

Fluorouracil and leucovorin with or without interferon alfa-2b in advanced colorectal cancer: analysis of a prospective randomized phase III trial. Hellenic Cooperative Oncology Group.

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Source

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Abstract

PURPOSE:

To investigate if double modulation of fluorouracil (5-FU) with leucovorin (folinic acid [FA]) and interferon alfa-2b (IFN 2b) improves responses and survival in comparison to single modulation of 5-FU with FA.

PATIENTS AND METHODS:

One hundred six patients with histologically confirmed advanced colorectal cancer, measurable disease, and without previous chemotherapy were prospectively randomized into two groups. Patients in group A received 5-FU 450 mg/m² as an intravenous bolus in the midinfusion of FA weekly. FA was given at a dose of 200 mg/m² in 500 mL 0.9% normal saline solution in 2-hour infusion. Patients in group B received exactly the same regimen plus IFN 2b 5 million units subcutaneously three times weekly.

RESULTS:

All patients were well balanced in both groups regarding age, sex, performance status, number, and site of metastasis. One hundred two patients were assessable. All patients have died. There was no difference in response between the two groups (7.8% v 9.8%). Median survival was 10.1 months in group A, and 7.2 months in group B (P = .00189). Median time to progression was 8.4 and 5.2 months, respectively (P = .00196). Overall, better performance status and older age had a positive impact on survival. Toxicity was the most important and catastrophic aspect of this study. Patients who received IFN 2b had significantly worse anemia, neutropenia, diarrhea, anorexia, weight loss, flu-like syndrome, and psychological reactions.

CONCLUSION:

Based on this final analysis, the addition of IFN 2b to the combination of 5-FU and FA enhances toxicity and contributes to decreased survival.