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Original Research Article

An Observational Assessment of the Drug Utilization Pattern and Cost Effectiveness of Anti-Diabetic Drugs among Diabetic Patients in a Tertiary Care Teaching Hospital of Bihar

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Abstract

Aim: The aim of the study was to evaluate the utilization pattern of anti-diabetic drugs among diabetic outpatients in a tertiary care teaching hospital.

Material & Methods: The present study was taken in the Department of Pharmacology, SKMCH, Muzaffarpur, Bihar, India for three months. The patients were taken from the department of medicine. A total of 200 patients were included in the study. Data were collected by direct patient interview and from case records and discharge certificates. Informed consent was obtained from all patients included in the study.

Results: A total of 200 diabetic patients were evaluated during the study period. In the present study, neither male nor female preponderance was seen (males 51%; females 49%). Majority of our patients were in the age group of 51-60 years (40%). The mean age of the patients in the present study was 57.6 years (age range: 18-79 years). Our study found that 68% of patients studied received metformin alone and/or in combination followed by sulfonylureas (50%). 17 ADRs were reported during the study. Hypoglycemia was the most common ADR observed in eight patients (moderate intensity in seven patients and mild in one patient). Seven hypoglycemic episodes were probably related to the study medication.

Conclusion: Metformin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapies.

Keywords: Anti-Diabetic Drugs, Diabetes, Utilization Pattern.

Introduction

Diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels. [1] Various classes of anti-diabetic drugs including insulin and oral hypoglycemic agents (OHAs) are currently being used in the treatment of diabetes, which acts by various mechanisms to reduce the blood glucose levels in order to maintain optimal glycemic control. The utilization study of these medications is important in clinical practice because it serves as the foundation for implementing changes to drug

dispensing policies at the local and national levels. Irrational drug use can lead to adverse outcomes including an increase in the risk of hypoglycemia, a decline in medication adherence, the risk of drug-drug interactions, all of which can invariably lead to an increased risk of hospitalization, fatality rate, and healthcare costs. [2] Drug Utilization Research (DUR) was defined by the WHO in 1977 as "The study of the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic implications". [3]

According to World Health Organization, drug utilization is defined as the marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences. [4]

Diabetes mellitus is a main communal health problem in the developing as well as developed countries. All over the world, one in 20 deaths due to DM; 6 deaths every minute, 8700 deaths every day, 3.2 million deaths are due to diabetes every year. At least one death in ten adults from 35 to 64 years of age because of diabetes. [5] Management of DM requires both pharmacological and nonpharmacological interventions. Hypoglycemia is the common adverse drug reaction (ADR) of antidiabetic drugs and it is associated with substantial morbidity and mortality. [6]

The choice of agents largely depends upon:

- A1c reduction required and the ability of the drug to provide the reduction.
- Ability to address the components (fasting and post prandial) of glycemia.
- Ability to minimize hypoglycemia and weight gain.
- Safety in a variety of clinical situations including cardiovascular safety.
- Adverse events associated with the drug.
- Cost effectiveness of the therapy.

Assessing the economic burden of diabetes is challenging because of the complexity involved in identifying the direct and indirect costs of disease. As these patients have several other complications and co-morbidities, the annual cost of diabetes health care rises. The principal aim of drug utilization research is to facilitate rational use of drug in the populations.

Thus the aim of the study was to evaluate the utilization pattern of anti-diabetic drugs among diabetic outpatients in a tertiary care teaching hospital.

Material & Methods

The present study was taken in the Department of Pharmacology, SKMCH, Muzaffarpur, Bihar, India for three months. The patients were taken from the department of medicine. A total of 200 patients were included in the study. Data were collected by direct patient interview and from case records and discharge certificates. Informed consent was obtained from all patients included in the study.

Inclusion Criteria

Newly diagnosed and known cases of DM with other comorbidities who is receiving antihyperglycemic medicines and admitted as inpatients will be included. Inpatients of both sex and age group of 18 years and above were included.

Exclusion Criteria

Patients with gestational diabetes were excluded from the study.

Methodology

Details about demography, medical history, diagnosis data, duration of diabetes, family history of diabetes, co-morbid conditions, laboratory investigations, and anti- diabetic drug utilization, was collected. Each prescription contained the drug, quantity, duration and date of dispensing. Each antidiabetic medication will be classified into one of the following classes:

Metformin, Dipeptidyl peptidase-4 (DPP-4) Inhibitors, Glucagon-like peptide (GLP-1) receptor antagonists, Sodium-glucose co-transporter 2 (SGLT-2) inhibitors, Alpha-glucosidase inhibitors (AGIs), Thiazolidinedione (TZD), Sulfonylureas (SUs) and Insulin. The adverse drug reactions (ADRs) related to antidiabetic drugs was monitored and documented in suitably designed ADR monitoring forms. The severity and causality of the ADR was assessed. The severity of ADR were categorized as mild, moderate or severe as per standard definitions. The causality assessment of ADRs was done as per Naranjo scale.

Assessment of the cost of the therapy

Total cost per patient for antidiabetic drugs was calculated. The results were expressed as Mean± standard deviation.

Measurement of drug consumption in medicine ward in DDD/1000 patients/day Drug consumption in medicine ward was measured in DDD/1000 patients/day. The drugs were classified according to the anatomical therapeutic chemical (ATC) classification system. As per ATC classification system, the medicines were divided into different groups according to the organ or system on which they act and as per their chemical, pharmacological and therapeutic properties. The DDD/1000 patients/day was calculated using the formula:

$$\frac{\text{Total amount drug used during study period X 1000}}{\text{DDD (mg/units) X 365 days X total sample size}}$$

Statistical analysis

The descriptive data were reported in percentages for categorical variables and mean(\pm\)SD for continuous variables. All statistical calculations were done using IBM Statistical Package for the Social Sciences (SPSS) version 24 (IBM Corp., Armonk, NY).

Results

Table 1: Age groups and gender distribution

Age groups	N%
18‑30	4 (2)
31‑40	8 (4)
41‑50	30 (15)
51‑60	80 (40)
61‑70	60 (30)
71‑80	18 (9)
Gender	
Male	102 (51)
Female	98 (49)

A total of 200 diabetic patients were evaluated during the study period. In the present study, neither male nor female preponderance was seen (males 51%; females 49%). Majority of our patients were in the age group of 51-60 years (40%). The mean age of the patients in the present study was 57.6 years (age range: 18-79 years).

Table 2: Drug utilization pattern of anti‑diabetic drugs

Class	Drug	N%
Biguanides	Metformin	136 (68)
Sulfonylureas	Glimepiride	65 (32.5)
	Glibenclamide	18 (9)
	Glipizide	12 (6)

	Gliclazide	5 (2.5)
	Total	100 (50)
Insulin	Insulin	84 (42)
α-glucosidase inhibitors	Voglibose	12 (6)
	Acarbose	8 (4)
	Total	20 (10)
DPP-4 inhibitors	Sitagliptin	7 (3.5)
	Vildagliptin	5 (2.5)
	Linagliptin	2 (1)
	Total	14 (7)
Thiazolidinediones	Pioglitazone	8 (4)
	Rosiglitazone	2 (1)
	Total	10 (5)
Glucagon like peptide 1 agonist	Exenatide	1 (0.5)

Our study found that 68% of patients studied received metformin alone and/or in combination followed by sulfonylureas (50%).

Table 3: Adverse drug reactions

ADR	Number of patients	Percentage
Hypoglycemia	8	4
Nausea	3	2.5
Gastric irritation	3	2.5
Diarrhea	2	1
Abdominal discomfort	1	0.5

17 ADRs were reported during the study. Hypoglycemia was the most common ADR observed in eight patients (moderate intensity in seven patients and mild in one patient). Seven hypoglycemic episodes were probably related to the study medication.

Discussion

Diabetes mellitus (DM) is becoming an important public health problem in developing countries, especially in India. The number of people with diabetes has risen from 108 million in 1980 to 463 million adults in 2021. [7] Type 2 DM is very common among the elderly. [8] Various classes of anti-diabetic drugs including insulin and oral hypoglycemic agents (OHAs) are currently being used in the treatment of diabetes, which acts by various mechanisms to reduce the blood glucose levels in order to maintain optimal glycemic control. The utilization study of these medications is important in clinical practice because it serves as the foundation for implementing changes to drug dispensing policies at the local and national levels. Irrational drug use can lead to adverse outcomes including an increase in the risk of hypoglycemia, a decline in medication adherence, the risk of drug-drug interactions, all of which can invariably lead to an increased risk of hospitalization, fatality rate, and healthcare costs. [9] Drug Utilization Research (DUR) was defined by the WHO in 1977 as "The study of the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic implications". [10]

A total of 200 diabetic patients were evaluated during the study period. In the present study, neither male nor female preponderance was seen (males 51%; females 49%). Similar results were obtained in other studies conducted in

Kerala and Ahmedabad. [11,12] However, the results are in contrast to a few studies conducted in India and other countries which have reported either male or female preponderance. [13-17] Majority of our patients were in the age group of 51-60 years (40%). The mean age of the patients in the present study was 57.6 years (age range: 18-79 years) which is in concordance with the earlier published literature. [11,13,15,18] The mean age of the patients in the present study was 57.6 years (age range: 18-79 years), a finding similar to that obtained in studies conducted in Nepal and Ahmedabad, which have reported the mean age of patients as 56.9 and 56.8 years, respectively. [13,16] However, a study from Tenali, Andhra Pradesh reported the mean age of patients as 53.4 years. [18]

As diabetes progresses, functional decline in beta cells is usually apparent, and the need for combination therapy is unavoidable. Therefore, combination modalities have become an integral part of diabetes management. The basic rationale for combination therapy is to provide additive effects with different mechanisms of action and to allow lower doses for disease management. Unlike sulfonylureas, thiazolidinediones, and insulin, metformin is weight neutral, which makes it an attractive choice for obese patients. Furthermore, the management of Type 2 diabetes can be complicated by hypoglycemia, which can seriously limit the pursuit of glycemic control. Here, too, metformin has advantages over insulin and some types of insulin secretagogues; by decreasing excess hepatic gluconeogenesis without raising insulin levels, it rarely leads to significant hypoglycemia when used as a monotherapy. As a result, metformin is widely considered an ideal first-line agent for the treatment of Type 2 diabetes. In addition, the cost of metformin is very low, thus making it affordable by the patients in economically weak countries like India. Our study also supported the same conclusion; 68% of patients studied received metformin alone and/or in combination followed by sulfonylureas (50%). Our results are in concordance with the results of some other studies. [13,15,16,17,19] Among the sulfonylureas, glimepiride was the most frequently prescribed (32.5%) followed by glibenclamide (10%).

In the studies by Vengurlekar et al [15] and Patel et al. [16] glimepiride + metformin was the most commonly prescribed combination. In the study by Kumar et al. [18] insulin + metformin (16.6%) was the most prescribed anti-diabetic combination followed by glimepiride + metformin (10%). However, the most prescribed three drug combination was insulin + glimepiride + metformin (8.3%) which is consistent with our results. Four and five drug combination therapy was received by 4.6% and 0.5% patients, respectively. Sulfonylureas and metformin were part of majority of the four and five drug combinations. [20] Two patients were not on anti-diabetic drugs. 17 ADRs were reported during the study. Hypoglycemia was the most common ADR observed in eight patients (moderate intensity in seven patients and mild in one patient). Seven hypoglycemic episodes were probably related to the study medication.

Conclusion

Metformin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy. However, the study has its own limitations since follow-up of the patients was not possible and hence the effectiveness of the anti-diabetic agents could not be assessed. In the future one can investigate the appropriateness of prescriptions and adherence to evidence based recommendations.

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