Does this patient have breast cancer? The screening clinical breast examination: should it be done? How?

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Authors' objectives
To collect evidence on the effectiveness of clinical breast examination (CBE) in screening for breast cancer, and information on the best technique to use.

Searching
MEDLINE was searched from 1966 to 1997 using the search terms 'physical examination', 'palpation, breast', 'breast diseases, diagnosis', 'diagnostic tests', 'sensitivity' and 'specificity'. The reference lists of retrieved articles and other articles known to the authors were reviewed. The search was limited to English language articles only.

Study selection

Study designs of evaluations included in the review
For the review of the effectiveness of screening CBE, controlled trials and case-control studies were eligible for inclusion. No inclusion criteria relating to study design were specified for studies of test characteristics, and the study designs of those included were not described.

Specific interventions included in the review
The included studies had to use CBE as at least part of the screening modality. Studies of screening with CBE alone, or CBE plus mammography were included in the review.

Reference standard test against which the new test was compared
For data on the test characteristics of screening CBE, the included studies had to confirm all breast cancer diagnoses histologically. The breast cancer outcome for all screens had to be determined within a defined follow-up period.

Participants included in the review
No inclusion criteria relating to the study population were specified. The included studies were mostly of women aged 40 to 64 years (a few studies included in the review include younger and older women). For test characteristics, the included studies were required to determine CBE accuracy using data from asymptomatic women; it is not clear whether all the studies included in this section of the review met this criteria.

Outcomes assessed in the review
No inclusion criteria in respect of outcome measures were specified for the evaluation of the effectiveness of screening CBE. The included studies used the number of cases of breast cancer detected and breast cancer mortality rate within a defined follow-up period as the outcome measures. Where reported, the follow-up periods ranged from 7 to 18 years.

The included studies of test characteristics had to report all screening outcomes. The sensitivity, specificity, and positive and negative likelihood ratios (LRs) were calculated from the raw data reported in the included studies. Sensitivity was defined by the authors as the number of women who had histologically confirmed cancer on CBE, divided by the sum of screen-detected cancers (found by CBE or mammography) and cancers diagnosed in the year following screening. Specificity was defined by the authors as the number of women who had normal CBE results and did not develop cancer during follow-up, divided by all the women without cancer at the end of the follow-up period.

How were decisions on the relevance of primary studies made?
All the authors reviewed and agreed on the studies selected for inclusion in the pooled analysis. It is unclear whether this was independent or not.

Assessment of study quality
The authors did not state that they assessed quality.
Data extraction
The authors did not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. An unspecified number of investigators were contacted for unpublished data.

Methods of synthesis

How were the studies combined?
Summary measures of the sensitivity and specificity of CBE and LRs of a positive or negative examination were based on published data from the reported trials that met the reviewers’ inclusion criteria. A random-effects model was used to generate summary effect measures and confidence intervals (CIs).

How were differences between studies investigated?
Between-study heterogeneity was not investigated. A random-effects model was used when pooling data to give a conservative estimate of the effect size.

Results of the review

Effectiveness of CBE: one randomised controlled trial (RCT; n=60,696) and one case-control study (n=216) compared the combination of screening CBE yearly plus mammography yearly with no screening; one RCT (n=44,288) and one non-randomised controlled trial (n=173,065) compared CBE yearly plus mammography on alternate years with no screening; one RCT (n=50,430) compared CBE yearly plus mammography yearly with CBE once only; one RCT (n=39,405) compared CBE yearly plus mammography yearly with CBE yearly.

Accuracy of CBE: data on test characteristics were reported from 6 studies included in the review. The study designs and numbers of participants included in this element were not reported.

Precision of CBE: 4 studies of inter-observer variation in screening CBE were included in the review. The numbers of participants included in these studies were not clear.

Effectiveness of CBE: no trial compared CBE alone with no screening. One RCT and one case-control study compared the combination of screening CBE yearly plus mammography yearly with no screening; these showed statistically-significant decreases in breast cancer mortality for women between 40 and 64 years of 23% (relative risk, RR=0.77, 95% CI: 0.62, 0.97) and 71% (RR 0.29, 95% CI: 0.14, 0.62), respectively. Two trials comparing CBE plus mammography with CBE alone showed no statistically-significant reduction in breast cancer mortality.

Precision of CBE: using a narrative synthesis of 4 studies of inter-observer variation (the characteristics of these studies were not tabulated), the authors concluded that clinicians using unstandardised CBE methods have demonstrated moderate degrees of agreement beyond that expected by chance.

Accuracy of CBE: the pooled sensitivity of CBE (data from 6 studies) was 54.1% (95% CI: 48.3, 59.8) and the pooled specificity (data from 5 studies) was 94% (95% CI: 90.2, 96.9). The pooled positive and negative LRs (data from 4 studies) were 10.6 (95% CI: 5.8, 19.2) and 0.47 (95% CI: 0.40, 0.56), respectively.

The authors state that it is difficult to summarise the precision and accuracy of CBE because it is known that the conduct of the examination varies widely, and it is not well described in the majority of studies. Also, the available studies included women differing in age, history of symptoms (symptomatic and asymptomatic) and practice setting (primary care or surgical).

Authors’ conclusions
The indirect evidence supports the effectiveness of CBE in screening for breast cancer. While the screening clinical examination by itself does not rule out disease, the high specificity of certain abnormal findings greatly increases the probability of breast cancer. An overall view of the evidence suggests that carefully performed CBE detects cancers that are potentially curable.

CRD commentary
The review posed a clear question in terms of the intervention and the main outcomes of interest, although there was confusion in terms of what details were given for studies that assessed the issues of effectiveness, accuracy and precision. Participant characteristics were not explicitly stated. Only one database (MEDLINE) was searched and only English language studies were included, which may have limited the number of relevant trials retrieved and introduced publication and language bias. The use of specific terms relating to characteristics of diagnostic tests may also have limited study retrieval. The study design of the included studies was stated for studies of effectiveness only, and there was no mention of whether, or how, the quality of the included studies was assessed. The report lacked details of the review process, such as whether decisions were made by more than one person and whether this was independent.

The narrative synthesis of results, where used, seemed appropriate. The effectiveness data were not pooled and data from the individual studies were clearly tabulated; this approach also seems appropriate. Not all of the studies that
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contributed to the results, such as precision, were described in the tables. The meta-analysis was inappropriately used to pool data on test characteristics from individual studies; the use of a random-effects model alone to adjust for heterogeneity, without investigation of sources of heterogeneity or the impact of threshold effect, is not adequate. The authors do point out the problem of heterogeneity between the trials and make some attempt to explain it. However, given the likely heterogeneity of the study populations and the possibility of threshold effect where a subjective test is being assessed, the use of summary ROC curves along with an investigation of sources of heterogeneity may have been more appropriate.

The authors were explicit about most of the available evidence on the effectiveness of CBE being indirect, and about the importance of using good technique. However, in the absence of sufficient direct evidence, their conclusions may be too strongly in favour of CBE.

Implications of the review for practice and research

Practice: The authors state that screening CBE should be conducted for women who are at risk for breast cancer, and for whom screening for breast cancer has been shown to be effective (this presently includes women older than 40 years).

Research: The authors state that standardisation of CBE is sorely needed, and further work should be done to determine which standardised method can improve sensitivity and specificity. The contribution of visual inspection to CBE should be investigated. A comparison of standardised CBE with mammography in women older than 70 years is also needed, as are studies to determine whether standardised CBE can contribute to decreasing mortality rates in women younger than 50 years. The cost-effectiveness of CBE screening deserves study, as does the cost effectiveness of programmes to train providers in how to perform the examination.

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