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Original Article

Analysis of Prescribing Patterns and Adverse Drugs Reactions in Diabetic Patients at Tertiary Care Hospital, Lucknow

Usmani Humaira Shadab[1], Vikas Aagrahari[1], Wajid Ali[1], Zakir Ali[1], Dr.Mohd. Muazzam Khan[1,*], Dr. Usama Ahmad[1], Dr.Mohd Ajmal[1],Dr. Parvez Saeed[1], Abu Raihan Shams[1]

1 Department of Pharmacy, Integral University, Lucknow, Uttar Pradesh, 226026 India

Corresponding Author*:Dr. Mohd. Muazzam Khan, Associate Professor, Department of Pharmacy, Integral University, Lucknow, Uttar Pradesh, 226026 India

Email ID:Khanmuazzam936@gmail.com
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Abstract:

Objective: To study the prescribing pattern and adverse drug reactions (ADRs) of anti-diabetic drugs in a tertiary care hospital in Lucknow, India. **Methods**: A prospective study was conducted over a period of 6 months at the inpatient and outpatient departments of the hospital. A total of 100 patients with diabetes were included in our study. Demographic characteristics were recorded and 100 prescriptions were analyzed. ADRs were reported and analyzed. **Results**: Among the 100 patients, 58 were male and 42 were female. The majority of the patients were in the age group of 41-60 years. Biguanides (38%) and sulphonylureas (31%) were the most commonly prescribed anti-diabetic drugs. A total of 8 ADRs were reported, including hypoglycemia, gastric irritation, and abdominal discomfort. Metformin had the highest number of ADRs among the oral hypoglycemic drugs. **Conclusion**: The study showed that the prescribing pattern of anti-diabetic drugs in the hospital was in line with the essential medicine list. ADRs were reported, with hypoglycemia being the most common ADR observed. Continuous monitoring and reporting of ADRs is necessary for the safe and effective use of anti-diabetic drugs.

Keywords: Prescribing pattern, adverse drug reactions, anti-diabetic drugs, diabetes, metformin

Introduction:

Prescription pattern analysis refers to analysing the current use of drugs in order to ensure rational drug therapy [1]. A prescription is a vital means of communication between a doctor and a patient, providing written instructions for the patient's medication regimen [2]. Prescription pattern analysis can guide healthcare professionals in implementing measures for the rational utilization of available drugs [1].

Diabetes mellitus (DM) is a category of metabolic diseases characterized by high levels of blood sugar. It is associated with abnormalities in the metabolism of carbohydrates and fats, which can lead to chronic complications such as microvascular and macrovascular disorders [3]. The major challenge for patients with diabetes is to prevent complications and improve their quality of life. Diabetes mellitus is a significant public health concern, causing a substantial amount of morbidity and mortality across all age groups [4].

In India, diabetes affects a large section of the population and is rapidly becoming a global diabetes capital. According to the Diabetes Atlas (DA) by the International Diabetes Federation (IDF), it is estimated that there will be an increase in the number of cases to about 70 million by 2025, and every fifth person in India will be suffering from diabetes. A similar rise in diabetes cases is expected worldwide, with estimates suggesting that the number of cases will escalate to about 366 million by 2030 [5].

DM is a group of metabolic disorders that result in hyperglycaemia due to an imbalance in the metabolism of carbohydrates and fats, ultimately leading to micro and macrovascular complications [6].

The World Health Organization (WHO) defines adverse drug reactions (ADRs) as unintended and harmful responses to drugs occurring at doses used for the diagnosis, prophylaxis, treatment, or modification of physiological functions. This definition excludes errors in drug administration, drug abuse, and overdose [7]. ADRs are a leading cause of mortality in many countries and can increase the length of hospital stay and healthcare costs [8]. The study of ADRs falls under the realm of pharmacovigilance, which is defined by the WHO as the science and activities related to the detection, assessment, understanding, and prevention of ADRs or other drug-related problems. Pharmacovigilance provides continuous information on the safety of drugs used [9,10]. The rising prevalence of anti-diabetic medications highlights the importance of clinical pharmacists in monitoring and reporting any suspected ADRs.

Aims and objectives

- **Primary Objective:** To analyze the prescription pattern of anti-diabetic drugs at tertiary care hospital Lucknow, India.
- **Secondary Objective:** To study adverse drugs reaction of Anti-diabetic drugs in diabetic patients at tertiary care hospital Lucknow, India.

Materials and Methods

Study Design

The study design involved a hospital-based prospective observational approach, with a duration of 6 months, focusing on diabetic patients at a tertiary care hospital in Lucknow. The study site comprised the inpatient and outpatient departments of an 800-bedded tertiary care and teaching hospital. The Department of Pharmacy, Integral University, and the Department of Medicine, Integral Institute of

Medical Sciences and Research, Integral University, were the departments involved. A total of 100 eligible diabetic patients, who were willing to participate and meeting the inclusion and exclusion criteria, were selected for the study. Inclusion criteria comprised diabetic patients aged 18 years or above, irrespective of gender, including pregnant and lactating patients. Exclusion criteria comprised mentally retarded and unconscious patients, those not prescribed any antidiabetic agent, patients admitted to the intensive care unit (ICU), severely ill patients, and patients not willing to participate in the study

Sources of data

Data were collected from physicians' prescribing records, patient medication profiles, medical records, treatment charts, nursing notes, physician notes, direct patient interviews, and weekly diary cards.

Data Collection

This study collected data using a structured questionnaire with open-ended questions to interview the participants. Prior to the commencement of the study, written consent was obtained from all participants. The questionnaire was designed to obtain patient profile data, such as age, sex, weight, patient address, and marital status. Additionally, information on prescribed drugs, including their generic/brand name, dose, and frequency, was also collected.

Participants were given weekly diary cards to record their daily drug intake to monitor adherence to the prescribed drug regimen. The criterion for non-compliance was defined as less than 80% of the recommended intake of prescribed drugs. The data were collected in a structured data collection form.

Evaluation of parameters

The following parameters were evaluated: types of anti-diabetic drugs prescribed, gender distribution among diabetic patients, age distribution amongst diabetic patients, average number of anti-diabetic drugs per prescription, average age range of patients utilizing anti-diabetic drugs, comparison of anti-diabetic drugs prescribed in monotherapy vs. fixed-dose combination therapy, comparison of anti-diabetic drugs prescribing by generic vs. brand name, compliance or adherence (using weekly diary cards), mode of administration of drugs, and most commonly used agents of a particular class. The criterion for non-compliance was defined as < 80% of the recommended intake of prescribed drugs.

ADRs identification

The ADRs was identified by an independent expert after reviewing the patient’s medical record and evaluating it against different guidelines including the American diabetes association guidelines, the world health organization guidelines, Micromedex, Medscape, naranjo scale, and different therapeutic guidelines for their appropriateness in the order of indication

Statistical analysis

Descriptive statistics was applied to the collected data using Microsoft Excel software. Results will be expressed in percentages. ANOVA / Student’s t- test will be applied on the collected data to

evaluate the statistical significance (P-value). A statistical significance level of less than 0.05 ($p < 0.05$) was considered as indicating statistical significance.

Ethical considerations

The study was complied fully with the WHO guidelines and will be done after obtaining approval from Institutional Research and Ethics Committee and Institutional review board with approval no IEC/IIMS&R/2021/65. The Protocol and the corresponding Informed Consent Form (ICF) will be submitted to the Integral Institute of Medical Sciences and Research (IIMSR) hospital, Integral University for the approval of conduct of this study.

Informed consent form

An oral and written consent was obtained from parents before the participation of the subjects in the study.

Results

Demographic Data

According to the data collected from the hospital on the basis of inclusion and exclusion criteria in the period 6 months. Total 100 patient were participated in our study. Among our study population, majority are male patient (58%) as compare to female patient (42%). According to the study population the lowest numbers of patients were from the age group 20-40 years and the highest percentages were in 41- 60 years group [Table 1].

Table 1: Demographic Data of Study Participant

Age (in Yrs.)	Male	Female	P- value
20-40	12	6	0.03
41-60	34	26	
61- Above	12	10	
Total	58	42	

Types of Anti-Diabetic Prescribed

In this prescribing pattern study, 100 prescriptions were analyzed. A total of 187 antidiabetic drugs prescribed, of which 38 % were Biguanides, 31% sulphonylureas, 17.11% were insulin. DPP-4 Inhibitors were 8%, 3.8% were thiazolidinedione's, 0.04% were α-Glucosidase inhibitors. Most of the anti-diabetic prescribed were from the essential medicine list [Table 2].

Table 2: Type of anti-diabetic prescribed

Drug Class	Number of Drugs	Percentage	P-value
Insulin	32	17.11%	0.01
Biguanides	71	38%	
Sulphonylureas	58	31%	
DPP-4 Inhibitors	15	8%	
Thiazolidinediones	7	3.8%	
α - glucosidase inhibitor	4	0.04%	
Total	187	100%	

Number of Drugs per Prescription

This study analyzed the prescribing pattern of 100 prescriptions. Among the prescriptions analyzed, it was observed that in 56 of them, only a single drug was prescribed, while in the remaining 44, more than one drug was prescribed.

Type of Adverse Drug Reactions

During the study, a total of 8 adverse drug reactions (ADRs) were reported. Among these, 3 were of the moderate type, while the remaining 5 were mild. The most commonly observed ADRs among the study population were hypoglycemia and gastric irritation. Hypoglycemia was reported in 3 patients, while gastric irritation was reported in 3 patients. 2 patients reported experiencing abdominal discomfort [Table 3].

Table 3: Type of adverse drug reactions

Types of ADRs	No of Patients	Percentage (%)	P-value
Hypoglycemia	3	37.5%	0.001
Gastric irritation	3	37.5%	
Abdominal discomfort	2	25%	

Classification of ADRs on the basis of severity

During the study, adverse drug reactions (ADRs) were reported. Of the reported ADRs, 62.5% were classified as mild, 37.5% as moderate, and no severe ADRs were detected.

ADRs Associated with Drugs.

This study analyzed the association of adverse drug reactions (ADRs) with different classes of antidiabetic drugs. The sulphonylureas class included glimepiride, glipizide, and gliclazide, with 2 cases reported. The associated ADRs were hypoglycemia, weight gain, dizziness, and gastric irritation. Metformin, a biguanide, was associated with 3 cases of ADRs, including gastric irritation, dizziness, decreased appetite, and tiredness. DPP4 inhibitors such as teneligliptin, sitagliptin, and vildagliptin were associated with 1 case of ADRs, including hypoglycemia, weight gain, and edema. Insulin drugs, including Lantus and Glargine, were associated with 2 cases of ADRs, including hypoglycemia and weight gain [Table 4].

Table 4: ADRs associated with drugs

Class of Drug	Name of Drug	No of Cases	Associated ADRs
Sulphonylureas	Glimepiride, Glipizide, Gliclazide	02	Hypoglycemia, Weight gain, Dizziness, Gastric irritation
Biguanides	Metformin	03	Gastric irritation, Dizziness, Decreased appetite. Tiredness
DPP4 Inhibitors	Teneligliptin, Sitagliptin, Vildagliptin	01	Hypoglycemia, Weight gain, Edema
Insulin	Lantus, Glargine	02	Hypoglycemia, weight gain

Discussion

The clinical study i.e.; Prescribing pattern and there ADRs of anti-diabetic drug used in diabetes is carried out at inpatient and outpatient department of tertiary care hospital, Lucknow India.

In our study, it was observed that over 100 persons (suffering from various diseases) visited the inpatient department of tertiary care Hospital over a period of 6 months. 100 patients, on the basis of inclusion and exclusion criteria, were selected for the present study.

According to a study, the majority of patients were male (62.97%), while female patients accounted for 37.02%. The highest proportion of patients belonged to the age group of 41 to 60 years (45.53%), while the lowest proportion of patients were 20 to 40 (6.38%) [11].

In our study, demographic characteristics showed that males suffering from Diabetes was more than females. It was observed that among them (male and female) 58 were male and 42 were females. Further, it was found that a majority of the patients who were having diabetes were in the age group of 41-60 years and the lowest % was in 20-40 years of age groups.

In a certain study, the most commonly prescribed anti-diabetic agent was Biguanides (Metformin), with a prescription rate of 17.04% initially and 13.33% after 18 months. Insulin (Short-acting Soluble/Regular Insulin) was prescribed in only one patient initially (0.74%). The most frequently prescribed drug was Metformin-500 mg three times a day, which was prescribed at both the initial visit and 18-month follow-up [12].

In this prescribing pattern study, 100 prescriptions were analyzed. A total of 187 antidiabetic drugs prescribed, of which 38 % were Biguanides, 31% Sulphonylureas, 17.11% were insulin. DPP-4 Inhibitors were 8%, 3.8% were thiazolidinediones, 0.04% were α-Glucosidase inhibitors. Most of the anti-diabetic prescribed were from the essential medicine list.

Another study conducted an analysis of adverse drug reactions (ADRs) associated with Glucophage/Metformin in medical literature. The study found that diarrhoea was the most common symptom associated with the use of Glucophage/Metformin and was often accompanied by vomiting and nausea [13]. In our study, Metformin, caused adverse reactions in three patients, leading to symptoms such as upset stomach, dizziness, reduced appetite, and fatigue.

ADRs were reported during the study, among which 5 cases of mild (62.5%), 3 cases of moderate (37.5%), and no cases of severe (00%) types of ADRs were detected.

In this prescribing pattern study, 100 prescriptions were analyzed. In 56 prescription only 1 drug was prescribed and in 44 prescription more than one drugs was prescribed. The prescribing pattern of anti-diabetic drugs in our study showed that biguanides were the most commonly prescribed drugs, followed by sulphonylureas and insulin. This finding is consistent with previous studies conducted in India and other countries. Most of the anti-diabetic drugs prescribed were from the

essential medicine list, indicating the availability and accessibility of these drugs in the hospital setting. The ADRs observed in our study were mild to moderate, with hypoglycemia being the most common ADR. Metformin had more ADRs than other oral hypoglycemic drugs, which is consistent with previous studies. Therefore, close monitoring of patients who are taking metformin is essential to prevent ADRs. The results of our study provide valuable information for clinicians to make informed decisions regarding the selection and management of anti-diabetic drugs.

Overall, 8 ADRs were reported during the study (table). Hypoglycemia was the most common ADR observed in 5 patients (moderate intensity in 3 patients and mild in 5 patient). Whereas gastric irritation occurs in 3 patients and abdominal discomfort occurs in 02 patients.

ADRs were reported during the study, among which 5 cases of mild (62.5%), 3 cases of moderate (37.5%), and 0 cases of severe (00%) types of ADRs were detected.

From the list of ADRs associated with drugs it was found that, metformin (03) has more number of ADRs among the other oral hypoglycaemic drugs. While other agents have Very low number of ADRs.

Limitation of study

Our study has many limitations. The study was carried out over a six-month period, and the seasonal variations in disease pattern and drug prescribing pattern were not considered. Furthermore, the no of patient was low and the study was restricted only one hospital, hence the result cannot be considered representatives of the whole country. However, in the spite of all these limitations, our study highlighted some rational prescribing practices. Continuing education on rational drugs use and development of easy to use treatment guidelines for common disease suggested. In, our future endeavours, we plan to study the effect of regulatory and education interventions of drug use patterns in management of diabetes mellitus.

The use of only the drugs available in the hospital pharmacy was identified as a significant limitation of our study. While this approach ensured that the drugs analyzed were accessible to patients, it may have also introduced potential biases that could impact the study's results. Future research should consider expanding the range of drugs studied to more accurately capture the broader population of patients, taking into account the availability and accessibility of these drugs in different healthcare settings. By doing so, we can increase the reliability and generalizability of our findings and ultimately provide more effective and personalized treatment options for patients.

Conclusions

The present study was conducted to analyse the rational prescribing of drugs in the medicine ward of a tertiary care hospital using WHO core indicators. Males were more prone to diabetes mellitus. Metformin was the most commonly used drug. The prescribing trend also appears to be

moving towards combination therapy particularly two drugs therapy.

Confidentiality of data

The data identifying each study subject by name was kept confidential and accessible to the study personnel and if necessary, to the Integral Institute of Medical Sciences and Research (IIMSR) hospital Institutional Review Board. The Protocol and the corresponding Informed Consent Form (ICF) was submitted to the Integral Institute of Medical Sciences and Research (IIMSR) hospital, integral university for the approval of conduct of this study.

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Author contributions

All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

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Data availability

The patient's data have not been made public. They are kept with all the authors. If anyone need this data then request to corresponding author via e-mail.

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