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Surgical Management of Early-Stage Invasive Breast Cancer Practice Guideline Report #1-1 Version 2.2003

Members of the Breast Cancer Disease Site Group

ORIGINAL GUIDELINE: January 21, 2003

This practice guideline report replaces an earlier version of the report that was completed in 1996 and published as:

Mirsky D, O'Brien SE, McCready DR, Newman TE, Whelan TJ, Levine MN and the Breast Cancer Disease Site Group. Surgical Management of Early Stage Invasive Breast Cancer (Stage I and II). *Cancer Prevention & Control*, 1997; 1(1): 10-17.

SUMMARY

Guideline Questions

- In the surgical management of patients with early-stage invasive breast cancer (Stage I and II) who are candidates for breast conservation therapy, how does breast conservation therapy compare to modified radical mastectomy in terms of survival, disease recurrence and quality of life?
- What is the optimum management of the axilla?

Target Population

Women with early-stage (Stage I and II) invasive breast cancer who are eligible for either breast conservation therapy or mastectomy.

Recommendations

- Women who are eligible for breast conservation therapy should be offered the choice of either breast conservation therapy with axillary dissection or modified radical mastectomy.
- Removal and pathological examination of level I and II axillary lymph nodes should be the standard practice in most cases of Stage I and II breast carcinoma.
- There is promising but limited evidence that is not as yet sufficient to support recommendations regarding sentinel lymph node biopsy alone. Patients should be encouraged to participate in clinical trials investigating this procedure. However, axillary dissection is the standard of care.

Qualifying Statements

- With no difference in survival or distant recurrence, the choice between breast conservation therapy with axillary dissection and modified radical mastectomy should be dependent upon patient preference where appropriate.
- Each patient should be fully informed of the risks and benefits of each procedure.

- Patients should be aware that breast conservation therapy involves tumour excision with clear margins, axillary dissection, and adjuvant breast irradiation.
- Patients who choose breast conservation therapy should be aware that there is also the potential need for further surgery, possibly a mastectomy, in cases of local recurrence.
- Evidence surrounding quality of life after surgery is conflicting, but there is some evidence suggesting that women who receive breast-conserving therapy may have higher body self image than those who undergo mastectomy.
- In some instances, preoperative chemotherapy can shrink a large primary tumour and allow for breast conservation therapy. However, in such circumstances, there may be an increased risk of local breast cancer recurrence following breast irradiation.

Methods

The literature was searched using MEDLINE (through June 2002), and the Cochrane Library (Issue 2, 2002). The Physician Data Query (PDQ) database, clinical trial and practice guideline Internet sites, abstracts published in the proceedings of the annual meetings of the American Society of Clinical Oncology and the American Society of Radiation Oncology, article bibliographies, and personal files were also searched to June 2002.

Evidence was selected and reviewed by six members of the Practice Guidelines Initiative Breast Cancer Disease Site Group and methodologists. This practice guideline has been reviewed and approved by the Breast Cancer Disease Site Group, which is comprised of surgeons, medical oncologists, radiation oncologists, epidemiologists, pathologists, a medical sociologist, and a patient representative.

External review by Ontario practitioners was obtained through a mailed survey. Final approval of the practice guideline report has been obtained from the Practice Guidelines Coordinating Committee.

The Practice Guidelines Initiative has a formal standardized process to ensure the currency of each guideline report. This consists of periodic review and evaluation of the scientific literature and where appropriate, integration of this literature with the original guideline information.

Key Evidence

- Eleven large randomized trials that followed participants for up to 20 years did not detect significant differences in overall survival or in rates of distant recurrence between breast-conserving surgery and mastectomy.
- Six randomized trials, spanning four decades, detected absolute improvements in survival rates ranging from 4% to 16% with axillary node dissection compared to no axillary dissection. Meta-analysis of results from the six trials detected a significant survival benefit of 5.4% (95% confidence interval, 2.7% to 8.0%; $p < 0.01$) for axillary node dissection. However, evolving treatment modalities may diminish the effect of the survival benefit.

Related Guidelines

- Practice Guidelines Initiative's Practice Guideline Report #1-2: *Breast Irradiation in Women with Early-Stage Invasive Breast Cancer Following Breast Conserving Surgery*.
- Practice Guidelines Initiative's Evidence Summary #13-1: *Treatment of Lymphedema Related to Breast Cancer* (under development).

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*The Practice Guidelines Initiative is sponsored by:
Cancer Care Ontario & the Ontario Ministry of Health and Long-term Care.*

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PREAMBLE: About Our Practice Guideline Reports

The Practice Guidelines Initiative (PGI) is a project supported by Cancer Care Ontario (CCO) and the Ontario Ministry of Health and Long-Term Care, as part of the Program in Evidence-based Care (PEBC). The purpose of the Program is to improve outcomes for cancer patients, to assist practitioners to apply the best available research evidence to clinical decisions, and to promote responsible use of health care resources. The core activity of the Program is the development of practice guidelines by multidisciplinary Disease Site Groups of the PGI using the methodology of the Practice Guidelines Development Cycle.¹ The resulting practice guideline reports are convenient and up-to-date sources of the best available evidence on clinical topics, developed through systematic reviews, evidence synthesis, and input from a broad community of practitioners. They are intended to promote evidence-based practice.

This practice guideline report has been formally approved by the Practice Guidelines Coordinating Committee, whose membership includes oncologists, other health providers, patient representatives and Cancer Care Ontario executives. Formal approval of a practice guideline by the Coordinating Committee does not necessarily mean that the practice guideline has been adopted as a practice policy of CCO. The decision to adopt a practice guideline as a practice policy rests with each regional cancer network that is expected to consult with relevant stakeholders, including CCO.

Reference:

- ¹ Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. *J Clin Oncol* 1995;13(2):502-12.

For the most current versions of the guideline reports and information about the PGI and the Program, please visit our Internet site at:

<http://www.ccopebc.ca/>

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