# Complete Summary

## GUIDELINE TITLE

Role of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy.

## BIBLIOGRAPHIC SOURCE(S)

Baron TH, Mallery JS, Hirota WK, Goldstein JL, Jacobson BC, Leighton JA, Waring JP, Faigel DO. The role of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy. Gastrointest Endosc 2003 Nov;58(5):643-9. [50 references] PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

SCOPE
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
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## SCOPE

### DISEASE/CONDITION(S)

Pancreaticobiliary malignancy including ampullary carcinoma, pancreatic adenocarcinoma (head; body/tail), cholangiocarcinoma (hilar; non-hilar), and metastatic disease

**Note**: The approach to patients with purely intrahepatic malignancies, suspected cystic neoplasms, or islet cell tumors is not addressed.

### GUIDELINE CATEGORY

Evaluation
Management
Treatment

## CLINICAL SPECIALTY

Gastroenterology
Oncology

## INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

To review the approach to the evaluation and treatment of the patient with suspected pancreaticobiliary malignancy

## TARGET POPULATION

Patients with suspected pancreaticobiliary malignancy

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis/Evaluation

1. Serum bilirubin
2. Serum alkaline phosphatase
3. Complete physical examination
4. Serum tumor markers (i.e., CA 19-9 and carcinoembryonic antigen [CEA])
5. Chest x-ray
6. Transabdominal ultrasonography (TUS)
7. Helical computed tomography (CT) scan
8. Endoscopic ultrasound (EUS)
9. Endoscopic retrograde cholangiopancreatography (ERCP)
10. Magnetic resonance cholangiopancreatography (MRCP)
11. Fine-needle aspiration (FNA) tissue sampling
12. Biopsy
13. Magnetic resonance imaging (MRI) including MRI, MR cholangiopancreatography (MRCP), or MR angiography
14. Percutaneous transhepatic cholangiography (PTC)
15. Intraductal ultrasonography (IDUS)

### Management

1. Pancreaticoduodenectomy
2. Surgical resection
3. Nonoperative palliation of obstructive jaundice
4. Chemotherapy and/or radiation therapy
5. PTC with stent placement
6. Endoscopic palliation

## MAJOR OUTCOMES CONSIDERED

- Signs and symptoms
- Sensitivity and specificity of diagnostic tests

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In preparing this guideline, a MEDLINE literature search was performed, and additional references were obtained from bibliographies of the identified articles and from recommendations of expert consultants.

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate utilization of endoscopy are based on a clinical review of the available data and expert consensus.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Not stated

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Recommendations are followed by evidence grades (A-C) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

### 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 X-ray may be appropriate to exclude pulmonary metastases. Obtaining serum tumor markers such as CA 19-9 and carcinoembryonic antigen (CEA) may be appropriate. Once there is a clinical suspicion of a pancreaticobiliary malignancy, further investigation with abdominal imaging studies is appropriate.

### Types of Pancreaticobiliary Malignancies

*Ampullary Adenocarcinoma*

- Pancreatic Adenocarcinoma
  - Head
  - Body/tail
- Cholangiocarcinoma
  - Hilar

    - Non-hilar
- Metastatic Disease

**Ampullary Carcinoma**

Ampullary carcinoma is suspected based upon 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 using standard transabdominal ultrasound or helical computed tomography (CT) scanning. Endoscopic retrograde cholangiopancreatography (ERCP) allows for direct identification and biopsy confirmation, although biopsy is not 100% accurate . Magnetic resonance cholangiopancreatography (MRCP) may allow identification of the lesion and obviate diagnostic ERCP. Endoscopic ultrasound (EUS) allows for more accurate diagnosis and staging of these lesions than CT, and also allows for forceps and fine-needle aspiration (FNA) tissue sampling. EUS may also allow selection of patients that can undergo local resection instead of pancreaticoduodenectomy (Whipple operation). Once the lesion is identified and staged, palliation of jaundice or operative resection for cure is similar as is discussed for carcinoma of the pancreatic head, below.

**Pancreatic Malignancy**

The approach to the patient with pancreatic carcinoma involving the pancreatic head is different than 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
c. Tissue acquisition under imaging guidance

The American Joint Committee on Cancer staging system has recently been updated:

| **PRIMARY TUMOR (T)** | |
|---|---|
| TX | Primary tumor cannot be assessed |
| TO | 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)** | |

| PRIMARY TUMOR (T) | |
|---|---|
| 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 |
| IIII | T4 | Any N | M0 |
| V | Any T | Any N | M1 |

Transabdominal Ultrasonography (TUS)

TUS will suggest biliary obstruction by the demonstration of biliary ductal dilation. It may also 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. Recent advances in TUS such as color-power Doppler ultrasonography, ultrasonographic angiography, harmonic imaging (tissue harmonic imaging and contrast harmonic imaging), and 3-dimensional ultrasonography (including virtual endoscopy) may improve the usefulness of this modality in the staging of pancreatic cancer. 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. Helical CT is an accurate means for the detection of pancreatic adenocarcinoma and determining resectability. Multislice (multidetector) CT has been introduced and may improve the accuracy even further than helical CT. 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 may rarely result in tumor seeding at the needle track or within the peritoneum and has been reported to increase the risk of postoperative recurrence.

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 chemo and/or radiation therapy, tissue acquisition can be performed at the time of palliative ERCP. If a tissue diagnosis cannot be made at that time, then transabdominal biopsy (CT-guided or ultrasound) of the mass or metastatic disease sites (i.e. liver lesions), or EUS-guided FNA of the mass or metastatic sites should be performed.

Magnetic Resonance Imaging (MRI)

MRI of the pancreas may include MRI, MRCP, or MR angiography. 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. Additionally, it is more expensive and more time consuming to perform than CT.

Endoscopic Ultrasound (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 intraoperative or postoperative 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. 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. EUS-guided FNA biopsy allows for a definitive tissue diagnosis of a pancreatic mass when results on other biopsy methods are negative but pancreatic cancer is suspected. If EUS suggests resectability, EUS-guided biopsy of the mass is not necessary prior to 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). It also allows for preoperative patient counseling. Potential disadvantages of preoperative EUS-guided FNA include the risks of pancreatitis, bleeding, and tumor seeding. The latter has never been reported and appears to be inconsequential in most cases since the needle path will usually be within the resected specimen. Ideally EUS should be performed prior to ERCP with stent placement since this may interfere with the accuracy of EUS staging and EUS findings of unresectable carcinoma allows patient selection for self-expanding metallic stent placement. In patients with unresectable cancer EUS-guided celiac plexus neurolysis has been shown to control disabling abdominal pain.

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 considerably delay operative intervention resulting in a decreased potential for curative resection. Furthermore, even if no ERCP-related complications occur, several studies suggest postoperative complications following pancreaticoduodenectomy are higher when a preoperative ERCP is performed. 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.

Palliation of obstructive jaundice can be achieved with ERCP and biliary stent placement. Randomized trials comparing ERCP and biliary stenting to surgery demonstrate equal palliation of jaundice with ERCP, though more frequent recurrence of jaundice. Unfortunately, these studies were performed prior to the advent of self-expandable metal biliary stents 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. In those patients in whom ERCP is unsuccessful, percutaneous transhepatic cholangiography (PTC) and stent placement should be offered for palliation of obstructive jaundice. Plastic stents occlude from the deposition of bacterial biofilm resulting in cholangitis and recurrence of jaundice. Biliary self-expandable metal stents (SEMS) have a significantly longer patency rate than 10Fr plastic stents. 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 three to four months and/or those patients without liver metastases.

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

*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 can usually be localized to a level above the pancreatic head, but at or below the level of the hepatic bifurcation.

The differentiation of hilar versus 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. Please refer to the figure titled "The Bismuth classification of cholangiocarcinoma" in the original guideline document.

*Non-Hilar Cholangiocarcinoma*

If the level of obstruction is traced to below the level of the bifurcation (Bismuth type I lesions, see figure titled "The Bismuth classification of cholangiocarcinoma" in the original guideline document) by imaging studies, operative resection should be considered in fit patients without metastatic disease. If the patient is a poor operative candidate, then palliation using plastic or metal stents as for 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. Therefore after an abdominal CT scan has suggested hilar cholangiocarcinoma, MRCP and MRI should be performed to determine ductal anatomy. If the CT and MRI suggest resectable disease, the patient should be sent for surgery if their health status permits. If the lesion is deemed unresectable by MRI or the patient is unfit for surgery, unilaterally directed endoscopic biliary stent placement directed by MRI should be performed since unilateral stent placement offers palliation of jaundice equal to bilateral placement but with less risk of cholangitis. This method also appears to be more cost-effective.

Endoscopic Ultrasonography

EUS has not been proven to offer more information than that which may be obtained 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. Intraductal ultrasonography (IDUS) at the time of ERCP may add useful information in the patient with a suspected pancreaticobiliary malignancy, especially cholangiocarcinoma. 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. CT scan findings may mimic primary malignant disease of the bile ducts or pancreas. MRI may be useful in establishing perihilar obstructive disease. If disease is widespread, palliation of obstruction is achieved as discussed for primary malignancies. Surgical resection may be indicated in selected cases.

A suggested algorithm for evaluation and management of patients with pancreaticobiliary malignancy can be found in the figure titled "A suggested algorithm for diagnosis and management of pancreaticobiliary malignancy" of the original guideline document.

**Summary**

- 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 or 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 using the MRCP as a guide to unilateral drainage to minimize cholangitis **(A)**.

**Definitions**

**A**: Prospective controlled trials
**B**: Observational studies
**C**: Expert opinion

## CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for the diagnosis and management of pancreaticobiliary malignancy.

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and classified for the recommendations using the following scheme:

**A** = Prospective controlled trials
**B** = Observational studies
**C** = Expert opinion

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate utilization of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy

### POTENTIAL HARMS

- Standard transabdominal ultrasonography (TUS) is operator dependent and has a poor sensitivity for detecting small neoplasms of the pancreatic head.
- Potential disadvantages of preoperative endoscopic ultrasonography (EUS)-guided fine-needle aspiration (FNA) include the risks of pancreatitis, bleeding, and tumor seeding. The latter has never been reported and appears to be inconsequential in most cases since the needle path will usually be within the resected specimen.
- Preoperative endoscopic retrograde cholangiopancreatography (ERCP) does not add further staging information and may result in complications (pancreatitis, perforation) that may make operative intervention more difficult and/or considerably delay operative intervention resulting in a decreased potential for curative resection. Furthermore, even if no ERCP-related complications occur, several studies suggest postoperative complications following pancreaticoduodenectomy are higher when a preoperative ERCP is performed.
- 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 amenable to drainage.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- 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.
- The information in this guideline is intended only to provide general information and not as a definitive basis for diagnosis or treatment in any particular case. It is very important that individuals consult their doctors about specific conditions.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Baron TH, Mallery JS, Hirota WK, Goldstein JL, Jacobson BC, Leighton JA, Waring JP, Faigel DO. The role of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy. Gastrointest Endosc 2003 Nov;58(5):643-9. [50 references] PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2003 Nov

### GUIDELINE DEVELOPER(S)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

### SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

### GUIDELINE COMMITTEE

Standards of Practice Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

### GUIDELINE STATUS

This is the current release of the guideline.

### GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy (ASGE) Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

### AVAILABILITY OF COMPANION DOCUMENTS

None available

### PATIENT RESOURCES

None available

### NGC STATUS

This NGC summary was completed by ECRI on October 18, 2004. The information was verified by the guideline developer on November 5, 2004.

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