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RESEARCH ARTICLE

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To Study the Pharmacotherapy of Diabetes Mellitus Type 2 Patient in Echo Health Care & Research Centre, Indore"

Swati Yadav*1, Deepak Kumar Gupta2, P.H.Patil3, Akhilesh Tiwari2, Pranay soni2

Corresponding Author: Swati Yadav

- 1.Institutes of Pharmaceutical Science, Sage university, Indore (M.P.)
- 2.Department of pharmacy, Indira Gandhi national tribal university, Amarkantak (M.P.)
- 3.Institute **Pharmaceutical** Education, Boradi (Maharashtra)



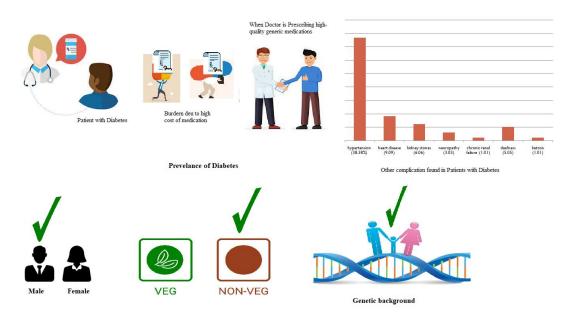
Abstract:

In this research, it was discovered that there were 2.5 medications per prescription on average. It was discovered that diabetic patients had a moderate incidence of polypharmacy. The highest cost of treatment for the study subjects' patients was determined to be Rs. 100. The average price per prescription was discovered to be INR 214.45. The cost of prescriptions can be further decreased by selecting high-quality generic medications. The pattern of prescription was carried out in accordance with accepted treatment standards. Unacceptably high rates of numerous problems are present in our DM patients, and those who have these abnormalities are receiving treatment. According to this study, hypertension (38.38%), heart disease (9.09%), kidney stones (6.06%), neuropathy (3.03%), chronic renal failure (1.01%), deafness (5.05%), and ketosis (1.01%) are the most frequent consequences related to diabetes. In this study, the patterns of incidence of lipid abnormalities are seen to be influenced by gender, age, the length of diabetes mellitus, the anti-diabetic medication provided, and anthropometric indices. Ischemic heart disease and hypertension were the two most common comorbidities of type 2 diabetes mellitus. Another finding showed that non-vegetarian behaviours were considerably more prevalent among patients who were illiterate across all study populations. This study found that the hereditary component was mostly to blame for the prevalence of the diabetes component and that this prevalence is rising daily. Male individuals with diabetes are more affected than female patients overall. According to three definitions, it was discovered that men were more affected than women by the prevalence rate of diabetic complications among diabetic patients. In both boys and females, the prevalence rate was higher in accordance with the WHO definition than IDF and ATP III.

KEY WORDS: Type 2 Diabetes mellitus, Prescription pattern, Antidiabetic medication, prescribing patterns, body mass index, Dyslipidaemia, Diabetic complication.

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Introduction

At the cellular level, diabetes is one of the most common endocrine disorders characterised by inappropriate hyperglycaemia caused by a relative or absolute deficiency of insulin or by a resistance to the action of insulin at the cellular level (1). (4). Diabetes mellitus is a group of syndromes hyperglycaemia, characterised by metabolism of lipids, carbohydrates, and proteins, and an increased risk of complications from vascular diseases (2). As per the classification, DM is classified under three main categories, which comprise type-I, type-II, and other specific types of diabetes. Type-I diabetes is insulindependent and it is a genetic disorder as well (3). The prevalence of diabetes is rapidly rising all over the globe at an alarming rate. Over the past 30 years, the status of diabetes has changed from being considered a mild disorder of the elderly to being one of the major causes of morbidity and mortality affecting young and middle-aged people (4). Although there is an increase in the prevalence of type-I diabetes, the major driver of the epidemic is the more common form of diabetes, namely type-II diabetes, which accounts for more than 90 percent of all diabetes cases (5). The diabetes epidemic is more pronounced in India as the World Health Organization (WHO) reports showed that 32 million people had diabetes in the year 2002 and it is expected that it may rise to 80 million in 2030(6). Type-II diabetes is the most frequent form of diabetes and accounts for 90-95% of patients worldwide (7). The long-term exposure to untreated DM and a lack of awareness regarding the diagnosis and treatment of diabetes leads to the development of diabetes-associated complications that result in a plethora of hospitalizations and premature death cases across the globe. These complications are increasing not only the number of hospitalizations and deaths, but also the financial burden on individuals (8). The cost of treating diabetes and its complications affects households as well as national spending. Economic analyses of diabetes care in India show that the usual cost of care is a fraction of the total cost and remains controllable (9). Total direct and indirect costs associated with health problems throughout life, as well as economic consequences for individuals, families, and society, particularly as microvascular and macrovascular complications of the disease emerge (10). The current investigation shows the evaluation of the Pharmacoeconomics of diabetes treatment along with the newer anti-diabetic medications' effects on the health consequences and quality of life of the specific patient population.

Methodology: The prospective and observational study was conducted to investigate various

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complications in diabetic patients and prescription patterns of the existing drugs by the physicians in type 2 diabetic patients in the outpatient ward of the Echo Health Care & Research Centre, Indore. This cross-sectional study comprises the 150 subjects with DM who participated in the Echo Health Care & Research Centre, Indore for seven months. All necessary and relevant information was collected via OPD cards, treatment charts, laboratory data reports, patient history records, and verbal communication with patients or their guardians. All the personal information of the patients was collected on a signed informed consent form. Patients were selected based on the following inclusion and exclusion criteria:

Inclusion criteria:

- Patient of either sex (male or female).
- Patients with age more than 18 years.
- Patients with a history of type 2 Diabetes mellitus or currently diagnosed with type 2 Diabetes Mellitus and prescribed antidiabetic agents.

Exclusion criteria:

- All type 1 diabetic patients.
- Diabetic patient on steroid therapy.
- Pregnant & Lactating women.

Statistical Analysis:

The prescribing pattern and drug utilisation were assessed in terms of individual drug use, their classes, and their percentage value was calculated. Using Microsoft Excel 2003 or 2007, the results were expressed as mean (Standard Deviation (SD) or Standard Error Mean (S.E.M.).

Results:

1. Age distribution of patients: The prevalence of diabetes was found in the age group between 41-50 years 63 (42%) followed by 51-60 years 38 (25.33%). The normal weight patient in both these groups was found to be highest at 27 and 10 respectively. Comparative less prevalence of disease was found in elder and older people among the study population that is age group 18-30, 31-40 years 9 (6%), 20 (13.33%) respectively and in age group 61-70,71-80,81-90 years 13 (8.6%), 4 (2.6%), 3 (2%) respectively (figure 1).

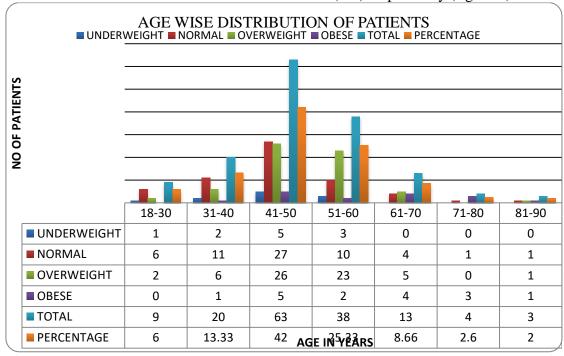


Figure 1: Age wise distribution of patients

2. Family History of diabetes: The family history was defined as positive when a person

enrolled has a first-degree relative (a parent, grandparent, sibling, or child) who has ever

been diagnosed with diabetes mellitus. The family history was defined as negative if the person reported the absence of diabetes among first-degree relatives. **Following** verbal communication with the patient, it was discovered that 85 (56.66%) of the 150 had a positive family history and 65 (43.33%) had no or negative family history. (Figure 2)

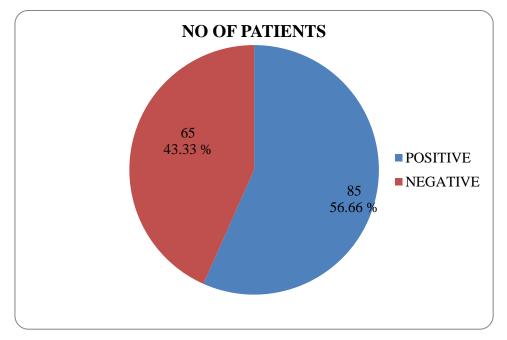


Figure 02: Family History of diabetes

3. Duration of diabetes: The long duration of uncontrolled diabetes increases the progression complications also of and encourages the physician to use polypharmacy, which leads to increased cost and patient noncompliance with therapy. In the present study, 98 (65.33%) patients had

new-onset up to 5 yrs. of diabetic history, followed by 38 (25.33%) with 6-10 yrs. of duration, and only 2 (1.33%) had more than 20 yrs. of DM. Out of 98 patients with 0-5 years of duration, 16 are new-onset diabetics. (Figure 3).

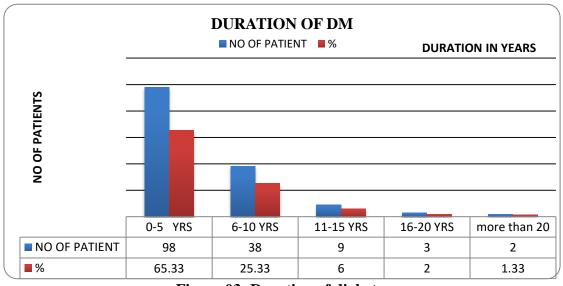


Figure 03: Duration of diabetes

- 4. Number of drugs per prescription: The monotherapy includes either OHA or insulin, and the combination therapy includes OHA and/or insulin according to blood sugar levels. Several drugs are available either alone or in combination, generally used for effective long-term management of DM. Among the study patients, one, two, three, and four drugs were prescribed to 79 (52.66 %), 54 (36%), 14 (9.33%), and 3 (2 %) patients,
- respectively. The average number of drugs per prescription was 2.5.
- **5.** Class of antidiabetics: The total class of antidiabetic drugs prescribed in patients patients' prescriptions 150 **Biguanides** (50%),followed by Sulphonylureas (31.29%), Thiazolidinediones were prescribed in 26 (8.38%), insulin was prescribed in 34 (10.96%), and glucosidase inhibitor was prescribed in 3 (0.96%) prescriptions. (Figure 4)

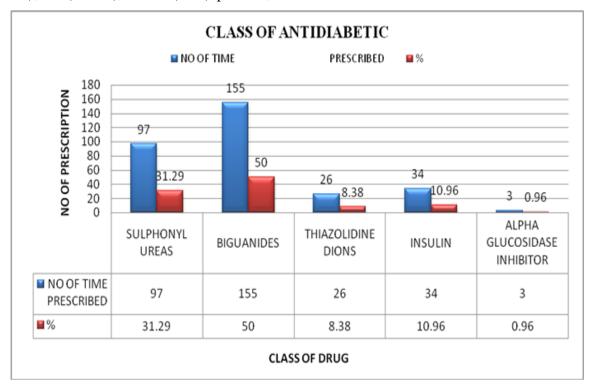


Figure 4: Class of antidiabetics.

6. Patients received monotherapy with various classes: According to ADA guidelines, the use of monotherapy should be the initial choice for the treatment of diabetes with exercise and diet. In the present study, it was observed that 72 prescriptions contained monotherapy. Most

frequently, Metformin accounts for 27 (37.5%)prescriptions as monotherapy, Gliclazide followed bv (22.22%). 16 Glimepiride 10 (13.38%), Glipizide 7 (9.72%), and Insulin 12 (16.66%). (Figure 5)

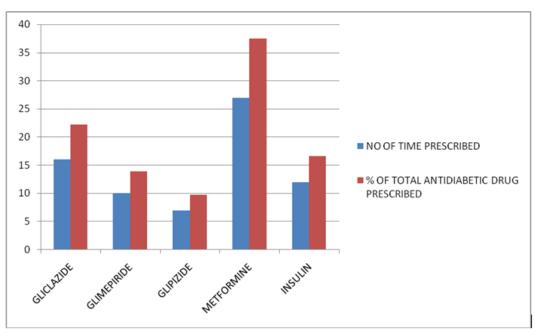


Figure 05: Distribution of monotherapy

7. Patients received combination therapy with various classes: In this study, 78 prescriptions encompassed a combination of two or more drugs. Biguanides and Sulphonyl urea's were found to be the most commonly prescribed combinations two-drug in 33 (42.3%)prescriptions, followed by Biguanides,

Sulphonyl Urea's, and Thiazolidinediones, a three-drug combination in 6 (7.69%), and Biguanides, Sulphonyl Thiazolidinediones, and Insulin, a four-drug combination in 2 (2.56 %) were also prescribed.

Table 1: Distribution of combintion therapy

No of drug in combination	Class of Drugs in Combination	No. of Time Prescribed	% Of total antidiabetic drug Prescribed
2	Biguanides + Sulphonyl urea's	33	42.3
	Biguanides + Thiazolidine dions	4	5.12
	Sulphonyl urea's + Thiazolidine dions	11	14.1
	Insulin + Biguanides	5	6.41
	Insulin +Sulphonyl urea's	6	7.69
3	Biguanides + Sulphonyl Urea's + Insulin	5	6.41
	Biguanides + Sulphonyl Urea's + Thiazolidine dions	6	7.69
	Biguanides + Insulin + Thiazolidine dion	2	2.56
	Insulin + sulphonyl urea's + Thiazolidine dions	2	2.56
4	Biguanides +Sulphonyl Urea's + Thiazolidine dions + α glucosidase	2	2.56

inhibitor		
Biguainides +Sulphonyl Urea's + α glucosidase inhibitor + Insulin	-	-
Biguainides +Sulphonyl Urea's +Thiazolidine dion + Insulin	2	2.56

8. Type of insulin prescribed: The physician practices insulin alone or in combination with OHA's in this study, 34 patients received insulin. Out of that, 22 received insulin in combination with other OHA's, and 12

received insulin alone. Insulin (30/70) was prescribed in 21 (61.76%) patients, Insulin Act rapid in 6 (17.64%), and regular insulin in 7 (20.58%) patients.

Table 02: Type of insulin prescribed

Type of Insulin	No of Prescription	%
Inj. Insulin Mixtard 30/70	21	61.76
Inj. Insulin Actrapid	6	17.64
Inj. Regular Insulin	7	20.58

9. Cost analysis: The cost of antidiabetic drug therapy was calculated for each prescription and it was found that 48 (32%) prescriptions were below Rs.100 per prescription, followed by 39 (26%) were between Rs.101-200, 25 (16.66%) were between Rs.201-300, 20

(13.33%) were between Rs. 301-400, 10 (6.66%) were between Rs. 401-500, and 8 (5.33%) were more than Rs. 500. The average cost per prescription was INR 214.45 (US \$24).

Table 03: Cost of therapy

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COST IN RUPEES	NO OF RESCRIPTIONS	%		
<100	48	32		
101-200	39	26		
201-300	25	16.66		
301-400	20	13.33		
401-500	10	6.66		
>500	8	5.33		

Discussion:

Diabetes and its complications are key players in mortality and morbidity in patients. The previously mentioned factors not only cause morbidity or mortality, but they also increase the extra burden on individuals' pockets (11). It is also increasing the overall cost of diabetes treatment, whether it is Type-I or Type-II. People who live in areas that have not become westernised tend not to get type 2 diabetes. Type 2 diabetes has a stronger genetic basis than type 1, yet it also depends more on environmental factors, no matter how high their genetic risk is (Drong, 2012 # 13).

We observed that 85 (56.66%) patients had a positive family history. In the present study, nearly two-thirds (65.33%) of the patients had a diabetic history of fewer than five years. Physicians practise either monotherapy or a combination of two different categories of antidiabetics to control blood sugar. Monotherapy includes either OHA or insulin, and combination therapy includes OHA and/or insulin according to blood sugar levels. The choice of anti-diabetic depends on the type of patient, their concurrent illness, cost factors, as well as the availability of medicines. As per the International Diabetes Federation, 2005 and ADA 2009 guidelines, oral

glucose-lowering drugs should be started when lifestyle interventions alone are unable to maintain blood glucose control at target levels. According to the guidelines, metformin in monotherapy should be used as the first choice unless there is evidence or risk of renal impairment. In the present study, we found that metformin as a monotherapy is prescribed in the highest percentage (37.5%) among all antidiabetic drugs, gliclazide. followed by In addition monotherapy, various combinations are used when the targeted level of blood glucose cannot be achieved by lifestyle interventions and monotherapy. The average number of drugs per prescription was 2.5. In general, due to multiple diseases, diabetes patients are at a greater risk of polypharmacy. In chronic diabetes cases, a combination of antidiabetic drugs was prescribed, which included 3 or 4 drugs at a time. The present that Biguanides shows Sulphonylureas were most frequently used in combination 33 (42.3%), followed by Biguanides, Sulphonyl Urea's, and Thiazolidine dions threedrug combination in 6 (7.69%). A four-drug combination was also prescribed in 2 (2.56%) of the patients. Many patients with type 2 diabetes eventually lose natural insulin function, thereby requiring insulin replacement. Oral agents and insulin can be used together to achieve optimal blood glucose levels. For patients with type 2 diabetes, insulin analogues include rapid or longlasting insulin derivatives that simulate the normal insulin response. In our study, 34 patients received insulin therapy. Of those, only 12 patients were on insulin therapy alone, and 22 were on insulin as well as an oral agent. Regular Insulin Injection came in second at 7 (20.58%), followed by Insulin Act rapid at 6 (17.64%). The cost of drug therapy is a cause of non-adherence. The total annual cost of treating India's diabetic patients (including direct and indirect expenses) is estimated at \$420 per capita. If this per capita expenditure were to remain constant, the total estimated cost of treating the disease would reach \$30 billion by 2025. In our study, the average cost per prescription was found to be INR 214.45, approx. (US \$2.80). One of the most effective ways to reduce prescription costs is to prescribe lower-cost brands. Moreover, the cost of metformin is very

low and is prescribed by the highest percentage, making it affordable for the patients in the socioeconomically weak group. Prescription costs can be significantly reduced by prescribing less expensive alternatives. However, while choosing cheaper brands, one should keep in mind the quality of the brands. The rising cost of diabetes and its complications includes the cost of medicines, tests, consultation fees, hospitalization, etc. As a result, many patients are unable to pay the high cost of new diabetes drugs. In addition, drug affordability is an important factor in adherence to medication. This investigation mainly focused on the economic burden of disease treatment. We can reduce the burden through awareness, using cheaper drugs, especially generics, and long-lasting diabetes therapies.

Conclusion:

The current investigation focuses on age, prescription patterns, and cost analysis of diabetes treatment in a particular patient population. This research also demonstrates the importance of cost analysis and the need for affordable and long-lasting diabetes therapy. The study gave a clear idea of the major problem of diabetes awareness, complications, and available treatments in India.

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Author contributions: SY conceptualized and drafted the manuscript and also designed the experimental methodology. AT & DKG was a major contributor in editing and revising and prepared figures. PHP substantively reviewed the draft with given idea of this research. All authors read and approved the final manuscript.

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Availability of data and materials: All data generated or analysed during this study are included in this published article.

Declarations:

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Consent for publication: Yes.

Competing interests: The authors declare that they have no competing interests.

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