Evidence-based Series 1-10 Version 2.2006 IN REVIEW

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Management of Ductal Carcinoma in Situ of the Breast


Report Date: September 19, 2006

An assessment conducted in March 2016 placed Evidence-based Series (EBS) 1-10 Version 2.2006 IN REVIEW. This means that it is undergoing a review for currency and relevance. The Breast Cancer Disease Site Group has determined that it is still appropriate for this document to continue to be available while this updating process unfolds.

The full EBS is comprised of 3 sections and is available on the CCO Website on the PEBC Breast Cancer DSG page

| Section 1: | Clinical Practice Guideline |
| Section 2: | Systematic Review |
| Section 3: | Guideline Development and External Review |

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Management of Ductal Carcinoma in Situ of the Breast: A Clinical Practice Guideline


A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: September 19, 2006
Replaces Original Report dated 1998

Questions
- What is the optimal surgical management of ductal carcinoma in situ (DCIS) of the breast?
- Should breast irradiation be offered to women with DCIS, following breast-conserving surgery (defined as excision of the tumour with microscopically clear resection margins)? Are there patients who could be spared breast irradiation post-breast-conserving surgery for DCIS?
- What is the role of tamoxifen in the management of DCIS?

Target Population
These recommendations apply to women with DCIS.

Recommendations and Key Evidence

Surgical Management

Women with DCIS of the breast who are candidates for breast-conserving surgery should be offered the choice of breast-conserving surgery or total mastectomy.

Mastectomy with the option for reconstruction remains an acceptable choice for women preferring to maximize local control.

- No randomized trials designed to compare total mastectomy with breast-conserving surgery for DCIS were found. The National Surgical Adjuvant Breast Project (NSABP) B-06 trial (1) involved women with invasive malignancy. However, a small number of women entered were found, on pathology review, to have only DCIS. An analysis based on this subgroup of DCIS patients (2) found a trend towards a much higher local recurrence rate in patients who received breast-conserving surgery alone (9/21; 43%), compared with those who received either breast-conserving surgery plus radiotherapy (2/27; 7%) or mastectomy (0/28; 0%). Two meta-analyses (3,4), consisting mainly of non-randomized trials, also demonstrated higher local recurrence in patients treated by breast-conserving surgery alone versus those treated by mastectomy. One reported no significant differences in local recurrence rates.
between patients treated by breast-conserving surgery followed by radiotherapy and mastectomy, whereas the second showed improved local recurrence rates with mastectomy. To date, no survival benefit for either type of surgery has been reported. The expert opinion of the Breast Cancer DSG is that this non-randomized data supports the recommendation that breast-conserving surgery followed by radiation is an acceptable treatment option, in addition to mastectomy.

Qualifying Statements
- When breast-conserving surgery is performed, all mammographically suspicious calcifications should be removed and margins should be microscopically clear of DCIS.
- Mastectomy, with the option of reconstruction, is recommended for those women who have an area of DCIS large enough that breast-conserving surgery would leave them with an unacceptable cosmetic result.

Radiotherapy

Women with DCIS who have undergone breast-conserving surgery should be offered adjuvant breast irradiation.

Randomized trials of post-lumpectomy radiation versus observation in patients at relatively low risk of recurrence following surgery alone are ongoing. Until the results of those studies are available, these patients should be referred to a radiation oncologist for a thorough discussion of what is currently known about the potential benefits and toxicities of post-lumpectomy radiation in their particular situation.

- Three randomized trials (5-12) investigated the role of radiotherapy after breast-conserving surgery in patients with DCIS. In each, the risk of invasive and non-invasive ipsilateral recurrence was reduced with adjuvant radiotherapy. There were no significant differences in distant metastasis or overall survival.

Tamoxifen

While there is some evidence to suggest that tamoxifen is effective in the reduction of ipsilateral recurrence and contralateral incidence in women with DCIS, the absolute benefit is small and the evidence is conflicting.

Women should be informed of the option of five years of tamoxifen therapy and of the potential toxicities and benefits associated with tamoxifen.

- Two trials (12,13) investigated the role of tamoxifen versus no tamoxifen in addition to breast-conserving surgery and radiotherapy in the treatment of DCIS. The first demonstrated a significantly lower cumulative incidence of ipsilateral or contralateral breast malignancy for patients in the tamoxifen group versus those in the placebo group. In the second, tamoxifen treatment did not significantly reduce the incidence of either ipsilateral or contralateral breast malignancy.

Qualifying Statement
- In a subset analysis of one of the randomized studies (14), the beneficial effect of tamoxifen was most apparent in the estrogen receptor-positive patients. Therefore, if it is felt that a patient might benefit from tamoxifen for one of the above reasons, hormone receptor assessment could be considered in order to aid in the decision regarding tamoxifen treatment.
- Randomized studies suggest that women who are most likely to have a positive benefit/risk ratio with tamoxifen are those who are less than 50 years of age or who have positive resection margins and refuse further surgery. Women who have a contraindication to
radiation or who refuse this treatment but still want to avoid mastectomy should also be considered for tamoxifen therapy.

**Related Guidelines**
- Practice Guideline Report #1-1: *Surgical management of Early Stage Invasive Breast Cancer.*

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