### **Original Research Article**

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# Prevalence of sensory peripheral neuropathy in diabetic patients at diabetes care centre: a cross sectional study

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#### ABSTRACT

**Background:** Diabetic neuropathy is a nerve damaging disorder associated with diabetes; result from micro vascular injury involving small blood vessels that supply to the nerve (vas nervorum) in addition to macro vascular condition that can culminate in diabetic neuropathy. By the year 2025 hundreds of people were estimated to become diabetic. The rates of prevalence of neuropathy increasing worldwide which is directly related to the nonmodifiable risks like age, duration of diabetes, obesity, alcoholism, gender.

**Methods:** A cross sectional interventional study was conducted on diabetic patients. Questionnaire, instruments and demographic details were used to collect data from patients. The diabetic neuropathy is conformed in patients by using biothesiometric analysis, tuning fork, monofilament, NSS and NDS.

**Results:** Total 331 subjects included in the study, 200 cases diagnosed with DPN according to biothesiometry and prevalence percentage was found to be 60.4% and incidence was found to be 8.76% respectively. A significant greater proportion of males reported neuropathy more than females. The association between the obesity and the DPN was ( $r^2$ =0.7922) low positive correlation. High positive correlation was confirmed with NSS, NDS respectively.

**Conclusions:** It was concluded that there is a higher prevalence (60.4%) and incidence (8.76%) of neuropathy among the diabetic subjects and it may go on increasing as the age progress.

Keywords: Biothesiometry, Diabetic peripheral neuropathy, Obesity, Prevalence

#### **INTRODUCTION**

Diabetic neuropathy (DN) is a nerve damaging disorder associated with diabetes. This condition is thought to be result from micro vascular injury involving small blood vessels that supply to the nerve (vas nervorum) in addition to macro vascular condition that can culminate in diabetic neuropathy. Neuropathy frequently results in significant morbidities such as a pain, loss of sensation, foot ulcers, gangrene and amputations which is much feared sequel that results in hospitalizations. Diabetic neuropathy is the third most common neurological disorder and it ranges about 54% among 1,00,000 people per year. Previous population based studies have reported prevalence rate of neuropathy ranges 8.54% in type 1 and 13.46% in type 2 diabetic patients. Risk factors most consistently associated with polyneuropathy in type 2 diabetes mellitus patients at population level were increasing age, duration of diabetes mellitus, height and poor glycemic control.<sup>1-3</sup> India has one of the highest prevalence of type-2 diabetes mellitus in the world. It is estimated that by the year 2030 there will be nearly so million Indians with type-2 diabetes mellitus in the country. There is witnessing increase in proportion of persons of 60 years or older in parallel with a decline in the proportion of young such that by 2050 it is expected that the proportion of elderly persons will have risen from 15-25%. In India, peripheral neuropathy is compounded by poor foot hygiene, improper foot wear, frequent bare foot walking and noncompliance to medications. The

prevalence of diabetic peripheral neuropathy (DPN) in type -2 diabetes mellitus ranges from 10-48%, depending upon the population studied and method used to evaluate neuropathy those are in view of poor awareness and lack of regular screening programs. Those initiate and predisposes to an increased rate of micro vascular complications at onset. The prevalence in some other studies of painful diabetic peripheral neuropathy ranges from 10-20% of patients with diabetes and 40-50% of those with diabetic neuropathies, whereas peripheral neuropathy is 13.3% in diabetic subjects, 8.7% in individuals with impaired fasting tolerance, 4.2% in individuals with impaired fasting glucose levels, and 1.2% in normal glucose tolerance. In western world, prevalence was found to be 66% in type-1 and 59% in type-2 considering these prevalence percentages there is an undesirable need to prepare primary data for more strengthening of literature and educating patients regarding the disorder by the proper interventions.<sup>4-6</sup> Obesity is a marker of insulin resistance which may account for poor glycemic control and predisposed to peripheral neuropathy and other complications. Weight loss depicts severity of type 1 diabetes mellitus which may account for complications. Even after considering the factors such as age, duration of diabetes women still had greater values of prevalence of getting diabetic neuropathies.<sup>4,7</sup> Glycemic control, lipids, hypertension are the quality measures go well together, it requires frequency assessment and adjustment in diet exercise and physiological therapies. Documenting regular frequency of foot exams often visits for follow-up are important for preventing complications. Claudication and non-healing foot ulcers are common in type 2 diabetes patients.<sup>8-10</sup> This study was conducted to determine the prevalence of sensory peripheral neuropathy in diabetic patients and the primary objective and secondary objective was to document the prevalence of sensory peripheral neuropathy in diabetic patients, to document the incidence of diabetic neuropathy, to calculate ratio of prevalence of sensory peripheral neuropathy in obese and non-obese diabetic patients, to determine sensory peripheral neuropathy in diabetic patients using nonmodifiable risks in the base line characteristics respectively.

#### **METHODS**

The present study was conducted in the Department of Endocrinology, Sree Diabetes Care Centre, Kurnool for a period of 6 months December 2016 to May 2017. The study population was 331 patients from Diabetic outpatient clinic of both male and female. Present study was a cross sectional interventional study.

#### Study materials

- Patient data collection proforma
- Informed consent form (ICF)
- Neuropathy symptoms score (NSS)
- Neuropathy disability score(NDS)

- Biothesiometer (VPT)
- Semmes-Weinstein monofilament
- Tuning fork (TF) 256Hz.

#### Inclusion criteria

• Diabetic patients of both type I and type II with age above 30 years who have given their consent to participate in the study.

#### Exclusion criteria

• Tubercular neuropathy, drug induced neuropathy and Vitamin B1, B2, B6, foliate deficiency neuropathic patients.

#### Method of data collection:

This cross-sectional study was carried out after obtaining the permission of Institutional Ethics Committee. All diabetic patients who attended the Endocrinology Outpatient Department of Sree Diabetis Care Centre, between December 2016 to May 2017, were included in the study. Patients below the age of 30 years are excluded from study. A specially designed proforma was used for collecting data which includes patient demographics, past medical history, family and surgical history, comorbidities, diagnosis and present medications prescribed for each patient. The data obtained by direct patient interview and from patient case profiles. 331 cases were collected from Endocrinology Department, according to study criteria. All the patients with diabetes were screened to determine the presence of sensory peripheral neuropathy by using instruments (Biothesiometer, Semmes- Weinstein monofilament, Tuning fork 256Hz) and by NSS, NDS examination scores.

#### RESULTS

In this current study, a total of about 331 study participants were included among them about 60% (198/331×100) were males and 40% (133/331×100) were females. In this study, the patient was being asked for different kind of questions regarding their health condition weather laboratory examination was done or not to determine the presence of neuropathy. The total prescription analysis is shown in Table 1. The parameters like age, BMI, alcohol and duration of diabetes with standard deviation and percentages are shown in Table 2. Duration of diabetes is shown in Table 3. At any duration of diabetes, males are comparatively more affected than females and the 6-10 and 11-15 duration groups have more number of patients and among them males had significantly increased proportion. The patients were detected with neuropathy with various methods with different values and those results were as shown in the Table 4. Among all the methods the patients diagnosed less were with the tuning fork and the highest number of patient diagnosed was with NDS and NSS. Comparatively both the instruments (tuning fork and monofilament) have the variability in causing sensation in the foot of patients which is clearly been understood as shown in Table 5.

It showed that sensation was not found in 52% patients only when tested with the tuning fork where as it was 89% when tested with the monofilament. This shows the great variability in the testing instruments. Thus, we cannot conclude the patient was neuropathic with a single instrumental evaluation. There was a close relation of the percentage of patients affecting with the diabetic peripheral neuropathy, when tested with biothesiometer, NSS, and NDS. According to the patient's severity the neuropathy scoring is given in Table 6.

Total of 331 diabetic patients, 200 participants were identified as neuropathic and 131 were non-neuropathic subjects. Over all prevalence of diabetic neuropathy was found to be 60.4% (200/331×100). We have observed the prevalence of males with diabetic neuropathy was found to be more and it is about 61% (122/200×100) and females was 39% (78/200×100) respectively. The prevalence of neuropathy in diabetic patients was found to be 60.4% (200/331×100) whereas the incidence of diabetic neuropathy was found to be 60.4% (200/331×100) whereas the incidence of diabetic neuropathy was found to be 8.76% (29/331×100) (Figure 1). The obese diabetic patients were about 144 among them grade 1 was 89 patients, grade 2 was 55 patients, it is shown in Table 7.

#### Table 1: Prescription analysis.

Prescription analysis	Total count
Total no. of cases	331
Total male participants	198 (59.82%)
Total female participants	133 (40.18%)
Total no. of neuropathy cases	200
Total neuropathy in males	122 (61%)
Total neuropathy in females	78 (39%)
Total no. of obese patients	250
Total no. of obese males	135
Total no. of obese females	115
Total no. of obese with neuropathy	144
Total no. of obese neuropathy males	75 (52.08%)
Total no. of obese neuropathy females	69 (47.91)
Total no. of alcoholics	57 (17.22%)
Total neuropathic alcoholics	33 (16.5%)

### Table 2: Values are shown as mean±SD, alcoholic consumption only in males.

Variables	Males (n=198)	Females (n=133)	Total (n=331)
Age	53.05 <u>+</u> 10.39	51.35 <u>±</u> 9.99	52.40±10.39
BMI	27.47 <u>±</u> 4.13	28.68 <u>±</u> 4.15	27.95±4.13
Alcohol	59 (29.64)	0	59 (17.82)
Duration of diabetes	8.62 <u>+</u> 6.10	7.25 <u>±</u> 6.12	8.06 <u>±</u> 6.10

#### Table 3: Duration of diabetes.

Duration of DM	Males	Females
0-5	18	17
6-10	37	26
11-15	39	25
16-20	18	7
21-25	6	2
26-30	3	1
31-35	1	0

#### Table 4: Neuropathy testing with various methods.

Test	No. of DPN cases
Biothesiometer	200
Tuning fork	104
Monofilament	178
NDS	284
NSS	279

## Table 5: Sensation with tuning fork and<br/>monofilament.

Variable	Tuning fork	Monofilament
Yes	96 (48%)	22 (11%)
No	104 (52%)	178 (89%)

#### Table 6: Severity score of different test.

Test	Mild	Moderate	Severe	Total
NSS	133 (47.6%)	90 (32.2%)	56 (20.1%)	279
NDS	145 (51.05%)	101 (35.6%)	38 (13.4%)	284
VPT	63 (31.5%)	62 (31%)	75 (37.5%)	200

#### Table 7: Obesity with neuropathy positive patients.

Grade	Male	Female
Grade-1 (89)	45	44
Grade-2 (55)	30	25
Grade-3 (0)	0	0





From grade 1, number of male patients was 45 and number of female patients was 44. From grade 2, the number of male patients was 30 and number of female patients was 25. Among 200 patients of diabetic neuropathy 72% (144) were obese this supports that there was a direct relation between the overweight and neuropathic pain. The association between the obesity cases and the DPN, biothesiometer ( $r^2=0.7922$ ) showed it was a low positive correlation, by NSS ( $r^2=0.9516$ ) it was a high positive correlation, as shown in Figure 2, 3 and 4 respectively.



Figure 2: Correlation between obesity and neuropathy diagnosed with Biothesiometer.



Figure 3: Correlation between obesity and neuropathy diagnosed with NSS.



Figure 4: Correlation between obesity and neuropathy diagnosed with NDS.

#### DISCUSSION

DPN is the most common complication of DM, which leads to high morbidity, mortality and enormous financial cost. DN is most common in developed countries; it is a reason for most hospitalizations than all the other diabetic complications.<sup>10</sup> Most of the studies have declared that the neuropathy in diabetic patients is a result of loss of myelinated fibres of all nerves. No axonal loss is seen in diabetics, the neuropathic result is only due to the demyelination. The reduction in amplitude of the sensory action potentials and slowing of nerve conduction velocity were the main causes of signs and symptoms of neuropathy. We have undertaken the detailed information from each and every patient to obtain a perfect result of prevalence.<sup>15</sup> Duration of diabetes showed significant effect on prevalence of neuropathy in present study association between duration of diabetes and risk of neuropathy is strong. Diabetic neuropathy is present in all types of diabetic patients at the time of or any time after diagnosis of diabetes and in patients after 5 years of diabetes history.<sup>2</sup> So it is imperative to perform the neurological testing in the laboratory and scoring systems should also be included. It is better to educate patients to examine their foot at least annually and the early detection of DN makes the health care professionals and patients to initiate the preventive measures and can evaluate the therapeutic options. To facilitate early detection of the DN we have used the instruments like tuning fork, monofilaments, biothesiometer and the scorings scales like NSS and NDS. Along with these we have specifically collected the symptoms of the patients which would be related to the neuropathic presence. We have detected the high prevalence of DN in our diabetic clinical care settings. Diabetic neuropathy was directly associated with age, duration of diabetes and obesity. A significant greater proportion of males reported neuropathy more than females. On comparison with the Abott CA et al study, they have concluded that females have 50% increased risk of painful symptoms than males.<sup>15</sup> Popscu S et al study have given a statement that for every advance of 1 year in patients age there was an increase in 11.2% of developing neuropathy where as our present study cannot predict those values which is a drawback and this prediction from the present study can only be done by the follow up of the study and the elaboration of the same study to some more months. Similarly, the same study has concluded that there was an increase in the neuropathic prominence with age but they have not specifically mentioned about the age groups. According to the present study, neuropathy is most prominent in the ages of 51-60 years as shown in Figure 1. Ashok S et al, had reported the neuropathic prevalence about 19.1%.<sup>16</sup> kiani J et al, study suggests that their study population have prevalence of 45.7%.<sup>17</sup> Sobhani S et al study suggests that the prevalence of neuropathy is very high among the population with diabetes in Iran but they have not given any percentage of prevalence whereas our current study revealed 60% of prevalence of neuropathy in the diabetic patients.<sup>18</sup> Mythili A et al

study using nerve conduction suggest that the prevalence of neuropathy is about 71%, this percentage is very near to our present study we have not conducted the nerve conduction studies.<sup>19</sup> Lee C et al, have suggested in their cohort study that there is a high risk of neuropathy for type 2 diabetes which is similar with the prevalence of new onset diabetes. In present findings, we have included the patients who are known case of diabetes so we have no data about the pre-diabetic patients.<sup>11</sup> According to Gill HK et al, the prevalence of neuropathy was 29.2%. The prevalence is similar in males (26.1%) and females (33.8%) and according to their study In NDS 44.5% were found abnormal with 20% having a moderate-severe grade score. In NSS 50% were found abnormal with moderate-severe symptoms in 35%. An Abnormal was detected in 43% of patients with VPT.<sup>4</sup> In the present study there is a close relation of the percentage of patients affecting with the diabetic peripheral neuropathy when tested with biothesiometer, the patients suffers with the mild moderate and severe kind of neuropathy were about (48%, 32%, 20%), (51%, 36%, 13%), (31%, 31%, 38%) when tested with NSS, NDS, Biothesiometer respectively. Despite the serious scientific work, data on the morbidity, prevalence and incidence were limited in our country where the peripheral neuropathy has a high incidence and prevalence values. Abott CA et al, have given a report on the incidence of neuropathy is about 7.2% and our present study have concluded that 8.76%.<sup>16</sup> We could not determine the association between the HbA1c levels with the neuropathic progression however it is not directly associated and not easy to calculate directly. Mythili A et al, study shows that there has been calculated raise by approximately 10-15% for every 1% raise in HbA1c.<sup>19</sup> Among 200 patients of diabetic neuropathy 72% (144) were obese. In the present study, the association between them found as low with biothesiometer and high positive correlation with NSS and NDS respectively this supports that there is a direct relation between the obesity and neuropathic pain this and the work done by Hozumi J et al, they had confirmed that obesity frequently tends to demonstrate limited activity of daily living and have suggested that the weight loss intervention might improve neuropathic pain severity.<sup>20</sup> Major strength of this epidemiological study compared with others is that it is substantially longer than any previously published study on the prevalence of DPN. Although Biothesiometry is a useful clinical tool for screening of neuropathy, its sensitivity is probably much lower than performing on nerve conduction studies diagnosing neuropathy. The limitation to for Biothesiometry is that it was an observer dependent as a subjective assessment is made based on the patient's response. Even though there is a limitation still it is a widely used screening test for quick assessment of neuropathy in a busy outpatient clinic or in a field setting.<sup>4</sup> We found that VPT testing can be confidentially used for annual screening of DPN.

#### CONCLUSION

We conclude that there is a higher prevalence (60.4%) and incidence (8.76%) of sensory peripheral neuropathy among the observed diabetic patients and it may go on increasing as the age progress. Thus, the proper identification of the complication and counseling can help to reduce the progression. DPN remains a challenge for a physician to prevention of progression through long term glycemic control. As well as the clinical pharmacist plays a key role in reduction of prevalence by counseling, drug related problems detection and by recommending rational drug therapy.

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