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Research Article

PHARMACOECONOMIC EVALUATION OF ANTIDIABETIC THERAPY AT A TERTIARY HEALTH CARE INSTITUTION

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ABSTRACT

Objective: The present study was aimed to estimate the direct cost of pharmacotherapy, laboratory tests, and medical tests incurred by patients, to analyze the health-related quality of life (HRQoL) for diabetic patient with macrovascular complications, to estimate the direct health system costs of treating patients with diabetes, to analyze the drug utilization trend of anti-diabetic therapy, to estimate the annual total direct medical costs of managing patients with diabetes, and to evaluate pharmacoeconomic impact on outcomes or beneficence of diabetic therapy.

Methods: A prospective cross-sectional study at SRM Medical College, Hospital and Research Centre, Kattankulathur – General Medicine Department with a sample size of 200 patients.

Results: During study, 200 diabetic patients were enrolled based on the inclusion and exclusion criteria at SRM Medical College and Hospital. Out of 200 diabetic patients (100%), 83 (41.5%) patients were females, and 117 (58.5%) patients were males. Out of 200 (100%) diabetic patients, 18 (9%) of the patient were within the age group of 20–39 years, 78 (39%) of the patients were within the age range of 40–59, the group with the highest frequency was aged from 60 to 79 with 93 (46.5%) patients while the age group of 80–99 had the lowest frequency of 11 (5.5%) of patients. The patient sample had 14 (7%) type 1 diabetic patients out of which two patients (14.3%) were females and 12 (85.7%) were males. A total of 186 (93%) patients had type 2 diabetes where 81 (43.5%) were females and 105 (56.5%) were males. Drug utilization trend: In the patient sample, anti-diabetic drugs were the most frequently used. Oral and parenteral dosage forms were used which included insulin administration subcutaneously and intravenously together with intravenous fluids to correct cases of hyperglycemia and hypoglycemia. HRQoL is the measure of patient value in terms of impact of disease and its treatment on physical functioning and psychological well-being. Out of 200 patients, 25% had severe problems with mobility.

Conclusion: Diabetes is characterized by a very high-cost burden. Education on the prevention and management of diabetes must be prioritized. It must be provided to the diabetic patients and the society at large. Therefore, it is suggested that health-care providers and policy-makers must put more attention to the factors that result in an increased hospital care. A lower financial burden on patients would greatly increase the treatment compliance, complications, and comorbidity progression. This will result in a reduction of diabetes economic burden on patients, society, and health-care system. Further multicenter studies can be carried out in a larger population in different geographical regions in India or it can be done at a national scale.

Keywords: Diabetes, Health, Co-morbidity, Compliance.

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INTRODUCTION

The health-care system currently is evolving from the conventional systems due to the advancement in medical technology, for instant, diagnostic and therapeutic options thereby resulting in an increased financial burden on patients and the society at large [1]. Despite the improved quality of care provided in the health sector globally, advanced medical technology has significantly increased the operating cost and the daily medical expenditure [2]. Diabetes is usually treated for a lifetime; hence, it is characterized by high costs due to its chronicity, complications, and high resource utilization. Health outcomes research and patient-reported outcomes especially, aim at understanding patient value in terms of the impact of disease and its treatment on physical functioning and psychosocial well-being, known also as health-related quality of life (HRQoL). It is the description and analysis of the costs of drug therapy to health care systems and society [3]. In India, the situation has worsened claiming nearly 62 million Indian population with an average onset of 42.5 years and it is expected to rise to 109 million cases by 2035 [4]. Pharmacoeconomics is a subfield of health economics. The pharmacoeconomics field consists of comparing outcomes, whether clinical, humanistic, or economic and resource consumption or costs of pharmaceutical programs or services to the next best alternatives from the selected perspectives [5]. The main goal for this approach is to determine, measure value, and establish the link between both outcomes and resource consumption for the relative worth of selected services, programs, and pharmaceutical products can be determined. The combination of cost and outcome analysis is in different forms [Table 1].

METHODS

Study design

This was a prospective cross-sectional study.

Study site

This study was conducted at the SRM Medical College, Hospital and Research Centre, Kattankulathur – General Medicine Department.

Sample size

The sample size was n=200 patients.

Ethical committee approval

Ethics clearance number: 1278/IEC/2017.

Inclusion criteria

- Patients with either type 1 or type 2 diabetes mellitus on therapy
- Inpatients and outpatients
- Sex – male and female

- Age – 20–90 years
- Patients willing to give informed consent.

Exclusion criteria

The following criteria were excluded from the study:

- Pregnant and lactating women
- Patient age <20 years
- Patients not willing to give informed consent.

The personnel costs for physicians, pharmacists, and nurses will be calculated. The average time for completion of 15 random observations for completion of tasks such as consultation, dispensing, and blood tests was determined and recorded. The salary of health professionals will be obtained from the accounts department of the hospital. The average will be considered when necessary and the mean salary per minute is calculated [Table 2].

Equation 4

Mean salary/min=Annual salary/Hours/week*no of weeks/annum*6

- In the calculation, the respective number of visits will be considered. Furthermore, the transport cost for each patient will be computed for all visits using the standard tariff and patient destination as indicated in the given residential address in the patient's address
- Drug costs are going to be obtained from the pharmacy department of the hospital and therefore the cost per defined daily dose is calculated considering the duration of therapy. Furthermore, the cost of diagnosis will be obtained from the hospital laboratory. All the above-mentioned costs will be added for each patient and for all patients to obtain the total. The average cost per patient was then calculated and recorded.

Table 1: Types of pharmacoeconomics evaluation techniques

Method	Cost measurement	Outcome measurement	Decision rule
Cost–minimization analysis	Monetary	Outcomes of alternatives assumed identical	Lowest monetary cost
Cost-effectiveness analysis	Monetary	All outcomes translated into monetary units	Net monetary gain
Cost utility analysis	Monetary	Non-monetary physical units of effectiveness	CE ratios using incremental of marginal analysis
Cost utility analysis	Monetary	Utility values and quality adjusted life years (QALY)	Cost per QALY and league tables
Cost outcomes analysis or cost-consequence analysis	Monetary	Combination of quality of life and natural units	Choice left to the decision maker

Table 2: Types of outcomes

Clinical outcomes	Humanistic outcomes	Economic outcomes
Final Mortality e.g. • Number of deaths/lives saved • Life years gained • Cure rate Morbidity, for example, stroke, myocardial infarction, days of hospitalization, days of disability Intermediate mortality, for example, · Cases identified · Response rate Morbidity, for example, BP, serum cholesterol, drugs correctly prescribed	Intangibles • Quality of life • Utility (QALY)	Utilization of health resources e.g. • Hospital days • Physician visits • Medication • Services such as nursing or food • Delivery Non-monetary • Absenteeism • Job changes • Time for returning to work • Productivity

RESULTS

Demographic variables

The project entitled "pharmacoeconomic evaluation of anti-diabetic therapy at a tertiary health care institution" was conducted as described in the previous chapters for 6 months. During the study, 200 diabetic patients were enrolled based on the inclusion and exclusion criteria at SRM Medical College and Hospital. The data on patients were analyzed statistically and the outcomes are presented in this section.

Gender distribution

Out of 200 diabetic patients (100%), 83 (41.5%) patients were females, and 117 (58.5%) patients were males. In this study, male patients had the highest frequency. There were more males than females in the study.

Age distribution

Age-wise distribution of patients was enrolled in the study. Out of 200 (100) diabetic patients, 18 (9%) of the patient were within the age group of 20–39 years, 78 (39%) of the patients were within the age range of 40–59, the group with the highest frequency was aged from 60 to 79 with 93 (46.5%) patients while the age group of 80–99 had the lowest frequency of 11 (5.5%) of patients.

Diabetes type distribution

Patients enrolled were either type 1 diabetic patient or type 2 diabetic patients. The patient sample had 14 (7%) type 1 diabetic patients out of which two patients (14.3%) were females and 12 (85.7%) were males. A total of 186 (93%) patients had type 2 diabetes. Eighty-one (43.5%) were females and 105 (56.5%) were males.

Comorbid conditions of the patients

The comorbid conditions that were observed in the patients with diabetes mellitus enrolled were collected in the patient profile form that was used in data collection [Table 3].

Table 3: Comorbid conditions of patients

Comorbid conditions	Frequency (n)	Percentage
SHTN	19	9.5
CAD	8	4
CKD	13	6.5
DFU	35	17.5
CKD/CAD	9	4.5
NIL	18	9
SHTN, HYPOTHYROID/CKD	13	6.5
SHTN/CAD/CKD	21	10.5
SHTN/CAD/CVA/MI	16	8
SHTN/CAD/CKD/CVA	15	7.5
CAD/CKD/Retino/Seizure	20	10
SHTN/CKD/Retino/NEUR/DLP	5	2.5
HIV/NEURO,CKD/CVA	1	0.5
LEPROSY/CAD/DFU	1	0.5
SHTN/CKD,CAD/CVA/DLP	4	2
SHTN/Neuro/DLP/CKD/PVD/DVT	2	1
Total	200	100.0

CAD: Coronary artery disease, CKD: Chronic kidney disease, DFU: Diabetic foot ulcer, CVA: Cerebrovascular accident, DLP: Dyslipidemia, PVD: Peripheral vascular disease, DVT: Deep vein thrombosis, MI: Myocardial infarction, HIV: Human immunodeficiency virus, SHTN: Systolic hypertension

Table 4: Descriptive statistics

Characteristics	T1DM n= 14	T2DM n= 186	All patients n =200
Age (mean±SD)	52.8±20.1	59.9±19.6	58.6±19.8
<55 years (%)	8 (57.1)	88 (47.3)	96 (48)
65+ years (%)	6 (48.9)	98 (52.7)	104 (52)
Male (%)	12 (85.7)	105 (56.5)	117 (58.5)
Female (%)	2 (14.3)	81 (43.5)	83 (41.5)
Smoking (%)	3 (21.4)	19 (10.2)	22 (11)
Alcohol (%)	4 (28.6)	32 (17.2)	36 (18)
Diet			
Mixed	11 (78.6)	179 (96.2)	190 (95)
Veg	3 (21.4)	7 (3.8)	10 (5)
Blood pressure>140/90 mmHg	5 (35.7)	90 (48.4)	95 (47.5)
HbA1c < 6.0%	8 (57.1)	119 (64)	127 (63.5)
cAG> 140mg/dl	5 (35.7)	109 (58.6)	117 (58.5)
RBS> 140mg/dl	11 (78.6)	136 (73.1)	147 (73.5)
Tchol> 200md/dl	3 (21.4)	34 (18.3)	37 (18.5)
HDL<40mg/dl	7 (50)	24 (12.9)	31 (15.5)
TG> 150mg/dl	2 (14.3)	41 (22)	43 (21.5)
Prescribed therapies			
Monotherapy	13 (93)	51 (27.4)	64 (32)
Double therapy	1 (7.1)	62 (33.3)	63 (31.5)
3+ drugs	––	73 (39.2)	73 (36.5)
Co-morbidity			
No co-morbidity (%)	6 (42.9)	12 (6.5)	18 (9)
1 comorbidity (%) and 2+ comorbidities (%)	4 (28.6)	71 (38.2)	75 (37.5)
Length of stay days			
Median (IQR)	7 (3–22)	9 (4.5–15)	7 (3–12)
Hospitalization costs (USD)			
Average cost per admission (95%C1)	177.5 (98–257)	134.5 (82–187)	130 (85–75)
Minimum-Maximum	(45–400)	34–467	248.5 (30–467)
Median cost per admission (IQR)	125 (40–210)	251.5 (113–390)	252.5 (105–400)
Total patients<65 years cost	590	4,700	8,700
Total social security cost	904	2,300	3,600
Payment method			
Out of pocket cash	12 (85.7)	127 (68.3)	139 (69.5)
State paying (social security scheme)	3 (21.4)	19 (10.2)	21 (10.5)
Medical insurance	4 (28.6)	32 (17.2)	36 (18)

Cost from patient perspective, IQR: Interquartile range, SD: Standard deviation, cost in USD United State dollars $1: ₹60, social security

Table 5: Estimated mean hospitalization costs for diabetic patients

Patient characteristics	Discharged Mean cost (95% C1) n (% discharge)	Mean cost (95% C1) n (% discharged)
Women		
<65 years of age	467 (117,828) 18 (69.2)	308 (101,691) 8 (30.8)
>65 years of age	137 (197,349) (96)	424 (202,505) (4)
Men		
<65 years of age	443 (116,866) 99	386 (289,681) 0.99
>65 years of age	120 (110,367)	286 (184,440)
Procedures		
No procedure	114 (99,380) 98	68 (58,113) 2
Hemodialysis	347 (290,650) 95	479 (401,730) 5
Physiotherapy	56 (40,125) 98	73 (47,146) 2
Amputation	130 (103,238) 99	537 (283,996) 1
Surgery	185 (375,512) 86	106 (235,345) 14
Blood transfusion	116 (100,256)	112 (245,356)
Wound care	288 (204,414)	158 (103,315)

Forward stepwise regression analysis of variables predictive of hospitalization cost [Tables 6 and 7]

Stepwise regression analysis of variables such as Prescribed therapies, procedures and co-morbidities of hospitalization cost are discussed under [Table 6] and also the Estimated cost for individual drug for patients on drugs per annum is discussed in [Table 7].

Table 6: Regression analysis n=200

Variables	Coefficient	Std error	p-value
(Intercept) Age			
Reference:<65 years of age	5.59	0.27	<0.001
65+ years	–0.29	0.08	
Prescribed therapies			
3+ therapies	1.66	0.23	<0.001
2 therapies	1.24	0.25	<0.001
Procedures			
Wound care	0.78	0.20	<0.001
Amputation	1.16	0.35	<0.001
Dialysis	0.65	0.18	<0.001
Physiotherapy	0.22	0.10	0.026
Comorbidity			
2+ co-morbidities	0.32	0.14	0.026
Systolic blood pressure	–0.002	0.001	0.031

Drug utilization trend

In the patient sample, anti-diabetic drugs were the most frequently used. Oral and parenteral dosage forms were used which included insulin administration subcutaneously and intravenously together with intravenous fluids to correct cases of hyperglycemia and hypoglycemia. Due to the presence of comorbid conditions, the cost burden of drugs increased, and the percentage distribution is shown in the diagram below [Table 8].

Table 7: Estimated cost for individual drug for patients on drugs per annum

Drug	Total cost	% drug cost	Number of patients	% patients
Metformin	51,810 (863.5)	10.7	147	53
Glimepiride	47,227 (787.11)	14.3	67	33.5
Glipizide	30,408 (506.8)	3.3	33	16.5
Saxagliptin	11,340 (189)	1.2	25	12.5
Sitagliptin	9474 (157.90)	1	58	29
Vildagliptin	38,451 (640.85)	4.2	43	21.5
Voglibose	2,034 (33.90)	0.2	13	6.5
Glimepiride+metformin	127,191.6 (2119.86)	13.9	99	49.5
Metformin+sitagliptin	58,710 (978.50)	6.4	78	39
Metformin+vidagliptin	20,588 (343.14)	2.3	68	34
Metformin+voglibose	10,961.4 (182.69)	1.2	21	10.5
Other diabetic drugs	49,680 (828.0)	5.4		
Insulin	170,588.4 (2843.14)	18.7	43	21.5
Other non-diabetic agent	285,653.4 (4760.89)	31.3	171	85.5
Total	914,116.8 (15235.28)	100		

Table 8: Cost of illness for patients

Cost components	Total cost of drug INR, USD	% total illness cost
Drugs	914,116.8 (15,235.28)	57.7
Transport	26,610 (443.5)	1.7
Diagnostic tests	72,066 (1,201.1)	4.5
Procedures	438,051 (7,300.85)	27.7
Personnel cost	133,267.2 (2,221.12)	8.4
Total	1,584,111 (26,401.85)	100

Table 9: Characteristics of patients' diabetic complications

Complications and risk factors	Diabetic patients n=200
Diabetes duration (years), mean (SD)	22.1 (14.2)
Body mass index ,kg/m^2, mean (SD)	25.8 (4.8)
Smoking	22 (11)
Alcohol	36 (18)
Complications	
Impaired vision	28 (14)
Myocardial infarction	33 (16.5)
Angina	19 (9.5)
Nephropathy	49 (24.5)
Foot ulcer	41 (20.5)
Amputation	37 (18.5)
Stroke	19 (9.5)
Neuropathy	17 (8.5)
Other	53 (26.5)
None	19 (9.5)

Table 10: Distribution of levels of perceived problem in each of the dimensions of EQ-5D descriptive system in diabetic patients

levels of perceived problem	Type 1 and type 2 patients (n=200), Levels of perceived problem n (%)		
Dimension	1*	2*	3*
Mobility	80 (40)	78 (39)	50 (25)
Self-care	110 (55)	60 (30)	30 (15)
Usual activities	97 (48.5)	76 (38)	27 (13.5)
Pain/discomfort	40 (20)	87 (43.5)	73 (36.5)
Anxiety/depression	57 (28.5)	68 (34)	75 (37.5)

*Level 1: No problem, 2: Moderate problem, 3: Severe problem

HRQoL

HRQoL is the measure of patient value in terms of the impact of disease and its treatment on physical functioning and psychological well-being. The data in this section show the diabetes complications and their influence on the HRQoL. This was analyzed using the linear regression model and the binomial logistic regression of responses to the EQ-5D descriptive system [Tables 9 and 10].

Out of 200 patients, 25% had severe problems with mobility. Most of these patients had a history of amputation once or twice, either toe, or below-knee amputation. About 39% of the patients had reported having moderate problems in mobility while 40% of the patients had no problems at all. In self-care, 15% of the patients had severe problems and had to rely on family members and caregivers, 30% had some level of difficulty, and 55% of the patients had no problem at all. About 13.5% of patients had problems with usual activities, 46.5%, and 36.5% had moderate to severe pain and discomfort, respectively. Furthermore, 34% and 37.5% of the patients suffered from moderate to severe depression [Tables 11-13].

DISCUSSION

Diabetes is a metabolic disorder characterized by high cost since its a chronic condition treated for a lifetime, complications, and high resource utilization. Diabetes is an awfully expensive disease for the patient and the state health-care system. The patients' socio-demographic characteristics, resource utilization, that is, medical comorbidity, medical complications, and outcome (discharged or decrease), prescribed treatment, and procedures increase the total hospital cost.

Out of 200 diabetic patients (100%), 83 (41.5) patients were females, and 117 (58.5%) patients were males. In this study, male patients had the highest frequency. There were more males than females in the study. Eighteen (9%) of the patients were within the age group of 20–39 years, 78 (39%) of the patients were within the age range of 40–59, the group with the highest frequency was aged from 60 to 79 with 93 (46.5) patients while the age group of 80–99 had the lowest frequency of 11 (5.5%). Patients enrolled were either type 1 diabetic patient or type 2 diabetic patients. The patient sample had 14 (7%) type 1 diabetic patients out of which 2 (14.3%) were females and 12 (85.7%) were males. A total of 186 (93%) patients had type 2 diabetes out of which 81 (43.5%) were females and 105 (56.5) were males.

The comorbid conditions of the 200 patients of the study were: About 58.5% of the patients had hypertension and hence anti-hypertensive drugs were prescribed and some of them were of beneficence in the kidney by reducing volume overload for patients who have both hypertension and chronic kidney disease (CKD). In diabetic patients who had CKD, mostly insulin was prescribed. Any drug that has nephrotoxic effects is contraindicated as they exacerbate sugar levels. Cardiovascular disorders had the highest frequency as a comorbid condition and they further increased the cost burden to the patient. Some patients were placed on hemodialysis and others

Table 11: Linear multivariate regression of EQ-5D index

n	Type 1, 14, Coefficient (95% C1)	P>|t|	Type 2, 186, Coefficient (95% C1)	P>|t|
Constant	1.092 (0.921 to 1.263)	<0.001	0.990 (0.787 to 1.193)	<0.001
Sex (male=0, female=1)	0.041 (–0.023 to 0.105)	0.210	0.024 (–0.016 to 0.064)	0.240
Age (in 10 years)	–0.003 (–0.022 to 0.016)	0.749	0.0004 (–0.017 to 0.017)	0.967
Impaired vision (no=0, yes=1)	–0.063 (–0.169–0.044)	0.245	–0.012 (0.074 to 0.051)	0.711
Ischemic heart disease (no=0, yes=1)	–0.181 (–0.331 to –0.031)	0.019	–0.037 (–0.103 to 0.030)	0.276
Proteinuria (no=0, yes=1)	0.089 (–0.036 to 0.215)	0.161	0.043 (–0.019 to 0.106)	0.174
Foot ulcer (no=0, yes=1)	–0.083 (–0.271 to 0.105)	0.383	–0.016 (–0.134 to 0.101)	0.783
Stroke (no=0, yes=1)	–0.291 (–0.475 to –0.108)	0.002	–0.135 (–0.247 to –0.023)	0.018
Neuropathy (no=0, yes=1)	–0.358 (–0.535 to–0.180)	<0.001	–0.187 (–0.316 to –0.057)	0.005
Body mass index (kg/m2)	–0.004 (–0.008 to 0.001)	0.123	–0.002 (–0.007 to 0.002)	0.307
Disability pension (no=0, yes=1)	–0.111 (–0.191 to –0.030)	0.008	–0.100 (–0.153 to –0.046)	<0.001
Number of hospital admissions during the past 6 months	0.003 (–0.042 to 0.049)	0.880	–0.028 (–0.076 to 0.020)	0.255
Receives help from others (no=0, yes=1)	–0.090 (–0.217 to 0.037)	0.166	–0.123 (–0.185 to –0.060)	<0.001
Hypoglycemia index*	–0.023 (–0.071 to 0.025)	0.337	–0.004 (–0.039 to 0.032)	0.839
Fear of hypoglycemia** (small=0 , large=1)	–0.021 (–0.071 to 0.025)	0.432	–0.078 (–0.129 to –0.028)	0.003
Limitations at work** (small=0, large=1)	–0.023 (–0.089 to 0.043)	0.494	–0.087 (–0.148 to –0.025)	0.006
Limitations socially** (small=0, large=1)	–0.107 (–0.188 to –0.026)	0.010	–0.002 (–0.049 to 0.046)	0.944

*Self-reported episodes of hypoglycemia, with four levels of severity (level 1: Hypoglycemia cured with the intake of, for example, fluid containing sugar; no help required, level 2: Hypoglycemia cured with the intake of, for example, fluid containing sugar; help from others required, level 3: Hypoglycemia with help from doctor required (no hospital admission), level 4: Hypoglycemia resulting in hospital admission), then added with severity weights (level 1*1, level 2*2, level 3*3, level 4*4), and finally divided into three groups: 0, 1–11 and 12 to max. Self-reported on a scale from 1 to 5 (1=not at all, 5=very much), recorded to two levels (> and <2.5 due to imputed values having values with decimals)

Table 12: Multivariate logistics regression of responses to the ED-5D items in diabetic patients: Odds ratio 95% CI, EQ 5D distribution

Items in diabetic patients	Mobility	Self-care	Usual activities	Pain/ discomfort	Anxiety/ Depression
Sex: Male=0 Female=1	0.48 (0.38–1.21)	0.59 (0.23–1.54)	*0.47 (0.25–0.88)	0.82 (0.53–1.27)	0.91 (0.54–1.52)
Age in 10 years	*1.36 (1.03–1.80)	0.83 (0.55–1.25)	1.34 (1.00–1.80)	1.03 (0.83–1.24)	*0.78 (0.62–0.99)
Impaired vision: Normal=0 Reduced=1	2.96 (1.44–6.10)	2.99 (0.77–6.75)	0.89 (0.39–2.04)	––	1.46 (0.71–3.01)
Ischemic heart disease: No=0,Yes=1	1.97 (0.91–4.25)	1.77 (0.54–5.86)	1.14 (0.48–9.39)	2.51 (1.27–4.97)	1.15 (0.56–2.50)
Proteinuria No=0,Yes=1	––	––	––	––	0.42(0.14–1.29)
Foot ulcer	0.32 (0.07–1.39)	0.73 (0.11–4.67)	2.11 (0.48–9.39)	2.18 (0.54–8.79)	*7.00 (1.53–31.97)
Stroke No=0,Yes=1	3.50 (1.13–10.82)	––	––	––	––
Neuropathy No=0,Yes=1	12.07 (3.30–44.12)	2.74 (0.57–8.95)	3.08 (0.84–11.26)	Predicts correctly#	1.29 (0.40–4.16)
BMI Kg/m^2	1.12 (1.05–1.19) **	––	––	––	––
Number of hospital visits/ admissions in past 6 months	––	––	––	––	*1.87 (1.14–3.07)
Hypoglycemic index	––	––	––	1.68 (1.13–2.49)	1.08 (0.7–1.68)
Fear of hypoglycemia Small=0, Large=1	––	––	––	––	***5.76 (3.36–9.87)
Limitations at work; small=0, Large=1	––	––	***6.95 (3.95–13.56)	––	––
Limitations socially: Small=0, Large=1	––	––	1.33 (0.67–2.62)	–––	––
Nephropathy dialysis: No=0, Yes=1	3.96 (2.05–8.09)	2.11 (0.56–7.11)	0.73 (0.12–4.56)	1.23 (2.31–9.87)	6.71 (1.97–9.67)
Log likelihood	–136.08	–66.13	–136.85	232.10	–187.32

*p<0.05, **p<0.01, ***p<0.001, #All patients reporting neuropathy also reports having problems in PAIN/DISCOMFORT dimensions of the EQ-5D. Cells with dotted line indicate that the variable was not included in the model. ##Self-reported episodes of hypoglycemia, with four levels of severity (level 1=hypoglycemia cured with the intake of, for example, fluid containing sugar; no help from others required, level 2=hypoglycemia cured with the intake of, for example, fluids containing sugar; help from others required, level 3=hypoglycemia with help from the doctor required (no hospital admission), level 4=hypoglycemia resulting in hospital admission); added with severity weights (level 1*1, level 2*2, level 3*3, level 4*4) and finally divided into three groups: 0, 1-11 and 12 to max. ###Self-reported on a scale from 1 to 5 (1=not at all, 5= very much), recorded to two levels (> and < than 2.5 due to imputed values having values with decimals)

on conservative treatment. One case was because of chronic use of NSAIDs. Regular screening of diabetic patients at risk of nephropathy might and the routine monitoring of renal functions will improve the risk of the patient developing more complications as the disease progresses.

The high cost of therapy results in poor patient compliance by some patients thus, leading to other complications in addition to renal problems which affects the quality of life adversely. Diabetic foot ulcer, if not treated properly will result in amputation, toe or below-knee amputation, and also the risk of developing another case of

Table 13: Mean EQ-5D index utility values with and without diabetes-related complications

Number of complications	Type 1 diabetes			Type 2 diabetes		
	EQ-5D index	95% CI	n	EQ-5D index	95% CI	n
0	0.90	0.88–093	6	0.85	0.82–0.8	12
1	0.76	0.66–0.86	4	0.80	0.75–0.85	71
≥2	0.55	0.37–0.73	4	0.64	0.56–0.71	103
Any complications	0.68	0.59–0.77	8	0.73	0.69–0.78	174
All patients	0.83	0.79–0.87	14	0.81	0.79–0.83	186

ulcer or delayed wound healing which results in increased length of stay. Neuropathy consisted of 8.5% of cases that were recorded while retinopathy cases were 14% of the population sample.

Measures such as the diabetic compatible lifestyle improve compliance to the need of medication to be taken into consideration to prevent the complications associated with Diabetes, thereby, subsequently improving the quality of life. Other modalities entail possible home visits by the social workers or community pharmacy workers to improve patient compliance even though the procedure may result in an increased cost burden. It should be noted that the cost beneficence of such programs must also be considered.

The total cost of illness as stipulated in this study results implied that the estimated total cost of illness was (INR 5,584,111), USD 26401.85 for all the 200 patients. The average cost per year per patient is INR (15,180) USD $253, transport accounted for (INR 26,610) USD $443, diagnostic tests (INR 72,066) USD $1,201, procedures (INR 438,051) USD $7300.85, and personnel cost (INR 133,267.2) USD $2,221.2. This considers the direct cost of therapy that is the procurement cost of drugs, transport cost, diagnostic test cost, personnel cost of health professionals in the event of hospitalization or routine hospital visits, and check-ups. The average cost per year represents 41.1% of the yearly per capita income. The indirect cost of diabetes disease management was excluded from the study, however spending about 40.6% of the annual per capita income on disease management is a great economic burden. The total cost of drug procurement was (INR 914,116.8) USD 15,235.28 of the total cost of illness. This is a ridiculously huge amount and therefore any measures that can be taken to reduce the financial load and promote more rational drug selection such as economic evaluation of therapy, regular updates of the formulary, and evidence-based standard treatment guidelines, will be most valuable in ensuring effective resource utilization.

The effects of blood glucose controlling diabetes treatment are measured in terms of glycosylated hemoglobin that reflects mean blood glucose levels during the recent 2–3 months. Having uncontrolled blood glucose levels over time leads to diverse consequences which may be short-term complications defined as symptoms directly caused by hyperglycemic or hypoglycemic episodes, long-term microvascular or macrovascular complications, and loss of life years.

Long-term complications lead to decreased quality of life. The cost for reduction of HbA1c values by 1% ranges from (INR 6,900) $115-$164 (9,840). This value is cost-effective when compared to overall cost savings that have been estimated to result from a 1% HbA1c reduction which amounts to $1,200 (INR 72,000).

Out of 200 patients, 25% had severe problems with mobility. Most of these patients had a history of amputation once or twice, toe or below-knee amputation. About 59% of the patients had reported having moderate problems in mobility while 40% of the patients had no problem at all. In self-care 15% of the patients had severe problems and had to rely on the family members and caregivers, 30% had some level of difficulty, 55% of the patients had no problem at all. About 13.5% of patients had problems with usual activities, 46.5%, and 36.5% had moderate to severe pain and discomfort, respectively. Furthermore, 34% and 37.5% of the patients suffered from moderate to severe depression. The mean EQ-5D index score was 0.83 (SD=0.24) in type 1 diabetes and 0.81 (SD=0.22) in type 2 (p=0.32). For patients without reported complications, the mean EQ-5D index scores were 0.90 in type 1 diabetes and 0.85 in type 2 diabetes. The presence of one complication decreased values to 0.76 and 0.80. With two or more diabetes-related complications, values were 0.55 and 0.64. HRQoL was largely dependent on the presence of major diabetes-related complications. Complications with the most severe impact were amputation, neuropathy, nephropathy, stroke, ischemic heart disease, and myocardial infarction.

In the regression analysis of diabetes on EQ-5D dimension responses, age, impaired vision, fear of hyperglycemia, ischemic heart disease, foot ulcer, neuropathy, body mass index, hospital admissions, and receiving help from others were statistically significant determinants for mobility problems and anxiety/depression.

CONCLUSION

The research study provides a general estimate of the cost of illness of diabetes and the impact of diabetic complications on the HRQoL. Diabetes is characterized by a very high-cost burden. Education on the prevention and management of diabetes must be prioritized. It must be provided to diabetic patients and the society at large. Therefore, it is suggested that Health-care providers and policy-makers must put more attention to the factors that result in increased hospital care. Furthermore, the introduction of intensive disease management interventions to diabetic patients to delay the progression of complications or comorbidities will result in a reduction of health care expenditure and improved quality of life and the life years, thereby decreasing the premature mortality rate caused by diabetes. A lower financial burden on patients would greatly increase the treatment compliance, complications, and comorbidity progression. This will result in a reduction of diabetes' economic burden on patients, society, and the health-care system. This study was limited due to time constraints. Further multicenter studies can be carried out in a larger population in different geographical regions in India or it can be done at a national scale.

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