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Impact of residual suspicious lymph nodes after axillary lymph node dissection and radiotherapy in breast cancer patients

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ABSTRACT

Background: Radiotherapy (RT) of the dissected axilla is only recommended in case of residual axillary lymph node (ALN) metastases. Identifying residual, initially suspicious ALN (rsALN) in planning CT is challenging after pretreatment. This study systematically compared pre- and postoperative axillary assessments to investigate rsALN metastases and its impact on patient outcomes.

Material & methods: We analyzed 152 patients with cN+ breast cancer undergoing RT after ALND. Three experienced radiologists reviewed ALN based on the initial staging and postoperative planning CT regardless of persistent malignancy criteria. Oncologic follow-up was assessed.

Results: ALND was performed in 6 hospitals by 39 surgeons. In this high-risk collective, 47.2% had rsALN after ALND; mostly in level I. The median number of initial ALN metastases was 6 (1−33) and after resection of 11 (4–35) ALN 2 rsALN (1–15) remained.

While the presence of rsALN did not correlate with the number of resected ALN, ≥4 initial ALN metastases were a strong predictor of rsALN.

All rsALN patients received breast/chest-wall RT with median 50.4 Gy. >90% received incidental or intentional dose coverage of ≥85% of the prescribed dose in level I.

After a follow up of 30.0 months (7–85), one recurrence (1.4%) occurred among rsALN patients. Distant metastases were more frequent in rsALN patients (16.6% vs. 5%; p 0.032). After stratification for initial nodal tumor burden, there was no significant difference in local recurrence or distant metastasis between patients with and without rsALN.

Conclusion: While rsALN are common in patients with high initial nodal burden, adequate RT appears to mitigate adverse oncologic outcomes.

1. Introduction

The interdisciplinary management of the axillary lymph node (ALN) region is of utmost clinical relevance in primary breast cancer patients. Over the past decades, it has undergone a profound paradigm shift: given the increasing awareness of the high risk of treatment-related morbidity with often limited additional oncological benefit through axillary lymph node dissection (ALND) ([1–4], gynecologists progressively aim to de-escalate the axillary surgery whenever possible [5–7]. Thus, in patients with clinically node-negative disease sentinel lymph node biopsy (SLNB) became standard of care [8]. Newest data show that even that SLNB can be omitted in patients with clinically small, hormone-receptor positive and node-negative breast cancers [9–11].

Despite this trend, ALND remains standard of care in patients with

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heavy nodal tumor burden either after poor response to primary systemic therapy (PST) or in an upfront surgical setting [12].

If additional regional nodal irradiation (RNI) is indicated, it should generally only comprise the un-dissected axillary region [4]. Nonetheless, adjuvant irradiation of the dissected axilla is indicated in case of extensive nodal disease including involved axillary soft tissue after ALND [13]. Moreover, in case of residual axillary lymph node metastases after surgery, additional radiotherapy of the total axilla can be necessary [14].

It is known that after a positive sentinel lymph node biopsy (SLNB), 27.3% - 51.3% of patients have residual lymph node metastases in the axilla [15], however this is not associated with a worse clinical outcome if postoperative RT with adequate incidental or intentional irradiation of the axilla is being performed [8,15,16].

While the optimal treatment and radiotherapy after positive SLNB have been extensively discussed, there are still uncertainties regarding the optimal treatment of the axilla after ALND in patients with extensive lymph node involvement. It is likely that patients with a high nodal burden have a high risk of residual lymph nodes after ALND. In this context the trend towards surgical de-escalation of the extent of resection during ALND has a potential impact. The complete removal of ALN in level I-III aiming for surgical clearance has been left in favor of a less comprehensive axillary sampling in the past decades [17]. The historical recommendation to resect at least 10 lymph nodes [18] is also no longer strictly valid today [17,19].

The critical matter of residual ALN is the increasing risk of (subclinical) lymph node metastases remaining in the axilla. If residual suspicious ALN appear after surgery, patients should preferably undergo biopsy to prove metastatic involvement and complete dissection. When further surgical removal is not feasible or desired, the residual suspicious ALN should be addressed with radiotherapy [14]. Since radiation oncologists are mostly the first ones to review the postoperative axillary status, it is highly relevant to thoroughly assess the axillary lymph nodes in the planning CT before irradiation.

In this study, we investigated the prevalence of non-dissected axillary lymph nodes after ALND that were initially classified as suspicious by radiologists specialized in breast imaging. Specifically, we aimed to define the frequency and anatomical location of residual suspicious axillary lymph nodes (rsALN) following axillary lymph node dissection (ALND). Furthermore, we evaluated the factors associated with the presence of rsALN and their impact on oncologic outcomes.

2. Material & Methods

2.1. Patient collective

For this study, we screened data from 1542 patients receiving planning CT of the chest in our institution between 2019 and 2024 for primary breast cancer patients with presence of initial contrast-enhanced staging CT undergoing ALND and irradiation. Exclusion criteria were clinically node-negative patients, ductal carcinoma in situ or synchronous distant metastasis. We included 152 high-risk patients with clinically positive ALN from primary breast cancer undergoing ALND with or without PST and adjuvant irradiation. If available, additional imaging data from ultrasound (US), magnetic resonance imaging (MRI) and/or positron emission tomography/computed tomography (PET/CT) was also utilized for analysis. All patients gave written consent and treatment followed national guidelines. Assessment and evaluation of all patient data was carried out pseudonymized in our institution. The study was approved by the local ethics board (2024–373-S-CB).

2.2. Assessment of the axillary status

The evaluation of ALN in this was conducted systematically by 3 independent radiological raters (attending and/or board approved radiologists specialized in breast cancer imaging). Initial lymph node assessment was based on RECIST criteria [20] in pretreatment staging CT (sCT) with determination of number and level of suspicious ALN. Subsequently, for each initially suspicious lymph node it was assessed whether this lymph node was still present after ALND in the planning CT (plCT) irrespectively of response to PST (if any).

Each case was assessed independently and in a blinded fashion by two specialized breast radiologists. Cases with discordant results ($n = 67$; 44%) were re-evaluated by a third radiologist, who served as an adjudicator to resolve the discrepancy. If the third radiologist did not agree with either of the initial ratings ($n = 9$; 5.9%), the third radiologist made the final decision.

For each case, patient characteristics, treatment information and oncologic follow-up was assessed Figs 1 and 2.

2.3. Statistical analysis

The primary endpoint of this study was the presence of residual suspicious axillary lymph nodes (rsALN) after ALND. The secondary endpoint was the outcome (local recurrence (LR), regional recurrence (RR) and distant metastasis (DM)) of patients with vs. without rsALN.

Data collection, descriptive statistical analysis and visualization were conducted using SPSS Statistics (Version 26; IBM, Armonk, NY, USA) and GraphPad Prism Software (Version 10.2.3, GraphPad software Inc., San Diego, CA, USA). Continuous variables are reported as mean ± SD for normally distributed data and skewed data as median (range). Categorial variables are presented as total numbers (percentage).

Associations between rsALN and categorial variables were assessed using Chi-squared test or Fishers' exact test depending on the structure of the data. To identify potential risk factors for local recurrences, regional axillary recurrences or distant metastasis, univariate logistic regression analyses were performed. Due to the expected high prognostic value of the initial extent of ALN involvement, an additional subgroup analysis was performed stratified for the number of initially suspicious ALN into 0–3 suspicious ALN, 4–9 ALN or at least 10 ALN according to the pathological classification of lymph nodes as defined by AJCC TNM Eighth Edition [21]. Statistical significance was defined as $p < .05$.

3. Results

3.1. Patient collective

147 of 152 patients (94.7%) included in this study were female. Median age was 55 years (29–85) at time of diagnosis. The primary tumor had a diameter of more than 2 cm in 76.3% and a positive hormone receptor status in 68.4%. 58.6% of patients received mastectomy, 77.6% PST and 9.2% adjuvant chemotherapy. Patients undergoing PST showed partial or complete response in the primary tumor in 37.3% and 24.6%, respectively. Complete nodal response occurred in 32.2% of patients receiving PST. ALND was performed in 6 different hospitals by 39 different surgeons and comprised level I -II in 98.7% and Level I-III in 1.3%.

During ALND, a median of 11 (4–35) ALN were resected, of which a median of 3 (0–17) were positive. Further patient characteristics are shown in Table 1.

3.2. Radiotherapy

Treatment planning CT was performed on a Siemens Somatom Emotion 16 device (Siemens Healthineers, Erlangen, Germany). Clinical target volume delineation was performed in Varian Eclipse Software (Version 13.0, Medical Systems, Palo Alto, CA, USA) and followed ESTRO consensus guideline [22]. All patients received adjuvant irradiation of the breast or chest wall and – if applied – regional nodal basins with a median delivered dose of 50.4 Gy (7.2–50.4) in 28 fractions (4–30). Radiotherapy was ended early in $n = 6$ patients (3.9%). Regional

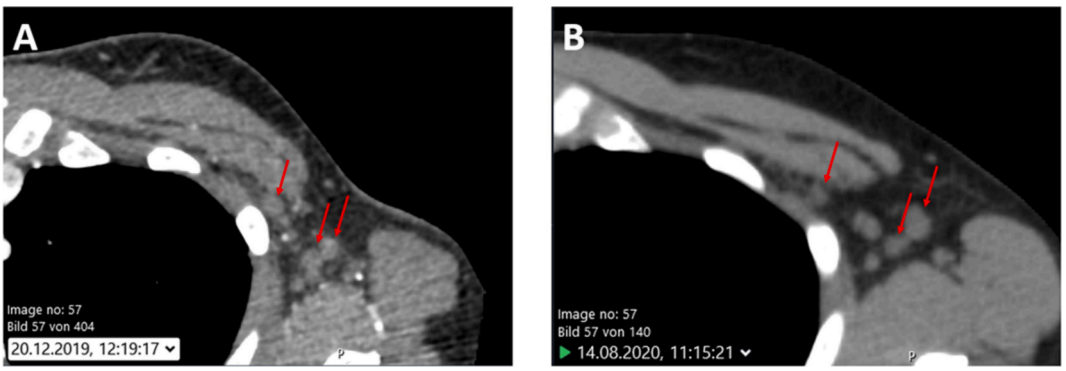


Fig. 1. Example of a 30-year-old, left-sided primary breast cancer patient with residual, initially suspicious axillary lymph nodes after ALND. A) initial staging CT with 3 of 4 suspicious lymph nodes in the axillary lymph node levels I and II. B) postoperative planning CT after 6 months of primary systemic therapy and breast conserving therapy (partial remission in the breast) and ALND (0/11 nodes) with presence of 3 residual, initially suspicious axillary lymph nodes in level I and II. Abbreviations: ALND: Axillary lymph node dissection; CT: Computer tomography

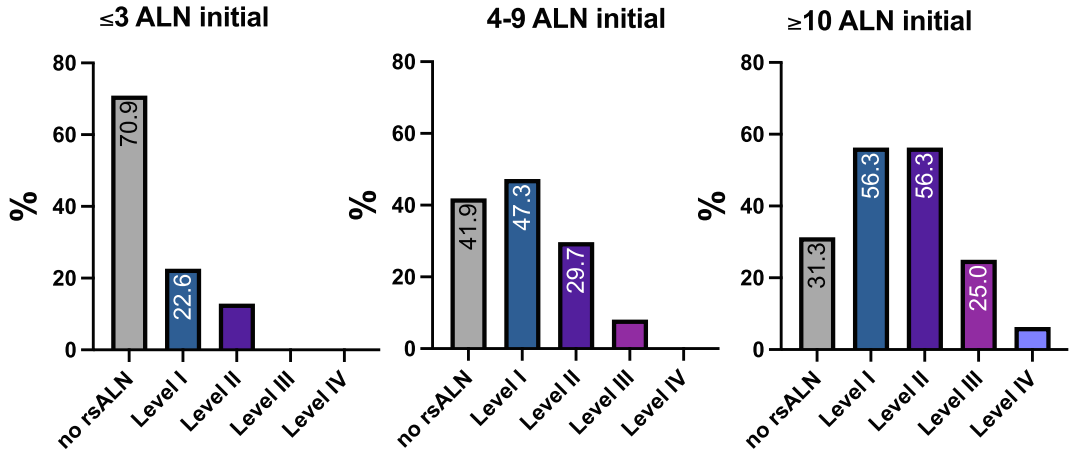


Fig. 2. Presence and location of residual suspicious axillary lymph nodes (rsALN) after axillary lymph node dissection depending on the number of initially suspicious axillary lymph nodes (ALN) in percent.
Abbreviations: ALN: Axillary lymph nodes; rsALN: Residual suspicious axillary lymph nodes

nodal irradiation was performed in 151 patients (99.3%). 99.3% of treatment plans utilized 6× photon beams of a Varian Clinac DHX linear accelerator in volume modulated arc therapy (VMAT) technique (Varian Medical Systems, Palo Alto, CA). One patient (0.7%) received 6× photon 3-dimensional conformal radiotherapy (3D-CRT).

3.3. Comparison of axillary status pre- and postoperatively

Evaluation of the initial sCT revealed a median of 6 (1–33) suspicious ALN, which were located in level I (46.7%), II (33.8%), III (16.4%) and IV (3.1%). In the postoperative plCT, rsALN were detected in 72 patients (47.4%) with a median of 2 (1–15) rsALN. In case of rsALN, these were mostly located in level I (53.7%) or level II (36.1%), whereas presence of rsALN in the plCT were less frequent in level III (9.1%) or IV (0.9%).

3.4. Risk factors for residual initially suspect axillary lymph nodes

The number of resected ALN had no impact on the presence of rsALN (p 0.715). However, univariate analysis revealed a significant association between rsALN and the number of initially suspicious ALN in sCT ($p < .001$; OR 1.27 [1.12–1.43]). Moreover, a higher amount of involved ALN among resected ALN was also significantly associated with rsALN (p 0.022; OR 1.35 [1.04–1.75]). Other tested variables such as the extent of ALND (<10 vs. ≥10 ALN; p 0.678), initial tumor size (p 0.748), site (p 0.381), grading (p 0.358), subtype (p 0.369), performed PST (p 0.772), response to PST (p 0.967), hospital (p 0.877), surgeon (p 0.765) or type of breast surgery (p 0.499) did not show a significant association.

Nodal irradiation in patients with residual suspicious axillary lymph nodes

98.6% of patients with rsALN had intentional irradiation of level III/IV. Level I and II were intentionally included in the target volume in 61.1% and 94.4% of patients with rsALN, respectively. 78.5% of patients with rsALN without intentional irradiation of level I received a mean dose of at least 85% of the prescribed dose (see Fig. 3). Median mean dose coverage in patients with rsALN was 49.9 Gy (19–57.8) in level I and 51.1 Gy (16–56.7) in level II.

Follow up of patients with residual suspicious axillary lymph nodes

The median follow-up was 30.0 months (7–85). In patients with rsALN, local recurrence occurred in 3 patients (4.2%) and regional axillary recurrence in 1 patient (1.4%). 12 patients (16.6%) with rsALN presented with distant metastasis, of which 4 were in bones, 2 in the brain, one each in lung, liver and adrenal gland and 3 patients had multiple metastatic disease. In patients without rsALN, no local or regional axillary recurrence occurred. Distant metastases occurred in 4 patients (5.0%), of which one was bone metastasis and 3 were multiple metastatic diseases (See Fig. 4).

While there was no difference in local recurrences between patients with and without rsALN (p 0.997), the likelihood of distant metastasis was significantly higher in patients with rsALN (p 0.032; OR 3.66 [1.12–11.95]). Moreover, the number of initially suspicious ALN (p

Table 1
Patient characteristics of all patients, patients with residual suspicious axillary lymph nodes (rsALN) and those without residual suspicious axillary lymph nodes (no rsALN).

Patient characteristics		total		rsALN		no rsALN	
		$n = 152$	%	$n = 72$	%	$n = 80$	%
sex	female	147	96.7	72	100	75	93.8
	male	5	3.3	–	–	5	6.3
age (years)	mean	56.6		54.6		58.7	
	median	55	(29–85)	52.5	(29–84)	58	(32–85)
iT	1	36	23.7	16	22.2	20	25.0
	2	65	42.8	32	44.4	33	41.3
	3	34	22.4	15	20.8	19	23.8
	4	17	11.2	9	12.5	8	10.0
pT / ypT	0	30	19.7	13	18.1	17	21.3
	is	5	3.3	2	2.8	3	3.8
	1	41	27.0	20	27.8	21	26.3
	2	44	29.0	20	27.8	24	30.0
	3	28	18.4	15	20.8	13	16.3
	4	4	2.6	2	2.8	2	2.5
response primary tumor	no	45	38.1	20	35.7	25	40.3
	partial	44	37.3	24	42.9	20	32.3
	complete	29	24.6	12	21.4	17	27.4
	no PST	34	–	16	–	18	–
positive nodes	mean	3.5		4.1		3.0	
	median	3	(0–17)	3	(0–17)	2	(0–16)
resected nodes	mean	12.8		12.6		12.9	
	median	11	(4–35)	11	(4–35)	12.5	(4–31)
nodal response	no	81	68.6	41	73.2	40	64.5
	response	37	31.4	15	26.8	22	35.5
	no PST	34	–	16	–	18	–
tumor site	medial	22	14.5	9	12.5	13	16.2
	central	35	23.0	13	18.1	22	27.5
	lateral	95	62.5	50	69.4	45	56.3
molecular subtype	HR+/HER2-	104	68.4	47	65.3	57	71.3
	HR+/HER2+	13	8.6	7	9.7	6	7.5
	HR-/HER2+	11	7.2	4	5.6	7	8.8
	TNBC	24	15.8	14	19.4	10	12.5
grading	1	9	5.9	3	4.2	6	7.5
	2	101	66.4	52	72.2	49	61.3
	3	41	27.0	17	23.6	24	30.0
	missing	1	0.7	–	–	1	1.3
lymphatic invasion	no	98	64.5	46	63.9	52	65.0
	yes	54	35.5	26	36.1	28	35.0
vascular invasion	no	143	94.1	67	93.1	76	95.0
	yes	9	5.9	5	6.9	4	5.0.0
perineural invasion	no	143	94.1	69	95.8	74	92.5
	yes	9	5.9	3	4.2	6	7.5
affected breast	left	75	49.3	41	56.9	34	42.5
	right	77	50.6	31	43.1	46	57.5
surgery of primary tumor	BCS	63	41.4	30	41.7	33	41.3
	mastectomy	89	58.6	42	58.3	47	58.7

Abbreviations: rsALN: residual suspicious axillary lymph nodes; PST: primary systemic therapy; HR: hormone receptor status; HER2: HER2neu status, TNBC: triple negative breast cancer; BCS: breast conserving surgery.

0.043; OR 2.17 [1.03–4.59]), a high amount of involved ALN among resected ALN (p 0.009; OR 1.61 [1.13–2.29] and the tumor subtype (p 0.047; OR 1.43 [1.05–2.10]) were significantly associated with presence of recurrence or distant metastasis. Due to low number of overall events, multivariate logistic regression was not performed. After subgroup analysis with stratification for the initial extent of axillary metastasis, there was no significant difference in distant metastasis or local recurrence observed between patients with and without rsALN (0–3 ALN p 0.897; OR 1.18 [0.10–13.86]/ 4–9 ALN p 0.078; OR 4.22 [0.85–20.94]/ $\geq$10 ALN p 0.931; OR 0.89 [0.61–12.89]). The number of rsALN was also not significantly associated with recurrence of distant metastasis (p 0.129; OR 1.17 [0.96–1.44]).

4. Discussion

To the best of our knowledge, the present study is the first to investigate residual suspicious axillary lymph nodes (rsALN) by systematic comparison of initial staging CT (sCT) and postoperative planning CT (plCT) scans following axillary lymph node dissection (ALND) in high-risk breast cancer patients. To achieve the most robust results, a comprehensive, multi-step process was conducted in which three radiological experts specializing in breast cancer imaging performed the evaluations independently and in a blinded fashion. Our investigation reveals three key findings:

Frequency and Location: rsALN occur frequently in patients with a high initial nodal tumor burden, particularly those with $\geq$4 suspicious nodes prior to surgery. When present, rsALN were most commonly located in axillary level I, identifying this as a high-risk zone despite comprehensive surgical intervention.

Number of removed ALN: The absolute number of lymph nodes removed during ALND did not correlate with the presence of rsALN or clinical outcomes.

Oncologic Outcome: rsALN appear to have a negligible impact on regional control and distant metastasis if adjuvant axillary radiotherapy is performed.

The primary goal of curative breast cancer surgery is the removal of all macroscopic disease [23]. However, it is well-established that subclinical disease may persist even after complete surgical resection

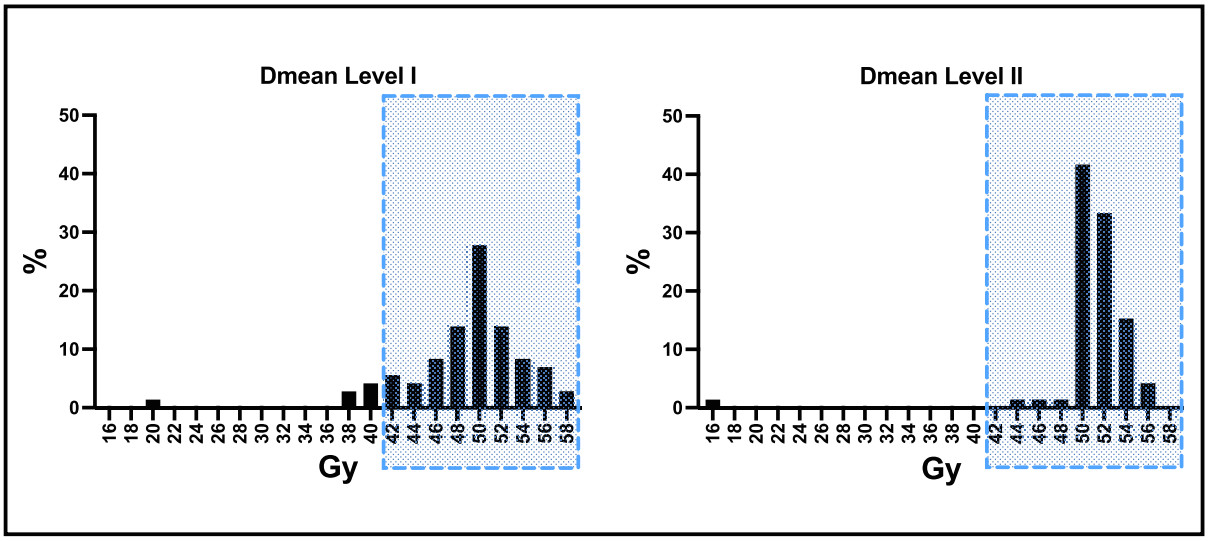


Fig. 3. Histogram showing the proportion of patients (%) receiving a specific dose in Gy to the axillary levels I (left) and II (right) during adjuvant irradiation after axillary lymph node dissection.
Abbreviations: Dmean: Mean dose; RNI: Regional nodal irradiation; Dmean: Mean dose

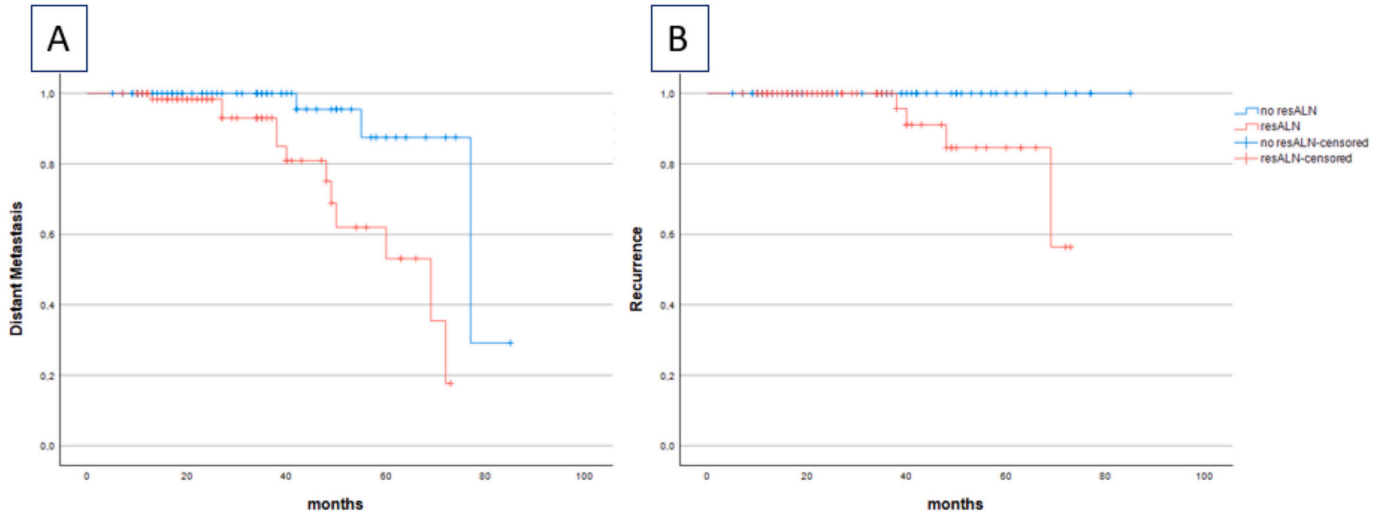


Fig. 4. Kaplan-Meier curves showing the probability of A) distant metastasis and B) local or locoregional axillary recurrence for patients with rsALN (red) vs. without rsALN (blue). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)
Abbreviations: rsALN: Residual suspicious axillary lymph nodes

[19,24]. RNI has the potential to eradicate these microscopic residuals, thereby improving regional control, distant metastasis-free survival, and disease-specific survival [4,25–27].

In certain clinical scenarios, such as cN3 disease involving the supra−/infraclavicular fossa or the internal mammary chain, complete surgical excision would be associated with excessive morbidity. Historical data indicates that additional surgery in these regions does not provide superior oncologic outcomes compared to radiotherapy alone, despite the presence of macroscopic residual disease. The efficacy of RNI in managing macroscopic nodal disease is further supported by several randomized trials [4,15] showing the equivalence of axillary radiotherapy and ALND after SLNB, despite the likely presence of additional nodal involvement in approximately one-third of patients.

While axillary surgery has been continuously de-escalated in the last years, ALND remains indicated for patients undergoing upfront surgery with extensive cN+ disease, T4 tumors, or ≥ 3 involved sentinel nodes [23]. After PST, ALND is recommended for those with ≥4 initially involved nodes or residual nodal disease. Current guidelines generally do not recommend routine irradiation of the dissected axilla unless residual metastases are detected [14,23]. However, in clinical practice, a systematic comparison between planning CT and initial diagnostic imaging to detect such residuals is often omitted.

In our cohort, we observed a remarkably high incidence of 47.4% of residual ALN after ALND. Importantly, our analysis did not aim to determine the clinically suspicious lymph nodes remaining after ALND, but rather to assess the presence of initially suspicious lymph nodes that could still be identified on planning CT after ALND. Moreover, to ensure methodological accuracy and account for potential differences in surgical practice, we assessed information on the individual surgeons and hospitals where ALND was performed. Given the substantial heterogeneity of 39 different surgeons across six different hospitals, the unexpectedly high number of rsALN does not necessarily allow for conclusions to be drawn regarding the quality of ALND.

Crucially, after stratification for initial nodal involvement, the presence of rsALN had no significant effect on patient outcomes after a median follow-up of 30 months. Despite this particular high-risk

collective — characterized by a young median age (55 years), high initial tumor burden (median of 6 initially suspicious nodes), and a non-pCR rate of 75.4%—we observed good regional control in case of rsALN.

We attribute this to the fact that over 90% of patients with rsALN received therapeutic dose coverage of the lower axilla, whether intentionally or incidentally. This suggests that adjuvant irradiation significantly compensated for rsALN after surgery, consistent with the paradigms established by earlier studies [4,15,27,28]. Whether an additional simultaneous integrated boost (SIB) to the specific nodal region provides further benefit, as suggested by some guidelines [11,21,22], remains to be investigated as currently only small retrospective series exist on this issue.

The quality and extent of ALND are important considerations when interpreting our findings. However, this also highlights one of the inherent challenges of ALND in current clinical practice, as surgical techniques and the extent of dissection are not standardized and may vary considerably between surgeons and institutions. The clinical relevance of this heterogeneity, particularly regarding oncological outcomes, remains incompletely understood. Our finding that the number of removed ALN did not influence recurrence or survival aligns with previous multicenter data suggesting that surgical extent is not a primary impact factor for the prognosis in cN+ patients [29]. While older studies provided mixed evidence on the necessity of extensive nodal removal [18,24], modern diagnostic precision and effective adjuvant therapies have largely diminished the need for extreme surgical radicality.

Finally, the management of the axilla in the PST setting remains a subject of debate. While non-responders require aggressive multimodal treatment, responders benefit from de-escalation [30]. Recent data from the NSABP B-51 and RAPCHEM trials demonstrated that RNI may be safely omitted in certain patients who achieve pCR (yN0) [31,32]. However, in patients with rsALN after ALND, currently evidence is lacking.

A central limitation of the present study is the relatively short median follow-up period of 30 months, which restricts the assessment of long-term oncological outcomes, particularly late axillary recurrences. In patients with hormone receptor-positive disease, previous studies have shown that the risk of recurrence persists beyond 5 years and rises steadily for up to 20 years [33]. Therefore, the current follow-up period is insufficient to draw definitive conclusions regarding long-term recurrence rates. However, the primary objective of determining the prevalence of rsALN after comprehensive prior axillary surgery is independent of follow-up duration and remains clinically relevant for radiooncological treatment planning.

5. Conclusion

This CT-based analysis demonstrates that postoperative rsALN are common in high-risk patients after ALND, regardless of the number of dissected lymph nodes. Initial nodal burden is the strongest predictor for rsALN. Strikingly, even in case of rsALN locoregional control remains excellent when axillary radiotherapy is applied with similar distant metastases rates compared to patients without rsALN. Future studies with longer follow-up are required to confirm the significance of rsALN for postoperative radiotherapy planning and its prognostic value.

CRediT authorship contribution statement

Sophie T. Behzadi: Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Thomas Huber:** Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Data curation, Conceptualization. **Nicolas S. Lenhart:** Writing – review & editing, Methodology, Data curation. **Antonia Wiedemann:** Writing – review & editing, Methodology, Data curation. **Luisa Allwohn:** Writing – review & editing, Validation. **Denise Bernhardt:** Writing – review & editing, Validation. **Sophia Kiesl:** Writing – review & editing, Validation, Methodology, Investigation. **Sophie Maier:** Writing – review & editing, Validation. **Rebecca Moser:** Writing – review & editing, Validation. **Jana Nano:** Writing – review & editing, Validation, Methodology, Formal analysis. **Evelyn Klein:** Writing – review & editing, Validation. **Georg P. Schmidt:** Writing – review & editing, Validation. **Marion Kiechle:** Writing – review & editing, Validation. **Stephanie E. Combs:** Writing – review & editing, Validation, Supervision, Project administration. **Kai J. Borm:** Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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