



**Evidence-Based Series #17-5: Section 1**

**Sentinel Lymph Node Biopsy in Early-stage Breast Cancer:  
Guideline Recommendations**

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The full Evidence-based Series #17-5 is comprised of 3 sections and is available on the CCO website (<http://www.cancercare.on.ca>)  
PEBC Surgery page at:  
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**Section 1: Guideline Recommendations**  
**Section 2: Evidentiary Base**  
**Section 3: EBS Development Methods and External Review Process**

This guideline addresses the role of sentinel lymph node biopsy (SLNB) in the surgical management of early-stage breast cancer. The Expert Panel on SLNB in Breast Cancer identified the American Society of Clinical Oncology (ASCO) 2005 guideline on SLNB in early stage breast cancer (1) as a suitable base on which to develop recommendations for Ontario, following an evidence update of the ASCO guideline.

Five questions from the ASCO guideline regarding clinical practice were addressed in this guideline through an updated evidence review. Two additional questions regarding technical aspects of SLNB and how to organize the delivery of SLNB were drafted by the Expert Panel.

**QUESTIONS**

**Clinical Practice**

1. Should SLNB be the recommended standard of care for women and men with proven breast cancer, whose clinical presentation is suggestive of early-stage disease?
2. How should the results of SLNB be utilized in clinical practice?

- a. Can level I/II axillary lymph node dissection (ALND) be avoided in patients with negative findings on sentinel lymph node biopsy (SLNB)?
- b. Is level I/II ALND necessary for all patients with positive findings on SLNB?
3. What is the role of SLNB in special circumstances in clinical practice? (special circumstances include large and locally advanced invasive tumours, multicentric tumours, inflammatory breast cancer, ductal carcinoma in situ (DCIS), older age (65 years or more), obesity, male breast cancer, pregnancy, evaluation of the internal mammary nodes, presence of suspicious palpable axillary nodes, prior breast or axillary surgery, and preoperative systemic therapy).
4. What factors affect the success of SLNB (including low rates of complications and false-negative results)?
5. What are the potential benefits and harms associated with SLNB?

### Technical Aspects of SLNB

1. What is the recommended mapping technique for SLNB?
2. What operative technique is recommended?
3. What is the recommended technique for pathological processing, handling, and reporting?

### Organization of Care

1. How should the delivery of SLNB be organized in Ontario with respect to team membership, experience and training, and the institutional setting?
  - a. What is the recommended experience and training for surgeons who perform SLNB?
  - b. What are the recommended criteria and resources for institutions performing SLNB?

### TARGET POPULATION

The target population for this guideline is all patients, both male and female, with early-stage breast cancer.

### INTENDED USERS

The intended users of this evidence-based series are clinicians involved in breast surgery, including surgeons, pathologists, medical oncologists, radiation oncologists, nuclear medicine practitioners, radiologists, other allied health professionals (e.g., nurses, physiotherapists), administrators, and also breast cancer patients.

### CLINICAL PRACTICE RECOMMENDATIONS AND EVIDENCE

The following recommendations address the role of sentinel lymph node biopsy in patients with early-stage breast cancer:

*Recommendations appear in shaded boxes, Evidence appears in unshaded boxes.*

SLNB is recommended as the preferred method of axillary staging for all patients with a clinical presentation of early-stage breast cancer in the absence of clinically or pathologically positive lymph nodes

#### **Evidence**

Four randomized controlled trials (RCTs) reported high sentinel node (SN) detection rates (95.1%, Sentinella-GIVOM (2,3)) to 97.2%, NSABP B-32 (4) and accuracy (94.4% Sentinella-GIVOM (2) to 97.6%, ALMANAC (5)). False-negative rates were low (e.g., 6.7%, ALMANAC (5)), with the exception of one RCT that had no training component or requirement for use of the blue dye (16.7%, Sentinella-GIVOM (2,3,6)). Node-positive rates were similar in all cases

between ALND and any SLNB-alone arms. In the Sentinella-GIVOM non-inferiority trial (2,3,6), there was only one axillary recurrence in 345 SN-negative (SN-) patients at 55.6 months of follow-up, and similar disease-free and overall survival rates. (See Section Two for summaries of the RCTs and the prospective series data.)

ALND (Level I/II) is recommended for:

- Positive results on SLNB (see *Qualifying Statement*)
- Failed SLNB attempts (failure is defined as no localization of a sentinel node)
- Positive results from a needle biopsy of clinically suspicious adenopathy

**Evidence**

The Expert Panel continues to support full Level I/II ALND for patients that are SN positive (SN+) based on the updated review and the findings of the ASCO Guideline (1). While the ACOSOG Z0011 trial (7) includes an arm of SN+ patients treated without a completion ALND, no data on treatment-related outcomes were available at the time of this review.

**Qualifying Statement**

While ALND (Level I/II) is recommended for patients with positive findings on SLNB, exceptions might include:

- Individuals with life-shortening co-morbidities, high perioperative risk, and low risk of residual disease. The decision not to perform Level I/II ALND should be made on a case-by-case basis and ideally in the context of a multidisciplinary case conference.
- High or low risk of residual axillary disease is indicated by several factors, which include: size of primary tumour, size of metastases, absence or presence of extra-nodal extension, lymphovascular invasion, ratio of positive to negative sentinel nodes, and total number of nodes assessed. Online decision aids are available for use that may help in these cases (8).

**Evidence**

This recommendation is based on the opinion of the Expert Panel.

ALND (Level I/II) is not recommended when the results of SLNB are negative

**Evidence**

Full ALND can be avoided when SNs are negative on pathologic examination as evidenced by the Sentinella-GIVOM trial (2,3,6), where no statistically significant difference was detected between the SLNB and the ALND group in overall survival (OS) or recurrence-free survival (RFS) at 55.6 months

Preoperative needle biopsy can be performed for clinically suspicious nodes. Patients with a biopsy confirming metastatic disease would proceed directly to ALND, thus avoiding SLNB.

**Evidence**

This recommendation is based on the opinion of the Expert Panel.

**The Role of SLNB in Specific Clinical Circumstances**

In general, the SLNB Expert Panel recommends the use (or not) of SLNB in each of the following clinical circumstances, noting that the decision to use SLNB in these circumstances should be individualized for each patient.

**Clinical circumstances recommended for SLNB**

- T1 or T2 tumours
- Multicentric tumours
- DCIS (with mastectomy)
- Older age\*
- Obesity\*

- Bilateral breast cancer

**Evidence**

The majority of patients in the four RCTs reviewed were T1/2, although this was not consistent throughout the trials. The use of SLNB in DCIS with mastectomy is supported by a Standards document (9) and an online Clinical Practice Guideline (10). The recommendations for the use of SLNB with multicentric tumours, older age, obesity, and bilateral breast cancer were based on Expert Panel consensus, a subset analysis from the ALMANAC trial, and results of prospective and cohort series. (see Section 2, pages 19 and 20).

\*While SLNB is recommended for both older age and/or obesity, clinicians and patients should be aware that both are risk factors for failed SLN mapping.

**Clinical circumstances not recommended for SLNB**

- Inflammatory T4 breast cancer
- Prior axillary surgery\*

**Evidence**

All four RCTs reviewed excluded patients with inflammatory breast cancer by not including T4 lesions; the Expert Panel agrees these patients should not be considered candidates for SLNB. \*Two of the RCTs reviewed (ALMANAC (5,11-17) and ACOSOG Z0011 (7)) specifically excluded patients with prior axillary surgery. The Expert Panel agrees that these are not appropriate patients for SLNB but would consider a patient eligible if the previous axillary surgery was a minor operation unlikely to interfere with lymphatic mapping.

**Clinical circumstances with inconclusive or inadequate evidence**

- Internal mammary lymph nodes\*
- Before preoperative therapy\*
- T3 or T4 tumours\*
- DCIS (without mastectomy)\*
- Suspicious palpable axillary nodes\*
- After preoperative systemic therapy\*
- Prior diagnostic or excisional breast surgery\*
- Prior non-oncologic breast surgery\*
- Pregnancy\*\*

**Evidence**

There is insufficient evidence to support or refute the use of SLNB in these settings. The Expert Panel will review new evidence as it becomes available.

\* For all of these circumstances, treatment decisions must be made on a case-by-case basis.

\*\* For pregnant patients, there exist concerns about the safety of blue dye, and only small case-series describe its use. Investigational studies suggest acceptable fetal radiation exposures with non-iodine radioisotopes in the dosages used for the sentinel node technique. Additional information and resources can be found on most nuclear medicine speciality society web sites (e.g., The British Nuclear Medicine Society (available at: <http://www.bnmsonline.co.uk>) [accessed January 9, 2009] (go to "Guidelines and procedures", "Other guidelines", Section 7 of "Notes for the guidance of the clinical administration of radiopharmaceuticals"); The European Association of Nuclear Medicine (available at: [https://www.eanm.org/scientific\\_info/guidelines/gl\\_onco\\_sent\\_node.pdf](https://www.eanm.org/scientific_info/guidelines/gl_onco_sent_node.pdf)) [accessed January 13, 2009]). Individual cases must be reviewed with a nuclear medicine specialist. Most Expert Panel members would use the SLNB technique in a pregnant woman beyond the 1<sup>st</sup> trimester, weighing risk versus benefit on a case-by-case basis.

**Factors that Affect the Success of SLNB**

Several factors are associated with successful SLNB (defined as low complication and false-negative rates [FNRs]) in all patients.

The SLNB Expert Panel acknowledges that success (defined as low complication and FNRs) is dependent on team experience, case volume, and adherence to established protocols in nuclear medicine, pathology, and surgery and recommends these factors as quality indicators.

<p><b>Evidence</b></p> <p>Evidence from prospective series data show SN detection rates are negatively affected by minimal surgeon training (18-20). Surgeon experience was found to have a significant effect on SN detection rates (20). A Standards Document recommends that SLNB should only be performed by surgeons who have had proper training in the techniques and who have been audited for performance (9). Two online Clinical Practice Guidelines stated that SLNB requires a multidisciplinary team and that its success depends on the strengths of the individual components (10,21).</p>
<p>The SLNB Expert Panel <u>recommends</u> the use of periareolar injection technique and combined blue dye and radiotracer protocol (see <i>Qualifying Statement</i>).</p>
<p><b>Evidence</b></p> <p>The majority of study protocols incorporated the dual injection technique, as stated in the original ASCO guideline (1), and the Expert Panel continues to endorse this recommendation. High localization rates are obtained when using a periareolar injection in the meridian of the tumour (22).</p>
<p><b>Qualifying Statement</b></p> <p>The evidence suggests lower localization rates in the obese and in patients who have had a prior lumpectomy</p>
<p><b>Evidence</b></p> <p>One RCT (ALMANAC (5,11-17)) demonstrated that SN detection rates are negatively affected by a high body-mass index (BMI), and the NSABP B-32 trial (4) showed higher FNRs after prior excisional biopsy versus needle biopsy.</p>

**Potential Harms and Benefits**

Reduced morbidity is the major benefit of SLNB. The panel strongly favours the SLNB technique, which demonstrates less morbidity with equivalent positive node detection rates, compared with ALND.

<p><b>Benefits</b></p> <ul style="list-style-type: none"> <li>• Less invasive surgery (outpatient procedure and no need for drains)</li> <li>• Fewer complications (e.g., sensory changes, lymphedema)</li> <li>• Enhanced pathologic staging</li> </ul>
<p><b>Evidence</b></p> <p>The Sentinella-GIVOM (2) trial detected a difference between ALND and SLNB for lymphedema at 12 months, in favour of SLNB, and shorter term benefits in numbness, pain, and arm movement (2,6). For impairment of shoulder function, neither the ALMANAC (5,11-17) nor the Sentinella-GIVOM trial (2,6) detected a long-term difference between the groups. For infection rates, the ALMANAC trial did not detect a difference between the groups. A prospective series that reported on these outcomes detected significant benefits favouring SLNB over ALND for muscle weakness, shoulder stiffness, pain in arm, numbness in breast area, numbness in arm, and strange sensations in arm (all <math>p &lt; 0.05</math>) (23).</p>

<p><b>Harms</b></p> <ul style="list-style-type: none"> <li>• Possible allergic reactions to blue dye</li> <li>• Caution of FNRs</li> <li>• No long-term survival data</li> </ul>
<p><b>Evidence</b></p> <p>In the RCT evidence reviewed, FNRs ranged from 6.7% (ALMANAC (5)) to 16.7% (Sentinella-GIVOM (2,3)), and in the prospective series reviewed, FNRs ranged from 1.9% (24) to 25% (25).</p>

The Expert Panel notes that adequate training and technique are required to achieve low FNRs.

**Technical Aspects SLNB**

**A. Mapping Technique**

The recommended mapping technique is the dual injection technique with radioisotope and vital blue dye to maximize localization rates.

**Evidence**

The majority of study protocols incorporated the dual injection technique, as stated in the original ASCO guideline (1), and the Expert Panel continues to endorse this recommendation. High localization rates are obtained when using a periareolar injection in the meridian of the tumour (22).

**B. Operative Technique**

The Expert Panel recommends using both radioisotope and blue dye for sentinel lymph node mapping. Using this technique, the incision may be guided by gamma probe readings, allowing the surgeon to identify the sentinel node/s with the probe as well as visually inspect for blue-stained nodes and palpate for clinically suspicious nodes. With the use of the radioisotope, it is also possible to demonstrate that radioactive nodes have been removed by performing ex vivo counts on the resected tissue.

**Evidence**

This recommendation is based on Expert Panel consensus and is supported by the NSABP B-32 trial protocol (4).

**C. Pathology**

The recommended pathology technique is that excised sentinel lymph nodes be cut into sections no thicker than 2.0 mm parallel to the longest meridian. This allows for the recognition of small metastatic deposits that might be missed by the examination of a lymph node that has been bivalved. Hematoxylin & Eosin (H/E) staining is routinely employed. While published protocols vary across institutions, all advocate some form of serial sectioning for the evaluation of sentinel nodes.

**Evidence**

The Expert Panel continues to support the recommendation in Appendix 3 of the 2005 ASCO Guideline (1). Immunohistochemistry (IHC) may be used to help identify very small tumour deposits, but its use is not considered routine.

**ORGANIZATION OF CARE RECOMMENDATIONS**

**Team Recommendation**

SLNB should be performed by an experienced team to ensure results equivalent to those obtained with ALND. The proportion of patients successfully mapped correlates with false-negative rates and is a reasonable indicator of quality. Consistent pathology and nuclear medicine protocols need to be adhered to.

**Evidence**

Patient outcomes should be audited against the current standards of SN detection and FNRs (21,26).

Two online Clinical Practice Guidelines state that SLNB requires a multidisciplinary team (see INTENDED USERS, Section One), and its success depends on the strengths of the individual components (10,21). The Expert Panel also endorses these recommendations.

**Surgeon Training Recommendation**

The surgeon training recommendation is completion of at least one of the following options for surgeons who perform SLNB:

1. Training during a residency or fellowship program.
2. Mentorship with an experienced surgeon (may include a formal didactic course).
3. Combining the procedure with a number of completion dissections to demonstrate acceptable accuracy (may include a formal didactic course).

The SLNB Expert Panel acknowledges that the training will be different for those surgeons involved with an experienced team versus those with little or no experience.

**Evidence**

A Standards Document (9) and a Position Paper (26) supported this recommendation, one recommending that SLNB should only be performed by surgeons who have received the proper training in the technique and who have been audited for accuracy (9), and the other recommending that surgeons and team should have taken training followed by a period of self and team audit where success is measured against the outcomes of SN detection rates and FNRs (26). The Expert Panel also endorses these recommendations.

**System Recommendations**

The minimum system recommendations are that clinicians and patients should have access to:

- a licensed nuclear medicine facility that follows a defined SLNB protocol to perform injection
- a surgeon with:
  - appropriate training and experience in sentinel node detection and extraction
  - access to a hand-held gamma probe, which is used to detect the SN
- a pathologist who assesses the SLN specimens according to a standardized protocol (for examples, see Appendix 3 of the ASCO guideline (1) and the Methods section of the NSABP B-32 trial report (4)).

**Evidence**

These recommendations are supported by the Team and Surgeon Training evidence as well as the protocols of several RCTs (ALMANAC, NSABP B-32). The Expert Panel also endorses these recommendations.

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