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
Alternative breast cancer treatments, that is, breast-conserving surgery with radiation (BCSRT) versus mastectomy, were examined.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women aged 65 years or older receiving a diagnosis of early-stage breast cancer.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from 1992 to 1997 (final interview). The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were not reported. Eligible patients were identified from a 5% random sample of all Medicare claims for patients with a breast cancer diagnosis or surgery procedure, for the calendar years 1992 to 1994. Women with a history of cancer diagnosis, carcinoma-in-situ diagnosis, metastasis diagnosis, or bilateral procedure were excluded. Also excluded were cases that lacked a surgical procedure core, were missing a physician identifier, or occurred in women younger than 67 years of age. Further exclusions were cases for which breast cancer was not the primary procedure code, or for which breast cancer was not the primary diagnosis, and cases for which the surgeon could not be identified. Only women whose physicians were successfully contacted were included. Moreover, women whose cost data were not available in the claim files were also excluded, as were those who had breast-conservation surgery without radiation therapy.
The final sample included 2,517 patients. There were 704 in the BCSRT group and 1,813 in the mastectomy group. The BCSRT group comprised 66.62% in the age group 65 - 74 years, 22.30% in the age group 75 - 79 years, 9.23% in the age group 80 - 84 years, and 1.85% in the 85+ age group. The mastectomy group comprised 54.16% in the age group 65 - 74 years, 23.88% in the age group 75 - 79 years, 13.9% in the age group 80 - 84 years, and 8.05% in the 85+ age group. A total of 71.44% of patients in the BCSRT group had Stage I breast cancer versus 50.91% of patients in the mastectomy group.

**Study design**
This was a retrospective observational study that was carried out in several centres. The study formed part of the Outcomes and Preferences for Treatment in Older Women Nationwide Survey (OPTIONS) project. Treatment assignment was based on inpatient or outpatient claims. The length of follow-up was not reported but follow-up ended in December 1997. The assessments were conducted 3 to 5 years after surgery on 1,320 of the surviving women. A regression analysis was used to input missing values.

**Analysis of effectiveness**
The analysis of the clinical study considered all women included in the final study sample. The outcome measures used were 5-year survival and health-state preferences. These were obtained from women interviewed in 1997 using the visual analogue scale (VAS) from the EuroQol instrument. Women in the BCSRT group were significantly more likely to be younger, have earlier-stage cancer, have lower costs before surgery, have fewer co-morbid conditions, have had BCSRT in the later years of the study period, live in areas that were more urban, be more affluent, and be more highly educated.

**Effectiveness results**
The estimated survival and health-state preferences were only depicted graphically. Specific values were not presented. The authors stated that slightly higher survival was associated with BCSRT treatment. Also, there was no difference in health-state preferences among survivors.

**Clinical conclusions**
Survival data and health-state preferences were combined in order to estimate quality-adjusted life-years (QALYs).

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the number of QALYs. These were discounted at an annual rate of 3% because a time horizon of 5 years was considered. Three estimates of QALYs were reported. More specifically, unadjusted, adjusted using observable risk factors, and adjusted using propensity score (to control for observable confounders). For the adjusted estimate using observable risk factors, the authors used a least-squares regression and the following covariates: treatment group, age at the time of surgery, cancer stage, co-morbidity index, health care costs in the year before surgery, race, and market-area characteristics.

**Direct costs**
Discounting was relevant since the costs were incurred during a 5-year timeframe. An annual discount rate of 3% was applied. The unit costs were not presented separately from the quantities of resources used, and a detailed breakdown of the cost items was not provided. The economic evaluation included all 5-year payments from inpatient, outpatient, and part B claims of all medical costs associated with the treatment of breast cancer. The cost/resource boundary of the third-party payer was adopted. Only costs covered by Medicare were included. Resource use was estimated using data derived from the sample of women included in the effectiveness study. The costs were adjusted for inflation using the medical Consumer Price Index. However, no price year was explicitly reported.

**Statistical analysis of costs**
Statistical analyses were carried out to test the statistical significance of differences in the costs. Confidence intervals (CIs) were also estimated. As in the analysis of QALYs, three estimates of costs were reported (unadjusted, adjusted using observable risk factors, and adjusted using propensity score). An imputation technique was used to derive missing cost data.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were performed to examine the robustness of the results of the analysis to variations in the base-case estimates. Limited information on the type of analysis was provided. A nonparametric bootstrap approach was also used to determine CIs. In the secondary analysis, the proportion of women selecting BCSRT in the open regimen was also varied (doubled and halved).

**Estimated benefits used in the economic analysis**
In the unadjusted analysis, the 5-year QALYs were 3.075 with mastectomy and 3.326 with BCSRT. The difference was 0.251 QALYs (95% CI: 0.158 - 0.344).

In the analysis adjusted using observable risk factors, the 5-year QALYs were 3.122 with mastectomy and 3.205 with BCSRT. The difference was 0.083 QALYs (95% CI: -0.013 - 0.179).

In the analysis adjusted using propensity score, the 5-year QALYs were 3.120 with mastectomy and 3.184 with BCSRT. The difference was 0.064 QALYs (95% CI: -0.035 - 0.175).

**Cost results**
The regression analysis identified treatment as a significant predictor of the total costs. Other covariates were age 80 - 84 years, high-stage cancer, higher previous medical costs, and more co-morbid conditions.

In the unadjusted analysis, the 5-year costs were $40,130 with mastectomy and $48,519 with BCSRT. The difference was $8,389 (95% CI: 4,605 - 12,171).

In the analysis adjusted using observable risk factors, the 5-year costs were $38,623 with mastectomy and $52,398 with BCSRT. The difference was $13,775 (95% CI: 9,853 - 17,697).

In the analysis adjusted using propensity score, the 5-year costs were $38,664 with mastectomy and $52,718 with BCSRT. The difference was $14,054 (95% CI: 9,791 - 18,317).

**Synthesis of costs and benefits**
An incremental cost-utility ratio was calculated to combine the costs and QALYs of the alternative treatment strategies.

The incremental cost per QALY gained with BCSRT over mastectomy was $33,421 (95% CI: 17,079 - 60,647) in the unadjusted analysis, $165,964 (95% CI: 75,243 to dominated) in the analysis adjusted using observable risk factors, and $219,594 (95% CI: 80,992 to dominated) in the analysis adjusted using propensity score.

The secondary analysis (assuming that the proportion of women selecting BCSRT in the open regimen was 28%) showed that if the open regimen provided an additional 0.031 QALYs over the restricted regimen, then the incremental cost per QALY would be $80,440. The results were sensitive to the proportion of women selecting BCSRT in the open.
regimen. If it was set at 56%, the incremental cost per QALY increased to $117,747, while if it was set at 14%, the incremental cost per QALY went down to $49,238.

Authors’ conclusions
Breast-conserving surgery with radiation (BCSRT) led to higher costs in comparison with mastectomy, without improving quality-adjusted survival among women with early-stage breast cancer. However, the authors noted that breast cancer surgery should not be restricted only to mastectomy because of the substantial value of choice for well-informed women who have different preferences for the optimal surgical option.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate as both strategies represented two commonly used treatments for early-stage breast cancer. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data came from a retrospective review of outcomes in a sample of women derived from a large Medicare dataset. The sample size appears to have been representative of the patient population. The sample was quite large, but there was no evidence of how appropriate the sample size was. Further, the estimated clinical outcomes were not reported. The exact length of the follow-up period was not described. The study groups were not well matched at baseline, and this could have introduced some selection bias and confounding factors. A retrospective design was used to estimate the clinical outcomes. However, extensive statistical analyses were carried out to take potential predictors of clinical outcomes into consideration.

Validity of estimate of measure of benefit
The use of QALYs as the summary benefit measure was appropriate because it incorporates the impact of the interventions on survival and quality of life. The utility values were derived from a sample of patients. QALYs are comparable with the benefits of other health care interventions. Discounting was applied, as recommended in US guidelines.

Validity of estimate of costs
The authors stated explicitly the perspective adopted in the study and included all the relevant direct medical costs. However, the costs were not broken down in micro-categories and only the total costs were reported. The source of the data was provided and statistical analyses on the costs were carried out. However, the cost estimates were specific to the study setting and no sensitivity analyses were performed on the economic estimates. The price year was not reported, which reduces the possibility of reifying the results of the study. Adjusted cost estimates were calculated to consider the impact of potential predictors. The authors noted that no distinction between cancer-related costs and non cancer-related costs was made.

Other issues
The authors compared their findings with those from published studies, especially the cost results. The issue of the generalisability of the study results to other settings was not addressed, and the results of the sensitivity analyses were not reported clearly. This reduces the external validity of the analysis. The authors noted some limitations to the validity of their study. For example, lack of a longer time horizon and the potential impact of confounding factors.

Implications of the study
The study results supported the use of mastectomy for the treatment of early-stage breast cancer within a framework where both mastectomy and BCSRT are available.
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Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
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