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A prospective study on Drug Utilization Pattern of Antidiabetic Drugs at Tertiary Care Teaching Hospital

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Abstract

INTRODUCTION

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 can facilitate rational drug use in patients with diabetes. Drug utilization studies provide useful insights into the current prescribing practices and also identify irrational prescribing. Drug utilisation study of antidiabetic agents is of paramount importance to promote rational drug use in diabetics and make available valuable information for the healthcare team.

MATERIALS AND METHODS

This is a prospective observational study was conducted in the Department of Pharmacology and Medicine at Index Medical College over a period of 2-Years. All the data were collected on a predesigned case record form from diabetic patients attending the medicine outpatient department (OPD). The study sample included in-patients admitted to the hospital and suffering from diabetes mellitus (type-I and type-II) and hypertension (primary and secondary).

RESULTS

A total number of 300 prescriptions of diabetic patients were evaluated. The sample has a higher proportion of males compared to females. Specifically, males outnumber females by a margin of about 31.33 percentage points. This disparity could be indicative of various factors depending on the context of the study or survey. Most of the patients affected were of the age group of 41 to 60 years (48.9%), followed by the age group of 61 to 80 years (31.1%). Distribution of study subjects on the basis of family history of Type 2 Diabetes. Family history of Type 2 Diabetes was recorded in the enrolled population at both the health facilities. It was observed that 213 (71%) individuals presented a positive family history out of 300 recruited from hospital. The mono and combination therapies for the treatment of type II DM. The present study revealed that most of the physicians initially prescribed mono therapy (23.66%)

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followed by dual therapy (32.66%) FDC of Drugs and triple therapy 131 (43.66%) were used more commonly over dual therapy (32.66%) to control hyperglycaemic.

CONCLUSION

To conclude with the available wide range of oral hypoglycemic agents, metformin (Biguanides) was the most preferred oral hypoglycemic agents which could achieve good glycemic control when used either alone or in combination with other oral hypoglycemic agents / insulin preparations. This study reveals a rational use of medications although the prescriptions with generic names were about 15%. However, the prescription pattern was observed to be largely in compliance with the NICE guidelines. Despite of polypharmacy practice by the physicians no adverse drug event was reported among the treated participants.

Keywords: Diabetes mellitus, Drug utilization studies, World Health Organization

INTRODUCTION

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 can facilitate rational drug use in patients with diabetes. [1] Drug utilization studies provide useful insights into the current prescribing practices and also identify irrational prescribing. [2]

The consequences of irrational prescribing include non-adherence to medications, which can result in complications due to uncontrolled blood glucose levels and also escalate drug costs and health care costs. [3] Drug utilization studies results can suggest modifications in the current prescribing practices to the prescribers, policy makers and drug and therapeutic committees to encourage rational use of drugs. [4]

As per World Health Organization (WHO), around 31.7 million individuals in India were affected by diabetes during the year 2000 which may further rise to 79.4 million by the year 2030. [29, 30] Diabetes mellitus (DM) is the chronic disorder emerging as major health problem which increases the rate of morbidity and mortality. [5] Poor management of this disorder leads to several complications. Management of type-2 DM requires both pharmacological and non-pharmacological interventions. [6]

According to Intercontinental Marketing Service (IMS) data, the leading groups of drugs utilized worldwide are cardiovascular drugs which are usually co-prescribed along with anti-diabetic drugs as result of co-existence of cardiovascular diseases and diabetes. The prevalence of type 2 diabetes mellitus is major among Indian individuals. [7]

Diabetes is a common and very prevalent disease affecting the citizens of both developed and developing countries and is the most common endocrine disorder globally. [8] Concurrent illness such as hypertension in diabetics makes it more difficult to avoid multiple drug use; hence diabetics are more prone to polypharmacy and sometimes to irrational prescriptions. [9]

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Drug utilisation study of antidiabetic agents is of paramount importance to promote rational drug use in diabetics and make available valuable information for the healthcare team. [10] This study is therefore aimed at determining the pattern of drug prescription among type-2 diabetic patients so as to evaluate the degree of physicians' compliance to current evidence and clinical guidelines and analyse the prescription according to WHO core drug prescribing indicators. [11]

Hence, the study has been planned out Drug Utilization Pattern of Antidiabetic Drugs at Tertiary Care Teaching Hospital.

MATERIALS AND METHODS

This is a prospective observational study was conducted in the Department of Pharmacology and Medicine at Index Medical College over a period of 2-Years. All the data were collected on a predesigned case record form from diabetic patients attending the medicine outpatient department (OPD).

Study Sample

The study sample included in-patients admitted to the hospital and suffering from diabetes mellitus (type-I and type-II) and hypertension (primary and secondary).

Inclusion criteria

- Patients diagnosed with diabetes mellitus and hypertension with or without complications admitted to (IPD) in-patient department of the hospital.
- Patients visited the hospital for follow-up.
- Both genders with age $\geq$18 years.

Exclusion criteria

- Patients were not willing to participate in the study.
- Pediatric patients.
- Pregnant and lactating mothers.

Sources of Data

The data were collected from patient case sheets, medication charts, billing, and laboratory test reports. The data was collected in the data collection form (Annexure-III) after taking written informed consent from the patients.

The case record form was designed in such a manner to include all demographic characteristics of the patient, disease profile, drug profile, and prescription profiles. A copy of the patient's pharmacy bill was also collected from the indoor pharmacy and was analyzed. The drug formulation, its individual retail price, manufacturer details, the monthly cost borne by the patient was noted down. Further, the cost of particular drug which was manufactured by

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different companies, in the same strength and dosage form were evaluated, and the difference in maximum and minimum price were calculated. For the drugs whose generic names were not written on prescription and price was not mentioned in the bill, we used Current Index of Medical Specialties and Indian Drug Review issues to find the generic names, the combinations and their cost.

Study Tool

Data collection form (DCF) and patients' informed consent form (PIC) were prepared and approved by three experts in two languages. **(Annexure-I and II).** A pre-developed and validated tool (DCF and PIC) was identified after a thorough literature review, which could serve this study's objectives. Items for assessing drug utilization patterns, assessing adverse drug reactions caused by various antidiabetic and antihypertensive drugs, pharmacoeconomics analysis, drug interactions, date of admission, date of discharge, laboratory investigations, diet, and physical activities were included based on information gathered after the literature review. The developed data collection form contained105 variables and was subjected to content validity by a panel of three experts, including a researcher, an expert in clinical pharmacy, and a consultant medicine. The data collection form and patients' informed consent form was modified based on the experts' recommendations and were used in the study. For collection, assessment, and reporting of suspected ADR's during the study period, a pre-validated (Adverse, Drug Reaction Reporting Form) by Indian Pharmacopoeia Commission and CDSCO was used (World Health Organization (WHO), 2014). The suspected adverse drug reaction reporting form was submitted to the Adverse Drug Reaction Monitoring Centre (AMC) ISF College of Pharmacy, Moga. The information provided to AMC was kept confidential. The causality assessment is carried out at AMCs by using the WHO-UMC scale.

Guidelines Followed

The present study was conducted following STROBE guidelines (Strengthening the reporting of observational studies in epidemiology).

As per the recommendation of the RDC (Research Development Cell) panel, all cases collected during the study were validated by the hospital authorities and report of the same submitted to the university. The data of all patients and their demographic details were kept confidential. Every six months, progress reports were also submitted to the Institutional Ethics Committee of College.

Statistical analysis

The collected patient's data were coded, cleaned, checked for completeness, and entered using software SPSS version 26 and MS Office Excel.

The data were analyzed and mentioned in simple frequencies and percentages.

Ethical Approval

Diabetic patients were enrolled in the study after taking written informed consent from each patient. Permission was obtained from Institutional Ethics Committee.

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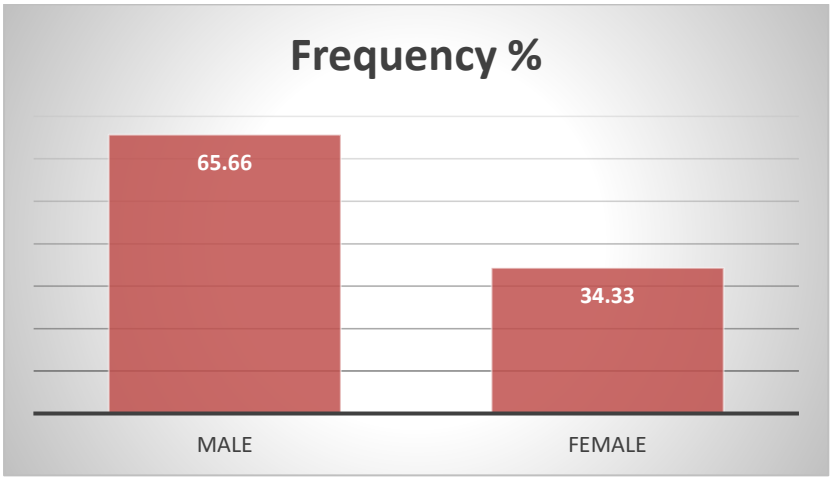
RESULTS

A total number of 300 prescriptions of diabetic patients were evaluated.

Graph 1: Distribution of Gender



Gender Distribution Analysis:

In the provided sample, there is a notable difference in the number of males and females:

1. Male Participants: 197 (65.66%)

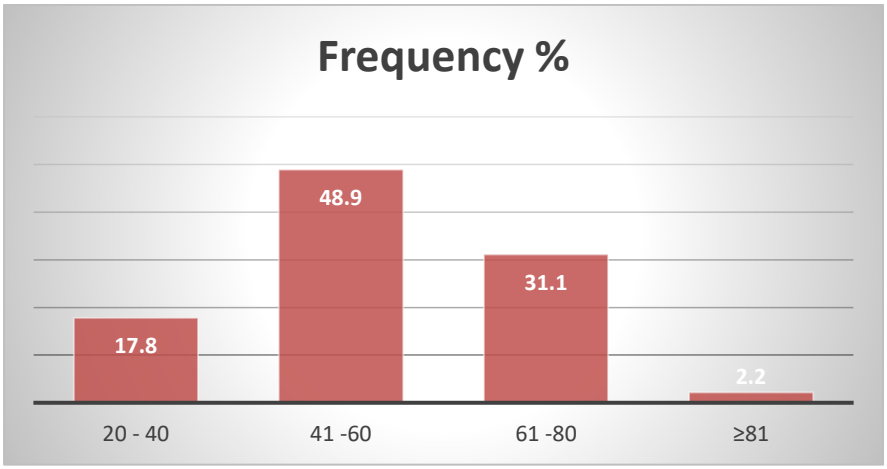
Description: The majority of participants are male, representing over two-thirds of the sample. This indicates a significant male predominance within the group.

2. Female Participants: 103 (34.33%)

Description: Females make up approximately one-third of the sample. This proportion is notably smaller compared to the male participants.

The sample has a higher proportion of males compared to females. Specifically, males outnumber females by a margin of about 31.33 percentage points. This disparity could be indicative of various factors depending on the context of the study or survey.

Table 2: Age distribution



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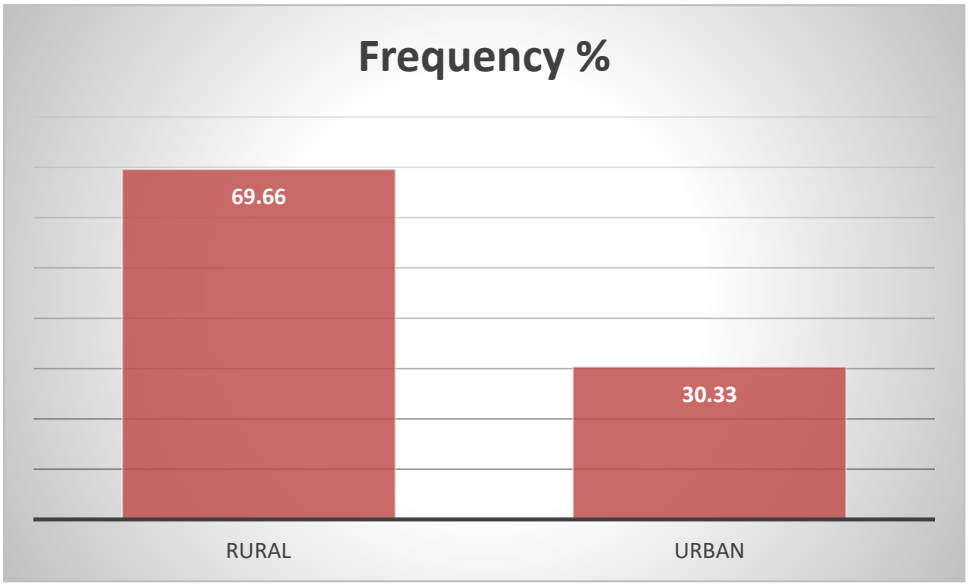
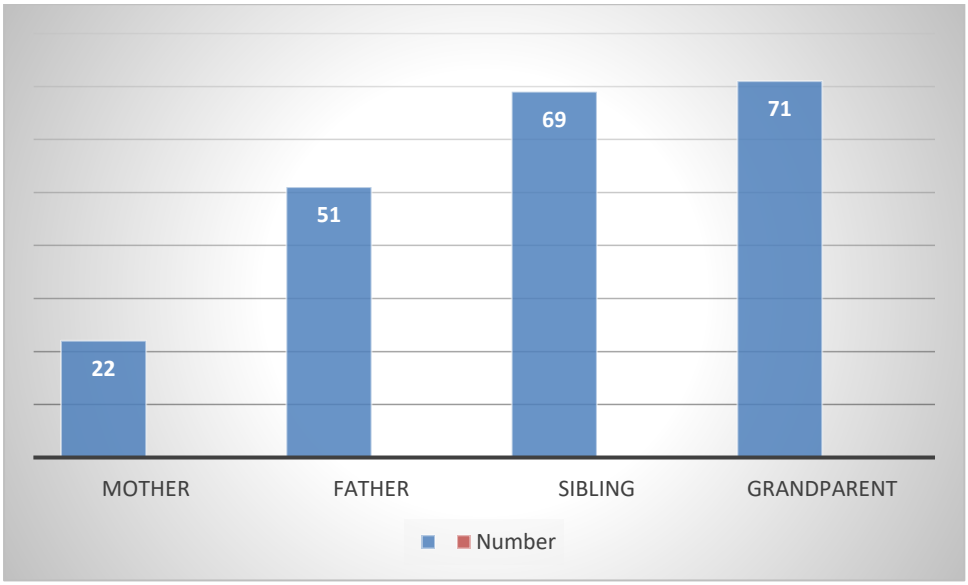
Most of the patients affected were of the age group of 41 to 60 years (48.9%), followed by the age group of 61 to 80 years (31.1%; **Graph** 2).

Graph 3: Distribution of Area of living



As shown in **Graph** 3, study individuals in health facilities were distributed on the basis of area of living into urban or rural. Of 300 subjects it was observed that maximum percentage of study population was rural constituting 69.66% and 30.33% were urban.

Graph 4: Distribution of Diabetic individuals in both Health Facilities on the basis of Family History of Diabetes



Distribution of study subjects on the basis of family history of Type 2 Diabetes. Family history of Type 2 Diabetes was recorded in the enrolled population at both the health facilities. It was

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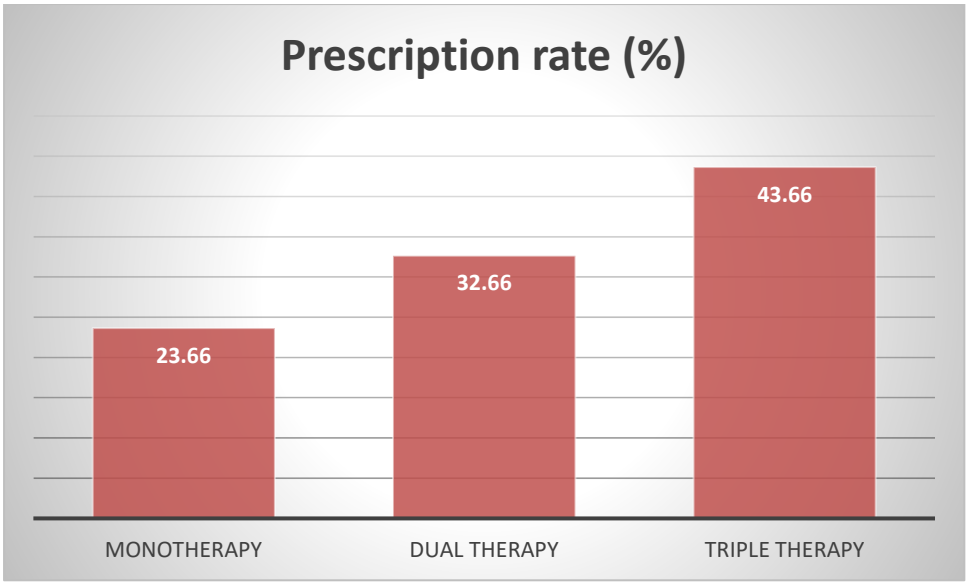
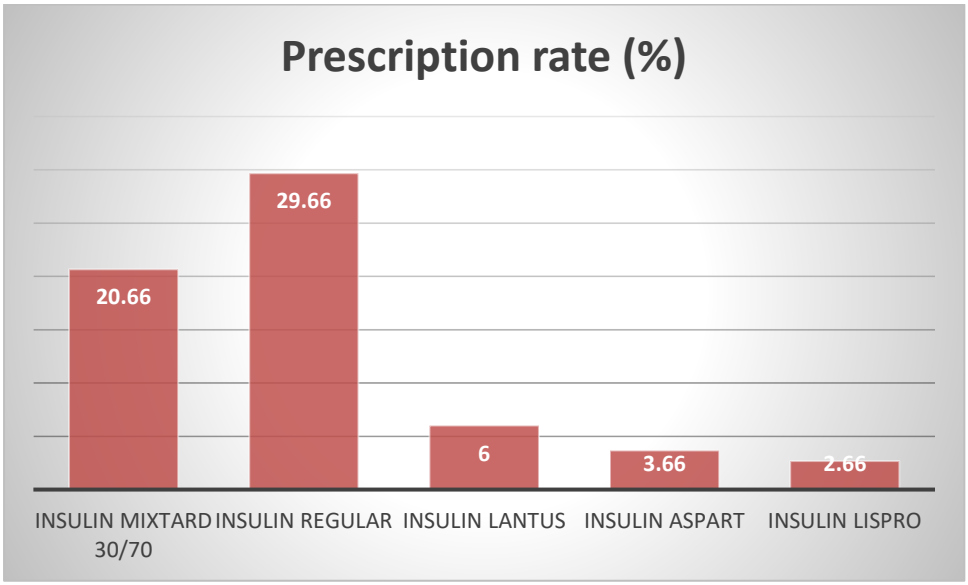
observed that 213 (71%) individuals presented a positive family history out of 300 recruited from hospital as shown in **Graph** 4.

Graph 5: Distribution of drug therapy.



In **Graph** 5, shows that mono and combination therapies for the treatment of type II DM. The present study revealed that most of the physicians initially prescribed mono therapy (23.66%) followed by dual therapy (32.66%) FDC of Drugs and triple therapy 131 (43.66%) were used more commonly over dual therapy (32.66%) to control hyperglycaemic.

Graph 6: Various insulin preparation



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Graph 6 shows various insulin preparations prescribed, with regular insulin as the most commonly used preparation (29.6%), followed by insulin mixtard (20.66%) and lantus (6%).

DISCUSSION

India is the diabetes capital of the world with 41 million Indians having diabetes; every fifth diabetic in the world is an Indian. It also leads in prevalence of metabolic syndrome as well as obesity. 20 million Indians are either obese or abdominally obese with children being the prime targets and by 2025; the expected number is 68 million. [12] Therefore, the prevalence of diabetes in India is increasing at an alarming rate, which needs to increase the awareness among people about causative factors for diabetes and its consequences. [13]

Diabetes being chronic debilitating disease requires lifelong management. The sedentary stressful life lack of exercise, irregular food habits all these environmental factors along with the predominant genetic inheritance increase the risk of type II diabetes mellitus. [14] Style, 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. [15]

In our study the sample has a higher proportion of males compared to females. Specifically, males outnumber females by a margin of about 31.33 percentage points. This disparity could be indicative of various factors depending on the context of the study or survey. The research on drug utilization studies for the ant diabetic agents conducted by Sudha V et al. (2008) show that there occurs male preponderance in the prevalence of diabetes, while in contrast to these studies several other studies conducted by Lisha et al. (2012) have reported a high proportion of diabetes in female patients. [16] However, our study findings are also in concurrence with the earlier studies which show male preponderance in prevalence of DM with the male: female ratio being 2:1.

In this study most of the patients affected were of the age group of 41 to 60 years (48.9%), followed by the age group of 61 to 80 years (31.1%). In current study, Distribution of study subjects on the basis of family history of Type 2 Diabetes. Family history of Type 2 Diabetes was recorded in the enrolled population at both the health facilities. It was observed that 213 (71%) individuals presented a positive family history out of 300 recruited from hospital as shown in Table 4.

It was however found to be difficult to obtain a good glycaemic control as per NICE guidelines in the diabetic individuals who were included in our studies, probably because of either improper & irregular medications or the existing comorbid conditions. In those patients who were not achieving targeted glycaemic control insulin preparations were preferred either alone or in combination with oral hypoglycaemic agents. Regular insulin (30) was the most commonly prescribed while, Lantus (5) was least prescribed. This helped in achieving a good glycaemic control and in good prognosis. In our study various insulin preparations prescribed, with regular insulin as the most commonly used preparation (29.6%), followed by insulin mixtard (20.66%) and lantus (6%).

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Polypharmacy was observed to be practiced in the management of the diabetes where in selection of the individual agents was made on the basis of their glucose lowering effectiveness and other characteristics suitable to the patients 'conditions. However, when adding second and potentially third ant hyperglycemic Medications, the synergy of particular combinations and other interactions were considered. Insulin plus metformin and insulin plus a thiazolidinediones (TZD) are particularly effective by means of lowering hyperglycemia but the increased risk of fluid retention with the latter combination must be considered. (TZD in combination with insulin is not currently approved in the European Union.) [18]

CONCLUSION

To conclude with the available wide range of oral hypoglycemic agents, metformin (Biguanides) was the most preferred oral hypoglycemic agents which could achieve good glycemic control when used either alone or in combination with other oral hypoglycemic agents / insulin preparations. This study reveals a rational use of medications although the prescriptions with generic names were about 15%. However, the prescription pattern was observed to be largely in compliance with the NICE guidelines. Despite of polypharmacy practice by the physicians no adverse drug event was reported among the treated participants.

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