

Association of Axillary Lymph Node Dissection With Oncological Outcomes in Patients With Residual Micrometastases After Neoadjuvant Chemotherapy: The OPBC-07/microNAC study

Synopsis

Principal investigators

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Clinical question: Is axillary dissection indicated for residual micrometastases after neoadjuvant chemotherapy?

Study design: Multicenter retrospective cohort study

Population: Consecutive patients with residual micrometastases after neoadjuvant chemotherapy treated with or without axillary dissection.

Minimum number of cases per institution: 5

Eligibility:

- Women and men aged 18 years or older with a diagnosis of stage I-III breast cancer (any histological and receptor subtype)
- Completed neoadjuvant chemotherapy
- Residual micrometastases detected on SLNB or TAD or MARI biopsy (on frozen section or final pathology)
- Concomitant presence of ITCs on other sentinel nodes is allowed
- Received axillary treatment with completion ALND, axillary RT, both, or none
- At least 1-year follow-up (inclusion should end in May 2023)
- Had surgery at any time point until May 2023 at the latest
- For cN0 at presentation: any axillary staging technique including palpation is allowed (dual tracer mapping not required for SLNB)
- For cN+ at presentation: cytological or histological confirmation is required. Axillary staging should be performed with sentinel lymph node (SLNB) with dual mapping or targeted axillary dissection (TAD: imaging-guided localization of sampled node in combination with SLN procedure with or without dual mapping) or the MARI (Marking Axillary Lymph Nodes with Iodine Seeds) procedure
- Prior history of stage I-III (not stage IV) BC is allowed

Exclusion:

- Did not undergo SLNB/TAD/MARI (i.e. went straight to ALND)
- Presence of ITCs alone or macrometastases on the sentinel node (or TAD node or MARI node)
- Stage IV disease at presentation
- Inflammatory breast cancer at presentation
- Neoadjuvant endocrine therapy
- Micrometastases detected by OSNA

Primary outcomes:

- 5-year rate of any axillary recurrence (defined as isolated or combined with local or distant recurrence) and 5-year rate of isolated axillary recurrence
- To compare 5-year rate of axillary recurrence in patients treated with and without axillary dissection

Secondary outcomes:

- Proportion with patients with additional positive lymph nodes (micro- or macrometastases) at ALND
- 5-year rates of locoregional and any invasive recurrence
- To compare 5-year rate of locoregional and any invasive recurrence in patients treated with and without axillary dissection

List of variables to be collected:

- Center
- Age (at surgery)
- Race (Asian, Black, Caucasian, other)
- Ethnicity (Hispanic, non-hispanic)
- cT at presentation
- cN0 or cN+ (biopsy-proven) at presentation
- Date of surgery
- Type of breast surgery: BCT/mastectomy
- Type of axillary surgery
 - SLNB with dual mapping (in cN+ and cN- cases) or
 - TAD (in cN+ cases)
 - single or dual mapping?
 - MARI
 - SLNB with single tracer (in cN0 cases)
- Number of SLNs removed
- Number of SLNs with micromets
- Number of concomitant SLNs, TAD, or MARI nodes with ITCs
- Detection on frozen section? y/n
- Method of detection? H&E or IHC?
- ALND y/n
- Number of additional LNs removed
- Number of additional positive lymph nodes
- Size of the largest nodal metastasis found in the ALND specimen: ITCs/micrometastasis/macrometastasis
- Histology (NST/lobular/other)
- Breast pCR: yes/no
- Residual tumor size in the breast: size (cm)
- Tumor grade
- Receptor status
 - ER+ and/or PR+ HER2-;
 - ER+ and/or PR+/Her2+;
 - ER-/PR- Her2+;
 - ER-/PR-/HER2-;
- Type of NAC regimen for HER2- (AC-T/AC-t + Carbo/AC-free regimen/other)
- Type of NAC regimen for HER2+ (AC-TH/AC-THP/TCHP/other)

- Adjuvant capecitabine: yes/no
- If HER2+: type of post-surgical anti-HER2 treatment (H/HP/TDM-1)
- If HR+: received adjuvant endocrine therapy: yes/no
 - if yes: type of endocrine therapy
- Adjuvant Abemaciclib yes/no
- Adjuvant Olaparib yes/no

Radiotherapy: yes/no

- Target Volume:
 - Whole breast irradiation: y/no
 - Chest wall irradiation: y/no
 - Regional nodal irradiation y/no

Follow-up

Date of last follow up

- Recurrence: yes/no
- Type of recurrence: local/regional/locoregional/synchronous (regional and distant, local and distant, locoregional and distant)
- Type of regional recurrence: axillary only, axillary and supraclavicular or internal mammary, supraclavicular or internal mammary without axillary
- Date of recurrence
- Deceased: yes/no
- Date of death
- Cause of death