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## Clinical Outcomes of MRI-Guided Breast Biopsy – a Systematic Review

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## Abstract

**Background.** Breast cancer diagnosis relies heavily on accurate identifying suspicious lesions. Magnetic resonance imaging (MRI) has become one of the most sensitive methods for detecting breast cancer, mainly for invasive carcinomas and ductal carcinoma in situ (DCIS). When lesions which are visible only on MRI, are identified, MRI-guided vacuum-assisted breast biopsy (VABB) is the standard of care.

**Aim.** To systematically review the clinical outcomes, diagnostic accuracy and safety profile of magnetic resonance imaging—MRI-guided vacuum-assisted breast biopsy (VABB) for lesions visible only on MRI.

**Material and methods.** A comprehensive literature search was conducted across major databases, including PubMed and Scopus, up to February 2025 in accordance with PRISMA 2020 guidelines to identify studies on MRI-guided vacuum-assisted breast biopsy (VABB).

Two independent reviewers selected original clinical investigations reporting primary outcomes such as technical success, malignancy rates, and underestimation of high-risk lesions, while excluding single case reports and unstratified data.

**Results.** Technical success rates for MRI-guided VABB consistently exceeded 95%. The overall malignancy rate for biopsied lesions ranged from 25% to 30%. High-risk (B3) lesions represented a significant diagnostic challenge, with histological underestimation rates varying widely from 14.6% to 50% across studies. Complication rates were low, mainly consisting of minor hematomas.

**Conclusions.** MRI-guided VABB is a safe and highly accurate technique, essential for managing MRI-only breast lesions. While it effectively rules out malignancy in benign concordant cases, the management of high-risk lesions requires multidisciplinary correlation due to significant upgrade rates.

**Key words:** MRI-guided breast biopsy, VABB, clinical outcomes, breast cancer, systematic review.

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## 1. Introduction

Breast magnetic resonance imaging (MRI) has become one of the most sensitive methods of detecting breast cancer, particularly for invasive carcinomas and ductal carcinoma in situ (DCIS) that may be invisible on mammography and ultrasound (Lambert et al., 2021; Imschweiler et al., 2014). However, the high sensitivity of MRI is often accompanied by variable specificity, leading to the detection of enhancing lesions that require histological verification (Heywang-Köbrunner et al., 2009).

When "MRI-only" lesions (suspicious findings without mammographic or sonographic correlates) are identified, MRI-guided vacuum-assisted breast biopsy (VABB) is the standard of care (Plantade et al., 2014; Heywang-Köbrunner et al., 2009). Unlike fine-needle aspiration or core needle biopsy, VABB utilizes a vacuum mechanism to acquire larger tissue volumes, which is critical for accurate diagnosis and the potential removal of small lesions (Imschweiler et al., 2014).

This systematic review aims to synthesize clinical outcome data regarding the technical success, diagnostic yield, underestimation of high-risk lesions and safety profile of MRI-guided VABB.

## 2. Research materials and methods

### 2.1. Data sources and search strategy.

A comprehensive literature search was conducted in PubMed/MEDLINE, Embase, Scopus and Web of Science from database inception to February 2025. Two independent reviewers performed the search using both controlled vocabulary (i.e. MeSH and Emtree terms)

and free-text keywords. Search terms included variations and Boolean combinations of: “MRI-guided breast biopsy”, “MRI-guided vacuum-assisted biopsy”, “VABB”, “vacuum-assisted breast biopsy”, “clinical outcomes”, “technical success”, “malignancy rate”, “underestimation”, “B3 lesions”, “high-risk lesions”, “puncture”, “complications” and related terms.

Citation lists of all proper studies and relevant reviews were manually screened to identify additional publications. No restrictions were applied regarding language, study design or publication year. The review was designed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines.

## **2.2. Study selection criteria.**

Two reviewers independently screened all retrieved titles, abstracts and full-text articles using predefined eligibility criteria with disagreements resolved by consensus or consultation with a third reviewer. Studies were included if they were original clinical investigations, such as prospective or retrospective cohort studies or cross-sectional analyses, that evaluated MRI-guided vacuum-assisted breast biopsy (MRI-guided VABB) and reported primary clinical outcomes relevant to this review. Eligible outcomes included technical success or procedural feasibility, malignancy detection rates, underestimation (upgrade) rates of high-risk or B3 lesions and documented complications such as hematoma, bleeding, infection, vasovagal episodes or pain. Clinical guidelines and high-quality review articles that addressed procedural challenges, diagnostic performance or the clinical role of MRI-guided VABB were also included to contextualize and support the evidence base.

Studies were excluded if they consisted only of single case reports or very small case series with fewer than five patients, or if they failed to stratify outcomes specifically for MRI-guided biopsy when multiple imaging guidance modalities were used. Additionally, articles were excluded when they did not provide extractable or clearly defined clinical outcome measures relevant to MRI-guided VABB.

## **2.3. Data collection and analysis.**

Data collection was performed independently by two reviewers using a standardized template. Extracted variables included: author, year of publication, country, study design, patient recruitment period, sample size, demographic characteristics, lesion type and classification, needle gauge, MRI field strength, procedural protocol, technical success

definition and all reported clinical outcomes (diagnostic yield, malignancy rate, underestimation rate and complications).

Quality and risk of bias were assessed independently by two reviewers using the GRADE framework, classifying evidence as high, moderate, low or very low quality based on study design, consistency, precision, directness and risk of bias.

### **3. Research results**

#### **3.1. Technical success and procedure reliability.**

The technical success of MRI-guided VABB, defined as the successful sampling of the target lesion and post-procedure visualization of the biopsy cavity/clip, is consistently high across the literature (Plantade et al., 2014).

For instance, an analysis of Swiss centers reported a technical success rate of 98.4% (548/557), which is comparable to stereotactic biopsy (99.1%) and slightly lower than ultrasound-guided biopsy (99.6%) (Imschweiler et al., 2014). Similarly, a long-term single-center study (n=600) reported a 99.3% success rate over 19 years (Lambert et al., 2021). While early experiences in smaller cohorts indicated slightly lower success rates (86.7%) due to non-visualization of the lesion or technical learning curves, established data supports the reliability of the procedure (An et al., 2013).

Additionally, approximately 8% to 13% of scheduled procedures are cancelled due to lesion non-visualization on the day of the biopsy, with factors often including lesions smaller than 1 cm, high background parenchymal enhancement and minimal lesion enhancement kinetics (plateau) (Brennan et al., 2011).

#### **3.2. Diagnostic yield and malignancy rates.**

The prevalence of malignancy in lesions subjected to MRI-guided VABB is generally reported between 20% and 30%. Studies report malignancy rates of 27.7% and 30.8% (Lambert et al., 2021; An et al., 2013). A large comparative study found no significant difference in malignancy detection between MRI-guided (26%) and stereotactic (24%) biopsies (Imschweiler et al., 2014). Regarding lesion characteristics, mass-like enhancement is more frequently associated with malignancy than non-mass enhancement (NME), although NME remains a common indication for biopsy (Crystal et al., 2011).

### **3.3. High-risk (B3) lesions and underestimation.**

A critical clinical challenge is the management of high-risk (B3) lesions, such as atypical ductal hyperplasia (ADH), lobular neoplasia (LN) and flat epithelial atypia (FEA), which constitute approximately 19% to 26% of MRI-guided biopsy diagnoses (Crystal et al., 2011; Rescinito et al., 2024). The "underestimation rate", defined as B3 lesions upgraded to malignancy upon surgical excision, represents a significant diagnostic issue. Crystal et al. reported a high underestimation rate of 50% (13/26 excised lesions) with ADH and LN specifically showing upgrade rates of 50% (Crystal et al., 2011). Other studies report variable but significant upgrade rates, ranging from 14.6% to 23% depending on the cohort size and inclusion criteria (Rescinito et al., 2024; Lourenco et al., 2014). Due to the difficulty in predicting upgrades based on imaging features alone, surgical excision is frequently recommended for high-risk lesions diagnosed via MRI-guided VABB.

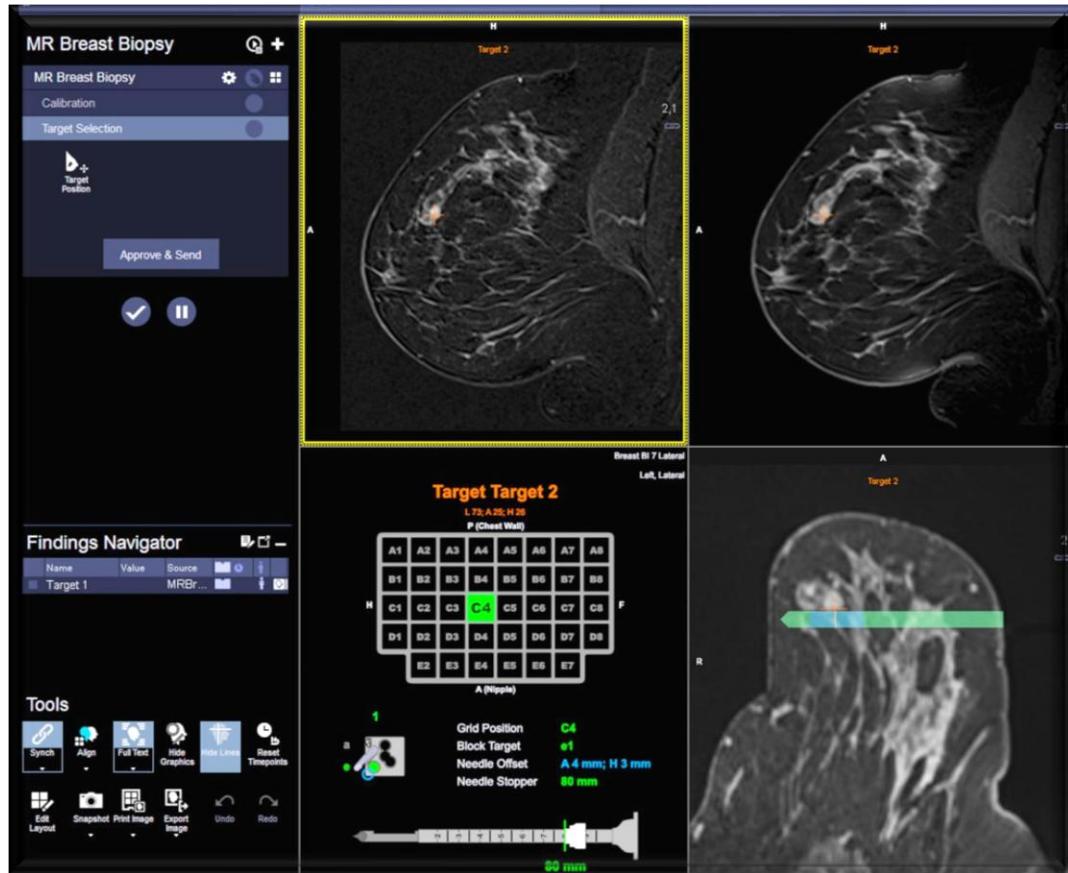
### **3.4. Safety and Complications.**

MRI-guided VABB is considered a safe procedure with a low incidence of severe complications (Heinze et al., 2024). Minor hematomas (mean size 23.5 mm) are the most frequent complication, occurring in up to 61.5% (8/13) of patients in some small cohorts, although it was usually managed conservatively without intervention (An et al., 2013). Serious complications such as severe bleeding or infection are rare; for instance, one large study (n=544) reported a 7% rate of haemorrhage without the need for open revision and zero infections (Imschweiler et al., 2014). Additionally, the procedure presents challenges regarding patient experience, notably anxiety, discomfort and neck strain due to prolonged prone positioning (Niketa et al., 2022).

### **3.5. Long-Term Follow-Up of Benign Lesions.**

For lesions with benign histopathology that are compatible with imaging findings, the risk of false negatives is extremely low.

Research involving long-term follow-up, with a mean duration of 7.6 years, revealed a false negative rate of only 0.3% (Lambert et al., 2021). While some guidelines suggest a 6-month follow-up MRI, this long-term data suggests that for benign concordant lesions, immediate short-term follow-up may yield limited additional value, though it remains a prudent practice in many centers (Lambert et al., 2021).



**Figure 1. Sample MRI-guided breast biopsy planning in dedicated software application—Brevis (Siemens, Erlangen).**

#### 4. Discussion

The primary indication for MRI-guided VABB is a lesion that is visible only on MRI (BI-RADS 4 or 5) (Heywang-Köbrunner et al., 2009). The procedure fills a critical gap in breast diagnostics; however, it is technically more demanding than ultrasound-guided biopsy due to the lack of real-time visualization and the "washout" phenomenon where contrast enhancement fades during the procedure (Niketa et al., 2022).

A unique phenomenon in MRI-guided biopsy is the "disappearing lesion" where a target seen on diagnostic MRI is not visible on the day of biopsy. This occurs in approximately 8% to 13% of cases (Brennan et al., 2011). While often attributed to hormonal fluctuations or

compression effects, the malignancy rate in these cancelled cases is low (approx. 2%) (Brennan et al., 2011). Nevertheless, short-term follow-up is recommended to ensure the lesion does not reappear or grow.

Procedural success can also be influenced by patient physique. Small breasts (less than 3 cm compressed thickness) and posterior lesions near the chest wall pose significant access challenges (Niketa et al., 2022). Strategies such as the "pillar and post" method or using blunt-tipped needles (Petit needles) have been suggested to reduce these risks (Niketa et al., 2022).

Finally, a critical clinical challenge is the management of high-risk (B3) lesions, where variability in underestimation rates for B3 lesions (ranging from about 15% to 50% across studies) highlights a lack of consensus regarding which B3 lesions can be safely observed and which should be excised (Crystal et al., 2011; Lourenco et al., 2014). While Crystal et al. argue for routine excision of all high-risk lesions, recent meta-analyses suggest that specific subtypes (e.g., pure FEA without atypia) may carry lower risks, excluding ADH which remains a strong indication for surgery (Özcan et al., 2023).

## 5. Conclusions

MRI-guided vacuum-assisted breast biopsy is a highly accurate and safe technique with a technical success rate exceeding 98% in experienced centers. It plays a vital role in the diagnosis of MRI-only breast lesions, carrying a malignancy detection rate of approximately 25-30%. While benign concordant results are highly reliable, the diagnosis of high-risk (B3) lesions carries a significant risk of histological underestimation, often requiring surgical excision.

## Disclosure

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