



**INCIDENCE AND PATTERN OF DIABETES AND PHARMACOECONOMIC ANALYSIS
OF ANTIDIABETIC DRUG THERAPY AT A TERTIARY CARE HOSPITAL**

Ijtaba Fazili¹, Masood Tanvir², Amreen Naqash¹ and G.N.Bader¹

²Department of Medicine, Government Medical College, Srinagar.

¹Department of Pharmaceutical Sciences, University of Kashmir, Hazratbal, Srinagar, Kashmir-190006.

***Corresponding Author: G.N. Bader**

Department of Pharmaceutical Sciences, University of Kashmir, Hazratbal, Srinagar, Kashmir-190006.

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ABSTRACT

Diabetes is most common non-communicable disease worldwide. It is a chronic disorder and requires lifelong treatment. So the cost of antidiabetic drug is the major deciding factor for the patient's compliance. The present study was undertaken to assess the incidence and pattern of diabetes in patients in a tertiary care hospital in the heart of Kashmir valley. Main objectives of the study included documentation of various treatments being given to in- patients and outpatients for treating the disease, recording of all the expenses involved in the treatment, such as, cost of drug therapy, cost of various laboratory tests and hospital charges and evaluation of the adherence to treatment guidelines by diabetic patients. Overall objective of the study was to improve patient care by ensuring appropriate and cost-effective drug therapy. Suitable pharmacoeconomic evaluation method namely "Cost of Illness" analysis was applied to determine the total cost of illness for diabetic patients during the study. It was found that urban population was more affected by the disease than rural population, with urban females mostly affected. Hypertension and dyslipidemia were most comorbid conditions associated with the disease. Metformin and glimipride were most commonly prescribed drugs. Cost of illness was found to be in the range of INR100-400.

KEYWORDS: *Diabetes, antidiabetic drugs, pharmacoeconomic evaluation.*

INTRODUCTION

The WHO defines diabetes mellitus as "A metabolic disorder of multiple etiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from the defects in the insulin secretion, insulin action or both. Around nine percent of world's population is affected by diabetes mellitus (Kannan et al,2011). In developing countries like India, the majority of diabetics are in the age group of 45-64 years. In contrast in developed countries it is highly prevalent in the age group of more than 65 year (Scheen et al,1998).The management of type 1 diabetes mellitus depends mainly on insulin, whereas the oral antidiabetic drugs are the first line of treatment for type 2 diabetes mellitus (Chaudhary,2013). Complications due to hyperglycaemia in diabetes mellitus can be prevented by 'rational use' of oral antidiabetic drugs (OHA's) and insulin. (Hermansen et al,2008). Rational use of drugs is defined as " the patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community"(Sivasankari,2013). Selection of oral antihyperglycaemic agents as first-line drug or combined therapy could be based on both the pharmacological properties of the compounds (efficacy and safety profile) and the clinical characteristics of the patient (stage of

disease, body weight, etc) (Sicree,2006).

NEED FOR THE STUDY

A growing diabetes pandemic is unfolding with rapid increase in the prevalence of type 2 diabetes. Global increase in the prevalence of diabetes is due to population growth, aging, urbanization and an increase in obesity and physical inactivity (sedentary life style). As the number of people with diabetes grows worldwide, the disease takes an ever-increasing proportion of national health care budgets. Immediate action is needed to introduce cost- effective treatment strategies to reverse this trend. The high cost is related to late Diabetes Complications (DC), the economic loss is due to Lost Man-Days (LMD) or Lost Economic Opportunity (LEO). Moreover Nearly 80% of people with diabetes live in low and middle- income countries, where cost of illness is the most important consideration. Cost of drugs is an important factor influencing compliance by a patient to the treatment (Ravi et al,2006). In the developing countries the cost of the drug is a major concern to both physician and patient.

MATERIALS AND METHODS

A prospective, cross-sectional study was carried out in the Department of Medicine, Govt Medical College Srinagar, for six months from June 2015 to December

2015. All the demographic data and complete prescriptions were collected on predesigned case record form. All the diabetic patients attending the medicine outdoor and indoor department were enrolled in the study after explaining to them, the aim of the study. Prior approval of concerned authorities was obtained. Patients receiving any of the anti-diabetic drugs were included in the study irrespective of their gender except for pregnant and those having insufficient data or records. All patients of diabetes mellitus admitted to the medicine ward of S.M.H.S and OPD polyclinic during the study period were enrolled in the study Anatomical therapeutic classification was used to designate each drug prescribed.

DATA COLLECTION

All the demographic details of the patients were filled in the already designed Data collection forms from the out and in patients department of Medicine, relating to their MRD No. (Medical Record Department). From the selected prescriptions, patient's code number was used to trace their case-notes at Medical record department for obtaining other relevant information required in the data collection form that were not available on the filled prescriptions. The information included weight, diagnosis, duration of present regimen, physician's remark on glycemic control and adherence to prescription, relevant diagnostic/monitoring test (latest FBS, HbA1c) and blood pressure. Data collection continued in a systematic random sampling on diabetes clinic days upto December, 2015 and their case-notes within the inclusion criteria were obtained.

INCLUSION CRITERIA

All patients diagnosed with diabetes mellitus and admitted to the General Medicine ward including those attending one of the OPD clinics of Medicine at SMHS during the study period were included in the study irrespective of all age groups and genders.

EXCLUSION CRITERIA

Diabetic patients with or without any antidiabetic drugs prescribed and admitted to wards other than that of General Medicine at SMHS, Diabetic patients with or without any antidiabetic drugs prescribed and presenting to OPD clinics other than those of General Medicine at

SMHS, Diabetic patients with or without any antidiabetic drugs prescribed and presenting to General Medicine OPD clinics other than those attended by the investigator and Non-diabetic patients prescribed with antidiabetic drugs both at IPD and OPD of General Medicine and other Departments of SMHS were all excluded from the study.

RESULTS AND DISCUSSION

The place of study, SMHS hospital (a leading tertiary care hospital) is located in the heart of Kashmir: Srinagar and thus caters the needs of a wide range of population of Kashmir, urban as well as rural, male and female, young and adult etc. Thus the study included all the segments of society, a prerequisite for such type of study.

In this study, the highest number of patients (291: 58.2%) belonged to the age group: 51-65 years and 30% to the age group: 41-50 years (table 7). 140 (28%) were male and 360 (72%) were female (table 1). Urban population was more affected by the disease (65.4%) than rural population (34.6%). Four branded drugs namely Glucophage (metformin), Pioplus (glimipiride+ metformin+ pioglitazone), Isryl fort (glimipiride) and Amaryl (also glimipiride) were prescribed to various patients. All these drugs showed good activity in all types of population All these significantly decreased the glucose levels in these patients, evidenced by their increased t values and decreased p values. (tables 2,3,4,5). Most commonly used drug was metformin, which was prescribed to 178 (35.6%) patients (table 10). Drug combination was used for a number of patients (who did not respond or showed minimal response to monotherapy) and most commonly used drug combination was Glimepiride and Metformin (Pioplus). Hypertension and hyperlipidemia (95.6% and 20.4% respectively) were the most common co-morbidities associated with diabetes besides hyperthyroidism and obesity (table 9). A very less amount of drugs were given by injections (26%) as compared to oral hypoglycaemic agents (72.8%). Only 1.2% patients were kept on conservative treatment i.e diet controll (table 6). Cost of prescription, an important consideration in chronic diseases like diabetes ranged from 100-400 INR per month.

Table 1: showing rural/urban and sex wise distribution of diabetic patients in the s study

Total observations (n=500)	Percentage population (%)
Total males	28
Total females	72
Urban males	17.8
Urban females	47.6
Rural males	10.2
Rural females	24.4

Table 2: showing comparison & efficacy of various antidiabetic drugs in urban males.

Drug used	Mean glucose level \pm std error		t-value	p-value
	Before taking drug	After taking drug		
Metformin	154.27 \pm 1.33	129.09 \pm 0.82	17.75	<0.0001
Pioplus	149.50 \pm 1.89	127.90 \pm 0.69	12.44	<0.0001
Isryl	148.70 \pm 1.74	125.50 \pm 0.91	13.12	<0.0001
Glimepiride	149.80 \pm 2.23	126.20 \pm 1.20	10.37	<0.0001

Data presented as mean \pm standard error. *p* value < 0.0001 highly significant
>0.0001: significant & 0.1 = insignificant.

Table 3: showing comparison & efficacy of various antidiabetic drugs in urban females

Drug used	Mean glucose level \pm std error		t-value	p-value
	Before taking drug	After taking drug		
Metformin	152.4 \pm 0.90	126.8 \pm 0.42	37.65	<0.0001
Pioplus	153.3 \pm 1.65	127.2 \pm 0.84	18.07	<0.0001
Isryl	148.4 \pm 1.26	126.0 \pm 0.55	15.59	<0.0001
Glimepiride	149.2 \pm 1.29	127.9 \pm 0.83	16.52	<0.0001

Data presented as mean \pm standard error. *p* value < 0.0001 highly significant, >0.0001 significant & 0.1 = insignificant.

Table 4: showing comparison & efficacy of various antidiabetic drugs in rural males

Drug used	Mean glucose level \pm std error		t-value	p-value
	Before taking drug	After taking drug		
Metformin	149.2 \pm 1.37	126.8 \pm 0.87	15.36	<0.0001
Pioplus	153.2 \pm 2.40	126.7 \pm 1.01	08.95	0.0001
Isryl	148.7 \pm 2.46	124.7 \pm 0.73	12.70	<0.0001
Glimepiride	147.2 \pm 3.20	127.4 \pm 2.03	14.59	0.0001

Data presented as mean \pm standard error.*p* value < 0.0001 highly significant, >0.0001: significant & 0.1 = insignificant.

Table 5: showing comparison & efficacy of various antidiabetic drugs before & after taking drugs in rural females

Drug used	Mean glucose level \pm std error		t-value	p-value
	Before taking drug	After taking drug		
Metformin	152.03 \pm 1.93	128.37 \pm 0.63	15.36	<0.0001
Pioplus	151.05 \pm 2.00	126.55 \pm 0.95	08.95	0.0001
Isryl	149.90 \pm 2.08	124.84 \pm 1.34	12.7	<0.0001
Glimepiride	150.70 \pm 1.47	126.90 \pm 0.58	14.59	0.0001

Data presented as mean \pm standard error.*p* value < 0.0001 highly significant >0.0001: significant & 0.1 = insignificant.

Table 6: showing treatment protocol given to various diabetic patients in the study.

On oral hypoglycemics		On parenteral therapy (insulin)		On conservative treatment (diet control)	
364	(72.8%)	130	(26%)	6	(1.2%)

Table 7: showing age wise distribution of diabetic population in the study

Age groups	Total	Urban females	Urban males	Rural females	Rural males
41-50 years	134	108	3	15	8
51-65 years	291	141	48	68	34
Above 65 years	75	48	5	19	3

Table 8: showing types of diabetes prevalent in rural and urban population under study

Patients	Type-2 diabetes (T2DM)	Type-1 diabetes (T1DM)
Urban females	175	63
Urban males	74	15
Rural females	89	33
Rural males	40	11

Table 9: showing overall distribution of associated Comorbidities.

Type of population	Hypertension	Obesity	Dyslipidemia	Hyperthyroidism
Urban males	85	7	15	5
Urban females	230	28	42	25
Rural males	47	2	10	2
Rural females	117	19	35	13
Percentage (%)	95.8	11.2	20.4	9

Table 10: showing various treatments given to patients

Treatment	No of patients	%
Metformin	178	35.6
Insulin	130	26
Pioplus	62	12.4
Isryl fort	67	13.4
Glimipride	58	11.6
Others	5	1

In this study we found the disease more prevalent in urban females than other components of the society (table-1). The most important reasons are population growth, aging, urbanization and an increase in obesity and physical inactivity (sedentary life style) besides stress. The disease is more prevalent in urban females (47.6%) than other components of the society. Usually urban females live in an atmosphere of congestion, where there is limited scope of physical activity, (or as a status symbol, they hire services of a domestic aid—again limiting their physical activity, eat more unhealthy junk food, where as rural females have a lot to do (farming, household work etc, don't take usually junk food at all) thus opposite type of life style, which is an important factor contributing towards the less incidence of disease in them. Similar is the case of urban and rural males. Rural males besides their routine office work, supervise or actively get involved with their household and field work, whereas urban males don't have much to do after office work, limiting their physical exercise and thus are more prone to the disease than rural males.

In developing countries like India, the majority of diabetics are in the age group of 45-64 years. In contrast in developed countries it is highly prevalent in the age group of more than 65 years.(Scheen,2009). In this study we found that majority of population, (58.2%) were 51-65 years of age which is in accordance with findings for a developing country.

The cost of therapy in this study for a diabetic patient (type II) ranged from 100-400 Indian Rupees INR, which

as per the economic status of India is on the higher side. To overcome the cost factor, often patients miss some doses or some medication, leading to non compliance and non adherence to therapy, resulting in deterioration of their health status. Not only this, there is economic loss due to Lost Man Day (LMD) or Lost Economic Opportunity (LEO). The patient would have worked, but because of hospital visit can't do so, besides the quality and quantity of work both are affected because of health status. Selection of oral antihyperglycaemic agents as first-line drug or combined therapy could be based on both the pharmacological properties of the compounds (efficacy and safety profile) and the clinical characteristics of the patient (stage of disease, body weight, etc) (Secree et al,2006). There exists a wide range of variation in the prices of drugs marketed in India and other countries of the world. In the Indian market various antidiabetic drugs of different brands are available creating disarray in physician's mind to decide the drug of choice for individual patients.

Healthcare practitioners, regardless of practice setting, can benefit from applying the principles and methods of pharmacoeconomics to their daily practice settings. One of the primary applications of pharmacoeconomics in clinical practice today is to aid clinical and policy decision making. Through the appropriate application of pharmacoeconomics, practitioners and administrators can make better, more informed decisions regarding the products and services they provide. Complete pharmacotherapy decisions contain assessments of three basic outcome areas whenever appropriate: Economic,

Clinical and Humanistic Outcomes (ECHO). Traditionally, most drug therapy decisions were based solely on the clinical outcomes (e.g., safety and efficacy) associated with a treatment alternative. However, over the past 20 years, it has become quite popular also to include an assessment of the economic outcomes associated with a treatment alternative. The current trend is also to incorporate the humanistic outcomes associated with a treatment alternative, that is, to bring the patient back into this decision-making equation. This ECHO model for medical decision making has become prevalent in current healthcare settings.

Pharmacoeconomic data can be a powerful tool to support various clinical decisions, ranging from the level of the patient to the level of an entire healthcare system. Various decisions that can be supported using pharmacoeconomics, include effective formulary management, individual patient treatment, medication policy and resource allocation. The application of pharmacoeconomics to decision making is divided into two basic areas: drug therapy evaluation and clinical pharmacy service evaluation.

The application of pharmacoeconomics also can be useful for making a decision about an individual patient's therapy. Evaluating the impact a drug has on a patient's HRQOL (health related quality of life) can be useful when deciding between two agents for customizing a patient's pharmacotherapy.

The cost of prescription can be reduced by choosing most economic drugs without compromising their quality. Branded products can be substituted with generic products which must comply to the official standards and thus be acceptable to patients, who otherwise think these products to be of inferior quality. The use of generic names for drug purchasing as well as prescribing carry considerations of clarity, quality and price. Furthermore these generic names are more informative than branded names, facilitate purchasing of products from multiple suppliers (competitive bidding) and facilitate product substitution whenever appropriate (reduce inventory). Generic drug programmes are today probably the most relevant economic strategy for drug supply. If generic substitution does not exist, price competition will not exist either.

The result of this study is evidence-based information that can be used to influence prescription practice. Prescription of branded anti-diabetic drugs/drugs for other associated diseases or drugs for other chronic illnesses, which are used for lifetime by a diabetic patient. The present study also echoes that ECHO model for decision making should be taken into consideration in deciding the medication to these patients, as only then there will be compliance by the patient to the physician's prescription when all the three approaches i.e. Economic, Clinical and Humanistic Outcomes are given due consideration.

CONCLUSION

In this study we arrived at the following conclusion:

Diabetes is mostly prevalent in females. Urban females are more affected by the disease (47.5%). The disease is more prevalent in urban population (65.4%) than rural population. Most cases of the diabetics fall in the age group of 51-65 years. Hypertension is present as a comorbidity in most of the cases, besides dyslipidemia, obesity and hyperthyroidism. In most of the patients oral hypoglycemic agents were prescribed (72.8%). Insulin was the main drug used parenterally (26%). Most commonly prescribed oral drug was Metformin (35.6%). Sulfonylurea and biguanide combination drugs were also used where monotherapy was not effective, and in that metformin and glimipride combination was mostly used. Cost of the treatment for a diabetic patient varied from INR 100-400 per month. Cost can be reduced by applying ECHO model of Pharmacoeconomics, hence ensuring adherence to prescription.

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