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A single center observational drug utilization study of oral antidiabetic agents in type 2 diabetic patients

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Abstract---Diabetes mellitus is a major healthcare problem in India. Oral anti diabetic agents are the most commonly prescribed drugs for type 2 diabetes. The aim of the study was to evaluate the recent pattern of drug utilization of anti-diabetic drugs in diabetic patients and observe adverse drug events (ADEs) associated with anti-diabetic therapy. Methods: A prospective study was carried out in diabetic patients visiting the Diabetic OPD and those fulfilling inclusion criteria were included in study. Demographic data, drug utilization pattern and ADEs due to Anti-diabetic drugs were summarized. Results: In the present study, 110 (58.25%) were males and 96 (46.60%) were females. Majority of patients, Metformin was the most commonly prescribed drug. 71.1 % of patients were prescribed with triple therapy. Co-morbid condition was found in 91 patients where hypertension (18.44%) being the most common co-morbid condition. 81 ADRs were observed with GIT upset being the most common ADR reported. Conclusions: The present study helps to find out recent prescribing pattern of oral diabetic medications with different co-morbidities. Therefore, understanding of the existing prescribing

patterns, trends of antidiabetic drugs their beneficial effect and mechanism can help to overcome progression of disease.

Keywords---diabetes mellitus 2, anti- diabetic drug, adverse drug events, drug utilization.

Introduction

Diabetes is a chronic disorder defined as metabolic cum vascular syndrome of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both leading to changes in both small blood vessels (Microangiopathy) and large blood vessels (Macroangiopathy). According to WHO, around 31.7 million Indians are effected by diabetes by 2000 and it is estimated that it may increase to 79.4 million by 2030. [1] The most alarming fact is that incidence of diabetes is also increasing in rural parts of India due to urbanization, obesity, unsatisfactory diet, sedentary life style, etc shattering all myths of being the disease of the urban population. National programme of prevention and control of cancer, diabetes, cardiovascular disease and Stroke (NPCDCS) has been tarted. The focus of programme is on promotion of healthy life style, early diagnosis and management of diabetes, hypertension, cardiovascular and common cancer [2]. The choice of agents largely depends upon: Relief from symptoms of diabetes and improvement in quality of life

- HbA1c reduction
- Glycemic control and prevention of acute complications
- Identification and management of comorbid conditions like obesity, hypertension and dyslipidaemia
- Prevention of microvascular complications like retinopathy, neuropathy and nephropathy and macro-vascular complications like cardiovascular, cerebrovascular and peripheral vascular disease.
- Cost effectiveness of the therapy
- Adverse events associated with the drug- Pharmacovigilance of antidiabetic drugs can play a crucial role in detecting ADRs and providing feedback to physicians on the possibility and details of such events, thereby protecting the patients from avoidable harmful effect.

Drug utilisition is defined by WHO as “the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical,social and economic consequences” (WHO, 1977). [3] These studies play a crucial role in making essential drug list, understanding current drug prescribing practices and also identifying irrational prescribing of drugs [2]. These studies play a crucial role in making essential drug list, understanding current drug prescribing practices and also identifying irrational prescribing of drugsOral anti diabetic agents are the most commonly prescribed drugs for type 2 diabetes. The current pharmacotherapy of diabetes mellitus includes treatment with drugs such as insulin and oral hypoglycemic agents. The main classes include agents sulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinediones, dipeptidyl

peptidase-4 inhibitors [4] It is necessary to follow a treatment protocol to manage Diabetes Mellitus 2, associated comorbidities to prevent disease progression. Rational use of medicine play important role to prevent adverse drug reaction associated with drugs. So proposed study conducted to study the drug utilization pattern of Antidiabetic drugs in diabetes mellitus Patients at NSCB Medical College, Jabalpur (MP)

Method

This was an prospective observational study conducted over a period of 6 months on patients with type 2 Diabetes Mellitus attending Diabetic OPD of Medicine Department and Department of Pharmacology at NSCB Medical college Jabalpur (MP). All the participants included in the study were explained clearly about the purpose and nature of the study in the language they understood and were included in the study only after obtaining a written Informed Consent.

Inclusion criteria

- All cases diagnosed with diabetes mellitus (Old and New onset DM Type 2)
- Patient with type 2 DM with associated Comorbidity
- Patient receiving Oral anti diabetic drugs.
- Patient more than 18 year of age

Exclusion criteria

- Pregnant and Lactating mothers
- Patient diagnosed with Type 1 DM
- Patient not receiving Oral Antidiabetic Agents

A total of 206 patients diagnosed with Diabetes Mellitus type 2 visiting Diabetic OPD were screened for the study. The detailed information of the participants pertaining to age, gender, relevant medical history, past history and drug therapy administered and any ADR observed were obtained from their Diabetic Diary and were recorded in the Case Record Form. Details regarding the treatment of diabetes such as the drugs used, the dose, duration and the frequency of administration, type of dosage form used etc. were also recorded. Newly diagnosed and known cases of diabetes with co morbidities were also included in the study. The individuals included in the study were followed up for 6 months, the prognosis or any adverse drug reactions during the treatment and change in the treatment if any done were recorded.

Statistical analysis

The collected data is expressed in the percentile form.

Discussion

India is the diabetes capital of the world with 41 million Indians having diabetes; every fifth diabetic in the world is an Indian. It also leads in prevalence of metabolic syndrome as well as obesity. 20 million Indians are either obese or

abdominally obese with children being the prime targets and by 2025, the expected number is 68 million. Therefore, the prevalence of diabetes in India is increasing at an alarming rate, which needs to increase the awareness among people about causative factors for diabetes and its consequences. [5]bIn present study, total of 206 patients with DM type 2 were evaluated and it was observed that male had preponderance in the prevalence of diabetes (Males 58.25%; Females 46.60%). (FIG 1) Similar study conducted by Vengurlekar S et al, Boccuzzi SJ et al, Johnson et al, Yurgin N et al, also showed that male had preponderance in the prevalence of diabetes. [6]

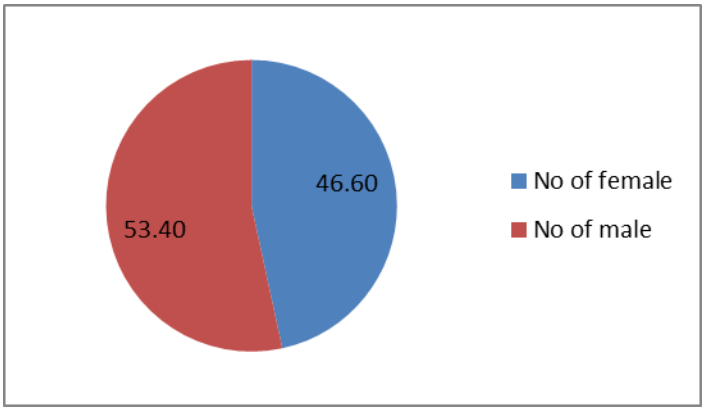

Figure 1. Distribution of diabetic patient according to gender

Maximum number of patients had a history of Diabetes duration between 1-4 (57.7%) years followed by less than 1 year (23.30%) years followed by 5-10 years (18.93%). (FIG 2)

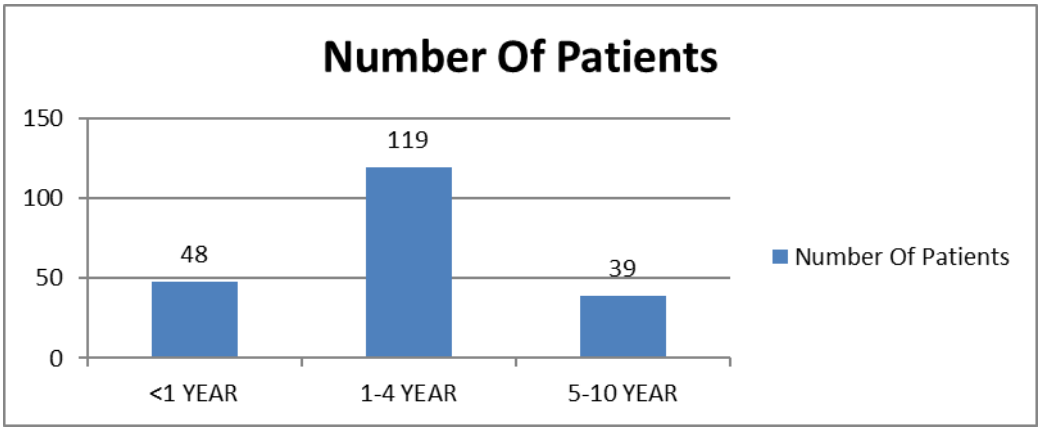

Figure 2. Duration Of Diabetes Mellitus 2

In the present study, single co-morbid condition was found in 91 patients. 12 Patients had more than two comorbid conditions. Similar study conducted by Chaudhary P et al,who reported more patients were suffering from a single co-morbid condition. [7] The comorbid conditions found were cardiovascular (hypertension, dyslipidemia), Chronic Kidney Disease (CKD), CKD with Hypertension, Hyperthyroidism. Hypertension accounted for Maximum (18.44%)

of the total comorbidities followed by dyslipidemia, CKD with hypertension ,CKD, Hyperthyroidism.(FIG 3)

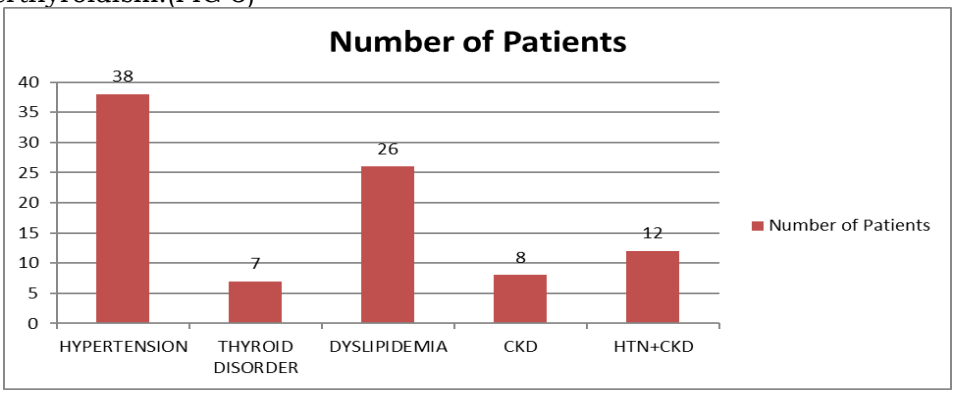

Figure 3. Co- morbid condition of diabetic patient

In the present study, it was found that 71.1% of patients were on triple therapy with oral hypoglycemic agent compared to 16 % on dual therapy. Prescriptions with three or more drugs were found to be common among patients above 45 years of age. Maximum no. (71.1 %) of patients were prescribed with triple therapy while 16% patients were prescribed with Dual therapy and 9.7 % patients was prescribed with more than five drugs. With the advancing age, the co-morbidities also increase and consequently increase the number of prescribed medications. This could explain the reason for increased number of medication in patients above 45 years of age. (FIG 4)

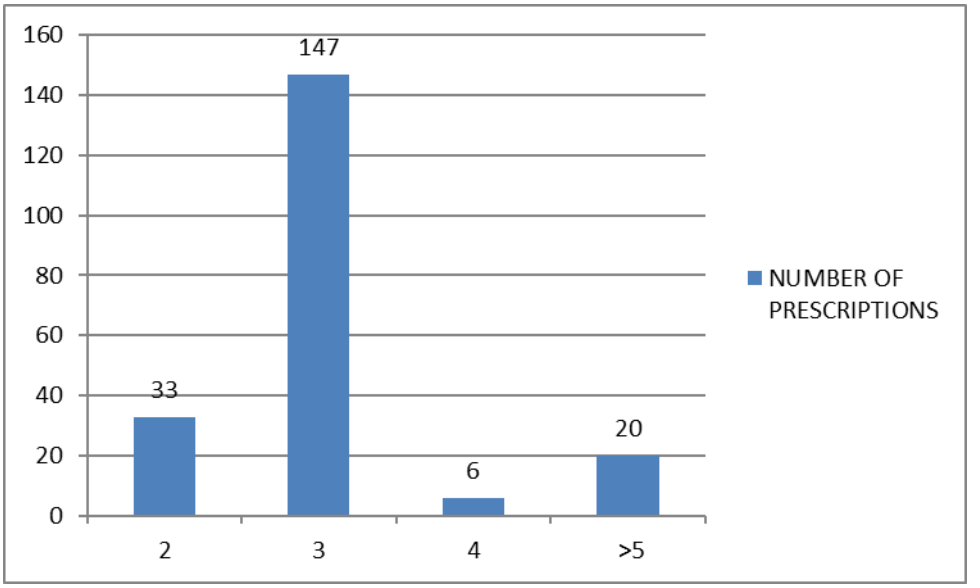

Figure 4. No. of drugs/prescription in diabetic patient

Most prescribed primary drug for treatment was metformin which was highest of all group of drugs. DPP-4 Inhibitors was prescribed in 197 patients of which vildagliptin (105) was the most commonly prescribed drugs, 182 patients were

prescribed with sulfonylureas group of drugs of which glimepride (170 patient) was the most commonly prescribed drugs. Thiazolidinediones was prescribed in 15 patients and α- Glucosidase Inhibitors in 28, SGLT2 inhibitors was prescribed in 9 patients. These results are shown in FIG 5.

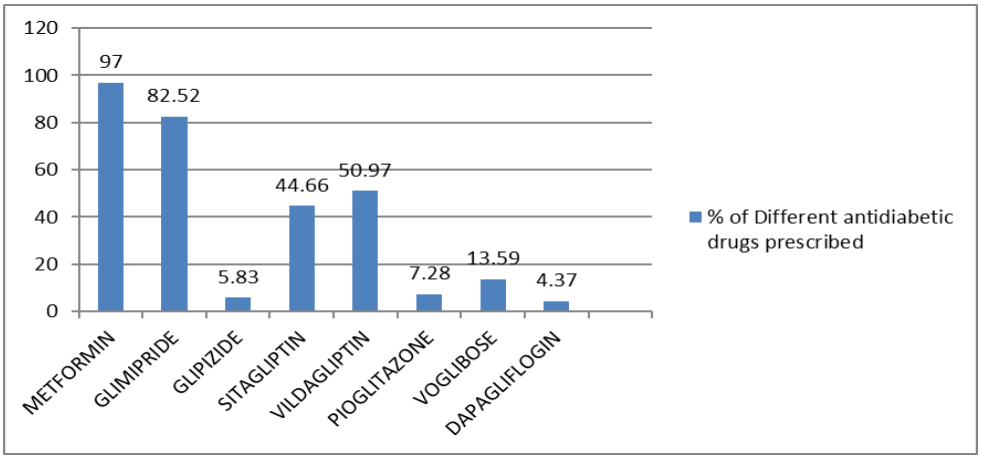

Figure 1. Different antidiabetic drugs prescribed among the studied prescriptions

In this study, 81 patients reported ADRs out of which 45 patients reported GIT upset followed by hypoglycemia in 15 patients, headache in 15 patients and upper respiratory tract infection was seen in 6 patients. (FIG 6) Pharmacovigilance of antidiabetic drugs can play a crucial role in detecting ADRs and providing feedback to physicians on the possibility and details of such events, thereby protecting the patients from avoidable harmful effect.

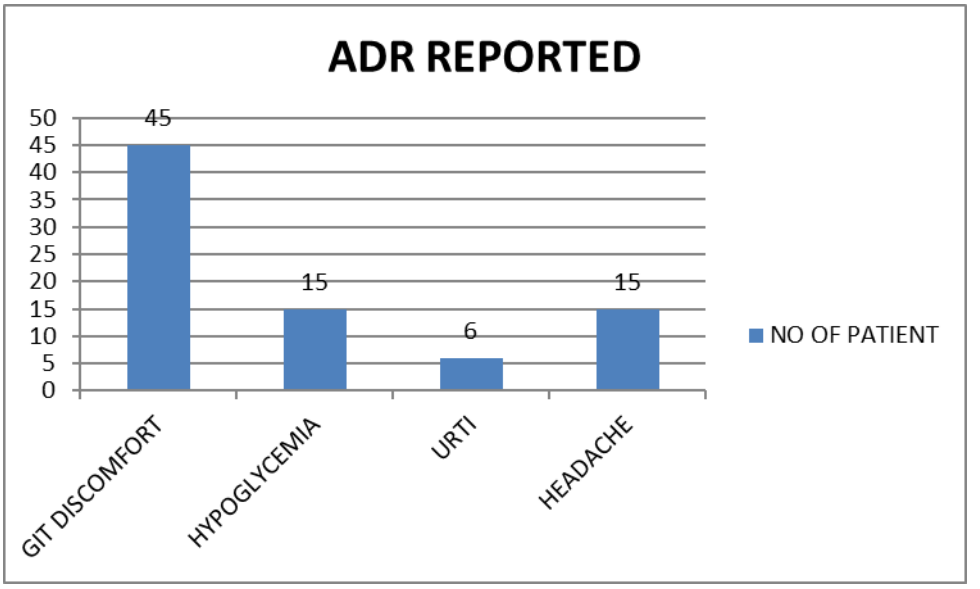

Figure 2. ADR REPORTED

Limitation of our study was small sample size, duration of study.

Conclusion

In our study, the prescribing pattern was found to be combination therapy with main target to prevent disease progression. Among oral antidiabetic agents, metformin along with glimepiride and vildagliptin was most commonly used combination. Most common reported ADR was GIT upset followed by hypoglycemia. Therefore, understanding of the existing prescribing patterns, recent trends and advances of antidiabetic drugs targeting different mechanism can help to overcome progression of disease and attempts can be made to improve the quality and efficiency of drug therapy.

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