Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i3.4786

AN ASSESSMENT OF DRUG PRESCRIPTION PATTERN AND THEIR SAFETY CONCERN AMONG PATIENT TREATED WITH ANTIDIABETIC DRUGS IN TERTIARY CARE TEACHING HOSPITALS

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Abstract

Introduction: In India, Diabetes Mellitus is probably becoming a pandemic. India's diabetes population is predicted to grow from approximately 69.2 million in 2015 to 123.5 million in 2040. It can be treated by various types of Antidiabetic Drugs that has not only beneficial effect; it also causes adverse drug reactions.

Method: This was a prospective and observational study conducted in Department of Pharmacology, Santosh Medical College in Collaboration with Department of Medicine, Muzaffarnagar Medical College (MMC), Muzaffarnagar, UP. A total of 109 Diabetic patients treated with Antidiabetic drugs presented in Medicine OPD of MMC Hospital were included and data were assessed for rational prescription as per WHO prescription indicators and also for drug safety concern.

Results: Maximum number of drug prescribed in this study was Biguanide derivative and its FDCs Sulphonylureas + Biguanide + Thiazolidinedione showed less number of ADRs (B/R, 0.13) is a safe drug either alone or with FDCs.

Conclusion: ADRs could be minimized with rational prescription and FDCs.

Key search- Antidiabetic Drugs, ADRs, B/R ration, Drug Safety

❖ Introduction

Diabetes mellitus (DM) is a chronic illness that impairs the metabolism of carbohydrates, proteins, and fats because of defects in insulin response and/or secretion. To prevent acute complications and lower the risk of morbidity and mortality, DM patients need lifelong medical care as well as ongoing support and self-management [1, 2].

Diabetes has a very high rate of morbidity and death due to its potential microvascular or macrovascular consequences, which poses serious healthcare challenges for families as well as society at large. The patient's quality of life will be enhanced and the advancement of diabetic complications will be delayed or prevented with optimal glycemic management [3, 4].

In India, DM is probably becoming a pandemic [5]. India's diabetes population is predicted to grow from approximately 69.2 million in 2015 to 123.5 million in 2040 [6].

By 2025, it is widely agreed upon to stop the rise in obesity and diabetes. India accounts for one in six cases of diabetes worldwide. According to the data, the country is among the top 10 countries in the world for the number of diabetics, with an estimated 77 million individuals living with the disease ranking second. Leading the list with more than 116 million diabetics is China.[7]. Maintaining optimal glucose control is the most effective approach to manage diabetes. Anti-diabetic medications are now successful; nevertheless, glycemic control is associated with a number of factors, including patient adherence, diabetes education, lifestyle adjustment, and prescription kind and cost [8-10]. Adverse Drug Reactions (ADRs) are defined as unfavourable and detrimental consequences that arise when a medicine is delivered at therapeutic quantities for the purpose of treating, mitigating, or diagnosing any illness [11]. Drug safety is the beneficial role of drug which shows minimal negative consequences of drugs effect.

The obstacles to patient compliance and therapy adherence are medication costs, complicated regimens, and irrational prescribing, which can result in poor glycemic control and higher rates of morbidity and death [12, 13]. Drug prescribing studies are helpful in identifying illogical prescribing as well as providing information about present practices and theirs safety concern are more important for patient care. Therefore, the present study was designed to assess of Drug Prescription Pattern and their safety Concern among Patient Treated with Antidiabetic Drugs in tertiary care Teaching Hospitals.

❖ Material and Methods

This was an Eighteen-month prospective and observational study from June 2019 to December 2020 conducted in department of Pharmacology, Santosh Deemed to be University, Ghaziabad in Collaboration with Department of Medicine, Muzaffarnagar Medical College Muzaffarnagar, Uttar Pradesh.

The institutional ethics committee granted ethical permission for the investigation to begin. The study included 109 diabetic patients who were visited in OPD’s Department of General Medicine Muzaffarnagar Medical College, Muzaffarnagar, Uttarpradesh. Prescription patterns have been analysed on a regular basis using prescribing indicators from the World Health Organisation (WHO).

Patients who satisfied the inclusion criteria were included in the study, and those who met the exclusion criteria were removed, in accordance with the study's standards.

Only patients who were over 18 years old were included in the study. Individuals having a diagnosis of diabetes and additional co-morbidities were chosen. Additionally, those receiving treatment with oral hypoglycemic medications and insulin therapy were included in the research.

Statistical Analysis was done with the help of Microsoft Excel.

❖ **Observation and Results:**

A total 109 Type2 DM patients of both gender above 18 years old were collected from Medicine OPD of Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, of whose prescription pattern and Safety concern were observed and assessed as follows:

Table 1.0 shows demographic data

S. No.	Characteristics	Frequency	Percentages (%)
1	**Gender**		
	Male	50	45.9
	Female	59	54.1
2.	**Age (yrs.)**		
	<20	01	0.9
	21-40	26	23.9
	41-60	60	55.0
	61-80	22	20.2
	>80	0	0
3	**As per diseases presentations**		
	Diabetes alone	109	100
4	**As per duration of diseases(yrs.)**		
	<1	06	5.5
	1-5	62	56.9
	6-10	28	25.7
	11-15	12	11.0
	>15	01	0.9
5	**As per body wt. (kg)**		
	<40	0	0
	41-60	14	12.8
	61-70	25	22.9
	71-80	39	35.8
	>80	31	28.5

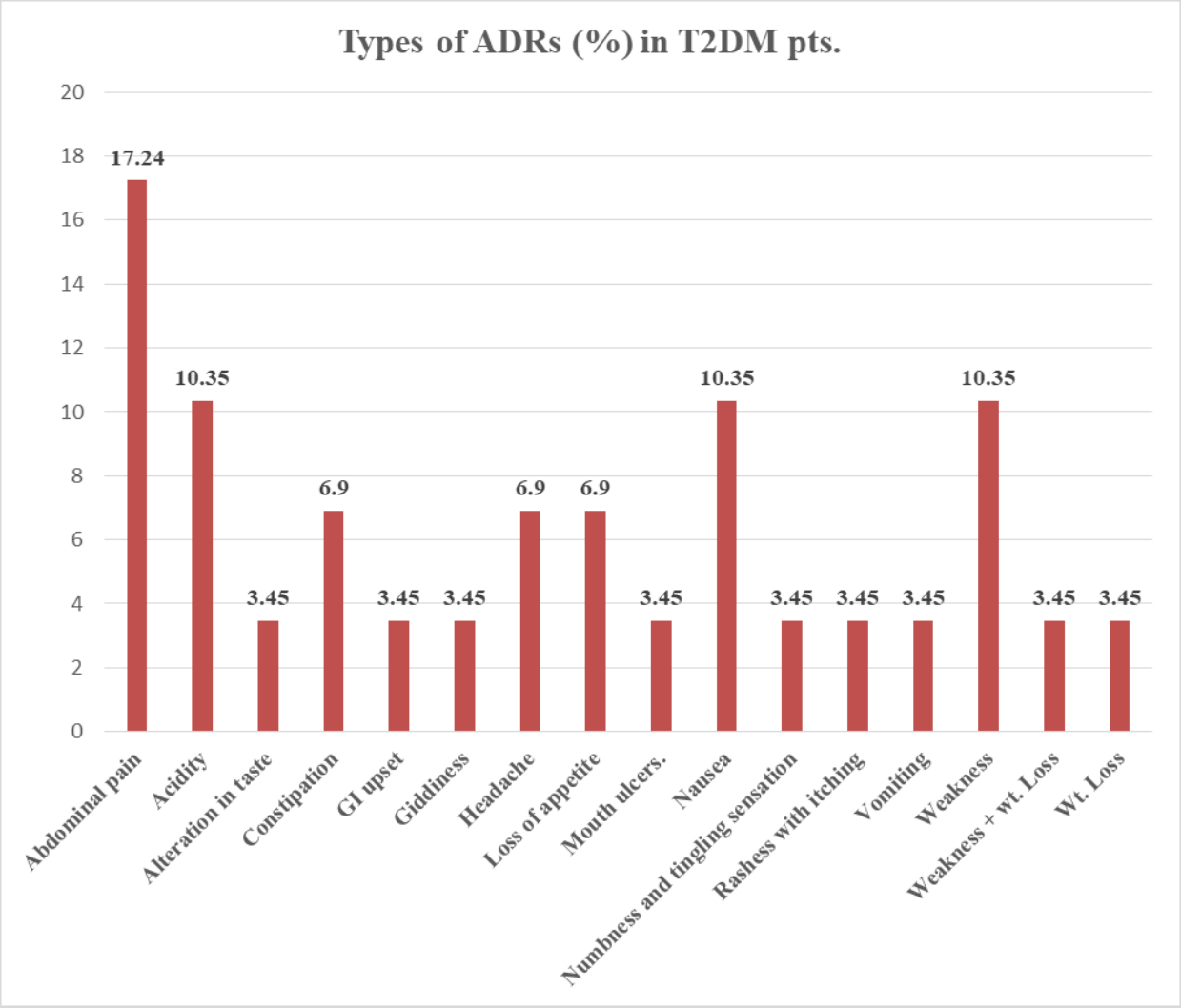
Table: 2.0 W.H.O. Prescription Indicators:

S. No.	Prescription Indicators	Frequency
1	Total number of prescriptions analysed (n)	**109**
2	Total number of medicines used in the study (n)	**16**
3	Average number of medicines per prescription (n)	**3**
4	Percentage of medicines prescribed on their generic name (%)	**35**
5	Number of drugs prescribed from the WHO essential drug list (%)	**75.9**
6	Percentage of prescription contains injectable preparations (%)	**5.5**
7	Number of prescriptions with oral preparations (%)	**94.5**
8	Number of FDCs	**62**
9	Number of prescriptions with less than five drugs	**101**
10	Number of prescriptions with more than five drugs	**08**

Table: 3.0. Types of Drug Showing ADRs

S. No.	Types of Drug	ADRs (+)	ADRs (-)	(Benefit/Risk) Ratio
1	Alpha-glycosidase Inhibitors	01	05	0.17
2	Biguanide	10	25	0.29
3	Biguanide + DPP4 Inhibitor	02	05	0.29
4	Insulin Derivative	01	05	0.17
5	Sulfonylureas + Biguanide	14	33	0.3
6	Sulfonylureas + Biguanide + Thiazolidinedione	01	07	0.13

Fig.1. Types of ADRs Observed in T2DM Patients



❖ Discussion:

Studies on anti-diabetics drug prescription and its assessment can lead to the promotion of rational drug therapy and effective treatment procedure that eventually can help to achieve optimal glycemic control and therapy adherence, which reduces the morbidity and mortality, total cost of treatment in diabetic patients.

A total 109 Type2 DM patients were observed during study period for the prescription Writing and theirs safety concern, among them maximum patients were Female 54.1% (n=59) followed by Male 45.9% (n=50) as shown in Table 1.0, and was similar to study performed by Mellitusi***ji Keezhipadathil (2023)***[14] and opposite to study performed by ***Ardoino, I.et al (2023)***[15]**.**

Present study showed that Maximum number of patients belonged to the age group 41-60 Yrs (55%) followed by age group 21-40 Yrs. (23%) and were belongs to older age group and was responsible for the occurrence of the ADRs. It showed that ageing was important factor for the occurrence of ADRs as shown in Table 1.0.

The maximum number of drug prescribed in this study were belong to rational prescription included Sulfonylureas + Biguanide (n= 47), followed by Biguanides alone (n=35), Suphonylureas + Biguanide + Thiazolidinedione (n=8) Biguanide + DPP4 inhibitors (n=7), Alphaglycosidase Inhibitors (n=6) and Insuline Derivates (n=6) as shown in table 3.0

The detection of Adverse Drug Reactions (ADRs) has become significant because of introduction of such a large number of drugs in the last two to three decades. Adverse drug reactions may occur daily in hospitals adversely affecting patient's life, often causing considerable morbidity and mortality.

Study also showed that a large number (94.5%) of drug prescribed through Oral route and was responsible for the occurrence of GIT related ADRs as shown in table 2.0 and Fig. 1.0 and hence routes of drug administration has important role for the drug beneficial effects.

Study data showed that Suphonylureas + Biguanide + Thiazolidinedione FDCs were responsible for fewer occurrences of ADRs (B/R-0.13) and indicates that occurrence of ADRs associated with Antidiabetic drug could be minimized by combining more drug FDCs as shown in Table 3.0.

Thus B/R mainly relies a qualitative assessment of drug safety in patients care as no method provides fully satisfactory solution of benefit –Risk ratio assessment.

❖ Conclusion:

Drug safety could be assessed by rational prescription and Benefit Risk Ratio evaluation which is essential process throughout the whole life cycle of drug therapy.

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