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ASSESSMENT OF THE PRESCRIPTION PATTERN OF ORAL HYPOGLYCEMIC DRUGS IN UNCOMPLICATED DIABETES MELLITUS PATIENTS AT TERTIARY CARE HOSPITAL

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ABSTRACT: Aim and Objective: Drug utilization research help in identification of the clinical use of drugs in population and its impact on health care system and to evaluate the rational drug usage. To study prescription pattern, to evaluate the adherence to treatment guidelines in diabetic patients attending the medical outpatient department in a tertiary care teaching hospital. Drug utilization research help in identification of the clinical use of drugs in population and its impact on health care system. To select the rational use of drugs as a predominant technique for the utilization of selective drugs in diabetes mellitus patients. **Methodology:** A cross-sectional retrospective study was carried out for 6 months in diabetic patients in the General Medicine Department. Data of 280 patients were collected and evaluated. **Results:** Total 280 diabetes mellitus patients were admitted. In this study, almost all prescriptions were with polypharmacy. The pattern of drug prescription in diabetes mellitus shows that insulin (22.14%) was most frequently prescribed followed by glimepiride (16.78%) and metformin (8.21%). In sulfonylureas monotherapy are 50.7%, a combination of two drugs are 21% and the combination of three drugs is 2.14%. Combination therapy was prescribed to 44.41% and monotherapy to 52.48% of patients; 54.28% of these patients were male and 45.71% were female. **Conclusion:** Glimepiride and insulin have been most frequently prescribed, before prescribing to the patients, evaluation of medications with the suitable criteria is required. In other words, rational use drug must be strictly followed.

INTRODUCTION: Diabetes mellitus is an alarming rise from 40 million to 70 million people by 2025 in India^{4, 12}. It is a chronic disease that requires long-term medical attention both to limit the development of its devastating complications and to manage them if they do occur. The WHO defines diabetes mellitus as “A metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in the insulin secretion, insulin action, or both”^{3, 4, 18}.

The management of type 1 diabetes mellitus depends mainly on insulin, whereas the oral hypoglycemic drugs are the first line treatment for type II diabetes mellitus¹⁸. Complications due to hyperglycemia in diabetes mellitus can be prevented by using in rational use of the drugs in population can be effectively studied with drug utilization reviews^{12, 18}. The two most common types of diabetes mellitus, type 1 diabetes mellitus mostly occurs before the age of 40 and is distinguished by a total or near-total lack of insulin.

It accounts for about 10 - 15 % of all diabetes mellitus cases and type II diabetes mellitus usually occurs after the age of 40 and accounts for 85-90 % of all diabetes mellitus cases. It is distinguished by reduced insulin production or inability of the body to use insulin properly (insulin resistance). In India, 20 % of the elderly has type 2 diabetes mellitus.

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It is the more common of disease engulfing around 90 % of all the diabetes mellitus cases worldwide. This is due to many socio-demographic factors such as increased life expectancy, high rates of obesity and changes in dietary habits³. Drug utilization studies create a sound sociomedical and health economic basis for healthcare decision-making⁹. A retrospective drug utilization study is an approved, systemic process that captures, reviews, analysis, and interprets aggregate medication use data within specific healthcare environments^{10, 15}.

Data are archival in nature, in other words, collected and analyzed after the events of major interest (the prescription, dispensing, and use of drugs) have occurred¹⁵. The specific healthcare environment influences retrospective drug utilization because the quality and quantity of the data¹¹ determine the scope, nature, and application of the review¹⁵.

These studies have little impact on immediate patient care but rather serve to identify trends in prescribing practices that may lead to interventions aimed at enhancing prescribing behavior. Their potential for preventing problems is limited, because the actual review may not take place for weeks after an error has been made or an inappropriate therapy has been administered. Retrospective studies are inexpensive, can be conducted rapidly and have easily accessible data. In this article, we include type 1.5 diabetes mellitus. Type 1.5 diabetes mellitus is also known as Latent Autoimmune Diabetes mellitus in Adults (LADA).

LADA is considered by some experts to be a slowly progressive form of Type 1 diabetes mellitus. This is sometimes thought of as Type I diabetes mellitus that is diagnosed in adults over the age of 30-type 1 diabetes mellitus is commonly diagnosed in children and younger adults. Type 1.5 diabetes mellitus is often found along with Type II diabetes mellitus: up to 25 % of individuals with type 1.5 diabetes mellitus also have characteristics of type II diabetes mellitus¹⁷.

This is sometimes called “double diabetes mellitus”. Individuals with type 1.5 diabetes mellitus are all eventually dependent on insulin for

treatment and have a very high risk of requiring insulin within months or years (up to six years) after the initial diagnosis. The main causes of Type 1.5 diabetes mellitus are immune system has become “confused” and begins to act against the beta cells of the pancreas-the source of the insulin needed to control blood sugars. Both type 1 diabetes mellitus and type 1.5 diabetes mellitus have antibodies to glutamic acid decarboxylase or anti-GAD antibodies.

As with type 1 diabetes mellitus, individuals with type 1.5 diabetes mellitus tend not to be obese, whereas, in type 2 diabetes mellitus, most individuals are overweight or obese. The symptoms of type 1.5 diabetes mellitus are similar to the other forms of diabetes mellitus increased the frequency of thirst, increased the frequency of urination and unintentional weight loss. Others - blurriness of vision or fatigue may occur.

Objective: To evaluate the glycemic control achieved by patients receiving different treatment regimens for type II diabetes mellitus, including immunotherapy with an oral hypoglycemic agent, multiple oral hypoglycemic agents, oral hypoglycemic agents with insulin, insulin monotherapy.

A collection of individual data of diabetic patients (280 prescriptions) as per their Name, Age, Sex, Family History, Duration, Personal History and Prescribed Drugs. To study the prescribing pattern of anti-diabetic drugs through a data entry format.

METHODOLOGY: The study was carried out for a period of six months from Jan 2017 To June 2017

Research Design:

Type of Study: Cross-sectional retrospective study

Sample Size: 280 patients

Data Collection: Data were collected from the hospital pharmacy as per data entry format

Study Duration: Six months (Jan 2017 to June 2017)

Inclusion Criteria: Patients of both sex, who were prescribed anti-diabetic drugs either orally or systemically from the community pharmacy in the rural hospital.

Exclusion Criteria:

- Patients who left without medical advice.
- Patients below the age of 7 years are not included in the study.
- Patients above 93 years were also not included in this study.

Study Site: The study was conducted in the Department of General Medicine in Manipal super specialty Hospital, Vijayawada, India.

Data Analysis: Data was analyzed on MS Excel and descriptive statistics were used for analyzing the result of the study.

TABLE 1: DIFFERENT TYPES OF DIABETES MELLITUS

Feature	Type 1 Diabetes Mellitus	Type 2 Diabetes Mellitus	LADA
Nature of onset and age of diagnosis	Occurs in children to young adults, usually age 25 or under	Usually over a long period of time. Predictors of risk include insulin resistance, prediabetes mellitus gestational diabetes mellitus, obesity, PCOS, and metabolic syndrome.	Usually presents as type II occurring slowly, usually over years. Does not affect children
Genes, triggers and contributing factors	Idiopathic, type 1 diabetes mellitus may involve genetic factors and an environmental trigger, usually an exposure to a virus	Hereditary component. The most common trigger for type 2 diabetes mellitus is a sedentary lifestyle and obesity	Genetic predisposition and environmental the trigger is suspected as the causes of LADA
Genetic and other Markers	ICA-Found in 80% of new cases GAD-yes, but more commonly present in adults than in children IA2- Found in 50-70% of all newly diagnosed with type 1 diabetes mellitus HLA – yea C-peptides – low	ICA-no GAD-rare, if present may be indication of LAD and/or predictor of future insulin dependence HLA-no C-peptides-normal-high	GAD-very often and more common than in the juvenile form. IA2-often (those with both GAD and IA2 progress more rapidly to insulin dependence C-peptides-low
Features at Diagnosis	Often DKA, recent weight loss, a person is usually thin	May go undiagnosed for long periods of time. Patient typically is overweight and may have had preexisting metabolic disorders	Maybe undiagnosed for long periods of time, then identified as non-obesity related type 2 diabetes mellitus
Treatment	Type1 diabetes mellitus always requires daily replacement of insulin	For many, in early stages of type 2, changes in lifestyle may control the disease. Oral insulin-sensitizing drugs may be given, as well as antidiabetes mellitus medications	Sulfonylureas may help some insulin-sensitive patients at first, but will not stop or slow down progression

RESULTS AND DISCUSSION: The only prescription for patients who were diagnosed with diabetes mellitus was included in the study. Prescription of patients with serious medical conditions requiring subsequent hospital admissions was excluded.

TABLE 2: THIS SHOWS DIFFERENT AGE GROUP OF PATIENTS AFFECTED BY DIABETES MELLITUS

Age Group	Male	Female	Total Patients	% of Patients
20-30	12	8	20	7.14%
31-40	28	25	53	18.92%
41-50	28	20	48	17.14%
51-60	43	35	78	27.85%
61-70	30	30	60	21.42%
71-80	11	10	21	7.5%
Total	152	128	280	100

All illegible, improperly and incompletely written prescriptions were noted and excluded from final

analysis. Confidentiality and anonymity of the patient information were maintained during and after the study.

In our study, we found total 280 members those belong to different age groups. The total patient's age group between 20 - 80 years. Out of these 20-30 years age group patients are 7.14% (n=20) in this female patients are 8 members and male patients are 12 members, followed by 31- 40 age group patients are 18.92% (n=53) in this group female patients are 25 members and male groups are 28 members were found next to that 41-50 age group patients are 17.14% (n=48) in this male patients are 28 members and female patients are 20 members were found and next group is 51 - 60 age group patients are 27.85% (n=78) in this group

male patients are 43 members and female patients are 35 members were found and followed by 61 -70 years age group patients are 21.42 % (n=60) in this group male patients are 30 members and female patients are 30 members were found and 71 - 80 age group patients are 7.5% (n=21) in this male

patients are 11 members and female patients are 10 members. In this study, we found a high number of patients in 51 - 60 years age group (n=78) and the low number of patients were found in 20 - 30 years age group patients (n=20).

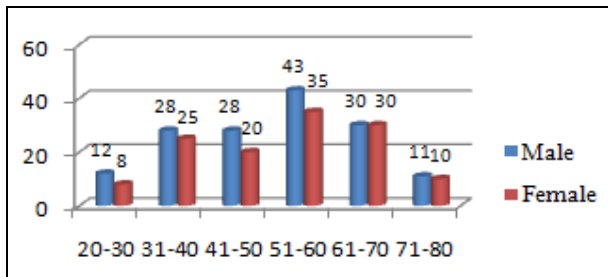


FIG. 1: SHOWN PERCENTAGE OF PATIENTS AFFECTED BY DIABETES MELLITUS

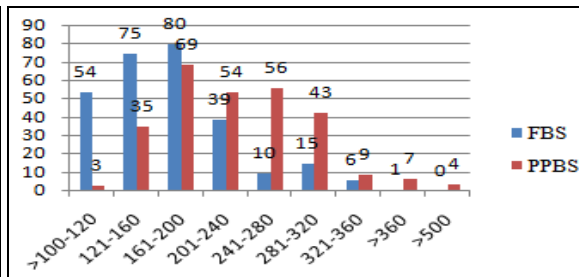


FIG. 2: SHOWN PERCENTAGE OF BLOOD SUGAR LEVELS IN VARIOUS LEVELS

TABLE 3: THIS TABLE SHOWS BOTH FASTING BLOOD SUGAR AND POST PRANDIAL BLOOD SUGAR LEVELS

Sugar levels	FBS	% of FBS	PPBS	% of PPBS
>100-120	54	19.2	3	1.07
121-160	75	26.7	35	12.5
161-200	80	28.5	69	24.6
201-240	39	13.9	54	19.28
241-280	10	3.57	56	20
281-320	15	5.35	43	15.35
321-360	6	2.1	9	3.21
>360	1	0.35	7	2.5
>500	0	0	4	1.42

FBS: Fasting Blood Sugar, PPBS: Post Prandial Blood Sugar

In this study we found various types of abnormal values in both FBS and PPBS those values are from below 100 to above 500. Both FBS and PPBS levels below 100 to 120 mg/dl was found 19.2% (n=52) and 1.07% (n=3) followed by 121-160 mg/dl was found to be 26.7% (n=75) and 12.5% (n=35). Next to that 161-200 mg/dl was 28.5% (n=80) and 24.6% (n=69) and for 201-240 mg/dl was found to be 13.9 % (n=39) and 19.28% (n=54) then followed by 241-280 mg/dl 3.57% (n=10) and 20% (n=56). Next to that 281-320 mg/dl 5.35% (n=15) and 15.35% (n=43) and then 321-360 mg/dl, >360 mg/dl and >500 the FBS levels were found to be 2.1% (n=6), 0.35% (n=1) , 0%(n=0) and the PPBS levels are 3.21% (n=9), 2.5% (n=7) and 1.42% (n=4) respectively.

Out of these values more patients with FBS and PPBS levels between 161-200 mg/dl i.e., 28.5% and 24.6% respectively and low number of patients were found to be in FBS was above 360 mg/dl 0.35% (n=1) and PPBS was both >100mg/dl -120 mg/dl 1.07% (n=3).

TABLE 4: PERCENTAGE OF DRUGS USED IN DIFFERENT PATIENTS

Drug Name	No. of Patients used drugs	% of drugs
Glimepiride	47	16.78
Insulin	62	22.14
Metformin	23	8.21
Pioglitazone	10	3.57
Repaglinide	5	1.78
Metformin + Insulin	16	5.71
Metformin + Glimiperide	36	12.8
Insulin + Glimiperide	23	8.21
Metformin + Acarbose	12	4.28
Glimiperide + Acarbose	6	2.14
Glimiperide + Telmisarton	9	3.21
Metformin + Sitagliptine	7	2.5
Metformin + Rosiglitazone	4	1.42
Metformin + Glimiperide + Insulin	5	1.78
Sitagliptin + Pioglitazone + Metformin	6	2.14

In our study, we found the usage of drugs in various types of dosage forms are used some are using oral hypoglycemics with or without the combination. In combination type of drugs, some are using two drug combinations and some are using three-drug combinations and some of the patients using parenteral such as insulin, some of the patients using alone and some of the patients using along with a combination of oral hypoglycemics. In our study we found highest use of drug is Insulin 22.14% (n=64), next highest use of the drug is oral hypoglycemics in that especially Glimiperide use in high-level 16.78% (n=47), followed by combination drug glimepiride with Metformin 12.8% (n=36), next to that highest

position is insulin with glimiperide and metformin alone 8.12% (n=23) and the lowest level of drugs

used in our study is metformin along with rosiglitazone 1.42% (n=4).

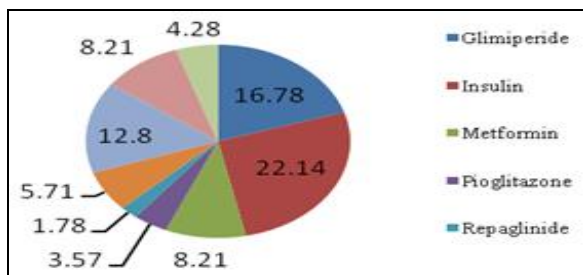


FIG. 3: SHOWS PERCENTAGE OF DRUGS IN DIFFERENT TYPES OF PATIENTS

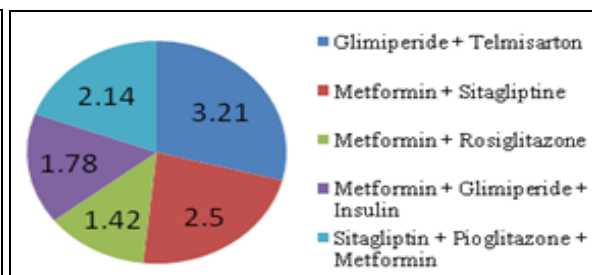


FIG. 4: SHOWS PERCENTAGE OF DRUGS IN DIFFERENT TYPES OF PATIENTS

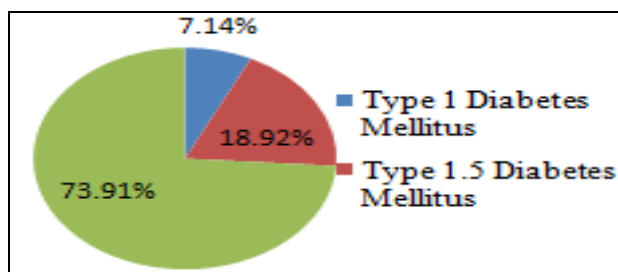


FIG. 5: SHOWS PERCENTAGE OF PATIENTS WITH DIFFERENT DIABETES MELLITUS

Prescription Analysis: Finally, we found a total number of prescription analyzed in our study is 280. A total number of medications prescribed is 350 and the average number of medications per prescription is 0.57 %, Percentage of medications prescribed by generic name is 60.28 % and the brand name is 39.71 %, Percentage of medications prescribed by solid dosage form is 55.71 % and the parenteral form is 44.28 %.

TABLE 5: PRESCRIPTION ANALYSIS

S. no.	Prescription Analysis	Results
1	Total number of prescription analyzed	280
2	Total number of medications prescribed	350
3	Average number of medications per prescription	2-3 (0.57%)
4	Percentage of medications prescribed by generic name	211 (60.28%)
5	Percentage of medications prescribed by brand name	139 (39.71%)
6	Percentage of medications prescribed by solid dosage form	195 (55.71%)
7	Percentage of medications prescribed by parenteral	155 (44.28%)

This table shows a number of patients in different types of diabetes mellitus *i.e.*, Type 1 diabetes mellitus patients are 7.14% (n=20), followed by type 1.5 diabetes mellitus the patients are 18.92%

and the finally Type II diabetes mellitus the patients are 73.91%. We differentiate the three types by age group wise *i.e.*, below 30 years age group patients we considered as type 1 diabetes mellitus, 31 - 40 years age group patients we considered as type 1.5 diabetes mellitus and >40 years age group patients we considered as type II diabetes mellitus.

TABLE 6: THIS TABLE SHOWS THE NUMBER OF PATIENTS IN THREE DIFFERENT TYPES OF DIABETES MELLITUS

Type of Diabetes mellitus	No. of Patients	Percentage of Patients
Type 1 DM	20	7.14 %
Type 1.5 DM	53	18.92%
Type II DM	207	73.91%

CONCLUSION: In our study, we found a maximum number of patients in 51 - 60 years age group 78 members and lowest number of patients were found to be 20-30 years age group, 20 members. We found the highest use of the drug is Insulin 22.14 %, next highest use of the drug is oral hypoglycemics in that especially glimiperide use in high-level 16.78 % and the lowest level of drugs used in our study is metformin along with rosiglitazone 1.42 %. In our study, we included Type 1.5 diabetes mellitus because we found 18.93% *i.e.*, 52 patients in type 1.5 diabetes

mellitus. The development of the formulary will have a major impact on prescribers and healthcare professionals and for clinical practice. Before prescribing to the patients, evaluation of medications with the suitable criteria is required. In other words, the rational drug must be strictly followed.

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CONFLICT OF INTEREST: Nil

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