



A STUDY TO EVALUATE THE PREDICTORS OF DIABETIC PERIPHERAL NEUROPATHY AND UTILITY OF MICHIGAN NEUROPATHY SCREENING INSTRUMENT AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS

General Medicine

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ABSTRACT

Background and Objective: Diabetic neuropathy significantly lowers the quality of life. The objective of study is to assess the predictors of peripheral neuropathy in patients with type 2 Diabetes Mellitus attending diabetes clinic and to evaluate the sensitivity and specificity of Michigan Neuropathy Screening Instrument considering neurothesiometer as standard. **Methods:** In 110 type 2 diabetic patents attending diabetic clinic in Bangalore Medical and Research institute , a cross sectional study conducted where they are screened for diabetic peripheral neuropathy using Michigan Neuropathy Screening Instrument and compared with Neurothesiometer as standard which is further compared to patient's duration of diabetes, treatment modality and glycemc control. **Results:** Overall the prevalence of diabetic peripheral neuropathy in this study was 51.8 % using the neurothesiometer as standard, large fibre neuropathy in 43.8 %, small fibre neuropathy in 24.5% and both in 31.5%. Of total 51.8% patients with neuropathy 59.6 % have mild neuropathy, 19.2% have moderate and 21.2 % have severe neuropathy. The Michigan Neuropathy Screening Instrument (MNSI) is found to have Sensitivity of 91%, Specificity of 60%, PPV of 71%, NPV of 86% and Accuracy 76% **Conclusion:** The study shows that a significant association is found between age of patient, duration of diabetes, glycemc control (HbA1c), BMI and Diabetic peripheral neuropathy. With accuracy of Michigan Neuropathy Screening Instrument 76 % is helpful to detect peripheral neuropathy in initial stages in clinical settings, in a simple and cost effective manner.

KEYWORDS

Diabetes mellitus, Diabetic peripheral neuropathy, HbA1c

INTRODUCTION

According to the WHO research, an estimated 422 million persons worldwide had diabetes in 2014, up from 108 million in 1980.¹

Diabetic peripheral neuropathy is defined simply in clinical practise as "the existence of symptoms and/or indications of peripheral nerve damage in persons with diabetes after ruling out other causes." Diabetic neuropathies impact numerous sections of the nervous system and manifest in a variety of clinical symptoms. The most prevalent neuropathy is distal symmetric sensorimotor poly neuropathy (DSPN).²

Diabetic neuropathies are the most prevalent chronic complications of diabetes.³ Lifestyle prevalence of diabetic neuropathy is approximately 50% which makes it one of the most common diabetic complication .Due to lack of treatments that rectify the underlying nerve damage, prevention is the major component of diabetes care.³

Diabetic neuropathy is one of the leading cause for disability due to foot ulceration and amputation, gait disturbance and fall related injury, 20 to 30% of diabetic patients suffer from neuropathic pain.⁵⁻⁸ Diabetic neuropathy significantly lowers the quality of life and increases health costs associated with diabetes.⁹ Diabetic neuropathy is common and costly disease.¹⁰

Diabetic neuropathy occurs in approximately 50 % of individuals with long standing type 1 and type 2 DM.¹¹ The prevalence of neuropathy increases with the duration of diabetes mellitus. The major risk factors of diabetic peripheral neuropathy include diabetes duration ,hyperglycemia, and age, followed by hypertension ,dyslipidemia, obesity and metabolic syndrome.³

In India, 40,000 legs are being amputated every year of which 75% are neuropathic feet which are potentially preventable.¹² The annual incidence of diabetic foot ulcer in India ranges from 10 to 4.1% and the prevalence ranges from 4 to 10 %,with overall lifetime incidence of up to 25% in diabetics.¹³

Screening for symptoms and signs of diabetic neuropathy is also critical and necessary in clinical practice , as it detecting the earliest stages of neuropathy enables early intervention.¹⁴

The early recognition and appropriate management of neuropathy in

diabetic patients is necessary as Diabetic neuropathy is a diagnosis of exclusion and Nondiabetic neuropathies may be present in patients with diabetes and may be treatable by specific measures, many treatment options are available for symptomatic diabetic neuropathy, recognition and treatment of autonomic neuropathy may improve standard of living.¹⁴

Screening tests for DPN ranges from quantitative methods such as nerve conduction studies and biesthesiometer, validated questionnaires such as MNSI, clinical examinations such 10g SWM test, 128Hz tuning fork test and ankle reflex. Early screening and identification of neuropathy in diabetics can prevent foot ulcers and amputation while preserving the quality of life and ameliorating the social and economic costs of diabetic foot disease.

The study is planned to evaluate the usefulness of above simple screening tests with the standard well validated methods of detecting DPN in diabetic patients.¹⁵⁻¹⁹

OBJECTIVES

- To assess the predictors of peripheral neuropathy in patients with type 2 Diabetes Mellitus attending diabetes clinic.
- To evaluate the sensitivity and specificity of Michigan Neuropathy Screening Instrument considering neurothesiometer as standard

METHODOLOGY

Source of data :Data was collected from patients visiting diabetic out patient clinic in hospitals attached to Bangalore Medical College and Research Institute.

Study design : Cross sectional study

Study period : November 2018 to May 2020.

Inclusion Criteria

- Age >18 years <70 years of either gender.
- Patient willing to give written informed consent (Annexure 1)
- Type 2 diabetes mellitus diagnosed as per ADA GUIDELINES (Annexure 2)

Exclusion Criteria

- Patient not willing to give informed consent.

2. Pregnant women
3. Alcohol or drug dependence (CAGE Criteria –Annexure 3)¹⁴
4. Clinically suspected peripheral neuropathy due to other causes
5. Drugs causing neuropathy

After obtaining Institutional ethical committee clearance, cases were selected as per inclusion criteria mentioned above and written informed consent was taken in language understood by the patient. Case record form was used to record diabetes history, duration and treatment. Relevant blood investigations were done. Type 2 DM Patients included in the study were screened for diabetic peripheral neuropathy using MNSI and irrespective of the MNSI result vibration test is conducted using neurothesiometer in all. The permission to use MNSI questionnaire as part of the study is granted by Mapi Researchtrust ,Lyoon, France. The Name of the owner of MNSI is Michigan Center for Diabetes Translational Research (MCDTR) (USA) and copyright notice is MNSI,University of Michigan ,2000. 13 Based on the results of the neurothesiometer (considering neurothesiometer as standard)patients were divided into two groups , those with diabetic peripheral neuropathy and without diabetic peripheral neuropathy.

Sample Size Estimation

Based on previous study Turkan Mete,et al¹⁷ ,overall MNSI score was 4.12+/-3.24. The sample size calculation is:

$$n = \frac{Z_{\alpha}^2 \times \sigma^2}{d^2}$$

Z α = standard table value for 95% CI=1.96
 σ = standard deviation =3.24
 d = 15% of mean =0.618
 N=(1.96)²X (3.24)²/(0.618)² n=110
 A sample size of **110** is taken.

Statistical Analysis

Collected data were analyzed by descriptive statistics. The Chi square test will be used to study association of qualitative variables both clinical and investigative variables with diabetic peripheral neuropathy and ROC analysis were used to study quantitative variables. Any other relevant statistical test were used based on the data.

RESULTS

In our study the mean age was 54.92±9.14 , 55.5 % of 110 patients studied were females. The mean duration of diabetes is 7.10±4.13 years, less than 5 years is 30.9 % , between 5 to 10 years is 50.9% and more than 10 years is 18.2%. Our study showed that in the type 2 diabetic population with increasing age the prevalence of DPN increased and a significant association between increasing age of the patient and Diabetic peripheral neuropathy is seen. 29.8% in 41 to 50 years age group have DPN compared to 43.9% in 61 to 70 years age group.

In this study 91.9% of study population were on oral hypoglycemic agents , 4.5% on Insulin and 3.6% were on both and no significant association is found between the modality of treatment and prevalence of Diabetes peripheral neuropathy.

The mean BMI of study population is 25.25±2.67 kg/m² Majority belonged to Obese I with 20 % Normal, 22.7% overweight, 52.7% obese I and 4.6% Obese II. 54% of type 2 diabetes patients involved in the study with BMI > 22.5 have DPN and a significant association between increasing BMI of the patient and Diabetic peripheral neuropathy is seen.

The mean HbA1c is 7.95±1.62 , 48.2 % of study population with HbA1c less than or equal to 7 suggestive of good glycemic control and 51.8% with Hb A1c more than 7 suggestive of poor glycemic control .Of 110 patients involved 13 (22.8%) with good glycemic control have DPN compared to 44(77.2%) patients with poor glycemic control have DPN. A significant association between glycemic control and Diabetic peripheral neuropathy is seen.

A significant association between duration of diabetes and Diabetic peripheral neuropathy is seen with 8 % with duration less than 5 years have DPN compared to 49% with duration more than 5 years.

Overall the prevalence of diabetic peripheral neuropathy in this study

was 51.8 % using the neurothesiometer as standard , large fibre neuropathy in 43.8 % , small fibre neuropathy in 24.5% and both in 31.5%. Of total 51.8% patients with neuropathy 59.6 % have mild neuropathy, 19.2% have moderate and 21.2 % have severe neuropathy.

The **Michigan Neuropathy Screening Instrument (MNSI)** is found to have Sensitivity of 91%, Specificity of 60% ,PPV of 71% ,NPV of 86% and Accuracy 76% .

It is shown that a significant association is found between age of patient, duration of diabetes , glycemic control, BMI and Diabetic peripheral neuropathy.

Peripheral neuropathy is a preventable micro-vascular complication of uncontrolled diabetes mellitus, which if not detected early in a diabetic patient lowers the patient standard of life. The MNSI is an, easy cost effective way to detect peripheral neuropathy in diabetics in a clinical setting, with comparable results with the neurothesiometer. Early interventions and screening tests to detect peripheral neuropathy in diabetic patients reduces the morbidity significantly.

Table No 1: Association between Demographic parameters and DPN

Parameters		DPN		Chi-Square Value	P Value
		Present	Absent		
SEX	Male	27(47.4)	22(41.5)	0.382	0.537
	Female	30(52.6)	31(58.5)		
AGE	31 to 40 Years	0(0.0)	10(18.9)	16.324	0.001
	41 to 50 Years	17(29.8)	13(24.5)		
	51 to 60 Years	15(26.3)	19(35.8)		
	61 to 70 Years	25(43.9)	11(20.8)		
BMI	Normal	03(5.3)	19(35.8)	20.575	0.0001
	Overweight	11(19.3)	14(26.4)		
	Obese I	39(68.4)	19(35.8)		
	Obese II	04(7.0)	01(1.9)		
HBA1C	<=7	13(22.8)	40(75.5)	30.509	0.0001
	>7	44(77.2)	13(24.5)		
Duration	<5 Years	08(14.0)	26(49.1)	16.105	0.0001
	5 to 10 Years	35(61.4)	21(39.6)		
	>10 Years	14(24.6)	06(11.3)		
HTN	Yes	11(19.3)	03(5.7)	4.599	0.032
	NO	46(80.7)	50(94.3)		
Treatment	Insulin	04(7.0)	1(1.9)	5.751	0.056
	OHA	49(86.0)	52(98.1)		
	Both	04(7.0)	0(0.0)		

Significant association is seen between age of patient , duration of diabetes, glycemic control and prevalence of DPN in the given study population.

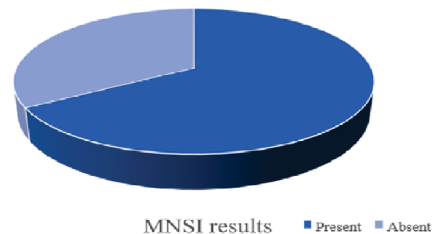


Figure 27: MNSI Results of study participants

Table No 15: Diagnostic accuracy of MNSI by DPN

MNSI	DPN		Total
	Positive	Negative	
Positive	52	21	73
Negative	05	32	37
Total	57	53	110

Sensitivity	91
Specificity	60
PPV	71
NPV	86
Accuracy	76

DISCUSSION

In our study the mean age was 54.92±9.14 , 55.5 % of 110 patients studied were females. The mean duration of diabetes is 7.10±4.13 years, less than 5 years is 30.9 % , between 5 to 10 years is 50.9% and more than 10 years is 18.2%. in a similar study by Turkan Mete,et al¹⁷ duration of diabetes was 8.29±6.71 years. The mean duration of diabetes mellitus in the study population was found to be 9.8±2.8 years (range 5-40 years) in a similar study by D'Souza et al¹⁸

In this study 91.9% of study population were on oral hypoglycemic agents , 4.5% on Insulin and 3.6% were on both, when compared with population based study by Turkan Mete,et al¹⁷ patients on Oral antidiabetics were 57 % , on Insulin were 24 % and Oral antidiabetics with insulin were 21%.12.7 % of the study population had hypertension and were on antihypertensive medications and 87.3% had no comorbidities.

The mean BMI of study population is 25.25±2.67 kg/m² Majority belonged to Obese I with 20 % Normal, 22.7% overweight, 52.7% obese I and 4.6% Obese II. Our finding matches the study done by Sangeetha Meena²⁰ with 51.5% of the study population had their BMI in the obese range. The mean BMI was 25 Kg/m², 47.5% had normal BMI, while 36.3% were overweight and only 16.1% were obese in a study by Al Gefferi et al¹⁶.

In our study the mean Fasting blood glucose is 173.79±60.01 mg/dl, more than 120 mg/dL is 81.8% and less than 120 mg/dL 18.2% and mean Post Prandial Blood sugar is 271.02±80.37 mg/dl more than 180 mg/dL is 88.2% and less than 180 mg/dL is 11.8% , compared to D'Souza et al¹⁸ Fasting blood glucose levels More than 120 mg/dL was 48.7% and Less than 120 mg/dL 51.3%

The mean HbA1c is 7.95±1.62 , 48.2 % of study population with HbA1c less than or equal to 7 suggestive of good glycemic control and 51.8% with HbA1c more than 7 suggestive of poor glycemic control . In a study by Turkan Mete,et al¹⁷ Mean HgbA1c value of the patients was 8.4±2.3 .In another study by Sangeetha et al⁶⁵ Almost 88% of the study population had HbA1C levels> 6.5%. In a population study by Moghtaderi A¹⁹ the mean HbA1c was 8.9±1.6% with 40.3% had HbA1c below 7.5%.

In our study 30.9 % of patients with duration of diabetes less than 5 years, 50.9% between 5 to 10 years and 18.2 % more than 10 years are found.

Of the study population involved in our study 66.4% have symptoms of diabetic peripheral neuropathy and 33.6 % did not have any symptoms. In a study by D'Souza¹⁸ 18.3% were symptomatic

In our study using MNSI Questionnaire part 1(patient version) 56% have diabetic peripheral neuropathy and from part 2 (Examination Based) 42.7 % have diabetic peripheral neuropathy . It also suggests that 13.3 % of patients with symptomatic DPN did not have neuropathy signs on examination.

The MNSI part 1 score range is as follows 43.6% within 0 to 6 ,52.7% within 7 to 10 and 3.6% within 11 to 15. 62 patients out of 110 had a score of 7 or more suggestive of diabetic peripheral neuropathy.

The MNSI part 2(examination version) score range is as follows 57.2 % within 0 to 1, 36.4 % within 2 to 5 and 64% within 5 to 10. 47 patients out of 110 had a score of 7 or more suggestive of diabetic peripheral neuropathy.

According to the MNSI history version 62 out of 203 had DPN, that was 31% and 48 out of 203 had DPN as per the MNSI examination version, that was 24% as per study by Sangeetha Meena⁶⁵. The screening results revealed that 45% was the overall prevalence of diabetic peripheral neuropathy as assessed by MNSI . 81.7% of them were symptomatic and 18.3% were having asymptomatic DPN as per Al Gefferi et al¹⁶

In a study by D,Souza et al¹⁸ the prevalence of DPN according to the patient history version was found out to be 18.3% and based on MNSI examination which was 32.2%, contradicting our finding .Similar findings were observed in a study conducted in UAE.²¹ The difference in prevalence rates using two methods is an important discovery and it indicates the limitations related to patient's self-perception of symptoms of DPN. The same study showed prevalence of DPN using MNSI examination was 32.2%. Similar findings seen in studies conducted in Iran, Turkey and Spain²²⁻²⁵. However, the prevalence of DPN in other studies conducted elsewhere showed a lot of variation, ranging from 13% to 75%.²⁶⁻³⁰ .Overall using MNSI Questionnaire as screening test 66.4% have Diabetic Peripheral Neuropathy and 33.6% did not have Diabetic Peripheral Neuropathy.the results of MNSI are compared with Neurothesiometer , which as considered as standard in our study and accuracy of MNSI is calculated as follows.

The Michigan Neuropathy Screening Instrument (MNSI) is found to have Sensitivity of 91%, Specificity of 60% ,PPV of 71% ,NPV of 86% and Accuracy 76% .

In a study by Moghtaderi¹⁹ MNSI was found to have Sensitivity of 65%, Specificity of 83% ,PPV of 71% ,NPV of 76% and Accuracy 76 % . When only MNSI score was used for diagnosis,34 of 106(32.1%). patients had diabetic peripheral neuropathy .30 (91.2%) of the patients diagnosed with diabetic peripheral neuropathy by MNSI were diagnosed with thin fibre neuropathy by neurothesiometer and 20 (58.8%) had EMG consistent with diabetic peripheral neuropathy according to study by Turkan Mete,et al¹⁷

In our patients with 21 patients who had score more than 7 in part 1 questionnaire had normal neurothesiometer results . In a study by Turkan Mete,et al¹⁷ of 34 patients who were diagnosed as diabetic neuropathy based on MNSI, 24 gave positive responses to ≥7 questions, and of the 72 patients who were not found to have diabetic neuropathy, positive responses to ≥7 questions was given by 28 patients. These results suggest that diagnosing neuropathy depending only on symptoms sometimes can be misleading leading to wrong diagnosis.In our study Monofilament test revealed large fibre neuropathy in 12.7 % and 87.3% have normal findings. The detection rate using the10-g SWM was 31.4% in a study by Al-Gefferi¹⁶ .

In our study Vibration Perception threshold Test showed normal results in 62.7% patients, 37.3 % have decreased perception of Vibration suggestive of large fibre neuropathy with 16.4% have mild, 10.9% have moderate and 10% have severe neuropathy

Cold Perception Threshold Test revealed normal study in 80.9% of our study population and remaining 19.1% had decreased threshold for perception of cold sensation suggestive of small fibre neuropathy , 10% have mild, 7.3% have moderate and 7.3 % have severe neuropathy

Warm Perception Threshold Test revealed normal study in 72.8% of our study population and remaining 27.2% had decreased threshold for perception of cold sensation suggestive of small fibre neuropathy , 13.6% have mild, 10% have moderate and 3.6% have severe small fibre neuropathy

Overall the prevalence of diabetic peripheral neuropathy in this study was 51.8 % using the neurothesiometer as standard , large fibre neuropathy in 43.8 % , small fibre neuropathy in 24.5% and both in 31.5%. Of total 51.8% patients with neuropathy 59.6 % have mild neuropathy, 19.2% have moderate and 21.2 % have severe neuropathy. Of total 110 patients 11 patients who are asymptomatic on evaluation have peripheral neuropathy on Neurothesiometer testing.

In a population based study by Turkan Mete,et al¹⁷ neurothesiometer evaluations revealed change in heat and/or vibration thresholds in 79 of 106 patients (74.5%). Cold sensation threshold was increased in 5 patients and heat sensation in 10 patients. 18 patients had threshold increase both in cold and heat sensations, 13 patients had increase in vibration sense threshold, and 33 patients had increase in both thermal (cold and heat) and vibration sense thresholds.

On comparing the clinical variables with prevalence of Diabetic peripheral neuropathy in our study we observed that 47% of the male population and 52.6 % of female population had diabetic peripheral neuropathy and there is no significant association between gender and Diabetic peripheral neuropathy.

Our study showed that in the type 2 diabetic population with increasing age the prevalence of DPN increased and a significant association between increasing age of the patient and Diabetic peripheral neuropathy is seen. 29.8% in 41 to 50 years age group have DPN compared to 43.9% in 61 to 70 years age group. 54% of type 2 diabetes patients involved in the study with BMI > 22.5 have DPN and a significant association between increasing BMI of the patient and Diabetic peripheral neuropathy is seen.

Of 110 patients involved 13 (22.8%) with good glycemic control have DPN compared to 44(77.2%) patients with poor glycemic control have DPN. A significant association between glycemic control and Diabetic peripheral neuropathy is seen. A significant association between duration of diabetes and Diabetic peripheral neuropathy is seen with 8 % with duration less than 5 years have DPN compared to 49% with duration more than 5 years.

No significant association is found between the modality of treatment and prevalence of Diabetes peripheral neuropathy in our study.

In a study by Sangeetha et al.²⁰ age more than 50 years had a significant association with the prevalence of DPN. In a study by Azidah A.K., et al., it was stated that the prevalence of peripheral neuropathy among elderly diabetics was high and associated with increased risk of falls. Many other studies have also concluded that the prevalence of DPN is more common among elderly diabetics³¹⁻³³. There was no significant association between DPN and other determinants like gender, duration of diabetes and BMI in this study. Dr. Athar Javed, et al. have concluded the same in his study concluded at King Edward University Hospital.³⁴ There was a statistically significant association between glycemic control and the prevalence of DPN which was also proved by many other studies³⁵⁻³⁶

CONCLUSIONS

The aim of the study is to assess the predictors of peripheral neuropathy in patients with type 2 Diabetes Mellitus and it is shown that a significant association is found between age of patient, duration of diabetes. Glycemic control, BMI and Diabetic peripheral neuropathy.

The sensitivity and specificity of Michigan Neuropathy Screening Instrument considering neurothesiometer as standard is found to be 91% and 63% respectively. With accuracy of 76% MNSI is a simple clinical based screening tool to make a diagnosis of peripheral neuropathy in everyday practice.

The limitation of this study is that its cross sectional and long term follow up is not done. Secondly, the other microvascular and macrovascular complications of diabetes are not included in this study.

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