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ORIGINAL ARTICLE

Screening patients at risk for diabetic foot ulceration: a comparison between measurement of vibration perception threshold and 10-g monofilament test

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Abstract

The aim is to compare the frequency of increased vibration perception threshold (VPT) with abnormal 10-g Semmes-Weinstein monofilament (SWF) testing in a non-selected diabetic population, and to assess the agreement between these two screening methods. VPT was measured using a neurothesiometer at the pulp of the hallux and 10-g SWF was applied on three plantar sites on each foot according to the guidelines of the International Working Group on the Diabetic Foot, in 400 consecutive diabetic patients. VPT was considered as abnormal if ≥25 V and SWF was considered as abnormal if the patient was unable to feel ≥2 applications at a single site.
Both tests were normal in 240 patients (60%) and both abnormal in 78. In 21 patients, only SWF was abnormal whereas only VPT was abnormal in 61. As a whole, 160 patients (40%) were considered at risk for foot ulceration by VPT and/or SWF. Agreement between the two screening methods was only moderate with a kappa coefficient of 0·52 (95% CI: 0·43–0·60). Using VPT as a predictor for foot ulceration, the number of patients at risk is much higher than identified by SWF. This discrepancy might have potential effects on costs and prevention policies.

Introduction

Many cross-sectional and cohort studies have clearly shown that the loss of foot protective sensation (LOPS) due to peripheral sensory neuropathy is associated with and predictive of diabetic foot ulceration (DFU) and amputation (1,2). Thus, identification of LOPS in diabetic patients is of paramount importance to implement specific actions in order to prevent foot problems. Nevertheless, there is no consensus about the methods to be adopted to identify LOPS (3,4). Indeed, many screening instruments have been proposed (2,4,5–7). Inexpensive, easy and rapid to administer and well validated, the Semmes-Weinstein filament (SWF) remains the most widely used instrument to screen for LOPS (1,8,9) but determination of vibratory perception threshold (VPT) has also been advocated as a valuable means to identify diabetic patients at risk of ulceration (10). While both tools are supposed to test

Key Messages

- many cross-sectional and cohort studies have clearly shown that the loss of foot protective sensation (LOPS) due to peripheral sensory neuropathy is associated with and predictive of diabetic foot ulceration (DFU) and amputation
- thus, identification of LOPS in diabetic patients is of paramount importance to implement specific actions in order to prevent foot problems
- this study aimed to compare VPT and SWF results in diabetic patients and to assess agreement between the two tests
- from April 2009 to December 2010, all diabetic patients consecutively assessed for risk of foot ulceration were retrospectively included in the study
- four hundred patients were included in the study

- the main result of this study is the lack of agreement between SWF and VPT to identify diabetic patients at risk for foot ulceration
- the difference in prevalence of neuropathy in the selected population may account for the conflicting results regarding diagnostic performance of screening tests
- from a practical point of view, SWF has some advantages over VPT measurement as it is more rapid and easier to perform, is inexpensive and does not require special skills; on the other hand, SWF gives only a binary response and does not quantify the severity of neuropathy
- whatever the pros and cons of both tests, the lack of a reference screening method is a problem
- from our study, it is not possible to determine the most accurate test among VPT and SWF for prediction of DFU
- Thus, a prospective study is urgently needed to assess the reference test to be used for identifying diabetic patients at risk of foot ulceration and to determine more rationally the patients in whom preventive measures must be taken

the function of $A_{\alpha\beta}$ large myelinated sensory axons, results of clinical studies are conflicting: some claimed that SWF test is more accurate for detecting diabetic peripheral sensory neuropathy (11, 12) whereas others favoured assessment of vibration perception (13). However, studies directly comparing these two instruments are scarce and comparison between studies is difficult due to differences in design, population and endpoints. In a cross-sectional study, it was shown that insensitivity to SWF was more sensitive than a VPT value $\geq$25V to detect patient with a current or prior history of DFU (11); on the contrary, Miranda-Palma *et al*. (14) found that a VPT $\geq$25V had a higher sensitivity than SWF for identifying diabetic patients with foot ulceration. Overall, all these studies suggest that SWF test and assessment of vibration perception are not equivalent and interchangeable to detect diabetic patients at risk of foot ulceration; nevertheless, the International Working Group on the Diabetic foot (IWGDF) recommend to use either of these two tests for screening patients at risk of DFU (15). This study aimed to compare VPT and SWF results in non-selected diabetic patients and to assess agreement between the two tests.

Patients and methods

Study population and methods

From April 2009 to December 2010, all diabetic patients consecutively assessed for risk of foot ulceration were retrospectively included in the study. They were theoretically free from DFU but in a few people ulceration was ascertained for this purpose. All patients were screened for sensory neuropathy using both 10-g SWF and biothesiometry. SWF examination was performed according to the IWGDF recommendations (15) using validated 10-g monofilaments (Bailey Instruments, Chorlton, Manchester, UK) (16). Three sites (the pulp of the hallux and the plantar aspect of the first and fifth metatarsal head) on both feet were tested; on each site, the monofilament was applied three times in a random order. Patients were asked if they felt the pressure (yes/no) and on which foot (right/left) they felt the sensation. The answer was considered incorrect if the patient did not feel the contact or if he was wrong about the site of application. Peripheral sensation was considered impaired if at least two of three answers were incorrect, even on one of the three sites, and then the patient was graded at risk of foot ulceration. VPT was assessed using a Horwell neurothesiometer. After the patient was familiarised with the vibration sensation by applying the rubber tractor on the wrist and tuning the amplitude to its maximum (50 V), the vibrating probe was held perpendicularly in contact with the pulp of the hallux and the amplitude of vibration was gradually increased from 0 until the patient said that he felt it. Both feet were tested three times in a random order and the VPT for each foot was determined as the average value of the three measurements. According to Young *et al*., patients were considered at risk of foot ulceration if VPT was $\geq$25 V, as this value is associated with an eightfold increased ulcer risk (17).

All the tests were performed in the same room, in a relaxed atmosphere, by the same two experimented research nurses (LR and MG).

Statistical analysis

Quantitative data were described by their mean $\pm$ standard deviation and range values; qualitative data were given by numbers and percentages. Results of SWF and VPT were converted in binary variables (preserved versus impaired peripheral sensation).

The relationship between VPT on the right and left feet was assessed by simple linear regression and agreement by Bland and Altman plot (18). Agreement between the two tests was assessed by the Kappa statistics (κ) and its 95% confidence interval (95% CI). According to Landis and Koch (19), agreement was poor for $\kappa \leq 0$, slight for κ between 0·01 and 0·20, fair for κ between 0·21 and 0·40, moderate for κ between 0·41 and 0·60, substantial for κ between 0·61 and 0·80 and almost perfect for $\kappa > 0{\cdot}81$.

Using VPT values higher than 25 V as the reference standard, diagnostic performances (sensitivity, specificity, positive and negative predictive values, false-positive and false-negative rates) of 10-g monofilament testing were assessed. *P* value was considered statistically significant at a level $\leq$0·05.

Results

Four hundred patients were included in the study. Patients' characteristics are listed in Table 1. Of the patients, 95% were suffering from type 2 diabetes. The duration of diabetes ranged from <1 to 58 years, with a mean of 13 years. The range of age was also wide from 21 to 90 years. Thirty-three patients had an ongoing ulcer which was recurrent in 13; 16 patients had a prior history of foot ulceration with no active lesion at the inclusion.

Table 1 Patient characteristics

Characteristics	
Men/women	188 (47%)/212 (53%)
Age (years)	63 ± 12 [21–90]
Type of diabetes (1/2)	22 (5·5%)/378 (94·5%)
Duration of diabetes (years)	13 ± 12 [0–58]
HbA1c level (%)	8·0 ± 1·9 [4·8–17]
History of foot ulceration	49 (12·3%)

Data are *n* (%) or means ± SD with range in square brackets.

VPT values on the right and left feet were closely related with a correlation coefficient of 0·84; Bland and Altman plot showed a rather good agreement between measurements on the right and left feet with a mean difference of 0·09 V. However, visual inspection showed wide individual variations: the standard deviation of the differences was 6·8 V giving a value of −13·5 and 13·7 V for the lower and upper limits of agreement, respectively.

As shown in Table 2, VPT identified 139 patients at risk for foot ulceration compared with 99 using SWF. VPT was significantly higher in patients with impaired peripheral sensation defined by SWF (37·7 ± 12·1 V) than in those with preserved peripheral sensation (17·4 ± 9·8 V); there was no statistically significant difference for age and diabetes duration between these two groups. Peripheral sensation was found preserved in 240 patients (60%) and impaired in 78 (19·5%) by both VPT and SWF examinations, corresponding to a concordance rate of 79·5%. Twenty-one patients (5·3%) were considered at risk of foot ulceration by SWF alone as opposed to 61 (15·3%) by VPT alone. Using VPT and/or SWF results, 160 patients were deemed at risk for DFU, 38·1% by VPT only, 13·1% by SWF only and 48·8% ($n = 78$) by both tests. Using a neurothesiometer reading higher than 25 V as the reference standard for detection of LOPS, sensitivity and specificity of 10-g monofilament testing were 56% and 92%, respectively; positive and negative predictive values were 79% and 80%, whereas the false-positive and false-negative rates were 8% and 44%, respectively.

In patients with a current or prior history of foot ulceration ($n = 49$), 31 (63·3%) had an impaired peripheral sensation using SWF and 36 (73·5%) using VPT; 26 patients had impaired sensation using both tests, whereas 5 patients had only an abnormal SWF test and 10~~9~~ only a VPT >25 V. Hence so 41 patients with a history of foot ulceration (84%) had an impairment of peripheral sensation using SWF and/or VPT. Concordance rate between SWF and VPT results was 69·4% (Table 3).

Table 2 Comparison between SWF and VPT testing in the study population

		VPT		
		≥25 V	<25 V	Total
SWF	Impaired sensation	78	21	99
	Preserved sensation	61	240	301
	Total	139	261	400

Table 3 Comparison between SWF and VPT testing in diabetic patients with a past or current foot ulcer

		VPT		
		≥25 V	<25 V	Total
SWF	Impaired sensation	27	5	32
	Preserved sensation	9	8	17
	Total	36	13	49

Table 4 Agreement of SWF and VPT in the whole population and according to sex, diabetes type and duration, age and HbA1c level

	N	Kappa coefficient
Total population	400	0·52 [0·43–0·60]
Men	188	0·47 [0·35–0·59]
Women	212	0·52 [0·38–0·.66]
Type 1 diabetes	22	0·58 [0·16–1·00]
Type 2 diabetes	378	0·51 [0·42–0·60]
Age ≤50 years	55	0·84 [0·62–1·00]
Age >50 years	345	0·48 [0·39–0·57]
Diabetes duration ≤5 years	128	0·72 [0·55–0·88]
Diabetes duration >5 years	272	0·44 [0·33–0·54]
HbA1c level <8%	224	0·53 [0·41–0·65]
HbA1c level ≥8%	176	0·49 [0·35–0·62]

95% CI in square brackets.

The agreement between VPT and SWF was moderate, as shown by a kappa coefficient of 0·52 (95% CI: 0·43–0·60). The latter kappa coefficient was not significantly influenced by the sex, the type of diabetes or the HbA1c level whereas its value was higher in patients older than 50 years and with diabetes duration longer than 5 years (Table 4).

Discussion

The main result of this study is the lack of agreement between SWF and VPT to identify diabetic patients at risk of foot ulceration. Indeed as a whole, 139 of 400 patients were identified as having impaired sensation based on VPT values compared with only 99 based on SWF results. Moreover, 21 patients were considered at risk only when using SWF in isolation as opposed to 61 when testing only VPT. Finally, agreement between VPT and SWF as assessed by kappa statistics was just moderate. Such a discrepancy looks rather surprising as both VPT and SWF are supposed to test the integrity of large myelinated fibre ($A_{\alpha\beta}$) function via Meissner and Pacinian corpuscles, to accurately detect LOPS and were shown to be predictive of the risk for foot ulceration in diabetic individuals (1,2,3,8,20). Olaleye *et al*. showed that SWF and vibration perception tests had similar diagnostic performances for predicting diabetic peripheral neuropathy defined by abnormal nerve conduction (21). Nevertheless, results are difficult to compare with our own findings, as vibration perception was tested using a 128 Hz tuning fork by the on–off method and SWF was applied four times only on a single site on each foot, on the dorsum of the first toe. In a more recent study of a cohort of 175 diabetic patients without baseline neuropathy whom were followed-up during

4 years, it was shown that SWF examination had a better overall diagnostic accuracy than VPT measurement to predict the incidence of diabetic neuropathy diagnosed on clinical and electrophysiological criteria (11); however, for a cut-off level of ≤5 sensate stimuli, the specificity was rather low (64%) and the positive predictive value was really poor (46%). Finally, in a Swedish study, prevalence of peripheral neuropathy was two times more frequent using VPT value ≥25 V as diagnostic criteria than using SWF (22).

Paisley *et al*. (23) in an observational study showed that inability to feel more than two out of ten SWF applications (two applications on five sites on the plantar aspect of each foot) detected a VPT ≥ 25V with a high sensitivity (91%) but a specificity of only 64%; hence, both tests were concordant in 93 of 123 patients (76%); both were abnormal in 49 patients, whereas 25 had only abnormal SWF and 5 only a VPT ≥ 25 V. On the other hand, in a study on 1044 consecutively included diabetic patients, Jayaprakash *et al*. reported that 10-g SWF had a high level of specificity of 99% but a low sensitivity (63%) and an overall accuracy of 78% for prediction of a VPT value ≥25 V (13), suggesting that abnormality of VPT alone was more frequent than that of SWF alone. These findings are in accordance with those of the present study in which sensitivity was low and specificity high: if VPT is considered as the gold standard to predict occurrence of DFU, then SWF might not be an appropriate screening test, as a high sensitivity level is of paramount importance in order not to miss at-risk patients. Moreover, Miranda-Palma *et al*. (14) found that 10-g SWF testing (≥1 insensate site/8) has a lower sensitivity but a higher specificity than a VPT ≥ 25 V for detecting foot ulceration and suggested that SWF may not be the optimum method for identifying individuals at risk of DFU. In accordance with the latter study, we found that a VPT ≥ 25 V was more sensitive but less specific than abnormal SWF testing to identify those patients with a past or current DFU among the whole population (data not shown). We are aware of only a single prospective study comparing performances of SWF and VPT for predicting DFU (19): inability to feel SWF at the hallux had a sensitivity close to VPT ≥ 25 at the same site but a lower specificity; false-positive rate was high (66% versus 44%). Gin *et al*. have compared SWF and VPT in a previous study similar to our own, in 250 consecutive patients (24): results of VPT and SWF were both abnormal in 33 patients whereas SWF only was abnormal in 5 and VPT only in 37. These findings are in agreement with those of our study, suggesting that neurothesiometer identify by far more patients with impaired peripheral sensation than did SWF and that VPT measurement might identify diabetic peripheral neuropathy at an earlier stage than SWF testing. Therefore, data from the literature are conflicting possibly because of differences in SWF testing regarding the methodology used for conducting the tests, the number and location of the sites to be tested, the number of applications per site and the criteria for defining an insensate foot (25). Moreover, it was shown that physical properties of SWF may vary according to the manufacturers or because of changes of external factors such as temperature or relative humidity (8,16,26–28). VPT measurement is more standardised but the cut-off value may differ among studies, though a value ≥25 V is generally considered as indicative of a significant peripheral neuropathy putting the foot at risk for ulceration (10). Nevertheless, some discrepancies have been reported between devices (29,30). In this study, the monofilaments used were those recommended in clinical practice (16) and the procedure adopted was recommended by the IWGDF (15). VPT was measured in accordance with Young *et al*. in their pivotal prospective study on prediction of DFU (17). However, a limitation in our study was that the cut-off value was set at 25 V, whereas VPT has been shown to increase with age (31): it is therefore possible that some readings were improperly considered abnormal because of the subjects mean age, explaining the high number of patients assessed at risk for DFU by VPT value alone. But, this hypothesis is unlikely as agreement between VPT and SWF was significantly better in people older than 50 years when compared with those younger than 50. The reported increase of VPT along the age might be linked to the well-established association between age and prevalence of neuropathy (32). The difference in prevalence of neuropathy in the selected population may account for the conflicting results regarding diagnostic performance of screening tests.

The discrepancy between results obtained by SWF and VPT is problematic with respect to costs, outcomes and implementation of preventive measures. Diabetic patients with VPT ≥ 25 V have been estimated to incur five times more direct medical costs for DFU and amputations (33). If insensitivity of SWF is retained as the sole predictor of DFU, it may be anticipated that costs would be lower. These costs might further decrease if LOPS is defined by abnormality of both SWF and VPT as recently suggested (4). Accordingly, Mc Gill *et al*. in a case–control study comparing diabetic patients with (neuropathy group) and without (control group) high VPT (>30 V) showed that annual incidence of ulceration was 0·5% in the control group, 4% in the neuropathic patients with high VPT but normal SWF testing and 10% in patients with both high VPT and abnormal SWF (34). Conversely, VPT screening alone might falsely detect patients at risk of DFU and increase educational and medical workload without benefit for patients.

From a practical point of view, SWF has some advantages over VPT measurement as it is more rapid and easier to perform, is inexpensive and does not require special skills; on the other hand, SWF gives only a binary response and does not quantify the severity of neuropathy. Neurothesiometry is time consuming, costs money but allows grading the severity of neuropathy: it is obvious that a VPT of 45 V indicate a more severe neuropathy (and hence a higher risk for foot ulceration) than a value of 25 V. Whatever the pros and cons of both tests, the lack of a reference screening method is a problem. From our study, it is not possible to determine the most accurate test among VPT and SWF for prediction of DFU. Very simple means are currently developed to assess peripheral sensory neuropathy in diabetes (35,36). Thus, a prospective study is urgently required to assess the reference test to be used for identifying diabetic patients at risk of foot ulceration and to

determine more rationally the patients in whom preventive measures must be taken.

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