

A phase II trial of 5-fluorouracil, leucovorin and mitomycin C in patients with advanced gastric cancer

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ABSTRACT

Aims and background. Low-dose leucovorin is a well known potentiator of 5-fluorouracil activity in colorectal cancer but not in gastric cancer. To assess their efficacy on response rate and survival, 5-fluorouracil and low-dose leucovorin were combined with mitomycin C.

Methods. Fifty patients with gastric cancer and metastatic disease, unresectable or relapsed disease were treated with the following regimen every 28 days: mitomycin C, 7 mg/m² IV bolus on day 1, and leucovorin, 20 mg/m² IV, followed immediately by 5-fluorouracil, 375 mg/m² on days 1-5. All had measurable disease and were assessable for toxicity. Prognostic factors were analyzed to examine any association with response rate or overall survival.

Results. Nineteen of the 48 assessable patients (39.6%; 95% confidence interval [CI], 25.8-53.4) responded, including 4 complete responses (8.3%). The median progression-free survival was 108 days (range, 18⁺ - 146), and the median duration of survival was 338 days (11.3 months; range, 18⁺ - 903 days). Response rate and overall survival were not significantly associated with CEA level, performance status, age, or primary and metastatic tumor sites. Toxicity associated with the chemotherapy was tolerable, and all patients were treated at the outpatient clinic. Leukopenia and thrombocytopenia WHO grade ≥ 3 occurred in 5% and 1% of the patients, respectively. Nausea and vomiting were the most frequent adverse effects (29%), all grade 1 or 2.

Conclusions. Combination chemotherapy of 5-fluorouracil plus leucovorin with mitomycin C is effective for the treatment of advanced gastric cancer and is well tolerated.

Key words: 5-fluorouracil, advanced gastric cancer, leucovorin, mitomycin C, overall survival, response.

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