Pancreatic Cancer Surgical Practice Guidelines

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Scope and Format of Guidelines

The Society of Surgical Oncology surgical practice guidelines focus on the signs and symptoms of primary cancer, timely evaluation of the symptomatic patient, appropriate preoperative extent of disease evaluation, and role of the surgeon in diagnosis and treatment. Separate sections on adjuvant therapy, follow-up programs, or management of recurrent cancer have been intentionally omitted. Where appropriate, perioperative adjuvant combined-modality therapy is discussed under surgical management. Each guideline is presented in minimal outline form as a delineation of therapeutic options.

Since the development of treatment protocols was not the specific aim of the Society, the extensive development cycle necessary to produce evidence-based practice guidelines did not apply. We used the broad clinical experience residing in the membership of the Society, under the direction of Alfred M. Cohen, MD, Chief, Colorectal Service, Memorial Sloan-Kettering Cancer Center, to produce guidelines that were not likely to result in significant controversy. Following each guideline is a brief narrative highlighting and expanding on selected sections of the guideline document, with a few relevant references. The current staging system for the site and approximate 5-year survival data are also included. The Society does not suggest that these guidelines replace good medical judgment. That always comes first. We do believe that the family physician, as well as the health maintenance organization director, will appreciate the provision of these guidelines as a reference for better patient care.

Society of Surgical Oncology Practice Guidelines: Pancreatic Cancer

Symptoms and Signs

- Adenocarcinoma involving the pancreatic head or uncinate process often causes obstruction of the intrapancreatic portion of the common bile duct, resulting in jaundice.
- Tumors in the pancreatic body and tail do not obstruct the bile duct, and therefore, patients are rarely diagnosed prior to the development of locally advanced or metastatic disease.
- In the absence of jaundice, patients often present with complaints of vague upper abdominal or back pain, weight loss due to anorexia, decreased energy level, and nonspecific upper gastrointestinal or dyspeptic symptoms.
- An occasional patient may present with a change in bowel habits secondary to pancreatic exocrine insufficiency due to tumor obstruction of the pancreatic duct; bowel movements may be loose, malodorous, and consistent with steatorrhea.
- New-onset hyperglycemia
- Nausea and vomiting secondary to duodenal obstruction

Evaluation of the Symptomatic Patient

Work-up

- History
- Physical examination
- Liver function tests and ultrasound (to confirm extrahepatic biliary obstruction in jaundiced patients)
- Extent of disease (both locoregional and distant) is assessed by contrast-enhanced helical CT scan.

1. Distant metastatic disease:

   - Confirm cytologic diagnosis.
   - Fine needle aspiration (FNA) cytology--CT-guided, endoscopic ultrasound (EUS)-guided, fluoroscopy-guided paracentesis (if ascites is present)

No distant metastatic disease:

   - Mass in pancreas considered unresectable-- EUS-guided or CT-guided FNA
   - No mass in pancreas--endoscopic retrograde cholangiopancreatography (ERCP) with biopsy demonstrating a malignant stricture

**Appropriate timeliness of surgical referral**

- Evaluation should begin as soon as symptoms are reported.

**Preoperative Evaluation for Extent of Disease**

- History and physical examination
- In the absence of hyperbilirubinemia, routine laboratory studies are of little value in arriving at the diagnosis of a pancreatic neoplasm. Most patients with adenocarcinoma will evidence a mild degree of hyperglycemia, yet this finding is often subtle and difficult to discriminate from very mild adult-onset diabetes mellitus.
- In the absence of extrahepatic biliary obstruction, elevated liver function tests should raise the suspicion of metastatic disease (as is true with other solid tumors).
- Intraoperative biopsy has a false-negative rate of at least 30% and has been associated with such complications as pancreatic fistula and pancreatitis. Since a negative biopsy is unlikely to alter the therapeutic strategy, intraoperative biopsy of the pancreas should generally be avoided.
- Many surgeons, however, are reluctant to proceed with pancreaticoduodenectomy in the absence of cytologic or histologic confirmation of disease. For those surgeons, EUS-guided or CT-guided FNA is a reasonable alternative. In patients eligible for clinical trials examining the value of preoperative radiation, chemotherapy, or both, preoperative EUS-guided FNA is the preferred method of cytologic confirmation of disease.
- Local criteria for resectability can be determined with a high degree of accuracy by preoperative imaging modalities.
- The use of contrast-enhanced helical CT obtained at 1.5- or 3.0-mm section thickness and 5-mm scan interval gives precise information regarding the relationship of the tumor to the superior mesenteric artery (SMA), hepatic artery, and celiac axis. The relationship of the tumor to the superior mesenteric-portal venous confluence is less reliably assessed by CT scan. However, the absence of a normal fat plane between the tumor and this venous structure should suggest the potential for tumor involvement of the lateral or posterior wall of the superior mesenteric or portal vein.
- Celiac and SMA angiography with venous phase imaging in selected patients (ie, patients considered for reoperative pancreaticoduodenectomy)
- Absolute criteria for unresectability include:

   1. The presence of distant metastatic disease
   2. Encasement of the celiac axis or SMA
   3. Occlusion of the superior mesenteric-portal venous confluence

**Role of the Surgeon in Initial Management**

The majority of patients with pancreatic cancer present with locally advanced or metastatic disease. The surgeon is often the entry point for the patient into the realm of therapeutic options.
Following an initial evaluation consisting of a physical examination, chest x-ray, and contrast-enhanced CT, it is possible to determine the extent of disease and the potential for surgical resection.

- Biliary decompression, when necessary, in patients with locally advanced, unresectable primary tumors and/or metastatic disease, should be performed endoscopically.
- Transhepatic decompression is a second-line alternative.
- Laparoscopically assisted cholecystojejunostomy in carefully selected patients
- In general, biliary enteric bypass via a standard laparotomy should be reserved for patients who experience repeated episodes of stent occlusion or cholangitis. The majority of operative biliary enteric bypass procedures should be performed in patients who are brought to the operating room for planned pancreatectomy and are found to be unresectable due to unsuspected metastatic disease or locally advanced primary tumors.

**Surgical considerations**

- For tumors to the right of the mesenteric vessels—pancreaticoduodenectomy (standard, pylorus-preserving, or extended pancreatectomy to include vascular resection and reconstruction in highly selected patients)
- For tumors to the left of the mesenteric vessels—distal pancreatectomy if resectable
- Palliative open or laparoscopic bypass surgery in selected patients not amenable to nonoperative biliary decompression
- Endoscopic, laparoscopic, and open laparotomy for biliary decompression or gastric bypass are all useful in selected patients. The role of each procedure in the individual patient depends on many variables, and definitive algorithms are lacking.

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Pancreatic cancer remains the fourth leading cause of cancer-related deaths in adults in the United States. Its etiology is unknown, and there is currently no effective method of early diagnosis. The development of molecular techniques to diagnose pancreatic cancer at a time when the tumor is localized to the pancreas would allow a greater number of patients to receive potentially curative therapy. In addition, effective treatment of subclinical, micrometastatic disease (which exists in the liver of most patients at the time of removal of the primary pancreatic tumor) would dramatically increase long-term survival rates following pancreaticoduodenectomy. These are areas of active laboratory investigation and early preclinical study.

**Staging**

TNM staging based on radiographic and operative findings (Table 1) does not directly correlate with treatment recommendations and therefore is not commonly used. Patients are best classified as having potentially resectable (T1-2, selected T3, NX, M0), locally advanced (T3, NX, M0), or metastatic disease (T1-3, NX, M1). Only recently has a pathologic staging system for resected specimens been suggested.[1]

**Recent Management Advances**

Recent advances in the clinical care of patients with pancreatic cancer have focused on: (1) decreasing treatment-related toxicity by utilizing accurate preoperative imaging, and (2) improving the quality and length of patient survival through the use of innovative multimodality therapy directed at known patterns of disease recurrence.[2,3]

**Preoperative Assessment**

Surgical resection, as part of a multimodality approach for patients with resectable pancreatic cancer, represents the only potentially curative treatment strategy. However, only 16% to 30% of patients who undergo operation with curative intent have their tumors successfully removed; the remaining patients are found to have unsuspected liver or peritoneal metastases or local tumor extension to the mesenteric vessels.[4] Only patients whose tumors are completely resected enjoy a survival benefit. Therefore, the majority of patients who undergo surgical exploration for presumed
cancer of the pancreatic head derive no survival benefit, yet the laparotomy results in a perioperative morbidity of 20% to 30%, a mean hospital stay of 14 to 20 days (with the recovery period lasting an additional 15 to 20 days), and a median survival of only 6 months. Furthermore, in patients whose tumors are resected with positive margins, survival is no better than in patients with locally advanced, unresectable disease treated by palliative chemotherapy and irradiation.[2,5] The need for accurate preoperative assessment is evidenced by the large number of positive margin resections recently reported[6] and the high incidence of local tumor recurrence following pancreaticoduodenectomy.[2,4] In addition, in patients with unresectable disease, endoscopic, percutaneous, and laparoscopic methods of biliary decompression make laparotomy for palliation unnecessary.

Contrast-enhanced helical CT can accurately assess the relationship of the tumor to the celiac axis and superior mesenteric artery (SMA). Potentially resectable primary tumors in the pancreatic head or uncinate process are defined preoperatively (on CT) by: (1) the absence of extrapancreatic disease; (2) no evidence of tumor extension to the celiac axis or SMA; and (3) a patent superior mesenteric vein (SMV) and portal vein.[2] Patients with locally advanced disease are not subjected to the potential morbidity and prolonged recovery period associated with a laparotomy, but instead, can receive biliary decompression, if needed, by means other than a laparotomy.

**Multimodality Treatment**

Aggressive multimodality treatment is reserved for patients with potentially resectable primary tumors defined by the CT criteria stated previously. Current treatment programs build on past experience, largely in unresectable tumors, using preoperative or postoperative chemotheraphy and radiation therapy combined with surgery.[7,8] The Gastrointestinal Tumor Study Group (GITSG) first demonstrated a survival advantage for pancreatic cancer patients treated with adjuvant chemoradiation (40 Gy of external-beam irradiation plus concomitant fluorouracil [5-FU]) following pancreaticoduodenectomy, compared with patients treated with surgical resection alone (median survival, 20 vs 11 months).[9]

This treatment advantage was confirmed in a group of 30 additional patients treated with postoperative chemoradiation.[10] Delivery of adjuvant therapy, however, was hindered by the prolonged recovery time of most patients following pancreaticoduodenectomy. Many patients required more than 10 weeks to achieve a performance status necessary for treatment with chemoradiation.

The inability of some patients to tolerate postoperative therapy, combined with the growing popularity of neoadjuvant therapy in patients with other solid tumors, caused investigators to consider giving radiation and chemotherapy prior to surgery in patients with potentially resectable pancreatic cancer. The use of preoperative chemoradiation is supported by the following considerations[2]: (1) Radiation therapy is more effective in well-oxygenated cells that have not been exposed to the devascularization of surgery. (2) Radiation therapy before surgical exploration may prevent the implantation and dissemination of tumor cells at the time of laparotomy, thereby decreasing subsequent peritoneal failure. (3) Patients with disseminated disease evident on restaging studies after chemoradiation are not subjected to laparotomy.[3]

**Management Principles**

The following management principles can be applied to most patients with presumed adenocarcinoma of the pancreas:

- **Endoscopic retrograde cholangiopancreatography (ERCP)** is performed when CT demonstrates obstruction of the intrapancreatic portion of the extrahepatic bile duct without a low-density mass in the pancreatic head.
- When CT demonstrates a low-density tumor mass in the pancreatic head, resectability is assessed preoperatively (as defined above). Patients with CT evidence of arterial encasement, venous occlusion, or extrapancreatic disease are not considered for surgical resection. Biliary decompression, if necessary, is usually performed endoscopically.
- The decision to proceed with pancreaticoduodenectomy is made preoperatively based on high-quality imaging studies. There are few indications for intraoperative biopsy of the pancreas. For those surgeons who will not proceed with pancreaticoduodenectomy in the absence of tissue confirmation of malignancy, data suggest that preoperative CT-guided FNA provides a safe and accurate alternative.[11] Endoscopic ultrasound-guided FNA is currently replacing CT-guided FNA at most centers. Experience with reoperative pancreatectomy...
supports the opinion that there is no place for "exploratory" laparotomy in patients with
biopsy-proven or suspected pancreatic cancer; rather, the operative plan should be carefully
outlined preoperatively.[12]
- A definitive algorithm for palliative decompression of unresectable patients is lacking. Stent
placement and laparoscopic or open operative decompression are all useful bypass
strategies.

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