

(PC). After disease progression, there is no standard regimen available. In a previous phase II trial, S-1 has been reported to show marginal efficacy, achieving a response rate of 15%, a median progression-free survival (PFS) of 2.0 months and a median overall survival time (MST) of 4.5 months in Gem-refractory PC patients. The schedule of Gem administration, with fixed dose rate (FDR) infusion of 10 mg/m²/min, would maximize the intracellular rate of accumulation for Gem triphosphate, and may improve clinical efficacy. The aim of this study was to determine the dose-limiting toxicity (DLT) and maximum-tolerated dose (MTD) of combination therapy with FDR-Gem and S-1 in patients with Gem-refractory PC.

Materials and Methods: Gem-refractory patients with histologically or cytologically proven metastatic PC were enrolled. The patients received Gem intravenously as an FDR (10 mg/m²/min) on day 1 and S-1 orally twice daily from days 1 to 7. Cycles were repeated every 14 days until disease progression. Patients were scheduled to receive Gem (mg/m²/week) and S-1 (mg/m²/day) at four dose levels: 800/80 (level 1), 1,000/80 (level 2), 1,200/80 (level 3) and 1,200/100 (level 4).

Results: A total of 15 patients (pts) were enrolled in this study between June 2006 and April 2006. All three pts at the level 4 demonstrated DLT involving grade 4 neutropenia in two pts and grade 3 stomatitis in one. The MTD was Level 3. Fourteen pts are currently evaluable for response in this ongoing trial. There have been 4 confirmed partial responses (27%), 8 pts with stable disease, and only 2 pts with progressive disease. The median PFS was 3.5 months and MST has not been reached. Final results will be presented at the meeting.

Conclusions: This biweekly, outpatient regimen may offer a good compliance and quality of life, and may be a promising treatment for Gem-refractory PC patients. This regimen will be evaluated in Phase II studies on Gem-refractory PC patients.

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POSTER

Long-term results of the phase II study on radiotherapy combined with nedaplatin and 5-FU for postoperative locoregional recurrent esophageal cancer

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Background: Although the effectiveness of radiotherapy with concurrent administration of several anti-tumor drugs for postoperative recurrent esophageal cancer has been demonstrated, the results are not satisfactory. In June 2000, we started a phase II study on treatment of postoperative locoregional recurrent esophageal cancer with radiotherapy combined with nedaplatin and 5-fluorouracil. We have reported a preliminary result of the present study, however, we show the long-term results of the phase II study on this occasion.

Materials and Methods: From June 2000 to May 2005, 32 patients with locoregionally postoperative recurrent esophageal cancer were treated with radiotherapy (60 Gy/30 fractions/6 weeks) combined with chemotherapy consisting of two cycles of nedaplatin (70 mg/m²/2 hours) and 5-fluorouracil (500 mg/m²/24 hours for 5 days). The primary endpoint of the present study was overall survival rate, and the second endpoints were irradiated-field control rate, tumor response and toxicity. The mean follow-up period of survival patients was 41.6 months (range, 24.0 to 80.0 months).

Results: The 3-year and 5-year overall survival rates were 35.7% and 22.3%, respectively, with a median survival period of 22.5 months (95%CI= 12.8-32.2), and the 5-year local control rates were 71.4%. Complete response and partial response were observed in 18.8% and 53.1% of the patients, respectively. Grade 3 or higher leukocytopenia and thrombocytopenia were observed in 37.5% and 3.1% of the patients, respectively, but renal toxicity of grade 3 or higher was not observed. The regimen was completed in 84.4% of the patients.

In univariate analysis, the difference between survival rate in preradiotherapy performance status (p=0.031), number of recurrent regions (p=0.018) and recurrent pattern [worse for patients with anastomotic recurrence (p=0.036)] were statistically significant.

Conclusions: Radiotherapy combined with nedaplatin and 5-FU is a safe and effective salvage treatment for postoperative locoregional recurrent esophageal cancer.

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POSTER

(XELOX)Capecitabine plus Oxaliplatin: clinical efficacy and safety in first-line treatment for metastatic gastric cancer

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Background: Capecitabine is an oral fluoropyrimidine with proven efficacy and favourable safety in colorectal cancer, whose administration does not require hospitalisation or placement of central iv line. The trial was designed to evaluate the efficacy of XELOX in metastatic gastric cancer.

Materials and Methods: To date 22 pts were enrolled in this study and treated with Oxaliplatin 120 mg/mq on day 1 and capecitabine 1.000 mg/mq twice daily from day 2 to day 15 every 3 weeks until disease progression or unaccepted toxicity. The evaluation of efficacy was performed every 3 cycles.

The characteristics of enrolled patients were: M/F = 13/9, Median age 56 yrs; median ECOG status 1 (range 0-2), all patients had adequate haematological, liver and renal function. The sites of disease were liver 10 pts, lymph nodes 7 pts, bone 1 pts and peritoneum 4 pts.

Results: All patients were evaluable for efficacy and toxicity. Were registered 3 RC and 6 RP with an overall Response Rate of 40%, in 8 pts we registered a SD, 5 patients progressed. Two patients of 3 with RC had a single liver localization. The schedule was well tolerated, the main G 3/4 toxicity (according to NCI-CTC) observed were neutropenia 13% of the pts, diarrhoea 8% of pts. Neuropathy G2 was recorded in 3 pts (13%). No treatment related was reported.

Conclusions: XELOX appears to be effective and well tolerated in first-line and treatment of pts with metastatic gastric cancer. These results are superior to those of historical controls from this institution, but is necessary to confirm these data with a longer follow up and more patients.

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POSTER

Image-guided intensity modulated radiation therapy (IG-IMRT) for extrahepatic cholangiocarcinoma: Results from a mature case control comparison with conventional radiotherapy (CRT)

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Purpose: Cholangiocarcinomas are comparatively rare neoplasms, and the optimum role of radiotherapy remains to be determined. The specific aim of this study was to report the clinical results of a single-institution cholangiocarcinoma series treated with modern radiotherapeutic techniques, and to ascertain if clinical benefit was observed using ultrasound (US) image-guided intensity-modulated radiation therapy (IG-IMRT).

Methods and Materials: From 2001 to 2005, 11 patients with primary adenocarcinoma of the extrahepatic bile ducts were treated by daily US-guided IG-IMRT to a mean dose of 57 Gy. To compare outcomes, data from a sequential series of 8 patients treated between 1995 and 2005 with conventional radiotherapy techniques (CRT) were collected in a comparator set. Demographic and treatment parameters were collected. Endpoints included treatment-related acute toxicity and survival.

Results: A statistically significant higher mean dose was given to patients receiving IG-IMRT compared to CRT, 57 vs. 45 Gy (p<0.01). At last contact 3 patients were living, with a median follow-up of 32 months or those alive at last contact. Median estimated survival for all 19 patients was 11.1 months (range 2-62 months). 1- and 3-year survival for the IG-IMRT cohort was 64% and 23%, compared to 12.5% and 0% for the CRT patients. A statistically significant survival differential between IG-IMRT and CRT cohorts was observed (median 15.0 vs 6.9 months, p=0.01). Surgical resection was associated with improved survival (p<0.01). One IG-IMRT patient (9%) experienced an RTOG acute toxicity score >2, specifically upper GI grade 3 nausea/vomiting requiring tube or parenteral support; no CRT patients experienced a score >2. The most commonly reported GI toxicity requiring medication (RTOG Grade ≥2) was nausea and abdominal pain relieved with oral medication, experienced by 25% of CRT patients and 54% of IG-IMRT patients (p=n.s.).

Conclusion: This hypothesis generating series presents the first mature clinical outcomes of extrahepatic cholangiocarcinomas treated with IG-IMRT. IG-IMRT shows potential for improved survival in biliary tract tumors,