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SAGES Evidence-Based Guidelines for the Laparoscopic Resection of Curable Colon and Rectal Cancer

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PREAMBLE

The following recommendations regarding the safe performance of laparoscopic resection for curable colon and rectal cancer are intended for surgeons experienced in both minimally invasive surgery and the surgical treatment of patients with colon and rectal cancer. This document will not address the endoscopic screening or surveillance for colorectal cancer. SAGES and the ASCRS have previously published a joint statement regarding the credentialing process.[1] SAGES also has published guidelines that specifically address credentialing surgeons for laparoscopic procedures in general.[2]

DISCLAIMER

Guidelines for clinical practice are intended to indicate preferable approaches to medical problems as established by experts in the field. These recommendations will be based on existing data or a consensus of expert opinion when little or no data are available.

Guidelines are applicable to all physicians who address the clinical problem(s) without regard to specialty training or interests, and are intended to indicate the preferable, but not necessarily the only acceptable approaches due to the complexity of the healthcare environment. Guidelines are intended to be flexible. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision.

Guidelines are developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons and its various committees, and approved by the Board of Governors. Each clinical practice guideline has been systematically researched, reviewed and revised by the guidelines committee, and reviewed by an appropriate multidisciplinary team. The recommendations are therefore considered valid at the time of its production based on the data available. Each guideline is scheduled for periodic review to allow incorporation of pertinent new developments in medical research knowledge, and practice.

This guideline, written by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), was

reviewed and approved for endorsement by the Executive Council of the American Society of Colon and Rectal Surgeons (ASCRS) on 23 February 2012.

I. INTRODUCTION

Colorectal cancer is the fourth most common malignancy in the United States and the second most common cause of death from cancer in this country. In 2006, 139,127 people were diagnosed with colorectal cancer, and 53,196 people died from it.[3] One of the most controversial issues in minimally invasive surgery has been the implementation of laparoscopic techniques for resection of curable colorectal malignancies. Initial concerns included the potential violation of oncologic principles, the effects of carbon dioxide insufflation, and the phenomenon of port site tumor recurrence.[4, 5]

Basic science research and large randomized controlled trials are now demonstrating that these fears were unjustified. The laparoscopic approach, however, involves a steep learning curve and requires the surgeon and ancillary operating room staff to have advanced skills in laparoscopy.

II. DEFINITIONS

Both the quality of the evidence and the strength of the recommendation for each of the below recommendations was assessed according to the GRADE system[6] (see Table 1). There is a 4-tiered system for judging quality of evidence (very low (**+)**, low (**++)**, moderate (**+++)**, or high (**++++)**) and a 2-tiered system for determining the strength of recommendations (weak or strong). Additional definitions are provided by SAGES in "The Definitions Document: A Reference for Use of SAGES Guidelines".

III. DIAGNOSTIC EVALUATION

Standard guidelines for colorectal cancer screening should be followed.[7, 8] Published guidelines on preoperative assessment for open resection of curable colon or rectal cancer should be followed.[9] A laparoscopic approach requires additional considerations.

A. Tumor localization

Recommendation: When approaching colon resection laparoscopically, every effort should be made to localize the tumor preoperatively. Small lesions should be marked endoscopically with permanent tattoos before surgery to maximize the surgeon's ability to identify the lesion. Surgeons should be prepared to use colonoscopy intraoperatively if lesion localization is uncertain. (++OO, strong)

Once a colon or rectal cancer has been detected, preoperative staging, assessment for 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 approach requires accurate localization of the tumor, as a known cancer may not be visually apparent or palpable laparoscopically.[10] Without accurate localization, it is possible that an unaffected segment of colon may be removed.[11, 12] While colonoscopy is accurate for localization of tumors in the rectum and cecum, it is inaccurate in other areas.[13, 14] Other methods for identifying the segment of colon involved include tattooing at the time of colonoscopy [15-17], barium enema, and CT colonography [18]. CT scan may be helpful in the setting of a large tumor, but does not reliably localize smaller tumors. Tattooing is extremely important for intraoperative localization especially for small tumors or polyps and should be pursued at the time of preoperative colonoscopy. Tattooing should be accomplished using suspended carbon black, commercially prepared for this purpose. Multiple carefully placed

intramural injections should be made circumferentially in the colonic wall adjacent to the lesion to maximize the surgeon's ability to localize the lesion intraoperatively. Transmural injections can result in diffuse intraabdominal staining, and may predispose to adhesion formation.[17, 19] If the tumor is not localized preoperatively or the preoperative marking cannot be reliably identified during surgery, intraoperative colonoscopy should be used[10]. When intraoperative colonoscopy is utilized, carbon dioxide insufflation may be preferable as its rapid absorption lessens the risk of a persistently distended colon interfering with surgery.

B. Diagnostic evaluation for metastases

Recommendation: We recommend that for patients with colon or rectal cancer, the chest, abdomen, and pelvis be evaluated preoperatively with CT scan. In patients with rectal cancer, we also recommend preoperative locoregional staging with endorectal ultrasound or MRI. (**++OO, strong**)

Routine cross sectional imaging should be used preoperatively for patients with colon or rectal cancer. Metastases of >1cm diameter are detected by CT scan with sensitivities and specificities of 90 and 95%. [20] In the case of rectal cancer, thoracoabdominopelvic staging evaluation should always be conducted preoperatively as the finding of pulmonary, hepatic, or other metastases is likely to change the operative approach employed and to impact overall patient care. [21] In patients with rectal cancer, locoregional staging also is vital to preoperative planning; endorectal ultrasound and MRI are most commonly utilized. [22] A discussion of locoregional staging for rectal cancer is beyond the intended scope of this guideline, but readers are referred to the Rectal Cancer Guidelines of the American Society of Colon and Rectal Surgeons. [23]

IV. PREPARATION FOR OPERATION

Standard guidelines have been published regarding the safety of outpatient bowel preparation[21, 22], use of prophylactic antibiotics[24], blood cross matching[25, 26] and venous thromboembolism prophylaxis.[27]

Recommendation: We suggest that preoperative mechanical bowel preparation be used to facilitate manipulation of the bowel during the laparoscopic approach and to facilitate intraoperative colonoscopy when needed. (++OO, weak)

The use of preoperative mechanical bowel preparation (MBP) is common practice in North America, despite a lack of clear evidence of benefit from meta-analyses [28, 29] and randomized controlled trials.[30-33] It should be noted that these studies evaluated the use of MBP in open colorectal surgery. It is unclear if results from these trials can be extrapolated to laparoscopic colorectal surgery. Furthermore, the role of mechanical bowel preparation in open rectal surgery remains controversial, especially in low colorectal or coloanal anastomoses since most trials exclude such patients.[28] This continually evolving body of literature suggests that MBP is optional for resections of the colon and the upper rectum, but MBP is advised before resections of the lower rectum or when proximal diversion is planned after rectal resection and anastomosis. The literature suggests that MBP facilitates manipulation of the bowel during laparoscopic resection, and readies the colon for intraoperative colonoscopy when it is required for lesion localization or to assess anastomoses. [34-36].

V. SURGICAL TECHNIQUE AND OPERATIVE CONSIDERATIONS

A. Surgical Technique – Colon

Recommendation: We recommend that laparoscopic resection follow standard oncologic principles: proximal ligation of the primary arterial supply to the segment harboring the cancer, appropriate proximal and distal margins, and adequate lymphadenectomy. (++++, strong)

Guidelines established by the 2000 National Cancer Institute (NCI)-sponsored Colon and Rectal Cancer Surgery Consensus Panel state that the margins of resection for colon cancer are determined by the arterial supply feeding the affected segment of colon. [38] Proximal ligation of vessels supplying tumors, or of multiple feeding vessels when the tumor falls between arterial distributions, should result in adequate proximal and distal resection margins. Lesions should be excised *en bloc* with oncologically appropriate tumor-free radial margins (R0) to be considered curative. [37]

The five adequately powered randomized trials of laparoscopic colectomy for curable colon cancer [38-42] followed these oncologic principles and showed no significant difference in proximal and distal 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.[38] Four of these trials showed that long-term survival and recurrence were no different for patients treated with open and laparoscopic surgery.[39,41-43] In subgroup analysis, patients enrolled in the Barcelona trial with resectable, node-positive colon cancer, AJCC stage III, who were treated using a laparoscopic approach had improved overall survival, cancer-related survival, and decreased recurrence compared with an open approach although the trial was not powered to answer this question.[40]

Extended lymphadenectomy and the “no-touch” technique have not been shown to result in improved survival in open resection.[43, 44] Extended margins of resections have not been shown to confer additional survival benefit. [45] Some surgeons employ a medial-to-lateral approach with early ligation of the mesenteric vessels. [46-48] No oncologic benefit of this approach has been shown.

Excessive force, the use of instruments not suitable for handling the bowel, and other techniques that predispose to inadvertent perforation [11] should be avoided considering

that perforation at the tumor site results in increased rates of local recurrence and a significant reduction in 5-year survival. [49] Atraumatic handling of the bowel should be the goal of every surgeon and can be achieved by blunt retraction, grasping of the epiploic appendages, and the use of atraumatic graspers.

Inability to adhere to all accepted oncologic principles including appropriate vascular ligation should prompt conversion to an open operation if conversion will permit adherence. Careful patient selection, complete preoperative staging, accurate tumor localization, and an experienced surgeon working with an experienced operating room staff all contribute to maximizing patient benefit and minimizing conversion to open resection. [50]

The decision to administer adjuvant therapy is independent of the technique used for colon resection and should mirror recommendations for open resection. [51, 52]

B. Surgical Technique – Rectum

Recommendation: We recommend that laparoscopic resection for rectal cancer follow standard oncologic principles: Adequate distal margin, ligation at the origin of the arterial supply for the involved rectal segment, and mesorectal excision. (+++O, strong)

Resection of very low rectal cancers, intersphincteric resection, and other sphincter-sparing techniques are beyond the intended scope of this guideline but readers are referred to the Rectal Cancer Guidelines of the American Society of Colon and Rectal Surgeons. [23]

Operative guidelines for open rectal surgery have been established with levels of evidence and grades of

recommendation for techniques relevant only to the rectum.[37, 53] Malignant lesions of the upper rectum should be resected with 5cm minimum distal margins, while lesions of the mid and lower rectum require total mesorectal resection including an oncologically appropriate distal margin. In order to ensure a tension free anastomosis, vascular ligation should occur either at the takeoff of the inferior mesenteric artery from the aorta or just distal to the takeoff of the left colic artery. Despite the use of standardized surgical techniques and pathology processing protocols, the number of lymph nodes resected with rectal cancers remains variable, and may not serve as a useful indicator of surgical quality. [53-55]

The confines of the pelvis confer additional challenges when utilizing the laparoscopic approach, particularly for distal rectal tumors. The ability to perform an oncologically adequate resection for rectal cancer laparoscopically will depend on tumor size and location, and on anatomical factors like narrow pelves, obesity, bulky uterus, and the effects of presurgical radiation. Inability to adhere to oncologic principles should prompt conversion to an open operation provided that conversion will enhance adherence to established principles. Selection of the anastomotic method or creation of a temporary or permanent ostomy should be made in a manner that is identical to making these decisions in patients undergoing laparotomy.

Several prospective [54-56] and retrospective [57, 58] case series have demonstrated that laparoscopic total mesorectal excision can be performed safely and adequately. Mid and long-term oncological outcomes appear similar between open and laparoscopic approaches. To date, only one randomized trial included long-term results of laparoscopic and open surgical treatment of rectal cancer. The UK MRC-CLASSIC Trial Group found no difference in overall survival, disease-free survival, local recurrence, wound recurrence, or quality of life between the two approaches. [59, 60] Thirty four per cent of the patients randomized to the laparoscopic group underwent conversion to an open procedure and this cohort had a higher incidence of post-operative complications ($p = 0.002$) as well as worsened overall survival, but equivalent disease-free survival at five years.[60] Furthermore, in patients undergoing laparoscopic low anterior resection, there was a higher rate of positive circumferential margins, although this did not impact local recurrence or survival.[59] Overall, male sexual and erectile function was worse in the laparoscopic group.[61]

The COREAN trial randomized 340 patients with T3N0-2 mid or low rectal cancers, < 9 cm from the anal verge, to undergo laparoscopic or open surgery following neoadjuvant chemoradiation treatment. [62] The primary endpoint was 3-year disease free survival. Patients were treated by 7 surgeons experienced in laparoscopic colorectal surgery at 3 institutions. Their short-term outcomes demonstrated lower blood loss in the laparoscopic group (200 ml versus 217.5 ml, $p=0.006$) albeit with a longer operating time (244.9 min versus 197 min, $p<0.0001$). Involvement of the circumferential margin, macroscopic quality of the total mesorectal excision specimen, number of harvested lymph nodes, and perioperative morbidity did not differ between the groups. Conversion rate to open resection was only 1.2%. Three months following either the proctectomy, or ileostomy reversal if one was used, the laparoscopic group had better quality of life scores when assessing physical function, fatigue, micturition, and gastrointestinal function. The COLOR II, Japanese JCOG 0404, and ACOSOG Z6051 trials are other randomized controlled trials currently underway that seek to compare laparoscopic and open surgery for rectal cancer, assessing morbidity and long-term oncological outcome.[62-65]

The decision to offer adjuvant or neoadjuvant chemoradiation should be based on tumor and patient specific factors and not on the surgical approach. The optimal timing of surgery for rectal cancer following neoadjuvant therapy has been examined in several trials, and although it is still debated, should not be altered based on the technique chosen for resection. [66-68] A complete discussion of adjunctive treatment is beyond the intended scope of this guideline but readers are referred to the Rectal Cancer Guidelines of the American Society of Colon and Rectal Surgeons. [23]

C. Locally Advanced Adherent Colon and Rectal Tumors

Recommendation: For locally advanced adherent colon and rectal tumors, an en bloc resection is recommended. We suggest an open approach if a laparoscopic *en bloc* resection cannot be performed adequately. (++OO, weak)

Up to 15% of patients with colon cancer and 5-12% of patients with rectal cancer will have tumors adherent to adjacent organs [69-71]. Current guidelines for open colon and rectal cancer surgery recommend *en bloc* resection to manage locally advanced adherent colorectal tumors.[9, 37] Histologically negative margins achieved with *en bloc* resection are considered curative. Preoperative cross-sectional imaging including CT scan, MRI, or ultrasound might suggest a bulky tumor invading into adjacent structures, guiding the decision to perform an open resection.[72] The ability to perform *en bloc* resection laparoscopically is dependent on the structure to which the tumor is adherent, and the surgeon's skill and experience. When the goal is curative resection, intraoperative discovery of a T4 lesion often requires conversion, unless the surgeon is able to effectively resect the lesion *en bloc*. However, *en bloc* resection might not be possible using either technique, and therefore, the surgeon must decide if conversion is likely to afford curative resection. Occasionally, the laparoscopy may become diagnostic, with closure followed by reimaging and multidisciplinary consultation prior to a definitive resection at a later date. In some situations, based on the initial laparoscopy, the goals of surgery may shift from cure to palliation. To date, there have been no randomized trials comparing laparoscopic and open approaches to T4 colonic or rectal cancers.

D. Obstructing Colon Cancer

Recommendation: We recommend that patients with an obstructing right or transverse colon cancer undergo a right or extended right colectomy. The open approach is required if the laparoscopic approach will not result in an oncologically sound resection. (++OO, strong)

Patients with an obstructing right or transverse colon cancer should undergo a right or extended right colectomy with primary ileocolic anastomosis in the appropriate clinical setting. Performing an anastomosis and/or the creation of a diverting stoma is dependent on the patient's general condition. Multiple nonrandomized studies have demonstrated that a primary anastomosis is safe in the absence of mechanical bowel preparation. [73, 74] The decision to proceed laparoscopically should take into account the patient's

condition, including hemodynamic stability, extent of abdominal distension, the resectability of the carcinoma, and the surgeon's ability to perform a curative resection in this setting. Although there have been some retrospective studies demonstrating feasibility of laparoscopic resection with benefits in short-term outcomes, [75, 76] a prospective randomized controlled trial has not yet been published.

Recommendation: We suggest that for patients with an obstructing left-sided colon cancer, the procedure be individualized according to clinical factors. Colonic stenting may increase the likelihood of completing a one-stage procedure and may decrease the likelihood of an end colostomy. (+++O, weak)

For patients who present with an obstructing cancer of the left colon, a variety of options have been advocated. [77, 78] The most frequently used are resection with end-colostomy and Hartmann's pouch, resection with on-table lavage and primary anastomosis with or without diverting ostomy, and subtotal colectomy with ileorectal anastomosis. More recently, colonic stenting in appropriately selected patients may obviate obstruction, permitting colonic decompression and elective resection with primary anastomosis, decreasing the rate of colostomy creation in this setting. One randomized controlled trial compared endoluminal stenting followed by laparoscopic resection vs. immediate open surgical resection of obstructing left-sided colon cancers. [79] The authors found that more patients in the stenting and laparoscopic resection group underwent one-stage operations (66% vs. 37.5%; $p = 0.04$) and that no patients in this group required colostomy, compared with 25%

of patients in the open surgery group who received end colostomy.

VI. Prevention of Wound COMPLICATIONS

Recommendation: The use of a wound protector at the extraction site and the irrigation of port sites and extraction site incisions may reduce abdominal wall cancer recurrences. (++OO, strong)

Wound implants, or abdominal wall cancer recurrences, have been reported at both extraction site and port site incisions [4, 38, 39, 59, 80], prompting extensive research [81-90] and initially calling the oncologic safety of the laparoscopic approach into question. [91]

It is now accepted that port-site recurrence is a technical complication of laparoscopic colectomy and not an inevitable consequence of the laparoscopic approach. Several large case series and randomized trials comparing laparoscopic versus open colectomy for colon carcinoma have confirmed port-site recurrences well below 1%.[38, 39, 59, 92-94] This is similar to the rate of incisional recurrence noted after open colorectal cancer resection.[39, 94, 95]

In a consensus report from the European Association of Endoscopic Surgeons, Veldkamp *et al.* collected all reported cases of port-site recurrences from a total of 28 different studies from Europe, Asia, Australia, and North America. [72] There were 38 overall port-site recurrences on a denominator of 5225 combined patients, corresponding to an overall incidence of 0.72%.

Most surgeons performing laparoscopic colectomy use wound protectors to isolate specimens from contact with the abdominal wall.[72] Irrigation of the port site with a variety of tumoricidal solutions reduces tumor implants in animal models, but there is no consensus on the ideal irrigant or whether this laboratory observation holds value in the performance of colon cancer resections in humans.[96-101]

VII. ROBOTIC SURGERY

Recommendation: While robotic surgery for colon and rectal cancer appears feasible and safe, in the absence of long-term oncologic outcome studies, no clear recommendation can be made. (++OO, weak)

Case reports suggest that the use of robotics is feasible and safe in selected patients with colon and rectal cancer. [102-115] Robotic devices were developed to overcome the disadvantages of conventional laparoscopic surgery such as an assistant-dependent unstable camera platform, two-dimensional view, limited dexterity associated with the use of traditional laparoscopic instruments in confined spaces, and fixed instrument tips. Moreover, the robotic system provides excellent ergonomics, tremor stabilization, enhanced ambidextrous capability, motion scaling, and instruments capable of moving with multiple degrees of freedom. Robotic surgery has the drawbacks of diminished haptic feedback, increased operative times, and increased procedural cost. Large-scale prospective randomized trials will be required to evaluate long-term clinical outcomes of robotic surgery and to identify actual clinical benefit.

VIII. TRAINING AND EXPERIENCE

Recommendation: Before surgeons apply the laparoscopic approach for the resection of curable colon and rectal cancer, they must have adequate knowledge, training, and experience in laparoscopic techniques and oncologic principles. (+++O, strong)

Some studies reviewed mandated a minimum of 20 laparoscopic colon cancer operations for surgeon inclusion

into clinical trials, [37, 38] whereas studies examining the learning curve for laparoscopic colectomy have suggested that at least 50 cases are required to gain proficiency. [116-118] Advanced laparoscopic training during residency or fellowship and training on simulators may shorten the learning curve toward proficiency. Surgeons must carefully observe the principles applicable to resection of colon and rectal cancers to confer similar long-term outcomes as open resections afford patients. Mentoring, proctoring, and working with an experienced assistant have each been shown effective in the adoption of techniques new to a surgeon's skill set. [119]

SUMMARY OF RECOMMENDATIONS

Tumor localization

Recommendation: When approaching colon resection laparoscopically, every effort should be made to localize the tumor preoperatively. Small lesions should be marked endoscopically with permanent tattoos before surgery to maximize the surgeon's ability to identify the lesion. Surgeons should be prepared to use colonoscopy intraoperatively if lesion localization is uncertain. (++OO, strong)

Diagnostic evaluation for metastases

Recommendation: We recommend that for patients with colon or rectal cancer, the chest, abdomen, and pelvis be evaluated preoperatively with CT scan. In patients with rectal cancer, we also recommend preoperative locoregional staging with endorectal ultrasound or MRI. (**++OO, strong**)

Preparation for operation

Recommendation: We suggest that preoperative mechanical bowel preparation be used to facilitate manipulation of the bowel during the laparoscopic approach and to facilitate intraoperative colonoscopy when needed. (++OO, weak)

Surgical Technique – Colon

Recommendation: We recommend that laparoscopic resection follow standard oncologic principles: proximal ligation of the primary arterial supply to the segment harboring the cancer, appropriate proximal and distal margins, and adequate lymphadenectomy. (++++, strong)

Surgical Technique – Rectum

Recommendation: We recommend that laparoscopic resection for rectal cancer follow standard oncologic principles: Adequate distal margin, ligation at the origin of the arterial supply for the involved rectal segment, and mesorectal excision. (+++O, strong)

Contiguous Organ Attachment

Recommendation: For locally advanced adherent colon and rectal tumors, an en bloc resection is recommended. We suggest an open approach if a laparoscopic *en bloc* resection cannot be performed adequately. (++OO, weak)

Obstructing Colon Cancer (Right-sided)

Recommendation: We recommend that patients with an obstructing right or transverse colon cancer undergo a right or extended right colectomy. The open approach is required if the laparoscopic approach will not result in an oncologically sound resection. (++OO, strong)

Obstructing Colon Cancer (Left-sided)

Recommendation: We suggest that for patients with an obstructing left-sided colon cancer, the procedure be individualized according to clinical factors. Colonic stenting may increase the likelihood of

completing a one-stage procedure and may decrease the likelihood of an end colostomy. (+++O, weak)

Prevention of Wound Complications

Recommendation: The use of a wound protector at the extraction site and the irrigation of port sites and extraction site incisions may reduce abdominal wall cancer recurrences. (++OO, strong)

Robotic Surgery

Recommendation: While robotic surgery for colon and rectal cancer appears feasible and safe, in the absence of long-term oncologic outcome studies, no clear recommendation can be made. (++OO, weak)

Training and Experience

Recommendation: Before surgeons apply the laparoscopic approach for the resection of curable colon and rectal cancer, they must have adequate knowledge, training, and experience in laparoscopic techniques and oncologic principles. (+++O, strong)

Table 1: ***GRADE system for rating the quality of evidence for SAGES guidelines.***

Quality of Evidence	Definition	Symbol Used
High quality	Further research is very unlikely to alter confidence in the estimate of impact	
Moderate quality	Further research is likely to alter confidence in the estimate of impact and may change the estimate	
Low quality	Further research is very likely to alter confidence in the estimate of impact and is likely to change the estimate	
Very low quality	Any estimate of impact is uncertain	

Table 2: ***GRADE system for recommendations based on the quality of evidence for SAGES guidelines.***

Strong	It is very certain that benefit exceeds risk for the option considered
Weak	Risk and benefit well balanced, patients and providers faced with differing clinical situations likely would make different choices, or benefits available but not certain regarding the option considered

Adapted from Guyatt et al.1

1. Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

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