SUMMARY - Objective: To compare normal and pathologic values of three different tests for screening patients at risk of foot complications: mono-filament, tuning fork and vibration threshold perception (VTP).

Methods: Two hundred and fifty consecutive patients followed-up in a diabetic clinic were screened for sensitive polyneuropathy by three different tests in three different examinations in a blind design. The 10 g mono-filament, tuning fork and Horwell neuro-esthesiometer were applied to different sites on the patients’ legs and feet.

Results: Thirty eight patients were identified having abnormal tests and being at risk of foot complications using the mono-filament test; 33 of them and 9 more (42 patients) were identified using the tuning fork applied to the malleolus and eight more (50 patients) when the tuning fork was applied to the big toe; twenty more patients (70 patients) were identified as being at risk using the VTP at a cut-off of 25 V.

Conclusion: The mono-filament test identified patient with the highest risk of foot complications, but 37 more patients were identified to be at risk from a VTP > 25 V. These patients were not detected using the mono-filament test. The VTP test provides numerical values that can help to follow the course of the risk for foot insensitivity by allowing the care team to grade the education and follow-up of the at-risk group.

Key-words: peripheral diabetic neuropathy, mono-filament, tuning fork, vibratory threshold perception, diabetes mellitus.

RÉSUMÉ - Comparaison entre le monofilament, le diapason et un neuroesthésiomètre pour le dépistage des patients à risque de « pied diabétique ».

Objectif: Comparer les valeurs normales et pathologiques de trois tests différents pour mieux identifier les patients à risque de complication à type de « pied diabétique ».

Patients et méthodes: Deux cent cinquante patients régulièrement suivis dans un service de diabétologie ont été examinés à la recherche d’une neuropathie sensitive par trois tests différents réalisés chacun par un opérateur différent : le mono-filament 10 g, le diapason et le neuro-esthésiomètre type Horwel ont été appliqués à différents sites de la jambe et du pied des patients.

Résultats: Trente-huit patients sont identifiés à risque de complications au niveau des pieds par le mono-filament ; parmi eux 33 et 9 autres patients (42 patients) sont identifiés par le diapason placé au niveau de la malléole et 50 (33 + 9 + 8) quand le diapason est placé au niveau du gros orteil ; quand le neuro-esthésiomètre est appliqué au niveau du gros orteil, ce sont 70 patients qui sont identifiés comme étant à risque pour un seuil vibratoire de 25 V.

Conclusions: Le mono-filament dépiste les patients avec le plus haut risque de lésions au niveau des pieds mais le neuro-esthésiomètre identifie 37 patients supplémentaires eux aussi à risque certain mais méconnus par le mono-filament. De plus le neuro-esthésiomètre fournit des résultats chiffrés qui peuvent aider à quantifier et donc aider l’équipe soignante dans l’intensité et le suivi de l’éducation.

Mots-clés: neuropathie diabétique, mono-filament, neuro-esthésiomètre.
It has been demonstrated that foot complications and lower-extremity amputations can be reduced when patients are provided with foot screens, education, proper fitting footwear and routine care for foot problems [1-3].

Although all diabetic patients may be informed about the risk of foot complications, intensive education in foot care for all diabetic patients is time consuming and costly and may discourage patients who are not at any particular risk. Detection of insensitive foot can identify those patients at most risk of foot ulceration who will require more information, more education and more care. However, different degrees of foot low sensitivity may incur different levels of risk. Patients with a rapid deterioration in sensitivity may be at higher risk and so need to be better trained and followed-up more often. Those with less reduced sensitivity in the feet should be aware of the need for foot care, and their sensitivity monitored, but they probably do not require such intense foot self-care and medical follow-up.

Thus by quantifying the decrease in foot sensitivity, we would be able to graduate the level of training in foot care and medical follow-up, with a consequent gain in cost-effectiveness.

Tests available for assessing foot sensitivity include the tuning fork, neuro-esthesiometer and 10 g mono-filament. All these methods have been shown to be of value in identifying patients with loss of protective sensation and at risk of diabetes-related foot complications [4, 5]. However, they have not yet been compared in the same population of patients.

The 10 g mono-filament is recommended by the ADA, the WHO Association, the ALFEDIAM and ANAES. It has been shown to be a stable [6] and reliable [7-9] instrument. It is reproducible, the patients saying “yes” or “no” if they either felt or not the 10 g bending force [10]. However, there is no graduation. Some authors have compared the 4 g and the 10 g in an attempt to quantify the sensory deficiency [5, 11, 12]. It has been shown that patients with no sensitivity for the 10 g force are at higher risk for foot ulceration [13].

The neuro-esthesiometer test is not widely used, although it is convenient and provides a quantified value for the sensitivity. The technique is highly reproducible and is not influenced by skin temperature [13]. The neuro-esthesiometer can discriminate those patients with the higher risk of foot complications from those at low risk and from those with little risk. It has been shown that patients failing to feel a stimulus of 25 V have a seven-fold higher risk of foot ulceration over the four subsequent years than do patients with a lower threshold sensitivity [4, 14]. Moreover the neuro-esthesiometer provides a quantification of sensitivity that will help to condition the degree of education and follow-up required.

The tuning fork is also recommended for screening low foot sensitivity and is of low cost, but the vibration must be induced with care to discriminate patients with higher risk of foot complication.

In the present study, we compared these three different tests for the screening of patients at risk of foot complications in the same population of diabetic patients.

### PATIENTS AND METHODS

Two hundred and fifty consecutive patients (133 men and 117 women) were studied in our diabetic clinic. Mean age was 54 ± 18 years (range 16 to 88 years). There were 130 type 2 and 120 type 1 diabetic patients with a mean duration of diabetes of 12.7 ± 11.6 years (range 1 to 64 years). One hundred eighty (72%) had clinical poly-neuropathy with tendon reflexes’ abolition, 17 had renal failure with a calculated creatinine clearance lower than 50 ml/min, 182 had a normal microproteinuria lower than 30 mg/24 h, 52 had a microproteinuria between 30 and 300 mg/24h and 16 a macroproteinuria between 330 and 3,000 mg/24 h; 105 had a background retinopathy, and 25 had a proliferative retinopathy; 5 had previous foot ulceration and 2 have an evolutive foot lesion. They were poorly controlled (HbA1c, 9.1 ± 2.2%). They were all screened for at risk foot by three different tests in a blind design. We used the VTP (vibration threshold perception) as a reference test, the tuning fork as a routine test and the mono-filament as the screening test recommended by the ADA, WHO, ALFEDIAM, and ANAES.

The VTP was measured with a neuro-esthesiometer (Horwell, Owen Mumford, Vernon, France). The probe was applied to the lateral-dorsal side of the big toes, the voltage was gradually increased from zero and the result was recorded when the subjects indicated that they could feel the vibrations. When the patient gave a correct response, the voltage was decreased by 10% on each trial until the patient made an error. The test was repeated three times and the mean voltage was recorded. We selected a nadir of 25 V for the cut-off between high and low risk, which has been reported to identify patients liable to suffer from neuropathic ulceration even with relatively minor injury [4]. The vibration perception threshold was also measured at the malleolus and patella.

### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>DPN</td>
<td>Diabetic Polyneuropathy</td>
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<tr>
<td>VTP</td>
<td>Vibration Threshold Perception</td>
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<tr>
<td>ALFEDIAM</td>
<td>Association de Langue Française pour l’Etude du Diabète et des Maladies métaboliques</td>
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<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>ANAES</td>
<td>Agence Nationale d’Accréditation et d’Évaluation en Santé</td>
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Another vibration test was conducted by another operator using a 128 Hz tuning fork applied to the bony prominence on the lateral-dorsal side of the big toes, the malleolus and patella.

A third test was conducted using a 10 g monofilament applied to a non-callosed site. It was repeated six times on both feet, over the first, third and fifth metatarsal head of the dorsal side and on the plantar side of the foot. The 10 g filament was applied to each site and the patient was asked to answer “yes” if he or she felt the filament. Four correct answers out of six applications for each site were considered normal.

Each test was conducted by three different investigators blinded to the results of the other two tests.

### RESULTS

The results for the neuro-esthesiometer screen for the whole population are shown in Table I. The interest of these tests is that we have numerical values as results rather than yes/no responses. Table I also shows the results for each patient at the patella, malleolus and hallux. If we retain a cut-off of 25 V, that has been demonstrated to be predictive for foot ulceration in subsequent years, 70 patients were at risk on the basis of the results obtained at the hallux. The results from the malleolus, the patella and the hallux were concordant for each patient with a higher threshold noted at the hallux.

The vibration fork was either felt or not, so the responses were “yes” or “no”. The fork was applied to the patella, malleolus and hallux. When the response was “no” at the patella, the response was also “no” at both malleolus and hallux in 24 patients. The response at the patella was “yes” but “no” at both malleolus and hallux in 42 patients, while 52 patients gave a “no” response only at the hallux. Comparing the results between the malleolus and hallux, ten more patients were identified as being at risk on the basis of the results from the hallux than from the malleolus.

All the patients with a negative result with the tuning fork at the hallux had a threshold at the hallux of more than 25 V with the neuro-esthesiometer but they were only 52 patients with a negative result with the tuning fork versus 70 with VTP higher than 25 V; the screening test with the tuning fork thus did not identify 18 patients at high risk for foot ulceration as determined by the reference neuro-esthesiometer test.

The 10 g monofilament was not felt in 13 patients and weakly felt in 25 out of a total of only 38 patients with an abnormal filament test result. Thirty three of these patients also had an abnormal result in the tuning fork test and VPT. This left five patients with an abnormal monofilament test, but with normal results for both tuning fork test and VPT.

The number of the detected patients by each screening test at different site is shown in Fig. 1.

<table>
<thead>
<tr>
<th>Vibratory intensity (volt)</th>
<th>Number Of Patients</th>
<th>Patella</th>
<th>Malleolus</th>
<th>Hallux</th>
</tr>
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<tbody>
<tr>
<td>0–9</td>
<td>111</td>
<td>104</td>
<td>96</td>
<td></td>
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<tr>
<td>10–19</td>
<td>62</td>
<td>57</td>
<td>47</td>
<td></td>
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<tr>
<td>19–24</td>
<td>43</td>
<td>43</td>
<td>37</td>
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<tr>
<td>25–30</td>
<td>15</td>
<td>20</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>31–40</td>
<td>12</td>
<td>17</td>
<td>25</td>
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<tr>
<td>41–50</td>
<td>7</td>
<td>9</td>
<td>13</td>
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<tr>
<td>TOTAL</td>
<td>250</td>
<td>250</td>
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**Table I.** Vibration threshold measured at the patella, the malleolus and the hallux in a population of 250 diabetic patients.

![Fig 1. Number of patients identified as being at risk of foot complications using 3 different tests (the 5 negative patients in the MF group were only identified by the monofilament but not with the other tests).](image-url)
DISCUSSION

Diabetes is a self-managed disease in which patients provide most of their own daily care [1, 2]. It has been shown that when patients are educated about their disease, they have a lower incidence of concurrent complications. Foot ulcerations have been considerably reduced when patients are provided with foot screens, education, and routine care for foot problems [15, 16]. Although all diabetic patients may be informed about the risk of foot complications, not all diabetic patients are at risk of foot complications; detection of insensitive foot can identify those patients at most risk of foot ulceration who will require more information, more education and more care [17]; this would prompt training patients in preventive self care with regular foot surveillance, thereby reducing morbidity.

Various methods with differing degrees of reliability are available for detection of the insensitive foot [18, 19]. The 5.07/10 g Semmens Wintrobe monofilament is recommended by the American Diabetic Association (ADA) [20], the World Health Organization (WHO) [21] and the ALFEDIAM and ANAES [22], but other tests have been evaluated and it has been demonstrated prospectively that the VTP can identify diabetic patients with an increased risk of foot ulceration for a VTP > 25 V.

In our population, only 38 patients out of 250 had an abnormal result with the monofilament test; this would indicate that these 38 patients are at high risk for foot ulceration and have an important education need for foot self-care, but it does not mean that the other patients had a normal threshold of sensitivity in their feet. In fact among the patients in our population with 25 V insensitivity at the hallux, 37 had a a normal result with the neuro-filament test. These 37 patients at risk of foot complications would thus not have been detected using the sole mono-filament test.

Moreover, the neuro-esthesiometer provides a quantification that will help to condition the degree of education and follow-up required. The rare patients with 40 to 50 V threshold are those with the highest risk. Although these patients did not feel the monofilament, this test was unable to evaluate the sensory deficit. The neuro-esthesiometer, however, did provide an estimate of severity. In our population, they were patients who had suffered foot complications over the previous two years. The neuro-esthesiometer can thus discriminate those patients with the higher risk of foot complications from those at low risk and from those with little risk. It has been shown that patients failing to feel a stimulus of 25 V have a seven-fold higher risk of foot ulceration over the four subsequent years than do patients with a lower threshold sensitivity [4, 14].

Our study, which was designed to compare three tests in the same population, indicated that although the neurofilament is a good tool for the higher risk patients, it failed to identify 37 patients at real risk for foot ulceration who had a threshold of over 25 mV in the neuro-esthesiometer test.

The tuning fork appeared to be also a good tool as it was positive for most of patients with a positive mono-filament test, but also for patients with a 25 V threshold in the neuro-esthesiometer. For reliable screening, the tuning fork must be applied to the hallux and not the malleolus. If the patient was positive at the maleollus, he was always positive at the hallux, but the converse was not the case; so the tuning fork at the malleolus is as good as the monofilament but not better. Early screening with the tuning fork thus requires testing at the most distal part of the foot.

We found considerable differences in results from the three tests, and there is a danger that patients may be falsely informed about their sensory deficit with one or other test. The possibility of false negatives is a serious limiting factor for the mono-filament.

Our screening tests identified 75 high risk patients (70 with the VTP and 5 more with the neurofilament test) out of a population of 250 patients. These 75 patients require intensive education in foot care and more frequent follow-up. This can exclude 175 patients from an intensive education program for foot care as long as their annual foot examinations and VTP neurological examinations are normal. In this way the resources of the care team can be focused on the high risk patients.

Our study also demonstrated that the recommended 10 g neurofilament test is of value for identification of very high risk patients, but is somewhat less sensitive for screening patients who may require intensive education in preventive foot care. However, the efficacy of such an educational program will need to be evaluated in a longitudinal prospective study.

In addition, sensory threshold screening does not detect patients with foot deformation or calluses that may enhance susceptibility to foot ulceration in the absence of severe neuropathy. The appearance and the shape of the foot should be taken into account to further stratify the risk of complications and define the type of education and follow-up required [23, 24].

REFERENCES


