INAHTA Briefs

Issue 2011/038

Title **A Randomized Controlled Trial of Post-Operative Radiotherapy Following Breast-Conserving Surgery in a Minimum-Risk Population. Quality Of Life at 5 Years in the PRIME Trial**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

Reference Volume 15.12. ISSN 1366-5278. www.hta.ac.uk/project/1697.asp

Aim

To assess whether omission of postoperative radiotherapy (RT) in women with low-risk axillary node-negative breast cancer (tumor size <5 cm [T0–2] although the eligibility criteria further reduce the eligible size to a maximum of 3 cm) treated by breast-conserving surgery and endocrine therapy improves quality of life and is more cost effective.

Conclusions and results

The hypothesized improvement in overall quality of life with the omission of RT was not seen in the summary domains of the European Organization for Research in the Treatment of Cancer (EORTC) scales. Some differences were apparent in subscales of the EORTC questionnaires, and insights into the impact of treatment were also provided by the qualitative data obtained by open-ended questions added by the trial team. Differences were most apparent shortly after the time of completion of RT. RT was then associated with increased breast symptoms and with greater (self-reported) fatigue, but with lower levels of insomnia and endocrine side effects. These statistically significant differences in breast symptoms persisted for up to 5 years after RT (mean difference, RT was 5.27 units greater than no RT, 95% confidence interval [CI] of 1.46 to 9.07) with similar, though nonsignificant, trends in insomnia. No significant difference was found in the overall quality-of-life measure, with the no RT group having 0.36 units greater quality of life than the RT group (95% CI –5.09 to 5.81). Breast RT is tolerated well by most older breast cancer patients without impairing their overall health-related quality of life (HRQoL). Although HRQoL should always be taken into account when determining treatment, our results show that adding RT does not impair overall quality of life. Further economic modeling on the longer-term costs and consequences of omitting RT is required.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1697.asp.

Methods

See Executive Summary link www.hta.ac.uk/project/1697.asp.

Further research/reviews required

Primary recommendation for further research: Further economic modeling of longer-term costs and consequences of omitting RT. Secondary recommendations: 1) Omission of RT in this group of patients has a short-term economic benefit. However, evidence of the longer-term benefit requires longer follow-up to determine local recurrence rates with and without postoperative whole breast RT. 2) Investigate the application of novel methodologies (eg, touch-screen technology) to capture and grade comorbidities and quality of life at baseline and in clinical follow-up. 3) Investigate the influence of specific types and degrees of comorbid disease on quality of life. 4) Refine methodologies and develop software to integrate the prediction of recurrence rates from breast cancer with the competing effects of mortality from other diseases. 5) Develop a validated questionnaire/scale to assess the impact of access to healthcare services for older patients.

Written by Dr Linda Williams, University of Edinburgh, NETSCC, United Kingdom