CRD summary
This review concluded that fine-needle aspiration cytology of palpable breast masses was highly accurate for the diagnostic differentiation of benign from malignant tumours. Given a lack of clarity for parts of the review process, uncertain study quality and heterogeneity between studies, this conclusion should be treated with caution.

Authors' objectives
To assess the diagnostic accuracy of fine-needle aspiration (FNA) cytology of palpable breast masses.

Searching
MELINE, Medscape, ERIC and EMBASE were searched without language restrictions from 1985 to 2007; search terms were reported.

Study selection
Studies in which the diagnostic accuracy of FNA was confirmed by histological presence or absence of breast cancer was confirmed by either excisional biopsy or mastectomy were eligible for inclusion. Studies without histologic confirmation were excluded as were those with insufficient information to calculate sensitivity and specificity. The number of aspirations in included studies ranged from one to six; more than half of the studies undertook one. Included studies were retrospective and prospective; most were retrospective.

The authors stated neither how the studies were selected for the review nor how many reviewers were involved in the selection process.

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

Data extraction
Sensitivity and specificity for FNA of palpable breast masses were either extracted or calculated from 2x2 tables, together with true and false positive and negative results for each study. Diagnostic odds ratios were calculated for each study and 95% confidence intervals (CI) were calculated for each outcome measure. To account for zero cells a continuity correction of 0.5 was applied.

Three reviewers independently extracted data for the review. Disagreements were resolved through consensus.

Methods of synthesis
Pooled estimates of sensitivity, specificity and diagnostic odds ratio, along with their corresponding 95% CI, were calculated using a random-effects model. Heterogeneity was assessed using either I^2 test or Cochran's Q test. Summary receiver operating curves (sROC) were plotted and the area under the curve (AUC) calculated. Meta-regression was used to explore the effects of covariates in terms of year of publication, number of aspirations, percentage of insufficient material and study design.

Results of the review
A total of 25 studies met the inclusion criteria (n=10,455; range 37 to 2,623).

FNA cytology with a histologic diagnosis: Sensitivity ranged from 78% to 100%. Specificity ranged from 76% to 100%. diagnostic odds ratios ranged from 15.83 to 33,198. The pooled estimates were 0.93 for sensitivity (95% CI 0.92 to 0.94), 0.98 for specificity (95% CI 0.97 to 0.99) and 505.21 for diagnostic odds ratio (95% CI 273.08 or 934.95).
These analyses were subject to significant heterogeneity (sensitivity $I^2=88.8\%$, specificity $I^2=85.1\%$ and DOR $I^2=74.1\%)$.

The overall diagnostic accuracy according to the results of SROC analysis was $0.95 \pm 0.0032$, and the overall weighted area under the curve was $0.99 \pm 0.0014$. The diagnostic odds ratio was significantly greater for studies published after 1990 than for those before (relative diagnostic odds ratio $3.98$, 95% CI $1.22$ to $13.02$), perhaps due to the technological improvements in diagnostic tools. Increasing the number of aspirations did not result in a significant increase in the relative diagnostic odds ratio of the FNA cytology. Increasing the percent of insufficient material above 10% resulted in a statistically nonsignificant decrease in the diagnostic odds ratio of FNA.

**Authors’ conclusions**
FNA cytology of palpable breast masses was highly accurate for the diagnostic differentiation of benign from malignant tumors.

**CRD commentary**
The review addressed a clear research question supported by appropriate, but brief, inclusion criteria. Several sources were searched and attempts to avoid language bias were implemented. There was no specific search for unpublished data, so publication bias can not be ruled out. This was not investigated. Data extraction was conducted in duplicate, but it was unclear whether similar methods to reduce error and bias were employed during study selection. No assessment of the methodological quality of the included studies was reported. Very few details on the included primary studies were reported, so the generalisability of the findings was unclear and it was not possible to make a judgement of the quality of the included evidence, although the majority of studies were retrospective. There was significant heterogeneity in the pooled estimates, therefore, the reliability of the pooled estimates of sensitivity and specificity are uncertain. The authors’ conclusions were supported by the data, but should be interpreted with caution due to a lack of clarity of parts of the review process, uncertain study quality and heterogeneity between studies.

**Implications of the review for practice and research**
**Practice:** The authors did not state implications for practice.

**Research:** Further studies were required to assess the safety, tolerance and cost-effectiveness of FNA; such studies should follow recommendations of the Standards for Reporting of Diagnostic Accuracy initiative to ensure that they included enough subjects.

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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.