

Pharmacoeconomic Evaluation on Treatment of Diabetic Patients in a Charitable Hospital

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Sunny *et al.*: Pharmacoeconomic Evaluation of Diabetic Treatment

This study aimed to conduct a pharmacoeconomic evaluation of the treatment of diabetic patients in a charitable hospital. A retrospective study was carried out for a period of 8 months from August 2016-March 2017. Patients admitted in general medicine with age above 18 years diagnosed with diabetes and on at least one antidiabetic medication. Patient's data was collected by referring patient's treatment charts and case notes, hospital billing system, medical record department and hospital pharmacy department. In this study, the direct medical cost was analysed. A total number of 212 diabetic patients were enrolled in the study of which 131 (61.8 %) were males, and 81 (38.2 %) were females. It was found that 67 % of patients had comorbid conditions and 33 % without any complications. One hundred and eleven (52.35 %) patients were prescribed a combination of insulin and oral hypoglycaemic agents, 66 (31.13 %) patients received insulin alone and 35 (16.50 %) patients received only oral hypoglycaemic agents. The annual median cost incurred for the management of diabetes with and without complications per patient was INR 14 959.60 and INR 8619.90, respectively. The study revealed that the costs for males with and without diabetes complications were INR 21 095 and INR 11 644.70, respectively. The corresponding figure for females was INR 12 030 and INR 8515. The cost incurred for nephropathy and peripheral circulatory co-morbidities was the highest (INR 53 795.50), whereas the cost for managing diabetes with nephropathy, neuropathy, retinopathy and peripheral circulatory comorbidities was INR 37 888.00. The study concluded that the cost of treatment could be drastically reduced by early identification and treatment of diabetes thereby preventing the development of diabetes-associated comorbidities.

Key words: Pharmacoeconomics, diabetes, cost analysis, drug evaluation

Diabetes mellitus (DM) is a chronic disorder with various complications that affect all age groups. The International Diabetes Federation (2017) estimates 1 in 11 adults have DM (425 million) and 1 in 2 adults with DM are undiagnosed (212 million)^[1]. Twelve percent of worldwide health expenditure is on DM (\$727 billion) and there will be 629 million people with DM in the world by 2045. In India, 72.9 million individuals are living with DM and the country is ranked second in the world, after China. The Indian total healthcare cost on diabetic patients in 2017 was \$ 31 billion^[2]. In individuals who have controlled blood glucose level, the complications such as macrovascular and microvascular are less frequent and less severe^[3,4]. The cost of medication is a significant obstacle in the effective treatment of the disease and consistency towards the medication regimen. The studies on the cost of illness have established that 3 times rise in the direct costs of diabetic patients compared with non-diabetic patients^[5]. In India, cost studies in diabetes were conducted in Bengaluru urban district, Chennai, Warangal and North India^[6,7,8,9]. The present study was conducted in a Charitable hospital, Mangaluru, Dakshina Kannada District to evaluate the direct medical cost of diabetic patients.

A retrospective study was carried out for a period of 8 mo from August 2016-March 2017 at Justice K. S. Hegde Charitable Hospital, Dakshina Kannada, Mangaluru. This study was approved by the Institutional

Ethical Committee (REF: INST.EC/EC/72/2016-17). The sample size was calculated using the formula, $n = Z^2_{1-\alpha/2} [2 S_p^2] / d^2$, where, $Z = 1.96$, $\alpha =$ level of significance (5 %), $d =$ precision (10 %), $S_p =$ standard deviation (50), $n =$ number of patients. The minimum sample size required for this study is 192 patients.

The study was carried out based on following inclusion and exclusion criteria. Patients admitted in general medicine department with age above 18 y and diagnosed with DM and treated with at least one antidiabetic medication (oral antidiabetic drugs or insulin) and with or without complications. Patients hospitalised for a minimum of 2 d were only included in the study. The patients being treated as outpatients, with incomplete medical records and gestational diabetes patients were excluded from the study.

The data was collected by referring patient's treatment charts and case notes, hospital billing system, medical record department (MRD) and hospital pharmacy department. Patient demographic parameters such as age, gender, social habits, family history, body mass index (BMI), complications and length of hospitalization,

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and laboratory tests were recorded during the treatment period. Details of drug therapy such as generic and brand name of the drug, dosage form, frequency, route of administration, and number of drugs per prescription were recorded. For pharmacoeconomic evaluation, laboratory investigation, treatment bills of the antidiabetic therapy (unit dose prescribed, frequency, and route of administration and duration of treatment), physician consultations, nursing services and hospital charges were collected. Costs in Indian Rupee (INR) were converted into the United States Dollar (USD) at the rate of 1 USD = 64.62 INR (During the period of the study).

Continuous variables such as age, gender, BMI, the total number of drugs prescribed, types of antidiabetic medications prescribed were expressed as mean±standard deviation, and skewed variables such as length of hospital stay, duration of diabetes, the annual median cost of diabetes were expressed as a median and inter-quartile range (Q_3-Q_1). The categorical variables were expressed as frequency and percentage. The data analysis was carried out using the Statistical Package for Social Science (SPSS) 20.0 version.

Two hundred and twelve diabetes patients were included in this study. Out of these patients, 145 (68.4 %) patients have been diagnosed with type 2 DM and 67 (31.6 %) patients with type 1 DM. In this study, 131 (61.8 %) male patients outnumbered the females 81 (38.2 %). The mean age and BMI of the study population was 55.59 ± 14.61 y and 23.97 ± 2.38 kg/m², respectively. The median length of hospital stay was 10 (6-20) d. The mean number of drugs prescribed for patients was 12.88 ± 6.56 . Ninety eight (46.2 %) patients were non-alcoholics and non-smokers, followed by both alcoholic and smoker 57 (26.9 %), only smoker 31 (14.6 %) and only alcoholic 26 (12.3 %). One hundred forty three (67.4 %) patients had no family history of diabetes and the remaining 69 (32.6 %) had family history either maternal, paternal or both. It was found that 142 (67 %) of diabetic patients were presented with complications and 70 (33 %) without complications. 37.7 % of patients had peripheral circulatory (hypertension and diabetic foot ulcer) complications, 14.3 % had ophthalmic complications and 13 % of patients had neurological complications. The detailed results of age wise distribution, domiciliary status, annual hospital stay, length of hospital stay, number of medications prescribed and complications are summarized in Table 1.

The data showed that 111 (52.35 %) patients were prescribed a combination of insulin and oral hypoglycaemic agents (OHA) followed by insulin alone 66 (31.13 %) and OHAs 35 (16.50 %). It was found that biguanides (47.6 %) were the mostly prescribed class of oral antidiabetic drug followed by sulphonylureas (25.2 %) and other classes of oral hypoglycaemic agents. The complete data are summarized in Table 2. The most commonly prescribed OHAs were, metformin 68 (47.5 %), voglibose 27 (18.9 %), glimepiride

TABLE 1: DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS

Demographic characteristics	Number of patients (%) (n = 212)
Age group (y)	
18-39	27 (12.73 %)
40-59	90 (42.45 %)
≥ 60	95 (44.48 %)
Domiciliary status	
Rural	96 (45 %)
Urban	116 (55 %)
Duration of diabetic history (y)	
<1	36 (16.98 %)
1-5	51 (24.05 %)
6-10	61 (28.77 %)
≥11	64 (30.18 %)
Number of annual hospitalizations	
1	151 (71.22 %)
2	37 (17.45 %)
3	15 (7.07 %)
4	9 (4.24 %)
Length of annual hospital stay (d)	
1-15	141 (66.50 %)
16-30	40 (18.86 %)
31-45	19 (8.96 %)
46-60	8 (3.77 %)
>60	4 (1.88 %)
Complications of DM	
Retinopathy+nephropathy	
Retinopathy+neuropathy	4 (1.88 %)
Retinopathy+neuropathy +peripheral circulatory	5 (2.35 %)
Nephropathy+peripheral circulatory	8 (3.77 %)
Neuropathy+peripheral circulatory	3 (1.41)
Retinopathy+peripheral circulatory	6 (2.83 %)
Retinopathy+neuropathy	7 (3.33 %)
Nephropathy+neuropathy +retinopathy+peripheral circulatory	15 (7.07 %)
Nephropathy+retinopathy +peripheral circulatory	11 (5.18 %)
Peripheral circulatory	80 (37.73)
Neuropathy	28 (13.20)
Ophthalmic	30 (14.15)
Nephropathy	15 (7.54 %)
Number of medication per prescription	
1-10	92 (43.39 %)
11-20	88 (41.50 %)
21-30	32 (15.09 %)
≥31	1 (0.47 %)

21 (14.6 %), gliclazide, glibenclamide, repaglinide 6 (4.1 %), pioglitazone 5 (3.4 %), glipizide 3 (2 %) and sitagliptin 1 (0.69 %), respectively.

The annual median cost incurred for the management of DM with and without complications per patient was INR 14 959.60 and INR 8619.90, respectively. The detailed cost categories of the DM patients with and without complications are summarized in Tables 3 and 4. The study results revealed that the costs for male patients with and without complications (21 095 INR and 11 644.70 INR) were more than female (12 030 INR and 8515 INR). The annual cost incurred in the presence of nephropathy and peripheral circulatory was 53 795.50 INR, which was the highest followed by patients with nephropathy, neuropathy, retinopathy and peripheral circulatory conditions

TABLE 2: PRESCRIBING PATTERN OF DIFFERENT CLASSES OF ORAL HYPOGLYCAEMIC AGENTS

Class of oral hypoglycaemic agents	Number of patients (%) (n=212)
Sulphonylureas	36 (25.2 %)
Biguanides	68 (47.6 %)
Meglitinides	6 (4.2 %)
Thiazolidinediones	5 (3.5 %)
Dipeptidyl peptidase-4 inhibitors	1 (0.7 %)
α -glucosidase inhibitors	27 (18.8 %)

(37 888 INR) and others complications are summarized in Table 5.

The rise in the incidence of diabetes produces clinical, financial and social burden. The cost of diabetic care is increasing globally^[10]. The present study was intended to analyse the medical cost involved in the management of diabetic patients with or without complications. Cost analysis of a total of 212 diabetic patients was performed during the study period. Out of 212 patients, most of the patients were male (61.8 %). Among them, the maximum number of patients was in the age 60 or above (44.48 %). These findings are consistent with studies reported by Akari *et al.*, Al-Maskari *et al.*, and Raj *et al.*^[9,13,14]

In the present study, majority of the DM patients admitted only once (71.25 %) in the annual hospitalization report, this might be due to proper prescription of drugs, patient counselling and adherence to the treatment regimen. Contradictory results were reported by Assefa *et al.* that diabetic patients had 3-6 (52.31 %) hospitalizations per annum^[15].

Sixty nine (32.6 %) patients under study had no family history, which is significantly less that reported by Akari *et al.*, who showed 58 % patients had a positive family history of diabetes^[9]. The mean BMI of the

TABLE 3: ANNUAL COST PER DIABETIC PATIENT WITH COMPLICATIONS

Cost category	Cost of DM patients with complications	Cost of DM patients with complications
	Median (Q ₃ -Q ₁) in INR	Median (Q ₃ -Q ₁) in USD
Anti-diabetic medications	517 (1332.60-298.40)	13.86 (20.62-4.62)
Medications for complications	1889 (3991-213)	29.23 (61.76-3.30)
Other medications	697.30 (1690.50-296)	10.79 (26.16-4.58)
Laboratory tests	2225.70 (5225-773.70)	34.44 (80.85-3.56)
Consultation	2078.80 (4387.50-230)	32.17 (67.89-3.56)
Nursing services	549.40 (1352.50-253.70)	8.50 (20.93-3.93)
Hospitalization	2027.50 (3640-1515)	31.38 (56.33-23.44)
Miscellaneous	1384.40 (3362.50-593.70)	21.42 (52.03-9.19)
TOTAL	14959.60 (36168-6549)	231.50 (559.70-101.35)

INR- Indian Rupees, USD- United State Dollars

TABLE 4: ANNUAL COST PER DIABETIC PATIENT WITHOUT COMPLICATIONS

Cost category	Cost of DM patients without complications	Cost of DM patients without complications
	Median (Q ₃ -Q ₁) in INR	Median (Q ₃ -Q ₁) in USD
Antidiabetic medications	417.90 (1060-224.20)	6.47 (16.40-3.47)
Other medications	382.90 (931.40-165.60)	5.92 (14.41-2.56)
Laboratory tests	934.50 (2128.70-560)	14.46 (32.94-8.67)
Consultation	899 (2192.50-255)	13.91 (33.93-3.95)
Nursing services	296.30 (857.50-265)	4.58 (13.26-4.10)
Hospitalization	575 (910-260)	8.90 (14.08-4.02)
Miscellaneous	715 (1440-410)	11.06 (22.28-6.34)
TOTAL	8619.90 (14129-2999)	133.39 (218.65-46.41)

INR- Indian Rupees, USD- United State Dollars

TABLE 5: ANNUAL COST OF COMPLICATIONS

Type of complication	Cost of patients with complications Median (Q ₃ -Q ₁) in INR	Cost of patients with complications Median (Q ₃ -Q ₁) in USD
Nephropathy	9481 (26818-6913)	146.71 (415.01-106.97)
Retinopathy	12171.50 (30546.00-6226.50)	188.35 (472.7-96.35)
Neuropathy	7759 (21816-4482.70)	120.07 (337.6-69.37)
Peripheral circulatory	15469.50 (33101-8561)	239.39 (512.24 -132.48)
Retinopathy+nephropathy+peripheral circulatory	15131 (20577.20-5709.20)	234.15 (318.43-88.35)
Retinopathy+peripheral circulatory	14583 (54586.00-8925.50)	225.67 (844.72-138.12)
Nephropathy+neuropathy+retinopathy+peripheral circulatory	37888 (62593-11657)	586.32 (968.63-180.39)
Neuropathy+peripheral circulatory	8603 (27431.20-4795.70)	133.13 (424.50-74.21)
Nephropathy+peripheral circulatory	53795.50 (80705-26886)	832.48 (1248.91- 416.06)
Retinopathy+neuropathy+peripheral circulatory	22329 (42311.20-7082.50)	345.54 (654.77-109.60)
Retinopathy+neuropathy	3879.50 (7940.70-2855.70)	60.03 (122.88-44.19)
Retinopathy+nephropathy	29493 (31441-7584)	456.40 (486.55 -117.36)

INR- Indian Rupees, USD- United State Dollars

study population was 23.97 ± 2.38 kg/m², whereas other studies by Acharya *et al.*, Akari *et al.*, and Al-Maskari *et al.* reported BMI values higher than 25 kg/m²[5,9,13].

It was observed that 67 % of patients had co-morbidities and 33 % were without co-morbidities, these findings were consistent with the reported by Rayappa *et al.*, which also had maximum patients with co-morbid conditions^[17]. In this study, majority of the patients had peripheral circulatory complications (37.7 %), which included hypertension and diabetic foot ulcers followed by ophthalmic complications (14.3 %). A similar study conducted by Acharya *et al.*, reported that maximum patients had microvascular complications^[5]. In the present study, complications were categorized individually rather than classifying it as microvascular and macrovascular.

Regarding the class of drugs used for the management of diabetes, 52.35 % of patients were prescribed with a combination of insulin and OHAs followed by insulin alone (31.13 %) and OHAs (16.50 %). Contradictory results were reported by Acharya *et al.*, that the majority of patients were on OHAs followed by insulin^[5]. Among the different class of OHAs prescribed, it was found that biguanides were mostly prescribed 47.6 % followed by sulphonylureas 25.2 %. These findings are similar to the study conducted by Alex *et al.*^[12].

The overall annual hospitalization cost of diabetes with complications was found to be higher than diabetes without complications. Similar results were reported by Acharya *et al.* in which the hospitalization cost was 1.2 times higher for diabetic patients with complications^[5]. The annual median medication cost of diabetes with complications was found to be

2.5 times higher than diabetes without complications. These findings are similar to those reported by Acharya *et al.*, who reported a 1.7 times higher cost for diabetes with complications than diabetes without complications^[5]. The study conducted by Kapur *et al.* reported that diabetic complications were responsible for most of the diabetes-related direct health costs in India^[7]. The overall median annual cost of diabetes with complications was found to be higher in male patients (\$ 326.40) than female patients (\$ 186.16). These results are comparable to the study of Akari *et al.*^[9] for diabetes with and without complications.

In the present study, the annual cost incurred for diabetes with nephropathy and peripheral circulatory complications (\$ 832.48) was the highest followed by for diabetes with nephropathy, neuropathy, retinopathy and peripheral circulatory complications (\$ 586.32), followed by others complications. A similar study conducted by Akari S *et al.*, revealed that the cost for macrovascular complications (\$ 129) was more than that for microvascular complications (\$84.64)^[9]. Previous study results also showed that the costs of macrovascular complications were higher than the microvascular complications^[13,18,19].

The total annual cost of treatment in patients with complications (14 959.60 INR) was higher compared to without complications (8619.90 INR). The yearly cost incurred for the treatment of people with diabetes with nephropathy and peripheral circulatory complications (53 795.50 INR) was highest followed by diabetes with nephropathy, neuropathy, retinopathy and peripheral circulatory complications (37 888 INR) and other diabetic complications, respectively. Poorly managed diabetes increases the financial burden on the family

and society. The outcomes of the study reveal the need for early identification and prevention of diabetic complications to control the cost of diabetes.

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None

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