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A PROSPECTIVE OBSERVATIONAL STUDY AND EVALUATION OF ANTI DIABETIC DRUGS TREATMENT OF TYPE II DIABETES MELLITUS PATIENTS

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ABSTRACT
The aim is to assess the safety and efficacy of anti-diabetic drugs; a prospective observational study was carried out at the department of general medicine in a tertiary care teaching hospital for a period of 6 months. For this study we selected the patients above 18 years of either sex, with co-morbidities, diabetes was included. It was observed that there was predominance of male (62%), female (38%) in the age group of <40-80 years, among that widely distributed in the age group of 51–60 years with frequency of 37%. we noted, larger numbers of patients were prescribed with metformin (22%) as OHA. It was found that majority of patients were administered with regular insulin sc (21%) as an insulin analogue, (because of co-morbid conditions, patients were often switched to insulin therapy in comparison with the metformin). Various other combinations of OHA and insulin analogues were also prescribed. The significant risk factor was found to be age (70%) followed by sedentary lifestyle (58%) and hypertension (47%). Upon analysis it is concluded that diabetes was more prevalent in the males and in the age group of 51–60 years, with majority being prescribed with metformin and regular insulin. While counselling it was recognized that the majority of patients were illiterate about the disease and counselling for the diabetes lifestyle management had a positive impact in maintaining their blood glucose levels and improved their condition.

KEYWORDS: diabetes mellitus, anti-diabetic drugs, counselling, risk factors.

INTRODUCTION

Type 2 diabetes mellitus is adding at an intimidating rate and has been honored as one of the leading causes of death and disability worldwide. Hence, this study concentrated on tradition patterns, medicine- related problems, drug adherence, and health- related quality of life. Diabetes is an opportunistic killer. roughly 77 million people in India suffer from diabetes. A person develops diabetes due to inheritable predilection, family history, rotundity, lack of physical exertion, diet low in fruits and vegetables.[1]

Diabetes mellitus (DM) is a mixed metabolic complaint characterized by habitual hyperglycemia with disturbances in carbohydrate, fat, and protein metabolism. However, it can lead to shock, cardiovascular complaint, If the diabetes mellitus is left undressed. tradition pattern analysis serves as an insight to being drug operation to ensure rational drug remedy.[2]

There is an intimidating rise in complaint, from 40 million in 2007 to 80 million by 2030. In India, according to the Diabetes Graphics published by the International Diabetes Federation, every fifth person in the world with diabetes will be an Indian.

For individual cases, rational use of drug implies the tradition of a well- proved drug in an optimal cure on the right suggestion, with correct information and at an affordable price.[3]

Evaluation of anti- diabetic drug use pattern helps the healthcare professionals to identify early signs of fallacious prescribing and to plan intervention to optimize the benefit of treatment authority. Medicine plays a major part in the cure, defense, and inhibition of complaint, but it also exposes the case to drug- related problems.

According to Pharmaceutical Care Network Europe volume 9.0, drug related problems are events or circumstances involving drug remedy that actually or potentially interferes with asked health issues. Medicine adherence is taking medicines as advised and specified by health care professionals for a stated duration. nearly half the population suffering from habitual ails do not stick to their medicine authority, and 50 of them indulge in non- adherence after a time of treatment.[4]

There are multitudinous styles for assessing medicine adherence, but patient tone- reporting measures remain the most common approach. The Morisky Medication Adherence Scale ranks the degree of adherence.[5]

Health- Related Quality of Life (HRQoL) is an existent's perception of the extent to how conditions, disability or complaint affect physical, emotional and social status. It's an important factor that must be taken into consideration when assaying health affiliated issues of cases with type 2 diabetes mellitus. Health related quality of life can be measured with a standardized questionnaire for medical outgrowth studies, the 12- point Short Form Health Survey.[6]

MATERIALS AND METHODS

Over the course of six intriguing months, from February 2024 to December 2024, a vibrant cross-sectional study unfolded. The researchers meticulously gathered demographic information and comprehensive prescriptions, all documented on a thoughtfully designed case record form. Each diabetic patient who wandered into the bustling outdoor medicine department was carefully recruited, all while being gently informed about the study's purpose. They gave their written informed consent, a crucial step in this collaborative journey. Before diving into the research, approvals were secured from several pivotal figures, the Institutional Ethics Committee, the hospital superintendent, and the head of the medicine department all crucial gatekeepers ensuring that the study adhered to ethical standards. The inclusivity of the study was notable; any patient on anti-diabetic medications, regardless of gender, was welcomed into the fold, while those who were pregnant or lacking sufficient data were set aside to maintain the study's integrity. Each prescribed medication was classified using anatomical therapeutic categories, a systematic approach that added clarity to the data.[7]

Interestingly, the majority of medications were noted by their brand names, a common practice in the field. For prescriptions lacking the generic name or price details, the researchers turned to reliable sources like the Current Index of Medical Specialties (CIMS) and the Indian Drug Review (IDR) to fill in the blanks.[8]

Inclusion criteria[9]

1. Newly diagnosed patients of diabetes mellitus type 2.
2. Patients with age more than 18 years.
3. Patients of either sex
4. Patients having base line (pretreatment) biochemical parameters other than blood sugar (i.e. liver function test, kidney function test) within normal range.
5. Patients having no associated comorbidities.

Exclusion criteria[9]

1. Patients who were unwilling to participate and did not give consent in the study
2. Patients who were unable to give interview.
3. Patients with incomplete medical records.
4. Patients with chronic liver disease such as cirrhosis, chronic hepatitis and acute viral hepatitis
5. Terminally ill patients
6. Patients with concurrent major psychiatric illness and/or concurrent major medical illnesses

Data Management and Analysis

Statistical analysis[10]

Categorical variables were presented in number and percentage (%). Qualitative variables were compared using Chi-Square test /Fisher's exact test as appropriate.

A p value of <0.05 was considered statistically significant. Statistical analysis was performed using GraphPadQuickCalcs software available online at http://graphpad.com/quickcalcs/. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULT AND DISCUSSION

1. **Gender-Wise Distribution of Patients:** Based on the data collected from 500 cases of Type 2 Diabetes Mellitus, results were evaluated. We found that diabetes was prevalent among (310) 62% Males followed by (190) 38% Females as in figure.

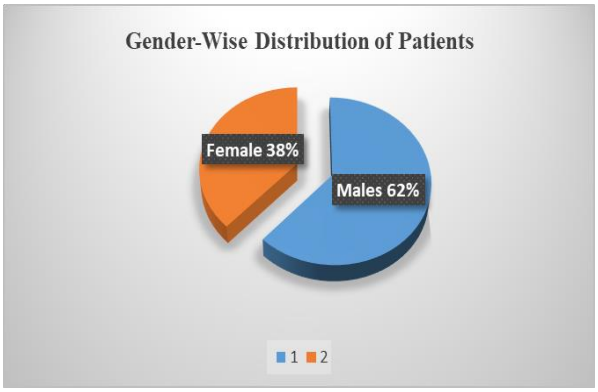

Fig. No. 1: Gender-Wise Distribution of Patients.

2. **Distribution Of Data Based On Oral Hypoglycemic Drugs:** Based on data collected during the study, It was found that most of the patients were on metformin which is an oral hypoglycemic drug accounting for 22%, followed by a combination of Canagliflozin + Metformin 2% followed by Glimepiride + Metformin 27% followed by triple combination of Glimepiride + Metformin +

pioglitazone 5% followed by Glibenclamide + Metformin 12% followed by triple combination of Glibenclamide + Metformin + pioglitazone 3% followed by Glipizide+ Metformin 8% followed by Human Mix insulin+ Metformin 21% as in shown in table.

Table No. 1: The Anti-Diabetic Drug Usage Pattern prescription.

Drugs Prescribed	Numbers of Patients	Percentage (%)
Metformin	110	22 %
Canagliflozin + Metformin	10	02 %
Glimepiride + Metformin	135	27 %
Glimepiride + Metformin + pioglitazone	25	05 %
Glibenclamide + Metformin	60	12 %
Glibenclamide + Metformin + pioglitazone	15	03 %
Glipizide+ Metformin	40	08 %
Human Mix insulin+ Metformin	105	21 %
Total	500	100%

3. **Age-Wise Distribution of Patients:** All the patients were grouped as per the age. Majority of the patients in the study belonged to the age group of <40 years is 14%, 41-50 years (25%) 51-60 years (33%), 61-70 years (22%) followed by age group 71-80 (8%) as in figure 2.

Table No. 2: Age-Wise Distribution of Patients.

Sl. No.	Age Group	Number of Patients	%
1	40	70	14
2	41-50	125	25
3	51-60	165	33
4	61-70	100	20
5	71-80	40	8

4. **Distribution of Patients Based On Addiction:** Among the study population, 52% of the patients were with no addictions followed by 26% of alcoholics, 19% of smokers and 7% of tobacco chewers as in figure 3.

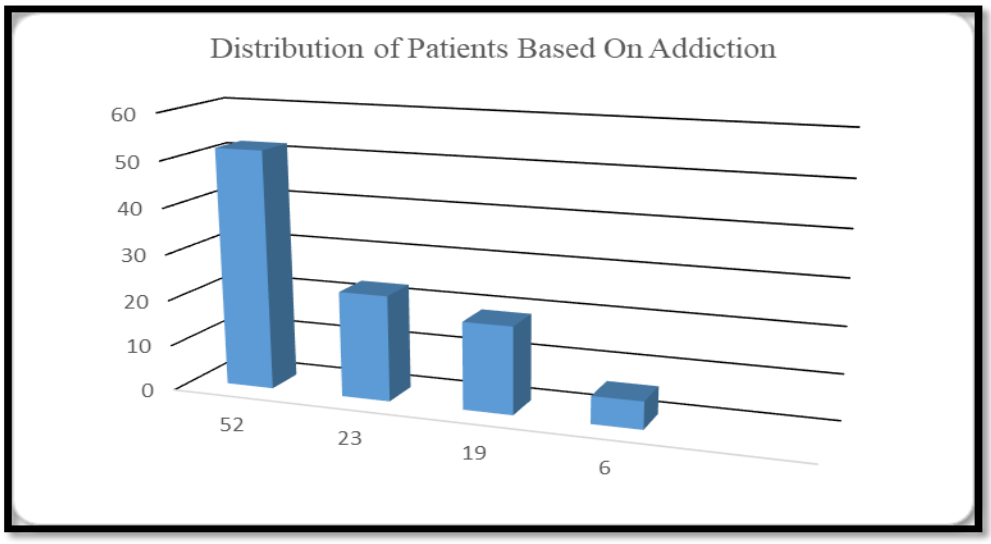

Fig. No. 2: Distribution of Patients Based On Addictions.

5. **Distribution of Patients Based On Co morbidities:** Among the study population, 58% of patients had cardiovascular diseases as co morbid condition followed by 18% respiratory tract infections 17 patients with CNS diseases, 15% with other infections, 13% with kidney diseases, and 12% with blood disorders as in figure.

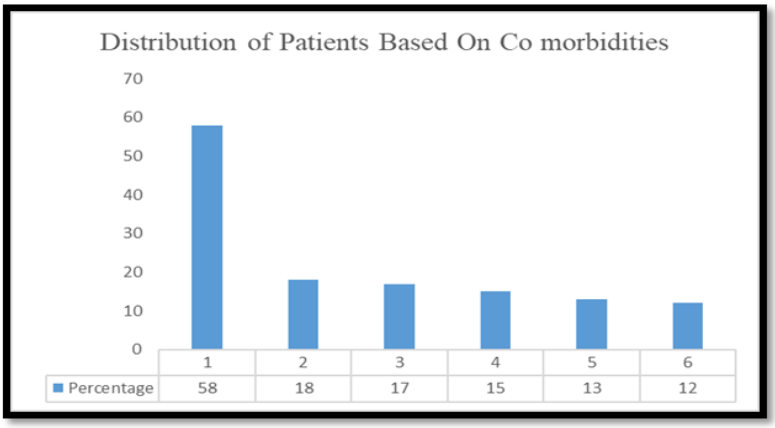

Fig. No. 3: Distribution of Patients Based on Co morbidities.

6. **Distribution of Data Based on Hba1c Levels:** Based on the above data collected, 78% patients had not performed the HbA1C test whereas 18% had their Hb1AC >6.5 followed by 4% having their Hb1AC levels between 5.7-6.4.

7. **Distribution of Data Based on Complication of Disease:** Among the study population, 73% of the patients were found to exhibit no complications followed by 10% exhibiting Diabetic Ketoacidosis and 8% Diabetic Foot Ulcers as in figure.

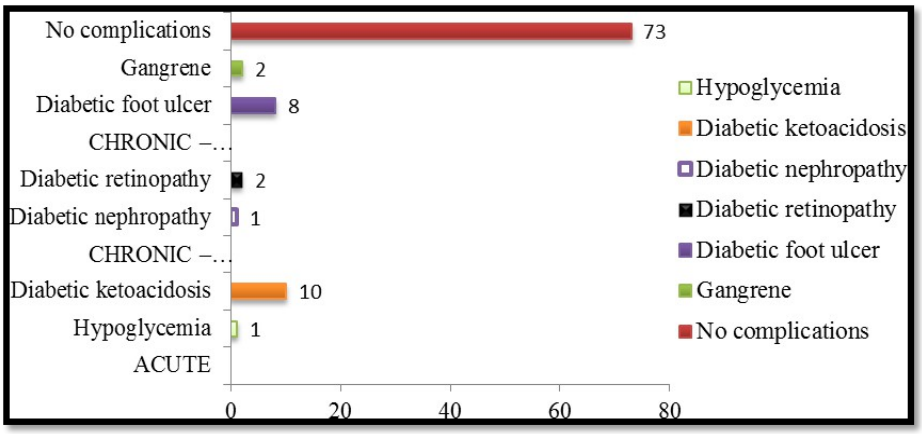

Fig. No. 4 Distribution of Data Based On Complication of Disease.

8. **Distribution of Patients Based on Risk Factors:** Upon the data collected, patients were classified based on risk factors. 76% of the patients were above 45 years of age, followed by 63% of the patients who were habituated to sedentary lifestyles and 52% of the patients having high blood pressure and 8% having high cholesterol levels as in figure.

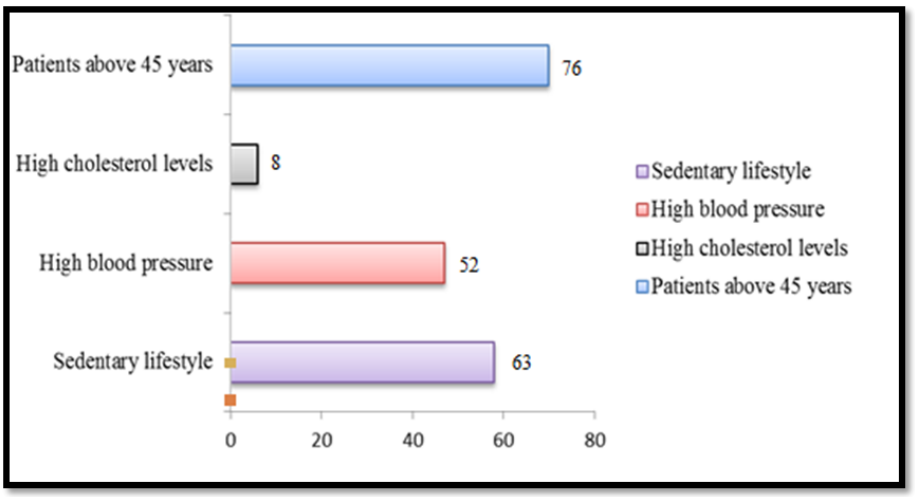

Fig. No. 5: Distribution of Patients Based On Risk Factors.

CONCLUSION

In this study Effectiveness of the treatment was estimated and diabetes mellitus associated threat factors were linked and effective case comforting was done for effecting the quality of life in cases with diabetes.

It can be concluded from our findings that; male cases were more affected than female cases and those between the age group of 51- 60 times are more prone to type 2 diabetes mellitus and the study also concludes that maturity of the cases had a diabetic duration in between 1- 10 times.

The study shows the prevalence of colorful threat factors, among them Age> 45 times of the age followed by sedentary life and hypertension were the major threat factors associated with diabetes, whose revision and threat operation could lead to positive health issues precluding further complications. We've also studied several complications; among them the most current bone was Diabetic ketoacidosis followed by the Diabetic bottom ulcer. Each diabetic case in this study had one or further co morbid conditions; cardiovascular conditions were the most current.

The most generally specified medicine for the treatment of T2DM in convalescents was insulin (Regular Human Insulin), followed by Biguanides (Metformin) and Sulfonylureas. Subcutaneous route of administration was the most favored route for insulin. It was set up that maturity the medicines specified were according to AHA guidelines. The study also shows there's a high drug adherence of about 62.

The current study has showed that involvement of clinical druggist in assessing the stylish treatment issues with effective case comforting can surely have a positive impact on health issues and also improves the quality of life in case.

During our consultation, we encountered many patients who lacked understanding in managing their lifestyle, diet and physical activity. So, through this consultation, they learned many different ways to control their blood sugar besides taking medicine.

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Conflict of interest: None declared.

Ethical Approval: The study was approved by the Institutional Ethics Committee.

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