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Modified FOLFOXIRI in Advanced Pancreatic Cancer

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Context The combination regimen of 5-fluorouracil, folinic acid, oxaliplatin and irinotecan named FOLFIRINOX has been proposed as a new standard of care for metastatic pancreatic cancer patients. However, FOLFIRINOX was associated with high incidence of grade 3 and 4 toxicities (neutropenia in 45.7% of patients with G-CSF use in 42.5% of patients; febrile neutropenia in 5.4%; diarrhea in 12.7%). Our group had developed a very similar schedule in colorectal cancer named FOLFOXIRI which contains no bolus 5-fluorouracil and a slight lower dose of irinotecan. **Objective** The objective of this study was to prospectively evaluate the tolerability and activity of a modified (m)FOLFOXIRI regimen in metastatic or locally advanced pancreatic cancer patients. **Methods** The regimen included a lower dose of irinotecan (administered at 150 mg/m^2 on day 1 every 14 days) and of infusional 5-fluorouracil (2,800 mg/m^2 administered as a 48-hour continuous infusion on days 1 to 3 every 14 days). Folinic acid and oxaliplatin remained unchanged. **Results** Thirty-nine patients with cytological or histological diagnosis of pancreatic adenocarcinoma have been treated with (m)FOLFOXIRI from August 2010 onwards; 17 had metastatic disease while 22 had locally advanced disease. A total of 260 cycles have been administered so far. The grade 3-4 toxicities reported are: neutropenia in 35.9% of patients, thrombocytopenia 2.6%, diarrhea 5.1%, stomatitis 7.7%, nausea/vomiting 5.1%, fatigue 2.6%, liver toxicity 5.1%, sensory neuropathy 5.1%. No toxic deaths and no febrile neutropenia have been occurred. G-CSF has been used in seven patients (18%). A delay in the administration of chemotherapy was required in 12 patients (31%) and a reduction of doses in 7 cases (18%). Among 30 evaluable patients 11 partial responses (36.7%) and 14 stable disease (46.7%) have been observed. Median progression-free survival (PFS) was 11.5 months and median overall survival (OS) 25.5 months. For metastatic patients only, response rate resulted 33% with a PFS and OS of 8.4 and 14.8 months, respectively. **Conclusion** The (m)FOLFOXIRI regimen as we used resulted feasible and quite well tolerated and it maintained its good activity in metastatic pancreatic cancer.