and dose escalation using IG-IMRT represents a reasonable approach which should be further investigated in future prospective trials.

3548 POSTER

A phase II study of S-1 and irinotecan combination chemotherapy in patients with advanced gastric cancer as a first-line therapy

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Background: Irinotecan plus intravenous 5-FU with leucovorin is effective against gastrointestinal cancer. S-1 is an oral fluoropyrimidine derivative combining tegafur with the modulators 5-chloro-2,4-dihydropyrimidine and potassium oxonate. S-1 has a high response rate of about 40% in advanced gastric cancer (AGC). We evaluated antitumor activity and toxicities of S-1 and irinotecan combination in patients with AGC as a first-line therapy.
Methods: Patients with histologically confirmed AGC with unresectable or metastatic diseases, measurable lesions, PS 0−2, age between 18 and 70, and no contraindication to chemotherapy were eligible for this study. Treatment included S-1 40 mg/m^2 p.o. twice daily on days 1−14 and irinotecan 150 mg/m^2 i.v. on day 1 every 3 weeks until disease progression or unacceptable toxicities.
Results: Between Sep 2005 and Mar 2007, total 45 patients (pts) were enrolled and 41 pts were analyzed because 4 pts were too early for analysis. The median age was 56 years (range, 36−70). After a median 6 (range, 1−20; total, 291) cycles of chemotherapy, 38 pts were evaluable for response and 40 pts (290 cycles) for toxicity. In intention-to-treat analysis, the overall response rate was 48.8% (95% C.I., 33.5%-64.1%), including 0 CR, 20 PRs. After a median follow-up of 8.1 months (range, 1.1−18.6), median time to progression was 5.7 months (95% C.I., 4.5−6.8) and median overall survival was 9.3 months (95% C.I., 5.0−13.6). Commonly observed grade 3/4 adverse events were neutropenia (30.0% of pts), vomiting (12.5%), nausea (10.0%) and diarrhea (7.5%). Treatment was delayed during 9 cycles (3%). The dose of S-1 and irinotecan were reduced during 71 cycles (24.5%) and 69 cycles (23.8%), respectively. There were two pts of neutropenic fever, but none of treatment-related death.
Conclusion: S-1 and irinotecan combination chemotherapy was active and tolerable as a first-line therapy for AGC.

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Venous thromboembolism as a complication of chemotherapy for upper gastrointestinal malignancy

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Background: Patients with metastatic malignancy are at an increased risk of venous thromboembolism (VTE) both by the nature of their disease and the treatment they receive, particularly with cisplatin based chemotherapy. While previously diagnosed at presentation with symptoms, modern multi-slice CT has led to the diagnosis of increasing numbers of asymptomatic thromboembolic events.
Patients in the UK with operable oesophagogastric cancer are commonly treated with peri-operative cisplatin containing chemotherapy, with cisplatin carrying a particular risk of VTE. In our practice we have seen increasing numbers of patients with early stage disease diagnosed with asymptomatic VTE. VTE carries a significant morbidity both in terms of the disease itself and associated treatment, and in early disease may impact on the safety of subsequent surgery.
Methods: We reviewed the case notes of all patients referred to our centre over a 12 month period for management of oesophageal, gastric or oesophagogastric junction cancers.
Results: 108 patients were referred to our centre from 01/01/05 to 31/12/05 for management of an upper gastrointestinal malignancy. 61 patients received systemic chemotherapy, 43 for local disease (70.5%) and 18 for metastatic disease (29.5%). 53 (86.9%) of the patients receiving chemotherapy were treated with a cisplatin containing regimen. There were 11 cases of VTE; 5 were of pulmonary embolus, all diagnosed on staging scans, 1 at the time of diagnosis and four at post chemotherapy assessment. The remaining 5 were lower limb deep vein thrombosis (DVT) and 1 upper limb catheter associated DVT. Of those patients receiving cisplatin chemotherapy 9 had a diagnosis of VTE (17.0%; 95% CI 8.1−29.8%). Within the overall chemotherapy group 10 patients had an episode of VTE (16.4%). The Odds Ratio for an episode of VTE in patients undergoing chemotherapy was 9.0 (95% CI 1.4−56.2, p = 0.015). 31 of the 61 patients receiving chemotherapy were planned for subsequent surgery. 5 of those developed an episode of VTE (16.1%), 1 requiring placement of an IVC filter prior to surgery.
Conclusions: VTE is a significant problem in this population, particularly those receiving cisplatin-containing chemotherapy. Our data shows similar rates of VTE in an unselected population to that reported in the REAL 2 trial (18% and 15% in the cisplatin containing arms). We propose a prospective study of the role of thromboprophylaxis in this patient group.

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Capecitabine plus hepatic intra-arterial epirubicin and cisplatin in unresectable biliary cancer: a phase II study

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Background: the prognosis of advanced biliary tract cancer is very poor. The rationale for the use of intra-arterial hepatic chemotherapy is related to the natural history of these tumors, with a growth through a local extension rather than distant metastases and to the high hepatic extraction upon the first pass of some drugs that reach bile canaliculi at high concentration. Aim of this study is to evaluate the activity of hepatic intra-arterial infusion of epirubicin and cisplatin combined with oral capecitabine, in patients (pts) with unresectable biliary cancers.
Materials and Methods: twenty pts were treated by bolus infusion of epirubicin 50 mg/m^2 and cisplatin 60 mg/m^2 in the hepatic artery through an angiografic catheter placed with Seldinger technique on day 1, combined with oral capecitabine 1000 mg/m^2 bid, from day 2 to day 15.
Results: tumor site were intrahepatic bile ducts in 12 patients, gallbladder in 7 and choledochus in 1. Nineteen pts are evaluable for response. Partial responses were observed in 6 pts (31.5%), stable disease in 9 (47.5%), progression in 4 (21%). The median progression-free and overall survival periods were 11.6 and 18.0 months, respectively, and 1-year survival was 74%. One patient died after the first cycle because of G4 gastro-intestinal toxicity. The other pts had a good tolerance, with minimal hematologic toxicity and only 1 G3 vomiting.
Conclusions: this combined intra-arterial and oral approach to pts with biliary carcinomas was found to be active and safe and seems to produce interesting survival.

3551 POSTER

Role of adjuvant chemoradiotherapy for ampulla of Vater cancer

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Background: The purpose of this study is to evaluate the role of adjuvant chemoradiotherapy for ampulla of Vater cancer.
Materials and Methods: Between January 1991 and December 2002, 118 patients with ampulla of Vater cancer underwent en bloc resection. There were 69 males and 49 females, and median age was 57 years (range; 28−78). Forty patients had Whipple's operation, and 78 had pylorus-preserving pancreaticoduodenectomy. Forty-one patients received adjuvant chemoradiotherapy [CRT(+) group], and 77 did not [CRT(−) group]. Postoperative radiotherapy was delivered to tumor bed and regional lymph nodes up to 40 Gy at 2 Gy per fraction with a two-week planned rest. Intravenous 5-fluorouracil (500 mg/m^2/day) was given on day 1 to 3 of each split course. The median follow-up period was 65 months.
Results: Despite more advanced pathologic features of T stage, N stage and histologic differentiation in CRT(+) group (p = 0.0012, 0.0013, and 0.0472, respectively), the 5-year overall survival rates of CRT(−) and CRT(+) groups were comparable (66.9% and 52.8%, respectively, p = 0.4397). The 5-year local-regional relapse-free survival rates of CRT(−) and CRT(+) groups were 79.9% and 80.2%, respectively (p = 0.9306). When age, type of operation, T stage, N stage, histologic differentiation, and the use of adjuvant chemoradiotherapy were incorporated into