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Evaluating the role of sentinel lymph node biopsy in patients with DCIS treated with breast conserving surgery

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ABSTRACT

Introduction: The role of sentinel lymph node biopsy (SLNB) for patients with ductal carcinoma in-situ (DCIS) is limited given the rarity of nodal metastasis in non-invasive disease. Although SLNB is typically a safe procedure, there are potential complications and associated costs. The purpose of this study is to assess national surgical practice patterns and clinical outcomes with respect to the use of SLNB for DCIS in patients undergoing breast conserving surgery (BCS).

Methods: Case-level data from the National Cancer Data Base (NCDB) was assessed to identify adult patients $\geq$ 18 with DCIS, who underwent BCS and SLNB. Patient demographics and hospital characteristics were grouped for analytic purposes. A multivariate analysis was performed for patient and hospital characteristics.

Results: We identified 15,422 patients with DCIS undergoing BCS in 2015, of which 2,698 (18%) underwent SLNB. A multivariate analysis demonstrated a significant association between greater frequency of SLNB in patients age range of 60–69, receipt of care at a community facility, and higher nuclear grade DCIS. Positive sentinel nodes metastasis was identified in 0.9% patients undergoing BCS and SLNB for DCIS.

Conclusion: The role of SLNB in patients with DCIS undergoing BCS is limited and does not routinely provide meaningful information or benefit to clinical management. Despite this, nearly one in five patients undergoing BCS for DCIS had lymph node sampling performed. Given the potential increased morbidity and financial implications, this finding represents an opportunity for further education and improvement in patient selection for SLNB.

Background

The role of sentinel lymph node biopsy (SLNB) for patients with ductal carcinoma in-situ (DCIS) is limited given the rarity of nodal metastasis in non-invasive disease.[1–4] By definition, DCIS does not metastasize to the lymph nodes as the lesion is confined within the ducts and does not reach lymphatic vessels. Therefore, cases of nodal involvement with DCIS likely represent misclassification due to occult invasive or micro-invasive disease. In patients undergoing mastectomy, SLNB may be indicated especially when the risk of identifying incidental invasive disease is elevated, as it may not be feasible to perform accurate sentinel node mapping following removal of the breast. However, for patients undergoing breast conserving surgery (BCS), the option exists to accurately perform SLNB as a subsequent operative procedure, if invasive disease is identified in the surgical pathology specimen. Although performing SLNB with BCS may avoid a second operation, DCIS upstages to invasive breast cancer in only ~25% of patients diagnosed with DCIS on core needle biopsy.[5] The risk of upstaging is especially remote

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with low-grade DCIS not associated with a mass or other suspicious radiographic finding. Moreover, the risk of nodal involvement with occult/incidental disease is low and the significance of nodal involvement in these cases (typically isolated tumor cells or micrometastasis) is questionable.[6]

SLNB is generally a safe procedure; however, data have demonstrated the potential for perioperative morbidity and unnecessary costs. Complication rates as high as 17% were observed in certain patient groups (e.g. elderly).[7–9] Given the lack of demonstrable benefit of axillary evaluation in patients with DCIS, national clinical guidelines recommend omitting SLNB when performing BCS for DCIS.[10–13] Despite these recommendations, recent data have reported ongoing utilization of SLNB for patients with DCIS undergoing BCS.[14]

Determining strategies to optimize management of DCIS has been identified as a research priority. The purpose of this study is to evaluate national trends in the use of SLNB in patients with DCIS undergoing BCS. We also seek to determine the clinical significance of SLNB for DCIS based on lymph node pathology. The data will allow for the analysis of surgical practice variation with respect to clinical outcomes, and may also provide validation for proposed quality metrics pertaining to axillary staging for DCIS.

Methods

Case-level data for this study were pulled from the National Cancer Data Base (NCDB), a nationwide outcomes database that tracks all types of cancers. The NCDB is a joint program of the American College of Surgeons and the American Cancer Society, in existence since 1989. At the time of this publication, the NCDB contained 31 million cases across all disease sites submitted from approximately 1,500 hospitals.[15] An institutional IRB waiver was obtained for this study.

The authors identified 26,824 DCIS breast cancer cases diagnosed between January 1st 2015 and December 31st 2015 (Fig. 1). Data were abstracted according to the Facility Oncology Registry Data Standards (FORDS) manual. Tumors were identified using the International Classification of Diseases for Oncology 3rd edition (ICD-O-3) and grouped by primary site topography code C50.X. TNM was defined using the American Joint Committee on Cancer 7th ed. Manual. Adult patients >18 at the time of diagnosis were selected for the study. Tumor behavior in-situ was specified as clinical TisN0. Cases were included if they were the only or first cancer diagnosis reported in the patient's lifetime. Patients received all or part of their first course treatment at the reporting facility. After selecting patients that underwent a breast conservation surgery, the analytic cohort included 18,435 cases. Cases that underwent a prior excisional biopsy were excluded from the analysis. A prior excisional biopsy was identified as any patient that underwent a prior surgery where a date of definitive resection was recorded after the index procedure. This selection resulted in 2,013 cases being excluded, with 15,422 remaining. From this group, cases were excluded where regional lymph node status was unknown (n = 30), as well as where patients had undergone either axillary lymph node dissection (n = 665) or excisional biopsy or aspiration of regional lymph nodes (n = 40). This resulted in an analytical cohort of 2,698 cases comprised of patients with who had undergone sentinel lymph node biopsy.

Patient demographics and hospital characteristics were grouped for analytic purposes. Age at diagnosis was collapsed into five groups: 18–49, 50–59, 60–69, 70–79, and >79. The following cancer program categories were included: Community Cancer Program (accessions more than 100 but fewer than 500 newly diagnosed cases per year), Comprehensive Community Cancer Program (accessions 500 or more newly diagnosed cases per year),

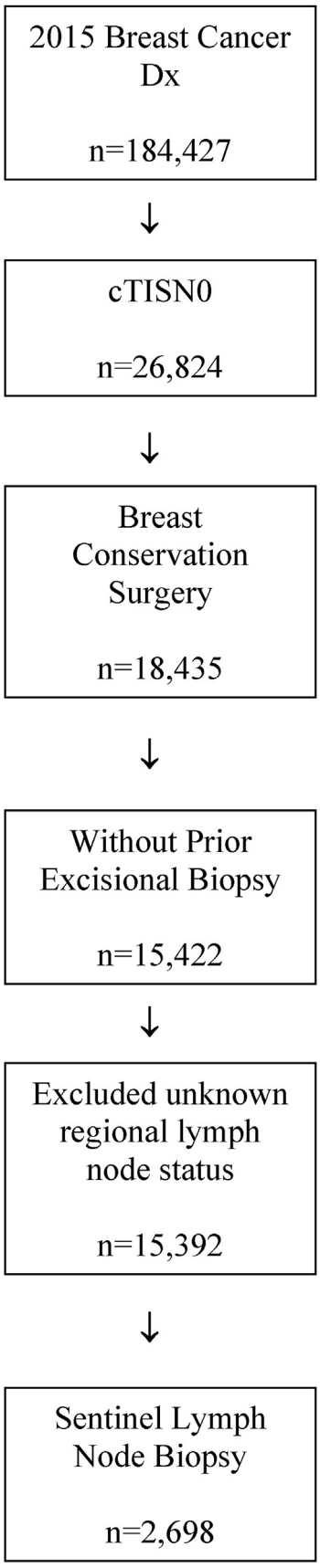

Fig. 1. Case selection criteria.

Academic Comprehensive Cancer Program (accessions 500 or more newly diagnosed cases per year and participates in postgraduate medical education in at least 4 program areas), and NCI-Designated Comprehensive Cancer Center Program (designated as a Comprehensive Cancer Center by the NCI with no minimum caseload requirement). Uninsured and Medicaid cases were grouped together; private insurance, Medicare, and other government insurance were also combined. Ethnicity was grouped into non-Hispanic white, non-Hispanic black, Hispanic, and Asian/Hawaiian/Pacific Islander. Comorbid conditions as described by Charlson/Deyo were mapped from as many as ten reported ICD-9-CM or ICD-10 secondary diagnosis codes. The Charlson/Deyo value is a weighted score derived from the sum of the scores for each of the comorbid conditions. The urban-rural continuum codes were used to specify geographic residence. The 2012 US Census socioeconomic metrics for income and percentage of no high school diploma are area-based and represent zip code of patient residence.

Descriptive cross-tabulations were generated for patient demographics and hospital characteristics. A multivariate hierarchical regression model assessed sentinel lymph node biopsy use after adjusting for age at diagnosis, hospital category, insurance status, ethnicity, Charlson/Deyo comorbid condition score, grade (as defined by the National Cancer Data Base Participant User File (PUF) Data Dictionary 2016), USDA urban-rural continuum codes, and the median income and education estimates. Odds ratios with 95% confidence intervals were generated; odds >1.0 indicate an increased likelihood of chance. Significance was determined at $p < 0.0001$. All data analyses were conducted using SAS v9.2 (The SAS Institute, Cary NC).

Results

A total of 15,422 patients with DCIS undergoing BCS with no prior excisional biopsy were identified from the NCDB in 2015 (Table 1), of which 2,698 underwent a sentinel lymph node biopsy. Among the 15,422 patients with DCIS undergoing BCS, the median age group was 60–69. A majority of patients were non-Hispanic White (74%) and lived in metropolitan areas (84%). The median household income range was >$63,000. Most patients had a Charlson/Deyo comorbid condition score of 0 (88%). The majority of patients had either private/other government insurance (59%) or Medicare (34%). Patients were most commonly treated at a Comprehensive Community Cancer Program (47%), followed by Academic Comprehensive Cancer Program (23%). Tumors were predominately grade III.

Surgery for axillary lymph node evaluation was assessed (Table 2). Among the dataset, 30 patients were excluded from analysis due to unknown lymph node surgical procedure status. Of the remaining 15,392 patients, 2,698 (18%) underwent SLNB at the time of BCS.

A multivariate analysis of the studied cohort included age, facility type, insurance status, ethnicity, comorbidity score, tumor grade, geographic residence, median household income, and level of education (Table 3). Age 60–69 (OR 1.71), care at a Comprehensive Community Cancer Program (OR 1.15), and DCIS with higher nuclear grade (OR 1.76) were significantly associated with greater frequency of SLNB during BCS. Insurance status, ethnicity, comorbidity, geographic residence, household income, and educational level did not show any significant association with use of SLNB in patients with DCIS receiving BCS.

Nodal status following surgery was assessed (Table 4). Of the sentinel nodes removed in patients with DCIS undergoing BCS, no pathological lymph nodal involvement was observed in 99.1% of cases [pN0 = 1,913 (70.9%), pN0(I+) = 31 (1.1%), pN0(I-) = 662 (24.5%), pN0(mol-) = 1 (0.0%)]. Among the 0.9% of patients with positive nodal metastasis, 47.8% (n = 11) consisted of micrometastases and 52.2% (n = 12) involved N1 disease.

Table 1
Study demographics.

Category	Sentinel Lymph Node Biopsy	Total
Ages		
18–39	26 (13.6%)	190
40–49	399 (15.7%)	2,529
50–59	785 (17.8%)	4,407
60–69	944 (19.6%)	4,815
70–79	447 (16.1%)	2,775
80–120	97 (13.7%)	706
Type of institution		
Academic	447 (12.7%)	3,514
Community	276 (17.7%)	1,556
Comprehensive	1,461 (20.3%)	7,177
NCI-CCC	163 (13.0%)	1,251
Other/Unknown	351 (18.2%)	1,924
Insurance		
Not Insured, Medicaid	165 (16.6%)	996
Private Insurance, Other Government	1,594 (17.8%)	8,980
Medicare	912 (17.4%)	5,235
Unknown	27 (12.8%)	211
Ethnicity		
Non-Hispanic White	1,979 (17.4%)	11,355
Non-Hispanic Black	359 (18.2%)	1,971
Hispanic	178 (17.6%)	1,009
Asian/Pacific Islander	146 (18.0%)	810
Other/Unknown	36 (13.0%)	277
Comorbid condition		
No Comorbid Conditions	2,374 (17.4%)	13,609
1 Comorbid Condition	267 (17.9%)	1,490
2 or more Comorbid Conditions	57 (17.6%)	323
Grade		
Grade I	336 (15.4%)	2,170
Grade II	927 (17.1%)	5,425
Grade III	1,059 (24.2%)	4,384
Grade IV	52 (30.1%)	173
Unknown	324 (9.9%)	3,270
Rural-Urban Continuum code		
Metro	2,268 (17.2%)	13,155
Urban	318 (19.2%)	1,655
Rural	49 (23.2%)	211
Unknown	63 (15.7%)	401
Median Income		
<$38,000	366 (17.7%)	2,070
$38,000-$47,999	550 (18.8%)	2,925
$48,000-$62,999	730 (18.2%)	4,002
≥$63,000	1,046 (16.4%)	6,382
Unknown	6 (13.9%)	43
No High School Diploma		
<7%	788 (17.0%)	4,642
7–12.9%	862 (16.9%)	5,075
13–20.9%	621 (18.1%)	3,421
21.0%	421 (18.8%)	2,245
Unknown	6 (15.4%)	39

Discussion

National analysis reveals an 18% rate of SLNB use in patients with DCIS undergoing BCS. Positive nodal metastasis was identified in only 0.9% of cases. The majority of patients who undergo SLNB for DCIS do not derive any benefit from the axillary procedure, and increase their risk of complications as well as short and long-term morbidity. Given the added cost and potential morbidity associated with this procedure, the value of this approach to patients with DCIS is debatable and suggests possible 'overuse' in this population of patients with non-invasive disease.

These findings must be weighed against the inconvenience and potential distress to patients who may be required to return to the operating room in circumstances where occult invasive disease is identified in the surgical pathology specimen. Prior studies have

Table 2
Sentinel lymph node biopsy distribution.

Lymph Node Procedure	Number (%)
No regional lymph node surgery	11,989 (77.7%)
Excisional biopsy or aspiration of regional lymph nodes	40 (0.26%)
Sentinel LN Biopsy	2,698 (17.5%)
(Axillary LN Dis.) number of regional lymph nodes removed unknown	8 (0.0%)
(Axillary LN Dis) 1–3 regional lymph nodes removed	256 (1.7%)
(Axillary LN Dis) > 3 regional lymph nodes removed	93 (0.6%)
Combination Sentinel LN Biopsy and Axillary LN Dis at same time	293 (1.9%)
Combination Sentinel LN Biopsy and Axillary LN Dis at different times	15 (0.1%)
Regional lymph node surgery status unknown	30 (0.2%)

demonstrated that the frequency of this occurrence is low, especially in the absence of high-grade disease, an associated mass, or suggestion of micro-invasion.[16] Of note, performing SLNB following BCS is largely feasible from a technical standpoint,[17,18] and offers an appropriate alternative to routinely performing SLNB at the index operation.

Our study identified an area of clinical practice variation in the use of SLNB during breast conserving surgery for patients with non-invasive disease, including specific predisposing factors. Specifically, the use of SLNB was more frequent with increasing patient age, peaking at age 60–69, and then declining for women 70 and over. This finding may reflect the overall lower use of axillary assessment with advancing age,[19,20] which may be influenced by the lack of impact on local regional recurrence and breast cancer mortality in this age group.[21,22]

Patients receiving care at a Comprehensive Community Cancer Program were more likely to undergo SLNB with breast conserving surgery for DCIS, followed by Community Cancer Programs. In comparison, patients receiving care at an Academic Comprehensive Cancer Program and NCI-Designated Comprehensive Cancer Center

Table 3
SLNB multivariate analysis.

Covariate	*Odds Ratio (95% CI)*	*Covariate Significance*	*Categorical Significance*
Ages 80-120	Reference		
18–39	1.23 (0.74-2.06)	$p < 0.0001$	$p = 0.4096$
40–49	1.47 (1.11-1.94)		$p = 0.0061$
50–59	1.59 (1.22-2.07)		$p = 0.0005$
60–69	1.71 (1.34-2.19)		$p < 0.0001$
70–79	1.34 (1.04-1.72)		$p = 0.0197$
Community	Reference		
Academic	0.68 (0.54-0.87)	$p < 0.0001$	$p = 0.1633$
Comprehensive Community	1.15 (0.94-1.39)		$p = 0.0022$
NCI-CCC	0.68 (0.47-0.97)		$p = 0.0372$
Not Insured, Medicaid	Reference		
Private Insurance, Other Government	1.03 (0.84-1.25)	$p = 0.9641$	$p = 0.7440$
Medicare	1.02 (0.82-1.27)		$p = 0.8227$
Non-Hispanic White	Reference		
Non-Hispanic Black	1.12 (0.96-1.29)	$p = 0.3807$	$p = 0.1310$
Hispanic	1.07 (0.88-1.31)		$p = 0.4844$
Asian/Pacific Islander	1.16 (0.94-1.42)		$p = 0.1659$
2 or more Comorbid Conditions	Reference		
1 Comorbid Condition	0.93 (0.67-1.31)	$p = 0.8691$	$p = 0.7026$
No Comorbid Condition	0.92 (0.67-1.25)		$p = 0.6124$
Grade I	Reference		
Grade II	1.13 (0.98-1.31)	$p < 0.0001$	$p = 0.0791$
Grade III	1.76 (1.52-2.03)		$p < 0.0001$
Grade IV	2.28 (1.56-3.34)		$p = 0.0001$
Rural	Reference		
Metro	0.78 (0.54-1.13)	$p < 0.5468$	$p = 0.1924$
Urban	0.80 (0.55-1.17)		$p = 0.2630$
<$38,000 Median Income	Reference		
$38,000-$47,999	1.12 (0.95-1.33)	$p < 0.6081$	$p = 0.1815$
$48,000-$62,999	1.09 (0.91-1.31)		$p = 0.3382$
≥$63,000	1.08 (0.88-1.33)		$p = 0.4530$
<7% No HS Diploma	Reference		
7–12.9%	0.91 (0.80-1.03)	$p < 0.3848$	$p = 0.1711$
13–20.9%	0.97 (0.83-1.15)		$p = 0.7976$
21.0%	1.02 (0.83-1.25)		$p = 0.8273$

Table 4
Pathologic N of DCIS cases that underwent a lumpectomy with axillary surgery.

Node Pathology	Cases
pNX	68 (2.5%)
pN0	1,913 (70.9%)
pN0I+	31 (1.1%)
pN0I-	662 (24.5%)
pN0M-	1 (0.0%)
pN1	1 (0.0%)
pN1A	11 (0.4%)
pN1MI	11 (0.4%)

Program were less likely to use SLNB with BCS for DCIS. This observation may represent variations in practice patterns associated with facilities that are lower volume, as well as differences in care process observed in non-academic and non-NCI designated centers.[23–27] Volume appears to be the primary determinant of outcome. Indeed, Hershman et al. indicated surgeon volume as the most significant predictor of SLNB in women undergoing BCS for DCIS.[11] In this study, higher-volume surgeons were less likely to perform SLNB for DCIS when compared to low-volume surgeons.

Our data also demonstrated that patients with high-grade DCIS were statistically more likely to undergo SLNB. One possible explanation for this finding is that there is a greater concern of upstaging to invasive cancer in patients with high-grade DCIS.

Notably, our study showed that socioeconomic status, education level, and comorbidity score were not significantly associated with utilization rates of SLNB for DCIS.

Our study represents a contemporary national analysis that aligns with findings from prior reports in the literature, where rates of SLNB use in patients undergoing BCS were as high as 29%.[11,28–30] Although the use of SLNB for DCIS has decreased over the period of these studies, it appears to have remained relatively stable (17–19%) in recent years. Additionally, our data demonstrated an extremely low rate of metastasis (<1%) identified in sentinel nodes. This low rate of nodal involvement provides a strong argument against the routine use of SLNB for patients with DCIS undergoing BCS. Additionally, in the era of the ACOSOG Z0011 trial results, the identification of minimal, low burden axillary disease is unlikely to alter management or have any impact on loco-regional control or overall survival.[31]

Limitations of our study consist of those inherent to retrospective studies relying on clinical databases. The NCDB does not provide additional clinical factors, including associated masses, other suspicious radiographic findings, potential micro-invasion, or additional factor that may influence use of SLNB.

Despite these limitations, our study demonstrates that in a large dataset of patients with DCIS, positive sentinel node metastasis is rarely identified. This indicates a potential opportunity for education and quality improvement in the application of SLNB for the surgical management of breast disease.

Conclusions

The role of SLNB in patients with DCIS undergoing BCS is limited and does not routinely provide meaningful information or benefit for clinical management. Despite this finding, nearly one in five patients nationally undergoing BCS for DCIS has lymph nodes sampled. Given the potential increased morbidity and financial implications associated with this approach, quality measures to promote best practice and strategies to strengthen implementation of clinical guidelines are indicated.

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