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A PROSPECTIVE OBSERVATION STUDY ON DIABETES COMPLICATION AND PRESCRIBING PATTERN OF ANTIDIABETIC AGENTS

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ABSTRACT

Background: Diabetes is one of the largest global health emergencies of this century, ranking among the top ten leading causes of mortality alongside diseases such as cardiovascular disease, respiratory disease, and cancer. India is one of the epicenters of the diabetes mellitus pandemic. Rapid socioeconomic development, demographic changes, and an increased genetic susceptibility among Indian individuals have led to an explosive rise in the prevalence of diabetes mellitus in India over the past several years. The risk of diabetes is influenced by ethnicity, age, obesity, physical inactivity, unhealthy diet, behavioral habits, genetics, and family history. The prevention and management of diabetes and its associated complications present a significant challenge in India due to several issues and barriers, including the lack of a multisectoral approach, insufficient surveillance data, lack of awareness regarding diabetes, its risk factors and complications, and limited access to healthcare settings and affordable medicine.^[1]

Methods: The prospective observational study was conducted over a period of 6 months at Venus Hospital Surat. Ethical clearance was obtained from the SDPC Institutional Ethics Committee. The data of 120 patients were collected and recorded in case report form based on inclusion and exclusion criteria. **Results:** Out of 120 patients, the majority were males

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(53%) and primarily aged between 61 and 70 years (42.5%). Hypertension (59.17%) was the most commonly found comorbid condition. Overall, monotherapy was more predominant than combination therapy, with most patients being treated with a single drug, metformin. Among those receiving insulin therapy, Insulin Human Actrapid was the most frequently prescribed (11.21%). Microvascular complications were more common than macrovascular complications. **Conclusion:** The results highlight, the study provides valuable insights into the prevalence of diabetes complications and the current prescribing patterns of anti-diabetic agents in our study population. It has been concluded that the selection of anti-diabetic drugs has changed only slightly compared to prior studies.

KEYWORDS: Diabetes Mellitus, Antidiabetic Medications, Diabetes Complications.

INTRODUCTION

Diabetes mellitus, often referred to as a silent epidemic, has firmly rooted itself as one of India's most pressing health challenges.^[1] With over 77 million adults living with diabetes, India is home to the second-largest diabetic population in the world, a number that is projected to exceed 100 million by 2030.^[2] This staggering growth is fueled by rapid urbanization, changes in dietary habits, and increasingly sedentary lifestyles, which have significantly altered the traditional Indian way of life.^[3]

The impact of diabetes extends far beyond the clinical realm, deeply affecting the daily lives of individuals and families.^[4] In a country where cultural practices and dietary habits are deeply ingrained, managing diabetes requires a careful balance between tradition and health.^[5] The psychological burden of constant glucose monitoring, strict dietary control, and the looming risk of complications such as cardiovascular diseases, kidney failure, and neuropathy, makes diabetes a relentless adversary.^[6] This burden is particularly heavy for those in lower socioeconomic groups, where access to healthcare and diabetes management tools is limited, exacerbating the inequalities in health outcomes.^[7]

Despite these challenges, millions of Indians are navigating this condition with remarkable resilience, adapting to new lifestyles and embracing innovations in treatment.^[8] The rise of digital health solutions, including telemedicine and mobile health applications, has provided new avenues for managing diabetes, particularly in remote and underserved areas.^[9] Additionally, there has been a growing awareness of the importance of early diagnosis and

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preventive measures, with government initiatives aiming to increase screening and education about diabetes.^[10]

However, the growing prevalence of diabetes in both urban and rural settings highlights the urgent need for a comprehensive approach to diabetes management in India. ^[11] This includes not only improving healthcare infrastructure but also addressing the social determinants of health, such as education, nutrition, and access to clean water and sanitation, which play a critical role in the prevention and management of diabetes. ^[12] The battle against diabetes in India is a multifaceted challenge that requires the collective efforts of individuals, communities, healthcare providers, and policymakers.

AIM

To study the prescribing pattern of anti-diabetic agents with prevalence of diabetes and its complication.

OBJECTIVES

- 1. To analyze the total number of anti-diabetic agents prescribed per prescription
- 2. To assess the percentage of most commonly prescribed anti-diabetic agents based on the prescription.
- 3. To determine the route of administration of anti-diabetic agents in the patient
- 4. To analyze the complication of diabetes in the patient.
- 5. To evaluate and determine the study population in the patient.

METHODOLOGY

Study site: This study was conducted on patients with diabetic patient in the Venus Hospital, Surat.

Study duration: The study is conducted over a period of 6 months.

Study design: The study is a prospective observational study

Sample size: The total number of patient enrolled in the study was 120.

Study method: Data were collected in the data collection form which was designed based on the inclusion and exclusion criteria after the approval from the ethics committee. The study was over the period of six months at venus hospital, surat. This study was a single centric study

Study criteria

Inclusion criteria

- 1. Data on diabetic patients receiving anti-diabetic medication were included in the study.
- 2. Data were collected from diabetic patients based on age, ranging from 18 to 75 years.
- 3. Data from both male and female participants were collected in the study
- 4. Data were collected only from the In-Patient Department throughout the entire duration of the study.

Exclusion criteria

- 1. Incomplete data of the patient's.
- 2. Data of the out-patient department.
- 3. Patient diagnosed with type I diabetes mellitus.
- 4. Data of pregnant women with gestational diabetes.

RESULTS

A) Gender-wise distribution

A total of 120 prescriptions were analysed and out of which 64(53.33%) were male and 56(46.67%) were female. The incidence of diabetes was found more in males as compared females.

| Gender | Number of patients | Percentage(%) |
|--------|---------------------------|---------------|
| Male | 64 | 53.33% |
| Female | 56 | 46.67% |

Table 1: Gender Wise Distrubution Of DM Patients.

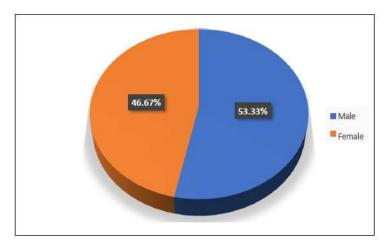


Figure 1: Pie Chart- Gender Distrubution of DM Patients.

B) Age-wise distribution

Patients were grouped into 8 groups based on their age. 4(3.33%) patients were found to be in the age group of 21-30 years, 1(0.83%) patients were found to in age group 31-40, 10(8.33%) patients were found to be in age group 41-50, 41(34.17%) were found to be in age group 51-60, 51(42.50%) were found to be in age group 61-70, 10(8.33%) were found to be in age group 71-80, 2(1.67%) were found to be in age group 81-90, 1(0.83%) were found in age age group 91-100. More patients was found in age group of 61-70 51(42.50%).

| Age in years | No. of patients | Percentage (%) |
|--------------|-----------------|----------------|
| 21-30 | 4 | 3.33% |
| 31-40 | 1 | 0.83% |
| 41-50 | 10 | 8.33% |
| 51-60 | 41 | 34.17% |
| 61-70 | 51 | 42.50% |
| 71-80 | 10 | 8.33% |
| 81-90 | 2 | 1.67% |
| 91-100 | 1 | 0.83% |

Table 2: Age Wise Distribution of DM Patients.

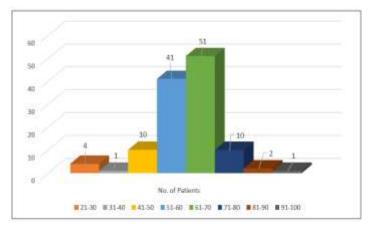


Figure 2: Bar Graph - Age Distribution Of DM Patients.

C) HbA1c levels in individual patients

HbA1c provides a long term trend, similar to an average of how high blood sugar level have been over a period of time. We found that 3(2.50%) patients had HbA1c below 6.5, 53(44.17%) patients had level between 6.5-8.5, 46(38.33%) patients had level between 8.5-10.5, 18(15%) patients had level more than 10.5. Among 120 patients, majority of the population had HbA1c ranging between 6.5-8.5 that is 53(44.17%).

| HbA1C level | No. of patient | Percentage (%) |
|-------------|----------------|----------------|
| <6.5 | 3 | 2.50% |
| 6.5-8.5 | 53 | 44.17% |
| 8.5-10.5 | 46 | 38.33% |
| >10.5 | 18 | 15% |

Table 3: Level of HbA1c in individual patient's.

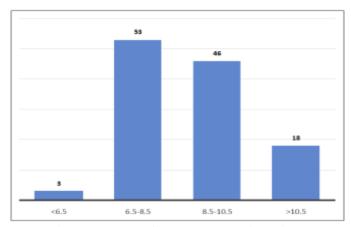


Figure 3: Bar Graph-Level of HbA1c.

D) Distribution of patients based on co-morbidities

In this study, patient were distributed based on co morbid condition And we found that majority of patients was having co-existing illness in which hypertension was found to be the highest 71(59.17%) and commonest co-morbidity observed than followed by ckd 31(25.83%) and dka 20(16.67%).

| Co-morbidities | p-morbidities observed | Percentage (%) |
|--------------------------|------------------------|----------------|
| HTN | 71 | 59.17% |
| CKD | 31 | 25.83% |
| DKA | 20 | 16.67% |
| IHD | 15 | 12.50% |
| Acute coronary syndrome | 13 | 10.83% |
| CV Stroke | 10 | 8.33% |
| Diabetic retinopathy | 6 | 5.00% |
| AKI | 4 | 3.33% |
| Myocardial infraction | 4 | 3.33% |
| Coronary artery disease | 4 | 3.33% |
| Cad-TVD | 3 | 2.50% |
| Congestive heart failure | 3 | 2.50% |
| Unstable angina | 3 | 2.50% |
| Hyperthyroidism | 1 | 0.83% |
| Dic nephropathy | 1 | 0.83% |

Table 4: Distribution of Patients Based On Co-morbidities.

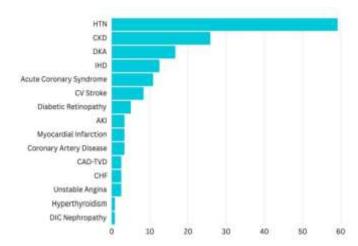


Figure 4: Percentage wise Distribution of Patients Based On Co-morbidities.

E) Distribution of patient based on family history

Genetics is also one of the etiology of diabetes mellitus, among 120 patients 42(35%) had family history and 78(65%) have no family history.

| Family history of DM | No. of patient | Percentage (%) |
|----------------------|----------------|----------------|
| YES | 42 | 35% |
| NO | 78 | 65% |

Table 5: Distribution of patient based on family history.

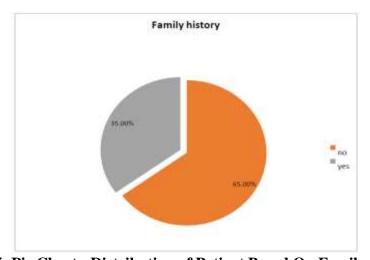


Figure 5: Pie Chart - Distribution of Patient Based On Family History.

F) Distribution based on complications

In this study, patients were distributed based on complications and we found that majority of patients had complication found was DKA 20 (16.67%). Stoke and diabetic nephropathy had same number of patient 12(10%) followed by coronary artery disease 11(9.17%) and MI

9(7.50%).7 (5.83%) patient had peripheral vascular disease, 5(4.17%) patient had diabetic foot and 4(3.33%) patient had diabetic neuropathy.

| Complication | No. of complication observed | Percentage% |
|-----------------------------|------------------------------|-------------|
| DKA | 20 | 16.67% |
| Stroke | 12 | 10% |
| Coronary Artery Disease | 11 | 9.17% |
| MI | 9 | 7.50% |
| Peripheral Vascular Disease | 7 | 5.83% |
| Diabetic Foot | 5 | 4.17% |
| Diabetic Neuropathy | 4 | 3.33% |

Table 6: Distribution of complications.

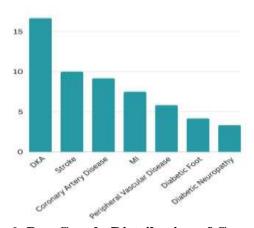


Figure 6: Bar-Graph Distribution of Complications.

G) Distribution based on types of Anti-diabetic medications administered in patient's

In this study most used insulin therapy was Inj HAI while hospitalization followed by Inj mixtard and Inj lantus. Among oral hypoglycemic agent metformin was prescribed more than any other medicine followed by sitagliptin. Among combination therapy metformin+glipizide was prescribed more compare to other.

| Medication | Number of Medication observe | Percentage% |
|--------------------------------|------------------------------------|-------------|
| Voglibose+Glimepride+Metformin | 6 | 5.17% |
| Metformin+Glipizide | 13 | 11.21% |
| Tenegliptin | 3 | 2.59% |
| Acarbose | 4 | 3.45% |
| Dapaglofzin | 3 | 2.59% |
| Pioglitazone | 3 | 2.59% |
| Linagliptin | 8 | 6.90% |
| Sitagliptin | 9 | 7.76% |
| Repagliptine | 3 | 2.59% |

| Metformin+ Pioglitazone+Glimepride | 7 | 6.03% |
|------------------------------------|----|--------|
| Empagliflozin | 2 | 1.72% |
| Metformin | 11 | 9.48% |
| Glipizide | 8 | 6.90% |
| Inj hai | 13 | 11.21% |
| Inj lantus | 7 | 6.03% |
| Inj mixtard | 9 | 7.76% |
| Vildagliptin+metformin | 7 | 6.03% |

Table 7: Distribution Based On types of Anti-diabetic Medication administered in the patient's.

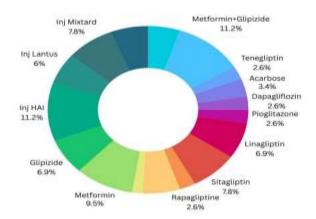


Figure 7: Pie-chart Distribution Based On types of Anti-diabetic Medication administered in the patient's.

DISCUSSION

The study analyzed the gender-wise distribution of diabetes mellitus (DM) among patients, revealing a slightly higher incidence in males (53.33%) compared to females (46.67%), which aligns with previous research indicating a higher prevalence of DM in males due to factors such as differences in body fat distribution, lifestyle, and hormone levels.^[13]

In terms of age-wise distribution, the highest prevalence of DM was observed in the 61-70 age group, accounting for 42.50% of the total patients. This trend is consistent with the general understanding that the risk of DM increases with age, particularly due to the accumulation of metabolic risk factors over time.^[14]

The analysis of HbA1c levels showed that a majority of the patients (44.17%) had HbA1c levels between 6.5% and 8.5%, indicating a substantial proportion of the study population had uncontrolled blood glucose levels despite treatment.^[15] This finding is critical as it highlights the need for more aggressive or tailored treatment strategies in this population.^[16]

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When examining the distribution of patients based on co-morbidities, hypertension (HTN) was the most common co-existing condition, observed in 59.17% of the patients. The high prevalence of HTN among DM patients is well-documented and is often attributed to the shared risk factors between the two conditions, such as obesity and insulin resistance. [17]

Regarding family history, 35% of the patients had a positive family history of DM, reinforcing the role of genetics in the development of the disease. [18] This emphasizes the importance of screening and preventive measures in individuals with a family history of DM.[19]

In terms of complications, diabetic ketoacidosis (DKA) was the most frequently observed complication, present in 16.67% of the patients. This finding is in line with the literature that suggests DKA remains a significant risk in DM patients, particularly those with poor glycemic control.[20]

Lastly, the study highlighted the distribution of anti-diabetic medications, with insulin therapy being the most commonly used treatment during hospitalization. Metformin, the firstline oral hypoglycemic agent, was also widely prescribed, consistent with current treatment guidelines.^[21] The preference for metformin, both as monotherapy and in combination with other agents like glipizide, reflects its efficacy and safety profile in managing DM. [22]

CONCLUSION

This study provides significant insights into the demographic and clinical characteristics of patients with diabetes mellitus. The findings reveal a higher prevalence of diabetes in males, particularly in the age group of 61-70 years, highlighting the increased risk associated with aging. The analysis of HbA1c levels indicates that a substantial proportion of patients have uncontrolled blood glucose levels, underscoring the need for more tailored and aggressive treatment strategies to achieve better glycemic control.

The high prevalence of co-morbidities, especially hypertension, emphasizes the necessity of comprehensive management approaches that address both diabetes and its associated conditions. The role of family history in the etiology of diabetes further reinforces the importance of early screening and preventive interventions, particularly in individuals with a genetic predisposition.

The study also highlights the occurrence of serious complications such as diabetic ketoacidosis, which remains a significant risk among poorly controlled diabetes patients. The findings support the continued use of insulin therapy and metformin as effective treatments, in line with current guidelines, while also suggesting the potential benefits of combination therapies for optimal disease management.

Overall, this research underscores the importance of personalized treatment strategies, regular monitoring, and a holistic approach to managing diabetes mellitus, considering the complex interplay of demographic factors, co-morbidities, and treatment responses. These insights can contribute to better clinical outcomes and improve the quality of life for patients with diabetes.

Abbreviations

AKI: Acute Kidney Injury

CKD: Chronic Kidney Diseases

CAD: Coronary Artery Diseases

DM: Diabetes Mellitus

DKA: Diabetic Ketoacidosis

HTN: Hypertension

HbA1c: Hemoglobin A1c

IHD: Ischemic Heart Disease

MI: Myocardial Infarction **TVD:** Triple Vessel Disease

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