Nodal recurrence following axillary downstaging with neoadjuvant chemotherapy and omission of axillary lymph node dissection (OPBC-04/EUBREAST-06)

**Study design:** Multicenter retrospective cohort study

**Population:** Biopsy proven N+ breast cancer who achieved nodal pCR after neoadjuvant chemotherapy and did not undergo axillary lymph node dissection

**Eligibility:**
- At least 1-year follow-up (inclusion period until end of 2020)
- Use of sentinel lymph node (SLN) procedure with dual mapping or targeted axillary dissection (TAD: imaging-guided localization of sampled node in combination with SLN procedure with or without dual mapping)
- Site must include a minimum of 10 cases

**Primary outcome:** Rate of nodal recurrence

**Secondary outcomes:** Rate of local and distant recurrence and overall survival

**List of variables to be collected:**
- Center
- Technique used to stage the axilla after NAC:
  - SLNB y/n
  - dual mapping (mandatory in case of SLN only without TAD)
  - single mapping (only allowed in case of TAD)
  - Imaging-guided localization of sampled node node y/n
    - Type of imaging:
      - US only y/n
    - Type of localization:
      - wire/seed/tattoo/others
  - TAD y/n
- Sampled node clipped y/n
  - If yes: Clipped node removed y/n/unknown (documented by specimen radiography or operative/pathology reports)
- Number of negative SLNs
- Number of negative non-SLNs
- Date of surgery
- Age (at surgery)
- Ethnicity
- cT
• cN
• Histology (NST/lobular/other)
• Tumor grade
• Receptor status
  - ER pos and/or PR pos HER2neg;
  - ERneg/PRneg/HER2neg;
  - ERpos and/or PR pos/Her2pos;
  - ERneg/ PRneg Her2pos
• Type of NAC regimen (Taxan/Anthracyclin/Platin containing)
• Type of anti-HER2 therapy (Trastuzumab alone/Trastuzumab+Pertuzumab/other)
• Type of breast surgery: BCT/mastectomy
• Date of surgery
• Breast pCR: yes/no
• Nodal pCR: yes/no (should be excluded if no)
• 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
• Radiotherapy: yes/no
• Target Volume:
  - Whole breast irradiation: y/n
  - Thoracic wall irradiation: y/no
  - Regional nodal irradiation y/no
• Date of last follow up
• Recurrence: yes/no
• Type of recurrence: local/regional/locoregional/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
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