Original Articles

High direct costs of medical care in patients with type 1 diabetes attending a referral clinic in a government-funded hospital in northern India

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ABSTRACT

Background. There is little information regarding costs of managing type 1 diabetes mellitus (T1DM) from low- and middle-income countries. We estimated direct costs of T1DM in patients attending a referral diabetes clinic in a government-funded hospital in northern India.

Methods. We prospectively enrolled 88 consecutive T1DM patients (mean [SD] age 15.3 [8] years) with age at onset <18 years presenting to the endocrine clinic of our institution. Data on direct costs were collected for 12 months—6 months retrospectively followed by 6 months prospectively.

Results. Patients belonged predominantly (77%) to the middle socioeconomic strata (SES); 81% had no access to government subsidy or health insurance. The mean direct cost per patient-year of T1DM was ₹27 915 (inter-quartile range [IQR] ₹19 852–32 856), which was 18.6% (7.1%–30.1%) of the total family income. A greater proportion of income was spent by families of lower compared to middle SES (32.6% *v.* 6.6%, $p<0.001$). The mean out-of-pocket payment for diabetes care ranged from 2% to 100% (mean 87%) of the total costs. The largest expenditure was on home blood glucose monitoring (40%) and insulin (39.5%). On multivariate analysis, total direct cost was associated with annual family income ($\beta=0.223$, $p=0.033$), frequency of home blood glucose monitoring ($\beta=0.249$, $p=0.016$) and use of analogue insulin ($\beta=0.225$, $p=0.016$).

Conclusions. Direct costs of T1DM were high; in proportion to their income the costs were greater in the lower SES. The largest expenditure was on home blood glucose monitoring and insulin. Support for insulin and glucose testing strips for T1DM care is urgently required.

Natl Med J India 2016;29:64–7

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INTRODUCTION

The incidence of type 1 diabetes mellitus (T1DM) varies in different regions of the world.[1] While the epidemiology of T1DM is not well studied in India, a report from Chennai estimates the incidence to be 10.5/100 000/year.[2] As nearly 40% of the Indian population is below 18 years of age, India is likely to have one of the largest number of children with T1DM in the world. Unfortunately, there is little information on the economic burden of T1DM in the India.

The care of patients with T1DM results in a large expenditure for the family, public health authorities and society.[3,4] This is a result of numerous factors unique to T1DM, such as onset at a young age, life-long dependence on insulin, the need for frequent glucose monitoring, regular clinic evaluations, frequent hospitalizations and a high prevalence of microvascular complications. To design an effective programme for management of T1DM a scientific assessment of costs involved is essential.

Most studies on cost of care in T1DM have focused on patients in high-income countries.[3–11] Socioeconomic factors in T1DM are likely to differ greatly between high-income and low- or low- and middle-income nations.[12,13] In the latter, actual incomes are low, health insurance is rarely utilized, government aid is scarce, medical facilities and specialists are not easily available and supplies (insulin, glucose testing strips) are expensive. In the only previous study from India, conducted in Chennai in 2002, 22% of the family income was spent for direct costs related to T1DM care.[14] However, in this retrospective study, we did not assess various factors associated with the cost of care.

In view of the importance of delineating costs of care, and the paucity of such studies from the Indian subcontinent, we estimated the direct costs of T1DM in Indian patients with an age at onset <18 years.

METHODS

Study population

We prospectively recruited patients from the outpatient clinic for T1DM at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh. This is a state government-supported academic hospital with referrals for T1DM management from the entire state and adjoining regions. The costs for availing medical services and professional care in the hospital are nominal, while investigations and hospital admissions are charged to the

patient at rates lower than those in private sector clinics. Insulin, blood glucose measuring strips and other supplies are available at wholesale rather than retail rates through the hospital pharmacy.

Eighty-eight consecutive children and young adults, who fulfilled the inclusion criteria, and attended the clinic between November 2011 and May 2012, were included in the study. Inclusion criteria were: age at onset ≤18 years, plasma glucose >300 mg/dl at onset and a continuous requirement for insulin since diagnosis. For uniformity in cost calculations, we included only patients with diabetes of ≥1 year duration. Patients with previous serious illness not attributable to diabetes were excluded. We also excluded two patients with advanced diabetic nephropathy and moderate chronic renal failure, whose high annual expenditure (₹118 919 and ₹352 777) was related to treatment of renal failure. All patients and/or their parents gave informed written consent and the study was approved by the institutional ethics committee.

The study population had a mean (SD) age of 15.3 (8) years and 66% were males. The patients visited the diabetes clinic 2–4 times during the study period. Ten (11%) patients required in-patient admission during this period, most frequently for education and assessment of poor glycaemic control (8) or management of ketoacidosis (2).

Cost assessment

All patients were interviewed by a single investigator (KK). Information related to demographic and socioeconomic status (SES), clinical details, present treatment and direct costs were noted. SES was assessed on the basis of a classification that included education level, occupation and family income.[15] The families were divided into upper, upper-middle, lower-middle and low SES. The costs related to diabetes care were assessed retrospectively for 6 months at the time of the initial interview and again prospectively after 6 months of follow-up. The costs assessed for these two time periods did not differ (paired *t* test, p=0.09), hence the data were collated for assessing annual costs. Nine patients did not come for the second follow-up. The data of the previous 6 months were extrapolated in these patients.

Direct costs were calculated separately for each patient. These included expenses incurred in hospital admissions for diabetes-related causes and costs of ambulatory care, i.e. physician fees, hospital registration fees, cost of insulin, insulin syringes/pens/needles, glucose-measuring meters and strips, lancets, as well as other medications, e.g. for hypertension and investigations. In addition, expenses for travel, food and accommodation during clinic visits were noted. Costs were calculated for visits to the diabetes clinic as well as to any local physician for diabetes-related care. The costs were validated for each patient individually using prescriptions and receipts from the pharmacy, in-patient admissions, clinic visits, travel tickets, hotel bills, etc.

Investigations

HbA1c (normal range 4%–5.6%) was measured at each clinic visit. The mean value over the period of study was used for analysis. HbA1c was determined by high-performance liquid chromatography (D-10, Biorad, Hercules, CA, USA).

Statistical analysis

The demographic and clinical data were expressed as mean and standard deviation. Despite some parameters not being normally distributed, we followed the recommendations for depiction of data for such studies by Barber and Thompson, 1998, and expressed the data for direct costs (calculated as total costs per patient-year) as mean (inter-quartile range, IQR).[16] The Student *t* test and chi-squared test were used for comparison of continuous and categorical variables, respectively. In view of small differences in the annual incomes, for purpose of analysis we combined data of families of upper and upper-middle SES and lower-middle and lower SES. The association between total direct cost of treatment and the variables was estimated by univariate linear regression analysis. Variables which were significant in this analysis (age at onset, annual income, SES, frequency of home-based glucose monitoring [HBGM], type of insulin) were then assessed in multivariate backward stepwise linear regression analysis. p<0.05 was considered significant. Statistical analysis was performed using the Statistical Program for Social Sciences (SPSS) version 16 (IBM, Chicago, USA).

RESULTS

Clinical and demographic details (Table I)

Most patients belonged to the lower-middle or upper-middle SES and a higher proportion were from urban areas. Families with a rural residence were more likely to be of lower and lower-middle income SES compared to those residing in urban areas (60% *v.* 18%, p<0.001). A government subsidy of ₹10 000–15 000 per annum was available to families whose income was below the official poverty line (6% of total) for hospital registration fees, investigations, and consumables available in the hospital pharmacy as well as for in-patient admissions. In 81% of patients all treatment costs were borne by the families themselves.

Seventy-eight (89%) patients were on daily multiple subcutaneous insulin injections (thrice daily regular insulin along with twice daily neutral protamins hagedorn [NPH] or glargine insulin), while the rest used a twice daily split-mix regimen. Insulin analogues (mainly glargine) were used by 22 patients

TABLE I. Demographic and clinical variables of study patients (*n*=88)

Parameter	Value
Mean (SD) age (years)	15.3 (8.0) range 3–39
Males	59 (65)
Mean (SD) age at onset (years)	8.2 (4.4); range 1–18
Mean (SD) duration (years)	6.8 (5.8); range 1–25
Location: Urban	69 (78)
*Socioeconomic class** (*n*=87)	
Upper	14 (16)
Upper-middle	50 (57)
Lower-middle	17 (20)
Lower	6 (7)
Mean income (according to socioeconomic class) in ₹	
Upper	473 846
Upper-middle	372 000
Lower-middle	87 741
Lower	65 100
Insulin regimen	
Multiple subcutaneous insulin injections	78 (89)
Twice daily split mix	10 (11)
Mean (SD) HbA1c (%)	8.8 (1.6)
Mean (SD) home blood glucose monitoring (tests/week)	13.6 (4.1); range 7–28
Source of funding†	
None	71 (81)
Government assistance	5 (6)
Medical insurance by employer	12 (13)

* Socioeconomic class on the basis of modified Kuppuswamy classification[15]
† Government subsidy given to those with annual income <₹24 000

TABLE II. Direct costs of care per patient-year of patients with type 1 diabetes mellitus

Item	Mean (IQR) cost in ₹	Mean (IQR) costs in US$	Percentage of total direct cost
Insulin (including syringes, pen needles)	11 017 (7287–13 926)	207 (137–261)	39.5
Glucose strips (including lancets, meters)	11 178 (6264–15 696)	210 (118–294)	40.0
Transportation, food and accommodation	2587 (454–3947)	49 (9–74)	9.2
Hospital and physician fees	413 (100–200)	8 (2–5)	1.5
Investigations	894 (500–1180)	17 (9–22)	3.2
Medicines (other than insulin)	867 (0)	16 (0)	3.1
Total outpatient cost	26 928 (18 460–32 349)	505 (346–607)	96.5
In-patient cost*	988 (0)	19 (0)	3.5
Total direct cost	27 915 (19 852–32 856)	524 (372 616)	100

US$ 1= ₹53.3 Percentage of total direct cost calculated using mean costs * Ten patients required hospital admission during the study period
IQR interquartile range

(25%) while rapid-acting insulins were used by only 4 patients. The median HBGM frequency was 13 (7–28)/week. Nine (10%) patients had microvascular complications (albuminuria 5, peripheral neuropathy 5 and retinopathy 3 patients).

Direct costs

The mean total direct cost per patient-year was ₹27 915 (Table II). The mean out-of-pocket payments were 87% (range 2%–100%) of total costs. Expenditure was predominantly on ambulatory care. The proportion of annual family income spent for diabetes care was 18.6% (IQR 7.1%–30.1%). The largest portion of total direct costs was for insulin and related supplies (39.5%) and glucose test strips and lancets (40%). When compared with patients using regular and NPH insulin, patients using insulin analogues had higher total direct costs (₹34 528 *v.* ₹25 711, p=0.003), as well as costs for insulin/delivery devices (₹16 512 *v.* ₹9186, p<0.001). The next largest expenditure (9%) was for transport, food and accommodation during clinic/hospital visits. Other components of ambulatory costs constituted only a small proportion of direct costs. Hospital admission costs formed only a small proportion of total direct expenditure. For the 10 patients who required hospitalization, the mean cost of in-patient care was ₹8693 (range ₹500–29 000).

Ambulatory cost of care was higher in the upper/upper-middle *v.* lower/lower-middle group (₹28 506 *v.* ₹21 913, p=0.011). However, the proportion of annual income spent on diabetes care was significantly higher in the latter group compared with the former (32.6% *v.* 6.6%, p<0.001). Patients residing in a rural location spent a greater proportion of annual family income on diabetes compared to those living in urban areas (33.1% *v.* 15.6%; p<0.001). No differences in total direct costs were noted between boys and girls, pubertal and post-pubertal patients and subjects with HbA1c <8% and those with higher levels.

On univariate regression analysis, the total cost per patient-year had a significant association with age at onset of diabetes, annual family income, frequency of HBGM and use of analogue insulin. There was no association with age, sex, duration of diabetes, dose of insulin and HbA1c. On multivariate analysis, direct cost was associated with family income (β=0.223, p=0.033), frequency of HBGM (β=0.249, p=0.016) and analogue use (β=0.225, p=0.016).

DISCUSSION

Our study brings to attention some relevant issues regarding the costs of T1DM in a lower and middle-income country such as India. These include the high proportion of annual income spent on care of T1DM, the disproportionate burden borne by families of lower SES and the high costs of insulin and glucose monitoring.

The mean direct cost of T1DM per patient-year was ₹27 915 (US$ 524), which represented 19% of the mean annual family income. Since insulin, glucose testing strips and other consumables were available at wholesale rates to our patients, direct costs are likely to form an even higher proportion of income for those receiving care in other settings. For example, our hospital annual registration was ₹200 (for all visits/consultations) *v.* ₹300–500/visit in a private clinic. The cost of consumables in our pharmacy varied from ₹80–140/400 unit vial of regular/NPH insulin, ₹7.50/glucose monitoring strip and ₹2.50/insulin syringe. In comparison, costs in the open market, were ₹120–160/400 units, ₹25/glucose strip and ₹5/insulin syringe. In the only previous study on costs of T1DM from India, conducted nearly 14 years ago, the annual cost per person was ₹13 800 (US$ 310), while the median proportion of income spent on ambulatory care was 16% (23% in those requiring hospitalization).[14] Together, both these studies bring out the high economic burden borne by families of patients with T1DM in India. Studies from other developing countries have had similar findings. Costs in a nation-wide study from Brazil were US$ 1319 per annum,[17] US$ 283 per annum (23% of annual income) in Khartoum, Sudan[18] and US$ 1690 per annum in Mexico City, Mexico.[19]

Expenses related to insulin and HBGM contributed equally to nearly 80% of total direct costs. The high costs of insulin may result in patients using doses lower than prescribed or even missing injections. The low frequency of HBGM (median 13/week) noted in the study may be, in part, a consequence of the high cost of glucose strips. In India, while patients with T1DM are provided human insulin free of cost in some government clinics, glucose testing strips are not covered. Reports from other developing countries have also mentioned that the largest expenses in T1DM relate to insulin and glucose-testing strips. In Brazil, these two items constituted 53% of costs, while in Mexico City expenditure on insulin and HBGM were 15% and 53%, respectively of the total expenditure.[17,19]

In our study, the third largest expenditure (9% of costs) was related to travel, accommodation and food for clinic visits. This is a reflection of the long distances patients have to travel, often resulting in overnight stays, due to paucity of dedicated clinics. In contrast with many previous studies,[10–14] costs of in-patient care were only a small proportion of total expenses. This may be due to our emphasis on frequent clinic visits (at least 3/year) and regular contact on cell phone with the teaching nurse or physician. Alternatively, most patients included had ≥2 visits in the year, and those with poorer compliance and higher risk of hospitalizations may have been excluded.

Overall, mean out-of-pocket costs for families were 87% of total direct costs. A government subsidy or partial medical

reimbursement from the employer was available in only 19%, and the rest had to pay the entire costs. Of special concern was the fact that the proportion of total family income spent for diabetes care was nearly five-times more among families of lower or lower-middle SES (33%) compared with the higher SES (7%). Similarly, rural families spent a higher proportion of their income (2.1-fold) on diabetes care than those in urban areas. A special effort needs to be directed at subsidizing the costs of care for T1DM in these vulnerable groups. In an earlier study from Chennai, the median income spent on T1DM was 59% in the low socioeconomic group and 12% in the high-income group.[14] In a nation-wide study from Brazil, regional variations in income were associated with differences in costs and treatment for T1DM.[20]

On multivariate analysis, total direct cost per patient-year was positively associated with higher annual income. Lack of financial resources is likely to lead to inadequate spending on T1DM and adversely affect quality of care. Total cost was also associated with frequency of HBGM. Previous studies have shown that decreased frequency of HBGM results in worse glycaemic control.[21] The use of insulin analogues (mainly glargine) increased total costs. Use of glargine is associated with a decreased frequency of hypoglycaemia at night and between-meals as compared with human NPH insulin.[22] However, the cost-effectiveness of glargine insulin in T1DM has been debated.[23]

In addition to the direct costs, which we measured, indirect costs of the care of T1DM include loss of wages for the patient/care giver due to clinic visits or hospital admissions or due to absence from work due to diabetes-related illness. In addition, absence from school or college, reduced productivity due to decreased quality of life and diabetes-related disability or premature mortality is also included. Indirect costs are similar,[24] or even higher,[8] than direct costs of T1DM in high-income countries. While similar studies are not available from low or lower-middle income countries, it is likely that indirect costs of care will also be high in India.

Our study was limited to a single centre (government-funded referral hospital) and thus the direct costs may not be representative of those in other clinical settings. Costs of care in India will vary depending upon the SES, region (urban/rural), type of clinic (government/private) and available government subsidies. They are likely to be substantially higher in the private centres, where costs of consultation, investigations, consumables and hospitalization may be much greater. Nevertheless, our study provides useful information on the large burden on families and items that constitute costs of care in India, which are unlikely to differ in other settings.

In summary, a high proportion of annual family income was spent on costs related to T1DM, with disproportionate burden being borne by lower and lower-middle income and rural families. The majority of costs of care were related to glucose strips and insulin. Support from the government for these essential items, as well as provision of more centres for providing quality care, will reduce the burden on families with T1DM.

ACKNOWLEDGEMENT

We acknowledge the excellent technical assistance of Mr Ram Singh.

Conflict of interest. None declared

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