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Research Article

Pharmacology for drug discovery

Assessment of Prescribing Pattern and Factors Associated with Clinical Outcomes in Type-2 Diabetes Patients in A Tertiary Care Hospital

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Abstract: Our study is aimed to evaluate the prescribing pattern of antidiabetic drugs and factors associated with clinical outcomes in type-2 diabetes patients. The objectives of the study were to identify and evaluate the class of drugs, rationality, monotherapy or combination therapies prescribed, and demographic characteristics of the patients with the disease prospective observational study was conducted for 6 months in the General Medicine Department of KIMS Al Shifa Super Specialty Hospital, Perinthalmanna, Kerala. whichTotal113 subjectswere selected based on inclusion and exclusion criteria.Allrelevant patient datawere collected using a structured data collection form. Data were analyzed using the SPSS statistical software version 20 and MS Excel for descriptive statistics. Out of 113 patients studied, 55 (48.68%) were male and 58 (51.32%) were female. The majority of the patients were over the age of 65, with the fewest being under the age of 45. The mean age of the study population was found to be 59.64 years. The common comorbidity observed in the study population with Type-2 Diabetes Mellitus was hypertension (65%). 30 (26.54%) patients were found to have complications from diabetes mellitus. The average number of anti-diabetic drugs per prescription was 1.73. Thus, the study reveals that the presence of comorbidities and complications has a significant influence on glycaemic control. Elderly patients are at a higher risk of developing Type-2 diabetes mellitus. Metformin is the most commonly prescribed oral hypoglycemicagent, both in monotherapy and combination therapy. The prescribing trend appears to be moving towards combination therapy, particularly two drug therapies.

Keywords: Type-2 Diabetes Mellitus, Prescribing Pattern, Metformin, Comorbidities and Complications

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1. INTRODUCTION

Diabetes mellitus (DM) is an important public health problem in developing countries. Drug utilization study of anti-diabetic agents is of significant importance to promote rational drug use in diabetes patients. The term "Diabetes mellitus" describes a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from insulin secretion, insulin action, or both.[1] The world health organization estimates that diabetes resulted in 1.5 million deaths in 2012, making it the 8th leading cause of death.[2]However another 2.2 million deaths worldwide were attributable to high blood glucose and the increased risks of associated complications (e.g.heart disease, stroke, kidney failure), which often result in premature death and are often listed as the underlying cause of death certificates rather than diabetes.[3]Until recently, India had more diabetics than any other country in the world, according tothe International Diabetes Foundation.[4] Diabetes currently affects more than 62 million. Indians, which is more than 7.2% of the adult population.[5]DM is associated with various common comorbidities such as dyslipidemia, hypertension, and cardiovascular disorders.[6]The pathologic hallmark of DM involves the vasculature leading to both microvascular and macrovascular complications.[7] Oral hypoglycemic agents (OHAs) are the major treatment for Type-2 Diabetes Mellitus patients and these agents are targeted for intensive blood-glucose control which leads to a decrease in microvascular complications, such as nephropathy and retinopathy.[8] It is also suggested to be advantageous to introduce insulin therapy much earlier in the disease course to achieve tight glycaemic control.[9]Multiple therapies is an integral part of diabetic patients and is apparently beneficial. Prescription pattern studies are powerful exploratory tools to ascertain the role of drugs in society. They create a sound socio-medical and health-economic basis for health decision-making. Drug utilization studies aim to provide feedback to the prescriber and create awareness among them about the rational use of drugs. The provision of accurate and timely drug information to health care professionals is an important aspect to promote safe and effective treatment and such service is lacking in India.[10]The primary goal of pharmacological therapy is to control hyperglycemia in patients with diabetes mellitus. Therefore, rational drug therapy is necessary to achieve adequate glycaemic control and improve quality of life. However, a number of factors are linked to clinical results, including patient adherence, diabetes education, lifestyle adjustment, drug cost & kind, and so on.[11] The study of prescribing patterns is a component of medical audit that monitors and evaluates the prescribing practices of the prescribers as well as recommends necessary modifications to achieve rational and cost-effective medical care.[12] These studies aim to analyze the type of drug prescribed, their dosage schedule and the adequacy of the prescription for a specific diagnosis. By using prescription data, it is possible to analyze the pattern of drug use among patient groups defined by age, gender or diagnosis.[13]Assessing the treatment pattern including glycaemic control and associated factors is of enormous importance for better patient care. Data on drug usage patterns can be used to validate evidence-based practice and inform decision-making. The drug utilization study has the potential to partially alleviate the problem by improving the appropriate use of medications if conducted correctly. There have been several studies on the prescribing pattern in Type-2 Diabetes Mellitus patients; however, in this study, we looked at the prescribing pattern as well as the relationship between clinical outcomes and characteristics such as age, gender, comorbidities and complications, which increases the uniqueness of the study.

2. MATERIALS AND METHODS

2.1 Study Type

This study was a prospective observational study

2.2 Study Period

The study was conducted for 7months commencing from January 2021 to July 2021

2.3 Place of Study

The study was carried out in the General Medicine Department, KIMS Al Shifa Super Specialty Hospital, Kerala

2.4 Study Population

A sample of 113 diabetic patients were selected based on inclusion and exclusion criteria

2.5 Inclusion Criteria

- Type 2 diabetes mellitus patients who were admitted In-patient in General medicine department irrespective of age and sex
- Patients who are prescribed at least one oral hypoglycemic agent or insulin
- Patients who received antidiabetic therapy for at least 3 months

2.6 Exclusion Criteria

- All patients without medication therapy
- Patients with gestational diabetes or type 1 diabetes mellitus
- Patient who has
- Malignancy
- Psychiatric disorders
- Any major surgical interventions in previous 3 months

2.7 Ethical Clearance

This study was approved by the Institutional Ethics Committee vide reference number KAS/ADM/EC/0200/21 dated April 26, 2021 and an official consent from the participants was also obtained for the purpose of carrying out this study.

2.8 Study Design

A prospective observational study was conducted for a period of 7months that focused on appraisal of prescribing patterns of anti-diabetic drugs and factors associated with clinical outcomes in Type 2 Diabetes Mellitus patients. A properly designed data collection form was used, to collect and record the patient data which describes the patient's demographics, medical history, lab investigation details, medications, generic names, dosing, route, frequency of antidiabetic drugs used, presence of comorbidities, complications such as microvascular and macrovascular and whether the patient attained optimum glycaemic control during the treatment period which is recorded in the laboratory data.All relevant

datasets for the study were gathered from a variety of sources including case files, case reports, treatment charts, laboratory reportsanddischarge summaries and were entered into the data collection form. The demographic data includes age, gender, weight, MRD number, department, date of admission, date of discharge, etc.

2. STATISTICAL ANALYSIS

Data was analyzed using the SPSS statistical software version 20.0 and MS Excel for analyzing descriptive statistics. A Chi-square analysis was used to find the significance of the study. The level of significance was fixed at p=0.05 and any value less than or equal to 0.05 was considered to be statistically significant.

3. RESULTS AND DISCUSSION

113 patients, diagnosed with Type-2 Diabetes mellitus were selected and analyzed in the study.

3.1 Gender Wise Distribution of Type-2 Diabetes Patients

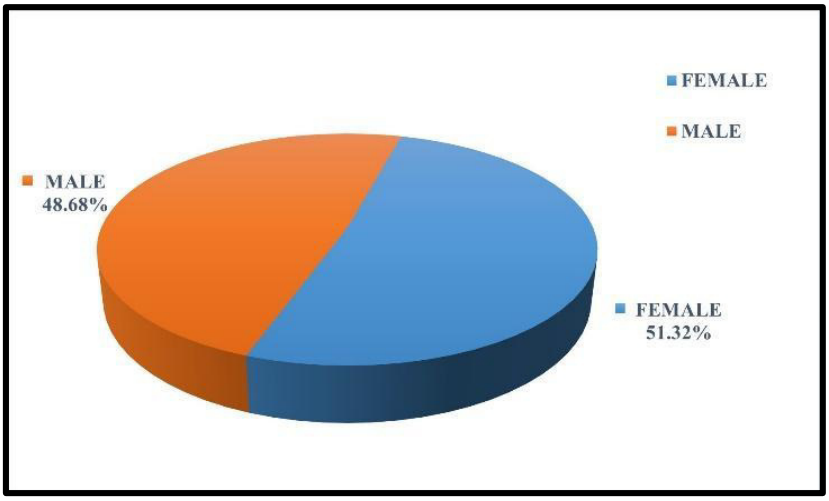

Fig. 1 illustrates the gender-wise distribution of type-2 diabetes patients. Out of 113 patients, 55 (48.68%) were male and 58 (51.32 %) were female. A similar study conducted by M Mahmood et. al., depicted 62.97% were male and 37.02% were female.[14]Thus, the present study revealed the prevalence of diabetes among females as compared to the previous study.

Fig. 1: Gender Wise Distribution of Type-2 Diabetes Patients

3.2 Age Wise Distribution of Type-2 Diabetes Patients

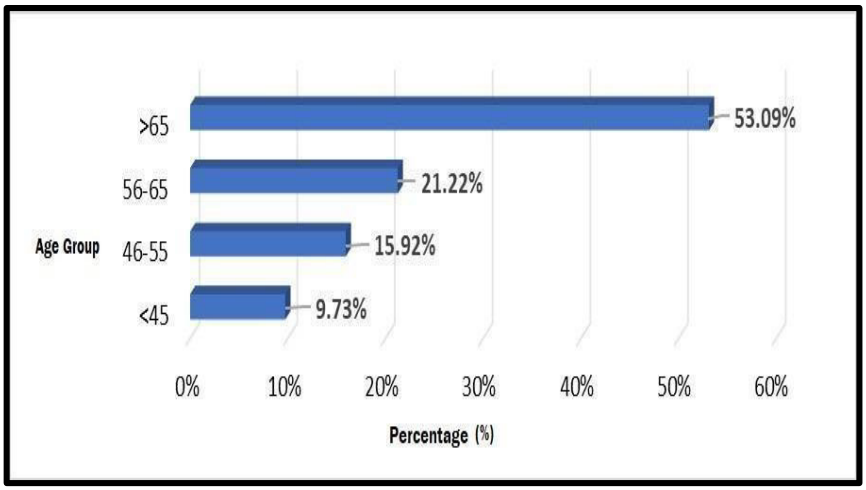

Fig. 2 illustrates the age wise distribution of type-2 diabetes patients. The patients were divided into four age groups in order to determine which age group was more likely to develop Type 2 Diabetes Mellitus. The majority of the patients (53.09%) were in the age group >65 years. Simultaneously, the group aged <45 years old has the smaller number of patients. The mean age of the study population was found to be 59.64 years. This shows that the occurrence of Type-2 DM increases with age. This is similar to the study conducted by P. Bhavana et. al.[15]

Fig. 2: Age Wise Distribution of Type-2 Diabetes Patients

3.3 Comorbidities of Type-2 Diabetes Patients

Table 1: Distribution of Comorbidities of Type-2 Diabetes Patients

Comorbidities	Number (%)
Hypertension	73 (65%)
Cardiac diseases	49 (43%)
Renal diseases	18 (16%)
Liver diseases	8 (7%)
Gastro-intestinal diseases	4 (3%)
Thyroid diseases	2 (2%)
Lung diseases	9 (8%)
Neurological diseases	34 (30%)
Miscellaneous	18 (16%)

Table 1 presents the distribution of comorbidities of type-2 diabetes patients. Out of 113 patients studied, 108 (95.57%) of them had comorbidities. The common comorbidities observed in the study population with Type-2 Diabetes Mellitus were Hypertension (65%), cardiovascular diseases (43%), Neurological diseases (30%), Renal Disorders (16%). However, Other comorbidities were also analysed. It includes GI disorders (3%), Liver disorder (7%), Lung disorder (8%), Thyroid disorder (2%) and Other non-specific conditions (16%). Hypertension was found to be the most common comorbid condition with Type-2 Diabetes Mellitus. Comorbid conditions in Type-2 DM patients found to have statistically significant influence in obtaining glycaemic control. Effective management of diabetes often poses enormous challenges. It is not surprising that clinicians and patients alike can be overwhelmed by the need to treat chronic comorbidities in addition to the patient's diabetes-specific treatment goals. However, neglecting the concomitant management of the disease may lead to ineffective control of diabetes-specific risk factors and may miss opportunities to improve patient function, quality of life and risk of death.[16, 17]

3.4 Distribution of Types of Complications of Type-2 Diabetes Patients

Table 2: Distribution of Types of Complicationsof Type-2 Diabetes Patients

Complications	Frequency	Percentage
Macrovascular	5	4.42%
Microvascular	14	12.38%
Others	11	9.73%
Total	30	26.54%

Table 2 presents the distribution of types of complications of type-2 diabetes patients. Type 2 diabetes is associated with disabling and potentially life-threatening microvascular and macrovascular complications.[18] Out of 113 patients, 30 (26.54%) patients were found to have complications of Diabetes Mellitus. The most common complication observed was Microvascular complications in 14 (12.38%) patients, followed by Macro-vascular and other complications.

3.5 Distribution of Microvascular Complicationsof Type-2 Diabetes Patients

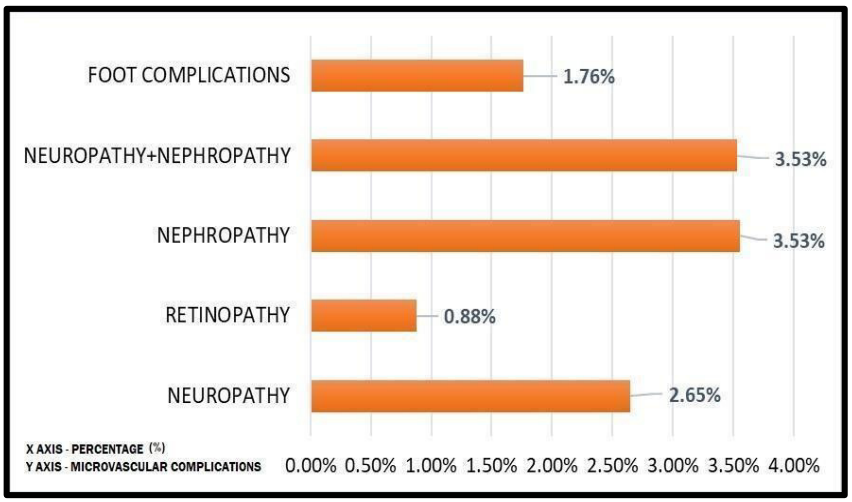

Fig. 3 illustrates the distribution of microvascular complications of type-2 diabetes patients. In Patients withmicrovascular complications, 4 (3.53%) have Diabetic Nephropathy and 4 (3.53%) haveNeuropathy+ Nephropathy. (2.65%) patients have Diabetic Neuropathy, 2 (1.76%) have diabetic foot complications and 1 (0.88%) have Diabetic Retinopathy.

Fig. 3: Distribution of Microvascular Complications of Type-2 Diabetes Patients

3.6 Type & Distribution of Hypoglycaemic Drugs Per the Prescription of Type-2 Diabetes Patients

Table 3: Type & Distribution of Hypoglycaemic Drugs per the prescription of Type-2 Diabetes Patients	
Types of Therapy	**Number (%)**
Monotherapy	30 (25 %)
2 drug therapies	47 (42 %)
3 drug therapies	27 (24 %)
>3 drugs therapies	9 (9 %)
Distribution of types of therapy	
Oral Hypoglycemic Agent (OHA)	49 (43.36 %)
Insulin	26 (23.00 %)
OHA + Insulin	38 (33.62 %)

Table 3 presents the type & distribution of hypoglycaemic drugs per prescription of type-2 diabetes patients. In 113 prescriptions studied, most of the patients [85 (75.23%)] received more than one anti-diabetic drug. Only 30 patients received Monotherapy. Most of the Patients were prescribed two or more drugs to achieve glycaemic control. In 113 patients, the majority of patients received 2 drug anti-diabetic therapy, followed by Monotherapy (25%), 3drug therapy (24 %) and more than 3 (9%) drug therapy. It is comparable with a previous study done by BP Anilasreeet.al.[19]The possible reason for the combination therapy is that type-2 diabetes is a chronic disease. As the function of β cells continues to deteriorate, blood sugar control graduallydeteriorates.[20]Therefore, monotherapy for type-2 diabetes may not be sufficient for long-term maintenance of blood sugar control.

3.7 Distribution of Types of Insulin of Type-2 Diabetes Patients

Table 4: Distribution of Types of Insulin of Type-2 Diabetes Patients	
Distribution of Types of Insulin	**Number (%)**
Rapid-acting	4%
Short-acting	59%
Intermediate-acting	26%
Long Acting	11%

Table 4 presents the distribution of types of insulin of type-2 diabetes patients. In a total of 113 Prescriptions, 64(56.63%) patients received insulin. Total number of insulin preparations was found to be 80. The short acting insulin was prescribed to 59% of patients, followed by intermediate acting insulin 26%, long-acting insulin 11% and rapid acting insulin 4%.Type-2 DM patients require insulin therapy when their blood glucose is not controlled with oral hypoglycaemic agents.[21]

3.8 Distribution of Insulin Preparations of Type-2 Diabetes Patients

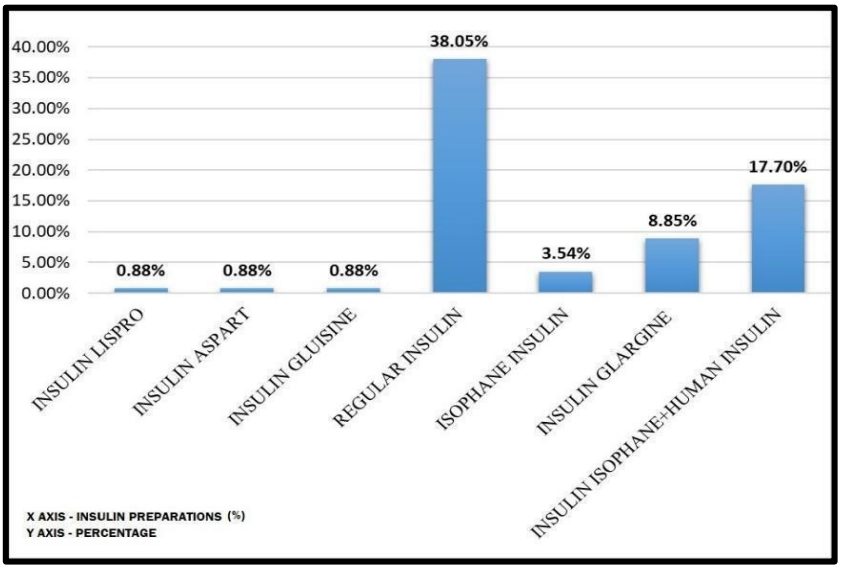

Fig. 4 illustrates the distribution of insulin preparations of type-2 diabetes patients. Regular insulin [Human Insulin] (38.05%) was the most prescribed Insulin preparation, followed by Isophane and Human insulin combination (17.70%), Insulin glargine (8.85%) and Isophane alone (3.54%). Least number of patients received Lispro, Gluisine and Aspart Insulin.

Fig. 4: Distribution of Insulin preparations of Type-2 Diabetes Patients

3.9 Distribution of Oral Hypoglycaemic Agents (OHA) Category of Type-2 Diabetes Patients

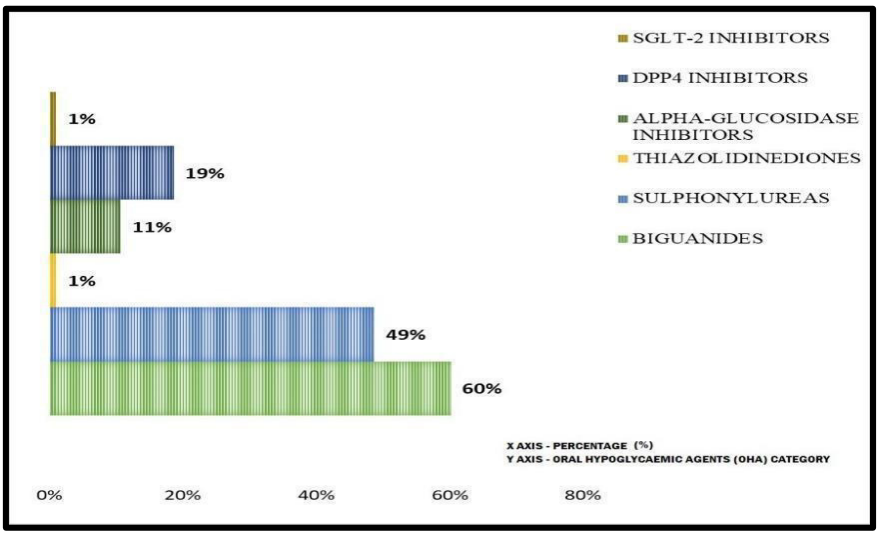

Fig. 5: Distribution of Oral Hypoglycaemic Agents (OHA) category of Type-2 Diabetes Patients

Fig. 5 illustrates the distribution of oral hypoglycaemic agents (OHA) category of type-2 diabetes patients. In the overall utilization pattern of 113 patients, 116 oral hypoglycaemic agents were prescribed in which, Biguanides (60%) was the most commonly prescribed drug followed by sulphonylureas (49%). DPP-4 Inhibitors (19%) was the third most prescribed class of drugs followed by alpha glucosidase inhibitors (11%).

3.10 Distribution of Oral Hypoglycaemic Agents (OHA) of Type-2 Diabetes Patients

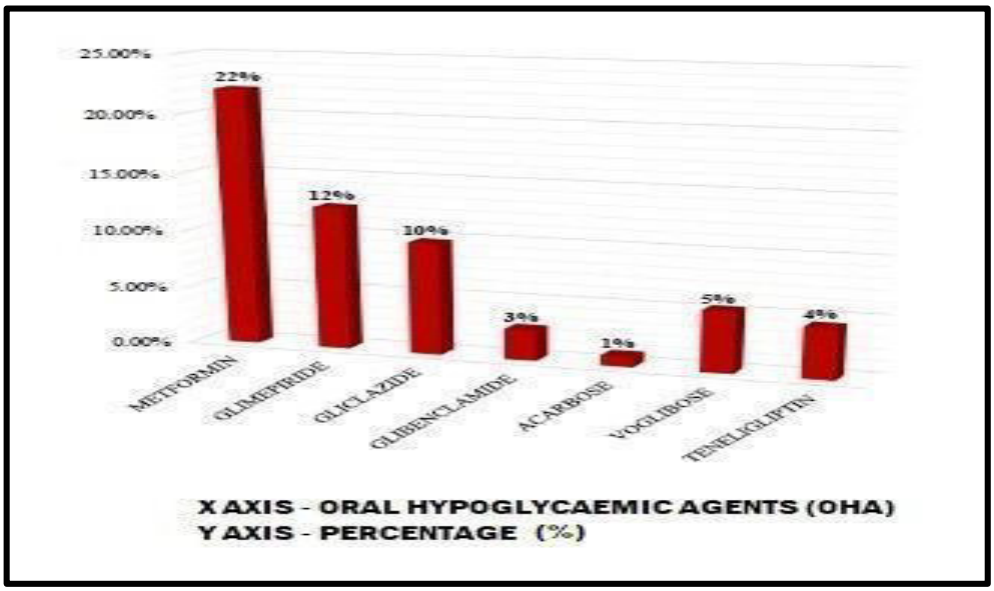

Fig. 6: Distribution of Oral *Hypoglycaemic* Agents (OHA)of Type-2 Diabetes Patients

Fig. 6 illustrates the distribution of oral hypoglycaemic agents (OHA) of type-2 diabetes patients. Sulphonylureas is the second preferable class of oral hypoglycaemic agents, as it reduces micro vascular risks, and promote increased systemic bioavailability of insulin.[22] The utilization pattern of thiazolidinedione's and SGLT-2 inhibitors was relatively very low compared to other drugs. Metformin is usually preferred as the best choice due to its obvious advantages over other hypoglycaemic like, increased safety profile, decrease LDL cholesterol, increase HDL cholesterol, reduce platelet aggregation, effectiveness in individuals with insulin resistance and does not cause weight gain.

3.11 Distribution of Oral Hypoglycaemic Agents (OHA) Combinations of Type-2 Diabetes Patients

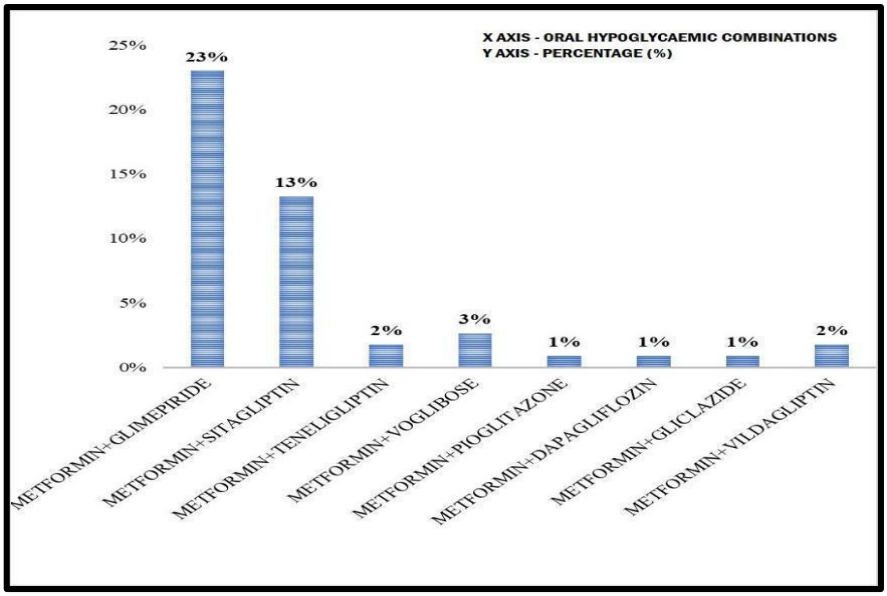

Fig. 7: Distribution of Oral Hypoglycaemic Agents (OHA) combinations of Type-2 Diabetes Patients

Fig. 7 illustrates the distribution of oral hypoglycaemic agents (OHA) combinations of type-2 diabetes patients. Patients were administered 51 OHA combinations in this study. Glimepiride+Metformin was the most commonly prescribed combination (23%), followed by Metformin+Sitagliptin (13%), and other combinations. Metformin+Vildagliptin, Metformin+Teneligliptin, Metformin+Voglibose, Metformin+Dapagliflozin, Metformin+Gliclazide, and Metformin+Pioglitazone are some of the combinations available.Glimepiride and Metformin combination has a rational basis of use. i.e., both of these agent's act through different mechanisms, the former as an insulin secretagogue and the latter as an insulin sensitizer.[23] Therefore, this contributes to better control of glucose levels in the patients.

3.12 Distribution of Drugs for Comorbid Conditions of Type-2 Diabetes Patients

Table 5: Distribution of Drugs for Comorbid Conditions of Type-2 Diabetes Patients

Drugs	No. of Prescriptions	Percentage
Antihypertensives	60	53%
Antiplatelet Agents	55	49%
Anticoagulants	17	15%
Hypolipidemics	34	30%
Cardioprotectives	19	17%
Diuretics	21	19%
Antimicrobials	50	44%
Antiasthmatics	11	10%
Sedatives/Hypnotics	27	24%

Table 5 presents the distribution of drugs for comorbid conditions of type-2 diabetes patients. Anti-hypertensive drugs (53%) were the most commonly prescribed drug for comorbid conditions, as Hypertension was the most common comorbid condition in the study. Anti-Platelets were the second most prescribed drug comprising 49% of the total comorbid drug, followed by Antimicrobials (44%) and Hypolipidemics (30%). Utilization of Drugs like Anticoagulants (15%), Diuretics (19%), Cardio-protectives (17%), Sedative/hypnotic (24%), Anti-asthmatics (11%) were also analysed. The most commonly co-prescribed medications along with Anti-diabetic drugs were Antihypertensive drugs which are similar to a study conducted by Sekhar Mandal et. al.[24] The high anti-hypertensive prescription reflects the high rate of comorbidity of hypertension and diabetes.[25]

3.13 Distribution of RBS Levels Type-2 Diabetes Patients

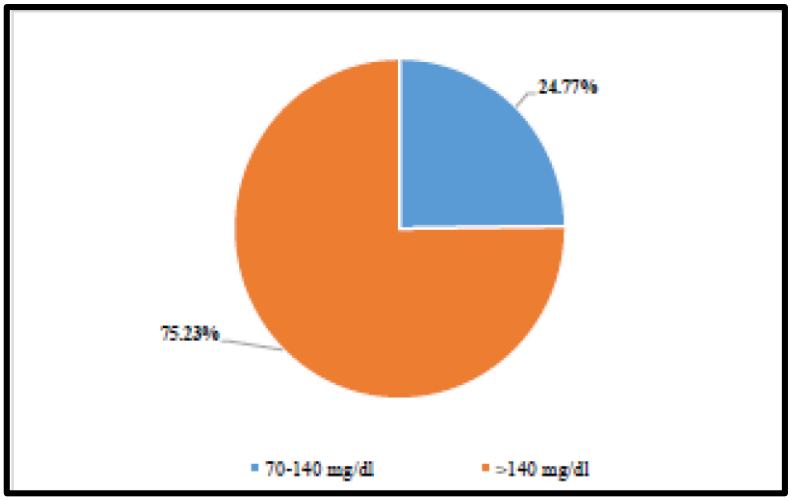

Fig. 8: Distribution of RBS levels Type-2 Diabetes Patients

Fig. 8 illustrates the distribution of RBS levels of type-2 diabetes patients. Regardless of age group, the majority of the patients in this study have uncontrolled blood glucose levels. Even though there is no link between glycaemic control and age, the majority of patients > 55 have poor glycaemic control. The results of this study reveal that as people get older, their glycaemic control deteriorates. However, as the American Diabetes Association states, blood glucose control becomes more difficult as a patient's age increases.[26] This is partially due to the expected age-related change in insulin sensitivity (insulin resistance) or impaired insulin production, rather than insulin resistance, as previous studies have revealed. Increased adiposity, decreased physical activity, altered nutrition, and impaired pancreatic functioning are all age-related alterations.[27]

3.14 Factors Affecting Clinical Outcomes of Type-2 Diabetes Patients

Table 6: Factors affecting clinical outcomes of Type-2 Diabetes Patients

Characteristics	Controlled DM [n=28]	Uncontrolled DM [n=85]	Total [n=113]	P-Value
Gender				
Male	22 (19.46%)	33 (29.20%)	55 (48.66%)	0.482
Female	27 (23.89%)	31 (27.43%)	58 (51.32%)	
Age (Years)				
<45	5 (4.42%)	6 (5.30%)	11 (9.72 %)	<0.021*
46-55	7 (6.19%)	11 (9.73%)	18 (15.92 %)	
56-65	8 (7.07%)	16 (14.15%)	24 (21.22 %)	
>65	8 (7.07%)	52 (46.01%)	60 (53.08 %)	
Comorbidities				
Yes	30 (26.54%)	78 (69.02%)	108 (95.56%)	<0.026*
No	4 (3.53%)	1 (0.88%)	5 (4.42%)	
Complications				
Yes	18 (15.92%)	12 (10.61%)	30 (26.54%)	<0.018*
No	30 (26.54%)	53 (46.90%)	83 (73.44%)	

Statistically Significant

Table 6 presents the factors affecting clinical outcomes of type-2 diabetes patients. The prevalence of comorbidities and complications has a considerable impact on glycaemic control. Glycaemic control is poorer in patients with comorbidities and complications. Poor glycaemic control can be caused by advancing age or the presence of different underlying illnesses. The majority of these individuals were taking multiple medications, resulting in polypharmacy. Polypharmacy raises the risk of a variety of unfavourable health outcomes in both adults and the elderly. Interprofessional collaboration is the most effective method for improving polypharmacy. Our results are comparable with previous studies by Mansour Almetwazi, et. al.[28]

3.15 Who Prescribing Indicators

Table 7: WHO Prescribing Indicators

Parameters	Frequency (%)
Total no. of drugs prescribed	711
Average no. of drugs per prescription	6.30

Total no. of anti-diabetic drugs prescribed	196
Average no. of anti-diabetic drugs per prescription	1.73
Total no. of antimicrobials prescribed	50
Average no. of antimicrobials per prescription	0.44
No. of prescriptions with monotherapy	28 (24.77%)
No. of prescriptions with polytherapy	85 (75.23%),

Table 7 presents the WHO prescribing indicators. A total of 711 medicines were prescribed to the participants in the study. Anti-diabetic medications accounted for 196 (27.56%) of the total. Per prescription, the average number of medications was 6.30. The majority of the medications are taken orally.This study's high average number of medications prescribed is not surprising. It is well known that people with diabetes mellitus are prescribed more medications than other patients. However, 1.73 anti-diabetic medicines were determined to be the average. Antimicrobials were given in a total of 50 cases (0.44%). This could be due to diabetes problems, which necessitate the use of antibiotics to prevent and cure infections.[29]

4. CONCLUSION

The study showed that elderly patients were at higher risk of developing Type-2 Diabetes Mellitus. Among various comorbidities, cardiovascular complications caused a major threat and hypertension was the major one. The presence of comorbidities and complications also hasa greater influence on obtaining glycaemic control, the patients with comorbidities and complications have relatively poor glycaemic control. Uncontrolled glycemia (RBS level) was seen in a significantly higher number of men than women in our study. This study revealed that Insulin alone or in combination with Metformin or Metformin alone or in combination with other drugs or PPIs, Vitamin and its combinations, anti-hypertensive drugs, lipid-lowering agents, and other unfavorable which were prescribed for the treatment of patient suffering from diabetes. Metformin is the most commonly prescribed oral hypoglycemic agent both in Monotherapy and combination therapy. Newer antidiabetics were prescribed less frequently. The prescribing trend also appears to be moving towards combination therapy, particularly two drug therapies. These findings highlighted the importance of proper management in older adult patients in order to prevent type-2 diabetes complications. To improve the patient's health, proper management and constant observation are recommended. Patients with variables associated with poor glycaemic management, such as hypertension and microvascular problems, should be given special attention.

5. ACKNOWLEDGMENT

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6. AUTHORS CONTRIBUTION STATEMENT

TB conceived the original idea and supervised all the aspects of its execution. SM and SB were responsible for the conceptualization & design of the study, data analysis & interpretation, and drafting of the manuscript. SK and SBR were responsible for critical review of the manuscript and approval of the final manuscript. BA, AR, SPT & KM analyzed the data and took the lead in writing the manuscript as well. All authors have critically reviewed and approved the final draft and they are responsible for the manuscript's content and similarity index.

7. SOURCE OF FUNDING

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8. CONFLICT OF INTEREST

The authors declare no relevant conflicts of interest.

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