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Easier operation and similar power of 10 g monofilament test for screening diabetic peripheral neuropathy

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Abstract

Objective: The 10 g Semmes–Weinstein monofilament evaluation (SWME) of 4 sites on each foot is recommended for distal symmetric polyneuropathy screening and diagnosis. A similar method has been proposed to diagnose 'high-risk' (for ulceration) feet, using 3 sites per foot. This study compared the effectiveness of SWME for testing 3, 4 and 10 sites per foot to identify patients with diabetic neuropathy.

Methods: We included 3497 subjects in a SWME of 10 sites; records from the 10-site SWME were used for a SWME of 3 and 4 sites. Neuropathy symptom scores and neuropathy deficit scores were evaluated to identify patients with diabetic peripheral neuropathy.

Results: The sensitivities of the 10 g SWME for 3, 4 and 10 sites were 17.8%, 19.0% and 22.4%, respectively. The Kappa coefficients for the SWME tests of 3, 4 and 10 sites were high (range: 0.78–0.93).

Conclusions: There were no significant differences in the effectiveness of 3-, 4- and 10-site SWME testing for diabetic peripheral neuropathy screening. SWME testing of 3 sites on each foot may be sufficient to screen for diabetic neuropathy.

Keywords

Diabetic peripheral neuropathy, diabetes, 10 g Semmes–Weinstein monofilament evaluation, sensitivity, specificity, polyneuropathy screening

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Introduction

Diabetic peripheral neuropathy (DPN) is a significant independent risk factor for diabetic foot ulcers, which are the main cause of lower extremity amputation in patients with diabetes.[1,2]

The 10 g Semmes–Weinstein monofilament evaluation (SWME) is commonly used to assess the loss of protective sensation and to screen for DPN in clinical practice.[3] However, there is no consensus on the most valid method of using the 10 g SWME and previous studies have used the SWME on 3,[4,5] 4[6,7] and 10 sites[8–10] on each foot.

Screening for DPN using the 10 g SWME on 10 sites is complicated and time-consuming, increasing both operator workload and patient burden. Furthermore, the 2017 position statement by the American Diabetes Association has recommended that distal symmetric polyneuropathy screening and diagnosis should be conducted using the 10 g SWME on 4 sites on each foot, and has recommended similar methods for diagnosing 'high-risk' (for ulceration) feet using 3 sites on each foot.[11] It is therefore difficult for clinicians to choose the best method of using the 10 g SWME to screen for DPN. A comparison of these different methods of using the 10 g SWME is needed to help clinicians choose the easiest and most effective method.

In this study, we hypothesized that the 3-site SWME is the easiest and most powerful way to screen for DPN. The study aim was to compare the effectiveness of SWME for testing 3, 4 and 10 sites on each foot to identify patients with DPN.

Research design and methods

Study population

The study population was enrolled from the ShangHai Diabetic neuRopathy Epidemiology and Molecular Genetics Study (SH-DREAMS)[12] and the Jing'An District-Medical-Service-Union Study (Jing'An-DMSU). These two studies were both conducted by our group in urban Shanghai communities. In the SH-DREAMS, 2035 non-pregnant residents aged >25 years without type 1 diabetes or renal failure were enrolled from two communities from July 2011 to May 2012. Of these, there were 453 patients with diabetes mellitus (DM), 604 patients with pre-diabetes mellitus (Pre-DM) and 978 patients without diabetes. In the Jing'An-DMSU, 1462 community residents who had a self-reported type 2 diabetic history or were found to have abnormal results in an oral glucose tolerance test (OGTT) during community screening were enrolled from five communities from January 2012 to December 2016 (Supplement).

All individuals had a 10 g SWME conducted on 10 sites on each foot; additionally, neuropathy symptom scores (NSS) and neuropathy deficit scores (NDS) were obtained. All subjects provided written informed consent and this study was approved by the Huashan Hospital Ethics Committee.

Anthropometric measurements

All subjects completed a questionnaire to collect demographic information. A physical examination was conducted to record height and weight.

Laboratory measurements

A fasting venous blood sample was collected from all subjects. Subjects recruited from the SH-DREAMS received a 75-g OGTT, except for those with a validated history of diabetes, who received a 100-g steamed bread meal test. All subjects from the Jing'An-DMSU received a 75-g OGTT. Levels of glycated hemoglobin (HbA1c) were measured via high-pressure liquid

chromatography using an analyzer (HLC-723G8, Tosoh Corporation, Japan).

Neuropathy symptom score (NSS)/ neuropathy deficit score (NDS)

DPN was evaluated using the NSS and NDS, which have been described previously.[12] The NSS/NDS have been used to screen DPN in several studies[13,14] and correlate well with nerve conduction results.[15] The NSS reflects symptoms of burning, numbness, tingling, fatigue, cramping and aching. The NDS reflects symptoms of a sense of vibration, pain, temperature sensations and ankle jerk reflexes.

10 g Semmes–Weinstein monofilament evaluation

All operators who performed the 10 g SWME, NDS and NSS evaluations were trained according to standard operating procedures. The SWME was performed on 10 sites on each foot: the plantar surfaces of the first (NO. 1), third (NO. 2) and fifth digits (NO. 3); the plantar surfaces of the first (NO. 4), third (NO. 5) and fifth metatarsal heads (NO. 6); the plantar medial side of the mid-foot (NO. 7); the plantar area of the heel (NO. 8); the dorsal medial side of the mid-foot (NO. 9); and the dorsal surface of the foot between the base of the first and second toes (NO. 10). Based on the results of the 10-site evaluation, the following procedure was used.

Patients responded affirmatively each time they felt the application of the monofilament. Measurements were taken at each of 10 sites on each foot. If patients did not perceive the monofilament on any of the test sites, the SWME was classed as abnormal.[9] The SWME was additionally conducted for 3 (NO. 1, NO. 4, NO. 6) and 4 (NO. 1, NO. 4, NO. 5, NO. 6) sites on each foot chosen from the 10 sites.

Definitions

DM was diagnosed according to 2012 American Diabetes Association standards.[16] Pre-DM was defined as a fasting plasma glucose level of 5.6–6.9 mmol/L, a 2-hour postprandial glucose level in the 75-g OGTT of 7.8–11.0 mmol/L and/or a HbA1c level of 5.7%–6.4%.

DPN was diagnosed according to the NSS/NDS results: NDS $\geq$3 and NSS $\geq$5 or NDS $\geq$6.[14,17]

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics, Version 22.0 (IBM Corp., Armonk, NY, USA). Normally distributed and continuous variables were expressed as means $\pm$ standard deviations and categorical variables were presented as frequencies and proportions. Kappa coefficients were used to measure the level of agreement of the 10 g SWME test results among the 3, 4 and 10 sites. Sensitivity and specificity of the 10 g SWME for the various sites were calculated using the NSS/NDS as a standard method to diagnose DPN; differences between the site sensitivities were evaluated using receiver operating characteristic curves. P values <0.05 were considered statistically significant.

Results

Of those enrolled (n = 3497: 2035 from SH-DREAMS and 1462 from Jing'An-DMSU), 1915 and 604 subjects were diagnosed with DM and Pre-DM, respectively, and the remaining 978 subjects did not have DM. Based on the results of the NSS and NDS evaluations, 174 subjects were diagnosed with DPN (Table 1).

The SWME had low sensitivities (17.8%, 19.0%, 22.4%, respectively) and high specificities (96.2%, 95.6%, 94.2%, respectively) for the testing of 3, 4 and

Table 1. Clinical characteristics of the study population

	DPN group (n = 174)	Non-DPN group (n = 3323)	*P*
Age (y)	74.07 ± 9.41	64.67 ± 10.78	<0.001*
Male/Total	71/174 (40.8%)	1335/3323 (40.2%)	0.869
Diabetic duration (y)	10.26 ± 9.85	5.80 ± 8.33	<0.001*
Smoking	24/174 (13.8%)	549/3323 (16.5%)	0.343
Alcohol drinking	8/174 (4.6%)	192/3323 (5.7%)	0.513
BMI (kg/m^2)	23.75 ± 7.11	24.47 ± 57.75	0.870
HbA1c (mmol/L)	5.80 ± 3.40	5.61 ± 2.76	0.454
Abnormal percentage of SWME (10 sites)	39/174 (22.4%)	194/3323 (5.8%)	<0.001*
Abnormal percentage of SWME (3 sites)	31/174 (17.8%)	126/3323 (3.8%)	<0.001*
Abnormal percentage of SWME (4 sites)	33/174 (19.0%)	148/3323 (4.5%)	<0.001*

*$P < 0.001$. DPN: diabetic peripheral neuropathy; BMI: body mass index; HbA1C: glycated hemoglobin; SWME: Semmes–Weinstein monofilament evaluation.

Table 2. Sensitivity and specificity of the 10 g SWME for tests of 3, 4 and 10 sites

		Total (n = 3497)	DM (n = 1915)	Pre-DM (n = 604)	Non-DM (n = 978)
DPN/Total		174 (5.0%)	135 (7%)	27 (4.5%)	12 (1.2%)
Sensitivity %	3-site SWME	17.8	11.1	29.6	66.7
	4-site SWME	19.0	12.6	29.6	66.7
	10-site SWME	22.4	16.3	29.6	75.0
Specificity %	3-site SWME	96.2	98.0	93.9	94.3
	4-site SWME	95.6	97.6	92.9	93.3
	10-site SWME	94.2	97.0	90.1	91.4

Sensitivities and specificities of the 10 g SWME were calculated based on the results of the neuropathy symptom scores and neuropathy deficit scores. DM, diabetes mellitus; DPN, diabetic peripheral neuropathy; SWME, Semmes–Weinstein monofilament evaluation.

10 sites in all subjects (Table 2). Similarly, low sensitives and high specificities of the 10 g SWME were also observed in patients with DM, patients with Pre-DM and patients without DM. There were no statistically significant differences between the sensitivities of the SWME for the testing of 3 and 10 sites, or for 4 and 10 sites (Table 3).

The Kappa coefficients for the SWME for the testing of 3, 4 and 10 sites were high (range: 0.78–0.93; Table 4) for the total population, patients with DM, patients with Pre-DM and patients without DM.

Table 3. Differences between the sensitivities of the 10 g SWME for tests of 3 and 10 sites, and 4 and 10 sites

	χ^2	*P*
3-site vs 10-site SWME	2.5077	0.113
4-site vs 10-site SWME	2.1673	0.141

Data obtained from receiver operating characteristic curves. SWME, Semmes–Weinstein monofilament evaluation.

Discussion

To the best of our knowledge, no other studies have compared the effectiveness of

Table 4. Kappa coefficients of the 10 g SWME for diagnosing DPN for tests of 3, 4 and 10 testing sites

	Total (n = 3497)	Without DM (n = 978)	Pre-DM (n = 604)	DM (n = 1915)
3 sites–10 sites	0.794	0.797	0.777	0.797
4 sites–10 sites	0.867	0.874	0.845	0.870
3 sites–4 sites	0.925	0.921	0.929	0.925

DM, diabetes mellitus; DPN, diabetic peripheral neuropathy; SWME, Semmes–Weinstein monofilament evaluation.

10 g SWME tests for 3, 4 and 10 sites to identify patients with DPN. There were no statistically significant differences in SWME sensitivities for tests of 3 and 10 sites, or for tests of 4 and 10 sites. Our findings indicate that the three SWME methods were equally effective for screening DPN patients. Furthermore, the SWME test results for 3, 4 and 10 sites showed good agreement (Kappa coefficients: 0.78–0.93).

Owing to a lack of consensus on SWME methods, the number of testing sites used vary considerably between studies. Miranda-Palma et al.[6] found that testing 4 sites identified 86% of patients with one or more insensate sites. Another study found a 30% sensitivity of the 3-site SWME for DPN screening.[5] Lee et al.[10] found a sensitivity of 93.1% for the 10-site SWME. However, we found no differences in the effectiveness of the SWME for identifying patients with DPN, regardless of the number of sites tested. The 3 sites tested in the present study are high-risk areas for diabetic foot ulcers[13] and were thus deemed acceptable for DPN screening. A review by Feng et al. recommended a 3-site SWME test to maximize the diagnostic value of the 10 g SWME.[14] In contrast, Tan et al. have suggested that the 4-site SWME test is more effective.[15] However, these previous studies did not compare the effectiveness of the SWME using different sites to screen for DPN, as we did in the present study. Testing only 3 sites using the 10 g SWME saves time and reduces operator workload, compared with 4- and 10-site SWME testing.

This study had some limitations. We used the NSS and NDS evaluations as the gold standard for DPN screening. Compared with nerve conduction tests, the NSS/NDS are less objective and have lower specificity. However, the NSS/NDS are more appropriate for DPN screening in large populations, and are widely considered the gold standard in epidemiological investigations. Moreover, the percentage of patients with DPN in our study was low and may have affected the study results. Finally, we did not conduct separate SWME testing on 3 and 4 sites; the 10 g SWME test results for 3 sites and 4 sites were obtained from the records of the 10-site SWME.

We found no differences in the effectiveness of 3-, 4- and 10-site SWME testing for DPN screening. SWME testing using 3 sites on each foot may save time and reduce operator workload, and is therefore recommended.

Author contributions

Qi Zhang, Yiming Li, Renming Hu, Hongying Ye, Linuo Zhou and Lu Bin conceived and designed the study. Qi Zhang, Jie Wen, Xiaoxia Liu and Shuo Zhang analyzed the data. Qi Zhang and Bin Lu wrote the manuscript.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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