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Role of Treadmill testing (TMT) in Type Two diabetic Patients in Kirkuk - A Prospective Clinical Study

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Abstract

Coronary artery disease is the common impact of death worldwide in type 2 Diabetes mellitus. High rate of asymptomatic coronary heart disease in type 2 DM. Stress testing, and subsequent intervention, might reduce patients' risk of cardiovascular morbidity and mortality. Hence a prospective study conducted during the period 2016-2017We studied the prevalence of silent myocardial ischemia (SMI) in asymptomatic type 2 diabetes mellitus by using treadmill test. Further analysis was performed using binary logistic regression for the predictors of positive TMT findings in DM patients in this study, the duration of DM was the stronger significant predictor of positive TMT, [odds ratio (OR = 2.79), P = 0.002], patients with longer duration of DM were about 2.8-fold more likely to have positive TMT findings. Being old age diabetic male patient increase the risk of having positive TMT by almost 1.82 folds (OR = 1.82, P = 0.023), other were higher level of Triglycerides (OR = 1.68), larger BMI (OR = 1.44), and male gender (OR = 1.33). In conclusion, the current study documented that a significant proportion of type two diabetes mellitus patients had silent myocardial Ischemia detected by treadmill testing which showed an important role in detecting the silent myocardial ischemia older age, male gender, longer duration of diabetes, large body mass index and elevated triglycerides levels are significant predictors of silent myocardial ischemia in diabetic patients.

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Keywords

Type two Diabetes Mellitus, Cardiovascular diseases, Silent myocardial Ischemia

Introduction

Diabetes Mellitus (DM) is a disordered metabolic syndrome with hyperglycemia either due to defectin insulin secretion or insulin resistance. It may cause progressive tissue damage and both micro and macrovascular complications. More than 95% of diabetes are type 2 DM. They always had insidious, latent, along with asymptomatic phase. Therefore management of DM has changed not only controlling symptoms but also preventing complications (Swaminathan and Gayathri 2016).

It is estimated that 9% of adults or 347 million people worldwide have diabetes mellitus, and cardiovascular disease including coronary artery disease (CAD), stroke, peripheral arterial disease, heart failure, and cardiomyopathy is estimated to account for between 50% and 80% of deaths in diabetics. Diabetes mellitus has been designated as a cardiovascular disease risk equivalent for both lipid and hypertension treatment goals and risk factor modification is recommended in all diabetics. Nevertheless, as the number of diabetics is expected to grow, total deaths from diabetes mellitus are projected to increase by >50% in 10 years. CAD tends to be more severe and to occur at an earlier age in diabetics. In patients with diabetes mellitus and known CAD, the risk for future events is particularly high. Considering the magnitude of the problem of diabetes mellitus–related cardiovascular disease, stress testing of diabetics with known or suspected CAD would seem a reasonable approach to guide therapy, including intensive medical therapy and coronary revascularization. Stress testing, and subsequent intervention, might reduce patients' risk of cardiovascular morbidity and mortality.

A substantial percentage of patients with T2DM have silent myocardial ischemia (SMI) (Upchurch and Barrett 2012),

Silent Ischemia

Silent ischaemia is a common, under-recognised condition that is associated with an adverse prognosis. It is a marker of significant underlying coronary artery disease and therefore of future cardio- vascular events. It is more prevalent in the diabetic popu- lation and diagnosis is usually made by a positive exercise tolerance test, positive myocardial perfusion scan or stress echo. Among patients with known CAD the prevalence of silent ischaemia is quite high. It has been reported that 15–30% of MI survivors have silent ischaemia, as do 30–40% of patients with unstable angina despite optimal medical therapy.1,7 In patients with stable angina, it is estimated that up to two thirds of ischaemic episodes are silent.(Albers, Krichavsky, and Balady 2006; Dweck *et al.*, 2009; Lee, Fearon, and Froelicher 2001)

Individuals with SMI are at greater risk for cardiovascular events and SMI is two- to fourfold more frequent in type 2 diabetic patients as compared with the non-diabetic population(Cosson *et al.*, 2011; Mokdad *et al.*, 2003). On the other hand, SMI has been reported in 10–65% of the diabetic population and is a strong predictor for incident coronary events and premature death (Cosson *et al.*, 2003, 2011; Young *et al.*, 2009) especially when it is associated with silent CAD (Cosson *et al.*, 2011). Routine screening of type 2 diabetics for asymptomatic coronary artery disease with ECG remains controversial, as majority of them present with normal ECG(American Diabetes Association 2010). However, progressive coronary artery disease remains asymptomatic in many cases of type 2 diabetes and this makes diagnosis difficult at proper time Many studies have been published showing relationship between DM and silent ischemia(Lavekar and Salkar 2013). Additionally, screening asymptomaticT2DMpatients with myocardial perfusion imaging may produce a significant number of high-risk scans (Cosson *et al.*, 2011; Kumar 2014; Lavekar and Salkar 2013; Upchurch and Barrett 2012). One retrospective study suggested that some of these scans will uncover patients with angiographic findings that merit surgical revascularization (left main, three-vessel, and/or proximal left anterior descending) (Rajagopalan *et al.*, 2005), possibly leading to better survival with coronary artery bypass grafting (CABG) over medical therapy. In either scenario, screening could potentially prevent cardiac outcomes by intervening before a first event (Sorajja *et al.*, 2005).

The interest is to determine the proportion of silent ischemia in patients having type 2 DM, who are asymptomatic for CAD and have normal resting ECG and 2D Echo using Treadmill Test (TMT). Moreover, to determine the predictors of silent ischemia in the population who underwent TMT (Lavekar and Salkar 2013). Therefore, knowledge of silent coronary disease may allow one to more accurately predict risk and possibly implement more aggressive risk reduction.

Prognosis

Silent ischaemia is associated with an adverse clinical outcome across a range of patient groups. The MrFIT trial of 12,866 asymptomatic diabetic and non-diabetic men with two or more risk factors showed a significant relationship between silent ischaemia and mortality (Dweck *et al.*, 2009; Rutter *et al.*, 2002)

Silent ischaemia appears to be an especially important prognostic factor in patients with diabetes. Silent ischaemia was significantly related to future coronary events in asymptomatic diabetic patients after 2.8 years (risk ratio of 21; 95% cI 2 to 204). The combination of silent ischaemia and microalbuminuria identified a particularly high-risk group(Rutter *et al.*, 2002).

Cardiac stress test

A cardiac stress test (also referred to as a cardiac diagnostic test, cardiopulmonary exercise test, or abbreviated CPX test) is a cardio-logical test that measures the heart's ability to respond to external stress in a controlled clinical environment. The stress response is induced by exercise on a treadmill, or by intravenous pharmacological stimulation, with the patient connected to an electrocardiogram (ECG). People who cannot use their legs may exercise with a bicycle-like crank that they turn with their arms(Lavekar and Salkar 2013; Lee *et al.,* 2001). Cardiac stress tests compare the coronary circulation while the patient is at rest with the same patient's circulation during maximum physical exertion, showing any abnormal blood flow to the myocardium (heart muscle tissue). The results can be interpreted as a reflection on the general physical condition of the test patient. This test can be used to diagnose coronary artery disease (also known as ischemic heart disease) and assess patient prognosis after a myocardial infarction (heart attack).(Albers *et al.,* 2006; Hage *et al.,* 2013; Singh, Sharma, and Singh 2002).

Treadmill testing using Bruce protocol is the most commonly performed form of exercise ECG. As with all tests, the posttest probability of coronary disease is dependent on the accuracy of the test and the pre-test probability of the disease. Since the asymptomatic patients never underwent angiography, an observational approach analysis puts the positive predictive value of the test between 25-72%

The predictive value of this test is influenced not only by ST-segment response but other non- ECG variables also (Singh *et al.,* 2002). These factors are as follow

T-segment response

Previous studies have replaced or supplanted the use of greater than 0.1 mV ST-segment depression with the ST-integeral and the ST\HR slope. The latter is thought to be better predictor of outcome. It iscalculated by dividing the difference of ST depression at rest and peak of exercise by exercise induced increase in heart rate(Singh *et al.,* 2002)

Exercise capacity

Patients who develop ST- depression at lower level of work load have a higher risk of subsequent events.(Singh *et al.,* 2002)

Risk factors for CAD

Patients with more risk factors tend to have more true positive results and vice versa.

Stress imaging tests

The study of Blumenthal *et al.,* showed that addition of an imaging modality e.g. thallium imaging to exercise ECG substantially increased its predictive value.(Hage *et al.,* 2013; Singh *et al.,* 2002)

Indications for Stress Testing

Evaluation of patients with a high likelihood of coronary artery disease (CAD) (Cardiovascular imageing Center 2017)

Angina

Arrhythmia (e.g., patients presenting with ventricular tachycardia, ventricular fibrillation)

Syncope

Heart failure, including pulmonary edema

Arrhythmias in patients with exercise-induced presyncope or syncope

Significant vascular obstructive disease indicative of co-existence of occult coronary artery disease (e.g., carotid obstructive disease, peripheral vascular disease involving the lower extremities, abdominal aortic aneurysm)

Evaluation of the prognosis and severity of disease (Cardiovascular imageing Center 2017)

Known CADi. Prior to major surgery for evaluation of risk of anesthesia and surgical interventionii. When the patient's individual clinical situation indicates there is high likelihood of progression of disease requiring changes in treatment

Stable Angina-As an initial evaluation of drug management

Post-MI-The post-MI evaluation is limited by the severity of the disease

Post-PTCA-The use of stress testing may be required when the patient is symptomatic after restenosis. This is typically within a six month period. After six months, symptoms are not typically considered in the post-PTCA period. This would be considered a new episode of illness.

Post-CABG-The use of stress testing may be required when the patient is symptomatic, if the patient has had a previous "silent" (asymptomatic) ischemic event or to evaluate the rehab plan for the patient.

Evaluation of functional capacity

Valvular heart disease

Cardiomyopathy

Status post intervention or drug change in patient with known CAD (Cardiovascular imageing Center 2017).

Treadmill testing in diabetic patients

Progressive Coronary Artery Disease (CAD) remains asymptomatic in many cases of type 2 diabetes mellitus (DM) and this makes diagnosis difficult. Routine screening of type 2 DM for silent ischemia with electrocardiography (ECG) remains controversial as majority of patients present with normal ECG. Stress treadmill test is a readily available, cost effective, first line test for identification of coronary heart disease in DM of longer duration without any symptoms of angina.(Lavekar and Salkar 2013; Lee *et al.*, 2001; Swaminathan and Gayathri 2016).American Diabetic Association recommends use of TMT and coronary arterial angiography for diagnosis of silent ischemia that is useful initial diagnostic test in patients with an intermediate pretest probability (25%–75%) of coronary artery disease. It is cheaper, relatively safe, widely and easily available noninvasive diagnostic test which act as an important. Moreover, previous studies referred that exercise TMT remains a well-established, inexpensive test (GK, Rahman, and Patil 2016)available to assist clinicians in the diagnosis and prognosis of CAD in diabetic patients. It appears to have similar diagnostic sensitivity (50%) and specificity (80%)(Albers *et al.*, 2006; Kumar 2014) for diabetic patients presenting with angina as for non-diabetic patients. It can identify a subgroup of asymptomatic diabetic patients who have significant CAD as defined by angiography, and in lower-risk diabetic cohorts, it may offer short- term prognostic reassurance to those asymptomatic patients with negative tests. However, considerable prognostic power of the exercise ECG test lies beyond the ST-segment response(Albers *et al.*, 2006; Kumar 2014; Singh *et al.*, 2002; Upchurch and Barrett 2012).

Patients and Methods

This was a prospective study conducted during the period 2016-2017, included 58 patients with type 2 diabetic patients without established clinical diagnosis of coronary artery disease attending medicine department, during the study period. Patients were informed about the nature and design of the study and they are free to participate or not and that their participation or non-participation will not influence their management protocol. Then patients consents were obtained from those who agreed to participate and enrolled in the study, additionally, all official agreements were obtained from Kirkuk general hospital and the Central Kirkuk health directorate.

All patients were assessed for detailed history of presenting complaints with emphasis on cardiac symptoms analysis, past medical history, duration of diabetes and treatment history.

A complete physical examination with a detailed cardiovascular assessment in addition to full routine lab investigations were performed.

Investigations included complete blood count, renal function test, Liver function test, blood glucose, lipid profile, cardiac markers, chest X-ray, echocardiography, resting 12 lead electrocardiogram and electrocardiogram J. TMT Test (looking for ST segment changes during maximum exercise, ST segment changes at 6 min recovery, arrhythmia during TMT test, arrhythmia at 6 min recovery period, pulse rate and blood pressure record during exercise test.

Patients enrolled in the study were all type 2diabetic outpatients of both genders aged 35 – 60 years and were asymptomatic with normal resting ECG

Patient was excluded from the study if he/she had one or more of the following; previous history of MI, heart failure, Suspected of angina angina pectoris based on the symptoms, anaemia, hypertension, renal disease, ECG evidence of Q wave MI, ischemic ST–segment or T wave abnormality or complete lower bundle branch block (LBBB), cancer, End stage renal diseases or liver disease.

The patients were educated about the test and the importance of test for them. The patients were also made aware of the risks involved with the test. Written consent of the patients for performing the test and their participation in study were obtained

Technique of treadmill test

The patient was instructed not to eat or drink caffeinated beverages three hours prior to testing and to wear comfortable shoes and loose fitting clothes. A brief physical examination was performed prior to the test and a written informed consent was taken. A standard 12 lead electrocardiogram was taken following which a torso ECG was obtained in the supine position and in the sitting or standing position. Blood pressure was recorded in both positions and the patient was instructed on how to perform the test. Standard multistage maximal exercise test was done on a motorised treadmill according to Bruce protocol. The heart rate, blood pressure and electrocardiograms were recorded at the end of each stage of exercise, immediately before and after stopping the exercise and for each minute for at least 5 to 10 minutes in the recovery phase. Exercise test was terminated in all patients following the achievement of target heart rate or an abnormal ischemic response. This was defined as development of 0. 10 mV (1 mm) of J point depression measured from the PQ junction, with a relatively flat ST segment slope (<lmV/sec), depressed ≥ 0.10 mV 60 to 80msec after the J point in three consecutive beats with a stable baseline. Exercise test was also terminated if patient developed dyspnea, fatigue or chest pain.

Statistical analysis was performed with the aid of the statistical package for social sciences version 24, appropriate statistical tests and procedures were applied according to the types of parameters, level of significance was set at 0.05.

Results and Discussion

The study included 58 patients with a mean age of 48.6 years, males were 72.4%, the mean duration of diabetes was 6.8 years, ranged 1 – 20 years, and almost half of the patients had their disease since five years or less (Figure 1). Majority of patients, 84.5%, were on oral hypoglycemic while 9 patients controlled their DM by diet management. Family history of DM was positive in 62.1%, BMI was normal in 50% of the patients, overweight were 32.8% and 17.2 of the patients were obese (*Table 1*). The clinical and laboratory parameters of the studied group are summarized in (*Table 2*).

Treadmill testing revealed that 15 patients (25.9%) had positive findings, (Figure 2), indicating a prevalence of silent myocardial ischemia of 25.9% of diabetes patients. Positive TMT findings were significantly associated with advancing age of the patients, male gender, and longer duration of DM, in all comparison, (P<0.05), (*Table 3*). No significant association had been found between positive TMT findings and type of treatment and family history of DM, (*Table 4*). Among the clinical and laboratory findings, the only significant correlation was reported between positive findings of TMT and higher level of triglycerides, (P<0.001), (*Table 5 and Figure 3*).Interestingly, patients with positive TMT findings had lower BMI than those with negative findings, (P<0.05), (*Figure 4*).

Further analysis was performed using binary logistic regression for the predictors of positive TMT findings in DM patients in this study, results of this analysis are shown in (*Table 6*), where the duration of DM was the stronger significant predictor of positive TMT, [odds ratio (OR = 2.79), P = 0.002], indicated that patients with longer duration of DM were about 2.8-fold more likely to have positive TMT findings. The second predictor was the old age, being old age diabetic increase the risk of having positive TMT by almost 1.82 folds (OR = 1.82, P = 0.023), other predictors in descending sequence were higher level of Triglycerides (OR = 1.68), larger BMI (OR = 1.44), and male gender (OR = 1.33).

Coronary Artery Disease detection in asymptomatic type 2 DM is often delayed. The preponderance of SMI in type 2 DM is variable and ranges from 9to75%. (Cosson *et al.,* 2011; Rajagopalan *et al.,* 2005; Rutter *et al.,* 2002)

The present study found that 25.9% of diabetic patients had positive findings on TMT, indicating a hidden, silent myocardial ischemia, making those patients at higher risk and complications, our findings agreed that reported by Rutter *et al.,* in 2002 Young *et al.,* in 2009 and, and Dweck *et al.,* in 2009, (Dweck *et al.,* 2009; Rutter *et al.,* 2002; Young *et al.,* 2009).

A previous study was conducted by Lavekar and Salkar found that 21.1% of diabetic patients had SMI and they were asymptomatic but diagnosed on 24 hours ambulatory monitoring exercise electrocardiogram (Lavekar and Salkar 2013). On the other hand, predominance of SMI among diabetic patients was approved by other study conducted on diabetic patients and compared to non-diabetic (Kalita and Deka 2016)

Another Indian study was conducted by Sarginetal. In 2005 Reported that 38.3% of DM with no symptomatic prior CAD had SMI on treadmill test (Sargin *et al.,* 2005)

Additionally, higher proportion of SMI among DM patients was reported among Indian, where Ahluwalia *et al.,* found that almost 50% of diabetic patients had SMI on TMT (Ahluwalia *et al.,* 1995)

Table.1 Baseline characteristics of the studied group

Variable	No.	%
Age (year)		
≤ 40	6	10.3
41 - 50	30	51.7
> 50	22	37.9
Mean (SD*)	48.6 (8.2)	
Gender		
Male	42	72.4
Female	16	27.6
Duration of DM		
≤ 5	30	51.7
6 - 10	14	24.1
11 - 15	8	13.8
> 15	6	10.3
Mean (SD*)	6.8 (5.2)	
Type of Treatment		
Diet	9	15.5
OHA	49	84.5
Family history		
Positive	36	62.1
Negative	22	37.9
BMI		
Normal	29	50.0
Overweight	19	32.8
Obese	10	17.2

SD: standard deviation

Table.2 Clinical and laboratory parameters of the studied group

Variable	Mean	SD*	Minimum	Maximum
Pulse	76	6	68	90
SBP	128	4	120	136
DBP	75	5	60	84
FBS	179.14	37.13	125.00	291.00
Cholesterol	180.81	29.30	133.00	234.00
TG	141.33	39.87	80.00	230.00
Urea	29.03	5.39	18.00	40.00
Creatinine	0.81	0.19	0.50	1.30

Table.3 Comparison of TMT findings of the studied group according to age, gender and duration of DM

Variable	TMT positive (n = 15)		TMT negative (n = 43)		P. value
	No.	%	No.	%	
Age					
≤ 40	2	33.3	4	66.7	**0.023**
41 - 50	5	16.7	25	83.3	
> 50	8	36.4	14	63.6	
Gender					
Male	12	28.6	30	71.4	**0.014**
Female	3	18.8	13	81.3	
Duration of DM					
≤ 5	4	13.3	26	86.7	**0.001**
6 - 10	3	21.4	11	78.6	
11 - 15	5	62.5	3	37.5	
> 15	3	50.0	3	50.0	

Table.4 Comparison of TMT findings of the studied group according to family and treatment history

Variable	TMT positive (n = 15)		TMT negative (n = 43)		P. value
	No.	%	No.	%	
Treatment type					
Diet	2	22.2	7	77.8	0.78
OHA	13	26.5	36	73.5	
Family history					
Positive	10	27.8	26	72.2	0.67
Negative	5	22.7	17	77.3	

Table.5 Comparison of TMT findings of the studied group according to Clinical and laboratory findings

Variable	TMT positive (n = 15)		TMT negative (n = 43)		*P. value*
	Mean	SD	Mean	SD	
Pulse	75.9	6.1	76.4	6.2	0.79
SBP	127.9	3.2	128.6	4.7	0.58
DBP	74.3	4.8	75.7	5.2	0.35
FBS	182.14	33.10	170.53	38.35	0.33
Cholesterol	174.40	31.75	183.05	28.45	0.30
TG	176.60	43.83	129.02	30.29	< **0.001**
Urea	29.65	3.45	27.27	5.83	0.14
Creatinine	0.87	0.20	0.81	0.18	0.47

Table.6 Results of Binary logistic regression for the predictors of positive TMT status

Variable	OR	95% CI OR	P. value
Age (older)	**1.82**	1.32 – 4.69	**0.023**
Gender (male)	**1.33**	1.08 – 2.28	**0.041**
Duration of DM (long)	**2.79**	1.64 – 6.13	**0.002**
BMI (larger)	**1.44**	1.12 – 2.85	**0.011**
Triglycerides (elevated)	**1.68**	1.17 – 3.34	**0.008**

Fig.1 Distribution of duration of DM of the studied group

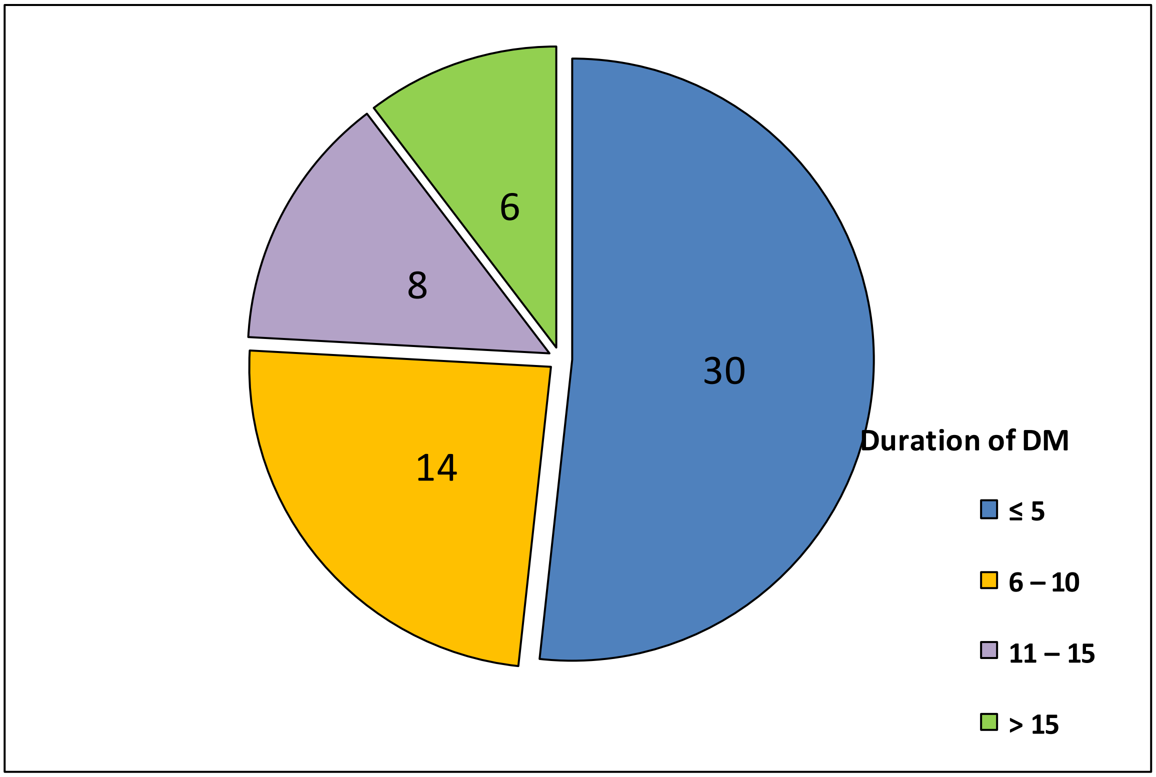


Fig.2 TMT findings of the studied group

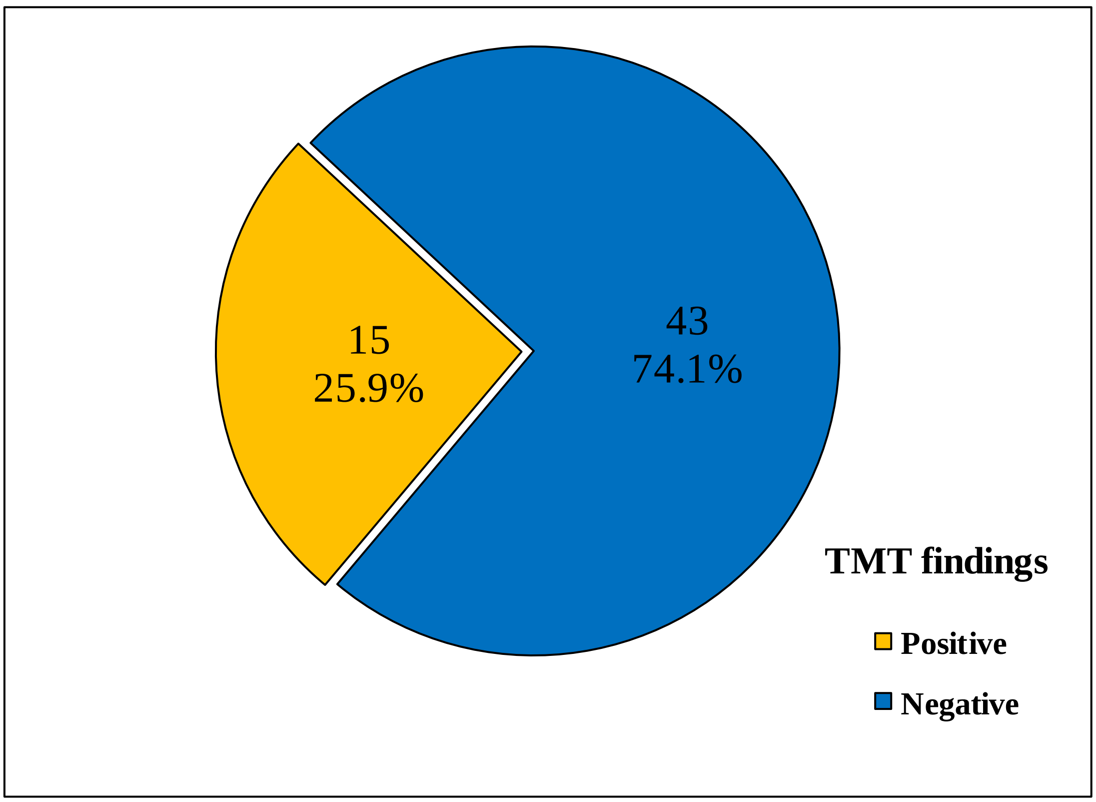


Fig.3 Boxplot of comparison of mean TG across the TMT findings

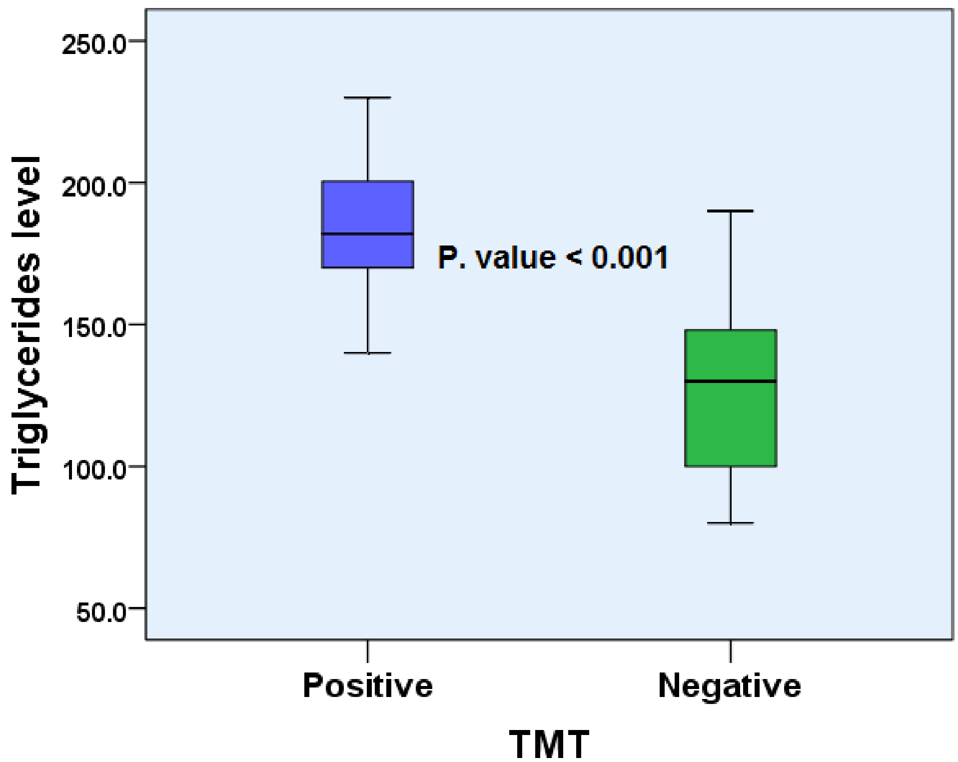
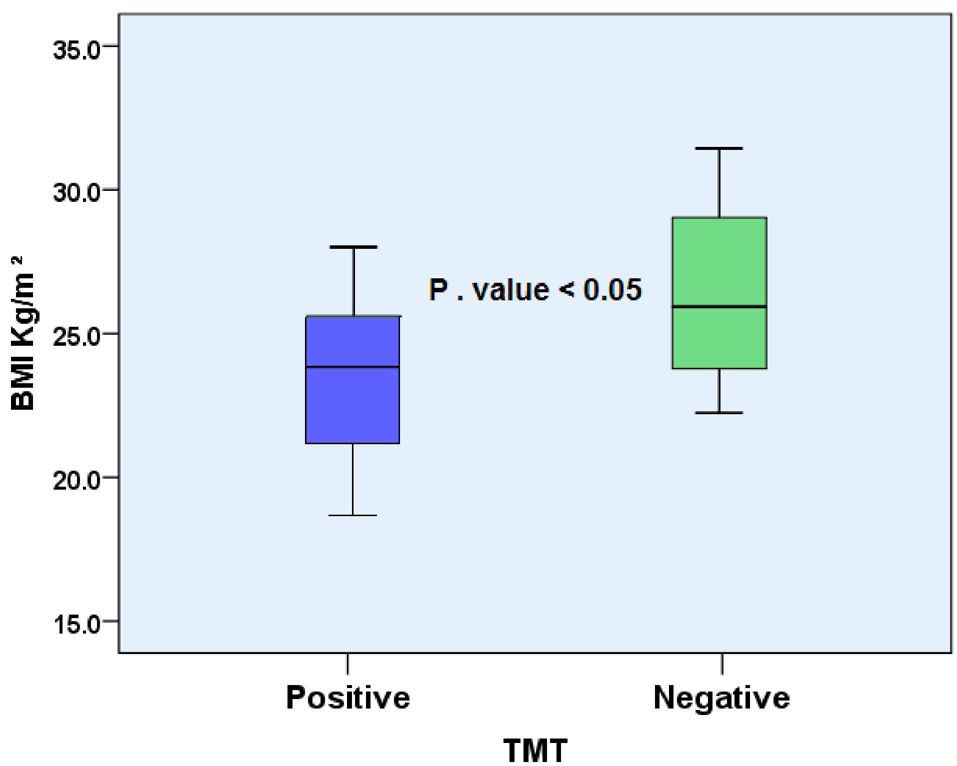


Fig.4 Boxplot of comparison of mean BMI across the TMT findings



Our study findings were close to that documented in a previous larger study on 522 DM patients were 22% found to have SMI on TMT testing. (Quek, Khor, and Ong 1992)

Our findings regarding the proportion of SMI was higher than that reported in a previous study by Gupta and Pandit (Gupta and Pandit 1992)

Our study documented that the abnormalities of exercise test were significantly associated with older age, male gender, larger BMI, higher TG levels and longer duration of DM which appeared as significant predictors of positive TMT findings. In other words, those patients had higher proportions of positive TMT. These findings were not unexpected, and also supported by previous studies that indicated such significant correlations;

Boras *et al.*, suggested that Valsalva (lower Valsalva heart rate ratio), male sex and longer diabetes duration. are strongest predictors for abnormal TMT (Boras *et al.*, 2010)

In fact, the higher prevalence of asymptomatic myocardial ischemia or with atypical symptoms in elderly is explained by increased pain threshold related to nociceptive changes and by the great prevalence of diseases such as depression and diabetes mellitus. Increased beta-endorphins levels have also been described in patients with asymptomatic myocardial ischemia (Ochiai *et al.*, 2014) (Ahmed *et al.*, 2007). On the other hand, differences in results of stress tests between men and women have been the subject of considerable controversy (Ahmed *et al.*, 2007)

Gupta and Pandit found that abnormalities of exercise test were significantly associated with longer duration of DM (Gupta and Pandit 1992)

Ahuwalia study found that triglyceride levels were elevated in 28 treadmill positive cases compared to 15 treadmill negative cases. (Ahluwalia *et al.*, 1995)

Furthermore, Tandon and Bajpai, also reported a significant correlation between incidence of CAD and elevated triglyceride levels (Tandon, Bajpai, and Agarwal 1985)

However, Stevens reported that dyslipidemia is more common in diabetic patients and it is well established as a significant risk factor for CAD among those patients. (Stevens 1993). Moreover, Age, duration of DM and family history of DM / IHD were identified as significant covariates. Total cholesterol, Triglycerides, LDL/HDL, TC/HDL, poor glycemic control, diabetic nephropathy and retinopathy were the key predictors of silent ischemia in patients who underwent TMT (Lavekar and Salkar 2013)

In conclusion, the current study documented that a significant proportion of type two diabetes mellitus patients had silent myocardial Ischemia detected by treadmill testing which showed an important role in detecting the silent myocardial ischemia older age, male gender, longer duration of diabetes, large body mass index and elevated triglycerides levels are significant predictors of silent myocardial ischemia in diabetic patients, hence we suggested to use treadmill testing and to be taken into account as a diagnostic and monitoring tool for the early detection of asymptomatic cardiac abnormalities in diabetic patients and further studies with larger sample size including more parameters, are needed for further assessment of the role of treadmill testing.

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Conflict of interest

Authors declare no conflict of interest

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