

Drug Utilization Evaluation of Antidiabetic Drugs in a Tertiary Care Teaching Hospital: Analysis from a Randomized Controlled Study

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ABSTRACT

Background: Diabetes Mellitus (DM) is a chronic metabolic condition characterized by high blood glucose levels and changes in carbohydrate, lipid and protein metabolism due to insulin secretion, action, or both.¹ Diabetes affects 537 million persons worldwide in 2021 and its management and selection of antidiabetic drugs is a major health concern. **Objectives:** The study was aimed to evaluate the prescription pattern of antidiabetic drugs in a tertiary care hospital in Hubballi, Karnataka. **Materials and Methods:** It was a Prospective randomized controlled study where the participants were randomized into two groups i.e., the interventional or study group and control group. **Results:** Of the 300 diabetic patients, 150 were included in the control group and another 150 in the observational group in which 218 (72.6%) were males and 82 (27.3%) were females. Males were higher than females. The maximum number of patients were in the age group of 61-70 years, followed by 51-60 years. 175 (58.33%) subjects were taking two medications followed by 82 (27.33%) were receiving three medications. 152 (50.66%) were receiving diabetic medications two times in a day followed 122 (40.66%) were taking once in a day. Out of 300 Patients, 205 (68.33%) patients were prescribed insulin, of which regular insulin was the highest. **Conclusion:** It was found that metformin and insulin use is greater with higher use among middle-age patients. Regular insulin was the most often used insulin.

Keywords: Antidiabetic drugs, Diabetes mellitus, Drug utilization evaluation, Randomized controlled study, Tertiary care hospital.

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INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic condition characterized by high blood glucose levels and changes in carbohydrate, lipid, and protein metabolism due to reduced insulin secretion, action, or both.¹ It is the most common endocrine illness that is widely regarded as the most serious public health issue and concern to human health, impacting people in both developed and developing countries. This chronic illness can have a consequence on almost every system in the human body, resulting in long-term macro and microvascular complications.²

Global prevalence of DM is expected to increase by 5.4% and in India alone around 57.2 million population are expected to be diabetic by year 2025.³ Over the time DM may leads to serious

health complications of heart, blood vessels, eyes, kidneys and nerves thus emphasizing the need of diagnosis, treatment, management and prevention. World Health Organization (WHO) has been putting efforts globally to prevent risk and provide equitable, comprehensive and affordable care to ensure quality treatment.⁴ Several standardised guidelines have been proposed by American Diabetes Association and Indian Council of Medical Research for effective care and management Diabetes. Diabetes management either by insulin⁵ or non-insulin⁶ therapies have seriously associated comorbidities namely hypoglycemia, weight gain etc. necessitating the need for safer long term treatment modalities.⁷ Additional burden of polypharmacy and physicians incompetency to distinguish appropriate and inappropriate has been leading to adverse health outcomes in DM patients.⁸ Considering the chronic nature of diabetes management and long-term treatment regimen, there is need to assess the class of antidiabetic drugs, their utilization, prescription pattern, drug regimens and adherence to WHO prescribing core indicators. Therefore the proposed study emphasizes on evaluation of utilization of Antidiabetic medications in DM patients.



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MATERIALS AND METHODS

Study designed was a Prospective randomized controlled study where the participants were randomized into two groups i.e., the interventional or study group and control group. The study was conducted at a Vivekananda General Hospital, Hubballi, Karnataka. The target population for the study included patients diagnosed with DM. Population with DM, aged above 18 years who visited the general medicine ward outpatient and inpatient department during the study period were enrolled into the study. A total of 300 subjects divided into two groups of 150 each were considered for study. Data obtained from this study were grouped and analysed by tables using Statistical Package for Social Sciences (SPSS) version 21.0.

The data collected were analyzed using modified WHO prescribing core indicators core and WHO ATC Code as mentioned. The prescribing indicators that were measured included 1. Average number of drugs per encounter = Total number of drugs prescribed / total number of encounters 2. Percentage of drugs prescribed by generic name = (Number of drugs prescribed by generic name / Total number of drugs prescribed) x100 3. Percentage of encounter with antibiotics prescribed = (Number of patients encounters with antibiotics / Total number of drugs prescribed) x100 4. Percentage of encounters with injectable drug prescribed = (Number of patients encounters with injections / Total number of drugs prescribed) x100 5. Percentage of drugs prescribed from NLEM = Number of drugs prescribed from NLEM/ Total number of drugs prescribed) x 100.⁷

Randomization

Computer generated simple randomization was employed, while SNOSE method was used to allot participants randomly to the study group or control group. The randomization numbers under concealment and were known after recruiting the patient to the study by filling patient details on closed envelope. SNOSE method - Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) was used for concealment.

Study procedure

Once patients satisfied the eligibility criteria and consent was taken, patients were subjected for randomization to either study or control group. Sources of data were patient Data Collection Forms, Patient's Case records during Hospital stay, Medication Charts and Lab reports.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethical Committee of KLE Academy of Higher Education and Research. All the patients were randomized after the written informed consent. Reference number: KAHER/EC/19-20/290619004.

RESULTS

Of the 300 diabetic patients, 150 were included in the control group and another 150 in the observational group. The 300 patients with DM who were on oral hypoglycemic agents, insulin only or in combination with oral hypoglycemic agents were enrolled in the study, out of which 218 (72.67%) were males, and 82 (27.33%) were females. Males were higher than females. Among the study population, the maximum number of patients were in the age group of 61-70 years, followed by 51-60 years. Demographic details of enrolled patients are presented in Table 1.

Out of 300 subjects, 108 (36.00%) of subjects were found to be overweight, followed by 85 (28.33%) belonging to the obese class. Similarly, 102 (34.00%) subjects were shown to have diabetes duration of >10 years, and 28 (9.33%) were recently diagnosed subjects with less than one year of duration.

It was evident from Table 2 that, out of 300 study population, 175 (58.33%) subjects were taking two medications followed by 82 (27.33%) were receiving three medications. 121 (40.33%) of the subjects were found to be in Lower Middle socio-economic class, followed by 68 (22.67%) of subjects belonging to upper lower class.

It was revealed that out of 300 patients, 67 (22.33%) had total medicine expenditure each month of less than 100 rupees. Similarly, the total cost of medicine per month for 144 (48.00%) patients was between 100 and 200 rupees, whereas the total cost of drug per month for 89 (29.66%) patients was more than 200 rupees. Out of 300 study subjects, 152 (50.66%) were receiving diabetic medications two times in a day followed by 122 (40.66%) were taking once in a day. Whereas only about 26 (8.66%) subjects were taking diabetic medications three times a day. These results are shown in Table 3.

Of the 300 patients, 162 (54.00%) times Metformin and Sulfonylureas dual drug regimen was highest prescribed followed by 132 (44.00%) times metformin+regular insulin. In triple therapy, metformin+sulfonylureas+DPP4 inhibitors prescribed was 117 (39.00%) followed by Metformin+thiazolidine diones+alphaglucoisidase inhibitors 48 (16.00%). The highest four drug regimen, Metformin+Voglibose+NPH insulin+Regular insulin was prescribed 18 (6.00%) times. These results are shown in Table 4.

Out of 300 Patients, 205 (68.33%) patients were prescribed with insulin, of which regular insulin was the highest. 203 (67.66%) patients were prescribed sulfonylureas, of which Glimpiride 78 (26.00%) was the most commonly prescribed drug. It was observed that 162 (54.00%) patients were prescribed with biguanides. α -Glucosidase Inhibitors in 102 (34.00%) patients and DPP-4 Inhibitors were prescribed in 61 (20.33%) patients of which vildagliptin was the most commonly prescribed drug. Thiazolidinediones class of drugs were prescribed in 80 (26.66%)

Table 1: Clinical Characteristics of the Study Population.

Variables	Sub variables	No. of Subjects	Percentage
Gender	Male	218	72.67
	Female	82	27.33
Age Distribution	21-30	06	02.00
	31-40	36	12.00
	41-50	52	17.33
	51-60	74	24.67
	61-70	82	27.33
	>70	50	16.67
BMI (kg/m ²)	Underweight (< 18.5)	33	11.00
	Normal Weight (18.5-24.9)	74	24.66
	Overweight (25-30)	108	36.00
	Obese (> 30)	85	28.33
Duration of Diabetes	<1 Year	28	09.33
	1-5 Years	76	25.33
	6-10 Years	94	31.33
	>10 Years	102	34.00

Table 2: Number of Medications and Socio-economic Status of the study population.

Sl. Noo	No. of Medications	No. of Subjects	Percentage	Socio-Economic Status	No. of Subjects	Percentage
1	One	18	06.00	Upper	27	09.00
2	Two	175	58.33	Upper Middle	48	16.00
3	Three	82	27.33	Lower Middle	121	40.33
4	Four	16	5.33	Upper lower	68	22.67
5	> Four	09	3.00	Lower	36	12.00

Table 3: Cost therapy of medication per month and distribution of regimen in the study population.

Sl. No	Cost of drug/month	No. of Subjects	Percentage	Regimen	No. of Subjects	Percentage
1	<100	67	22.33	Once Daily	122	40.66
2	100-200	144	48.00	Twice Daily	152	50.66
3	>200	89	29.66	Thrice Daily	26	8.66

patients, while GLP-1 analog 06 (02.00%), was the least prescribed drug. These results are shown in Table 5.

Table 6 demonstrates adherence to WHO drug prescribing indicators. The total number of drugs prescribed in 300 prescriptions were 819. The average number of drugs per encounter was found to be 2.73. The percentage of drugs prescribed in generic name was 58.60% and the percentage of antibiotics and injectable drugs were found to be 22.22% and 29.91% respectively. The percentage of drugs prescribed from Essential drug list was 82.17%. Fixed dose combinations of various drugs in the prescriptions studied was found to be 98.29%.

DISCUSSION

In India, Diabetes is a serious health issue. DM is defined by the World Health Organization as a chronic, metabolic condition marked by increased blood glucose (or blood sugar) levels that lead to significant damage to the heart, blood vessels, eyes, kidneys, and nerves over time.⁹ Drug use is defined by the WHO as the marketing, distribution, prescription, and use of pharmaceuticals in a society, taking into account the medical, social, and economic repercussions.¹⁰ According to the WHO, India had 32 million diabetes patients in 2000, which is expected to rise to 80 million by 2030. Diabetes is becoming more prevalent in India at an alarming rate, necessitating more public knowledge regarding the causes of diabetes and its repercussions.¹¹

Table 4: Utilization pattern of most commonly encountered multidrug ADD regimens.

Sl. No	Name of the drugs	Number of times prescribed	Percentage
Dual drug regimens			
1	Metformin+sulfonylureas	162	54.00
2	Metformin+thiazolidine diones	80	26.66
3	Metformin+alphaglucoisidase inhibitors	44	14.66
4	Metformin+DPP4 inhibitors	37	12.33
5	Metformin+meglitinides	21	07.00
6	Sulfonylureas+thiazolidine diones	64	11.33
7	Sulfonylureas+alphaglucoisidase inhibitors	27	09.00
8	Metformin + regular insulin	132	44.00
Total Dual drug regimens (n) = 567			
Triple drug regimens			
8	Metformin+sulfonyl ureas+ DPP4 inhibitors	117	39.00
9	Metformin+thiazolidine diones+alphaglucoisidase inhibitors	48	16.00
10	Metformin + acarbose + premixed insulin	31	10.33
Total Triple drug regimens (n) = 196			
Four drug regimens			
11	Metformin + voglibose + NPH insulin + regular insulin	18	06.00
12	Metformin + glimepiride + pioglitazone + voglibose	24	08.00
Total Four drug regimens (n) = 42			

During the course of the study, 300 diabetic individuals were analysed, and it was discovered that males had a higher prevalence of diabetes than females (Males 72.60%; Females 27.30%). A similar study by Vengurlekar S *et al.*, Boccuzzi SJ *et al.*, Johnson *et al.*, Yurgin N *et al.*, found that males had a higher prevalence of diabetes than females, while a few studies by Lisha *et al.*, Saiyad *et al.*, Ramesh R *et al.*, contradicted our findings, which found a high proportion of diabetes in female patients.¹²⁻¹⁴

The majority of diabetes patients (27.33% and 24.67%) in this study are in the 61-70 and 51-60 year old age group respectively. Upadhyay *et al.* and Venkateswaramurthy *et al.* observed a greater incidence of diabetes in the same age range, which is consistent with our findings.¹³ According to the findings of our research, we found that more patients were obese and overweight. According to Boffetta *et al.*, there is a clear link between BMI and diabetes prevalence in Asian people.¹¹ Maximum patients in our research had a DM history less than ten years. These findings were comparable to the study conducted by Siddiq *et al.*²

Two medicines per prescription were found to be greater in the current investigation, comparable to Pankaj CK *et al.*⁵ The majority of the patients in this study were from the lower middle socioeconomic class, which contrasts with Ashutosh K *et al.* findings, which indicated that the upper middle socioeconomic class was dominant.⁹ Our study's cost of medicine per month was

between 100 and 200 rupees, which was lower in Pankaj CK *et al.*'s study. The patients receiving diabetic medications two times in a day were higher which was similar by Siddiq *et al.*²

According to our findings, Patients hospitalized to the medicine ward were usually provided insulin, either as monotherapy or in combination with oral antidiabetic medications. Regular insulin was the most often administered insulin preparation (44.00%), followed by NPH insulin mixtard (14.00%) which was a similar outcome in the Mahmood *et al.* and Gautam *et al.* study.¹⁵ Metformin was the most commonly prescribed medicine for T2DM is metformin (54.00%). Metformin was administered as monotherapy or as part of a polytherapy followed by glimepiride (26.00%). Similar outcomes were found in a number of other studies done around the country.¹⁵ The increasing prevalence of insulin prescriptions, particularly regular insulin, is related to the fact that patients admitted to indoor wards with co morbidities frequently require insulin because of its safety profile and speedier start of action. This also decreases the risk of medication interactions and improves the hospitalized patients' glycemic control.⁶

Because of its lengthy $t_{1/2}$, higher extrapancreatic activity, reduced hyperinsulinemia, and lower incidence of hypoglycemia, glimepiride has emerged as a front-liner among the SU. An alpha-glucosidase inhibitor was employed as an adjunct therapy

Table 5: Prescribing pattern of oral hypoglycemic drug as single drug regimen based on various classes of drugs.

Sl. No	ATC Code	Class of ADDs	Drugs (ATC Code)	Number of Patients	Percentage (%)
1	A10BA	Biguanides	Metformin A10BA02	162	54.00
2	A10BB	Sulfonylureas	Glimepiride A10BB12	78	26.00
			Glipizide A10BB07	64	21.33
			Glibenclamide A10BB01	47	15.66
			Gliclazide A10BB09	14	04.66
			Total	203	67.66
3	A10BF	α - Glucosidase inhibitors	Voglibose A10BF03	54	18.00
			Acarbose A10BF01	32	10.66
			Miglitol A10BF02	16	05.33
			Total	102	34.00
4	A10BG	Thiazolidinediones	Pioglitazone A10BG03	53	17.66
			Rosiglitazone A10BG02	27	09.00
			Total	80	26.66
5	A10BH	Dipeptidyl peptidase-4 (DPP-4) inhibitors	Vildagliptin A10BH02	41	13.66
			Linagliptin A10BH05	14	04.66
			Tenagliptin A10BH08	06	02.00
			Total	61	20.33
6	A10BJ	GLP-1 analog	Exenatide A10BJ01	06	02.00
7	A10A	Insulin A10AB	Regular insulin A10AB01	132	44.00
			NPH insulin A10AC	42	14.00
			premixed insulin A10AB30	31	10.33
			Total	205	68.33

Table 6: WHO core prescribing indicators.

Sl. No	Core Indicators	Value
1	Average number of drugs prescribed per prescription.	2.73
2	Percentage of drugs prescribed by generic name.	480 (58.60%)
3	Percentage of encounters with antibiotic prescribed.	182 (22.22%)
4	Percentage of encounters with injectable drug prescribed.	245 (29.91%)
5	Percentage of drugs prescribed from NLEM (National List of Essential Medicines).	673 (82.17%)
6	Percentage of encounters with Fixed drug combination.	805 (98.29%)
Total number of drugs prescribed (<i>n</i>) = 819		

as a dual medication regime in 44 prescriptions with metformin because of considerable postprandial hyperglycemia with managed Fasting Plasma Glucose (FPG) in majority of these follow-up encounters, this was done in accordance with the 2016 standards of the International Diabetes Federation.⁴

Only 102 prescriptions out of 300 patients contained Voglibose 54 (18.00%), Acarbose 32 (10.66%) and Miglitol 16 (05.33%) where similar results found in the study by Lahiry S *et al.* It was against the evidence supporting the use of acarbose as a first-line adjuvant for lowering cardiovascular mortality in T2DM patients when compared to voglibose.⁴

Overall, thiazolidinediones are used as monotherapy by 80 (17.66%) of patients, with pioglitazone and rosiglitazone being used as add-on therapy by 53 (17.66%) and 27(09.00%) of patients, respectively and similar result by Pankaj CK *et al.*⁵ In 80 (26.66%) of the prescriptions, metformin and thiazolidinediones were prescribed together. It's possible that pioglitazone was dispensed from the hospital pharmacy. Although the combination of metformin and pioglitazone has been demonstrated to improve insulin resistance and cardiovascular morbidity, it was found to be an underused class in our analysis, perhaps because of concerns about side effects.^{4,5}

DPP4 inhibitors accounted in 61 prescriptions (20.33%) where Vildagliptin 41 (13.66%), Linagliptin 14 (04.66%) and Teneligliptin 06 (02.00%). A research by Pankaj CK *et al.* found a similar effect when it came to biguanides and sulfonylureas. Sulphonylureas were described as the most often prescribed antidiabetic medication in late 1990s studies in South Africa, the United States, and India by Truter I and Boccuzzi SJ *et al.*, which contradicts the current study.⁵ The GLP-1 analog Exenatide 06 (02.00%) is less used anti-diabetic drug in the study.

This study showed that metformin + sulfonylureas 162 (54.00%) dual drug regime was the commonly used in most of the patients and which was similar in the study conducted by Lahiry S.⁴ It is followed by Metformin + regular insulin 132 (44.00%) and Metformin+thiazolidine diones 80 (26.66%).

Among three drug combination Metformin+sulfonyl ureas+DPP4 inhibitors 117 (39.00%) were most frequently prescribed fixed dose combination. In four drug regime most widely used is Metformin + glimepiride + pioglitazone + Voglibose which accounts for 24 (08.00%) and Metformin + voglibose + NPH insulin + regular insulin is 18 (06.00%).¹⁴

We found out that the average number of drugs prescribed per prescription for treatment with antidiabetic drugs was almost half the average number of drugs per prescription found out by Okoro RN *et al.*¹⁶ Data was analysed for WHO drug utilization indicators in which we saw a trend of using generic name for prescribing which stood at 58.60%. This was way higher than the study done by Acharya, *et al.*¹⁷ The percentage of encounters with antibiotics prescribed is at 22.22% in our study. The percentage of prescriptions with injections/injectable drugs in our study was 29.91%, which is higher than the derived standard value for WHO (13.4-24.1%)¹⁸ and lower than the value reported by Sahu G *et al.*¹⁵ Hannan A *et al.* study showed the percentage of drugs prescribed from NLEM was 65.82% whereas our study shows the percentage of drugs prescribed from NLEM at 82.17%.¹⁹ We saw 98.29% of encounters with fixed drug combination.

This study has reported the antidiabetic drug usage pattern in different age groups with varying disease durations. The prescription patterns suggest the usage of wide class of antidiabetic drugs including different types of Insulin's and oral hypoglycaemic agents in the study population. Since the DM is a chronic metabolic disorder, therapy cost, long term consequences, effect on comorbid conditions, and adverse drug reactions arising out of chronic diabetic medications are to be explored for better quality of life.

CONCLUSION

Diabetes should be managed properly to enhance the patient's quality of life. The majority of the prescriptions in the research were reasonable, but there is still room for improvement. More than 90% of patients were diagnosed with type 2 diabetes. Oral hypoglycemic medications were administered often, indicating greater glycemia at the time of diagnosis. Based on the results of the randomization study on prescription patterns, which included 300 patients, it was found that metformin and insulin use is greater in men, with higher use among middle-age patients.

Regular insulin was the most often used insulin because it was less expensive than insulin analogues. Insulin preparations aid in the reduction of insulin resistance, resulting in improved glycemic control. Dose and duration, as well as interactions with

other drugs, should all be considered while prescribing rationally. Patients and physicians should work together to achieve the goal of glucose levels and live a happier, healthier life.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DM: Diabetes Mellitus; **ADA:** American Diabetes Association; **ICMR:** Indian Council of Medical Research; **WHO:** World Health Organization; **SPSS:** Statistical Package for social sciences; **SNOSE:** Sequentially numbered opaque sealed envelopes; **FPG:** Fasting Plasma glucose; **NLEM:** National List of Essential Medicines.

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