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FULL RESEARCH ARTICLE

Radial sclerosing lesions diagnosed by percutaneous breast biopsy: histologic upgrade rate and management implications

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ABSTRACT

Introduction: *Management of benign radial sclerosing lesions (RSLs) remains controversial, with no consensus on surgical excision. The aims of this study were to compare the rate of histologic underestimation of high-risk lesions or carcinomas associated with benign RSLs based on breast biopsy method and to determine the upgrade of RSLs after surgical excision, when performed, or during imaging follow-up.* **Material and methods:** *This retrospective cohort study analyzed RSLs in women who underwent percutaneous breast biopsy followed by surgical excision or at least 24 months of imaging surveillance. RSLs were detected by mammography, ultrasound (US) and/or magnetic resonance imaging (MRI) and were confirmed histopathologically. Diagnostic methods included percutaneous ultrasound core needle biopsy (US-CNB), ultrasound vacuum-assisted biopsy (US-VAB), stereotactic vacuum-assisted biopsy (VAB) and/or surgical excision. Histologic diagnoses were benign RSLs, RSLs with high-risk lesions or breast cancer associated.* **Results:** *Ninety-seven women with 97 RSLs were included — 75 with US-CNB and 22 with VAB. The upgrade rate varied by biopsy method. With US-CNB, 8 (10.7%) lesions were upgraded to high-risk lesions after surgical excision and one (1.3%) was upgraded to carcinoma in situ (CIS). Another case (1.3%) had a percutaneous diagnosis of high-risk RSL was upgraded to microinvasive cancer. There were no upgrades to high-risk lesions or cancer in 12 US-VAB cases. All remained stable during follow-up (n = 10, 83.3%) or were confirmed benign surgically (n = 2, 16.7%). Of the 10 RSLs sampled with stereotactic VAB, one (10.0%) was upgraded to a high-risk lesion.* **Conclusion:** *In our study, US-VAB demonstrated no histologic underestimation of malignancy compared with US-CNB or stereotactic VAB. Given this low risk, semiannual imaging for two years is a safe alternative to surgical excision in patients with RSLs diagnosed on percutaneous biopsy.*

Keywords: *Radial sclerosis lesion. Architectural distortion. Breast imaging. Histologic underestimation. Vacuum-assisted breast biopsy. Ultrasound vacuum-assisted biopsy.*

INTRODUCTION

Radial scars and complex sclerosing lesions, often referred to as radial sclerosing lesions (RSLs), are breast lesions with a central fibroelastic core surrounded by entrapped ducts and lobules. Their imaging appearance is architectural distortion[1]. Benign RSL imaging features overlap with those of malignancy and are often targets for imaging-guided biopsy because of their suspicious appearance[1-8]. RSLs can be identified in isolation or associated with atypia or other high-risk lesions with intrinsic malignant potential, increasing the risk of carcinoma and affecting RSL prognosis and management[1].

The increased use of digital breast tomosynthesis (DBT) has led to higher detection of RSLs, prompting renewed discussion of its clinical significance and

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appropriate management[1,9]. Surgical excision of RSLs has traditionally been recommended due to concerns that associated high-risk lesions or carcinomas might be missed with insufficient sampling[5]. Recent evidence suggests that benign RSLs without atypia have a low underestimation rate, especially when vacuum-assisted biopsy (VAB) is performed[4,9]; this method can be performed with various imaging modalities, including ultrasound (US), stereotaxy, DBT, contrast-enhanced mammography, and magnetic resonance imaging (MRI)[10].

Clinical recommendations for optimal benign RSL management are inconsistent[1,5]. Some authors support routine surgical excision in selected cases after a percutaneous diagnosis of RSLs[3,6,7,11], others advocate conservative approaches, especially when adequate sampling and absence of atypia are ensured[4,5]. In Mexico, there is little data to support evidence-based decisions in this context[12]. The aims of this study were to compare the rate of histologic underestimation of high-risk lesions or carcinomas associated with benign RSLs based on breast biopsy method and to determine the upgrade of RSLs after surgical excision, when performed, or during imaging follow-up.

MATERIAL AND METHODS

This retrospective cohort study was conducted between 2019 and 2022 at the Breast Imaging Departments of San José Hospital and Zambrano Hellion Hospital, Tec Salud, in Monterrey, Nuevo León, Mexico. Inclusion criteria were women aged over 20 with a histopathologic diagnosis of RSL by surgical excision and/or imaging examination follow-up of at least 24 months**.** Cases in which RSL was an incidental finding on histopathologic examination or in which no follow-up data were available were excluded. Informed consent was waived due to the retrospective nature of the study and the use of data obtained during routine clinical care. The Institutional Research and Ethics Committees approved this study.

Study development and variables

We retrospectively reviewed all RSL cases identified by mammography, US, or MRI and confirmed by core needle biopsy (CNB) or VAB using electronic image records from a Picture Archiving and Communication System (PACS) (Carestream, Philips, Rochester, NY, USA).

Age, Breast Imaging Reporting and Data System (BI-RADS) categories, and histopathology results of percutaneous and excisional biopsies were recorded. Women diagnosed with benign RSLs were enrolled in a systematic imaging follow-up protocol of two years. Patients with benign RSLs associated with high-risk lesions or breast carcinoma were referred for definitive surgical treatment.

Image acquisition and analysis

Mammograms were performed using either the Selenia Dimensions™ system (Hologic, Inc., Bedford, MA, USA) or the IMS Giotto Tomo Digital Mammography system (IMS, Sasso Marconi, BO, Italy). After mammography, a US examination of the breast was performed using the iU22, EPIC 7G, or EPIC 7W systems (Philips Co., Bothell, WA, USA) equipped with linear multifrequency transducers. Imaging examination was performed in grayscale, color Doppler, and power Doppler US modes. BI-RADS 5th Edition categories were assigned based on mammography and US findings[13].

Breast biopsy

US-guided percutaneous biopsies (US-CNB and US-VAB) and stereotactic-VAB or excisional biopsy with a marking clip were included. US-CNB was performed with a 12-gauge core needle, obtaining a minimum of ten cores per lesion. VABs were performed with a vacuum-assisted 10-gauge biopsy needle under US or stereotactic guidance. All percutaneous biopsies were performed in a minor procedure unit with topical anesthesia. All CNB and VAB biopsies were performed by breast radiologists averaging 16 years of experience (range 7 to 25 years).

Excisional biopsies were performed by a breast surgeon under general anesthesia in an operating room. The tissue samples were submitted to the Department of Pathology for histopathologic evaluation by a breast pathology subspecialist (GGM) with 13 years of experience. Histopathology results were classified as benign, high-risk lesions – including atypical ductal hyperplasia, papillary lesions, and lobular neoplasia – or malignant breast lesions.

Statistical analysis

Numeric variables are described using measures of central tendency and dispersion (standard deviation). Categorical variables are reported as absolute frequencies and percentages. The association between categorical variables was examined using the chi-square test.

A p value < 0.05 was statistically significant. SPSS version 25 (IBM Corp., Armonk, NY, USA) was used for statistical analyses.

RESULTS

We examined 4,715 percutaneous biopsies performed during the study period. One hundred and ten cases were identified as RSL by percutaneous biopsy. Thirteen RSLs were excluded because of ipsilateral breast cancer (n = 9) or no images were available (n = 4). We included 97 women with 97 RSLs. Asymptomatic women were referred from the screening program (n = 61, 62.9%) or a diagnostic examination (n = 36, 37.1%).

Comparison of percutaneous biopsy methods and histopathologic diagnosis in 97 women with RSLs

The patients' ages ranged from 24 to 73 years, with a mean of 47.8 ± 9.5 years (range 24 to 73) (Table 1). RSLs were identified as architectural distortion alone or, in some cases, were associated with calcifications, focal asymmetry, a mass, or non-mass lesions. According to the BI-RADS classification, most lesions were 4B (n = 77, 79.4%), followed by 4A (n = 11, 11.3%) and 4C (n = 9, 9.3%). All 97 women with a diagnosis of RSL underwent a percutaneous biopsy. The most common method was US-CNB (n = 75, 77.3%) followed by US-VAB (n = 12, 12.4%), and stereotactic VAB (n = 10, 10.3%).

Histopathology of percutaneous biopsies showed benign RSLs in 77 (79.4%) of 97 cases. High-risk RSLs were identified in 18 (18.6%), mainly papillary lesions (n = 9) and atypical ductal hyperplasia (n = 7). Carcinoma in situ (CIS) was found in 1 (1.0%) case, and microinvasive carcinoma in 1 (1.0%) case of RSL.

Sixty-eight (70.1%) of the 97 women underwent surgical excision with wire localization. Benign RSLs were confirmed in 45 (66.2%) cases, while high-risk RSLs were found in 19 (27.9%), CIS in 3 (4.4%), and malignant microinvasive carcinoma in 1 (1.5%).

Figures 1 and 2 show breast architectural distortion on mammography of an asymptomatic 46-year-old woman. Contrast-enhanced breast MRI shows a non-mass lesion associated with architectural distortion. A US-CNB was performed, and the histopathologic diagnosis was benign RSL.

Table 1. Comparison of percutaneous biopsy methods and histopathology diagnosis in 97 women with RSL

Description	Parameter
Age (years), mean ± SD (min-max)	47.8 ± 9.5 (24-73)
BI-RADS, n (%)	
4A	11 (11.3)
4B	77 (79.4)
4C	9 (9.3)
Percutaneous biopsy method, n (%)	
US-CNB	75 (77.3)
US-VAB	12 (12.4)
Stereotactic VAB	10 (10.3)
Histopathologic diagnosis by percutaneous biopsy, n (%)	
Benign RSL	77 (79.4)
RSL with associated high-risk lesions	18 (18.6)
RSL with associated CIS	1 (1.0)
RSL with associated microinvasive carcinoma	1 (1.0)
Histopathology diagnosis after surgical excision[a], n (%)	
Benign RSL	45 (66.2)
RSL with associated high-risk lesions	19 (27.9)
RSL with associated CIS	3 (4.4)
RSL with associated microinvasive carcinoma	1 (1.5)

[a]Only 68 (70.1%) of 97 women.
BI-RADS: Breast Imaging Reporting and Data System; RSL: radial sclerosing lesion; US-CNB: ultrasound-guided core needle biopsy; US-VAB: ultrasound-guided vacuum-assisted biopsy; VAB: vacuum-assisted biopsy; CIS: carcinoma in situ.

Upgrade rate of RSLs related to the percutaneous breast biopsy method

Regarding biopsy methods, 75 (77.3%) of the 97 RSLs were sampled using ultrasound-guided 12-gauge spring-loaded core needle devices (US-CNB), while 12 (12.4%) cases were performed using US-VAB, and 10 (10.3%) with stereotactic VAB (Table 2). Sixty-eight (70.1%) of the 97 cases underwent surgical excision, and 29 (29.9%) underwent semiannual imaging examination for at least 24 months. None of the RSLs that were followed with imaging showed suspicious interval changes of RSL upgrade. They were classified as benign at the end of the follow-up period.

The overall histologic upgrade rate for benign RSL varied by biopsy method. In US-CNB, 8 (10.7%) of 75 RSLs were upgraded to high-risk after surgical excision, one (1.3%) was upgraded to CIS, and another (1.3%) had a percutaneous diagnosis of a high-risk

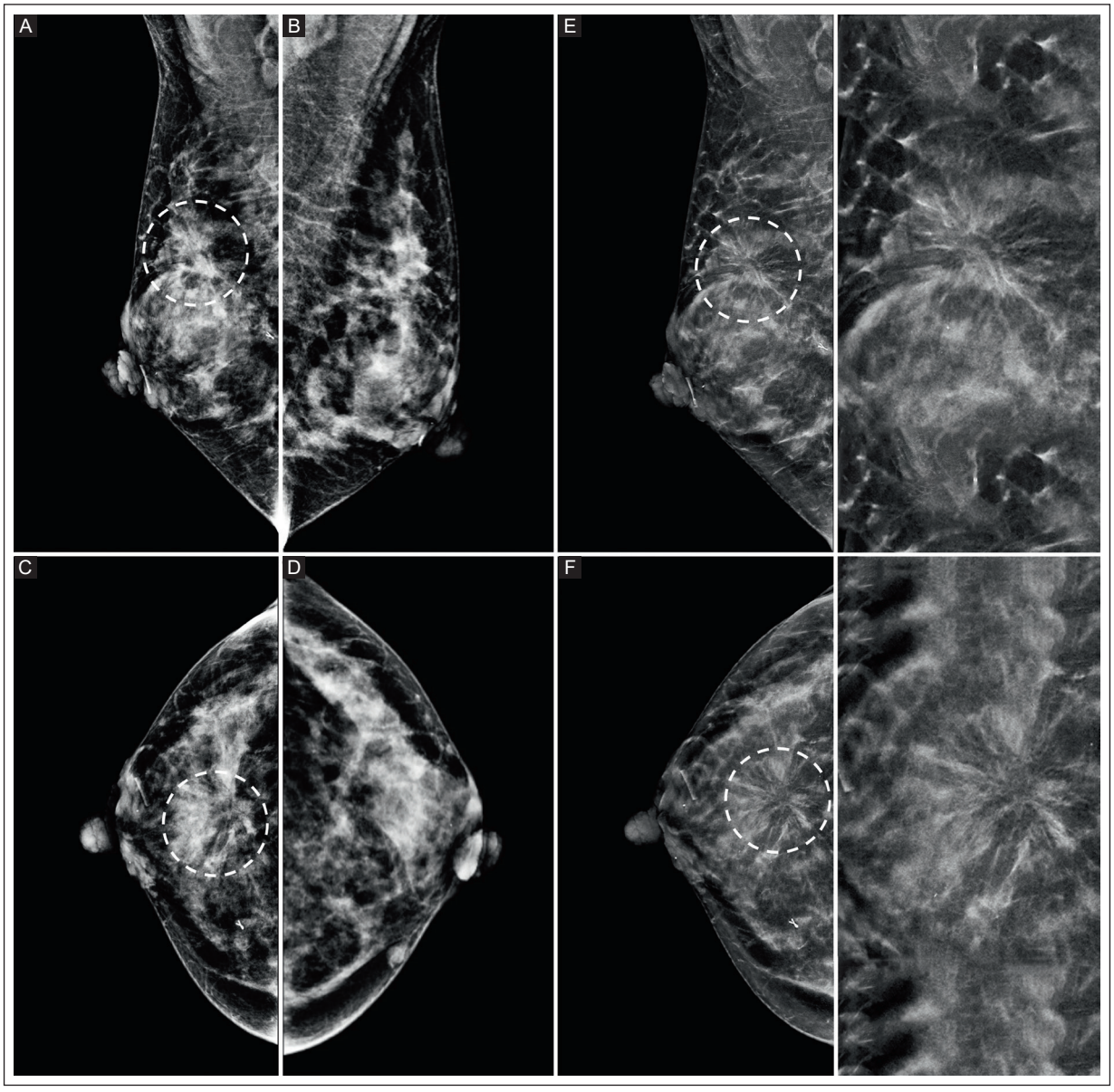

Figure 1. An asymptomatic 46-year-old woman with a positive family risk factor for breast cancer. She had a history of a percutaneous biopsy of the right breast that reported a benign intraductal papilloma, BI-RADS 4A. **A, B, C, D:** bilateral mammography, MLO and CC views of the right breast show extremely dense breast tissue (category d) with an area of architectural distortion at the junction of the upper quadrants (dashed circles), with no suspicious lesions in the left breast. **E-F:** DBT, MLO, and CC views and digital magnifications of the right breast show better delineation of architectural distortion (dashed circles).

DBT: digital breast tomosynthesis; MLO: mediolateral oblique; CC: craniocaudal; BI-RADS: Breast Imaging Reporting and Data System.

RSL that was subsequently upgraded to microinvasive cancer.

No histologic RSL upgrades to high-risk or cancer were found in the 12 cases diagnosed with US-VAB. These lesions remained stable during follow-up (n = 10, 83.3%) or were confirmed benign after surgical excision (n = 2, 16.7%). Of the 10 RSLs sampled with stereotactic VAB, one (10.0%) was upgraded to a high-risk lesion, while none were upgraded to cancer. US-VAB was the sampling method with no histologic underestimation of high-risk lesions or malignancy compared to the other methods (US-CNB or stereotactic VAB).

Figure 3 shows a 50-year-old woman with a percutaneous CNB with architectural distortion, BI-RADS 4C, with discordance between imaging and pathology. The histopathology report identified fibrosis and non-atypical proliferative changes. Contrast-enhanced breast MRI shows a non-mass lesion with architectural

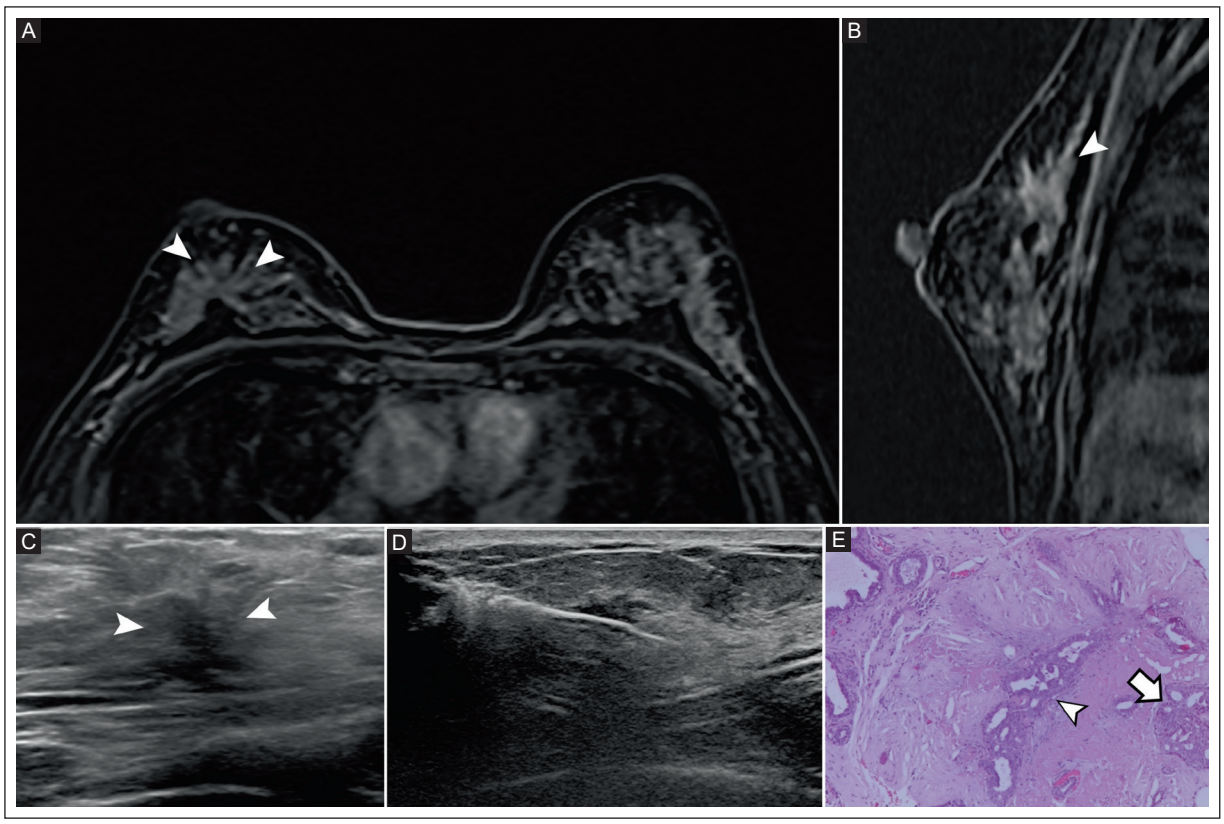

Figure 2. The same patient as in Figure 1. **A-B:** a contrast-enhanced breast MRI shows a non-mass lesion associated with architectural distortion at the junction of the upper quadrants of the right breast at 11 o'clock in the middle third of the breast (arrowheads). **C:** grayscale US, radial view, shows a poorly defined hypoechoic area with architectural distortion without posterior acoustic shadowing (arrowheads). **D:** US-CNB was performed targeting the lesion. **E:** histology section with 10X H&E staining shows distorted tubules within a background of diffuse fibrosis (arrowhead), with moderate usual ductal hyperplasia toward the periphery (arrow). The histopathology diagnosis was a benign RSL.

US-CNB: ultrasound-guided core needle biopsy; H&E: hematoxylin and eosin; RSL: radial sclerosing lesion; MRI: magnetic resonance imaging.

Table 2. Comparison of RSL histologic upgrade by percutaneous biopsy method

Description	Total (n = 97)	US-CNB (n = 75)	US-VAB (n = 12)	Stereotactic-VAB (n = 10)
No upgrade of RSLs, n (%)				
Surgical excision[a]	57	51 (68.0)	2 (16.7)	4 (40.0)
≥ 24 months imaging follow-up	29	14 (18.7)	10 (83.3)	5 (50.0)
Histologic upgrade of RSLs after surgical excision, n (%)				
RSL to risk lesion	9	8 (10.7)	0	1 (10.0)
RSL with associated risk lesion to CIS	1	1 (1.3)	0	0
RSL to microinvasive cancer	1	1 (1.3)	0	0

[a]Only 68 (70.1) of 97 women.
RSL: radial sclerosing lesion; CIS: carcinoma in situ; US-CNB: ultrasound-guided core needle biopsy; US-VAB: ultrasound-guided vacuum-assisted biopsy; VAB: vacuum-assisted biopsy.

distortion, associated with three hyperenhanced irregular solid masses. Grayscale US shows a hypoechoic mass with minimal posterior acoustic shadowing and associated architectural distortion. The diagnosis was RSL with atypical ductal hyperplasia. Figure 4 shows a mammogram of a 42-year-old woman with architectural distortion, BI-RADS 4B. Figure 5 shows a contrast-enhanced breast MRI with non-mass enhancement

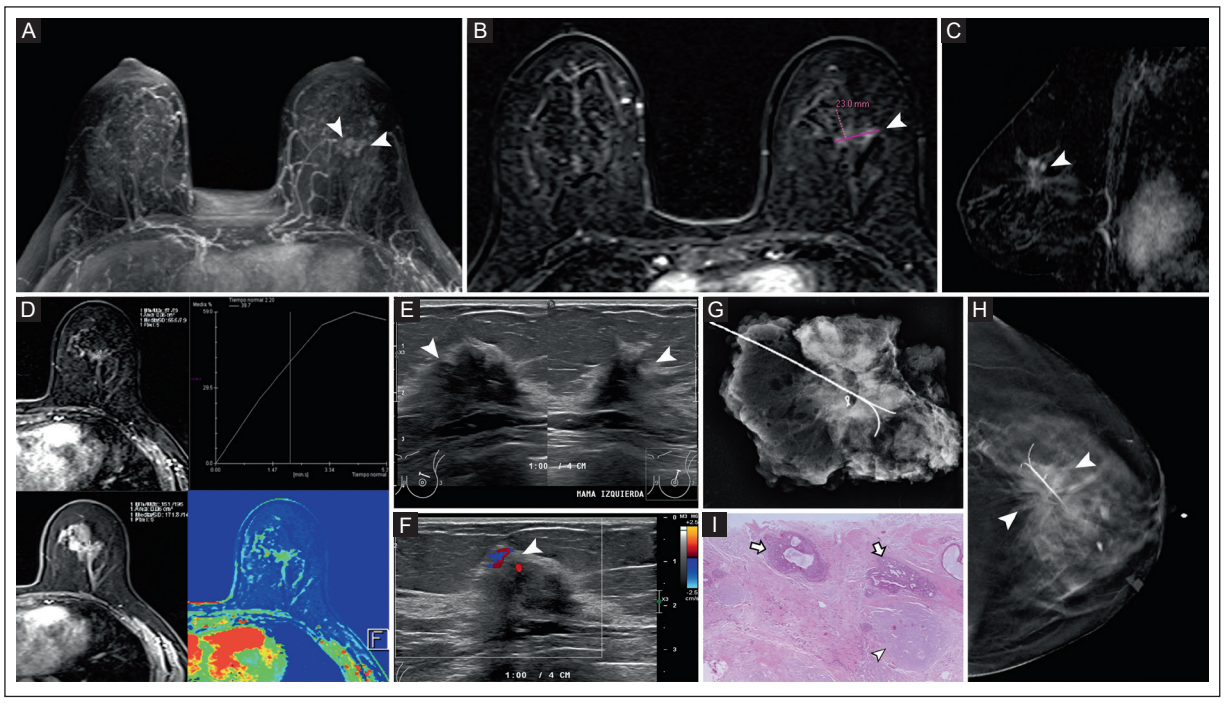

Figure 3. A 50-year-old woman with a recent percutaneous CNB of an architectural distortion in the left breast, BI-RADS 4C, with discordance between the imaging findings and the histopathology report. **A, B, C, D:** contrast-enhanced breast MRI shows a non-mass lesion with architectural distortion at 12 o'clock associated with three hyperenhanced irregular solid masses. The largest is 7 mm in diameter (arrowheads). Functional assessment shows a kinetic curve with persistent type I enhancement. **E-F:** grayscale US shows a hypoechoic mass with minimal posterior acoustic shadowing and associated architectural distortion at 12 o'clock (arrowheads). Color Doppler US examination shows minimal peripheral vascularity. **G:** X-ray of the specimen confirms excision of the targeted breast lesion. **H:** DBT, CC view of the left breast shows stereotactic VAB wire localization with accurate placement in architectural distortion (arrowheads). **I:** histologic section with H&E 5X staining shows a sclerotic stroma with tubular entrapment (arrowhead). At the periphery, there are distended ducts with focal rigid lumens and others with slit-like lumens, containing a single population of cells in focal areas (arrows). The histopathology diagnosis was RSL associated with atypical ductal hyperplasia.

DBT: digital breast tomosynthesis; CNB: core needle biopsy; CC: craniocaudal; H&E: hematoxylin and eosin; RSL: radial sclerosing lesion; BI-RADS: Breast Imaging Reporting and Data System; US: ultrasound; MRI: magnetic resonance imaging; VAB: vacuum-assisted biopsy.

with architectural distortion showing a clumped enhancement pattern. Stereotactic VAB was performed. The diagnosis was RSL with CIS.

DISCUSSION

The overall histologic upgrade rate of RSLs in our study varied by biopsy method. US-VAB was the most reliable diagnostic approach for benign RSLs with no histologic underestimation of high-risk lesions or malignancy compared with the other biopsy methods (US-CNB or stereotactic VAB). In addition, semiannual imaging follow-up for two years was a safe alternative to surgical excision in selected patients.

VAB minimizes histologic underestimation of RSLs and can reduce the need for surgical excision when appropriately used[3-5,9,14]. Ferreira et al.[7] found a significantly lower histologic upgrade rate with VAB (4.0%; 1/25) compared to CNB (23.9%; 16/67) in a retrospective study in Portugal involving 113 women with RSL diagnosed by percutaneous biopsy (p = 0.041). The authors concluded that RSLs without atypia, when adequately sampled by VAB, represent a low-risk subgroup in whom clinical surveillance could be a safe alternative, potentially avoiding surgical excision. In our study, the overall histologic upgrade rate of RSLs varied by biopsy method. RSLs sampled using US-CNB had a higher histologic upgrade rate (13.3%, 10/75 cases). With stereotactic VAB, only one lesion, which was an atypical papilloma (10.0%, 1/10 cases), was upgraded to a high-risk lesion. There was no histologic upgrade in 12 RSL cases with US-VAB, suggesting that this method may provide a more accurate histologic diagnosis. Our results are consistent with the recommendation that VAB is an ideal alternative for managing RSLs without atypia in selected cases, especially when there is concordance between

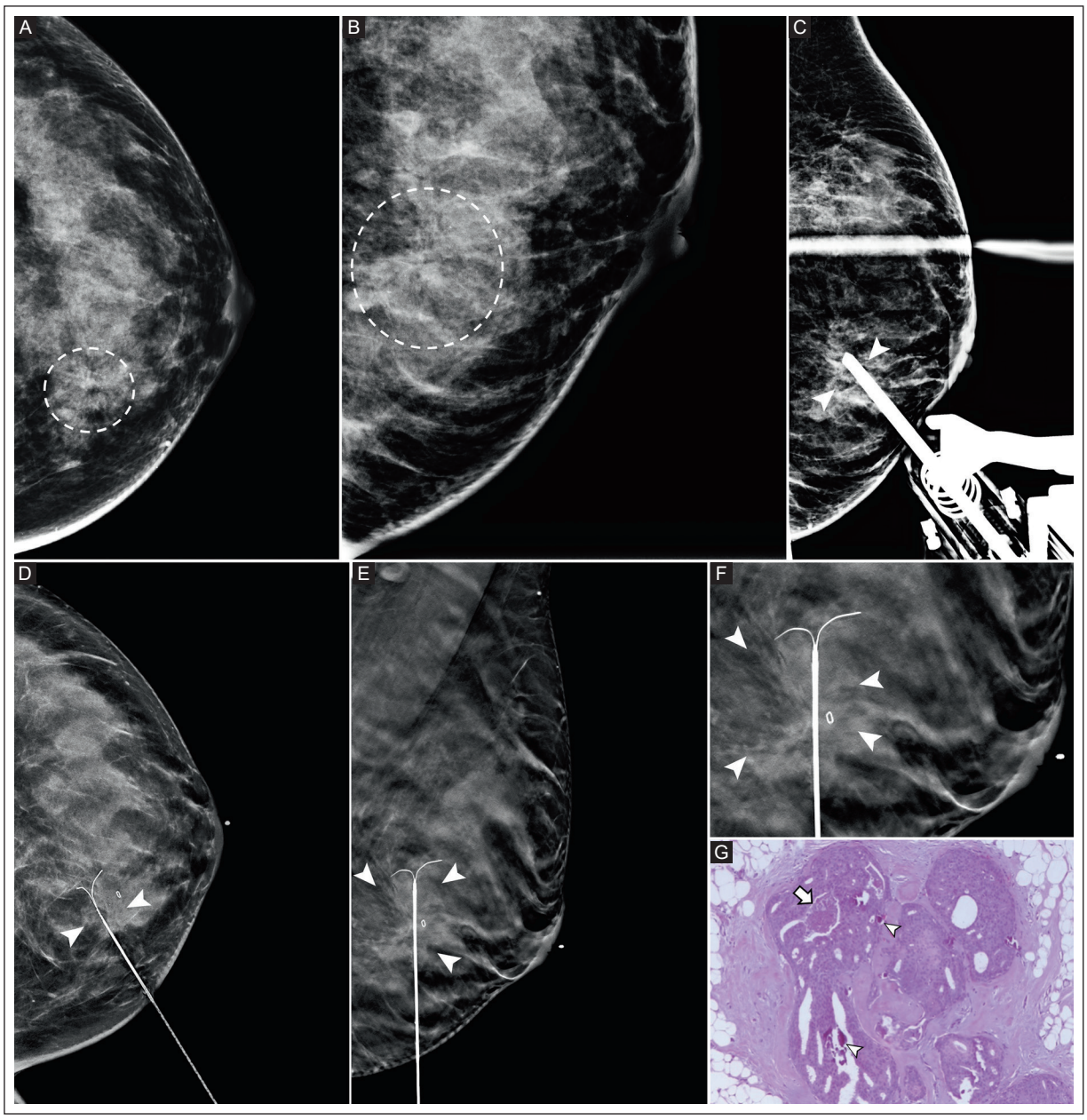

Figure 4. A 42-year-old woman with an architectural distortion seen at mammography in the left breast. **A:** mammography, CC view of the left breast, showing an area of architectural distortion in the lower inner quadrant, associated with scattered microcalcifications (dashed circle), BI-RADS 4B. **B:** a magnified CC view with left breast compression shows better delineation of the architectural distortion (dashed circle). **C:** a stereotactic VAB was performed (arrowheads). **D, E, F:** preoperative wire localization with DBT (arrowheads). **G:** histologic section with H&E 10X staining shows central sclerosis with tubular distortion and marked intraductal dilatation, along with severe atypia, focal necrosis (arrow) with microcalcifications (arrowhead), and myoepithelial cell preservation. The histopathology diagnosis was CIS-associated RSL.

DBT: digital breast tomosynthesis; CC: craniocaudal; H&E: hematoxylin and eosin; RSL: radial sclerosing lesion; CIS: carcinoma in situ; BI-RADS: Breast Imaging Reporting and Data System. VAB: vacuum-assisted biopsy.

radiologic and pathologic diagnosis[5,15]. The diagnostic reliability of VAB supports its role as a conservative approach in managing select cases of RSLs. Our results support a tailored approach to RSL management and emphasize the importance of the biopsy method in clinical decision-making. VAB could be a cost-effective alternative to the recommended excisional biopsy in certain cases[16].

With the introduction of population-based breast cancer screening programs and the increasing use of DBT, the detection rate of RSLs has increased in recent years, with a reported incidence of 0.03% to 0.09%[7].

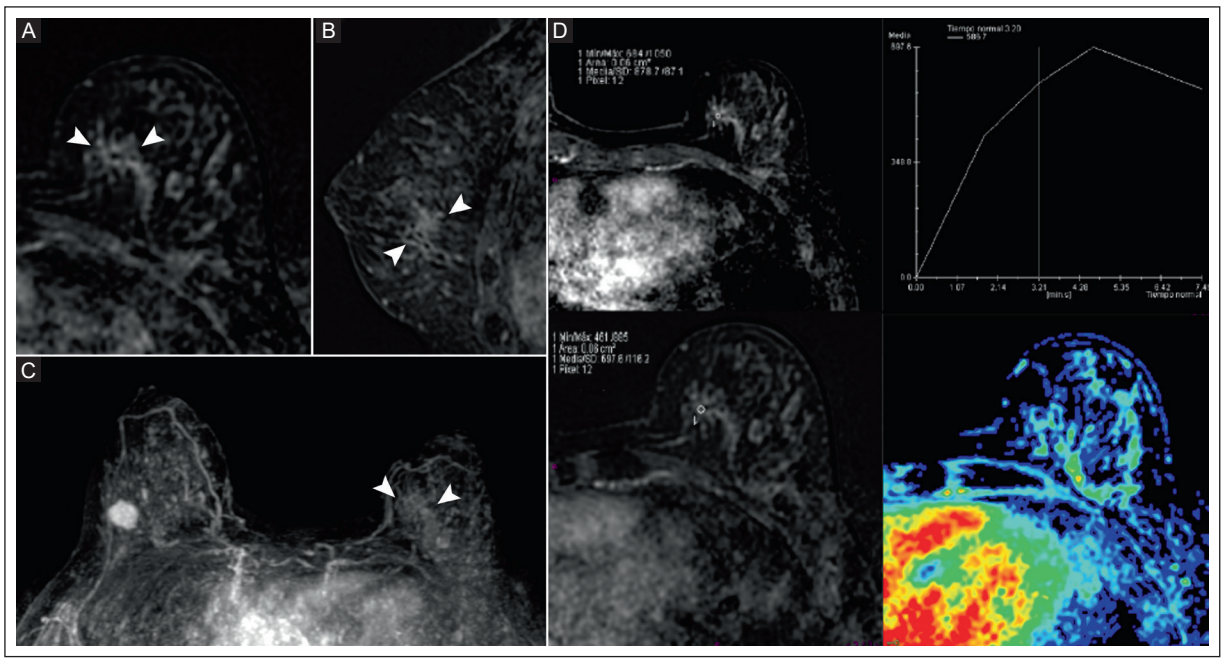

Figure 5. The same patient as in figure 4. **A-B:** contrast-enhanced breast MRI with axial and sagittal T1- weighted fat-saturated postcontrast subtraction shows non-mass enhancement with associated architectural distortion (arrowheads) at the junction of the inner quadrants of the left breast, at 3 o'clock. It shows a clumped enhancement pattern. **C:** axial MIP image shows a hyperenhanced area of architectural distortion at the junction of the inner quadrants of the left breast at 3 o'clock (arrowheads). A previously known fibroadenoma is seen in the right breast. **D:** functional MRI evaluation of the lesion shows a type 3 kinetic plateau curve. The histopathology diagnosis was CIS-associated RSL.
MIP: maximum intensity projection; MRI: magnetic resonance imaging.

On the other hand, prevalence varied in the literature, ranging from 6.2 to 29%[17]. However, the histologic upgrade rate to malignancy at surgical excision has remained low (3-6%), suggesting that the vast majority of RSLs diagnosed by CNB are benign. Only a small proportion are associated with high-risk lesions or breast malignancy[4,5]. Yan et al.[14] found benign RSLs in 117 (80.1%) of 146 RSLs in 142 American women examined with mammography and DBT, while 29 (19.9%) RSLs were associated with atypia. A low rate (0.9%) of histologic upgrade to malignancy was reported. Sherwell-Cabello et al.[12] examined 123 Mexican women in a retrospective study. They found RSL associated with breast cancer in 1.6% of cases. In our study, the prevalence of benign RSL diagnosed by percutaneous biopsy was 79.4% (n = 77), a finding comparable to other studies[4,14]. High-risk lesions were associated with RSLs in 18 cases (18.6%). Breast cancer was found in 2 (2.1%) of 97 cases, which is also comparable to other studies[2,7,14,17] that reported similar frequencies of high-risk lesions and very low rates of carcinoma associated with RSLs. The high prevalence of benign RSLs without atypia suggests that imaging examination surveillance may be appropriate[4,18].

Earlier studies by Berg et al.[8] and Aroner et al.[19] reported higher rates of discordance and upgrades in RSLs, leading to recommendations for routine excision. In 2002, Brenner et al.[6] advocated conservative management of RSLs without concomitant atypia. They found that there was no increase in malignancy when lesions were sampled with VAB or CNB using at least 12 cores. If these conditions were not met, surgical excision is recommended[6]. Later reports,[4,7,18] have shown that the accuracy of CNB can improve with modern imaging methods and multidisciplinary evaluation, supporting more conservative management strategies in increasing confidence in percutaneous biopsy results[4,17,18,20,21]. Extensive samples obtained by percutaneous biopsy may spare a patient from undergoing surgical excision, as they are more representative of the lesion. Our study showed high concordance between US-CNB and surgical excision for benign RSLs, supporting the diagnostic reliability of percutaneous biopsy when adequately sampled[3,9]. Consensus statements and guidelines, including those by Elfgen et al.[5] and Rubio et al.[18], also advocate individualized management and acknowledge that excision may be unnecessary for benign RSLs without atypia with concordance between

imaging and pathology[5,18]. Comparable results of benign RSLs diagnosed by CNB were rarely upgraded after excision[2,7,22]. CNB is a sufficient diagnostic tool in selected cases where CNB findings and imaging are concordant, suggesting that surgical excision may not provide additional diagnostic value. Benign RSLs on CNB, especially when performed by experienced breast radiologists with adequate sampling and interpreted by experienced pathologists with adequate imaging and pathologic concordance, may not require surgical excision and could continue routine clinical and close imaging follow-up.

The strengths of our study include standardized biopsy protocols, US-VAB performed by experienced breast radiologists, and systematic two-year imaging follow-up to ensure diagnostic accuracy. In addition, there was high concordance between radiology and pathology results based on the European B3 guidelines and the international consensus, supporting the safety of non-surgical management for appropriately selected patients[2,5,18]. Several limitations of our study are related to the small sample size and insufficient power to determine the statistical significance of the type of percutaneous biopsy in relation to the absence of histologic upgrading. The retrospective study design, with non-random case selection, may introduce selection bias and limit the generalizability of the results. In addition, not all benign RSLs were surgically removed in our study, preventing a full assessment of potential underestimation in the entire cohort.

CONCLUSION

Our study showed that US-VAB is a reliable diagnostic approach for benign RSLs and may reduce the risk of histologic underestimation. Furthermore, semiannual imaging surveillance of benign RSLs for at least 2 years is a safe alternative to surgical excision in selected patients with radiologic–pathologic concordance. This study provides valuable insights into the management of RSLs in a Mexican cohort and highlights the diagnostic performance of VAB, particularly in patients presenting with architectural distortion. In selected concordant cases, systematic imaging follow-up represents a reliable alternative to excision.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of human subjects and animals. The authors declare that the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the World Medical Association and the Declaration of Helsinki (1964) and subsequent amendments.

Confidentiality, informed consent, and ethical approval. The authors have obtained approval from the Ethics Committee for the analysis of routinely collected and anonymized clinical data; therefore, individual informed consent was not required. Relevant ethical recommendations have been followed.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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