Calcifications highly suggestive of malignancy: comparison of breast biopsy methods

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
The health technology studied was stereotactic biopsy with a 14-gauge automated needle, a 14-gauge vacuum-assisted probe, or an 11-gauge vacuum-assisted probe.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with calcifications highly suggestive of malignancy. Stereotactic biopsy was not offered to women who had a bleeding diathesis, or who were unable to co-operate with the procedure, or in whom the lesion could not be targeted using stereotactic equipment.

Setting
The setting was hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness, resource use, and cost data related to the period July 1993 to July 2000. The price year was 2000.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
One hundred and thirty-nine women with calcifications highly suggestive of malignancy underwent diagnostic biopsy. Of these, 89 women had stereotactic biopsy with a 14-gauge automated needle (n=25), a 14-gauge vacuum-assisted probe (n=17), or an 11-gauge vacuum-assisted probe (n=47). Fifty women had diagnostic surgical biopsy. No power calculations were reported. The sample was selected on the basis of consecutive lesions that underwent diagnostic biopsy. Patients were aged in their early fifties. The median lesion size at mammography was 3.1 cm with stereotactic biopsy with a 14-gauge automated needle, 2.3 cm with a 14-gauge vacuum-assisted probe, 2.1 cm with an 11-gauge vacuum-assisted probe, and 2.1 cm with diagnostic surgical biopsy. The median number of specimens obtained was 7 with stereotactic biopsy with a 14-gauge automated needle, 16 with a 14-gauge vacuum-assisted probe, and 16 with an
11-gauge vacuum-assisted probe.

**Study design**
The authors carried out a prospective cohort study set at a single centre. The duration and loss to follow-up were not reported. Lesions were classified prospectively before tissue diagnosis in accordance with the BI-RADS categories.

**Analysis of effectiveness**
The analysis of the clinical study was based on intention to treat. Primary health outcomes used in the analysis were final histologic diagnosis, histologic size of infiltrating carcinoma, and the probability of achieving tumour resection with clear margins at the first operation. Groups were comparable at analysis in terms of patient age. Lesions that were subjected to 14-gauge automated core biopsy were slightly larger. More specimens were obtained at vacuum-assisted biopsy than at 14-gauge automated core biopsy.

**Effectiveness results**
The effectiveness results were as follows:

The final histologic diagnosis was carcinoma in 89% of women who underwent stereotactic biopsy and 74% of women who underwent surgical biopsy, ($p=0.04$, 95% CI: 1.0 - 7.7).

Median histologic size of infiltrating carcinoma was 0.4 cm in women who underwent stereotactic biopsy and 0.5 cm in women who underwent surgical biopsy. The median number of operations was one with stereotactic biopsy and two with diagnostic surgical biopsy. The likelihood of undergoing a single operation was 68% with stereotactic biopsy and 38% with diagnostic surgical biopsy, ($p<0.001$) among all women and among women treated for breast cancer (71% versus 16%, $p<0.001$). Stereotactic 11-gauge vacuum-assisted biopsy as compared with 14-gauge automated core or 14-gauge vacuum-assisted biopsy was more likely to spare a surgical procedure, (77% versus 38%, $p=0.0005$).

Benign findings without atypia were found in 9% of women who underwent stereotactic biopsy and 24% of women who underwent surgical biopsy.

The likelihood of achieving tumour resection with clear margins at the first operation was greater if the initial diagnostic procedure was stereotactic rather than surgical biopsy, among all women with breast cancer (75% versus 22%, $p<0.01$, 95% CI: 4.0 - 32.3), and among women treated with breast-conserving surgery (57% versus 33%, $p=0.16$, 95% CI: 0.7 - 10.3).

**Clinical conclusions**
Stereotactic biopsy was more likely to achieve tumour resection with clear margins at the first operation than diagnostic surgical biopsy.

**Measure of benefits used in the economic analysis**
The authors did not report a summary health benefit and left outcomes disaggregated. Hence, a cost-consequences analysis was conducted.

**Direct costs**
Direct costs were not discounted due to the short time horizon of the study (less than one year). Quantities and costs were reported separately. Direct costs related to costs of stereotactic breast biopsy, and costs of needle localisation and surgical breast biopsy. The quantity/cost boundary adopted was that of the hospital. Costs were calculated using Medicare data. The price year was 2000.
Statistical analysis of costs
The authors reported cost savings per case.

Indirect Costs
Indirect costs were not included in the study.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were reported.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
Cost savings relative to diagnostic surgical biopsy amounted to -$143 with stereotactic biopsy with a 14-gauge automated needle, -$198 with a 14-gauge vacuum-assisted probe and $315 with an 11-gauge vacuum-assisted probe.

Synthesis of costs and benefits
The authors did not combine cost and health benefit measures into a cost-effectiveness ratio.

Authors' conclusions
The authors concluded that, for women with calcifications highly suggestive of malignancy, the use of stereotactic rather than surgical biopsy decreased the number of operations. Stereotactic 11-gauge vacuum-assisted biopsy as compared with 14-gauge automated core or 14-gauge vacuum-assisted biopsy was significantly more likely to spare a surgical procedure and had the highest cost savings.

CRD COMMENTARY - Selection of comparators
The justification of the comparator was that it represented the traditional approach. You, as a user of this database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective cohort study, which was appropriate for the study question. The study sample was representative of the study population. The authors reported demographic characteristics of patients in each group and showed that groups were comparable in terms of patient age, but not in terms of lesion size or number of specimens obtained. There was a greater frequency of cancer among women who had stereotactic rather than surgical biopsy. The extent to which these differences in characteristics between groups explain differences in outcome measures was not clear. However, the authors analysed the results for the women with cancer in each group to account for the greater frequency of cancer among women who had stereotactic rather than surgical biopsy. The authors noted that the improved outcome of stereotactic 11-gauge vacuum-assisted biopsy might reflect the learning curve of the doctors.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.
Validity of estimate of costs
Good features of the cost analysis were that all relevant direct cost categories were included, quantities and costs were reported separately, and the price year was reported. However, the authors did not conduct sensitivity or statistical analyses on quantities or costs which limits the validity and generalisability of the results. The authors did not consider the costs associated with additional work required for histologic analysis of the larger volume of tissue obtained at vacuum-assisted biopsy. The authors noted that, because of rapid changes in technology, the impact of percutaneous biopsy on costs continues to evolve.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies, and did not address the issue of generalisability to other settings. However, the authors did not seem to present their results selectively. The study considered women with calcifications highly suggestive of malignancy, and this was reflected in the authors’ conclusions. The authors considered a few effectiveness estimates but no measure of benefit, which makes it difficult to compare the results with those of other studies that examined similar health technologies. Instead the authors primarily focussed on resource utilisation and associated cost savings.

Implications of the study
The authors concluded that, for women with calcifications highly suggestive of malignancy, the use of stereotactic rather than surgical biopsy decreases the number of operations. Stereotactic 11-gauge vacuum-assisted biopsy as compared with 14-gauge automated core or 14-gauge vacuum-assisted biopsy is significantly more likely to spare a surgical procedure and has the highest cost savings.

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