General

Guideline Title
Practice parameters for the management of colon cancer.

Bibliographic Source(s)


Guideline Status
This is the current release of the guideline.


Regulatory Alert

FDA Warning/Regulatory Alert
Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs: The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children’s brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children’s brain development.

Recommendations

Major Recommendations
The levels of evidence and the grades of recommendations (1A-2C) are defined at the end of the "Major Recommendations" field.
Evaluation and Risk Assessment

A thorough disease history should be obtained eliciting disease-specific symptoms, associated symptoms, and family history. Routine laboratory values, including carcinoembryonic antigen (CEA) levels, should also be evaluated, as indicated. Grade of Recommendation: 1C

Some patients have symptoms of change in bowel habits, blood in their stool, anemia, or are found to be fecal occult blood positive. Less often, a patient may have pain or obstructive symptoms or symptoms of metastatic disease. A complete history, including family history and colon cancer-specific history can guide the surgeon to suspect hereditary cancer syndromes, look for associated pathology or metastatic disease, and initiate additional workup such as mutational analysis of the tumor. Patients meeting clinical criteria for or having a family history of an increased susceptibility to colorectal cancer should be referred for genetic counseling for formal evaluation.

Routine laboratory examinations including complete blood cell count, liver function tests, and chemistry panel should be performed, based upon patient comorbidities, as indicated for preparation for general anesthesia. Because anemia can be common in patients with colon cancer, a complete blood count including platelets is recommended before surgical intervention. Carcinoembryonic antigen levels should be assessed before elective surgery for colon cancer for the establishment of baseline values and during the surveillance period to monitor for signs of recurrence. Although higher levels of CEA have been correlated with poorer prognosis, the data are insufficient to justify the use of a high preoperative CEA as an indication for adjuvant therapy. A confirmed rise in the postoperative CEA during surveillance should prompt further investigation for recurrent disease. At present there is insufficient evidence to support the routine use of other tumor markers such as CA19-9 in the routine evaluation of patients with colon cancer.

When possible, all patients with presumed or proven colon cancer should undergo a full colonic evaluation with histologic assessment of the colonic lesion before treatment. Grade of Recommendation: 1C

Although the majority of patients are diagnosed with colon cancer during a full colonoscopy, new screening recommendations have recently been published that give alternatives to endoluminal examination. An increasing number of patients may be diagnosed by these newer methods and may be referred for surgical therapy without having previously undergone complete endoluminal examination with histologic tissue diagnosis. In cases without documented complete intracolonic evaluation, full endoluminal examination with biopsy is advocated. Whenever possible, the histologic diagnosis of colon cancer should be confirmed before elective surgical resection because nonneoplastic processes such as diverticulitis or inflammatory bowel disease (IBD) may be associated with the endoscopic appearance of colon cancer.

The risk for synchronous carcinomas or adenomas within the colon may be as high as 10% in the general population. Preoperative evaluation and diagnosis allow the surgeon to diagnose and potentially treat other colonic polyps, or, in the case of a synchronous cancer, choose the correct extent of colonic resection. The identification of synchronous cancers may also lead to workup for underlying predisposing risk factors such as inheritable colorectal cancer syndromes. In addition, endoscopic marking of the lesion location (tattoo) could be performed, especially in cases where laparoscopic resection is planned.

Some patients undergo colonoscopy, but the examination cannot be completed. In the absence of a clinically complete obstruction or perforation, a radiological study should be obtained to complete the colonic evaluation. These include contrast enemas (e.g., barium enema) or preferably computed tomography (CT) colonography or positron emission tomography (PET)/CT colonography. In circumstances where the examination could not be completed but the patient meets indications for adjuvant chemotherapy, the completion colonoscopy should be performed soon after completion of chemotherapy.

Preoperative radiological staging should be routinely performed. Grade of Recommendation: 1B

Preoperative radiographic staging including a CT scan of the chest, abdomen, and pelvis should be routinely performed before the elective surgical resection of colon cancer. This permits the detection and evaluation of the extent of synchronous metastases that may require a change in the treatment strategy, e.g., chemotherapy rather than surgery first or potential simultaneous resection of both the primary tumor and the metastatic sites. The preoperative CT scan findings may also result in the operative plan being altered based on identification of the tumor location, adjacent organ or abdominal wall involvement, in addition to the presence of metastatic disease. In the event that a patient has been referred with CT imaging only of the abdomen and pelvis, at minimum, a preoperative chest x-ray should be obtained and a CT of the chest should be performed postoperatively. In patients with hypersensitivity to the iodine contrast dye, or in the appropriate clinical setting to work up indeterminate lesions on CT, an 18F-fluorodeoxyglucose positron emission tomography (18FDG-PET) fused CT scan or noncontrast chest CT with a magnetic resonance imaging (MRI) of the abdomen and pelvis may be considered. In some situations, a preoperative or intraoperative ultrasound may provide additional information.

Staging of Colon Cancer

Colon cancer staging should be performed according to the American Joint Committee on Cancer (AJCC)/TNM system and include an
assessment of the completeness of surgical resection designated by the residual tumor code "R." Grade of Recommendation: 1B

The tumor depth, nodal metastasis, and distant metastasis have been shown to be predictors of prognosis in colon cancer. These characteristics are described by the Union for International Cancer Control/AJCC TNM staging system, initially described in 2002, but that recently has been updated with the 7th edition of the AJCC Cancer Staging Manual and is presented in Table 1 of the original guideline document.

In addition to TNM staging, the histologic grade of the tumor as well as the completeness of the resection should be assessed. Histologic grade has also been shown to be an important predictor of outcome and is an important consideration for treatment recommendations. The absence or presence of residual tumor following resection is designated by the letter R in accordance with the AJCC prognostic factors, as indicated below, and where possible should be indicated in the operative report:

- R0—complete tumor resection with all margins histologically negative
- R1—incomplete tumor resection with microscopic surgical resection margin involvement (margins grossly uninvolved)
- R2—incomplete tumor resection with gross residual tumor that was not resected (primary tumor, regional nodes, macroscopic margin involvement).

Surgical Treatment of the Primary Tumor

The primary treatment for localized resectable colon cancer is colectomy with en bloc removal of all associated regional lymph nodes and involved adjacent structures. A thorough exploration should be performed at the time of resection. The value of the "no touch" technique in which the vascular supply to and from the tumor are divided before manipulating the tumor has remained controversial, and definite benefit has not been demonstrated. However a principle of gentle handling of the tumor during operation should be observed to avoid the risk for tumor spillage or perforation, in particular, in the management of locally advanced tumors or those with associated abscess.

- A thorough surgical exploration should be performed and the findings documented in the operative report. Grade of Recommendation: 1C
- The extent of resection of the colon should correspond to the lymphovascular drainage of the site of the colon cancer. The lymphadenectomy should be complete and en bloc with the bowel segment. Grade of Recommendation: 1A
- Clinically positive lymph nodes located outside the standard field of resection identified at the time of resection and suspected to contain metastatic disease should be biopsied or removed at the time of primary resection. Grade of Recommendation: 2B
- Resection of involved adjacent organs should be en bloc. Grade of Recommendation: 1B

Synchronous colon cancers can be treated by two separate resections or subtotal colectomy. Grade of Evidence: 1B

Sentinel lymph node (SLN) mapping for colon cancer does not replace standard lymphadenectomy. Grade of Recommendation: 1B

Laparoscopic and open colectomy achieve equivalent oncological outcomes for localized colon cancer. The use of the laparoscopic approach should be based on the surgeon's documented experience in laparoscopic surgery as well as on patient- and tumor-specific factors. Grade of Recommendation: 1A

Treatment of the malignant polyp is determined by the morphology and histology of the polyp. Grade of Recommendation: 1B

Refer to the original guideline document for further discussion of surgical treatment of the primary tumor.

Prophylactic Oncological Resection of Extraintestinal Organs

Oophorectomy is advised for grossly abnormal ovaries or contiguous extension of the colon cancer, but routine prophylactic oophorectomy is not necessary. Grade of Recommendation: 1C

If 1 ovary is involved with metastatic disease, a bilateral oophorectomy should be performed.

Management of Synchronous Stage IV Disease

Resectable Stage IV Disease

The treatment of patients with resectable stage IV colon cancer should be individualized based on comprehensive multidisciplinary evaluation. Grade of Recommendation: 1B

When the metastatic disease is potentially resectable, resection of the primary tumor should be complete and radical consistent with oncological principles of resection for localized disease as previously outlined in this document. In general, medically fit patients with resectable hepatic and/or pulmonary metastases will benefit from curative resection of the metastases. The sequence of chemotherapy, resection of the primary tumor, and resection of metastasis should be individualized and determined by multidisciplinary consensus. The disease of some patients may be converted to
resectable after systemic chemotherapy. Neoadjuvant approaches to systemic chemotherapy before surgical resection may assist in identifying patients who are candidates for surgical resection. Patient survival is improved by the addition of systemic chemotherapy to surgical resection.

Unresectable Stage IV Disease

Palliative intervention or resection of the symptomatic primary tumor should be considered, but routine resection of the asymptomatic primary tumor is not recommended. Grade of Recommendation: 1B

Patients with unresectable metastatic disease should be treated with systemic chemotherapy with palliative intent. More recent prospective data support only selective primary tumor resection for treatment of symptoms, and patients who are asymptomatic from their primary tumor may therefore be closely followed with serial endoscopic evaluation for obstruction. Routine resection of the asymptomatic primary tumor is not recommended.

Tumor-Related Emergencies

Tumor complications (bleeding, perforation, and obstruction) are serious and potentially life-threatening conditions of locally advanced tumors. The goals of treatment for these conditions are to 1) avert the immediate negative impact of the complication (e.g., death, sepsis), 2) achieve the best possible tumor control, and 3) ensure timely recovery to permit initiation of appropriate adjuvant or systemic treatment.

Bleeding

Surgical resection to stop severe blood loss from localized colon cancer should follow the same oncological principles as in elective resection. Grade of Recommendation: 2C

Immediate management includes resuscitation of the patient and potential selective embolization, but surgical resection is the most effective and definitive approach. Preoperative or intraoperative efforts to localize the site of bleeding may be pursued in the clinically stable patient. In the very uncommon instance in which the site of bleeding cannot be determined either before operation or intraoperatively, but a colonic tumor is suspected, a subtotal colectomy adhering to oncological principles to each segment of the colon may be considered.

Perforation

Perforation is a life-threatening complication. After resuscitation of the patient, surgical resection to address both the perforation and the tumor should be performed, if at all possible. Grade of Recommendation: 1B

When perforation of uninvolved colon proximal to an obstructing tumor has occurred, whenever possible, resection of the tumor following the oncological principles outlined above should be performed in addition to resection of the perforated segment. In most instances, an ostomy will provide effective fecal diversion and allow for patient recovery until the acute peritonitis has resolved. If the perforation occurs at the site of the tumor but is contained by adjacent structures, resection should ideally incorporate the adjacent structures en bloc. In cases of free perforation with peritonitis, the involved segment should be resected and proximal fecal diversion constructed. A primary anastomosis (with/without proximal diversion) may be considered in selected patients with minimal contamination, healthy tissue quality, and clinical stability.

Obstruction

The management of patients with an obstructing cancer should be individualized but may include a definitive surgical resection with primary anastomosis. Grade of Recommendation: 1B

Options for the treatment of obstructing tumors depend on the site of obstruction and the presence of proximal colonic distention with fecal load. Options for treatment may include resection with or without anastomosis (e.g., Hartmann resection), resection of the distended bowel (e.g., subtotal/total colectomy), or temporary relief of obstruction and fecal load (e.g., preoperative stenting as a bridge to resection).

Management of Locoregional Recurrence

The treatment of patients with locoregionally recurrent colon cancer should be multidisciplinary, and curative resection should adhere to the principles of primary resection. Grade of Recommendation: 1C

Management of Peritoneal Carcinomatosis

The treatment of patients with peritoneal carcinomatosis should be multidisciplinary and individualized and may include surgical cytoreduction. The role of intraperitoneal chemotherapy remains insufficiently defined. Grade of Recommendation: 2C

Palliative Procedures
In patients with extensive incurable extent of tumor burden, palliative surgical interventions should be individualized based on the presence of symptoms. Grade of Recommendation: 1B

Patients who present with widely metastatic colon cancer are usually not candidates for surgical cure. Other patients may not be candidates for radical, curative resection because of systemic comorbidities. In these situations, a multidisciplinary approach to potential palliation should be recommended. The goals of palliation should be relief of symptoms caused by the cancer and maintenance of quality of life. In asymptomatic patients, prophylactic resection of the primary tumor is generally not necessary. Patients with asymptomatic primary lesions in the setting of distant metastasis should be referred for systemic chemotherapy unless initial resection of the primary tumor is determined to be the first stage of the multidisciplinary curative treatment plan. Palliative surgical interventions for obstruction of the gastrointestinal tract or intractable bleeding caused by colon cancer include resection, endoluminal stent therapy, ablative procedures, internal bypass, or creation of a diverting stoma. The avoidance of resection in asymptomatic patients allows the patient to more rapidly initiate systemic chemotherapy, averts the risk for surgical morbidity, and results in improved outcomes. While observing patients with intact primary tumors, serial endoscopic evaluation should be performed to detect evidence for progressive disease and permit interventions to avoid acute obstruction. An individual patient's overall life expectancy should also be considered in the decision for the type of palliative intervention (e.g., resection or stent).

Recommendations Regarding Documentation

The surgical report for colorectal cancer should include information regarding the diagnostic workup, intraoperative findings, and technical details of the procedure. Grade of Recommendation: 1C

The ideal surgical report should clearly communicate the workup, intraoperative findings, and technical details of the procedure. The report should include a description of preoperative treatments and relevant workup and findings on exploration, including the presence of synchronous metastases or gross involvement of mesenteric lymph nodes, tumor site, and adjacent organ involvement. The report should also describe treatment details, including type of incision, extent of bowel and mesenteric resection, anastomotic technique, en bloc resection of contiguously involved organs, and an intraoperative assessment of the completeness of resection including margin status.

Adjuvant Therapy

Decisions regarding adjuvant treatment following curatively resected colon cancer should be based on the clinical findings at resection, including stage of disease and patient comorbidities. The choice of the adjuvant chemotherapy regimen should be made jointly by the patient and the physician. Radiation therapy plays a minimal role in the adjuvant treatment of colon cancer.

Adjuvant chemotherapy should be recommended for patients with stage III colon cancer. Grade of Recommendation: 1A

The first-line adjuvant chemotherapy regimen should include a fluoropyrimidine (5-fluorouracil/leucovorin or capecitabine) and oxaliplatin. However, grade 3 peripheral sensory neuropathy occurs in approximately 12% of patients who receive oxaliplatin, which may make it unsuitable for some patients.

At present, there is no role for the addition of irinotecan in the adjuvant setting after resection of localized colon cancer.

At present, there is no evidence to support the routine addition of biological agents in the adjuvant setting.

Adjuvant chemotherapy may be considered for patients with high-risk stage II colon cancer. Grade of Recommendation: 2B

The benefit of adjuvant chemotherapy in stage II patients has not been definitively shown, and patients with stage II colon cancer should be encouraged to participate in adjuvant therapy clinical trials. Patients with stage II colon cancer are considered to be at high risk in the presence of T4 stage, perforation, peritumoral lymphovascular or neural involvement, or poorly differentiated histology. In addition, those patients in whom fewer than 12 lymph nodes were evaluated may also be considered to be at high risk, and adjuvant chemotherapy may be recommended.

Definitions:

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) System—Grading Recommendations

<table>
<thead>
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<th>Methodological Quality of Supporting Evidence</th>
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RCT = randomized controlled trial


Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Colon cancer

Guideline Category

Evaluation
Management
Risk Assessment
Treatment

Clinical Specialty

Colon and Rectal Surgery
Gastroenterology
Internal Medicine
Oncology
Guideline Objective(s)

To address the issues related to the evaluation and treatment of patients who have been diagnosed with colon cancer

Target Population

Patients with colon cancer

Interventions and Practices Considered

Evaluation/Risk Assessment/Tumor Staging

1. Thorough disease history including disease-specific symptoms, associated symptoms, and family history
2. Routine laboratory values, including carcinoembryonic antigen (CEA) levels
3. Preoperative radiographic staging including a computed tomography (CT) scan of the chest, abdomen, and pelvis and $^{18}$F-fluodeoxyglucose positron emission tomography ($^{18}$FDG-PET) fused CT scan or noncontrast chest CT with a magnetic resonance imaging (MRI) of the abdomen and pelvis
4. Colon cancer staging according to the American Joint Committee on Cancer (AJCC)/TNM system

Treatment/Management

1. Surgical treatment of primary tumor (colecotomy with en bloc removal of all associated regional lymph nodes and involved adjacent structures)
2. Identification and biopsy of clinically positive lymph nodes located outside the standard field of resection
3. Laparoscopic approach versus open colecotomy
4. Prophylactic oncological resection of extraintestinal organs (routine oophorectomy not recommended)
5. Individualized management of patients with resectable stage IV colon cancer based on comprehensive multidisciplinary evaluation
6. Use of systemic palliative chemotherapy for patients with unresectable metastatic disease
7. Management of tumor-related complications (bleeding, perforation, and obstruction)
8. Multidisciplinary management of patients with locoregionally recurrent colon cancer (curative resection according to principles of primary resection)
9. Multidisciplinary and individualized management of patients with peritoneal carcinomatosis including surgical cytoreduction
10. Palliative surgical interventions
11. Surgical documentation (information regarding the diagnostic workup, intraoperative findings, and technical details of the procedure)
12. Adjuvant chemotherapy (first-line adjuvant chemotherapy regimen including a fluoropyrimidine [5-fluorouracil/leucovorin or capecitabine])
Major Outcomes Considered

- Morbidity and mortality
- Cancer recurrence
- 5-year and overall survival
- Relief of symptoms
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This parameter is based on the previous parameter published in 2004. An organized search of MEDLINE, PubMed, EMBASE, and the Cochrane Database of Collected Reviews was performed through February 2010. Key word combinations included colonic or colorectal neoplasms, adenocarcinoma, chemotherapy, colonoscopy, staging, lymph node, neoplasm metastasis, peritoneal neoplasm, surgical procedures, and recurrence. Directed searches of the embedded references from the primary articles were also performed in selected circumstances. All English language articles and studies of adults were reviewed by the primary authors. In selected instances where a full article was not yet available, reports of conference proceedings were reviewed.

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

See the "Rating Scheme for the Strength of the Recommendations" field, below.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated
Methods Used to Formulate the Recommendations

Description of Methods Used to Formulate the Recommendations

This parameter is based on the previous parameter published in 2004.

Recommendations were formulated by the primary authors and reviewed by the entire Standards Committee. The final grade of recommendation was performed by using the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system and reviewed by the entire Standards Committee (see the "Rating Scheme for the Strength of Recommendations" field).

Rating Scheme for the Strength of the Recommendations

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) System—Grading Recommendations

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RCT = randomized controlled trial

Cost Analysis

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

Method of Guideline Validation

Description of Method of Guideline Validation
Not applicable

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" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits
Appropriate management of patients with colon cancer

Potential Harms
Not stated

Qualifying Statements

Qualifying Statements
- These guidelines are inclusive, and not prescriptive. Their purpose is to provide information on which to base decisions, rather than dictate a specific form of treatment.
- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

Implementation of the Guideline

Description of Implementation Strategy
An implementation strategy was not provided.

Implementation Tools

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

Identifying Information and Availability

Bibliographic Source(s)


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

Date Released
2004 Aug (revised 2012 Aug)

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American Society of Colon and Rectal Surgeons - Medical Specialty Society

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Guideline Committee
Standards Practice Task Force of the American Society of Colon and Rectal Surgeons

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 of Colon and Rectal Surgeons Web site.

Print copies: Available from the American Society of Colon and Rectal Surgeons 85 W. Algonquin Rd., Suite 550, Arlington Heights, IL 60005

Availability of Companion Documents

None available

Patient Resources

The following is available:

- Colorectal cancer. Available from the American Society of Colon and Rectal Surgeons 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

This NGC summary was completed by ECRI on January 10, 2005. This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection. This summary was updated by ECRI Institute on December 26, 2008 following the FDA advisory on Innohep (tinzaparin). This summary was updated by ECRI Institute on January 7, 2009 following the FDA advisory on oral sodium phosphate (OSP) products for bowel cleansing. This summary was updated by ECRI Institute on November 21, 2012. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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