

Revisiting local excision of early rectal cancer

by David M. Ota, MD, FACS, Durham, NC, and Heidi Nelson, MD, FACS, Rochester, MN

Organ preservation is highly desirable for cancer patients who present with early disease. Lumpectomy and postoperative radiation therapy is a paradigm for other organ sites. Early stage rectal cancer is defined as ultrasound T1 or T2 and was the subject of enthusiasm for transanal local excision of distal rectal cancer followed by postoperative radiation therapy. However, a 20 percent local recurrence rate was reported for T2 rectal cancers that were locally excised and treated with postoperative radiation therapy.* Because a 20 percent local recurrence rate for T2 rectal cancer is high, local excision is being done less frequently.

The search for a conservative surgical approach to treating T2 rectal cancer remains. Consider the following hypothetical patient encounter. A relatively obese 58-year-old man presents with rectal bleeding and a biopsy-proven 2.0 cm diameter distal rectal adenocarcinoma. The patient has read about an abdominoperineal resection (APR) and a permanent colostomy and is interested in sphincter preservation. Transrectal

ultrasound shows that this is a T2 lesion with no mesorectal adenopathy and chest X ray and computed tomography scan show no evidence of regional or distant disease. So far, this is good news for the patient.

On the digital rectal exam, the distal edge of the tumor is 2 cm above the anorectal ring and 5 cm from external anus by rigid proctoscopy. When discussing treatment options with the patient, including APR, he indicates he is not very enthusiastic about a permanent colostomy. He is relatively young, has good health, and is concerned about sexual function. A low anterior resection and low rectal anastomosis, either by stapler or coloanal method, is another possibility, but in a relatively obese man, this will require two surgeons, a long operation, and a possible positive tumor margin at the distal end of the resected rectum. You are not enthused about this prospect. You and the patient search for another option.

The American College of Surgeons Oncology Group (ACOSOG) offers such an option. Z6041 is a new protocol that offers a different strategy for the conservative surgical approach to early distal rectal cancer. Preoperative chemoradi-

ation therapy for T3 and T4 rectal cancer results in significant tumor regression and affords surgeons the opportunity to offer low anterior resection for patients who might otherwise require an APR and postoperative chemoradiation therapy. Z6041 adopts this preoperative therapeutic approach to induce tumor regression before a transanal local excision.

This is a clever and novel approach. Locally excising a 2.0 cm diameter T2 rectal cancer through a transanal approach does not offer the best exposure and it is a challenge to obtain a 1 cm mucosal margin around a 2 cm tumor. However, if a pre-treatment regimen can induce tumor regression so that a 2.0 cm tumor becomes a residual ulcer smaller than 0.5 cm, the prospect of a complete tumor-free local excision of the rectal cancer becomes higher. In fact, one of the important maneuvers in this trial is to endoscopically tattoo the rectal cancer site before preoperative chemoradiation therapy is started. One of the challenges of preoperative therapy for early rectal cancer is that tumor regression can be so significant that identifying the tumor site during the local excision procedure can be difficult if there is a complete clinical re-

* Steele GD, Herndon JE, Bleday R, et al. Sphincter-sparing treatment for distal rectal adenocarcinoma. *Ann Surg Oncol*. 1999;6:433-441.

gression and no residual ulcer.

Z6041 is a phase II nonrandomized trial that requires 85 patients. The preoperative chemoradiation therapy for Z6041 consists of capecitabine (Xeloda) and oxaliplatin with 54 Gy pelvic radiation therapy. Both agents are commercially available. Toxicity will be monitored closely. Local excision will be performed approximately four to six weeks after completion of chemoradiation therapy. The primary endpoint of the trial is tumor-free survival at three years. Other endpoints include negative margins in the resected specimen, pathologic complete response in the excised tissue, and quality of

life and anorectal function records.

ACOSOG needs your participation in Z6041. If you have patients with early ultrasound staged T2 distal rectal cancers and want to offer your patient an option to APR or low anterior resection and low rectal anastomosis, we urge you to consider this novel treatment approach for your patients. This ACOSOG protocol offers a local excision approach to ultrasound T2 rectal cancers and patient accrual into this protocol from multiple institutions is critical. Only through this evidence-based approach can surgeons evaluate the safety and effectiveness of new surgical approaches to rectal cancer. Your

participation and enrollment of patients is crucial to determine if preoperative therapy followed by local excision is effective in local control of this disease. The synopsis and entire protocol are available on the ACOSOG Web site, www.acosog.org.


For more information about becoming an ACOSOG member, contact Helen Harbett at harbet001@notes.duke.edu. For enrollment questions, contact Beth Martinez at marti025@surgeytrials.duke.edu, Dr. David Ota at david.ota@duke.edu, or Dr. Heidi Nelson at nelsonh@mayo.edu.

Dr. Ota and Dr. Nelson are ACOSOG Group Co-Chairs.

RESIDENCY ASSIST PAGE

RAP

American College of Surgeons



Division of Education

The Residency Assist Page of the American College of Surgeons offers a medium for program directors to acquire updates and advice on topics relevant to their needs as administrators and teachers.

Our goals are to offer practical information and approaches from summaries of published articles, invited editorials, and specific descriptions of lessons learned from program directors' successful and not-so-successful strategies. Through the development of the Residency Assist Page, the ACS intends to support program directors and faculty by providing helpful information for addressing the challenges associated with administering state-of-the-art residency education.

www.facs.org/education/rap/index.html

For additional information, please contact Linda Stewart at lstewart@facs.org, or tel. 312/202-5354.

