



Radial Scars Without Atypia Diagnosed at Percutaneous Core Needle Breast Biopsy: Support for Imaging Surveillance

Dogan S. Polat¹, Stephen J. Seiler¹, Jordan Goldberg², Rishi Arya³, Emily E. Knippa¹, Sally H. Goudreau¹

¹Department of Diagnostic Radiology, University of Texas Southwestern Medical Center, Dallas, Texas

²Solis Mammography, Dallas, Texas

³Seacost Radiology PA, Dover, New Hampshire

ABSTRACT

Objective: Radial scar (RS) is a low-risk breast lesion that can be associated with or mimic malignancy. Management guidelines remain controversial for patients with RS without atypia on core needle biopsy (CNB). The aim was to evaluate the upgrade rate of these lesions and factors associated with malignancy risk and excision rate to more definitively guide management.

Materials and Methods: In this retrospective study, 123 patients with RS without atypia, diagnosed with CNB between January 2008 to December 2014 who were either referred for surgical excision or followed-up with imaging, were reviewed. The differences in clinical presentation, imaging features, and biopsy technique among the benign RS patients and those upgraded, as well as the excised versus the observed patients were compared.

Results: Of 123 RS reviewed, 93 cases of RS without atypia as the highest-grade lesion in the ipsilateral breast and with either 24-month imaging follow-up or surgical correlation were included. Seventy-four (79.6%) lesions were surgically excised and 19 (20.4%) were followed-up for at least 24 months. A single upgrade to malignancy (1%) and 15 upgrades to high-risk lesions (16%) were found. There was no association of any upgraded lesion with presenting symptoms or imaging features. The use of vacuum-assistance and larger biopsy needles, along with obtaining a higher number of samples, was associated with fewer upgrades and lower surgical excision rates.

Conclusion: The upgrade rate of RS without atypia in our population was low, regardless of the imaging features and biopsy technique utilized. Close imaging surveillance is an acceptable alternative to surgical excision in these patients.

Keywords: Radial scar; breast cancer; biopsy; ultrasound; mammography; upgrade

Cite this article as: Polat DS, Seiler SJ, Goldberg J, Arya R, Knippa EE, Goudreau SH. Radial Scars Without Atypia Diagnosed at Percutaneous Core Needle Breast Biopsy: Support for Imaging Surveillance. Eur J Breast Health 2023; 19(1): 76-84

Key Points

- Upgrade rate to malignancy was low in patients with radial scar lesions without atypia (1%).
- Close imaging surveillance rather than surgical excision is an acceptable management option for radial scar lesions without atypia.
- Vacuum-assisted biopsy and a larger number of samples allow better evaluation of the lesion and facilitate the follow-up decision for radial scars without atypia.

Introduction

A radial scar (RS), also known as a radial sclerosing lesion or complex sclerosing lesion when larger than 1 cm, is a proliferative, low-risk breast lesion characterized histologically by a central fibroelastic core with ducts and lobules radiating outward, giving the lesion its characteristic stellate appearance (1, 2). This appearance often translates mammographically to architectural distortion or a spiculated mass, commonly prompting core needle biopsy (CNB). Atypia or other high-risk breast lesions, when found in conjunction with a RS, are strong risk factors for malignancy with upgrade rates, defined as rate of transformation into malignant or other high-risk breast lesions, reportedly varying widely (0–20%) (3–5). It is therefore standard practice to surgically excise all RS with atypia found with percutaneous CNB, although most of these procedures will yield benign disease. The management of benign RS without atypia diagnosed with image-guided CNB remains controversial. Historically at our institution, we have referred patients with benign RS without atypia for surgical excision if vacuum assisted biopsy (VAB) was not

Corresponding Author:
Dogan S Polat; Dogan.polat@utsouthwestern.edu

Received: 22.09.2022
Accepted: 18.11.2022
Available Online Date: 01.01.2023

performed or if fewer than 12 core samples were obtained, regardless of the biopsy technique used. More recently, however, after institutional review of all RS diagnosed at CNB, we now return patients without atypia to screening and only review cases of RS with atypia at our Multidisciplinary Breast Conference to determine whether these patients will be referred for surgical excision or mammographic follow-up. Although benign RS without atypia lesions carry a low cancer upgrade risk, treatment decisions remain non-uniform, often based on surgeon, radiologist, and patient preferences, patient clinical history and correlation of radiological and pathological characteristics (2-5).

Multiple small series have shown that, in the appropriate setting, RS diagnosed as benign at CNB can be safely followed-up (4, 6-9). Biopsy and pathologic criteria, such as the absence of atypical hyperplasia in biopsy samples, retrieval of at least 12 specimens, and extensive sampling with vacuum-assisted large-core biopsy devices have been identified as factors that may spare RS lesions from surgical excision (6, 9-11). National Health Service, Arbeitsgemeinschaft Gynäkologische Onkologie guidelines and the Swiss Consensus recommend excision of RS lesions with or without atypia with VAB, followed by routine screening (12-14). Alternatively, some studies have recommended that all RS be surgically excised because of possible underestimation of malignancy due to sampling limitations (15-17). Additionally, it can be challenging for pathologists to histologically identify a RS, as the presence of glands trapped at the center of this lesion can be confused with entities such as tubular carcinoma (18).

Studies looking at RS without atypia range in size from 50–400 cases, with most of them focusing on the pathologic features of the lesion (3-5, 7-9, 19-22). The primary aim of the present relatively large cohort study was to evaluate the surgical upgrade rate to malignancy of RS without atypia diagnosed with image-guided percutaneous CNB from a radiologic standpoint. Secondarily, we aimed to understand if any clinical or imaging factors correlate with the decision to excise the lesion and/or the rate of upgrade to malignancy to better understand the current variable practice patterns and consequently develop more standardized management algorithms.

Materials and Methods

This study is approved by the University of Texas Southwestern Institutional Review Board (IRB) with IRB number “STU 122013-053”. In this study, we retrospectively reviewed all cases of RS without atypia detected by mammography, ultrasound (US) or magnetic resonance imaging (MRI) and confirmed with CNB or VAB, between January 1, 2008 to December 31, 2014 at our comprehensive hospital-based imaging centers: A safety-net community hospital, in which patients from a wide range of socioeconomic backgrounds are cared for, regardless of their insurance status or financial ability to pay for the care they received, and a tertiary-care university hospital.

Patient Selection and Data Collection

Patients with a pathologic diagnosis of RS without atypia as the highest-grade lesion in the ipsilateral breast and with either 24-month imaging follow-up or surgical correlation were included in this study. Patients with other ipsilateral high-risk breast lesions, including atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), flat epithelial atypia (FEA), and/or lobular carcinoma in situ (LCIS), ductal carcinoma *in situ* (DCIS) or invasive breast cancer were excluded from the study, while patients with contralateral high-risk lesions or breast cancer were not excluded. If a lesion was unchanged

with 24 months or longer imaging follow-up, it was considered benign and the patient returned to routine screening. Patients who were not compliant with a 24-month follow-up were excluded, if surgery was not performed instead. Surgical pathologic correlation included both focal lesion excision and mastectomy specimens.

The imaging and pathology report was reviewed for each case by a radiologist specializing in breast imaging. For cases deemed concordant, pathology was not re-reviewed. If the RS was thought to be an incidental finding (for instance, RS diagnosed with several other associated benign pathologies), pathology was re-reviewed to confirm that the targeted lesion seen with imaging represented the dominant RS without atypia diagnosed pathologically.

Medical records were reviewed for patient demographics, patient symptoms (asymptomatic, palpable mass, pain bloody or non-bloody nipple discharge), history of ipsilateral or contralateral breast cancer, imaging modality of lesion detection, imaging guidance method for biopsy, radiologic lesion size, type of biopsy device (spring-loaded versus vacuum), needle size, and number of specimens obtained. Our cohort includes patients referred from screening and patients presenting with symptoms. Imaging and pathology reports were reviewed for all lesions. Histologic lesion size (mm), presence or absence of atypia, radiological lesion type (architectural distortion, focal asymmetry or mass, calcifications, MRI mass, MRI non-mass enhancement), and histologic classification of cancers (invasive cancer or *in situ* lesion) or high-risk lesions (ADH, ALH, FEA, LCIS) found upon surgical excision were recorded for each lesion.

Imaging and Biopsy Techniques

Digital mammographic examinations performed included at least standard mediolateral oblique and craniocaudal images (Hologic Selenia and Hologic Selenia Dimensions). Targeted sonography was performed using a broadband, 5–12 MHz linear array transducer (HDI 5000, GE E9, Philips iU22). Contrast enhanced breast MRI was performed using a 1.5 T magnet (GE 450W Optima and Philips Achieva). Percutaneous biopsy was performed using MRI, US or stereotactic (Hologic, Marlborough, MA, USA) guidance and a clip was placed to mark the biopsy site. In patients with mammographically detected microcalcifications, a specimen radiograph was obtained to confirm the presence of calcifications in the obtained biopsy samples. The biopsies were performed either with vacuum-assisted or spring-loaded devices.

All examinations were performed and/or interpreted by fellowship-trained breast radiologists, with 4–38 years of practice experience.

Reference Standard

The surgical pathology report for each excised lesion was classified according to the highest-grade lesion in one of the following categories: malignant (DCIS or invasive carcinoma), high-risk (ADH, ALH, FEA, or LCIS), or benign (proliferative changes without atypia, other benign lesions). These final pathology results upon excision served as the reference standard. Also, imaging follow-up without radiologic upgrade for >24 months are accepted as reference standard.

Data Storage and Statistical Analysis

Data were stored using a computerized spreadsheet (Microsoft Excel; Microsoft Corporation, Redmond, WA, USA). Statistical analysis was performed according to the reference standard with commercial software (SPSS, IBM Inc., Armonk, NY, USA). Differences in

categorical variables, imaging features and biopsy techniques among the benign vs upgraded (to malignancy or high-risk lesions) and observed vs excised RS were compared using the chi-square test. The number of biopsy cores obtained and biopsy needle sizes were categorized as <12 vs ≥12 cores and <14-gauge vs ≥14-gauge, respectively. The means, standard deviations (SD), and ranges of continuous variables (lesion size, patient age) were compared across the groups using the t-test and Wilcoxon–Rank Sum test.

Results

Patient and Lesion Characteristics

Of the 123 RS without atypia reviewed, 93 lesions diagnosed at percutaneous biopsy in 92 women were included in the study. The other 30 (24.4%) lesions were excluded due to history of ipsilateral breast cancer (n = 5) or insufficient imaging or surgical follow-up (n = 25). The patient selection is illustrated in a flowchart in Figure 1.

Among the 93 lesions from 92 patients included in the study, 79 (85%) patients were asymptomatic and were referred from screening, while 14 (15%) patients presented with symptoms. Of these, 74 (79.6%) lesions were surgically excised and 19 (20.4%) were followed-up with imaging for at least 24 months. The median (range) length of follow-up was 41 (24–61) months. The mean ± SD radiologic lesion size was 13.7±8.6 mm (range: 3–50 mm) and mean ± SD patient age was 51.5±9.3 years (range: 29–71 years). Of the 82 lesions diagnosed either with mammography or breast US, 31 (33.3%) were identified as architectural distortion, 24 (25.8%) were calcification and 27 (29%) were focal asymmetry or mass. Of the 59 VABs performed, 44 (74.6%) were stereotactic, 8 (13.5%) were US-guided and 7 (11.8%) were MRI guided. The other 34 lesions were biopsied with spring-loaded devices (≥14 gauge). Lesion features and information about detection and biopsy modalities are summarized in Table 1.

Factors Associated with Surgical Upgrade

Only one lesion among 93 [1.1%, 95% confidence interval (CI), 0–5.8%] was upgraded to malignancy after surgery. This single case of malignancy (intermediate grade DCIS) presented in a 62-year-old, asymptomatic woman as a 1 cm area of architectural distortion detected independently with both screening mammography and automated whole breast screening sonography. Six 14-gauge biopsy samples were obtained using US-guidance (Figure 2).

There were 15 (15/93, 16.1%, 95% CI: 9–25%) cases of high-risk pathology identified after surgical excision. These cases included ADH, ALH, FEA, and LCIS. There was no significant association of these lesions with upgrade to either atypia or malignancy with respect to patient symptoms, imaging modality of detection, lesion size, imaging guidance method for biopsy, type of biopsy device, needle size, or number of specimens. A meaningful statistical analysis could not be performed due to the limited number of upgrades. The mean lesion size of benign lesions was 13.2±8.5 mm and that of high-risk lesions was 15.3±9.0 mm (p = 0.4). The mean patient age was 51.0±9.2 years in the benign group and 53.5±9.5 years in the high-risk group (p = 0.3). The features of the high-risk lesions and the one malignant lesion are summarized in Table 2.

None of the 19 lesions followed-up for 24 months or longer developed any suspicious interval change and all were therefore considered benign at the end of the follow-up period. A case successfully followed up for 24 months is demonstrated in Figure 3.

Factors associated with Excision

The surgical excision rate was significantly lower in the university hospital (30/45, 66.7%) patients as compared to the safety net hospital patients (44/48, 91.7%) [odds ratio (OR): 0.18, 95% CI: 0.05–0.6, p = 0.003]. MRI masses (6/6, 100%), architectural distortion (27/31,

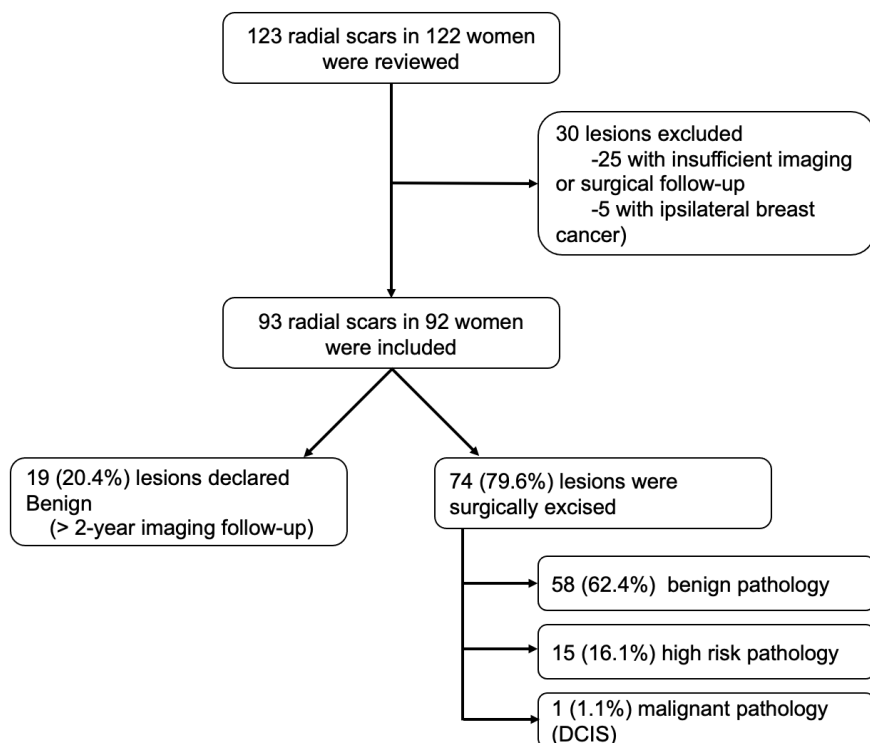


Figure 1. Flowchart describing patient selection

Table 1. Lesion and biopsy features

Features		Frequency (%)
Hospital	University Hospital	45 (48.4)
	Safety Net Hospital	48 (51.6)
Presenting symptom	Asymptomatic	79 (85)
	Mass	11 (11.8)
	Pain	1 (1.1)
	NBNDC	1 (1.1)
	BNDC	1 (1.1)
	Architectural distortion	31 (33.3)
Lesion type	Calcification	24 (25.8)
	Focal asymmetry or mass	27 (29)
	MRI mass	6 (6.5)
	MRI non-mass enhancement	5 (5.4)
	US	9 (9.2)
Detection modality	Mammography	73 (78.5)
	MRI	11 (11.8)
	US	41 (44.1)
Biopsy modality	Stereotactic	45 (48.4)
	MRI	7 (7.5)
VAB	Yes	59 (63.4)
	No	34 (36.6)
	9	53 (56.9)
Needle gauge	14	32 (34.4)
	Other	8 (8.6)
Number of biopsy samples ^a	<12	48 (51.6)
	≥12	41 (44)

NBNDC: non-bloody nipple discharge; BNDC: bloody nipple discharge; VAB: vacuum assisted biopsy; US: ultrasound; MRI: magnetic resonance imaging;
^a: This information is missing for 4 (4.3%) cases

87.1%) and palpable masses (23/27, 85.2%) were excised more frequently than calcifications without masses (15/24, 62.5%) and MRI non-mass enhancement (3/5, 60%) ($p = 0.07$). The surgery rate was significantly lower among VAB (43/59, 72.9%) compared to spring-loaded CNB (31/34, 91.2%) (OR: 0.26, 95% CI: 0.07–0.97, $p = 0.035$).

Although the biopsy modality was not significantly associated with the surgical excision rate ($p = 0.08$), lesions biopsied with smaller needles (≥ 14 gauge) were excised more frequently than those biopsied with larger needles (< 14 gauge) [31/34 (91.2%), 43/59 (72.9%), OR: 3.8, 95% CI: 1.0–14.4, $p = 0.03$]. The number of core samples obtained during biopsy was also significantly associated with the excision rate, with lesions sampled with less than 12 cores being excised more frequently than lesions sampled with greater than or equal to 12 cores [44/48 (91.7%) vs 29/41 (70.7%), OR: 11.0, 95% CI: 0.7–2.4, $p = 0.01$].

The mean size of the observed lesions was 12 ± 8.1 mm and that of the surgically excised lesions was 14.1 ± 8.6 mm ($p = 0.3$). The mean patient age was 54.6 ± 9.1 years in the follow-up group and 50.7 ± 9.2 years in the surgery group ($p = 0.1$). The presenting symptoms and radiographic lesion types were not significantly associated with the decision to excise. The features of excised vs observed lesions are further summarized in Table 3.

Discussion and Conclusion

The rate of upgrade to malignancy was 1% ($n = 1$) among the 93 RS lesions without atypia in our series. The single case upgraded to malignancy was shown to be an intermediate grade DCIS upon surgical excision identified in an asymptomatic 62-year-old patient sampled with a 14-gauge needle using US guidance. There were no cases of invasive malignancy identified. Sixteen percent (15/93, 16.1%) of high-risk lesions were detected upon surgical excision including ADH, ALH, FEA, and LCIS. None of the 19 lesions followed-up

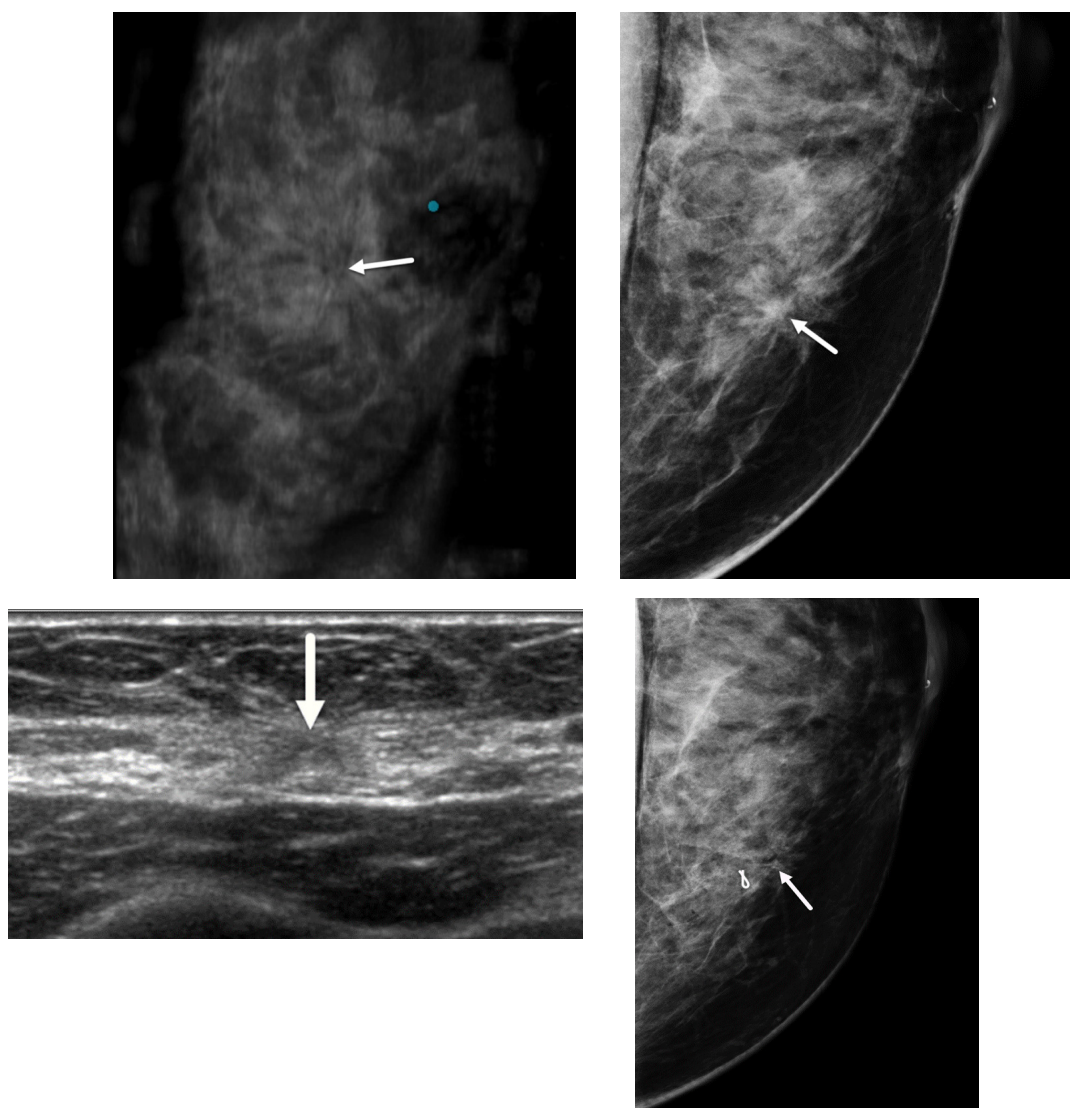


Figure 2. A benign radial scar case in a 62-year-old asymptomatic screening patient upgraded to DCIS upon surgical excision, **A.** Screening whole breast ultrasound revealed architectural distortion (arrow) in the lower inner quadrant of the left breast, **B.** Left craniocaudal (CC) image confirms distortion (arrow) medially within the left breast. **C.** Targeted ultrasound confirms an irregular hypoechoic mass with obscured margins (arrow) in the 9 o'clock left breast, located 4 cm from the nipple. An ultrasound-guided biopsy was performed with a 14-gauge core needle biopsy device, taking 6 cores. The pathology yielded benign radial scar with fibrocystic changes associated with microcalcifications. **D.** Left CC image following the biopsy confirms the placement of a ribbon-shaped clip (arrow) in close proximity to the distortion. Subsequent wire-guided localization (not shown) and excision also revealed intermediate grade ductal carcinoma *in situ* with positive margins requiring re-excision

DCIS: ductal carcinoma in situ

with imaging for at least 24 months developed malignancy. Our results agree with and further support those of other studies suggesting that concordant RS without atypia diagnosed with CNB have a low malignancy risk and can be safely followed-up rather than excised (9, 15, 20, 22-25).

Studies addressing the malignant upgrade of percutaneously diagnosed RS without atypia have reported variable upgrade rates, ranging from 0 to 20% (3-5, 8, 9, 19, 20, 26, 27). Such variability is attributable primarily to limited study cohort sizes, differences in inclusion criteria, and possible biases when making excision decisions. In addition to

differences in sample size, variability in pathologists' interpretations of core biopsy specimens may also account for the differing results, as it can be challenging to distinguish RS from low grade carcinoma, especially those of tubular subtype (28). Despite numerous published studies, management of RS remains controversial. Radiologists and surgeons still routinely recommend excision of RS. Moreover, with tomosynthesis becoming commonplace in both the screening and diagnostic setting, there is increasing detection of architectural distortion that frequently yield RS. Thus, this study is more relevant than ever and has increasing ramifications on health care costs and overall patient care.

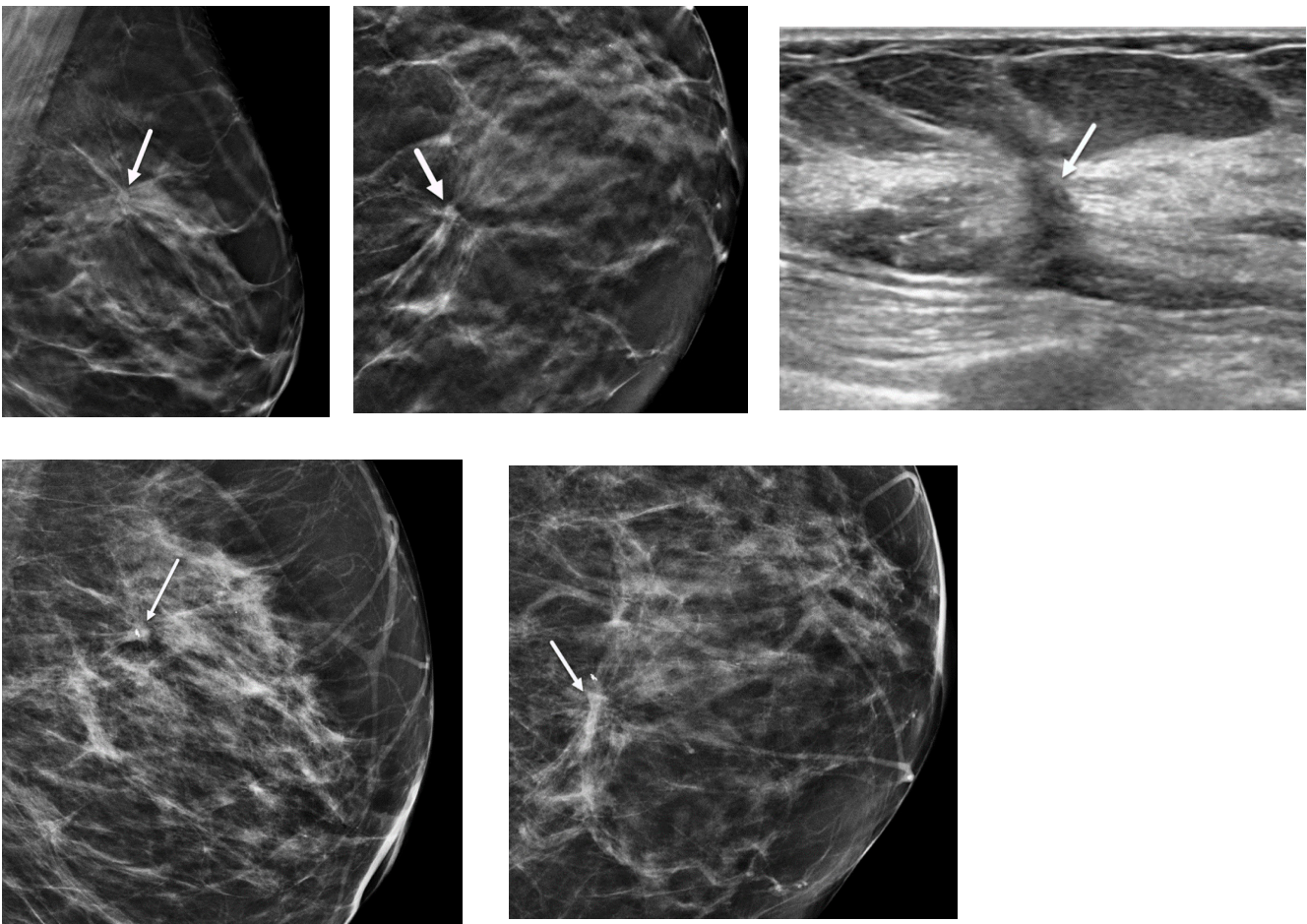


Figure 3. Radial scar case successfully managed with 24-month imaging follow-up in a 53-year-old woman who presented for screening mammography prior to planned lung transplantation, **A and B.** Left MLO and CC tomosynthesis slices depict architectural distortion (arrows) in the upper inner quadrant of the left breast. **C.** A targeted ultrasound of the distortion reveals an irregular hypoechoic mass with spiculated margins (arrow) in the 11 o'clock left breast, located 2 cm from the nipple. An ultrasound-guided biopsy was performed with a 14-gauge core needle biopsy device, taking three cores. The pathology yielded benign radial scar without proliferative changes. **D and E.** Left MLO and CC digital mammogram images 3 years after the initial biopsy show stable architectural distortion (arrows) and a nearby biopsy clip in the upper inner quadrant of the left breast

MLO: mediolateral oblique; CC: craniocaudal

Our study further supports imaging follow-up of RS as reasonable management, in that these lesions have a low probability of causing clinically overt disease (29-32). In our series, there was no significant difference in upgrade to atypia or malignancy with respect to patient symptoms, imaging modality of detection, lesion size, imaging guidance method for biopsy, type of biopsy device, needle size, or number of specimens. In contrast, some smaller studies have shown patient age, lesion size and calcifications within the lesion to be associated with an increased malignancy risk of these RS lesions (4, 5, 19).

The use of percutaneous CNB for the initial evaluation of clinically occult breast lesions is now widespread and is a practical alternative to open surgical biopsy for most patients. In previous studies, investigators have reported high rates of concordance between the histologic findings of percutaneous biopsy and surgical biopsy (9, 33-35). Compared with spring-loaded biopsy needles, VAB usually provides pathologists with larger individual samples, thereby inherently improving visualization of the architecture of RS (8). It has been suggested that the highest diagnostic yield with stereotactically-guided VAB can be achieved with

12 specimens per lesion and that this yield is not improved with more than 12 specimens (36). Although we did not observe any significant association between upgrade rate and the use of vacuum-assistance, biopsy modality guidance, needle size or number of cores obtained; the surgery rate was significantly lower when vacuum-assistance or a larger needle (<14 gauge) was used or when more cores were obtained (≥ 12 cores). Although there were no firmly adopted policies at either facility regarding excision or imaging follow-up of RS, these identifiable procedural parameters seen to be associated with excision of these lesions are important to highlight in order to better understand the current variable practice patterns and consequently develop more standardized management algorithms. This trend in and of itself introduces a bias regarding excision decisions.

Limitations of our study include apparent bias, as above, in regard to the decision to surgically excise lesions. Also, we did not perform pathologic re-evaluation to confirm the diagnoses of RS without atypia, except for pathologically discordant lesions and suspected incidental lesions. Additionally, if a patient in our cohort was not an established patient of a breast surgeon and the radiologist recommended follow-up

Table 2. Features of lesions upgraded to malignancy or atypia after surgical excision

	Site	Modality diagnosed	Lesion type	Modality biopsied	Age	Needle gauge	No of samples	Size (mm)	Vacuum biopsy?	Symptoms
M1	UH	Mammo	AD	US	62	14	6	10	No	Asymptomatic
HR1	SNH	Mammo	AD	US	52	14	4	15	No	Asymptomatic
HR2	SNH	Mammo	AD	Stereo	63	9	7	5	Yes	Asymptomatic
HR3	SNH	Mammo	AD	Stereo	55	9	12	13	Yes	Asymptomatic
HR4	SNH	Mammo	Calc	Stereo	40	9	12	35	Yes	Asymptomatic
HR5	SNH	Mammo	AD	US	61	14	3	8	No	Asymptomatic
HR6	SNH	Mammo	AD	Stereo	42	9	12	23	Yes	Asymptomatic
HR7	SNH	Mammo	AD	Stereo	39	9	12	12	Yes	Pain
HR8	UH	Mammo	Calc	Stereo	53	9	12	4	Yes	Asymptomatic
HR9	UH	Mammo	Calc	Stereo	67	9	12	10	Yes	Asymptomatic
HR10	UH	Mammo	AD	Stereo	72	9	12	25	Yes	Asymptomatic
HR11	UH	US	Mass	US	60	14	N	5	No	Asymptomatic
HR12	UH	Mammo	AD	US	48	14	7	25	No	Asymptomatic
HR13	UH	Mammo	Calc	Stereo	53	9	12	20	Yes	Asymptomatic
HR14	UH	MRI	NME	MRI	46	9	12	10	Yes	Mass
HR15	UH	US	Mass	US	49	14	4	20	No	BNDC

M1: malignant lesion 1; HR1-15: high-risk lesions 1 to 15; SNH: safety Net Hospital, UH: university hospital, Stereo: stereotactic; AD: architectural distortion; Calc: calcification; BNDC: bloody nipple discharge; N: this information is missing for this case

after CNB based on concordance and confidence in adequate sampling of the RS, that patient was not referred to a surgeon and excision was not performed. If, however, a patient was already established with a breast surgeon, the radiologist recommendation of excision versus imaging follow-up was noted, but the ultimate decision to excise was based on the surgeon and patient preference.

Notably, the excision rate was higher in the safety net hospital population compared to the university hospital (91.7% vs 66.6% $p = 0.003$). These variable excision rates are largely the result of the varying management of these lesions by the surgeons at our institution. One explanation for this difference in management is that the follow-up of safety net patients has proven to be difficult due to observed compliance issues within that population stemming from lack of transportation and language barriers. Additionally, the management of asymptomatic lesions, not otherwise managed by a surgeon, is driven by the radiologist and the radiologists' recommendations after biopsy of a benign RS without atypia was not consistent or formally standardized for concordant lesions. If the imaging appearance was discordant with the biopsy results, or if clinical symptoms warranted excision, these patients were referred for surgical consultation. With the present study, it was hoped to determine if any imaging features and/or the biopsy technique correlated with the decision to excise the lesion in order to better understand these discrepancies and hopefully develop more uniform management algorithms.

Another possible limitation of this study was the use of a 24-month imaging follow-up period as a surrogate for benign status. Although it is possible that a RS can develop associated high-risk lesions or malignancy beyond two years, it is highly unlikely (37). Furthermore, the median follow-up period in our study was 41 months ($n = 19$).

In addition, practice guidelines regarding management of RS lesions without atypia was changed within the timeframe of our study, which could have caused variations in the management. Another potential limitation is that lesions without surgical correlation or 24-month imaging follow-up were excluded from the study ($n = 27$), decreasing our cohort size and statistical power. Given that our academic site is a tertiary care center, a subset of these patients may have returned to their referring institutions after the diagnosis and may not be truly lost to follow-up. The possibility of subsequent breast cancer among these patients could not be ruled out, as this information was not provided to us. Lastly, although this study included seven years of data and 93 RS, the relatively low rate of upgrade to malignancy among RS resulted in a lack of statistical power for finding predictors of upgrades. Future studies using an enriched population of RS cases with upgrade to malignancy may reveal factors associated with the malignancy risk of RS.

This study represents one of the largest multi-institution studies of RS without atypia diagnosed with CNB. RS without atypia has a sufficiently low upgrade rate to malignancy (1%) and high-risk lesions (16%) that imaging surveillance seems to be an acceptable alternative to surgical excision in the absence of another high-risk lesion that could change management. At our institution patients upgraded to high-risk lesions are individually presented at our Multidisciplinary Breast Conference to discuss the need for risk reduction chemoprophylaxis and/or enhanced imaging surveillance. Larger prospective studies or a meta-analysis of multiple studies may be helpful to determine if the patient's presenting symptoms, imaging features of the lesions or biopsy techniques are associated with the decision to excise and/or the upgrade rates.

Table 3. Features of excised vs observed lesions

Features		Surgery		p
		Yes (%)	No (%)	
Hospital	University Hospital (n = 45)	30 (66.6)	15 (33.3)	0.003
	Safety Net Hospital (n = 48)	44 (91.7)	4 (8.3)	
Presenting symptom	Asymptomatic (n = 79)	60 (75.9)	19 (24)	0.5
	Mass (n = 11)	11 (100)	0 (0)	
	Pain (n = 1)	1 (100)	0 (0)	
	NBND (n = 1)	1 (100)	0 (0)	
Lesion type	BND (n = 1)	1 (100)	0 (0)	0.07
	Architectural distortion (n = 31)	27 (87.1)	4 (12.9)	
	Calcification (n = 24)	15 (62.5)	9 (37.5)	
	Focal asymmetry or mass (n = 27)	23 (85.2)	4 (14.8)	
Detection modality	MRI mass (n = 6)	6 (100)	0 (0)	0.6
	MRI non-mass enhancement (n = 5)	3 (60)	2 (40)	
	US (n = 9)	8 (88.9)	1 (11.1)	
Biopsy modality	Mammography (n = 73)	57 (78.1)	16 (21.9)	0.08
	MRI (n = 11)	9 (81.8)	2 (18.2)	
	US (n = 41)	32 (71.1)	13 (28.9)	
VAB	Stereotactic (n = 45)	37 (90.2)	4 (9.8)	0.035
	MRI (n = 7)	5 (71.4)	2 (28.6)	
Needle gauge	Yes (n = 59)	43 (72.9)	16 (27.2)	0.03
	No (n = 34)	31 (91.2)	3 (8.8)	
	<14 (n = 59)	43 (72.9)	16 (27.1)	
Number of biopsy samples ^a	≥14 (n = 34)	31 (91.2)	3 (8.8)	0.001
	<12 (n = 48)	44 (91.7)	4 (8.3)	
	≥12 (n = 41)	29 (70.7)	12 (29.3)	

NBND: non-bloody nipple discharge; BND: bloody nipple discharge; ^a: This information is missing for 4 cases; VAB: vacuum assisted biopsy; US: ultrasound; MRI: magnetic resonance imaging

Ethics Committee Approval: The study was approved by the Southwestern Medical Center, Institutional Review Board (IRB-8843) (approval date: February 10, 2014, number: STU 122013-053).

Informed Consent: Retrospective study.

Peer-review: Internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: D.S.P, E.E.K., J.G., R.A., S.H.G., S.J.S.; Concept: E.E.K., S.H.G., S.J.S.; Design: D.S.P, E.E.K., S.H.G., S.J.S.; Data Collection and/or Processing: D.S.P, J.G., R.A.; Analysis and/or Interpretation: D.S.P, E.E.K., J.G., R.A., S.H.G., S.J.S.; Literature Search: D.S.P, J.G., R.A.; Writing: D.S.P, E.E.K., J.G., R.A., S.H.G., S.J.S.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

References

- Rosen PP. Rosen's Breast Pathology. Lippincott-Raven; 1997.p.465-477. [\[Crossref\]](#)
- Racz JM, Carter JM, Degnim AC. Challenging Atypical Breast Lesions Including Flat Epithelial Atypia, Radial Scar, and Intraductal Papilloma. *Ann Surg Oncol* 2017; 24: 2842-2847. (PMID: 28766216) [\[Crossref\]](#)
- Farshid G, Buckley E. Meta-analysis of upgrade rates in 3163 radial scars excised after needle core biopsy diagnosis. *Breast Cancer Res Treat* 2019; 174: 165-177. (PMID: 30460464) [\[Crossref\]](#)
- Ferreira AI, Borges S, Sousa A, Ribeiro C, Mesquita A, Martins PC, et al. Radial scar of the breast: Is it possible to avoid surgery? *Eur J Surg Oncol* 2017; 43: 1265-1272. (PMID: 28215506) [\[Crossref\]](#)
- Ha SM, Cha JH, Shin HJ, Chae EY, Choi WJ, Kim HH, Oh HY. Radial scars/complex sclerosing lesions of the breast: radiologic and clinicopathologic correlation. *BMC Med Imaging* 2018; 18: 39. (PMID: 30390667) [\[Crossref\]](#)

6. Brenner RJ, Jackman RJ, Parker SH, Evans WP 3rd, Philpotts L, Deutch BM, et al. Percutaneous core needle biopsy of radial scars of the breast: when is excision necessary? *AJR Am J Roentgenol* 2002; 179: 1179-1184. (PMID:12388495) [\[Crossref\]](#)
7. Cawson JN, Malara F, Kavanagh A, Hill P, Balasubramaniam G, Henderson M. Fourteen-gauge needle core biopsy of mammographically evident radial scars: is excision necessary? *Cancer* 2003; 97: 345-351. (PMID: 12518358) [\[Crossref\]](#)
8. Chou WYY, Veis DJ, Aft R. Radial scar on image-guided breast biopsy: is surgical excision necessary? *Breast Cancer Res Treat* 2018; 170: 313-320. (PMID: 29532340) [\[Crossref\]](#)
9. Leong RY, Kohli MK, Zeizafoun N, Liang A, Tartter PI. Radial Scar at Percutaneous Breast Biopsy That Does Not Require Surgery. *J Am Coll Surg* 2016; 223: 712-716. (PMID: 27542917) [\[Crossref\]](#)
10. Becker L, Trop I, David J, Latour M, Ouimet-Oliva D, Gaboury L, Lalonde L. Management of radial scars found at percutaneous breast biopsy. *Can Assoc Radiol J* 2006; 57: 72-78. (PMID: 16944680) [\[Crossref\]](#)
11. Resetkova E, Edelweiss M, Albarracin CT, Yang WT. Management of radial sclerosing lesions of the breast diagnosed using percutaneous vacuum-assisted core needle biopsy: recommendations for excision based on seven years' of experience at a single institution. *Breast Cancer Res Treat* 2011; 127: 335-343. (PMID: 18626769) [\[Crossref\]](#)
12. Borrelli C, Cohen S, Duncan A, Given-Wilson R, Jenkins J, Kearins O, Pinder S, Sharma N, Sibbering M, Steel J, Turnbull A, Wallis MG. NHS Breast Screening Programme Clinical guidance for breast cancer screening assessment. 2016. <https://associationofbreastsurgery.org.uk/media/1414/nhs-bsp-clinical-guidance-for-breast-cancer-screening-assessment.pdf>. [\[Crossref\]](#)
13. S. Fallenberg EM, Sinn, Lesions of Uncertain Malignant Potential (B3). 2020. <https://www.ago-online.de/>. (Accessed 2/22/2021 2021). [\[Crossref\]](#)
14. Ragoth CJ, O'Flynn EAM, Pinker K, Kubik-Huch RA, Mundinger A, Decker T, et al. Second International Consensus Conference on lesions of uncertain malignant potential in the breast (B3 lesions). *Breast Cancer Res Treat* 2019; 174: 279-296. Erratum in: *Breast Cancer Res Treat* 2019; 176: 481-482. (PMID: 30506111) [\[Crossref\]](#)
15. Linda A, Zuiani C, Furlan A, Londero V, Girometti R, Machin P, et al. Radial scars without atypia diagnosed at imaging-guided needle biopsy: how often is associated malignancy found at subsequent surgical excision, and do mammography and sonography predict which lesions are malignant? *AJR Am J Roentgenol* 2010; 194: 1146-1151. (PMID: 20308524) [\[Crossref\]](#)
16. Adler DD, Helvie MA, Oberman HA, Ikeda DM, Bhan AO. Radial sclerosing lesion of the breast: mammographic features. *Radiology* 1990; 176: 737-740. (PMID: 2389032) [\[Crossref\]](#)
17. López-Medina A, Cintora E, Múgica B, Operé E, Vela AC, Ibañez T. Radial scars diagnosed at stereotactic core-needle biopsy: surgical biopsy findings. *Eur Radiol* 2006; 16: 1803-1810. (PMID: 16708220) [\[Crossref\]](#)
18. Harris JR, Lippman ME, Osborne CK, Morrow M. *Diseases of the Breast*. Wolters Kluwer Health. 2012.
19. Andacoglu O, Kanbour-Shakir A, Teh YC, Bonaventura M, Ozbek U, Anello M, et al. Rationale of excisional biopsy after the diagnosis of benign radial scar on core biopsy: a single institutional outcome analysis. *Am J Clin Oncol* 2013; 36: 7-11. (PMID: 22134516) [\[Crossref\]](#)
20. Conlon N, D'Arcy C, Kaplan JB, Bowser ZL, Cordero A, Brogi E, et al. Radial Scar at Image-guided Needle Biopsy: Is Excision Necessary? *Am J Surg Pathol* 2015; 39: 779-785. (PMID: 25634748) [\[Crossref\]](#)
21. Douglas-Jones AG, Denson JL, Cox AC, Harries IB, Stevens G. Radial scar lesions of the breast diagnosed by needle core biopsy: analysis of cases containing occult malignancy. *J Clin Pathol* 2007; 60: 295-298. (PMID: 16731590) [\[Crossref\]](#)
22. Lee KA, Zuley ML, Chivukula M, Choksi ND, Ganott MA, Sumkin JH. Risk of malignancy when microscopic radial scars and microscopic papillomas are found at percutaneous biopsy. *AJR Am J Roentgenol* 2012; 198: W141-W145. (PMID: 22268203) [\[Crossref\]](#)
23. Donaldson AR, Sieck L, Booth CN, Calhoun BC. Radial scars diagnosed on breast core biopsy: Frequency of atypia and carcinoma on excision and implications for management. *Breast* 2016; 30: 201-207. (PMID: 27371970) [\[Crossref\]](#)
24. Matrai C, D'Alfonso TM, Pharmed L, Drotman MB, Simmons RM, Shin SJ. Advocating Nonsurgical Management of Patients With Small, Incidental Radial Scars at the Time of Needle Core Biopsy: A Study of 77 Cases. *Arch Pathol Lab Med* 2015; 139: 1137-1142. (PMID: 25607999) [\[Crossref\]](#)
25. Miller CL, West JA, Bettini AC, Koerner FC, Gudewicz TM, Freer PE, et al. Surgical excision of radial scars diagnosed by core biopsy may help predict future risk of breast cancer. *Breast Cancer Res Treat* 2014; 145: 331-338. (PMID: 24748568) [\[Crossref\]](#)
26. Phantana-Angkool A, Forster MR, Warren YE, Livasy CA, Sobel AH, Beasley LM, et al. Rate of radial scars by core biopsy and upgrading to malignancy or high-risk lesions before and after introduction of digital breast tomosynthesis. *Breast Cancer Res Treat* 2019; 173: 23-29. (PMID: 30242581) [\[Crossref\]](#)
27. Dominguez A, Durando M, Mariscotti G, Angelino F, Castellano I, Bergamasco L, et al. Breast cancer risk associated with the diagnosis of a microhistological radial scar (RS): retrospective analysis in 10 years of experience. *Radiol Med* 2015; 120: 377-385. (PMID: 25155350) [\[Crossref\]](#)
28. Sanders ME, Schuyler PA, Dupont WD, Page DL. The natural history of low-grade ductal carcinoma in situ of the breast in women treated by biopsy only revealed over 30 years of long-term follow-up. *Cancer* 2005; 103: 2481-2484. (PMID: 15884091) [\[Crossref\]](#)
29. Grimm LJ, Ryser MD, Partridge AH, Thompson AM, Thomas JS, Wesseling J, et al. Surgical Upstaging Rates for Vacuum Assisted Biopsy Proven DCIS: Implications for Active Surveillance Trials. *Ann Surg Oncol* 2017; 24: 3534-3540. (PMID: 28795370) [\[Crossref\]](#)
30. Hwang ES, Hyslop T, Lynch T, Frank E, Pinto D, Basila D, et al. The COMET (Comparison of Operative versus Monitoring and Endocrine Therapy) trial: a phase III randomised controlled clinical trial for low-risk ductal carcinoma in situ (DCIS). *BMJ Open* 2019; 9: e026797. (PMID: 30862637) [\[Crossref\]](#)
31. Hwang ES, Malek V. Estimating the magnitude of clinical benefit of local therapy in patients with DCIS. *Breast* 2019; 48 Suppl 1: S34-S38. (PMID: 31839157) [\[Crossref\]](#)
32. Welch HG, Prorok PC, O'Malley AJ, Kramer BS. Breast-Cancer Tumor Size, Overdiagnosis, and Mammography Screening Effectiveness. *N Engl J Med* 2016; 375: 1438-1447. (PMID: 27732805) [\[Crossref\]](#)
33. dos Santos RL, Lasmar RB, Fontes TM, Fonseca Rde C, Saldanha Pde A, dos Santos RF. Percutaneous core biopsy of palpable breast lesions: accuracy of frozen section histopathological exam in the diagnosis of breast cancer. *Rev Col Bras Cir* 2014; 41: 7-10. (PMID: 24770767) [\[Crossref\]](#)
34. Holloway CM, Al-Riyees L, Saskin R. Utilization of Percutaneous Needle Biopsy for Breast Diagnosis in a Comprehensive Breast Center: Implications for Development of Quality Indicators. *World J Surg* 2016; 40: 1590-1599. (PMID: 26530690) [\[Crossref\]](#)
35. Liberman L. Clinical management issues in percutaneous core breast biopsy. *Radiol Clin North Am* 2000; 38: 791-807. (PMID: 10943278) [\[Crossref\]](#)
36. Lomoschitz FM, Helbich TH, Rudas M, Pfarl G, Linnau KF, Stadler A, et al. Stereotactic 11-gauge vacuum-assisted breast biopsy: influence of number of specimens on diagnostic accuracy. *Radiology* 2004; 232: 897-903. (PMID: 15273332) [\[Crossref\]](#)
37. Lv M, Zhu X, Zhong S, Chen W, Hu Q, Ma T, Zhang J, Zhang X, Tang J, Zhao J. Radial scars and subsequent breast cancer risk: a meta-analysis. *PLoS One* 2014; 9: e102503. (PMID: 25019286) [\[Crossref\]](#)