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Patients with breast cancer and axillary involvement undergoing Sentinel LYMph-node biopsy versus Targeted axillary dissection after primary systemic treatment: which axillary staging saves more lymphnodes? A registry-based randomized controlled trial (SLYMT-AXSANA/EUBREAST 3-R trial)

EUBREAST

Maria Luisa Gasparri[1,2], Steffi Hartmann[3], Michael Hauptmann[4], Maggie Banys-Paluchowski[5], Nina Ditsch[6], Rosa Di Micco[7], Oreste D. Gentilini[8], Thorsten Kuehn[9]

1.Gynecology and Obstetrics, Ente Ospedaliero Cantonale, Lugano, SWITZERLAND 2. University of Italian Switzerland, Lugano, SWITZERLAND 3.Gynecology and Obstetrics, University Hospital of Rostock, Rostock, GERMANY 4.Institute of Biostatistics and Registry Research, Brandenburg Medical School Theodor Fontane, Neuruppin, GERMANY 5. Gynecology and Obstetrics, University Hospital of Schleswig-Holstein, Campus Luebeck, Luebeck, GERMANY, 6. Gynecology and Obstetrics, University Hospital Augsburg, Augsburg, GERMANY, 7. Breast Surgery Unit, San Raffaele University Hospital, Milan, ITALY, 8. Breast Cancer Center, Die Filderklinik and University of Ulm, Filderstadt, GERMANY.

Study Lead: EUBREAST

Study design: registry-based randomized controlled trial

Target accrual: 340 patients

Enrollment begin: September 2026

Inclusion criteria

- 18 years or older.
- cN+ breast cancer (confirmed by core biopsy) converting to ycN0 after primary systemic treatment
- Tumor Size: cT1-3
- Clinical Nodal Status: cN1-3
- Signed Informed consent
- Probe-guided localization methods in case of TAD

Exclusion criteria

- Patients with distant metastasis, recurrent breast cancer, inflammatory breast cancer, or extramammary breast cancer
- Pregnant women
- Unsuitability/Insufficient Primary Systemic Treatment (=fewer than 4 cycles of neoadjuvant chemotherapy)
- Unsuitability for surgery
- Bilateral breast cancer
- History of a malignant tumor, previous surgery on the axilla, radiation therapy to the breast or chest
- Patients lacking personal freedom, civil capacity, mental disorders, or addictions, and those deemed ineligible by the investigator are also excluded.

BACKGROUND: Most of the patients with breast cancer and axillary involvement undergo primary systemic treatment in order to achieve axillary surgical de-escalation in case of response. In this case, the minimally invasive procedure commonly adopted in upfront surgery, consisting of the identification and removal of the first lymph node to which cancer cells are likely to spread from a primary tumor (sentinel lymph node biopsy, SLNB), requires the removal of at least 3 lymph nodes to be accurate and obtain a low false negative rate. Alternatively, the most representative lymph node that undergoes biopsy prior to primary systemic treatment, can be marked and removed together with one sentinel lymph node (Targeted Axillary dissection, TAD).

RATIONALE: Despite several attempts to reduce arm morbidity after axillary surgery, it is well known that the higher the number of axillary lymph nodes removed, the higher the morbidity rate. Both SLNB and TAD are equally considered acceptable surgical axillary staging procedures from an oncological point of view and represent surgical de-escalation procedures with lower body impact and arm injury when compared to full axillary lymphadenectomy. However, there is no consensus on which procedure is most effective at minimizing the number of lymph nodes removed in initially node positive patients with breast cancer in achieving a clinical and radiological response after primary systemic treatment. Accordingly, a lack of standardization and a wide heterogeneity among countries, institutions, and guidelines characterize the surgical staging in this setting and therefore, the choice of treatment belongs more to Institutions' and/or surgeons' preferences than to reliable benefits for the patients.

AIM: To compare the number of lymph nodes removed during SLNB versus TAD performed as surgical axillary staging procedures and related morbidity in patients with breast cancer who initially present with clinically node-positive status that convert to clinical node-negative after receiving primary systemic treatment.
Number of additional nodes included, the failure of techniques, and the need for subsequent axillary lymphadenectomy according to the results of the frozen section during SLNB versus TAD procedures will be assessed in order to better define both the techniques.

Primary outcomes

- Number of lymph nodes removed at the time of the axillary staging in the SLNB group (group 1) versus TAD group (group 2)

Secondary outcomes

- Patient-centered outcome measures (PROMs) to monitor changes in symptoms, functioning, and well-being over time in the 2 groups (e.g. lymphedema assessment, QoL questionnaire, pre- and post-treatment anxiety scores.)
- Number of additional nodes include, during SLNB versus TAD procedures
- Number of axillary lymphadenectomy as completion of the axillary staging in group 1 versus group 2
- Number of failed procedures (defined as no identification of target/sentinel node)
- Operative time, complication rate, cost

The number of lymph nodes removed during the axillary staging will serve as the variable that enables us to determine whether TAD or SLNB is the most convenient axillary staging procedure, in terms of lymph nodal sparing and therefore axillary morbidity!