Accuracy of monofilament testing to diagnose peripheral neuropathy: a systematic review

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CRD summary
This review assessed accuracy of monofilament testing in diagnosing peripheral neuropathy of the feet from any cause and concluded that there was insufficient data to recommend sole use of this test to diagnose peripheral neuropathy. This conclusion reflected the lack of evidence identified by the review and is likely to be reliable.

Authors' objectives
To assess the accuracy of monofilament testing in diagnosing peripheral neuropathy of the feet from any cause.

Searching
MEDLINE and EMBASE were searched from inception to June 2007. No language restrictions were applied. The full search strategy was reported in an online appendix. Bibliographies of included studies were screened for additional articles.

Study selection
Studies that assessed monofilament testing with a 5.07/10-g monofilament for diagnosis of peripheral neuropathy of the feet were eligible for inclusion. Studies were required to use a nerve conduction study as the reference standard to determine diagnosis. Studies in patients with a visible ulcer were excluded.

All included studies were of patients with diabetes mellitus (one was a case control study of patients with diabetes and non-diabetic controls). Mean age of participants was 54 to 59 years. Two studies reported monofilament testing at different numbers of sites (10 and one) using different diagnostic thresholds: ≥5 of 10 incorrect (1 foot) and ≥5 of 8 incorrect (both feet) in patients with diabetes; and ≥2 of 8 incorrect (both feet) in the control group. A third study reported no details of test methods.

Two reviewers independently assessed studies for inclusion. Disagreements were resolved by consensus.

Assessment of study quality
Methodological quality of included studies was assessed with the 14-item QUADAS checklist to assess reporting quality, generalisability, selection bias, blinding/review biases, verification biases and handling of incomplete and indeterminate results.

Quality assessment was undertaken by two reviewers. Disagreements were resolved by consensus.

Data extraction
Data to populate 2x2 contingency tables (number of true positive, false negative, false positive and true negative test results) were extracted. Sensitivity and specificity with 95% confidence intervals (CIs) were calculated.

The authors did not state how many reviewers performed data extraction.

Methods of synthesis
Studies were summarised narratively and in a table.

Results of the review
Three studies (641 participants comprised 589 with diabetes and 52 controls) were included in the review. The authors stated that all studies showed methodological limitations that could have inflated estimates of sensitivity or specificity. Limitations to methodological quality were noted in footnotes to the results table: two studies did not clearly describe their selection criteria, one of these studies did not account for withdrawals and the other study may have interpreted
test results without blinding to other results; and the third study did not fully describe the index test and reference standard.

Sensitivity estimates ranged from 40.9% (95% CI 36% to 46%) to 93.1% (95% CI 77% to 99%) in patients with diabetes (three studies). Sensitivity in control participants was 77.0% (95% CI 72% to 81%; one study).

Specificity estimates ranged from 94.9% (95% CI 86% to 99%) to 100% (95% CI 63% to 100%) in patients with diabetes (three studies). Specificity in control participants was 68.3% (95% CI 58% to 77%; one study).

**Authors' conclusions**
The authors concluded that despite frequent use of the Semmes-Weinstein monofilament test, its accuracy for detecting neuropathy in feet that did not have visible ulcers could not be determined because diagnostic studies with adequate methodology were lacking.

**CRD commentary**
The review addressed a clearly stated research question defined by appropriate inclusion criteria. Searches were conducted without language restrictions and were supplemented by reference screening. No specific attempt to identify unpublished studies was reported. Measures were taken to minimise the possibility of error and/or bias in study selection and quality assessment; it is unclear whether similar measures were applied to data extraction. Methodological quality of included studies was assessed, but full results were not reported. The narrative synthesis was appropriate given the small number of included studies and differences in the tests assessed. Overall the authors' conclusions were appropriate to the lack of data available and are likely to be reliable.

**Implications of the review for practice and research**
**Practice:** The authors stated that they did not recommend sole use of a monofilament test to diagnose peripheral neuropathy.

**Research:** The authors stated that optimal test application and defining a threshold should be prioritised in future research that evaluated monofilament testing, as this test was advocated in many clinical guidelines.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.