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# Omission of axillary surgery in early breast cancer with negative lymph nodes: a systematic review and meta-analysis of randomized clinical trials

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**Objective:** To assess whether there are differences in clinical outcomes regarding the omission of axillary surgery in patients with early-stage breast cancer and clinically negative nodes. **Methods:** A systematic review and meta-analysis including randomized clinical trials was conducted, comparing the no-axillary surgery with standard axillary-surgery (sentinel lymph node biopsy [SLNB] or axillary dissection [AD]). The study was registered in the International Prospective Register of Systematic Reviews (PROSPERO; under CRD420250653779) and the selection process followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. The search strategy included the terms: (“breast cancer”) AND (“axillary dissection” OR “axillary surgery” OR “no axillary surgery” OR “sentinel lymph node”) AND (“randomized study” OR “randomized clinical trial”) within the PubMed and Web of Science databases, with the last search in March 2025. The primary outcomes were overall survival, disease-free survival, and axillary recurrence rates. Data selection was performed using Rayyan software. Meta-analysis was performed using RevMan version 5.4 software, with dichotomous variables assessed using odds ratios (OR) and 95% confidence intervals (CI). Heterogeneity was assessed using the  $I^2$  test and corrected using a random-effects model. The risk of bias was assessed with the RoB-2 instrument. **Results:** Of the 550 retrieved studies, 91 duplicates were excluded, and after data selection, a total of 8,806 patients from seven randomized clinical trials were included in the analysis. Of these, 2,915 patients were in the no-surgery group and 5,891 in the axillary-surgery group. Among these trials, two compared no-axillary surgery with SLNB, while five compared no-axillary surgery with AD. Overall survival (OR 1.02; 95%CI 0.86–1.20;  $p=0.84$ ;  $I^2=36\%$ ) and disease-free survival (OR 0.80; 95%CI 0.63–1.00;  $p=0.05$ ;  $I^2=63\%$ ) showed no significant differences between the groups. Axillary recurrence was lower in the axillary-surgery group (OR 0.18; 95%CI 0.10–0.31;  $p<0.01$ ;  $I^2=39\%$ ). **Conclusion:** Omission of axillary surgery in early-stage breast cancer with negative nodes did not affect overall survival or disease-free survival rates.

**Keywords:** breast cancer; sentinel lymph node biopsy; disease-free survival; survival rate; randomized clinical trials.