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ORIGINAL RESEARCH

Malignancy Upgrade Rates of Radial Sclerosing Lesions at Breast Cancer Screening

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Purpose: To determine the upgrade rate for biopsy-proven radial scars and radial sclerosing lesions (RS).

Materials and Methods: In this retrospective study, radiology and pathology databases from two tertiary breast centers were searched to identify patients with biopsy-confirmed RS between March 1, 2012, and December 31, 2017, during which all mammography was performed with digital breast tomosynthesis (DBT). Adjunct modalities such as MRI or US are performed at our centers to better characterize lesions identified at DBT. Patient demographics, imaging, needle and excisional biopsies, and follow-up data were collected at the patient level. Clopper-Pearson interval estimate for upgrade was calculated for 95% confidence using PropCIs package with R version 4.1.0 (R Foundation for Statistical Computing) (1).

Results: During the study period, a total of 155 885 DBT examinations were performed. From these examinations, 146 biopsy-proven RS were identified in 142 women (median age, 58 years; age range, 26–87 years). A total of 80.1% (117 of 146) of all RS did not have associated atypia or malignancy, and 19.9% (29 of 146) had associated atypia at initial biopsy. A total of 66.7% (78 of 117) of RS without atypia or malignancy were surgically excised, 25.6% (30 of 117) were followed (median, 3 years; range, 1–7 years) with benign findings on imaging, and 7.7% (nine of 117) were lost to follow-up. The rate of malignancy upgrade was 0.9% (one of 117 [95% CI: 0.02, 4.7]); one RS without concurrent atypia or malignancy demonstrated invasive carcinoma at surgical excision.

Conclusion: RS without atypia had a low upgrade rate.

Radial sclerosing lesions (RS) are uncommon, with a reported incidence of 0.03%–0.8% of core-needle breast biopsy results (2,3). After detection on imaging, diagnosis of RS is histologically confirmed, with histologic features frequently displaying a central fibroelastotic core with radiating spokes of ducts and lobules (4). There is unifying evidence that digital breast tomosynthesis (DBT) has improved sensitivity for lesion detection and characterization as compared with digital mammography (DM) (5–9) and has increased detection of RS (10,11).

DBT has also demonstrated higher detection rates of architectural distortions (AD) compared with DM (4,6,11–15). One of the common manifestations of RS is as AD, defined as spiculations radiating from a central point without a central mass (16). In the era of DBT, a greater proportion of DBT-detected ADs are RS compared with those detected with DM (11,13,17), with one study reporting 33% of DBT-detected ADs being RS, versus 12% of DM-detected ADs being RS (13). The positive predictive value for malignancy in DBT-detected ADs is lower than that for those detected with DM (13,18), given the greater proportion of RS.

Management of RS detected at core-needle biopsy remains controversial. RS with associated atypia have higher rates of malignant upgrade compared with RS without atypia (19–22) and are often excised. Multiple studies (23–25) suggest that RS found alone without associated atypia rarely upgrade to malignancy, with respective upgrade rates of 0% (zero of 80), 0.5% (one of 219), and 1.0% (one of 96). Most of these studies were prior to DBT or when DBT was less commonly available. As more patients are imaged with DBT and more RS are identified, breast imagers need methods to assess optimal patient management options. Concerns of patient management raise the question of whether patients with RS without atypia may be better served with follow-up imaging rather than surgical excision. This decision is particularly relevant as more RS are discovered with DBT biopsy (11), and many patients routinely undergo excision for RS without atypia (26).

We hypothesized that in the era of DBT, the rate of malignant upgrade for RS without atypia would be low enough to support imaging follow-up over surgical excision as the most optimal management practice. Given the rarity of these lesions, the estimates provided here are intended to inform future power and meta-analyses.

Materials and Methods

This was a Health Insurance Portability and Accountability Act–compliant retrospective study that was approved by our institutional review board. The need for informed consent was waived.

Study Sample

We conducted a retrospective review of our radiology and pathology databases at two tertiary breast centers to capture all instances of patients of any age with "ra-

Abbreviations

AD = architectural distortions, BI-RADS = Breast Imaging Reporting and Data System, DBT = digital breast tomosynthesis, DCIS = ductal carcinoma in situ, DM = digital mammography, RS = radial sclerosing lesion

Summary

Radial sclerosing lesions without associated atypia detected at screening had a low malignancy potential.

Key Points

- Only one radial sclerosing lesion (RS) without atypia (0.9%; one of 117 [95% CI: 0.02, 4.7]) was upgraded to an invasive carcinoma.
- All RS (100%; 30 of 30) without atypia followed with imaging (median, 3 years; range, 1–7 years) rather than excision were benign.

Keywords

Mammography, Breast

dial scar," "radial sclerosing lesion," or "complex sclerosing lesion" identified at core-needle biopsy of the breast between March 1, 2012, and December 31, 2017. We included all patients who had histologically verified RS, radial scar, or complex sclerosing lesion, excluding sclerosing adenosis, sclerosed papillomas, and incidental RS (for example, those completely excised and separate from the imaging target). Pathology reports were reviewed, and lesions were separated into two cohorts: those without associated malignancy or atypia and those with associated atypia. Lesions with other associated nonatypia pathologic features were categorized as RS without associated atypia. Pathologic slides were not rereviewed for this study.

Image Acquisition

DBT images were obtained with Selenia Dimensions units (Hologic), US with iU22 (Philips Healthcare), and MRI pre- and postcontrast enhancement with dedicated breast coils at 1.5 T (Siemens Magnetom Symphony) or 3 T (Siemens Verio).

Data Collection

The electronic medical record was accessed to identify the following: *(a)* patient age, *(b)* initial imaging findings prompting biopsy, *(c)* imaging modalities where findings were visible, *(d)* Breast Imaging Reporting and Data System (BI-RADS) assessment, *(e)* imaging modality used for biopsy, *(f)* biopsy needle gauge, *(g)* number of samples taken and pathologic results of needle biopsy, *(h)* results of excisional biopsy if performed, *(i)* time interval to most recent available follow-up imaging, *(j)* follow-up imaging modalities, and *(k)* follow-up imaging findings through October 2020.

Data were entered into the Health Insurance Portability and Accountability Act–compliant REDCap database (Vanderbilt University) (27). Upgrade to malignancy was defined as discovery of ductal carcinoma in situ (DCIS) or invasive carcinoma at the same site as RS upon surgical excision.

Imaging and Biopsy Interpretation

Imaging performed during the study period included screening and diagnostic DBT mammography (full-field digital mammography and DBT, 2012–2014; DBT and synthesized mammography, 2014–2017), US (diagnostic and screening), and MRI (high-risk screening and extent of disease in new cancer diagnoses). Imaging was interpreted by one of 13 fellowship-trained board-certified breast radiologists with 1–25 years of experience (including A.P.L. and L.D.). Image-guided biopsies were performed using the modality in which the lesion of interest was best visualized and was performed by the same group of breast radiologists. Histopathologic findings were interpreted by fellowship-trained board-certified pathologists, and histopathologic results for all lesions were collected from needle biopsy and surgical excisional biopsy reports. The interpreting pathologist determined whether the core-needle biopsy showed radial scar, complex sclerosing lesion, atypia, or malignancy according to standard pathologic standards applied in clinical practice. Radiologic-histopathologic concordance and discordance were determined by the radiologist performing the biopsy by assessing if histopathologic findings were representative of the imaging findings. At our institution, cases of RS are generally not presented in multidisciplinary conferences. In the case of discordance, the radiologist and pathologist may confer personally.

Statistical Analysis

Data were analyzed to determine the rate of malignancy upgrade upon surgical excision of RS. Given the rarity of these lesions, estimates are intended for subsequent meta and power analyses and, as such, are provided as counts and percentages. Clopper-Pearson interval estimate for upgrade was calculated for 95% confidence using PropCIs package with R 4.1.0 (R Foundation for Statistical Computing) (1). Comparisons between present study data and pooled results from the literature were conducted using generalized linear modeling assuming a binomial distribution with the GLIMMIX procedure with SAS software version 9.4 (SAS Institute). Demographics are provided at the patient level. Analyses were conducted by the statistical author (G.L.B.).

Results

Demographics

A total of 155 885 screening DBT were performed during the study period. A total of 142 patients with 146 biopsy-proven RS were identified from a search of the pathology database. One patient had three RS and two patients had two RS. All patients were women with median age of 58 years (range, 26–87 years). Average predicted lifetime risk of breast cancer for patients for whom Gail score was obtainable (n = 73) was 12.0% (range, 2.3%–38.6%).

Manifestation on Imaging

Of our cohort, the majority (71.9%, 105 of 146) of RS were found at screening DBT; 16.4% (24 of 146) were found at

Table 1: Imaging and Biopsy Characteristics of Patients Found to Have RS

Parameter	Data
Initial imaging modality RS visualized with	
Screening DBT	71.9 (105)
Diagnostic DBT	16.4 (24)
US or MRI	11.6 (17)
Initial imaging findings	
Mass at DBT	33.6 (49)
AD at DBT	27.4 (40)
Calcifications at DBT	25.3 (37)
Asymmetry at DBT	2.7 (4)
Mass at US	3.4 (5)
Enhancing mass at MRI	4.8 (7)
Nonmass enhancement at MRI	2.7 (4)
Management recommendation following biopsy when available	
Excision	81.5 (119)
Surgical consultation	4.1 (6)
Imaging follow-up	11.6 (17)
BI-RADS category at initial imaging	
BI-RADS 3	0.7 (1)
BI-RADS 4	97.3 (142)
BI-RADS 5	1.4 (2)
BI-RADS 6*	0.7 (1)
Biopsy needle gauge and modality	
9-gauge vacuum-assisted DBT	50.7 (74)
14-gauge spring-loaded US	24.7 (36)
12-gauge vacuum-assisted US	15.8 (23)
9-gauge vacuum-assisted MRI	6.2 (9)
Surgical excisional biopsy	2.7 (4)
Median no. of biopsy samples	
12-gauge vacuum-assisted US	3 (2–4)†
14-gauge spring-loaded US	5 (1–5)†
9-gauge vacuum-assisted MRI and DBT	6 (5–12)†

Note.—Unless otherwise indicated, data are percent of radial sclerosing lesions (RS), with numbers in parentheses (n = 146). BI-RADS = Breast Imaging Reporting and Data System, DBT = digital breast tomosynthesis.
*This lesion would have been better assessed as BI-RADS 4, as additional biopsy was recommended for a lesion distinct from the known malignancy.
†Data are median with range in parentheses.

diagnostic DBT. Of the 146 biopsy-proven RS, 33.6% (49 of 146) manifested on DBT images as a mass, 27.4% (40 of 146) as an AD, 25.3% (37 of 146) as calcifications, and 2.7% (four of 146) as asymmetry. A total of 3.4% (five of 146) were best visualized at US as a mass; 4.8% (seven of 146) were best visualized as an enhancing mass on MR images and 2.7% (four of 146) as nonmass enhancement. All patients underwent screening or diagnostic DBT initially, though the diagnostic lesion was better visualized with other modalities in the above cases of US or MRI findings (Table 1).

Imaging Assessment

A majority of the lesions (97.3%, 142 of 146) were categorized as BI-RADS category 4 by the radiologist, indicating a suspicious abnormality where biopsy should be considered. A total of 0.7% (one of 146) of the radiographic lesions were assessed as BI-RADS 3; 1.4% (two of 146) were assessed as BI-RADS 5, and 0.7% (one of 146) were assessed as BI-RADS 6 (patient with newly diagnosed breast cancer who underwent additional biopsy for indeterminate microcalcifications). This lesion would have been better assessed as BI-RADS 4, as additional biopsy was recommended for a lesion distinct from the known malignancy.

The radiologist who performed the biopsy recommended excision for 81.5% (119 of 146) of the detected RS. For 4.1% (six of 146) of the lesions, the radiologist recommended surgical consultation for consideration of excision versus imaging follow-up. For 11.6% (17 of 146) of the lesions, the radiologist recommended imaging follow-up. One lesion (one of 146, 0.7%) went directly to excision, as needle biopsy was not feasible. The radiologist recommendations were not available in 2.0% (three of 146), and 2.7% (four of 146) were assessed as discordant and recommended for excision, including one RS with atypia (Table 1).

A total of 79.5% (93 of 117) of the lesions without atypia at initial biopsy were recommended for excision and 0.9% (one of 117) of these were upgraded at excision. This was assessed as concordant following needle biopsy and was recommended for excision.

Biopsy Modalities

Details of image-guided biopsies, including needle type and number of samples obtained, are shown in Table 1.

Histopathologic Assessment

Of the 146 biopsy-proven RS lesions, 80.1% (117 of 146) demonstrated radial scar without associated atypia or cancer at the biopsy site and were classified as RS without atypia. The remaining 19.9% (29 of 146) had concurrent atypia at the biopsy site (Fig 1).

Of the 29 RS with atypia, 14% (four of 29) were upgraded to DCIS or carcinoma at the time of surgical excision. The remaining 86% (25 of 29) had no upgrade at surgical excision. Of the RS with atypia at initial biopsy, 41% (12 of 29) had atypia at excision: 21% (six of 29) had lobular neoplasia, and 48% (14 of 29) had atypical ductal hyperplasia, with some having more than one type of atypia at the biopsy site. Specific pathologic features at needle biopsy and surgical excision of the four RS lesions with atypia that were upgraded at surgical excision are presented in Table 2.

Of the 117 RS lesions without atypia, 66.7% (78 of 117) were surgically excised. The remaining 33.3% (39 of 117) were either lost to follow-up (7.7%, nine of 117) or showed benign findings at follow-up imaging (25.6%, 30 of 117), with median follow-up

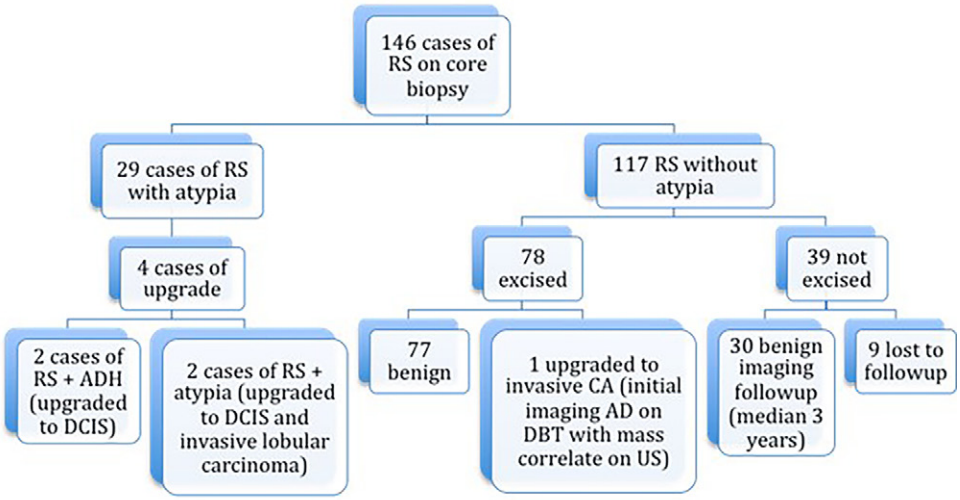

Figure 1: Flow diagram of cases of radial sclerosing lesions (RS) and radial scars with and without atypia at core biopsy and results of excision or imaging follow-up. AD = architectural distortions, ADH = atypical ductal hyperplasia, CA = carcinoma, DBT = digital breast tomosynthesis, DCIS = ductal carcinoma in situ.

Table 2: Biopsy and Histopathologic Findings in Patients with RS with Atypia at Initial Biopsy and Upgraded to Malignancy at Surgical Excision

Parameter	Patient 1	Patient 2	Patient 3	Patient 4
Clinical history	Screening	Screening	Biopsy-proven malignancy in right breast, 11-o'clock position	Biopsy-proven malignancy in right breast, 10-o'clock position
Imaging findings	Calcifications at DBT, right breast, 10-o'clock position	Architectural distortion at DBT, 9-mm mass at US, left breast, 2-o'clock position	14-mm focal area of enhancement at MRI, 8-mm mass at US, right breast, 4-o'clock position	Calcifications at DBT, right breast, 8-o'clock position
Biopsy modality	Stereotactic 9-gauge vacuum-assisted biopsy	US 14-gauge spring-loaded biopsy	US 14-gauge spring-loaded biopsy	Stereotactic 9-gauge vacuum-assisted biopsy
No. of biopsy samples	7	4	5	6
Initial needle biopsy pathology report	At least ADH, radial scar, calcifications present associated with ADH, and benign ducts and stroma	Complex sclerosing lesion with columnar cell alteration, hyperplasia, focal atypia, and focal microcalcifications	RS with atypia and microcalcifications	ADH and flat epithelial atypia involving a complex sclerosing lesion
Surgical excisional pathology report	DCIS, pTis pNx cMx, solid and cribriform type, nuclear grade 2–3 of 3, with focal necrosis and calcification, no evidence of invasive carcinoma	Invasive lobular carcinoma, ER+, PR+, Her2–	DCIS with cancerization of lobules, solid and cribriform type, nuclear grade 1–2 of 3	Focal DCIS with RS

Note.—ADH = atypical ductal hyperplasia, DBT = digital breast tomosynthesis, DCIS = ductal carcinoma in situ, ER+ = estrogen receptor–positive, Her2– = human epidermal growth factor receptor 2–negative, PR+ = progesterone receptor–positive, RS = radial sclerosing lesion.

of 3 years (range, 1–7 years). One hundred percent (30 of 30) of RS lesions without atypia that were followed with imaging alone were benign.

One RS without atypia at biopsy was upgraded to invasive carcinoma (0.9%, one of 117 [95% CI: 0.02, 4.7]). This lesion presented as AD at DBT (Fig 2A–2C) with a corresponding mass at US (Fig 2D, 2E). Mammogram obtained after biopsy clip placement shows the clip in the abnormality (Fig 2F, 2G), but the US biopsy image (Fig 2E) shows the needle slightly superficial to the mass. This patient had a history of contralateral breast cancer treated with segmental excision and radiation therapy 7 years prior. At excisional biopsy, a 7-mm estrogen receptor–positive,

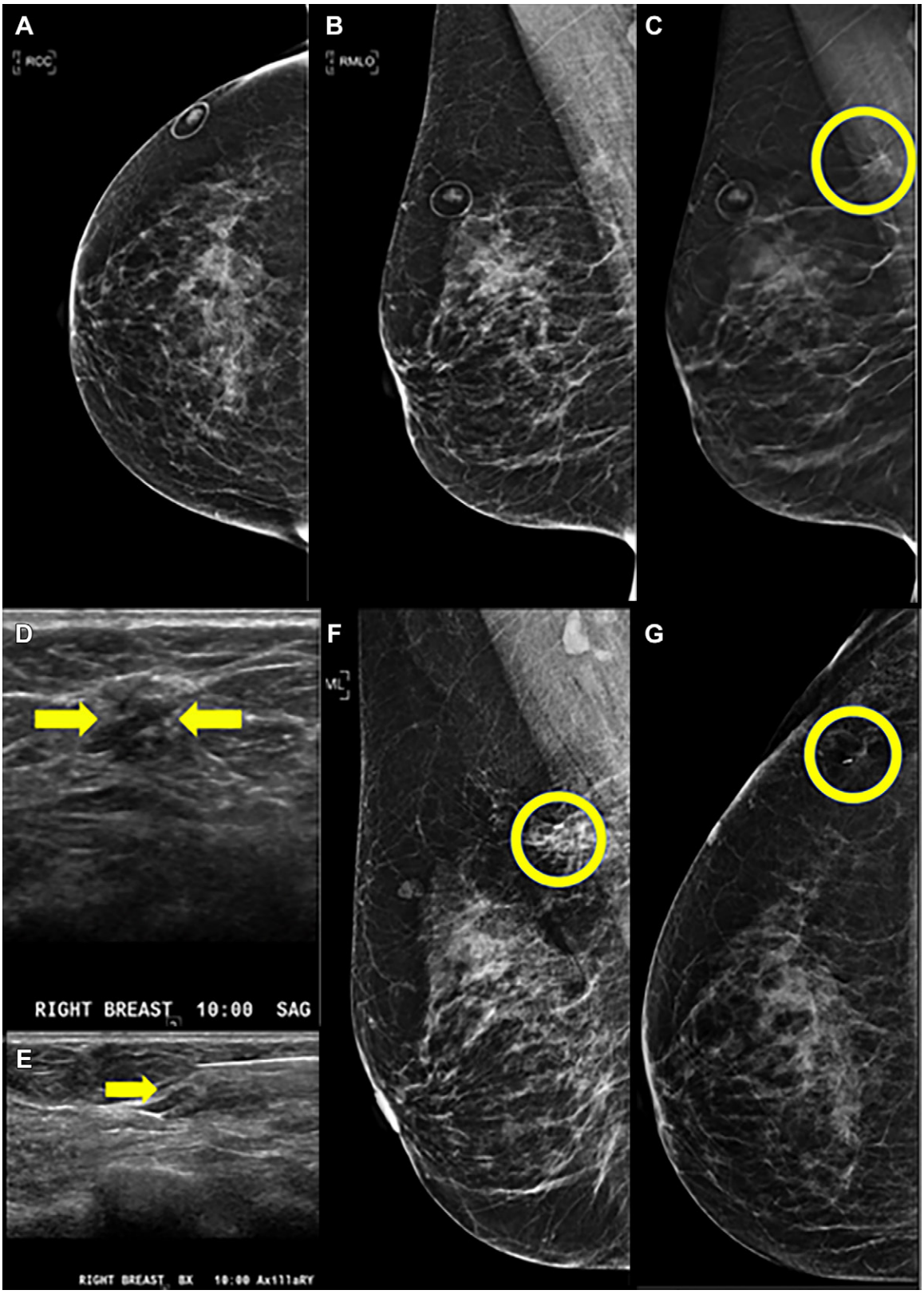

Figure 2: Images in a 66-year-old woman with previous history of left breast cancer treated with segmental excision and radiation therapy 7 years prior. Digital breast tomosynthesis (DBT) helped detect radial sclerosing lesion (RS) without atypia in the contralateral (right) breast, which was upgraded to invasive carcinoma after surgical excision. **(A)** Craniocaudal (CC) digital mammogram and **(B)** mediolateral oblique (MLO) digital mammogram as well as **(C)** MLO DBT views. Architectural distortion with possible associated mass in the upper right breast posteriorly was optimally observed on DBT MLO view (circle). **(D, E)** Sagittal and biopsy US images show a subtle 7-mm hypoechoic mass (arrows) corresponding to the DBT finding. **(F, G)** Postbiopsy mediolateral and laterally exaggerated CC digital mammograms demonstrate clip placement within the area of architectural distortion. Core biopsy returned radial scar, which was assessed as concordant. Surgical excision was recommended. Final surgical excisional pathologic analysis demonstrated a 7-mm estrogen receptor–positive, progesterone receptor–positive, human epidermal growth factor receptor 2–negative, invasive tubular carcinoma Nottingham grade I of III with no lymphovascular invasion, which was identified adjacent to, but distinct from, the biopsy needle track.

progesterone receptor–positive, human epidermal growth factor receptor 2–negative, invasive tubular carcinoma Nottingham grade I of III with no lymphovascular invasion was identified adjacent to, but distinct from, the biopsy needle track. Sampling error likely contributed to this upgrade.

Discussion

Conventional two-dimensional mammography has been a stalwart of breast radiology practice. With the advent of DBT, this new technology is now the predominant form of screening in 41.8% of hospital referral regions in the United States and has improved the sensitivity of screening mammography and our ability to characterize lesions (5–9,28). As widespread clinical use of DBT has identified more RS (4,6,11–13), appropriate management of newly detected RS remains unclear. The purpose of this study was to determine the rate of upgrade to malignancy in RS without atypia and with atypia during a study period when all mammography was performed with DBT. We found that the majority (80.1%, 117 of 146) of RS were without concurrent atypia or malignancy and that the rate of malignancy upgrade among those lesions was minimal (0.9%, one of 117). In contrast, the rate of upgrade was 14% (four of 29) for RS with associated atypia. The proportion of RS without atypia or malignancy that we found (80.1%) is comparable to other studies (reported at 75% [91 of 157], 81% [77 of 95], and 87% [76 of 88]) (or 80.1% [95% CI: 62.3, 90.8] vs pooled: 71.8% [95% CI: 60.2, 81.0]; $P = .19$) (29–31, respectively). The proportion of RS with associated atypia we found (19.9%, 29 of 146) was also comparable to other studies reporting 25% (66 of 157), 19% (18 of 95), and 13% (12 of 88) (or 19.9% [95% CI: 9.2, 37.7] vs pooled: 28.2% [95% CI: 19.0, 39.8]; $P = .19$) (29–31, respectively).

The upgrade rate for RS associated with atypia in this study was 14%, which is within the range of upgrade rates reported previously (upgrade rate of 35% [38 of 108] for RS with atypical ductal hyperplasia [32] and upgrade rates of 17% [one of six] and 10% for RS with atypia [five of 49] [33,34]). These upgrade rates support surgical excision as an optimal management decision for patients with RS with atypia at biopsy.

Our very low upgrade rate of 0.9% (one of 117) for RS without atypia at biopsy strongly supports imaging follow-up over surgical excision as the best treatment for these patients. Similar upgrade rates have been reported in other studies (0% [zero of 92], 0.9% [one of 107], 1.9% [two of 105] 1% [one of 97]) for RS without atypia or malignancy at biopsy (26,32,33,35, respectively). In one study of DBT-biopsied RS by Martaindale et al, a similar upgrade rate of 2.8% (one of 36) was reported for cases without atypia at biopsy (33). Interestingly, Rakha et al demonstrated that the upgrade rate for RS and concurrent atypical ductal hyperplasia was similar to the upgrade rate of atypical ductal hyperplasia alone (32), supporting the hypothesis that atypical ductal hyperplasia is likely the main contributor to malignant potential.

An earlier study from our center (23) identified 100 RS without atypia before the widespread use of DBT; 0% (zero of 100) of these were upgraded to malignancy, though only 41 underwent surgical excisional biopsy. In contrast, in this current study, the majority of RS were detected with DBT, and the majority of biopsies were obtained with DBT guidance. This is not surprising, as DBT has been shown to help detect more AD and RS (4,6,11–13).

As Cohen et al postulated, biopsy sampling error may contribute to radiologic-histopathologic discordance and to false-negative findings (31,32,36). Our single upgraded RS without atypia was 7 mm in size and had three samples taken with a 12-gauge needle. Excisional histopathologic analysis demonstrated the biopsy needle tracked adjacent to, but not involving, the invasive carcinoma. In addition, US images from the biopsy show the needle was likely superficial to the targeted mass, thus sampling error likely contributed to this upgrade. While some studies have shown that taking more than 12 samples at biopsy (19,37) reduces the likelihood of missed associated carcinoma, AD poses a challenge with regard to sampling error, as the spiculations and distortion can extend over a fairly substantial distance. Another study demonstrated that a majority of RS upgrades had a needle track that missed the nearby malignancy by 6 mm or less (37). The single upgraded lesion in this study likely falls into this category. Precise needle targeting is critical to decreasing false-negative biopsy results.

In our study, 30 RS lesions without atypia did not undergo surgical excision; all had stable, benign imaging findings for a median duration of 3 years following biopsy, strongly supporting benignity. Another study demonstrating similar results is Kraft et al, where 50 of 50 patients undergoing active surveillance instead of excision did not progress on follow-up imaging (35). This is a larger cohort than in previous studies followed with imaging alone rather than surgical excision (23,33, 34, 38). For example, in Martaindale et al, 13 lesions were followed successfully for a median of 18 months with benign findings (33). The majority (66.7%, 78 of 117) of RS without atypia in our study were surgically excised. Replacing surgical excisions with follow-up imaging could have positive mental, emotional, and cosmetic outcomes for patients, with minimal risk of a missed cancer. Notably, we had nine patients who were lost to follow-up. This emphasizes the need to recommend follow-up with imaging carefully; establishing benignity in vulnerable populations who may have sporadic health care access necessitates a shared discussion of the feasibility of imaging follow-up. Increasing data regarding the minimal upgrade rates of RS without atypia in the DBT era may help inform management recommendations, potentially allowing more lesions to safely be followed with imaging rather than undergoing surgical excision.

This study was limited in its ability to recommend management practice given the small sample size. These are inherent limitations when studying an uncommon pathologic state at a small number of centers, though it does examine a larger cohort than some previous studies (33,35,39). In addition, nine patients were lost to follow-up; the upgrade rate could thus potentially be higher than the one reported. The radiologists interpreting imaging and performing needle biopsies were all fellowship-trained breast radiologists; thus, the results may not generalize to a general radiology practice. Additionally, we did not consider how other factors, such as the presence of multiple radial scars, distantly located concurrent cancer, or the unique breast cancer risk

of the individual, may affect outcomes. With the small numbers of cases, it would be difficult to discern significance for any of these metrics. The one case of upgrade did have previously diagnosed contralateral breast cancer 7 years prior.

RS without atypia diagnosed at core-needle biopsy after DBT screening had a very low (0.9%) rate of upgrade to malignancy. Excision of RS without atypia may not be warranted; imaging follow-up of these lesions may be a reasonable management plan instead.

Author contributions: Guarantors of integrity of entire study, P.Y., A.P.L.; 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; agrees to ensure any questions related to the work are appropriately resolved, all authors; literature research, P.Y., L.D., A.P.L.; clinical studies, P.Y., L.D., A.P.L.; statistical analysis, P.Y., G.L.B.; and manuscript editing, all authors

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