

Original Research Article

Clinical and electrophysiological correlation of peripheral neuropathy in newly diagnosed type 2 diabetes mellitus

Ashok K. Bhuyan, Sonali Appaiah*

Department of Endocrinology, Gauhati Medical College and Hospital, Guwahati, Assam, India

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*Correspondence:

Dr. Sonali Appaiah,

E-mail: sonaliappaiah2@gmail.com

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ABSTRACT

Background: The study was undertaken to evaluate the prevalence of peripheral neuropathy in newly diagnosed type 2 Diabetes mellitus (DM) by clinical examination and nerve conduction study (NCS), and to correlate them with risk factors.

Methods: Eighty newly detected cases of type 2DM of age ≥ 18 years attending Endocrinology Department of Gauhati Medical College and Hospital, Assam, India were evaluated. Grading of symptoms and signs was done using the Neuropathy Symptoms Score (NSS) and Neuropathy Disability Score (NDS) respectively followed by NCS. Neuropathy was diagnosed based on abnormal NSS, NDS or NCS.

Results: Prevalence of peripheral neuropathy was 68.75 % based on abnormal NCS/NDS/NCS. The most common symptom was presence of paraesthesia in 70.9%, followed by weakness in lower limbs in 16.36%. The most common sign was impairment of vibration perception in 76.3%, followed by absent ankle reflex in 56.36%. Abnormal NCS finding was seen in 55% of patients with neuropathy. Of all the patients with neuropathy, only 2.5% had subclinical neuropathy that is abnormal NCS finding in absence of sign and symptoms. Peripheral neuropathy had significant association with age at diagnosis, presence of hypertension, fasting plasma glucose (FPG), HbA1c, serum creatinine and estimated glomerular filtration rate (eGFR) ($p < 0.05$). On multiple linear regression analysis, only age at diagnosis and FPG were independently associated with neuropathy ($p < 0.05$).

Conclusions: Patients with type 2DM have a high prevalence of peripheral neuropathy at diagnosis and very few of them harbour subclinical neuropathy. This study has shown that clinical examination still remains the main tool for detection of neuropathy.

Keywords: Nerve conduction study, Neuropathy symptoms score, Neuropathy disability score, Peripheral neuropathy, Type 2 Diabetes mellitus

INTRODUCTION

Neuropathy has been defined as demonstrable disorder, either clinically evident or subclinical, that occurs in the setting of diabetes without other causes for peripheral neuropathy.¹ Diabetic distal symmetrical sensory or sensory motor polyneuropathy (DSPN) is the most common manifestation affecting about 30% of community-based people with diabetes mellitus. The

most common etiological risk factors associated with Diabetic peripheral neuropathy are poor glycaemia control, visceral obesity, duration of diabetes, height, hypertension, age, smoking, hypoinsulinemia and dyslipidemia.²

Peripheral neuropathy is one of most common long-term complications of diabetes and it is associated with significant morbidity and mortality.^{3,4} It accounts for

more hospitalizations than all the other diabetic complications combined; and it is responsible for 50% to 75% of non-traumatic amputations.^{5,6} In spite of the significant morbidities and high cost of therapy associated, neuropathy is grossly under diagnosed by both endocrinologists and nonendocrinologists. The true prevalence of diabetic neuropathy in different studies varies substantially, depending on specific diagnostic criteria and methods used to define neuropathy. In the United States, prevalence ranges from 5% to 100%.^{3,5,6} This study was conducted to find the prevalence and risk factors of peripheral neuropathy in newly diagnosed Indian patients with type 2 Diabetes mellitus (DM).

METHODS

This cross-sectional study was done at Gauhati Medical College and Hospital, Guwahati, Assam from December 2016 to December 2017. Eighty (80) randomly selected patients of newly diagnosed type 2 DM attending Endocrinology OPD of Gauhati Medical College and Hospital were recruited for the study. Inclusion criteria included age ≥ 18 years and duration of diabetes ≤ 6 months at the time of presentation. Type 2 DM was diagnosed as per the American Diabetic Association 2018 guidelines.⁷ Patient with confounding causes of neuropathy like chronic renal failure, chronic liver disease, chronic airways disease, carcinoma, infections, critical illness, vitamin B12 deficiency and patients on drugs known to affect nerve function were excluded from the study. Informed written consent was obtained from all subjects.

A detailed medical history was taken, and complete clinical examination was done in all patients. Baseline measurements of blood pressure, height, weight and body mass index (BMI) were done. Symptoms among the patients were evaluated using the Neuropathy Symptom Score (NSS). All patients were asked whether they experienced paraesthesia in their legs. A description of burning, numbness, or tingling was assigned a score of 2, and fatigue, cramping, or aching was assigned a score of 1. If the patient described the symptoms as occurring in their feet, calves, and elsewhere, scores of 2, 1, and 0 were assigned, respectively. Nocturnal exacerbation of symptoms was scored as 2; exacerbation of symptoms during the day as well as night was scored as 1, and exacerbation of symptoms during the daytime alone was scored as 0. If the symptoms had ever woken the patient from sleep, a score of 1 was assigned.

The patients were asked if any manoeuvre could reduce their symptoms; walking was assigned a score of 2, standing 1, and sitting or lying down 0. Thus, the maximum symptom score was 9. A minimum score of 3 was taken as the cut off to label a patient to have clinical neuropathy. Severity of symptoms were graded as: mild (scores: 3-4), moderate (scores: 5-6), and severe (scores: 7-9).⁸ Similarly, the signs were graded using the Neuropathy Deficit Score (NDS). Examination of

vibration (using a 128-Hz tuning fork), pin-prick sensation (using pin), temperature sensation (using warm and cool water filled test tubes), and Achilles tendon reflex (using a tendon hammer) were done. The 3 perceptions were scored 0 if present and normal, and 1 if absent, reduced, or uncertain. On either side, the ankle reflex was scored 0 if present and normal, and 2 if absent. The maximum score was 10. A minimum score of 3 was taken as the cut off to label a patient to have clinical neuropathy. The severity of NDS graded as, mild (scores: 3-5), moderate (scores: 6-8), and severe (scores: 9-10).⁸

Routine blood investigations including fasting plasma glucose (FPG), postprandial plasma glucose (PPPG), HbA1c, serum creatinine and fasting lipid profile were done in all patients.

Estimated glomerular filtration rate (eGFR) was calculated using the MDRD (Modification of Diet in Renal Disease Study Equation) formula. Nerve conduction study (NCS) was done by conventional method with surface electrodes with limbs kept warm at a temperature of 38°C.

In present study, neuropathy was diagnosed if abnormality in any one of the three parameters i.e. NSS, NDS and NCS was present. Neuropathy was further divided into types based on Toronto Consensus Panel into Possible DSPN, Probable DSPN, Confirmed DSPN and Subclinical DSPN.⁹

Possible DSPN

The presence of symptoms or signs of DSPN may include the following: symptoms- decreased sensation, positive neuropathic sensory symptoms (e.g., "asleep numbness," prickling or stabbing, burning or aching pain) predominantly in the toes, feet, or legs; or signs—symmetric decrease of distal sensation or unequivocally decreased or absent ankle reflexes.

Probable DSPN

The presence of a combination of symptoms and signs of neuropathy including any two or more of the following: neuropathic symptoms, decreased distal sensation, or unequivocally decreased or absent ankle reflexes.

Confirmed DSPN

The presence of an abnormality of nerve conduction and a symptom or symptoms, or a sign or signs, of neuropathy confirm DSPN. If nerve conduction is normal, a validated measure of small-fibre neuropathy (SFN) (with class 1 evidence) may be used.

To assess for the severity of DSPN, several approaches can be recommended: for example, the graded approach outlined above; various continuous measures of sum scores of neurologic signs, symptoms, or nerve test

scores; scores of functions of activities of daily living; or scores of predetermined tasks or of disability.

Subclinical DSPN

The presence of no signs or symptoms of neuropathy are confirmed with abnormal nerve conduction or a validated measure of SFN (with class 1 evidence).¹⁰

Statistical Analysis

X2 test and Student’s t-test were applied to compare frequencies and means respectively. ‘One way between group ANOVA’ was used to find correlation of risk factors in mild, moderate and severe neuropathy. Multiple logistic regression model was used to find risk factors associated with peripheral neuropathy.

RESULTS

A total of 80 patients of newly diagnosed type 2 diabetes mellitus were evaluated. Mean age of diagnosis was 47.1(SD±12.05) years.

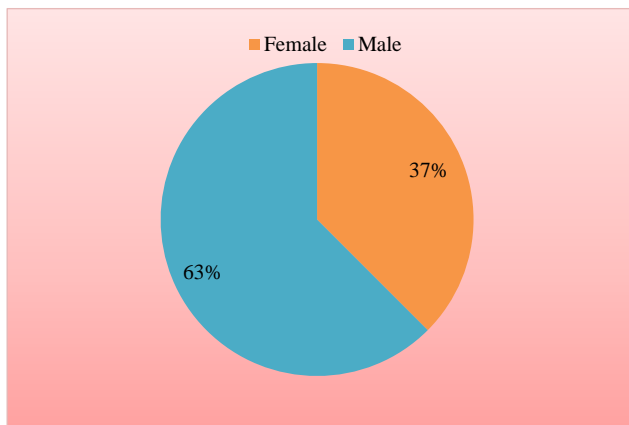


Figure 1: Sex distribution of study population.

Among them 63% (50) were male and 37% (30) were female patients. Age distribution of the patients was as follows: 29 % (23) in between 20-39 years, 56 % (45) in between 40-59 years and 15% (12) above the age of 60 years.

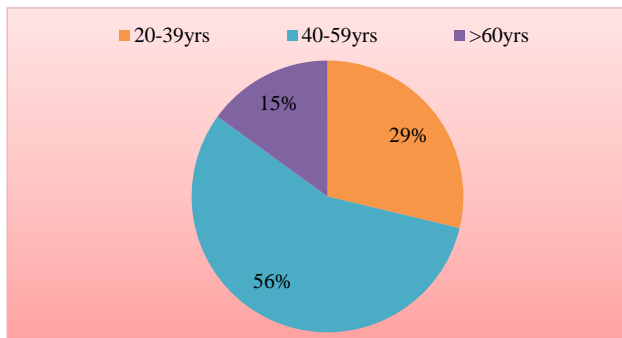


Figure 2: Age distribution of study population.

Hypertension was present in 23.75% (19) of the patients. Mean BMI was 23.8 (SD±2.8) kg/m², 12% (15) were overweight (BMI 23-24.9 Kg/m²) and 24% (30) were obese (BMI ≥ 25Kg/m²). The mean±SD of HbA1c among the patients was 10.5±2.5, while the mean serum creatinine and eGFR were 0.79±0.19 mg/dl and 108±33.8ml/min/1.73m² respectively. Lipid profile showed mean±SD levels of total cholesterol of 199±44 mg/dl, HDL of 35.3±8.9 mg/dl, LDL of 122.4±36 mg/dl and triglyceride of 207.7±90.6 mg/dl.

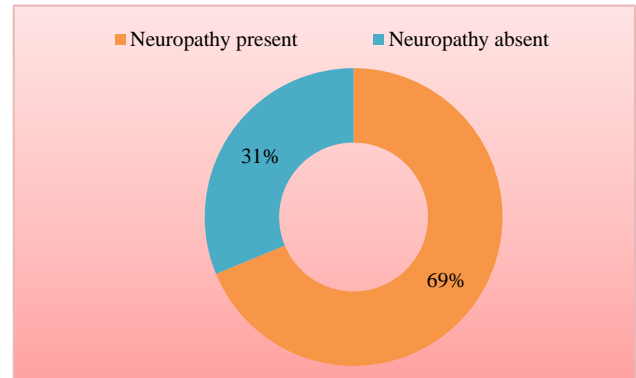


Figure 3: Prevalence of neuropathy in study population.

The overall prevalence of peripheral neuropathy among newly diagnosed type 2 diabetes mellitus patients was 68.75% (55) based on the presence of abnormal NSS or NDS or NCS.

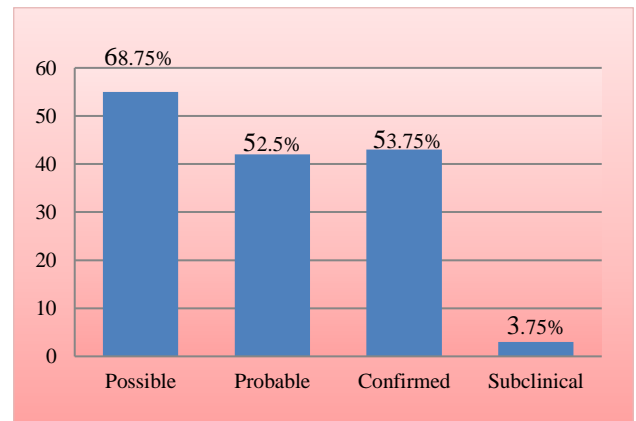


Figure 4. Type of neuropathy based on Toronto consensus panel.

Neuropathy was further divided into types based on Toronto Consensus Panel into Possible DSPN, Probable, Confirmed and Subclinical DSPN. In present study 68.75 % (55) had Possible DSPN, 52.5% (42) had Probable DSPN, and 53.75% (43) had confirmed DSPN and 3.75% (3) had subclinical DSPN.

The most common symptom was the presence of paraesthesia like tingling, burning and numbness over

feet seen in 70.9 % (39) followed by weakness in lower limbs seen in 16.36% (9).

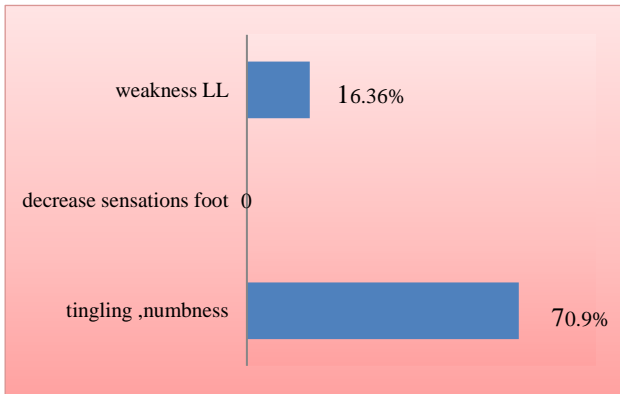


Figure 5: Presenting symptoms of subjects with neuropathy.

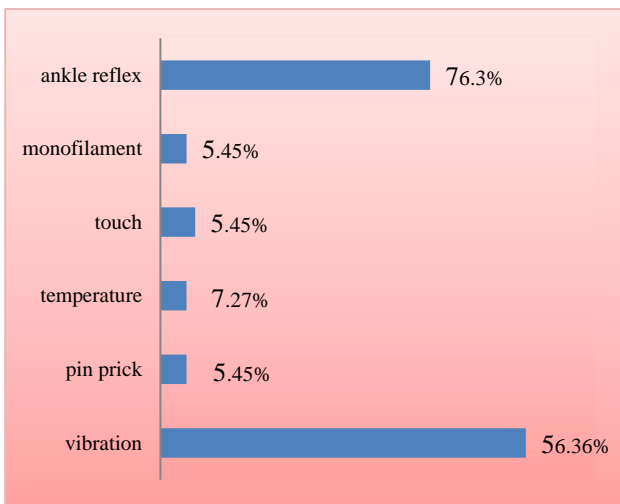


Figure 6: Presenting SIGNS of subjects with neuropathy.

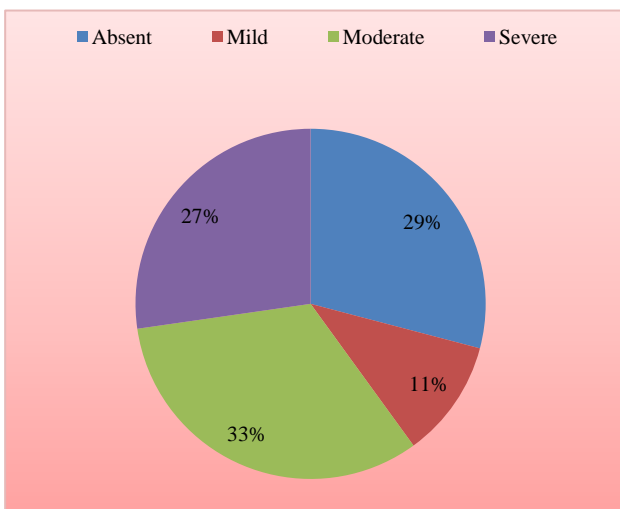


Figure 7: Grading of severity of symptoms and signs by Neuropathy Symptom Score (NSS).

Abnormal NSS was seen in 48.75% (39) of the patients. The symptoms were found to be mild in 10.9% (6), moderate in 18 (32.7%) and severe in 15(27.27%). The most common sign was the impairment of vibration perception in 76.3 % (42), followed by absent ankle reflex in 56.36% (31). Impairment of touch was seen in 7.27 % (4) and perception of temperature, pain and pressure sensation was affected in 5.45% (3) each.

Abnormal NDS was seen in 38.75% (31). The signs were found to be mild in 9.09% (5), moderate in 41.8 % (23), severe in 5.54% (3). Absence of symptoms and absence of signs were seen in 29% (16) and 43.63% (24) patients respectively.

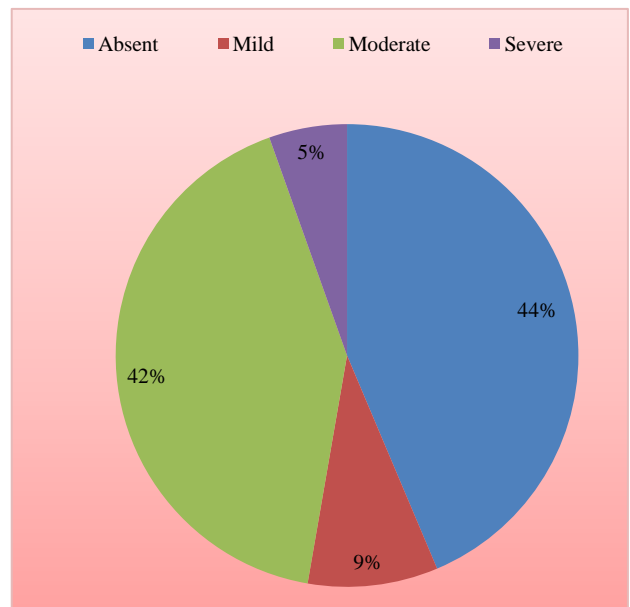


Figure 8: Grading of severity of symptoms and signs by Neuropathy Deficit Score (NDS).

When comparing baseline characteristics of patients with and without neuropathy, age at diagnosis was higher with a mean (\pm SD) of 51.09 (\pm 11.54) years in patients with neuropathy as compared to 38.76 (\pm 8.57) years in patients without neuropathy and was statistically significant ($p < 0.05$). Males were affected more than the females in both the groups, (65.45:34.55) and (56:44) in neuropathic and non-neuropathic groups respectively, although the difference was not statistically significant. Hypertension was seen in 30.9% of patients with neuropathy, whereas it was seen only in 8% in patients without neuropathy, with a p value of 0.007. Mean FPG was statistically higher at 221.1 (\pm 82) mg/dl in patients with neuropathy as compared to 164.2 (\pm 60.7) mg/dl in patients without neuropathy ($p = 0.0007$). Similarly, the mean PPPG in patients with neuropathy (326 ± 93.2 mg/dl) was higher than the mean PPPG of the patients without neuropathy (270.3 ± 96.4 mg/dl), and the difference was statistically significant ($p = 0.019$). HbA1c was significantly higher in patients with neuropathy at $11.1 \pm (2.26\%)$ compared to $9.2 (\pm 2.46\%)$ in patients

without neuropathy (p=0.0019). Serum creatinine was significantly lower (p=0.002) and eGFR was higher (p=0.0005) among patients without neuropathy. There is

no significant difference in BMI and lipid parameters among the neuropathic and non-neuropathic groups as shown in Table 1.

Table 1: The baseline characteristics of patients with and without neuropathy.

Parameter	With Neuropathy (NSS/NDS/NCS)	Without Neuropathy	P value
Number of patients	55(68.75%)	25(31%)	
Male	36(65.45%)	14(56%)	0.43
Female	19(34.55%)	11(44%)	
Age (years)	51.09 ± 11.54	38.76 ± 8.57	0.0000001
BMI (kg/m ²)	23.98 ± 2.83	23.57 ± 2.87	0.55
Hypertension (%)	17(30.9%)	2(8%)	0.007
Neuropathy symptoms duration (days)	54.5 ± 57.4	-	
NSS (Absent, Mild, Moderate, Severe)	70.9 % (29%, 10.9%, 32.7%, 27.27%)	-	
NDS (Absent, Mild, Moderate, Severe)	81.8 % (43.63%, 9.09%, 41.8%, 5.54%)	-	
FPG (mg/dl)	221.1 ± 82.4	164.2 ± 60.7	0.0007
PPPG (mg/dl)	326 ± 93.2	270.3 ± 96.4	0.019
HbA1C (%)	11.1 ± 2.26	9.2 ± 2.46	0.0019
S creatinine (mg/dl)	0.83 ± 0.19	0.69 ± 0.17	0.002
eGFR(ml/min/1.73 m ²)	99.2 ± 32.66	126.6 ± 29.61	0.0005
S Cholesterol (mg/dl)	198.56 ± 42.66	200.2 ± 50.48	0.88
HDL (mg/dl)	34.50 ± 9.26	37.2 ± 8.24	0.19
LDL (mg/dl)	123.1 ± 31.44	122.4 ± 46.66	0.93
VLDL (mg/dl)	41.3 ± 16.75	40.5 ± 20.12	0.86
TG (mg/dl)	206.8 ± 84.30	203 ± 100.70	0.86

NSS- Neuropathy Symptoms Score NDS-Neuropathy disability score, FPG- Fasting plasma glucose, PPPG-Post prandial plasma glucose, e GFR- Estimated glomerular filtration rate

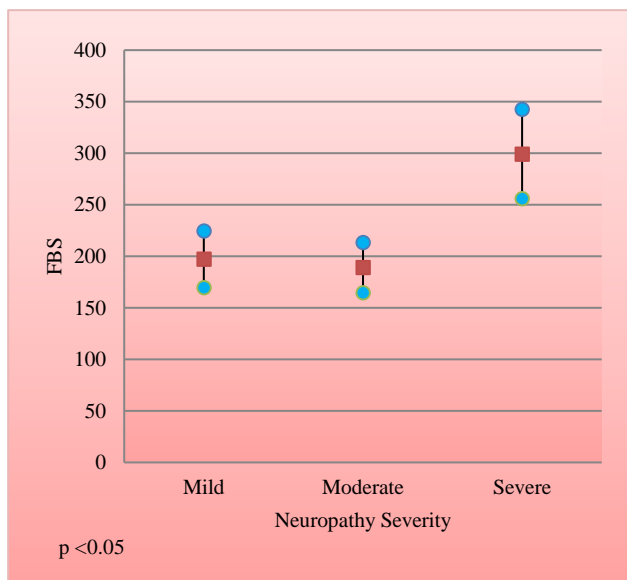


Figure 9: Subgroup analysis of mild, moderate and severe neuropathy by ‘one way between group Anova’, with statistically significant difference in FBS, between the groups (p<0.05).

However, on multiple linear on analysis, of all the variables only age at diagnosis and FPG were independently associated with peripheral neuropathy. (p<0.05).

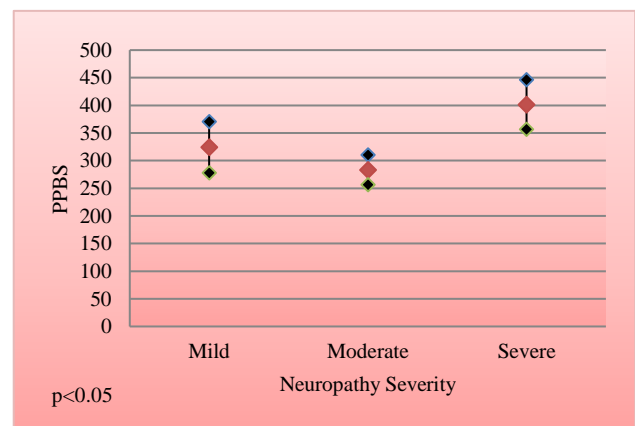


Figure 10: Subgroup analysis of mild, moderate and severe neuropathy by ‘one way between group Anova’, with statistically significant difference in PPBS, between the groups (p<0.05).

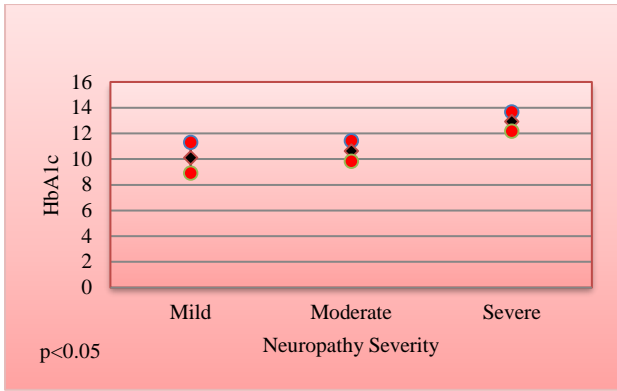


Figure 11: Subgroup analysis of mild, moderate and severe neuropathy by ‘one way between group Anova’, with statistically significant difference in HbA1c, between the groups (p<0.05).

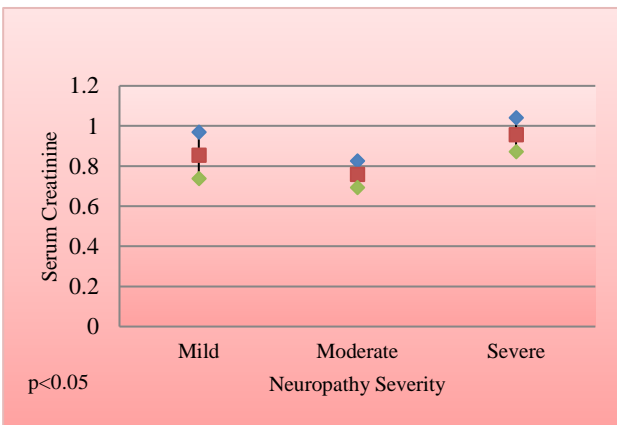


Figure 12: Subgroup analysis of mild, moderate and severe neuropathy by ‘one way between group ANOVA’, with statistically significant difference in Serum Creatinine, between the groups (p<0.05).

In subgroup analysis of mild, moderate and severe neuropathy, ‘one way between group ANOVA’ showed statistically significant difference in HbA1c, FPG, PPPG and serum creatinine between the groups (p < 0.05).

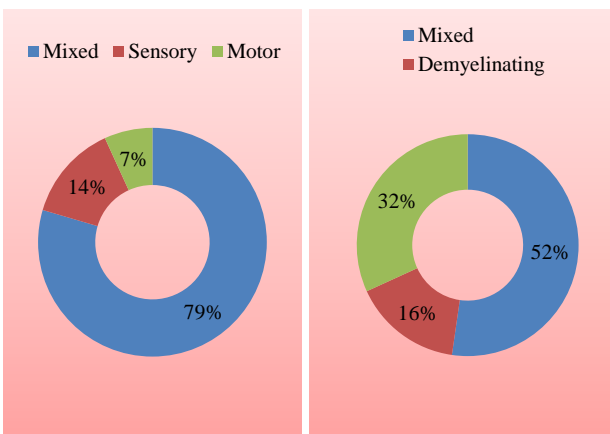


Figure 13: Types of neuropathy in nerve conduction study.

Among the 80 newly diagnosed patients of type 2 diabetes mellitus, 55% (44) patients had abnormal NCS. Neuropathy was sensory in distribution in 13.6% (6), motor in 6.8% (3) and mixed in 79.54% (35). The aetiology of neuropathy was demyelinating in 15.9 % (7), axonal in 31.8% (14) and mixed in 52.27% (23).

Mean (±SD) of age at diagnosis was statistically higher in patients with positive NCS (54.2 ±9.79) years, as compared to 38.3 (±8.16) years in patients with negative NCS. Presence of hypertension and duration of symptoms correlated significantly (p<0.05) with positive NCS.

Clinical signs assessed by NDS was seen in a significantly higher number of individuals with abnormal NCS (90.9%) as compared to only 25% patients with normal NCS(p<0.05). Clinical symptoms assessed by NSS seen in 65.9% of patients with abnormal NCS, compared to 30.5% in patients with normal NCS (p<0.05).

Table 2: The baseline characteristics of patients with and without abnormal NCS.

Variable	NCS positive	NCS negative	P value
No of patient	44 (55%)	36 (45%)	
Age	54.2±9.79	38.3±8.16	<0.05
Sex			
Male	30 (68.1%)	20 (55.55%)	0.25
Female	14 (13.8%)	16 (44.44%)	
No. of patients with hypertension	14 (31.8%)	5 (13.8%)	0.054
BMI Kg/m ²	23.85±2.88	23.75±2.80	0.86
Duration neuropathy symptoms (days)	60.68±62.55	10.83±17.7	0.001
NSS	25 (65.9%)	11 (30.5%)	<0.05
NDS	40 (90.9%)	9 (25%)	<0.05
FPG	240±81.6	159.80±53.33	<0.05
PPPG	352.8±90.9	259.61±82.55	<0.05
HbA1C	12±1.76	8.80±2.14	<0.05
S creatinine	0.88±0.18	0.66±0.14	<0.05
eGFR (ml/min/1.73m ²)	89.85±21.79	130.35±32.69	<0.05
S. cholesterol	205.31±39.65	191.33±50.17	0.17
HDL	34.09±9.39	36.91±8.35	0.15
LDL	126.47±31.15	117.55±42.66	0.29
VLDL	43.68±17.51	38.82±18.58	0.23
TG	218.59±88.27	194.47±93.005	0.24

NSS- Neuropathy Symptoms Score, NDS- Neuropathy disability score, FPG- Fasting plasma glucose, PPPG-Post prandial plasma glucose, GFR- Estimated glomerular filtration rate

Similarly mean FPG, PPPG, HbA1c, serum creatinine was significantly higher (p<0.05) and eGFR was significantly lower (p<0.05) in patients with positive NCS finding. There is no significant difference in BMI and lipid parameters among the patients with or without abnormal NCS as shown in Table 2.

However, on multiple linear on analysis, of all the variables age at diagnosis, NDS, HbA1c, and eGFR ($p<0.05$) were independently associated with peripheral neuropathy.

DISCUSSION

India is home to 69.1 million people with DM and is estimated to have the second highest number of cases of DM in the world after China in 2015.¹¹ Type 2 Diabetes Mellitus has an insidious onset with asymptomatic preclinical phase, resulting in the presence of microvascular and macrovascular complications even at diagnosis.

In present study we found a high prevalence of peripheral neuropathy of 68.75 % in newly diagnosed type 2 Diabetes mellitus based on NSS/NDS/NCS. Neuropathy was confirmed by NCS in 55% of the patients. Among patients enrolled in present study, 68.75 % had Possible DSPN, 52.5% had Probable DSPN, and 53.75 % had confirmed DSPN and only 3.75% had subclinical DSPN. Percentage of patients diagnosed with neuropathy clinically (52.5%); with both symptoms of neuropathy and signs on examination (probable DSPN) was almost equal to percentage of confirmed DSPN (Abnormal NCS with either symptoms or signs- 53.75%), indicating that clinical examination still remains the main tool for detection of neuropathy.

Many studies in India have shown different prevalence rates of peripheral neuropathy in newly diagnosed Type 2 Diabetes mellitus due to different diagnostic criteria, variable sample size, difference in mean age at diagnosis and ethnicity. In a study done by A. dutta et al, the prevalence of peripheral neuropathy in newly diagnosed diabetes mellitus was 29%, based on the presence of abnormality in 2 or more of NSS, NDS and NCS.¹² H K Gill et al showed a prevalence of 30% based on presence of abnormality in both NSS and NDS whereas another Indian study showed lower prevalence of peripheral neuropathy of only 13.15%.^{13,14} Present study has found a higher prevalence of peripheral neuropathy in newly diagnosed type 2 DM (68.75%). One reason for such a high prevalence may be the use of abnormality in any of the parameters of NSS, NDS or NCS as criteria to diagnose neuropathy. Studies from Sri Lanka showed a prevalence of peripheral neuropathy of 25.2% and 48.3% in Amsterdam.^{15,16}

In present study, peripheral neuropathy had significant association with age at diagnosis, presence of hypertension, FBS, HbA1c, serum creatinine and eGFR ($p<0.05$). Multiple linear regression analysis showed age at diagnosis and FPG to be independently associated with peripheral neuropathy. In subgroup analysis of mild, moderate and severe neuropathy, 'one way between group ANOVA' showed statistically significant difference in HbA1c, FBS, PPBS and serum creatinine between the groups ($p<0.05$).

Abnormal NCS had a significant association with age at diagnosis, presence of hypertension, symptoms and signs of neuropathy (NSS, NDS), FPG, PPPG, HbA1c, serum creatinine and eGFR ($p<0.05$). Positive NCS had a significant association by multiple linear regression analysis showed independent association of age at diagnosis, NDS, HbA1c, and eGFR ($p<0.05$) with abnormal NCS.

In study by HK Gill et al, regression analysis revealed an increase in risk for DPN with increasing age, duration of symptoms of diabetes prior to presentation and central obesity. On multiple logistic regression analysis, age and duration of symptoms of diabetes were independently associated with DPN.¹² D Bansal et al showed that aging and triglyceride levels were identified as independent risk factors for neuropathy.¹⁷ Similarly other studies have shown that age, poor glycaemic control, increasing duration of diabetes, gender, height, body mass index, retinopathy, hypertension, smoking, and alcohol consumption are risk factors.^{15,16,18,19}

CONCLUSION

Patients with type 2DM have a high prevalence of peripheral neuropathy at diagnosis and very few of them harbour subclinical neuropathy. This study has shown that clinical examination still remains the main tool for detection of neuropathy.

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Ethical approval: Not required

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