

Contact: KMR Communications, Inc.
P: 212.213.6444
F: 212.213.4699
info@kmrcommunications.com



**New Breast Cancer Diagnostic Procedures May Save Women
From Chemotherapy And Lymphedema. Two New Studies
May Identify Women At Lowest Risk For Relapse**

New York, NY December 26, 2002 - When breast cancer is diagnosed, women (and men) must often undergo axillary lymph node dissection (i.e., removal of underarm nodes) to check for the spread of cancer. This process is part of "staging" the cancer. Unfortunately, the removal of these lymph nodes can lead to lymphedema (chronic swelling) of the arm in about 10 to 15 percent of cases. Dr. Pat Whitworth, a Nashville, Tennessee breast surgical oncologist is at the forefront of clinical studies funded by The National Cancer Institute to investigate the power of two new techniques to predict which breast cancer patients may have a particularly good prognosis. "We may be able to identify patients who do not need the standard chemotherapy or further lymph node removal", he says. The first study (ACOSOG Z0010) combines two procedures, Sentinel Lymph Node Biopsy and Bone Marrow Aspiration. The second (ACOSOG Z0011) is designed to determine whether further lymph node removal is needed when the Sentinel Node harbors breast cancer cells.

As he explains, "this is a new diagnostic procedure used to determine whether breast cancer has spread (metastasized) to axillary lymph nodes (i.e., lymph glands under the arm). Thus far, 10,000 patients worldwide have had this procedure performed allowing for more accurate and specific diagnosis of breast cancer. What's more, this technology may save patients from undergoing chemotherapy in cases where it is not warranted."

A sentinel lymph node biopsy requires the removal of only one to three lymph nodes for close review by a pathologist. If the sentinel nodes do not contain tumor (cancer) cells, this may eliminate the need to remove additional lymph nodes in the axillary area." Early research on this technique indicates that sentinel lymph node biopsy may be associated with less pain and fewer complications than standard axillary dissection. However, because the procedure is so new, long-term data are not yet available.

Why is Sentinel Lymph Node Biopsy Performed?

Sentinel lymph node biopsy may help in determining which patients can avoid axillary node dissection and the removal of 10 to 30 lymph nodes. Most patients have only one to three sentinel lymph nodes under the arm. Thus, an average of only two lymph nodes are removed in each patient with a sentinel node biopsy. This, in turn, may reduce post-operative complications. A standard axillary node dissection, removal of the underarm lymph nodes, usually requires a larger four to six inch incision and a longer recovery period than a sentinel node biopsy. Researchers are currently investigating whether sentinel node biopsy should routinely be performed in place of axillary node dissection. Sentinel node biopsy or axillary node dissection helps surgeons determine if breast cancer has spread to the lymphatics and the extent of the spread.

How is Sentinel Lymph Node Biopsy Performed?

Before going to the operating room, the surgeon injects a small dose of a low-level radioactive tracer called technetium-99 into the breast in the region of the patient's tumor. Technetium-99

contains less radiation than a standard x-ray. A blue dye is also injected to help visually track the location of the sentinel node during surgery. The surgeon then uses a hand held counter to detect the radioactive tracer and locate the sentinel node. Next, the surgeon will wait for the technetium-99 and dye to travel from the tumor region to the sentinel lymph node(s), just as cancer cells might spread. Depending on the protocol followed, the surgeon usually waits between 45 minutes to 8 hours after injection before bringing a patient to the operating room for the biopsy. At some point during the procedure, a small amount of blue dye will also be injected into the breast tissue near the area of the tumor. Once the technetium-99 tracer and dye have reached the nodes, the surgeon will scan the area with an electric, hand-held gamma ray counter (called a Geiger counter) to detect the radioactive technetium-99.

The gamma ray counter is attached to a small probe which the surgeon traces over the axilla to locate the sentinel node(s). When the radioactive agent is found, the gamma ray counter will emit an audible tone, revealing the exact location of the sentinel node(s). Once the area has been pinpointed, the surgeon will make a small incision (usually one-half inch) and remove the sentinel node(s) for a pathologist to examine under a microscope. The blue dye provides additional visual confirmation of the sentinel node's location during surgical removal. Several clinical trials have revealed that in the vast majority of cases, if the sentinel node does not contain cancer, then the cancer has not spread past the breast. Sentinel node biopsy does not usually require the placement of a fluid drainage tube.

If the sentinel node is determined to be cancerous while the patient is still in surgery, the surgeon will usually remove additional lymph nodes in the axilla. As Dr. Whitworth explains, "the final pathology report is not available until after the surgery has been completed, and patients should schedule a follow-up visit with the surgeon to discuss the final report. Sometimes, the final report indicates a positive (cancerous) sentinel node that was not seen on preliminary review. If this occurs, then additional surgery may be necessary to remove more nodes for examination."

Most women who undergo sentinel node biopsy spend one day or less in the hospital. Occasionally, sentinel node biopsy may be performed on an outpatient basis.

###

For additional information, to schedule an interview or to request products, please contact KMR Communications, Inc. at 212.213.6444, or info@kmrcommunications.com. KMR Communications, Inc. is a vital communications resource, fulfilling the interview of the news media with experts from the medical, fitness and beauty industry.