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ORIGINAL ARTICLE – BREAST ONCOLOGY

Second Axillary Sentinel Lymph Node Biopsy for Breast Tumor Recurrence: Experience of the European Institute of Oncology

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ABSTRACT

Purpose. This retrospective study aimed to determine the feasibility, accuracy, and recurrence rates of lymphoscintigraphy and the new sentinel lymph node biopsy (SLNB) for patients with ipsilateral breast tumor recurrences who were treated previously with conservative surgery and had negative SLNB results.

Methods. The study was conducted at the European Institute of Oncology in Milan and included 212 patients with the diagnosis of operable local breast cancer recurrence. They had been treated previously with conservative surgery and showed negative SLNB results. They subsequently underwent additional breast surgery and a second SLNB between May 2001 and December 2011.

Results. Preoperative lymphoscintigraphy demonstrated at least one new axillary sentinel lymph node (SLN) in 207 patients (97.7 %), whereas no drainage was observed in five patients (2.3 %). One or more SLNs were surgically removed from 196 of the 207 patients. Isolation of SLNs from the remaining 11 patients could not be accomplished. The success rate for the SLNB was 92.5 %. Extra-axillary drainage pathways were visualized in 17 patients (8 %). The annual axillary recurrence rate after a median follow-up period of 48 months was 0.8 %, and the cumulative incidence of axillary recurrence at 5 years was 3.9 %.

Conclusions. A second SLNB should be considered for patients with operable local breast tumor recurrence who underwent conservative surgery and had negative SLNB results. The procedure is technically feasible and accurate for selected patients.

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Sentinel lymph node biopsy (SLNB) is the standard technique for axillary staging of patients with primary operable breast cancer and a clinically negative axilla because it avoids unwarranted axillary dissection and consequently reduces postoperative morbidity.[1–3] With widespread use of breast-conserving surgery (BCS) and increased accuracy of diagnostic imaging techniques, the rate of ipsilateral breast tumor recurrence (IBTR) within 10 years after BCS has been minimized to approximately 5–10 %.[4,5] However, optimum management of the axilla in IBTR patients previously treated with BCS who had negative SLNBs remains controversial.

In a recent update of the American Society of Clinical Oncology (ASCO), the indications for SLNB for patients with early-stage breast cancer definitively were broadened. The guidelines indicate the feasibility and acceptable accuracy of SLNBs for patients who have undergone prior nononcologic axillary surgery, as corroborated by retrospective data.[6] However, no recommendations are made for patients who have previously undergone SLNB or ALND as a part of conservative breast cancer management. Therefore, ALND still is commonly used as the standard axillary treatment for IBTR after lumpectomy and negative SLNB results.[7] However, several studies have convincingly demonstrated acceptable second SLNB success rates and high

TABLE 1 Characteristics and results from the largest studies (≥15 patients) of second sentinel lymph node biopsies for patients with ipsilateral breast tumor recurrences after previous breast-conserving surgery and sentinel node biopsy

Author (year)	*n*	Median follow-up after sSLNB (mos)	Success rate of sSLNB % (*n*)	Percentage of extra-axillary drainages % (*n*)	No. of axillary recurrences *n* (%)
Port et al.[10] (2007)	54	26	74.1 (40/54)	5.5 (3)	0
Cox et al.[12] (2008)	56	26	80.4 (45/56)	2.2 (1)	0
Schrenk et al.[16] (2008)	15	–	80 (12/15)	14.3 (2)	–
van der Ploeg et al.[11] (2010)	36	39	72.2 (26/36)	47 (17)	0
Maaskant-Braat et al.[17] (2013)	41	–	53.7 (22/41)	25 (10/41)	–
Intra et al.[8] (2014)	212	48	92.5 (196/212)	8 (17)	7 (3.3)

n number of patients, *sSLNB* second sentinel lymph node biopsy

identification rates of subsequent SLN for patients with previous negative SLNB results.[8–15]

To date, five retrospective studies of 15 or more IBTR patients previously managed with BCS and SLNBs have been published, demonstrating a variable rate of success for the second SLNB ranging from 72.2 to 80.4 %[10–12,16,17] (Table 1). A recent meta-analysis of 26 articles and case reports and one published abstract regarding repeated SLNBs for 692 patients with locally recurrent breast cancer showed high success rates for SLNB used for lymphatic mapping, identification of SLN, and acceptable identification of extra-axillary drainage for patients with previous axillary surgery.[18]

In the current study, the feasibility and accuracy of lymphoscintigraphy and a second SLNB, the percentages and types of extra-axillary drainage, and recurrence rates were investigated in 212 patients with IBTR and previous negative SLNBs. This study aimed to clarify whether second SLNB procedures are safe and feasible in selected cases of IBTR, to evaluate the accuracy of second SLNBs according to the number of axillary recurrences observed during the follow-up period, and to report long-term outcomes in terms of recurrence for patients with IBTR who underwent a second SLNB.

MATERIAL AND METHODS

Patient Population and Study Parameters

The medical records of 212 IBTR patients previously treated with BCS who had negative SLNB results in their initial management between 1998 and 2010 were retrospectively analyzed. Of these patients, 185 had been treated at the European Institute of Oncology (EIO), and 27 had been treated elsewhere. All the patients had been treated for IBTR at the EIO between May 2001 and December 2011.

At the initial surgery, the diagnosis for 185 patients (87 %) was invasive breast cancer, and the diagnosis for 27 patients (13 %) was ductal intraepithelial neoplasia (DIN). The patients who underwent mastectomy as a primary intervention, irrespective of the type of axillary surgery performed, those with clinical evidence of metastasis at the IBTR diagnosis, and those treated with ALND at the first surgery were excluded from the current analysis and will be subjects of future investigations.

For the purpose of this study, IBTR was defined as biopsy-proven reappearance of DIN or invasive cancer in preserved ipsilateral breasts. After a median period of 4.1 years (range, 0.4–11.4 years), 191 patients (90 %) with invasive breast tumor recurrence and 21 patients (10 %) with DIN recurrence were offered a second SLNB. The patients agreed to the procedure and gave informed consent.

The demographic, clinical, and treatment-related variables included age at recurrence, histopathologic characteristics of primary and recurrent breast tumors, pathologic status of the first and second sentinel lymph nodes (SLNs), number of removed SLNs at both surgeries, time from primary intervention to IBTR, type of surgery, and type of radiation therapy delivered. To evaluate the feasibility of second SLNBs, success rates of the second lymphoscintigraphy, intraoperative identification of the second SLN, and percentage of extra-axillary drainages were considered.

Breast Cancer Treatment

The locoregional management of primary breast tumors consisted of lumpectomy–quadrantectomy and SLNB. Local recurrences were managed with conservative surgery or mastectomy and a second SLNB. The decision between BCS and mastectomy was carefully considered, with patient preference and other clinical features such as tumor location, tumor size, and breast size taken into account.

According to institutional protocols, the patients underwent complete ALND only when macrometastases were identified in SLNs. No further axillary surgery was performed for patients with negative SLNs, isolated tumor cells (ITCs) only, or micrometastases in SLNs. Systemic adjuvant therapies were chosen by using a multidisciplinary approach considering prognostic and predictive factors. A

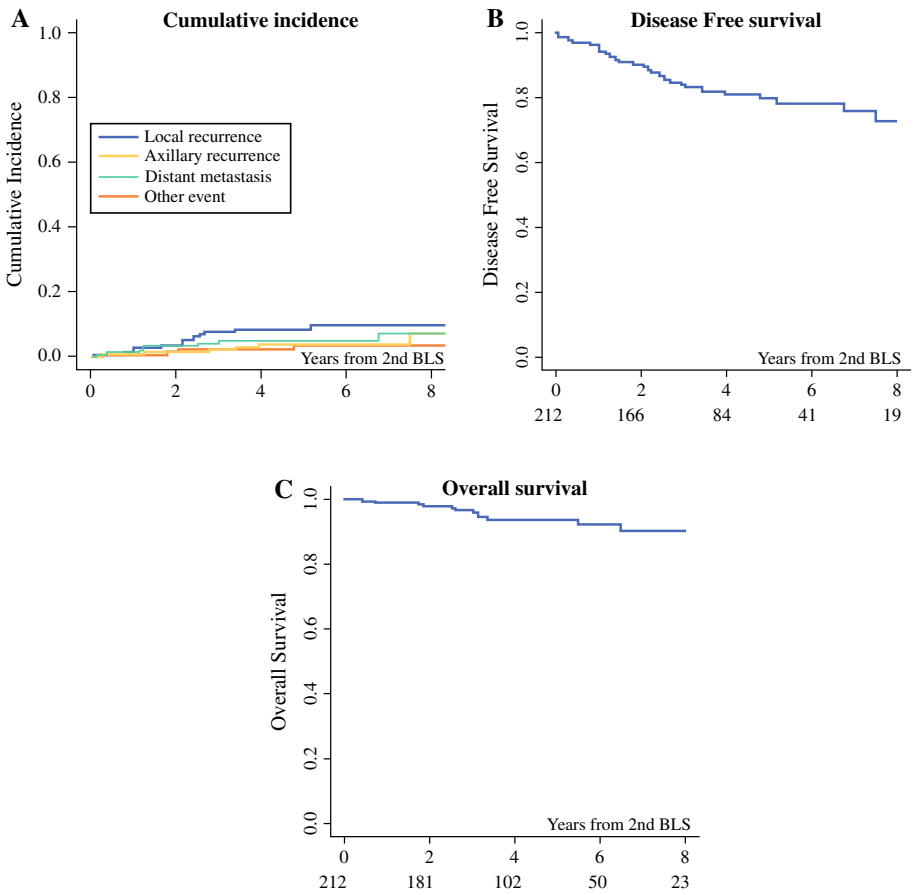

FIG. 1 Cumulative incidence of local recurrence, axillary recurrence and distant metastasis; disease free survival; overall survival after second sentinel node biopsy

total of 201 patients (185 with invasive carcinoma and 16 patients with grade 2 or 3 DIN) had received adjuvant radiotherapy at a standard dosage after their initial surgery. For 66 patients with a diagnosis of invasive BC, a full dose of intraoperative radiotherapy (corresponding to 21 Gy) was delivered, and four patients received a boost of intraoperative radiation therapy followed by external irradiation. For 11 patients with low-grade DIN, radiotherapy had not been performed.

All the patients were clinically examined at 6-month intervals and underwent annual mammography with or without ultrasonography. All the patients were followed up for at least 1 year after the second surgery.

Breast Cancer Outcomes

We noted local and axillary failures, distant metastases (as first events), and patient deaths from medical records. Causes of death were categorized as breast cancer, other malignant tumors, and unknown cause. Overall survival (OS), disease-free survival (DFS), and cumulative incidence of local relapse, axillary recurrence, distant metastasis, and other events at 5 years were assessed (Fig. 1).

Lymphoscintigraphy and Histopathologic Examination of SLNs

Lymphoscintigraphy was performed according to previously reported standard techniques.[1,8] All the patients were injected with less than 80 nm of human ^{99m}Tc-labeled albumin nanocolloids (Nanocoll; Nycomed Amersham-Sorin, Saluggia, VC, Italy, and Nanoalbumon; Radiopharmacy Laboratory Ltd., Budaörs, Hungary) 1 day before surgery, with a median activity of 20 MBq in a volume of 0.2 ml. The injection type (subdermal or peritumoral) was selected according to the depth of the tumor. Planar scintigraphic scans of involved breasts and axillary regions were obtained 15–30 min after administration of the radiotracer, and delayed images were acquired where necessary.

At 2–20 h after the injection, SLNBs were performed, and an intraoperative gamma ray detection probe (Neoprobe 2000; Ethicon, Somerville, NJ, USA) was used during surgery to confirm locations of the sentinel nodes and to facilitate their removal. All nodes that had absorbed the radiotracer were removed and sent for histopathologic examination. All SLNs removed in the first and second procedures were examined as frozen sections according to previously described standard techniques.[1]

TABLE 2 Clinicopathologic features of patient groups

Variable	Primary tumor (1st surgery)	Breast tumor recurrence (2nd surgery)
No. of patients	212	212
Type of second surgery		
BCS and SLNB	212	110
Mastectomy and SLNB	–	102
Mean tumor size (cm)	1.3	1.1
Histologic SLN status		
Macrometastasis	0	25
Micrometastasis	14	8
ITC	2	1
Negative	196	178
No. of LNs removed		
0	0	11
1	126	136
2	53	43
3+	33	17
Histologic subtype		
Invasive ductal carcinoma	149	158
Invasive lobular carcinoma	18	19
Mixed carcinoma	4	3
Other invasive tumors	14	11
DIN	27	21
Grade		
1	23	10
2	97	51
3	77	48
Unknown	15	103
ER/PgR status		
Negative/negative	54	72
Positive/negative	26	45
Positive/positive	128	92
Unknown	4	3
HER2 status		
Positive	44	54
Negative	153	149
Missing	15	9
Ki67		
<20	86	71
>20	119	133
Missing	7	8

BCS breast-conserving surgery, *SLNB* sentinel lymph node biopsy, *ITC* isolated tumor cells, *LNs* lymph nodes, *DIN* ductal intra-epithelial neoplasia, *ER* estrogen receptor, *PgR* progesterone receptor

Statistical Analysis

Exact 95 % confidence intervals (CIs) of proportions and rates were calculated using binomial and Poisson methods. The evaluated breast cancer end points included cumulative incidence of local, axillary, and distant recurrence as well as DFS, and OS. DFS was defined as the period from the second SLNBs to the first relapse including ipsilateral breast recurrence, contralateral breast cancer, appearance of second primary cancers, and death. OS was defined as the period from the second SLNBs until death from any cause. The causes of death were categorized as breast cancer, other malignant tumors, and unknown cause. Cumulative incidence functions were estimated according to the methods described by Kalbfleisch and Prentice, with competing causes of recurrence taken into account.[19] Estimates of DFS and OS functions were performed using the Kaplan-Meier method. All analyses were performed using SAS software (SAS Institute, Cary, NC, USA).

RESULTS

Patient Population and Tumor-Related Characteristics

The clinical and histopathologic characteristics of the primary and recurrent tumors are listed in Table 2. As management for the recurrent tumors, mastectomy and a second conservative surgery were performed for 102 and 110 patients, respectively. Complete ALND was performed for 25 patients with macrometastatic SLNs. Second SLNBs were negative for 178 patients, and micrometastasis disease was identified in eight sentinel nodes. In one patient, ITCs were visualized in the sentinel node. Invasive and DIN relapses developed at recurrence for respectively 191 (90 %) and 21 patients (10 %). The median time between first surgery and IBTR was 4.1 years (range, 0.4–11.4 years). The mean tumor size was 1.3 cm for the primary tumors and 1.1 cm for the IBTRs. The average number of nodes removed at first surgery was 1.7 (range, 1–7 nodes), and only 33 patients (16 %) had three or more lymph nodes removed.

Feasibility of Second Sentinel Node Biopsy Technique

For 207 of the 212 patients with IBTR, preoperative lymphoscintigraphy demonstrated at least one new axillary SLN (1 in 128 patients, 2 in 47 patients, and 3 or more in 25 patients). In 17 patients (8 %), additional extra-axillary aberrant drainages were observed in the contralateral axilla, intramammary, interpectoral, and internal mammary regions and in the infraclavicular fossa (Table 3). Aberrant drainage pathways were not routinely dissected. Only those accessible during surgery were removed. No metastases were found in the dissected aberrant drainages.

Lymphoscintigraphy failed to identify any SLNs in five patients (2.3 %) but was successful for 207 patients (97.7 %; 95 % CI, 94.6–99.2 %). Successful SLN biopsies

TABLE 3 Sites and numbers of patients with aberrant drainage at second lymphoscintigraphy

Site of aberrant drainage	*N*
Contralateral axilla	6
Intramammary	4
Interpectoral region	4
Internal mammary	2
Infraclavicular fossa	1
Total	17

were performed for 196 of the 207 patients in whom lymphoscintigraphy identified at least one SLN. Isolation of SLNs from the remaining 11 patients could not be accomplished. In the vast majority of the patients (87 %), one or two SLNs were identified and removed. In 17 patients (8 %), three or more SLNs were identified at surgery, for an identification rate of 94.7 % (95 % CI, 90.7–97.3 %).

Breast Cancer Outcomes

After a median follow-up period of 48 months (range, 2–144 months; 95 % CI, 0.3–1.7 months), the annual axillary recurrence rate was 0.8 %. The cumulative incidence of local recurrence at 5 years was 8.3 % (95 % CI, 4.2–12.4 %), whereas the incidences of axillary recurrence, distant metastases, and other events were respectively 3.9 % (95 % CI, 0.7–7.0 %), 4.7 % (95 % CI, 1.7–7.8 %), and 3.2 % (95 % CI, 0.2–6.3 %). Distant metastases occurred in ten patients (annual rate, 1.2 %; 95 % CI, 0.6–2.2 %). Of these metastases, four were in bones, two were in the liver, three were multiple metastases, and one was of unknown location.

In the entire cohort, 39 events were identified including breast-related events, second primary cancers, and deaths from other causes as the first event, with an annual event rate of 4.6 % (95 % CI, 3.4–6.3 %). The 5-year DFS rate was 79.9 % (95 % CI, 72.7–85.3 %). Overall, 12 of 212 patients (5.7 %) died after the second procedure (ten of breast cancer and two of unknown causes), for an annual mortality rate of 1.3 % (95 % CI, 0.7–2.2 %). The 5-year OS was 93.9 % (95 % CI, 88.8–96.7 %).

DISCUSSION

The main argument against second SLNB is that lymphatic channels and drainages are considered to be disrupted due to fibrosis after axillary surgery and radiotherapy, with potentially serious effects on lymphatic mapping at the time of recurrence.[15,20–23] However, after the disruption of lymphatic channels, a physiologic restoration of the axilla's drainage anatomy (and that of other extra axillary locoregional nodes) occurs, rendering the aforementioned obstacle only temporary. Thus, the time between the first axillary surgery and the recurrence enables restoration of the lymphatic net, with new lymphatic bridges connecting the breast with the surgically managed axilla. This postoperative collateralization of lymphatics occurs as a physiologic compensatory mechanism, and new lymphatic pathways allow identification of novel SLNs as indicative of new tumors as the first SLN was for the first tumor. Thus, the logical argument against a second SLNB may paradoxically also be a strong argument in its favor, introducing a more dynamic concept of SLN: from "one SLN forever" to "always a new SLN."[8,10,24]

It is important to standardize the period between the first negative SLNB and the IBTR so that true second SLNs can be identified on lymphoscintigraphy. However, early recurrences (within the first 6 months) are conventionally considered as residual disease from the first tumor rather than true recurrences. In these cases, the first SLN retains its predictive value for both the first tumor and the early recurrence, and a second SLNB might not be indicated.

The percentage of aberrant lymph drainage pathways outside the ipsilateral axilla in patients with previous BCS and SLNBs is 2.2–47 %,[10–12,16,17] indicating a central role of preoperative lymphoscintigraphy for these patients. Although the rate of extra-axillary lymphatic drainage was quite low (8 %) in the current study, we recommend routine use of lymphoscintigraphy for SLNB.

In a prospective study of 44 patients with recurrent breast cancer by Axelsson and Jonsson,[14] preoperative lymphoscintigraphy showed SLNs in 51 % of the patients. At the time of intervention, SLNs were located in 20 (45 %) of the 44 patients, corresponding to 83 % of patients with positive lymphoscintigraphy.

To determine success rates for second SLNBs, both intraoperative identification of sentinel nodes and success rates for the second lymphoscintigraphy must be considered. However, in the absence of preoperative visualization of SLN on lymphoscintigraphy, our institutional policy is to consider axillary dissection only after a careful evaluation of all patient and tumor characteristics that increase axillary metastatic risk.

The median number of axillary lymph nodes removed in the first surgery may be the most important factor for successful identification of SLNs during the second surgical intervention. Two publications from the Memorial Sloan-Kettering Cancer Center addressed the issue of second SLNBs in locally recurrent breast cancers. The authors of the first study[9] reported an overall SLN identification rate of 75 %. In contrast, the second paper,[10] which was an update of data from 117 patients with IBTR after BCS, reported an SLN identification rate of only 55 %,

possibly due to the inclusion of more patients with previous ALND. Second SLNBs failed for 39 (62 %) of 63 patients with previous ALND but for only 14 (26 %) of 54 patients with prior SLNBs ($p = 0.0002$). The authors concluded that the success rate for second SLNBs is inversely correlated with the number of lymph nodes removed at the first intervention and directly correlated with positive lymphoscintigraphy findings.[10]

A recent systematic review and meta-analysis of 26 articles by Maaskant-Braat et al.[18] analyzed 692 patients with locally recurrent breast cancer who underwent second SLNBs. Of these patients, 301 had undergone previous SLNBs, 361 had undergone ALNDs, and 30 had undergone no previous surgical staging. The overall identification rate was 65.3 % (452 of 692 patients), but the rate was significantly higher ($p < 0.0001$) for the patients who had undergone previous SLNBs (81.0 %, 243 of 301 patients) than for the patients who had undergone ALNDs (52.2 %, 166 of 318 patients). Aberrant drainage pathways were visualized in 43.2 % of these patients, which tended to be more frequent after ALND. The current study included only patients who had received a combination of BCS and SLNBs and showed a higher SLN identification rate.

CONCLUSIONS

The current study demonstrates an apparent rational basis for performing second SLNBs for IBTR patients previously treated with BCS who had negative SLNB results. The lymphoscintigraphic technique enables the most appropriate preoperative selection of patients for axillary and extra-axillary SLNB or ALND, thereby enabling optimal surgical programming and adequate preparation of patients.

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