Diagnosis of palpable breast lesions in younger women by the modified triple test is accurate and cost-effective

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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
Modified Triple Test (MTT) consisting of physical examination, ultrasonography and fine needle aspiration (FNA) in the diagnosis of palpable breast lesions in younger women (below the recommended age of screening mammography).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Women under the age of 40 referred to clinic for unilateral, palpable breast lesions.

Setting
Secondary care. The economic study was carried out in Oregon, USA.

Dates to which data relate
The data used in the effectiveness analysis and for resources used belong to the period from October 1992 to July 1995. The date for the prices used was not clearly reported (charges were determined "using our current charges").

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

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

Study sample
No power calculations were reported. The total number of patients was 55. The physical examinations were evaluated by two specialist clinicians, sonograms were read by two specialists and FNAs were read first by a cytopathologist who then reviewed the findings with another cytopathologist. The confirmation of diagnosis was conducted by performing open biopsies and/or clinical follow up according to the following criteria: Cases with concordant negative MTTs (all three examinations indicating a malignant condition or all indicating a benign condition) were followed up using clinical evaluation, with subsequent open biopsy performed only if the patient requested it; for concordant positive and non-concordant cases (with FNA being considered suspicious or malignant), open biopsies were performed on the index lesion. The study patients had a mean age of 33 years.
Study design
The study was a prospective case series, carried out in a single centre. The duration of follow up varied, with a mean value of 11 months (range: 1 - 45 months). No loss to follow-up was reported.

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The primary health outcomes used were sensitivity, specificity, accuracy, positive predictive value and negative predictive value and number of biopsies avoided.

Effectiveness results
The sensitivity of MTT was 100%; specificity, 57%; positive predictive value, 74%; negative predictive value, 100%; accuracy, 84%. The number of biopsies avoided relative to the standard criterion was 46.

Clinical conclusions
Consistent with the authors' goal of avoiding unnecessary breast biopsies in young women, the majority of non-cystic lesions in this study (32 of 41) were evaluated clinically rather than biopsied.

Measure of benefits used in the economic analysis
The benefit measure was the number of biopsies avoided. This was obtained from the number of biopsies that would have been performed had the standard criterion been used.

Direct costs
Costs were not discounted due to the short-term follow-up period. Some quantities were reported separately. The cost items were reported separately. The costs measured were operating costs. The boundary adopted was the hospital. The quantities were based on actual data and assumptions (MTT performed in one clinic visit); unit costs were based on actual charges. The source of quantities was the study records, whereas the source of unit costs was the institution's Current Procedure Terminology (CPT) codes. The quantities were measured from October 1992 to July 1995. The prices used were not clearly reported as belonging to a specific date ("current charges"). The costs excluded were initial outpatient visits, which were thought to be equal for each strategy, whereas the 'outpatient clinic biopsy' charge was used (excluding anaesthesia and recovery room fees) due to that type of biopsy being the standard practice in the institution at the time of the study.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
With the use of MTT, 46 biopsies were avoided relative to the 'criterion standard'.
Cost results
The charge per patient was $478 using MTT. The charge per case using the 'criterion standard' would have been $1,018. Therefore, the net saving from the application of the MTT diagnosis strategy would be $540.

Synthesis of costs and benefits
A synthesis of costs and benefits was not required as the MTT strategy was shown to be dominant.

Authors' conclusions
"Use of MTT for the diagnosis of unilateral, palpable breast lesions in younger women yields high diagnostic accuracy without the need for routine open biopsy, resulting in an overall reduction in patient charges”

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
The study may have been adversely affected by the low sample size; in particular, the authors report that one of the study findings (that of physical examination being as accurate as FNA) contradicts results from previous studies, and that this is likely to be in part explained by "the low numbers in our study”. The use of clinical evaluation (rather than a biopsy), as a confirmation of diagnosis for the majority of non-cystic lesions, coupled with the maximum length of follow-up (45 months), could have resulted in cases of cancer being missed.

Validity of estimate of costs
Resource utilisation was not systematically reported separately from the costs, although adequate details of methods of cost estimation were given. Charges were used in place of true costs and the study lacked a prospective cost analysis.

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

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