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Out-of-pocket direct cost of ambulatory care of type 2 diabetes in Delhi: Estimates from the Delhi diabetes community-II (DEDICOM-II) survey

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ABSTRACT

Background & aim: Much of the cost data from India is restricted to patients recruited purely from healthcare institutions and do not explore determinants. Therefore, the out of pocket expenditure for ambulatory diabetes care was evaluated in Delhi.

Methods: The DEDICOM-II survey used a two-stage probability-proportionate-to-size(systematic) cluster design. Thirty clusters were chosen to recruit 25 to 30 subjects per area. We used questionnaires to estimate the direct out-of-pocket expenditure (OOPE) on drugs, investigations, consultation and travel, excluding hospitalization, and then analysed its determinants and impact on quality of care.

Results: We enrolled 843 subjects with a mean age of 53.1 years. The annual direct OOPE on ambulatory care of diabetes was US$ 116.3 (95 % CI 93.8–138.9) or INR 8074.8 (95 % CI 6512.9–9636.7), corresponding to 3.6 % (95 % CI 2.9–4.3) of the yearly family income. The burden of expenses was disproportionately higher for those visiting private providers from lower-income groups(19.1 %). Duration of disease and treatment with insulin predicted higher annual OOPE while care at public facilities was less expensive. Cost was higher for those adhering to the recommended processes of care. Quality of care was better for institutional care and worse for alternative medicine or self-care.

Conclusions: The study provides representative estimates of the high cost of diabetes management in Delhi across the socio-economic and care provider spectra. Poorer patients suffer a high financial burden from diabetes, highlighting the need for enhancing equity in diabetes care.

1. Introduction

Diabetes is one of this century's largest global health emergencies. It ranks among the ten leading causes of mortality together with cardiovascular disease (CVD), respiratory disease, and cancer [1,2]. The International Diabetes Federation reports that 537 million(10.5 %) people (20–79 years) are living with diabetes in 2021, globally. By 2030, this number is projected to increase to 643 million (11.3 %) and by 2045 to 783 million (12.2 %) [1]. Diabetes prevalence has increased at a faster pace in low and middle income nations than in high-income countries during the last decade [3]. In India, the diabetes pandemic has been driven by the rising prevalence of overweight/obesity and unhealthy lifestyles [4], and the burden of diabetes has been increasing steadily since 1990 [5] (5.5 %), rising from 7.1 % in 2009 [6] to 11.4 % in 2021 [7]. India ranks second after China in the global diabetes epidemic with 101 million people with diabetes [4], which will increase to more than 134 million by 2045 [8]. Traditionally perceived to be a disease of the rich, several issues plague our response to this evolving tragedy. Amongst the ignored dimensions of the care of diabetes patients is the high and rising Out-Of-Pocket (OOP) cost of care [9].

Globally, diabetes is estimated to cost 825 billion dollars a year, with the largest share incurred in China ($170 billion), the United States ($105 billion), and India ($73 billion) [10]. Several studies have reported the rapid rise of costs related to diabetes care worldwide and periodic updates are shared from a variety of settings [8,11–13]. However, much of the data from India and elsewhere is restricted to patients recruited from healthcare institutions and hence proactively seeking some care [8,14]. These studies do not cover a substantial segment of diabetes patients who do not access any healthcare service(likely the most disadvantaged and/or non-compliant) and hence can be reached only through community-based research. Moreover, where data is gathered by community based cost of illness methods, there is lack of

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analogous information on the quality of diabetes care or the socio-economic context or the care provider setting(public or private hospitals, clinic, self-care or alternative medicine), reducing the usefulness of the data [15,16]. Hence, the currently available data sources have several limitations that prevent a more comprehensive analysis of the health-seeking behaviour and outcomes of people with diabetes. For example, they do not provide information on the correlation between cost and quality of care across different types of providers, such as public, private, or alternative. They also do not evaluate the impact of high OOP expenses on the ability of the poorest sections to access or utilize or comply even with public health care. Moreover, they do not account for the impact of self-care or alternative choices on diabetes control, amongst patients who can easily afford conventional treatment. To provide representative estimates and explore some of these contexts, in 2005, we conducted the costs of care analysis for the first community-based survey in Delhi (1st DEDICOM survey) and presented the direct cost of ambulatory diabetes care, evaluated the socio-demographic correlates of spending, and ascertained the relationship of the expenditure with delivered quality of care [17]. However, the original survey was restricted to the middle and high-income groups of Delhi and the data is now more than 18 years old. Hence, hypothesising that the previous data is limited and outdated, we undertook the current exercise of estimating the direct cost of ambulatory diabetes care as part of the recently concluded DEDICOM-II house-to-house community survey (covering all socio-economic strata) from Delhi and to study its relationship with the quality of care received and the care provider setting.

2. Subjects, materials and methods

This paper presents unpublished cost of care data collected as part of the Delhi Diabetes Community (DEDICOM-II) survey conducted between April 2018 and July 2020 [18,19]. As published elsewhere [19], subjects with known diabetes for more than one year (diagnosed by a registered medical practitioner based on blood glucose estimation) in the age group of 35–65 years were included in the survey. Subjects with Type 1 diabetes/gestational diabetes, cancer, a renal, hepatic, or intestinal disease requiring continuing treatment or hospital admission (>1 week in last one year) or inability to communicate (due to mental illness or physical disability) were excluded.

The methodology for this survey has been detailed in a previous publication [19]. In summary, the survey employed a two-stage cluster-randomized sampling strategy to select 30 wards from a total of 150 in the first stage, mirroring the approach used in the initial survey. A computer-generated random seed value was used to select wards at a predefined sampling interval, calculated as (population*30)/150, using the Probability-Proportionate-to-Size-systematic method. In the second stage, a comprehensive house-to-house survey was conducted in the selected wards to identify a maximum of 40 known diabetes patients sequentially. Subjects who agreed to participate were administered a standardized, pre-tested proforma through an interview. Patient records, when available, were also reviewed. The sociodemographic profile of the subjects was recorded, including age, gender, waist circumference, Body Mass Index (BMI), age at diagnosis (in years), duration since diagnosis (in years), ongoing treatment, birthplace, education, occupation, gross family income, qualification of the Primary Care Provider (PCP), place of health care (government or private institution, individual practitioner, alternative medical practitioners such as homoeopathy/ayurvedic/naturopathy, or no provider), number of visits to the PCP in the last year, and habits like smoking and alcohol use. The annual gross family income was classified into one of the four categories (INR <0.12 million per annum (p.a.), INR 0.12–0.24 million p.a., INR 0.25–0.49 million p.a., and ≥ INR 0.50 million p.a.) to avoid apprehension related to revealing of exact income. The Kuppuswamy classification, adjusted using the Consumer Price Index for Industrial Workers in India for 2017 [20] was used to assess the socioeconomic class of the subjects. The Information on self-reported pre-existing co-morbidity (coronary artery disease, hypertension, and brain stroke) and use of medications were collected from available records and by interview. An overnight fasting blood sample (5 ml) was drawn to estimate Fasting blood glucose, HbA1c, and lipid profile.

In Cost of Illness(COI) studies 'Direct costs' are defined [21] as "costs incurred by the health system, society, family and individual patient, the direct costs consist of healthcare costs and non-healthcare costs. The former is defined as the medical care expenditures for diagnosis, treatment, and rehabilitation, etc., while the latter is related to the consumption of non-healthcare resources like transportation, household expenditures, relocating, property losses, and informal cares of any kinds". The term 'indirect' in COI studies refers to "productivity losses due to morbidity and mortality, borne by the individual, family, society, or the employer". In our study costs related to loss of wages or other indirect losses were not included in the calculation (only direct costs were counted). Costs reimbursed by the employer or insurance provider or not incurred (free services from government/public facilities or insurance coverage providing cashless services were excluded; only Out-Of-Pocket (OOP) expenses were counted in our study). Costs related to hospital admissions were not included (only ambulatory expenses were counted). Information on out-of-pocket direct expenditure related to ambulatory diabetes care was collected in two ways. First, the patients were asked to give a rough estimate, i.e. Patient Impression-based Estimate of Expenditure (PEE) of their total monthly OOP expenditure on the care of diabetes including total medicines (oral hypoglycaemic drugs, insulin, cholesterol-lowering drugs and blood thinning drugs), blood tests, consultation, Self-Monitoring Blood Glucose (SMBG) and travel (for consultation, medicine purchase, and tests) under which these expenses could have been incurred.

More data was collected on the kind of healthcare provider, based on the physician's credentials and the amount and kind of drugs/medication used. The frequency and type of tests conducted in the past year, the frequency of Self-Monitoring Blood Glucose (SMBG) by the patient, and travel costs for consultations, medications, and tests were also recorded to calculate the Calculation Based Expenditure (CBE) for the last year. In the absence of bills or receipts, the cost of consultation was confirmed verbally by asking about the fees paid per visit to the diabetes care provider and was multiplied by the total visits made in the last year. The Maximum Retail Price (MRP; Appendix 1) of medicines was used to calculate spending on medicines. Patients either showed their prescription or the strips of medicines they were consuming, along with the frequency of consumption. Subjects were also asked to mention the duration of consumption of each medicine to calculate the mean intake in the last year. The expenditure on blood tests was confirmed from the laboratory named by the participant, with the frequency of tests repeated in the last year. For Self-Monitoring Blood Glucose, a fixed rate of INR 20/test (for the purchase of strip and lancet) was considered constant for all subjects (except for those who did it from Gurdwara or other free camps). Expenditure on healthcare-related travel (for consultation with diabetes care provider, medicines, and tests) was noted as claimed by the participant.

The history of advice received in the last one year from their health care provider on nutrition counselling, special care for feet, weight loss, diabetes education, smoking cessation, aspirin intake, and pneumococcal/influenza vaccine was collected. Patient records were examined for investigations including but not limited to urine examination, microalbuminuria, dilated eye examination, ECG, TMT, ECHO, chest X-ray, HbA1c, lipid profile, Liver Functioning Test, and Renal Functioning Test. This information was collected to allow evaluation of the relationship between spending and the quality of care received.

2.1. Statistical analysis

Data was entered, curated and analysed using SPSS v.25.0. Cost of care estimates for care provider categories were calculated using the complex samples procedure CSDESCRIPTIVES. This weighted the descriptive estimates for the cluster (probability proportionate to size) sampling design of the survey (intra and inter-cluster variations). Such estimates were also calculated as a proportion of family income to provide socioeconomic context to the expenses. Similarly, complex samples linear (CSGLM) and logistic regression (CSLOGISTIC) models were used to study the relationship of demographic characteristics with the calculated expenditure and to evaluate the association between the expenditure and the quality of diabetes care by National Diabetes Quality Improvement Alliance (NDQIA) criteria. Factors identified as possible determinants by literature review were evaluated by univariate correlation analysis. Variables that were significantly correlated were added to a multivariate linear regression model by the "Enter" approach.

3. Results

Details of the survey aspects are previously published [19]. In summary, 11,490 houses were screened (289–1030 per cluster). This screening identified 1640 individuals known to have diabetes. However, 238 individuals did not meet the study's inclusion criteria. Additionally, 87 patients were excluded from the study. Among those who met the selection criteria, 472 declined to participate. Hence, 843 known diabetes patients were administered the DEDICOM-II questionnaire which included questions related to cost of care. The laboratory data was available for 800 subjects, as 43 refused to give blood samples after initial participation. Also, the subjects who refused consent specifically for blood sampling (n = 43) were comparable to those who consented (n = 800) for all baseline characteristics ($p > 0.05$; data previously published;[18]).

The socio-demographic profile of the subjects visiting various types of care providers is presented in Table 1 and Supplementary Table 1. The mean age of the subjects was ~53 years, with a mean duration of diabetes for the last ~7 years. According to Kuppuswamy classification [20], 30.2 % of patients belonged to LSEC, 63.2 % to MSEC, and 6.6 % to USEC. 41.2 % of patients were consulting in institutions (34.6 % Government hospital; 6.6 % private hospital), 28.9 % were consulting local doctors, and around 1/4th of the subjects (26.7 %) were not consulting any health care provider for diabetes care in the last one year. Very few patients (3.1 %) were taking alternative medicine (Homeopathy/Ayurvedic/Naturopathy) consultations. Of the subjects who were consulting a care provider (592/843; government or private or local doctors), the majority (56.4 %) were consulting a general physician, 8.4 % were consulting an endocrinologist/diabetologist, 2.6 % a specialist physician, 6.5 % were visiting doctors whose qualification was not known to the participants (Qualification not Known). The remaining 26.2 % had not visited a care provider in the last one year and managed as advised previously or by their own understanding (Selfcare).

Table 2 presents the annual direct OOP expenditure on ambulatory care of diabetes classified by the category of expense by CBE method and a summary expense by PEE method. As presented, the mean CBE on diabetes care was US$ 116.3 (INR 8074) per annum whereas the corresponding PEE was US$ 194.0 (INR 13461) (67 % higher self-estimates of spending than the calculated expenditure). Out of the 5 expenditure categories, more than two-thirds of the expenditure was incurred on medicines (68.5 %). The mean total expense on diabetes care was significantly higher in patients who had co-morbidities (CAD, brain stroke, hypertension (mean difference US$ 48.6 (INR 3374.7); $p = 0.003$)) as compared to patients with no co-morbidity.

Table 3 and Supplementary Table 2 provides the expenses incurred categorised by the type of care provider with the quality of care received and the control of diabetes achieved. As presented patients seeking care at government facilities or with alternative medicine providers incurred the minimum expenses while the OOP expenses at private institutions were ~10 times higher. As a proportion, families were spending 3.6 % of their annual family income on care of diabetes. As expected, this proportion was lowest for higher-income groups compared to lower-income groups. It is noteworthy that lower-income patients receiving care from private providers (individual practitioners or institutions) were spending up to 11.8 %–19.1 % of their annual family income directly on ambulatory diabetes care (Mean 11.8 % (95 % CI 4.1–19.5) local practitioners; Mean 19.1 % (95 % CI 7.8–30.4) for private institutions). In comparison high income groups were spending less than 1.9 % of their annual family income.

As presented participants on self-care or alternative medicine were worse than their peers for compliance with 'processes of care' considered advisable as per the ADA guidelines [22] and the 'control of diabetes' in biochemical terms. Also, subjects receiving institutional care (Government or Private hospitals) were better than those receiving care by individual practitioners. Differences in care between government and private institutions were few (higher rates of weight management, aspirin advice and urine testing at private institutions). The patients who were not consulting any healthcare facilities for the last 1 year were still incurring significant OOP expenses on self-care of diabetes care while having very poor control of HbA1c, Cholesterol or Blood Pressure.

To further understand the relationship of socio-demographic determinants with the CBE we conducted a correlation and regression analysis. As presented in Table 4, duration of disease, care provider facility and treatment with insulin were significant independent predictors of the annual direct OOPE of care. At the same time, gender, medical benefits, income, education and presence of co-morbidities did not have any significant independent association with the annual expenditure on diabetes when adjusted for covariates.

To further explore the relationship of annual direct CBE with the quality of care received, a sensitivity analysis was conducted for those achieving diabetes control processes and targets with those not achieving the same (Table 5). There was a trend towards higher expenditure for better quality of care although achievement of target levels for biochemical parameters did not relate to expenses. Those receiving recommended 'process of care' (nutrition counselling, special care for feet, weight loss, diabetes education, exercise program, and aspirin advice) or regularly monitoring clinical/biochemical parameters were spending more than others. The annual ambulatory expenditure by subjects receiving any three or more 'process of care' was US$ 107.6 (95 % CI 56.2–158.9) (INR 7466 (95 % CI 3903.7–11028.6)) higher than others after adjusting for covariates.

4. Discussion

4.1. Interpretation of key findings

The study documents that diabetes-related expenditure causes a considerable financial burden on patients even in a city like Delhi (~3.6 % of annual family income) where all types of care are almost universally accessible. This translates to a massive 4 billion INR (50 million dollars; $116*25.2 %(prevalence estimate)*1.67 million(population estimate) per year for the city on care of diabetes. Also, the burden is expected to rise as the duration since diagnosis increases leading to more morbidities and care needs. These estimates, which do not include indirect expenses and hospitalisations, are intrinsically conservative. As expected, the burden is catastrophic (>10 % of annual family income) for those with the least affordability and those seeking private care (up to ~19.1 %) and the care/control is worst for those on selfcare/alternative medicines. Even patients receiving care at public facilities incur a low but significant amount on travel and purchase of medicines. Within the pay-for-care facilities, institutional care tended towards higher expense, better standardisation and compliance. The patient estimate of expenditure was higher as compared to the calculated cost, which could be because of the unaccounted expenses (the purchase of diabetes-specific home remedy food, disposables, and one-time expenses like glucometer, BP apparatus, etc.) or an impression caused by indirect expenses or a biased assessment.

Table 1
Sociodemographic profile of diabetes patients: Type of care providers *.

		Type of diabetes care provider				
Characteristics	All subjects (n = 843)	Government Hospital (n = 292)	Private Hospital (n = 56)	Local Doctor (n = 244)	Alternative Medicine (n = 26)	Selfcare (n = 225)
Age (years)	53.1 (52.1–54.1)	54.6 (53.1–56.1)[a]	54.6 (52.0–57.3)[b]	52.6 (50.9–54.2)[a]	50.4 (45.8–55.1)	51.8 (50.6–52.9)[a,b]
Males (%)	51.5 (47.0–55.9)	46.1 (38.6–53.8)[a]	41.6 (26.4–58.6)[b]	47.7 (38.6–57.0)[c]	56.9 (30.3–80.0)	64.3 (54.4–73.2)[a,b,c]
Females (%	48.5 (44.1–53.0)	53.9 (46.2–61.4)[a]	58.4 (41.4–73.6)[b]	52.3 (43.0–61.4)[c]	43.1 (20.0–69.7)	35.7 (26.8–45.6)[a,b,c]
Body Mass Index (BMI) (kg/m^2)	28.1 (27.7–28.5)	27.5 (26.7–28.3)[a]	28.7 (27.6–29.7)[a]	28.9 (28.3–29.5)[a]	25.9 (22.3–29.5)	28.1 (27.3–28.9)
Waist Circumference (WC) (cm)	100.7 (99.6–101.7)	99.6 (97.9–101.3)[a]	102.5 (99.3–105.6)[a]	102.2 (100.6–103.7)[a]	96.8 (88.6–104.8)	100.3 (98.5–102.0)
Mean Age at diagnosis (yrs)	45.9 (44.9–46.9)	47.5 (45.5–49.5)[a]	45.4 (42.7–48.1)	45.1 (43.6–46.7)[a]	42.4 (34.5–50.3)	45.5 (44.2–46.8)
Duration since diagnosis (yrs)	7.1 (6.7–7.6)	7.1 (6.2–8.0)[a]	9.2 (7.3–11.1)[a,b]	7.4 (6.6–8.3)	8.0 (4.1–11.9)	6.3 (5.1–7.4)[b]
Prescribed treatment (%)						
Oral hypoglycaemic agent	74.4 (70.4–78.0)	77.0 (67.3–84.5)[a]	68.7 (49.4–83.2)[b]	85.0 (80.0–88.9)[c]	57.1 (29.5–80.9)[b,c]	61.2 (53.4–68.4)[a,b,c]
Insulin	2.4 (1.3–4.5)	2.4 (1.0–5.7)[a]	6.0 (0.9–32.0)b	2.1 (0.7–5.9)[b,c]	0	2.3 (0.6–8.0)[a,b,c]
Oral Hypoglycaemic Agent + Insulin	7.0 (5.0–9.8)	10.2 (6.0–16.8)[a]	18.8 (9.0–35.0)[b]	6.6 (4.3–10.1)[c]	0	1.7 (0.6–5.1)[a,b,c]
Neither	16.2 (13.3–19.6)	10.4 (6.3–16.8)[a]	6.5 (2.0–19.0)b	6.3 (3.1–12.3)[c]	42.9 (19.1–70.5)[a,b,c]	34.7 (25.9–44.7)[a,b,c]
Education level (%)						
Illiterate	17.3 (11.3–25.6)	22.1 (13.1–34.9)	24.6 (13.2–41.2)	14.6 (8.7–23.4)	6.5 (1.6–22.4)	14.2 (7.1–26.6)
Primary school	15.0 (12.6–17.9)	15.6 (11.0–21.8)[a]	28.2 (13.0–50.7)[b]	15.7 (11.5–21.1)[c]	1.0 (0.2–5.0)[a,b,c,d]	12.3 (7.6–19.2)[c,d]
Middle or high school	47.9 (41.2–54.6)	44.5 (34.8–54.7)[a]	28.2 (15.1–46.3)[b]	47.2 (38.9–55.6)	45.9 (20.5–73.7)	57.5 (48.1–66.5)[a,b]
College Education	19.8 13.2–28.6)	17.7 (7.6–36.0)[a]	19.0 (8.3–37.9)	22.6 (12.7–36.9)	46.5 (20.0–75.2)[a,d]	16.0 (10.0–24.6)[d]
Annual Income of family (INR) (%)						
<0.12 million	26.3 (20.0–33.9)	33.9 (22.2–47.9)[a]	19.8 (10.9–33.3)	17.9 (12.8–24.5)[a,c]	18.6 (6.8–41.6)	29.4 (20.5–40.3)[c]
0.12–0.25 million	30.0 (23.8–37.1)	27.8 (18.7–39.2)	37.2 (24.6–51.8)	30.0 (21.2–40.5)	16.5 (4.6–44.4)	32.9 (25.4–41.4)
0.25–0.50 million	20.4 (15.7–26.0)	13.1 (7.7–21.4)[a]	23.4 (10.2–45.1)	24.6 (17.6–33.3)[a]	42.6 (16.7–73.3)[a]	21.2 (15.0–29.2)
≥0.50 million	23.2 (14.7–34.7)	25.2 (10.4–49.3)	19.6 (8.2–39.9)	27.5 (16.5–41.9)	22.3 (6.3–55.1)	16.5 (10.2–25.4)
Socio Economic status (%)[^]						
USEC	6.6 (2.6–15.6)	6.4 (1.4–24.5)	6.4 (0.8–35.6)	10.0 (2.6–32.0)	8.5 (1.0–45.7)	2.3 (0.9–5.8)
MSEC	63.2 (54.2–71.3)	55.1 (43.4–66.3)[a]	57.8 (42.8–71.5)	67.5 (53.3–79.0)	83.9 (56.0–95.5)[a]	66.9 (57.1–75.5)[a]
LSEC	30.2 (22.0–40.0)	38.4 (24.2–54.9)[a]	35.8 (21.9–52.6)[b]	22.5 (15.6–31.3)[a,b,c]	7.6 (2.2–22.8)[a,b,d]	30.8 (22.4–40.6)[c,d]
Birth place Delhi (%)	40.6 (32.7–49.0)	30.2 (19.5–43.5)[a]	42.9 (25.0–62.8)	46.8 (38.0–55.9)[a]	36.3 (16.8–61.7)	46.0 (38.8–53.3)[a]
Primary care provider (%)						
Endocrinologist/ Diabetologist	8.4 (5.6–12.3)	3.8 (1.0–13.2)[a]	13.9 (5.3–32.0)	19.8 (14.0–27.2)[a]	NA	NA
Specialist Physician[€]	2.6 (1.4–4.7)	1.7 (0.6–5.0)[a]	13.5 (4.6–33.4)[a,b]	3.9 (1.5–9.4)b	NA	NA
General Physician[£]	56.4 (51.3–61.4)	88.0 (76.1–94.1)[a]	67.0 (46.5–82.6)[a]	73.4 (65.2–80.3)[a]	NA	NA
Qualification not known	6.5 (3.4–12.0)	6.5 (2.6–15.6)[a]	5.5 (1.3–20.6)	3.0 (1.2–7.3)[a]	100	NA
Selfcare	26.2 (19.7–33.8)	–	–	–	–	100
Medical benefits[@] (%)	44.7 (34.1–55.7)	44.6 (27.6–63.1)a	38.1 (25.4–52.7)	45.9 (33.4–58.9)	66.7 (39.6–85.9)a	42.0 (29.3–55.9)
Current Smoker[¥](%)	15.6 (11.8–20.5)	16.9 (11.4–24.3)	8.3 (2.8–22.4)	12.2 (6.9–20.8)	10.4 (2.7–32.4)	20.4 (15.6–26.2)
Current Alcohol user[Φ] (%)	24.5 (21.1)	20.6 (12.5–32.1)	12.1 (5.2–25.6)b	25.7 (19.9–32.4)	13.9 (3.5–42.3)	31.9 (25.7–38.7)b
Co-morbidity[#] (%)	42.8 (39.5–46.3)	46.2 (40.7–51.7)a	63.8 (45.5–78.8)b	47.9 (40.3–55.5)c	32.8 (13.7–60.1)	29.1 (24.5–34.2)a, b,c

*Data are presented as cluster-adjusted mean (95 % CI) or percentage (95 % CI).
Alternative medicine includes homeopathy/Naturopathy/Ayurvedic medicine.
[^]Kuppuswamy Socioeconomic Scale[20]: USEC is Upper socioeconomic Class (score 26–29); MSEC: Middle Socioeconomic Class (11–25); LSEC: Lower Socioeconomic Class (1–10).
[@]Individuals receiving any government insurance schemes/private medical insurance/medical reimbursement.
[¥] smoking at the time of data collection.
[Φ]Consuming alcohol at the time of data collection.
[#]Includes history of any coronary artery disease/hypertension/brain stroke; reported by subjects.
[€]Other than endocrinologist (MBBS and MD in any other specialty).
[£]Those who were MBBS or MD in general medicine.
Self-care defined as who did not receive any advice from any health care provider in last one year and following earlier advice/friends or family advice.
a = 5 % level of significance of Government hospital vs private hospital/local doctor/alternative (homeopathic/ayurvedic/naturopathy)/Selfcare.
b = 5 % level of significance of Private hospital vs Local doctor/alternative medicine (homeopathic/ayurvedic/naturopathy)/Selfcare.
c = 5 % level of significance Local doctor vs alternative (homeopathic/ayurvedic/naturopathy)/Selfcare.
d = 5 % level of significance Alternative (homeopathic/ayurvedic/naturopathy) vs. Selfcare.

4.2. Strengths and limitations

The estimates come from a house-to-house community survey of diabetes patients of all income groups, maximising its representativeness. The study uses standardised methods to provide both self-perceived summary expenditure and calculation-based expenditure. The study is unique in its interpretation of cost in the context of socio-demography and the quality of care received. The

Table 2
Annual direct cost of ambulatory care of diabetes mellitus (n = 843)[a].

Category	Calculation Based Expenditure (CBE,US$) Mean (95 % CI)						Patient Estimate of Expenditure (PEE,US$)
	Calculated cost of consultation	Calculated cost of medicines	Calculated cost of tests	Calculated cost of SMBG	Calculated cost of travel	Total calculated cost	Total estimated cost
Gender							
Overall	12.5 (7.5–17.5)	79.7 (62.3–97.2)	12.0 (8.8–15.2)	7.1 (4.6–9.5)	5.1 (3.9–6.3)	116.4 (93.8–138.9)	194.0 (154.3–233.6)
Males	10.9 (6.4–15.3)	86.1 (62.1–110.0)	12.8 (8.5–17.0)	6.3 (3.0–9.6)	5.9 (4.2–7.6)	121.9 (91.0–152.9)	199.8 (145.4–254.3)
Females	14.0 (5.4–22.6)	73.8 (54.8–92.7)	11.3 (8.0–14.6)	7.8 (4.2–11.3)	4.3 (3.2–5.4)	111.1 (85.7–136.5)	188.4 (141.9–235.0)
Duration (years since diagnosis)							
1–5 yrs	7.8 (4.4–11.2)	47.5 (33.3–61.8)	8.8 (6.4–11.2)	4.8 (1.8–7.7)	3.8 (2.2–5.5)	72.8 (54.2–91.4)	136.6 (103.4–169.9)
5.1–10 yrs	12.7 (6.8–18.6)	86.5 (58.6–114.5)	13.3 (6.8–19.7)	6.6 (2.8–10.3)	5.0 (2.9–7.1)	124.1 (83.2–164.9)	215.1 (149.9–280.4)
10.1–15 yrs	7.7 (2.8–12.6)	99.3 (57.7–140.9)	11.1 (5.1–17.0)	7.2 (2.5–11.9)	6.5 (3.1–9.9)	131.7 (82.7–180.7)	208.6 (130.0–287.2)
≥15.1 yrs	49.8 (0.1–99.6)	221.9 (119.6–324.1)	29.3 (12.7–46.0)	22.8 (8.0–37.6)	10.5 (6.2–14.7)	334.3 (203.7–464.9)	456.4 (268.9–643.9)
Gross Annual Family Income (INR)							
<0.12 million	3.9 (2.2–5.7)	48.7 (28.1–69.4)	6.1 (3.8–8.4)	1.8 (1.0–2.5)	5.2 (3.5–7.0)	65.8 (44.6–86.9)	114.9 (85.2–144.6)
0.12–0.24 million	9.1 (4.9–13.3)	74.8 (56.7–92.8)	9.5 (6.0–13.0)	8.1 (2.6–13.6)	5.4 (3.7–7.0)	106.8 (83.3–130.4)	167.4 (129.2–205.7)
0.25–0.49 million	16.7 (9.4–23.9)	103.1 (74.8–131.5)	14.2 (7.7–20.8)	6.6 (2.5–10.7)	4.9 (2.5–7.3)	145.6 (109.3–181.9)	257.1 (170.6–343.7)
≥0.50 million	22.9 (2.5–43.3)	101.4 (47.2–155.6)	20.0 (10.3–29.6)	12.2 (6.1–18.3)	4.7 (2.0–7.5)	161.2 (81.1–241.3)	263.9 (128.0–399.7)
Education (maximum qualification)							
Illiterate	9.1 (3.2–15.1)	46.0 (33.3–58.7)	8.6 (3.5–13.7)	3.1 (0.3–5.8)	5.7 (3.9–7.5)	72.6 (57.0–88.1)	136.7 (103.5–169.9)
Primary school	8.5 (4.9–12.1)	84.7 (47.4–122.0)	7.9 (4.6–11.2)	7.4 (−2.1-16.8)	5.4 (2.9–8.0)	113.9 (64.5–163.3)	158.0 (118.7–197.3)
Middle school	15.1 (6.9–23.2)	53.3 (34.5–72.1)	11.7 (5.8–17.6)	7.7 (0.4–15.0)	4.8 (3.0–6.6)	92.6 (61.7–123.5)	158.9 (83.4–234.3)
Higher school	9.1 (6.2–12.0)	95.1 (54.6–135.5)	12.0 (6.4–17.6)	6.4 (1.8–11.0)	4.7 (3.1–6.3)	127.3 (83.4–171.2)	219.8 (149.9–289.7)
Secondary school	9.1 (1.5–16.7)	86.7 (42.2–131.2)	13.6 (6.0–21.2)	4.8 (2.2–7.4)	3.0 (1.0–4.9)	117.2 (62.7–171.6)	253.7 (140.7–366.6)
Graduate or Post-graduate	22.9 (−6.1-52.0)	92.3 (44.7–139.9)	16.3 (6.6–25.9)	12.3 (5.7–18.9)	5.2 (1.9–8.4)	148.9 (71.2–226.7)	220.1 (114.4–325.8)
Professional	20.5 (4.5–36.4)	129.7 (43.6–215.9)	20.9 (4.8–37.0)	10.1 (0.8–19.3)	7.7 (0.3–15.2)	188.9 (66.3–311.5)	284.3 (85.2–483.5)
Employment status							
Profession	16.9 (2.5–31.4)	134.3 (−0.1-268.7)	19.4 (4.4–34.5)	19.0 (13.0–25.0)	5.4 (1.3–9.5)	195.1 (35.5–354.7)	297.9 (31.6–564.1)
Semi-profession	30.5 (−9.6-70.7)	76.5 (28.4–124.6)	20.2 (9.5–31.0)	10.6 (−0.2-21.3)	6.0 (1.4–10.7)	143.8 (50.7–237.0)	233.2 (87.3–379.1)
Clerical, Shop-owner	9.0 (3.6–14.4)	85.0 (58.2–111.8)	8.9 (4.5–13.4)	6.4 (1.1–11.6)	4.1 (2.0–6.2)	113.4 (80.9–146.0)	193.6 (138.0–249.3)
Skilled worker	6.7 (2.1–11.4)	57.4 (16.1–98.7)	7.2 (4.8–9.5)	8.6 (0.4–16.7)	3.4 (2.0–4.7)	83.2 (32.6–133.9)	179.3 (74.6–284.0)
Semi-skilled worker	18.2 (5.7–30.7)	56.1 (38.7–73.5)	10.8 (5.6–16.0)	2.3 (0.3–4.2)	4.5 (1.8–7.1)	91.8 (60.3–123.4)	158.3 (92.4–224.2)
Unskilled worker	3.0 (0.1–5.9)	32.0 (9.7–54.2)	2.4 (0.9–4.0)	1.2 (−0.7-3.2)	2.9 (0.3–5.6)	41.5 (15.2–67.9)	71.0 (36.5–105.5)
Unemployed	10.2 (6.3–14.2)	89.4 (64.8–113.9)	13.0 (8.2–17.8)	6.8 (2.8–10.8)	6.1 (4.4–7.7)	125.4 (94.9–156.0)	199.9 (148.5–251.3)
Socio Economic status							
USEC	19.7 (0.2–39.1)	108.7 (−6.0-223.3)	20.6 (5.0–36.2)	15.1 (9.6–20.6)	4.0 (0.9–7.1)	168.0 (14.1–321.9)	336.0 (39.2–632.8)
MSEC	15.6 (8.5–22.7)	87.0 (71.2–102.8)	13.2 (9.5–17.0)	8.9 (5.2–12.7)	5.2 (3.8–6.6)	129.9 (105.8–153.9)	208.7 (166.2–251.2)
LSEC	4.5 (2.7–6.2)	58.8 (30.4–87.2)	7.6 (4.3–10.9)	1.5 (0.7–2.2)	5.2 (3.6–6.7)	77.5 (48.3–106.6)	133.3 (94.3–172.4)
Medical Benefits							
Availing	16.0 (5.9–26.0)	93.7 (56.9–130.5)	16.7 (10.6–22.7)	8.5 (3.5–13.5)	5.4 (3.4–7.4)	140.2 (95.1–185.4)	236.1 (155.4–316.9)
Not availing	9.7 (6.4–13.0)	68.5 (54.0–82.9)	8.2 (6.3–10.2)	5.9 (2.8–9.0)	4.8 (3.2–6.4)	97.1 (77.3–116.8)	159.9 (127.9–192.0)
Place of diabetes care							
Government Hospital	0.7 (−0.1-1.5)	13.1 (5.7–20.5)	4.1 (2.6–5.6)	3.5 (2.0–5.0)	6.5 (3.7–9.3)	27.9 (18.3–37.4)	50.1 (29.2–71.0)
Private Hospital	57.0 (−3.4-117.3)	154.9 (92.4–217.4)	30.3 (13.1–47.6)	12.1 (3.9–20.3)	15.7 (6.3–25.1)	270.1 (154.8–385.3)	451.9 (308.5–595.4)
Local Doctor	28.1 (22.9–33.4)	150.7 (120.0–181.3)	23.8 (16.5–31.1)	12.9 (7.6–18.1)	5.5 (3.7–7.3)	221.0 (185.3–256.8)	373.0 (296.1–449.9)

(*continued on next page*)

Table 2 (*continued*)

Category	Calculation Based Expenditure (CBE,US$) Mean (95 % CI)						Patient Estimate of Expenditure (PEE,US$)
	Calculated cost of consultation	Calculated cost of medicines	Calculated cost of tests	Calculated cost of SMBG	Calculated cost of travel	Total calculated cost	Total estimated cost
Alternative Medicine	1.4 (−0.5-3.2)	19.6 (4.4–34.9)	2.5 (0.5–4.5)	0.8 (−0.4-2.1)	1.8 (−0.7-4.4)	26.1 (6.6–45.7)	124.3 (−21.3-269.9)
Selfcare	–	68.3 (43.4–93.1)	4.7 (3.4–5.9)	4.1 (−0.3-8.5)	0.9 (0.1–1.6)	77.9 (49.8–106.0)	110.0 (70.9–149.0)
Current treatment							
OHA	11.2 (8.6–13.9)	78.8 (62.9–94.7)	11.9 (8.9–14.9)	4.6 (2.7–6.5)	4.9 (3.7–6.1)	111.4 (91.9–131.0)	191.1 (153.2–229.1)
Insulin	23.2 (−4.6-51.0)	192.0 (50.6–333.4)	40.8 (2.1–79.5)	14.5 (1.1–27.8)	13.2 (−3.5-29.8)	283.6 (86.9–480.4)	485.8 (209.9–761.7)
OHA + Insulin	48.5 (−9.1-106.0)	235.8 (107.7–364.0)	21.5 (6.4–36.6)	45.2 (17.4–73.0)	14.5 (5.6–23.4)	365.4 (196.6–534.3)	500.6 (253.4–747.8)
Neither	1.0 (0.0–1.9)	0.0 (0.0–0.0)	3.9 (1.6–6.3)	0.9 (0.4–1.3)	0.8 (0.2–1.5)	6.6 (3.7–9.6)	31.5 (12.6–50.5)
Co-morbidity							
Present	15.1 (10.1–20.1)	96.2 (71.3–121.2)	15.9 (10.3–21.4)	10.8 (6.0–15.6)	6.2 (4.4–7.9)	144.2 (110.7–177.6)	258.0 (198.3–317.7)
Absent	10.5 (2.6–18.4)	67.4 (51.9–82.9)	9.1 (6.2–11.9)	4.3 (2.7–5.9)	4.3 (2.9–5.7)	95.5 (75.5–115.6)	146.0 (112.7–179.3)

Alternative medicine includes homeopathy/Naturopathy/Ayurvedic medicine.
Self-care defined as who did not receive any advice from any health care provider in last one year and following earlier advice/friends or family advice.
OHA is Oral Hypoglycaemic Agents.
United States Dollar (US$) rates were taken for the year 2018 and 2019 when the data was collected (1US$ = 69.4 INR) [41].
[a] Data are presented as cluster-adjusted mean (95 % CI).

survey data reveals that if subjects for the cost of diabetes studies were recruited exclusively from health facilities, it would exclude ~29 % of the subjects in Delhi as this is the proportion of diabetes patients who are not visiting any health care professional/facility for diabetes management. This implies that earlier studies could have overestimated expenses as this category of subjects spent less on diabetes care. Also, in the context of care, these are the subjects with the worst care/control of diabetes. The study distinctively provides estimates from the city of Delhi. The city has one of the largest single concentrations of diabetes patients globally but also provides a unique healthcare setting. The city boasts of all varieties of health infrastructure in close proximity. It is hence presumable that the determinants of 'choice of care provider' and related cost are at play with minimum influence of infrastructure available/accessibility. This allows our study to provide unique insight into such determinants. Also, uniquely, our study compares cost estimates from the same city where the same group conducted a similar study 18 years ago using a similar study methodology, allowing for apple-to-apple comparison on time trends. The same are discussed below.

The study is limited by the poor availability of medical records and expenses with patients and the lack of a centralized repository of medical records, precluding accurate estimates. The study is also limited by the lack of data on food, disposables, and 'one-time' expenses, which is further expected to underestimate the direct ambulatory expenditure. The study does not evaluate the costs reimbursed to the patients by insurance providers or employers(non OOP expenses) and does not include any loss of productivity or absences from work for self or family (indirect costs) and hence underestimates the actual total cost.

4.3. Comparison with existing literature

A recent systematic review attempted to evaluate articles published between 1999 and 2019 on the cost of diabetes from various locations, such as the South zone, the North zone, the Northeast zone, and the west zone, and India as a whole [8]. Data from 32 studies indicated the median direct cost of diabetes of US$ 272.2 (INR 18,890) p.a. for the north zone, US$ 152.2 (INR 10,585) p.a. for the south zone, US$ 659.8 (INR 45,792) p.a. for the north-east zone and US$ 127.1(INR 8822) p.a. for the west zone. Similarly, a pan-India study conducted by Nagarathna et al., 2020 presented the self-reported total cost of illness for diabetes, covering 50 districts in 25 states/union territories had exhibited the average annual expenditure of INR 16,292 which reflected approximately 17 % of the total household expenditure [23]. In summary, the annual direct health care expenses from different places in India ranged from US$ 99.0 to 365.9 (INR 6871 to INR 25,391) [15,24–28]. At first glance, our estimates seem lower than the average for North India previously reported. However, this would not be a fair assessment as there is wide variation in the methodology used for calculating expenditures like the inclusion/exclusion of hospitalization, the severity of disease, co-morbidities, the time frame of studies conducted, poverty in the population, and utilization of public health care.

Ghosh et al. conducted a study in 2021 that analysed the cost of illness studies from 2010 to 2020, focusing on the economic impact of diabetes and its determinants [29]. Their findings indicated that diabetes complications, insulin therapy, treatment in private institutions, and hospitalization events significantly contributed to the overall cost. These findings align with the results of our study. Sharma et al., 2016 highlighted a substantial disparity in the annual direct expenditure between private clinics and government hospitals, amounting to US$ 281.7 (INR 19,552) and US$ 17.3 (INR 1204), respectively [30]. This discrepancy was also observed in our current study. We found that patients consulting in private hospitals and local doctors were spending US $ 270.1 (INR 18,743) and US$ 221.0 (INR 15,339), respectively, while those consulting in government hospitals were spending only US$ 27.9 (INR 1934) annually on diabetes care. Eshwari et al., in 2022 and Sharma et al., in 2016 also reported that patients visiting private health facilities incurred higher costs for diabetes-related care [24,30]. Olickal et al. underscored travel expenses as the primary out-of-pocket (OOP) expenses for individuals seeking care at public facilities [31]. Furthermore, Pham et al. and Li et al. identified diabetes duration and disease-related complications as key determinants of cost [32,33]. The overall themes of these reported determinants are consistent with the results of our analysis.

The annual direct healthcare expenditure for the care of type 2 diabetes patients from low-middle income countries like Nigeria, Zimbabwe, Ghana, Ethiopia, Pakistan, and Kenya also varied widely (from US$106.3 to US$ 646.7) [34–38]. Still, it was roughly comparable to the above mentioned Indian studies and our current study (~$100).

Table 3
Quality of Care received, Control of Diabetes achieved and Cost of Care(CBE) incurred by Type of Care Provider*.

	All subjects (n = 843)	Government Hospital (n = 292)	Private Hospital (n = 56)	Local Doctor (n = 244)	Alternative Medicine (n = 26)	Self (n = 225)
Total yearly expenditure (CBE; US $)	116.4 (93.8–138.9)	27.9 (18.3–37.4)[a]	270.1 (154.8–385.3)[a,b]	221.0 (185.3–256.8)[a,c]	26.1 (6.6–45.3)[b,c,d]	77.9 (49.8–106.0)[a,b,c,d]
Table 3a: Yearly expense as proportion of family income (%)						
Overall	3.6(2.9–4.3)	1.2(0.7–1.7)	8.3 (4.8–11.8)	6.4 (4.8–8.0)	1.0 (0.2–1.8)	2.4 (1.8–3.0)
High income (> Rs 41,430 p.m.) (n = 133)	1.9 (1.0–2.8)	0.2 (0.1–0.4)[a]	6.6 (2.2–10.9)[a,b]	3.2 (2.2–4.2)[a,c]	0.1 (0.0–0.2)[a,b,c,d]	1.5 (1.0–2.0)[a]b,c,d
Middle income (Rs 10,356 to 41,430 p.m.) (n = 451)	3.5 (2.9–4.1)	0.9 (0.4–1.4)[a]	5.3 (2.9–7.8)[a,b]	6.3 (5.4–7.1)[a,c]	0.9 (0.0–1.9)[b,c]	2.5 (1.3–3.7)[a,c]
Low income (< Rs 10,356 p.m.) (n = 258)	5.2 (3.5–6.8)	2.3 (1.5–3.0)[a]	19.1 (7.8–30.4)[a,b]	11.8 (4.1–19.5)[a,c]	2.1 (0.6–3.7)[b,c]	2.6 (1.4–3.9)[b,c]
Table 3b: Compliance with "processes of care" within last 1 year (%)						
Nutrition counselling	56.0 (51.7–60.2)	74.1 (65.9–80.9)[a]	72.9 (52.3–86.8)[b]	79.6 (70.3–86.5)[c]	51.4 (26.2–75.9)[c,d]	1.2 (0.3–5.1)[a,b,c,d]
Special care for feet	13.4 (10.3–17.3)	17.3 (13.1–22.4)[a]	15.4 (7.2–30.2)[b]	19.5 (14.0–26.6)[c]	12.7 (3.1–40.1)[d]	0.8 (0.1–5.8)[a,b,c,d]
Special care for weight loss	20.1 (16.6–24.2)	23.6 (17.6–30.8)[a]	40.1 (25.1–57.3)[a,b]	30.1 (21.4–40.4)[c]	0[a,b,c]	1.7 (0.5–5.3)[a,b,c]
Diabetes education (more than 15 min)	11.3 (8.6–14.7)	12.8 (8.4–19.0)[a]	16.6 (6.2–37.6)[b]	18.0 (13.5–23.5)[c]	6.1 (0.7–37.0)	0.8 (0.1–6.1)[a,b,c]
Exercise program	50.5 (46.2–54.8)	63.5 (52.4–73.3)[a]	79.2 (63.7–89.2)[b]	74.4 (65.8–81.5)[a,c]	20.7 (8.0–43.9)[a,b,c,d]	2.1 (0.7–6.0)[a,b,c,d]
Smoking cessation (n = 120)[#]	47.2 (40.3–54.3)	73.2 (46.9–89.4)[a]	89.3 (62.5–97.7)[b]	69.0 (56.9–78.9)[c]	–	3.2 (0.4–21.3)[a,b,c]
Aspirin intake	9.7 (7.4–12.7)	12.2 (7.9–18.5)[a]	27.6 (16.4–42.6)[a,b]	12.8 (8.7–18.6)[b,c]	0[a],[b,c]	0.1 (0.0–0.6)[a,b,c]
Pneumococcal/Influenza vaccine	0.7 (0.2–1.9)	1.3 (0.4–4.0)[a]	0.6 (0.1–4.8)[b]	0.6 (0.1–2.8)[c]	0[a],[b,c]	0[a,b,c]
Table 3c: Compliance with Monitoring guidance within last 1 year (%)						
Weight checked (at every visit)	21.3 (15.3–28.7)	18.2 (9.7–31.6)[a]	47.1 (31.4–63.4)[a,b]	36.8 (25.3–50.0)[a,c]	18.5 (2.5–67.0)[d]	0.8 (0.1–5.4)[a,b,c,d]
BP checked (at every visit)	57.9 (52.2–63.4)	73.2 (64.6–80.3)[a]	93.6 (80.2–98.2)[b]	83.6 (73.1–90.5)[a,c]	37.7 (13.9–69.5)[a,b,c,d]	1.8 (0.5–6.1)[b,c,d]
Urine examination	13.4 (10.5–17.0)	14.0 (9.7–19.8)[a]	26.5 (16.0–40.5)[a]	14.1 (10.3–9.1)	32.6 (11.2–64.9)d	6.8 (3.0–14.5)[b,d]
Microalbuminuria	0.7 (0.3–1.8)	1.2 (0.3–4.7)[a]	0.3 (0.0–2.6)[b]	0.8 (0.1–5.2)[c]	0a,b,c	0a,b,c
Eye examination	1.2 (0.5–2.9)	1.1 (0.3–4.5)[a]	0[a,b]	1.7 (0.6–5.0)[c]	0a,c	1.0 (0.2–4.2)[b]
ECG	10.3 (7.6–13.8)	10.2 (6.2–16.4)	16.6 (7.0–34.5)	13.0 (9.4–17.8)[c]	6.6 (0.9–35.3)	6.1 (2.4–14.5)[c]
TMT	0.5 (0.1–1.7)	0.6 (0.1–4.3)[a]	0.2 (0.0–2.0)[b]	0.5 (0.1–2.4)[c]	0[a,b,c,d]	0.3 (0.0–1.7)[a,d]
ECHO done	1.8 (1.1–3.1)	2.6 (1.1–6.1)[a]	7.2 (1.8–24.5)[b]	1.3 (0.4–4.4)[c]	0[a,b,c]	0.5 (0.1–2.1)[a,b]
Chest X-ray done	3.8 (2.2–6.4)	3.7 (1.7–7.5)[a]	5.3 (1.2–20.9)[b]	4.2 (2.0–8.9)[c]	0[a],[b,c]	3.5 (1.4–8.6)
HbA1c	19.6 (15.1–25.0)	20.2 (12.2–31.4)[a]	34.1 (22.0–48.8)[b]	28.6 (22.5–35.7)[c]	3.0 (0.3–21.9)[b,c]	6.6 (2.8–14.8)[a,b,c]
Lipid profile	18.1 (14.3–22.7)	16.4 (10.9–23.9)[a]	25.9 (14.0–42.7)	26.2 (20.5–32.8)[a,c]	9.6 (2.1–34.2)	9.7 (4.8–18.6)[c]
Liver functioning test	19.5 (14.1–26.3)	20.6 (12.0–33.0)[a]	26.9 (15.0–43.4)[b]	25.9 (19.1–34.2)[c]	28.1 (7.5–65.1)	7.6 (3.9–14.3)[a,b,c]
Renal functioning test	22.3 (17.1–28.5)	23.3 (15.1–34.1)[a]	33.9 (20.5–50.5)[b]	29.4 (21.8–38.4)[c]	32.6 (11.2–64.9)	8.5 (3.8–17.8)[a,b,c]
Table 3d: Control of Diabetes by Glycaemic, Lipid and Blood Pressure control(n = 800)*						
Mean FBS (mg/dl)	176.3 (166.9–185.6)	176.4 (165.0–187.8)[a]	172.1 (142.3–201.9)[b]	166.0 (149.5–182.6)c	225.1 (185.8–264.3)[a,b,c,d]	184.1 (168.9–199.3)[d]
FBS control[@]	29.8 (26.1–33.7)	31.5 (25.4–38.3)	26.4 (13.8–44.5)	32.2 (23.9–41.9)	16.6 (4.2–47.0)	26.9 (19.3–36.3)
Mean HbA1C (%)	8.9 (8.6–9.2)	8.8 (8.4–9.3)[a]	8.6 (7.9–9.4)b	8.7 (8.2–9.2)[c]	10.6 (9.3–11.9)[a,b,c,d]	9.1 (8.7–9.4)[d]
HbA1C control[&] (%)	41.6 (37.0–46.4)	43.1 (36.4–50.0)	40.8 (25.4–58.2)	46.4 (36.6–56.5)[c]	15.2 (4.0–43.9)c	37.1 (30.4–44.3)
Mean TC (mg/dl)	186.3 (181.8–190.9)	179.2 (171.1–187.2)[a]	172.1 (159.9–184.2)[b]	189.4 (181.2–197.6)[a,b]	196.6 (176.1–217.1)	192.7 (185.6–199.8)[a,b]
TC control[£] (%)	63.5 (58.1–68.6)	67.7 (58.4–75.8)	70.5 (54.4–82.7)	61.3 (53.6–68.5)	64.4 (32.7–87.0)	59.9 (49.6–69.3)
Mean TG (mg/dl)	191.9 (181.7–202.2)	184.0 (170.5–197.6)[a]	157.9 (131.8–184.1)[b]	213.5 (191.9–235.1)[a,b,c]	177.3 (124.8–229.9)	183.5 (166.9–200.2)c
TG control[£] (%)	41.7 (36.5–47.1)	42.4 (32.9–52.5)	54.4 (39.3–68.8)[b]	33.3 (25.6–41.9)[b,c]	48.0 (18.2–79.3)	47.8 (37.8–58.1)c
LDL (mg/dl)	114.5 (110.5–118.4)	109.8 (103.6–116.1)[a]	104.3 (92.5–115.9)[b]	113.6 (106.9–120.3)	128.2 (107.5–148.9)	121.6 (113.4–129.7)[a,b]
LDL control[α] (%)	32.8 (28.6–37.2)	38.2 (30.3–46.8)[a]	39.9 (28.0–53.3)[b]	35.1 (27.6–43.4)[c]	5.7 (1.3–22.0)[a,b,c,d]	25.0 (17.1–35.2)[b,d]
HDL (mg/dl)	45.0 (43.9–46.1)	44.9 (43.3–46.5)	45.4 (41.7–49.0)	44.3 (42.2–46.5)	46.1 (36.4–55.8)	45.8 (43.6–47.9)
HDL control[¥] (%)	48.3 (44.9–51.7)	46.3 (39.5–53.2)	41.0 (25.5–58.6)	46.5 (40.0–53.1)	46.7 (19.4–76.2)	54.6 (46.0–62.9)
SBP (mmHg)	138.9 (136.8–141.1)	138.2 (134.0–142.4)[a]	145.9 (140.6–151.4)[a,b]	138.2 (134.2–142.2)[b]	141.4 (123.7–159.2)	138.9 (136.2–141.8)[b]
SBP control[β] (%)	53.8 (47.6–59.9)	54.6 (42.7–66.0)	37.8 (24.1–53.8)	55.1 (44.6–65.1)	54.2 (29.6–76.9)	54.7 (45.2–63.8)
DBP (mmHg)	90.4 (88.6–92.2)	89.5 (86.5–92.6)	90.6 (86.2–94.9)	89.6 (86.9–92.3)	93.4 (85.2–101.6)	92.2 (89.6–94.9)
DBP control© (%)	51.6 (44.4–58.7)	53.9 (43.7–63.8)	55.6 (34.7–74.7)	52.4 (42.4–62.2)	49.2 (25.0–73.7)	47.0 (36.2–58.2)

*Data are presented as cluster-adjusted mean (95 % CI) or percentage (95 % CI).

FBS= Fasting Blood Sugar; TC = Total Cholesterol; TG = Triglycerides; HDL=High Density Lipoproteins; LDL = Low Density Lipoproteins; SBP=Systolic Blood

Pressure.
DBP = Diastolic Blood Pressure.
#Smoking cessation advice data of subjects who were current smoker.
@FBS control: <125 mg/dl.
&HbA1C control: HbA1c <8 %.
€TC control: <200 mg/dl.
£TG control: <150 mg/dl.
¥HDL control: HDL >40 mg/dl for men and >50 mg/dl for women.
αLDL control: LDL <100 mg/dl.
βSBP control: <140 mmHg.
©DBP control: <90 mmHg[22].
a = 5 % level of significance of Government hospital vs private hospital, Government hospital vs local doctor; Government hospital vs alternative medicine(homeopathic/ayurvedic/naturopathy) and Government hospital vs selfcare.
b = 5 % level of significance of Private hospital vs Local doctor; Private hospital vs alternative medicine (homeopathic/ayurvedic/naturopathy) and Private hospital vs selfcare.
c = 5 % level of significance Local doctor vs alternative (homeopathic/ayurvedic/naturopathy) and Local doctor vs selfcare.
d = 5 % level of significance Alternative (homeopathic/ayurvedic/naturopathy) vs selfcare.

Table 4
Determinants of OOPE on ambulatory diabetes care (CBE; n = 843).

Socio-demographic characteristics	B-coefficient$^{\alpha}$	95 % CI		p-value
Co-variates				
Age (per year increase)	−1.31	−2.83	0.21	0.088
Gender (Male vs Female)	−15.13	−41.61	11.35	0.252
Duration Since (per year increase)	6.04	1.90	10.18	0.006
Medical benefit (received vs. not received)	20.17	−22.87	63.21	0.345
Education (graduate vs. school or lesser)	12.25	−39.80	64.30	0.633
Annual Gross family income (≥0.25 vs. <0.25 million) (n = 842)	25.78	−2.75	54.30	0.075
Comorbidity (any or none)	15.74	−9.49	40.98	0.212
Factors				
Care Provider Facility				
Private health care[a]	190.64	152.73	228.54	<0.001
Public health care[b]	83.32	59.89	106.75	<0.001
Self/Alternate Care	0			
Hypoglycaemic treatment				
OHA use	62.60	32.36	92.84	<0.001
(Insulin and OHA) or insulin Alone	261.66	140.25	383.07	<0.001
No OHA/insulin	0			

Multivariate linear regression analysis; $R^2 = 0.353$; Independent variables were age, gender, duration of diabetes, private health care, medical benefits, educational qualification(graduate vs. lesser as a Kuppuswamy classification), gross family income(≥0.25 vs. <0.25 million annual income as per Kuppuswamy scale), comorbid conditions, OHA and/insulin use. Age and duration were taken as continuous variables while dummy variables were created for other variables. α = Beta coefficient represents the change in cost per unit change in the independent variable for continuous variables like age and duration while it represents the difference between the presence and absence of a factor in case of discrete variables i.e. gender, medical benefit, education, annual gross family income and comorbidity (e.g. Medical benefits received vs not received represents the average difference between those who received medical benefits vs. those who did not after adjustment for co-variates) and Care Provider Place and Hypoglycaemic treatment was taken as factors.
[a] Private health care included private hospitals and local doctors.
[b] Public health care included government hospitals.

As expected, these estimates are much lower than estimates from the United States ($ 5480 to $13,340) [12] and European countries (€499 to €15,299) [39].

Compared to our earlier work on the same subject in the same city [17], estimates of annual direct ambulatory health care expenses were higher by ~32 % (INR 6000 vs INR 7903). If the expenses for the same socioeconomic categories are adjusted for inflation or compared in dollar terms, the expenses are roughly comparable to earlier estimates of more than a decade ago. This indicates that the OOP spending on diabetes has been stable. This may be attributed to improvement in coverage of insurance or other medical benefits, especially in the middle and higher-income groups (40.7 % vs. 48.3 % for higher and middle-income groups) and a higher proportion of subjects attempting to manage by self-care (10 % vs. 17.2 % in the higher and middle-income groups). Alternatively, this could reflect lower costs of medicines with more use of generics dispensed by government pharmacies (*Jan Aushadhi*) and/or lower costs of tests due to stiffer competition and economics of scale.

4.4. Clinical relevance

The findings from this study have important implications for the clinical management of diabetes in urban settings, especially where the burden of the disease is high and the health system is weak. The study shows that the direct out-of-pocket (OOP) expenditure on diabetes care is substantial and varies significantly by income level and type of provider. The low-income groups and those seeking private care bear the highest financial burden, which may compromise their ability to access and afford quality care for diabetes. As a result, many patients may experience poor adherence to treatment, suboptimal glycemic control, and increased risk of complications and morbidity. The study also reveals that a significant proportion of patients resort to self-care or alternative medicine use, which is associated with low expenditure but also low quality and control of diabetes. This may reflect the lack of awareness and education among patients about the importance of regular and appropriate care for diabetes, as well as the perceived or actual unavailability or unaffordability of conventional care. This highlights the need for improving the health literacy and empowerment of patients with diabetes, as well as ensuring the availability and affordability of

Table 5
Increment in direct ambulatory OOP expenditure(CBE) in subjects receiving quality care.

Quality of care	% of the population	Mean difference (US$)	95 % CI	p-value
Achieving Targets of care (n = 800)				
FBS Control[b]	29.8	4.12	−31.8 to 40.0	0.816
Glycaemic Control (HbA1c)[c]	41.6	5.67	−32.9 to 44.3	0.766
TC control[d]	63.5	6.24	−32.6 to 45.1	0.744
TG control[e]	41.7	11.33	−34.6 to 57.3	0.618
Lipid control (LDL)[f]	32.8	32.78	−6.1 to 71.7	0.096
Lipid control (HDL)[g]	48.3	3.16	−37.0 to 43.3	0.873
Lipid control (LDL:HDL control)	14.2	48.55	−15.9 to 113.0	0.134
SBP control[h]	53.8	−5.45	−50.4 to 39.5	0.806
DBP control[i]	51.6	2.19	−42.9 to 47.3	0.922
Good glycaemic, lipid and blood pressure control (achieving – not achieving)	3.7	57.68	−43.4 to 158.7	0.252
Recommended Process of Care[a] (n = 843)				
Nutrition counselling (by doctor/dietitian)	56.0	66.92	30.4 to 103.4	0.001
Special care for feet	13.4	115.86	39.1 to 192.6	0.004
Special care for weight loss	20.1	110.76	37.4 to 184.1	0.004
Diabetes education (more than 15 min)	11.3	88.26	6.1 to 170.4	0.036
Exercise program	50.5	59.87	14.9 to 104.8	0.011
Take Aspirin daily	9.7	138.26	21.7 to 254.8	0.022
Pneumococcal/Influenza vaccine	0.7	320.69	−217.0 to 858.4	0.232
Recommended "process of care" (≥3)[a]	32.0	107.58	56.2 to 158.9	<0.001
Monitoring of tests within last 1 year (n = 843)				
Urine examination	13.4	64.63	−18.1 to 147.3	0.121
Microalbuminuria	0.7	−77.34	−124.3 to 30.4	0.002
Dilated Eye examination	1.2	24.93	−57.8 to 107.7	0.542
ECG	10.3	48.47	−47.1 to 144.1	0.308
TMT	0.5	165.98	−68.4 to 400.4	0.158
ECHO done	1.8	178.36	12.3 to 344.4	0.036
Chest X-ray done	3.8	−10.97	−76.7 to 54.7	0.735
HbA1c	19.6	145.54	57.1 to 234.0	0.002
Lipid profile	18.1	114.49	32.6 to 196.4	0.008
Liver functioning test	19.5	108.50	13.5 to 203.5	0.027
Renal functioning test	22.3	100.76	16.2 to 185.3	0.021

[a] Processes of care for the purpose of this analysis included nutrition counselling, special care for feet, special care for weight loss, diabetes self-management education (more than 15 min), advice for exercise program, advice for aspirin, and pneumococcal influenza vaccine. FBS= Fasting Blood Sugar; TC = Total Cholesterol; TG = Triglycerides; HDL=High Density Lipoproteins; LDL = Low Density Lipoproteins; SBP=Systolic Blood Pressure; DBP = Diastolic Blood Pressure.
[b] FBS control: <125 mg/dl.
[c] HbA1C control: HbA1c <8 %.
[d] TC control: <200 mg/dl.
[e] TG control: <150 mg/dl.
[f] LDL control: LDL <100 mg/dl.
[g] HDL control: HDL >40 mg/dl for men and >50 mg/dl for women.
[h] SBP control: <140 mmHg.
[i] DBP control: <90 mmHg[22].

evidence-based and culturally appropriate care options. The high OOPE for participants of the study who went to public health facilities shows the importance of improving the public health system and making sure that essential medicines, tests, and services for diabetes care are accessible and low-cost.

4.5. Implications

Based on existing Indian and international literature [29,36,37], it can be presumed that the total direct expense on diabetes (including hospitalization, surgery, and other costs) is likely to be 1.5–4 times the annual direct ambulatory health care expenses. Further, indirect expenses may contribute to financial losses 1.5–2.5 times the direct expenses [12,40]. Thus, families with diabetes patients may be losing 10–40 % of their gross family income to expenses related to diabetes care. These calculations may still underestimate the impact, as the estimated percentages are related to the gross family income and not the individual's income. Also, it is common for families to have two or three diabetes patients.

Further, their corresponding proportion is likely worse in lower-income households. If we crudely use our per-patient estimates to project the cost for the country, in that case it may be estimated that India is spending ~10 billion dollars on direct ambulatory costs, 15–40 billion dollars on direct expenses, and 25–100 billion dollars(1–2.5 % of GDP) on all expenses related to diabetes. As highlighted previously, income levels are likely to be lower, and accessibility to care is likely to be worse in the vast majority of the country, making it reasonable to presume that diabetes is having a significant impact on the economics of a substantial proportion of Indian households.

5. Conclusions

The cost data in the present study highlights the economic impact of the disease in the context of the poor quality of care in a capital city with some of the best healthcare infrastructure in the country. These vulnerabilities are inequitable, being worst for the poorest sections of society, and have the potential of pushing a substantial fraction of the population into poverty. These expenses and vulnerabilities can be minimized by improving barriers to seeking healthcare at public facilities, improving health insurance coverage for diabetes patients, promoting the use and quality of generic medicine from Jan Aushadhi shops, and creating guideline-based diabetes care hospital packages, allowing for predictability in timing and expenses for the patients.

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Author contributions

JN conceived the idea, developed the study design, supervised the execution of the study plan, supervised the data analysis and will act as guarantor for the paper. SR was involved with the study design, data analysis. NB and SR drafted the manuscript. SG led the data collection in the community. RY and NB executed the analysis plan and carried out the data analysis. JN and SR were involved in the finalization of the manuscript. All authors listed have reviewed and approve the submitted version of the manuscript. No third-party authors contributed to the manuscript and AI-written text was not used in the paper.

Ethical approval

The project was approved by the Institutional Ethics Committee at Sitaram Bhartia Institute of Science and Research (ref no IEC/SBISR/2015/2).

Novelty statement

Our research paper provides a unique perspective on the cost of diabetes care. Existing studies are mostly based on hospital data, which excludes those visiting smaller care providers/clinics or those on self-care/alternative care. Our study uses data from a community survey including all categories of patients, including those visiting smaller clinics/alternative medicine providers/on self-care. Hence, uniquely, our study provides more accurate and representative estimates, including estimates for categories of patients not included in previous studies. Existing community studies on cost of care gather limited information on "Quality of Diabetes Care" received.

In contrast, our study specifically evaluates cost in the context of diabetes control (glycaemic control, BP control Lipid control) achieved and the processes of care followed. Hence, provides useful information on cost in the context of quality of care received/the glycaemic control achieved. Existing studies provide limited/no information on the socio-economic context of the cost incurred and hence the equity in healthcare accessibility. Uniquely, our study provides cost as a proportion of the income helping us provide estimates of the burden on the family. The study provides estimates from the city of Delhi, which has one of the largest single concentrations of diabetes patients in the world but also provides a unique healthcare setting. The city boasts of all types of health infrastructure in close proximity. Hence, It is presumable that the determinants of care provider choice and related cost are at play with minimum influence of available infrastructure/accessibility. This allows our study to provide unique insight into such determinants as reported. Also, our study evaluates the cost in the context of diabetes control achieved, providing useful information on cost in the context of quality of care received. Furthermore, our study compares cost estimates from the same city where the same group conducted a similar study 18 years ago using a similar study methodology allowing for apple-to-apple comparison on time trends.

Conflict of interest

None to declare.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Dr Jitender Nagpal reports financial support was provided by Indian Council of Medical Research. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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