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Pharmacoeconomic analysis of type 2 diabetes mellitus and its microvascular complications

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ABSTRACT

The international society for pharmacoeconomics and outcomes research (ISPOR) defines "Pharmacoeconomics as the field of study that evaluates the behaviour of individuals, firms and markets relevant to the use of pharmaceutical products, services and programs and which frequently focuses on the costs (inputs) and consequences (outcomes) of that use". It is the description and analysis of the cost of drug therapy to health care systems and society. This prospective observation study was carried out for over a period of 6 months commencing from March 2014 to August 2014 among inpatients of General medicine and Nephrology departments of a tertiary care referral hospital in Kerala. All diabetes mellitus patient treated in the Inpatient department of General medicine and Nephrology department during March-August 2014 were monitored, collect relevant data and entered into the data sheet. Based on the inclusion and exclusion criteria of the protocol approved by the IEC, patients belonging to the age group 40-70 of both sex were selected and enrolled for the study.

Keywords: ISPOR; COI; HbA1C; RBS.

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INTRODUCTION

The international society for pharmacoeconomics and outcomes research (ISPOR) defines "Pharmacoeconomics as the field of study that evaluates the behaviour of individuals, firms and markets relevant to the use of pharmaceutical products, services and programs and which frequently focuses on the costs (inputs) and consequences (outcomes) of that use". It is

the description and analysis of the cost of drug therapy to health care systems and society.

Cost of illness (COI) evaluation is also known as burden of disease. It is an economic evaluation method used to identify and estimate the overall cost of a particular disease for a defined population. It involves measuring the direct and indirect costs attributable to a specific disease. Direct cost is the obvious cost ie, the cost of the health service. It includes physicians fees, cost of administering the medication, costs of treating an adverse drug reaction, cost of drugs, supplies, laboratory tests etc. Indirect cost is the one borne by the patient and family Eg. Cost of travel/ transportation, expenses incurred on accommodation needed near the treatment center, on food, family care, loss of family/ patient income due to absenteeism from work. It includes lost productivity from a disease like wages and salaries lost due to morbidity, loss of earnings, and loss of leisure time. COI evaluation is not used to compare competing treatment programs or treatment alternatives. It is used to provide an estimation of the financial burden or economic load of a disease. It estimates the maximum amount that could potentially be saved or gained if a disease was eradicated. Numerous cost of illness studies have been conducted since 1970s throughout the world highlighting the influence of the magnitude of the impact of illness on society. They are limited in determining how resources are to be allocated because

they do not measure benefits. An estimate of costs is often useful, however, when considering planning, decision-making, and regulatory development. Cost-of-illness studies are used most often by policymakers, governmental and nongovernmental organizations, researchers, and pharmaceutical companies.

The cost of illness study of diabetes mellitus is very important in the present situation because the prevalence and complication of diabetes is increases day by day .Diabetes mellitus is a chronic and non-communicable disease that is widespread. It is the fourth or fifth leading cause of death in most high income countries. Diabetes is undoubtedly one of the most challenging health problems of the 21st century. According to IDF diabetic atlas 6th edition 2014 about 8.3% of adults ie, 382 million people have diabetes, and the number of people with the disease is set to rise beyond 592 million by 2035.About 80% live in low and middle income countries. The greatest number of people with diabetes is between 40-59 years of age. Yet, with 175 million of cases currently undiagnosed, a vast amount of people with diabetes are progressing towards complications unawares. Diabetes caused 5.1 million deaths in 2013. Every six seconds a person dies from diabetes. Peoples with type 2 diabetes can remain undiagnosed for many years, unaware of the long term complication such as micro and macrovascular complications being caused by the disease. The major reason behind the complication and early death is poorly managed diabetes. More than 21 million live births were affected by diabetes during pregnancy in 2013.^[1]

Diabetes is a disease whose primary risk factors are obesity, ageing and poor dietary habits (together with genetics). It is a costly disease because it is chronic and can lead to complications that require medical and hospital treatment. People who develop diabetes may live with the disease for decades. With the rise in inactivity, obesity and ageing. Type II diabetes is a condition of elevated blood-sugar levels. The body's organs, the eyes, heart, kidneys, liver and the brain, need a certain level of blood-sugar to work efficiently. A blood-sugar level that is either too high or too low will lead to the failure of one or more of the body's organs. A consistently high blood-sugar level can lead to hypertension, stroke or kidney problems. Each complication requires specific treatment. For instance, hypertension is treated with medication that helps to lower blood pressure, whereas kidney problems may ultimately require dialysis or kidney transplant. It is easy to understand why the treatment of diabetes before any of these occur is essential, for the consequences are generally fatal, or at the very least, highly debilitating for the patient. Yet the cost of treating diabetic complications is non-trivial for two reasons: 1) diabetes is incurable and the patient will live with the risk of developing any of these complications for decades; and 2) the costs of medical and hospital treatment are high. These direct costs are coupled with indirect costs, that is, the opportunity

cost to society of an individual not being able to work because of her case of diabetes.^[2]

METHODOLOGY

The prospective observation study was carried out for over a period of 6 months commencing from March 2014 to August 2014 among inpatients of General medicine and Nephrology departments of a tertiary care referral hospital in kerala. The study was approved by the ethics committee of hospital and was certified by the Institutional ethics committee met and approved the proposal. All diabetic patients with inadequate glycemic control are included in this study. An observational pilot study was conducted before the initiation of study. All diabetes mellitus patient treated in the Inpatient department of General medicine and Nephrology department during March-August 2014 were monitored, collect relevant data and entered into the data sheet. Based on the inclusion and exclusion criteria of the protocol approved by the IEC, patients belonging to the age group 40-70 of both sex were selected and enrolled for the study.

Inclusion criteria:

1. Male and female outpatients with diabetes mellitus.
2. Patients in the age group of 40 to 70 years.
3. Patients with inadequate glycemic control.
4. Duration of diabetes since 5 years to 35 years.
5. Diabetes mellitus patients who are willing to co-operate with the study.
6. Patients without any history of psychiatric disorders, language and communication problems.

Exclusion criteria:

1. Male and female inpatients without diabetes mellitus.
2. Patients in the age group below 40 and above 70 years.
3. Patients with adequate glycemic control.
4. Duration of diabetes since below 5 years and above 35 years.
5. Diabetes mellitus patients who are not willing to co-operate with the study.
6. Patients with any history of psychiatric disorders, language and communication problems.

The data collection form is used to register the personal, family, disease and treatment details of the enrolled patients. It contains details of patient's demographics ,comorbidities, duration of diabetes mellitus, past medication history for diabetes, diabetic microvascular complications, family history, social status, occupation, annual income, psychosocial status, diet, life style and laboratory parameters such as BP,FBS, RBS ,PPBS, HbA1c, protein creatinine ratio,

serum creatinine, blood urea nitrogen, fasting lipid profile, urinary albumin/creatinine, drug therapy for diabetes, nephropathy, neuropathy and retinopathy expenses incurred for treatment and all the relevant things which are necessary for the study. All the relevant information regarding demographics, socioeconomics and lifestyle characteristics (smoking, alcohol, consumption) were collected by interviewing the patients, and patient care givers. Anthropometric measurement including weight, height, and body mass index were carried out at the time of admission. Clinical systolic BP, diastolic BP level, blood sugar level including RBS, FBS, HbA1C, lipid profile, serum creatinine, blood urea, urine analysis reports are extracted from available medical record. Socioeconomic status was assessed using the modified Kuppuswamy's scales, which consider the education qualification, occupation of the family head and family income per month of the participant. For calculating the cost of illness, interviewed the patients on economic aspect of treatment which includes direct medical cost like physician fee, Investigation report charges, cost of drugs, direct non-medical costs like cost of transportation, expense incurred on food, room rent on time of hospitalization and indirect non-medical costs like patient per day salary loss and by stander wage loss if occurred to carry out cost of illness analysis diabetes mellitus. All the relevant data were collected in a predesigned paper case record form with prior consent of the participant.

RESULTS AND DISCUSSION

Age wise distribution

Table 1: Age wise distribution cost of illness

Age wise cost of illness	N	Mean	Std. Deviation
Direct medical cost	45 - 60	19852.13	15039.42
	61 - 70	21651.13	14726.37
Direct non medical cost	45 - 60	2793.10	1362.56
	61 - 70	2983.67	1206.78
Total cost of illness	45 - 60	22645.23	15263.78
	61 - 70	24634.80	14835.03

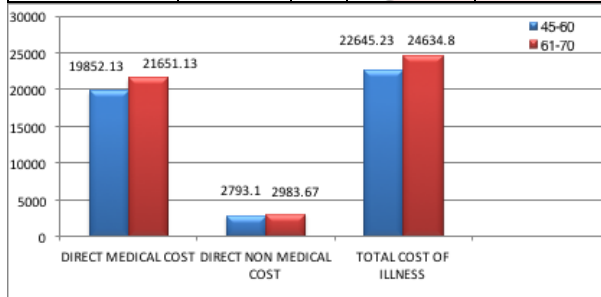


Figure 1; Age wise distribution cost of illness

Out of 52 patients studied direct medical cost was found to be higher (mean=21651.13 Rs, standard deviation+14726.37) in patient belongs to 61-70 year age group. The total cost of illness was also higher in patient with this age group (mean=24634.80 Rs, standard deviation=14835.03). The patient belong to

this age group may suffered from other comorbidities and microvascular complications, so the cost of illness was found to be higher in those patients as compared with other age group.

Table 2: sexwise cost of illness

Sex wise cost of illness	N	Mean	Std. Deviation
Direct medical cost	Male	25743.84	17225.90
	Female	15227.22	8441.66
Direct non medical cost	Male	3050.71	1073.48
	Female	2730.76	1463.25
Total cost of illness	Male	28794.55	17298.90
	Female	17957.98	8667.21

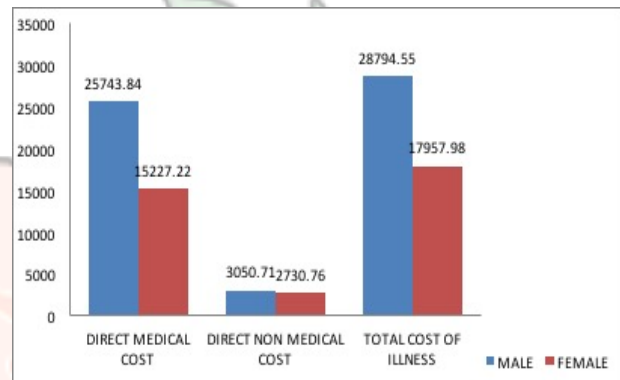


Figure 2: sex wise distribution

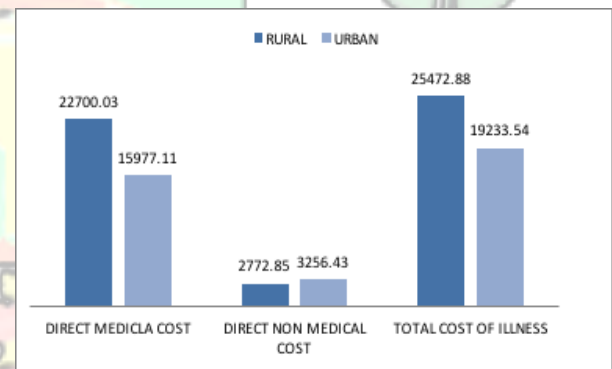


Figure 3: Area wise distribution of cost of illness

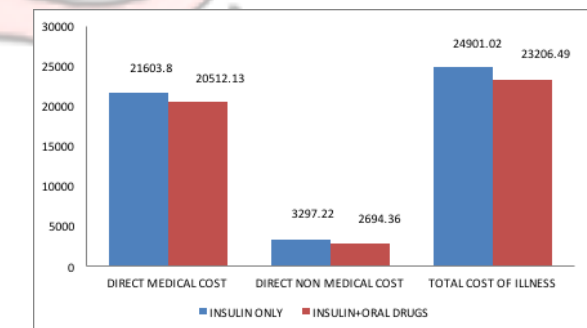


Figure 4: Therapy wise distribution of cost of illness

Table 3: Area wise distribution of cost of illness

Area wise cost of illness		N	Mean	Std. Deviation	Std. Error mean
Direct medical cost	Rural	38	22700.03	15908.54	2580.71
	Urban	14	15977.11	9820.03	2624.51
Direct non medical cost	Rural	38	2772.85	1255.17	203.62
	Urban	14	3256.43	1270.90	339.66
Total cost of illness	Rural	38	25472.88	16056.68	2604.74
	Urban	14	19233.54	10331.59	2761.23

Table 4: Therapy wise distribution of cost of illness

Type of therapy		N	Mean	Std. Deviation
Direct medical cost	Insulin only	18	21603.80	9775.33
	Insulin+oral drug	34	20512.13	16914.72
Direct non medical cost	Insulin only	18	3297.22	1169.78
	Insulin+oral drug	34	2694.36	1280.89
Cost of illness	Insulin only	18	24901.02	9933.31
	Insulin+oral drug	34	23206.49	17068.45

Table 5: socioeconomic status of patients

Socioeconomic status	Frequency	Percent(%)
Lower middle	14	26.9
Upper	2	3.8
Upper lower	25	48.1
Upper middle	10	19.2
Upper lower	1	1.9

Table 6: cost of illness of patients

Cost of illness (in rs)	Mean	Std. Deviation	Minimum	Maximum
Direct medical cost	20890.01	14739.61	5967.45	69451.50
Direct non medical cost	2903.04	1265.55	500.00	6350.00
Total cost of illness	23793.06	14901.74	6917.45	73121.50

Compare the cost of illness between microvascular patients and non microvascular patients.

The direct medical cost (mean=35205.18), direct non-medical cost (mean =3180.53) and total cost of illness (mean=38385.71) was higher in diabetic nephropathy (n=19) than diabetic retinopathy and diabetic neuropathy. Here the P value obtained for direct cost and total cost of illness was 0.0001, which is a significant result. In diabetic retinopathy the direct medical cost, direct non-medical cost and total cost of illness obtained was 26361.25, 3261.43 and 29622.68 respectively. Here the P value obtained for total cost of illness was 0.087, which was not significant. In diabetic neuropathy the direct medical cost, direct non-medical cost and total cost of illness obtained was 24227.42, 3428 and 27655.42 respectively. The P value obtained is 0.141, which was not significant.

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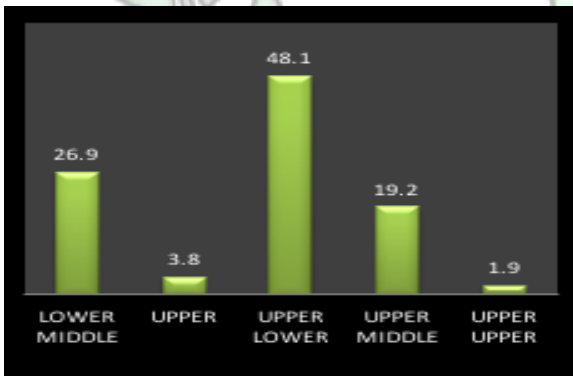


Figure 5: Socioeconomic status

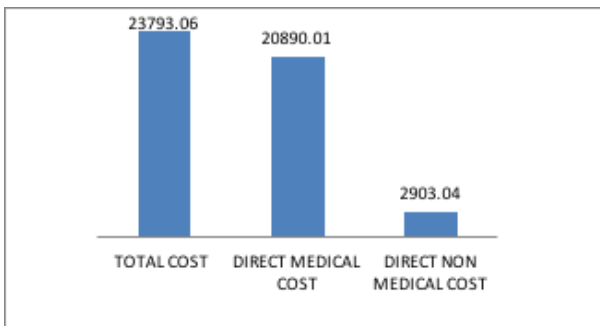


Figure 6: cost of illness of patients