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Phase II trial of combination chemotherapy with gemcitabine, 5-fluorouracil and cisplatin for advanced cancers of the bile duct, gallbladder, and ampulla of Vater

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ABSTRACT

Aims and background. For advanced cancers of the bile duct, gallbladder and ampulla of Vater, there are only a few treatment options. We explored the efficacy of the combination of gemcitabine, 5-fluorouracil and cisplatin for advanced biliary cancers.

Methods. From September 2003 to April 2010, 28 patients with recurrent or metastatic biliary tract cancer were enrolled. A treatment regimen consisting of gemcitabine (800 mg/m^2 at a fixed dose rate on days 1 and 8), 5-fluorouracil (1 g/m^2/day continuous infusion for 4 days) and cisplatin (60 mg/m^2 on day 2) was repeated every 3 weeks.

Results. One (3.6%) patient showed complete response, 8 (28.6%) partial response, 14 (50%) stable disease and 5 (17.9%) disease progression. Overall, the objective response rate was 32.1% (95% CI, 17.9-50.6%) and the disease control rate was 82.1% (95% CI, 64.4-92.1%). Median progression-free survival and overall survival were 7.6 months (95% CI, 5.5-9.7) and 11.2 months (95% CI, 6.8-15.5), respectively. G3/4 neutropenia was observed in 44 (24.3%) of 181 cycles and G3/4 thrombocytopenia in 48 (26.5%) of 181 cycles. There was no treatment-related mortality.

Conclusions. The combined regimen of gemcitabine, 5-fluorouracil and cisplatin has comparable activity for patients with advanced cancer of the bile duct, gallbladder and ampulla of Vater. Toxicity was tolerable but substantial.

Key words: biliary tract cancer, cisplatin, 5-fluorouracil, gemcitabine, overall survival, response.

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