The Tactile Circumferential Discriminator

A new, simple screening device to identify diabetic patients at risk of foot ulceration

L. VILEIKYTE, MD
G. HUTCHINGS, MD
S. HOLLIS, MSC
A.J.M. BOULTON, MD, FRCP

OBJECTIVE — To evaluate the tactile circumferential discriminator (TCD) (Tacticon Medical Enterprises, West Chester, PA), a new, simple, handheld quantitative sensory testing device, in the identification of patients at potential risk of neuropathic ulceration.

RESEARCH DESIGN AND METHODS — Patients with diabetes (n = 133) attending the Manchester Diabetes Centre or diabetic foot clinic seen within a 5-week period were assessed using the TCD, monofilaments, and vibration perception threshold (VPT) measured over the hallux. The sensitivity and specificity of each method in the identification of "high-risk" patients were compared.

RESULTS — The TCD was easy to use, and there was a highly significant correlation between the results obtained compared with both filaments and VPT ($P < 0.0001$). Similarly, in the identification of patients at risk of ulceration, the TCD agreed with VPT in 75.2% of cases and with the monofilaments in 78.9%. In the identification of the 37 foot ulcer patients, TCD was highly sensitive (100%) but less specific (58.3%) than VPT (86.5%; 79.2%) and the monofilaments (91.9%; 76.0%).

CONCLUSIONS — These data suggest that the TCD is a simple and reliable new technique for population screening for neuropathy and foot ulcer risk.

Foot ulceration is a common major complication of diabetes which is associated with significant morbidity and is the commonest reason for hospitalization of diabetic patients in the Western world (1,2). Amputation remains depressingly common among diabetic patients, and an alarming 50–70% of all nontraumatic amputations occur in diabetic patients, who, after age-adjustment, have an amputation rate 15 times higher than that of the general population (2,3). However, Pecoraro et al. (4) estimated that over 80% of amputations should be potentially preventable if appropriate screening and preventative measures were instituted. Peripheral neuropathy has been implicated as a major contributory factor in over 90% of foot ulcers (5), and as most amputations are preceded by ulceration, there is an urgent need to identify those "high-risk" neuropathic patients, particularly as a recent prospective study has confirmed that neuropathic patients have a sevenfold increased risk of ulceration (6).

The need for early identification and education of patients at risk of ulceration has recently been confirmed in a number of studies (7). Malone et al (8). reported that a 1-h education session for high-risk patients resulted in a threefold reduction in amputations over a 2-year period, and Barth et al. (9) confirmed that foot care education resulted in a significant fall in the incidence of new problems.

Quantitative sensory testing (QST) and electrophysiology can detect and quantify neuropathy (10), but many of these methods are time-consuming, requiring expensive equipment, while conventional clinical examination is subjective and relies mainly on the skills of the individual clinician (11). A simple, inexpensive, and effective screening device is therefore required for the routine detection of the diabetic patient with peripheral neuropathy in the physician's office.

Vibration perception threshold (VPT) measurement using the biothesiometer (Biomedical Instruments, Newbury, OH) or neuroesthesiometer (Scientific Laboratory Supplies, Nottingham, U.K.) is one possible measure, but is not inexpensive. The use of nylon monofilaments, first used in screening leprosy patients (12), has recently been studied in diabetic patients. The filaments, otherwise known as the Semmes-Weinstein monofilament esthesiometer (GW Long Hansen's Disease Center, Carville, LA), are modifications of the von-Frey hairs and consist of graded pressure-sensitive nylon filaments of increasing caliber that buckle at reproducible stresses. Inability to perceive the 10-g monofilament in the foot has been shown to be strongly associated with foot ulceration (13) and a reliable and sensitive predictor of foot lesions (14).

The tactile circumferential discriminator (TCD) (Tacticon Medical Enterprises, Inc., West Chester, PA) is a new, portable sensory testing device, consisting of a handheld disc with eight protruding rods of increasing circumference that tests large-fiber nerve function (two-point discrimination) (Fig. 1). In this study we report the ability of this device to identify high-risk patients and compare its sensitivity with other screening methods.

RESEARCH DESIGN AND METHODS

Patients

We studied 133 diabetic patients who attended the Manchester Diabetes Centre or Diabetic Foot clinic during a 5-week period; of these, 37 had a history of neuropathic foot ulceration. There were 76 men, and 32 patients had type I diabetes. Mean

From the Department of Medicine (L.V., G.H., A.J.M.B.), Manchester Royal Infirmary, Manchester; and Medical Statistics Unit (S.H.), University of Lancaster, Lancaster, U.K.

Address correspondence and reprint requests to A.J.M. Boulton, MD, FRCP, Department of Medicine, Manchester Royal Infirmary, Oxford Rd., Manchester M13 9WL, U.K.

Received for publication 9 September 1996 and accepted in revised form 4 November 1996.

QST, quantitative sensory testing; ROC, receiver operating characteristic; TCD, tactile circumferential discriminator; VPT, vibration perception threshold.

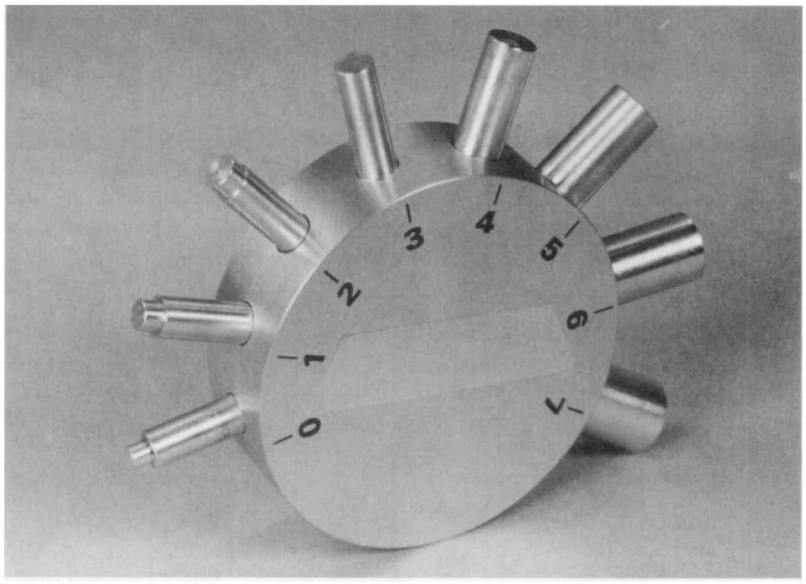

Figure 1—*The TCD.*

Table 1—*Criteria employed to define risk of insensitive foot ulceration*

	Not at risk	At risk
VPT (V)	<35	>35
Monofilaments (ability to perceive)	4.17, 5.07	6.10 or >6.10
TCD	0–5	6–>7

Table 1. To assess the sensitivity and specificity of each method to identify risk of ulceration, the results were analyzed in two ways: first, taking the 37 patients with a history of previous neuropathic ulcers as the criterion for risk; and second, to assess the sensitivity and specificity of the filaments and the TCD, taking the previously validated criterion for significant neuropathy of a VPT >35 V (14,17).

age was 56.6 (range 22–89) years, and median duration of diabetes was 14.8 (interquartile range 0.5–18) years.

Methods

All patients were assessed by the same investigator, and both feet were examined using each of the three devices: the TCD, neuroesthesiometer, and monofilaments. The tactile discrimination threshold was assessed with the TCD, which was developed in the U.S. as a test of two-point discrimination, a measure of large-fiber function (Fig. 1). This device consists of a cylindrical aluminum disk, with eight fixed solid rods, numbered 0 through 7, protruding from the outside: the circumference of the rods progressively increases from 12.5 to 40 mm. All tests were performed on the plantar aspect of the great toe, and subjects were asked to discriminate between stimuli that differ in circumference. First, the smallest rod ("0") was presented followed by the largest ("7"), with a standard contact time of 2 s. The algorithm then followed is designed to determine the smallest difference in circumference, relative to rod 0, that could be consistently detected using an ascending and descending method of stimulus presentation and a two-alternative forced-choice response procedure, as recommended for QST (15). Threshold values for neuropathy previously described were used: scores are denoted as the lowest rod that the patient is able to discriminate from 0 (i.e., a score of 5 indicates that the patient is only able to differentiate rods 5,6, and 7 from 0). A score of 6 or higher was defined as identifying significant neuropathy (R. Maser, personal communication, 1995).

The Semmes-Weinstein monofilaments were used to determine the pressure perception threshold on the plantar surface of the great toe as previously described (14). Three filaments were tested, the 4.17, 5.07, and 6.10, which buckle when forces of 1, 10, and 75g, respectively, are applied (12–14). Using a simple forced-choice procedure, the smallest monofilament felt by the patient was recorded. Inability to perceive the 5.07 filament was defined as identifying significant neuropathy (14,16).

Vibration perception threshold (VPT) was determined over the apex of the hallux using the neuroesthesiometer (Scientific Laboratory Supplies Ltd., Nottingham, U.K.), as previously described (17,18). The vibrating probe was applied to the hallux, and the voltage gradually increased until vibration was felt by the patient. The mean of three readings was recorded (17). As previously defined using a biothesiometer, a virtually identical instrument (Biomedical Instrument, Newbury, OH), a reading of 35 V represents significant neuropathy with risk of ulceration (17). We have previously reported a highly significant agreement between VPT results using the biothesiometer and neuroesthesiometer (18).

For each of the quantitative tests outlined above, the higher of the results for left and right feet was used to determine risk of ulceration. The criteria are summarized in

Statistical methods

VPT results were summarized by the median and interquartile range. TCD and filament results are presented only as counts and percentages because of their discrete nature. Correlations between methods were calculated using Spearman's rank-sum correlation. Sensitivity and specificity were calculated as true-positives/total number of positives and true-negatives/total number of negatives respectively and displayed on a receiver operating characteristic (ROC) curve (19).

RESULTS — All three devices were easy to use, and patients were able to follow the simple algorithms without difficulty. The numbers of patients able to perceive the TCD at the varying circumferences are presented in Table 2, with the mean VPT and filament results for each level of circumference differentiation. There was a highly significant agreement between the TCD and both the filaments (r_s = 0.73; $P <$ 0.0001) and the VPT (r_s = 0.76; $P <$ 0.0001).

Using the predetermined although arbitrary TCD score of 6 to denote those patients with significant neuropathy and therefore at potential risk of ulceration, the TCD correctly identified 100% of those 37 patients with a history of ulceration. Similarly, inability to perceive the 10-g monofilament identified over 90% of those patients with previous ulcers. In the identification of those with previous ulceration, there was agreement between the TCD and VPT in

Table 2—*Results of TCD, monofilament, and VPT assessment in 133 diabetic patients*

TCD	Patients	VPT	Filaments	History of ulcers
1	3	6 (5–18)	—	—
2	11	10 (5–20)	1 (9.1)	—
3	17	11 (8–18)	—	—
4	16	19 (11–27)	1 (6.3)	—
5	9	27 (16–31)	2 (22.2)	—
6	10	27 (25–36)	4 (40)	3 (30)
7	8	30 (23–36)	4 (50)	1 (12.5)
>7	59	49 (32–51)	45 (76.3)	33 (55.9)

Data are n (%) except for VPT where data are median (interquartile range). This table summarizes the results obtained according to the tactile circumference discrimination levels of 1–>7. Corresponding results for the VPT and filaments are shown; results for filaments represent numbers of patients insensate to filament 5.07.

75.2% of cases and between the TCD and monofilaments in 78.9% of cases. The sensitivity and specificity of each of the instruments to identify foot ulcer patients are presented in Table 3. It can be seen using pre-defined arbitrary cutoffs that, whereas the TCD and the filaments are both highly sensitive, they both identify a significant number of false-positives, whereas VPT is less sensitive but more specific. To further demonstrate the sensitivity and specificity of each instrument, the results are presented as a ROC curve in Fig. 2. It can be seen from the ROC curves, that, with appropriately chosen cutoffs, the performances of the three instruments are very similar.

Finally, the sensitivity and specificity of the filaments and the TCD for identifying any patients with significant neuropathy using the predetermined "value" of a VPT >35 V using the neurothesiometer (17), were calculated and are presented in Table 4.

CONCLUSIONS — The need for screening and early identification of all diabetic patients at risk of foot ulceration is increasingly recognized for several key reasons: first, education of a high-risk population has been shown to reduce the incidence of both ulceration and amputation (7–9); second, because of the immense economic burden of diabetic foot disease, which has further been highlighted in a recent study from Sweden where Apelqvist et al. (20) estimated the cost of a single foot ulcer episode to be $7,300 if primary healing occurred and $49,000 if amputation was required. Finally, several national and international organizations have set targets on reducing amputations in diabetes, such as the St. Vincent Declaration (21), which proposes a 50% reduction within 5 years in Europe. However, although the most easy to identify, it must be remembered that neuropathy is only one of several contributory factors for foot ulceration (1,5).

Until now, the only simple and tested screening device confirmed in appropriately designed studies has been the Semmes-Weinstein monofilaments, which are portable, lightweight, and relatively cheap (cost in U.K. for one set of three filaments £38.20 = $61) (12,14,16). These also have the advantage of ease of use in primary care (16) and in mass-population screening for risk in countries with less well-developed diabetes services.

In the present study, for the first time we have described a sensitive and portable alternative screening device to the filaments, which proved to be 100% sensitive though less specific in identifying patients with a history of foot ulceration. In the present study, VPT produced fewer false-positive results (i.e., it was more specific), but false-negative results were obtained. This is significant, as is the context of identifying patients who should receive preventative foot-care education, it is clearly

Table 3—*Measures of validity: TCD, filaments, and VPT*

	TCD	VPT	Filaments
Sensitivity	100	86.5	91.9
Specificity	58.3	79.2	76.0

Data are %. This table shows the sensitivity and specificity of the three instruments in the identification of those 37 patients with previous neuropathic ulceration. Criteria employed: TCD ≥6; VPT ≥35; monofilaments: inability to perceive 5.07 or 6.10; sensitivity: true-positives/(true-positives + false-negatives); specificity: true-negatives/(true-negatives + false-positives).

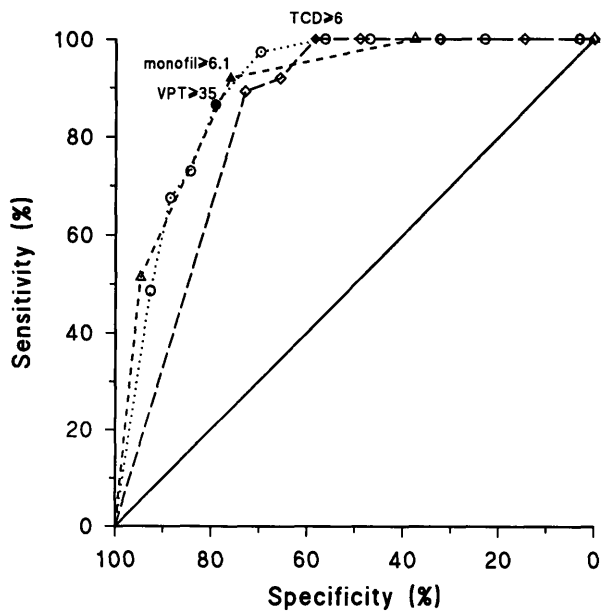

Figure 2—*ROC curve for prediction of previous history of foot ulcers by VPT (cutoffs of 5, 10, 15,...50: ○ and · · · ·), monofilaments (cutoffs of 4.17, 5.07, 6.10, and >6.10: △ and - - -), and TCD (cutoffs of 1–7 and >7: ◇ and — — —). The threshold for each method in the identification of patients at risk of foot ulcer is marked on Figure 1. The points corresponding to the criteria shown in Table 1 are indicated by solid symbols. The increasing cutoff values give points further to the left of the graph; thus a high cutoff only picks out extreme cases so it is not very sensitive, but it does not pick up any false-positives so it is highly specific.*

Table 4—*Sensitivity and specificity of filaments and TCD in the identification of patients with significant neuropathy and at potential risk of ulceration*

	TCD	Filaments
Sensitivity	92.3	86.5
Specificity	64.2	85.2

Data are %. Results were calculated on the basis of risk of foot ulceration in all individuals with VPT ≥35 V (17) (n = 52).

more important not to miss any potential foot ulcer patients, than it is to avoid educating some who may not be at risk (14): thus, both the filaments and the TCD at the defined thresholds for risk outlined in Table 1 were more sensitive. However, it can be seen by studying the ROC curve (Fig. 2) that, with appropriate thresholds, the performances of all three devices are similar. Certainly, if the VPT criterion for ulcer risk of 25 V that we previously used in a prospective study (6) had been used in the present report, it can be seen from Fig. 2 that this would have been 100% sensitive, but <60% specific in identifying those with previous ulceration. Thus, the cutoffs chosen for the present study, although based on previous publications, may not necessarily have been the optimal ones.

When comparing the relative merits of the three devices, all three were easy to use and portable, although the neurothesiometer is more bulky, expensive (cost £987/$1,580), and runs on a battery that requires regular recharging. Both the TCD and the filaments are highly sensitive, cost-effective, and ideally suited to community screening. Whereas the usefulness of both VPT and the filaments have been confirmed in cross-sectional and longitudinal studies (6,12–14,16–18), in this preliminary report, we have shown in a cross-sectional study that the TCD is potentially a sensitive screening device for use in population screening for foot ulcer risk. These findings now need to be extended and confirmed in a longitudinal study.

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