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## The Use of Preoperative Radiotherapy in the Management of Patients with Clinically Resectable Rectal Cancer Practice Guideline Report #2-13

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ORIGINAL GUIDELINE: December 12, 2002  
MOST RECENT LITERATURE SEARCH: January 2004  
NEW EVIDENCE ADDED TO GUIDELINE REPORT: January 2004

Based on the publication peer-review process and updating procedures, the Gastrointestinal Cancer Disease Site Group has modified this practice guideline report. The revised sections are labelled UPDATE.

### SUMMARY

#### Guideline Questions

Should patients with resectable rectal cancer receive preoperative radiotherapy to improve survival and prevent or delay local recurrence? Should preoperative radiotherapy replace the present common practice of postoperative combined radiotherapy and chemotherapy?

#### Target Population

These recommendations apply to adult patients with clinically resectable rectal cancer. This report does not consider the use of preoperative radiotherapy to convert locally advanced, initially unresectable rectal cancer to resectable cases, to preserve the anal sphincter or to delay the need for colostomy.

#### Update

##### Recommendations

- Preoperative radiotherapy is an acceptable alternative to the standard practice of postoperative radiotherapy for patients with stage II and III resectable rectal cancer.
- Both preoperative and postoperative radiotherapy decrease local recurrence but neither improves survival as much as postoperative radiotherapy combined with chemotherapy. Therefore, if preoperative radiotherapy is used, chemotherapy should be added postoperatively, at least for patients with stage III disease.

#### Qualifying Statement

- Patients who choose preoperative radiotherapy as a treatment option instead of postoperative combined radiotherapy and chemotherapy need to be made aware that, because pathological stage is unknown until surgery is performed, many patients who will not benefit from treatment will be exposed to the risk of radiation-induced morbidity and mortality.

## **Methods**

Entries to MEDLINE (1966 to January week 1 2004), EMBASE (1980 to week 3 2004), CANCERLIT (1983 to October 2001), the Cochrane Library (Issue 3, 2003), and the proceedings of the 1998 to 2003 annual meetings of the American Society of Clinical Oncology and the 1999 to 2003 annual meetings of the American Society for Therapeutic Radiology and Oncology were searched for relevant trial reports. Relevant articles and abstracts were selected and reviewed, and the reference lists from these sources were searched for additional trials. A search of personal reprint files was also conducted. The Physician Data Query (PDQ) clinical trials database on the Internet was searched for reports of on-going trials.

Evidence was selected and reviewed by four members of the Practice Guidelines Initiative's Gastrointestinal Cancer Disease Site Group and the methodologists. This practice guideline report has been reviewed and approved by the Gastrointestinal Cancer Disease Site Group, which is comprised of medical and radiation oncologists, surgeons, a pathologist, a hematologist, a gastroenterologist and community representatives.

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

## **Key Evidence**

- Randomized trials demonstrate that preoperative radiotherapy followed by surgery is significantly more effective than surgery alone in preventing local recurrence in patients with resectable rectal cancer, and may also improve survival. However, because the pathological stage is unknown until surgery is performed, preoperative therapy requires the treatment of most rectal cancer patients and, consequently, exposes many patients, who will not benefit, to the risk of radiation-induced morbidity and mortality.
- A single trial, using surgery with total mesorectal excision, has shown that preoperative radiotherapy induces a greater than 50% decrease in local recurrence.
- Results of trials comparing preoperative radiotherapy with the commonly used postoperative radiotherapy plus chemotherapy are not available for review at this time.

## **Future Research**

- Patients with evidence of locally advanced but resectable rectal cancer should be encouraged to participate in randomized clinical trials evaluating the role of preoperative radiotherapy versus postoperative radiotherapy and chemotherapy combined.
- As optimal surgery including total mesorectal excision can also reduce the probability of locally recurrent rectal cancer, this surgical modality should be tested against the value of adjuvant radiotherapy in a randomized trial.

## **Related Guideline**

Practice Guidelines Initiative Practice Guideline Report #2-3: *Postoperative Adjuvant Radiotherapy and/or Chemotherapy for Resected Stage II or III Rectal Cancer.*

*For further information about this practice guideline report, please contact: Dr. Jean Maroun, Chair, Gastrointestinal Cancer Disease Site Group, Ottawa Regional Cancer Centre, General Division, 501 Smyth Road, Ottawa, Ontario, K1H 8L6; TEL (613) 737-7000, ext. 6708; FAX (613) 247-3511.*

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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.<sup>1</sup> 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:

- <sup>1</sup> 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.

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