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An Investigation to Identify the Factors for Negative Sentinel Lymph Node Metastasis in Early Breast Cancer Cases

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Background

Sentinel Lymph Node Biopsy (SLNB) in breast cancer is a standard procedure used to determine whether breast cancer has spread to the axillary lymph nodes. It has replaced full axillary lymph node dissection (ALND) in early-stage clinically node-negative breast cancer patients. However, SLNB is associated with some rare complications such as pain, seroma and lymphedema. Omission of SLNB in breast cancer is an evolving area in clinical practice. In selected patient populations, omitting SLNB may be a safe and reasonable option. To identify cases in which SLNB was negative, we conducted a retrospective study using early breast cancer data from our hospital registry.

Patients and Methods

1. A total of 2,589 breast cancer patients underwent SLNB between June 2016 and April 2025. Of these, 1,956 cases of clinically node negative (cN0) invasive breast cancer who did not undergo preoperative chemotherapy were included in this retrospective study.
2. Table 1 shows the patient characteristics. Patients over 50 years of age accounted for 70.7%, and 77.5% had a tumor diameter of ≤2 cm detected by an ultrasound (US). The cases with ER ≥1% and PgR ≥1% were 90.3% and 80.7%, respectively. In terms of the HER2 status, HER2-low accounted for 60.1%.
3. Pathological diagnosis using frozen section or one-step nucleic acid amplification (OSNA) method was used for the diagnosis of SLNs.
4. The disease-free survival (DFS) was calculated using the Kaplan-Meier method and analyzed using the log-rank procedure. The median follow-up period was 44.3 months after operation.
5. Multivariate analysis of factors for negative SLN were performed using logistic regression analysis.

Table 1. Clinicopathological Characteristics in All patients

Age (years)	≤ 50	573 (29.3)
	> 50	1383 (70.7)
Tumor size by Ultrasound	≤ 2cm	1516 (77.5)
	>2cm	398 (20.3)
	Unknown	42
ER expression	< 1%	182 (9.3)
	≥1%	1767 (90.3)
	Unknown	7
PgR expression	< 1%	370 (18.9)
	≥1%	1579 (80.7)
	Unknown	7
HER2 status	Negative	540 (27.6)
	Low	1175 (60.1)
	Positive	199 (10.2)
	Unknown	42
Ki-67 index value	< 15%	877 (44.8)
	≥15%	948 (48.5)
	Unknown	131
Histological Grade	1	825 (42.2)
	2	632 (32.3)
	3	274 (14.0)
	Unknown	225
Surgical Procedure	Breast Conserving Surgery	959 (49.0)
	Total Mastectomy	997 (51.0)
Total		1956

Results

Figure 1. An overview of SLNB in all cases
The number of SLNs examined ranged from 1 to 7, with a median of 2.0 nodes. Metastasis to the SLNs was observed in 379 cases (19.4%) including micro-metastasis. The median number of metastatic SLNs was 1.0. Of cases with positive metastatic SLNs, 334 cases (17.1%) received ALND. Ultimately, metastasis beyond the SLNs was recognized in 106 cases (5.4%).

Table 2. Metastasis to the SLNs and the clinicopathological characteristics
Metastasis to the SLNs significantly correlated with age, tumor size, Ki-67 index value, HG, and surgical procedure. There was a significantly higher metastatic rate to the SLNs in patients ≤50 years of age, tumors >2 cm, a Ki-67 index value ≥15%, a HG of 2-3, and those who underwent total mastectomy.

Fig. 1. An overview of SLNB in all cases

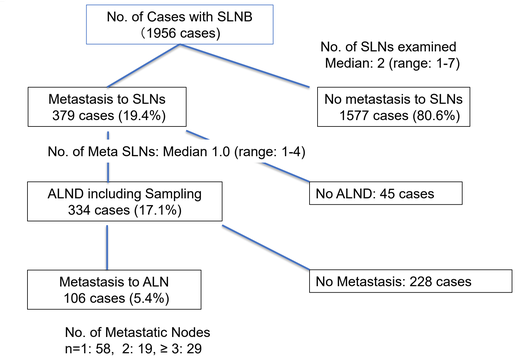


Table 2. Metastasis to the SLNs and the clinicopathological characteristics

Variable	Category	Metastasis to SLN		Total	p value
		Negative	Positive		
Age (years)	≤ 50	442 (77.1)	131(22.9)	573	0.008
	> 50	1135 (82.1)	248(17.9)	1383	
Tumor size	≤ 2cm	1269 (83.7)	247 (16.3)	1516	<0.001
	>2cm	272 (68.3)	126 (31.7)	398	
ER expression	< 1%	154 (84.6)	28 (15.4)	182	0.146
	≥1%	1416 (80.1)	351 (19.9)	1767	
PgR expression	< 1%	305 (82.4)	65 (17.6)	370	0.31
	≥1%	1265 (80.1)	314 (19.9)	1579	
HER2 status	Negative	424 (78.5)	116 (21.5)	540	0.418
	Low	948 (80.7)	227 (19.3)	1175	
	Positive	164 (82.4)	35 (17.6)	199	
Ki-67 index value	< 15%	740 (84.4)	137 (15.6)	877	<0.001
	≥15%	718 (75.7)	230 (24.3)	948	
Histological grade	1	707 (85.7)	118 (14.3)	825	<0.001
	2	483 (76.4)	149 (23.6)	632	
	3	207 (75.5)	67 (24.5)	274	
Surgical procedure	BCS	820 (85.5)	139 (14.5)	959	<0.001
	TM	757 (75.9)	240 (24.1)	997	

Results

Table3. Correlation between metastasis to SLNs, histological types, and subtypes
In the most common cases of invasive ductal carcinoma (IDC), the metastatic rate to SLNs was 19.9%, while cases of invasive micropapillary carcinoma and invasive lobular carcinoma showed significantly higher metastatic rates of 37.5% and 28.1%, respectively. The Luminal B type had a significantly higher metastatic rate of 25.1% compared to the Luminal A and TN subtypes.

Table 4. Multivariate analysis of factors for negative SLNs
The significant factors were age, tumor size, and HG, but only a marginal significant relationship was found in the Ki-67 index value, regardless of the presence or absence of a surgical procedure. Moreover, the surgical procedure was a significant factor for metastasis.

Figure 2. Disease-free survival in all cN0 and selected cN0 cases according to the SLN status
There was a significant difference in the postoperative 7-year DFS rate between SLN positive and negative cases in all cN0 cases. However, the DFS rate of cases >50 years of age, a tumor size of ≤2 cm, and a HG of 1 was favorable regardless of the presence or absence of SLN metastasis (99.5% for negative SLN and 100% for positive SLN).

Table3. Correlation between metastasis to SLNs, histological types, and subtypes

a) Histological types

Histological type	Metastasis to SLN		Total	p value (vs. IDC)
	Negative	Positive		
IDC	1260	313(19.9)	1573	-
ILC	87	34 (28.1)	121	0.031
Mucinous	105	15 (12.5)	120	0.048
Apocrine	13	1 (7.1)	14	0.23
IMPC	15	9 (37.5)	24	0.033
Intracystic	22	0 (0)	22	0.0196
Metaplastic	10	1 (9.1)	11	0.37
Microinvasive	40	2 (4.8)	42	0.015
Others	25	4 (13.8)	29	
	1577	379 (19.4)	1956	

b) Subtypes

Subtype	Metastasis to SLN		Total	p value (vs. Luminal B)
	Negative	Positive		
Luminal A	700 (84.0)	133 (16.0)	833	<0.001
Luminal B	571 (74.9)	191 (25.1)	762	-
Luminal/HER2	99 (81.8)	22 (18.2)	121	0.10
HER2 enriched	66 (82.5)	14 (17.5)	80	0.13
Triple negative	64 (85.3)	11 (14.7)	75	0.045
Unknown	77 (90.6)	8 (9.4)	85	
Total	1577	379	1956	

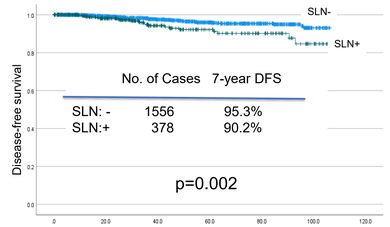
Results

Table 4. Multivariate analysis of factors for negative SLNs

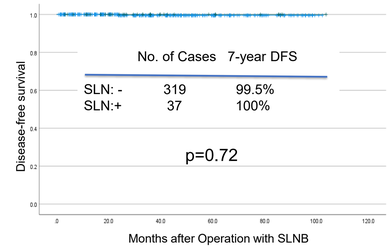
Variables	Category	p value	HR (95% CI)	p value	HR (95% CI)
Age (years)	≤50 vs >50	<0.001	0.618 (0.475 - 0.805)	<0.001	0.641 (0.493 - 0.833)
Ki-67 value (%)	<15% vs ≥15%	0.09	1.272 (0.963 - 1.680)	0.073	1.289 (0.977 - 1.701)
Tumor size (cm)	≤2.0 vs >2.0	<0.001	1.811 (1.345 - 2.438)	<0.001	2.093 (1.574 - 2.783)
Histological grade	1 vs 2, 3	0.006	1.490 (1.120 - 1.981)	0.003	1.530 (1.152 - 2.032)
Surgical procedure	BCS vs TM	0.001	1.556 (1.192 - 2.030)	–	–

Fig. 2. Disease-free survival in all cN0 and selected cN0 cases according to SLN status

a) All cN0 cases



b) Cases > 50 years of age, a tumor size of ≤ 2 cm, and a HG of 1



Conclusion

Metastasis to SLNs were found in 19.4% of the cN0 breast cancer cases. Factors related to negative SLN were age (≥50 years), tumor size (≤2 cm), HG of 1, and surgical procedure (BCS).
Moreover, the positive SLN rate was significantly higher in cases with the Luminal B subtype.
The prognosis for cases with the above predictive factors (age, tumor size, and HG) were satisfactory, and recurrences were rarely observed.
In the future, whether SLNB is required will depend on the above-mentioned patient characteristics.

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