and 64.05±10.90% respectively, p<0.05, Kaplan-Mayer's method) and in D2-D3 group compared with D1 group (97.50±2.47% and 85.87±3.65% respectively, p<0.01). Survival rate didn't depend on hystologic type of tumor. 5-year survival of mucosal cancer (Tis, T1m) was 92.47±2.97% and of submucosal cancer (T1sm) - 81.80±5.95% (p>0,05).

Conclusion: Reasons to extensive D2-D3 lymph node dissection for EGC are 1) the higher survival rate of patients in D2-D3 group with the absence of increasing postoperative mortality and morbidity; 2) difficulty in assessment the accuracy of modern technologies in diagnosing and staging of EGC. D2 resection is radical for the most EGC patients, but we propose more aggressive method, combined D2 resection with lymph node dissection node _12 group.

1164 POSTER

Docetaxel and 5-FU continuous infusion (DF) versus epirubicin, cisplatin and 5-FU (ECF) for advanced gastric adenocarcinoma; a randomized phase II study

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Purpose: Docetaxel shows promising activity as single agent against gastric cancer. To develop a combination chemotherapy (DF) for an ambulant setting we initiated this study. We used a randomized trial design comparing DF with ECF, one of the best investigated regimens, serving as an internal control arm to avoid selection bias. Eligibility: Metastatic or locally advanced gastric adenocarcinoma; PS 0-2; no prior chemotherapy. Methods: Patients (pts) are randomized to receive either ECF (Epirubicin 50mg/sqm d1, Cisplatin 60mg/sqm d1, 5-FU 200mg/sqm d1-21, q3w) or DF (Docetaxel 75mg/sqm d1, 5-FU 200mg/sqm d1-21, q3w).

Results: 55 pts are randomized so far. The study is ongoing. Baseline data is available of 48 pts: M/F 36/12; age 32-75 yrs (median 62); ECOG PS 0:18pts, 1:29pts, 2:1pt. 46pts are evaluable for toxicity: ECF 24pts, DF 22pts. Toxicity [%of pts, worst grade] ECF: Grade 1/2: nausea 71%, emesis 58%, asthenia 58%, diarrhoea 25%, stomatitis 33%, hand-foot 17%, paraesthesia 33%, neutropenia 13%, renal 8%. Grade 3/4: nausea 4%, emesis 4%, stomatitis 4%, hand-foot-syndrome 4%, neutropenia 54%, neutropenic fever 8%, non neutropenic fever 4%, renal toxicity 4%. 1 toxic death occurred in the ECF arm due to renal failure as part of a hepatorenal syndrome. DF: Grade 1/2: nausea 59%, emesis 27%, asthenia 73%, diarrhoea 45%, stomatitis 55%, hand-foot 36%, paraesthesia 36%, neutropenia 32%, renal 5%. Grade 3/4: asthenia 5%, diarrhoea 5%, stomatitis 5%, hand-foot-syndrome 5%, neutropenia 50%, no neutropenic fever, skin tox. 5%, cardiac tox. 5%, thrombosis 5%. 40 pts are evaluable for response (ECF 20 pts, DF 20 pts): ECF: CR 1/20, PR 9/20, NC 4/20, PD 6/20; DF: CR 2/20, PR 7/20, NC 4/20, PD 7/20. Tumor control rate (CR+PR+NC) is 70% for ECF and 65% for DF.

Conclusion: These preliminary results show that DF is a feasible combination which can safely be given in a fully ambulant setting. DF seems to be at least as tolerable as ECF and shows promising efficacy. The study is ongoing.

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Changes in circulating dendritic cells in metastatic or locally advanced pancreatic carcinoma patients during chemotherapy

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Purpose: Since dendritic cells (DC) are the most potent antigen-presenting cells required for the initiation and maintenance of an effective anti-tumor response, the present study was performed to explore the possible relationship between the efficacy of the chemotherapy and changes in circulating DC in metastatic or locally advanced pancreatic carcinoma patients (pts).

Methods: We studied 12 pts, 9 male and 3 female (age range 51-84); 5 of them underwent medical treatment with 5-FU continuous infusion for 6 weeks, Cisplatin weekly and Gemcitabine on days 1-8-28-35. Controls were programmed every two months. DC were generated by culturing peripheral blood adherent cells from pts and normal subjects in granulocyte-macrophage colony-stimulating factor (GM-CSF) and interleukin-4 (IL-4) for 7 days, and characterized by flow cytometric analysis, capacity to release IL-12, and ability to stimulate eterologous T-cell proliferation and IFN-gamma production.

Results: DC from pts exhibited high levels of CD14 and lower levels of CD1a and CD40 expression as compared with those from healthy volunteers (p=0.02). CD40L-induced IL-12 p40 production of DC was generally increased in pts compared with controls (p=0.02), while bioactive IL-12 p70 was decreased (p=0.04). The T-cell stimulatory activity of DC was lower in pts than in controls (p=0.01), as well as the IFN-gamma production by T cells (p=0.04). After 2-4 months from chemotherapy, a slight increase in CD1a positive DC were found, together with an increase in IL-12 p70 (p=0.04) and a decrease in IL-12 p40 (p=0.02) production in response to CD40-L. In 50% of treated pts, DC increased their ability to induce IFN-gamma by T cells. However, in general, no significant changes in T cell stimulatory activity was observed.

Conclusion: These preliminary results suggest that DC from metastatic or locally advanced pancreatic carcinoma pts are functionally defective and that chemotherapy seem to be effective in modulating their biological activity.

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A phase II study of weekly docetaxel and concurrent radiation in patients (pts) with unresectable esophageal cancer

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Background: The prognosis of patients (pts) with unresectable esophageal cancer treated with radiotherapy alone is poor, with a 2-year survival of only 10%. In contrast, concurrent chemoradiotherapy with cisplatin and fluorouracil regimens is superior to irradiation alone, but this combination is associated with substantial toxicity (Herskovic, 1992). Docetaxel has demonstrated a high radiosensitizing potential in preclinical studies (Mason, 1997). Likewise, weekly docetaxel 20 mg/m2 with concomitant radiotherapy is feasible and active in esophageal cancer (Mauer, 1998). The present study was designed to determine the response and toxicity of weekly docetaxel plus concomitant radiotherapy in pts with unresectable esophageal cancer.

Patients and Methods: Since November 1998, 18 pts with locoregionally advanced esophageal cancer have been treated with weekly docetaxel (20 mg/m2 as 1 hour IV infusion) plus concomitant standard radiotherapy to a total dose of 66 Gy. Patient characteristics: 17 (94%) male; median age, 64 years (range 41-88); median Karnofsky index, 80% (range 70-100%); 14 (77%) squamous cell carcinoma. At diagnosis, pts were considered unresectable due to involvement of tracheobronchial tree in 6 pts (33%), age older than 75 years in 3 pts (16%), distant lymph node metastases in 2 pts (10%) and medically unfit for surgical therapy in 7 pts (39%).

Results: To date, 15 pts have completed therapy. Major responses were seen in 6 pts (40%) including 4 complete responses (27%) and 2 partial responses (13%). No patients progressed during the therapy. Median survival duration is 10 months, and the 1-year is 57%. Hospitalization for toxicity was required in 7 pts (46%), the majority for esophagitis, but significant myelosuppression was not observed. There was one death during the treatment.

Conclusions: This study confirms the feasibility of weekly docetaxel with concurrent radiotherapy in pts with unresectable esophageal cancer. The 1-year survival achieved in this group of patients is promising. Further patient accrual is planned to confirm these results.

1167 POSTER

Gemcitabine (GEM) and capecitabine (CAP) for advanced pancreatic cancer. A phase I/II trial

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Purpose: GEM is presently the standard agent for the treatment of advanced pancreatic cancer. Preclinical studies suggest positive interactions between GEM and CAP, an oral 5-fluorouracil prodrug. In this study we in-