is an active and attractive regimen for gastric cancer but with significant hematological toxicities. A multicenter phase II study was designed to establish an active regimen with good tolerability by using weekly docetaxel-oxaliplatin (DO) combination in GC patients.
Materials and Methods: Eligible patients had histologically confirmed stage IV gastric cancer without previous palliative chemotherapy; age $\geqslant$18, ECOG performance status $\leqslant$2, at least one measurable lesion, adequate hematologic, renal and liver functions. All patients received premedications with dexamethasone and 5-HT3 antagonist before chemothearpy. Docetaxel (Taxotere®, sanofi-aventis) 30 mg/m^2 followed by oxaliplatin (Eloxatin®, sanofi-aventis) 65 mg/m^2 were administrated on day 1 and 8 of each 21-day cycle. Treatment continued until disease progression, intolerable toxicity, or consent withdrawal. Toxicities were graded by CTCAE version 3.0. Tumor responses were evaluated every 2 cycles by RECIST criteria.
Results: From May 2007 to December 2008, a total of 47 patients were enrolled. There were 8 females and 39 males with a median age of 57 years old (range 26−76). Forty-three patients were evaluated for response. The complete response was 2 (4.7%), partial response rate was 12 (27.9%), stable disease was 20 (46.5%), and progression disease was 9 (20.9%), respectively. The total response rate was 32.6% (95%CI 19.1−48.5%). The median time to disease progression was 4.2 months and the median time of overall survival was 7 months. All 47 patients were assessable for toxicity. A total of 202 cycles were given in 47 patients with a median cycle of 4 (1−10). Major grade 3/4 hematologic toxicities were anemia (5 patients, 10.6%), leukopenia (2patients, 4.3%), and neutropenia (1 patient, 2.1%). The most common grade 3/4 non-hemtaologic toxicities were fatigue (3 patients, 6.4%) and AST elevation in 3 patients (6.4%).
Conclusions: The combination of weekly DO demonstrated a well tolerable profile with moderate activity in the treatment of advance gastric cancer.

6550 POSTER

Adjuvant chemoradiation in stage III-IV radically resected gastric cancer patients: a pilot study

M. Orditura[1], E. Martinelli[1], F. De Vita[1], G. Galizia[1], P. Muto[2], F. Vitiello[1], A. Romano[1], T. Troiani[1], F. Morgillo[1], F. Ciardiello[1]. *[1]II Policlinico- Second University of Naples, Dipartimento di Medicina Clinico- Sperimentale "F. Magrassi e A. Lanzara", Naples, Italy; [2]Second University of Naples, Radiotherapy Division, Naples, Italy*

Objective: Adjuvant chemoradiation (CT-RT) in resected high-risk gastric cancer patients does not represent the standard care but the results from phase II and randomized trials suggest an improvement of overall survival. This study was aimed to determinate feasibility and toxicity of CT (FOLFOX-4) and RT combination as adjuvant treatment in locally advanced gastric cancer.
Patients: Twenty-nine patients (male 24, female 5, median age of 57 year; PS ECOG 0 for 23 patients, PS ECOG 1 for 6 patients) with T_4N_+ or any T N_{2-3} gastric cancer, previously treated with potentially curative surgery were enrolled. All patients received a combined scheme of adjuvant chemotherapy with FOLFOX-4 (Oxaliplatin 85 mg/mq d1, 5-FU 400 mg/mq bolus ev d1−2 and CI 1200 mg/mq ev over 48 hours, Lederfolin 200 mg/mq ev d1−2 every 2 weeks) for a total of 8 cycles, and concomitant RT for a total 45 Gy in 25 daily fractions over 5 weeks. Radiation therapy started after the first 2 cycles of FOLFOX4, with a dose reduction of 80% during the all period of concomitant radiation therapy. Treatment toxicity was assessed according to the NCT-CTC classification. Overall (OS) and progression-free (PFS) survival rates; identification of prognostic indicators of outcome.
Results: All patients completed treatment. Severe hematological and gastrointestinal toxicities were 10% and 33%, respectively. Nor acute hepatic neither renal toxicity was observed; one patient experienced grade 3 neurotoxicity. PFS and OS rates at 1, 2 and 3-year were 79%, 35%, 35%, and 85%, 62.6%, 50.1%, respectively; substantially better than percentages observed in untreated patients. Long-term outcome was related to TNM stage, basal serum tumour marker levels, and, particularly, to the lymph node ratio.
Conclusions: The multimodal approach with FOLFOX4 and radiation is feasible and active for the treatment of high-risk resected gastric cancer patients.

6551 POSTER

Toxicity of neoadjuvant intraperitoneal and systemic chemotherapy in gastric cancer with peritoneal dissemination

A. Muñoz Martín[1], P. García Alfonso[1], V. Martínez Marín[1], L. Gonzalez Bayon[2], S. Gonzalez Moreno[3], J. Torres Melero[4], P. Reche[5], Y. Jerez Gilarranz[1], L. Cabezon Gutierrez[1], R. Gonzalez del Val Subirats[1]. *[1]Hospital General Gregorio Maranon, Medical Oncology, Madrid, Spain; [2]Hospital General Gregorio Maranon, General Surgery, Madrid, Spain; [3]MD Anderson Madrid, General Surgery, Madrid, Spain; [4]Hospital Torrecardenas, General Surgery, Almeria, Spain; [5]Hospital Torrecardenas, Medical Oncology, Almeria, Spain*

Background: Neoadjuvant intraperitoneal and systemic chemotherapy (NIPS) is a new treatment modality in gastric cancer with peritoneal seeding. It was developed to increase the rate of complete cytoreduction of peritoneal carcinomatosis. In 2006 Yonemura et al [1] published the results of a phase II clinical trial with NIPS and cytoreductive surgery with an increase in overall survival in patients who achieved a complete resection compares to historical controls and with an acceptable toxicity. We report the toxicity of the first experience in Spain with NIPS in gastric cancer with peritoneal carcinomatosis.
Materials and Methods: Chemotherapy was delivered through an implantable peritoneal catheter. All patients received the following treatment: docetaxel 40 mg intraperitoneal (ip) and carboplatin 150 mg ip in 30 minutes infusion and methotrexate 100 mg/m^2 intravenous (iv) and 5-fluorouracil 600 mg/m^2 iv both in bolus the same day on a weekly basis. Eleven patients have been enrolled in this protocol in three different spanish centers in a compassionate use program. Five patients received 6 doses, 2 patients 5 doses, 2 patients 4 doses and 2 patients 3 doses. Male/female: 63% vs 37%. Median age: 50.2 years.
Results: The most common adverse event was diarrhoea (81% overall and grade [gr] 3−4 18.2%). Febrile neutropenia gr 3−4 18.2% and thrombocytopenia gr 3−4 9%. No primary prophylaxis with G-CSF was used. Abdominal pain gr 3−4 9% and asthenia gr 3−4 9%. No other gr 3 or 4 toxicities have been described. No treatment-related deaths. One patient discontinued chemotherapy due to toxicity (febrile neutropenia and diarrhoea). There were no complications due to the peritoneal catheter. Late and unexpected toxicities have not been observed.
Conclusions: The first results suggest this regimen is feasible and safe. A longer follow up is needed to define the morbidity and mortality associated to surgery after NIPS. Data from phase III clinical trials are essential to confirm these results and define the optimal use of NIPS.

References

[1] * Yonemura Y, Banou E, Sawa T et al. Neoadjuvant treatment of gastric cancer with peritoneal dissemination. Eur J Surg Oncol. 2006 Aug;32(6):661−5.

6552 POSTER

Phase II study of weekly paclitaxel as thirrd line chemotherapy for advanced or recurrent gastric cancer (Osaka Gastrointestinal Cancer Chemotherapy Study Group: OGSG0602)

M. Yoshida[1], T. Sato[2], H. Takiuchi[1], M. Gotoh[1], S. Iijima[3], S. Nakae[4], T. Shimokawa[5], Y. Kurokawa[6], A. Hotta[5], H. Furukawa[7]. *[1]Osaka Medical College, Cancer Chemotherapy Center, Takatsuki, Japan; [2]Kinki Univesity School, Medical Oncology, Sayama, Japan; [3]Mono City Hospital, Gastrointestinal Center, Mino, Japan; [4]Nakatsu Saiseikai Hospital, Surgery, Mino, Japan; [5]OGSG, Data center, Osaka, Japan; [6]Osaka National Hospital, Surgery, Osaka, Japan; [7]Sakai Municipal Hospital, Surgery, Sakai, Japan*

Background: The median survival time was longer than 1 year in randomized phase III studies for advanced or recurrent gastric cancer (GC) recently conducted in Japan. Although progression free survival of first-line chemotherapy has improved, many patients receive for second-line or later therapies with new agents such as paclitaxel or docetaxel after first-line treatment. It may contribute greatly to prolong overall survival. This study evaluated the efficacy and safety of weekly paclitaxel as thirrd line chemotherapy in patients with advanced or recurrent GC.
Material and Methods: The criteria for eligibility were histologically proven advanced or recurrent GC, had given with prior two regimens including S-1 and irinotecan, age $\geqslant$20, performance status (PS) 0−2, adequate organ function, and informed consent received paclitaxel 80 mg/m^2 on day 1, 8 and 15 of a cycle for 4 weeks until progression. Primary endpoint is feasibility and secondary endpoints are safety, overall survival, progression free survival (PFS), time to treatment failure (TTF) and relative dose intensity in this study.

Results: A total of 22 patients, 18 males and 4 females with a median age of 60 years old (54−82), 2/19/1 in PS 0/1/2 were enrolled between Dec. 2006 and Sep. 2008. All patients had received first line chemotherapy including S-1 and second line including irinotecan. Patients received median of 4 (range 1−12) cycles of treatment. Reasons for discontinuation were progression in 18 and withdrawal in 4. Grade 3 adversed events included neutropenia in 3 (14%), anemia in 1 (4%), appetite loss in 1 (4%). Overall response rate was 14%, disease control (PR+SD) rate was 77%, median TTF was 79 days, median PFS was 78 days, median overall survival don't reach.
Conclusions: A weekly regimen of paclitaxel was well tolerated and achieved a good disease control rate, and acceptable TTF relatively for advanced or recurrent GC. Although follow-up is ongoing on survival.

6553 POSTER

Neoadjuvant chemotherapy followed by transthoracic resection for locally advanced carcinoma of the esophagus: a randomized study

V. Bokhyan[1], I. Stilidi[1], O. Malikhova[2], A. Tryakin[3]. *[1]N. N. Blokhin Russian Cancer Research Center, Surgical Department of Thoracoabdominal Oncology, Moscow, Russian Federation; [2]N. N. Blokhin Russian Cancer Research Center, Endoscopy, Moscow, Russian Federation; [3]N. N. Blokhin Russian Cancer Research Center, Clinical Pharmacology and Chemotherapy, Moscow, Russian Federation*

Background: A prospective trial was undertaken to investigate whether the chemotherapy followed by surgery results in increase of overall survival in patients with resectable thoracic esophageal cancer.
Material and Methods: 90 previously untreated patients with stage $T_{3-4}N_{0-1}M_0$, $T_{1-2}N_1M_0$ resectable esophageal cancer admitted to our center between March 2001 and December 2006. Patients were allocated either to two 3-day cycles of FLEP consisting of cisplatin 80–100 mg/m^2, day 1; etoposide 100 mg/m^2, leukovorine 20 mg/m^2 and 5-fluorouracil 500 mg/m^2, days 1−3; 21 days apart, followed by surgical resection (Ch-S group, n = 45), or resection alone (S group, n = 45). Patients' characteristics (tumor stage and histology, coexisting disorders, demographic data) were well balanced between the two treatment groups. Chemotherapy was completed in 42 patients. Four weeks after completion of chemotherapy or admission, patients were operated on. Transthoracic extended 2 or 3-field esophagectomy with intrapleural esophago-gastrostomy through I. Lewis approach was performed in 44 patients of Ch-S group and in all cases of S group.
Results: All patients but one had squamous cell cancer, one had adenocarcinoma. Complete response was observed in 4 patients (8.8%), partial response in 27 (60%), progression of disease in 3 patients (6.7%), and no change in 11 patient (24.5%) of Ch-S group. Eight patients had grade 3−4 neutropenia. There were no other serious manifestations of toxicity and no preoperative toxic deaths.
Resections were R0 in 39 patients in Ch-S group and 28 in S group (p = 0.06). Postoperative complications were reported in 53.3% Ch-S and 48.9% S patients (p = 0.7). Overall 3-year and 5-year survival rates were 39.8% and 28.5% in the S group; 62.9% and 40.4% in the Ch-S group (p = 0.08). 5-year disease-free survival benefit achieved statistical significance: 17.6% versus 32.7% (p = 0.04).
Conclusion: Two cycles of preoperative chemotherapy with 5-fluorouracil, cisplatin, leucovorin and etoposide followed by extended esophagectomy improve disease free survival of patients with resectable thoracic esophageal cancer.

6554 POSTER

High-dose versus standard-dose radiation therapy in combined modality therapy for esophageal cancer

C. Lee[1], Y. Suh[1], I. Lee[1], S. Yoo[1], J. Cha[1], H. Yoon[1], K. Keum[1], J. Seong[1], C. Suh[1], G. Kim[1]. *[1]Yonsei Medical Center, Radiation Oncology, Seoul, South Korea*

Background: To compare the survival, local control, and toxicity of combined-modality therapy using high-dose (63 Gy) versus standard-dose (54 Gy) radiation therapy for the treatment of patients with esophageal cancer.
Materials and Methods: From January 1996 to July 2007, a total of 207 patients treated with concurrent chemoradiotherapy were analyzed. Of the 207 patients, 65 received $\leqslant$54 Gy (standard dose group) and 142 received $\geqslant$59.4 Gy (high dose group). The median doses in the standard and high dose groups were 54 Gy (range, 45−54 Gy) and 63 Gy (range, 59.4−70 Gy), respectively. The superior and inferior borders of the initial radiation field were 5 cm beyond the primary tumor. The superior and inferior borders of the boost field were decreased to 2 cm beyond the tumor. The median dose to the initial field was 36 Gy (range, 30.6−41.4 Gy) for both groups. Cisplatin and 5-fluorouracil were administrated to 85% of the patients, and the other patients received 5-fluorouracil mono-chemotherapy.
Results: There were no significant differences in patients' age, sex, pathology, and histological grade between the two groups. But Stage I-II patients were significantly higher in standard dose group (41% versus 19%). The median disease progression free survival and overall survival in all patients were 13 months and 24 months, and no significant differences were found between the two groups. But complete responses were higher in the high dose group (68% versus 33%, p = 0.04). Two-year local control rate was significantly higher in high dose group (75% vs. 64%, p = 0.05). No significant treatment related late toxicities were observed in both groups.
Conclusion: High dose group showed comparable survivals and higher complete response rate and local control rate without increasing toxicity compared to standard dose group while patients with advanced stage were higher in the high dose group.

6555 POSTER

Outcomes of advanced gastric cancer in younger patients aged 45 years or less treated with first-line combination chemotherapy

K. Kim[1], S.H. Park[2], J. Lee[2], J.O. Park[2], Y.S. Park[2], H.Y. Lim[2], W.K. Kang[2]. *[1]Soonchunhyang University, Internal Medicine, Seoul, South Korea; [2]Samsung Medical Center, Medicine, Seoul, South Korea*

Background: The current study was performed to determine whether younger age is an independent prognostic factor among AGC patients receiving first-line chemotherapy and to evaluate how age relates to other known prognostic parameters.
Methods: The records of 1843 AGC patients who were consecutively treated with first-line combination chemotherapy at Samsung Medical Center (Seoul, Korea) between 2000 and 2007, including 570 patients aged 45 years or younger, were retrieved from a prospective cancer chemotherapy database.
Results: In the younger group, there were significantly more bone metastases, ascites, poor performance status, low albumin, elevated alkaline phosphatase, and resections that were non-curative than in the older patients. Progression-free survival (PFS) and overall survival (OS) was shorter in younger patients (PFS, 4.2 months; OS, 7.1 months) than in older ones (PFS, 4.9 months; OS, 8.4 months). Nonetheless, younger age did not show an independent association with PFS or OS. Stratified analyses showed that younger age was related with poor outcome in the subgroups of good performance status and no bone metastasis.
Conclusion: When matched for other prognostic factors, the prognosis of younger AGC patients receiving first-line combination chemotherapy does not differ from that of older patients. The poor survival of younger patients may be attributed to the association with other adverse prognostic factors.

6556 POSTER

Updated long-term outcomes and failure pattern in patients with resectable esophageal cancer receiving one cycle of induction chemotherapy (capecitibine, cisplatin) followed by concurrent chemoradiation

G. Jang[1], S.B. Kim[1], S.I. Park[2], J.H. Kim[3], H.Y. Jung[4], J.H. Lee[4], J.H. Park[3], J.H. Ahn[1], H.Y. Song[5], K.J. Cho[6]. *[1]Asan Medical Center, Oncology, Seoul, South Korea; [2]Asan Medical Center, Thoracic Surgery, Seoul, South Korea; [3]Asan Medical Center, Radiation Oncology, Seoul, South Korea; [4]Asan Medical Center, Gastroenteology, Seoul, South Korea; [5]Asan Medical Center, Diagnostic Radiology, Seoul, South Korea; [6]Asan Medical Center, Pathology, Seoul, South Korea*

Background: Previously, we performed phase II study of one cycle of induction chemotherapy with capecitabine and cisplatin followed by concurrent chemoradiotherapy (CRT) in patients (pts) with resectable esophageal cancer (ASCO 2005 abstract 4063). We expanded the study population and analyzed the long-term results and pattern of treatment failure.
Material and Methods: From March 2003 to December 2006, a total of 106 pts with stage II/III resectable esophageal squamous cell carcinoma were enrolled. Patients received one cycle of induction chemotherapy (cisplatin 60 mg/m^2, D1, capecitabine 1000 mg/m^2 bid, D1−14) and followed by radiotherapy (46 Gy, 2 Gy/fraction) concurrent with weekly chemotherapy (cisplatin 30 mg/m^2, D1, 8, 15, 22, capecitabine 800 mg/m^2 bid, 5 days/week) during the entire course of radiation. Surgery was performed 4−6 weeks after completion of radiation therapy.
Results: The median age including 98 men (93%) was 63 years (range, 45−74). One hundred two pts completed concurrent CRT. Overall clinical response in the intention-to-treat population after CRT was 93% (99 pts) including 48% (51 pts) of complete response (CR) rate. Seventy eight pts (74%) underwent surgical resection. Pathologic CR was achieved in