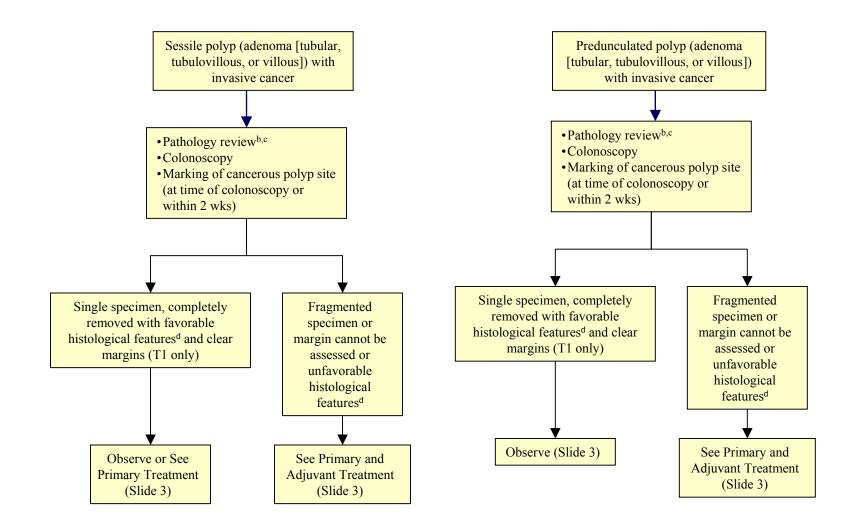
Rectal Cancer Treatment Guidelines Slide I





Rectal Cancer Treatment Guidelines Steeplechase Slide 2 at Somerset Medical Center T1-2, N0e T3, N0 or T any, N1-2 T3, N0 or T any, N1-2 T4 and/or Patients with medical contraindication to locally combined modality therapy. unresectable Transabdominal Transanal excision, if Transabdominal Preoperative 5-FU/RT Continuous IV 5-FU/RT or bolus 5appropriate^f (cat 2B for T2) (preferred) (cat 1 for node resection^f resection^f positive disease) or bolus 5-FU FU + leucovorin/RT + leucovorin/RT or or capecitabine/RT capecitabine/RTk (cat 2B) (cat 2B)k pT1-2. pT3, N0, M0 T1-T2, NX; pT3, N0, M0^{l,m} T1, NX; T2, NX; pT1-2. Transabdominal Resection, if Pathological Findings N₀. M₀ or pT1-3, N1-2 Margins High risk Margins N₀. M₀ or pT1-3, N1-2 resection^f possible negative features⁹ negative 5-FU± leucovorin or 5-FU ± leucovorin or Any T FOLFOX^j (cat 2B) or FOLFOX^{j,o} (cat 2B) or capecitabine^j (cat 2B), capecitabine^j (cat 2B), then then continuous 5-FU/RT 5-FU ± continuous 5-FU/RT or or bolus 5-FU + leucovorin (cat leucovorin/RT (cat 2B) or bolus 5-FU + 5-FU ± leucovorin Transabdominal 5FU/RT 1) or capecitabine/RTk (cat leucovorin/RT (cat 2B) or Observe Observe Observe or FOLFOX^{j,o} (cat FOLFOX^{j,o} 2B), then 5-FU \pm resectionf capecitabine/RTk (cat 2B) 2B) or capecitabine leucovorin or FOLFOXi (see above) (cat 2B) or then 5-FU ± leucovorin or (cat 2B) (cat 2B) or capecitabine Consider FOLFOX^{j,o} (cat 2B) or capecitabine^j (cat 2B) systemic chemo capecitabine^j (cat 2B) (cat 2B) • History and physical every 3-6 mo for 2 y, then every 6 mo for a total of 5 y. • CEA^t every 3-6 mo for 2 y, then every 6 mo for a total of 5y for T2 or greater lesions • Chest/abdominal/pelvic CT annually x 3y for patients at high risk of recurrence^{u,v} • Colonoscopy in 1 y except if no preoperative colonoscopy due to obstructing lesion, colonoscopy in 3-6 mo: if abnormal repeat in 1 y; if no advanced adenoma, repeat in 3 y, then every 5 vx • Consider proctoscopy every 6 mo x 5 y for patients status post LAR^y • PET scan is not routinely recommended • See NCCN Principles of Survivorship

Serial CEA elevation or documented recurrence

See Workup and Treatment (Slide 6)

Rectal Cancer Treatment Guidelines Slide 3



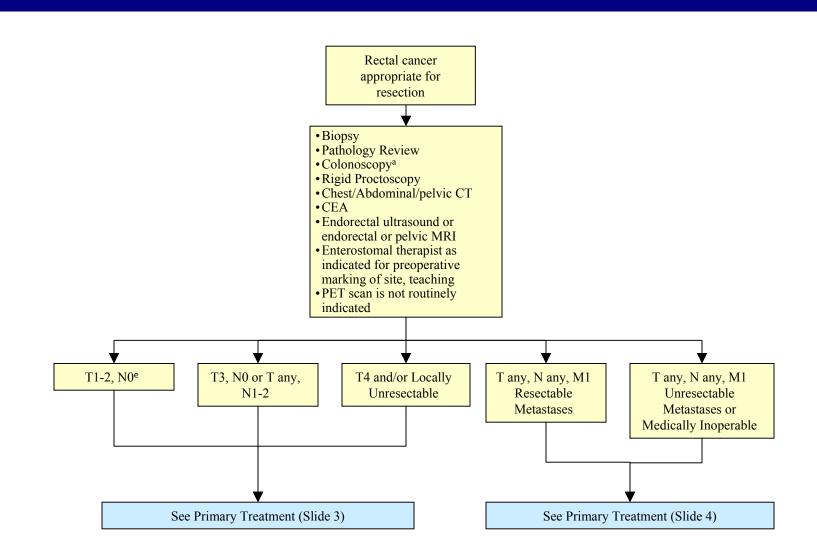
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Clinical Presentation

Work U

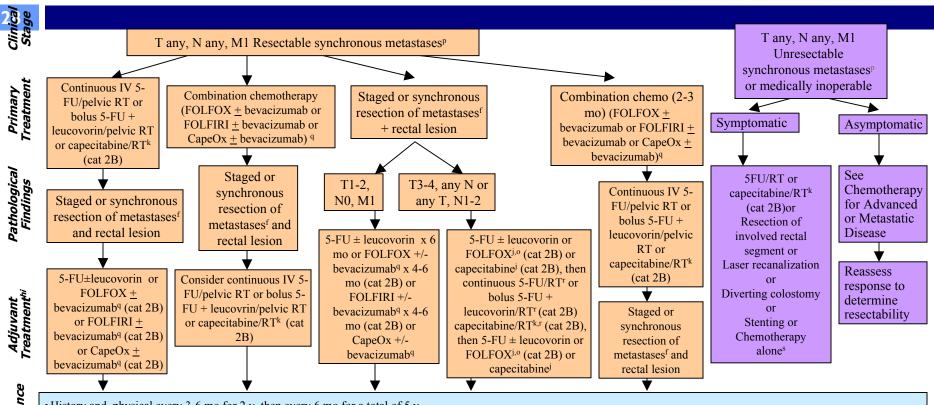
Clinical Stage

Treatment



Rectal Cancer Treatment Guidelines Steeplechase Slide 4



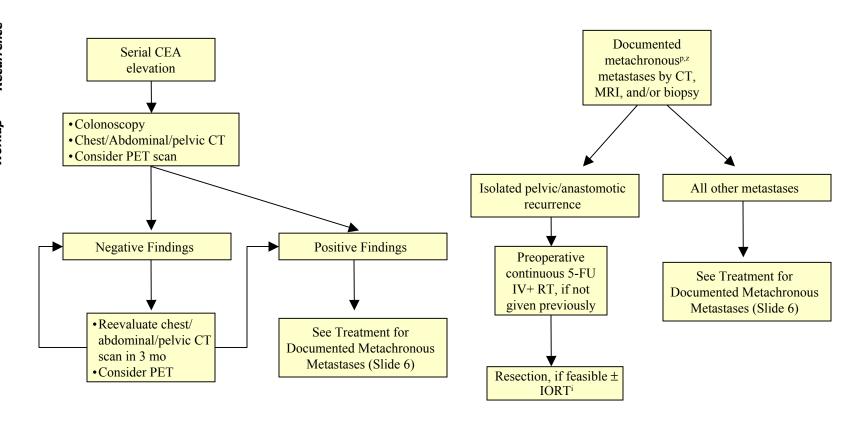


- History and physical every 3-6 mo for 2 y, then every 6 mo for a total of 5 y.
- CEA^t every 3-6 mo for 2 v. then every 6 mo for a total of 5v for T2 or greater lesions
- Chest/abdominal/pelvic CT annually x 3y for patients at high risk of recurrence^{u,v}
- Colonoscopy in 1 y except if no preoperative colonoscopy due to obstructing lesion, colonoscopy in 3-6 mo: if abnormal repeat in 1 y; if no advanced adenoma, repeat in 3 y, then every 5 vx
- Consider proctoscopy every 6 mo x 5 y for patients status post LAR^y
- PET scan is not routinely recommended
- See NCCN Principles of Survivorship

Serial CEA elevation or documented recurrence See Workup and Treatment (Slide 6)

Rectal Cancer Treatment Guidelines Slide 5

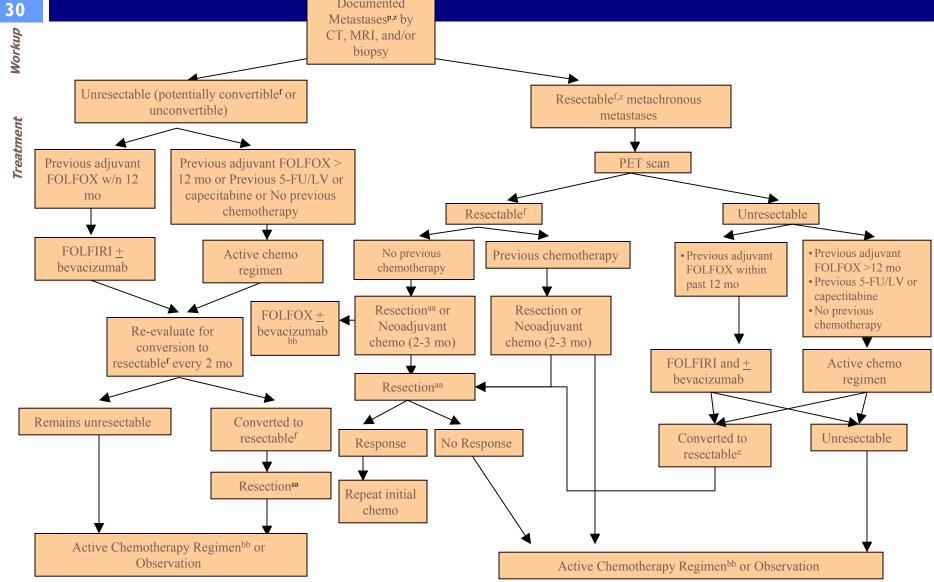




Rectal Cancer Treatment Guidelines

Slide 6

Documented
Metastases^{p,2} by
CT, MRI, and/or
biopsy



Rectal Cancer Treatment Guidelines Steeplechase Slide 6; Citations



^aAll patients with colon cancer should be counseled for family history. Patients with suspected HNPCC, FAP, and attenuated FAP, see NCCN Colorectal Cancer Screening Guidelines.

^bConfirm the presence of invasive cancer (pTI). pTis has no biological potential to metastasize.

elt has not been established if molecular markers are useful in treatment determination (predictive markers) and prognosis. College of American Pathologists. See NCCN Principles of Pathologic Review – Endoscopically removed malignant polyp.

eTI-2, N0 should be based on assessment of endorectal ultrasound or MRI.

See NCCN Principles of Surgery

gHigh risk features include positive margins, lymphovascular invasion and poorly differentiated tumors.

hSee NCCN Principles of Adjuvant Therapy

See NCCN Principles of Radiation Therapy

The use of FOLFOX or capecitabine is an extrapolation from the available data in colon cancer. Trials are still pending in rectal cancer.

^kData regarding the use of capecitabine/RT is limited and no phase III randomized data are available. Trials are pending,

The use of agents other than fluoropyrimidines are not recommended concurrently with RT.

"For patients with proximal T3, N0 disease with clear margins and favorable prognostic features, the incremental benefit from RT is likely to be small. Consider chemotherapy alone.

Postop therapy is indicated in all patients who receive preop therapy, regardless of the surgical pathology results.

An ongoing Intergroup trial compares 5-FU-leucovorin, FOLFOX and FOLFIRI after surgery.

PDetermination of tumor KRAS gene status. See NCCN Principles of Pathologic Review – KRAS Mutation Testing.

The safety of administering bevacizumab pre or postoperatively, in combination with 5-FU-based regimens, has not been adequately evaluated. There should be at least a 6 wk interval between the last dose of bevacizumab and elective surgery. There is an increased risk of strok and other arterial events especially in patients 65 years and older. The use of bevacizumab may interfere with wound healing.

rRT only recommended for patients at relative risk for pelvic recurrence.

See Chemotherapy for Advanced or Metastatic Disease

^tIf a patient is a potential candidate for resection of isolated metastasis.

"Desch CE, Benson III AB, Somerfield MR, et al. Colorectal cancer surveillance: 2005 update of the ASCO Practice Guideline.

°CT scan may be useful for patients at high risk for recurrence (eg, lymphatic or venous invasion by tumor, or poorly differentiated tumors).

"Villous polyp, polyp > 1 cm, or high grade dysplasia.

*Rex, DK, Kahi, CJ, Levin B, et al. Guidelines for colonoscopy surveillance after cancer resection, Gastroenterology 2006; 130:1865-71.

Patients with rectal cancer should also undergo limited endoscopic evaluation of the rectal anastomosis to identify local recurrence. Optimal timing for surveillance is not known. No specific data clearly support rigid versus flexible proctoscopy. The utility of routine endoscopic ultrasound for early surveillance is not defined.

Patient should be evaluated by a multidisciplinary team including surgical consultation for potentially resectable patients.

aaHepatic artery infusion +/- systemic 5-FU/leucovorin (cat 2B) is also an option at institutions with experience in both the surgical and medical oncologic aspects of this procedure.

bbTherapy may be considered for a maximum of 6 months.

SOURCE: NCCN Rectal Cancer Treatment Guidelines v.2.2009.

NOTE: All recommendations are category 2A unless otherwise indicated.

CLINICAL TRIALS: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged. INTERVENTIONAL RADIOLOGY: Consider Interventional Radiology techniques with unresectable metastatic disease.