American Society For Gastrointestinal Endoscopy

The role of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy

This is one of a series of statements discussing the utilization of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts.

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus. Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

INTRODUCTION

With the advancement in imaging technology, the evaluation and management of the patient with pancreaticobiliary malignancy has changed. This document will review the approach to the evaluation and treatment of the patient with suspected pancreaticobiliary malignancy. Table 1 outlines the types of malignancies discussed in this guideline. The approach to patients with purely intrahepatic malignancies, suspected cystic neoplasms, or islet cell tumors will not be addressed.

PRESENTATION, CLINICAL EVALUATION

Patients with suspected pancreaticobiliary malignancy may present clinically with obstructive jaundice, abdominal pain, anorexia, abnormal liver enzymes, weight loss, new onset diabetes mellitus, or steatorrhea. Elevations in the levels of serum bilirubin and alkaline phosphatase suggest biliary obstruction. Conversely, patients with pancreatic malignancy and no biliary involvement usually have normal liver enzymes. A history of inflammatory bowel disease or previously diagnosed malignancies should be sought. A complete physical examination, including assessment for abnormal lymph nodes, jaundice, hepatomegaly, palpable gallbladder, or mass should be performed. A chest radiograph may be appropriate to exclude pulmonary metastases. Obtaining serum tumor markers such as CA 19-9 and CEA may be appropriate.[1,2,3] Once there is a clinical suspicion of a pancreaticobiliary malignancy, further investigation with abdominal imaging studies is appropriate.

Table 1. Pancreaticobiliary malignancies

Ampullary adenocarcinoma
Pancreatic adenocarcinoma
Head
Body/tail
Cholangiocarcinoma
Hilar
Non-hilar
Metastatic disease

TYPES OF PANCREATICOBILIARY MALIGNANCIES (TABLE 1)

Ampullary carcinoma

Ampullary carcinoma is suspected based upon the demonstration of obstructive jaundice, often with dilation of the pancreatic and biliary ducts seen on abdominal imaging studies. A discrete mass may or may not be identifiable by using standard transabdominal US (TUS) or helical CT scanning. ERCP allows for direct identification and biopsy confirmation,[4] although biopsy conformation is not 100% accurate.[5] MRCP may allow identification of the lesion and obviate diagnostic ERCP.[6] EUS allows for more accurate diagnosis and staging of these lesions than CT and also allows for forceps and FNA tissue sampling.[7,8,9] EUS also may allow selection of patients that can undergo local resection instead of pancreaticoduodenectomy (Whipple operation).[10] Once the lesion is identified and staged, palliation of jaundice or operative resection for a cure is similar

Table 2. The 2003 revised American Joint Committee on Cancer TNM staging system for pancreatic adenocarcinoma

Primary tumor (T)			
TX	Primary tumor cannot be assessed		
T0	No evidence of primary tumor		
Tis	Carcinoma in situ		
T1	Tumor limited to the pancreas 2 cm or less in greatest dimension		
T2	Tumor limited to the pancreas more than 2 cm in greatest dimension		
T3	Tumor extends beyond the pancreas but without involvement of the celiac axis or superior mesenteric artery		
T4	Tumor involves the celiac axis or superior mesenteric artery (unresectable primary tumor)		
Regional lymph nodes (N)			
NX	Regional lymph nodes cannot be assessed		
N0	No regional lymph node metastasis		
N1	Regional lymph node metastasis		
Distant metastasis (M)			
MX	Distant metastasis cannot be assessed		
M0	No distant metastasis		
M1	Distant metastasis		
Stage grouping			
0	Tis	N0	M0
IA	T1	N0	M0
IB	T2	N0	M0
IIA	T3	N0	M0
IIB	T1	N1	M0
	T2	N1	M0
	T3	N1	M0
III	T4	Any N	M0
IV	Any T	Any N	M1

as is discussed for carcinoma of the pancreatic head (see below).

Pancreatic malignancy

The approach to the patient with pancreatic carcinoma involving the pancreatic head is different than in the patient with body/tail lesions in terms of curative potential and accessibility, as well as palliation. They will be discussed separately.

Pancreatic head. Most patients with cancer of the pancreatic head present with obstructive jaundice. Radiological imaging studies are performed allowing for (a) detection of the tumor,(b) determination of tumor resectability, and (c) tissue acquisition under imaging guidance. The American Joint Committee on Cancer staging system has recently been updated and can be seen in Table 2.

Transabdominal US. Transabdominal US will suggest biliary obstruction by the demonstration of biliary ductal dilation. It also may identify the presence of obvious liver metastases. However, standard TUS is operator dependant and has a poor sensitivity for detecting small neoplasms of the pancreatic head.[11] Recent advances in TUS, such as color-power Doppler US, US angiography, harmonic imaging (tissue harmonic imaging and contrast harmonic imaging), and 3-dimensional US (including virtual endoscopy), may improve the usefulness of this modality in the staging of pancreatic cancer.[12] Nonetheless, more information regarding staging and extent of disease, and possible nodal or vascular involvement is obtainable with other imaging modalities.

Computed tomography. Helical CT scanning of the abdomen with fine cuts through the pancreas during the arterial and portal phases of contrast enhancement has a high sensitivity and specificity for the detection of pancreatic carcinoma. It allows for detection of tumor extension, liver metastases, and invasion of vascular structures.[13] Helical CT is an accurate means for the detection of pancreatic adenocarcinoma and determining resectability.[14] Multislice (multidetector) CT has been introduced and may improve the accuracy even more than helical CT.[14] If the CT findings are found to be highly suggestive of resectable pancreatic carcinoma in the appropriate clinical setting and the patient is felt to be an operative candidate, a reasonable approach is to refer the patient directly for surgical resection (pancreaticoduodenectomy) without further imaging or diagnostic testing. Transabdominal or CT-guided biopsy of the pancreatic mass rarely may result in tumor seeding at the needle track or within the peritoneum and has been reported to increase the risk of postoperative recurrence.[15,16]

If the CT scan reveals overt evidence of unresectable pancreatic cancer or the patient is a nonoperative candidate because of comorbid medical conditions, nonoperative palliation of obstructive jaundice should be performed at the time of ERCP (see below). If a definitive tissue diagnosis is required for the administration of chemotherapy and/or radiation therapy, tissue acquisition can be performed at the time of palliative ERCP.[17,18] If a tissue diagnosis cannot be made at that time, then transabdominal biopsy (CT-guided or US) of the mass or metastatic disease sites (i.e., liver lesions), or EUS-guided FNA of the mass or metastatic sites should be performed.[19]

Magnetic resonance imaging. Magnetic resonance imaging (MRI) of the pancreas may include MRI, MRCP, or magnetic resonance angiography.[20] Standard abdominal MRI appears to be an accurate modality for staging pancreatic carcinoma, though it does not appear to be more specific or sensitive than helical CT.[14,21] In addition, it is

more expensive and more time consuming to perform than CT.

EUS. If expertise in EUS is readily available, it should be used as a preoperative staging modality in patients with suspected pancreatic cancer. This is particularly important in patients with equivocal findings on CT or those with comorbidities and, therefore, at higher risk for intra-operative or post-operative complications. EUS allows identification of vascular invasion as well as sampling of suspicious-appearing lymph nodes, which, if positive, may change the treatment approach as it alters prognosis.[22] EUS appears to be complementary to helical CT, with EUS better at detecting small (<3 cm) masses, staging the portal vein, and detecting lymph node metastases, while helical CT is superior for staging arterial involvement and distant metastases.[22] A EUS-guided FNA biopsy specimen allows for a definitive tissue diagnosis of a pancreatic mass when results on other biopsy methods are negative but pancreatic cancer is suspected.[23,24] If EUS suggests resectability, EUS-guided biopsy of the mass is not necessary before proceeding with operative resection, although this point remains controversial. Advantages of needle biopsy of the mass include identification of alternative diagnoses to primary pancreatic adenocarcinoma (lymphoma, islet cell tumors, metastatic disease).[25] It also allows for preoperative patient counseling. Potential disadvantages of preoperative EUS-guided FNA include the risks of pancreatitis, bleeding, and tumor seeding.[26] The latter has never been reported and appears to be inconsequential in most cases since the needle path usually will be within the resected specimen. Ideally, EUS should be performed before ERCP with stent placement since this may interfere with the accuracy of EUS staging[27] and EUS findings of unresectable carcinoma allows patient selection for self-expanding metallic stent (SEMS) placement. In patients with unresectable cancer, EUS-guided celiac plexus neurolysis has been shown to control disabling abdominal pain.[28]

ERCP. The pathognomonic findings on ERCP of a pancreatic head cancer are strictures of the bile and pancreatic ducts with proximal dilation ("double-duct" sign). While ductal abnormalities are almost invariably present in patients with adenocarcinoma, other imaging modalities (CT, MR, EUS) have supplanted ERCP in the diagnosis of pancreatic cancer. Preoperative ERCP does not add further staging information and may result in complications (pancreatitis, perforation) that may make operative intervention more difficult and/or may considerably delay operative intervention resulting in a decreased potential for curative resection.[29] Furthermore, even if no ERCP-related complications occur, several studies suggest post-operative complications after pancreaticoduodenectomy are higher when a preoperative ERCP is performed.[29] However, if the patient suffers from cholangitis or severe pruritus, or if there is a substantial delay in operative resection, preoperative ERCP with biliary drainage should be performed.[29]

Palliation of obstructive jaundice can be achieved with ERCP and biliary stent placement. Randomized trials comparing ERCP and biliary stenting with surgery demonstrate equal palliation of jaundice with ERCP, though more frequent recurrence of jaundice.[30,31] Unfortunately, these studies were performed before the advent of biliary SEMS or duodenal stents (for palliation of gastric outlet obstruction). A recent meta-analysis suggests that surgical or endoscopic palliation is appropriate and should be tailored to the individual patient.[32] In those patients in whom ERCP is unsuccessful, percutaneous transhepatic cholangiography, and stent placement should be offered for palliation of obstructive jaundice.[33] Plastic stents occlude from the deposition of bacterial biofilm resulting in cholangitis and recurrence of jaundice. Biliary SEMS have a significantly longer patency rate than 10F plastic stents.[34] This advantage will only be realized if the patient survives more than the anticipated time to stent occlusion of 3 to 4 months. Since biliary SEMS are significantly more expensive than plastic stents, their use should be reserved for patients whose estimated survival is greater than 3 to 4 months[35] and/or those patients without liver metastases.[36]

In patients with unresectable pancreatic carcinoma who develop malignant gastric outlet obstruction, endoscopic palliation may be achieved by using self-expandable gastroduodenal stents.[37,38]

Pancreatic body/tail. Patients with pancreatic cancer involving the body and tail are less likely to have resectable tumors since symptoms generally do not occur until they have advanced disease. A similar approach to the patient with pancreatic carcinoma of the head is in order, though ERCP has little, if any, role in the diagnosis and palliation of these patients. EUS allows for tissue diagnosis and staging.

Suspected cholangiocarcinoma

A primary tumor of the bile duct should be suspected based upon clinical and imaging findings. Abdominal CT scans will show biliary dilation without an associated pancreatic mass or pancreatic ductal dilation, and the level of obstruction usually can be localized to a level above the pancreatic

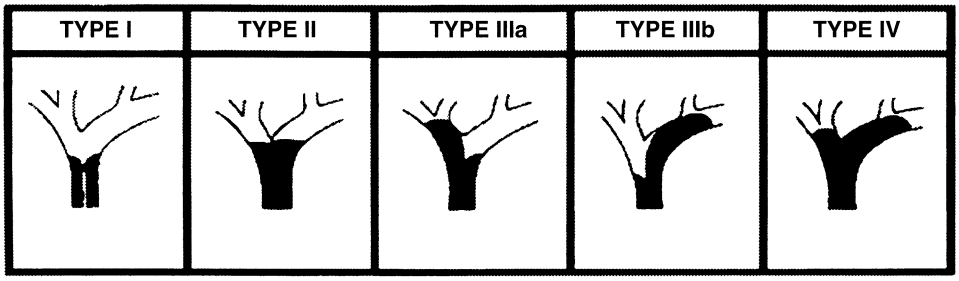

Figure 1. The Bismuth classification of cholangiocarcinoma. (Reprinted with permission from Cheng JL et al, Gastrointest Endosc 2002;56:33-9.)

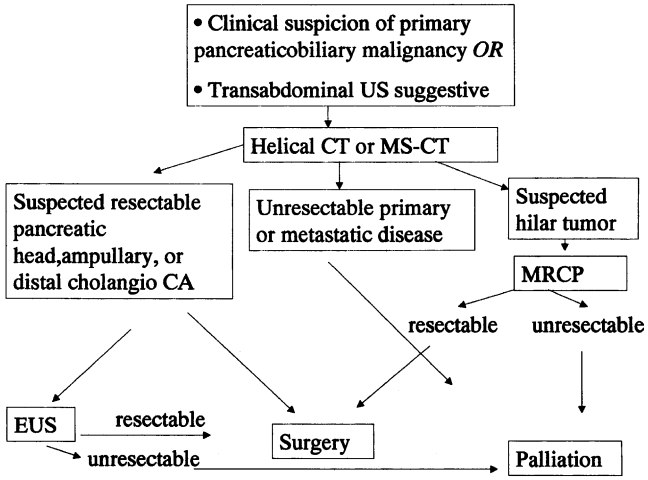

Figure 2. A suggested algorithm for diagnosis and management of pancreaticobiliary malignancy.

head but at or below the level of the hepatic bifurcation.

The differentiation of hilar vs. non-hilar tumors is important because of both the difficulty in resection of hilar tumors, as well as the approach to endoscopic palliation in these patients. The Bismuth classification of cholangiocarcinoma is useful for determining surgical resectability and type of surgery, and is shown in Figure 1.

Non-hilar cholangiocarcinoma. If the level of obstruction is traced to below the level of the bifurcation (Bismuth type I lesions, Fig. 1) by imaging studies, operative resection should be considered in fit patients without metastatic disease. If the patient is a poor operative candidate, then palliation with plastic or metal stents, as with pancreatic carcinoma, should be undertaken.

Hilar cholangiocarcinoma. The approach to the patient with cholangiocarcinoma involving the bifurcation requires definition of the biliary anatomy to determine operative resectability. Extensive injection of contrast during ERCP to define the anatomy usually results in contrast injection into both intrahepatic systems. This should be avoided as it increases the risk of post-procedural cholangitis since the entire biliary tree may not be amenable to drainage.[39] Therefore, after an abdominal CT scan has suggested hilar cholangiocarcinoma, MRCP, and MRI should be the performed to determine ductal anatomy.[40] If the CT and MRI suggest resectable disease, the patient should be sent for surgery if the patient's health status permits. If the lesion is deemed unresectable by MRI or if the patient is unfit for surgery, unilaterally directed endoscopic biliary stent placement directed by MRI should be performed,[41] since unilateral stent placement offers palliation of jaundice equal to bilateral placement but with less risk of cholangitis.[42] This method also appears to be more cost-effective.[43]

EUS. EUS has not been proven to offer more information than that which may be obtained by

using other imaging modalities in patients with suspected cholangiocarcinoma. One small series suggests that EUS may allow a definitive tissue diagnosis to be made in patients with hilar tumors.[44] Intraductal US (IDUS), at the time of ERCP, may add useful information in the patient with a suspected pancreaticobiliary malignancy, especially cholangiocarcinoma.[45,46] However, there are limited data to date, the exact role has yet to be defined, and the availability of this technology is limited to specialized centers.

Metastatic disease

A variety of malignant diseases may metastasize to and around the biliary tree resulting in obstruction. These may lead to biliary obstruction either intrinsically or extrinsically (porta hepatic involvement) from the level of the bifurcation to the ampulla. The diagnosis may be obvious based upon known widespread malignancy, or more occult and discovered at the time of surgical resection or endoscopic evaluation.[47] CT scan findings may mimic primary malignant disease of the bile ducts or pancreas.[48] An MRI may be useful in establishing perihilar obstructive disease.[49] If disease is widespread, palliation of obstruction is achieved as discussed for primary malignancies.[50] Surgical resection may be indicated in selected cases.

A suggested algorithm for evaluation and management of patients with pancreaticobiliary malignancy is seen in Figure 2.

SUMMARY

For the following points: *(A),* prospective controlled trials; *(B),* observational studies; *(C),* expert opinion.

- The evaluation of patients with suspected pancreaticobiliary malignancy should include helical or multislice CT of the abdomen. *(B)*
- EUS, if available, should be performed for further staging and possible FNA of the primary tumor and/or suspicious lymph nodes unless obvious metastatic disease is present. *(B)*
- If the disease is resectable and the patient is fit, surgical resection of the lesion should be performed. *(B)*
- If the lesion is unresectable or the patient is unfit for surgery, then endoscopic palliation of jaundice *(A)* or gastric outlet obstruction should be undertaken. *(B)*
- Preoperative ERCP should be avoided unless there is cholangitis or significant delay in surgery and the patient is symptomatic. *(B)*
- If the CT suggests cholangiocarcinoma, particularly of the bifurcation, an MRCP should be obtained to assess for resectability. If unresectable, endoscopic palliation of jaundice should be performed by using the MRCP as a guide for unilateral drainage to minimize cholangitis. *(A)*

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