ACR Appropriateness Criteria® Pretreatment Staging of Colorectal Cancer

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Because virtually all patients with colonic cancer will undergo some form of surgical therapy, the role of preoperative imaging is directed at determining the presence or absence of synchronous carcinomas or adenomas and local or distant metastases. In contrast, preoperative staging for rectal carcinoma has significant therapeutic implications and will direct the use of radiation therapy, surgical excision, or chemotherapy. CT of the chest, abdomen, and pelvis is recommended for the initial evaluation for the preoperative assessment of patients with colorectal carcinoma. Although the overall accuracy of CT varies directly with the stage of colorectal carcinoma, CT can accurately assess the presence of metastatic disease. MRI using endorectal coils can accurately assess the depth of bowel wall penetration of rectal carcinomas. Phased-array coils provide additional information about lymph node involvement. Adding diffusion-weighted imaging to conventional MRI yields better diagnostic accuracy than conventional MRI alone. Transrectal ultrasound can distinguish layers within the rectal wall and provides accurate assessment of the depth of tumor penetration and perirectal spread, and PET and PET/CT have been shown to alter therapy in almost one-third of patients with advanced primary rectal cancer.

The ACR Appropriateness Criteria® are evidence-based guidelines for specific clinical conditions that are reviewed every 2 years by a multidisciplinary expert panel. The guideline development and review include an extensive analysis of current medical literature from peer-reviewed journals and the application of a well-established consensus methodology (modified Delphi) to rate the appropriateness of imaging and treatment procedures by the panel. In those instances in which evidence is lacking or not definitive, expert opinion may be used to recommend imaging or treatment.

Key Words: Appropriateness criteria, colorectal neoplasms, tumor staging, computed tomography, magnetic resonance imaging, ultrasound

J Am Coll Radiol 2012;9:775-781. Copyright © 2012 American College of Radiology

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The ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria® through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply individual or society endorsement of the final document.

Max P. Rosen, MD, MPH, is a stock holder of Anvita Health; Mark E. Baker, MD, reported a research agreement with Siemens Healthcare (hardware; software), monetary support for research forthcoming (agreement not signed).

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0091-2182/12/$36.00 • http://dx.doi.org/10.1016/j.jacr.2012.07.025

SUMMARY OF LITERATURE REVIEW

Introduction/Background

Colorectal cancers are the second most common tumors in the United States and the most common gastrointestinal cancer. The National Cancer Institute [1] estimated that >141,000 new cases of colorectal cancer would be diagnosed in 2011. 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. 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].

Rectal Malignancy

The 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 chemotherapy and radiation followed by primary resection have shown improved survival in patients who present with transmural invasion or who are lymph node positive [5]. Thus, preoperative imaging for local staging of rectal cancer is used routinely [5-7].

Imaging Modalities

The relative merit of numerous imaging modalities for the pretreatment staging of colorectal cancer is provided in the variant tables (see Variants 1, 2, and 3). CT scanning, MRI, and transrectal ultrasound (TRUS) have all been extensively evaluated in initial staging of colorectal carcinoma [2,3,5,8-26]. 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 help 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 it may carry a higher patient acceptance [4]. Alternatively, in patients with transmural disease, preoperative radiation may improve survival. These decisions, however, cannot be made without accurate presurgical staging. Although reports suggest that MRI and TRUS may provide better methods than CT for staging rectal cancer, to date, they have not been successful enough to be used routinely as the sole imaging modality [27-29].

CT. Initially, CT was the first "staging" modality evaluated. Early enthusiastic reports of accuracy ranged between 85% and 90% [5], and it was reported to be an excellent preoperative staging method, with the ability to depict both tumor and metastases. CT is still 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 [22,30].

Larger, more carefully controlled studies, however, have shown that the overall accuracy of CT is in the 50% to 70% range, varying directly with the stage of the lesion (ie, T4 lesions are more accurately assessed than T2 or T3 lesions) [8,26,30,31]. Overstaging is far more common because it is difficult to accurately determine T stage (depth of bowel wall penetration) on CT [19]. Another complicating factor, particularly in rectal cancer, is that perirectal spiculation can be confused with desmoplastic

Variant 1. Rectal cancer (small or superficial)

Radiologic Procedure	Rating	Comments	Relative Radiation Level
Ultrasound pelvis endorectal	8	For assessment of level of rectal wall involvement.	O
CT chest abdomen pelvis with contrast	8		☢☢☢☢
X-ray chest	8	If chest CT is not performed.	☢
MRI pelvis without and with contrast	7	See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI abdomen without and with contrast	6	See statement regarding contrast in text under "Anticipated Exceptions."	O
CT chest abdomen pelvis without contrast	5		☢☢☢☢
CT chest abdomen pelvis without and with contrast	5		☢☢☢☢
MRI pelvis without contrast	5		O
MRI abdomen without contrast	5		O
FDG PET/CT whole body	5		☢☢☢☢

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. FDG = ^{18}F-fluorodeoxyglucose.

Variant 2. Rectal cancer: large lesion

Radiologic Procedure	Rating	Comments	Relative Radiation Level
CT chest abdomen pelvis with contrast	8		☢☢☢☢
FDG PET/CT whole body	8	Has been shown to alter staging compared with CT. May be used in place of CT without PET.	☢☢☢☢
X-ray chest	8	To evaluate for metastatic disease if chest CT is not performed.	☢
MRI pelvis without and with contrast	8	See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI abdomen without and with contrast	7	See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI pelvis without contrast	6		O
Ultrasound pelvis endorectal	6		O
MRI abdomen without contrast	5		O
CT chest abdomen pelvis without contrast	5		☢☢☢☢
CT chest abdomen pelvis without and with contrast	5		☢☢☢☢

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. FDG = ^{18}F-fluorodeoxyglucose.

peritumoral inflammation, which can also lead to overstaging [32].

There is little agreement on the critical cutoff diameter to determine if lymph nodes are involved in the disease process. One study suggested 4.5 mm; however, nodal size is not seen as a predictor of nodal status at surgery [7,33]. Because the detection of nodes involved with tumor remains a difficult problem, if colonic resection is planned, local node groups are encompassed in a properly performed cancer operation. The specificity for detecting lymph nodes involved with tumor is only 45% [22].

Liver metastases are detected by CT with 85% accuracy and 97% specificity [26]. The detection of liver metastases by CT improves as the disease stage increases. Among a group of 100 patients who underwent CT, CT arterioportography, and MRI, the sensitivity and specificity for liver metastases were 73% and 96.5% for CT, 87.1% and 89.3% for CT arterioportography, and 81.9% and 93.2% for MRI [31]. In addition, abdominal and pelvic CT has a high negative predictive value of 90% [10].

The detection of possible lung metastases is also an important part of the initial imaging evaluation of patients with colorectal carcinoma. Among patients with potentially resectable liver metastases and negative initial chest radiographic results, additional imaging with chest CT revealed pulmonary metastases in only 5% of patients [34]. However, one study showed that rectal cancer is more likely than colon cancer to present with lung metastases without liver metastases and that this risk increases with advancing T stage. Although this study advised CT imaging of the chest in all patients with rectal cancer, it was limited by the lack of pathologic correlation [35].

Virtual colonoscopy (or CT colonography [CTC]) has proved a valid tool in identifying both primary and syn-

Variant 3. Colon cancer (other than rectum)

Radiologic Procedure	Rating	Comments	Relative Radiation Level
CT chest abdomen pelvis with contrast	8	To evaluate for synchronous lesions, CTC may be done in conjunction with CT of abdomen and pelvis.	☢☢☢☢
X-ray chest	8	To evaluate for metastatic disease if chest is not imaged by CT.	☢
FDG PET/CT whole body	7		☢☢☢☢
MRI abdomen and pelvis without and with contrast	7	If CT is contraindicated or liver lesion requires further characterization. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI abdomen and pelvis without contrast	5		O
CT chest abdomen pelvis without and with contrast	5		☢☢☢☢
CT chest abdomen pelvis without contrast	5		☢☢☢☢

Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate. CTC = CT colonography; FDG = ^{18}F-fluorodeoxyglucose.

chronous colonic lesions and for detecting extracolonic metastases. CT colonography is beneficial after incomplete colonoscopy to evaluate the remainder of the colon and is currently being advocated for use as a screening test [36]. More than 95% of patients prefer CTC to routine colonoscopy [37], and its use may increase patient willingness to receive regular screening for colorectal cancer. CT colonography has a staging accuracy of 81% [38] and has sensitivity of 93% and specificity of 97% for detecting polyps >1 cm. Sensitivity and specificity fall to 86% and 86%, respectively, for polyps measuring <1 cm [39].

MRI. Data from the Radiology Diagnostic Oncology Group study [26] showed that MRI had an accuracy of 58% for detecting local staging of rectal cancer and was equal to CT for detecting colonic neoplasms. Accuracy in the identification of lymph node metastases was similar to that of CT, with sensitivity of 85%, and MRI was slightly superior for detecting liver metastases.

Recently, several groups, using endorectal MR coils and 3.0-T magnets [40], 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 [27-29]. There is no consensus in the literature as to whether endorectal coils should be used routinely in practice. Some authors contend that endorectal coils provide improved diagnostic accuracy compared with phased-array coils alone for T staging, with sensitivity reaching 100% and specificity of 86%. Endorectal coils have limitations in assessing upper rectal tumors and lateral pelvic and inferior mesenteric lymph nodes. Although phased-array coils are far superior in detecting lymph node metastases, they are limited in the imaging of obese patients and in the evaluation of lower rectal tumors [41,42]. With the advent of 3.0-T imaging, most imaging can be performed with a pelvic phased-array coil only.

MRI can aid in the accurate prediction of a histologically involved circumferential resection margin, with reported sensitivity of 94% to 100% and specificity of 85% to 88%. The distance to the mesorectal fascia is an important prognostic factor for determining the risk for local recurrence. MRI has accuracy of 86% in predicting the circumferential margin involvement [43,44]. Furthermore, from a surgical perspective, assessment of the mesorectal fascia involvement and tumor-free circumferential resection margin is crucial for surgical planning that determines whether total or extended mesorectal excision should be performed [45-47].

Diffusion-weighted imaging has been shown to be more sensitive and specific than standard contrast-enhanced MRI with gadolinium or superparamagnetic iron oxide–enhanced MRI, with values of 82% and 94%, respectively [48,49]. It is believed to be superior for tumor detection and characterization and for monitoring tumor response. Adding diffusion-weighted imaging to conventional MRI yields better diagnostic accuracy than conventional MRI alone [49]. Diffusion-weighted imaging does not use contrast and is more sensitive than contrast-enhanced CT in detecting metastases [50]. It also has the potential to be clinically effective for the evaluation of preoperative TNM staging and the postoperative follow-up of colorectal cancer.

TRUS. Transrectal ultrasound has become the standard imaging procedure for staging rectal carcinoma [17,18,20,51]. Because TRUS enables one to distinguish layers within the rectal wall, it is an accurate method for detecting the depth of tumor penetration and perirectal spread [9,13]. Reported sensitivities range between 83% and 97% [12,25]. The T-stage accuracy for TRUS (84.6%) is far superior to that of CT (70.5%) [33]. However, overstaging can be a problem, especially when differentiating T2 from T3 lesions [52]. However, TRUS is of value in assessing apparently superficial rectal carcinomas that are potentially suitable for treatment by transanal or local excision or endocavitary radiation [11,53](Variant 1 and 2).

One study compared the frontal ultrasound probe to the radial probe and found that the accuracy for T staging was 89% with the frontal probe but only 69% with the radial probe, with no overstaging seen with the radial probe [54].

The detection of lymph node involvement with TRUS is difficult. Sensitivity is 50% to 57% [16], and overall accuracy is 62% to 83% [32]. Although TRUS can frequently be used to detect regional lymph nodes, it has not been shown to be predictive of the histology of the visualized lymph nodes [16,19]. Many lymph nodes measuring <5 mm in diameter have associated micrometastases, and some early-stage T1 and T2 tumors are likely to have lymph node micrometastases missed on TRUS. This may be responsible for the high rate of pelvic recurrence within this patient group [55].

Nuclear Medicine. PET and PET/CT have been shown to alter therapy in almost one-third of patients with advanced primary rectal cancer [56](Variant 2). In a study comparing PET/CT with TRUS, MRI, and helical CT in imaging patients with low rectal carcinoma, PET/CT identified discordant findings and was far superior in 38% of patients. The result was up-staging in 50% of these patients and down-staging in 21% [57]. A relatively new concept of PET/CTC has been reported to be significantly more accurate in defining TNM stage [58] than CTC alone [59]. However, it is not used routinely at most centers. The accuracy of PET/CT is similar to that of CT in terms of T stage [58] but is far superior in detecting hepatic and peritoneal metastases (sensitivity of 89% and specificity of 64%) [60]. The sensitivity of detecting nodal metastases is only 43%, with specificity of 80%, and again, size is not a helpful characteristic.

Table 1. Relative radiation level designations

Relative Radiation Level	Adult Effective Dose Estimate Range (mSv)	Pediatric Effective Dose Estimate Range (mSv)
O	0	0
☢	<0.1	<0.03
☢☢	0.1-1	0.03-0.3
☢☢☢	1-10	0.3-3
☢☢☢☢	10-30	3-10
☢☢☢☢☢	30-100	10-30

Note: Relative radiation level assignments for some of the examinations cannot be made because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The relative radiation levels for these examinations are designated as "Varies".

There is also a potential role for PET in restaging colorectal cancer after chemoradiotherapy by measuring the pretreatment and posttreatment standard uptake volume and assessing response by decreasing standard uptake volume (Variants 2 and 3) [61]. Limitations of PET include decreased sensitivity in detecting small colonic lesions 5 to 10 mm in diameter and decreased ^{18}F-fluorodeoxyglucose uptake by mucinous tumors [60].

SUMMARY

- The preoperative staging assessment of rectal carcinoma has significant therapeutic implications in terms of surgical planning and neoadjuvant chemotherapy and radiation therapy.
- CT of the chest, abdomen, and pelvis is recommended in the initial evaluation of all patients scheduled for colorectal carcinoma surgery.
- Transrectal ultrasound enables one to distinguish layers within the rectal wall. It is an accurate method for detecting the depth of tumor penetration and perirectal spread. However, it is associated with overstaging and is not fully accurate in differentiating T2 from T3 lesions.
- CT colonography is a valid tool for identifying both primary and synchronous colonic lesions and for detecting extracolonic metastases.
- The sensitivity and specificity of endorectal MRI for predicting circumferential margin involvement are 94% and 85%, respectively. No consensus is seen in the literature as to whether an endorectal coil or a phased-array coil should be used routinely, as both have limitations.
- Diffusion-weighted imaging has been shown to be more sensitive and specific than standard contrast-enhanced MRI with gadolinium contrast.

ANTICIPATED EXCEPTIONS

Nephrogenic systemic fibrosis is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It seems to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rates (ie, <30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding nephrogenic systemic fibrosis. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk and to limit the type and amount in patients with estimated glomerular filtration rates < 30 mL/min/1.73 m^2. For more information, please see the ACR's *Manual on Contrast Media* [62].

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 indication has been included for each imaging examination. The relative radiation levels 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. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the relative radiation level dose estimate ranges for pediatric examinations are lower compared with those specified for adults (Table 1). Additional information regarding radiation dose assessment for imaging examinations can be found in *ACR Appropriateness Criteria®: Radiation Dose Assessment Introduction* [63]. (Variant 3).

For additional information on ACR Appropriateness Criteria, refer to http://www.acr.org/ac.

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