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Title **A Randomized Controlled Trial of Postoperative Radiotherapy following Breast-Conserving Surgery in a Minimum-Risk Older Population. The PRIME Trial**

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Aim

To assess whether the omission of postoperative radiotherapy in older women with 'low risk', axillary node negative breast cancer (To-2, No-1, Mo) treated by breast conservation with wide local excision and endocrine therapy: a) improves quality of life; b) is more cost effective.

Conclusions and results

The hypothesized overall improvement in quality of life with the omission of radiotherapy was not seen in the EuroQol assessment, or in the functionality and symptoms summary domains of the EORTC scales. Some differences were apparent within subscales of the EORTC questionnaires, and insights into the impact of treatment were also provided by the qualitative data obtained by open-ended questions. Differences were most apparent shortly after the time of completion of radiotherapy. Radiotherapy was then associated with increased breast symptoms and with greater fatigue, but with less insomnia and endocrine side effects. Patients had significant concerns about the delivery of radiotherapy services, eg, transport, accommodation, and travel costs associated with receiving radiotherapy. By the end of followup, patients receiving radiotherapy were expressing less anxiety about recurrence than those who had not received radiotherapy.

Treatment did not greatly affect functionality. In the RCT, the Barthel Index demonstrated a small but significant fall in functionality with radiotherapy compared to no radiotherapy. Results from nonrandomized patients did not confirm this effect. Cosmetic results were better in those not receiving radiotherapy, but patients did not appear to view this as important. Home-based assessments by a research nurse proved to be effective in obtaining high-quality data.

Costs to the NHS associated with postoperative radiotherapy were calculated at around GBP 2000 per patient. Followup in this study yielded no recurrences, and the quality-of-life utilities from EuroQol were almost identical. Hence, within this time frame, no radiotherapy is the cost-effective choice. In the longer term, cost effectiveness will depend on recurrence rates in patients not receiving radiotherapy and the effect of recurrence on their quality adjusted life years.

Recommendations

Although there are no global differences in quality-of-life scores between the treatment groups, several dimensions exhibit significant differences. Over the first 15 months, radiotherapy for this population is not cost effective. However, the early postoperative outcome does not give a complete answer, and the eventual cost effectiveness will only become clear after long-term followup. Extrapolations suggest that radiotherapy may not be cost effective unless it results in a recurrence rate at least 5% lower in absolute terms.

Methods

See Executive Summary link above.

Further research/reviews required

1. Obtain long-term data on quality of life and clinical outcomes in PRIME or similar trials.
2. Economic modeling on the longer term costs and consequences of omitting radiotherapy.
3. Use of novel methodologies (eg, touch-screen technology) in capturing and grading comorbidity and quality of life at baseline and at clinical followup.
4. Investigate the influence of specific types and degrees of comorbid disease on quality of life.
5. Refine methodologies to integrate the prediction of recurrence rates from breast cancer with the competing effects of mortality from other diseases to improve clinical decision making.
6. Develop a validated questionnaire/scale to assess the impact of access to healthcare services.

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