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DRUG UTILIZATION PATTERNS OF ANTI-DIABETIC AGENTSIN DIABETICS WITH CO-MORBIDITIES IN A TERTIARY CARE HOSPITAL: AN OBSERVATIONAL STUDY

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SCIENCES

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ABSTRACT: Type 2 diabetes mellitus is a lifestyle disorder with a deficiency in insulin secretion or loss of insulin sensitivity in the body. As the prevalence is becoming more global, a focus was made on the innovation of analyzing the latest treatments. A prospective observational study on drug utilization patterns for diabetes was conducted on 119 diabetic patients admitted in a tertiary care hospital. A specified informed consent form was collected from the patients prior to the study. All the relevant data was collected and analyzed. In the present study, the prevalence of Type 2 diabetes mellitus was highest in patients aged 60-69 years, affecting 43.7% males and 56.3% females. The commonest co-morbid condition was hypertension (63%) followed by coronary artery disease (10.9%) and chronic kidney disease (9.2%). When it comes to the treatment, insulin was prescribed for about 90 (75.6%) diabetic patients, followed by oral hypoglycaemic agents (OHAs) (n=29; 24.4%). Amongst the drugs, it was also noted that 61 patients (51.2%) were administered metformin alone while the remaining patients were given insulin and other OHAs. The above results concluded that metformin was the only drug prescribed persistently and was the drug of choice for type 2 diabetes mellitus. The prescribing patterns in the present study give way to clinician/physician to go for better drugs in co-morbid conditions, considering the drug interactions as well.

INTRODUCTION: Type II diabetes mellitus is considered the most prevalent non-communicable and lifestyle disorder affecting about half of the global population by the end of the year 2045. In India, the present scenario is alarming; about 74 million of the population aged between 20-79 years is suffering from this diabetes as calculated in the year 2021¹.

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When a keen observation was made on the age of people affirmed as 20 years, that is on the lower limit; moreover, this limit was not observed in the previous reports/data. When a trivial focus is made on this regard, people are being diagnosed with type II diabetes mellitus at an early age (beginning at the age of 20 years); this might be because of lifestyle changes, getting stressed about trivial things, being emotional, lack of physical activity, overweight and sometimes obesity 2 .

A persistent rise in blood glucose levels leads to many complications and morbidity. Hence to combat such deleterious effects. Pharmacotherapy plays a crucial role and also depends on the severity of the disease, age, and any other comorbid condition. Diabetes mellitus can be treated by two treatments - Pharmacological and nonpharmacological. The non-pharmacological treatment includes a controlled caloric diet, adopting a few exercises such as yoga practices, and following some stress relieving methods ³. The cornerstone of diabetes is grasping acceptable glycemic control and minimizing complications like cardiovascular and cerebrovascular diseases, are avoidable and achievable which with conventional use of medications pertinently with regular check-ups and investigations¹.

Nevertheless, currently, people diagnosed with type II diabetes mellitus at an earlier stage are adopting non-pharmacological treatment, which a is otherwise called "Reversal of Diabetes". Adopting a lifestyle change, intake of food, balanced diet, and weight management with physical exercise is perhaps making this reversal of diabetes possible ⁴. However, this might become complex in the long run and remains skeptical. Furthermore, few observational studies need to be conducted. In a lifetime, at a certain stage, it becomes a mandate for a diabetic patient to rely upon medication to avoid the risk of the development of complications in the future. Also, it is imperative to have awareness and minimum knowledge of the antidiabetic agents to avoid the adverse effects ⁵.

Certainly, there are many oral hypoglycemic agents (OHAs) available in the market, along with insulin as a part of therapy for people with diabetes. A clinician always evaluates a diabetic individual based on the severity, co-morbid condition, need of combination of drugs, their economic background, adverse effects, and drug-drug interactions. In this context, there can be every possibility of committing mistakes in prescribing the drugs when it comes to the use of a combination of drugs in order to avoid the ensuing complications 6 . Sometimes, small negligence might affect the treatment and patient's compliance. Despite numerous guidelines for managing diabetes mellitus, treatment varies from doctor to doctor depending on the available information, sources, hospital configuration, and patient-related factors such as age, gender, Body mass index (BMI), tolerance. comorbidities diseases. and socioeconomic level. Diabetes is always diagnosed with symptoms such as polyphagia, polydipsia, and

polyuria. Sometimes it is accompanied by comorbid conditions like hypertension, dyslipidemia, heart-related diseases, *etc.* The few studies noted that 75 % of adults with diabetes also have hypertension, and a keen observation was made that people acquire both diabetes and hypertension together as they are diagnosed ⁷.

Clinically, under the co-morbid conditions, a dominant factor is also elated along with diabetes mellitus, for instance, cancers, end-stage renal disease, class IV heart failure, and depression⁸. To have a successful diabetes treatment, it is mandated for a physician/clinician to have close surveillance of the associated ailments which are related to diabetes and also other co-morbid condition ⁹. Hence, developing different treatment strategies, any necessity of special treatment, adequate knowledge on the possibility of adverse drug reactions/events when polypharmacy is used, and lastly, heed of the drug-drug interactions ¹⁰. This substantially improvises the quality of life and patient compliance. In clinical practice, drug utilization research was found to be crucial as it authorizes a clinician to embrace a diabetic patient when a new drug is added or withdrawn towards the treatment.

Globally, various drug utilization studies on antidiabetic agents were conducted and reported in the healthcare system to recognize the disease among the patients¹¹. Using an appropriate drug at an appropriate time also is pivotal for favorable and successful treatment. Despite the origin of many propitious anti-hyperglycemic agents, few challenges are being faced, such as using effective drugs, possessing steady glucose levels, managing long-term complications, and maintaining patient compliance. Hence, drug utilization research helps a clinician revise drug policies and embrace different prescribing patterns, ultimately to unclog rational drug use ¹². In developing countries like India, it is quite necessary to facilitate strategies and utilize health resources in a productive manner ¹³. In the year 1977, Drug Utilization Research (DUR) was defined by WHO (World Health Organization) as "The study of the marketing, distribution, prescription, and use of drugs in a society, along with the prominence on the medical and socioeconomic implications" ¹⁴. The main intention of such studies is to promote the rational

use of medication. As an exemplification, when the drugs/medications are prescribed irrationally for a diabetic patient, there can be every chance of fronting with adverse drug reactions and events such as hypoglycaemia, diminished medication adherence, and chances of developing drug-drug interactions and a disturbance in medication reconciliation. All these may universally have inclined to the heightened risk of hospitalization and mortality rate ¹⁵.

The projection of diabetes by WHO has set down a burden on the healthcare system concerning the precise diagnosis and treatment as there is an expansion of older adults worldwide. This eventually creates an overload on the health care system additionally, as the disease burden imports. As there is a rise in the prevalence and frequency of diabetes mellitus, people are sometimes in chaos which might lead to the use of ill-suited drugs that further develop into macro and microvascular complications. Additionally, irrational prescription patterns from clinicians, diverged therapy, lack of awareness about the disease, and augmented adverse drug reactions impacted this study. This study was taken up to analyze the prescription patterns followed in treating diabetes in patients with co-morbid conditions.

MATERIALS AND METHODS:

Study Area, Period and Design: The study was observational and prospective and was conducted in the general ward, sharing ward, cubical, or OP of the hospital during six months' period from October 2019- March 2020 in New Life Thumbay Hospital, Hyderabad.

Determination of Sample size: 119 patients (n=119) were included in the present study.

Study Criteria:

Inclusion Criteria: In the current study, in-patients belonging to cubicles, sharing rooms, and general ward suffering from diabetes and co-morbid conditions were included. Patients range from the age of >18 years of age. Outpatients who visited the clinic were also included in the study.

Exclusion Criteria: Patients admitted to the emergency room were excluded from the study. Paediatric age group and pregnant women were excluded from the study.

Collection of Data: Informed consent form was taken from all the participants (patients). A suitably designed data collection form was prepared with the following details of patients, which included: Age, sex, body weight, height, ward, IP number, date of administration, diagnosis, patient's allergy status to drugs and food, laboratory data, medication history, description of the reaction, on the set of action.

Prescribing details such as Generic name, Strength, Manufacturer, Batch number, Dose, Route of administration, Frequency, Drug therapy, Risk factors, serious interactions, Drug-Drug interaction, Management, Outcome of management, Details of reporter, and details of the clinician. The data was collected from patient's case sheets, medical records, adverse drug reaction documentation, and laboratory investigations.

Ethics: Ethical committee approval bearing IEC number as MRM/IEC/2019/05 Institutional Ethics Committee was obtained from MRM College of pharmacy, Chintapallyguda, Ibrahimpatnam, Ranga Reddy District. Telangana State.

Analysis of Data: The data collected was doublechecked, structured, and entered in excel. The data were expressed in the form of frequency and % and also analyzed and presented using tables and figures. Chi-squared test was used to determine the significance of the values. A $p \le 0.001$ was Considered as the statistically significant.



FIG. 1: GRAPHICAL ABSTRACT OF DRUG UTILIZATION STUDIES FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS

RESULTS: 119 patients (n=119) were included in the study. Among them, 52 male patients were

diagnosed with type II diabetes mellitus (43.7%) and 67 (56.3 %) were female. Most of the patients were in the age group of 60-69 years in both males and females **Table 1**.

TABLE 1: INCIDENCE OF AGE GROUPS WITH GENDER

Age group (yrs)	Sex distribution n (%)		
	Male	Female	
20-29	2 (3.8)	2 (2.9)	
30-39	4 (7.6)	6 (8.9)	
40-49	6 (11.5)	5 (7.4)	
50-59	14 (26.9)	14 (20.8)	
60-69	16 (30.7)	21 (31.3)	
70-79	5 (9.6)	15 (22.3)	
80-89	2 (3.8)	4 (5.7)	
90-99	3 (5.7)	0 (0)	
	52 (43.7)	67 (56.3)	

With the Presence of Comorbidities: 119 patients were associated with comorbidities such as hypertension, coronary artery disease (CAD), and so on. Amongst all, hypertension (63 %) was found to be one of the most frequently occurring comorbidity, followed by CAD (10.9 %) and CKD (9.2%). The other comorbidities were Low respiratory tract infection (LRTI) with a frequency of 8.4 %, hypothyroidism (3.3%) followed by diabetic foot and sepsis, each with a frequency of 2.5% each, respectively Fig. 2.



FIG. 2: REPRESENTS THE COMORBIDITIES ALONG WITH DIABETES

Administration of Anti-diabetic agents: In the total number of patients (n=119) the patients who were on Insulin therapy were about 29 in the age group between 60-69 y, followed by 21 which was in the age between 50-59 y and 15 in the age group between 70-79 y. Regarding oral hypoglycaemic agents, 9 patients have fallen into the age group

between 60-69 y, followed by 5 patients each in 40-49, 50-59, and 70-79 years.

TABLE2:	DISTRIB	UTION	OF	ANTI	-DIABETIC
THERAPY	AMONG	THE	DIAB	ETIC	PATIENTS
(N=119)					

Age group (yrs)	Anti-diabetic the	Anti-diabetic therapy n (%)		
	Insulin	OHAs		
20-29	4 (4.4)	0 (0)		
30-39	8 (8.8)	3 (10.3)		
40-49	7 (7.77)	5 (17.2)		
50-59	21 (23.3)	5 (17.2)		
60-69	29 (32.2)	9 (31.03)		
70-79	15 (16.6)	5 (17.2)		
80-89	4 (4.4)	2 (6.9)		
90-99	2 (2.2)	0 (0)		
	90 (75.6)	29 (24.4)		

In the prescription pattern, 58 (48.7%) patients received the combination of drugs and insulin, while 61 (51.2%) patients were on metformin alone. A total of 97 patients received a combined therapy of drugs (Metformin, sulfonyl ureas, and thiazolidinediones) in **Fig. 3.**



In the total number of prescriptions, i.e., around 151 prescriptions (present and previous), there were 35 dosage-related errors in prescriptions noticed. These errors were more remarkable in older adults aged 60-69 y (28.5%) followed by 50-59 y (25.7%). In the total number of patients (n=119), the drug-drug interactions perceived were the major and moderate types of interactions. The major interactions were 35 (29.4%), followed by moderately identified interactions which were 15 (12.6%). In the remaining patients, there were no interactions **Fig. 4.**

Age group (yrs)	Dosage errors n (%)	
20-29	0 (0)	
30-39	3 (8.5)	
40-49	1 (2.8)	
50-59	9 (25.7)	
60-69	10 (28.5)	
70-79	7 (0.2)	
80-89	2 (5.7)	
90-99	3 (8.5)	
	n=35	

TABLE3:DISTRIBUTIONOFMEDICATIONERRORS AMONG THE DIABETIC PATIENTS





In the total number of patients, n=119, the rational prescriptions were 115 (96.6%), and the irrational prescriptions were only 4 (3.4%).

DISCUSSION: India is the capital of diabetes and now it's in an alarming state that excessively requires attention and awareness among people to understand the causative factors and the possibility of satiable treatment. Diabetes is a devitalizing disease that needs management to persist for a long time. Sedentary, stressed lifestyles, lack of exercise, irregular eating habits, and all of these environmental variables, together with a genetic predisposition to type 2 diabetes raise the chance of developing the disease ². Although food, exercise, and lifestyle changes remain the cornerstones of diabetes management, consistent pharmacological treatment is required to avoid the long-term consequences of diabetes. Numerous research was conducted on drug utilization studies was found that in a study evaluated by Sudha V *et al.* (2008) and Yurgin N (2007) $^{16, 17}$, the male predominance was more in the prevalence of diabetes. In the contrary, females were dominating in bearing the disease, a study conducted by Lisha et al. (2012)¹⁵ revealed. In the current study, the preponderance was higher in males than in females, consistent with previous studies. Regarding the co-morbid conditions, from the previous investigation, it was observed that hypertension was more common in type 2 diabetes mellitus (about 50-70%)¹⁸.

In the present study, it was observed that about 50% of the patients were identified with hypertension as co-morbid. At the same time, diabetic patients were also associated with chronic kidney disease (CKD) and coronary artery disease While prescribing the drugs (CAD). for hypertension, it is mandated to note the hypoglycaemic condition and monitor the other adverse effects ¹⁸. Besides, the presence of a comorbid condition in a diabetic patient imposes a burden on the therapy and the patient, finally creating a deteriorated quality of life. Hence, thorough knowledge is essential for a clinician on the existing co-morbid condition to ameliorate the individual's wellbeing.

In the prescriptions analyzed, drugs were alone and combined with other OHAs. Regular insulin (58) was administered with Lantus as the least prescribed one. The current study discovered that metformin was the most commonly prescribed medicine at the time of discharge, but insulin was prescribed during the stay ¹⁹. To achieve a good glycaemic control, there can be a necessity of preferring polypharmacy practice for managing diabetes, keeping in mind the effectiveness of drugs and patient's current situation. When adding a second and maybe third anti-hyperglycemic medicine, the synergy of different combinations and additional interactions were considered. For example, insulin plus metformin and insulin plus thiazolidinediones (TZD) are particularly effective lowering hyperglycemia, but the latter at combination comes with a higher risk of fluid retention²⁰.

Additionally, a combination of metformin and thiazolidinediones (TZD) productively increases insulin sensitivity. Amongst the different classes of OHAs, Metformin was mostly the prescribed drug either administered alone or in combination with other anti-diabetic drugs. The current study also emphasized the use of metformin alone or in combination, which coincided with the previous studies ²¹. In the bargain, some studies have proven that metformin was used in combination with

sulfonylureas, with the most possible and deadly combination being metformin + glimiperide ²¹. Antimicrobials and antibiotics were prescribed for patients with co-morbid conditions and infections like urinary tract infections and respiratory tract infections. Among antibiotics, Cephalosporins were found to be the most prescribed for the patients in the present study. It is imperative to notice the comorbid conditions developed later (might be infections and inflammation) as a part of uncontrolled glycaemic control or any other ailments. This information provides a clinician to treat a diabetic patient meticulously with a desirable outcome ²².

In the patterns observed in the prescriptions, prescription writing plays a vital role and tends to be very important for a patient to follow and do accordingly. It must be legible and precisely written by a physician/clinician. One previous study revealed that most physicians do not follow the regulatory body's guidelines. The right prescription can have a big impact on drug therapy as well as the patient's health. The WHO-defined study on prescribing medicine is a systematic approach that assesses a healthcare provider's performance in terms of drug utilization. The prescribing error is a preventable drug error that frequently occurs in hospitals worldwide. In the UK, 1.5 percent of prescriptions ordered during hospital stays were found to be incorrect, while in the United States, up to 6.2 percent were found to be incorrect 23 .

Prescription errors were shown to be responsible for 70% of drug errors. The total number of prescriptions analyzed in the current study, 35 were noticeable, with medication errors ²⁴. This might be due to a few reasons, such as problems in handwriting, abbreviated forms, and insufficient medication orders ²⁵. Excessive and inappropriate prescribing has serious repercussions, including waste of public funds, higher toxicity risk, increased adverse drug reactions, increased antibiotic resistance and a loss of trust in the medical profession. Irrational prescribing has been linked to a lack of communication between patients and prescribers, self-medication, and unethical drug promotion. Drug safety can be improved by a computerized prescription order input system, medication review manual and pharmacist

participation in physician rounds ²⁶. Hence, it is the responsibility of a clinician to adhere to the guidelines framed by WHO to minimize errors ²⁷. A computerized prescription order input system, manual medication review, and pharmacist participation in physician rounds can all help to improve drug safety ²⁴. As a result, the patient's drug needs must be adequately analyzed to avoid unfavourable side effects. Otherwise, the medicine may have more negative side effects than it cures the patient's ailment. As a result, the patient's drug needs must be adequately analyzed in order to avoid unfavourable side effects.

Otherwise, the medicine may have more negative side effects than it cures the patient's ailment. Pharmacists play a critical role in detecting and preventing possible medication errors. As a result, the current research will aid in the understanding of prescribing habits and errors, which will lead to the development of an appropriate healthcare policy, which will, in turn, improve the quality of medicine and healthcare facilities ^{28, 29}. Globally, the irrational use of medicines has gained more concern due to a lack of collaboration and coordination between healthcare professionals, patients, and entire communities. In the present study, the irrational use of medicines was only 3.4%, with 96.6 % rational use of medicines. Considering patient safety, it is mandated to tackle irrational medical use with an effort to improvise the health care system, which finally inclined for patient safety ³⁰.

On the contrary, in the present study, few drugdrug interactions were reported. It might have a connection with the medication errors identified. The drug-drug interactions can be avoided by following a few measures such as avoiding the combination of drugs entirely, adjusting the dose of the object drug, spacing dosing times to avoid the interaction, checking for early detection, and providing information on the patient risk factors ³¹. Overall, the prescribing patterns in the study were rational and acceptable compared to the other previous studies. There is also a need to extemporize further for the safety and welfare of the patient.

CONCLUSION: In conclusion, it can be derived that metformin was prescribed as the most

commonly used anti-diabetic drug alone and in combination. New drugs were minimally prescribed. Keeping in mind about the co-morbid conditions in diabetics the drugs were prescribed. In the present study, understanding and analyzing the prescription patterns was observed and was evident from the rational use of drugs. This approach will enable the healthcare system to optimize the treatment strategies for diabetes, avoiding drug-drug interactions.

Limitations of the Study: The current project was a short-term research proposal with a restricted sample size. Thus, similar studies can be conducted in a large population to confirm the findings and provide sufficient information to a clinician about prescribing patterns. Also, the study was confined to a single-centered, *i.e.*, unicentric, drug utilization pattern from multiple centers can be planned and obtained.

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