Microalbuminuria testing in diabetes: is a dipstick as effective as laboratory tests?

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CRD summary
This review compared dipstick testing with a laboratory method for the detection of microalbuminuria in diabetics. The author concluded that the Micral-Test II had high sensitivity, but not high specificity, and a low positive predictive value compared with laboratory detection. Thus, the test can be considered adequate for screening but not for diagnosis. The author's conclusions are likely to be reliable.

Authors' objectives
To compare the diagnostic performance of dipstick testing with a laboratory method for the detection of microalbuminuria in people with diabetes.

Searching
MEDLINE (from 1996 to 2003), CINAHL, EMBASE (from 1988 to 2003) and the Cochrane Library were searched. In addition, diabetic journals were handsearched and the NICE website and PubMed were searched. Details of the search strategy were presented.

Study selection

Diagnostic accuracy studies were eligible for inclusion if assessors of the urine samples were blind to the other test results.

Specific interventions included in the review
Studies of the Micral-Test II were eligible for inclusion, whereas studies of the Micral-Test were excluded. In the included studies, urine for testing was collected at various time points (24 hour sample, or first or second morning voided sample or spot sample).

Reference standard test against which the new test was compared
Studies that compared the Micro-Test II with an established laboratory test in the same sample of people were eligible for inclusion. The included studies used radioimmunoassay, immunoturbidimetry, or nephelometry laboratory methods. The review only included data from patients for whom the reference level for raised albumin was 20 mg/L.

Participants included in the review
Studies of patients with diabetes were eligible for inclusion. Studies that included people with diabetes, but did not report the results separately for this group, were excluded.

Outcomes assessed in the review
It was unclear whether only studies that presented sensitivity and specificity data were eligible. The outcome measures used in the review were sensitivity, specificity, negative and positive predictive values and, where possible, the receiver-operating characteristic (ROC) curve.

How were decisions on the relevance of primary studies made?
The author did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Validity was assessed using the criteria described by Greenhalgh and Donald for screening or diagnostic tests (see Other Publications of Related Interest). The author did not state who performed the validity assessment.
Data extraction
The author did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
A narrative synthesis of the studies was undertaken.

How were differences between studies investigated?
Differences between the studies were briefly discussed with reference to the laboratory tests used and the timing of urine collection.

Results of the review
Four diagnostic studies (2,916 patients) were included.

The included studies fulfilled all the criteria of Greenhalgh and Donald, apart from the power calculation. However, the author stated that the sample sizes were relatively large (the author reported a range of 196 to 2,228, although the review only included the 81 patients from one study for whom the reference level was 20 mg/mL).

The sensitivity ranged from 79 to 98.9% and the specificity ranged from 68.6 to 93%. The positive predictive value ranged from 72 to 89% and the negative predictive value (3 studies) ranged from 91 to 98.6%. The area under the ROC curve (2 studies) was 0.89 (95% confidence interval, CI: 0.84, 0.94) and 0.95 (CI not reported).

Authors' conclusions
The Micral-Test II had high sensitivity, but not high specificity, and a low positive predictive value when compared with the laboratory detection of microalbuminuria. Thus, it can be considered adequate for screening but not for diagnosis.

CRD commentary
The review question was clear in terms of the study design, intervention, participants and outcomes. Several relevant sources were searched and the search terms were stated. It was unclear whether any language restrictions had been applied. The methods used to select the studies, assess validity and extract the data were not described; hence, any efforts made to reduce errors and bias cannot be judged. Validity was assessed using an established checklist, but the specific criteria used were not listed in the review although the checklist was referenced.

Relevant information on the included studies was tabulated, while additional information was reported in the text of the paper. However, no details of the participants were given, so it is not possible to assess the comparability of populations across the studies. Given the small number of studies, a narrative synthesis may have been appropriate. The author called this a ‘mini review’ and, as such, made no attempt to combine the studies quantitatively, even if this had been appropriate. Potential reasons for one study reporting a lower sensitivity (79%) than the other studies (>90%) were not adequately discussed. The evidence presented appears to support the author's conclusions.

Implications of the review for practice and research
Practice: The author stated that the Micral-Test II may be useful in excluding patients who do not have albuminuria, but is not so useful for confirming that they actually have microalbuminuria.

Research: The author stated that further research is required to examine the cut-off levels of the test strip and to determine the levels of false-positive results. Studies comparing the cost-effectiveness of dipstick with laboratory testing are also required. The author also stated that if the Micral-Test II is taken up in clinical practice, then research is required to assess patient outcomes and to determine whether there is a reduction in the prevalence of diabetic
nephropathy.

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