Original Investigation

MRI Findings After Cryoablation of Primary Breast Cancer Without Surgical Resection

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Abbreviations

DCIS
ductal carcinoma *in situ*
HER2
human epidermal growth factor 2
ICC
intraclass correlation coefficient
MRI
magnetic resonance imaging

Rationale and Objectives: To retrospectively evaluate findings on serial magnetic resonance imaging (MRI) after cryoablation for breast cancer lesions without subsequent surgical resection.

Materials and Methods: This study was approved by the Institutional Review Board and the requirement to obtain informed consent waived. Ductal carcinoma *in situ* or invasive carcinoma $\leq$15 mm, nuclear grade 1 or 2, estrogen receptor positive/human epidermal growth factor 2 negative without lymph node metastasis were treated with cryoablation without subsequent excision. Two observers independently reviewed the first two postcryoablation MRIs for shape (none, focus-to-mass, or nonmass enhancement) and suspicion of residual disease (positive or negative). Fisher's exact or the Mann−Whitney *U* test was used to assess significance. Interobserver agreement on findings was evaluated by calculating κ values.

Results: Fifty-four patients were enrolled. The first and second postcryoablation MRIs were performed 22−171 days and 82−487 days after cryoablation, respectively. Interobserver agreement ranged from fair to moderate (κ = 0.356−0.434). Observer 1 or 2 identified suspicious areas on the first postcryoablation MRI in seven cases (13.0%). These were significantly associated with focus-to-mass shape (vs non−focus-to-mass: nonmass enhancement or none) and residual disease or recurrence suspected by both observers ($p < 0.001$). There were no cases of both observers identifying suspicious findings on the second postcryoablation MRI.

Conclusion: Suspicious findings can be detected within the treated area at the first postcryoablation MRI. These can resolve during subsequent adjuvant therapies and follow-up.

Key Words: Croablation; breast cancer; magnetic resonance imaging.

INTRODUCTION

Cryoablation is a minimally invasive means of administering thermal treatment for cancer. Though tumor cells may remain in the treated region unless it is removed surgically, several mechanisms, including direct cell injury, vascular injury and ischemia, apoptosis, and immunomodulation evoked by cryoablative damage, are thought to contribute to tumor death (1). It is reportedly feasible to treat low-risk or early-stage malignant tumors of various organs, including the kidney, prostate, liver, and lung, with cryoablation (2−5). Thus, cryoablation is a plausible possible alternative to surgical resection of early stage malignancies.

In some studies, exploring the feasibility of cryoablation for breast cancer, the treated area has been resected following cryoablation (6−10), whereas in others cryoablation has been used only on patients who were unsuitable for, or who had refused to undergo, surgical treatment (11−13). Thus far, there have been few published studies evaluating cryoablation as an alternative to surgery in individuals with operable primary breast cancer and methods of post-therapeutic surveillance remain controversial.

Contrast-enhanced magnetic resonance imaging (MRI) reveals tumor vascularity and is used both in breast cancer detection and diagnosis and to assess response to neoadjuvant systemic therapy and predict prognosis after treatment. After cryoablation, breast cancer cells with impaired viability remain in the treated area. Here, we hypothesized that contrast-enhanced breast MRI could be useful for evaluating responses to cryoablation for breast cancer.

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The aim of this study was to retrospectively evaluate the findings on MRI after cryoablation for breast cancer.

MATERIALS AND METHODS

Study Cohort

This retrospective study was approved by the Institutional Review Board of our institution and the requirement to obtain informed consent was waived. Data extracted from our institution's database were reviewed.

Between October 2006 and October 2014, cryotherapy without subsequent resection and with adjunctive radiotherapy had been administered as primary local treatments to 87 patients who had been selected according to varying inclusion criteria during the initial (from October 2006 to December 2013, $n = 56$) and second phases (from January to October 2014, $n = 31$). The inclusion criteria during the initial phase were ductal carcinoma *in situ* (DCIS) or invasive carcinoma; no history of ipsilateral breast cancer; largest tumor diameter no more than 10 mm according to pretreatment diagnostic mammography, ultrasound, and MRI; no synchronous ipsilateral suspicious lesions; nuclear grade 1 or 2, estrogen receptor positive/human epidermal growth factor 2 (HER2) negative by immunohistochemical analysis of percutaneous biopsy specimens in cases of invasive carcinoma; and no ipsilateral axillary lymph node metastases detected on sentinel lymph node biopsy. The inclusion criteria during the second phase were the same except that the largest tumor diameter was extended to no more than 15 mm. The criteria of estrogen receptor positive/HER2 negative by immunohistochemical analysis were adopted as a surrogate means of assessing luminal A gene expression.

This retrospective study included only patients who had been followed up for more than 2 years after cryoablation and had no evidence of distant metastases; four patients in the second phase had shorter follow-ups and were excluded accordingly. In addition, another 28 patients were excluded for the following reasons: adjunctive radiotherapy had not been administered to four patients in the primary phase, the index lesion was not visible on pretreatment breast MRI in 24 patients (21 in the primary and three in the secondary phase), and the second postcryoablation MRI was not performed in one patient in the primary phase.

After these 32 patients had been excluded, relevant data for the remaining 54 (31 in the primary and 23 in the secondary phase; age, 38−79 years old; mean, 56.9 years, standard deviation (SD), 11.1 years) were analyzed.

Cryoablation Procedure

After informed consent for the procedure was obtained from the patients, cryoablation was performed using one of two treatment systems: Visica I (Sanarus Medical, Pleasanton, California, from October 2006 to April 2012) or IceSense 3 (IceCure Medical, Collierville, Tennessee, from May 2012 to October 2014). The Visica I system uses argon gas as the cryogen, whereas IceSense 3 utilizes liquid nitrogen.

All ablation procedures were performed under ultrasound guidance, and one cryoprobe was used for ablation. Local anesthesia was achieved with 1% lidocaine with epinephrine. The skin incision site was selected to achieve penetration of the cryoprobe along the longest diameter of the lesion. The probe was placed through the lesion's center such that the tip of the probe to the mid portion of the lesion, where the lowest temperature is expected, was around 20 mm. Treatment session comprised an initial freezing, thawing, a second freezing, and warming. The first freezing, thawing, and second freezing were each 10 minutes in duration with Visica I, whereas they were 9, 8, and 9 minutes, respectively, with IceSense 3. Saline was injected into the gap between the skin and subcutaneous fascia before and during ablation to avoid thermal injury to the skin. The long diameter of the ice ball formed at the end of freezing ranged from 29 to 47 mm (mean, 36.7 mm). At the end of the treatment, the probe was warmed to enable easy and safe extraction.

Adjunctive Therapies

After cryoablation, radiation oncologists administered external beam radiation therapy to the ipsilateral breast; this was considered appropriate because cryoablation was performed as an alternative to breast-conserving surgery. Hormone therapy was prescribed for patients with invasive carcinoma.

MRI Acquisition

All the images shown in this article were acquired using a 1.5-T system (Magnetom Avanto 1.5T; Siemens Healthcare, Erlangen, Germany) or a 3-T system (Magnetom Skyra 3T; Siemens Healthcare from August 2013). Dynamic studies of both breasts were performed in the coronal plane. Dynamic coronal image acquisition using a volumetric interpolated breath-hold examination sequence was performed at 30, 90, and 270 seconds after contrast injection. In addition, high in-plane resolution images of right and left breasts were acquired in the sagittal plane, using a volumetric interpolated breath-hold examination sequence at 190 and 250 seconds (3-T system) or 150 and 210 seconds (1.5-T system) after contrast injection. The parameters of the dynamic studies are shown in Supplementary Table. Additionally, fat-suppressed T2-weighted images were obtained before or after administration of contrast material.

Observer Study

Two radiologists (Observer 1: A.S. with 16 years of experience in breast imaging [approximately 4300 breast MRI examinations]; Observer 2: T.I. with 16 years of experience in breast imaging [approximately 7500 breast MRI examinations]) independently reviewed the breast MRIs. They were required to assess the first and second postcryoablation breast

MRIs with reference to the precryoablation MRI (primary review). They evaluated the following factors: longest diameter of the treated area; shape of regions of enhancement (none, focus-to-mass, nonmass enhancement), and degree of suspicion of residual disease or recurrence (none, nonspecific, indeterminate, or suspicious) within the treated area. In particular, focus and mass were integrated to a single entity: “focus-to-mass.” Observers had reviewed several MRIs after cryoablation for breast cancer and had reached consensus on the shape of the regions of enhancement. Although they were informed before review that they were going to assess breast MRI after breast cancer cryoablation, they were blinded to the clinical outcomes.

The observers were provided with all image sequences from each MRI evaluated the selected factors on both these and reformatted images.

Statistical Analysis

Suspicion of residual disease or recurrence classified as "indeterminate" or "suspicious" was considered positive, whereas "none" and "nonspecific" was considered negative.

Fisher's exact test was used for dichotomous variables and the Mann−Whitney *U* test for continuous variables. Interobserver agreement was evaluated calculating κ values for dichotomous variables or intraclass correlation coefficients (ICCs) for continuous variables.

Statistical analyses were performed using SPSS statistics 23 (IBM, Armonk, New York). κ values and ICCs were classified as slight (<0.20), fair (0.21−0.40), moderate (0.41−0.60), substantial (0.61−0.80), or almost perfect (0.81−1.0). $p < 0.05$ was defined as indicating a statistically significant difference.

RESULTS

Study Cohort

Histopathological diagnoses on examination of percutaneous biopsies performed before cryoablation were invasive carcinoma of no special type ($n = 51$) and DCIS ($n = 3$: two low-grade DCIS cases and one intermediate grade DCIS case). Lesions measured 3−14 mm (mean, 8.5 mm; SD, 2.4 mm) on preoperative breast MRI. The morphologies of the lesions on preoperative MRI were focus ($n = 2$), mass ($n = 51$), and nonmass enhancement ($n = 1$). Adjunctive radiotherapy was initiated 34−181 days after cryoablation (mean, 76.5 days; SD, 30.3 days). The first and second postcryoablation MRIs were performed 22−171 days (mean, 42.7 days; SD, 22.5 days) and 82−487 days (mean, 193.4 days; SD, 77.8 days) after cryoablation. The first postcryoablation MRI was performed 99 days before to 28 after (mean, 25.5 days before; SD 33.8 days) the start of radiotherapy (in one patient who underwent the first postcryoablation MRI 28 days after the start of radiotherapy, the first postcryoablation MRI was performed 5 days after completion of radiotherapy). The second postcryoablation MRI was performed 49 days before to 423 days after (mean, 89.2 days after; SD, 75.8 days) completion of radiotherapy (in three patients who underwent the second postcryoablation MRI 49−20 days before completion of radiotherapy, the second postcryoablation MRI was performed 1−29 days before the start of radiotherapy).

The duration of follow-up after cryoablation was 25−104 months (mean, 40.6 months, SD, 20.3 months). Ipsilateral breast cancer recurrence occurred in a 53-year-old woman with invasive carcinoma in the outer-upper quadrant of the right breast treated with cryoablation. Preoperative imaging had revealed a target lesion measuring 6 mm without any other ipsilateral suspicious lesion. Percutaneous vacuum-assisted biopsy revealed invasive carcinoma of no special type that was estrogen positive and HER2 negative. Cryoablation was performed successfully and the patient received adjuvant hormonal therapy and radiation 1 month after cryoablation. However, ipsilateral breast carcinoma *in situ* was detected by MRI 54 months after cryoablation. This recurrent lesion manifested as segmental nonmass enhancement outside the originally treated area on the seventh postcryoablation breast MRI (and was therefore not included in the observer study). MRI-guided vacuum-assisted biopsy resulted in a histopathological diagnosis of DCIS. The patient underwent total mastectomy and was free of recurrence or metastasis for the subsequent 2 years.

Observer Study

The longest diameter of the treated area on the first postcryoablation MRI was 15−60 mm (mean, 39.0 mm; SD, 10.9 mm; Observer 1) and 12−60 mm (mean, 37.5 mm; SD, 10.6 mm; Observer 2); that on the second postcryoablation MRI was 14−50 mm (mean, 27.7 mm; 7.5 mm; Observer 1) and 9−46 mm (mean, 24.0 mm; SD 7.6 mm; Observer 2). There was substantial interobserver agreement on the longest diameter of the treated area (ICC = 0.77 for the first pot-cryoablation MRI and 0.79 for the second). The longest diameter of the treated area was significantly smaller on the second than the first pot-cryoablation MRI according to both observers ($p < 0.001$ for both Observers 1 and 2).

The two observers’ findings are listed in Tables 1 and 2. Interobserver agreement on enhancement shape was fair to moderate ($\kappa = 0.356$ and 0.434 on the first and second postcryoablation MRI, respectively). Interobserver agreement for degree of suspicion for residual disease or recurrence was also fair to moderate ($\kappa = 0.369$ on the first and 0.434 on the second postcryoablation MRI). When "indeterminate" and "suspicious" were combined as positive, and "none" and "nonspecific" as negative, interobserver agreement for suspicion of residual disease or recurrence was moderate ($\kappa = 0.559$) on the first postcryoablation MRI. This variable could not be calculated for the second postcryoablation MRI because all findings were interpreted as negative by both observers (Fig 1).

TABLE 1. Shapes of Regions of Enhancement on Postcryoablation MRI

Observer 1 / Observer 2

Inside the Treated Area

	The First Postcryoablation MRI				The Second Postcryoablation MRI		
	FTM	NME	None		FTM	NME	None
FTM	3	1	0	FTM	0	0	0
NME	1	10	1	NME	0	5	2
None	1	17	20	None	0	7	40

Periphery of the Treated Area

	The First Postcryoablation MRI				The Second Postcryoablation MRI		
	FTM	NME	None		FTM	NME	None
FTM	4	12	9	FTM	0	3	1
NME	1	16	11	NME	1	27	3
None	0	0	1	None	1	9	9

FTM, focus-to-mass; NME, nonmass enhancement.

Observer 1 or 2 reported suspicion of residual disease or recurrence on the first postcryoablation MRI in 7 of 54 patients (13.0%; Fig 2, Table 2). In all seven, the primary lesion had been diagnosed pathologically as invasive carcinoma of no special type. The first postcryoablation MRI was acquired 29−60 days (mean, 43.7 days; SD, 9.7 days) after cryoablation and 29−81 days (mean, 49.1; SD, 15.2 days) before starting adjunctive radiotherapy. There were no significant differences in age ($p = 0.88$), histopathology (invasive carcinoma vs DCIS; $p = 1.0$), lesion size on precryoablation MRI ($p = 0.21$), interval between cryoablation and first postcryoablation MRI ($p = 0.85$), or the timing of first postcryoablation MRI (before or after radiotherapy; $p = 1.0$) between the seven patients with suspicion of residual disease or recurrence and the remaining 47 patients (Table 3). Relationships between shape of region of enhancement and degree of suspicion of residual disease or recurrence are shown in Table 4. There were significant associations between focus-to-mass, opposed to nonmass enhancement or none, enhancement shape, and suspicion for residual disease or recurrence for both observers (both $p < 0.001$). Among the seven patients with suspected residual disease or recurrence, the second postcryoablation MRI was performed 126−348 days (mean, 221.4 days; SD, 83.0 days) after cryoablation and 20 days before to 255 days after (mean, 99.3 days after; SD, 96.0 days) completing radiotherapy (in one patient who underwent cryoablation 20 days before completing radiotherapy, it was performed one day before starting radiotherapy). As stated previously, both observers interpreted all second postcryoablation MRIs as negative in all cases, including these seven patients.

Neither of the two observers detected suspicious enhancement within the treated area on the first and second postcryoablation breast MRIs of the patient who subsequently developed ipsilateral breast cancer recurrence.

TABLE 2. Degree of Suspicion of Residual Disease or Recurrence on Postcryoablation MRI

Observer 1 / Observer 2

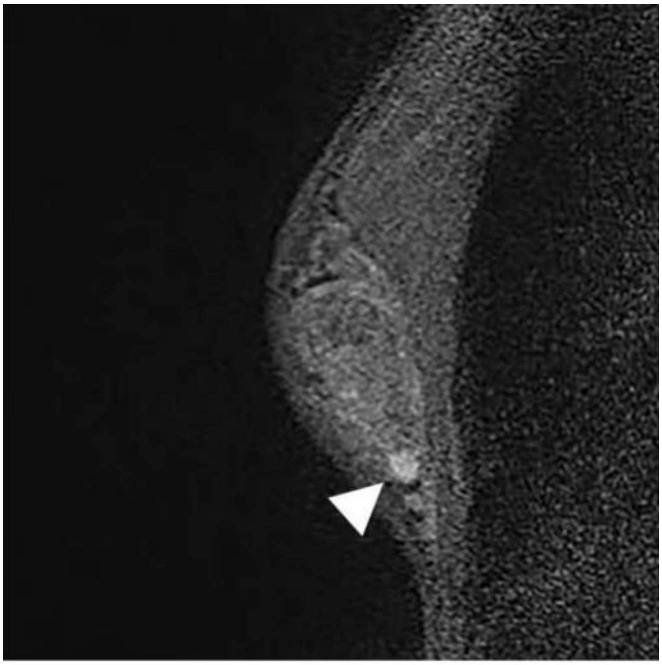
The First Postcryoablation MRI

		Positive Suspicious	Indeterminate	Negative Nonspecific	None
Positive	Suspicious	1	0	1	0
	Indeterminate	0	2	0	1
Negative	Nonspecific	0	1	10	0
	None	0	1	17	20

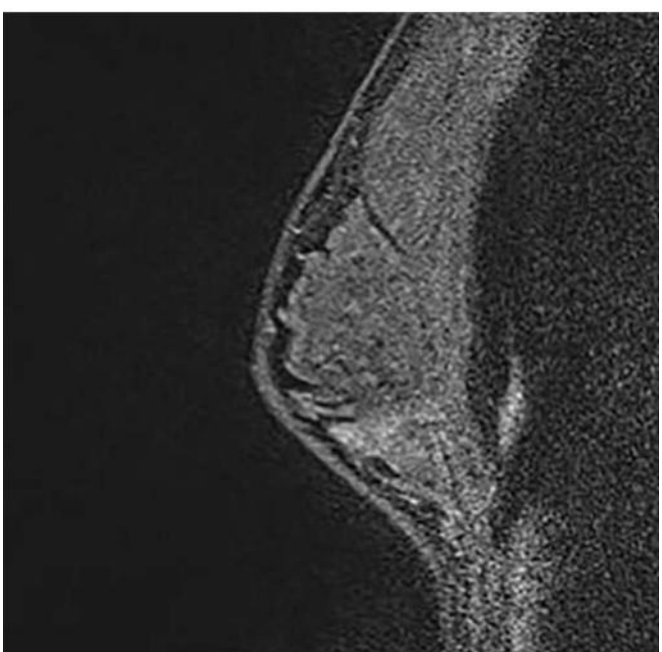
The Second Postcryoablation MRI

		Positive Suspicious	Indeterminate	Negative Nonspecific	None
Positive	Suspicious	0	0	0	0
	Indeterminate	0	0	0	0
Negative	Nonspecific	0	0	5	2
	None	0	0	7	40

MRI, magnetic resonance imaging.



(a)



(b)

Figure 1. A 42-year-old woman with invasive carcinoma of no special type. (a) Brest magnetic resonance imaging (MRI) before cryoablation showing an irregularly shaped mass of diameter 7 mm in the outer-lower quadrant of the right breast. (b) First postcryoablation MRI: there is no enhancement inside the treated area with faint linear-shaped peripheral enhancement. The patient remained free of local recurrence or distant metastasis for more than 5 years.

DISCUSSION

In this study, we investigated the findings on MRI after cryoablation for breast cancer as determined retrospectively by two independent radiologists. These radiologists identified some suspicious findings within the treated area on the first postcryoablation MRIs of 7 of 54 (13.0%) of study patients; focus-to-mass-shaped regions of enhancement were significantly associated with this suspicion. All these suspicious findings had resolved by the second postcryoablation MRI.

No such suspicious findings were reported in a previous study by Littrup et al of the feasibility of cryoablation without subsequent excision for 22 breast cancer foci in 11 patients who refused surgery (Stages I−IV) (12). They reported that postcryoablation breast MRIs showed avascular ablation areas surrounded by symmetrical peripheral rim enhancement. There are several possible explanations for this discrepancy. Our study included 54 patients with breast cancer, whereas their study included only 11. In addition, they used MRI machines with lower magnetic fields (1.0 T or 1.5 T) than in our study (1.5 T or 3.0 T); tiny enhancing structures may have been overlooked in MRIs with lower magnetic fields.

What is considered enhancement within treated areas varies between studies. Manenti et al reported identifying persistent suspicious enhancement in 2 of 40 patients (5%) who underwent cryoablation to treat breast cancer (7). They subsequently excised the lesions and found viable tumor cells on histopathological examination. Poplack et al reported identifying central enhancement at the ablation site in 2 of 17 patients (11.8%); however, residual carcinoma was found on histopathological analysis of subsequently excised tissue in neither of these two cases. In our study, participants received adjunctive radiotherapy and hormone therapy for invasive cancer. Suspicious findings within the treated area, which we identified on the first postcryoablation MRIs in some cases, had resolved by the second postcryoablation MRI. Because we lacked pathological findings for some areas of suspicious enhancement, it is unclear whether all the changes we identified resolved after treatment or whether persistent viable tumor tissue within ablated areas was sometimes subsequently treated by adjuvant radiation therapy or hormone therapy. However, the results of our study suggest that enhancement within treated areas after cryoablation can resolve during subsequent adjuvant therapies and follow-up.

Suspicious enhancement has been reported in several studies that investigated MRI findings after cryoablation therapy for renal cancer. Porter et al (14) reported that 8 of 23 (34.8%) renal masses imaged within 6−36 hours after ablation were enhanced on MRI, three of which had persistent enhancement 3 months after cryoablation. Takaki et al (15) reported false-positive tumor enhancement in 15 tumors (60.0%) 2−3 days after cryoablation of renal cell carcinoma, the enhancement still being present in 13 tumors (52.0%) after 5−7 days and in one tumor (4.0%) 1 month after

Figure 2. A 51-year-old woman with invasive carcinoma of no special type. (a) Breast magnetic resonance imaging (MRI) before cryoablation showing an irregularly shaped mass of diameter 8 mm in the inner-lower quadrant of the left breast. (b) First postcryoablation MRI: focus-to-mass-shaped enhancement within the treated area was judged as suspicious by both observers. MRI-guided vacuum assisted biopsy revealed no residual cancer. (c) Second postcryoablation MRI: there is no enhancement. The patient remained free of local recurrence or distant metastasis for more than 3 years.

cryoablation. In the present study, suspicious enhancement was detected in 7 of 54 lesions (13.0%) by at least one of the two observers on breast MRIs acquired 29–60 days (mean, 43.7 days) after cryoablation. Transient enhancement within the treated area could be reported after cryoablation of tumors of various organs, the frequency and duration varying with differences in patient and tumor characteristics, cryoablation and MRI techniques, and study design. Further investigations are necessary to determine its significance.

This study was limited by its retrospective design and relatively small cohort; notably, only three cases of DCIS were included. However, to the best of our knowledge, this is the first reported study to evaluate MRI findings in detail after cryoablation therapy for early breast cancer. Our findings should be investigated further in prospective trials. Another limitation is that the interobserver agreement on findings ranged from fair to moderate; this seems low and raises the concern that the results of this study are not generalizable. This low interobserver agreement may be attributable to the observers having had relatively little experience in the interpretation of postcryoablation breast MRIs. Both observers had reviewed only a few MRIs after cryoablation for breast cancer prior to this study; however, they reached consensus on the shapes of the regions of enhancement after this review. Their future learning curves may improve agreement between observers on MRI findings after cryoablation. In this study, focus and mass were integrated to a single entity, namely "focus-to-mass," and this modification to lexicons of the Breast Imaging Reporting and Data System (16) might have influenced our results. Furthermore, other features listed in the Breast Imaging Reporting and Data System, including the shape of the lesion, margin of the mass, distribution or internal enhancement pattern of nonmass enhancement, and enhancement kinetics, were not assessed in this study. Further investigation would be necessary to evaluate the significance of these enhancement features on postcryoablation breast MRI. In addition, other imaging modalities, including contrast-enhanced spectral mammography, which can assess vascularity of cancerous lesions (17–19), may be useful for surveillance after cryoablation. Studies comparing these imaging modalities are necessary.

In summary, we here investigated MRI findings according to two independent radiologists after cryoablation for early breast cancer. Some patients had suspicious findings within the treated area at the first postcryoablation MRI that had resolved by the second postcryoablation MRI. This suggests that the

TABLE 3. Relationship Between Clinical Factors and Evaluation of the First Postcryoablation MRI

	Evaluation of the First Postcryoablation MRI Positive by Either of the Two Observers ($n = 7$)	Negative by Both Observers ($n = 47$)	p
Age (years)	39–75 (mean, 57; SD, 12.2)	38–79 (mean, 56.9; SD, 10.9)	0.88
Histopathology			1
Invasive carcinoma	7	44	
Ductal carcinoma *in situ*	0	3	
Lesion size on precryoablation MRI (mm)	5–14 (mean, 8.9; SD, 2.8)	3–14 (mean, 8.5; SD, 2.4)	0.85
Interval between cryoablation and first postcryoablation MRI (days)	29–60 (mean, 43.7; SD, 9.7)	22–171 (mean, 42.6; SD, 23.8)	0.21
Timing of first postcryoablation MRI			1
Before radiotherapy	7	46	
After radiotherapy	0	1	

MRI, magnetic resonance imaging; SD, standard deviation.

TABLE 4. Relationships Between Shape of Region of Enhancement and Degree of Suspicion of Residual Disease or Recurrence

Observer 1					Observer 2				
The First Postcryoablation MRI									
	Degree of Suspicion					Degree of Suspicion			
Shape	Positive Suspicious	Negative Indeterminate	Nonspecific	None	Shape	Positive Suspicious	Indeterminate	Negative Nonspecific	None
FTM	2	2	0	0	FTM	1	4	0	0
NMS	0	1	11	0	NMS	0	0	28	0
None	0	0	0	38	None	0	0	0	21
The Second Postcryoablation MRI									
	Degree of Suspicion					Degree of Suspicion			
Shape	Positive Suspicious	Negative Indeterminate	Nonspecific	None	Shape	Positive Suspicious	Indeterminate	Negative Nonspecific	None
FTM	0	0	0	0	FTM	0	0	0	
NME	0	0	7	0	NMS	0	0	12	0
None	0	0	0	47	None	0	0	0	42

FTM, focus-to-mass; NME, nonmass enhancement.

enhancement that can be found on MRI images within the treated area after cryoablation for early breast cancer can resolve during subsequent adjuvant therapies and follow-up.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.acra.2018.07.012.

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