INPLASY PROTOCOL

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None declared.

Efficacy of sentinel lymph node biopsy versus standard axillary care for operable breast cancer: a systematic-review and meta-analysis

Wen, ZH[1].

Review question / Objective: **Axillary lymph nodes dissection (ALND) is the standard treatment for early breast cancer, but this procedure can cause overtreatment, destroy the patient's lymph nodes, cause shoulder function damage, and affect the prognosis. Sentinel lymph node biopsy (SLNB) is minimally invasive and safe, and different studies have been divergent on whether it can comprehensively replace ALND. In this study, we investigated the application of SLNB and ALND techniques in early breast cancer surgery by means of literature meta-analysis to compare their efficacy.**
Information sources: **Pubmed, Web of science, Scopus, the Cochrane central register of controlled trials, Wiley online, Google Scholar, ICTRP and ClinicalTrials.gov.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2022 and was last updated on 09 August 2022 (registration number INPLASY202280032).

INTRODUCTION

Review question / Objective: **Axillary lymph nodes dissection (ALND) is the standard treatment for early breast cancer, but this procedure can cause overtreatment, destroy the patient's lymph nodes, cause shoulder function damage, and affect the prognosis. Sentinel lymph node biopsy (SLNB) is minimally invasive and safe, and different studies have been divergent on whether it can comprehensively replace ALND. In this study, we investigated the application of SLNB and ALND techniques in early breast cancer surgery by means of literature meta-analysis to compare their efficacy.**

Condition being studied: **①Literature type is defined as randomized controlled trial**

(RCT); ②All patients are diagnosed with breast cancer (regardless of gender, but more women), all are early operable patients, clinical TNM stage is I or II, clinical axillary lymph node is negative, no distant metastasis; ③The study needs to adopt a certain randomization strategy to group the patients, in this meta-analysis, the patients will be divided into the SLNB group and the ALND group, SLNB frozen section and pathological examination of sentinel lymph node will determine whether there is sentinel lymph node metastasis, if there is no metastasis, total mastectomy or local resection will be performed, if there is metastasis, elective ALND will be performed, as shown in Figure 1; ④Study indicators. In this study, short-term outcome and long-term outcome were used as the main outcome indicators, and short-term outcomes included: Shoulder function scale score and quality of life score after intervention. Long-term outcomes include: overall survival hazard ratio (HR), event-free survival HR.

METHODS

Participant or population: A total of 6319 patients were included in this study.

Intervention: Application of SLNB and ALND techniques in early breast cancer surgery.

Comparator: Normal patients.

Study designs to be included: Literature type is defined as randomized controlled trial (RCT).

Eligibility criteria: Non-english manuscript.

Information sources: Pubmed, Web of science, Scopus, the Cochrane central register of controlled trials, Wiley online, Google Scholar, ICTRP and ClinicalTrials.gov .

Main outcome(s): Among all 11 included literatures, a total of 5 literatures(23-27) reported the comparison of shoulder function evaluation scores after SLNB and ALND, including 1144 patients who underwent SLNB surgery and 1074 patients who underwent ALND surgery, with pooled I^2=99%, P<0.00001. The random-effects model was used to obtain a pooled value: [SMD=1.25, 95%CI(0.18,2.32), Z=2.29, P=0.02], that means compared with ALND, patients treated with SLNB had faster recovery of shoulder function after operation.

Quality assessment / Risk of bias analysis: In this study, the literature did not clearly specify the randomization method on the grouping and had a high risk of bias, while the literature had the risk of bias deviating from the established intervention and the others had no risk. In the overall risk evaluation, there were 7 literatures with low risk, 2 literatures with some concerns and 2 literatures with high risk.

Strategy of data synthesis: ①Due to the different scales used for shoulder joint function and quality of life reported in each study, the pooled SMD (Standard Mean Difference) value and 95%CI report were used as the effect size, the forest plot was used to present the results, P0.05 indicated that the literatures had no heterogeneity and good consistency, and the fixed effect model could be used for analysis; if there was heterogeneity, the random effect model was used for analysis, and the pooled HR value was calculated by Inverse Variance Ratio method. ③Use Publication bias was assessed by the Funnel plot test.

Subgroup analysis: None.

Sensitivity analysis: None.

Country(ies) involved: China.

Keywords: breast cancer; sentinel lymph node biopsy; axillary dissection; meta-analysis.

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