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ORIGINAL ARTICLE

5-year oncological outcomes of targeted axillary sampling in pT1-2N1 breast cancer

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Summary *Background:* axillary lymph nodes dissection (ALND) has been a standard treatment in breast cancer with positive sentinel LNs. However, various short- and long-term postoperative morbidities have been reported after conventional ALND. To define the concept of targeted axillary sampling (AS) and to assess its oncological feasibility for breast cancer. We compared the oncological outcomes in the axillary area between conventional ALND and targeted AS with or without radiotherapy.
Methods: One hundred and twenty-nine female patients with cT1-2N1 breast cancer underwent breast and axillary surgery. We defined the concept of targeted AS in clinical and pathological terms, and the oncological outcomes were compared between ALND and AS, and between AS with and without radiotherapy.

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Results: There were no significant differences in oncological outcomes in the axilla between conventional ALND and AS, or between AS with radiotherapy and AS alone.
Conclusions: The 5-year oncological outcomes of targeted AS were not inferior to those of conventional ALND, regardless of whether radiotherapy was added.

1. Introduction

Axillary lymph node (ALN) status has strong prognostic value in breast cancer and is a key factor in the TNM staging system for breast cancer. Theoretically, the most accurate method to evaluate the status of ALN metastasis and calculate the tumor burden of breast cancer would be to remove all of the visible ALNs. However, this method may lead to high morbidity, including axillary pain and limitation of arm movements, and numbness and lymphedema as long-term complications that disrupt quality of life.[1–3]

The approach for evaluating ALNs in breast cancer has changed over the years. In the early 1990s, ALN dissection (ALND) was the only way to discover and manage metastatic ALNs.[4] Subsequently, sentinel LN biopsy (SLNB) became a standard method for evaluation of ALNs.[5,6] More recently, several surgeons have reported a new concept of axillary management, named axillary sampling (AS), which involves limited or partial ALND. However, the concept and technique of AS have not yet been fully defined, therefore, its use in clinical practice has been limited.[7–11]

The aims of this study were to: (1) define the concept of targeted AS; (2) compare the oncological outcomes in the axillary area of conventional ALND and AS with or without radiotherapy; and (3) assess the oncological feasibility of AS for breast cancer by targeting metastatic or suspicious LNs and removing the surrounding, including targeted LNs. We also aimed to clarify the practice guidelines by further evaluating the effect of radiation in the targeted AS group.

2. Material and methods

Between 2009 and 2013, 129 female patients with cT1-2N1 breast cancer underwent breast and axillary surgery. All breast cancer was diagnosed by needle or excision biopsy and ALN metastasis was confirmed by fine-needle aspiration cytology. The size, number and location of the tumor were identified through mammography, ultrasonography and breast magnetic resonance imaging (MR) prior to surgery. All patients provided written informed consent to undergo breast surgery and ALND. And all of the breast and axillary surgery was performed by four different breast surgeons who were specialist in breast disease. Conventional ALND included level I and II of axillary lymph nodes and performed when the patient agreed to the procedure and accepted its short- or long-term morbidities. Targeted AS was only performed when patients refused conventional ALND and axillary radiation was added randomly.

Breast cancer was removed with breast-conserving surgery or partial mastectomy and surgical margins were evaluated with intraoperative frozen sections. When the total number of removed ALNs in the final pathological report was <4 in the AS group or <10 in the ALND group, the patients were excluded because of the low reliability of LN staging.[12–16] All patients were followed up after completing adjuvant treatment biannually for the first 2 years and annually for a further 3 years. Tumor recurrence or metastasis was evaluated with blood tests, tumor markers, mammography, breast ultrasonography, breast magnetic resonance imaging, chest X-ray and bone scan (Fig. 1).

The clinical variables assessed including age, body mass index, types of breast cancer, clinical and pathological tumor size, length of hospital stay, number of metastatic and removed ALNs, overall cancer stage, and results of immunohistochemical staining. The treatment variables assessed included adjuvant chemotherapy, radiotherapy and hormone therapy, and the oncological results included disease-free survival, locoregional recurrence, distant metastasis and death.

Statistical analysis was performed using SPSS version 12 (SPSS, Chicago, IL, USA). For comparison of ALND versus AS, and AS with and without axillary radiotherapy, the χ^2 test or Student's t test was used depending on the presence of categorical or continuous variables.

2.1. Definition of ALND and targeted AS

Radiologists targeted and marked suspicious LNs using a tattooing method with 1.5 ml charcoal injection before surgery and the surgeon removed groups of ALNs within 24 h including SLNs and stained LNs. The charcoal solution should not be injected more than 2 ml, because the charcoal solution is too thick and dark which can interfere with identifying cancer cells in lymph nodes. And the removed lymph nodes were sent to pathologists immediately to assess breast cancer metastasis[17] (Fig. 2).

After AS was performed, the axillary vein, long thoracic nerve and thoraco-dorsal nerve were not exposed even if a few suspicious LNs were removed, including targeted LNs and SLNs. Conventional ALND is defined as gross removal of most of the ALNs, with exposure of the axillary vein, long thoracic nerve and thoracodorsal nerve[18] (Fig. 3). Clinically, we defined AS as removal of a bunch of ALNs located around SLNs and targeted LNs, but without full exposure of the axillary vein, long thoracic nerve and thoracodorsal nerve. Pathologically, we defined AS as the removal of 5–10 ALNs.

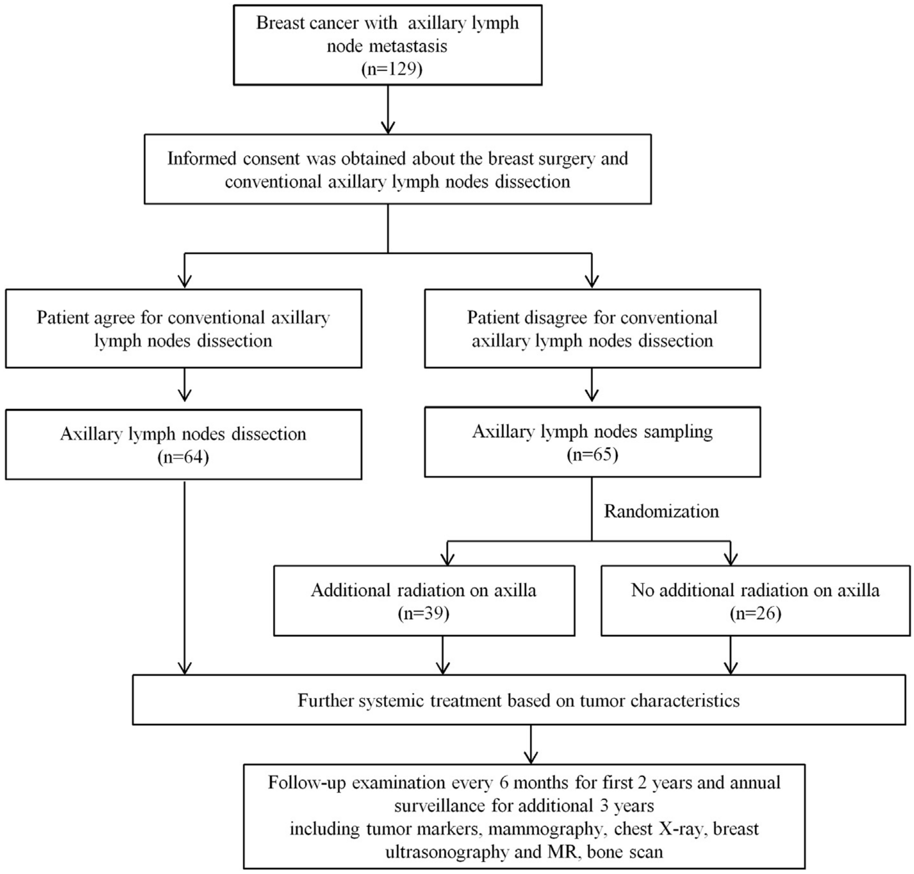

Figure 1 Flow chart showing management of breast cancer with axillary lymph node metastasis and follow-up protocol.

3. Results

The mean ± SD age of the ALND group was 48.5 ± 8.8 years compared with 52.7 ± 12.1 years in the targeted AS group (Table 1). In both groups, body mass index was similar and the most common tumor type was invasive ductal carcinoma. In the ALND group, the mean clinical and pathological tumor sizes were 2.1 ± 0.8 and 1.9 ± 0.7 cm, respectively. In the targeted AS group, the corresponding sizes were 2.2 ± 1.5 and 2.1 ± 1.2 cm, respectively. The mean hospital stay was significantly longer in the ALND group ($p = 0.046$). Although the mean number of metastatic ALNs was similar in both groups, the mean number of LNs removed was significantly higher in the ALND group ($p < 0.001$). Overall stage and tumor characteristics did not differ significantly between the groups. There was one case of local recurrence in the ipsilateral breast in both groups. During 5-years follow-up, the oncological results did not differ significantly between the groups.

Mean age, body mass index, and tumor types did not differ significantly between the targeted AS only and targeted AS with radiotherapy groups (Table 2). The mean clinical and pathological tumor sizes were 2.5 ± 1.3 and 2.1 ± 0.9 cm, respectively, in the targeted AS only group and 2.3 ± 1.6 and 2.2 ± 1.4 cm, respectively, in the targeted AS with radiotherapy group. T stages were all included in pT1-2 and the overall stage, tumor characteristics did not differ significantly between the groups.

The disease-free interval was 62.3 ± 21.2 months in the targeted AS only group and 59.7 ± 27.7 months in the targeted AS with radiotherapy group. There was one case (2.6%) of local recurrence and two deaths (5.1%) in the targeted AS with radiotherapy group. Distant metastasis occurred in one case (3.8%) in the targeted AS only group and in three cases (7.7%) in the targeted AS with radiotherapy group, although this difference was not significant.

4. Discussion

For many years, ALND was the only management option to evaluate breast cancer metastasis and treat ALNs.[4,19] However, ALND is associated with high morbidity, including postoperative seroma, shoulder movement restriction, axillary paresthesia, and lymphedema.[20–23]

A new concept of axillary management, SLNB, replaced ALND for axillary staging and management in the late 1990s.[24–26] This method was an innovative procedure to reduce postoperative morbidity, including pain, numbness and lymphedema. However, ALND was still performed when metastasis was diagnosed in SLNs and patients frequently had several complications. Recently, the question arose as to whether ALND should be performed in breast cancer with only 1–3 metastatic LNs, and changes in axillary management were recommended by the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial.[27,28] Since

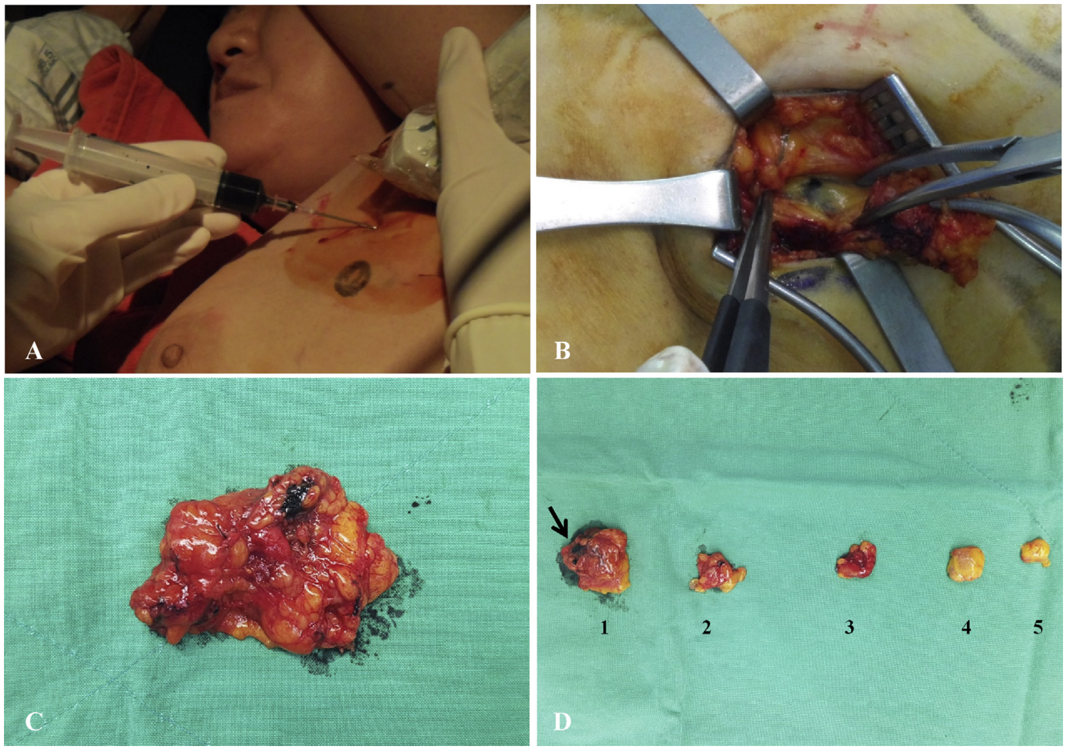

Figure 2 Targeted AS procedure. (A) Before surgery, a radiologist injected 1.5 ml-charcoal tracer under sonographic guidance at the side of the suspicious LN. (B) During surgery, an incision was made on the skin overlying the suspicious LN and the surgeon followed the tract of the injected dye. AS was performed, including the tattooed and sentinel LNs. (C) LNs removed by targeted AS. The stained LN was removed with part of the surrounding tissue. (D) Five fat-trimmed axillary LNs. The first LN was stained by tattoo ink and blue dye. A small amount of ink was found at the cortical side of the LN (arrow). The second and third LNs were sentinel LNs and stained with blue dye. The fourth and fifth LNs were not stained with charcoal or blue dye and were classed as non-sentinel LNs. AS, axillary sampling; LN, lymph node.

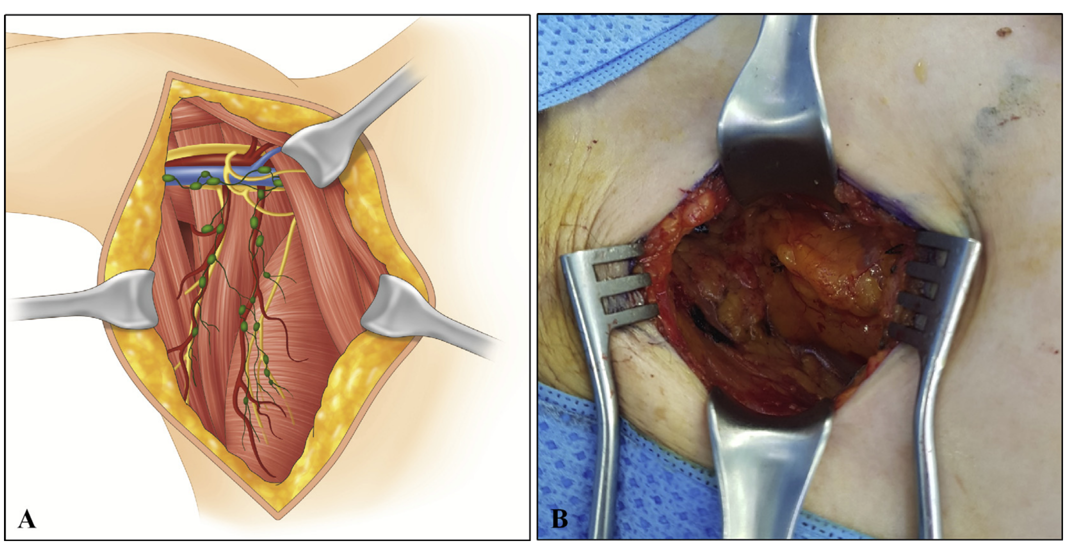

Figure 3 Gross views after surgery for ALNs. (A) After conventional ALN dissection, the axillary vein is exposed superiorly and the long thoracic nerve and thoracodorsal nerve are exposed medially and laterally, respectively. (B) After targeted axillary sampling, the axillary vein, long thoracic nerve and thoracodorsal nerve are not fully exposed, even if a bunch of ALNs are removed. ALN, axillary lymph node.

then, many physicians have considered resection of only a few metastatic LNs by AS, SLND, or partial or limited ALND.[7–11]

Although AS can significantly reduce postoperative complications, many surgeons still cannot fully accept the procedure because of the lack of evidence for its

Table 1 Clinical characteristics and oncologic outcomes of patients with pN1 breast cancer who underwent the axillary lymph nodes dissection or targeted axillary sampling.

	Axillary lymph nodes dissection (n = 64)	Targeted axillary sampling (n = 65)	p-value
Age (mean ± SD, years)	48.5 ± 8.8	52.7 ± 12.1	0.053
Body mass index (mean ± SD, kg/m^2)	24.4 ± 3.0	24.3 ± 3.3	0.762
Types of tumor (n, %)			0.149
Invasive ductal carcinoma	62 (96.9)	59 (90.8)	
Invasive lobular carcinoma	1 (1.6)	4 (6.2)	
Mucinous carcinoma	1 (1.6)	1 (1.5)	
Metaplastic carcinoma	0	1 (1.5)	
Clinical tumor size (mean ± SD, cm)	2.1 ± 0.8	2.2 ± 1.5	0.327
Pathologic tumor size (mean ± SD, cm)	1.9 ± 0.7	2.1 ± 1.2	0.198
Hospital stay (mean ± SD, days)	12.3 ± 3.2	8.1 ± 4.1	0.046
No. of metastatic lymph nodes (mean ± SD)	1.6 ± 0.7	1.6 ± 0.8	0.772
No. of removed lymph nodes (mean ± SD)	19.6 ± 5.7	7.7 ± 1.8	<0.001
Pathologic stage (n, %)			0.177
IIA	44 (68.8)	36 (55.4)	
IIB	20 (31.3)	25 (38.5)	
IIIA	0	4 (6.2)	
Estrogen receptor positivity (n, %)	47 (73.4)	42 (64.6)	0.518
Progesterone receptor positivity (n, %)	43 (67.2)	40 (61.5)	0.944
c-erbB2 protein positivity (n, %)	5 (7.8)	7 (10.8)	0.409
Triple negative breast cancer (n, %)	9 (14.1)	11 (16.9)	0.158
Adjuvant chemotherapy (n, %)	58 (90.6)	49 (75.4)	0.061
Adjuvant radiotherapy on axilla (n, %)	0	39 (60.0)	<0.001
Adjuvant hormonal therapy (n, %)	46 (71.9)	53 (81.5)	0.197
Mean follow-up period (mean ± SD, months)	73.1 ± 15.0	65.7 ± 21.7	0.726
Mean disease-free interval (mean ± SD, months)	70.0 ± 17.2	61.2 ± 25.7	0.602
Local recurrence (n, %)	1 (1.6)	1 (1.5)	0.991
Distant metastasis (n, %)	3 (4.7)	4 (6.2)	0.716
Expired (n, %)	1 (1.6)	2 (3.1)	0.572

oncological results. Many studies of AS have been reported but the definition of the procedure is still not clear. This problem may prevent accurate comparison of each study and the results may not be reliable. We tried to define AS in clinical and pathological terms through multidisciplinary team discussion and by comparing the oncological results with those of conventional ALND. Targeted AS involves removal of a bunch of ALNs including targeted LNs and SLNs. However, surgeons cannot distinguish how many LNs are actually contained in the specimen. Therefore, we focused upon the fact that the axillary vein, long thoracic nerve and thoracodorsal nerve are fully exposed in conventional ALND. We defined targeted AS clinically as removal of a bunch of LNs containing targeted LNs and SLNs but without full exposure of the axillary vein, long thoracic nerve and thoracodorsal nerve. Although we also provided a pathological definition of targeted AS, the extent of resection that is performed by surgeon is the most important factor in determining the name of surgical procedure. Therefore, whether additional treatment is required should be determined when the clinical definition of targeted AS has been established.

SLNB should be performed even if the suspicious LN is targeted with charcoal injection, because the concordance rate between SLNs and targeted suspicious LNs is 92–97%.[29–31] The incidence of complications is higher in cases of axillary recurrence, even if the isolated axillary recurrence rate is only 1% in breast cancer. Overall survival is not generally affected by axillary recurrence if appropriate management is applied at the time of recurrence.[32–34] In a recent study, the local recurrence rate was only 1.6% and there was no axillary recurrence. In the present study, there was no significant difference in oncological results between AS with and without axillary radiotherapy. However, these results were only based on 5-years follow-up data, so further follow-up should be conducted.

There are several limitations in our study. First, the population was relatively small and all data were from only a single center. However, the reliability would be high because the operations were conducted by four different surgeons and the follow-up period was more than five years. Second, the definition of AS is still ambiguous to perform an accurate comparative study. However, we focused not only on the oncological outcomes of 5-year follow-up but also on forming a definition of targeted AS. Although there are several reports about targeted AS procedures, clear definition is still lacking. As a result, the technical or oncological safety cannot be compared accurately. Because the anatomical structure of the axillary

Table 2 Clinical characteristics and oncologic outcomes of patients with pN1 breast cancer who underwent the targeted axillary sampling with or without axillary radiation.

	Targeted axillary sampling only (n = 26)	Targeted axillary sampling with radiotherapy on axilla (n = 39)	p-value
Age (mean ± SD, years)	55.5 ± 10.1	51.5 ± 12.8	0.236
Body mass index (mean ± SD, kg/m^2)	24.5 ± 3.7	24.1 ± 2.9	0.622
Types of tumor (n, %)			0.401
Invasive ductal carcinoma	22 (84.6)	37 (94.9)	
Invasive lobular carcinoma	4 (15.4)	0	
Mucinous carcinoma	0	1 (2.6)	
Metaplastic carcinoma	0	1 (2.6)	
Clinical tumor size (mean ± SD, cm)	2.5 ± 1.3	2.3 ± 1.6	0.658
Pathologic tumor size (mean ± SD, cm)	2.1 ± 0.9	2.2 ± 1.4	0.718
No. of metastatic lymph nodes (mean ± SD)	1.5 ± 0.6	1.6 ± 1.0	0.896
No. of removed lymph nodes (mean ± SD)	7.9 ± 1.8	7.5 ± 1.8	0.343
Pathologic stage (n, %)			0.454
IIA	12 (46.2)	24 (61.5)	
IIB	13 (50.0)	12 (30.8)	
IIIA	1 (3.8)	3 (7.7)	
Estrogen receptor positivity (n, %)	17 (65.4)	26 (66.7)	0.147
Progesterone receptor positivity (n, %)	14 (53.8)	26 (66.7)	0.770
c-erbB2 protein positivity (n, %)	4 (15.4)	3 (7.7)	0.374
Triple negative breast cancer (n, %)	5 (19.2)	6 (15.4)	0.803
Adjuvant chemotherapy (n, %)	21 (80.8)	28 (71.8)	0.419
Adjuvant hormonal therapy (n, %)	18 (69.2)	35 (89.7)	0.057
Mean follow-up period (mean ± SD, months)	63.5 ± 20.6	62.6 ± 26.1	0.490
Mean disease-free interval (mean ± SD, months)	62.3 ± 21.2	59.7 ± 27.7	0.416
Local recurrence (n, %)	0	1 (2.6)	0.324
Distant metastasis (n, %)	1 (3.8)	3 (7.7)	0.509
Expired (n, %)	0	2 (5.1)	0.160

area and the number of LNs after targeted AS vary among patients, we defined targeted AS in clinical and pathological terms. Third, we included only the patient who underwent breast conserving surgery or partial mastectomy followed by receiving conventional breast radiotherapy which includes some area of axillar and the patient had less than three metastatic lymph nodes. Therefore, this surgical technique should be carefully applied to those patients with pre-described conditions.

5. Conclusion

The 5-year oncological outcomes of targeted AS in our study were not inferior to those of conventional ALND, regardless of whether additional radiotherapy was applied. However, the AS can be only applied limited population and further follow-up of oncological results and long-term complications should be evaluated to demonstrate the usefulness of targeted AS.

Conflict of interest

There is no conflict of interest.

Acknowledgments

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.asjsur.2018.10.004.

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