Economic evaluation of diagnostic follow-up after primary treatment for breast cancer: results of the working group on economic organizational aspects of follow-up

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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
Intensive versus minimum surveillance follow-up protocols after primary treatment of breast cancer. The 'intensive' strategy was defined as that including physician visits with bone scans, liver echocardiography, chest roentgenography, and laboratory tests being performed at predetermined intervals. The 'minimum' strategy involved the physician visits at the same frequency but performing clinically indicated tests only.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Italian women younger than 70 years with non-inflammatory, unilateral primary breast cancer (stage I, II, and III) undergoing surgery.

Setting
Primary care.

Dates to which data relate
The effectiveness data were based on a previously published study, in which data were collected between September 1986 and June 1993 (GIVIO 1994). The resource use data were identified based on the protocol of the same study. The price year was 1994.

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

Study sample
Power calculations determined that 1,400 patients was the target size to detect a 20% relative reduction in mortality for patients receiving intensive follow-up, with an 80% power at the 5% significance level (one-tail). A total of 1,441 patients was enrolled in the study, with 121 (8.4%) excluded from the analysis. The final study sample was, therefore, 1,320 patients, of whom 655 were in the intensive group, and 665 were in the 'minimum' group.

Study design
This was a randomized controlled multicentre trial involving 26 general hospitals and another 12 breast referral centres.
The duration of follow-up was 5 years. Patients were randomized by computer-generated lists using stratification by institution and pathologic axillary nodal status; the second study stratified patients by centre only. The loss to follow-up was 9.3% (123 patients, 63 in the intensive and 57 in the control regimen).

Analysis of effectiveness
The analysis was based on the intention to treat principle. The primary health outcome measured was survival based on information obtained on patients followed up until 30 June 1993 for a median of 71 months (range: 59 - 81 months). The study also measured health-related quality of life status at 6, 12, 24, and 60 months of follow-up. Patient groups were shown to be comparable in terms of age, menopausal status, nodal status, pathological tumour size and estrogen receptor status.

Effectiveness results
Survival, at a median follow-up of 71 months, in the intensive group was 80%, whereas the minimum group had a survival rate of 82%, (odds ratio = 1.12; 95% CI: 0.87 - 1.43; compliance >80%). The overall survival curves were not significantly different in statistical terms over the follow-up period. Health-related quality of life measurements showed similar results in both groups at all measurement time points.

Clinical conclusions
Similar 5-year survival benefits for asymptomatic patients who have undergone breast cancer surgery can be derived from the two follow-up strategies (intensive or minimum).

Measure of benefits used in the economic analysis
Since the effectiveness analysis showed similar benefits between the strategies investigated, the economic analysis was based on the difference in costs only (cost minimisation analysis).

Direct costs
The cost analysis was divided in two parts. The first part was based on the protocol used in the first of the clinical studies reported. In this, it was further assumed that no deviations from the protocol occurred, so that the costs were calculated in straightforward fashion from the definition of the strategies in that study using the corresponding unit cost for Italy. Costs were discounted at 5%. The perspective adopted was that of the health service, the patient, and the private health insurance fund. The second part focused on the population-level analysis, based on Italian data on prevalence of disease and the survival rates reported in the main clinical study. Worthy of note is the fact that the authors stated that no discounting was applied to the data, given that it was not necessary "as the costs referred to the same year (1994)". The cost per unit of the health care facility in which the clinical trial was performed or, alternatively, the fees paid by the health service to private contracted outpatient clinics, was used in the analysis from the health service perspective, whereas minimum fees from the Ministry of Health for self-employed physicians and fees for reimbursement established by a representative fund (FASI), were used for the patient's and health insurance fund's perspective. The costs associated with travel were excluded from the analysis due to lack of data. The analysis implicitly assumed that from the 6th year onwards, no difference would exist in the two follow-up regimens, so that all such costs were excluded from the analysis.

Indirect Costs
Indirect costs were not measured, based on the premise that it was unlikely that hours of work missed in the study population due to the time involved in diagnostic tests would be "subtracted from work" given the "high female unemployment rate" in Italy.

Currency
Italian lire (L).
Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The cost per patient analysis yielded figures for the national health service (SSN) of L0.5 million for the "minimum", and L1.7 million-L2.6million (range: cost of trial facilities - contracted outpatient clinics) for the 'intensive' protocols. The corresponding figures from the patient's perspective were L0.9 million and L4.6 million, respectively. The reimbursements by health insurance funds turned out to be L1.5 million (minimum strategy) and L4.1 million (intensive strategy). For the population cost analysis (calculated for a cohort of 5-year surviving patients), the health service perspective yielded figures of L13.2 million for the minimum strategy and L41.9 million for the intensive follow-up programme. This calculation used the cost of the trial facilities whereas using rates for outpatient contracted clinics would widen the difference. The patient's, and insurance fund's perspectives generated figures (in millions of Italian lire) of 22.5 (minimum) and 114.8 (intensive), and 38.1 (minimum) and 100.6 (intensive), respectively.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The implementation of a 'minimum' follow-up protocol, rather than an intensive protocol, would lead to savings with the possibility of generating benefits when used in breast cancer screening programmes.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. Controversy about the effectiveness of reducing mortality in breast cancer patients by using a follow-up protocol involving chest roentgenogram and bone scan had led to the proposition that limited surveillance, including physical examination and annual contralateral mammography, would be a potentially beneficial and cost-effective strategy. You, as a user of this database, should consider whether this is a widely used strategy in your own setting.

Validity of estimate of measure of benefit
The conclusion that the programmes have similar effectiveness was based on evidence from a randomized controlled trial and the results are, therefore, likely to be internally valid, although the trial did not reach the targeted size based on power calculations. All the main methodological issues were adequately addressed. The study employed double-blinding in the assessment of outcomes, and both investigations controlled for relevant patient characteristics at baseline.

Validity of estimate of costs
Although the cost analysis did not consider the costs of initial surgery, this is not relevant for the analysis. However, including the costs of treatment arising as a consequence of recurrences, which were omitted from the analysis, might alter the study findings (this was not discussed in the paper). In their population level analysis the authors justified the lack of discounting on the grounds that they considered one-year treatment costs for a cohort of surviving patients who had undergone breast surgery from 1 to 5 years previously. The authors noted that the results might underestimate the cost savings reported due to the unrealistic assumption of 100% compliance with the protocols (which was in contradiction with the results of the original clinical studies) and due to the exclusion of the commonly used tumour markers. The authors also pointed out that the 'minimum fees' used for the patient's perspective analysis do not really reflect the average fees actually paid.
Other issues
The authors' conclusions were justified given the uncertainties in the data. The issue of generalisability was not addressed in the study, but the multicentre design of the effectiveness study would make it well representative in Italian settings. Comparisons with other studies were not reported. The results were not presented selectively.

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None stated.

Bibliographic details

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Other publications of related interest
The evidence for effectiveness was based on:


Another study reporting similar results on effectiveness:

Indexing Status
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MeSH
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