

Original Research Article

A study of prevalence of peripheral neuropathy in patients with impaired glucose tolerance

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ABSTRACT

Background: It is estimated that about half of the diabetics develop diabetic peripheral neuropathy (DPN). Prediabetes is the precursor of type 2 diabetes and it is projected that by 2045 nearly 8.6% of the global adult population may be affected by prediabetes. Pre diabetics also shares the vascular complications of diabetes. Evaluation of impaired glucose tolerance (IGT) and its association with neuropathy is hence very essential. According to International Diabetes Federation, number of global impaired glucose regulation (IGR) patients will reach 471 million by 2035. It is imperative that management strategies aimed at timely diagnosis and prevention of these complications be framed.

Methods: 30 patients with IGT were recruited from outpatient/inpatient department of JSS hospital who met the following WHO diagnostic criteria (HbA1C of 5.7-6.4%, fasting blood sugar of 100-125 mg/dl, oral glucose tolerance test (OGTT) 2-hour blood sugar of 140-199 mg/dl) were included in the study. All the patients underwent nerve conduction studies as per the established clinical practice and results were compared with the standard values of our laboratory.

Results: 13 patients (43.33%) had neuropathy based on nerve conduction studies (NCS). Sensory neuropathy (53.85%) was most common followed by motor and mixed types with 3 patients each (23.08%).

Conclusions: Prevalence of neuropathy was high in prediabetics. Small fibre involvement as manifested by sensory component was predominant in our study. Family history of diabetes was an important risk factor associated with higher neuropathy prevalence.

Keywords: Pre-diabetes, Peripheral neuropathy, IGT, IGR

INTRODUCTION

The WHO estimated that diabetes mellitus affected 422 million people in 2014. It is estimated that about half of the diabetics develop diabetic peripheral neuropathy (DPN). About one fifth of type 2 diabetics have DPN at presentation. Prediabetes is the precursor of type 2 diabetes and is diagnosed commonly by criteria laid down by the WHO.¹ It is projected that by 2045 nearly 8.6% of the global adult population may be affected by prediabetes.

It has been documented that pre diabetics also share the vascular complications of diabetes mellitus.

The Toronto International Consensus for DPN laid down that for definitive diagnosis of neuropathy, a patient has to have at least one sign and symptom attributable to the neuropathy along with abnormality on nerve conduction studies (NCS).² The drawback in this recommendation is that NCS predominantly studies the large diameter fibers. However, it is predominantly the smaller diameter nerve fibers that are affected earlier in DPN. The small diameter

fibers can be assessed only by skin biopsy and corneal confocal microscopy -which are not easily available at all centers. The conventional use of a 128 Hz tuning fork or a monofilament identifies neuropathy only when it is advanced.

There have been various studies conducted at different centers to estimate the prevalence of neuropathy in pre diabetics. They have thrown up varying incidences depending on the population studied and the methods used for detection of neuropathy.

Some of the techniques that have been used include nerve conduction studies, electrochemical skin conductance, and quantitative vibration sensation. A few authors have used physical examination alone for diagnosing diabetic polyneuropathy.³

Combining the incidence of polyneuropathy in both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) results in a higher incidence than in isolated IFG/IGT. It is interesting to note that progression of small fiber changes in patients of IGT is reflected in the patient developing diabetes mellitus. Conversely decrease in the mean blood sugars towards normal is associated with increase in number of small diameters fibers.⁴

PN in diabetics is either distal symmetrical sensory polyneuropathy and/or autonomic neuropathy. The constant remodeling of the epidermis may make the small diameter fibers (type C) more prone to injuries in metabolic diseases like diabetes. Similarly autonomic fibers may be involved in diabetes. It is postulated that the autonomic fibers which are again small diameter fibers are also prone for early injuries due to the metabolic derangements in prediabetes. This is reflected by the presence of autonomic neuropathy at the time of diagnosis of type 2 diabetes.⁵

Aims and objectives

This study is aimed at augmenting the existing limited literature on PN in Indian prediabetic patients by studying the prevalence of neuropathy in these patients, using electrophysiological techniques, who otherwise had no other identifiable cause of neuropathy.

The primary aim of the study was to study the occurrence of PN using electrophysiological techniques in subjects with IGT and no other identifiable cause of neuropathy with a specific objective of evaluating the prevalence of PN in patients with IGT.

METHODS

Study type

This was a prospective observational cross-sectional study.

Study site

The study was conducted at the Department of Neurology at the JSS Hospital, Mysore after obtaining ethical clearance from the institutional ethical committee.

Study duration

The study was conducted from December 2020 to December 2021.

Sample size

Convenience sample of 30 patients with IGT were recruited from outpatient/inpatient department of JSS Hospital, Mysore after obtaining written informed consent.

Inclusion criteria

A diagnosis of IGT or prediabetes based on Revised American Diabetes Association (ADA) criteria: HbA1C of 5.7-6.4%, fasting blood sugar of 100-125 mg/dl, and an oral glucose tolerance test (OGTT) 2-hour blood sugar of 140-199 mg/dl.⁶

Exclusion criteria

The following patients were excluded from the study if they were not willing to participate in the study or had diseases or treatment which could cause PN like: patients with abnormal vitamin B12 levels and thyroid function; patients with documented serum antinuclear antibodies (ANA) positive or past history of connective tissue disease; individuals who had non-healing skin sores or any foot deformities; history of exposure to agents such as heavy metals, anti-tuberculosis drugs, cancer drugs, anti-convulsant, steroids or opioid drugs were excluded from the study; chronic smokers and alcoholics were also excluded from the study; and patients with chronic diseases (e.g. chronic liver disease and chronic kidney disease) or any malignancy were excluded from the study.

Study flow and methodology

All the eligible patients presenting in the Department of Neurology - outpatient/inpatient department (OPD/IPD) were screened for the inclusion and exclusion criteria.

Patients who met the inclusion criteria and were willing to give the written informed consent were included for analysis.

The subjects were labelled prediabetic according to ADA criteria: if the fasting plasma glucose was between 100-125 mg/dl or, the 2-hour OGTT was between 140-200 mg/dl, or HbA1C was between 5.7-6.4%.⁶

Each participant had to undergo an interview of general health and function at the time of study entry followed by

a standard assessment, including medical history, physical and neurological examination.

Baseline parameters like the demographic details and clinical/comorbidity history were recorded along with the glycaemic parameters.

Laboratory investigations were done at the baseline which included vitamin B12 levels, thyroid function tests (TFT), serum ANA, fasting lipid profile, renal function tests (RFT), and liver function test (LFT).

All the patients underwent nerve conduction studies as per the established clinical practice and protocols. Nerve conduction studies were done among the patients and results were compared with the standard values of our laboratory. Based on the above, subjects were labelled with neuropathy and also the type of neuropathy - sensory, motor, and mixed.

Data was recorded and analysed as per the statistical analysis plan.

Statistical analysis plan

The data was compiled and analyzed using Microsoft excel (R) office 365, GraphPad prism 8.4.2 and statistical package for the social sciences (SPSS) version 25. Descriptive statistics were presented in the form of proportions/percentages for categorical variables and mean and standard deviation for continuous data variables. A comparison of the profile of patients with and without neuropathy was done. Fisher exact test/Chi square test was used for the comparison of proportions (categorical variables). Continuous variables were analyzed using the Mann Whitney test/student t test (independent group/unpaired data) and Wilcoxon sign rank test/paired t test (for paired data) based on the normality of the data. P value of <0.05 was considered significant.

RESULTS

Thirty patients with IGT as suggested by fasting blood sugar (FBS), post-prandial blood sugar (PPBS) and HbA1c levels were recruited for the study.

An assessment of the neuropathy status in these patients using the nerve conduction studies was done and the results have been summarized in the following sections - section 1: overall profile of the patients - glycaemic parameters, section 2: neuropathy status, and section 3: comparative assessment based on neuropathy status.

Section 1: overall profile

Total number of patients included in the study were 30.

It was observed that FBS was impaired in 26 patients (86.67%) while PPBS was impaired in 20 patients (66.67%) and 25 patients had impaired HbA1c.

Table 1: Parameter wise IGTT count.

Parameter wise IGTT (n=30)	Overall	%
IGTT based on FBS	26	86.67
IGTT based on PPBS	20	66.67
IGTT based on HbA1c	25	83.33

Glycemic parameters levels

The average FBS in the study was 114.73±12.95 mg/dl, PPBS was 149.53±27.54 mg/dl and mean HbA1C was 5.83±0.69%.

Table 2: Glycemic parameters - summary.

Glycaemic parameters	Overall
Mean FBS	114.73
Standard deviation	12.95
Mean PPBS	149.53
Standard deviation	27.54
Mean HbA1C (%)	5.83
Standard deviation	0.69

Section 2: neuropathy status

Out of the 30 patients with IGT levels, 13 patients (43.33%) had neuropathy based on the nerve conduction test studies (NCS).

Table 3: Neuropathy status.

Total number of patients (30)	Number	%
Neuropathy - (on NCS)	17	56.67
Neuropathy + (on NCS)	13	43.33

Type of neuropathy

Sensory neuropathy (53.85%) was the most common type of neuropathy seen in the study followed by motor and mixed types with 3 patients each (23.08%).

Section 3: comparative assessment based on neuropathy status

Age comparison

The mean age overall in the study was 58.07 years with a standard deviation of 9.09 years. 56.67% patients had age more than 60 years. It was seen that the average age of the patients was similar (59.53 versus 56.15 years, p value=0.3211) with no significant difference. There was a male preponderance overall in the study and across both the groups with no significant gender related difference between the two groups (p=0.9369).

BMI

The average BMI was 23.73±3.21 kg/m² for the study overall. The average BMI was slightly higher for the

patients with neuropathy, but the difference was not significant statistically ($p=1509$).

The proportion of overweight patients was higher in the neuropathy group (Table 6).

Comorbidity profile

It was seen that the proportion of patients with family history of diabetes was significantly higher in the patients with neuropathy (69.23% versus 11.76%, $p=0.0015$) (Table 7).

Glycemic parameter comparison

It was seen that a significantly higher proportion of the patients with neuropathy had all three parameters in the impaired range (84.62% versus 23.52%, $p=0.0011$).

Table 4: Neuropathy type.

Neuropathy type	Number	%
Mixed	3	23.08
Motor	3	23.0
Sensory	7	53.85
Grand total	13	100.00

The proportion of patients with impaired glycemic parameters was higher in the neuropathy group (100% versus 76.47% in FBS, 92.30% versus 47.05% in PPBS and 92.30% versus 76.47% in HbA1c) with significant findings with respect to the PPBS ($p=0.0104$). The average levels of glycemic parameters (FBS, PPBS, and HbA1c) were higher for the patients with neuropathy. The difference was almost significant for the PPBS levels ($p=0.0504$).

Table 5: Age and gender comparison based on neuropathy.

Variables	No neuropathy	Neuropathy +	Overall	P value
Age and neuropathy status				
Number	17	13	30	0.3211*
Average age	59.53	56.15	58.07	
Standard deviation	9.10	9.06	9.09	
Minimum	42.00	45.00	42.00	
Maximum	71.00	69.00	71.00	
Number >60 years	11 (64.70%)	6 (46.15%)	17 (56.67%)	
Gender				
Female	5 (29.41)	4 (30.76)	9 (30)	0.9369**
Male	12 (70.59)	9 (69.23)	21 (70)	
Grand total	17	13	30	

*Student t test, **Chi square test.

Table 6: BMI based comparison.

BMI and neuropathy	No neuropathy	Neuropathy +	Overall	P value
Number	17	13	30	0.1509*
Average BMI	22.99	24.70	23.73	
Standard deviation	3.30	2.92	3.21	
Minimum	17.46	19.18	17.46	
Maximum	28.94	29.34	29.34	
Number of overweight (BMI>25)	6 (35.29%)	7 (53.84%)	13 (36.67%)	

*Student t test.

Table 7: Clinical/comorbidity profile.

Clinical/comorbidity profile	No neuropathy	Neuropathy +	Overall	P value
Number of patients	17	13	30	0.5569
Peripheral neuropathy symptoms	6 (35.39%)	6 (46.15%)	12 (40%)	
HTN	5 (29.41%)	4 (30.76%)	9 (30%)	
F/H/O DM	2 (11.76%)	9 (69.23%)	11 (36.67%)	

*Chi square test.

Table 8: IGTT status - parameter wise.

IGTT status	No neuropathy	Neuropathy +	P value
Only one parameter deranged	4 (23.52%)	0	0.0648
Two parameters	9 (52.94%)	2 (15.38%)	0.0375*
All three parameters deranged	4 (23.52%)	11 (84.62%)	0.0011*
Grand total	17	13	

*Chi square test.

Table 9: Parameter wise IGTT.

Parameter wise IGTT	No neuropathy (n=17)	Neuropathy + (n=13)	P value
IGTT based on FBS	13 (76.47)	13 (100)	0.0647
IGTT based on PPBS	8 (47.05)	12 (92.30)	0.0104*
IGTT based on HbA1c	13 (76.47)	12 (92.30)	0.2570

*Chi square test.

Table 10: Glycemic parameters.

Glycaemic parameters	No neuropathy	Neuropathy +	P value
FBS (mean)	112.00	118.31	0.1881
Standard deviation	14.73	9.56	
PPBS (mean)	141.00	160.69	0.0504*
Standard deviation	28.59	22.47	
HbA1C (%) (mean)	5.78	5.91	0.6151
Standard deviation	0.79	0.54	

*Student t test.

DISCUSSION

Impaired glucose regulation (IGR), also known as prediabetes, is defined as the intermediate stage that is higher than the normal value of blood glucose but lower than the diabetes threshold. IGR consisted of IFG and IGT, and 5-10% IGR patients may develop DM per year.⁷ According to a report by the International Diabetes Federation, it is predicted that the number of global IGR patients will reach 471 million by 2035.⁸

Neuropathy was earlier thought to be a result of advanced DM. However, recent reports suggest that neuropathy can occur early in the stage of prediabetes. Also 10% of diabetic patients have PN (PN) at the time of the initial diagnosis, suggesting an early axonal injury in the course of glucose intolerance.⁹ Evaluation of IGT and its association with neuropathy is important as it was projected by 2011 there would be 77.2 million people with prediabetes in India.¹⁰

Prediabetes is an independent predictor of conversion to type 2 DM and most can be identified by doing fasting glucose. Both IFG and IGT are risk factors for type 2 DM and risk is even greater when IFG and IGT occur together.¹¹ Fateh et al showed that NCS with Michigan neuropathy screening instrument (MNSI) is a useful modality for the detection of subclinical neuropathy. This can be a test useful for periodic evaluation of diabetic patients.¹²

As per Table 8, in our study that half of all the patients (15.50%) had all three glycaemic investigations (FBS, PPBS, and HbA1C) in the impaired range. Four patients (13.33%) had only one of the three parameters in IGT range while 11 patients had two of the three parameters deranged (36.67%).

Neuropathy status

According to Tables 3 and 4 we observed in our study that out of the 30 patients with IGT levels, 13 patients (43.33%) had neuropathy based on the nerve conduction test studies (NCS). In these 13 patients, sensory neuropathy (53.85%) was the most common type of neuropathy followed by motor and mixed types with 3 patients each (23.08%). Kirthi et al in their systematic review on prevalence of neuropathy in pre-diabetes showed that there was a wide range of prevalence estimates (2-77%, IQR: 6-34%), but the majority of studies (n=21, 72%) have reported a prevalence $\geq 10\%$.¹³

The three highest prevalence estimates of 77% (95% CI: 54% to 100%), 71% (95% CI: 55% to 88%) and 66% (95% CI: 53% to 78%) were reported using plantar thermography, multimodal quantitative sensory testing, and nerve conduction tests, respectively. In general, studies evaluating small nerve fibre parameters yielded a higher prevalence of PN.

Due to a variation in study populations and methods of assessing neuropathy, there have been differences in the estimates of neuropathy in prediabetics. Most studies have reported a higher prevalence of small fibre PN in prediabetes, than would be expected in the background population.

Talib et al in their study on 60 prediabetic patients showed that amplitude of bilateral sural SNAP and tibial CMAP were significantly lower in the affected pre-diabetics and asymptomatic diabetics.¹⁴ They showed that significant f wave latency was also shown in these groups. However, these findings were not significant statistically. The prevalence rate for neuropathy was 30% in the pre-diabetes group. We did not observe such findings in our study.

Liu et al showed that IGR patients have PN characterized by impaired functions of large and small fibres focused on small fibre and lower limb sensory nerves. They evaluated contact heat evoked potential (CHEP) which could detect small fibre damage earlier than sympathetic skin response (SSR) and NCS. In addition to NCS and SSR they used MNSI in their patients and observed abnormal values of 18.3%, 22.5%, and 39.2%, respectively. All patients with abnormal NCS values had impairment in SSR.⁷

Brett in their study on PN showed that according to MNSI scores, prevalence of neuropathy was 29%, 49%, and 50% in euglycemic, prediabetic, and diabetic participants, respectively. However, in analysis based on an automated device (a neurothesiometer) that measures vibration perception threshold, prevalence of neuropathy was 5% to 10% with no significant difference between the groups.¹⁵

Kannan et al conducted a study on 58 subjects with impaired OGTT along with 30 matched controls. They did not use HbA1c levels for categorizing IGT. They assessed neuropathy using NCS, autonomic function tests, and quantitative sensory testing (QST). They showed that out of 58 subjects, 19 (32.8%) had neuropathy. Nerve conduction studies showed evidence of neuropathy in 14 (24.13%) subjects, autonomic neuropathy was detected in 8 (13.8%), and QST was found to be abnormal in 16 (27.6%) subjects. They showed that small fibre neuropathy was most common type of neuropathy in their study group.¹¹ In comparison the prevalence of neuropathy in our study was slightly higher at 43.33%. However, our study is limited by the fact that small fibre functions were not assessed.

Similar to our study, Sahin et al showed that the prevalence of neuropathy in IGT/prediabetes patients was 44.40% in their study.¹⁶ Two population-based studies have assessed the prevalence of neuropathy in IGT: the San Luis Valley (USA) and the MONICA/KORA Augsburg (Germany) studies.^{17,18} Using differing diagnostic criteria, the results of these two epidemiologic surveys were remarkably similar, with neuropathy present in 11-13% of IGT and 26-28% of diabetic subjects along with 4-8% of the nondiabetic control populations.²

Table 11: Neuropathy prevalence - comparison with some major studies.

Study name (year)	Neuropathy prevalence (%)
Present study	43.33
Talib et al (2018)	30
Kannan et al (2014)	32.80
Brett et al (2015)	49
Sahin et al (2008)	44.40

Profile and risk factors for neuropathy

According to Tables 5 and 6 it was seen that the average age of the patients was similar for the two groups based on neuropathy status (59.53 versus 56.15 years) with no significant difference (p value=0.3211). There was no gender and body mass index (BMI) based difference also between patients with and without neuropathy. A higher proportion of these patients had PN symptoms (46.15% versus 35.39%). Kannan et al noted that BMI had no significant impact on the occurrence of neuropathy. However, our study had a greater number of overweight patients.

Clinical profile

One interesting finding in our study was that the proportion of patients with family history of diabetes was significantly higher in the patients with neuropathy (69.23% versus 11.76%, p=0.0015). This has not been commented upon by others and needs a larger study.

Glycaemic parameter profile

It was seen that higher proportion of the patients with neuropathy had impairment of FBS, PPBS and HbA1c (84.62% versus 23.52%, p=0.0011). This difference was statistically significant. The other laboratory parameters were similar between the two groups (liver function, renal function, and hematological parameters).

In contrast Kuriso et al in their study on the polyneuropathy could not find any difference between normal and patients of prediabetes whereas diabetics had clinical polyneuropathy or nerve conduction abnormalities.

Lu in their Chinese study on neuropathy and its factors showed that the prevalence of PN was 8.4%, 2.8%, and 1.5% in DM, IGR, and NGT subjects, respectively (p<0.05 for diabetes versus NGT and IGR).

They assessed neuropathy based only on neuropathy symptoms and neuropathy disability scores. In comparison our patients were screened with nerve conduction studies. The subjects with known diabetes had the highest frequency of PN (13.1%). Among the subjects without diabetes, those with PN were older, had a higher waist circumference and 2-hour postprandial plasma glucose levels, and were more likely to be hypertensive. Similar

findings were noted in our study where patients with increased BMI and PPBS had increased incidence of neuropathy. Among the IGR subjects, other than age, the 2-hour postprandial plasma glucose level was an independent factor significantly associated with PN.

Limitations

Because of the short duration of the study, we did not follow up the patients and our study had no matched controls. Only one single method (nerve conduction study) for evaluation was used for the neuropathy assessment and we did not systematically study the small fibre conduction.

This study was an observational study with a likelihood of selection bias. The number of subjects recruited was small because of the ongoing COVID-19 pandemic

CONCLUSION

The study showed that the prevalence of neuropathy was high in prediabetes group of patients. As shown by other studies as well, the small fibre involvement as manifested by the sensory component was predominant in our study. Family history of diabetes was an important risk factor associated with higher neuropathy prevalence. PPBS was seen to be in the impaired range suggesting the role of PPBS based monitoring of these patients. All three glycaemic parameters deranged together was an important predictor for neuropathy as the same was seen in 4 out of 5 patients with neuropathy. Overall, the findings of this study will have to be validated by larger studies/population-based registries with multicentric study designs.

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