



Complete Summary

GUIDELINE TITLE

Staging laparoscopy for pancreatic adenocarcinoma. In: Diagnostic laparoscopy guidelines.

BIBLIOGRAPHIC SOURCE(S)

Staging laparoscopy for pancreatic adenocarcinoma. In: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Diagnostic laparoscopy guidelines. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2007 Nov. p. 24-35.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for diagnostic laparoscopy. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2002 Mar. 5 p.

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SCOPE

DISEASE/CONDITION(S)

Pancreatic adenocarcinoma

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Gastroenterology
Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist surgeons' decisions about the appropriate use of staging laparoscopy in patients with pancreatic adenocarcinoma
- To update the previous 2002 guidelines on this topic

TARGET POPULATION

Patients with pancreatic adenocarcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

Use of staging laparoscopy in patients with pancreatic adenocarcinoma

MAJOR OUTCOMES CONSIDERED

- Conversion to open procedure rate
- Procedure-related/intraoperative complications
- Procedure-related morbidity
- Port-site recurrence rate
- Postoperative hospital length of stay
- Cost-effectiveness
- Mortality

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

A systematic literature search of MEDLINE for the period 1995-2005 was limited to English language articles. The search strategy is shown in Figure 1 in the original guideline document. Using the same strategy, the Cochrane database of

evidence-based reviews and the Database of Abstracts of Reviews of Effects (DARE) were searched.

Abstracts were reviewed by three committee members and into the following categories:

- Randomized studies, meta-analyses, and systematic reviews
- Prospective studies
- Retrospective studies
- Case reports
- Review articles

Randomized controlled trials, meta-analyses, and systematic reviews were selected for further review along with prospective and retrospective studies that included at least 50 patients; studies with smaller samples were reviewed when other available evidence was lacking. The most recent reviews were also included. All case reports, old reviews, and smaller studies were excluded.

The reviewers graded the level of evidence of each article and manually searched the bibliographies for additional articles that may have been missed by the search. Any additional relevant articles were included in the review and grading.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization Or Cohort of case-control studies Or Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

To maximize the efficiency of the review, articles were divided into three subject categories:

- Staging laparoscopy for cancer
- Diagnostic laparoscopy for acute conditions
- Diagnostic laparoscopy for chronic conditions

Reviewers graded the level of each article (see "Rating Scheme for the Strength of the Evidence.")

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The statements included in this guideline are the product of a systematic review of published work on the topic, and the recommendations are explicitly linked to the supporting evidence. The strengths and weaknesses of the available evidence are described and expert opinion sought where the evidence is lacking. This is an update of previous guidelines on this topic (last revision 2002) as new information has accumulated.

The guidelines were developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons and the guidelines committee and approved by the Board of Governors.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Scale Used for Recommendation Grading

Grade A	Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
Grade B	Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel
Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

COST ANALYSIS

Although high quality evidence on the cost effectiveness of staging laparoscopy (SL) is lacking, the literature suggests that SL is more cost-effective than open exploration when it is the only procedure required (i.e., in patients with unsuspected metastatic disease identified during SL). This is a consequence of

decreased patient length of stays. On the other hand, the cost-effectiveness of SL when applied in the diagnostic algorithm of all pancreatic cancer patients appears to be linked directly to the yield of the procedure in identifying patients with imaging occult disease. In a cost utility analysis of the most effective management strategy for pancreatic cancer patients, at least a 30% yield was needed for SL to be more cost-effective than open exploration.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations of each guideline undergo multidisciplinary review and are considered valid at the time of production based on the data available. This statement was reviewed by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), November 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of the recommendations (**A, B, C**) and the levels of evidence (**I, II, III**) are provided at the end of the "Major Recommendations" field.

General Recommendations for Diagnostic Laparoscopy

Diagnostic laparoscopy is a safe and well tolerated procedure that can be performed in an inpatient or outpatient setting under general or occasionally local anesthesia with intravenous sedation in carefully selected patients. Diagnostic laparoscopy should be performed by physicians trained in laparoscopic techniques who can recognize and treat common complications and can perform additional therapeutic procedures when indicated. During the procedure, the patient should be continuously monitored, and resuscitation capability must be immediately available. Laparoscopy must be performed using sterile technique along with meticulous disinfection of the laparoscopic equipment.

Staging Laparoscopy (SL) for Pancreatic Adenocarcinoma

Technique

The feasibility of SL has been demonstrated in multiple studies with success rates ranging from 94-100% (**Level II, III**). Dense adhesions that impair inspection and examination with the ultrasound probe are the main reason for technical failures. Nevertheless, even patients with adhesions can be examined; however, the extent and yield of the examination may be compromised. Conversions to open surgery are uncommon and have been reported to occur in <2% of patients in a large series (**Level III**).

The procedure is usually performed under general anesthesia, and the majority of reports have used 15 mm Hg insufflation pressures. A thorough evaluation of peritoneal surfaces is performed. The suprahepatic and infrahepatic spaces, the surface of the bowel, the lesser sac, the root of the transverse mesocolon and small bowel, the ligament of Treitz, the paracolic gutters, and pelvis are inspected with frequent bed position changes as necessary. In addition to visual inspection, peritoneal washings can be performed, ascitic fluid, if present, sent for cytology, and biopsy specimens of lesions suspected to be malignant obtained. When no metastatic disease is identified on inspection, a detailed laparoscopic ultrasound examination can be employed during which the deep hepatic parenchyma, the portal vein, mesenteric vessels, celiac trunk, hepatic artery, the entire pancreas, and even pathologic periportal and paraaortic nodes can be evaluated and biopsied. The addition of color flow Doppler can further assist in the assessment of vascular patency.

A controversy exists in the literature about the extent of SL for pancreatic adenocarcinoma patients. Advocates of a short duration procedure that is based only on inspection of abdominal organ surfaces argue that the procedure can be performed quickly (usually within 10–20 min), can be done through one port, does not require significant expertise, minimizes the risk of potential complications by the dissection near vascular structures, and has good diagnostic accuracy (**Level III**). On the other hand, advocates of a more extensive procedure that includes opening the lesser sac and assessment of the vessels argue that the diagnostic accuracy of the procedure can be enhanced by detecting metastatic lesions in the lesser sac, vascular invasion by the tumor, or deep hepatic metastasis, often missed by visual inspection alone, and that it can be performed safely without a significant increase in morbidity and within a reasonable time (**Level II, III**).

It is very important, therefore, to consider these differences in the SL technique when evaluating reports of the diagnostic yield of this procedure in patients with pancreatic adenocarcinoma.

Indications

- As a staging procedure for pancreatic adenocarcinoma
- For detection of imaging occult metastatic disease or unsuspected locally advanced disease in patients with resectable disease based on preoperative imaging prior to laparotomy
- For assessment prior to administration of neo-adjuvant chemoradiation
- For selection of palliative treatments in patients with locally advanced disease without evidence of metastatic disease on preoperative imaging

Recommendations

SL can be performed safely in patients with pancreatic adenocarcinoma (**Grade B**). The procedure should be considered after high quality imaging studies have excluded metastatic disease in appropriately selected patients with either localized or locally advanced pancreatic adenocarcinoma (**Grade C**). The use of laparoscopic ultrasound and peritoneal washings is encouraged, since they may improve the diagnostic accuracy of the procedure (**Grade C**). Based on the available evidence, selective rather than routine use of the procedure may be

better justified and more cost-effective (**Grade C**). Patient selection may be based on the available evidence that suggests that the diagnostic accuracy of SL may be higher in patients with larger tumors, tumors of the neck, body, and tail or with clinical, laboratory (such as higher levels of Ca 19-9), or imaging findings suggestive of more advanced disease (**Grade C**). Nevertheless, the effectiveness of such selection criteria needs to be verified by additional prospective studies.

For details of the rationale for the procedure and its diagnostic accuracy, see the original guideline document.

Definitions:

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
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Level III	Descriptive case series, opinions of expert panels

Scale Used for Recommendation Grading

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Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Avoidance of unnecessary exploratory laparotomy with its associated higher morbidity and cost in patients with metastatic disease
- Appropriate selection of patients with true locally advanced disease and exclusion of patients with computed tomography-occult metastatic disease from further unnecessary treatment (chemotherapy or chemoradiation) with its associated morbidity and cost
- Minimizes the delay of primary treatment (chemotherapy or chemoradiation) in the subset of patients whose disease is unresectable by avoiding laparotomy and its associated longer convalescence period

POTENTIAL HARMS

- False negative studies that lead to unnecessary exploratory laparotomies and unnecessary cost
- Procedure-related/intraoperative complications (see "Procedure-related Complications and Patient Outcomes" section in the original guideline document)

CONTRAINDICATIONS

CONTRAINDICATIONS

- Known metastatic disease
- Inability to tolerate pneumoperitoneum or general anesthesia
- Multiple adhesions/prior operations

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. The approach suggested may not be the only acceptable approach given the complexity of the health care environment. These guidelines are intended to be flexible, as the surgeon must always choose the approach best suited to the patient and variables in existence at the time of the decision.

Literature Controversies

The main controversy regarding staging laparoscopy (SL) is whether it should be used routinely or selectively in patients with pancreatic adenocarcinoma deemed resectable on preoperative imaging. Proponents for the routine use of SL cite the high incidence of imaging occult metastatic disease found during laparoscopic examination of the abdominal cavity that leads to avoidance of unnecessary operations and thus benefits patients. Proponents for the selective use of SL argue that when high quality imaging is used, only a small percentage of patients

benefit from SL, and under these circumstances the procedure is not cost-effective. As discussed in the technique section (see "Major Recommendations"), there is also a controversy about whether to perform a limited or extended procedure.

Limitations of the Available Literature

The quality of the available studies on SL for patients with pancreas cancer is limited; no level I evidence exists. Furthermore, population-based data are very limited, as the majority of studies are single institution reports from highly specialized centers, making generalizations difficult and allowing institutional and personal biases to be introduced into the results.

In addition, reported data are not uniform across studies, making their analysis difficult. A number of studies assess the role of laparoscopy indirectly without having ever performed a single laparoscopic staging procedure (referred to as 'phantom' studies by some authors) and assume that only visible metastatic disease would have been detected at the time of laparoscopy, ignoring the value of laparoscopic ultrasound and cytology. Other studies do not clearly report the quality of preoperative imaging, the criteria used to define resectability, and the number of R0 resections. Importantly, studies often evaluate inhomogeneous patient samples, including patients with localized and locally advanced pancreatic cancers, with periampullary and other non-pancreatic cancers or even with benign disease and do not report results separately. Moreover, the information on the cost-effectiveness of the procedure is limited, and there are no studies that assess the quality of life of patients undergoing SL compared with patients undergoing open exploration.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

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

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

1998 Apr (revised 2007 Nov)

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [Society of American Gastrointestinal and Endoscopic Surgeons \(SAGES\) Web site](#).

Print copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Patient information for diagnostic laparoscopy from SAGES. Available in English and Polish from the [Society of American Gastrointestinal and Endoscopic Surgeons \(SAGES\) Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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