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Fixed-Dose Rate Gemcitabine Plus Capecitabine as Second-Line Treatment for Metastatic Pancreatic Cancer Patients Pretreated with Oxaliplatin

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Context There is no consensus about second-line chemotherapy for pancreatic cancer. The addition of oxaliplatin to 5-fluorouracil/folinic acid improved outcome in gemcitabine refractory patients. However, first-line options for these patients are changing and combination chemotherapy containing oxaliplatin such as FOLFIRINOX is frequently used. **Objective** We performed a phase II trial to evaluate the activity of a regimen with fixed-dose rate gemcitabine and capecitabine (FDR GEM-CAP) as second-line treatment for metastatic pancreatic cancer patients pretreated with oxaliplatin. **Methods** Patients with cytological or histological diagnosis of pancreatic adenocarcinoma, with ECOG performance status (PS) 0 or 1, who progressed after first-line chemotherapy including oxaliplatin were enrolled into the study and treated with capecitabine 650 mg/m^2 *bid* on days 1 to 14 plus FDR gemcitabine 800 mg/m^2 infused in 80 minutes on days 1 and 8, with cycles repeated every 21 days. The main end-point of the study was the percentage of patients free of progression at 2 months after beginning of chemotherapy; with a p0=0.50 and p1=0.70, an α=0.10 and β=0.20, a total of 20 patients should be necessary for the analysis. **Results** Twenty patients were enrolled; M/F=9/11; PS 0/1=13/7. Median age was 60 years (range 42-75 years). First-line treatment was gemcitabine plus oxaliplatin (GEMOX) in 13 patients and FOLFIRINOX in 7. The median number of cycles of second-line FDR GEM-CAP was 4 (range 2-14), with a total of 108 cycles administered. The only grade 3 toxicity recorded was anemia in 1 patient. Only 9 cycle delays (8.3%) were needed for toxicity. Among 18 patients so far evaluable for response, 2 partial responses (11.1%) and 7 stable diseases (38.9%) have been observed. The trial met its primary end-point; median progression-free survival was 4.3 months with a percentage of patients free of progression at 2 months of 79%. Median overall survival from the beginning of second-line was 12 months. **Conclusion** The combination of FDR GEM-CAP as we used is well tolerated and active in metastatic pancreatic cancer patients and could be an interesting second-line option for selected patients treated with first-line FOLFIRINOX.