
**“Prevalence of Peripheral Neuropathy
among Type-2 diabetes mellitus
patients in an urban community”**

**Submitted by
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Dissertation

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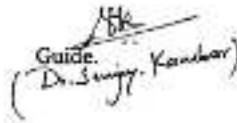
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LIST OF ABBREVIATIONS USED

1	DM	Diabetes mellitus
2	NCD	Non-Communicable Diseases
3	BP	Blood Pressure
4	DPN	Diabetic Peripheral Neuropathy
5	MNSI	Michigan Neuropathy Screening Instrument
6	HDL	High-Density Lipoprotein
7	DSPN	Distal Symmetrical Polyneuropathy
8	HbA1c	Glycated Hemoglobin
9	GDM	Gestational Diabetes Mellitus
10	SEC	Socioeconomic class
11	SWM	Semmes-Weinstein Monofilament
12	SPSS	Statistical Package For The Social Sciences
13	CF	Correction factor
14	BMI	Body Mass Index
15	WC	Waist circumference
16	HC	Hip circumference
17	WHR	Waist Hip Ratio
18	OHA	Oral Hypoglycemic Agent
19	NCV	Nerve Conduction Velocity
20	ANM	Auxiliary nurse midwife

ABSTRACT

Title: Prevalence of Peripheral Neuropathy among Type-2 Diabetes mellitus patients in an urban community

Introduction: The chronic nature of diabetes mellitus causes numerous debilitating complications thereby reducing the quality of life. Peripheral neuropathy is one of the most common complications of diabetes mellitus. Diabetes causes nerve damage through different mechanisms, including damage due to hyperglycemia and decreased blood flow to nerves by damaging small blood vessels supplying to the nerves (vasa nervorum). This nerve damage leads to loss of sensations such as vibration, pain and temperature which leads to damage to limbs (delayed, non-healing ulcers) and ultimately leads to lower limb amputations.

Objectives:

1. To determine the prevalence of peripheral neuropathy among type-2 diabetes mellitus patients in an urban community.
2. To estimate vitamin B12 levels among diabetes peripheral neuropathy patients.

Materials and Methods: This was a community-based cross-sectional study conducted for a period of one year from January 2020 to December 2020 among type-2 diabetes mellitus patients. After obtaining written informed consent, socio-demographic details were obtained followed by which a pre-tested, validated questionnaire MNSI was administered and then physical assessment to determine peripheral neuropathy was done. The patients who had diabetic peripheral neuropathy were then subjected to serum Vitamin B12 estimation.

Results: Among 350 participants, the mean age was 51.59 ± 10.54 years. Majority were female participants at 58.3%. DPN was present among 94 (26.9%) participants in this study. Among the cases with DPN, 50% participants had low normal vitamin

B12 and 36.2% of the participants were found with vitamin B12 deficiency. There were significant associations noted between duration of DM, family history of DM, habit of alcohol consumption, treatment history, regular physical activity, type of diet and absence of peripheral pulsation with presence of DPN.

Conclusions: The burden of DPN among the cases with T2DM was notably high with predominant vitamin B12 deficiency among them. Hence, it is essential to strengthen the screening for DPN for all the cases with DM at the community level in order to diagnose early and treat promptly before the onset of foot related complications.

Keywords: Diabetic Peripheral neuropathy, Diabetes Mellitus, Type-2 Diabetes Complications, MNSI.

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INTRODUCTION

Diabetes Mellitus (DM) is the most common public health concern among Non-communicable diseases (NCDs) not only in India but also worldwide. The well-known fact is that type 2 diabetes mellitus is more common than type 1 diabetes mellitus. Type 2 diabetes mellitus affects about 382 million population throughout the world and in future it is expected that diabetes mellitus will affect 592 million people by the year 2035¹.

The complications of uncontrolled diabetes mellitus pose a threat to the health care system. The two types of complications which occur due to type 2 diabetes mellitus are microvascular and macrovascular among which microvascular complications like neuropathy, nephropathy and retinopathy are frequently reported.

Distal symmetrical neuropathy is the commonest type of diabetic neuropathy with significant disability and morbidity^{2,3}. Symptoms of diabetic neuropathy include loss or reduced sensation, numbness, paresthesia, hyperesthesia and pricking type of pain which eventually leads to reduced mobilization and substantial risk of developing non healing foot ulcers and amputation.

Incidence of diabetic peripheral neuropathy was reported as 10– 50% of cases with type 2 diabetes mellitus³. During the time of diagnosis of diabetes mellitus itself, neuropathy was reported among almost 10% of diabetic cases and the prevalence of diabetic peripheral neuropathy is as high as 50% among the cases with diabetes mellitus for more than 25 years^{4,5}. Diabetic peripheral neuropathy is the initial step, which usually presents with pricking type of pain in foot with reduced sensation, which subsequently develops to diabetic foot ulcer. Due to reduced sensation in the

foot and inappropriate weight distribution in the pressure points of the foot, the foot ulcers develop in the high-risk areas (pressure points)⁶.

Diabetic peripheral neuropathic pain is defined as pain arising as a direct consequence of abnormalities in the peripheral somato-sensory system among the cases with diabetes mellitus⁸. In addition, diabetic peripheral neuropathy is also associated with morbidities like foot or ankle fractures, ischemic ulceration and lower-limb amputations¹¹⁻¹³. The risk of foot amputation is 15 times higher among the cases with diabetic peripheral neuropathy⁵. Hence, early diagnosis and treatment of diabetic neuropathy is particularly important for preventing secondary complications and improving quality of life.

Risk factors suggested to be associated with diabetic neuropathy includes high blood pressure (BP), hyperlipidemia and cigarette smoking⁶.

Another concern related to diabetic peripheral neuropathy is the level of serum vitamin B12¹². Vitamin B12 deficiency can result in nerve damage, or it may contribute to cause diabetic peripheral neuropathy¹³. Vitamin B12 deficiencies can often be left unnoticed because the presentations range from asymptomatic to a wide spectrum of hematological disorders and neuropsychiatric disorders¹⁵.

Hence, we conducted this study to know the burden of peripheral neuropathy among type-2 diabetes mellitus patients in an urban community and we estimated serum vitamin B12 levels among those patients with diabetes peripheral neuropathy.

OBJECTIVES

- To determine the prevalence of peripheral neuropathy among type-2 diabetes mellitus patients in an urban community.
- To estimate vitamin B12 levels among diabetes peripheral neuropathy patients.

REVIEW OF LITERATURE

Diabetic Peripheral Neuropathy (DPN) is defined as a group of debilitating, diabetes-related nerve disorders and is one of the most common microvascular complications of DM, affecting up to two thirds of cases with type 2 DM¹⁹⁻²¹.

Prevalence of Diabetic Peripheral Neuropathy

Based on Michigan Neuropathy Screening Instrument (MNSI), the prevalence of DPN were reported with findings ranging from 10% - 54.4%²².

Pathogenesis and Mechanism of DPN

Increased blood sugar levels promote sorbitol accumulation with significant increase in cellular osmolarity and also it shunts to the hexose pathway, which results in oxidative stress and the formation of advanced glycation end products^{9,25}.

Damage to peripheral nerves leads to hyperexcitability in nociceptors. There is generation of spontaneous impulses within the axons including the dorsal root ganglion^{23,24}. This mechanism is suggestive of an abnormality contributing to the pain in DPN.

MNSI

The Michigan Neuropathy Screening Instrument (MNSI), a 15-item structured questionnaire, was applied to determine the presence of diabetic peripheral neuropathy²⁶ among the cases with type 2 DM and physical examination with six neurological tests were performed to evaluate sensation, deep reflexes, force and vibration.

Based on history out of 15 questions, each yes response carry score of 1 except for question number 7 and 13 where the response no carries score of 1. A score of ≥ 7 was considered abnormal. On examination, each abnormal finding carries score of 1 and the total possible score is 10 points and, in the published scoring algorithm, a score ≥ 2.5 is considered abnormal.

Recent Literatures:

Moghtaderi et al²⁷ (2006) performed a study among 176 type 2 diabetic cases patients to assess the diagnostic performance of the test characteristics and cut-off point of MNSI scoring for the diagnosis of DPN. MNSI scores of 1.5, 2.0, 2.5 and 3.0 were assessed as cut-off values. Sensitivities were 79%, 65%, 50% and 35% and specificities were 65%, 83%, 91% and 94%, respectively.

Tres et al²⁸ (2007) in their cross-sectional study conducted in Brazil among 340 cases with type 2 DM reported the prevalence of DPN as 22.1% using MNSI.

Wu EQ et al²⁹ (2007) conducted a community-based cross-sectional study in France among 1023 participants with known DM and reported the prevalence of DPN by using MNSI as 11% in their study.

Pfipsen et al³⁰ (2009) conducted a hospital-based cross-sectional study among 203 DM cases and reported 22% of their study participants had vitamin B12 deficiency in their study.

Boyraz et al³¹ (2010) conducted a study among 70 cases with type 2 diabetic patients and reported the frequency of peripheral neuropathy using MNSI as 61.3% and 46.2% among the obese and non-obese cases with type 2 DM, respectively.

Malazy et al³² (2011) performed a cross-sectional study to assess the prevalence of DPN and its associated risk factors in Iran among 124 type 2 DM cases using various diagnostic scales and techniques of DPN. They reported the 31.9% of cases had DPN using MNSI. They also reported that tingling in the lower extremity was the most frequent complaint (42%). They reported that age more than 50 years, duration of DM for more than 10 years, and fasting blood sugars more than 200 mg/dl were the main risk factors for development of DPN in their study.

Geffari et al³³ (2012) conducted a cross-sectional study to assess the prevalence of DPN using MNSI in a primary care setting. In their study, they included 242 randomly selected type 2 DM cases and reported the prevalence of DPN as 45% in the primary care setting.

Won et al³⁴ (2012) performed a cross-sectional hospital study in Korea among 4000 type 2 DM cases to assess the prevalence of DPN and reported that prevalence of neuropathy was 33.5% using MNSI. Age, female gender, duration of DM, lower glycosylated haemoglobin, treatment with oral hypoglycaemic agents or insulin, presence of retinopathy, history of cerebrovascular or peripheral arterial disease, presence of hypertension or dyslipidaemia, and history of foot ulcer were found to be associated with DPN in their study.

Azura et al³⁵ (2012) conducted a cross-sectional study in Malaysia to identify the risk factors for peripheral neuropathy among newly diagnosed Type 2 DM cases. They involved 254 cases and reported that 8.7% of their study participants were found to have DPN using MNSI. Presence of diabetic retinopathy and age were found to be associated with presence of DPN in their study.

Pawde et al³⁶ (2013) in their hospital-based cross-sectional study conducted among 283 type 2 DM patients and reported prevalence of neuropathy among type 2 DM cases as 33.3%, using MNSI. Cases with hypertension and dyslipidaemia were found to have a higher risk of developing neuropathy.

Sarihin et al²² (2013) conducted a descriptive study among 202 cases with DM in Assam and reported the prevalence of DPN as 55% and 54% among the males and females with type 2 DM respectively using MNSI.

Lee CM et al³⁷ (2014) conducted a registry-based cross-sectional study in Taiwan among 377 participants with known type 2DM cases and reported the prevalence of DPN by using MNSI as 34.5% in their study.

Li et al³⁸ (2014) conducted a cross-sectional study to find the prevalence and risk factors of DPN in Type 2 DM cases. Among the 3359 cases with type 2 DM, the prevalence of DPN was found to be 33.1% using MNSI. Age, duration of DM and HbA1c were found to be the risk factors for DPN in their study.

Bansal et al³⁹ (2014) conducted a cross-sectional study to assess the prevalence of DPN. They included 1637 known cases of DM and found the prevalence of DPN as 29.2% using MNSI. They reported the prevalence of mild, moderate, and severe neuropathies as 8.1%, 14.6% and 6.6%, respectively. Age, duration of diabetes, dyslipidemia, glyated hemoglobin, the presence of other micro vascular and macro vascular complications and alcoholic status were the risk factors found to be associated with the presence of DPN.

Wang et al⁴⁰ (2014) conducted a cross-sectional study to investigate the prevalence and correlates of DPN (DPN) in Saudi population. They included 552 diabetic cases

and they reported that their study included 62.7% males. The prevalence of DPN in this study population was 19.9% using MNSI. Longer duration of diabetes, abdominal obesity, and higher levels of fasting blood glucose were associated with higher odds of DPN in their study.

Kaabi et al⁴¹ (2014) conducted a cross-sectional study to estimate prevalence and identify relevant determinants of peripheral neuropathy United Arab Emirates. They reported prevalence of peripheral neuropathy was 10.4% based on the MNSI-history score of more than or equal to 7 and 25.6% based on the MNSI-sign score of more than or equal to 3, in their study. HbA1c and physical activity were found to be significant predictors of presence of DPN based on MNSI score in their study.

Najafi et al⁴² (2014) performed a study among 107 cases with DM and reported the prevalence as 78% using MNSI. They assessed the diagnostic efficacy of each MNSI factor comparing with overall MNSI factors. They reported that muscle cramp and weakness were found to be most accurate and sensitive factors whereas numbness and prickling had lower sensitivity but greater specificity. In physical assessment, the most accurate signs were appearance of feet, ankle reflexes and vibration perception.

Mete et al⁴³ (2014) performed a study among 106 cases with type 2 DM and reported the prevalence of DPN as 32.1% using MNSI in their study.

Salvotelli L et al⁴⁴ (2015) performed a hospital-based cross-sectional study among type 2 diabetes to assess the prevalence of DPN among 3591 cases. The prevalence of DM was reported as 30% using MNSI. They reported that the cases with DPN were found to likely suffer from other micro and macro vascular complications of DM also.

D'Souza et al⁴⁵ (2015) conducted a cross-sectional study in Mangalore (India) among 208 cases with type 2 DM who had diabetes for more than 5 years were included in the study to assess the prevalence of DPN. The prevalence of DPN using the MNSI history version and MNSI examination were found to be 18.3% and 32.2% respectively. Risk factors found to be associated with presence of DPN includes male gender, smoking and age more than 40 years.

Adeniyi et al⁴⁶ (2015) conducted a hospital-based cross-sectional study in Ibadan among 264 participants with known type 2 DM cases and reported the prevalence of DPN by using MNSI as 24.1% in their study.

Hashim et al⁴⁷ (2016) in their cross-sectional study to assess the prevalence and correlates of DPN in a Qatari population reported the prevalence of DPN as 21.3% based on MNSI. In their study, diabetic patients with neuropathy were older than patients without neuropathy and they had a longer duration of diabetes. Similarly, patients with DPN had high fasting blood glucose levels and were more likely to be their native population, had hypertension and had high serum creatinine.

Fateh et al⁴⁸ (2016) performed a study among 125 cases with known DM and reported the mean neuropathy score of MNSI as 2.3 ± 1.7 and the prevalence was found to be 69% based on MNSI. They reported a significant relationship between number cases with neuropathies and mean of diabetes duration and development of retinopathy in their study.

Anbarasu et al⁴⁹ (2016) conducted a cross-sectional study to determine the prevalence of Distal Sensory neuropathy in asymptomatic Type 2 DM. They included 400 cases of type 2 DM and reported the 18% had asymptomatic peripheral neuropathy, using MNSI.

Jaiswal et al⁵⁰ (2017) performed a cross-sectional study among cases with type 2 DM and reported the prevalence of DPN as 22% in youth with type 2 DM, using MNSI. In youth with type 2 DM, risk factors were older age, male sex, longer diabetes duration, smoking, and lower high-density lipoprotein (HDL). Glycemic control over time was worse among those with DPN compared to cases without DPN among type 2 DM cases in their study.

Banoy et al⁵¹ (2017) conducted a study among 93 Colombian DM cases and reported the prevalence of DPN as 25.8% using MNSI. Among the cases with DPN, distal symmetrical polyneuropathy (DSPN) was reported in three cases, and they were found to be associated with age factor, worsening renal function and insulin treatment in their study.

Jember et al⁵² (2017) performed a hospital-based cross-sectional study in Ethiopia among 368 cases with DM and reported the prevalence of peripheral Sensory Neuropathy as 52.2% using MNSI. The common risk factors found to be associated with DPN includes age more than 50 years, obese, duration of DM, reduced physical exercise and male gender.

Titilope et al⁵³ (2017) conducted a study to determine the prevalence of peripheral neuropathy and associated factors among type 2 DM patients in Nigeria. They reported the prevalence of peripheral neuropathy as 65.7% using MNSI and associated factors were age more than 65 years and diabetes duration more than 10 years in their study.

Tahrani et al⁵⁴ (2017) performed a cross-sectional study among 126 south Asian diabetic cases in United Kingdom and reported the prevalence of DPN as 38.1% using

MNSI whereas among 140 white Caucasians diabetic cases in United Kingdom, they reported the prevalence of DPN as 54.3% using MNSI in their study.

Pai YW et al⁵⁵ (2018) conducted a hospital-based cross-sectional study in Taiwan among 2837 diabetic population and reported the prevalence of DPN as 21.3% among them using MNSI in their study.

Khawaja et al⁵⁶ (2018) performed a cross-sectional study in Jordan among 1003 cases with type 2 DM to determine the prevalence of DPN and its associated factors. They reported the prevalence of DPN based on MNSI as 39.5%. In their study, they reported numbness (32.3%), pain with walking (29.7%), history of amputation (1.3%) and loss of sensation in legs (3.8%) as the common presenting symptoms among cases with type 2 DM.

Algeffari et al⁵⁷ (2018) conducted a cross-sectional study among 242 type 2 DM cases in Riyadh and reported that 35% of patients with type-2 diabetes in this study had painful DPN using MNSI in their study.

Meena et al⁵⁸ (2019) in their cross-sectional study conducted among 203 type 2 DM cases in Kancheepuram district of Tamil Nadu and reported the prevalence of DPN using the MNSI history version and MNSI examination were found to be 31% and 24% respectively. Risk factor includes age more than 50 years, HbA1c more than 6.5 were found to be associated with the presence of DPN.

Darivemula et al⁵⁹ (2019) performed a cross-sectional study to estimate the prevalence of DPN using monofilament test and reported the prevalence of DPN was 39.3% among the cases with type 2 DM using MNSI with 28.9% in males and 10.4% in females. Glycated hemoglobin (HbA1c) more than 7, burning sensation in the foot,

numbness of the foot and pricking sensation in the foot were found to be associated with presence of DPN.

Ugoya et al⁶⁰ (2006) performed a case control study in Nigeria among 120 cases with type 2 DM and 60 controls in order to assess the frequency of occurrence and grades of diabetes peripheral neuropathy using clinical measures. They reported the prevalence of DPN as 75%. They also stated that sensory motor neuropathy was the commonest type of DPN in their study.

PopBusui R et al⁶¹ (2009) conducted a hospital-based longitudinal-study in USA among 2314 cases with known DM and reported the prevalence of DPN by using MNSI as 51% in their study.

Wang et al⁶² (2017) performed a meta-analysis including 18 studies involving type 2 DM cases to assess the association between vitamin B12 levels and the risk of DPN. They reported that reduced vitamin B12 was found in patients with DPN compared with patients with type 2 DM but without DPN in their study.

Sun et al⁶³ (2019) conducted a meta-analysis using 29 studies with a total of 50,112 participants and reported the pooled prevalence of DPN was 31.5% among cases with type 2 DM in their study.

Shiferaw et al⁶⁴ (2020) performed a meta-analysis to estimate the overall prevalence of DPN in type 2 DM cases in Africa. They included 23 studies with 269,691 participants and overall pooled prevalence of DPN was 46% in their study.

Muneeh et al⁶⁵ (2017) performed a cross-sectional study in Hyderabad, to assess the prevalence of vitamin B12 deficiency among 510 cases with DM and vitamin B 12 deficiency was reported in 35.9% of cases with a level of less than 200 pg/ml.

Based on the review of literature, the prevalence of diabetic peripheral neuropathy differs with respect to population. Moreover, the association between the vitamin B12 levels among the cases with DPN is unclear. Hence, this study was conducted to determine the prevalence of peripheral neuropathy among type-2 DM patients in an urban community and to estimate vitamin B12 levels among diabetes peripheral neuropathy patients.

MATERIALS AND METHODS

Study Design

A community-based cross-sectional study was conducted to find the prevalence of peripheral neuropathy among type-2 diabetes mellitus patients in an urban community.

Study Area

This study was conducted in urban field practice areas under the department of Community Medicine in Jawaharlal Nehru Medical College, Belagavi.

Study population

Type 2 diabetes mellitus patients residing in urban field practice areas of JNMC, Belagavi under Ashok Nagar and Rukmini Nagar Urban Health Centers.

Study period:

The study was conducted during the period from January 2020 to December 2020.

Inclusion criteria for cases:

- Known Type-2 diabetes mellitus patients aged between 35-70 years were included in this study.

Exclusion criteria:

- Type-1 diabetes mellitus patients.

- Patients with documented history with nerve root compression, cerebral vascular disease, Guillain-Barre syndrome, hypothyroidism, malignancy, amyloidosis, pernicious anemia, porphyria, chronic alcoholism, tuberculosis, leprosy and HIV.
- Patients taking chemotherapeutic agents like vinca alkaloids, taxanes that may cause neuropathy.
- Gestational Diabetes Mellitus (GDM), Pre-GDM patients.

Sample size:

Based on the literature, considering the prevalence of diabetic peripheral neuropathy as 32.2%, Sample size was calculated using the formula

$$n = 4pq/d^2$$

where,

n = sample size

p = 32.2

q = (100 – p) = (100 – 32.2) = 67.8

d = 5 (absolute error)

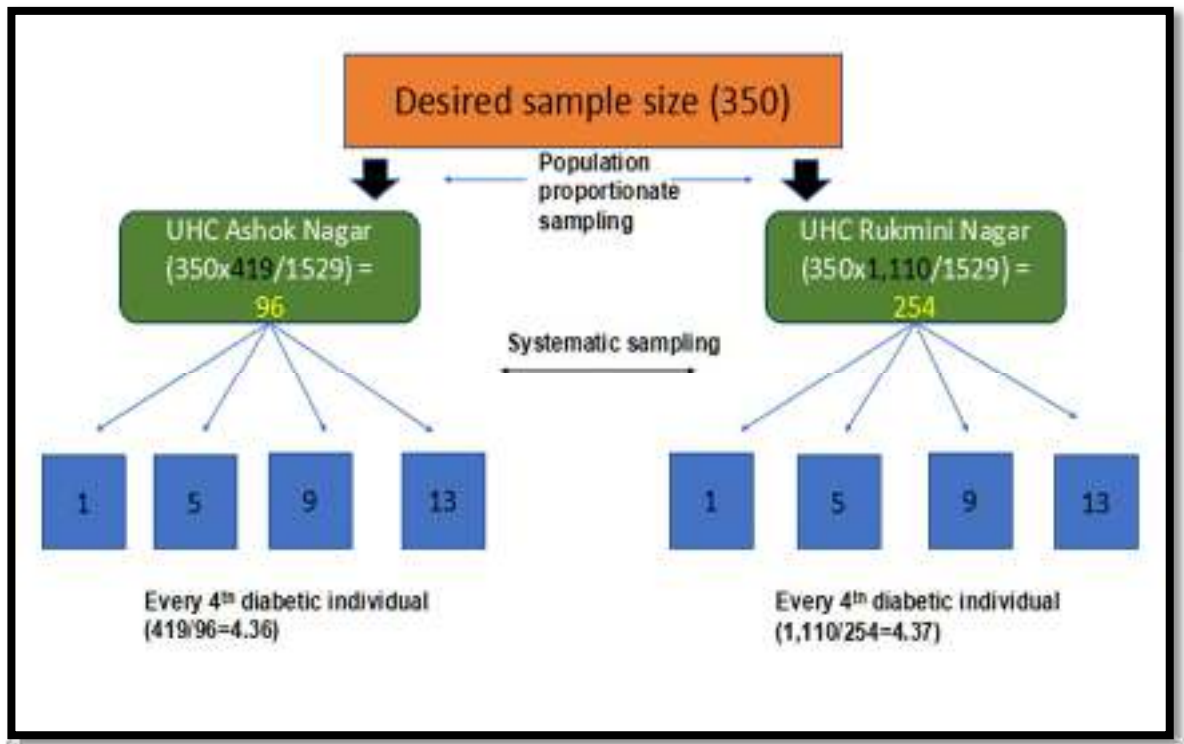
$$n = \frac{4 \times 32.2 \times 67.8}{5 \times 5} \quad n = 349.3 \text{ approximated to } \mathbf{350}.$$

Hence, a total of 350 participants with type 2 diabetes mellitus were included in this study.

Sampling method

Firstly, population proportionate sampling was used, and smaller subsets of the desirable sample size (350) were estimated from each of the two UHCs. Then, systematic sampling method was used to select the patients from the smaller subsets.

FLOW DIAGRAM OF SAMPLING METHOD



Ethical committee approval:

Ethical committee approval was obtained for this study to find the prevalence of diabetic peripheral neuropathy among type-2 diabetes mellitus patients in an urban community from the JNMC Institutional Ethics Committee on Human Subjects Research.

Data Collection:

All the study participants were explained about the study, and they were also assured that, their identity would be kept strictly confidential and that they have the option to withdraw at any time from participation in the study.

Written informed consent was obtained from the study participants prior to the interview. Consent forms in English and in native languages are enclosed in Annexure.

From the sampling frame, data was collected from the type-2 diabetes mellitus patients by house-to-house visits. After collecting the demographic and basic clinical profile of the participants, the screening for DPN was conducted by the investigator using a predesigned, validated tool called Michigan Neuropathy Screening Instrument (MNSI). It consists of two parts; first part is History Version (to be completed by the person with diabetes) which constitutes patient's perception of symptoms related to DPN and the second part is

Physical Assessment (to be completed by the investigator) which is done to detect the presence of signs related to DPN that include the following

- i. Vibration perception at great toe using 128-Hz Tuning Fork,
- ii. Elicitation of deep tendon reflex at the ankle using Queen Square Reflex Hammer and
- iii. Monofilament testing using 10-g Semmes-Weinstein monofilament (SWM).

A participant scoring ≥ 7 in history version along with score ≥ 2.5 in physical assessment was considered to have DPN in our study.

A total of 5 ml of venous blood from antecubital vein from diagnosed DPN patients was collected in plain vial for serum vitamin B12 level estimation. Blood samples were sent to a certified diagnostic laboratory where serum vitamin B12 level was estimated by chemiluminescence method. Classification of the results were based on the use of the following as normal reference range⁶⁶:

Normal Serum vitamin B12: ≥ 400 pg per mL (295 pmol per L)

Low-Normal Serum vitamin B12: 150 - 399 pg per mL (111 - 294 pmol per L)

Low Vitamin B12 (deficiency): < 150 pg per mL

A predesigned and pretested questionnaire was used to collect information regarding socio-demographic details, risk factors, anthropometric measurements, duration of diabetes, presence of other co morbid conditions and current anti-diabetic medications.

Data analysis

The data were entered in Microsoft Office Excel and analyzed using SPSS (Version 25). Descriptive statistics with mean, standard deviation and proportions (%) were calculated for quantitative variables. To test the hypothesis, Chi-Square test was used. p value < 0.05 was considered as statistically significant.

Definition of proforma variables:

Age: Age of the participant in completed years as on their last birthday.

Sex: Either male or female was mentioned.

Religion: Participant's religion was classified as Hindu, Muslim, Christian or others as stated by them.

Education: Every study subject was asked about their educational status. It was classified as:

Illiterate: A person who could not read and write any language.

Primary school: A person who had studied from first to fifth standard.

Middle school: A person who had studied from sixth to eighth standard.

High school: A person who had studied ninth and tenth standard.

Pre-university: The person who had studied up to Pre-University College second year.

Degree: A person who had a degree in a diploma or under graduation course.

Occupation: Every study subject was asked about their occupation. It was classified as:

Homemaker: An individual whose primary activity is conducting household tasks without being paid.

Retired: An individual who has earned income during some period in the workforce or as an employer and who is no longer working due to age.

Employed: An individual who currently has a job or business and is hired by either government office or any agency and is paid a salary or wages or who produces goods for sale or earns an income through provision of services to different people.

Unemployed: An individual who could work but does not currently have a job or business (excluding homemaker).

Marital Status: Marital status was classified as "Married", "Unmarried" and "Widowed" or "Divorced/ Separated."

Family:

Joint Family: It consists of number of married couples and their children who live in the same household.

Nuclear Family: The family consisting of married couple along with their dependent children.

Broken Family: A family where the parents have separated, or where death of one or both the parents has occurred.

Problem Family: Those families which lag behind the rest of the community. Standards of life are far below the accepted minimum and home life is unsatisfactory.

Socioeconomic status: Information regarding per capita income (in Rupees/ month) was collected and socio-economic status was classified using Modified B. G. Prasad's classification for the study period of 2019⁶⁷.

Monthly Per Capita Income = Total monthly income of family/ Total members of family

Modification was done with the aid of Correction factor (CF), which was obtained as below:

As the study period was from 1st January to 31st December 2019, the mean consumer price index for the period was considered.

Average consumer price index for year 2019 was 307

$$CF = \text{Value of consumer price index average (2019)} \times 4.93 \times 4.63 / 100$$

$$CF = 307 \times 4.93 \times 4.63 / 100 = 70.07$$

Classification = Per capita family monthly income of 1961 x CF

Socio-Economic Class	Prasad's classification 1961 (per capita income in Rupees/ month)	Modified Prasad's classification 2019 (per capita income in Rupees/ month)
I	100 and above	7008 and above
II	50-99	3504-7007
III	30-49	2102-3503
IV	15-29	1051-2101
V	<15	1050 and below

The details regarding duration of diabetes and patients' history of any major medical illness were noted.

Family History: Family history of diabetes was enquired regarding parents and siblings of the participants.

Mode of treatment based on the current pharmacological therapy being used to control diabetic status was noted.

Patients' personal habits such as alcohol consumption and tobacco consumption were asked.

Alcohol consumption: For the assessment of history of alcohol consumption, period of recall was considered for the past one year.

Alcoholics: Participants who had consumed any drink containing alcohol either in the past or at present were categorized as "alcoholics".

Non-Alcoholics: Participants who had never consumed alcohol.

Tobacco consumption: For the assessment of history of use of tobacco in any form (smoking or smokeless), period of recall was considered for the past one year and was based on WHO guidelines for tobacco use surveillance.

Tobacco Consumers: Participants who had used either smoke or smokeless form of tobacco in the past or at present were considered as "tobacco consumers".

Non tobacco consumers Smokers: Participants who had never used any form of tobacco (smoke/ smokeless) were considered as "non-tobacco consumers".

Physical activity: Regular physical activity or exercise (walking, running, yoga) and the duration of the exercise were enquired.

Diet:

Non-Vegetarian: Participants those who consume both non-vegetarian and vegetarian food were considered as "Non-Vegetarians"

Vegetarian: Participants those who consume only vegetarian food were considered as "Vegetarians"

General physical examination: Includes looking for pallor, icterus, cyanosis, clubbing, edema, palpable lymph nodes, calculation of waist - hip ratio and calculation of Body Mass Index based on height and weight.

Height: The participant was asked to stand straight without footwear, with heels, buttocks and back straight and arms hanging by side. The height was measured from head to heel. The coinciding reading was measured to the nearest 0.1 cm using a metallic measuring tape.

Weight: Body weight was measured without any foot wear and with minimal clothing to the nearest 0.1 kilogram using a standard portable adult weighing machine, which was standardized periodically during the study. The scale was adjusted to zero before each session and weight was recorded in kilograms.

Calculation of Body Mass Index: $\text{Weight in kg} / (\text{Height in m})^2$. BMI calculated was categorized as per the WHO criteria⁶⁸

Category	Body Mass Index
Underweight	<18.5 kg/m ²
Normal	18.5 – 27.9 kg/m ²
Overweight	23.0 - 27.9 kg/m ²
Obese	>28 kg/m ²

Waist circumference (WC): The measurement was made at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest and the subject stands with arms at the sides, feet positioned close together, and weight evenly distributed across the feet. Waist circumference > 80 centimeter for female and > 90 centimeter for male was considered to have abdominal obesity.

Hip Circumference (HC): It is the maximum circumference in the horizontal plane measured over the buttocks at the level of greater tubercle.

Waist hip ratio (WHR): The ratio of waist circumference to the hip circumference less than 0.85 in female and less than 0.95 in male was considered normal.

Patients' vitals were checked, which included pulse, respiratory rate, blood pressure and temperature.

Blood Pressure: Blood pressure was recorded in the sitting position and then classified according to updated JNC-7 guidelines recommendations

Category	Systolic Blood Pressure (mm of Hg)	Criteria	Diastolic Blood Pressure (mm of Hg)
Normal	<120	And	<80
Pre-hypertensive	120-139	Or	80 – 89
Hypertension Stage I	140 – 159`	Or	90 – 99
Hypertension Stage II	≥160	Or	≥100

Systemic Examination: Systemic examination was done to check cardiovascular system, respiratory system, central nervous system and gastrointestinal system by inspection, auscultation and percussion for the completeness.

Laboratory investigations:

Serum Vitamin B12 level: Serum Vitamin B12 levels were assessed using Chemiluminescence method.

RESULTS

In this study, there were 17.4% of the participants in the age group of 35-45 years, in the age range of 46 to 55 years, 21.4% of the participants were present whereas in the age groups of 56 to 65 years and above 65 years of age, there were 29.4% and 31.7% participants respectively. Female participants were found to be 58.3% and male participants were about 41.7%.

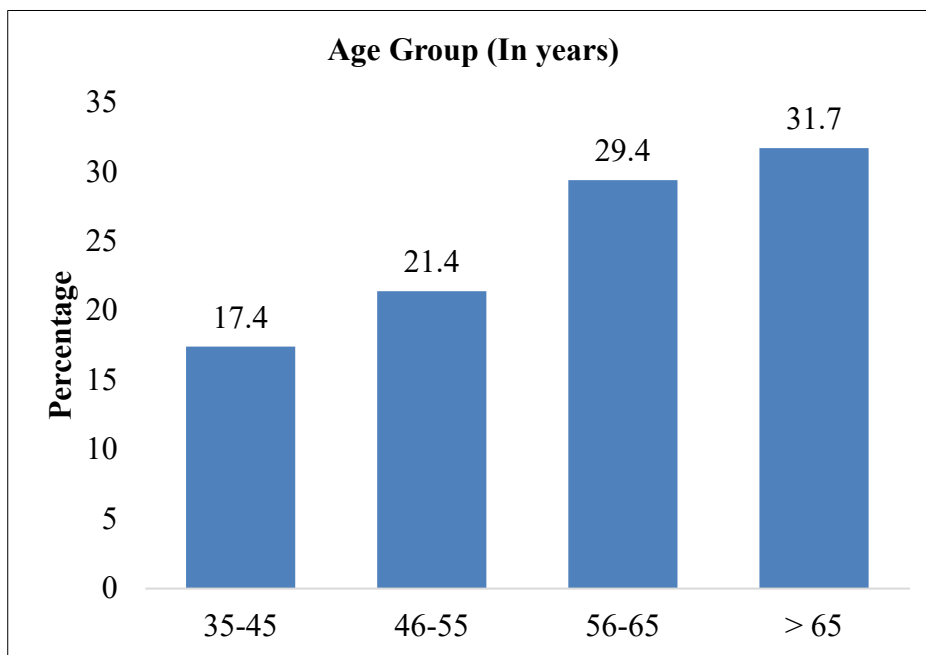
Table 1: Proportion of participants based on Age group

Age group (In years)	Frequency	Percentage
35-45	61	17.4
46-55	75	21.4
56-65	103	29.4
> 65	111	31.7
Total	350	100

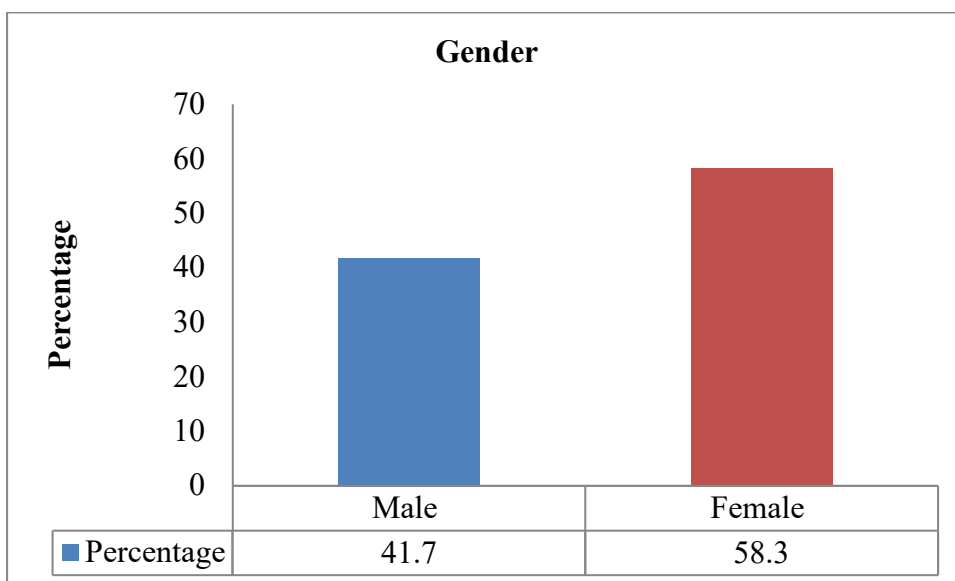
Table 2: Proportion of participants based on Gender

Gender	Frequency	Percentage
Male	146	41.7
Female	204	58.3
Total	350	100

Graph 1: Proportion of participants based on Age group



Graph 2: Proportion of participants based on Gender



Among the study population, maximum of 34.6% of the participants had completed their high school while 22% of the participants had done their pre university education and 18% of the participants had completed till middle school. Primary schooling was completed by 10.6%, degree holders were 6% of the participants and

8.9% of the participants were illiterate. In this current study, 43.1% of the participants were homemakers, 24% of the participants were employed, 22.6% of the participants were unemployed while 10.3% were retired.

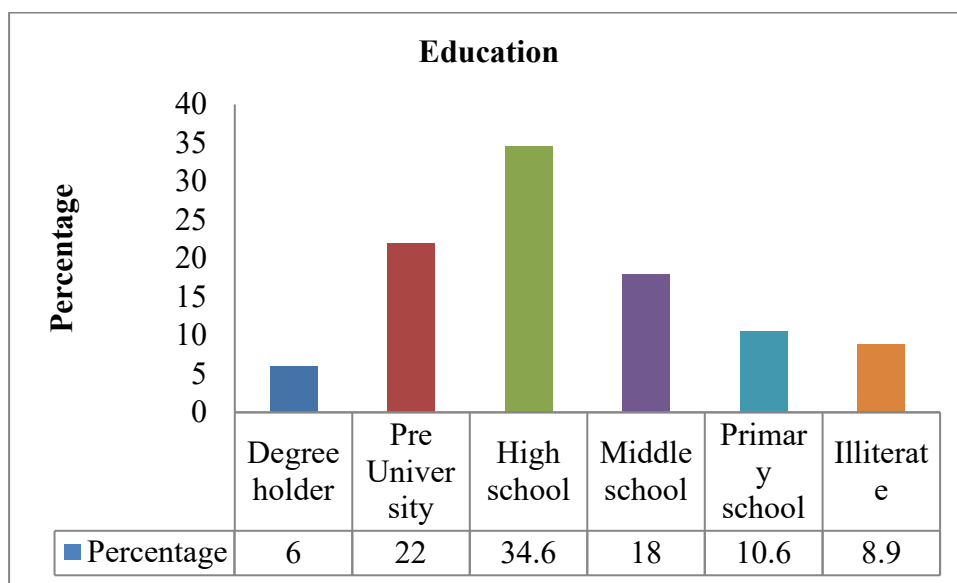
Table 3: Proportion of participants based on Education

Education	Frequency	Percentage
Degree holder	21	6.0
Pre-University	77	22.0
High school	121	34.6
Middle school	63	18.0
Primary school	37	10.6
Illiterate	31	8.9
Total	350	100

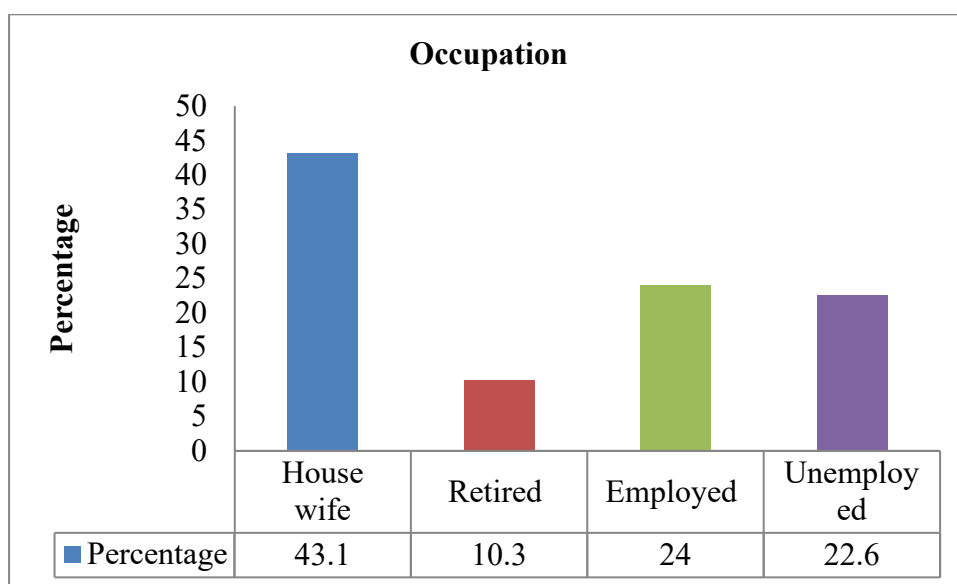
Table 4: Proportion of participants based on Occupation

Occupation	Frequency	Percentage
Homemaker	151	43.1
Retired	36	10.3
Employed	84	24.0
Unemployed	79	22.6
Total	350	100

Graph 3: Proportion of participants based on Education



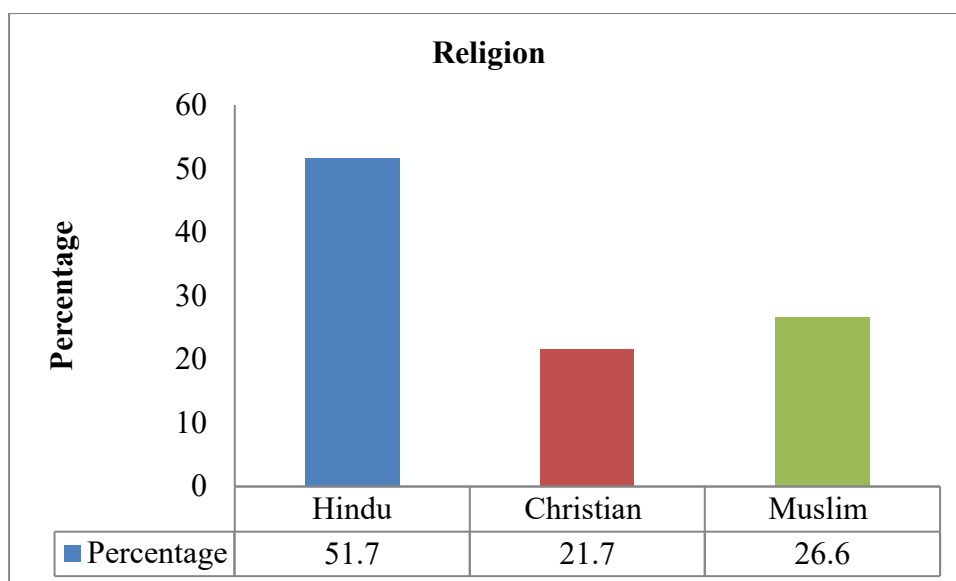
Graph 4: Proportion of participants based on Occupation



Based on the religion, 51.7% of the population were Hindus, followed by 26.6% were Muslims and 21.7% of the participants were Christians.

Table 5: Proportion of participants based on Religion status

Religion	Frequency	Percentage
Hindu	181	51.7
Christian	76	21.7
Muslim	93	26.6
Total	350	100

Graph 5: Proportion of participants based on Religion status

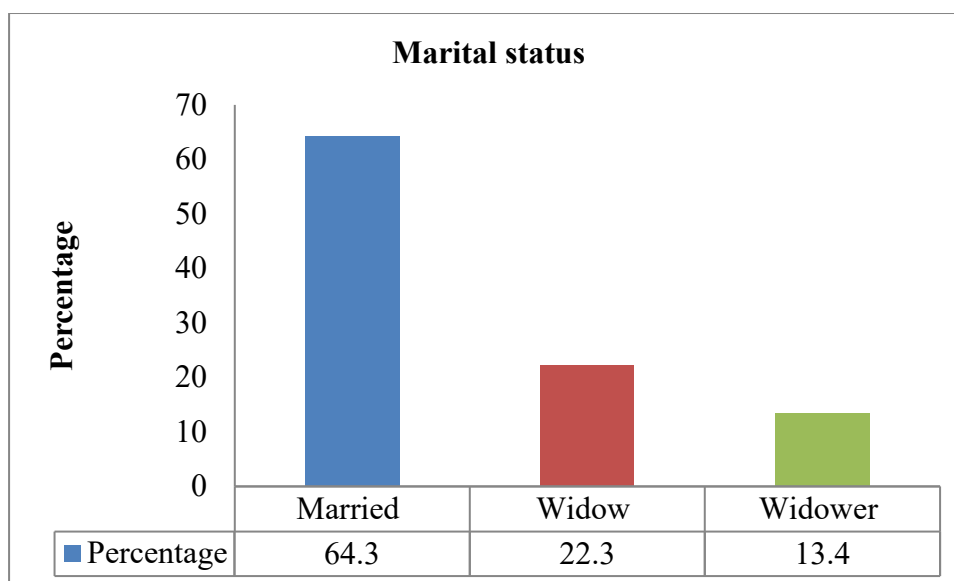
In this current study, 64.3% of the participants were married, 22.3% of the participants were widows and 13.4% of the participants were found to be widowers. 62.3% of the participants were living in nuclear family whereas 35.7% of the participants were living in joint family. Other type of families were found to be 2% in our study.

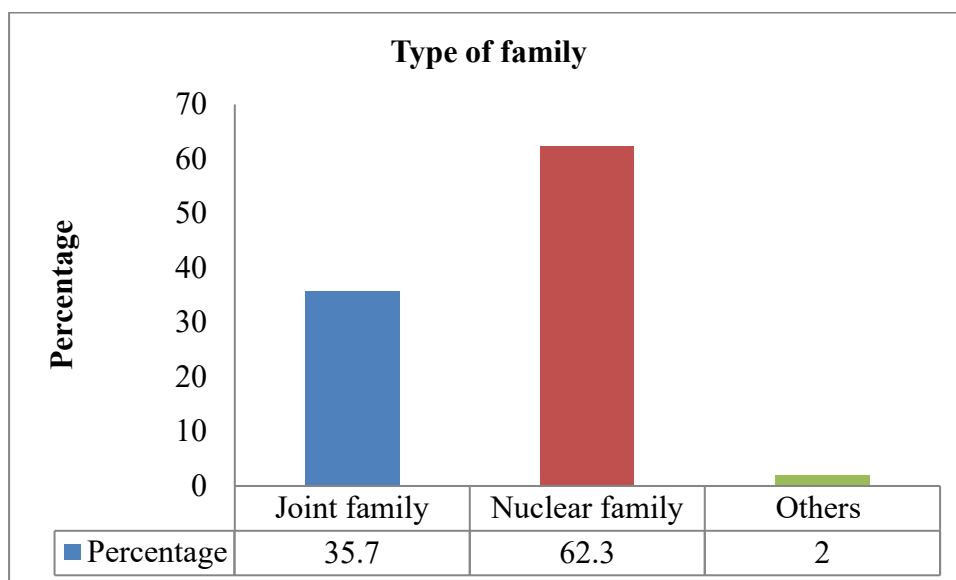
Table 6: Proportion of participants based on Marital status

Marital status	Frequency	Percentage
Married	225	64.3
Widow	78	22.3
Widower	47	13.4
Total	350	100

Table 7: Proportion of participants based on Type of family

Type of family	Frequency	Percentage
Joint family	125	35.7
Nuclear family	218	62.3
Others	07	2.0
Total	350	100

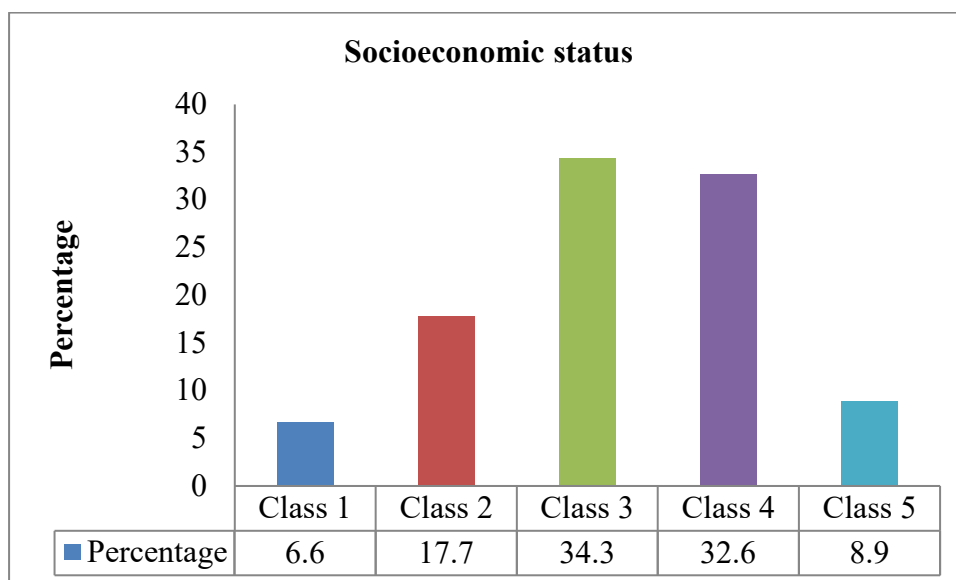
Graph 6: Marital status among the study participants

Graph 7: Type of family among the study participants

On assessing the socioeconomic status, 34.3%, 32.6%, 17.7%, 8.9% and 6.6% of the participants belonged to Class III, Class IV, Class II, Class V And Class I respectively.

Table 8: Socioeconomic status of the study participants

SEC	Frequency	Percentage
Class 1	23	6.6
Class 2	62	17.7
Class 3	120	34.3
Class 4	114	32.6
Class 5	31	8.9
Total	350	100

Graph 8: Socioeconomic status of the study participants

In this current study, for 40.6% of the participants, the duration of diabetes mellitus was around 6 to 10 years, followed by 26% of the participants who had diabetes more than 10 years. The duration of diabetes was between 1 to 5 years among 24.3% of the participants and less than a year for 9.1% of the study subjects. Co-morbidities like Hypertension, Dyslipidemia and Bronchial asthma were found among 28.3%, 24.9% and 3.4% of the participants.

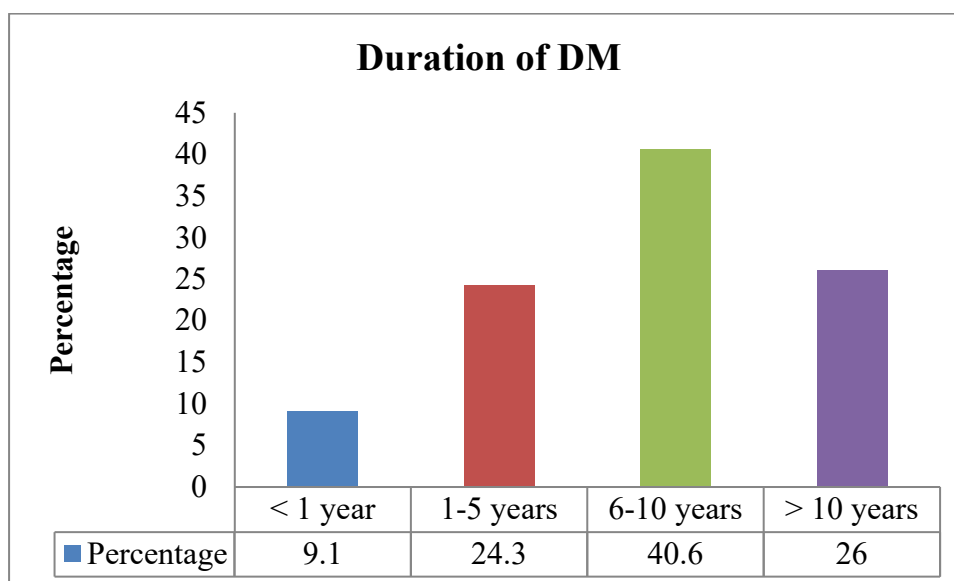
Table 9: Duration of Diabetes Mellitus among study participants

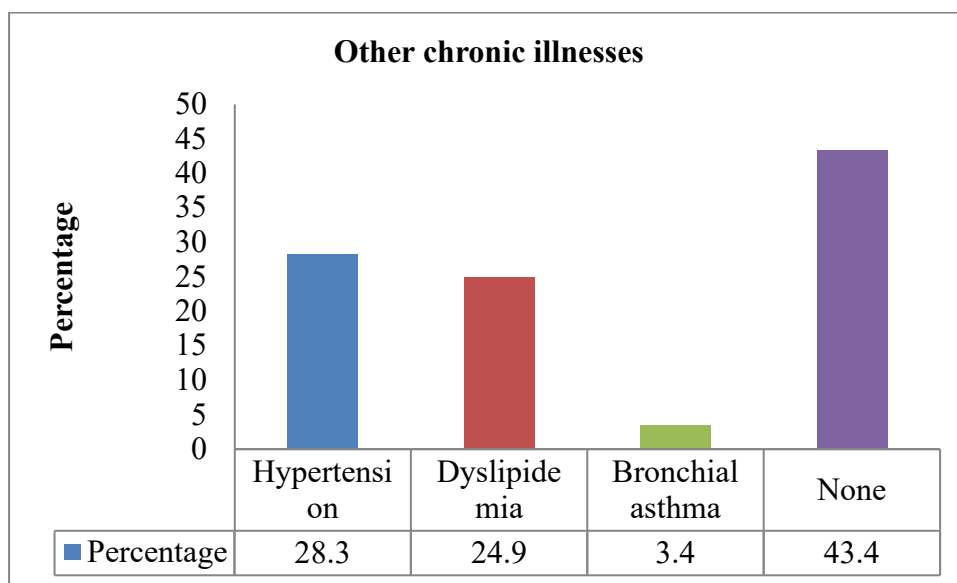
Duration of DM	Frequency	Percentage
< 1 year	32	9.1
1-5 years	85	24.3
6-10 years	142	40.6
> 10 years	91	26.0
Total	350	100

Table 10: Co-morbidities among study participants

Co-morbidities	Frequency	Percentage
Hypertension	99	28.3
Dyslipidemia	87	24.9
Bronchial asthma	12	3.4
None	152	43.4
Total	350	100

Graph 9: Duration of Diabetes Mellitus among study participants



Graph 10: Co-morbidities among study participants

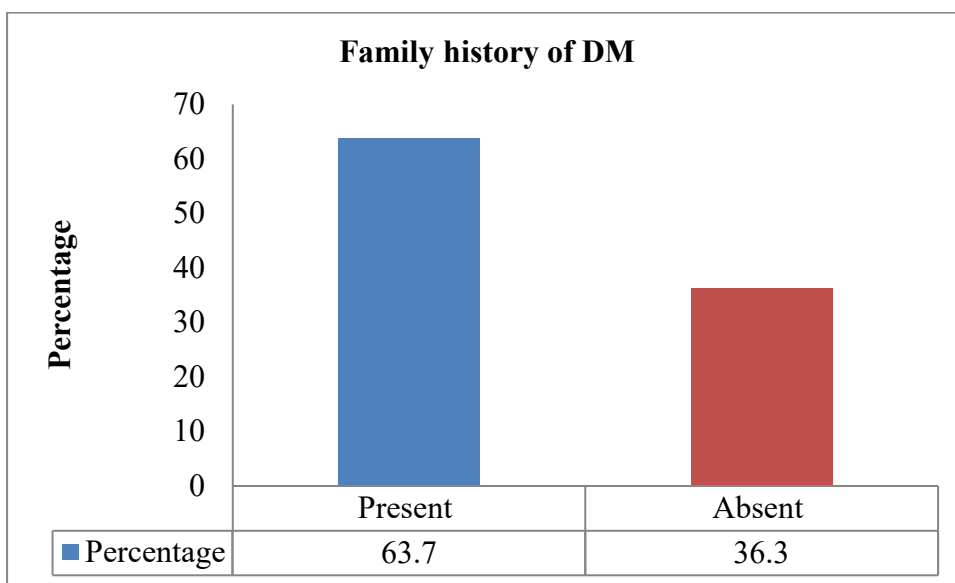
Family history of DM was recorded in 63.7% of the participants. Family members affected by DM in relation to the study participants were found to be father among 41.3% participants, mother among 54.3% participants and siblings among 30% of the participants.

Table 11: Family history of Diabetes and relationship to known DM case in the family

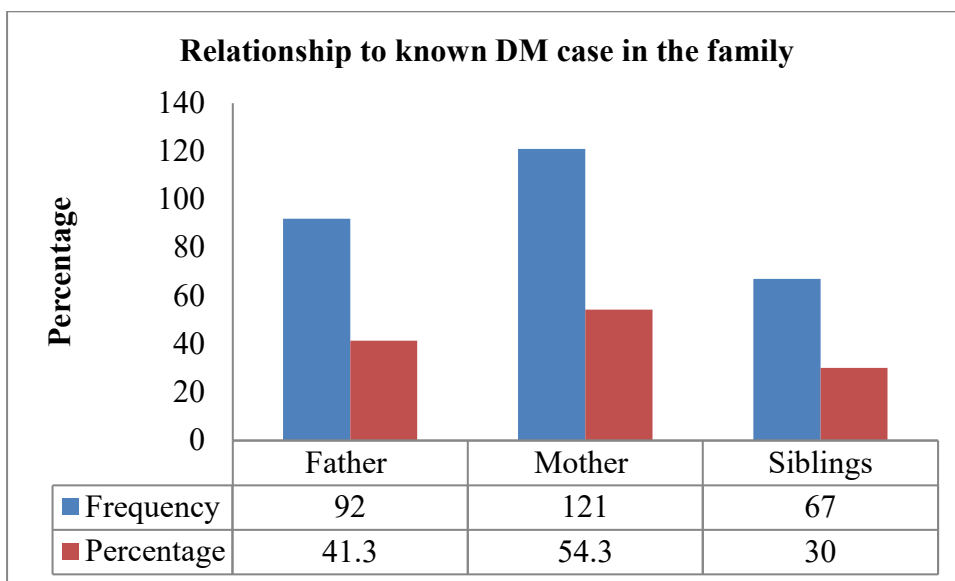
Family history of DM	Frequency	Percentage
Present	223	63.7
Absent	127	36.3
Total	350	100
Relationship to known DM case in the family*	Frequencyn=223	Percentage
Father	92	41.3
Mother	121	54.3
Siblings	67	30.0

*Multiple response

Graph 11: Family history of Diabetes



Graph 12: Relationship to known DM case in the family

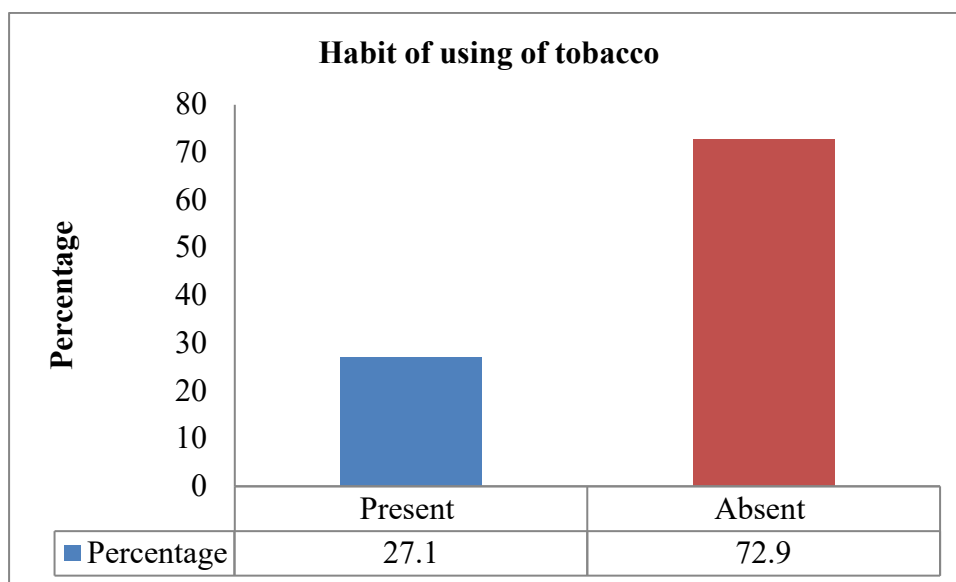


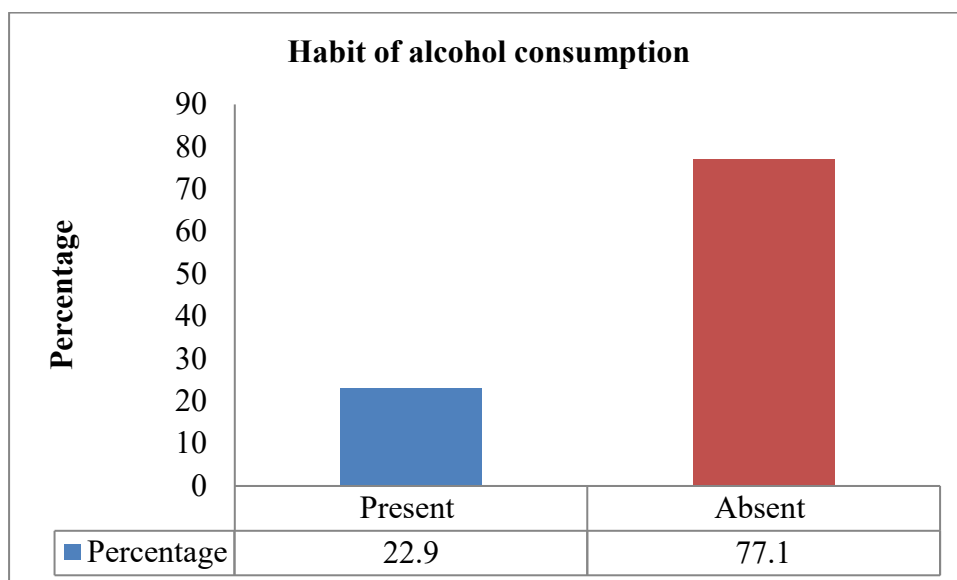
Regarding tobacco usage, 27.1% of the participants had a habit of tobacco consumption while 22.9% of the participants had a habit of alcohol consumption while 77.1% of the participants had no history of alcohol use.

Table 12: Tobacco and alcohol consumption among the participants

Habit of using of tobacco	Frequency	Percentage
Present	95	27.1
Absent	255	72.9
Total	350	100
Habit of alcohol consumption	Frequency	Percentage
Present	80	22.9
Absent	270	77.1
Total	350	100

Graph 13: Tobacco consumption among the participants

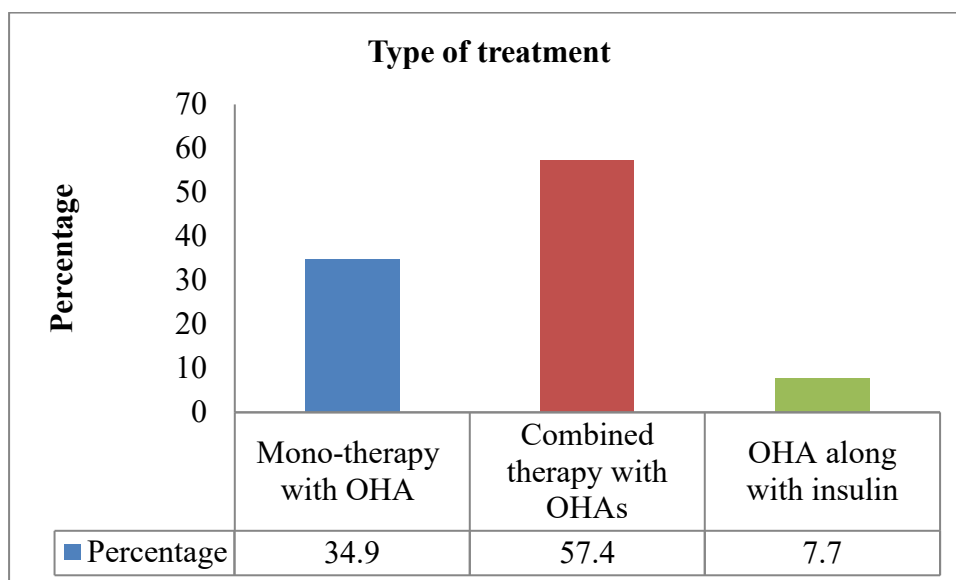


Graph 14: Alcohol consumption among the participants

Based on type of treatment, most of the participants (57.4%) were on combined therapy with OHAs, followed by 34.9% of the participants who were on Monotherapy with OHA and 7.7% of the participants were taking OHA along with insulin.

Table 13: Proportion of participants based on type of treatment

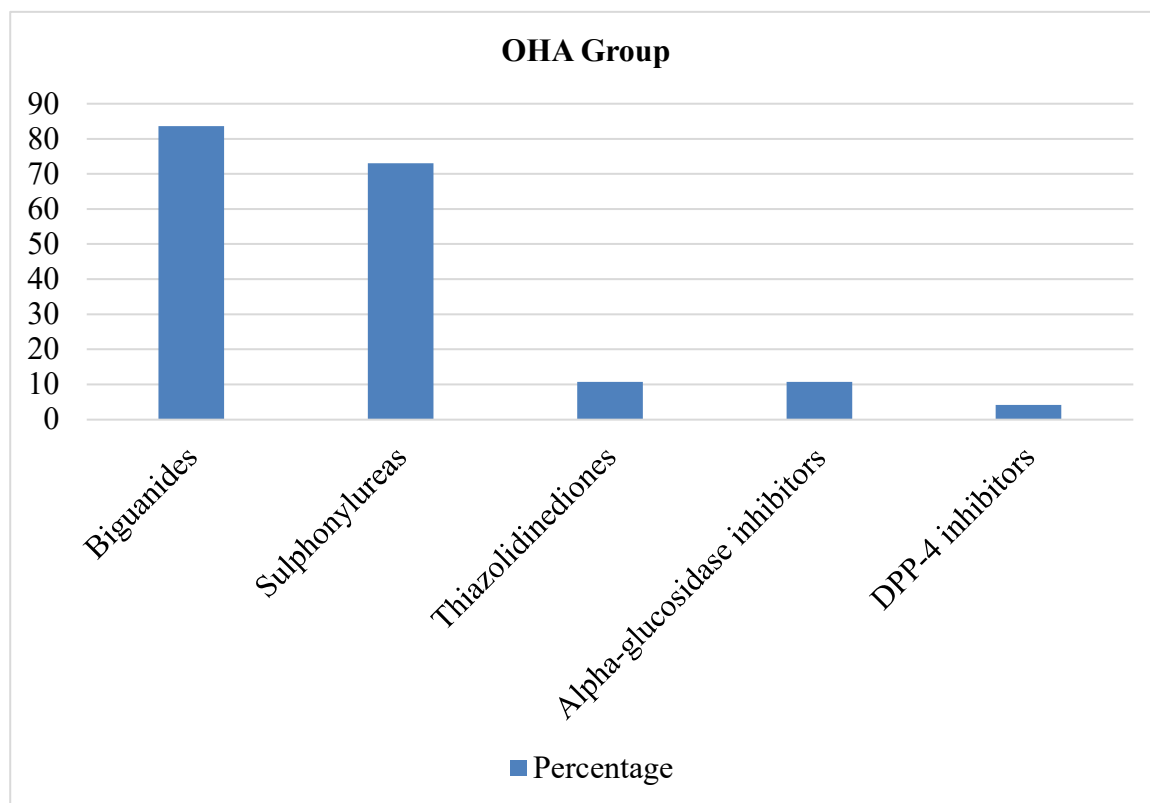
Type of treatment	Frequency	Percentage
Monotherapy with OHA	122	34.9
Combined therapy with OHAs	201	57.4
OHA along with insulin	27	7.7
Total	350	100

Graph 15: Proportion of participants based on type of treatment

Regarding the OHA group, 83.6% of the participants were taking Biguanides as mono or combined therapy, 73% of the participants were on different drugs from Sulphonylureas group among which glimepiride was the common one, 10.7% of the participants were using Thiazolidinediones while another 10.7% were on Alpha-glucosidase inhibitors and 4.1% participants were on DPP-4 inhibitors.

Table 14: Proportion of participants taking different OHA groups

OHA group	Frequency	Percentage
Biguanides	102	83.6
Sulphonylureas	89	73.0
Thiazolidinediones	13	10.7
Alpha-glucosidase inhibitors	13	10.7
DPP-4 inhibitors	05	4.1

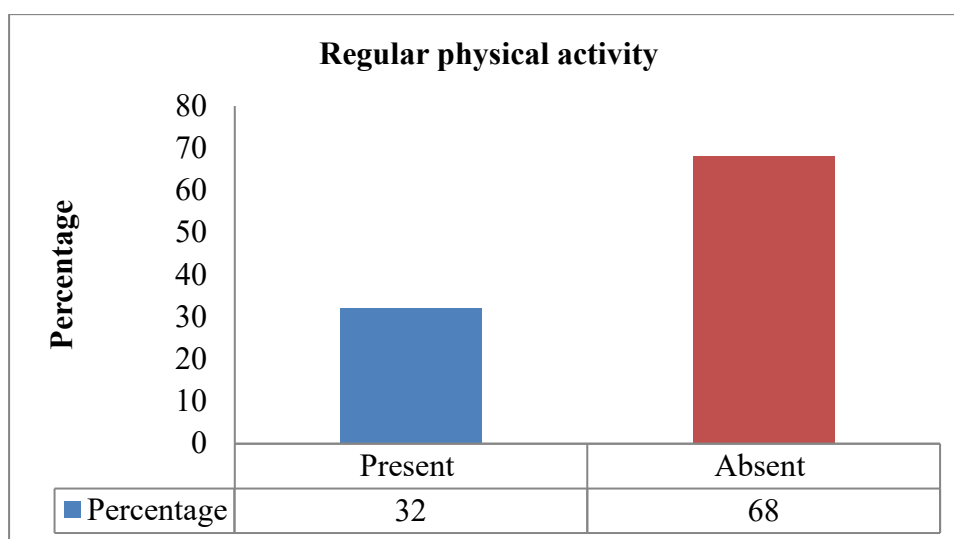
Graph 16: Proportion of participants taking different OHA group

Regular physical activity was present among 32% of the study participants. Walking was the type of activity in 77.6% participants, 15.2% participants were doing cycling, yoga was practiced by 6.3% participants and running was found among 0.9% participants. Among all, the duration of exercise in a week was less than 3.5 hours among 26.8% participants, 3.5 to 7 hours among 43.8% participants and more than 7 hours among 29.5% of the study subjects.

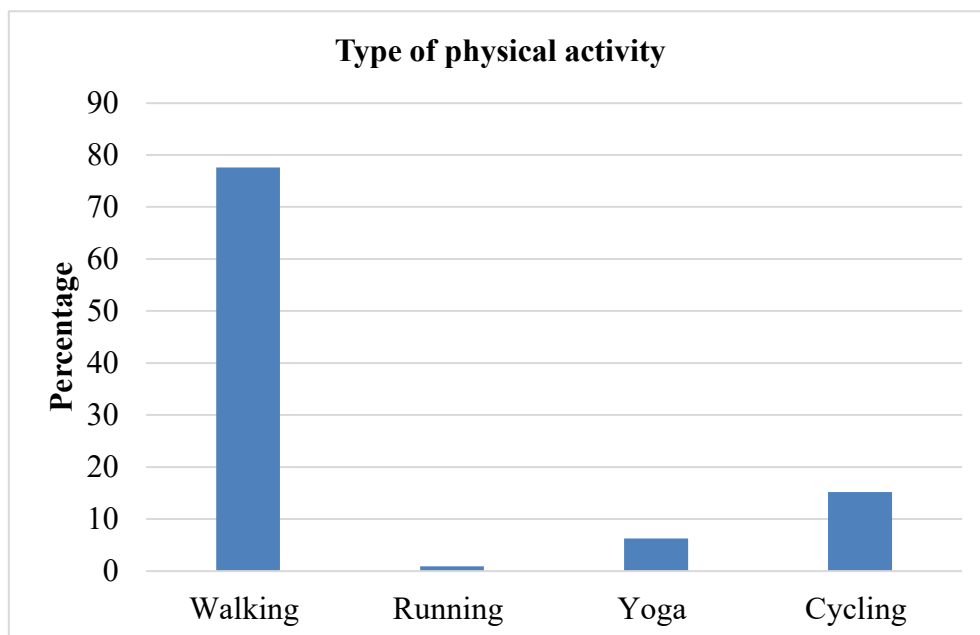
Table 15: Physical activity among the study participants

Regular physical activity	Frequency	Percentage
Present	112	32.0
Absent	238	68.0
Total	350	100
Type of physical activity	Frequency	Percentage
Walking	87	77.6
Running	01	0.9
Yoga	07	6.3
Cycling	17	15.2
Total	112	100.0
Duration of exercise/ week	Frequency	Percentage
< 3.5 hours	30	26.8
3.5 - 7 hours	49	43.8
> 7 hours	33	29.5
Total	112	100.0

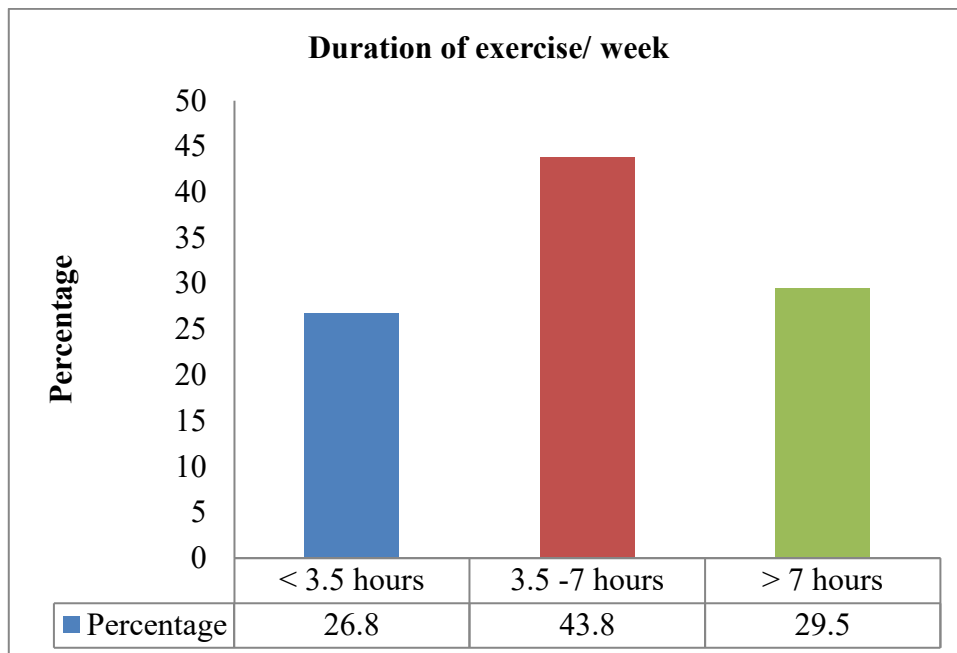
Graph 17: Regular physical activity among the study participants



Graph 18: Type of physical activity among the study participants



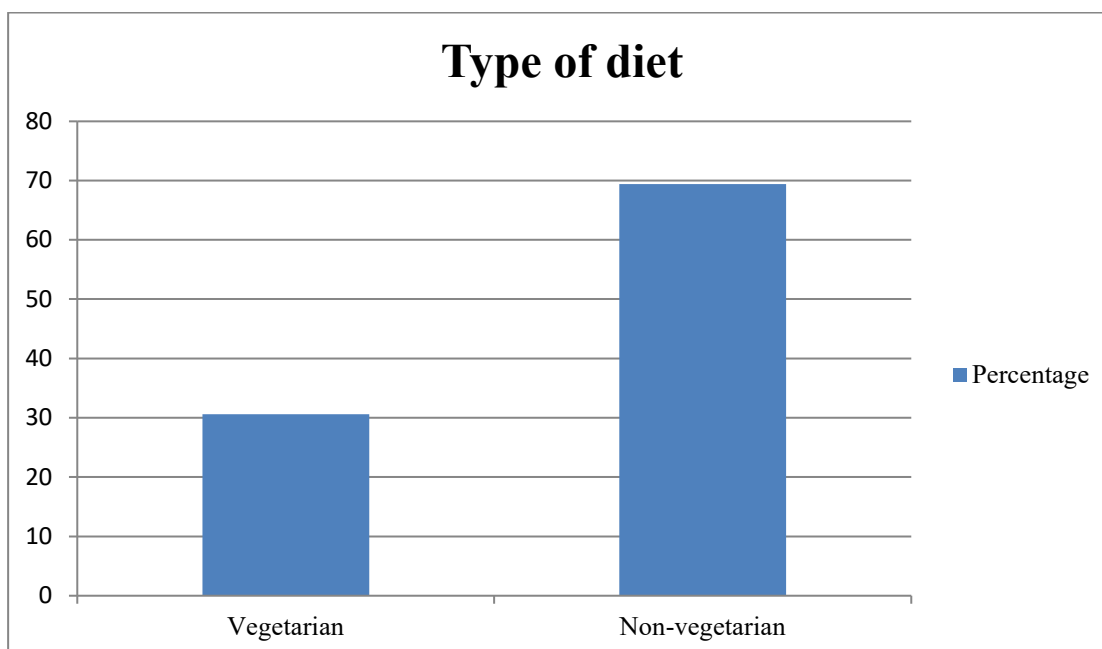
Graph 19: Duration of exercise/ week among the study participants



Regarding the diet pattern, 69.4% of the study participants were on non-vegetarian diet while 30.6% of the participants were found to be vegetarians.

Table 16: Proportion of participants based on type of diet

Type of Diet	Frequency	Percentage
Vegetarian	107	30.6
Non-vegetarian	243	69.4
Total	350	100

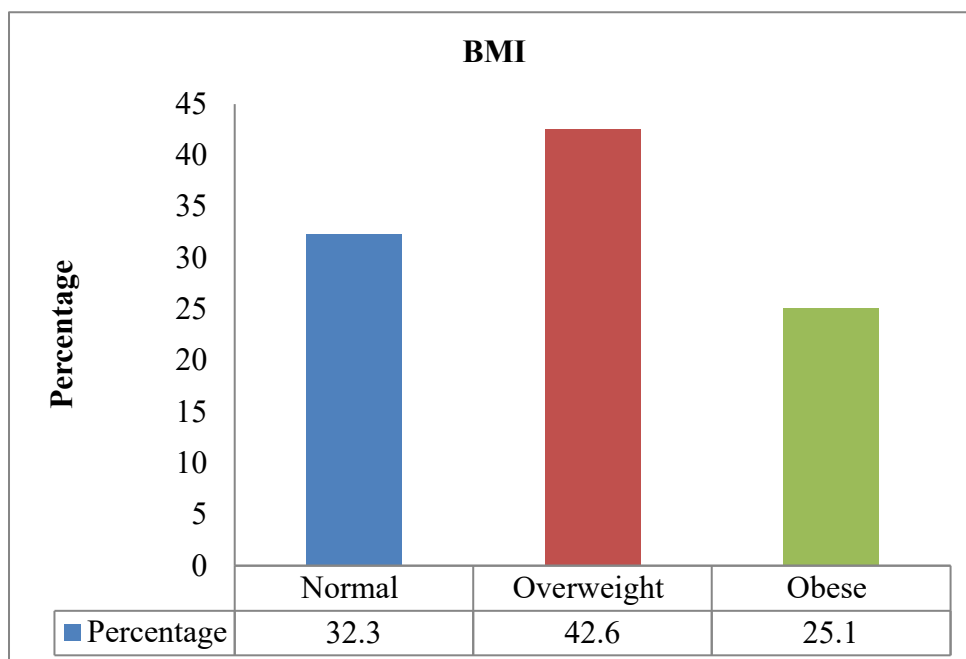
Graph 20: Proportion of participants based on type of diet

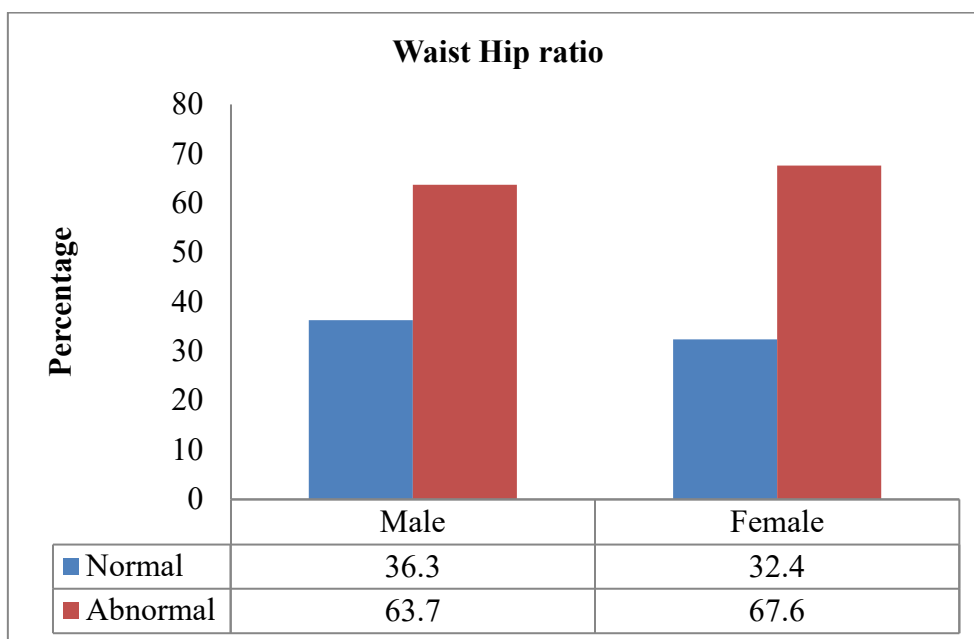
On assessing the BMI, 32.3% of the participants were found to be normal, 42.6% and 25.1% of the participants were found to be overweight and obese respectively. Waist hip ratio was on the abnormal side for 67.6% of females while for males, it was abnormal for 63.7% of the participants.

Table 17: BMI and waist hip ratio among the study participants

BMI	Frequency	Percentage
Normal	113	32.3
Overweight	149	42.6
Obese	88	25.1
Total	350	100
Waist Hip ratio	Male	Female
	Frequency (%)	Frequency (%)
Normal	53 (36.3)	66 (32.4)
Abnormal	93 (63.7)	138 (67.6)
Total	146 (100)	204 (100)

Graph 21: BMI ratio among the study participants



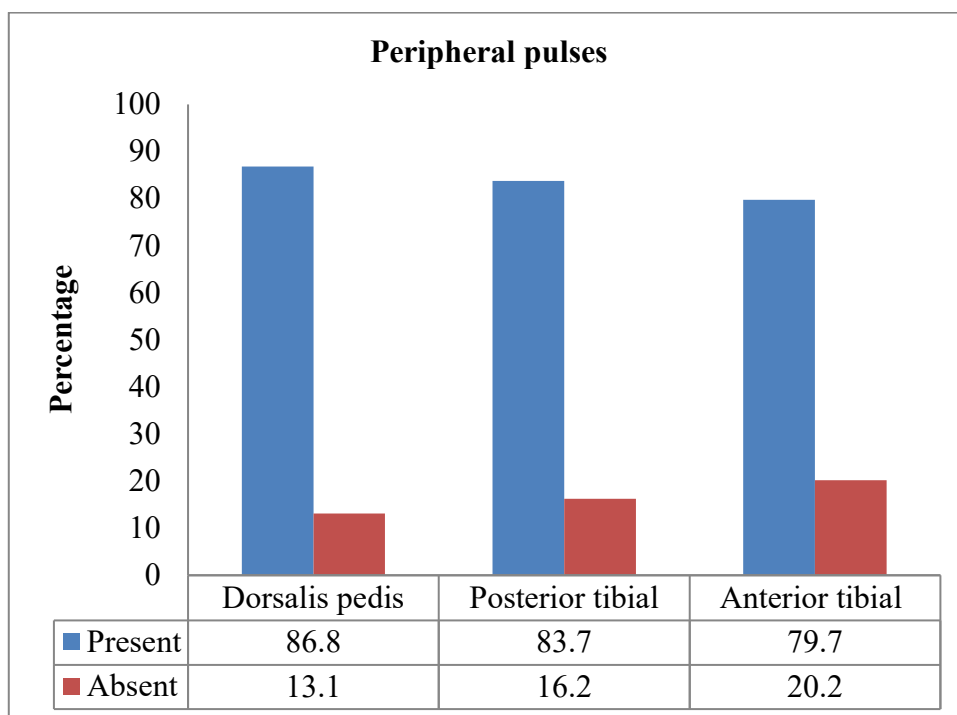
Graph 22: Waist hip ratio among the study participants

Posterior tibial pulse was absent among 16.2% of the participants, Dorsalis pedis pulse was absent in 13.1% of the participants and 20.2% of the participants had absent anterior tibial pulse.

Table 18: Peripheral pulses among the study participants

Peripheral pulses	Present	Absent
Dorsalis pedis	304 (86.8)	46 (13.1)
Posterior tibial	293 (83.7)	57 (16.2)
Anterior tibial	279 (79.7)	71 (20.2)

Graph 23: Peripheral pulses among the study participants

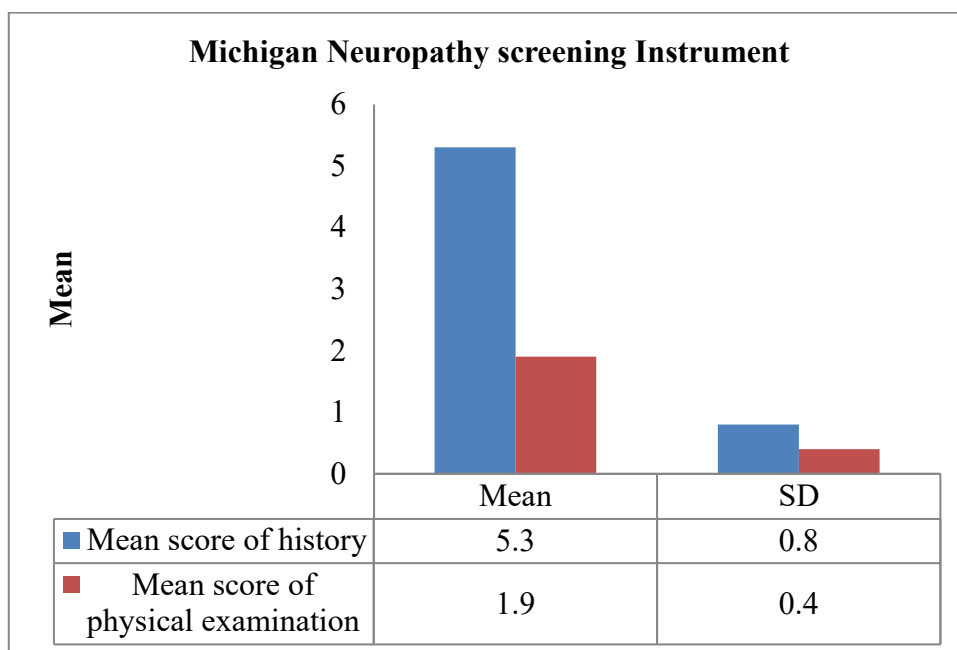


Based on the Michigan Neuropathy screening Instrument, the mean score of history version was 5.3 ± 0.8 . The Mean score of physical examination was 1.9 ± 0.4 .

Table 19: Mean score based on Michigan Neuropathy screening Instrument

Michigan Neuropathy screening Instrument	Mean	SD
Mean score of history version	5.3	0.8
Mean score of physical examination	1.9	0.4

Graph 24: Mean score based on Michigan Neuropathy screening Instrument



Based on Michigan Neuropathy screening Instrument History part, the common history noted was numbness (56%) and 42.6% of the participants checked water temperature before bathing, burning pain history was present among 34.6% participants. The least history based on MNSI was found to be open sore among 18% of the participants and amputation which was done for one participant.

On physical assessment based on MNSI, for 81.7% participants and for 85.4% participants, the appearance of feet were abnormal on right side and left side respectively. Dry skin, callus were noted in 3.4% participants on right side and 4.9% of the participants on left side. Infection was noted among 0.9% and 0.6% of the participants on right and left side respectively. Varicose vein was noted in 0.3% of the participant on the right side alone. Ulceration was seen in 2% of the participants on the right foot and 2.6% of the participants in the left foot.

Ankle reflexes were present/reinforcement among 70.6% participants in the right side and 70.9% participants on the left side while for 12% participants, in the right side, ankle reflexes were absent while for 13.7% participants, in the left side, ankle reflexes were absent. Vibration perception at great toe was decreased among 12.3% and 11.7% of the participants on the right side and left side leg respectively, while it was absent in 6.6% and 10.6% participants on the right and left side respectively. Monofilament test was reduced among 14% and 16.9% participants on the right and left side respectively whereas it was absent in 8.9% of the participants on the right side and 10.6% of the participants on the left side.

Table 20: Michigan Neuropathy screening Instrument – History

Michigan Neuropathy screening Instrument – History		
Parameter	Yes Frequency (%)	No Frequency (%)
Numbness	196 (56.0)	154 (44.0)
Burning pain	121 (34.6)	229 (65.4)
Sensitive to touch	91 (26.0)	259 (74.0)
Muscle cramps	64 (18.3)	286 (81.7)
Prickling feel	132 (37.7)	218 (62.3)
Hurts when bed cover touches feet	48 (13.7)	302 (86.3)
Checked water temperature before bathing	149 (42.6)	201 (57.4)
Had an open sore	63 (18.0)	287 (82.0)
Doctor told that patient had diabetic neuropathy	132 (37.7)	218 (62.3)
Feel weak	67 (19.1)	283 (80.9)

Symptoms worse at night	78 (22.3)	272 (77.7)
Hurts when walks	87 (24.9)	263 (75.1)
Sense the feet while walking	159 (45.4)	191 (54.6)
Dry skin	181 (51.7)	169 (48.3)
Had an amputation	01 (0.3)	349 (99.7)

Table 21: MNSI physical assessment of feet among the study participants

MNSI- Physical assessment	Right Frequency (%)	Left Frequency (%)
Appearance of feet		
Normal	286 (81.7)	299 (85.4)
Abnormal	64 (18.3)	51 (14.6)
Total	350 (100)	350 (100)
Findings		
Deformities	01 (0.3)	01 (0.3)
Dry skin, callus	12 (3.4)	17 (4.9)
Infection	03 (0.9)	02 (0.6)
Fissure	00 (0.0)	00 (0.0)
Varicose veins	01 (0.3)	00 (0.0)
Ulceration		
Present	07 (2.0)	09 (2.6)
Absent	343 (98.0)	341 (97.4)
Total	350 (100)	350 (100)

Table 21: MNSI - Physical assessment of feet among the study participants

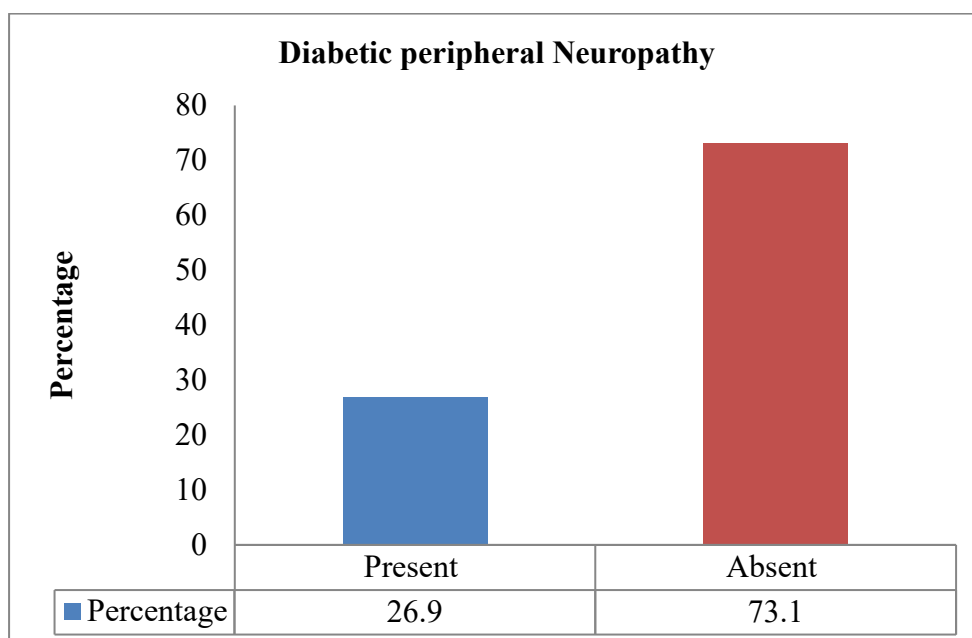
MNSI - Physical assessment	Right Frequency (%)	Left Frequency (%)
Ankle reflexes		
Present	247 (70.6)	248 (70.9)
Present/ reinforcement	61 (17.4)	54 (15.4)
Absent	42 (12.0)	48 (13.7)
Total	350 (100)	350 (100)
Vibration perception at great toe		
Present	284 (81.1)	272 (77.7)
Decreased	43 (12.3)	41 (11.7)
Absent	23 (6.6)	37 (10.6)
Total	350 (100)	350 (100)
Monofilament		
Normal	270 (77.1)	254 (72.6)
Reduced	49 (14.0)	59 (16.9)
Absent	31 (8.9)	37 (10.6)
Total	350 (100)	350 (100)

Diabetic peripheral neuropathy (DPN) was present among 94 (26.9%) participants in this study and was not reported among the remaining 256 (73.1%) participants.

Table 22: Diabetic peripheral neuropathy among the study participants

Diabetic peripheral Neuropathy	Frequency	Percentage
Present	94	26.9
Absent	256	73.1
Total	350	100

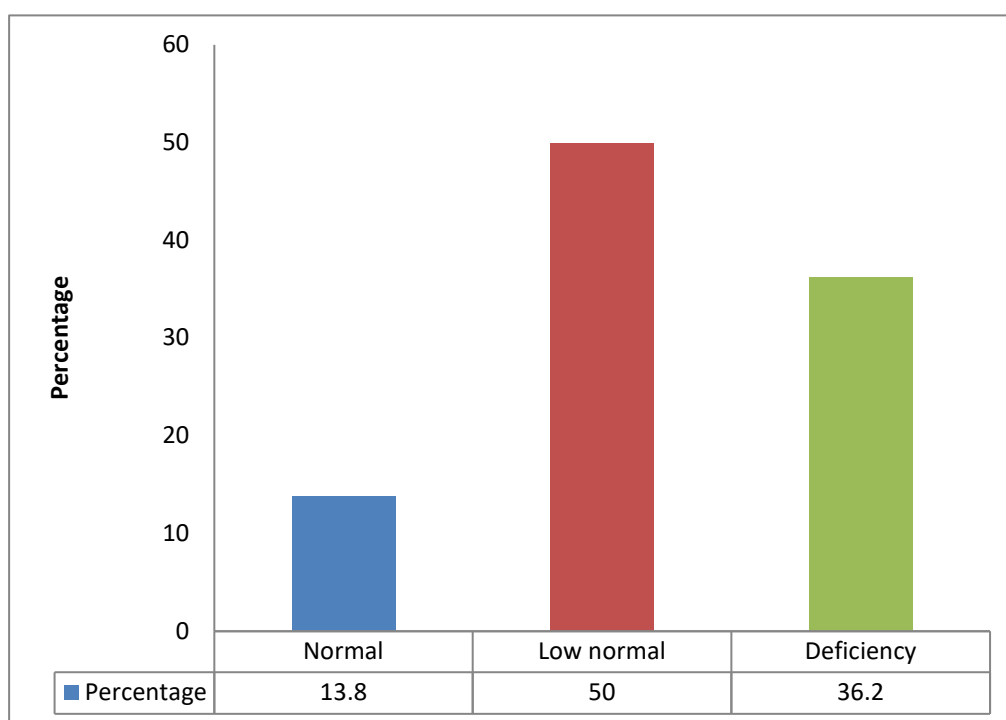
Graph 25: Diabetic peripheral neuropathy among the study participants



Among the cases with DPN, based on the biochemical serum vitamin B12 values, 13.8% participants had normal B12 levels, 50% participants had low normal vitamin B12 and 36.2% of the participants were found with vitamin B12 deficiency.

Table 23: Vitamin B12 interpretation among the study participants

Vitamin B12 interpretation	Frequency	Percentage
Normal	13	13.8
Low normal	47	50.0
Deficiency	34	36.2
Total	94	100

Graph 26: Vitamin B12 interpretation among the study participants

Diabetic peripheral neuropathy was found among 3.4%, 5.4%, 8.3% and 9.7% of the participants in the age group of 35-45 years, 46-55 years, 56-65 years and more than 65 years respectively. The association for DPN between different age group was found to be statistically insignificant (P value 0.4601). Among male participants, DPN was found to be 11.7% and among female participants, it was 15.1% but there was no significant statistical difference found for gender and DPN (P value 0.6617).

Table 24: Association between DPN and age group

Variables	DPN Present	DPN Absent	Total	P value
Age group				
35-45 years	12 (3.4)	49 (14.0)	61 (17.4)	0.4601
46-55 years	19 (5.4)	56 (16.0)	75 (21.4)	
56-65 years	29 (8.3)	74 (21.1)	103 (29.4)	
> 65 years	34 (9.7)	77 (22.0)	111 (31.7)	
Total	94 (26.9)	256 (73.1)	350 (100)	

Table 25: Association between DPN and gender

Variables	DPN Present	DPN Absent	Total	P value
Gender				
Male	41 (11.7)	105 (30.0)	146 (41.7)	0.6617
Female	53 (15.1)	151 (43.1)	204 (58.3)	
Total	94 (26.9)	256 (73.1)	350 (100)	

In this present study, DPN was noted in 9.1% participants who had completed high school, 6.3% of the participants with middle school education, 6% of the participants who had completed pre university; 2%, 1.7% and 1.7% of the participants who had done primary school, degree holder and illiterates respectively. There was no significant association recorded for DPN based on the education status (P value 0.5197). Among 10.3% of homemakers, 3.1% of retired people, 6.6% employed persons and 6.9% unemployed persons, DPN was noted which was not statistically significant (P value 0.6913).

Table 26: Association between DPN and education

Education	DPN Present	DPN Absent	Total	P value
Degree holder	06 (1.7)	15 (4.3)	21 (6.0)	0.5197
Pre-University	21 (6.0)	56 (16.0)	77 (22.0)	
High school	32 (9.1)	89 (25.4)	121 (34.6)	
Middle school	22 (6.3)	41 (11.7)	63 (18.0)	
Primary school	07 (2.0)	30 (8.6)	37 (10.6)	
Illiterate	06 (1.7)	25 (7.1)	31 (8.9)	
Total	94 (26.9)	256 (73.1)	350 (100)	

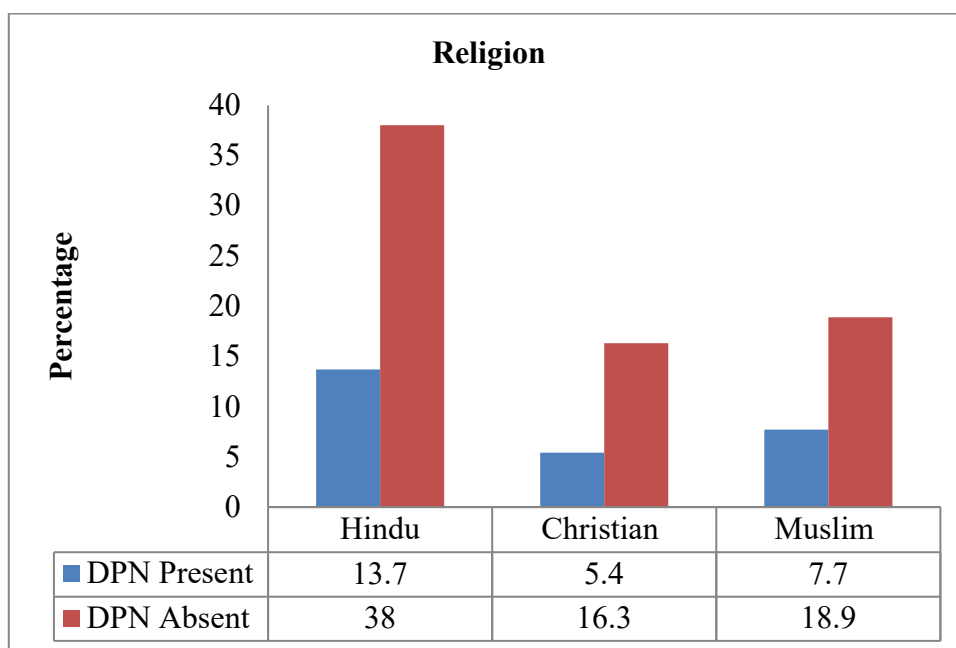
Table 27: Association between DPN and occupation

Occupation	DPN Present	DPN Absent	Total	P value
Homemaker	36 (10.3)	115 (32.9)	151 (43.1)	0.6913
Retired	11 (3.1)	25 (7.1)	36 (10.3)	
Employed	23 (6.6)	61 (17.4)	84 (24.0)	
Unemployed	24 (6.9)	55 (15.7)	79 (22.6)	
Total	94 (26.9)	256 (73.1)	350 (100)	

DPN was seen in 13.7% among Hindus, 5.4% among Christians and 7.7% among Muslims. There was no significant statistical association found for religion and DPN in this study (P value 0.8319).

Table 28: Association between DPN and religion

Religion	DPN Present	DPN Absent	Total	P value
Hindu	48 (13.7)	133 (38.0)	181 (51.7)	0.8319
Christian	19 (5.4)	57 (16.3)	76 (21.7)	
Muslim	27 (7.7)	66 (18.9)	93 (26.6)	
Total	94 (26.9)	256 (73.1)	350 (100)	

Graph 27: Association between DPN and religion

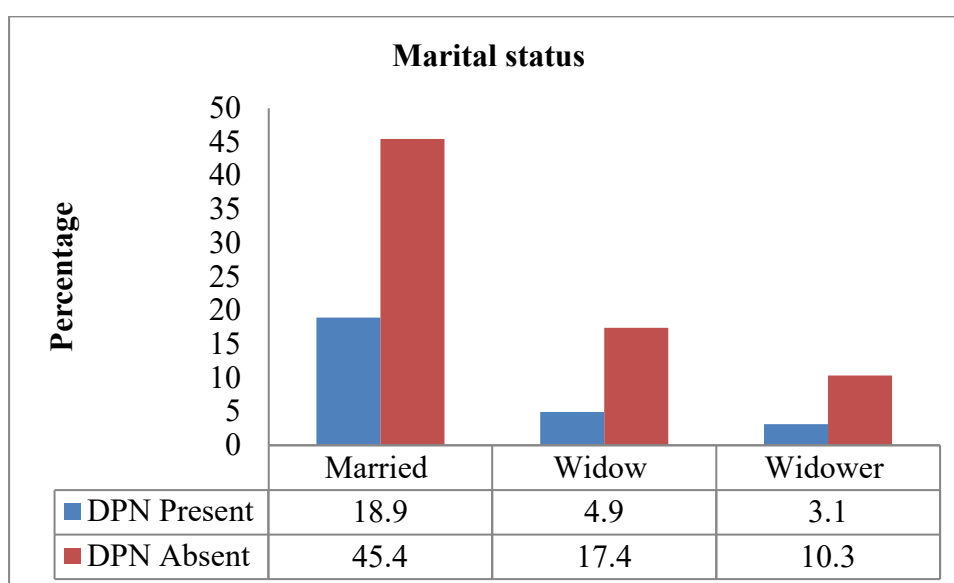
Among married participants, DPN was found to be 18.9%. Among widows, it was 4.9% and among widowers, DPN was 3.1%. There was no statistically significant association found between marital status and DPN (P value 0.3669). Likewise, there was no statistically significant association found for DPN and type of family in this study (P value 0.3252).

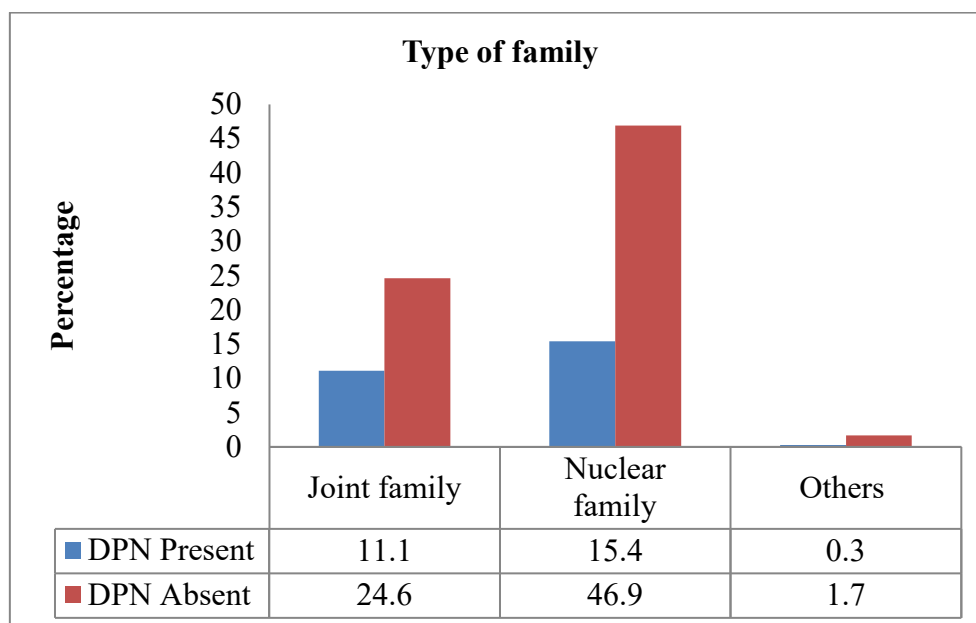
Table 29: Association between DPN and marital status

Marital status	DPN Present	DPN Absent	Total	P value
Married	66 (18.9)	159 (45.4)	225 (64.3)	0.3669
Widow	17 (4.9)	61 (17.4)	78 (22.3)	
Widower	11 (3.1)	36 (10.3)	47 (13.4)	
Total	94 (26.9)	256 (73.1)	350 (100)	

Table 30: Association between DPN and type of family

Type of family	DPN Present	DPN Absent	Total	P value
Joint family	39 (11.1)	86 (24.6)	125 (35.7)	0.3252
Nuclear family	54 (15.4)	164 (46.9)	218 (62.3)	
Others	01 (0.3)	06 (1.7)	07 (2.0)	
Total	94 (26.9)	256 (73.1)	350 (100)	

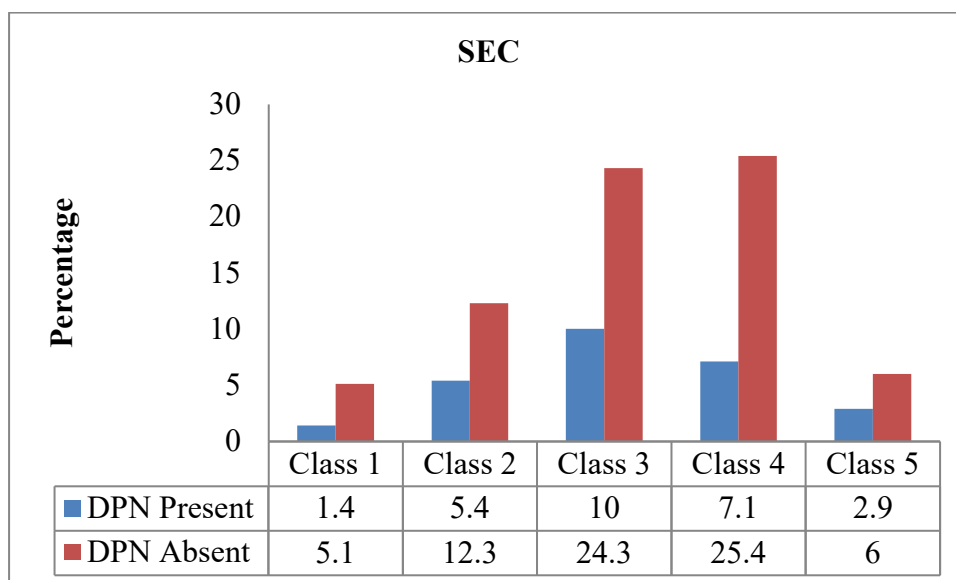
Graph 28: Association between DPN and marital status

Graph 29: Association between DPN and type of family

In this current study, DPN was found in 10% of the participants from Class III SEC, 7.1% participants from Class IV, 5.4% participants from Class II. In Class I and Class V SEC, 1.4% and 2.9% participants were affected with DPN. The association between SEC and DPN was statistically insignificant (P value= 0.5654).

Table 31: Association between DPN and SEC among the study participants

SEC	DPN Present	DPN Absent	Total	P value
Class 1	05 (1.4)	18 (5.1)	23 (6.6)	0.5654
Class 2	19 (5.4)	43 (12.3)	62 (17.7)	
Class 3	35 (10.0)	85 (24.3)	120 (34.3)	
Class 4	25 (7.1)	89 (25.4)	114 (32.6)	
Class 5	10 (2.9)	21 (6.0)	31 (8.9)	
Total	94 (26.9)	256 (73.1)	350 (100)	

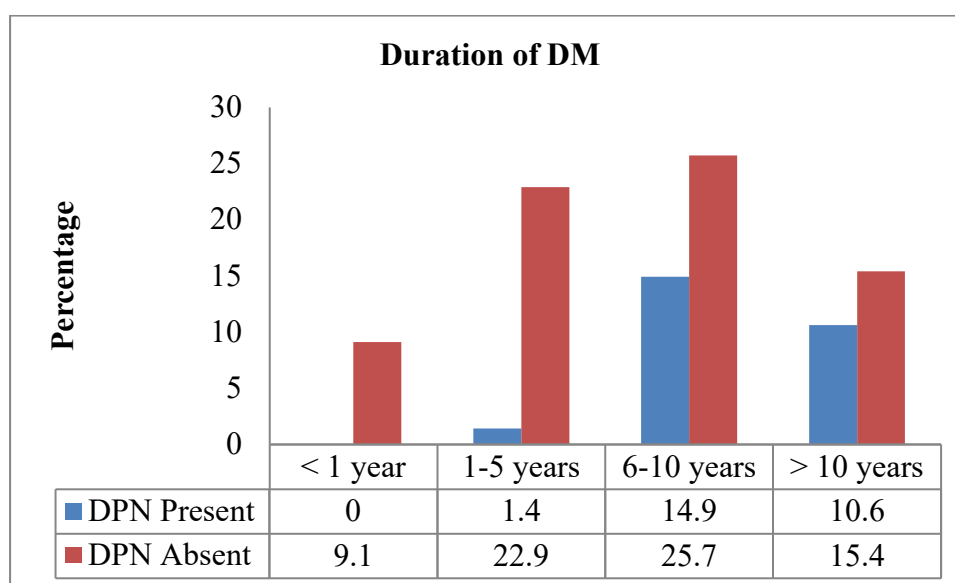
Graph 30: Association between DPN and SEC among the study participants

On assessing the duration of DM, DPN was noted among 1.4% of the participants who had DM for 1-5 years, 14.9% of the participants with DM for 6-10 years and 10.6% of the participants with DM more than 10 years. There was statistically significant association found for DPN and duration of DM (P value 0.0001).

Table 32: Association between DPN and duration of DM

Duration of DM	DPN Present	DPN Absent	Total	P value
< 1 year	00 (0.0)	32 (9.1)	32 (9.1)	0.0001*
1-5 years	05 (1.4)	80 (22.9)	85 (24.3)	
6-10 years	52 (14.9)	90 (25.7)	142 (40.6)	
> 10 years	37 (10.6)	54 (15.4)	91 (26.0)	
Total	94 (26.9)	256 (73.1)	350 (100)	

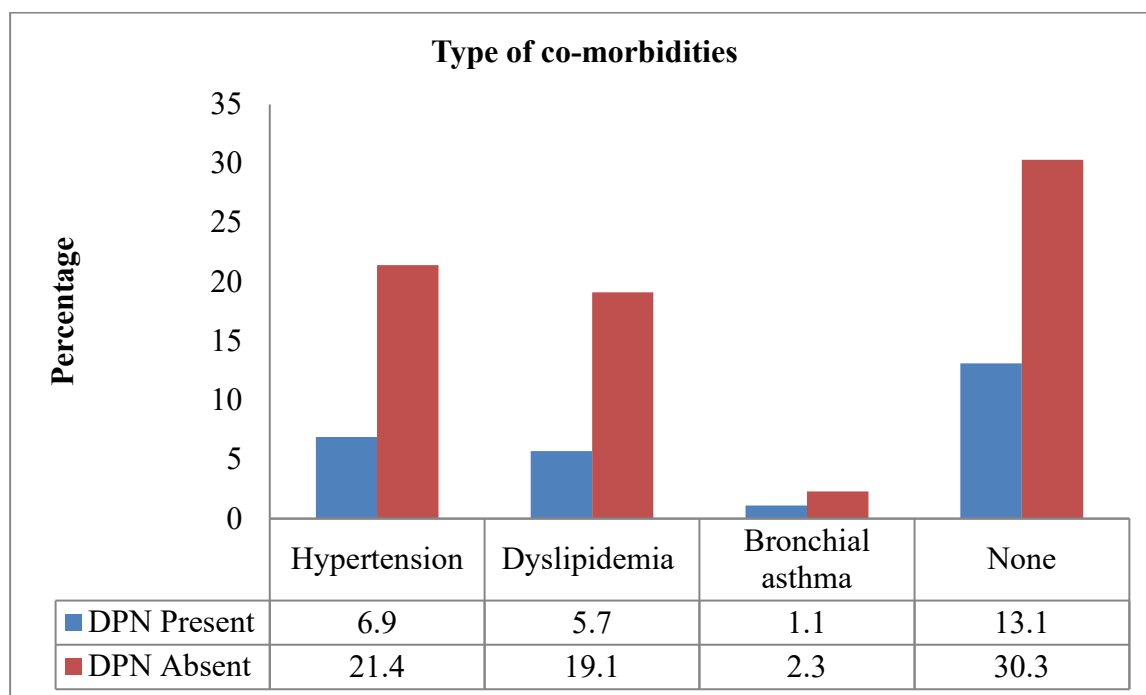
*Significant

Graph 31: Association between DPN and duration of DM

Based on type of co-morbidities, DPN was present among 6.9%, 5.7%, and 1.1% of the participants with hypertension, dyslipidemia and bronchial asthma respectively. Among 13.1% participants who had no co-morbid conditions, DPN was diagnosed. The association between DPN and chronic illnesses was statistically insignificant (P value 0.5396).

Table 33: Association between type of co-morbidities and DPN

Type of co-morbidities	DPN Present	DPN Absent	Total	P value
Hypertension	24 (6.9)	75 (21.4)	99 (28.3)	0.5396
Dyslipidemia	20 (5.7)	67 (19.1)	87 (24.9)	
Bronchial asthma	04 (1.1)	08 (2.3)	12 (3.4)	
None	46 (13.1)	106 (30.3)	152 (43.4)	
Total	94 (26.9)	256 (73.1)	350 (100)	

Graph 32: Association between type of co-morbidities and DPN

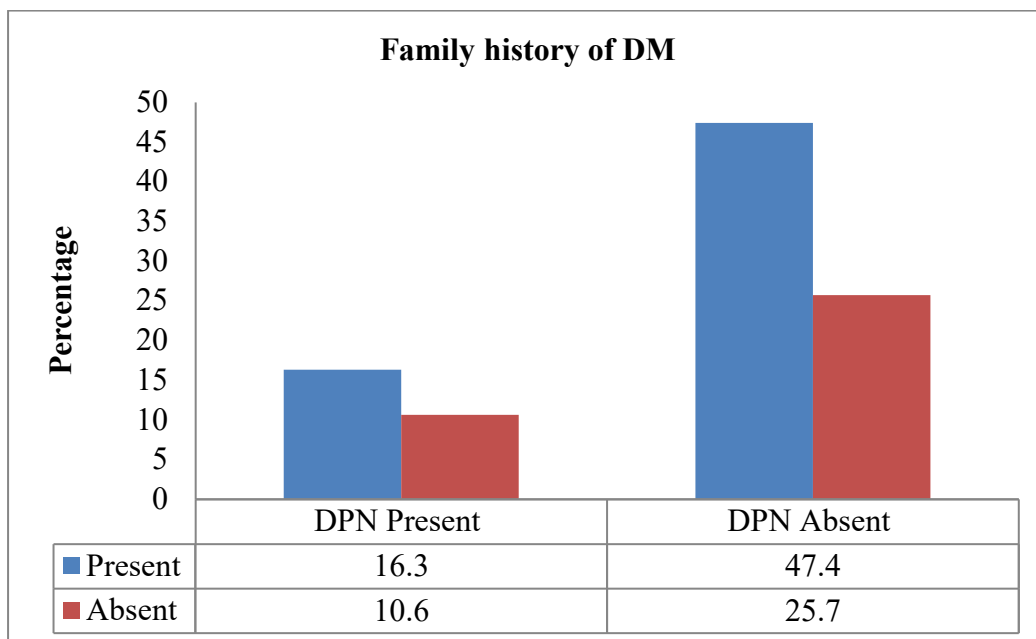
Among participants with family history of DM, 16.3% had DPN and 10.6% had DPN without family history of DM. The difference was found to be statistically significant (P value 0.0028). The odds of developing DPN were 2.3 times higher among participants with family history of DM.

Table 34: Association between DPN and family history of DM

Family history of DM	DPN Present	DPN Absent	Total	OR (95% CI)	P value
Present	72 (16.3)	151 (47.4)	223 (63.7)	2.3 (1.3-3.9)	0.0028*
Absent	22 (10.6)	105 (25.7)	127 (36.3)		
Total	94 (26.9)	256 (73.1)	350 (100)		

*Significant

Graph 33: Association between DPN and family history of DM



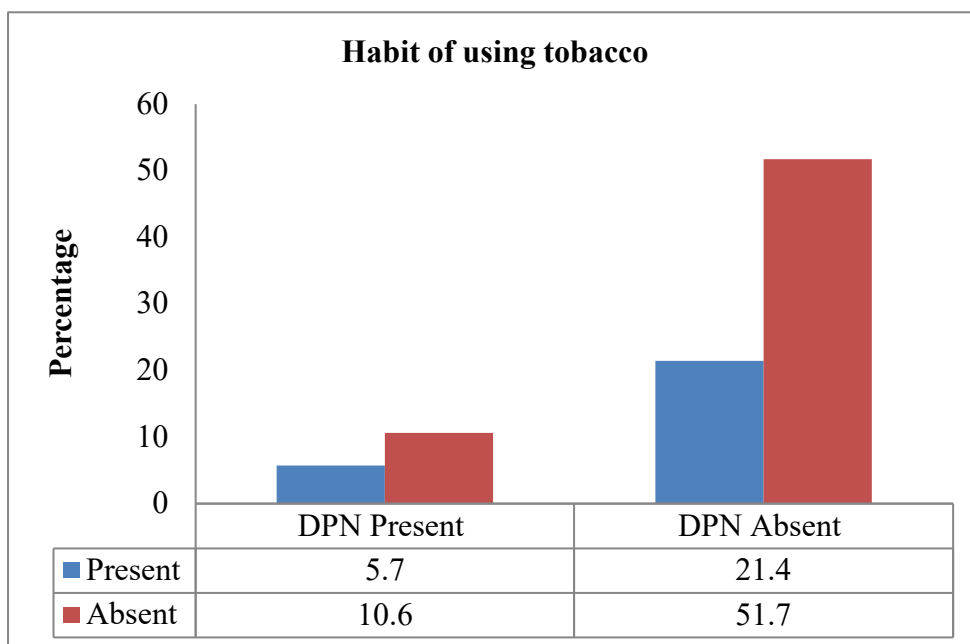
DPN was found among 5.7% and 10.6% of the study subjects with and without the habit of tobacco respectively but there was no statistically significant difference found between DPN and tobacco usage (P value 0.1347). Likewise, DPN was noted among 8.3% and 18.6% of the study subjects with and without the habit of alcohol consumption, the difference between alcohol consumption was found to be statistically significant (P value 0.0309) with odds of 1.8 which indicated the risk of acquiring DPN is 1.8 times higher among alcoholics.

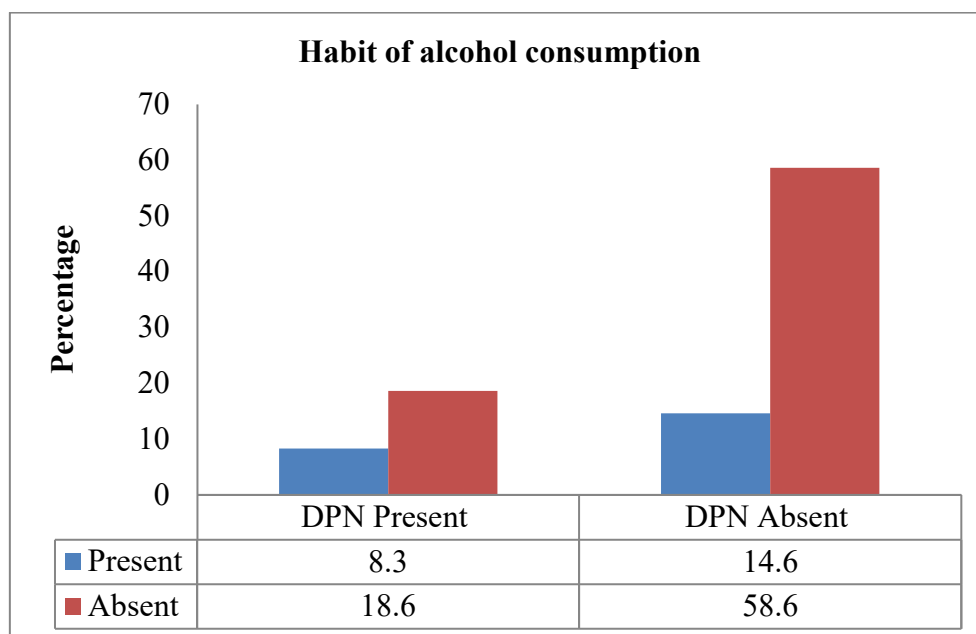
Table 35: Difference between DPN and tobacco and alcohol consumption

Variables	DPN Present	DPN Absent	Total	OR (95% CI)	P value
Habit of using tobacco					
Present	20 (5.7)	75 (21.4)	95 (27.1)	0.6 (0.4-1.1)	0.1347
Absent	74 (10.6)	181 (51.7)	255 (72.9)		
Total	94 (26.9)	256 (73.1)	350 (100)		
Habit of alcohol consumption					
Present	29 (8.3)	51 (14.6)	80 (22.9)	1.8 (1.1-3.1)	0.0309*
Absent	65 (18.6)	205 (58.6)	270 (77.1)		
Total	94 (26.9)	256 (73.1)	350 (100)		

*Significant

Graph 34: Difference between DPN and tobacco consumption



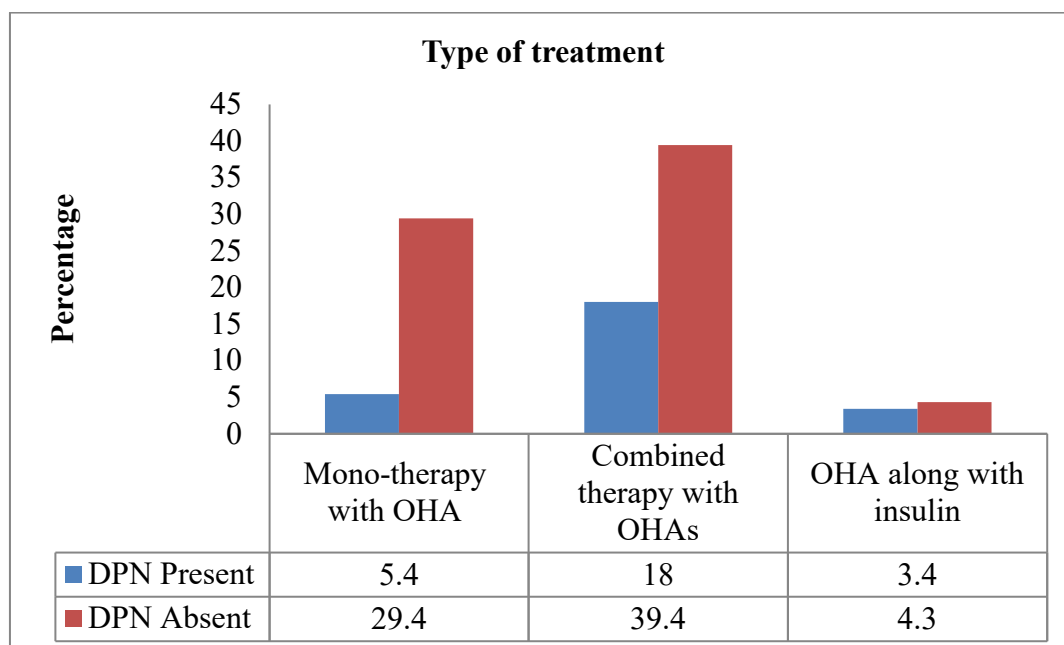
Graph 35: Difference between DPN and alcohol consumption

In this current study, 5.4% participants who were on monotherapy with OHA had DPN while 18% participants who were on combined therapy with OHAs had DPN and 3.4% of the participants who were on OHA along with insulin had DPN. The association between drug therapy and DPN was found to be statistically significant with p value of 0.0008.

Table 36: Association between DPN and type of treatment

Type of treatment	DPN Present	DPN Absent	Total	P value
Monotherapy with OHA	19 (5.4)	103 (29.4)	122 (34.9)	0.0008*
Combined therapy with OHAs	63 (18.0)	138 (39.4)	201 (57.4)	
OHA along with insulin	12 (3.4)	15 (4.3)	27 (7.7)	
Total	94 (26.9)	256 (73.1)	350 (100)	

*Significant

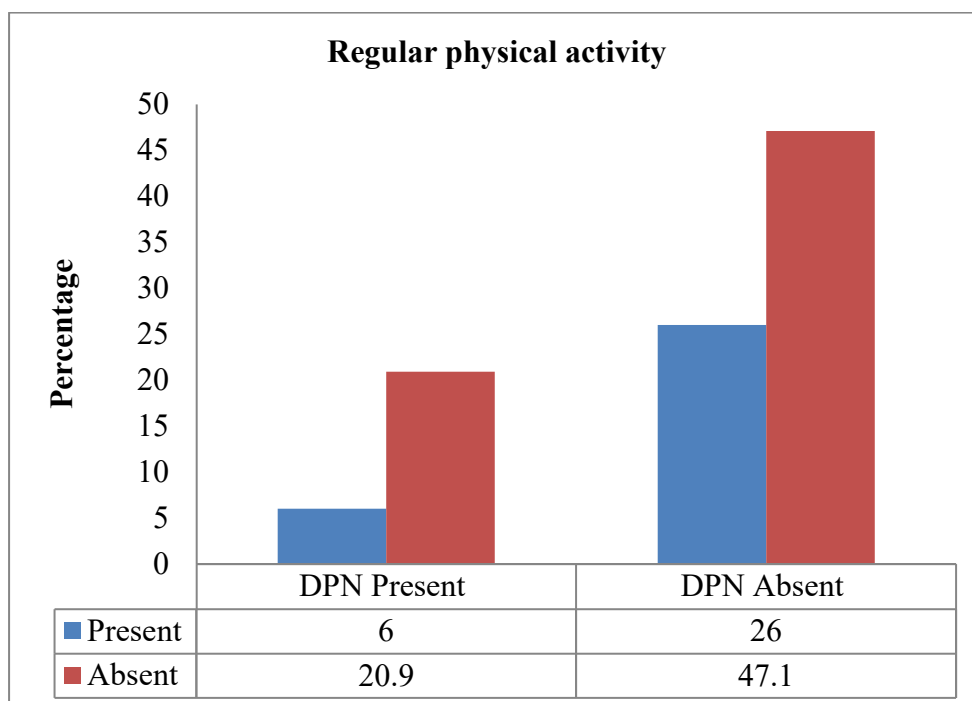
Graph 36: Association between DPN and type of treatment

Regarding physical activity, 6% of the participants who were on regular physical activity had DPN whereas 20.9% of the participants without regular physical activity had DPN and the difference between DPN and physical activity was statistically significant (P value 0.0189).

Table 37: Difference between DPN and physical activity

Regular physical activity	DPN Present	DPN Absent	Total	OR (95% CI)	P value
Present	21 (6.0)	91 (26.0)	112 (32.0)	0.5 (0.3-1.0)	0.0189*
Absent	73 (20.9)	165 (47.1)	238 (68.0)		
Total	94 (26.9)	256 (73.1)	350 (100)		

*Significant

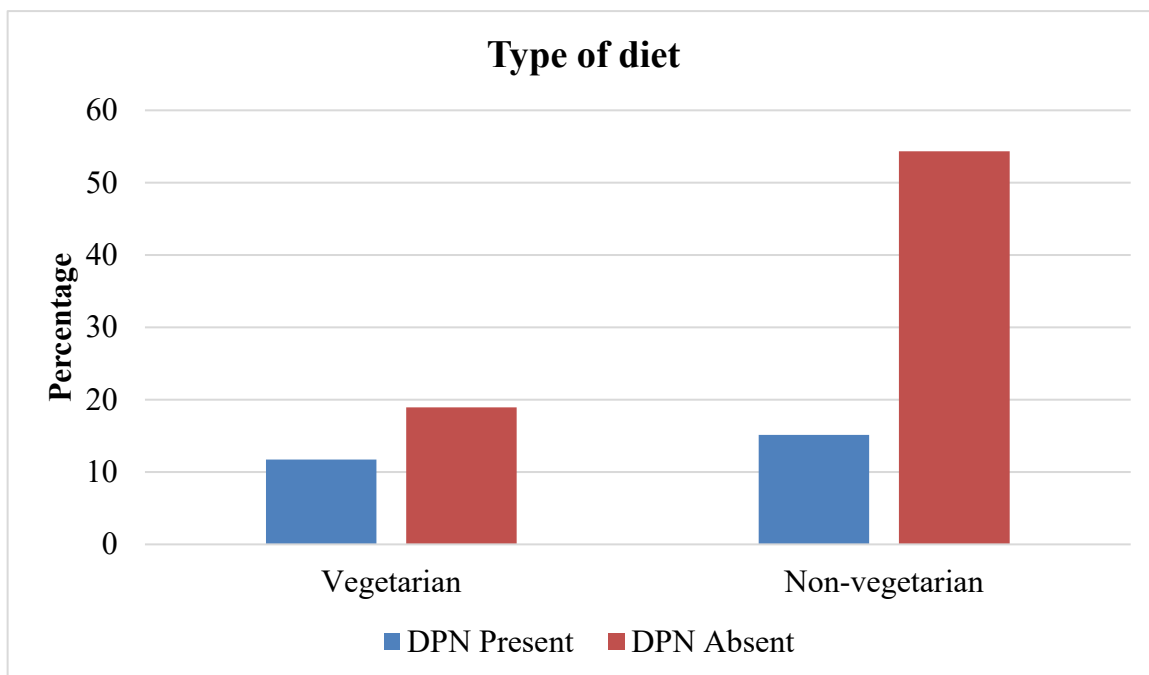
Graph 37: Difference between DPN and physical activity

DPN was noted among 11.7% of vegetarians while it was noted in 15.1% of non-vegetarians. The risk of getting DPN was 2.2 times higher among non-vegetarian participants. The difference between DPN and diet was found to be statistically significant with p value 0.0013.

Table 38: Difference between DPN and Type of diet

Type of Diet	DPN Present	DPN Absent	Total	OR (95% CI)	P value
Vegetarian	41 (11.7)	66 (18.9)	107 (30.6)	2.2 (1.4-3.6)	0.0013*
Non-vegetarian	53 (15.1)	190 (54.3)	243 (69.4)		
Total	94 (26.9)	256 (73.1)	350 (100)		

*Significant

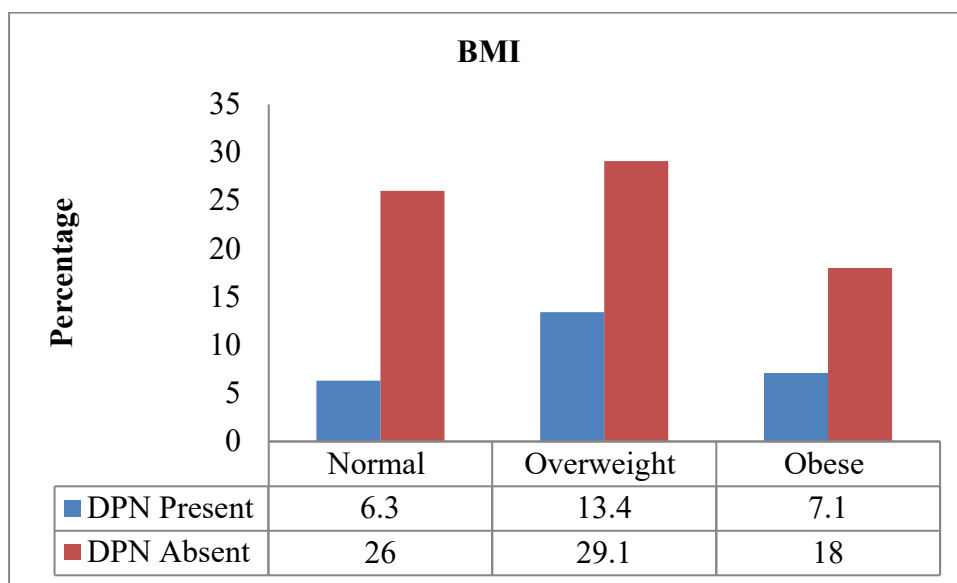
Graph 38: Difference between DPN and Type of diet

Based on BMI, diabetic peripheral neuropathy was seen among 6.3%, 13.4% and 7.1% of the participants who were normal, overweight and obese respectively but there was no significant statistical association found between BMI and DPN (P value 0.0857).

Table 39: Association between BMI and DPN

BMI	DPN Present	DPN Absent	Total	P value
Normal	22 (6.3)	91 (26.0)	113 (32.3)	0.0857
Overweight	47 (13.4)	102 (29.1)	149 (42.6)	
Obese	25 (7.1)	63 (18.0)	88 (25.1)	
Total	94 (26.9)	256 (73.1)	350 (100)	

Graph 39: Association between BMI and DPN



DPN was present among 18% participants with palpable dorsalis pedis pulsation while DPN was found to be 8.9% among participants with absent dorsalis pedis pulsation, the difference between dorsalis pedis pulsation and DPN was statistically significant (P value 0.0001). Participants with palpable posterior tibial artery pulsation were found to have DPN among 16.3% and 10.6% of the participants had DPN among whom posterior tibial artery pulsation was not seen, the difference was noted to be statistically significant for posterior tibial pulsation and DPN (P value 0.0001). Likewise, the difference in anterior tibial pulsation and DPN were also statistically highly significant (P value 0.0001).

Table 40: Difference between peripheral pulsation Vs DPN

Peripheral pulses	DPN present	DPN absent	Total	OR (95% CI)	P value
Dorsalis pedis					
Present	63 (18.0)	241 (68.9)	304 (86.9)	0.1 (0.1-0.2)	0.0001*
Absent	31 (8.9)	15 (4.3)	46 (13.1)		
Total	94 (26.9)	256 (73.1)	350 (100)		
Posterior tibial					
Present	57 (16.3)	236 (67.4)	293 (83.7)	0.1 (0.1-0.2)	0.0001*
Absent	37 (10.6)	20 (5.7)	57 (16.3)		
Total	94 (26.9)	256 (73.1)	350 (100)		
Anterior tibial					
Present	52 (14.9)	227 (64.9)	279 (79.7)	0.2 (0.1-0.3)	0.0001*
Absent	42 (12.0)	29 (8.3)	71 (20.3)		
Total	94 (26.9)	256 (73.1)	350 (100)		

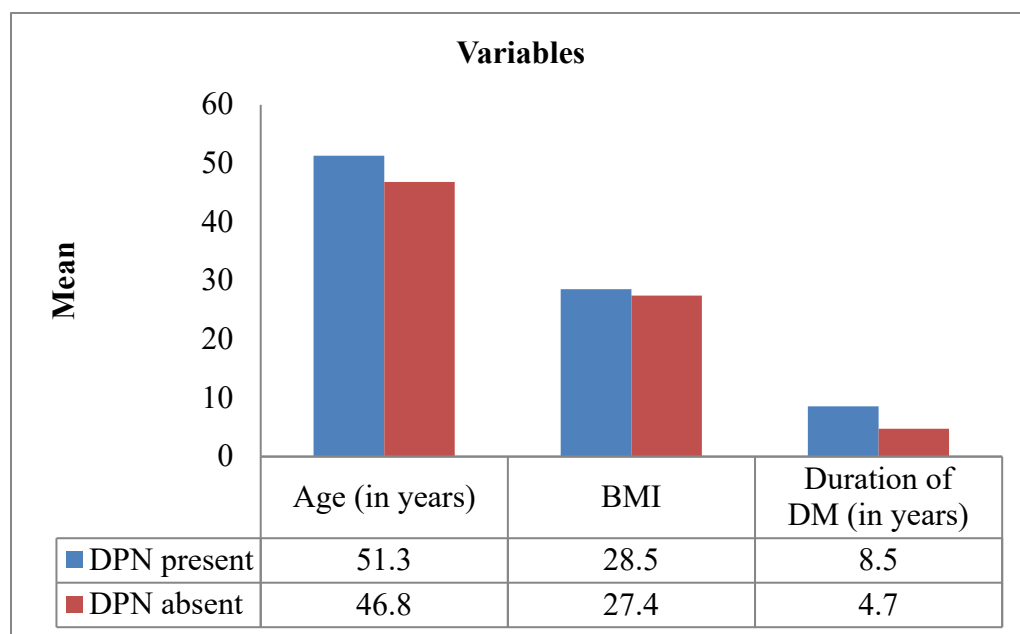
*Significant

The difference in mean age group for DPN was found to be statistically significant with p value of 0.0002. The difference in mean duration of diabetes mellitus for DPN was also found to be statistically highly significant with p value of <0.0001 and the difference in mean BMI for DPN was statistically insignificant (P value 0.0885).

Table 41: Difference in mean Age group, BMI and Duration of DM Vs DPN

Variables	DPN present	DPN absent	P value
Age (In years)	51.3 ± 9.2	46.8 ± 10.2	0.0002*
BMI	28.5 ± 1.9	27.4 ± 1.6	0.0885
Duration of DM (In years)	8.5 ± 3.8	4.7 ± 3.6	<0.0001*

*Significant

Graph 40: Difference in mean Age group, BMI and Duration of DM vs DPN

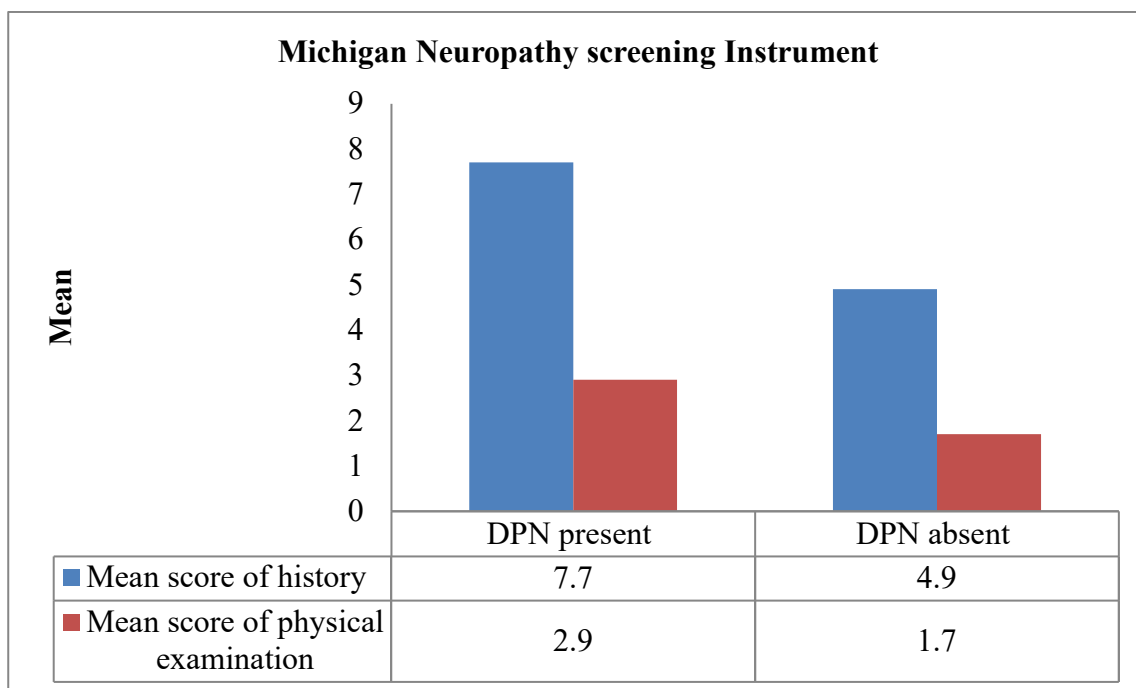
In this present study, the difference in mean scores of history version based on Michigan Neuropathy screening Instrument for DPN was statistically significant (P value <0.0001) while the difference in Mean scores of physical examination was also found to be statistically significant (P value of <0.0001).

Table 42: Difference between mean scores (Michigan Neuropathy Screening Instrument) vs DPN

Michigan Neuropathy screening Instrument	DPN present	DPN absent	P value
Mean score of history version	7.7±0.4	4.9 ± 0.5	<0.0001*
Mean score of physical examination	2.9±0.5	1.7±0.3	<0.0001*

*Significant

Graph 41: Difference between mean scores (Michigan Neuropathy Screening Instrument) vs DPN



DISCUSSION

The present study was a cross-sectional study conducted for a period of one year from January 2020 to December 2020. The study was conducted among Type 2 diabetes mellitus patients residing within urban field practice areas under Department of Community Medicine, JNMC, Belagavi to know the prevalence of peripheral neuropathy.

SOCIO-DEMOGRAPHIC VARIABLES

Age and Gender of participants

In this study, in the age groups of 56 to 65 years and above 65 years of age, there were 29.4% and 31.7% participants respectively. A similar study done in Tamil Nadu showed that 36.6% of participants belonged to age group of 51 to 60 years and 28% of participants belonged to above 60 years of age⁵⁸.

Female participants were found to be higher at 58.3%. A similar study done in Korea showed female were majority at 51.5%³⁴.

Education status and occupation of participants

Among the study population, 34.6% of the participants had completed their high school. A study done in Qatar showed that 26.4% had completed high school education⁴⁷. Degree holders were at 6% which was much lower compared to the study done in Qatar. This may be due to reduced access and increased cost of education. Illiterates were at 8.9% and a similar study done in Mangalore showed an illiteracy level which was comparable to our study⁴⁵.

In this study, 22.6% of the participants were unemployed. These findings are comparable to a study done in Malaysia³⁵. Almost half of the participants (43.1%) were housewives which is much higher compared to a study done in Ethiopia⁵². This may be attributed to cultural factors in our study setting where women are mostly expected to take care of the family and household whereas men are the majority daily bread earners.

Religion and Marital status of participants

Majority (51.7%) of the population were Hindus. 26.6% of the participants were Muslims which is comparable to the study done in Ethiopia⁵².

In this study, 64.3% of the participants were married, 22.3% of the participants were widows and 13.4% of the participants were found to be widowers. The percentage of married individuals is lower compared to the Ethiopian study⁵².

Type of family and Socioeconomic status of participants

Majority of the participants (62.3%) were living in nuclear family whereas 35.7% of the participants were living in joint family.

On assessing the socioeconomic status, Almost half (41.5%) of the participants belonged to socioeconomic class of Class IV and Class V which is similar to a study done in Saudi Arabia where 41.7% belonged to the lower income tertile⁴⁰.

Duration of DM among participants

In this current study, for 40.6% of the participants, the duration of DM was around 6 to 10 years which is lower when compared to a study done in Saudi Arabia in a primary health setting⁵⁷. About one-fourth of the participants (26%) had diabetes

more than 10 years. This is comparable to the study done in Tamil Nadu⁵⁸. The duration of diabetes was between 1 to 5 years among 24.3% of the participants which is comparable to the study done in Saudi Arabia⁴⁰.

Presence of co-morbidities among participants

Co-morbidities like Hypertension was found among 28.3% which was lower compared to the study in Saudi Arabia⁴⁰. Dyslipidemia was found in 24.9% of the participants which is lower compared to the study by Algeffari in Saudi Arabia⁵⁷. Testing for lipid levels is not done at the primary health setting which may be a plausible factor for the lower percentage of dyslipidemia in our setting.

Family history of DM among participants

Family history of DM was recorded in 63.7% of the participants. This finding is much lower compared to a similar study done in Jordan⁵⁶. The family members affected by DM in relation to the study participants were found to be father among 41.3% participants, mother among 54.3% participants and siblings among 30% of the participants.

Tobacco use and Alcohol consumption among participants

About one-fourth of the participants (27.1%) had a habit of tobacco use. This finding is higher compared to a study done in Taiwanese adults⁵⁵. Almost one-fifth of the participants (22.9%) had a habit of alcohol consumption which is higher compared to the study done in Mangalore⁴⁵. The higher level of substance abuse in our study setting may be due to lack of awareness regarding their adverse effects.

Type of treatment among participants

Majority of the participants (92.3%) were on oral hypoglycemic agents which is higher compared to the study done in Jordan⁵⁶. This may be due to the low cost and ease of taking oral tablets. Biguanides were the most commonly used OHA at 83.6% either taken as mono or combined therapy followed by Sulphonylureas group (73%).

Physical activity and type of diet of participants

More than one-fourth of the study participants (32%) who followed regular physical activity. This is higher than the finding in the study done at Jordan⁵⁶. This may be due to an increase in awareness regarding healthy lifestyles through various government campaigns. Walking was the most common physical activity followed.

Majority of the study participants (69.4%) were on non-vegetarian diet.

BMI and Waist-hip ratio of participants

On assessing the BMI, more than two-fifth of the participants (42.6%) were found to be overweight which is comparable to a study in Taiwan⁵⁵.

Waist-hip ratio was abnormal for more than two-thirds (67.6%) of female and majority (63.7%) of male participants.

Presence of peripheral pulsations among participants

Anterior tibial pulsations were absent in 20.2% of the participants and posterior tibial pulse was absent among 16.2% of the participants. In a study done at Jordan by Al-Sarihin et al, this sign of lower limb ischemia was much lower²².

Michigan Neuropathy Screening Instrument – history version

The mean score of history was 5.3 ± 0.8 . The mean score of physical examination was 1.9 ± 0.4 . The common history noted was numbness (56%) and 42.6% of the participants checked water temperature before bathing, burning pain history was present among 34.6% participants. The least history based on MNSI was found to be open sore among 18% of the participants and amputation which was done for one participant. These findings were similar to a study done in Jordan by Khawaja et al where the most common symptom reported was numbness and the least common symptom being history of amputation but contrary to the study by D'Souza et al where the most common symptom noted was leg pain while walking^{45,56}. Malazy et al reported that tingling in the lower extremity was the most frequent complaint (42%)³².

Michigan Neuropathy Screening Instrument – physical assessment

The appearance of feet was abnormal on right side and left side at 81.7% participants and for 85.4% participants respectively. These findings are higher compared to a study done among by Tahrani et al⁵⁴. Various factors like lack of awareness regarding foot self-care, reduced hygiene may render patients to be more prone for dryness of skin, callus formation and infections.

Ulceration was seen in 2% of the participants on the right foot and 2.6% of the participants in the left foot which is lower compared to the study done among white Caucasians⁵⁴. Health promotion regarding daily inspection of feet, reinforcing behaviours like checking footwear before wearing and checking water temperature before bathing are of importance.

Monofilament test was absent in 8.9% of the participants on the right side and 10.6% of the participants on the left side which is higher compared to a study done at Italy by Salvotelli et al which reported a 7% pathology⁴⁴.

Prevalence of Peripheral Neuropathy

Diabetic Peripheral Neuropathy (DPN) was present among 94 (26.9%) participants in this study. These findings are comparable to studies done by Tres et al who reported a prevalence of DPN as 22.1%²⁸. Won et al, Salvotelli et al and Malazy et al reported the prevalence of DPN as 33.5%, 30% and 31.9% respectively which is higher^{32,34,44}. The prevalence in our study was lower compared to a study done by Boyraz et al³¹ who reported the frequency of peripheral neuropathy as 61.3% and 46.2% among the obese and non-obese cases with type 2 DM respectively. These conflicting values can be due to differences in study sample size, eligibility criteria and diagnostic cut-offs used in MNSI.

Serum Vitamin B12 level among neuropathy patients

Among the DPN patients, the serum vitamin B12 levels among participants showed that half of the participants (50%) had low normal levels of serum vitamin B12 and more than one-third (36.2%) of the participants had vitamin B12 deficiency.

FACTORS ASSOCIATED WITH PERIPHERAL NEUROPATHY

Association of DPN with age

Prevalence of DPN was higher among participants in the age groups of 56-65 years and more than 65 years at 8.3% and 9.7% respectively. The association for DPN between different age group was not found to be statistically significant. These

findings are similar to studies done by Malazy et al³² who found age of more than 50 years to be associated with DPN. The difference in mean age group between DPN and non-DPN cases was found to be statistically significant which is similar to a study done in Qatar⁴⁷.

Association of DPN with gender

The prevalence of DPN among female participants was higher at 15.1% compared to male participants but there was no significant statistical difference found for gender and DPN. A study by Won et al³⁴ found female gender to be associated with DPN.

Association of DPN with variables like education, occupation, religion, marital status, type of family and Socioeconomic status

Association of DPN with education status was not statistically significant. Studies done in Qatar and Ethiopia also revealed that education was not associated with DPN^{47,52}. Association of DPN with variables like occupation, religion, type of family was found to be not statistically significant. Association of DPN with marital status showed no statistically significant association. This finding is similar to studies done in Mangalore and Jordan but contrary to the findings in the study done in Ethiopia^{45,52,56}. Association of DPN with socioeconomic status was found to be not statistically significant. These findings are similar to studies done in Qatar and Ethiopia^{47,52}.

Association of DPN with duration of DM

Prevalence of DPN was high in participants with a duration of DM of 6 to 10 years and more than 10 years at 14.9% and 10.6% respectively. There was statistically

significant association found for DPN and duration of DM. This is similar to findings observed in studies done at Qatar, Jordan, Taiwan and United Kingdom^{22,48,55,56}. This is contrary to the studies done in Tamil Nadu, France, Saudi Arabia which showed no association^{29,33,36,58}. The difference in mean duration of DM among DPN and non-DPN cases was also found to be statistically significant.

Association of DPN with presence of co-morbidities

Prevalence of DPN was present among 6.9% and 5.7% of the participants with hypertension, and dyslipidemia respectively. The association between DPN and chronic illnesses was statistically insignificant. These findings are contrary to findings of the study done in Qatar which found systolic hypertension to be a significant correlate of DPN and studies done in Tamil Nadu and Jordan which showed both hypertension and dyslipidemia to be associated with development of DPN^{22,36,47,56}. The possible reason behind the conflicting evidence may be due to variations in methodology of the study. Recent literature also shows that patients with DPN without pain had lower levels of total cholesterol and triglyceride⁵⁵.

Association of DPN with family history of DM

Prevalence of DPN was higher among participants who had a family history of DM compared to those without family history of DM at 16.3% and 10.6% respectively. The difference was found to be statistically significant. This finding is comparable to the study done in Jordan⁵⁶. Univariate analysis also showed that the odds of developing DPN were 2.3 times higher among participants with family history of DM.

Association of DPN with tobacco use

There was no statistically significant association found between presence of DPN and tobacco usage. This finding is similar to the studies previously reported from Qatar, Jordan, Saudi Arabia and Ethiopia but contrary to the study done in Mangalore^{22,45,47,52,56,57}. Also, a study done in Taiwan reported that smoking habit was a risk factor of painless DPN⁵⁵.

Association of DPN with alcohol consumption

The prevalence of DPN was high (8.3%) among participants with habit of alcohol consumption which was found to be statistically significant. The risk of acquiring DPN was 1.8 times higher among alcoholics. This finding is similar to the study done in Mangalore⁴⁵.

Association of DPN with type of treatment

Prevalence of DPN was high among participants who consumed OHAs either as monotherapy or combined therapy. The association between type of treatment and DPN was found to be statistically significant. This is similar to the studies done at Jordan and Taiwan^{55,56}.

Association of DPN with physical activity

DPN was higher among participants without regular physical activity (20.9%). There was a statistically significant association between DPN and physical activity. This is similar to a study done in Ethiopia and a study in Jordan^{52,56}.

Association between DPN and type of diet

The prevalence of DPN was higher among participants who consumed a non-vegetarian diet. The difference between DPN and diet was found to be statistically significant. The odds of developing DPN was 2.2 times higher among non-vegetarians.

Association of DPN with BMI

There was no significant statistical association found between BMI and DPN and the difference in mean BMI for DPN was statistically insignificant. These findings were similar to the studies done in Tamil Nadu, Jordan and Saudi Arabia⁵⁶⁻⁵⁸.

Association of DPN with presence of peripheral pulsations

Prevalence of DPN was high among participants who had absent peripheral arterial pulsations which was statistically significant.

Association between DPN and mean scores of MNSI

The difference in mean scores of history and mean scores of physical examinations based on MNSI were statistically significant.

CONCLUSIONS

On assessing the association between duration of DM, family history of DM, habit of alcohol consumption, treatment history, regular physical activity, type of diet and absence of peripheral pulsation with presence of DPN, there were significant association noted in this study. However, on assessing the parameters like age, gender, educational status, occupational status, religion, marital status, type of family, socio economic status, presence of co-morbidities, habit of smoking and BMI with the presence of DPN, there were no significant association reported. We infer that the burden of DPN among the cases with T2DM was notably high with predominant vitamin B12 deficiency among them. Hence, it is essential to strengthen the screening for DPN for all the cases with DM at the community level in order to diagnose early and treat promptly before the onset of foot related complications.

RECOMMENDATIONS

- There is scope for further research in the form of a longitudinal study or cohort study with additional increase sample size which would determine incidence of DPN.
- Serum Vitamin B12 levels, HbA1c levels and NCV studies may be done at regular follow-up visits for better understanding of DPN progression and its management.
- Health education regarding glycemc control to prevent diabetic complications.
- Health education regarding foot self-care to reduce diabetes related foot complications.
- Regular follow-up for screening of complications.
- Screening of DPN at the community by training the auxiliary nurse midwives (ANM) or through periodic health camps and special NCD clinics.
- Patients with DPN who are screened for serum vitamin B12 levels can be advised on high-dose oral vitamin B12 supplements, wherever necessary.

STRENGTHS

- This study was a community-based study which covered the diabetic population residing in the urban field practice areas, hence, the results of this study can be generalized.
- The study accounted for one important potential confounder which is Vitamin B12 deficiency which might mimic the symptoms of DPN.
- The study used a validated, easy to use scale in the community on an adequate sample of our population.

LIMITATIONS

- Our study did not use nerve conduction velocity (NCV) studies which is a definitive tool for diagnosis of DPN.
- Vitamin B12 levels were estimated only for patients with DPN, hence, comparison was not possible.
- Glycated hemoglobin (HbA1c) was not estimated due to paucity of funds which could provide further insight regarding glycemic control.

SUMMARY

Diabetes mellitus (DM) is the most common public health concern among Non-Communicable Diseases (NCDs) not only in India but also worldwide. The two types of complications which occur due to type 2 diabetes mellitus are microvascular and macrovascular among which microvascular complications like neuropathy; nephropathy and retinopathy are frequently reported. Early diagnosis and treatment of diabetic neuropathy is particularly important for preventing secondary complications and improving quality of life.

A community-based cross-sectional study was conducted in urban field practice areas under the department of Community Medicine in Jawaharlal Nehru Medical College, Belagavi among type 2 diabetes mellitus patients during the period from January 2020 to December 2020.

Based on the literature, considering the prevalence of diabetic peripheral neuropathy as 32.2%, sample size was calculated to be 350 in this study. From the sampling frame, data was collected from the type-2 diabetes mellitus patients by house-to-house visits. After collecting the demographic and basic clinical profile of the participants, the screening for diabetes peripheral neuropathy was conducted by the investigator using a predesigned, validated tool called Michigan Neuropathy Screening Instrument (MNSI).

A total of 5 ml of venous blood from antecubital vein from diagnosed DPN patients was collected in plain vial for serum vitamin B12 level estimation. Blood samples were sent to a certified diagnostic laboratory where serum vitamin B12 level was estimated by chemiluminescence method.

In this study, in the age groups of 56 to 65 years and above 65 years of age, there were 29.4% and 31.7% participants respectively. Female participants were found to be higher at 58.3%. Among the study population, 34.6% of the participants had completed their high school. In this study, 22.6% of the participants were unemployed. Almost half of the participants (43.1%) were housewives. Majority (51.7%) of the population were Hindus. Majority (64.3%) of the participants were married. Majority of the participants (62.3%) were living in nuclear family. On assessing the socioeconomic status, Almost half (41.5%) of the participants belonged to socioeconomic class of Class IV and Class V. In this current study, for 40.6% of the participants, the duration of DM was around 6 to 10 years and about one-fourth of the participants (26%) had diabetes more than 10 years.

Co-morbidities like Hypertension was found among 28.3% and dyslipidemia was found in 24.9% of the participants. Family history of DM was recorded in 63.7% of the participants. About one-fourth of the participants (27.1%) had a habit of tobacco use. Almost one-fifth of the participants (22.9%) had a habit of alcohol consumption. Majority of the participants (92.3%) were on oral hypoglycemic agents. Physical activity and type of diet of participants More than one-fourth of the study participants (32%) followed regular physical activity. Majority of the study participants (69.4%) were on non-vegetarian diet. On assessing the BMI, more than two-fifth of the participants (42.6%) were found to be overweight.

The mean score of history was 5.3 ± 0.8 . The mean score of physical examination was 1.9 ± 0.4 . The common history noted was numbness (56%) and 42.6% of the participants checked water temperature before bathing, burning pain history was present among 34.6% participants. The least history based on MNSI was

found to be open sore among 18% of the participants and amputation which was done for one participant.

The appearance of feet was abnormal on right side and left side at 81.7% participants and for 85.4% participants respectively. Ulceration was seen in 2% of the participants on the right foot and 2.6% of the participants in the left foot. Monofilament test was absent in 8.9% of the participants on the right side and 10.6% of the participants on the left side.

Diabetic Peripheral Neuropathy (DPN) was present among 94 (26.9%) participants in this study. Among the DPN patients, the serum vitamin B12 levels among participants showed that half of the participants (50%) had low normal levels of serum vitamin B12 and more than one-third (36.2%) of the participants had vitamin B12 deficiency.

Prevalence of DPN was higher among participants in the age groups of 56-65 years and more than 65 years at 8.3% and 9.7% respectively. The association for DPN between different age group was not found to be statistically significant. The prevalence of DPN among female participants was higher at 15.1% but there was no significant statistical difference found for gender and DPN.

Association of DPN with variables like education, occupation, religion, marital status, type of family and Socioeconomic status were not statistically significant.

There was statistically significant association found for DPN and duration of DM and family history of DM.

There was no statistically significant association found between presence of DPN and tobacco usage. The prevalence of DPN was high (8.3%) among participants with habit of alcohol consumption which was found to be statistically significant.

Prevalence of DPN was high among participants who consumed OHAs either as monotherapy or combined therapy. The association between type of treatment and DPN was found to be statistically significant.

DPN was higher among participants without regular physical activity. The prevalence of DPN was higher among participants who consumed a non-vegetarian diet. There was no significant statistical association found between BMI and DPN. Prevalence of DPN was high among participants who had absent peripheral arterial pulsations which was statistically significant. The difference in mean scores of history and mean scores of physical examinations based on MNSI were statistically significant. We infer that the burden of DPN among the cases with T2DM was notably high with predominant vitamin B12 deficiency among them. Hence, it is essential to strength the screening for DPN for all the cases with DM at the community level in order to diagnose early and treat promptly.

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ANNEXURE I – ETHICAL CLEARANCE LETTER

	K.J.S. ACADEMY OF HIGHER EDUCATION AND RESEARCH (Deemed-to-be-University)
	Accredited 'A' Grade by NAAC (12 th Cycle) Placed in Category 'A' by MHRD (2014)
JAWAHARLAL NEHRU MEDICAL COLLEGE, NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)	
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Ref: MDC/DOME/ 200	Date: 24/12/2019
To, Dr. <input type="text"/> PG student in Community Medicine, J.N.Medical College, BELAGAVI.	
Sub: Institutional Ethical Clearance for the study.	
With reference to the above, we wish to inform you that your proposed research project titled "PREVALENCE OF PERIPHERAL NEUROPATHY AMONG TYPE-2 DIABETES MELLITUS PATIENTS IN AN URBAN COMMUNITY" , is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.	
 (Dr. Anita Dalal) Member Secretary JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.	 (Dr. Ranga M Bellad) Chairman, JNMC Institutional Ethics Committee on Human Subjects Research, J.N.Medical College, Belagavi.

ANNEXURE II - INFORMED CONSENT

“Prevalence of peripheral neuropathy among type-2 diabetes mellitus patients in an urban community”

Investigator: Dr.

PG Student, Department of Community Medicine,
Jawaharlal Nehru Medical College, KAHER, Belagavi - 590010.

Guide: Dr.

Professor,
Department of Community Medicine,
Jawaharlal Nehru Medical College,
Specialist in Diabetes, Diabetes Centre,
KLEs Dr. Prabhakar Kore Hospital and Medical Research Centre,
KAHER, Belagavi – 590010.

INTRODUCTION

Diabetes mellitus causes numerous debilitating complications and thereby, reduces the quality of life. Peripheral neuropathy is the most common complication in diabetes mellitus. Diabetes causes nerve damage through different mechanisms, including damage due to hyperglycemia and decreased blood flow to nerves by damaging small blood vessels supplying to the nerves (vasa nervorum). This nerve damage leads to loss of sensations such as vibration, pain and temperature which leads to damage to limbs (delayed, non-healing ulcers) and ultimately leads to lower limb amputations. Therefore, this study is being conducted to determine the prevalence of peripheral neuropathy among type-2 diabetes mellitus patients residing

in the urban field practice areas of Ashok Nagar and Rukmini Nagar urban health centres and you are requested to participate in this study. Participation in this study is completely voluntary.

EXPLANATION OF PROCEDURES

In this study, you will have to answer questions about your general health information, socio-demographic details, nutritional health status and screening for peripheral neuropathy will be done. If diagnosed positive, venous blood will be collected. The entire procedure may take 1 hour.

POSSIBLE BENEFITS

The investigator does not promise or guarantee that you will receive direct benefit by being in this study. It will benefit the whole community because by this study, we will know the prevalence of peripheral neuropathy in type-2 diabetes mellitus in the community and accordingly, the preventive and control measures can be taught.

POSSIBLE RISKS

1. Hematoma
2. Swelling, tenderness and inflammation at the site
3. Persistent bleeding
4. Rare adverse effects: Thrombosis of the vein due to trauma and thrombophlebitis due to infection.

CONFIDENTIALITY

Your identity will not be revealed. All information will be collected, coded and anonymized so that no one will know the identify.

WITHDRAWAL

Participation in this study is voluntary. If you do not wish to participate in this study, you will not lose benefits to which you are entitled.

COSTS OF PARTICIPATION

The cost of the study will be borne by the investigator. There will be no additional cost to you for participating in this study.

PAYMENT OF PARTICIPATION

There will be no incentives to you for participating in this study.

AUTHORIZATION TO PUBLISH RESULTS

The investigators may use the information gathered from this study for presentation in scientific journals. However, your identity will not be disclosed in such presentation or publication.

LEGAL RIGHTS

By signing this consent form, you are not waiving any of your legal rights.

QUESTIONS

If you have any questions about this study, you may contact DR. _____
DR. _____ If you have any questions about your rights as a study participant,
you may contact DR. ROOPA BELLAD, Chairperson, JNMC Institutional Ethics
Committee on human subjects' research at 0831-2741701.

CONSENT STATEMENT

“I have been explained all the contents of this consent form in my local
language and have understood and clarifies all my queries about the study to the best
of my knowledge. Furthermore, I recognize that I have the complete right to withdraw
the consent at any point during the study. I understand that the information given by
me will be confidential and will be used for research purpose only. Further, I am
aware that the result of this research will be presented/published without disclosing
any personal identification of the participants.

I hereby give my voluntary consent for participation in this study. I do sign the
informed consent form in front of an eyewitness whom I recognize.”

Name of the participant: _____ Signature/ left thumb impression

Name of the eyewitness: _____ Signature/ left thumb impression

Name of the investigator: Dr. _____ Signature: _____

Name of the guide: Dr. _____ Signature: _____

Date:

ANNEXURE III - QUESTIONNAIRE**PART-1 SOCIO-DEMOGRAPHIC ASPECTS**

Name:

Sex:

Age: _____ years

Area of residence:

1. Religion:

a. Hindu	b. Muslim	c. Christian	d. Others (specify)
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2. Education:

a. Illiterate	b. Primary school	c. High school	d. Pre university I & II	e. Degree
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3. Occupation:

4. Marital Status:

a. Unmarried	b. Married	c. Widowed	d. Divorced/ Separated
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5. Type of Family:

a. Joint	b. Nuclear	c. Broken family	d. Problem family
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6. a. Monthly income of the family:

b. Total number of family members:

c. Monthly per capita income:

7. Socio-economic status – Modified B.G. Prasad classification

a. Class I	b. Class II	c. Class III	d. Class IV	e. Class V
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8. Menstrual History (If Female):

a. Last menstrual period:

b. Regular/ Irregular

c. Excessive/ Reduced menstrual flow

9. Do you have children? Yes/ No

If yes, do you have history of miscarriage? Yes/ No

If yes, please specify the number of miscarriages –

PART II – PAST HISTORY

10. How long have been diagnosed with type-2 diabetes mellitus?

11. Any past history of chronic illness? Yes/ No

If yes, please specify –

PART III – FAMILY HISTORY

12. Does anyone in your family have diabetes or any other chronic illness? Yes/ No

If yes, please specify –

PART IV – PERSONAL HEALTH HABITS

13. Do you have a history of tobacco use? Yes/ No

If yes, please specify smoke/ smokeless tobacco and duration _____

14. Do you consume alcohol? Yes/ No

If yes, duration _____

PART V – DRUG HISTORY

15. List of prescribed drugs taken regularly

DRUGS	STRENGTH	FREQUENCY

PART VI – PHYSICAL ACTIVITY AND NUTRITIONAL HISTORY

16. Do you participate in regular physical activity or exercise? Yes/ No

If yes, what kind of physical activity?

- i. Walking
- ii. Running
- iii. Yoga
- iv. Others, please specify _____

17. How long do you exercise/ week? _____

18. Type of diet: Vegetarian/ Non – vegetarian

PART VII – CLINICAL EXAMINATION

I. GENERAL PHYSICAL EXAMINATION

1. Build and Nourishment: Poor/ Moderate/ Fair
2. Height (cm):
3. Weight (kg):
4. BMI (kg/m²):
5. Waist/ Hip Ratio:
6. Pallor: Present/ Absent
7. Icterus: P/ A
8. Cyanosis: P/ A
9. Clubbing: P/ A
10. Lymphadenopathy: P/ A
11. Pedal edema: P/ A

Vital signs

1. Respiratory Rate (/min):
2. Pulse (/min):
3. Peripheral Pulses:
 - a. Dorsalis pedis: P/ A
 - b. Posterior tibial: P/ A
 - c. Anterior tibial: P/ A
4. Blood Pressure (mm/Hg):

At supine position:	At standing position:
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5. Temperature (°C): Febrile/ Afebrile

II. SYSTEMIC EXAMINATION

Cardiovascular System:	Respiratory System:
Central Nervous System:	Per abdomen:

PART VIII – INVESTIGATION PROFILE

TEST	RESULT
Serum vitamin B12 level	

PART IX – MICHIGAN NEUROPATHY SCREENING INSTRUMENT

Patient Version

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

A. History (To be completed by the person with diabetes)

Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel. Thank you.

1. Are you legs and/or feet numb? Yes No
2. Do you ever have any burning pain in your legs and/or feet? Yes No
3. Are your feet too sensitive to touch? Yes No
4. Do you get muscle cramps in your legs and/or feet? Yes No
5. Do you ever have any prickling feelings in your legs or feet? Yes No
6. Does it hurt when the bed covers touch your skin? Yes No
7. When you get into the tub or shower, are you able to tell the hot water from the cold water? Yes No
8. Have you ever had an open sore on your foot? Yes No
9. Has your doctor ever told you that you have diabetic neuropathy? Yes No
10. Do you feel weak all over most of the time? Yes No
11. Are your symptoms worse at night? Yes No
12. Do your legs hurt when you walk? Yes No
13. Are you able to sense your feet when you walk? Yes No
14. Is the skin on your feet so dry that it cracks open? Yes No
15. Have you ever had an amputation? Yes No

Total: _____

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

A. Physical Assessment (To be completed by health professional)

1. Appearance of Feet

Right

a. Normal 0 Yes 1 No

b. If no, check all that apply:

- Deformities
- Dry skin, callus
- Infection
- Fissure
- Other
-

specify: _____

Left

Normal 0 Yes 1 No

If no, check all that apply:

- Deformities
- Dry skin, callus
- Infection
- Fissure
- Other

specify: _____

Right

Absent 0 Present 1

2. Ulceration

0

1

Left

Absent 0 Present 1

0

1

Present 0 Present/Reinforcement 0.5 Absent 1

3. Ankle Reflexes

0

0.5

1

Present 0 Present/Reinforcement 0.5 Absent 1

0

0.5

1

Present 0 Decreased 0.5 Absent 1

4. Vibration perception at great toe

Present 0 Decreased 0.5 Absent 1

Normal 0 Reduced 0.5 Absent 1

5. Monofilament

0

0.5

1

Normal 0 Reduced 0.5 Absent 1

0

0.5

1

Signature: _____

Total Score _____ /10 Points

ANNEXURE IV - KEY TO MASTER CHART

Age (in years): 35 - 70

Sex : 1) Male 2) Female

1] Religion : 1) Hindu 2) Muslim 3) Christian 4) Others

2] Education : 1) Illiterate 2) Primary school 3) High school

4) Pre university I & II 5) Degree

3] Occupation : 1) Housewife 2) Retired 3) Employed 4) Unemployed

4] Marital status : 1) Unmarried 2) Married 3) Widowed 4) Divorced/ Separated

5] Type of the family : 1) Joint 2) Nuclear 3) Broken family 4) Problem family

6] a. Monthly income of the family (in Rs.): 4000 – 27000

b. Total number of family members: 3 - 9

7] Socio economic status (modified B.G. Prasad's classification): 1) Class I

2) Class II

3) Class III

4) Class IV

5) Class V

8] Menstrual History (If Female):

a. 1) Regular 2) Irregular

b. 1) Excessive 2) Reduced menstrual flow

9]

a. Do you have children? 1) Yes 2) No

b. Do you have history of miscarriage? 1) Yes 2) No

10] How long have been diagnosed with type-2 diabetes mellitus? (in years)

11] Any past history of chronic illness? 1) Yes 2) No

12] Does anyone in your family have diabetes or any other chronic illness? 1) Yes
2) No

13] Do you have a history of tobacco use? 1) Yes 2) No

14] Do you consume alcohol? 1) Yes 2) No

15] List of prescribed drugs taken regularly. 1) Biguanides 2) Sulfonylureas
3) Others

16] Do you participate in regular physical activity or exercise? 1) Yes 2) No

17] What kind of physical activity? 1) Walking 2) Running 3) Yoga 4) Others

18] Type of diet: 1) Vegetarian 2) Non – vegetarian

General Physical Examination

1] Build and Nourishment: 1) Poor 2) Moderate 3) Fair

2] BMI:

3] Waist/ Hip Ratio:

Pallor- 1) Present 2) Absent

Icterus- 1) Present 2) Absent

Cyanosis- 1) Present 2) Absent

Clubbing- 1) Present 2) Absent

Lymphadenopathy- 1) Present 2) Absent

Pedal edema- 1) Present 2) Absent

Vital signs

1] Respiratory Rate: 1) Normal 2) Abnormal

2] Pulse: 1) Normal 2) Abnormal

3] Peripheral Pulses:

a. Dorsalis pedis: 1) Present 2) Absent

b. Posterior tibial: 1) Present 2) Absent

11. Are your symptoms worse at night? 1) Yes 2) No
12. Do your legs hurt when you walk? 1) Yes 2) No
13. Are you able to sense your feet when you walk? 1) Yes 2) No
14. Is the skin on your feet so dry that it cracks open? 1) Yes 2) No
15. Have you ever had an amputation? 1) Yes 2) No

Physical Assessment

1] Appearance of Feet

Right: Normal: 1) Yes 2) No

Left: Normal: 1) Yes 2) No

2] If Abnormal,

Right: 1) Deformities 2) Dry skin, callus 3) Infection 4) Fissure 5) Other

Left: 1) Deformities 2) Dry skin, callus 3) Infection 4) Fissure 5) Other

3] Ulceration

Right: 1) Absent 2) Present

Left: 1) Absent 2) Present

4] Ankle Reflexes

Right: 1) Present 2) Present/ Reinforcement 3) Absent

Left: 1) Present 2) Present/ Reinforcement 3) Absent

5] Vibration perception at great toe

Right: 1) Present 2) Decreased 3) Absent

Left: 1) Present 2) Decreased 3) Absent

6] Monofilament

Right: 1) Present 2) Reduced 3) Absent

Left: 1) Present 2) Decreased 3) Absent

Sno	Age	sex	1	2	3	4	5	6a
	35-70	1-M	1- Hindu	1-Illiterate	1-housewif	1-Unmarrie	1-Joint	Monthly in
		2-F	2-Muslim	2-Primary s	2-retired	2-Married	2-Nuclear	4000-2700i
			3-Christian	3-High schc	3-employee	3-Widowec	3-Broken family	
			4-Others	4-Pre unive	4-unemplo	4-Divorced	4-Problem family	
				5-Degree				

6b	7	8b	8c	9a	9b	10	11	11a
Total numt	1-Class I	1-Regular	1-Excessive	1-Yes	1-Yes	1-Yes		
3--9	2-Class II	2-Irregular	2-Reduced	2-No	2-No	2-No		
	3-Class III							
	4-Class IV							
	5-Class V							

12 12a	13 13a	14 14a	15	16	17
1-Yes	1-Yes	1-Yes	1-Yes	1-Walking	
2-No	2-No	2-No	2-No	2-Running	
				3-Yoga	
				4-others	

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general Physical examination

1-Vegetari	1	4	5	6	7	8	9	10
2-Non-veg	1-Poor BMI	1-waist	1-present	1-present	1-present	1-present	1-present	1-present
	2-Moderate	2-Hip ratio	2-absent	2-absent	2-absent	2-absent	2-absent	2-absent
	3-Fair							

Vitals

11	1	2	3a	3b	3c	4a	4b	5
1-present	Respiratory	Pulse	1-present	1-present	1-present	At suspine	At standing	1-Febrile
2-absent			2-absent	2-absent	2-absent			2-Afebrile

Systemic ex				B12				
1	2	3	4	1-normal	1	2	3	4
Cardiovasc	Respiratory	Central ner	per abdom	2-insufficie	1-Yes	1-Yes	1-Yes	1-Yes
				3-deficienc	2-No	2-No	2-No	2-No
				0-not done				

							Physical examination	
14	15	1a-R	1a-L	1b-R	1b-L	2-R	2-L	3-R
1-Yes	1-Yes	1-Yes	1-Yes	1-Deformit	1-Deformit	1-absent	1-absent	1-present
2-No	2-No	2-No	2-No	2-Dry skin,	2-Dry skin,	2-present	2-present	2-Present/I
				3-Infection	3-Infection			3-absent
				4-Fissure	4-Fissure			
				5-other	5-other			

3-L	4-R	4-L	5-R	5-L
1-present	1-present	1-present	1-Normal	1-Normal
2-Present/1	2-Decrease	2-Decrease	2-Reduced	2-Reduced
3-absent	3-absent	3-absent	3-Absent	3-Absent

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