



# Oncologic outcomes in breast cancer patients with metastatic nodes and pathological nodal response following neoadjuvant chemotherapy without axillary dissection: a literature review

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**Background and Objective:** With promising nodal pathological complete response (pCR) after neoadjuvant chemotherapy, the role of axillary lymph node dissection (ALND) was questioned. While there is much data on the accuracy of axillary staging after neoadjuvant chemotherapy to predict nodal pCR, limited data on the oncological safety of omitting ALND exists. We aim to review the oncological safety of omitting ALND in patients with initially metastatic nodes achieving nodal pCR, based on axillary staging, following neoadjuvant chemotherapy.

**Methods:** A PubMed search of relevant articles from 1<sup>st</sup> January 2013 to 15<sup>th</sup> September 2022 was performed. Studies with duplication of patients, ALND only, no oncological details, initially N0 patients only and patients without nodal pCR were excluded.

**Key Content and Findings:** Fifteen studies with 1,515 eligible patients (range, 29–242 patients) were analysed. There was heterogeneity of patients among the included studies and patients had varying TN staging, making selection criteria for omission of ALND inconclusive. Sentinel lymph node biopsy (SLNB) was the most studied mode of axillary staging in 1,416 (93.5%) patients, though 35.7% had <3 SLN harvested. On average median follow-up of 52.8 months (range, 9–110 months), axillary recurrence ranged from 0% to 3.4%. There was limited data on survival outcomes.

**Conclusions:** In node positive breast cancer patients who achieved nodal pCR after neoadjuvant chemotherapy, the axillary recurrence rate was low without ALND. However, survival data was limited. The selection criteria and ideal axillary staging technique for patients, who are suitable for axillary preservation, are unclear. More prospective studies with longer follow-up, providing survival data, are needed.

**Keywords:** Breast cancer; neoadjuvant chemotherapy; sentinel lymph node biopsy (SLNB); survival; axillary recurrence

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## Introduction

For node positive (N+) breast cancer patients with no systemic metastasis, axillary lymph node dissection (ALND) used to be the treatment of choice. However, with the promising results of nodal pathological complete response (pCR) with neoadjuvant chemotherapy (1), axillary staging, in the form of sentinel lymph node biopsy (SLNB) alone (2) or combined with clipped node excision via targeted axillary dissection (TAD) (3) or clipped node alone (4) have been reported. Depending on the results of the axillary staging, an ALND could potentially be omitted.

While there was much data on the various types of localising agents used for clipping the node (5) and the accuracy of SLNB or TAD in predicting nodal pCR for this group of patients (3,6), there is limited data on the oncologic safety of omitting ALND following neoadjuvant chemotherapy in patients with initial metastatic nodes. We aim to perform a narrative review of the axillary recurrence and survival rates in this group of patients with nodal pCR after neoadjuvant chemotherapy, who underwent SLNB, TAD or clipped node staging only. This is the first such reported review, to the best of our knowledge. We present the following article in accordance with the Narrative Review reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-4961/rc>).

## Methods

A PubMed search was conducted for relevant publications dated between 1<sup>st</sup> January 2013 to 15<sup>th</sup> September 2022, using the following search terms: breast cancer, neoadjuvant chemotherapy, SLNB, TAD, survival, axillary recurrence, clipped node (*Table 1*). Publications were only searched from the year of 2013 because the concept of axillary staging after neoadjuvant chemotherapy without ALND for patients with initially metastatic nodes, was only introduced around that time (7). Only publications in the English language consisting of female patients were included. Publications without an abstract, such as editorials and letters to the editor were excluded.

This review included patients with initially N+ disease who underwent only SLNB/TAD/clipped node following neoadjuvant chemotherapy and achieved ypN0 based on histological axillary staging, to follow-up on their oncologic outcomes. We excluded publications with duplication of the study population, patients who underwent ALND or had no recurrence data. Patients with no clinical or pathological

nodal metastasis prior to neoadjuvant chemotherapy were excluded too.

The PubMed search was conducted independently by two authors. The abstract was first assessed for its relevance. If found to be relevant, the full article was retrieved for the extraction of relevant details. For relevant publications, the references in the publications were also assessed for relevance to add to the review. For any relevant publication, a PubMed search was also conducted to look for similar related articles. In cases of discordance, the two authors would reassess the article again to reach a consensus.

## Results

A total of 22 studies were found relevant to this review. However, 7 studies had to be excluded as 2 studies (8,9) had duplication of patients. For such duplicated cases, studies with a longer follow-up (10,11) were included instead. Another publication (12) included patients from 2 centres, of which there was duplication of the patients from one of the centres with another study (11). Since the patients from the various centres in the study could not be differentiated, this study (12) was excluded. In addition, though the multicentre study by Kang *et al.* (13) demonstrated in their subgroup analysis that ypN0 patients undergoing SLNB versus ALND did not have a statistical difference in axillary and distant metastasis-free survival, it did not provide further specific recurrence or survival data relevant to our study population. As a result, it was excluded. Three other studies (14-16) analysed their data using the National Cancer Database which contained no recurrence data and were hence excluded.

After excluding these 7 studies, 15 studies with 1,515 eligible patients (range, 29–242 patients) (10,11,17-29) were analysed in this review (*Table 2*). All studies were retrospective in nature except for a study which was prospective (26). In addition, there could be duplication of some patients in these two same single centre studies (26,29) since there was an overlap of the study period in both studies, reported from 2007 to 2015 and 2002 to December 2007 respectively. However, as the former was a prospective study and the period overlap was not significant, decision was made to include both studies. In two studies (21,26), nodal isolated tumour cells after neoadjuvant chemotherapy were considered as having achieved nodal pCR.

For the patients' characteristics, there was heterogeneity of the patient cohort among the included studies and patients had varying TN staging. Though we only included

**Table 1** The search strategy summary

Items	Specification
Date of search	15 <sup>th</sup> September 2022
Databases and other sources searched	PubMed
Search terms used	Breast cancer, neoadjuvant chemotherapy, sentinel lymph node biopsy, targeted axillary dissection, survival, axillary recurrence, clipped node
Timeframe	1 <sup>st</sup> January 2013 to 15 <sup>th</sup> September 2022
Inclusion and exclusion criteria	Included: studies with patients who (I) were initially N+ disease; (II) underwent only SLNB/TAD/clipped node following neoadjuvant chemotherapy; (III) achieved pathological NO; (IV) had oncological outcomes  Excluded: (I) non-English publications; (II) publications without female subjects; (III) publications without abstract, such as editorials and letters without patient's details etc.; (IV) publications with duplication of the study population
Selection process	Two authors conducted the search independently. In cases of discordance, the two authors would reassess the article again to reach a consensus
Any additional considerations, if applicable	For relevant publications, the references in the publications were also assessed for relevance. A PubMed search was also conducted to look for similar related articles for all the relevant publications

SLNB, sentinel lymph node biopsy; TAD, targeted axillary dissection.

patients with nodal metastasis prior to neoadjuvant chemotherapy in this review, not all nodal metastasis were pathologically proven. Only 7 studies had patients with strictly pathologically proven nodal metastasis, while the rest of the studies included patients with either clinical or/and imaging based nodal metastasis.

SLNB was the most studied mode of axillary staging in 1,416 (93.5%) patients. Of these patients, 8 studies of 505 patients (35.7%) had less than 3 median lymph nodes harvested. Only 1 study reported on the use of clipped node (17). In that study, the clipped node ypN status and the number of abnormal nodes on positron emission tomography (PET)/computed tomography (CT) done prior to neoadjuvant chemotherapy were used to decide the need for adjuvant axillary radiotherapy.

Radiotherapy details were not explicitly reported in some studies and if reported, it was unclear in 4 studies (11,21,22,24) how many of these patients specifically received axillary radiotherapy.

Average median follow-up was 52.8 months (range, 9–110 months). Reported axillary recurrence was low and ranged from 0% to 3.4%. Data on regional recurrence was reported in 9 studies, mainly in the supraclavicular nodes, while there was no mention of regional metastasis in the other studies. Survival specific to this group of patients with N+ converted to nodal pCR after neoadjuvant chemotherapy and omitted ALND was not well reported.

Survival, of varying parameters, was reported for only 5 studies. In the study with the longest median follow-up of 110 months and 123 eligible patients, 11 breast cancer related deaths were reported (10).

## Discussion

In a review of 15 studies comprising of 1,515 patients with initial N+ status and subsequent nodal pCR after neoadjuvant chemotherapy with omission of ALND, SLNB was the most used method for axillary staging. On an average median follow-up of 52.8 months (range, 9–110 months), the reported axillary recurrence rates were low. Survival data, specific to this group of patients, was only reported by few studies.

With the promising results of nodal pCR of about 40% with neoadjuvant chemotherapy, the need for an ALND in such cases was questioned. This led to a trend towards de-escalation of axillary surgery in neoadjuvant patients identified to have nodal pCR during axillary staging by SLNB, excision of clipped node or TAD. In fact, NCCN guidelines state that SLNB may be attempted in selected post-neoadjuvant, clinically node-negative cases (30). While axillary staging can achieve acceptably low false negative rates (3,6), there are currently limited studies on its oncologic outcomes if ALND was omitted in patients deemed to have achieved pCR based on axillary staging.

**Table 2** Summary of findings from studies in chronological order

1 <sup>st</sup> author	Year of publication	Patient cohort in the study	No. of patients who met criteria	cN+ or pN+	Type of axillary staging	Median nodes retrieved, n	Axillary radiotherapy, n (%)	Median months of follow-up	Axillary recurrence, n (%)	Survival	Comments
van Loevezijn AA (17)	2022	Stage I-III, N+	99	pN+	Clipped node	1	43 (43.4)	36	1 (1.0)	-	1 other regional recurrence
Barrio AV (18)	2021	T1-3N1	234	pN1	SLNB	≥3	164 (70.1)	40	1 (0.43) <sup>®</sup>	-	-
Cabioğlu N (19)	2021	T1-4N1-3	211	pN+	SLNB	70.6% had ≥3	211 (100.0)	36	0 (0.0)	88%*, 96.2%**	No other regional recurrence
Kahler-Ribeiro-Fontana S (10)	2021	T1-3N0-2	123	cN1/2 or pN+	SLNB	<3	-	110	2 (1.6)	11 breast cancer deaths	2 other regional recurrences
Sharp NE (20)	2021	T1-4N0-3	68	pN+	SLNB	<3	-	46.8	2 (3.0) <sup>®</sup>	-	-
Lee SB (21)	2021	T1-4N0-3	242	pN+ or imaging	SLNB	Mean >3	204 (84.3) <sup>#</sup>	-	7 (2.9, 5-year axillary recurrence rate) <sup>®</sup>	5-year OS 87%	5-year DMFS 90%^^^
Damin AP (22)	2021	T1-4N1/2	38	cN1/2	SLNB	Mean =2	33 (86.8) <sup>#</sup>	55.8	2.6%	-	Distant metastasis 7.9%. No other regional recurrence. SLNB in T1-3 patients only
Wong SM (23)	2021	T1-3cN0-2	58	pN+	SLNB	4	70.7%	36	0 (0.0)	-	5-year distant recurrence 13.7%. No other regional recurrence
Kim H (24)	2021	cT1-4N1-3	94	cN+	SLNB	2.2	93 (98.9) <sup>#</sup>	57	1 (1.1)	5-year OS 96.3%	5-year DFS 89.2%, 3 other locoregional recurrence
Riogi B (25)	2021	N+	29	cN+	SLNB	2	-	43	0 (0.0) <sup>®</sup>	-	Axillary radiotherapy was planned
Martelli G (26)	2020	T2N0-1	81	cN1	SLNB	2	-	87	0 (0.0) <sup>®</sup>	-	cT2 tumour only^^
Ogawa Y (27)	2018	T1-4N0-3	29	cN1-3	SLNB	<3	-	59	1 (3.4)	-	Another 4 supraclavicular node recurrences
Nguyen TT (28)	2018	T0-4N1	82	pN1	SLNB	3	-	9	0 (0.0)	-	No other regional recurrence
Choi HJ (11)	2018	T1-4N1-3	84	pN+	SLNB	>3	70 (82.4) <sup>#</sup> ^	51	2 (2.9)	OS 92.9%^	1 regional recurrence
Martelli G (29)	2017	T2N0-1	43	cN1	SLNB	<3	-	72	0 (0.0) <sup>®</sup>	-	cT2 tumour only

\* , 5-year DFS; \*\*, 5-year disease-specific survival; <sup>®</sup>, no mention of regional metastasis; <sup>#</sup>, nodal radiotherapy not specified; <sup>^</sup>, included a patient with ypN1 disease on final histology; <sup>^^</sup>, ypN0 (i) not considered as nodal metastasis. DFS, disease-free survival; DMFS, distant metastasis-free survival; OS, overall survival; SLNB, sentinel lymph node biopsy; TAD, targeted axillary dissection.

There was heterogeneity of the patient cohort in the reviewed studies, with some studies including only T2 patients (26,29) versus T1–4 patients in other studies. Also, the nodal status in the studies varied from N0 to N3, of which only those with N+ disease was analysed for this review. In some studies, there was inclusion of only N1 disease while other studies included more extensive nodal disease of N2–3. Whether ALND can safely be omitted in patients with initially advanced cancer stage such as T4 or N2–3 disease but achieved nodal pCR based on axillary staging, is still controversial. Some studies (31,32) have suggested the use of axillary staging if there was a good clinical response after neoadjuvant chemotherapy in patients with initially high nodal burden as nodal pCR could still be achieved. This was especially so in patients with chemotherapy sensitive subtypes such as triple negative and Her2-positive disease (32). With heterogeneity of the study population in this review and lack of the specific details about the patient cohort of interest in most studies, it is difficult to establish the selection criteria for initially N+ patients who are suitable for ALND omission following neoadjuvant chemotherapy.

Besides the controversy on the selection criteria, the type of axillary staging technique is also debatable. Most of the studies in this review relied on SLNB for axillary staging and interestingly, 35.7% of patients with SLNB had a median yield of less than 3 lymph nodes. In fact, one study (20) specifically determined the effect of the number of harvested sentinel lymph nodes on recurrence rates and found that despite the higher false negative rate associated with <3 sentinel lymph nodes, the recurrence rate in this group was not significantly higher. This observation was also noted in the other settings whereby occult axillary disease following SLNB may not translate into a clinically meaningful detrimental oncologic outcome (33), though data in the neoadjuvant setting is lacking.

There was one study (17) that relied on excision of clipped node only for axillary staging, and it showed comparable low axillary recurrence rate. The ideal number of harvested lymph nodes involving clipped node/TAD is currently unknown. With the increasing availability of the localising devices, it is likely that more studies on the oncologic outcomes of using clipped node or TAD solely without ALND will surface in future.

In this review, a low axillary recurrence was observed. This finding could be explained by the following reasons. Firstly, not all patients had a pathologically proven node, hence some of the lymph nodes which were deemed initially

to be N+ based on clinical and/or imaging prior to NACT may have been false positives, contributing to an observed low axillary recurrence rate. However, in other studies with pathologically confirmed nodes prior to neoadjuvant chemotherapy, the axillary recurrence rates were similarly low. Secondly, these patients may have received axillary radiotherapy which could explain the low axillary recurrence rates, though this detail was not explicitly mentioned in most of the included papers in this review. The role of radiotherapy in cases of ALND omission is currently unclear and the results of the prospective NSABP B-51/RTOG 1304 trial (34) investigating the role of axillary radiotherapy in our subgroup of patients are eagerly awaited. Finally, the average median follow-up of all the studies in the review was 52,8 months (range, 9–110 months). With longer follow-up, more recurrences may be observed.

Finally, although the axillary recurrence rate may be low, it is also important to study, in this group of patients, other oncologic parameters such as regional or distant recurrence and survival etc. It is also unclear if omitting ALND can be associated with a higher risk of regional nodal recurrence, particularly to the supraclavicular nodal basin, although supraclavicular nodal metastases had been reported to occur independently of axillary nodal metastases (35). Unfortunately, besides axillary recurrence rates, other oncologic parameters were not explicitly documented in the included studies, hence the overall oncologic safety of omitting ALND in this group of patients must be interpreted with caution.

Strengths of this review included that this is the first reported review of the oncologic outcomes of this specific group of N+ patients who achieved nodal pCR after neoadjuvant chemotherapy and omitted ALND. As there are currently limited studies in literature reporting on the oncologic outcomes of this group of patients, our pooled analysis of the relevant studies would provide a representative summary from the larger, combined cohort of patients.

Limitations of this review included the retrospective nature of most studies. Pathological confirmation of nodal status was not performed for all. Heterogeneity of the patient cohorts with varying TN staging and non-standardisation of the axillary staging techniques also made analysis difficult. In addition, survival data, supraclavicular lymph node or distant recurrence rates of this group of patients were not specifically mentioned in most of the included studies. Finally, we restricted our article search only to PubMed and may not have captured relevant articles that may be found in other databases.

## Conclusions

In node positive breast cancer patients with nodal pCR after neoadjuvant chemotherapy, the axillary recurrence rate was found to be low in women who did not undergo ALND. There was however limited reported survival data. The selection criteria and ideal axillary staging technique for patients, who are suitable for axillary preservation, are also unclear. As the findings were based on few studies which were mostly retrospective in nature, more prospective studies providing survival data over a long follow-up duration will be useful.

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## Footnote

*Reporting Checklist:* The authors have completed the Narrative Review reporting checklist. Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-4961/rc>

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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