

Drug Utilization Study in Type 2 Diabetic Patients Attending Clinic of Tertiary Care Hospital Rajasthan

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Received: 25-08-2022 / Revised: 25-09-2022 / Accepted: 30-10-2022

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Conflict of interest: Nil

Abstract

Background: Diabetes has gradually emerged as one of the most serious public health problems in our country. To focus and manage effectively, the illumination of current knowledge about the pattern of anti-diabetic drug utilization is important. As a result, it is necessary to evaluate the pattern of anti-diabetic medication use among diabetes patients determine if there is room for improvement in light of current knowledge.

Aim: To evaluate the drug utilization pattern of oral anti-diabetic drugs in type 2 diabetic patients in a tertiary care hospital.

Materials and Methods: Observational cross sectional study conducted in Department of Pharmacology in association with Department of Endocrinology of Maharana Bhupal Hospital Udaipur, 300 patients were included. Patients with type 2 DM and age above 25 years were included in this study.

Results: Maximum patients (116, 38.7%) received 3 antidiabetic drugs while 30.0% patients received 2. 70.42% of patients who had more than 5 years of duration of diabetes have taken 3 or more different drugs while 57.59% of patients with less than 5 years of duration of diabetes taken 3 or more drugs. Among the antidiabetic, Biguanides were the most commonly prescribed drugs followed by Sulphonylureas. PDD: DDD ratio was ranged between 0.314-2.13 with Gliclazide having maximum ratio (2.13) followed by Glimepiride (1.695)

Conclusion: Metformin was most commonly prescribed antidiabetic drug followed by Glimepiride, majority of patients had taken 3 antidiabetic drug combination.

Keywords: Drug utilization study, Antidiabetics, Multiple drug therapy, Utilization pattern

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Introduction

World Health Organization (WHO) defines Drug Utilization study as marketing, distribution, prescription and use of drugs in a society, with special

emphasis on the resulting medical, social, and economic consequences. [1]

In medical practice drug utilization studies provide powerful, exploratory tools to

ascertain role of drugs. Such studies lay emphasis on the various determinants encompassing the prescribing, dispensing, administering, and related events, including medical as well as nonmedical aspects of drug utilization, its varied effects and consequences on drug use, beneficial or adverse effects [2,3]

Organising regular studies of pattern of drug utilization in various hospital settings or patient population is therefore important and crucial to critically analyse the recent hospital drug policies and to recommend various guidelines for benefit and improvement of current drug usage pattern observed for future times, if required. It is of utmost importance in a developing and resource poor country like India. This will ensure optimum and appropriate utilization of available scarce resources. [4,5]

Diabetes mellitus (DM) is a chronic disorder emerging as major health problem which increases the rate of morbidity and mortality. It is a syndrome characterised by abnormal carbohydrate, protein and lipid metabolism [6]. In 2020 according to the international diabetes federation (IDF) 463 million people have diabetes in the world and by 2045 this will rise to 700 million. In India 77 million people are living with diabetes and by 2045 this will rise to 134 million [7]. As this demographic group expands, the disease burden increases as well, Proper evaluation of their problems, correct diagnosis, and suitable treatment are the key factors in reducing this disease burden. This aids in the improvement in the patients' quality of life, which is extremely important. Without knowledge of how drugs are being prescribed and used, it is difficult to suggest measures to change prescribing habits for the better. [8] It, therefore, becomes important to assess the pattern of the usage of anti-diabetic drugs among the diabetic patients. In this pre-set we planned our study in a tertiary care teaching hospital due to lack of adequate data on the drug utilization pattern of

antidiabetic medicines. We tried to mend this informational gap. The present study has been carried out to evaluate the drug utilization pattern of oral anti-diabetic drugs in type 2 diabetic patients in a tertiary care hospital. Such information would help in Improving the quality of health care provided and to facilitate the rational use of drugs in population.

Materials and Methods

The present study was a observational cross sectional study conducted by Department of Pharmacology in association with Department of Endocrinology of Maharana Bhupal Hospital Udaipur, Rajasthan conducted for a period of 6 months from July 2019 to December 2019 and data of 300 patients were included.. An appropriate study protocol and Performa were developed. The study protocol, performa and other documents like informed consent was taken. Patients with type 2 DM and age above 25 years were included in this study. while Age < 25 years, DM type 1, pregnant and lactating mothers were excluded from this study. Statistical tools like frequencies, means, SD, percentages were applied regarding average number of oral antidiabetic medicines prescribed per prescription, relationship between patient demographics and prescription patterns: indicators for which antidiabetics were prescribed, percentage usage of various oral anti-diabetics, dosage forms, FDC, polypharmacy etc. Measurement of drug utilization using ATC/DDD metric system was done.

Results

Total 300 patients were included in this study. Mean age of the patients was 57.06 ± 1.10 years. Out of 300 patients, 109 (36.3%) were male and 191 (63.7%) were female. Maximum patients 129 (43.0%) belonged to the age group of 46-60 years followed by 119 (39.7%) in > 60 years and 50 (16.7%) in 31-45 years. out of 300 patients 40.66% patients had a Diabetic

history of 2-5 years, 31.33% patients had a Diabetic history of 6-10 years and 16%

patients had a Diabetic history of more than 10 years.

Table 1: Age and sex distribution

Age (years)	Male	Female	Total (%)
12-30	0 (0%)	2 (0.7%)	2 (0.7%)
31-45	14 (4.7%)	36 (12.0%)	50 (16.7%)
46-60	49 (16.3%)	80 (26.7%)	129 (43.0%)
>60	46 (15.3%)	73 (24.3%)	119 (39.7%)
Total	109 (36.3%)	191 (63.7%)	300 (100%)

With DM 2 53.3% were suffering from concurrent hypertension followed by concurrent dyslipidemia (42.7%). Other commonly associated conditions were CAD (11.3%), Hypothyroidism (6.0%), BPH (2.7%), Depression (2.7%), CVA infarct (2%), Gout (1.3%) and Osteoarthritis (0.7%).

In present study 75 (25%) patients were suffering from Diabetic Neuropathy. Other present complications were diabetic retinopathy, fungal infection, diabetic nephropathy and diabetic foot. In this study about 62.66 % per cent of patients had BMI more than normal and around 12 per cent were obese or morbidly obese.

Table 2: Distribution pattern of BMI

Class	BMI (kg/m ²)	No. of patients (N=300)
Underweight	<18.5	0 (0%)
Normal weight	18.5-24.9	112 (37.3%)
Overweight	25-29.9	152 (50.7%)
Obesity (Class I)	30-34.9	28 (9.3%)
Obesity (Class II)	35-39.9	7 (2.3%)
Extreme obesity (Class III)	≥40	1 (0.3%)

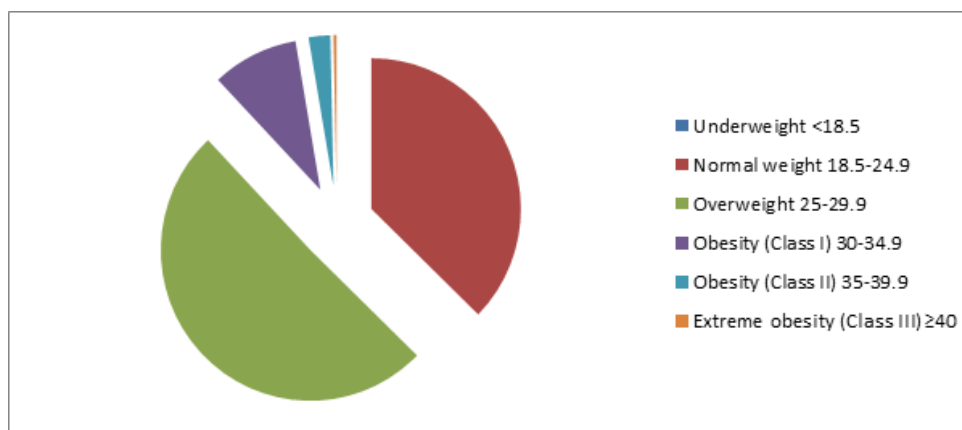


Figure 1: Distribution pattern of BMI

Table 3: Average number of antidiabetics and total drugs per encounter

Total no. of encounters	Total and avg no. of antidiabetic drugs prescribed	Total and avg no. of drugs prescribed
300	856	2188
	2.85±0.99	7.29±2.94

The average number of antidiabetic drugs per encounter was 2.85 in present study with range of 1 to 5 while average number of total drugs per encounter was 7.29 with range of 1 to 18 and 98% patients were receiving 3 or more drugs.

Table 4: Total number of antidiabetic drugs prescribed per encounter

No. of drugs	Total no. of patients (%)
0	2 (0.7%)
1	17 (5.7%)
2	90 (30.0%)
3	116 (38.7%)
4	60 (20.0%)
5	15 (5.0%)

Maximum patients (116, 38.7%) received 3 antidiabetic drugs while 30.0% patients received 2, 20% receive 4 followed by 5.7% received 1, 5% received 5 antidiabetic drugs.

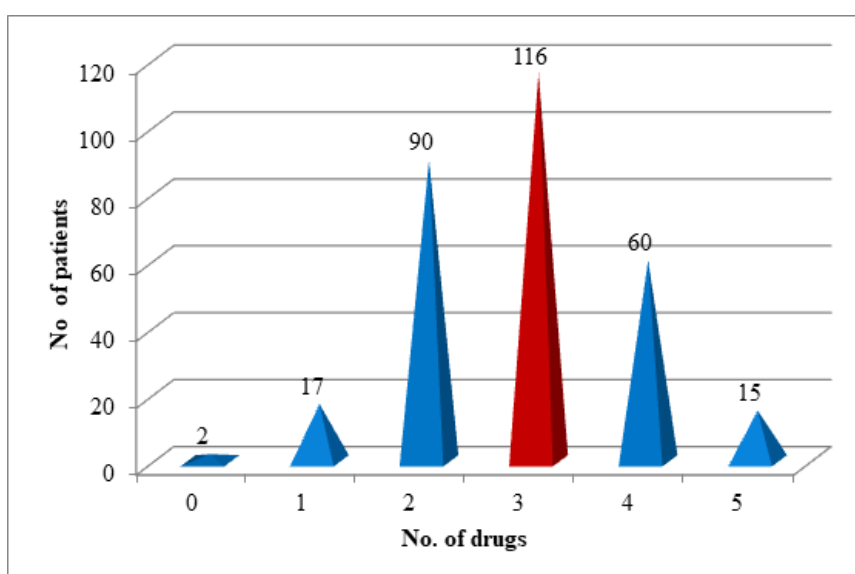


Figure 2: Total number of antidiabetic drugs prescribed per encounter

Table 5. Duration of diabetes and total number of ADA prescribed per encounter

Duration	No. of drugs	No. of patients
<2 years	0	2 (0.7%)
	1	2 (0.7%)
	2	18 (6.0%)
	3	12 (4.0%)
	4	2 (0.7%)
	5	0 (0%)
2-5 years	0	0 (0%)
	1	9 (3.0%)
	2	36 (12.0%)
	3	47 (15.7%)
	4	22 (7.3%)
	5	8 (2.7%)
6-10 years	0	0 (0%)
	1	6 (2.0%)
	2	26 (8.7%)

	3	37 (12.3%)
	4	18 (6.0%)
	5	7 (2.3%)
>10 years	0	0 (0%)
	1	0 (0%)
	2	10 (3.3%)
	3	20 (6.7%)
	4	18 (6.0%)
	5	0 (0%)

In this study 70.42%% of patients who had more than 5 years of duration of diabetes have taken 3 or more different drugs as compared to 57.59% of patients who had less than 5 years of duration of diabetes have taken 3 or more drugs.

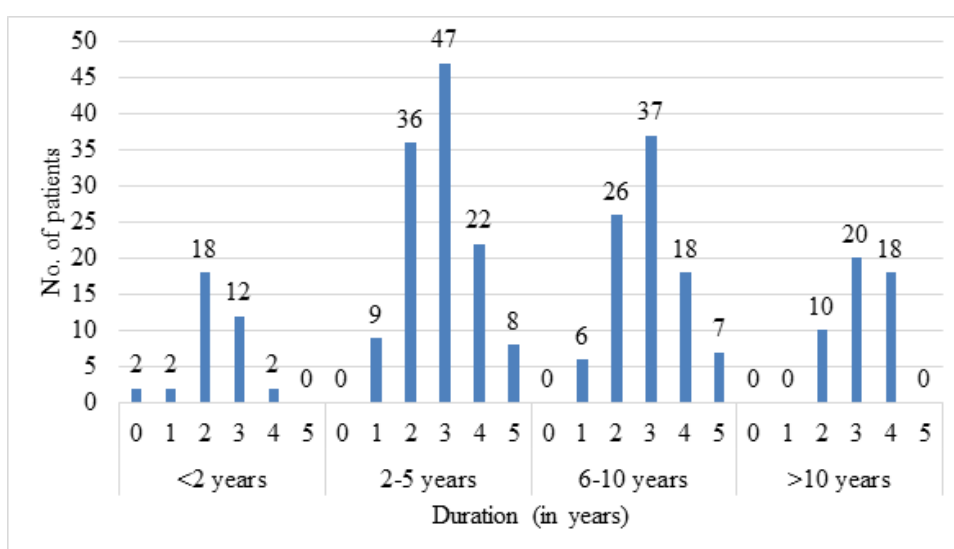


Figure 3: Duration of diabetes and total number of ADA prescribed per encounter

Table 6. Commonly used drug groups in study subjects

Drugs	No. of patients (%)
Antidiabetic drugs:	
Biguanides (Metformin)	292 (97.3%)
Sulphonylureas	267 (89.0%)
Glimepiride	202 (67.3%)
Glipizide	28 (9.3%)
Gliclazide	20 (6.7%)
Glibenclamide	17 (5.7%)
Insulin	50 (16.7%)
Thiazolidinediones (Pioglitazone)	37 (12.3%)
Alpha-glucosidase inhibitors	48 (16.0%)
Voglibose	30 (10.0%)
Acarbose	18 (6.0%)
DPP-4 inhibitors	166 (55.3%)
Teneligliptin	156 (52.0%)
Sitagliptin	6 (2.0%)
Vildagliptin	4 (1.3%)

Among the antidiabetic, Biguanides were the most commonly prescribed drugs followed by Sulphonylureas, DPP-4 Inhibitors, Insulin, Alpha-glucosidase inhibitors and Thiazolidinediones.

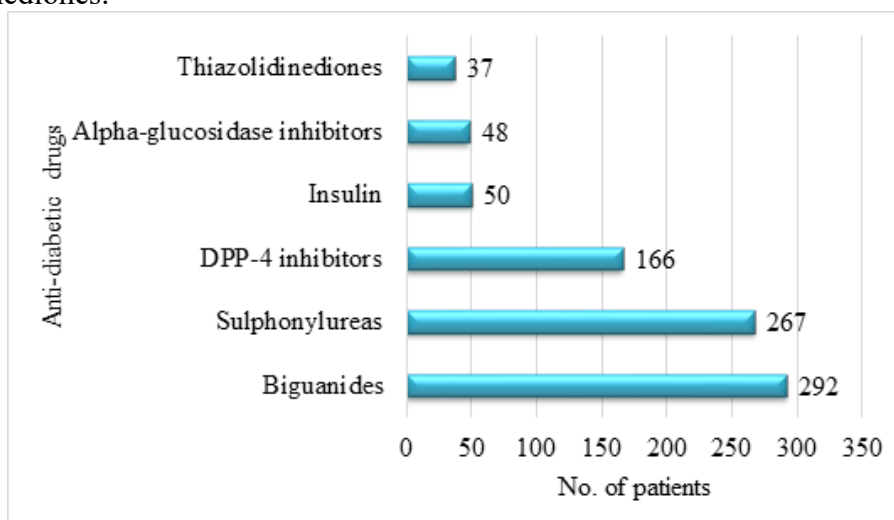


Figure 4: Commonly used anti-diabetic drug groups in study subjects

Table 7: Utilization pattern of different antidiabetic drugs

Drugs	No. of patients (%)
SINGLE DRUG	17 (5.7%)
Metformin	13 (4.3%)
Glipizide	2 (0.7%)
Insulin	2 (0.7%)
TWO DRUG COMBINATION	90 (30.0%)
Metformin + Glimepiride	56 (18.7%)
Metformin + Glipizide	12 (4.0%)
Metformin + Teneligliptin	10 (3.3%)
Metformin + Glibenclamide	4 (1.3%)
Metformin + Glicazide	4 (1.3%)
Metformin + Insulin	4 (1.3%)
THREE DRUGS COMBINATION	116 (38.7%)
Metformin + Glimepiride + Teneligliptin	63 (21.0%)
Metformin + Glimepiride + Pioglitazone	12 (4.0%)
Metformin + Gliclazide + Teneligliptin	10 (3.3%)
Metformin + Glipizide + Teneligliptin	8 (2.7%)
Metformin + Glimepiride + Insulin	5 (1.7%)
Metformin + Glimepiride + Voglibose	4 (1.3%)
Metformin + Glibenclamide + Teneligliptin	2 (0.7%)
Metformin + Glimepiride + Acarbose	2 (0.7%)
Metformin + Glibenclamide + Voglibose	2 (0.7%)
Metformin + Glipizide + Pioglitazone	2 (0.7%)
Insulin + Acarbose + Teneligliptin	2 (0.7%)
Metformin + Gliclazide + Voglibose	2 (0.7%)
Metformin + Voglibose + Teneligliptin	2 (0.7%)
FOUR DRUGS COMBINATION	60
Glimepiride + Metformin + Teneligliptin + Insulin	16 (5.3%)
Glimepiride + Metformin + Pioglitazone + Teneligliptin	12 (4.0%)

Glimepiride + Metformin + Voglibose + Teneigliptin	8 (2.7%)
Glimepiride + Metformin + Voglibose + Sitagliptin	4 (1.3%)
Glimepiride + Metformin + Acarbose + Teneigliptin	4 (1.3%)
Glimepiride + Metformin + Pioglitazone + Voglibose	2 (0.7%)
Glimepiride + Metformin + Pioglitazone + Sitagliptin	2 (0.7%)
Glimepiride + Metformin + Acarbose + Teneigliptin	2 (0.7%)
Glipizide + Metformin + Teneigliptin + Insulin	2 (0.7%)
Gliclazide + Metformin + Insulin + Teneigliptin	2 (0.7%)
Gliclazide + Metformin + Insulin + Acarbose	2 (0.7%)
Glimepiride + Metformin + Insulin + Voglibose	2 (0.7%)
Glimepiride + Metformin + Insulin + Vildagliptin	2 (0.7%)
FIVE DRUGS COMBINATION	15 (5.0%)
Insulin + Metformin + Glibenclamide + Pioglitazone	5 (1.7%)
Insulin + Metformin + Glimepiride + Acarbose	4 (1.3%)
Insulin + Metformin + Glipizide + Teneigliptin	2 (0.7%)
Metformin + Glimepiride + Voglibose + Pioglitazone	2 (0.7%)
Metformin + Glimepiride + Voglibose + Acarbose	2 (0.7%)

The present study observed that multiple drug (93.66%) therapy was more common than single drug therapy (5.66%). In this study, 38.66% of the patients had received 3 antidiabetic drugs, followed by 2 drugs (30%), 4 drugs (20%) and 5 drugs (5%).

Present study found Metformin + Glimepilide (18.7%) was the most commonly prescribed combination of two antidiabetic agents, followed by Metformin + Glipizide (4%) and Metformin + Teneigliptin (3.3%). This

study found Metformin + Glimepilide + Teneigliptin (21%) as most commonly prescribed three drug combinations followed by Metformin + Glimepilide + Pioglitazone (4%), Metformin + Gliclazide + Teneigliptin (3.3%), Metformin + Glipizide + Teneigliptin (2.7%). In four drugs combination Glimepiride + Metformin + Teneigliptin + Insulin (5.3%) was the commonly used combination .

Table 8: ATC, PDD and DDD of antidiabetic drugs

Drug	ATC code	PDD	DDD	PDD : DDD ratio
Insulin	A10AD30	29.04 IU	40 IU	0.726
Metformin	A10BA02	1.23 gm	2 gm	0.618
Glibenclamide	A10BB01	10 mg	10 mg	1
Glimepiride	A10BB12	3.39 mg	2 mg	1.695
Glipizide	A10BB07	7.14 mg	10 mg	0.714
Gliclazide	A10BB09	128 mg	60 mg	2.13
Pioglitazone	A10BG03	24.72 mg	30 mg	0.824
Acarbose	A10BF01	94.44 mg	300 mg	0.314
Voglibose	A10BF03	0.6 mg	0.6 mg	1
Vildagliptin	A10BH02	100 mg	100 mg	1
Sitagliptin	A10BH01	100 mg	100 mg	1

In present study prescribed daily dose of Insulin (29.04 IU), Metformin (1.23 gm), Glibenclamide (10 mg), Glimepiride (3.39 mg), Glipizide (7.14 mg), Gliclazide (128 mg), Pioglitazone (24.72mg), Acarbose

(94.44 mg), Voglibose (0.6mg), Vildagliptin (100mg) and Sitagliptin (100mg) was observed. PDD: DDD ratio was ranged between 0.314-2.13 with Gliclazide having maximum ratio (2.13)

followed by Glimepiride (1.695), Glibenclamide (1), Voglibose (1), Vildagliptin (1), Sitagliptin (1), Pioglitazone (0.824), Insulin (0.726), Glipizide (0.714), Metformin (0.618) and Acarbose (0.314).

Discussion

Diabetes is a chronic disease requiring lifelong treatment. Although lifestyle modifications play an important role in diabetes management, drugs become unavoidable in many patients. This study analyzed the prescription pattern in diabetic patients attending the diabetic clinic of a tertiary care hospital.

In this study 300 patients were included out of them 191 (63.66%) were female and 109 (36.33%) were male. Females shows higher prevalence of DM 2 in comparison to male. These finding were correlates with study conducted by M Ashok Kumar et al [9] and P Das et al [10]. Most common age group involved in our study was 46-60 years (43%) followed by >60 years (39.66%) & 31-45 years (16.66%). Study by M Ashok Kumar et al also found most common age group 41-60 years (55.63%), followed by 61-80 years (28.87%). [9] Mean age in our study was 57.06 ± 1.10 years. Study by Patel KP et al has found mean age in study subject 56.8 ± 10.5 years. [11] In present study, 40.66% patients had a diabetic history of 2-5 years, 31.33% patients had history of 6-10 years and 16% patients more than 10 years. Mean duration of diabetes in this study was $6.78 + 4.29$ years. Patients with chronic diseases like diabetes usually suffer from other associated conditions. [10] In present study, In our study we found most common morbidity (53.33%) was concurrent Hypertension. Other commonly associated conditions were Dyslipidaemia (42.66%), Hypothyroidism (11.33%), CAD (6%). Similar study by Abdul Gafar et al found hypertension (43.9%) as the most frequent co-morbidity. [12] In patients with longer duration of diabetes, chances of complications are

high. So, tight glycaemic control is needed. Obesity is a well-recognised risk factor for type 2 diabetes and increase in diabetes incidence is associated with increased risk for morbidity and mortality. [13] In present study, about 63% patients had BMI more than normal and around 12% were obese or morbidly obese. Similar study conducted by Mandal S et al [14] found almost half of the patients were obese and 29.3% were overweight.

In present study, the average number of antidiabetic drugs per encounter was 2.86 ± 0.99 with range of 0 to 5. Similar study by Acharya KG et al in 2012 has reported 2.18 ± 0.96 drugs per encounter [15]. The observed difference might be because of different demographic profile of study population, different prescribing practices and availability of drugs. Diabetes is associated with various concurrent diseases and its complications so polypharmacy is quite prevalent. [16] Diabetes is a progressive disease. As the disease progresses, it is difficult to control the blood sugar and this requires combination of drugs. In this study, the number of drugs prescribed to patients is more for those who had longer duration of diabetes. In this study 70.42% of patients who had more than 5 years of duration of diabetes have taken 3 or more different drugs as compared to 57.59% of patients who had less than 5 years of duration of diabetes have taken 3 or more drugs. Among the antidiabetics, we found Biguanides were the most commonly prescribed drugs followed by Sulphonylureas and DPP-4 Inhibitors. [17]

Metformin was the commonest drug prescribed (97.33%) followed by Glimepiride (67.33%), Teneligliptin (52%), Insulin (16.66%), Pioglitazone (12.33%), Voglibose (10%), Glipizide (9.33%), Gliclazide (6.66%), Acarbose (6%), Glibenclamide (5.66%), Sitagliptin (2%) and Vildagliptin (1.33%). Majority of the drugs were prescribed in oral dosage form. These results comply with study

done by Patel KP et al [11] & Gholamreza Yusefzadeh et al. [16] A contrast study by ashok kumar et al reported Sulfonylureas as the most common drug class followed by Insulin. [9] This difference may be due to physician's choice with relation to type of patients, their concurrent illness, as well as the availability of medicines. The present study observed that multiple drug (93.66%) therapy was more common than single drug therapy (5.66%). In this study, 38.66% of the patients had received 3 antidiabetic drugs, followed by 2 drugs (30%), 4 drugs (20%) and 5 drugs (5%). In study by Patel KP reported monotherapy (81.58%) as most commonly prescribed pattern followed by two (65.78%) and three drug (7.02%) regimen. [11] Present study found Metformin + Glimepiride (18.7%) was the most commonly prescribed combination of two antidiabetic agents, followed by Metformin + Glipizide (4%) and Metformin + Teneligliptin (3.3%). Patel KP et al also found Metformin + Glimepiride (50%) was the most commonly prescribed combination of two antidiabetic agents followed by Metformin + Voglibose (7.02%). [11]

In this study we found Metformin + Glimepiride + Teneligliptin (21%) as most commonly prescribed three drug combinations followed by Metformin + Glimepiride + Pioglitazone (4%), Metformin + Gliclazide + Teneligliptin (3.3%), Metformin + Glipizide + Teneligliptin (2.7%). Jimoh AO et al found Metformin + Glibenclamide + Pioglitazone (10.6%) as most commonly prescribed three drug combinations followed by Insulin + Metformin + Glibenclamide (5.2%). [12] Patel KP et al found Metformin + Glimepiride + Pioglitazone (7.02%) as most commonly prescribed three drug combinations. [11] Glimepiride + Metformin + Teneligliptin + Insulin (5.3%) was the most common four drug combination followed by Glimepiride + Metformin + Pioglitazone + Teneligliptin (4%). While in five drugs

combination Insulin + Metformin + Glibenclamide + Pioglitazone (1.7%) was the most commonly used combination.

In this study 60 drugs used out of them 26 (43.33%) drugs were prescribed from WHO model list of essential medicines, 2019 and 32 (53.33%) drugs were prescribed from National list of essential medicines of India, 2015. Study by Patel KP et al found 22.45% drugs prescribed from WHO model list while 45.49% drugs from National list of essential medicines. [11] Use of drugs from the essential drug list should be promoted for optimal use of limited financial resources, to have acceptable safety and to satisfy the health needs of the majority of the population.

In present study prescribed daily dose of Insulin (29.04 IU), Metformin (1.23 gm), Glibenclamide (10 mg), Glimepiride (3.39 mg), Glipizide (7.14 mg), Gliclazide (128 mg), Pioglitazone (24.72mg), Acarbose (94.44 mg), Voglibose (0.6mg), Vildagliptin (100mg) and Sitagliptin (100mg) was observed. PDD: DDD ratio was ranged between 0.314-2.13 with Gliclazide having maximum ratio (2.13) followed by Glimepiride (1.695), Glibenclamide (1), Voglibose (1), Vildagliptin (1), Sitagliptin (1), Pioglitazone (0.824), Insulin (0.726), Glipizide (0.714), Metformin (0.618) and Acarbose (0.314). It denotes that PDD:DDD for Glibenclamide (1), Voglibose (1), Vildagliptin (1), Sitagliptin (1) indicative of appropriate utilization pattern of these drugs. While PDD:DDD ratio of Gliclazide (2.13) and Glimepiride (1.695) suggest overutilization of this antidiabetic drugs. Predicting that the PDD:DDD ratio depends on patient related factors-irrespective of indication or severity of the disease or sociodemographic factors like age or gender-the ratio should not change with a change of the drug. However, factors such as the severity of the Diabetes or the doctor's dissatisfaction with the efficacy of a drug may lead to a change of drugs or

change of dose-seem to be responsible for alteration of PDD:DDD ratio.

Conclusion

Studies on utilization pattern of antidiabetic drugs appear to be lacking in this part of the country. Thus, this study provided a baseline data regarding the prescribing pattern in diabetic patients that showed overall prescribing pattern of ADA is rational as per guideline. This study has provided a scope for further research in this area.

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