



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS

Surgery Tames Small Soft Tissue Sarcomas

BY BRUCE JANCIN
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COLORADO SPRINGS — Limb-sparing surgery alone may be adequate treatment for selected patients with a small soft tissue sarcoma on an extremity, Dr. Waddah B. Al-Refaie said at the annual meeting of the Western Surgical Association.

Adjuvant radiotherapy didn't affect 5-year overall or cancer-specific survival, compared with surgery alone, for extremity soft tissue sarcomas classified as T1 (those measuring 5 cm or less) in a large population-based study, reported Dr. Al-Refaie of the University of Minnesota, Minneapolis.

This new finding from his analysis of the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) tumor registry, coupled with other reports indicating that surgery alone provides satisfactory local control, suggests that the time has come to reconsider the routine use of adjuvant radiotherapy in this setting. Radiotherapy as a standard element of limb-sparing therapy for extremity soft tissue sarcoma dates back to an era when the prevailing cancer treatment philosophy was to administer the maximum tolerable dose rather than minimal yet still effective therapy, he said.

In 2007, there were slightly more than 9,200 new cases of soft tissue sarcoma in U.S. patients, half of which occurred on an extremity. This cancer is sufficiently uncommon that an adequately powered, randomized trial of adjuvant radiotherapy is unlikely ever to be done, so Dr. Al-Refaie analyzed the SEER database to determine the value of adjuvant radiation.

He identified 1,708 adult patients in the database for 1988-2003 who underwent limb-sparing surgery for a T1 extremity soft tissue sarcoma. The median age at diagnosis was 51 years, and the patients' median tumor size was 3 cm.

Of those patients, 49% got adjuvant radiotherapy. Unadjusted, 5-year, cancer-specific survival in patients with histologically low-grade

tumors was 92.2% in the adjuvant radiotherapy group and 93.4% in the no-radiotherapy group. Among patients with high-grade tumors, the rates were 82.7% and 87%, respectively.

Older patients and those with tumors that were high grade, larger than 3 cm, or in a deep location were more likely to be given adjuvant radiotherapy. Upon adjustment for these potential confounders in a multivariate analysis, radiotherapy had no effect on survival.



Adjuvant radiotherapy didn't affect 5-year overall or cancer-specific survival, vs. surgery alone.
DR. AL-REFAIE

In fully 30% of cases in the SEER registry, tumor grade went unrecorded. "It was due to coding error, underreporting, or inadequate surgical or pathologic care. All raise concerns about quality of care," Dr. Al-Refaie said.

He added that he will still offer adjuvant radiotherapy to patients with a T1 extremity soft tissue sarcoma who are at increased risk for mortality—namely, patients older than about age 70 years, or those with a tumor location that makes it difficult to achieve an R0 (having no residual tumor) resection with microscopically negative final surgical margins.

"Patients with a midhigh malignant fibrous histiosarcoma are better able to tolerate multiple reoperations to achieve an R0 resection, as compared to a patient with an inguinal canal soft tissue sarcoma," Dr. Al-Refaie noted.

Discussant Dr. Charles R. Scoggins of the University of Louisville said that the limitations of the SEER database leave unanswered the question of whether patients treated with surgery alone have a higher local failure rate.

He noted that a recent prospective study led by Dr. Peter W. Pisters, an ACS Fellow with the University of Texas M.D. Anderson Cancer Center, Houston, provides some reassurance. The cumulative incidence of local recurrence in 74 patients who underwent R0 resection and were treated by surgery alone was 7.9% at 5 years and 10.6% at 10 years, with a 10-year cancer-specific death rate of 3.2% (Ann. Surg. 2007;246:675-81). ■

Drop in Radiotherapy Tied to Breast Cancer Recurrence

BY BRUCE JANCIN
Elsevier Global Medical News

SAN ANTONIO — The use of radiotherapy following breast-conserving surgery for invasive cancer is declining in the United States—and that's a trend spelling trouble, Beth A. Virnig, Ph.D., asserted at the San Antonio Breast Cancer Symposium.

Breast-conserving surgery (BCS) without radiotherapy constitutes a failure to provide adequate local tumor control. Some prominent epidemiologists predict this will lead to increased late mortality, although that prediction is controversial. Regardless, compelling evidence indicates this failure results in increased risk of local recurrences requiring additional, more aggressive surgery—often mastectomy—along with systemic chemotherapy.

Thus, the declining rate of radiotherapy serves to undermine the whole point of breast-conserving therapy: to provide outcomes equivalent to mastectomy, but with better quality of life, explained Dr. Virnig of the University of Minnesota School of Public Health, Minneapolis.

"On a population basis, this trend is going to cause some real problems," she added in an interview. "It seems like what we're doing is delaying treatment for these women until they'll end up needing more aggressive therapies that probably could have been avoided."

She analyzed treatment trends in more than

175,000 women in the National Cancer Institute Surveillance, Epidemiology, and End Results registry who underwent treatment for nonmetastatic breast cancer during 1992-2003. In 1992, the year after an NCI consensus panel declared BCS plus irradiation to be the preferred strategy over mastectomy in women with early-stage cancer, 41% of patients received BCS. That rate climbed to 60% by 2003. Meanwhile, the use of radiotherapy following BCS dropped from 79% to 71% during the same period.

In patients under age 55 who received BCS, the rate of radiotherapy fell from 81% in 1992 to 67% in 2003. Radiotherapy use was also less frequent in women with estrogen receptor-negative tumors. "We were particularly troubled that it was the younger women who had the steepest decline, and the ones with estrogen receptor-negative tumors, because they have the highest risk of recurrence and don't have tamoxifen or the aromatase inhibitors as a protective net. These are women for whom there really isn't a preventive treatment available right now other than chemotherapy or irradiation," Dr. Virnig said.

The task now, she added, is to figure out why the decline in radiotherapy is occurring and how to address it. It's unclear how much of the problem is caused by insurance issues, lack of convenient access, truly informed patient preference, or surgeon reluctance to refer to radiation oncologists. ■

FDA Eyes Cancer, Mortality Risks Linked to Erythropoiesis Agents

More evidence associating erythropoiesis-stimulating agents with increased tumor growth and mortality in patients with cancer is being reviewed at the Food and Drug Administration and could result in additional action by the agency.

The new data are from two studies, according to a recent FDA statement. In one study of 733 women who received chemotherapy before undergoing breast cancer surgery, 14% of those who received Aranesp, one of the ESAs marketed in the United States, had died 3 years later, compared with 9.8% of those who did not receive the drug. Tumor growth also was faster among those who received the drug.

In another study of patients receiving chemotherapy and radiation for cervical cancer, 59% of Procrit patients were alive and free of cancer growth 3 years later, compared with 66% of those who did not receive the drug. (In that study, patients were given Procrit to maintain a hemoglobin level above

12 g/dL, or blood transfusions as needed.)

These two studies, along with six other studies that were summarized in recent revisions to ESA labels, "show more rapid tumor growth or shortened survival when patients with breast, non-small cell lung, head and neck, lymphoid or cervical cancers received ESAs compared to patients who did not receive this treatment," according to the statement.

The agency might take additional action regarding the ESAs, and plans to hold a public advisory panel meeting in early 2008 to discuss the new data.

Until then, the agency "recommends that health care providers review the risks and benefits of ESAs outlined in the product label and discuss this information with their patients," Dr. Janet Woodcock, the FDA's chief medical officer and acting director of the FDA's Center for Drug Evaluation and Research, said in the statement.

—Elizabeth Mechatie

Patient Portals: Not the Open Floodgates Physicians Fear

Studies suggest messaging raises patient satisfaction without any corresponding increase in workload.

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

NEW ORLEANS — Rather than unlocking a Pandora's box of nattering e-mails, an electronic patient portal that allows messaging and even access to test results can improve patient satisfaction and decrease patient visits.

"Many physicians think that this type of access is frightening," Dr. Gretchen P. Purcell said at the annual clinical congress of the American College of Surgeons. "They think they'll be barraged with messages, that patients will misinterpret their test results, and that physicians could even be held legally liable if they don't respond in time to an urgent message."

But health care providers, who are about 10 years behind the curve in the digital world, need to face up to the facts of the 21st century, said Dr. Purcell of the surgery department at the Children's Hospital at Vanderbilt in Nashville, Tenn. "Patients are demanding the same kind of online access to their medical information as they have for all other aspects of their lives. Those health care institutions that do not have a patient portal now probably will within the next 5 years."

Patient portals can be designed to suit the needs of different practices and to fulfill various functions. At a minimum, they allow patients to pay bills, schedule or change appointments, and request prescription refills. Other portals are more

robust and give patients the ability to review medical records, view test results, and send messages to their health care provider, said Dr. Purcell, who is also with the biomedical informatics department at Vanderbilt Medical Center.

Among the most controversial topics are messaging and the ability to access test results, she said.

"Messaging is probably the function physicians fear the most. Many think it's the equivalent of getting and sending personal e-mail, and this brings up all kinds of worries about security and privacy."

E-mail and messaging, however, are not the same things. Messages don't go to a personal e-mail account; instead, they go to a dedicated in-box.

"This message box is routinely checked by an administrative assistant or nurse—someone who can often answer many of the questions, and who would involve the physician only when necessary—similar to phone call triage."

There also are concerns that these electronic exchanges aren't part of a patient's documented record. "Some portals can make messaging part of the medical record, and some physicians have found ways to charge for this 'online consultation,'" Dr. Purcell said.

It's important to set clear expectations about response time and emergency issues. Most messaging systems tell patients that they may have to wait 2-3 business days for a personal reply and advise them

to call 911 for a medical emergency.

It's not unreasonable to assume that electronic communication could allow patients to bombard offices with questions and requests. Although data are still limited, the studies that are out there suggest just the opposite, Dr. Purcell said.

Two studies published in 2005 indicate that messaging increases patient satisfaction without any corresponding increase in workload.

The first study randomized 200 patients to secure messaging or usual care. Only 46% of the patients who were given access

calls between the groups, but the patients in the portal group reported better satisfaction with communication and overall care, even if they never used the portal (J. Med. Internet Res. 2005;7:e48).

The same study indicated that secure messaging probably would not overwhelm anyone during working hours, Dr. Purcell said. "Patients tended to use the portal during nonclinic hours—the most convenient time for them—with about 73% of messaging occurring from 5 p.m. until midnight."

Patients may even be willing to pay for the added convenience of messaging, the authors concluded. Of 341 patients surveyed, 162 (48%) were willing to pay for online correspondence with their physician, with \$2 cited as the median payment they thought fair.

Patient access to test results is another area of clinician concern, she said. "Obtaining test results is probably the most commonly desired and most commonly used function of a patient portal, and one that makes physicians very nervous," Dr. Purcell said.

The MyHealthAtVanderbilt system (www.myhealthatvanderbilt.com) has three tiers of test results—two can be available to patients online. "Some low-risk, high-value test results, such as cholesterol levels, are available immediately, and some results are available with a delay, such as tests that require interpretation in a specific clinical context," Dr. Purcell said. "But some results, such as cancer pathology and HIV tests, and others that require intensive patient counseling, are never available though the portal." ■

PORTALS CAN MAKE MESSAGING PART OF THE MEDICAL RECORD, AND SOME PHYSICIANS HAVE FOUND WAYS TO CHARGE FOR THIS 'ONLINE CONSULTATION.'

sent any messages at all; the average was just 1.5 messages per patient per year. And although messaging didn't reduce the number of telephone calls the office received, the number of office visits in the intervention group did go down (Int. J. Med. Inform. 2005;74:705-10).

The second study randomized 606 patients to a patient communication portal or to a Web site with general health information. Only 31% of the patients given access used the portal. The message box received only one message per day per 250 patients. Again, there was no difference in the number of office telephone

Trauma Mortality Affected by Race, Insurance Status

BY MICHELE G. SULLIVAN
Elsevier Global Medical News

NEW ORLEANS — Minority and uninsured patients are significantly more likely to die after injury than are white, insured patients, Dr. Adil H. Haider reported at the annual clinical congress of the American College of Surgeons.

He concluded that black uninsured patients were 78% more likely to die after trauma, and that Hispanic patients without insurance were more than 130% more likely to die than white insured patients, even after controlling for numerous confounding factors.

"I don't think this has to do with genetics or biology, as much as with insurance status," he said in an interview. "This is a public health problem and has to be addressed as such."

Dr. Haider, a trauma surgeon at Johns Hopkins University, Baltimore, extracted his data from the 2001-2005 National Trauma Data Bank. He assessed mortality after moderate to severe trauma in 377,000 patients, of whom 69% were white, 19% black, and 11% Hispanic. Patients included

in the study were adults between the ages of 18 and 65 (mean age 36 years), and 70% were male.

Overall, 53% of patients had some kind of commercial medical insurance, and 47% were either self-pay or Medicaid recipients. Blacks were most likely to be uninsured (69%), followed by Hispanics (62%) and whites (38%).

Hispanics had the highest crude mortality, with 9% dying after their injury, compared with 8% of blacks and 5.5% of whites. Mortality was also significantly different between insured and uninsured

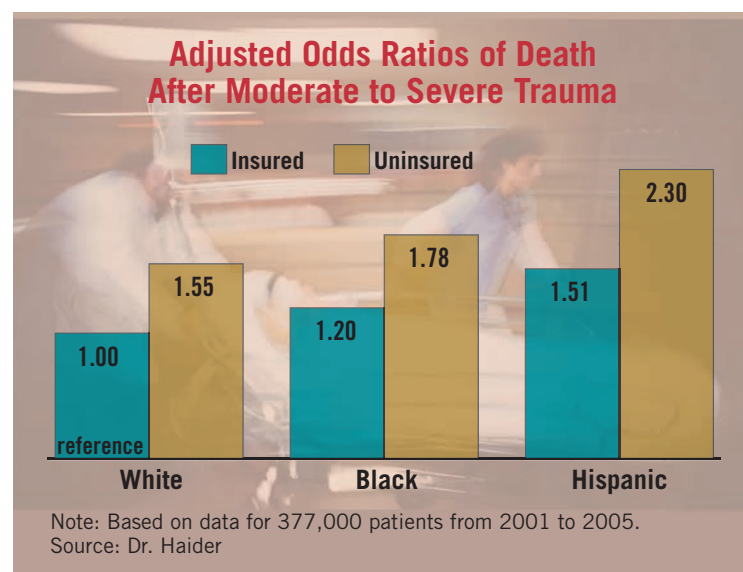
patients (8% vs. 4% in the unadjusted analysis).

The adjusted mortality analysis controlled for injury severity using the Injury Severity Score, Revised Trauma Score, and Abbreviated Injury Scale. Dr. Haider also controlled for age, gender, severe extremity injury, type of injury (blunt vs. penetrating), and mechanism of injury, based on ICD-9 codes.

The multivariate analysis showed that race and insurance were still significantly associated with the risk of death. Compared with whites, blacks were 17% more likely to die and Hispanics 47% more likely to die. Uninsured patients were 46% more likely to die than were insured patients.

To further stratify the effect of race and insurance, Dr. Haider broke down the groups according to both factors. Compared with insured white patients, insured black patients and uninsured Hispanic patients were still significantly more likely to die (20% and 51%, respectively).

Uninsured white and black pa-



tients were significantly more likely to die (55% and 78%, respectively) than were insured white patients.

Uninsured Hispanic patients faced the highest risk: They were 2.3 times more likely than insured white patients to die from similar injuries.

"We have shown that patients with no insurance have poorer outcomes than [do] those with

insurance, across all three races [or] ethnicities. Does this suggest that giving everyone insurance would save lives?" he asked. "If this is true, then one way to decrease racial disparities would be to expand insurance coverage among minorities. We are just at the beginning of defining the stakeholders involved in this problem. There is a lot more work ahead." ■



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DR. HAIDER