ORIGINAL INVESTIGATION

Choosing a Practical Screening Instrument to Identify Patients at Risk for Diabetic Foot Ulceration

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Objective: To evaluate the sensitivity and specificity of 3 sensory perception testing instruments to screen for risk of diabetic foot ulceration.

Methods: This case-control study prospectively measured the degree of peripheral sensory neuropathy in diabetic patients with and without foot ulcers. We enrolled 115 age-matched diabetic patients (40% male) with a case-control ratio of approximately 1:3 (30 cases and 85 controls) from a tertiary care diabetic foot specialty clinic. Cases were defined as individuals who had an existing foot ulceration or a history of a recently (<4 weeks) healed foot ulceration. Controls were defined as subjects with no foot ulceration history. Using receiver operating characteristic analysis, we evaluated the sensitivity and specificity of 2 commonly used neuropathy assessment tools (vibration perception threshold testing and the Semmes-Weinstein 10-g monofilament wire system) and a 4-question verbal neuropathy score to evaluate for presence of foot ulceration.

Results: A vibration perception threshold test using 25 V and lack of perception at 4 or more sites using the Semmes-Weinstein 10-g monofilament wire system had a significantly higher specificity than the neuropathy score used. The neuropathy score was most sensitive when 1 or more answers were affirmative. When modalities were combined, particularly the monofilament wire system plus vibration perception threshold testing and the neuropathy score plus the monofilament wire system, there was a substantial increase in specificity with little or no diminution in sensitivity.

Conclusions: The early detection of peripheral neuropathy or loss of "protective sensation" is paramount to instituting a structured treatment plan to prevent lower extremity amputation. The results of our study suggest that all 3 sensory perception testing instruments are sensitive in identifying patients at risk for ulceration. Combining modalities appears to increase specificity with very little or no diminution in sensitivity.

Arch Intern Med. 1998;158:289-292

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THE MORBIDITY, direct cost, and mortality associated with lower extremity complications among patients with diabetes mellitus have been well described in the medical literature.[1-6] Peripheral sensory neuropathy is one of the strongest risk factors for both foot ulceration and amputation in this population.[7,8] In the absence of neuropathy, people rarely develop foot ulcers. Because of the lack of painful feedback, peripheral neuropathy provides a permissive environment that allows repetitive tissue injury to occur such that a person may wear a hole in the bottom of his or her foot much in the way that he or she may wear a hole in a stocking. Certainly, the early detection of a level of peripheral neuropathy sufficient to contribute to the development of foot wounds or "loss of protective sensation"[9] is one of the most important criteria to identify high-risk patients for foot complications and is paramount when instituting a structured treatment plan to prevent lower extremity complications.[10-12]

The notion that neuropathy is generally necessary to produce a diabetic foot ulcer has been well established. However, the methods of testing to identify loss of protective sensation along the spectrum of neuropathy have been quite variable and ill defined. In an attempt to provide a simple, inexpensive, and reliable means of testing for the absence of protective sensation, the Semmes-Weinstein monofilament wire system (SW) has been widely advocated as a screening tool. Several reports have discussed the potential clinical use of monofilaments, particularly the 10-g monofilament, in identifying patients at risk for foot ulceration.[9,13-15] Additionally, measurement of the vibration perception threshold (VPT) using a simple handheld tactor is another popu-

SUBJECTS, MATERIALS, AND METHODS

This project was conducted as a case-control study with 115 age-matched diabetic patients (40% male) with a case-control ratio of approximately 1:3 (30 cases and 85 controls). Further descriptive subject characteristics are listed in **Table 1**. Cases were defined as subjects who had an existing or recently (<4 weeks) healed foot ulceration. Controls were defined as subjects with no foot ulceration history. We evaluated the sensitivity and specificity of 2 commonly used neuropathy assessment tools and a simple questionnaire. These included VPT testing, which was measured using a biothesiometer (Biomedical Instrument Corporation, Newbury, Ohio), and the SW system (North Coast Medical, San Jose, Calif). These devices have been shown to have very high intrarater and interrater reliability.[16,20] The University of Texas Subjective Peripheral Neuropathy verbal questionnaire included 4 queries to identify the presence of burning, formication, numbness, and paresthesias:

Do your feet ever feel numb?
Do your feet ever tingle, as if electricity were traveling into your foot?
Do your feet ever feel as if insects were crawling on them?
Do your feet ever burn?

A positive answer to any 1 of the 4 verbal questions constituted 1 point. A negative answer constituted 0 points.

The instrument used to conduct the VPT testing was a handheld device with a rubber tactor that vibrates at 100 Hz. The handheld unit was connected by an electrical cord to a base unit. This unit contains a linear scale that displays the applied voltage, ranging from 0 to 50 V. The method of testing was standardized. The device was held with the tactor balanced vertically on the pulp of the toe. At this time, the voltage was increased on the base unit until the patient could perceive a vibration. A mean of 3 readings (measured in volts) was used to determine the VPT for each foot.[10]

The SW testing was performed using a standard yes-no method of administration. This method instructed the patient to say yes each time he or she perceived the application of the monofilament. Measurements were taken at each of 10 sites on the foot,[21] including the plantar aspects of the first, third, and fifth digits; the plantar aspects of the first, third, and fifth metatarsal heads; the plantar medial and lateral sides of the midfoot; the plantar area of the heel; and the dorsal aspect of the midfoot. Additionally, we evaluated the sensitivity and specificity of a subjective neuropathy score (NS). For purposes of analysis, we used 4 different VPT cutoff points (15, 20, 25, and 30 V), 5 different SW cutoff points (inability to perceive 1-5 sites), and 4 questionnaire cutoff points (1-4 positive responses) to evaluate the most effective level at which to identify foot ulcer risk. For selecting the optimal diagnostic cutoff points on the scale of measurement, receiver operating characteristics curves were used.[22,23]

Table 1. Descriptive Patient Characteristics

Characteristics	History of Foot Ulcer (n=30)	No History of Foot Ulcer (n=85)
Mean (±SD) age, y	52.2±8.9	51.4±11.6
Sex, % M	63.3	31.8
Type 2 diabetes mellitus, %	100	96.5
Mean (±SD) duration of diabetes mellitus, y	14.7±8.8	10.2±9.0

lar method for establishment of a threshold for protective sensation.[10,16] Finally, some investigators have measured specific subjective symptoms and included them in the overall assessment of protective sensation.[17] While all these studies support the notion that these instruments may be clinically useful, inconsistent testing methods, different sites of testing on the foot, and various recommendations for interpreting the data have contributed to confusion. Furthermore, many of these studies have reported sensitivity and specificity data with very small sample sizes and in some cases, no control group for comparison.[9,14,18,19] The purpose of this study was to evaluate the sensitivity and specificity of 3 simple, commonly used sensory perception testing instruments to screen for risk of diabetic foot ulceration.

RESULTS

All 3 modalities used to evaluate sensory perception were sensitive to detect patients at risk of ulceration. The sensitivity and specificity of the 10-g monofilament, the neuropathy questionnaire, and the VPT are illustrated in **Figure 1**, **Figure 2**, and **Figure 3**, respectively. When the 10-g monofilament was evaluated, specificity increased with little change in sensitivity as the number of sites that could not be perceived increased up to 4 imperceptible sites. We noticed a significant decrease in sensitivity and specificity when we moved beyond 5 imperceptible sites. The sensitivity of the neuropathy questionnaire was 100% when we used 1 or more positive answers as a criterion for loss of protective threshold (NS1), but it decreased dramatically as the cutoff point for positive answers increased, with only a mild increase in specificity. Vibration perception threshold testing using the biothesiometer showed a steady increase in specificity with little change in sensitivity until 25 V, above which there was a significant decrease in sensitivity. Overall, VPT testing and 4 or more imperceptible sites using the monofilament wire (SW4) had significantly higher specificity than the verbal neuropathy questionnaire. When modalities were combined, particularly SW4 plus VPT and NS1 plus SW4, there was a substantial increase in specificity with little or no diminution in sensitivity. These data are outlined in **Table 2**.

COMMENT

The results of our study suggest that all 3 sensory perception testing methods are sensitive in identifying patients at risk for foot ulceration. Combining modalities appears to increase specificity with very little or no dimi-

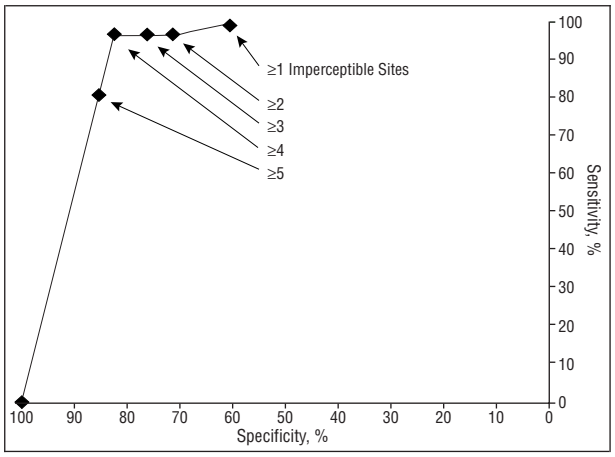

Figure 1. *The sensitivity and specificity of Semmes-Weinstein 10-g monofilament wire, plotted as a receiver operating characteristics curve.*

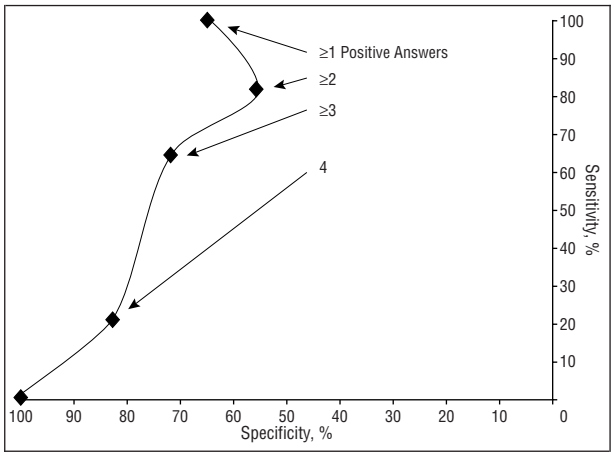

Figure 2. *The sensitivity and specificity of the neuropathy questionnaire, plotted as a receiver operating characteristics curve.*

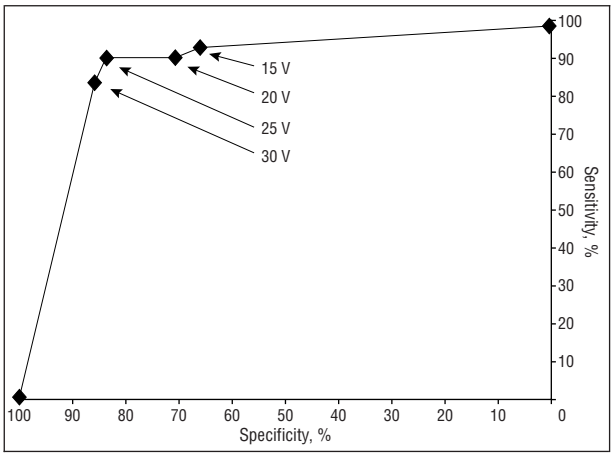

Figure 3. *The sensitivity and specificity of vibration perception threshold, plotted as a receiver operating characteristics curve. The threshold was measured at 15, 20, 25, and 30 V.*

Table 2. Neuropathy Testing Instruments in Combination*

Instrument	Sensitivity, %	Specificity, %
SW4 or VPT25	100	76.5
SW4 and VPT25	88.2	88.2
NS1 and SW4	96.7	85.9
NS1 and VTP25	90.0	83.5
NS1, SW4, and VPT25	86.7	89.4

**SW4 indicates Semmes-Weinstein 10-g monofilament imperceptible at 4 or more sites on the affected foot; VPT25, vibration perception threshold at 25 V; and NS1, neuropathy score with patient reporting 1 or more symptoms on the University of Texas Subjective Peripheral Neuropathy Verbal Questionnaire.*

nution in sensitivity. Previous studies have identified that both SW and VPT are reliable and reproducible measurements. However, we have been unable to identify any other reports that have compared modalities in a large group of patients with and without wounds that specifically detail the method of measurement and reported the sensitivity and specificity of these instruments. Furthermore, this is the first report in the medical literature, to our knowledge, that reports on a marriage of simple peripheral sensory testing modalities to screen for risk of diabetic neuropathic ulceration. It appears that, while all these modalities are relatively sensitive, a combination of modalities, particularly the SW4 plus VPT and NS1 plus SW4, provides increased specificity with little or no diminution in sensitivity.

Neuropathy is the most important component in the causal pathway to diabetic ulceration, lower extremity amputation, and Charcot arthropathy. Yet despite its critical clinical importance, the technique for measuring peripheral sensory neuropathy and, more importantly, loss of sensory protective threshold has received little attention in the majority of physical diagnosis texts.[24-26] It has been reported that basic physical examination skills may not improve significantly beyond graduation from medical school.[27] Therefore, it may be inferred that many physicians, having not been exposed to techniques to evaluate the presence of sensory protective threshold in persons with diabetes mellitus early in their training, may never develop these skills. We have noted that, of patients admitted to a university teaching hospital with diabetes-related foot pathological findings, less than 15% receive a minimally competent lower extremity examination, which includes evaluation of sensory protective threshold.[28]

Since peripheral sensory neuropathy is a pivotal element in the causal pathway to both foot ulceration and amputation, selecting a quick, inexpensive, and accurate instrument to evaluate the high-risk patient is essential to make decisions about the allocation and distribution of medical resources and personnel. Allocation of appropriate intervention modalities in high-risk diabetic patients has been shown to decrease the rate of reulceration by up to 60% and lower extremity amputation by up to 85%.[29-31] However, intervention in this patient population is expensive. In a health care system saddled with limited resources and charged with serving an aging population with an increasing prevalence of chronic diseases (such as diabetes), it is important to identify high-risk patients to allocate resources and implement aggressive medical care in populations in which they will have the greatest impact. In this era of expensive high-tech gadgetry, it is exciting to identify a situation where

common sense, a bit of patient history, and simple tools provide essential medical information. The instruments described in this article offer an inexpensive and reliable method that can be easily incorporated by nurses, primary care physicians, or specialists into clinical practice. These tests can be performed relatively quickly (in <5 minutes) at regular intervals (eg, every 6 months). By identifying patients at risk, these "low-tech" instruments may have the most profound impact in the eventual implementation of appropriately directed care and the subsequent reduction of diabetes-related lower extremity amputations.

Accepted for publication June 3, 1997.

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