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Posted Date: 27 March 2025

doi: 10.20944/preprints202503.2054.v1

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Article

Current Indications for the Seed Marked Axillary Lymph Node Dissection in Breast Cancer

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Simple Summary: Marker placement in pathological lymph nodes can improve resection rates in breast cancer with limited axillary involvement. Our goal was to assess in which cases the seed marked axillary lymph node dissection (SMALND) is indicated. Our findings concluded that the most prevalent indication was after neoadjuvant therapy, followed by initial surgery and axillary recurrence. The extirpation rate of the marked axillary node was 100% and, in the case of targeted axillary dissection (TAD), the rate of concordance between the sentinel node and the marked axillary node was 85%. The use of seeds has proven to be highly useful in neoadjuvant therapy and in cases of primary surgery with low axillary involvement or single axillary recurrence.

Abstract: Marker placement in a pathological node improves extirpation rates in breast cancer cases with limited axillary involvement. Our goal was to assess current indications for seed marked axillary lymph node dissection (SMALND). We conducted a descriptive observational study including 93 patients with cN1 breast cancer between January 2019 and December 2023. Seed placement was performed under ultrasound guidance days before the procedure. Intraoperative detection was achieved using a probe, and resection was confirmed radiologically. The primary indication was post neoadjuvant therapy (72 patients: 60 chemotherapy and 12 hormone therapy), followed by initial surgery (13), and single axillary recurrence (8). The extirpation rate of the marked axillary lymph node was 100%. In Target Axillary Dissection (TAD), the concordance rate between sentinel node and marked axillary node was 85%. In the 12 cases of initial surgery, axillary lymphadenectomy was avoided because the marked node matched the sentinel node and was the only one involved. The use of seeds has proven to be highly useful in axillary surgery, both in cases of negativization following neoadjuvant therapy and in those with low axillary involvement or single axillary recurrence.

Keywords: axillary recurrence following breast cancer; seed marked axillary lymph node dissection; targeted axillary dissection; seed marking

1. Introduction

Breast cancer is the most commonly diagnosed malignancy and the leading cause of cancer-related death among women [1].

Axillary node involvement is one of the most important prognostic factors. As lymph node involvement increases, survival rate decreases, regardless of tumor size [2]. Therefore, accurate loco-regional staging is essential for appropriate treatment planning.

Until recently, the standard treatment for axillary disease was lymphadenectomy, regardless of axillary tumor burden. However, axillary lymphadenectomy is associated with a series of severe complications, such as upper limb lymphedema, restricted mobility and decreased quality of life [3,4].

Currently, in early stages breast cancer without axillary involvement, the most reliable method for loco-regional staging is sentinel lymph node biopsy (SLNB). The sentinel node (SN) is the first lymph node to receive direct lymphatic drainage from the tumor and serves as predictor of involvement in the remaining nodal pathway. When lymph nodes are initially affected axillar management becomes more complex and requires additional considerations based on specific clinical scenarios.

Axillary involvement and neoadjuvant therapy. Neoadjuvant therapy allows for less extensive breast surgeries when tumors respond adequately. Recently, in cases of limited lymph node involvement (cN1, positive puncture or biopsy) and clinical-radiological normalization following neoadjuvant therapy, SLNB has been proposed as a possibility; avoiding the lymphadenectomy if non-histological involvement of the sentinel lymph node is demonstrated [5]. However, trials such as ACOSOG Z1071 [6] have reported an unacceptable false negative rate (FNR), as it did not fall below 10%. This highlighted the need for a new approach to improve sensitivity and reduce the FNR.

In this scenario, ensuring the resection of the previously affected node during SLN is crucial, as it helps reduce the FNR and improves the assessment of residual disease following neoadjuvant therapy [7]. The ACOSOG Z1071 trial concluded that placing a clip in the metastatic node at diagnosis and ensuring its removal during surgery after neoadjuvant chemotherapy reduced the false negative rate to 6.8 %. In contrast, when the affected node was not clipped, the FNR increased to 13.4% [8].

Subsequently, in an attempt to reduce unnecessary lymphadenectomies, pre-surgical localization and TAD of the affected node with the use of a radioactive seed (iodine-125), clip and carbon ink was developed [9]. We currently have the option of using magnetic or radar seeds to this effect.

Other possible scenarios for the use of seeds are the localization of the single metastatic nodes in patients undergoing primary surgery or single node recurrence resection.

Axillary involvement and primary surgery. In patients with clinically negative axilla who meet ACOSOG Z-0011 [10] criteria (T1 or T2 tumors with one or two positive sentinel nodes) the lymphadenectomy can be avoided. In these cases an axillary ultrasound could lead to overtreatment, since patients with cytological or histological diagnosis of axillary involvement will be subject to axillary lymphadenectomy, based on some current recommendations. Many of these patients could have been candidates for SLNB if the ultrasound had not been made. However, it is possible that some of them with axillary involvement and higher probability of lower axillary tumor burden could be candidates for targeted axillary dissection (TAD) or similarly, to SMALND plus SLNB [11].

Single axillary recurrence. In the case of non-palpable axillary recurrence or palpable recurrence which becomes non-palpable after neoadjuvant therapy, marking would ensure removal regardless of whether or not the lymphadenectomy is completed. Since radiological diagnosis of axillary recurrence is quite rare [12], there are no data on how to mark these lesions. In 2018, our institution introduced the use of magnetic seeds for localization of non-palpable breast lesions [13], and the pre-surgical localization of the metastatic axillary node following neoadjuvant treatment. In addition, the same method has been used to mark affected lymph nodes in cases of initial surgical treatment of a single metastatic axillary lymph node.

The main objective of our study was to define the scenarios where SMALND is indicated. Secondary objectives included to determining the advantages of SMALND calculating the seed retrieval rate, assessing the concordance between SN and seed marked axillar nodes (ANs), and evaluating the safety of the technique.

2. Materials and Methods

2.1. Study Design

We designed a retrospective, descriptive observational study including patients diagnosed with breast cancer with limited axillary involvement (cN1). It was approved by the Ethics Committee of our Hospital.

We included ninety-three patients treated for breast cancer between January 2019 and December 2023. Every patient was over 18 years and had been diagnosed with breast cancer with limited axillary involvement and underwent SMALND.

Confidentiality of all study data has been respected.

Data from the electronic medical records were obtained, and the following variables were collected: age of the patient at diagnosis, anatomy-pathologic diagnosis, molecular classification, TNM classification, number of radiological affected lymph nodes, number of marked nodes, complications during placement of the seed, type of neoadjuvant therapy, clinical-radiological response, type of breast surgery, whether or not a selective SLNB was performed, number of sentinel nodes, result of the SLNB, whether or not a lymphadenectomy was performed, SMALND, concordance or not of the sentinel lymph node with the marked node, definitive breast surgery result, definitive result of the sentinel node if it didn't match to the marked node; result of the lymphadenectomy, number of affected lymph nodes and total number of nodes obtained, as well as pathological TNM stage.

2.2. Procedures

Upon suspected axillary involvement, a puncture/biopsy was performed by the Radiology Service. Cytological or histological confirmation of involvement was conducted by the Anatomical Pathology Department. Following approval by the Multidisciplinary Committee, a coil-type marker was placed in the lymph nodes in cases requiring primary systemic treatment (chemotherapy or hormone therapy). Following completion of neoadjuvant treatment, a radiological assessment of the response was conducted. Upon committee approval to perform TAD, the seed was placed in the affected lymph node.

In cases not requiring neoadjuvant treatment (initial surgery or some cases of single metastasis), direct placement of the seed was performed.

Both the SMALND and the breast surgery were conducted by one or two Gynecologist of the Breast Unit.

The seed placement in the metastatic lymph node was conducted by the Breast Radiologist of our institution under ultrasound guidance. First, the axillary lymph node to be marked is located on the ultrasound, and the approach is planned. After disinfecting the area, local anesthesia is administered at the access point and in the subcutaneous pathway. After that, a small incision is made in the skin with a scalpel, through which the needle containing the seed is inserted (with gauges ranging between 14G, 16G and 18G depending on the seed used). The needle moves forward until its tip is inside the node, and at this time the safety lock of the needle is removed and the seed is released. Once released, the needle is removed and adequate placement is verified via ultrasound. Upon completion of the procedure, the correct localization of the seed in the lymph node is radiologically verified.

In cases of TAD, migration of the radiotracer to the SN and concordance with the seed marked AN is checked by means of lymphogammagraphy by the Nuclear Medicine Service.

For intraoperative localization of the seed marked lymph node, the corresponding probe was used. At our institution, we can use three types of devices for localizing non-palpable lesions: magnetic systems such as Magseed® and Sirius Pintuition® or radar, such as Savi Scout®. Following resection of the marked lymph node, the presence of the seed in the node was confirmed either macroscopically or radiologically.

In the cases of TAD where pathologic complete response (PCR) was expected after neoadjuvant treatment and where the intention was to avoid a lymphadenectomy, the lymph nodes were studied intra-operatively with hematoxylin-eosin staining of sections by the Anatomical Pathology service. In cases of upfront surgery, the nodes were studied by deferred ultrastadification with OSNA (one-step nucleic acid amplification)

3. Results

During the studied period, 93 SMALND procedures were performed. The initial radiological study detected 1 node in 67 cases, 2 in 17 cases, and 3 in 9 cases (patients who have received neoadjuvant chemotherapy).

Indications for SMALND:

72 cases following primary systemic treatment: 60 after neoadjuvant chemotherapy and 12 following neoadjuvant hormone therapy.

13 cases of initial surgery.

8 cases of single axillary recurrence.

Table 1 shows TAD results (SMALND plus SLNB) of the cases after neoadjuvant hormone-therapy (NAHT). Table 2 shows initial surgery cases. Table 3 shows axillary recurrence cases.

Table 1. Targeted axillary dissection after neoadjuvant hormone-therapy.

Affected lymph nodes on image	Marked lymph nodes	Number of SNs	The SMAN matches the SN	Non-concordant SN, intra-operative +	Non-concordant SN, intra-operative -	Positive lymph nodes in AL	Total lymph nodes in AL	SMAN result
2	2	4	Yes	0	3	0	0	Negative
1	1	2	Yes	1	0	3	11	Positive
1	1	1	No	0	1	0	0	Positive
1	1	1	No	0	1	0	0	Positive
1	1	0	Yes	0	0	0	0	Positive
2	2	2	No	2	0	8	12	Positive
1	1	3	Yes	1	1	0	9	Positive
1	1	3	Yes	1	1	0	0	Positive
1	1	5	Yes	2	2	0	0	Positive
1	1	3	Yes	0	2	0	0	Positive
1	1	2	Yes	0	1	0	0	Positive
2	1	3	Yes	1	1	0	0	Positive

Acronyms: SN: sentinel node; SMAN: seed marked axillary node; AL: axillary lymphadenectomy. Table 1 shows TAD results (SMALND plus SLNB) of the cases following neoadjuvant hormone-therapy (NAHT).

Table 2. Cases with initial surgery.

Affected lymph nodes on image	Marked lymph nodes	Number of SNs	The SMAN matches the SN	Non-concordant SN, intra-operative +	Non-concordant SN, intra-operative -	Positive lymph nodes in AL	Total lymph nodes in AL	SMAN result
1	2	2	Yes	1	0	0	9	Positive
2	2	3	Yes	0	2	0	0	Positive
1	1	2	Yes	0	1	0	0	Positive
1	1	2	Yes	0	1	0	0	Positive
1	1	2	Yes	0	1	0	0	Positive
1	1	3	Yes	0	2	0	0	Positive
1	1	2	Yes	0	1	0	0	Positive
1	1	3	Yes	1	1	0	0	Positive
1	1	3	Yes	0	2	0	0	Positive
2	1	4	Yes	1	2	0	0	Positive
1	1	3	Yes	0	2	0	0	Positive
1	1	3	No	1	2	0	0	Positive
1	1	3	Yes	0	2	0	0	Positive

Acronyms: SN: sentinel node; SMAN: seed marked axillary node; AL: axillary lymphadenectomy.

Table 3. Cases of axillary recurrence.

Case	Year of primary cancer diagnosis	Initial treatment	Years until relapse	Treatment of relapse
1	2013	Mastectomy plus AL	9	SMALND
2	2015	Lumpectomy plus AL (3/10)	7	SMALND
3	2016	Mastectomy plus SN (Neg)	4	SMALND only due to metastatic progression
4	2016	Mastectomy plus AL (2/4)	6	SMALND plus rescue AL
5	2017	Lumpectomy plus AL	4	SMALND
6	2017	Mastectomy plus SN (not migrated)	6	SMALND plus AL
7	2018	Lumpectomy plus AL (5/13)	5	SMALND
8	2022	Lumpectomy plus SN (Neg)	1	SMALND plus AL

Acronyms: SN: sentinel node; SMALND: seed marked axillary node dissection; AL: axillary lymphadenectomy.

There was axillary Pathological Complete Response (PCR) in 27 (45%) cases following neoadjuvant chemotherapy (NACT).

Of the 12 cases of Neoadjuvant endocrine therapy (NAHT) , PCR was found in one case (8%).

Of the 13 patiетns of initial surgery, only in one axillary lymphadenectomy was performed because a second positive unmarked SN.

Of the eight cases of recurrence, only SMALND was performed in five, while in the, an axillary lymphadenectomy was also performed in three.

The detection rate of the marked axillary lymph node was 100%, even though the seed was found in the node capsule in 5 cases.

TAD was performed in 79 cases, and in 66 (84%) of them the SN matched the marked node.

Magseed® was used in 67 (72%) cases; the Savi Scout® seed was used in 20 (21.5%); and the Sirius Pintuition® seed was used in 6 cases (6.5%).

4. Discussion

In our case studies, the most prevalent indication of SMALND was TAD after neoadjuvant treatment. TAD following neoadjuvant chemotherapy has been well studied. In a systematic review from 2021, the combined analysis showed that the FNR associated with SMALND alone was 6.28% and in combination with SLNB was 5.18%. Concluding that both approaches are very accurate in staging the axilla in breast cancer patients with positive lymph nodes following NACT [14]. In our case studies, there have been 12 **cases following NAHT**. At our site, NAHT has been a routine practice for a few years [15]. In these cases, it is important to consider that most lymph nodes are detected by ultrasound subsequently non-palpable. Additionally, many of the palpable nodes become non-palpable after NAHT despite not achieving PCR. Thus, it is very important to mark these lesions as soon as possible, preferably before initiating systemic treatment. On the other hand, it is important to consider the low probability of PCR following NAHT when planning TAD with the possibility of avoiding a lymphadenectomy. In our case studies, we only found PCR in one of the 12 patients treated with NAHT. If we consider that the number of affected lymph nodes is significantly higher in patients in whom axillary metastasis was detected by means of ultrasound guided biopsy [16], and that the number of suspicious lymph nodes in the axillary ultrasound is related to the final axillary burden [17], it is important to select patients who are more likely to have lower axillary tumor burden to be able to consider performance of the TAD. Ideal cases are probably those with up to a maximum of two positive nodes [18,19], smaller, non-lobular, non-G3 tumors, with low KI67 [11]. Thus, the need to prove intra-operatively the existence of a sentinel node without metastatic involvement,

different from the pathologic one, to be able to make the decision not to perform an axillary lymphadenectomy. At our institution, we increased the probability of obtaining a sentinel node other than the one marked with the double marking technique (technetium-99m radioisotope and indocyanine green). With the indocyanine green technique, a higher number of sentinel nodes is obtained on average [20]. Of the twelve cases in our case studies, lymphadenectomy could be avoided in 9 patients who had, at least, an intra-operatively negative node different than the marked one. In all cases, response to NAHT had been demonstrated by performing a biopsy at 2-3 weeks post-treatment to analyze ki67 (<10%) and, on the other, with the radiological tests that confirmed both changes in the tumor and in the affected lymph nodes.

Every patient treated with NAHT received axillar radiotherapy after surgery.

With respect to cases treated with **initial surgery with limited axillary involvement**, we use the same criteria as for the cases of neoadjuvant hormone therapy to decide on the feasibility of TAD. In 11 cases, imaging tests showed an affected lymph node, while there were two affected lymph nodes in only two cases. In 12 (92%) cases, axillary lymphadenectomy could be avoided since there was at least one negative sentinel lymph node other than the marked. All cases presented luminal breast tumors.

Treatment of **single axillary recurrence** requires management by a multidisciplinary team including oncology, radiotherapy and surgery, among others [21]. Surgical treatment is not well defined. Until two decades ago, the usual treatment of axillary recurrence following a lymphadenectomy was a second rescue lymphadenectomy [22,23]. There is evidence on the safety of a second SLNB in patients with recurrent ipsilateral breast tumors who were previously treated with conservative surgery and who had negative SLNB [24,25]. However, the performance of a second SLNB following axillary recurrence after a first SLNB has not been yet considered. In studies on axillary recurrence following SLNB, the usual treatment included a lymphadenectomy [26]. Currently, thanks to the availability of the seeds, we can consider SMALND. Of the 8 cases of our study, four had a previous ipsilateral axillary AL, only the affected lymph node was removed, avoiding a second rescue lymphadenectomy. In two cases with a history of negative SLNB, given the lack of evidence of the safety of a second SLNB, a lymphadenectomy was performed in addition to the seed marked ALND. In case number 4 with a history of AL, the rescue AL was performed given the history of the incomplete initial AL. In case 3, only the SMALND was performed due to metastatic progression.

No complications have been recorded related with the seed placement, or with the fact of carrying it for a time period until the surgery.

The localization and removal rate of the seed and the marked lymph node has been 100%, although in five cases, the seed was localized next to and not inside the node. Results are similar to those reported in the studies using modern seeds to mark the affected node [27,28].

Of the cases in which TAD was performed (SLNB + SMALND), in 84% the SN matched the marked node. In a study with 81 patients where Magseed was used as marker (the most widely used marker in our study), the general concordance rate between the marked lymph node and the sentinel lymph node was 81.5%. [28]. These results are consistent with the expected false negative rate of SLNB following chemotherapy [29].

5. Conclusions

In the event of axillary involvement, the most prevalent indication of SMALND was following Primary systemic Therapy (PST) in the context of TAD. Although we observed an increased indication in the case of initial surgery or single axillary recurrence.

The implementation of SMALND decreases the number of axillary lymphadenectomies in the three scenarios described, mainly for primary surgery with low axillary burden and in the excision of affected lymph node following PST.

The localization and removal rate of the lymph node marked with seed is 100%.

Complications related to placement or with the fact of carrying the seed in the pathologic node are null.

The concordance rate between the marked lymph node and the SN is high.

Author Contributions: “Study design, A.L. and J.I.S.-M.; acquired the data, A.L., Y.N., M.M., E.M., D.G., and A.B.; analyzed and interpreted the data, A.L., and L.F.; writing and editing the manuscript, A.L., Y.N., E.M., and L.F.; supervised the work and contributed to the design of the manuscript, C.M., A.H. and J.I.S.-M. All authors have read and agreed to the published version of the manuscript”.

Funding: “This research received no external funding”.

Institutional Review Board Statement: The protocol of the present study was approved by the Ethics Committee for Research with Medicines of the La Paz University Hospital of Madrid on May 14, 2024. HULP internal code: PI-6181. 2024-345.

Informed Consent Statement: The need for informed consent was waived as part of the ethics approval of our study due to the retrospective design and low risk to the subjects.

Data Availability Statement: This study is based on real-world patient data, including demographics and comorbidity factors that cannot be communicated due to patient privacy concerns.

Acknowledgments: To Sysmex Spain for their help with the publication of the article.

Conflicts of Interest: “The authors declare no conflicts of interest”.

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