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Resection of Locally Advanced Pancreatic Cancer after Neoadjuvant Chemotherapy with Modified FOLFIRINOX: A Prospective Phase II Study

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Context Twenty percent of the patients have a primary-resectable pancreatic ductal adeno-carcinoma (PDAC) and in 30-40% surgery is denied because of local tumor growth in the absence of metastasis. These patients could be still considered for resection, if responsive to neoadjuvant chemotherapy. **Objective** We report the results of a phase II clinical trial, coupling high-dose multi-drug neoadjuvant chemotherapy with aggressive surgery. **Methods** All patients enrolled were selected by a multidisciplinary workgroup. Selection criteria: stage III locally advanced-PDAC (suspected arterial involvement), ECOG PS 0-1, age 18-75 years. A modified FOLFIRINOX regimen was used. Tumor response was evaluated according to RECIST. The opportunity to add a local treatment, either surgery or radiation-therapy, was evaluated after every CT follow-up. **Results** Between Nov 2010 and Nov 2012, 26 patients (mean age 59 years) were enrolled: 9/26 celiac axis involvement; 11/26 superior mesenteric artery; 6/26 celiac axis and superior mesenteric artery. Nine had a partial response (35%), 15 stable disease (58%), 2 progressed (8%). Fourteen (54%) underwent to surgery and 11 (42%) to resection with curative intent: 2 pancreaticoduodenectomies and 9 total-splenopancreatectomies. Mean-operative-time was 618 minutes. In-hospital mortality was 9%, overall-postoperative-morbidity 62%, surgical morbidity 12%, medical morbidity 50%. Mean hospital stay was 26 days. Eleven out of 11 were R0. Resected lymph-nodes mean number was 67 and nodal-metastasis mean number was 4. Twelve percent of resected venous segments and 33% of resected arterial segments were not involved on histology. Overall progression free survival was 17.6 months, resected patient progression free survival 17.8 months, out-of-surgery patient progression free-survival 10.3 months, and median overall survival 24 months. **Conclusion** The modified-FOLFIRINOX protocol in PDAC allows extended resection in a relevant percentage of stage III PDAC with results comparable to those in primary resectable patients. New data from further studies are needed before any final conclusion may be drawn.