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.

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

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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.

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

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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.

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

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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.