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RESEARCH ARTICLE

The Semmes-Weinstein monofilament examination as a single effective screening tool in diagnosing diabetic peripheral neuropathy when compared to vibration perception threshold

Babitha R, Subathra T A

Department of Physiology, Annapoorana Medical College and Hospital, Salem, Tamil Nadu, India

Correspondence to: Subathra T A, E-mail: subathradr.13@gmail.com

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ABSTRACT

Background: Diabetic peripheral neuropathy (DPN) leads to foot ulcers and non-traumatic amputation, which is a major cause for morbidity and disability in India. At present, no precise pharmacological agent has confirmed efficacy in preventing disease progression or reversing neuropathy symptoms. Clinically, it is crucial to find an effective screening tool for diagnosing DPN. Although vibration perception threshold (VPT) testing and Semmes-Weinstein monofilament examination (SWME) are considered as combined diagnostic tools to diagnose DPN, a single effective screening method to identify DPN is quite unavailable in India. **Aim and Objective:** This study aimed to evaluate the usefulness of the SWME in DPN when compared to VPT. **Materials and Methods:** Fifty control subjects and 50 DPN subjects aged between 30 and 70 years were included in the study. The anthropometric parameters, fasting blood sugar (FBS), duration of diabetes mellitus, VPT, and the SWME were recorded. **Results:** There was a significant difference in body mass index, FBS, VPT, and SWME in DPN subjects ($P < 0.0001$) when compared with control subjects. The increased duration of DPN increases the VPT (0.805) values and decreases the SWME (−0.488) values. In the kappa test, the measure of agreement between SWME and VPT was significant (0.960), meaning both tests are equally effective in screening DPN subjects. **Conclusion:** The present findings show that SWME can be used as a single effective screening tool in diagnosing DPN when compared with VPT. This can reduce the risk of ulceration and lower extremity amputation in DPN subjects at the earliest.

KEY WORDS: Diabetic Peripheral Neuropathy; Semmes-Weinstein Monofilament Examination; Vibration Perception Threshold

INTRODUCTION

Diabetic peripheral neuropathy (DPN) with peripheral nerve dysfunction is a common microvascular complication due to type 2 diabetes mellitus (DM).[1,2] The prevalence of DPN in India varies widely from 9.6% to 78% in different study groups because DPN patients tend to neglect the subtle signs of nerve damage, thinking it as a part of age-related changes. Furthermore, DPN is a significant independent risk factor for 15% diabetic foot ulcers and more than 50% non-traumatic amputations which lead to increased morbidity and mortality.[2-5] Although physicians use validated questionnaires such as Michigan Neuropathy Screening Instrument or clinical examinations such as nerve conduction study (NCS), vibration perception threshold (VPT), pinprick, and ankle reflex to diagnose DPN, as of now no single screening test is available.

The previous studies showed Semmes-Weinstein monofilament examination (SWME) and VPT together as a combined effective tool in identifying DPN.[6] To perform

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VPT, costly instrument with the adequate power source is required. On the contrary, an attractive option is SWME as it is a non-invasive, cheap, quick, and easy-to-perform test often used in primary health care and clinical testing for routine DPN assessment. The 5.07/10 g monofilament is applied to the site perpendicularly until it bends for about a second. The cost of disposable monofilaments used in SWME is around $0.50 (Rs 38) when compared to other costly tests.[7] Hence, we have designed this study to assess the usefulness of SWME as a single objective tool for screening DPN patients at the earliest when compared with VPT.

MATERIALS AND METHODS

This is a case–control study with 100 subjects. The ethical clearance from the Ethical Committee of Annapoorna Medical College and Hospital was obtained. The patients in the age group of 30–70 years with established type 2 diabetes (the WHO criteria)[8] with duration more than 3 years and DNS score of 1 or higher from Annapoorana Medical College and Hospital were recruited. Fifty such DPN subjects were considered for the study. Fifty age, height, and sex-matched healthy subjects with fasting blood sugar (FBS) <100 mg/dl, and DNS score 0 were included in the control group. Informed consent was taken from all subjects. Those with symptoms related to other neuropathies, chronic renal failure, previous spinal injury, history of cervical or lumbar discopathies, history of Vitamin B12 or folate deficiency, history of alcohol abuse, and skin diseases (neurodermatitis, psoriasis, scleroderma and allergy to metals, Raynaud syndrome, hyperhidrosis, or acrocyanosis) were excluded from the study.

SWME

Light touch/pressure perception was assessed using a 5.07/10 g monofilament which was devised in 1960 with some modifications.[9,10] The participant was blinded to the presentation of the SWME, and a "Yes/No" method was used for testing. The monofilament was applied on both feet centrally at the heel and on the plantar surface of the hallux. The end of the filament was pressed centrally at the heel and on the plantar surface of the hallux with enough pressure to make the monofilament to buckle for about a second. This was completed 6 times at each point. The patient says yes each time when he/she perceives the stimulus of the monofilament, and no, he/she does not sense the stimulus. The ability to appropriately sense the SWME in six trials on the plantar surface of the hallux and centrally at the heel was found to be normal, whereas the inability to perceive the monofilament appropriately in one or more trials was defined as disturbed.

VPT

VPT was performed using a hand-held biothesiometer (Sensitometer, Dhansai Lab, Mumbai). The patient was made to relax in a supine position in a quiet room, and the procedure was explained. The vibration was augmented gradually from the lowest voltage, and the changeover from no vibration to the start of sensing vibration was taken as VPT. Here also, "Yes/No" method was used. The VPT is tested on the recommended six areas on the plantar aspect of both the feet – the hallux, the 1st metatarsal head, the 3rd metatarsal head, the 5th metatarsal head, the instep, and the heel. An average of all the areas examined was taken as the VPT of the subject. A voltage of more than 25 mV was taken as the presence of neuropathy.[11]

Statistical Analysis of Data

Statistical analysis was performed by SPSS software version 26 (SPSS; SPSS Inc., Chicago, IL, USA) for Windows. The data were subjected to the Kolmogorov–Smirnov normality test. All the data were expressed as mean ± SD with student *t*-test. SWME and VPT in DPN subjects were correlated with FBS, body mass index (BMI), and duration of DPN using Pearson's correlation analysis. Kappa test was performed between SWME and VPT.

RESULTS

There was a significant difference in BMI, FBS, VPT, and SWME in DPN subjects ($P < 0.0001$) when compared with control subjects [Table 1]. Pearson correlation showed no significant correlation of SWME with FBS and BMI. The duration of DPN was positively correlated with VPT (0.805) and negatively correlated with SWME (−0.488), meaning decreased perception of stimulus at various sites. Furthermore, VPT and SWME were negatively correlated [Table 2]. In the kappa test, the measure of agreement between SWME and VPT was significant (0.960), meaning both tests were equally effective in screening DPN subjects [Table 3].

DISCUSSION

In the present study, the BMI, FBS, VPT, and SWME in DPN subjects were significantly higher ($P < 0.0001$) compared to normal subjects [Table 1]. There was no statistical significance between the correlation of SWME, BMI, and FBS as the DPN subjects were under strict glycemic control [Table 2]. The infiltration of glucose in large diameter nerve fibers and disruption of Meissner's corpuscles and Merkel touch domes proprioceptors in long-standing DPN showed the decreased perception of SWME and increased duration of VPT [Table 2]. While the use of VPT is quantitative and widely accepted, it is still expensive, requires calibration, and power source and has poor repeatability in the same subject. Since DPN is an explicit form of axonal neuropathy related to diabetes which is defined clinically by the progressive disease that first comprises distal and symmetrical peripheral neuropathy of sensory nerve fibers,[12] selecting a rapid, reasonable, and

Table 1: Comparison of BMI, FBS, VPT, and SWME between control and DPN subjects

Parameters	Controls (*n*=50)	DPN (*n*=50)	*P* value
BMI (Kg/m^2)	24.28±2.57	24.76±2.45	<0.00001***
FBS (mg/dl)	83.40±7.67	136.98±14.05	<0.00001***
VPT (mV)	20.28±2.23	36.94±7.51	<0.00001***
SWME	7.92±0.27	5.98±1.10	<0.0001**

Values expressed as mean±SD. Analysis done by one-way ANOVA. *Comparison of controls with diabetic peripheral neuropathy subjects. *P<0.05, **P<0.0001, ***P<0.00001; BMI: Body mass index, FBS: Fasting blood sugar; VPT: Vibration perception threshold, SWME: Semmes-Weinstein monofilament examination

Table 2: Correlation of SWME and VPT with BMI, FBS, and duration of DPN

Parameters	VPT	SWME
BMI (Kg/m^2)	−0.020	0.245
VPT	1	−0.379**
SWME	−0.379**	1
FBS	−0.045	0.021
Duration of DPN	0.805**	−0.488**

**Correlation is significant at the 0.01 level (two-tailed) BMI: Body mass index, VPT: Vibration perception threshold, SWME: Semmes-Weinstein monofilament examination, FBS: Fasting blood sugar, DPN: Diabetic peripheral neuropathy

Table 3: Measure of agreement between SWME and VPT

Variables		Value	Asymp. std. error[a]	Approx. T[b]	Approx. sig.
Measure of agreement	Kappa	0.960	0.028	9.608	0.000
N of valid cases		100			

[a]Not assuming the null hypothesis, [b]Using the asymptotic standard error assuming the null hypothesis. SWME: Semmes-Weinstein monofilament examination, VPT: Vibration perception threshold

precise instrument is needed to detect DPN subjects. Hence, apart from VPT, we used SWME for screening DPN subjects which have sensitivity 95% and specificity 82%.[13,14] To the best of our knowledge, the outcome of our present study revealed for the first time that SWME and VPT were equally effective in detecting DPN subjects [Table 3].

Our study is supported by the International Diabetes Federation, the Center for Medicare and Medicaid Services, and the World Health Organization[15] who recommends SWME as a tool to test the feet with DPN to prevent foot ulcers. Moreover, our study concurs with Holewski *et al*.[16] and Kumar *et al*.[17] who also used 5.07/10 g monofilament to detect DPN and set the diagnostic threshold for detecting SWME.[17] Furthermore, three prospective studies obtained the same conclusion, declaring that SWME as a single tool to detect the increased risk of foot ulceration.[18-20] However, studies done by Dros *et al*.[21] and Wang *et al*.[22] suggested that SWME has limited sensitivity due to lack of reliable criterion standard, in detecting DPN subjects, which was counterintuitive to our study. Furthermore, studies done by Jayaprakash *et al*.[23] and others concluded that combined bedside clinical tests increase sensitivity and accuracy and show the good correlation in identifying DPN subjects that do not corroborate with our reports.

While many inconsistencies occur in the existing literature concerning SWME, in India, our study is the first to show SWME as a more objective single screening method with the possible merits of cheap, quick, simple, easy to perform, painless, and accurate test during a physical examination with practical reproducibility and less time-consuming procedure. Furthermore, SWME allows DPN to be identified before evidence of visual signs such as calluses and foot deformities. Based on cost $61.31 (Rs 4636) and availability of NCS[24] and VPT, we recommend SWME as a wiser option for many speciality and primary care physicians to detect DPN subjects. Furthermore, when DPN is identified by SWME at the earliest, intensive foot-care education and suitable therapeutic footwear can be given to DPN subjects that can reduce the risk of foot ulceration by 60% and limb amputation by 85%.[25] However, the limitations of our present study are due to the variability in alteration in testing procedures, application of SWME (site, number, and definitive thresholds), standard references, and the interval between screening DPN and quantitative analysis. The optimal level of screening by SWME can be influenced by changes in cutaneous morphology, especially in developing countries like India, was foot care practices was scarcely followed, and barefoot walking is still common. A large cross-sectional study should also be performed to validate the diagnostic value of SWME.

CONCLUSION

The SWME method may be the first alternative to NCS in the initial evaluation of DPN subjects. Ultimately, SWME is an effective single screening tool for diagnosing DPN, as the detection of subtle signs of DPN at the earliest could decrease the controllable microvascular complication of type 2 DM, thereby improving the quality of life in DPN patients when compared with VPT.

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