

Original Research Article

A prospective study on drug utilization pattern of anti-diabetic drugs in a tertiary care teaching hospital of eastern Uttar Pradesh, India

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ABSTRACT

Background: Diabetes mellitus is a metabolic disorder with common denominator of hyperglycemia, arising from a variety of pathogenic mechanisms. The aim of the study was to evaluate the drug utilization pattern of anti-diabetic drugs in diabetic patients and observe adverse drug events (ADEs) associated with anti-diabetic therapy in a prospective way.

Methods: A prospective study was carried out in diabetic patients visiting the Departments of General Medicine in a tertiary care teaching hospital. Demographic data, drug utilization pattern and ADEs due to Anti-diabetic drugs were summarized.

Results: In the present study, 153 (54%) of the 282 diabetic patients were males and 129 (46%) were females. Majority of patients were in the age group of 51-60 years (31.20%) and most of the patients (31.56%) had a diabetic history of 11-15 years. Metformin was the most commonly prescribed drug (64.89%). Majority of the patients (36.87%) were on multidrug therapy. Co-morbid condition was found in 232 patients (82.26%) where hypertension (22.69%) being the most common co-morbid condition. 32 ADRs were observed with Nausea being the most common ADR reported.

Conclusions: The present study helps to find out current prescribing pattern of oral diabetic medications with different co-morbidities with respect to diagnosis, cost of treatment and it also highlight the need for comprehensive management of diabetic patients, including life style changes, dietary control, hypoglycemic agents, cardiovascular prevention, treatment of complications and co-morbidity. Therefore, through the existing prescribing patterns, attempts can be made to improve the quality and efficiency of drug therapy.

Keywords: Anti-diabetic drug, Adverse drug events, Drug utilization

INTRODUCTION

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.¹ The principal aim of drug utilization studies (DUS) is to facilitate the rational use of drugs in population.

Diabetes Mellitus (DM) is a most common metabolic disorder characterized by hyperglycemic.² Diabetes has emerged as a major healthcare problem in India. India has the largest population of diabetes in the world. The international diabetes federation (IDF) estimates the number of people with diabetes in India will reach

80million by the year 2025. A survey depicts that 4% of adults in India suffered from diabetes in the year 2000 and is expected to increase to 6% by the year 2025.³

The world health organization (WHO) has projected that the global prevalence of type-2 diabetes mellitus will more than double from 5 million in 1995 to 300 million by 2025. Between 1995 and 2025, there will be a 35% increase in worldwide prevalence of diabetes mellitus, from 4 to 5.4%.⁴

Worldwide prevalence of DM is estimated to rise from 382 million in 2013 to 592 million in 2035.⁵ The prevalence of type 1 diabetes (T1DM) is about 5% to 10% and type 2 diabetes mellitus (T2DM) is about 90% to 95%.⁶

There is no specific cause for DM, but both etiologic factors and risk factors are associated with it. The risk factors are heredity, obesity, increasing age, emotional stress, autoimmune β -cell damage, endocrine diseases (e.g. Cushing disease).⁷ In addition to that the incidence is increasing in rural parts of India due to urbanization, obesity, unsatisfactory diet, sedentary life style, etc.⁸ Both types of diabetes have microvascular and macrovascular complications.^{9,10}

The American Association of Clinical Endocrinologists/American College of Endocrinology (AAACE/ACE-2015) is considered the “gold standard” consensus guidelines for the management of DM. The other guidelines are 2015 American Diabetes Association (ADA) and 2015 National Institute for Health and Care Excellence (NICE).¹¹⁻¹³

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.¹⁴⁻¹⁶

It is necessary to follow a treatment protocol in common co-morbidities associated with type 2 diabetes. So, authors have aimed to study the drug utilization pattern of Antidiabetic drugs in diabetes mellitus Patients in a tertiary care teaching hospital of Eastern Uttar Pradesh, India.

METHODS

This prospective observational study was conducted over a period of 6 months (June-November 2018) in the outpatient departments of General Medicine at Government Medical College and superfacility hospital, a tertiary care teaching hospital. 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 (ICF).

Inclusion criteria

All cases diagnosed with diabetes mellitus (both type 1 and type 2) admitted at the In and out patient Department of General Medicine.

Exclusion criteria

- Patients with gestational diabetes.
- Pregnant female having diabetes.

A total of 282 patients were being a known case of DM under treatment of both genders and aged between 30 to >70 years were included in the study. The detailed information of the participants pertaining to age, sex, occupation, relevant medical history, past history and drug therapy administered were obtained from their case files and were recorded in the Case Record Form (CRF). 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. The individuals included in the study were regularly followed up during their stay in the hospital in order to observe for their management, the prognosis or any adverse drug reactions during the treatment and change in the treatment if any done, till they were discharged.

Assessment of the cost of the therapy

Total cost per patient for antidiabetic drugs was calculated. The results were expressed as Mean \pm standard deviation.

Statistical analysis

The gathered data is expressed in the percentile form.

RESULTS

During the study period, a total of 282 patients with Diabetes Mellitus were included from Department of medicine. Out of the 282 patients, 154 (54.6%) were males and 129 (45.74%) were females as shown in Figure 1.

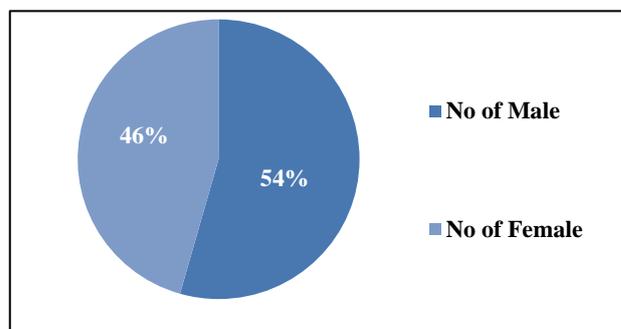


Figure 1: Distribution of diabetic patient according to sex (n=282).

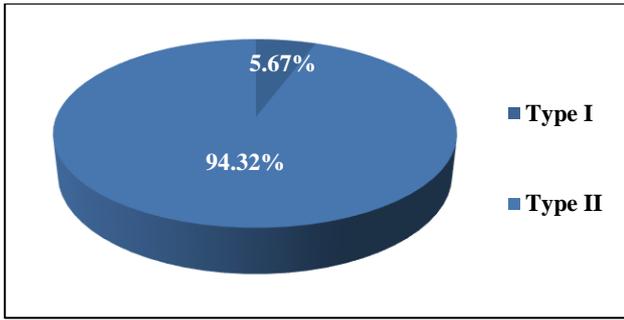


Figure 2: Distribution of diabetic patient according to type of DM.

Out of 282 Patients of DM, 266 patients were diagnosed as type 2 diabetes mellitus while 16 were diagnosed as type 1 diabetes mellitus. These results are represented in Figure 2. Out of 282 Patients of DM, it was observed that Majority of patients were in the age group pf 51-60 (31.20%) years followed by age group of 41-50 (25.17%) years while Patients with age group of 30-40 (9.57%) was found to be least as shown in Table 1.

Table 1: age and sex distribution of diabetic patients.

Age group (years)	Male	Female	Total	Percentage (%)
30-40	16	11	27	9.57
41-50	38	33	71	25.17
51-60	47	41	88	31.20
61-70	27	25	52	18.43
>70	25	19	44	15.60
Total	153	129	282	100

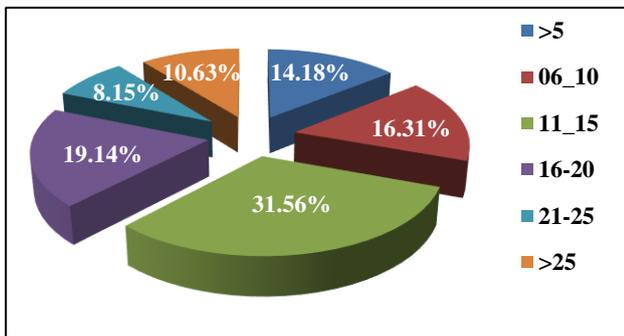


Figure 3: Duration of diabetes.

Among 282 patients of DM maximum no. of patients had a history of Diabetes between 11-15 (31.56%) years followed by 16-20 (19.14%) years followed by 6-10 (16.31%) years while only 23 (8.15%) patients had a history of diabetes 21-25 years as depicted in Figure 3.

Out of 282 Patients, Co-morbid conditions were found in 232 patients. Among the 232 patients, 36 Patients had more than two comorbid conditions in our study while 50 Patients were without any comorbidity. The comorbid conditions found were cardiovascular (hypertension,

coronary artery disease), Chronic Kidney Disease (CKD), Micro vascular Complications (MVCs) like neuropathy, retinopathy etc. while 16 (9.25%) Patients was found with other types of complication. Hypertension accounted for Maximum (22.69%) of the total comorbidities followed by CKD, CAD. These results are depicted in Figure 4.

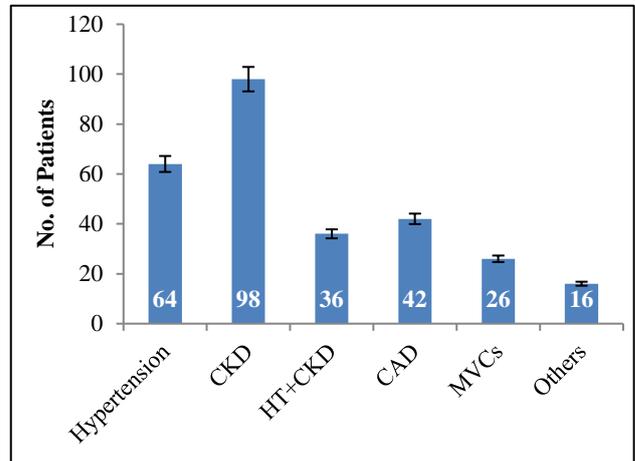


Figure 4: Co-morbid condition of diabetic patient.

Out of 282 patients, maximum no. (104) of patients were prescribed with dual therapy (36.87%) while 87(30.85%) patients were prescribed with triple therapy and 28 (9.92%) patients was prescribed with monotherapy. 63 (22.34%) patients were prescribed with more than three drugs as depicted in Figure 5.

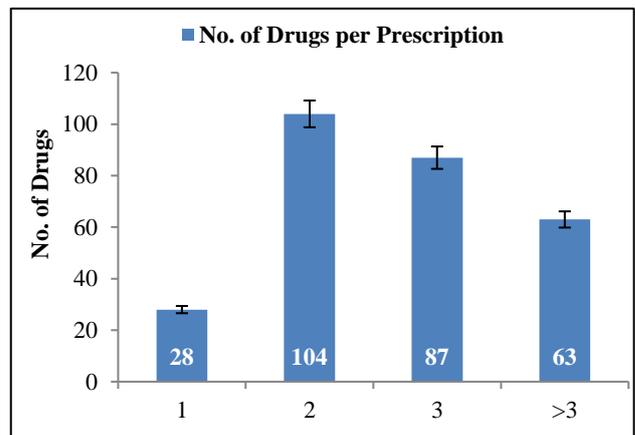


Figure 5: No. of drugs/prescription in diabetic patient.

Out of 282 Patients it was observed that 183 (64.89%) Patients was prescribed with metformin which was highest of all group of drugs. 152 (53.90%) patients were prescribed with sulfonylureas group of drugs of which glimepride (24.11%) was the most commonly prescribed drugs. Insulin was prescribed in 80 (28.36%) patients. DPP-4 Inhibitors was prescribed in 84 (29.78%) Patients of which vildagliptin was the most commonly prescribed drugs. Thiazolidinediones was prescribed in 22 (7.80%) patients and α - Glucosidase Inhibitors in 19 (6.73%)

patients while GLP-1 Analog was the least commonly prescribed drugs 9 (3.19%). These results are shown in Table 2.

Table 2: Anti-diabetic Drugs (ADDs) used by the patients with diabetes mellitus.

Class of ADDs	Name of drug	No. of patients	Percent (%)
Biguanides	Metformin	183	64.89
	Glimepride	68	24.11
Sulfonylureas	Glibenclamide	60	21.27
	Glipizide	16	5.67
	Gliclazide	8	2.83
	Total	152	53.90
	Insulin	Insulin	80
α- Glucosidase inhibitors	Voglibose	13	4.60
	Acarbose	6	2.12
	Total	19	6.73
DPP-4 inhibitors	Sitagliptin	29	10.28
	Vildagliptin	45	15.59
	Linagliptin	10	3.54
	Total	84	29.78
Thiazolidinedi ones	Pioglitazone	19	6.73
	Rosiglitazone	3	1.06
	Total	22	7.80
GLP-1 analog	Exenatide	9	3.19

Table 3: Cost therapy of medication per month.

Cost pf drug/ month	No. of patients	Percentage (%)
<100	152	53.90
100-200	73	25.88
>200	57	20.21

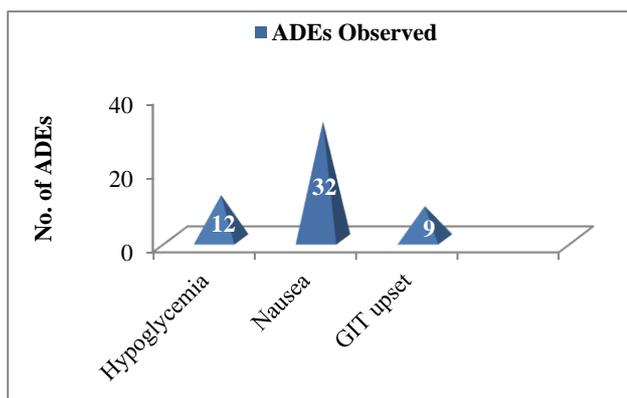


Figure 6: ADEs observed.

It was observed that out of 282 patients, in 152 (53.90%) patients’ total cost of drug per month was less than 100 rupees. Similarly, in 73 (25.88%) patients, total cost of drug per month was between 100-200 rupees while in 57 (20.21%) patients, total cost of drug per month was more than 200 rupees. These results are represented in Table 3.

In present study, 53 (18.79%) patients were observed with ADEs out of which 32 (11.34%) was seen with nausea followed by hypoglycemia in 12 (4.25%) patients and GIT Upset was seen in 9 (3.19%) of patients as shown in Figure 6.

DISCUSSION

Diabetes mellitus is a chronic lifelong disease affecting a large spectrum of population in the developing countries including 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”.¹⁷

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.¹⁸ 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.¹⁹

In present study, total of 282 diabetic patients were evaluated during the study period and it was observed that male had preponderance in the prevalence of diabetes (Males 54.60%; Females 45.75%). 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, while few studies conducted by Lisha et al, Saiyad et al, Ramesh R et al, was contradictory to our study which have reported a high proportion of diabetes in female patients.²⁰⁻²⁵

In present study DM was found to be most prevalent 88 (31.20%) in the age group of 51-60 years as aging causes increase prevalence of diabetes and carbohydrate intolerance in the elderly due to associated decrease in insulin secretion in response to glucose load as well as increased insulin resistance in peripheral tissues.²⁶ Further, insulin sensitivity also decreases with increasing age and obesity.²⁷ Present study was in concordance with the earlier done study by Vengurlekar S et al, Upadhyay DK et al, and Kannan et al.^{20,28,29}

In current study, authors found that the average number of drugs per prescription was 1.94 drugs. A previous study from India also reported an average of 1.95 drugs.³⁰ In this 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).^{28,31} However, the average number of drug prescribed is more compared to that reported by Kannan et al, (1.4 per prescription).²⁹ Total numbers of anti-diabetic drugs prescribed were 549 which was slightly lower in study by done Priya D et al, (475 drugs).³² More

number of drugs was prescribed in study by Karthikeyan V et al.³¹

Prescriptions with two or more drugs were found to be common among patients above 51 years of age. 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 51 years of age. In the present study, it was found that 28 (9.92%) of patients were on monotherapy with oral hypoglycemic agent compared to 104 (36.87%) on combination therapy. Present study was contradictory from a study conducted in Tamil Nadu by Sivasankari V et al, who reported monotherapy, and two drug combination therapies were prescribed in 21.7% and 78.3% patients, respectively.³³

80 (28.36%) of the 282 diabetic patients were on insulin therapy. The most commonly prescribed anti-diabetic drug class was biguanides (metformin) both as monotherapy and/or in combination therapy, metformin accounted for 183 (64.89%) of the total drugs prescribed, followed by sulfonylureas 152 (53.90%) of which glimepiride 68 (24.11%) was most commonly prescribed sulfonylureas and then DPP4 inhibitors 84 (29.78%) (vildagliptin 45 (15.59%). Similar result regarding biguanides and sulfonylureas has been documented in study conducted by Alex SM et al.³⁴ Studies conducted by Truter I, and Boccuzzi SJ et al, in South Africa, US and India during the late 1990s have reported sulphonylureas as the most frequently prescribed antidiabetic agent which is contradictory from the present study.^{35,36}

Duration of diabetes has a significant role in its management. Patients who have diabetes for <5 years could usually be managed with single drug therapy while combination therapy is required in patients having diabetes for more than this period. In the present study, most of the patients 89 (31.56%) had a diabetic history of 11-15 years, a finding which was contradictory with that of other studies.^{28,29}

Co-morbidity has been shown to intensify health care utilization and to increase medical care costs for patients with diabetes. In the present study, co-morbid condition was found in 232(82.26%) patients. 196 patients were suffering from a single co-morbid condition, and 36(12.76%) were suffering from more than one co-morbid condition.

50 patients had no other diseases apart from diabetes. Hypertension 64 (22.69%) was the most common co-morbid condition, followed by CKD (17.02%). Different studies from India and other countries have reported a similar observation with regard to the co-morbidity in patients with diabetes. However, the prevalence of hypertension has ranged from 31 to 70% in a study conducted by Patel B et al, Alam MS et al.^{37,38} The combination of hypertension and diabetes is clinically

important since it magnifies the risk of diabetic complications.

53 (18.79%) ADRs were reported during the study. Nausea was the most common ADR observed in 32 patients followed by 12 hypoglycemic ADRs was reported in present study.

Cost of prescription is very important in chronic disease like diabetes as it may be a major cause for non-adherence to treatment. In our study, cost for both insulin and oral antidiabetic agent was under 100 INR/patient/month for 152 (53.90%) Patients both at hospital stay and at the time of discharge, which was lower in comparison to study conducted by Acharya et al, where average cost was between 100-400 INR/patient/month.³⁹ The reason for low cost of the therapy in our study was because, being a government set up metformin was given free of cost to the patients and insulin also is supplied at low cost to below poverty line patients in hospital. Another reason for low cost in our study was found to be the prescription of cheapest brand of antidiabetic agents as most of the patients belong to low socio-economic status being in a rural set up.

In present study out of 282 Diabetic Patients, 16(5.67%) was suffering from Type I DM while 266 (94.32%) was suffering Type II DM which is almost similar to a study done by Agrawal R et al, who reported 96.52% of patients with Type II DM while 3.48% with Type I DM out of 230 Patients.⁴⁰

CONCLUSION

Diabetes should be managed properly to enhance the quality of life of the patient. In the study carried out most of the prescriptions were rational, but further improvement is needed.

The present study has clearly delineated the drug utilization pattern of diagnosed diabetic patients at GMC, Azamgarh a tertiary care teaching hospital in Eastern Uttar Pradesh, India. More than 90% of patients were diagnosed as type 2 DM. High frequency of oral hypoglycemic agents were prescribed, reflecting higher glycemia at the time of diagnosis. Amongst this group of drugs biguanides accounted for the most commonly prescribed drug. Polypharmacy was found to be low, suggestive of more rational mode of prescribing. Present study showed, low cost of drugs per prescription as Generic drugs has been prescribed to the patients. So, it is necessary to taken care of quality of drugs.

The choice of drug should be based economic status, associated conditions. Rational prescribing should focus on dose and duration as well as interaction with other medications. This can be done by prescribing a proper drug regimen consisting of hypoglycemic agents as well as diet control and exercise. Efforts from both patients

and the physician should be made to meet the target glucose levels and have a better and healthy life.

Therefore, through a thorough understanding of the existing prescribing patterns, attempts can be made to improve the quality and efficiency of drug therapy. Besides, setting standards and assessing the quality of care through performance review should be a part of everyday clinical practice.

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