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Research Article

Drug utilization study in patients with type 2 diabetes mellitus attending diabetes clinic of a tertiary care hospital in rural Bengal

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ABSTRACT

Background: Diabetes mellitus (DM) is a common and important health problem affecting the citizens of developed as well as developing nations. Not only does it require long term therapy, it is also crippling in terms of cost of management. Drug utilization studies help to determine rational drug use especially in poorer and rural populations. The objective of this study was to evaluate drug utilization pattern in type-2 diabetes patients in a diabetic clinic of a tertiary care teaching hospital in rural Bengal.

Methods: This was a prospective observational study including 181 patients for a period of 6 months in Bankura Sammilani Medical College. Patients diagnosed as type 2 diabetes mellitus were included in the study. The demographic data, disease data and utilization of different classes of oral hypoglycaemic agents and insulin as well as other individual drugs were analysed using the World Health Organization (WHO) indicators for drug utilization studies.

Results: The study population was predominantly male (61.33%) and nearly a third (30.9%) belonged to the age group of 50-59 years. Co-morbid conditions were found in 74% patients, among which hypertension (51.1%) was the most common co-morbid condition. The average number of drugs per prescription was 4.22 and the average number of antidiabetic drugs per prescription was 2.18. Metformin was the most commonly prescribed drug (79.6%), followed by sulfonylurea class of drugs (66.9%). Nearly 17.7% patients were on insulin preparations. Glimepiride and metformin was the most common combinations used (45.5%). Antibiotics were included in 15.5% prescriptions and proton pump inhibitors were prescribed in 32% cases. All the medicines were prescribed as generics and injections were prescribed in 17.7% cases.

Conclusions: This study gives a picture of the pattern of drug use among diabetes patients in our set up. While metformin was the commonest drug used, glimepiride and metformin combination was the commonest combination therapy.

Keywords: Diabetes mellitus, Drug utilization, Metformin

INTRODUCTION

The main aim of drug utilization research is to assess whether the drug treatment is rational or not. To reach this goal, methods of auditing drug therapy towards rationality are necessary.[1] History has taught us that successful research in drug utilization requires multidisciplinary collaboration between clinicians, clinical pharmacologists, pharmacists and epidemiologists.[1] The study of drug utilization is an evolving field. The use of large computerized databases that allow the linkage of dug utilization data to diagnosis is contributing to expansion of this area.[2]

Diabetes is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood

vessels.[3] According to International diabetes federation (IDF), 65.1 million of adults in India suffered from diabetes in the year 2013.[4] It has been predicted that the prevalence of diabetes in the adult population in India will be 6% by the year 2025.[5] Modern principles of management of diabetes focus on disease prevention, screening high risk individuals and aggressive treatment of individuals in the pre-diabetic state.[6-8]

As per American diabetes association (ADA) guidelines 2015, the treatment protocols for type 2 diabetes mellitus would be Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacological agent for type 2 Diabetes. If the A1c target is not achieved after approximately 3 months, consider a combination of metformin and one of these six treatment options: sulfonylureas, thiazolidinedione's, DPP-4 inhibitors, SGLT2 inhibitors, GLP-1 receptor agonists or basal insulin.[9]

In this pre-set we planned our study in a tertiary care teaching hospital where there was a separate clinic for diabetes patients but lack of adequate data on the drug utilization pattern of antidiabetic medicines. We tried to mend this informational gap.

METHODS

The objective of this study was to evaluate drug utilization in a diabetic clinic of a tertiary hospital. And to assess the number of antidiabetic drugs used per prescription. And to assess if the prescriptions are as per standard guidelines or not.

Study conducted was diabetes clinic of Bankura Sammilani Medical College, Bankura.

Inclusion criteria

All type 2 diabetes mellitus cases between the age group of 30 to 70 years, attending diabetes clinic of BSMC.

Exclusion criteria

- Type 1 DM
- Young diabetics below 30 years of age
- Gestational DM.

Methods of data collection

The study was conducted after obtaining ethical clearance from the institutional ethics committee of Bankura Sammilani Medical College, Bankura. Informed consent was taken from all study subjects fulfilling the criteria. Then data were collected from the OPD prescriptions and a brief interview of the individuals, which was conducted with the help of the pre-designed case report form. Within the study period, 6 months April 2014- September 2014 was allotted for data collection from the study subjects.

The design of this study was institution based longitudinal prospective observational unicentric study

A total of 181 prescriptions were randomly evaluated for prescribing pattern in type 2 diabetes mellitus patients using WHO drug indicators like drug class, dosage form, fixed dose combinations (FDCs), generic and branded drugs and drugs from NLEM 2011. DDD/1000 inhabitants/day was also calculated.

DDD/1000/day

The DDD/1000/day was calculated as follows,

$$DDD/1000\,inhabitant/day = \frac{\text{Total no. of dosage form units prescribed} \times \text{strength of each dosage unit}}{\text{DDD} \times \text{Duration of study} \times \text{total sample size}}$$

Statistical analysis

IBM SPSS version 22 (statistical package for social sciences Inc., USA) software package was used for data stratification and analysis. Descriptive statistics were used. Paired t-test was used wherever required.

RESULTS

Demographic details

Total 181 patients were included in this study.

Among them 111 (61.33%) patients were male and 70 (38.67%) were female. Male: female ratio was 1.58:1 (approx.).

Majority of the patients (30.9%) were in the age group of 50 to 59 (Figure 1). The mean age of the study population was found to be 52.50 years with a standard deviation of 9.949 years (Table 1).
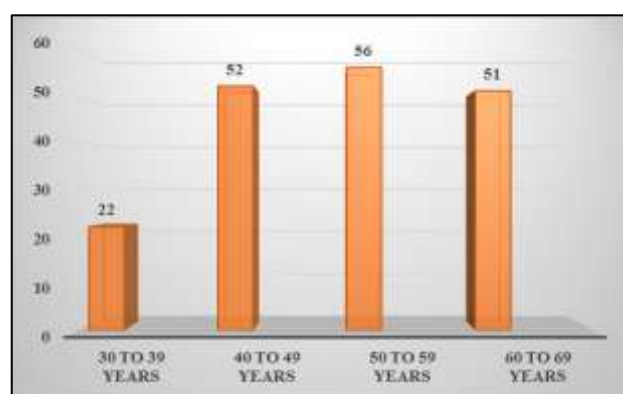

Figure 1: Age group wise distribution.

Almost half of the patients were found to be obese and 29.3% were overweight (Figure 2). As per Asia Pacific perspective for Asians (WHO IOTF 2003).[10]

Table 1: Demographic variables of study subjects.

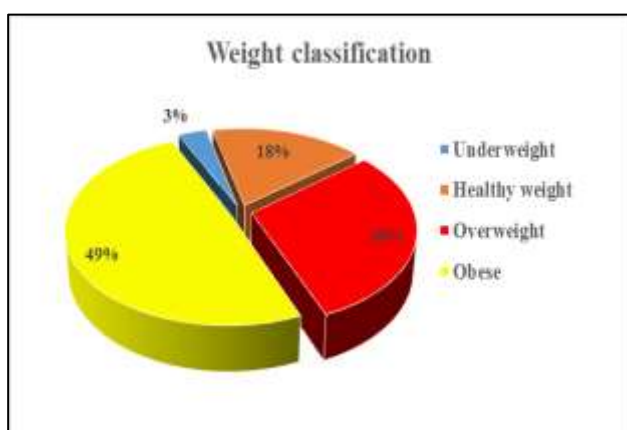| Parameters	Mean value	Standard deviation	Maximum	Minimum
Age in years	52.50	9.949	69	31
Height (cm)	162.39	5.847	185	150
Weight (kg)	65.10	8.875	90	42
BMI (kg/m^2)	24.62	2.59	30.49	17.48
Monthly family income (INR)	13230	7188	42000	1500

Figure 2: Distribution of study samples as per their BMI.

Significant comorbidities

Total 134 patients (74.0%) were suffering from associated comorbidities. Hypertension (50.8%) being the commonest comorbidity followed by dyslipidemia (24.3%), neuropathy (13.8%) coronary vascular diseases (10.5%) and nephropathy (3.9%) (Figure 3).
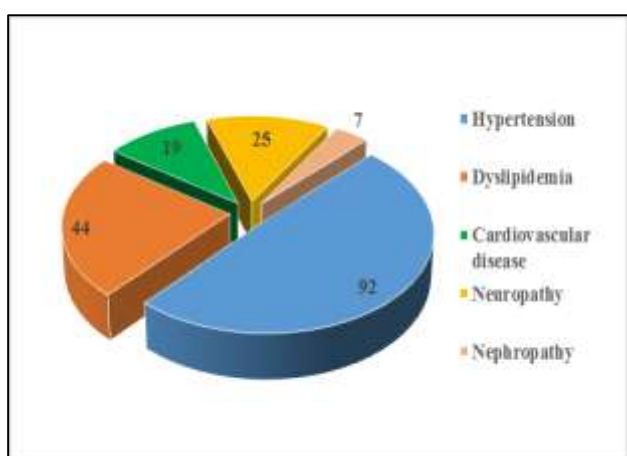

Figure 3: Chart of significant comorbidities.

Pattern of drug use

Antidiabetic drugs prescribed

In the overall utilization pattern, metformin (79.6%) was the most frequently prescribed oral hypoglycaemic agent followed by sulfonylureas (66.9%). Thiazolidinedione's (pioglitazone) were prescribed in 20.4% cases. DPP4 inhibitors and α glucosidase inhibitors were prescribed 16.6% cases only. Thus amongst the antidiabetic agents used the maximum percentage was of metformin, followed by sulfonylureas, insulin and thiazolidinedione's. α -Glucosidase inhibitors and DPP4 inhibitors were used to a much lesser extent (Figure 4).

Metformin was prescribed in different doses ranging from 500 mg to 2000 mg daily. Most commonly prescribed dose was 1000 mg daily (55.6%). Daily dose of 500 mg, 1.5 gm and 2 gm were prescribed to 37, 15 and 10 patients respectively out of 144 receivers (Figure 5).

Among sulfonylureas the commonest drug used was glimepiride (78.51%) and most frequently prescribed daily dose was 2 mg (Figure 6).

Insulin was prescribed in 32 (17.7 %) patients. Among them 7 patients got regular insulin and the rest of them were given premixed human insulin.
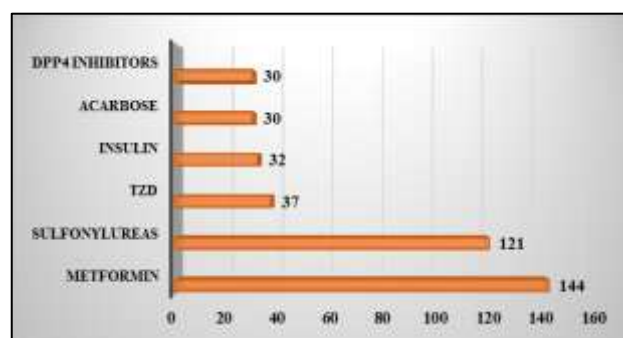

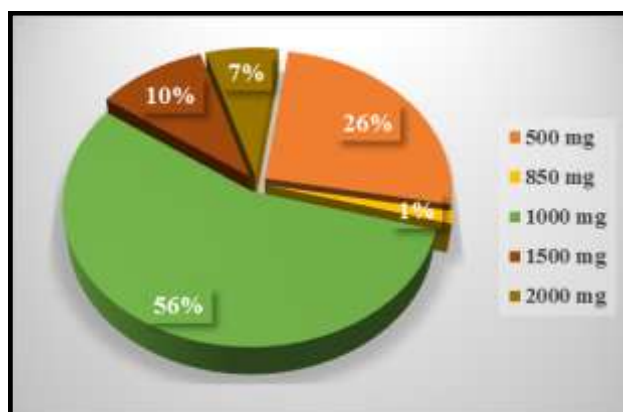**Figure 4: Pattern of antidiabetic drugs prescription.**

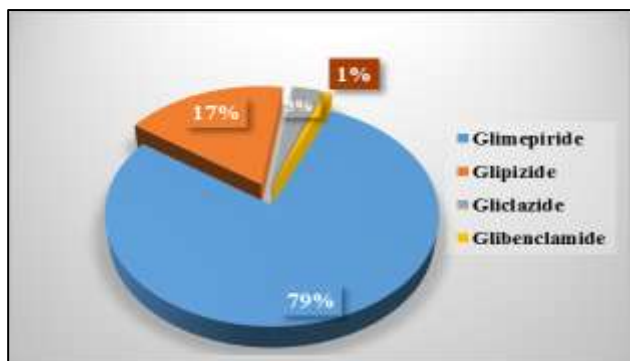**Figure 5: percentage of use of metformin in different doses (n=144).**

Figure 6: Percentage of use of different sulfonylureas. (n=121).

Distribution of antidiabetic therapy

Most of the patients received more than 1 antidiabetic drug. Monotherapy was given to 28 patients (15.5%) only. More than a half (55.87) of the study samples received 2 antidiabetic drugs and almost a quarter (24.3%) of all the subjects received 3 drug therapy. Very few (4.4%) have got 4 drug therapies (Figure 7).

Table 2: Prescription pattern of antidiabetic drugs based on combination therapy.

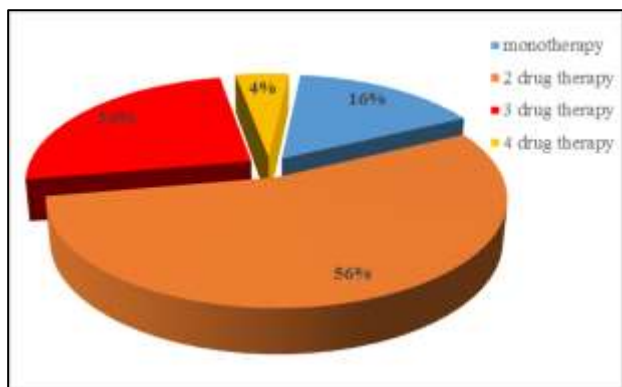| Two-drug combination therapy (n=101)	Frequency	Percentage
Metformin+glimepiride	46	45.54
Metformin+insulin	6	5.94
Metformin+glipizide	12	11.88
Metformin+voglibose	10	9.9
Metformin+pioglitazone	5	4.95
Three-drug combination therapy (n=44)		
Metformin+glimepiride+ pioglitazone	16	36.36
Metformin+glimepiride+ insulin	4	9.09
Metformin+glimepiride+ voglibose	4	9.09
Metformin+glipizide+pio glitazone	3	6.81

Figure 7: Distribution of antidiabetic therapy (n=181).

The most commonly prescribed two drug combination was metformin and glimepiride (45.54%). In three drug combinations, metformin glimepiride and pioglitazone were most frequently prescribed (36.36%) (Table 2).

Other drugs

Antihypertensive drugs were prescribed very commonly as hypertension was the most frequent associated comorbidity in the study samples. Among them angiotensin converting enzyme inhibitors/ angiotensin receptor blockers were given in 63 patients (34.80%) (Figure 8). Calcium channel blockers were given in 29 (16%) cases. Diuretics were prescribed in 19 cases (10.49%). Beta blockers were less frequently used, being only in 12 cases (6.62%).

Anticoagulants were prescribed to 33 patients (18.23%). Among them aspirin 75 mg was given most commonly (31 cases) and clopidogrel 75 mg was given only in 2 cases.

HMG-Co A reductase inhibitors were given in 95 patients (52.48%). Atorvastatin was given to 75 patients and rosuvastatin in 20 patients. For diabetic neuropathy, patients were prescribed cyclic GABA analogues. They were given to 25 patients (13.82%). Nitrates were given in 9 cases. Proton pump inhibitors were prescribed in 58 cases (32.04%). Among them pantoprazole was commonest (38 cases).

Antimicrobials were prescribed in 28 encounters only (15.47%). Antibiotics were given to patients who had some infections e.g. urinary tract infection, respiratory tract infection, etc. Azithromycin (21.42%) and levofloxacin (21.42%) was used most commonly among antibiotics (Figure 8).
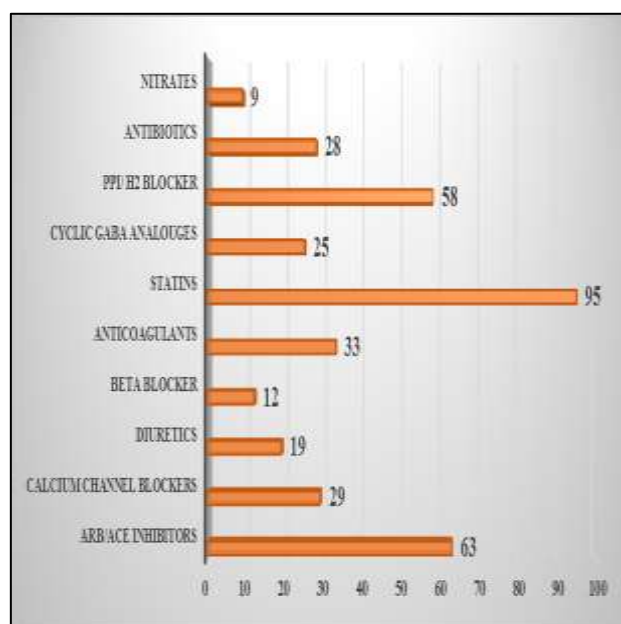

Figure 8: Pattern of other drugs prescription.

Core drug use indicators

Key prescribing indicators

- Average number of drugs per prescription (encounter) - 4.22
- Average number of antidiabetic drugs per prescription (encounter) - 2.18
- Percentage of drugs prescribed by generic name - 78.86%
- Percentage of encounters with an antibiotic prescribed - 15.47%
- Percentage of encounters with an injection prescribed - 17.7%
- Percentage of drugs prescribed from essential drugs list (NLEM 2011) - 42.31%
- Average drug cost per encounter - 13.50 INR.

Patient care indicators

- Average consulting time - 8.48 minutes
- Average dispensing time - 1.26 minutes
- Percentage of drugs actually dispensed - 85%
- Patient's knowledge of correct dosage - 69.06%.

Facility indicators

- Availability of copy of essential drug list or formulary - Yes
- Availability of key drugs - 90%.

While comparing the average daily dose of the drug with WHO/ATC defined daily dose, it was found that average daily doses of most of the antidiabetic drugs were less than their DDD. Gliclazide had higher average daily dose while that of linagliptin and saxagliptin was same as their DDD (Table 3).

Table 3: Difference between averages prescribed doses and defined daily doses of drugs for the treatment of type 2 diabetes mellitus.

Drugs	Average dose	DDD
Metformin (A10BA02	990.97 mg/day	2000 mg
Insulin (A10AC01)	32.09 IU/day	40 IU
Glimepiride (A10BB12)	1.50 mg/day	2 mg/day
Glipizide (A10BB07)	5.23 mg/day	10 mg/day
Gliclazide (A10BB09)	70 mg/day	60 mg/day
Glibenclamide (A10BB01)	5 mg/day	7 mg/day
Pioglitazone (A10BG03)	14 mg/day	30 mg/day
Acarbose (A10BF01)	37.5 mg/day	300 mg/day
Voglibose (A10BF03)	0.29 mg/day	NA
Vildagliptin (A10BH02)	50 mg/day	100 mg/day
Linagliptin (A10BH05)	5 mg/day	5 mg/day
Sitagliptin (A10BH01)	50 mg/day	100 mg/day
Saxagliptin (A10BH03)	5 mg/day	5 mg/day

Calculation of DDD/100 inhabitants/day

DDD/1000 inhabitants/day was calculated for antidiabetic drugs. It was not possible for voglibose as the DDD was not mentioned for this drug by WHO/ATC. It was found to be highest for glimepiride followed by metformin (Table 4).

Table 4: DDD/100 inhabitants/day of the antidiabetic drugs.

Antidiabetic drug	DDD/1000 inhabitants/day	Percentage
Glimepiride	502	38.14
Metformin	394	29.93
Insulin	142	10.79
Pioglitazone	95.3	7.24
Glipizide	60.77	4.62
Sitagliptin	38.67	2.94
Vildagliptin	35.91	2.73
Gliclazide	25.78	1.96
Linagliptin	11.05	0.84
Saxagliptin	5.52	0.42
Glibenclamide	3.94	0.30
Acarbose	1.38	0.11

Calculation of DU 90%

Consumption of all the antidiabetic drugs were calculated in terms of their DDDs and it was found that DU90% of the drugs comprised:

- Glimepiride
- Metformin
- Insulin
- Pioglitazone
- Glipizide.

(Ranked as per their consumptions during the study period in volumes of DDDs).

Index of adherence

As per ADA guidelines, metformin is preferred drug for the treatment of type 2 diabetes mellitus if there is no contraindication to use metformin. In our study metformin was prescribed to 79.6% patients. In contrast, glimepiride was found to be more utilized when we calculated the consumption in terms of their DDDs. There is underutilization of metformin in terms of DDD.

Adverse drug reactions

Adverse drug reactions were noted and recorded. Causality was assessed using WHO-UMC scale and severity was assessed using Hartwig-Siegel criteria. The adverse drug reactions that we had found during the study period were;

- Metformin induced GI upset in 5 patients. Glimepiride induced hypoglycemia in 3 patients, and rash in 2 patients. Voglibose induced flatulent dyspepsia in 5 patients
- Amlodipine induced pedal edema in 1 patient. ACE inhibitors induced dry cough in 3 patients. Beta blockers induced bradycardia in 2 patients
- Pregabalin induced dizziness in 2 patients.

No serious adverse event occurred during the study period.

DISCUSSION

In this study, the prevalence of diabetes was found to be more common among male population with a male: female ratio of 1.58:1. This is comparable with a similar previous study done by Rani J et al where they found the ratio to be 1.4:1.[11] Male preponderance was seen in other studies done in India, USA and other countries.[12-15]

In our study it was found that prevalence of type 2 diabetes was high in the middle aged persons, i.e. 40 to 60 years of age. The mean age of the study population was found to be 52.5 years. This was similar with few recent studies done in India and outside but is lower when compared to some other previous studies where the mean age was found to be around 60 years.[16-21] It may be attributed to the fact that type 2 DM is now-a-days affecting younger population compared to previous days.

Almost half of the patients were found to be obese and 29.3% were overweight. It clearly indicates the prevalence of type 2 diabetes in obese and overweight patients. The mean BMI of the study population was 24.62.

Most of the patients (74%) were suffering from other co-morbid conditions like hypertension (50.8% patients), dyslipidemia (24.3% patients), etc. the comorbidities played a major role on the disease burden and also it increases cost of therapy and deteriorates the quality of life.

Amongst antidiabetic medications, metformin was the most commonly prescribed drug which was given in 144 (79.6%) patients followed by sulphonylureas in 121 (66.9%) and pioglitazone in 37 (20.4%) patients. Similar utilization pattern was observed in another study by Vengurlekar S et al and Dhanaraja et al Most of the patients required two or more drugs to achieve glycemic control.[22,23] The most possible reason for this is that type 2 DM is a chronic disease with a progressive deterioration in glycemic control due to the continuing loss of β-cell function and hence forth. Monotherapy for type 2 diabetes may therefore not be sufficient to maintain glycemic control over time.[24]

The most commonly prescribed two drug combination was metformin and glimepiride (45.54%). Similar results were obtained in the studies done by Dutta S et al, Vengurlekar S et al and Patel B et al.[16,22,25]

In this study we have found that insulin was prescribed in 32 patients i.e. 17.7% of the total study sample. It is quite high when compared to a study done in Northern India by Dutta S et al, where the frequency of Insulin prescription was 1.80%.[16] This pattern is somehow similar to the pattern of Insulin use in a tertiary care hospital of western India, as highlighted by Dave DJ et al.[26]

The most commonly co-prescribed medications along with antidiabetic drugs were antihypertensive drugs which is similar with a study from India and Nigeria.[16,27] The high antihypertensive prescriptions reflect the high rate of co-morbidity of hypertension and diabetes.

The total number of drugs prescribed per prescription was 4.22, which was similar when compared to a study done by Dutta S et al, where average number of drugs per prescription was 3.98, but is less if compared to the studies by Kumar MA et al and Patel B et al, where 6.51 and 7.58 drugs were prescribed per prescription respectively.[16,28,25] Drugs were prescribed by their respective generic names in 78.86% times. This was higher compared to similar studies. This indicated the increase in the trend of prescribing generic drugs. A low percentage of injection utilization from this study was observed because we had taken only type-2 diabetes patients attending diabetic clinic which is an outpatient department. The only prescribed injection was insulin. This finding was in accordance with a study done in western part of India.[25]

DDD/100 inhabitants/day was calculated for the antidiabetic drugs prescribed and it was found to be highest for glimepiride followed by metformin. DU 90% comprised of glimepiride, metformin, insulin, pioglitazone and glipizide.

Cost of prescription is important in chronic diseases like diabetes. In this study, average prescription cost per day was INR 13.50, which was less than the other studies by Kannan et al and Dutta S.[16, 29] The reduced cost may be due to prescribing medicines by generic names and less number of medications per prescription.

The other area which needed attention was patient education and knowledge. 30.94% of patients lacked adequate knowledge of dosage schedule, possibly due to communication error. Pharmacists can be urged to spend more time with dispensing since at the moment only 1.26 minutes were spent for each encounter. This simple measure would probably help patients understand their dosage schedule better.

The overall prescribing practice was found to be rational and good compared to other parts of India, but there are many scopes to improve.

The limitations of this study was all studies, ours too had some limitations. Some of the notable limitations of our study included -

- Sample size of our study was small
- The study was done in a very short period. Further long term studies can be done to attain more reproducible data
- The study was based on OPD only. It can be done in inpatients department in future to know utilization of antidiabetic drugs in admitted patients
- As it is a unicentric study, utilization pattern from others centers treating diabetes could not be obtained.

CONCLUSION

This study showed that type 2 DM is more prevalent in men than in women, obese and overweight patients are at higher risk. Type 2 DM is not confined to urban population or the upper class of the society. The study had shown metformin as the most commonly prescribed oral antidiabetic drug both in monotherapy or combination therapy, but still there was underutilization of this drug. Newer antidiabetic drugs were prescribed less frequently. Adherence of the prescriptions to the recent ADA guideline was found to be good, but it could have been better with a higher prescription of metformin. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy. Patient care indicators were found to be good as the average patient consulting time was adequate and most of the drugs were dispensed. But many patients did not have adequate knowledge about correct dosage. From our study we can conclude that most of the prescriptions were rational, but further improvement in prescribing practices is necessary.

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