# THE ELECTROCARDIOGRAM FEATURES IN PATIENTS ASYMPTOMATIC FOR CARDIAC DISEASE AND THE UTILITY OF POOR R WAVE PROGRESSION IN DETECTING CARDIAC FUNCTION


DISSERTATION SUBMITTED TOWARDS FULFILLMENT OF THE RULES AND REGULATIONS FOR THE MD GENERAL MEDICINE EXAMINATION OF THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY TO BE HELD IN MAY 2019.

# THE ELECTROCARDIOGRAM FEATURES IN PATIENTS ASYMPTOMATIC FOR CARDIAC DISEASE AND THE UTILITY OF POOR R WAVE PROGRESSION IN DETECTING CARDIAC FUNCTION

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October 2019

# BONAFIDE CERTIFICATE

I declare that the dissertation entitled "Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in predicting cardiac function." done towards fulfillment of the requirements of the Tamil Nadu Dr. MGR Medical University, Chennai, for examination of the Tamil Nadu Dr. M.G.R. Medical University, Chennai to be held in May 2020 is a bona fide original work done by Dr Shobhit Priyanshu Joseph.

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This work is carried under my guidance in the department.

Dr Ramya I

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# LIST OF ABBREVIATIONS

1. PRWP – Poor R wave progression
2. ECG – Electrocardiogram
3. CVD – Cardiovascular disease
4. IGT – Impaired glucose tolerance
5. QTc – Corrected QTc
6. QTd- Corrected QT dispersion
7. HFrEF – Heart failure with reduced ejection fraction
8. HFpEF – Heart failure with preserved ejection fraction
9. LVH – Left ventricular hypertrophy
10. LAD – Left axis deviation
11. DM – Diabetes mellitus
12. LAE – Left atrial enlargement

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# INTRODUCTION

*Diabetes mellitus is an important metabolic disorder that can affect nearly every organ system in the body. Cardiovascular morbidity and mortality associated with diabetes mellitus is a major point of concern in health care system. Silent painless ischemia is seen in diabetic patients and early pathological myocardial changes in the myocardium can be picked up by simple bedside tool – 12 lead electrocardiogram.*

*Poor R wave progression in ECG can be seen in patients with old anteroseptal myocardial infarction and left ventricular hypertrophy. Hence this study was done to look at the ECG features of patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in predicting cardiac function.*

# AIM AND OBJECTIVES

## HYPOTHESIS:

In patients who are asymptomatic for cardiac disease a simple bedside tool – 12 lead Electrocardiogram can identify early cardiac disease.

## AIM:

To determine the electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in predicting cardiac function.

## OBJECTIVES:

**Primary objective:** To determine the electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease.

**Secondary objective:** To determine the utility of poor R wave progression in predicting cardiac function.

# LITERATURE REVIEW

# DIABETES MELLITUS – HISTORY:

Diabetes mellitus was described 3000 years ago by the ancient Egyptians. The term "diabetes" was first coined by Araetus of Cappodocia in 81-133 A.D. which means “a siphon” in greek, because people with diabetes used to “pass water like a siphon”. The word mellitus – “honey sweet” was added by Thomas Willis (Britain) in 1675 after rediscovering the sweetness of urine. Later, in 1776 that Dobson (Britain) firstly confirmed the presence of excess sugar in urine and blood as a cause of their sweetness. Claude Bernard (France) in 1857 discovered an important milestone in the pathogenesis of diabetes - the role of the liver in glycogenesis, and the concept that diabetes is due to excess glucose production. Mering and Minkowski (Austria) 1889 – proved the role on pancreas in insulin secretion which later helped Banting and Best (Canada) in1921 to isolate insulin and it’s clinical use. In 1955 the first oral hypoglycaemic agent was marketed – insulin secretagouges : Tolbutamide and Carbutamide. (1) Since then the various classes of potent oral anti diabetic agents, insulin and various administration techniques have been discovered for better and convenient treatment strategies. But the microvascular, macrovascular, autonomic complications related to diabetes mellitus are still the area of huge concern.

# DIABETES MELLITUS – EPIDEMIOLOGY

WHO estimates, globally 422 million adults aged over 18 years were living with diabetes in 2014.(2) Globally the prevalence of diabetes has grown from 4.7% in 1980 to 8.5% in 2014. The prevalence of diabetes has grown faster in low- and middle-income countries than in high-income countries in the past decade.

***TABLE – PREVALENCE OF DM***

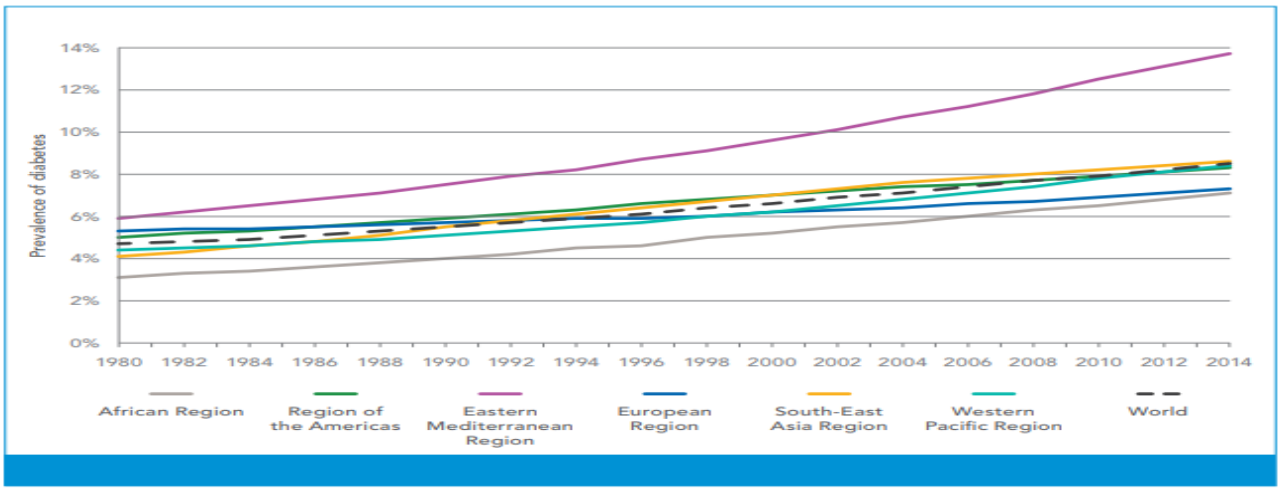
**TABLE 2. ESTIMATED PREVALENCE AND NUMBER OF PEOPLE WITH DIABETES (ADULTS 18+ YEARS)**

| WHO Region | Prevalence (%) | | Number (millions) | |
|---|---|---|---|---|
| | 1980 | 2014 | 1980 | 2014 |
| African Region | 3.1% | 7.1% | 4 | 25 |
| Region of the Americas | 5% | 8.3% | 18 | 62 |
| Eastern Mediterranean Region | 5.9% | 13.7% | 6 | 43 |
| European Region | 5.3% | 7.3% | 33 | 64 |
| South-East Asia Region | 4.1% | 8.6% | 17 | 96 |
| Western Pacific Region | 4.4% | 8.4% | 29 | 131 |
| Total[a] | **4.7%** | **8.5%** | **108** | **422** |

a. Totals include non-Member States.

*Source: (4).*

**FIGURE 4B. TRENDS IN PREVALENCE OF DIABETES, 1980–2014, BY WHO REGION**



# DIABETES MELLITUS – EPIDEMIOLOGY : INDIA

India is a country which is experiencing rapid socioecononomic development and urbanization. Epidemiological studies have shown the escalation of the prevalence of diabetes not only in urban area but also in rural area, probably due to urbanization of lifestyle. The prevalence of diabetes among adults has reached approximately 13% in urban populations and approximately 6% in rural populations.(3)

According to IDF/ WHO South East Asia the prevalence of diabetes is 8.8% and Prediabetes is 10.3% in 2017.(4) According to the recent studies with present prevalence of metabolic syndrome, sedentary life styles, food habits the numbers the expected to double by the year 2025.

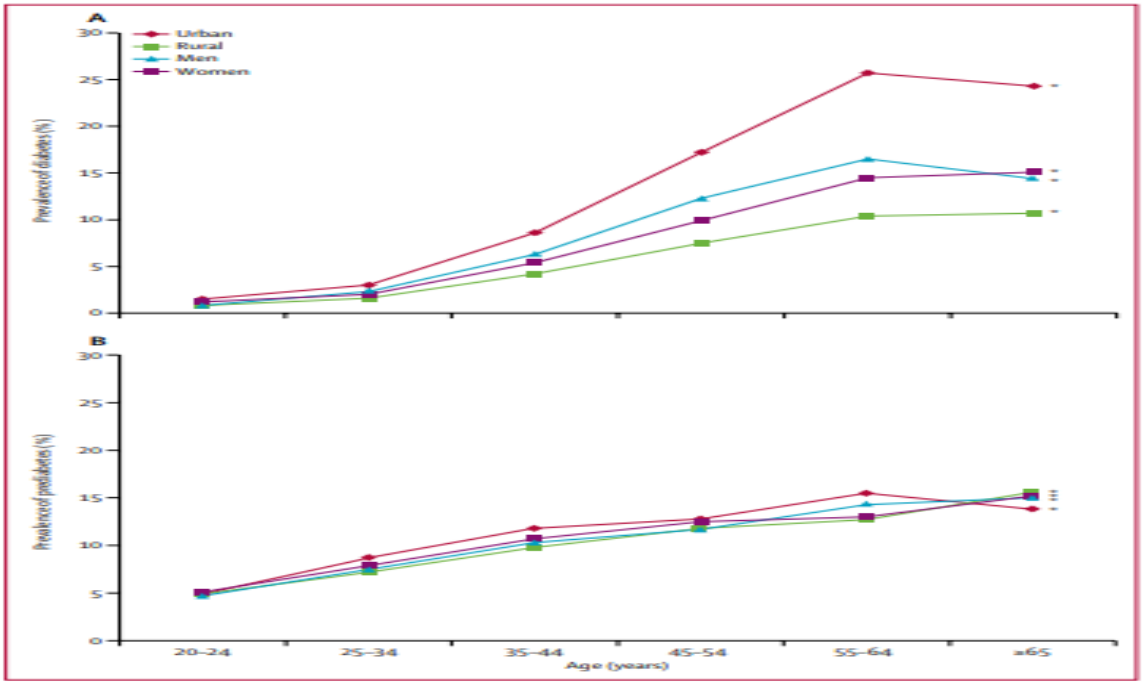



Figure 1: Age, gender, and area-specific prevalence of diabetes (A) and prediabetes (B) in 15 states in India
*p for trend <0·0001.

# COMPLICATIONS OF DIABETES MELLITUS

The complications of diabetes mellitus are broadly classified into:

**A. ACUTE**

1. Diabetic ketoacidosis,
2. Hyperglycemic hyperosmolar state,
3 .Hypoglycemia.

**B. CHRONIC**

**I- <u>Microvascular</u>**

1. Neuropathy,
2. Nephropathy,
3. Retinopathy,
4. Dermopathy,
5. Diabetic foot.

**II- <u>Macrovascular</u>**

1. Cardiovascular diseases,
2. Cerebrovascular diseases.
3. Peripheral artery occlusive disease.

Cardiovascular complications in diabetics stands out as a major burden in healthcare system. It increases both morbidity and mortality of the patient with severe economical burden. Early detection of the cardiac diseases in the asymptomatic diabetics is of utmost clinical importance.

# EPIDEMIOLOGY OF CARDIOVASCULAR COMPLICATIONS IN DIABETES MELLITUS – WORLDWIDE

Globally, cardiovascular diseases affects approximately 32.2% of all persons with type 2 diabetes mellitus. CVD is a major cause of mortality among people with type 2 diabetes mellitus. Coronary artery disease and stroke are the major contributors. (5)

A systematic review analyzed 57 articles to look at the prevalence of cardiovascular diseases in type 2 diabetes mellitus worldwide from 2007-2017.

CVD affected 32.2% overall, out of which 29.1% had atherosclerosis, 21.2% had coronary heart disease, 14.9% heart failure, 14.6% angina, 10.0% myocardial infarction and 7.6% stroke. CVD was the cause of death in 9.9% of type 2 diabetes mellitus patients - representing 50.3% of all deaths.(6)

# EPIDEMIOLOGY OF CARDIOVASCULAR COMPLICATIONS IN DIABETES MELLITUS – INDIA

Cardiovascular complications in diabetes mellitus carries a huge burden and lethality. The Chennai Urban Population study revealed the prevalence of coronary artery disease was 21.4 percent among diabetic subjects compared to 9.1 percent in non diabetics .(7) The prevalence of coronary artery disease in IGT subjects were 14.9 per cent in the same study. Half of the fatal deaths in diabetics is due to acute coronary syndrome (8), hence early identification of the individual at risk and appropriate intervention may bring down the disease burden.

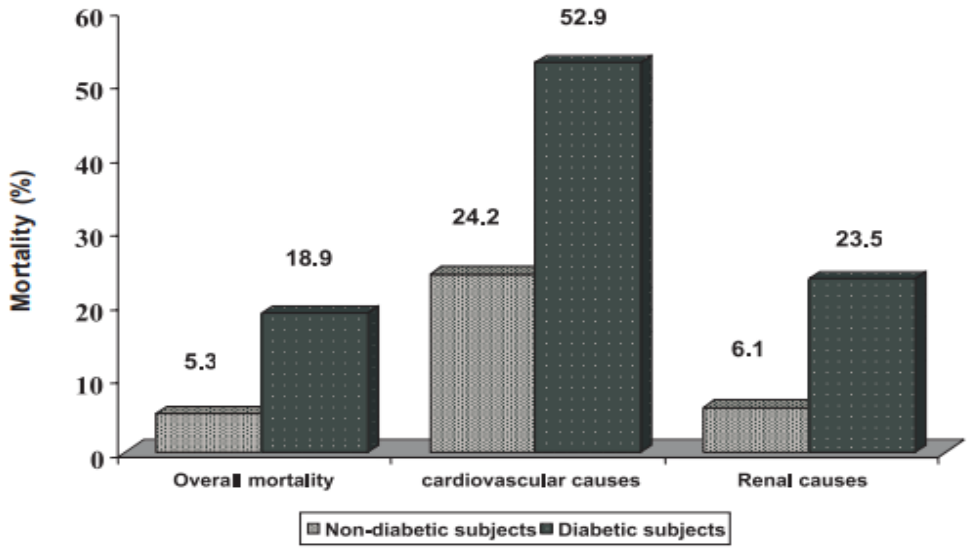



**Fig. 6.** Differences in mortality rates among diabetic and non-diabetic individuals - the Chennai urban population study (CUPS). *Source*: Ref. 36.

# SILENT ISCHEMIA IN DIABETES MELLITUS

"Silent ischemia is defined as objective evidence of myocardial ischemia in the absence of chest discomfort or other angina equivalents".(9)

Anginal pain is a poor indicator and underestimates the frequency of significant cardiac ischemia in diabetics.

## COHN'S CLASSIFICATION OF SILENT ISCHEMIA

1. TYPE 1 : Never experienced angina at any point of time.
2. TYPE 2 : Previous history of documented acute coronary syndrome.
3. TYPE 3 : Intermittent episodes of silent ischemia and classical angina. (10)

# EPIDEMIOLOGY OF SILENT ISCHEMIA IN DIABETICS

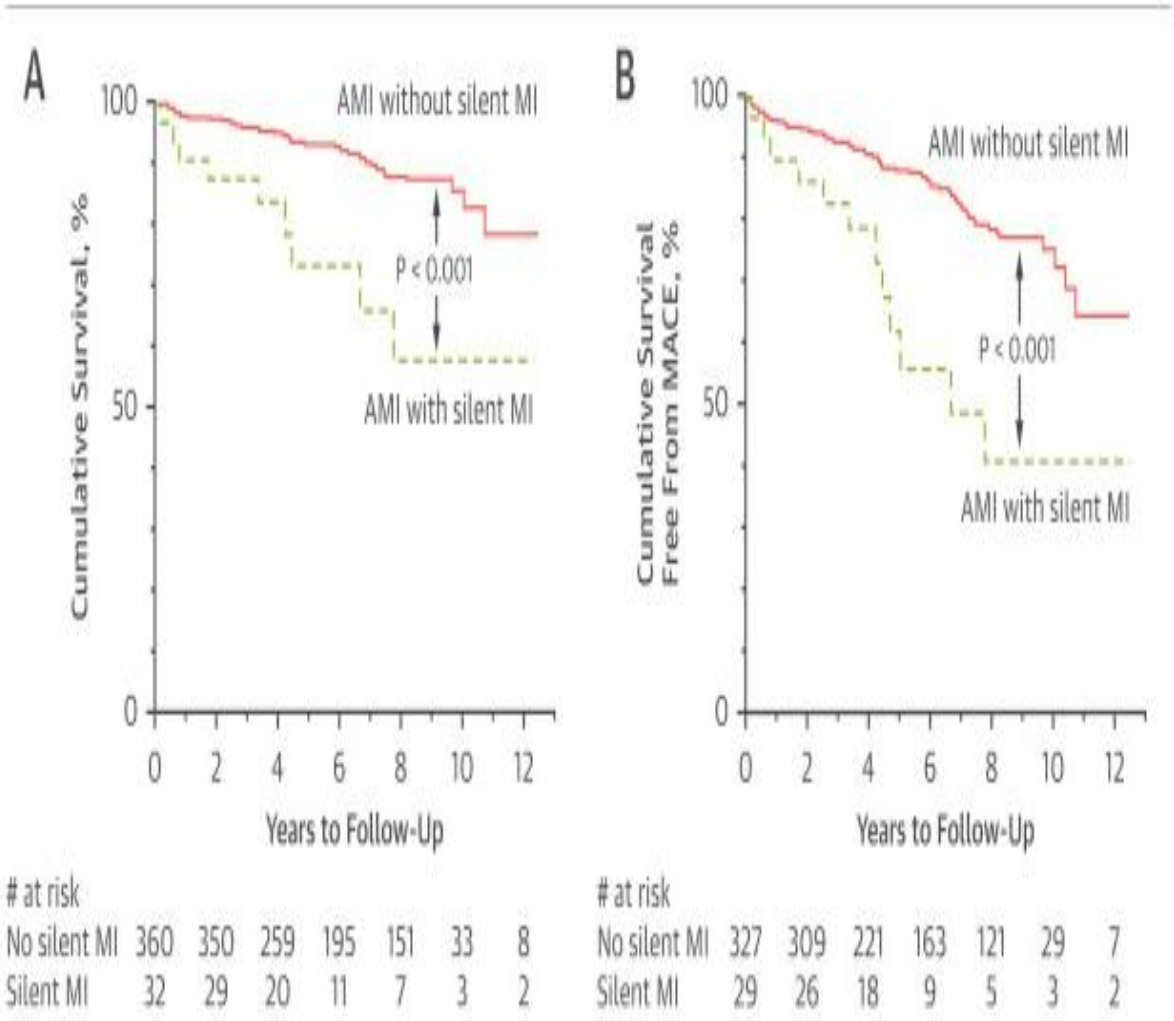
Coronary artery disease is usually more advanced at presentation in diabetics as compared to non diabetics and has unfavourable prognosis. The delay in diagnosis can be attributed to the recurrent silent ischemia that diabetics patients undergo.

In the large cohort studies, the presence of Q wave in ECG was suggestive of previous silent myocardial infarction. ECG detected silent myocardial infarction have accounted for 5-44% of all myocardial infarction. (11)

Another study in stable coronary artery disease the prevalence of ECG detected silent myocardial infarction has been reported 8-36%.(12)

The large multicenteric PUMI Swedish study which enrolled 253 patients with stable CAD without prior history of acute coronary syndrome showed the prevalence of 25 % of silent myocardial infarction.(13)

The cumulative survival and major adverse cardiac events in diabetics with silent acute MI was lower than without silent MI.



# PATHOGENESIS OF CARDIOVASCULAR DISEASE IN DIABETES MELLITUS

## A. MACROVASCULATURE

Atherosclerosis is a major threat to macrovascular in formation of plaques and thrombus. In diabetics the small, dense form of LDL are predominantly seen, they are more atherogenic than large LDL.

The characteristics of small form of LDL which predispose to high atherogenic activity are –

1. Smaller particles penetrate easily and attach firmly to the arterial wall.
2. More susceptible to oxidation.

The oxidized LDL particles acts as pro-atherogenic and acts as foreign antigen which attracts leucocytes, macrophages, enhance formation of foamy cells and endothelial and fibroblast proliferation ultimately forms an atherosclerotic plaque.

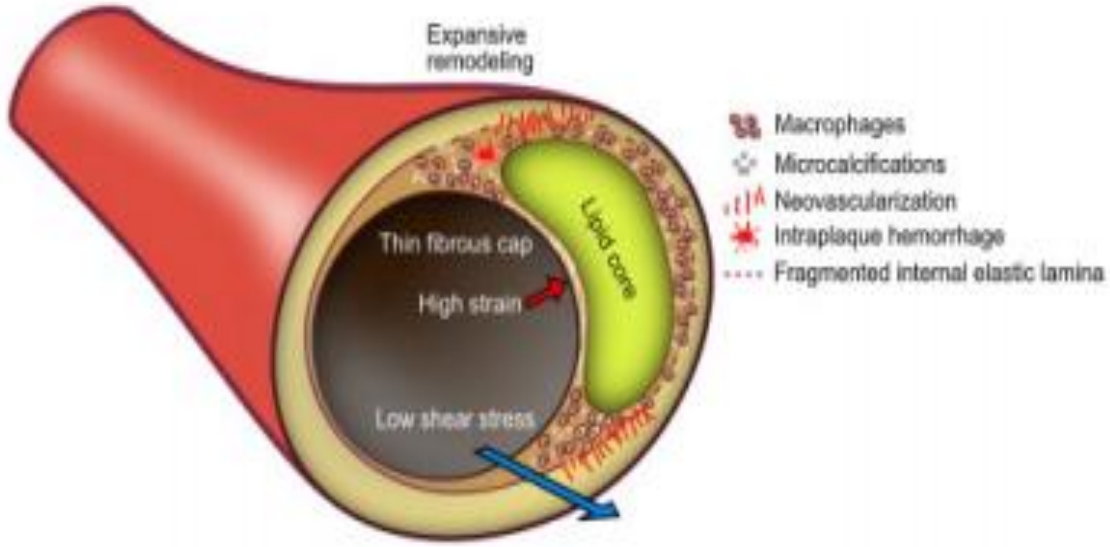



*Figure 1. Atherosclerotic plaque. Pathobiologic and local hemodynamic features of high-risk (rupture prone) plaque. Reprinted with permission from Elsevier [22].*

**LDL GLYCATION:** Glycation of LDL lengthens its half-life and therefore increases the ability of the LDL to promote atherogenesis.(14)

# PATHOGENESIS OF CARDIOVASCULAR DISEASE IN DIABETES MELLITUS

## B. MICROVASCULAR

### 1. AUTONOMIC DYSFUNCTION

The microcirculation is regulated by central and local regulatory mechanisms. The central regulation is via autonomic sympathetic and parasympathetic nerves that reach the vascular smooth muscle. Local regulation is carried out by substances produced by the endothelial cells and by local products of metabolism – Nitric oxide (vasodilator), Endothelin-1 (vasoconstrictor). These regulatory mechanisms adjust instantaneously to meet the metabolic needs of the tissue. Diabetes contributes to defects in the autonomic nervous system- the endothelium, and local metabolism, all of which can result in microvascular disease. In diabetic autonomic neuropathy due to the disruption of the regulatory flow in the microvasculature there is inadequate cardiac flow reserve that is activated under conditions of increased demand for myocardial perfusion which may explain sudden cardiac death and high mortality rate in the population.

## 2. INFLAMMATION

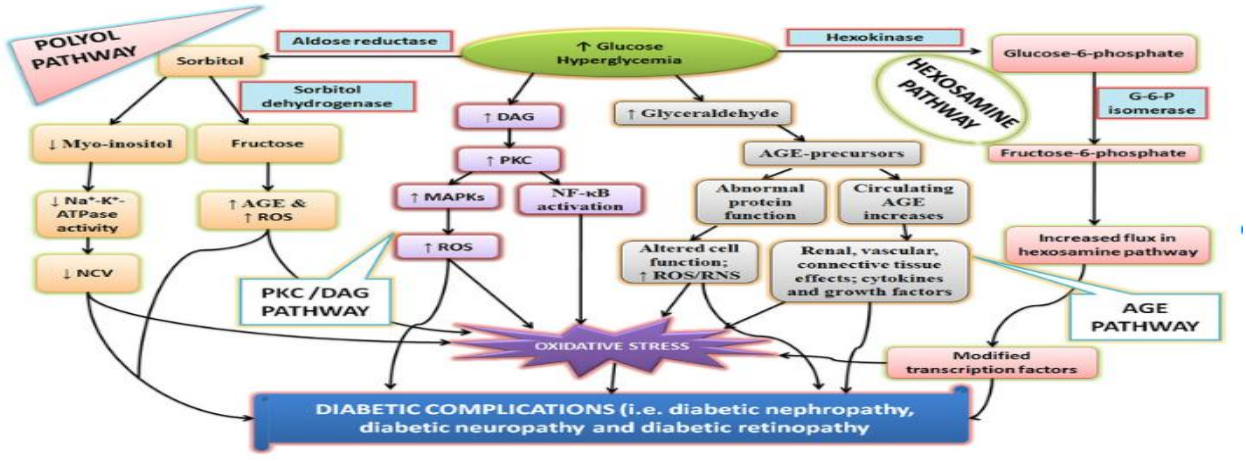
Diabetes has been considered as a state of chronic, low-level inflammation.

-***Serum sialic acid,*** a marker of low-grade inflammation is seen in type 2 diabetes mellitus and also independent predictive marker for cardiovascular mortality in type 2 diabetes mellitus.

-Increased levels of a number of adipokines (cytokines released from adipose tissue), Including tumor necrosis factor-α, interleukin 1β, interleukin 6, and plasminogen activator inhibitor 1 (PAI-1), all linked to the inflammatory response.

## 3. OXIDATIVE STRESS

Oxidative stress is currently the most important factor in the development of diabetes complications.(15)



# PATHOGENESIS OF SILENT ISCHEMIA IN DIABETES MELLITUS

Postulated mechanisms-

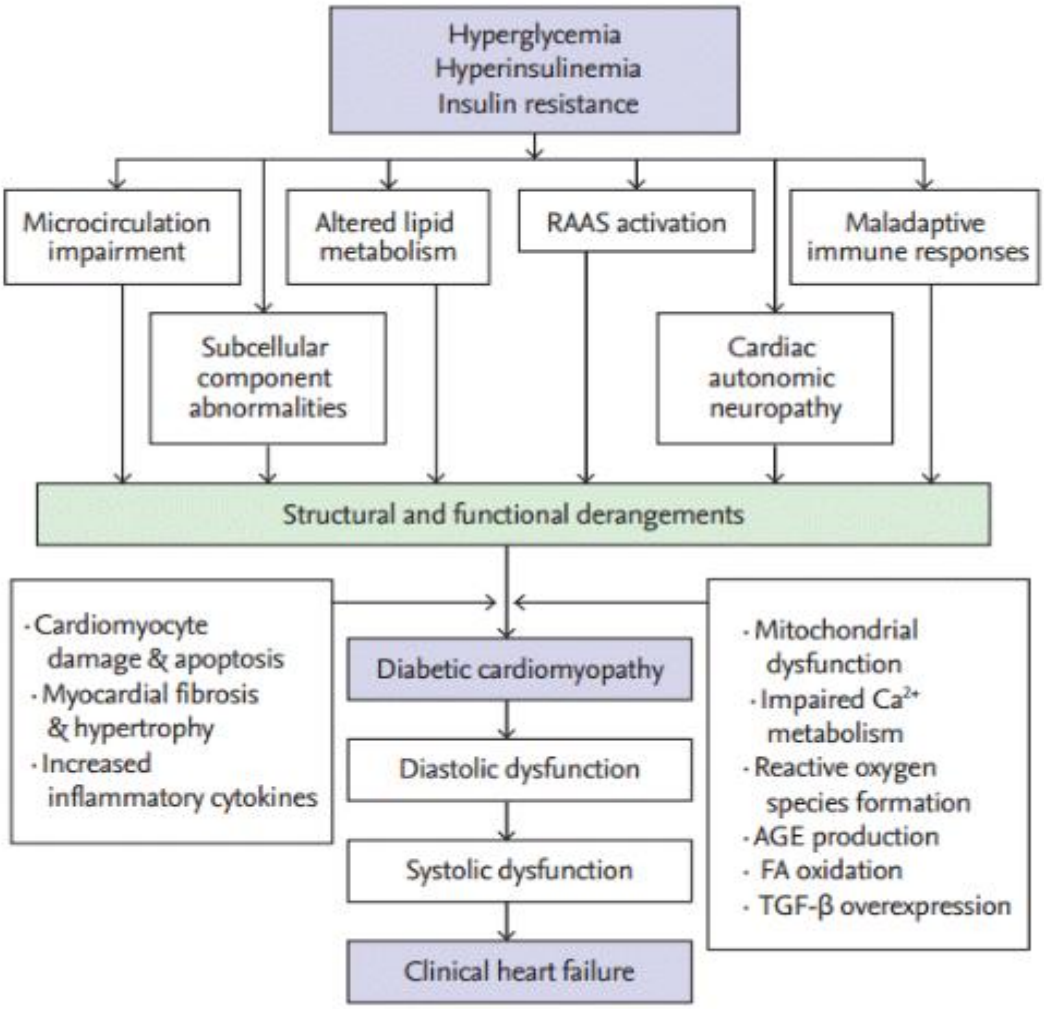
- Production of the anti-inflammatory cytokines which blocks the pain transmission pathways.
- Cardiac autonomic neuropathy- complete denervation of afferent fibers.
- Higher beta endorphin levels.
- Inadequate pain stimulation to reach the threshold to cause pain.
- Defective perception to pain stimuli.
- Less severe and shorter angina episodes. (16)

Silent ischemia is associated with a circadian pattern, and most of the events occur in the morning. The reason being an increased myocardial oxygen demand caused by elevated heart rate and blood pressure, higher catecholamine concentrations, increased coronary vasomotor tone, greater platelet aggregation, and reduced intrinsic fibrinolytic action.

# PATHOGENESIS OF CARDIAC DYSFUNCTION IN DIABETES MELLITUS

Heart failure in a patient with diabetes may arise from myocardial injury arising from an ischemic or thrombotic event.

Diabetic cardiomyopathy is defined as myocardial disease in patients with diabetes that cannot be attributed coronary artery disease, but due to microvascular dysfunction. (17)



# SCREENING TOOLS FOR DETECTING ASYMPTOMATIC CORONARY ARTERY ISCHEMIA IN PATIENTS WITH DIABETES MELLITUS

As the prevalence of asymptomatic coronary artery ischemia is significant in patients with diabetes mellitus, early detection with appropriate screening tools is very important.

- The gold standard being invasive method - Coronary angiography.(18)

**The non –invasive test recommended by AHA are-**

**A. FUNCTIONAL TEST**

1. Resting 12-lead electrocardiogram.
2. Stress testing – Treadmill test.
3. SPECT (Single proton emission computed tomography).
4. Myocardial perfusion imaging with PET scan.
5. Dobutamine stress echocardiography.

B. **ANATOMIC (IMAGING) TECHNIQUES**

1. Coronary artery calcium scoring.

2. Multidetector - row computed tomography (MRCT) angiography.

3. Cardiac MRI- Gadolinium.(19)

# ELECTROCARDIOGRAM FEATURES IN DIABETIC PATENTS –ASYMPTOMATIC FOR CARDIAC DISEASE

The 12-lead ECG is a simple cost effective bedside tool which has maintained its significance for the diagnosis and triage of patients with suspected coronary heart disease. It is used both in the diagnostic and the researcher pursuit as a detection and screening tool of myocardial injury.

Pathologically, fibrotic changes in the basal area of the heart have been observed in diabetic patients even when the cardiac involvement is clinically not evident.(20)

Hyperinsulinemia induced hypoglycemia also causes QTc prolongation with risk of arrhythmias.(21)

Transient conduction abnormalities are seen in 24 hours holter monitoring in patients with diabetes mellitus.(22)

## ECG SIGNS IN ASYMPTOMATIC DIABETIC PATIENTS :

The most important ECG signs seen with asymptomatic diabetic patient are-

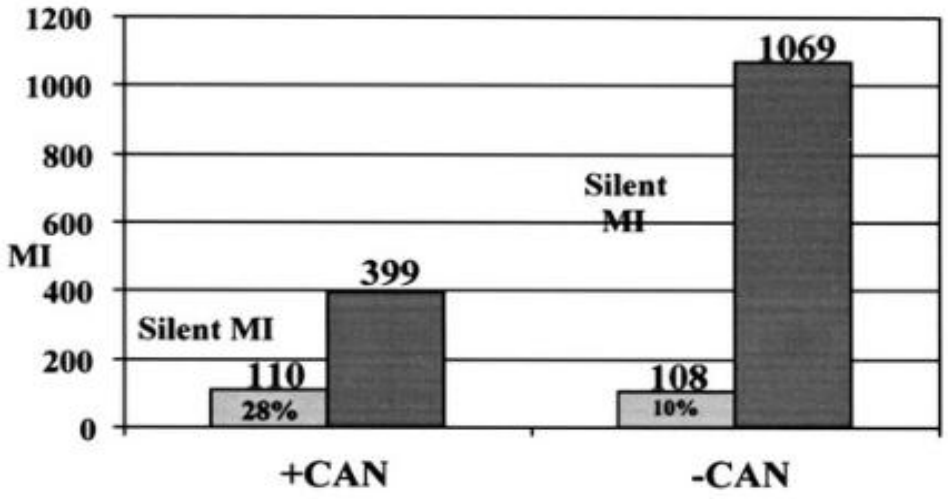
1. Sinus tachycardia.
2. Altered heart rate variability.
3. Left ventricular hypertrophy.
4. QTc prolongation.
5. QT dispersion which is defined as difference in QTc max – Qtc min.
6. ST-T changes – ST depression and repolarization abnormality.
7. Arrythmias – Atrial fibrillation, Atrial flutter.
8. Pathological Q waves – Old silent MI. (23)

# SINUS TACHYCARDIA AND ALTERED HEART RATE VARIABILITY IN ECG –

Due to baroreceptor dysfunction the vagal response is lost in diabetics, so the bradycardic response is lost in such patients. On prospective study done which looked at the 24-hour ECG, on both time and frequency domain analyses, day and night heart rate recordings were similar, because of the reduced night time vagal modulation of the heart rate in these patients.(24)

So, sinus tachycardia – resting sinus tachycardia, loss in heart variability during day and night are the important ECG features which suggesting cardiac autonomic neuropathy.

ECG becomes a simple tool in detecting cardiac autonomic neuropathy which has an increased risk of silent ischemia.




(25)

# LEFT VENTRICULAR HYPERTROPHY –

Previous studies have shown the independent association of type 2 diabetes mellitus with left ventricular hypertrophy.(26)

Presence of type 2 diabetes mellitus was associated with an approximately 1.5-fold increase in risk of having LV mass - 75th percentile of the general population.(26)

Comparison of ECHO data in DM vs. Non DM in one study (27)

***TABLE – ECHO IN DM VS. NON DM***

Comparison of echocardiographic data

| Variable | Overall (n = 1,932) | DM | | p Value* |
|---|---|---|---|---|
| | | Yes (n = 443) | No (n = 1,489) | |
| LV mass (g) | | | | |
| Overall | 177 ± 59 | 189 ± 60 | 174 ± 59 | <0.0001 |
| Black | 187 ± 64 | 202 ± 59 | 181 ± 65 | 0.003 |
| Hispanic | 175 ± 59 | 184 ± 59 | 173 ± 58 | 0.009 |
| White | 173 ± 55 | 187 ± 58 | 170 ± 54 | 0.03 |
| Septal wall thickness (mm) | 11.3 ± 2.2 | 11.7 ± 2.2 | 11.1 ± 2.2 | <0.0001 |
| Posterior wall thickness (mm) | 10.9 ± 1.8 | 11.3 ± 1.8 | 10.8 ± 1.8 | <0.0001 |
| LV end-diastolic diameter (mm) | 44.3 ± 5.4 | 44.7 ± 5.5 | 44.1 ± 5.3 | 0.03 |

* Values indicate comparisons between diabetics and nondiabetics.

Fibrotic changes, especially in the basal area of the left ventricle, have frequently been observed in diabetic patients, even when cardiac involvement is clinically not yet evident.(28)

Early ECG features of mid ventricular hypertrophy are-

1. T wave inversion in aVL and lead I
2. Tall R wave in lead III>lead I. (29)

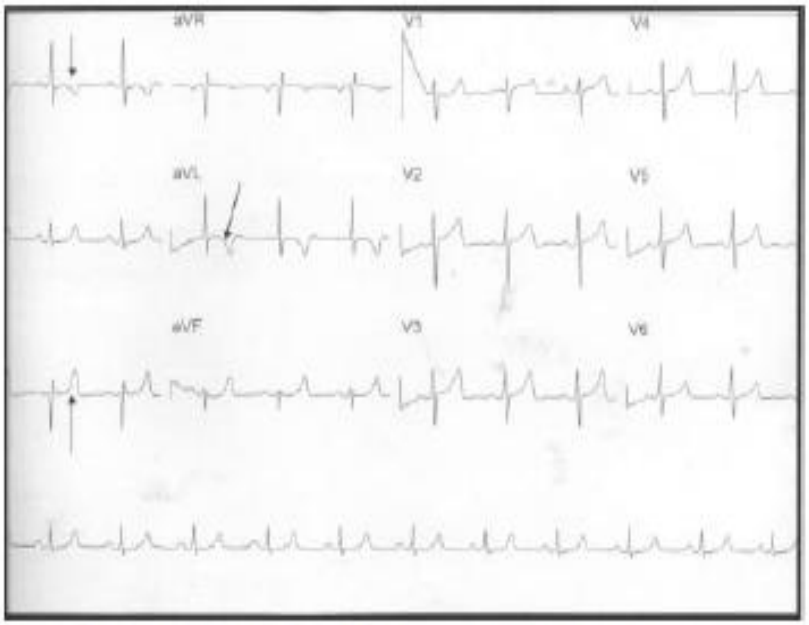



**Figure 2.** ECG of a 55-year-old woman with longstanding type 2 diabetes mellitus without overt signs of cardiovascular disease. Note the inverted T-waves in $L_I$ and aVL and T taller in $L_{III}$ than in $L_I$, with horizontal heart position (arrows); this pattern indicates fibrosis in the midventricular area.

# QTc PROLONGATION AND QTc DISPERSION –

QT interval predisposes to ventricular arrhythmias, silent ischaemia, and cardiac arrest. Hence, early detection and prevention is essential.

Cardiac autonomic neuropathy is a well recognized complication of diabetes mellitus, with reported incidence from 20-40%.(30)

Symptomatic cardiac autonomic neuropathy is only seen in 5% of diabetics.(31)

There are battery of tests such as heart rate response to Valsalva manoeuver, B.P. response to standing and handgrip, are available but these are difficult to perform bedside in every patient.

In 1980, an association of prolonged QT interval with cardiac autonomic neuropathy was established which opened the possibility of rapid objective method to detect cardiac dysautonomia.(32)

Hence, QTc is considered as an indices of autonomic dysfunction in diabetes.

Since the QTc interval is considered as a measurement of myocardial depolarization and repolarization, which is influenced by central autonomic neural tone and kinetics of cardiac myocytes, therefore, QT dispersion with correction of QT with heart rate is considered better than QTc in evaluation of cardiac autonomic dysfunction.(33)

QT dispersion = QTc max- QTc min. QT dispersion of more than 50 ms is considered as feature of early and severe cardiac autonomic neuropathy.(34)

## MECHANISM OF QTc PROLONGATION IN DIABETES MELLITUS

Exact mechanism of QTc prolongation is not clearly defined, but it has been suggested that sympathetic imbalance is responsible for QTc prolongation.

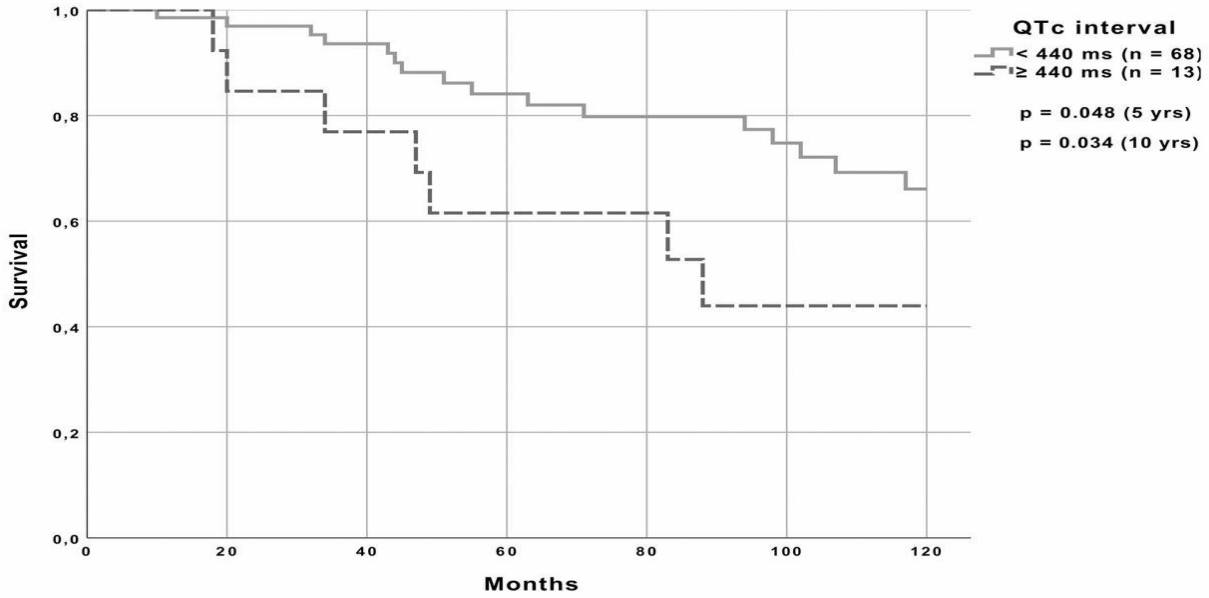
Insulin induced hypoglycemia is also associated with QTc prolongation.(35)

Previous studies have shown that the prevalence of QTc prolongation is higher in patient with diabetes and it's complications, particular with diabetic cardiac autonomic neuropathy.(36) QTc prolongation predisposes to arrhythmias and sudden cardiac death in patients with IDDM.

According the the EURODIAB IDDM Study the the prevalaence of the QTc prolongation was 16% in the whole population and 11% in males and 21% in females ($p < 0.001$).(37)

**Figure 1.**

**Mortality by QTc prolongation.**



There was an independent association of QTc with –

1. Age,

2. HbA1c,

3. Blood pressure.

In the above study there was a correlation of the QTc prolongation with underlying ischemic heart disease and nephropathy.(38)

| Study group | Nephropathy (%) | Retinopathy (%) | Somatic neuropathy (%) |
|---|---|---|---|
| Diabetics with autonomic neuropathy (*n*=33) | 10<br>30.3 | 9<br>27.3 | 29<br>87.9 |
| Diabetics without autonomic neuropathy (*n*=17) | 2<br>11.8 | 1<br>5.9 | 5<br>29.4 |

So, QTc prolongation and QTd constitute an excellent parameter to detect cardiac dysautonomia early and its further prolongation indicates severe autonomic neuropathy.

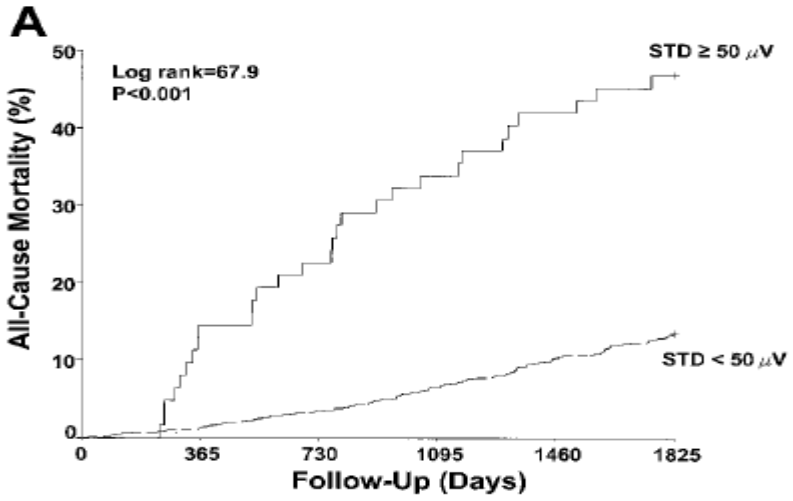
12- lead ECG becomes an easy bedside tool to detect cardiac autonomic neuropathy in diabetics.

# ST-T CHANGES ON ECG IN DIABETICS-

ST-T segment represent the repolarisation of the cardiac activity.

The STRONG HEART STUDY inferred that both ST depression (2.36, 1.38–4.02) and QTc (2.03, 1.32–3.12) predicted all-cause mortality in diabetics.

Supporting the use of above findings on ECG to identify high-risk individuals with diabetes. (39)




So, ST-T changes becomes an important finding in ECG of diabetics to predict underlying repolarization abnormality and warrants close cardiac monitoring.

# PATHOLOGICAL Q WAVE IN ECG – SILENT MI IN DIABETICS

Pathological Q waves are the most well accepted marker of myocardial necrosis on a surface ECG, when seen incidentally, it is often called silent, or unrecognized, MI.

The prevalence of unrecognized or silent MI appears to be higher in patients with diabetes mellitus compared with non- diabetics, ranging from 2% to 7%.(40)

**Table 2. Incidence of Silent Myocardial Infarction in Diabetes Trials**

| | Follow-up, y | Silent MIs Detected,n | Total MIs Detected,n | Percent of Total MIs | Silent MI Associated With Outcomes? |
|---|---|---|---|---|---|
| FIELD[15] | 4 | 269 | 730 | 36.8 | Yes |
| RECORD[10] | 2 | 2 | 8 | 25 | No |
| BARI-2D[13] | 5.3 | 23 | 243* | 9.4 | Yes |
| IDNT[12] | 2.5 | 14 | 108 | 14.1 | No |
| PRoACTIVE[14] | ≈3 | 43 | 288 | 14.9 | … |

* indicates non-fatal MI.

Screening and serial ECGs may be useful in identifying unrecognized MI because they will increase the overall event rate by 10% to 25%.(41)

However, any newly identified Q wave requires further confirmation with a follow-up ECG and a clinical history. Cardiac imaging should be performed to identify the presence and extent of myocardial damage before a “silent” MI is diagnosed.

Hence, ECG becomes and important screening tool to detect silent MI.

# ARRYTHMIAS IN DIABETICS-

Chronic hyperglycaemia in Type 2 diabetes mellitus causes long term damage to heart resulting in coronary artery disease, myocardial infarction , congestive heart failure and sudden death from arrhythmias.

According to one study published in Germany which looked at the arrhythmias associated with diabetics found that most common arrhythmias seen were – Atrial fibrillation and ventricular arrhythmias.(42)

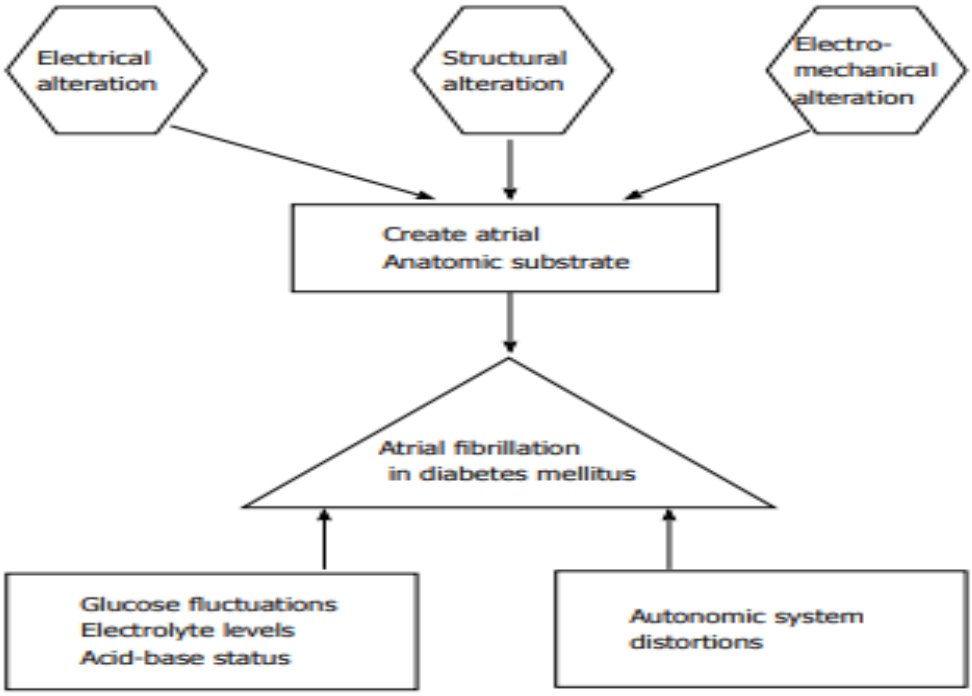



**Figure 1 Potential pathophsiological mechanisms of atrial fibrillation in patients with diabetes mellitus.**

According to one Indian study which looked at the different arrhythmias in type 2 diabetes mellitus found that, Sinus tachycardia (ST) was the most common arrhythmia, found in 32% of patients (20 males and 12 females) followed by 15% (5 males and 10 females) had sinus bradycardia (SB), and 15% (8 males and 7 females) had atrial fibrillation (AF). Ventricular premature complex (VPC) was found in 10% (7 males and 3 females) and 3% (2 males and 1 female) had atrial premature complex (APC). Nearly 3% (2 males and 1 female) had first degree atrioventricular (AV) block, whereas 1% (female) had paroxysmal supraventricular tachycardia (PSVT), and another 1% (male) had ventricular tachycardia (VT).(43)

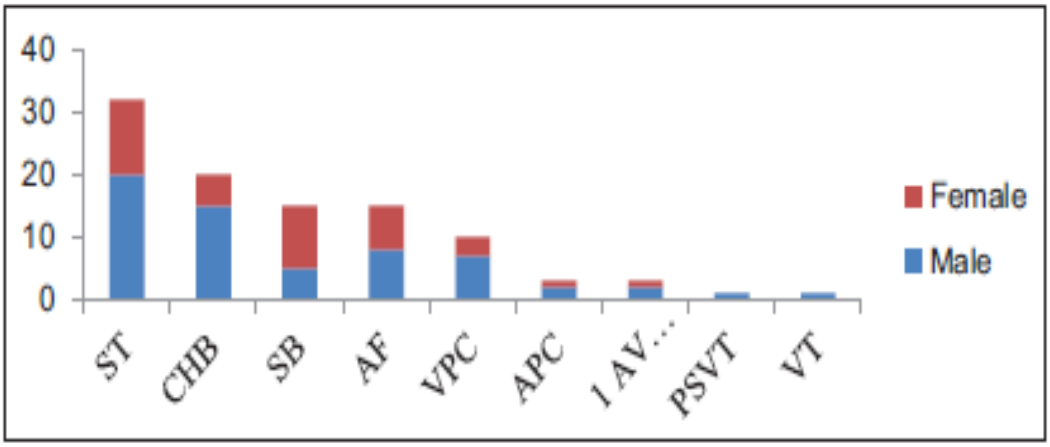



**Figure 1:** Frequency of different types of arrythmias

# POOR R WAVE PROGRESSION IN ASYMPTOMATIC DIABETICS

Poor R wave progression as an ECG finding with R wave amplitude <3 mm in V3 (de pace definition) seen in an old AWMI. It has clinical utility in diabetics in predicting an old AWMI and diabetic cardiomyopathy. In electrocardiograms (ECGs), the poor R-wave progression can be seen in patients with left ventricular hypertrophy and previous anteroseptal myocardial infarction. Poor R- wave progression has been correlated with myocardial cell loss.

Early pathological changes, diastolic dysfunction and LV hypertrophy can be seen to accompany preserved LV systolic function. Heart failure can occur after these pathological changes in subsequent years.(44)

One Turkish study found LV diastolic dysfunction is more frequently observed in diabetic patients with poor R-wave progression in ECG, which may be an early sign of left ventricular dysfunction.(45)

In this study we determine the electrocardiographic features and assessing the utility of Poor R wave progression in predicting cardiac function in patient with diabetes who are asymptomatic for cardiac disease by assessing the ejection fraction in an echocardiogram.

# ECG IN ASYMPTOMATIC DIABETICS AND UTILITY OF POOR R WAVE PROGRESSION IN ASSESSING CARDIAC FUNCTION-

We postulate that a bedside 12- lead ECG is a common, easily available, simple and cost effective method for assessing cardiac risk in patients with diabetes. This study is conducted to determine the electrocardiographic features in asymptomatic diabetics to assess cardiac autonomic neuroapathy and various other cardiac structural and conduction pathologies. And also assess the utility of poor R wave progression in predicting cardiac function in patient with diabetes who are asymptomatic for cardiac disease.

The resting ECG should be an integral part of the examination of all patients with diabetes as it could help significantly in reducing the morbidity and mortality associated with its complications.

# MATERIALS AND METHODS

# METHODS

## ETHICAL APPROVAL

This study was conducted after obtaining permission from the Institutional review board (IRB Number dated 04.06.2018 Appendix number 2) prior to commencement of the study.

## SETTING

This study was done in The Christian Medical College in the Department of medicine among outpatients who would be recruited at the time of diagnosis of diabetics who are asymptomatic for cardiac disease. The study was done during a period of 12 months from June 2018 to June 2019.

# PARTICIPANTS

## STUDY GROUP:-

## INCLUSION CRITERIA:

All the adult patients age > or = to 40 years who come to the Department of General Medicine OPD during the study period with Type 1 or 2 diabetes mellitus asymptomatic for any cardiac disease.

## EXCLUSION CRITERIA:

- Documented ischaemic heart disease
- Prior history of angina or congestive cardiac failure.
- Documented evidence of cardiac diseases like cardiomyopathy, valvular heart disease, congenital heart disease.
- Hypertension, COPD
- If the patient is on rate limiting agents- digoxin, beta blockers.
- Not willing to take part in the study.

# METHODS:

This was a prospective observational study which was done between June 2018 and June 2019. Patients were recruited from among those coming to Medicine outpatient clinic at Christian Medical College, Hospital Vellore.

Once patients were identified, they were given the Information sheet, following which written informed consent was obtained (Copy of Information sheet in Appendix number 2). All study data were collected by the principal investigator on a specially designed Clinical Research form (CRF) (Copy of the CRF in Appendix number 3).

The participants of the study or their bystanders were interviewed and data were collected. Demographic data including name, age, sex, occupation, and height and weight were obtained. The ECG was performed for all the participants, the ECG features and parameters such as gender, age, coexistent micro- macro vascular complications and longer duration of disease in patients with type 1 and type 2 diabetes mellitus was analysed by the chief investigator of the study.

An Echocardiography for patient with poor R wave progression was done to look for cardiac function by ejection fraction and it was compared with the participants without poor R wave progresson of similar baseline characterstics. ECHO was done by the cardiology registrar and findings were confirmed and finalized by the experienced cardiology consultant.

**Primary outcome** was to determine the electrocardiographic features in patients with diabetes mellitus that were predictive of underlying cardiac disease.

**Secondary outcome** was to determine the utility of poor R wave progression in predicting cardiac function.

The PRWP was defined by-

**De pace definition**

R wave amplitude <3 mm in V3.

Later, ECHO was done for all the patients with PRWP and the cardiac function was assessed by M-mode ejection fraction and compared with those with no PRWP.

# DATA ANALYSIS :

Descriptive statistics was reported using Frequency and percentage for categorical data. Continuous data was reported using Mean ±SD. Association between the ECG features and primary and secondary outcomes were assessed by using Chi-square/Fisher's exact test as appropriate for categorical variables derived from clinical and radiological parameters. Continuous variables were assessed using two independent sample t-test after checking for normality. The Risk factor analysis was done using Binary logistic regression using stepwise method. P value significant at 0.05 level was considered statistically significant.

# DATA MANAGEMENT :

All data were collected by the principal investigator on the study CRF and then entered in Epidata 3.1 software. This was exported for analysis to SPSS version 17, IBM Corporation. All data analysis was performed by primary investigator with the assistance of a biostatistician.

# SAMPLE SIZE :

The prevalence of silent ischemia among diabetics in ECISS study done by Fazzini et al was found to be to 13.5%.

Prevalence (p) : 13.5%

Precision (d) : 6%

Confidence interval (z): 95% (1.96)

Sample size = $z^2 * p * q / d^2$

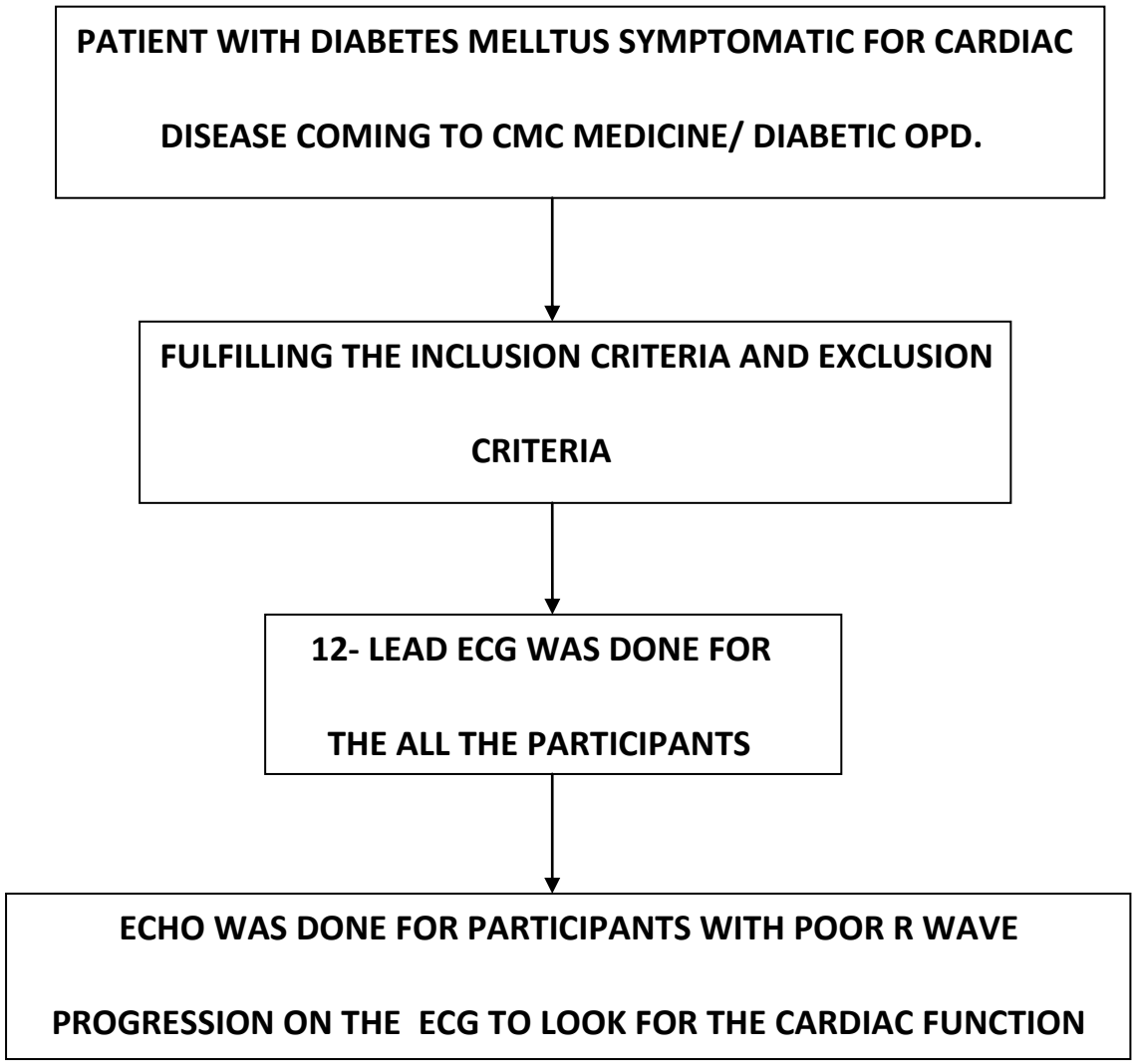
$= 1.96^2 * 13.5 * 86.5 / 36 = 125.$

Hence the estimated sample size would be 125 for this study.

# FUNDING AND APPROVAL:

The study was funded by an internal grant of the Hospital called the Fluid grant (22 Z 240) (appendix 2).

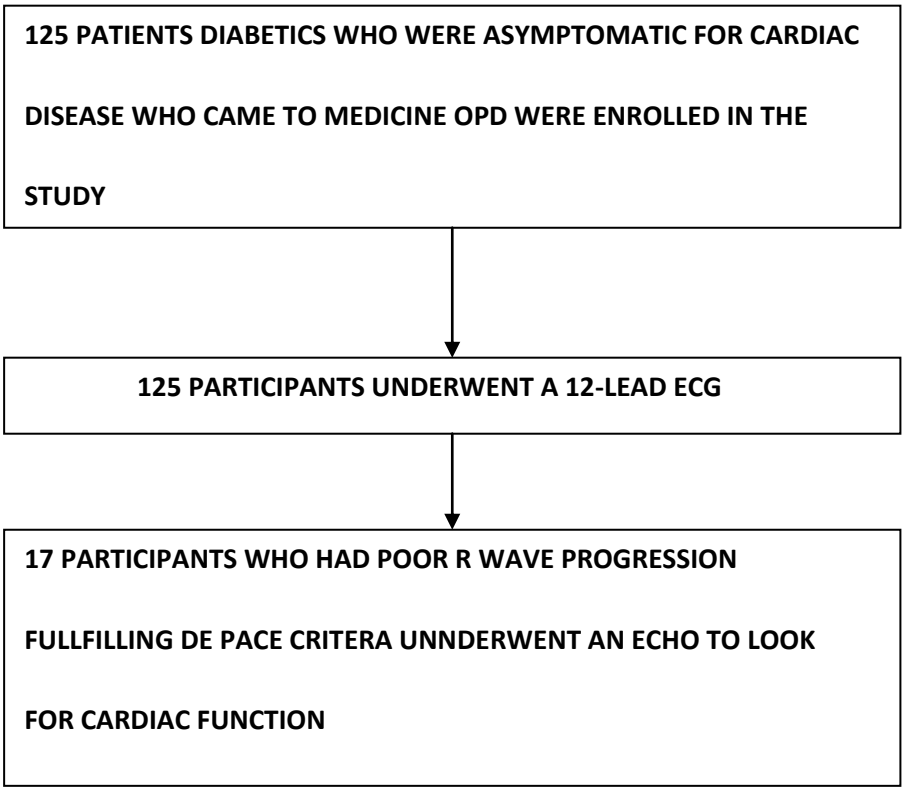
# STUDY ALGORITHM



# RESULTS

Between June 2018 to July 2018 , all patients with a diagnosis of diabetes mellitus who were asymptomatic for cardiac disease screened for the study. All patients who were fulfilling inclusion criteria and who gave informed consent and a 12-lead ECG were included in the study. Total of 125 patients were enrolled in the study. 17 patients had poor R wave progression according to de Pace criteria, those patients underwent a 2-D ECHO to look for cardiac function.

*STROBE FIGURE*



# BASELINE CHARACTERTICS

Our study included 125 individuals, in which the mean age group 54.45 years, 59.2% were males and 40.8% were females. The mean duration of DM was 9.6 years and mean HbA1c was 8.27%. The following table gives the baseline characteristics of the study population.

***TABLE – BASELINE CHARACTERSTICS***

| **CHARACTER** | | **PERCENTAGE/ SD** |
|---|---|---|
| **AGE - MEAN** | 54.45 | SD - 8.36 |
| **MALE** | 74(125) | 59.2% |
| **FEMALE** | 51(125) | 40.8% |
| **DURATION OF DM - MEAN** | 9.60 | SD - 4.46 |
| **HbA1C - MEAN** | 8.27 | SD - 1.61 |
| **NEUROPATHY** | 50(125) | 40% |
| **RETINOPATHY** | 49(125) | 39.2% |
| **NEPROPATHY** | 49(125) | 39.2% |
| **CEREBROVASCULAR DISEASE** | 1(125) | 0.8% |
| **PERIPHERAL ARTERY OCCLUSIVE DISEASE** | 1(125) | 0.8% |
| **SMOKING** | 46(125) | 36.8% |

# DEMOGRAPHIC DISTRIBUTION

In this study the gender distribution revealed a predominance of male patients.

The following graph depicts the gender and age distribution of the patients included in the study. The demographic distribution revealed -

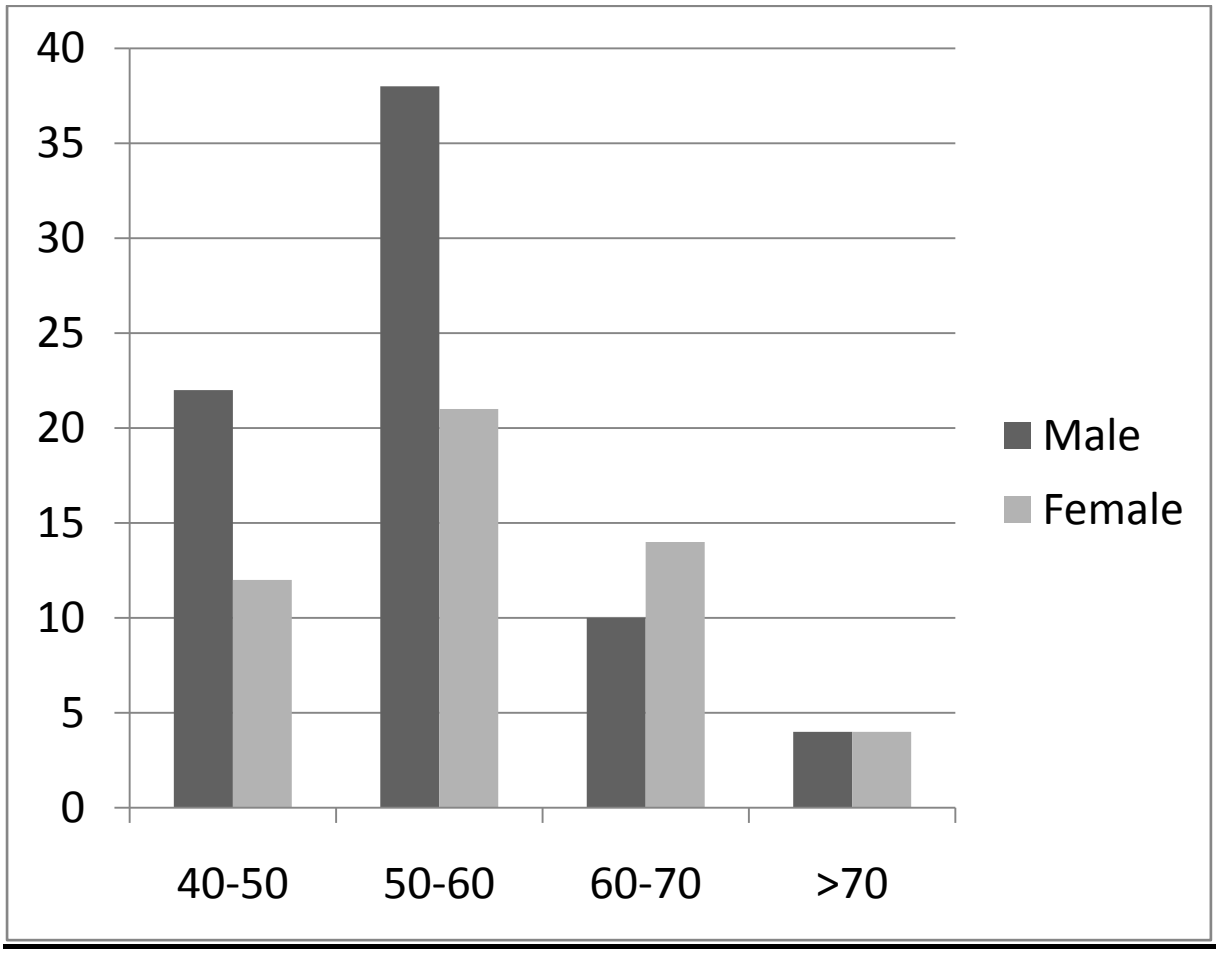



***FIGURE - AGE-SEX DISTRIBUTION***

# ECG FEATURES

In this study 19.2% of the diabetics who are asymptomatic for cardiac disease had normal ECG and 80.8% of them had following ECG changes. Among which the most common were – Resting sinus tachycardia – 6.4%, Left ventricular hypertrophy – 13.6%, Left atrial enlargement – 5.6%, ST-T changes – 12%, QTc prolongation or QTc dispersion – 11.2% and Poor R wave progression – 13.6%.

***TABLE – COMMON ECG FEATURES IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE***

| | N = 125 | % |
|---|---|---|
| **NORMAL** | **24** | **19.2** |
| **SINUS TACHYCARDIA** | **8** | **6.4** |
| **SINUS BRADYCARDIA** | **2** | **1.6** |
| **LEFT AXIS DEVIATION** | **10** | **8** |
| **RIGHT AXIS DEVIATION** | **1** | **0.8** |
| **LEFT VENTRICULAR HYPERTROPHY** | **17** | **13.6** |
| **RIGHT VENTRICULAR HYPERTROPHY** | **1** | **0.8** |
| **LEFT ATRIAL ENLARGEMENT** | **7** | **5.6** |
| **RIGHT ATRIAL ENLARGEMENT** | **1** | **0.8** |
| **ST-T CHANGES** | **15** | **12** |
| **QTc PROLONGATION/ QTc DISPERSION** | **14** | **11.2** |
| **LEFT BUNDLE BRANCH BLOCK** | **2** | **1.6** |
| **RIGHT BUNDLE BRANCH BLOCK** | **1** | **0.8** |
| **BIFASCICULAR BLOCK** | **1** | **0.8** |
| **ECTOPICS – VPC/ APC** | **2** | **1.6** |
| **BENIGN EARLY REPOLARIZATION** | **2** | **1.6** |
| **POOR R WAVE PROGRESSION** | **17** | **13.6** |

# PERCENTAGE OF INDIVIDUALS WITH NORMAL AND ECG CHANGES

In this study 19.2% of the diabetics who are asymptomatic for cardiac disease had normal ECG and 80.8% of them had ECG changes.

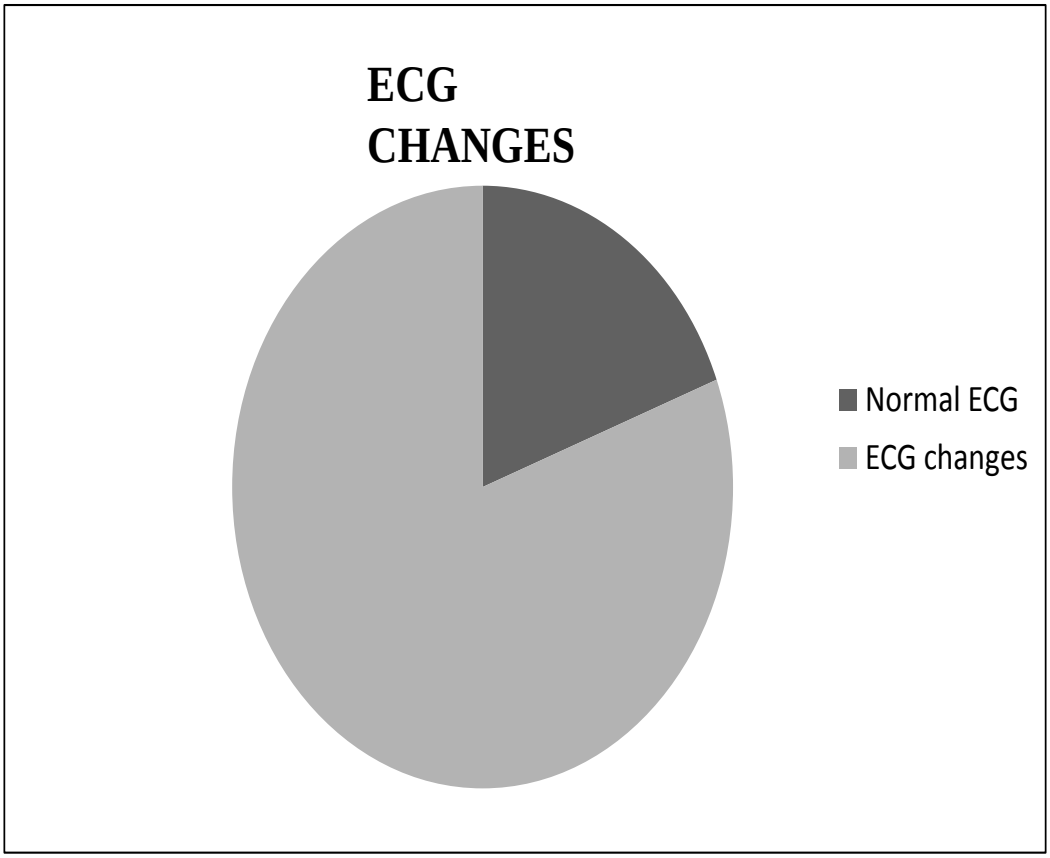



***FIGURE – PERCENTAGE OF NORMAL AND ECG CHANGES***

# COMMON ECG CHANGES IN DIABETIC ASYMPTOMATIC FOR CARDIAC DISEASE

The most common ECG findings were – Resting sinus tachycardia – 6.4%, Left ventricular hypertrophy – 13.6%, Left atrial enlargement – 5.6%, ST-T changes – 12%, QTc prolongation or QTc dispersion – 11.2% and Poor R wave progression – 13.6%.

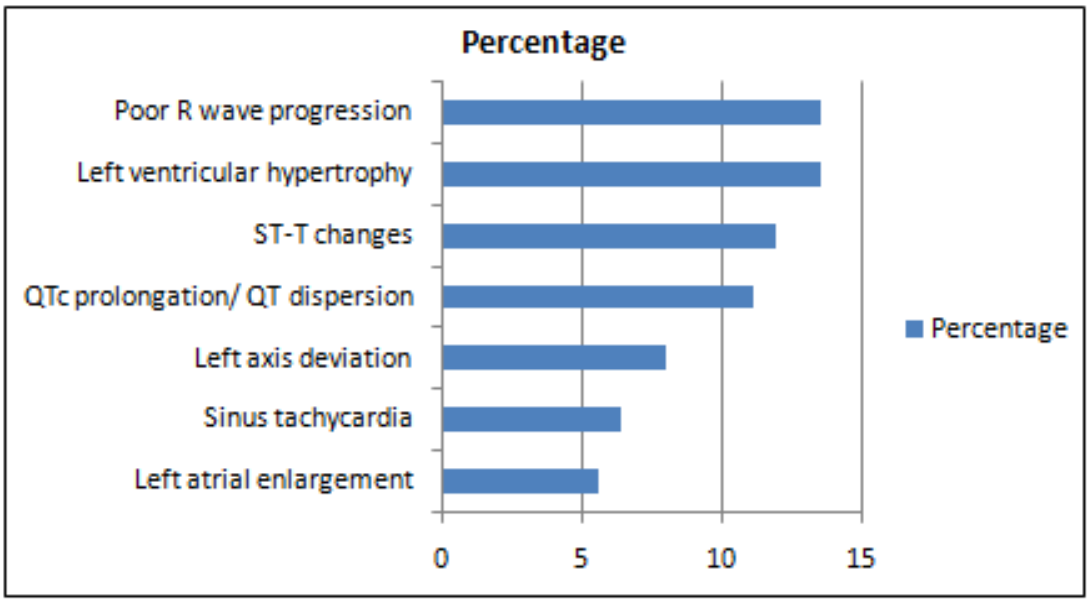



***FIGURE – COMMONEST ECG FINDINGS***

# POOR R WAVE PROGRESSION IN DIABETICS – ASYMPTOMATIC FOR CARDIAC DISEASE

Poor R wave progression was seen in 17 out of 125 (13.6%) of diabetics who were asymptomatic for cardiac disease.

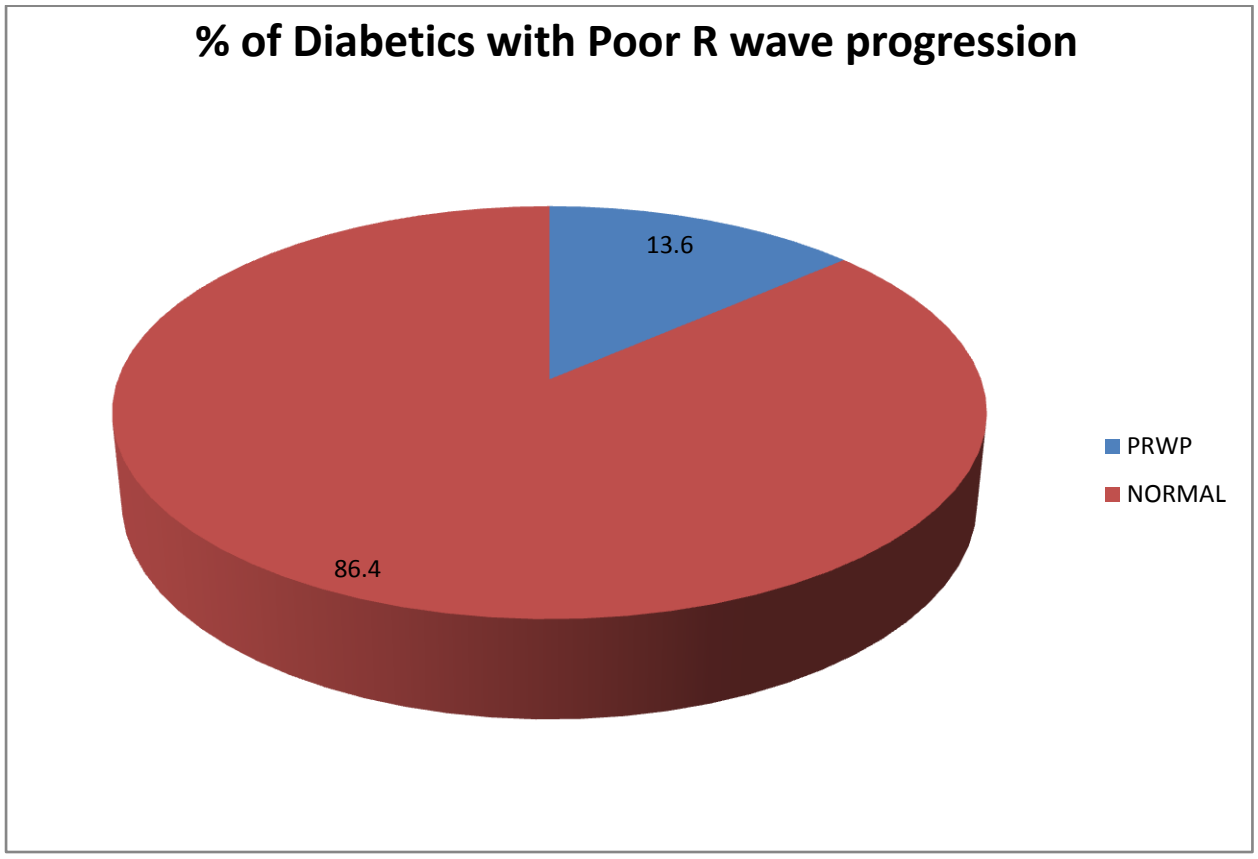



***FIGURE – PERCENTAGE OF DIABETIC WITH POOR R WAVE PROGRESSION***

# PREDICTORS OF POOR R WAVE PROGRESSION IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE

## AGE, HbA1c, DURATION OF DIABETES IN PATIENTS WITH POOR R WAVE PROGRESSION

### A. POOR R WAVE PROGRESSION

***TABLE- PRWP AND DETERMINANTS***

| | **MEAN** | **SD** |
|---|---|---|
| **AGE (YEARS)** | 56.59 | 8.35 |
| **HbA1C (%)** | 8.45 | 1.23 |
| **DURATION OF DM (YEARS)** | 10.82 | 4.68 |

### B. NO POOR R WAVE PROGRESSION

| | **MEAN** | **SD** |
|---|---|---|
| **AGE (YEARS)** | 54.11 | 8.35 |
| **HbA1C (%)** | 8.25 | 1.66 |
| **DURATION OF DM (YEARS)** | 7.09 | 4.22 |

***TABLE - POOR R WAVE PROGRESSION***

The duration of diabetes was more in patients with PRWP than with no PRWP.

The age and HBA1c were similar in both the groups.

# DURATION OF DIABETES IN PATIENTS WITH POOR R WAVE PROGRESSION

| | NO. | MEAN | SD |
|---|---|---|---|
| **PRWP** | 17 | 10.82 | 4.68 |
| **NO PRWP** | 108 | 7.09 | 4.22 |

***TABLE – DURATION OF DIABETES AND PRWP***

The difference among the means were 3.73 with 95% confidence interval difference of the difference being 1.47 – 5.89.

Based on the T –test for significance. The p- value is 0.006.

Hence, the duration of diabetes was an independent predictor of the PRWP in diabetics asymptomatic for cardiac disease.

# DIABETIC NEUROPATHY AND POOR R WAVE PROGRESSION

| NEUROPATHY | PRWP | NO PRWP | |
|---|---|---|---|
| YES | 11<br>(64.7%) | 39<br>(36.4%) | 50<br>(40.32%) |
| NO | 6<br>(35.3%) | 69<br>(63.6%) | 75<br>(59.68%) |
| | 17 | 108 | 125 |

***TABLE – NEUROPATHY AND PRWP***

The relative risk = Incidence of PRWP with Neuropathy/ Incidence of no PRWP with Neuropathy

= 0.22/0.08 = 2.75

Hence, the risk of getting PRWP on ECG was 2.75 times higher in patient with diabetic neuropathy compared without diabetic neuropathy.

p – value : 0.027.

Hence, diabetic neuropathy was an independent predictor of PRWP in diabetics asymptomatic for cardiac disease.

# DIABETIC NEPHROPATHY AND POOR R WAVE PROGRESSION

| NEPHROPATHY | PRWP | NO PRWP | |
|---|---|---|---|
| YES | 10<br>(58.82%) | 39<br>(36.45) | 49<br>(39.52) |
| NO | 7<br>(41.18%) | 69<br>(63.55%) | 76<br>(60.48%) |
| | 17 | 108 | 125 |

***TABLE – NEPHROPATHY AND PRWP***

The relative risk = Incidence of PRWP with Nephropathy/ Incidence of no PRWP with Nephropathy

= 0.20/ 0.09 = 2.22

Hence, the risk of getting PRWP on ECG was 2.22 times higher in patient with diabetic nephropathy compared without diabetic nephropathy.

p – value : 0.08.

# DIABETIC RETINOPATHY AND POOR R WAVE PROGRESSION

| RETINOPATHY | PRWP | NO PRWP | |
|---|---|---|---|
| YES | 9 (52.94%) | 40 (37.38%) | 49 (39.52%) |
| NO | 8 (47.06%) | 68 (63.62%) | 76 (60.48%) |
| | 17 | 108 | 125 |

***TABLE – RETINOPATHY AND PRWP***

The relative risk = Incidence of PRWP with Retinopathy/ Incidence of no PRWP

with retinopathy

= 0.183/ 0.10 = 1.83

Hence, the risk of getting PRWP on ECG was 1.83 times higher in patient with diabetic retinopathy compared without diabetic retinopathy.

p – value : 0.223.

# POOR R WAVE PROGRESSION AND CARDIAC FUNCTION IN DIABETICS WHO ARE ASYMPTOMATIC FOR CARDIAC DISEASE

In our study 17 patients had PRWP on ECG and out of which 7 (41.17%)

had heart failure on the 2-D ECHO.

Out of 7 patients, 4 (57.14%) had heart failure with reduced ejection fraction[HfrEF]

and 3 (42.86%) had heart failure with preserved ejection fraction[HfpEF].

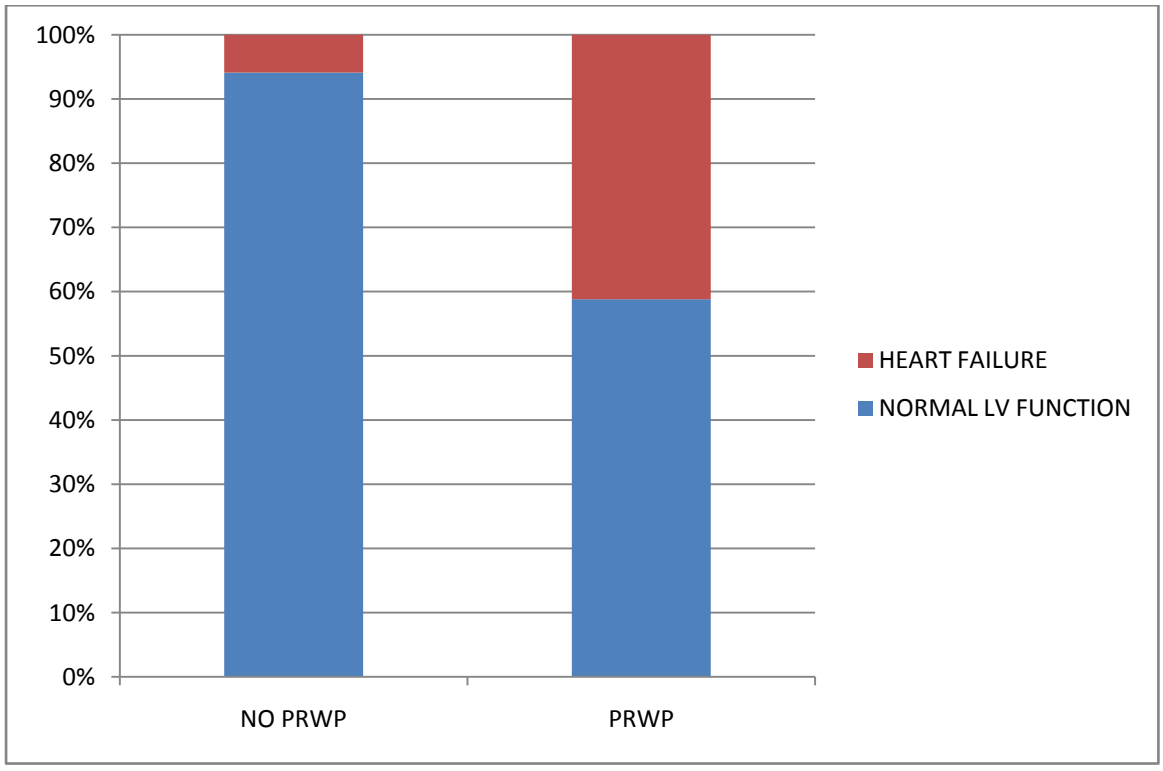



***FIGURE – PRWP AND HEART FAILURE***

# POOR R WAVE PROGRESSION AND HEART FAILURE

| | PRWP | NO PRWP | |
|---|---|---|---|
| NORMAL LV FUNCTION | 10 (38.46%) | 16 (61.54%) | 26 |
| HEART FAILURE | 7 (87.50%) | 1 (12.50%) | 8 |
| | 17 | 17 | 34 |

***TABLE – PRWP AND HEART FAILURE***

p- value – 0.015.

Hence, PRWP was an independent predictor of heart failure in diabetics

asymptomatic for cardiac disease.

# PRWP AND TYPE OF HEART FAILURE

Out of 7 patients, 4 (57.14%) had heart failure with reduced ejection fraction[HfrEF] and 3 (42.86%) had heart failure with preserved ejection fraction[HfpEF].

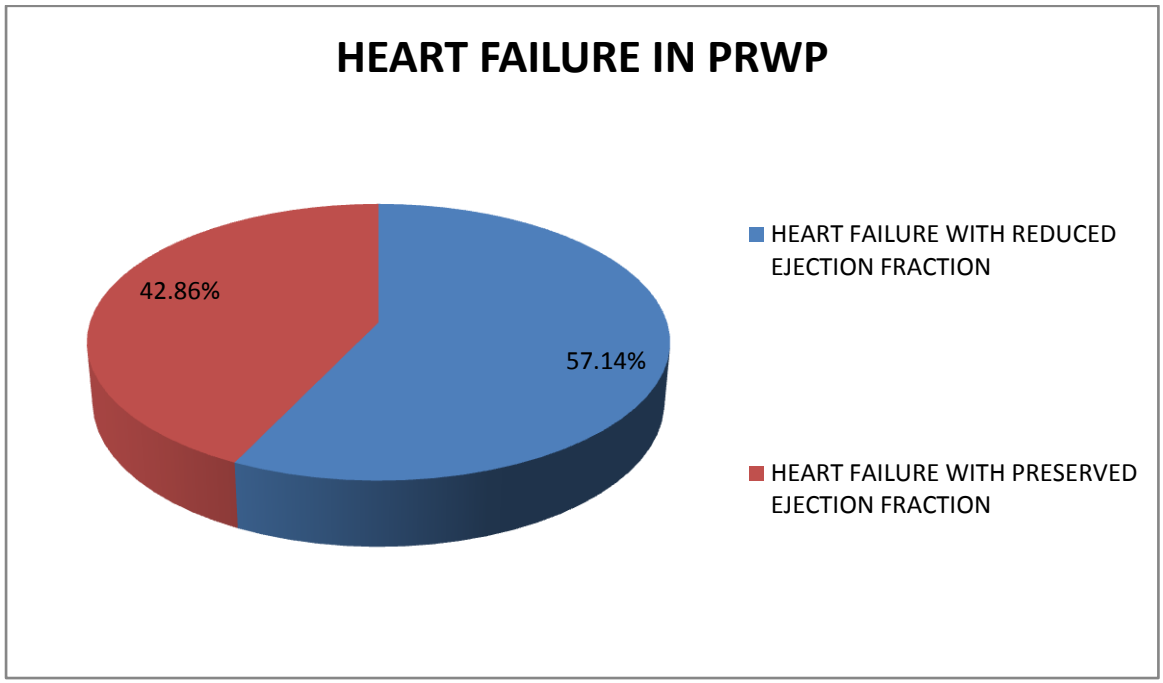



*TABLE – PRWP AND TYPE OF HEART FAILURE*

## PRWP AND HEART FAILURE WITH REDUCED EJECTION FRACTION [HFrEF]

| | PRWP | NO PRWP | |
|---|---|---|---|
| NORMAL LV FUNCTION | 10 (38.46%) | 16 (61.54%) | 26 |
| HFrEF | 4 (80%) | 1 (20%) | 5 |
| | 14 | 17 | 31 |

***TABLE – PRWP AND HFrEF***

p- value – 0.08.

## PRWP AND HEART FAILURE WITH PRESERVED EJECTION FRACTION [HFpEF]

| | PRWP | NO PRWP | |
|---|---|---|---|
| NORMAL LV FUNCTION | 10 (38.46%) | 16 (61.54%) | 26 |
| HFpEF | 3 (75%) | 1 (25%) | 4 |
| | 13 | 17 | 30 |

***TABLE – PRWP AND HFpEF***

p- value – 0.170.

# PREDICTORS OF LVH IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE-

## DIABETIC NEUROPATHY AND LVH

| NEUROPATHY | LVH | NO LVH | |
|---|---|---|---|
| YES | 4 (23.53%) | 46 (42.39%) | 50 (40%) |
| NO | 13 (76.47%) | 62 (57.41%) | 75 (60%) |
| | 17 | 108 | 125 |

The relative risk = Incidence of LVH with Neuropathy/ Incidence of no LVH

with neuropathy

= 0.08 / 0.17 = 0.4

p – value : 0.223.

## DIABETIC RETINOPATHY AND LVH

| RETINOPATHY | LVH | NO LVH | |
|---|---|---|---|
| YES | 4 (23.53%) | 45 (41.67%) | 49 (39.20%) |
| NO | 13 (76.47%) | 63 (58.33%) | 75 (60.80%) |
| | 17 | 108 | 125 |

The relative risk = Incidence of LVH with Retinopathy/ Incidence of no LVH with retinopathy

= 0.08 / 0.17 = 0.47 p – value : 0.154.

## DIABETIC NEPHROPATHY AND LVH

| NEPHROPATHY | LVH | NO LVH | |
|---|---|---|---|
| YES | 5 (29.41%) | 44 (40.74%) | 49 (39.20%) |
| NO | 12 (70.59%) | 64 (59.26%) | 75 (60.80%) |
| | 17 | 108 | 125 |

The relative risk = Incidence of LVH with Nephropathy/ Incidence of no LVH with nephropathy

= 0.10 / 0.15 = 0.667

p – value : 0.374.

## DIABETIC RETINOPATHY AND SINUS TACHYCARDIA

| RETINOPATHY | SINUS TACHYCARDIA | NO SINUS TACHYCARDIA | |
|---|---|---|---|
| YES | 2 (25%) | 47 (40.17%) | 49 (39.20%) |
| NO | 6 (75%) | 70 (59.83%) | 76 (60.80%) |
| | 8 | 108 | 125 |

The relative risk = Incidence of Sinus tachycardia with Retinopathy/ Incidence of no sinus tachycardia with retinopathy

= 0.04 / 0.07 = 0.5 p – value : 0.395.

## DIABETIC NEPHROPATHY AND SINUS TACHYCARDIA

| NEPHROPATHY | SINUS TACHYCARDIA | NO SINUS TACHYCARDIA | |
|---|---|---|---|
| YES | 2 (25%) | 47 (40.17%) | 49 (39.20%) |
| NO | 6 (75%) | 70 (59.83%) | 76 (60.80%) |
| | 8 | 108 | 125 |

The relative risk = Incidence of sinus tachycardia with nephropathy/ Incidence of no sinus tachycardia with nephropathy

= 0.04 / 0.07 = 0.5 p – value : 0.395.

## DIABETIC NEUROPATHY AND SINUS TACHYCARDIA

| NEUROPATHY | SINUS TACHYCARDIA | NO SINUS TACHYCARDIA | |
|---|---|---|---|
| YES | 2 (25%) | 48 (41.03%) | 50 (40%) |
| NO | 6 (75%) | 69 (58.97%) | 75 (60%) |
| | 8 | 117 | 125 |

The relative risk = Incidence of neuropathy with Sinus tachycardia / Incidence of no sinus tachycardia with neuropathy

= 0.04/ 0.08 = 0.5 p – value : 0.371.

## DIABETIC NEUROPATHY AND LEFT AXIS DEVIATION (LAD)

| NEUROPATHY | LAD | NO LAD | |
|---|---|---|---|
| YES | 5 (50%) | 45 (39.13%) | 50 (40%) |
| NO | 5 (50%) | 70 (60.87%) | 75 (60%) |
| | 10 | 117 | 125 |

The relative risk = Incidence of LAD with neuropathy/ Incidence of no LAD with neuropathy = 0.1/ 0.06 = 1.66

p – value : 0.501

## DIABETIC RETINOPATHY AND LAD

| RETINOPATHY | LAD | NO LAD | |
|---|---|---|---|
| YES | 5<br>(50%) | 44<br>(38.26%) | 49<br>(39.20%) |
| NO | 5<br>(50%) | 71<br>(61.74%) | 76<br>(60.80%) |
| | 10 | 117 | 125 |

The relative risk = Incidence of LAD with retinopathy/ Incidence of no LAD with

retinopathy = 0.1/ 0.06 = 1.66

p – value : 0.466

## DIABETIC NEPHROPATHY AND LAD

| NEPHROPATHY | LAD | NO LAD | |
|---|---|---|---|
| YES | 5<br>(50%) | 44<br>(38.26%) | 49<br>(39.20%) |
| NO | 5<br>(50%) | 71<br>(61.74%) | 76<br>(60.80%) |
| | 10 | 117 | 125 |

The relative risk = Incidence of LAD with nephropathy/ Incidence of no LAD with

nephropathy = 0.1/ 0.06 = 1.66

p – value : 0.466.

## DIABETIC RETINOPATHY AND ST-T CHANGES

| RETINOPATHY | ST-T CHANGES | NO ST-T CHANGES | |
|---|---|---|---|
| YES | 5 (33.33%) | 45 (65%) | 50 (40%) |
| NO | 10 (66.67%) | 65 (59.09%) | 75 (60%) |
| | 15 | 110 | 125 |

The relative risk = Incidence of ST-T changes with retinopathy/ Incidence of no ST- T changes with retinopathy = 0.1/ 0.13 = 0.76

p – value : 0.574.

## DIABETIC NEPHROPATHY AND ST-T CHANGES

| NEPHROPATHY | ST-T CHANGES | NO ST-T CHANGES | |
|---|---|---|---|
| YES | 5 (33.33%) | 44 (40%) | 49 (39.20%) |
| NO | 10 (66.67%) | 66 (60%) | 76 (60.80%) |
| | 15 | 110 | 125 |

The relative risk = Incidence of ST-T changes with nephropathy/ Incidence of no ST-T changes with nephropathy = 0.1/ 0.13 = 0.76

p – value : 0.620.

## DIABETIC NEUROPATHY AND ST-T CHANGES

| NEUROPATHY | ST-T CHANGES | NO ST-T CHANGES | |
|---|---|---|---|
| YES | 5 (33.33%) | 44 (40%) | 49 (39.20%) |
| NO | 10 (66.67%) | 66 (60%) | 76 (60.80%) |
| | 15 | 110 | 125 |

The relative risk = Incidence of ST-T changes with neuropathy/ Incidence of no ST-T changes with neuropathy = 0.1/ 0.13 = 0.76

p – value : 0.620.

## DIABETIC NEUROPATHY AND QTc PROLONGATION

| NEUROPATHY | QTc PROLONGED | NORMAL QTc | |
|---|---|---|---|
| YES | 6 (42.85%) | 44 (39.64%) | 49 (40%) |
| NO | 8 (57.14%) | 67 (60.36%) | 76 (60%) |
| | 14 | 111 | 125 |

The relative risk = Incidence of QTc prolongation with neuropathy/ Incidence of normal QTc changes with neuropathy = 0.12/ 0.1 = 1.20

p – value : 0.817.

## DIABETIC RETINOPATHY AND QTc PROLONGATION

| RETINOPATHY | QTc PROLONGED | NORMAL QTc | |
|---|---|---|---|
| YES | 6<br>(42.85%) | 43<br>(38.74%) | 49<br>(39.20%) |
| NO | 8<br>(57.14%) | 68<br>(61.26%) | 76<br>(60.80%) |
| | 14 | 111 | 125 |

The relative risk = Incidence of QTc prolongation with retinopathy/ Incidence of

normal QTc changes with retinopathy = 0.12/ 0.10 = 1.20

p – value : 0.76.

## DIABETIC NEPHROPATHY AND QTc PROLONGATION

| NEPHROPATHY | QTc PROLONGED | NORMAL QTc | |
|---|---|---|---|
| YES | 5<br>(35.71%) | 44<br>(39.64%) | 49<br>(39.20%) |
| NO | 9<br>(64.29%) | 67<br>(60.36%) | 76<br>(60.80%) |
| | 14 | 111 | 125 |

The relative risk = Incidence of QTc prolongation with nephropathy/ Incidence of

normal QTc changes with nephropathy = 0.10/ 0.11 = 0.9

p – value : 0.77.

## DIABETIC NEUROPATHY AND ATRIAL ENLARGEMENT

| NEUROPATHY | ATRIAL ENLARGEMENT | NORMAL ATRIUM | |
|---|---|---|---|
| YES | 4 (50%) | 46 (39.32%) | 50 (40%) |
| NO | 4 (50%) | 71 (60.68%) | 75 (60%) |
| | 8 | 117 | 125 |

The relative risk = Incidence of atrial enlargement with neuropathy/ Incidence of

normal atrium with neuropathy = 0.08/ 0.05 = 1.3.

p – value : 0.55.

## DIABETIC RETINOPATHY AND ATRIAL ENLARGEMENT

| RETINOPATHY | ATRIAL ENLARGEMENT | NORMAL ATRIUM | |
|---|---|---|---|
| YES | 4 (50%) | 45 (38.46%) | 49 (39.20%) |
| NO | 4 (50%) | 72 (61.54%) | 76 (60.80%) |
| | 8 | 117 | 125 |

The relative risk = Incidence of atrial enlargement with neuropathy/ Incidence of

normal atrium with retinopathy = 0.08/ 0.05 = 1.3

p – value : 0.518.

# DIABETIC NEPHROPATHY AND ATRIAL ENLARGEMENT

| NEPHROPATHY | ATRIAL ENLARGEMENT | NORMAL ATRIUM | |
|---|---|---|---|
| YES | 4 (50%) | 45 (38.46%) | 49 (39.20%) |
| NO | 4 (50%) | 72 (61.54%) | 76 (60.80%) |
| | 8 | 117 | 125 |

The relative risk = Incidence of with atrial enlargement with nephropathy/ Incidence of normal atrium with nephropathy = 0.08/ 0.05 = 1.3

p – value : 0.518.

# DISCUSSION

# DISCUSSION:

This prospective observational cohort study was designed to assess the common electrocardiographic features in diabetics who were asymptomatic for cardiac disease. We also looked at the correlation between most common ECG findings seen in our study – PRWP, LVH, LAD, Sinus tachycardia, ST-T changes, Left atrial enlargement and QTc prolongation with the age, sex, duration of DM, mean HbA1c and microvascular complications – Diabetic neuropathy, retinopathy, nephropathy, The patients with PRWP also had an ECHO done to look for cardiac function which was compared with the similar group and characterstics without PRWP.

## CLINICAL PROFILE OF THE PATIENTS

In our study total 125 patients were included. The demographic data showed predominance of the male patients- 59.2% were males and 40.8% were females. The mean duration of DM was 9.6 years and mean HbA1c was 8.27%. 40% of them had diabetic neuropathy, 39.2% had diabetic retinopathy and nephropathy respectively.

# ECG FEATURES IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE-

In this study 19.2% of the diabetics who were asymptomatic for cardiac disease had normal ECG and 80.8% of them had ECG changes. Among which the most common were – Resting sinus tachycardia – 6.4%, Left ventricular hypertrophy – 13.6%, Left atrial enlargement – 5.6%, ST-T changes – 12%, QTc prolongation or QTc dispersion – 11.2% and Poor R wave progression – 13.6%.

So, 12-lead ECG is an important tool in diagnostic and the researcher pursuit as a detection and screening tool of myocardial injury.

# POOR R WAVE PROGRESSION IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE-

Poor R wave progression was seen in 17 out of 125 (13.6%) of diabetics who were asymptomatic for cardiac disease.

# PREDICTORS OF PRWP-

The duration of diabetes was more in patients with PRWP- Mean - 10.82 years than with no PRWP- Mean- 8.25 years.

The difference among the means were 3.73 with 95% confidence interval difference of the difference being 1.47 – 5.89. Based on the T –test for significance. The p- value is 0.006. Hence, in our study the duration of diabetes was an independent predictor of the PRWP in diabetics asymptomatic for cardiac disease .

The age and HBA1c were similar in both the groups and did not show any statistical significant association in our study.

## PREDICTORS OF PRWP WITH MICROVASCULAR COMPLICATION IN DM-

In our study 11 out of 17- 64.7% of the patients with diabetic neuropathy had PRWP. With the relative risk of 2.75, p- value of 0.027. Hence, diabetic neuropathy was an independent predictor of PRWP in diabetics asymptomatic for cardiac disease.

Diabetic retinopathy and nephropathy did not show any association with PRWP.

## POOR R WAVE PROGRESSION AND CARDIAC FUNCTION IN DIABETICS ASYMPTOMATIC FOR CARDIAC DISEASE-

In our study 17 patients had PRWP on ECG and out of which 7 (41.17%) had heart failure on the 2-D ECHO, p-value - 0.015.

Hence, PRWP was an independent predictor of heart failure in diabetics asymptomatic for cardiac disease and showed a strong association.

As seen in PUMI Swedish study silent MI in diabetics were detected in 25% of the individuals. So, PRWP can be used an independent predictor of heart failure and previous myocardial injury.

## PRWP AND TYPE OF HEART FAILURE-

Out of 7 patients, 4 (57.14%) had heart failure with reduced ejection fraction[HfrEF] and 3 (42.86%) had heart failure with preserved ejection fraction[HfpEF].

The p values were not significant due to small number of the positive results.

# PREDICTORS OF COMMON ECG FINDINGS WITH MICROVASCULAR COMPLICATION-

In our study diabetic neuropathy had showed positive effect with QTc prolongation and left atrial enlargement with relative risk of 1.20 and 1.3 respectively but not a true association as it was not statistically significant with p- value of 0.76 and 0.516 respectively.

# CONCLUSION

# CONCLUSION-

1. Diabetes mellitus is a disease with significant mobidity and mortality because of the underlying microvascular and macrovascular complications. But appropriate early screening and diagnostic tests can prevent the progression of the complications.

2. 12-lead Electrocardiogram is an important tool in both diagnostic and the researcher pursuit as a detection and screening tool of myocardial injury.

3. Certain ECG features like resting sinus tachycardia, left ventricular hypertrophy, QTc prolongation, ST-T changes, left atrial enargement and left axis deviation can be seen in diabetics asymptomatic for cardiac disease which appear early in the ongoing pathology of the myocardial injury.

4. PRWP is independent predictor of heart failure in diabetics asymptomatic for cardiac disease.

5. Duration of diabetes is an independent predictor of PRWP on ECG in diabetics asymptomatic for cardiac disease.

6. Diabetic neuropathy is an independent predictor of PRWP on ECG in diabetics asymptomatic for cardiac disease.

7. Diabetic neuropathy seems to have a positive effect on developing QTc prolongation and left atrial enlargement, but may not be true association as it was statistically not significant.

# LIMITATIONS OF THE STUDY

1. As it is a hospital based study the asymptomatic patients will not come to the hospital, which was the major limitation in getting higher number of participants.

2. Long term follow up is needed as atherosclerosis and development of cardiovascular complications are a chronic and continuous process.

3.Normal resting ECG does not rule out cardiovascular disease.

# ANNEXURE 1: BIBLIOGRAPHY

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# ANNEXURE 2: IRB APPROVAL FORM

**OFFICE OF RESEARCH**
**INSTITUTIONAL REVIEW BOARD (IRB)**
**CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

**Dr. B.J. Prashantham,** M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

**Dr. Anna Benjamin Pulimood,** M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

**Dr. Biju George,** M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

October 30, 2018

Dr. Shobhit Priyanshu Joseph,
PG Registrar,
Department of Medicine - 5
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the in predicting cardiac function.
Shobhit Priyanshu Joseph , Employment Number: 29652, PG Registrar, Medicine 5 Unit, Dr. Ramya I Employment Number: 31571, General Medicine Unit 5, Dr. OC Abraham, Dr. J. Mohammad Sadiq, Dr. Ravikar, Dr. Vignesh, Medicine.

Ref: IRB Min. No. 11349 [OTHER] dated 01.06.2018

Dear Dr. Shobhit Priyanshu Joseph,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the in predicting cardiac function" on June 04, 2018.

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board
Christian Medical College, Vellore - 632 002.

Cc: Dr. Ramya I, Medicine - 5, CMC Vellore



Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 2284284, 2284282 Fax: 0416 2262788, 2284481 E-mail: research@cmcvellore.ac.in

# OFFICE OF RESEARCH
# INSTITUTIONAL REVIEW BOARD (IRB)
# CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

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October 30, 2018

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Sub: **Fluid Research Grant: New Proposal:**
Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the in predicting cardiac function.
Shobhit Priyanshu Joseph , Employment Number: 29652, PG Registrar, Medicine 5 Unit, Dr. Ramya I Employment Number: 31571, General Medicine Unit 5, Dr. OC Abraham, Dr. J. Mohammad Sadiq, Dr. Ravikar, Dr. Vignesh, Medicine.

Ref: IRB Min. No. 11349 [O-I-III-R] dated 04.06.2018

Dear Dr. Shobhit Priyanshu Joseph,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the in predicting cardiac function" on June 04, 2018.

The Committee reviewed the following documents:

1. IRB application format
2. Consent form and Information sheet (English, Tamil, hindi, Bengali)
3. Clinical Research Form
4. Permission Letter
5. Cvs of Drs. Shobhit, Ramya and Vignesh.
6. Nos. of documents 1- 5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on June 04th 2018 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.



Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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# OFFICE OF RESEARCH
# INSTITUTIONAL REVIEW BOARD (IRB)
# CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

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**Dr. Biju George,** M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

| Name | Qualification | Designation | Affiliation |
|---|---|---|---|
| Dr. Biju George | MBBS, MD, DM | Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore | Internal, Clinician |
| Rev. Joseph Devaraj | BSc, BD | Chaplaincy Department, CMC, Vellore | Internal, Social Scientist |
| Dr. B. J. Prashantham | MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling) | Chairperson, Ethics Committee, IRB, Director, Christian Counseling Centre, Vellore | External, Social Scientist |
| Dr. Anuradha Rose | MBBS, MD, MHSC (Bioethics) | Associate Professor, Community Health, CMC, Vellore | Internal, Clinician |
| Dr. Thomas V Paul | MBBS, MD, DNB, PhD | Professor,Endocrinology, CMC, Vellore | Internal, Clinician |
| Mr. C. Sampath | BSc, BL | Advocate, Vellore | External, Legal Expert |
| Dr. Jayaprakash Muliyil | BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC | Retired Professor, CMC, Vellore | External, Scientist &Epidemiologist |
| Ms. Grace Rebekha | M.Sc., (Biostatistics) | Lecturer, Biostatistics, CMC, Vellore | Internal, Statistician |
| Mr. Samuel Abraham | MA, PGDBA, PGDPM, M. Phil, BL., | Sr. Legal Officer, CMC, Vellore | Internal, Legal Expert |
| Dr. RatnaPrabha | MBBS, MD (Pharma) | Associate Professor, Clinical Pharmacology, CMC, Vellore | Internal, Pharmacologist |
| Mrs. Pattabiraman | BSc, DSSA | Social Worker, Vellore | External, Lay Person |
| Mrs. Sheela Durai | MSc Nursing | Professor, Medical Surgical Nursing, CMC, Vellore | Internal, Nurse |



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OFFICE OF RESEARCH
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Chairperson, Research Committee & Principal

**Dr. Biju George,** M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

| | | | |
|---|---|---|---|
| Dr. Tunny Sebastian | P.hd., (Biostatistics) | Lecturer, Biostatistics, CMC, Vellore | Internal, Statistician |
| Mrs. Nirmala Margaret | MSc Nursing | Addl. Deputy Nursing Superintendent, College of Nursing, CMC, Vellore | Internal, Nurse |
| Dr. Sathish Kumar | MBBS, MD, DCH | Professor, Child Health, CMC, Vellore | Internal, Clinician |
| Dr. Barney Isaac | M.B.,B.S. D.N.B (Respiratory Diseases) | Associate Professor, Pulmonary Medicine, CMC, Vellore | Internal, Clinician |
| Dr. John Antony Jude Prakash | MBBS, MD | Professor, Clinical Microbiology, CMC, Vellore | Internal, Clinician. |
| Dr. AjithSivadasan | MD, DM | Professor, Neurological Sciences, CMC, Vellore | Internal, Clinician |
| Dr. RekhaPai | BSc, MSc, PhD | Associate Professor, Pathology, CMC, Vellore | Internal, Basic Medical Scientist |
| Dr SnehaVarkki | MBBS, DCH, DNB | Professor, Paediatrics, CMC, Vellore | Internal, Clinician |

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the in predicting cardiac function" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

*Fluid Grant Allocation:*
*A sum of 77,350/- INR (Rupees Seventy Seven Thousand Three Hundred and Fifty Only) will be granted for 1 year.*

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS, MD, DM,
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 11349 [OTHER] dated 04.06.2018

4 of 4

# ANNEXURE 3: INFORMATION SHEET AND CONSENT FORM

## PATIENT INFORMATION FORM:

**Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the electrocardiogram in predicting cardiac function. – AN OBSERVATIONAL STUDY**

**Date: 1/5/2018**

**What is the study about?**

Diabetes mellitus is an important metabolic disorder that can affect nearly every organ system in

the body. About one third of patients presenting with acute myocardial infarction have diabetes mellitus, the prevalence of which is steadily increasing. This study is conducted to determine the electrocardiographic features and assessing the utility of poor R wave progression in predicting cardiac function in patient with diabetes who are asymptomatic for cardiac disease.

**If you take part, what will you have to do?**

All you would be required to do is to answer a few questions that will be asked to you regarding your illness and yourself. A 12- lead electrocardiogram will be done at diagnosis and if there is presence of poor R wave progression you will be called for a non invasive echocardiography test.

**Are there any risks for you if you take part in the study?**

By enrolling yourself into this study you subject yourself to no risk at all. Your treatment will not be altered in any form as a consequence of your participation in this study..

**What are the benefits to you and others if you take part in the study?**

By participating in this study, you will go a long way in helping the health care community better understand the mechanisms of the illness so that complications could be anticipated early and preventive measures can be instituted in time to prevent them from occurring. And new research areas would open up if significant results arise from the study.

**Can you decide not to participate?**

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

**Will your personal details be kept confidential?**

All information provided by you will be kept confidential and your identity will not be revealed to a third party under any circumstances. Any publications arising from the study will not have any patient identifiable data.

Thank you

Shobhit Priyanshu Joseph

For any further queries

Contact No : 9944581757 E mail ID : shobhit_zealot@yahoo.co.in

Address for communication : Dept of Medicine 5 , CMC Vellore

**CONSENT FORMS:**

# நோயாளியின் தகவல் படிவம்

இதய நோய்க்கான அறிகுறிகள் இல்லாத நீரிழிவு நோயாளிகளின் எலக்ட்ரோ கார்டியோகிராஃபிக் (ஈ.சி.ஜி) பரிசோதனையில் 'R' அலைகளின் உயர்வு மற்றும் அவர்களின் செயல்பாட்டை கணிக்க உதவுமா என கண்டறிவதற்கான ஆய்வு.

# ஒப்புதல் படிவம்

## ஆராய்ச்சி ஆய்வில் பங்கு பெற ஒப்புதல் படிவம்

ஆய்வுத் தலைப்பு: " இதய நோய்க்கான அறிகுறிகள் இல்லாத நீரிழிவு நோயாளிகளின் எலக்ட்ரோ கார்டியோகிராஃபிக் (ஈ.சி.ஜி) பரிசோதனையில் 'R' அலைகளின் உயர்வு மற்றும் அவர்களின் செயல்பாட்டை கணிக்க உதவுமா என கண்டறிவதற்கான ஆய்வு. "

ஆய்வு எண் : _____

பெயர் : _____

பிறந்த தேதி : _____

வயது : _____

i. ஒப்புதல் படிவத்தில் உள்ள தகவல்களை நான் _____ அன்று படித்து புரிந்து கொண்டேன் என்று உறுதிப்படுத்துகிறேன். மேற்கண்ட ஆய்வில் பங்கு கொள்ள வாய்ப்பு கொடுத்தமைக்கு நன்றி.

ii. மேற்கண்ட ஆய்வில் பங்குபெற என்னை யாரும் கட்டாயப்படுத்தவோ, வற்புறுத்தவோ இல்லை. என்னுடைய மருத்துவப் பரிசோதனை மற்றும் மருத்துவத் துறையின் சட்ட திட்டங்களுக்கு உட்பட்டு நான் எப்போது வேண்டுமானாலும், எந்த முன்னறிவிப்பும் இல்லாமல் மேற்கண்ட ஆய்வில் இருந்து விலக்கிக் கொள்ள எனக்கு முழு உரிமை உள்ளது என உறுதி கூறுகிறேன்.

iii. நெறிமுறைக் குழு மற்றும் கட்டுப்பாட்டு அதிகாரிகள் என்னுடைய மருத்துவ அறிக்கையின் விவரங்களை மேற்கண்ட ஆய்வுக்காகவும் மற்றும் எதர்காலத்தில் மேற்கண்ட ஆய்விற்கு சம்மந்தமான ஆய்வுகளுக்கு பயன்படுத்திக் கொள்ள எனக்கு எந்த விதமான ஆட்சேபனையும் இல்லை. மேலும், என்னுடைய சுய விவரங்களை ஆய்விற்கு சம்மந்தமில்லாத நபர்களுக்கோ அல்லது வேறு யாருக்கோ தெரியப்படுத்தக்கூடாது.

iv. இந்த ஆய்வின் முடிவிலிருந்து கிடைக்கும் தரவு மற்றும் முடிவுகளை அறிவியல் ரீதியாகப் பயன்படுத்திக் கொள்ள எந்தவொரு தடையுமில்லை என உறுதியளிக்கிறேன்.

v. மேற்கண்ட ஆய்வில் பங்கேற்க ஒப்புக் கொள்கிறேன்.

ஆய்வில் பங்கேற்பவரின் கையொப்பம் (அல்லது) கட்டைவிரல் கைரேகை

கையொப்பம்

(அல்லது)

கட்டைவிரல் கைரேகை

நாள் : _____

கையொப்பமிட்டவரின் பெயர் : _____

**Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the electrocardiogram in predicting cardiac function**

**Informed Consent Form**

Informed Consent form to participate in a research study

**Study Title:**

Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the electrocardiogram in predicting cardiac function.

**Study Number: _____**

**Subject's Initials: _____**
**Subject's Name: _____**

**Date of Birth / Age: _____**

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

(v) I agree to take part in the above study. Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or

Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____

मधुमेह मेलिटस वाले मरीजों में इलेक्ट्रोकार्डियोग्राफिक फीचर्स जो हृदय रोग के लिए असम्बद्ध हैं और कार्डियक फ़ंक्शन की भविष्यवाणी में इलेक्ट्रोकार्डियोग्राम में poor R wave progression की उपयोगिता।

सूचित सहमति प्रपत्र

एकशोध अध्ययन में भाग लेने के लिए सूचित सहमति फॉर्म
अध्ययन का शीर्षक: मधुमेह मेलिटस वाले मरीजों में ईसीजी सुविधाएं जो हृदय रोगों के लिए असम्बद्ध हैं और कार्डियक फ़ंक्शन की भविष्यवाणी करने के लिए ecg में poor R wave progression की उपयोगिता हैं।

अध्ययन संख्या:.....

विषय के प्रारंभिक विषय का नाम:.....

जन्म / आयु की तिथि:.....

1. मैं पुष्टि करता हूं कि मैंने उपर्युक्त अध्ययन के लिए ..... की सूचना पत्र पढ़ और समझ ली है और प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में भागीदारी स्वैच्छिक है और मैं किसी भी समय अपनी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित होने के बिना वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि नैतिकता कमेटी और नियामक प्राधिकरणों को वर्तमान स्वास्थ्य के संबंध में मेरे स्वास्थ्य रिकॉर्ड और मेरे संबंध में किए जा सकने वाले किसी भी अन्य शोध को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैंने परीक्षण से वापस ले लिया हो। मैं इस पहुंच से सहमत हूं। हालांकि, मैं समझता हूं कि मेरी पहचान तीसरे पक्ष को प्रकाशित या प्रकाशित किसी भी जानकारी में प्रकट नहीं होगी।

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए ही हो।

5. मैं उपरोक्त अध्ययन में हिस्सा लेने के लिए सहमत हूं।

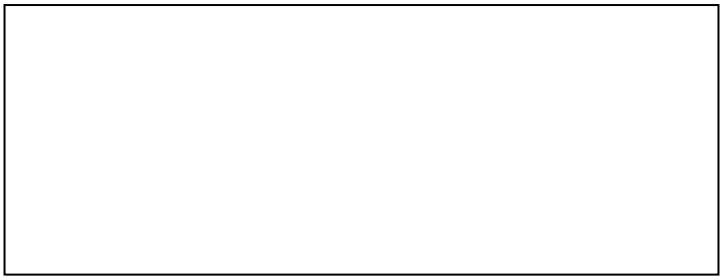
विषय / कानूनी रूप से स्वीकार्य के हस्ताक्षर (या अंगूठे इंप्रेशन)

तारीख:

हस्ताक्षरकर्ता का नाम ..... हस्ताक्षर

या

प्रतिनिधि:



तारीख:

हस्ताक्षरकर्ता का नाम:

जांचकर्ता का हस्ताक्षर:

तारीख:

अध्ययन जांचकर्ता का नाम:

गवाह के हस्ताक्षर या अंगूठे की छाप:

तारीख:

ডায়াবেটিস মেলিটাসের রোগীদের মধ্যে ইলেকট্রোক্রেডিওগ্রাফিক বৈশিষ্ট্য যারা কার্ডিয়াক রোগের জন্য অর্শ্বরোগ এবং কার্ডিয়াক ফাংশনের পূর্বাভাসে ইলেকট্রোক্রেডোগ্রামে দরিদ্র আর তরঙ্গের অগ্রগতির উপযোগিতা।

সম্মতি ফর্ম

একটি গবেষণা অধ্যয়নে অংশগ্রহণের জন্য জ্ঞাত কনসেন্ট ফর্ম

অধ্যয়ন শিরোনাম:
ডায়াবেটিস মেলিটাসের রোগীদের মধ্যে ইলেকট্রোক্রেডিওগ্রাফিক বৈশিষ্ট্য যারা কার্ডিয়াক রোগের জন্য অর্শ্বরোগ এবং কার্ডিয়াক ফাংশনের পূর্বাভাসে ইলেকট্রোক্রেডোগ্রামে দরিদ্র আর তরঙ্গের অগ্রগতির উপযোগিতা।

অধ্যয়ন সংখ্যা: _____

বিষয়টির প্রাথমিক: _____ বিষয়টির নাম:
_____

জন্ম তারিখ / বয়স: _____

(i) আমি নিশ্চিত করছি যে উপরের অধ্যয়নের জন্য আমি _____ এর তথ্যপত্র পড়েছি এবং বুঝতে পেরেছি এবং প্রশ্নগুলি জিজ্ঞাসা করার সুযোগ পেয়েছি।

(ii) আমি বুঝতে পারি যে আমার গবেষণায় অংশগ্রহন স্বেচ্ছাসেবী এবং যে কোনও কারণে বিনামুল্যে আমি আমার চিকিৎসার বা আইনগত অধিকার ব্যতীত অন্য কোনও কারণে প্রত্যাহার করতে পারি।

(iii) আমি বুঝতে পারি যে, এথিকস কমিটি এবং নিয়ন্ত্রক কর্তৃপক্ষকে আমার বর্তমান স্বাস্থ্য গবেষণাপত্রের দিকে নজর রাখার জন্য আমার অনুমতির প্রয়োজন হবে না এবং বর্তমান গবেষণা এবং তার সাথে সম্পর্কযুক্ত যে কোনও গবেষণার প্রয়োজন হয়, এমনকি যদি আমি তা থেকে সরে যাই ট্রায়াল। আমি এই অ্যাক্সেসের জন্য সম্মত। যাইহোক, আমি বুঝতে পারি যে আমার পরিচয় তৃতীয় পক্ষের কাছে প্রকাশিত বা প্রকাশিত কোন তথ্য প্রকাশ করা হবে না।

(iv) আমি এই গবেষণা থেকে উদ্ভূত কোন তথ্য বা ফলাফল ব্যবহার সীমিত করতে সম্মত হন তবে এই ধরনের ব্যবহার শুধুমাত্র বৈজ্ঞানিক উদ্দেশ্যে (গুলি) জন্য।

(v) আমি উপরের গবেষণায় অংশ নিতে সম্মত হই।

বিষয় / আইনত গ্রহণযোগ্য এর স্বাক্ষর (বা আঙুল ছাপ)

তারিখ: _____ / _____ / _____

স্বাক্ষরকারীর নাম: _____ স্বাক্ষর:

অথবা

প্রতিনিধি: _____

তারিখ: _____ / _____ / _____

স্বাক্ষরকারীর নাম: _____

তদন্তকারীর স্বাক্ষর: _____

তারিখ: _____ / _____ / _____

অধ্যয়ন তদন্তকারীর নাম: _____

সাক্ষীর স্বাক্ষর বা আঙুলের ছাপ: _____

তারিখ: _____ / _____ / _____

সাক্ষীর নাম ও ঠিকানা: _____

# ANNEXURE 4: CLINICAL RESEARCH FORM

**CASE REPORT FORM**

**Electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in the electrocardiogram in predicting cardiac function.**

**Serial number:**

**Informant:**

**Time of collection of data:**

**Date: ( DD/MM/YYYY)**

**Identification for a patient:**

**Department:**

**Hospital ID:**

**Unique ID created by the investigator**

**Date of birth:**
**Age:**
**Gender: Male /Female**
**Height:**
**Weight:**
**BMI:**

**Smoking: Yes / No**
**Type: Cigarette / Beedi**
**Duration:**
**Pack years:**

**Alcohol consumption:**
**Type: Beer / Wine / Rum**
**Duration:**

**Diabetes mellitus:**
**Duration:**
**Hba1c:**
**AC / PC :**

**Fasting Lipid profile:**
**Total cholesterol:**
**Triglycerides:**
**HDL:**
**LDL:**

**Microvascular complications:**
**Neuropathy: 10 gm monofilament test: yes / no**

**Nephropathy: Yes / No**

**Urinary microalbumin:**

**Retinopathy: Yes / No**
**Grade: Non proliferative diabetic retinopathy – mild / moderate / severe**
**Proliferative diabetic neuropathy**

**Macrovascular complications:**

**Cerebrovascular accident:**
**History: yes / no**
**Examination: yes / no**

**Peripheral artery occlusive disease: Yes / No**
**ABPI:**

**ECG Findings:**

**Rate:**
**Rhythm:**
**Axis:**
**P wave morphology:**
**PR interval:**
**QRS complex:**
**QTc interval:**
**QT dispersion:**
**ST-T changes:**
**Poor R wave progression:**
**Interpretation:**

**Poor R wave progression: yes/no**
**Ejection fraction:**
**Interpretation:**

# ANNEXURE 5: DATA SHEET

| no | name | hospno | age | gender | smoking | alcohol | dmdura | hba1c | neuropatl | nephropa | urinary | retinopatl | cerebrova | periartery | rate | rhythm | axis | pwave | printer | qrscom |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABDUL RO | 018361G | 58 | 1 | 2 | 2 | 8 | 7.1 | 1 | 1 | 151 | 1 | 2 | 2 | 112 | SINUS TAC | 3 | 3 | 128 | |
| 2 | EHILAMAT | 436787B | 49 | 2 | 2 | 2 | 4 | 6.8 | 2 | 2 | 6 | 2 | 2 | 2 | 90 | SINUS | 3 | 3 | 154 | |
| 3 | PACHIAMI | 576165C | 49 | 2 | 2 | 2 | 8 | 11.7 | 2 | 2 | 28 | 2 | 2 | 2 | 82 | SINUS | 3 | 3 | 148 | 9 |
| 4 | SUKANTA | 630187H | 42 | 1 | 2 | 2 | 4 | 7.3 | 2 | 2 | 8 | 2 | 2 | 2 | 92 | SINUS | 1 | 3 | 136 | |
| 5 | AUGUSTIN | 855137F | 64 | 1 | 2 | 2 | 12 | 6.6 | 1 | 1 | 162 | 1 | 2 | 2 | 80 | SINUS | 3 | 3 | 220 | 1 |
| 6 | MALLIKA | 950380D | 62 | 2 | 2 | 2 | 8 | 6.3 | 1 | 1 | 120 | 1 | 2 | 2 | 92 | SINUS | 1 | 3 | 122 | |
| 7 | YASOTHA | 544295G | 68 | 2 | 2 | 2 | 12 | 6.5 | 1 | 1 | 110 | 1 | 2 | 2 | 66 | SINUS | 3 | 3 | 146 | |
| 8 | SHAIKH | 294959H | 46 | 1 | 1 | 2 | 4 | 9.7 | 1 | 2 | 9 | 1 | 2 | 2 | 90 | SINUS | 1 | 3 | 128 | |
| 9 | KAILASH | 627312H | 40 | 1 | 1 | 1 | 10 | 9.6 | 1 | 1 | 400 | 1 | 2 | 2 | 96 | SINUS | 1 | 3 | 150 | |
| 10 | MANOJ | 627307H | 55 | 1 | 1 | 2 | 10 | 9.3 | 2 | 2 | 28 | 2 | 2 | 2 | 110 | SINUS TAC | 3 | 3 | 122 | |
| 11 | MD IYAZ | 613781G | 58 | 1 | 1 | 2 | 12 | 11 | 1 | 1 | 400 | 1 | 2 | 2 | 106 | SINUS TAC | 3 | 3 | 174 | |
| 12 | MD.NAZIF | 388842H | 50 | 1 | 2 | 2 | 8 | 7.8 | 1 | 1 | 120 | 1 | 2 | 2 | 82 | SINUS | 3 | 3 | 124 | |
| 13 | MANOHA | 599642H | 51 | 1 | 2 | 2 | 2 | 8.8 | 2 | 2 | 20 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 168 | |
| 14 | RAJA | 698470D | 49 | 1 | 1 | 2 | 2 | 8.8 | 2 | 2 | 4 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 160 | |
| 15 | SAMBASI | 484864D | 41 | 1 | 1 | 1 | 1 | 8.7 | 2 | 2 | 8 | 2 | 2 | 2 | 78 | SINUS | 3 | 3 | 142 | |
| 16 | CHANDRE | 787639C | 61 | 1 | 2 | 2 | 12 | 6.8 | 1 | 1 | 150 | 1 | 2 | 2 | 90 | SINUS | 3 | 3 | 144 | |
| 17 | SIDHANDI | 103043D | 70 | 1 | 1 | 1 | 25 | 11 | 1 | 1 | 280 | 1 | 2 | 2 | 86 | SINUS | 3 | 3 | 140 | |
| 18 | LAKSHMI | 446075H | 52 | 2 | 2 | 2 | 8 | 10.4 | 1 | 1 | 52 | 1 | 2 | 2 | 92 | SINUS | 3 | 3 | 144 | |
| 19 | PREMA | 855140H | 58 | 2 | 2 | 2 | 6 | 7 | 2 | 2 | 8 | 2 | 2 | 2 | 72 | SINUS | 3 | 3 | 112 | |
| 20 | KALAISEL | 381545C | 40 | 2 | 2 | 2 | 1 | 8.8 | 2 | 2 | 20 | 2 | 2 | 2 | 120 | SINUS TAC | 3 | 3 | 170 | |
| 21 | CHANDRA | 352653G | 44 | 2 | 2 | 2 | 6 | 6.7 | 2 | 1 | 54 | 2 | 2 | 2 | 98 | SINUS | 3 | 3 | 114 | 1 |
| 22 | SP SINGH | 410328H | 58 | 1 | 1 | 2 | 4 | 7.2 | 2 | 2 | 12 | 2 | 2 | 2 | 70 | SINUS | 3 | 3 | 120 | 1 |
| 23 | SOUNDAR | 399561D | 43 | 2 | 2 | 2 | 6 | 11.2 | 2 | 2 | 33 | 2 | 2 | 2 | 82 | SINUS | 3 | 3 | 142 | |
| 24 | BANDANA | 181972F | 45 | 2 | 2 | 2 | 2 | 8.4 | 2 | 2 | 6 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 126 | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 24 | BANDANA | 181972F | 45 | 2 | 2 | 2 | 2 | 8.4 | 2 | 2 | 6 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 126 |
| 25 | RAVI | 149199D | 57 | 1 | 1 | 2 | 8 | 8.7 | 1 | 1 | 110 | 1 | 2 | 2 | 90 | SINUS | 3 | 3 | 124 |
| 26 | VARAMA | 721629 | 65 | 2 | 2 | 2 | 7 | 6.7 | 2 | 2 | 4 | 2 | 2 | 2 | 70 | SINUS | 1 | 3 | 160 |
| 27 | RAMANA | 922967C | 53 | 1 | 2 | 2 | 6 | 7.2 | 2 | 2 | 22 | 2 | 2 | 2 | 96 | SINUS | 3 | 3 | 154 |
| 28 | SETU | 763881B | 50 | 1 | 1 | 1 | 4 | 7.4 | 2 | 2 | 8 | 2 | 2 | 2 | 92 | SINUS | 3 | 3 | 130 |
| 29 | SARAVAN | 140437H | 41 | 1 | 1 | 2 | 8 | 9 | 1 | 1 | 239 | 1 | 2 | 2 | 70 | SINUS | 2 | 3 | 170 |
| 30 | GOPI | 280474A | 59 | 1 | 2 | 2 | 10 | 7.9 | 1 | 1 | 100 | 1 | 2 | 2 | 90 | VENTRICU | 3 | 3 | 160 |
| 31 | VARALAK | 394114H | 48 | 2 | 2 | 2 | 4 | 5.6 | 2 | 2 | 14 | 2 | 2 | 2 | 102 | SINUS TAC | 3 | 2 | 146 |
| 32 | MOHAN | 241505C | 63 | 1 | 1 | 2 | 7 | 6.9 | 2 | 2 | 19 | 2 | 2 | 2 | 70 | SINUS | 1 | 3 | 182 |
| 33 | GOWRI | 270290D | 59 | 2 | 2 | 2 | 6 | 6.7 | 2 | 2 | 3 | 2 | 2 | 2 | 64 | SINUS | 3 | 3 | 138 |
| 34 | ARUMUG | 680028G | 42 | 1 | 1 | 1 | 2 | 7.7 | 2 | 2 | 8 | 2 | 2 | 2 | 70 | SINUS | 3 | 3 | 164 |
| 35 | ANBAZGH | 569545H | 55 | 1 | 1 | 1 | 8 | 9 | 1 | 1 | 200 | 1 | 2 | 2 | 96 | SINUS | 3 | 3 | 110 |
| 36 | UMA DEVI | 052713A | 67 | 2 | 2 | 2 | 10 | 7 | 2 | 2 | 28 | 2 | 2 | 2 | 74 | SINUS | 3 | 3 | 158 |
| 37 | MD JAHID | 568374H | 49 | 1 | 2 | 2 | 10 | 9 | 1 | 1 | 300 | 1 | 2 | 2 | 84 | SINUS | 3 | 1 | 140 |
| 38 | GOVINDR | 620812H | 61 | 1 | 1 | 2 | 12 | 9 | 1 | 1 | 110 | 1 | 2 | 2 | 96 | SINUS | 3 | 1 | 156 |
| 39 | TAPAS | 620611H | 40 | 1 | 1 | 1 | 2 | 6.7 | 2 | 2 | 28 | 2 | 2 | 2 | 86 | SINUS | 3 | 3 | 140 |
| 40 | KUMAR | 631587H | 57 | 1 | 1 | 2 | 12 | 10.4 | 1 | 1 | 400 | 1 | 2 | 2 | 76 | VENTRICU | 3 | 3 | 122 |
| 41 | DAMODH | 609680f | 67 | 1 | 1 | 1 | 12 | 6.5 | 1 | 1 | 110 | 1 | 2 | 2 | 48 | SINUS BRA | 1 | 3 | 160 |
| 42 | REVATHI | 680164B | 45 | 2 | 2 | 2 | 2 | 6.6 | 2 | 2 | 20 | 2 | 2 | 2 | 80 | SINUS | 3 | 3 | 120 |
| 43 | DEEPAK | 635839H | 48 | 1 | 2 | 2 | 2 | 6.6 | 2 | 2 | 20 | 2 | 2 | 2 | 72 | SINUS | 3 | 3 | 180 |
| 44 | GUNASEK | 838234C | 56 | 1 | 2 | 1 | 3 | 6.8 | 2 | 2 | 6 | 2 | 2 | 2 | 108 | SINUS TAC | 3 | 3 | 120 |
| 45 | JOSEPH | 457462H | 48 | 1 | 2 | 1 | 2 | 8.9 | 2 | 2 | 10 | 2 | 2 | 2 | 86 | SINUS | 3 | 3 | 160 |
| 46 | SARALA | 151179C | 40 | 2 | 2 | 2 | 1 | 7.1 | 2 | 2 | 7 | 2 | 2 | 2 | 102 | SINUS TAC | 3 | 3 | 144 |
| 47 | ANANDI | 160517D | 52 | 2 | 2 | 2 | 6 | 7.4 | 2 | 1 | 50 | 2 | 2 | 2 | 104 | SINUS TAC | 3 | 3 | 112 |
| 48 | JAYANTA | 632178H | 40 | 1 | 1 | 2 | 2 | 7.5 | 2 | 2 | 20 | 2 | 2 | 2 | 76 | SINUS | 3 | 3 | 154 |

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| 49 | RAGUPATI | 357124D | 45 | 1 | 1 | 1 | 2 | 10 | 2 | 2 | 10 | 2 | 2 | 2 | 86 | SINUS | 3 | 3 | 150 | 1 |
| 50 | POORNIM | 586405H | 55 | 2 | 2 | 2 | 4 | 10.3 | 2 | 2 | 8 | 2 | 2 | 2 | 104 | SINUS TAC | 3 | 3 | 154 | |
| 51 | SUSEELA | 413964A | 66 | 2 | 2 | 2 | 12 | 10.2 | 1 | 1 | 150 | 1 | 2 | 2 | 74 | SINUS | 1 | 3 | 120 | |
| 52 | VIJAYAN | 224741F | 55 | 1 | 2 | 1 | 6 | 8.5 | 2 | 2 | 8 | 2 | 2 | 2 | 86 | SINUS | 3 | 3 | 160 | |
| 53 | JAISANKA | 380630H | 47 | 1 | 2 | 1 | 6 | 7.7 | 1 | 2 | 38 | 2 | 2 | 2 | 82 | SINUS | 3 | 3 | 142 | |
| 54 | SAMUEL | 486581F | 55 | 1 | 2 | 1 | 6 | 8 | 2 | 2 | 4 | 2 | 2 | 2 | 98 | SINUS | 3 | 3 | 146 | |
| 55 | JAYA | 690616B | 47 | 2 | 2 | 2 | 6 | 7.7 | 2 | 2 | 6 | 2 | 2 | 2 | 92 | SINUS | 3 | 3 | 146 | 1 |
| 56 | STELLA | 268834F | 62 | 2 | 2 | 2 | 6 | 7.2 | 1 | 1 | 120 | 1 | 2 | 2 | 98 | SINUS | 1 | 3 | 154 | |
| 57 | GANGAMI | 954292G | 48 | 2 | 2 | 2 | 4 | 6.9 | 2 | 1 | 140 | 1 | 2 | 2 | 76 | SINUS | 3 | 3 | 140 | |
| 58 | DAVID | 750358F | 58 | 1 | 1 | 1 | 4 | 9.5 | 2 | 2 | 8 | 2 | 2 | 2 | 68 | SINUS | 1 | 3 | 144 | 1 |
| 59 | ANALPARI | 206308C | 48 | 2 | 2 | 2 | 4 | 9.2 | 2 | 2 | 9 | 2 | 2 | 2 | 92 | SINUS | 3 | 3 | 120 | |
| 60 | SHANTHI | 946744F | 64 | 2 | 2 | 2 | 15 | 7.2 | 1 | 1 | 230 | 1 | 2 | 2 | 92 | SINUS | 3 | 3 | 150 | |
| 61 | RAJAN | 797442C | 66 | 1 | 1 | 2 | 12 | 7.9 | 1 | 1 | 340 | 1 | 2 | 2 | 90 | SINUS | 3 | 3 | 120 | |
| 62 | SAGAYAM | 701345A | 55 | 2 | 2 | 2 | 4 | 10.3 | 2 | 2 | 12 | 2 | 2 | 2 | 92 | SINUS | 3 | 3 | 152 | |
| 63 | ARUMUGA | 620275H | 52 | 1 | 1 | 2 | 4 | 9 | 2 | 2 | 10 | 2 | 2 | 2 | 98 | SINUS | 3 | 3 | 120 | |
| 64 | SHIRLY | 168527F | 56 | 2 | 2 | 2 | 8 | 7.8 | 1 | 1 | 142 | 1 | 2 | 2 | 110 | SINUS TAC | 3 | 1 | 130 | |
| 65 | TAMIL SEL | 865799G | 49 | 2 | 2 | 2 | 3 | 6.7 | 2 | 2 | 5 | 2 | 2 | 2 | 70 | SINUS | 1 | 3 | 138 | |
| 66 | SUBRAMA | 252931F | 70 | 1 | 1 | 2 | 20 | 13.6 | 1 | 1 | 142 | 1 | 2 | 2 | 120 | SINUS TAC | 3 | 3 | 176 | |
| 67 | SANTHAM | 667225B | 43 | 2 | 2 | 2 | 2 | 7.8 | 2 | 2 | 20 | 2 | 2 | 2 | 74 | SINUS | 3 | 3 | 136 | 1 |
| 68 | SELVAM | 031018H | 56 | 1 | 1 | 1 | 12 | 6.2 | 1 | 1 | 326 | 1 | 2 | 2 | 68 | SINUS | 3 | 3 | 154 | |
| 69 | SATHIYA | 785817F | 55 | 2 | 2 | 2 | 12 | 8.7 | 1 | 1 | 241 | 1 | 2 | 2 | 120 | SINUS TAC | 3 | 3 | 160 | |
| 70 | SASIKUMA | 426199H | 48 | 1 | 2 | 2 | 2 | 6.7 | 2 | 2 | 9 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 150 | |
| 71 | RAJESHW | 273284F | 59 | 1 | 2 | 2 | 10 | 7 | 1 | 2 | 240 | 1 | 2 | 2 | 80 | SINUS | 1 | 3 | 140 | |
| 72 | ASHA T. | 143193A | 65 | 2 | 2 | 2 | 6 | 10 | 2 | 2 | 24 | 2 | 2 | 2 | 78 | SINUS | 3 | 3 | 146 | |
| 73 | GOPAL | 661644H | 52 | 1 | 1 | 1 | 2 | 11.5 | 2 | 2 | 24 | 2 | 2 | 2 | 96 | SINUS | 3 | 1 | 140 | |

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| 75 | ASKARI | 622905H | 60 | 2 | 2 | 2 | 12 | 12.9 | 1 | 1 | 142 | 1 | 2 | 2 | 100 | SINUS | 1 | 1 | 130 | |
| 76 | SELVARAJ | 624198H | 79 | 1 | 1 | 2 | 14 | 12 | 1 | 1 | 200 | 1 | 1 | 1 | 92 | SINUS | 3 | 3 | 160 | |
| 77 | TAHIR | 738183G | 57 | 1 | 2 | 2 | 4 | 8.2 | 2 | 2 | 8 | 2 | 2 | 2 | 94 | SINUS | 3 | 3 | 120 | |
| 78 | HEMLATH | 488815H | 54 | 2 | 2 | 2 | 10 | 10.4 | 1 | 1 | 120 | 1 | 2 | 2 | 102 | SINUS TAC | 3 | 3 | 134 | 1 |
| 79 | GEETHA | 297831D | 56 | 2 | 2 | 2 | 10 | 6.9 | 2 | 2 | 11 | 2 | 2 | 2 | 70 | SINUS | 3 | 3 | 140 | |
| 80 | RADHA | 675056C | 58 | 2 | 2 | 2 | 8 | 6.6 | 2 | 2 | 19 | 2 | 2 | 2 | 76 | SINUS | 1 | 3 | 140 | 1 |
| 81 | LAKSHMI | 515247H | 63 | 2 | 2 | 2 | 6 | 9 | 2 | 2 | 8 | 2 | 2 | 2 | 84 | SINUS | 3 | 1 | 104 | |
| 82 | KARUNAN | 392614H | 45 | 1 | 1 | 2 | 2 | 10.5 | 2 | 2 | 20 | 2 | 2 | 2 | 90 | SINUS | 3 | 3 | 100 | 4 |
| 83 | TAMILARA | 583570H | 64 | 2 | 2 | 2 | 10 | 8.6 | 2 | 2 | 7 | 2 | 2 | 2 | 90 | SINUS | 3 | 3 | 142 | |
| 84 | ANNADUF | 755141H | 42 | 1 | 2 | 2 | 2 | 7 | 2 | 2 | 24 | 2 | 2 | 2 | 78 | SINUS | 3 | 3 | 134 | |
| 85 | NIRANJAN | 527331G | 59 | 1 | 1 | 2 | 10 | 9.7 | 1 | 1 | 47 | 1 | 2 | 2 | 110 | SINUS TAC | 3 | 3 | 110 | 1 |
| 86 | BARNABA | 093713H | 51 | 1 | 2 | 2 | 10 | 8 | 1 | 1 | 54 | 1 | 2 | 2 | 82 | SINUS | 3 | 3 | 140 | |
| 87 | PRAKASH | 653508H | 54 | 1 | 1 | 1 | 12 | 9.5 | 2 | 2 | 150 | 1 | 2 | 2 | 78 | SINUS | 3 | 3 | 130 | |
| 88 | SONA | 427577H | 62 | 2 | 1 | 1 | 10 | 8.4 | 2 | 2 | 8 | 2 | 2 | 2 | 94 | SINUS | 3 | 3 | 138 | |
| 89 | KATHIRAN | 244305B | 52 | 1 | 1 | 2 | 4 | 7.5 | 2 | 2 | 10 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 164 | |
| 90 | SANGEETH | 670234F | 43 | 2 | 2 | 2 | 2 | 7 | 2 | 2 | 8 | 2 | 2 | 2 | 110 | SINUS TAC | 3 | 3 | 110 | |
| 91 | LOGANAT | 415977D | 63 | 1 | 2 | 2 | 8 | 6.9 | 2 | 2 | 24 | 2 | 2 | 2 | 80 | SINUS | 3 | 3 | 150 | |
| 92 | PARATHA | 130665H | 56 | 1 | 1 | 2 | 8 | 7.3 | 2 | 2 | 24 | 2 | 2 | 2 | 70 | SINUS | 3 | 3 | 140 | |
| 93 | MALATHI | 166276H | 59 | 2 | 2 | 2 | 8 | 7.1 | 2 | 2 | 3 | 2 | 2 | 2 | 90 | SINUS | 3 | 3 | 136 | |
| 94 | SAKUNTH | 023772G | 55 | 2 | 2 | 2 | 8 | 7.4 | 2 | 2 | 24 | 2 | 2 | 2 | 100 | SINUS | 3 | 3 | 110 | 1 |
| 95 | AMAL | 478321A | 69 | 1 | 1 | 1 | 6 | 7.8 | 2 | 2 | 9 | 2 | 2 | 2 | 110 | SINUS TAC | 1 | 3 | 120 | 1 |
| 96 | CHELLADU | R559064 | 41 | 1 | 2 | 2 | 14 | 12.3 | 1 | 1 | 210 | 1 | 2 | 2 | 92 | SINUS | 1 | 3 | 130 | |
| 97 | SAMUEL | 323787G | 67 | 1 | 2 | 2 | 10 | 11.5 | 1 | 1 | 35 | 1 | 2 | 2 | 78 | SINUS | 3 | 3 | 170 | |
| 98 | NAGARAJ | 382812A | 67 | 1 | 1 | 2 | 12 | 7.6 | 1 | 1 | 92 | 1 | 2 | 2 | 84 | SINUS | 1 | 3 | 154 | |
| 99 | RAJENDRA | 662326H | 57 | 1 | 1 | 1 | 12 | 8.3 | 1 | 1 | 86 | 1 | 2 | 2 | 62 | SINUS | 3 | 3 | 172 | 1 |

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| 101 | RAVI | 553420H | 55 | 1 | 2 | 2 | 8 | 7 | 2 | 2 | 24 | 2 | 2 | 2 | 100 | SINUS | 1 | 3 | 140 |
| 102 | SWAPAN | 605732B | 62 | 1 | 2 | 1 | 8 | 6.6 | 2 | 2 | 3 | 2 | 2 | 2 | 80 | SINUS | 1 | 3 | 146 |
| 103 | BALAJI | 335309C | 56 | 1 | 1 | 2 | 12 | 6.5 | 1 | 1 | 179 | 1 | 2 | 2 | 100 | SINUS | 1 | 3 | 150 |
| 104 | CHITRA | 041617A | 47 | 2 | 2 | 2 | 6 | 7.1 | 2 | 2 | 11 | 2 | 2 | 2 | 90 | SINUS | 3 | 3 | 130 |
| 105 | ASHOK | 854799D | 48 | 1 | 1 | 2 | 4 | 7.2 | 2 | 2 | 5 | 2 | 2 | 2 | 88 | SINUS | 3 | 3 | 150 |
| 106 | SANTANU | 576440H | 46 | 2 | 1 | 2 | 4 | 9.2 | 2 | 2 | 11 | 2 | 2 | 2 | 90 | SINUS | 1 | 3 | 160 |
| 107 | MURUGES | 224727H | 48 | 1 | 1 | 1 | 4 | 7.5 | 2 | 2 | 10 | 2 | 2 | 2 | 102 | SINUS | 3 | 3 | 132 |
| 108 | RAVICHAI | 652794H | 55 | 1 | 2 | 2 | 6 | 6.2 | 2 | 2 | 24 | 2 | 2 | 2 | 84 | SINUS | 3 | 3 | 150 |
| 109 | RUKMANI | 672595H | 69 | 2 | 2 | 2 | 14 | 8.4 | 1 | 1 | 140 | 1 | 2 | 2 | 82 | SINUS | 1 | 3 | 140 |
| 110 | VENKATE | 915669D | 51 | 1 | 1 | 2 | 6 | 7 | 2 | 2 | 24 | 2 | 2 | 2 | 110 | SINUS TAC | 3 | 3 | 130 |
| 111 | MD SHAUI | 673433H | 57 | 1 | 2 | 2 | 8 | 8.5 | 2 | 2 | 11 | 2 | 2 | 2 | 98 | SINUS | 1 | 3 | 150 |
| 112 | PERUMAL | 134996G | 57 | 1 | 1 | 1 | 12 | 8 | 1 | 1 | 50 | 2 | 2 | 2 | 80 | SINUS | 3 | 3 | 140 |
| 113 | SYED | 673433H | 57 | 1 | 1 | 2 | 10 | 8.5 | 2 | 2 | 11 | 2 | 2 | 2 | 98 | SINUS | 1 | 3 | 154 |
| 114 | RAZIA | 404201D | 58 | 2 | 2 | 2 | 12 | 9.1 | 1 | 1 | 110 | 1 | 2 | 2 | 80 | SINUS | 1 | 3 | 104 |
| 115 | DHARMA | 549455A | 64 | 1 | 2 | 2 | 14 | 6.2 | 1 | 1 | 77 | 1 | 2 | 2 | 96 | SINUS | 1 | 3 | 160 |
| 116 | SAROJA | 614883 | 69 | 2 | 2 | 2 | 20 | 7.8 | 1 | 2 | 7 | 2 | 2 | 2 | 64 | SINUS | 3 | 3 | 130 |
| 117 | SHANTHI | 621220H | 46 | 2 | 2 | 2 | 8 | 10.2 | 1 | 1 | 150 | 1 | 2 | 2 | 120 | SINUS | 3 | 3 | 140 |
| 118 | SEKAR | 951630C | 63 | 1 | 1 | 2 | 15 | 10 | 1 | 1 | 160 | 1 | 2 | 2 | 84 | SINUS | 3 | 3 | 130 |
| 119 | PUNITHA | 667496A | 53 | 2 | 2 | 2 | 7 | 7.1 | 2 | 2 | 12 | 2 | 2 | 2 | 76 | SINUS | 3 | 3 | 130 |
| 120 | ANNAMA | 131532C | 68 | 2 | 2 | 2 | 20 | 6.9 | 1 | 1 | 237 | 1 | 2 | 2 | 120 | SINUS TAC | 3 | 1 | 122 |
| 121 | SOHAIL | 624372H | 41 | 1 | 1 | 2 | 6 | 10.5 | 1 | 1 | 120 | 1 | 2 | 2 | 84 | SINUS | 3 | 3 | 140 |
| 122 | TAHIRA | 798900 | 60 | 2 | 2 | 2 | 12 | 9.7 | 1 | 1 | 70 | 1 | 2 | 2 | 80 | SINUS | 3 | 3 | 140 |
| 123 | VELAN | 202086G | 50 | 1 | 1 | 1 | 8 | 9.1 | 2 | 2 | 24 | 2 | 2 | 2 | 92 | SINUS | 1 | 3 | 108 |
| 124 | GANDIMA | 755261G | 53 | 2 | 2 | 2 | 8 | 8.2 | 1 | 1 | 100 | 1 | 2 | 2 | 92 | SINUS | 3 | 3 | 148 |

# ANNEXURE 6: ABSTRACT


## BACKGROUND:

Diabetes mellitus is an important metabolic disorder that can affect nearly every organ system in the body. In India, it is estimated that the prevalence of diabetes is likely to go up to 57.2 million by the year 2025. Cardiac dysfunction and silent MI are major life threatening complications in diabetes so we aim to determine the electrocardiographic features in patients with asymptomatic diabetes mellitus and determine the utility of poor R wave progression in predicting cardiac function.

**TITLE OF THE ABSTRACT:**

To determine the electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and utility of poor R wave progression in predicting cardiac function.

**DEPARTMENT** : General Medicine

**NAME OF THE CANDIDATE** : Shobhit Priyanshu Joseph

**DEGREE AND SUBJECT** : M.D. General Medicine

**NAME OF THE GUIDE** : Dr. Ramya Iyadurai

**OBJECTIVES:** To determine the electrocardiographic features in patients with diabetes mellitus who are asymptomatic for cardiac disease and to determine the utility of poor R wave progression in predicting cardiac function.

**DESIGN:** Prospective observational study.

**SETTING:** General Medicine and Diabetic OPD at Christian Medical College, Hospital Vellore.

**PATIENTS:** 125 diabetics who are asymptomatic for cardiac disease and fulfilled the inclusion criteria.

## METHODS:

This was a prospective observational study which was done between June 2018 and June 2019. Once patients were identified, they were given the Information sheet, following which written informed consent was obtained. All study data were collected by the principal investigator. The participants of the study or their bystanders were interviewed and data were collected. Demographic data including age, sex, occupation, and BMI were obtained. The ECG was performed for all the participants, the ECG features and parameters such as gender, age, coexistent micro- macro vascular complications and duration of type 1 and 2 diabetes mellitus was analysed. An Echocardiography for patient with poor R wave progression was done to look for cardiac function by ejection fraction and it was compared with the participants without poor R wave progression of similar baseline characterstics.

## RESULTS:

In this study 19.2% of the diabetics who were asymptomatic for cardiac disease had normal ECG and 80.8% had ECG changes. The most common ECG changes were – Resting sinus tachycardia – 6.4%, Left ventricular hypertrophy – 13.6%, Left atrial enlargement – 5.6%, ST-T changes – 12%, QTc prolongation or QTc dispersion – 11.2% and Poor R wave progression (PRWP)– 13.6%. PRWP was seen in 13.6% of asymptomatic diabetics.

The duration of diabetes was more in patients with PRWP- Mean - 10.82 years than with no PRWP- Mean- 8.25 years. The difference among the means were 3.73 with 95% confidence interval difference of the difference being 1.47 – 5.89, p- value was 0.006. Hence, in our study the duration of diabetes was an independent predictor of the PRWP in asymptomatic diabetics. 11 out of 17- 64.7% of the patients with diabetic neuropathy had PRWP, with the relative risk of 2.75, p- value of 0.027. Hence, diabetic neuropathy was an independent predictor of PRWP in diabetics asymptomatic diabetics. Also 7 (41.17%) out of 17 patients who had PRWP on ECG had heart failure on the 2-D ECHO, p-value - 0.015. Hence, PRWP was an independent predictor of heart failure in diabetics asymptomatic diabetics and showed a strong association.

## CONCLUSION:

Diabetes mellitus is a disease with significant mobidity and mortality because of the underlying microvascular and macrovascular complications. But appropriate early screening and diagnostic tests can prevent the progression of the complications.

12-lead Electrocardiogram is an important tool in both diagnostic and the researcher pursuit as a detection and screening tool of myocardial injury. Certain ECG features like sinus tachycardia, LVH, LAD, QTc prolongation, ST-T changes, Left atrial enlargement and PRWP can be seen in diabetics asymptomatic for cardiac disease which appear early in the ongoing pathology of the myocardial injury.

Duration of diabetes and diabetic neuropathy are an independent predictor of PRWP on ECG in diabetics asymptomatic for cardiac disease. PRWP is independent predictor of heart failure in diabetics asymptomatic for cardiac disease.