INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: The current meta-analysis aims at determining the accuracy of SWE combined with SMI in the differential diagnosis between benign and malignant breast lesions to provide

Diagnostic accuracy of ultrasound shear wave elastography combined with superb microvascular imaging for breast tumors: A protocol for systematic review and meta-analysis

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Review question / Objective: The current meta-analysis aims at determining the accuracy of SWE combined with SMI in the differential diagnosis between benign and malignant breast lesions to provide reference for the diagnosis and clinical treatment of breast cancer.

Condition being studied: Super Microvessel Imaging (SMI) is a new non-invasive Doppler ultrasound imaging method, which uses a new clutter suppression algorithm to identify and eliminate the movement of tissue itself, extract blood flow signals at a relatively high frame rate, and provide highresolution details of vascular branches without ultrasound contrast agent. SMI can display blood flow information with high spatial resolution and high frame rate, while keeping the minimum low-speed blood flow components. It can diagnose diseases closely related to angiogenesis at a relatively early stage.Studies indicate that SWE combined with SMI is of great value in differential diagnosis of benign and malignant breast masses. However, the results of these studies have been contradictory.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 May 2021 and was last updated on 19 May 2021 (registration number INPLASY202150075).

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METHODS

Participant or population: The patients should be those who had undergone breast tumors

Intervention: This study compared the diagnostic value of SWE combined with SMI and pathology in breast tumors.

Comparator: This study compared the diagnostic value of SWE combined with SMI and pathology in breast tumors.

Study designs to be included: This study will only include high-quality clinical cohort or case-control studies and the patients should be those who had undergone breast tumors.

Eligibility criteria: 1. 1.Type of study. This study will only include high-quality clinical cohort or case-control studies. 1. 2. Type of patients. The patients should be those who had undergone breast tumors. 1. 3. Intervention and comparison. This study compared the diagnostic value of SWE combined with SMI and pathology in breast tumors. 1. 4. Type of outcomes. The primary outcomes include sensitivity, specificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

Information sources: PubMed, Web of Science, Cochrane Library, and Chinese

biomedical databases will be searched from their inceptions to April 18, 2021, without language restrictions. The search strategy for PubMed is shown in Table 1. Other online databases will be used in the same strategy.

Main outcome(s): The primary outcomes include sensitivity, specificity, positive and negative likelihood ratio, diagnostic odds ratio, and the area under the curve of the summary receiver operating characteristic.

Quality assessment / Risk of bias analysis: To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.The threshold effect was assessed using Spearman correlation coefficients. The Cochrans Q-statistic and I test were used to evaluate potential heterogeneity between studies. If significant heterogeneity was detected (Q test P50%), a random effects model or fixed effects model was used. We also performed subgroup and meta-regression analyses to investigate potential sources of heterogeneity. To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.

Strategy of data synthesis: Methodological quality was independently assessed by 2 researchers based on the quality assessment of studies of diagnostic accuracy studies (QUADAS) tool. The QUADAS criteria included 14 assessment items. Each of these items was scored as "yes" (2), "no" (0), or "unclear" (1). The QUADAS score ranged from 0 to 28, and a score \geq 22 indicated good quality. Any disagreements between 2 investigators will be solved through discussion or consultation by a 3rd investigator.

Subgroup analysis: The Cochrans Qstatistic and I test were used to evaluate potential heterogeneity between studies. If significant heterogeneity was detected (Q test P50%), a random effects model or fixed effects model was used. We also performed sub-group and meta-regression analyses to investigate potential sources of heterogeneity. To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.

Sensitivity analysis: To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.

Country(ies) involved: China.

Keywords: breast tumors, meta-analysis, shear wave elastography, superb microvascular imaging.

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