Cost-effectiveness of adding an electron-beam boost to tangential radiation therapy in patients with negative margins after conservative surgery for early-stage breast cancer


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 use of tangential radiation therapy, with and without an electron-beam boost (EBB), was compared for the treatment of patients with negative margins following conservative surgery for early-stage breast cancer.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of 60-year old patients with early-stage breast cancer, who had opted for breast-conserving therapy for 10 years. No other patient characteristics or inclusion and exclusion criteria were reported.

Setting
The setting was secondary care. The study was conducted in the USA.

Dates to which data relate
The analysis was performed over a timeframe of 10 years. The efficacy and resource use data were taken from trials published between 1995 and 1998. The price year for the direct medical costs was 1995.

Source of effectiveness data
The effectiveness data were obtained from a review and synthesis of published studies.

Modelling
A Markov decision-analytical model, originally constructed to evaluate the cost-effectiveness of additional radiation therapy after breast conserving surgery, was used. This estimated the yearly costs and quality-adjusted life-years (QALYs) associated with each treatment strategy for the 10 years following breast-conserving therapy.

Outcomes assessed in the review
The probability estimates assessed in the review were:

the annual probability of local recurrence with tangential whole-breast radiation therapy alone;
the reduction in the annual probability of local recurrence with the addition of an EBB;
the reduction in the annual probability of death with the addition of an EBB;
the probability of salvaging local recurrence by mastectomy and reconstructive surgery, following treatment with or without an EBB;
the annual probability of death after the first diagnosis of distant metastases;
the annual probability of death after the progression of metastases following first remission; and
the annual probability of death from causes other than breast cancer.

The following health state utilities were also assessed:
treatment with or without an EBB, without evidence of recurrence;
treatment with or without an EBB, with local recurrences salvaged by mastectomy and reconstructive surgery;
a diagnosis of distant metastases and undergoing salvage chemotherapy;
in remission with distant metastases.

Study designs and other criteria for inclusion in the review
The inclusion criteria for the studies were unclear. The efficacy data from two randomised clinical trials were used in preference to reports of retrospective series.

Sources searched to identify primary studies
The authors did not report the search strategy used, or the sources searched to identify the primary studies.

Criteria used to ensure the validity of primary studies
The criteria used to ensure the validity of the primary studies were unclear.

Methods used to judge relevance and validity, and for extracting data
The methods used to judge the relevance and validity of the studies, and to extract the data, were not specified.

Number of primary studies included
The effectiveness data were derived from two studies.

Methods of combining primary studies
The primary data sources were not combined.

Investigation of differences between primary studies
The authors did not investigate or explain explicitly the differences between the primary data sources in terms of the number of participants, interventions and outcome measures. The decision to estimate the baseline from the B-06 trial data (see Other Publications of Related Interest no.1), rather than from the Lyon trial (see Other Publications of Related Interest no.2), was based on the differences in the follow-up period and the clinical practice of the two trials.
Results of the review
The base-case estimates for the outcomes included in the model were:

0.92% for the annual probability of local recurrence with tangential whole-breast radiation therapy alone;

20% for the reduction in the annual probability of local recurrence with the addition of an EBB;

0% for the reduction in the annual probability of death with the addition of an EBB;

100% for the probability of salvaging local recurrence by mastectomy and reconstructive surgery, following treatment with or without an EBB;

50% for the annual probability of death after the first diagnosis of distant metastases;

100% for the annual probability of death following progression of the metastases after the first remission; and

0.8 to 2% for the annual probability of death due to causes other than breast cancer.

Measure of benefits used in the economic analysis
The model estimated the costs and QALYs associated with each treatment strategy during each yearly cycle. The authors stated that the quality of life data were incorporated into the analysis through the use of utilities, which were measured using the standard gamble technique. The health state utilities were derived from a single published study using standard gamble on 97 patients, and from expert opinion. The utility values were:

0.92 for treatment with or without an EBB, without evidence of recurrence;

0.82 for treatment with or without an EBB, with local recurrences salvaged by mastectomy and reconstructive surgery;

0.72 for a diagnosis of distant metastases and undergoing salvage chemotherapy; and

0.75 for in remission with distant metastases.

Direct costs
The direct medical costs of the facility, professional staff, time and travel were considered in the analysis. The costs of the facility and professional staff were derived from published data. The facility costs were estimated by multiplying the Medicare charges for the treatment of planning, dosimetry and administration of eight EBB treatments, by the Medicare cost-to-charge ratio for radiation therapy at the Medical College of Virginia in 1995. The professional costs were estimated by multiplying the relative units of work associated with administering the boost, as estimated by Healthcare Consultants Inc., by an estimate of the cost per unit of work ($8.00) on the basis of the California and Florida state medical associations’ physician payment scales.

The time costs were calculated by multiplying the time spent by the patient in travelling to and undergoing eight additional treatments, by an estimate of the average hourly wage for women in their 60s ($9.40 per hour). The transportation costs were estimated by multiplying estimates of the miles travelled to undergo each additional treatment by the cost per mile ($0.31), then adding the cost of parking ($2.00). The future costs and benefits were all discounted at a rate of 3% in the baseline model.

Statistical analysis of costs
No statistical analysis of costs was carried out.

Indirect Costs
No indirect costs were included in the analysis.
Currency
US dollars ($).

Sensitivity analysis
A one-way threshold analysis was used to identify those variables that changed the incremental cost-effectiveness ratio to a predefined minima. The authors initially assessed the validity of the cost-effectiveness ratio for the boost by performing a number of one-way threshold analyses. These considered thresholds of $20,000, $50,000 and $100,000 per QALY whilst varying the following parameters: the reduction in the annual probability of local recurrence arising from the addition of an EBB; the cost of adding an EBB; and the utility of EBB treatment with no evidence of recurrence. A Monte Carlo simulation was then applied to estimate the mean cost-effectiveness ratio, its 95% confidence intervals (CIs), and the probability that the ratio would be below a threshold of $50,000 per QALY.

The Monte Carlo simulation was run 10,000 times using values chosen at random from their probability distributions in the Markov model.

Estimated benefits used in the economic analysis
The expected number of QALYs was 7.164 for the EBB strategies and 7.157 for the no-boost strategies. The difference between the strategies was just 0.0065 QALYs, or 2.4 quality-adjusted days. The results were based on a 10-year timeframe, which was discounted at 3%. The side-effects of the treatment were not reported or considered in the analysis.

Cost results
The expected costs were discounted at a rate of 3%. These were $23,192 for the EBB strategy and $21,184 for the no-boost strategy. The incremental cost of the EBB was $2,008. The costs included the costs of long-term follow-up and recurrence.

Synthesis of costs and benefits
The authors reported that adding the EBB led to an additional cost of $2,008. This represented an increase of 0.0065 QALYs, and therefore, an incremental cost-effectiveness ratio of $308,000 per QALY.

The threshold analyses indicated that the relative reduction in local recurrence would have to increase from 20 to 63% for the cost-effectiveness ratio to fall to $50,000 per QALY. Alternatively, for the ratio to fall to $50,000 per QALY, the total cost of the boost itself would have to fall from its baseline value of $2,400 to $754; $754 would cover the cost of just two EBB treatments. Finally, increasing the utility for treatment with the boost and no local recurrence from 0.92 to 0.925 resulted in a cost-effectiveness ratio of $50,000. The results of the Monte Carlo simulation indicated a mean cost-effectiveness ratio of $71,000 per QALY (95% CI: 53,000 per QALY - 105,000 per QALY). The probability that the EBB cost less than $50,000 per QALY was 0.85%.

Authors' conclusions
The authors stated that, on the basis of the currently available data, the cost-effectiveness ratio for the electron-beam boost (EBB) was well above the commonly cited threshold for cost-effective care, i.e. $50,000 per QALY. The EBB only becomes cost-effective if patients place an unexpectedly high value on the small absolute reduction in local recurrences achievable with it.

CRD COMMENTARY - Selection of comparators
The comparator was justified on the basis that it was current practice in the authors' setting. You should decide if this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The authors did not state whether a systematic review of the literature had been undertaken, and did not report the methods used to identify relevant research and to minimise biases. In addition, no details were provided on the methods used to judge the relevance and validity of the included studies, and to extract the data. The probability data for the Markov model were estimated from randomised controlled trials only. The authors used the data from the selected studies selectively, but did not consider the differences between the primary studies when estimating effectiveness.

The outcomes were estimated using a Markov model. Whilst the authors described the model, they did not report the methods used to test its validity or to assess its robustness. A threshold analysis and Monte Carlo simulation were used to test the sensitivity of the results to variation in the data.

Validity of estimate of measure of benefit
The authors estimated QALYs using the survival predicted from the model, and the utilities of different health states. The utility values were estimated from the published data and expert opinion. The robustness of the results was tested using a threshold analysis and Monte Carlo simulation.

Validity of estimate of costs
The prices and resource use data were not reported separately. The direct medical costs were estimated from actual data, although the sources of the data were not always reported. Although the authors reported that the costs were estimated from a societal perspective, the indirect costs were not considered in the study. The robustness of the results was tested using a threshold analysis and Monte Carlo simulation.

Other issues
The authors discussed the results of the analysis in the context of other clinical and economic studies. The study showed a number of limitations. These included the use of preliminary data from a trial where the follow-up was not completed, truncation of the analysis at 10 years, and an estimation of the number of EBB treatments needed. However, the threshold analyses indicated that these factors were unlikely to affect the results.

Implications of the study
The authors stated that the benefits of the EEB were not sufficiently large to justify its cost.

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None stated.

Bibliographic details

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Other publications of related interest

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Subject indexing assigned by NLM

MeSH
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