Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Using stereotaxic core breast biopsy or surgical excisional biopsy in the diagnosis of women with nonpalpable breast abnormalities.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
A hypothetical cohort of women with nonpalpable breast abnormalities found on mammography.

Setting
Hospital. The economic study was carried out in Virginia, USA.

Dates to which data relate
The effectiveness data was partly based on literature published between 1990 and 1994. The resource use data were based on information collected in 1994-1995. The price year was not clearly reported.

Source of effectiveness data
The evidence for the final outcomes was derived from a decision tree model. The clinical probabilities were based on the literature and experts' opinion.

Modelling
A decision tree was used to estimate cost and benefits. The model incorporated cost and outcomes associated with the early detection of invasive or in situ breast cancer, the 6-month delayed diagnosis (achieved by a mammographic follow-up at that point in time), cases diagnosed beyond 6 months, and unnecessary (negative) excisional biopsies.

Outcomes assessed in the review
The percentage of surgical confirmation of stereotaxic core breast biopsy was separately reported from 7 different studies. The probability of a suspicious lesion being invasive cancer or in situ cancer was derived from the literature. The clinical probabilities and their range of values related to surgical biopsies and mammogram at 6-month follow-up (sensitivities and specificities, and the probability of surgical biopsy being inadequate or indeterminate) were reported from the literature.
Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The results for percentage of surgical confirmation of stereotaxic core breast biopsy were separately reported from 7 different studies. In the estimation of clinical probabilities related to invasive and in situ cancer 3 studies were used. Five studies were used to derive the probabilities related to surgical biopsies and mammogram at 6-month follow-up. Overall, fifteen studies were directly or indirectly used to derive the clinical probabilities.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The probability of a suspicious lesion being invasive cancer or in situ cancer was 10% in each case. The probability of surgical biopsy being inadequate was 0.01 or being indeterminate was 0.00. The sensitivity of surgical biopsy for invasive cancer and in situ cancer was 0.99 in each case. The specificity of surgical biopsy for invasive cancer and in situ cancer was 1.00. The sensitivity of mammogram at 6-month follow-up was 0.85%, while the specificity was 0.95%. The percentage of surgical confirmation of stereotaxic core breast biopsy was separately reported for each of 7 studies and the percentages were synthesised by the authors to estimate the sensitivity of stereotaxic core breast biopsy.

Methods used to derive estimates of effectiveness
The authors synthesised the available evidence in the literature in order to derive the clinical probabilities related to stereotaxic core breast biopsy (sensitivities and specificities, and the probability of surgical biopsy being inadequate or indeterminate).

Estimates of effectiveness and key assumptions
For the intervention, the false negative rate was 0.08 for invasive cancer and 0.13 for in situ cancer. The true positive rate (sensitivity) was in turn estimated to be 0.90 for invasive cancer and 0.85 for in situ cancer. The probability of surgical biopsy being inadequate or indeterminate was 0.05 and 0.02, respectively. A long list of 8 assumptions was used to derive the final outcomes of the model.

Measure of benefits used in the economic analysis
The measures of benefits in the economic analysis were the number of cases missed to early diagnosis and cases missed to diagnosis within 6 months. A decision model was used in estimating the benefits.

**Direct costs**
The quantities of resource use were not reported separately from the costs. The cost items were not reported separately. The costs included operational costs associated with the diagnosis and treatment procedures. The cost analysis was performed from a societal perspective. The cost estimation was based on actual data from a hospital in Virginia, where all biopsies were carried out on an outpatient basis. Costs were estimated from charges using cost to charge ratios. The estimates of costs of professional services were based on relative value units data. The cost analysis covered a 6-month follow-up period. The price date was not specified.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
A set of one-way sensitivity analyses was performed by varying the cancer prevalence rates, the false negative rates associated with the intervention, and incorporating the costs of additional local re-excisions or subsequent mastectomy (surgery) use, and by varying the assumption that the 6-month delay in diagnosis did not affect the prognosis of the corresponding women.

**Estimated benefits used in the economic analysis**
The cases, per 1,000 women tested, missed to early detection (at initial biopsy and the diagnosis delayed until 6-month follow-up) for invasive and in situ cancer were 6.4 and 10.6, respectively for the stereotaxic biopsy versus 0.8 and 0.8, respectively for the surgical biopsy. The number of cases, per 1,000 women tested, missed to detection beyond 6-month follow-up for invasive and in situ cancer were 1.3 and 2.8, respectively for the stereotaxic biopsy versus 0.2 and 0.2, respectively for the surgical biopsy.

**Cost results**
The average cost of diagnosis per woman was $1,066 for the stereotaxic biopsy versus $2,131 for the surgical biopsy. The corresponding figure for definitive treatment was $1,975 for the stereotaxic biopsy versus $2,779 for the surgical biopsy.

**Synthesis of costs and benefits**
The incremental cost per diagnosis and treatment after 6 months was adopted as the cost-effectiveness measure. The incremental cost per additional invasive and in situ cancer detected and treated after 6 months was $217,300 with excisional biopsy relative to the stereotaxic biopsy (intervention). The corresponding figure for cases missed to early detection was $42,100. If the total prevalence of cancer changed from 20% to 10% and 30%, the corresponding figures for early detected cancer would be $100,000 and $24,000, respectively. If no cases of invasive cancer were missed by the intervention, the incremental cost-effectiveness ratio would be $240,000. Alternative assumptions regarding the costs of additional surgery and mastectomy use would increase the respective base case estimates for early detection and treatment within 6 months. The gain in survival by early detection was estimated based on assumptions regarding the effect on prognosis of delayed diagnoses. This analysis yielded an estimate of $156,700 per additional life year gained with the initial excisional biopsy.
Authors' conclusions
Using conservative estimates for the false-negative rate of stereotaxic biopsy is projected to have substantial cost savings with a slight compromise in the rate of early detection. Whether the decremental cost-effectiveness is acceptable is dependent on the natural history of cancers whose diagnosis is delayed.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator. The comparator was reported as the standard of care.

Validity of estimate of measure of benefit
Due to the fact that the literature review included no quality assessment of the primary studies, there is insufficient information to assess the internal validity of the estimates of the benefits.

Validity of estimate of costs
Resource use was not reported separately from the costs. Adequate details of the methods of cost estimation were not given. The price year was not clearly reported. Indirect costs were not included in the analysis despite the societal perspective adopted in the analysis.

Other issues
Given the problem with the literature review referred to above and the lack of statistical analysis of the costs, the results may need to be treated with some caution.

Implications of the study
Further studies are needed to address fully the research question posed by this investigation.

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