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Impact of American College of Surgeons Oncology Group Z11 on surgical training at an academic cancer center

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Abstract

Background—The application of the American College of Surgeons Oncology Group Z0011 trial (Z11) has resulted in fewer completion axillary lymph node dissections (ALNDs) for select patients. We hypothesize that the application of Z11 may result in fewer ALND cases for surgeons in training.

Methods—In the setting of an academic cancer center incorporating Z11 into routine practice, we compared the total number of ALND performed in a pre-Z11 period (January 2007–April 2011, 52 mo) and post-Z11 period (April 2011–February 2014, 34 mo). We also identified the number of patients in the post-Z11 era in whom ALND was omitted as a result of Z11. Clinical and pathologic characteristics among these groups were analyzed.

Results—A total of 279 and 191 ALNDs were performed in the pre-Z11 and post-Z11 groups, respectively. Variables were similar among these groups with respect to demographics, tumor characteristics, and surgeries performed. There was no difference in the monthly rates of ALND between groups—5.37 cases/mo (pre-Z11) and 5.62 cases/mo (post-Z11), $P = 0.52$. We identified a total of 53 patients for whom ALND was omitted due to Z11 application in the post-Z11 period, representing a potential 21.7% decrease ($53/191 + 53$) in the number of ALNDs in this period.

Conclusions—Although the application of Z11 could potentially impact surgical training with a 21.7% decrease in ALND cases ($53/191 + 53$), the surgical case volume at an academic cancer center absorbs this decrease and maintains consistent levels of training for ALND.

Keywords

Z11; Surgical training; Axillary lymph node dissection

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Disclosure

The authors have nothing to disclose.

1. Introduction

The results of the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial (Z11) were published in February 2011 and reported similar survival outcomes in women undergoing breast conservation found to have 1–2 positive sentinel lymph nodes when treated with either sentinel lymph node biopsy (SNB) alone or completion axillary lymph node dissection (ALND) [1]. Enrolled patients had clinical T1–T2, N0 disease and received whole breast irradiation after lumpectomy. Patients who had extranodal extension or had received neoadjuvant chemotherapy were excluded from the trial.

For this specific patient population, the conclusions of Z11 have changed the practice pattern of many surgeons. Rather than performing completion ALND for even one positive lymph node, surgeons have adopted the practice of omitting ALND when the patient meets the criteria described by Z11. Although controversial at its onset, the surgical community has gradually altered practice patterns to reflect the conclusions of Z11 [2–5]. The National Comprehensive Cancer Network has adopted the conclusions of Z11 into its guidelines [6]. A large single-institution study suggested that nearly 75% of SNB-positive patients could avoid ALND if Z11 were applied [7]. This may have significant effects on the surgical training of residents and fellows, with potentially fewer ALND procedures. However, the impact of Z11 on surgical training has not been previously examined.

In the setting of a free-standing, academic comprehensive cancer center (CCC) practicing Z11, we sought to determine whether the application of Z11 has resulted in fewer ALND performed and therefore fewer cases available for the training of residents and fellows. We hypothesized that Z11 would result in exposure to fewer ALNDs, which may have implications on the technical experience with ALND obtained during training.

2. Methods

The Roswell Park Cancer Institute (RPCI) is a free-standing tertiary cancer center. It is a CCC as designated by the National Cancer Institute, participates as a member of the National Comprehensive Cancer Network, and offers fellowships in both breast surgery and complex surgical oncology. The breast fellowship is accredited by the Society of Surgical Oncology, and the surgical oncology fellowship is accredited by the Accreditation Council for Graduate Medical Education. RPCI also supports training in diseases of the breast for general surgery residents who attend the University of Buffalo and visiting residents. Fellows and general surgery residents routinely participate in breast surgery procedures.

In this setting, we performed a retrospective review of all patients undergoing ALNDs performed on female patients at RPCI from January 2007 to February 2014 using a prospectively maintained institutional breast surgery database that consecutively records every breast surgery case. This database is maintained by the Clinical Data Network (CDN), a professional research group at RPCI, which collects and validates data entries. At the time of this study, the CDN had validated data up to and including February 2014. The study was reviewed and approved by the institutional review board at RPCI. The current procedural

terminology codes used to identify patients included: 19307 (modified radical mastectomy), 38525 and 38745 (axillary dissection), and 19302 (partial mastectomy with SNB).

It was predetermined that the faculty at RPCI predominantly adopted Z11 into practice in April of 2011, a few months after the publication of Z11. The practice was changed gradually over this month in 2011 such that Z11 became the standard of care for the appropriately selected patients. The total cohort was divided into a pre-Z11 group, comprised of patients from January 2007 until April 2011 (52 mo) and a post-Z11 group, comprised of patients from April 2011 to February 2014 (34 mo). Rates of ALND per month are calculated for each group to account for the differences in group duration. Although it was possible to choose a similar duration of time for the pre-Z11 cohort, incorporating more months in this cohort allowed for more comprehensive data analysis. Furthermore, evaluation based on monthly rates of cases also standardized comparisons. As mentioned, the post-Z11 group period was defined by the time of Z11 adoption of RPCI faculty to the most current month of validation by the CDN. The total number of clinic visits during the two periods was also quantitated and compared based on the average monthly rate of visit.

In addition, in the period of the post-Z11 group, we identified all female patients who did not undergo ALND after meeting the Z11 criteria. Patients with clinical T1–T2, N0 breast cancer who underwent lumpectomy with SNB who were found to have one–two positive sentinel lymph nodes on final pathology and underwent adjuvant breast radiation were included. Patients who received neoadjuvant chemotherapy followed by breast conservation or who were found to have extranodal extension of the SNB were excluded and therefore underwent completion axillary lymph node dissection (cALND). Derived from these inclusion and exclusion criteria, this group represented patients who would have likely undergone ALNDs in the pre-Z11 period and was designated as the “Z11 applied” group.

For statistical analysis, the monthly rates of clinic visits, overall breast surgeries and specifically ALNDs between the pre-Z11 and post-Z11 groups were compared using a conditional test about two Poisson means. Patient characteristics are reported by group using the mean, median, and standard deviation for continuous variables; and using frequencies and relative frequencies for categorical variables. Patient characteristics and surgery types are compared between groups using the Mann–Whitney *U* and Fisher’s exact tests for continuous and categorical variables, respectively. All analyses are conducted in SAS v9.4 (Cary, NC) at a significance value of 0.05.

3. Results

A total of 1472 patients were selected from our institutional database from January 2007 to February 2014 based on the relevant current procedural terminology codes described previously.

In the pre-Z11 group, 525 partial mastectomies with SNB and 279 ALNDs (including modified radical mastectomy, partial mastectomy with ALND, and ALND alone) were performed. The overall rate of ALND was 5.37 cases per mo (279/52 mo). In the post-Z11 group, 477 partial mastectomies with SNB and 191 ALNDs were performed, for an ALND

rate of 5.62 cases per mo (191/34 mo). There was no significant difference in the rates of ALND between the two groups, $P=0.52$. The number of ALNDs performed per surgeon at RPCI is summarized in Table 1.

Table 2 summarizes the comparison of patient demographics, tumor characteristics, and specific procedures performed between the pre-Z11 and post-Z11 groups. Statistically significant differences were observed for pathologic stage and tumor histology. In the pre-Z11 group, six patients underwent ALND in the setting of stage IV disease. Of these patients, two required surgery for palliative reasons as a result of symptomatic, locally invasive primary tumors. The other four patients had metastatic disease to a single site (two with single brain lesions, one with multiple liver lesions, and one with two pulmonary lesions) who responded to systemic treatment. Multidisciplinary recommendations included surgery of the primary site and axilla to control local regional disease. In the post-Z11 group, one patient underwent ALND in the setting of stage IV disease for palliation.

In the post-Z11 period, a total of 477 partial mastectomies with SNB were performed. Of these, 59 patients met both the inclusion and exclusion criteria for Z11. However, only 53 of 59 patients did not undergo ALND, with reasons as to why six patients did undergo ALND explained in the next paragraph. This group of 53 patients represents cases that would have contributed to the education of trainees had Z11 not been applied. In the absence of Z11, the number of cases in the post-Z11 group may have reached 244 (191 + 53), resulting in a rate of 7.2 cases per mo. Thus, application of Z11 resulted in a potential 21.7% (53 of 244) decrease in the number of ALND cases available to trainees. Table 3 summarizes the characteristics of patients in the Z11-applied group and its comparison to the post-Z11 group. As expected, significant differences were observed with respect to procedure, tumor size, number of nodes resected, and number of positive nodes. Differences in biomarkers were also found.

Within the post-Z11 group, a total of 24 patients underwent partial mastectomy and cALND in the setting of one or two positive SNB. Of these, 18 of 24 patients met the Z11 inclusion criteria but not the exclusion criteria. Specifically, 9 of 24 patients received neoadjuvant chemotherapy, and another 9 of 24 patients were found to have extranodal extension on final pathology. The remaining 6 of 24 patients did meet both the Z11 inclusion and exclusion criteria and represent a deviation from Z11 practice whereby cALND was not omitted. These patients represent the 6 of 59 patients discussed in the previous paragraph. Of these, two patients preferred cALND due to patient anxiety in the setting of a high-risk personal or family history. The reason for cALND in the other four patients was not specified or determined from the medical record. Thus, the compliance rate of Z11 in the post-Z11 period was approximately 90% (53 of 59). Removing these six cases from the total number of ALND performed in the post-Z11 group did not have a large effect on the average monthly rate of ALND during this period, 191 of 34 (5.62 ALND per mo) *versus* 185 of 34 (5.44 ALND per mo).

Finally, Table 4 summarizes the comparison of the total number of breast clinic visits during each period and the number of common breast surgical procedures. Although the monthly average of patients seen in the clinic during the post-Z11 group was higher than that of the

pre-Z11 group, this difference was not statistically significant. The total number of cases in each period was also similar. With regard to type of cases, the proportion of cases in the post-Z11 group that involved an ALND (191 of 1760 = 10.9%) was similar to that in the pre-Z11 group (279 of 2820 = 9.9%). If the Z11-applied group ($n = 53$) was added to the post-Z11 group, the proportion of ALND cases would have been 13.9% (244 of 1760).

4. Discussion

The results of ACOSOG Z11 have brought about a significant change in the management of select breast cancer patients with one–two positive axillary lymph nodes. Recognizing the benefits and limitations of the study [1,8–10], the surgeons in the breast surgery department at RPCI adopted Z11 into practice. Some studies report that up to 70%–75% of node-positive patients may avoid ALND as a result of the application of Z11 [7,11,12]. The compliance rate at our institution was approximately 90%. Intuitively, it is reasonable to hypothesize that Z11 may translate into fewer ALNDs performed and in turn fewer cases that are encountered during surgical training for both residents and fellows.

The importance of this study is reflected in the potential implications of Z11 on surgical training. Historically, when SNB was adopted as the standard of care for patients without clinical nodal involvement, the experience of some surgeons-in-training with ALND decreased, and based on institutional surveys, these trainees expressed a decreased level of confidence with the ALND procedure [13]. Intuitively, this could have effects on surgeons' technical abilities after training when out in practice, possibly affecting complication rates such as nerve or axillary vein injury or compromising the completeness of the node dissection. Thus, determining whether adoption of Z11 to surgical training has led to a decreased experience with ALND, similar to when SNB was adopted, is quite clinically relevant so that any deficits in training can be addressed before training completion.

From our single-institution retrospective study, we determined that the number of ALNDs performed at RPCI did not significantly change after the adoption of Z11. There was no difference in the rates of ALND between the pre- and post-Z11 period (pre-Z11 = 5.37 cases/mo *versus* post-Z11 = 5.62 cases/mo, $P = 0.52$). This was similar to the rate of ALND that was observed despite the omission of 53 cases (Z11-applied group) representing a potential 20% of total ALND that would have been performed.

The incidence of breast cancer in the United States has been relatively stable over the last 10 y [14]. Thus, it is unlikely that the higher ALND rate in the post-Z11 period compared with that in the pre-Z11 group can be solely attributed to an increase in the incidence of breast cancer. This is consistent with the results of this study as there was no statistically significant difference in the number of breast clinic visits during the two periods. Alternatively, there may be several factors that account for this finding. First, as an academic CCC, the institution receives many referrals from a large catchment area, including many difficult tertiary referrals, which may require multidisciplinary care. Changes in the community practice patterns or a decrease in the number of outside surrounding surgeons can influence the volume of cases performed at RPCI. Second, depending on the region or treatment facility, the number of patients who may avoid ALND by meeting the Z11 criteria vary

significantly. Whereas studies suggest that up to 70%–75% of node-positive patients are applicable to Z11 [7,11,12], other studies have suggested that the applicable proportion is in the range of 10%–20% [15,16]. Therefore, different patient populations surrounding the treating facility may influence the stage of breast cancer and subsequently the applicability of Z11 in various regions. In some settings, the total number of ALNDs performed for all indications may be large enough to absorb the cases that were obviated as a result of Z11. This was consistent with the findings of our study, whereby the number of patients in whom Z11 applied was about 20% of patients with positive nodes. Third, based on analysis of the data in Table 4, the proportion of ALND cases in the post-Z11 group (10.9%) was similar to that in the pre-Z11 group (9.9%). Had the Z11-applied group been included in the post-Z11 group, this proportion would have been 13.9%. Thus, the overall similar rate of ALND in the post-Z11 group may have been sustained by patients presenting with more advanced disease who required ALND.

One advantage of our study is that the analysis was derived from a prospectively maintained database, which captures all the surgical procedures performed at our institution. Residents and fellows routinely participate in breast cases. Thus, the number of breast cases experienced during training at our institution can be confidently determined. This method of data extraction is superior to conducting resident and/or fellow surveys, which request the trainee to self-report his or her number of breast cases. Such surveys often have low to moderate response rates. Alternatively, although residents and fellows are required to keep an up-to-date log of their cases as mandated by the Accreditation Council for Graduate Medical Education, compliance may not be complete. Many trainees may log cases until the minimum requirement is reached, after which they may stop logging cases for a particular specialty. The use of our prospectively maintained database of all breast cases helps to minimize errors in data pertaining to resident and fellow experience with ALND.

It is important to note that the application of our findings is limited to stand-alone, tertiary academic centers where the faculties have adopted Z11 into practice. Many training programs may have faculties who have not adopted Z11 into practice, and therefore numbers of ALND may not be expected to change in this setting. Furthermore, the size and type of the training program might be expected to affect the overall ALND case volume.

We recognize that there are important limitations in our study. As a department, there were more surgeons in the post-Z11 period compared with the pre-Z11 period. However, one of these surgeons was just starting in practice (surgeon #4), and the overall contribution to the number of ALNDs was low. Another surgeon took on a part-time role before the adoption of Z11 (surgeon #2). As summarized in Table 1, the number of cases for this surgeon decreased and was offset by the addition of a third surgeon (surgeon #3). Therefore, although there were more faculties present in the post-Z11 period, the cases were redistributed among them.

Our study is retrospective and thus is limited by the data acquisition. There is a substantial amount of missing data with regard to patient comorbidities or patient preferences, which may influence the decision to pursue ALND. As discussed previously, events external to our institution, such as changes in the case volume experienced by other hospitals or centers in

the surrounding community, may potentially influence the numbers of ALNDs performed at RPCI during the study period. These changes are often difficult to detect and quantify.

Finally, this study does not capture the impact of more recent data supporting the use of SNB after neoadjuvant chemotherapy, which may potentially result in a decrease in ALND training. As reported in Section 3, 9 of 24 patients in the post-Z11 group who underwent wide local excision with SNB and were found to have either one–two positive SNB still had a subsequent cALND. For these patients, the underlying reason was because they had received neoadjuvant chemotherapy, which was an exclusion criterion in the Z11 trial design. However, new data have emerged supporting the use of SNB after neoadjuvant chemotherapy. The ACOSOG z1071 trial and the SENTINA study showed that SNB after neoadjuvant chemotherapy is feasible, albeit with an increased false-negative rate [17,18]. Further studies have characterized factors and ancillary methods to increase the accuracy of SNB after neoadjuvant chemotherapy [19,20]. The growing body of evidence that SNB is feasible and accurate after neoadjuvant chemotherapy may have significant implications on cALND. More surgeons may consider applying Z11 criteria to patients who have received neoadjuvant chemotherapy, and this would potentially lead to a subsequent decrease in the number of ALNDs performed and, in turn, the number of ALNDs obtained during surgical training. In addition, ongoing studies may lead to further decreases in ALND, such as NCT01901094, which is comparing axillary radiation to ALND in node-positive patients who received neoadjuvant chemotherapy [21].

Despite these limitations, we have shown that the application of Z11 in an academic cancer center with fellowships in breast and surgical oncology has not resulted in a decrease in the number of ALNDs performed during surgical training. Although our hypothesis was that the adoption of Z11 would result in a decrease in ALND performed during surgical training, this was not found as a result of this study. We proposed several reasons why case numbers have remained steady at our institution. This warrants further study to uncover more specifically the reasons accounting for this finding. As the application of studies regarding SNB after neoadjuvant chemotherapy become more widespread, the experience with ALND in training may become increasingly relevant. We believe this study poses interesting questions as to whether the same observations can be concluded in different training settings, such as large academic residency programs or smaller community-based training programs. We believe that it is important to identify programs where Z11 has resulted in a decreased number of ALND cases so that measures can be taken, if needed, to ensure appropriate technical surgical training in the ALND technique.

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Table 1

Number of axillary dissections performed per surgeon before and after adoption of Z11.

Surgeon	Pre-Z11(52 mo)	Post-Z11 (34 mo)	Overall (86 mo)	P value	Applied Z11 (34 mo)
Surgeon 1 [*]	199 (71.3%)	70 (36.6%)	269 (57.2%)	<0.001	27 (50.9%)
Surgeon 2 [†]	67 (24.0%)	27 (14.1%)	94 (20.0%)		9 (17.0%)
Surgeon 3 [‡]	13 (4.7%)	86 (45.0%)	99 (21.1%)		17 (32.1%)
Surgeon 4 [§]	N/A	8 (4.2%)	8 (1.70%)		0
Total	279	191	470		53

^{*} This surgeon left the faculty in July 2013.

[†] This surgeon was a member of the faculty for the entire duration of this study, despite being assumed a part-time role during the study.

[‡] This surgeon joined the faculty in October 2010 and currently works at RPCI.

[§] This surgeon joined the faculty in July 2013 and currently works at RPCI.

Table 2

Comparison of patients in the pre-Z11 and post-Z11 groups.

Clinical and pathologic variables	Pre-Z11 (52 mo) <i>n</i> = 279	Post-Z11 (34 mo) <i>n</i> = 191	<i>P</i> value
Age (y)	58.6 ± 13.9	56.7 ± 13.2	0.14
Mean ± standard dev			
Race			0.73
White	230 (82.4%)	152 (79.6%)	
Black	42 (15.1%)	33 (17.2%)	
Other	7 (2.5%)	6 (3.1%)	
Laterality			0.45
Right	138 (49.5%)	87 (45.5%)	
Left	141 (50.5%)	104 (54.5%)	
Procedure			0.048
WLE* + ALND	122 (43.7%)	62 (33.0%)	
MRM	134 (48.0%)	111 (58.1%)	
ALND alone	23 (8.2%)	18 (9.4%)	
Level			0.85
II	260 (93.2%)	179 (93.7%)	
III	19 (6.8%)	12 (6.3%)	
Path stage			0.13
I	16 (5.8%)	10 (5.2%)	
II	153 (54.8%)	91 (47.6%)	
III	104 (37.4%)	89 (46.6%)	
IV	6 (2.2%)	1 (0.5%)	
Tumor size (cm)	2.91 ± 2.72	3.19 ± 2.68	0.20
# nodes resected	19.86 ± 7.66	19.53 ± 8.66	0.46
# nodes positive	3.62 ± 4.81	4.52 ± 5.24	0.06
Histology			0.14
DCIS	0 (0%)	1 (0.5%)	
Invasive ductal	225 (80.6%)	158 (82.7%)	
Invasive lobular	37 (13.3%)	24 (12.6%)	
Inflammatory	14 (5.0%)	3 (1.6%)	
Other	3 (1.1%)	5 (2.6%)	
ER status			0.92
Negative	73 (26.2%)	49 (25.7%)	
Positive	206 (73.8%)	142 (74.3%)	
PR status			0.28
Negative	101 (36.2%)	59 (30.9%)	
Positive	178 (63.8%)	130 (68.1%)	
HER-2 status			1.00
Negative	238 (85.3%)	162 (84.8%)	

Clinical and pathologic variables	Pre-Z11 (52 mo) <i>n</i> = 279	Post-Z11 (34 mo) <i>n</i> = 191	<i>P</i> value
Positive	39 (14.0%)	26 (13.6%)	
Unknown	2 (0.01%)	2 (0.01%)	

MRM = modified radical mastectomy; DCIS = ductal carcinoma in situ; ER = estrogen receptor; PR = progesterone receptor.

* WLE = wide local excision, lumpectomy, partial mastectomy.

Table 3

Comparison of patients in the post-Z11 and Z11-applied groups.

Variable	Post-Z11 (34 mo) <i>n</i> = 191	Z11 applied (34 mo) <i>n</i> = 53	<i>P</i> value
Age (y)	56.7 ± 13.2	59.5 ± 11.6	0.10
Mean ± standard dev			
Race			0.38
White	152 (79.6%)	45 (84.9%)	
Black	33 (17.2%)	8 (15.1%)	
Other	6 (3.1%)	0 (0.0%)	
Laterality			0.28
Right	87 (45.5%)	29 (54.7%)	
Left	104 (54.5%)	24 (45.3%)	
Procedure			<0.001
WLE + ALND	62 (33.0%)		
MRM	111 (58.1%)		
ALND alone	18 (9.4%)		
WLE + SNB		53 (100.0%)	
Level			<0.001
I		53 (100.0%)	
II	179 (93.7%)		
III	12 (6.3%)		
Path stage			<0.001
I	10 (5.2%)	2 (3.8%)	
II	91 (47.6%)	51 (96.2%)	
III	89 (46.6%)	0 (0.0%)	
IV	1 (0.5%)	0 (0.0%)	
Tumor size (cm)	3.19 ± 2.68	1.82 ± 0.96	0.001
# nodes resected	19.53 ± 8.66	3.58 ± 2.03	<0.001
# nodes positive	4.52 ± 5.24	1.21 ± 0.41	<0.001
Histology			0.11
DCIS	1 (0.5%)	0 (0.0%)	
Invasive ductal	158 (82.7%)	51 (96.2%)	
Invasive lobular	24 (12.6%)	2 (3.8%)	
Inflammatory	3 (1.6%)	0 (0.0%)	
Other	5 (2.6%)	0 (0.0%)	
ER status			0.027
Negative	49 (25.7%)	6 (11.3%)	
Positive	142 (74.3%)	47 (88.7%)	
PR status			0.009
Negative	59 (30.9%)	7 (13.2%)	
Positive	130 (68.1%)	46 (86.8%)	

Variable	Post-Z11 (34 mo) <i>n</i> = 191	Z11 applied (34 mo) <i>n</i> = 53	<i>P</i> value
HER-2 status			0.82
Negative	162 (84.8%)	45 (84.9%)	
Positive	26 (13.6%)	8 (15.1%)	
Unknown	2 (0.01%)	0 (0.0%)	

MRM = modified radical mastectomy; WLE = wide local excision; DCIS = ductal carcinoma in situ; ER = estrogen receptor; PR = progesterone receptor.

Table 4

Comparison of total number of clinic visits and overall cases for patients in the pre-Z11 and post-Z11 groups.

Variable	Pre-Z11 (52 mo)	Post-Z11 (34 mo)	P value
Total clinic visits	7936	6970	0.50
Monthly average	152.6	205.0	
Procedure			
Total cases (monthly average)	2820 (54.2)	1760 (51.7)	0.51
Partial mastectomy	789 (15.2)	429 (12.6)	0.001
Simple mastectomy			
Unilateral	619 (11.9)	336 (9.9)	
Bilateral	99 (1.9)	76 (2.2)	
Partial/simple with SNB	1034 (19.9)	728 (21.4)	
WLE + ALND	122 (2.3)	62 (1.8)	
MRM	134 (2.6)	111 (3.2)	
ALND alone	23 (0.4)	18 (0.5)	

MRM = modified radical mastectomy; WLE = wide local excision.