IJBPAS, October, 2024, 13(10): 5049-5059

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

A CROSS- SECTIONAL STUDY ON ASSESSMENT OF DIABETIC PERIPHERAL NEUROPATHY BY USING 10G SEMMES WEINSTEIN MONOFILAMENT IN A TERTIARY CARE HOSPITAL

SINGH DS*[1], THOMAS A[2], ATHIRA K [2], RAJ GA[2], VAGHESE SM[2] AND DHIVYA K[2]

1: Assistant Professor, Department of Pharmacy Practice,C. L. Baid Metha College of Pharmacy, Chennai

2: C. L Baid Metha College of Pharmacy, Chennai

***Corresponding Author: Dr. Daniel Sundar Singh: E Mail:** danielsundar79@gmail.com

Received 24th Sept. 2023; Revised 25th Oct. 2023; Accepted 8th Jan. 2024; Available online 1st Oct. 2024

https://doi.org/10.31032/IJBPAS/2024/13.10.8393

ABSTRACT

Background: According to the International Diabetes Federation, 415 million people have diabetes and half of the population is unaware of its complications, one of the major complications is Diabetic Peripheral Neuropathy which result in morbidity and mortality in patients. 50% of the causes are asymptomatic in patients with DPN, leading to economic burden which slowly progress to loss of protective sensation and finally leading to amputation.

Objective:

1. To assess Diabetic Peripheral Neuropathy [DPN] by using 10g Semmes Weinstein monofilament [SWME].

2.To determine the association between socio-demographic data and Loss of Protective Sensation [LOPS] in left and right foot.

Result: Out of 300 samples in our study, we compared the age, gender, BMI and frequency of check-up with LOPS of left leg and right leg. There is a significant association with male [gender] [P value=0.024] and frequency of check-up [rarely] [P value=0.049]. Age, BMI have no significance towards LOPS of left leg. We also found that here is no significant correlation between age, gender, BMI and frequency of check-up towards LOPS of right leg. There is a

significant association between RBS, HbA1C and LOPS of left leg [P value=0.048**, P value=0.004] and right leg [P value=0.048, P value=0.009]

Conclusion: Our result showed significant association between gender [P value=0.024] and frequency of check-up [P value=0.049] of left leg. RBS and HbA1C also showed significant association with LOPS of left and right leg.

Keywords: Diabetes peripheral neuropathy, Semmes Weinstein Monofilament, Loss of protective Sensation, Body Mass Index

INTRODUCTION:

Diabetes mellitus is a metabolic disorder characterised by inadequate levels of insulin secretion [type 2] or insulin resistance [type 1] in the cells. According to the WHO, diabetes is a chronic metabolic disease characterised by elevated blood glucose that causes serious damage to various organs of the body over time **[1]**. DM cause metabolic abnormalities and severity is based on duration and type of DM. Uncontrolled DM may cause coma and death due to diabetic ketoacidosis **[2]**. World widely, 1 in 11 adults has diabetes mellitus in that last, 90% are affected with T2DM. The T1DM gradually starts from under the age of 20[about 40%] and increases from birth and peaks at ages 4-6 years and then again from 11 to 14 years **[3]**.

According to International Diabetes Federation [IDF], one in 12 adults or more than 74 million people living in India are diabetic. By 2045 the burden of diabetes is assumed to increase by 134 million according to the 2019 estimation **[4]**.

In T1DM, the insulin producing cells of the pancreas, which are the beta cells of the islets of Langerhans, are destroyed. It is insulin-dependent diabetes mellitus, which is usually developed and diagnosed in children and young adults, also known as juvenile diabetes **[5]**. In T2DM [adult- onset diabetes] enough insulin is not produced or not utilised properly in the body and it occurs in middle age people. Gestational diabetes is diabetes developed during pregnancy. Prediabetes is the stage before diabetes mellitus **[6]**. It commonly develops from obesity, aging, family history, sedentarism, and inflammation. Loss of the Glut-4 receptor leads to insulin resistance in peripheral tissues **[7, 8]**. DM occurs due to either deficiency of insulin secretion or insulin resistance and insufficient insulin secretion to compensate **[9]**. Patients with diabetes mellitus most commonly present with increased thirst, increased urination, lack of energy and fatigue, bacterial and fungal infections, and delayed wound healing. Some patients can also complain of

numbness or tingling in their hands or feet or with blurred vision **[10]**. Diabetes patients have a two-to-fourfold increase in cardiovascular mortality. The main cause of death is heart attack. Another complication is end-stage renal disease [ESRD] caused by diabetes **[11]**. The most common risk factors for the development of complication of diabetes are: Blood pressure, Lipid profile, Heart rate, Body weight, Uric acid **[12]**.

Diabetic peripheral neuropathy [DPN] is that the most frequent neurological complication of diabetes mellitus and also the commonest style of neuropathy within the developed world. It is the most common form of neuropathy and causes increased hospitalisation **[13]**. Clinical examination is very important in the case of DPN. It leads to loss of sensation or severely painful symptoms that go unnoticed and it can lead to foot infections and gangrene, which are the most common complications **[14] [15]**.

The prevalence of DPN is higher in T2DM compared to T1DM. In T2DM, PN was present in 26%of youths, according to Diabetes Youth Study. In the [ACCORD]Action to Control Cardiovascular Risk in Diabetes, 42% of adults with T2DM was present with PN **[16]**. It is higher in older age and among adults with long standing type1 and type2 dm.

DPN has become a burden in both macrovascular and microvascular complications of Diabetes Mellitus. It has become the most common obstacle among Diabetic patients, with a prevalence ranging from 18.8–61.9% in India **[17]**. According to the International Diabetes Federation, 387 million people have diabetes in the year 2014, and it will increase to 592 million by the year 2035. With a national Diabetic prevalence of 80% and a total of 668,468,800 people with DM, India stands second to China in relation to the burden of Diabetes Mellitus **[18]**.

DM has become a burden due to its chronic nature causing many complications and DPN is one of them **[19]**. 50% of patients with DPN has loss of sensation or pain, which results from nerve damage in the toes, feet or hands **[20]**. In most cases diagnosis is delayed due to appropriate clinical tests. Patients experience symptoms such as paraesthesia, dysesthesias, and neuropathic pain. Since its related to pain, it called as DPN **[21]**.

10g Semmes Weinstein Monofilament is used as a screening device to determine whether the patient has neuropathy or whether the patient has loss of protective sensation which can prone to ulceration. The Semmes-Weinstein monofilament is made of fine nylon and designed in such a way that the amount of pressure applied to the plantar surface. Until the monofilament buckles, the tip of the monofilament is placed perpendicular to the surface. Approaching skin contact and removing the monofilament

should take 1.5 seconds **[22]**. The monofilament force should also be greater to cause a buckle. Patients without any neuropathy should sense the monofilament. If the patient is not able to sense, it is considered neuropathy. If not able to sense a monofilament of 5.07, it is considered severe neuropathy and loss of protective sensation. Semmes-Weinstein monofilament is a non-invasive, low-cost, quick, and simple to apply material. It's applied to the test perpendicularly until they bend for about one second. The patients are asked to say "yes" each time if they sense the monofilament on their foot. In case if they failed the test site is insensate **[23]**.

Objective:

1.To assess Diabetic Peripheral Neuropathy [DPN] by using 10g Semmes Weinstein monofilament [SWME].

2.To determine the association between socio-demographic data and Loss of Protective Sensation [LOPS] in left and right foot.

Materials and Methods:

A cross sectional study was conducted with patients of diabetes attending OPD in a tertiary care hospital involving a patient of 300 for 6 months.

Eligibility criteria:

Inclusion criteria

- All patients with diabetes mellitus.
- Patients who are willing to participate.

Exclusion criteria

- Conditions that affect peripheral nerve function, such as peripheral neuropathy Malnutrition, familial etc.
- Amputations/ulcers in patients.
- Evidence of any other peripheral nerve lesions/lumbar disc Radiculopathy/ lumbar canal stenosis.
- Patients with cardiac pacemaker/cardiac rhythm abnormalities.
- Patients with Charcot's foot.
- Patients with obesity [Absence of SNAPs in these patients could be due to technical errors].

Method of data collection:

A cross-sectional study involving diabetic patients was carried out in the outpatient department at a tertiary care hospital. Data were obtained by using a self-defined proforma.

Study procedure:

A cross-sectional observation study was carried out based on the inclusion and exclusion criteria. In this study total 300 [n=300] patients were recruited from the department of diabetology in a tertiary care hospital. Patient data collection tool was used to collect the demographics and health information of patients. I0 g Semmes-Weinstein monofilament was used to access DPN.

Statistical analysis:

Data were entered into a Microsoft Excel datasheet and was analysed using SPSS 20 version software. Categorical data were represented in the form of Frequencies and proportions. Chi square and Pearson correlation was used to determine association between two categorical variables. P value [<0.05] was considered statistically significant.

RESULT:

In the present study a total of 300 participants were collected using data collection form, from the department of diabetology in a tertiary care hospital, Chennai. Study was conducted with 300 participants and their socio- demographic details, frequency of check-up in association with LOPS of left and right foot in diabetic population were analysed.

Total sample = 300

- The data were not normally distributed. Descriptive, Chi-square test & Correlation were used.
- Pearson Correlation was used here to see the relationship between two variables/ strength of that relationship. - The data shows relationship between Blood sugar- Hba1c & LOPS [Left, Right] & Blood sugar- RBS & LOPS [Left, Right]
- Chi Square test was used to examine the association between two categorical variables. - There was statistically significant difference between Left LOPS& Gender, Left LOPS & Frequency of check-up.

Descriptive Statistics: (Table 1)

Out of 300 samples in our study, we compared the age, gender, BMI and frequency of check-up with LOPS of left leg. **Table 2** reveals that there is a significant association with male [gender] [P value=0.024] and frequency of check-up [rarely] [P value=0.049]. Age, BMI have no significance towards LOPS of left leg.

From the **Table 3** there is no significant correlation between age, gender, BMI and frequency of check-up towards LOPS of right leg.

Left leg:

Table 4 illustrated that there is a significant association between RBS, HbA1C and LOPS left leg [P value=0.048*, P value=0.004].

Right leg:

Table 4 illustrates that there is a significant association between RBS, HbA1C and LOPS right leg [P value=0.048, P value=0.009].

Table 1

Variables		%
Age	>18	2%
	19-30	5.02%
	31-60	43.1%
	<60	50.2%
Gender	Male	59%
	Female	41%
BMI	Under weight (Below 18.5)	5%
	Normal	25%
	Pre-Obesity	50%
	Obesity	20%
Comorbidities	DM	100%
	HTN	68.3%
	CAD	27.3%
	Others	5%
Duration DM in Years	>1	2%
	1-5	9.7%
	6-10	38%
	<10	50.3%
Family History	DM	52%
	HTN	25.3%
	CAD	8.3%
	Others	15%
Social History in Years	Smoking – Y	30%
	N	70%
	Alcohol – Y	15%
	N	85%
	Others – None	2%
Food Habit	Veg	60%
	Non-Veg	40%
Type of Work	S	24.3%
	Mode	41%
	Light	24.7%
	Heavy	10%
BP	High	45%
	Low	4.3%
	Normal	50.7%
HR	Normal	74.3%
	Abnormal	25.7%
HB	Normal	78%
	Abnormal	22%
HbA1C	Normal	46%
	Pre-Diabetes	39%
	Diabetes	15%
Frequency of Check up	Yearly once	9.6%
	Monthly Once	53.3%
	Rarely	5%
	Never	32%
Class of Antidiabetic drug	Metformin	56%
	Sulphonyl Ureas	28%
	DPP4 Inhibitors	11%
	Others	4.7%
Types of Therapy	Mono	27.3%
	Combination	72.7%
Foot Examination	Dry Skin	27.3%
	Deformities	2.7%
	PPN	58%
	PPD	12%
Monofilament	Left	40.7%
	Right	59.3%

Table 2: Age, Gender, BMI, Frequency of check-up vs LOPS Left leg

		Left LOPS		Chi square value	P value
		Below 7	Above 7		
Age	19 to 30	80%	20%	2.167	0.705
	31 to 60	84.5%	15.5%		
	Less than 18	66.7%	33.2%		
	More than 60	79.9%	20.1%		
Gender	Female	75.6%	24.4%	5.108	0.024*
	Male	85.9%	14.1%		
BMI	Normal	92%	8%	7.37	0.061
	Obesity	80%	20%		
	Pre obesity	77.3%	22.7%		
	Underweight	80%	20%		
Frequency of checkup	Monthly once	84.9%	15.1%	11.124	0.049*
	Never	79.2%	20.8%		
	Rarely	73.3%	26.7%		
	Yearly once	82.1%	17.9%		

Table 3: Age, Gender, BMI, Frequency of check-up vs LOPS Right leg

		Right LOP		Chi square value	P value
		Below 7	Above 7		
Age	19 to 30	80%	20%	0.410	0.982
	31 to 60	78.3%	21.7%		
	Less than 18	83.3%	16.7%		
	More than 60	77.9%	22.1%		
Gender	Female	75.6%	24.4%	0.00	0.992
	Male	80.2%	19.8%		
BMI	Normal	76%	24%	4.478	0.214
	Obesity	88.3%	11.7%		
	Pre obesity	76%	24%		
	Underweight	73.3%	26.7%		
Frequency of checkup	Monthly once	80%	20%	3.288	0.656
	Never	72.9%	27.1%		
	Rarely	86.7%	13.3%		
	Yearly once	82.1%	17.9%		

Table 4: Association between blood sugar [FBS, RBS, PPBS, HbA1C] and LOPS [left and right leg]

Variables	N	Correlation value	P Value
Blood Sugar – FBS	300	0.038	0.516
LOPS Left	300		
Blood Sugar – PPBS	300	0.042	0.469
LOPS Left	300		
Blood Sugar – RBS	300	0.114	0.048**
LOPS Left	300		
Blood Sugar – HbA1C	300	0.165	0.004**
LOPS Left	300		
Blood Sugar – FBS	300	-0.040	0.485
LOPS Right	300		
Blood Sugar – PPBS	300	-0.009	0.877
LOPS Right	300		
Blood Sugar – RBS	300	-0.115	0.048*
LOPS Right	300		
Blood Sugar – HbA1C	300	0.151	0.009**
LOPS Right	300		

DISCUSSION:

In the present study a total of 300 participants were collected using data collection form, from the department of diabetology in a tertiary care hospital, Chennai. Socio- demographic details, frequency of check-up in association with LOPS of left and right foot in diabetic population were analysed. The data were not normally distributed. Descriptive, Chi-square test & Correlation were used. The data shows relationship between Blood sugar- HbA1c & LOPS [Left, Right] & Blood sugar- RBS & LOPS [Left, Right]. There was statistically significant difference between Left LOPS& Gender, Left LOPS & Frequency of check-up.

From the study, we observed that DPN was majorly affected in males [59%] compared to females. Major participants were from greater than 60 [50.2%] and the smallest participants were from less than 18[2%]. We assessed diabetic peripheral neuropathy by using 10g SWME of diabetic patients. LOPS has become a common implication in patients with diabetes mellitus.10g monofilament helps in early detection and prevention of LOPS, thus it reduced the rate of amputation as well as increased the quality of life of the patient. Semmes-Weinstein monofilament is a non-invasive, low-cost, quick, and simple-to-apply material. This study was conducted among diabetes patients in a tertiary care hospital.

Ruban David *et al*, [2018] [24] conducted a similar study on Assess the peripheral neuropathy by using Semmes Weinstein monofilament among type II diabetic patient at a selected village, Vellore. In their study they found out that it was very necessary for every diabetes mellitus to be screened for peripheral neuropathy at least once a year as it is the important risk factor that causes foot ulcer and foot amputation.

Due to the frequent and rigorous follow-up that is required, as well as the significant training, pharmacy professionals can be extremely important in the care of diabetes. A country like India needs more clinical plan to prevent the complication of DPN. To improve the better clinical practise in diabetes mellitus, we need more specific, continuous monitoring and screening progress in diabetic clinic.

CONCLUSION:

DPN has become one of the major complications of diabetes mellitus. Our study was conducted using 10 g Semmes Weinstein Monofilament to assess the diabetic peripheral neuropathy of diabetes patients. Using Semmes Weinstein monofilament, we could assess the patients with risk of developing diabetic peripheral neuropathy. Furthermore, the study offered an insight into the need for early detection of diabetic peripheral neuropathy which may prevent the progression of the complications

into amputation and enhance the quality of life.

Acknowledgement:

We would like to thank the participants and authors for the fullest support.

Funding:

All the author(s) received no financial support for the research, authorship, and/or publication of this article.

Declaration of Conflicting interest:

The author(s) declare(s) that there is no conflict of interest.

REFERENCES:

[1] https://www.who.int/health-topics/diabetes#tab=tab_1

[2] Kharroubi AT, Darwish HM. Diabetes mellitus: The epidemic of the century. World J Diabetes. 2015 Jun 25;6[6]:850-67. doi: 10.4239/wjd.v6.i6.850. PMID: 26131326; PMCID: PMC4478580.

[3] Maahs DM, West NA, Lawrence JM, Mayer-Davis EJ. Epidemiology of Type 1 Diabetes. Endocrinology and Metabolism Clinics of North America [Internet]. 2010Sep;39[3]:481–97. Available from: https: // www. endo. theclinics. com/ article/ S0889-8529[10]00043-5/ abstract

[4] Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. Indian journal of ophthalmology. 2021 Nov;69[11]:2932.

[5] Noble JA, Valdes AM. Genetics of the HLA region in the prediction of type 1 diabetes. Current diabetes reports. 2011 Dec; 11:533-42.

[6] Chentli F, Azzoug S, Mahgoun S. Diabetes mellitus in elderly. Indian journal of endocrinology and metabolism. 2015 Nov;19[6]:744.

[7] American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes care. 2009 Jan 1;32[Supplement_1]: S62-7.

[8] Noble JA, Valdes AM. Genetics of the HLA region in the prediction of type 1 diabetes. Current diabetes reports. 2011 Dec;11[6]:533-42.

[9] Banday MZ, Sameer AS, Nissar S. Pathophysiology of diabetes: An overview. Avicenna journal of medicine. 2020 Oct;10[04]:174-88.

[10] Vinik AI, Nevoret ML, Casellini C, Parson H. Diabetic neuropathy. Endocrinology and metabolism clinics. 2013 Dec 1;42[4]:747-87.

[11] Goyal R, Jialal I. Diabetes mellitus type 2.

[12] Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. Nature reviews

endocrinology. 2018 Feb;14[2]:88-98.

[13] Jasmine A, GV A, Durai V, Shriraam V, V S, Mahadevan S. Prevalence of peripheral neuropathy among type 2 diabetes mellitus patients in a rural health centre in South India. International Journal of Diabetes in Developing Countries. 2021 Jun; 41:293-300.

[14] Baxi H, Habib A, Hussain MS, Hussain S, Dubey K. Prevalence of peripheral neuropathy and associated pain in patients with diabetes mellitus: evidence from a cross-sectional study. Journal of Diabetes & Metabolic Disorders. 2020 Dec;19[2]:1011-7.

[15] Darivemula S, Nagoor K, Patan SK, Reddy NB, Deepthi CS, Chittooru CS. Prevalence and its associated determinants of Diabetic Peripheral Neuropathy [DPN] in individuals having type-2 diabetes mellitus in Rural South India. Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine. 2019 Apr;44[2]:88.

[16] Hicks CW, Selvin E. Epidemiology of peripheral neuropathy and lower extremity disease in diabetes. Current diabetes reports. 2019 Oct;19:1-8.

[17] Jasmine A, GV A, Durai V, Shriraam V, V S, Mahadevan S. Prevalence of peripheral neuropathy among type 2 diabetes mellitus patients in a rural health centre in South India. International Journal of Diabetes in Developing Countries. 2021 Jun;41:293-300.

[18] D'Souza M, Kulkarni V, Bhaskaran U, Ahmed H, Naimish H, Prakash A, Tabreez S, Dahiya B, Thapar R, Mithra P, Kumar N. Diabetic peripheral neuropathy and its determinants among patients attending a tertiary health care centre in Mangalore, India. Journal of public health research. 2015 Jul 30;4[2]:jphr-2015.

[19] Meena S, Manikandan RC. Prevalence of peripheral neuropathy among diabetic patients in a tertiary care hospital.

[20] Brod M, Pohlman B, Blum SI, Ramasamy A, Carson R. Burden of illness of diabetic peripheral neuropathic pain: a qualitative study. The patient-patient centered outcomes research. 2015 Aug;8[4]:339-48

[21] IndINeP Study Group. Burden of neuropathic pain in Indian patients attending urban, specialty clinics:

results from a cross sectional study. Pain Practice. 2008 Sep;8[5]:362-78.

[22] Feldman EL, Stevens MJ. Clinical testing in diabetic peripheral neuropathy. Canadian Journal of Neurological Sciences. 1994 Nov;21[S4]: S3-7.

[23] Baraz S, Zarea K, Shahbazian HB, Latifi SM. Comparison of the accuracy of monofilament testing at various points of feet in peripheral diabetic neuropathy screening. Journal of Diabetes & Metabolic Disorders. 2014 Dec; 13:1-7.

[24] Ruban David *et al*. Assess the Peripheral Neuropathy By Using Semmes Weinstein 10 G Monofilament Among Type Ii Diabetic Patient At A Selected Village, Vellore. International Journal of Pharmacy & Technology. June-2018, Vol. 10, Issue No.2, 31303-31311.