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Percutaneous Approach to Irreversible Electroporation of the Pancreas: Miami Protocol

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Despite advances in the treatment of unresectable locally advanced pancreatic cancer, outcomes remain poor. Irreversible electroporation is a nonthermal ablative modality whose role in the management of locally advanced pancreatic cancer is being studied. This review highlights patient selection, preparation, and follow-up as well as discusses the techniques to achieve safe and effective tumor ablation in this challenging location.
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Background

Pancreatic adenocarcinoma incidence continues to increase with an estimated 46,420 new cases expected to occur in the United States in 2014.[1] The most common risk factor is cigarette smoking but others include family history of pancreatic cancer, history of chronic pancreatitis, diabetes, and obesity. Treatment options include surgery, chemotherapy, and radiation therapy, but are seldom curative. Unfortunately, less than 20% of patients are anatomically resectable on presentation. Approximately 40% of patients present with locally advanced pancreatic cancer (LAPC) and 40% present with metastatic pancreatic cancer (MPC).[1-3] The 1- and 5-year relative survival rates are poor at 27% and 6%, respectively, for all stages combined.[1] In patients with local disease 5-year survival is 24% compared with those with distant disease, in which it is 2%.[1]

Tumor staging usually begins with a contrast-enhanced multidetector computed tomography (CT) to establish resectability. Fluorine-18 fluorodeoxyglucose positron emission tomography (FDG-PET) can aid in detection of distant disease and may predict early recurrence after resection.[4] Contraindications to surgery include metastatic disease, and involvement of the celiac axis, hepatic artery, or superior mesenteric artery as indicated by unclear fat planes. The extent of venous involvement and arterial abutment determines if the lesion is classified as borderline resectable. If the superior mesenteric vein cannot be reconstructed or if there is portal vein occlusion, the disease is classified as unresectable LAPC.[5] Staging laparoscopy may be useful in patients with apparent resectable disease, but with poor prognostic factors such as tumors larger than 3 cm, and elevated cancer antigen (CA-19-9) levels.[6] If no surgical intervention is planned, tissue diagnosis may be obtained by brushings at the time of endoscopic retrograde cholangiopancreatography, fine-needle aspiration directed by endoscopic ultrasound, or image-guided percutaneous biopsy. Endoscopic ultrasound–guided fine-needle aspiration is favored given ability to detect and target smaller tumors.[6]

Pancreatic cancer is relatively resistant to both chemotherapy and most targeted therapies. When possible, surgical resection offers a proven survival benefit. The median survival after resection with margins of at least 1 mm that are free of disease (R0) is 22 months, increased from 11-18 months with locally advanced disease and 6-11 months with metastatic disease.[7] At resection, it is not uncommon to find microscopic involvement in one of the margins (R1 disease). There is still a survival benefit to patients with R1 resections over patients receiving chemotherapy alone.[7]

For LAPC, combined chemoradiotherapy has been able to downstage disease in approximately 30% of cases.[8] Combinations have included 5-fluorouracil or gemcitabine. There are data to support induction chemotherapy followed by combined chemoradiotherapy for example

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with gemcitabine or FOLFIRINOX.[9] The role of radiation therapy is still controversial as studies with conventional external-beam radiation have mixed results.[10] Stereotactic body radiation therapy combined with chemotherapy is a shorter treatment and is better tolerated, achieving comparable results to those of external-beam radiation therapy.[10]

For MPC, the choice of agent is directed by performance status. In patients with poor performance status, gemcitabine monotherapy is recommended and the best supportive care is appropriate if chemotherapy is not tolerated. In patients with a good performance status, FOLFIRINOX (5-fluorouracil, irinotecan, and oxaliplatin) offers improved median overall survival (OS) in patients with MPC of 11.1 months over 6.8 months with gemcitabine.[3] Adverse events such as sensory neuropathy, diarrhea, thrombocytopenia, and neutropenia often occur when receiving FOLFIRINOX. For patients who cannot tolerate FOLFIRINOX, gemcitabine-based doublets with *nab*-paclitaxel or erlotinib also provide an improvement in median OS over gemcitabine alone.[3] When possible, a patient with good performance status should be enrolled in a clinical trial.

The role of ablation in the management of LAPC has not been established. Thermal ablation in the pancreas has mostly been performed using an open approach and has been associated with significant morbidity and mortality from thermal injury to adjacent structures.[11] Girelli et al[12] reported a complication rate of 24% and Wu et al[13] report a mortality rate of 25%.

Irreversible electroporation (IRE) is different from thermal ablative techniques in that it triggers cell death by creating nanopores in the cell membrane. The extracellular matrix is preserved, allowing ablation adjacent to critical structures. Vessel patency has been demonstrated in tumors with vascular encasement.[14] Open, laparoscopic, and percutaneous approaches have been studied and initial evidence shows an acceptable safety profile with a possible survival benefit in selected patients.[15-18] This review outlines our institutional approach to percutaneous use of IRE in the pancreas.

Indications

IRE in the pancreas can be applied in patients who have undergone multiple lines of chemotherapy and radiation, where the goal of care is to control local disease in the pancreas. It can also be performed in the setting of LAPC or low-volume metastatic disease that has been stable over time. In patients with borderline resectable or unresectable LAPC, IRE may downsize tumor to allow resection.[18] In patients who have undergone resection, local recurrence may be managed with IRE.

Contraindications

Patients with cardiac arrhythmias cannot undergo IRE as the electrical pulses cannot by synchronized with the cardiac R waves, increasing risk for ventricular arrhythmias. Other contraindications include unsafe access for a percutaneous approach such as overlying colon obscuring the window or varices in the approach to the lesion. Gastric varices can bleed profusely and prescreening imaging should be evaluated to identify this risk. Finally, patients with uncorrectable coagulopathy and those who are unfit to undergo general anesthesia are excluded. Renal insufficiency is treated with premedication, prehydration, and consultation with nephrology services as needed.

Patient Evaluation

Cases are reviewed in a multidisciplinary tumor board with interventional radiologists, medical oncologists, radiation oncologists, and surgeons to determine eligibility. Patients are then evaluated in the interventional oncology clinic to complete the preprocedure workup. All patients are informed that this is an off-label use of the technology.

Performance status is documented using the Eastern cooperative oncology group criteria. A performance status greater than 2 indicates poor prognosis and a life expectancy less than 3 months. These patients usually do not benefit from any intervention and are excluded.

All patients should have biopsy-proven disease. A detailed cardiac history is obtained as cardiac arrhythmias prevent the ability to synchronize pulse delivery with the R wave and can result in ventricular arrhythmias.[19] Adequate liver, kidney, and bone marrow functions are required. Coagulation tests, renal function, metabolic panel, and blood count are evaluated. Preprocedure imaging includes cross-sectional imaging and PET/CT, which should be obtained within 1 month of the date of consultation. The PET/CT helps define active disease especially in cases with prior radiation. Clearance to undergo general anesthesia is required with focused assessment on ability to tolerate deep muscle paralysis, which is required to decrease unintended contractions caused by electrical pulses.

Special Considerations

IRE can be performed safely in peribiliary tumors.[20] Patients with an incompetent ampulla from a stent or resection from a Whipple procedure are at increased risk of infection and require extended antibiotic coverage. All patients receive bowel preparation similar to a colonoscopy to decrease risk of infection and decrease the chance of colon obscuring the pancreatic bed.

Timing of chemotherapy and the IRE procedure is coordinated with the referring oncologist to optimize bone marrow recovery before the intervention. Although vascular endothelial growth factor therapy is not commonly used in pancreatic cancer, if patients have any history of receiving bevacizumab (half-life of approximately 20 days), this must be held for at least 4 weeks before IRE.[21]

In the case of large lesions (greater than 5 cm), the patient is encouraged to continue chemotherapy when possible, and reassessed for a decrease in size on follow-up

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