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ASSESSMENT OF PRESCRIBING PATTERN AMONG TYPE-II DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

In India, Diabetes Mellitus is probably becoming a pandemic. India's diabetes population is predicted to grow from approximately 69.2 million in 2015 to 123.5 million in 2040. It can be treated by various types of Antidiabetic Drugs that has not only beneficial effect; it also causes adverse drug reactions. This was a prospective, observational study carried out among patients of Type II Diabetes Mellitus in a tertiary care hospital of Dehradun to evaluate prescription pattern monitoring studies (PPMS). Study was carried out by reviewing prescription of 180 Type II Diabetes Mellitus patients. Out of 180 patients 55.5% were male and 44.5% were females. The majority of the patients were in age group of 41 - 60 years (70.5%). Among 180 patients, 48.33% were alcoholic, 51.67% were non-alcoholic. Most commonly prescribed drugs were Biguanides (42.73%), followed by Sulfonylureas (20.88%) and DPP-4 inhibitor (19.18%). Most commonly prescribed Biguanides drugs were Metformin (100%), Sulfonylureas drugs were Glimepiride (93.10%) and DPP-4 inhibitor drugs were Teneligliptin (53.17%). Among all drugs prescribed, 35.20% was prescribed as monotherapy and remaining 64.80% was prescribed as combination therapy. Most commonly prescribed combination drug therapy was Metformin + Vildagliptin (31.67%). Due to high value of average number of drugs per patient, problem of concern was polypharmacy which requires the control through rational prescribing practices

the drugs prescribing practices in the Type II Diabetes Mellitus treatment.

KEYWORDS: Type II diabetes Mellitus, Prescribing pattern, Biguanides, Sulfonylureas, Polypharmacy.

INTRODUCTION

Diabetes has emerged as a major healthcare problem in India. According to Diabetes Atlas (DA) published by the International Diabetes Federation (IDF), there is an alarming rise in disease progression from 40 million in 2007 to 70 million by 2025 in India and every fifth person with diabetes will be an Indian. A projected to rise from 171 million in 2000 to 366 million in 2030 is noted worldwide. The urban population in developing countries is projected to double between 2000 and 2030.[1] The World Health Organization predicted a 50% increase in deaths from diabetes over next 10 years, and by 2030, diabetes is projected to be the seventh leading cause of death. These estimated extrapolations and predictions are worrisome statistics in relation to the potential burden that diabetes may impose upon the country.[2]

The aim of the study was to determine the drug utilization pattern in patients of Type II diabetes mellitus according to WHO Core prescribing indicators. Recently since 2009 a new class of antidiabetic drugs; the dipeptidyl peptidase inhibitors (DPP-IV Inhibitors) have been introduced in the market. This has broadened the choice for the treatment of diabetes. The study will help to identify any change if any in the prescription trends of antidiabetic drugs as monotherapy as well as combination therapy in light of the new drugs being introduced and widely being used clinically.[3]

AIM AND OBJECTIVES

Aim: To assess the prescribing pattern among Type-II Diabetes Mellitus patients in Tertiary Care Hospital.

Objectives

The main objectives of the study include.

1. Demographic analysis of Type II Diabetes Mellitus patients.
2. Assessment of prescribing pattern among Type II Diabetes Mellitus patients.

i. Categorization of drug therapy prescribed.

ii. Most commonly prescribed drugs.

iii. Assessment of single v/s combination drug therapy.

iv. Average number of drugs per prescription.

METHODOLOGY

Study design: Prospective observational study.

Study Site: The study was conducted in General Medicine Out-patient Department of Shri Mahant Indiresh Hospital, Dehradun, Uttarakhand.

Study Duration: The study duration was 6 months.

Study Criteria

- ***Inclusion Criteria***

i. All patients attending OPD of General Medicine diagnosed with type II Diabetes Mellitus.

ii. Aged ≥18 years of age who were diagnosed with Type II Diabetes.

iii. Type II Diabetes Mellitus patients with or without co-morbid condition.

iv. Both genders.

- ***Exclusion Criteria***

i. All the in-patients of concerned department.

ii. Patients with Type-I diabetes.

iii. Patients who does not gave consent to participate in the study.

iv. Patients from pediatrics, pregnancy and lactating groups.

Source of Data

The study data was collected from the following sources.

1. Direct interview of patients at OPD of General Medicine Department.

2. Data Collection Form provides the information regarding the demographic details of the patient which includes age, gender, occupation, social history, past medical history and prescription details which includes medicines prescribed, dose, frequency, duration and dosage form.

Data Collection

Study data was collected in the format containing patients demographics as well as medicines related information (Appendix-I) after obtaining informed consent (Appendix-II).

Study Procedure

The study was carried out after getting approval from the Institutional Review Board. Permission to carry out the study was also obtained from Head of General Medicine Department before starting the study. Data from patients attending the respective OPDs diagnosed with Type II Diabetes Mellitus during the study period was collected. Detailed information on age, gender, diagnosis, drugs used including name of the drug, dosage schedule (dosage form, route, and frequency) was recorded from the prescriptions given to the patients. The brand names of the drugs prescribed was decoded to generic names using latest version of standard Current Index of Medical Specialities (CIMS) India - (October 2018 - January 2019). Rationality of prescribing the drugs was evaluated by using the WHO core drug prescribing indicators.

Data Analysis

Data was analyzed by preparing tables and graphs using Microsoft excel.

RESULTS

❖ **Demographic Analysis of COPD Patients**

The study was conducted among 180 Type II Diabetes Mellitus patients in General Medicine OPD at Shri Mahant Indiresh Hospital, Dehradun. All subjects were evaluated to get the following results under demographic assessment.

I. Gender wise distribution of patients

Demographic assessment of 180 Type II Diabetes patients was involved in this study. Among them, 100 (55.5%) were males and 80 (44.5%) were female (Table 1 and Figure 1).

Table 1: Gender wise distribution of patients.

S. No.	Gender	No. of patients (%) (n = 180)
1.	Male	100 (55.5%)
2.	Female	80 (44.5%)

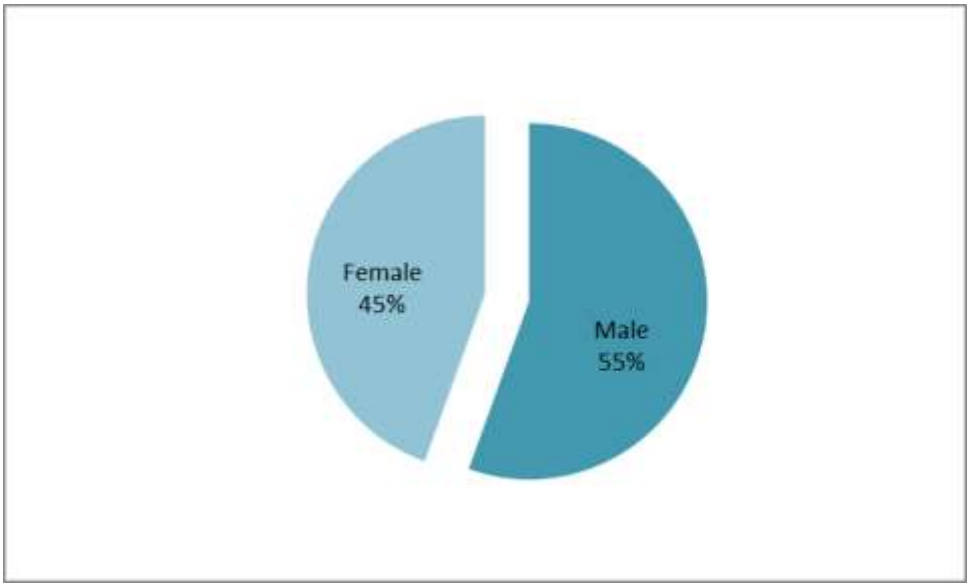

Figure 1: Gender wise distribution of patients.

II. Age wise distribution of patients

From Table 2 and Figure 2, out of total 180 patients, 11.7% patients were in age group of 20 - 40 years, 70.5 % patients were in age group of 41 - 60 years and 17.8% patients were in age group of above 65 years.

Table 2: Age wise distribution of patients.

S. No.	Age (Year)	No. of Patients (%) (n = 180)
1.	20 - 40	21 (11.7%)
2.	41 – 60	127 (70.5%)
3.	> 65	32 (17.8%)

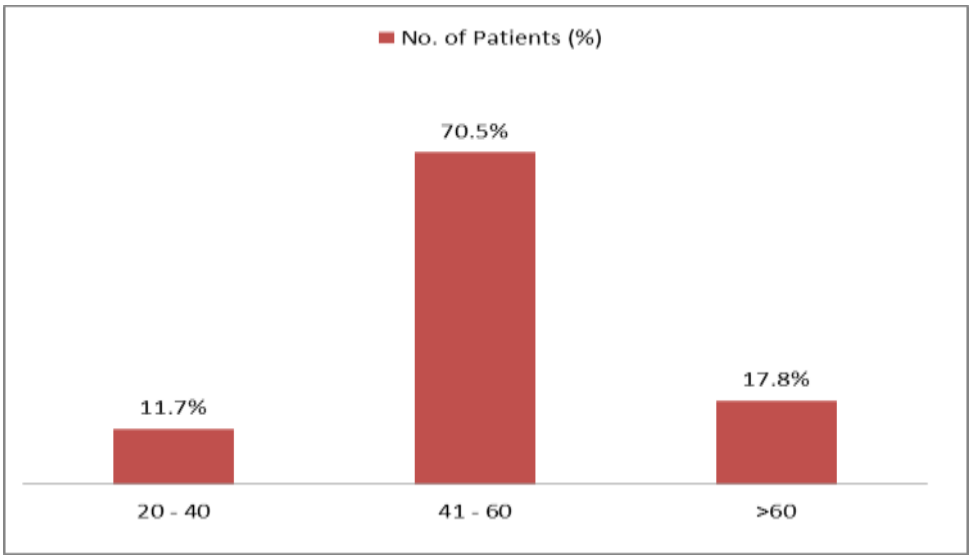

Figure 2: Age wise distribution of patients.

III. Distribution of patients according to social habit

From the study, out of 180 patients, 86 (47.8%) male and 02 (5.12%) female were found alcoholic while 59 (32.8%) male and 01 (12.82%) female were found with smoking habit while 18 (10%) male and 17 (9.4%) female were found with other habits (Table 3 and Figure 3).

Table 3: Distribution of patients according to social habit.

S.No.	Social habit	No. of patients (%) (n = 180)		
		Male	Female	Total
1.	Alcohol	86 (47.8%)	02 (5.12%)	58 (48.33%)
2.	Smoking	59 (32.8%)	01 (12.82%)	79 65.83%)
3.	Other	18 (10%)	17 (9.4%)	35 (19.4%)

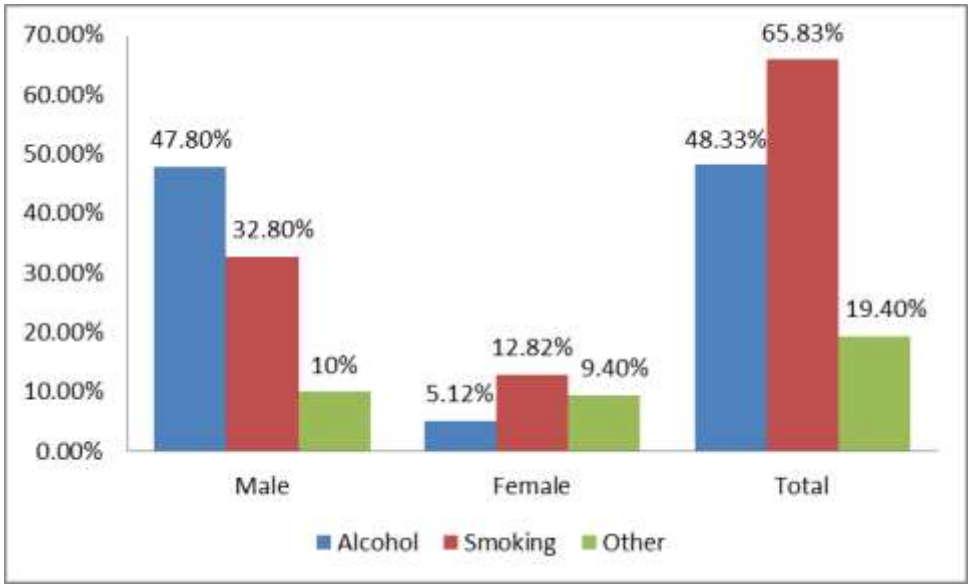

Figure 3: Distribution of patients according to social habit.

❖ **Assessment of Prescribing Pattern among Patients**

- **Categorization of drug therapy prescribed**

A sum total of 412 drugs were prescribed among 180 Patients. Table 4 and Figure 4 showed that most commonly prescribed drugs were Biguanides (42.73%) followed by Sulfonylureas (20.88%), DPP-4 inhibitor (19.18%), Meglitinide (7.03%), Alpha-glucosidase inhibitor (4.61%), Human-insulin (2.91%) and Thiazolidinediones (2.66%).

Table 4: Categorization of drug therapy among Type II Diabetes Mellitus patients.

S. No.	Class of Drugs	Number of Drugs (%) (n = 412)
1.	Biguanides	176 (42.73%)
2.	Sulfonylureas	86 (20.88%)
3.	Alpha-glucosidase inhibitor	19 (4.61%)
5.	DPP-4 inhibitor	79 (19.18%)
6.	Thiazolidinediones	11 (2.66%)
7.	Meglitinide	29 (7.03%)
8.	Human-insulin	12 (2.91%)

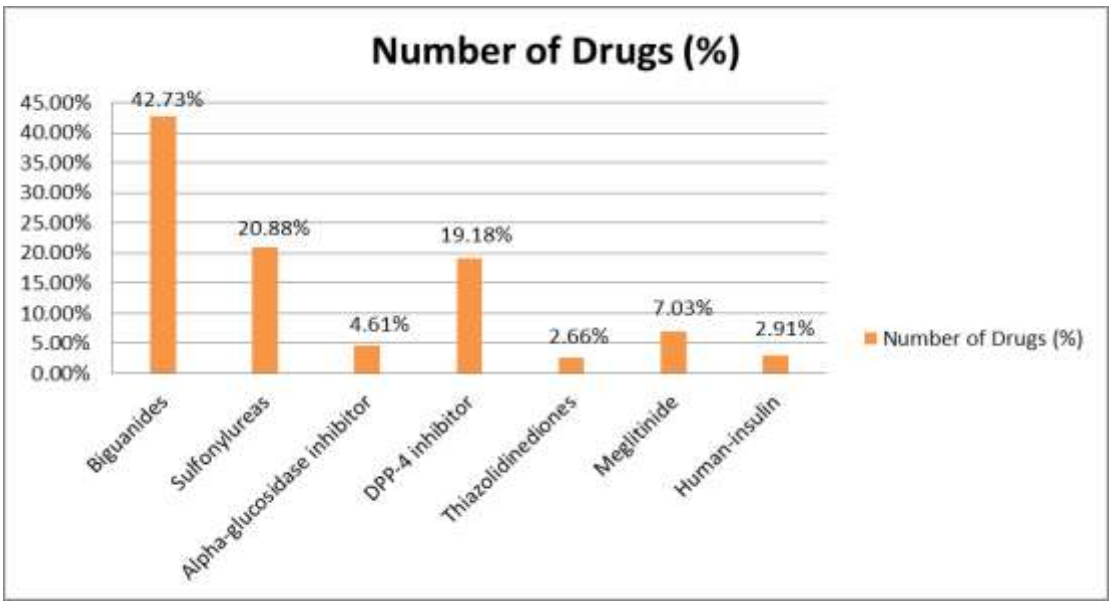

Figure 4: Categorization of drug therapy among Type II Diabetes Mellitus patients.

- **Most commonly prescribed drugs**

➢ **Distribution of prescribed Biguanides**

Table 5 and Figure 5 showed that Metformin (100%) were mostly prescribed drugs among Biguanides.

Table 5: Distribution of prescribed Biguanides.

S.No.	Biguanides	No. of Drugs (%) (n = 176)
1.	Metformin	176 (100%)

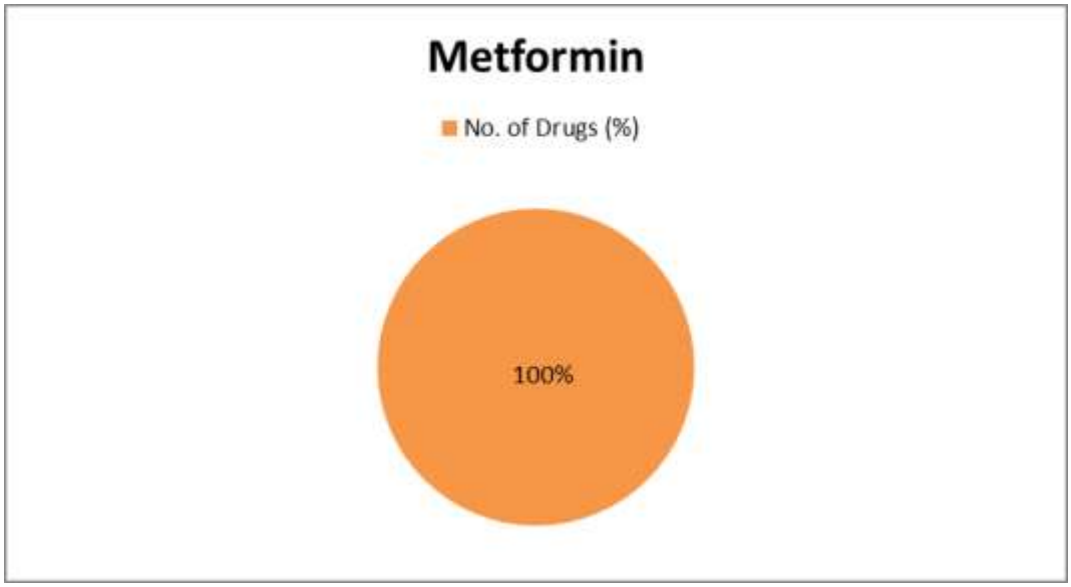

Figure 5: Distribution of prescribed Biguanides.

➢ **Distribution of prescribed Sulfonylureas**

Table 6 and Figure 6 showed that Glimepiride (93.10%), Glipizide (4.60%) and Glibenclamide (2.30%) were mostly prescribed drugs among Sulfonylureas.

Table 6: Distribution of prescribed Sulfonylureas.

S.No.	Sulfonylureas	No. of Drugs (%) (n = 87)
1.	Glimepiride	81 (93.10%)
2.	Glipizide	04 (4.60%)
3.	Glibenclamide	02 (2.30%)

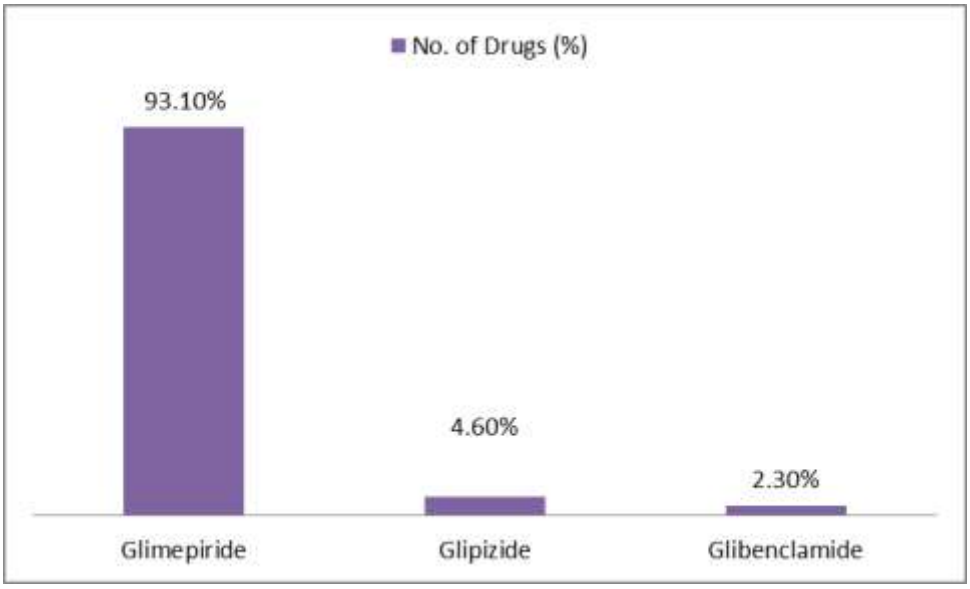

Figure 6: Distribution of prescribed Sulfonylureas.

➢ **Distribution of prescribed DPP-4 inhibitor**

Table 7 and Figure 7 showed that Teneligliptin (53.17%), Vildagliptin (44,30%) and Sitagliptin (2.54%) were mostly prescribed drugs among DPP-4 inhibitor.

Table 7: Distribution of prescribed DPP-4 inhibitor.

S.No.	DPP-4 inhibitor	No. of Drugs (%) (n = 79)
1.	Sitagliptin	02 (2.54%)
2.	Teneligliptin	42 (53.17%)
3.	Vildagliptin	35 (44.30%)

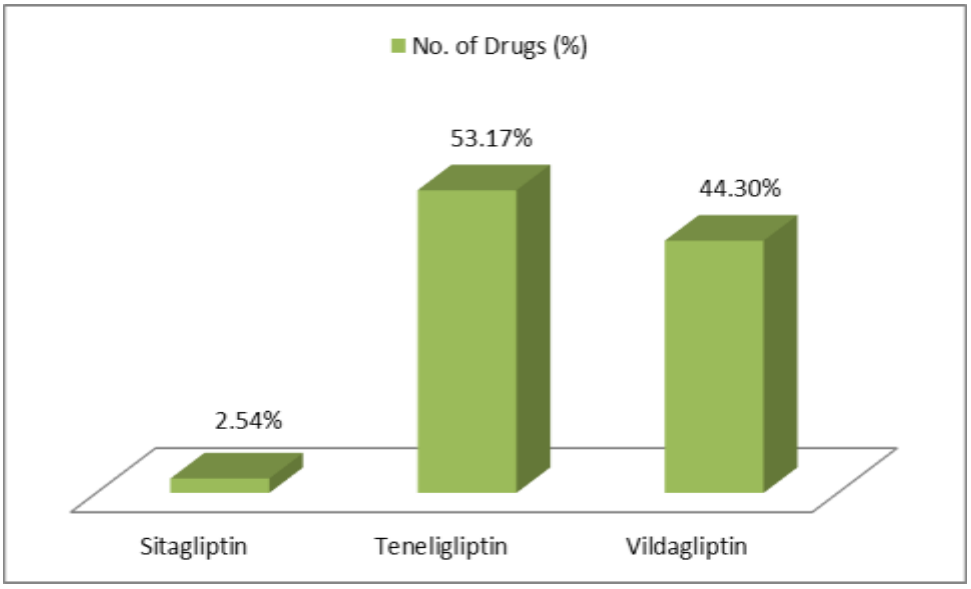

Figure 7: Distribution of prescribed DPP-4 inhibitor.

➢ **Distribution of prescribed Alpha-glucosidase inhibitor**

Table 8 and Figure 8 showed that Voglibose (78.95%) and Acarabose (21.05%) were mostly prescribed drugs among Alpha-glucosidase inhibitor.

Table 8: Distribution of prescribed Alpha-glucosidase inhibitor.

S.No.	Alpha-glucosidase inhibitor	No. of Drugs (%) (n = 19)
1.	Voglibose	15 (78.95%)
2.	Acarabose	04 (21.05%)

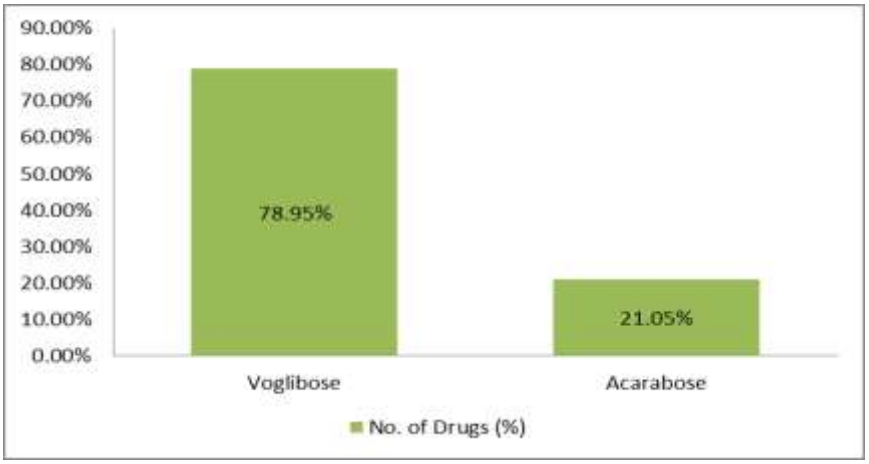

Figure 8: Distribution of prescribed Alpha-glucosidase inhibitor.

- **Assessment of single v/s combination drug therapy drugs**

Out of 412 drugs prescribed, 35.20% was prescribed as monotherapy and remaining 64.80% was prescribed as combination therapy. Among monotherapy, 17.97% drugs were prescribed to males and 17.23% drugs were prescribed to females while among combination therapy, 32.52% drugs were prescribed to males and 32.28% drugs were prescribed to females (Table 9 and Figure 9).

Table 9: Assessment of single v/s combination drug therapy.

S.No.	Drug Therapy	No. of Drugs Prescribed (%) (n = 412)		
		Males	Females	Total
1.	Monotherapy	74 (17.97%)	71 (17.23%)	145 (35.20%)
2.	Combination Therapy	134 (32.52%)	133 (32.28%)	267 (64.80%)

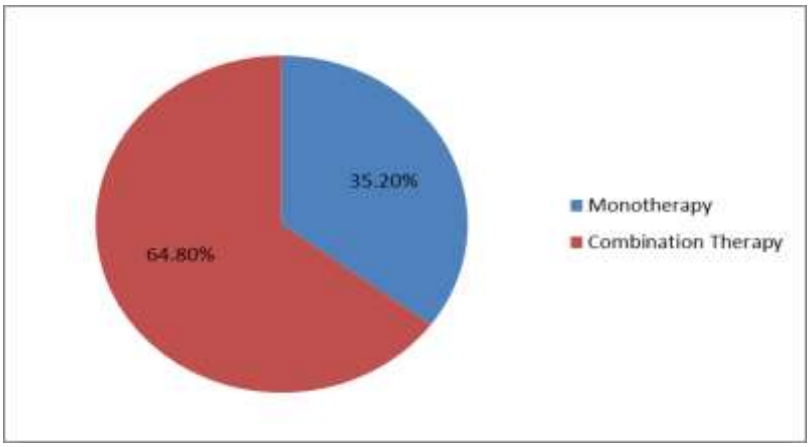

Figure 9: Assessment of single v/s combination drug therapy.

- **Assessment of combination drug therapy**

Table 10 and Figure 10 showed that Metformin + Vildagliptin (31.67%), Metformin +

Glimepiride (26.67%), Metformin + Repaglinide (20.55%), Biguanide + sulfonylureas+ Alfa glucosidase inhibitor (16.11%) and Metformin + Teneligliptin (5%) were mostly prescribed combination drug therapy.

Table 10: Assessment of combination drug therapy.

S. No.	Combination Drugs	No. of Patients (%) (n = 180)
1.	Metformin + Vildagliptin	57 (31.67%)
2.	Metformin + Teneligliptin	09 (5%)
3.	Metformin + Glimepiride	48 (26.67%)
4.	Metformin + Repaglinide	37 (20.55%)
5.	Biguanide + sulfonylureas+ Alfa glucosidase inhibitor	29 (16.11%)

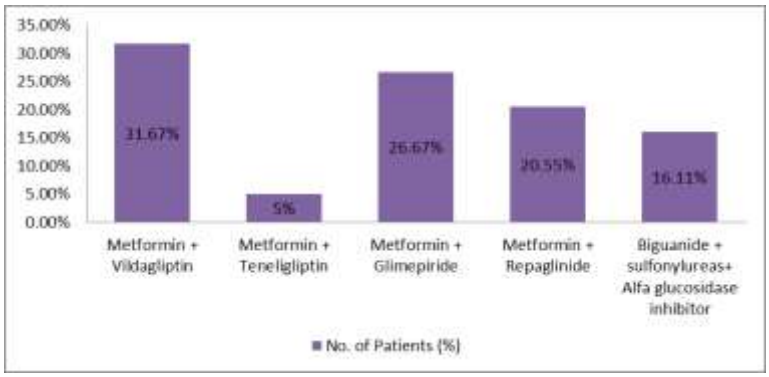

Figure 10: Assessment of combination drug therapy.

- **Average number of drugs per patients**

Table 11 showed that average number of drugs per patients was found to be 412/180 = 2.29. Maximum number of drugs per patient was 10 among 18.89% patients while least number of drugs per patient was 2 among 1.11% patients. Such greater number of drug use per patients reflects the concept of polypharmacy.

Table 11: Average number of drugs per patients.

No. of Drugs per Patient	No. of Patients (%) (n = 180)
2	02 (1.11%)
3	08 (4.44%)
4	16 (8.89%)
5	07 (3.89%)
6	13 (7.22%)
7	18 (10%)
8	19 (10.55%)
9	22 (12.22%)

10	34 (18.89%)
11	17 (9.44%)
12	24 (13.33%)

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". A survey on Indian population shows that 4% of the adults suffered from diabetes mellitus in the year 2000 and it is expected to rise to 6% by the year 2025.[4] In developing country like India, the majority of diabetics are in the age group of 45-64 years in contrast to developed countries where it is highly prevalent in age group more than 65 years of age.[5] According to Diabetes Atlas (ADA) published by the International Diabetes Federation (IDF), there is an alarming rise in disease progression from 40 million in 2007 to 70 million by 2025 in India and every fifth person in the word with diabetes will be an Indian.[6] Therefore studies focusing on various aspects of diabetes mellitus and its management are of paramount importance.

The present study was a hospital based prospective observational study conducted in the tertiary care hospital focusing on drug prescribing pattern among Type-II diabetic patients. The primary objective of the study was to assess the prescribing pattern among Type-II Diabetes Mellitus patients in Tertiary Care Hospital.

180 patients participated in the present study. Majority of the respondents (70.5%) belonged to the age group of 41 - 60 years followed by age group above 65 year (17.8%). This finding is inconsistent with study conducted by Angel Dominic et al. (2016).[7]

In the present study the male to female ratio was found to be 1.34 {male patients (55.5%) and female patients (44.5%)}. This trend is similar to various studies conducted in India such as Alex SM et al.[8]

In the present study majority of the patients belonged to the upper middle socio-economic class which is similar to study conducted by Sharma M et al.[9] These results do not concur with the findings reported by Shah V et al[10], who found nearly 60% of patients were from low socio-economic status.

Most of the diabetic patients (92.3%) were on Oral Hypoglycemic Agents only and 7.7% were on Insulin and oral hypoglycemic agent (OHA) combination therapy. Only insulin was not prescribed to any patient attending Out Patient Department whereas study conducted by Gopinath B et al[11], states that in 66.4% of the cases OHA only, insulin in (2.8%) and combination therapy (OHA + Insulin) in (30.8%) cases was prescribed. Similar studies have been reported by various authors in literature. Satpathy SV et al[12], have also reported that OHA is the most commonly prescribed therapy.

This study focused on the prescription pattern among diabetic patients attending the outpatient departments in the hospital the principal aim of drug utilization research is to facilitate the rational use of drugs in populations. For the individual patient, the rational use of a drug implies the prescription of a well-documented drug at an optimal dose, together with the correct information, at an affordable price. Knowledge of how drugs are being prescribed and used, will help to identify issues if any addressing rational drug use or suggest measures to improve prescribing habits. With this point of view the study was designed.

Result demonstrated that the average number of drugs encountered per prescription was found to be 2.29. In this study, average number of drugs prescribed is less as compared to result of Upadhyay DK et al[13], (3.76 per prescription) and V. Karthikeyan et al[14], (4.83 per prescription). However the average number of drug prescribed is more compared to that reported by Das Priya et al[15], (1.83 per prescription). Total numbers of anti-diabetic drugs prescribed were 412 similar number of drugs was prescribed in study by Pathak R et al[16], (475 drugs). More number of drugs was prescribed in study by V. Karthikeyan et.al[17], (1232 drugs) whereas less number of drugs was prescribed in study by Bhardwaj RA et al[18], (366 drugs).

Drugs prescribed from national essential drug list were 61.74% which was more reported in study conducted by V. Karthikeyan et.al[14] (74.30%) but less (31.36%).than published in the study conducted by Bhardwaj RA et.al.[18] In the present study no drug was prescribed by generic name. All were prescribed by brand names. Medical Council of India (MCI) called upon the doctors practicing medicine to prescribe Drugs with Generic names, as far as possible. The MCI circular reinforced that all Registered Medical Practitioners under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 should comply with it without fail. Inspite of these regulations, prescription by brand name is a matter of concern. These results concur with finding observed specially by Bhardwaj RA et

al[18], and Das Priya et.al.[16] In our study Encounter with parenteral preparation (injection) was 12.27% this was more (17.04%) in study by V. Karthikeyan et al.[17]

In the present study, it was found that 35.20% of patients were on monotherapy with oral hypoglycemic agent compared to 64.80% on combination therapy. Similar results were reported by study conducted in Kerala by Alex SM et al[8], (58.4% polytherapy). In a study conducted in Tamil Nadu by Gopinath B et al[11], monotherapy, and two drug combination therapies were prescribed in 21.7% and 78.3% patients, respectively.

The most commonly prescribed anti-diabetic drug class was Biguanides (Metformin) both as monotherapy and/or in combination therapy, Metformin accounted for (100%) of the total drugs prescribed, followed by Sulfonylureas (Glimepiride), (93.10%) and then DPP4 inhibitors (Teneligliptin, Vildagliptin). Similar result regarding Biguanides and Sulfonylureas has been documented in study conducted by Alex SM et al[8], 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 II diabetes. In addition, the cost of Metformin is very low, thus making it affordable by the patients in economically weak countries like India.

Interestingly results did not concur with the usage pattern of DPP4 inhibitors. Alex SM et al[8], Documented less utilization patterns compared to that reported in the present study. Results emphasize the increase in clinical usage of this relatively new class of antidiabetic drugs. The potential benefits of DPP-4 inhibitors include their complementary mechanism of action with other antidiabetic medications, a favorable adverse-effect profile, and a neutral effect on weight. With a low risk of hypoglycemia, DPP-4 Inhibitors are advantageous for patients who are close to their target HbA1c but who continually experience elevated glucose levels after meals.[19]

The most commonly prescribed fixed dose combination among two drug combination was found to be Metformin + Vildagliptin (31.67%) followed by Metformin + Glimepiride (26.67%). Among three drug combination Biguanide + sulfonylureas + Alfa glucosidase

inhibitor were most frequently prescribed fixed dose combination. Satpathy SV et al[12], showed similar results formetformin combination. Yerramilli A et al[20], 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. The present study DPP4 inhibitors were initiated in patients with higher body mass index and Glycated hemoglobin greater than 9%. However Alex SM et al[8], reported Metformin + Glimipirideas the most common combination prescribed.

To summarize, among the total hypoglycaemic agents prescribed, Biguanides accounted for (42.73%) of all the prescribed drugs, followed by Sulfonylureas (20.88%), DPP4 inhibitors (19.18%), Meglitinide (7.03%) Glucosidase inhibitors (4.61%) and Thiazolidinediones (2.66%) Insulin (2.91%). Among Fixed drug combination, prescription of Metformin + Vildagliptin was the most common. We could not analyze the doses of prescribed antidiabetic drugs, or evaluate the appropriateness of therapy. Despite these limitations, the present study showed the prescription pattern in practice for a large number of patients with type II diabetes. In conclusion, the antidiabetic prescribing trend has moved away from monotherapy with Sulphonyluras 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 diabetes followed by Sulfonylureas (Glimepiride). Among antidiabetic drugs used as monotherapy, most commonly utilized drug class was biguanides followed by sulfonylureas. Metformin with Glimpiride was the most frequently prescribed combination therapy.

Among Fixed drug combination, prescription of Metformin + Vildagliptin was the most common. Majority of drugs were prescribed from national essential drug list. Average number of drugs per prescription was found to be 2.29. None of the drugs were prescribed by generic name. All drugs were prescribed with brand name.

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