Results of MR Imaging Screening for Breast Cancer in High-Risk Patients with Lobular Carcinoma in Situ[1]

Lauren C. Friedlander, MD
Susan Orel Roth, MD
Sara C. Gavenonis, MD

Purpose: To determine the outcome of screening breast magnetic resonance (MR) imaging examinations performed in patients with lobular carcinoma in situ (LCIS) at the authors' institution.

Materials and Methods: This study was approved by the institutional review board and was compliant with HIPAA. Retrospective review of screening breast MR imaging examinations at the institution from 1996 through September 2009 was performed in patients with prior biopsies demonstrating LCIS. Patients with prior breast cancer diagnosis were excluded. American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) recommendations were recorded. Pathologic results of all consequent biopsies were obtained from the electronic medical records.

Results: A total of 445 breast MR examinations in 198 patients with LCIS were identified. Of these, 308 were screening examinations in 134 patients. One patient was a *BRCA* mutation carrier and was excluded. Of the remaining 307 screening examinations, 254 (82.7%) had BI-RADS category 1 or 2 findings; 27 (8.8%) had BI-RADS category 3 findings; and 27 (8.8%) had B-IRADS category 4 or 5 findings. Of the 27 studies that led to a biopsy recommendation, 10 (37%) yielded benign pathologic findings, five (18.5%) yielded malignant pathologic findings, and seven (25.9%) yielded high-risk lesions. Of the 27 studies with BI-RADS 3 findings, two (7.4%) resulted in biopsy, findings of both were benign. Overall, malignancy was detected in five of 307 screening studies (1.6%) and in five of 133 screened patients (3.8%). The positive predictive value (PPV) of these screening studies for which biopsy was recommended was 18.5%. The PPV 3 (studies for which biopsy was recommended and actually performed, as described in the BI-RADS guidelines) was 23.8%.

Conclusion: Screening breast MR imaging helped identify breast cancer in LCIS patients at a rate similar to that shown in high-risk populations for whom screening breast MR imaging is currently consistently recommended.

[1] From the Department of Radiology, Columbia Presbyterian, New York, NY 10032 (L.C.F.); and Department of Radiology-Breast Imaging, Hospital of the University of Pennsylvania, 3400 Spruce St, 1 Silverstein, Philadelphia, PA 19104 (S.O.R., S.C.G.). Received January 10, 2011; revision requested March 7; revision received May 20; accepted June 13; final version accepted June 27. **Address correspondence to** L.C.F. (e-mail: *lf2386@columbia.edu*).

Breast cancer is the most common solid malignancy in women in the United States, with an estimated 207 090 new cases diagnosed in 2010. It is the second most fatal malignancy in women, with an estimated 39 840 deaths in 2010 (1). The widespread adoption of mammographic screening, which began in the 1980s, has been reported to contribute to the improvements in breast cancer mortality (2). Breast magnetic resonance (MR) imaging has been reported as a useful adjunctive screening tool in specific high-risk populations, and it is well established that patients with a genetic predisposition toward breast cancer benefit from MR imaging screening (3–6). There remain, however, populations with increased risk of breast cancer in whom the benefits of MR imaging screening remain uncertain. The absence of adequate data makes breast MR imaging screening guidelines inconsistent and thus often unobserved (3–10). As the clinical applications of breast MR imaging expand, it has become increasingly important to define groups of patients who will benefit from this imaging tool as it gains momentum in the breast cancer screening arena (11).

Specifically, there are varying guidelines regarding screening MR imaging in patients with a history of lobular carcinoma in situ (LCIS). When these patients develop breast cancer, it may occur in either breast and is more commonly invasive lobular cancer (12–14). Lifetime risk estimates of breast cancer in this patient population range from 10% to 20% (12–14). Though patients with a history of LCIS have been shown to carry increased risk of subsequent breast cancer, there are varying guidelines for the use of MR imaging in a screening context in this patient population. The 2007 American Cancer Society guidelines for screening breast MR imaging advised that there is insufficient evidence to recommend for or against MR imaging screening in this patient population (8). The 2009 National Comprehensive Cancer Network guidelines, however, advised consideration to annual breast MR imaging as an adjunct to mammography and clinical examination in patients with LCIS (15). This variation may reflect the relative paucity of published data on the utility of screening breast MR imaging in patients with a history of LCIS. Other than a 2007 report from Port et al (16) indicating that MR imaging may facilitate cancer detection in patients with LCIS, to our knowledge, there is a dearth of studies specifically addressing this issue. Thus, given the current literature and varying guidelines regarding screening MR imaging in this patient population, the purpose of this study was to determine the results of screening breast MR imaging examinations performed at our institution in women with a history of LCIS.

Advance in Knowledge

- In this study, screening breast MR imaging helped identify breast cancer in 3.8% of screened patients with lobular carcinoma in situ (LCIS), a rate similar to that shown in higher risk populations for whom screening breast MR imaging is currently consistently recommended.

Implications for Patient Care

- The results of this study support current guidelines that advise consideration to annual breast MR imaging screening in patients with LCIS.
- Patients at increased risk for developing breast cancer because of a history of LCIS are likely appropriate candidates for screening breast MR imaging.

Materials and Methods

Study Selection

The institutional review board approved this retrospective study with waiver of informed consent. The study was compliant with the Health Insurance Portability and Accountability Act.

By using the department's Pathology-Radiology Enterprise Search Tool, a retrospective search was performed for breast MR imaging examinations at our institution from 1996 through September 2009 in patients with prior breast biopsies demonstrating LCIS. Studies were identified via report query from our institution's radiology information system by using the search terms "breast MRI LCIS," "breast MRI lobular carcinoma in situ," and "breast MRI lobular neoplasia." Report review ensured that only completed diagnostic breast MR imaging studies performed in patients with prior biopsy-proved LCIS were included. History was established on the basis of the study indication in the radiology report, with corroboration from the patient's electronic medical record. Further, for each study that met this criterion, reports of other breast MR imaging studies for that patient were reviewed to capture additional eligible studies. Returned search results that represented reviews of breast MR imaging studies performed at other institutions or MR imaging-guided biopsy reports were excluded. Studies that were not completed and were nondiagnostic were also excluded. Patients with a prior history of breast cancer were excluded, as were patients in whom the diagnosis of LCIS remained uncertain due to discrepancies in the radiology reports and electronic medical record. In cases where the right and left breasts were imaged on different but

Published online before print
10.1148/radiol.11103516 **Content code:** BR

Radiology 2011; 261:421–427

Abbreviations:
BI-RADS = Breast Imaging Reporting and Data System
LCIS = lobular carcinoma in situ
PPV = positive predictive value

Author contributions:
Guarantors of integrity of entire study, all authors; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, all authors; clinical studies, all authors; statistical analysis, L.C.F., S.C.G.; and manuscript editing, all authors

Potential conflicts of interest are listed at the end of this article.

consecutive days, the two examinations were counted as a single study.

Recorded data for each study included patient's date of birth; indication for the study, including whether the study was done purely for screening purposes or in the setting of a clinical or other imaging abnormality; and American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) results and recommendations in the radiology report. Biopsy results for any patient who underwent biopsy were obtained from the electronic medical record.

Breast MR Imaging Technique

During the retrospective study period of 1996–2009, breast MR imaging continued to mature as a breast imaging technology. Though specific breast MR imaging parameters at our institution varied, basic aspects and principles of imaging remained. These are reflected in the current clinical protocol, in which MR imaging is performed with the patient prone in a 1.5-T imager (Magnetom Espree; Siemens Medical Solutions, Malvern, Pa) equipped with a dedicated surface breast coil array. Current clinical breast MR imaging protocol at our institution reflects the essentially unchanged basic approach to breast MR imaging during the study period and includes bilateral fat-suppressed T2-weighted images in the sagittal plane (repetition time msec/echo time msec, 6530/86), sagittal T1-weighted non–fat-saturated images (9.76/4.76), sagittal T1-weighted fat-saturated images before contrast agent administration, and dynamic sagittal images after contrast agent injection for three time points (14.6/3.61; flip angle, 30°; bandwidth, 280 Hz per pixel; 90-second intervals). A delayed axial postcontrast series is also obtained as part of the current protocol (8.13/3.83). For contrast agent injection, a rapid bolus of gadolinium-based contrast agent (currently used is MultiHance, 0.1 mmol/kg gadobenate dimeglumine; Bracco Diagnostics, Princeton, NJ) is administered, followed by a saline flush by means of peripheral intravenous access. Subtraction images are obtained by subtracting the precontrast images from the postcontrast images by using an automated process. Dynamic signal-intensity curves are assessed qualitatively or are created via regions of interest selected by the interpreting radiologist.

Breast MR Imaging Interpretation

All breast MR imaging examinations were interpreted by radiologists with expertise in breast imaging or breast MR imaging and with 1–15 years of experience (more senior levels of experience increased as the study time period progressed). Images were reviewed on the picture archiving and communication system (Centricity; GE Healthcare, Dynamic Imaging Solutions, Allendale, NJ) in conjunction with the provided clinical history. Assessment was reported by using the American College of Radiology BI-RADS (17) categories 1–5. As per BI-RADS, studies with "probably benign" enhancement (BI-RADS 3) led to a recommendation for short-term follow-up, and studies with "suspicious" or "highly suspicious" enhancement (BI-RADS 4 or 5) led to a recommendation for biopsy.

Statistics

The positive predictive value (PPV) for screening breast MR imaging was calculated by using the PPV1, PPV2, and PPV3 equations described in the BI-RADS guidelines (17). The PPV1 reflects the percentage of all screening studies yielding a diagnosis of cancer based on an abnormal screening study and is calculated as the number of true-positive findings divided by the number of abnormal screening examinations. The PPV2 reflects the percentage of all screening studies yielding a diagnosis of cancer based on recommendation for biopsy and is calculated as the number of true-positive findings divided by the number of cases recommended for biopsy. In our study, the PPV1 and PPV2 are equal, as an abnormal study was defined by the recommendation for biopsy. The PPV3, or biopsy yield of malignancy, reflects the percentage of screening studies that result in a diagnosis of cancer based on the number of biopsies performed. This is calculated as the number of true-positive findings divided by the number of biopsies performed.

Results

Our search method returned 730 completed diagnostic breast MR imaging examinations in 319 patients during the queried time period. A total of 248 studies in 121 patients with known breast cancer were excluded, leaving 482 studies in 198 patients without initially known cancer. A total of 19 of these studies were performed prior to establishing the diagnosis of LCIS and were, therefore, excluded. Eighteen of the 463 studies were also excluded as they were performed after the diagnosis of malignancy was made in a previously screened patient. Thus, we identified 445 breast MR imaging examinations completed in 198 patients with a history of LCIS. Within this group, 308 studies were performed in 134 patients purely for screening purposes. One of these 134 patients who underwent one screening examination was also a *BRCA* mutation carrier and was therefore excluded, for a final study population of 133 patients who underwent 307 screening examinations. The remaining 137 studies were excluded from the study population as follows: Fifty-eight studies were performed in 58 patients as a first MR imaging examination in the weeks following the initial biopsy diagnosis of LCIS, often following core biopsy but prior to surgical excision. These studies were generally done to further establish the diagnosis of LCIS alone and to find incidences of undersampling in which the LCIS was associated with carcinoma. Eighteen studies were performed in 16 patients who reported a clinical symptom or abnormality. Sixteen studies were performed in 16 patients in whom an abnormality was depicted with another breast imaging modality. Four studies were performed in four patients in whom both a clinical abnormality and an abnormal finding were depicted with another breast imaging modality. Forty-one studies were performed in 37 patients as a recommended short-term follow-up examinations following prior

breast MR imaging studies. Because many patients had undergone breast MR imaging examinations for more than one indication during the study period, the sum of the patients in each subcategory does not equal the total 319 patients originally identified (Fig 1).

In summary, 307 studies in 133 patients fulfilled our inclusion criteria. The mean patient age was 53 years (range, 39–70 years). These studies were all performed as screening examinations in patients with prior biopsy-proved LCIS and no prior history of breast cancer or documented clinical or other imaging abnormality. On the basis of review of the patient's reports and the electronic medical record, no *BRCA* mutation carriers were included in the study population and no patients with documented elevated lifetime risk for breast cancer based on family history were included. During the study period, the frequency of MR imaging screening varied: 65 patients underwent one screening study; 25 patients, two studies; 14 patients, three studies; 12 patients, four studies; nine patients, five studies; three patients, six studies; three patients, seven studies; one patient, eight studies; and one patient, 10 studies.

Among these 307 studies performed purely for screening purposes, findings of 89 (29.0%) were read as normal (BI-RADS 1) and findings of 165 (53.7%) were read as benign (BI-RADS 2). Thus, these 254 (82.7%) studies led to a recommendation of routine follow-up. Findings of 27 (8.8%) studies in 26 (19.5%) patients were read as being probably benign (BI-RADS 3), requiring short-term follow-up. Findings of 26 (8.5%) studies were read as suspicious (BI-RADS 4) and one (0.3%) was read as highly suspicious for malignancy (BI-RADS 5). Thus, 27 studies (8.8%) in 25 patients (18.8%) led to a biopsy recommendation. One study had both probably benign and suspicious findings (BI-RADS 3 and 4), which led to recommendations for short-term follow-up, as well as biopsy (Table 1).

Of the 27 biopsies recommended, 10 (37.0%) yielded benign disease. Benign pathologic findings were fibroadenoma, fat necrosis, benign breast tissue with adenosis, papilloma, and fibrocystic change (Fig 2). Five biopsies (18.5%) yielded malignant disease. There were two invasive ductal carcinomas, one invasive lobular carcinoma (Fig 3), one ductal carcinoma in situ (DCIS) versus atypia, and one carcinoma in situ with ductal and lobular features (Table 2). Four of the five cancers were detected at the first screening breast MR imaging performed at our institution. One malignancy was detected at the third breast MR imaging, including one short-term follow-up examination. None of the patients with MR imaging-detected malignancies had preceding abnormal mammographic findings documented in the MR imaging report. Seven biopsies (25.9%) yielded high-risk lesions. These included additional LCIS, atypical lobular hyperplasia, atypical ductal hyperplasia, and complex sclerosing lesion or radial scar. There were no malignancies reported at subsequent surgical excision in these high-risk results cases. Biopsy was not performed in four cases (14.8%) in which the suspicious lesions could not be identified at the time of the planned biopsy and in one case (3.7%) for reasons that, upon review of the medical record, were uncertain (Table 3).

Of the 27 studies with findings for which short-term follow-up was recommended, two (7.4%) ultimately resulted in biopsy, both yielding benign pathologic findings (glandular tissue with fibrosis and benign fibrocystic change). Findings of 18 studies (66.7%) were reported as normal or benign at follow-up. For two studies, continued short-term follow-up was required beyond the conclusion of the study period. For five studies (18.5%), there was no recommended follow-up performed for reasons that were unclear based on the review of the medical record. During the study period, no study for which short-term follow-up was recommended led to a diagnosis of malignancy (Table 4).

Overall, malignancy was detected in five of 307 screening studies (1.6%) and in five of 133 screened patients (3.8%). The PPV incorporating all abnormal screening studies for which biopsy was recommended (PPV1 and PPV2) was 18.5%. The biopsy yield of malignancy (PPV3) was 23.8%.

Discussion

Breast MR imaging has been reported to have a high sensitivity but a variable specificity for the detection of breast malignancy (18–22). It is crucial, therefore, to define an appropriate high-risk population for MR imaging screening to maximize the positive and negative predictive values of the screening. While there is sufficient data supporting MR imaging screening of patients with *BRCA* mutations, untested family members of *BRCA* carriers, and those with lifetime breast cancer risk of 20%–25% or greater (3–6,9,10), there are moderately high-risk patients, including those with LCIS, for whom the benefits of MR imaging screening have not been clearly shown. As the clinical application of breast MR imaging continues to expand, it will be important to determine whether MR imaging screening benefits this population of patients with a history of LCIS.

The National Comprehensive Cancer Network has published the most recent guidelines for breast MR imaging screening (15). In this 2009 publication, the panel includes in their recommendations consideration to annual breast MR imaging in patients with LCIS. These guidelines differ slightly from those published by the American Cancer Society in 2007. The American Cancer Society reported that there is insufficient evidence to recommend for or against MR imaging screening in several other high-risk groups, including patients with LCIS (8).

To our knowledge, no new data on MR imaging screening and LCIS were reported between the two sets of guidelines. Rather, likely because of insufficient data, consensus opinion differed between the two groups. To our knowledge, only one prior study has been published addressing this question specifically, with results suggesting that MR imaging screening facilitates detection of cancer in patients with LCIS. In that study, Port et al (16) retrospectively reviewed data from a population of high-risk patients with atypical hyperplasia

Radiology

Figure 1

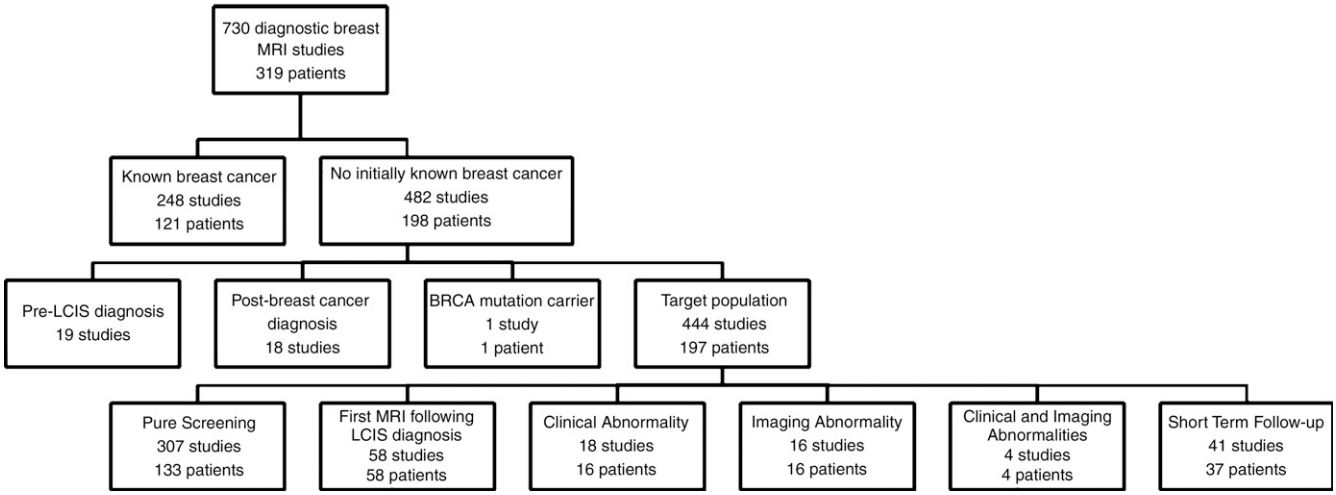

Figure 1: Flow chart of the inclusion criteria. From a total of 730 studies in 319 patients identified through the search method, 307 studies in 133 patients fulfilled the inclusion criteria. Because many patients underwent breast MR imaging for more than one indication during the study period, the sum of the patients in each subcategory does not equal the total 319 patients originally identified.

Table 1

Results of 307 Screening Breast MR Examinations in Patients with History of LCIS

Variable	Datum
Total no. of studies completed	307
Total no. of patients	133
BI-RADS 1 studies	89 (29.0)
BI-RADS 2 studies	165 (53.7)
BI-RADS 1 or 2 studies	254 (82.7)
BI-RADS 3 studies	27* (8.8)
BI-RADS 4 studies	26* (8.5)
BI-RADS 5 studies	1 (0.3)
BI-RADS 4 or 5 studies	27 (8.8)

Note.—Data in parentheses are percentages.

*One study had two findings, one for which short-term follow-up was recommended and one for which biopsy was recommended.

Figure 2

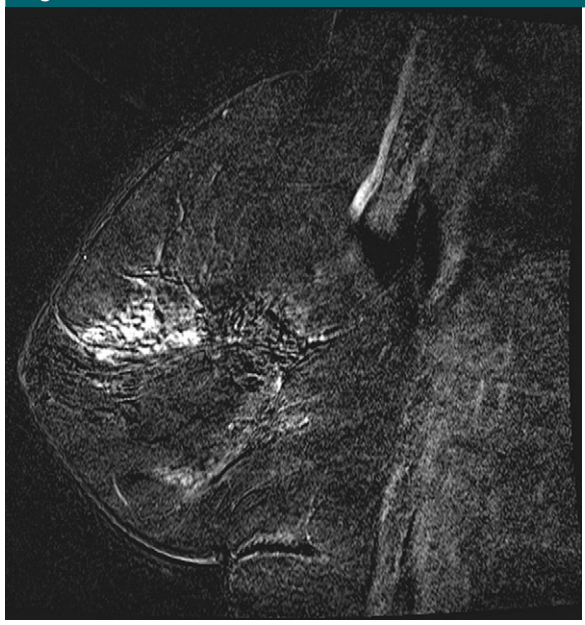

Figure 2: Screening MR imaging in a 60-year-old woman with a history of LCIS. Dynamic subtraction image obtained approximately 180 seconds after contrast medium injection shows non-masslike heterogeneous enhancement in the upper central right breast. MR imaging-guided core biopsy demonstrated proliferative fibrocystic changes and pseudoangiomatous stromal hyperplasia. Subsequent surgical excision demonstrated LCIS and proliferative fibrocystic changes.

and LCIS. Approximately half of the patients were screened with breast MR imaging. In the patients screened with MR imaging, 55 biopsies were recommended in 46 of 182 patients (25%) with either LCIS or atypical hyperplasia. Forty-six of 55 (84%) biopsies were based on MR imaging findings alone. Of those 46 biopsies, six yielded a diagnosis of malignancy in five patients. All of the cancers were found in patients with LCIS and not in patients with atypical hyperplasia. Thus, five of 135 patients (4%) with LCIS who were screened with breast MR imaging had MR imaging-detected cancers. The authors conclude that MR imaging provided no added value in their patients with atypical hyperplasia and a small benefit for their patients with LCIS.

Our data support the findings made by Port et al for patients with LCIS, with screening MR imaging depicting malignancy in five of 134 (3.8%) patients with LCIS. While the number of patients is small, the results are also quite similar to those shown in higher risk populations for whom breast MR imaging screening is currently consistently recommended. In 2006, Lehman (23) reported a meta-analysis of eight clinical trials evaluating screening breast

Figure 3

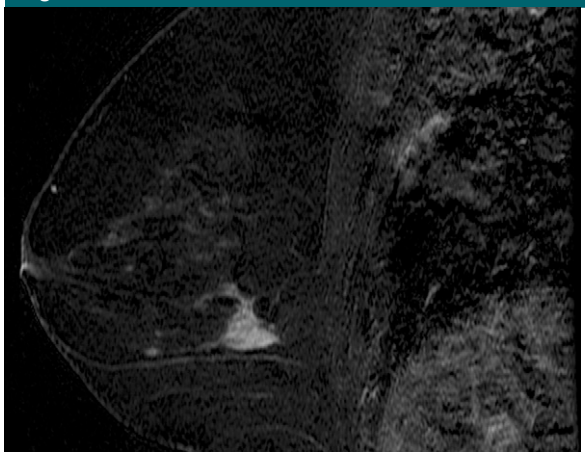

Figure 3: Screening MR imaging in a 60-year-old woman with a history of LCIS. Dynamic subtraction image obtained approximately 180 seconds after contrast medium injection shows irregular, heterogeneously enhancing mass in the lower central right breast. MR imaging-guided biopsy demonstrated invasive lobular carcinoma.

Table 3

Results of 27 Recommended Biopsies Following Screening Breast MR Examinations Reported as BI-RADS 4 or 5 in Patients with History of LCIS

Result	Datum
Benign disease	10 (37.0)
Malignant disease	5 (18.5)
High-risk lesions	7 (25.9)
Aborted biopsies due to lesion resolution	4 (14.8)
No biopsy due to other imaging and clinical findings	1 (3.7)

Note.—Data in parentheses are percentages.

Table 2

Pathologic Findings for MR-depicted Malignancies at Core Biopsy and Subsequent Excision

Case No.	Tumor Histology at Core Biopsy	Tumor Histology at Final Excision	Size (cm)	Grade	Receptor Status
1	Infiltrating ductal carcinoma and DCIS	Invasive tubular carcinoma	0.3	3	ER positive (70%) PR positive (30%) HER2/*neu* negative
2	Infiltrating ductal carcinoma	Invasive ductal carcinoma and DCIS	1.0	9	ER negative PR negative HER2/*neu* negative
3	Invasive lobular carcinoma	Invasive lobular carcinoma	3.2	2	ER positive (100%) PR positive (100%) HER2/*neu* negative
4	Atypia versus DCIS*	Not available	Not available	Not available	Not available
5	In situ mammary carcinoma with ductal and lobular features	Invasive carcinoma with mixed ductal and lobular features; extensive in situ mammary carcinoma with mixed lobular and ductal features	0.6	Not available	ER positive (90%) PR negative (90%) HER2/*neu* negative

Note.—DCIS = ductal carcinoma in situ. ER = estrogen receptor, HER2 = human epidermal growth factor receptor 2, PR = progesterone receptor.

*Original pathology report not available. Per electronic medical record, pathologic examination yielded atypia versus DCIS and was managed as DCIS.

Table 4

Follow-up Results for 27 Screening Studies with Findings for Which Short-term Follow-up MR Imaging Was Recommended

Result	Datum
Normal or benign findings (BI-RADS 1 or 2) at follow-up	18 (66.7)
Additional short-term follow-up recommended at follow-up (BI-RADS 3)	2 (7.4)
Biopsy recommended at follow-up (BI-RADS 4)	2 (7.4)
No follow-up performed	5 (18.5)

Note.—Data in parentheses are percentages. Biopsy results for the two cases in which biopsies were ultimately recommended were benign.

MR imaging in high-risk patients, most with a greater than 25% lifetime risk of breast cancer. A total of 144 breast cancers were found in 4271 patients, a 3% cancer yield. This similarity supports the idea that screening MR imaging may be a valuable adjunct to mammography and clinical examination in this population of patients with LCIS.

Our study is limited by its retrospective nature and by its relatively small number of patients. A theoretical limitation related to the retrospective design is that not all patients with LCIS as their main risk factor may have undergone breast MR imaging in the study time period, and that the clinical decision making that led to the actual performance of the MR imaging studies included in this retrospective review is not fully documented for a retrospective study. It is important to note, however, that the manner in which MR imaging was being applied in a screening context to the patient population with LCIS resulted in a cancer yield similar to that that has been previously published from another institution and similar to that of MR imaging screening in high-risk populations such as *BRCA* mutation carriers.

In addition, we relied on the clinical indications documented in the radiology reports to identify those studies that were performed purely for screening purposes in patients with LCIS. It

is theoretically possible that some of these provided clinical histories were incomplete and that some of the included studies were performed in patients with other risk factors for breast cancer. Though the latter factor is a theoretical possibility, it is thought less likely given that the electronic medical record and multiple reports were reviewed, and no other detailed history that would confer substantial additional risk was found in the documented clinical record.

Nevertheless, despite these limitations, our data suggest that further research on this topic is warranted and that patients at increased risk for developing breast cancer because of a history of LCIS are likely appropriate candidates for screening breast MR imaging.

Disclosures of Potential Conflicts of Interest: LC.F. No potential conflicts of interest to disclose. **S.O.R.** No potential conflicts of interest to disclose. **S.C.G.** Financial activities related to the present article: none to disclose. Financial activities not related to the present article: research support for digital breast tomosynthesis from Hologic, author was a reader in a digital breast tomosynthesis research study from ACRIN and co-investigator in digital breast tomosynthesis research studies-Department of Defense. Other relationships: none to disclose.

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