	1375 (700-2000)	0.019
	$22.00 USD (11.20-32.00)	
Household size	4 (4-5)	0.320
Number of living siblings	2 (2-3)	0.036
Number of living siblings with T1D	0 (0-0)	N/A
Level of education (years)	10 (8-13)	0.909
Attending school	77 (75)	0.749
Paid work	19 (19)	0.847
Parental education		
Maternal (years)	10 (10-12)	0.013
Paternal (year)	12 (10-15)	0.048
Travel to DT		
Distance (km)	132 (20-300)	0.714
Time (min)	132 (100-400)	0.943
Cost of diabetes		
Sponsorship		
IDF life for a child	10 (10)	0.767
Foreign sponsor	53 (55)	
Local sponsor	8 (8)	
Other	25 (26)	
Cost of travel to DT (INR)	200.0 (100.0-400.0)	0.972
	$3.20 USD (1.60-6.40)	
Personal income spent on T1D monthly (INR)[a]	100 (100-200)	0.057
	$1.60 USD (1.60-3.20)	
Percentage personal income spent on T1D monthly[a]	0.3 (0.2-0.9)	0.374
Psychosocial burden of T1D		
Number of persons aware of T1D diagnosis outside of family and DT		
1-10	2 (2)	0.388
10-30	4 (4)	
>30	19 (19)	
Everyone	77 (75)	
How worried is the patient that persons outside their family will learn they have TID?		
Not worried at all	6 (8)	0.371
A little worried	13 (17)	
Somewhat worried	26 (35)	
Worried	24 (32)	
Very worried	6 (8)	

Contd...

Table 2: Contd...

DT patient characteristics	Median (IQR) or *n* (%) (*n*=102)	Univariate association with HbA1c *P* (*n*=74)
How worried is the parent that persons outside their family will learn of patient's TID?		
Not worried at all	4 (4)	0.140
A little worried	15 (15)	
Somewhat worried	26 (26)	
Worried	32 (32)	
Very worried	24 (24)	
How worried is the patient about their future as a result of T1D?		
Not worried at all	7 (9)	0.442
A little worried	12 (16)	
Somewhat worried	15 (19)	
Worried	32 (42)	
Very worried	11 (14)	
How worried is the parent about patient's future as a result of T1D?		
Not worried at all	4 (5)	0.731
A little worried	14 (17)	
Somewhat worried	16 (19)	
Worried	30 (36)	
Very worried	20 (24)	
Has the patient experienced a serious social penalty (stigma) for having T1D?		
Yes	36 (38)	0.574
No	66 (62)	
Type of social stigma experienced		
Refusal to marry	4 (13)	0.404
Rejection from school	17 (55)	
Inability to get a job	8 (26)	
Other	2 (6)	

[a]For supplies not covered by DT. HbA1c: Glycated haemoglobin, T1D: Type 1 diabetes, DT: DREAM Trust, DREAM: Diabetes Research Education and Management, IQR: Interquartile range, IDF: International Diabetes Federation, INR: Indian rupees

care. This pre- and post-analysis could not be completed with HbA1C as there were insufficient patients with historical HbA1C values available. BMI was categorised as 'underweight' or 'not underweight' according to the World Health Organization (WHO) definitions. For children aged 5–19 years, BMI standard deviation scores (SDS) were used: 'underweight BMI' was defined as <−2 SDS and 'not underweight BMI' was defined as equal to or >−2 SDS. For youth over 19-years-old, absolute BMI values were used: 'underweight BMI' was defined as BMI <18.5 kg/m^2 and 'not underweight BMI' was defined as BMI equal to or >18.5 kg/m^2. The underweight BMI pre- and post-analysis used the McNemar test for paired data. The value of $P < 0.05$ was considered statistically significant.

Results

In total, 112 DT patients were eligible and invited to take part in the study, of which 102 agreed to participate and completed an interview and chart review. Patients' medical and sociodemographic characteristics are presented in Tables 1 and 2. Patients' median age was 16 years (IQR, 13–21), T1D duration 6 years (IQR, 3–9), and 51% were female. Median HbA1c was 10.4% (IQR, 8.8–11.9) or 90.2 mmol/mol (IQR, 72.7–106.6). The median number of insulin injections per day was 3 (IQR, 3–3), using regular and intermediate acting insulins only; no insulin analogues or insulin pumps were used. Monitoring of glycaemic control was limited with a median number of BG tests per 30 days of 4 (IQR, 2–8).

Mean rates (standard deviation) of acute diabetes-related complications were 0.069 (0.14) episodes of diabetic ketoacidosis (DKA) and 0.03 (0.12) episodes of severe hypoglycaemia per patient per year following presentation to DT. Most participants did not have acute diabetes-related complications; 71% had no DKA episodes and 88% had no severe hypoglycaemia since being followed at DT.

Of the 102 participants in this study, 74 had at least one HbA1c measurement at the time of interview. Due to the lack of funds, Glenmark Pharmaceuticals was unable to complete its commitment to DT of an HbA1c measurement for each participant every 3 months for a year (also the reason that not all participants had an HbA1c measured at interview); the median number of HbA1c measurements per participant was 2.0. When >1 HbA1c was collected for a participant over the study, the patient's mean HbA1c was used for analysis.

Diabetes Research Education and Management Trust patient characteristics associated with haemoglobin A1c

In univariate analysis, higher HbA1c was associated with a fewer number of BG tests per month, higher insulin dose per kilogram, insulin storage not in a refrigerator, lower maternal education, lower paternal education and holding a Below the Poverty Line Certificate [Table 3].

In multivariate regression analysis, HbA1c was independently associated with insulin dose per kilogram and holding a Below the Poverty Line Certificate. Each increase of 0.1 unit/kg/day in insulin dose was associated with a 0.31% (3 mmol/mol) increase in HbA1c ($P < 0.001$), and holding a Below the Poverty Line Certificate was associated with a 1.38% (15 mmol/mol) increase in HbA1c ($P = 0.004$) [Table 4].

There was no statistically significant association between HbA1c and age, sex, caste or religion [Tables 1 and 2]. There was also no significant association observed between glycaemic control and the experience of stigma, worry about people outside of the family knowing about the child's diagnosis, or worry about the child's future with a diagnosis of T1D [Table 2]. However, a significant psychosocial burden of T1D was reported by the study participants. Although 94% of participants reported that >30 people or everyone outside of their immediate family and DT knew about their diagnosis, 40% of patients and 56% of parents were 'worried' or 'very worried' that people outside of their family would learn about their T1D diagnosis. This can be contextualised with the observation that 38% of participants had experienced stigma related to T1D, including refusal to marry, rejection from school and inability to get a job. Both patients and parents reported concern about their future as a result of T1D; 43% of patients and 50% of parents were 'worried' or 'very worried'.

Pre-post analysis: impact of Diabetes Research Education and Management Trust patient management

Percentage of underweight participants was evaluated pre- and post-DT intervention. This analysis was based on 73 participants with BMI data available both at the time of interview and at the time of presentation to DT (where this was not equivalent to their date of T1D diagnosis). There was a significant decrease in the percent of underweight patients from the time of DT presentation (38%) to time of interview (22%) ($P = 0.005$). BMI was the only outcome variable that was reported at both time points in sufficient numbers for analysis.

Discussion

In this study of the T1D patient population managed by the DT in Nagpur, India, we found that: (1) the median HbA1c of DT's patient population was significantly elevated above the target of ≤7.5% (58.5 mmol/mol) set out by the International Society of Pediatric and Adolescent Diabetes (ISPAD);[16] (2) higher HbA1c was independently associated with higher insulin dose per kilogram and holding a Below the Poverty Line Certificate; (3) there was no significant association between HbA1c and age, sex, caste, religion or experience of stigma; (4) the psychosocial burden of T1D was extensive; and (5) there was a significant decrease in the percent of underweight patients after being managed at DT.

The median HbA1c for DT's patient population of 10.4% (IQR, 8.8–11.9) or 90.2 mmol/mol (IQR, 72.7–106.6) is much above

Table 3: Diabetes Research Education and Management Trust patient characteristics associated with glycated haemoglobin in univariate analysis ($n=74$)

Characteristics	Median (IQR) or *n* (%)	Coefficient	*P*
HbA1c (%)	10.4 (8.8-11.9)	-	-
HbA1c (mmol/mol)	90.2 (72.7-106.6)		
Blood glucose tests/30 days	4 (2-8)	−0.121	0.005
Insulin dose (units/kg/day)	1.0 (0.9-1.2)	+0.330[a]	<0.001
Insulin storage			
Refrigerator	46 (62)	−1.690	0.043
Ceramic pot	23 (31)	−0.504	
Other	2 (3)	+0.319	
No storage unit	3 (4)	-	
Number of living siblings	2 (2.3)	+0.486	0.036
Weekly household income (INR)	1000 (700-2000) $16.00 USD (11.20-32.00)	−0.017[b]	0.019
Personal income spent on T1D monthly (INR)	100 (50-100) $1.60 USD (1.60-3.20)	−0.061[b]	0.057
Below the poverty line certificate			
Yes	19 (25)	+1.510	0.003
No	55 (75)		
Mother's education (years)	10 (10-12)	−0.162	0.013
Father's education (years)	12 (10-15)	−0.121	0.048

[a]Per 0.1 unit/kg/day, [b]Per 100 INR. INR: Indian rupees, HbA1c: Glycated haemoglobin, T1D: Type 1 diabetes, IQR: Interquartile range

Table 4: Diabetes Research Education and Management Trust patient characteristics associated with glycated haemoglobin in multivariate analysis ($n=74$)

Variable	Multivariable adjustment to HbA1c (%)	*P*
Intercept	6.77	<0.001
Insulin dose (units/kg/day)	0.31[a]	<0.001
Below the poverty line certificate	1.38	0.004

[a]Per 0.1 unit/kg/day. HbA1c: Glycated haemoglobin

the target of ≤7.5% (58.5 mmol/mol) set out by ISPAD.[16] Although this is the target HbA1c for children of all ages, it can be difficult to achieve in practice, even in resource-rich environments. The Hvidore study, which assessed mean HbA1cs of patients from 21 international paediatric diabetes centres in 17 developed world countries, found a mean HbA1c of 8.62% ± 0.03% (70.7 ± 0.3 mmol/mol) in 1995 and 8.67% ± 0.04% (71.3 ± 0.4 mmol/mol) in 1998.[17] We postulate that the higher overall HbA1c in the DT patient population is due to their low socioeconomic status and associated lack of BG monitoring, factors which have previously been found to be related to poor glycaemic control in T1D.[18-27]

The clear difference in DT's low-cost treatment model is the absence of regular BG and HbA1c monitoring. However, the BG monitoring and frequent HbA1c measurements that are commonplace in T1D management in wealthy countries are simply not feasible for most patients in India, where a single BG test strip can cost an entire day's wages (average cost $0.23 USD).[11] In this study, the number of BG tests per month was associated with HbA1c on univariate but not multivariate analysis. This may be due to the low number of BG tests being performed in this population, which is insufficient to adequately inform insulin dose adjustments. Studies from high-income countries have clearly shown that BG monitoring improves glycaemic control.[26,27] Similarly, in a study of paediatric T1D patients in Asia and the Western Pacific Region, median HbA1c was 8.3% (IQR, 7.4–9.5) or 67.2 mmol/mol (IQR, 57.4–80.3) in those who practiced home BG monitoring, vs. a median HbA1c of 10.6% (IQR, 8.8–11.9) or 92.4 mmol/mol (IQR, 72.7–106.6) in those who did not.[28] This is consistent with the median HbA1c in the DT population, where BG monitoring is not routinely practised.

The two variables independently associated with higher HbA1c in multivariate regression analysis were higher insulin dose per kilogram and holding a Below the Poverty Line Certificate, indicative of extreme poverty [Table 4]. In India, in 2011, this certificate corresponded to a daily per capita income of <33 Indian Rupees (INR) (=$0.49 USD) in urban areas and <27 INR ($0.40 USD) in rural areas.[29] This definition meant that 21.9% of the Indian population lived in poverty and thus qualified for governmental assistance.[29] Thus, despite DT's interventions to help with diabetes management, the extreme poverty of this subset of patients (25% of DT's patients in this study) resulted in a clinically and statistically significant increase in HbA1c of 1.38% (15 mmol/mol) ($P = 0.004$). This is consistent with literature from around the world describing worse glycaemic control in association with lower socioeconomic status.[18-25,30]

The observed association between higher HbA1c and higher insulin doses is more challenging to interpret but has been previously reported in both resource-rich and resource-poor environments.[28,31,32] In their study of the paediatric T1D patient population in Asia and the Western Pacific Region, Craig *et al*. attributed this same finding to insulin resistance.[28] While this finding of association is not indicative of causation, we postulate some reasons for this observation. First, it may be an indicator of a patient's inability to adhere to their prescribed diabetes regimen (insulin and/or dietary), leading to poor glycaemic control and thus an increase in insulin dose by DT staff to address symptoms of hyperglycaemia and poor weight gain. Second, this association could be observed secondary to insulin resistance, which may be related to pubertal status (not assessed in this study). Overall, the median insulin dose of 1.1 unit/kg/day (IQR 0.9–1.2) recorded in DT patients, however, was within normal range for this age group (up to 1.5 units/kg/day in pubertal children).[33] The final possibility is that some patients may have had more residual endogenous insulin production, resulting in lower insulin doses and better glycaemic control. T1D autoantibodies appear to be less common in Indian children who have a clinical diagnosis of T1D,[34] which may suggest that 'atypical' forms of diabetes are occurring.

An important finding of our study is that these higher insulin doses (associated with worse glycaemic control) were not attributable to insulin storage outside of a refrigerator (for up to 3 months). Previous studies have shown no decline in the potency of insulin stored in clay pots (26°C) vs. refrigerator (4°C) when studied for up to 6 weeks.[35,36] A recent study also assessed clay pots and other cooling devices (including DT clay pots) and found that they were all effective in reducing temperature, with a reduction of 7.0 ± 1.1°C ($P < 0.001$ vs. ambient temperature) in the DT clay pots at the ambient temperature and humidity.[15]

One very important finding of this study is that there was no significant association between HbA1c and age, sex, caste, religion or experience of social stigma [Tables 1 and 2]. This indicates that DT is providing a universally available charitable service that does not discriminate based on these key sociodemographic factors.

We did not find a statistically significant association between HbA1c and the psychosocial burden of T1D. We did learn, however, that 38% of patients reported an experience of T1D-related stigma, whereas 40% of patients, and 56% of their parents, were either 'very worried' or 'worried' about non-family members learning of their disease. There are few systematic studies of T1D-related stigma in India, but anecdotal reports routinely focus on problems of employability, depression, social integration

and – particularly for girls – marriageability.[37-40] Gender discrimination in India is high, and girls appear to suffer the most from T1D-related ostracising. Our findings on this count are consistent with other studies of T1D and stigma in the developing world, or of other disease-related stigmas in India.[41,42] Stigma aside, we found that other psychosocial burdens were similarly high; 43% of patients and 50% of parent caregivers, for example, reported being 'very worried' or 'worried' about their future as a result of T1D. DT has recognised T1D-related stigma to be of significant concern for years and has addressed this by developing programmes that go beyond medical management of T1D and aim to establish self-reliance. These programmes include providing educational grants, bicycles (for transportation to school to prevent drop-outs) and funds for individuals to start their own small businesses.[13]

Despite the poor glycaemic control in DT's patient populations, there was a relatively low rate of acute diabetes-related complications. DT's rate of 7 episodes of DKA/100 patient years (after diagnosis) is comparable to that of 1 to 10 episodes/100 patient years (after diagnosis) quoted in the literature.[43] The rate of 3 episodes of severe hypoglycaemia/100 patient years is significantly lower than the rate of 115 to 320/100 patient years quoted in the literature,[44,45] likely related to less stringent glycaemic control in this population. Thus, DT's model of care is safe and is reaching its primary goal of keeping children alive and well in the short term. A clear limitation of this study, however, is that we were unable to report on chronic micro- and macro-vascular complications of diabetes. Based on the median HbA1c of DT's patient population, we anticipate that these children and adolescents will, unfortunately, be at high-risk of diabetes-related complications as they progress into early adulthood.[46,47] Consistent with this, DT reports anecdotally that retinopathy and nephropathy are often seen 10 years after T1D diagnosis.

We acknowledge certain limitations of this study, including a lack of complete patient records. In particular, we lack historic HbA1c testing (due to high cost) and HbA1c measurements on all participants at the time of interview (due to funding constraints). The lack of a sufficient number of historic HbA1C tests resulted in an inability to report on change in HbA1c during management at DT. Pre- and post-analysis was possible with the percentage of underweight patients as a proxy for glycaemic control; however, this analysis is limited by possible confounding factors such as socioeconomic status and other medical conditions. Possible selection bias also needs to be considered. Although all eligible patients were recruited serially at the time of their clinic visit over the 4-month study and the refusal rate was low, there were some patients meeting eligibility criteria who were not seen in the clinic during the study (e.g., to avoid school absenteeism, travel costs). We cannot exclude that these patients were in some way (s) different from those included in the study.

Conclusion

DT is a charitable intervention in Nagpur, India that overcomes status and gender inequalities and provides life-saving treatment to children with T1D. The psychosocial burden of T1D and stigma experienced by this patient population is substantial, although not found to be associated with glycaemic control. The DT model has been successful in its primary goal of keeping children alive and well over the short term. However, the poor glycaemic control observed in this population places DT patients at high risk of diabetes-related micro and macrovascular complications over the longer term.[46,47] High HbA1c levels in this population are attributed to the overall socioeconomic status of DT's patient population and a lack of resources, with those living in extreme poverty at highest risk. We hypothesize that the lack of access to regular BG monitoring and associated education (regarding the use of BG data) are key contributing factors to poor diabetes control in this patient population.[26-28] Our study highlights the challenges of providing diabetes care in a resource-poor setting and identifies potential areas of focus should limited additional resources or funding become available. Further study is currently underway to assess the impact of the addition of limited BG monitoring on glycaemic control in DT's patient population.

Acknowledgment

We would like to thank Glenmark Pharmaceuticals for funding HbA1c measurements for this study. We would also like to thank Dr. Shamal Khadase and Ms. Trupti Kukde for their help with data collection for this study.

Financial support and sponsorship

Glenmark Pharmaceuticals funded HbA1c measurements for this study. They were not otherwise involved in the study conception/design or interpretation of findings.

Conflicts of interest

There are no conflicts of interest.

References

1. Patterson CC, Dahlquist GG, Gyürüs E, Green A, Soltész G; EURODIAB Study Group. Incidence trends for childhood type 1 diabetes in Europe during 1989-2003 and predicted new cases 2005-20: A multicentre prospective registration study. Lancet 2009;373:2027-33.
2. Dabelea D. The accelerating epidemic of childhood diabetes. Lancet 2009;373:1999-2000.
3. Daneman D. State of the world's children with diabetes. Pediatr Diabetes 2009;10:120-6.
4. Patterson C, Guariguata L, Dahlquist G, Soltész G, Ogle G, Silink M. Diabetes in the young – A global view and worldwide estimates of numbers of children with type 1 diabetes. Diabetes Res Clin Pract 2014;103:161-75.
5. Bhatia E. Type 1 diabetes mellitus in India. Curr Diab Rep 2012;12:224-6.
6. Bhatia E, Aggarwal A. Insulin therapy for patients with type 1 diabetes. J Assoc Physicians India 2007;55 Suppl:29-34, 39-40.
7. Beran D, Yudkin JS, de Courten M. Access to care for patients with insulin-requiring diabetes in developing countries: Case studies of Mozambique and Zambia. Diabetes Care 2005;28:2136-40.
8. Beran D, McCabe A, Yudkin JS. Access to medicines versus access to treatment: The case of type 1 diabetes. Bull World Health Organ 2008;86:648-9.

9. Ramachandran A, Ramachandran S, Snehalatha C, Augustine C, Murugesan N, Viswanathan V, *et al.* Increasing expenditure on health care incurred by diabetic subjects in a developing country: A study from India. Diabetes Care 2007;30:252-6.
10. Ogle GD, Middlehurst AC, Silink M. The IDF Life for a Child Program Index of diabetes care for children and youth. Pediatr Diabetes 2016;17:374-84.
11. Ogle GD, Kim H, Middlehurst AC, Silink M, Jenkins AJ. Financial costs for families of children with type 1 diabetes in lower-income countries. Diabet Med 2016;33:820-6.
12. Famuyiwa OO, Edozien EM, Ukoli CO. Social, cultural and economic factors in the management of diabetes mellitus in Nigeria. Afr J Med Med Sci 1985;14:145-54.
13. Pendsey S. DREAM Trust. Available from: http://www.dreamtrust.org/. [Last accessed on 2017 Apr 03].
14. Pendsey S. Keeping Insulin Cool Naturally – The DREAM Trust Storage System. Diabetes Voice 2006;51:19. Available from: https://www.idf.org/sites/default/files/attachments/article_462_en.pdf. [Last accessed on 2017 Apr 03].
15. Ogle GD, Abdullah M, Mason D, Januszewski AS, Besancon S. Insulin storage in hot climates without refrigeration: Temperature reduction efficacy of clay pots and other techniques. Diabet Med 2016;33:1544-53.
16. IDF. Global IDF/ISPAD Guideline for Diabetes in Childhood and Adolescence. Brussels, Belgium: IDF; 2011.
17. Danne T, Mortensen HB, Hougaard P, Lynggaard H, Aanstoot HJ, Chiarelli F, *et al.* Persistent differences among centers over 3 years in glycemic control and hypoglycemia in a study of 3,805 children and adolescents with type 1 diabetes from the Hvidøre Study Group. Diabetes Care 2001;24:1342-7.
18. Secrest AM, Costacou T, Gutelius B, Miller RG, Songer TJ, Orchard TJ. Associations between socioeconomic status and major complications in type 1 diabetes: The Pittsburgh epidemiology of diabetes complication (EDC) Study. Ann Epidemiol 2011;21:374-81.
19. Carter PJ, Cutfield WS, Hofman PL, Gunn AJ, Wilson DA, Reed PW, *et al.* Ethnicity and social deprivation independently influence metabolic control in children with type 1 diabetes. Diabetologia 2008;51:1835-42.
20. Stallwood L. Relationship between caregiver knowledge and socioeconomic factors on glycemic outcomes of young children with diabetes. J Spec Pediatr Nurs 2006;11:158-65.
21. Gallegos-Macias AR, Macias SR, Kaufman E, Skipper B, Kalishman N. Relationship between glycemic control, ethnicity and socioeconomic status in Hispanic and white non-Hispanic youths with type 1 diabetes mellitus. Pediatr Diabetes 2003;4:19-23.
22. Johns C, Faulkner MS, Quinn L. Characteristics of adolescents with type 1 diabetes who exhibit adverse outcomes. Diabetes Educ 2008;34:874-85.
23. Cutfield SW, Derraik JG, Reed PW, Hofman PL, Jefferies C, Cutfield WS. Early markers of glycaemic control in children with type 1 diabetes mellitus. PLoS One 2011;6:e25251.
24. Ismail IS, Nazaimoon WM, Mohamad WB, Letchuman R, Singaraveloo M, Pendek R, *et al.* Sociodemographic determinants of glycaemic control in young diabetic patients in peninsular Malaysia. Diabetes Res Clin Pract 2000;47:57-69.
25. Araujo MB, Mazza CS. Assessment of risk factors of poor metabolic control in type 1 diabetic children assisted in a public hospital in Argentina. Pediatr Diabetes 2008;9:480-7.
26. Schütt M, Kern W, Krause U, Busch P, Dapp A, Grziwotz R, *et al.* Is the frequency of self-monitoring of blood glucose related to long-term metabolic control? Multicenter analysis including 24,500 patients from 191 centers in Germany and Austria. Exp Clin Endocrinol Diabetes 2006;114:384-8.
27. Ziegler R, Heidtmann B, Hilgard D, Hofer S, Rosenbauer J, Holl R; DPV-Wiss-Initiative. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. Pediatr Diabetes 2011;12:11-7.
28. Craig ME, Jones TW, Silink M, Ping YJ. Diabetes care, glycemic control, and complications in children with type 1 diabetes from Asia and the Western Pacific Region. J Diabetes Complications 2007;21:280-7.
29. Singh MK. New Poverty Line: Rs 32 in Villages, Rs 47 in Cities. The Times of India; 07 July, 2014. Available from: http://timesofindia.indiatimes.com/india/New-poverty-line-Rs-32-in-villages-Rs-47-in-cities/articleshow/37920441.cms. [Last accessed on 2017 Apr 03].
30. Zuijdwijk CS, Cuerden M, Mahmud FH. Social determinants of health on glycemic control in pediatric type 1 diabetes. J Pediatr 2013;162:730-5.
31. Baskaran C, Volkening LK, Diaz M, Laffel LM. A decade of temporal trends in overweight/obesity in youth with type 1 diabetes after the Diabetes Control and Complications Trial. Pediatr Diabetes 2015;16:263-70.
32. Delahanty LM, Nathan DM, Lachin JM, Hu FB, Cleary PA, Ziegler GK, *et al.* Association of diet with glycated hemoglobin during intensive treatment of type 1 diabetes in the Diabetes Control and Complications Trial. Am J Clin Nutr 2009;89:518-24.
33. Danne T, Bangstad HJ, Deeb L, Jarosz-Chobot P, Mungaie L, Saboo B, *et al.* ISPAD Clinical Practice Consensus Guidelines 2014. Insulin treatment in children and adolescents with diabetes. Pediatr Diabetes 2014;15 Suppl 20:115-34.
34. Dayal D, Samprati M, Kaur N, Minz RW, Jayaraman D. Prevalence of beta-cell, thyroid and celiac autoimmunity in North Indian children with recent onset type 1 diabetes (T1D). J Clin Diagn Res 2015;9:SM01-2.
35. Al Shaibi K, Falata W, Sayes N, Al Shareef M, Al Taweel M, Abozenadah A, *et al.* Storing insulin in a clay pot in the desert causes no loss of activity: A preliminary report. Ann Saudi Med 1999;19:547-9.
36. Vimalavathini R, Gitanjali B. Effect of temperature on the potency and pharmacological action of insulin. Indian J Med Res 2009;130:166-9.
37. Kesavadev J, Sadikot SM, Saboo B, Shrestha D, Jawad F, Azad K, *et al.* Challenges in type 1 diabetes management in South East Asia: Descriptive situational assessment. Indian J Endocrinol Metab 2014;18:600-7.
38. Prasanna Kumar KM, Dev NP, Raman KV, Desai R, Prasadini TG, Das AK, *et al.* Consensus statement on diabetes in children. Indian J Endocrinol Metab 2014;18:264-73.
39. Kalra B, Kalra S, Kumar A. Social stigma and discrimination: A care crisis for young women with diabetes in India. Diabetes Voice 2009;54:37-9.
40. Kanungo A. Myths about type 1 diabetes: Awareness and education. Indian J Endocrinol Metab 2015;19 Suppl 1:S24-5.
41. Elissa K, Bratt EL, Axelsson ÅB, Khatib S, Sparud-Lundin C. Societal norms and conditions and their influence on daily life in children with type 1 diabetes in the West bank in Palestine. J Pediatr Nurs 2017;33:16-22.
42. Barrett R. Self-mortification and the stigma of leprosy in Northern India. Med Anthropol Q 2005;19:216-30.
43. Lévy-Marchal C, Patterson CC, Green A; EURODIAB ACE Study Group. Europe and Diabetes. Geographical variation of presentation at diagnosis of type I diabetes in children: The EURODIAB study. European and Dibetes. Diabetologia 2001;44 Suppl 3:B75-80.
44. UK Hypoglycaemia Study Group. Risk of hypoglycaemia in types 1 and 2 diabetes: Effects of treatment modalities and their duration. Diabetologia 2007;50:1140-7.
45. Donnelly LA, Morris AD, Frier BM, Ellis JD, Donnan PT, Durrant R, *et al.* Frequency and predictors of hypoglycaemia in type 1 and insulin-treated type 2 diabetes: A population-based study. Diabet Med 2005;22:749-55.
46. Diabetes Control and Complications Trial Research Group, Nathan DM, Genuth S, Lachin J, Cleary P, Crofford O, *et al.* The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-86.
47. Nathan DM, Cleary PA, Backlund JY, Genuth SM, Lachin JM, Orchard TJ, *et al.* Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. N Engl J Med 2005;353:2643-53.