

Drug Utilization Study in Type 2 Diabetes Mellitus Patients at a Tertiary Care Teaching Hospital - A Prospective Observational Study

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ABSTRACT

Background: Diabetes mellitus (DM) is a common and important health problem affecting the citizens of developed as well as developing nations. Diabetes a chronic disease is associated with significant morbidity, complications with poor glycemic control. Drug utilization studies help to determine rational drug use especially in poorer and rural populations. This prospective non interventional study aimed to gather and study the drug utilization pattern in diabetic patients.

Methods: A prospective observational study was conducted for three months at Navodaya Medical College Hospital and Research Centre with a sample size of 80. Patients diagnosed as type 2 diabetes mellitus with other comorbidities were included in the study. Data on patient demographics, diagnoses, and laboratory data were collected and analysed. Study participants were followed throughout their hospital stay, and data were collected from the treatment charts as well as through interactions with the study participants.

Results: Among the 80 patients observed, 53(66.25%) were males. Most of the patients who are having 50-60 age group. Co-morbid conditions were found in 60% patients, among which hypertension (45.83%) was the most common comorbid condition. Among 80 patients nearly 68(85%) patients were diagnosed as diabetes in their past. Metformin was the most commonly prescribed drug for patients 73(91.25%), followed by sulfonylurea class of drugs 27 (33.8%). Most of the patients were treated with two-drug combination therapy 51(63.75%) patients. Very less patients were treated with three-drug combination therapy 6(7.50%) patients.

Conclusion: To conclude, the study reveals that Metformin continues to be the choice of oral hypoglycemic agents with least adverse effects and insulin was used to treat uncontrolled state. This

study revealed that the pattern of antidiabetic prescription was rational.

Keywords: Diabetes mellitus, Drug utilization, Metformin, Insulin, Oral hypoglycemic agents,

I. INTRODUCTION

The World Health Organization (WHO) defined drug utilization studies as the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resultant medical, social and economic consequences. The studies are meant to ascertain whether the patterns of prescription, dispensing and usage of medicines are valid and reliable relative to standard guidelines.⁴ The main aim of drug utilization research is to assess whether the drug treatment is rational or not. To reach this goal, methods of auditing drug therapy towards rationality are necessary. History has taught us that successful research in drug utilization requires multidisciplinary collaboration between clinicians, clinical pharmacologists, pharmacists and epidemiologists.¹

Diabetes mellitus (DM) is an important public health problem in developing countries. Several anti-diabetic drug utilization studies have been published in the healthcare setting from various parts of world. Drug utilization studies provide useful insights into the current prescribing practices and also identify irrational prescribing.²

Diabetes mellitus (DM) is a group of chronic metabolic disorders characterized by a deficiency of insulin secretion and/or insulin effect, which causes hyperglycemia and is associated with abnormalities in carbohydrate, fat and protein metabolism; and results in chronic complications including microvascular and macrovascular and neuropathic disorders. It is a disease related to the endocrine system and is noted as one of the leading causes of death and disability worldwide. India has

the highest number of diabetic patients in the world. It has been estimated that by 2025, there will be more than 57.2 million cases of diabetes mellitus. Diabetes mellitus can be managed if proper diagnosis, monitoring, medication, diet and exercise are maintained. The management of Type-1 diabetes depends mainly on insulin, whereas the management of Type-2 diabetes is mainly using oral hypoglycaemic agents.³

The type I diabetes is usually managed with insulin whereas type II diabetes is managed with oral hypoglycaemic agents & insulin preparations or both as per the patient's need. A wide range of oral hypoglycaemic agents that are available for the management of type 2 diabetes gives a way for the practitioners to choose the medications according to patient's need. The mainstay of diabetes management is aimed to obtain a good glycaemic control and reduce the chronic complications of diabetes and the comorbid diseases such as cardiovascular, cerebrovascular diseases, which are preventable and manageable with proper punctual medication, good regular follow ups and investigations.⁵

The aims of the present study were to describe the treatment and outcome in terms of degree of metabolic control in patients with diabetes, assess the agreement between the doses of antidiabetic drugs reported by the patient and those written in the medical record, and describe the drug utilization characteristics in relation to the standards of care.⁶

II. MATERIALS AND METHODS

Study site

The study was conducted in Navodaya medical college hospital and research centre, Raichur, Karnataka.

Study duration

The study duration was 3 months after getting consent from the ethics committee.

Study method and size

A prospective observational study was conducted with consecutive sampling, and 80 patients were included in the study.

Inclusion Criteria

- All the inpatients who were diagnosed with diabetes and also with Co morbidity diseases were included.
- Patients of both gender who are above the age of 18 years.

- Prescriptions with drugs prescribed throughout hospitalization has been only included for the study.

Exclusion Criteria

- Participants who were not willing to participate in the study are excluded from this study.
- Patients who were pregnant and lactating/nursing a child.
- Outpatients at the time of study.

Study Design

Prospective observational research was conducted for three months. 80 data altogether were gathered. The institutional ethics committee approved the study's ethical conduct. A data collection form was designed to collect patient demographics, past medical and medication history, personal history, diagnosis, laboratory data and treatment chart.

Sampling and Selection Techniques

Data was analysed using the SPSS statistical software version 20 and Microsoft Excel 2007 (statistical package for social sciences Inc., USA) software package was used for data stratification and analysis. Descriptive statistics were used.

Analysis of data

Prospective data was gathered from all the study participants during the study period. The data were analysed and monitored for the following variables:

- Age
- Patient past medical history
- Patient diagnosis
- Significant Comorbidities
- Medication chart

III. RESULTS

Distribution of participants according to age group:

A total of 80 patients who met the inclusion criteria were recruited in the study by calculating the sample size based on the prevalence. Out of 80 patients who were willing to participate in study most if they were in the age group of 50 - 60 (31.25%) followed by age group of >60 (27.50%). This is depicted in table 1.

Table 1 : Distribution of participants according to age group (n=80)

SI. No	Age in years	No. of patients	Percentage (%)
1	< 40	12	15%
2	40 – 50	21	26.25%
3	50 – 60	25	31.25%
4	>60	22	27.50%
Total		80	100%

Gender-wise distribution of diabetic patients:

In our study among 80 patients observed, majority of patients were male 53(66.25%). This is depicted in table 2.

Table 2: Gender-wise distribution of diabetic patients(n=80)

SI. No	Gender	No. of patients	Percentage (%)
1	Male	53	66.25%
2	Female	27	33.75%
Total		80	100%

Distribution of participants according to their past medical history (Diabetes):

In a total of 80 patients were observed and reviewed the case sheet, it was found that 68 (85%)

patients were diagnosed as diabetes in their past. Only few were found that non-diabetes in their past medical history. This is depicted in table 3.

Table 3: Distribution of participants according to their past medical history (Diabetes)(n= 80)

SI. No	Past History	No. of patients	Percentage (%)
1	Diabetes	68	85%
2	Non- Diabetes	12	15%
Total		80	100%

Distribution according to significant comorbidities:

In a total of 80 patients, 48 were suffering from associated comorbidities. Hypertension

(45.83%) being the commonest comorbidity followed by Cardio vascular disease (20.83%), dyslipidemia (16.66%), neuropathy (6.25%) and nephropathy (10.41%). This is depicted in table 4.

Table 4: Distribution according to significant comorbidities (n=48)

SI. No	Comorbidities	No. of patients	Percentage (%)
1	Hypertension	22	45.83%
2	Dyslipidemia	8	16.66%
3	Neuropathy	3	6.25%
4	Cardio vascular Disease	10	20.83%
5	Nephropathy	5	10.41%
Total		48	100%

Distribution of treatment pattern for diabetes in hospitalized patients:

In the overall utilization pattern among 80 patients, in monotherapy metformin (69.56%) was the most frequently prescribed oral hypoglycaemic agent followed by sulfonylureas (13.04%). Thiazolidinedione's (8.70%), Insulin (8.70%). Most

of the patients received more than 1 antidiabetic drug. Monotherapy was given to 23 patients (28.75%) only. More than a half 51(63.75%) of the study samples received 2 antidiabetic drugs and 6 patients (7.5%) of all the subjects received 3 drug therapy

Table 5: Distribution of treatment pattern for diabetes in hospitalized patients (n=80)

Sl. No	Drug Therapy	No of patients	Percentage (%)
Mono therapy (n=23)			
1	Insulin	2	8.70%
2	Metformin	16	69.56%
3	Sulfonylureas	3	13.04%
4	Thiazolidinedione	2	8.70%
Two-drug combination therapy (n=51)			
5	Metformin + Insulin	15	29.42%
6	Metformin + Sulfonylureas	19	37.25%
7	Metformin + Thiazolidinedione	17	33.33%
Three-drug combination therapy (n=6)			
8	Insulin + Metformin + Sulfonylureas	6	100%

IV. DISCUSSION

Diabetes mellitus is a major public-health problem worldwide. Its prevalence is rising in many parts of the developing world, and India is no exception to this. India will become diabetes capital of the world in near future. Individuals with Type 2 DM are considered on high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of complications.

Diabetes being chronic debilitating disease requires lifelong management. The sedentary stressful life style, lack of exercise, irregular food habits...all these environmental factors along with the predominant genetic inheritance increase the risk of type II diabetes mellitus. Although diet and exercise along with life style modifications remains the mainstay of diabetes management, regular treatment with the drugs is essential to delay the anticipated long term complications of diabetes.

In this study, the prevalence of diabetes was found to be more common among male population. It was found that the prevalence of type 2 diabetes was high in the middle aged persons. The mean age of the study population was found to be (50-60) years. This was similar with few recent studies done in India and outside. Most of the patients (%) were suffering from other comorbid conditions like hypertension (22 patients), dyslipidemia (8 patients), etc. the comorbidities played a major role on the disease burden and also it increases the risk in quality of life. Amongst antidiabetic medications, metformin was the most commonly prescribed drug which was given in 73 (91.25%) patients followed by sulphonylureas in 27 (33.8%) insulin in 24 (30%) and Thiazolidinedione in 19 (23.7%) patients. The most commonly prescribed two drug combination was metformin and insulin(37.27%). The most commonly co-

prescribed medications along with antidiabetic drugs were antihypertensive drugs.

The other area which needed attention was patient education and knowledge. Most of the patients lacked adequate knowledge of dosage schedule, possibly due to communication error. Pharmacists can be urged to spend more time with dispensing since at the moment only 1.26 minutes were spent for each encounter. This simple measure would probably help patients understand their dosage schedule better. The overall prescribing practice was found to be rational and good compared to other parts of India, but there are many scopes to improve.

V. CONCLUSION

Diabetes is a chronic and potentially disabling disease that represents an important public health and clinical concern. This study showed that type 2 DM is more prevalent in men than in women. Type 2 DM is not confined to urban population or the upper class of the society. The study had shown metformin as the most commonly prescribed oral antidiabetic drug both in monotherapy or combination therapy. This study reveals a rational use of medications although the prescriptions with generic names. However, the prescription pattern was observed to be largely in compliance with the NICE guidelines. It is needless to mention that such guidelines are aimed for choosing the treatment alternatives. Patient counselling needs to be encouraged to overcome the ever-rising problem of non-compliance in diabetes mellitus patients.

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CONFLICT OF INTEREST

The authors declare that no conflict of interest exists.

ABBREVIATIONS

DM – Diabetes Mellitus **NICE** – The National Institute for Health and Care Excellence

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