

An ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may

Clinical Condition:**Pretreatment Staging of Colorectal Cancer****Variant 2:****Rectal cancer—large lesion.**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
CT abdomen and pelvis with or without contrast	8	To evaluate for synchronous lesions, CTC may be done in conjunction with CT of abdomen and pelvis.	High
FDG-PET whole body	8	Has been shown to alter staging compared to CT.	High
X-ray chest	8	To evaluate for metastatic disease.	Min
MRI abdomen with or without contrast	6	To be done if CT cannot be performed (eg, because of iodine allergy). See comments regarding contrast in text under “Anticipated Exceptions.”	None
MRI pelvis with or without contrast	6	Endorectal coil. See comments regarding contrast in text under “Anticipated Exceptions.”	None
US rectum transrectal	6		None
US abdomen	4		None
X-ray contrast enema	4		Med
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

Variant 3:**Colon cancer (other than rectum).**

Radiologic Procedure	Rating	Comments	<u>RRL*</u>
CT abdomen and pelvis with or without contrast	8	To evaluate for synchronous lesions, CTC may be done in conjunction with CT of abdomen and pelvis.	High
X-ray chest	8	To evaluate for metastatic disease.	Min
FDG-PET whole body	6		High
MRI abdomen and pelvis with or without contrast	6	To be done if CT cannot be performed (eg, because of iodine allergy). See comments regarding contrast in text under “Anticipated Exceptions.”	None
US abdomen	4		None
X-ray contrast enema	4		Med
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

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PRETREATMENT STAGING OF COLORECTAL CANCER

Expert Panel on Gastrointestinal Imaging: Max Paul Rosen, MD, MPH¹; Robert L. Bree, MD, MHSA²; W. Dennis Foley, MD³; Spencer B. Gay, MD⁴; Thomas H. Grant DO⁵; Jay P. Heiken, MD⁶; James E. Huprich, MD⁷; Tasneem Lalani, MD⁸; Frank H. Miller, MD⁹; Gary S. Sudakoff, MD¹⁰; Frederick L. Greene, MD¹¹; Don C. Rockey, MD.¹²

Summary of Literature Review

Colorectal cancers are the second most common tumors in the United States and the most common gastrointestinal cancer. Approximately 160,000 new cases are diagnosed each year. Most of these patients undergo surgery for palliation or possible cure.

Colonic Malignancy

Barring contraindications from associated medical conditions, virtually all patients with colonic cancer will undergo some form of surgical therapy for attempted cure or palliation. Studies correlating pathological staging (eg, Duke's) with radiological assessment consistently yield poor results [1]. The purpose of the preoperative imaging workup is directed at determining the presence or absence of synchronous carcinoma, additional adenomas, contiguous organ involvement, or distant metastases. Staging information also aids in comparing the effectiveness of different therapies [2,3]. Because most adenocarcinomas of the colon cannot be cured by radiation therapy or chemotherapy, virtually all patients with colorectal cancer will undergo operations for attempted cure or palliation.

Rectal Malignancy

Unlike colonic malignancies, preoperative staging assessment of rectal carcinoma has significant therapeutic implications. Patients with node negative rectal carcinomas that have not reached the serosa may be adequately treated by radiation therapy with or without transanal excision [4]. Furthermore, clinical trials combining preoperative radiation followed by primary resection have shown improved survival in patients who present with transmural invasion or who are lymph node positive [1]. Thus preoperative imaging for local staging of rectal cancer is used routinely. If disease can be shown

to be localized, curative resection by alternative methods (ie, transanal incision) may be considered.

Imaging Modalities

Computed tomography (CT) scanning, magnetic resonance imaging (MRI), and transrectal ultrasound (TRUS) have all been extensively evaluated in initial staging of colorectal carcinoma [1-3,5-23]. There are few initial therapeutic options for patients with colon carcinoma beyond surgery. Surgical excision with satisfactory margins is necessary to provide a significant disease-free interval. However, in rectal carcinoma, several other parameters can determine the definitive treatment. Transanal excision has been shown to provide long-term survival equivalent to surgery in selected cases (ie, node negative lesions without extension into the muscularis layer), and may carry a higher patient acceptance [4]. Alternatively, in patients with transmural disease, preoperative radiation may improve survival. Obviously, these decisions cannot be made without accurate presurgical staging. There have been reports that MR staging and TRUS may provide better methods for staging colorectal cancer than CT, which to date has not been successful enough to be used routinely [24-26].

Computed Tomography

Initially, CT was the first "staging" modality evaluated, with early enthusiastic reports of accuracy ranging between 85%-90%. It was reported to be an excellent preoperative staging method with the ability to depict tumor and metastases. Early reports stated an accuracy of over 85%-90% [1]. Larger, more carefully controlled studies showed that the accuracy was more in the 50%-70% range, varying directly with the stage of the lesion [5]. Results from a multi-institutional study reported 74% accuracy for CT assessment of wall invasion, and a sensitivity of 48% in evaluating lymph node metastases. CT demonstrated 85% accuracy and 97% specificity in detecting liver metastases [23]. Local staging by CT improves as disease stage increases. Among a group of 100 patients who underwent CT, CT arteriography (CTAP) and MRI the sensitivity and specificity for liver metastases were 73% and 96.5% for CT, 87.1% and 89.3% for CTAP and 81.9% and 93.2% for MRI [27]. Staging-specific accuracy for local disease with CT improves when a prepared colon is evaluated and insufflated with either air or water, but does not approach the results of TRUS [8,28]. CT is recommended in the initial evaluation of all patients scheduled for colorectal carcinoma surgery because of its ability to obtain a rapid global evaluation and demonstrate complications (perforation, obstruction, etc) that may not be clinically apparent [19,29]. Furthermore, abdominal/pelvic CT has a high negative predictive value [7]. The accuracy rate for assessing lower stage lesions is not as good as that for

¹Principal Author and Panel Vice-Chair, University of Pennsylvania, Philadelphia, Pa; ²Panel Chair, University of Washington, Seattle, Wash; ³Froedtert Hospital East, Milwaukee, Wis; ⁴University of Virginia Health Science Center, Charlottesville, Va; ⁵Northwestern University Feinberg School of Medicine/NMH, Chicago, Ill; ⁶Mallinckrodt Institute of Radiology, Saint Louis, Mo; ⁷Mayo Clinic, Rochester, Minn; ⁸Inland Imaging Associates, Seattle, Wash; ⁹Northwestern University Feinberg School of Medicine/NMH, Chicago, Ill; ¹⁰Froedtert Hospital, Milwaukee, Wis; ¹¹Carolinas Medical Center, Charlotte, NC, American College of Surgeons; ¹²University of Texas, Southwest Medical Center, Dallas, Texas, American Gastroenterological Association.

Reprint requests to: Department of Quality & Safety, American College of Radiology, 1891 Preston White Drive, Reston, VA 20191-4397.

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advanced lesions. This discrepancy relates to the limited ability of CT to determine depth of bowel wall penetration [16]. The specificity for detecting lymph nodes involved with tumor is approximately 50% [19]. As detection of nodes involved with tumor remains a difficult problem, if a colonic resection is planned, local node groups are encompassed in a properly performed cancer operation. Among patients with potentially resectable liver metastases and a negative initial chest x-ray, additional imaging with a chest CT detected pulmonary metastases in only 5% of patients [30].

The role of virtual colonoscopy, (or CT colonography [CTC]) in patients with obstructing colorectal lesions has been evaluated in one study [31]. Among 34 patients, CTC identified all colorectal masses. CTC correctly staged 13 of 16 colorectal cancers (81%) and detected 16 of 17 (93%) synchronous polyps. CTC overstaged two Duke's stage A cancers and understaged one Duke's stage C cancer. A total of 97% (87/90) of all colonic segments were adequately visualized at CTC in patients with obstructing colorectal lesions compared with 60% (26/42) of segments at barium enema ($p < 0.01$). Colonic anastomoses were visualized in all nine patients, but in one patient CTC could not distinguish between local tumor recurrence and surgical changes.

Magnetic Resonance Imaging

MRI has also been evaluated in staging colorectal carcinoma [32,33]. Data from the Radiology Diagnostic Oncology Group (RDOG) study [23] showed that MRI had an accuracy of 58% for local staging of rectal cancer, and was equal to CT for colonic neoplasms. Accuracy in identification of lymph node metastases was equal to CT, and slightly superior for detection of liver metastases. It should be noted that MRI technology has significantly improved compared with what was available at the time of this study. However, recent studies indicate that fast MRI sequences and more liberal use of MR IV contrast may afford improved accuracy [21,34].

MRI suffers from some of the same difficulties at CT [20]. Some reports have shown that it does have a better spatial resolution at the organ level and may be able to determine degree of involvement of adjacent organs, although these findings have not been confirmed in controlled clinical trials [26]. Several groups using endorectal coils have shown impressive results in the depiction of the layers of the rectal wall with resultant improvement in the accuracy of assessing the depth of bowel wall penetration [25]. Scattered reports of MR identification of tumor-bearing lymph nodes based on signal differences have emerged.

MRI may be beneficial in determining involvement of the pelvic musculature and adjacent organs. MRI may be considered in preoperative evaluation of patients with sensitivity to iodinated contrast material, particularly in

the evaluation of the liver. IV contrast-enhanced MRI, augmented with endorectal coils, is an appropriate primary strategy in patients with rectal cancer.

Several groups, using endorectal MR coils, have shown impressive results in depicting the layers of the rectal wall with resultant improvement in the accuracy of assessing the depth of bowel wall penetration [24-26]. The accuracy of MRI to predict circumferential margin resection has been reported to be 86% [35]. In meta-analysis of the pooled sensitivity and specificity of MRI for predicting circumferential margin involvement, they were reported to be 94% and 85%, respectively [36]. Combined endorectal and phased-array coil MRI can be used reliably to select which patients should receive preoperative chemotherapy. MRI is highly predictive in terms of excluding T3 tumors, but still has limitations in predicting lymph node metastasis [37].

Transrectal Ultrasound

TRUS has become the gold standard procedure for staging rectal carcinoma [14,15,17,38]. Because TRUS enables one to distinguish layers within the rectal wall, it appears to be an accurate method for detecting depth of tumor penetration and perirectal spread [6,10]. Reported sensitivities range between 83%-97% [9,22]. Lymph node involvement is less easy to determine (sensitivity is 50%-57%) [13]. TRUS is more sensitive than CT for detecting perirectal spread. However, not surprisingly, the differences in accuracy decrease in more advanced lesions. Fourteen percent of patients with tumors confined to the bowel wall may have regional node metastases [18]. Although TRUS can frequently detect regional lymph nodes, and is superior to CT at this task, to date it cannot predict the histology of the visualized lymph nodes [13,16]. Other pitfalls have been described [11].

There is considerable interest in the use of TRUS for assessing the depth of tumor invasion in patients with rectal carcinoma [12]. Unlike CT, TRUS enables one to distinguish layers within the rectal wall. Tumor invasion is characterized by a hypoechoic mass that causes disruption of one or more of three layers. More important, TRUS appears to be an accurate method for detecting perirectal tumor spread; it has a reported sensitivity of 83%-94% [12]. Lymph node involvement is less easy to determine (sensitivity is 50%-57%) [38], but is nonetheless an important part of the examination. TRUS is more sensitive than CT for detecting perirectal spread [14]. However, not surprisingly, the differences in accuracy decrease in more advanced lesions. These findings suggest that this technique may be of value in assessing apparently superficial rectal carcinomas that are potentially suitable for treatment by transanal or local excision or endocavitary radiation [8,28]. Endoscopic sonography (also known as endoscopic ultrasound or EUS) is commonly used in the rectum, and has expanded

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the application of sonographic methods to the entire gastrointestinal tract.

Nuclear Medicine

Several centers are actively evaluating a variety of nuclear imaging strategies. Examples include positron emission tomography (PET) scanning [39], and radioimmunoscintigraphy [40,41]. These techniques hold significant promise because of the separation of sensitivity in detecting disease-bearing sites without the need to detect anatomic abnormality [42]. Although the major utility investigated has been in evaluation of suspected recurrence, PET has been shown to alter therapy in almost a third of patients with advanced primary rectal cancer [43]. Among patients with low rectal carcinoma, when compared to TRUS or MRI or spiral CT, PET/CT identified discordant findings in 38% of patients, which resulted in upstaging in 50% of these patients and downstaging in 21% [44]. Compared to CT, PET/CT colonography has been reported to be significantly more accurate in defining TNM stage [45]. When compared to CT alone, PET/CT has been shown to yield a cost savings of \$2,671 per patient, and to avoid exploratory surgery in 6.1% of patients [46].

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF), also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF [47-49], a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (eg, >0.2mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a “black box” warning concerning these contrast agents (http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR <30 mL/min/1.73m²), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment

suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s) [48].

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations	
Relative Radiation Level	Effective Dose Estimate Range
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

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