the reservoir on an out patient basis, and repeated every 4 weeks. Patients continued to receive carboplatin emulsion until disease progression or the appearance of unacceptable toxicity including hepatic failure.
Results: Thirty-two patients were enrolled between January 2000 and December 2004. One patient deteriorated before receiving chemo infusion and was excluded from further evaluation. The average number of arterial infusions given during the follow-up period ranged from 3 to 31 (median, 13.7). Out of 31 eligible patients, 15 patients had partial responses, for an objective responses rate of 48.4%; 7 patients had no change, and 9 had progressive diseases. The median survival time was 17.7 months (95%c.i. 14.1–21.2 months). The cumulative survival rates were 76.6% and 47.2% for the periods of 12 and 24 months, respectively. The grade 3–4 toxicities (NCI-CTC) observed were leucopoenia (12.9%), thrombocytopenia (19.4%), and increased AST (3.2%).
Conclusions: Repeated hepatic arterial infusion of carboplatin mixed with degradable starch microsheres by using reservoir is active and well tolerated in patients with advanced HCC underlying liver cirrhosis.

745 POSTER

Final report of Phase I/II study of docetaxel and S-1 for patients with advanced gastric cancer

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Background: This phase I/II study was conducted to evaluate efficacy and safety of new combined regimen with docetaxel (DOC) plus S-1 in patients (pts) with advanced gastric cancer (AGC). DOC and S-1 have different modes of actions respectively, and showed both of anti-tumor activities for AGC and synergistic effect in combined administration.
Methods: Eligibility criteria included; pathologically confirmed AGC, measurable lesions, PS 0–1, $\leqslant$1 prior chemotherapy, $\geqslant$20 years old, adequate organ functions and written IC. In phase I part, the dose of DOC was elevated from the starting dose of 50 mg/m^2 and S-1 dose was fixed to 80 mg/m^2. DOC was administered on day 1 and S-1 was administered orally on days 1–14 consecutively, and the treatment was repeated every 4 weeks. Identifying recommended dose (RD) of combined DOC+S-1, phase II part was started to evaluate the profiles of efficacy and safety of this combined regimen.
Results: 50 pts were enrolled in this study from 9/02 to 6/04. In phase I part, all 3 pts enrolled in the starting dose level showed intolerable toxicities (grade 3 neutropenia with infection in one pt and grade 4 neutropenia on day 8 during S-1 administration in 2 pts). Then the dose of DOC was de-escalated to 40 mg/m^2 and this dose level was determined as RD for phase II part. 46 out of 47 pts enrolled were eligible and evaluable for safety and efficacy, respectively. Pt characteristics were as follows; median age 65 (range 42–79), M/F 31/15, PS0/1 29/17, histological type intestinal/diffuse 29/17 and chemonaïve/pre-treated 25/21 pts. ORR, MST and 1 year survival rate were 45.7% (95%CI: 30.9–61.0%), 14.2 months and 56.6%, respectively. Common grade 3/4 toxicities were neutropenia (67.4%), leukopenia (41.3%), anemia (21.7%), and anorexia (21.7%). These toxicities were tolerable and manageable. No treatment-related death was observed. The interim results were presented at ASCO2005 meeting (Abstract 4064), and final and mature results will be presented at ECCO13 meeting.
Conclusions: This new regimen with DOC and S-1 showed manageable toxicities and favorable survival benefit to warrant a further phase III study with this regimen in pts with AGC.

746 POSTER

Oxaliplatin and Irinotecan in advanced gastric cancer. A multicenter phase II trial

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Treatment options for advanced gastric cancer are limited therefore inclusion of novel substances is mandatory. Several agents have recently emerged as potential new options for advanced gastric cancer. The combination of Doxetaxel/Cisplatin and 5-FU showed high respons rates and a small survival benefit at the cost of increased toxicity. The aim of this study was to evaluate the safety, feasibility and efficacy of an Oxaliplatin/Irinotecan combination in patients suffering from unresectable, locally advanced and/or metastatic gastric cancer. Both substances show activity in gastric cancer as single agent or in combination with other drugs but the combination of Oxaliplatin and Irinotecan has not been evaluated in this setting. The combination of Oxaliplatin 85 mg/m^2 biweekly with Irinotecan 125 mg/m^2 biweekly was chosen for the present study since it has been shown in colorectal cancer that a biweekly dose of at least 85 mg/m^2 oxaliplatin is superior to a lower dose and toxicity of Irinotecan is much lower if given fractionated into two doses. Furthermore the Irinotecan dose below MTD considers concerns about increased toxicity of Irinotecan in gastric cancer patients. 43 patients with histologically proven unresectable and/or metastatic gastric adenocarcinoma and no previous palliative chemotherapy and/or immunotherapy were selected. Median age: 61 years (range 32 –81 years), male/female ratio: 24/19, PS 0:11 patients, PS <3: 32 patients, single metastatic site: 19 patients, multiple metastases: 19 patients, previously adjuvant radiochemotherapy: 4 patients. This outpatient regimen was generally well tolerated. Frequently reported adverse events (more than 20% of patients) were grade 1 or 2 and included neutropenia (44% of patients), thrombocytopenia (30%), anemia (77%), nausea 67%), diarrhea (51%), alopecia (35%). Grade 3 and 4 toxities included neutropenia in 2/43 pts., anemia in 3/43 pts., nausea in 2/43 pts., and diarrhea in 4/43pts. 3 patients were taken off-study due to toxicity (asthenia, nausea, reversible renal failure). Sensory neuropathy occurred only as grade 2 in 15%, no grade * toxicity was observed. 35 patients are assessable for response with 2 pts. (5.7%) showing a CR, PR in 19 pts. (54%), SD in 11 pts. (31%), PD in 3 pts. (8.6%). Final results on TTP and OS will be presented during the meeting.
Conclusion: Oxaliplatin/Irinotecan is a feasabile outpatient regimen with low overall toxicity and manageable side effects and a response rate within the range of other combination therapies and represents an alternative 1st line regimen.

747 POSTER

Final efficacy results of a neoadjuvant chemoradiation phase II trial: paclitaxel, carboplatin and 5-FU with concomitant 45 Gy radiotherapy for stage II-III oesophageal cancer

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Introduction: The outcome for patients with oesophageal cancer undergoing surgical resection with curative intention is poor. In an attempt to improve outcome, neoadjuvant strategies have been studied. Neoadjuvant chemoradiation is most promising. Pathologic complete response (pCR) rates of 20–30% have been published. We aimed to assess the feasibility and efficacy of a new treatment strategy, neoadjuvant chemoradiation followed by surgery in patients with stage II-III oesophageal cancer.
Methods: In the period from Jan 2002 – Nov 2004, 50 patients with a potential resectable stage II-III oesophageal cancer received chemotherapy with paclitaxel 175 mg/m^2 iv and carboplatin AUC 5 iv on day 1 and 22, 5-Fu 200 mg/m^2 on day 1 to 42 in combination with radiotherapy 45 Gy in 25 fractions starting on day 1. Surgery followed 6–8 weeks after completion of neoadjuvant treatment.

Results: 50 patients have completed neoadjuvant therapy. Patient characteristics: M/F: 44/6, median age 60 yrs (34–75), median WHO 1 (0–2), adenoca (n = 42), squamous cell ca (n = 8).
Toxicity: no treatment related deaths due to chemoradiation. One patient died after completion of neoadjuvant therapy due to a myocardial infarction. Uncomplicated grade 3 leucopenia in 23 pts (46%). All patients experienced oesophagitis, usually mild (⩽gr 2), however 13 pts needed nasogastric enteral feeding during therapy.
2 patients showed metastatic disease at surgery, hence 47 pts underwent surgery with a curative intention (transhiatal n = 44, transthoracic n = 3).
Pathologic complete response was achieved in 20 of 47 operated patients (43%). R0 resection was achieved in 45 of 47 operated patients (96%) There were 4 post-operative deaths (8.5%), due to major anastomotic complications of the gastric tube (n = 3) and a progressive chylothorax (n = 1). Post-operative complications: anastomotic leakage (major n = 5, minor n = 11), pulmonary (n = 15), recurrent nerve palsy (temporary n = 3, permanent n = 1) and cardiac dysrhythmias (n = 3).
As follow-up is short no data can be given of total- and disease free survival.
Conclusions: This novel combined-modality neoadjuvant approach for treatment of patients with stage II-III oesophageal cancer is feasible and preliminary assessment of efficacy is encouraging, with 43% of the patients having a pCR and 96% R0 resection rate. Follow-up data have to be awaited to obtain data on survival. A nationwide phase III trial has been started.

748 POSTER

Oesophageal cancer: the prognostic value of the pre-treatment 18FDG PET

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Objectives: Since oesophageal cancer is associated with poor prognosis, proper assessment of prognosis is necessary in order to determine the most appropriate treatment. The aim of the study was to determine the ability of ^{18}FDG-PET in predicting the clinical outcome of patients with newly diagnosed oesophageal cancer.
Material and Methods: 37 patients (32 men, 5 females; mean age 63±10.8) with newly diagnosed oesophageal cancer (27 squamous cell cancer – 9 adenocarcinoma – 1 verrucous cancer) were included in this study between March 2003 and November 2004. All patients underwent ^{18}FDG PET imaging for initial staging. The maximum SUV of the primary mass was calculated and the presence of FDG positive nodes or FDG avid distant metastases was recorded for all patients. The events for survival analysis were defined as recurrence or metastasis and cancer related death. The disease free or overall survival rates of each variable were estimated by the Kaplan-Meier method.
Results: In all patients the sensitivity of 18FDG PET was 100% for the primary lesion. At the time of the last follow up 21 patients were alive. Using univariate survival analysis, higher clinical stage and sex were associated with poorer prognosis. A maximum SUV higher than 9 in the primary mass was a significant prognostic factor for overall survival ($P < 0.05$). In the group of SUVmax >9, no patient was alive at 1 year, while in the group of lower SUVmax, the 1 year survival was 70%. The presence of PET positive nodes was not a significant prognostic factor. The presence of 18FDG avid metastases was associated with a median survival of only 8 months versus 15 in cases where no metastasis was detected using PET.
Conclusion: In addition to the pathologic stage, 18FDG PET before treatment provides non invasively independent prognostic information using SUV in the primary mass. Those results support the use of 18FDG for the initial evaluation of patients with oesophageal cancer in order to identify those with poor prognosis.

749 POSTER

Combination chemotherapy with capecitabine (X) and cisplatin (P) as a first line treatment of advanced gastric cancer: experience of 246 patients with prognostic factor analysis

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Background: Combination chemotherapy consisting of capecitabine (X) and cisplatin (P) has been shown to be effective in the treatment of advanced gastric cancer (Kim TW, et al. Ann Oncol 2002, Kang HJ, et al. Br J Cancer 2005). The aim of the current study is to evaluate the efficacy and feasibility of XP combination for the treatment of AGC in clinical practice and to elucidate the prognostic factors affecting the treatment outcomes.
Methods: Clinical data of 246 patients (pts) with previously untreated metastatic, unresectable, or recurrent gastric adenocarcinoma treated with XP chemotherapy as a 1st line treatment in Asan Medical Center from March. 2003 to Dec. 2004 were reviewed. XP chemotherapy consisted of oral capecitabine 1000–1250 mg/m^2 twice daily, days 1–14, and i.v. cisplatin 60–80 mg/m^2 on day 1. The cycle was repeated every 3 weeks.
Results: Among 246 pts, 114 patients had distant metastasis and did not have gastrectomy (metastatic), 88 pts had recurrent disease after previous curative gastrectomy (recurrent), and 44 pts had distant metastasis but had palliative gastrectomy (resected metastatic). A median of 4 cycles (range, 1–12) was administered. Among 125 pts with measurable diseases, 7 pts achieved a complete response and 45 pts had partial responses, giving an overall response rate (RR) of 41.6% in the intention-to-treat population (95% CI, 32.9%-50.2%). There was no difference in RR between the initially metastatic and recurrent groups; 40.0% vs. 42.9% ($P = 0.748$). After a median follow-up of 28.2 months (mo), the median time to progression (TTP) was 6.3 mo (95% CI, 5.3–7.4 mo) and the median overall survival (OS) was 11.1 mo (95% CI, 9.4–12.9 mo). The TTP and OS were significantly different among the 3 groups; Median TTP of 5.3 mo, 6.8 mo, and 9.4 mo ($p = 0.0006$), median OS of 9.4 mo, 12.4 mo, and 17.2 mo ($p = 0.0068$) in metastatic, recurrent, and resected metastatic groups, respectively. Multivariate analysis revealed minimal residual disease achieved by palliative gastrectomy (OR = 0.45, 95% CI, 0.20–0.99, P = 0.047) and good performance status (OR = 0.31, 95% CI, 0.16–0.61, P = 0.001) were independent prognostic factors affecting overall survival.
Conclusions: The combination of capecitabine and cisplatin was active and well tolerated for the 1st line treatment of AGC in general clinical practice. The disease status and performance status of the pts were the most important factors for the treatment outcomes of XP chemotherapy.

750 POSTER

Concurrent chemoradiation therapy with 24-hour infusional gemcitabine in locally advanced pancreatic cancer: a phase II study

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Background: Prolonged exposure of gemcitabine, a potent radiosensitizer, is known to increase intracellular concentration of gemcitabine triposphate, subsequently leading to enhanced antitumor activity. We conducted a phase II trial to determine the efficacy and feasibility of weekly 24-hour infusional gemcitabine with concurrent radiation therapy in patients with locally advanced pancreatic adenocarcinoma.
Material and methods: The 125 mg/m^2 of gemcitabine was given weekly as a 24-hour infusion for 5 consecutive weeks with concurrent external beam radiation (45 Gy in 25 fractions).
Results: Between June 1999 and December 2003, 27 patients with histologically proven, locally advanced adenocarcinoma of pancreas were enrolled in this study. There were 18 male and 9 female, their median age was 54 years (range, 40–70). Median ECOG performance status was 1 (range, 0–1). In total, 104 cycles of chemotherapy were administered with a median of 5 cycles per patient (range, 1–5) and 9 patients (33.3%) had at least 1-week delay. 22 patients were evaluable for response. The objective response rate was 27.3% (95% CI, 7.1–47.5%) with no CR and 6 PRs, 7 patients (31.8%) had stable disease and 9 patients (40.9%) showed tumor progression. One patient received Whipple's operation and achieved complete response. 13 of 19 symptomatic patients (68.4%) had improved abdominal pain after chemoradiation therapy. The median progression-free survival was 5 months (range, 2–66+ months) and median overall survival was 9 months (range, 1–67+ months). Grade 3/4 hematological toxicity included neutropenia in 5 patients (18.5%) and thrombocytopenia in 6 patients (22.2%). No patients required hospitalization for the management of febrile neutropenia. Non-hematological toxicities included fatigue, diarrhea, nausea and vomiting which were not significant.
Conclusions: These results showed that weekly 24-hour infusion of gemcitabine with concurrent radiation therapy was effective and tolerable. Thus further studies are warranted.