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Author Affiliation:The First People's Hospital of
Lanzhou New Area.**A Systematic Review and Meta-analysis of the Performance of Prediction Models for Pathological Upgrade in Patients Diagnosed with Atypical Ductal Hyperplasia by Ultrasound-Guided Core Needle Biopsy**

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ADMINISTRATIVE INFORMATION**Support** - No support.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2026100115**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 October 2026 and was last updated on 27 October 2026.**INTRODUCTION**

Review question / Objective To systematically evaluate the methodological quality and predictive performance of models for pathological upgrade in patients diagnosed with atypical ductal hyperplasia (ADH) on core needle biopsy (CNB), and to pool the area under the receiver operating characteristic curve (AUC) separately for training and testing datasets.

Condition being studied ADH is a high-risk breast lesion that may be upgraded to ductal carcinoma in situ (DCIS) or invasive breast cancer following surgical excision. Accurate prediction of pathological upgrade may help identify patients at higher risk and support individualized clinical decision-making while potentially reducing unnecessary surgery.

METHODS

Participant or population Patients diagnosed with ADH on CNB of a breast lesion. Studies involving

mixed populations will be included only if data for patients with ADH can be extracted separately.

Intervention Prediction models developed or evaluated to estimate pathological upgrade after an ADH diagnosis on CNB, using clinical, imaging, ultrasonographic, pathological, or demographic predictors and methods such as logistic regression and machine-learning algorithms.

Comparator No mandatory comparator is required. Different prediction models or algorithms will be compared descriptively when reported.

Study designs to be included Prospective or retrospective cohort studies and randomized controlled trials that develop or evaluate eligible prediction models.

Eligibility criteria Two reviewers will independently screen studies and extract data, with disagreements resolved by discussion or a third reviewer.

Inclusion criteria: (1) patients diagnosed with ADH on CNB; (2) prediction models for pathological upgrade to DCIS or invasive breast cancer following surgical excision; (3) numerical AUC reported for at least one eligible model; and (4) eligible study design and sufficient data for extraction.

Exclusion criteria: (1) studies of other high-risk breast lesions without separately extractable ADH data; (2) studies reporting risk factors without developing or evaluating prediction models; (3) survival or time-to-event models without an eligible AUC for pathological upgrade; (4) reviews, meta-analyses, case reports, insufficient conference abstracts, and animal studies; (5) duplicate or overlapping publications; and (6) studies without sufficient accessible data.

Information sources PubMed, Embase, Web of Science, and the Cochrane Library will be searched from inception to August 2026. Relevant clinical trial registries and reference lists of eligible studies will also be searched. Search terms will include atypical ductal hyperplasia, ADH, core needle biopsy, prediction models, malignancy, breast cancer, and pathological upgrade.

Main outcome(s) Predictive performance measured by AUC, with training-set and testing-set AUCs pooled separately. Corresponding 95% confidence intervals (CIs) will be extracted where available.

Quality assessment / Risk of bias analysis Two reviewers will independently assess risk of bias and applicability using the Prediction Model Risk of Bias Assessment Tool (PROBAST), covering participants, predictors, outcomes, and analysis. Disagreements will be resolved by consensus or a third reviewer.

Strategy of data synthesis R version 4.5.2 will be used. Random-effects models will pool training-set and testing-set AUCs separately. Heterogeneity will be assessed using Cochran's Q test ($\alpha=0.10$) and the I^2 statistic, with I^2 around 50% indicating potentially substantial heterogeneity. The best-performing eligible model from each study will be selected according to reported selection criteria. Leave-one-out sensitivity analysis will assess robustness. Funnel plots and formal tests for asymmetry will be considered only when the number of studies is sufficient.

Subgroup analysis Where sufficient studies are available, subgroup analyses will explore

heterogeneity by predictor-selection method, model type, and validation strategy.

Sensitivity analysis Leave-one-out sensitivity analyses will be performed separately for training-set and testing-set AUCs to assess the influence of individual studies.

Country(ies) involved China.

Keywords Atypical ductal hyperplasia; core needle biopsy; pathological upgrade; breast cancer; prediction models; machine learning; systematic review; meta-analysis.

Contributions of each author

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