
ACOSOG news

“Never...was so much owed by so many to so few”: An update on Z6041

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

ACOSOG (American College of Surgeons Oncology Group) Z6041 is a phase II trial of neoadjuvant chemoradiation and local excision for uT2uN0 rectal cancer. Patients receive capecitabine and oxaliplatin concomitantly with 54 Gy external-beam radiotherapy followed by local excision of the primary tumor.

Although Z6041 has a neoadjuvant chemoradiation therapy component, it is an example of a procedure-oriented trial. Many T2 distal rectal cancers are treated either with a low anterior resection or coloanal resection and anastomosis or abdominoperineal resection. More surgeons are performing excision for T2 rectal cancer followed by radiation therapy,* but Z6041 describes the role of neoadjuvant chemoradiation therapy followed by transanal local excision. Preservation of sphincter function is an important goal in the ACOSOG rectal cancer portfolio of trials.

In June 2006, ACOSOG published in the *Bulletin* a call for participation in

Z6041. Enrollment of patients into ACOSOG trials was critically important. The response has been excellent and the monthly accrual rate has exceeded expectations. There are 51 surgeons with Institutional Review Board (IRB) approval who have been credentialed by Julio Garcia-Aguilar, MD, FACS, Chair of

the study. For this trial, 19 surgeons have enrolled at least one patient. As of April 2007, 35 patients had been enrolled into this trial, which has a target enrollment of 85 patients. The targeted accrual rate was three patients per month. Four patients per month were enrolled in February and March 2007;

Physicians participating in Z6041

H. Randolph Bailey, MD, FACS, Methodist Hospital
Ronald Bleday, MD, FACS, Brigham and Women's Hospital
Peter A. Cataldo, MD, FACS, Fletcher Allen Healthcare
Jacques Heppell, MD, Mayo Clinic Scottsdale
Alan J. Herline, MD, FACS, Vanderbilt University
Richard Hoefer, DO, Surgical Oncology Associates
Craig S. Johnson, MD, FACS, Natalie W. Bryant Cancer Center
Natalie E. Joseph, MD, FACS, Fox Chase Cancer Center
Kirk Allen Ludwig, MD, FACS, Duke University
Najjia N. Mahmoud, MD, FACS, University of Pennsylvania Cancer Center
Jorge E. Marcet, MD, FACS, Tampa General Hospital
Michael S. McNevin, MD, Holy Family Hospital
David S. Medich, MD, FACS, Allegheny Cancer Center Network
Samuel C. Oommen, MD, FACS, John Muir Medical Center
Alessaio Pigazzi, MD, City of Hope
Roger K. Pons, MD, FACS, United Hospital Center
Miguel A. Rodriguez-Bigas, MD, FACS, M. D. Anderson Cancer Center
Bruce G. Wolff, MD, FACS, Mayo Clinic Rochester
Earl Yeager, MD, FACS, Saint Joseph's Hospital

*You YN, Baxter N, Stewart A, Nelson H. Is the increasing rate of local excision for stage I rectal cancer in the United States justified?: A nationwide cohort study from the National Cancer Database (NCDB). *Ann Surg.* 2007;245:726-733.

in April 2007, seven patients were enrolled. Based on the current accrual rate, this trial could complete enrollment by April 2008. A successor trial design based on the pathologic response rate is already being discussed.

Although we are pleased with the higher-than-expected enrollment rate for this trial, we remain optimistic to engage even more surgeons to participate in the trial. We have reviewed the National Cancer Data Base (NCDB) and have found that there are more than 400 high-volume sites for T2 rectal cancers. When the NCDB high-volume list was compared with the Z6041 enrolling sites, we realized that we have engaged only 1 percent of the potential high-volume sites. We have more work to do in order to recruit more

surgeons to participate in this trial.

Patient eligibility and study schema can be found on the ACOSOG Web site at *www.acosog.org*. A list of IRB investigators for Z6041 can be found at *clinicaltrials.gov* by doing a search with the trial code. We want to thank those surgeons who have enrolled patients into Z6041 and who have contributed to the success of this trial thus far. (See the sidebar on page 44 for a list of participating surgeons and their institutions.)

These 19 surgeons have contributed to the success of Z6041. Although the number of surgeons participating in Z6041 may seem small on a national scale, these few surgeons have shown that despite the low frequency of distal stage I rectal cancers,

ACOSOG surgeons can enroll patients and complete a complex multisite trial that potentially can establish a new treatment paradigm for patients with this diagnosis.

On behalf of patients and surgeons, as Sir Winston Churchill said in 1940, "Never...was so much owed by so many to so few."[†]

To learn more about becoming an ACOSOG member, go to the ACOSOG Web site or contact Helen Harbett at har011@dcri.duke.edu.

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

[†]The Winston Churchill Centre. "The Few." Available at: <http://www.winstonchurchill.org/i4a/pages/index.cfm?pageid=420>. Accessed May 31, 2007.

Papers being accepted for 2008 Resident Trauma Papers Competition

The ACS Committee on Trauma (COT) is now accepting papers for the 2008 Resident Trauma Papers Competition, which will be held during the COT's annual meeting March 13–15, 2008, in Washington, DC.

The Resident Trauma Papers Competition is open to general surgical residents, surgical specialty residents, and trauma fellows. The papers should describe original

research in the area of trauma care and/or prevention, categorized as basic laboratory research or clinical investigation. Papers should be sent to the appropriate ACS state/provincial chair. The list of chairs' names can be found at <http://www.facs.org/trauma/regional.html>.

The papers competition has been funded by the Eastern and Western States COTs, Region 7 COTs, Wyeth Phar-

maceuticals, and the American College of Surgeons.

Deadline for submission of papers to the region chief is November 14, 2007. Further information can be obtained on the ACS Web site at <http://www.facs.org/trauma/traumapapers.html> or by calling Bridget Blackwood, ACS Trauma Programs Coordinator, at 312/202-5380 or e-mail bblackwood@facs.org.