
Early Breast Cancer Diagnosis: Axillary Ultrasound Protocols Overview



Axillary lymph node status is crucial in diagnosing and treating early breast cancer. Detecting the presence of lymph node metastases plays an essential role in determining outcomes. Axillary ultrasound (US) is commonly used to assess nodal involvement in clinically node-negative (cN0) patients, especially those treated with breast-conserving therapy. Recent debates and trials have focused on de-escalating surgical staging, questioning the need for sentinel lymph node biopsy (SLNB) in these cases. However, differences in axillary ultrasound protocols pose challenges to consistent and reliable clinical outcomes. An article published in the *European Journal of Radiology* explores these protocols and their variations, examines recent and ongoing trials on de-escalating axillary surgical staging, and discusses the implications for future breast cancer management.

Axillary Ultrasound in Breast Cancer Staging: Protocols and Variations

Axillary US is an essential imaging technique to evaluate nodal involvement in breast cancer. The criteria for identifying suspicious lymph nodes can include various features like cortical thickening, round or irregular morphology, and effacement of the fatty hilum. However, there is no uniform agreement on the acceptable cut-off values for cortical thickness, leading to practice variability. Some trials suggest that a cortical thickness greater than 2.3 mm should be classified as suspicious, while others use a threshold of 3.0 mm or more. This inconsistency affects the clinical interpretation of nodal status and influences decisions on whether to proceed with biopsy and surgical staging. Additionally, the choice of biopsy technique—whether fine-needle aspiration (FNA) or core-needle biopsy (CNB)—also affects sensitivity in detecting lymph node metastases, with CNB generally demonstrating a higher sensitivity than FNA.

Overview of De-escalation Trials and Axillary Ultrasound Protocols

Several recent and ongoing trials have examined the feasibility of omitting axillary surgical staging in cN0 early breast cancer patients treated with breast-conserving therapy. Among these trials are the INSEMA, BOOG 2013-08, NAUTILUS, and SOUND trials, each investigating the potential non-inferiority of omitting SLNB in terms of survival outcomes and axillary recurrence rates.

INSEMA Trial (Germany & Austria): This trial includes over 5,500 patients and examines whether omitting SLNB affects invasive disease-free survival. The trial lacks a defined cortical thickness cut-off for determining suspicious nodes, and patients with suspicious ultrasound findings require a negative CNB or FNA for inclusion. Preliminary results have suggested a higher incidence of arm symptoms in patients undergoing SLNB compared to those who did not, highlighting the potential benefits of de-escalation in terms of patient quality of life.

BOOG 2013-08 Trial (Netherlands): The BOOG trial aims to compare regional recurrence rates after omitting SLNB. It adopts a cortical thickness cut-off of 2.3 mm as the criterion for a suspicious lymph node, which is lower than the thresholds used in some other trials. Another feature of this trial is the inclusion of patients who received neoadjuvant chemotherapy, providing a broader context for evaluating the impact of axillary surgical staging decisions.

NAUTILUS Trial (South Korea): The NAUTILUS trial seeks to compare SLNB with no SLNB in patients with invasive breast cancer. It utilizes a cortical thickness cut-off of 3.0 mm and emphasises the need for mandatory biopsy (FNA or CNB) for patients with one low-suspicion axillary lymph node. This stricter criterion for suspicious nodes aims to refine the accuracy of identifying true negative lymph node status.

SOUND Trial (Italy): Recently published, the SOUND trial demonstrated non-inferiority in omitting SLNB for small (cT1) breast cancers with clinically negative axillary nodes. The five-year disease-free survival was comparable between patients who underwent SLNB and those who did not, supporting the idea that SLNB may be safely omitted in select patient populations. However, the trial did not provide specific information on cortical thickness cut-off values, suggesting the need for further clarification and uniformity in protocols.

Challenges in Uniformity and Implications for Clinical Practice

The variability in axillary ultrasound protocols across trials poses a significant challenge in translating research findings into clinical practice.

Differences in cortical thickness cut-off values, biopsy techniques, and eligibility criteria make it difficult to compare trial results directly and extrapolate them to diverse patient populations. A consensus on the criteria for identifying suspicious lymph nodes would help standardise axillary US protocols and improve the accuracy of clinical nodal evaluation.

Moreover, since biopsy techniques vary in sensitivity, establishing a standardised approach for ultrasound-guided axillary lymph node biopsy is crucial. As ongoing trials explore the safety and efficacy of de-escalating axillary surgical staging, achieving uniformity in axillary US protocols is paramount to ensure consistent and reliable outcomes.

Prospective trials on de-escalating axillary surgical staging in clinically node-negative early breast cancer have demonstrated potential benefits in omitting SLNB without compromising survival outcomes. However, variations in axillary ultrasound protocols among these trials highlight the need for a unified approach to assess clinical nodal status accurately. Standardising the cut-off values for cortical thickness and biopsy techniques would enhance the comparability of research findings and support the implementation of de-escalation strategies in clinical practice. Achieving uniformity in axillary ultrasound protocols will be a critical step toward optimising care for patients with early breast cancer.

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