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**ADMINISTRATIVE INFORMATION****Support** - There is no financial support.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202470074**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2024 and was last updated on 20 July 2024.**INTRODUCTION**

**Review question / Objective** Objectives: To evaluate the value of high-b-value DWI in the diagnosis of benign and malignant breast lesions by meta-analysis. **Methods:** PubMed, Embase, Cochrane, Scopus, and Web of Science were searched for English literature on the evaluation of benign and malignant breast lesions by high b-value DWI from self-established databases to June 2024, and the quality of the final included literature was evaluated and data extracted. Stata 16.0 software was used for heterogeneity analysis, and the forest plot, Deek's funnel and receiver working SROC curves were plotted, and the area under the curve AUC was calculated. Spearman correlation analysis was performed using Meta-Disc 1.4 software to observe the correlation between the logarithm of sensitivity and the logarithm of specificity, and whether there was a threshold effect between studies, and Mtea regression was used to analyze the source of heterogeneity.

**Condition being studied** Breast cancer is the most common malignancy in women, and GLOBOCAN provides updated estimates of cancer incidence and mortality at the end of 2020. In 2020, it was estimated that there were 19.3 million new cancer cases worldwide and nearly 10 million deaths from cancer. In addition, breast cancer surpassed lung cancer for the first time to become the world's most common malignant tumor, posing a serious threat to women's health. Given the increasing global burden of breast cancer, early detection and diagnosis are critical to improving patient outcomes and reducing mortality.

**METHODS**

**Participant or population** PubMed, Embase, Cochrane, Scopus, Web of science, were searched from the time of construction to June 2024, and detailed search terms are provided in Appendix 2. The results obtained from the search were independently screened by two physicians for eligible articles based on title and abstract, and then further read through the full text to determine

their suitability for inclusion in this study, with disputes, if any, resolved through discussion and negotiation.

**Intervention** This study is a diagnostic meta-analysis.

**Comparator** Study on the accuracy of differentiating the benign and malignant lesions of breast cancer with high b-value DWI using pathological diagnosis as the gold standard.

**Study designs to be included** Diagnostic meta-analysis.

**Eligibility criteria** The inclusion criteria for this study were as follows:

- English language study of DWI assessment of benign and malignant breast lesions;
- The study population was patients with suspected breast cancer;
- The b-value was  $\geq 1000$ s/mm<sup>2</sup> and the field strength was 1.5T or 3.0T;
- Patients with breast lesions confirmed by pathological examination;
- The data required for the four-cell table can be extracted;
- Mean ADC values for benign and malignant lesions;
- Accuracy, sensitivity, and specificity are measured or can be derived;
- English-language literature;

Exclusion criteria were as follows:

- Review, case report, dissertation, and other types;
- Studies on animals or patients with confirmed breast cancer;
- Studies that were not relevant to the study population;
- Studies with incomplete data;
- Non-English language.

**Information sources** A comprehensive literature search was conducted in PubMed, Embase, Cochrane Library, Scopus, and Web of Science databases for English-language articles evaluating the use of high b-value DWI in differentiating benign and malignant breast lesions.

**Main outcome(s)** The following descriptive information was extracted from each study: author, country, year of publication, study design, MR scanner company (vendor), b-value, total number of subjects, lesions (benign and malignant), mean ADC value of benign and malignant lesions, field strength, sensitivity and specificity thresholds of

ADC values used for differential diagnosis, diagnostic efficacy of DWI, etc.

#### Quality assessment / Risk of bias analysis

Completed by two physicians based on the trial evaluation tool (QUADAS instrument, a good evaluation tool developed specifically for systematic opinion on diagnostic accuracy studies).

**Strategy of data synthesis** Stata 16.0 software was used to analyze the heterogeneity ( $I^2 \geq 50\%$  heterogeneity was heterogeneous), and the summary receiver operating characteristic (SROC) curve was plotted, and the area under the curve (AUC) was calculated. The combined sensitivity, combined specificity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio of high b-value DWI in the differential diagnosis of benign and malignant breast lesions were calculated, and Deek's funnel plot was plotted to observe publication bias. Spearman correlation analysis was performed using Meta-Disc 1.4 software to observe the correlation between the logarithm of sensitivity and the logarithm of specificity, and whether there was a threshold effect between studies, and Meta-regression was used to analyze the source of heterogeneity.  $P < 0.05$  was statistically significant.

**Subgroup analysis** Subgroups were analyzed according to the type of study (prospective vs. retrospective), equipment (GE, Philips, Siemens), and field strength difference (1.5 vs. 3.0).

**Sensitivity analysis** Sensitivity analyses were performed by the stata software to reflect sensitivity by the change in effect size after deletion of an article.

**Country(ies) involved** China.

**Keywords** Breast cancer, DWI, ADC, meta analysis.

#### Contributions of each author

Author 1 - zhang ju peng.

Author 2 - wu qi.