Results: This study remains on schedule from Nov. 2009 to Mar. 2011. In 23 centers, 157 patients have been screened with 1 screen failure. Interim analysis will be done in Jun 2011, the enrollment is planned to be completed in Apr 2012. Up to now, 20 patients withdrew from the study, with 1 of capecitabine allergy, 2 of paclitaxel allergy, 4 of consent withdrawn, 2 of withdrawn after randomization, and 11 lost follow-up. Severe adverse event (SAE) is reported in 9 cases (cut-off date 31 Jan, 2011), 1 of multiorgan dysfunction syndrome (MODS), 2 of intestinal obstruction, 1 of liver dysfunction, 1 of hemorrhage, 1 of bone marrow failure, 1 of thrombosis, 1 of paclitaxel allergy, and 1 of diarrhea. One treatment-related death was suspected in all patients. Safety data is now under collection for interim safety analysis.
Conclusion: PX-X as first-line treatment was promising in AGC. Interim safety results and primary efficacy analysis are eagerly awaited.

6601 POSTER

Oxaliplatin, Leucovorin and Fluorouracil for Untreated Recurrent or Metastatic Esophageal Carcinoma − a Phase II Study

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Background: Esophageal carcinoma is one of the most common cancers, as well as one of the leading causes of cancer death in China. In Western countries, clinical trials are now primarily focusing on the treatment of adenocarcinoma, owing to the recent increase in the prevalence of this type of esophageal cancer. In China and other eastern Asian countries, squamous cell carcinoma is the main type of esophageal cancer. Monotherapy with oxaliplatin or 5-Fu has been demonstrated anticancer activity in esophageal cancer. This study was designed to evaluate the efficacy and toxicity of oxaliplatin, leucovorin and fluorouracil (FOLFOX6) in untreated recurrent or metastatic esophageal carcinoma.
Materials and Methods: Patients with recurrent or metastatic esophageal cancer ineligible for definitive radiotherapy were given FOLFOX6:oxaliplatin 100 mg/m^2, leucovorin 400 mg/m^2, fluorouracil (400 mg/m^2) as an i.v. bolus, fluorouracil (2400 mg/m^2) as a 46-h continuous infusion on day 1. Treatment cycles were administered every 14 days. The primary end point was progression-free survival (PFS). Secondary end points included objective response (OR), overall survival (OS) and safety.

Table 1. Adverse effects of 40 patients treated with FOLFOX6

Adverse effect	Number of patients				
	Total, N (%)	Grade 1	Grade 2	Grade 3	Grade 4
Leukopenia	32 (80%)	10	12	8	2
Neutropenia	28 (60%)	7	9	9	3
Anemia	22 (55%)	16	3	3	1
Thrombocytopenia	11 (27.5%)	3	5	3	0
Neuropathy	25 (62.5%)	23	2	0	0
Nausea	24 (60%)	18	5	3	0
Vomiting	15 (37.5%)	12	3	0	0
Stomatitis	25 (62.5%)	21	4	0	0
Diarrhea	5 (12.5%)	5	0	0	0
Fatigue	30 (75%)	20	8	3	0
Alopecia	8 (20%)	8	0	0	0
Hyperbilirubinemia	3 (7.5%)	3	0	0	0
Elevation of AST/ALT	5 (12.5%)	5	0	0	0

Results: Between Oct, 2008 and Dec, 2010, a total of 40 patients with median age of 56 years old were enrolled. Baseline characteristics: male/female: 35/5; squamous/adenocarcinoma: 36/4; surgery/radiotherapy/neoadjuvant or adjuvant chemotherapy: 26/17/16; metastasis: 1 site:5 pts, 2 sites:11 pts, 3 sites:10 pts, 4 sites:12 pts, 5 sites:2 pts; mediastinal lymph node(LN) metastasis(M): 29pts,supreclavicular LN M: 21pts,retroperitoneal LN M: 17pts,liver M: 15pts,lung M: 10pts,anastomotic recurrence: 9 pts,soft tissue M: 5 pts, bone M: 5pts,gastric M: 4pts,cervical LN M: 3pts. Median cycles of FOLFOX6 were 4. PR: 17.5% (7/40),SD: 45% (18/40),PD: 32.5% (13/40),unassessable: 5% (2/40). With median follow up of 10 months, twenty-four patients died. Median PFS was 5.8 months(95% CI: 4.1−7.5). Median survival was 8.5 months (95% CI: 7.1−9.8). FOLFOX6 was well tolerated. Adverse effects were listed in table 1.
Conclusion: Chemotherapy with FOLFOX6 for untreated advanced esophageal cancer had promising efficacy and good tolerance. It is worthy being test further.

6602 POSTER

Immune Therapy Targeting for HER2 in Esophageal Squamous Cell Carcinoma

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Background: In spite of the combined modality therapy, the prognosis with advanced esophageal squamous cell carcinoma (ESCC) patients remains poor. On the other hand, cytotoxic T lymphocytes (CTL) therapy and molecular targeting therapy for HER2 were effective in a variety of tumours. These therapies are therefore an attractive approach as a novel immune-adjuvant therapy for ESCC patients. To examine the possibility of these therapies for ESCC patients, we investigated the HER2 expression in ESCC patients, the effect of molecular targeting therapy for HER2 in ESCC cell lines and MHC class I expression in ESCC patients as tumour-antigen specific CTL recognize peptide epitopes on MHC class I.
Materials and Methods: We assessed the HER2 expression in ESCC patients (n = 85) and ESCC cell lines (n = 9) by HercepTest and Fluorescence in situ hybridization (FISH). We also assessed the MHC class I expression in ESCC patients (n = 80) by immunohistochemistry with anti-MHC class I monoclonal antibody. In a panel of ESCC cell lines, the effects of Herceptin and Lapatinib on anti-proliferative effect and apoptosis-inducing activity was evaluated, furthermore, the accumulation of HER2 on cell surface by Lapatinib and the combined effect of Lapatinib together with Herceptin on cell-mediated cytotoxicity were evaluated.
Results: In ESCC patients, FISH positive; 9.4%, HercepTest 2+/3+; 11.8% and HercepTest 1+; 17.6%. The down-regulation of MHC class I expression was observed in 38.7%, furthermore, there was a significantly inverse correlation of HER2 overexpression (FISH positive) with MHC class I expression ($\chi 2$ test p = 0.002). One ESCC cell line expressed HercepTest 3+ and FISH positive. Herceptin and Lapatinib inhibited cell proliferation and induced apoptosis in ESCC cell lines and Lapatinib induced greater effectiveness. Lapatinib caused the surface accumulation of HER2 in all ESCC cell lines and increased Herceptin-mediated antibody-dependent cell-mediated cytotoxicity by 15−25% with 3 ESCC cell lines including a HER2-overexpressing cell line and two non-HER2-overexpressing cell lines.
Conclusions: Although HER2 overexpressing ESCC patients are not so good candidates for CTL therapy because HER2 overexpressing ESCC cells reduced their sensitivity for CTL by MHC class I down-regulation, Herceptin and Lapatinib have activity in HER2 expressing ESCC cells and the combination therapy of Herceptin and Lapatinib is a promising strategy in ESCC.

6603 POSTER

Prognostic Factors of 127 Patients With Advanced Small-bowel Adenocarcinoma Treated With Systemic Chemotherapy

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Background: No standard care has been established for advanced small-bowel adenocarcinoma (SBA). The aim of this retrospective study is to explore a most promising chemotherapy regimen for advanced SBA after adjusting the background factors by multivariate analysis.
Methods: The subjects were 132 patients with advanced SBA who were treated by chemotherapy. Main inclusion criteria were 1) histologically proven SBA excluding ampullary carcinoma, 2) no previous chemotherapy or radiotherapy, 3) ECOG PS 0−2. Patients were classified into the following 5 groups according to the first-line chemotherapy: A) FU alone; B) FU + CDDP; C) FU + Ox; D) FU + CPT-11; E) others. Progression free survival (PFS) and overall survival (OS) were compared with the log-rank test, and every hazard ratio (HR) was calculated using univariate and multivariate analysis with Cox's proportional hazards model.