

## INPLASY

Radiologic–pathologic discordance in breast biopsy:  
a systematic review of prevalence and outcomes

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## ADMINISTRATIVE INFORMATION

**Support** - None.**Review Stage at time of this submission** - The review has not yet started.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202610057**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 January 2026 and was last updated on 17 January 2026.

## INTRODUCTION

**Review question / Objective** To systematically review the literature to determine the prevalence of radiologic–pathologic discordance after image-guided breast biopsy and to summarize the associated clinical outcomes, including malignancy (upgrade) rates and management actions following discordance.

**Condition being studied** Radiologic–pathologic discordance in breast biopsy refers to a mismatch between imaging findings and histopathologic results obtained from image-guided percutaneous breast biopsy. This condition arises when the pathology diagnosis does not adequately explain or account for the imaging characteristics of a breast lesion identified on modalities such as ultrasound, mammography (including digital breast tomosynthesis), or magnetic resonance imaging. Discordance may occur across a range of breast lesions, including masses, architectural distortion, and calcifications, and is most clinically significant

when imaging suggests malignancy but histopathology yields a benign diagnosis, commonly termed “discordant benign.” Radiologic–pathologic correlation is a critical quality assurance step in breast imaging and diagnostic pathways, aimed at reducing false-negative biopsy results and missed breast cancers. Failure to recognize discordance can lead to delayed diagnosis and adversely affect patient outcomes. When discordance is identified, additional management—such as repeat percutaneous biopsy, vacuum-assisted biopsy, or surgical excision—is often recommended to clarify the diagnosis.

The clinical importance of radiologic–pathologic discordance lies in its association with malignancy upgrade at repeat sampling or excision. Reported upgrade rates vary widely across studies, reflecting differences in biopsy technique, imaging modality, lesion characteristics, and criteria used to define discordance. Understanding the prevalence of discordance and its downstream clinical consequences is essential for optimizing

diagnostic accuracy, guiding management decisions, and improving patient safety in breast cancer care. This systematic review focuses on radiologic–pathologic discordance following image-guided breast biopsy, with particular emphasis on its prevalence, subsequent clinical outcomes, and management strategies reported in the literature.

## METHODS

**Participant or population** Patients undergoing percutaneous, image-guided breast biopsy for an imaging-detected breast lesion.

**Intervention** Radiologic–pathologic correlation (radiology–pathology review) after image-guided biopsy, with lesions classified as discordant.

**Comparator** None.

**Study designs to be included** Randomized controlled trials, non-randomized comparative studies, prospective or retrospective cohort studies, and cross-sectional studies reporting extractable data on radiologic–pathologic discordance prevalence and/or downstream clinical or management outcomes after image-guided breast biopsy.

**Eligibility criteria** In addition to the PICOS-defined criteria, studies will be eligible if they report original data on radiologic–pathologic discordance following percutaneous, image-guided breast biopsy and allow extraction of numerical data for at least one predefined outcome. Studies must clearly describe the biopsy technique (e.g., core needle biopsy or vacuum-assisted biopsy) and the process of radiologic–pathologic correlation, including criteria used to determine concordance or discordance. Studies focusing exclusively on technical aspects of biopsy without reporting discordance frequency or downstream clinical or management outcomes will be excluded. When multiple publications report overlapping populations, the most comprehensive or most recent study with the largest sample size or most complete outcome data will be included. No restrictions will be applied regarding clinical setting (screening vs diagnostic), imaging modality, or geographic location, provided the eligibility criteria are met.

**Information sources** The following electronic databases will be systematically searched from inception to 17 January 2026: MEDLINE (via PubMed) and Scopus. DOAJ will be searched as a supplementary source to identify additional open-

access articles. The reference lists of all included studies and relevant review articles will be manually screened to identify any additional eligible studies. No trial registers or gray literature sources will be searched. Authors of primary studies will not be contacted for additional data.

**Main outcome(s)** The primary outcome of this review is the prevalence (proportion) of radiologic–pathologic discordance following percutaneous, image-guided breast biopsy, defined as the number of discordant cases divided by the total number of biopsied lesions undergoing formal radiologic–pathologic correlation. Prevalence will be reported as proportions with corresponding 95% confidence intervals, using study-reported denominators.

Secondary outcomes include the prevalence of discordant benign results among lesions with benign histopathologic diagnoses, and clinical outcomes following discordance, particularly the malignancy (upgrade) rate identified at repeat biopsy or surgical excision. Where reported, the pathologic characteristics of upgraded lesions (e.g., ductal carcinoma in situ or invasive carcinoma) will be summarized.

Additional outcomes include clinical management actions undertaken after discordance, such as repeat percutaneous biopsy, vacuum-assisted biopsy, surgical excision, or imaging surveillance, expressed as proportions of discordant cases. Timing of outcome assessment will be based on the interval between the index biopsy and subsequent diagnostic procedures, when available. Effect measures will primarily include pooled proportions; comparative measures will be summarized descriptively if reported.

**Quality assessment / Risk of bias analysis** The methodological quality and risk of bias of included studies will be assessed independently by two reviewers using Joanna Briggs Institute (JBI) Critical Appraisal Tools, selected according to study design. The JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data will be applied to studies primarily reporting the prevalence of radiologic–pathologic discordance. The JBI Critical Appraisal Checklist for Cohort Studies will be used for studies evaluating downstream clinical outcomes, such as malignancy upgrade following repeat biopsy or surgical excision.

Each checklist item will be judged as yes, no, unclear, or not applicable. Any disagreements between reviewers will be resolved through

discussion or consultation with a third reviewer. The results of the quality assessment will be summarized in tabular form and considered in the interpretation of findings; however, no study will be excluded solely on the basis of risk of bias.

**Strategy of data synthesis** Data from included studies will be synthesized using quantitative and narrative approaches, as appropriate. For outcomes reported by at least two studies with sufficient methodological homogeneity, pooled analyses will be performed. The primary quantitative synthesis will estimate the pooled prevalence of radiologic–pathologic discordance after image-guided breast biopsy using a random-effects model, with proportions and corresponding 95% confidence intervals. Where applicable, pooled estimates of discordant benign prevalence and malignancy (upgrade) rates among discordant lesions will also be calculated.

Statistical heterogeneity will be assessed using the  $I^2$  statistic and Cochran's Q test. Prespecified subgroup analyses may be conducted based on biopsy modality (e.g., ultrasound-guided, stereotactic/DBT-guided, MRI-guided) or biopsy technique (core needle vs vacuum-assisted), subject to data availability. Sensitivity analyses may be performed by excluding studies at high risk of bias.

If meta-analysis is not appropriate due to substantial heterogeneity or limited data, findings will be summarized using a structured narrative synthesis, with results presented in tables and figures. All analyses will be conducted using standard statistical software, and the synthesis approach will be guided by methodological recommendations for prevalence and outcome reviews.

**Subgroup analysis** Where sufficient data are available, subgroup analyses will be conducted to explore potential sources of heterogeneity. Prespecified subgroups include biopsy modality (ultrasound-guided, stereotactic or digital breast tomosynthesis-guided, and magnetic resonance imaging-guided biopsy), biopsy technique (core needle biopsy versus vacuum-assisted biopsy), and lesion type (mass, calcifications, or architectural distortion). Additional subgroup analyses may be performed according to imaging assessment (e.g., BI-RADS category) or study design (prospective versus retrospective), depending on data availability.

Subgroup analyses will be considered exploratory and interpreted cautiously, particularly when the number of studies within subgroups is limited.

**Sensitivity analysis** Sensitivity analyses will be performed, where feasible, to assess the robustness of the pooled estimates. Planned sensitivity analyses include repeating meta-analyses after excluding studies assessed as having high risk of bias, and excluding studies with small sample sizes or unclear definitions of radiologic–pathologic discordance. Additional sensitivity analyses may be conducted by restricting the analysis to studies with explicit multidisciplinary radiology–pathology review or to studies reporting complete follow-up of discordant cases.

The consistency of findings across sensitivity analyses will be examined to evaluate the stability of the results and the impact of methodological assumptions.

**Language restriction** English.

**Country(ies) involved** Thailand.

**Keywords** Radiologic–pathologic discordance; breast biopsy; imaging–pathology correlation; discordant benign; malignancy upgrade; image-guided biopsy.

#### **Contributions of each author**

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