

Laparoscopic, Open Colectomy at 5-Year Parity

BY BRUCE JANCIN

Denver Bureau

COLORADO SPRINGS — Overall and disease-free survival at 5 years were equivalent in patients with curable colon cancer assigned to laparoscopic, compared with open, colectomy in the randomized prospective Clinical Outcomes of Surgical Therapy trial, Dr. Heidi Nelson said at the annual meeting of the American Surgical Association.

The 5-year COST trial results expand upon the previously reported interim 3-year data (N. Engl. J. Med. 2004;350:2050-9), noted Dr. Nelson, COST lead investigator and professor of surgery and chair of colon and rectal surgery at the Mayo Clinic, Rochester, Minn.

COST was a National Cancer Institute–funded study involving 872 patients with curable colon cancer randomized to laparoscopic or open colectomy at 48 participating centers. The study was undertaken in response to concerns arising in the mid-1990s that laparoscopic colectomy might produce inferior oncologic outcomes. Indeed, the procedure's introduction into clinical practice stalled at that point because of reported extremely high rates of recurrent cancer at surgical wound sites as a re-

sult of intraoperative tumor cell dissemination. The question became whether the poor outcomes were caused by suboptimal performance of a new procedure or to problems inherent in the operation.

At 5 years' follow-up in COST, laparoscopic and open colectomy showed similar rates of both local and distant recurrences, and the rate of wound site recurrences was less than 1% in each group.

Prior COST analyses showed faster recovery and significantly better quality-of-life scores in patients undergoing laparoscopic colectomy than in those who had open colectomy. A cost-effectiveness comparison is planned as well.

A much-quoted single-center, 219-patient randomized trial by University of Barcelona surgeons concluded that the risks of tumor relapse and all-cause and cancer-specific mortality were significantly lower in patients with stage III tumors treated laparoscopically (Lancet 2002; 359:2224-9). But a new COST subgroup analysis was unable to confirm this finding; in COST, designed by statisticians as a noninferiority study, patients with stage III disease had closely similar recurrence and mortality rates regardless of which surgery they received, according to Dr. Nelson.

Discussant Dr. David A. Rothenberger hailed COST as "a landmark study" and recalled how controversial it was early on.

"I remember that my group had several heated discussions about whether or not we wanted to participate in this trial and ultimately voted against doing so because of concerns about the oncologic outcomes and our worries that we just weren't at that point good enough to be doing laparoscopic colectomy for cancer. I'm certainly happy our fears were unfounded and that you had the courage and tenacity to fight for and complete this trial," said Dr. Rothenberger, professor of surgery and chief of the divisions of colon and rectal surgery and surgical oncology at the University of Minnesota, Minneapolis.

Dr. Michael Zenilman, professor and chairman of surgery at the State University of New York, Brooklyn, said COST "sets the standard" for how to appropriately introduce new surgical procedures into broad clinical practice.



Dr. Heidi Nelson, COST lead investigator, favors the use of surgical videos in the board certification process.

He noted that as a condition of involvement in the trial, the 66 participating COST surgeons had to undergo a unique credentialing procedure. Each had to submit 20 laparoscopic colectomy operative pathology reports along with an unedited video of the surgeon performing critical elements of the procedure. Surgeons also agreed to ongoing monitoring of their techniques by video audit to ensure they were doing laparoscopic colectomy at a high level of expertise.

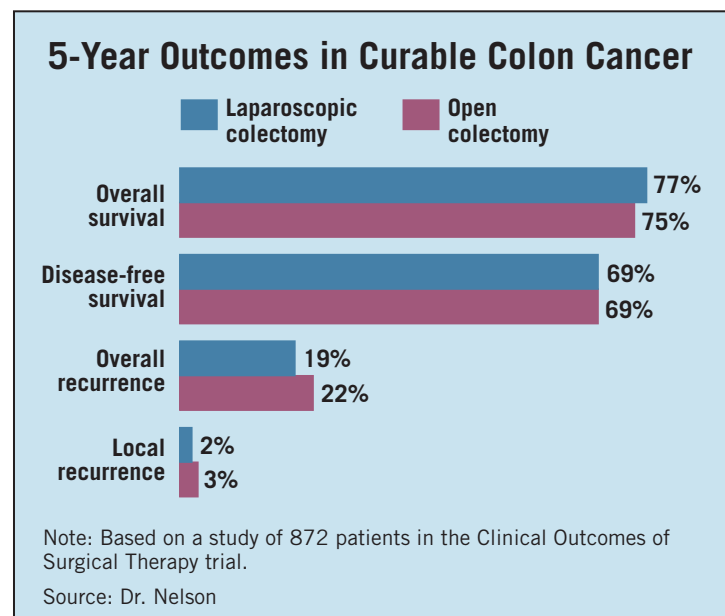
Perhaps similar clinical trials, carried out by credentialed surgeons, could be used to evaluate novel procedures such as natural orifice surgery—which may be the next big wave in surgical innovation—before they become widely disseminated, Dr. Zenilman said.

Dr. Nelson predicted that's quite likely, since COST has created the organizational structure needed to conduct further large randomized trials addressing key questions in cancer surgery.

As a senior board examiner for the American Board of Colon and Rectal Surgery, she likes the idea of incorporating unedited surgical videos into the board certification process and requests for hospital privileges.

"There's no reason down the road a trainee couldn't go into their board exam and hand over a videorecorded procedure that can be viewed and defended," she said.

All papers presented at the 127th annual meeting of the ASA are subsequently submitted to the *Annals of Surgery* for consideration. ■



Minor Hepatectomy Safe During Colorectal Cancer Surgery

BY BRUCE K. DIXON

Chicago Bureau

Selected patients with colorectal cancer metastasized to the liver can undergo a single procedure to remove lesions at both locations, according to a multicenter study presented at the Society of Surgical Oncology in Washington.

The traditional approach has been to remove the primary tumor and then place the patient on chemotherapy prior to doing a hepatic resection, said Dr. Bryan Clary, chief of hepatobiliary surgery Duke University, Durham, N.C.

"The rationale for that approach has been the perception that simultaneous hepatic and colorectal surgery is excessively morbid, but a growing body of evidence has called this strategy into question," Dr. Clary said in an interview.

In about a third of patients newly diagnosed with colorectal cancer, disease already has spread to the liver, he added.

The Duke University researchers teamed with investigators from Johns Hopkins Medical Institutions in Baltimore and the

University of Texas M.D. Anderson Cancer Center in Houston to conduct a retrospective outcomes study of 610 patients who had undergone either simultaneous (135) or separate (475) procedures for removal of synchronous colorectal and liver cancer.

Data for the years 1985 through 2006 were drawn from three large-volume hepatobiliary centers.

"We found that for patients who require a minor hepatectomy in conjunction with their colorectal operations, the risk does not seem to be increased in comparison with those undergoing staged liver resection," Dr. Clary said.

In the minor hepatectomy cohort, defined as the removal of fewer than three liver segments, 99 were done simultaneously with colorectal surgery and 184 were staged procedures. Measures of intraoperative red blood cell transfusion, blood loss, positive resection margins, mortality, and morbidity were statistically similar. However, in the major hepatectomy group, mortality, overall morbidity, and severe morbidity were significantly higher for the simultaneous procedure, compared

with the staged approach (8% vs. 1%, 44% vs. 27%, and 36% vs. 15%, respectively).

Simultaneous resection resulted in a significantly shorter median length of hospital stay (8.5 vs. 14 days) at the single institution where hospital time was calculated for both procedures, Dr. Clary explained.

Survival data were similar for simultaneous and staged resection. However, posthepatectomy chemotherapy significantly prolonged survival for patients with synchronous hepatic metastases, regardless of whether the resection was done simultaneously with or separate from colorectal procedure.

The 1-, 3-, and 5-year survival rates following posthepatectomy chemotherapy were 98%, 75%, and 55%, respectively. When no chemotherapy was given, those rates fell to 95%, 60%, and 41%.

"There is no compelling evidence that giving chemotherapy beforehand makes a difference, so in general, patients whose disease is resectable should have a resection, whereas marginal medical patients with a lot of comorbidities should be given

chemotherapy prior to a complex operation," Dr. Clary said in an interview, adding that these complex cases need to be much more carefully selected because in general, severe morbidity rates are increased with the simultaneous approach.

Chemotherapy is appropriate in patients whose liver disease is not resectable, in cases where hepatic resection has a low likelihood of achieving a negative margin, and where disease is suspected elsewhere in the body, he said.

Dr. Clary stressed the importance of early patient evaluation by a multidisciplinary team that includes a surgeon experienced in doing hepatic surgery.

Patients with obstructing colon cancers in urgent need of removal and those with significant bleeding from their primary tumors should not undergo this procedure, he said.

"The bottom line is that a single surgery should be considered in the patient who likely would require a minor hepatectomy for extirpation of their liver disease following early evaluation by a competent hepatic surgeon," Dr. Clary said. ■