Stereotactic and ultrasound core needle breast biopsy performed by surgeons

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
Stereotactic core needle biopsy (SCNB) or ultrasound core needle biopsy (UCNB) for the diagnosis of malignancy in mammographic lesions.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Women with mammographic abnormalities referred for surgical investigation following breast screening and diagnostic mammograms or diagnostic ultrasound evaluation.

Setting
The practice setting was the hospital. The economic study was carried out in Tennessee, USA.

Dates to which data relate
Effectiveness and resource use data related to the period from April 1995 to August 1996. The price date was not specified.

Source of effectiveness data
Evidence for final outcomes of core needle biopsy was based on a single study and for NLB was based on the authors’ opinions.

Link between effectiveness and cost data
Costing was performed prospectively on the same sample at that used in the effectiveness study.

Study sample
463 consenting consecutive patients underwent core needle biopsy for 499 breast lesions over 17 months. The number who were not eligible, or who refused to participate, was not stated. SCNB was performed on 324 lesions in 319 patients and UCNB was performed on 157 lesions in 144 patients. The mean age of patients undergoing SCNB was 54.2 years (range: 24 - 85) and for patients undergoing UCNB was 50.3 years (range: 20 - 83). Power calculations were not used to determine sample size.
Study design
The study was of a prospective case series design, conducted at a single centre. Patients were allocated to SCNB or UCNB according to clinical judgement. The mean follow up time for all patients was 13.5 months (range: 5 - 22). No loss to follow up was reported.

Analysis of effectiveness
The analysis was based on the whole patient sample. The primary health outcome was the malignancy rate. The level of pain experienced during the procedure, procedural bleeding (recorded by the surgeon based on patients response to questions), and haematoma formation were also assessed. The rate of NLB following core needle biopsy was also reported. Groups were not shown to be comparable in terms of clinical or demographic characteristics.

Effectiveness results
The malignancy rate for the SCNB group was 19% (66 malignancies detected in 342 biopsies) and the rate for UCNB was 17% (26 malignancies detected in 157 biopsies). Approximately 80% of SCNB patients and 91% of UCNB patients experienced no more than slight discomfort during the procedure. Procedural bleeding was easily controlled in 85% of patients in the SCNB group and in 83% of patients in the UCNB group. Haematoma formation was minimal in both groups, occurring at 4% overall. Excisional biopsy was carried out in 29 (6%) patients, 17 (59%) of whom were in the SCNB group.

Clinical conclusions
The accuracy of core needle biopsy, while thought to be excellent, will require longer follow-up to allow for appropriate interpretation and reporting.

Methods used to derive estimates of effectiveness
The authors referred to five studies in the medical literature to support an estimate for the malignancy detection rate of NLB.

Estimates of effectiveness and key assumptions
The yield of malignant lesions found by NLB was assumed to be 16%.

Measure of benefits used in the economic analysis
Effectiveness results were not converted to a single measure of benefit.

Direct costs
Quantities and costs were not reported separately. Costs were analysed from the perspective of the hospital. The cost of SCNB and UCNB included the technical component, supplies, physician fees, and pathology cost. The cost of NLB was based on the resource use of the 29 patients who underwent NLB and included fees for operating and recovery rooms, the surgeon, the anaesthesiologist, radiologic wire placement, pathologist and preoperative testing where indicated. Resource use data were taken from the period from April 1995 to August 1996, but the price date was not stated.

Statistical analysis of costs
A statistical analysis of costs was not performed.

Indirect Costs
Not included.
Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was not performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The total mean biopsy cost was $1,658 for SCNB, $683 for UCNB and $3,037 for NLB. Had all biopsies been performed using NLB, the total cost would have been $1,460,797. By using SCNB and UCNB for the initial diagnosis, cost savings of $721,963 (49%) were achieved.

Synthesis of costs and benefits
A synthesis of costs and benefits was not performed.

Authors’ conclusions
Minimally invasive breast biopsy procedures can safely and reliably be performed by surgeons in clinical practice with increased patient convenience and decreased costs.

CRD COMMENTARY - Selection of comparators
The authors implicitly assumed that all patients would have been diagnosed with NLB, in the absence of core needle biopsy. You, the user of the database, should decide if this is a widely used diagnostic tool in your own setting.

Validity of estimate of measure of benefit
The study was of a prospective cohort design, with patients allocated to type of core needle biopsy according to clinical judgement. This may have introduced systematic biases into the effectiveness results, which were not excluded by the demonstration of comparability in patient groups, in terms of clinical and demographic characteristics. The number of false positive results detected by each method was not reported. The effectiveness result for NLB was based on 5 references from the medical literature, but no detail of the review methods used was reported. The statistical significance of the effectiveness results was not reported.

Validity of estimate of costs
Quantities and prices were not reported separately, and inadequate detail of the methodology used to estimate costs was given. It is unclear how the mean estimates were derived from the total cost figures. These factors limit the generalisability of the results to other settings. Statistical and sensitivity analyses were not performed to investigate any areas of uncertainty in the mean estimates of cost. The strategy of SCNB and UCNB both included referral for NLB, but the cost of this procedure was not included in the total intervention cost. However, the authors did include the cost in their estimate of cost savings.

Other issues
The authors acknowledged the limitations of the effectiveness analysis, but nevertheless concluded that both core needle biopsy procedures are safe and cost effective. This conclusion is not supported by results reported in this study.

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