

(MTD)/recommended Phase II dose (RD) and DLTs. Secondary end points included determination of preliminary radiographic response rates.

**Results:** 3 patients were enrolled at the following dose levels of pemetrexed: 500 mg/m<sup>2</sup> (Level 1), 400 mg/m<sup>2</sup> (Level 0), respectively. All of the IMRT plans met the optimization criteria. At dose level 1, DLTs (grade 3 neutropenia/esophagitis/vomiting) occurred in two of three patients. However, none of the patients entered into Level 0 developed DLT. The preliminary radiographic response rates were evaluated. The complete response (CR) and partial response (PR) were observed in 5 and 1 patients, respectively. Furthermore, no patient experienced cancer progression with a median follow-up of 7 months (range 1.5–11 months).

**Conclusions:** The concurrent selective lymph node LCAF IMRT and chemotherapy is feasible. DLT was mainly observed at Level 1 (pemetrexed 500 mg/m<sup>2</sup>). The MTD of pemetrexed in this regimen was 500 mg/m<sup>2</sup> once every 21 days for two cycles and RD for phase II trial was 400 mg/m<sup>2</sup>. Although the toxicities were common, the protocol was safe and well-tolerated, as well as achieving an encouraging outcome for locally advanced SCC of esophagus.

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POSTER

# **Modified left side mobilization of stomach during extended-combined gastrectomy**

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**Background:** To evaluate the effectiveness of combined resection of the involved organs with regard to survival in patients with locally advanced gastric cancer.

**Material and Methods:** We developed and offered the left side mobilization (LSM) and lymph dissection during total gastrectomy due to gastric cancer with germination to the pancreas. The essence of the offered way consists that process extended-combined gastrectomy begins with LSM of the stomach. 87 patients randomized from 2000 to 2006. In the 1st group 45 patients were undergone to the gastrectomy with LSM. In the 2nd group 42 patients were undergone to the total gastrectomy with traditional mobilization. In 12 (26.6%) patients of the 1st group and in 11 (26.2%) patients of the 2nd group the operation were combined with splenectomy and resection of pancreas tail, in 7 (15.5%) cases of the 1st group and in 5 (11.9%) cases of the 2nd group there were performed hemipancreatectomy. In 12 (26.6%) cases of the 1st group and 13 (30.9%) cases of the 2nd group there were performed superficial resection of the body and head of pancreas.

**Results:** Postoperative complications developed in 8 (17.8%) patients of the 1st group and in 8 (19%) patients of 2nd group. Unsuppurative pleuritis in 2, after operation pancreatitis in 2 in both groups, pancreatic fistula in 1 of the 1st group and in 2 of the 2nd group, pancreonecrosis in 1 patient of the 2nd group, inconsistency esophago-intestinal anastomosis in 1 patient in both groups, thromboembolia of pulmonary artery in 1 of the main group and cardiac-pulmonary insufficiency in 1 of the main group. Though postoperative complications turned out to be alike in both groups, LSM have some advantages. 1) LSM more suitable for estimation the process invasion to pancreas and for making the identical volume of resection. 2) Volume of blood lost turned out to be at the average less on +100 ml under LSM in comparison with usual way of mobilization. 3) Time of operations was abbreviated on 20 minutes under LSM in comparison with usual way of mobilization. 4) R0-resections were achieved in 42 (93.3%) cases in the 1st group and in 33 (78.5%) cases in the 2nd group.

**Conclusion:** LSM and lymph dissection shortens the time of operation and blood lost. Meanwhile method is enough suitable and less traumatic. Curative (R0) resection improves prognosis and even long-term survival can be achieved in selected individual cases.

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POSTER

# **Prospective study of docetaxel in combination with cisplatin and an oral fluoropyrimidine in patients with gastric and esophagogastric junction adenocarcinoma**

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**Background:** Docetaxel in combination with cisplatin and 5-FU is an approved regimen for the treatment of advanced gastroesophageal cancer (AEGC) in patients who have not received prior chemotherapy for advanced disease. It is based on the results of a randomized multinational phase III study (TAX-325). Two phase III trials (REAL-2 and ML17032) have

evaluated capecitabine in combination with other agents in patients with AEGC with positive results in comparison to 5-FU. Based on these results, we designed a prospective study to evaluate the efficacy and safety of an oral fluoropyrimidine (capecitabine or tegafur) in combination with docetaxel and cisplatin as the first-line treatment in consecutive patients with AEGC.

**Material and Methods:** Patients with histologically confirmed adenocarcinoma or undifferentiated carcinoma of the gastroesophageal junction or stomach with no prior treatment (except in adjuvant setting) were included. Normal hepatic, renal and haematological parameters were required. Each cycle of treatment lasted 21 days, consisting of docetaxel 75 mg/m<sup>2</sup> day 1, cisplatin 60 mg/m<sup>2</sup> day 1 and an oral fluoropyrimidine on days 2–15 (either capecitabine 825 mg/m<sup>2</sup> bid or tegafur 500 mg/m<sup>2</sup> bid and continuous levofofolic acid 25 mg/m<sup>2</sup>). Patients were assessed for response by RECIST criteria every 3 cycles and treatment was maintained until progression or unacceptable toxicity. Dose adjustments were made according to the CTCAE v3.0.

**Results:** 46 patients, 34 men with median age 64 years (31–78), were included from 2003 to 2008. Thirty-one patients were assessable for efficacy and 41 for toxicity. Forty-five patients had metastatic disease (40% liver, 32% peritoneal, 35% ganglionic). Seventy-five percent received 6 cycles, with a mean of 4.5 cycles per patient. Dose reductions were required in 21% and 36% needed G-CSF support. Grade 3–4 adverse events included neutropenia (26%), asthenia (17%), diarrhoea (8%) and nausea/vomiting, stomatitis and hand-foot syndrome (6%). ORR was 61% (7 complete responses, 12 partial responses). PFS was 5.2 months (0.1–14.6) and median OS was 10.0 months (0.2–41). A non-statistically significant trend to a better OS and PFS was found in patients treated with capecitabine versus tegafur.

**Conclusions:** The efficacy results and toxicity profile of the combination of docetaxel, cisplatin and an oral fluoropyrimidine in the first-line treatment of AEGC are comparable to previous trials using 5-fluorouracil. Oral fluoropyrimidines provide convenience to patients who can swallow with a similar toxicity profile to 5-FU. The combination with capecitabine has a trend to a better OS and PFS than tegafur.

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POSTER

# **A retrospective study of first-line platinum-based combination chemotherapy in patients with recurrent and advanced gastric cancer**

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**Background:** Cisplatin-based chemotherapy, in combination with fluoropyrimidines or taxanes, have demonstrated efficacy against advanced gastric cancer (AGC). This retrospective study was performed with the data obtained from our cancer chemotherapy registry.

**Methods:** In 2008, a total of 252 AGC patients were treated with cisplatin-based doublet chemotherapy in the first-line setting: capecitabine plus cisplatin (XP, n=78), S-1 plus cisplatin (SP, n=76), docetaxel plus cisplatin (DP, n=67), and 5-fluorouracil plus platinum (FP, n=31). The primary endpoints were response rate and progression-free survival (PFS).

**Results:** Median follow up duration was 4.8 months (95% CI, 5.1–6.0) and median delivered number of chemotherapy cycles were XP: 4 (95% CI, 3.6–4.6), SP: 5 (95% CI, 3.9–5.2), DP: 5 (95% CI, 4.0–5.2) and FP: 3 (95% CI, 3.9–6.9), respectively. Objective tumor responses were achieved in 60.5%, 39.5%, 37.3% and 22.6% patients who were treated with XP, SP, DP and FP. Median PFS was 5.1 months (95% CI: 3.6–6.7) for XP, 5.7 months (95% CI, 3.0–8.4) for SP, 3.9 months (95% CI, 3.3–4.5) for DP, and 2.8 months (95% CI, 0.5–5.2) for FP.

**Conclusion:** All of the cisplatin-based doublet chemotherapy regimens appear to be active as first-line chemotherapy for AGC.

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POSTER

# **Cyfra21-1 and CEA are useful markers for predicting the sensitivity to chemoradiotherapy of esophageal carcinoma**

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**Background:** Esophageal cancer is a common malignant neoplasm throughout the world. The common practice is esophagectomy for surgically resectable tumors and chemoradiotherapy (CRT) for locally advanced, unresectable tumors. Sensitivity of tumors to CRT differs from one case to another and may be influenced by the expression of biological molecules. Some reports have revealed that patients who responded well to CRT had favorable outcomes while poor responders conversely showed a worse

prognosis. If factors that allow prediction of the effect of CRT are found, a more effective therapeutic strategy can be designed. The aim of this study was to identify biological markers predicting sensitivity to CRT of esophageal carcinoma.

**Methods:** 91 patients with esophageal carcinoma treated with CRT were enrolled. The regimen comprised protracted 5-fluorouracil infusion and a two-hour infusion of cisplatin combined with radiotherapy which 59.6 Gy was administered using conformal radiotherapy or intensity modulated radiotherapy from a 15-MV linear accelerator in 34 fractions. The concentration of serum tumor markers cytokeratin 19 fragment antigen 21-1, carcino-embryonic antigen, neuron-specific enolase were measured in venous blood obtained before treatment from 91 patients. The cut-off value of CYFRA21-1, CEA and NSE was defined as 3.4 ng/ml, 3.3 ng/ml and 17 ng/ml respectively. The response to CRT was evaluated by WHO criteria in solid tumors.

**Results:** The complete response rate of the primary tumor estimated by CT was 16.2% (6/37) in patients with CYFRA21-1 positive group, 15.38% (4/26) in patients with CEA positive group, and 16.6% (3/18) in the NSE positive group. The complete response (CR) rate between CYFRA21-1 and CEA positive and negative groups were significantly different ( $P=0.001$ ,  $0.002$  respectively). However, NSE did not show a significant correlation with the response of the primary lesion to CRT ( $P=0.306$ ).

**Conclusion:** CYFRA21-1 and CEA may be helpful in predicting the chemoradiosensitivity to CRT of esophageal carcinoma, although the results should be confirmed in larger, more homogeneous studies.

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POSTER

**A phase II study of biweekly chemotherapy with irinotecan, 5-fluorouracil, and leucovorin (FOLFIRI) in patients with advanced gastric cancer after failure of prior chemotherapy including taxane, fluoropyrimidine, and platinum**

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**Background:** Irinotecan is one of the chemotherapeutic agents proven active in advanced gastric cancer (AGC) and also suggested synergistic with 5-fluorouracil (5-FU) in preclinical studies. We performed this study to evaluate the efficacy and toxicities of a combination of irinotecan, 5-FU, and leucovorin (LV) continuous infusion regimen (FOLFIRI) as a salvage treatment in patients with AGC after failure of prior chemotherapy including taxane, fluoropyrimidine, and platinum.

**Materials and Methods:** A total of 43 patients were enrolled in this study between October 2004 and April 2008. Treatment comprised irinotecan (150 mg/m<sup>2</sup> on day 1) as 2-hour infusion followed by LV 100 mg/m<sup>2</sup>, and 400 mg/m<sup>2</sup> of bolus plus 2400 mg/m<sup>2</sup> of continuous infusion of 5-FU over 46 hours. Cycles were repeated every 2 weeks.

**Results:** Among a total of 43 patients, 8 (18.6%; 95%CI, 6-31%) achieved partial response, and 18 (41.9%) showed stable disease. With a median follow-up of 11.9 months (range, 7-20.4 months) in surviving patients, the median progression free survival (PFS) was 4.5 months (95%CI, 3.1-5.9 months) and the median overall survival (OS) was 10.3 months (95%CI, 8.5-12.1 months). The major factor determining PFS and OS by FOLFIRI was time to progression after previous chemotherapy (TTP). The median PFS was 2.4 months (TTP <2 months) vs. 7.0 months (TTP ≥2 months,  $P=0.001$ ). The median OS was 8.6 months (TTP <2 months) vs. 18.5 months (TTP ≥2 months,  $P=0.002$ ). Grade 3/4 neutropenia was observed in 61.3%, however, neutropenic fever was rare (4.5%). Grade 3/4 nonhaematologic toxicities were asthenia (9.1%), anorexia (6.8%), nausea (4.5%), and vomiting (4.5%). There was no related mortality.

**Conclusions:** FOLFIRI was active and tolerable as a salvage regimen after failure of previous chemotherapy with taxane, fluoropyrimidines, and platinum.

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POSTER

**Feasibility of adjuvant S-1 plus docetaxel against stage II-III gastric cancer following R0 resection in gastrectomy**

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**Background:** The present standard treatment in Japan for patients (pts) with stage II-III gastric cancer (GC) following R0 gastrectomy is adjuvant S-1 chemotherapy. In advanced GC pts, several studies of S-1 plus docetaxel have shown a good response rate with a longer median overall survival (OS). Here, we evaluated the feasibility and safety of adjuvant S-1 plus docetaxel for stage III GC pts following R0 resection.

**Materials and Methods:** This study was conducted by two stage design (UMIN000000857; 2007/10/19). Patients were administered S-1 (80 mg/m<sup>2</sup>/day) orally for 2 consecutive weeks plus docetaxel (40 mg/m<sup>2</sup> as the first stage or 30 mg/m<sup>2</sup> as the second stage) intravenously on day 1, and repeated every 3 weeks. Treatment was repeated for 4 cycles followed by S-1 monotherapy until 1 year after gastrectomy. Feasibility in the first ten patients was evaluated at the end of 2 cycles. Total 20 patients could be enrolled, if the treatment completion could be performed in more than 60% (6/10) of patients. Study would go forward the second stage, if that could be seen in less than 50% (5/10) of those. The patient inclusion criteria were as follows: with curatively resected pathological stage II-III GC receiving D2 dissection; age, 20-80 years; performance status ≤1; no previous adjuvant treatment; adequate organ function; provided informed consent. The study endpoints were as follows; primary endpoint: feasibility of the 4 cycles of S-1 plus docetaxel; secondary endpoints: safety, progression-free survival, and OS.

**Results:** Between 6/2007 and 4/2008, 23 pts (16 males and 7 females; median age, 62 years) were enrolled. Pathological stages included Stage II (n=9), IIIA (n=9), IIIB (n=4), and IV (n=1). This study was finished in the first stage with a feasibility of more than 60% of first ten patients at 2 cycles. Of 22 pts, 15 were administered the planned 4 treatment cycles, with a feasibility of 68.2%. Reasons for discontinuation were recurrent cancer (n=0) and adverse events (n=7). Of the 22 pts, 2 (9%) developed grade 3/4 neutropenia, but there was no grade 3 febrile neutropenia. Grade 3 or higher non-hematological toxicities included diarrhea (9%), anorexia (5%), nausea (5%), syndrome of inappropriate antidiuretic hormone (5%), and hand-foot syndrome (5%). Treatment-related deaths did not occur.

**Conclusions:** Adjuvant S-1 plus docetaxel showed a good profile of adverse events and was well tolerated. This regimen shows great potential for future phase III trials for identifying the best adjuvant chemotherapy for advanced GC pts following R0 resection in gastrectomy.

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POSTER

**Blood group A and risk of gastric cancer in Colombia**

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**Background:** There is possibility of increased risk among group blood A and gastric cancer. Our objective was to detect association between blood group A and gastric cancer

**Materials and Methods:** Design: Case-control study. Place: Oncology Unit, Universidad Industrial de Santander UIS, Colombia.

Fulfilled criteria for inclusion 153/278 medical records with histopathological diagnosis of gastric cancer who sought medical since January 2001 to December 2005. The controls were inpatients in Internal Medicine for medical reasons other than gastric with normal upper gastrointestinal endoscopy. Data were obtained through systematic review of medical records and telephone contact. Data were processed in software stata 9.0.

**Results:** The prevalence of blood groups among 153 patients 56.74% for group O, 32.17% for group A, 10.22% for group B, and 0.87% for group AB. We found statistically significant association between gastric cancer and blood group A, OR=2.22 (95% CI: 1.38-3.57); was also associate, gastric cancer with the presence of first-degree relatives with no gastric cancer OR=1.91 (95% CI: 1.05-3.46). The logistic regression analysis showed aged <50 aged years old as a protective factor OR=0.44 (95% CI: 0.26-0.77). There was no association between eating habits and consumption of fruits, cereals, vegetables, coffee, arepa santandereana