Wanted: Surgeons and Patients to Participate in Studies Testing Sentinel Node Biopsy for Breast Cancer

One hundred forty-two surgeons are now approved to perform the sentinel node biopsy procedure as part of two breast cancer clinical trials sponsored by the National Cancer Institute (NCI). These surgeons are in 35 states throughout the United States, in addition to Washington, D.C., and three Canadian provinces. Both studies, however, continue to actively seek additional surgeons to participate. NCI, in Bethesda, Md., is sponsoring these trials because the long-term effects of sentinel node biopsy in breast cancer remains unproven.

The two studies – one conducted by the National Surgical Adjuvant Breast and Bowel Project and another conducted by the American College of Surgeons-Oncology Group – are comparing the effects of removing only one or a few lymph nodes, the sentinel nodes, to the standard practice of removing a much larger number of underarm lymph nodes. Both trials require documentation of experience and/or additional training before surgeons are approved to participate.

Sentinel nodes are a limited set of lymph nodes to which cancer is most likely to spread first. In
sentinel node biopsy, only one or a few lymph nodes are removed for laboratory analysis when a patient has a lumpectomy or mastectomy.

“Although sentinel node biopsy has attracted widespread attention by surgeons and patients alike, the procedure has not been compared to the time-tested standard of complete axillary dissection in a clinical trial designed to assess cancer recurrences and overall survival,” said Jeffrey Abrams, M.D., of NCI’s Division of Cancer Treatment and Diagnosis. He added, “Until this type of comparison occurs, surgeons are well advised to consider participation in a clinical trial if they and their patients are interested in this procedure.”

“Research suggests that the sentinel node can be used to determine whether cancer has spread to other lymph nodes, but we still don’t know what the impact of removing only the sentinel node will have on cancer control and survival,” noted David Krag, M.D. Krag, of the University of Vermont, is surgical leader of the NSABP trial, which has already enrolled more than 500 patients. “The trial provides a unique opportunity to potentially change the standard of care for this disease,” he said. “If we really want to know whether sentinel node biopsy can safely replace more invasive surgery, participation by surgeons across the country is essential.”

Patients are seeking alternatives to conventional full axillary, or underarm, lymph node dissection because several complications can arise from removal of the axillary nodes. Some reports indicate that more than 80 percent of women who undergo a complete axillary dissection have at least one complication after surgery. These complications are of varying severity, but can include lymphedema (swelling in the arm caused by excess fluid buildup), numbness, a persistent burning sensation, infection, and limited movement of the shoulder.

Patricia Heise, a participant in the NSABP study of sentinel node biopsy in Burlington, Vt.,
shared these words about sentinel node biopsy research: “If there’s anything women can do to make treatment easier and still effective, I think it’s a great way to go . . . I feel very confident about participating in the study. It helps to promote further research and to make our care better.”

The two complementary trials are asking different but important questions. The National Surgical Adjuvant Breast and Bowel Project (NSABP), an NCI-sponsored Clinical Trial Cooperative Group, is conducting its study to examine whether sentinel lymph node biopsy can replace axillary lymph node dissection in breast cancer patients with negative sentinel nodes. The study of the American College of Surgeons-Oncology Group (ACOS-OG), a newly formed NCI-sponsored Clinical Trials Cooperative Group, will examine the same issue in women with positive sentinel nodes. Both NSABP and ACOS-OG researchers hope to learn if long-term survival for patients who do not receive an axillary node dissection is any different than in those who do undergo a complete dissection. The studies will also compare the post-surgical side effects between the two groups.

In the NSABP trial, patients are divided into two groups. One group will undergo the current conventional surgery for breast cancer – a lumpectomy or mastectomy – and a sentinel node biopsy followed by an axillary dissection. The second group will also undergo tumor removal and sentinel node biopsy. If the sentinel node is negative for cancer, women in this group will not undergo axillary dissection. If the sentinel node is positive, the other axillary nodes will be removed.

The second clinical trial, carried out by ACOS-OG, is also enrolling women with early-stage breast cancer, but will challenge the standard practice of removing axillary lymph nodes in women whose sentinel node biopsies are positive for cancer. Patients who enroll in the study will have a lumpectomy to remove the breast tumor followed by removal and biopsy of the sentinel node or nodes. Those whose sentinel nodes are positive will be randomly divided into two groups. One group will
have a full axillary dissection, in which many more lymph nodes are removed. This is now the standard approach. The other group will have no other lymph nodes removed at that time.

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For more information about the sentinel node biopsy trials and a list of participating institutions, please visit http://cancertrials.nci.nih.gov/types/breast/treatment/sentnode or call NCI’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). For more information about cancer, visit NCI's Web site: http://www.cancer.gov.