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Decreasing rates of axillary lymph node dissections over time: Implications for surgical resident exposure and operative skills development

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ABSTRACT

Background: Sentinel lymph node biopsy has supplanted axillary lymph node dissection (ALND) in clinically node-negative breast cancer and select node-positive disease. We hypothesized a decreasing rate of both ALND and resident exposure over time.
Methods: We identified women with clinical Stage I-III breast cancer in the National Cancer Data Base (2004–2014). Adjusted multivariate logistic regression was used to estimate the effect of various factors on receipt of ALND. Yearly procedural rates for residents were extracted from surgical case log reports for comparison against procedural rates.
Results: 1,131,363 patients were identified; 255,306 received ALND, 876,057 underwent non-ALND management. ALND rates declined from 2004 (32%) to 2014 (16%, $p < 0.001$), with the largest decline occurring between 2010 and 2011 (24%–20%). After adjustment, this effect was maintained, with ALND rates decreasing with each additional year ($OR = 0.90$, 95% CI 0.89–0.90). Resident procedure volumes similarly declined from 1999 to 2017 ($p < 0.001$).
Conclusions: Significant declines in both ALND rates and procedural volume in residency may impact outcomes, as ALNDs are being performed in ever more challenging oncologic scenarios by potentially less-experienced surgeons.

Introduction

Axillary lymph node dissection (ALND) was previously the long-established gold standard for nodal staging in breast cancer, intending to establish nodal stage, optimize regional control, and presumably maximize survival. Unfortunately, the procedure is associated with a multitude of potential risks and significant morbidity including lymphedema, pain, and damage to neurovascular structures with concomitant changes in sensation, mobility, and strength.[1,2] The concept of a sentinel lymph node biopsy (SLNB) was developed in the 1990s to minimize the morbidity of ALND while maintaining equivalent oncologic staging and outcomes.[3,4]

The NSABP Protocol B-32 was the largest randomized sentinel lymph node trial and established equivalence in overall survival (OS), disease-free survival (DFS), and regional control for SLNB, as compared to ALND, with an acceptable false negative rate.[5] SLNB is now a widely accepted means of axillary staging in women with clinically node-negative breast cancer.[5,6]

In select women with *pathologic* node-*positive* disease, SLNB has also now become incorporated into axillary staging in patients with low volume nodal metastases being managed with breast conservation and tangential whole breast radiation therapy.[7] The American College of Surgeons Oncology Group (ACOSOG) Z0011 trial enrolled patients with small (cT1 or T2), *clinically* node-*negative* cancers, with 1 or 2 positive sentinel nodes. Patients were

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randomized to ALND versus no further surgery (with planned whole breast radiation). They found no difference in OS, DFS, or locoregional failure rates (0.9% nodal recurrence in SLNB alone group).[7] For this specific group of pathologic node-*positive* patients, SLNB alone is guideline concordant care, but may not be applicable for several groups of patients excluded from the Z0011 trial criteria. Exclusion criteria may include those who were clinically node positive, had >2 pathologically positive SLNs, matted nodes, underwent mastectomy, or breast-conservation without radiation.[6]

In the last few years, multiple prospective randomized trials have altered contemporary management of *clinically* node-*positive* patients receiving neoadjuvant chemotherapy (NAC).[8,9] Considerable rates of nodal eradication are seen following NAC in certain subsets of breast cancer patients, prompting evaluation of SLNB following NAC. The European SENTINA and ACOSOG Z1071 trials evaluated the accuracy of SLNB following neoadjuvant chemotherapy. These robust trials found utilizing dual agent mapping and retrieval of three or more sentinel lymph nodes dropped the false negative rate to under 10%. Finally, performing a "targeted axillary dissection" (TAD), in which the previously biopsied and clipped node is retrieved and evaluated, has been shown to reduce FNR to even lower levels (<5%), and is, increasingly being used in clinical practice.[10]

In the wake of these landmark, practice-changing trials, we hypothesized that ALND rates are rapidly decreasing over time, and that this in turn may have an impact on trainee exposure and operative skill development. Here, we report the results of our study to evaluate national rates of axillary lymph node dissection over time.

Materials and methods

All adult patients diagnosed with clinical Stage I-III invasive breast cancer from 2004 to 2014 were identified from the American College of Surgeons and Commission on Cancer's National Cancer Data Base (NCDB). Patients with an unknown number of lymph nodes retrieved were excluded. ALND was defined as removal of 10 or more lymph nodes, and non-ALND management was defined as 0–9 lymph nodes removed. Hospital volume was calculated as the total number of breast cancer cases presenting at a given facility divided by the total number of years that facility reported treating at least one breast cancer case. Groups were defined as low (<148), moderate (148–298), and high (>298 breast cases/year) hospital volume based on previously published thresholds defined by restricted cubic spline analysis.[11] The full NCDB breast 2004–2014 dataset was used to assign volume group to each hospital.

Patient characteristics were summarized by N (%) for categorical variables, and median (range) for continuous variables, for all patients, by ALND or non-ALND, and by year for ALND patients only (early: 2004–2006 vs. Late: 2012–2014). Groups were compared using the chi-square test for categorical variables and the *t*-test for continuous variables. A multivariate logistic regression model was used to identify factors associated with ALND. Covariates included age, year of diagnosis, gender, race/ethnicity, education level, income level, insurance type, facility type, facility location, annual hospital volume, Charlson/Deyo comorbidity score, tumor grade, clinical T-stage, clinical N-stage, and surgery type. Additional logistic models were conducted that incorporated hospital volume*year and facility type*year interaction terms to determine if the change over time in odds of ALND differed based on these covariates.

Yearly procedural rates for residents ("Surgeon Chief" and "Surgeon Junior") were extracted from the Accreditation Council for Graduate Medical Education (ACGME) surgical case logs statistical reports from 1999-2017.[12] Average and maximum, number of individual cases reported as a "Major Lymphadenectomy" (which includes both ALND and inguinal dissections) or a "Modified Radical Mastectomy" (MRM, i.e., mastectomy and simultaneous ALND), as well as the total number of cases reported within the categories of "Skin and Soft Tissue" and "Breast" procedures. These were used to calculate the percent of cases that included a lymphadenectomy within each category (skin/soft tissue or breast) for each available year, and were plotted over time.

Only patients with available data for all covariates were included in each model and effective sample sizes are reported for each table/figure. No adjustments were made for multiple comparisons. All statistical analyses were conducted using SAS, version 9.4 (SAS Institute, Cary NC). The study was deemed exempt by the Duke Institutional Review Board due to use of de-identified patient data.

Results

This study included 1,131,363 patients with clinical Stage I-III invasive breast cancer, who underwent breast-conserving surgery or mastectomy, with a known number of lymph nodes removed. 255,306 underwent ALND (≥10 lymph nodes removed), and 876,057 underwent non-ALND management of the axilla (0–9 lymph nodes). Patient demographics, tumor characteristics, and treatments received are shown in Table 1 by early- (2004–2006) vs. Late-years (2012–2014) in our study. The median age for the entire cohort was 61 years. Over the study time period, 80.9% were cN0, while 15.9% were cN1-3. Pathologic nodal stage included 65.4% pN0 and 26.9% pN1-3. Median tumor size was 1.6 cm (2.5 cm among those with ALND, 1.5 cm in non-ALND) Table 2.

For those who received ALND, the median number of positive nodes and total lymph nodes removed, were 2 and 15, respectively. For those who underwent non-ALND management, there were a median of 0 positive nodes and 2 lymph nodes removed. The mean nodal count (i.e. number of nodes removed) for both ALND (16.5–16.7 nodes) and non-ALND (3.0–2.8 nodes) did not change over the study time period (2004–2014).

Overall rates of ALND declined during the study period from 32% in 2004 to 16% in 2014 ($p < 0.001$), with the largest decline occurring between 2010 and 2011 (24%–20%). This decline occurred steadily and similarly across all facility types (academic, comprehensive, integrated network, and community), hospital volume groups (low, moderate, and high), by chemotherapy timing (neoadjuvant vs. Adjuvant) and type of surgical procedure (lumpectomy vs. Mastectomy; Fig. 1). After adjustment, this effect was maintained, with the odds of ALND decreasing with each additional year (OR = 0.90, 95% CI 0.89–0.90). The change over time did not differ by facility type or hospital volume (interaction p's > 0.05). On multivariate analysis, factors associated with ALND included younger age, Non-Hispanic Black or Hispanic race/ethnicity, low annual hospital volume, non-private insurance, comorbidity score of 1 or more, tumor grade of 2–3, higher clinical T- and N-stage, and receipt of mastectomy (all p's < 0.05).

Resident exposure to ALND also steadily declined from 1999 through 2017 for both major lymphadenectomy and MRM. In 1999, chief residents performed an average of 1.5 major lymphadenectomy procedures and 3.6 MRMs. However, by 2017 chief residents performed only half the 1999 volume of major lymphadenectomies (1.5–0.7), and only 20% the volume of MRM (3.6 cases to 0.7). A similar decline was seen among surgeon-junior cases, with residents in 2016–2017 performing only 50% and 40%, respectively, of the 1999–2000 case volume (2.3 vs 4.5 major lymphadenectomies, 3.9 vs 10.2 MRMs). The proportion of cases that included a lymphadenectomy within each category (skin/soft tissue and breast) also declined over the study time period from 25% to 6% for skin/

Table 1
Patient demographics, tumor characteristics, and treatment received by year of axillary lymph node dissection.

	ALND in Early Years (2004–2006) (N = 44,881) N (%)[a]	ALND in Late Years (2012–2014) (N = 74,336) N (%)[a]	*p*-value
Age (years), median (range)	57 (19–90)	58 (20–90)	<0.001
Distance Traveled to Treating institution (miles), median (range)	8.7 (0–3340)	9.4 (0–4958)	0.12
Race/Ethnicity			<0.001
Non-Hispanic White	31,394 (69.9%)	52,784 (71%)	
Non-Hispanic Black	5059 (11.3%)	10,626 (14.3%)	
Hispanic	2728 (6.1%)	5329 (7.2%)	
Other	1459 (3.3%)	3529 (4.7%)	
Insurance Status			<0.001
Private	25,939 (57.8%)	40,024 (53.8%)	
Government	16,436 (36.6%)	31,038 (41.8%)	
ot Insured	1301 (2.9%)	2224 (3%)	
Facility Type			<0.001
Academic	14,532 (32.4%)	25,017 (33.7%)	
Community	5138 (11.4%)	8085 (10.9%)	
Comprehensive	21,423 (47.7%)	33,280 (44.8%)	
Integrated Network	3788 (8.4%)	7954 (10.7%)	
Facility Location			<0.001
Midwest	11,862 (26.4%)	19,548 (26.3%)	
Northeast	9063 (20.2%)	14,125 (19%)	
South	15,458 (34.4%)	27,979 (37.6%)	
West	8498 (18.9%)	12,684 (17.1%)	
Hospital Volume (annual)			<0.001
High	18,147 (40.4%)	31,699 (42.6%)	
Moderate	12,450 (27.7%)	21,431 (28.8%)	
Low	14,284 (31.8%)	21,206 (28.5%)	
ER Positive Status	30,789 (68.6%)	57,637 (77.5%)	<0.001
PR Positive Status	25,640 (57.1%)	50,332 (67.7%)	<0.001
HER2 Positive Status[b]	181 (0.4%)	13,814 (18.6%)	<0.001
Tumor Grade			<0.001
1	5526 (12.3%)	7586 (10.2%)	
2	16,740 (37.3%)	29,888 (40.2%)	
3	19,787 (44.1%)	31,243 (42%)	
Clinical T-Stage			<0.001
1	18,292 (40.8%)	27,549 (37.1%)	
2	17,061 (38%)	32,060 (43.1%)	
3	4751 (10.6%)	9116 (12.3%)	
4	3238 (7.2%)	4512 (6.1%)	
Clinical N-Stage			<0.001
0	23,576 (52.5%)	35,159 (47.3%)	
1	12,710 (28.3%)	29,553 (39.8%)	
2	3680 (8.2%)	5345 (7.2%)	
3	1656 (3.7%)	2925 (3.9%)	
Pathologic T-Stage			<0.001
1	18,463 (41.1%)	27,356 (36.8%)	
2	16,845 (37.5%)	30,579 (41.1%)	
3	3956 (8.8%)	8028 (10.8%)	
4	1955 (4.4%)	2307 (3.1%)	
Pathologic N-Stage			<0.001
0	13,674 (30.5%)	15,849 (21.3%)	
1	16,820 (37.5%)	32,918 (44.3%)	
2	7086 (15.8%)	15,257 (20.5%)	
3	4285 (9.5%)	8969 (12.1%)	
Received Chemotherapy			<0.001
Any Chemotherapy	31,251 (69.6%)	56,059 (75.4%)	
Adjuvant Chemotherapy[c]	19,536 (62.5%)	34,376 (61.3%)	
Neoadjuvant Chemotherapy[c]	8836 (28.3%)	20,033 (35.7%)	
Received Endocrine Therapy	23,544 (52.5%)	49,854 (67.1%)	<0.001
Received Radiation	25,627 (57.1%)	47,280 (63.6%)	<0.001
Tumor Size (cm), median (range)	2.4 (0.1–99)	2.6 (0.1–99)	<0.001
Number Positive LN, median (range)	1 (0–84)	2 (0–65)	<0.001
Number LN Removed, median (range)	15 (10–90)	15 (10–90)	<0.001
Surgery Type			<0.001
Breast Conserving Surgery	16,894 (37.6%)	19,715 (26.5%)	
Mastectomy	27,987 (62.4%)	54,621 (73.5%)	

ALND Axillary Lymph Node Dissection, *LN* Lymph Nodes.
[a] Percentages may not add up to 100 due to rounding or missing values.
[b] Reliable coding of HER2 status began in 2010.
[c] Out of all patients who received chemotherapy.

Table 2
Tumor characteristics and treatment received by axillary management group.

	All Patients (N = 1,131,363) N (%)[a]	ALND (N = 255,363) N (%)[a]	Non-ALND (N = 876,057) N (%)[a]	*p*-value
Tumor Size (cm), median (range)	1.6 (0.1–99)	2.5 (0.1–99)	1.5 (0.1–99)	<0.001
Number of Positive LN, median (range)	0 (0–90)	2 (0–90)	0 (0–9)	<0.001
Number of LN Removed, median (range)	3 (0–90)	15 (10–90)	2 (0–9)	<0.001
Surgery Type				<0.001
Breast Conserving Surgery	641,684 (56.7)	81,922 (32.1)	559,762 (63.9)	
Mastectomy	489,679 (43.3)	173,384 (67.9)	316,295 (36.1)	
Received Chemotherapy				<0.001
Any Chemotherapy	493,278 (43.6%)	187,494 (73.4)	305,784 (34.9)	
Adjuvant Chemo[b]	339,937 (68.9)	120,882 (64.5)	219,055 (71.6)	
Neoadjuvant Chemo[b]	127,670 (25.9)	56,063 (29.9)	71,607 (23.4)	
Received Endocrine Therapy	722,748 (63.9)	160,178 (62.7)	562,570 (64.2)	<0.001
Received Radiation	669,374 (59.2)	156,837 (61.4)	512,537 (58.5)	<0.001

ALND Axillary Lymph Node Dissection, *LN* Lymph Nodes.
[a] Percentages may not add up to 100 due to rounding or missing values.
[b] Out of all patients who received chemotherapy.

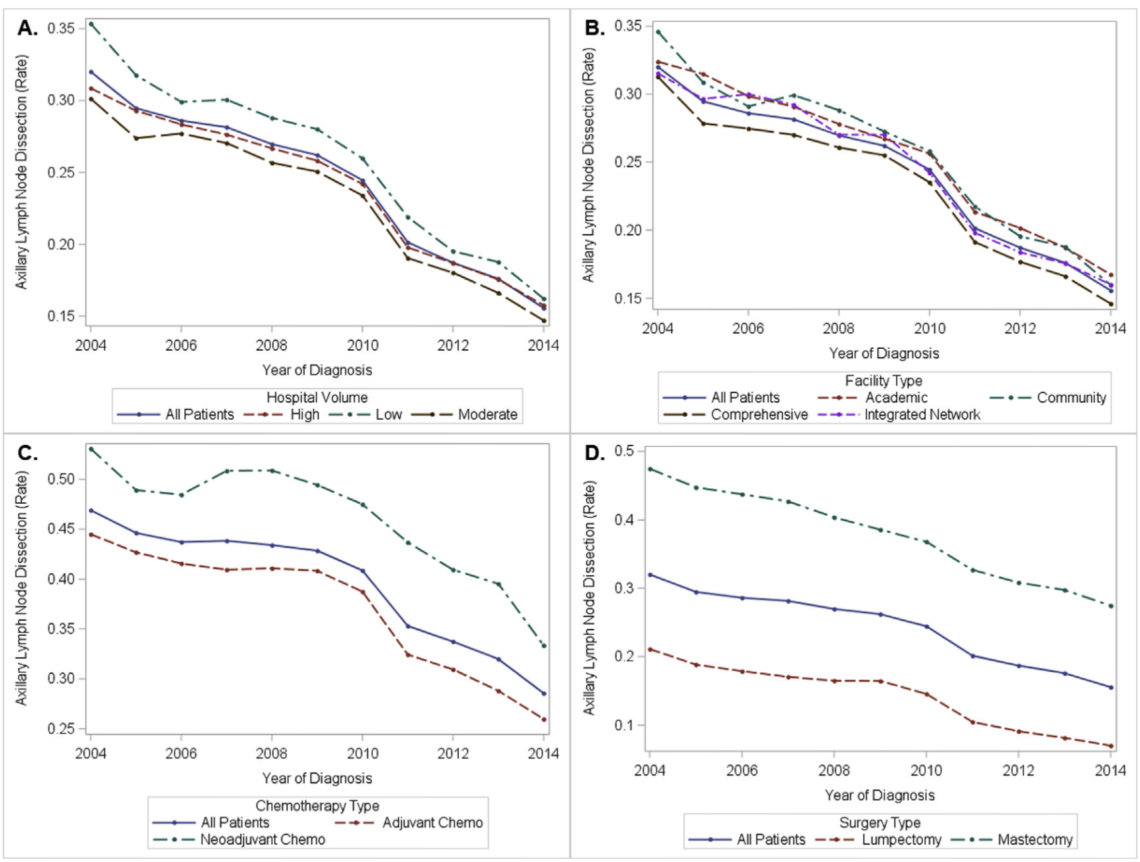

Fig. 1. Axillary lymph node dissection rates over time by hospital volume (**A.**), facility type (**b.**), chemotherapy timing (**c.**), and surgery type (**D.**).

soft tissue cases and from 29% to 9% for breast cases among chief residents. For the surgeon juniors, the observed decline was from 22% to 5% for skin/soft tissue, and from 17% to 7% for breast (Fig. 2).

Discussion

We are now in the decade following adoption of SLNB for axillary staging[5]; practice-changing prospective, randomized trials permitting SLNB alone for specific subsets of low volume node positive disease[7,13]; and multiple randomized trials[8,9] revealing acceptable false negative rates of SLNB following neoadjuvant chemotherapy. These developments have led to a marked reduction in the rates of ALND being performed over time. Our study using the NCDB revealed rates of ALND of 32% in 2004, dropping steadily to 16% in 2014. This reduction is seen independent of hospital volume, facility type, timing of chemotherapy (adjuvant vs. Neoadjuvant), or the type of primary breast operation (breast conservation vs. Mastectomy). While we did not specifically evaluate the *appropriateness* of omission of ALND in this study based on oncologic details, we suspect that a majority of these findings are likely guideline-concordant reductions in ALND rates.

Our study also determined that reductions in trainees' operative exposure to ALND have occurred over this time period. We evaluated the ACGME case log system to capture rates of ALND performed by surgical trainees. ALND may be logged within two potential categories. In the "Skin, Soft Tissue" category, cases are

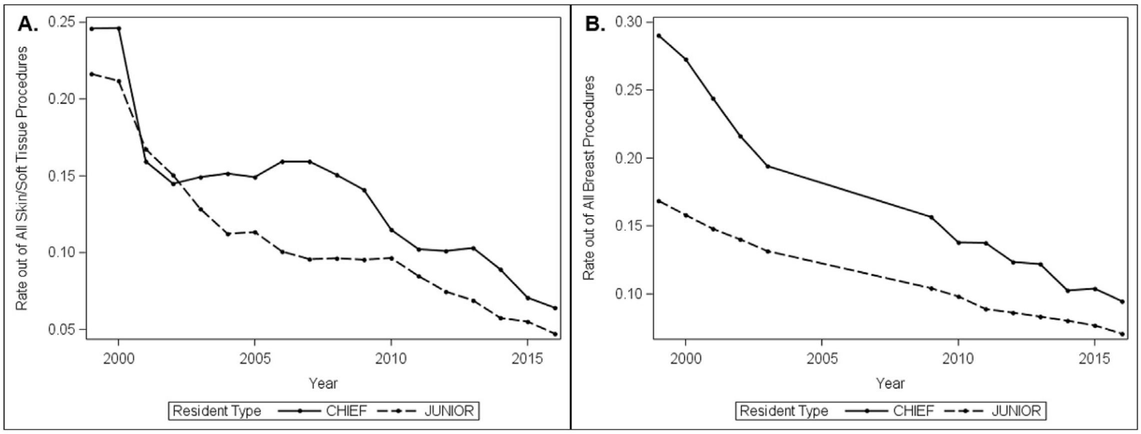

Fig. 2. Resident exposure to lymphadenectomies over time; rates of major lymphadenectomy out of all skin/soft tissue procedures (**A.**), and rates of modified radical mastectomy out of all breast procedures (**b.**).

specifically logged as a "major lymphadenectomy" regardless of indication (e.g., melanoma staging, or an ALND for breast cancer performed with breast conserving surgery). Once captured as a "major lymphadenectomy", it is no longer identifiable as being performed for breast cancer or another indication. The second category for ALND is within the "Breast" category. Unfortunately, to date, ALND is not, and has never been, captured as an independent procedure. Upon development of SLNB, the ACGME now captures SLNB specifically, but not *breast-specific* ALND. Thus, in order to capture axillary node dissections specific to breast cancer, we also evaluated rates of MRM over time.

Similar to the reduction in rates of ALND over time from the NCDB, we found a parallel reduction in trainee exposure to both "major lymphadenectomies" and MRMs. The absolute number of cases performed is low, with the average chief resident performing only *a single* major lymphadenectomy case in her or his chief year (mean = 1.5), and the average junior resident performing only 4 in the junior clinical year (mean = 4.5). In many academic training centers, junior residents may only spend one or two months on a designated breast oncology service, with most not returning as a senior resident. Accordingly, the total number of surgical training procedures per resident is likely less than 5–10 major lymphadenectomies. In addition, as surgeon-educators at a high-volume academic training center, we suspect that the majority of residents who are logging ALNDs, are likely not performing the critical portion of the procedure (i.e., freeing the axillary vein of fatty and nodal tissue). This concept is supported by a study at the University of Pennsylvania, where it was reported that junior residents, in their first two years of training, were significantly more likely to cover complex breast cases than residents in years three through five.[14] As total absolute numbers of ALND continue to decline for graduating surgical residents, these individuals are entering fellowship or primary surgical practices with less exposure and likely lower proficiency in performing these procedures. We presume this trend is also occurring within ACGME- and SSO-sponsored fellowship programs in Complex General Surgical Oncology and Breast Surgical Oncology, respectively. While one study[15] found stable rates ALND in the pre-, and post-Z0011 era, suggesting academic centers continue to perform these procedures with regularity, overall our study finds the ever-increasing infrequency of this case. The authors recommend ALNDs should be specifically identified and trainee coverage assigned, even if this requires the shifting of trainees for a given day.

A similar trend was recently published in an article in the *Journal of Surgical Education* evaluating operative experience for surgical residents in all breast case categories. They found an overall 17% volume reduction in breast cases, despite a 2% increase in total resident operative volume (2000–2015).[16] The authors highlight statistically significant declines in SLNB cases, with residents logging an average of 4.6 cases during their training, a number far below previously reported optimal surgeon experience for this procedure.[17–19] Current ACGME minimum defined case numbers require only 5 axillary procedures and 5 mastectomy procedures, as a portion of 40 total breast cases.[20] Similarly, SSO-sponsored surgical breast oncology fellowships requires only 5 ALNDs for certification.

Following development of the SLNB procedure, numerous studies evaluated the threshold of case volume needed to obtain proficiency. One study evaluated over 200 surgeons, and found improvement in SLN identification and reduced false negative rates after 20 cases.[17] Surgeons participating in the ACOSOG Z0010 study were initially required to submit 30 sequential SLNB followed by ALND, to document skills verification and surgeon performance before study participation.[18] Another study suggested that a minimal threshold of competence is variable and concluded that experience with 20–30 cases is likely adequate in high-volume breast centers but that community surgeons with broad-based practices might need as many as 60 cases.[19] While our study evaluated ALND and did not specifically evaluate SLNB rates, these final resident case numbers of SLNB are relatively similar to that of ALND reported herein and are far below the probable number needed to minimize complications and achieve oncologic adequacy.

Surgical skills and proficiency may have a profound effect on complications and sequelae of ALND (e.g., motor nerve injury, bleeding, lymphedema) and on long-term oncologic outcomes (e.g., node retrieval, adequate staging). A large volume of literature links surgical volume to clinical decision-making and outcomes, and this has been demonstrated at both the hospital and surgeon level. One notable SEER study evaluated annual breast surgery case volume and appropriateness of the type of axillary staging performed. They found low-volume surgeons were more likely to perform an ALND in pathologically node-*negative* women than higher-volume surgeons, even after adjustment for patient/tumor characteristic.[21] Surgeon specialization has also been linked to improved outcomes, and procedure-specific volume may also play a substantial role in outcomes.[22,23] Although procedural mastery may not be achieved until years following formal surgical training, and with additional volume or experience, a minimum volume threshold must be achieved for safety, or there should be collectively agreed upon measure of technical procedural competency.

This concept of procedural competency is certainly not unique to ALND and is being evaluated for numerous procedures as surgical sub-specialties become more technically specialized and complex (i.e. robotic pancreaticoduodenectomy). Strategies are being developed nationally to define competency and certification for procedures with minimal exposure during training and for new technology being adopted into practice. Current Hepato-Pancreato-Biliary (HPB) Fellowships require high procedural requirements including 20 major hepatectomies, 20 pancreaticoduodenectomies, and 15 biliary procedures for certification.[24] The authors consider a reasonable threshold to be 15–20 ALNDs for trainees based on these and other oncologic training thresholds.

There are several limitations of our study. For this study using the NCDB, the performed axillary procedure is not specified; therefore, we cannot define which patients underwent SLNB alone versus an ALND. NCDB reports only the number of LNs examined, (and number positive), so if LNs removed is recorded as zero, this indicates no nodes examined but does not guarantee that no axillary procedure was attempted. Thus we used a proxy definition of ALND ($\geq$10 LN examined). As previously noted, another limitation is that the procedure coded as "Major Lymphadenectomy" within the ACGME case log system may also include inguinal dissections and is not specific to axillary lymph node dissections. However, this would be expected to show higher, rather than lower case volumes, which would suggest that the actual volume is even lower than the very low estimates presented here.

Conclusions

Over the past decade, there has been a significant decline in the national rates of ALNDs. This trend may have an adverse impact on surgical education and intraoperative skill development. This trend may also have subsequent impact on patient and oncologic outcomes, as ALNDs are being performed in ever more challenging oncologic scenarios (e.g. residual tumor following neoadjuvant chemotherapy). We propose that minimum numbers of SLNB and ALND cases be mandated at the resident level. Similarly, minimal case numbers should be significantly increased at the fellowship level, in light of overall declining exposure at the resident level, to ensure adequate case exposure for proficiency and patient safety.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2019.07.013.

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