Original Article Open Access

Archives Of Breast Cancer

DOI: 10.32768/abc.2025122164-170

Number of Sentinel Lymph Nodes Removed in Breast Cancer Patients – A Real-World Experience

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ARTICLE INFO

Received:
14 October 2024
Revised:
11 March 2025
Accepted:
15 March 2025

Keywords:
sentinel lymph node biopsy, breast neoplasms, disease-free survival, body mass index, lymph node excision, lymphedema

ABSTRACT

Background: Retrieval of <3 sentinel lymph nodes (SLN) has been shown to be associated with decreased disease-specific survival. We aimed to find out if the real-world experience replicates the data.

Methods: Overall, 529 patients with breast cancer who underwent SLN biopsy from January 2010 to December 2014 were retrospectively reviewed. Data were analyzed using SAS 9.4 software. The chi-square test was used to see if body mass index (BMI) influences the number of SLN retrieved and to detect possible differences between using blue dye and radioisotopes for detecting SLN.

Results: The proportion of retrieving 1, 2, and ≥3 SLNs was 21%, 35%, and 44%, respectively, with a median of 2 SLNs. There was no difference in the number of lymph nodes retrieved if the radioisotope was used alone or in combination with blue dye (P=0.88). No change was noted in the median number of SLN retrieved in different quadrants of the breast. We obtained BMI in 454 patients. The rate of retrieving >2 SLNs in patients with normal BMI was 16%. This rate was 12% in overweight patients and 18% in those who were obese. We compared the SLN≤2 vs SLN>2 group, which were cross-tabbed against 3 BMI categories of normal, overweight, and obese. This was statistically significant, with a P-value of 0.028.

Conclusion: The real-world data suggest suboptimal retrieval of the number of median SLN compared to clinical trials. A higher BMI was associated with <3 SLN retrieved.

INTRODUCTION

Sentinel lymph nodes (SLN) biopsy is considered the standard of care for breast cancer patients undergoing surgery for the removal of the primary tumor. This standard of care is supported by multiple randomized, prospective clinical studies conducted over recent decades. These studies have demonstrated that the procedure is not inferior to complete axillary lymph node dissection in terms of outcomes, local recurrence, disease-free, and overall survival.[1–3] SLN biopsy is associated with less morbidity in terms of lymphedema, arm mobility, sensory loss, and shoulder abduction deficit.[4–14] Achieving a low false negative rate is important to avoid under-treatment of patients in terms of both systemic and radiation therapy. Several factors have been identified that could affect the false negative rate. The experience of the surgeon is required to achieve a low false negative rate. In one study, the number of false negative cases dropped by half in surgeons who had performed at

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least 20 procedures.[15] In a multicenter validation study, it was noted that the rate of false negative cases was between 0% and 29% among participating surgeons. The rate of false negative cases declined from 79% to 98% after 5 training cases.[16] The removal of fewer than three lymph nodes during SLN biopsy has been linked to reduced disease-specific survival rates and an increased likelihood of false-negative results. In the National Surgical Adjuvant Breast and Bowel Project (NSABP) trial B-32 study, removal of 2 sentinel nodes rather than 1 almost halved the false negative rate.[17] Other retrospective data suggest that there is no difference in median disease-free survival in patients with either one or more SLN removed.[18] SLN is detected by the blue dye method or with the radioactive colloid. The combined use of both tracers has shown a reduction in false negative rates in the majority of the studies.[19,20] Higher body mass index (BMI) is associated with SLN mapping failures, with a smaller number of SLN retrieved. There is less accumulation of radio colloid in SLN in obese patients.[21–23]

The province of Saskatchewan (SK) has an area of 651,900 square kilometers, with a small population of 1,098,352.[24] This population is widely distributed throughout the province with variable access to health care. Delivery of health care is a challenge considering the vast land and scattered population throughout this province. The purpose of this study is to investigate whether the data obtained in clinical trials can be replicated in community settings with geographical and access to care challenges. This study also provides us with an opportunity to review other confounding factors, besides the technical aspects of the procedure.

METHODS

Study Design and Population: This is a retrospective chart review done at Saskatchewan Cancer Agency. Saskatchewan Cancer Agency data access committee and the University of Saskatchewan Bioethics research board approved the study (Approval ID Bio-727). Female Patients with breast cancer who underwent Sentinel lymph node biopsy (SLNB) from January 2010 to December 2014 were identified from the cancer registry. Overall, 529 charts were reviewed retrospectively. Exclusion criteria included male BC, pathology other than invasive ductal or lobular, locally advanced or metastatic disease, primary tumor being T4, patients who received neoadjuvant therapy, patients who had declined or were unable to receive post-operative recommended adjuvant systemic or radiation therapy, and patients with full axillary lymph node dissection. The primary objective of the study was to see if adequate numbers of SLNs are retrieved in our province as a quality measure.

Variable Measurements

Medical records were reviewed for the type of breast cancer, tumor grade, stage of the tumor based on TNM classification 7th edition, estrogen, progesterone, and human epidermal receptor 2, type of surgery as mastectomy versus breast conservation surgery, adjuvant radiation therapy, adjuvant endocrine therapy, adjuvant chemotherapy, total number of SLN removed, methods of SLN detection, location of tumor in the breast and patients' height and weight to calculate BMI. Data were also collected to see if the variables such as high BMI, presence of tumors in certain quadrants of the breast, and use of 2 versus 1 method in detecting SLN could impact the outcome of the number of SLN retrieved. We also looked at the rate of mastectomies in our patients. Surgeries were performed by multiple surgical colleagues providing care to breast cancer patients in the province of Saskatchewan.

Statistical Methods

Data were collected using an MS Excel sheet and analyzed using SAS 9.4 software. The chi-square test was used to assess if BMI had any effect on the number of SLN retrieved, with the significance level considered at 5%. We aimed to examine whether the use of the radioactive colloid method in combination with the use of vital blue dye versus the use of the radioactive colloid method alone would have any impact on the number of SLN retrieved. We used two groups with either ≥3 or <3 SLNs retrieved. The chi-square test was used with the significance level considered at 5%.

RESULTS

Females with breast cancer who underwent SLN biopsy from January 2010 to December 2014 were identified. A total of 529 charts were reviewed. Baseline patient characteristics are reported in Table 1. Patients with infiltrating ductal carcinoma were 477 (90%), whereas 48 patients (9%) had infiltrating lobular carcinoma. T1 tumors were seen in 399 (75%), while 125 patients (24%) had T2 tumors, and 5 patients (1%) had T3 tumors. Grade I tumor was seen in 194 (37%), while 190 patients (36%) had Grade II, and 141 patients (27%) had Grade III tumors. Estrogen receptor (ER) or Progesterone receptor (PR) positive disease was noted in 461 patients (87%), while 66 patients (12%) had ER and PR negative disease. Human epidermal growth factor receptor 2 (HER2) positive tumors were 62 (12%), while there were 460 (87%) HER2 negative tumors. Breast conservation surgery has been performed in

323 (61%) of the patients, and 206 (39%) underwent mastectomy. Adjuvant radiation therapy was given to 323 (61%) of the patients, and 207 (39%) did not receive it. Adjuvant chemotherapy was given to 172 (33%) of the patients, and 357 (67%) did not receive chemotherapy. Adjuvant Hormonal therapy was given to 365 patients (69%), and 159 (30%) did not receive it.

Table 1. Baseline Characteristics of Patients Who Underwent SLN Biopsy

Baseline characteristics	N=529	%
Tumor histology	529	
Infiltrating ductal carcinoma	477	90.17
Infiltrating lobular carcinoma	48	9.07
Not available	2	0.37
T Stage		
T1	399	75.42
T2	125	23.62
T3	5	0.94
Grade		
I	194	36.67
II	190	35.91
III	141	26.65
Not available	4	0.75
Estrogen receptor		
Positive	461	87.14
Negative	66	12.47
Not available	2	0.37
Progesterone receptor		
Positive	421	79.58
Negative	106	20.03
Not known	2	0.37
HER-2		
Positive	62	11.72
Negative	460	86.95
Not known	4	0.75
Breast surgery		
Lumpectomy	323	61.05
Total mastectomy	206	38.94
Radiotherapy		
Performed	322	60.86
Not performed	207	39.13
Chemotherapy		
Given	172	32.51
Not given	357	67.48
Hormonal therapy		
Given	365	68.99
Not given	159	30.05
Data not available	5	0.94

HER-2, human epidermal growth factor receptor; SLN, sentinel lymph node.

Proportions of 1, 2, and ≥3 SLN retrieval were 21%, 35%, and 44%, respectively (Table 2), with a median of 2 (IQR=1). Patients with positive lymph nodes comprised 14%. We were able to confirm the method of SLN detection in 528 patients. Both the vital blue dye and radioactive colloid methods for the detection of SLN were used in 261 patients (49.4%). In 267 patients (50.5%), the radioactive colloid method alone was used to detect lymph nodes (Table 3).

Table 2. Number of SLN Retrieved in Patients Who Underwent SLN Biopsy

Number of SLN	N=529	% SLN retrieved
1	110	21
2	185	35
3+	234	44

SLN, sentinel lymph node.

The number of patients with greater than or equal to three SLN retrieved using both methods was 116 verses 117 out of 233 patients using radioactive isotope alone. The number of patients with less than three SLN retrieved using the combination vs. radioisotope alone was 145 and 150, respectively. There was no significant difference between the 2 groups in terms of the number of SLN retrieved with a median of 2 (P=0.8821; α=0.05).

Table 3. Method of Detecting SLN in Patients Who Underwent SLN Biopsy

	Radioisotope alone	Radioisotope + blue dye combined	Total
≥3 SLNs retrieved	117	116	233
<3 SLN retrieved	150	145	295
Total	267	261	528

SLN, sentinel lymph node. P=0.8821

In terms of location of tumors, 274 tumors were in the upper outer quadrant (UOQ) with the mean number of 2.8 lymph nodes retrieved. Tumors in the upper inner quadrant of breast (UIQ) were 120, with a mean of 3 SLNs, centrally (C) located tumors were 29, with a mean of 2 SLNs retrieved at 2.2. Tumors in the lower inner quadrant of breast (LIQ) were found in 45 patients where the mean of SLNs retrieved were 3.

Table 4. Mean and Median Number of SLNs in Different Areas of the Breast in Patients Who Underwent SLN Biopsy

Tumor location within the breast	No. of tumors	Median of SLN	Mean of SLN
Central	29	2.0	2.2
Lower inner quadrant	45	2.0	3.0
Lower outer quadrant	56	2.0	2.4
Not otherwise specified	4	1.5	2.5
Overlapping	10	2.5	2.7
Upper inner quadrant	120	2.0	3.0
Upper outer quadrant	274	2.0	2.8

SLN, sentinel lymph node.

Lower outer quadrant (LOQ) was seen in 56 patients with the mean of 2.4 SLNs retrieved. Overlapping areas of the breast (O) were seen in 10 patients with the mean of 2.7 SLNs retrieved. Location of 4 tumors could not be ascertained with a mean of 2.5 SLNs retrieved. No change was noted in the median number of SLNs retrieved in different quadrants and the central part of the breast, with the median of 2 (Table 4).

We were able to obtain the BMI in 454 patients (Table 5). A normal BMI (15 to <25 kg/m^2) was noted in 131 patients (29%), while 122 patients (27%) were overweight with a BMI of 25 to <30 kg/m^2.

The number of obese patients with a BMI of >30 was 201 (44%). More than 2 SLN retrievals were observed in 16% of patients with a normal BMI, but this figure was 12% and 18% in overweight and obese patients, respectively. There was a difference between>2 SLNs retrieved in obese versus overweight and normal BMI patients combined. This was statistically significant (P=0.028; α=0.05) (Table 6).

We also found that 39% of the patients had a mastectomy as primary surgery. This is despite the fact that the majority of the tumors were either T1 or T2.

Table 5. BMI Categories vs Number of SLN Removed in Patients Who Underwent SLN Biopsy

BMI Category	Number of SLN			
	1	2	2+	Total
Normal (15.1 to <25)	21 (4.6%)	37 (8.1%)	73 (16%)	131 (29%)
Overweight (25 to < 30)	22 (4.8%)	47 (10.35%)	53 (11.6%)	122 (27%)
Obese (>30)	46 (10%)	72 (15.8%)	83 (18.2%)	201 (44%)
Total	89 (19.7%)	156 (34.3%)	209 (46%)	454 (100%)

BMI, body mass index; SLN, sentinel lymph node.

DISCUSSION

The results from our study suggest that although we did well in identifying and retrieving >1 lymph node at SLN biopsy, we were not able to achieve the target of a minimum of 3 lymph node samples in the majority of our patients. Our study suggests that SLNB in the community setting is possible, but the high bar set by the landmark clinical trials for a minimum of 3 SLNB may not be achievable in the community setting.

It will be important to see if there is any difference in disease-related outcomes, such as disease-free survival and local control rates, in patients who had <3 SLNs removed by surgery. With more data from the Sound and INSEMA trials, it is becoming evident that not all patients need lymph node sampling as part of breast cancer surgery.[25,26] However, SLN biopsy is still required in patients with tumors ≥2 cm in size, even in low-risk groups. At this stage, it is not clear whether omission of SLN biopsy in this group of patients results in inferior or better breast cancer-related outcomes. Thus, adequate SLN sampling is important in such patients to determine the necessity of further adjuvant radiation and systemic therapies. We noted that the method for detecting SLN varied, finding that 50% of the time, both radioactive colloid and blue dye methods of detecting SLN were used. We observed no difference in the number of lymph nodes retrieved in the radioactive colloid plus vital blue dye versus the use of radioactive colloid alone. However, we had a small cohort of patients. The use of blue dye in addition to radiotracer colloid is controversial, and its value is under question. In the landmark NSABP B-32 clinical trial, for patients with clinically node-negative breast cancer, both blue dye and radio colloid injection were used to detect SLNs intraoperatively. Most of the sentinel nodes were both hot and blue (65%), while 24% were hot only, 5% were blue only, and 3.9% were neither hot nor blue, but palpably abnormal.[16] In a systematic review of the data conducted by an expert panel of the American Society of Clinical Oncology, the use of both blue dye and radio colloid was associated with a significant trend toward fewer false negative results (7% vs 9.9%, P=0.07).[1] Using blue dye in addition to radioactive colloid can be justified in certain situations, such as for patients with high BMI, surgeons learning the technique, after neoadjuvant therapy, and patients with previous breast or axillary surgeries. It is also useful in situations where radiotracer colloid fails to detect the SLN. We also noted that our study population had a high rate of high BMI patients (44%), with overweight patients found to have a BMI rate of 27%. Only 29% of our patients had a normal BMI. When we looked at the patients with a BMI>30 and compared them with normal and the overweight groups, we found a statistically significant difference in patients with >2 SLNs retrieved in favor of those with a BMI less than 30. We also noted that in our province, the rate of mastectomy was 39%, which is quite high despite the fact that the majority of tumors were T1 or T2. This could be related to patients' preferences, as travel to receive post-breast conservation radiation therapy can be difficult given our geography. The other reason is

failure to communicate with patients adequately regarding available surgical options.

The main limitation of our study is its retrospective nature and the small sample size, resulting in inadequate power to detect any differences in outcomes for patients with less than three lymph nodes retrieved at SLNB. The lack of a control group was another limiting factor. Potential selection biases might have been present as the selection of cases was random. We could not include all patients who underwent surgery for breast cancer in our study. This study was initiated as a part of a summer student project and, hence restricted by time and resources. However, despite all these limitations, we were able to note a key quality indicator deficiency. We were also able to identify that in only half of our patients, both methods were used to detect SLN.

Retrieval of less than three lymph nodes at the time of SLN biopsy has been shown to be associated with a decrease in disease-specific survival and a high false-negative rate.[4,16] In the NSABP B-32 study, removal of two sentinel nodes rather than one almost halved the false negative rate.[16] Other retrospective data suggest that there is no difference in median disease-free survival (DFS) in patients with ≥1 SLNs removed.[17] Interestingly, our study suggested that in a community setting, this goal cannot be achieved, and further quality improvement measures need to be taken to avoid adverse outcomes in this group of patients. One of the reasons could be the higher number of patients with a BMI of ≥30 in our study cohort.

Quality improvement projects in this area, such as retraining and frequent audits, are suggested. Large, pooled data from community centers with a long follow-up can provide us with some data if the retrieval of less than three SLN affects disease-free outcomes. Dual tracer and blue dye methods should be used for patients with a BMI ≥30. High rates of mastectomies suggest that a policy to improve patient education regarding surgical options needs to be instituted. Barriers to access to the availability of specialists at the time of diagnosis for making informed decisions should be addressed. Further studies may need to consider whether the choice of surgery is due to the long distance of travel to receive adjuvant radiation therapy. We unfortunately did not look at this variable in our cohort of patients, and we hope to investigate this in the future.

CONCLUSION

Our study suggests that in the real world, we were not able to achieve the target SLN retrieval of a minimum of 3 lymph nodes. Our study suggests that patients with a BMI ≥30 had fewer SLNs retrieved compared to the group with a BMI less than 30. We noted that the majority of our patients were either obese or overweight based on BMI criteria. We could not confirm factors such as the location of the tumor or the use of the 2 methods of detecting SLN simultaneously as the reason for this failure; we noted that in half of our patients, both radioactive colloid and blue dye methods were used simultaneously to detect SLN. We also identified that 39% of our patients had a mastectomy as their primary surgery. This is despite the fact that the majority of the tumors were either T1 or T2. Thus, this study emphasizes the need for quality improvement projects to reduce the incidence of adverse outcomes in breast cancer patients.

FUNDING

This work was supported by the University of Saskatchewan, College of Medicine, as part of the Dean's summer project.

ETHICAL CONSIDERATIONS

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the biomedical research ethics board of the University of Saskatchewan (BIO ID 727, December 30, 2018). Prior approval was also obtained from the Saskatchewan Data Access Review Committee for data collection. Patient consent was waived for the retrospective chart review as no identifiable data were used and the study posed minimal risk to the patients.

DATA AVAILABILITY

The source trustee of the data is the Saskatchewan Cancer Agency. Non-identifiable data are only available by request, and identifiable data are not available to the public due to privacy or ethical restrictions.

CONFLICTS OF INTEREST

None of the authors reports any conflict of interest.

ACKNOWLEDGMENTS

None.

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How to Cite This Article

Wees T, Qureshi K, Narasimhan G, Ahmed S, Chandrasekhar A, Souied O, et al. Number of Sentinel Lymph Nodes Removed in Breast Cancer Patients – A Real-World Experience. Arch Breast Cancer. 2025; 12(2):164-70.
Available from: https://www.archbreastcancer.com/index.php/abc/article/view/1043