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PRESCRIBING PATTERNS OF ANTIDIABETIC DRUGS IN PATIENTS WITH CARDIOVASCULAR AND KIDNEY DISEASE IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background: Diabetes mellitus (DM) is a major global health concern, frequently associated with cardiovascular disease (CVD) and chronic kidney disease (CKD). The coexistence of these comorbidities poses unique therapeutic challenges, necessitating the rational selection of antidiabetic agents. Recent advancements, such as sodium-glucose co-transporter-2 (SGLT2) inhibitors and Dipeptidyl Peptidase-4 inhibitors (DPP-4), provide additional renal and cardiovascular protection. However, real-world prescribing trends require evaluation to ensure adherence to evidence-based guidelines. **Objective:** To analyse the prescribing pattern of antidiabetic drugs among patients with cardiovascular and kidney diseases in a tertiary care teaching hospital, and to assess their rationality in comparison with national and international essential medicine lists. **Methodology:** A prospective observational study was conducted over six months at a tertiary care teaching hospital. A total of 220 inpatients aged >40 years with DM and associated CVD and/or CKD were included. Data on demographics, comorbidities, prescription patterns, and drug formulations were collected, analysed, and compared with the NLEM (2022) and WHO EML (2023) standards. **Results:** Among the 220 patients, males (61.36%) predominated, with the largest age group being 60–69 years (31.82%). Hypertension was the most common comorbidity

(36.36%), often coexisting with CVD (31.82%) and CKD (16.82%). Drug utilization revealed that 40.46% received monotherapy, 50.45% dual therapy, and 9.09% triple therapy. Human Actrapid was the most frequently prescribed monotherapy (83.15%), while metformin + glimepiride was the most common dual therapy (38.74%). In triple therapy, metformin + glimepiride + human actrapid was predominant (55%). Overall, injectable formulations (50.30%) were slightly more common than oral agents (49.70%). Metformin (35.97%) and its combinations remained the most frequently prescribed oral hypoglycaemic agents. Importantly, 87.63% of prescriptions adhered to NLEM and 80.9% to WHO EML. Co-prescription of antihypertensives (43.15%) and statins (24.62%) was frequent, reflecting the burden of comorbidities. Diabetic foot (43.3%) and nephropathy (20%) were the most observed complications. **Conclusion:** The prescribing trend in this study emphasizes predominant use of insulin preparations, particularly Human Actrapid, followed by metformin and sulfonylurea combinations. Although most prescriptions aligned with essential medicine guidelines, use of newer agents such as SGLT2 inhibitors and DPP-4 was limited. These findings highlight the need to strengthen evidence-based prescribing practices, optimize therapeutic outcomes, and promote the integration of newer cardio-protective and Reno protective agents in managing diabetes with CVD and CKD.

KEYWORDS: Diabetes mellitus; Cardiovascular disease; Chronic kidney disease; Prescription pattern; Antidiabetic drugs; WHO model of Essential Medicines List; National List of Essential Medicines.

INTRODUCTION

Diabetes mellitus (DM) is one of the oldest diseases known to man, which was first reported in Egyptian literature about 3000 years ago. The name diabetes was first given by the Greek Physician Aretaeus (30-90 CE). Avicema is the famous Arabian physician who first described the complications and progression of the disease.[1]

Diabetes is not a single disease rather than it is a heterogeneous group of syndromes including microvascular and macrovascular disorders characterised by an elevation of blood glucose caused by a relative or absolute deficiency of insulin. Numerous factors have been associated with the development of diabetes, such as obesity, increase in age, heredity, endocrine disease, emotional stress, viral stress, drugs such as cortisone, oestrogen, thyroid, phenytoin and thiazide diuretics.[2]

CLASSIFICATION[3]

Diabetes Mellitus may be categorised into several types, but the two major types are Type 1 and Type 2

TYPE 1(1a,1b)	Beta cell destruction with little or no endogenous insulin-secreting capacity. Autoimmune Idiopathic
TYPE 2	Ranges from relative insulin deficiency to disorders of insulin secretion and insulin resistance.
Other specific types	Genetic defects of beta-cell function. Genetic defects in insulin secretion. Disease of the exocrine pancreas. Endocrinopathy. Drug–induced or chemical-induced infection (congenital rubella). Uncommon forms of immune-mediated diabetes. Other genetic syndromes are sometimes associated with diabetes. Gestational diabetes.

DIAGNOSIS OF DIABETES MELLITUS

HbA1c >6.5 %

Or

Fasting (defined as no caloric intake for at least 8 Hrs) plasma glucose > 126 mg/dl.

Or

2 hr plasma glucose > than 200 mg/dl during an oral glucose tolerance test using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.

Or

A raised random plasma glucose > 200mg/dl. In a patient with classical symptoms of Hyperglycaemia.[4]

The clinical diagnosis of diabetes is often indicated by the presence of symptoms such as polyuria, polydipsia, and unexplained weight loss and is confirmed by measurement of abnormal hyperglycaemia. People with Type 2 diabetes have a greater incidence of cardiovascular disease, cerebrovascular disease and renal disease than the general population.[5]

CHRONIC KIDNEY DISEASE

Chronic kidney disease (CKD) is a progressive loss of renal function over three months or years. Clinical practice guidelines define chronic kidney disease as kidney damage or a glomerular filtration rate below 60 ml/min per 1.73 m3 for three months or longer. Kidneys can be damaged from a mechanical injury or a disease like diabetes or increased blood

pressure, and are usually associated with a reduction in glomerular filtration rate (GFR) and proteinuria.[6]

CARDIOVASCULAR DISEASE

The cardiovascular system, comprising the heart and blood vessels, is a critical physiological network responsible for circulating blood throughout the body. Cardiovascular disease, also referred to as heart disease (CHD), arises from myocardial perfusion, leading to clinical manifestations such as angina pectoris, myocardial infarction (MI) and heart failure.[7]

ANTI-DIABETIC AGENTS[8]

CLASS OF DRUG	BENEFITS	RISK FACTORS
1. Short-acting Insulin: Humulin R, Novolin R 2. Intermediate acting: NPH insulin 3. Long-acting insulin : Insulin glargine	It treats the high potassium levels	If a proper diet is not taken, it may lead to hypoglycaemia and may lead to death
Biguanides e.g. Metformin	First-line treatment, used to treat macrovascular complications and death	Lactic acidosis, gastrointestinal side effects
Sulfonylureas e.g. chlorpropamide	It is used to reduce glycosylated haemoglobin (HbA1c)	Hypoglycaemia, weight gain, liver dysfunction and gastrointestinal disturbances
Thiazolidinediones e.g. pioglitazone	Use in combination with metformin and sulfonylureas. It reduces the development of diabetes in patients with impaired fasting glycaemia	Patients with a history of heart failure, symptoms of coronary ischemia, may experience complications
Alpha-glycosidase inhibitors e.g. acarbose	Used in patients who cannot use other oral hypoglycaemic drugs.	Improper use may lead to flatulence, diarrhoea
Meglitinides e.g. repaglinide	It is used as third-line therapy in combination with metformin or glitazone	Hypersensitivity reactions occur, such as anaphylaxis, angioedema

The study of prescribing patterns is a component of medical audit that monitors and evaluates the prescribing practice of the prescribers as well as recommends necessary modifications to achieve rational and cost-effective medical care.[9] Prescribing pattern is one of the most important tools that communicate between the physician and the patient, and also a written order of medication schedule to the patient.[10]

Cardiovascular disease is a major cause of mortality and morbidity among people with DM. Type 2DM is a significant predictor of chronic heart failure. DM induces CHF through various mechanisms, including coronary artery disease, microvascular complications, arterial

thickening, endothelial and vasomotor dysfunction. DM is the most well-known cause of chronic kidney disease and end-stage renal disease, and more than 50% of people with DM are likely to develop chronic kidney disease.[11]

The World Health Organisation (WHO) Essential Medicine List (EML) and the Indian National List of Essential Medicine (NLEM) provide frameworks for rational, evidence-based and affordable drug use. For chronic diseases like diabetes, these lists highlight safe and effective agents to ensure optimal care and accessibility. Evaluating prescribing patterns against EML/NLEM is therefore essential to promote rational therapy and strengthen diabetes management practices.[12]

MATERIALS AND METHODS

STUDY SITE

The study was conducted in the inpatient of department of General Medicine at Chigateri District Hospital, a tertiary care teaching hospital in Davangere, over a period of 6 months.

STUDY DESIGN

Prospective observational study.

PROPOSED SAMPLE SIZE

A total of 220 inpatients were included in the study.

SOURCE OF DATA

Data were collected from the case sheets of inpatients admitted to the General Medicine and Emergency Departments.

STUDY CRITERIA

The study was carried out by considering the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- Patients above 40 years.
- Patients with cardiovascular diseases and renal diseases.
- Patients of both genders.
- Patient admitted to the General Medicine and Emergency Department.

EXCLUSION CRITERIA

- Patients who do not get any antidiabetic drugs.
- Outpatients, surgery patients, and non-comorbid cases.
- Pregnant and lactating women.
- Patients below 40 years of age.

STUDY PROCEDURE

A prospective observational study was conducted over 6 months. Medical records of patients aged above 40 years receiving at least one antidiabetic drug were reviewed. Data collected included demographic details, comorbidities and treatment patterns. Prescriptions were compared with the National List of Essential Medicines (NLEM, 2022) and WHO Essential Medicines List (EML, 2023).

RESULTS

5.1) GENDER-WISE DISTRIBUTION OF THE STUDY POPULATION

Out of 220 patients evaluated, it was found that a total number of male patients were 135 (61.36%) of study population compared to female were 85 (38.64%) in this study population.

Gender	Number of patients (N)	Percentage (%)
Male	135	61.36%
Female	85	38.64%
Total	**220**	**100%**

5.2) AGE-WISE DISTRIBUTION OF THE STUDY POPULATION

Out of 220 cases, the patients are divided into five categories according to their age. The majority of patient belonged to the 60-69 years age group (31.82%).

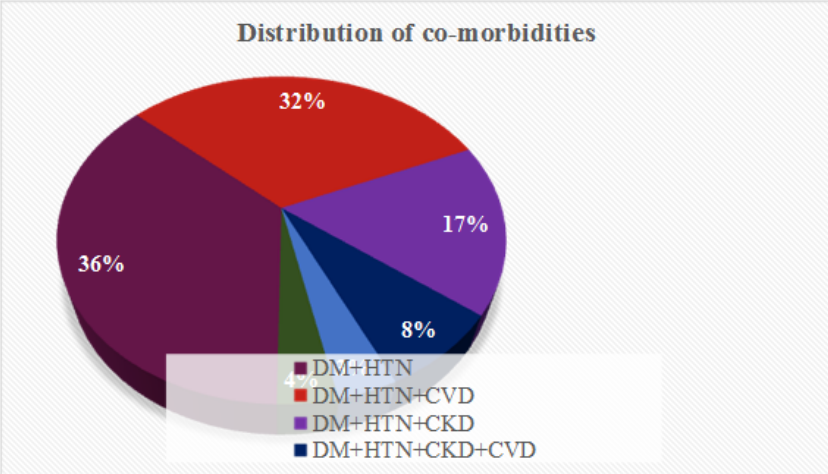
Age groups	No. of patients (N)	No. of male patients	No. of female patients	Percentage (%)
40-49 years	35	23	12	15.91%
50-59 years	59	40	19	26.82%
60-69 years	70	41	29	31.82%
70-79 years	30	18	12	13.64%
>80 years	26	14	12	11.82%
Total	**220**	**136**	**84**	**100%**

5.3) DISTRIBUTION OF CO-MORBIDITIES OF THE STUDY POPULATION

Among the 220 patients, 80(36.36%) patients had diabetes mellitus + hypertension followed by 70(31.82%) patients had diabetes mellitus + hypertension + cardiovascular diseases Only

few patients had diabetes mellitus + cardiovascular diseases 8(3.64%) and diabetes mellitus + chronic kidney disease 8(3.64%) is the least.

Co-morbidities	No. of patients	Percentage (%)
DM+HTN	80	36.36%
DM+HTN+CVD	70	31.82%
DM+HTN+CKD	37	16.82%
DM+HTN+CKD+CVD	17	7.72%
DM+CKD	8	3.64%
DM+CVD	8	3.64%
Total	**220**	**100%**



5.4) DRUG UTILIZATION PATTERN OF HYPOGLYCEMIC AGENTS

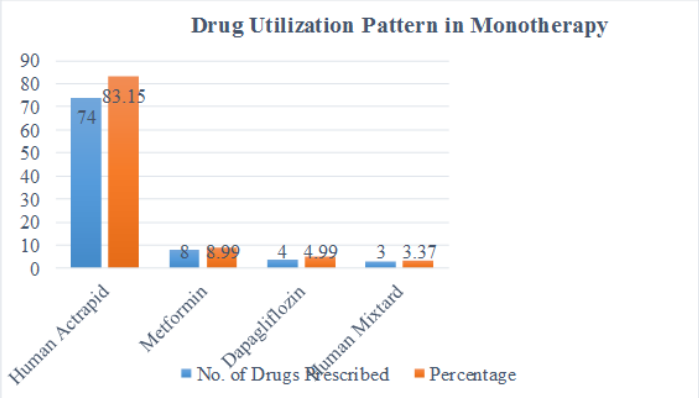
Among all the patients, N=89(40.46%) were treated with monotherapy, N=111(50.45%) treated with dual therapy and N=20(9.09%) were on triple therapy.

Drug therapy	No. of patients (N)	Percentage (%)
Monotherapy	89	40.46%
Dual therapy	111	50.45%
Triple therapy	20	9.09%
Total	**220**	**100%**

5.5) DRUG UTILIZATION PATTERN IN MONOTHERAPY

Out of 89 patients who underwent monotherapy with the antidiabetic therapy 74(83.15%) patient were prescribed Human Actrapid, 8(8.99%) patients were prescribed with metformin followed by dapagliflozin were used by 4(4.49%) patients and only 3(3.37%) patients were prescribed Human Mixtard.

Monotherapy drug name	No. of drugs prescribed (N)	Percentage (%)
Human Actrapid	74	83.15%
Metformin	8	8.99%
Dapagliflozin	4	4.99%
Human Mixtard	3	3.37%
Total	**89**	**100%**



5.6) DRUG UTILIZATION PATTERN IN DUAL THERAPY

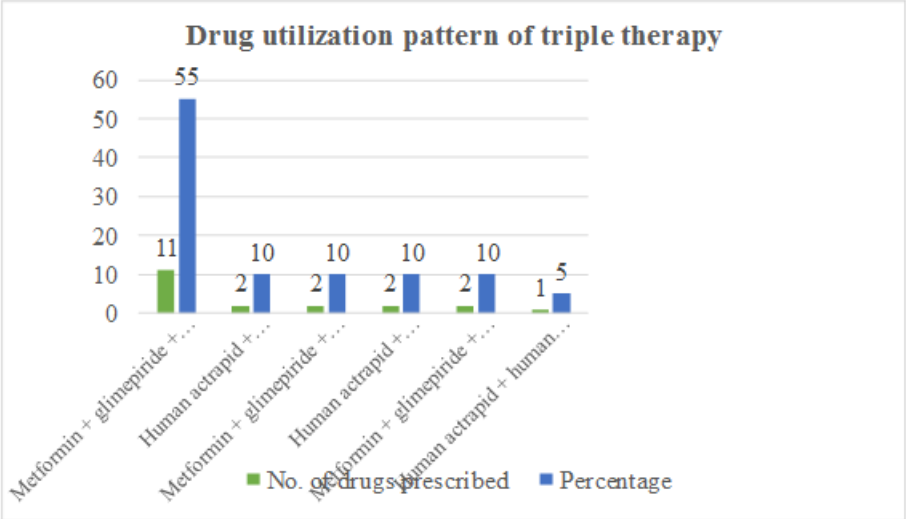
The result revealed that, out of 111 patients treated with dual therapy, 43(38.74%) patients were prescribed with metformin + glimepiride was the highest in result followed by second highest combination of metformin + actrapid 28(25.23%).

Dual drug therapy	No. of drugs prescribed (N)	Percentage (%)
Metformin + glimepiride	43	38.74%
Metformin + human actrapid	28	25.23%
Human Actrapid + dapagliflozin	21	18.92%
Human Actrapid + linagliptin	6	5.41%
Human Actrapid + vildagliptin	4	3.60%
Human Actrapid + glimepiride	3	2.70%
Human Actrapid + Human mixtard	2	1.80%
Metformin + dapagliflozin	2	1.80%
Metformin + Human mixtard	2	1.80%
Total	**111**	**100%**

5.7) DRUG UTILIZATION PATTERN OF TRIPLE THERAPY

The result revealed that, Out of 20 patients treated with triple therapy, 11(55%) patients was the most frequently observed with a combination of metformin + glimepiride + human actrapid. The combination of human actrapid + human mixtard + dapagliflozin were prescribed only in 1(5%) patient.

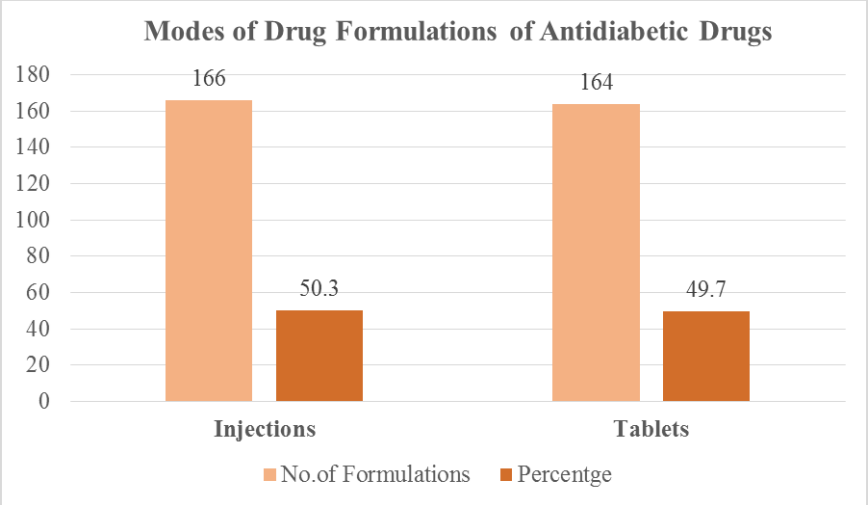
Triple drug therapy	No. of drugs prescribed (N)	Percentage (%)
Metformin + glimepiride + human actrapid	11	55%
Human Actrapid + metformin + dapagliflozin	2	10%
Metformin + glimepiride + human mixtard	2	10%
Human Actrapid + metformin + vildagliptin	2	10%
Metformin + glimepiride + dapagliflozin	2	10%
Human Actrapid + human mixtard + dapagliflozin	1	5%
Total	**20**	**100%**



5.8) MODES OF DRUG FORMULATIONS OF ANTIDIABETIC DRUGS

In this study result, 330 formulations were reviewed to assess the modes of antidiabetic drug dosage forms. Out of these 166(50.30%) were in the form of injections and 164(49.70%) were in the form of tablets.

Dosage forms	No. of formulations per prescription (N)	Percentage (%)
Injections	166	50.30%
Tablets	164	49.70%
Total	**330**	**100%**



5.9) PATTERN OF CO-PRESCRIBED MEDICATIONS

Out of 220 prescription, 170(43.15%) were prescribed with anti-hypertensives marked as highest as hypertension was the most frequent co-morbidity in the study sample, followed by 97(24.62%) of statins were marked as second highest co-prescribed medications.

Class of drugs	No. of patients (N)	Percentage (%)
Anti-hypertensives	170	43.15%
Statins	97	24.62%
Anti-platelets	101	25.63%
Anti-coagulants	26	6.60%
Total	**394**	**100%**

5.10) PRESCRIPTION PATTERN OF ORAL HYPOGLYCEMIC AGENTS

Among total prescriptions, 164(49.70%) oral hypoglycemic agents were prescribed in some patients. Metformin was the most frequently prescribed drug to 59(35.97%) patients followed by combination of metformin and glimepiride in 42(25.61%) observed as the second most prescribed (OHA)

Oral antidiabetic drugs	No. of prescribed drugs (N)	Percentage (%)
Metformin	59	35.97%
Metformin + Glimepiride	42	25.61%
Dapagliflozin	34	20.73%
Glimepiride	17	10.37%
Linagliptin	6	3.66%
Vildagliptin	6	3.66%
Total	**164**	**100%**

5.11) PRESCRIPTION PATTERN OF INJECTABLE HYPOGLYCEMIC AGENTS

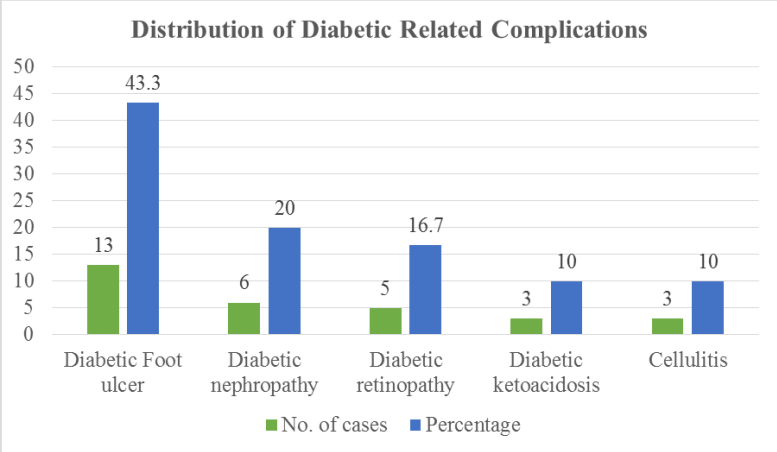
In these prescriptions about 166(50.30%) antidiabetic drugs were prescribed as injections. Among these 154(92.73%) were Human Actrapid observed as the most frequently prescribed. Only few patients 12(7.27%) were prescribed with Human Mixtard.

Antidiabetic drugs	No. injections prescribed (N)	Percentage (%)
Human Actrapid	154	92.73%
Human Mixtard	12	7.27%
Total	**166**	**100%**

5.12) DISTRIBUTION OF DIABETES-RELATED COMPLICATIONS

Out of the total patients, 30 patients have diabetes related complications with the most common complication being 13(43.3%) diabetic foot, followed by 6(20%) diabetic nephropathy cases. The least common complication were diabetic ketoacidosis and cellulitis observed in 3(10%) patients.

Complications	No. of cases (N)	Percentage (%)
Diabetic Foot Ulcer	13	43.3%
Diabetic nephropathy	6	20%
Diabetic retinopathy	5	16.7%
Diabetic ketoacidosis	3	10%
Cellulitis	3	10%
Total	**30**	**100%**



5.13) EVALUATION OF ANTIDIABETIC DRUGS FROM ESSENTIAL MEDICINE LIST

In this study the prescribed hypoglycemic agents are compared with the WHO Essential Medical List (2023) and the NLEM (2022). Among this the percentage of antidiabetic drugs

prescribed from WHO essential drug list was 80.9% (301) and percentage of antidiabetic drugs prescribed from National Essential Drug List of India was 87.63% (326).

DISCUSSION

Diabetes Mellitus (DM) is one of the most prevalent chronic conditions worldwide, often complicated by comorbidities such as cardiovascular disease and chronic kidney disease. The primary aim of our study was to evaluate the prescription pattern of antidiabetic drugs among cardiovascular and kidney disease patients in a tertiary care teaching hospital. A total of 220 participants were included to assess drug utilization trends, adherence to the essential medicine list, and the extent of co-prescription with other cardiovascular and renal drugs. In our study, out of 220 patients evaluated, 61.36% were males and 38.64% were females, which is similar to the study conducted by Venkatesh et al.,[13] at Chigateri District Hospital, Davangere. Our study result shows that the majority of the diabetic patients belong to the age group of 60-69 (31.82%), which was similar to the study of Jamuna Rani et al.,[14] conducted in Osmania Medical College, Hyderabad. Hypertension (36.36%) was the most common comorbidity along with DM, aligning with the report by Ponnachan et al.,[15] conducted at Chigateri District Hospital, Davangere, reflecting the strong interlink between DM and HTN in the high-risk population.

Therapeutic trends revealed that Dual therapy (50.45%) was the most frequently prescribed regimen, which was consistent with the study conducted by Mohammed Taher Ali et al.,[16] at Malabar Medical College, Kerala. The result of our present study reveals that (N=89) received Monotherapy, and the most frequently prescribed drug in monotherapy was Human Actrapid (83.15%), which was also similar to the study conducted on VSS Institute of Medical Science and Research, Burla, Odisha, by Ratna Agarwal et al.,[17] The preferred Dual therapy combination was Metformin + Glimepiride (N=43), which was the accordance with the study of Sriram A et al.,[18] conducted at RMMC Hospital, Chidambaram. For Triple therapy, Metformin + Glimepiride + Human Actrapid (N=11), which differs from the result of a study conducted by Sekhar Mandal et al.,[19] conducted at Sammilani Medical College, Bankura, which shows Metformin + Glimepiride + Pioglitazone as the highest. In our study, Human Actrapid was preferred as it can be safely used in renal impairment with dose adjustment, and patients had a high prevalence of CVD and CKD, where Pioglitazone is avoided due to risk of fluid retention, heart failure, DCM, and IHD patients.

The most highly prescribed antidiabetic dosage form in our study among 220 patients was injections (50.30%), followed by tablets, which was similar to a study conducted by Kumar P et al.,[20] at Tertiary Care Teaching Hospital, Kurnool. Anti-hypertensives (43.15%) were the most common co-prescribed medications, reflecting the high burden of hypertension among diabetic patients, which was similar to the study of Abbasi et al.,[21] conducted at Hyderabad. Among OHA, Metformin (35.97%) was the most frequently prescribed, consistent with the study conducted by Mahmood M et al.,[22] at the tertiary care Hospital, Medchal District. The most commonly prescribed injectable antidiabetic drug was Human Actrapid (N=154) 92.73% which was also similar to the result of a study conducted at a tertiary care Hospital in Navi, Mumbai by Agarwal et al.,[23]

In this study, diabetic foot ulcer (43.3%) was the most common complication observed, which was different from the study result of Anilasree B P et al.,[24] conducted on PVS Hospital, Calicut, which shows cellulitis as predominant. This variation may be explained by the high prevalence of increased peripheral vascular disease and neuropathy, leading to poor wound healing in uncontrolled diabetes with CVD and CKD patients. Cellulitis was also observed as a secondary infection since reduced immunity and delayed healing make them more prone to soft tissue infections.

The percentage of drugs prescribed from the WHO EML was (80.9%) and from the NLEM was (87.63%) which was not similar to the findings of Dinesh Prasad Sinha et al., (25) conducted at Patna Medical College, Bihar, possibly due to the use of agents like Linagliptin and Vildagliptin in our study population this can be justified by their favourable safety and efficacy profile in high-risk patients with CVD and CKD. Both agents belong to the DPP-4 inhibitor class, which offer effective glycaemic control with a minimal risk of hypoglycaemia in elderly patients and those on multiple comorbid therapies. Linagliptin is unique among DPP-4 inhibitors as it is eliminated through the hepatobiliary route; therefore, no dose adjustment is required in a renal impairment elderly patient, where the use of metformin and sulfonylureas is limited in CKD patients. Vildagliptin requires some dose adjustment in renal dysfunction also considered safer than sulfonylureas in hypoglycaemia risk, weight neutrality, and an alternative oral therapy in patients intolerant to standard first-line drugs. These agents are not listed in the WHO EML/NLEM. Hence, they are clinically justified as they are needed for safer, well-tolerated, and patient-centred glycaemic control in individuals with cardio-renal comorbidities.

Overall, our findings indicate a preference for insulin and dual therapy in complex, high-risk patients, with prescribing practices largely consistent with the EML/NLEM guidelines but adapted to clinical scenarios requiring safety in renal and cardiovascular impairment.

CONCLUSION

Diabetes mellitus (DM) is a major global health concern, frequently associated with cardiovascular disease (CVD) and chronic kidney disease (CKD). The present prospective observational study provides valuable insights into the prescribing trends of antidiabetic drugs among 220 patients complicated by CVD and CKD in a tertiary care Teaching Hospital. The majority of patients were elderly males, with hypertension being the most common comorbidity. Metformin and Insulin (Human Actrapid) emerged as the most frequently prescribed antidiabetic agents, either alone or in combination with glimepiride. While dual therapy was the predominant treatment approach, a significant proportion of patients required polytherapy due to complex co-morbid conditions.

The study also revealed that a large proportion of prescribed drugs were in accordance with the WHO EML (2023) and the NLEM (2022), reflecting rational prescribing practices. However, the use of newer antidiabetic agents such as SGLT2 inhibitors and DPP-4 inhibitors remained limited despite their proven cardiovascular and renal protective benefits.

Overall, the findings highlight the need for continued emphasis on evidence-based prescribing, greater utilization of newer agents with cardio-renal benefits, and regular prescription audits to ensure rational and patient-centred diabetes management in high-risk populations.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTEREST

All authors declare that there are no conflict of interest.

ETHICS DECLARATION

The Institutional Ethics Committee from S.C.S College of Pharmacy approved the protocol. All residents provided inform consent.

CONSENT FOR PUBLICATION

All authors have consent to the publication of their work.

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