Complete Summary

GUIDELINE TITLE

Practice parameters for the management of rectal cancer (revised).

BIBLIOGRAPHIC SOURCE(S)

Tjandra JJ, Kilkenny JW, Buie WD, Hyman N, Simmang C, Anthony T, Orsay C, Church J, Otchy D, Cohen J, Place R, Denstman F, Rakinic J, Moore R, Whiteford M. Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum 2005 Mar;48(3):411-23. [143 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of rectal carcinoma. Arlington Heights (IL): American Society of Colon and Rectal Surgeons; 1998-1999. 3 p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Rectal cancer

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Colon and Rectal Surgery
Gastroenterology
Internal Medicine
Oncology

INTENDED USERS

Health Care Providers
Patients
Physicians

GUIDELINE OBJECTIVE(S)

To provide appropriate recommendations for the management of patients with rectal cancer

TARGET POPULATION

Patients with rectal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

Preoperative Assessment

1. Examination
    - Evaluation for medical fitness to undergo surgery
    - Clinical assessment including family history to evaluate familial risk
    - Digital rectal examination and rigid proctosigmoidoscopy
    - Full colonoscopy
    - Barium enema
2. Imaging studies
    - Computed tomography (CT) scanning of the abdomen and pelvis
    - Transrectal ultrasound (TRUS)
    - Magnetic resonance imaging (MRI)
    - Routine chest radiographs or chest CT scanning
3. Laboratory studies
    - Carcinoembryonic antigen (CEA) level

Treatment/Management

Surgical Techniques

1. Use of a 2-cm distal margin (a 1-cm distal margin is acceptable in smaller cancers of the low rectum)
2. Proximal lymphovascular ligation at the origin of the superior rectal artery
3. Total mesorectal excision (TME) (distal rectal cancers)
4. Tumor-specific mesorectal resection (upper rectal cancers)

5. *En bloc* resection (rectal cancers with adjacent organ involvement)
6. Routine prophylactic oophorectomy (considered, but not recommended)
7. Intraoperative rectal washout (considered, but not recommended)
8. Curative local excision (T1 rectal cancers)
9. Laparoscopic-assisted resection (oncologic effectiveness remains uncertain)
10. Emergency primary resection of an obstructing or perforated carcinoma

Adjuvant Therapy (Preoperative or Postoperative)

1. Adjuvant or neoadjuvant chemotherapy
2. Pelvic radiation
3. Combined modality therapy

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality
- Tumor recurrence rate
- Sensitivity and specificity of diagnostic tests
- Survival and disease-free survival

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

I. Meta-analysis of multiple well-designed, controlled studies, randomized trials with low false-positive and low false-negative errors (high-power)
II. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low-power)
III. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series

IV. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
V. Case reports and clinical examples

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

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
B. Evidence of Type II, III, or IV and generally consistent findings
C. Evidence of Type II, III, or IV but inconsistent findings
D. Little or no systematic empirical evidence

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (classes I-V) and the grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

Preoperative Assessment

1. Patients should be evaluated for their medical fitness to undergo surgery. When an ostomy is a consideration, preoperative counseling with an enterostomal therapist should be offered when available. **Level of Evidence: III; Grade of Recommendation: B**.

   Appraisal of operative risk, especially with respect to cardiopulmonary comorbidity, is an essential part of the preoperative process. History and physical examination are the cornerstones of diagnostic evaluation and may prompt further investigation and intervention to optimize operative risk. In selected cases, a nonsurgical approach to the lesion may be necessary. Several perioperative, risk-assessment scoring systems have been published to help guide the surgeon. The need for ancillary laboratory tests is guided by history and physical examination.

2. Clinical assessment should include a family history to identify patients with familial cancer syndromes and to evaluate familial risk. **Level of Evidence: III; Grade of Recommendation: B**.

   A family medical history should be taken from patients with rectal cancer to identify close relatives with a cancer diagnosis. The clinician should look for patterns consistent with the genetic syndromes of hereditary nonpolyposis colorectal cancer, familial adenomatous polyposis, and familial colorectal cancer because this may affect surgical decisions.

   The colorectal cancer risk in family members increases with the number of affected members, the closeness of the relationship to the patient, and earlier age of onset. Medical information that patients provide about their relatives often is inaccurate. If a family medical history seems to be significant but proves difficult to confirm, it may be appropriate to seek expert help from a familial cancer clinic.

3. Digital rectal examination and rigid proctosigmoidoscopy are typically required for accurate tumor assessment. **Level of Evidence: Class V; Grade of Recommendation: D**.

   Digital rectal examination enables detection and assessment of the size and degree of fixation of mid and low rectal tumors. Although digital assessment of the extent of local disease may be imprecise, it provides a rough estimate of the local staging of rectal cancer. Rigid proctosigmoidoscopy is usually performed in conjunction with the digital rectal examination. It usually allows the most precise assessment of tumor location and the distance of the lesions from the anal verge. These issues are critical in optimizing preoperative planning.

4. Full colonoscopy should be performed to exclude synchronous neoplasms. Barium enema may be used for those patients unable to undergo complete colonoscopy. **Level of Evidence: III; Grade of Recommendation: B**.

   Colonoscopy is currently the most accurate tool for screening the colon and rectum for neoplasms. The sensitivity of colonoscopy for colon cancer is typically in the range of 95 percent. Colonoscopy allows biopsy and histologic

confirmation of the diagnosis. It also allows for identification and endoscopic removal of synchronous polyps.

5. Computed tomography (CT) scanning of the abdomen and pelvis and transrectal ultrasound (TRUS) or magnetic resonance imaging (MRI) should typically be performed in patients who are potentially surgical candidates. **Level of Evidence: III; Grade of Recommendation: B**.
6. Routine chest radiographs or chest CT scanning should usually be performed. **Level of Evidence: III; Grade of Recommendation: B**.

   Rectal cancer is more likely than colon cancer to be associated with lung metastases without liver metastases. The finding of pulmonary metastases often will alter patient management decisions and therefore is warranted in most clinical situations. Abnormal findings on plain radiographs usually warrant chest CT scanning.

7. Carcinoembryonic antigen (CEA) level should usually be determined preoperatively. **Level of Evidence: III; Grade of Recommendation: B**.

Treatment Considerations

Surgery is the mainstay of treatment for rectal cancer. The risk of recurrence is dependent on the TNM stage (See Table 1 in the original guideline document titled, "Definition of TNM"). Early stage cancer can be treated by surgical resection alone. More advanced lesions require adjuvant therapy to increase the probability of cure.

Surgical Therapy

Resection Margin

A 2-cm distal margin is adequate for most rectal cancers. **Level of Evidence: Class III; Grade of Recommendation: B**.

In smaller cancers of the low rectum without adverse histologic features, a 1-cm distal margin is acceptable. **Level of Evidence: Class III; Grade of Recommendation: B**.

Margins >1 cm should be obtained with larger tumors, especially those demonstrating adverse histologic features. The margins of resection should be measured in the fresh, pinned out specimen. The formalin-fixed specimen may shrink up to 50 percent in length.

Level of Proximal Vascular Ligation

Proximal lymphovascular ligation at the origin of the superior rectal artery is adequate for most rectal cancers. **Level of Evidence: Class III; Grade of Recommendation: B**.

Appropriate lymphadenectomy is based on the ligation of the major vascular trunks. There is no demonstrable survival advantage for a high ligation of the

inferior mesenteric artery at its origin. Available evidence suggests that for colorectal cancer without clinically suspicious nodal disease, removal of lymphovascular vessels up to the origin of the primary feeding vessel is adequate. Thus for rectal cancer, this is at the origin of the superior rectal artery, just distal to the origin of the left colic artery. In patients with lymph nodes thought to be involved clinically, removal of all suspicious nodal disease up to the origin of inferior mesenteric artery is recommended. Suspicious periaortic nodes may be biopsied for staging purposes. High ligation of the inferior mesenteric vessels may be helpful to provide additional mobility of the left colon, as often is required for a low colorectal anastomosis or a colonic J-pouch construction.

Circumferential Resection Margin

For distal rectal cancers, total mesorectal excision (TME) is recommended. For upper rectal cancers, a tumor-specific mesorectal resection is adequate. **Level of Evidence: Class II; Grade of Recommendation: A**.

En Bloc Resection of Adherent (T4) Tumors

Rectal cancers with adjacent organ involvement should be treated by en bloc resection. **Level of Evidence: Class III; Grade of Recommendation: B**.

Inadvertent Perforation

Inadvertent perforation of the rectum worsens oncologic outcome and should be documented. Level of Evidence: **Class III; Grade of Recommendation: B**.

Other Operative Considerations

1. Grossly normal ovaries need not be removed. **Level of Evidence: Class III; Grade of Recommendation: B**.

   Ovarian metastases from rectal cancer occur in up to 6 percent of patients and are usually associated with widespread disease and poor prognosis. There are no data to support routine prophylactic oophorectomy. Direct invasion of the ovary is treated with an en bloc resection. Oophorectomy should be considered if the organ is grossly abnormal in postmenopausal females or in females who have received preoperative pelvic radiotherapy. Bilateral oophorectomy is indicated if only one ovary is involved, because there is a high risk of occult metastatic disease in the contralateral ovary.

2. There is insufficient evidence to recommend intraoperative rectal washout. **Level of Evidence: Class IV; Grade of Recommendation: C**.
3. Curative local excision is an appropriate treatment modality for carefully selected T1 rectal cancers. **Level of Evidence: Class II; Grade of Recommendation: B**.

   Local excision of rectal cancer is an appropriate alternative therapy for selected cases of rectal cancer with a low likelihood of nodal metastases. This probability is dependent on the depth of tumor invasion (T stage), tumor differentiation, and lymphovascular invasion. Comparative trials to

abdominoperineal resection support transanal local excision with curative intent for T1, well-differentiated cancers that are <3 cm in diameter and occupy <40 percent of the circumference of the rectal wall.

The tumor must be excised intact by full-thickness excision with clear margins. It should be orientated and pinned out for complete pathologic examination. If unfavorable features are observed on pathologic examination, a radical excision is warranted.

4. Laparoscopic-assisted resection of rectal cancer is feasible but requires specific surgical expertise. Its oncologic effectiveness remains uncertain at this time. **Level of Evidence: Class II; Grade of Recommendation: B**.
5. Emergency intervention: Primary resection of an obstructing or perforated carcinoma is recommended unless medically contraindicated. **Level of Evidence: Class III; Grade of Recommendation: A**.

   Hemorrhage, obstruction, and bowel perforation are the most common indications for emergency intervention for rectal cancer. Appropriate management must be individualized with options, including resection with anastomosis and proximal diversion, or diversion alone followed by radiation. Other alternatives include endoluminal stenting or laser/cautery recanalization. Self-expandable metallic stents can be used to relieve obstruction by a proximal rectal cancer. This allows for mechanical bowel preparation, elective resection, and anastomosis. In some cases with advanced metastatic disease or major comorbidities, it may constitute definitive treatment.

Adjuvant Therapy

Adjuvant chemoradiation should be offered to patients with Stage II and III rectal cancers. **Level of Evidence: Class I; Grade of Recommendation: A**.

Definitions:

Levels of Evidence

1. Meta-analysis of multiple well-designed, controlled studies, randomized trials with low false-positive and low false-negative errors (high-power)
2. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low-power)
3. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
4. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
5. Case reports and clinical examples

Grades of Recommendations

A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV

B. Evidence of Type II, III, or IV and generally consistent findings
C. Evidence of Type II, III, or IV but inconsistent findings
D. Little or no systematic empirical evidence

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 of the recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation and management of patients with rectal cancer

POTENTIAL HARMS

- The surgeon is a critical variable with respect to morbidity, sphincter preservation rate, and local recurrence. One study found that local recurrence ranged from <5 to 15 percent amongst different surgeons with no difference in case mix. In a Scottish study, the operative mortality and ten-year survival rate after "curative" surgery varied with the surgeon, ranging from 0 to 20 percent and 20 to 63 percent, respectively.
- Inadvertent rectal perforation during the resection of rectal cancer is associated with a statistically significant reduction in five-year survival and an increase in local recurrent rates.
- Self-expandable metallic stents can be used to relieve obstruction by a proximal rectal cancer. Complications include perforation (5 percent), stent migration (10 percent), bleeding (5 percent), pain (5 percent), and reobstruction (10 percent).
- The morbidity associated with postoperative adjuvant therapy can be significant. In the Danish, Dutch, and Medical Research Council (MRC) postoperative therapy trials, >20 percent of patients did not complete their allocated treatment because of postoperative complications and/or patient refusal. Furthermore, functional outcomes may be compromised by postoperative combined modality therapy (CMT). In a review of two National Surgical and Adjuvant Breast and Bowel Project (NSABP) trials, a significant increase in severe diarrhea was noted from CMT particularly in patients receiving a low anterior resection. Other acute side effects included cystitis, skin reactions, and fatigue. One study emphasized both acute and chronic effects, including radiation enteritis, small-bowel obstruction, and rectal stricture.
- A major concern of short-course radiotherapy (RT) remains the increase in short-term and long-term toxicity, as has been noted with short-course RT at

other sites. A subgroup of patients from the Swedish Rectal Cancer Trial completed a questionnaire regarding anorectal dysfunction. Abnormal function included frequency, urgency and incontinence, and reduced social activities in 30 percent of patients who received short-course radiation *vs*. 10 percent of patients after surgery alone ($P < 0.01$). The authors suggested a radiation effect on the anal sphincter or its nerve supply. These complications are similar to those after postoperative radiotherapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are inclusive, and not prescriptive. Their purpose is to provide information on which decisions can be made, 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.
- The practice parameters set forth in this document have been developed from sources believed to be reliable. The American Society of Colon and Rectal Surgeons makes no warranty, guarantee, or representation whatsoever as to the absolute validity or sufficiency of any parameter included in this document, and the Society assumes no responsibility for the use or misuse of the material contained.

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

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Tjandra JJ, Kilkenny JW, Buie WD, Hyman N, Simmang C, Anthony T, Orsay C, Church J, Otchy D, Cohen J, Place R, Denstman F, Rakinic J, Moore R, Whiteford M. Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum 2005 Mar;48(3):411-23. [143 references] PubMed

ADAPTATION

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

DATE RELEASED

1993 (revised 2005 Mar)

GUIDELINE DEVELOPER(S)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Standards Task Force of the American Society of Colon and Rectal Surgeons

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Joe J. Tjandra, MD; John W. Kilkenny, MD; W. Donald Buie, MD; Neil Hyman, MD; Clifford Simmang, MD; Thomas Anthony, MD; Charles Orsay, MD; James Church, MD; Daniel Otchy, MD; Jeffrey Cohen, MD; Ronald Place, MD; Frederick Denstman, MD; Jan Rakinic, MD; Richard Moore, MD; Mark Whiteford, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of rectal carcinoma. Arlington Heights (IL): American Society of Colon and Rectal Surgeons; 1998-1999. 3 p.

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 ASCRS, 85 W. Algonquin Road, Suite 550, Arlington Heights, Illinois 60005.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 15, 2000. The information was verified by the guideline developer on November 7, 2000. This summary was updated by ECRI on July 15, 2005.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 11/3/2008