Original Article

Eur J Breast Health 2023; 19(1): 1-27
DOI: 10.4274/ejbh.galenos.2022.2022-12-1

Performance Benchmark Metrics and Clinicopathologic Outcomes of MRI-Guided Breast Biopsies: A Systematic Review and Meta-Analysis

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ABSTRACT

Objective: To determine key performance metrics of magnetic resonance imaging (MRI)-guided breast biopsies (MRGB) to help identify reference benchmarks.

Materials and Methods: We identified studies reporting MRGB results up to 04.01.2021 in the Embase database, Ovid Medline (R) Process, Other Non-Indexed Citations, Ovid Medline (R) and completed a PRISMA checklist and sources of bias (QUADAS-2). The inclusion criteria were English language, available histopathological outcomes, or at least one imaging follow-up after biopsy. A random intercept logistic regression model was used to pool rates. Between-study heterogeneity was quantified by the I^2 statistic.

Results: A total of 11,215 lesions in 50 articles were analyzed. The technical success rate was 99.10% [95% confidence interval (CI): 97.89–99.62%]. The MRI indications were staging in 1,496 (28.05%, 95% CI: 26.85–29.28%), screening in 1,427 (26.76%, 95% CI: 25.57–27.97%), surveillance in 1,027 (19.26%, 95% CI: 18.21–20.34%), diagnostic in 1,038 (19.46%, 95% CI: 18.41–20.55%), unknown primary in 74 (1.39%, 95% CI: 1.09–1.74%), and other in 271 (5.08%, 95% CI: 4.51–5.71%). Histopathology was benign in 65.06% (95% CI: 59.15–70.54%), malignant in 29.64% (95% CI: 23.58–36.52%) and high risk in 16.69% (95% CI: 9.96–26.64%). Detection of malignancy was significantly lower in those patients who underwent MRI for screening purposes (odds ratio 0.47, 95% CI: 0.25–0.87; p = 0.02), while mass lesions were more likely to yield malignancy compared to non-mass and foci [27.39% vs 11.36% (non-mass),18.03% (foci); $p<0.001$]. Surgical upgrade to invasive cancer occurred in 12.24% of ductal carcinoma *in situ* (95% CI: 7.76–18.77%) and malignancy in 15.14% of high-risk lesions (95% CI: 10.69–21.17%). MRI follow-up was performed in 1,651 (20.92%) patients after benign results [median=25 months (range: 0.4–117)]. Radiology-pathology discordance (2.48%, 95% CI: 1.62–3.77%), false negative after a benign-concordant biopsy (0.75%, 95% CI: 0.34–1.62%) and biopsy complications (2.36%, 95% CI: 2.03–2.72%) were rare.

Conclusion: MRGB is a highly accurate minimally-invasive diagnostic technique with low false-negative and complication rates. MRI indication and lesion type should be considered when evaluating the performance of institutional MRGB programs.

Keywords: Breast; cancer; magnetic resonance imaging; biopsy

Cite this article as: Özcan BB, Yan J, Xi Y, Baydoun S, Scoggins ME, Doğan BE. Performance Benchmark Metrics and Clinicopathologic Outcomes of MRI-Guided Breast Biopsies: A Systematic Review and Meta-Analysis. Eur J Breast Health 2023; 19(1): 1-27

Key Points

- Magnetic resonance imaging (MRI)-guided breast biopsy methods and clinicopathological outcomes may vary between institutions.
- MRI-guided breast biopsy is an efficient, highly accurate technique with high technical success [99.10%, 95% confidence interval (CI): 97.89–99.62%], low false-negative (0.75%, 95% CI: 0.34–1.62%), and low complication (2.36%, 95% CI: 2.03–2.72%) rates.
- The surgical upgrade to malignancy is common among high-risk lesions 15.14% (95% CI: 10.69-21.17%), especially atypical ductal hyperplasia (31.81% (95% CI: 25.57-38.77%).

Introduction

Magnetic resonance imaging (MRI) has a high sensitivity (88–92%) and a moderate specificity (67–77%) for the detection of breast cancer (1). It has been well established that MRI-guided tissue sampling is necessary for the histological verification of lesions that are otherwise occult (1-5). Furthermore, due to the overlap of the MRI findings of the benign and malignant lesions, in order to distinguish between them, an MRI-guided breast biopsy is necessary (6).

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Received: 05.12.2022
Accepted: 22.12.2022
Available Online Date: 01.01.2023

Surgical biopsy after MRI-guided wire localization and MRI-guided percutaneous needle biopsies have been described before the first experiences with MRI-guided vacuum-assisted biopsy were reported in the late 1990s (7, 8). Since then, MRI-guided vacuum-assisted biopsy has achieved broad acceptance in clinical practice due to its speed, accuracy, and safety, which has been found to be as good as MRI-guided wire localization without the associated complications and cost of surgery (7-13). MRI-guided needle biopsy also allows for the placement of marker clips and so aids the subsequent mammographic localization of the lesion if an operation becomes necessary.

Tissue sampling with fine-needle aspiration and core-needle biopsy devices requires visual confirmation of needle placement directly into the target to ensure accurate sampling. The suction of the MRI-guided vacuum-assisted biopsy device provides for adequate sampling when the needle is placed within a few millimeters of a small lesion, provided that the suction chamber is preferentially directed toward the target. Thus, the use of vacuum assistance has allowed for the accurate targeting of smaller lesions. In addition, because the vacuum system continuously suctions any hemorrhage which may occur during sampling, tissue shift and subsequent sampling errors are mitigated.

MRI-guided breast biopsy can be a challenging procedure for radiologists. Determining radiologic-pathologic concordance for MRI-guided biopsies is often more difficult than biopsies performed using other imaging modalities. Since it is not a real-time procedure, it lacks the direct needle visualization advantage of ultrasound-guided biopsies. Unlike stereotactic biopsies where intra-procedure specimen radiographs ensure the accuracy of targeting, *ex vivo* confirmation of sampling is not possible. Furthermore, wash-out of the gadolinium contrast agents during the procedure and post-biopsy changes including air, hemorrhage, and local anesthesia obscure the targeted lesion, making it more challenging to confirm the accuracy of sampling. It is a procedure which obligates sliding the table on the gantry to place the guiding system and performing the biopsy again, without real-time visualization of the lesion. These factors render radiologic-pathologic correlation critical. Lesion enhancement is another challenge while performing MRI-guided biopsy because lesion conspicuity decreases with time after contrast injection due to the enhancement kinetics. Compression of the breast needs to be adequate to immobilize the breast and to ensure hemostasis without obstructing lesion contrast enhancement.

MRI-guided breast biopsy is a time-consuming and complex procedure which requires specific equipment and expertise. Current MRI-guided breast biopsy methods and subsequent clinicopathological outcomes may vary between institutions. Our goal was to identify benchmark metrics to help define a successful breast MRI-guided biopsy program and guide institutional audits. To accomplish our goal, we identified and systematically reviewed studies in order to determine indications, technical success, histopathological outcomes, false-negatives, and upgrade rates of MRI-guided breast biopsies for institutional referencing.

Materials and Methods

The preferred reporting items for systematic reviews and meta-analyses (PRISMA) guideline was used for reporting (14).

Literature Search and Article Selection Criteria

The requirement to obtain institutional review board approval was waived for this literature review, which involved only publicly available data. The Ovid MEDLINE® In-Process & Other Non-Indexed Citations, Ovid MEDLINE®, and Embase databases were searched systematically for English language articles published from January, 1946 up to April, 2021 for articles on MRI-guided breast biopsy outcomes by an investigator trained in conducting comprehensive literature searches. Three investigators then independently reviewed and confirmed the selected articles and extracted the relevant information.

The search terms included breast neoplasm, MRI/MRI, and image-guided biopsy from articles involving human subjects. The search strategy is shown in Supplementary Table 1.

Our inclusion criteria were English language literature, the availability of reported histopathological outcomes of benign, malignant, and high-risk lesions, and the availability of final histopathology (gold standard) or at least one-time imaging/clinical follow-up after biopsy. We excluded meta-analyses, review papers, case-control studies, and matched-pair studies, and included original articles which reported novel data.

We excluded studies that were non-English in their full text, and those where the following information was not reported: Technical factors (magnet strength, needle type, needle gauge), imaging or clinical follow-up descriptions, or time unavailable after a high-risk or benign biopsies. The results of the literature search and applied study selection criteria are summarized in Figure 1.

Data Collection and Quality Assessment

We collected mean/median patient ages, indications for MRI biopsy, magnet strengths, needle types/gauges, the number of cores sampled, rates of successfully performed MRI biopsies, causes of unsuccessful biopsies and pathological outcomes (benign, malignant, high risk) along with false negative rates and underestimation rates for ductal carcinoma *in situ* (DCIS), atypical ductal hyperplasia (ADH) and other high-risk lesions [lobular carcinoma *in situ* (LCIS), atypical lobular hyperplasia (ALH), flat epithelial atypical (FEA) radial scar (RSL)/complex sclerosing lesions (CSL)]. The lesion characteristics (mass, non-mass enhancement, focus and size information for each), enhancement kinetics (wash-out, plateau, progressive), complications (if any), and the types and durations of follow-up were also recorded.

One reader applied the modified quality assessment of diagnostic accuracy studies (QUADAS-2) items to assess study quality and the likelihood of bias (15). The risk of bias was judged as “low”, “high” or “unclear” on four domains: Patient selection, index test, reference standard, and flow and timing. Concerns about applicability were judged as “low”, “high” or “unclear” on three domains: Patient population, index test, and reference standard. A study was judged as “at risk of bias” or as having “concerns regarding applicability” when it was judged “high” or “unclear” in one or more domains. A second reader checked the results. If present, disagreement was solved in consensus. Detailed information on signaling questions in each domain is shown in Supplementary Table 2.

Table 1. Characteristics of the 50 studies included on MRI-guided breast biopsy

Author and publication year	Design	Setting	Years	n. Target lesion	n. Patients	Needle size (gauge)	n. Sampled cores†	Follow-up (months)†	False negative rate*,§	Underestimation rate§			Successful biopsy rate^,§
										DCIS	ADH	Other high risk¥	
An et al. (72)	Prospective	Single center	2009–2011	15	13	9	Mean, 9 (6–11)	Range, 6-12	0/9 (0)	-	-	-	13/15 (86.7)
Bahrs et al. (73)	Retrospective	Single center	N/A¶	299	252	8-11	Range 12–24	Median, 13 (5-24)	13/183 (7.1)	-	-	-	281/299 (94.0)
Belloni et al. (66)	Retrospective	Single center	2002–2008	70	66	12-18	Range 8–12	Mean 26 (11–68)	0/34 (0)	1/10 (10)	-	-	70/70 (100.0)
Carbognin et al. (74)	Retrospective	Single center	2007–2009	29	29	10	Mean, 18 (9–25)	At least 12	0/11 (0)	-	-	-	27/29 (93.0)
Chen et al. (75)	Retrospective	Single center	2001–2002	35	29	14	-	5–12	-	0/1 (0)	2/5 (40.0)	0/1 (0)	34/35 (97.1)
Crystal. et al. (76)	Retrospective	Single center	2006–2009	31	25	9	-	Mean, 14 (6-26)	-	-	3/6 (50.0)	10/20 (50.0)	31/31 (100.0)
Dogan et al. (77)	Retrospective	Single center	2008–2010	20	19	9	-	Range, 6–24	0/13 (0)	0/1 (0)	-	-	20/20 (100.0)
Dratwa et al. (68)	Retrospective	Multicenter (2 sites)	2009–2013	208	197	10-11	Median, 18 (6–27)	Range, 6–12	2/143 (1.4)	3/19 (15.8)	-	-	-
Ferre et al. (78)	Retrospective	Single center	2005–2013	259	255	10	Range, 6–18	Range, 6–24		3/40 (7.5)	8/15 (53.3)	8/32 (25.0)	253/259 (97.7)
Friedman et al. (69)	Retrospective	Single center	2006–2007	197	142	10	-	6	1/153 (0.7)	-	-	-	-
Gebauer et al. (48)	Retrospective	Single center	N/A	42	32	10	-	Mean, 18	0/27 (0)	-	-	0/3 (0)	42/42 (100.0)
Ghate et al. (79)	Retrospective	Single center	2004	20	19	10	Mean, 8 (5–12)	Range, 4–8	-	-	1/2 (50.0)	0/2 (0)	19/20 (95.0)
Han et al. (24)	Retrospective	Single center	2005	172	154	9-10	Range 4–10	12	4/89 (4.5)	1/15 (6.7)	-	0/17 (0)	150/172 (87.2)
Hauth et al. (80)	Prospective	Single center	2004–2006	34	33	10	Mean, 14.5 (2–25)	Mean, 7.5 (3–14)	1/20 (5.0)	-	-	-	29/34 (85.3)
Hayward et al. (70)	Retrospective	Single center	2005–2012	611	492	9	Range, 6–18	Mean, 33.1 (0.4–100.8)	2/367 (0.6)	-	-	-	-

Table 1. continued

Author and publication year	Design	Setting	Years	n. Target lesion	n. Patients	Needle size (gauge)	n. Sampled cores†	Follow-up (months)†	False negative rate*,§	Underestimation rate§			Successful biopsy rate^,§
										DCIS	ADH	Other high risk¥	
Heller et al. (38)	Retrospective	Single center	2007–2012	1,145	1003	9	10-12	Mean, 44 (36–54)	-	-	12/35 (12.9)	18/116 (15.5)	-
Huang et al. (21)	Retrospective	Single center	2007–2012	169	160	9	Median, 12 (6–27)	At least 24	1/168 (0.6)	-	-	-	-
Imschweiler et al. (13)	Retrospective	Multicenter (53 sites)	2009–2011	557	-	≤11	At least 12	-	8/283 (2.8)	-	-	-	548/557 (98.4)
Jung et al. (81)	Retrospective	Single center	2009–2011	22	22	9	Range, 12–18	Mean, 32.1 (15–44)	-	0/2 (0)	1/1 (100.0)	0/4 (0)	21/22 (95.5)
Kılıç et al. (82)	Retrospective	Single center	2011–2013	90	90	10–12	Range, 6–12	Range, 6–12	0/63 (0)	-	-	-	90/90 (100.0)
Lee et al. (83)	Retrospective	Single center	N/A¶	34	34	9	-	-	-	5/34 (14.7)	-	-	-
Lee et al. (71)	Retrospective	Single center	N/A¶	76	-	9	Median, 12 (6–20)	-	-	-	-	-	-
Lee et al. (84)	Retrospective	Single center	2006-2011	85	70	7, 8, 10	At least 9	Mean, 18 (3–75)	1/77 (1.3)	-	-	-	-
Lehman et al. (85)	Prospective	Single center	N/A	5	5	14	Range, 6–10	6	-	-	-	-	5/5 (100.0)
Lehman et al. (45)	Retrospective	Multicenter (2 sites)	2003	38	28	9–12	-	-	-	1/4 (25.0)	1/2 (50.0)	-	38/38 (100.0)
Li et al. (20)	Retrospective	Single center	N/A¶	543	514	9	-	Mean, 24 (7–53)	4/308 (1.3)	-	-	-	-
Liberman et al. (46)	Prospective	Single center	N/A	27	20	9	Median, 8 (6–14)	-	2/20 (10.0)	0/1 (0)	1/1 (100.0)	-	19/20 patients (95.0)
Liberman et al. (11)	Retrospective	Single center	N/A	112	106	9	Median, 12 (6–20)	Median, 7 (1–14)	1/52 (1.9)	1/13 (7.7)	2/4 (50.0)	1/6 (16.6)	95/112 (84.8)
Liberman et al. (86)	Retrospective	Single center	N/A¶	15	15	9	Median, 9 (8–18)	-	-	-	5/15 (33.3)	-	-

Table 1. continued

Author and publication year	Design	Setting	Years	n. Target lesion	n. Patients	Needle size (gauge)	n. Sampled cores†	Follow-up (months)†	False negative rate*,§	Underestimation rate§			Successful biopsy rate^,§
										DCIS	ADH	Other high risk¥	
Lourenco et al. (39)	Retrospective	Single center	2006–2010	96	96	9	Mean, 10 (6–13)	Mean, 31.2 (6–60)	-	-	6/20 (30.0)	10/76 (13.2)	-
Mahoney et al. (23)	Retrospective	Single center	2004–2007	55	47	10	At least 12	Minimum 6	-	-	2/3 (66.7)	2/4 (50.0)	55/55 (100.0)
Malhaire et al. (25)	Retrospective	Single center	2003–2008	72	72	10	Median, 18 (6–48)	Median, 12.8 (1–53)	3/26 (11.5)	2/9 (22.2)	1/1 (100.0)	0/9 (0)	-
Meeuwis et al. (87)	Retrospective	Single center	2007–2010	119	119	9–14	Up to 12	Range, 6–24	-	-	-	-	118/119 patients (99.2)
Myers et al. (88)	Retrospective	Single center	2006–2012	200	168	10	At least 6	Mean, 20.5 (4–67)	3/142 (2.1)	1/5 (20.0)	4/7 (57.1)	0/32 (0)	-
Noroozian et al. (89)	Retrospective	Single center	2006–2007	75	75	9	At least 6	Range, 6–12	-	3/3 (100.0)	0/2 (0)	1/5 (20.0)	-
O'Connor et al. (90)	Retrospective	Single center	2007–2012	126	126	9	Range, 8–24	Range, 10-74	-	5/16 (31.3)	-	-	-
Orel et al. (47)	Retrospective	Single center	2003–2004	85	75	9	-	-	0/13(0)	4/17 (23.5)	2/8 (25.0)	0/10 (0)	-
Perlet et al. (10)	Retrospective	Multicenter (5 sites)	N/A	538	517	11	At least 20	Median 32 (4–48)	0/354 (0)	3/64 (4.7)	5/17 (29.4)	-	517/538 (96.1)
Perretta et al. (91)	Retrospective	Single center	2003–2006	47	47	10	-	Mean 18	0/28 (0)	1/7 (14.3)	1/4 (25.0)	-	47/47 (100.0)
Peters et al. (92)	Retrospective	Single center	2005–2008	31	30	14	Range, 3–5	-	2/19 (10.5)	-	-	-	29/31 (93.5)
Rauch et al. (31)	Retrospective	Single center	2005–2010	218	197	9	Range, 6–12	Mean, 29 (6–69)	0/132 (0)	4/22 (18.2)	3/13 (23.1)	1/6 (16.6)	-
Schrading et al. (93)	Retrospective	Single center	2005–2007	316	200	9–10	11	Range, 6–12	0/186 (0)	-	-	-	-

Table 1. continued

Author and publication year	Design	Setting	Years	n. Target lesion	n. Patients	Needle size (gauge)	n. Sampled cores†	Follow-up (months)†	False negative rate*,§	Underestimation rate§			Successful biopsy rate^,§
										DCIS	ADH	Other high risk¥	
Spick et al. (65)	Prospective	Single center	2009–2013	1,432	865	9	Mean, 39 (24–60)	Median, 28 (24–51)	0/571 (0)	3/276 (1.1)	-	-	1412/1432 (98.6)
Schrading et al. (64)	Retrospective	Single center	2007–2010	376	336	9	Range, 10–12	Mean, 27 (5–63)	1/233 (0.4)	-	-	-	-
Speer et al. (42)	Retrospective	Single center	2007–2012	99	90	9	Median, 12 (min. 6)	Mean, 70.8 (12-117)	-	-	4/21 (19.04)	2/78 (2.6)	-
Spick et al. (65)	Retrospective	Single center	2006–2013	487	467	8–10	Range, 12–24	At least 12	0/317 (0)	5/34 (14.7)	-	-	-
Tozaki et al. (94)	Retrospective	Single center	2007–2009	102	100	11	-	6	0/59 (0)	3/28 (10.7)	2/4 (50.0)	-	102/102 (100.0)
Verheyden et al. (41)	Retrospective	Multicenter (9 sites)	2007–2014	1,509	180	7–10	Mean, 12 (12–14)	-	-	27/118 (22.9)	17/72 (23.6)	-	-
Weindfurtner et al. (40)	Retrospective	Single center	2007–2013	257	247	9	At least 6	-	-	-	4/18 (22.2)	0/11 (0)	-
Zebic-Sinkovec et al. (95)	Retrospective	Single center	N/A	15	15	9	Median, 8 (4–17)	-	-	-	-	-	14/15 patients (93.3)

n.: number; ADH: atypical ductal hyperplasia; DCIS: ductal carcinoma *in situ*; N/A: not applicable; *: the false-negative rate was defined as the rate of malignancy identified in patients with benign-concordant magnetic resonance imaging guided needle biopsies; ¥: other high-risk lesions include lobular carcinoma *in situ*, papillary lesions (intraductal papilloma and papilloma with atypia), atypical lobular hyperplasia, flat epithelial atypical radial scars/complex sclerosing lesions; ^: successful biopsy rate is calculated as the number of successfully completed biopsies divided by the number of recommended biopsies. Recommended biopsy number includes the number of non-enhancing lesions on the day of biopsy.

¶: exact date not provided: Bahrs et al. (73) 6-year, Lee et al. (83) 42-month, Lee et al. (71) 45-month, Li et al. (20) 54-month, Liberman et al. (86) 33-month period; †: data in parentheses are range;

§: data in parentheses are percentages

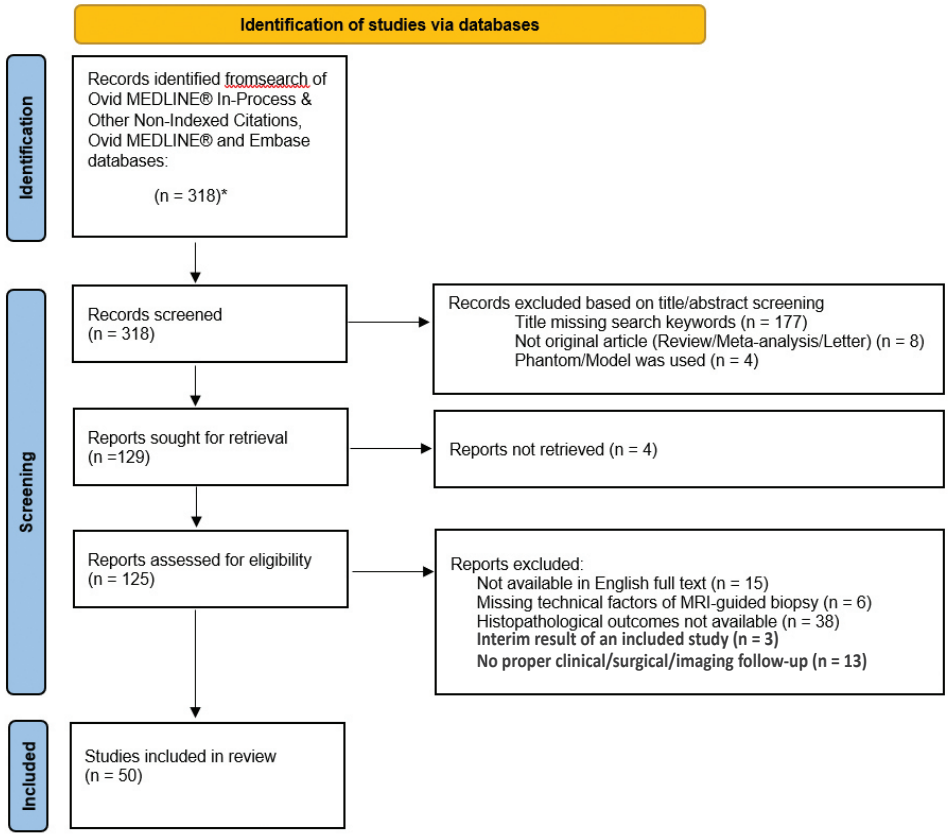

Figure 1. Flow diagram of study selection process

**: after exclusion of duplicates*

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Table 2. Pooled rates of malignant, benign and high-risk lesions identified in 4,647 MRI guided breast biopsies

Lesion type	Benign	Malignant	High risk	Total
Mass	2,417 (60.35%)	1,097 (27.39%)	491 (12.26%)	4,005*
Non-mass enhancement	360 (61.96%)	66 (11.36%)	155 (26.67%)	581*
Focus	42 (68.85%)	11 (18.03%)	8 (13.12%)	61*
Total				4647**

*: corresponding histopathological results were missing in 1,140 of masses (1,140/5,145, 22.16%), 1,571 of non-mass enhancements (1,571/2,152, 73.00%) and 82 of foci (82/143, 57.34%); **: lesion type on MRI was available for 67.11% of total successful biopsies (7,440/11,087). In 4,647 of them (4,647/7,440, 62.46%) corresponding histopathology results were also available; MRI: magnetic resonance imaging

Our primary outcomes were:

1) Rate of successfully performed MRI biopsies, 2) rate of pathological outcomes of benign, malignant, high-risk, 3) false negative rate, 4) follow-up outcomes after a benign MRI-guided breast biopsy.

We aimed to identify potential technical and patient clinicopathological factors which may have influenced MRI-guided breast biopsy outcomes.

Reference Standards

A false-negative result was defined as a pathologically proven malignancy after follow-up or immediate excision or re-biopsy following an MRI-guided benign biopsy. Discordant biopsy results occur when benign pathology results do not account for the imaging findings and MRI-guided benign histopathology results include both imaging-concordant and -discordant ones. The false-negative rate was defined as the rate of malignancy identified in those patients with benign-concordant MRI-guided breast biopsies.

High-risk lesions were ADH, LCIS, papillary lesions (intraductal papilloma and papilloma with atypia), ALH, FEA, and RSL/CSL (16). High-risk lesions which were diagnosed at MRI-guided biopsy, and in which a subsequent diagnosis of invasive cancer or DCIS lesion was made at surgical excision or follow-up re-biopsy, were considered as underestimations.

The high-risk lesion underestimation rate was defined as the number of these underestimated lesions divided by their high-risk lesion category (ADH vs other high-risk lesions) at MRI-guided biopsy on histologic examination.

The underestimation rate in DCIS was considered if a pathologically proven invasive carcinoma was seen at surgical excision or follow-up re-biopsy when the MRI-guided biopsy result was DCIS.

A biopsy was counted as technically successful if it was possible to see the target lesion on MRI on the day of the procedure, and the biopsy could be safely performed according to the performing physician.

Statistical Analysis

We performed descriptive statistics on our database using IBM SPSS Statistics for Windows, Version 28.0 (Armonk, NY). Qualitative variables were summarized by count and percentage, which included MRI indication, lesion type, and post-biopsy complications. Quantitative variables such as the average core number, age, follow-up time, and lesion size were reported as mean/median.

We tabulated numbers from all studies but some studies were excluded on a per-question basis when they did not report the numbers we were investigating. A random intercept logistic regression model was used to pool technical success rates, canceled biopsy rates, histopathology results, false-negative results, discordant rates, false-negative rates after excluding benign-discordant biopsies and upgrade rates in DCIS, ADH, and other high-risk lesion types. Weighted mean proportion and 95% confidence intervals (CIs) were reported. Of note, the random effects model uses weighted proportions, so: 1) pooled rates were not calculated by dividing the nominator by the denominator, 2) the denominators were different for each analysis, and 3) the pooled rates might not add up to 100%. Clopper-Pearson exact binomial intervals were calculated for each pooled proportion. Between-study heterogeneity was quantified by Higgin's & Thompson's I-squared statistic (25% low heterogeneity, 25–50% medium, >50% high) (17). Odds ratios were pooled using the random effects model.

Meta-regression with mixed-effects models was used to test the moderator effect of the year that the study was published (before or in 2010 versus after 2010), the average number of cores sampled (more than 13 cores sampled vs others), needle size (≤11G vs >11G) and mean lesion size (≤12 mm vs >12 mm) with the outcomes of false-negative rates, DCIS upgrade rates, ADH upgrades, and other high-risk lesions upgrade rates. The corresponding *p*-values were reported and $p<0.05$ was considered statistically significant. We used the R 4.2.1 (R core team, Vienna, Austria) and meta package (18).

Results

Analyzed Data Cohort and Included Studies

A total of 318 abstracts were identified after the exclusion of the repeated articles. Of these 318 abstracts, 189 (59.43%) were excluded after title/abstract screening due to the title missing key research words (n = 177), not being an original article with novel data (n = 8), and using phantoms/models (n = 4). The remaining 129 studies (40.57%) were retrieved and 125 (39.31%) were reviewed in their full text. Seventy-five (25.58%) were excluded due to not being available fully in English (n = 15, 4.72%), missing technical factors of the MRI-guided biopsy (n = 6, 1.89%), not having histopathological outcomes (n = 38, 11.95%), being an interim result of an included study (n = 3, 0.94%) or lacking proper clinical/surgical/imaging follow-up (n = 13, 4.10%). The remaining 50 (15.72%) studies were included in this study and reviewed systematically (Figure 1). Table 1 summarizes the remaining 50 studies which met our inclusion criteria.

The studies we included in this meta-analysis had an overall moderate to low risk of bias. Detailed information on the risk of biases of the studies included is shown in Figure 2.

Technical factors and biopsy success

Pooled reported data from 50 studies with 11,215 target lesions were reviewed. Varying magnet strength (1.5 or 3 Tesla), needle gauges (7–18), and needle types were used for biopsy.

Twenty-five studies out of 50 (50.00%) provided the number of recommended biopsies along with the number of successful ones. The rates were pooled using the random effects model. The pooled rate for canceled biopsies due to non-enhancement on the day of the procedure was 4.58% (95% CI: 1.81–11.11%) (Figure 3a). Canceled biopsies due to non-enhancement were excluded from the technical success analysis yielding a final technical success rate of 99.10% (95% CI: 97.89–99.62%) (Figure 3b).

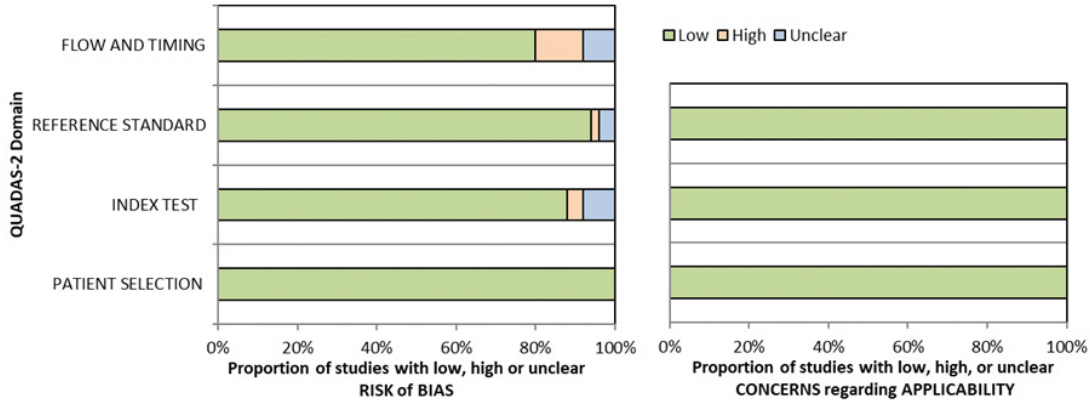

Figure 2. QUADAS-2 graph demonstrates the risk of bias and the applicability of assessment results

A total of 11,087 successful MRI-guided biopsies were included in this review. A median of 13 cores (range: 2–60) was obtained per biopsy. Despite collecting enhancement kinetics data, these were not included in our analysis due to the insufficient number of studies describing lesion enhancement kinetics.

The number of patients was reported in 48/50 (96.0%) studies. In 10,463 successful biopsies in 7,893 women, the mean patient age was 51.8 years (range of mean/median, 45.5–58, standard deviation: ±2.8).

Indications for breast MRI

MRI indication information was available for 5,333 patients (5,333/7,893, 67.57%). The indication was breast cancer staging in 1,496 (28.05%, 95% CI: 26.85–29.28%), screening in 1,427 (26.76%, 95% CI: 25.57–27.97%), breast cancer surveillance in 1,027 (19.26%, 95% CI: 18.21–20.34%), diagnostic (abnormal mammogram/ultrasound or clinical symptoms) in 1,038 (19.46%, 95% CI: 18.41–20.55%), unknown primary in 74 (1.39%, 95% CI: 1.09–1.74%), and other in 271 (5.08%, 95% CI: 4.51–5.71%) (Supplementary Figure 1).

Those patients undergoing MRI for breast cancer surveillance [odds ratio (OR) 1.36 (95% CI: 0.96–1.93; p = 0.09)], diagnostic indication (OR 1.20, 95% CI: 0.87–1.67; p = 0.27) or breast cancer staging (OR 1.20, 95% CI: 0.79–1.82; p = 0.40) had higher rates of malignant outcomes. Of the MRI indications, fewer malignant outcomes were observed in screening (OR 0.47, 95% CI: 0.25–0.87; p = 0.02) (Figure 4).

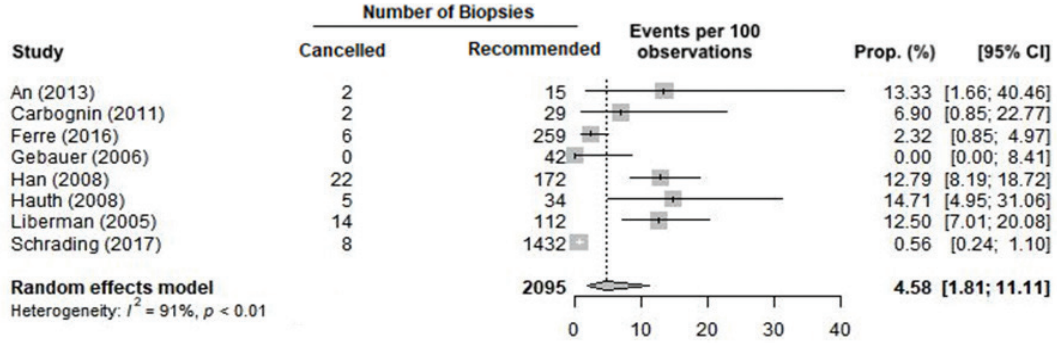

Figure 3a. Forest plot of the rate of the cancelled biopsies due to non-enhancement on the day of the MRI-guided breast biopsy

CI: confidence interval; I²: I squared; Prop.: proportion; MRI: magnetic resonance imaging

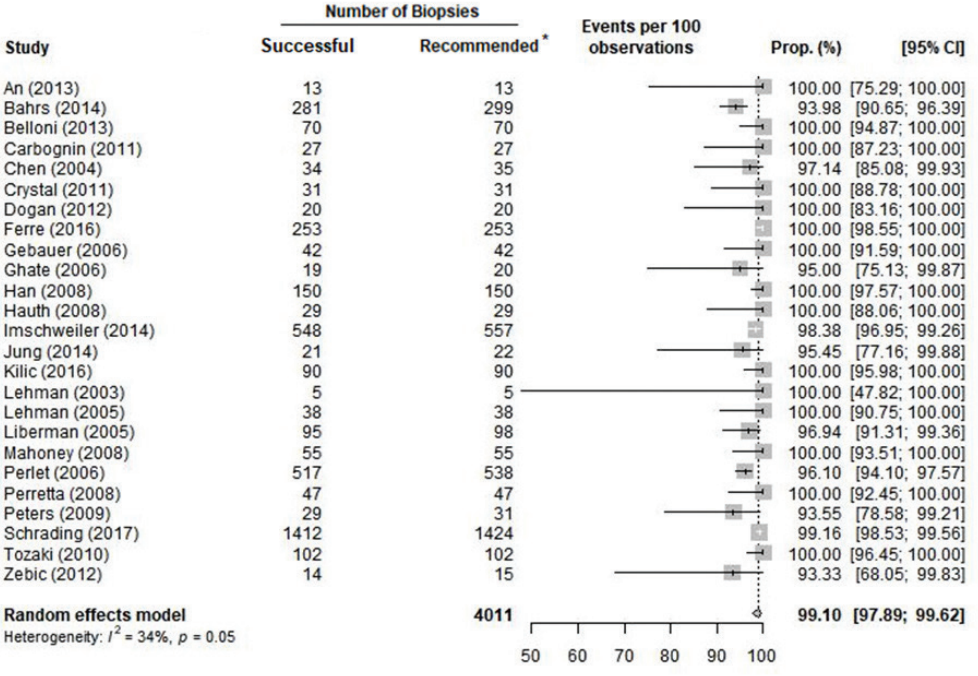

Figure 3b. Forest plot of the technical success rates in MRI-guided biopsies

Prop.: proportion; CI: confidence interval; I²: I squared (25% low heterogeneity, 25–50% medium, >50% high).

*p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-squared statistic). A low p-value (<0.05) indicates that there is significant heterogeneity between studies. *: cancelled biopsies due to non-enhancement on the day of biopsy were excluded from the technical success analysis. Recommended biopsy number reflects that exclusion*

Histopathology results and lesion types

Of 11,087 successful biopsies, the pooled rate for histopathology results was benign in 65.06% (95% CI: 59.15–70.54%), malignant in 29.64% (95% CI: 23.58–36.52%; invasive cancer, 15.16%, 95% CI: 12.56–18.18%; DCIS, 9.51%, 95% CI: 7.63–11.80%) and high risk in 16.69% (95% CI: 9.96–26.64%; ADH, 6.33%, 95% CI: 4.24–9.36%; other high-risk lesions, 12.73%, 95% CI: 7.12–21.73%) (Supplementary Figure 2). The pooled rate for invasive cancer among the malignant results was 62.10% (95% CI: 57.09–66.87%) and it was 40.00% (95% CI: 33.48–46.89%) for DCIS (Supplementary Figure 3). Among the high-risk lesions, the ADH pooled rate was 44.56% (95% CI: 30.84–59.15%) and the pooled rate for high-risk lesions other than ADH was 63.17% (95% CI: 51.40–73.55%) (Supplementary Figure 4).

Lesion type on MRI was available in 7,440 (67.11%) biopsies [5,145 mass (44.93%), 2,152 non-mass enhancement (18.79%), 143 focus (1.25%)]. The average mass enhancement size was 10.1 mm (range: 2–60) while the average non-mass enhancement size was 22.8 mm (range: 4–140), yielding an overall average lesion size of 12.4 mm (range: 2–140). Corresponding histopathological results were missing in 1,140 masses (1,140/5,145, 22.16%), 1,571 non-mass enhancements (1,571/2,152, 73.00%) and 82 foci (82/143, 57.34%). Of the 4,005 mass lesions, 2,417 (60.35%) were benign, 1,097 (27.39%) were malignant and 491 (12.26%) were high-risk. Overall, mass lesions were more likely to yield malignancy compared to non-mass and foci lesions [27.39% vs 11.36% (non-mass) and 18.03% foci, $p<0.001$]. Table 2 shows lesion types on MRI with the corresponding histopathology results.

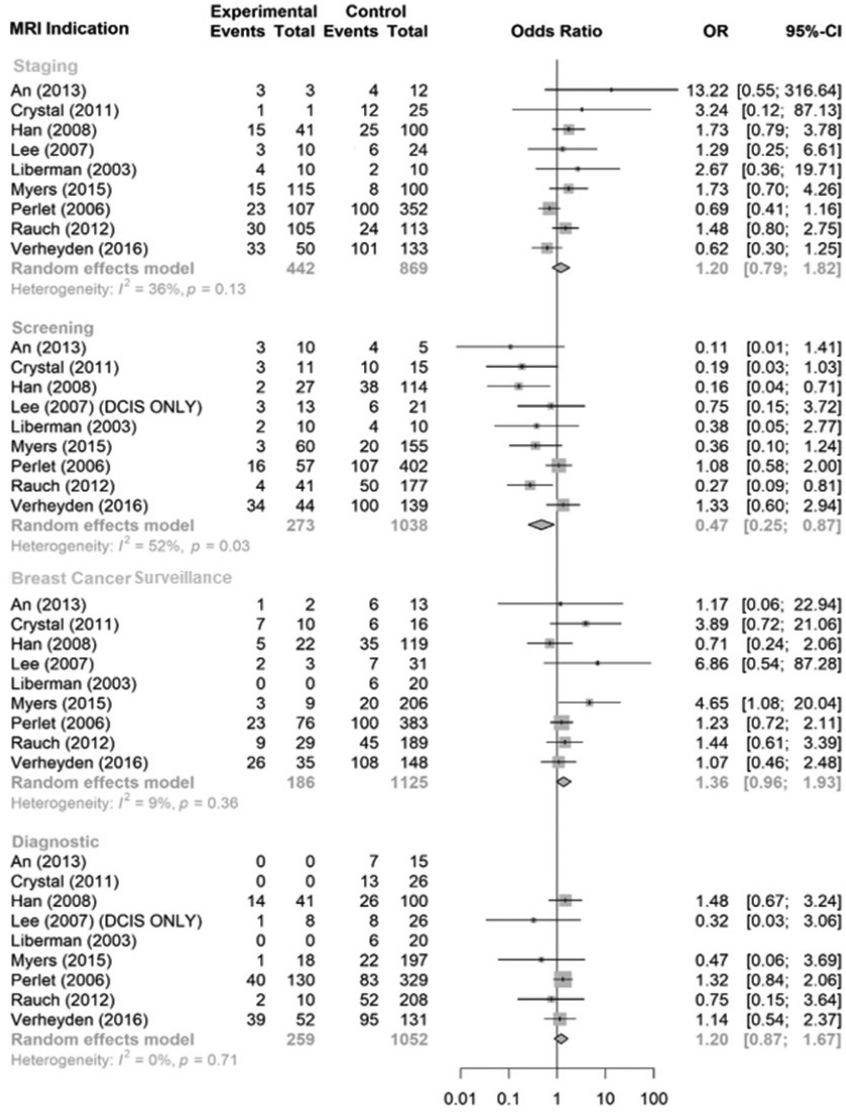

Figure 4. Forest plot showing the association of MRI indication with the likelihood of malignancy outcome in MRI-guided breast biopsy

MRI: magnetic resonance imaging; OR: odds ratio; CI: confidence interval; I²: I squared (25% low heterogeneity, 25–50% medium, >50% high); DCIS: ductal carcinoma in situ

p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates there is significant heterogeneity between studies

Upgrade Rates

Surgical upgrade to invasive cancer occurred in 12.24% of DCIS lesions (95% CI: 7.76–18.77%) (Figure 5a). The upgrade rate among all high-risk lesions was 15.14% (95% CI: 10.69–21.17%) (Figure 5b). Of 294 ADH lesions, upgrade to DCIS or invasive cancer was seen in 31.81% (95% CI: 25.57–38.77%) (Figure 5c) while a pooled upgrade rate of 6.75% (95% CI: 2.57–16.56%) (Figure 5d) was seen in high-risk lesions other than ADH (LCIS, ALH, FEA RSL/CSL). Among high-risk lesions, ADH had the highest upgrade rate to malignancy [OR 3.51 (95% CI: 2.18–5.65), p<0.001].

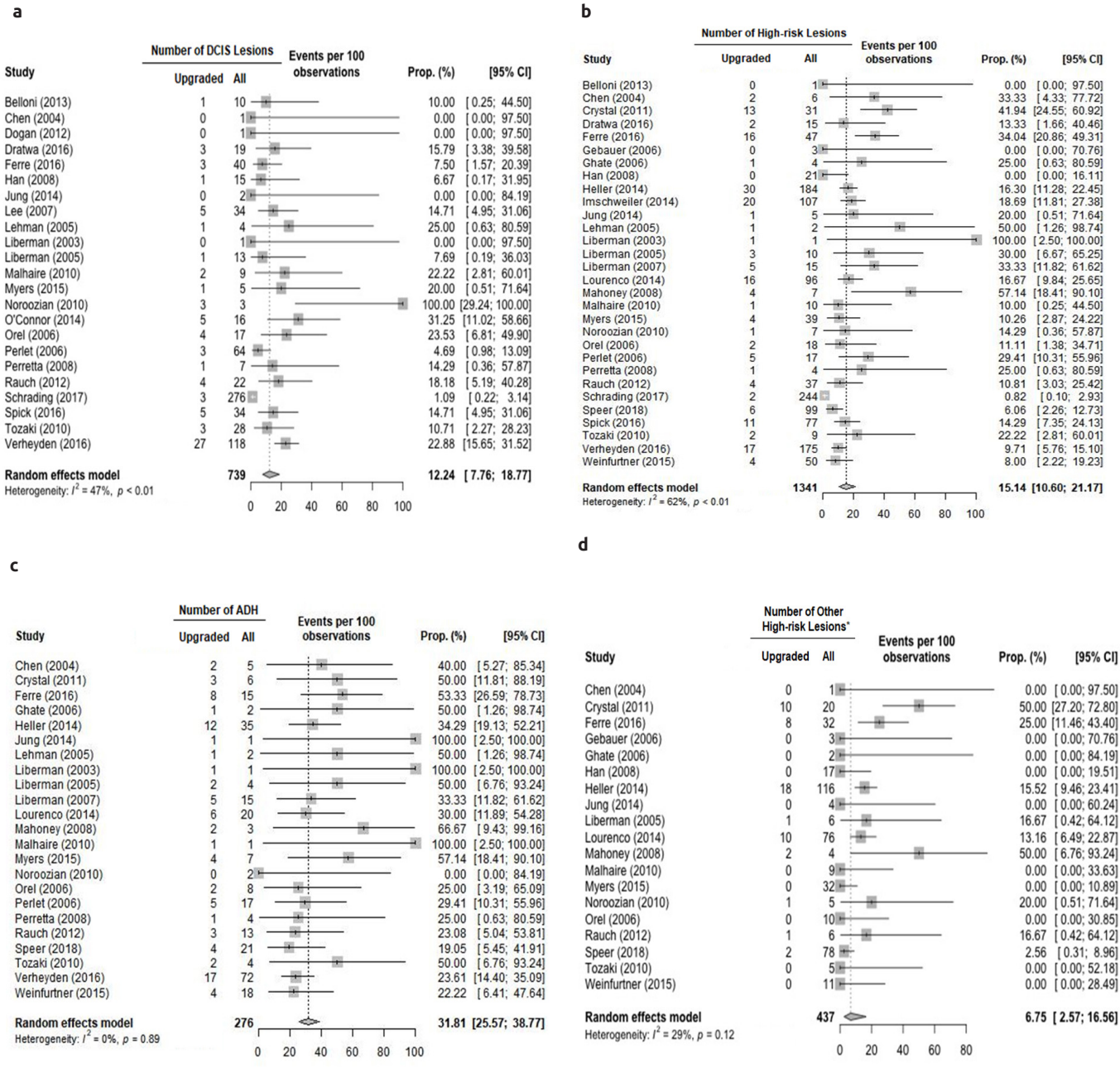

Figure 5. Forest plots of upgrade rates of ductal carcinoma *in situ* (DCIS) to invasive cancer, b.) high-risk lesions to DCIS or invasive cancer, c.) atypical ductal hyperplasia (ADH) to DCIS or invasive cancer, and d.) high-risk lesions other than ADH to DCIS or invasive cancer after MRI-guided breast biopsy

Prop.: proportion; CI: confidence interval; I^2: I squared (25% low heterogeneity, 25–50% medium, >50% high); DCIS: ductal carcinoma in situ; ADH: atypical ductal hyperplasia

p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-squared statistic). A low p-value (<0.05) indicates that there is significant heterogeneity between studies.

**: other high-risk lesions include lobular carcinoma in situ, papillary lesions (intraductal papilloma and papilloma with atypia), atypical lobular hyperplasia, flat epithelial atypical radial scars/complex sclerosing lesions*

Benign-discordant biopsies and false negative rates

Short-term follow-up with a median of 25 months (range: 0.4–117) was performed in 1,651 (20.92%) patients. The pooled malignancy rate after the benign biopsy result was 1.64% (95% CI: 0.96–2.81%) (Figure 6a). The pooled radiology-pathology discordance rate was 2.48% (95% CI: 1.62–3.77%) (Figure 6b). When benign-discordant biopsies were excluded, the pooled false negative rate was 0.75% (95% CI: 0.34–1.62%) (Figure 6c).

When we compared studies based on the year published (before/in 2010 versus after 2010), needle size (≤11G vs >11G), the average number of cores sampled (more than 13 cores sampled vs others), and average lesion size (≤12 mm vs >12 mm), we did not find enough evidence to establish any association with the false negative rate, DCIS to invasive cancer or the high-risk lesion upgrade rate (*p*-values: 0.13–1.00). Table 3 represents the comparison results in detail.

Post-biopsy Complications

Post-biopsy complications [158 (1.42%) hematoma, 17 (0.15%) vasovagal response, 19 (0.17%) other] were rare and seen in 186 out of 7,893 patients (2.36%, 95% CI: 2.03–2.72%).

Discussion and Conclusion

MRI-guided breast biopsy is an efficient and highly accurate technique with high technical success (99.10%, 95% CI: 97.89–99.62%) and a low false-negative rate (0.75%, 95% CI: 0.34–1.62%). We found a low false-negative rate in benign-concordant lesions, which supports that there is no need to follow-up patients with MRI after a benign-concordant biopsy result (19-22).

We found that benign biopsies accounted for more than half of all MRI-guided breast biopsies (65.06%, 95% CI: 59.15–70.54%) in all lesion types (60.35% in mass, 61.96% in non-mass enhancement, 68.85% in focus). Our findings suggest that enhancing lesion type by ACR BI-RADS descriptors influenced the malignancy rate and that mass lesions were more likely to yield malignancy compared to non-mass lesions and foci (27.39% vs 11.36% non-mass and 18.03% foci, $p<0.001$). This finding is in keeping with previous studies which reported that the malignancy rate is higher for masses (34–60%) (23-25). However, our pooled malignancy rate in mass lesions was somewhat less than had been previously reported. Masses are more likely to be identified on second-look ultrasound (58–65%) than non-mass-like lesions (12–54%), and consequently were more likely to undergo ultrasound-guided needle biopsy (26-29). It was also reported that lesions which were seen on second-look ultrasound were more likely to be malignant (57.4–91.7%) (28-31). Collectively, this results in only those masses likely to be benign undergoing MRI-guided biopsy, which can be the reason why we saw a low pooled malignancy rate.

In our study, the pooled rate for malignancy was 29.64% (95% CI: 23.58–36.52%). Patients undergoing MRI for breast cancer surveillance, diagnostic indication, and breast cancer staging had a higher rate of malignant results (OR, 1.36, 1.20, and 1.20; respectively), although none of them were statistically significant (p=0.09–0.40).

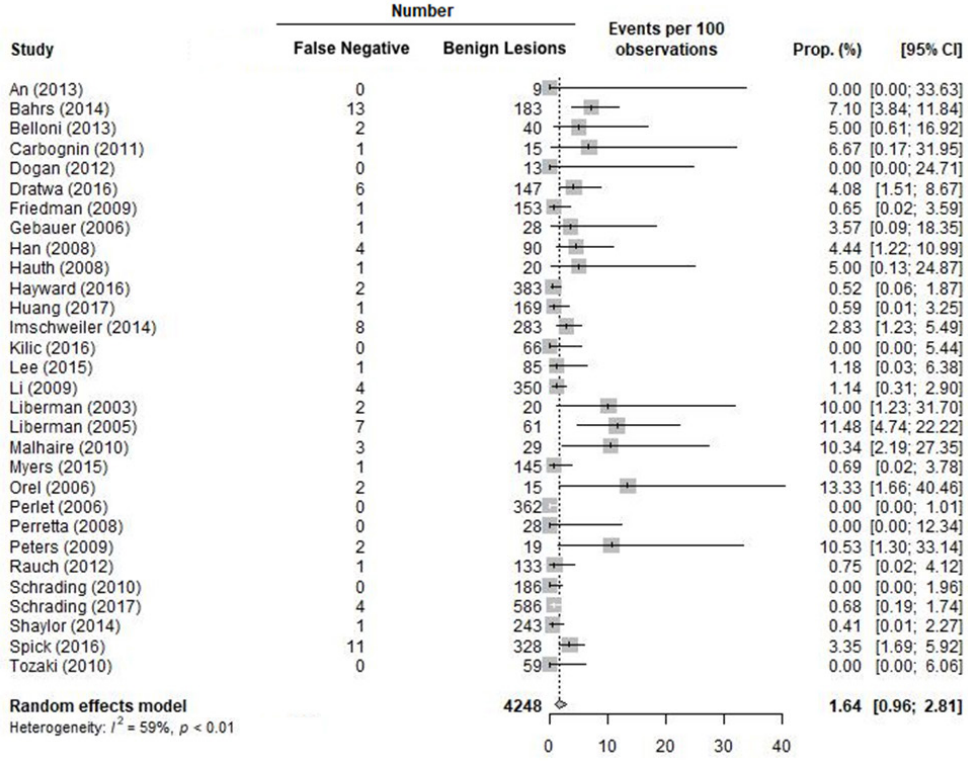

Figure 6a. Forest plots demonstrating malignancy and radiology-pathology discordance rates following a benign MRI-guided breast biopsy, pooled forest plot of overall malignancy rates after a benign MRI-guided breast biopsy

Prop.: proportion; CI: confidence interval; I²: I squared (25% low heterogeneity, 25–50% medium, >50% high).

*p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates that there is significant heterogeneity between studies; *: identified after follow-up (median, 25; range, 0.4-117 months) or immediate excision or re-biopsy*

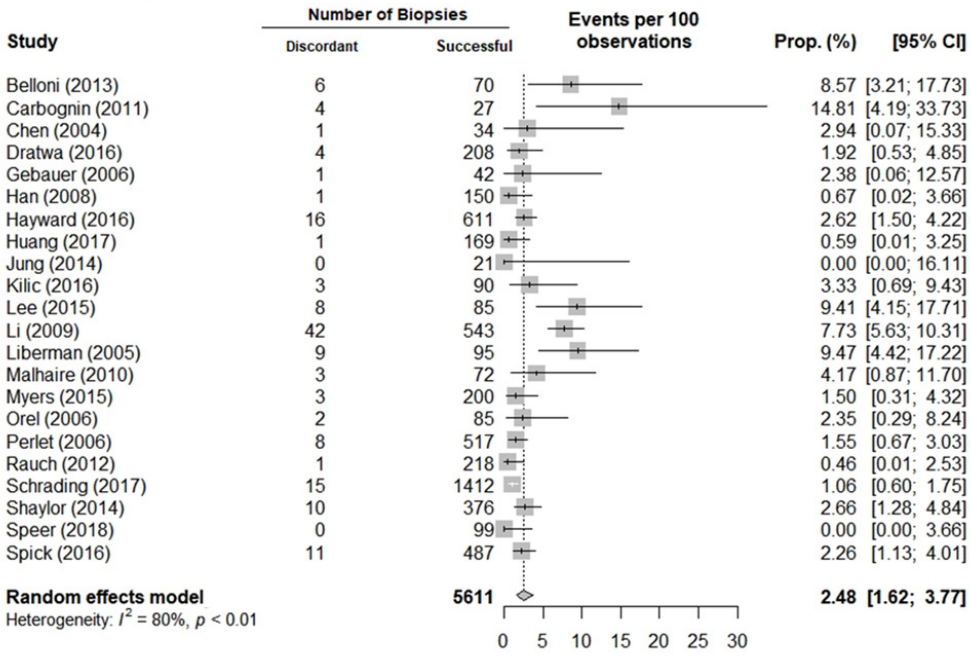

Figure 6b. Forest plots demonstrating malignancy and radiology-pathology discordance rates following a benign MRI-guided breast biopsy, radiology-pathology discordance rate after MRI-guided breast biopsy

Prop.: proportion; CI: confidence interval; I²: I squared (25% low heterogeneity, 25–50% medium, >50% high).

*p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates that there is significant heterogeneity between studies; *: identified after follow-up (median, 25; range, 0.4-117 months) or immediate excision or re-biopsy*

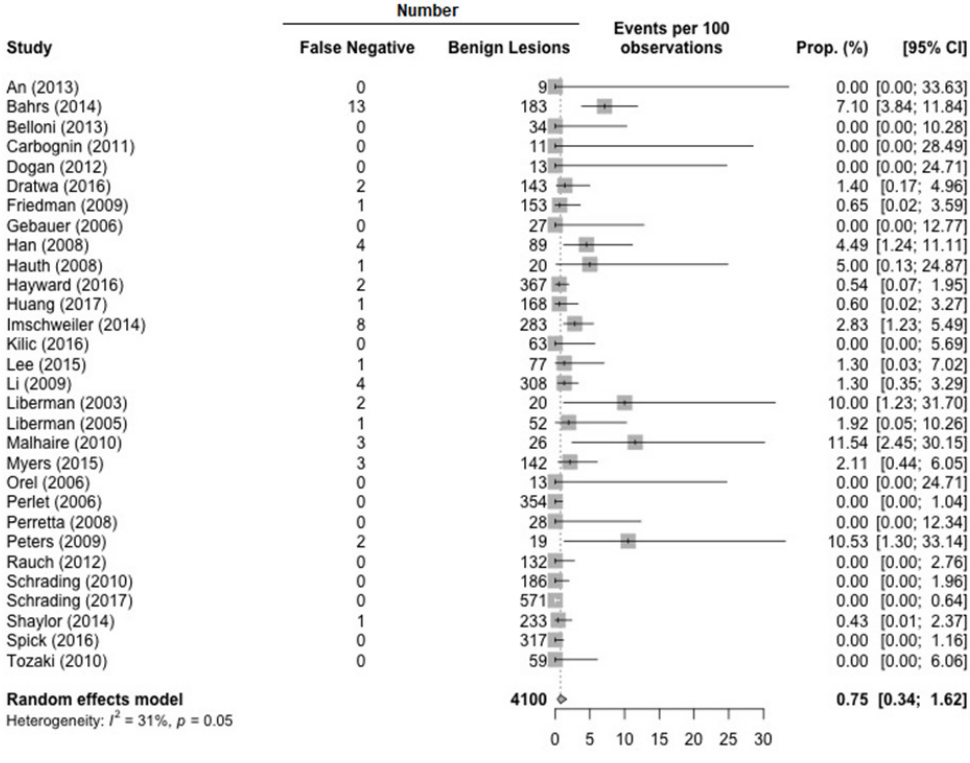

Figure 6c. Forest plots demonstrating malignancy and radiology-pathology discordance rates following a benign MRI-guided breast biopsy, malignancy identified* following a benign-concordant MRI-guided breast biopsy

Prop.: proportion; CI: confidence interval; I²: I squared (25% low heterogeneity, 25–50% medium, >50% high).

*p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates that there is significant heterogeneity between studies; *: identified after follow-up (median, 25; range, 0.4-117 months) or immediate excision or re-biopsy*

Table 3. Comparison of false negative, DCIS upgrade and high-risk lesion upgrade rates based on study characteristics

	Study year			Needle size			Number of cores sampled			Lesion size		
	Before or in 2010	After 2010	p*	≤11G	>11G	p*	≤13 cores	>13 cores	p*	≤12 mm	>12 mm	p*
False negative rate (%)	1.16 (0.4, 3.5)	0.5 (0.2, 1.5)	0.22	0.7 (0.3, 1.6)	2.5 (1.4, 4.6)	0.40	0.9 (0.2, 4.9)	1.2 (0.1, 10.2)	0.73	2.0 (0.6, 6.2)	0.1 (0, 32.2)	0.33
DCIS to Invasive cancer upgrade rate (%)	13.51 (7.8, 22.5)	10.9 (5.5, 20.5)	0.63	12.3 (7.5, 19.3)	13.3 (3.4, 40.5)	0.97	12.5 (5.7, 25.2)	6.2 (1.2, 27.1)	0.64	13.0 (7.1, 22.5)	19.8 (15.1, 25.5)	0.18
ADH upgrade rate (%)	36.8 (26.2, 48.8)	30.3 (23.1, 38.5)	0.29	31.5 (25.2, 38.5)	42.9 (14.4, 77.0)	0.53	30.2 (20.1, 42.5)	100 (0,-)	1.00	35.7 (16.1, 61.7)	27.0 (19.6, 35.8)	0.52
Other high risk lesion upgrade rate¥ (%)	3.8 (0.5, 25.7)	9.0 (3.2, 23.2)	0.39	6.9 (2.6, 16.8)	0 (0,-)	0.98	7.2 (2.7, 17.9)	0 (0,-)	1.00	3.0 (1.0, 8.9)	10.3 (0.9, 59.1)	0.13

DCIS: ductal carcinoma in situ; ADH: atypical ductal hyperplasia; G: gauge; all values are percentages. Data in parentheses are 95% confidence intervals. Upper limit of some proportions was not estimable due to small sample size. ¥: other high-risk lesions include lobular carcinoma in situ, papillary lesions (intraductal papilloma and papilloma with atypia), atypical lobular hyperplasia, flat epithelial atypical radial scars/complex sclerosing lesions; *p-values were calculated using meta-regression with mixed effects models

Detection of malignancy was significantly lower in those patients who underwent MRI for screening purposes (OR 0.47, 95% CI: 0.25, 0.87; p=0.02). When interpreting our results, it should be considered that the study results included were homogeneous in breast cancer surveillance, staging, and diagnostic indication groups whereas in the screening group, they were heterogeneous (*p*-values of the random effects models were: 0.36, 0.13, 0.71, and 0.03, respectively). In contrast to previous studies which reported the frequency of malignancy to be significantly higher in those patients presenting for diagnostic versus screening purposes (screening 10–14% vs diagnostic 28–36%; $p<0.05$) (24, 31), we did not compare individual indications with each other. Rather, with a Bayesian model, we compared whether the indication of interest affected the MRI biopsy outcome or not. This difference in analyzing methods should be considered.

ADH identified with MRI-guided biopsy was found to have a pooled underestimation rate of 31.13% (95% CI: 25.17–37.78%), slightly higher than that of stereotactic biopsy (mean 20%, range 10–27%, with 11-gauge vacuum-assisted biopsy probe) (32-37). ADH has high upgrade rates (15.0–53.3%) verified over multiple studies (31, 38-42). In a recent study by Michaels et al., it was found that ADH was more likely to upgrade to cancer at surgical excision than other high-risk lesions (22.5% vs 3.4%, p=0.005) and that larger high-risk lesions had a greater tendency for an upgrade than smaller lesions (1.8 vs 1.2 cm, p=0.073). Furthermore, Rauch et al. (31) and Heller et al. (38) reported that the risk of upgrade in MRI-detected high-risk lesions was higher if the high-risk lesion was identified in the same breast as a prior malignancy, or if the patient had had a recent diagnosis of malignancy. Our findings underscore that the surgical upgrade to malignancy is common among high-risk lesions, especially ADH. Traditionally, it has been recommended to surgically remove high-risk lesions due to their high degree of underestimation on biopsy. However, the most recent recommendations advocate a more cautious multidisciplinary approach to assess the individual risk of patients and to avoid surgical excision whenever possible (43, 44). Unfortunately, due to a lack of correlating data on patient history, we could not further investigate multivariable associations on the surgical upgrade of high-risk lesions diagnosed at MRI-guided breast biopsy to predict the individual risks of patients.

MRI-guided breast biopsy is a safe technique with low complication rates (0–6%) (3, 10, 11, 45-48). Complications are generally minor (hematomas, malaise, skin damage) and easily managed (11, 47, 48). In our systematic review, we found a complication rate of 2.36%, almost all comprising hematomas, and none of them requiring major interventions, such as surgery.

Occasionally, a finding identified as suspicious on prior breast MRI no longer enhances on the day of the biopsy. It has been hypothesized that these cancellations occur as a result of changing hormonal status (related to the menstrual cycle, menopausal status, age, hormone suppression, or replacement therapy) which can affect background parenchymal enhancement, patient positioning, or the over-compression of the breast within the MRI-biopsy coil (11, 24, 49-55). It has also been reported that non-visualization was more commonly seen in non-mass enhancement (54). In our review, 4.58% (95% CI: 1.81–11.11%) of the scheduled biopsies were canceled due to non-enhancement on the day of the biopsy, with single center reports ranging from 6.9–13% (11, 24, 49, 50, 53-55). The lower pooled cancellation rate due to non-enhancement in our study may be due to our inclusion of newer

studies performed over the last decade, which reflect the learning curve to appropriately recognize normal but variably enhancing parenchyma by radiologists, resulting in fewer biopsies recommended for benign background enhancement. Previously, it had been reported that the cancer detection rate among lesions for which biopsy was canceled due to non-enhancement was low (2–10%) (49, 53, 55). This rate could not be analyzed in our systematic review.

Careful radiologic-pathologic correlation is necessary to confirm the concordance of imaging findings with pathology. In our review, imaging-pathologic discordance occurred in 2.48% (95% CI: 1.62–3.77%) of MRI-guided biopsies. This discordance rate is similar to rates reported for stereotactic and ultrasound-guided needle biopsies (1.3–4.4%) and further validates the MRI-guided breast biopsy technique (56-60). Previously, it was found that lesions which were missed rather than sampled on MRI-guided biopsies had a higher rate of imaging discordance, and lesions with discordant imaging had a higher risk of malignancy (30–100%) (47, 56, 61). This malignancy risk was higher than had been reported for stereotactic-guided biopsy (11.7–53.8%) (58-60) and ultrasound-guided biopsy (0.1–2.4%) (57, 62, 63). This could have been caused by the MRI patient population characteristics, which includes high-risk patients, patients with newly diagnosed breast cancer or a history of breast cancer. Since a similar discordance rate was observed in MRI-guided biopsy with higher malignancy, there should be a standard reference for reporting false-negative rates in MRI-guided biopsies. We realized that there is no standard of reference and, in some studies, benign-discordant biopsies which were found to be malignant after re-biopsy or surgical excision were counted as false-negatives (64-66), while in others, those cases were excluded from the false negative cases (67). In our systematic review, we defined the false negative rate as the rate of malignancy identified after a benign-concordant MRI-guided breast biopsy, and the pooled false-negative rate for the studies included was 0.75% (95% CI: 0.34–1.62%).

The limitations of this meta-analysis include the heterogeneity between the groups and the across studies (I-squared >25%). Most studies were retrospective in design, with only three prospective studies contributing data into the pooled estimates. As a result, bias and confounding could not be fully eliminated, and the interpretation of our findings should factor in the heterogeneity between the studies.

In the series published to date, the reported false-negative rates were determined only for those cases in which follow-up or immediate excision/re-biopsy was performed. In addition to that, due to the retrospective study design, only those lesions which were successfully biopsied were reported in some of the studies included (21, 38, 68-71). Thus, the technical success rate was missing. We did not pool those studies' data in our technical success rate analysis so as not to inflate the technical success rate. However, the true false-negative and the technical success rates of MR-guided breast biopsy remain to be determined, and this was another limitation of our study.

Most of the articles lacked correlating data between histopathology and clinical indication. Hence, we had to perform our correlation analysis with 9 studies (out of 50 the studies included), which limited the statistical power of our analysis. Another limitation was inconsistent reporting of study-level data for variables such as age, number of cores sampled, lesion sizes, and follow-up times. We used the available mean or median values for those variables in our pooled analysis.

The lack of standardization in reporting the technical success rates and false negative rates made it hard to pool the available data. Despite this, we had determined our reference standards before we began our literature search and stuck to those standards. Three investigators independently extracted the relevant information in addition to reviewing and confirming the selected articles. We also applied Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) items to assess study quality and the likelihood of bias (15). Our estimates, therefore, represent the most comprehensive evidence summary on breast MRI-guided biopsy outcomes, despite the above-mentioned limitations inherent in this study-level meta-analysis.

MRI-guided breast biopsy is a highly accurate technique with a high technical success rate, and negligible false negative and complication rates. Our findings can be used to guide breast radiologist practice, to inform transparent discussion with patients on the consequences of having an MRI-guided breast biopsy, and to assist the development of evidence-based clinical guidelines on follow-up recommendations in benign-concordant breast lesions. The substantial degree of variation in performance metrics across the studies included in our analysis suggests that ongoing quality improvement efforts are needed.

Ethics Committee Approval: The requirement to obtain institutional review board approval was waived for this literature review, which involved only publicly available data.

Informed Consent: Informed consent was not needed in this study.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Concept: S.B., B.E.D.; Design: B.B.Ö., Y.X., S.B., M.E.S., B.E.D.; Data Collection or Processing: B.B.Ö., J.Y., Y.X., S.B., B.E.D.; Analysis or Interpretation: B.B.Ö., J.Y., Y.X., S.B., M.E.S., B.E.D.; Literature Search: B.B.Ö., J.Y., Y.X., S.B., M.E.S., B.E.D.; Writing: B.B.Ö., J.Y., Y.X., S.B., M.E.S., B.E.D.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: This study is supported by an internal grant by the University of Texas Southwestern, Simmons Cancer Center.

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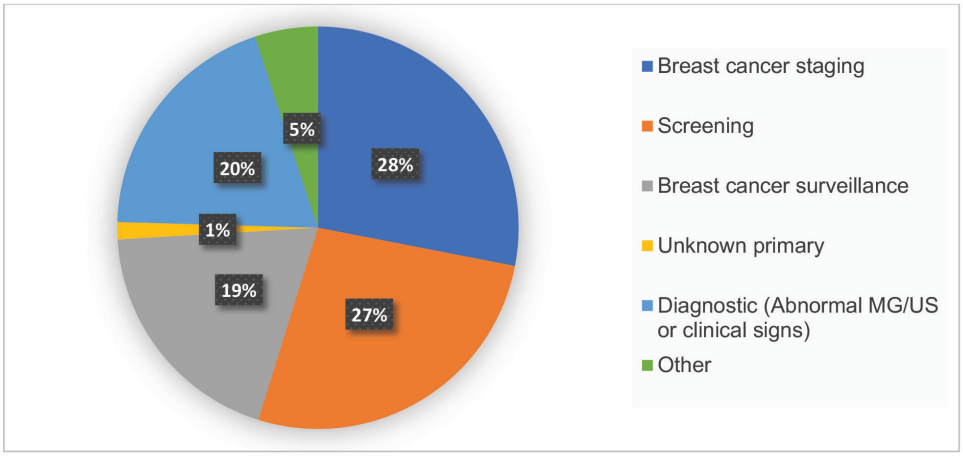
Supplementary Table 1. Databases searched and search strategies

Database(s): Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present

#	Searches	Results
1	exp BREAST/	35377
2	exp BREAST NEOPLASMS/	235614
3	(breast* or mammar* or mastectom*).ti,ab.	382212
4	or/1-3	421273
5	limit 4 to yr="2000 -Current"	255896
6	exp MAGNETIC RESONANCE IMAGING/	341859
7	MAGNETIC RESONANCE IMAGING, INTERVENTIONAL/	1005
8	(MRI or "magnetic resonance").ti,ab.	331892
9	(MR adj2 (guid* or direct* or detect*1 or detected or detecting or screen* or control*)).ti,ab.	3498
10	or/6-9	475519
11	5 and 10 [breast + MRI]	8477
12	exp BIOPSY/	236167
13	biops*.ti,ab.	312377
14	or/12-13	440694
15	11 and 14 [breast + MRI + biopsy]	1825
16	((MR or MRI or "magnetic resonance") adj5 (biops* or VAB or vacuum) adj5 (breast* or mammar* or mastectom*)).ti,ab.	222
17	15 and 16	197
18	exp MASS SCREENING/	106278
19	(screen* or surveillance).ti.	158825
20	or/18-19	214191
21	11 and 20 [breast + MRI + screening]	594
22	((MR or MRI or "magnetic resonance") adj5 screen* adj5 (breast* or mammar* or mastectom*)).ti,ab.	290
23	(21 and 22) not 17 [non-biopsy records]	203
24	PREDICTIVE VALUE OF TESTS/	155709
25	(PPV* or "predictive value*" or NPV).ti,ab.	81737
26	(false adj3 (positive* or negative*)).ti,ab.	60591
27	((diagnostic* or biops*) adj3 yield*).ti,ab.	8702
28	(diagnostic* adj3 (perform* or specificity or precision or value)).ti,ab.	48191
29	((cancer* or neoplas* or carcinom* or malignan*) adj3 (rate or rates or frequen*)).ti,ab.	44057
30	((patholog* or histopatholog* or histolog* or radiopatholog*) adj3 correlat*).ti,ab.	24752
31	exp *BREAST NEOPLASMS/pa and (exp *MAGNETIC RESONANCE IMAGING/mt or MAGNETIC RESONANCE IMAGING, INTERVENTIONAL/mt or exp IMAGE-GUIDED BIOPSY/)	683
32	or/24-31 [PPV & related terms]	370031
33	17 and 32 [most likely relevant biopsy]	112
34	17 not 33 [other biopsy]	85
35	23 and 32 [most likely relevant screening]	71
36	23 not 35 [other screening]	132
37	limit 17 to english language	180
38	17 not 37 [biopsy non-English]	17
39	limit 23 to english language	196
40	23 not 39 [screening non-English]	7

Supplementary Table 2. Review-tailored QUADAS-2 tool

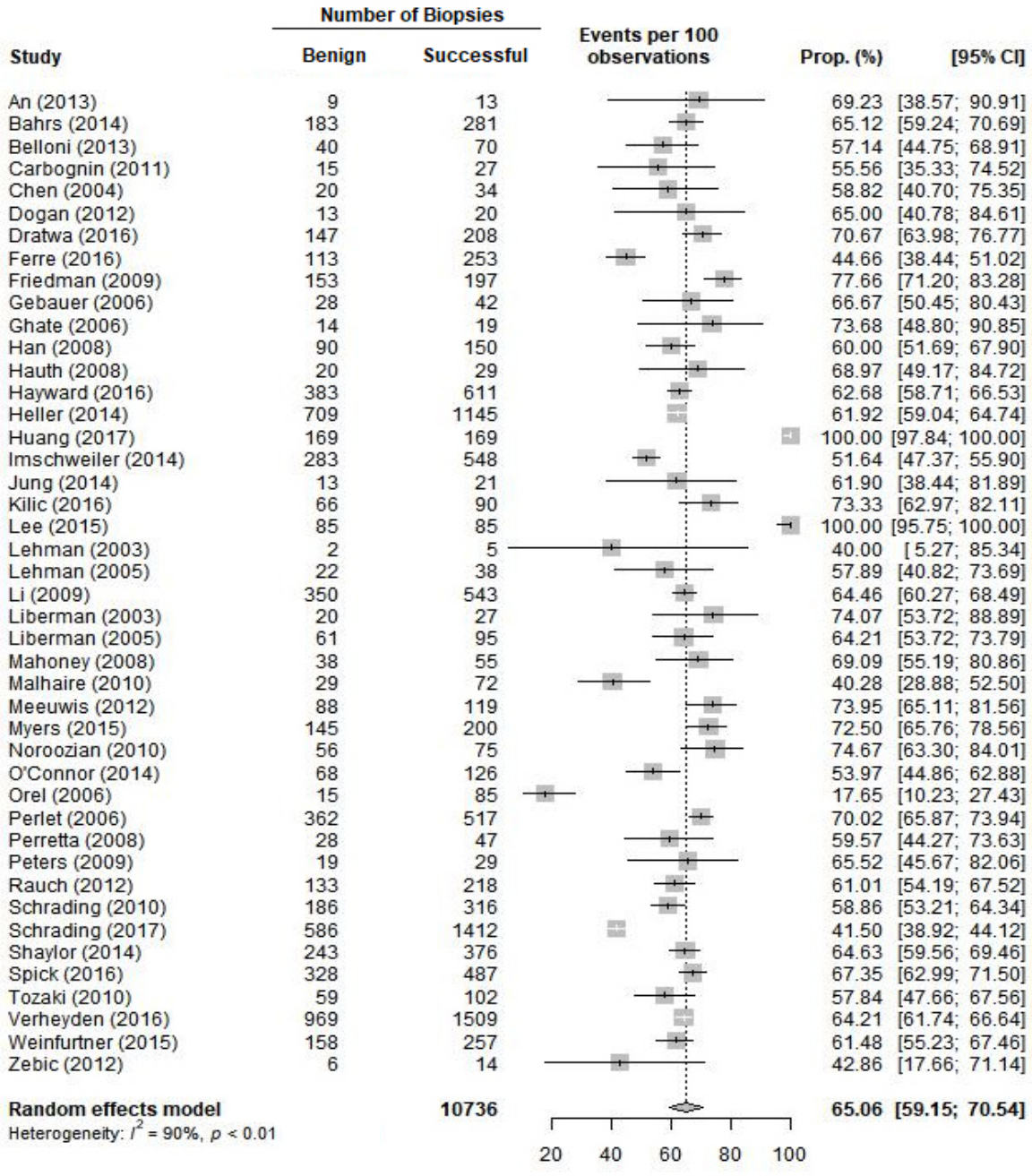
Domain	Signaling questions	Risk of bias	Concerns regarding applicability
Patient selection	Was a consecutive or random sample of patients enrolled? Was a case-control design avoided? Did the study avoid inappropriate exclusions?	Could the selection of patients have introduced bias?	Are there concerns that the included patients do not match the review question?
Index Test	Were the index test results interpreted without knowledge of the results of the reference standard? Were the technical factors of the index test (Magnet strength, needle size) pre-specified?	Could the conduct or interpretation of the index test have introduced bias?	Are there concerns that the index test, its conduct, or interpretation differ from the review question?
Reference standard	Is the reference standard likely to correctly classify the target condition?	Could the reference standard, its conduct, or its interpretation have introduced bias?	Are there concerns that the target condition as defined by the reference standard does not match the review question?
Flow and timing	Was there an appropriate interval between index test(s) and reference standard? Did all patients receive a reference standard?	Could the patient flow have introduced bias?	



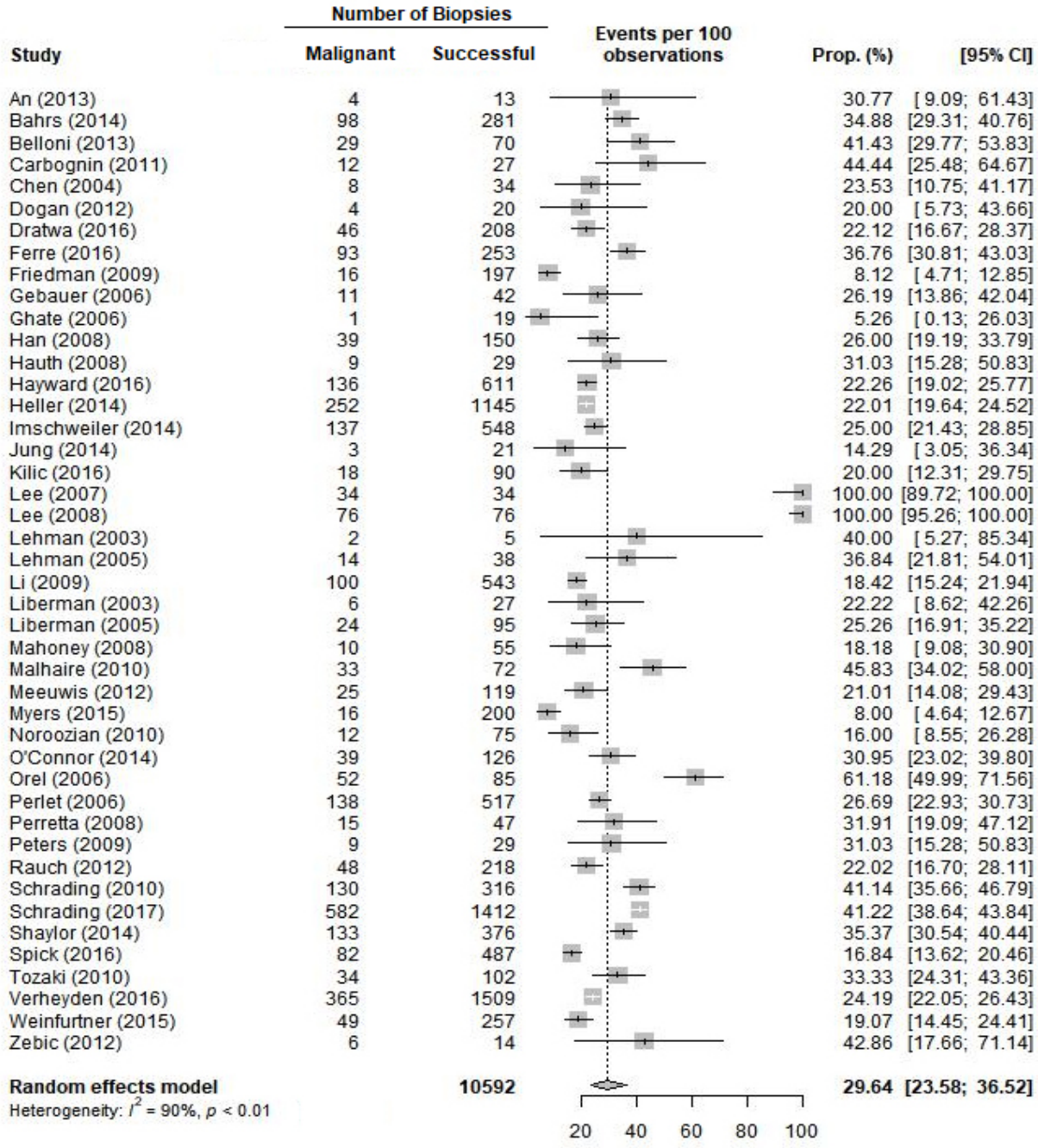
Supplementary Figure 1. Pie chart showing diagnostic indication for MRI-guided breast biopsy

MG: mammography; US: ultrasound; MRI: magnetic resonance imaging

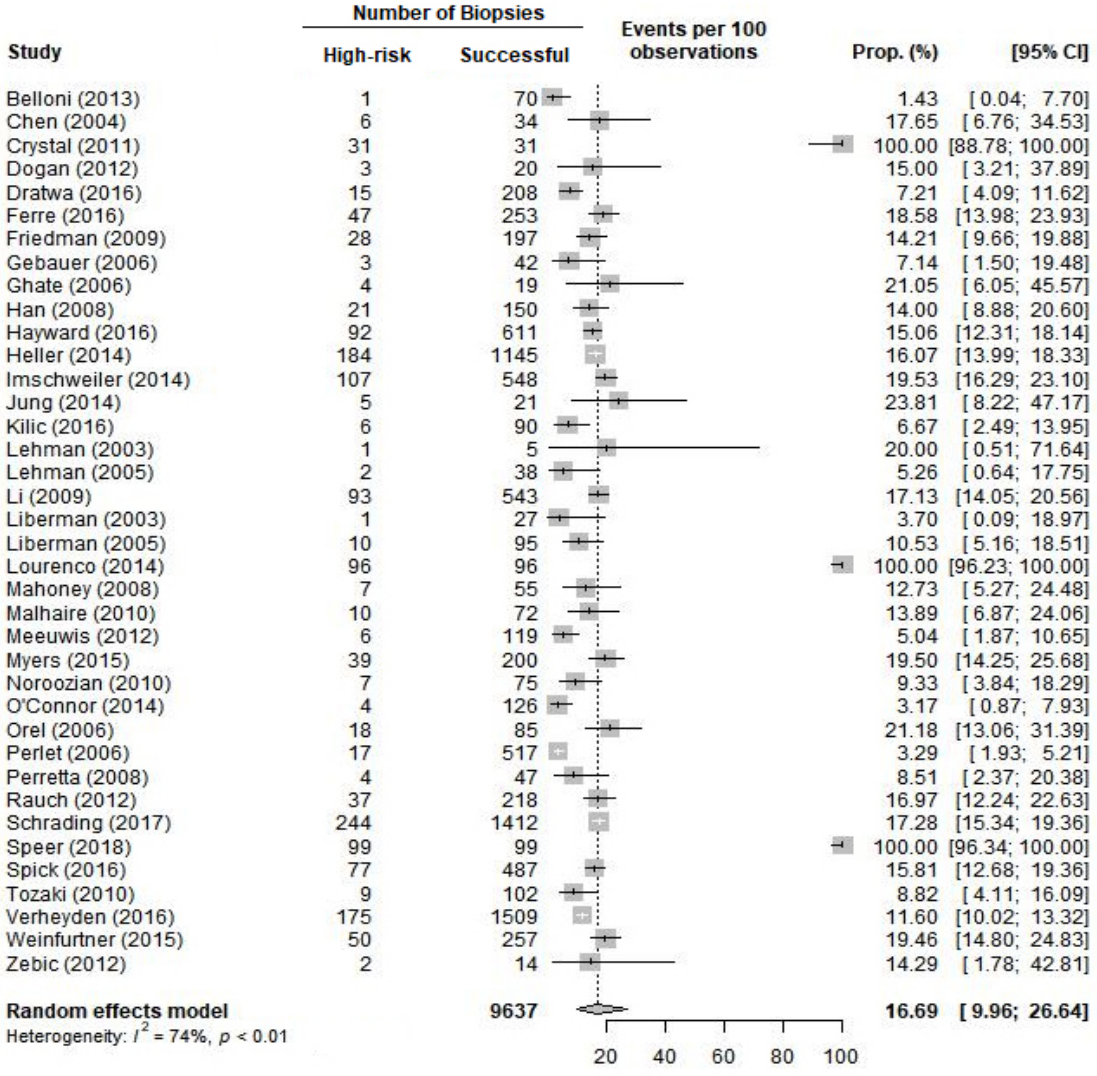
a


Number of Biopsies
Study
Benign
Successful
Events per 100 observations
Prop. (%)
[95% CI]
An (2013) 9 13 69.23 [38.57; 90.91]
Bahrs (2014) 183 281 65.12 [59.24; 70.69]
Belloni (2013) 40 70 57.14 [44.75; 68.91]
Carbognin (2011) 15 27 55.56 [35.33; 74.52]
Chen (2004) 20 34 58.82 [40.70; 75.35]
Dogan (2012) 13 20 65.00 [40.78; 84.61]
Dratwa (2016) 147 208 70.67 [63.98; 76.77]
Ferre (2016) 113 253 44.66 [38.44; 51.02]
Friedman (2009) 153 197 77.66 [71.20; 83.28]
Gebauer (2006) 28 42 66.67 [50.45; 80.43]
Ghate (2006) 14 19 73.68 [48.80; 90.85]
Han (2008) 90 150 60.00 [51.69; 67.90]
Hauth (2008) 20 29 68.97 [49.17; 84.72]
Hayward (2016) 383 611 62.68 [58.71; 66.53]
Heller (2014) 709 1145 61.92 [59.04; 64.74]
Huang (2017) 169 169 100.00 [97.84; 100.00]
Imschweiler (2014) 283 548 51.64 [47.37; 55.90]
Jung (2014) 13 21 61.90 [38.44; 81.89]
Kilic (2016) 66 90 73.33 [62.97; 82.11]
Lee (2015) 85 85 100.00 [95.75; 100.00]
Lehman (2003) 2 5 40.00 [5.27; 85.34]
Lehman (2005) 22 38 57.89 [40.82; 73.69]
Li (2009) 350 543 64.46 [60.27; 68.49]
Liberman (2003) 20 27 74.07 [53.72; 88.89]
Liberman (2005) 61 95 64.21 [53.72; 73.79]
Mahoney (2008) 38 55 69.09 [55.19; 80.86]
Malhaire (2010) 29 72 40.28 [28.88; 52.50]
Meeuwis (2012) 88 119 73.95 [65.11; 81.56]
Myers (2015) 145 200 72.50 [65.76; 78.56]
Noroozian (2010) 56 75 74.67 [63.30; 84.01]
O'Connor (2014) 68 126 53.97 [44.86; 62.88]
Orel (2006) 15 85 17.65 [10.23; 27.43]
Perlet (2006) 362 517 70.02 [65.87; 73.94]
Perretta (2008) 28 47 59.57 [44.27; 73.63]
Peters (2009) 19 29 65.52 [45.67; 82.06]
Rauch (2012) 133 218 61.01 [54.19; 67.52]
Schrading (2010) 186 316 58.86 [53.21; 64.34]
Schrading (2017) 586 1412 41.50 [38.92; 44.12]
Shaylor (2014) 243 376 64.63 [59.56; 69.46]
Spick (2016) 328 487 67.35 [62.99; 71.50]
Tozaki (2010) 59 102 57.84 [47.66; 67.56]
Verheyden (2016) 969 1509 64.21 [61.74; 66.64]
Weinfurtner (2015) 158 257 61.48 [55.23; 67.46]
Zebic (2012) 6 14 42.86 [17.66; 71.14]
Random effects model 10736 65.06 [59.15; 70.54]
Heterogeneity: I^2 = 90%, p < 0.01
20
40
60
80
100

b


Number of Biopsies
Study
Malignant
Successful
Events per 100 observations
Prop. (%)
[95% CI]
An (2013) 4 13 30.77 [9.09; 61.43]
Bahrs (2014) 98 281 34.88 [29.31; 40.76]
Belloni (2013) 29 70 41.43 [29.77; 53.83]
Carbognin (2011) 12 27 44.44 [25.48; 64.67]
Chen (2004) 8 34 23.53 [10.75; 41.17]
Dogan (2012) 4 20 20.00 [5.73; 43.66]
Dratwa (2016) 46 208 22.12 [16.67; 28.37]
Ferre (2016) 93 253 36.76 [30.81; 43.03]
Friedman (2009) 16 197 8.12 [4.71; 12.85]
Gebauer (2006) 11 42 26.19 [13.86; 42.04]
Ghate (2006) 1 19 5.26 [0.13; 26.03]
Han (2008) 39 150 26.00 [19.19; 33.79]
Hauth (2008) 9 29 31.03 [15.28; 50.83]
Hayward (2016) 136 611 22.26 [19.02; 25.77]
Heller (2014) 252 1145 22.01 [19.64; 24.52]
Imschweiler (2014) 137 548 25.00 [21.43; 28.85]
Jung (2014) 3 21 14.29 [3.05; 36.34]
Kilic (2016) 18 90 20.00 [12.31; 29.75]
Lee (2007) 34 34 100.00 [89.72; 100.00]
Lee (2008) 76 76 100.00 [95.26; 100.00]
Lehman (2003) 2 5 40.00 [5.27; 85.34]
Lehman (2005) 14 38 36.84 [21.81; 54.01]
Li (2009) 100 543 18.42 [15.24; 21.94]
Liberman (2003) 6 27 22.22 [8.62; 42.26]
Liberman (2005) 24 95 25.26 [16.91; 35.22]
Mahoney (2008) 10 55 18.18 [9.08; 30.90]
Malhaire (2010) 33 72 45.83 [34.02; 58.00]
Meeuwis (2012) 25 119 21.01 [14.08; 29.43]
Myers (2015) 16 200 8.00 [4.64; 12.67]
Noroozian (2010) 12 75 16.00 [8.55; 26.28]
O'Connor (2014) 39 126 30.95 [23.02; 39.80]
Orel (2006) 52 85 61.18 [49.99; 71.56]
Perlet (2006) 138 517 26.69 [22.93; 30.73]
Perretta (2008) 15 47 31.91 [19.09; 47.12]
Peters (2009) 9 29 31.03 [15.28; 50.83]
Rauch (2012) 48 218 22.02 [16.70; 28.11]
Schrading (2010) 130 316 41.14 [35.66; 46.79]
Schrading (2017) 582 1412 41.22 [38.64; 43.84]
Shaylor (2014) 133 376 35.37 [30.54; 40.44]
Spick (2016) 82 487 16.84 [13.62; 20.46]
Tozaki (2010) 34 102 33.33 [24.31; 43.36]
Verheyden (2016) 365 1509 24.19 [22.05; 26.43]
Weinfurtner (2015) 49 257 19.07 [14.45; 24.41]
Zebic (2012) 6 14 42.86 [17.66; 71.14]
Random effects model 10592 29.64 [23.58; 36.52]
Heterogeneity: I^2 = 90%, p < 0.01
20
40
60
80
100

c

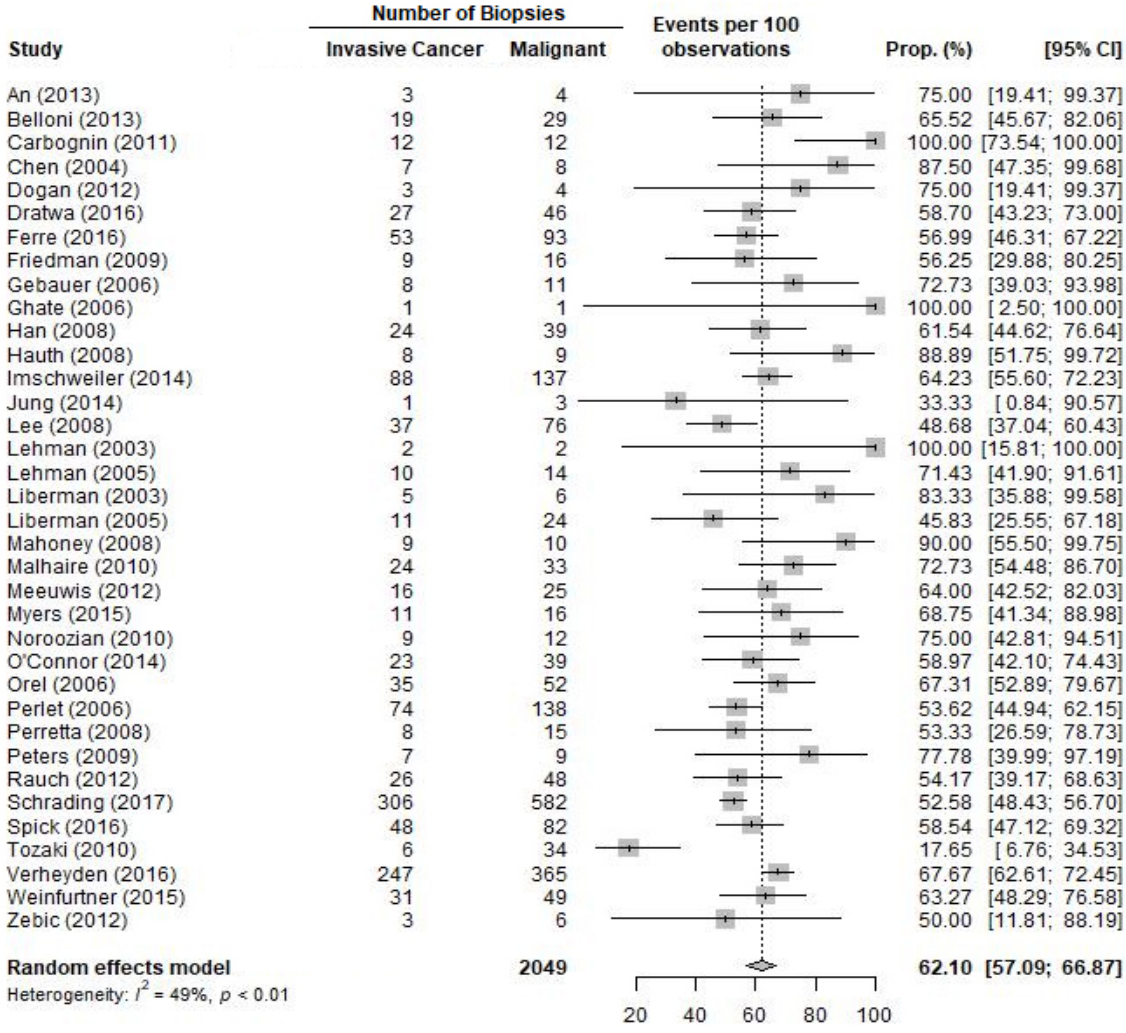


Supplementary Figure 2. Forest plot of **(a)** benign **(b)** malignant **(c)** high-risk lesion rates in successfully performed MRI-guided breast biopsies

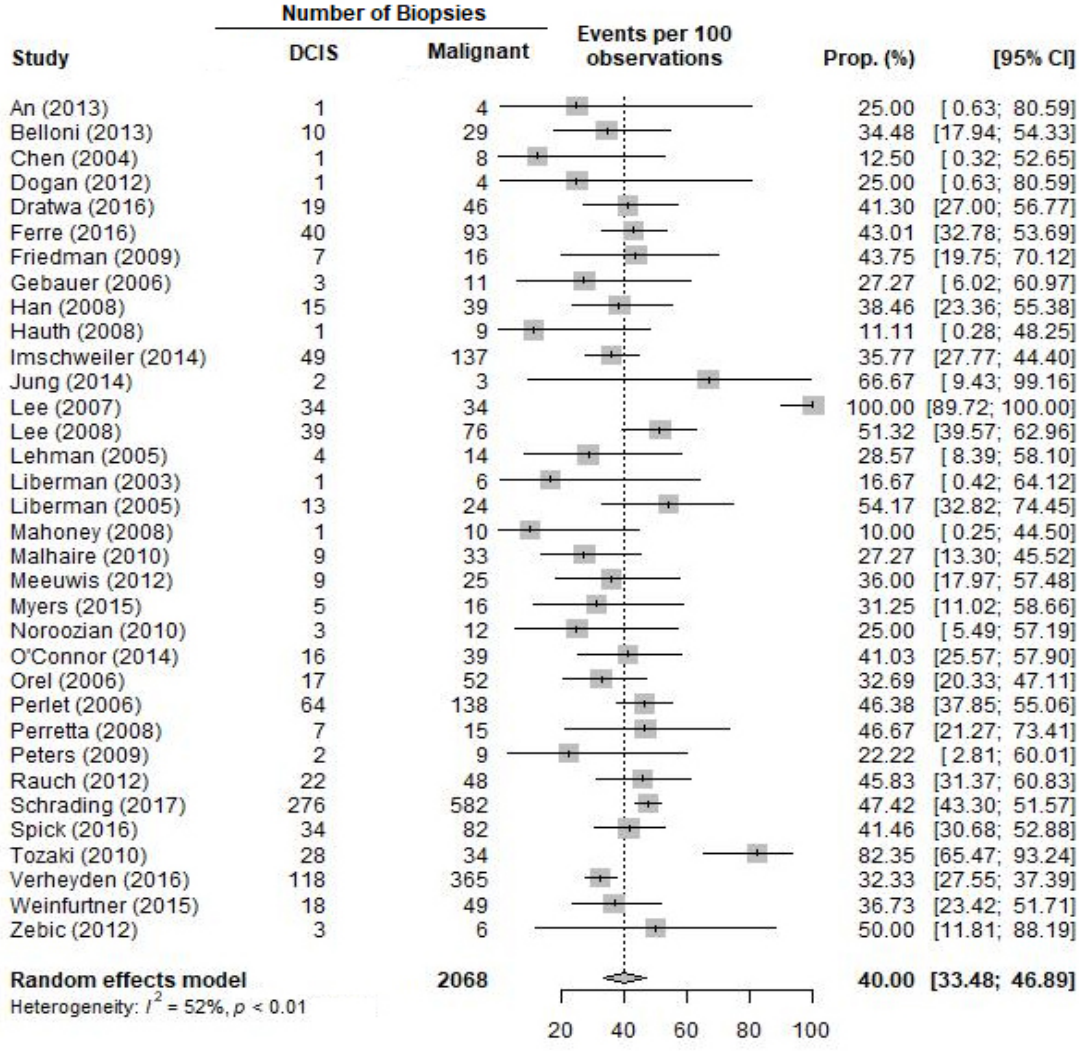
MRI: magnetic resonance imaging; Prop.: proportion; CI: confidence interval; I^2: I square (25% low heterogeneity, 25–50% medium, >50% high); p-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates there is significant heterogeneity between studies.

High-risk lesions include atypical ductal hyperplasia, lobular carcinoma in situ, papillary lesions (intraductal papilloma and papilloma with atypia), atypical lobular hyperplasia (ALH), flat epithelial atypical radial scars/complex sclerosing lesions

a


Number of Biopsies
Study
Invasive Cancer
Malignant
Events per 100 observations
Prop. (%)
[95% CI]
An (2013) 3 4 75.00 [19.41; 99.37]
Belloni (2013) 19 29 65.52 [45.67; 82.06]
Carbognin (2011) 12 12 100.00 [73.54; 100.00]
Chen (2004) 7 8 87.50 [47.35; 99.68]
Dogan (2012) 3 4 75.00 [19.41; 99.37]
Dratwa (2016) 27 46 58.70 [43.23; 73.00]
Ferre (2016) 53 93 56.99 [46.31; 67.22]
Friedman (2009) 9 16 56.25 [29.88; 80.25]
Gebauer (2006) 8 11 72.73 [39.03; 93.98]
Ghate (2006) 1 1 100.00 [2.50; 100.00]
Han (2008) 24 39 61.54 [44.62; 76.64]
Hauth (2008) 8 9 88.89 [51.75; 99.72]
Imschweiler (2014) 88 137 64.23 [55.60; 72.23]
Jung (2014) 1 3 33.33 [0.84; 90.57]
Lee (2008) 37 76 48.68 [37.04; 60.43]
Lehman (2003) 2 2 100.00 [15.81; 100.00]
Lehman (2005) 10 14 71.43 [41.90; 91.61]
Liberman (2003) 5 6 83.33 [35.88; 99.58]
Liberman (2005) 11 24 45.83 [25.55; 67.18]
Mahoney (2008) 9 10 90.00 [55.50; 99.75]
Malhaire (2010) 24 33 72.73 [54.48; 86.70]
Meeuwis (2012) 16 25 64.00 [42.52; 82.03]
Myers (2015) 11 16 68.75 [41.34; 88.98]
Noroozian (2010) 9 12 75.00 [42.81; 94.51]
O'Connor (2014) 23 39 58.97 [42.10; 74.43]
Orel (2006) 35 52 67.31 [52.89; 79.67]
Perlet (2006) 74 138 53.62 [44.94; 62.15]
Perretta (2008) 8 15 53.33 [26.59; 78.73]
Peters (2009) 7 9 77.78 [39.99; 97.19]
Rauch (2012) 26 48 54.17 [39.17; 68.63]
Schrading (2017) 306 582 52.58 [48.43; 56.70]
Spick (2016) 48 82 58.54 [47.12; 69.32]
Tozaki (2010) 6 34 17.65 [6.76; 34.53]
Verheyden (2016) 247 365 67.67 [62.61; 72.45]
Weinfurtner (2015) 31 49 63.27 [48.29; 76.58]
Zebic (2012) 3 6 50.00 [11.81; 88.19]
Random effects model 2049 62.10 [57.09; 66.87]
Heterogeneity: I^2 = 49%, p < 0.01
20
40
60
80
100

b

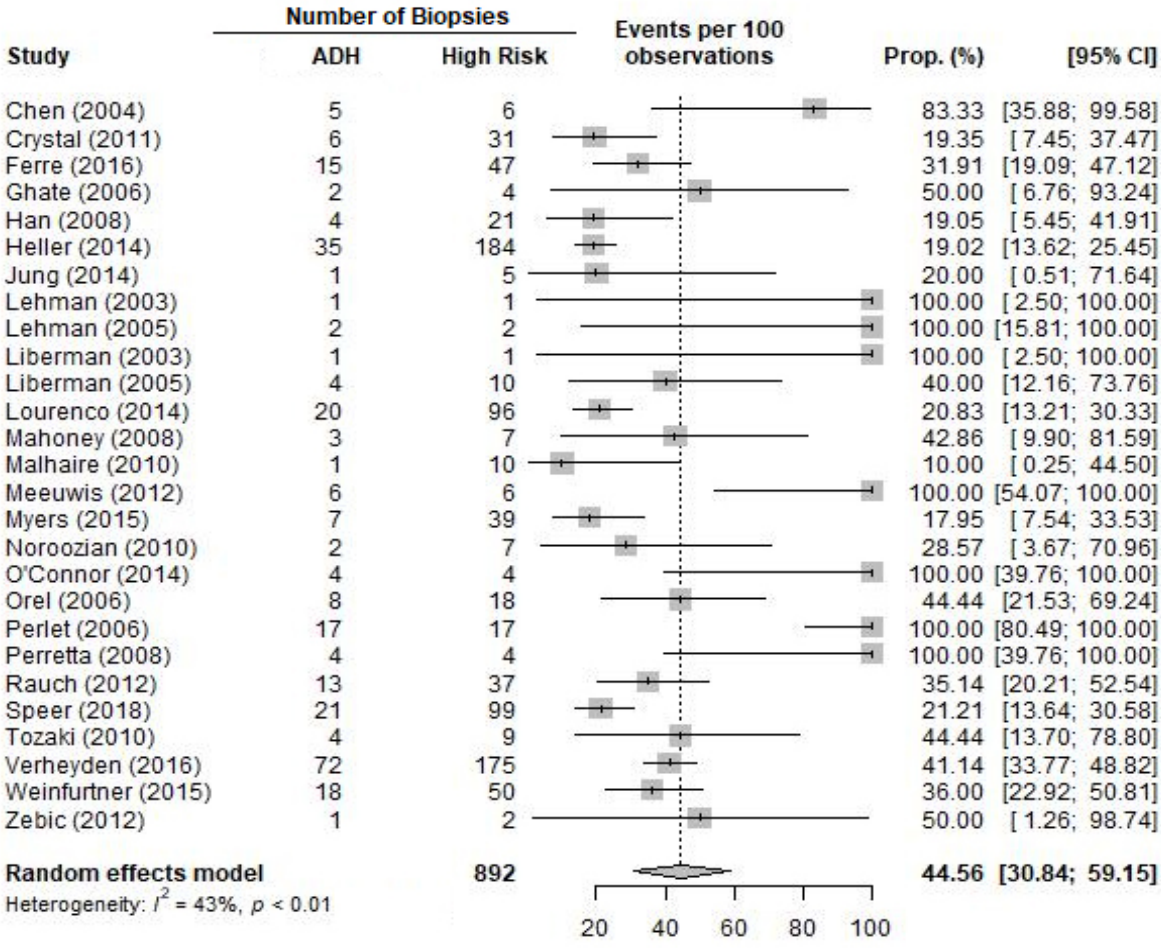


Supplementary Figure 3. Forest plot of **(a)** invasive cancer, and **(b)** ductal carcinoma *in situ* (DCIS) rates among malignant MRI-guided breast biopsies.

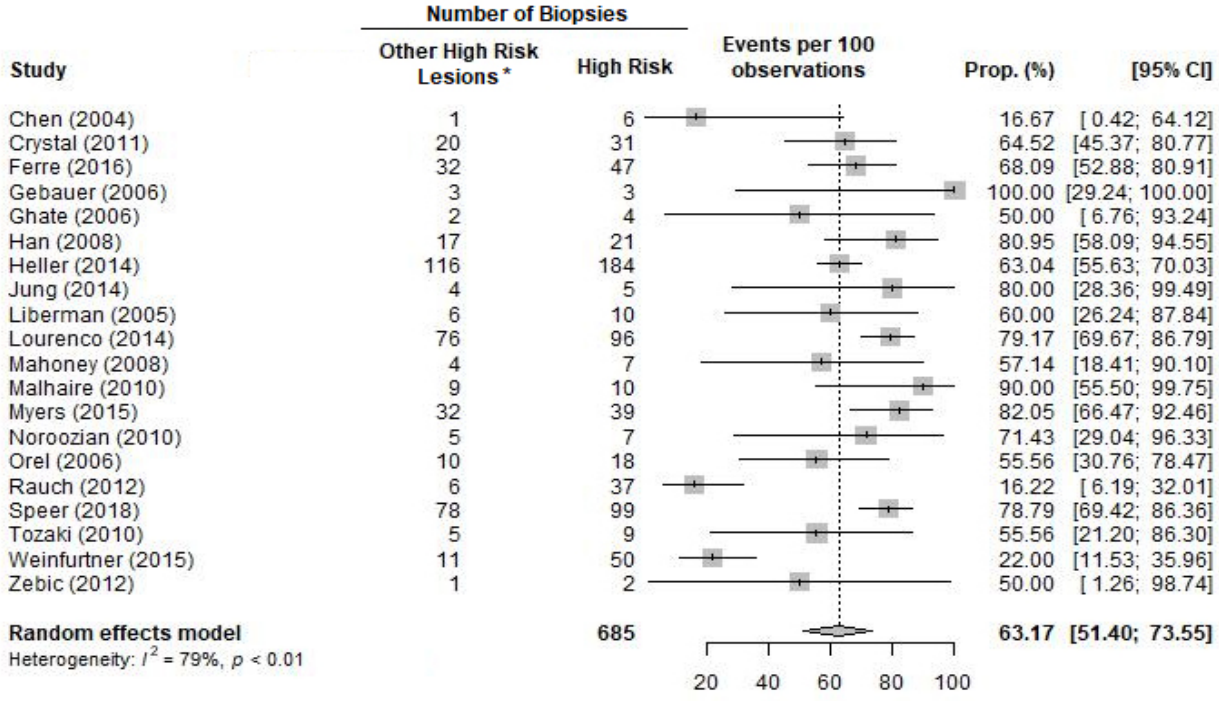
Prop.: proportion; CI: confidence interval; DCIS: ductal carcinoma in situ, I2: I square (25% low heterogeneity, 25–50% medium, >50% high).

P-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates there is significant heterogeneity between studies

a


Number of Biopsies
Study
ADH
High Risk
Events per 100 observations
Prop. (%)
[95% CI]
Chen (2004) 5 6 83.33 [35.88; 99.58]
Crystal (2011) 6 31 19.35 [7.45; 37.47]
Ferre (2016) 15 47 31.91 [19.09; 47.12]
Ghate (2006) 2 4 50.00 [6.76; 93.24]
Han (2008) 4 21 19.05 [5.45; 41.91]
Heller (2014) 35 184 19.02 [13.62; 25.45]
Jung (2014) 1 5 20.00 [0.51; 71.64]
Lehman (2003) 1 1 100.00 [2.50; 100.00]
Lehman (2005) 2 2 100.00 [15.81; 100.00]
Liberman (2003) 1 1 100.00 [2.50; 100.00]
Liberman (2005) 4 10 40.00 [12.16; 73.76]
Lourenco (2014) 20 96 20.83 [13.21; 30.33]
Mahoney (2008) 3 7 42.86 [9.90; 81.59]
Malhaire (2010) 1 10 10.00 [0.25; 44.50]
Meeuwis (2012) 6 6 100.00 [54.07; 100.00]
Myers (2015) 7 39 17.95 [7.54; 33.53]
Noroozian (2010) 2 7 28.57 [3.67; 70.96]
O'Connor (2014) 4 4 100.00 [39.76; 100.00]
Orel (2006) 8 18 44.44 [21.53; 69.24]
Perlet (2006) 17 17 100.00 [80.49; 100.00]
Perretta (2008) 4 4 100.00 [39.76; 100.00]
Rauch (2012) 13 37 35.14 [20.21; 52.54]
Speer (2018) 21 99 21.21 [13.64; 30.58]
Tozaki (2010) 4 9 44.44 [13.70; 78.80]
Verheyden (2016) 72 175 41.14 [33.77; 48.82]
Weinfurtner (2015) 18 50 36.00 [22.92; 50.81]
Zebic (2012) 1 2 50.00 [1.26; 98.74]
Random effects model 892 44.56 [30.84; 59.15]
Heterogeneity: I^2 = 43%, p < 0.01
20
40
60
80
100

b



Supplementary Figure 4. Forest plot of **(a)** atypical ductal hyperplasia, and **(b)** other high-risk lesions* rates among high-risk MRI-guided breast biopsies

Prop: proportion; CI: confidence interval; I2: I square (25% low heterogeneity, 25–50% medium, >50% high), ADH: atypical ductal hyperplasia.

P-values belong to between-study heterogeneity test (the Higgin's & Thompson's I-square statistic). A low p-value (<0.05) indicates there is significant heterogeneity between studies.

**Other high-risk lesions include lobular carcinoma in situ (LCIS), papillary lesions (intraductal papilloma and papilloma with atypia), atypical lobular hyperplasia (ALH), flat epithelial atypical (FEA) radial scars (RSL)/complex sclerosing lesions (CSL)*