and 8.8±8.7% in group 3, respectively. Statistically significant differences of overall survival haven't been obtained (p = 0.06). The influence of TACE with oxaliplatin on RFS and OS has been demonstrated by Cox regression analysis (HR 0.24 [95% CI 0.09–0.64], p = 0.003 for RFS and HR 0.28 [95% CI 0.09–0.86], p = 0.014 for OS).
Conclusions: Using TACE with oxaliplatin and LR in CRC resectable liver metastases patients has improved recurrence-free survival and has reduced disease recurrence and death risks. Phase III of clinical trial is under consideration.

6049 POSTER

Phase II Study of Neoadjuvant Chemoradiotherapy With Oxaliplatin-Containing Regimen in Locally Advanced Rectal Cancer

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Background: Preoperative fluorouracil (FU)-based chemoradiotherapy was associated with improved local control and less toxicity but did not improve overall survival. Oxaliplatin also has radiation sensitization properties. Patients with pathological complete response (ypCR) following chemoradiation have better survival than do those without ypCR.
Purpose: The aim of this study was to assess tolerance of this regimen and evaluate the response of rectal cancer following chemoradiotherapy containing oxaliplatin preoperatively.
Methods: Between August 2008 and August 2010, thirty patients with clinical T3/T4 or N+ rectal adenocarcinoma located in mid or lower rectum without metastasis were entered onto the study in single institute. Data were analyzed according to the intention-to-treat principle. Leucovorin was administered at 20 mg/m^2 followed by continuous infusion of 5-FU of 350 mg/m^2 on days 1 to 5 and 29 to 33. Oxaliplatin was administered at 130 mg/m^2 on days 1 and 29 simultaneously with leucovorin. Radiation dose was 180 rad/fraction to a total dose of 50.4 Gy (28 fractions). Surgery was scheduled 6 to 8 weeks after completion of chemoradiotherapy. Adverse effects were graded according to the Common Toxicity Criteria of the National Cancer Institute. Tumours following surgery were graded by tumour regression. All statistical analyses were conducted using SPSS 18.0. This study was approved by the institutional review board of our institution.
Results: Thirty one patients were entered onto the study. Six patients (19.4%) experienced grade 3 diarrhea. Grade 2 nausea and vomiting occurred in 5 and 2 patients, respectively. Severe neurotoxicity was not observed: grade 1 sensory neuropathy occurred in 10 patients (32.3%). Myelosuppression was mild and grade 2 anemia, neutropenia, and thrombocytopenia occurred in 2, 2, and 1 patient, respectively.
All patients underwent surgical resection: 23 underwent low anterior resection, 6 had coloanal anastomosis, and 2 received Hartmann's procedure. Sphincter-saving surgery was performed in 28 patients (93.5%). Mean distance of the tumour from anal verge was 5 cm. Anastomotic leakage occurred in 4 of 29 (13.8%) patients with anastomosis. Mean number of harvested lymph nodes was 8.4. Mean distal margin of tumour was 1.5. The circumferential resection margin was involved in two patients (6.5%). Overall 24 patients (77.4%) responded to the treatment. Four of the 31 patients (12.9%) taken to surgery had ypCRs. When ypCR was combined with only few residual cells, the rate was 22.6%.
Conclusion: The overall toxicity of combined oxaliplatin to continuous infusion of 5-FU and radiation was well tolerable. The neoadjuvant chemoradiation with oxaliplatin-containing regimen for patients with locally advanced rectal cancer was associated with higher rates of sphincter preservation and down-staging. Further prospective randomized trials are necessary to better define the benefits as oncologic outcomes.

6050 POSTER

A 12-week Regimen With Interdigitating FOLFOX Chemotherapy and Pelvic Chemoradiation for Simultaneous Primary and Metastatic Rectal Cancer

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Background: Chemotherapy dose used during chemoradiation is adequate for radiosensitization but suboptimal for systemic control. The aim of this study was to evaluate tolerability, and local and systemic benefits of a new treatment regimen delivering intensive chemotherapy and radical radiotherapy in an interdigitating manner. (ClinicalTrials.gov Identifier: NCT00422864)
Materials and Methods: This was a single arm prospective study for patients presenting with untreated simultaneous symptomatic primary and metastatic rectal cancer. The treatment regimen was 12 weeks long. FOLFOX chemotherapy (oxaliplatin 100 mg/m^2 day 1, leucovorin 200 mg/m^2 day 1, 5-FU 400 mg/m^2 bolus day 1, then continuous infusion 2.4 g/m^2 over 46 hours) was given in week 1, 6, and 11. Pelvic radiotherapy (25.2 Gy in 3 weeks in 1.8 Gy/fr with concurrent oxaliplatin 85 mg/m^2 day 1 and 5-FU continuous infusion 200 mg/m^2/day) was given in week 3−5, and week 8−10. In total, patients received, in 12 weeks, 3 courses of FOLFOX and pelvic radiation 50.4 Gy with concurrent oxaplatin and 5-FU. All patients were staged with CT, MRI and PDG-PET before and after treatment.
Results: Twenty-six patients were treated in this study. The mean age was 61 (range 33−82) years. 69% were male. MRI stage of the rectal primary was T2 4%, T3 81% and T4 15%. Liver, lung, and extra-pelvic nodal metastases were present in 81%, 35% and 23% of patients, respectively. 38% of patients had more than one site of metastatic disease. Twenty-four patients (92% [95% CI:75%-99%]) completed the 12-week treatment regimen. All patients received the planned radiation dose. 65% (95% CI:44%-83%) of patients received the planned number of courses of oxaliplatin with 88% of patients receiving at least 75% of the protocol oxaliplatin dose. In this 12-week period, grade 3 toxicities were neutropenia 23%, diarrhoea 15%, and radiation perineal skin reaction 12%. All grade 4 toxicity was due to neutropenia 15%. There was no febrile neutropenia. PET metabolic response (CR+PR) rate for rectal primary was 96% (95% CI:80%-100%). Overall PET metabolic response rate for metastatic disease was 60% (95% CI:39%-79%) (CR rate 16%).
Conclusions: It is feasible to deliver intensive chemotherapy and radiotherapy to treat primary and metastatic rectal cancer simultaneously. High completion and response rates are encouraging. This regimen is the subject of a current phase II neoadjuvant trial for resectable rectal cancer (TROG 09.01).

6051 POSTER

Combined Modality Treatment in Anal Canal Carcinoma − Impact of Full Dose Treatment and Clinical Stage Category on Outcomes

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Background: Since N Nigro's report in 1974, combined modality treatment, chemo-radiotherapy (CCRT), has been the standard in anal canal carcinoma. We report the results of this treatment with regard to compliance, toxicity, clinical outcomes and we intent to determine if full dose treatment and clinical stage has an impact in this patient group.
Material and Methods: Between 1999 and 2009, 42 patients received CCRT with no planned gap (45 Gy at 1.8 Gy/fraction +/− boost 9 Gy at 1.8 Gy/fraction; 5-fluorouracil, 1000 mg/m^2, Days 1−4 and 29−32, mitomycin C, 10−15 mg/m^2, Days 1 and 29). Median age 62 years (28−83); 11 (26%) males (6 HIV positive), 31 (74%) females; Stage I = 6 (14%), II = 13 (31%), IIIA = 8 (19%), IIIB = 15 (36%). Median overall treatment time (OTT) was 35 (14−53) days, 36 (81%) patients received full dose treatment (FDT), 2 patients had grade 4 toxicity, and 1 treatment related death. Median follow up was 63.8 months with a minimum of 25 months.
Results: For the whole study sample Kaplan–Meier 5-year rate of loco-regional control (LRC) was 78%, colostomy free survival (CFS) 73%, distant metastases free survival (DMFS) 76%, disease free survival (DFS) 65% cancer-specific survival (CSS) 69% and overall survival (OS) 46%. The