OP 6-6

A Phase 2 Trial Of Neoadjuvant Modified FOLFIRINOX Chemotherapy For Resectable Pancreatic Adenocarcinoma

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Background : Pancreatic cancer is notorious for poor prognosis as it recurs systemically within 2 years even after radical curative surgery. For borderline resectable pancreatic cancer, FOLFIRINOX chemotherapy has proven efficacy and safety as a preoperative treatment with improved survivals. This pilot study is a phase 2 trial of neoadjuvant modified FOLFIRINOX(mFOLFIRINOX) chemotherapy for initially 'resectable' pancreatic cancer.

Methods : We include patients with pancreatic ductal adenocarcinoma confirmed by histologically and evaluated as 'resectable' according to the NCCN guidelines in imaging tests. For patients who gave written informed consent, we administrate 6 cycles of mFOLFIRINOX and re-evaluate the resectability. In case of unable to complete 6 cycles of chemotherapy due to the chemo-toxicity, disease progression or patient refuse, the patients will be withdrawn from the study. The period of patients enrollment is from May, 2020 to May, 2022 and the follow up period for survival is 2 years. We compared clinicopathologic characteristics and surgical outcomes between the enrolled patients of this study and the patients diagnosed as resectable pancreatic cancer and underwent upfront surgery previously in our institution.

Results : Of the 21 patients enrolled in study until December 2021, two patients are ongoing neoadjuvant chemotherapy, one patients was excluded due to the initial liver metastasis and finally, total 18 patients underwent curative surgery. Of these patients, 13 patients completed the protocol of this study, and 5 patients did not complete 6 cycles of chemotherapy due to the chemo-toxicity(n=2), disease progression (n=2) and patient refuse (n=1). 14 patients underwent PPPD (open: 8 cases, laparoscopic: 2 cases, robotic: 4 cases) and 4 patients underwent DPS (open: 1 case, laparoscopic: 3 cases). In comparison of upfront surgery group (n=292) and study group (n=18), preoperative characteristics(age, sex, preoperative tumor marker), surgical outcome(operation type and time, blood loss and transfusion) and pathologic outcome (T, N stage, number of positive lymph node) did not differ significantly. R0 resection rate was higher in study group (76.0% vs 94.4%, p=0.077) without statistical significance. These result were similar in comparison of upfront surgery group (n=292) and protocol completed group (n=13) without statistical significance.

Conclusions : Neoadjuvant chemotherapy followed by radical surgery shows feasible and comparable result in resectable pancreatic cancer. It has possibility of improving margin negative resection rate and further study is needed.

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