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PRESCRIBING PATTERN OF ANTIDIABETIC DRUGS IN TYPE-2 DIABETIC PATIENTS

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ABSTRACT: Diabetes is a rapid gaining status of potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. Drug utilization studies are important for the optimization of drug therapy and have received a great attention in recent years. 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. These studies serves as a tool of investigation for clinical pharmacology and as source of suggestive information for epidemiology. The present study aimed to evaluate the drug utilization pattern of standard antidiabetic drugs in a medicine outpatient clinic of a tertiary care teaching hospital. It's a retrospective observational epidemiological study undertaken for a period of 8 months in outpatient unit of a tertiary care Hospital, Erode. The study enrolled 175 patient prescriptions. A total of 175 patients had co-morbid conditions along with diabetes. Commonly seen co-morbid condition in the study was hypertension. The study has shown metformin as the predominantly prescribed oral antidiabetic drug both as monotherapy as well as combination therapy. 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. This study revealed that the pattern of antidiabetic prescription was largely comply with NICE guidelines.

INTRODUCTION: Diabetes is a rapid gaining status of potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease.^{1, 2} The statistical report in the year 2000 precisely reported that India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) with the United States (17.7 million) in second and third place respectively. According to Wild et al.,³ the prevalence of diabetes is predicted to be double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India.

It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million), significant increases will be seen in all affected areas by the disease.^{3, 4} India currently facing an uncertain future in relation to the potential burden that diabetes may impose upon the country. Many influences affect the prevalence of disease throughout a country, and identification of those factors is necessary to facilitate change when facing health challenges.

Drug utilization studies are important for the optimization of drug therapy and have received a great attention in recent years. Drug utilization has been defined by the WHO as the marketing, distribution, prescription, and use of drugs in a society with a special emphasis on the resulting medical, social, and economic consequences.⁵ These studies serves as a tool of investigation for

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clinical pharmacology and as source of suggestive information for epidemiology. 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 a medicine outpatient clinic of a tertiary care teaching hospital.

MATERIALS AND METHODS:

It's a retrospective observational epidemiological study undertaken for a period of 8 months in outpatient unit of a tertiary care Hospital, Erode. The study enrolled 175 patient prescriptions. Informed verbal consent form was signed and received from each patient & they were further inquired for other comorbidities. The contents of the prescriptions were assessed & brand names were decoded to generic names using standard CIMS India & internet. Prescriptions of diabetic patients being treated at the hospital during the past six months were also included in this study. The study protocol was approved by the Institute's Ethics Committee. The subjects were evaluated for social, demographical and clinical variables and medications.

Patients' Inclusion Criteria:

- Outpatients suffering from type 2 diabetes
- Patients with a history of previously using oral antidiabetic drugs
- Diabetic patients of both genders.
- Diabetic patients ageing above 20 years.
- Patients having concurrent illness like hypertension, ischaemic heart disease & obesity

Patients' Exclusion Criteria:

- Gestational diabetes patients.

- Juvenile diabetes patients.
- Inpatients of other specialties.
- Patients enrolled in clinical trials or on treatment with any of the investigational drug(s).
- Incomplete medical records.

Observations:

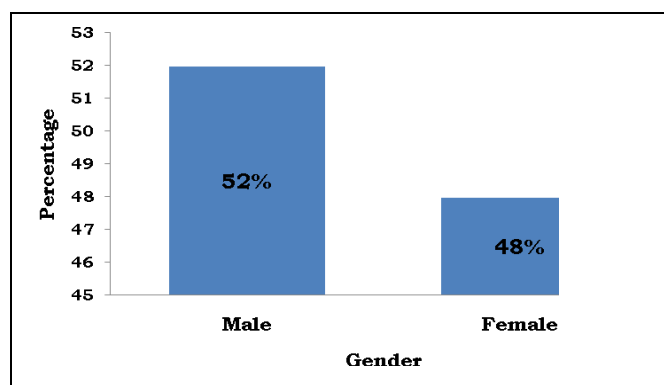


FIG. 1: DISTRIBUTION OF THE DIABETIC PATIENTS ACCORDING TO GENDER (N=175)

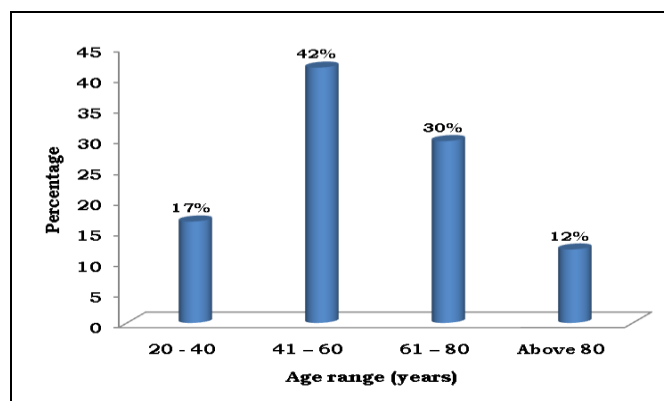


FIG. 2: DISTRIBUTION OF THE DIABETIC PATIENTS ACCORDING TO AGE (N=175)

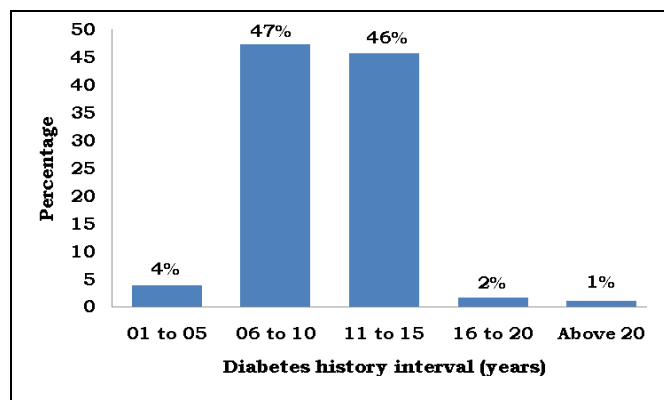


FIG. 3: DISTRIBUTION OF PATIENTS ACCORDING TO DURATION OF DISEASE (N=175)

TABLE 1: DISTRIBUTION OF THE DIABETIC PATIENTS ACCORDING TO UTILIZATION PATTERN

Drugs	No. of Patients(n= 175)	Percentage (%)
Monotherapy	136	78.61
Two drug combination	31	17.92
Three drug combination	8	4.62

TABLE 2: THE UTILIZATION PATTERN OF ANTI-DIABETIC DRUG THERAPY (MONOTHERAPY)

Drugs	No. of Patients (n= 136)	Percentage (%)
Metformin	74	42.25
Glimepiride	16	9.14
Glibenclamide	24	13.70
Gliclazide	5	2.86
Glipizide	9	5.14
Voglibose	4	2.28
Sitagliptin	2	1.14
Saxagliptin	2	1.14

TABLE 3: THE UTILIZATION PATTERN OF ANTI-DIABETIC DRUG THERAPY (TWO DRUG COMBINATION)

Drugs	No. of Patients (n=31)	Percentage (%)
Metformin+Glimepiride	12	6.85
Metformin+Glibenclamide	8	4.57
Metformin+Pioglitazone	5	2.86
Metformin+Gliclazide	3	1.71
Metformin + voglibose	3	1.71

TABLE 4: THE UTILIZATION PATTERN OF ANTI-DIABETIC DRUG THERAPY (THREE DRUG COMBINATION)

Drugs	No. of Patients (n= 8)	Percentage (%)
Metformin+Glimepiride +Pioglitazone	5	2.86
Metformin + glimepiride + sitagliptin	3	1.71

RESULTS AND DISCUSSION: A drug utilization study was considered to be one of the most effective method to assess and to evaluate the prescribing attitude of a physician and helps to promote the rational use of drugs. Diabetes mellitus is a major public-health problem over worldwide. Its' prevalence was rising in many parts of the developing world and in India there is no exception to this. Individuals with Type 2 diabetes were considered on high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of many complications.

Type 2 diabetes is a chronic disease requiring lifelong treatment. Although life style modification

plays an important role in managing diabetes, the usage of medication became unavoidable in many patients. A prescription based study was considered as one of the most effective method to assess and to evaluate the prescribing pattern of medications. This study analyzed the prescription pattern in type 2 diabetic patients who visited the tertiary care Hospital, Erode.

This retrospective study involved 175 prescriptions of patients with Type 2 diabetes. Out of 175, 91 (52%) males and 84 (48%) females were participated (**Fig.1**).

The study found a higher incidence of diabetes among elderly patients, with a high incidence in the age group of 41-60 years (42% of the total) followed by age group 61-80 years (30% of the total) (**Fig.2**). Upadhyay et al⁶ from his study reported that the higher incidence of diabetes in elderly patients with a high incidence in age group 41-60 years.

Duration of the disease plays an important role in patients suffering from longtime. A firm glycemic control results in lesser incidence of complications but complications like retinopathy was related to duration of diabetes but not based on its severity. In this study, majority of prescriptions (96%) had diabetic duration of > 5yrs, same finding was concluded by Upadhyay et al.,⁶

Out of 175 patients, 57 patients (32.5%) had family history of diabetes which was comparable with the study done by Lisha Jenny⁷ and Ramesh.⁸

In this study, hypertension (51%) was the commonest co-morbidity observed. From the total study population 91% of patients was having co-existing illness in which hypertension was found to be the highest (51%). Hypertension was frequently associated with diabetes mellitus and its incidence get double in diabetics when compared with the general population. This high prevalence was associated with increased stiffness of large arteries, which often precedes macro vascular events.

Various studies^{9, 10} reported with similar observation regarding the co-morbidity in patients with diabetes.

The duration of diabetes plays a key role for its management. In patients with a long duration of diabetes, a firm glycaemic control results in lesser incidence of complications. From this study, it was found that greater number of patients (47%) have a diabetic history of 6-10 years, followed by 46% of patients with a diabetic history of 11-15 years. Cardiovascular complications were detected in 31% of prescriptions and they were treated with various other drugs like nitrates, antiplatelet drugs etc. Micro vascular complications were present in 4% (**Fig.3**).

Lifestyle modifications such as dietary choices, smoking, alcohol consumption, overweight, sedentary lifestyle and pharmacotherapy comparatively reduce the risk factors of the disease. Dieticians should be consulted for an accurate diet plan. Appropriate control on the calorie intake makes the core of dietary modifications. Regular physical activity improves body response to insulin.

Lifestyle modifications are usually the first intervention that is sought in the treatment and prevention of DM. In this study, we reported that more than half of patients (78.61%) were treated with a single drug. In elder patients with type 2 diabetes treatment may be initiated with monotherapy followed by early intervention with a combination of oral antidiabetic drugs. The therapeutic approach mainly depends on the severity of the disease and on physician's perspective.

Drugs were prescribed as monotherapy in 78.61% patients. Two drug combinations were prescribed to 17.92% patients and three drug combinations were prescribed to 4.62% patients (**Table 1**).

Metformin was the only anti-diabetic drug that was commonly prescribed in both monotherapy and in combination therapy in the present study.

This result contrasts the reports of some studies done in India¹¹ and Hong Kong¹² which reported that Glibenclamide was the most commonly prescribed antidiabetic drug. Sudha et al.,¹³ reported that in their study metformin was the most prescribed drug. Among the second generation sulfonylureas, glimepiride was the most commonly

prescribed along with metformin which is in accordance with study from India.¹¹

Metformin is the drug of choice for overweight and obese patients with type 2 diabetes. Metformin is a peripheral sensitizer of insulin and has beneficial effects on insulin resistance, it's an important factor in pathogenesis of type 2 diabetes.¹⁴ Accordingly, metformin was reported as the first drug of choice for most of the patients with type 2 diabetes. Metformin does not promote weight gain and has beneficial effects on several cardiovascular risk factors.

This study reported that 9.14% of patients with diabetes were treated with glimepiride monotherapy (**Table 2**). Again there are studies indicating that metformin was not significantly better than glimepiride in improving the glycemic control of type 2 DM, and glimepiride would be a good choice as secondary to metformin in monotherapy for patients with type 2 DM.¹⁵

In this study, among the second generation sulfonylureas, glimepiride and glibenclamide were most commonly prescribed. Glibenclamide was prescribed for 13.7% of total drugs followed by glimepiride (9.14%). The major advantages of glimepiride was its long half life which allows a single daily dose leading for better compliance and formation of inactive metabolites eliminating the risk of hypoglycaemia (**Table 2**). Among the fixed drug combinations, the study found that combination of metformin and glimepiride (6.85%) was the most commonly prescribed regimen followed by metformin + glibenclamide (4.57%), metformin + pioglitazone (2.86%), metformin + gliclazide (1.71%) and metformin + voglibose (1.71%) (**Table 4**). Metformin + sitagliptin was the most common combination observed by Lisha Jeeny et al study,¹⁶ while in Al Khaja KA et al, 2001 study,¹⁷ metformin + sulfonylurea was the most common combination. Metformin was considered to be safer and cost effective drug over others in terms of hypoglycemia could be the probable reason for this finding.

Under three-drug combinations, the combination of metformin, pioglitazone, and glimepiride (2.86%)

was highly prescribed followed by metformin + glimepiride + sitagliptin (1.71%) (**Table 4**).

Pioglitazone comes under thiazolidinediones that helps in increasing insulin sensitivity in target tissues. In combination with other hypoglycemic drugs, pioglitazone is an effective protocol in attaining glycemic control. Voglibose comes under alpha-glucosidase inhibitor that lowers the daily glycemic conversions and inhibits over work of the pancreatic beta cells and shows a little effect on insulin sensitivity in patients with NIDDM. Several new drugs with certain advantages like high glucose-lowering efficacy are available, that include injectable glucagon-like peptide-1 agonists and DPP-4 inhibitors. These agents offer a low risk of hypoglycemia combined with sustained weight loss. Oral drug therapy for type 2 DM will achieve a greater control on glycemic targets when its' used appropriately and safely with certain assistance patients can achieve glycemic targets within the short period. However, the progressive nature of type 2 DM usually requires a combination of two or more oral agents in the longer term, often as a prelude to insulin therapy.¹⁸

Issues related to safety and tolerability notably weight gain often limit the optimal applications of antidiabetic drugs such as sulfonylureas and thiazolidinediones. Moreover, the impact of different drugs, even within a single class, on the risk of long-term vascular complications has come under scrutiny.¹⁹ Type 2 DM has been classically thought as a condition that can be managed initially with diet and exercise. Later, with the progressive failure of insulin secretory capacity, oral agents are generally used to promote insulin secretion (sulfonylureas and repaglinide), to improve insulin action in the liver (metformin), or to delay the absorption of carbohydrate from the meal (acarbose and miglitol). In recent years, combinations of oral agents have been used to attack the pathophysiology of DM at multiple points in cases where insulin secretion is still moderate.²⁰

From the data collected, it was observed that among the antidiabetic drug category, drugs were found to be prescribed in the following

order: Metformin> Glibenclamide> combination of Metformin and Glimepiride> Pioglitazone.

CONCLUSION: The current study reported that type 2 diabetes was more prevalent in males than in females. A total of 175 patients had co-morbid conditions along with diabetes. Commonly seen co-morbid condition in the study was hypertension. The study has shown metformin as the predominantly prescribed oral antidiabetic drug both as monotherapy as well as combination therapy. 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. This study revealed that the pattern of antidiabetic prescription was rational and largely comply with NICE (National Institute for Health and Clinical Excellence) guidelines.

To maintain the clinical standard of prescribing, a constant effort is mandatory for every physician to follow the guidelines recommended by various International bodies. The study was done for a short period of time and the number of patients studied was low. Hence similar studies covering large number of patients are needed to confirm this study.

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