

Performance and Practice Guidelines for Sentinel Lymph Node Biopsy in Breast Cancer Patients

Article I - Introduction

This American Society of Breast Surgeons (ASBrS) Performance and Practice Guideline summarizes the indications for and technique of sentinel lymph node (SLN) biopsy. The Guideline reflects the consensus of a panel comprising members of the Education Committee, the Board of Directors, and the Executive Committee, and is based on multiple sources from the peer-reviewed literature. This Guideline reflects what ASBrS considers to be optimal practice but may require modification based on the clinical circumstance, the physician's judgment, the patient's preference, and as scientific evidence continues to evolve.

Article II - Indications

SLN biopsy is well established as standard care for axillary lymph node staging in most patients with cN0 breast cancer. Compared to axillary lymph node dissection (ALND), the staging accuracy and oncologic outcomes of SLN biopsy are comparable and the morbidity is less. Current indications for SLN biopsy are as follows:

- a. T1-2 invasive breast cancer with a clinically negative axilla
- b. DCIS sufficient to require mastectomy, or DCIS with suspected/proved microinvasion
- c. Patients with clinically negative axillary nodes following neoadjuvant chemotherapy

Although the evidence is limited, SLN biopsy *may* be suitable for selected patients with multicentric cancers, T3 disease, or pregnancy. SLN biopsy is not indicated for patients with inflammatory breast cancer.

Article III – Surgeon Qualifications

Surgeons must have successfully completed an American Board of Medical Specialties-approved surgical residency program and must have attained, or be admissible for, board certification by the American Board of Surgery (ABS) or its equivalent. Training in the technique of SLN biopsy is part of the surgical curriculum in all accredited training programs.

Article IV – Procedure Details and Prerequisites

A. Prerequisites

SLN biopsy is a team effort requiring close collaboration between the nuclear medicine physician, surgeon, and pathologist, but is a robust procedure and works well with a variety of techniques. The success of isotope mapping is superior to that of blue dye and, except for

the most experienced centers, the success of isotope plus dye mapping is superior to that of either method alone. Isotope may be injected the day before or the morning of surgery; lymphoscintigraphy is done at the discretion of the nuclear medicine physician and surgeon. Blue dye is injected at the start of surgery. The success and accuracy of SLN biopsy are comparable with a variety of injection sites (peritumoral, intratumoral, intradermal, subdermal, subareolar), injection volumes, isotope preparations, and blue dyes. SLN biopsy is done under local or general anesthesia, in the supine position, with the patient's arm abducted at 90 degrees and (at the surgeon's preference) sterilely draped into the operative field. Prophylactic antibiotics are given prior to induction.

B. Technique

SLN biopsy is most often done through an axillary incision separate from that of the mastectomy or lumpectomy. The goal of SLN biopsy is to remove sufficient "hot" and/or blue nodes and/or palpably suspicious nodes to accurately stage the axilla. A typical number of SLN is 1-3 with a median of 2 in most series; staging accuracy does not increase by removing more than 3-4 SLN. Regarding isotope, one should aim to remove the "hottest" SLN, and many surgeons remove all nodes whose counts are 10% or more of the hottest node ("10% rule"). Regarding blue dye, one should aim to remove blue nodes or nodes contiguous with blue-stained lymphatics. Regarding palpably suspicious nodes at surgery, one should aim to remove these even if they are neither blue nor hot. Intraoperative pathologic assessment of SLN by frozen section or touch prep is not required for those patients who meet the Z0011 selection criteria; for all others, intraoperative assessment and, if positive, immediate ALND remain standard care.

Article V – Documentation

Documentation prior to surgery should include an informed consent, encompassing all treatment options and a full discussion of risks and benefits. The operative report should include all appropriate patient identifiers, the name of the operation, the type of anesthesia, and a succinct description of the clinical setting, indication for surgery, and operative findings. The number and mapping characteristics (hot and/or blue and/or palpable) of each SLN should be noted, along with the results of intraoperative assessment, if done. A copy of the operative report should go to all treating physicians and should be part of the permanent medical record. A plan for follow-up, including discussion of pathology results, wound care, and arm exercises should be part of the overall survivorship program.

Article VI – Equipment Specification and Quality Control

Standard general surgical instruments, operating room equipment, and (for isotope mapping) a gamma probe are required. Although the radiation doses involved in isotope mapping are trivial (and well within the safety limits for pregnant patients), specimens should be handled as required by each institution's own radiation safety protocols. Isosulfan blue dye is associated with a low rate of allergic reactions (1%), but some of these are anaphylactic, and its safety has not been established for pregnant patients.

Article VII – Quality Assessment/Improvement

- a. Using standard protocols, SLN should be identified in >95% of eligible patients.
- b. SLN are falsely negative in 5%-10% of node positive patients but the long-term rate of axillary local recurrence in SLN-negative patients is only about 1%.
- c. A policy for ongoing review of emerging evidence regarding the indications and outcomes of SLN biopsy should be in place.
- d. A policy to monitor and manage the acute and long-term complications of SLN biopsy should be in place.
- e. The medical record should document a plan for referral to the appropriate specialists for post-surgical care, and for long-term follow-up.

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Board of Directors
The American Society of Breast Surgeons

This statement updates the Original Guidelines (November 1998), First Revision (August 2000), Second Revision (November 2002), Third Revision (October 2003), Fourth Revision (December 2005), and Fifth Revision (November 2010).

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