CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017

Dissertation submitted to

THE TAMIL NADU Dr. MGR MEDICAL UNIVERSITY In partial fulfillment of the requirements for the degree of

M.D. BRANCH XV COMMUNITY MEDICINE



THE TAMIL NADU Dr. MGR MEDICAL UNIVERSITY, CHENNAI, TAMIL NADU.

MAY - 2019

CERTIFICATE OF THE GUIDE

This is to certify that the dissertation titled "CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017 " is a bonafide work carried out by Dr. F. MUNIRA, Post Graduate student in the Institute of Community Medicine, Madras Medical College, Chennai-3, under my supervision and guidance towards partial fulfillment of the requirements for the degree of M.D. Branch XV Community Medicine and is being submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai.

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DECLARATION

I, solemnly declare that the dissertation titled "CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017" was done by me under the guidance and supervision of Dr. T.S. SELVAVINAYAGAM, M.D., D.P.H., D.N.B., Professor, Institute of Community Medicine, Madras Medical College, Chennai-3. The dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University towards the partial fulfillment of the requirement for the award of M.D. degree (Branch XV) in Community Medicine.

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ACKNOWLEDGEMENT

I gratefully acknowledge and sincerely thank **Dr.R.Jayanthi MD**, **Dean**, **Madras Medical College, Chennai-3** for granting me permission to carry out this community based study.

I would like to extend my sincere and profound gratitude to my guide **Dr.T.S. SELVAVINAYAGAM, M.D., D.P.H., D.N.B.,** Director & Professor, Institute of Community Medicine, Madras Medical College and my co-guide **Dr. RAMASUBRAMANIAN, M.D.,** Associate Professor, Institute of Community Medicine, Madras Medical College, Chennai-3 for having been the ever present guiding and driving force behind my study and without whom, this study would not have taken its present shape.

I also thank **Dr. JOY PATRICIA PUSHPARANI, M.D.,** Professor, Institute of Community Medicine, Madras Medical College, for giving her valuable suggestions for the study.

I also thank **Dr. R. ARUNMOZHI, M.D., Ph.D.,** Professor, Institute of Community Medicine, Madras Medical College, for her extended support and encouragement during the course of this study.

I also thank **Dr.A.CHITRA**, **M.D.**, Professor, Institute of Community Medicine, Madras Medical College, for giving her valuable suggestions for the study. I also thank **Dr. S. SUDHARSHINI, M.D.,** Associate Professor, Institute of Community Medicine, Madras Medical College, for her extended support and encouragement during the course of this study.

I also thank **ALL THE FACULTIES** of Institute of Community Medicine, Madras Medical College for their valuable suggestions and encouragement during the course of the study.

I would like to always remember with extreme sense of thankfulness, the cooperation and constructive criticism shown by my fellow post graduate colleagues and friends. I also thank my friends who helped me in data collection.

I deeply thank my family members for their moral support and love they have for me. Above all, I thank God for his grace and blessings which helped me to complete this task successfully.

I extend my gratitude to The Director of Public Health, The Deputy Director of Health Services of Sankarankoil Health Unit District and the Medical Officer of the Primary Health Centres and the Village Health Centres for their extended support in helping me in obtaining information about the diabetic patients in the locality.

Finally, I thank all the study participants for their active cooperation and participation in the study without whom this study would not have become a reality.

ABBREVIATIONS

ABI	Ankle Brachial Index	
AGE	Advanced End Glycation Product	
BMI	Body Mass Index	
BP	Blood Pressure	
CI	Confidence Interval	
CKD	Chronic Kidney Disease	
CORE	Centre of Observational and Real World Evidence	
CRP	C-Reactive Protein	
CURES	Chennai Urban Rural Epidemiology Study	
CVD	Cardio Vascular Disease	
DCCT	Diabetic Control of Complication Trial	
DR	Diabetic retinopathy	
HR	Heart Rate	
HUD	Health Unit District	
ICMR	Indian Council of Medical Research	
IDF	International Diabetes Federation	
LEAD	Lower Extremity Arterial Disease	
MI	Myocardial infarction	
NFHS	National Family Health Survey	
NO	Nitric Oxide	
РКС	Protein Kinase c	

PSN	Peripheral Sensory Neuropathy	
PVD	Peripheral Vascular Disease	
RAS	Reactive Angiotensin System	
ROS	Reactive Oxygen Species	
SD	Standard Deviation	
SPSS	Statistical Package for the Social Sciences	
T2DM	Type 2 Diabetes Mellitus	
UKPDS	United Kingdom Prospective and Diabetic Study	
VPT	Vibration Perception Threshold	
WHO	World Health Organization	
WHR	Waist Hip Ratio	

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Introduction

1. INTRODUCTION

The world in the recent decades is experiencing a shift from infectious diseases towards Non communicable diseases like Diabetes Mellitus, Hypertension, coronary artery disease etc⁽¹⁾ Chronic non - communicable diseases are in an increasing trend among the adult population and also gaining importance in both developed and developing countries.⁽²⁾ Diabetes Mellitus (DM) is one of the most prevalent non communicable diseases. According to Diabetes Foundation of India, 50.9 million people suffer from diabetes and the figure is likely to go up to 80 million by 2025 making India, the diabetes capital of the world.⁽³⁾ Urbanization, rapid socioeconomic development and the increased susceptibility of Indians have led to the explosive increase in the prevalence of Diabetes in India. Not only the prevalence of diabetes, but also the prevalence of complications of Diabetes is on the rise.

Diabetes and its complications imposes large economic burden on the health care system. The burden can be measured in terms of direct medical cost, indirect costs associated with productivity loss, premature mortality and the negative impact of diabetes on Nations' Gross Domestic Product (GDP).⁽⁴⁾

1.1. DIABETES MELLITUS

Diabetes Mellitus (DM) is characterized by chronic state of hyperglycemia resulting from a diversity of etiologies, including environmental and genetic, also jointly.⁽²⁾ There are two broad categories of diabetes mellitus, designated type 1 and type 2 DM. Type 1 Diabetes is the result of complete (or) near total insulin

deficiency. Type 2 Diabetes (T2DM) is much more common than type 1.Type 2 DM is a heterogeneous group of disorders characterized by variable degree of insulin resistance, impaired insulin secretion and increased glucose production. When not adequately treated or not diagnosed earlier the diabetics are at the risk of developing multiple chronic complications.⁽²⁾

1.2. GLOBAL TRENDS IN DIABETES

Globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. The global prevalence (age-standardized) of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population.⁽⁵⁾

In the recent decades, the prevalence of diabetes has increased faster in low- and middle-income countries as compared to high-income countries.⁽⁶⁾

At the time of diagnosis >10% of patients have Peripheral Vascular Disease (PVD) and Peripheral Neuropathy (PN) which are important risk factors for foot disease. Increase global prevalence of T2DM will also increase the prevalence of diabetic foot ulcer. According to studies, worldwide 3-10% of people with diabetes have a foot ulcer. Amputation due to diabetic foot ulcer is one of the preventable complications by proper foot care.⁽⁶⁾

1.3. DIABETIC TRENDS IN INDIA

In 2000, India with 31.7 million diabetics had the maximum number followed by China. The global prevalence is expected to double in 2030 with the

maximum increase in India. According to study done in 2017, the prevalence of diabetes in India is 7.5%. Around 10.4% of adult population in Tamilnadu has diabetes. ⁽⁷⁾

Increasing prevalence of Diabetes in India will increase the complications. In India attention on peripheral vascular disease and peripheral neuropathy is very less when compared to other complications of diabetes. Although the prevalence of diabetics in rural areas is less compared to urban areas, the accessibility to health care and the knowledge of foot care and screening of diabetic complications are very poor in rural areas than urban.⁽⁷⁾

1.4. MICRO & MACRO VASCULAR COMPLICATIONS

Diabetes of all types can lead to complications in many systems of the body and can increase the overall risk of dying prematurely. Acute and chronic complications of diabetes mellitus are main causes of hospital admissions in developing countries. The Asian Indian phenotype is more prone to insulin resistance, lower adiponectin and high sensitive c-reactive protein levels. Moreover, many Asian patients had more evidence of macro and micro vascular diseases at the time of diagnosis of diabetes.⁽⁸⁾

Micro Vascular complications include Diabetic nephropathy, neuropathy and retinopathy. Studies conducted in Punjab revealed that the prevalence of retinopathy was 23.7%. The prevalence of nephropathy in Asian Indians in UK was much higher (22.3%) as compared to the prevalence in those Asian Indians in Chennai (5.5%).⁽⁸⁾ Diabetic neuropathy is one of the most common micro vascular complications of type 2 diabetes mellitus. The risk of developing neuropathy is directly proportional to the magnitude and duration of Hyperglycemia. Neuropathies are differentiated into peripheral and autonomic. Peripheral neuropathy (PN) is common cause of foot ulcer. Non healing foot ulcers may end up in lower extremity amputation. Indian studies showed that the prevalence of neuropathy among Indians was 27.5%. From many studies, it was observed that peripheral neuropathy was more prevalent as compared to nephropathy and retinopathy⁽⁸⁾.

Macro vascular complications include peripheral vascular disease [PVD], cardiovascular disease [CVD], and cerebrovascular events [CVA]. Peripheral vascular disease is defined as disease of any blood vessel that is not part of heart or brain .the most common form of peripheral vascular disease (PVD) is observed in lower extremity which is termed as the lower extremity arterial disease [LEAD].⁽⁸⁾ From previously done Indian studies, it was evident that the prevalence of CVD was 11.4% which was much higher as compared to other studies.⁽⁸⁾

Peripheral Vascular Disease (PVD) is characterized by atherosclerotic occlusive disease of the lower extremities and is a marker for athero thrombotic disease in other vascular beds. The prevalence of peripheral vascular disease among Diabetics according to studies is 3.2% in South India⁽⁹⁾.

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Justification

2. JUSTIFICATION

- In spite of increasing burden of diabetes, there is an inadequate resource in the health care system in terms of funding, material and man power for screening of diabetes and its complications as well as the treatment.
- The complications of Diabetes are easily preventable by adequate health education of the patients which is also lacking in our country.
- In a developing country like India, with growing economy, there should be more focus on the primary prevention aspects rather than secondary and tertiary prevention aspects.
- Diabetes and its complications bring about substantial economic loss to people with diabetes and their families and to health systems and national economies in terms of direct medical costs and loss of work and wages.
- Diabetes increases the risk of lower extremity amputation because of infected non healing ulcers. Amputation is the only preventable complication of diabetes mellitus.
- Early screening of Peripheral Vascular Disease and Peripheral Neuropathy with improving knowledge about foot care among diabetic patient with or without complication will reduce the prevalence of foot ulcers and henceforth the prevalence of lower extremity amputation.

- Tirunelveli has the highest rural parts in the Tamilnadu state and there is very few study was conducted related to prevalence of complication of Type 2 Diabetes Mellitus⁽¹⁰⁾.
- Many of the studies done previously among diabetics to identify the risk factors of micro and macro vascular complications in Type 2 Diabetes patients were mainly done in other countries. There is relative lack of studies to identify the prevalence and risk factors among rural diabetics in India. This study makes an attempt to identify them.

Review of Literature

3. REVIEW OF LITERATURE

3.1 DIABETES MELLITUS-DEFINITION

Diabetes Mellitus is a clinical syndrome comprising a heterogeneous group of metabolic diseases that are characterized by chronic hyperglycaemia and disturbances in carbohydrate, fat and protein metabolism, secondary to defects in insulin secretion, insulin action or both.⁽¹¹⁾

3.2 GLOBAL BURDEN

In 2013, the International Diabetes Federation (IDF) has estimated that globally about 382 million people are affected by diabetes mellitus and predicted that the number will rise beyond 592 million in less than 25 years. 80% of the global prevalence belongs to low and middle income countries. China, India and USA contribute to 50% of the prevalence having 98.4, 65.1 and 24.4 millions of diabetics respectively.^(6,12)

ICMR – INDIA B study was conducted in 2 phases. I phase was conducted in 4 States – Tamilnadu, Chandigarh, Jharkhand and Maharashtra between November 2008 to April 2010. The prevalence of Diabetes in Tamilnadu was 10.4 percentage.⁽⁷⁾

II Phase was conducted in 11 States – Andhra Pradesh, Bihar, Gujarat, Karnataka, Punjab, Assam, Mizoram, Arunachalpradesh, Tripura, Megalaya and Manipur from 2012 to 2015. Over all prevalence of DM in both the phases was 7.3 percentage. (Bihar - 4.3%, Punjab - 10%).⁽⁷⁾

3.3 CLASSIFICATION OF DIABETES MELLITUS

The following are the different types of Diabetes mellitus

- 1. Type1 Diabetes
- 2. Type2 Diabetes
- 3. Gestational Diabetes
- 4. Impaired Glucose Tolerance⁽¹¹⁾

Among the different types, 90 to 95% of diabetes belongs to type2 diabetes⁽¹³⁾

3.4 RISK FACTORS OF DIABETES

Indians are more prone to the risk of developing diabetes because of increasing urbanization, industrialization and globalization. Also it has been proposed that obesity, Body mass index (BMI), age, family history of diabetes, genetic factors and lack of exercise contribute to increased risk.⁽²⁾

3.5 COMORBIDITY IN TYPE 2 DIABETES

About 67% of adult diabetic patients have hypertension also. Hypertension and diabetes are found to share common risk factors and complications. Macro vascular complications like coronary artery disease, stroke, congestive heart failure, and peripheral vascular disease are sequelae to both diabetes and hypertension.⁽¹⁴⁾

United Kingdom Prospective Diabetes Study (UKPDS) 36 prospective observational study by Amanda I Adler et al shows that a decrease of every 10 mmHg of mean systolic blood pressure was associated with 12% reduction in the risk for any complication related to diabetes and 15% reduction of risk for death due to diabetes, 11% for myocardial infarction and 13% for micro vascular complication.⁽¹⁵⁾

A study done by the Centre of Observational and Real-world Evidence (CORE) showed that the most common co-morbidities with diabetes are hypertension (82.1%), hyperlipidaemia (77.2%), chronic kidney disease (24.1%) and cardiovascular disease (21.6%).⁽¹⁶⁾

3.6 COMPLICATIONS OF DIABETES

3.6.1 Micro vascular Complications

- 1. Neuropathy
- 2. Retinopathy
- 3. Nephropathy^(1,11)

3.6.2 Macro vascular Complications

- 1. Cardio Vascular Disease
- 2. Cerebral Vascular Disease
- 3. Peripheral Vascular Disease^(2,11)

3.7 PATHOPHYSIOLOGY OF MICRO AND MACRO VASCULAR COMPLICATIONS

The micro vascular and macro vascular complications of diabetes mellitus have similar etiologic characteristics. Chronic hyperglycaemia plays a major role in developing vascular complications of diabetes by means of many metabolic and

structural derangements of blood vessels, like production of advanced glycation end products (AGE), abnormal production of signalling cascades (e g..Protein kinase C (PKC)), elevated production of reactive oxygen species (ROS) and abnormal stimulation of renin angiotensin system (RAS).^(12,17)

3.7.1 MICROVASCULAR COMPLICATIONS

The UK prospective and diabetes study (UKPDS) and Diabetes Control of Complication Trial (DCCT) show the association between glucose control and micro vascular complication of diabetes. Micro vascular diseases are seen predominantly in those tissues where the glucose uptake is independent of insulin like kidney, retina, and vascular endothelium. So in these tissues glucose uptake is directly related blood glucose levels. Tissue damage in these areas is due to glucose mediated endothelial damage, oxidative stress because of super oxide over production, production of sorbitol and end product of glycation in state of hyperglycaemia. These metabolic injuries may cause endothelial damages that will lead to changes in the blood flow and endothelial permeability. The changes in the endothelial permeability lead to extra vascular protein deposition and coagulation resulting in organ dysfunction. Increased blood pressure is found to be an independent risk factor for the retinopathy and nephropathy.⁽¹⁷⁾

3.7.1.1 Diabetic retinopathy

Diabetic retinopathy (DR) is one of the micro vascular complications that can affect peripheral retina or the macula or both and will lead to disability and blindness in people with diabetes. The severity of DR ranges from nonproliferative and pre-proliferative to severe proliferative. Total or partial loss of vision occurs through the vitreous haemorrhage or retinal detachment. Prevalence of DR increases through the duration of diabetes and also with insulin resistance and hypertension and higher body mass index. Hyperglycaemic condition leads to impairment of retinal blood flow, inflammatory cell adhesion to retinal blood vessel, and capillary blockage can result in hypoxia and damage to retina.⁽¹⁷⁾

3.7.1.2 Diabetic neuropathy

Neuropathy is the most common complication of diabetes. Nerves are damaged due to hyperglycaemia and decreased blood flow by endothelial injury of small blood vessels supplying them. Diabetic neuropathy is of two types, namely peripheral neuropathy and autonomic neuropathy. Characteristics of peripheral neuropathy includes axonal thickening with progression to axonal loss, basement membrane thickenings, pericyte loss, loss of microfilaments like actin and myosin, decreased blood flow to C fibres leading to decreased nerve perfusion and endometrial hypoxia. Neuronal microvasculature is impaired in presence of hyper glycaemia and this impairment is mediated through initiation of signalling cascade, leading to the demyelination associated with diabetes. Diabetes-related cardiac autonomic neuropathy is often associated with tachycardia, exercise intolerance, resting heart rate variability, orthostasis, silent myocardial infarction.⁽¹⁷⁾

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Peripheral neuropathy is clinically presented with neurologic symptoms like loss of sensations or abnormal sensations. It may lead to problems in lower limbs leading to diabetic foot.

It can be clinically diagnosed by

- Biothesiometer vibration sensation is tested for using the measurement of vibration perception threshold
- Monofilament test- Using Simmes-Winston monofilament to test touch sensation over 10 sites in both feet
- Nerve conduction test⁽¹⁸⁾

3.7.1.3 Diabetic nephropathy

Diabetic nephropathy is defined as proteinuria or albuminuria in diabetic patients. In proteinuria patient excretes more than 500mg of protein in 24 hours of urine where as in micro albuminuria the patient excretes 30-299 mg of micro albumin in 24 hours urine collection. About 7% of the diabetics have nephropathy at the time of diagnosis. As per the UKPDS study, the incidence of microalbuminuria per year is 2% and the prevalence after 10 years of diagnosis of diabetes is 25%. The following are some of the pathological changes that occur in diabetic nephropathy.^(12,17)

- Increased glomerular membrane thickness
- Micro aneurysm formation
- Messangial nodule formation⁽¹⁷⁾

3.7.2 MACROVASCULAR COMPLICATIONS

The important pathological mechanism for macro vascular complication is the process of atherosclerosis formation. Because of the endothelial injury from hyperglycaemia oxidized lipid from LDL (low density lipoproteins) particles accumulate in the endothelial wall of arteries. Angiotensin II may promote the oxidation of such particles. Monocytes then infiltrate the arterial wall and differentiate into macrophages, which engulf the lipid cells to form foam cells. This will in turn stimulate T-lymphocytes. These T-lymphocytes will activate smooth muscle proliferation and collagen accumulation. Finally, a lipid rich atherosclerotic lesion with fibrous cap forms and occludes the blood vessel. Rupture of this lesion can cause infarction.⁽¹³⁾

3.7.2.1 Cardio vascular disease

Patients with diabetes have 4 fold increased risk of developing cardio vascular disease (CVD) and diabetes is an independent risk factor for CVD. Cardio vascular disease is the primary cause of death in patients with both type1 and type2 diabetes. People with diabetes have 5 fold greater risk of developing myocardial infarction (MI) and poor long term prognosis after MI leading to increased risk of congestive heart failure and death.⁽¹⁷⁾

3.7.2.2 Stroke

Diabetes affects the intra cranial and extra cranial blood circulation by atherosclerosis and diabetes alone is a strong predictor for stroke.⁽¹⁷⁾

3.7.2.3 Peripheral arterial disease

Peripheral arterial disease is due to occlusion of arteries supplying lower extremities. It causes intermittent claudication and pain, commonly during exercise and activity thereby leads to impairment of daily activities. Epidemiological studies show an increased association between peripheral arterial disease and diabetes. The abnormal metabolic state in the diabetes causes inflammatory response that increases C-reactive protein (CRP). CRP act as a pro coagulation factor that increases tissue factor, decreases the endothelial cell nitric oxide (NO) synthase and inhibits plasmin synthesis. This, in turn facilitates platelets aggregation. In addition, production of endothelin-1, increases the vascular tone and vascular smooth muscle cell growth and migration leading to progression of atherosclerotic lesion. A severe peripheral vascular disease (PVD) ends in foot ulceration and amputation. People with diabetes are at 15 times more risk of having amputation.^(13,16)

PVD can be diagnosed by

- Presence of claudication pain.
- Clinical examination Absence of Dorsalis pedis and posterior tibial arterial pulse.

• Ankle Brachial blood pressure index (ABI) by Vascular Doppler method. Neuropathy and peripheral arterial disease lead to foot ulcer in diabetic patients, which when left untreated, results in amputation of foot.

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3.8 RISK FACTORS FOR MICRO AND MACRO VASCULAR COMPLICATION^(19,20)

- Hyper glycaemia: Uncontrolled chronic higher blood glucose level is found to be a risk factor for all the complications of diabetes including retinopathy, neuropathy, nephropathy, Cardio vascular disease (CVD) and PAD. Hyperglycaemia is the main factor for pathogenesis of cardiovascular complication of diabetes. It increases production of Reactive Oxygen Species (ROS) and decreases the NO, which causes endothelial dysfunction and thereby develops complications
- Hyper insulinemia: It is seen as a risk factor for cerebro vascular disease
- Age: Age is found to be a risk factor for many complications of diabetes namely retinopathy, neuropathy, nephropathy and cardio vascular disease but not for cerebrovascular disease and peripheral arterial disease
- **Tobacco use**: This is established as a risk factor for all micro and macro vascular complications except peripheral arterial disease
- **Dyslipidaemia** : This is detected as a risk factor for retinopathy, neuropathy, nephropathy and cardiovascular disease, but not for cerebrovascular disease and peripheral arterial disease
- **Pregnancy**: Pregnancy is found to be a risk factor for retinopathy

- **Renal disease**: This is also established as one of the risk factors for retinopathy
- Elevated homocystein level: This is found to be only associated with developing diabetes associated retinopathy.
- **Duration of diabetes mellitus**: Chronic diabetes mellitus is mostly seen to be associated with developing neuropathy than other complication
- **Hypertension**: this is seen to be associated with developing neuropathy than macro vascular diseases CVD, PAD and cerebro vascular disease
- **Obesity**: Obesity is found to be significantly associated with developing diabetes associated cerebro vascular disease and PAD.
- **Physical inactivity**: This is seen to be commonly associated with macro vascular complications like cardio vascular disease and PAD.
- Proteinuria, microalbuminuria, heart failure, hyperuricemia, blood inflammatory molecules, blood fibrinogen level, keto acidosis, coronary artery disease also the other risk factors established for developing diabetes associated micro and macro vascular complications.

3.9 PREVALENCE OF MICRO AND VASCULAR COMPLICATIONS IN TYPE 2 DIABETIC PATHENTS

3.9.1 A cross sectional study in Guntur

A cross sectional study done in Guntur was done by ChinnariHarika et al among 1200 diabetic patients in 2012. The prevalence of neuropathy (31.5%), nephropathy (26%), cardio-vascular diseases (19.1%), retinopathy (13.5%) and peripheral vascular diseases (9.75%) was found. Age of the participants was found to be associated with all the complications, whereas duration of disease was associated with retinopathy, nephropathy, neuropathy and PVD. Glycated haemoglobin was associated with retinopathy, nephropathy and neuropathy. Systolic Blood pressure was associated with retinopathy, nephropathy, nephropathy, neuropathy and CAD. There was a significant association between the diastolic blood pressure and complications like retinopathy, neuropathy and CAD.⁽²¹⁾

3.9.2 A cross sectional baseline study in Danish DD2 cohort

Anne Gedebjerg et al study was conducted on 6958 type 2 diabetic patients. In this cohort study, 12% had microvascular complications during the time of enrolment to the study whereas 17% had macrovascular complication and 6% had both. Out of those with micro vascular complications, 13% had retinopathy, 4% had neuropathy and 3% had nephropathy. Out of the diabetic patients with macro vascular complications, 15% had ischemic heart disease, 5% had atherosclerotic cerebrovascular disease and 2% had atherosclerotic peripheral vascular disease. In this study, higher age, male sex, high waist hip ratio (WHR) and BMI were found to be associated with presence of both micro and macro vascular complications and macro-vascular complications alone. Micro-vascular complications were found to be increasing in patients of age more than 70 years and not influenced by sex⁽²²⁾.

3.9.3 Epidemiology of diabetic complications in Korea

An article by Jung Hee Kim compiles the results of various studies all over the world. In this article, there was a prevalence of 14.9% of hypertension among the diabetic patients and 3.2% of them had dyslipidemia. 44.6% of them had neuropathy. The prevalences of coronary artery disease, cerebro vascular disease and peripheral artery disease among the diabetic population are 8.7%, 6.7% and 3% respectively. 4.4% of the diabetic patients had diabetic foot and 44.8% of the patients were with an amputated foot. 23.6% of the diabetics had cardio vascular complication. The prevalence of macro vascular complication was 10.8%.

40-44% of the diabetic patients had peripheral neuropathy. Age duration of diabetes and glycemic control were found to be closely associated with micro-vascular complications. Cardio vascular disease is the major cause for death and disability among the diabetics.⁽²³⁾

3.9.4 Prevalence of Peripheral neuropathy in Sweden

A research by Lars Karvestedt et al shows that the prevalence of peripheral sensory neuropathy (PSN) was 15% by monofilament, 24% by tuning fork, and 28% by vibration perception threshold (VPT). 29% had retinopathy, 22% had nephropathy. The prevalence of macro vascular complications was 62% for CVD, 26% for PVD and 11% for cerebrovascular lesion (CVL).⁽²⁴⁾

3.9.5 A cross sectional study in Bikaner, India

A study done in India by RP Agrawal et al revealed that among 4400 type 2 diabetic patients, 32.5% had nephropathy, 30.1% had neuropathy, 28.9% had retinopathy, 19.2% had coronary artery disease and 18.1% had peripheral vascular disease. In India, a high prevalence of micro and macro vascular complications especially nephropathy and neuropathy was documented.

Age of the diabetic patients was found significantly associated with retinopathy, nephropathy, neuropathy, CAD and PVD. Duration of the diabetes was found to be statistically associated with the complications like retinopathy, nephropathy, neuropathy and PVD. Systolic blood pressure of the diabetics was associated with retinopathy, nephropathy, neuropathy and CAD. There was a significant association between diastolic blood pressure and the following complications : retinopathy, neuropathy and CAD. Glycated haemoglobin A1c (HbA1c) was seen to be associated with retinopathy, nephropathy, nephropathy, nephropathy and neuropathy.⁽²⁵⁾

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3.10 ASSOCIATION OF DURATION OF DIABETES AND AGE WITH COMPLICATIONS OF TYPE 2 DIABETIC PATIENTS

3.10.1 Multicentric study in UK

A multicentre study was conducted in 6487 diabetic patients by MJ Young et al. 37.4% were type 1 diabetic patients .The overall prevalence of diabetic peripheral neuropathy was 28.5%. Type 2 diabetics (32%) had statistically significant higher prevalence of peripheral neuropathy than type 1 diabetic patients (22.7%) (p value <0.001). The prevalence of peripheral neuropathy was found to increase with the duration of diabetes, 20.8% in those with diabetes for less than 5 years and 36.8% in those with 10 years of diabetes. Hence, the duration of diabetes was found to have a statistically significant association with developing complications. Similarly, the prevalence of peripheral neuropathy was found to increase with the age of the patients, from 5% in those of age 20-29 years to 44.2% in those of age 70-79 years.⁽²⁶⁾

3.10.2 A study in Chennai, India

A study by S.A Ashok et al was conducted in type 2 diabetic patients, attending a diabetes centre in south India in 2002. In this study, 19.1% had peripheral neuropathy. Using neuropathy as dependent variable in multiple regression, age and duration were found to be associated with the development of the complication. The prevalence of peripheral neuropathy within the first 5 years of diagnosis of diabetes 7.9% and after 20 years of duration of DM is 54.2%. Age

and duration of diabetes in the patients were found to be statistically significant with complications of type 2 diabetes.⁽²⁷⁾

3.10.3 Peripheral neuropathy in Type 2 Diabetes in a tertiary care setting in Chandigarh

A research was conducted by Dipika bansal et al in a tertiary care centre Chandigarh, India. The study was conducted among 1637 previously known diabetic patients and 369 newly diagnosed diabetic patients. The overall prevalence of diabetic peripheral neuropathy was 29.2%. This was higher among previously known diabetic patients which than that among newly diagnosed diabetes mellitus patients. Regression analysis showed age, socioeconomic status, duration of diabetes, dyslipidaemia, glycated haemoglobin, hypertension, the presence of other micro as well as macro vascular complications and alcoholic status, were statistically associated with development of diabetic peripheral neuropathy.⁽²⁸⁾

3.10.4 An epidemiological research in Korea

Sang Youl Rhee et al had done a research in which multiple studies in Asia, Europe and America were considered. The study shows that among the patients with diabetes of above 40 years of age, 20% were associated with symptoms of peripheral vascular disease and 11.9% had low ankle brachial index (ABI). 1.9% of those with low ABI were in the age group of 40 to 59 years and 8.1% were in the age group of 60 to 74 years and 17.5% in the age group of >75 years. Hence, the age and ethnicity of diabetic patients was proved to be

statistically significant with complications of type 2 diabetes. The prevalence of PVD among diabetics with cardiovascular complications was found to be higher than the others.⁽²⁹⁾

3.10.5 CURES III study

The Chennai urban rural epidemiology study (CURES III), 2014 in India by Rajendra Pradeepa et al was conducted in 1755 South Indian diabetic patients to detect the prevalence of PVD in type 2 diabetes. The prevalence of peripheral vascular disease was found to be 8.3%. Those known to be diabetic patients previously had higher prevalence (8.6%) than the newly detected diabetic patients (less than 3 months of duration) (6.8%).

The prevalence was found to be higher among women (10.2%) than men (5.7%) and the difference was statistically significant (p value 0.001). Also, the diabetics with PVD had longer duration of disease (p value <0.001), higher HbA1c (p value 0.003), higher value of serum LDL cholesterol (p value 0.037). Also, those with PVD were found to have higher prevalence of CVD and neuropathy. And, the prevalence of smoking was found to be greater among the patients with PVD.⁽³⁰⁾

3.11 ASSOCIATION OF HYPER GLYCEMIA WITH COMPLICATION OF TYPE 2 DIABETIC PATIENTS

3.11.1 A study in UK

Stratton IM et al had studied the association of glycaemia with microvascular and macro-vascular complications of type 2 diabetes in an observational
study in 2002 in England, Scotland and Ireland. The prevalence of PVD and amputation was seen to be 0.3%, when HbA1c was less than 6%. There was an increase in prevalence of PVD and amputation to about 4.9% with the increase of HbA1c to more than 9%. Similarly, the proportion of micro vascular diseases increased from 3.9% to 32.8% with an increase of HbA1c from <6% to >10%. This study showed a strong statistical association between hyperglycemia and complications of diabetes.⁽³¹⁾

3.12 PREVALENCE OF DIABETIC FOOT ULCRES

Ch Manes et al had done a study titled "Prevalence of Diabetic Neuropathy and Foot Ulceration: Identification of Potential Risk Factors -A Population-Based Study" among 821 diabetic patients that included 304 men, 781 type 2 patients. The prevalence of neuropathy was 33.5% (95% confidence limits 30.3-36.7%) and prevalence of foot ulcer was 4.75 % (95% confidence limits 3.3-6.2%) the prevalence of peripheral vascular disease (PVD) was 12.7 % (95% confidence limits 10.7-14.7%). Patients with foot ulcers had more severe neuropathy than those without foot ulcers and the difference was found to be statistically significant.⁽³²⁾

A study by M.A.Tresierra et al done in 2017 in Peru was conducted among 322 type-2 diabetic patients where the prevalence of peripheral arterial disease with foot ulcers among 129 patients. Here, the prevalence of peripheral arterial diseases and foot ulcers were significantly associated. ⁽³²⁾

Objectives

4. OBJECTIVES

4.1 Primary Objective

• To estimate the prevalence of Peripheral Vascular Disease (PVD) and Peripheral Neuropathy (PN) in Type 2 Diabetic patients.

4.2 Secondary Objective

• To assess the factors influencing occurrence of Peripheral Vascular Disease (PVD) and Peripheral Neuropathy (PN) in diabetes.

Methodology

5. METHODOLOGY

5.1. Study Design:

The study was conducted as a community based cross sectional study to estimate the prevalence of peripheral vascular disease and peripheral neuropathy among Type 2 Diabetics in rural areas of Tirunelveli district.

5.2. Study Place:

The study was conducted in rural areas of Sankarankovil HUD (Health Unit District), Tirunelveli district, Tamilnadu.

5.3. Study Duration:

The study was carried out from July 2017- August2018. The period of field study was from September 2017 to January 2018.

5.4. Study Population:

The study population comprised of Type2 diabetes mellitus patients in selected areas of Sankarankovil HUD of Tirunelveli district.

5.5. Inclusion Criteria:

- Both men and women of age 30 years and above previously diagnosed as Type 2 Diabetes Mellitus
- Those who are giving informed consent

5.6. Exclusion Criteria:

- Those who are not available on 2 consecutive visits at the time of data collection.
- Those who are very sick and not able to respond.

5.7. Sample Size Calculation:

5.7.1 Sample Size:

Sample size was calculated using the formula:

$$N = \frac{Z_{\alpha}^{2}pq}{d^{2}}$$

Where,

Z_{α} is the	standard normal deviate corresponding to 95%
	confidence interval (=1.96)
p is the	proportion of target population estimated to have a
	particular characteristic, q is (100- p)
d is the	absolute precision.

Based on the study titled "A study on prevalence of micro and macro vascular complications in type 2 diabetes and their risk factor, Guntur, India", the prevalence of peripheral vascular disease was 9.75%, neuropathy 31.5% .⁽²¹⁾ The confidence interval is fixed to be 95% and a absolute precision of 5% is expected.

The Sample size is calculated to be

Sample size N = $\frac{1.96*1.96*9.75*90.25}{5*5} = 135$

Assuming a non-response rate of 10%, the sample size was arrived around

150 [135+13.5 = 149]

5.8 Sampling method

The samples were selected through Multi stage sampling.



List of households was obtained from Village Health Nurse from which 1 house hold was chosen randomly. After that next consecutive houses were selected. If there were more than 1 diabetics in the same house, all of them were included in the study.

5.9. Study tool:

The study was conducted as one to one interview with a questionnaire which also included Anthropometric measurements, Blood Pressure measurement, Clinical examination and Specific examination using 10gm Monofilament Test and by measuring Ankle Brachial Index. (Annexure 3)

It consisted of two parts

SECTION 1:

It contained questions related to socio demographic details, factors influencing complication of Diabetes Mellitus, signs and symptoms of Peripheral Vascular Disease and Peripheral Neuropathy.

SECTION 2:

Clinical examination:

This constituted General examination, Measurement of Height, Weight, Pulse, Blood pressure by automatic blood pressure device and specific local examination of Ankle Brachial Pressure (ABP) index by automatic blood pressure device for peripheral vascular disease and 10mg monofilament test for peripheral neuropathy.

5.10 Operational definition:

5.10.1 Socio Demographic details

- a. Age: Completed age at the time of interview was considered for the study.
- b. Employed: the person who got daily or fixed monthly salary for their work.
- c. Unemployed: the person who did not get any salary or wages.
- d. Socio-Economic Status: The socio-economic status was classified based on Modified B.G. Prasad classification, 2017⁽³⁴⁾.
- e. Smoker: Every individual who declared himself a smoker during data collection is considered smoker, regardless of the number of cigarettes consumed.

f. Alcoholic: Every individual who reported consumption of alcohol during data collection is considered alcoholic, regardless of amount of alcohol consumed.

5.10.2 Anthropometry

- Height measurement: Standing height was measured by a Stadiometer. In elders having kypho-scoliosis half – arm span was measured and multiplied by two to get the height.
- Weight measurement: By Bathroom scale weighing machine. The nearest whole number was taken. Correction to zero was ensured before each reading.
- BMI: Formula: weight (kg) / $[height (m)]^2$
- Body Mass Index is defined as a person's weight in kilograms divided by the square of height in meters (kg/m²). According to the BMI, the individuals are classified into various categories of obesity. Those individuals whose BMI is within 18.5 to 24.99 were considered as normal and 25 and above as Overweight or Obesity. ⁽³⁵⁾
- **Blood pressure:** Blood Pressure was measured with Omron automatic blood pressure machine in the both side ankle and arm in lying posture.

5.10.3 Health Profile

Pre-existing diseases such as Hypertension, Coronary Heart Disease, Chronic kidney disease, Cancer and Stroke in the present study are taken into account from the medical records available.

5.10.4 General examination:

Pallor, Pitting pedal edema, Blood pressure

5.10.5 Local examination of legs (Annexure 8)

Both the lower limbs were examined for the presence of the following.

- 1. Color change
- 2. Corns / Callus
 - Callus: thickened layers of skin on feet, this may be due to poor fitting shoes and barefoot working
 - Corns: Distinctly shaped callus commonly seen on bottom of feet
- 3. Ulcer
 - A break in skin or mucous membrane with loss of surface tissue, disintegration and necrosis of epithelial tissue

4. Wasting

- Decrease in muscle mass of legs and feet
- 5. Neurological examination of legs by Monofilament test(Annexure 9)

It is done with Semmes-weinstein 5.07/10gm mono filament, to test the sensation over 10 sites including dorsum and sole of both feet.

Procedure:⁽³⁶⁾

- a. Examination was done in a quiet and relaxed room.
- b. The patient was well explained about the procedure
- c. The procedure was performed after obtaining consent from the patient.

- d. The patient was made to lay down in supine position in such a manner that the patient cannot see the examining site.
- e. Firstly, before examining the foot, the monofilament was tested on the inner side of wrist so the patient knows the feel of touch with monofilament.
- f. The monofilament was tested in each site of the foot for about 2 seconds in sufficient force so as to cause the filament to bend or buckle. All the ten sites of the foot are tested in the same way.
- g. If there is any corn, callus or ulcer present in the testing site, the monofilament was applied not directly on them but at the site adjacent to it.
- h. If the patient not able to feel the touch, that site was re-examined 2 times.

a. Interpretation

If the patient not able to feel the touch with monofilament in 4 out of 10 sites, the patient was diagnosed to have loss of protective sense due to neuropathy.⁽³⁷⁾

Semmes-weinstein Monofilament Examination (SWME) had a sensitivity ranging from 57% to 93%, specificity ranging from 75% to 100%, positive predictive value (PPV) ranging from 84% to 100% and negative predictive value (NPV) ranging from 36% to 94%.⁽³⁸⁾

6. Diabetic neuropathic symptoms score (DNS)

If the patient had any one of the following symptoms like numbress, burning sensation, pricking sensation over the feet and unsteadiness in gait the patient diagnosed to have a peripheral neuropathy. Each symptoms gain a score of one ,maximum score is 4, minimum score is 0. If score is 0 there is no neuropathy.⁽³⁹⁾

The patient was diagnosed with Peripheral neuropathy if the patient had any one of the following –

- Monofilament test positive
- Diabetic Neuropathy Symptom Score ≥ 1

5.10.6 Ankle Brachial Index (ABI)

Ankle brachial blood pressure index was calculated by measuring the ratio between ankle and brachial systolic blood pressure. In this study, blood pressure was measured using Omron automatic blood pressure machine.

Procedure:

The procedure was done after explaining the procedure and getting consent for the same. The blood pressure was recorded in both arms and both legs separately with the patient lying in supine position.

S. No.	ABI value	Interpretations
1.	0.91-1.4	Normal
2	0.8-0.9	Mild PVD
3	0.5-0.8	Moderate PVD
4	<0.5	Severe PVD
5	>1.4	Hardening of blood vessel

In this study, ankle pressure measured by using Omron automatic blood pressure machine instead of using Doppler machine based on the study by Bachemol et al 2009 which states that the correlations between the automatic and Doppler methods were good in left and right legs (r = 0.84 and 0.78, respectively; p < 0.001). In subjects with an abnormal automatic index, correlations with Doppler indexes were good in both legs (r = 0.67, p < 0.001). In terms of detecting an abnormal index in a routine preventive examination, the automatic method had good sensitivity (92%), specificity (98%), positive predictive value (86%), negative predictive value (99%) and accuracy (97% compared with the Doppler method).⁽⁴⁰⁾

If the ABI of the patient is less than or equal to 0.9, the patient was diagnosed to have peripheral vascular disease. ABI index more than 0.9 is Normal.⁽⁴¹⁾

5.11 Data collection

- a) Data collection was done in the study area after obtaining prior permission from the Director, Institute of Community Medicine and The Dean, Madras Medical College and approval of Institutional Ethics Committee, Madras Medical College. (Annexure 4)
- b) Data collection was done in the Sankarankovil Health Unit district after obtaining prior permission from The Deputy Director of Health Services, Sankarankovil.

Each participant was given a brief introduction about the study in the each house and informed written consent was obtained from all a thumbprint was obtained from all illiterate participants in front of witnesses.

Relevant information was obtained from the respondent using the Tamil version of the questionnaire at their homes. Questions were read out to the study participants in exactly the same order as listed in the questionnaire and sufficient time was given to the subjects to respond. If the study subjects haven't understood the question, the question was repeated in the same manner without probing for the answer.

Results & Analysis

6. RESULTS AND ANALYSIS

A total of 150 participants were interviewed in this study. Table 1 shows the socio demographic profile of the study participants. Majority (87.3%) of them were married and had diabetes mellitus for duration of less than 10 years (70.7%). The mean age of the participants was 53.2 years and standard deviation was 8.8 years.

Sl. No.	Characteristics of the participants		Characteristics of the participants		Number of participants (n=150)	Percentage
1	Age Mean + SD	<53 years	62	41.3		
1	(53.2 ± 8.8)	≥53 years	88	58.7		
2	Sov	Male	72	48		
2	Sex	Female	78	52		
3	Marital status	Married	131	87.3		
	iviaritai status	Widow/widower	19	12.6		
	Occupation	Employed	61	40.7		
4	Occupation	Unemployed	89	59.3		
5	Education	Illiterate	99	66		
2	Education	Literate	51	34		
6	Socioeconomic	Up to lower middle class	46	30.7		
	status	Lower class	104	69.3		

Table 1: Socio demographic profile of the study participants

With regards to the personal habits, most of them were non-smokers and non alcoholics. Table 2 shows the various personal habits among the participants.

S. No.	Personal habit		Number of participants (n=150)	Percentage
1	Smoking	Yes	23	15.3
1		No	127	84.7
2	Alcohol	Yes	21	14
		No	129	86
3	Exercise	Yes	34	22.7
		No	116	77.3
4	Dietary fibre	Yes	83	55.3
		No	67	44.7

Table 2: Personal habits of the study participants

The following Table 3 shows the various measurements in the participants

Table 3: Mean and standard deviation of anthropometric measurements ofparticipants

Sl.No.	Variables	Mean	Standard deviation
1	Height (cms)	157	6.529
2	Weight (kgs)	58.7	10.6
3	Body mass index (kg/m ²)	23.9	4.5

The anthropometric measurements of the participants are shown in the Table 4. About 38% of the participants were overweight or obese.

Sl. No.	Anthropom	etry	Number of participants (n=150)	Percentage
	Body mass index (BMI)	Under weight	9	6
1		Normal	84	56
1		Over weight	39	26
		Obese	18	12
2	Height (cms)	<157 cms	53	35.3
		≥157 cms	97	64.7
3	Weight (kgs)	<58 kgs	83	55.3
		≥58 kgs	67	44.7

 Table 4: Anthropometry of the participants

The median duration of the diabetes among the study population is 5 years with Inter Quartile Range 3 years-10years. The duration of diabetes mellitus among the study participants is shown in the figure below (Figure 1)



Hypertension was the most common co-morbid condition seen in 61.3% of the study population. The different co-morbidities among the diabetics are shown in the table 5.

Sl. No.	Co-morbidity	Number of participants (n=150)	Percentage
1	Hypertension	92	61.3
2	Pallor	43	28.7
3	Cataract	33	22
4	Cardiac problem	10	6.7
5	Cancer	2	1.3
6	Goitre	2	1.3

Table 5: Co-morbidities among the diabetic patients

Among the 150 diabetic patients, 23 had problems in lower limb. This is shown in Figure 2



Table 6 shows the Findings of local examination of legs

Sl. No.	Problems in legs	Number of participants (n=150)	Percentage	
1	Corn/callus	14	9.3	
2	Ulcer	2	1.3	
3	3 Varicose 2		1.3	
4	Oedema	8	5.3	

Table 6: Findings of local examination of legs

Figure 3 shows the proportion of patients who complained of pain in lower limbs.



6.1 Prevalence of peripheral neuropathy and peripheral vascular disease



Figure 4 shows the proportion of diabetic patients with peripheral neuropathy

Figure 5 shows the proportion of peripheral vascular disease among the diabetic patients.



About 20.7% of the patients had monofilament test positive for peripheral neuropathy. This is shown in the Figure 6.



Among the 150 diabetic patients of the study, 38% were found to have peripheral neuropathy by the diabetic neuropathic symptom score as shown in the figure 7.



Out of the 150 diabetic patients, 61 (40.7%) had symptoms of neuropathy in lower limb. Table 7 shows the different neuropathic symptoms among the diabetic patients.

Sl. No.	Neuropathic symptoms	Number of participants (n=150)	Percentage
1	Numbness	53	35.3
2	Burning	15	10
3	Pricking	5	3.3
4	Unsteady gait	4	2.7

Table 7: Prevalence of neuropathic symptoms among the diabetic patients

Regarding the knowledge of the diabetic patients on foot care, about twothirds had good knowledge. Figure 8 shows the knowledge among the study participants.



Majority of the participants (62.7%) reported that they knew that they must wash their feet daily. Table 8 shows the various questions regarding the knowledge of diabetic patients on foot care.

SI. No.	Question	Yes (N)	Percentage
1	Do you know that you should not walk barefoot?	85	56.7
2	Do you know you should examine your feet daily?	24	16
3	Do you know you should use shoes/slippers both in indoor and outdoor?	12	8
4	Do you know you should not touch the very hot or cold things with your bare foot?	69	46
5	Do you know if you are not wearing correct slippers/shoes it will lead to foot complication?	11	7.3
6	Do you know you should wash your feet daily?	94	62.7
7	Do you know you should not cut/use chemicals to remove callus?	90	60

 Table 8: Knowledge of diabetic patients on foot care.

Among the diabetic patients, 35.3% reported that they have their family support with regards to their disease and treatment as shown in the Figure 9.



The different support provided by the family are shown in the following Figure 10.



6.2 Factors associated with peripheral neuropathy

Table 9 shows the different factors associated with peripheral neuropathy among the patients with diabetes mellitus

Table 9: Factors associated with peripheral neuropathy among
patients with diabetes mellitus

CL N-	Variables		Peripheral neuropathy N (%)		u ² ualua	р	Odda vetia
51.INO.			Yes	No	χ value	value	Odds ratio
1	Sev	Female	35 (48.6)	37 (51.4)	3 662	0.057	1.892
1	Sex	Male	26 (33.3)	52 (66.7)	5.002	0.057	(0.97-3.659)
2	Age	≥53 years	56 (62.9)	33 (37.1)	14 07	0.0001	19.0 (6.916-52.2)
2	Age	<53 years	5 (8.2)	56 (91.8)	44.92		
3	Education	Literate	12 (23.5)	39 (76.5)	- 9.405	0.002	0.341
5		Illiterate	49 (49.5)	50 (50.5)			(0.147-0.670)
4	Occupation	Unemployed	38 (42.7)	51 (57.3)	0 274	0.541	1.231
		Employed	23 (37.7)	38 (62.3)	0.374	0.341	(0.637-2.398)
5	Marital status	Married	53 (40.5)	78 (59.5)	0.010	0.801	1.070
		Widow/ widower	8 (42.1)	11 (57.9)	0.019	019 0.891	(0.404-2.838)

Sl.No.	Variables		Peripheral neuropathy N (%)		χ ² value	р	Odds ratio
			Yes	No		value	
6	Per capita income	Up to middle class	23 (50)	23 (50)	2 305	0.122	1.737 (0.860-3.50)
		Lower class	38 (36.5)	66 (63.5)	2.393		
7	Duration of diabetes	≥10 years	32 (72.7)	12 (27.3)	26 524	0.0001	7.080 (3.217- 15.585)
		<10 years	29 (27.4)	77 (72.6)	20.324		
8	Body mass index	\geq 25 kg/m ²	25 (43.9)	32 (56.1)	0.288	0.533	1.237 (0.637-2.415)
		$<25 \text{ kg/m}^2$	36 (38.7)	57 (61.3)	0.300		

The age and education of the participants as well as the duration of diabetes mellitus were found to be statistically association with the development of peripheral neuropathy. The diabetic patients of age 53 years and above are 19 times at risk of developing peripheral neuropathy than those patients who are younger. Also, patients with diabetes mellitus who are literates are 0.341 times less likely to suffer from peripheral neuropathy as compared to illiterates. Similarly, those patients with diabetes for a period of more than 10 years are 7.08 times likely to be affected by peripheral neuropathy in comparison to those with lesser duration of disease. The table that follows (Table 10) describes the association of personal habits with prevalence of peripheral neuropathy among patients with diabetes mellitus.

SI.	Variables		Peripheral neuropathy N (%)		χ²value	p	Odds ratio
110.			Yes	No		value	
1	Smoking	Yes	14 (66.7)	7 (33.3)	4.595	0.032	2.648 (1.064-6.588)
		No	47 (36.4)	82 (63.6)			
2	Alcohol	Yes	12 (57.1)	9 (42.9)	2.747	0.097	2.172 (0.855-5.42)
		No	49 (38)	80 (62)			
3	Exercise	Yes	14 (41.2)	20 (58.8)	0.005	0.945	1.028 (0.472-2.235)
		No	47 (40.5)	69 (59.5)			
4	Dietary fibre	Dietary fibre No	31 (37.3)	52 (62.7)	0.847	0.357	0.735 (0.382-3.360)
			30 (44.8)	37 (55.2)			

 Table 10: Association of personal habits with peripheral neuropathy among diabetics

Among the different personal habits studied, smoking was found to be significantly associated with development of peripheral neuropathy among the diabetic population. Diabetics who were current Smokers had 3.489 times increased risk of developing peripheral neuropathy than non smokers. The association of co-morbid conditions on the development of peripheral neuropathy among diabetic population is shown in the Table 11.

Table 11: Association of co-morbid conditions on the peripheral neuropathy

among diabetic population

Sl.	Variables	Perip neuro N (heral pathy %)	χ ² value	p	Odds ratio
110.			Yes	No		value	
1	Hypertension	Yes	52 (56.5)	40 (43.5)	24.788	0.0001	7.078 (3.112-16.097)
		No	9 (15.5)	49 (84.5)			
2	Cardiac problem	Yes	3 (30)	7 (70)	0.505	0.472	0.606 (0.150-7.539)
		No	58 (58.6)	82 (41.4)			
3	Cataract	Yes	21 (63.6)	12 (36.4)	9.251	0.002	3.369 (1.505-7.539)
		No	40 (34.2)	77 (65.8)			
4	Anaemia	Yes	17 (39.5)	26 (60.5)	0.022	0.858	0.936 (0.455-1.928)
		No	44 (41.1)	63 (58.9)	0.032		

Hypertension and cataract were found to be significantly associated with the prevalence of peripheral neuropathy among the diabetic population. The diabetic patients were at the risk of developing peripheral neuropathy 7.078 times if they are hypertensive as well. The diabetic patients with cataract have 3.369 times higher prevalence of peripheral neuropathy than those without cataract.

The presence of ulcer or callus in the lower limbs is analysed with the prevalence of peripheral neuropathy as shown in the table 12.

 Table 12: Findings of local examination of legs in comparison with peripheral neuropathy

SI.	Variables		Peripheral neuropathy N (%)		2value	р	Odda natio
No.			Yes	No	L value	value	
1	Ulcer	Yes	2 (100)	0 (0)		0.164#	0.399 (0.327-0.486)
		No	59 (39.9)	89 (60.1)			
2	Corn/callus	Yes	6 (42.9)	8 (57.1)	0.031	0.861	1.105 (0.363-0.486)
		No	55 (40.4)	81 (59.6)			

[#] - p value by Fisher's exact test.
6.3 Factors associated with peripheral vascular disease

Among the 150 diabetic patients studied in this study, 9 had peripheral vascular disease. The various factors associated with the complication are discussed below.

Sl. No.	Variables		Perij vas dis N	pheral cular ease (%)	χ²value	p value	Odds ratio
			Yes	No			
		≥53 years	7 (7.9)	82 (92.1)			2.518
1	Age	<53 years	2 (3.3)	59 (96.7)	1.350 0.245		0.505- 12.552)
2	Sex	Female	4 (5.1)	74 (94.9)	0.210 0.640		1.381
		Male	5 (6.9)	67 (93.1)	0.219	0.040	5.356)
3	Education	Literate	4 (7.8)	47 (92.2)		0.400#	1.6
		Illiterate	5 (5.1)	94 (94.9)	0.490	6.238)	
4	Occupation	Unemployed	6 (6.7)	83 (93.3)		0.739#	1.398 (0.336- 5.816)
		Employed	3 (4.9)	58 (95.1)			
5	Marital status	Married	8 (6.1)	123 (93.9)		1.000#	0.854
		Widow/widower	1 (53)	18 (94.7)			(0.101- 7.237)

 Table 13 : Factors associated with peripheral vascular disease among

 diabetic patients

Sl. No.	Variables		Perij vaso dis N	pheral cular ease (%)	χ²value	p value	Odds ratio
		Yes	No				
6	Per capita income	Up to middle	3 (6.5)	43 (93.5)		1 0 0 0 #	1.140 (0.272- 4.769)
		Lower	6 (58)	98 (94.2)		1.000"	
7	Duration of diabetes	≥10 years	4 (9.1)	40 (90.9)	1.055 0.450	2.02	
		<10 years	5 (4.7)	101 (95.3)		0.450	(0.516- 7.908)
8	Body mass index	≥25 <25	5 (8.8)	52 (91.2)	1.252	0.265	2.139 (0.550- 8.324)
			4 (4.3)	89 (95.7)			

[#] - p value by Fisher's exact test.

None of the socio demographic factors namely age, sex, education and occupation of the diabetic population were found to be statistically associated with the peripheral vascular disease among them. There was no significant association with duration of the disease and presence of obesity as well.

The following table (Table 14) shows the association between peripheral vascular disease and personal habits of the diabetic patients.

Sl.No.	Variables		Peripheral vascular disease N (%)		χ²value	p value	Odds ratio
			Yes	No			
1	Smoking	Yes	2 (9.5)	19 (90.5)		0.628#	1.633 (0.317-8.403)
		No	7 (5.4)	122 (94.6)			
2	Alcohol	Yes	2 (9.5)	19 (90.5)		0 (14#	1.835 (0.354-9.497)
		No	7 (5.4)	122 (94.6)		0.614	
3	Exercise	Yes	2 (5.9)	32 (94.1)	0.001	1.000	0.973 (0.193-4.918)
		No	7 (6)	7 109 5) (94) 0.001	0.001		
4	Dietary fibre	Yes	6 (7.2)	77 (92.8)	0.400		1 662
		fibre No	No	3 (4.5)	64 (95.5)	0.498	0.732

Table 14: Association between peripheral vascular disease and personalhabits of the diabetic patients

[#] - p value by Fisher's exact test.

None of the personal habits like smoking, alcohol drinking, lack of exercise, intake of dietary fibre of the diabetic population were found to be statistically associated with the peripheral vascular disease among them. Table 15 shows the association of different co-morbid conditions in the diabetic patients to the development of peripheral vascular disease.

Sl. No.	Variables		Peripheral vascular disease N (%)		χ²value	p value	Odds ratio		
		Yes	No						
1	Hypertension	Yes	9 (9.8)	83 (90.2)		0.013#	1.108 (1.036-1.186)		
		No	0 (0)	58 (100)					
2	Cardiac problem	Yes	1 (10)	9 (90)		0.472#	1.833		
		No	8 (5.7)	132 (94.3)			(0.206-16.312)		
3	Cataract	Yes	3 (9.1)	30 (90.9)		0.413#	1.850 (0.437-7.835)		
		No	6 (5.1)	111 (94.9)					
4	Anaemia	Yes	3 (7)	40 (93)	0 102	02 0.716	1.263		
		No	6 (5.6)	132 (94.4)	0.102		(0.301-5.294)		
[#] - p value by Fisher's exact test.									

Table 15: Association of different co-morbid conditions to Peripheral

vascular disease.

Among the different co-morbid conditions, hypertension and ulcer in the lower limb are found to be statistically associated with the presence of peripheral vascular disease among the diabetic population. Diabetic patients with hypertension are found to be affected by peripheral vascular disease 1.108 times than those without hypertension.

Sl. No.	Variables		Perip vaso diso N (Yes	oheral cular ease (%) No	χ²value	p value	Odds ratio
1	Ulcer	Yes	2 (100)	0		0.003#	94.3 (4.15-2144.8)
		No	7 (4.7)	141 (95.3)			
2	Corn/callus	Yes	1 (7.1)	13 (92.9)		0.596#	1.231 (0.143-10.627)
		No	8 (59)	128 (94.1)			
		No	6 (5.6)	132 (94.4)			

 Table 16: Association of Findings of local examination of legs to Peripheral vascular disease.

- p value by Fisher's exact test.

There is a significant association of presence of ulcer in lower limb and peripheral vascular disease among the diabetic patients as shown in table above (Table 16). The odds of having peripheral vascular disease are 94.3 times in those with ulcers in legs as compared to the others without ulcer.

6.4 BINARY LOGISTIC REGRESSION FOR FACTORS ASSOCIATED WITH PERIPHERAL NEUROPATHY

The table 17 shows the various factors influencing the prevalence of peripheral neuropathy among diabetic patients

Sl. No.	Factors	Odds ratio (95% Confidence interval)	Adjusted Odds ratio (95% Confidence interval)	p value
1	Age of the participant	19.0 (6.916-52.2)	1.720 (0.883-3.351)	0.111
2	Education of the participant	0.341 (0.147-0.670)	0.175 (0.084-0.368)	<0.001
3	Duration of diabetes	7.080 (3.217-15.585)	2.695 (1.113-6.524)	0.028
4	Smoking status	2.648 (1.064-6.588)	0.753 (0.265-2.142)	0.595
5	Hypertension	7.078 (3.112-16.097)	1.211 (0.628-2.336)	0.567

 Table 17: Factors associated with peripheral neuropathy among diabetic

 patients

After adjustment for confounders, the educational status of the participants and the duration of diabetes are found to be statistically associated with the prevalence of peripheral neuropathy among diabetic patients.

A diabetic who is a literate is 0.175 times less likely to have peripheral neuropathy than a diabetic who is an illiterate, after adjusting for other factors.

After making necessary adjustments for various confounders, the odds of having peripheral neuropathy in diabetic patients are 2.695 times more likely if the duration of diabetes is more than 10 years as compared to those with lesser duration of diabetes.

Discussion

7. DISCUSSION

7.1 Demography of study population

This community based cross sectional study was conducted among 150 type 2 diabetic patients above the age of thirty years in the villages of Tirunelveli. The mean age and standard deviation of the study population are 53 and 8.8 years respectively. This study has 52% of females and 48% of males. Majority of them (59.3%) were unemployed. According to Modified BG Prasad socio economic status scale, majority (69.3%) of study population belonged to lower class. Among the study population, most of them 66% were illiterate.

More than half (58.7%) of the study population were diabetic for a duration of less than 5 years and 18% were having diabetes for a duration of more than 10 years.15.3% of the study population were smokers and 14% were alcoholic. 22.7% of the study subjects engaged themselves in regular physical activity daily apart from the routine. Also, 55.3% of the study population reported that they regularly take one serving of green leafy vegetables at least three times per week.

7.2 Descriptive Statistics

The mean height and standard deviation of the study population were found to be 157 and 6.5cms respectively. The mean weight and standard deviation of the study population were 58.7 and 10.6 kgs respectively. Based on the Body Mass Index, 6% (9) of the study population were underweight (<18.49).

Among the study population, 26% (39) were overweight and 12% (18) were obese. About 56% (84) of the study population had normal body mass index. The mean and standard deviation of random blood sugar of the study population were determined to be 188.62 and 74.7 mg/dl respectively. The mean systolic blood pressure was recorded to be 143.5 mmHg (SD 20 mmHg), whereas the mean diastolic blood pressure was 87 mmHg (SD 11.64 mmHg).

7.3 Comorbid conditions

Based on the clinical records available with the study population, around 6.7% of study population had cardiac problem. Also, 61.3% of the study population reported they are hypertensive. About 1.3% had undergone/ was undergoing treatment for cancers (namely cancer breast and thyroid malignancy). Further, on clinical examination, about 22% of them had cataract, 28.7% were anaemic and 1.3% were having goitre.

7.4 Complications of diabetes and factors associated.

The prevalence of peripheral neuropathy was found to be 40.7% among the study population which was much higher than that of peripheral vascular disease (6%). Factors such as age, education and habit of smoking of the participants and duration of diabetes and associated hypertension were found to be statistically associated with the prevalence of peripheral neuropathy. The prevalence of peripheral vascular disease was statistically higher among the diabetic patients who have hypertension also. About two-thirds of the study subjects were found to have good knowledge of foot care.

7.5 Comparison of Co morbid conditions in study population along with other studies

In this study, the prevalence of hypertension among T2DM was 61.3%. The systematic review done by Ann D Colosia et al in 2013, showed that prevalence of hypertension reported in most of the studies was above 60%, which is similar to current study.⁽⁴²⁾ The National Diabetes fact sheet of United States released by Center for Disease Control and prevention (CDC) 2011 revealed that the prevalence of hypertension (among diabetic patients was similar to the present study.⁽¹⁴⁾ In contrast, a study by Kristy Iglay et al in 2016 showed that the prevalence of hypertension was much higher (82.1%) than the present study.⁽¹⁶⁾

In this study, the prevalence of cardiac problem was 6.7% among the diabetic patients. This was similar to the prevalence of coronary artery disease (8.7%) seen among the diabetics in the study by Jung Hee Kim et al from Korea 2011.⁽²³⁾ In contrast to the present study, Kristy Iglay et al study in USA and Agrawal et al study done in India showed that there was higher prevalence of coronary artery disease which was 21.6% and 19.2% respectively.^(16,25) In the current study cardiac problems were self-reported by the study participants so there is a chance of unidentified patients with cardiac problems.

7.6 Prevalence of peripheral neuropathy

Peripheral neuropathy is one of the commonest micro vascular complications of diabetes mellitus. In this study, out of 150 study population about 40.7% had peripheral neuropathy. The prevalence of peripheral neuropathy in this study was similar to ChinnariHarika et al study done at Guntur of 2012 (31.5%), Dipika Bansal et al study done at Chandigarh in India (29.2%) and Ch manes et al (33.5%).^(21,28,32) The prevalence of peripheral neuropathy in the present study was also in concordance with studies from Korea by Seung Hyun et al of 2012 (14.1% to 54.5%) and Jung Hee Kim et al of 2012 (40% to 44%)^(23,43).

In a study done by Karvestedt Lars et al, the prevalence of peripheral neuropathy was 15% by monofilament test, which was lower than the peripheral neuropathy detected by monofilament test (20.7%) in the current study.⁽²⁴⁾ A multicentre study by MJ Young et al in United Kingdom in 2013, showed that the prevalence of diabetic peripheral neuropathy was 28.5% and it varied among the different counties.⁽²⁶⁾ The prevalence of peripheral neuropathy in this study was lower than present study because of geographical variation, and ethnic variation causing changes in the genetics, poor glycemic control, hypertension or other socio economic, cultural and environmental factors.

7.7 Prevalence of peripheral vascular disease

In this study, peripheral vascular disease or peripheral arterial disease diagnosed by ankle brachial index and that was calculated in ratio of ankle and brachial systolic blood pressure. ABI ratio less than 0.9 was considered positive for peripheral vascular disease. In current study, about 9 of the subjects (6%) had peripheral vascular disease which was similar to the results of study done by Rajendrapradeepa et al in Chennai (8.3%).⁽³⁰⁾ In contrast prevalence was higher in study done by Ch manes et al (12.7%), Chinnariharika et al (19.1%) in 2012.^(21,32)

The study done by Sang Youl Rhee et al from Korea described the prevalence of peripheral vascular disease in various countries; like United States of America had 4.7%, among German people the prevalence of low ABI was

26.3% in diabetic patients of more than 65 years and among Koreans it was 11.9% among diabetics of more than 50 years. The higher prevalence of peripheral vascular disease in Germany and Korea might be attributed to the higher age group of study subjects.⁽²⁹⁾

The prevalence of PVD was 2% in the study by Anne Gedebjerg et al and 3% in the study by Jung Hee Kim et al which was lower than the current study. These differences with current study might be due to diagnosing procedure and study population. ^(22,23)

7.8 Factors Associated with Peripheral neuropathy

The current study had higher prevalence of peripheral neuropathy among more than 53 years of age group and the different between age groups was found to be statistically significant (p<0.0001). Morkrid et al from Bangladesh showed similar results as this study, with age more than 60 years being associated with peripheral neuropathy.⁽⁴⁴⁾ The studies done by Wang et al from Saudi Arabia, MJ Young et al multicentre study, Jung Hee Kim et al from Korea, ChinnariHarika et al from India and RP Agrawal from India showed the association of age with peripheral neuropathy.^(21,23,25,26,45) Most of the studies in various countries show that diabetes with ageing will increase the risk of developing peripheral neuropathy. Also, in this study, prevalence of peripheral neuropathy was higher in illiterate than literate and statistically significant. In current study, prevalence of peripheral neuropathy was found to be associated statistically significant with duration of diabetes. Dipika Bansal et al and RP Agrawal et al from India had found a difference in peripheral neuropathy among different groups of diabetics based on their duration of disease similar to current study.^(25,28) The studies by MJ Young et al and Jung Hee Kim et al showed a similar association of duration of diabetes with peripheral neuropathy. In most of the studies, risk for peripheral neuropathy increases with duration of diabetes.^(23,26)

In present study, the prevalence of peripheral neuropathy was higher among smokers and the difference was statistically significant. The study done by Monisha D' Souza et al Mangalore in India 2015 reveals that smoking has statistically significant association with peripheral neuropathy.⁽⁴⁶⁾ The study done by Yeboah et al from Accra, Ghana showed peripheral neuropathy was associated with smoking.⁽⁴⁷⁾ The study done by Dipika Bansal et al was in contrast with current study, where the smoking status is not associated with the prevalence of diabetic peripheral neuropathy. Smoking is also the risk factors for various complications like peripheral vascular disease and coronary artery disease.⁽²⁸⁾

In present study, peripheral neuropathy was higher among those diabetics who are hypertensive and it was statistically significant (p<0.0001). The results of the studie by Dipika Bansal et al, Yeboah et al, Wang et al were in concordance with this study.^(28,47)

In this study no statistical association between the sex and peripheral neuropathy was found. This was similar to A Ashok et al from Chennai and Morkrid et al from Bangladesh 2010 which also showed that no difference between male and female was found in peripheral neuropathy.^(27,44) In contrast, the study by Yeboah Kwame et al 2016 from Accra had shown higher prevalence of peripheral neuropathy among males.⁽⁴⁷⁾

In this study prevalence of peripheral neuropathy was determined to be higher among patients with cataract and it was statistically significant (p<0.002). Peripheral neuropathy is a long term complication of diabetes mellitus, so is cataract. This might be the reason for the co-existence of cataract and peripheral neuropathy in diabetic patients. In this study percentage of patients with ulcer and callus was higher among the patient with peripheral neuropathy, but the increased prevalence was statistically not significant. Patients with peripheral neuropathy and corn or callus in lower limb had higher risk of developing foot ulcer which may lead to amputation.

7.9 Factors associated with Peripheral vascular disease

In this study, prevalence of PVD was higher among known hypertensive and the difference in prevalence of PVD among smokers and non-smokers was found to be statistically significant (p<0.013). The study done by Rajendrapradeepa et al, Rhee and Kim et al 2015 showed a similar difference in prevalence of PVD among smokers and non-smokers.⁽³⁰⁾ In this study, based upon Ankle brachial index, the prevalence of peripheral vascular disease was 6%. Prevalence of PVD was higher among those of more than 53 years of age and those with more than 10 years of diabetes. But these differences were statistically not significant. The study done by Rabia et al in Malaysia showed there was no association between the duration of diabetes and peripheral vascular disease.⁽⁴⁸⁾

The study done by Rajendrapradeepa et al from Chennai and Sang Youl et al from Korea showed that PVD was significantly associated with increasing age and increasing duration of diabetes.^(29,30)

In this study the prevalence of peripheral vascular disease was higher among lower socio economic class, widow/widower, unemployed and body mass index \geq 53 but statistically not significant. The prevalence of PVD was higher among males (6.6%) than males which was similar to the study by ChinnariHarika et al. ⁽²¹⁾

Summary & Conclusion

8. SUMMARY AND CONCLUSION

A community based cross sectional study was done to assess the prevalence of peripheral neuropathy and peripheral vascular disease among Type 2 Diabetes patients.

The study carries significance as very few studies have documented the prevalence of Diabetic complications in rural areas Tamil Nadu. A semi structured pre tested questionnaire was used to collect details on socio demographic factors, factors influencing complication of Diabetes Mellitus, signs and symptoms of Peripheral Vascular Disease and Peripheral Neuropathy.

Clinical examination was also done including general and local examination of limbs for corns, callus, ulcers, measuring the Ankle Brachial Pressure (ABP) index by automatic blood pressure device for peripheral vascular disease and 10mg monofilament test for peripheral neuropathy.

The study revealed the following findings:

Among the 150 studied, 87.3% were married, 70.7% were diabetics for less than 10 years duration. The mean age of the study participants and standard deviation was 53.2 years and 8.8 years.60% were unemployed. 15.3% of the study group were smokers, 20% were doing exercise regularly and 55.3% were consuming dietary fibre. The mean BMI was 23.9 kg / m^2 and random blood sugar was 188.62 mg / dl. 12% of the studied diabetics were obese.

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Hypertension was the most common comorbid illness. 9.3% had corn/callus. The study revealed that 40.7% of the diabetics were having peripheral neuropathy 6% were having peripheral vascular disease. Two thirds of the study population had good knowledge on foot care. 35.3% of the diabetics had family support.

There was a statistically significant association found between the following factors and PN, PVD.

- Peripheral Neuropathy was associated with age, educational status, duration of diabetes, smoking, hypertension and cataract.
- 2. Peripheral Vascular Disease was associated with Hypertension and ulcer.
- 3. It was observed by Binomial logistic regression that the educational status and duration of diabetes were having statistically significant association with the prevalence of peripheral neuropathy.

Limitations

9. LIMITATIONS

- 1. Due to recall bias the actual magnitude of the morbidity could not be elicited.
- The cross sectional study has its own inherent limitations, hence the temporal relationship between risk factors and Peripheral Vascular Disease and Peripheral Neuropathy could not be established.

Recommendations

10. RECOMMENDATIONS

- 1. Diabetic patients should examine their feet on a daily basis.
- Behaviour change communication activities must be ensured among diabetics regarding foot care, exercise.
- 3. Adequate health education should be given to them on foot care.
- 4. Diabetic patients should be advised to use slippers both indoor as well as outdoor. Also they should be encouraged to wear the correct size slippers.
- 5. They should be advised that they should never walk barefoot.
- 6. They should be advised to wash and dry their feet at least once a day.
- 7. Diabetic patients should be advised to quit smoking.
- 8. Lifestyle modification with regular exercise should be part of diabetic patients daily life.

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Annexures

ANNEXURE - 1

INFORMATION SHEET

"CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017".

In this study, we will be asking questions regarding your socio demographic profile, work profile and those related to health problems, any comorbid conditions and drug intake along with clinical examination.Blood sugar will be measured by using Glucometer. The privacy of the participants in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment or prevention.

Signature of investigator

Signature or Thumb impression of the participant

ஆய்வு தகவல் தாள்

"திருநெல்வேலியின் கிராமங்களில் இரன்டாம் வகை நீரிழிவு நோயாளிகளில் புறவழி இரத்தக்குழாய் மற்றும் புறவழி நரம்பு மண்டல பாதிப்பை அறிவதற்கான குறுக்காய்வு- 2017"

இந்த ஆய்வில் தங்களுடைய சமூக விவரம் மற்றும் நாள்பட்ட நோய்களின் விவரம் கேட்கப்படும்.

இந்த ஆய்வின் முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆய்வின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த ஆய்வில் பங்கேற்பது தங்களுடைய விருப்பத்தில் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆய்விலிருந்து வெளியேறலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்பு பரிசோதனையின் முடிவுகளை ஆய்வின் பொது அல்லது ஆய்வின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

ANNEXURE - 2

INFORMED CONSENT FORM

"CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017".

Name of the participant:

Age/Sex:

Study ID No:

Date:

(1) I have been explained in detail about the study and its procedure. I confirm that I had completely understood the study and have had the opportunity to ask questions

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

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

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

(5) I agree to my participation in the above study.

Signature of investigator Date:

Signature of the participant

ஆய்வு ஒப்புதல் கடிதம்

"திருநெல்வேலியின் கிராமங்களில் இரன்டாம் வகை நீரிழிவு நோயாளிகளில் புறவழி இரத்தக்குழாய் மற்றும் புறவழி நரம்பு மண்டல பாதிப்பை அறிவதற்கான குறுக்காய்வு- 2017"

பெயர்

வயது: பால்:

ஆய்வு சேர்க்கை எண்.

தேதி:

- இந்த ஆய்வின் விவரங்களும் அதன் நோக்கங்களும் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது. எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு நான் எனது சமதத்தைத் தெரிவிக்கிறேன்.
- 2. இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆய்விலிருந்து எந்நேரமும் வெளியேறலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.
- 3. இந்த ஆய்வின் விவரங்களை கொண்ட தகவல் தாளை பெற்றுக்கொண்டேன். நான் என்னுடைய சுயநினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆய்வில் என்னை சேர்த்துக்கொள்ள சம்மதிக்கிறேன்.
- 4. ஆய்வாளர் மற்றும் அவரை சார்ந்தவர்களோ நெரிமுறைக்குழு இந்த ஆய்விலிருந்து உருப்பினர்களோ நான் விலகினாலும் என்னுடைய அனுமதியின்றி எனது உடல்நிலை குறித்த தகவல்களை ஆய்விற்கோ இது கொடர்பான ഖേന ஆய்விற்கோ இந்த பயன்படுத்திக்கொள்ள முடியும் என்று புரிந்து கொண்டு சம்மதம் ஆனாலும் எனது அடையாளம் அளிக்கிறேன். வெளியிடப்பட மாட்டாது என்பதை புரிந்து கொள்கிறேன்.
- 5. இந்த ஆய்வின் தகவல்கலையும் முடிவுகளையும் அறிவியல் நோக்கத்திற்காக பயன்படுத்துவதற்கு நான் அனுமதிக்கிறேன். இந்த ஆய்வில் பங்குப்பெற நான் சம்மதிக்கிறேன்.

ஆராய்ச்சியாளர்

பங்கேற்பாளர் கையொப்பம்

கையொப்பம்
<u>ANNEXURE – 3</u>

QUESTIONNAIRE

TITLE: "Cross sectional study to assess the prevalence of peripheral vascular disease and peripheral neuropathy in Type 2 Diabetic patients of rural area of Tirunelveli 2017"

		Date	:	
1. Name:				
2. Age/sex:				
3. Education:				
4. Occupation: 5.Per capi	ita Income	:		
6. Marital status:				
7. Do you have the habit of Smoking; a) yes b) no				
8. Do you drink alcohol? a) yes b)no				
9. Do you have the habit of Betel nut chewing? a) y	/es	b)no		
10. How long are you suffering from diabetes melli	itus?			
10a. Are you having medicines regularly? a) yes		b)no		
11. Do you have hypertension? a) yes b)r	10			
11a. Are you under regular treatment? a) yes	b)no			
12. Do you have any cardiac problem? a) yes	b)no			
12a. If yes are you under regular treatment? a) yes		b)no		
13. Do you have any Cerebro Vascular Accident?	a) yes		b)no	
13a. If yes are you under regular treatment? a) yes		b)no		
14. Do you do any physical exercise? a) yes	b)no			
15 . Do you add green leafy vegetables in your diet	? a) yes		b)no	
16. Do you have family support for going hospital?	a) yes		b)no	
17. Do your family members reminds you to take ta	ablets? a)y	es		b)no

QUESTIONS FOR PERIPHERAL VASCULAR DISEASE

18. Do you have

i. (1) pain in legs while walking?	a)yes	b)no	
(2) If yes, after what distance do u	have pain?		
a) 100 mts b) >100mts c) >500mt	S		
QUETIONS FOR PERIPHERAL NEURO)PATHY		
19. Do you have any of the following probl	lems?		
i. numbness on your legs		a)yes	b)no
ii. Not able to hold your slippers		a)yes	b)no
iii. Not able to differentiate hot or co	old with your legs	a)yes	b)no
iv. Pricking sensation	a)yes	b)no	
v. burning sensation	a)yes	b)no	

QUESTIONS FOR AWARENESS OF FOOT CARE

- -20. Do you know that you should not walk barefoot?
- 21. Do you know you should wash your feet daily?
- 22. Do you know you should not cut/use chemicals to remove callus and corn?
- 23. Do you know you should examine your feet daily ?
- 24. Do you know you should use shoes/slippers both in indoor and outdoor?
- 25.Do you know you should not touch the very hot or cold things with your foot?
- 26.Do you know if you are not wearing correct slippers/shoes it will lead to foot complication?

CLINICAL EXAMINATION:

GENERAL EXAMINATION	YES/NO
Icterus	
Pallor	
Pedal oedema	
clubbing	
Goitre	

Gait: Steady /Unsteady

Height:

Weight:

Body Mass Index:

LOCAL EXAMINATION OF	RIGHT	LEFT
LEGS		
Discoloration		
Ulcer		
Gangrene		
Wasting		
Corn foot		
callosity		
Dilatation of vessels/ varicosity		

BLOOD PRESSURE & ANKLE BRACHIAL INDEX:

BLOOD PRESSURE	RIGHT	ABI RIGHT	LEFT	ABI LEFT
Brachial				
Ankle				

MONOFILAMENT TEST:

10th site- Dorsum of the foot

Right			
*1great toe		*2	3*
*4		*5	*6
* 7	*8		
*	9		

Left

*great toe1		*2	*3
*4		*5	*6
* 7	*8		
	*9		

கேள்வித்தாள்

- 1) பெயர்:
- 2) வயது/ பாலினம் :
- 3) கல்வித்தகுதி:
- 4) ඛෙනහ:
- 5) தனிநபா் வருமானம:
- 6) தீருமண தகுதீ:
- 7) உங்களுக்கு புகை பிடிக்கும் பழக்கம் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 8) உங்களுக்கு மது அருந்தும் பழக்கம் உள்தா?
 அ) ஆம்
 ஆ) இல்லை
- 9) உங்களுக்கு வெற்றிலை, பாக்கு போடும் பழக்கம் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 10) உங்களுக்கு நீரிழிவு நோய் எவ்வளவு காலம் உள்ளதா?
- 10.அ) அதற்கான மருந்துகள் ஒழுங்காக உட்கொள்கிறீர்களா? அ) ஆம் ஆ) இல்லை
- உங்களுக்கு உயர் இரத்த அழுத்த நோய் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 11.அ அதற்கான மருந்துகள் ஒழுங்காக உட்கொள்கீறீர்களா? அ ஆம் ஆ) இல்லை
- 12) உங்களுக்கு இருதய சம்பந்தமான நோய் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 12.அ அதற்கான மருந்துகள் ஒழுங்காக உட்கொள்கீறீர்களா? அ ஆம் ஆ) இல்லை
- 13) உங்களுக்கு பக்கவாத நோய் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 13.அ) அதற்கான மருநதுகள் ஏதேனும் உட்கொள்கிறீா்களா? அ) ஆம் ஆ) இல்லை
- 14) உங்களுக்கு உடற்பயிற்சி செய்யும் பழக்கம் உள்ளதா?
 அ) ஆம்
 ஆ) இல்லை
- 15) நீங்கள் பச்சை காய்கறிகளை உணவில் சேர்த்துக்கொள்கிறீர்களா?
 அ) ஆம்
 ஆ) இல்லை

தேதி :

- 16) மருத்துவமனை அழைத்து செல்வதற்கு உங்கள் குடும்ப உறுப்பினர்கள் உதவுகீறார்களா? அ) ஆம் ஆ) இல்லை
- 17) நீங்கள் மருந்து உட்கொள்வதற்கு உங்கள் குடும்ப உறுப்பினர்கள் ஞாபகப்படுத்துவார்களா?
 அ) ஆம்
 ஆ) இல்லை

புறவழி இரத்தக்குழாய் நோய் சம்பந்தமான கேள்விகள்

- 18) உங்களுக்கு நடக்கும் பொழுது கால்களில் வலி ஏற்படுகிறதா?
 அ) ஆம்
 ஆ) இல்லை
- 18. அ. ஆம் எனில், எவ்வளவு தூரத்தில் வலி ஏற்படுகிறது?

புறவழி நரம்பு மண்டலம் சம்பந்தமான கேள்விகள்

- 19) கீழே குறிப்பிட்டுள்ள தொந்தரவுகள் ஏதேனும் உள்ளதா? 1) கால் மரத்துப்போதல் அ) ஆம் ஆ) இல்லை கால்களில் இருந்து செருப்பு நழுவுதல் அ) ஆம் ஆ) இல்லை 3) கால்களில் சூடு மற்றும் குளிர் தன்மைகளை பிரித்து உணராத தன்மை அ) ஆம் ஆ) இல்லை கால்களில் ஊசி குத்தும் உணர்வு அ) ஆம் ஆ) இல்லை 4) கால்களில் எரிச்சல் ஆ) இல்லை அ) ஆம் கால்கள் பாதுகாப்பிற்குரிய விழிப்புணர்வு பற்றிய கேள்விகள் 20) கால்களில் செருப்பு இல்லாமல் நடக்ககூடாது என்று நீங்கள் அறிவீர்களா? ஆ) இல்லை அ) ஆம்
- 21) கால்களை கழுவி தீனமும் சுத்தமாக வைத்துக்கொள்ள வேண்டும் என நீங்கள் அறிவீா்களா? அ) ஆம் ஆ) இல்லை
- 22) தோல் தடிப்பு மற்றும் கால் ஆணியை தானாக வெட்டவோ அல்லது வேறு மருந்துகள் பயன்படுத்தவோ கூடாது என அறிவீர்களா? அ) ஆம் ஆ) இல்லை

- 23) நீங்கள் கால்களை தினமும் பரிசோதிக்க வேண்டும் என நீங்கள் அறிவீர்களா? அ) ஆம் ஆ) இல்லை
- 24) நீங்கள் வீட்டிற்குள் மற்றும் வீட்டிற்கு வெளியில் காலணிகள் அணிய வேண்டும் என்பதை அறிவீா்களா? அ) ஆம் ஆ) இல்லை
- 25) வெறும் கால்களால் சூடான அல்லது குளிர்ச்சியான பொருட்களை உணரக்கூடாது என நீங்கள் அறிவீர்களா? அ) ஆம் ஆ) இல்லை
- 26) சரியான அளவு காலணிகளை நீங்கள் அணியாவிடின் பாதங்களில் தொந்தரவு ஏற்படும் என்பதை நீங்கள் அறிவீர்களா? அ) ஆம் ஆ) இல்லை

உடற்பரிசோதனை

பொது பரிசோதனை	ஆம்/ இல்லை
மஞ்சள் காமாலை	
இரத்த சோகை	
கால்களில் வீக்கம்	
க்ளப்பிங்	27
தைராய்டு வீக்கம்	

உயரம்:

எடை:

பி.எம்.ஐ. :

நடையில் தடுமாற்றம்: ஆம் / இல்லை

கால்கள் பரிசோதனைஇடதுவலதுநிறமாற்றம்காலில் புண்அழுகல்சதை இழப்புகால் ஆணிகாலில் தோல் தடுப்புஇரத்தக்குழாய் சுருண்டு இருத்தல்

MONOFILAMENT TEST:

10th site- Dorsum of the foot

Right			
*1great toe		*2	3*
*4		*5	*6
* 7	*8		
*	9		

Left

*great toe1		*2	*3
*4		*5	*6
* 7	*8		
	*9		

<u>ANNEXURE – 4</u>

INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013 Telephone No.044 25305301 Fax: 011 25363970

CERTIFICATE OF APPROVAL

To Dr.F.Munira I Year Post Graduate in Community Medicine Institute of Community Medicine Madras Medical College Chennai 600 003

Dear Dr.F.Munira,

The Institutional Ethics Committee has considered your request and approved your study titled "CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI 2017" -NO.15072017

The following members of Ethics Committee were present in the meeting hold on **07.07.2017** conducted at Madras Medical College, Chennai 3

1. Prof.Dr.C.Rajendran, MD.,	:Chairperson
2. Prof.R.Narayana Babu, MD., DCH., Dean MMC, Ch-3 :Dep	uty Chairperson
3. Prof.Sudha Seshayyan, MD., Vice Principal, MMC, Ch-3 :M	ember Secretary
4. Prof.S.Mayilvahanan, MD, Director, Inst. of Int.Med, MMC, Ch-3	: Member
5. Prof.A.Pandiya Raj, Director, Inst. of Gen.Surgery, MMC	: Member
6. Prof.Shanthy Gunasingh, Director, Inst. of Social Obstetrics, KC	GH : Member
7. Prof.Rema Chandramohan, Prof. of Paediatrics, ICH, Chennai	: Member
8. Prof. Susila, Director, Inst. of Pharmacology, MMC, Ch-3	: Member
9.Thiru S.Govindasamy, BA., BL, High Court, Chennai	: Lawyer
10.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist
11.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary - Ethics Committee MEMBER SECRETARY MADRAS MEDICAL COLLEGE CHENNAI-600 003

<u>ANNEXURE – 5</u>



Urkund Analysis Result

Analysed Document: Submitted: Submitted By: Significance: PLAGIARISM CHECK.docx (D43121665) 10/26/2018 5:02:00 PM muniraithris@gmail.com 2 %

Sources included in the report:

Thesis draft(without references).docx (D41236328) plagiarism_asnath.docx (D42503553) A STUDY OF THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND ITS ASSOCIATED RISK FACTORS AMONG ADULTS.docx (D42687551) Yash Patel Ch 6.pdf (D42862784) https://www.duo.uio.no/handle/10852/30161 http://www.doria.fi/handle/10024/92382 https://www.duo.uio.no/handle/10852/30151 https://www.duo.uio.no/handle/10852/46013 https://www.duo.uio.no/handle/10852/30170 https://www.researchgate.net/profile/Ahmad_Ariffin3/ publication/267639893_Prevalence_and_Associated_Risk_Factors_of_Diabetic_Peripheral_Neuro pathy_Among_Diabetic_Patients_in_National_Center_of_Diabetes_in_Yemen/ links/54570b4a0cf2bccc490f3a0e.pdf? inViewer=true&pdfJsDownload=true&disableCoverPage=true&origin=publication_detail http://care.diabetesjournals.org/content/26/12/3333 https://www.ncbi.nlm.nih.gov/pubmed/23121724

Instances where selected sources appear:

17

PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled "CROSS SECTIONAL STUDY TO ASSESS THE PREVALENCE OF PERIPHERAL VASCULAR DISEASE AND PERIPHERAL NEUROPATHY IN TYPE 2 DIABETIC PATIENTS OF RURAL AREA OF TIRUNELVELI-2017" of the candidate Dr. F. MUNIRA with registration Number 201625003 for the award of M.D. COMMUNITY MEDICINE in the branch of XV. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows <u>2 percentage</u> of plagiarism in the dissertation.

Guide & Supervisor sign with Seal

ANNEXURE 6 - MASTER CHART

Xa	ge	eight	reight	ducation	ccupation	ercapitaincome	harital status	moking	lcohol	uration of diabetes	ypertension	xercise	iet fibre	imily tablet support	amily hosp support	ardiac problem	troke	ancers	ain_inlegs	audication	umness	nsteadyness	urning	ricking	lippers slipping ain at night	are foot	rashing	allus removal	xamine Moor/out	aretouch	orrectshoes	nowledge score	allor	atract	otre	arm systilic ank-sys	ankle sys	arm sys	arm dias	arm dias	ankle dias	dine uias hod curr	lou suy: setim	/dStirity /	dema	aricose	lcers	nonofilament rt	nonofilament It	M
Male	re 51	ء 153	► 78	literate	o unemployed	<u>م</u> 1000	⊆ married	Yes	ro No	12	Yes	No	No	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0	- <u> </u>	0	3	no	no	5 10 1	53 143	= 148	= 143	E 83	83 8	1 8:	3 36	, s 18 n	.0 (5 0 0 1	0	0	E 10	- 10 7	<u> </u>
Male	52	158	75	illiterate	unemployed	2750	married	Yes	Yes	1	No	Yes	No	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0) 1	0	3	no	yes	10 1	53 130	153	130	93	90 9	5 90	0 15	i2 n	o '	1 0	0	0	10	10	30
Male	41	164	59	literate	unemployed	2255	married	Yes	No	6	Yes	Yes	Yes	0	0	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0) 0	0	1	no	no	no 1	57 147	152	147	87	87 8	5 8	7 16	,6 n	0 (0 0	0	0	10	10 2	21.9
Male	50	150	60	literate	unemployed	2400	married	Yes	No	20	Yes	No	No	0	0	0	No	No	No	No	0	0	0	0	0 No	1	0	0	0 0) ()	0	0	no	no	10 1	53 143	148	143	83	83 8	1 83	3 39	/3 n/	0 (0 0	0	0	8	8 2	26.7
Male	62	158	49	illiterate	unemployed	3700	married	Yes	No	1	No	Yes	No	0	0	0	No	No	No	No	0	0	0	0	0 No	0	0	1	0 0) 0	0	0	no	no	no 1	60 150	160	148	80	80 8	D 71	8 30	10 n/	0 (0 0	0	0	10	10 1	19.6
Male	53	158	47	illiterate	employed	500	married	Yes	Yes	9	Yes	No	Yes	0	0	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0) ()	0	1	no	no	no 1	53 130	153	130	93	90 9	5 9	0 17	'6 n/	0 (0 0	0	0	8	8 1	18.8
Male	62	168	48	illiterate	unemployed	1000	married	Yes	No	5	No	No	No	0	0	0	No	No	No	No	0	0	0	0	0 No	0	0	0	0 0) 0	0	0	no	no	no 1	77 144	174	146	84	84 8	5 8	2 23	0 n	0 (0 0	0	0	10	10	17
Male	58	165	85	literate	employed	2030	married	Yes	No	12	Yes	No	Yes	1	1	0	No	No	No	No	1	0	1	0	0 No	1	1	0	0 0	0 0	0	1	no	yes	no 1	56 146	151	146	86	86 8	4 8	6 45	7 n	0 (0 0	0	0	6	6 3	31.2
Male	65	158	54	literate	unemployed	500	married	Yes	No	10	Yes	No	Yes	1	1	0	No	No	Yes	No	1	0	0	0	0 No	0	1	1	0 0	0 0	0	1	yes	yes	no 1	40 160	130	150	80	70 8	90	J 24	7 no	o 1	1 0	0	1	5	5 2	21.6
Male	70	160	65	illiterate	employed	2550	married	Yes	No	24	Yes	Yes	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	no 1	60 150	164	154	94	90 9	5 9	6 14	4 no	0 (0 0	0	0	2	2 2	25.4
Male	68	158	40	illiterate	employed	3400	married	Yes	Yes	20	Yes	No	Yes	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	60 150	164	154	94	90 9	5 90	5 14	5 nr	о (0 0	0	0	3	3	16
Male	62	164	50	illiterate	employed	4000	married	Yes	No	12	Yes	No	Yes	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	50 140	150	148	83	84 7	8 7	3 14	5 nr	о (0 0	0	0	3	3 1	18.6
Male	60	158	47	illiterate	unemployed	2500	married	Yes	Yes	11	Yes	Yes	Yes	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	50 130	150	140	80	80 7	0 70	J 14	7 nr	о (0 0	0	0	5	5 1	18.8
Male	55	138	55	illiterate	unemployed	500	married	Yes	Yes	13	Yes	No	Yes	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	no 1	30 140	128	148	90	90 8	D 80	J 14	8 nr	0 (0 0	0	0	6	6 2	28.9
Male	58	157	65	illiterate	employed	1000	married	Yes	No	15	Yes	No	Yes	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	no 1	42 123	144	142	76	78 7	B 70	5 14	5 nr	0 (0 0	0	0	3	3 2	26.4
Male	70	158	40	illiterate	unemployed	2300	married	Yes	No	5	Yes	Yes	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	52 142	147	142	82	82 8	D 8:	2 15	1 nr	0 (0 0	0	0	9	9	16
Male	65	145	42	illiterate	unemployed	2700	married	Yes	No	10	Yes	No	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	51 141	146	141	81	81 7	9 8	1 14	9 nr	D (0 0	0	0	7	7	20
Male	69	158	65	illiterate	unemployed	1000	married	Yes	No	15	Yes	Yes	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 2	10 200	210	200	90	100 10	0 10	10 15	1 nr	0 (0 0	0	0	9	9	26
Male	55	151	65	illiterate	employed	500	married	Yes	Yes	9	Yes	Yes	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 2	00 190	200	190	110	100 10	0 9	3 15	0 nr	0 (0 0	0	0	8	8 2	28.5
Male	70	156	63	illiterate	unemployed	500	married	Yes	No	10	Yes	No	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	70 140	160	150	90	100 9) 91) 14	9 n	0 (0 0	0	0	7	7 2	25.9
Male	60	160	70	illiterate	unemployed	600	married	Yes	No	7	Yes	No	No	0	0	0	No	No	Yes	No	1	0	0	0	0 No	1	1	1	0 0) 1	0	4	no	no	10 1	90 170	190	180	110	100 10	0 10	0 15	0 nr	0 (0 0	0	0	8	8 2	27.3
Male	60	160	48	illiterate	unemployed	2000	Widow	Yes	No	6	No	No	Yes	0	0	0	No	No	Yes	No	0	0	0	0	0 No	0	1	1	0 0) 1	0	3	yes	yes	10 1	50 140	158	146	100	100 10	0 9	1 10	7 no	0 0	0 0	1	0	10	10 1	18.8
Male	48	169	54	illiterate	unemployed	500	Widow	Yes	No	5	No	No	No	0	0	0	No	No	Yes	No	0	0	0	0	0 No	0	0	1	0 0) 1	0	1	yes	yes	10 1	69 150	170	150	60	60 8	5 7	5 10	7 no	0 0	0 0	1	0	10	10 1	18.9
Male	55	150	54	illiterate	unemployed	1000	married	No	No	5	No	No	Yes	0	0	0	No	No	No	No	0	0	0	0	0 No	1	0	0	0 0) 0	0	0	no	no	10 1	59 148	160	150	87	90 8	7 9	7 23	2 no	0 1	1 0	0	0	10	10	24
Male	55	154	47	literate	employed	1200	married	No	Yes	5	No	No	No	1	1	0	No	No	No	No	0	0	0	0	0 No	1	0	0	0 0) 0	0	0	no	no	10 2	28 184	226	186	116	114 13	6 13	4 11	0 no	0 1	1 0	0	0	10	10 1	19.8
Male	51	152	55	literate	employed	500	married	No	No	11	No	Yes	Yes	1	1	1	No	No	Yes	No	0	0	0	0	0 No	0	0	1	0 0) 0	0	0	no	no	10 1	40 124	142	126	73	74 9	4 94	4 89) na	0 1	1 0	0	0	9	8 2	23.8
Male	39	162	54	illiterate	employed	500	married	No	Yes	0.5	No	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	0	0	0 0) 0	0	0	no	yes	10 1	50 120	150	130	70	80 8	D 80) 10	4 no	0 1	1 0	0	0	10	10 2	20.6
Male	54	158	50	literate	employed	2500	married	No	No	5	No	Yes	Yes	0	0	0	No	No	No	No	0	0	0	0	0 No	0	0	0	0 0	0 0	0	0	no	no	10 1	30 110	130	110	80	80 8) 8) 13	4 no	0 0	0 0	0	0	9	9	20
Male	35	150	56	literate	employed	2200	married	No	No	3	Yes	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	1 (0 0	0	3	no	no	10 1	30 137	130	130	95	87 8	3 90	5 17	8 no	0 0	0 0	0	0	10	10 2	24.9
Male	42	155	55	illiterate	employed	2500	married	No	No	0.5	No	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	0	0	0 0) 0	0	0	no	yes	10 1	90 200	210	220	100	100 9	9	J 10	4 no	0 0	0 0	0	0	10	10 2	22.9
Male	44	158	50	literate	unemployed	2000	married	No	No	2	Yes	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	1	1 1	1	1	7	no	no	10 1	43 138	144	140	83	80 7	3 7:	3 33	5 no	0 0	0 0	0	0	10	10	20
Male	43	158	58	literate	employed	2700	married	No	No	3	Yes	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0	0 0	0	1	no	no	10 1	69 163	170	170	96	94 7	9 8) 28	8 no	0 0	0 0	0	0	10	10 2	23.2
Male	42	147	68	literate	employed	2350	married	No	Yes	4	Yes	No	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	1 () 0	0	3	no	no	10 1	40 135	140	140	98	100 8) 8	J 17	8 no	0 0	0 0	0	0	10	10 3	31.5
Male	60	158	60	illiterate	employed	2500	married	No	No	4	No	Yes	No	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	1	0 0) 1	1	5	no	no	10 1	57 147	152	147	87	87 8	5 8	7 17	8 no	0 0	0 0	0	0	10	10	24
Male	50	157	74	illiterate	employed	3000	married	No	No	10	Yes	Yes	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	0	0 0	0 0	0	1	no	no	10 1	10 113	115	114	76	78 7	1 7	5 28	8 nr	0 (0 0	0	0	10	10	30
Male	45	158	65	illiterate	employed	1000	married	No	Yes	1	Yes	Yes	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	1	0 0) 1	1	5	no	no	10 1	07 160	110	162	78	82 8	5 9	J 21	1 nr	0 (0 0	0	0	10	10	26
Male	55	158	68	illiterate	employed	1000	married	No	No	1	Yes	Yes	Yes	1	1	0	No	No	No	No	0	0	0	0	0 No	1	1	1	0 0) 1	1	5	no	no	10 1	63 173	150	174	91	91 9	1 9	1 21	1 no	D (0 0	0	0	10	10 2	27.2

sex	age	height	weight	education	occupation bercapitaincome		marital status	smoking	alconol duration of diabetes	hypertension	exercise	diet fibre	family tablet support	family hosp support	cardiac problem	stroke	cancers	pain_inlegs	claudication	unsteadyness	burning	pricking	slippers slipping	pain at night	bare foot	washing	callus removal examine	indoor/out	baretouch	correctshoes	knowledge score	pallor catract	gotre	rt arm systilic	r-ank-sys H ankla sus	It arm sys	rtarm dias	It arm dias	rt ankle dias	It ankle dias	blood sugr	Wasting	corn/callus edema	varicose	ulcers	monofilament rt	monofilament It	BMI
Male	42	154	60	illiterate	employed 60	00 m	narried	No N	lo 5	No	No	Yes	0	0	0	No	No	No	No) 0	0	0	0	No	0	1 (0 0	0	0	0	1 0	no no	no	140	140 14	4 140	90	90	90	90	131 n	10 (0 0	0	0	10	10	25.3
Male	55	158	54	illiterate	employed 70	00 m	narried	No N	lo 2	Yes	s No	Yes	0	0	0	No	No	No	No) 0	0	0	0	No	0	1	1 0	0	0	0	1 у	es no	no	160	150 15	0 160	90	88 1	100	80	187 n	10 (0 0	0	0	10	10	21.6
Male	46	158	47	literate	unemployed 60	00 m	narried	No N	lo 5	Yes	s No	Yes	1	1	0	No	No	No	No) 0	0	0	0	No	0	0 0	0 0	0	0	0	1 0	no no	no	158	148 15	3 148	88	88	86	88	166 n	10 (0 0	0	0	10	10	18.8
Male	55	158	47	literate	unemployed 100	00 m	narried	No Y	es 5	No	No	Yes	0	0	0	No	No	No	No) 0	0	0	0	No	0	0 0	0 0	0	0	0	1 0	no no	no	150	140 15	3 142	85	82	60	83	214 n	10 (0 0	0	0	10	10	18.8
Male	45	160	70	literate	unemployed 100	00 m	narried	No Y	es 1	Ye	s No	Yes	1	1	1	No	No	No	No) 0	0	0	0	No	1	1	1 0	0	1	0	4 r	no ye	s no	140	123 14	2 123	77	77	73	73	190 n	10 (0 0	0	0	10	10	27.3
Male	54	160	59	literate	employed 60	00 m	narried	No N	lo 2	No	No	Yes	0	0	0	No	No	No	No) 0	0	0	0	No	0	0	1 0	0	0	0	1 0	no no	no	131	115 13	1 115	i 72	74	72	72	196 n	10 (0 0	0	0	10	9	23.1
Male	51	162	69	literate	unemployed 100	00 m	narried	No N	lo 4	No	Yes	Yes	1	1	0	No	No	No	No) 0	0	0	0	No	0	1	1 1	0	0	0	3 1	no no	no	184	160 18	0 160	100	98	90	90	162 n	10 (0 0	0	0	10	10	26.3
Male	48	164	87	literate	employed 100	00 m	narried	No N	lo 7	Ye	s No	No	1	1	1	No	No	No	No) 0	0	0	0	No	1	1	1 0	0	1	0	4 r	no ye	s no	160	136 16	0 138	85	86 1	102	100	190 n	10 (0 0	0	0	10	10	32.4
Male	49	164	75	illiterate	employed 130	00 m	narried	No N	lo 5	No	No	No	0	0	0	No	No	No	No) 0	0	0	0	No	0	1 (0 0	0	0	0	1 0	no no	no	120	100 12	0 110	70	70	70	70	200 n	10 (0 0	0	0	10	10	27.9
Male	52	160	78	illiterate	unemployed 60	00 m	narried	No N	lo 5	Yes	s No	No	1	1	0	No	No	No	No) 0	0	0	0	No	0	0 (0 0	0	0	0	0 у	ves no	no	170	135 17	2 140	74	74	83	84	176 n	10 (0 0	0	0	10	10	30.5
Male	60	158	49	illiterate	unemployed 90	00 m	narried	No N	lo 4	No	Yes	No	0	0	1	No	No	No	No) 0	0	0	0	No	1	1 (0 0	0	0	0	1 r	no no	no	160	115 16	0 116	83	83 1	100	103	115 n	10 (0 0	0	0	9	9	19.6
Male	58	164	53	illiterate	employed 100	00 m	narried	No Y	es 5	No	No	Yes	0	0	0	No	No	No	No) 0	0	0	0	No	0	0	1 0	0	0	0	1 O	no no	no	186	130 18	6 130	080	80 1	109	109	244 n	10 (0 0	0	0	10	10	19.7
Male	52	162	54	literate	unemployed 120	00 m	narried	No N	lo 5	No	No	Yes	1	1	0	No	No	No	No) 0	0	0	0	No	1	0 0	0 0	0	0	0	1 0	no no	no	180	160 17	0 140	100	100 1	110	100	110 n	10 (0 0	0	0	10	10	20.6
Male	47	153	70	illiterate	unemployed 100	00 m	narried	No N	lo 4	No	No	No	1	1	0	No	No	No	No) 0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	180	140 18	0 144	97	97 1	100	100	167 n	10 (0 0	0	0	10	10	29.9
Male	54	160	85	literate	unemployed 190	00 m	narried	No N	lo 1	No	No	Yes	0	1	0	No	No	No	No	0	0	1	0	No	1	1	1 0	0	0	0	3 1	no ye	s no	160	150 15	0 140	90	80	80	90	150 n	10 1	1 1	0	0	3	10	33.2
Male	54	159	68	illiterate	employed 200	00 m	narried	No N	lo 9	Ye	s No	Yes	1	1	1	No	No	No	No	0	1	0	0	No	1	1 () 1	0	0	0	3 1	no ye	s no	130	137 13	0 130	95	87	83	96	135 n	10 1	1 0	0	0	7	6	26.9
Male	50	160	81	literate	employed 250	00 m	narried	No N	lo 9	Ye	s No	Yes	1	1	1	No	No	Yes	No	0	1	0	0	No	0	0	1 0	0	1	0	1 r	no no	no	126	150 12	6 153	87	87 1	100	100	102 n	10 (0 0	0	0	3	3	31.6
Male	55	151	57	literate	employed 180	00 m	narried	No N	lo 15	i Ye	s No	No	1	1	1	No	No	Yes	No	0	1	0	0	No	0	0	1 0	0	1	0	1 r	no no	no	130	140 13	4 148	90	90	80	80	102 n	10 (0 0	0	0	1	2	25
Male	61	162	53	illiterate	unemployed 200	00 m	narried	No N	lo 10) Ye	s Yes	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	170	163 17	0 170	100	100 1	100	100	147 n	10 (0 0	0	0	5	5	20.2
Male	65	162	75	illiterate	employed 260	00 m	narried	No N	lo 20) Ye	s No	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	151	141 14	6 141	81	81	79	81	144 n	10 (0 0	0	0	2	2	28.6
Male	58	169	48	illiterate	employed 50	00 m	narried	No N	lo 10) Ye	s No	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	140	140 14	0 140	70	70	80	80	146 n	10 (0 0	0	0	4	4	16.8
Male	54	162	54	illiterate	employed 50	00 m	narried	No Y	es 13	Ye:	s No	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	150	149 15	0 140	080	86	80	80	146 n	10 (0 0	0	0	4	4	20.6
Male	58	158	70	illiterate	unemployed 50	00 m	narried	No N	lo 12	? Ye	s No	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	150	140 15	8 146	100	100 1	100	91	146 n	10 (0 0	0	0	4	4	28
Male	55	160	80	illiterate	unemployed 55	i0 m	narried	No N	lo 10) Ye	s No	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	150	130 14	0 139	80	80	90	80	147 n	10 (0 0	0	0	5	5	31.3
Male	60	152	55	illiterate	unemployed 100	00 m	narried	No Y	es 12	Ye:	s Yes	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	154	116 15	4 116	74	72 1	100	100	148 n	10 (0 0	0	0	6	6	23.8
Male	55	168	48	literate	unemployed 250	00 m	narried	No Y	es 10) No	No	No	0	0	0	No	No	No	No	0	0	0	0	No	0	1	1 0	0	1	0	з г	no no	no	120	112 12	2 110	76	78	76	78	246 n	10 (0 0	0	0	7	6	17
Male	63	160	57	literate	unemployed 150	00 m	narried	No Y	es 19	No	Yes	Yes	0	0	0	No	No	No	No	0	0	0	0	No	0	1	1 0	0	1	0	з г	no no	no	140	124 14	0 126	76	78	80	80	246 n	10 (0 0	0	0	7	6	22.3
Male	63	154	47	illiterate	unemployed 200	00 m	narried	No N	lo 15	i Ye	s Yes	Yes	0	0	0	No	No	No	No	0	1	1	1	No	1	0	1 0	0	1	0	з г	no no	no	171	156 17	0 154	96	94	91	90	320 n	10 (0 0	0	0	10	10	19.8
Male	45	144	70	illiterate	unemployed 100	00 wi	vidower	No Y	es 1	No	No	No	0	0	0	No	No	Yes	No	0	0	1	0	No	1	1	1 0	0	0	0	3 у	ves ye	s no	140	130 14	0 126	80	80	78	78	208 n	10 (0 0	0	0	8	8	33.8
Male	55	145	50	illiterate	employed 210	00 m	narried	No Y	es 2	Yes	s No	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	152	142 14	7 142	82	82	80	82	153 n	ю (0 0	0	0	10	10	23.8
Male	55	160	60	illiterate	unemployed 250	00 m	narried	No Y	es 5	Yes	s No	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	150	140 14	5 140	80	80	78	80	153 n	ю (0 0	0	0	10	10	23.4
Male	52	150	66	illiterate	employed 50	00 m	narried	No N	lo 1	Yes	s No	Yes	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	188	180 19	0 180	105	100 1	100	100	152 n	10 (0 0	0	0	10	10	29.3
Male	51	150	88	illiterate	employed 100	00 m	narried	No N	lo 7	Yes	s Yes	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	150	140 14	5 140	80	80	78	80	152 n	10 (0 0	0	0	10	10	39.1
Male	41	150	54	illiterate	unemployed 50	0 wi	vidower	No Y	es 2	Ye	s No	No	0	0	0	No	No	No	No	0	0	0	0	No	0	0	1 0	0	1	0	1 r	no ye	s no	140	110 14	0 110	70	70	70	70	167 n	10 (0 0	0	0	10	10	24
Male	56	156	67	illiterate	employed 100	00 m	narried	No N	lo 1	Yes	s No	No	0	0	0	No	No	Yes	No	0	0	0	0	No	1	1	1 0	0	1	0	4 r	no no	no	152	142 14	7 142	82	82	80	82	152 n	10 (0 0	0	0	10	10	27.5
Female	44	169	51	illiterate	unemployed 40	0 V	Nidow	No	lo 10) No	No	Yes	0	0	0	No	No	No	No	0 0	0	0	0	No	0	1	1 0	0	0	1	3 1	no no	no	130	140 13	0 140	81	78	80	80	140 n	10 1	1 0	0	0	6	8	17.9
Female	44	158	80	illiterate	unemployed 230	00 V	Nidow	No	lo 10) No	No	No	0	0	0	No	No	No	No	0 0	0	0	0	No	0	1	1 0	0	0	1	з г	no no	no	155	145 15	0 145	85	85	83	85	140 n	10 (0 0	0	0	6	8	32.1
Female	46	159	50	illiterate	employed 200	00 m	narried	No	lo 5	No	No	No	0	0	0	No	No	No	No	0 0	0	0	0	No	0	0 (0 0	0	0	0	1 0	no no	no	180	170 20	0 170	100	100 1	100	100	230 n	10 1	1 0	0	0	10	10	19.8
Female	40	147	56	illiterate	employed 100	00 m	narried	No N	lo 2	No	No	No	1	1	0	No	No	No	No) 0	0	0	0	No	1	1	1 1	1	1	0	1 d	no no	no	158	148 15	3 148	88	88	86	88	101 n	10 1	1 0	0	0	10	10	25.9

sex	age	height	weight	education	occupation	percapitaincome	marital status	smoking	alcohol	duration of diabetes	hypertension	exercise Hist fibre	family tablet support	family hosp support	cardiac problem	stroke	cancers	pain_inlegs	claudication	numness	unsteadyness	ourning oricking	slippers slipping	pain at night	bare foot	washing	callus removal	indoor/out	baretouch	correctshoes	knowledge score	pallor	cauaci gotre	rt arm systilic	r-ank-sys	t ankle sys	tt arm sys rtarm dias	t arm dias	rt ankle dias	tt ankle dias	blood sugr	wasting	corn/callus	edema	Váliuuse Inare	moters monofilament rt	monofilament It	BMI
Female	39	154	59	literate	employed	3000	Widow	No	No	2	No N	lo Ye	es 0	1	0	No	No	No	No	0	0	0 0	0	No	0	1	1 1	0	1	0	4	yes n	io no	157	148	176 1	46 91	88	83	88	120	no	0	0 C) () 10	10	24.9
Female	43	160	85	illiterate	employed	3000	married	No	No	2	Yes N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	1 1	1	0	1	4	no n	io no	160	165	162 1	68 11	2 11:	2 96	98	220	no	0	0 C) () 9	10	33.2
Female	41	157	57	literate	employed	2500	married	No	No	2	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	1	1 0	0	0	0	1	yes n	io no	126	127	128 1	26 77	78	78	78	187	no	0	0 C) () 10	10	23.1
Female	60	154	60	illiterate	unemployed	2000	Widow	No	No	7	Yes Y	es Ye	es 0	0	0	No	No	Yes	No	0	0	0 0	0	No	1	0	1 1	0	0	0	3	no n	io no	184	182	182 1	83 99	99	90	90	90	no	0	0 C) () 9	10	25.3
Female	39	164	51	literate	unemployed	2500	Widow	No	No	2	No N	lo Ye	es 0	1	0	No	No	No	No	0	0	0 0	0	No	0	1	1 1	0	1	0	4	yes n	io no	157	148	176 1	46 91	88	83	88	120	no	0	0 C) () 10	10	19
Female	63	145	46	illiterate	unemployed	2500	married	No	No	8	Yes N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	1	0 0	0	1	0	1	yes n	io no	154	144	149 1	44 84	, 84	82	84	219	no	0	0 C) () 9	8	21.9
Female	40	160	48	literate	employed	3500	married	No	No	1	Yes N	lo Ye	es 1	1	0	No	No	No	No	0	0	0 0	0	No	0	1	1 0	0	0	0	1	no n	io no	140	140	120 1	10 70) 70	90	80	230	no	0	0 C) () 10	10	18.8
Female	43	164	59	illiterate	unemployed	2000	married	No	No	5	Yes N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	0	0	0	0	yes n	io no	170	140	167 1	45 60) 60	83	72	168	no	0	0 C) () 10	10	21.9
Female	56	165	52	literate	unemployed	500	married	No	No	0.25	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	1	1 0	0	0	0	1	no n	io no	144	160	130 1	50 80) 70	80	90	200	no	0	0 C) () 10	10	19.1
Female	53	144	65	illiterate	unemployed	300	married	No	No	9	Yes N	lo N	o 1	1	0	No	No	No	No	0	0	0 0	0	No	1	0	1 1	0	1	0	4	yes n	io no	160	170	160 1	40 11	J 100	0 100	100	225	no	0	0 C) () 10	10	31.4
Female	51	150	80	illiterate	unemployed	520	married	No	No	2	No N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	0	0	0	0	no n	io no	170	170	180 1	60 10	J 11(0 100	90	300	no	0	0 C) () 10	10	35.6
Female	42	152	65	literate	employed	560	married	No	No	3	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	0	0	0	yes n	io no	150	150	160 1	40 90	90	90	90	168	no	0	0 C) () 10	9	28.1
Female	49	159	65	literate	employed	1000	married	No	No	3	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	0	0	0	yes n	io no	170	163	170 1	70 10	0 100	0 100	100	168	no	0	0 C) (J 10	9	25.7
Female	48	144	60	illiterate	unemployed	500	married	No	No	6	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	1	1	1 0	0	1	0	4	no n	io no	210	200	210 2	00 90) 10(0 100	100	220	no	0	0 C) () 10	10	28.9
Female	39	162	56	literate	employed	500	married	No	No	3	Yes N	lo Ye	es 1	1	1	No	No	No	No	0	0	0 0	0	No	1	1	0 0	0	1	0	3	no n	io no	180	170	200 1	70 10	0 100	0 100	100	123	no	0	0 C) (J 10	10	21.3
Female	57	138	49	literate	unemployed	1000	married	No	No	10	Yes N	lo N	o 1	1	0	No	No	No	No	0	0	0 0	0	No	1	1	0 0	0	1	0	3	no n	io no	160	150	150 1	60 90	88 (100	80	230	no	0	0 C) () 10	10	25.7
Female	54	169	48	literate	unemployed	500	married	No	No	9	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	1	1	1 0	0	1	0	4	no n	io no	156	146	151 1	46 86	, 86	84	86	147	no	0	0 C) () 8	7	16.8
Female	37	159	60	literate	employed	800	married	No	No	5	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	0	0	0	0	no n	io no	155	145	150 1	45 85	, 85	83	85	100	no	0	0 C) () 10	10	23.7
Female	36	152	58	literate	employed	500	married	No	No	2	Yes N	lo N	o 1	1	1	No	No	No	No	0	0	0 0	0	No	1	1	0 0	0	1	0	3	no n	io no	177	165	177 1	66 11	5 11 <i>t</i>	6 87	87	123	no	0	0 C) () 10	10	25.1
Female	44	160	65	illiterate	unemployed	1000	married	No	No	12	Yes Y	es Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	1	1	1 0	0	0	0	3	no n	io no	140	130	140 1	26 80	80	78	78	238	no	0	0 C) () 10	10	25.4
Female	50	144	50	illiterate	unemployed	500	married	No	No	0.5	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	1	1 0	0	0	0	1	no n	io no	130	120	130 1	30 90	90	80	80	150	no	0	0 0) (<i>i</i> 10	10	24.1
Female	39	145	46	literate	employed	600	married	No	No	5	Yes Y	es N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	0	0	0	yes n	io no	120	110	120 1	16 60	80	80	80	212	no	0	0 0) (<i>i</i> 10	10	21.9
Female	55	160	57	illiterate	employed	550	married	No	No	4	No Y	es Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	1	0	1 1	0	1	0	4	yes n	io no	140	123	142 1	23 77	77	73	73	103	no	0	0 0) (<i>i</i> 10	10	22.3
Female	46	162	54	illiterate	unemployed	1000	married	No	No	5	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	1	1	1 0	0	0	0	3	no n	io no	160	140	160 1	44 90	88	90	88	238	no	0	0 0) (<i>i</i> 10	10	20.6
Female	55	150	56	illiterate	employed	1200	Widow	No	No	5	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 1	1	0	0	1	no n	io no	210	180	200 1	70 10	0 100	0 100	100	92	no	0	0 0) (<i>i</i> 10	10	24.9
Female	62	158	54	illiterate	unemployed	500	married	No	No	10	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	0	0	0	yes n	io no	180	154	182 1	56 11	3 110	0 100	100	113	no	0	0 0) (<i>i</i> 10	8	21.6
Female	42	155	55	literate	employed	600	married	No	No	5	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	0	0	0	0	no n	io no	120	100	120 1	10 70	70	70	70	100	no	0	0 0) (<i>i</i> 10	10	22.9
Female	41	158	40	literate	unemployed	500	married	No	No	1	No N	lo Ye	es 1	1	0	No	No	No	No	0	0	0 0	0	No	1	0	0 0	1	0	1	3	yes n	io no	169	140	170 1	44 88	90	88	90	150	no	0	0 0) (<i>i</i> 10	10	16
Female	55	162	59	illiterate	unemployed	1000	married	No	No	4	No N	lo Ye	es 1	1	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	1	1	0	3	no n	io no	228	184	226 1	86 11	6 11 <i>4</i>	4 136	134	112	no	0	0 0) (/ 10	10	22.5
Female	58	169	54	illiterate	unemployed	800	married	No	No	10	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	1	0	1 0	0	0	0	1	no n	io no	170	135	172 1	40 74	74	83	84	190	no	0	0 0) (/ 10	10	18.9
Female	43	160	59	illiterate	unemployed	600	married	No	No	5	No N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	1	0	1 0	0	0	0	1	no n	io no	189	150	190 1	56 80	82	93	90	190	no	0	0 0) (/ 10	10	23.1
Female	48	158	49	literate	unemployed	600	married	No	No	5	No N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	0	0	0	yes y	es no	174	131	176 1	31 87	80	94	92	290	no	0	0 0) (/ 10	10	19.6
Female	56	158	47	illiterate	unemployed	500	Widow	No	No	10	No N	lo Ye	es 1	1	0	No	No	No	No	0	0	0 0	0	No	0	0	0 0	0	1	0	0	yes y	es no	186	136	186 1	40 10	5 105	5 96	96	220	no	0	0 0) (, 8	8	18.8
Female	53	158	58	illiterate	unemployed	1000	married	No	No	6	No N	lo N	o 0	0	1	No	No	No	No	0	0	0 0	0	No	1	1	0 0	0	0	0	1	no n	io no	186	130	186 1	30 80	80	109	109	115	no	0	0 C) (ı 9	9	23.2
Female	45	154	70	illiterate	employed	1800	married	No	No	0.5	Yes N	lo Ye	es 0	0	0	No	No	No	No	0	0	0 0	0	No	1	1	1 0	0	1	0	4	yes n	io no	184	182	182 1	83 99	99	90	90	200	no	0	0 C) (ı 10	10	29.5
Female	40	147	65	literate	unemployed	1500	married	No	No	5	Yes Y	es Ye	es 1	1	0	No	No	No	No	0	0	0 0	0	No	0	0	1 0	0	0	0	0	no n	io no	160	150	150 1	40 90	80	80	90	295	no	0	0 0) (10	10	30.1
Female	53	165	52	literate	unemployed	1200	married	No	No	3	No Y	es Ye	es 0	0	0	No	No	Yes	No	0	0	0 0	0	No	1	1	0 1	0	1	0	4	yes n	io no	131	119	132 1	20 76	76	56	56	275	no	0	0 0) (10	10	19.1
Female	45	156	63	illiterate	employed	500	married	No	No	5	Yes N	lo N	o 0	0	0	No	No	No	No	0	0	0 0	0	No	0	1	0 0	0	0	0	0	no n	io no	128	116	128 1	16 68	70	80	80	160	no	0	0 0) (10	10	25.9
Female	51	156	70	literate	unemployed	880	married	No	No	3	No Y	es Ye	es 0	0	0	No	No	Yes	No	0	0	0 0	0	No	1	1	0 1	0	1	0	4	yes n	io no	180	163	180 1	64 10	2 100	0 108	102	275	no	0	0 0) (10	10	28.8

sex	age	height	education	occupation	percapitaincome	marital status	smoking	alconol duration of diabetes	hypertension	exercise	diet fibre	family tablet support	family hosp support	cardiac problem	stroke	cancers	pani_inegs claudication	numness	unsteadyness	burning	pricking	slippers slipping	pain at night	bare foot	washing callus removal	examine	indoor/out	baretouch	correctshoes	niovicage score pallor	catract	gotre	rt arm systilic r-ank-sys	It ankle sys	It arm sys	rtarm dias	It arm dias	rt ankle dias **	It drive uras blood sugr	wasting	corn/callus	edema	varicose	ulcers	monofilament rt	monotilament it BMI
Female	46	154 5	9 illiterate	unemployed 6	00 V	Widow	No N	lo 5	No	Yes	Yes	0	0	0	No	No N	o N	0	0	0	0	0	No	0	0 1	0	0	1	0	ye	s yes	no	169 150	170	150	60	60 8	36 7	6 14) no	0	0	0	0	10 1	10 24.9
Female	45	152 5	8 illiterate	unemployed 6	00 V	Widow	No N	lo 4	No	No	No	0	0	0	No	No Y	es No	0	0	0	0	0	No	0	1 0	0	0	1	0	ye	s yes	no	140 124	142	126	73	74 Ģ	9 4 9	4 12	6 no	0	0	0	0	9 (9 25.1
Female	54	157 5	7 literate	unemployed 5	i50 m	married	No N	lo 3	No	No	Yes	0	0	0	No	No N	o N	0	0	0	0	0	No	0	1 0	1	0	0	0	ye	s no	no	142 125	i 138	130	80	80 8	30 8 ^r	0 19) no	0	0	0	0	10 1	0 23.1
Female	54	158 6	0 illiterate	unemployed 10	000 m	married	No N	lo 4	Yes	No	Yes	1	1	0	No	No N	o N	0	0	0	0	0	No	1	1 1	1	1	0	1 (i no	o no	no	180 140	180	144	97	97 10	00 10	JO 12	5 no	0	0	0	0	10 1	0 24
Female	45	152 5	5 literate	employed 7	'50 m	married	No N	lo 2	Yes	No	No	1	1	0	No	No N	o N	0	0	0	0	0	No	1	1 0	0	0	1	0 3	3 no	o no	no	159 120	140	145	80	80 7	75 7	0 23) no	0	0	0	0	10 1	0 23.8
Female	50	165 5	2 illiterate	unemployed 5	20 m	married	No N	lo 13	No	No	Yes	0	0	0	No	No N	o N	0	0	0	0	0	No	0	0 0	0	0	0	0 0) ye	s no	no	156 117	156	117	81	80 10	00 10	JO 11	3 no	0	0	0	0	10 8	8 19.1
Female	38	144 5	0 illiterate	employed 5	i00 m	married	No N	lo 9	No	No	No	1	1	0	No	No N	o N	0	0	0	0	0	No	1	0 1	1	0	0	1 4	l no	o no	no	156 117	156	117	81	80 10	00 10	JO 16	∂ no	0	0	0	0	10 1	0 24.1
Female	43	162 5	3 illiterate	unemployed 15	500 m	married	No N	lo 5	No	Yes	No	0	0	0	No	No N	o N	0	0	0	0	0	No	0	0 1	0	0	0	0 0) no	o no	no	160 115	i 160	116	83	83 10	00 10	J3 24	4 no	0	0	0	0	10 1	0 20.2
Female	41	152 6	5 literate	unemployed 12	200 m	married	No N	lo 5	No	No	No	0	0	0	No	No N	o N	0	0	0	0	0	No	0	0 0	0	0	0	0 0) ye	s yes	no	170 120	160	120	90	80 8	30 8/	0 290) no	0	0	0	0	10 1	0 28.1
Female	54	160 5	9 illiterate	employed 5	i00 m	married	No N	lo 15	Yes	Yes	Yes	1	1	0	No	No N	o N	0 1	0	1	1	1	No	1	0 1	0	0	0	0	ye	s yes	no	189 179	189	170	88	88 9	} 0 8′	8 20) no	0	1	0	0	2	1 23.1
Female	55	164 7	8 illiterate	unemployed 15	500 m	married	No N	lo 11	No	No	Yes	1	1	0	No	No Y	es No	0 1	1	1	0	0	No	1	0 1	1	1	1	1 (i ye	s yes	no	158 130	160	138	90	90 8	39 8/	8 15) no	0	0	0	0	2	2 29
Female	54	162 5	6 illiterate	unemployed 5	00 m	married	No N	lo 12	No	No	No	1	1	0	No	No N	o N	0 1	0	1	0	0	No	0	0 0	0	0	0	0 0) ye	s yes	no	154 116	154	116	74	72 10	00 10	JO 31	4 no	1	1	0	0	2	2 21.3
Female	57	158 5	0 illiterate	unemployed 4	50 m	married	No N	lo 15	Yes	No	Yes	0	0	0	No	No Y	es No	0 1	0	1	0	0	No	1	1 0	0	0	0	0	n	o no	no	120 110	120	116	60	80 8	30 8/	0 110) no	1	0	0	0	2	2 20
Female	57	148 5	0 illiterate	unemployed 5	i00 m	married	No N	lo 10	Yes	Yes	Yes	0	0	0	No	No N	o N) 1	0	1	0	0	No	0	0 0	0	0	0	0 0) ye	s yes	no	180 146	190	140	80	80 8	30 90	0 313	2 no	0	0	0	0	2 3	3 22.8
Female	55	164 5	4 literate	unemployed 20	000 m	married	No N	lo 12	Yes	No	No	1	1	0	No	No Y	es No) 1	0	0	0	0	No	0	1 1	0	0	0	0	ye	s yes	no	113 170	100	160	90	80 6	54 5r	0 24	/ no	0	0	0	1	5 5	5 20.1
Female	55	169 4	8 illiterate	unemployed 27	755 m	married	No N	lo 12	Yes	Yes	Yes	1	1	0	No	No N	o N	0 0	0	0	0	0	No	0	0 0	0	0	1	0 0) ye	s yes	no	159 149	154	149	89	89 8	37 80	9 21	5 no	0	1	0	0	2	2 16.8
Female	60	158 6	7 illiterate	unemployed 20	000 V	Widow	No N	lo 10	Yes	No	Yes	0	0	0	No	No N	o N	0	0	0	0	0	No	1	0 1	0	0	1	0 3	3 no	o yes	no	144 170	100	160	100	100 9) 0 80	0 10	l no	0	0	0	0	2 3	3 26.8
Female	64	162 5	6 illiterate	unemployed 5	i00 m	married	No N	lo 5	Yes	No	No	0	0	0	No	No N	o N) 1	0	1	1	0	No	0	0 1	0	0	0	0 0) ye	s no	no	112 128	111	128	91	90 7	12 72	2 31!	i no	0	0	0	0	10 1	0 21.3
Female	59	152 5	5 illiterate	unemployed 26	650 m	married	No N	lo 10	Yes	No	No	1	1	0	No	No N	o N) 1	0	1	0	0	No	0	1 0	0	0	0	0 0) no	o no	no	159 149	154	149	89	89 8	37 89	9 21	no ذ	1	0	0	0	8 {	8 23.8
Female	60	145 4	2 illiterate	unemployed 21	100 V	Widow	No N	lo 7	Yes	No	No	1	1	0	No	No Y	es No	0	1	1	0	0	No	1	1 0	0	1	1	0 4	l ye	s yes	no	154 144	149	144	84	84 8	32 8/	4 14) no	0	0	0	0	9 0	9 20
Female	60	156 5	6 literate	employed 36	650 m	married	No N	lo 5	Yes	Yes	Yes	1	1	0	No	No N	o N) 1	0	1	0	0	No	0	0 0	0	0	0	0 0) ye	s no	no	151 141	146	141	81	81 7	79 8'	1 42	l no	0	0	0	0	10 1	0 22.4
Female	51	164 7	0 illiterate	employed 10	000 m	married	No N	lo 1	Yes	No	Yes	1	1	0	No	No N	o N	0	1	0	0	0	No	1	1 0	0	1	1	0 4	l no	o yes	yes	158 148	153	148	88	88 8	36 81	8 40) no	0	1	0	0	10 1	.0 26
Female	58	158 4	7 illiterate	employed 4	00 m	married	No N	lo 1	Yes	No	Yes	0	0	0	No	No N	o N) 1	0	0	0	0	No	0	0 1	1	1	1	0 4	l no	o no	no	153 143	148	143	83	83 8	31 8:	3 33.	2 no	0	1	0	0	10 1	0 18.8
Female	58	158 4	7 literate	employed 7	00 m	married	No N	lo 1	Yes	No	No	1	1	0	No	No N	o N	0	1	0	0	0	No	1	1 0	0	1	1	0 4	l no	o yes	yes	150 140	150	148	83	84 7	78 78	8 40) no	0	1	0	0	10 1	.0 18.8
Female	72	164 8	5 illiterate	unemployed 22	250 m	married	No N	lo 1	Yes	No	No	0	0	0	No	No N	o N) 1	0	0	0	0	No	1	1 0	1	0	0	0 3	3 ye	s yes	no	133 140	133	138	104	100 8	38 88	8 15) no	0	0	0	0	8 8	8 31.6
Female	57	164 5	3 illiterate	employed 25	560 V	Widow	No N	lo 5	Yes	No	Yes	0	0	0	No	Yes Y	es No) 1	0	0	0	0	No	1	1 1	0	0	0	0 3	3 ye	s yes	no	124 120	134	123	80	80 8	30 8.	2 12	3 no	0	0	0	0	10 1	.0 19.7
Female	54	158 5	0 illiterate	unemployed 5	00 V	Widow	No N	lo 0.5	Yes	No	Yes	0	0	0	No	No N	o N) 1	0	0	0	0	No	0	0 1	1	0	1	0 3	3 no	o no	no	160 140	160	144	100	98 9	30 90	0 17	3 no	0	0	0	0	10 1	.0 20
Female	55	165 6	0 illiterate	employed 10	000 V	Widow	No N	lo 5	Yes	No	Yes	0	0	0	No	No N	o N) 1	0	0	0	0	No	0	1 1	1	0	1	0 4	l no	o no	no	166 143	160	144	90	90 9	<i>3</i> 93	3 17:	3 no	0	0	0	0	10 1	.0 22
Female	53	138 4	9 literate	unemployed 13	300 m	married	No N	lo 5	No	No	Yes	0	0	0	No	No N	o N) 1	0	0	0	0	No	0	1 0	0	0	0	0 () no	o no	no	170 140	160	150	90	100 9	<i>}</i> 0 9(0 29	7 no	0	0	0	0	10 1	.0 25.7
Female	55	162 5	6 illiterate	unemployed 5	i00 m	married	No N	lo 6	Yes	No	No	0	0	0	No	No N	o N) 1	0	0	0	0	No	1	1 0	1	0	0	0 3	3 ye	s yes	no	180 140	170	150	90	90 9	<i>}</i> 0 9(0 15) no	0	0	0	0	8 8	8 21.3
Female	56	152 5	5 illiterate	unemployed 5	50 m	married	No N	lo 12	Yes	No	No	0	0	0	No	No Y	es No) 1	0	0	0	0	No	1	1 0	0	0	0	0 .	ye	s no	no	180 140	170	150	90	90 9	<i>}</i> 0 9(0 210) no	0	0	0	0	8 0	9 23.8
Female	59	162 7	5 illiterate	unemployed 5	i00 m	married	No N	lo 4	Yes	No	No	0	0	0	No	No N	o N	o 1	0	0	0	0	No	1	1 1	0	0	0	0 3	3 ye	s no	no	190 170) 190	180	110	100 10	00 10	10 14	5 no	0	0	0	0	10 1	0 28.6
Female	54	148 5	0 illiterate	unemployed 5	i00 m	married	No N	lo 2	No	No	No	1	1	0	No	No N	o N	0	0	1	0	0	No	0	1 1	0	0	0	0 .	no	o yes	no	180 160	170	140	100	100 1	10 10	JO 201) no	0	0	0	0	10 1	.0 22.8
Female	53	159 5	0 illiterate	unemployed 6	60 V	Widow	No N	lo 5	Yes	No	No	0	0	0	No	Yes Y	es No) 1	0	0	0	0	No	1	1 1	0	0	0	0 3	3 ye	s yes	no	187 165	186	170	87	87 8	38 88	8 12	3 no	0	0	0	0	10 1	.0 19.8
Female	55	158 5	4 literate	unemployed 12	200 m	married	No N	lo 5	No	No	No	0	0	0	No	No N	o N) 1	0	0	0	0	No	0	1 0	0	0	0	0 () no	o no	no	150 130	140	139	80	80 9	<i>i</i> 0 8	0 29	/ no	0	0	0	0	10 1	0 21.6

<u>ANNEXURE – 7</u>

KEY TO MASTER CHART

sex		
age		
height	in cms	
weight	in kgs	
education		
occupation		
percapitaincome	In rupees	
marital status		
smoking	Do you have the habit of Smoking	
alcohol	Do you drink alcohol	
duration of diabetes	How long are you suffering from diabetes mellitus (in years)	
hypertension	Do you have hypertension	
exercise	Do you do any physical exercise	
diet fibre	Do you add green leafy vegetables in your diet	
family tablet support	Do your family members remind you to take tablets	1-yes,0-no
family hosp support	Do you have family support for going hospital	1-yes,0-no
cardiac problem	Do you have any cardiac problem	1-yes,0-no
stroke	Do you have any Cerebro Vascular Accident	
cancers		
pain_inlegs	Do you have pain in legs while walking	
claudication	If yes, after what distance do u have pain	
numness	numbness on your legs	1-yes,0-no
unsteadyness	Gait: Steady /Unsteady	1-yes,0-no
burning	burning sensation	1-yes,0-no
pricking	Pricking sensation	1-yes,0-no
slippers slipping	Not able to hold your slippers	1-yes,0-no
pain at night	Not able to differentiate hot or cold with your legs	
bare foot	Do you know that you should not walk barefoot?	1-yes,0-no
washing	Do you know you should wash your feet daily?	1-yes,0-no
callus removal	Do you know you should not cut/use chemicals to remove callus and corn?	1-yes,0-no

examine	Do you know you should examine your feet daily ?	1-yes,0-no
indoor/out	Do you know you should use shoes/slippers both in indoor and outdoor?	1-yes,0-no
baretouch	Do you know you should not touch the very hot or cold things with your foot?	1-yes,0-no
correctshoes	Do you know if you are not wearing correct slippers/shoes it will lead to foot complication	1-yes,0-no
knowledge score	Total score of knowledge of study participants	
pallor	Pallor in General examination	
catract	cataract in oje or both eyes	
gotre	Presence of Swelling of thyroid in general examination	
rt arm systilic	Systolic blood pressure in right upper limb in (mmHg)	
r-ank-sys	Systolic blood pressure in left upper limb in (mmHg)	
lt ankle sys	Diastolic blood pressure in left lower limb in (mmHg)	
lt arm sys	Systolic blood pressure in left upper limb in (mmHg)	
rtarm dias	Diastolic blood pressure in right upper limb in (mmHg)	
lt arm dias	Diastolic blood pressure in left upper limb in (mmHg)	
rt ankle dias	Diastolic blood pressure in right lower limb in (mmHg)	
lt ankle dias	Diastolic blood pressure in left lower limb in (mmHg)	
blood sugr	Random blood sugar level in mg/dl	
wasting	presence of muscle wasting in general examination	
corn/callus	presence of corn / callus inone or both foot	1-yes,0-no
edema	presence of edema inone or both foot	1-yes,0-no
varicose	presence of varicose veins inone or both foot	1-yes,0-no
ulcers	presence of ulcers inone or both foot	1-yes,0-no
monofilament rt	monofilament test results on right foot	score out of 10
monofilament lt	monofilament test results on left foot	score out of 10
BMI	body mass index	

ANNEXURE – 8

CORN/CALLUS



Source : foot callus corn - Saferbrowser Yahoo Image Search Results [Internet]. [cited 2018 Oct 26]. Available from: https://images.search.yahoo.com/yhs/search

DIABETIC FOOT ULCER



Source : diabetic ulcer foot - Saferbrowser Yahoo Image Search Results [Internet]. [cited 2018 Oct 26]. Available from: https://images.search.yahoo.com/yhs/search



WASTING OF MUSCLES IN FEET (GROOVING SIGN)

Source : muscle wasting in foot - Saferbrowser Yahoo Image Search Results [Internet]. [cited 2018 Oct 26]. Available from: https://images.search.yahoo.com/yhs/search

ANNEXURE 9

10 SITES OF MONOFILAMENT TEST



Source : monofilament test sites - Yahoo Image Search Results [Internet]. [cited 2018 Oct 26]. Available from: https://images.search.yahoo.com/search/images.