A meta-analysis of the diagnostic accuracy of the monofilament in detecting diabetic peripheral neuropathy
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CRD summary
This review concluded that monofilament assessment has fairly good diagnostic accuracy in detecting diabetic peripheral neuropathy but should not be used as a sole diagnostic method. Given the poor study quality and substantial variation across the studies, the usefulness of the pooled results and the reliability of the conclusions is unclear.

Authors' objectives
To assess the diagnostic accuracy of the monofilament assessment in identification of diabetic peripheral neuropathy in people with diabetes.

Searching
MEDLINE, EMBASE, CINAHL, BIOSIS Previews, Web of Science, AMED, EBM Reviews and Dissertations and Theses were searched from 1950 to September 2007. Search terms were reported. Bibliographies were checked, relevant conference proceedings and journal reviews were reviewed and experts were contacted for further studies. Only studies reported in English were eligible for inclusion.

Study selection
Eligible studies compared monofilament assessment with a gold standard for the identification of diabetic peripheral neuropathy which reported data on sensitivity and specificity.

Studies used the following reference standards: vibration perception threshold, neuropathy verbal questionnaire, nerve conduction velocity, neuropathy disability score, clinical examination as per San Antonio consensus medical records and neurometer. The majority of studies used a yes-no method for assessing monofilament sensation; the remainder used a forced choice. Monofilament sizes ranged from 1g to 100g; most used 10g. Number of monofilaments ranged from one to eight; eight studies used a single monofilament. Between one and ten application sites were used. Patient characteristics reported in original studies was limited. Where reported, the mean duration of diabetes ranged from 14 to 20 years, mean patient age from 46.7 to 56 years and the proportion of male participants from 48% to 56%. Level of medication required varied between studies. Clinical settings varied with outpatient clinics, specialty clinics, general practitioners and general hospitals represented.

The author did not state how many reviewers were involved in study selection.

Assessment of study quality
The studies were assessed for validity using the 25 items of the Standards for Reporting Studies of Diagnostic Accuracy (STARD) statement.

One reviewer assessed the studies for validity on three separate occasions.

Data extraction
Data on sensitivity and specificity of monofilament assessment were extracted using a standard coding sheet.

The author did not state how many reviewers were involved in data extraction.

Methods of synthesis
A random-effects model meta-analysis was used to calculate pooled estimates of sensitivity and specificity and diagnostic odds ratios (DOR) with 95% confidence intervals (CI). A subgroup analysis of studies was conducted using an instrument gold standard (nerve conduction velocity, vibration perception threshold or neurometer) was conducted. A ROC curve was constructed and the area under the curve calculated using the Moses-Littenberg method. A threshold effect assessment was carried out. Heterogeneity was assessed using I^2 and X^2.

Results of the review

Fourteen studies (3,142 participants) were included in the review. Sample size ranged from 37 to 544. The quality of study reporting was poor with only four studies that reported over 50% of the STARD items and only three studies that reported blinding of examiners.

The pooled sensitivity for all studies was 62% (95% CI, 60 to 64; I^2= 98.2%) and the pooled specificity was 73% (95% CI, 72% to 75%; I^2= 98.8%). The analysis restricted to studies using an instrument gold standard showed a pooled sensitivity of 74% (95% CI 71 to 76; I^2 = 96.6%) and specificity of 70% (95% CI, 68 to 72; I^2= 98.7%). The pooled DOR was 17.34 (95% CI, 8.75 to 34.39; I^2= 88.4%) for all studies and 19.97 (95% CI, 8.11 to 49.18; I^2 not reported) for the ten studies using an instrument gold standard. The area under the curve was 0.88 for the full set of studies and 0.90 for the restricted set.

In the meta-regression, only patient age and the technique for monofilament assessment impacted on results.

Authors' conclusions

Monofilament assessment demonstrated fairly good diagnostic accuracy in detecting diabetic peripheral neuropathy; it may be helpful as a screening tool but should not be used as a sole diagnostic method.

CRD commentary

The review question was clear and was supported by appropriate inclusion criteria. The author searched a number of relevant databases and other sources and made attempts to identify unpublished studies. However, the restriction of the review to studies reported in English may have led to the omission of relevant studies and the potential for language bias. The author did not report that they used methods designed to reduce reviewer bias and error in the selection of studies or the extraction of data; some attempt to do so was noted for the assessment of validity. The validity assessment involved appropriate criteria but reporting of the results was limited and mostly restricted to comment on summary scores.

Pooled estimates of sensitivity and specificity were calculated separately; more robust methods using a summary receiver operating curve were available which could provide combined pooled estimates. The level of clinical and statistical heterogeneity was very high in all the analyses for which it was reported.

The appropriateness of the statistical pooling of the studies and the usefulness of the pooled results was open to question. Given this concern, the author's conclusions should be treated with caution.

Implications of the review for practice and research

Practice: The author stated that where monofilament assessment was used a forced two-choice option was recommended.

Research: The author stated that there was a need for longitudinal studies to assess protective sensation in culturally diverse older diabetic and non-diabetic populations. More research was needed on diabetic peripheral neuropathy in Hispanic Americans, Native Americans, African Americans Asian Americans and populations with pre-diabetes. A comprehensive double-blinded case-control study of diagnostic accuracy of monofilaments needs to be conducted using 10 pedal sites including the dorsal and plantar surface of the foot and involving a diverse patient population. A study assessing the relationship between the lack of protective sensation in peripheral neuropathy and balance, quality of life and depression was recommended.

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