Breast-conserving surgery with or without radiotherapy in women with ductal carcinoma in situ: a meta-analysis of randomized trials
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CRD summary
This review concluded that compared with excision alone, addition of radiotherapy to lumpectomy led to a reduction in risk of a local in-breast recurrence, but there was no benefit for survival or distant metastasis. This review was generally well conducted. The conclusions are likely to be reliable.

Authors' objectives
To compare the effectiveness of adjuvant radiotherapy versus observation alone following breast conserving surgery in the treatment of women with ductal carcinoma in situ.

Searching
MEDLINE (from 1966), CancerLit (from 1998) and The Cochrane Library (from 1998) were searched up to 2006 and EMBASE was searched, but search dates were not reported. There were no language restrictions. Search terms were reported. Reference lists of retrieved publications were screened. Conference proceedings of Annual Meetings of American Society of Clinical Oncology (through 2005) were searched. Recent issues of relevant journals were searched.

Study selection
Randomised controlled trials (RCTs) that compared adjuvant radiotherapy versus observation alone following breast-conserving surgery in women with ductal carcinoma in situ were eligible for inclusion. Outcomes reported in the review were: mortality; ipsilateral ductal carcinoma in situ recurrence; ipsilateral invasive breast cancer recurrence; contralateral breast cancer recurrence; and distant metastasis rate.

The dose of radiotherapy in most of the included studies was 50 Gy/25 Fractions. Percentage of central pathological review of included studies ranged from 20% to 85%.

Two reviewers independently assessed studies for inclusion.

Assessment of study quality
Study quality was assessed using the Jadad scale, a five-point scale of randomisation, blinding and withdrawal.

Two reviewers independently performed the validity assessment. Any disagreements were resolved by consensus.

Data extraction
Event rates were extracted to enable calculation of odds ratios (ORs) with 95% confidence internals (CIs).

Two reviewers independently performed data extraction. Any disagreements were resolved by consensus.

Methods of synthesis
Studies were combined in a meta-analysis. A random-effects model was used in the presence of significant heterogeneity and otherwise a fixed-effects model was employed. Pooled odds ratios and 95% CIs were calculated. All analyses were performed on an intention-to-treat basis. Statistical heterogeneity was assessed using the Chi$^2$ and I$^2$ statistics. Publication bias was assessed using a funnel plot.

Results of the review
Four RCTs (n=3,665) were included in the review. Sample size ranged from 818 to 1,046. All included trials were
high quality (Jadad score of 4). Median follow-up of included studies ranged from four to twelve years.

Compared with observation alone following breast conserving surgery, adjuvant radiotherapy was associated with a significant reduction in ipsilateral ductal carcinoma in situ recurrence (OR 0.40, 95% CI 0.31 to 0.53; four RCTs) and ipsilateral invasive breast cancer recurrence (OR 0.40, 95% CI 0.33 to 0.60; four RCTs), but with a significant increase in contralateral breast cancer recurrence (OR 1.53, 95% CI 1.05 to 2.24; four RCTs). There was no significant difference in overall mortality and distant metastasis rate between the two groups.

Significant heterogeneity was only observed in the outcome of ipsilateral ductal carcinoma in situ recurrence ($I^2=69.2\%$). Little evidence of publication bias was found.

**Authors’ conclusions**
Addition of radiotherapy to lumpectomy led to a reduction in risk of a local in-breast recurrence compared with excision alone, but there was no benefit for survival or distant metastasis.

**CRD commentary**
This review's inclusion criteria were clear. Relevant sources were searched. Efforts were made to find both published and unpublished studies with no language restriction, which minimised potential for publication and language biases. Publication bias was further assessed, but using a funnel plot to evaluate publication bias in a small number of studies might not have been appropriate. Sufficient attempts were taken to minimise biases and errors in the review process. Relevant criteria were used to assess study quality. Statistical heterogeneity was assessed and appropriate methods were used to pool results. This review was generally well conducted. The authors’ conclusions reflected the evidence presented and are likely to be reliable.

**Implications of the review for practice and research**
**Practice:** The authors stated that radiation should be recommended after lumpectomy for all patients with ductal carcinoma in situ without contraindications.

**Research:** The authors stated that further trials were required to identify subgroups of patients with ductal carcinoma in situ for whom radiation therapy after lumpectomy was not necessary. Longer follow-up studies were needed to evaluate whether the benefit of radiotherapy on local control improved survival rates.

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**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.