INPLASY PROTOCOL

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None declared.

Breast specific gamma imaging versus ultrasound and mammography for breast cancer screening and diagnosis: A meta-analysis

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Review question / Objective: **The purpose of this meta-analysis was to compare breast specific gamma imaging (BSGI), ultrasound and mammography with respect to diagnostic performance in the differential diagnosis of benign and malignant breast lesions.**
Eligibility criteria: **The inclusion criteria were as follows: (1) all patients were examined by BSGI, ultrasound and mammography simultaneously before diagnosis; (2) breast cancer was confirmed by pathological examination, or imaging follow-up; (3) at least 30 patients were included in each study; (4) enough data were provided to calculate the true-positive (TP), false-positive (FP), true-negative (TN) and false-negative (FN) values; and we excluded literature that: (1) reviews, letters, case reports, comments, conference abstracts and male or animal studies; (2) patients were undergoing chemotherapy; (3) studies with duplicated data; (4) studies with incomplete data.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 March 2022 and was last updated on 26 March 2022 (registration number INPLASY202230148).

INTRODUCTION

Review question / Objective: **The purpose of this meta-analysis was to compare breast specific gamma imaging (BSGI), ultrasound and mammography with respect to diagnostic performance in the differential diagnosis of benign and malignant breast lesions.**

Condition being studied: **Female breast cancer has now overtaken lung cancer as the highest global incidence in 2020, with approximately 2.3 million new cases, representing 11.7% of all cancer cases. Since early detection, diagnosis and treatment have contributed to the improvement of prognosis, appropriate imaging examinations have become the**

focus of the fight against breast cancer. The optimal breast detection strategy, however, is still unclear.Breast specific gamma imaging (BSGI), also known as "molecular breast imaging", a nuclear medicine breast imaging modality that uses high resolution and small field-of-view breast specific gamma camera designs, is increasingly used for the diagnosis of breast cancer in clinical practice, but its sensitivity is not influenced by breast density. Many studies confirm its accuracy in finding cancers, even in dense breasts, and suggest improved specificity compared with other technologies. Although there are many separate studies on BSGI, mammography or ultrasound, comprehensive comparisons between these techniques have rarely been reported. Byond that, the whole-body dose remains a significant concern. BSGI is not yet a method for routine clinical use. Here, we performed a meta-analysis comparing the diagnostic value of BSGI, ultrasound and mammography for differentiating benign and malignant breast lesions. The main purpose is to explore the applicability of BSGI in daily clinical application.

METHODS

Search strategy: A systematic literature search was conducted up to 30 December 2021 using PubMed, EMBASE and Scopus to identify studies evaluating the diagnostic performance of BSGI in the detection of breast cancer compared with mammography and ultrasound. There were no language restrictions. To gain as much relevant study as possible, a broad search strategy was adopted by us with no limits on "mammography" and "ultrasound". The following search terms were used: "breast neoplasms" or "breast cancer" or "breast carcinoma" and "BSGI" or "breast-specific gamma imaging" or "molecular breast imaging". The references of the documents identified after the initial search were also reviewed manually to guarantee the inclusion of all possible studies.

Participant or population: Breast cancer patients. There are no limitations in age, race, or nationality.

Intervention: Breast specific gamma imaging.

Comparator: Mammography and ultrasound.

Study designs to be included: We will include studies that evaluated the relative diagnostic efficacy of BSGI, ultrasound and mammography as a means of differentiating between malignant and benign breast lesions in the same cohort of patients. These may be either prospective or retrospective. There will be no limitations on language, publication year, and publication status.

Eligibility criteria: The inclusion criteria were as follows: (1) all patients were examined by BSGI, ultrasound and mammography simultaneously before diagnosis; (2) breast cancer was confirmed by pathological examination, or imaging follow-up; (3) at least 30 patients were included in each study; (4) enough data were provided to calculate the true-positive (TP), false-positive (FP), true-negative (TN) and false-negative (FN) values; and we excluded literature that: (1) reviews, letters, case reports, comments, conference abstracts and male or animal studies; (2) patients were undergoing chemotherapy; (3) studies with duplicated data; (4) studies with incomplete data.

Information sources: Qualifying studies were retrieved from PubMed, EMBASE and Scopus up to 30 December 2021. The references of the documents identified after the initial search were also reviewed manually to guarantee the inclusion of all possible studies.

Main outcome(s): The primary outcomes are sensitivity, specificity, 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: Original data were independently collected by 2 authors from

the literatures for the final analysis and based on the following categories where available: first author, published year, study design, sample size, age, standard reference, percentage of malignant lesions and BSGI technique. The TP, TN, FP and FN values were extracted or calculated based on the diagnostic sensitivity and specificity provided in the studies to directly construct 2×2 contingency tables for comparing the diagnostic accuracy of the three imaging modalities. Any disagreements were resolved by consensus.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the quality and applicability of the selected studies using the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2 tool), and disagreements were resolved by discussion and consensus. Publication bias was assessed by Deek's funnel plot using Stata 12.0 software, with $P < 0.05$ indicating significant publication bias.

Strategy of data synthesis: The TP, TN, FP and FN values were extracted or calculated from the selected articles. Data were statistically analysed using MetaDisc1.4 software (Unit of Clinical Biostatistics, Madrid, Spain). We explored the heterogeneity caused by the threshold effect by calculating Spearman's correlation coefficient. Threshold effects were considered significant if $P < 0.05$ and accuracy statistics were suggested to be pooled by fitting the summary receiver operating characteristic (SROC) curve. The Cochran-Q test and inconsistency index (I2) test were used to test heterogeneity (apart from the threshold effect), and $P < 0.05$ or $I2 > 50\%$ suggested the existence of heterogeneity. Summary sensitivity, specificity, positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic odds ratio (DOR), with their 95% confidence intervals (95% CIs), and the areas under the SROC curves (AUC) were analysed. The analysis was performed using the random effects model if heterogeneity was considered significant. Publication bias was assessed by Deek's funnel plot using Stata 12.0 software, with $P < 0.05$ indicating significant publication bias.

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: Sensitivity analysis was carried out by Stata 12.0 to test the stability of the meta-analysis results.

Language: None restriction.

Country(ies) involved: China.

Keywords: breast specic gamma imaging; ultrasound; mammography; breast cancer; meta-analysis.

Contributions of each author:

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