Accuracy of estrogen receptor, progesterone receptor, and HER2 status between core needle and open excision biopsy in breast cancer: a meta-analysis

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CRD summary
This review concluded that core needle biopsy had high diagnostic accuracy in evaluating oestrogen receptor, progesterone receptor, and human epidermal growth factor receptor-2 status, compared with open excision biopsy, for patients with breast cancer. There was no information on the quality of the included evidence, and accuracy could have been overestimated, so the conclusions should be treated with caution.

Authors' objectives
To compare the accuracy of core needle biopsy, with that of open excision biopsy, for oestrogen receptor, progesterone receptor, and human epidermal growth factor receptor (HER)2 status detection, in patients with breast cancer.

Searching
MEDLINE, EMBASE and Web of Science were searched for studies published in English between 1995 and May 2011; search terms were reported. Reference lists from identified articles were searched.

Study selection
Studies assessing the accuracy of core needle biopsy, with at least 10 women with breast cancer, were eligible for inclusion if they used the biomarker results from open excision biopsy as the reference standard. Studies had to provide sufficient data to construct 2x2 tables of test performance.

In the included studies, where reported, most women had invasive ductal carcinoma, at an early stage (T0, T1, or both), and were lymph node status N0. The biopsy needle gauge ranged from 11 to 18, and the number of biopsies ranged from one to over 24. The cutoff values for a positive test ranged from 1% to 20% for oestrogen and progesterone receptors, and were at least two on immunohistochemistry for HER2. A small number of studies used fluoresce in situ hybridisation (FISH) to detect HER2. These details were not available for many of the included studies.

Two reviewers independently selected studies for the review.

Assessment of study quality
The authors did not assess study quality.

Data extraction
Two reviewers independently extracted the data to produce 2x2 tables of test performance, for oestrogen receptor, progesterone receptor, and HER2 separately; sensitivity, specificity and the diagnostic odds ratio were calculated. Disagreements were resolved by discussion or by a third reviewer. Where there was a zero in a table cell, 0.5 was added to all four cells.

Methods of synthesis
Summary estimates of sensitivity, specificity and the diagnostic odds ratio, with 95% confidence intervals, were calculated; the model used was not reported. Summary receiver operating characteristic curves were produced; the model used was not reported. Heterogeneity was assessed using I².

Meta-regression and subgroup analyses were used to investigate publication year, the number of patients, the number of invasive ductal carcinoma patients, the gauge of the needle, the oestrogen receptor positive rate, the progesterone receptor positive rate, the HER2 positive ratio, and the number of biopsies. Publication bias was assessed using funnel plots.

Results of the review
Twenty-seven studies were included in the review, with 3,565 participants (range 26 to 500).
Oestrogen receptor: From 21 studies, the summary sensitivity was 97% (95% CI 96.1 to 97.7; $I^2=42.5\%$), specificity was 79% (95% CI 75.4 to 82.3; $I^2=90.8\%$), and the diagnostic odds ratio was 122.2 (95% CI 54.5 to 274.1; $I^2=73.8\%$).

Progesterone receptor: From 20 studies, the summary sensitivity was 91% (95% CI 89.6 to 92.6; $I^2=79.9\%$), specificity was 73% (95% CI 69.6 to 76.1; $I^2=86.6\%$), and the diagnostic odds ratio was 31.2 (95% CI 16.0 to 61.0; $I^2=78.4\%$).

HER2: With status confirmed by immunohistochemistry two, three or FISH, from 10 studies, the summary sensitivity was 80% (95% CI 74.5 to 84.6; $I^2=20.0\%$), specificity was 89% (95% CI 86.9 to 90.9; $I^2=83.2\%$), and the diagnostic odds ratio was 31.2 (95% CI 17.1 to 56.8; $I^2=49.7\%$). With status confirmed by immunohistochemistry three or FISH, from 15 studies, the summary sensitivity was 81% (95% CI 75.8 to 86.0; $I^2=51.8\%$), specificity was 98% (95% CI 97.0 to 98.4; $I^2=77.8\%$), and the diagnostic odds ratio was 202.1 (95% CI 92.0 to 443.9; $I^2=46.6\%$).

Meta-regression showed the number of women with invasive ductal carcinoma and the publication year were statistically significant for progesterone receptor status, and the number of women with invasive ductal carcinoma was significant for HER2 status, confirmed by FISH. The results for positivity rates, impact of prevalence, and area under the curve, were given. The funnel plots indicated that publication bias could have been present.

Authors’ conclusions
Core needle biopsy had high diagnostic accuracy in evaluating oestrogen receptor, progesterone receptor, and HER2 status compared with open excision biopsy in breast cancer patients. Oestrogen receptor and progesterone receptor status should be detected both on core needle biopsy and open excision biopsy, especially for patients with initial negative status on open excision biopsy.

CRD commentary
The authors addressed a clear review question, supported by reproducible inclusion criteria. Several sources were searched, but only studies published in English were included, so some relevant studies could have been missed. Study selection and data extraction were conducted in duplicate, reducing the risk of error and bias. Study quality was not assessed, leaving it uncertain whether the included studies were subject to bias; the authors stated that data from high-quality prospective studies were limited.

The authors did not specify the models used to synthesise the data; it appears that summary estimates of sensitivity and specificity were derived separately, and that the Moses-Littenberg model was used to produce the summary receiver operating characteristic plots. This method has particular problems when there is a high degree of heterogeneity across the studies, as accuracy can be overestimated; most of the analyses had moderate to substantial statistical heterogeneity. More robust methods are available that can produce summary estimates of sensitivity and specificity without breaking the link between these related measures.

Given the lack of information on the quality of the included evidence, and the potential for the overestimation of accuracy, the conclusions should be treated with caution.

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

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