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Omitting axillary lymph node dissection for sentinel-node macrometastases in a resource-limited region: a single-centre study

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Abstract

Background.

Axillary lymph node dissection (ALND) can be omitted in clinically node-negative patients with one or two sentinel lymph node (SLN) macrometastases who receive adjuvant radiotherapy, but safe implementation in resource-limited regions depends on local radiotherapy capacity. At a regional hospital in Fukushima, we quantified the residual nodal disease left by omitting completion ALND and the consequences of omitting intraoperative SLN diagnosis.

Methods.

In this single-centre retrospective study, residual nodal disease was assessed in clinically node-negative patients undergoing completion ALND for intraoperatively confirmed SLN macrometastasis before omission (n = 32). After omission, all clinically node-negative SLN-biopsy patients (n = 159) were reviewed for delayed completion ALND and adequacy of adjuvant axillary treatment, defined per AMAROS and SENOMAC as completion ALND or axillary-covering regional nodal irradiation (RNI). Analyses were descriptive.

Results.

Completion ALND removed additional metastatic nodes in 15 of 32 breasts (46.9%; three or more in 21.9%; mean 1.8). After omission, macrometastasis was identified in 18/159 patients (11.3%); 16 with two or fewer macrometastases had ALND omitted and only 2 with three required delayed completion ALND. Of the 18 macrometastasis-positive patients, 9 did not receive axillary-covering RNI (potentially undertreated): 4 owing to patient factors and 5 to insufficient surgical-radiation oncology coordination.

Conclusions.

Residual nodal disease is common but, consistent with ACOSOG Z0011 and SENOMAC, does not make omission of ALND inappropriate; it underscores that omission is justified only with adequate regional radiotherapy. Omitting intraoperative diagnosis rarely required reoperation. The principal challenge is care coordination to ensure axillary radiotherapy coverage, especially in resource-limited regions.

Introduction

The surgical management of the axilla in breast cancer has been progressively de-escalated. Sentinel lymph node (SLN) biopsy replaced routine ALND for staging the clinically node-negative axilla, with equivalent accuracy and survival and less morbidity [1, 2]. The question of whether a positive SLN requires completion ALND was then addressed by randomized trials. In clinically node-negative (cT1-2

N0) patients with one or two positive SLNs treated with breast-conserving surgery (BCS), whole-breast radiotherapy, and systemic therapy, ACOSOG Z0011 found no inferiority in locoregional recurrence or survival when completion ALND was omitted, even though additional positive nodes would have been found at ALND in about a quarter of patients [3–5]. AMAROS and OTOASOR showed that axillary radiotherapy provided regional control equivalent to ALND with less lymphedema [6–8], and SENOMAC extended the evidence for omission of completion ALND to mastectomy, T3 tumours, and extracapsular extension, with most patients receiving nodal irradiation [9, 10]. Current ASCO and Japanese Breast Cancer Society guidance supports omission of completion ALND for up to two positive SLNs in patients receiving adequate radiotherapy [11, 12].

Across this evidence, regional control formerly achieved by ALND is achieved instead by radiotherapy. Implementing this substitution safely requires multidisciplinary coordination among surgery, pathology, radiation oncology, and medical oncology — coordination that is more difficult to assemble in rural and resource-limited settings, where specialists are fewer, case volumes lower, and radiotherapy facilities more distant. The Hamadori region of Fukushima Prefecture, affected by the 2011 Great East Japan Earthquake and Fukushima Daiichi nuclear accident, exemplifies these constraints; reduced radiation-oncology and pathology capacity is directly relevant because the safety of omitting ALND depends on adequate radiotherapy. Reliable intraoperative SLN diagnosis was previously made feasible at our hospital, which has no full-time pathologist, through a telepathology system, the early performance of which has been reported [13].

Against this background, this single-centre study at a regional hospital in coastal Fukushima had two aims. The first was to quantify the residual nodal disease that omission of completion ALND leaves unresected — that is, how many metastatic nodes completion ALND removed in SLN macrometastasis-positive patients — and to interpret this in light of the randomized evidence. The second was to describe the consequences of omitting intraoperative SLN diagnosis, in particular the need for delayed completion ALND and the adequacy of the adjuvant axillary treatment that replaces surgery.

Patients and Methods

Setting and evolution of axillary management

Jyoban Hospital of the Tokiwa Foundation is a 240-bed regional core hospital on the Pacific coast of Fukushima. Its Breast and Thyroid Center, established in 2018, is the largest breast cancer unit in the region. Axillary management evolved over four steps, driven by the combination of local resource constraints and accumulating evidence. Local intraoperative imprint (stamp) cytology for rapid SLN assessment was introduced in 2018. Telepathology support for intraoperative SLN diagnosis, in the absence of an on-site pathologist, was added in 2019. Omission of completion ALND for ≤ 2 SLN macrometastases after BCS began in 2021, following Z0011 and AMAROS. Finally, omission was extended to mastectomy and intraoperative SLN rapid diagnosis was concurrently omitted in 2024, following SENOMAC and the updated guidelines.

Study design and cohorts

This was a single-centre retrospective study using two cohorts. The pre-omission cohort, used to quantify residual nodal disease, comprised clinically node-negative patients who underwent completion ALND because intraoperative rapid diagnosis showed SLN macrometastasis (n = 32; 22 mastectomy, 10 BCS), within the period of remote intraoperative diagnosis (mastectomy 25 Sep 2019–16 Jun 2024; BCS 25 Sep 2019–15 Mar 2021). The post-omission cohort, used to assess the consequences of omitting intraoperative diagnosis, comprised all clinically node-negative patients who underwent SLN biopsy after intraoperative rapid diagnosis was omitted (n = 159; mastectomy from 17 Jun 2024, BCS from 16 Mar 2021). Patients treated with neoadjuvant chemotherapy were excluded from both cohorts.

Data collection

Data were extracted retrospectively from the electronic medical record and the final surgical pathology report for each breast. Collected variables comprised age at surgery, clinical tumour size and T category, invasive size and whole-tumour size, histological type, nuclear grade, estrogen receptor (ER), progesterone receptor (PgR), HER2 and Ki-67, the number of SLNs harvested and the number of positive SLNs (with non-SLNs counted as SLNs), the number of metastatic nodes at completion ALND, the surgical procedure, and the adjuvant treatment delivered. Sentinel-node and axillary results were taken from the final pathology rather than the intraoperative assessment. Histological type was grouped as invasive ductal carcinoma (scirrhous, solid-tubular, and papillotubular types) or other; nuclear grade was recorded for invasive ductal carcinoma only. ER and PgR were classed positive at ≥ 1% and negative at 0%; HER2 was classed positive when 3 + or 2 + with positive FISH; and Ki-67 was categorized as low (< 5%), intermediate (5–29%), or high (≥ 30%), following the Japanese Breast Cancer Society definitions. Analyses were performed on a per-breast basis, with bilateral cancers entered as independent records.

Definitions

Macrometastasis was defined as a nodal deposit larger than 2 mm. Adequate axillary treatment after omission of completion ALND was defined, in line with the AMAROS and SENOMAC trials, as completion ALND or regional nodal irradiation (RNI) encompassing the axilla (levels I-III) with or without the supraclavicular fossa [6, 9]. Patients with SLN macrometastasis who omitted completion ALND and received neither completion ALND nor axillary-covering RNI were classified as potentially undertreated; this classification is based on the treatment received and not on a clinical outcome.

Statistical analysis

Analyses were breast-based, with bilateral cancers treated as independent. Continuous variables are summarized as mean (standard deviation) and compared between mastectomy and BCS groups with the Student t-test or Mann-Whitney U test; categorical variables are summarized as n (%) and compared

with the chi-square or Fisher exact test. The distribution of the number of metastatic nodes removed at completion ALND was tabulated, and its relationship with baseline factors was summarized descriptively. Given the small sample size (n = 32 in the pre-omission cohort), no multivariable model was fitted. Nuclear grade, ER, PgR, HER2 and Ki-67 were classified according to the Japanese Breast Cancer Society definitions. A two-sided P value below 0.05 was considered statistically significant. The study was approved by the institutional ethics committee (approval no. JHTF-2025-019).

Results

Pre-omission cohort

Baseline characteristics of the pre-omission cohort are shown in Table 1. Mastectomy patients tended to have larger clinical, invasive, and whole-tumour sizes (whole-tumour size P = 0.006). Tumours were predominantly invasive ductal carcinoma (84.4%), estrogen-receptor positive (93.8%), HER2 negative (93.3%), and of intermediate proliferation (Ki-67 high in 37.5%); these typical breast-cancer factors did not differ significantly between mastectomy and BCS (Table 1).

Table 1
Characteristics of clinically node-negative patients who underwent completion ALND for intraoperatively confirmed SLN macrometastasis, breast-based (pre-omission era)

Variable	Total (n = 32)	Mastectomy (n = 22)	BCS (n = 10)	P
Age, years, mean (SD)	59.0 (12.4)	57.3 (12.2)	62.8 (12.7)	0.252
Clinical tumor size, mm, mean (SD)	18.6 (4.9)	19.7 (5.1)	16.1 (3.3)	0.051
Invasive size, mm, mean (SD)	23.1 (16.5)	26.8 (18.1)	14.8 (8.3)	0.055
Whole tumor size, mm, mean (SD)	34.5 (20.9)	41.1 (21.2)	20.1 (11.0)	0.006
Histological type, n (%)				0.325
Invasive ductal carcinoma	27 (84.4)	19 (86.4)	8 (80.0)	
Mucinous	2 (6.2)	2 (9.1)	0 (0.0)	
Adenoid cystic	2 (6.2)	1 (4.5)	1 (10.0)	
Apocrine	1 (3.1)	0 (0.0)	1 (10.0)	
Nuclear grade (within IDC), n (%)				0.104
Grade 1	16 (59.3)	9 (47.4)	7 (87.5)	
Grade 2	7 (25.9)	7 (36.8)	0 (0.0)	
Grade 3	4 (14.8)	3 (15.8)	1 (12.5)	
ER positive, n (%)	30 (93.8)	20 (90.9)	10 (100.0)	0.844
PgR positive, n (%)	28 (87.5)	19 (86.4)	9 (90.0)	1.000
HER2 positive, n (%)	2 (6.7)	2 (9.5)	0 (0.0)	0.873
Ki-67, n (%)				0.844
Intermediate (5–29%)	20 (62.5)	13 (59.1)	7 (70.0)	
High (≥ 30%)	12 (37.5)	9 (40.9)	3 (30.0)	

BCS, breast-conserving surgery; ER, estrogen receptor; PgR, progesterone receptor; SD, standard deviation. ER/PgR positive ≥ 1%; HER2 positive = 3 + or 2 + with positive FISH (HER2 assessed in 30 patients); Ki-67 categories low < 5%, intermediate 5–29%, high ≥ 30%; nuclear grade was assessed within invasive ductal carcinoma only. P by t-test (continuous), or chi-square / Fisher exact test (categorical).

Patients had a mean of 1.4 positive SLNs and 2.3 SLNs harvested at biopsy. Completion ALND removed a mean of 1.8 (SD 3.4) additional metastatic nodes, but the distribution was highly skewed (Table 2): 17 of 32 breasts (53.1%) had no further positive node, whereas additional positive nodes were found in 15 (46.9%), including three or more in 7 breasts (21.9%) and as many as 12 and 14 nodes in two patients. The mean was higher after mastectomy (2.2) than after BCS (0.8), although the difference was not

statistically significant (P = 0.287). Notably, several of the high-burden cases had more than two positive SLNs and would not meet current criteria for omission of completion ALND.

Table 2
Number of metastatic lymph nodes removed at completion ALND, breast-based (pre-omission era)

Metastatic nodes at completion ALND	Total (n = 32)	Mastectomy (n = 22)	BCS (n = 10)
0 nodes	17 (53.1%)	10 (45.5%)	7 (70.0%)
1 node	6 (18.8%)	5 (22.7%)	1 (10.0%)
2 nodes	2 (6.3%)	2 (9.1%)	0 (0.0%)
≥ 3 nodes	7 (21.9%)	5 (22.7%)	2 (20.0%)
Any additional node (≥ 1)	15 (46.9%)	12 (54.5%)	3 (30.0%)
Mean (SD)	1.8 (3.4)	2.2 (3.9)	0.8 (1.5)

ALND, axillary lymph node dissection; BCS, breast-conserving surgery; SD, standard deviation. The difference in the mean number of additional metastatic nodes between mastectomy and BCS was not statistically significant (P = 0.287).

Descriptively, the number of additional metastatic nodes tended to be greater in patients with a larger invasive tumour and a greater number of positive sentinel nodes.

Completion ALND therefore removed additional metastatic nodes in nearly half of patients, confirming that omission leaves residual nodal disease unresected. This does not indicate that omission of ALND is inappropriate: in ACOSOG Z0011, additional positive nodes would have been found in about a quarter of the omission-eligible (≤ 2 positive SLN) population, yet regional control was maintained without dissection [3–5]. Rather, the finding underscores that omission is appropriate only when adequate regional control, particularly radiotherapy, is provided, as in AMAROS and SENOMAC [6, 9, 10].

Post-omission cohort

Characteristics of the post-omission cohort are shown in Table 3; the typical breast-cancer factors were similar to the pre-omission cohort and did not differ significantly between mastectomy and BCS. Among 159 patients, macrometastasis was identified in 18 (11.3%), more often after mastectomy (13/78, 16.7%) than after BCS (5/81, 6.2%). Sixteen patients with ≤ 2 macrometastases (11 mastectomy, 5 BCS) had completion ALND omitted as intended; only 2 patients, both with 3 macrometastatic SLNs (above the omission threshold), underwent delayed completion ALND. The need for a second operation after omitting intraoperative diagnosis was therefore infrequent.

Table 3
Characteristics of all clinically node-negative patients undergoing SLN biopsy after omission of intraoperative rapid diagnosis, breast-based (current era)

Variable	Total (n = 159)	Mastectomy (n = 78)	BCS (n = 81)	P
Age, years, mean (SD)	61.8 (13.4)	65.2 (13.4)	58.5 (12.7)	0.001
SLNs harvested, mean (SD)	2.14 (1.52)	2.42 (1.62)	1.88 (1.37)	0.023
Nuclear grade (within IDC), n (%)				0.077
Grade 1	87 (75.0)	37 (75.5)	50 (74.6)	
Grade 2	8 (6.9)	6 (12.2)	2 (3.0)	
Grade 3	21 (18.1)	6 (12.2)	15 (22.4)	
ER positive, n (%)	147 (92.5)	71 (91.0)	76 (93.8)	0.713
PgR positive, n (%)	132 (83.0)	63 (80.8)	69 (85.2)	0.596
HER2 positive, n (%)	19 (11.9)	13 (16.7)	6 (7.4)	0.194
Ki-67, n (%)				0.350
Low (< 5%)	20 (12.7)	7 (9.1)	13 (16.2)	
Intermediate (5–29%)	97 (61.8)	51 (66.2)	46 (57.5)	
High (≥ 30%)	40 (25.5)	19 (24.7)	21 (26.2)	
Nodal status at SLN biopsy, n (%)				0.328
No metastasis	130 (81.8)	60 (76.9)	70 (86.4)	
SLN micrometastasis	11 (6.9)	5 (6.4)	6 (7.4)	
1 macrometastatic SLN	9 (5.7)	7 (9.0)	2 (2.5)	
1 macro SLN + 1 macro non-SLN	2 (1.3)	1 (1.3)	1 (1.2)	
2 macrometastatic SLNs	5 (3.1)	3 (3.8)	2 (2.5)	
3 macrometastatic SLNs	2 (1.3)	2 (2.6)	0 (0.0)	

Definitions as in Table 1. *Nuclear grade was assessed within invasive ductal carcinoma (n = 116); HER2 was not assessed in 8 patients. Macrometastasis was identified in 18/159 patients (11.3%) overall, 13/78 mastectomy (16.7%) versus 5/81 BCS (6.2%). Sixteen patients with ≤ 2 macrometastases (mastectomy 11, BCS 5) had ALND omitted; 2 patients with 3 macrometastases (both mastectomy) underwent delayed completion ALND. P by t-test (continuous), chi-square or Fisher exact test (categorical).*

Sentinel-node metastasis was present in 29 patients (Table 4): macrometastasis (≥ 2.1 mm) in 18 (62.1%) and micrometastasis in 11 (37.9%), and the mean size of the metastatic sentinel-node deposit

was 4.1 mm (SD 3.0), without a significant difference between mastectomy and BCS (4.7 mm vs 3.1 mm; P = 0.183). The adjuvant radiotherapy recorded in these node-positive patients comprised whole-breast irradiation in 8 and whole-breast plus regional nodal irradiation in 3 (all after BCS), and post-mastectomy radiotherapy in 5 (after mastectomy); the remaining node-positive patients, predominantly after mastectomy, did not receive nodal-field irradiation.

Table 4
Metastatic burden and adjuvant radiotherapy in the 29 sentinel-node-positive patients (current era)

Variable	Total (n = 29)	Mastectomy (n = 18)	BCS (n = 11)	P
Nodal metastasis type, n (%)				0.295
Macrometastasis (≥ 2.1 mm)	18 (62.1)	13 (72.2)	5 (45.5)	
Micrometastasis (< 2.1 mm)	11 (37.9)	5 (27.8)	6 (54.5)	
SN metastatic deposit size, mm, mean (SD)	4.1 (3.0)	4.7 (3.2)	3.1 (2.6)	0.183
Adjuvant radiotherapy, n (%)				
Whole-breast RT	8 (27.6)	0 (0.0)	8 (72.7)	
Whole-breast RT + RNI	3 (10.3)	0 (0.0)	3 (27.3)	
Post-mastectomy RT	5 (17.2)	5 (27.8)	0 (0.0)	

RNI, regional nodal irradiation; RT, radiotherapy; SN, sentinel node. Node-positive patients comprise 18 with macrometastasis and 11 with micrometastasis. The listed radiotherapy categories account for 16 patients; the remaining 13 node-positive patients (predominantly mastectomy) did not receive these nodal-field regimens, with per-case detail in Table 5. *P by chi-square / Fisher exact test (nodal type) or t-test (deposit size).*

The adjuvant management of the 18 macrometastasis-positive patients is shown in Table 5. Applying the trial-based definition above, 9 patients did not receive axillary-covering RNI after omission of completion ALND and were classified as potentially undertreated. In four (Mx2, Mx5, Mx10, BCS4), radiotherapy was deliberately limited or omitted because of patient factors such as advanced age, dialysis dependence, frailty, or comorbidity. In the other five (Mx1, Mx8, BCS2, BCS3, BCS5), axillary irradiation may not have been explicitly discussed between the surgical and radiation oncology teams, such that irradiation was planned as if a completion ALND had been performed and axillary coverage may have been inadequate.

Table 5
Detailed adjuvant management of the 18 patients with macrometastasis (current era)

Case	Age	SLN mets	Non-SLN mets	Adjuvant management (notes)
Mx 1	66	1/1, 8 mm		PMRT + RNI (supraclavicular); possible undertreatment (understanding/communication gap)
Mx 2	82	1/1, 5 mm		No PMRT (postoperative wound necrosis, age, dementia, financial burden)
Mx 3	65	1/3, 4 mm		PMRT + RNI (axilla + supraclavicular)
Mx 4	53	1/6, 6 mm		PMRT + RNI (axilla + supraclavicular)
Mx 5	61	1/1, 2.2 mm		No PMRT (dialysis patient, relatively small metastasis)
Mx 6	55	1/3, 7 mm		PMRT + RNI (axilla + supraclavicular)
Mx 7	73	1/4, 4 mm		PMRT + RNI (axilla + supraclavicular)
Mx 8	55	1/2, 6 mm	1/3, 8 mm	PMRT + RNI (supraclavicular); possible undertreatment (understanding/communication gap)
Mx 9	36	2/2, max 6 mm		PMRT + RNI (axilla + supraclavicular)
Mx 10	84	2/3, 7 & 3 mm		No PMRT (elderly, bedridden)
Mx 11	47	2/2, max 5 mm		PMRT + RNI (axilla + supraclavicular)
Mx 12	44	3/4, max 14 mm		Completion ALND (15/23) + PMRT + RNI (supraclavicular-axilla)
Mx 13	65	3/5, max 3 mm		Completion ALND (0/12) + PMRT + RNI (supraclavicular-level III)
BCS 1	60	1/2, 5 mm		WBRT + RNI (supraclavicular-axilla)
BCS 2	79	1/1, 3 mm		WBRT only (elderly, understanding/communication gap)
BCS 3	55	1/1, 4 mm	1/1, 3 mm	WBRT + RNI (right supraclavicular); understanding/communication gap
BCS 4	87	2/4, 8 & 7 mm		Radiotherapy omitted (elderly)

Case	Age	SLN mets	Non-SLN mets	Adjuvant management (notes)
BCS 5	83	2/4, max 7 mm		WBRT only (elderly, understanding/communication gap)

Mx, mastectomy; BCS, breast-conserving surgery; PMRT, post-mastectomy radiotherapy; WBRT, whole-breast radiotherapy; RNI, regional nodal irradiation. SLN mets shown as positive/harvested and largest deposit. Cases Mx1, Mx2, Mx5, Mx8, Mx10 and BCS2-BCS5 (n = 9) did not receive axillary-covering RNI after omission of completion ALND and were therefore classified as potentially undertreated: Mx2, Mx5, Mx10 and BCS4 because radiotherapy was limited or omitted on the basis of advanced age or dialysis dependence, and Mx1, Mx8, BCS2, BCS3 and BCS5 because axillary irradiation may not have been explicitly discussed between the surgical and radiation oncology teams, such that irradiation was planned as if a completion ALND had been performed and axillary coverage may have been inadequate.

Discussion

In this single-centre study from a resource-limited, post-disaster region, completion ALND for SLN macrometastasis removed additional metastatic nodes in nearly half of breasts, omission of intraoperative diagnosis rarely necessitated a second operation, and the main shortfall was the adequacy and coordination of the radiotherapy that replaces axillary surgery.

Additional positive nodes were found at completion ALND in 15 of 32 breasts (46.9%), with three or more in 21.9% — a higher proportion than the roughly one quarter reported in the omission-eligible ACOSOG Z0011 population, reflecting the inclusion in our historical cohort of patients with more than two positive SLNs and predominantly mastectomy. These data confirm that omission does not render the axilla disease-free [3–5]. Critically, this does not argue against omission in appropriately selected patients: the randomized evidence demonstrates equivalent regional control and survival when omission is paired with radiotherapy [6, 7, 9, 10]. The correct inference is therefore not that residual disease should be resected, but that the safety of omission is conditional on delivering adequate axillary/regional radiotherapy — a condition least assured in resource-limited settings. Descriptively, nodal burden tended to be greater in patients with larger invasive tumours and more positive sentinel nodes; confirming this in larger series could help identify patients in whom the adequacy of radiotherapy deserves particular attention.

Omission of intraoperative rapid diagnosis was supported by the rarity of delayed completion ALND (2/159). Its principal downstream effect was not surgical but organizational: once completion ALND is no longer planned, responsibility for the axilla passes to radiotherapy, and that transfer must be explicit. In five of our nine potentially undertreated patients, the radiotherapy plan appears not to have accounted for the omitted dissection, so the axilla may have been inadequately covered. A structured, documented hand-off between the surgical and radiation oncology teams at treatment planning is a low-cost safeguard. In the remaining four patients, radiotherapy was limited by patient factors; in such patients

the decision to omit surgery should explicitly consider whether the planned adjuvant treatment can realistically be delivered.

Reliable intraoperative SLN diagnosis was previously achieved at our hospital through telepathology despite the absence of an on-site pathologist [13]; as omission of completion ALND has become standard, the role of intraoperative diagnosis has narrowed and telepathology is now applied selectively. Taken together, the limiting factor for safe de-escalation in this setting is no longer the surgical decision but the reliable delivery and coordination of adjuvant radiotherapy.

Limitations

This is a single-centre, retrospective study with small case numbers and short follow-up. Recurrence and survival could not be used as endpoints, so nodal burden and process measures were used. Because of the small sample size, no multivariable analysis of the factors associated with nodal burden was performed, and the descriptive associations reported should be confirmed in larger series. The classification of potential undertreatment was based on the documented receipt of axillary-covering radiotherapy rather than on a clinical outcome, and radiotherapy field and dose data were incomplete. Selection and ascertainment bias cannot be excluded, and the findings reflect the resources and practice of one regional hospital and may not generalize to settings with different case mix or radiotherapy access.

Several data elements were not consistently available for this retrospective analysis and would allow firmer conclusions if collected prospectively: detailed radiotherapy records for each ALND-omitted patient (fields, nodal levels covered, and doses), to classify axillary coverage objectively rather than from the treatment summary; follow-up duration and locoregional recurrence and survival events, to move beyond surrogate measures; systemic therapy received (endocrine, chemotherapy, anti-HER2), which contributes to regional control; full biomarker and subtype distributions and the presence of extracapsular extension; and the eligible denominator and reasons for radiotherapy omission. With a larger sample, these data would permit an outcome-based rather than treatment-based assessment of undertreatment and a properly powered analysis of factors associated with nodal burden.

Conclusion

Omission of completion ALND for SLN macrometastasis leaves residual nodal disease in a substantial proportion of patients, but, consistent with ACOSOG Z0011 and SENOMAC, this does not make omission inappropriate; it underscores that omission is justified only when adequate axillary/regional radiotherapy is delivered. Omitting intraoperative SLN diagnosis rarely required a second operation. In regions facing workforce shortages, long travel distances, and limited access to radiotherapy, implementing axillary de-escalation can encounter challenges not anticipated in the original randomized trials. Our experience suggests that the success of de-escalation depends not only on its evidence base but also on the regional capacity to deliver and coordinate the adjuvant therapy that replaces axillary surgery.

Declarations

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Conflict of interest. The authors declare that they have no competing interests.

Ethics approval. This study was approved by the Ethics Committee (Institutional Review Board) of Jyoban Hospital of the Tokiwa Foundation through expedited review (approval no. JHTF-2025-019; reviewed 20 January 2026, institutional permission granted 26 January 2026) and was conducted in accordance with the Japanese Ethical Guidelines for Life Science and Medical Research Involving Human Subjects (2021) and the principles of the Declaration of Helsinki.

Consent to participate. Given the retrospective design, the requirement for written informed consent was waived by the ethics committee, and an opt-out opportunity was provided to patients.

Data availability. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author contributions. All authors contributed to the study conception and design, or to data collection, analysis, or interpretation. All authors critically revised the manuscript, and all approved the final version and agree to be accountable for the work.

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