Percutaneous large core needle biopsy versus surgical biopsy in the diagnosis of breast lesions


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 percutaneous large core needle biopsy (LCNB) or open surgical biopsy (SB) in the diagnosis of breast lesions (histological classification).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing biopsy for the diagnosis of breast lesions.

Setting
Hospital. The economic study was performed in Udine, Italy.

Dates to which data relate
Effectiveness data were collected between May 1992 and February 1995. The resource utilisation was extracted from Italian Federation of Pathological Anatomy and Cytology (FISAPEC) tables published in 1993. The dates of the price data were not specified.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was not performed on the same patient sample as that used in the effectiveness study. The costing was performed retrospectively.

Study sample
Power calculations were not used to determine the sample size. The study sample comprised 196 percutaneous biopsies performed on 190 patients (189 women and 3 men). A subsample of 70 cases was chosen to assess morphobiological parameters.

Study design
The study was a retrospective cohort study performed in one centre.

**Analysis of effectiveness**
The analysis of the clinical study was based on both intention to treat and treatment completers only. The main health outcome used in the analysis was the accuracy in the evaluation of histological degree, receptor state, protein c-erb B2 and p53.

**Effectiveness results**
LCNB had 97% sensitivity and 100% specificity. The calculated values of positivity and negativity predicted were 100% and 89% respectively. The correlation coefficients for the data obtained with SB and LCNB were 0.80 for receptor for estrogen (ER), 0.75 for PgR, 0.91 for p53, and 0.91 for c-erbB2.

**Clinical conclusions**
LCNB is an effective test for histological diagnosis and could be used as an alternative to SB in the diagnosis of breast lesions (histological classification).

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic study and only separate clinical outcomes were reported.

**Direct costs**
The quantities were not reported separately. The cost items were reported separately. The total costs of each procedure consisted of the cost of preparation/reading, estrogen receptor, progesterone receptor, c-erb B2 protein, and p53 protein. It was not explicitly specified from whose point of view the cost analysis was performed. The date of the price data was not specified.

**Indirect Costs**
Not considered.

**Currency**
Italian lira (L). A conversion to US dollars ($) was carried out at an exchange rate of $1 = L 1600.

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
No summary benefit measure was identified in the economic study and only separate clinical outcomes were reported.

**Cost results**
The cost of a complete LCNB test was L 551,800 ($344), versus L 995,960 ($598) for the cost of intraoperative SB to achieve the same data.

**Synthesis of costs and benefits**
A synthesis was not performed by the authors since LCNB was the dominant strategy.
Authors' conclusions
Percutaneous LCNB has high diagnostic accuracy for histological classification and the same accuracy as SB for morphological parameters. The cost of LNCB is markedly lower than SB.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of comparator (SB). It was considered as "still the most common analysis for the diagnosis of breast nodules". You, as a database user, should consider if this applies to your own setting.

Validity of estimate of measure of benefit
Lack of randomisation may cast doubt on the internal validity of the estimate of the measures of effectiveness.

Validity of estimate of costs
As few details of the methods of cost estimation were given, it is difficult to judge whether any important items were omitted.

Other issues
In view of the absence of randomisation, sensitivity analysis, and statistical analysis of costs, the results need to be treated with some caution. The issue of generalisability to other settings and countries was not addressed.

Source of funding
None stated.

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