ACOSOG news

To refer or not to refer: That is the question

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Many people are aware of Hamlet's famous question, "To be, or not to be," but is an adaptation of these words relevant to surgeons? Here is a common situation: You have great news for your postoperative patient, who is recovering from your uneventful colon resection. The pathology report shows stage II colon cancer, which has a high cure rate with surgery alone (80%) and the patient is very grateful to you. You explain to your patient that referral to a medical oncologist is the next step for consideration of postoperative chemotherapy. "I have heard about chemotherapy," the patient might say. "But if surgery has a high cure rate, why do you recommend that I see a medical oncologist? What are the side effects?"

One of the more controversial issues in oncology is the role of postoperative adjuvant chemotherapy for stage II colon cancer. The source of this controversy is the relatively high survival rates following surgical resection for stage II disease and although well-controlled, randomized phase III trials have shown a benefit, the increase in survival is in the range of 5 percent. Surgeons are aware of the favorable results of operative therapy for stage II colon cancer and recommending postoperative adjuvant therapy to patients can be confusing. Giving postoperative chemotherapy to all stage II patients exposes the majority of patients to unnecessary treatment and benefits only a few. The patient has total trust in you because you have just completed a successful operation. You are the gatekeeper to the oncology world for your patient, who then asks, "Doctor, what should I do?"

For surgeons, there is an answer to this question of whether to refer or not to refer. Identifying stage II patients who are at high risk for recurrence and who then could benefit from postoperative systemic adjuvant therapy would be a major advance. E5202 is a multi-institutional trial that has been endorsed by the American College of Surgeons Oncology Group (ACOSOG) to answer the question of postoperative adjuvant therapy in high-risk stage II colon cancer patients (*www.med.wright.edu/dcop/schemas/E5202.pdf*). This protocol will identify stage II patients who are at high risk for recurrence and are therefore eligible for postoperative adjuvant chemotherapy. Inclusion criteria are T3/4N0M0 colon cancer and ≥ 8 lymph nodes in the resected specimen. Patients who present with obstruction or perforation are excluded.

Initially patients are divided into groups based on high or low risk of recurrence as determined by laboratory assessment of the primary tumor. High risk is defined as microsatellite stability and loss of heterozygosity at 18q. Patients with stage II tumors who exhibit microsatellite stability or low-frequency instability have a significantly worse prognosis than those patients whose primary colon cancers have high microsatellite instability.* Allelic loss of chromosome 18q in the primary tumor decreases the survival of stage II patients.†

High-risk patients will be randomized into two groups: postoperatively, Group A will receive 5FU, Leucovorin, and oxaliplatin, and Group B will receive 5FU, Leucovorin, and oxaliplatin plus bevacizumab. Low-risk patients will not receive postoperative thera-

*Ribic CM, Sargent DJ, Moore MJ, et al. Tumor microsatellite instability status as a predictor of benefit from fluorouracil-based adjuvant chemotherapy for colon cancer. *N Engl J Med*. 2003;349:247-257.

†Jen J, Kim H, Piantadosi S, et al. Allelic loss of choromosome 18q and prognosis in colorectal cancer. *N Engl J Med*. 1994;331:213-221.

py and will be monitored as Group C. It is estimated that 40 percent of all stage II colon cancers will be in the high-risk category (Groups A and B). This protocol satisfies the need to separate the stage II colon cancer patients by those who are more likely to benefit from treatment versus those who will not benefit from treatment.

As E5202 offers a rational approach to postoperative adjuvant therapy for stage II patients, surgeons play an essential role in screening and enrolling patients into the trial. As oncology gatekeepers and respected advisors to patients, surgeons play an important role in the success of this trial. A sample size of 3,438 patients with stage II colon cancer is needed to complete this study, and ACOSOG has stepped forward to engage the surgical community in this trial. The uniqueness of E5202 is that surgeons will receive credit for identifying patients with stage II disease and for explaining the importance of the trial to their patients. A simple one-page form was developed so that the data center can track the credits. This form, with instructions, can be found at *www.acosog.org*.

ACOSOG needs surgeons who understand the trial design and patient eligibility criteria and who can explain the trial to their patients. ACOSOG needs your participation in E5202 by screening patients for stage II and supporting the treatment described in the protocol.

Prospective trials will help us obtain new knowledge so that recommending postoperative adjuvant chemotherapy to our stage II colon cancer patients does not become an awkward moment when we explain referral to a medical oncologist.

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

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physicians' medical records. For a consultation, simply retain a copy of the report that is sent to the requesting physician. If there is a common medical record, the required documentation may be maintained in it. In addition, the level of consultation code selected must be supported by the documentation in the medical record. Either the 1995 documentation guidelines or the 1997 documentation guidelines may be used.

E/M services, including consultations, remain a primary focus of program integrity efforts. Local Medicare carriers may audit a claim and request documentation to support the medical necessity of the service and the code level. Medicare providers have a responsibility to provide documentation when requested. If documentation is not provided, the claim will be denied. If the documentation does not support the claim, the claim will be denied or downcoded. Documentation requests may come from a physician's local Medicare carrier or from AdvanceMed, the company charged with administering Medicare's Comprehensive Error Rate Testing program.

In addition to documentation requests, many carriers have offered local provider education and training programs. These programs often compare a physician's use of services with that of other physicians in the same specialty. These programs are for educational purposes only and often request that the physician take some sort of coding training, which is often computer based. Providers are not required to respond to the letter or take the training, although carriers highly recommend the training. The recent OIG report will likely heighten interest in these activities. Ω