Node Biopsy: 'Standard Of Care' in Breast Ca

BY BRUCE JANCIN
Denver Bureau

San Antonio — Sentinel lymph node biopsy is as accurate as the traditional surgical practice of dissecting the entire axillary lymph node chain in women with breast cancer but inflicts far less nerve damage and fewer other complications, Mark Kissin, M.Chir., reported at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

The results of the first large-scale randomized trial of sentinel lymph node biopsy in breast cancer patients featuring comprehensive functional and quality of life assessment are so compelling that British health officials who have seen the data have directed that all U.K. surgeons undergo formal training in the technique, according to Dr. Kissin.

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DR. KISSIN

"There shouldn't really be a choice anymore. Sentinel node biopsy, for the patient, should be the standard of care," he declared.

Dr. Kissin was a coinvestigator in the Axillary Lymphatic Mapping Against Nodal Axillary Clearance (ALMANAC) trial, a multicenter U.K. study in which 1,031 women with clinically node-negative breast cancer were randomized to sentinel lymph node biopsy (SLNB) or to the traditional surgical practice of dissecting the entire axillary lymph node chain. Participating surgeons were required to have undergone systematic training in SLNB with demonstrated technical competence in its performance.

ALMANAC featured both patient assessments of functional status and quality of life as well as objective measurements of arm and shoulder morbidity, anxiety, and resource utilization at 1, 3, 6, 12, and 18 months. The 6-month follow-up data were the focus of presentations in San Antonio, although the 18-month data are being processed and should be available soon.

Only one-quarter of patients assigned to SLNB proved SLN-positive. That means three-quarters of women who undergo routine axillary node clearance needlessly experience the considerable associated morbidity that was documented in ALMANAC, explained Dr. Kissin, a surgeon at Royal Surrey County Hospital in Guildford, England.

During the first 3 months of follow-up, 83% of women who received standard axillary node dissection experienced at least one arm problem—lymphedema, shoulder stiffness and loss of range of motion, and/or sensory deficits; for 79%, the problem remained at 18 months.

For example, at 1 month, 62% of women randomized to axillary node clearance experienced sensory loss secondary to damage to the intercostal-brachial nerve, as did 43% at 6 months. In contrast, this was the case at 1 month in only 18% assigned to SLNB, and at 6 months in 16%.

It is worth emphasizing that ALMANAC employed an intent-to-treat analysis. Since all patients with a positive SLNB subsequently underwent full axillary clearance, and the associated morbidity was recorded on the SLNB side of the ledger, the study greatly underestimated the true benefits of having a negative SLNB.

At 6 months, 3% of women in the axillary clearance group had moderate to severe lymphedema, a rate sixfold greater than in the SLNB group.

ALMANAC principal investigator Robert E. Mansel, M.D., reported that the SLNB group had significantly lower infection rates and operating times and shorter hospital stays. There was no difference between the two study arms in anxiety levels as measured by the Spielberger State-Trait Anxiety Inventory. That's an important finding, noted Dr. Mansel, professor of surgery at the University of Wales, Cardiff. Had patients undergoing SLNB experienced increased anxiety, it might have cancelled out many of the other observed benefits.

ALMANAC isn't powered to reach definitive conclusions regarding breast cancer recurrence and survival. It's unlikely substantial differences exist in these end points between patients undergoing SLNB compared with routine axillary clearance, since patients with clinically node-negative disease enjoy a generally favorable long-term prognosis. For most candidates, the substantial quality of life advantages and reduced morbidity entailed by SLNB will be the decisive factor.

For recurrence and survival data, oncologists will look to the results of the National Surgical Adjuvant Breast and Bowel Project B-32 trial, the largest-ever randomized prospective trial evaluating SLNB in clinically node-negative patients.

Thomas B. Julian, M.D., presented preliminary technical results from the phase III trial in which 5,210 participants were randomized to SLNB with or without immediate conventional axillary dissection. Twenty-six percent of patients in both the SLNB and conventional axillary dissection groups proved SLN-positive. In 61.5% of SLN-positive patients, it was the only positive node.

The overall accuracy of SLNB was 97.2%, with a negative predictive value of 96.1% and a false-negative rate—"the number you've all been waiting for," Dr. Julian said—a less than stellar 9.7%. The false-negative rate was not affected by a surgeon's case experience, but it was influenced by the biopsy method employed. The highest false-negative rate—15.2%—occurred with excisional biopsy, for reasons not yet clear, according to Dr. Julian of NSABP headquarters in Pittsburgh.

Surgeons involved in NSABP B-32 had to complete a training protocol that included manualized instruction, a site visit, and performance of qualifying cases. ■

Ear Acupuncture May Ease Tamoxifen Hot Flashes

BY NANCY WALSH
New York Bureau

Exeter, England — A standardized ear acupuncture protocol effectively reduced hot flashes in women receiving tamoxifen as adjuvant treatment for breast cancer, according to an interim analysis presented at a symposium on alternative and complementary therapies sponsored by the universities of Exeter and Plymouth.

The National Acupuncture and Detoxification Association (NADA) protocol has been used for 30 years to treat withdrawal symptoms in substance abusers, most famously at the Lincoln Medical and Mental Health Center in New York City's South Bronx, Beverley de Valois said.

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Ms. de Valois, a Ph.D. candidate at Thames Valley University, London, and a research acupuncturist at the Lynda Jackson Macmillan Centre at Mount Vernon Hospital, Northwood, had previously done a study of traditional acupuncture for women experiencing adverse effects during tamoxifen treatment. "The results were encouraging, but the methodology is complex and time consuming, and our goal at the center is to make treatment for tamoxifen-related side effects widely and easily available."

There also were some difficulties in administering traditional acupuncture. Needling the limb on the affected side is discouraged because of fears that this might lead to lymphedema, she said. This restriction was particularly problematic for women who had had bilateral mastectomies.

She had previously worked with the NADA protocol, and because some of the side effects of tamoxifen—night sweats, anxiety, and sleep difficulties—resemble those of withdrawal, she thought this might be useful for these patients as well.

A total of 50 women were recruited for the study. They had to be taking tamoxifen for at least 6 months and having four or more vasomotor incidents per day. The treatment involved eight acupuncture sessions, five patients at a time, during a 29-week period. Participants recorded the frequency and severity of hot flashes in diaries and were asked how they subjectively rated the treatment.

There was no control group, and any placebo effect was not addressed.

An interim analysis of the first 35 patients showed a reduction in frequency from a mean of 10.32 flashes per day at baseline to 7.24 at the end of treatment, a statistically significant mean reduction of 24.4%, Ms. de Valois said. Sleep also improved as nocturnal hot flashes decreased.

Participants gave high marks to receiving the treatment in groups, where they met others with similar problems and were able to share experiences. ■

Baseline Anxiety Foretells Women's Adjustment to Cancer

Women who feel chronic anxiety or who suppress anxiety in daily life are more likely to be traumatized by a diagnosis of breast cancer, compared with women who are generally less anxious, reported Yumi Iwamitsu, Ph.D., of Kitasato University, Kanagawa, Japan, and colleagues.

They examined the differences in emotional responses among 21 women who had received a diagnosis of breast cancer and 72 women who had benign tumors. Their mean age was 46 years.

Each of the women completed the Profile of Mood States (POMS), the Courtauld Emotional Control Scale, and the Manifest Anxiety Scale during a first visit to an outpatient clinic for a breast biopsy (Psychosomatics 2005;46:19-24). The women completed the POMS again after a second visit at which they learned the biopsy results.

Both the breast cancer patients and the benign tumor patients were assigned to either low anxiety or high anxiety subgroups based on the Manifest Anxiety Scale scores, and either negative emotion suppression or negative emotion expression groups based on the Courtauld Emotional Control Scale scores. The researchers compared the POMS scores before and after the biopsy results among the eight subgroups.

Among the women with breast cancer, the total mood disturbance scores were significantly higher among those in the high anxiety subgroup than in the low anxiety subgroup. Those scores were higher in the negative emotion suppression group than in the negative emotion expression group.

Among women with benign tumors, those in the high anxiety subgroup showed higher overall total mood disturbance scores at the first visit, compared with women in the low anxiety subgroup. The total mood disturbance scores in the negative emotion expression group were not significantly different between the first and second clinic visits, regardless of diagnosis.

—Heidi Splete