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Abstracts

Gastrointestinal cancer

SECOND-LINE CHEMOTHERAPY IN ADVANCED CANCER OF THE PANCREAS: A MULTICENTER SURVEY OF THE GRUPPO ONCOLOGICO ITALIA MERIDONALE ON THE ACTIVITY AND SAFETY OF THE FOLFIRI REGIMEN IN CLINICAL PRACTICE

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Introduction: In daily clinical practice second-line chemotherapy is frequently given to patients with advanced pancreatic cancer failing gemcitabine-based first-line chemotherapy without solid scientific support.

Patients and methods: A retrospective survey was carried out including 26 patients pretreated with gemcitabine in monochemotherapy or in combination with oxaliplatin. Patients received standard FOLFIRI regimen biweekly until progression or unacceptable toxicity. FOLFIRI regimen included irinotecan (150 mg/m^2 on day 1), leucovorin (20 mg/m^2 bolus) before 5-FU (400 mg/m^2 bolus) followed by 22-hour continuous infusion of 600 mg/m^2 on days 1–2).

Results: Five partial responses (19%) and eight stabilizations (31%) were recorded for a tumor growth control rate of 50%. The median TTP was 4 months (range 2–7 months), and median overall survival was 6.5 months (range 3–9 months). A stabilization of PS and a subjective improvement of cancer-related symptoms was recorded in 15 patients (57%).

Conclusions: Data presented in this paper support the use of FOLFIRI regimen in the second-line treatment of APC patients. However, the use of second-line chemotherapy should be carefully proposed to patients with good PS or those who had a good response to first-line therapy.

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GASTROINTESTINAL STROMAL TUMOURS: TWO CASE REPORTS

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Introduction: Gastrointestinal stromal tumours are rare and characterised by slow growth and with late symptoms. Surgical removal and the last pharmacological innovations are the only possible and potentially curative treatments.

Methods: From 1999 to 2007 we observed 3 patients who received surgical treatment for gastrointestinal stromal tumours arising in two cases from the stomach and in one case from the oesophagus. We report one case of a stomach GIST intraoperative occasional finding, during laparotomy for a perforated diverticulitis, and one case of a distal oesophagus GIST causing mild dysphagia. The first patient underwent total gastrectomy with lymphadenectomy and Hartmann's operation and the second patient underwent tumour excision with a laparotomic transhiatal approach followed by a Nissen fundoplicatio.

Results: No postoperative mortality or major postoperative complications were observed. Patients are still alive and in good health.

Conclusion: The cases we report reopen the question of this pathology which, with further therapeutic innovations, shows a rather favourable course but requires a diagnosis at early stages. Moreover, the case of stomach GIST is particularly representative for the tumour remarkable size, other symptoms lacking which delayed diagnosis compared to other gastrointestinal localizations.

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SORAFENIB PLUS LONG-ACTING OCTREOTIDE IN ADVANCED HEPATOCELLULAR CARCINOMA. PRELIMINARY RESULTS OF A MULTICENTER ONGOING STUDY

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Background: Advanced hepatocellular carcinoma (HCC) not amenable to local therapies has limited chances of cure and has a poor prognosis. Sorafenib is a multikinase inhibitor with proven activity in advanced HCC. Octreotide is already used in this setting with conflicting but usually interesting results.

Methods: An original schedule with sorafenib and long-acting octreotide is currently tested in advanced HCC enrolled from different institutions. Sorafenib is administered at a dosage of 400 mg/daily for 28 d with a following week of rest. Ten days after starting sorafenib, long acting octreotide is administered at a dose of 40 mg with monthly scheduled administrations. Objectives of this study are the evaluation of activity and potential toxicity of the treatment. Tumor response is assessed bimontly.

Results: At the date of 28 April 2008, 57 patients were considered for study entry and 42 were enrolled (sex: 33M/9F; age range: 57–80 years; HCV: 26 patients, HBV: 10 patients, HCV + HBV: 1 patient; unknown etiology: 5 patients; child A/B: 31/11). Patients naïve from other therapies were 19, whilst all the others were previously treated with local and/or systemic treatments. Three patients were not evaluable because of premature treatment stopping caused by diarrhoea grade 3. Twenty-four patients were evaluated until now. Among 12 patients evaluable after 2 months of therapy, we registered 1 minimal response, 3 stable disease and 8 disease progression. Among 8 patients evaluable after 4 months, we reported 5 stable disease and 3 disease progression. Among 4 patients evaluable after 6 months, we reported 1 minimal response and 3 stable disease. Treatment was generally well tolerated apart from haemorrhoidal bleeding (2 patients), skin toxicity grade 2 and grade 3 in 2 patients, respectively, hypertension in 3 patients.

Conclusions: The association of sorafenib and long acting octreotide appears feasible in advanced hepatocellular carcinomas not susceptible of local therapies. Longer follow-up of this study is needed to evaluate clinical activity of this schedule.

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BI-WEEKLY ADMINISTRATION OF CAPECITABINE + OXALIPLATIN (XELOX-2) IN FIRST LINE TREATMENT OF ADVANCED COLORECTAL CANCER (ACRC): PRELIMINARY RESULTS

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Background: FOLFOX regimen represents a standard first line therapy for ACRC. Recent studies observed that tri-weekly XELOX administration is characterised by effectiveness and tolerance similar to FOLFOX 4 infusional schedule. This phase II multicenter study of the Gruppo Oncologcio dell'Italia Meridionale (GOIM) started to evaluate the activity and the toxicity of bi-weekly administration of capecitabine + oxaliplatin in ACRC patients.

Materials and methods: Thirty-two advanced colorectal cancer pts with measurable disease, ECOG PS $\leqslant$ 2, age 18–75 years (yrs) were enrolled. The schedule of treatment was as follows: oxaliplatin at 100 mg/mq i.v. on day 1 and capecitabine at 2000 mg/mq p.o. in a two daily administration from days 1 to 7, every 2 weeks. The recist and NCI criteria were employed to determine the activity and the toxicity of this combination, respectively.

Results: At present, 32 patients have been enrolled and up to now 29 of them are evaluable for activity and toxicity. The main characteristics were: sex (M/F) 23/9, median age 70 yrs (range 54–75), median PS 0, main sites of disease: liver 26 (81%), lymph-nodes 9 (28%) and lung 4 (12%). One CR (3%) and 12 PR (42%), 8 SD (27%) and 8 PD (27%) were observed. The main toxicity rate (G1–2 versus G3–4) were: thrombocytopenia 44/6, anaemia 41/0, nausea/vomiting 28/0, diarrhoea 22/0, neurotoxicity 50/0 and asthenia 16/3.

Conclusions: These preliminary data show that the bi-weekly administration of capecitabine + oxaliplatin is active and well tolerated by ACRC patients. This study is still ongoing.

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FOLFIRI VERSUS XELIRI IN UNTREATED ADVANCED COLORECTAL CANCER: A PHASE II RANDOMISED TRIAL OF THE GRUPPO ONCOLOGICO DELL' ITALIA MERIDIONALE (PROT. GOIM 2405)

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Background: Irinotecan (Cpt-11) plus fluorouracil (Fu) modulated by folinic acid (Fa) (folfiri regimen) is one of the standard first-line treatment in advanced colorectal cancer (ACC). The oral fluoropyrimidine xeloda (Xel) is equivalent in terms of efficacy and demonstrated a better safety profile than bolus Fu–Fa. Besides Xel can replace Fu continuous infusion. Also the combination of Cpt-11 plus Xel (xeliri regimen) demonstrated to be active as a first-line treatment in ACC patients. So the GOIM started a randomised multicenter phase II trial aiming to compare the activity and safety of folfiri and xeliri in this setting.

Methods: Untreated patients with histologically confirmed diagnosis of colorectal cancer entered into the trial if they satisfied the following inclusion criteria: presence of measurable disease (recist criteria), age > 18 years, performance status < 2 (Ecog scale), adequate bone marrow reserve and renal and hepatic function, informed written consent. The enrolled patients were randomised 1:2 to receive arm A: Cpt-11 at 180 mg/m^2 on day 1,