

Advocating Nonsurgical Management of Patients With Small, Incidental Radial Scars at the Time of Needle Core Biopsy

A Study of 77 Cases

Cathleen Matrai, MD; Timothy M. D'Alfonso, MD; Lindsay Pharmer, MD; Michele B. Drotman, MD; Rache M. Simmons, MD; Sandra J. Shin, MD

• **Context.**—Radial scars are benign sclerosing lesions that are routinely excised when diagnosed in a needle core biopsy. Optimal management for patients with incidental and small (≤ 5 mm) radial scars is uncertain.

Objective.—To assess pathologic upgrade of radial scars diagnosed in needle core biopsy samples and identify a subset of patients who could benefit from conservative management.

Design.—Patients with a diagnosis of radial scar in a needle core biopsy who underwent excision of the biopsied area were identified. Radial scars greater than 5 mm in size and those with coexisting atypia, carcinoma, and papillary lesions were excluded. After histologic-radiographic correlation, rates of pathologic upgrade were assessed.

Results.—Seventy-seven radial scars diagnosed in 66

patients were included. Overall, 9 of 77 (12%) showed upgrade to a high-risk lesion (6 lobular carcinoma in situ, 2 atypical ductal hyperplasia, 1 atypical lobular hyperplasia), while none (0%) showed upgrade to invasive carcinoma or ductal carcinoma in situ. One of 22 incidental radial scars (4.5%) showed upgrade on excision versus 6 of 36 (16.7%) for radial scars considered to be the radiographic target ($P = .23$). Older age was associated with upgrade ($P < .001$).

Conclusions.—No incidental or small (≤ 5 mm) radial scars excised revealed invasive carcinoma or ductal carcinoma in situ on excision. Provided there is good pathologic-radiologic concordance, it appears reasonable for these patients to be managed conservatively.

(*Arch Pathol Lab Med.* 2015;139:1137–1142; doi: 10.5858/arpa.2014-0550-OA)

Radial scars of the breast are benign sclerosing lesions commonly found as incidental microscopic findings in surgical excision specimens. These reactive proliferations are associated with a slight increase in risk for the development of subsequent breast cancer, similar to that of proliferative fibrocystic changes.¹ Radial scars may also be involved by or can be closely associated with malignancy.² While routine follow-up is appropriate management for patients with radial scars diagnosed in excisional biopsy or mastectomy specimens, the optimal clinical approach for such patients in

the needle core biopsy (NCB) setting is more uncertain. Surgical excision is largely motivated by the concern that carcinoma associated with the radial scar in the NCB has gone unsampled. Significantly variable rates of pathologic upgrade (finding a more significant lesion in the subsequent excisional biopsy) have been reported (0%–40%),³ which further augment clinicians' misgivings about the ideal practice in this clinical scenario.

At our institution as is true at many other hospitals, most radial scars diagnosed in an NCB sample are surgically excised, regardless of radial scar size or other radiologic or pathologic features. However, we as pathologists are keenly aware that "not all radial scars are created equal" and some that are encountered in NCB samples do not warrant excisional biopsy in their own right. These radial scars are often small (≤ 5 mm) and/or are not the radiographically targeted lesions (incidental in nature). More often than not, these lesions appear entirely removed in the NCB sample and not surprisingly, the subsequent excisional biopsy only reveals biopsy site changes in benign breast tissue. The need for open surgical biopsy in this setting is questionable, yet no definitive large-scale study has been undertaken to properly identify this subset of patients who could be reasonably managed in a conservative, nonsurgical manner.

We set out to evaluate the rates of pathologic upgrade on excision of small (≤ 5 mm) radial scars without atypia

Accepted for publication December 18, 2014.

Published as an Early Online Release January 21, 2015.

From the Departments of Pathology and Laboratory Medicine (Drs Matrai, D'Alfonso, and Shin), Breast Surgery (Drs Pharmer and Simmons), and Radiology-Division of Women's Imaging (Dr Drotman), Weill Cornell Medical College, New York, New York. Drs Matrai and D'Alfonso contributed equally to this study.

The authors have no relevant financial interest in the products or companies described in this article.

Presented at the 2014 United States and Canadian Academy of Pathology (USCAP) Annual Meeting; March 3, 2014; San Diego, California.

Reprints: Timothy M. D'Alfonso, MD, Department of Pathology and Laboratory Medicine—Starr 1031E, New York-Presbyterian Hospital/Weill Cornell Medical College, 525 East 68th St, Starr 1000, New York, NY 10065 (e-mail: tid9007@med.cornell.edu).

diagnosed in NCBs with a particular interest in identifying a subset of these patients who may benefit from conservative management.

MATERIALS AND METHODS

Sample Selection and Slide Review

This study was conducted under an institutional review board-approved protocol. We retrospectively identified patients with a diagnosis of radial scar in an NCB who underwent surgical excision at our institution. All patients underwent excision of the same biopsied area within 6 months from the time the NCB was performed.

Slides from NCBs were reviewed by a group of 3 pathologists (C.M., T.M.D., S.J.S.) for consensus of histologic findings. A radial scar was defined histologically as a proliferation of ducts and lobules in a stellate configuration radiating out from a central fibroelastotic core. Needle core biopsies containing coexisting atypical ductal hyperplasia (ADH), lobular carcinoma in situ (LCIS)/atypical lobular hyperplasia (ALH), and papillary lesions were excluded. In addition, any radial scar greater than 5 mm was excluded. In each biopsy specimen, the size of the radial scar, the presence of any proliferative epithelial changes associated with the radial scar, and the presence and location of calcifications in the NCB were recorded. Additionally, we evaluated whether the radial scar appeared to be completely removed in the NCB sample by the presence of at least a rim of nonlesional stroma surrounding the radial scar. For cases that were found to have a pathologic upgrade in the excisional biopsy specimen, slides of the excision were reviewed and the histologic findings confirmed. Pathologic upgrade was defined as the presence of a surgically actionable or high-risk lesion in the surgically excised tissue of the (needle core) biopsied area. Surgically actionable lesions included invasive carcinoma of any histologic type and ductal carcinoma in situ (DCIS), whereas LCIS, ADH, and ALH were defined as high-risk lesions. The distribution and extent of the upgraded lesion, as well as its relationship with the biopsy site and residual radial scar (if any) in the excisional biopsy, were also recorded.

Correlation of Microscopic and Imaging Findings

Microscopic findings were correlated with the imaging abnormalities that indicated the biopsies, as determined from radiographic reports. Any cases in which the excision was performed owing to radiologic-pathologic discordance were not included in the study. Radial scars were subclassified as targeted, incidental, or indeterminate in nature. Radial scars were considered to represent the “radiographic target” when the radiographic abnormality was a mass/nodule of similar size to the radial scar evident histologically and without histologic evidence of another coexisting mass-forming lesion in the biopsied material. For stereotactic biopsies performed for mammographic calcifications, the radial scar was considered the targeted lesion when calcifications were present predominantly within the radial scar and not elsewhere in the NCB sample. Radial scars were categorized as “incidental” in 2 scenarios: if calcifications were identified predominantly or entirely in breast tissue not associated with the radial scar or if found in a biopsy performed for a mass that correlated with another histologic finding in the biopsy and was not associated with the radial scar. “Indeterminate” radial scars were those for which a stereotactic biopsy showed calcifications to be within both the radial scar and adjacent breast tissue to a comparable degree or found in biopsies performed for magnetic resonance imaging (MRI) enhancement in which other proliferative changes could possibly account for the radiographic changes. Radial scars in biopsies for which the imaging abnormality was not specific (eg, thickening, unspecified distortion) were also classified as indeterminate.

Statistical Methods

Tests for statistical significance of the association between clinicopathologic parameters and pathologic upgrade were performed by using Fisher exact test and Student *t* test.

Characteristic	All Cases	Upgraded Cases	<i>P</i> Value
Age, mean ± SD, y	51.4 ± 10.03	62 ± 11.14	<.001
Breast cancer history			
Yes	4	1	.99
No	42	5	
Unknown	20	3	
RS size, mean size ± SD, mm	3.11 ± 1.3	3.1 ± 0.7	.94
Proliferative changes			
Yes	62	5	.07
No	15	4	
Calcifications in RS			
Present	27	4	.71
Absent	50	5	
RS removed in NCB			
Yes	11	5	.002
No	66	4	
Residual RS in excisional biopsy			
Yes	35	1	.03
No	42	8	

Abbreviations: NCB, needle core biopsy; RS, radial scar; SD, standard deviation.

RESULTS

Clinical Characteristics

The study included 77 radial scars diagnosed in 66 NCB samples from 66 patients, of whom 9 (13.6%) had multiple radial scars. All patients were women ranging in age from 37 to 79 years (mean, 51 years). Four patients reported a personal history of breast carcinoma (1 invasive ductal carcinoma, 2 DCIS, 1 unspecified “early stage” carcinoma). Seventeen patients (26%) reported a history of breast cancer in a first-degree relative. Two patients (3%) were known *BRCA* mutation carriers (1 *BRCA1*, 1 *BRCA2*).

Indications for Needle Core Biopsy and Biopsy Devices

Radial scars were present in biopsies performed for mammographic calcifications in 42 cases (55%), a mass/nodule in 23 cases (30%), mammographic architectural distortion in 4 cases (5%), and non-masslike MRI enhancement in 8 cases (10%). Tissue was sampled by using 14-, 16-, 18-, or 22-gauge core biopsy needles in 16 procedures (24%). In 29 procedures (44%), 7- through 11-gauge vacuum-assisted biopsies were performed, either stereotactically or MRI guided. The size of the biopsy device was not known in 21 biopsies (32%).

Microscopic Findings in Needle Core Biopsy Samples

Microscopic findings in NCB samples are summarized in Table 1. The mean size of all radial scars diagnosed in NCB samples was 3.11 mm (range, 1–5 mm). Twenty-seven radial scars (35%) were associated with calcifications. Fibrocystic changes including florid and papillary ductal hyperplasia and apocrine metaplasia were present in association with 62 radial scars (80.5%). Eleven of 77 radial scars (14%) were considered completely removed in the NCB samples. The mean size of radial scars that were

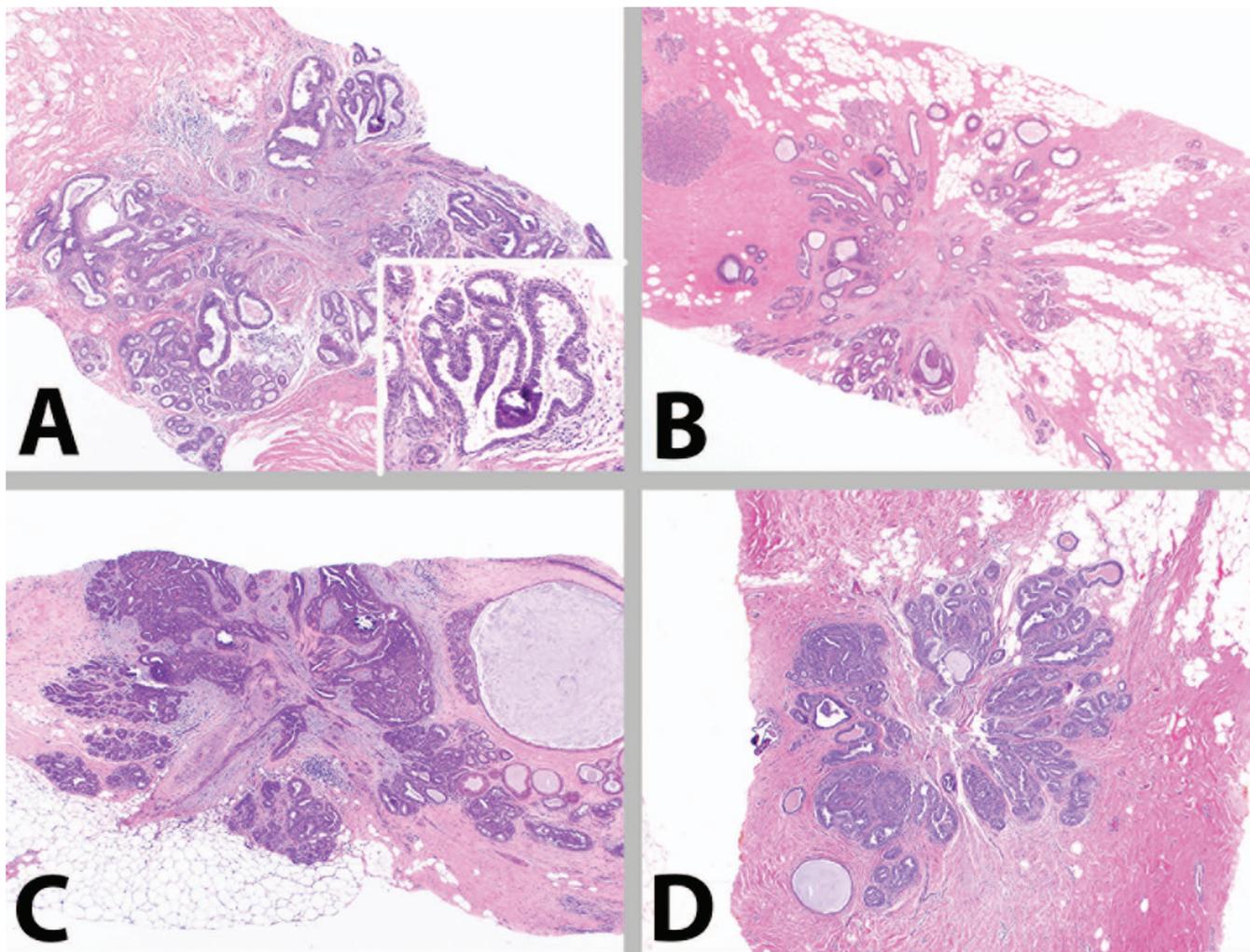


Figure 1. Photomicrographs of selected study cases. A, Radial scar that was considered the radiographic target in a biopsy performed for microcalcifications (inset: high-power magnification showing calcifications in benign glands). B, Incidental radial scar in a biopsy performed for calcifications. C, Radial scar considered incompletely removed in the core biopsy, compared with (D) a radial scar completely removed in the biopsy (hematoxylin-eosin, original magnifications $\times 40$ [A through D] and $\times 200$ [inset A]).

completely removed in the core biopsy was 2.55 mm (versus incompletely removed; mean size, 3.2 mm, $P = .06$). All biopsies in which radial scars were completely removed were performed by using 7-, 9-, or 11-gauge biopsy devices.

Histopathologic-Radiologic Correlation

Thirty-six of 77 radial scars (47%) were deemed to represent the radiographic target for the biopsy. Of these, 18 (50%) were targeted for calcifications (Figure 1, A) and 15 (42%) were targeted for a mass/nodule. The presence of architectural distortion was the radiographic target for the remaining 3 radial scars (8%).

Twenty-two of 77 radial scars (29%) were classified as incidental in nature (Figure 1, B). These included 17 radial scars (77%) present in biopsies performed for calcifications, 4 (18%) identified in biopsies targeting a mass/nodule, and 1 (5%) present in a biopsy for architectural distortion. In the 4 cases targeted for a mass/nodule and 1 case targeted for architectural distortion, the findings in the biopsy that were deemed to be the radiographic targets were fibroadenoma/fibroadenomatoid change (4 cases) and an involuted cyst with fibrosis (1 case), respectively.

Nineteen radial scars (25%) identified in NCBs comprised the indeterminate group owing to the uncertainty of whether they represented the radiographic target or not. In 7 of these cases (37%), a biopsy performed for calcifications showed a similar amount and quality (size, shape) of calcifications within the radial scar as in the adjacent breast tissue. Four radial scars (21%) were classified as indeterminate because they were present in biopsies targeting a mass/nodule. In these cases, fibrocystic changes including fibroadenomatoid change (1 case), multiple cysts (2 cases), and papillary ductal hyperplasia (1 case) were present in addition to the radial scar, none of which clearly represented the radiographic target. Finally, in 8 biopsies (42%) performed for non-masslike MRI enhancement, it could not be firmly established whether the radial scar or findings in adjacent breast tissue contributed to the targeted enhancement.

Assessment of Pathologic Upgrade on Excision

Overall, 9 of 77 radial scars (12%) showed a pathologic upgrade on excision (Table 2). All 9 cases showed a high-risk lesion in the excisional specimen, specifically LCIS (6

Table 2. Correlation of Imaging Findings With Pathologic Upgrade Diagnoses

Radiologic-Pathologic Concordance	No. (% Total)	No. Upgraded (Rate)	Upgraded Diagnoses	Imaging Indication for Upgraded Cases
Targeted radial scars	36 (46.7)	6 (16.7)	LCIS (3) ADH (2) ALH (1)	Calcifications (1 LCIS, 1 ADH, 1 ALH) Mass/nodule (1 LCIS, 1 ADH) Architectural distortion (1 LCIS)
Incidental radial scars	22 (28.6)	1 (4.5)	LCIS	Mass/nodule
Indeterminate radial scars	19 (24.7)	2 (10.5)	LCIS	Calcifications MRI enhancement

Abbreviations: ADH, atypical ductal hyperplasia; ALH, atypical lobular hyperplasia; LCIS, lobular carcinoma in situ; MRI, magnetic resonance imaging.

cases), ADH (2 cases), and ALH (1 case). No cases contained a surgically actionable finding (invasive carcinoma or DCIS) in the subsequent excisional biopsies.

The 6 cases of LCIS in the excisional biopsies were of the classical type with low-nuclear-grade LCIS that was multifocal in 4 cases and present as a single focus in 2 cases. In 3 cases, LCIS was present in close vicinity (3 mm, 1 mm, 1 mm) to the biopsy site, while in the remaining cases LCIS was present in breast tissue distant from (>5 mm) the biopsy site. The 2 cases upgraded to ADH and the 2 cases upgraded to ALH each showed a single focus distant (>5 mm) from the biopsy site.

The pathologic upgrade rates for targeted radial scars and incidental radial scars were 16.7% (6 of 36 cases: 3 LCIS, 2 ADH, 1 ALH) and 4.5% (1 of 22 cases: LCIS), respectively. Although the upgrade rate was higher for targeted radial scars than incidental radial scars, this difference was not statistically significant ($P = .23$). Radial scars that were indeterminate showed a pathologic upgrade rate of 10.5% (2 of 19 cases: 2 LCIS).

Thirty-five cases (45%) showed residual radial scar in the excisional biopsy, none of which were among the cases considered completely removed in the NCB (Figure 1, C and D). Among cases with residual radial scar in the excision, only 1 case showed a pathologic upgrade where 2 foci of LCIS were present in breast tissue distant (>5 mm) from the residual radial scar and biopsy site (Figure 2, A through C). Patients with an upgrade on excision were significantly older than patients whose excisional biopsies did not show an upgraded lesion (62.0 versus 49.9 years, $P < .001$). Complete removal of the radial scar in the NCB and absence of residual radial scar in the excisional biopsy were significantly associated with pathologic upgrade ($P = .002$, $P = .03$, respectively) in the excision. Other measured parameters such as radial scar size, associated proliferative changes, or associated calcifications were not significantly associated with pathologic upgrade.

COMMENT

Patients with a diagnosis of radial scar in an NCB routinely undergo surgical excision of the biopsied area. For palpable radial scars and those greater than 1 cm typically presenting as a radiographic mass, there is general agreement that these should undergo surgical excision owing to the higher risk of malignancy associated with larger radial scars and the potential for sampling error in these lesions.⁴ Other radial scars in NCBs are either smaller but radiographically apparent or entirely occult (incidental). In most studies, the rate of upgrade, or underestimation of

malignancy, of surgically excised radial scars has been variable, but most reported rates are in the range of 0% to 10%.^{3,5-14} However, most radiologists are not comfortable recommending clinical follow-up over surgical excision of radial scars because studies have not consistently demonstrated an upgrade rate of less than 2%, the cutoff for categorizing a lesion as “probably benign” according to the BI-RADS (Breast Imaging Reporting and Data System) system (BI-RADS 3).¹⁵ The variability in reported upgrade rates may be due to several factors including variability in study design, small sample sizes, and inconsistent radiologic-pathologic concordance. More importantly, there is currently no definitive study to identify a subset of these patients who may be sufficiently treated without surgical intervention.

In the current study, we were most interested in 2 subgroups of radial scars. We hypothesized that radial scars deemed to be incidental would have a lower pathologic upgrade rate than that of targeted radial scars. While the difference was not statistically significant, we found that the pathologic upgrade rate of 4.5% for incidental radial scars was noticeably lower than that for targeted ones (16.7%) and this was a trend that should not be completely dismissed. This is the largest study to date that addresses this question. Additional large-scale studies of this kind would be helpful to further confirm our observation and ideally demonstrate a statistically significant difference, which was not achieved in the current study.

Another important finding in our study was that none of our pathologic upgrade lesions were surgically actionable (invasive carcinoma or DCIS) but rather only high risk in nature, as defined by multiple other investigators who consider only the former group to represent “true” pathologic upgrade.^{3,6,7,16} It is also worthy to note that even the high-risk lesions (LCIS, ADH, ALH) considered as pathologic upgrades could, themselves, be considered incidental microscopic findings, as they would have remained clinically occult had an excisional biopsy not been performed in these cases.

To date, there is only 1 smaller published study that addresses the significance of incidental or “microscopic” radial scars in NCB samples. Lee et al¹⁶ studied the outcome of patients diagnosed with microscopic radial scars and papillomas in NCBs who underwent excision. In their analysis, none of 18 microscopic radial scars revealed malignancy (invasive carcinoma or DCIS) on follow-up excision, while 7 cases showed a high-risk lesion on excision (6 ADH, 1 atypical apocrine adenosis). Although their cohort was small and not limited to smaller radial scars,

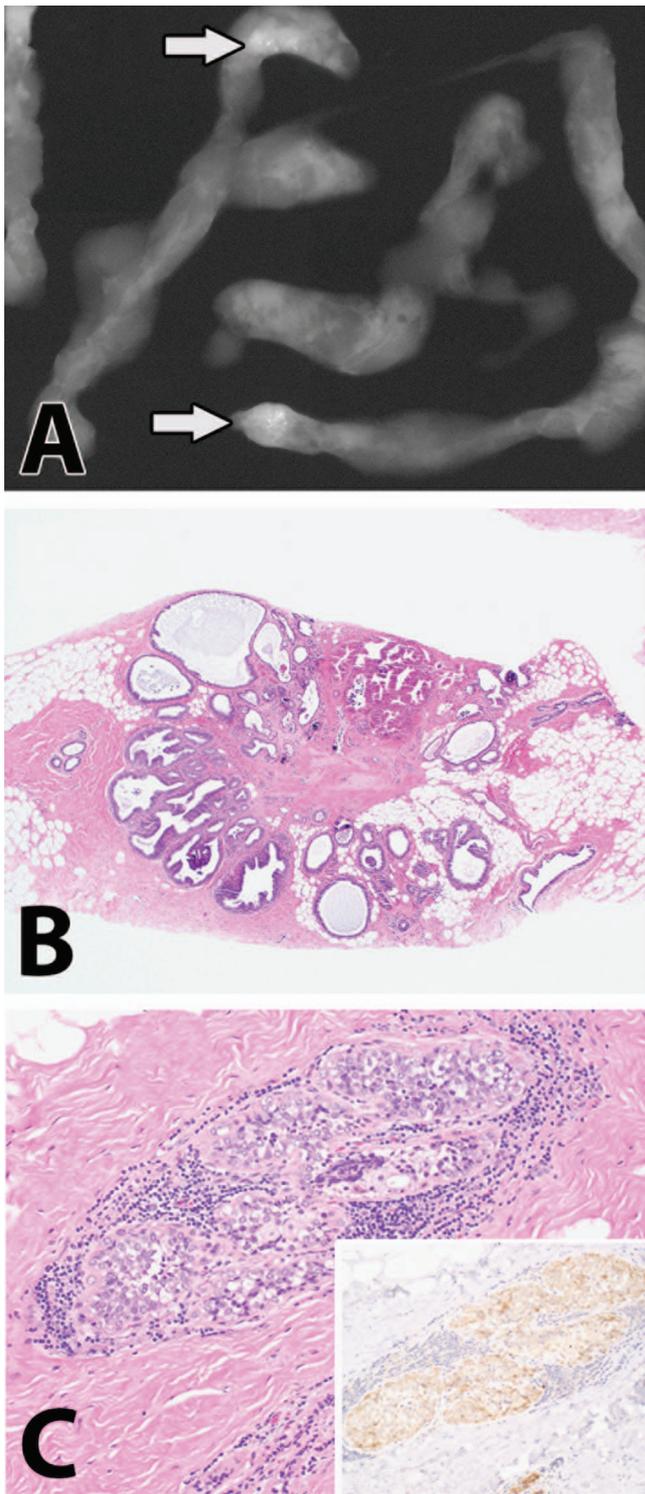


Figure 2. Radial scar targeted for calcifications that showed upgrade on excision. *A*, A specimen radiograph from the stereotactic biopsy shows clustered calcifications (arrows). *B*, The radial scar in the biopsy shows calcifications within the lesion (E-cadherin immunostain, original magnification $\times 40$). *C*, Classical-type lobular carcinoma in situ (LCIS) was identified in the excisional biopsy in breast tissue distant from the biopsy site. An E-cadherin immunostain (inset) shows weak fragmented staining in LCIS cells (hematoxylin-eosin, original magnification $\times 200$ [C]; original magnification $\times 200$ [inset C]).

their findings are in agreement with those found in the current investigation.

In comparing clinicopathologic features with rate of upgrade, we found older age to be positively associated with pathologic upgrade, which is consistent with findings in prior studies that show radial scars in older patients to be more likely associated with atypia and malignancy.^{4,7,17} Microscopic parameters including radial scar size, associated proliferative changes, or associated calcifications did not correlate with pathologic upgrade in our analysis. Cases in which the radial scar appeared entirely removed in the NCB and cases devoid of residual radial scar in the excisional biopsy were significantly associated with upgrade in our study. We suspect that these seemingly contradictory results are likely due to the small number of pathologic upgrades in our series as well as the small number of cases that were considered completely removed in the biopsy. Nevertheless, this finding further supports that upgrades to high-risk lesions in our study were incidental and not associated with the radial scar seen in the NCB.

Unlike other studies, we chose to limit our cohort to radial scars that were small, specifically 5 mm or smaller. These are more likely to be incidental in nature and their management is most controversial. The mean size of radial scars in our series was 3.11 mm, while those in other reports^{3,5,7,8,11,17,18} range in size from 1 mm up to 5.0 cm. This wide range in sizes is a result of variability of inclusion criteria among different studies. For instance, in one report by Resetskova et al,¹⁸ small incidental radial scars (<0.4 cm) were excluded from their cohort. We believe this variability in selection criteria leads to similarly variable results. Another strength of this study is the detailed pathologic correlation that is generally lacking from many published studies examining this clinical scenario.^{5,8,16} Our study is among few based on a cohort of patients with *histopathologically confirmed* radial scars. While it is intuitively obvious to maintain a pure study group, this necessary step is not performed in all studies. We acknowledge that our study is limited by its retrospective nature, which allows for a certain degree of selection bias for patients at risk for malignancy to have undergone excision. However, even considering this inherent bias, the true pathologic upgrade rate (to high-risk lesions) may actually be lower than reported here, while the rate to surgically actionable lesions, such as invasive carcinoma or DCIS, remains at 0%.

While high-risk (LCIS, ALH, ADH) diagnoses can lead to additional clinical management, such as chemoprevention for LCIS or ADH, we do not recommend excision of radial scars to discover these high-risk lesions even though they may be more prevalent in patients with radial scars.⁷ On the other hand, pinpointing the pathologic upgrade rate to surgically actionable lesions is of paramount importance, as this will ultimately direct clinical management for these patients. As in most settings, it is best to treat each individual patient by using a multidisciplinary approach, assessing risk factors, clinical parameters, and radiographic and pathologic findings. Based on our data and those of Lee et al,¹⁶ it appears reasonable for patients with small (and particularly if also incidental) radial scars to be managed conservatively, provided there is good pathologic-radio-graphic concordance.

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