

# INPLASY

## Predictive value of tumor-infiltrating lymphocytes in patients with breast cancer treated with neoadjuvant chemotherapy: A meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - Jiaxing Maternity and Child Health Care Hospital.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202380027

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 August 2023 and was last updated on 07 August 2023.

### INTRODUCTION

**Review question / Objective** The predictive value of tumor-infiltrating lymphocytes (TILs) in response to neoadjuvant chemotherapy (NAC) for breast cancer (BC) has received increasing attention. Here, a meta-analysis was conducted to evaluate the correlation between the expression of TILs and pathological complete response (pCR) after NAC in BC patients.

**Condition being studied** Selecting search terms included “breast cancer,” “tumor-infiltrating lymphocytes,” “neoadjuvant chemotherapy,” and “pathologic complete response.” The search was conducted by combining keywords with free words. After selecting eligible studies according to the inclusion and exclusion criteria, the data were extracted, and two investigators independently assessed the risk of bias in the included studies. Any disagreement was resolved through discussion to reach a consensus or through a

third-party opinion. The following details were extracted from each study: name of the first author and time of publication, country, TILs high expression threshold, study type, molecular subtype, total sample size, sample size of patients in the TILs group, and sample size of pCR events.

### METHODS

**Participant or population** Five researchers and the enrolled populations were exclusively BC patients who had received NAC.

**Intervention** TIL expression was regarded as a categorical variable, and TILs were assigned to the TILs high expression group and the TILs low expression group according to the threshold defined by the included literature.

**Comparator** TILs high expression group and the TILs low expression group.

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**Study designs to be included** retrospective cohort studies.

**Eligibility criteria** Can pathological complete remission be achieved.

**Information sources** A systematic literature search was conducted in the PubMed, Cochrane Library, Embase, and Web of Science databases from conception to February 5, 2023 to find relevant literature on TILs and the efficacy of NAC in BC.

**Main outcome(s)** The patients were assigned to the pCR and non-pCR groups according to the results of the postoperative pathological evaluation.

**Quality assessment / Risk of bias analysis** The quality of the selected studies was evaluated according to the Newcastle-Ottawa Scale (NOS).

**Strategy of data synthesis** All statistical analyses were performed according to the Cochrane Collaboration guidelines for meta-analysis by using Review Manager version 5.3 software and STATA version 16.0 software. Relative risk (RR) and its 95% confidence interval (95% CI) were used to calculate the pooled effect size.  $P < .05$  was considered statistically significant. The Q test and I<sup>2</sup> quantitative test were used to assess heterogeneity. Studies were considered to show significant heterogeneity at  $I^2 \geq 50\%$  or  $P < .1$ , and sensitivity analysis was performed to determine the source of heterogeneity. A fixed-effects model was used after excluding the source of heterogeneity.

**Subgroup analysis** Subgroup analysis according to different molecular subtypes and different high expression thresholds of TILs was performed to further detect and evaluate heterogeneity.

**Sensitivity analysis** In sensitivity analyses, the iterative omission of individual studies from pooled analyses did not impact the overall results.

**Country(ies) involved** China.

**Keywords** Breast cancer, Tumor-infiltrating lymphocytes, Neoadjuvant chemotherapy, Pathological complete response, Meta-analysis.

#### **Contributions of each author**

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