CRD summary
This review compared the accuracy of vacuum-assisted biopsy with automated-needle biopsy to evaluate non-palpable breast lesions. The authors concluded that vacuum biopsy can decrease the miss-rates for high-risk lesions and ductal carcinoma in situ. However, the comparison with automated-needle biopsy was based on data not derived from the review. This and other methodological weaknesses mean that the conclusions should be treated with caution.

Authors' objectives
To assess the diagnostic performance of vacuum-assisted breast biopsy and to evaluate its potential benefits.

Searching
MEDLINE was searched from 1995 to November 2001 for publications in English; the search terms were reported. A 'cross-reference' search was also used.

Study selection
Study designs of evaluations included in the review
Inclusion criteria for the study design were not specifically defined. Six of the 22 included studies reported consecutive recruitment of the participants. No further details were reported.

Specific interventions included in the review
Studies of vacuum-assisted breast biopsy, where the method of guidance was stereotaxis and the size of the probe used was reported, were eligible for inclusion. The included studies used 11-gauge (11G), 14G, or 11G plus 14G probes.

Reference standard test against which the new test was compared
Studies were eligible for inclusion if histological diagnoses were confirmed by either surgical biopsy or adequate follow-up (not defined in the report).

Participants included in the review
Inclusion criteria for the participants were not specifically defined. Where reported, the mean age of the participants in included studies ranged from 51.6 to 58.1 years and the proportion of participants with ductal carcinoma in situ (DCIS) and invasive cancer varied from 0 to 100%.

Outcomes assessed in the review
Studies were eligible for inclusion if the absolute numbers of benign and malignant diagnoses were derivable.

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

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
All four authors independently extracted the data from the studies using a standard extraction form. Any disagreements were resolved by consensus. Data were extracted on participant characteristics and selection, the methods used for the index test and reference standard, results and complication rates.
**Methods of synthesis**

How were the studies combined?

Estimates of the following were calculated for each included study:

- the proportion of inconclusive lesions (defined as those for which re-biopsy was indicated because histology was not concordant with mammographic findings);
- the high-risk underestimate rate (defined as the percentage of high-risk lesions on vacuum-assisted biopsy upgraded to DCIS or invasive cancer in the surgical specimen);
- the DCIS underestimate rate (defined as the percentage of DCIS lesions on vacuum-assisted biopsy upgraded to invasive cancer at subsequent excision); and
- the miss-rate (defined as the proportion of all carcinomas with a benign diagnosis on vacuum-assisted biopsy).

If the results between studies were considered homogeneous, pooled estimates with 95% confidence intervals (CIs) were calculated.

**How were differences between studies investigated?**

Differences between individual study results were assessed using the chi-squared test.

**Results of the review**

Twenty-two studies were included in the review. The total number of participants unclear.

Inconclusive results (7 studies).

The proportion of inconclusive lesions varied from 0.5% (1 out of 216) to 9.0% (32 out of 354), with a median of 1.2%.

High-risk underestimate rate.

The high-risk underestimate rate was 15.9% (95% CI: 12.1, 19.7) for the 11G probe (15 studies) and 23.3% (95% CI: 19.1, 31.5) for the 14G probe (3 studies). There was no statistically significant difference between the 11G and 14G vacuum biopsy results (P>0.05).

DCIS underestimate rate.

The DCIS underestimate rate was 10.6% (95% CI: 8.8, 12.4) for the 11G probe (13 studies) and 12.7% (95% CI: 9.5, 15.9) for the 14G probe (4 studies). However, the test for homogeneity was significant for the latter (14G probe) and this estimate should be treated with caution.

Miss-rate.

Incomplete follow-up of benign lesions in all studies meant that the miss-rate (and thus sensitivity) could not be calculated.

Three studies mentioned complications that occurred as a result of vacuum-assisted biopsy: bleeding or haematoma (n=4), vasovagal reaction (n=1), infection (n=1), seizure (n=1), and nausea (n=1). One study reported that no complications occurred.

**Cost information**

The authors stated that the costs associated with the disposable materials of vacuum-assisted biopsy were 10 to 15 times higher than those for 14G-automated-needle biopsy.
Authors' conclusions
The results of this review indicated that vacuum-assisted biopsy, compared with 14G-automated-needle biopsy (results reported in a prior meta-analysis, see Other Publications of Related Interest), can decrease high-risk underestimate rates and DCIS underestimate rates. However, it was unclear whether it could decrease the miss-rates for cancer. Therefore, it is currently impossible to assess whether the benefits outweigh the additional costs of this procedure.

CRD commentary
The review addressed a clear and relevant research question, and the inclusion criteria were adequately defined. The search strategy was very limited. The included studies were restricted to English language publications and no attempt to identify unpublished studies was reported, thus relevant studies might have been overlooked. Any methods used to minimise bias during the study selection process were not given, although steps were taken to avoid bias and error in the data extraction. However, no assessment of the methodological quality of the included studies was reported; the potential impact of methodological flaws upon the findings of the review is therefore unclear.

Details of the included studies were clearly reported. The estimates of diagnostic performance used were appropriate to the clinical question and the methods of pooling were appropriate. The comparison of the diagnostic performance of vacuum-assisted biopsy with that of 14G-automated-needle biopsy (in the 'Discussion' section) was dependent on data for 14G-automated-needle biopsy that were derived from another publication and, therefore, was not a direct result of this review. The validity of this comparison depends upon an assumption of equivalence between the populations of the two reviews. Given this and the limitations of the current review, the authors' conclusions should be treated with some caution.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

Bibliographic details

PubMedID
12888361

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Biopsy /methods /standards; Breast Neoplasms /pathology; Female; Humans; Risk Assessment; Risk Factors; Sensitivity and Specificity; Vacuum

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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.