



Drug Utilization Research in Adult Patients with Type 2 Diabetes

Naveen Poojar C M*, Sudhindra D and Ujwala N J
MBBS, MD, Bangalore, Karnataka

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*Corresponding Author Email: naveenpoojar.cm@gmail.com

Abstract

Background: Diabetes mellitus is an important public health problem in developing countries like India. Various classes of anti-diabetic drugs including Insulin and oral hypoglycemic agents are currently being used in the treatment of diabetes, which acts by various mechanisms to reduce the blood glucose levels in order to maintain optimal glycemic control. The drug utilization research is important in clinical practice. Irrational drug use can lead to adverse outcomes of the disease. **Objectives:** The objective of this study was to evaluate the pattern of drugs used in Type II diabetes mellitus and their rationality and to identify any immediate adverse drug reactions, related to drugs administered. **Methods:** Prospective, observational study was conducted for 6 months including 200 patients with Type 2 Diabetes Mellitus in IPD and OPD of Primary care hospital in the South Bengaluru. **Results:** Biguanide (Metformin) is the most commonly used drug with 84% of patients followed by Sulfonylureas in 48%, DPP-4 inhibitor in 42% and Human Insulin in 14% of the patients. Fixed drug combination prescribed in 172 (86%) among total prescriptions. Two drug combinations 124 (62%) and three drug combination 48 (24%). **Conclusion:** In this study, the prescribing trend was found to be dual drug therapy. Among oral antidiabetic agents, Metformin was most commonly used drug.

Keywords

Type II diabetes mellitus, Metformin, Combination therapy

INTRODUCTION:

Diabetes mellitus (DM) is defined as chronic metabolic disease characterized by derangements in metabolism of carbohydrates, protein and fat. The basic pathology behind Diabetes mellitus is either lack of insulin secretion or inability of insulin to act on tissues. It has emerged as an epidemic both in the developing and developed countries and shows no signs of regression [2].

According to the International Diabetes Federation, 387 million people globally suffer from diabetes which is estimated to rise to 592 million by 2035.[3] The prevalence of diabetes in India, which was 31.7

million in 2000,[4] has since climbed to 65.1 million in 2013 and is projected to reach 79.4 million by 2030. India has the distinction of being the diabetes capital of the world with the number of diabetics far exceeding that of China and America. India is also the largest contributor of diabetes-related mortality in South East Asia. Diabetes is thus a major health problem worldwide and even more so in India.

The new classification system identifies four types of diabetes mellitus i.e. Type I, Type II, Gestational Diabetes and other specific types of diabetes mellitus. Type I Diabetes Mellitus- IDDM (Insulin Dependent Diabetes Mellitus) is characterized by

destruction of beta cell triggered by an autoimmune process typically leading to absolute deficiency of insulin. Type II Diabetes Mellitus- NIDDM (Non-Insulin Dependent Diabetes Mellitus) is a chronic, progressive disease characterized by hyperglycemia, which rises from the progress of resistance of insulin in peripheral tissues, a failure of the pancreatic β -cells to secrete adequate insulin in response to glucose loads, and an insufficient suppression of glucagon production.⁵

Diabetes mellitus is associated with numerous complications including long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels [6]. They are broadly categorized into macrovascular and microvascular complications. Macrovascular complications include coronary artery diseases, cerebrovascular disease, peripheral arterial disease, etc. Microvascular complications include nephropathy, neuropathy and retinopathy.⁷

Poor Glycaemic control is a major worry in diabetes mellitus which can be prevented by rational use of oral Hypoglycaemic Agents (OHAs) and insulin [8]. Rational use of the drugs is defined as: "That 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" [9].

Drug utilization has been defined as the marketing, distribution, prescription, and use of drugs in a society, with emphasis on the resulting medical and social consequences.

[10] The principal aim of drug utilization study is to facilitate the rational use of drugs in population. The drug utilization data from type 2 diabetic patients can provide data for determining pattern of prescription.

The objective of this study was to evaluate the pattern of drugs used in Type II diabetes mellitus and their rationality and to identify any immediate adverse drug reactions, related to drugs administered.

MATERIALS AND METHODS:

A Prospective, observational study is conducted for 6 months (February 2022- July 2022) in IPD and OPD of Primary care hospital in the South Bengaluru.

Data is collected from case records of patients Type 2 Diabetes Mellitus in the case study form designed for the study including

- Demographic profile of patients

- Disease data
- Investigations conducted
- Drugs data
- Adverse drug reactions

Sample size- 200

Inclusion criteria:

1. Patients suffering from Type 2 Diabetes Mellitus
2. Patients willing to participate in the study

Exclusion criteria:

1. Patients with Type 1 and other types of Diabetes
2. Patients with other co-morbid conditions
3. Patients not willing to participate

The collected data was analyzed to calculate the Prescribing indicators & Patient indicators.

Prescribing indicators:

- a) % of different classes of drugs used.
- b) % of generic and brand prescription.
- c) % of different combinations of routes of drug administered

Patient indicators:

- a) Male female ratio
- b) Age distribution all patients
- c) Average duration of type 2 Diabetes Mellitus in years
- d) HBA1C levels
- e) % of patients with family history

Statistical Method

The data collected was analyzed statistically using descriptive statistics. Wherever necessary, the results are depicted in the form of percentages and graphs.

RESULT:

Out of 200 patients, 118(59%) were male and 82(41%) female. Age group of 51-60 years with 96(48%) patients are the majority, 58(29%) patients in 36-50 years and 46 (23%) patients above 60 years. Biguanide (Metformin) is the most commonly used drug with 84% of patients followed by Sulfonylureas in 48%, DPP-4 inhibitor in 42% and Human Insulin in 14% of the patients.

Fixed drug combination prescribed in 172 (86%) among total prescriptions. Two drug combinations 124 (62%) and three drug combination 48 (24%). Among two drug combination: Metformin + Glimepiride encountered in 46 (23%), Metformin + Teneligliptin 32 (16%), Metformin + Glipizide in 36 (18%) and Metformin + Sitagliptin in 48 (24%) cases. Adverse drug reactions observed included hypoglycemia in 24 patients (12%), abdominal pain in 16 patients (8%) and nausea in 34 patients (17%)

Fig 1: Gender

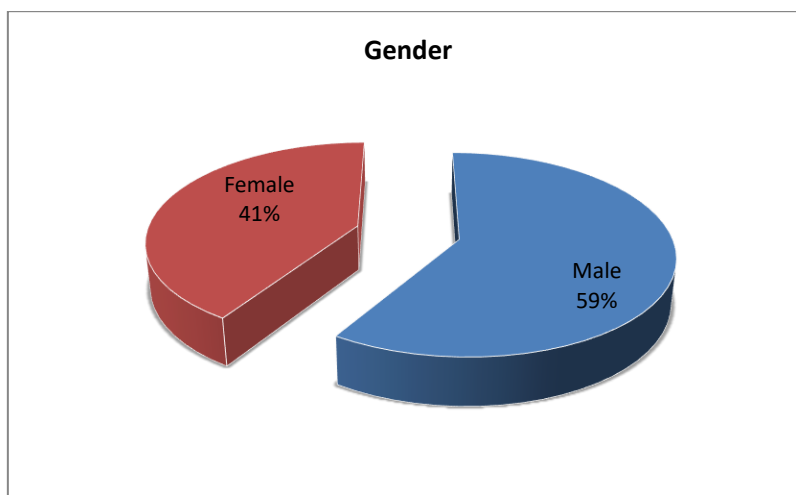


Fig 2: Age of Patients

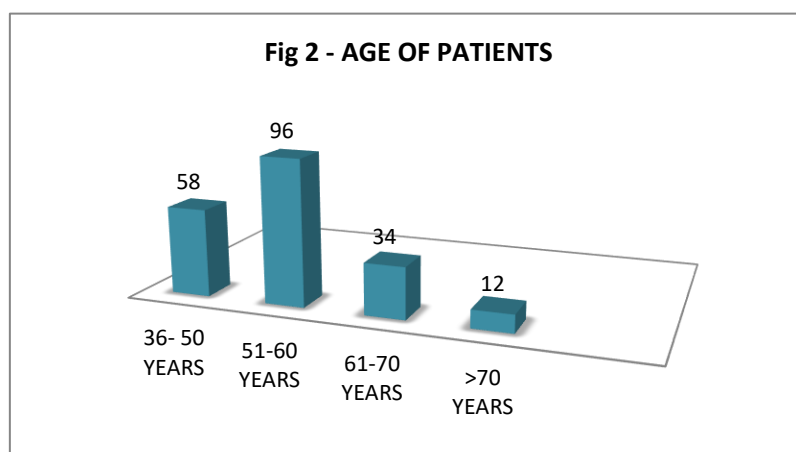


Table 1: Socio economic status

Socio economic status	No of Patients
Lower Middle class	32(16%)
Upper Middle class	104(52%)
Upper	64(32%)

Table 2: Total drugs prescribed

	Frequency
Total no of patients	200
Total no of drugs prescribed	442
Average anti diabetics per patient	2.2
Branded prescription	370
Generic prescription	72

Table 3: Drug distribution

	Percentage
Monotherapy	14%
Dual therapy	62%
More than 2 drugs	24%

Table 4: Different Class of drugs prescribed

Class of drugs	%
1 Sulfonylureas	48%
2 Biguanide	84%
3 Thiazolidinedione	4%
4 DPP-4 inhibitor	42%
5 SGLT-2 inhibitor	7%
6 Alpha-glucosidase inhibitor	9%
7 Insulin	14%

Fig 3: Different Class of drugs prescribed

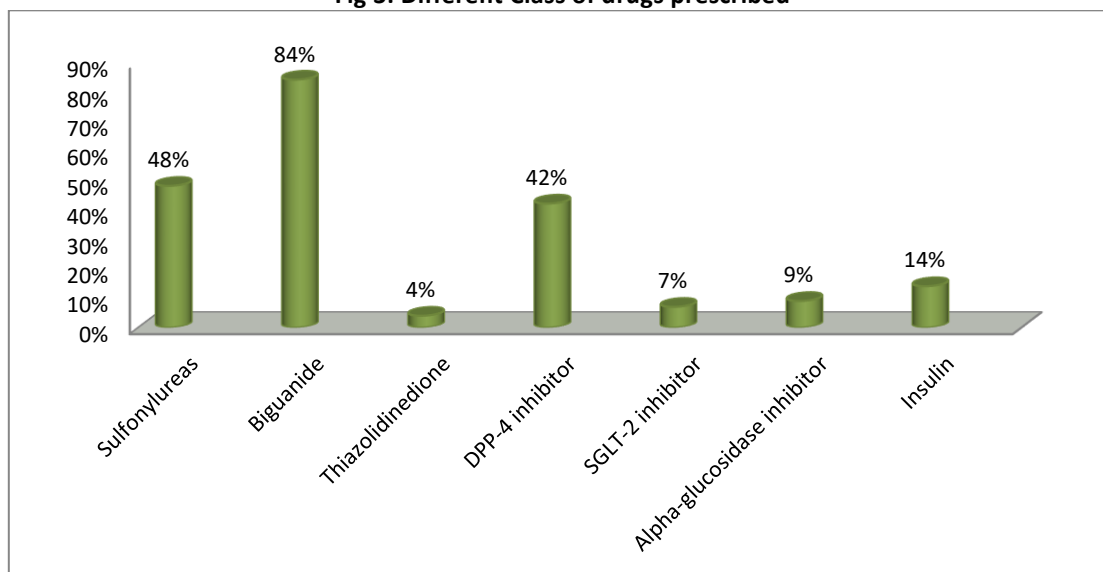
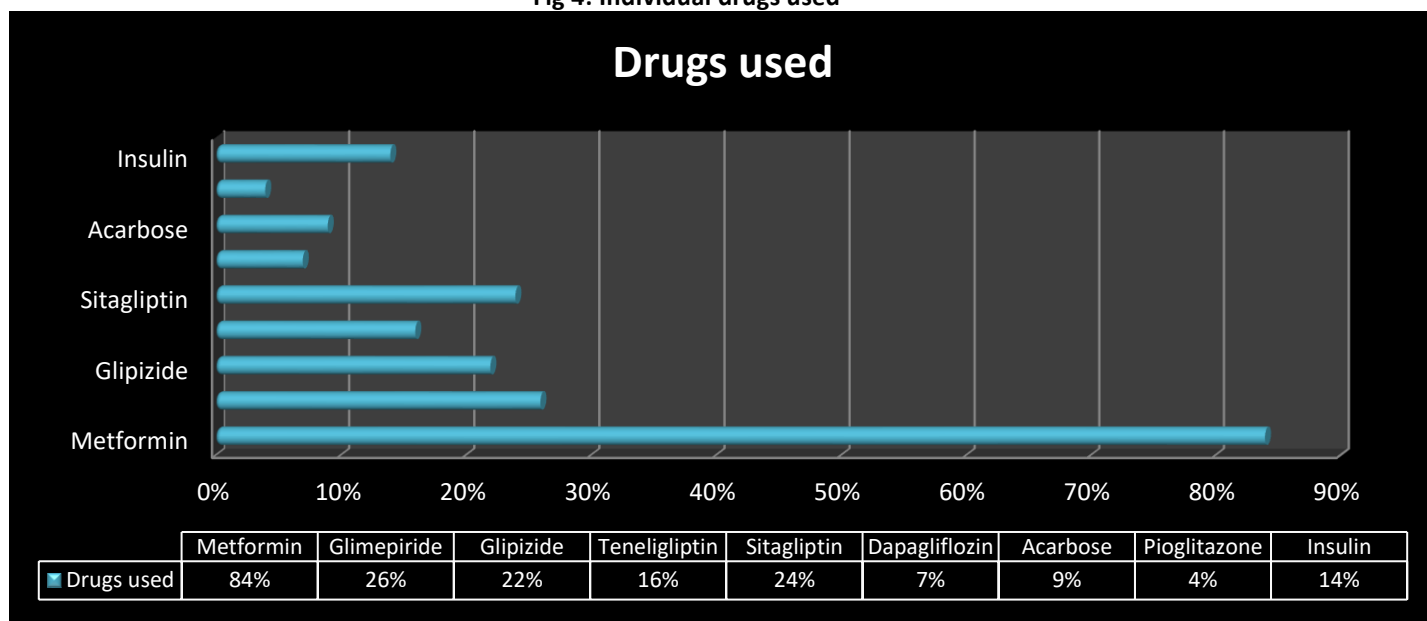


Fig 4: Individual drugs used



DISCUSSION:

Drug utilization study is a part of medical audit that does monitoring and evaluation of the drug prescribing patterns and suggests necessary modifications in prescribing practices to achieve rational therapeutic practice. [11] Analysis of 200 prescriptions in our study showed that Type 2 Diabetes Miletus was more prevalent in males (59%) than females (41%). This is in synonymous with the study conducted in Hyderabad, India by Naveed [12]. Incidence of Type 2 Diabetes Miletus was more common in elderly age group accounting to 48% in age group of 51-60 years, 17 % between 61-70years and 6% above 70 years.

In this study, the average number of drugs per prescription was 2.2 drugs. A previous drug utilization study from India also reported an average of 1.95 drugs. [13] In our study, average number of drugs prescribed is less as compared to result of Upadhyay DK et al, (3.76 per prescription) and Karthikeyan V et al, (4.83 per prescription). [14,15] However, the average number is more compared to that reported by Kannan et al, (1.4 per prescription).[16]

A good glycemic control is essential in the management of diabetes. In our study the most frequently prescribed drugs were Metformin 84%, followed by Glimepiride 26%, Sitagliptan in 24% and Glipizide in 22%. Metformin monotherapy and combination therapy was used in 84% of the patients. It was additionally the most frequently prescribed anti-diabetic drug. This is in line with that of Upadhyay *et al.*, [14] where Metformin accounted for 51.2% of the total antidiabetic medications. A study in Canada by Johnson *et al.*, similarly observed that 65% of the patients received metformin, alone or in combination.[17] Another study in Nepal noted Metformin to be the most frequently prescribed antidiabetic agent.[18] However, some studies conducted in India [19,20,21] and other countries, [22,23] showed that the sulfonylureas group of antidiabetics were observed to be the most commonly prescribed drug class. Metformin being the most frequently prescribed drug in this study is in accordance with its endorsement as the preferred anti-diabetic agent by current clinical guidelines. [24,25] It has even been recommended as the first choice oral medication in the subset of elderly diabetics.[26] Advantages of Metformin that makes it the preferred antidiabetic agent includes its efficacy in blood sugar reduction without risk of hypoglycemia, greater general tolerability, and relatively lower cost.[24] In obese diabetic patients, it has been found to significantly reduce glycosylated hemoglobin as compared to sulfonylureas and

insulin.[27] Among the sulfonylureas, Glipizide and Glimepiride together were prescribed in 48% of the patients. These second-generation sulfonylureas such as gliclazide, glipizide, and glimepiride are safer than glibenclamide and are preferred.[28]

The most common combination was metformin + sulfonylurea in 41% and Metformin + DDP-4 inhibitor in 40%. Metformin has beneficial effects on insulin resistance, while sulfonylurea helps to prevent insulin deficiency by stimulating its release by the pancreatic β -cells. Akshay A. Agarwal et al. [29] showed similar results for combination. Yerramilli A et al. [30], reported that most commonly prescribed combinations were Metformin and DPP4 inhibitor (62%) as 2nd line agent, Metformin + Sulphonylureas + DPP4 inhibitor (44%) as 3rd line agents.

From this study we can infer that the antidiabetic prescribing trend has moved away from monotherapy with Sulphonylureas and toward combination therapies to achieve better glycemic control with increased use of Biguanides and DPP-4 inhibitors.

CONCLUSION:

Metformin was the most frequently prescribed drug in Type 2 Diabetes followed by sulfonylureas and DDP-4 inhibitors. Among antidiabetic drugs used as monotherapy, most commonly utilized drug class was biguanides. Metformin with Sulphonylureas was the most frequently prescribed combination therapy followed by prescription of Metformin+ DDP-4 inhibitors. Others class of drugs prescribed includes SGLT-2 inhibitor, Thiazolidinedione, Alpha-glucosidase inhibitor and Insulin. All the drugs were prescribed from national essential drug list. Average number of drugs per prescription was found to be 2.2. Drug brand name was preferred in prescribing than generic name.

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