FA at 100 mg/m^2 as 2 h infusion on days 1–2, FU at 400 mg/m^2 as bolus on days 1–2 plus FU at 600 mg/m^2 as 22 h infusion on days 1–2 (folfiri) every 2 weeks, or arm B: Cpt-11 at 250 mg/m^2 on day 1 and xeloda 2000 mg/m^2 for 14 days (xeliri) every 3 weeks.

Results: Up to now 91 patients have been enrolled: 54 are evaluable for activity and toxicity (A/B: 20/34). The main characteristics of the evaluable patients are (A/B): median PS: 0/0; sites of disease: liver 12/26, lung 7/15, lymph-nodes 1/8, others 3/4. Among the evaluable patients we observed the following responses (A/B) CR: 1/0 (5/0%), PR: 4/18 (20/53%), SD: 11/11 (55/32%) and PRO: 4/5 (20/15%) for an ORR of 25% and 53%, respectively. Grades 3–4 haematologic toxicity (NCI criteria) were: neutropenia 15/21% and anaemia 5/3% whilst the main non haematologic side effect was diarrhoea observed in 5/18%, respectively.

Conclusions: Our preliminary results do not permit any definitive conclusion regard the activity of the two combinations. The toxicity profile of xeliri is similar to those of previous studies.

doi:10.1016/j.ejcsup.2008.06.041

BEVACIZUMAB + FOLFIRI AS FIRST-LINE TREATMENT IN ADVANCED COLORECTAL CANCER (ACC): A MULTICENTER PHASE II STUDY OF THE GRUPPO ONCOLOGICO DELL' ITALIA MERIDIONALE (PROT. GOIM 2601)

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Background: The addition of bevacizumab (BEV) to irinotecan (CPT-11) plus bolus fluorouracil (FU) and folinic acid (FA) (IFL regimen) demonstrated to be more active and more effective than chemotherapy alone in a randomised phase III trial. However IFL is considered more toxic than FOLFIRI regimen. So we started a phase II trial to evaluate the activity and the safety of the combination of BEV plus FOLFIRI as first-line therapy in ACC patients (pts).

Methods: Untreated pts with histologically confirmed diagnosis of colorectal cancer entered into the trial if they satisfied the following main inclusion criteria: presence of measurable disease, age > 18 years, performance status $\leqslant$ 2 (ECOG scale), adequate bone marrow reserve and renal and hepatic function, informed written consent. An history of cardiovascular disease, thromboembolic events and/or coagulative disorders were considered as exclusion criteria.

The enrolled pts were treated with CPT-11 at 180 mg/m^2 on day 1, FA at 100 mg/m^2 as 2 h infusion on days 1–2, FU at 400 mg/m^2 as bolus on days 1–2 and FU at 600 mg/m^2 as 22 h infusion on days 1–2 (FOLFIRI) plus BEV at the dosage of 5 mg/kg on day 1, every two weeks. A maximum of 12 cycles of chemotherapy was planned and a maintenance with BEV for 6 months was permitted. The evaluation of the activity (recist criteria) was performed every four cycles.

Results: Up to now 72 pts have been enrolled and 61 are evaluable for activity and safety (eleven pts are too early). The main characteristics of the evaluable pts were M/F: 32/29; median PS: 0 (range 0–2); median age 61 (range 33–73); primary site (colon/rectum): 40/21; main sites of disease: liver 45, lung 16, lymph-nodes 15, others 6; single site: 39 and multiple sites: 22.

Three CR (5%) and 25 PR (41%) were observed for an ORR of 46%; 26 pts had SD (43%) for an overall TGCR of 89%. Only 7 PRO (11%) were observed. The response rate according to site were: liver 21/45 (46.6%), lung 8/16 (50%). The only grades 3–4 toxicity (NCI criteria) were neutropenia 10% and thrombocytopenia 2%. Ten pts (16%) had hypertension but only one was uncontrolled by medical therapy and interrupted the study. One pts had epistaxis.

Conclusions: Our results indicate that the addition of BEV to FOLFIRI regimen is an active and well tolerated first-line treatment for ACC pts. Final data will be available for the meeting.

doi:10.1016/j.ejcsup.2008.06.042

RADIOCHEMOTHERAPY FOR ANAL CARCINOMA: OUR EXPERIENCE

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Background: Radiochemotherapy of anal carcinoma is an organ sparing approach with a high curative potential.

Patients and methods: Between August 1999 and June 2007, 18 patients were treated with external radiation therapy (RT) and concomitant chemotherapy (CT). The main characteristics of patients were: histology: 14 squamous carcinoma, 2 basaloid, 1 adenocarcinoma, 1 undifferentiated carcinoma; stage (2001 UICC classification): II 7 cases, III A 9, III B 2; age: median 61 year, range 33–79; sex (F/M): 10/8. RT was delivered at the whole pelvis with a four-field box technique followed by a boost at the primary tumour. The median dose of RT at the whole pelvis and at the primary tumours was 45 Gy and 55 Gy, respectively. CT was carried out during the first and last four days of RT with continuous infusion of 5-fluorouracil (1000 mg/m^2/day) plus bolus mitomycin C (10 mg/m^2 on day 1) in 16 patients or cisplatin (100 mg/m^2) in 2. After a rest period of 4-6 weeks two courses of cisplatin plus 5-Fluorouracil was delivered in 4 patients with locoregional advanced disease.

Results: CR were observed in 8 patients (44%), PR in 4 (22%), SD in 4, and PD in 2. Local recurrences occurred in 4 patients previously obtaining RC (1/8), RP (2/4), SD (1/4) and 2 of them were rescued by conservative surgery. Distant metastases occurred in two cases and inguinal failure in one. The median duration of response was 12 months (3–62) and the sphincter preservation rate was 90% (16 patients). Temporary interruption of the treatment as a result of acute toxicity (gastrointestinal) was necessary in 3 patients. With a median follow up of 17 months (range 5–57), 10 patients are alive and 9 disease-free. Eight patients died due to a progressive disease (locoregional failure in 5 patients, liver metastases in 2, lung metastases in 1).

Conclusions: The majority of patients with anal carcinoma can be treated with curative intent using a sphyincter-sparing approach of radiochemotherapy even with advanced disease. Challenges to be meet in the future include the prevention of metastases and tumour recurrences.

doi:10.1016/j.ejcsup.2008.06.043

CETUXIMAB INDUCED CUTANEOUS RASH: DOES IT AFFECT PSYCHOLOGICAL WELL-BEING IN COLORECTAL CANCER PATIENTS?

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Introduction: Colorectal cancer (CCR) is one of the most common invasive cancer in western countries with 20% of patients being initially diagnosed with locally advanced or metastatic disease. In the last decade, remarkable progress have been made in the treatment of metastatic CCR, owing to the introduction of drugs targeting epidermal growth factor receptors (EGFR) like cetuximab. Cetuximab is characterised by a peculiar skin toxicity including maculo-papular rash, that, when serious, could led patients to interrupt therapy, since it brings pruritus and deteriorates one's own physical appearance. There is a paucity of studies on psychological impact of cutaneous disfiguring conditions on cancer patients, thus it is not known how much skin rash can affect patients' psychological well-being.

Methods: Patients affected by advanced CRC and treated with cetuximab based-therapy entered the trial, if: (1) aged 18–75; (2) with ECOG: 0–2; and (3) have received a minimum of four cycles of cetuximab. The following questionnaires were used: The functional assessment of cancer therapy-colorectal (Fact-C) for quality of life (QoL), and psychological distress inventory (PDI). It was added a single question about social avoidance 'I avoid going out or seeing persons because of my skin toxicity', on a five-point likert scale.

Results: Seventy-nine advanced CRC patients were recruited, aged 33–74 years old (M = 59); 57% men, 43% women, with the following skin toxicity (NCI-2): no rash: 9%; G1: 45%; G2: 28%; G3: 15%; and G4: none (missing 3%). Thirty-two percent of patients shows psychological distress. To what concerns social avoidance, 22% of patients answered that they did avoid 'very much' going out. The remaining patients did not avoid going out or only 'in a certain way'. Social avoidance was not found to correlate to skin rash, but only to QoL. The correlation between cutaneous rash and psychological distress was not found also when controlling for patient's gender. A significant correlation was found between patient's psychological distress and overall quality of life (Pearson correlation coefficient = -0.67; $p < 0.0001$).

Discussion: In this sample, cutaneous rash does not negatively impact psychological distress. Two explanations were found: firstly, patients with a longer experience in cancer consider skin rash as part of the physical and psychological sufferance for cancer. Secondly, patients are encouraged by oncologists to carry on with treatment, because of a possible correlation between skin rash and illness' response. This expectation helps patients to find a meaning in bearing side effects: personal meaning is related to lower psychological distress because of the heightened sense of control on a specific event.

doi:10.1016/j.ejcsup.2008.06.044