Imaging Follow-up Versus Surgical Excision for Radial Scars Identified on Tomosynthesis-Guided Core Needle Biopsy

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Abbreviation

DBT
digital breast tomosynthesis

CNB
core needle biopsy

FFDM
full field digital mammography

DCIS
ductal carcinoma in situ

ADH
atypical ductal hyperplasia

ALH
atypical lobular hyperplasia

LCIS
lobular carcinoma in situ

ACR
American College of Radiology

Rationale and Objectives: We investigated if imaging or pathology features could determine when imaging follow-up is appropriate after diagnosis of radial scar on digital breast tomosynthesis (DBT)-guided core needle biopsy (CNB).

Materials and Methods: We conducted a retrospective review of all patients diagnosed with radial scars on DBT-guided CNB at our institution between November 2014 and December 2016. Cases were excluded if DCIS or invasive malignancy was present in the same core specimens. Patient age; needle size; number of cores; visibility on full-field digital mammography versus DBT; lesion size; presence of architectural distortion, mass, or calcifications; imaging stability; presence or absence of atypia; length of imaging follow-up, and excisional pathology were collected.

Results: Of 45 eligible biopsies, 6 cases had radial scars with associated atypia and 39 cases had no associated atypia. Twenty-four patients underwent surgical excision, including all patients with atypia on CNB. One case (4%) was upstaged to DCIS on surgical excision after CNB revealed a radial scar with associated ADH. There was also a case without atypia on CNB, but excisional pathology revealed associated ADH. In cases with radial scars and associated atypia on CNB, the upstage rate was 17%. In cases without atypia on CNB that underwent surgical excision, the upstage rate was 0%. Imaging follow-up was available in 13 patients who did not undergo surgical excision, with stability in all 13 with a median follow-up of 18 months.

Conclusion: Annual imaging follow-up appears reasonable in selected patients with radial scars but no atypia on DBT-guided CNB.

Key Words: Tomosynthesis; Core needle biopsy; Radial scar; Breast.

INTRODUCTION

Radial scars present a challenge to breast imagers because the appearance of radial scars can be difficult to differentiate from malignancy and management remains unclear. With growing popularity of digital breast tomosynthesis (DBT), imagers are noting an increase in the number of architectural distortions identified and a possible increase in the number of radial scars identified at core needle biopsy (CNB) (1–4). Therefore, there is a need to create reasonable management guidelines with cost-effective and safe approaches while decreasing unnecessary excisions.

Pathologically, radial scars are benign lesions characterized by a central fibroelastic core surrounded by radiating ducts and lobules. They are sometimes also referred to as complex sclerosing lesions when larger than 1 cm in size. While the

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appearance may mimic a scar, radial scars are not associated with prior trauma or surgical scars (5). Radial scars have been reported to be present in 14–26% of patients at autopsy, and an autopsy study by Wellings noted an average of 13 radial scars per involved breast (6,7).

Management guidelines have traditionally recommended surgical excision for radial scars identified at CNB due to the risk of associated malignancy. More recently, there is an agreement that radial scars with atypia at the time of core biopsy should be excised. However, management for radial scars without atypia remains controversial. Radial scars are associated with malignancy in 0–40% of cases (8–18). However, these studies are based on film-screen, full-field digital mammography (FFDM) and/or ultrasound findings. Recent literature evaluating the prevalence of radial scars identified on DBT is limited, with the only two publications identified reporting an associated malignancy rate of 6.2 and 29% (19,20). These findings raise the question of whether imaging or pathologic factors can be identified to guide the management of radial scars, particularly in light of increasing evidence that tomosynthesis reveals more architectural distortions and possibly more radial scars than FFDM or film-screen mammography. In this article, we assessed the outcomes of radial scars sampled by DBT-guided CNB.

MATERIALS AND METHODS

After institutional review board approval, we conducted a retrospective review of all patients diagnosed with a radial scar on DBT-guided CNB at our institution between November 2014 and December 2016. Cases were excluded if ductal carcinoma in situ (DCIS) or invasive malignancy was present in the same core specimens. Cases were excluded if the radial scar was an incidental pathologic discovery, unrelated to the targeted lesion.

All core biopsies were performed under DBT guidance by seven fellowship-trained breast radiologists averaging 7 years of experience in breast imaging (range, 3–20 years) using a Suros ATEC 9-gauge vacuum-assisted biopsy device attached to the Selenia Dimensions digital mammography system (Hologic Inc., Bedford, MA). Patient age, core biopsy needle size, number of cores, imaging factors (visibility on FFDM vs DBT, size, presence of architectural distortion, mass, and/or calcifications, and prebiopsy imaging stability), presence or absence of atypia within the core samples, length of imaging follow-up, and final surgical pathology were collected. The imaging features (architectural distortion, mass, and calcifications) of each lesion were further characterized into a primary feature and secondary features.

For purposes of statistical analysis, upstage on surgical excision was defined as identification of DCIS or invasive malignancy on the surgical excision specimen. Atypia was defined as any form of atypia noted by the pathologist, including atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), lobular carcinoma in situ (LCIS) or atypia not otherwise specified. For statistical analysis, we utilized exact binomial confidence intervals (CIs) and Fisher exact test. The software used for calculations was S-Plus for Windows version 8.0.

RESULTS

Between November 2014 and December 2016, 386 DBT-guided core needle biopsies were performed at our institution. We included all cases with a radial scar identified on the core biopsy pathology report and cases were excluded if DCIS or invasive malignancy was present in the same core specimens. Forty-five eligible biopsies in 44 patients were identified. The median age at the time of biopsy was 59 years (range, 36–88 years). The number of cores obtained ranged from 4 to 13, with a mean of 12 cores. Patient age, lesion size, and the number of cores obtained did not differ between the groups of radial scar with atypia and radial scar without atypia. Table 1 demonstrates several features of the biopsied radial scars, comparing the groups of those with and without atypia on core biopsy.

Six cases (13%) had radial scars with associated atypia and 39 cases (87%) had no associated atypia on DBT-guided CNB. Twenty-four patients underwent surgical excision, including all patients with atypia on the initial biopsy. One of these cases (4%) was upstaged on surgical excision. This case was upstaged to DCIS after the percutaneous biopsy revealed a radial scar with associated ADH (Fig 1). There was also a case that had no atypia on the initial biopsy, but final pathology revealed associated ADH (Fig 2). In cases with radial scar and associated atypia on core biopsy, the upstage rate was 17% (95% CI, 0–64%). In the patients who underwent surgical excision but did not have atypia on core biopsy, the upstage rate was 0% (95% CI, 0–19%).

TABLE 1. Features of Biopsied Radial Scars, Divided According to Presence or Absence of Atypia

Feature	Radial Scar with Atypia (SD)	Radial Scar without Atypia (SD)
Mean patient age (years)	57 (12)	57 (11)
Mean lesion size (cm)	1.3 (0.6)	1.3 (1.1)
Mean number of cores	10 (2.9)	10 (2.7)
	Number (%) of lesions	Number (%) of lesions
Total lesions	6 (13)	39 (87)
Imaging features*		
Architectural distortion	5 (11)	33 (73)
Calcifications	2 (4)	9 (20)
Mass	2 (4)	9 (20)
Lesion visibility		
Visible on FFDM	5 (11)	24 (53)
Visible on DBT only	1 (2)	15 (33)

DBT, digital breast tomosynthesis; FFDM, full field digital mammography; SD, standard deviation.

* Some lesions were characterized by more than one descriptor.

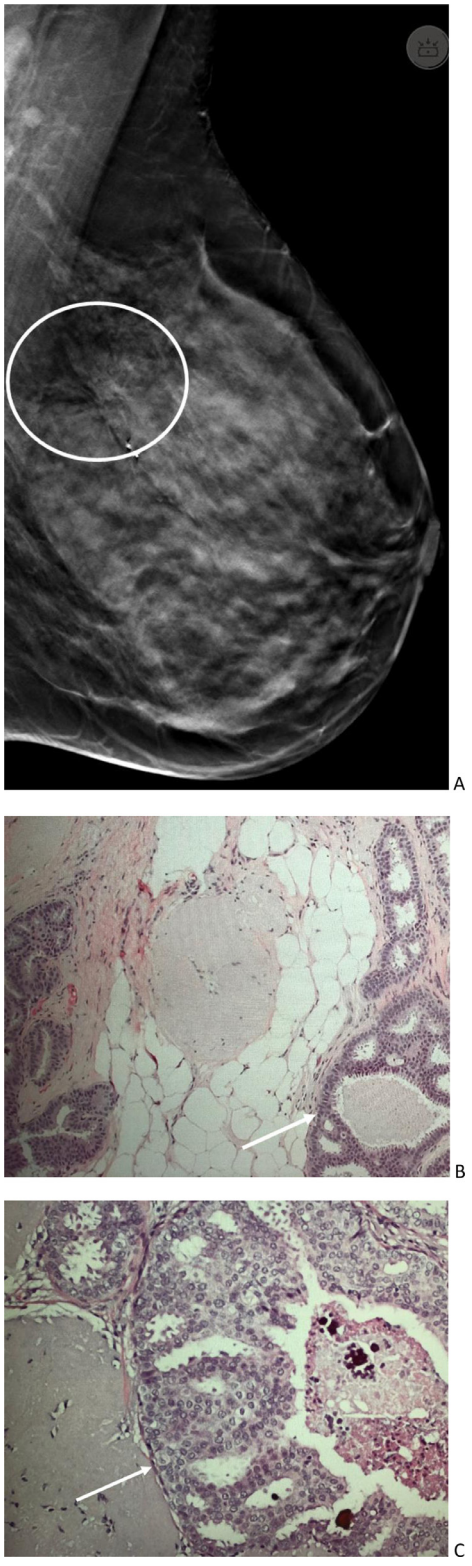

Fig. 1. A 44-year-old woman who presented for screening mammography. **A,** Mediolateral oblique (MLO) tomosynthesis image demonstrates architectural distortion (*circled*) in the left breast. **B,** Photomicrograph (H and E, 10x) of DBT-guided core needle biopsy specimen demonstrates radial scar with associated atypical ductal hyperplasia (ADH) (*arrow*). **C,** Photomicrograph (H and E, 20x) of the surgical excision specimen demonstrates ductal carcinoma in situ (DCIS) and central necrosis (*arrow*) within a radial scar. (Color version of figure is available online.)

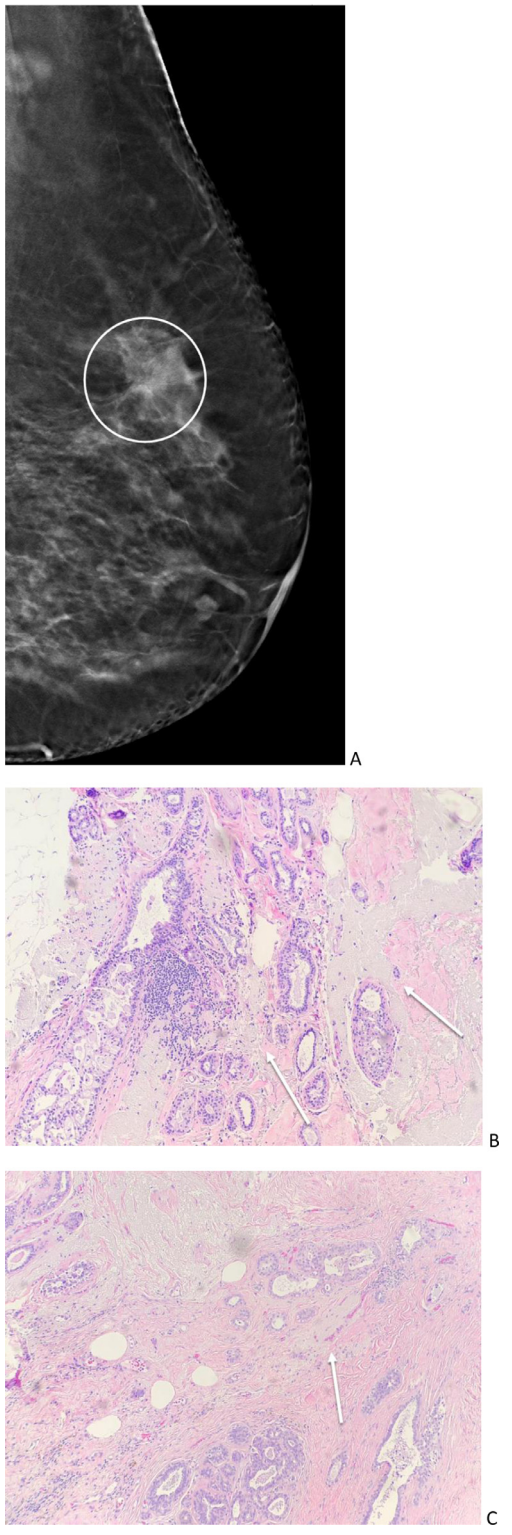

Fig. 2. A 64-year-old woman who presented for screening mammography. **A,** Exaggerated cradiocaudal lateral (XCCL) tomosynthesis image demonstrates architectural distortion (*circled*) in the left breast. **B,** Photomicrograph (H and E, 10x) of DBT-guided core needle biopsy specimen demonstrates portion of a radial scar without atypia. Arrow denotes elastosis with ductal hyperplasia. **C,** Photomicrograph (H and E, 10x) of surgical excision specimen demonstrates portion of a radial scar without atypia. Arrow denotes elastosis within the radial scar. (Color version of figure is available online.)

Of the patients who did not have surgical excision, imaging follow-up was available in 13 patients. The biopsied lesion was stable on imaging in all 13 patients with a median follow-up of 18 months (range, 12–40 months) and none of the patients undergoing follow-up presented with a subsequent breast cancer. Eight patients were lost to follow-up, with no surgical excision or imaging follow-up data available.

There were no lesion characteristics which significantly correlated with the likelihood of a lesion to have atypia. Architectural distortion was the primary imaging finding in 32 of 45 lesions (71%). A mass was the primary imaging finding in 6 of 45 lesions (13%) and calcifications were the primary imaging finding in 7 of 45 biopsied lesions (16%). Architectural distortion was noted as a secondary imaging feature in an additional six cases. Three out of 32 cases (9%) with architectural distortion as the primary imaging feature were associated with atypia on DBT-guided CNB. Two out of six cases (33%) with a mass as the primary imaging feature were associated with atypia on DBT-guided CNB. One out of seven cases (14%) with calcifications as the primary imaging feature was associated with atypia on DBT-guided CNB. No imaging features had a statistically significant association with atypia ($p = 0.15$). Table 2 further delineates the primary and secondary features of the biopsied lesions and the relationship of atypia with the primary imaging features.

Of the cases with atypia on DBT-guided CNB, one lesion was a new imaging finding and four lesions had a stable imaging appearance for an average of 46 months (range, 12–84 months) prior to biopsy. One lesion was detected on the patient's first DBT performed and the lesion was not visible on FFDM, so it is unclear if this was a new or stable finding. Of the 39 DBT-guided core needle biopsies which revealed radial scars without associated atypia, three lesions were new imaging findings and an additional six lesions were detected on the patient's first DBT study. It is unclear if these represent new or stable findings as the lesions were not visible on the prior FFDMs available for comparison. Twenty-three lesions had a stable imaging appearance for an average of 25 months (range, 12–60 months) prior to biopsy. Seven patients had no prior imaging available for comparison.

Of the 38 architectural distortions, 16 were visible on DBT only, 21 were visible on FFDM and DBT, and one patient did not have prebiopsy DBT but the lesion was visible on DBT scout images obtained at the time of biopsy. Of the 16 lesions visible on DBT only, one (6%) had atypia on initial biopsy and was classified as a radial scar with atypia not otherwise specified (not meeting clear criteria for ADH, ALH, or LCIS). On final surgical excision, the atypia remained unclassified.

DISCUSSION

Management recommendations for radial scars remain controversial, at least partially due to the wide range of reported upstage rates to invasive or in situ carcinoma at surgical excision. The current American College of Radiology (ACR) practice parameters recommend surgical consultations for high-risk lesions, including radial scars, found at CNB, but acknowledge some controversy exists regarding these lesions and endorses individualized care when appropriate (21).

Our paper focuses on DBT-guided CNB as lesions visible on DBT only are of particular interest because we know that more architectural distortions, and possibly more radial scars, are being discovered with the increasing use of DBT. These lesions may have been stable for many years on film-screen mammography or FFDM, though not clearly visible due to overlapping tissues and/or small size. While there is little published data specifically looking at upstage rates of radial scars in studies where DBT was utilized, the results of our study correlate with the results published on this topic. Lamb et al evaluated the upgrade rates at a single institution of several high-risk lesions, including radial scars, before and after the implementation of DBT (19). They found the prevalence of radial scars after the implementation of DBT was 15.3% compared to 11.7% in our study. The overall malignancy upgrade grade for radial scar was 6.2% in the paper by Lamb et al, but the study did not separate those lesions by the presence or absence of atypia on core biopsy pathology. In our study, the overall upstage rate was 2% (16.7% in the radial scar with atypia group and 0% in the radial scar without atypia group).

A paper by Freer et al specifically reviewed lesions that were visible on DBT only, without an ultrasound or a MRI correlate, that were subsequently targeted for DBT-guided localization and excision (20). Core biopsy pathology was not available as their center did not have the technology available at that time. In the study by Freer et al, 29% of radial scars were associated with malignancy. Direct comparison to our data is limited as there was no presurgical biopsy performed in the study by Freer et al and many of the cases in that publication would have likely been excluded from our study once malignancy was diagnosed on the core biopsy specimen.

Several recent publications have concluded that clinical follow-up of certain radial scars identified at CNB may not

TABLE 2. Prevalence of Primary and Secondary Imaging Features in Biopsied Radial Scars and Relation of Atypia to Primary Imaging Feature

Feature	Primary Imaging Feature	Secondary Imaging Feature	Atypia vs. Primary Imaging Feature
Architectural distortion	32/45 (71)	6/45 (13)	3/32 (9)
Mass	6/45 (13)	4/45 (9)	2/6 (33)
Calcifications	7/45 (16)	4/45 (9)	1/7 (14)

*All data displayed as number (percentage). Percentages have been rounded and may not total 100.

require excision. Donaldson et al reported no cases upstaged to malignancy when the CNB revealed a radial scar without associated atypia (22). The paper identified five lesions (16%) that had an associated high-risk lesion (ADH, ALH, LCIS) on the excisional specimen from the group of benign radial scars after CNB. All of the cases with high-risk lesions on excision were biopsied under ultrasound guidance with a 14-gauge core biopsy needle. In the same study, the benign radial scars biopsied with larger gauge core biopsy needles under stereotactic or MRI guidance revealed no associated high-risk lesions on excision. One patient detailed in the paper with a radial scar without atypia was diagnosed with DCIS in the ipsilateral breast 16 months after initial biopsy, but not at the site of the initially biopsied radial scar. The study by Donaldson et al did not exclude cases with carcinoma in the same CNB as the radial scar, which our study did. This limits comparison of our group of radial scars with associated atypia with the data reported by Donaldson as many of the lesions included in their study would have been excluded from our study.

A paper by Chou et al found an upgrade rate to breast cancer in 2.5% of the 81 patients who underwent surgical excision after CNB ($n = 122$) of a radial scar (23). Comparing those patients who had radial scar with atypia and those without atypia, the upgrade rate was 0% for the group with atypia and 4% for the group without atypia. Of the two cases with an upgrade to malignancy, the cancers were grade 1 invasive ductal carcinomas measuring less than 1 cm. Both of the upgraded cases were initially biopsied using a 14 gauge core biopsy needle under ultrasound guidance. None of the patients who were followed clinically developed a malignancy in the ipsilateral breast.

A study by Ferreira et al in 2017 reported a significantly lower upgrade rate when radial scars were biopsied using vacuum-assisted biopsy needles (24). A single lesion was upgraded (from radial scar without atypia to a radial scar with atypia) in the vacuum-assisted biopsy group compared to a 24% upgrade rate in the group biopsied with standard core biopsy needles. Ferreira also found that the presence of atypia in the initial CNB was associated with an approximately 10 times higher risk for upstage at surgical excision. Based on this, the authors concluded that the risk of upstage in patients with a radial scar without associated atypia who were biopsied using a vacuum-assisted core biopsy needle could safely be considered for clinical management.

In our study, all biopsies were performed using a 9-gauge vacuum-assisted biopsy needle under tomosynthesis guidance. Many recent papers make a note of the size of the biopsy needle playing a role in adequate sampling and recommend surgical excision for those lesions which may not have been adequately sampled. The case for conservative management of radial scars without associated atypia was made as early as 2002 by Brenner et al, who noted no upstaging to malignancy if lesions were sampled with a vacuum-assisted biopsy needle and at least 12 cores were obtained (8).

In our study, no cases of radial scar without associated atypia on initial CNB were upstaged to DCIS or invasive malignancy on surgical excision. This suggests that radial scars without associated atypia may not require surgical excision due to the very low risk of a missed malignancy at the location of the radial scar. This also highlights the need for additional studies regarding identification of lesions with an increased risk for ADH to guide management recommendations.

Our study has several limitations. Our study had a small sample size, a limitation present in most studies addressing this topic due to the relatively uncommon presence of radial scar on CNB. As individual institutions join to form larger hospital systems, there is a greater chance for multi-institutional trials with a larger number of cases. Some of our follow-up patients have a relatively short time of follow-up, either because they have not returned for additional mammography within our hospital system or because they were biopsied toward the end of our collection period and the time available for follow-up is short. Because biopsies were performed at a single center, there may be some features of our patient population that may cause our results to not be applicable to other populations. In addition, the study was conducted at a center with dedicated breast imaging radiologists, and our results may not generalize to other imaging centers.

CONCLUSION

In conclusion, our findings indicate that if the targeted lesion is well sampled, contains no atypia, and there are no confounding clinical factors (such as patient reliability or access to follow-up), radial scars without atypia on DBT-guided CNB with a 9-gauge or larger vacuum-assisted biopsy needle can safely undergo annual imaging follow-up rather than surgical excision.

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