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A PROSPECTIVE STUDY ON ORAL HYPOGLYCEMIC AGENTS (OHA) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND CARDIOVASCULAR DISEASE

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ABSTRACT

Aim: To assess the oral hypoglycemic agents in patients with type 2 diabetes and cardiovascular disease.

Objectives

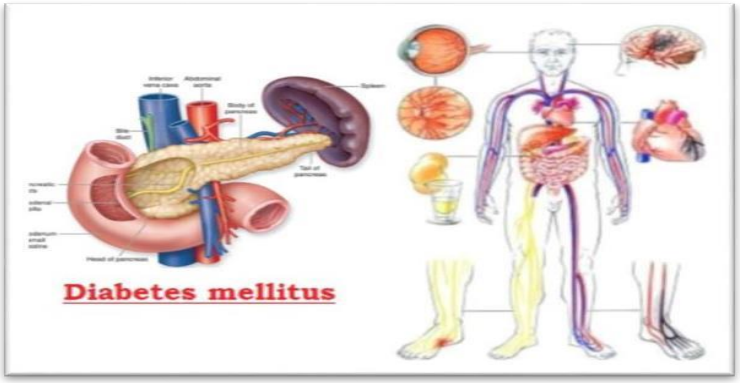
- To identify which hypoglycemic agents are safest for type2 diabetes and cardiovascular disease.
- To optimize oral hypoglycemic agents in type2 diabetes.
- To assess the effects of oral hypoglycemic agents on cardiovascular events.
- To reduce the symptoms and long-term complication of diabetes and cardiovascular disease.

Methodology: An observational study involving analysis of prescriptions of Type 2 diabetes diagnosed and treated for cardiovascular disease using patient data collection form and patient interview for a study period of 6 months. **Results:** This study examined the prevalence of cardiovascular diseases among type 2 DM in 110 Patients. Keeping it in view we monitored the glucose levels of all the patients and the results interpreted are the majority of the patients studied were over 41 years old and had Comorbidities such as Hypertension, Thyroid, CAD, CKD, AKI, UTI, CVA, Seizure's and Asthma. The study revealed that HYPERTENSION and CAD were the most prevalent cardiovascular diseases in patients, while it was more common in Male & Elderly Patients. Lab investigations were also analyzed, including Blood pressure and Blood glucose levels. The most commonly used anti-diabetic drugs were METFORMIN and DAPAGLIFLOZIN and many patients were also taking medication for other conditions such as hypertension and CAD. **Conclusion:** In conclusion, our study reveals a significant correlation between the use of oral hypoglycemic agents and cardiac health in type 2 diabetes patients with cardiovascular diseases. Notably, Metformin emerged as a frontrunner, demonstrating a remarkably high positive impact on cardiac health.

KEYWORDS: Type 2 Diabetes, Cardiovascular Diseases, Oral Hypoglycemic Agents, Metformin, Cardiac Health.

INTRODUCTION

Diabetes is identified as a persistent hyperglycemia metabolic disorder results from inadequate insulin action or secretion. Insulin helps to regulate blood sugar levels and loss of adequate control in insulin regulation leads to disturbances in maintaining glucose metabolism. Complications associated with the condition can involve cardiovascular disease, nephropathy, neuropathy, retinopathy and other foot pathology inadequate wound healing.[1,2]



DIABETES MELLITUS

CLASSIFICATON

TYPE 1

Type 1 DM is a condition in which the immune system attacks and destroys the pancreatic insulin- producing beta cells. This disease appears in childhood or adolescence, but onset can Be at any time. All persons affected by T1D need lifelong treatment with insulin; until now, there is no preventive cure.

TYPE 2

Type 2 DM implies insulin resistance, which describes a situation in which body cells are not receptive to the insulin produced, and a gradual decline in insulin production. Type 2 DM is the most prevalent type often associated with obesity associated with sedentary life and with a genetic predisposition.

GESTATIONAL DIABETES

Gestational diabetes (GDM) develops securely in the course of pregnancy and also typically transcends away after childbirth. Its untamed is going to highly risk the woman in getting type 2 diabetes in later life. After confirming a diagnosis of diabetes, these women require ongoing monitoring to avert complications for both mother and baby. Examples of other forms of diabetes include those attributed to genetic mutations, diseases of the pancreas in respect to diabetes, drug- or chemical-induced diabetes, or certain states- induced diabetes.[3,4,5]

ETIOLOGY

- **Autoimmune Destruction:** Type 1 DM caused due to the destruction of pancreatic beta cells, secreting insulin by the autoimmune system. This loss is usually caused by a genetic precondition, but an environmental trigger moves the process. Most genetic factors are concerned with the immune system, including certain HLA class II alleles (HLA-DR3 and HLA-DR4) that promote the development of T-cell-mediated immune responses. Communicable agents including enteric viral infections or dietary changes early in life are believed to trigger autoimmune responses.
- **Insulin Resistance and Obesity:** Type 2 diabetes is largely genetically predisposed with or without environmental triggers. Insulin resistance, the hallmark of T2D, is often associated with increased obesity and physical inactivity. Genetic factors play a major role in the heritage of certain genes promoting insulin secretion and glucose metabolism regulation. Chronic low-grade inflammation and visceral adiposity further aggravate insulin resistance.

RISK FACTORS IN DIABETES

- **Genetic predisposition:** Diabetes is more likely to happen in families having instances of diabetes in the past or in families having related diseases. Some genetic disorders could impair insulin production or function.
- **Obesity:** Obesity can only be associated with the buildup of too much fat and especially thousands in visceral tissues, the leading cause of insulin resistance and chronic inflammation, which disrupts normal glucose metabolism.
- **Physical Inactivity:** Physical inactivity decreases insulin sensitivity, induces weight increase, and promotes the onset of diabetes. Regular exercise helps control weight and allows absorption of glucose into muscles.
- **Unhealthy Dietary Habits:** Many who eat unhealthy foods like high levels of sugar, refined foods, and calorie-rich foods are at higher risk for diabetes. Such types of nutrition also contribute to overweight situations and hinder insulin function.
- **Increasing Age:** Increasing age diminishes insulin sensitivity and loss of beta-cell function.
- **Hormonal Changes during Pregnancy:** In gestational diabetes, hormonal adjustments cause insulin resistance during pregnancy. Women with a family history of diabetes, women who were overweight, or advanced maternal age are at risk. Pregnancy-related hormonal changes often unveil an underlying predisposition to glucose intolerance.
- **Medications:** Medications like glucocorticoids, antipsychotics and some immunosuppressants may also elevate the risk of diabetes by interfering with insulin action or secretion.
- **Smoking:** Smoking is also a risk factor type 2 diabetes as it promotes inflammation and insulin resistance, thus impairing glucose metabolism.[8,9,10]

PATHOGENISIS

DIAGNOSIS

1. Fasting Plasma Glucose (FPG) The FPG test is performed after the sample collection of plasma more than 8 hours, usually overnight. This test is a commonly used test for diagnosis of diabetes, as some high levels of glucose in fasting characterize poor blood sugar control.
2. Hemoglobin A1c (HbA1c) Test Average blood sugar levels over the previous two to three months are displayed by the hemoglobin A1c (HbA1c) test. It is frequently used to diagnose and track diabetes since it is a long-term indicator of glycemic control.

BLOOD GLUCOSE LEVELS

	No Diabetes	Prediabetes	Type 2 Diabetes
HbA1c	4 - 5.6%	5.7 - 6.4%	6.5+%
Fasting Blood Glucose	<100 mg/dL	100-125 mg/dL	126+ mg/dL
OGTT	< 140mg/dL	141-199 mg/dL	200+ mg/dL

3. Random Blood Glucose/Random Blood sugar (RBG) Test Random plasma glucose test diagnoses plasma glucose at any time of the day whether it has been a while since the patient has eaten or not. It is performed when symptoms such as severe polydipsia, polyuria, fatigue, and visual disturbances illustrate hyperglycemia. If the random glucose test result shows ≥ 200mg/dL and the patient is symptomatic for hyperglycemia, this is taken as a definite diagnosis for diabetes. Yet, this test is not very usually advised for diagnosing diabetes type without some confirmatory tests.

COMPLICATIONS

- **Cardiovascular:** Chronic hyperglycemia damages blood vessels and brings about arteriosclerosis, hypertension, and an increased risk of heart disease or stroke. Controlled management of blood sugar, blood pressure, and lipid levels will abate such risks.
- **Neuropathies:** Diabetic neuropathy comes with an infected peripheral and an automatic nerve. These symptoms can cause complaints by pain, tingling, and numbing in most reactive extremities. In severe cases, they will lead to ulcers and infections and may predominantly be ignored due to the ischemic effects of poisoned neuron fibers, resulting in a drop in sensation and slow healing.
- **Retinopathy:** Diabetic retinopathy results from the affected small blood vessels in the retina. This is projected to cause blindness in adults. The early stage is often non- symptomatic, but the late stage can result in varying degrees of visual loss. Regular eye examinations and glycemic control are very important for prevention.
- **Nephropathy:** Diabetic nephropathy is a major cause of chronic nephropathy and end- stage renal failure. Persisting hyperglycemia and hypertension cause glomerular injuries, leading to proteinuria and progressive renal failure. Early management and detection may slow the progression.

MANAGEMENT

Management of diabetes, including lifestyle modifications, involving a healthy diet, regular exercise, weight control, and pharmacological treatment. Metformin immunotherapy can manage blood glucose levels; there are further treatments with sulfonylureas, DPP-4 inhibitors, and SGLT2-inhibitors. In addition, the treatment of type 1 diabetes or advanced type 2 diabetes sometimes involves the use of insulin therapy. Regular blood glucose or HbA1c levels should also be checked, and treatment should be provided for associated comorbidities, including hypertension and dyslipidemia.

Classes of Oral Hypoglycemic Agents

Class	Examples
1. Sulfonylureas	Glimepiride, Glyburide, Glipizide
2. Meglitinides	Repaglinide, Nateglinide
3. Biguanides	Metformin
4. Thiazolidinediones (TZDs)	Pioglitazone, Rosiglitazone
5. Alpha-glucosidase Inhibitors	Acarbose, Miglitol
6. DPP-4 Inhibitors	Sitagliptin, Linagliptin, Saxagliptin
7. Bile Acid Sequestrants	Colesevelam
8. Dopamine Agonists	Bromocriptine
9. SGLT2 Inhibitors	Empagliflozin, Dapagliflozin, Canagliflozin
10. Oral GLP-1 Receptor Agonists	Semaglutide (oral)

MECHANISM OF ACTIONS

1. **Sulfonylureas:** The sulfonylureas are insulin secretagogues who are effective by causing stimulation and an increased release of insulin from

the beta cells of the pancreas. They act by binding to the sulfonylurea receptor 1 (SUR1), which acts as a subunit on an ATP-dependent potassium channel (adenosine triphosphate-sensitive potassium (K^+ - ATP) channel) found on pancreatic beta cells.

2. **Biguanides:** Metformin, a first-line treatment for Type 2 Diabetes Mellitus (T2DM) and a biguanide, acts on multiple mechanisms for lowering blood glucose levels. The chief means of lowering blood glucose is through reducing hepatic glucose production, which occurs due to its ability to suppress gluconeogenesis. This action is achieved through the activation of AMPK, which directly inhibits transcription of genes encoding enzymes controlling glucose synthesis in the liver.
3. **DPP-4 inhibitors:** Inhibitors of DPP-4, also known as gliptins (sitagliptin, linagliptin), have the common action of restraining the enzyme DPP-4 (dipeptidyl peptidase 4), which is responsible for inactivation of incretin hormones like GLP- 1(glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide). These incretins, in fact, are very important in glucose homoeostasis by way of Increasing insulin secretion, in a glucose-sensitive manner, and reduce glucagon release from pancreas.
4. **SGLT2 inhibitors:** SGLT2 inhibitors (empagliflozin, canagliflozin, and dapagliflozin) work to block the sodium- glucose co-transporter 2 (SGLT2) in the proximal convoluted tubule of kidneys. The SGLT2 transporter is responsible for reabsorbing about 90% of the filtered glucose from the urine back into the blood stream. By inhibiting this transporter, the reabsorption of glucose is prevented, increasing excretion of glucose into urine, thereby reducing levels of blood glucose.

METHODOLOGY

3.1 STUDY DESIGN: It is a Prospective Observational Study

3.2 DURATION OF THE STUDY: This Study was conducted for a period of 6 months.

3.3 STUDY POPULATION: 110 Patients were enrolled in this study.

3.4 SOURCES OF DATA AND MATERIALS:

- Patients Case files
- Medication charts
- Lab data reports

3.5 STUDY CRITERIA: The study was carried out by considering the following criteria.

3.6 INCLUSION CRITERIA

- Patients of either gender, age greater than 18 years.
- Patients with type 2 diabetes and cardiovascular diseases.
- Patients who are willing to participate in this study.
- Patients with prescribed oral anti-diabetic medications.

3.7 EXCLUSION CRITERIA

- Pregnant or Lactating women.
- Patients who are not willing to participate in this study.
- Patients with type 1 diabetes mellitus.
- Impaired patients.
- Children below 18 years.

3.8 METHOD OF DATA COLLECTION

- Data collection forms
- Case files

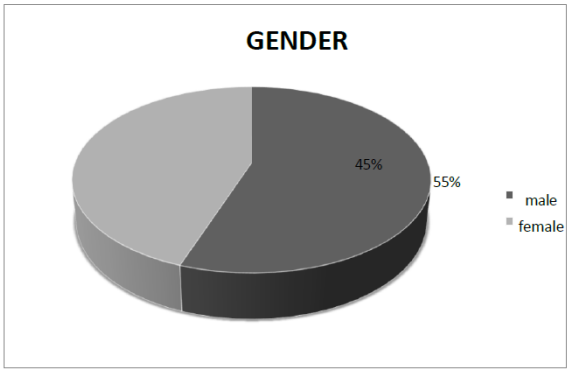
3.9 STUDY PROCEDURE

This a prospective observational study where patients eligible are enrolled into the study after obtaining the consent. The data collection form will be prepared and used. This form mainly contains the demographic of the patient and medication chart. The study will be conducted at care hospital. All information relevant to the study will be collected at the time of admission till the date of review follow up and the data will be analyzed after entering into Microsoft excel sheet and Calculated using suitable method for statistical analysis.

RESULTS

This is a prospective observational study on Oral Hypoglycemic agents in patients with Type 2 Diabetes & Cardiovascular diseases. A total of 110 patients were enrolled, with 61 being male patients and 49 being female patients.

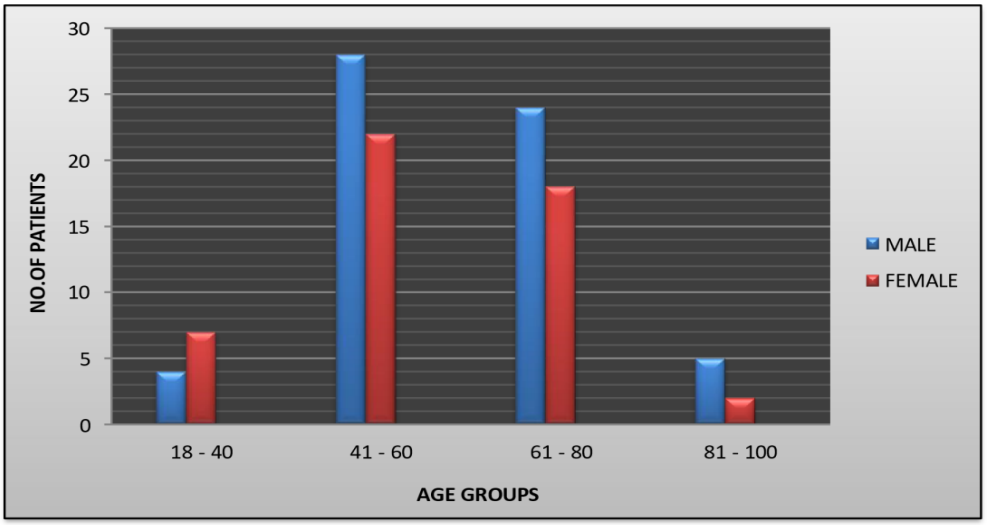
DISTRIBUTION OF PATIENTS BASED ON GENDER



Among the 110 patients, Gender distribution of the patients is as follows.

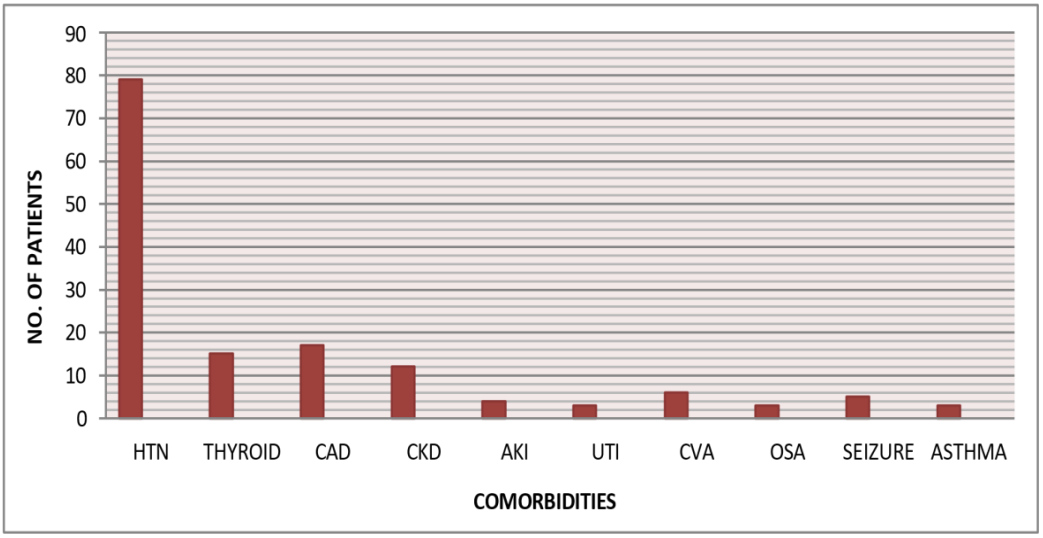
- 61 patients were male (55%).
- 49 patients were female (45%).

DISTRIBUTION BASED ON AGE GROUP AND GENDER



The sample size of 110 patients was categorized into four age groups - 10% patients were from 18-40 years, 45% were from 41-60 years, 38% patients were from 61-80 and 7% patients were from 81-100.

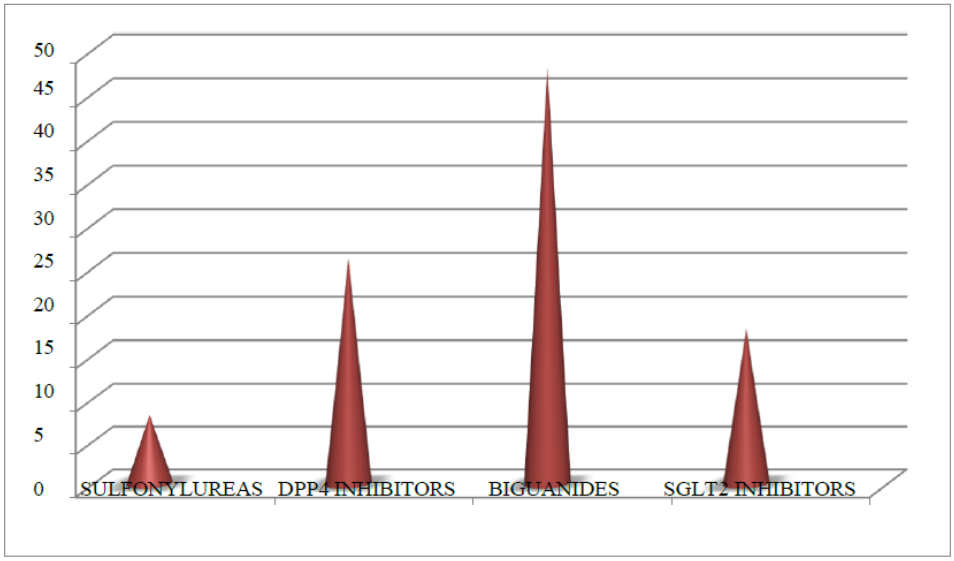
DISTRIBUTION BASED ON COMORBIDITIES



Our study has looked at various comorbidities among patients from which:

- 79 patients had Hypertension (HTN).
- 17 patients had Coronary Artery disease (CAD).
- 15 patients were diagnosed with Thyroid.
- 12 patients had chronic kidney disease (CKD).
- 4 patients also had Acute Kidney injury (AKI).
- 3 patients had Asthma.

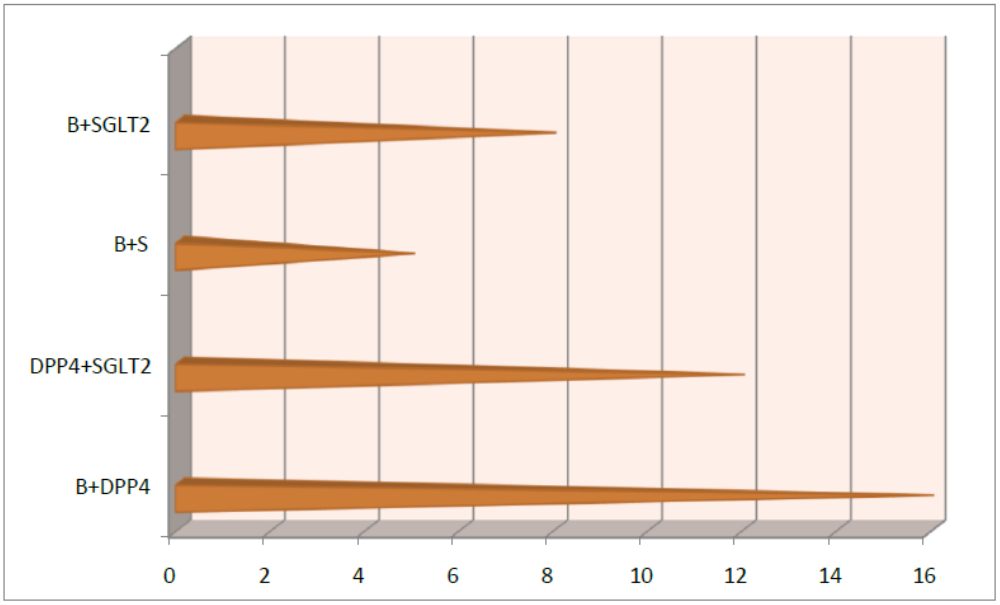
DISTRIBUTION BASED ON ORAL HYPOGLYCEMICS (MONOTHERAPY)



Among 110 patients distribution among usage from the different classes of drugs:

- 48 patients were found to use Biguanides.
- 26 patients used DPP4 inhibitors.
- 18 patients used SGLT2 Inhibitors.
- 8 patients used Sulfonylureas.

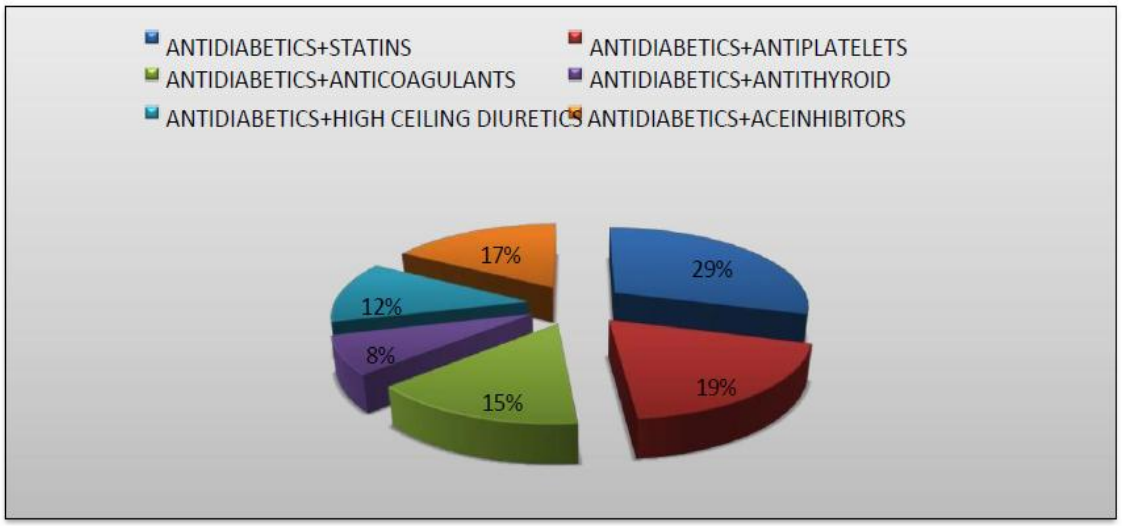
DISTRIBUTION BASED ON COMBINATION OF ORAL HYPOGLYCEMIC AGENTS



Among 110 patients distribution among usage of combination of drugs:

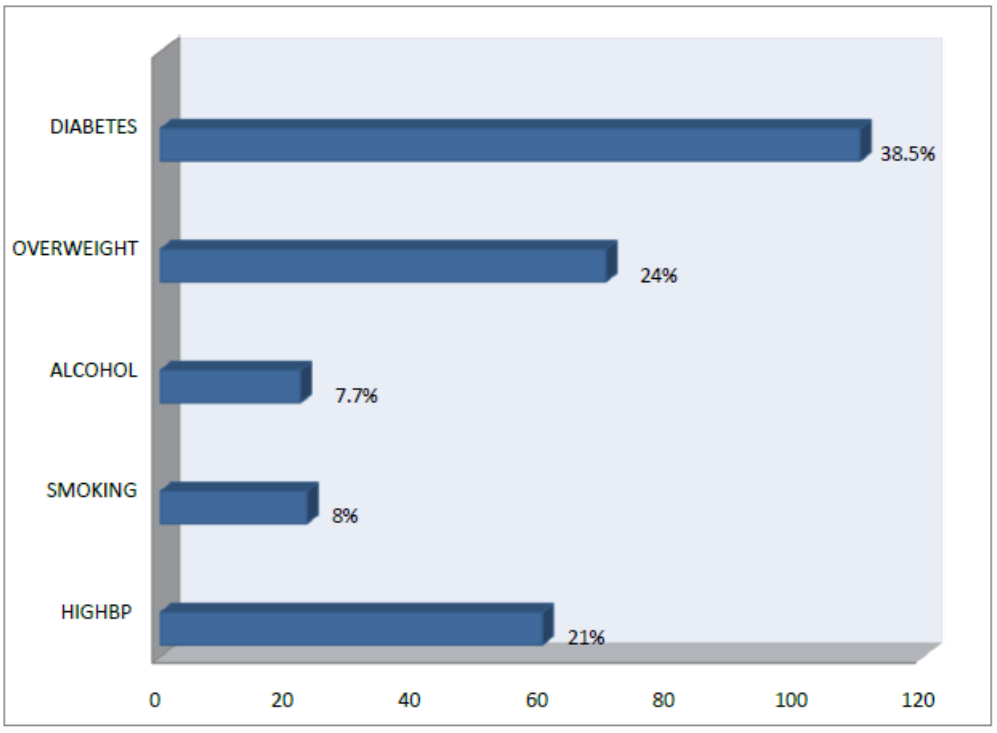
- 16 patients were prescribed combination of Biguanides and DPP4 inhibitors.
- 12 patients were prescribed combination of DPP4 inhibitors and SGLT2 inhibitors.
- 5 patients were prescribed combination of Biguanides and Sulfonylureas.
- 8 patients were prescribed combination of Biguanides and SGLT2 inhibitors.

COMBINATION OF ORAL HYPOGLYCEMICS WITH OTHER CLASS OF DRUGS



The combination analyzed are Anti-diabetics with statins accounting for 29% patients, Antidiabetics with Antiplatelet accounting for 19%, Antidiabetics with Anticoagulants accounting for 15%, Antidiabetics with Antithyroid drugs accounting for 8%, Antidiabetics with high ceiling diuretics for 12%, Antidiabetics with ACE inhibitors accounting for 17% of patients.

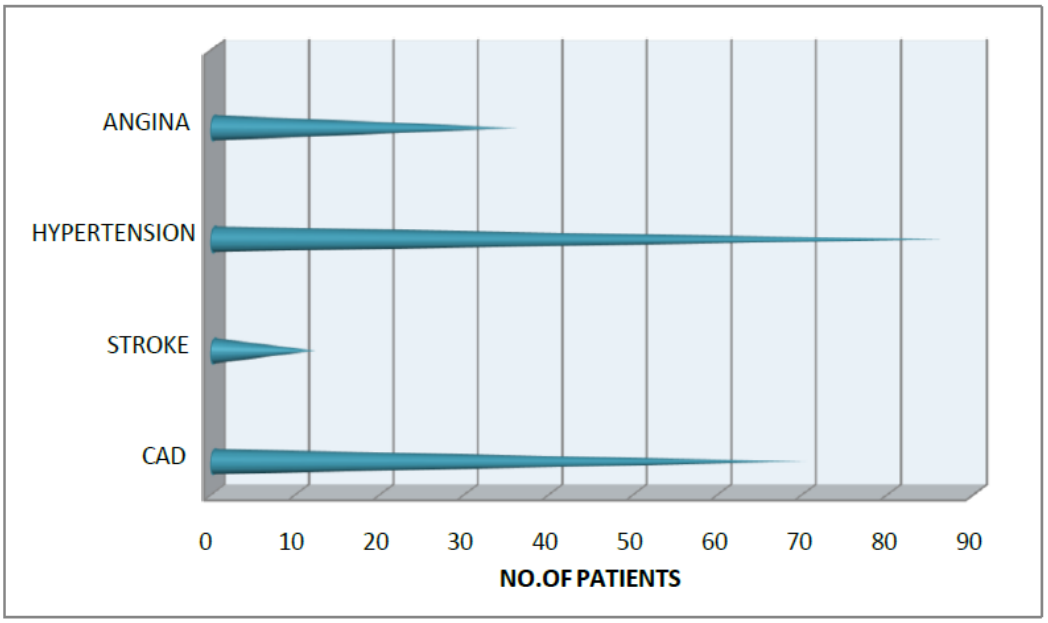
DISTRIBUTION BASED ON RISK FACTORS OF CVD



The risk factors for CVD analyzed were

- The no of patients with high blood pressure was 60.
- The no of patients who were smoking was 23.
- The no of patients who were alcoholics was 22.
- The no of patients with being overweight was 70.
- The no of patients with diabetes was 110.
- The majority of patients were diabetic.

CARDIAC DISEASES ASSOCIATED WITH DIABETES

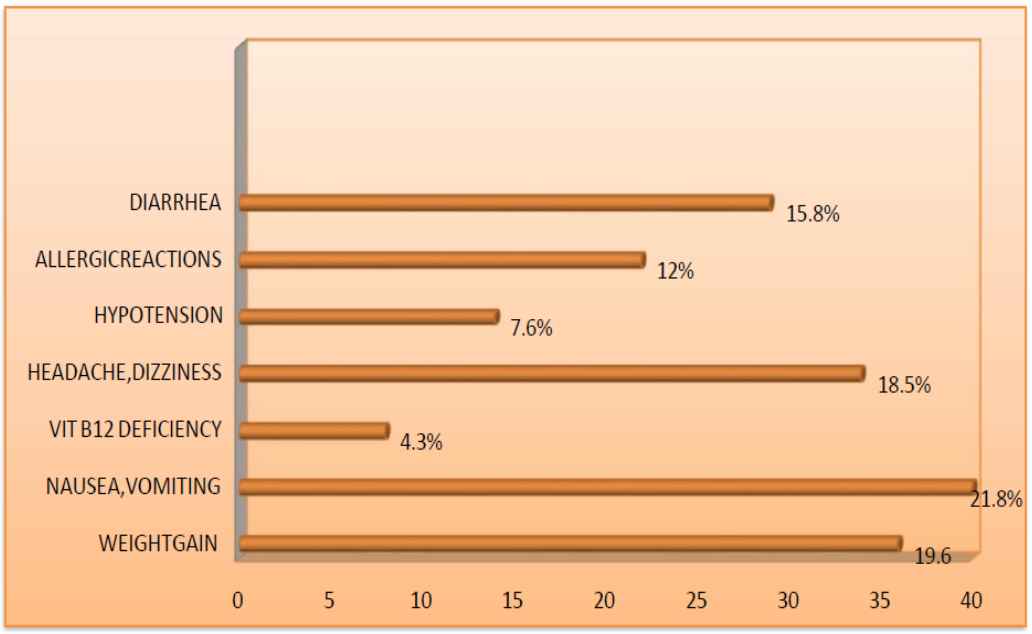


The cardiac diseases associated with diabetes are.

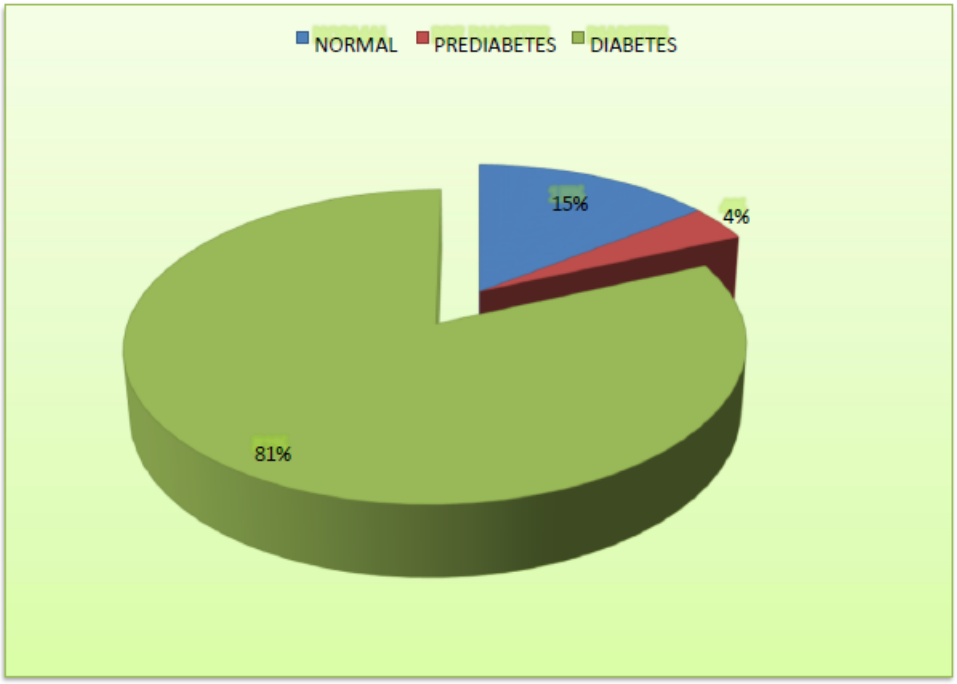
- 70 patients were having coronary artery disease (CAD).
- 12 patients were having stroke.
- 86 patients were having hypertension.
- 36 patients were having angina.
- The majority of patients were having hypertension.

ADVERSE EFFECTS ASSOCIATED WITH ANTIDIABETIC DRUGS

In this study population the adverse effects associated with antidiabetic drugs were weight gain, nausea and vomiting, vitamin B12 deficiency, headache and dizziness, hypotension, allergic reactions and diarrhea. The majority of patients were associated with vomiting and nausea.

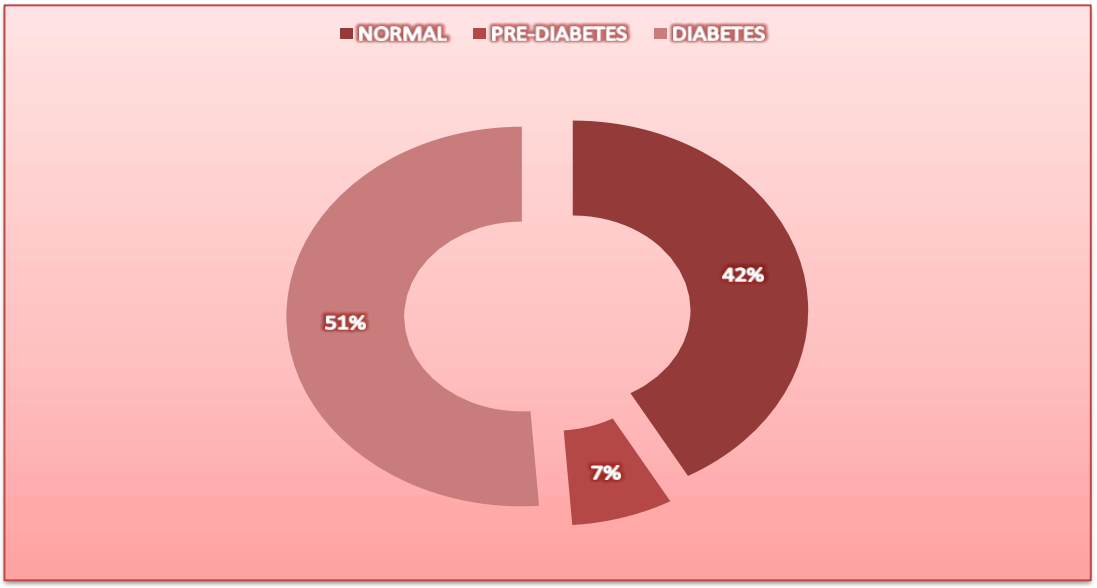


DISTRIBUTION BASED RANDOM BLOOD GLUCOSE LEVELS



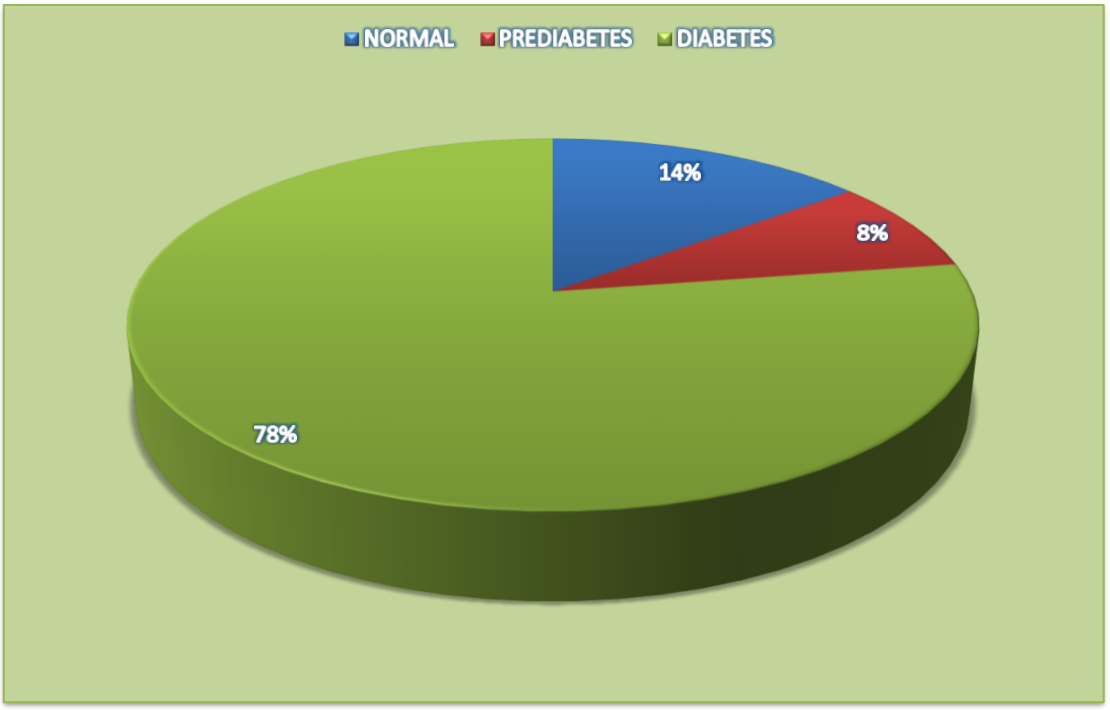
In this study population, 19 patients were having normal blood glucose levels and 5 patients were pre diabetic and 106 patients were having diabetes.

DISTRIBUTION BASED ON FASTING BLOOD GLUCOSE LEVELS



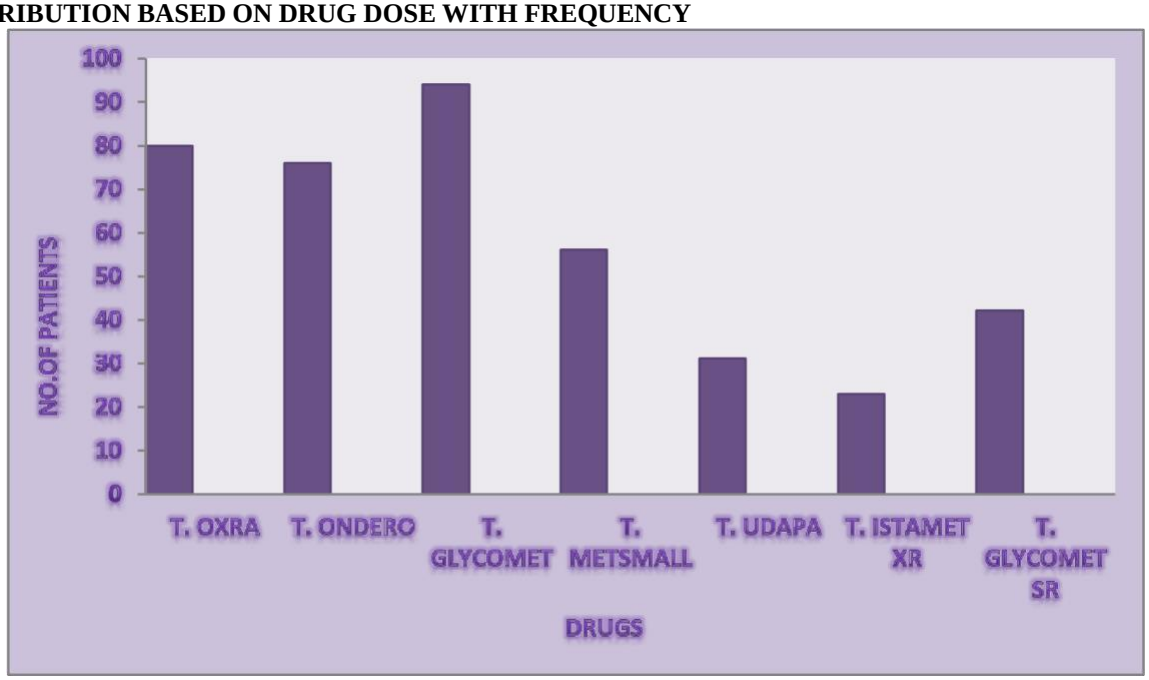
In this study population, the no of patients having normal range was 42%, 7% patients were pre- diabetic, the no of patients having diabetes are 51%.

DISTRIBUTION BASED ON HBA1C LEVELS



In this study population, the no of patients having normal range were 14%, 8% patients were pre- diabetic, the no of patients having diabetes are **78**%.

DISTRIBUTION BASED ON DRUG DOSE WITH FREQUENCY



In this study population, the drugs prescribed are as follows.

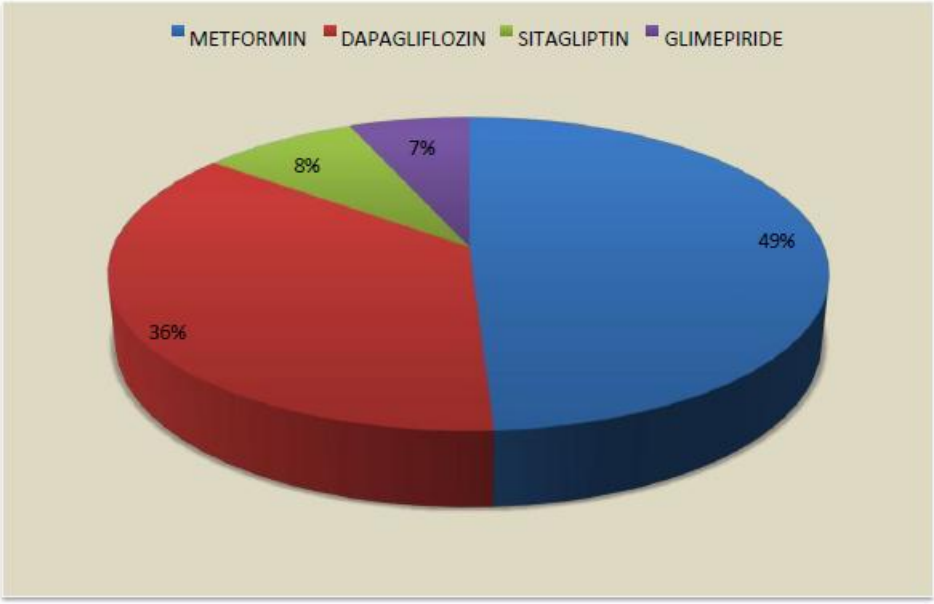
- 80 patients was prescribed tablet Oxra.
- 76 patients was prescribed tablet Ondero.
- 94 patients was prescribed tablet Glycomet.
- 56 patients was prescribed tablet Metsmall.
- 31 patients was prescribed tablet Udapa.
- 23 patients was prescribed tablet Istamet xr.
- 42 patients was prescribed tablet Glycomet sr.
- The majority of patients was prescribed tablet Glycomet.

IMPACT OF ORAL HYPOGLYCEMIC AGENTS ON CARDIAC HEALTH

Among 110 patients distribution based on impact of oral hypoglycemic on cardiac health

- 49% patients were prescribed metformin.
- 36% patients were prescribed dapagliflozin.

- 8% patients were prescribed sitagliptin.
- 7% patients were prescribed glimepiride.
- The majority of patients were prescribed metformin.



DISCUSSION

We carried out an observational study on 110 type 2 diabetes mellitus patients associated with cardiovascular diseases for 6 months. The patients enrolled for our study were as per the inclusion and exclusion criteria.

The main focus of our study was to determine the prevalence of cardiovascular diseases among type 2 DM Patients. Keeping it in view we monitored the glucose levels of all the patients and the results interpreted are the majority of the patients studied were over 41 years old and had comorbidities such as Hypertension, Thyroid, CAD, CKD, AKI, UTI, CVA, Seizure's and Asthma.

The study revealed that HYPERTENSION and CAD were the most prevalent cardiovascular diseases in patients, while it was more common in Male & Elderly Patients. The most commonly used antidiabetic drugs were METFORMIN and DAPAGLIFLOZIN and many patients were also taking medication for other conditions such as hypertension and CAD.

Metformin improves insulin sensitivity and reduces hepatic glucose production. It decreases atherosclerosis progression. Dapagliflozin reduces blood pressure, weight, and arterial stiffness. It enhances cardiac metabolism (shifts myocardial fuel toward ketone bodies). It lowers risk of CV death especially in heart failure with reduced ejection fraction.

Our study was a small-scale, single-center investigation. While it provides valuable insights, further research is necessary to fully understand the impact of diabetes medications on heart health in patients with type 2 diabetes and cardiovascular diseases. This will help us better address the growing concern of cardiovascular complications in this patient population**.**

CONCLUSION

The antidiabetic drugs in combination with other classes of drugs used by the patients were analyzed. Most patients above 41 years old age group are found to have Type 2 diabetes associated with cardiovascular diseases However, 110 cases were collected keeping in mind that this study is observational. The quantitative data were obtained following the guidelines and patient data was kept confidential throughout the study. Among the collected cases it was recorded that most patients have co-morbidities. The most seen comorbidities are HTN, THYROID, CAD, CKD, AKI, UTI, CVA, SEIZURE's and ASTHMA. Moreover, the people most affected are elderly.

Patients with cardiovascular diseases frequently experience type 2 diabetes, which may raise their risk of fatality. Complex pharmacological regimens, some of which may be linked to cardiovascular abnormalities, may be given to DM patients. To minimize problems in diabetic patients, it is crucial to stop using these medications whenever possible and maintain strict glycemic control.

To conclude, our study found a strong link between certain diabetes medications and heart health in patients with type 2 diabetes and cardiovascular diseases. Metformin stood out for its positive effects on heart health, with a high success rate. Metformin improves glycemic control it helps prevent long term complications. Reduces cardiovascular events (MI, Stroke) especially in over weight type 2 diabetes mellitus patients. These findings suggest that careful medication choices can play a crucial role in managing heart health

in these patients.

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