AB132. P108. Intraoperative radiotherapy (IORT) followed by concurrent chemotherapy (CCRT) or stereotactic radiotherapy (SBRT) for locally advanced pancreatic cancer

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Background: Pancreatic cancer is the fourth leading cause of cancer-related deaths worldwide. Approximately 30% of pancreatic cancer patients present with locally advanced, unresectable nonmetastatic disease, with median overall survival (OS) ranging from 5 to 11 months. Currently, no standard treatment has been established for these patients. In our previous study (Chen *et al.*, Medicine 2016), we retrospectively reviewed a large cohort in China. Two hundred and forty-seven consecutive patients with nonmetastatic locally advanced pancreatic cancer (LAPC) who underwent intraoperative radiotherapy (IORT) between January 2008 and May 2015 were identified and included in the study. The 1-, 2-, and 3-year actuarial survival rates were 40%, 14%, and 7.2%, respectively, with a median OS of 9.0 months. On multivariate analysis, an IORT applicator diameter <6 cm [hazards ratio (HR), 0.67; 95% confidence interval (CI), 0.47–0.97], no intraoperative interstitial sustained release 5- fluorouracil chemotherapy (HR, 0.46; 95% CI, 0.32–0.66), and receipt of postoperative chemoradiotherapy followed by chemotherapy (HR, 0.11; 95% CI, 0.04–0.25) were significantly associated with improved OS,1-, 2-, and 3-year OS rates of 70.5% , 25.1% , and 18.4%, respectively. We finally concluded that chemoradiotherapy followed by chemotherapy might be a recommended adjuvant treatment strategy for well-selected cases. The optimal treatment strategy followed IORT has not been clearly defined. We conducted a study to find the best model of combination of IORT and postoperative radiochemotherapy for pancreatic cancer.

Methods: We did a comparative (2 arms), single-center, randomized controlled trial in China National Cancer Center/Cancer Hospital. The trail started from January 1, 2016. Eligible participants were previously untreated patients with LAPC, and were confirmed by cytology. Patients had at least an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less. During the surgical procedure, IORT was delivered using the Mobetron linear accelerator (Intraop Medical Corporation, Sunnyvale, CA, USA). The electron energy was 9 MeV. The surgeon and radiation oncologist assessed the extent of disease at operation and a cylindric applicator of appropriate size was selected to cover the tumor comfortably within the field, usually with a 1-cm margin around the pancreatic mass. Cone sizes were selected to deliver a dose of about 15 Gy (range, 10–20 Gy, which was confirmed by calculation) to a field that included the primary tumor and a margin of 1 to 2 cm covering the regional lymph nodes. After IORT, we randomly assigned participants (1:1) to two groups. Participants in the stereotactic radiotherapy (SBRT) Group received SBRT (total dose: 45 Gy; single dose: 3 Gy; frequency: 15) followed by taking S-1 orally (40 mg/m^2, bid on day 1–28 in 42-day circles), while participants in the concurrent chemoradiotherapy (CCRT) Group received CCRT [total dose: 46 Gy; single dose: 2 Gy; frequency: 23; with an intravenous infusion of gemcitabine (300 mg/m^2 weekly)] followed by taking S-1 orally as the SBRT Group. Patients continued treatment until unacceptable toxicity, disease progression, or patient withdrawal. The primary endpoint was overall survival. Kaplan-Meier method was used to analyze the difference of survival time between the two groups. Statistical analyses was performed by using IBM SPSS Statistics (version 20; IBM, Chicago, USA). The study protocol was approved by the Ethics Committee of China National Cancer Center. This trail is registered at Clinical Trials.gov, number NCT02981641. This trial is in progress and we report the interim analysis here.

Results: Between January 1, 2016, and January 1, 2018, we randomly assigned 64 LAPC patients to treatment: 33 patients (51.6%) to the SBRT Group and 31 patients (48.4%) to the CCRT Group. There was no significant difference between the two groups in terms of gender, age, lifestyle factors, tumor locations, and tumor sizes. Median follow-up time was 8.10 (range, 0.3–25.3) months. Till the last follow up, 37 patients (57.8%) had died: 19 patients (57.6%) in the SBRT Group and 18 patients (58.1%) in the CCRT Group. The 1-year survival rate was 38.2% in the whole patients: 36.0% in the SBRT Group and

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40.6% in the CCRT Group, respectively. Median OS was 10.6 (95% CI, 7.8–13.4) months for the whole patients: 10.4 (95% CI, 6.1–14.5) months for the SBRT Group and 11.0 (95% CI, 7.6–14.3) months for the CCRT Group (log-rank test, P=0.604). No treatment-related death or fatal complications occurred till now.

Conclusions: IORT is an effective and safe strategy for LAPC. The median OS in LAPC patients who received CCRT after IORT was slightly longer than patients who received SBRT after IORT. However, the study need more patients to be included and a longer time to follow up.

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