THE METABOLIC SYNDROME AND ITS ASSOCIATION WITH MACRO VASCULAR COMPLICATIONS OF DIABETES MELLITUS AMONG WOMEN IN AN URBAN POOR POPULATION: A CROSS SECTIONAL STUDY

A dissertation submitted in partial fulfillment of the rules and regulations for the MD Branch – 1 General Medicine Degree Examination of the Tamil Nadu Dr M.G.R Medical university to be held in April 2013

CERTIFICATE:

This is to certify that the dissertation entitled " The Metabolic Syndrome and its association with macro vascular complications of Diabetes Mellitus among women in an urban poor population" is the original work of Dr Roshine Mary Koshy towards the M.D Branch 1 General Medicine Degree Examination of The Tamil Nadu Dr M.G.R Medical University, Chennai to be held in April, 2013.

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ACKNOWLEDGEMENTS

I would like to acknowledge my guide, Dr O C Abraham and my co guides Dr Sushil Mathew and Dr Venkatesan for their support, suggestions and encouragement throughout my work on this dissertation.

I would also like to thank Dr Nihal Thomas for his keen interest and helpful suggestions during the IRB meeting.

I would like to acknowledge the doctors and nursing staff of the Low Cost Effective Care Unit for their co operation while patients were being enrolled in their Out Patient Department.

I am indebted to the patients I have interviewed, for their time and willingness to be a part of this study.

I would also like to appreciate the efforts of my statistician, Ms Thenmozhi who helped me in analysing my data.

ABSTRACT

Title:

The metabolic syndrome and its association with macro vascular complications of Diabetes Mellitus among women in an urban poor population: A cross sectional study.

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Objectives:

The study aims to assess the association between metabolic syndrome and macrovascular complications of diabetes mellitus among women in an urban poor population.

Methods:

In this cross sectional study, newly or previously diagnosed female diabetic patients above the age of 30 years were recruited to the study from the out patient department of the Low Cost Effective Care Unit, a primary heath centre affiliated to the Christian Medical College and Hospital, catering to the urban poor population of Vellore city. All patients were screened for the metabolic syndrome according to the International Diabetes Federation criteria and evaluated for macrovascular complications of Diabetes Mellitus namely, ischemic stroke, ischemic heart disease and peripheral vascular disease. Data was analysed using Chi square test to determine the association between metabolic syndrome as a risk factor for prevalent macrovascular complications of Diabetes Mellitus.

Results:

75.3% of diabetic patients fulfilled the IDF criteria for the metabolic syndrome. The study showed a trend towards significant association between metabolic syndrome and macrovascular complications of diabetes mellitus with the overall prevalence of macro vascular complications being 60.3 % in diabetics with the metabolic syndrome and 47.4 % in those without the syndrome.(OR: 1.6, 95% CI :0.6 – 4.8 , p = 0.321) These results suggest the possibility of using the metabolic syndrome as a cost effective clinical tool in risk stratification in diabetics to aid in reducing the burden of Diabetes and its macro vascular complications in the urban poor population.

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INTRODUCTION

Developing countries in the Asian subcontinent have witnessed remarkable economic progress in the 21st century. The dynamics of urbanisation has contributed significantly to this growth. However, it has also brought with it further disparities between the rich and the poor, within and between nations.

India has been no stranger to this phenomenon, with the urban population contributing approximately 55% to the nation's GDP. The alarming facts are that the urban population in India is exploding, with estimates that India will have 41% percent of its population living in cities and towns by 2030 from the present level of 28%.And with increased urbanisation comes a steep increase in urban poverty with over 80 million poor people thought to be living in Indian cities and towns.(1) This phenomenon of urbanisation of poverty has great implications on the health of a nation.

The epidemiology of diseases in developing countries like India has dramatically changed over the past decades with chronic diseases like Diabetes mellitus becoming as prevalent as infectious diseases. The International Diabetes Federation ranks India second with an estimated 61.3 million people living with the disease in 2011 with 80 % of people with diabetes mellitus living in low and middle income families.(2)

Observational studies in the last century highlighted that the metabolic risk factors for Diabetes Mellitus and cardiovascular disease overlapped significantly. This led to the conceptualisation of the metabolic syndrome, a syndrome of insulin resistance manifested clinically in the form of abdominal obesity, hyperglycemia, dyslipidemia and hypertension.

Attempts by the International Diabetes Federation to categorise the metabolic syndrome as a separate diagnostic entity in clinical practice was fuelled by recent research showing substantial evidence that the metabolic syndrome could be used as an independent predictor of cardiovascular mortality.

Metabolic syndrome is very common in diabetics as shown by the Third National Health and Nutrition Examination Survey (NHANES III) conducted in US in which 87% of diabetics fulfilled the NCEP ATP III criteria for the metabolic syndrome. (3) In India, the prevalence of the metabolic syndrome among an urban diabetic population was found to be 87.71% in women and 69.33% in men with an overall prevalence of 77.2%.(4)

Several studies have attempted to elucidate the association between metabolic syndrome in the diabetic population and macro vascular complications of diabetes. The Verona Diabetes Complication Study, a prospective study that aimed to analyse this association concluded that the presence of metabolic syndrome independently predicted prevalent CVD (OR 2.01, P = 0.045) and incident CVD (OR 4.89, P = 0.031).(5)

With the incidence of diabetes in India reaching epidemic proportions and urbanisation of poverty becoming a reality in our country widening the gap between the rich and the poor, the epidemiology of chronic diseases like diabetes in India among the urban poor is a public health issue that needs to be addressed urgently.

With the urban poor bearing the burden of diabetes and its dreaded complications, the use of the metabolic syndrome as an independent predictor of macro vascular complications in the diabetic population would find clinical utility in identifying diabetics with this syndrome so that effective treatment strategies can be instituted early and efficiently. This would have a great bearing on the health statistics of the urban poor and the country's economy and growth as a whole.

This cross sectional study aims to evaluate the association between the metabolic syndrome and macrovascular complications of Diabetes Mellitus in female diabetic patients belonging to the urban poor population of Vellore city in Tamil Nadu.

REVIEW OF LITERATURE

1. DIABETES MELLITUS: MAGNITUDE AND BURDEN

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DIABETES MELLITUS : MAGNITUDE AND BURDEN

Diabetes is one of the most common non communicable disease globally and a challenging health issue in the 21st century.

The global burden of Diabetes Mellitus in the year 2011 is estimated to be 366 million, approximately 8.3% of the world population and is expected to reach 552 million, 9.9 % of the world's population by the year 2030.

Epidemiological studies have shown that one in five adult diabetics live in the south East Asian region. (2) Research in the epidemiology of Diabetes in the South East Asian population has suggested an increased predisposition for the disease in this population explaining the rapid increase in prevalence of diabetes in this region over the last two decades.(6)

India stands second with an estimated 61.3 million people living with the disease in 2011 with projected rates of 101.2 million by the year 2030.(2)

Alarming health statistics from the International Diabetes Federation show that 80 % of people with diabetes mellitus live in low and middle income families. (2) This adds on to the burden of the disease in a developing country like India where the rural urban divide is stark.

There is little systematic representative data on the prevalence of diabetes in the Indian population in the pre independence era. The first multi centric study conducted by the ICMR between 1972 and 1975 in those above 40 years of age found the

prevalence of diabetes mellitus to be 5% in urban and 2.8% in rural areas. The National Urban Diabetes Survey (NUDS) was a population based study conducted in 2001 on subjects over 20 yrs of age which recorded the age standardised prevalence of type 2 diabetes to be 12.1%, with the prevalence being the highest in Hyderabad (16.6%), followed by Chennai (13.5%), Bengaluru (12.4%), Kolkatta (11.7%), New Delhi (11.6%) and Mumbai (9.3%).(7) The PODIS Study (The Prevalence Of Diabetes In India Study) was a recent multistage cross-sectional population survey of adults in India in 2004 which recorded the standardized prevalence rates for DM in the total Indian population to be 4.3% with differences in prevalence rates in the urban and rural populations being 5.9% and 2.7% respectively.(8)

The first study to be conducted in south India was a hospital based retrospective study in Christian College and Hospital Vellore in 1964 which showed a prevalence of 2.5% in hospitalised patients.(9)

Subsequent population studies have shown that the prevalence varies between 0.7% in Pondicherry to 19.5% in Kochi in urban areas.

The Chennai Urban Rural Epidemiology Study (CURES) is unique in having data available for comparison of prevalence rates of diabetes in Chennai with earlier studies using the same methodology. The CURES study, by recording a 72.3% increase in the prevalence of diabetes in Chennai within a 14 year time frame highlighted the epidemic proportion of the disease.(10)

THE URBAN POOR POPUALTION:

URBANISATION OF POVERTY:

The past century has witnessed great economic growth in the developing countries but has brought along with it stark disparities within developing nations. There are predictions of the urban population in Asia and African continents doubling in a period of 30 years and of an increasing rich poor divide.

The urban Indian population is increasing at an alarming rate with estimates that India will have 41% percent of its population living in cities and towns by 2030 AD from the present level of 28%.(1) Urbanisation has paramount influence on the country's economy with the urban population contributing to over 55 % to the country's GDP.

The paradox of the contribution of urbanisation to the economy lies in the fact that with India becoming urban, so also there is an increase in urban poverty. Latest survey reports suggest that there are over 80 million poor people living in the cities and towns of India.

An interesting observation has been that the ratio of urban poverty in some of the larger states is higher than that of rural poverty leading to the phenomenon of 'Urbanisation of Poverty'.(1)

Statistics in the' India Urban Poverty report' which analysed health services in the urban population show that the wealthiest 20% of the population received about 25%

of the actual government health spending while the poorest 20% received only 15%.(1) The identity of the urban poor population is created by multiple factors. Lack of access to formal land market force the urban poor to live in unhealthy environments, social discrimination increases the gap between demand and supply of services and financial constraints further hamper their health seeking behaviour to access existing health care services.

Given the rapid rate of urbanisation and the significant contribution of the urban population to the country's economy, it is essential that this population is adequately represented in the health statistics of our country.

DIABETES MELLITUS: URBAN RURAL DIFFERENCES

There is consistent data regarding the urban and rural differences in the prevalence of diabetes in the country.

Studies done in South India in the early 90's recorded significant urban rural differences in prevalence of diabetes, 8.2% in the urban and 2.4% in the rural population.(11)

The National Non Communicable Diseases (NCD) Risk Factor surveillance study conducted between 2003 and 2005 highlighted the difference in the prevalence rates of diabetes in the urban, peri urban population with prevalence rates being 7.3%, 3.2% and 3.1%.(12) The Prevalence of diabetes in India study (PODIS) conducted in 2004 showed a prevalence of 5.9 % and 2.7 % among urban and rural areas respectively as per the WHO criteria.(8)

THE METABOLIC SYNDROME:

INTRODUCTION:

The metabolic syndrome is a cluster of risk factors namely, diabetes and pre diabetes, abdominal obesity, high cholesterol and high blood pressure which increases the risk of an individual to cardiovascular disease morbidity and mortality.

Though the 'metabolic syndrome' was conceptualised over the past two decades, the observation that the various components of this syndrome coexisted in a large proportion of patients was made almost 90 years ago.(13)

The description of syndrome X or the 'insulin resistance ' syndrome by G.M Reaven in 1988 heralded the scientific interest in this field and gave birth to the current evolving understanding of the ' metabolic syndrome'.(13,14)

Research in the past two decades show that insulin resistance confers on an individual a greater likelihood of developing glucose intolerance, specific lipid disturbances, essential hypertension and pro coagulant and pro inflammatory states, which in turn increase the risk of cardiovascular disease. The Metabolic Syndrome was created as a new diagnostic category to identify such persons at greater cardio vascular risk so that timely and appropriate management strategies could be implemented.(15)

PATHOGENESIS:

The evolution of the concept of the ‘metabolic syndrome’ came from observations that the metabolic risk factors for Diabetes Mellitus and cardiovascular disease overlapped significantly, with abdominal obesity, hyperglycaemia, dyslipidemia and hypertension identified as common risk factors.

The results of cross sectional studies corroborated by prospective studies have shown that elevation of insulin concentrations precede the development of the metabolic syndrome. This has led to the understanding of the underlying pathophysiology of the syndrome to be that of insulin resistance.(16,17)

Resistance to the action of insulin leads to impaired insulin-mediated glucose uptake by peripheral tissues and inhibition of gluconeogenesis and lipolysis. This manifests clinically as glucose intolerance and dyslipidemia (high triglycerides and low HDL).(18)

Insulin resistance was also found to be closely related to hypertension with studies suggesting enhanced renal sodium retention and increased sympathetic nervous system activity to be key factors in both insulin resistance and hypertension.(19)

Recent work on obesity leading to knowledge that the adipose tissue is an active endocrine organ has led to studies implicating free fatty acids and inflammatory mediators such as Tumour Necrosis Factor Alpha and Interleukin 6 in abnormalities in post receptor insulin signalling and hence the development of insulin resistance.

(19,20). Interesting to note was the observation that central obesity which reflected intra abdominal fat depots had a greater association with insulin resistance and cardiovascular disease than peripheral (gluteal / subcutaneous) fat depots. Though evidence of the pathophysiology of this phenomenon is debatable, one of the leading hypothesis is that intra abdominal adipocytes being lipolytically active, would increase intraportal FFA levels and promote insulin resistance by inhibiting insulin clearance by yet unidentified mechanisms.(21,22)

METABOLIC SYNDROME: CRITERIA

Recognising the metabolic syndrome as a diagnostic category fuelled attempts to formulate various criteria to be used in clinical practice.(23)

A working definition was proposed by the World Health Organisation in 1998 which suggested that impaired glucose regulation or diabetes with two or more of the following components constituted the metabolic syndrome: namely, raised blood pressure (more than or equal to 140/90 mm Hg), raised Triglycerides (more than or equal to 150 mg/dL) and/or low HDL (less than 35 mg/dL in males and less than 39 mg/dL in females), Central obesity(waist hip ratio more than 0.9 in men and more than 0.85 in women) and /or BMI more than 30 mg/m2 and Microalbuminuria (albumin creatinine ratio of more than 30 mg/gm).(24)

Since 1998, several other organisations have proposed other criteria, the widely used among them being the 2001 National Cholesterol Education Program (NCEP) Adult

Treatment Panel III (ATP III) guidelines and the International Diabetes Foundation World Wide definition of Metabolic syndrome as described below.

ATP III guidelines require the presence of three or more of the following components for the diagnosis of metabolic syndrome in an individual: abdominal obesity (waist circumference >102 cm in men and >88 cm in women), elevated blood pressure level (systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥85 mmHg), elevated triglycerides (≥150 mg/dl), decreased HDL cholesterol (<40 mg/dl in men and <50 mg/dl in women), and elevated fasting glucose (110–125 mg/dl).(25)

However, the International Diabetes Federation argued that the NCEP ATP III guidelines were formulated primarily for research purposes and promoted the need for a single, universally accepted diagnostic tool that is easy to use in clinical practice as well as in research settings.(26)

This led to the latest IDF consensus world wide definition of metabolic syndrome which states that for a person to be defined as having the metabolic syndrome, he/she must have:(27)

Central obesity (defined as waist circumference ≥ 94cm for Europid men and ≥ 80cm for Europid women, with ethnicity specific values for other groups **;**
South Asians Based on a Chinese, Malay and Asian-Indian population; Male ≥ 90 cm and Female ≥ 80 cm)

plus any two of the following four factors:

• Raised Triglyceride level: ≥ 150 mg/dL (1.7 mmol/L), or specific treatment for this lipid abnormality

• reduced HDL cholesterol: < 40 mg/dL (1.03 mmol/L) in males and < 50mg/dL (1.29 mmol/L) in females, or specific treatment for this lipid abnormality

• raised blood pressure*:* systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg, or treatment of previously diagnosed hypertension

• raised fasting plasma glucose (FPG) ≥ 100 mg/dL (5.6 mmol/L), or previously diagnosed type 2 diabetes

Studies comparing the impact of the use of the ATP 3 criteria and the IDF criteria in determining the prevalence of metabolic syndrome in populations demonstrated a high prevalence of the metabolic syndrome using the new IDF definition(28)

METABOLIC SYNDROME: PREVALENCE

The prevalence of this entity appears to be increasing in the West with comparison data from US adults of different race or ethnicity in 1988-1994 and 1999-2006 showing significant increase from 27.9+/-1.1% to 34.1+.-0.8%.(29) The National Health And Nutrition Examination Survey (NHANES III) revealed startling statistics with approximately one fourth of adults above the age of 20 years meeting the diagnostic criteria for metabolic syndrome.(30)

What is alarming is Indian data suggesting that metabolic syndrome may be approaching epidemic proportions in the Asian sub continent.

A population data base study of urban Asian Indian adults showed the prevalence of metabolic syndrome by ATP III criteria to be 41.1%.(31)

The Chennai Urban Population Study-7 (CUPS-7) focussed on intra urban differences in the prevalence of the metabolic syndrome based on socio economic factors. The study which was conducted in Chennai showed an overall prevalence of the insulin resistance syndrome to be 11.2% with the prevalence in the middle-income group (18.7%) to be significantly higher compared to the low income group , 6.5%;($P < 0.001$). (32,33)

METABOLIC SYNDROME IN DIABETES MELLITUS:

Epidemiological studies in diabetes have shown that the metabolic syndrome is very frequently observed in diabetics. According to the NCEP study done in the US which analysed data of adults above the age of 50 years from the Third National Health and Nutrition Examination Survey (NHANES III), 87% of diabetics fulfilled the NCEP ATP III criteria for the metabolic syndrome.(3) In India, the prevalence of metabolic syndrome as per the ATP 3 criteria in an urban diabetic population in Mumbai was found to be 87.71% in women and 69.33% in men with an overall prevalence of 77.2%.(4) A study done in an urban population in South India in 2005 reported the overall prevalence of metabolic syndrome as per the IDF criteria to be 73.3% with a prevalence of 83.3% in women. (34)

DIABETES MELLITUS: MACROVASCULAR COMPLICATIONS

Chronic hyperglycemia secondary to Diabetes mellitus has been classically described to cause micro and macro vascular complications.

Macro vascular complications which include coronary artery disease, cerebro vascular accidents and peripheral vascular disease share a common pathological phenomenon of atherosclerosis. Atherosclerosis is triggered by chronic inflammation and injury to the systemic arterial wall which in turn sets of a cascade of events modulated by inflammatory markers, macrophages and T lymphocytes eventually resulting in the formation of an atherosclerotic lesion which causes chronic hypoperfusion or if ruptured causes an acute vascular infarction .(35)

In addition to increased likelihood of atherosclerotic plaque formation in diabetics by yet unknown mechanisms, increased platelet adhesion and hypercoaguability also contribute to the individual's risk of developing cardiovascular disease.

Numerous studies have highlighted the association of cardiovascular disease and diabetes.

Data from the Framingham cohort reported a twofold to threefold increase in the risk of clinical atherosclerotic disease, with greatest impact on morbidity and mortality for intermittent claudication and congestive heart failure.(36)

Evidence that diabetics without prior myocardial infarction have as high a risk for a second acute coronary event as compared to non diabetics with history of prior myocardial infarction (37) has prompted further research emphasizing aggressive

management of cardiovascular risk factors in diabetics. In fact, The American Diabetes Association and American Heart Association have recommended considering diabetes as a coronary artery disease risk equivalent rather than a risk factor.

Diabetes is also a strong independent predictor of cerebro vascular disease with diabetes increasing ischemic stroke risk by 3% each year with the risk tripling with long-standing diabetes of 10 years duration. In one study, a multivariate analysis after adjusting for other known risk factors showed the relative risks for stroke mortality and morbidity associated with diabetes to be 1.8 in men and 2.2 in women.

Epidemiological studies on the prevalence of peripheral vascular disease in diabetics often underestimate the true prevalence of the condition as nearly half the patients are asymptomatic. A pilot study using doppler to measure ankle brachial index showed a prevalence of 33% of asymptomatic peripheral occlusive arterial disease.(38)

The Global Status on Non communicable Diseases Report 2011 circulated by the World Health Organisation reports that the year 2008 saw more than 2.5 million deaths from CVD in India, two-thirds due to CHD and one-third to stroke.(39)

Epidemiological studies show clear variation in mortality trends in India with coronary artery disease mortality being higher in the South Indian states while stroke mortality is higher in the eastern states of the country.(39)

In India, the CUPS study done in Chennai found Coronary artery disease prevalence rate to be 9.1% among non diabetics with prevalence rates in those diagnosed with diabetes to be 21.4%.(40)

The earliest community based epidemiological survey on stroke was conducted in 1969-1971 in Vellore which recorded a prevalence of stroke due to any cause to be 56.9 per 100,000.(41) There are few studies describing the trend of cerebro vascular diseases in South India. A study done in Kolkatta between 2003 to 2005 recorded a Annual Incidence Rate of 123 per 100,000 people.(42)

Data available regarding peripheral vascular disease in diabetic in India suggest that it is less common among the Asian population. A cross sectional study done in South India recorded a prevalence of 15.4% in the diabetic population.(43)

METABOLIC SYNDROME: A RISK FACTOR FOR MACROVASCULAR COMPLICATIONS IN DIABETICS

Knowledge of the primary patho physiology of the metabolic syndrome to be that of insulin resistance and studies suggesting that insulin resistance confers substantial cardiovascular risk in patients with Type 2 Diabetes mellitus has invoked interest among researchers in exploring the possibility of the clinical utility of the metabolic syndrome as a risk factor for predicting macro vascular complications in the diabetic population.(44)

Metascreen was a multicentric diabetes clinic based survey conducted in 2002 which aimed to assess the degree of association and the predictive power of the metabolic syndrome with regard to clinically detectable complications in patients with diabetes. The study concluded that the metabolic syndrome , defined according to AHA or IDF

diagnostic criteria, was an independent clinical indicator and may be involved in the pathogenesis of both macro and microvascular complications of diabetes.(45)

Further research in this area include data from the United Kingdom Prospective Diabetes Study which was analysed retrospectively to assess the impact of the Metabolic Syndrome on macrovascular and microvascular outcomes in patients with Type 2 Diabetes Mellitus. The study concluded that the metabolic syndrome identified diabetic patients at increased risk of future macrovascular complications which included sudden death, fatal or non fatal myocardial infarction and fatal or non fatal stroke. However, statistical analysis suggested that it lacked clinical value for cardiovascular Risk stratification in type 2 Diabetes mellitus.(46)

The Verona Diabetes Complication study using a prospective cohort sought to analyse the cardiovascular risk (fatal and non fatal coronary events, cerebro vascular accidents and peripheral vascular disease) associated with the presence of the metabolic syndrome in patients with Type 2 Diabetes mellitus. The study concluded that the presence of the metabolic syndrome independently predicted prevalent CVD (OR 2.01, P = 0.045) and incident CVD (OR 4.89, P = 0.031).(5)

Data is lacking in the Indian population as there are no studies specifically addressing this issue. With epidemiological trends showing an increase in the prevalence of diabetes and its macro vascular complications in the Indian urban poor, the use of the metabolic syndrome as a simple clinical tool at the primary health set up to identify diabetics at risk for cardiovascular disease and initiate cost effective and timely preventive strategies.

MATERIALS AND METHODS

An observational study of cross sectional design was conducted in the out patient Department of the Low Cost Effective Care Unit.

The Low Cost effective Care Unit (LCECU) is a primary level hospital affiliated to the Christian Medical College and Hospital providing health services to the urban poor population of Vellore city in the state of Tamil Nadu. It is a 48 bedded hospital with an out patient attendance of approximately 55,000 patients recorded the previous years. Around 1200 diabetic patients are seen every month in the Out Patient department, comprising around 33 % of the outpatient monthly statistics in the last one year. Weekly clinics are also conducted exclusively for diabetic patients with emphasis on health education regarding diabetes and its comprehensive management and screening of micro vascular complications.

Patients were recruited into the study from the Out Patient Department of LCECU if they fulfilled the following criteria.

Inclusion Criteria:

1. Age more than 30 years
2. Female gender
3. Previously diagnosed or newly diagnosed patients with Diabetes Mellitus Type 2 based on a fasting capillary blood glucose more than or equal to 126 mg/dL or a 2 hour post prandial capillary blood more than or equal to 200 mg/dl.

Patients were excluded if they fulfilled any of the following criteria.

Exclusion Criteria:

1. Age less than 30 years of age
2. Male gender
3. Pregnant women
4. Patients with Type 1 Diabetes Mellitus(Diagnosis made based on age of onset less than 30 years of age with ketosis at presentation)
5. Those not consenting to be part of the study

Exposure Variable:

All patients included in the study were screened for the metabolic syndrome.

A patient was said to have metabolic syndrome if she fulfilled the International Diabetes Federation criteria for the Metabolic syndrome (23):

1. Central obesity : defined as waist circumference >/= 80 cm in females

   Plus any two of the following two factors:
2. Raised Triglycerides >/= 150 mg/dl or specific treatment for this lipid abnormality
3. Reduced HDL < 50 mg/dl in females or specific treatment for this lipid abnormality
4. Raised blood pressure ,Systolic BP >= 130 mm Hg or Diastolic BP >= 85 mm Hg or treatment of previously diagnosed hypertension
5 .Raised fasting plasma glucose > 100 mg/dl or previously diagnosed Type 2 Diabetes Mellitus

Measurement of waist circumference : The patient is made to relax and stand with her arms at the side, in a straight and upright position with feet together and the waist is exposed. The hip bone and the iliac crest is located and the measuring tape is placed evenly around the bare abdomen at the level of the iliac crest and waist circumference is measured after breathing out normally.

Measurement of blood pressure: Blood pressure is measured from the right arm after the patient has been sitting for longer than 5 min using a standard mercury sphygmomanometer with cuff 13 cm wide and 42 cm long and using Korotkoffs sounds I and V. Systolic and diastolic blood pressure values are recorded to the nearest 2mm Hg.

An overnight fasting plasma sample was taken from all patients and fasting High Density Lipid levels and Triglyceride levels were measured.

Outcome variable:

The prevalence of the following macro vascular complications of Diabetes mellitus was measured in all diabetic patients included in the study.

a)Ischemic stroke as evidenced by the following:

1. Clinical findings as documented in medical records by a physician or elicited on

examination by the principal investigator

a) Cerebral cortical involvement: aphasia/neglect/motor deficit

b) Brain stem involvement: cranial nerve deficit

c) Cerebellar dysfunction

OR

2. Radiological findings

a) cortical/ subcortical /cerebellar /brain stem infarct of more than 1.5 cm on CT or MRI of brain (large artery occlusion)

b) subcortical / brain stem infarct of less than 1.5 cm on CT or MRI of brain (small artery /lacunar infracts)

b) <u>Ischemic Heart Disease</u> <u>as evidenced by the following</u>:

1) Previously diagnosed ischemic heart disease:

a) Physician Documented Acute Coronary Syndrome requiring hospitalisation

b) Exercise testing

c) Angiography

d) Revascularisation procedure

OR

2) Evidence of ischemic heart disease : Defined as a positive history of Angina / infarction/ angina equivalent as assessed by the London school of the modified Rose Questionnaire (50)

c) **Peripheral vascular disease** as evidenced by any one of the following, as documented by a physician

1. Gangrene of digits/limb OR

2. History of revascularisation procedures OR

3. History of Intermittent Claudication pain (as assessed by the Edinburg Claudication Questionairre) (53) OR

4 . Ankle Brachial Index ABI (palpatory method) < 0.9 (54) OR

5. Absence of both dorsalis pedis and posterior tibial arteries on one foot or absence of either of the two on both feet.

The ABI was calculated as the ratio between the highest systolic blood pressure of the ankle and the highest systolic blood pressure of the upper limbs as recorded by the palpatory method.Blood pressure measurements were taken on patients in a supine position, by detection of either the posterior tibial or of the dorsalis pedis artery during deflation of an appropriately sized cuff placed around the ankle. Pressure

readings were taken at reappearance of the foot pulse and approximated to two mmHg. Brachial blood pressures were taken by palpation of the radial pulse with pressure readings recorded at the reappearance of the radial pulse and approximated to two mmHg.

Bias:

As gender would be a major confounder , the cross sectional study included only female diabetic patients.

The other risk factors which might confound the outcomes, as listed below, were also taken into consideration during statistical analysis.

1. Age
2. Physical activity
4. Menopausal state
5. Family history of Diabetes Mellitus
6. Family history of premature Heart Disease
7. Duration and management of diabetes.
8. Treatment for diabetes, hypertension, dyslipidemia or coronary artery disease

Data including history and clinical examination was carried out by the principal investigator thereby minimizing inter observer bias.

Sample Size:

A detailed scientific literature review was done to identify studies done to determine the prevalence of macrovascular complications in diabetic patients with the metabolic syndrome.

The ' NCEP- Defined Metabolic Syndrome, Diabetes and Prevalence of Coronary Heart Disease Among NHANES III Participants Age 50 years and older ' study showed that the prevalence of metabolic syndrome in patients with Diabetes Mellitus was 86.5 % , the prevalence of CHD in diabetic patients with metabolic syndrome was 19.2%, the prevalence of CHD in diabetic patients without metabolic syndrome was 7.4%, with Metabolic syndrome being a significant univariate predictor of prevalent CHD (OR:2.07, 95 % CI 1.66 – 2.59)

Taking the prevalence of macrovascular complications of diabetes mellitus in diabetic patients with metabolic syndrome to be 19% and the prevalence of macrovascular complications of diabetes mellitus in patients without metabolic syndrome to be 7.4%, with an alpha error of 0.05 and a power of 80%, the number of patients required in each group was calculated to be 129.

Statistical analysis:

The prevalence of metabolic syndrome among diabetic patients was determined using the International Diabetes Federation criteria for metabolic syndrome and the prevalence of macro vascular complications of diabetes was determined in all diabetic patients included in the study.

The Chi Square test was used to analyse risk factors associated with metabolic syndrome and macro vascular complications of Diabetes Mellitus.

The study protocol was presented before and approved by the Institutional Review Board on 6.2.2012 (IRB Min No 7745).

RESULTS

The cross sectional study was carried out in the out patient clinic of the Low Cost Effective Care Unit from March 2012 to August 2012. A total of 106, newly or previously diagnosed female diabetic patients, above the age of 30 years were recruited into the study during this period. 29 were excluded from the final statistical analysis as they lacked data necessary for predictor analysis. All 106 patients were included in descriptive analysis while only those for whom complete data was available (77 patients) were included in the final statistical analysis.

Descriptive Data:

Given below is the descriptive analysis of the 106 diabetic patients recruited into the study.

a) 55.7% of the diabetic patients were above the age of 50 years.

b) 74.5% of patients were post menopausal.

c) 47.2% of patients had history of a first degree relative diagnosed with Diabetes Mellitus.

d) 7.5 % of patients had history of a first degree relative who died of premature coronary artery disease.

e) Duration of diabetes : 16 % of patients had been diagnosed to have diabetes for

more than 10 years, 50 % had the disease for a duration of 1 to 10 years while 31.1% of patients had been diagnosed less than a year back. Data was not available for 3 patients included in the study.

f) Clinical presentation at the time of diagnosis: 63.2 % of patients were diagnosed to have diabetes incidentally during a health visit while 18.9% of patients presented with non specific complaints. 8.5% of patients reported one of the cardinal symptoms of diabetes namely polydipsia, polyphagia or polyuria to their physician at presentation while 9.4% had an underlying infection detected at the time of diagnosis.

g) Management of diabetes: From available data, 4 patients were only on lifestyle modifications, exercise and diabetic diet as part of management of diabetes. Of the patients included in the study, 52.8% engaged in regular exercise which included at least half an hour of brisk walking for 5 days a week. 89.6% of patients were on oral anti diabetic agents while only 9.4% of patients required insulin therapy for glycemic control.

h) From available data, 41.5% of patients were also on some antihypertensive medication,13.2% were on statins and 8.5% were on Aspirin along with management of their diabetes.

i) Out of the 106 diabetics enrolled in the study,80 patients (75.5%) had a waist circumference more than or equal to 80 cm.

j) 63 patients (59.4%) had a fasting HDL less than 50 mg/dL or were on treatment with statins. 14 patients (13.2%) had the ideal HDL s above or equal to 50mg/dL. Data was missing for 29 patients (27.4%)

k) 34 patients (32.1%) had a fasting TGL more than or equal to 150 mg/dL or were on treatment with statins.43 patients (40.6 %) had the recommended TGL level of below 150 mg/dL .Data was missing for 29 patients (27.4%)

l) 65 patients (61.3%) had a systolic BP >/= 130 mm Hg or a diastolic BP >/= 85 mm Hg or were on treatment with antihypertensives. There were 42 patients (39.6%) who had a systolic BP < 130 mm Hg and a diastolic BP < 85 mm Hg and were not on any antihypertensives.

m) Of the patients who were diagnosed to have high blood pressures or were on antihypertensives, , 86.2% were on treatment with antihypertensives, 49.2% had a systolic BP >/= 130 mm Hg and 18.5% had a diastolic BP >/= 85 mm Hg.

n) Metabolic syndrome: 64.2% of diabetic patients included in the study fulfilled the International Diabetes Federation criteria for metabolic syndrome. 27.4% of patients did not satisfy the criteria while data was not available for categorisation in 8.5% of patients.

Statistical Analysis:

29 patients enrolled in the study lacked complete data that would be required for assessing associations as stated in the study objectives. Therefore, the predictor statistics, as described below, include only 77 out of the 106 patients enrolled in the study.

1) Of the 77 patients included in the final analysis, 58 patients (75.3%) fulfilled the International Diabetes Federation Criteria for the metabolic syndrome.

2) Of the 58 patients who had the metabolic syndrome, all of them had a waist circumference more than or equal to 80 cm, 51 patients (87.9%) fulfilled the criteria of having HDL levels less than 50 mg/dl, 37 patients (63.8%) satisfied the criteria of having a BP >/= 130/85 mm of Hg or were on antihypertensives and 27 patients (46.6%) satisfied the criteria of having TGL levels more than or equal to 150 mg/dl.

3) Association between Metabolic syndrome and macrovacsular complications of diabetes mellitus

The overall prevalence of macro vascular complications (both ischemic heart disease and peripheral vascular disease) was 60.3 % in diabetics with the metabolic syndrome and 47.4 % in those without the syndrome.(OR 1.69, 95% CI 0.6 – 5.0,

p=0.321)

a) Ischemic Stroke:

None of the patients included in the analysis, both those with and without the metabolic syndrome had evidence of ischemic stroke as evidenced radiologically or clinically.

b) Ischemic Heart Disease:

In our study, the prevalence of Ischemic heart disease was 29.3% (17) in diabetics with the metabolic syndrome and 10.5 % (2) in those without the syndrome (OR 3.53, 95% CI 0.7 – 16.9 , p = 0.099) .

Ischemic heart disease was previously diagnosed by a physician in only 2 patients while 16 patients had a positive response to the Rose's questionnaire, 9 patients with grade 1 angina/angina equivalent and 7 patients with grade 2 angina/angina equivalent.

One of the patients who was previously diagnosed with ischemic heart disease had grade 2 angina equivalent on rose's questionnaire.

Of the two patients with ischemic heart disease but without the metabolic syndrome, both patients had Grade 1 angina equivalent on Rose's questionnaire.

c) Peripheral Vascular Disease:

In our study, in diabetics without the metabolic syndrome, the prevalence of peripheral vascular disease was 36.8% (7 patients).

6 patients were diagnosed to have peripheral vascular disease based on an Ankle Brachial Index less than 0.9 performed by the palpatory method.

The diagnosis of peripheral vascular disease was made in 1 patient based on a positive response (Grade 2 claudication pain) on the Edinburgh claudication questionnaire. However, he had a normal Ankle brachial Index of more than 0.9.

However, if the cut off for peripheral vascular index was taken to be 0.8, the prevalence of PVD fell to 5.3% with diagnosis of PVD made on only one out of 19 diabetics without the metabolic syndrome. The patient had been diagnosed to have diabetes for less than a year, had grade 2 claudication pain on the Edinburg questionnaire but had an ABI>0.9.

Among the group of diabetic patients with the metabolic syndrome, 29 patients (50%) had evidence of peripheral vascular disease.

25 patients were diagnosed to have peripheral vascular disease based on an Ankle Brachial Index less than 0.9 performed by the palpatory method.
The diagnosis of peripheral vascular disease was made in 8 patients based on a

positive response to the Edinburgh claudication questionnaire with 5 patients and 3 patients describing Grade 1 and Grade 2 claudication pain respectively.

Of the 8 patients who were symptomatic with claudication pain, 4 of them (2 each with grade 1 and grade 2 claudication pain) had a normal Ankle Brachial Index (>0.9)

Similarly, if the cut off for ABI was taken as 0.8, only 6 diabetic with the metabolic syndrome had an ABI<0.8 bringing down the prevalence of PVD to 22.4% (13 patients).

Out of the 8 patients who were symptomatic with claudication pain, only one patient with grade 1 claudication pain had an ABI of 0.73.

Of the 13 patients with PVD, 1 patient had been diagnosed to have diabetes for more than 10 yrs, 7 had diabetes for duration of 1 to 10 years while 5 patients had been diagnosed less than a year.

In summary, the prevalence of peripheral vascular disease was 50% in diabetics with the metabolic syndrome and 36.8 % in those without the syndrome. (OR 1.71, 95% CI 0.6 – 5.0 , p = 0.318)

However if the cut off for ABI was taken as less than 0.8, the prevalence of PVD in diabetics with and without the metabolic syndrome was found to be 22.4% and 5.3% respectively.

Confounders:

Studies have shown that diabetic women have a greater risk of cardiovascular disease when compared to men, attributed to the fact that the burden of conventional risk factors namely elevated blood pressure, low HDL cholesterol and high triglycerides are greater in diabetic women than in diabetic men (47). Gender as a confounding factor was eliminated by including only female patients in the study.

As there was no association found between metabolic syndrome and macro vascular complications of diabetes, analysis adjusted for confounders was not done.

Table 1

BASELINE CHARACTERISTICS:

Baseline characteristics	Diabetics without the metabolic syndrome n = 19	Diabetics with the metabolic syndrome n = 58
Age		
> 50 years	12(63.2%)	26(44.8%)
Post menopausal state	14(73.7%)	40(69%)
Positive family history of Diabetes Mellitus	10(52.6%)	27(46.6%)
Positive family history of premature heart disease	2(10.5%)	6(10.3%)
Duration of Diabetes Mellitus		
< / = to 1 year	5(26.3%)	18(31%)
1 – 10 years	11(57.9%)	29(50%)
> 10 years	3(15.85)	9(15.5%)
Data not available		2(3.4%)

Baseline characteristics	Diabetics without the metabolic syndrome n = 19	Diabetics with the metabolic syndrome n = 58
Clinical presentation at diagnosis		
Incidental diagnosis	14(73.7%)	37(63.8%)
Non specific symptoms	3(15.8%)	12(20.7%)
Cardinal symptoms	1(5.3%)	4(6.9%)
Infection	1(5.3%)	5(8.6%)
Management of Diabetes		
Exercise	12(63.25%)	29(50%)
OHA's	18(94.7%)	50(86.2%)
Insulin	4(21%)	3(5.2%)
Use of other medication		
Antihypertensives	9(47.4%)	33(56.89%)
Statins	1(5.3%)	9(15.5%)
Aspirin	2(10.5%)	5(8.6%)

AGE :

N = 106

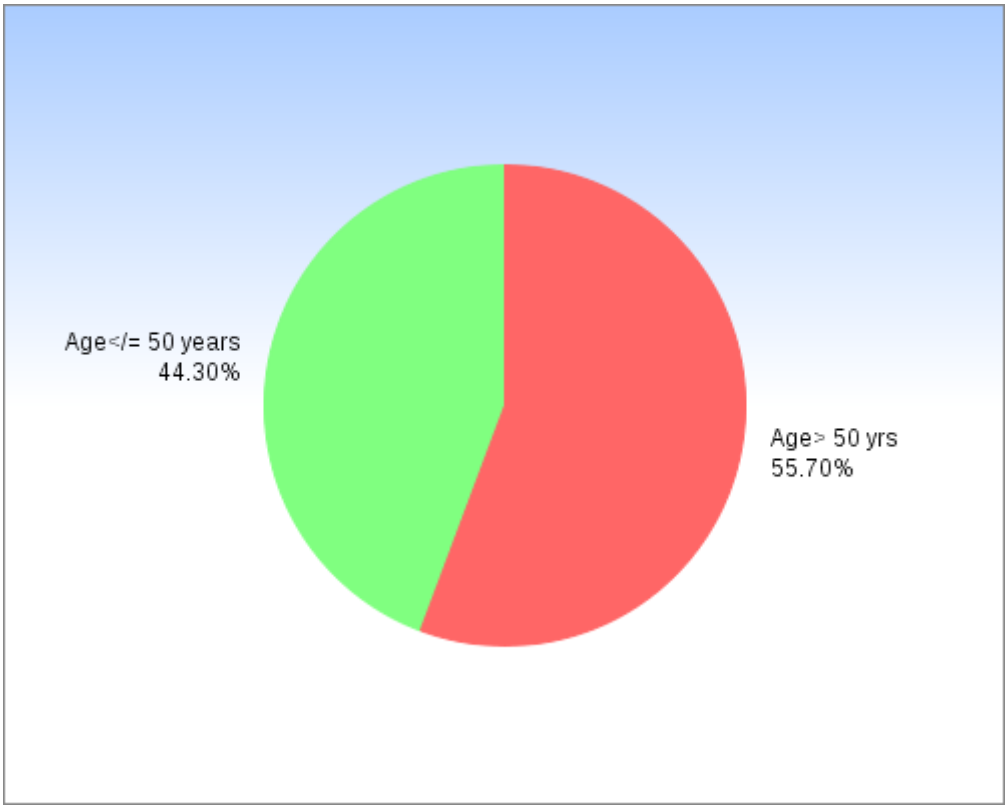


Figure 1: Age distribution of patients

MENOPAUSAL STATE:

N = 106

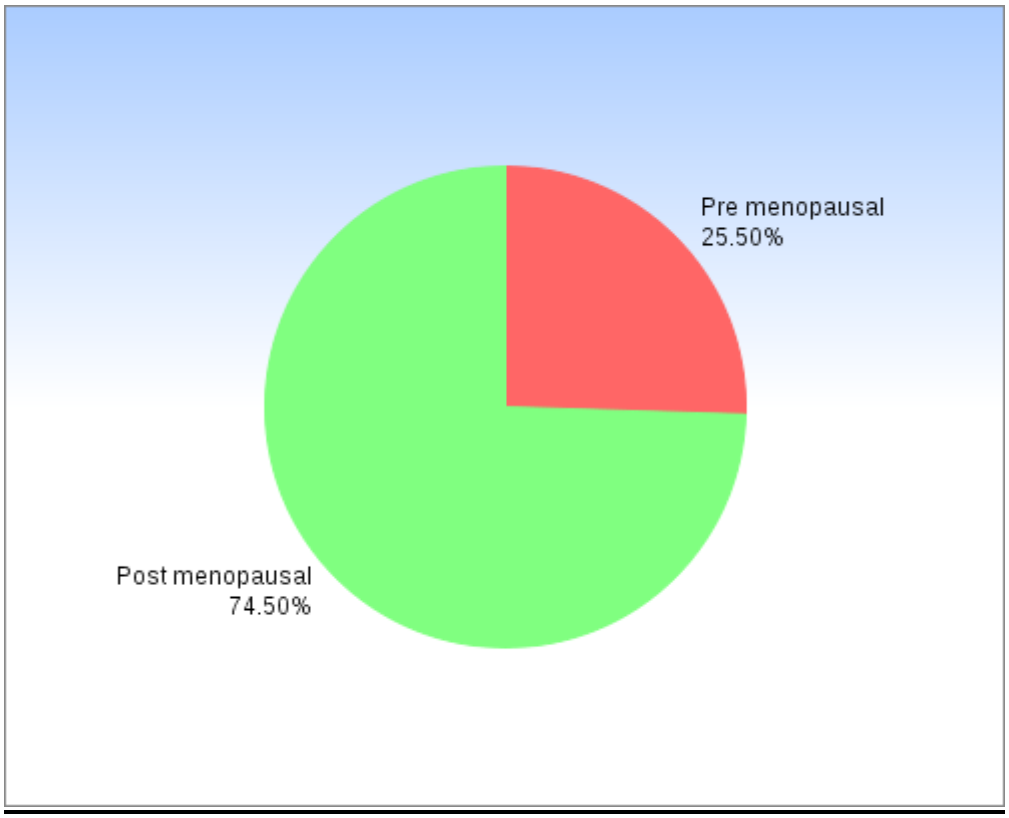


Figure 2: Menopausal state of diabetic women

FAMILY HISTORY OF DIABETES MELLITUS

N = 106

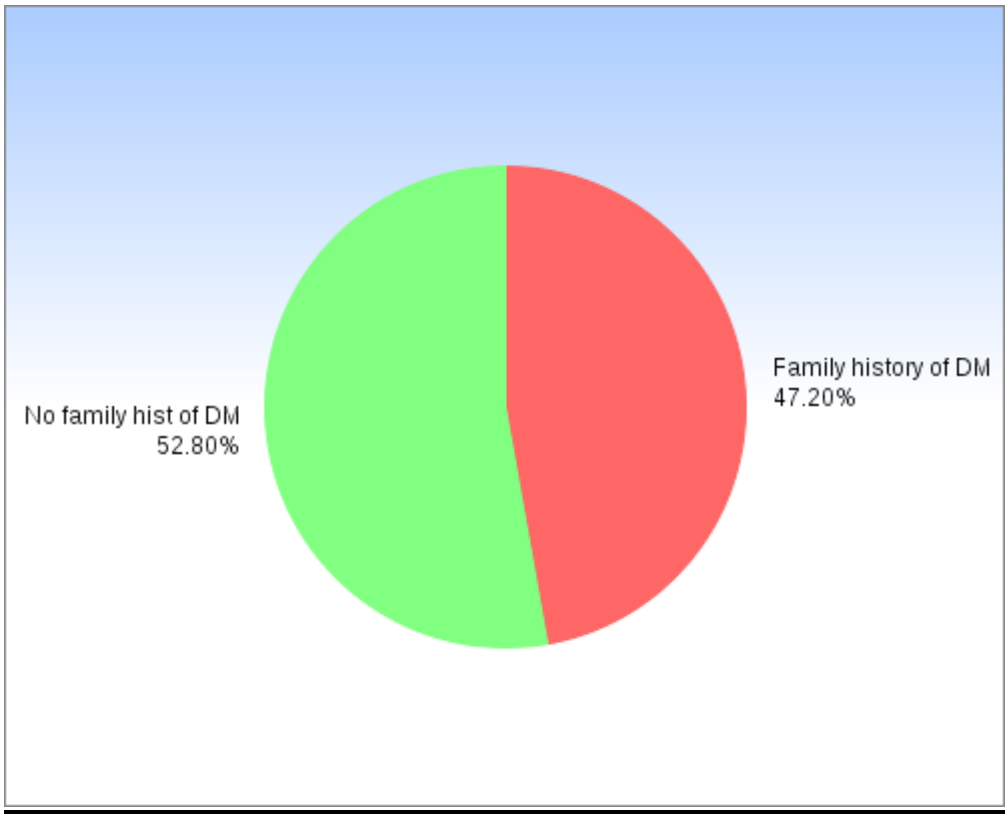


Figure 3 :Proportion of patients with history of a first degree relative diagnosed with diabetes mellitus

FAMILY HISTORY OF PREMATURE HEART DISEASE

N = 106

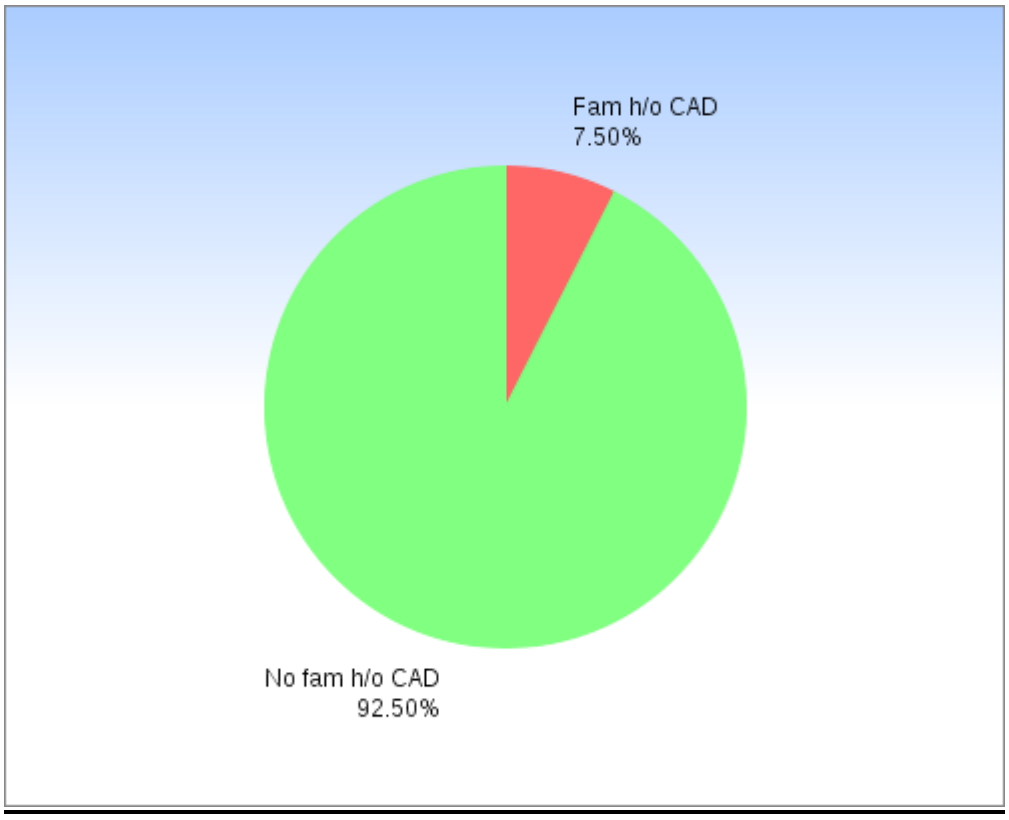


Figure 4: Proportion of diabetic patients with history of a first degree relative having died prematurely of an acute coronary event, less than 60 years for a male relative and less than 50 years in a female relative

DURATION OF DIABETES MELLITUS:

N = 106

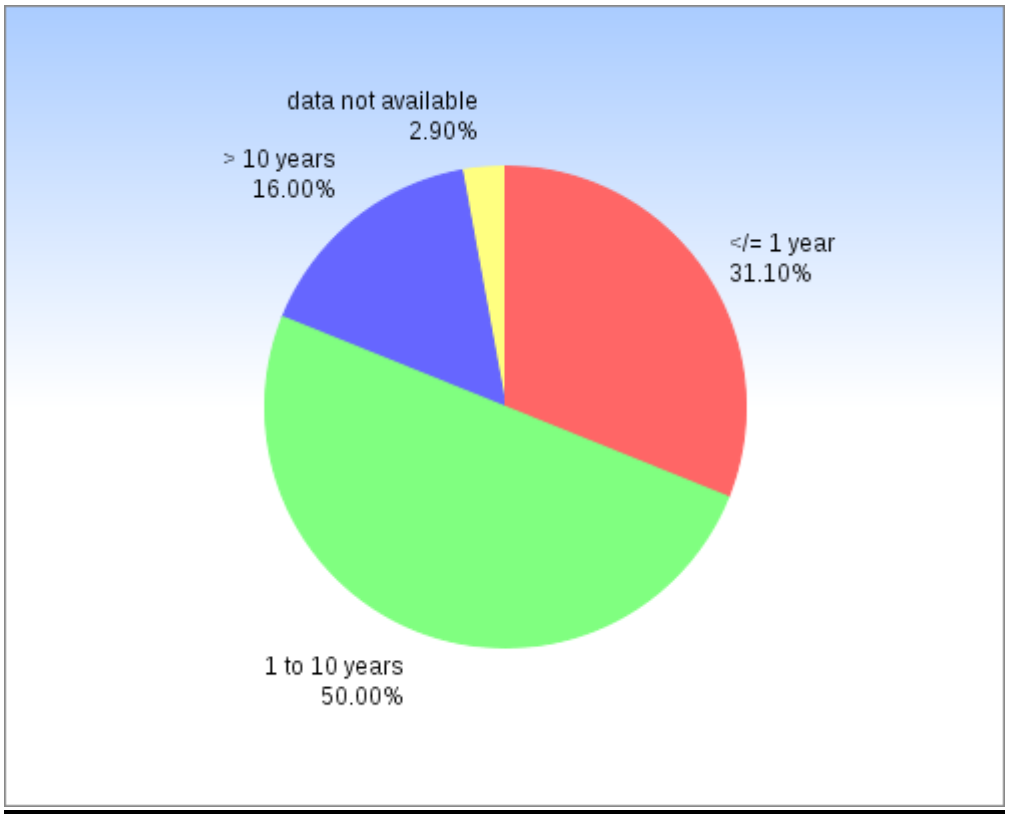


Figure 5 : Duration of diabetes

CLINICAL PRESENTATION AT DIAGNOSIS:

N = 106

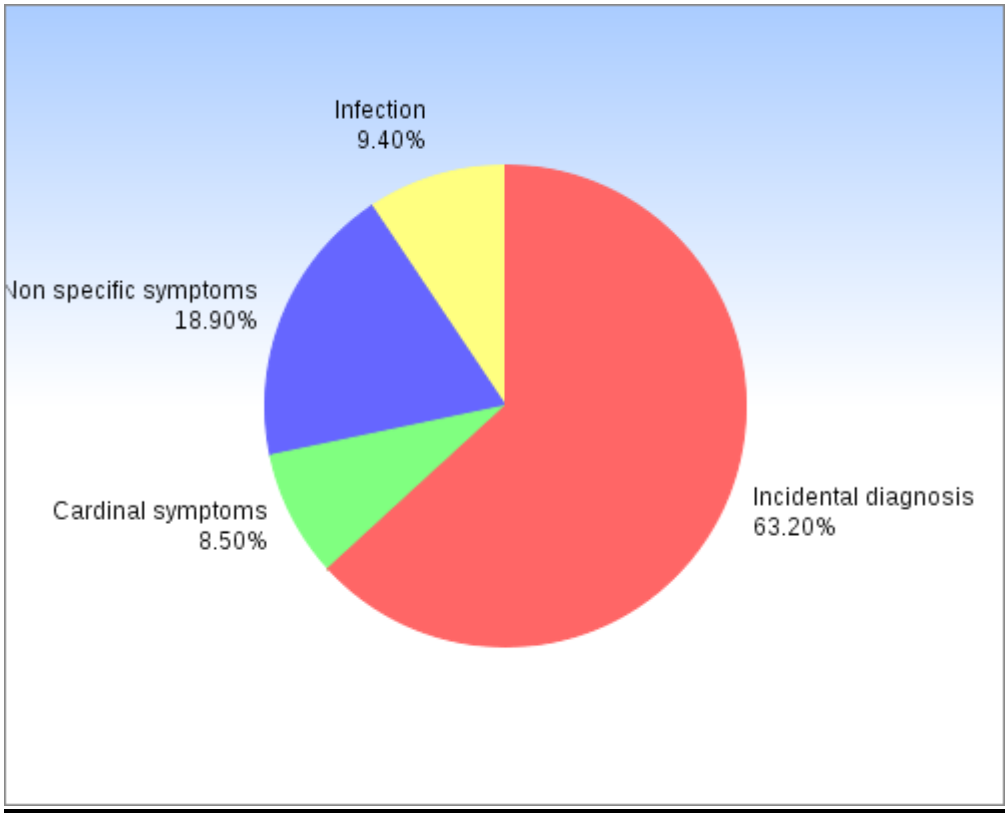


Figure 6 : Clinical features with which diabetic patients presented to their physician at the time of diagnosis

MANAGEMENT OF DIABETES:

N = 106

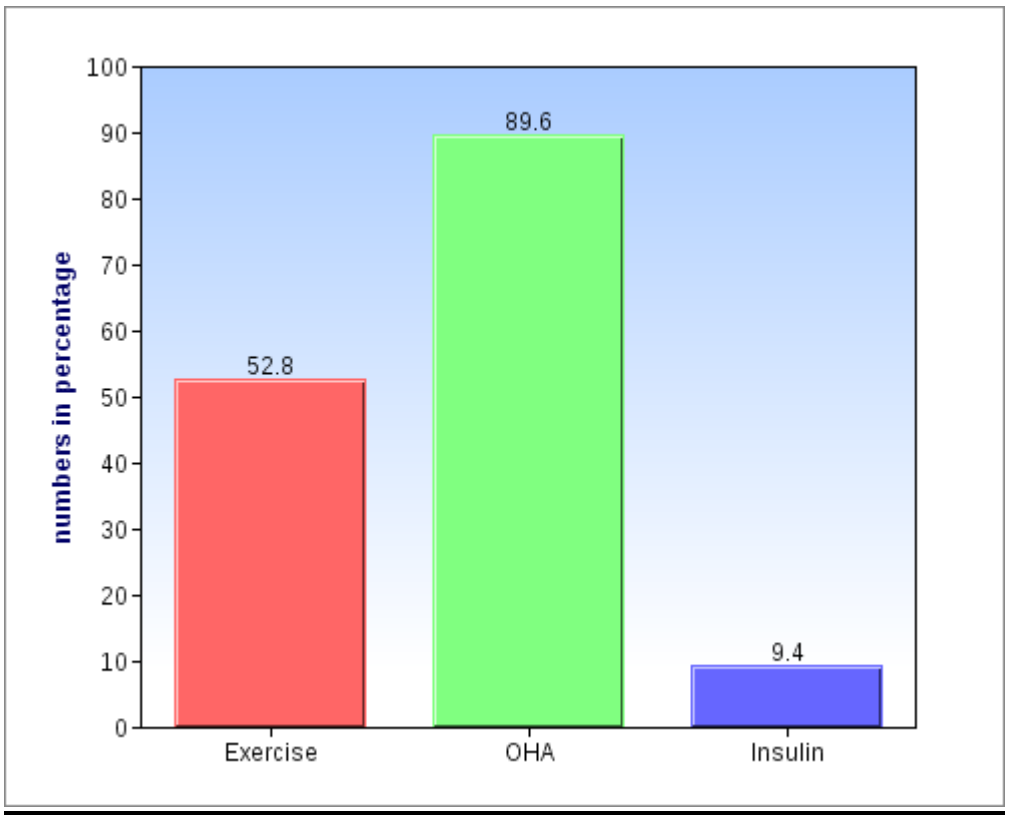


Figure 7 : Modalities of treatment of diabetes

OTHER MEDICATIONS:

N = 106

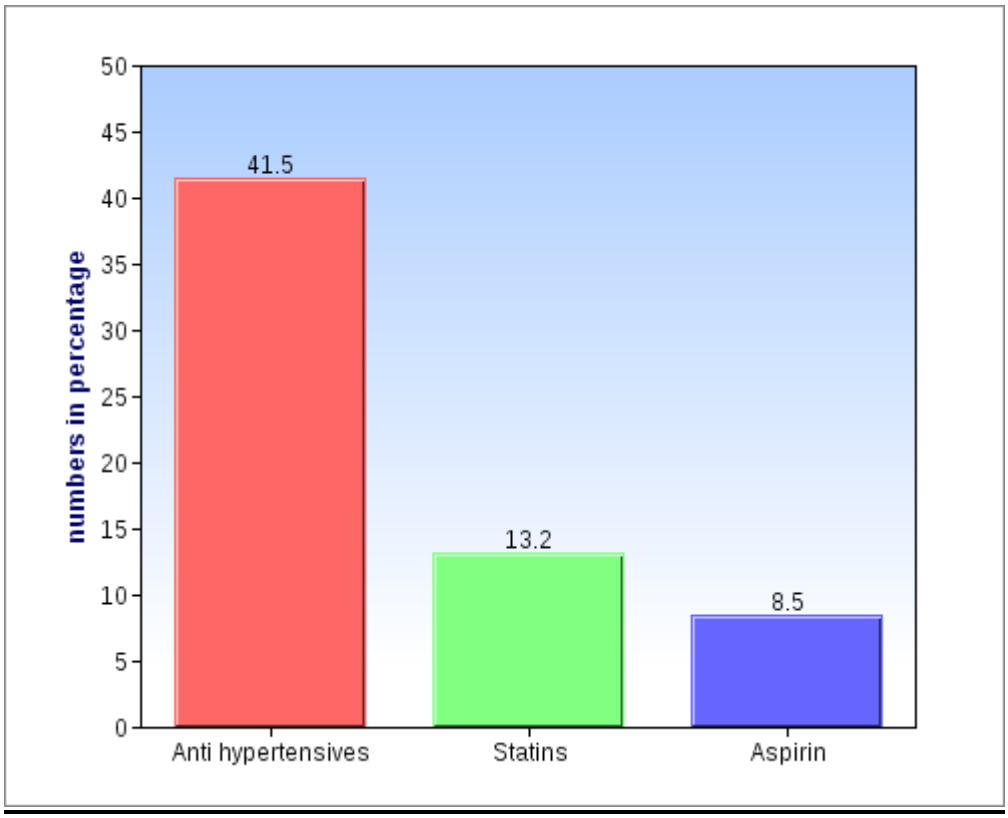


Figure 8 : Other medications that diabetic patients enrolled in the study were using apart from medical management of diabetes

METABOLIC SYNDROME

N = 106

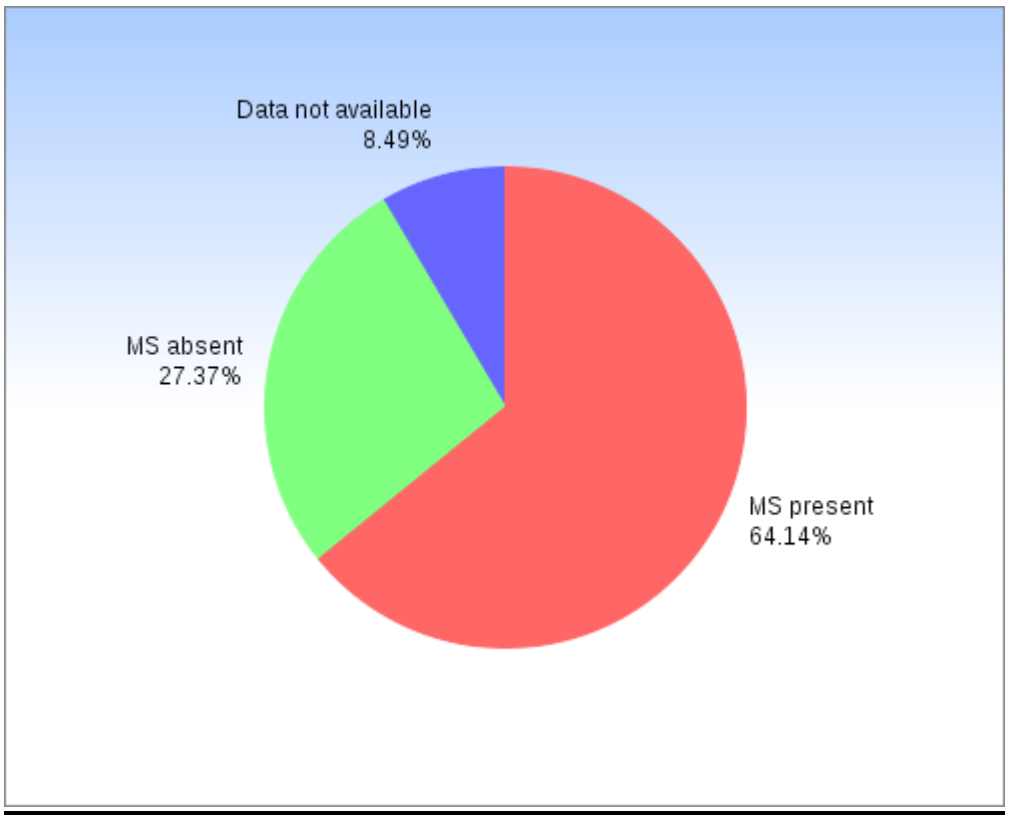
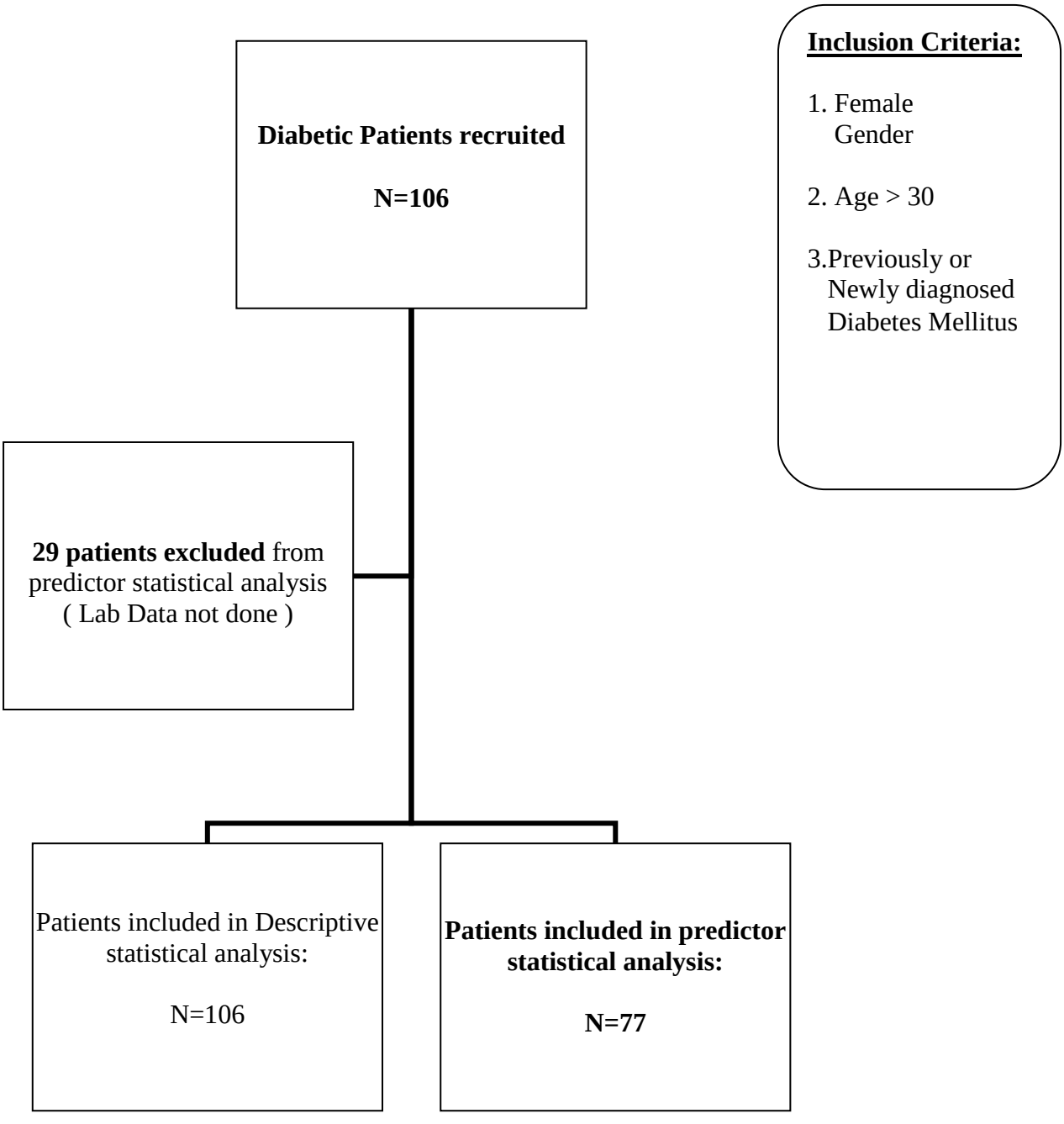


Figure 9 : Proportion of diabetic patients enrolled in the study satisfying the IDF criteria for the metabolic syndrome

PARTICIPANTS:



METABOLIC SYNDROME

N = 77

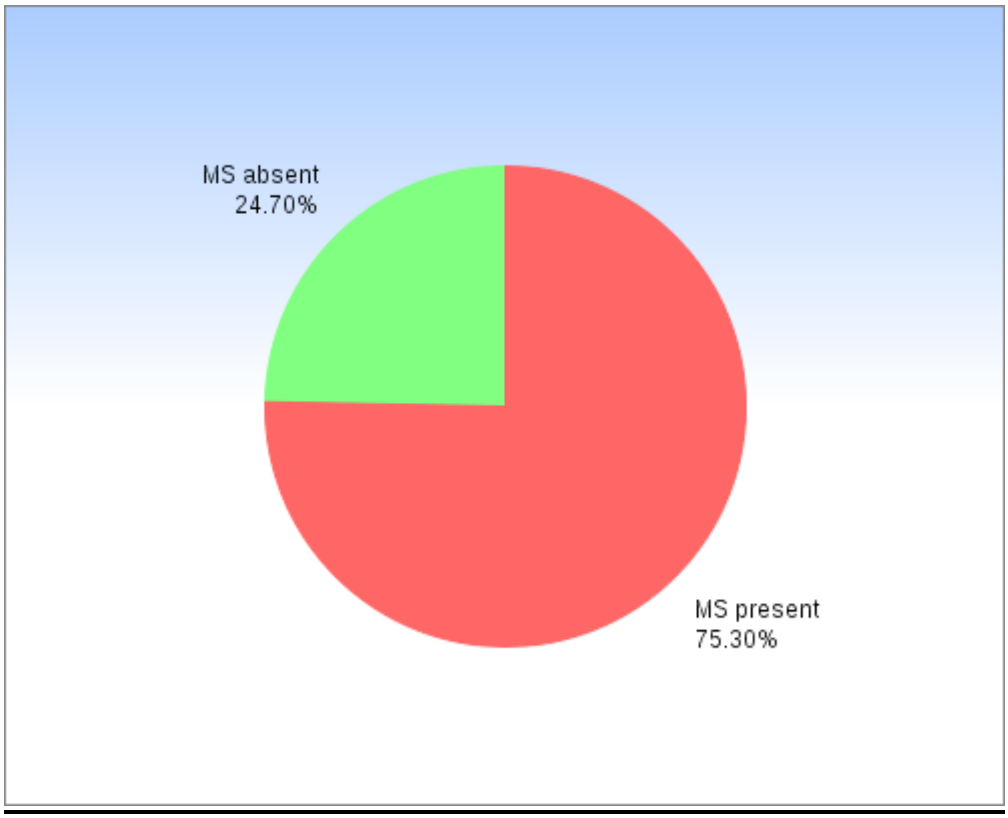


Figure 10: Proportion of diabetic patients (after exclusion of 29 patients due to lack of data) who satisfied the IDF criteria for the metabolic syndrome

DIABETIC PATIENTS WITH METABOLIC SYNDROME:

CRITERIA FULFILLED

N = 58

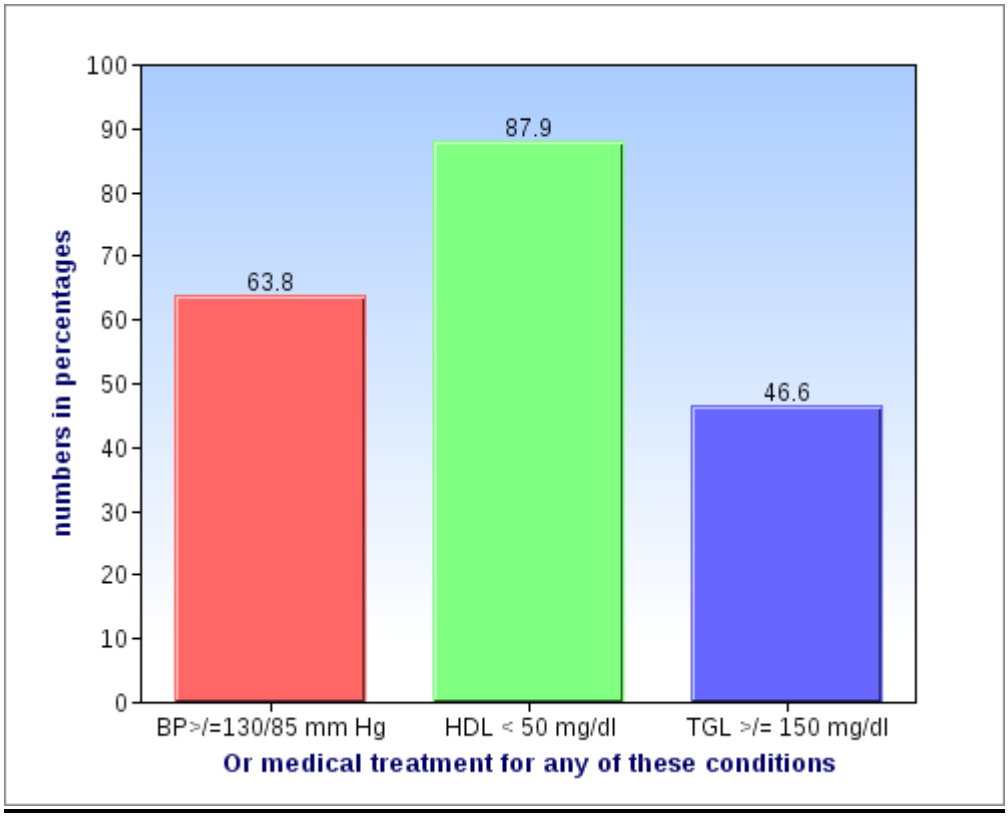


Figure 11: Frequency of criteria that were satisfied by diabetic patients with the metabolic syndrome

DIABETIC PATIENTS WITH METABOLIC SYNDROME:

MACROVASCULAR COMPLICATIONS

N = 58

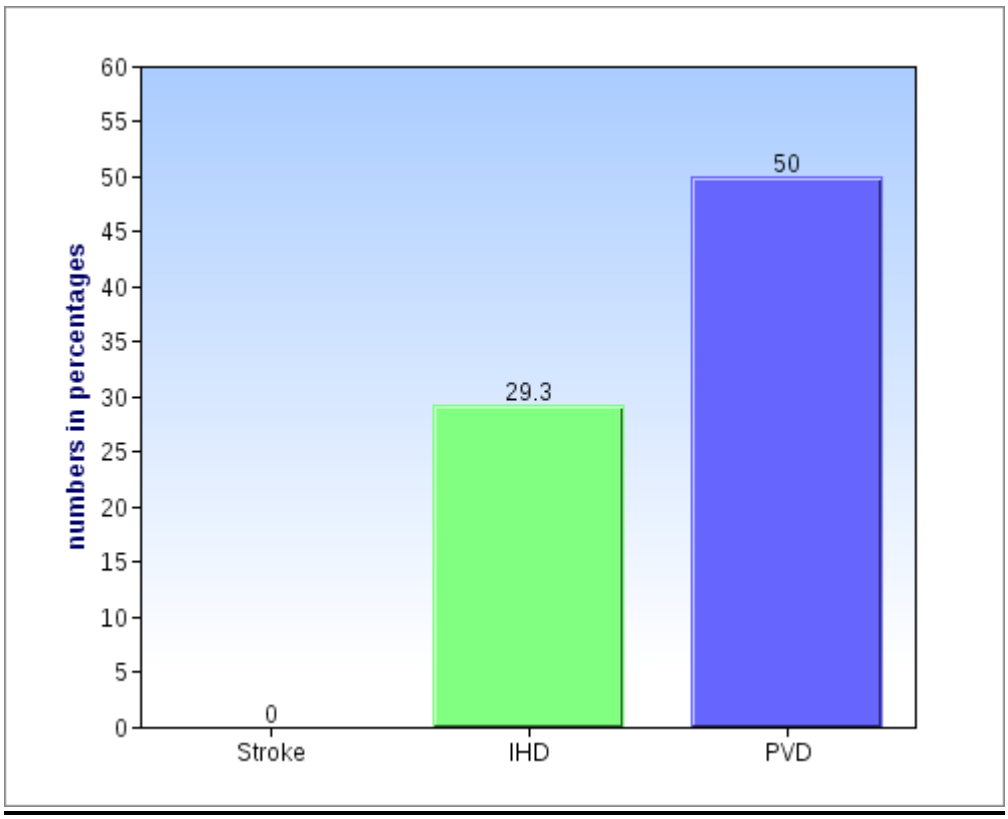


Figure 12: Prevalence of macrovascular complications in diabetics with the metabolic syndrome

1) ISCHEMIC HEART DISEASE

N = 17

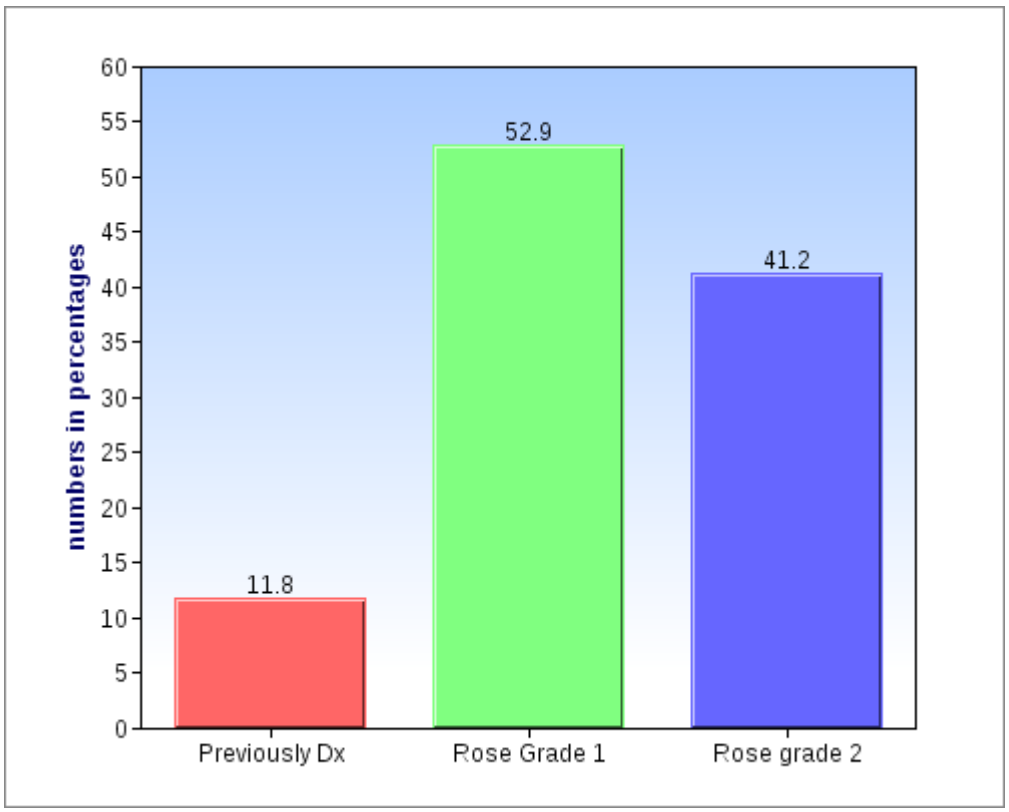


Figure 13: Criteria met by diabetic patients with the metabolic syndrome diagnosed with ischemic heart disease

2) PERIPHERAL VASCULAR DISEASE

N = 29

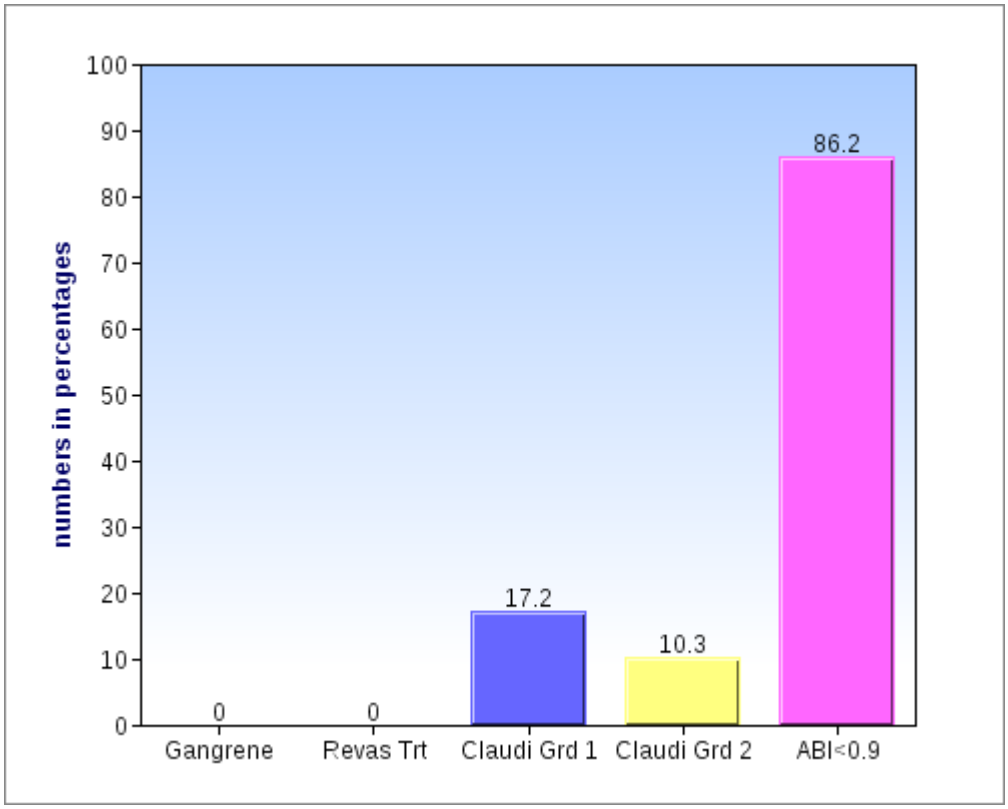


Figure 14 : Criteria met by diabetic patients with the metabolic syndrome diagnosed with peripheral vascular disease

B) DIABETIC PATIENTS WITHOUT METABOLIC SYNDROME:

MACRO VASCULAR COMPLICATIONS

N = 19

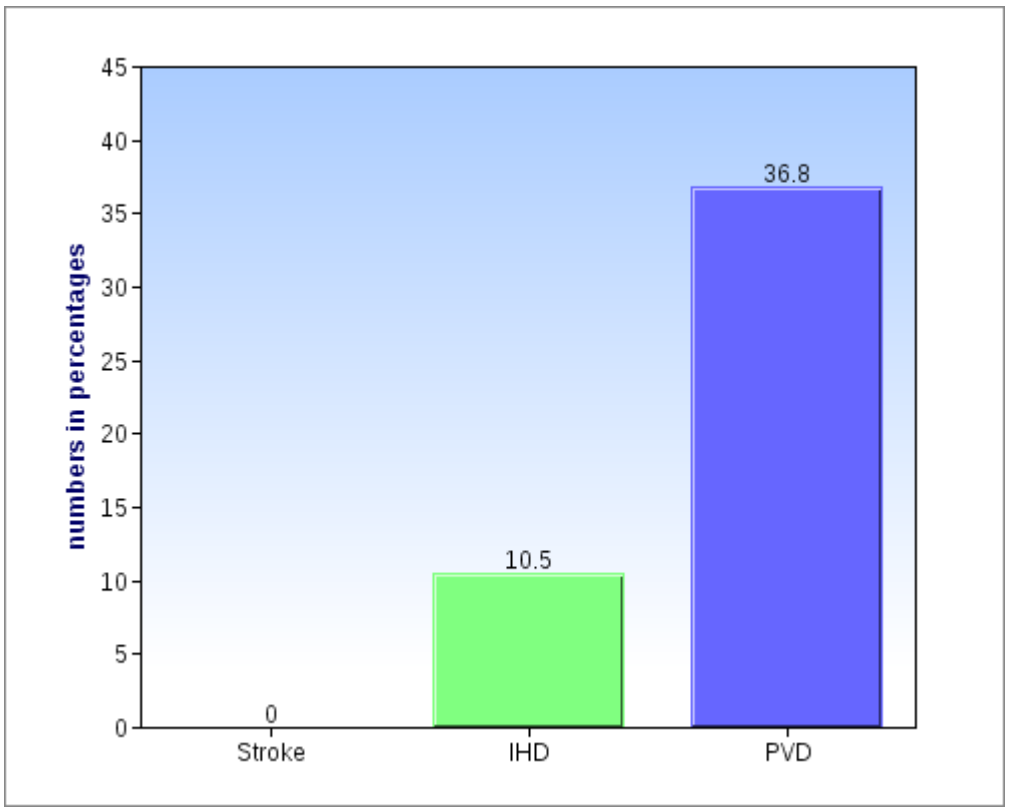


Figure 15: Prevalence of macrovascular complications in diabetics without the metabolic syndrome

1. ISCHEMIC HEART DISEASE

N = 2

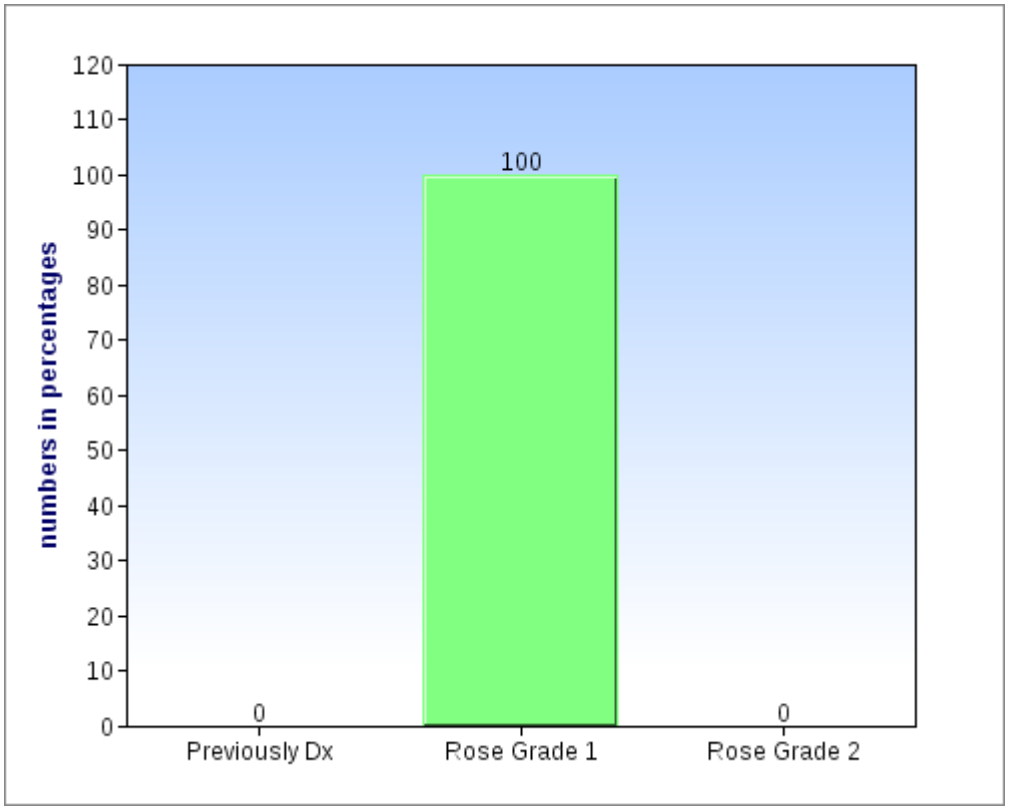


Figure 16 : Criteria met by diabetic patients without the metabolic syndrome diagnosed with ischemic heart disease

2. PERIPHERAL VASCULAR DISEASE

N = 7

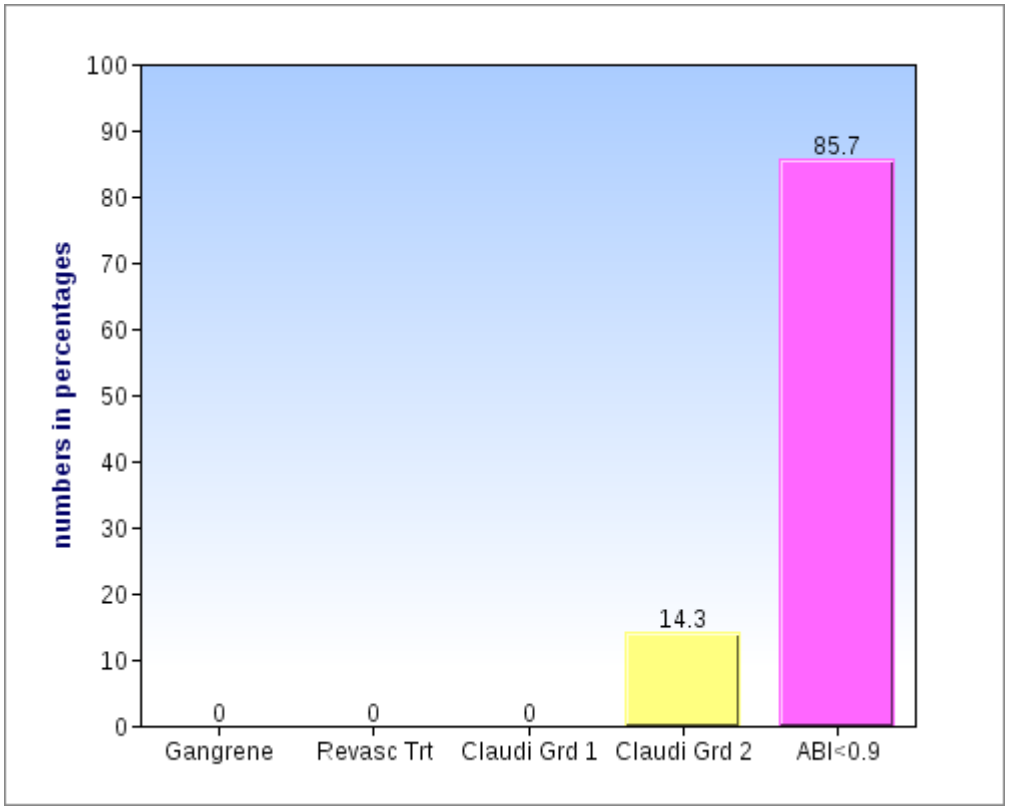


Figure 17: Criteria met by diabetic patients without the metabolic syndrome diagnosed with peripheral vascular disease

METABOLIC SYNDROME AND MACROVASCULAR COMPLICATIONS

N1 = 19 (Diabetics without the metabolic syndrome)

N2 = 58 (Diabetics with the metabolic syndrome)

OR : 1.69 , 95% CI : 0.6 – 4.8

P = 0.321

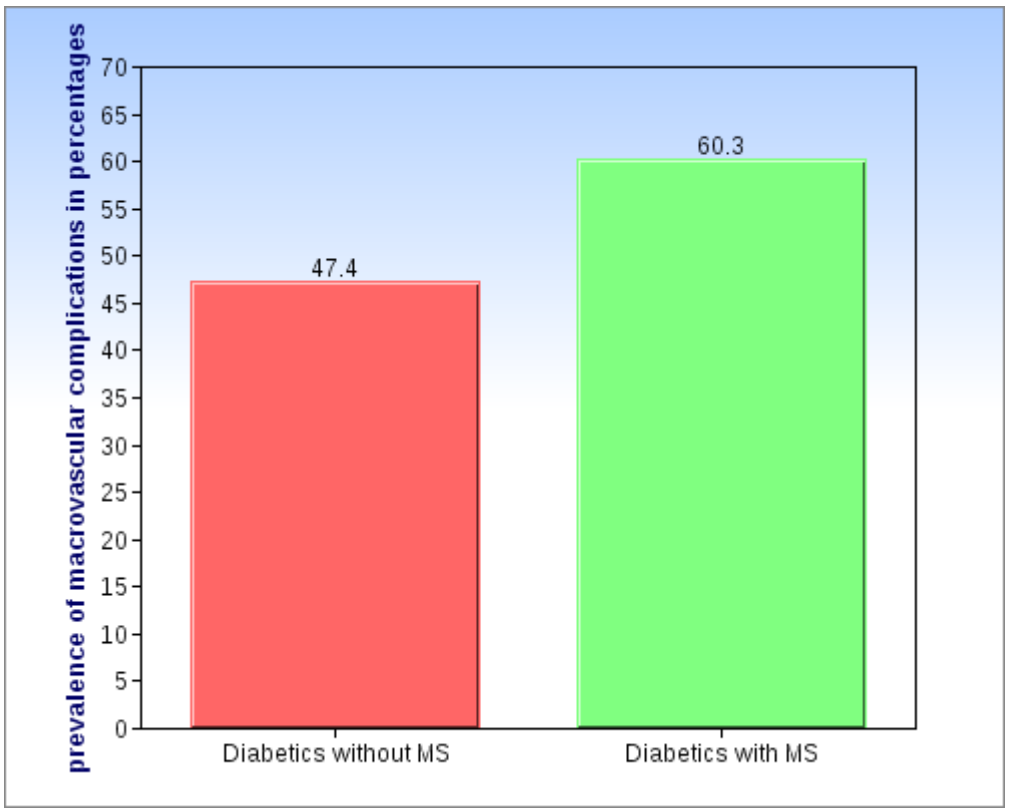


Figure 18: Prevalence of macrovascular complications (Ischemic heart disease or peripheral vascular disease) in diabetic patients with and without the metabolic syndrome

	MACROVASCULAR COMPLICATIONS	
METABOLIC SYNDROME	PRESENT	ABSENT
PRESENT	35	23
ABSENT	9	10

OR : 1.69 , 95% CI : 0.6 – 4.8, P = 0.321

Table 2 :The prevalence of macrovascular complications (Ischemic heart disease or peripheral vascular disease in diabetic patients with and without the metabolic syndrome

METABOLIC SYNDROME AND ISCHEMIC HEART DISEASE

N1 = 19 (Diabetics without the metabolic syndrome)

N2 = 58 (Diabetics with the metabolic syndrome)

OR : 3.52 , 95% CI : 0.7 – 16.9

P = 0.099

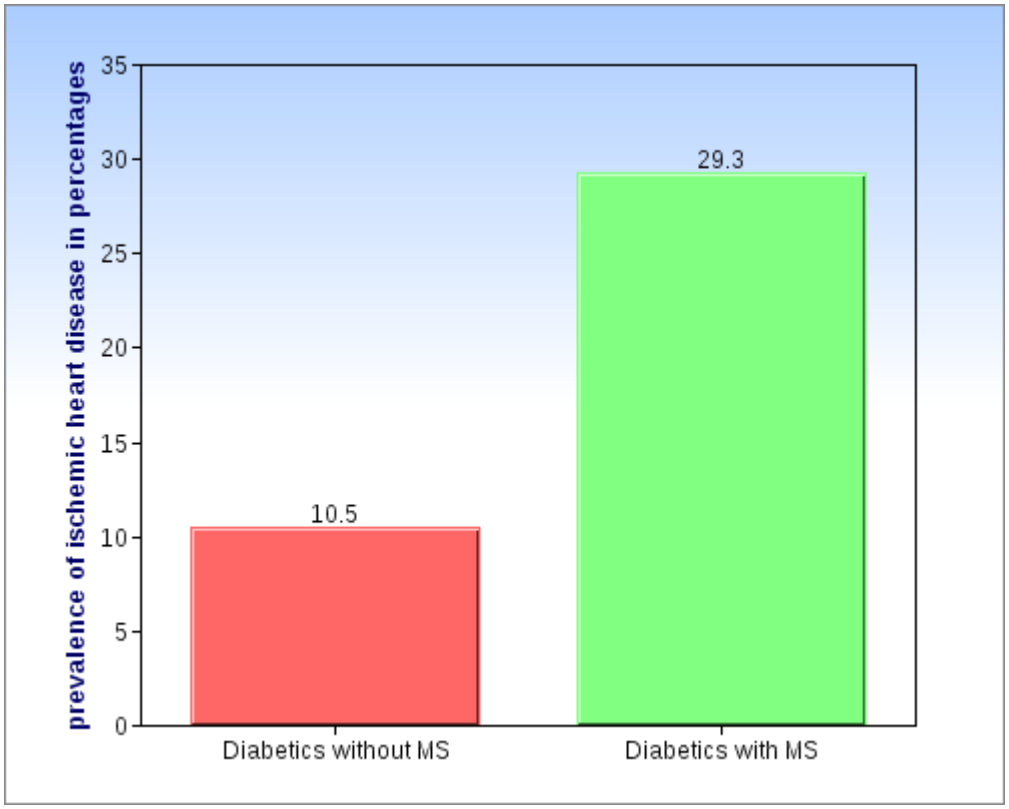


Figure 19 : Prevalence of ischemic heart disease in diabetic patients with and without the metabolic syndrome

		ISCHEMIC HEART DISEASE	
		PRESENT	ABSENT
METABOLIC SYNDROME	PRESENT	17	41
	ABSENT	2	17

OR : 3.52 , 95% CI : 0.7 – 16.9 , P = 0.099

Table 3:The prevalence of ischemic heart disease in diabetic patients with and without the metabolic syndrome

METABOLIC SYNDROME AND PERIPHERAL VASCULAR DISEASE

N1 = 19 (Diabetics without the metabolic syndrome)

N2 = 58 (Diabetics with the metabolic syndrome)

OR : 1.71 , 95% CI : 0.6 – 5.0

P = 0.318

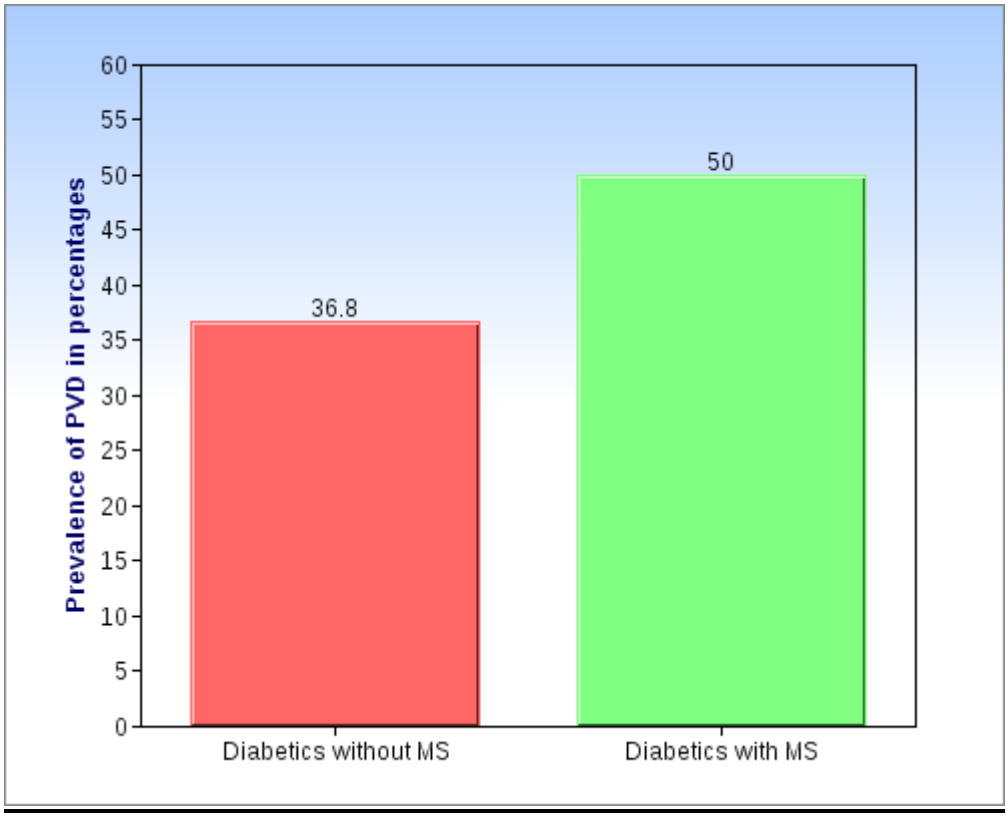


Figure 20: Prevalence of peripheral vascular disease in diabetic patients with and without the metabolic syndrome

METABOLIC SYNDROME	PERIPHERAL VASCULAR DISEASE: PRESENT	PERIPHERAL VASCULAR DISEASE: ABSENT
PRESENT	29	29
ABSENT	7	12

OR : 1.71 , 95% CI : 0.6 – 5.0, P = 0.318

Table 4 : The prevalence of peripheral vascular disease in diabetic patients with and without the metabolic syndrome

DISCUSSION

a) Metabolic syndrome in Diabetes mellitus:

Of the 77 patients included in the final analysis, 58 patients (75.3%) fulfilled the International Diabetes Federation Criteria for the metabolic syndrome. This high prevalence seen in diabetics is in keeping with the increased prevalence of the metabolic syndrome in diabetics as studied in an urban population in South India in 2005 which reported an overall prevalence of metabolic syndrome as per the IDF criteria to be 73.3% with a prevalence of 83.3% in women.(34)

In our study, the criteria that were fulfilled for categorising a diabetic patient to have metabolic syndrome in decreasing order of prevalence was low HDL levels less than 50 mg/dl (87.9%), Blood pressures >/= 130/85 mm of Hg or use of antihypertensives (63.8%) and TGL levels more than or equal to 150 mg/dl. (46.6%)

From results of the NCEP defined metabolic syndrome study done in the US, low levels of HDL was the least frequent criteria that was fulfilled by diabetic patients.(3) The high prevalence of diabetic patients with low levels of HDL in this study corroborates with evidence suggesting that South Asians have low HDL when compared to their Caucasian counterparts.(48).

In the study, only 52.8% of diabetic patients were on a regular exercise programme in addition to the use of oral antidiabetic agents or insulin. Diabetic patients with the metabolic syndrome should be encouraged to adhere to strict lifestyle modifications

which include regular moderate intenisty 30 minute exercise and atherogenic diet along with treatment of hypertension, diabetes and dyslipidemia as per current guidelines.

b) Association between Metabolic syndrome and macrovascular complications of diabetes mellitus

The study showed a trend towards significant association between metabolic syndrome and macrovascular complications of diabetes mellitus with the overall prevalence of macro vascular complications (both ischemic heart disease and peripheral vascular disease) being 60.3 % in diabetics with the metabolic syndrome and 47.4 % in those without the syndrome.(OR : 1.69, 95% CI 0.6 – 4.8,p = 0.321)

a) Ischemic Stroke:

None of the patients included in the analysis, both those with and without the metabolic syndrome had evidence of ischemic stroke as evidenced radiologically or clinically.

Studies done in the West have consistently shown that the metabolic syndrome as well as its individual determinants namely, hypertension, insulin resistance and abnormal lipid profile are independently and significantly related to cerebro vascular accidents.(49) However, the prevalence data for stroke in India is limited and the earliest available statistics from South India in published literature is a community based study done in Vellore which reported a crude prevalence of 57

per 100,000 and an annual incidence rate of 13 per 100,000.Similar studies done during the same decade show that the prevalence of stroke is lower in South Indian states when compared to the North.(41,50), which could possibly explain why there were no diabetic patients who were enrolled in the study with ischemic stroke.

b) Ischemic Heart Disease:

The ' NCEP- Defined Metabolic Syndrome, Diabetes and Prevalence of Coronary Heart Disease Among NHANES III Participants Age 50 years and older ' study showed that the prevalence of CHD in diabetic patients with metabolic syndrome was 19.2%, the prevalence of CHD in diabetic patients without metabolic syndrome was 7.4%.(3) CHD was diagnosed in the study based on a positive Rose's questionnaire or a self reported acute coronary event.(51)

In our study, the prevalence of Ischemic heart disease was 29.3% (17) in diabetics with the metabolic syndrome and 10.5 % in those without the metabolic syndrome (OR: 3.52, 95% CI 0.7 – 16.9, p = 0.099) .

Ischemic heart disease was diagnosed in our study based on either a previously documented coronary event or investigations favouring the same or a positive response to a modified Rose's questionnaire which included the symptomatology of angina or breathlessness on exertion and relieved by rest as an anginal equivalent in a diabetic. Including breathlessnesss on exertion as an anginal equivalent in the Rose's questionnaire is based on evidence which shows that

angina pectoris is a poor indicator of myocardial ischemia in the diabetic population.(52) This change in methodology could account for the increased prevalence of ischemic heart disease observed in our study.

Epidemiological studies have also shown that the Asian population genotype is more susceptible to coronary events , which accounts for their increased incidence in this population when compared to their Caucasian counterparts. In the CUPS study done in Chennai, where CAD was diagnosed based on a history of documented MI or ECG changes (Minnesota codes) the prevalence of CAD among diabetic patients was 21.4% when compared to those with normal glucose tolerance where the prevalence was 9.1%. (40,53).

c) Peripheral Vascular Disease:

The earliest published study looking at macro vascular complications in diabetics done in South India showed that in diabetics with disease of more than 25 years, the prevalence of peripheral vascular disease was 12.1% using the clinical criteria of claudication pain or absent pulses and 15.4% based on Doppler studies with peripheral vascular disease being diagnosed at an ABI less than 0.8.(43)

The Edinburgh claudication questionairre is a recommended epidemiological tool in surveys with a sensitivity of 91.3% (95% CI 88.1–94.5%) and a specificity of 99.3% (95% CI 98.9–100%).(54)

The use of the palpatory method of determining the ankle brachial index as a tool for diagnosing peripheral vascular disease was studied in a primary care setting which showed that the measurement of ABI by palpation in patients at intermediate cardiovascular risk, was a sufficiently sensitive method for it to be to used as a screening test for the exclusion of PAD.(55)

In our study, the prevalence of peripheral vascular disease was 50% in diabetics with the metabolic syndrome and 36.8 % in those without the syndrome (OR : 1.71, 95% CI 0.6 – 5.0, p = 0.318) .

PVD was diagnosed based on an ABI less than 0.9 in 6 out of 7 patients without the metabolic syndrome and 25 out of 29 patients with the metabolic syndrome. The low specificity of using the palpatory method of ABI could account for the higher prevalence of PVD obtained in the study. However if the cut off for ABI was taken as less than 0.8, the prevalence of PVD in diabetics with and without the metabolic syndrome was found to be 22.4% and 5.3% respectively.

There have been no studies in India addressing this issue and focussing on the urban poor population, a unique population influenced by the lifestyle changes of the cities and yet far behind in health awareness and access to the public heath care system in the cities.

The cross sectional study aimed to show a high prevalence of metabolic syndrome among diabetic women and a trend towards significant association between metabolic syndrome and macro vascular complications among female diabetic belonging to the

urban poor population of Vellore city. This has great implications on existing health services catering to the poor population in urban cities.

Metabolic syndrome is becoming a public health issue of populations belonging to the lower socio economic strata as well. With the ‘ urbanisation of poverty’, the poor living in Indian cities and towns are not only exposed to lifestyle changes which might contribute to its development, but lack of access to regular health care facilities delay recognition of this syndrome in diabetics and may lead to an increased incidence of the macro vascular complications of diabetes. This not only adds to mortality and morbidity but also imposes a huge economic burden on the urban poor.

The diagnosis of the metabolic syndrome in diabetics would serve as a cost effective clinical tool in identifying diabetic patients at a risk of developing macro vascular complications and would aid in initiating early and appropriate management strategies.

The treatment of metabolic syndrome in diabetics include reduction of abdominal obesity with diet and regular exercise, optimum glycaemic control, a goal serum LDL cholesterol of less than 100 mg/dL and lowering of blood pressures to less than 130/85 mm Hg.

The study was however not adequately powered curtailing its generalisability. Morever the population included in this study may not be truly representative of the urban poor population in the rest of India with respect to access to health care, health seeking behaviour or public awareness of health and disease. The patient population

included in the study had good access to a primary health hospital which has a dedicated health education programme addressing clinical assessment and management of their diabetic patients on an out patient basis. The prevalence of macro vascular complications in diabetics with metabolic syndrome may be higher in other states than that estimated in this study.

The strength of association between metabolic syndrome and macrovascular complications in diabetics as shown in this cross sectional study could pave the way for further prospective studies analysing the use of the metabolic syndrome as an independent predictor of cardio vascular risk and aid in early preventive management strategies in high risk individuals , thereby reducing the mortality, morbidity and economic burden associated with this disease in the urban population.

LIMITATIONS

1. The number of diabetics without the metabolic syndrome were considerably less than those with the syndrome. Therefore, though 106 patients were enrolled into the study within the given time frame , the numbers within each category was not adequate to elucidate associations by statistical analysis. Hence, the results of the primary objective of the study, aiming to look at association between metabolic syndrome and macrovascular complications of diabetes could not be accurately interpreted or extrapolated.

2. As the main missing data in the study included laboratory tests for fasting HDL and TGL, 29 patients lacking this data had to be excluded from the final statistical analysis.

CONCLUSIONS

Of the 77 female diabetics above the age of 30 years enrolled in the study, 58 patients (75.3%) satisfied the IDF criteria for metabolic syndrome, namely a waist circumference of more than or equal to 80 cm along with one of the following three criteria, HDL < 50 mg/dl , TGL > 150 mg/dl or use of statins or a BP>/=130/80 mm Hg or use of antihypertensives. The high prevalence of the metabolic syndrome is consistent with published reports from South India reporting a prevalence of 83.3% in women. (34) in an urban population in Chennai.

The criteria met by patients in decreasing order of frequency was low HDL levels in 87.9% of patients, BP>/=130/80 mg Hg or use of anti hypertensives in 63.8% and elevated TGL levels in 46.6% of patients. These results corroborate with the evidence that the Indian population have lower HDL's when compared to their Caucasian counterparts.

The study showed a trend towards significant association between metabolic syndrome and macro vascular complications of Diabetes Mellitus, namely, ischemic heart disease or peripheral vascular disease. The overall prevalence of macro vascular complications (both ischemic heart disease and peripheral vascular disease) was 60.3 % in diabetics with the metabolic syndrome and 47.4 % in those without the syndrome(OR : 1.69, 95% CI 0.6 – 4.8, p = 0.321). The prevalence of Ischemic heart disease was 29.3% in diabetics with the metabolic syndrome and 10.5 % in those without the syndrome (OR : 3.52, 95% CI 0.7 – 16.9, p = 0.099) .The prevalence of peripheral vascular disease was 50% in diabetics with the metabolic syndrome and 36.8 % in those without the syndrome (OR: 1.71, 95% CI 0.6 – 5.0, p = 0.318).

The cross sectional study provided a glimpse into the health parameters of women with Type 2 diabetes mellitus ,belonging to the urban poor population of Vellore, with particular reference to the prevalence of the metabolic syndrome and macrovascular complications of diabetes in this group.

The study reinforces the observation that the epidemiology of chronic diseases like Diabetes Mellitus in rural India is changing. The high prevalence of the metabolic syndrome as well as macrovascular complications of diabetes among diabetics in the urban rural population has great implications on the health statistics of the urban poor. The strength of association between metabolic syndrome and macrovascular complications in diabetics as shown in this study could support the clinical utility of the metabolic syndrome as a simple risk stratification tool in early identification and targeted management strategies aiding in reducing the burden of Diabetes Mellitus and its macro vascular complications on the urban poor population of India.

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APPENDIX

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
Director, Christian Counseling Centre
Editor, Indian Journal of Psychological Counseling
Chairperson, Ethics Committee, IRB

Dr. Alfred Job Daniel, MS Ortho
Chairperson, Research Committee &
Principal

Dr. Nihal Thomas
MD, MNAMS, DNB(Endo), FRACP(Endo), FRCP(Edin)
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

April 30, 2012

Dr. Roshine Mary Koshy
PG Registrar
Department of General Medicine
Christian Medical College
Vellore 632 002

Sub: **FLUID Research grant project NEW PROPOSAL:**
The metabolic syndrome and its association with macrovascular complications of Diabetes Mellitus in an urban poor population.
Dr. Roshine Mary Koshy, PG Registrar, General Medicine, Dr. O C Abraham, Medicine Unit I, Dr. Sushil Mathew, Dr. Venkatesan, Low Cost effective Care Unit.

Ref: IRB Min. No. 7745 dated 6.2.2012

Dear Dr. Koshy,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "The metabolic syndrome and its association with macrovascular complications of Diabetes Mellitus in an urban poor population" on February 6, 2012.

The Committees reviewed the following documents:

1. Format for application to IRB submission
2. Patient Information Sheet and Informed Consent Form (English and Tamil)
3. Patient Data Sheet
4. A CD containing documents 1-3

The following Institutional Review Board (Ethics Committee) members were present at the meeting held on February 6, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore- 632002.

INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE
VELLORE 632 002, INDIA

Dr.B.J.Prashantham, M.A.,M.A.,Dr.Min(Clinical)
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Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Name	Qualification	Designation	Other Affiliations
Dr. B.J.Prashantham	MA (Counseling), MA (Theology), Dr Min(Clinical)	Chairperson(IRB)& Director, Christian Counselling Centre	Non-CMC
Mr. Harikrishnan	BL	Lawyer	Non-CMC
Mrs. S. Pattabiraman	BSc, DSSA	Social Worker, Vellore	Non-CMC
Mrs. Ellen Ebenezer Benjamin (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Mrs. Shirley David (on behalf of Dr. Jayarani Premkumar)	M.Sc. (Nursing), Ph.D.	Nursing Superintendent, CMC.	
Dr. Nihal Thomas	MD MNAMS DNB(Endo)FRAC FRCP(Edin)	Secretary IRB (EC)& Dy. Chairperson (IRB), Professor of Endocrinology & Addl. Vice Principal (Research), CMC.	

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent and requires a copy of the final report.

A sum of ₹ 1,000/- (One thousand only) can be sanctioned for 12 months.

Yours sincerely,

Dr. Alfred Job Daniel
Principal & Chairperson (Research Committee)
Institutional Review Board

Chairperson (Research Committee) &
Principal
Christian Medical College
Vellore - 632 002, Tamil Nadu, India

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Total words	9763

First 100 words of your submission

THE METABOLIC SYNDROME AND ITS ASSOCIATION WITH MACRO VASCULAR COMPLICATIONS OF DIABETES MELLITUS AMONG WOMEN IN AN URBAN POOR POPULATION: A CROSS SECTIONAL STUDY A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE RULES AND REGULATIONS FOR THE MD BRANCH 1 GENERAL MEDICINE DEGREE EXAMINATION OF THE TAMIL NADU DR M.G.R MEDICAL UNIVERSITY TO BE HELD IN APRIL 2013 THE METABOLIC SYNDROME AND ITS ASSOCIATION WITH MACRO VASCULAR COMPLICATIONS OF DIABETES MELLITUS AMONG WOMEN IN AN URBAN POOR POPULATION: A CROSS SECTIONAL STUDY A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE RULES AND REGULATIONS FOR THE MD BRANCH 1 GENERAL MEDICINE DEGREE EXAMINATION OF THE TAMIL NADU DR M.G.R MEDICAL...

PARTICIPANT INFORMATION SHEET

Diabetes mellitus is a very common disease in our country and India is known to have the largest number of diabetic patients in the world.

Diabetic patients need to be regularly seen by their doctor to ensure that their sugars are under control. If not , patients can have complications like ischemic heart disease, strokes, visual problems and kidney disease.

There are some diabetic patients who also have hypertension, dyslipidemia or are obese. They are said to have ‘ the Metabolic syndrome’. They are more prone to develop ischemic heart disease and strokes. Hence, it is important to identify such patients so that they can be effectively treated.

In this study, you will be enrolled if you have been diagnosed to have Diabetes mellitus by your doctor in LCECU. You cannot be part of the study if you are less than 30 yrs of age or are pregnant.

You will examined by a doctor and will also be screened for other risk factors, namely hypertension , dyslipidemia and obesity. We will also evaluate you for evidence of ischemic heart disease or strokes in the past. We will also conduct a few routine blood tests.

As part of the study, we will be screening to see if you have the metabolic syndrome and also whether you have evidence of any complications of diabetes affecting your heart or your brain. This will help you to be more aware of your illness and receive effective timely treatment.

If you have any questions regarding the study, they can be conveyed to the doctor in charge at any time during the course of the study and every effort will be made to clarify your doubts.

Thank you for your co operation and time.

Dr Roshine Mary Koshy
TN council 81904
Ladies Interns Quarters
Christian Medical college and Hospital
Vellore
Tamil Nadu

Mobile no: 9442668213
Email: roshine@gmail.com

PATIENT CONSENT FORM

I have been explained in my own language the pertinent details of the study that I will be enrolled in after my consent. I understand that I will not be exposed to any additional risk being part of this study.

I understand that by being part of this study, I will be contributing to the scientific knowledge needed to improve treatment of diabetic patients.

I hereby give consent to be enrolled in the study.

Signature:

Name:

Address:

Contact no

Annexure IV: Patient data sheet

PATIENT DATA SHEET

Name:

Age:

Address: LCECU area: Yes/ No

Occupation:

History:

1.Year of diagnosis of DM / age at which DM was diagnosed

2. Clinical presentation when DM was first diagnosed:

a) Asymptomatic / incidentally diagnosed

b) Diabetic keto acidosis

c) Infection

d) ulcer/ Gangrene

e) Others

3. Macro vascular complications:

a) Ischemic stroke:

1) Date of occurrence of event :

2) Clinical findings - From medical records

- Clinical examination

a) Cerebral cortical involvement:
aphasia/neglect/motor deficit:

b) Brain stem involvement:
cranial nerve deficit:

c) Cerebellar dysfunction

3) Radiological findings:

a) Cortical/ subcortical /cerebellar /brain stem infarct of more than 1.5 cm on CT or MRI of brain (large artery occlusion)

b) Subcortical / brain stem infarct of less than 1.5 cm on CT or MRI of brain (small artery /lacunar infarcts)

4) Current neurological status/ deficits:

b) <u>Ischemic Heart disease:</u>

1) Previously diagnosed ischemic heart disease: Yes/No

a) Physician Documented Acute Coronary Syndrome requiring hospitalisation: Details

b) Exercise testing

c) Angiography

d) Revascularisation procedure

2) Definitive evidence of ischemic heart disease:

a) Angina (Rose Chest pain questionnaire): Yes/ No

c) <u>Peripheral vascular disease:</u>

Documented history of any of the following:

1. Gangrene of digits/limb: Yes/ No
2. History of revascularisation procedures: Yes/ No
3. History of Intermittent Claudication pain (as assessed by the Edinburg Claudication Questionairre): Yes/ No
4. Ankle Brachial Index by palpatory method:

Average of two reading of the highest systolic blood pressure in upper limbs: (nearest 2mm Hg):

Average of two reading of the highest systolic blood pressure in lower limbs: (nearest 2mm Hg):

Ankle brachial index:

4. Smoking: Currently smoking – Yes/ No

Past and current smoking history:

Duration of smoking:

Intensity (no of cigarettes/bidis per day)

Pack years:

Passive smoke exposure at home/work:

5. Alcohol consumption: Current consumption of alcohol

Past and current history of alcohol consumption

Duration:

Frequency:

Type of alcohol:

Quantity:

6. Physical activity level:

Past and current levels of physical activity :

Activity on job:

Activity in housework, child care:

Participation in regular exercise programme:
Specify

7. Menarchal state:

8. Family history of DM : Family tree

8.Family history of premature heart disease:

Cardio vascular disease or sudden cardiac death in a first degree male relative less than 55 yrs of age or a first degree female relative less

than 65 yrs of age:

Yes/ No

9. Current treatment:

a) Physical activity level:

b) Anti diabetic agents/Insulin: date, compliance

c) Other medication:
   - Antihypertensives:
   - Statins:
   - Antiplatelets:
   - Others:

Examination:

1. Weight (kg):
2. Height (cms):
3. Skin fold thickness:
4. Waist circumference (cms):
5. Blood pressure (mm Hg):

Single reading if already diagnosed hypertensive.
Average of three readings if not a known hypertensive.

Reading 1:

Reading 2:

Reading 3:

6. Ankle brachial Index:

Investigations

1.Diagnosis of DM based on:

a) Fasting plasma glucose >/= 126 mg/dL:
   Date:
   FPG:

b) 2 hr post prandial plasma glucose >/= 200 mg/dL:
   Date:
   2hr PP:

4. Fasting HDL

5. Fasting Triglycerides

Appendix 3

THE LONDON SCHOOL OF HYGIENE CHEST PAIN QUESTIONNAIRE — THE ROSE QUESTIONNAIRE[1]

(version for self-administration)

Part A

(a) Have you ever had any pain or discomfort in your chest?
1. Yes
2. No

(b) Do you get this pain or discomfort when you walk uphill or hurry?
1. Yes
2. No

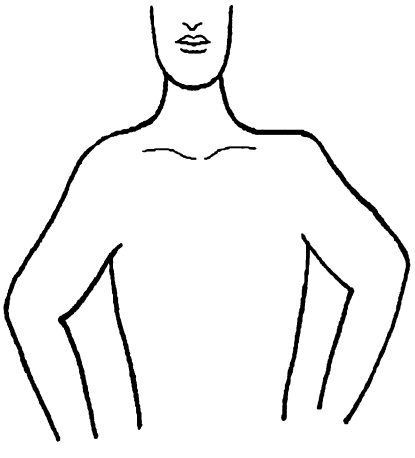
(c) Do you get it when you walk at an ordinary pace on the level?
1. Yes
2. No

(d) When you get any pain or discomfort in your chest what do you do?
1. Stop
2. Slow down
3. Continue at the same pace

(e) Does it go away when you stand still?
1. Yes
2. No

(f) How soon?
1. 10 minutes or less
2. More than 10 minutes

(g) Where do you get this pain or discomfort? Mark the place(s) with an X on the diagram.



Part B

Have you ever had a severe pain across the front of your chest lasting for half an hour or more?
1. Yes
2. No

DEFINITIONS OF POSITIVE CLASSIFICATIONS

A. Angina 'Yes' to (a) and (b),
'Stop' or 'Slow down' to (d),
'Yes' to (e),
'10 minutes or less' to (f).
Site must include either sternum (any level) or L. anterior chest and left arm.
GRADE 1 = 'No' to (c), GRADE 2 = 'Yes' to (c).
B. Possible infarction 'Yes' in this section.

Reference

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Appendix 4

THE EDINBURGH CLAUDICATION QUESTIONNAIRE[1]

(1) Do you get a pain or discomfort in your leg(s) when you walk?
Yes
No
I am unable to walk

If you answered "Yes" to question (1) - please answer the following questions.
Otherwise you need not continue.

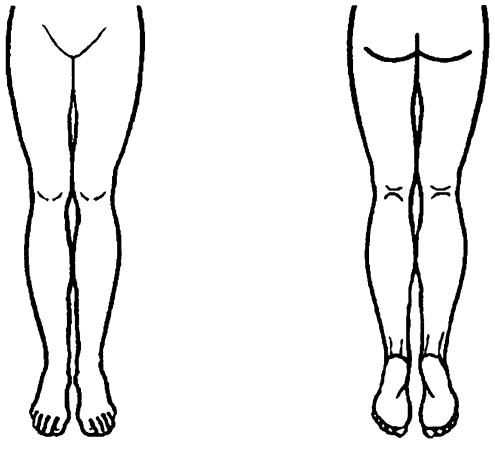
(2) Does this pain ever begin when you are standing still or sitting?
Yes
No

(3) Do you get it if you walk uphill or hurry?
Yes
No

(4) Do you get it when you walk at an ordinary pace on the level?
Yes
No

(5) What happens to it if you stand still?
Usually continues more than 10 minutes
Usually disappears in 10 minutes or less

(6) Where do you get this pain or discomfort? Mark the place(s) with "x" on the diagram below



Definition of positive classification requires all of the following responses:
'Yes' to (1),
'No' to (2),
'Yes' to (3), and
'Usually disappears in 10 minutes or less' to (5);
grade 1 = 'No' to (4) and grade 2 = 'Yes' to (4).

If these criteria are fulfilled, a definite claudicant is one who indicates pain in the calf, regardless of whether pain is also marked in other sites; a diagnosis of atypical claudication is made if pain is indicated in the thigh or buttock, in the absence of any calf pain. Subjects should not be considered to have claudication if pain is indicated in the hamstrings, feet, shins, joints or appears to radiate, in the absence of any pain in the calf.

Reference

1. Leng G, Fowkes F. The Edinburgh claudication questionnaire: an improved version of the WHO/Rose questionnaire for use in epidemiological surveys. *J Clin Epidemiol* 1992; **45:** 1101-1109.

HOSP NO	AGE	DUR DIAB	CF_ASYM	CF_CARD	CF_N SP	CF_INF	CF_GANG	CF_DKA
170094l	45	0	0	0	1	0	0	0
310207l	50	1	0	0	1	0	0	0
073093l	65	0	1	0	0	0	0	0
209411l	40	0	0	0	1	0	0	0
051494l	50	0	0	0	1	0	0	0
078907l	43	1	0	0	1	0	0	0
219011l	37	0	0	0	0	1	0	0
097512l	47	0	0	0	1	0	0	0
327505l	40	1	0	0	1	0	0	0
136804l	49	1	1	0	0	0	0	0
222603l	54	1	0	0	1	0	0	0
338799l	54	2	0	0	0	1	0	0
299705l	45	0	1	0	0	0	0	0
271101l	50	0	1	0	0	0	0	0
068111l	45	0	0	0	1	0	0	0
143111l	60	0	1	0	0	0	0	0
076411l	48	0	1	0	0	0	0	0
318699l	51	1	1	0	0	0	0	0
302608l	58	99	1	0	0	0	0	0
275649s	70	99	1	0	0	0	0	0
197994l	67	99	1	0	0	0	0	0
393201l	45	1	1	0	0	0	0	0
268108l	35	1	1	0	0	0	0	0
234210l	47	1	0	1	0	0	0	0
340347s	47	1	1	0	0	0	0	0

HOSP NO	AGE	DUR DIAB	CF_ASYM	CF_CARD	CF_N SP	CF_INF	CF_GANG	CF_DKA
170809l	60	1	0	0	1	0	0	0
119108l	47	1	0	0	1	0	0	0
072488l	50	1	1	0	0	0	0	0
168855s	60	1	0	0	0	1	0	0
081511l	42	0	1	0	0	0	0	0
123095l	65	1	1	0	0	0	0	0
059195l	60	2	1	0	0	0	0	0
230100l	80	1	1	0	0	0	0	0
094112l	60	0	1	0	0	0	0	0
129908l	65	1	1	0	0	0	0	0
230904l	60	1	0	0	0	1	0	0
037703l	60	2	0	0	0	0	0	0
110404l	50	1	1	0	0	0	0	0
074607l	65	1	1	0	0	0	0	0
176125s	70	1	0	1	0	0	0	0
340689s	65	1	1	0	0	0	0	0
087904l	65	2	0	1	0	0	0	0
097008l	40	1	1	0	0	0	0	0
034112l	41	1	1	0	0	0	0	0
175207l	60	1	1	0	0	0	0	0
157706l	55	1	1	0	0	0	0	0
295201l	60	0	1	0	0	0	0	0
238503l	60	1	1	0	0	0	0	0
055210l	65	1	1	0	0	0	0	0

HOSP NO	AGE	DUR DIAB	CF_ASYM	CF_CARD	CF_N SP	CF_INF	CF_GANG	CF_DKA
091309l	60	1	1	0	0	0	0	0
222974s	50	1	1	0	0	0	0	0
9999999	50	2	0	0	0	1	0	0
159689l	60	1	1	0	0	0	0	0
083412l	60	0	1	0	0	0	0	0
289602l	60	2	1	0	0	0	0	0
159705l	60	2	1	0	0	0	0	0
313004l	60	1	1	0	0	0	0	0
243511l	60	2	0	1	0	0	0	0
217008l	48	0	1	0	0	0	0	0
080607l	70	1	1	0	0	0	0	0
467306l	50	2	0	1	0	0	0	0
034912l	50	0	1	0	0	0	0	0
050511l	61	2	1	0	0	0	0	0
313506l	46	1	0	1	0	0	0	0
106911l	60	0	0	0	0	1	0	0
157607l	45	1	1	0	0	0	0	0
256004l	35	0	0	0	0	1	0	0
142810l	40	0	0	1	0	0	0	0
097712l	50	0	1	0	0	0	0	0
125204l	65	1	1	0	0	0	0	0
216501l	60	0	1	0	0	0	0	0
102104l	42	0	0	0	1	0	0	0
186694l	60	0	0	0	1	0	0	0
201689l	60	1	1	0	1	0	0	0

HOSP NO	AGE	DUR DIAB	CF_ASYM	CF_CARD	CF_N SP	CF_INF	CF_GANG	CF_DKA
045195l	55	1	0	0	1	0	0	0
476201l	48	0	1	0	0	0	0	0
013003l	38	1	1	0	0	0	0	0
209005l	56	0	0	0	1	0	0	0
098697l	55	1	0	0	0	1	0	0
329906l	62	2	1	0	0	0	0	0
089604l	40	1	1	0	0	0	0	0
341799l	46	1	1	0	0	0	0	0
155506l	50	0	1	0	0	0	0	0
117205l	75	2	1	0	0	0	0	0
068600l	70	1	0	1	0	0	0	0
070900l	65	1	1	0	0	0	0	0
100412l	35	0	1	0	0	0	0	0
422105l	59	1	1	0	0	0	0	0
026202l	65	2	0	0	0	1	0	0
084204l	40	0	1	0	0	0	0	0
242711l	38	0	0	0	1	0	0	0
123006l	36	0	0	0	1	0	0	0
060111l	65	1	1	0	0	0	0	0
319507l	57	0	1	0	0	0	0	0
121907l	62	1	1	0	0	0	0	0
132308l	60	1	1	0	0	0	0	0
188710l	60	1	1	0	0	0	0	0
1702/97a	63	1	1	0	0	0	0	0

HOSP NO	AGE	DUR DIAB	CF_ASYM	CF_CARD	CF_N SP	CF_INF	CF_GANG	CF_DKA
024305l	70	1	1	0	0	0		0
323399l	45	2	1	0	0	0	0	0
187802l	71	2	0	0	1	0	0	0
365406l	60	2	1	0	0	0	0	0

HOSP NO	IS_CF	IS_RF	IHD_PD	IHD_R1	IHD_R2	PVD_G	PVD_RV	PVD_IC1
170094l	0	0	0	0	0	0	0	0
310207l	0	0	0	0	0	0	0	0
073093l	0	0	0	0	1	0	0	0
209411l	0	0	0	1	0	0	0	0
051494l	0	0	0	0	0	0	0	0
078907l	0	0	0	1	0	0	0	0
219011l	0	0	0	0	0	0	0	0
097512l	0	0	0	0	0	0	0	0
327505l	0	0	0	0	0	0	0	0
136804l	0	0	1	0	1	0	0	0
222603l	0	0	0	1	0	0	0	0
338799l	0	0	0	0	0	0	0	0
299705l	0	0	0	0	0	0	0	0
271101l	0	0	0	0	0	0	0	0
068111l	0	0	0	0	0	0	0	0
143111l	0	0	0	0	0	0	0	0
076411l	0	0	0	0	0	0	0	0
318699l	0	0	0	0	1	0	0	1
302608l	0	0	0	0	0	0	0	0
275649s	0	0	0	0	0	0	0	0
197994l	0	0	0	0	0	0	0	0
393201l	0	0	0	0	0	0	0	0
268108l	0	0	0	0	0	0	0	0
234210l	0	0	0	1	0	0	0	0
340347s	0	0	0	0	0	0	0	0

HOSP NO	IS_CF	IS_RF	IHD_PD	IHD_R1	IHD_R2	PVD_G	PVD_RV	PVD_IC1
170809l	0	0	0	0	0	0	0	0
119108l	0	0	0	1	0	0	0	1
072488l	0	0	0	0	0	0	0	0
168855s	0	0	0	0	0	0	0	0
081511l	0	0	0	1	0	0	0	0
123095l	0	0	0	0	0	0	0	0
059195l	0	0	0	0	0	0	0	0
230100l	0	0	0	0	0	0	0	0
094112l	0	0	0	1	0	0	0	0
129908l	0	0	0	0	0	0	0	0
230904l	0	0	0	0	0	0	0	0
037703l	0	0	0	0	0	0	0	0
110404l	0	0	0	1	0	0	0	0
074607l	0	0	0	0	0	0	0	0
176125s	0	0	0	0	0	0	0	0
340689s	0	0	0	0	0	0	0	0
087904l	0	0	0	0	0	0	0	0
097008l	0	0	0	0	0	0	0	0
034112l	0	0	0	0	0	0	0	0
175207l	0	0	0	1	0	0	0	0
157706l	0	0	0	0	0	0	0	0
295201l	0	0	0	1	0	0	0	0
238503l	0	0	0	1	0	0	0	0
055210l	0	0	0	0	0	0	0	0

HOSP NO	IS_CF	IS_RF	IHD_PD	IHD_R1	IHD_R2	PVD_G	PVD_RV	PVD_IC1
091309l	0	0	0	0	0	0	0	0
222974s	0	0	0	0	0	0	0	0
9999999	0	0	0	1	0	0	0	0
159689l	0	0	0	1	0	0	0	1
083412l	0	0	0	0	0	0	0	0
289602l	0	0	0	0	0	0	0	0
159705l	0	0	0	0	0	0	0	0
313004l	0	0	0	0	0	0	0	0
243511l	0	0	0	0	1	0	0	0
217008l	0	0	0	0	1	0	0	0
080607l	0	0	0	0	0	0	0	1
467306l	0	0	0	1	0	0	0	0
034912l	0	0	0	0	0	0	0	0
050511l	0	0	0	0	0	0	0	0
313506l	0	0	0	0	0	0	0	0
106911l	0	0	0	0	0	0	0	0
157607l	0	0	0	0	0	0	0	0
256004l	0	0	0	0	0	0	0	0
142810l	0	0	0	0	0	0	0	0
097712l	0	0	0	0	0	0	0	0
125204l	0	0	0	0	1	0	0	0
216501l	0	0	0	0	0	0	0	0
102104l	0	0	0	0	0	0	0	0
186694l	0	0	0	0	0	0	0	0
201689l	0	0	0	0	1	0	0	1

HOSP NO	IS_CF	IS_RF	IHD_PD	IHD_R1	IHD_R2	PVD_G	PVD_RV	PVD_IC1
045195l	0	0	1	0	0	0	0	0
476201l	0	0	0	0	0	0	0	0
013003l	0	0	0	0	0	0	0	0
209005l	0	0	0	0	0	0	0	0
098697l	0	0	0	0	0	0	0	0
329906l	0	0	1	0	0	0	0	0
089604l	0	0	0	0	0	0	0	0
341799l	0	0	0	0	0	0	0	0
155506l	0	0	0	0	0	0	0	0
117205l	0	0	0	0	0	0	0	0
068600l	0	0	0	1	0	0	0	0
070900l	0	0	0	0	0	0	0	0
100412l	0	0	0	0	0	0	0	0
422105l	0	0	0	1	0	0	0	0
026202l	0	0	0	0	0	0	0	0
084204l	0	0	0	0	0	0	0	0
242711l	0	0	0	0	0	0	0	0
123006l	0	0	0	0	0	0	0	0
060111l	0	0	0	0	0	0	0	0
319507l	0	0	0	0	0	0	0	0
121907l	0	0	0	0	0	0	0	0
132308l	0	0	0	1	0	0	0	0
188710l	0	0	0	0	1	0	0	0
1702/97a	0	0	0	0	0	0	0	0

HOSP NO	IS_CF	IS_RF	IHD_PD	IHD_R1	IHD_R2	PVD_G	PVD_RV	PVD_IC1
024305l	0	0	0	0	1	0	0	0
323399l	0	0	0	0	1	0	0	0
187802l	0	0	0	0	1	0	0	0
365406l	0	0	0	0	0	0	0	0

HOSP NO	PVD_IC2	PVD_ABI	PA_E	POST MP	FAM_DM	FAM_IHD	T_INS	T_OHA
170094l	0	0	0	0	1	0	0	1
310207l	0	1	1	1	0	0	0	1
073093l	0	1	0	1	0	0	0	1
209411l	0	1	0	1	0	0	0	1
051494l	0	0	1	0	1	1	9	9
078907l	0	1	0	0	1	0	0	1
219011l	0	0	1	0	1	0	0	1
097512l	0	0	1	0	0	0	0	1
327505l	0	0	1	0	1	1	0	1
136804l	0	0	0	0	0	0	0	1
222603l	1	1	0	1	1	1	0	1
338799l	0	1	0	1	0	0	1	1
299705l	0	1	0	1	1	0	0	1
271101l	0	1	0	1	1	0	0	0
068111l	0	0	1	1	0	0	0	1
143111l	0	0	0	1	0	0	0	0
076411l	0	1	1	1	0	0	0	1
318699l	0	0	1	1	1	0	0	1
302608l	0	0	1	1	0	0	0	1
275649s	0	0	0	1	0	0	0	1
197994l	0	0	1	1	1	0	0	1
393201l	0	1	1	0	0	0	0	0
268108l	0	1	1	0	1	1	0	1
234210l	1	1	0	0	0	0	9	9
340347s	0	1	1	0	1	0	1	1

HOSP NO	PVD_IC2	PVD_ABI	PA_E	POST MP	FAM_DM	FAM_IHD	T_INS	T_OHA
170809l	0	0	0	1	0	0	0	1
119108l	0	0	1	1	0	0	0	1
072488l	0	0	1	1	1	0	0	1
168855s	0	0	1	1	0	0	0	1
081511l	0	0	0	0	1	0	0	0
123095l	0	0	1	1	0	0	0	1
059195l	0	0	1	1	0	0	1	1
230100l	0	1	0	1	0	0	0	1
094112l	0	0	1	1	0	0	0	1
129908l	0	0	0	1	0	0	0	1
230904l	0	0	1	1	1	0	0	1
037703l	0	1	0	1	0	0	0	1
110404l	0	0	1	0	0	0	0	1
074607l	0	0	0	1	0	0	0	1
176125s	0	1	0	1	0	0	1	1
340689s	0	0	1	1	1	0	0	1
087904l	0	0	0	1	1	0	1	1
097008l	0	1	1	1	1	0	0	1
034112l	0	0	0	0	1	0	0	1
175207l	1	0	0	1	0	0	0	1
157706l	0	0	1	1	0	0	0	1
295201l	0	1	1	1	0	0	0	1
238503l	0	0	0	1	0	0	0	1
055210l	0	0	0	1	0	0	9	9

HOSP NO	PVD_IC2	PVD_ABI	PA_E	POST MP	FAM_DM	FAM_IHD	T_INS	T_OHA
091309l	0	0	1	1	0	0	1	1
222974s	0	1	0	1	1	0	0	1
9999999	1	1	0	1	1	0	1	1
159689l	0	1	1	1	1	0	9	9
083412l	0	1	1	1	1	0	0	1
289602l	0	0	0	1	1	1	0	1
159705l	0	0	0	1	0	0	0	1
313004l	0	0	0	1	1	0	0	1
243511l	0	0	0	1	1	1	0	1
217008l	1	1	0	1	1	0	0	1
080607l	0	1	0	1	0	0	0	1
467306l	0	1	0	0	0	0	0	1
034912l	0	1	0	1	0	0	0	1
050511l	0	1	0	1	0	0	0	1
313506l	0	0	0	0	1	0	0	1
106911l	0	0	1	1	0	0	0	1
157607l	0	1	9	0	0	0	9	9
256004l	0	1	1	0	0	0	9	9
142810l	0	0	1	0	0	0	0	1
097712l	0	1	0	1	1	0	0	1
125204l	0	0	1	1	1	1	0	1
216501l	0	1	1	1	1	0	0	1
102104l	0	0	1	0	0	0	0	1
186694l	1	0	0	1	1	0	0	1
201689l	0	0	1	1	0	0	0	1

HOSP NO	PVD_IC2	PVD_ABI	PA_E	POST MP	FAM_DM	FAM_IHD	T_INS	T_OHA
045195l	0	0	1	1	0	0	0	1
476201l	0	0	1	0	0	0	0	1
013003l	0	0	1	0	1	0	0	1
209005l	0	0	0	1	1	0	0	1
098697l	0	1	1	1	1	0	0	1
329906l	0	1	1	1	1	0	0	1
089604l	0	1	1	0	0	0	0	1
341799l	0	0	1	1	1	0	0	1
155506l	0	0	0	1	0	0	0	1
117205l	0	0	0	1	1	0	0	1
068600l	0	0	0	1	1	0	1	1
070900l	0	0	0	1	1	0	0	1
100412l	0	1	0	0	0	0	0	0
422105l	0	0	1	1	0	0	0	1
026202l	0	0	1	1	1	0	0	1
084204l	0	0	1	0	0	0	0	1
242711l	0	0	1	0	1	1	0	1
123006l	0	0	0	0	0	0	0	1
060111l	0	1	0	1	0	0	0	1
319507l	0	0	1	1	0	0	0	1
121907l	0	0	1	1	1	0	0	1
132308l	0	0	1	1	1	0	0	1
188710l	1	1	0	1	1	0	1	1
1702/97a	0	0	1	1	1	0	0	1

HOSP NO	PVD_IC2	PVD_ABI	PA_E	POST MP	FAM_DM	FAM_IHD	T_INS	T_OHA
024305l	1	1	0	1	1	0	0	1
323399l	1	0	1	1	0	0	0	1
187802l	0	1	0	1	0	0	0	1
365406l	0	0	1	1	1	0	0	1

HOSP NO	T_HTNA	T_HTNB	T_HTNC	T_HTND	T_STAT	T_ASP	WEIGHT	HEIGHT
170094l	1	0	0	0	0	0	61	155
310207l	0	0	1	0	0	0	53	149
073093l	1	1	0	1	1	0	94	150
209411l	1	0	0	0	0	0	59	148
051494l	9	9	9	9	9	9	66	150
078907l	0	1	0	0	0	0	60	139
219011l	0	0	0	0	0	0	46	148
097512l	0	0	0	0	0	0	74	149
327505l	0	0	0	0	0	0	40	152
136804l	1	0	0	0	1	1	61	145
222603l	1	0	0	1	0	0	60	137
338799l	1	0	0	1	0	1	58	147
299705l	1	1	0	1	1	0	79	151
271101l	0	0	0	1	0	0	80	157
068111l	0	0	0	0	0	0	66	158
143111l	0	0	0	0	0	0	56	146
076411l	0	0	0	0	0	0	64	153
318699l	0	1	1	0	1	0	70	156
302608l	1	0	1	0	0	0	66	155
275649s	0	0	0	0	0	0	57	143
197994l	1	0	1	0	0	0	58	154
393201l	0	0	0	0	0	0	61	157
268108l	1	0	0	0	0	0	66	151
234210l	9	9	9	9	9	9	87	156
340347s	1	0	0	0	0	0	48	154

HOSP NO	T_HTNA	T_HTNB	T_HTNC	T_HTND	T_STAT	T_ASP	WEIGHT	HEIGHT
170809l	0	0	1	0	0	0	59	147
119108l	0	0	1	0	0	0	55	148
072488l	1	0	0	0	0	0	51	149
168855s	0	0	0	0	0	0	58	154
081511l	0	0	0	0	0	0	72	156
123095l	1	0	1	0	0	0	55	153
059195l	0	0	0	0	0	0	31	136
230100l	0	0	0	0	0	0	46	142
094112l	0	0	0	0	0	0	50	152
129908l	0	0	0	0	0	0	51	149
230904l	0	0	0	0	0	0	53	146
037703l	1	0	0	0	0	0	74	150
110404l	1	0	0	0	0	0	67	150
074607l	1	0	0	0	0	0	40	134
176125s	1	0	0	0	0	0	36	143
340689s	1	0	0	0	0	0	39	144
087904l	1	0	0	0	1	1	45	144
097008l	1	0	0	0	0	0	75	153
034112l	0	0	0	0	0	0	65	152
175207l	1	0	0	0	0	0	48	144
157706l	1	0	0	0	0	0	47	144
295201l	1	0	0	0	0	0	63	150
238503l	1	1	0	0	0	0	66	155
055210l	9	9	9	9	9	9	61	159

HOSP NO	T_HTNA	T_HTNB	T_HTNC	T_HTND	T_STAT	T_ASP	WEIGHT	HEIGHT
091309l	1	0	0	0	0	0	46	144
222974s	0	0	0	0	0	0	56	146
9999999	0	0	0	0	0	0	58	153
159689l	9	9	9	9	9	9	62	153
083412l	0	0	0	0	0	0	65	151
289602l	0	0	0	0	0	0	44	149
159705l	1	0	0	0	0	0	74	153
313004l	0	0	0	0	0	0	54	153
243511l	1	0	0	0	1	0	59	146
217008l	1	0	0	0	0	0	73	156
080607l	0	0	0	0	1	0	49	152
467306l	1	0	1	0	0	0	68	146
034912l	1	0	0	0	0	0	60	145
050511l	1	1	0	0	0	0	44	147
313506l	0	0	0	0	0	0	72	155
106911l	0	0	0	0	0	0	45	149
157607l	9	9	9	9	9	9	73	157
256004l	9	9	9	9	9	9	69	148
142810l	0	0	0	0	0	0	85	160
097712l	0	0	0	0	0	0	41	149
125204l	1	0	0	0	0	1	56	154
216501l	1	0	1	0	0	0	44	157
102104l	0	1	0	1	0	0	54	151
186694l	0	0	0	0	1	1	50	150
201689l	0	1	0	1	1	0	62	150

HOSP NO	T_HTNA	T_HTNB	T_HTNC	T_HTND	T_STAT	T_ASP	WEIGHT	HEIGHT
045195l	1	0	0	0	0	0	63	158
476201l	0	0	0	1	0	0	58	148
013003l	0	0	0	0	0	0	79	147
209005l	0	0	0	0	1	0	74	163
098697l	1	0	0	0	0	0	70	154
329906l	0	0	0	0	0	0	59	150
089604l	0	0	0	0	0	0	59	157
341799l	0	0	0	0	0	0	50	152
155506l	0	0	0	0	1	0	51	143
117205l	1	1	0	0	0	0	57	149
068600l	0	1	0	0	0	0	44	145
070900l	0	0	0	0	0	0	60	153
100412l	0	0	0	0	0	0	57	156
422105l	0	0	0	0	0	0	49	145
026202l	1	0	1	0	0	0	62	150
084204l	0	0	0	0	1	1	61	148
242711l	0	0	0	0	0	0	69	148
123006l	0	0	0	0	0	0	66	154
060111l	0	0	0	1	0	0	48	151
319507l	1	0	0	1	0	0	75	154
121907l	1	0	0	0	0	1	63	169
132308l	0	0	0	0	0	0	45	137
188710l	1	0	0	0	0	0	85	148
1702/97a	0	0	1	0	0	0	55	155

HOSP NO	T_HTNA	T_HTNB	T_HTNC	T_HTND	T_STAT	T_ASP	WEIGHT	HEIGHT
024305l	1	0	0	0	1	1	50	145
323399l	1	0	0	0	0	0	85	154
187802l	1	1	0	1	1	1	50	152
365406l	0	0	0	0	0	0	76	147

HOSP NO	BMI	WAIST C	BP_SYS	BP_DIAS	F HDL	F TGL	MET SYN	MET_SYN*
170094l	25.63	84	140	80	38	132	1	1
310207l	24.03	86	170	70	46	230	1	1
073093l	41.77	106	120	80	9	9	1	1*
209411l	27.01	96	160	90	27	395	1	1
051494l	29.33	92	120	86	36	139	1	1
078907l	31.05	93	110	80	9	9	1	1*
219011l	21.76	72	110	80	49	68	0	0
097512l	33.33	103	110	80	32	194	1	1
327505l	17.43	72	120	80	45	120	0	0
136804l	28.93	85	150	70	40	145	1	1
222603l	31.96	87	170	90	48	217	1	1
338799l	26.84	90	130	80	38	117	1	1
299705l	34.69	109	120	80	36	204	1	1
271101l	32.45	101	130	90	42	134	1	1
068111l	26.61	86	120	80	61	65	0	0
143111l	26.45	87	110	80	9	9	9	9
076411l	27.53	96	140	90	42	133	1	1
318699l	28.94	91	140	80	49	69	1	1
302608l	27.65	91	140	80	49	116	1	1
275649s	28.08	86	120	80	28	139	1	1
197994l	24.68	87	120	80	9	9	1	1*
393201l	24.91	82	120	80	45	73	1	1
268108l	29.33	91	160	90	57	127	1	1
234210l	35.75	103	140	90	9	9	1	1*
340347s	20.37	76	110	80	40	95	0	0

HOSP NO	BMI	WAIST C	BP_SYS	BP_DIAS	F HDL	F TGL	MET SYN	MET_SYN*
170809l	27.3	85	120	80	66	162	1	1
119108l	25.11	92	110	80	40	158	1	1
072488l	22.97	86	120	70	52	146	1	1
168855s	24.62	92	130	70	9	9	9	9
081511l	29.59	95	110	80	33	141	1	1
123095l	23.65	97	140	70	9	9	9	9
059195l	16.76	52	120	80	75	62	0	0
230100l	23	82	110	70	38	251	1	1
094112l	21.64	82	140	70	9	9	9	9
129908l	22.97	78	110	80	9	9	0	0*
230904l	25.03	95	120	80	43	128	1	1
037703l	33.11	100	130	80	46	361	1	1
110404l	29.78	88	130	80	56	57	1	1
074607l	22.27	76	130	80	33	192	0	0
176125s	17.6	58	120	80	9	9	0	0*
340689s	19.06	69	140	80	56	55	0	0
087904l	21.7	90	160	90	29	317	1	1
097008l	32.05	98	120	80	43	131	1	1
034112l	28.13	82	120	80	37	180	1	1
175207l	23.18	79	120	80	9	9	0	0*
157706l	22.7	81	120	80	49	131	1	1
295201l	28	96	120	80	38	186	1	1
238503l	27.5	98	160	90	9	9	1	1*
055210l	24.3	85	120	80	43	251	1	1

HOSP NO	BMI	WAIST C	BP_SYS	BP_DIAS	F HDL	F TGL	MET SYN	MET_SYN*
091309l	22.27	75	156	90	41	330	0	0
222974s	26.29	88	130	80	36	132	1	1
9999999	24.79	85	110	80	9	9	1	1*
159689l	26.5	84	120	80	33	208	1	1
083412l	28.51	89	110	80	38	54	1	1
289602l	19.82	76	120	80	30	170	0	0
159705l	31.62	94	120	80	35	180	1	1
313004l	23.08	85	120	80	37	75	1	1
243511l	27.7	90	120	80	34	227	1	1
217008l	30.04	94	110	80	36	182	1	1
080607l	21.21	89	110	80	39	301	1	1
467306l	31.92	100	130	70	47	127	1	1
034912l	29.85	89	120	80	43	144	1	1
050511l	20.37	78	120	80	36	250	0	0
313506l	35.29	88	110	80	43	248	1	1
106911l	20.27	77	110	80	9	9	0	0*
157607l	29.67	93	130	80	55	113	1	1
256004l	31.51	92	110	80	41	287	1	1
142810l	33.2	101	110	80	9	9	9	9
097712l	18.47	77	110	80	9	9	0	0*
125204l	23.63	89	100	80	35	169	1	1
216501l	17.89	77	150	70	53	212	0	0
102104l	23.68	75	130	80	9	9	0	0*
186694l	22.22	79	110	80	50	204	0	0
201689l	27.56	89	110	80	31	272	1	1

HOSP NO	BMI	WAIST C	BP_SYS	BP_DIAS	F HDL	F TGL	MET SYN	MET_SYN*
045195l	25.3	84	120	80	54	184	1	1
476201l	26.48	87	120	80	69	119	1	1
013003l	36.57	103	110	80	46	142	1	1
209005l	27.82	97	110	80	9	9	1	1*
098697l	29.54	94	110	90	35	167	1	1
329906l	26.22	94	130	80	9	9	9	9
089604l	23.98	86	110	70	57	49	0	0
341799l	21.65	76	110	70	29	78	0	0
155506l	25	87	110	80	32	232	1	1
117205l	25.68	93	120	80	34	99	1	1
068600l	20.95	72	110	80	40	197	0	0
070900l	25.64	92	120	80	42	80	1	1
100412l	27.94	83	110	80	58	98	0	0
422105l	22.58	79	120	70	42	99	0	0
026202l	27.6	93	120	80	9	9	9	9
084204l	27.8	85	110	80	44	222	1	1
242711l	31.5	97	100	80	37	138	1	1
123006l	27.8	81	120	80	36	90	1	1
060111l	21.1	75	140	80	36	146	0	0
319507l	31.6	94	120	80	9	9	1	1*
121907l	22.1	78	110	80	39	113	0	0
132308l	24	73	110	80	9	9	0	0*
188710l	38.8	103	140	80	9	9	1	1*
1702/97a	22.9	81	110	80	9	9	1	1*

HOSP NO	BMI	WAIST C	BP_SYS	BP_DIAS	F HDL	F TGL	MET SYN	MET_SYN*
024305l	23.8	76	130	80	9	9	0	0*
323399l	35.8	106	120	90	42	119	1	1
187802l	21.6	78	120	80	9	9	0	0*
365406l	35.2	102	140	80	9	9	9	9

Annexure VII: List of figures and tables

Tables:

Figures: