were analyzed retrospectively. Indolent tumor types (acinar cell carcinoma and mucinous cystadenocarcinoma) were excluded from the analysis.
Results: Of 292 patients who receivedsurgical resection with curative intent, 234 had curative (R0) and 58 had incomplete resection (R1/2). The median survival duration of all patients was 21.7 months. Multivariate analysis revealed that positive resection margin, CA 19−9>90, no postoperative CCRT, moderate or poorly differentiated histological grade and abnormal range of glucose level as significant independent prognostic factors for decreased OS ($p < 0.05$). OS was estimated on the basis of each prognostic factor: zero and one (good prognostic group), two and three (intermediate prognostic group), and over than four (poor prognostic group). The median OS for good (n = 49), intermediate (n = 204) and poor prognostic groups (n = 39) were 67.8, 24.4, and 11.0 months, respectively ($p < 0.001$). In subgroup analysis of 234 patients with R0 resection, postop CCRT was the only significant prognostic factor for decreased OS at multivariate level; CA 19−9>90, moderate or poorly differentiated histological grade and the presence of perineural and blood vessel invasion predicted reduced disease free survival (DFS) ($p < 0.05$).
Conclusion: The prognostic model based on readily available clinical data would be useful to predict the prognosis and to facilitate decision in clinical practice. The postop (adjuvant) CCRT was the only common independent prognostic factor for OS in patients after RO or R0+R1/2 resection of adenocarcinoma of the pancreas.

6593 POSTER

A phase II study of combination chemotherapy with gemcitabine, 5-fluorouracil, and cisplatin for advanced pancreatic cancer

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Background: Gemcitabine alone has been the standard regimen, but the median survival of the patients with advanced pancreatic cancer on it is only 5 months, needing more effective regimen desperately.
The combination of gemcitabine and 5-fluorouracil (5-FU) results in better response rate than gemcitabine alone, but the survival gain has not been demonstrated. The combination of gemcitabine/cisplatin was better than gemcitabine alone in the response rate and possibly in survival in a study. Gemcitabine has synergy with 5-FU and with cisplatin; 5-FU has synergy with cisplatin, making these 3 drugs have triple-synergy. They also have different dose-limiting toxicities. We hypothesized that this synergistic combination of these 3 active agents may be more active than gemcitabine alone.
Materials and Methods: Forty seven patients with pathologically proven adenocarcinoma of pancreas in stage III/IV were treated with the following regimen every 3 weeks: Gemcitabine 800 mg/m^2 IV on day 1 and 8, 5-FU 1 g/m^2/day IV in a 24 hour continuous infusion from day 1 to 4, and cisplatin 60 mg/m^2 IV on day 2, 24 hours after start of gemcitabine.
Results: The median age was 62 and male:female ratio was 33:14. A total of 158 cycles were administered with a median of 3 cycles per patient (range, 1−14 cycles). Among 37 patients evaluable for the response, 5 (13.5%) patients had a partial response (95% Confidence interval: 2.3−24.7%), and 21 patients (56.8%) a stable disease. The median duration of progression free survival and overall survival of all the enrolled patients were 189 days (95% CI:47–331) and 302 days (95% CI: 149–455), respectively. Grade 3/4 leucopenia, neutropenia and thrombocytopenia occurred in 20.3%, 27.9% and 28.5% of all the cycles, respectively. Grade 3/4 mucositis and nausea/vomiting were seen in 2.2% and 3.3%, respectively. No treatment related mortality was observed.
Conclusions: The regimen of gemcitabine, 5-FU and cisplatin has activity and good safety profiles for the treatment of advanced pancreatic cancer. A phase III study comparing with gemcitabine alone is warranted.

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Phase II study of gemcitabine as a fixed dose rate infusion and S-1 combination therapy (FGS) in gemcitabine-refractory pancreatic cancer patients

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Background: Gemcitabine (GEM) monotherapy or GEM-containing chemotherapy is the standard first-line therapy for advanced pancreatic cancer (PC), but there is no standard regimen for treatment after disease progression. In a previous phase II trial conducted on GEM-refractory PC patients S-1 was found to exhibit marginal efficacy, and the results showed a response rate of 15%, a median progression-free survival (PFS) of 2.0 months, and a median overall survival time (OS) of 4.5 months (Cancer Chemother Pharmacol. 2009; 63(2):313−9). GEM administration by fixed dose rate (FDR) infusion of 10 mg/m^2/min would maximize the intracellular rate of accumulation of GEM triphosphate and might improve clinical efficacy. A previous phase I trial determined the recommended dose of biweekly FDR-GEM and S-1 (FGS) in a phase II trial (C. Morizane et. al ECCO14, #3544). The present multicenter phase II study was conducted to confirm the efficacy and toxicity of FGS therapy in patients with GEM-refractory PC.
Materials and Methods: GEM-refractory patients with histologically or cytologically proven unresectable or metastatic PC were enrolled. GEM was given intravenously at a dose of 1200 mg/m^2 over 120 min on day 1, and S-1 was given orally at a dose of 40 mg/m^2 twice daily from day 1 to day 7, repeated every 2 weeks until disease progression. The primary end point of the study was objective response, and the secondary end points were toxicity, PFS, and OS.
Results: Forty patients from four institutions were enrolled between August 2006 and March 2009. A partial response has been confirmed in four patients (10%), and 22 patients (55%) have stable disease. Median OS and median PFS are 7.0 months and 2.3 months, respectively. Thirty-five patients are currently available for evaluation of toxicity in this ongoing trial. Grade 3 and 4 toxicities (%pts) have been fatigue (3%), rash (3%), and leukopenia (23%), neutropenia (34%), and anemia (3%).
Conclusion: The preliminary results have demonstrated safety and marginal activity of FGS therapy in GEM-refractory metastatic PC. The efficacy and toxicity analyses are ongoing. The final results will be presented at the meeting.

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Combination of gemcite & cisplatin chemotherapy in unresectables pancreatic cancer

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Background: Adenocarcinoma of the pancreatic accounts for approximately 2% of all malignant neoplasm. Though surgical resection is the treatment of choice, majority of the cases are unresectable. Different chemotherapeutic agents including 5Flurouracil, Mytomycin C, Cisplatin and Doxurobicin have been tried single or in combination. Partial response lasting from weeks to several months have been observed only in about 15%-20% of the cases and the median survival for patients with pancreatic cancer is approximately 4 months. Gemcitabine is a pyrimydine analogue of Deoxycytidine and has shown strong anti tumour activity in a variety of solid tumours. Cisplatin has synergistic activity with Gemcitabine. The aim of our study was to determine the response rate of Gemcitabine and Cisplatin combination in unresectable pancreatic cancer and to see the tolerability in Indian-Asian pollution.
Materials and Methods: During period from November 2004 to December 2008 we selected 102 consecutive patients with histologically proven unresectable measurable pancreatic cancer. The inclusion criteria were performance status more than 60% (Kornofsky) and normal liver (bilirubin <2) and kidney function (creatinine <2) function. All patient received Gemcitabine (1000 mg/m^2 intravenously over 30 minute) on day 1 and day 8 and Cisplatin total (100 mg/m^2 divided D1 to D3) every 21 days. Response assessment was done by CT scan after 3 cycles of chemotherapy. All 84 patients are eligible for efficacy and toxicity analysis.
Result: There were 17 (16.66%) complete responders, 37 (36.66%) partial responders, 27 (26.66%) with stable disease and 20 (20%) shows disease progression. The median time to progression was 22 weeks (range 12−30 weeks). The median duration of response was 15 weeks (range 5.6−60 weeks). The median over all survival was 22 weeks (range 11−32 weeks) with 1 year survival rate of 20%. WHO grade III or IV anaemia was seen in 19 (18.33%) patients. Fifteen (15%) patients experienced grade III or IV neutropenia while grade III or IV thompocytopenia was seen in 9 patients (8.33%).
Conclusion: The present study showed the Gemcitabin & Cisplatine combination was very useful in advanced unresectable pancreatic cancer. It was well tolerated by the patients.