ASCO Guideline Recommendations for Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer: Guideline Summary

Context

ASCO convened an Expert Panel to conduct a systematic review of the literature available through February 2004 on the use of sentinel lymph node biopsy (SNB) in early-stage breast cancer.

Recommendations

The following recommendations are based on the available evidence and address several questions posed by the Panel.

How Should the Results of SNB Be Utilized in Clinical Practice? Can Full Axillary Lymph Node Dissection Be Avoided in Patients Who Have Negative Findings on SNB?

The Panel supports the use of SNB for staging disease in most women with clinically negative axillary lymph nodes. SNB is a reliable technique in trained hands and has an acceptable false-negative rate in the setting of both mastectomy and breast-conserving surgery. Nevertheless, the Panel concludes that axillary lymph node dissection (ALND) should be performed when the SNB procedure fails or is technically unsatisfactory or when clinically suspicious nodes are present in the axilla after all sentinel lymph nodes (SLNs) have been removed. The Panel recommends that suspicious palpable nodes should also be submitted as SLNs, and that in this context, the surgeon should have a low threshold for default to ALND.

Is Full ALND Necessary for All Patients With Positive Findings on SNB?

Additional node disease is found at the time of ALND in almost half of all patients with a positive SLN. Thus, the Panel recommends routine ALND for patients with a positive SNB on the basis of routine histopathologic examination. The use of radiation therapy alone in this setting is the subject of ongoing studies. It remains unclear whether isolated tumor cells (pN0) detected with hematoxylin and eosin staining or special stains represent an adverse prognostic indicator. Metastasis is found in nonsentinel nodes in about 10% of patients with isolated tumor cells in the SLN and in 20% to 35% of patients with micrometastasis in the SLN. Until further studies addressing the clinical relevance of isolated tumor cells or micrometastases in the SLN are complete, the Panel recommends routine ALND for patients with micrometastases (> 0.2 mm but ≤ 2.0 mm) found on SNB, regardless of the method of detection.

What Is the Role of SNB in Special Circumstances in Clinical Practice?

The Panel does not recommend SNB for large or locally advanced invasive breast cancers (T3 and T4); for inflammatory breast cancer; for ductal carcinoma-in-situ (DCIS), when breast-conserving surgery is to be done; during pregnancy; in the setting of prior nononcologic breast surgery or axillary surgery; or when suspicious palpable axillary lymph nodes are present. The Panel recommends the use of SNB in other clinical circumstances, as detailed in Table 1.

Caution

What Factors Affect the Success of SNB?

The Panel believes that appropriate training in the SNB procedure and issues of quality control are critical. The strongest predictor of the false-negative rate across trials appears to be the proportion of patients for whom mapping is successful. Surgeons should be adequately trained and experienced in the SNB procedure because case volume and experience are important determinants of success. Similarly, pathologists evaluating SNB specimens should be experienced and strive to employ common methodology and reporting criteria, especially when examining the minimal amount of disease frequently found with the more extensive evaluation of SLNs.

What Are the Potential Benefits and Harms Associated With SNB?

SNB is thought to be associated with fewer complications such as infection (cellulitis) of the chest wall and arm, sensory changes, and lymphedema than conventional ALND. Nevertheless, the benefits and harms of the procedure, including the potential for a false-negative result, should be explained to the patient and provided in easy-to-understand, written educational materials. It should be explained that outcomes improve with greater experience of the surgeon and pathologist, and referrals to qualified teams should be offered routinely. The patient should also be told that there are limited data from controlled clinical trials in which the two procedures are compared.

The Panel recommends that, as with any medical procedure, written informed consent be obtained from all patients before SNB.

Methodology

Review of the literature yielded one published prospective randomized controlled trial in which SNB was compared with ALND, four limited meta-analyses, and 69 published single-institution and multicenter trials in which the test performance of SNB was evaluated with respect to the results of ALND. Currently, there are no data on the effect of SNB on long-term survival of patients with breast cancer.

Table 1. Recommendations for use of SNB and levels of evidence

Clinical Circumstance	Use of SNB	Level of Evidence*
T1 or T2 tumors	Acceptable	Good
T3 or T4 tumors	Not recommended	Insufficient
Multicentric tumors	Acceptable	Limited
Inflammatory breast cancer	Not recommended	Insufficient
DCIS with mastectomy	Acceptable	Limited
DCIS without mastectomy	Not recommended except for large DCIS (> 5 cm) on core biopsy or with suspected or proven microinvasion	Insufficient
Suspicious, palpable axillary nodes	Not recommended	Good
Older age	Acceptable	Limited
Obesity	Acceptable	Limited
Male breast cancer	Acceptable	Limited
Pregnancy	Not recommended	Insufficient
Evaluation of internal mammary lymph nodes	Acceptable	Limited
Prior diagnostic or excisional breast biopsy	Acceptable	Limited
Prior axillary surgery	Not recommended	Insufficient
Prior nononcologic breast surgery (reduction or augmentation mammoplasty, breast reconstruction, etc.)	Not recommended	Insufficient
After preoperative systemic therapy	Not recommended	Insufficient
Before preoperative systemic therapy	Acceptable	Limited

Abbreviations: SNB, sentinel lymph node biopsy; DCIS, ductal carcinoma-in-situ; ALND, axillary lymph node dissection.
* Levels of evidence: Good, multiple studies of SNB test performance based on findings on ALND; limited, few studies of SNB test performance based on findings on ALND or multiple studies of mapping success without test performance assessed; and insufficient, no studies of SNB test performance based on findings on ALND and few if any studies of mapping success.

However, a review of the available evidence demonstrates that, when performed appropriately by experienced clinicians, SNB appears to be a safe and acceptably accurate method for identifying patients with early-stage breast cancer without involvement of the axillary lymph nodes.

Limitations of the Guideline

Although the Panel concludes that SNB is a safe and effective staging procedure for most women with newly diagnosed early-stage breast cancer, it is associated with a recognized false-negative rate that varies considerably across reported studies. In addition, there are little data on the value of SNB in a number of special circumstances and only one randomized controlled trial has been published. The role of routine immunohistochemistry and/or molecular biologic analysis of the SNB remains unclear. For patients who have a positive SNB and for patients in whom a SLN is not identified intraoperatively, ALND should be considered standard practice until the results of ongoing clinical trials are evaluated. Limitations in understanding the full role of this procedure in the management of women with early-stage breast cancer will not be addressed until the results of ongoing randomized trials are available.

NEW PATIENT GUIDE AVAILABLE ON SENTINEL LYMPH NODE BIOPSY

ASCO recently released guidelines concerning the use of sentinel lymph node biopsy for early-stage breast cancer, which have been adapted for a patient audience. The ASCO Patient Guide: Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer includes the new ASCO recommendations, a brief analysis of what the recommendations mean for patients, questions patients can ask their doctors, and a list of resources for additional information. Background information about sentinel lymph node biopsy and how it differs from an axillary node dissection is also provided. The new guideline is now available at http://www.plwc.org/patientguides in text-only and PDF formats.

Additional Resources

In addition to the full text of the guideline recommendations, available online at http://ww.jco.org/cgi/reprint/JCO.2005.08.001v1.pdf, further resources from ASCO include a patient guide (http://www.plwc.org/plwc/external_files/SNB_Patient_Guide.pdf) and a PowerPoint slide set (http://www.asco.org/asco/downloads/SNB_Slides_Plain_Template_9-29-05.pdf).

The Guideline Recommendations for Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer were developed and written by Gary H. Lyman, Armando E. Giuliano, Mark R. Somerfield, Al B. Benson III, Diane C. Bodurka, Harold J. Burstein, Alistair J. Cochran, Hiram S. Cody III, Stephen B. Edge, Sharon Galper, James A. Hayman, Theodore Y. Kim, Cheryl L. Perkins, Donald A. Podoloff, Visa Haran Sivasubramaniam, Roderick R. Turner, Richard Wahl, Donald L. Weaver, Antonio C. Wolff, and Eric P. Winer.

It is important to realize that many management questions have not been comprehensively addressed in randomized trials and guidelines cannot always account for individual variation among patients. A guideline is not intended to supplant physician judgment with respect to particular patients or special clinical situations and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same results. Accordingly, ASCO considers adherence to this guideline to be voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances. In addition, the guideline describes administration of therapies in clinical practice; it cannot be assumed to apply to interventions performed in the context of clinical trials, given that clinical studies are designed to test innovative and novel therapies in a disease and setting for which better therapy is needed. Because guideline development involves a review and synthesis of the latest literature, a practice guideline also serves to identify important questions for further research and those settings in which investigational therapy should be considered.