calculated according to the Kaplan-Meier method, and the log-rank test was used to determine statistical differences between life tables, considering significant values of $p < 0.05$.

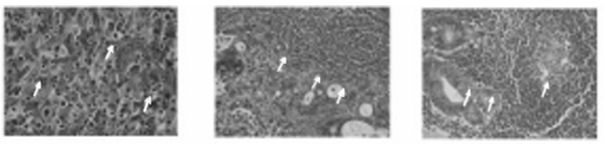

Fig. 1.

Results: Tumour associated mononuclear inflammatory cell, such as lymphocytes communicate with each other by extra cellular signals such as cytokines and their soluble receptors. Several cancer cell lines suggest that they are produced largely by tumour cell.
No statistically significant difference was observed in terms of age, sex, site of tumour, diameter, grading, CEA and Ca 19.9 levels, lymphatic and vascular invasion, classification (Lauren, Borrmann WHO).
The presence of IEL, PTL and CRL was showed in 26 patients (48.8%), 31 patients (56.8%) and 24 patients (43.2%) respectively.
Presence of IEL and CRL strong predicts a better disease free survival as shown in Figure 2. Patients with high levels of IEL and CRL demonstrate a lower rate of relapse ($p = 0.0003$ and $p = 0.005$ respectively). We did not found PLT and CRL in patients with relapse.

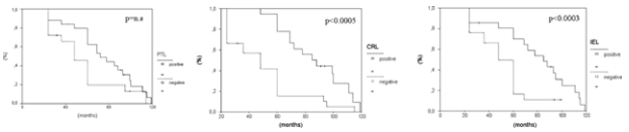

Fig. 2. Disease Free Survival

Conclusions: At present, there is no reason to expect a single predictive molecular factor to emerge that determines with high sensitivity and specificity that a patient is to expect disease recurrence or will profit from adjuvant therapy, respectively. But this preliminary study suggests that TILs may be useful as predictors of patient survival in surgically treated early stage gastric cancer.

767 POSTER

Targeting the tyrosine kinase platelet-derived growth factor beta-receptor (PDGFR-b) in advanced gastrointestinal malignancies-a phase I dose escalation study with imatinib in combination with 5-fluorouracil (5-FU) based chemotherapy

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Introduction: PDGFR-b is a mediator of tumor hypertension. Lowering of tumor interstitial hypertension has been shown to enhance tumor uptake of anticancer drugs. Imatinib, a specific inhibitor of the c-Kit, bcr-abl, and PDGFR gene products, enhanced the activity of 5-FU in animal models. This study was conducted to evaluate the feasibility, safety and efficacy of imatinib in combination with two different 5-FU based chemotherapeutic regimens in patients (pts) with advanced gastrointestinal malignancies.
Patients and methods: Pts were treated using a traditional 3-pts cohort dos-escalation strategy for defining the maximum tolerated dose (MTD) of imatinib in combination with chemotherapy, starting with 300 mg imatinib per day from day –4 to day 4 of chemotherapy with intravenous doses of 5-FU 2600 mg/m^2, leucovorin 200 mg/m^2 and oxaliplatin 85 mg/m^2 on day 1, qd15 (FLO, a modified FOLFOX-regimen) for 6 weeks (for gastric and colorectal cancer), or with 5-FU 2000 mg/m^2 and leucovorin 200 mg/m^2 on day 1 and 2, qd15 (FL) for 6 weeks (for pancreatic, cholangiocellular and gallbladder cancer). Prior to treatment, PDGFR-b and AKT in tumor and stroma were detected by immunohistochemistry. Imatinib pharmacokinetic assessments will be performed in pts receiving a dose of >500 mg/d or at the MTD.
Results: To date, 16 pts with previously treated gastrointestinal tumors were enrolled: 8 pts with pancreatic cancer, 5 pts with cholangiocellular cancer or cancer of biliary duct, 2 pts with colorectal cancer and 1 pt with gastric cancer. 6 pts were treated in the 300 mg cohort, 3 pts in the 400 mg cohort and 7 pts in the 500 mg cohort. All pts were evaluable for safety and 10/16 pts for efficacy. The treatment was generally well tolerated. NCI-CTC grade 3–4 toxicities were neutropenia (1/16), thrombocytopenia (1/16) and cardiac toxicity (1/16). Main grade 1–2 toxicities were anemia (9/16), neutropenia (5/16), nausea (5/16), constipation (5/16), and elevation of serum creatinine (5/16). Dose limiting toxicity occurred in 2 pt (NCI-CTC grade 4 neutropenia, mucositis, and infection in 1 pt in the 500 mg group, and grade 4 cardiac toxicity in the 300 mg group). 1 partial remission and 4 stable diseases of 10 evaluable pts were observed. The MTD has not been reached yet. Correlations to PDGFR-b expression and updated data will be presented at the meeting.
Conclusions: The combination of imatinib with oxaliplatin, 5-FU and leucovorin or 5-FU and leucovorin is feasible and safe.

Publication
GI – non-colorectal cancer

768 PUBLICATION

Oxaloplatin with biweekly, low dose leucovorin and bolus and continuous infusion 5-fluorouracil (modified FOLFOX 4) as salvage therapy for patients with advanced gastric cancer

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Background: To determine the activity and toxicities of low dose leucovorin (LV) plus fluorouracil (5-FU) regimen combined with oxaliplatin every two weeks (modified FOLFOX 4), as salvage therapy for patients with advanced gastric cancer.
Methods: Between December 2003 and December 2004, thirty-three patients were enrolled in this study. Patients were treated with oxaliplatin 85 mg/m^2 as a 2-hour infusion at days 1 plus LV 20 mg/m^2 over 10 minutes, followed by 5-FU bolus 400 mg/m^2 and 22 hour continuous infusion of 600 mg/m^2 at day 1–2. Treatment was repeated in 2 week intervals.
Results: The median age was 50 years (range: 31–74), 82% had a performance status of 0 or 1. Among 30 patients evaluable for tumor response, 8 patients achieved partial response, with an overall response rate of 26.7% (95% confidence interval (CI): 20.5–32.7%). Fifteen patients (50%) showed stable disease and seven patients (23.3%) progressed during the course of the treatment. The median time to progression was 3.5 months (95% CI: 2.6–4.4 months) and the median overall survival time was 7.9 months (95% CI: 5.9–9.9 months) from the start of the chemotherapy. Total 178 cycles analyzed for toxicity. Major grade 3/4 hematologic toxicities included neutropenia (48.4%) and thrombocytopenia (3.2%). There were only 2 cycles of neutropenic fever. The most common non-hematologic toxicities were grade 1–2 nausea/ vomiting (19.4%), diarrhea (12.9%) and neuropathy (12.9%). There was no treatment related deaths.
Conclusion: The modified FOLFOX 4 regimen is safe and effective regimen as salvage therapy in advanced gastric cancer patients.

769 PUBLICATION

Activity and tolerability of combination: capecitabine(c) plus gemcitabine(g) as first-line treatment in patients(pts) with locally advanced/metastatic pancreatic cancer

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The aim: of this study was to evaluate the efficacy and safety of C + G as first-line treatment in pts with locally advanced/metastatic pancreatic cancer.
Method: Eligible pts had measurable pancreatic cancer KPS $\geqslant$70% and adequate bone marrow, renal and hepatic function. Prior chemotherapy for pancreatic cancer and prior radiotherapy to the target lesion being measured in the study were not allowed. Pts received C 850 mg/m^2 orally twice daily on days 1–21 + G 1000 mg/m^2 by 30-infusion on days 1.8 and 15, every 4 weeks up to 6 cycles.
Results: Baseline characteristics of the 35 pts enrolled between march 2001 and February 2005: male/female (57% / 43%); mean age 57.5 + 8.2 years, liver metastases(49%). 32 pts are currently evaluable for safety and 30 for efficacy. The overall disease rate, 1-year progression-free survival and 1-year survival were 59% (9PR + 22SD), 57% and 58% respectively. Non-hematological adverse events (grade 2/3/4) were: vomiting (7/3/0%), nausea (8/3/0), anorexia (3/2/0%), hand–foot syndrome (6/0/0%), constipation (5/2/0%), general weakness (2/0/0%), insomnia (1/0/0%), and diarrhea (3/0/0%). Grade * neutropenia and grade3 thrombocytopenia occurred in 28% and 26% of pts, respectively.