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A systematic evaluation and meta-analysis based on the value of conventional ultrasound and elastography in the differential diagnosis of non-lactating mastitis and breast cancer

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### **ADMINISTRATIVE INFORMATION**

Support - No.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202540022

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 April 2025 and was last updated on 7 April 2025.

### **INTRODUCTION**

Review question / Objective The purpose of this study was to systematically and objectively evaluate the literature on the differential diagnosis efficacy of conventional ultrasound, ultrasound elastography and ultrasound combined with elastography in non-lactation mastitis and breast cancer by means of meta-analysis, so as to evaluate the differential diagnosis value of the three methods and provide references for clinical use. Meta-analysis was used to evaluate the value of conventional ultrasound, ultrasound elastography, and ultrasound combined with elastography in the differential diagnosis of non-lactating mastitis and breast cancer.

Rationale At present, many studies have shown that the differential diagnosis of non-lactation mastitis and breast cancer can be greatly improved by combining elastography with conventional ultrasound. However, it remains to be seen

whether the combination of conventional ultrasound or elastography has more advantages than conventional ultrasound or elastography alone. Firstly, there is a lack of evidence-based medical evidence, and secondly, various research methodologies and outcome indicators are not completely consistent.

Condition being studied Non-lactation mastitis (NLM) is a chronic inflammatory disease with unknown etiology. The main clinical pathological type is plasma cell mastitis (PCM), also known as periductal mastitis (PDM). granulomatous lobular mastitis (GLM), which has atypical clinical features, mainly consisting of a tough mass, partially accompanied by skin redness, sunken nipple, galactorrhea, and tenderness, and ultrasonically manifested as a low-echo mass with abundant irregular blood flow. Its clinical and ultrasonic features overlap with breast cancer, and the differential diagnosis of the two diseases is a key step in clinical diagnosis and treatment.

#### **METHODS**

Search strategy Computer search PubMed, EMBASE, the Cochrane Library, Web of Science, CNKI, China Biomedical Literature Database, Chongqing Weipu Database, Wanfang database. The literatures on the value of conventional ultrasound, elastography and ultrasound combined with elastography in the differential diagnosis of NPM and BC were searched. The terms included granulomatous mastitis, non-lactating mastitis, bresst cancer, echomammography, breast "ultrsound", "elastograthy", "differential diagnosis", etc. The search time was from the establishment of each database to March 8, 2025. The language limit is Chinese and English.

**Participant or population** The patients were pathologically diagnosed as non-lactating mastitis and pathologically diagnosed as breast cancer.

**Intervention** Conventional ultrasound or elastography alone, as well as their combination, were utilized as differential diagnostic modalities for distinguishing between the two diseases.

Comparator No comparison.

**Study designs to be included** Diagnostic trials, including retrospective and prospective design.

Eligibility criteria The diagnostic test data, including the four categories—true positive, false positive, false negative, and true negative—as well as other specific indicators, can be extracted. Additionally, the number of cases for both the mastitis group and the breast cancer group in each original article must exceed 30.

**Information sources** PubMed, EMBASE, the Cochrane Library, Web of Science, CNKI, China Biomedical Literature Database, Chongqing Weipu Database, Wanfang database.

**Main outcome(s)** The ultrasonic diagnosis was consistent with the pathological diagnosis.

**Data management** Noteexpress was used for literature screening.

Quality assessment / Risk of bias analysis Publication bias was detected by funnel plot and Egger test. The literature quality was evaluated by QUADAS2 tool.

Strategy of data synthesis Rstudio was used to combine sensitivity and specificity in a random-

effects model, Spearman's correlation coefficient was used to assess threshold effects, and Cochrane Q was used to assess the heterogeneity between studies. The bivariate random-effects model was used to generate the hierarchical summary receive operating characteristic (HSROC) curve, and the diagnostic odds ratio (DOR) was used to evaluate the accuracy of the diagnostic study.

**Subgroup analysis** Subgroup analysis was performed according to different grading criteria of strain elastic imaging technology. Correlation coefficients such as diagnostic odds ratio (DOR) were used as subgroup analysis evaluation indexes.

Sensitivity analysis After the study excluded small samples, the pooled effect size was recalculated to observe the stability of DOR and AUCThe combined effect size was recalculated after the small sample studies were excluded. The stability of DOR and AUC was observed.

Country(ies) involved China, Turkey.

**Keywords** Non-lactating mastitis; Granulomatous mastitis; Plasma cell mastitis; breast cancer; Breast ultrasound; Elastography; differential diagnosis.

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

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