Largest-ever breast cancer surgery study published

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A less invasive surgical procedure for detecting breast cancer spread has for the first time been proven to achieve the same cancer survival and recurrence control as traditional lymph node removal surgery in patients whose initial sentinel node biopsy tested negative for cancer. These findings are reported by an international team led by University of Vermont and Vermont Cancer Center physician-researcher David Krag, M.D., in the September 21 "Online First" edition of *Lancet Oncology*.

Pioneered by Krag, the radiotracer technique of sentinel node biopsy involves the removal of only a few key lymph nodes versus axillary dissection, which removes all lymph nodes in the armpit for examination. Sentinel node biopsy produces fewer long-term side effects, such as chronic swelling of the arm, infection, and loss of mobility in the area where surgery occurred. Radiotracer-guided sentinel lymph node biopsy uses a tiny amount of harmless radioactive dye injected into the breast to track the pathway that cancer cells would take on their way to the lymph nodes. A negative sentinel node biopsy accurately confirms that cancer cells have not spread to the lymph nodes. With this information, surgeons can remove only the cancer-effected lymph nodes, leaving the other nodes intact to control fluid balance and the proper function of the immune system. In addition to reduced long-term side effects, sentinel lymph node biopsy allows patients to return home on the day of the procedure, eliminates the need for a fluid drain at the surgical site, and reduces any need for physical therapy following the procedure.

To determine its efficacy, appropriateness and safety, the National Surgical Adjuvant Breast and Bowel Project (NSABP), a National Cancer Institute-sponsored cancer research group, launched what is the largest international breast cancer surgical study to date. The research study was begun in 1998, conducted over ten years' time and involved 5,611 study participants, including 238 from Vermont, and 233 surgeons from 80 institutions in the U.S, Canada, and Puerto Rico participating. While many surgeons already consider sentinel lymph node biopsy a standard of care for breast cancer and melanoma patients, the benefits of this procedure were not confirmed until the final tabulation and release of the results of the trial.

"What this means—beyond a shadow of a doubt—is that at least two-thirds of breast cancer patients do not need to have their lymph nodes removed," says Krag. "There is a significant benefit to sentinel node biopsy when it comes to improved recovery and potential side effects, because the area heals so quickly."

The study showed no significant negative effects of sentinel node resection and demonstrated an equivalent survival when compared to patients who underwent traditional axillary lymph node dissection.

"These data allow us to now confidently offer this treatment option to surgeons as a safe and effective therapy for breast cancer patients," says Krag. "Sentinel node surgery represents the next major step in reducing the extent of surgical procedures to treat breast cancer."

The study also required surgeons and pathologists to adhere to uniform protocols for performing sentinel node biopsy and pathological analysis of lymph nodes, and performance audits confirmed excellent adherence to surgical procedures. A study among surgeons participating in the sentinel node trial was published previously by Krag late in 2009 and showed that surgeons who are uniformly trained and carefully adhere to

training protocols have fewer procedural errors and better surgical performance outcomes when performing sentinel node biopsy.

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