

Irinotecan or oxaliplatin combined with leucovorin and 5-fluorouracil as first-line treatment in advanced colorectal cancer: a multicenter, randomized, phase II study.

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Source

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Abstract

BACKGROUND:

Irinotecan (IRI) and oxaliplatin (OXA) are effective in the treatment of colorectal cancer. Previously untreated patients with advanced colorectal carcinoma (CRC) were randomly assigned to receive IRI plus leucovorin (LV)/5-fluorouracil (5-FU), or OXA plus LV/5-FU in order to compare the response rates, time-to-tumor progression, overall survival rates, and toxicity profiles of these two agents.

MATERIALS AND METHODS:

From January 1999 to February 2002, 295 patients were randomized to receive either IRI/LV/5-FU or OXA/LV/5-FU. The treatment schedules consisted of weekly IRI 70 mg/m² or OXA 45 mg/m² plus LV 200 mg/m² followed immediately by intravenous bolus 5-FU 450 mg/m² for 6 weeks, followed by a 2-week rest period. Treatment was continued for up to four cycles or until disease progression, unacceptable toxicity or patient refusal.

RESULTS:

There were no significant differences between the study arms in the overall response rate (33% with IRI/LV/5-FU versus 32% with OXA/LV/5-FU based on responses demonstrated on a single evaluation; 23% with IRI/LV/5-FU versus 22.3% with OXA/LV/5-FU based on responses confirmed according to WHO criteria) median time to progression (8.9 versus 7.6 months), and median overall survival (17.6 versus 17.4 months). Toxicity profiles (grades 3 and 4) were similar in the IRI and OXA arms (diarrhea 12.3% and 9.8%, neutropenia 8.2% and 4.9%, and febrile neutropenia 1.4% and 1.4%, respectively), with the exception of grade 3 sensory neuropathy, which almost exclusively occurred in the OXA arm (0% versus 5.6%; P=0.003, Fisher's exact test).

CONCLUSION:

The IRI/LV/5-FU and OXA/LV/5-FU regimens demonstrated equally substantial efficacies and manageable toxicity profiles in the first-line treatment of patients with advanced CRC. However, IRI/LV/5-FU may be the preferable regimen to avoid significant neurotoxicity associated with OXA-LV/5-FU.

Comment in

- [Irinotecan or oxaliplatin for first-line treatment of advanced colorectal cancer?](#) [Ann Oncol. 2005]