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Surgical outcomes after neoadjuvant ablative dose radiation among patients with borderline resectable and locally advanced pancreas cancer from the multi-institutional phase 2 Stereotactic MR-Guided Adaptive Radiation Therapy (SMART) trial

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Surgical outcomes after neoadjuvant ablative dose radiation among patients with borderline resectable and locally advanced pancreas cancer from the multi-institutional phase 2 Stereotactic MR-Guided Adaptive Radiation Therapy (SMART) trial.

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Background: Acute grade 3+ toxicity was rare in the multi-institutional phase 2 stereotactic MR-guided on-table adaptive radiation therapy (SMART) trial (NCT03621644) for locally advanced and borderline resectable pancreatic cancer (LAPC/BRPC). Surgery may be considered after ablative SMART although the feasibility and safety of this is not well understood. Postoperative outcomes of the subset of patients in the SMART trial are examined here. **Methods:** Trial eligibility included BRPC or LAPC without metastases after a minimum of 3 months of induction chemotherapy. All patients received SMART prescribed to 50 Gy in 5 fractions using an integrated 0.35T MR-radiation therapy device equipped with cutting edge soft tissue tracking, automatic beam gating, and on-table adaptive replanning. Surgery was permitted after SMART, often after multi-disciplinary review. Perioperative details and postoperative outcomes, including morbidity, mortality, and overall survival (OS), were analyzed. **Results:** 136 patients across 13 sites were enrolled between 2019-2022. 44 patients (32.4%) had surgery after SMART (33 BRPC, 11 LAPC). Surgical procedures included pancreaticoduodenectomy (81.8%), distal pancreatectomy with splenectomy (9.1%), total pancreatectomy (6.8%), and distal pancreatectomy with celiac axis resection (2.3%). 52.3% required vascular resection/reconstruction, a majority of which were venous resections (65.2%), with a smaller proportion needing both venous/arterial (21.7%), or arterial (13%). Surgery was performed after a mean 51.4 ± 52.8 days from SMART. Postoperative hospitalization was 10.5 ± 8.9 days. Nine patients (20.5%) had Clavien-Dindo complications of grade III or higher; 3 deaths resulted from post-pancreatectomy hemorrhage in patients who had portal vein resection. One-year OS in patients who had surgery versus no surgery after SMART was 66% vs. 43%, respectively. **Conclusions:** These are the first prospectively evaluated surgical outcomes after 5-fraction ablative SMART for BRPC/LAPC. The rate of surgery for BRPC compares favorably to radiated patients on the Alliance A021501 trial. Despite the use of ablative radiation dose and frequent need for vascular resection, the incidence of serious surgical complications was similar to what is reported after non-ablative radiation therapy. However, several deaths occurred after surgery and we therefore we urge caution when considering surgery after ablative radiation therapy. Further analysis of other variables such as the time between SMART and surgery, approaches to vascular resections, and discrete events such as delayed gastric emptying, operative duration, and post-operative pancreatic fistula are needed to better understand the surgical morbidity seen in these patients. Clinical trial information: NCT03621644. Research Sponsor: ViewRay.