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AN OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF TELMISARTAN IN PATIENTS WITH CORONARY ARTERY DISEASE

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ABSTRACT

Background: The most prevalent kind of cardiac illness is coronary artery disease, it develops when the blood vessels are blocked due to the accumulation of cholesterol, and fatty deposits(plaques) which leads to a decline in the supply of blood to the heart and may cause chest pain (angina), SOB which results in cardiac problems like CAD/IHD, MI, or heart failure. Telmisartan is a angiotensin 2 receptor blocker. It works by blocking an internal substance that causes the tightening of blood vessels and alters their relationship, further resulting in reduced blood pressure and supplying the heart with more blood and oxygen. **Methods:** A total of 70 case records of patients were included in an observational study on the clinical safety and efficacy of telmisartan in patients with CAD that was conducted for six months. In this study, patients were considered by age, gender, BMI, co-morbidities, and different doses of a drug. This analysis was conducted through a patient-level survey conducted in both OP and IP hospital departments, aiming to discern the safety and efficacy of telmisartan. **Results:** Within the study, telmisartan was prescribed to individuals aged 35-85 years for both male and female patients. The prescribed doses were in doses i.e. 20mg, 40mg, and 80mg. In a sample of 70 patients, the efficacy of telmisartan is 100% i.e. using telmisartan in CAD patients reduces the blood pressure and reduces the workload of the heart. This indicates a substantial and positive effect on high blood pressure. **Conclusion:** In this observational study, telmisartan was prescribed to lower the blood pressure in CAD patients. No patients experienced serious adverse effects associated with the use of telmisartan. However, 10% of participants have experienced minor side effects such as dizziness, itching, and nausea.

INTRODUCTION

CHAPTER 1-INTRODUCTION

CORONARY ARTERY DISEASE(CAD)

Heart illness most commonly manifests as coronary artery disease (CAD). It is caused due to atherosclerotic alterations in the blood vessels that provide the heart with blood. It is also referred to as ischemic heart disease or coronary heart disease on occasion.

Heart disease caused by arteries impacts the heart's surface's big coronary arteries. Depending on the type like caused by an increase in cholesterol levels, the buildup of cellular waste products, fatty substances, calcium, and fibrin plaque that develops inside the coronary artery lining. The heart's major arteries may get blocked by this plaque accumulation.

Acute coronary syndrome which includes unstable angina, NSTEMI, STEMI, and atherosclerosis without symptoms are all included in the spectrum of clinical disorders that make up CAD.

A considerable portion of the population with CAD does not exhibit any symptoms. However, depending on the severity of the condition, angina may develop or develop into acute coronary syndrome, which can lead to a coronary infarction. Moreover, cardiac dysfunction or unexpected cardiac death(heart attack) can result from CAD.

In the US, CAD still has a major impact on death rates. The first line of defense against CAD is a preliminary assessment of risk variables.

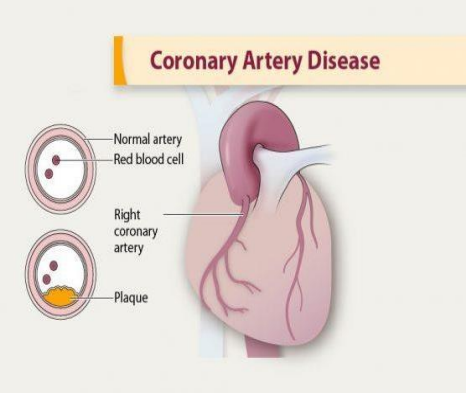

Fig. 1.1: CORONARY ARTERY DISEASE.

EPIDEMIOLOGY

Cardiovascular disease is one of the leading causes of death globally. In 2016 the, WHO estimated that CAD was the cause of about nine million fatalities.

Distinct trends in CAD mortality emerge between developed and developing nations.

Developed nations: During the past 20 years, there has been a general decline in the number of CAD deaths. A sharp rise in the prevalence of obesity and diabetes mellitus globally highlights the urgent need for better preventative and therapeutic approaches to address these serious public health issues, and there are concerns indications that this trend is slowing in the United States. Developing nations: are witnessing countries a deterioration in the status of CAD, marked by increasing mortality trends.

The decrease in death rates in industrialized nations can be attributed to the greater adoption of primary and secondary cardiovascular disease prevention strategies.

- For those with high risks who have never had a cardiovascular incident, primary prevention strategies are intended to prevent it.
- For patients with a history of CAD, secondary prevention strategies are medications that stop heart damage.

RISK ELEMENTS

Co-morbidities that raise the chance of CAD.

- Elevated cholesterol
- High blood pressure
- Hypoglycemia
- Heart disease running the family
- Tobacco use
- A state of obesity

ETIOLOGY

Non-Modifiable

- Gender
- Age
- Adaptable familial background Modifiable
- Chronic renal illness
- Fatness
- Tobacco use
- High cholesterol
- Individuals with type 2 diabetes mellitus Risk-enhancing factors
- Early end of menstrual cycles
- Steadily high neutral fats
- chronic Inflammatory conditions.

TYPES OF CAD

The following three categories of coronary artery disease exist:

1) Obstructive coronary artery disease
2) Non-obstructive coronary artery dysfunction
3) Spontaneous coronary artery dissection

- **Obstructive coronary artery disease**

When plaque buildup in the coronary arteries and the arteries constrict, thus results in prevents the blood supply from reaching the heart.

- **Nonobstructive coronary artery dysfunction**

Nonobstructive coronary artery dysfunction will not because of the buildup of plaque but occurs because of the following conditions such as:

a. compression of the heart muscle
b. vasospasms of coronary arteries
c. damage to endothelial lining

- **Spontaneous coronary artery dissection (SCAD)** When the coronary artery wall splits, either totally or partially, the heart blood supply is cut off, leading to SCAD. A heart attack follows this abrupt occurrence.

SIGNS AND SYMPTOMS

The following symptoms can be brought on by acute coronary events, such as heart attack: angina, which manifests as tightness, pressure, burning, or squeezing during exertion. Usually originating behind the breast bone, the pain and discomfort can also radiate to the arms, shoulders, chin, throat, or back. it feels like indigestion.

- Lightheadedness
- Nausea
- Irregular heartbeat
- Difficulty in breathing
- Sweating

Chest pain affects women somewhat less frequently than it does males. rather, individuals are more likely to encounter:

- Chest tightness or pressure
- Dizziness
- Fatigue
- Stomach ache

Additionally, women are more likely than males to be symptom-free from coronary heart disease.

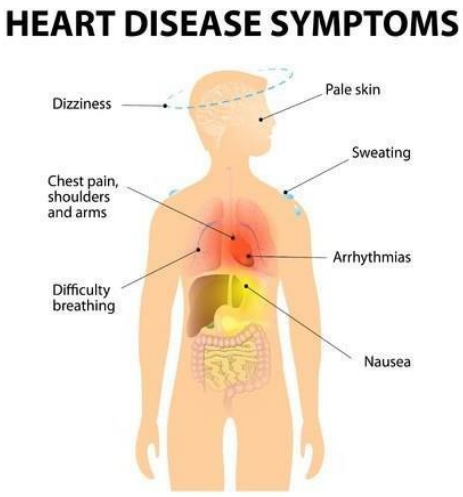

Fig. 1.2: Symptoms of CAD.

PATHOPHYSIOLOGY

1. **Atherosclerosis Initiation**
2. **Formation of fatty deposits(plaques)**
3. **Plaque growth and arterial narrowing**
4. **Reduced blood flow and ischemia**
5. **Plaque rupture and thrombosis**
6. **Acute coronary syndrome(ACS)**

1. Atherosclerosis Initiation

Atherosclerosis initiation begins with damage to the inner lining of coronary arteries, triggered by factors like high blood pressure, smoking, or high cholesterol. This damage prompts the release of inflammatory signals, attracting immune cells to the site.

2. Formation of fatty deposits (plaques)

Lipid Accumulation: After endothelial damage, LDL cholesterol enters the arterial wall, accumulating in the subendothelial space.

Inflammatory Response: Macrophages are attracted, engulfing lipids and transforming into foam cells, contributing to plaque growth.

Smooth Muscle Cell Activation: Arterial smooth muscle cells become activated, migrating to the injury site, and produce a fibrous cap over the growing plaque.

3. Plaque Growth and Arterial Narrowing

A developing plaque made of lipids, foam cells, and extracellular matrix has the potential to calcify over time.

Because the plaque protrudes into the artery lumen, blood flow is decreased and the channel narrows.

Certain plaques grow more prone to rupture because of things like inflammation or thin fibrous caps.

4. Reduce blood flow and Ischemia

As atherosclerotic plaques grow in coronary arteries, they narrow the vessel, restricting blood flow. This reduction in blood flow causes ischemia. Ischemia occurs when insufficient oxygen reaches the cardiac muscle and nutrients due to compromised blood supply, often resulting in symptoms such as chest pain (angina) during periods of increased demand or stress. The decrease in blood flow and subsequent ischemia are critical aspects of the progression of coronary heart disease.

5. Plaque rupture and Thrombosis

Plaque Rupture: Over time, atherosclerotic plaques can become vulnerable due to factors like inflammation or thin fibrous caps. When a plaque ruptures, its internal contents, including lipids and tissue debris, are exposed to the bloodstream.

Thrombosis: In response to plaque rupture, the body rapidly initiates a repair process. Platelets adhere to the exposed plaque surface, forming a blood clot or thrombus. This clot can grow quickly, obstructing the coronary artery and hindering blood flow.

6. Acute coronary syndrome (ACS)

Acute coronary syndrome refers to a dangerous heart disorder caused by an abrupt reduction in or blockage of the heart's blood supply.

7. Myocardial Infarction (Heart attack)

A portion of the heart muscle that suffers damage or dies as a result of an abrupt and protracted cutoff of blood supply.

Heart cells that are in distress start to perish if blood flow is not quickly restored. Heart attacks, also known as myocardial infarction, are the result of this irreversible process. Necrosis occurs in the afflicted area of the heart muscle, including the surrounding tissue.

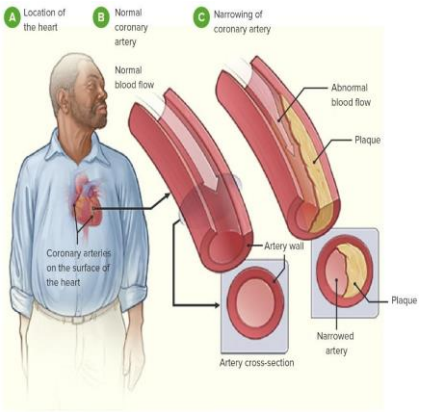

Figure 1.3: Mechanism involved in CAD.

DIAGNOSIS OF CAD

The initial steps in diagnosing coronary artery disease are risk factors, diagnostic tests, and medical and family histories.

Physical examination

Provides indirect clues for the diagnosis of CAD, like hyperlipidemia.

Diagnostic procedures and tests

Blood tests that measure blood levels of lipids, cholesterol, glucose, and proteins are among the diagnostic procedures and tests that are performed. Any deviations from normal cloud point to heart disease risk variables.

Lipid profile tests record total cholesterol, HDL, TG, higher concentrations of LDL and major risk factors for coronary artery disease include low levels of high-density lipoprotein.

An echocardiogram, or ECG, captures the electrical pulse of the heart, including its intensity and timing. It helps in determining the risk of coronary heart disease.

Imaging of the heart is produced via computer tomography (CT) scans. It is useful in determining when arteries are hardening and narrowing.

A stress test is intended to determine whether plaques in one or more coronary arteries that supply the heart obstruct blood vessels by 70% or more.

CORONARY ANGIOGRAPHY

Utilizing electron beam computed tomography, one can ascertain the likelihood of coronary artery disease by quantifying the calcium levels within and surrounding the coronary arteries. The higher the amount of calcium identified. But it is not verifiable to be accurate.

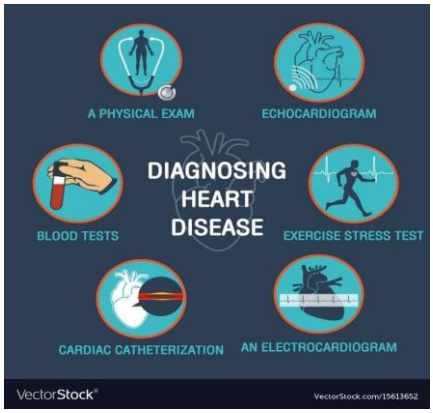

Figure 1.4: Diagnosis of heart disease.

TREATMENT

For coronary artery disease, there are numerous therapy options.

- Alterations in lifestyle
- Medical treatment: frequently prescribed pharmaceuticals (such as calcium channel blockers, beta-blockers, nitroglycerine, a cholesterol-lowering medication, etc).
- Coronary interventions, including coronary stent placement and angioplasty.
- coronary artery bypass surgery (CABG)

MEDICATIONS

- Antiplatelet drugs like Aspirin.
- Nitroglycerines
- Calcium channel blockers/beta blockers
- Statins, which lower cholesterol and lower the risk of heart disease and
- Angiotensin 2 receptor blockers

Generally, blood pressure should be reduced to less than 140/90mmHg. However, the diastolic blood pressure must not fall below 60mmHg. For this purpose, beta blockers are advised as the first line of treatment.

Aspirin

It lowers myocardial infarction (heart attack) risk but does not affect overall mortality risk in those who have never had heart disease. Adults with elevated cardiovascular risk, including postmenopausal women, men over 40, and individuals who are younger and have risk factors such as diabetes, hypertension, or a family history of heart disease, should take aspirin.

MOA: Acts via irreversible inhibition of platelet cox-1 to produce thromboxane production.

DOSE: 75 mg per day

❖ **Statins**

Statins are used in coronary artery disease (CAD) to lower cholesterol, stabilize arterial plaques, and reduce inflammation, thereby preventing cardiovascular events.

MOA: statins prevent the conversation of HMGOCOA reductase by blocking the active site and rate-limiting enzyme in the mevalonic acid pathway and HMGCOA reductase.

Ex**:** Rosuvastatin, Atorvastatin, simvastatin.

❖ **Beta-blockers**

To lower blood pressure, and oxygen requirement of the heart, and people with CAD and their heart rates, Beta-blockers are employed. This protects the cardiovascular system and stops more cardiac events**.**

Ex**:** Metoprolol, Propranolol

❖ **Calcium channel blockers**

Calcium channel blockers are used in the dilation of coronary arteries caused by CAD reduce blood pressure, decrease myocardial oxygen demand, help manage angina, and improve blood flow to the heart.

Ex**:** Amlodipine, Nifedipine

❖ **Nitrates**

when a patient has coronary artery disease (CAD), nitrates are used to widen blood arteries, reduce angina (chest pain), and enhance cardiac blood flow

Ex: Nitroglycerine, Isosorbide mononitrate

❖ **Angiotensin2 receptor blockers**

Angiotensin II receptor blockers (ARBs) are used in Coronary Artery Disease (CAD) to relax blood vessels, lower blood pressure, and mitigate cardiovascular strain, offering protection against further cardiac complications.

Ex**:** Telmisartan, valsartan, losartan.

NONPHARMACOLOGICAL TREATMENT

- Exercise helps to manage weight and high cholesterol levels
- A healthy diet should be followed
- Quitting smoking and consuming alcohol can improve cardiovascular health.

SURGERY

- Revascularization of ACS shows mortality benefit.
- Coronary artery bypass grafts seem to be more effective than percutaneous coronary intervention, less postoperative stock has been observed using more recent "an aortic".

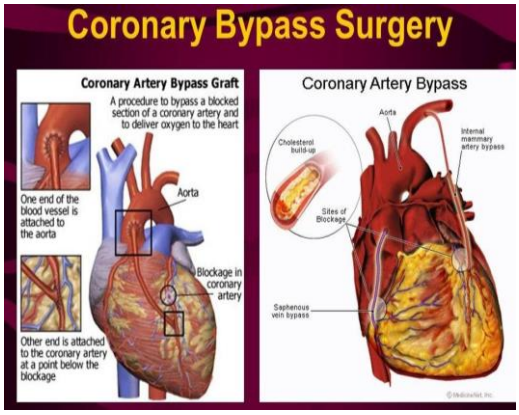

Figure 1.5: Coronary bypass surgery.

TELMISARTAN

One such angiotensin2 receptor blocker (ARB) is telmisartan. It works by blocking a substance that is produced inside that causes the blood vessels in the body to narrow. Thus, the blood vessels relax when using telmisartan. As a result, the heart receives more blood and oxygen while blood pressure is reduced.

Angiotensin II receptor blockers (ARBs) stand out as highly effective medications for managing high blood pressure, known for their tolerability akin to a placebo. Among the available ARBs, telmisartan holds a unique position with its extended half-life, lasting approximately 24 hours. This characteristic implies sustained effectiveness throughout a once- daily dosing regimen, ensuring continuous control of blood pressure Telmisartan apart from other ARBs is its notable lipophilicity, a quality that promotes superior tissue penetration, intracellular absorption, and overall bioavailability. This enhanced lipophilicity is evident in its substantial volume of distribution, approximately 500L. In comparison to compounds like losartan, telmisartan's higher lipophilicity may offer additional vascular protection, as observed in animal studies**.**

Dosage form: Tablet **Dose:** 20mg, 40mg, 80mg.

Indications

- Among people who have hypertension, reduce blood pressure.
- In people who already have additional risk factors and high BP, it lowers the chance of cardiovascular events including heart attacks and stroke.

The working mechanism

- Angiotensin II is a vasoconstrictor, increasing blood pressure.
- Telmisartan blocks AT1 receptors, preventing angiotensin II binding.
- Telmisartan blocks AT1 receptors, preventing vasoconstriction.
- Vasodilation results, lowering resistance and blood pressure
- Angiotensin II stimulates aldosterone release, causing salt and water retention.
- Telmisartan blocks angiotensin II, reducing aldosterone release, lowering salt and water retention, and decreasing blood volume and pressure.

Pharmacokinetics

- Telmisartan has a dose-dependent absolute bioavailability.
- Telmisartan metabolizes via conjugation to generate pharmacologically inactive acyl glucuronide.
- Telmisartan is strongly attached to plasma proteins (>99.5%)
- Total plasma clearance of telmisartan is >800 mL/min.

Contraindications

- Individuals who have a known hypersensitivity or allergy to telmisartan or any other components of the medication should not use it.
- Telmisartan is contraindicated during pregnancy, particularly during the second and third trimesters.
- Telmisartan is primarily metabolized in the liver, so individuals with severe hepatic impairment may not be able to clear the drug properly.
- Telmisartan and its metabolites are excreted in bile, conditions that cause biliary obstruction may interfere with the elimination of the drug.

Warning and precautions

- Prevent exposure of fetuses or newborns.
- Hypotension: before starting treatment, address any volume or salt deficiency.
- Avoid using ACE inhibitors and angiotensin receptor blockers concurrently.
- Keep an eye out for hypotension symptoms and signs.
- If pregnancy is discovered, stop taking telmisartan right away. The developing fetus may suffer harm or possibly pass away from medications that directly affect the renin- angiotensin system. and
- Monitor patients with impaired liver or kidney

function closely.

Adverse effects

- Hypotension
- Hyperkalemia
- Renal impairment
- Hypersensitivity reactions
- Impaired liver functions and Electrolyte imbalance.

Interactions of a drug

- NSAIDS: loss of the antihypertensive effect and an increased risk of renal impairment.
- Lithium: Concurrent use of telmisartan and lithium may lead to reversible increases in serum lithium concentrations.
- Digoxin: Telmisartan may increase digoxin concentrations.

NEED FOR THE STUDY

CHAPTER 2 - NEED FOR THE STUDY

- Telmisartan functions by obstructing the activity of the hormone angiotensin2, which causes blood vessels to narrow and raise blood pressure. Telmisartan relaxes blood arteries and lowers blood pressure by inhibiting aniotensin2.
- To access the telmisartan's efficacy in individuals suffering from coronary artery disease.
- To assess the safety of the drug including the adverse drug reaction

LITERATURE REVIEW

CHAPTER 3- LITERATURE REVIEW

1) According to the study conducted by "Bodh I Jugdutt" et.al: The clinical efficacy of telmisartan, either by itself or in conjunction with therapy, for reducing blood pressure and vascular risk indicates that it is an ARB. It functions by obstructing a substance within the body that tightens coronary arteries, causing the blood arteries to relax. This reduces blood pressure and raises oxygen and blood flow to the heart. It has been demonstrated that telmisartan helps treat CAD and HTN without causing weight gain, fluid retention, or heart failure that is linked to thiazolidine ligands. According to the study, telmisartan 40 mg once daily has demonstrated its efficacy in treating low diastolic blood pressure.
2) According to the study conducted by "Telmisartan Randomized Assessment Study in ACE intolerant subjects with Cardiovascular Disease (TRANSCEND) Investigators" et.al:
   In patients with cardiovascular disease who are intolerant to ARB, telmisartan effects on cardiovascular events in high-risk individuals who are ACE inhibitor intolerant suggest that ARB might be beneficial. Throughout the trial, the mean blood pressure in the telmisartan group was lower than in the placebo group. In the telmisartan group, 465 patients experienced the primary outcomes, while 504 patients in the placebo group did not experience them. Telma 40mg is useful in patients who are intolerant to ACE inhibitors after the run-in phase.
3) According to the study conducted by "Helmut Schumacher, Peggy Gao, Janice Pogue, Robert Fagard, Paolo Verdecchia, Michael Weber, Michael Böhm, Bryan Williams, Khalid Yusoff, Koon Teo," et.al:
   To ascertain whether blood pressure indicates the point at which cardiovascular protection is not accomplished in people with diabetes, research on the safety and effectiveness of low blood pressure was conducted. A total of 25584 people over the age of 55 who were at increased risk of heart problems were randomly allocated to receive telmisartan as the primary treatment, which was least common among patients with diabetes. Ultimately, we can say that in a diabetic patient, the correlation between blood pressure and total cardiovascular risk has the same impact. In diabetic patients, telmisartan was used either alone or in combination with other medications such as Telma-H to lower blood pressure and monitor glucose levels.
4) According to the study conducted by Frida Liane Plavnik and Artur Beltrame Ribeiro (on behalf of the Brazilian Group of Telmisartan Investigators0*) et.al:

The blood pressure reduction ranged from 180/90 mmHg (high) to 120/80 mmHg (normal) for the entire cohort. Before the administration of Telma, the mean blood pressure of the patients was 45.7% moderate and 54.2% high. Following the Administration, 17 (24%) people took 20 mg of telmisartan, according to a sub- analysis. During the trial, telmisartan 40 mg was taken by 45 patients (64%) and telmisartan 80 mg by 8 individuals (12%). All patients' blood pressure was normal at discharge, according to the research. Our findings thus support the idea that telmisartan, when used once daily, can effectively decreased blood pressure in individuals who have high, moderate, to normal CAD.

AIMS AND OBJECTIVES

CHAPTER 4- AIMS AND OBJECTIVES

AIM: To determine the clinical safety and efficacy of Telmisartan in patients with coronary artery disease.

OBJECTIVE

- A systemic evaluation to estimate the clinical safety and efficacy of Telmisartan
- We are assessing the effectiveness of telmisartan in relaxing coronary arteries to lower blood pressure and lower the risk of cardiovascular events.

To assess telmisartan's adverse medication reactions when administered in coronary artery disease patients.

MATERIALS AND METHODOLOGY

CHAPTER 5- MATERIALS AND METHODS

STUDY SITE

The study was done at a single location, Gleneagles

Global Hospital, Lakdikapul, Hyderabad, Telangana.

STUDY DESIGN
Observational research was carried out.

STUDY PERIOD
It was completed in six months.

SAMPLE SIZE
A population of 70 subjects was included in the study.

STUDY CRITERIA
- **INCLUSION CRITERIA**
- Male or female patients of age below 85 years.
- Patients with a confirmed diagnosis of Coronary Artery Disease
- Patients who are conscious and cooperative.
- Patients who can provide written informed consent.
- Patients who have received Telmisartan to treat hypertension may be included if their most recent treatment was at least 4 weeks before the study)
- **EXCLUSION CRITERIA**
- Patients who are not conscious/ not cooperative.
- Psychiatric patients
- Pregnant and Lactating females.

SOURCE OF THE DATA
All the relevant and necessary data was collected from
- Patient case sheets of out-patients and in-patients.
- Laboratory data.
- Treatment chart.
- Interviewing patients or patient caretakers about the patient and any other relevant resources

RESULTS
CHAPTER 6- RESULTS
The study was carried out with 60 patients who were prescribed Telmisartan in the department of cardiology.

Table 6.1: Gender wise distribution of the study population.
In the study population, out of 70 patients,49 are males (49%) and 21 are females (21%)

GENDER	POPULATION	PERCENTAGE(%)
Female	21	30%
Male	49	70%
Total	70	100%

POPULATION

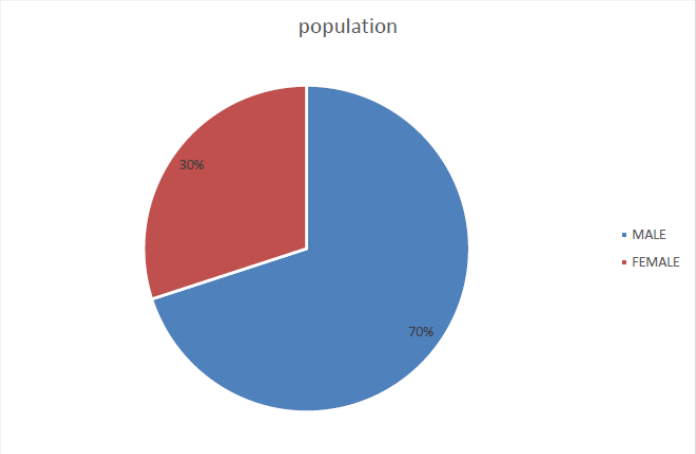

Fig. 6.1: Gender-wise distribution of the study population.

❖ The study includes 70 patients; males have a higher rate of CAD than females.

DISTRIBUTION OF THE STUDY POPULATION BY AGE
Out of 70 patients
Total age was categorized at intervals of 10

Table 6.2: Distribution of the study population by age.

Age of Patients	Total no. of Patients
35-45	5
46-55	26
56-65	20
66-75	17
76-85	2

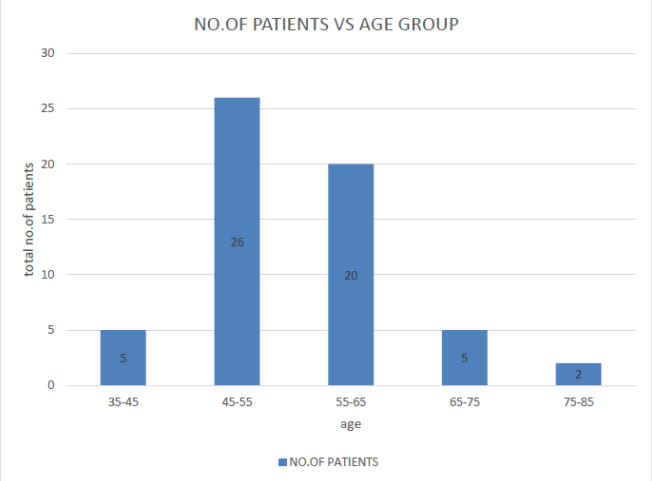

Fig. 6.2: Distribution of the study population by age.

PERCENTAGE DISTRIBUTION BY AGE

Table 6.3: Percentage distribution by age.

Age of Patients	Percentage
35-45	7.10%
45-55	37.14%
55-65	28.5%
65-75	24.2%
75-85	2.85%

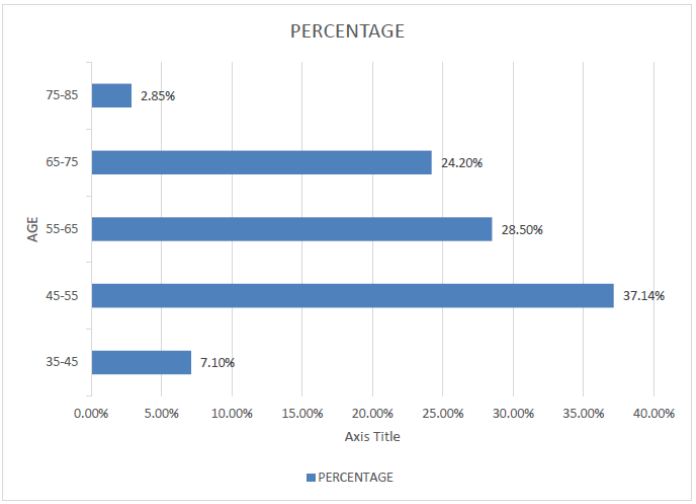

Fig. 6.3: Percentage distribution by age.

- Out of 70 patients, the age group of patients 35-45 is 7.10%, the age group of patients with 45-55 is 37.14%, the age group of patients with 55-65 is 45.70%, the age group of patients with 65-75 is 7.10%, age group of patients with 75-85 is 2.85%.

DISTRIBUTION BASED ON BODY MASS INDEX(BMI)

Out of 70 patients, 34 have a normal BMI, 25 are overweight and 11 are obese.

Table 6.4: Distribution based on body mass index(BMI).

Underweight	<18.4	0
Normal weight	18.5-24.9	34
Overweight	25-29.9	25
Obese	30-40	11

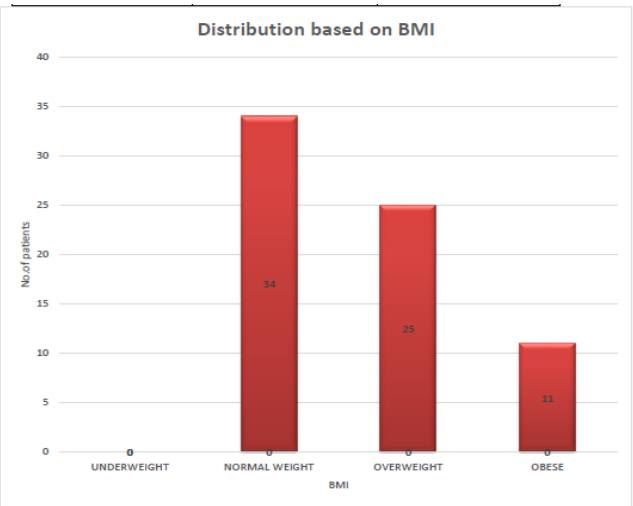

Fig. 6.4: Distribution based on body mass index (BMI).

DISTRIBUTION BASED ON CO-MORBIDITIES

Out of 49 male patients, 27 have DM, 49 have HTN, 0 have hypothyroid Out of 21 female patients, 11 have DM, 13 have hypothyroid, 21 have HTN.

Table 6.5: Distribution based on co-morbidities.

DISEASES	MALE	FEMALE
HTN	49	21
DM	27	11
HYPOTHYROID	0	13

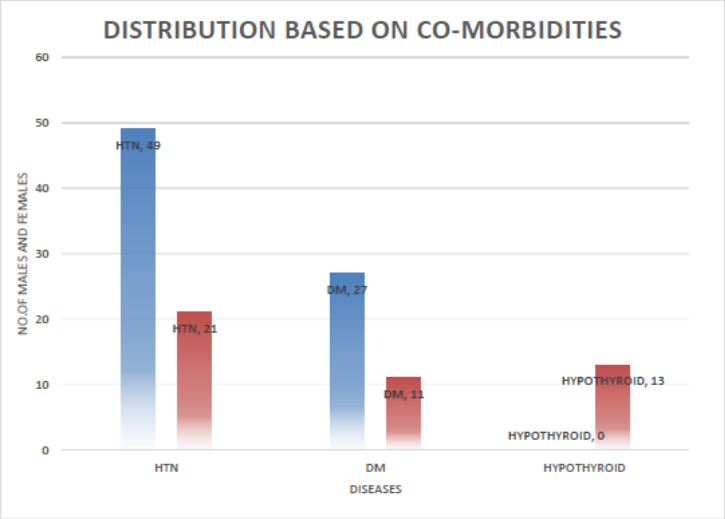

Fig. 6.5: Distribution based on co-morbidities.

DISTRIBUTION BASED ON DOSES OF A DRUG

Out of 49 male patients, telmisartan 20mg is taken by 9 patients, 40mg is taken by 35 patients, and 80mg is taken by 6 patients.

Out of 21 female patients, telmisartan 20mg is taken by 8 patients, 40mg is taken by 10 patients, and 80mg is taken by 2 patients.

Table 6.6: Distribution based on doses of a drug.

GENDER	TELMA 20	TELMA 40	TELMA 80
Male	9	35	6
Female	8	10	2

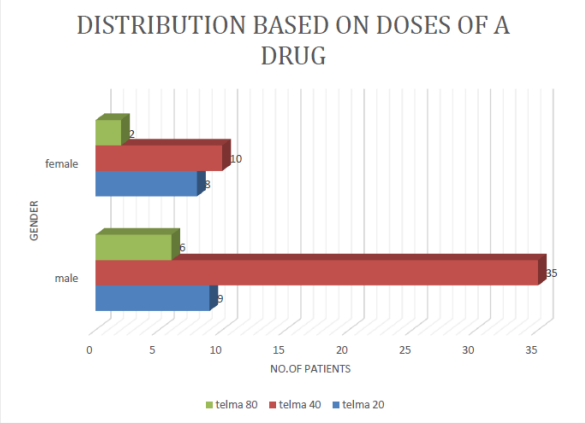

Fig. 6.6: Distribution based on doses of a drug.

PERCENTAGE DISTRIBUTION BASED ON DOSES OF A DRUG

Out of 49 male patients, 12.85% of patients are taking telmisartan 20mg, 50% of patients are taking telmisartan 40mg, and 8.57% of patients are taking telmisartan 80mg.

Out of 21 female patients, 11.42% of patients taking telmisartan 20mg, 14.28% of patients taking telmisartan 40 mg, and 2.85% of patients taking telmisartan 80mg.

Table 6.7: Percentage distribution based on doses of a drug.

Gender	Percentage		
	TELMA 20	TELMA 40	TELMA 80
MALE	12.85%	50%	8.57%
FEMALE	11.42%	14.28%	2.58%

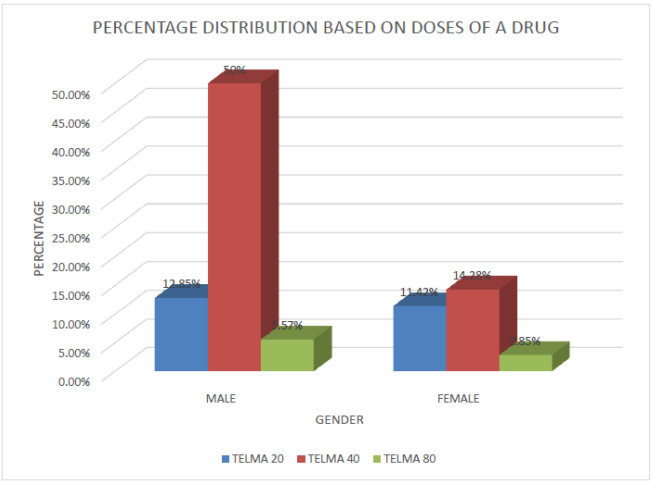

FIG: 6.7: Percentage distribution based on doses of a drug.

SAFETY

The safety results of Telmisartan in a sample of 70 individuals are as follows:

Out of 70 individuals

3 patients have experienced dizziness 2 patients have experienced itching 2patients have experienced nausea

It is important to note that the remaining 63 individuals did not have reported any side effects. These findings provide an overview of side effects associated with the drug telmisartan.

Table 6.8: Safety results of telmisartan.

Side Effects	NO. OF PATIENTS EXPERIENCED
No side effects	63
Dizziness	3
Itching	2
Nausea	2

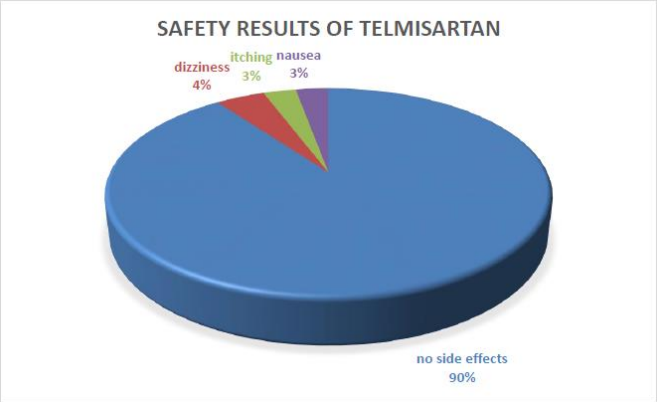

Fig. 6.8: Safety results of telmisartan.

EFFICACY

The efficacy of the drug telmisartan was most commonly evaluated by measuring the blood pressure in each patient which is considered an important factor. Pre-administration of telmisartan, moderate BP has 32 patients, high BP has 38 patients, and post-administration of telmisartan resulted in a drop to normal in 62 patients.

RANGES OF BP

- MODERATE BP ranges from 120/80mmHg to 129/80mmHg in the age group from below 60 years.
- HIGH BP ranges from 130/80mmHg to 180/90mmHg in the age group from above 60 years.
- NORMAL BP ranges from less than 120/80mmHg in all age groups.

Table: 6.9: The effectiveness of telmisartan pre and post-administration.

Age of Patients	Pre- Administration		Post Administration
	No. of Patients With Moderate BP	No. of Patients With High BP	No. of Patients With Normal BP
35-45	3	2	5
45-55	12	14	26
55-65	8	12	20
65-75	9	8	17
75-85	0	2	2

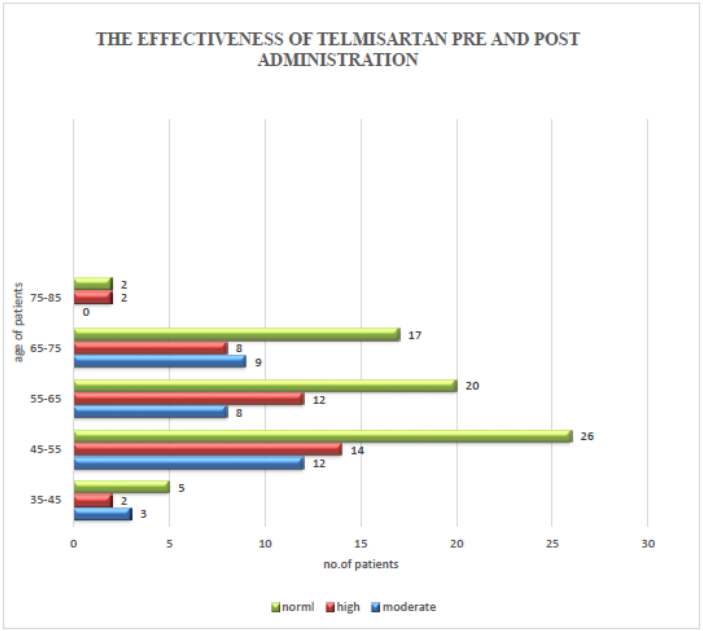

Fig. 6.9: The effectiveness of pre- and post-administration of telmisartan.

EFFICACY PERCENTAGE OF PRE-ADMINISTRATION OF TELMISARTAN

Out of 70 patients, the efficacy percentage of pre-administration of telmisartan, moderate BP is 45.7% population and high BP is 54.2% population.

Table 6.10: Efficacy percentage of pre-administration of telmisartan.

	Efficacyof Percentage of Pre- Administration
MODERATE	45.7%
HIGH	54.2%

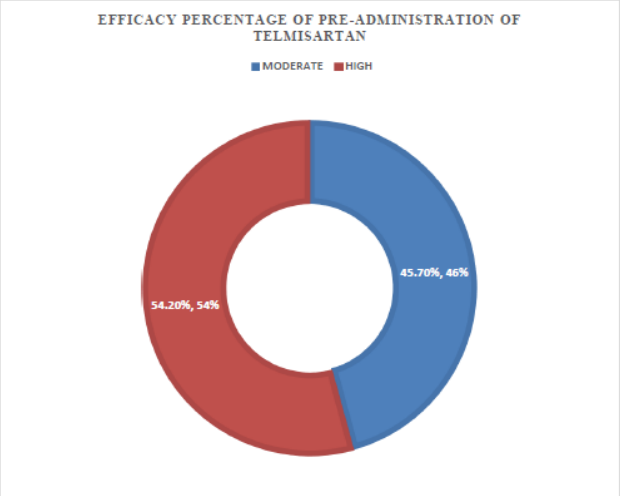

Fig. 6.10: Efficacy percentage of pre-administration of telmisartan.

EFFICACY PERCENTAGE OF POST-ADMINISTRATION OF TELMISARTAN

Out of 70 patients, the normal efficacy percentage of post-administration of telmisartan was 100%. This shows that BP is normalized after the administration of telmisartan to the patients. So by this, we can conclude telmisartan will reduce the workload of the heart decrease the blood pressure, and increase the supply of blood to the heart.

DISCUSSION

CHAPTER 7- DISCUSSION

We have conducted an observational study on the clinical safety and efficacy of telmisartan in patients with CAD, which includes 70 individuals, among them 49 were males and 21 were females.

Out of 70 individuals, 70% were males and 30% were females.

Patients prescribed telmisartan were within the age group of 35 to 85 years.

The patients in the study have co-morbidities, including conditions such as HTN, DM, and HYPOTHYROID. In this study, 70% of males have HTN, 38% have DM, and 0 have HYPOTHYROID and 30% of females have HTN, 15% have DM, and 18% have HYPOTHYROID.

Out of 70 patients, The majority of patients were prescribed Telma 40mg (64.28%). Telmisartan showed their effectiveness in post-administration i.e. (100%)

A small proportion of research participants- 10% reported mild side effects such as itching, vertigo, and nausea. This indicates that telmisartan has a generally good safety profile, with a low incidence of fewer side events in the population under observational study.

CONCLUSION

CHAPTER 8- CONCLUSION

An observational study was conducted at AWARE GLENEAGLES GLOBAL HOSPITALS carried out in the cardiology department to study the clinical safety and effectiveness of telmisartan in patients with CAD. This study includes a total of 70 individuals carried out for six months in both male and female patients.

The research found that among 70 patients, co-morbidities are present with the majority of 70% of males having HTN, 38% of males having DM and 30% of females having HTN, 15.7% of females having DM, and 18.5% having hypothyroid.

In this study, Telma was prescribed to lower the blood pressure in individuals with CAD patients. Telma was prescribed in three different doses Telma 20mg, 40mg, and 80mg. Telma 20mg was prescribed in males is 12.85%, in females is 11.42%, Telma 40mg was prescribed in males was 50% and in females is 14.28%. Telma 80mg was prescribed in males was 8.57% and in females is 2.58%.

Out of 70 patients, the efficacy percentage of pre-administration of telmisartan, moderate BP is 45.7% population, high BP is 54.2% population and normal BP is 100%

No patients reported serious adverse effects with the use of telmisartan in CAD patients. However, 10% of participants experienced minor side effects like dizziness, itching, and nausea.

ACKNOWLEDGEMENT

Primarily I would thank GOD almighty for being able to complete the project with success, with his grace and blessings this study has been accomplished successfully.

Then I would like to thank my parents, I am very grateful to my parents for their heart pledged to support and encouragement, their cooperation has strengthened me to accomplish my studies. I would dedicate my work to my family.

I would also like to thank our project guide **Dr. T. KAVYA,** who gave us constant guidance, encouragement, and support throughout the journey of turbulence.

I am grateful to **Dr. B. VENKLATESH** for his candid guidance, continuous support, and encouragement, and also for giving a long period of time to frame this manuscript.

I would like to express my special thanks of gratitude to our mentor **Dr. V. ANUDEEP,** for his guidance and support in completing our project.

I humbly extend my thanks to all concerned persons who co-operated with me in this regard.

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CHAPTER 9- BIBLIOGRAPHY

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ANNEXURE-1

INFORMED CONSENT FORM

TITLE: AN OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF TELMISARTAN IN PATIENTS WITH CORONARY ARTERY DISEASE

Name of the Principal Investigator: DR.B. VENKATESH

MD, PhD (Cardio), PDFC, MACC

Name of the Participant

Age of the Patient

Name of the Institution: Avanthi Institute of Pharmaceutical Sciences

- I confirm that I have read and understood the information sheet dated for the above study and had the opportunity to ask a question.
- I understood that my participation in the study is voluntary.
- I understood that the sponsor of the study on behalf of the ethics committee will not need my permission to look at my health record both respect to the current study and future research.
- I agree not to restrict the use of any data or result that arises from this study provided suchuse is only for the scientific purpose.
- I agree to take part in the above study.

Name of the Participant

Signature of the Participant

Thumbprint of the participant

Signature of the Investigator

Date:

Day/month/year:

ANNEXURE-2

PATIENT DATA COLLECTION FORM

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES

Gunthapally, Near Ramoji Film City, Hayat Nagar, Hyderabad-501512

"AN OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF TELMISARTAN IN PATIENTS WITH CORONARY ARTERY DISEASE."

PT. DETAIL	NAME	AGE	GENDER	Ht	Wt	BMI	IP/OP No	Department	DOA	DOD

Consultant	Unit
PATIENT MARITAL STATUS Married ☐ Unmarried ☐	**Social History** Smoker packs/day ☐ Others ☐ Alcoholic Drinks/week ☐ Tobacco ☐

CHIEF COMPLAINTS
PAST MEDICAL& MEDICATION HISTORY
PHYSICAL EXAMINATION

	Normal Range	Day	Day	Day	Day
Blood pressure(BP)	120/80 mm/Hg				
Pulse rate (PR)	<100 bpm				
Respiratory rate (RR)	16 – 20 breaths per minute				
Heart rate (HR)	60-100 bpm				
Temperature (T)	98.6^{o}F				
O2 saturation	94-99%				
CVS					
CNS					
RS					
P/A					

PROVISIONAL DIAGNOSIS
LABORATORY INVESTIGATIONS

	NORMAL RANGE	DAY	DAY	DAY
COMPLETE BLOOD PICTURE (CBP)				
Hemoglobin	F:12-16 M: 13-18%			
RBC Count	3.7-5.2 Million cells/cumm			
WBC Count	4000-11,000 cells/cumm			
Platelet Count	1.5-4 lakhs cells/cumm			
Lymphocytes	20-50%			
Monocytes	1-6%			
Eosinophils	40-75%			
Neutrophils	40-70%			

Basophils	**1-8%**			
Erythrocyte sedimentation rate (ESR)	**M: <10mm F:<20mm/hour**			
CRP	**CRP >6 : +ve**			
Clotting Time				
Activated Partial thromboplastin Time (APTT)				
Prothrombin Time (PT)				
LIVER FUNCTION TESTS				
Total bilirubin	**0.2-1mg/dl**			
Direct bilirubin	**0.02mg/dl**			
Indirect bilirubin				
SGPT (ALT)	**5- 48U/L**			
SGOT (AST)	**5-45U/L**			
Total Protein	**6.4-8.2g/dl**			
Albumin	**3.4-5g/dl**			
Globulin	**2.3-3.6g/dl**			
A/G ratio				
ALK Phosphatase				
RADIOLOGY				
EEG				
CT-Scan				
MRI				
ELECTROLYTES				
Sodium	**135-145meq/L**			
Potassium	**3.5-5.2 meq/L**			
Chloride	**95-105 meq/L**			
Calcium	**1.15-1.45 meq/L**			
Phosphorous				
Bicarbonates				

OTHER LAB INVESTIGATIONS

- Lipid profile test
- Electrocardiogram (ECG)&Echocardiogram

FINAL DIAGNOSIS

DRUG CHART

1. When were you diagnosed with CAD?
2. Have you been prescribed Telmisartan as part of your treatment plan?
3. How long have been taking Telmisartan?_____years/months?
4. Telmisartan dosage___mg/day and frequency
5. List of other medications you are currently taking along with dosage Medication name Dosage Frequency
6. Have you experienced any side effects since starting Telmisartan

a. Dizziness
b. Headache
c. Upper respiratory tract infections
d. Increased levels of blood potassium
e. Low blood pressure
f. Kidney problems
g. Diarrhea.

LETTER FOR PROJECT STUDY PERMISSION

To

THE INSTITUTIONAL ETHICAL COMMITTEE,

AVANTHI INSTITUTE OF PHARMACEUTICAL SCIENCES, GUNTAPALLY, HYDERABAD-501512.

SUBJECT: Permission for project study of “An Observational Study on Clinical Safety and Efficacy of the Telmisartan in Patients with Coronary Artery Disease.

Respected sir,

We, the students at Avanthi Institute of Pharmaceutical Sciences pursuing Pharm.D 5th year are interested in conducting the project study under the title "An Observational Study on Clinical Safety and Efficacy of the Telmisartan in Patients with coronary artery disease in the Department of Cardiology under the guidance of DR.B.Venkatesh in Gleneagles Global Hospital, Lakdikapul, Hyderabad, Telangana. Hence, we request you to kindly issue us permission for our project study for the year 2023-2024.

Thanking you

Yours obediently,

Pharm.D 5th year, (2023-2024).

Hospital guide: DR.B. Venkatesh

College Guide: DR. T. Kavya

Study batch: k. Bhanu Prakash

k. Manohar

A. Anupama

B. Sowmya