Evaluation of pharmacoeconomics, medication adherence and quality of life in type 2 diabetes mellitus patients

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ABSTRACT

In this study we assessed the cost-of-illness which involves measuring the direct and indirect costs incurred by Type 2 Diabetes Mellitus [T2DM] patient. The quality of life [QOL] of patients was measured using Quality of Life Instrument for Indian Diabetes Patients which is a questionnaire to assess the Indian diabetic patients. Adherence with medication usage is the measurement of prescribed doses of medication actually taken by a patient over a certain period of time. Patient's demographic details, medication, medical history duration, hospital stay as well as treatment and clinical profile of the patients were assessed. The direct medical and direct nonmedical cost will be documented. A validated questionnaire will be given to the patient at baseline to assess their medication adherence and quality of life. Statistical analysis was performed using Graphpad InStat 3 software. 'p value' less than 0.05 was considered to be statistically significant. We observed that out of 130 patients, the total cost of illness is estimated as Rs.1,38,348 out of which 97.14% was direct medical cost and 2.85% were direct nonmedical cost. The patients with low adherence were the patient who had a higher cost of illness due to the worsening of the disease. Patient with high QOL were observed in <10year. Diabetes is one of the major lifestyle diseases that can be a risk factor for several complications. Physicians and Pharmacists should also adopt interventions that should be executed to help patients remind to keep their clinic appointments and to take their anti-diabetic medications as prescribed in order to lower the complications of diabetic mellitus and to raise the quality of life of the patients.

Keywords: Diabetes mellitus; quality of Life; medication adherence; cost of illness; modified morisky medication adherence scale; pharmaeconomics.

INTRODUCTION

According to the World Health Organization (WHO), about 79.4 million Indians will be effected by T2DM by the year of 2030 as it is associated with changes in dietary patterns and reduced physical activity (Upadhyay, 2013). DM is considered as metabolic disorder which is described by resistance to the function of insulin or due to deficient insulin secretion, or even the two which is characterized by increased sugar levels. The diabetic patients are classified into the two main groups: type 1 diabetes that is caused by complete lack of insulin and type 2 diabetes as the insulin resistance with an increase in insulin secretion. Type 2 DM has leads to a massive economic burden to the society which is associated to health care costs in controlling the disease, indirect costs derived from productivity losses due to patient disability and premature mortality (Behaylu, 2014). Uncontrolled diabetes is followed by vasculopathy, neurologic abnormalities, and other

organ specific pathology such as microangiopathic complications particularly in the kidneys and retina regions. Diabetic retinopathy is one of the leading causes of new cases of blindness, reporting up to 24,000 patients annually. Major studies have shown that the morbidity and mortality associated with diabetic cardiovascular (CV) disease can be reduced gradually (Schrier, 2000). Treatment involves Oral antidiabetic drugs (OAD) like Sulphonyl urea (SU) and metformin (MF) as the first-line OAD. The second line OAD comprises of α-glucosidase inhibitor (AGI), thiazolidinediones (TZD) and non-insulin analogues. Even though these new classes of drugs were effective in clinical trial environment, there are insufficient data on their patterns of practice and effectiveness in clinical settings. An updated American Diabetes Association/European Association for the Study of Diabetes position estimated the input and refined recommendations, including merits and disadvantages, for anti-hyperglycemic agents for type 2 diabetic patients. Lifestyle modifications that improve health should be emphasized along with treatment of DM (Cefalu, 2015). Cost-of-illness studies characterize the resources used and potential resources lost due to the particular disease. In sync with prevalence, incidence, morbidity, and mortality data, these survey help to illustrate the impact of a disease on population. To advice clinical

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decision making, establish policies and protocol, and effectively designate resources, it is essential to perform cost-of- illness survey. (Varma, 2008). This study gives the details of preventive measures which can be taken against diabetes. Medication therapy management, adherence and surveillance of the current therapeutic approaches for diabetes and its cost of illness in India are warranted for the better management of DM (Schrier, 2000).The WHO describes Quality of Life (QOL) as an individual's approach of their position towards life in the context of the culture and value systems in which they live and in relation to their targets, possibility, standards and concerns. It is a wide ranging concept impressed by the person's physical status of health, psychological state, social relationships, range of independence, personal beliefs and also their relation to salient features of their environment (Jitender, 2010).

MATERIALS AND METHODS

This study was a prospective observational comparative study accepted by the Institutional Ethical Committee of The Oxford Medical College Hospital and Research Centre, Attibele, Bangalore. This study was continued for a period of 6 months duration in the inpatients, Department of General Medicine. A total of 130 Type 2 DM cases were collected in which patients of both the gender and of above 18 years with or without co morbidities were involved. The evaluation of pharmacoeconomics is done by calculation the total cost of illness which is the direct medical cost and direct non-medical cost. The direct medical cost includes the cost of drugs and laboratory charges whereas direct non-medical cost comprise the transportation cost.

Categorizing the patients based on health condition:

The T2DM patients are categorized into 5 groups based on the disease state which are T2DM, T2DM with comorbidity, uncontrolled T2DM, T2DM with complications and T2DM with complication and comorbidity. The cost of illness of each health condition is evaluated.The medication adherence to the prescribed medication is checked using the morisky medication adherence scale. The scores are marked respectively on the adherence scale. The scores are divided into three categories. The patient who scored 8 fall under the good adherence, patient who scored 6-7.9 are medium adherent and patient who scored below 6 are poor adherent to the prescribed medication.QOL is measured using the questionnaires. The patient's QOL is measured depending on the duration of disease.

RESULTS

A total of 130 cases were collected in which patients of both the sex and of above 18 years with or without co morbidities were included. Patients who are below 18 years, pregnant and lactating women were excluded from the study. The gender, age, class of the drugs,

quality of life and medication adherence drug therapy were reported.

Gender wise distribution of patients

Fig 1 shows that the overall gender distribution of the patients which were found to be 59.23% for males and 40.77% for males. It showed that the majority of the patients are male 77 against 53 females. The reason for this might be smoking, alcoholic habits and other life style changes as seen more commonly in males.

Mean COI of DM by patient's demographic characteristics

Table 1 shows that the average cost of illness for male patients from 77 patients was 977 ± 450.66 and the average cost of illness of 53 female patients were 1180 ± 560.22 which is higher than the cost estimation of males.

Cost of illness depending on direct medical cost and direct non-medical cost

As indicated in Table 2 and Fig 2, out of total 130 patients the total Cost of illness of diabetes was Rs 1,38,348. Out of which 97% was direct medical cost and 2.85% of the total cost of illness was direct non-medical cost. While looking into the components of different costs, the major element in direct medical cost was the drug cost, which is 65.7% of the total cost of illness. Fig 2 shows that out of the total cost of illness, the cost estimation of direct cost which includes the drug cost and the laboratory charges were significantly higher than the direct non-medical cost which includes the transportation charges.

Mean cost of illness of DM patients based on insulin and oral hypoglycemic treatment

Table 3 and Fig 3 indicate that insulin took the major share of the mean cost of illness. It accounted for 57% of the total drug cost as insulin and 43 % the total drug cost as OAD.

Mean cost of illness of DM based on patient's health conditions

As indicated in Table 4 and Fig 4, Out of the total 130 patients, the patients are categorized into 5 categories based on their health conditions. The patients were listed under the categories which are plainT2DM patients, T2DM with comorbidity, uncontrolled T2DM, T2DM with complications and T2DM patients with complications and comorbidity.

Medication adherence of T2DM patients according to Morisky medication adherence scale

Table 5 shows that medication adherence of each patient was measured using the morisky medication adherence scale. The total score of the scale were divided into three groups. The patient who scored 8 were listed as good adherence whereas the patients who

Table 1: shows the cost of illness based of demographic details

Gender	Number(n=130)	Percent	Mean cost of illness (INR)	P value
Male	77	59.23	977±450.66	<0.0001
Female	53	40.76	1180±560.22	

Table 2: Indicates the cost of illness depending on direct medical cost and direct non-medical cost

Types of costs	Total cost (INR)	Percent (%)
Direct medical cost	134404.74	97.14
Drugs	90899.74	65.7
Laboratory	43505	31.44
Direct non-medical cost	3944	2.85
Total cost of illness	138348.74	100

Table 3: Mean COI of T2DM patients based on insulin and oralhypoglycemic treatment

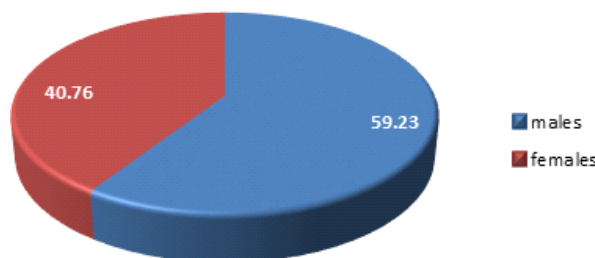| Treatment including insulin	n (no.patients)	Percent	Mean cost of illness (INR)	P value
NO	39	30	876.61±430.39	<0.0001
YES	91	70	1138.67±517.95	
TOTAL	130	100	1060.05±506.23	

Figure 1: Gender wise distribution of type2 DM
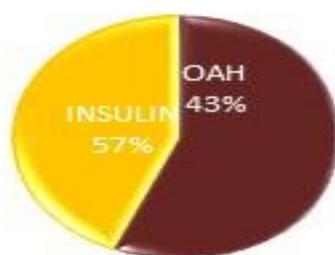

Figure 2: Total cost of illness

Figure 3: Mean COI of DM patients on insulin treatment

Table 4: shows the mean cost of illness based on the health conditions

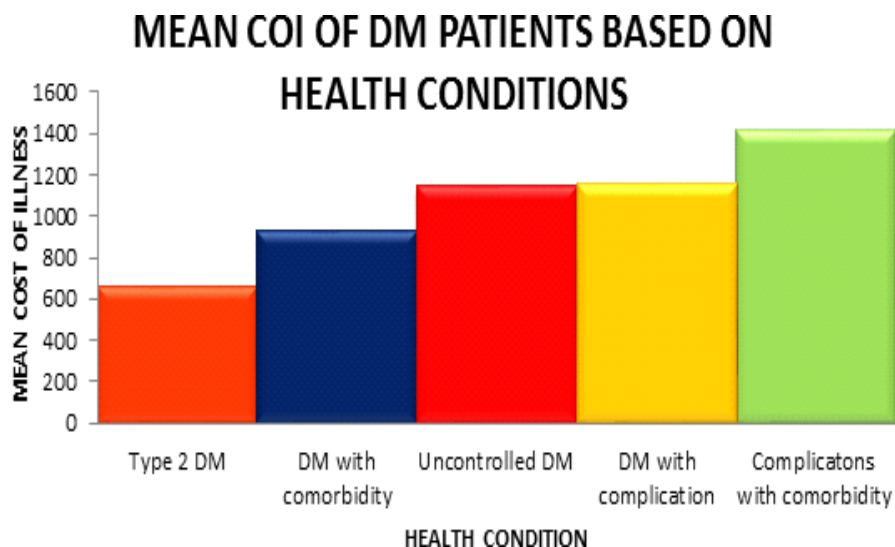| Health condition	Number (n=130)	Percent	Mean cost of illness (INR)	P value
Type 2 DM	19	14.61	656.73±254.03	
T2DM with comorbidity	30	23.07	929.5±420.18	
Uncontrolled DM	19	14.61	1143.57±283.41	<0.0001
T2DM with complications	45	34.61	1147.68±605.19	
T2DM with complications and comorbidity	17	13.07	1415.88±431.81	

Figure 4: Mean COI of DM based on patients health conditions

Table 5: shows medication adherence of T2DM patients based on morisky medication adherence scale

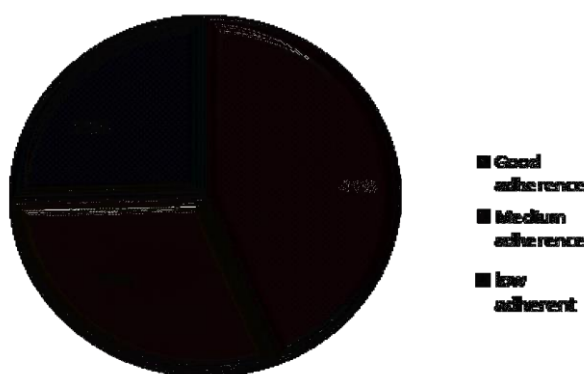| Medication adherence pattern	Number of patient	Percent (%)
Good adherence (8)	57	43.84
Medium adherence (6-7.9)	40	30.38
Low adherence (<6)	33	25.38
Total	130	100

Figure 5: Medication adherence in T2DM patients

Table 6: Medication adherence based on health conditions

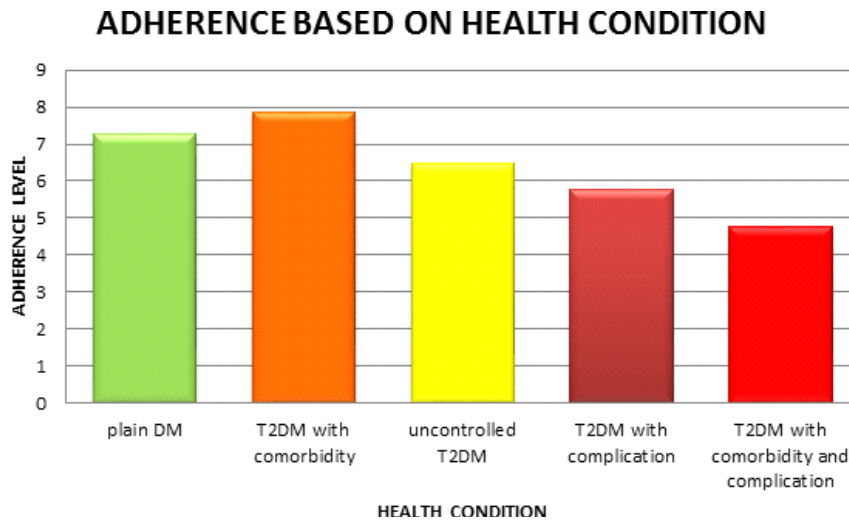| Health condition	Mean adherence score
plain type2 DM	7.26
type2DM with comorbidity	7.84
Uncontrolled T2DM	6.59
T2DM with complications	5.76
T2DM with comorbidity and complication	4.75

ADHERENCE BASED ON HEALTH CONDITION

Figure 6: Medication adherence based on health conditions
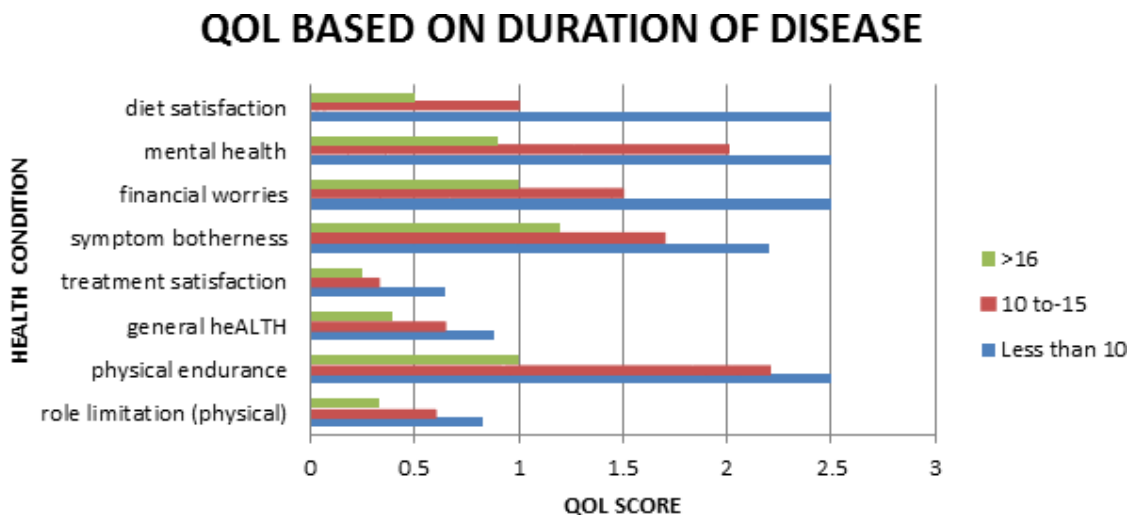
QOL BASED ON DURATION OF DISEASE

Figure 7: The influence of disease duration based on the parameters of quality of life

scored from 6-7.9 were categorized as medium adherence and the patients who scored below 6 were the low adherence patients. Fig 5 shows the evaluation of the patient's response to the 8-item morisky scale signifies that 44% of the patients had good adherence with given medication where as 31% patients had moderate adherence and 25% patients had decreased adherence.

Mean adherence score depending on health condition

Table 6 shows Medication adherence based on health conditions of the patients which showed that the mean score of adherence of patients with comorbidity and complication were 4.75, patients with complications scored 5.76, uncontrolled were 6.59, type2DM with comorbidity scored 7.84 and plain type2 DM were 7.26 respectively Fig 6 indicates that lower adherence leads to gradual increase in the blood glucose levels thus finally leading to complications. Fig 6 clearly states that the patients with low adherence were the patients who had T2DM with complications, and uncontrolled

T2DM which indicated that low adherence to prescribed medication leads to worsening of disease and leading to complications which further leads to increased cost of illness as mentioned in the pharmacoeconomic evaluation data mentioned earlier.

The influence of disease duration based on the parameters of quality of life

Fig 7 clearly states the occurrence of DM points to declining the quality of life in all domains. The average period of diabetes was 12.76 ± 8.8 years. Fig 6 explains the impact of disease duration on the criterion of quality of life. The best quality of life in all area was detected in patients diagnosed with diabetes less than 10 years prior.

DISCUSSION

The study showed that the direct medical cost constitute for about 92.48% (10663.7USD) of the total cost of illness and 7.52% (866.94USD) indicated for the direct non-medical cost. Further it states that the mean insu-

lin cost was 4 time increased cost than mean oral hypoglycemic agent cost (Behaylu A et al., 2011). In this study the direct medical cost accounted for 97% (134404) of the total cost of illness whereas the direct non-medical cost was found to be 2.85% (3944). The total cost of drugs is 65% (90899) of the direct medical cost, out of which cost of drugs for patients on insulin treatment was increased by 76% (69786) and patients on oral hypoglycemic agents was found to be 23% (2113.74).In the other study which indicated that the males dominated in the study group which is in accordance with the result of numerous other studies in India and the United States (Sajith M et al., 2014). The reason behind this might be smoking, alcoholic consumption and other life style changes as seen more frequently in male gender. These factor had significant effect on health including glycemic control according to the evaluation. Similarly, our study also indicates that percentage of males (59.23%) were higher than the percentage of females (40.76%). The 8-item morisky medication adherence scale (MMAS) was used to determine the medication adherence. As per the study, the patients with good adherence scored 8, patients with medium adherence scored 6-7.9 and patients who scored below 6 fall under the category of low adherence. Our study states that 57 patients were having good adherence, 40 patients were medium adherent and 33 patients were low adherent. This study also evaluates that the mean score of adherence of patients with complications were lower than that of patients without complications which concludes that lower adherence leads to gradual increase in the blood glucose levels thus finally leading to complications and increased health care cost. It is very mandatory for medical and clinical discipline to examine the quality of life and find opportunity to advance it. The result of our research has shown that people with T2DM have lower quality of life in all aspects than those without diabetes. Our study also evaluated that the best quality of life in all areas were observed in patients diagnosed with diabetes less than 10 years.

CONCLUSION

Diabetes is one of the major lifestyle diseases that can be a risk factor for several complications. The prevalence and the number of people living with diabetes in India is increasing every year, which imparts a burden on the economic growth. Cost of illness studies can give a structure for estimation of cost assessment for Cost Effectiveness and cost benefit study, the methods which are commonly employed for decision making while updating the formulary. Pharmacist can perform his role when making formulary decisions as a member of Pharmacy and Therapeutic Committee (PTC), using the information gathered from pharmacoeconomic evaluation. Pharmacist can also give patient counseling on diabetes to patients as lack of proper knowledge about the disease is also a contributing factor towards the cost of care. A proper knowledge about the disease can contribute to proper monitoring of diabetes and thereby the extent of complications can be reduced. Physicians and Pharmacists should also endorse interventions that are framed to assist patients remember to keep their clinic appointments and to take their anti-diabetic medications as given by the physician in order to decrease the complications of diabetic mellitus and to improve the quality of life of the patients.

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