International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

Original Research Article.

Study of Prevalence of Diabetic Peripheral Neuropathy in Newly Diagnosed Patients of Type 2 Diabetes Mellitus (T2DM) in a Tertiary Care Hospital

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ABSTRACT

Background: The prevalence of type 2 diabetes mellitus (T2DM) is growing worldwide, and these patients may be asymptomatic and present with complications at the time of diagnosis. Diabetic neuropathy is the most common complication affecting the patients who may present with distal polyneuropathy at the time of diagnosis and also poor glycaemic control. The Diabetic peripheral polyneuropathy affects approximately 1 in every 10 newly diagnosed patients, whereas two third of patients with diabetes mellitus have clinical or subclinical neuropathy.

Objective: This study is designed to find prevalence of diabetic peripheral neuropathy in Newly Diagnosed Patients of T2DM in a tertiary care hospital.

Materials and Methods: This observational study was carried out in patients diagnosed with T2DM as per ADA criteria. A thorough clinical examination; Nerve conduction velocity testing; evaluation of plasma glucose and glycosylated hemoglobin and assessment of neuropathy by using the Diabetic neuropathy index and diabetic neuropathy score was performed on all patients.

Results: 18% of patients had signs of peripheral neuropathy as shown by NCV testing at the time of diagnosis. These patients had elevated levels of glycosylated hemoglobin, fasting plasma glucose and 2-hour plasma glucose and lower scores of DNI and DNS which were statistically significant. The most common type of neuropathy seen in these patients was sensorimotor involvement with demyelinating type of neuropathy with more involvement of lower limbs. The NCV studies showed reduced distal latency and prolonged amplitude as well as conduction velocity in patients with diabetic neuropathy.

Conclusion: Our study showed that approximately 1 in 5 newly diagnosed patients with type 2 diabetes mellitus are at risk of developing diabetic peripheral neuropathy.

Keywords: Diabetes Mellitus, Nerve Conduction Velocity, Diabetic Neuropathy Index, Diabetic Neuropathy Score.

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Article History:

Received: 25-12-2018, **Revised:** 13-01-2019, **Accepted:** 29-01-2019

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2019.5.1.055	

INTRODUCTION

Diabetes mellitus is a common endocrine disorder characterized by hyperglycemia[1-3] and is categorized into type 1 diabetes mellitus (T1DM) which is a result of complete or near total deficiency of insulin, and type 2 diabetes mellitus (T2DM), which is a heterogeneous group of disease with variable insulin resistance, impaired insulin secretion and increased production of glucose.[1] Many factors contribute to resistance to insulin including obesity, aging, and a sedentary lifestyle; it also has a strong genetic factor and is frequently found in certain families and ethnic minority groups.[3]

The prevalence of diabetes continues to grow worldwide and is fast emerging as largest global public health emergencies of the 21st century.[3,4]

Approximately 415 million adults have diabetes mellitus (DM) and is set to rise to 642 million by the year 2040.[4] Twenty-three million Americans have diabetes, and there is an increase in the incidence of disease by 5% per year.[5] India has a higher prevalence of DM (4.3%) as compared with the West (1%–2%), as Asian Indians are more prone for insulin resistance and cardiovascular mortality.[6]

Consistently elevated blood glucose levels lead to protein glycation and overproduction of reactive oxygen species resulting in vascular damage and responsive activation of tissue specific growth/ repair system.[4] Patients suffering from T2DM might be asymptomatic and present with complications when diagnosed[3], approximately 8% of patient have cardiovascular disease at time of presentation, 37% have microanuerysm/retinopathy in one eye, 18% have microalbuminuria and 2.3-15.2% have polyneuropathy as per clinical signs and electrophysiological properties respectively.[7] 193 million people are estimated to be suffering from diabetes, undiagnosed and at greater risk of developing complications.[4] Macrovascular complications are associated with coronary artery disease, peripheral arterial disease and cerebrovascular disease which tend to substantially reduce the life expectancy in all age groups.[1,7] The frequency of microvascular diabetic complication is clearly correlated to the duration of diabetes, quality of metabolic control (HbA1c), systolic blood pressure, obesity, hyperlipidemia and insulin resistance have a considerable impact on the development and progression of microvascular diabetic complications[7] leading to retinopathy, nephropathy and neuropathy which increase the cost for health care resources.[1,7]

The incidence of diabetic neuropathy in India is not known, as per a study done in South India 19.1% type II diabetic patients had peripheral neuropathy.[6] Diabetic peripheral polyneuropathy affects approximately 8% of newly diagnosed patients and >50% of patients with long term DM.[1,2] Patients with type 2 diabetes mellitus may present with distal polyneuropathy at the time of diagnosis or even after few years of known poor glycaemic control.[1] Symptoms of diabetic neuropathy are symmetrical paresthesia and burning pain that predominantly occurs distally in the legs according to length dependency with severe complications can result in foot ulceration and non-traumatic amputation.[2] Chronic sensorimotor distal symmetric polyneuropthy is the common form leading to substantial sensory loss, muscle weakness, and pain which is gradual in onset and may go undiagnosed for years.[8]

A significant association between cholesterol and fasting triglycerides with diabetic neuropathy has been established by the EURODIAB study[5,9,10] Steinmetz in a review from the U.K. Prospective Diabetes Study Group and Fenofibrate Intervention and Event Lowering in Diabetes Study reported lower incidence of macrovascular and microvascular complications with lipid-lowering therapy.[5,11] As there is no treatment for diabetic peripheral neuropathy available, its prevention and early detection assume utmost importance.[2]

The severity of diabetic neuropathy is dependent on the duration of diabetes and degree of glycaemic control, diabetes mellitus affects peripheral nerves in somatosensory, auditory system, psychomotor responses and cognitive effect in uncontrolled patient thereby affecting reaction times.[2,5,8] Nerve conduction velocities are one of the sensitive indices for the severity of neuropathy and localize lesion.[1,12]

In many patients with normal clinical examination, a decrease in nerve conduction velocity is observed.[13] Nerve conduction velocity (NCV), has been one of the gold standards for diagnosing diabetic peripheral polyneuropathy with nerve dysfunctions, a composite score has been introduced for quantitative analysis of the results of NCV.[2,14]

A thorough literature search has shown that many patients diagnosed with diabetes mellitus might present with neuropathy at the time of diagnosis[1,2,5] as two third of patients with diabetes mellitus have clinical or subclinical neuropathy[6], hence, it was considered apt to study prevalence of Diabetic Peripheral Neuropathy in Newly Diagnosed Patients of Type II Diabetes Mellitus (T2DM) in a tertiary care hospital.

MATERIALS AND METHODS

This observational study was carried out in Department of Physiology, with the collaboration of General Medicine and Neurology Department in a tertiary care hospital of western Uttar Pradesh after approval from the Institutional Ethics Committee. All patients visiting the outpatient department of medicine and neurology diagnosed to be suffering from type II diabetes mellitus as per ADA guidelines[15] were enrolled in the study after obtaining written informed consent from 1st March, 2017 to 31st May, 2018.

All patients in the age group of 30-70 years, of both sexes willing to give written informed consent were enrolled in the study. All patients who were known to be suffering from alternative cause of peripheral neuropathy, alcoholics, renal failure, thyroid disease, autoimmune disease, cancer were excluded from the study. All patients with a positive family history of non-diabetic neuropathy in first-degree relatives, on drugs that could cause neuropathy or were unable to understand or cooperate with the procedure of the study were also excluded from the study. Pregnant and lactating females were also excluded from the study.

Procedure

After approval from the institutional ethics committee and written informed consent, patients diagnosed to be suffering from type II diabetes mellitus fulfilling the inclusion and exclusion criteria were enrolled in the study. Patients diagnosed with type II diabetes mellitus as per ADA guidelines.[15]

A thorough clinical examination (including neurological examination); Nerve conduction velocity testing; evaluation of plasma glucose and glycosylated hemoglobin; and assessment of neuropathy by using the Diabetic neuropathy index and diabetic neuropathy score was performed on patients. Data was entered in excel sheet and analyzed.

Primary Outcome Measures

- Nerve Conduction Velocity was assessed in median, ulnar, peroneal, sural and posterior tibial nerves, motor nerve conduction velocity was measured on the left forearm segment of the median nerve and the left peroneal nerve. A composite score was used for quantitative analysis of result of NCV. [2,14]
- Plasma glucose level and glycosylated haemoglobin level

Secondary Outcome Measures

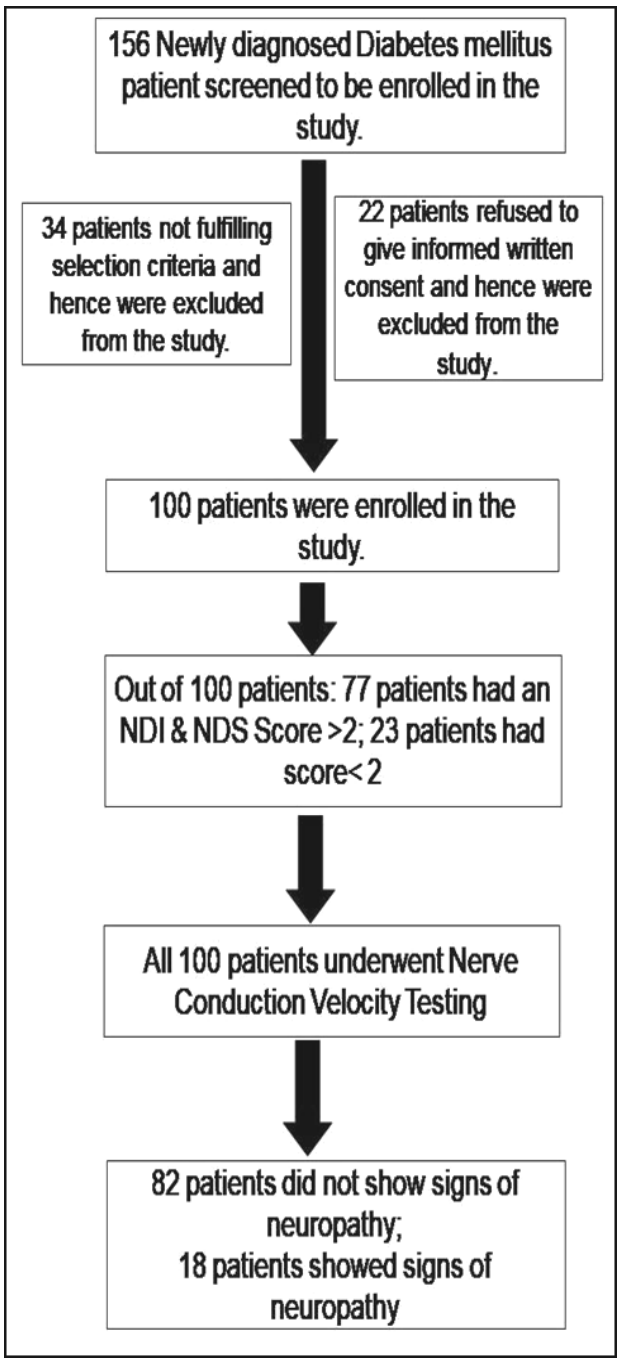
- Neuropathy was assessed by using the Michigan Neuropathy program which includes two steps; the Diabetic Neuropathy Index (DNI) and the Diabetic Neuropathy Score (DNS). Patients who score less than 2 on routine clinical examination and are asymptomatic are referred to be assessed by complete neurological examination done by nerve conduction studies.[16]

Statistical Analysis

The data was presented as mean ± standard deviation (Mean ± SD). The result was analyzed using appropriate parametric (two tailed student't' test) and non-parametric test (chi-square test,).

Nominal variable were compared using Chi-square test. The student 't' test was used to compare group means for normally distributed data and Mann-Whitney U test/ Wilcoxon Sign rank test was used for non-normally distributed data. Correlations between the variables were examined using the Pearson correlation coefficients. A $p<0.05$ was considered statistically significant.

Figure 1: CONSORT diagram



RESULTS

A total of 156 patients with newly diagnosed diabetes mellitus were screened for the study from March, 2017 to May, 2018. Thirty four (34) patients did not fulfil the inclusion and exclusion criteria and were excluded from the study; another 22 patients did not give written informed consent to participate in the study and hence were also excluded from the study. One hundred (100) patients who fulfilled the inclusion and exclusion were enrolled in the study after they give written informed consent (Figure 1). All the patients underwent a thorough clinical examination, all these patients were subjected to diabetic neuropathy index (DNI) and diabetic neuropathy score (DNS). Seventy seven (77) patients had DNS and DNI score more than 2, whereas 23 patients had a score less than 2. All the 100 patients were subjected to nerve conduction velocity (NCV) testing, 82 of these 100 newly diagnosed patients did not have neuropathy, whereas 18 of these patients had neuropathy.

The baseline parameters of all the patients are shown in Table1. The mean age of patients enrolled in the study was 55.31±11.38 years, a total of 45 males and 55 females were enrolled in the study. The average glycosylated haemoglobin (HbA1c) levels in these patients were 7.45±1.90 %. All these patients had elevated levels of fasting plasma glucose (FPG) and 2-hours plasma glucose (2h - PG). Any patient with DNI or DNS score less than 2 should be subjected to NCV, 23 patients in our study had a DNI or/and DNS score less than 2.

23 patients in our study had a DNI or/and DNS score less than 2. These patients were categorized in group A (n=23), whereas patients with patients with a DNI or/and DNS score more than 2 were placed in group B (n=77). The demographic and baseline characteristic of patients in both group is shown in Table 2. The patients with abnormal scores (Group A) had statistically significant ($p<0.05$) higher fasting plasma glucose levels, 2-hours plasma glucose levels and glycosylated haemoglobin levels as compared to group B.

All the other baselines parameters were higher in group A but it was not statistically significant. All patients underwent nerve conduction velocity and the results showed that 18 patients enrolled in the study had neuropathy associated with diabetes mellitus and all these patients belonged to the group with persistently low DNI and/or DNS Score (Group A).

Neuropathy – Type

The neuropathy diagnosed in new onset diabetes mellitus could be further classified into either motor, sensory or mixed. In our study as shown in Figure 2, most of the patients had presentation of sensorimotor neuropathy, and least patients had presentation of sensory neuropathy. As per the NCV testing, 2 patients were having sensory neuropathy, 4 patients had motor neuropathy and 12 patients had sensorimotor neuropathy.

Table 1: Baseline parameters of patients enrolled in the study.

Parameter	Patient enrolled (n=100)
Age (years) (Mean±SD)	55.31±11.38
Weight (kilograms) (Mean±SD)	71.32±8.46
Glycosylated Hemoglobin (HbA1c) (%)(Mean±SD)	7.45±1.90
Fasting Plasma Glucose (FPG) (mg/dL) (Mean±SD)	149.55±42.21
2-hours Plasma Glucose (2h-PG) (mg/dL) (Mean±SD)	215.77±26.89
Diabetic Neuropathy Index (DNI) (Mean±SD)	3.11±1.37
Diabetic Neuropathy Score (DNS) (Mean±SD)	3.81±1.79

Table 2: Demographic and Biochemical Parameters in both groups

Parameter	Group A (n=23)	Group B (n=77)
Age (Years) (Mean±SD)	59.09±10.4	54.18±11.5#
Sex (M:F)	11:12	34:43$
Weight (Kg) (Mean±SD)	72.96±8.1	70.83±8.6#
Fasting Blood Glucose (mg/dl) (Mean±SD)	216.61±43.3	96.36±3.8#*
2-hours Plasma Glucose (2h-PG) (mg/dL) (Mean±SD)	246.74±43.4	121.46±7.6#*
Glycosylated Hemoglobin (HbA_{1c}) (%)(Mean±SD)	10.64±1.5	6.51±0.3#*
Diabetic Neuropathic Index (Mean±SD)	3.30±1.9	3.55±1.2#
Diabetic neuropathy Score (Mean±SD)	3.52±2.3	4.42±1.6#

Using Student T test; $ Using Chi Square test

*p<0.05 as compared to other group

Figure 2: Neuropathy type as per NCV testing

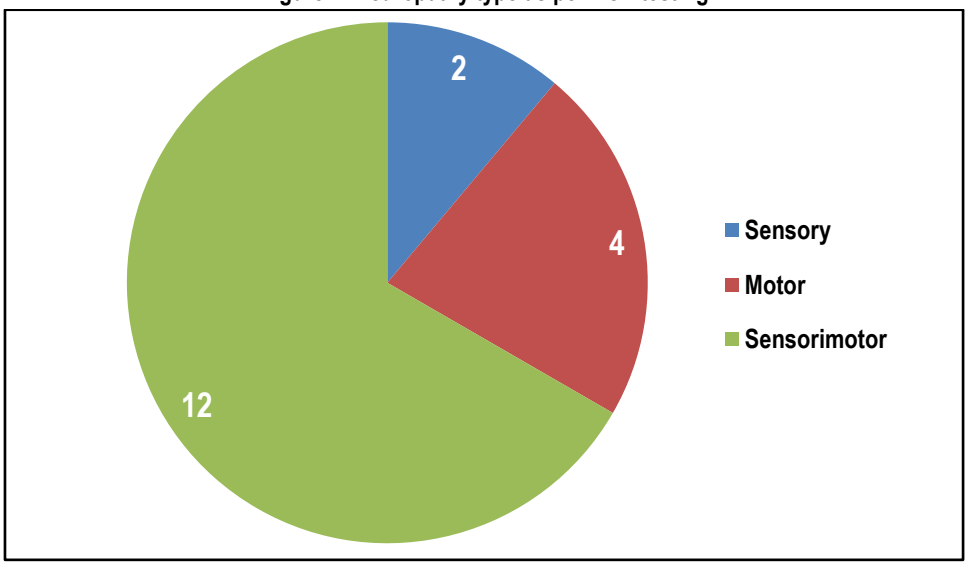


Figure 3: Neuropathy type as per NCV testing

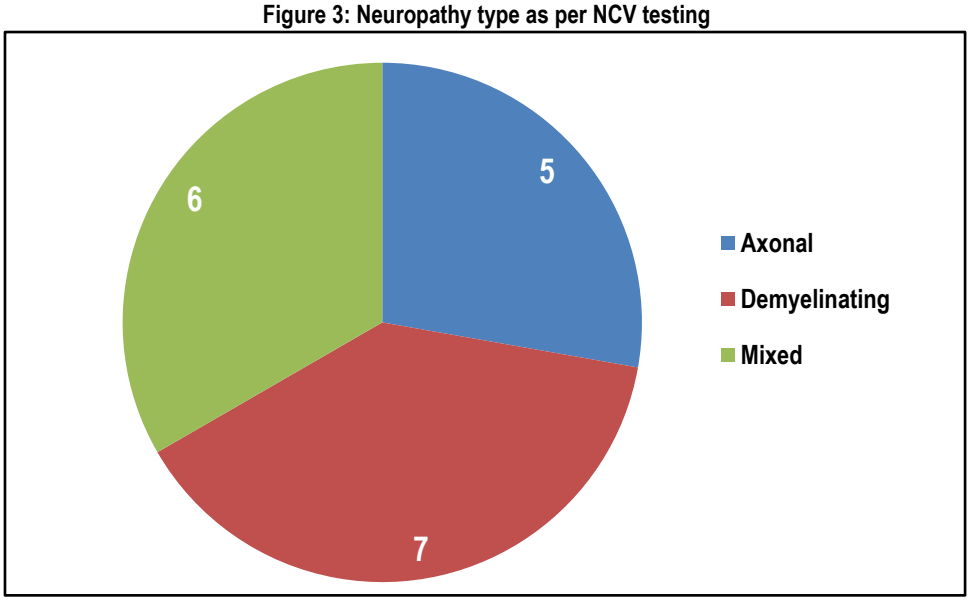


Table 3: Correlation of HBA_{1C} in both groups

Parameter	Group A (n=23)		Group B (n=77)	
	r	p	r	p
Fasting Plasma Glucose (FPG) (mg/dL)	0.93	<0.05*	-0.20	>0.05
2-hours Plasma Glucose (2h-PG) (mg/dL)	0.92	<0.05*	0.07	>0.05
Diabetic Neuropathy Index (DNI)	-0.68	<0.05*	-0.04	>0.05
Diabetic Neuropathy Score (DNS)	-0.70	<0.05*	0.09	>0.05

*p<0.05 as compared to other group

The neuropathy diagnosed in new onset diabetes mellitus could be further classified into either axonal, demyelinating or mixed type based on the results of NCV testing mainly conduction velocity, amplitude and Distal latency. In our study as shown in Figure 3, most of the patients had presentation of demyelinating neuropathy, and least patients had presentation of axonal neuropathy. As per the NCV testing, 5 patients were having axonal neuropathy, 7 patients had demyelinating neuropathy and 6 patients had mixed neuropathy.

Glycosylated hemoglobin was correlated with fasting plasma glucose, 2-hours plasma glucose, diabetes neuropathy index and diabetes neuropathy scores for all the patients. No correlation of HBA_{1C} with FBS, 2-hPG, DNI and DNS was seen in patients of Group B (n=77), whereas there was a statistically significant correlation of HBA_{1C} with FBS, PPBS, DNI and DNS in patients of Groups A (n=23).

DISCUSSION

Our study showed that 18% of patients had signs of peripheral neuropathy as shown by NCV testing at the time of diagnosis of type 2 diabetes mellitus, though, 23% patients had low scores in Diabetes Neuropathy Index and Diabetes Neuropathy Score with females being more effected as compared to males. The patients with diabetes neuropathy as compared to the subset of patients without neuropathy had elevated levels of glycosylated hemoglobin, fasting plasma glucose and 2-hour plasma glucose which were statistically significant. These patients also had lower scores on DNI and DNS which was statistically significant. The NCV studies showed reduced distal latency and prolonged amplitude as well as conduction velocity in patients with diabetic neuropathy. There was a positive correlation between glycosylated hemoglobin and fasting plasma glucose, 2-hour plasma glucose, DNI as well as DNS in patients with diabetic neuropathy, whereas in patients without diabetic neuropathy no correlation with glycosylated hemoglobin was found.

One study done in Western India, studied the association of duration of diabetes with auditory and visual reaction time, the patients were divided into two groups based on the duration of disease as more/less than 5 years demonstrated that patients with longer duration of disease had delayed reaction time. The study also demonstrated delayed reaction time could serve as an indicator for early nerve damage and could serve as a routine clinical screening procedure for neuropathy. Our study also used DNI and DNS are parameter to assess all the patients diagnosed with diabetes mellitus. The results of our study showed that higher number of patients had abnormal scores for both DNI and DNS which when subjected to NCV testing showed that 18 out of 23 patients had neuropathies. Though, our study limited itself to newly diagnosed patients of type 2 diabetes mellitus.[8] One more study done in Romania which evaluated the role of diabetic neuropathy with balance impairment and risk of fall in patients showed the prevalence of diabetic neuropathy of 28.8% which was associated with increased age, body mass index and increased depression severity. These patients had higher levels of glycosylated hemoglobin associated with impaired balance with increased risks of falls. Our study is somewhat similar to this study as in our study also the patients with diabetic neuropathy belonged to higher age groups and had statistically significant levels of glycosylated hemoglobin levels as compared to patients without diabetic neuropathy. The results of our study are different from this study as only 18% patients enrolled in our study had diabetic neuropathy and all the patients enrolled in the study were newly diagnosed patients. Moreover, we wanted to find out presence of diabetic peripheral neuropathy in newly diagnosed patients whereas in this study, they also wanted to evaluated the risk of fall in these patients.[4] Another study done in Korea to look into the risk factors for neuropathy as well as to study the correlation with severity and glycosylated hemoglobin level demonstrated that patients with diabetic neuropathy had higher levels of glycosylated hemoglobin as well as belonged to higher age group. The study also demonstrated the positive correlation of age and glycosylated hemoglobin levels with higher propensity of motor and sensory nerve involvement of nerves of lower limbs. The study also highlighted that duration of the disease was also one factor that had to be taken into consideration. The results of our study are also in similar lines as in our study also the patients with diabetic neuropathy had higher levels of glycosylated hemoglobin levels and plasma glucose levels. Our study differs from this study as in our study we laid emphasis on finding out the number of newly diagnosed patients of type 2 diabetes mellitus afflicted with neuropathy.[2] A study done by Mojaddidi, et.al. for early detection of impaired nerve functions, along with risk factors associated with diabetic neuropathy found that the mean duration of patients with diabetes of 14 years was associated with development of neuropathy. Along with the duration of disease, higher age group, abnormal levels of glycosylated hemoglobin levels as well as abnormal plasma glucose level were associated with diabetes neuropathy. The study also showed a slight higher prevalence of neuropathy in females as compared to males. The results of our study are similar to this study as more number of females was affected, a higher age group was affected and the patients also had abnormal plasma glucose levels. Our study only studied the newly diagnosed patients and this study showed a positive correlation of duration of disease with neuropathic changes.[12] Few studies done to find out the utility of nerve conduction studies as early indicator of neuropathy in diabetic patients showed that nerve conduction decreased progressively in diabetes patients, the results of our study are similar to this study as our study also showed a decrease in nerve conduction in patients with diabetes although our study differed from this study as we included newly diagnosed patients in our study.[17,18] A study done by Lee, et.al. – The PROMISE cohort for prevalence of peripheral neuropathy and nerve dysfunction for patients with high risk for type 2 diabetes mellitus with the aid of Michigan Neuropathy Screening Instrument and vibration perception threshold showed that prevalence of diabetic neuropathy in newly diagnosed patients with diabetes mellitus was 50%. The average age of the study population was 53 years with patients having neuropathy were older and had higher level of fasting plasma glucose as well as 2-hour plasma glucose. The results of our study are quite similar to this study as in our study also we found that the presenting mean age of patients in our study was 54 years almost similar to that in the PROMISE cohort. Our study also showed that patients with neuropathy were having a higher mean age and elevated fasting plasma glucose and 2-hour plasma glucose, which is similar to this study. Our study differed from this study, as in our study we only included patient who were newly diagnosed diabetic patients with 18% cases of diabetic

neuropathy, and we did not include the patients who were having normal glycemia or prediabetics. In our study we conducted NCV testing for all the patients as compared to PROMISE cohort where Vibration Perception Threshold was used.[19]

The strengths of our study are, after a thorough literature search this is the first study in the region that has tried to study the prevalence of neuropathy in newly diagnosed patients of type 2 diabetes mellitus. Secondly, all the patients who were diagnosed with diabetes mellitus were subjected to NCV testing to find out the neuropathy as it cannot be treated. There are certain limitations in our study; firstly the sample size of the study was small – as this was a time based study so we could not enroll higher number of patients which could have shown a different result. Secondly, we did not have any intervention in our study, as keeping an intervention for patients with diabetic neuropathy would not have solved the aim of our study. The aim of our study was to find the prevalence of peripheral neuropathy in patients who are newly diagnosed. Thirdly, we did not have a control group in our study, the patients who did not have diabetic neuropathy served as a control for the other group of patients and the purpose of our study was to evaluate diabetic neuropathy in patients with new onset diabetes mellitus.

To conclude our study showed that all patients with type 2 diabetes mellitus should be thoroughly examined for signs of diabetic neuropathy irrespective of the duration of the disease. As many patients with type 2 diabetes mellitus are often asymptomatic and are diagnosed with the disease after several years of illness. Our study showed that 23% of newly diagnosed patients had abnormal clinical examination and when subjected to NCV testing 18% of patients were diagnosed with neuropathy at the time of diagnosis of disease. Approximately 1 in 5 newly diagnosed patients with type 2 diabetes mellitus is at risk of developing diabetic neuropathy. The females had slightly higher preponderance, and patients with abnormally high levels of glycosylated hemoglobin, plasma glucose levels and lower score on neuropathic scales had higher chance of developing neuropathy. These patients had a positive correlation of glycosylated hemoglobin levels with plasma glucose levels. The NCV findings of these patients showed prolonged latencies, reduced amplitudes and reduced conduction velocity suggestive of neuropathy. The most common presentation of patients with diabetic neuropathy was sensorimotor involvement with demyelinating type of neuropathy.

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Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Jaspreet Kaur Jaura, Jayballabh Kumar, V K Singh, Rajendra K Pandey, Prithpal S Matreja, Ritu Adhana, Anuradha Gawarle, Anjali Verma. Study of Prevalence of Diabetic Peripheral Neuropathy in Newly Diagnosed Patients of Type 2 Diabetes Mellitus (T2DM) in a Tertiary Care Hospital. Int J Med Res Prof. 2019 Jan; 5(1):248-53. DOI:10.21276/ijmrp.2019.5.1.055