

**A PROSPECTIVE STUDY ON PRESCRIBING PATTERN OF ANTI- DIABETIC DRUGS
IN TYPE 2 DIABETES MELLITUS IN THE INPATIENTS OF GENERAL MEDICINE
DEPARTMENT OF A TERTIARY CARE HOSPITAL**Sara Shreen*¹, Dr. Maryam², Mohammadi Fizza Khan², Ramsha Farheen², Nazish Ahmed² and Madiha Khan²¹Department of Pharmacy Practice, Geethanjali college of Pharmacy, Cheeryal (V), Keesara (M)-501301, RangaReddy (Dist), Telangana, India.²Department of Pharmacy Practice, Deccan School of Pharmacy, Darussalam, Aghapura, Hyderabad -500001, Telangana, India.

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ABSTRACT

Background: This study aims to evaluate the prescribing pattern of Anti-diabetic drugs in patients with type 2 diabetes mellitus in a tertiary care hospital. **Methods:** Before the subjects enter into the study, the study was briefly explained to the subjects and an informed consent form was made to sign by the patient or the patient care taker by their willingness to participate in the study. The patient was then screened for the eligibility criteria to enter into the study. The subjects were followed (treated, monitored) according to the study design. The prescribing patterns and the co morbidities were checked and treatment was given according to their condition. The patients final data was analyzed and final reports were submitted. A total of 100 patients were enrolled into the study. **Results & Conclusion:** The patients were divided based on age groups, of which 55% of the patients belonged to age group 51-65 followed by 28% belonging to the age group of 36-59 and lowest with 17% blonging to age group of 66-80. The prescribing pattern of monotherapy was found to be 24%, dual therapy was found to be 57% and triple therapy was found to be 19%.

KEYWORDS: Anti-diabetic drugs, Type 2 diabetes mellitus, prescribing pattern, monotherapy, dual therapy, triple therapy.

INTRODUCTION

Definition: Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia due to impaired insulin secretion with or without insulin resistance and abnormalities in carbohydrate, fat, and protein metabolism.^[1,2]

Epidemiology: According to International Diabetes Federation (IDF), 382 million peoples were diabetes in 2013 and the number of people with type 2 diabetes is increasing in every country.^[3] International Diabetes Federation (IDF), India has got 2nd rank among top ten countries with 65.1 millions diabetic patients.^[3]

Types of DM^[1]

- **Type 1 DM** (Insulin Dependent Diabetes Mellitus- IDDM).
- **Type 2 DM** (Non- Insulin Dependent Diabets Mellitus-NIDDM).
- **Other specific types**
- Genetic defects of β -cell function.

- Genetic defects in insulin action.
- Diseases of the exocrine pancreas.
- Endocrinopathies.
- Drug or chemical induced, e.g., nicotinic acid, glucocorticoids, high-dose thiazides, pentamidine, interferon- α , etc.
- Infections.
- Uncommon forms of immune-mediated diabetes.
- Other genetic syndromes sometimes associated with diabetes.
- Gestational DM.

➤ **Type 1 DM^[4]** It causes destruction of the pancreatic β -cells which produce insulin, developed either due to auto-immune T-cell mediated destruction (Type 1A) or Idiopathic (Type 1B). It usually develops in age group of below 30, although it can develop in older adults and is usually associated with a rapid initiation of symptoms which leads to dependency on extrinsic insulin for survival.

➤ **Type 2 DM^[4]** It is characterized by a combination of some degree of insulin resistance and relative insulin deficiency. It is more common above age of 40.

Etiology^[5]

- **Causes related to type-1 diabetes:** Hereditary vulnerability, Autoimmune damage of Beta Cells, Ecological aspects *such* as foodstuffs, viruses and pollutants, etc.
- **Causes related to type-2 diabetes:** Hereditary vulnerability, Fatness and Physical Sluggishness, Insulin Resistance, Irregular Glucose Production through the Liver, etc.

Symptoms

- Lethargy.
- Polyuria.
- Nocturia.
- Polydipsia.
- Slow-healing incisions.

- Excessive thirst.
- Blurred vision.
- Candida and Urinary Tract Infections due to increased circulating glucose levels.
- Tingling or numbness in the feet or toes.
- Significant weight loss is less common ;patients are overweight or obese.^[2]
- Several other signs and symptoms can mark the onset of DM although they are not specific to the disease.

Treatment: The treatment for Diabetes Type 1 is only insulin therapy but in Diabetes Type 2, oral hypoglycemic and insulin therapy is added in therapeutic regimen depending upon severity of disease.^[6]

Oral Hypoglycemic Agents (OHAs)^[7]

Class of drugs	Benefits
Insulin's Short acting: humulin R, Novolin R Intermediate acting: NPH Insulin Long acting insulin Insulin glargine.	It treats the high potassium levels.
Biguanides e.g. Metformin	First line treatment, used to treat macro vascular complications and death.
Sulphonylureas e.g. chlorpropamide	It's used to reduce glycosylated hemoglobin (HbA1c)
Thiazolidinediones e.g. Pioglitazone	Used in combination with Metformin and Sulphonylureas. It reduce the development of diabetes in patients with impaired fasting glycaemia
Alpha-glycosidase inhibitors e.g. Acarbose	Used in patients who cannot use other oral hypoglycemic drugs
Meglitinides e.g. Exenatide	It's used as third line therapy in combination with Metformin or glitazone

Monotherapy

- Biguanides: Metformin
- Sulfonyl urea's: Glimpiride.
- Alpha glucosidase inhibitors: voglibose.
- Insulin

Dual therapy

- Metformin + Glimpiride.
- Insulin + Metformin
- Insulin + Glipizide
- Insulin + Glimpiride
- Sitagliptin + Metformin
- Metformin + Glimpiride + Pioglitazone

Triple therapy

- Insulin + Glimpiride + Metformin
- Metformin + Glimpiride + Voglibose
- Insulin + Metformin + Pioglitazone

Prescribing Pattern of Anti-Diabetic Drugs

Rational and cost effective pharmacotherapy can be achieved with the help of study of prescribing patterns, a component of medical audit, which seeks monitoring,

evaluation and necessary modifications in the prescribing practices.^[8] The purpose of Pharmacoepidemiology, a study of the use and effects/side-effects of drugs in large numbers of people is to support the rational and cost-effective use of drugs in the population thereby improving health outcomes.^[9] WHO defined Prescribing pattern as "marketing, distribution, prescription, and use of drugs in a society with a special emphasis on the resulting medical, social, and economic consequences".^[10] Together, drug utilization research and pharmacoepidemiology may provide much useful information on indirect data on morbidity, compliance with therapy, incidence of adverse drug reactions, effectiveness of drug consumption, economic burden of illness and choice of comparators.^[9] Studying the Prescribing Pattern of Anti-Diabetic drugs is of great significance for optimizing drug therapy and drug control.^[11] Although there is availability of various guidelines for the management of diabetes mellitus, the treatment method of all physicians differs depending upon the available sources, the hospital set up & the patient related factors such as the age, sex, body mass index, tolerance, the co-morbid conditions and economic status.^[12] Therefore, the present study aimed to evaluate

the drug utilization pattern of standard anti diabetic drugs in the Inpatient clinic of a tertiary care hospital.

AIM AND OBJECTIVES

Aim: To study the prescribing pattern of Hypoglycemics in type 2 DM in a tertiary care hospital.

OBJECTIVES

- To observe the prescribing pattern of type 2 DM patients.
- To decrease the medication error and their related problems.
- To rationalize the drug use by providing criteria and standards.
- To check for cost effectiveness of therapy.
- To assess the rationality of prescribing.

MATERIALS AND METHODS

Study design: The study is an observational, prospective type of study.

Study Approval: This study was approved by "Institutional Human Ethical Committee" of Geethanjali college of pharmacy, Cheeryal, Keesara.

Study Duration: The study was conducted for a period of six month.

Sample size: 100 patients of Type 2 DM admitted in the IPD for treatment were enrolled in the study.

Study Subjects: All the patients who were having type 2 diabetes mellitus admitted in the General Medicine IP department of the RVM hospital. Patients who met the eligibility criteria were enrolled in the study.

Eligibility Criteria

Inclusion criteria

- Patients with type 2 diabetes mellitus.
- Patients of age ≥ 18 years of both the genders
- Patients willing to participate in the study.

Exclusion criteria

- Paediatric patient were excluded
- Patients less than 18 years of Age were excluded
- Emergency care patient were excluded
- Pregnant women were excluded

- Mentally retarded patient were excluded
- Type 1 diabetes mellitus were excluded
- Subjects who were not willing to participate were excluded.

Source of data: Patients Prescription, Patients case sheets & Medication Charts.

Study Procedure: A prospective study on 100 patients was done in the general medicine, IP department of the RVM hospital for six month period. The aim and objective of the study was explained to the patients. Patients who met the eligibility criteria and who were willing to participate in the study were enrolled in the study. An Informed consent form was signed from the enrolled patients." Institutional Human Ethical Committee" of Geethanjali College of pharmacy, cheryal, kesara approval was obtained before starting the study. The details were entered in the structured patient profile form. All the above mentioned data and the completed prescriptions were collected on predesigned case record form.

After recording patient's detailed history and physical parameters. Patient receiving any of the anti-diabetic drugs or insulin or both were included in the study irrespective of their gender. Prescribing pattern of all the patients diagnosed as T2DM with or without co morbid condition was assessed.

Statistical Analysis: The data was collected, analyzed and appropriate statistics was applied to obtain meaningful information i.e., percentages were calculated for categorical variables.

RESULTS

A total of 100 patients were enrolled into the study who met the eligibility criteria. The patients were then proceeded for further evaluation.

Patient Demographics: Among the patients of all age groups the patients with age group of 51- 65 were found to be the highest with 55% followed by the age group of 36-50 with 28%, the age group of 20-35 years were least with 17% and 0% of patients with age group of 81-95 as given in Table No:1.

Table 1:Age-wise distribution of patients.

Age distribution	Number of patients (n)	Percentage of patientsn (%)
20-35	0	0%
36-50	28	28%
51-65	55	55%
66-80	17	17%
81-95	0	0%
Total	100	100%

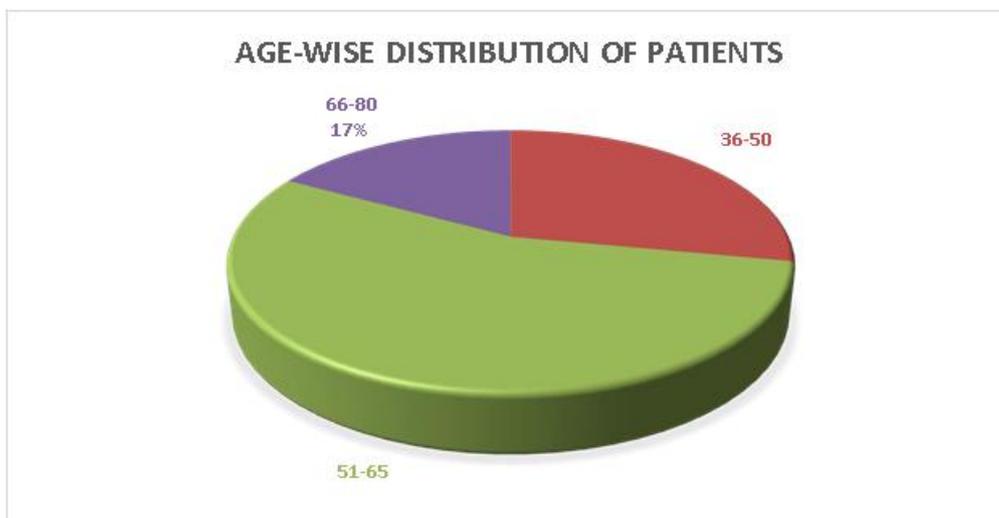


Fig. 1: Age-wise distribution of patients.

Among 100 Patients enrolled in the study, majority of subjects were male patients (63%) followed by females (37%).

Table 2: Gender-wise distribution of patients.

Gender distribution	Number of patients (n)	Percentage of patientsn (%)
Male	63	63%
Female	37	37%
Total	100	100%

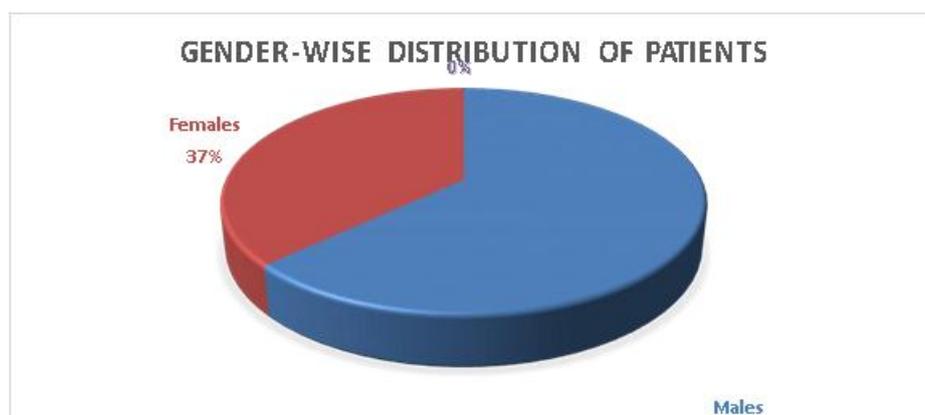


Fig. 2: Gender-wise distribution of patients.

The prescribing pattern of anti-diabetes drugs were based on the therapy given to the patient to treat diabetes. The therapy was based on mono and combination therapy in

combination therapy, dual therapy, and triple therapy was used. The patients with dual therapy were more in number when compared to mono and triple therapy.

Table 3: Prescribing pattern of Anti-Diabetic drugs.

Treatment	No of patients (n)	Percentage of patientsn (%)
Mono therapy	24	24%
Dual therapy	57	57%
Triple therapy	19	19%
	100	100%



Fig. 3: Prescribing pattern of mono and combination therapy.

Table 4: Prescription pattern of Anti-Diabetic drugs as Monotherapy.

Monotherapy	No of patients (n)	Percentage of patientsn (%)
Metformin	24	100%

Metformin was prescribed as monotherapy in all the patients (100%).

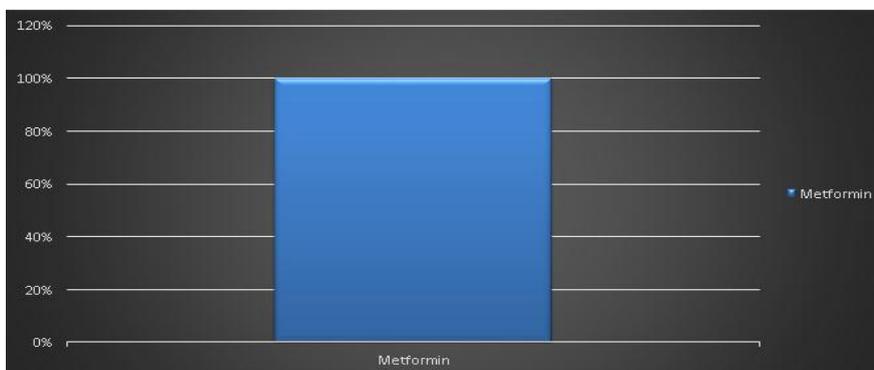


Fig. 4: Prescribing pattern of Anti -Diabetic drugs as mono therapy.

Table 5: Prescription pattern of Anti-Diabetic drugs based on Dual therapy.

Dual therapy	No of patients	Percentage of patients (%)
Metformin +Glimepride	34	59.64%
Metformin + Glipizide	12	21.05%
Metformin + Insulin	11	19.29%

During the study, among all the patients, combination of Metformin and Glimepride was prescribed to 59.64%, followed by Metformin + Glipizide(21.05%) and Metformin + Insulin(19.29%).

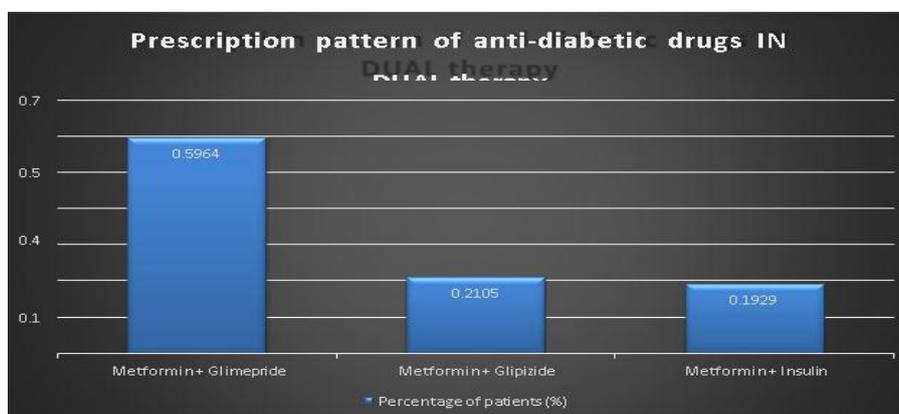


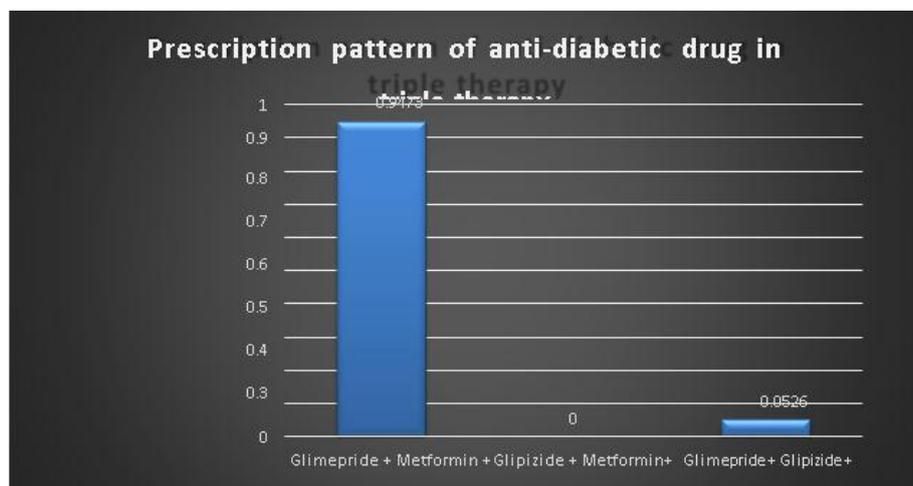
Fig. 5: Prescribing pattern of Anti-Diabetic drugs as dual therapy.

Table 6: Prescription pattern of Anti-Diabetic drugs based on Triple therapy.

Triple therapy	No of patients	Percentage of patients (%)
Glimepride+ Metformin + Insulin	18	94.73%
Glipizide+ Metformin+ Insulin	0	0%
Glimepride + Glipizide + Metformin	1	5.26%

During the study, among all the patients, combination of Glimepride+ Metformin + Insulin was prescribed to 94.73%, followed by Glimepride + Glipizide +

Metformin (5.26%) and Glipizide+ Metformin+ Insulin (0%).

**Fig. 6: Prescription pattern of Anti-Diabetic drugs based on triple therapy.**

DISCUSSION

Type 2 diabetes mellitus is one of the most common endocrinology diseases occurring in both male and female population. The intent of present is to determine the prescribing pattern of Anti- Diabetic drugs in type 2 diabetes mellitus. A total of 100 patients with type 2 diabetes were included in the study. The prescribing pattern of patients with type 2 diabetes in relation to age, individuals of the age group 51-65 years of age was found to be 55%, followed by 36-50 years of age group was found to be 28% followed by 66-80 years of age group was found to be 17%. The type 2 diabetes mellitus patients were treated by monotherapy, dual therapy and triple therapy. The prescribing pattern of monotherapy was found to be 24%, here metformin was used as a monotherapy in all 24 patients as it is indeed a first line agent and also provides extended life which was proved in animal studies^[13] as well as in humans. In a prospective, observational study on 20,000 people with type 2 diabetes mellitus and atherosclerosis was conducted which revealed that patients taking metformin had a 24% lower all-cause mortality when compared with patients who were not taking metformin.^[14] Whereas the patients with dual therapy were found to be highest with 57%, here we studied prescribing pattern of three combinations with metformin being the constant in all three including combination of Glimepride was prescribed to 59.64%, Glipizide(21.05%) and Insulin(19.29%). Here in majority of the combinations sulfonylureas are the add ons. A retrospective study on 309 low-income individuals with newly diagnosed T2D

initiated on OAs was conducted, showed that dual therapies were superior to monotherapies and that a dual therapy consisting of metformin and a sulfonylurea may have better A1c outcomes.^[15] The prescribing pattern of triple therapy was found to be 19% which was comparatively the lowest. In practice metformin is given with sulfonylureas and insulin which can be replaced with either a DPP-4 inhibitor or pioglitazone according to nice guidelines [NG28].^[16] However monotherapy turns out to be the second highest of the prescribing patterns due to the simplicity of dosing which eventually leads to improved adherence, lower treatment costs, and less potential for adverse reactions.^[17] The prescribing patterns of patients with type 2 diabetes in relation to gender, majority of subjects were Male patients (63%) followed by Females (37%). Majority of the population were males in this study maybe because of the smoking behavior which is observed in India, where majority of the smokers are male and no doubt that smoking evidently increases the risk of developing diabetes mellitus. Smokers are at a 30-40% increased risk of developing diabetes mellitus than that of non-smokers. A study showed that both active and passive smoking is related to higher risk of developing type 2 diabetes mellitus.^[18]

CONCLUSION

The study procedure was followed in compliance with the protocol and was approved by Institutional Ethical Committee. The study on prescribing pattern and co morbidities was carried out in type 2 diabetes mellitus

patients, who fits into the study based on the eligibility criteria. A total of 100 patients were enrolled into the study. The patients were divided according to the age. Among the 100 who were enrolled into the study patients with age group of 36-50 years age patients was about 28%, 51-65 age patients was about 55%, and 66-88 age group patients were about 17%. The prescribing pattern was based upon mono, dual and triple therapy. The prescribing pattern of monotherapy was found to be 24%, dual therapy was found to be 57% and triple therapy was found to be 19%. However, studies having a larger sample size and simultaneous monitoring of HbA1c in Indian populations can be done in the future to see the impact of different prescription patterns on a larger population.

CONFLICT OF INTEREST: The authors declare they have no conflict of interest.

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