Complete Summary

GUIDELINE TITLE

Guidelines for laparoscopic resection of curable colon and rectal cancer.

BIBLIOGRAPHIC SOURCE(S)

Guidelines for laparoscopic resection of curable colon and rectal cancer. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES), American Society of Colon and Rectal Surgeons (ASCRS); 2005 Jul. 12 p. [68 references]

GUIDELINE STATUS

This is the current release of the guideline.

Because new developments in medical research and practice can change recommendations, all guidelines undergo scheduled, periodic review to reflect any changes.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drug(s) for which important revised regulatory information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Colon and rectal cancer

Note: This document will not address the endoscopic screening or surveillance for colorectal cancer.

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Gastroenterology
Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide surgeons with recommendations on the safe performance of laparoscopic resection for curable colon and rectal cancer
- To provide suggestions for the overall clinical management of patients with curable colon and rectal cancer who are being treated by properly trained and experienced minimally invasive surgeons

TARGET POPULATION

Patients with curable colon and rectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Diagnostic evaluation

    - Localization and assessment of the tumor in the colon or rectum
    - Evaluation of the liver with computed tomography (CT) or ultrasound for detection of liver metastases
2. Preparation for operation
    - Preoperative mechanical bowel preparation
3. Laparoscopic tumor resection
4. Laparoscopic en bloc resection
5. Prevention of tumor perforation
6. Prevention of wound implants
7. Training and experience necessary for appropriate oncologic resection

MAJOR OUTCOMES CONSIDERED

- Survival
- Incidence of recurrence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

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 or 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

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades

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

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), July 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I–III) and grading of recommendations (A–C) are defined at the end of the Major Recommendations field.

I. Diagnostic Evaluation

Standard screening guidelines should be followed. Published guidelines on preoperative assessment for open resection of curable colon or rectal cancer should be followed. A laparoscopic approach requires additional considerations.

A. Recommendation: The segment of colon or rectum containing the tumor should be localized accurately preoperatively. (**Level III evidence, Grade C recommendation**)

Once a colon or rectal cancer has been detected, preoperative staging, assessment of resectability, and assessment of the patient's operative risks are indicated. The entire colon and rectum should be evaluated, usually with colonoscopy. Consideration of a minimally invasive surgical approach requires accurate localization of the tumor, as a known cancer may not be apparent during laparoscopic visualization from the serosal aspect of the bowel. Without accurate localization, the wrong segment of colon may be removed. Colonoscopy is accurate for localization of a tumor in the rectum and cecum only, and may otherwise be inaccurate. Other methods for identifying the segment of colon involved include tattooing at the time of colonoscopy, barium enema, and computed tomography (CT) colonography. CT scan may be helpful in the setting of a large tumor, but does not reliably localize smaller tumors. If the tumor is not localized preoperatively, intraoperative colonoscopy may be helpful.

B. Recommendation: The liver should be evaluated with preoperative CT scan or ultrasound (US), or intraoperative US (**Level II evidence, Grade B recommendation**)

The liver is not routinely evaluated preoperatively when open resection of colon cancer is performed. Liver metastases of >1 cm diameter are detected by CT scan with sensitivities and specificities of 90 and 95%. However, this rarely results in a change in the operative strategy in many institutions. Routine use is noted in centers where synchronous resection of the primary and metastatic tumors is performed. Instead, the liver is palpated intraoperatively or intraoperative US may be performed. A laparoscopic approach precludes the ability to palpate the liver, although the visualization provided may reveal surface lesions not detected by CT scan. Given the inability to palpate the liver intraoperatively, preoperative assessment of the liver by CT or US or intraoperative US should be performed.

In the case of rectal cancer, staging CT scan or transanal rectal US is routine and not impacted by the laparoscopic approach. Preoperative abdominal CT or hepatic US is required in planning surgical treatment for rectal cancer, as the findings may change the operative approach significantly.

II. Preparation For Operation

Standard guidelines are published regarding the safety of outpatient bowel preparation, use of prophylactic antibiotics, blood cross matching and thromboembolism prophylaxis.

Recommendation: Preoperative mechanical bowel preparation to facilitate manipulation of the bowel during a laparoscopic approach (**Level III evidence, Grade C recommendation**)

Preoperative mechanical bowel preparation is the common practice in North America, despite lack of clear evidence of benefit from meta-analysis and randomized controlled trials to support its use. Although some authors have recommended no preparation, an empty colon is generally considered to facilitate manipulation of the bowel during laparoscopic colon and rectal surgery. When considering a completely laparoscopic approach with intracorporeal anastomosis, a longer period of preparation is used by some authors.

III. Operative Issues

Operative Techniques – Colon

Recommendation: Laparoscopic resection should follow standard oncologic principles: proximal ligation of the primary arterial supply, adequate proximal and distal margins, and appropriate lymphadenectomy (**Level I evidence, Grade A recommendation**)

Existing guidelines for colon and rectal cancer surgery have established levels of evidence and grades of recommendation for the following: proximal and distal colonic resection margins (determined by the area supplied by the primary feeding arterial vessel(s)); lymphadenectomy with a minimum of 12 lymph nodes harvested; and ligation of the named feeding vessel at its origin. The two adequately powered randomized trials of laparoscopic colectomy for curable colon cancer followed these oncologic principles and showed no significant difference in proximal and distal bowel margins, number of lymph nodes retrieved, and, in the Clinical Outcomes of Surgical Therapy Study Group (COST) trial, perpendicular length of the primary vascular pedicle.

These recommendations determine which portions of the procedure may be performed intracorporeally or extracorporeally. In a patient with a normal body mass index undergoing right colectomy it is often feasible to ligate the base of the ileocolic pedicle via a periumbilical incision. In a heavier patient, this might best be performed intracorporeally. For all other vessels, the origin of the vessel will generally need to be ligated intracorporeally unless a larger incision such as used for hand-assisted procedures permits safe access to the base of the vessels. Inability to comply with oncologic principles should prompt conversion to an open operation.

Operative Techniques – Rectum

Recommendation: Laparoscopic resection for rectal cancer should follow standard oncologic principles: adequate distal margin, ligation of the base of the superior rectal/inferior mesenteric artery, and mesorectal excision (**Level II evidence, Grade B recommendation**)

Operative guidelines for open rectal surgery have been established with levels of evidence and grades of recommendation for techniques relevant only to the rectum. These include a distal margin of 1 to 2 cm, removal of the blood supply and lymphatics up to the origin of the superior rectal artery (or inferior mesenteric artery if indicated), and appropriate mesorectal excision with radial clearance.

Laparoscopic resection of rectal cancer has not been evaluated in a randomized trial. Prospective and retrospective case series have suggested that the procedure is feasible in carefully selected patients. The confines of the pelvis confer additional challenges on the laparoscopic approach, particularly for distal rectal tumors. The ability to perform an oncologically adequate laparoscopic resection for rectal cancer will depend on tumor factors such as size, proximal or distal location, and patient factors including anatomy of the pelvis (narrow or wide), obesity, bulky uterus, and effect of prior radiation on tissue planes. Inability to comply with oncologic principles should prompt conversion to an open operation.

Contiguous Organ Attachment

Recommendation: Open approach is required if a laparoscopic en-bloc resection for a T4 lesion cannot be safely performed. (**Level II evidence, Grade B recommendation**)

Current guidelines for open colon and rectal cancer surgery recommend *en bloc* resection to manage locally advanced adherent colorectal tumors. Histologically negative margins achieved with *en bloc* resection are considered curative. Preoperative studies such as CT scan may suggest a bulky tumor invasive into an adjacent organ and guide the decision to perform an open resection. A known T4 colonic cancer may prompt an open approach. The ability to perform en bloc resection laparoscopically is dependent on the structure to which the tumor is adherent, in addition to surgeon skill and experience. When the goal is curative resection, intraoperative discovery of a T4 lesion requires conversion, unless the surgeon is capable of properly resecting the lesion *en bloc*.

Tumor Perforation and the "No-Touch Technique"

Recommendation: Perforation of the tumor should be avoided. (**Level III evidence, Grade C recommendation**)

Excessive force or use of instruments not suited to handling of the bowel may cause inadvertent perforation. Inadvertent perforation results in increased local recurrence rates and a significant reduction in 5-year survival. Thus, although the "no-touch technique" (with early ligation of vessels) is not specifically recommended, avoidance of perforating the tumor with handling is advocated.

For open resection of curable colorectal carcinoma, the value of the no-touch technique, with early ligation of the vascular supply, has not been proven. In laparoscopic resection, some surgeons employ a medial-to-lateral approach with early ligation of the mesenteric vessels. No oncologic benefit of this approach has been shown.

Prevention of Wound Implants

Recommendation: The extraction incision should be mechanically protected during specimen retrieval. (**Level II evidence, Grade C recommendation**)

Wound implants, or recurrence of cancer, have been reported at both the extraction site incision and the port sites. The phenomenon has prompted extensive research.

Most measures suggested to prevent wound implants have been generated by *in vitro* and *in vivo* animal models, not clinical practice. The results of gasless laparoscopy are inconsistent, as some studies have shown a decrease in port site metastases, yet others have been unable to confirm this. Low insufflation pressures may result in reduced tumor growth. Carbon dioxide may enhance tumor implantation and growth but is the safest gas to work within the clinical arena. Helium may reduce the rate of wound implants but is not used clinically. Wound excision has been shown to both decrease and to increase the rate of wound recurrence.

Certain experimental findings have resulted in simple modifications of the laparoscopic approach. Aerosolization of tumor implants occurs in experimental models employing large numbers of tumor cells, although others doubt its role in tumor implants. As it is easy to desufflate the pneumoperitoneum via the trocars rather than via the incision, some experts advocate this practice. Related to this is the description of gas leakage along loosely fixed trocars (the "chimney effect") which was related to increased tumor growth in one study. Thus fixation of trocars or use of trocars with modifications preventing slippage is widely used. Reductions in port site metastases have been shown in animal models following irrigation of the peritoneal cavity and/or port site incisions with solutions such as povidone-iodine, heparin, methotrexate, cyclophosphamide, taurolidine and 5-fluorouracil. Although these models employ supra-normal numbers of cancer cells, a consensus panel of the European Association of Endoscopic Surgery reported that half the expert panel irrigated the port sites with either povidone-iodine, distilled water or tauroline and all the panel protected the extraction site and/or placed the specimen in a plastic bag prior to extraction.

The most significant impact on the incidence of port site metastasis has been that of experience and the development of laparoscopic techniques that permit an oncologic resection, identical to the open one, to be performed. Initial reports of port sites metastases ranging from 2-21% have dropped to less than 1% in large case series and randomized trials. This is similar to the rate for open colorectal cancer resection. In the COST study and Lacy's study the rates were 0.5% and 0.9% respectively. Surgical experience is considered the most important factor in the prevention of incisional implants.

In summary, experimental animal models have shown a reduction in wound implants if the wound is protected or treated with a tumoricidal substance. There is no consensus on the nature of the irrigant, but diluted povidone-iodine and distilled water were the most commonly used among experts. In the operating room, in addition to wound protection, other commonly used techniques are fixation of trocars, evacuation of the pneumoperitoneum via the ports, and wound irrigation. Wound implants should be kept at a rate less than 1% by correct oncologic technique and experience.

IV. Training and Experience

Recommendation: Adequate training and experience are necessary to perform an appropriate oncologic resection. (**Level II, Grade B**)

Laparoscopic colorectal resections are considered amongst the most complex of laparoscopic cases. Resection requires mobilization of a bulky structure, working in more than one quadrant of the abdomen, obtaining control of multiple large blood vessels, extraction of a large specimen, and creation of a safe anastomosis. For cancer, oncologic principles must be applied with the additional requirements of adequate distal and proximal margins, appropriate lymphadenectomy, proximal ligation of the vascular pedicle(s) and avoidance of handling and perforating of the tumor.

The level of experience for these procedures is likely variable and related to the specific procedure, the underlying pathology, and the skill and prior experience of the individual surgeon. Recognizing the need for experience resulted in the Society of Gastrointestinal and Endoscopic Surgeons co-endorsing the statement developed by the American Society of Colon and Rectal Surgeons to accompany the publication of the results of the COST study. Surgeons must be prepared to answer patients' questions regarding their experience.

Definitions:

Levels of Evidence

Level I: Evidence from properly conducted randomized, controlled trials

Level II: Evidence from controlled trials without randomization

Or

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Or

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Level III: Descriptive case series, opinions of expert panels

Recommendation Grades

Grade A - Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel

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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 the "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The safe performance of laparoscopic resection for curable colon and rectal cancer
- Appropriate clinical management of patients with curable colon and rectal cancer

POTENTIAL HARMS

Possible occurrence of wound implants and port site metastasis

CONTRAINDICATIONS

CONTRAINDICATIONS

Not stated

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, clinical practice and expert opinion. The approach suggested may not necessarily 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 individual patient and variables in existence at the moment of decision. These guidelines are applicable only to those physicians who are appropriately credentialed and address the clinical situation in question, regardless of specialty.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Guidelines for laparoscopic resection of curable colon and rectal cancer. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES), American Society of Colon and Rectal Surgeons (ASCRS); 2005 Jul. 12 p. [68 references]

ADAPTATION

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

DATE RELEASED

2005 Jul

GUIDELINE DEVELOPER(S)

American Society of Colon and Rectal Surgeons - Medical Specialty Society
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

SAGES members are assigned by leadership to the Guidelines Committee

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

Because new developments in medical research and practice can change recommendations, all guidelines undergo scheduled, periodic review to reflect any changes.

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 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

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 3, 2007. The information was verified by the guideline developer on May 13, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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