JAMA Oncology | Original Investigation

Surgeon Attitudes Toward the Omission of Axillary Dissection in Early Breast Cancer

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IMPORTANCE The American College of Surgeons Oncology Group (ACOSOG) Z0011 study demonstrated the safety of sentinel node biopsy alone in clinically node-negative women with metastases in 1 or 2 sentinel nodes treated with breast conservation. Little is known about surgeon perspectives regarding when axillary lymph node dissection (ALND) can be omitted.

OBJECTIVES To determine surgeon acceptance of ACOSOG Z0011 findings, identify characteristics associated with acceptance of ACOSOG Z0011 results, and examine the association between acceptance of the Society of Surgical Oncology and American Society for Radiation Oncology negative margin of no ink on tumor and surgeon preference for ALND.

DESIGN, SETTING, AND PARTICIPANTS A survey was sent to 488 surgeons treating a population-based sample of women with early-stage breast cancer (N = 5080). The study was conducted from July 1, 2013, to August 31, 2015.

MAIN OUTCOMES AND MEASURES Surgeons were categorized as having low, intermediate, or high propensity for ALND according to the outer quartiles of ALND scale distribution. A multivariable linear regression model was used to confirm independent associations.

RESULTS Of the 488 surgeons invited to participate, 376 (77.0%) responded and 359 provided complete information regarding propensity for ALND derived from 5 clinical scenarios. Mean surgeon age was 53.7 (range, 31-80) years; 277 (73.7%) were male; 142 (37.8%) treated 20 or fewer breast cancers annually and 108 (28.7%) treated more than 50. One hundred seventy-five (49.0%) recommended ALND for 1 macrometastasis. Of low-propensity surgeons who recommended ALND, only 1 (1.1%) approved ALND for any nodal metastases compared with 69 (38.6%) and 85 (95.5%) of selective and high-propensity surgeons ($P < .001$), respectively. In multivariable analysis, lower ALND propensity was significantly associated with higher breast cancer volume (21-50: −0.19; 95% CI, −0.39 to 0.02; >51: −0.48; 95% CI, −0.71 to −0.24; $P < .001$), recommendation of a minimal margin width (1-5 mm: −0.10; 95% CI, −0.43 to 0.22; no ink on tumor: −0.53; 95% CI, −0.82 to −0.24; $P < .001$), participation in a multidisciplinary tumor board (1%-9%: −0.25; 95% CI, −0.55 to 0.05; >9%: −0.37; 95% CI, −0.63 to −0.11; $P = .02$), and Los Angeles Surveillance, Epidemiology, and End Results site (−0.18; 95% CI, −0.35 to −0.01; $P = .04$).

CONCLUSIONS AND RELEVANCE This study shows substantial variation in surgeon acceptance of more limited surgery for breast cancer, which is associated with higher breast cancer volume and multidisciplinary interactions, suggesting the potential for overtreatment of many patients and the need for education targeting lower-volume breast surgeons.

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JAMA Oncol. 2018;4(11):1511-1516. doi:10.1001/jamaoncol.2018.1908
Published online July 12, 2018.

Changes in our understanding of the biology of breast cancer, the development of effective targeted systemic therapies, and the use of systemic therapy for the majority of small, node-negative breast cancers have altered the landscape of the surgical management of breast cancer in recent years. The American College of Surgeons Oncology Group (ACOSOG) Z0011 trial was a practice-changing study that demonstrated no significant differences in locoregional recurrence, disease-free survival, or overall survival in women with clinically node-negative breast cancer with metastases in 1 or 2 sentinel nodes (SNs) who were treated with breast-conserving surgery with whole-breast irradiation and randomized to axillary lymph node dissection (ALND) or sentinel node biopsy (SNB) alone.[1] Subsequent prospective randomized trials have demonstrated that ALND may be safely omitted in clinically node-negative patients with micrometastases in the SNs (International Breast Cancer Study Group [IBCSG] 23-01)[2] or when axillary irradiation is given after SNB alone (After Mapping of the Axilla: Radiotherapy or Surgery? [AMAROS] trial).[3]

In 2014, the Society of Surgical Oncology (SSO) and the American Society for Radiation Oncology (ASTRO) published a guideline recommending no ink on tumor as an adequate margin for patients treated with lumpectomy and whole-breast irradiation,[4] which was associated with a 16% decrease in additional surgery use after initial lumpectomy within 2 years of guideline dissemination.[5] The concept underlying both the omission of ALND and use of smaller negative-margin widths is the same, namely, that the systemic therapy and radiotherapy given to women undergoing breast-conserving surgery are contributors to local control and allow more limited, less-morbid surgical approaches.

Although new treatments with small incremental benefits are often embraced by the medical community, studies supporting the use of less therapy have been adopted more slowly.[6-8] The ACOSOG Z0011,[1] AMAROS,[3] and IBCSG 23-01 trials[2] provide high-quality evidence that ALND is no longer necessary for all women with SLN metastases, but little is known about current surgeon attitudes toward ALND and acceptance of omission of ALND in patients meeting clinical trial eligibility criteria. Herein, we examine surgeon perspectives regarding clinical circumstances in which ALND could be omitted and identify characteristics of surgeons associated with approval of omission of ALND in appropriate clinical circumstances. In addition, to determine whether these perspectives were particular to management of the ALNs or reflective of more general attitudes toward less surgical therapy, we examined the association between acceptance of the SSO-ASTRO minimal negative-margin width of no ink on tumor and surgeon propensity for ALND.

Key Points

Question Have surgeons accepted sentinel node biopsy alone for axillary management in patients undergoing breast-conserving surgery?

Findings In this survey of 376 surgeons, 49% would definitely or probably recommend axillary dissection for 1 sentinel node macrometastasis and 63% would definitely or probably recommend axillary dissection for 2 sentinel node macrometastases. In multivariable analysis, a lower propensity for axillary dissection was significantly associated with treatment of more breast cancer cases, acceptance of a lumpectomy margin of no ink on tumor, multidisciplinary tumor board participation, and Los Angeles Surveillance, Epidemiology, and End Results site.

Meaning The potential for overtreatment identified in this study indicates the need for education targeted toward lower-volume breast surgeons.

Methods

Sampling and Data Collection

The Individualized Cancer Care study is a population-based survey of patients with early-stage breast cancer and their clinicians. Women aged 20 to 79 years with ductal carcinoma in situ and stages I and II breast cancer who underwent definitive surgical therapy were identified using rapid case ascertainment from the Georgia and Los Angeles County Surveillance, Epidemiology, and End Results (SEER) registries between July 1, 2013, and August 31, 2015. Of the initial 7810 women selected, 7303 were eligible and 5080 patients responded (69.6% of those eligible). Patients were asked to identify their attending surgeon; 4755 (93.6%) did so. The 488 surgeons were mailed surveys toward the end of the patient data collection period; 376 (77.0%) responded. A modified Dillman method[9] was used to maximize response. Surgeons were mailed a packet containing an introductory letter, the survey, and a cash gift. A second survey was mailed to nonrespondents 4 weeks later, followed by a telephone call 4 weeks after that. A third survey was mailed to nonrespondents.

The surgeon questionnaire content was extensively pretested, as done in prior clinician surveys conducted by our team, and included (1) demographic/practice information, (2) scenario-based queries of attitudes about testing and treatment strategies, and (3) attitudes about patient communication and decision making.[10] This study was approved by the University of Michigan Institutional Review Board and the need for written consent was waived, as survey completion was believed to constitute consent.

Measures

The dependent variable—surgeon propensity to recommend ALND—was derived from 5 short clinical scenarios that were presented to the surveyed surgeons. The scenarios queried surgeon recommendation of ALND for a case typical of those included in the ACOSOG Z0011 and other trials. The case presented was a 48-year-old woman with clinically node-negative cancer with a 1.5-cm, palpable, grade 3, infiltrating ductal carcinoma, estrogen receptor (ER) positive, progesterone receptor (PR) positive, and *HER2* negative, undergoing lumpectomy and SNB. Surgeons were asked, "In a case like this, would you recommend axillary dissection for (1) isolated tumor cells in 1 SN, (2) micrometastases in 1 SN, (3) micrometastases in 2 SNs, (4) macrometastases in 1 SN, and (5) macrometastases in 2 SNs?" Response categories for each item were: definitely yes, probably yes, probably no, and definitely no.

Item responses were fit by a graded item response model to create a latent scale, with greater value indicating higher surgeon propensity to recommend ALND.[11] Scale values were calculated for 359 of the 376 responding surgeons with sufficient item information.

Additional measures of surgeon attitudes toward aspects of surgical management were evaluated in this study. For the 48-year-old woman in the case presentation above, we asked surgeons whether they: (1) would recommend ALND in the scenario of macrometastases in 3 SNs, (2) would say that "ALND should be done for any SN macrometatases" when discussing axillary management, and (3) would recommend a frozen section of the SN in such a case. Surgeons were also questioned if, for a patient undergoing mastectomy, they agreed that, "There is an option to omit ALND for macrometastasis in 1 or 2 SNs even if radiation therapy is not given." The response categories for these measures again ranged from definitely yes to definitely no. Surgeons were also asked whether they thought they performed ALND less often, about the same, or more often than other surgeons treating breast cancer in their community.

Last, we evaluated surgeon acceptance of a lumpectomy margin of no ink on tumor for invasive cancer in accordance with new guidelines.[4] The case scenario referenced for this question was a 60-year-old woman with a 0.8-cm mass in the upper quadrant of a large breast and a core biopsy showing grade 3 infiltrating ductal carcinoma, ER/PR positive/*HER2* negative, who received a lumpectomy and SNB to be followed by whole-breast irradiation. Surgeons were asked, "What negative margin width precludes the need for re-excision after lumpectomy with radiation?" with allowable responses of tumor cells not touching the ink, greater than 1 to 2 mm, greater than 5 mm, and greater than 1 cm. Other surgeon measures included number of years in practice, sex, breast cancer patient volume, percentage of newly diagnosed breast cancer patients discussed in a multidisciplinary meeting, and geographic practice site.

Statistical Analysis

We first described surgeon demographic and practice factors of interest (**Table**). We then evaluated surgeons' reports of their recommendation of ALND for the 5 clinical SNB scenarios. Following development of the 5-item scale for propensity to recommend ALND, surgeons were scored and categorized as having low, selective, or high propensity for recommending ALND using the outer quartiles of the ALND scores. We then examined the distribution of the ALND propensity groups by surgeon's annual breast cancer patient volume. We also assessed the distribution of ALND propensity groups by surgeon's reported negative margin needed to avoid re-excision following lumpectomy and irradiation in a 60-year-old woman with an ER/PR-positive tumor. Finally, we used a multivariable linear regression model to confirm the independent association between surgeon ALND propensity and breast cancer patient volume, controlling for geographic site, sex, years in practice, percentage of patients with newly diagnosed breast cancer discussed in a multidisciplinary meeting, and preferred negative margin. All analyses were conducted using SAS, version 9.4 (SAS Institute Inc). PROC GLM was used for multivariable linear regression. All statistical tests were 2-sided, with confidence at the 95% level; χ^2 tests were used to determine statistical significance for all differences in proportions, and *F* and *t* tests were used for linear regression effects.

Table. Surgeon Sample Characteristics (N = 376)[a]

Characteristic	Value
Age, y (n = 359), mean (range)	53.7 (31-80)
Years in practice (n = 371), mean (range)	20.8 (0-45)
Sex, No. (%)	
Female	92 (24.5)
Male	277 (73.7)
Missing	7 (1.9)
Surgeon volume of breast cancer patients in past 12 mo, No. (%)	
0-20	142 (37.8)
21-50	112 (29.8)
>50	108 (28.7)
Missing	14 (3.7)
Cases discussed in multidisciplinary tumor meeting, No. (%)	
0	59 (15.7)
1-9	63 (16.8)
≥10	246 (65.4)
Missing	8 (2.1)
Preferred negative margin for precluding re-excision after lumpectomy with irradiation, No. (%)	
Tumor cells not touching ink	245 (65.2)
>1 mm	69 (18.4)
>5 mm	44 (11.7)
Missing	18 (4.8)
SEER site	
USC	189 (50.3)
Emory	187 (49.7)

Abbreviations: SEER, Surveillance, Epidemiology, and End Results Registry; USC, University of Southern California.

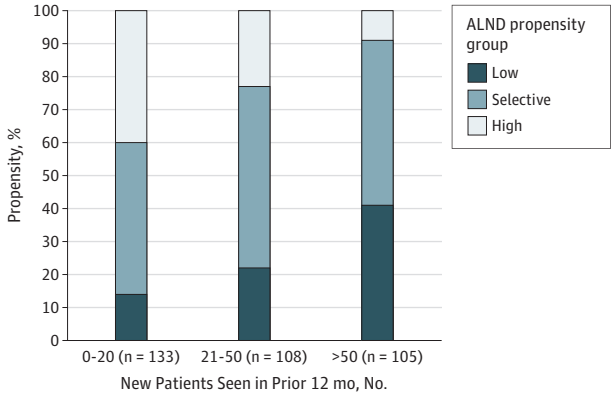
[a] Of the 376 who responded, 359 provided complete information.

Results

The Table summarizes the characteristics of the 376 responding surgeons; data on some variables were missing. The mean surgeon age was 53.7 years (range, 31-80) and 92 (24.5%) were women. Practice volume was varied, with 142 (37.8%) of respondents treating 0 to 20 breast cancer cases per year, and 108 (28.7%) treating more than 50 breast cancer cases per year. Although women constituted only 24.5% of the study participants, they represented 52.4% of the high-volume surgeons.

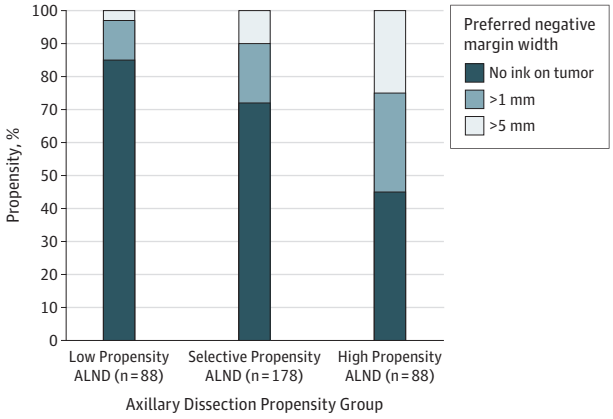
Substantial variation in report of recommendations for ALND was observed in response to the clinical scenarios (eFigure 1 in the Supplement). Surgeons were least likely to recommend ALND for patients with isolated tumor cells or micrometastases in a single SN, with 12.7% and 12.6% of surgeons, respectively, probably or definitely recommending

Figure 1. Association Between Surgeon Practice Volume and Propensity for Axillary Lymph Node Dissection (ALND)



Surgeon volume was reported as the number of new patients with a breast cancer diagnosis seen in the past 12 months after adjustment for sex, years in practice, and site. Propensity for ALND was described as low, selective, and high.

Figure 2. Association Between Surgeon Acceptance of Margin of No Ink on Tumor and Propensity for Axillary Lymph Node Dissection (ALND)



Acceptance of a margin of no ink on tumor was assessed using the scenario of a 60-year-old woman with a clinical T1bN0, estrogen receptor–positive, progesterone receptor–positive, *HER2*-negative cancer having lumpectomy with planned whole-breast irradiation. Propensity for ALND was described as low, selective, and high.

ALND for this minimal volume nodal disease. When a single nodal macrometastasis was present, 175 (49.0%) of the surgeons would definitely or probably recommend ALND, and for patients with macrometastasis in 2 nodes, 221 (62.6%) would recommend ALND.

Using outer quartiles of the ALND scale values, surgeons were categorized into low (89 [25%]), selective (181 [50%]), or high (89 [25%]) ALND propensity groups. Of surgeons who responded to the 5 items or questions from which the scale was created asking whether ALND should be done for any SN macrometastases, 1 of the 87 (1.1%) low ALND propensity group surgeons said that ALND should definitely or probably be done for any SN macrometastases compared with 69 (38.6%) of the selective ALND group (n = 179) and 85 (95.5%) of the high (n = 89) ALND propensity surgeons ($P < .001$). In addition, when asked whether they would recommend an intraoperative frozen section of the SN, 25 (28.7%) of responding surgeons in the low (n = 87) ALND propensity group would recommend the procedure compared with 78 (44.1%) of selective (n = 177) ALND propensity surgeons and 77 (86.5%) of high (n = 89) ALND propensity surgeons ($P < .001$).

Figure 1 shows the percentage of surgeons in each propensity group by breast cancer patient volume (n = 346). Forty-three of the 105 (41.0%) high-volume total surgeons (>50 cases/y) had a low propensity for ALND compared with 19 of 133 (14.3%) of low-volume surgeons (≤20 cases/y). Conversely, 40% of low-volume surgeons had a high propensity for ALND compared with 9% of high-volume surgeons. Surgeons with a high propensity for ALND were also less likely to accept lumpectomy margins of no ink on tumor (**Figure 2**). In the scenario of a 60-year-old woman with an ER/PR-positive, *HER2*-negative clinical T1bN0 cancer, 85% of respondents with a low propensity for ALND believed that a margin of no ink on tumor definitely or probably precluded the need for re-excision compared with 128 of 178 (71.9%) of those with a selective propensity for ALND and 40 of 88 (45.5%) responding surgeons with a high propensity for ALND.

A minority of surgeons appeared to extrapolate the results of clinical trials eliminating ALND in patients who did not meet trial selection criteria for whom guidelines continue to recommend ALND. Twenty-eight (7.8%) of surgeons did not recommend ALND for macrometastases in 3 SNs in a patient having breast-conserving therapy (BCT), and 2 (0.6%) stated that there was definitely an option to omit ALND in patients undergoing mastectomy without planned radiotherapy; 33 (9.2%) stated there was probably that option. Surgeons with a high propensity for ALND had a high level of awareness that they perform the procedure more frequently than their peers (eFigure 2 in the Supplement). High ALND propensity surgeons composed only 5.8% of the group who stated they performed ALND less frequently than their peers and 55.6% of the group who believed that they performed ALND more frequently than other surgeons.

Results of a multivariable linear regression analysis of factors associated with surgeon propensity for ALND are shown in eFigure 3 in the Supplement. The dependent variable, surgeon ALND propensity, had a mean (SD) of 0.04 (0.86) (range, −1.20 to 2.11) with lower scores indicating a lower propensity to recommend ALND and higher scores indicating a greater propensity to recommend ALND in the clinical case scenario. After adjustment for other factors, lower propensity to use ALND was significantly associated with higher annual patient volume (21-50: −0.19; 95% CI, −0.39 to 0.02; >51: −0.48; 95% CI, −0.71 to −0.24; $P < .001$), surgeon recommendation of minimal margin width (no ink on tumor) (1-5 mm: −0.10; 95% CI, −0.43 to 0.22; no ink on tumor: −0.53; 95% CI, −0.82 to −0.24; $P < .001$), higher proportion of cases being discussed in a multidisciplinary tumor board (1%-9%: −0.25; 95% CI, −0.55 to 0.05; >9%: −0.37; 95% CI, −0.63 to −0.11; $P = .02$), and Los Angeles County SEER site (−0.18; 95% CI, −0.35 to −0.01; $P = .04$).

Discussion

We have demonstrated variation among surgeons in omission of ALND, with a majority of surgeons recommending elimination of ALND for isolated tumor cells and micrometastases, but approximately half continuing to favor ALND for SN macrometastases. This is evidence of the potential for overtreatment in many patients based on data from prospective randomized trials indicating that ALND does not improve outcomes in these clinical scenarios.[1-3] In a prospective study performed at Memorial Sloan Kettering Cancer Center of 793 consecutive women meeting ACOSOG Z0011 eligibility criteria and found to have SN metastases, ALND was avoided in 84%,[12] suggesting that the widespread adoption of the ACOSOG Z0011, AMAROS, and IBCSG 23-01 results could substantially decrease the burden of breast cancer treatment. The use of ALND for isolated tumor cells is particularly concerning because such patients are classified as node-negative in the American Joint Committee on Cancer staging system.[13] This level of variation in a heterogeneous surgeon sample likely reflects the generally slow acceptance of less surgical therapy and the controversy that surrounded the ACOSOG Z0011 trial when it was initially published. Despite 6 prospective randomized trials supporting the safety of BCT and a 1990 National Institutes of Health consensus panel recommending its use,[14] fewer than 50% of women with early-stage breast cancer treated in 1994 underwent BCT,[8] and rates of use did not peak until 2005.[15] When ACOSOG Z0011 was initially published in 2011, concerns were raised regarding the representativeness of the patient population as well as the safety of eliminating ALND in younger women and those with *HER2* overexpressing or triple-negative breast cancers, and the 6.3-year median follow-up was believed to be too short for a population of women with ER-positive breast cancer in whom late recurrences are frequent.[16,17] Our survey was conducted prior to the publication of the 10-year outcomes of ACOSOG Z0011,[18] which confirmed no significant differences in local control or survival based on the performance of ALND, and it is possible that these mature data may lead to greater acceptance of omission of ALND among surgeons.

Our findings also indicate differences in acceptance of more limited surgical approaches among surgeons based on volume of breast cancer cases seen annually. Lower-volume surgeons were less likely to omit ALND and more likely to favor obtaining margins more widely clear than no ink on tumor in patients having BCT despite a 2014 meta-analysis and multidisciplinary guideline approved by the SSO, ASTRO, American Society of Clinical Oncology, and American Society of Breast Surgeons recommending no ink on tumor as an adequate margin for patients undergoing lumpectomy with whole-breast irradiation.[4] It is possible that the conceptual basis for the smaller surgical procedures or the body of evidence supporting them is less well known to lower-volume surgeons, indicating a need for education targeting this group. Presentation of cases at a multidisciplinary tumor board was an independent variable associated with decreased ALND use, providing a practical avenue for surgeons not fully comfortable with omission of ALND to discuss when it is appropriate to adopt this practice.

In addition to continued recommendation of ALND in situations where it is not warranted, such as patients with isolated tumor cells, micrometastases, or macrometastases in 1 to 2 SNs who are undergoing breast-conserving surgery with whole-breast irradiation, we also found evidence of extrapolation of existing evidence to clinical circumstances not addressed in randomized trials. Twenty-eight (7.8%) percent of surgeons would definitely or probably omit ALND for macrometastases in 3 or more SNs in a patient having BCT; this fact is evidence of undertreatment, as, to our knowledge, no data exist to support the safety of this practice. In ACOSOG Z0011,[1] the presence of macrometastases in 3 or more SNs was an indication for ALND, and in the AMAROS trial,[3] only 5% of randomized patients had metastases to 3 or more SNs. Omission of ALND for patients with SN macrometastases undergoing mastectomy without radiotherapy was considered definitely or probably an option by 10% of the respondents, despite the fact that this scenario was not included in ACOSOG Z0011[1] or AMAROS[3] and is being addressed in an ongoing clinical trial.[16]

Strengths and Limitations

Strengths of this study include the diverse sample of attending surgeons drawn from a contemporary population-based sample of patients from 2 large regions of the United States, the high surgeon response rate, and our ability to examine both practice attributes and surgeon attitudes toward clinically relevant scenarios commonly encountered in clinical practice. However, there were limitations. We relied on surgeon reports of whether or not they would perform ALND and did not have actual utilization data. Results were limited to surgeons who treated patients in Georgia and Los Angeles County.

Conclusions

Our findings have implications for clinical practice and health policy. Although ALND and SNB are both outpatient surgical procedures with a negligible risk of perioperative mortality, ALND is a longer operation than SNB, with a significantly higher risk of perioperative complications[19] and their associated costs. ALND is also associated with a longer period of disability for patients and, most significantly, a higher lifetime risk of lymphedema.[19,20] Patients report that lymphedema is the most-feared long-term consequence of breast cancer treatment, and behaviors adopted to minimize the risk of lymphedema may interfere with employment or negatively affect quality of life.[21] As demonstrated in our study, the decision to perform ALND is usually made with an intraoperative frozen section by surgeons with a high propensity for ALND, so interventions to reduce the use of ALND must take place prior to surgery. Women with clinically node-negative cancer undergoing BCT with whole-breast irradiation who are advised that ALND is routine for the finding of any SN metastases should seek a second opinion or reserve consent for ALND until final surgical pathologic test results are available to ensure

a complete discussion of the alternatives to ALND when SN metastases are present.

Educational programs targeting surgeons treating lower volumes of breast cancer, as well as their counterparts in radiation oncology and medical oncology that clearly articulate the available evidence in this area and define patient selection criteria for lesser surgical approaches, should be developed to avoid both harmful overtreatment and undertreatment. Appropriate axillary management now varies based on clinical nodal status, number of SNs containing metastases, choice of lumpectomy or mastectomy, and whether neoadjuvant therapy is given. Development of an evidence-based, practical guideline outlining acceptable alternatives to ALND in these patient subgroups should be a priority.

ARTICLE INFORMATION

Accepted for Publication: April 4, 2018.

Published Online: July 12, 2018. doi:10.1001/jamaoncol.2018.1908

Author Contributions: Dr Morrow had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Morrow, Jagsi, Katz.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Morrow, McLeod, Katz.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: McLeod.
Obtained funding: Morrow, Jagsi, Katz.
Administrative, technical, or material support: Morrow.

Conflict of Interest Disclosures: No conflicts were reported.

Funding/Support: This work was funded by grant P01 CA163233 to the University of Michigan from the National Cancer Institute.

Role of the Funder/Sponsor: The funding agency had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Meeting Presentation: This study was presented in part at the 2017 American Society of Clinical Oncology Annual Meeting; June 5, 2017; Chicago, Illinois.

Disclaimer: Dr Morrow is Associate Editor for Reviews and CME of *JAMA Oncology*, but she was not involved in any of the decisions regarding review of the manuscript or its acceptance.

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