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Original Research Article

Drug utilization pattern in type II diabetes mellitus patients attending non-communicable disease clinic in a tertiary care hospital

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ABSTRACT

Background: Diabetes mellitus is a metabolic disorder. Early institution of treatment is necessary to prevent complications. Since treatment of diabetes requires lifetime therapy; this study is designed to understand the prescription trends at Non Communicable Disease clinic set up and to provide rationale.
Methods: This cross-sectional, observational study was conducted over a period of 2 months (May 2017- June 2017). Details of demographic data, duration and family history of diabetes, antidiabetic medications prescribed, history of comorbid diseases and drugs prescribed by physician for the treatment of comorbid diseases were collected in a structured format. Height and weight were recorded, and body mass index was calculated.
Results: Study population included 294 patients and patients in the age groups of 40-59 years formed the bulk. 39% patients were overweight and 19.39% were obese. 93.20% patients were prescribed with metformin. 37 patients received insulin injection. 64.29% received more than one antidiabetic drug. Hypertension (82.05%) was the most common comorbid disease. Amlodipine was the most commonly prescribed antihypertensive drug.
Conclusions: Metformin was the most commonly prescribed antidiabetic drug. Utilization of newer antidiabetic drug is inferior. Use of rationale fixed dose combination improves patient compliance.

Keywords: Drug utilization, Non-communicable disease clinic, Type II diabetes mellitus

INTRODUCTION

Diabetes mellitus is a chronic disorder of public health importance. Its prevalence is increasing worldwide, especially in developing countries. According to International Diabetes Federation, global burden of type II diabetes mellitus (type II DM) in 2017 was 8.8%, which may increase to 9.9% in 2045. India ranks second among countries with highest number of diabetic patients.[1] Vascular changes of diabetes increase the risk of developing irreversible complications leading to morbidity and mortality.[2] Moreover, economic burden on health care systems due to rising prevalence of diabetes is a matter of concern for resource poor countries.[3]

Goal of pharmacotherapy is to achieve glycemic control and prevention of complications. This is achievable if medications are prescribed early and at adequate dosages along with lifestyle modifications. Numbers of newer agents have been marketed for the treatment of diabetes mellitus. This provides physician, an opportunity to select the best drug according to patient condition. A great extent of variability is seen in drug prescriptions in diabetic patients. Added to this, management of concurrent diseases generally leads to polypharmacy, drug related problems. Therefore, rationale drug prescription is important for benefit of patients as well as management of funds in government setup.

Drug utilization is defined as the marketing, distribution, prescription, and the use of drugs in society, with emphasis on the resulting medical and social consequences. Drug utilization studies provides information on diverse aspects of drug exposure such as prescribing behaviour of physician, clinical outcome, inappropriate drug use, patient compliance, and economic aspects of drug use at various levels. For regulatory authorities, drug utilization studies are powerful tools for the development of high-quality formularies and essential drugs lists.[4]

This study was carried out to monitor drug utilization pattern in type II diabetic patients attending non-communicable disease clinic (NCD clinic) outpatient department of BIMS hospital, Belagavi.

METHODS

This cross-sectional study was carried out in NCD clinic, BIMS, Belagavi over a period of 2 months between May 2017and June 2017. Approval of Institutional Ethics Committee was obtained prior to the study. Prescriptions of 294 Type II DM patients attending NCD Clinic, BIMS Hospital, were analysed. Repeat prescriptions were excluded. Informed consent was obtained from all patients.

Inclusion criteria

- Patients of either gender, diagnosed with type II DM,
- With or without comorbidities who are on treatment with antidiabetic drugs attending the NCD clinic at BIMS between May 2017 and June 2017.

Exclusion criteria

- Transient hyperglycaemia secondary to infection and surgery
- Patients with Type I diabetes mellitus
- Pregnant ladies with diabetes mellitus
- Hospitalized patients

Following details was collected in a structured format.

- Demographic data (age, gender).
- Duration of diabetes
- Family history of diabetes
- Antidiabetic medications prescribed in NCD clinic
- History of comorbid diseases and drugs prescribed by physician for the treatment of comorbid diseases, if any.
- Height and weight were recorded and Body Mass Index (BMI) was calculated.

Statistical analysis

Collected data was summarized using descriptive statistics. Results are represented in the form of graphs and tables.

RESULTS

Out of 294 Type II DM patients, 159 (54.08%) were males and 135 (45.92%) were females. Age groups of 40-59 years formed the bulk of study participants. Positive family history of diabetes was elicited in 44.56% of patients (Table 1).

Table 1: Basic demographic details of diabetic patients.

Demographic details	Frequency (n=294)	Percentage (%)
Sex		
Males	159	54.08
Females	135	45.92
Age distribution		
31-40	58	19.73
41-50	136	46.26
51-60	97	33
>60	3	1.02
Family history		
Present	131	44.56
Absent	163	55.44

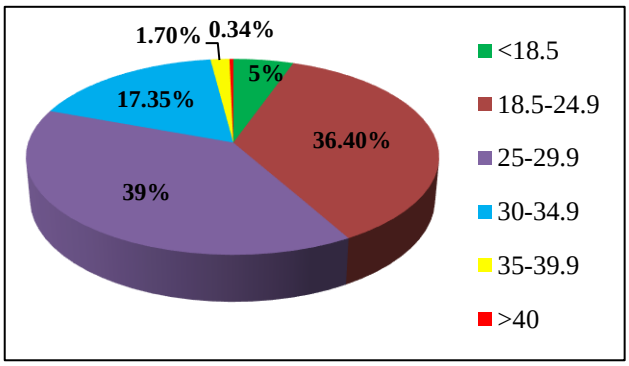

Figure 1: Distribution of patients according to BMI (n=294).

BMI of the patients was calculated, and 39% patients were found to be overweight (BMI in the range of 25-29.9); 19.39% of patients were found to be obese patients (class

I, II, and III); while, only 5% patients were underweight (Figure 1).

Past history of diabetes mellitus was recorded, and it was found that 27.90% patients were diagnosed recently within past 6 months, and 39.46% patients were diagnosed between past 6 months to 2 years. Only 3.06% patients had long standing history of diabetes (for >10 years) (Figure 2).

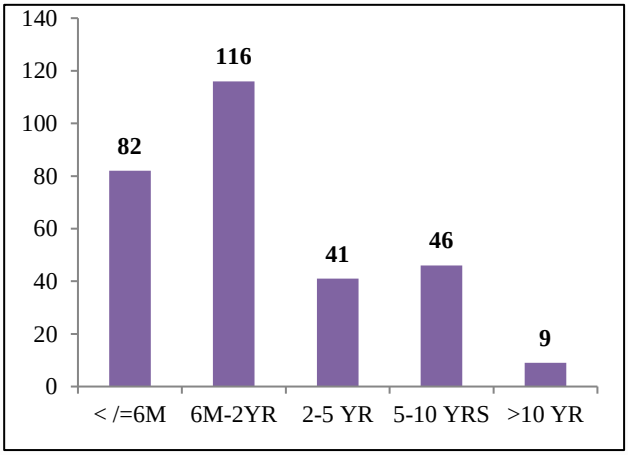

Figure 2: Duration of diabetes mellitus (n=294).

Pattern of antidiabetic drug use

Majority of patients (87.4%) treated with oral antidiabetic medications. 7.5% patients received the combination of oral drugs along with insulin. 5.1% patients treated with insulin alone (Table 2).

Table 2: Pattern of oral antidiabetics and insulin.

Oral anti diabetics/ insulin	Number of patients (n=294)	Percentage (%)
Oral antidiabetics	257	87.4
Oral antidiabetic+ insulin	22	7.5
Insulin alone	15	5.1

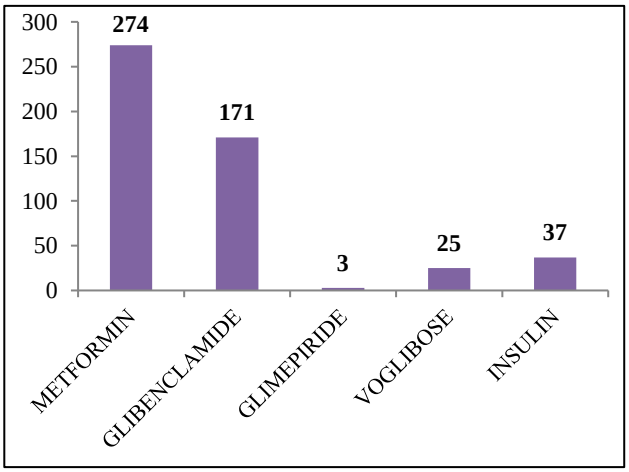

Figure 3: Pattern of antidiabetic drug use (n = 294).

Total 274 (93.20%) patients were prescribed metformin either alone or in combination with other antidiabetic drugs. Sulfonylureas were the second most frequently prescribed drugs; 59.19% patients received either glibenclamide or glimepiride. Voglibose was prescribed in 8.5% patients along with other antidiabetic drugs. Out of 37 patients who received biphasic isophane insulin injections, 15 were treated with insulin alone (Figure 3).

Monotherapy was preferred in 35.71% patients. Rest of the patients (i.e., 64.29%) received more than one antidiabetic drug, of which 85.71% patients received combination of 2 drugs, and 14.29% patients received combination of 3 antidiabetic drugs (Table 3).

Table 3: Prescription pattern of antidiabetic drugs.

Drugs	No. of prescriptions (n=294)	Percentage (%)
Monotherapy	105	35.71
Metformin	87	29.6
Glibenclamide	3	1.02
Glimepiride	0	0
Voglibose	0	0
Insulin	15	5.10
2 drug combinations	162	55.10
Metformin+ glibenclamide	143	48.64
Metformin+ voglibose	1	0.34
Metformin+ glimepiride	1	0.34
Insulin+ metformin	15	5.10
Insulin+ glibenclamide	2	0.68
3 drug combinations	27	9.18
Metformin+ glibenclamide+ voglibose	20	6.80
Metfotmin+ glimepiride+ voglibose	2	0.68
Insulin+ metformin+ glibenclamide	3	1.02
Insulin+ metformin+ voglibose	2	0.68

Comorbid diseases and treatment

In 117 patients, diabetes was associated with comorbid conditions; among which hypertension (82.05%) was the most common, followed by ischemic heart disease (IHD, n=13) and stroke (n=11) (Figure 4). Among hypertensive patients, amlodipine and atenolol was prescribed to 64.58% and 32.3% patients, respectively. Very few patients received angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARBs) (Table 4). Among 106 patients with significant cardiovascular disease (hypertension and IHD) and stroke, 63.21% patients were treated with a combination of 2

antidiabetic drugs, 27.36% with single antidiabetic drugs and 9.43% with combination 3 antidiabetic drugs (Figure 5).

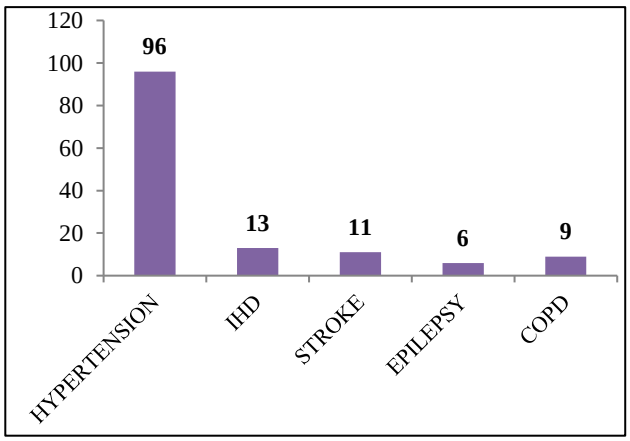

Figure 4: Pattern of comorbid diseases in study subjects (n=117).

Table 4: Treatment of comorbid diseases.

Drugs prescribed	Frequency (n=117)
Atenolol	31
Amlodipine	62
Enalapril	7
Losartan	23
Aspirin	9
Clopidogrel	8
Isosorbide mononitrate	6
Atorvastatin	6
Phenytoin	4
Sodium valproate	2

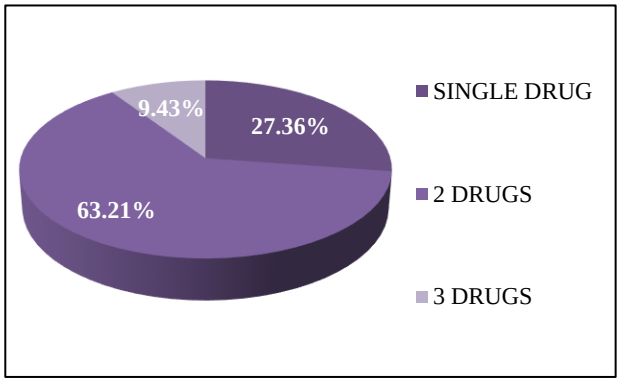

Figure 5: Antidiabetic drug utilization pattern in patients with significant cardiovascular diseases and stroke (n=106).

WHO drug use indicators

Average number of drugs per prescription was 2.27. 52.70% of drugs prescribed by generic name and 80% of drugs were prescribed from the essential drug list (Table 5).

Table 5: WHO drug use indicators.[4]

Key prescribing indicators	
Average number of drugs per encounter	2.27
Average number of antidiabetic drugs per prescription	1.73
Percentage of drugs prescribed by generic name	52.70%
Percentage of encounters with an antibiotic prescribed	0%
Percentage of encounters with an injection prescribed	12.59%
Percentage of drugs prescribed from essential drugs list	80%

DISCUSSION

Diabetes mellitus is a preventable and treatable metabolic disorder that needs life-long treatment. Pharmacotherapy involves the use of oral anti-diabetic drugs (OAD) and insulin.

In the present study, males out-numbered females. Patients with positive family history of diabetes mellitus were 44.56%. In a study conducted by Alam MS et al, familial association was observed in 18% patients.[5] According to the BMI, 36.4% patients were normal, 39% were overweight and 19.39% were obese. In a study by Sharma S et al, 22.4% patients were overweight and 5.6% were obese.[6] Problem of obesity is considerably more in our patients. More than two third of patients were diagnosed within past two years. Majority of patients were in the age group of 41-50 years (46.26%) followed by 51-60 years (33%). This is in contrast to observations of Alex SM et al, where 15.2% of diabetics were in the age group of 41-50 years and 39.6% were in the age group of 51-60 years.[7] Thus, we observed the onset of Type 2 DM, one decade earlier. This is explained by higher positive familial association and higher prevalence of obesity resulting from physical inactivity and changed dietary habits.

Oral antidiabetic drugs were preferred over injectable insulin. 257 patients were treated with one or more of OADs. Metformin was frequently prescribed drug (n=274), followed by glibenclamide (n=171) and insulin (n=37); either alone or in combination with other agents. Dashputra AV et al, reported that 80.66% diabetic patients attending OPD were prescribed metformin. Glimepiride was most frequently used sulfonylurea; but in the present study, glibenclamide was preferred over glimepiride.[8] Metformin does not promote weight gain and has beneficial effects on several cardiovascular risk factors. Accordingly, metformin is widely regarded as the first line drug for most of the patients with Type II DM.[9] Glibenclamide leads to an increased incidence of hypoglycaemia and weight gain. Sulfonylureas also increases cardiovascular mortality, but it is significantly lower with gliclazide or glimepiride.[10] This point needs a special attention, as most of our patients were treated with glibenclamide. Voglibose, an alpha

glucosidase inhibitor was used in combination therapy only. Many newer classes of OADs such as DPP-4 inhibitors, SGLT-2 inhibitors were also not prescribed.

Combination of antidiabetic drugs was given in 64.29% patients. In a study by Kakade A et al, 70% patients received combination therapy.[11] Two drug combination was frequently used in our patients. Adding a second agent is usually better than increasing the dose of an agent that has already been given in a nearly maximum dosage. In some patients, three drug combinations may be useful.[12] In the present study; none of the patients were prescribed fixed dose combination (FDC), because of non-availability of FDCs in the Government hospital. Introduction of rationale FDCs improves the compliance due to decreased pill burden.

Out of 37 (12.59%) patients who received biphasic isophane insulin preparation, 22 prescriptions consisted of combination with oral drugs. When compared to the reports of Acharya KG et al, insulin prescription was less in the present study.[13] Numerous studies have shown that a combination of insulin and sulfonylurea or metformin is more effective than insulin alone in the treatment of patients with Type II DM after secondary failure to oral drugs, leading to better glucose profiles and/or decreased insulin needs.[14,15]

Hypertension (n=96) was the most common comorbid disease. Amlodipine (53%) was most often used, followed by atenolol (26.5%). Majority of the hypertensive patients (72.64%) received combination of 2 or 3 antidiabetic drugs to achieve tight glycemic control. β-blockers are better avoided in diabetic patients, as they delay the recovery from hypoglycaemia due to insulin or oral antidiabetics. Even cardio-selective β-blockers such as metoprolol and atenolol are risky. ACE inhibitors and ARBs were prescribed to a lesser extent. Several randomised control trials have reported the beneficial effects of ACE inhibitors and ARBs on cardiovascular risk in hypertensive patients with Type II DM.[16-18]

Of 668 drugs prescribed, 510 drugs were antidiabetics. Average number of antidiabetic drugs per prescription was 1.73. This is similar to the findings of Maiti T et al.[19] Percentage of drugs prescribed by generic name was comparatively less. As per NLEM 2105, most of the drugs were prescribed from essential drug list (i.e., 80%).

CONCLUSION

Metformin was the most commonly prescribed antidiabetic drug. None of the prescriptions had thiazolidinediones, GLP-1 receptor agonists, DPP-4 inhibitors, SGLT-2 inhibitors; because of non-availability in Government hospital and physicians are bound to prescribe the drugs available in the hospital set-up. Utilization of glimepiride, gliclazide, newer oral antidiabetics and insulin preparations should be improved for better patient management. Among patients with cardiovascular risk factors, ACE inhibitors and ARBs are beneficial. Rationale FDCs of antidiabetic agents improves patient compliance. Overall, management of diabetic patients is rational but needs improvement.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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