Clinical Imaging 57 (2019) 50–55

Contents lists available at ScienceDirect

Clinical Imaging

journal homepage: www.elsevier.com/locate/clinimag

Breast Imaging

Do benign-concordant breast MRI biopsy results require short interval follow-up imaging? Report of longitudinal study and review of the literature

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ARTICLE INFO

Keywords:
Breast
Biopsy
MRI
Benign
Follow-up
Review

ABSTRACT

Objective: The objectives of this study were to examine the frequency and outcomes of short interval imaging follow up of benign, concordant breast MRI biopsies and review the published literature on this topic.

Materials and methods: This was an IRB-approved, HIPAA compliant retrospective review of women undergoing MRI-guided breast biopsies between October 1, 2008 and December 31, 2014. Patients with malignant or high risk lesions with recommendation for excision, discordant cases, and those undergoing breast conservation therapy in same quadrant, chemotherapy or mastectomy were excluded. At least 2 years imaging and/or clinical follow-up without development of cancer in the same quadrant as the biopsy was set as the benchmark to confirm benign etiology. A PubMed search of similar articles through 2018 was also performed for the literature review.

Results: 943 consecutive MRI-guided biopsies were performed in 785 women. Of these, 378/943 (40.1%) were benign and met inclusion criteria. Eleven cases were recommended for and underwent repeat MRI-guided biopsy or excision, 2 of which were malignant. The overall false negative rate for benign concordant MRI-guided biopsy was 2/378, 0.5% (95% CI 0.02 to 2.0%). Literature search demonstrated five articles with similar methodologies yielding 628 additional cases of benign concordant breast biopsies. Nine of these cases were eventually diagnosed as malignancy with a false negative rate of 1.4%. Combined with our data, the overall false negative rate is 1.1%.

Conclusions: Short interval follow-up exams for benign concordant MRI-guided breast biopsies may not be necessary given the low malignancy rate.

1. Introduction

MRI-guided breast biopsy is an established technique for obtaining histologic diagnosis of MRI-detected enhancing lesions that are otherwise mammographically and sonographically occult [1–3]. Determining radiologic-pathologic concordance for MRI-guided biopsies is often more challenging than biopsies performed using other modalities. While ultrasound-guided biopsies are performed in "real-time" and stereotactic biopsies usually involve obtaining intra-procedure specimen radiographs, there is limited ability to confirm the accuracy of targeting at the time of MRI-guided biopsy. Challenges in assessing accurate targeting include washout of the gadolinium-based contrast agents (GBCA) during the procedure and post-biopsy changes including air, hemorrhage, and local anesthesia that obscure the targeted lesion. The uncertainty has led to the common practice of recommending short interval follow-up MRI after benign biopsies [4–9]. In fact, Sung et al. colloquially refer to the 6 month follow-up as the MRI-guided biopsy equivalent of a "specimen radiograph." [6] Currently, there are no standardized guidelines establishing if and when follow-up imaging should be obtained.

As screening breast MRI programs expand and the volume of MRI-guided biopsies performed across the nation increases, questions regarding the necessity of short interval follow-up have been raised. Not only are these additional tests inconvenient for patients, some third party insurers are unwilling to cover the costs of the exam. Noncompliance rates for short-interval MRI follow-up exams after breast biopsy are reportedly high and have been documented to be up to 30% [10]. In addition, currently published studies analyzing the utility of short interval follow-up MRI after benign biopsies have variable conclusions and recommendations [4–9]. Therefore, our objective is examine the frequency and outcomes of short interval imaging follow-up of benign-concordant MRI-guided breast biopsies and review

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https://doi.org/10.1016/j.clinimag.2019.05.007
Received 16 April 2019; Accepted 15 May 2019

the published literature on this topic.

2. Materials and methods

2.1. Patient selection

This retrospective review of the electronic medical records of patients undergoing MRI-guided breast biopsy between October 2008 and December 2014 was Institutional Review Board approved and HIPAA compliant. Patients were included if MRI-guided breast biopsy was recommended for an ACR BI-RADS® 4 or 5 finding on a patient's screening or diagnostic MRI examination and two years of follow-up data (clinical and/or imaging) was available at the time of chart review in February 2017 [11]. Patients were excluded if they had malignant pathology, high risk pathology for which excision was recommended, discordant radiology-histopathology results, received chemotherapy within 6 months of their biopsy, had known metastatic disease at the time of biopsy, underwent breast conserving therapy for a lesion within the same quadrant (or, if an adjacent quadrant, < 2 cm from the known cancer), underwent ipsilateral mastectomy for unrelated reasons, biopsy was performed for research purposes, or lacked at least two years of follow-up after biopsy. This is summarized in Fig. 1.

2.2. MR imaging protocol

Screening and diagnostic MRI examinations were performed on a Signa 1.5-T or 3-T HDX (GE Healthcare) or a Trio 3-T (Siemens Healthcare) unit using a dedicated breast coil, with magnet choice dependent on scheduling. Standard sequences were obtained, including fat-saturated T2-weighted fast spin-echo or T2 STIR, fast spoiled gradient T1-weighted non-fat-saturated and T1-weighted fat-saturated sequences in the axial planes. In addition, dynamic gadolinium contrast enhanced fat-saturated 3D fast spoiled gradient-echo T1-weighted imaging was repeated four times in the axial plane and once in the sagittal plane. Prior to 2010, dynamic imaging was either performed in the sagittal or axial planes and then orthogonal imaging was obtained for the delayed imaging. Computer-aided diagnosis (CADstream, Sectra or VersaVue, iCAD) and subtraction images were obtained via post-processing following image acquisition.

2.3. MRI-guided breast biopsy protocol

MRI image interpretation and biopsies were performed by attending radiologists with 1–40 years of post-training experience in the field of breast imaging. The interpreting radiologist was not necessarily the same physician who performed the procedure. Biopsies were performed at a tertiary care center on either a Signa 1.5-T or 3-T HDX magnet (GE Healthcare) using a dedicated breast coil (InVivo 7-Channel Breast

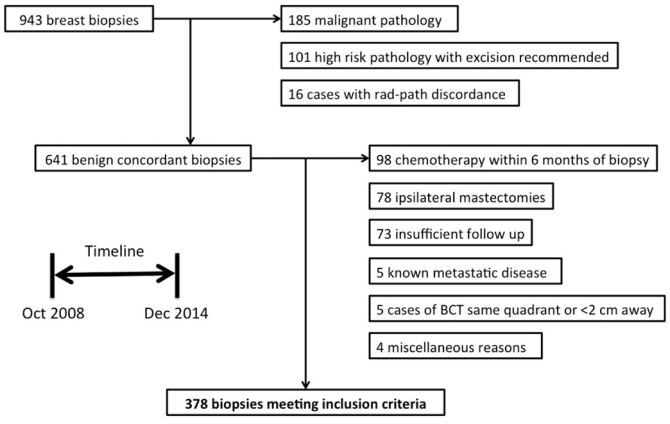

Fig. 1. Breakdown of included cases.

Table 1
Cases that were recommended for and underwent resampling based on follow up MRI. Bolded cases are the two that were subsequently upgraded to malignancy.

Case	Initial pathology	6 month f/u MRI recommended?	Months after initial biopsy resampled	Reason resampling recommended	Excise or re-biopsy?	Resampling pathology
1	Fragments of cyst wall	N	13	Radiologist discretion despite stable size	Excision	Intraductal papilloma
2	Complex sclerosing lesion, epithelial hyperplasia	N	13	Increase in size	Re-biopsy	Epithelial hyperplasia, PASH, fibroadenomatoid change
3	**Epithelial hyperplasia**	**Y**	**6**	**Radiologist discretion despite stable size**	**Re-biopsy**	**IDC (moderately diff), DCIS, PASH; node negative at surgery**
4	Benign breast tissue	Y	6	Radiologist discretion despite stable size	Re-biopsy	Sclerosing adenosis
5	Fibroadenoma	N	23	Increase in size	Re-biopsy	Benign breast tissue w/ focally dense stroma
6	Intraductal papilloma	Y	15	Increase in size	Excision	Benign breast tissue with intraductal papilloma
7	**Dense stroma and rare stromal microcalcifications**	**Y**	**7**	**Radiologist discretion despite stable size**	**Re-biopsy**	**ADH; upgraded to DCIS (without invasive component) at surgical excision**
8	Fibroadenomatous change with focal PASH	N	28	Increase in size	Excision	PASH
9	ALH	Y	7	Radiologist discretion despite stable size	Excision	LCIS/ALH
10	Fibroadenoma	N	21	Increase in size	Mastectomy[a]	Benign breast tissue
11	Benign breast tissue	Y	13	Increase in size	Excision	Benign breast tissue

[a] Included because rebiopsy was recommended, but patient elected mastectomy.

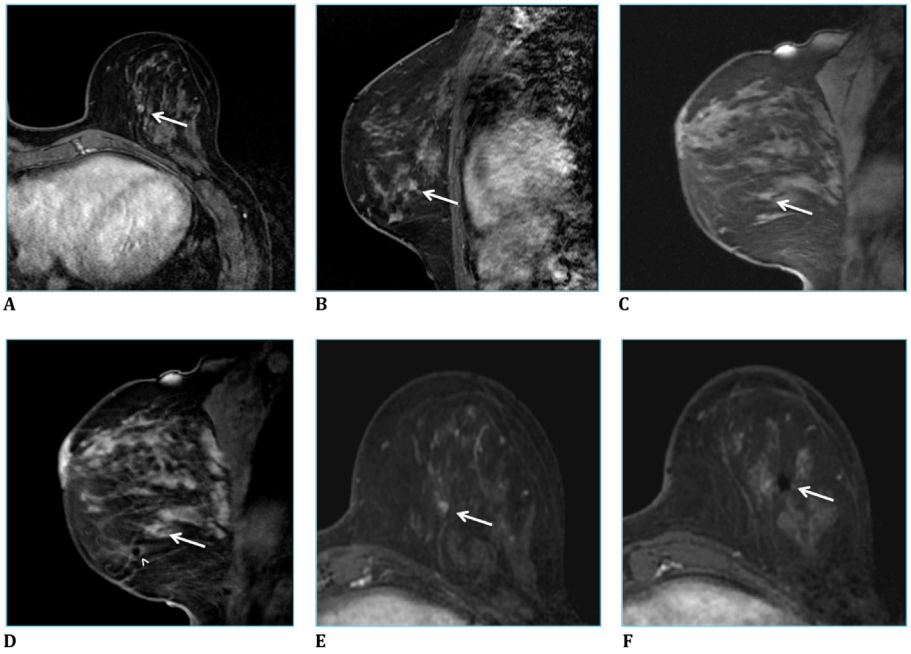

Fig. 2. 50 year-old female with history of prior contralateral breast cancer undergoing high risk screening MRI. Initial biopsy for an enhancing mass revealed epithelial hyperplasia. Re-biopsy was recommended at 6 month follow up because tissue marker was inferior and lateral to mass. Final pathology demonstrated IDC. Upon retrospective review, initial targeting was inaccurate and this case should have been considered discordant and re-sampled immediately.
A–F: Axial (A) and sagittal (B) MR images show the target mass (arrows). Sagittal intra-procedure images before (C) and after (D) obturator insertion show inaccurate targeting; target mass (arrow), obturator (arrowhead). 6 month follow up MR shows unchanged mass (E) with tissue marker (F) inferior and lateral to initial target.

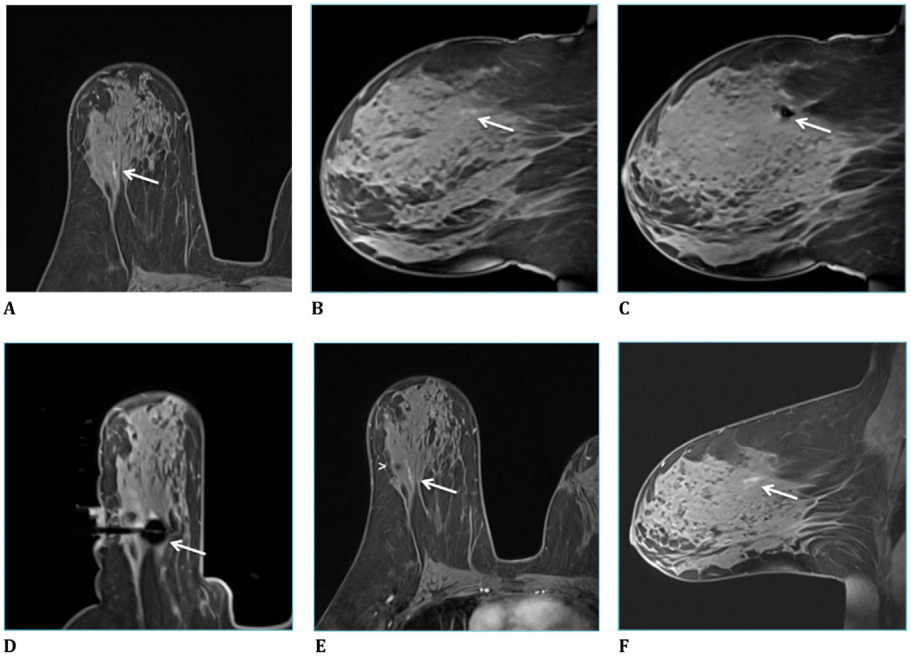

Fig. 3. 53 year-old female with BRCA-1 mutation and history of prior contralateral breast cancer undergoing high risk screening MRI. Initial biopsy for linear nonmass enhancement (NME) revealed dense stroma and rare stromal microcalcifications. Follow up MRI at 7 months showed the tissue marker was lateral to the target. Re-sampling demonstrated ADH, which was upgraded to DCIS at surgical excision.
A–F: Axial (A) and sagittal (B) MR images show the target NME (arrows). Sagittal pre-biopsy (C) and axial post-biopsy (D) intra-procedure images with obturator in place show accurate targeting. Axial (E) and sagittal (F) follow up MR images show the tissue marker (arrowhead) lateral to the target (arrowhead).

Biopsy Array, InVivo Research) with magnet choice dependent on scheduling. The patient was positioned prone and compression was applied in the latero-medial direction using a single use grid guidance plate (Breast Biopsy Device, InVivo Research). Multiple either 20 mm or 12 mm (petite) 9-gauge vacuum assisted biopsy cores were obtained using an ATEC console (Hologic).

2.4. Establishing concordance and recommendations

Radiologic-pathologic concordance was determined by the radiologist who performed the biopsy in most instances. Potentially discordant results were discussed at a routine bimonthly multidisciplinary radiology-pathology conference and consensus achieved. Discordant radiologic-pathologic cases were referred for surgical excision. The standard practice at our institution is to recommend surgical excision for any histopathologic result believed to be discordant, with the level of suspicion based on initial imaging. We also recommend excision for the following high risk lesions: atypical ductal hyperplasia, radial scars, complex sclerosing lesions, papillomas associated with atypia, lobular carcinoma in situ with pleomorphic or variant features, and possible phyllodes lesions. Recommendation for routine versus short interval follow-up was determined at the discretion of radiologist establishing concordance.

2.5. Retrospective review process

Medical records were reviewed using the electronic medical record (Epic, Epic Systems Corporation). Patient demographics, study indication, breast and lesion characteristics, biopsy technique, pathology results, recommendations following biopsy, follow-up interval and in

Table 2
Indication for exam and patient risk factors.

	Cases not resampled (%)	Cases resampled (%)	p-Value	Missed cancer
Indication for exam				
High-risk screening	184 (48.7)	9 (2.4)	0.06	2
Diagnostic	175 (46.3)	2 (0.5)	0.07	0
Not specified	8 (2.1)	0	–	0
Personal history of breast cancer				
Remote	89 (23.5)	3 (0.8)	0.73	2
Current diagnosis	51 (13.5)	0	–	0
Remote with current recurrence	4 (1.1)	0	–	0
None	223 (59.0)	8 (2.1)	0.54	0
BRCA mutation carrier				
Yes	41 (10.8)	4 (1.1)	0.03	1
No	326 (86.2)	7 (1.9)		1
Family breast cancer history				
Yes	128 (33.9)	6 (1.6)	0.21	1
No	239 (63.2)	5 (1.3)		1

Table 3
MR imaging characteristics of the lesions recommended for biopsy.

	Cases not resampled (%)	Cases resampled (%)	p-Value	Missed cancer
Background parenchymal enhancement				
Minimal	82 (21.7)	3 (0.7)	0.72	1
Mild	111 (29.3)	4 (1.1)	0.74	0
Moderate	83 (22.0)	4 (1.1)	0.29	1
Marked	22 (5.8)	0	–	0
Not specified	69 (18.3)	0	–	0
Lesion type				
Mass	154 (40.7)	6 (1.6)	0.54	1
Nonmass enhancement	171 (45.2)	4 (1.1)	0.56	1
Focus	39 (10.3)	1 (0.3)	1.00	0
Architectural distortion	1 (0.3)	0	–	0
Not specified	2 (0.5)	0	–	0
Lesion size				
5 mm or less	86 (22.8)	2 (0.5)	1.00	1 (5 mm)
6–10 mm	136 (36.0)	6 (1.6)	0.34	1 (10 mm)
11–15 mm	48 (12.7)	2 (0.5)	0.65	0
16–20 mm	29 (7.8)	0	–	0
21–25 mm	13 (3.4)	0	–	0
26 mm or greater	23 (6.1)	1 (0.3)	1.00	0
Not specified	32 (8.5)	0	–	0
BI-RADS® category assessment				
0	5 (1.3)	0	–	0
3	12 (3.2)	0	–	0
4A	103 (27.2)	4 (1.1)	0.51	2
4B	164 (43.4)	5 (1.3)	1.00	0
4C	13 (3.4)	1 (0.3)	0.34	0
4 (subcategory not specified)	25 (6.6)	1 (0.3)	0.55	0
5	0	0	–	0
6	5 (1.3)	0	–	0

certain cases, physical examination notes from primary care provider were recorded. The three authors retrospectively reviewed the imaging on PACS (Centricity, GE Healthcare) for all biopsy cases that were recommended for repeat tissue sampling. Statistical analysis was performed using GraphPad QuickCalcs software. Fisher's exact test was calculated to assess for statistical significance with alpha set at 0.05.

2.6. Literature review

A PubMed search was performed using the following keywords "Breast," "MRI," "Biopsy," "Benign," and "Follow up" through 2018. The articles were evaluated for relevancy and methodology, yielding five articles with similar design protocols to our own. Inclusion/exclusion criteria, number of cases, and false negative rates were recorded. Each false negative case was carefully reviewed to determine the timeframe after initial biopsy in which malignancy was diagnosed.

3. Results

943 MRI-guided breast biopsies were performed in 785 patients between October 1, 2008 and December 31, 2014 at our institution. Of these, 378 biopsies in 303 patients met inclusion criteria (Fig. 1). The mean age of these patients was 47.5 years with a range of 21–82 years. Short interval MRI follow-up was recommended in 188/378 cases (49.7%) and 149/188 (79.3%) were compliant with this recommendation. In all, 265/378 (70.1%) cases had a subsequent MRI at some point with a median follow-up of 9 months. The remaining 113/378 cases (29.9%) that did not undergo subsequent MRI demonstrated at least two years of mammographic and/or clinical stability.

Eleven out of the 378 benign concordant biopsies (11/378, 2.9%) were recommended for and underwent repeat tissue sampling based on subsequent MRI follow-up. Details of the 11 cases that underwent resampling because of recommendations at subsequent MR imaging are presented in Table 1. Two out of the 11 cases (2/11, 18.2%) were ultimately upgraded to malignancy.

The first false negative case was a 50 year-old female with a history of prior contralateral breast cancer undergoing high-risk screening (Fig. 2). MRI-guided biopsy was performed for a 5 mm enhancing mass demonstrating epithelial hyperplasia, considered concordant. Repeat biopsy was recommended at 6 month follow-up because the biopsy marker was inferior and lateral to the mass. Pathology revealed moderately differentiated invasive ductal carcinoma with ductal carcinoma in situ and was negative for metastatic spread to the axilla on sentinel lymph node biopsy at surgery. However, during our retrospective review of the case, it was noted that the targeting for the initial MRI-guided biopsy was inaccurate. This case was not excluded from the data because the radiologist who performed the biopsy prospectively considered this case concordant at the time.

The second case was a 53 year-old female with a BRCA-1 mutation and history of prior contralateral breast cancer undergoing high-risk screening (Fig. 3). MRI-guided biopsy was performed for linear nonmass enhancement spanning 10 mm, with pathology demonstrating dense stroma and rare stromal microcalcifications. This was thought to be concordant with the imaging findings. Seven month follow-up MRI showed stable nonmass enhancement with the biopsy marker 7 mm laterally displaced. Repeat MRI-guided biopsy revealed atypical ductal hyperplasia that was eventually upgraded to ductal carcinoma in-situ without an invasive component at surgical excision. During our retrospective review of this case, initial biopsy targeting was felt to be accurate.

The overall false negative rate for the MRI-guided biopsies in our series is 2/378 (0.5%, 95% CI 0.02 to 2.0%). If case #1 had been appropriately deemed discordant and resampled at time of initial biopsy, the false negative rate would have been 1/378 (0.3%).

Indication for exam and patient risk factors are presented in Table 2. A personal or family history of breast cancer did not correlate with whether repeat tissue sampling was recommended. On the other hand, if the patient was a BRCA mutation carrier, there was a statistically significant correlation with recommendation for resampling ($p = 0.03$). There was also a trend towards recommending resampling if the indication for exam was high-risk screening rather than for diagnostic purposes ($p = 0.06$).

The MRI characteristics of the lesions that were biopsied are

Table 4
Summary of the previous literature with similar methodologies to current study with aggregated results on the bottom line.

Author Journal Year	Years #months	Total # biopsies	Included benign concordant cases	Specified MRI f/u 1 year or less? #cases	Included MRI f/u > 1 year? #add cases > 1 year	Included mammo if no MRI f/u? #add cases with mammo only	Additional cases included	#under-going second biopsy or excision	#malignant on second biopsy	False negative rate of cases with MR f/u	Overall false negative rate	Pathology
Li AJR 2009	Not specified 54 months	543	177	177	N	N	N	17/177 (9.6%)	4/17 (23.5%)	4/177 (2.3%)	**4/177 (2.3%)**	IDC (11 mo) IDC (12 mo) DCIS (2 mo) DCIS (6 mo)
Shaylor Eur Radiol 2014	5/07–12/10 43 months	376	113	78 (allowed up until 13 mo)	Y 35	N	N	3/113 (2.6%)	1/3 (33.3%)	1/113 (0.9%)	**1/113 (0.9%)**	DCIS (24 mo)
Lee Breast J 2015	1/06–12/11 72 months	240	85	79	Y 6	N	N	1/85 (1.2%)	1/1 (100%)	1/85 (1.2%)	**1/85 (1.2%)**	IDC (24 mo)
Hayward Clin Imag 2016	4/05–12/12 92 months	611	84	59	Y 25	N	N	4/84 (4.8%)	2/4 (50%)	2/84 (2.4%)	**2/84 (2.4%)**	IDC (8 mo) DCIS (26 mo)
Huang AJR 2017	1/07–7/12 67 months	425	169	Not specified 87		Y 48	Y – cases with surgical correlation 34	Not specified	1	1/87 (1.1%)	**1/169 (0.6%)**	IDC (24 mo)
Pinkney Clin Imag 2019	10/08–12/14 74 months	943	378	203	Y 62	Y 108	Y – cases without imaging f/u, but > 2 yrs. clinical stability 5	11/378 (2.9%)	2/11 (18.2%)	2/265 (0.8%)	**2/378 (0.5%)**	IDC (6 mo) DCIS (7 mo)
Total		3138	1006	683 (assumes all Huang < 1 year)	128	156	39	36/837 (4.3%)	11/37 (29.7%) (unknown how many resampled Huang)	11/811 (1.4%)	**11/1006 (1.1%)**	6 cases IDC 5 cases DCIS

presented in Table 3. Degree of background parenchymal enhancement, lesion type (mass, nonmass enhancement, focus, or architectural distortion), or BI-RADS® category assessment did not correlate with a recommendation for repeat tissue sampling. Smaller lesions (10 mm or less, n = 8) were more often recommended for repeat tissue sampling than larger lesions (11 mm or more, n = 3), though this did not meet statistical significance (p = 0.14), possibly due to the small sample size.

4. Discussion

We report a very low (0.5%) false negative rate for benign, concordant MRI-guided breast biopsies performed at our institution. To our knowledge, our series represents the largest study to date, more than twice as large as the largest series previously reported on this subject [5]. Previous research related to follow-up of MRI-guided breast biopsies has demonstrated false negative rates ranging between 0.6 and 2.4% [4,5,7–9]. Of particular note, final recommendations from these studies for appropriate MRI follow-up have varied, adding to confusion amongst radiologists.

Since 2009, two research articles have been published recommending 6 month follow-up after all benign concordant MRI-guided breast biopsies. The first reported a false negative rate of 4/177 (2.3%) [5]. Of the four missed cancers, two were IDC and the other two were DCIS. One of the cases of IDC was stable in size at 11 months, but was biopsied due to mammographic changes. The other case of IDC had increased in size at 12 month follow up MRI. Both were node negative at surgery. For the two cases of DCIS, one had increased in size at 6 month follow-up MRI and the other was stable at 2 month follow-up MRI, but the biopsy marker was displaced from the target, so re-biopsy was recommended. The second study recommending 6 month follow-up MRI reported a false negative rate of 2/84 (2.4%) [8]. One case of IDC was diagnosed after 6 month follow-up MRI showed a stable but suspicious mass, prompting ultrasound guided biopsy. Nodal status at surgery was not reported. The other was a case of DCIS diagnosed at 26 months after demonstrating stability on 4 and 13-month follow-up MRIs.

On the other hand, three published articles argue that routine 6 month follow-up MRI exams are unnecessary [4,7,9]. The first reports a false negative rate of 1/113 (0.9%) for a single missed case of DCIS that was diagnosed at 24 months post biopsy [7]. The second study reports a false negative rate of 1/85 (1.2%) resulting from a missed IDC that was diagnosed at 24 months after remaining stable at 10 months and then increasing in size at 24 months. In this case, micrometastases were noted to be present in one sentinel lymph node at surgery [9]. Most recently, in 2017, a third group of researchers report a false negative rate of 1/169 (0.6%) for a single missed IDC that was diagnosed at 24 months after demonstrating new suspicious microcalcifications on mammography [4]. A summary of the previous literature is presented in Table 4.

In our series, we report a false negative rate of 2/378 (0.5%) after benign-concordant MRI-guided breast biopsies. Although both our cases were diagnosed prior to 12 months (at 6 and 7 months), management unlikely would have been altered if routine follow up at 12 months was performed instead, as neither lesion changed in size from the initial MRI. If our dataset is combined with the data from prior similar research, the overall false negative rate is 11/1006 (1.1%). This supports the conclusion that MRI-guided breast biopsies are highly accurate and demonstrates the low yield of obtaining short interval follow-up examinations. In fact, only six malignancies (6/1006; 0.6%) from the aggregated dataset and just three (3/1006; 0.3%) invasive cancers were diagnosed prior to 12 months.

Limitations of our research include a retrospective study design from a single institution. As a tertiary center, our findings may not be generalizable to a general practice. Finally, optimal follow-up is challenging because some patients continue care at local facilities and we are not linked to a tumor registry.

In summary, MRI-guided biopsies of the breast are becoming increasingly common and follow-up after benign, concordant biopsies is not standardized. Our large study of 378 MRI-guided biopsies demonstrates a low false negative rate (0.5%) which corroborates other similar studies. Therefore, if biopsy targeting and tissue sampling are deemed adequate at radiologic-pathologic correlation, routine six month follow-up after benign concordant MRI-guided breast biopsies is not necessary.

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