

Epirubicin, as a Single Agent or in Combination, for Metastatic Breast Cancer Practice Guideline Report # 1-6

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ORIGINAL GUIDELINE: March 11, 1997
MOST RECENT LITERATURE SEARCH: April 30, 2003
NEW EVIDENCE ADDED TO GUIDELINE REPORT: February 2002

New evidence found by update searches since completion of the original guideline is consistent with the original recommendations.

SUMMARY

Guideline Question

What is the effectiveness of epirubicin, compared with doxorubicin, in patients with metastatic breast cancer?

Target Population

Women with metastatic breast cancer.

Recommendations

Epirubicin, at doses equivalent to doxorubicin, has been shown to be equally efficacious and less toxic than doxorubicin. Doxorubicin, however, is an acceptable alternative.

Methods

Entries to MEDLINE (1966-April 2003), the Cochrane Library (Issue 1, 2003), and abstracts published in conference proceedings were searched for evidence relevant to this practice guideline.

Evidence was selected and reviewed by members of the Practice Guideline Initiative's Breast Cancer Disease Site Group. This practice guideline has been reviewed and approved by the Breast Cancer Disease Site Group, which is comprised of surgeons, medical oncologists, epidemiologists, a pathologist, a medical sociologist, and a patient representative.

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

- Seven randomized trials comparing epirubicin and doxorubicin at equal doses (as single agents in three trials and as part of multi-agent chemotherapy in four trials) found no significant differences in tumour response rate or survival between these two agents. Survival data from published reports of five trials and response data for six trials were available for meta-analysis by the guideline developers. The meta-analysis did not detect differences in pooled one-year survival rates (risk ratio for mortality, 1.01; 95% confidence interval, 0.85 to 1.2; p=0.87) or response rate (risk ratio, 1.04; 95% confidence interval, 0.92 to 1.18; p=0.51).
- Five randomized trials comparing epirubicin at a higher dose to doxorubicin (as single agents in four trials and as part of multi-agent chemotherapy in one trial) detected no significant differences between these two agents in response rate or survival.
- Significantly higher response rates were observed with higher doses of epirubicin in five of six randomized trials that compared escalating doses of epirubicin (as a single agent in two trials and as part of multi-agent chemotherapy in four trials); no differences in survival were observed between doses.
- Less nausea and vomiting (risk ratio, 0.76; 95% confidence interval, 0.63 to 0.92; p=0.0048), neutropenia (risk ratio, 0.52; 95% confidence interval, 0.35 to 0.78; p=0.0017), and cardiac toxicity (risk ratio, 0.43; 95% confidence interval, 0.24 to 0.77; p=0.0044), including a trend towards fewer episodes of congestive heart failure (risk ratio, 0.38; 95% confidence interval, 0.14 to 1.04; p=0.059), were observed with epirubicin compared to doxorubicin.

For further information about this practice guideline, please contact:

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*The Practice Guidelines Initiative is sponsored by:
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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. 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:
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