

INPLASY PROTOCOL

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submission:** The review has
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Conflicts of interest:
None declared.

The value of different imaging methods in the diagnosis of breast cancer: A protocol for a network meta-analysis of diagnostic test accuracy

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Review question / Objective: The objectives of this systematic review and NMA are to determine the diagnostic accuracy of imaging technologies for breast cancer and to compare the diagnostic accuracy of different index tests and to support guidelines development and clinical practice.

Condition being studied: Breast cancer (BC) is the most common cancer in women all over the world and the second most common cause of cancer-related mortality. Imaging examination plays an important role in the diagnosis of early breast cancer. Due to different imaging principles and methods, all kinds of examinations have their advantages and disadvantages. It is particularly important for clinicians to choose these examination methods reasonably to achieve the best diagnostic effect. The objectives of this systematic review and NMA are to determine the diagnostic accuracy of imaging technologies for breast cancer and to compare the diagnostic accuracy of different index tests and to support guidelines development and clinical practice.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 April 2021 and was last updated on 08 April 2021 (registration number INPLASY202140041).

INTRODUCTION

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METHODS

Search strategy: PubMed, Embase.com, the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang, and SinoMed will be searched to identify relevant studies up to August 31, 2021.

Participant or population: Breast cancer patients over 18 years old confirmed by pathology or cytology have received one or more imaging methods including ultrasound examinations, molybdenum target X-ray, nuclear magnetic resonance, or combined examinations. There are no limitations in age, race, or nationality.

Intervention: Breast cancer patients receive any kind of diagnostic ultrasound, molybdenum target X-ray examination, nuclear magnetic resonance examination, including B-ultrasound, contrast-enhanced ultrasound (CEUS), color Doppler ultrasound, full-field digital mammography (FFDM), contrast-enhanced spectral mammography (CESM), digital breast tomography (DBT), etc. It can be one or several imaging examinations.

Comparator: None.

Study designs to be included: We will include random controlled trials, cross-sectional studies, case-control studies, and

cohort studies that evaluated the diagnostic accuracy of different imaging methods for breast cancer. These may be either prospective or retrospective. There are no limitations in minimal quality, minimal sample size, or the number of patients. There will be no limitations on language, publication year, and publication status.

Eligibility criteria: (1) Case report, literature review, case analysis, and review; (2) The original literature was deficient in experimental design. (3) The experimental design of the original literature is defective or not rigorous, including the inclusion and exclusion criteria are vague, the sample size is too small to demonstrate the argument, or the sample information is incomplete, and the statistical methods are not used properly.

Information sources: We will search English databases: PubMed, Embase.com, the Cochrane Central Register of controlled trials (CENTRAL), and Web of Science, as well as Chinese databases: China National Knowledge Infrastructure (CNKI), Wanfang, and Sinomed. The keywords will include: Ultrasonography, X-Ray Microtomography, Echotomography, Ultrasonic Imaging, Medical Sonography, Ultrasonographic Imaging, Echography, Ultrasonic Diagnosis, MicroCT, X-Ray Micro-CAT Scan, X-Ray Micro-Computed Tomography, Xray MicroCT, sensitivity (SEN), specificity (SPE), false positive (FP) reactions, false negative (FN) reactions, ROC curve, breast cancer, breast tumor, breast cancer, breast cancer, breast tumor, breast cancer, and their synonym.

Main outcome(s): The primary outcomes are SEN, SPE, positive predictive value, negative predictive value, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), area under the curve (AUC), and their respective 95% confidence interval.

Additional outcome(s): None.

Data management: Two reviewers will independently screen the literature, extract

the data, and cross-check the data. In case of disagreement, a third party will be consulted to assist in judgment, and the author will be contacted to supplement the missing data if possible. In the process of literature selection, we will first read the titles and abstracts. After excluding the unrelated literatures, we will further read the full text to determine whether they are included. A draft data extraction sheet will be developed using Microsoft Excel 2013 (Microsoft Corp, Redmond, WA, <http://www.microsoft.com>). Data extraction will include: author name, year of publication, country of the first author, number of authors, journal name, country of journals, funding, types of studies, age and number of participants, number and name of imaging examination, number and name of reference test, the reported number of TPs, FNs, TNs, and FPs. If studies did not report these values, we will attempt to reconstruct the 2×2 tables from the diagnostic estimates presented in the article for each imaging examination.

Quality assessment / Risk of bias analysis:

Two review authors will independently assess the risk of bias in each study according to predefined criteria. We will resolve any disagreement by discussion or by involving a third assessor. The Quality Assessment of Diagnostic Accuracy Studies 2 quality assessment tool (QUADAS-2) will be used to assess the methodological quality. QUADAS-2 is composed of four important parts: ① case selection; ② to be evaluated diagnosis test; ③ diagnostic gold standard; ④ case selection process and progress. Two independent evaluators will answer and evaluate each part of the questions one by one, and negotiate if they are inconsistent solve. The evaluation results will be recorded in the form of QUADAS-2.

Strategy of data synthesis: A network plot will be drawn to describe and present the geometry of index tests using R software V.3.4.1. Trials will be excluded if they are not connected by index tests. Nodes in network geometry represent different imaging methods and edges represent

head-to-head comparisons. The size of nodes and thickness of edges are associated with sample sizes of index tests and numbers of included trials, respectively.

Subgroup analysis: If sufficient studies are available, subgroup analysis or univariate meta-regression analysis will be performed on the within-study factors (time, sample size) and between study factors (mean age, race) respectively to screen out the important factors leading to heterogeneity.

Sensitivity analysis: We will use STATA V.12.0 (Stata) and MetaDiSc 1.40 for constructing forest plots showing estimates of SEN, SPE, PLR, NLR, DOR, and their corresponding 95% confidence intervals for each imaging method. Chi2 test will be used to analyze the statistical heterogeneity of the results, and P-value and I2 will be used to quantitatively judge the heterogeneity. If the homogeneity of the included studies is low ($P > 0.1$ and $I^2 < 50\%$), the fixed-effect model will be used for meta-analysis; if there is heterogeneity between the included studies ($P < 0.1$ and $I^2 \geq 50\%$), the source of heterogeneity will be further analyzed. After excluding the influence of obvious clinical heterogeneity, the random effect model will be used for meta-analysis. We will draw the summary receiver operating characteristic curve (SROC). The area under the curve (AUC) will be calculated. The larger the AUC is, the closer it is to 1, which indicates that the authenticity of the diagnosis using this method is better. In addition, we will use STATA V.12.0 (Stata) and Review Manager 5.30 (RevMan) analysis software to build the hierarchical SROCs graphics for each imaging method.

Language: None.

Country(ies) involved: China.

Keywords: Breast cancer; Diagnostic test accuracy; Imaging diagnosis; Network meta-analysis.

Contributions of each author:

Author 1 - Mei Zhang - MZ planned and designed the research. MZ tested the feasibility of the study. MZ provided methodological advice and revised the manuscript.

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Author 2 - Rongna Lian - RNL planned and designed the research. RNL tested the feasibility of the study. RNL wrote the manuscript. All authors approved the final version of the manuscript.

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Author 3 - Ruinian Zhang - RNZ planned and designed the research. RNZ tested the feasibility of the study. RNZ provided methodological advice and revised the manuscript. RNZ wrote the manuscript. All authors approved the final version of the manuscript.

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Author 6 - Shifang Feng - SFF planned and designed the research. SFF tested the feasibility of the study. All authors approved the final version of the manuscript.

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