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Use of Gemcitabine in the Treatment of Advanced Pancreatic Adenocarcinoma Practice Guideline Report #2-10

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ORIGINAL GUIDELINE: May 22, 1998

MOST RECENT LITERATURE SEARCH: June 2003

NEW EVIDENCE ADDED TO GUIDELINE REPORT: June 24, 2003

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

SUMMARY

Guideline Question

Should gemcitabine be offered as treatment to patients with unresectable or advanced pancreatic adenocarcinoma?

Target Population

These recommendations apply to adult patients with unresectable or advanced pancreatic adenocarcinoma.

Recommendations

- Gemcitabine is a reasonable treatment option in patients with advanced or unresectable pancreatic cancer. There is evidence from one randomized controlled trial that gemcitabine improves symptoms and modestly improves survival in patients with advanced or unresectable pancreatic cancer. These patients were symptomatic, had a life expectancy of at least twelve weeks, and a Karnofsky performance status of at least 50% (equivalent to an Eastern Cooperative Oncology Group performance status of less than 3).

Methods

Entries to MEDLINE (through to May, week 2, 2003, CANCELIT (through to September 2002), and Cochrane Library (Issue 1, 2003) databases and abstracts published in the proceedings of the 1999-2003 annual meetings of the American Society of Clinical Oncology have been searched for evidence relevant to this practice guideline.

Evidence was selected and reviewed by one member of the Practice Guidelines Initiative Gastrointestinal Cancer Disease Site Group and methodologists. This practice guideline has been reviewed and approved by the Gastrointestinal Cancer Disease Site Group, which comprises medical oncologists, radiation oncologists, and surgeons. Patient representatives did not participate in the development of the original guideline report, but two patient

representatives sit on the current Disease Site Group, which is responsible for updating the guideline.

External Review by Ontario practitioners was obtained through a mailed survey. Final approval of the original guideline report was 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 the periodic review and evaluation of the scientific literature, and where appropriate, integration of this literature with the original guideline information.

Key Evidence

Two phase I trials, seven phase II trials, one trial with both a phase I and phase II design, and one randomized controlled trial comparing gemcitabine with 5-fluorouracil were reviewed.

In the randomized controlled trial, patients randomized to gemcitabine experienced improved symptomatic clinical benefit (23.8% versus 4.8%; $p=0.0022$), longer median survival (5.65 versus 4.41 months; $p=0.0025$), improved one-year survival rate (18% versus 2%; $p=0.0025$), and longer median progression-free survival (2.33 versus 0.92 months; $p=0.0002$), but there was no significant difference in tumour response (5.4% versus 0%) compared with those randomized to 5-fluorouracil. Gemcitabine and 5-fluorouracil were generally well tolerated by patients in this trial. Myelosuppression, and nausea and vomiting, were more pronounced in patients randomized to receive gemcitabine compared with patients randomized to receive 5-fluorouracil.

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.

*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. 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.

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