Assessment of drug utilization pattern of antidiabetic drugs in type-2 diabetes outpatient of a tertiary care teaching hospital western Rajasthan

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Received: 15 February 2021
Accepted: 12 March 2021

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ABSTRACT

Background: Glycemic control remains the major therapeutic objective for prevention of target organ damage and other complications arising from diabetes. Poor glycemic control in diabetes mellitus can be prevented by using rational use of oral hypoglycemic agents (OHA). Rational use of the drugs in populations can be effectively evaluated using drug utilization studies.

Methods: The present study was conducted in the outpatient departments of General Medicine at Sardar Patel Medical College associated group of PBM Hospital, a tertiary care teaching hospital. It was a cross sectional prospective study carried out over a period of four months from September 2020 to January 2021. Patients were enrolled on the basis of inclusion and exclusion criteria.

Results: Total 300 patient prescription patterns were studied, out of which 58.33% were males and 41.66% were females. Most of the patients were in the age group of 51-60 years. Average number of anti-diabetic drugs per prescription was found to be 1.99. biguanides was the most commonly prescribed drug (97%) as mono therapy and combination therapy followed by sulfonylureas (65.6%), DPP 4 inhibitors (24%) Majority of the patients (66%) were on multidrug therapy.

Conclusions: Metformin was the most frequently prescribed drug in diabetes. Prescription by Brand name is a matter of concern. Overall, monotherapy was found to be predominant over combination therapy. There was no significant increase in the prescribing of newer oral antidiabetic agents like GLP-1receptor inhibitors and DPP-4 inhibitors. glimepride + metformin combination was the most commonly prescribed combination.

Keywords: Diabetes mellitus, Prescribing pattern, Rational drug use, Oral hypoglycemic agent

INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia. It is associated with abnormalities in carbohydrates and fat metabolism, which results in chronic complications including microvascular and macrovascular disorders.

In India, diabetes has emerged as a major healthcare problem and highest population of diabetes in the world. The international diabetes federation (IDF) estimates the number of people with diabetes in India will reach 80 million by the year 2025. A survey depicts that 4% of adults in India suffered from diabetes in the year 2000 and is expected to increase to 6% by the year 2025. Worldwide prevalence of DM is estimated to rise from 382 million in 2013 to 592 million in 2035. The prevalence of type 1 diabetes (T1DM) is about 5% to 10% and type 2 diabetes mellitus (T2DM) is about 90% to 95%.2,3
Type 2 DM in geriatric group is significant and the intensity of the treatment in this age group is uncertain. The prevalence of DM increases with age and peaks at 60–69 years of age, and thus, this population should be cared in India to avoid complications due to DM. Type 2 diabetes mellitus and hypertension are diseases of middle or old age. Co-existence of both these diseases appears to be increasing in industrialized nations because populations are aging. Hypertension is frequently associated with diabetes mellitus and its prevalence doubles in diabetics compared to the general population.

There is no specific cause for DM, but both etiologic factors and risk factors are associated with it. The risk factors are heredity, obesity, increasing age, emotional stress, autoimmune β-cell damage, endocrine diseases (e.g. cushing disease). In addition to that the incidence is increasing in rural parts of India due to urbanization, obesity, unsatisfactory diet, sedentary life style, etc. Both types of diabetes have microvascular and macrovascular complications.

The current pharmacotherapy of diabetes mellitus includes treatment with drugs such as insulin and oral hypoglycemic agents. The main classes include agent’s sulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinediones, dipeptidyl peptidase-4 inhibitors.

The study of drug utilization or prescribing patterns is a component of medical audit, which seeks monitoring, evaluation and necessary modifications in the prescribing practices to achieve rational and cost effective pharmacotherapy. Studies on antidiabetic drug utilization are important for the optimization of drug therapy and drug control.

Therefore, the present study aimed to evaluate the drug utilization pattern of standard antidiabetic drugs in an outpatient medicine department of a tertiary care teaching hospital.

**METHODS**

The present study was conducted in the outpatient departments of General Medicine at Sardar Patel Medical College associated group of PBM Hospital, a tertiary care teaching hospital. It was a cross sectional prospective study carried out over a period of four months from September 2020 to Jan 2020. Before starting the study, ethical approval was obtained from the Institutional Ethics Committee. Written informed consent was taken from those patients, who fulfilled study criteria.

Total 300 patients of type II diabetes mellitus attending the medicine OPD for consultation were selected during our study and were analyzed on the basis of inclusion and exclusion criteria. All the patients with anti-diabetic drugs in their prescriptions, between 40-60 years of age were included in this study. Patients diagnosed with type 2 diabetes mellitus who received only oral anti diabetic drugs were included in this study. Patients having comorbid illness like hypertension, ischemic heart disease and obesity were included in this study. Patients who suffering from type I diabetes, pregnant women, including those with gestational diabetes, incomplete medical records and newly diagnosed patients were excluded from our study.

All the information was recorded in case record form (CRF) which was designed according to WHO criteria. It includes age, gender, information related with prescribed drug therapy including the diagnosis, dose, frequency of drug administration, routes of drug administration and duration of therapy, respectively.

**RESULTS**

Total 300 outdoor patient’s prescription were analysed on the basis of inclusion and exclusion criteria. During the study period total 300 patients with type 2 diabetes Mellitus were included from Department of medicine. Out of the 300 patients, 175 (58.33%) were males and 125 (41.66%) were females. Among 300 patients, maximum patients 199 were enrolled in 51-60 years age group followed by 101 patients 41-50 years age group. According to BMI range majority of the patients belongs to overweight 255 (85%) (Table 1).

The total number of anti-diabetic drugs which were prescribed to the patients was 597. Each patient, on average was prescribed anti diabetic drugs 1.99 per prescription. In this study observed that all anti diabetic drugs prescribed by generic name as a recommended by WHO (100%) (Table 2).

**Table 1: Socio demographic profile of type 2 diabetic patients.**

| Sr. No. | Parameters | Total N (number) | Percentage |
|---------|------------|-----------------|------------|
| 1 .     | Age        |                 |            |
|        | 41-50      | 101             | 33.6       |
|        | 51-60      | 199             | 66.3       |
| 2.      | Gender     |                 |            |
|        | Male       | 175             | 58.33      |
|        | Female     | 125             | 41.66      |
| 3.      | BMI (kg/m²) |                |            |
|        | Normal (18-25) | 34              | 11.33      |
|        | Overweight (25-30) | 255              | 85         |
|        | Obese (>30) | 11              | 3.66       |
Table 2: Prescribing indicators among the studied prescriptions (n=300).

| Prescribing indicators                                      | Number (%) |
|-------------------------------------------------------------|------------|
| Total number of drugs prescribed                            | 597        |
| Average number of antibiotics per prescription              | 1.99       |
| Number of prescriptions with monotherapy                    | 102 (34%)  |
| Number of prescriptions with polytherapy                    | 198 (66%)  |
| Percentage of drugs prescribed by generic name              | 100        |
| Percentage of drugs prescribed from the essential list      | 100        |

Table 3: Prescribing frequency of anti-diabetic drugs.

| Antidiabetic drug class | Drug    | ATC code | No of patients | Percentage |
|-------------------------|---------|----------|----------------|------------|
| Biguanides              | Metformin | A10BA02  | 291            | 97         |
| Sulfonylureas           | Glimepiride | A10BB01 | 197            | 65.6       |
| DPP-4 inhibitor         | Tenegliptin | A10BH-72 | 72             | 24         |
| Thiazolidinediones      | Pioglitazone | A10BG03 | 37             | 12.3       |

Figure 1: Single therapy vs combination therapy.

In this study oral hypoglycemic agents were the most common class of anti-diabetic drugs prescribed among which, metformin 291(97%) was the most commonly prescribed drugs followed by glimepiride 197 (65.6%), tenegliptin 72 (24%) and Pioglitazone 37(12.3%). In this study, a fixed dose combination (FDC) accounted for 34% of the total drugs prescribed among which combination metformin glimepiride and pioglitazone (Table 3).

The current study shows that out of 300 patients, maximum no. of patients was prescribed with dual therapy 134 (44.66%) while 64 (21.33%) patients were prescribed with triple therapy and 102 (34%) patients was prescribed with monotherapy (Figure 1).

DISCUSSION

Diabetes is a major healthcare problem in India. The WHO defines diabetes mellitus as “A chronic, metabolic disease characterized by elevated levels of blood glucose (or blood sugar), which leads over time to serious damage to the heart, blood vessels, eyes, kidneys, and nerves”.

The present study was a hospital based cross sectional study conducted in the diabetes centre of tertiary care hospital focusing on drug utilization pattern among type II diabetic patients. The primary objective of the study was to assess the anti-diabetic drug prescription pattern among diabetic patients attending the medicine outpatient department.

In our study, total of 300 type 2 diabetic patients were evaluated during the study period and it was observed that, demographic data showed that the number of male patients suffering from type 2 diabetes was more than the number of female patients. Similar study conducted by Vengurlekar et al, Boccuzzi et al, Johnson et al, Yurgin et
al, also showed that male had preponderance in the prevalence of diabetes.\textsuperscript{10,11}

The current study observed that, type 2 DM was found to be most prevalent 199 (66.3\%) in the age group of 51-60 years. As aging causes increase prevalence of diabetes and carbohydrate intolerance in the elderly due to associated decrease in insulin secretion in response to glucose load as well as increased insulin resistance in peripheral tissues. Further, insulin sensitivity also decreases with increasing age and obesity. Similar finding was reported by Vengulekar et al, Upadhayya et al, and Kannan et al.\textsuperscript{12,13}

In present study found that, average number of anti-diabetic drugs per prescription was 1.99. One previous study from India also reported average of 1.95 drugs per prescription.\textsuperscript{14} In this study, average no. of drugs per prescription is less as compared to other studies conducted by Upadhya et al (3.76 per prescription) and Karthikeyan et al (4.83 per prescription).\textsuperscript{12,15}

The most commonly prescribed anti-diabetic drug class was biguanides (metformin) both as monotherapy and/or in combination therapy, metformin accounted for (97\%) of the total drugs prescribed, followed by sulfonylureas (glimepiride), (65.6\%) and then DPP-4 inhibitors (teneligliptin) 24\% which is similar to other studies Alex et al. and Jain et al revealed that metformin and glimepiride most commonly prescribed drugs.\textsuperscript{16,17}

Unlike sulfonylureas, thiazolidinediones, and insulin, metformin is weight neutral, which makes it an attractive choice for obese patients. Furthermore, the management of type II diabetes can be complicated by hypoglycemia, which can seriously limit the pursuit of glycemic control. By decreasing excess hepatic gluconeogenesis without raising insulin levels, metformin rarely leads to significant hypoglycemia when used as a monotherapy. As a result, metformin is widely considered an ideal first-line agent for the treatment of type 2 diabetes. In addition, the cost of metformin is very low, thus making it affordable by the patients in economically weak countries like India.\textsuperscript{16}

In our study, it was observed that 34\% of total patients were on monotherapy with oral hypoglycaemic agents and 66\% in combination therapy. Similar findings were reported by study conducted in Kerala by Alexet al (58.4\% polytherapy).\textsuperscript{16} Another study conducted in Tamil Nadu by Sivasankari et al monotherapy, and two drug combination therapies were prescribed in 21.7\% and 78.3\% patients, respectively.\textsuperscript{18}

**CONCLUSION**

The present study was aimed to analyse the prescription pattern of the diabetic patients with or without comorbidity with specific objective to determine the current trend of anti-diabetic drugs.

The present study concludes that; metformin was the most frequently prescribed drug in diabetes followed by sulfonylureas (glimepiride). Among antidiabetic drugs used as monotherapy, most commonly utilized drug class was biguanides followed by sulfonylureas. Metformin with gliptin was the most frequently prescribed combination therapy. The present study showed, low cost of drugs per prescription as generic drugs has been prescribed to the patients. So, it is necessary to taken care of quality of drugs.

Overall, monotherapy was found to be predominant over combination therapy. There was no significant increase in the prescribing of newer oral antidiabetic agents like GLP-1 receptor inhibitors and DPP-4 inhibitors. Glimepiride + metformin combination was the most commonly prescribed combination.

Drug and therapeutics committees should be established in hospitals to monitor and implement interventions to improve the use of medicines. Proper measures should be taken to avoid the inappropriate use of medicines.

**Funding:** No funding sources

**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

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Cite this article as: Tanwar S, Acharya A, Hasan N. Assessment of drug utilization pattern of antidiabetic drugs in type-2 diabetes outpatient of a tertiary care teaching hospital western Rajasthan. Int J Basic Clin Pharmacol 2021;10:368-72.