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First-line chemotherapy with docetaxel for unresectable or metastatic carcinoma of the biliary tract. A multicentre phase II study.

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Source

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Abstract

The purpose was to evaluate the efficacy and safety profile of docetaxel as first-line chemotherapy for patients with locally advanced or metastatic biliary tract carcinoma. 25 chemotherapy-naïve patients with unresectable or metastatic biliary tract carcinoma were entered into this phase II trial. Docetaxel was given at the dose of 100 mg/m2 as a 1-h infusion on day 1, after appropriate premedication with dexamethasone; treatment was repeated every 21 days. Patients were assessed for response every three chemotherapy cycles. 24 patients were evaluable for response and 25 for toxicity. A total of 98 cycles were administered with a median of three cycles/patient. Two complete (CR=8%) and three partial (PR=12%) responses were observed (overall response rate: 20%; 95% confidence interval (C.I.) 4-36%); in addition, 6 (24%) patients had stable disease and 14 (58%) progressive disease. With a median follow-up of 8 months, the median duration of response was 4 months, the median time to tumour progression (TTP) was 6 months and the overall median survival was 8 months. The 1-year survival rate was 26%. Grade 3 and 4 granulocytopenia occurred in 36 and 20% of the patients, respectively, and febrile neutropenia was observed in 16% of them; there were no treatment-related deaths. Grade 2-3 fatigue was reported in 24% of patients. These results indicate that docetaxel is an active drug against adenocarcinomas of the biliary tract.