Sentinel Lymph Node Biopsy for Breast Cancer: How Many Nodes are Enough?

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Introduction: Sentinel lymph node (SLN) biopsy using blue dye and radioisotope often results in the removal of multiple SLNs. We sought to determine whether there is a point where the surgeon can terminate the procedure without sacrificing accuracy.
Methods: One thousand one hundred ninety-seven patients from University of Michigan and the Mayo Clinic undergoing SLN biopsy formed the study population. Surgeons removed all SLNs until counts within the axilla were less than 10% of the highest node ex vivo and recorded the order in which they were removed.
Results: The mean number of SLNs removed per patient was 2.5 (range 1–9). Approximately 42% of patients had three or more lymph nodes removed, while 19% had four or more lymph nodes removed. Eighteen percent of patients (132/725) at University of Michigan and 22% (103/472) at Mayo Clinic had a positive SLN. Ninety-eight percent (231/235) of patients with lymph node metastases were identified by the 3rd SLN while 100% were identified by the 4th SLN.
Conclusion: Among patients undergoing SLN biopsy for breast cancer, the only positive SLN is rarely identified in the 4th or higher node. Terminating the procedure at the 4th node may lower the cost of the procedure and reduce morbidity.
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INTRODUCTION

Sentinel lymph node (SLN) biopsy has become a standard method for staging the axilla in clinically node negative patients with breast cancer [1,2]. The benefit of SLN biopsy in providing accurate staging information while avoiding the morbidity of a complete axillary lymph node dissection has been well-documented [3–5]. The SLN is defined as the first lymph node to receive lymphatic drainage from the tumor and is therefore the most likely lymph node to harbor micrometastases if they exist. The practical definition of the SLN is different, however. With the combined use of technetium 99 m-sulfur colloid (^{99m}Tc) and blue dye to identify SLN, multiple lymph nodes are often found containing tracer. Any lymph node that exhibits radioactivity, is blue or has a blue afferent lymphatic channel, or is palpably suspicious is excised and labeled as a SLN [6].

A dual tracer technique with blue dye and radioisotope increases both the success rate and the accuracy of the procedure [7–9], but also increases the number of lymph nodes removed per case [10,11]. The degree of radioactivity necessary to excise and define a lymph node as 'sentinel' varies among surgeons [6,12–14]. Several authors have demonstrated that the hottest SLN (the node with the highest counts) is not always the node to harbor metastasis [10,15–17], and so a threshold for excising additional SLNs is necessary. What that threshold should be, however, remains in question. With a lower threshold, the surgeon is less likely to miss a positive SLN but more likely to remove more lymph nodes per case. Furthermore, the absolute number of counts in the node varies depending on factors such as the dose and

type of radioactive colloid, time interval from injection to operation, the type of gamma probe, and its calibration. The purpose of this analysis was to determine whether there is a threshold (based on number of SLNs removed) after which the surgeon does not need to excise additional lymph nodes.

MATERIALS AND METHODS

Medical records were reviewed for 1,197 breast cancer patients who underwent successful lymphatic mapping and SLN biopsy between October 1998 and December 2004 at the University of Michigan (n = 725) and from March 2003 to December 2005 at the Mayo Clinic (n = 472). Approval of this study was granted by the respective Institutional Review Boards. All patients underwent injection of ^{99m}Tc-sulfur colloid (CIS-US, Inc., Bedford, MA) either peri-tumorally or periareolar; injection was either the night before or the morning of the procedure. Isosulfan blue dye (Lymphazurin 1%; Hirsch Industries, Inc., Richmond, VA) was utilized in 710 patients (except 19 patients who had the procedure performed during a national shortage) at the University of Michigan, while methylene blue dye (American Regent, Inc., Shirley, NY) was used in all the patients at the Mayo Clinic. Blue dye was injected either peri-tumorally or at the subareolar location, followed by 3–5 min of massage to promote lymphatic flow. A handheld gamma probe (Navigator GPS; US Surgical) was used to identify transcutaneous hot spots and to guide dissection of the SLN(s).

Lymph nodes were removed and labeled as SLNs if they were palpably suspicious, blue, had blue-stained afferent lymphatic vessels, or were hot, defined as the hottest node plus any lymph node with at least 10% of the ex vivo counts per minute (CPM) of the hottest node. The SLNs were numbered in the order they were excised, so the first node was not necessarily the hottest node based on CPM. At the Mayo Clinic, a preliminary frozen section was performed on all SLNs, while this was performed selectively at the University of Michigan. If the SLN was negative for tumor, the node was measured and cut entirely along its longitudinal axis into sections of 1.5–2 mm thickness. The sections were submitted in formalin for paraffin section histology. At least four additional levels were examined with hematoxylin and eosin (H&E) and cytokeratin antibody (AE1/3, monoclonal antibody, 1/250; Boehringer Mannheim, Indianapolis, IN), together with a negative control. The routine use of IHC for cytokeratin was discontinued at the University of Michigan in July 2002. For the Michigan dataset, sentinel nodes positive by IHC but negative by H&E were considered negative. In contrast, IHC was utilized uniformly for all Mayo Clinic patients. Of 472 patients in the Mayo dataset, information on IHC staining was recorded for 414 patients. Of these, five patients had positive SLNs based on IHC alone (all were N0i+). IHC was not used on any non-SLNs.

RESULTS

The study group consisted of 1,197 patients; 725 from the University of Michigan and 472 from the Mayo Clinic. The median age of the patients was 55 years (range, 17–85 years) in the Michigan dataset and was 64 years (range, 24–90 years) in the Mayo dataset. Overall, 71% of patients had invasive ductal carcinoma and 11% had invasive lobular carcinoma. The patient and tumor characteristics presented in Table I were similar between the two institutions.

The mean number of SLNs removed by the surgeon in both the Michigan (range, 1–9) as well as in the Mayo dataset (range, 1–8) was 2.5. The number of lymph nodes surgically removed and pathologically examined at each institution is shown in Table II. Often, the surgeon removes and labels a single node as a SLN, but the pathologist identifies more than one node within the specimen. Based on pathology reports, the mean number of SLNs examined per patient was 3.1 (range, 1–24) at the University of Michigan and 2.8 (range, 1–9) at the Mayo Clinic. The frequency distribution of the number of SLNs removed by the surgeon and identified by the

TABLE I. Patient and Tumor Characteristics

	Michigan dataset, n = 725		Mayo dataset, n = 472	
	n	%	n	%
Tumor histology				
Invasive ductal	511	70	343	73
Invasive lobular	68	10	55	12
DCIS	55	7	42	9
DCIS with microinvasion	35	5	—	—
Other	56	8	32	6
Tumor size				
Tis	55	8	42	9
T1mic	35	5	8	2
T1a	76	10.5	25	5
T1b	181	25	91	20
T1c	249	35	193	42
T2	111	15.5	86	18
T3	7	1	18	4
Unknown	11		9	
Tumor grade (invasive)				
1	144	21.3	104	25
2	283	42.4	226	53
3	127	19.1	87	22
Unknown	116	17.2	13	
Estrogen receptor (invasive)				
Positive	448	66.8	374	87
Negative	159	23.6	56	13
Unknown	63		—	

TABLE II. Number of SLNs Excised and Examined

| | Excised by surgeon | | | | Examined by pathologist | | | |
| | Michigan dataset | | Mayo dataset | | Michigan dataset | | Mayo dataset | |
No. of SLN/s	n	%	n	%	n	%	n	%
1	168	23	97	22	147	20	91	19
2	261	36	151	34.5	216	30	133	28
3	162	22	99	23	156	22	115	24
4	81	11	51	12	77	11	67	14
5	30	4	21	5	44	6	31	6.5
6	12	1.7	10	2	28	4	21	4
7	6	0.8	1	0.2	11	1.5	9	2
8	2	0.3	2	0.4	15	2	3	0.6
9	2	0.3	—	—	8	1	2	0.4
10	—	—	—	—	9	1	—	—
11	—	—	—	—	6	0.8	—	—
≥12	—	—	—	—	5	0.7	—	—

pathologist was remarkably similar between the two institutions. Overall, 42% of patients had three or more SLNs removed while 19% had four or more lymph nodes removed. Nearly half of the patients had three or more and a quarter had four or more nodes examined histologically.

The position of the first positive node in the order of SLN removal is presented in Table III. Of the 725 patients undergoing successful SLN biopsy at the University of Michigan, 132 (18%) had metastasis to at least one SLN. There was an average of 1.5 positive SLN per node-positive patient. Of the 132 patients with lymph node metastases, 66% (87 patients) were positive in the first lymph node removed by the surgeon, 86% (114 patients) by the second node, 98% (130) by the third node, and 100% (132 patients) by the 4th node. There were no cases where the surgeon needed to excise more than four nodes to identify metastases.

Of the 472 patients having successful SLN biopsy at the Mayo Clinic, 103 (22%) had metastasis to at least one SLN (Table III). Of the 103 patients with SLN metastases, 87% (90) were positive in the 1st node removed by the surgeon, 95% (98) by the 2nd node, 98% (101) by the 3rd node, and 100% (103) by the 4th node. Similar to the Michigan study

population, there were no cases where the surgeon needed to excise more than four nodes to identify metastases. Despite the use of IHC at the Mayo Clinic and the five additional patients who were positive by IHC only, the routine use of IHC did not alter these results.

Terminating the procedure after the 3rd node would have shortened the operation for 133 (18%) at Michigan and 111 (26%) patients at Mayo, and avoided histological evaluation of 223 and 137 nodes, respectively, but would have missed disease in 4 of 235 patients (1.7%). In the Michigan dataset, terminating the procedure after the after the 4th node removed would not have missed any positive cases but overall spared 52 patients (7%) the extra time in the OR to identify additional nodes and the histologic evaluation of 90 additional nodes. In the Mayo dataset, this approach would spare 34 patients from the additional time in the OR (7% of the total) and the histologic evaluation of 52 nodes without missing any positive SLNs (Table IV).

DISCUSSION

Sentinel lymph node biopsy has evolved as the preferred technique for axillary staging in breast cancer.

TABLE III. Order In Which the First Positive SLN was Removed

| | Michigan dataset | | | Mayo dataset | | |
	n	% Of cases	Cumulative frequency (%)	n	% of Cases	Cumulative frequency (%)
Node negative	593	82	—	369	78	—
Node positive	132	18	—	103	22	—
1st Node removed	87	66	66	90	87	87
2nd Node removed	27	20	86	8	8	95
3rd Node removed	16	12	98	3	3	98
4th Node removed	2	2	100	2	2	100

TABLE IV. Number of Excess SLNs Removed by the Surgeon Beyond the 4th SLN

	Michigan dataset		Mayo dataset	
No. of excess SLNs	No. of patients	No. of excess nodes removed	No. of patients	No. of excess nodes removed
1	30	30	21	21
2	12	24	10	20
3	6	18	1	3
4	2	8	2	8
5	2	10	—	—
Total	52 (7% of total)	90	34 (7% of total)	52

Studies have shown that the SLN can be identified in 96% of cases with a low false negative rate [18–20]. The mean number of SLNs removed in the SLN biopsy procedure ranges from 1.2 to 3.4 per patient, with a total number ranging from 1 to 8 in the published literature [11,13,17,18]. Removal of more SLNs increases time in the OR, time for the pathologist, costs of the procedure, and axillary morbidity [21]. The ACOSOG Z0010 prospective trial of SLN biopsy in breast cancer reported significantly higher rates of axillary seroma and wound infection in patients who had five or more SLNs removed, compared to those with up to four nodes removed [21]. It is therefore worthwhile to determine how many SLNs should be excised to adequately stage the axilla. In this study we approached this question with a simple criterion—the number of SLNs removed by the surgeon. We sought to discover whether there is a numerical threshold after which the surgeon does not need to excise additional lymph nodes without sacrificing accuracy.

With excision of all blue, palpably suspicious, and hot nodes based upon a 10% rule, 19% of patients in our study had four or more lymph nodes removed, and 28% had a similar number of SLNs examined pathologically. Ninety-eight percent of SLN positive patients had metastasis in the first three SLNs removed, with the remaining 2% found in the fourth SLN. There were no cases where the surgeon needed to excise more than four SLNs to identify SLN metastases. These data suggest that it is rare to identify nodal metastasis in the 4th or higher sentinel node, assuming that all nodes meeting the definition of a SLN (see Material and Methods) have been removed.

The optimal techniques for SLN biopsy have been debated, but there is considerable support for a dual tracer technique [7–9], using both blue dye and radioisotope injection. Although a single SLN should in theory accurately reflect the status of the nodal basin, published clinical trial results confirm that in practice the false negative rate is lower with excision of more than one SLN [22]. When radioisotope is used for lymphatic mapping, some threshold of radioactivity is selected to define the number of SLNs removed. Various count ratios have been used: SLN to background, SLN to non-SLN, or SLN to hottest SLN. Most surgeons use a ratio of the in vivo CPM to the background radioactivity or to the ex vivo node counts compared to that of the node with the highest CPM [6,10,12–15,23]. A common practice is to remove all nodes with counts greater than 10% of the hottest node, based on results from published investigations [10,23].

Several groups have examined this subject and found similar results, with all positive nodes identified by the 4th node (Table V), although there were a few exceptions. The Axillary Lymphatic Mapping Against Nodal Axillary Clearance (ALMANAC) Trialists group reported that 99.6% of node positive patients were identified within the first four sentinel nodes removed [23]. McCarter et al. [24] from Memorial Sloan Kettering

TABLE V. Studies Examining How Many Nodes Needed to be Removed before Identifying All Positive SLN

Author and institution	# Pos SLN	1st Node (%)	2nd Node (%)	3rd Node (%)	4th Node (%)	5th Node (%)	6th–8th Node (%)
MDACC/Duke [29]	278 (11%)	79	96	99	**100**	N/A	N/A
University of Michigan	132 (18%)	66	86	98	**100**	N/A	N/A
Mayo Clinic	103 (22%)	87	95	98	**100**	N/A	N/A
Beaumont Hospital [25]	172 (24%)	76.6	91	97	98.8	99.4	100
Ludwig Boltzmann [30]	105 (40%)	91.4	99	**100**	N/A	N/A	N/A
Virginia Mason [31]	129 (24%)	65	98.4	99.2	**100**	N/A	N/A
MSKCC [24]	241 (15%)	75.3	92.9	98	99.1	99.6	**100**
Wagga Wagga [32]	33 (29%)	88	97	**100**	N/A	N/A	N/A
University South Florida [33]	128 (27%)	89	98.4	99.2	**100**	N/A	N/A
Ohio State University [34]	104 (29%)	83	97	98	99	**100**	N/A

Cancer Center, reported that 99.1% of patients with a positive SLN were found by the fourth SLN removed, and 99.6% were found in the first five nodes removed. Woznick et al. [25] from Beaumont hospital evaluated 172 patients with positive SLN and found that 100% of positive nodes were found by six nodes removed. Chagpar et al. [26] reviewed data from the Louisville Breast Sentinel Lymph Node Study and found that 100% of disease was not identified until >10 nodes were removed, although after 4 nodes were removed, 98.5% of positive SLN were identified. Even in these reports where four nodes did not identify 100% of disease, very few patients (<2%) would have been adversely affected by terminating the procedure at the 4th node. Mathematical models of the impact of a false-negative SLN biopsy on 10-year breast cancer mortality demonstrate an almost negligible impact with 1–2% changes in the false negative rate [27].

Sentinel lymph node biopsy has an inherent false negative rate in the range of 4–10% [18–20]. Based upon the findings of this study and the others summarized above, terminating the SLN biopsy procedure at four nodes should identify a positive SLN in almost all cases and thus increase the false negative rate by less than 1%. Attempts have been made by various researchers to define optimal surgeon experience for reducing false negative rate associated with SLN biopsy. Anywhere between 5 [18] and 20 procedures have been used as the cut-off point [28]. However, most of the validation studies for SLN biopsy technique are from the late 1990s and did not take surgeon's experience into account. Data from pre-randomization surgical training for the NSABP B-32 trial suggests that adherence to a standardized protocol of SLN biopsy procedure can lead to technical success rates of 96% among surgeons with a wide range of expertise for this procedure [18]. Based on these points it seems reasonable to presume that terminating the SLN biopsy procedure at four nodes should have minimal incremental impact on the false negative rate of SLN biopsy procedure, as long as it is performed after completion of recommended training in the procedure.

Some surgeons do advocate continuing the SLN biopsy procedure until all hot nodes are removed. However, there is a cost to this approach. Although it may seem callous to examine the costs of breast cancer care, the cost of health care in the United States is a significant problem. Even though the number of excess SLNs removed and examined per patient is small, given the additional time spent in the OR and time for the pathologist to thin-section each node, the cumulative effect of this practice on health care resources is substantial. A challenge to surgeons is to reduce unnecessary costs without compromising patient care; thus, physicians should bear in mind the costs of new technologies and treatments in cancer care. While it is

desirable to pursue the highest level of accuracy with the SLN biopsy procedure, the relative gains in accuracy from excision of multiple nodes may not be justified by the attendant increased cost and morbidity. In a procedure with a known false negative rate of approximately 7%, removing more than four SLNs will contribute little to improved accuracy, based on the available data.

In summary, our findings and other published literature support the conclusion that a positive sentinel node will be identified in 100% of cases within the first four sentinel nodes removed by the surgeon, according to current practices. Terminating the SLN biopsy procedure at four lymph nodes will have no impact on the false negative rate, but there is a cost savings associated with setting such a threshold. As long as the surgeon is confident that the blue and hottest node(s) have been removed, it is reasonable to limit sentinel node removal to four nodes in order to reduce both the cost as well as the morbidity of the procedure.

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