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Omission of axillary lymph node dissection in clinically node-negative breast cancer with sentinel node metastasis: a systematic review and meta-analysis of noninferiority randomized clinical trials

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Objective: To evaluate the de-escalation of axillary lymph node dissection (ALND) in clinically node-negative (cN0) breast cancer with sentinel node (SN) metastasis. **Methods:** A systematic review and meta-analysis (CRD420251000419) was conducted following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines and the PICOTS (patient/population, intervention, comparison, outcome, timing, and setting) framework. The databases PubMed, Embase, and Cochrane were searched for randomized clinical trials with ≥5-year follow-up that evaluated ALND omission in cN0 breast cancer with positive SN, assessing overall survival, disease-free survival, locoregional recurrence, or complications. Pooled hazard ratios (HR) and risk ratios (RR) were calculated using R software, with 95% confidence intervals (CI). Substantial heterogeneity was defined as $I^2 > 25\%$. A margin of 1.25 was set to assess non-inferiority (pni). **Results:** Eight randomized clinical trials were included, comprising 7,798 patients (no ALND: 50.6%; ALND: 49.4%). Omitting ALND was non-inferior for overall survival (HR 0.96; 95%CI 0.75–1.23; $I^2=12.9\%$; $p=0.731$; pni=0.0174) and disease-free survival (HR 1.02; 95%CI 0.89–1.16; $I^2=21.6\%$; $p=0.791$; pni=0.0013), but inferior for locoregional recurrence (HR 1.00; 95%CI 0.76–1.32; $I^2=20.6\%$; $p=0.999$; pni=0.0578). Sensitivity analysis showed similar results for 10-year endpoints. Omitting ALND significantly reduced the risk of lymphedema (RR 0.33; 95%CI 0.19–0.59; $I^2=35.9\%$; $p=0.009$). Subgroup analysis showed no significant disease-free survival differences by estrogen receptor status (positive vs. negative; $p=0.1656$), number of metastatic SNs (1 vs. ≥2; $p=0.4632$), tumor size (<2 vs. ≥2 cm; $p=0.8169$), and age (<65 vs. ≥65 years; $p=0.9971$). **Conclusion:** Omitting ALND provides equivalent overall survival and disease-free survival while reducing lymphedema, although non-inferiority in locoregional recurrence was not demonstrated.

Keywords: sentinel lymph node biopsy; breast neoplasms; lymphatic metastasis; meta-analysis.