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ORIGINAL ARTICLE

Tomosynthesis-guided Vacuum-assisted Breast Biopsy of Sonographically Occult Non-calcified Breast Lesions Detected on Tomosynthesis

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ABSTRACT

Objectives: *To analyse the pathological results from tomosynthesis-guided vacuum-assisted breast biopsy (VAB) of tomosynthesis-detected sonographically occult non-calcified breast lesions.*

Methods: *We performed a retrospective review of patients who had undergone tomosynthesis-guided VAB from December 2017 to May 2019. Imaging findings and pathological outcome were evaluated. The technical success rate and complications of tomosynthesis-guided VAB were reviewed.*

Results: *In our centre, all sonographically occult non-calcified lesions detected on digital breast tomosynthesis (DBT) with grade ≥4a or above according to Breast Imaging Reporting and Data System (BI-RADS) are selected for VAB under tomosynthesis guidance. Among the 41 cases reviewed, sampling was successful in 40 (97.6%). Among the 40 cases with pathologies, three malignancies, 14 high-risk lesions and 23 benign lesions were identified. All three malignancies in our study presented as architectural distortion, which was the main feature of the majority of DBT-detected sonographically occult non-calcified breast lesions (n = 38, 95%); the remaining two had focal asymmetry (n = 2, 5%). The positive predictive value for malignancy of architectural distortion detected on DBT only was 7.9%. All reported complications were clinically insignificant haematomas (n = 7, 17.5%).*

Conclusion: *Tomosynthesis-guided VAB is a safe and effective method for evaluation of sonographically occult lesions detected on DBT. The feature associated with the majority of these lesions was architectural distortion.*

Key Words: *Biopsy; Breast; Mammography*

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Contributors: WYF and EPYF designed the study. WYF acquired the data. All authors analysed the data. WYF draft the manuscript. EPYF, KMK, SKC, LKMW, WSM and DHYC critically revised the manuscript for important intellectual content.

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Ethics Approval: This study was approved by the Kowloon Central / Kowloon East Research Ethics Committee (Ref: KC/KE-21-0223/ER-2). The requirement for patient consent was waived for this retrospective study.

Data Availability: All data generated or analysed during the present study are available from the corresponding author on reasonable request.

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中文摘要

數位斷層合成攝影定位真空輔助乳房活檢對3D乳房X光檢測到的放射隱匿性非鈣化乳腺病灶

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目的：分析數位斷層合成攝影定位真空輔助乳腺活檢（VAB）對數位斷層合成攝影檢測到的放射隱匿性非鈣化乳腺病灶的病理結果。

方法：回顧2017年12月至2019年5月期間接受數位斷層合成攝影定位VAB的患者的影像學結果和病理結果，以及數位斷層合成攝影定位VAB的技術成功率和併發症。

結果：對3D乳房X光（DBT）檢測到，屬於乳腺影像報告和數據系統（BI-RADS）4a級或以上的所有放射隱匿性非鈣化病灶進行數位斷層合成攝影定位VAB。在檢視的41宗病例中，40宗（97.6%）成功抽樣。40例病灶中，發現惡性腫瘤3例、高危病灶14例、良性病灶23例。3例惡性腫瘤均呈結構變形，是大部分DBT 檢測到的放射隱匿性非鈣化乳腺病灶的主要特徵（n = 38，95%）；其餘2例為乳房局部不對稱（n = 2，5%）。僅在DBT上檢測到的結構變形惡性腫瘤的陽性預測值為7.9%。所有患者報告的併發症都是臨床影響不顯著的血腫（n = 7，17.5%）。

結論：數位斷層合成攝影定位VAB能安全並有效評估DBT上檢測到的放射隱匿病灶，而大部分病灶均出現結構變形。

INTRODUCTION

Digital breast tomosynthesis (DBT) has been found to have several advantages over planar digital mammography; it reduces anatomic noise by reducing tissue overlap.[1] It improves visualisation of subtle abnormalities, including architectural distortion and masses with spiculated margins.[1,2] Investigations of DBT have demonstrated its ability to reduce recall rates, with higher sensitivity and specificity rates compared with planar digital mammography.[3-9] With increased use of DBT, management of DBT-detected lesions becomes a new challenge. Among the DBT-detected lesions, some are sonographically occult and therefore cannot be biopsied under ultrasound guidance. Several studies have concluded that tomosynthesis-guided vacuum-assisted biopsy (VAB) is a safe and feasible procedure, which allows further evaluation of these lesions.[10-12] Rochat et al[13] suggested a difference in pathology outcome of tomosynthesis-guided VAB from stereotactic guided VAB that potentially results in a change in managing these lesions. The objective of our study was to analyse the pathological findings of sonographically occult non-calcified lesions biopsied with tomosynthesis-guided VAB. The technical success rate and complications of tomosynthesis-guided VAB were also evaluated.

METHODS

We performed a retrospective review of 41 consecutive cases of patients that had undergone tomosynthesis-guided VAB from December 2017 to May 2019 from a single institution (Well Women Clinic, Tung Wah Group of Hospitals).

Since the implementation of DBT in our institution, patients have been offered either planar digital mammography or DBT (Selenia Dimensions; Hologic, Bedford [MA], United States). Between December 2017 and May 2019, a total of 16,382 DBTs were performed in our centre. DBT imaging data were used to generate standard craniocaudal and mediolateral oblique views. Tomosynthesis slices and synthetic two-dimensional (2D) views were then generated from the raw data for reporting. All mammograms were reported by radiology fellows according to the Breast Imaging Reporting and Data System (BI-RADS) 5th edition.[14] Supplementary ultrasound was performed for evaluation of masses, asymmetry, and architectural distortion detected on DBT.

Suspicious lesions were discussed in multidisciplinary meetings for management such as timeframe of follow-up or modality of biopsy. For the suspicious mass lesions

detectable on ultrasound, we proceeded to ultrasound-guided biopsy. For suspicious calcifications, we proceeded to stereotactic mammography-guided biopsy. Tomosynthesis-guided VAB would be performed only on non-calcified lesions not readily seen on ultrasound, as it is a self-financed item in our setting. Suspicious lesions (categorised as BI-RADS ≥4a) without sonographic correlation were selected for tomosynthesis-guided VAB using an erect table system (Affirm Breast Biopsy Guidance System; Hologic, Marlborough [MA], United States).

Data Collection

Data on patients' demographics, DBT, ultrasound studies with reference to the BI-RADS, and pathology results were analysed. Patients' medical records including clinical notes, radiology reports, procedural records, surgical notes, and pathology reports were reviewed. The pathological outcome and positive predictive value (PPV) for malignancy were analysed. The technical success rate and complications of tomosynthesis-guided VAB were evaluated.

Biopsy Procedure and Postprocedural Management

Tomosynthesis-guided VAB was performed using a 9-gauge Eviva biopsy needle (Hologic) with an aperture of 20 mm. All biopsies were performed by radiology fellows after written informed consent was obtained. DBT scout images were acquired to determine the three-dimensional Cartesian coordinates of target lesions. The user was able to scroll among the DBT sections where the target was best seen to determine the Z coordinate (i.e., distance from target to breast support platform). A cursor was placed at the target in the selected section to determine X-Y coordinates, which were then sent to the biopsy system. Using sterile technique, a small skin incision was made for needle insertion after application of local anaesthesia. The 9-gauge needle was introduced and its position was confirmed with pre-fire stereotactic paired images. Multiple samples could be obtained by rotating the biopsy needle in different directions without needle reinsertion. Post-biopsy DBT images were taken to confirm that lesions had been correctly and sufficiently sampled. After lavage and aspiration of the biopsy site, a biocompatible titanium marker (TriMark) was deployed in all the cases. A post-marking DBT was performed to confirm marker placement at the site of original DBT-detected lesion. After biopsy and wound care, patients would be given a pressure wrap bandage and ice pack to apply to the biopsy site to minimise the chance of haematoma formation. All patients were assessed clinically to identify possible complications during or after procedures. Complications such as vasovagal reaction and haematoma were recorded in the standardised procedure report and checklist. Patients' clinical notes were reviewed for any delayed complication such as infection. Clinically significant complications were defined as complications that required additional surgical or medical intervention as a result of the biopsy.[15] Self-limited inflammation, ecchymosis, or minor interstitial haemorrhage were not considered as such.[15]

Pathological Outcomes

The pathological reports from tomosynthesis-guided VABs, and the mammographic findings, were reviewed for radiological-pathological concordance. For patients who underwent surgical excision or other means of biopsies, the pathological findings were compared with the results from VAB. The PPV for malignancy was calculated as the number of lesions with malignancies from tomosynthesis-guided VAB divided by the total number of lesions with biopsy performed. Any histological upgrade of any VAB-obtained tissue at subsequent surgical excision, e.g., ductal carcinoma in situ (DCIS) from VAB upgraded to invasive carcinoma at surgical excision, was recorded.

RESULTS

Technical Success

During the study period, there were 40 patients with 41 target lesions biopsied with tomosynthesis-guided VAB (Table 1). In one of the 40 patients (2.5%), two biopsy attempts were made because post-biopsy mammography after the first attempt showed that the biopsy site did not correspond to the site of architectural distortion. The second attempt was successful. Biopsies were successful in 40 out of 41 cases (97.6%). The failed one was a posteriorly located lesion that was at the edge of the compression paddle and not accessible by the biopsy needle.

Complications

All the reported complications were minor. There were seven cases of clinically insignificant haematoma (17.5%) and no occurrences of vasovagal syncope. None of the cases developed clinically significant complications that required medical or surgical treatment.

Pathology Analysis

Pathological findings were recorded for 40 patients with

40 target lesions (Table 2). There were no histological upgrades at surgical excision; the two DCIS were not upstaged to invasive carcinoma.

Among the architectural distortions (n = 38), three (7.9%) were malignant, 14 (36.8%) were high-risk, and 21 (55.3%) were benign. Both focal asymmetries (n = 2) were benign. The PPV for malignancy of DBT-detected sonographically occult non-calcified architectural distortion was 7.9%. The PPV for malignancy of DBT-detected sonographically occult focal asymmetries from VAB was 0%.

Table 1. Patient demographics, lesions characteristic, breast densities and biopsy procedures (n = 40).*

	No. (%) patients
Age, y, mean (range)	57.3 (37-74)
Family history of breast cancer†	6 (15%)
History of contralateral breast cancer	3 (7.5%)
Lesion type	
Architectural distortion	38 (95%)
Focal asymmetry	2 (5%)
BI-RADS category	
4a	27 (67.5%)
4b	12 (30%)
4c	1 (2.5%)
Breast density	
Extremely dense	2 (5%)
Heterogeneously dense	36 (90%)
Scattered fibroglandular densities	2 (5%)
Entirely fatty	0
Needle approaches	
Craniocaudal	15 (37.5%)
Reversed craniocaudal	3 (7.5%)
Mediolateral oblique	9 (22.5%)
Lateromedial	10 (25%)
Lateromedial oblique	3 (7.5%)
Total biopsy samples, mean (range)	11.4 (6-18)

Abbreviation: BI-RADS = Breast Imaging-Reporting and Data System.
* Data are shown as No. (%), unless otherwise indicated.
† In first-degree relatives.

One patient had undergone left mastectomy with sentinel lymph node biopsy (Figure 1). The surgical specimen showed a 25-mm invasive carcinoma of no special type with DCIS, i.e., stage II disease (pT2, N0, M0) without evidence of nodal and distant metastasis (Figure 2).

For the case with flat epithelial atypia with atypical ductal hyperplasia, supplementary ultrasound revealed two suspicious masses (BI-RADS grade 4a) in the ipsilateral breast that did not correspond to the architectural distortion. At 3 months after VAB, ultrasound-guided biopsy of both of the masses revealed DCIS. Lumpectomy of breast masses was performed. The pathology of surgical specimen showed DCIS with margin involvement. Second operation with mastectomy showed complete removal of residual tumour. The pathology of surgical specimen from second operation also showed DCIS. In this case, the patient had concurrent malignancy from masses detected incidentally from the supplementary ultrasound. It was not counted as a malignant upgrade because the masses did not correspond to the architectural distortion. Therefore, the malignant upgrade from high-risk lesion in our study is 0%.

Table 2. Pathology outcomes of digital breast tomosynthesis–detected sonographically occult non-calcified lesions from vacuum-assisted breast biopsy (n = 40).*

Subgroup	Malignant lesions	High-risk lesions	Benign lesions
Ductal carcinoma in situ	2 (5%)		
Invasive carcinoma of no special type with DCIS	1 (2.5%)		
Radial scar/CSL		12 (30%)	
Flat epithelial atypia and ADH		1 (2.5%)	
Atypical intraductal apocrine cell proliferation		1 (2.5%)	
Fibrocystic change			12 (30%)
Sclerosing adenosis			2 (5%)
PASH			1 (2.5%)
Sclerosing lymphocytic lobulitis			1 (2.5%)
Fibrous scar and fat necrosis			1 (2.5%)
Cholesterol granuloma			1 (2.5%)
Miscellaneous benign lesions			5 (12.5%)
Total	3 (7.5%)	14 (35%)	23 (57.5%)

Abbreviations: ADH = atypical ductal hyperplasia; CSL = complex sclerosing lesion; DCIS = ductal carcinoma in situ; PASH = pseudoangiomatous stromal hyperplasia.
* Data are shown as No. (%).

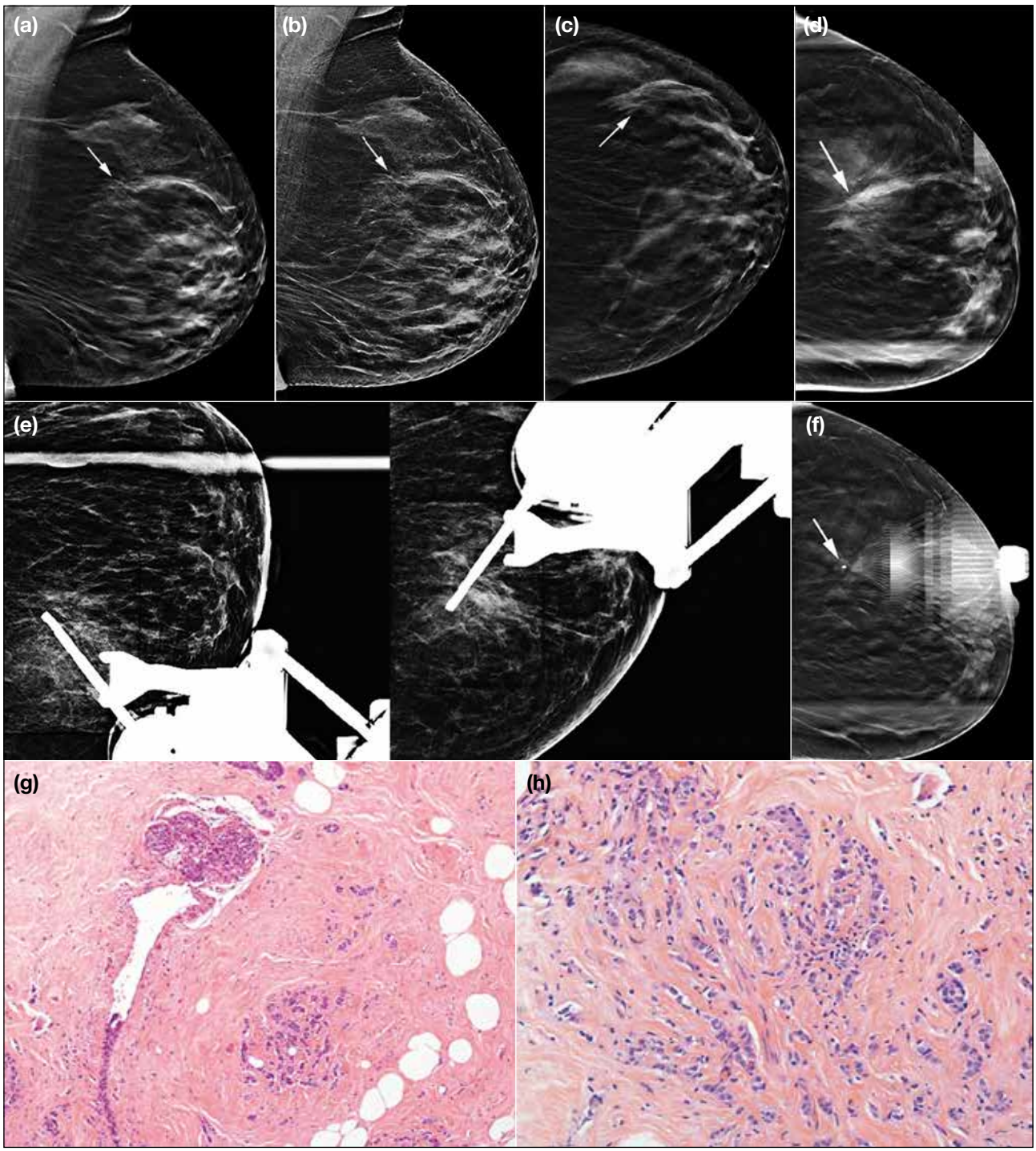

Figure 1. Invasive carcinoma of no special type: a 69-year-old woman with a history of right breast cancer and right mastectomy presented for screening mammography. (a) Left mediolateral oblique view generated from digital breast tomosynthesis (DBT) data with (b) a synthetic C view reveal architectural distortion (arrows) in the upper outer quadrant of the left breast, which is less conspicuous on the craniocaudal view (c). Tomosynthesis-guided vacuum-assisted biopsy was performed from a mediolateral (ML) approach. (d) DBT ML scout image confirms the location of architectural distortion (arrow). (e) Pre-fire paired stereotactic images confirmed the needle placement. (f) Post-deployment DBT confirmation marker (arrow) corresponds to the site of architectural distortion, suggesting a successful biopsy. (g) Microscopic examination shows an invasive carcinoma and ductal carcinoma in situ of low nuclear grade (original magnification: 100×). (h) The invasive carcinoma cells are arranged in cords dissecting through the fibrous stroma (original magnification: 200×).

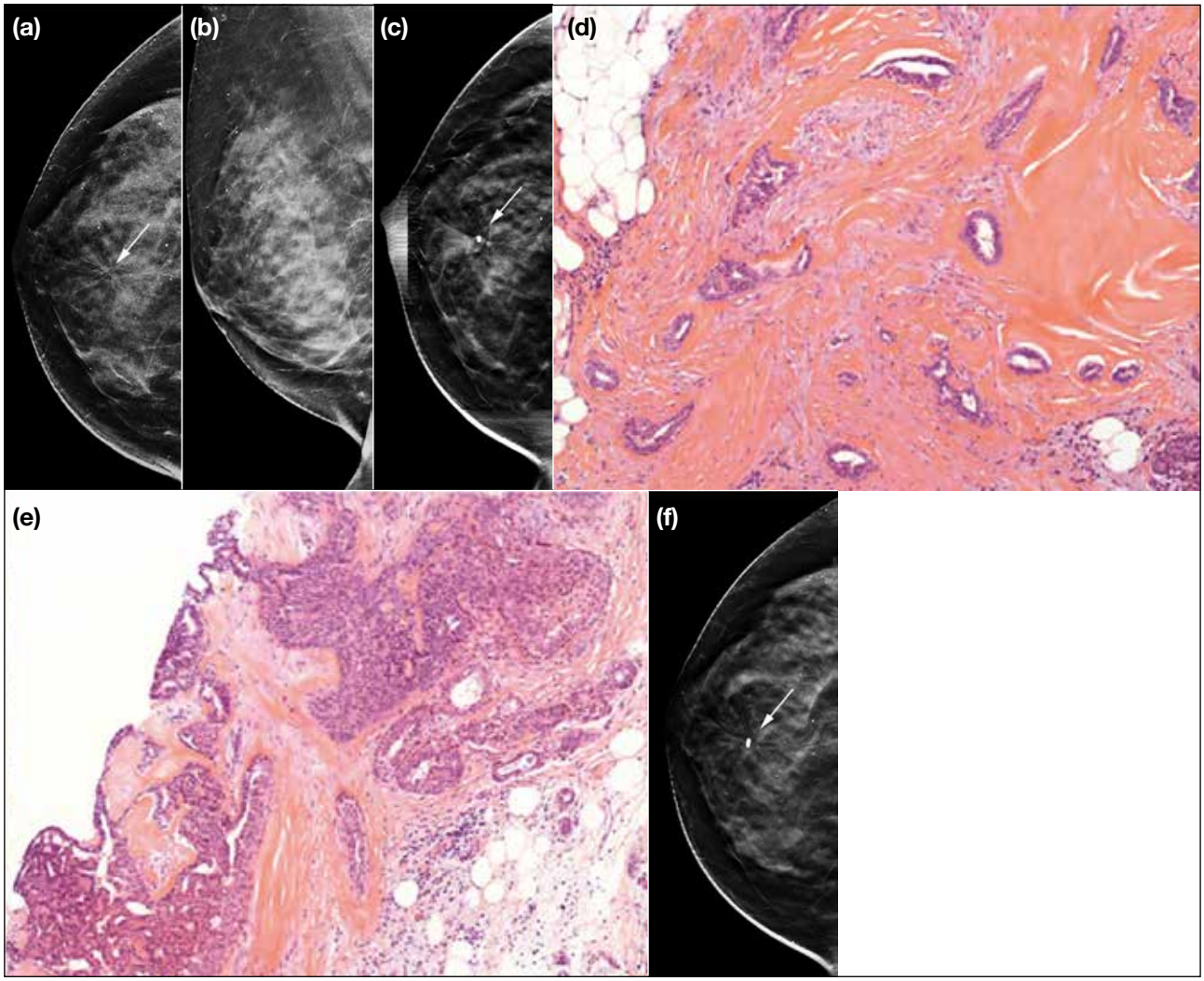

Figure 2. Radial scar without atypia: a 42-year-old woman presented for screening mammography. (a) A right craniocaudal (CC) view generated from digital breast tomosynthesis (DBT) data reveals an architectural distortion (arrow) in the central mid depth region of the right breast, which was not visible on right mediolateral oblique view (b). Tomosynthesis-guided vacuum assisted biopsy was performed from a CC approach. (c) Post-fire three-dimensional CC DBT image confirmed marker placement (arrow) corresponding to site of architectural distortion, indicating successful biopsy of the target lesion. Surgical excision was not performed after discussion in multidisciplinary meeting. (d) H&E-stained section showing angulated mammary ductules lined by a benign epithelium embedded in a fibroelastic stroma, characteristic of a radial scar/complex sclerosing lesion (original magnification: 100×). Associated florid usual epithelial hyperplasia is shown in (e) [original magnification: 100×]. (f) Follow-up DBT at 1 year demonstrated stability of the architectural distortion (arrow).

After multidisciplinary discussion, it was decided that surgical excision was not required for other high-risk lesions if they were removed during VAB. All the benign lesions were considered as concordant. Follow-up mammography was suggested for all benign and high-risk lesions to ensure stability and benignity. The follow-up period after biopsies ranged from 4 to 21 months (mean, 10.7 months).

DISCUSSION

Architectural distortion is the most common DBT-only finding,[16] and the most commonly missed as interval cancer in planar digital mammography.[17] It is well established that there has been an increase in the detection of architectural distortion with the advent of DBT,[18-20] thus increasing the cancer detection rate. Similar to the rest of the Asian population, most of the cases in our study had high breast density. In a recent meta-analysis, Phi et al[21] showed that DBT significantly increases the cancer detection rate in dense breasts.

The purpose of the present study was to analyse the

performance of tomosynthesis-guided VAB and pathological outcome for DBT-detected sonographically occult non-calcified lesions. The present study highlights that, after calcifications, the second most common finding in DBT-detected sonographically occult lesions was architectural distortion. A total of 44.7% instances of architectural distortion were found to be malignancy and high-risk lesions. The PPV for malignancy of DBT-detected sonographically occult non-calcified architectural distortion from tomosynthesis-guided VAB was 7.9%. Several studies have shown that architectural distortion is much less likely to represent malignancy if detected only on DBT,[22] is sonographically occult,[23,24] or is detected in a screening population.[23] Recent studies have shown similar PPV for DBT-only detected sonographically occult architectural distortion ranges from 7.7% to 26%,[22,24-27] which are not low enough to forgo biopsy. Therefore, histological correlations are warranted for these lesions. In the present study, we achieved a high technical success rate with tomosynthesis-guided VAB without any reported clinically significant complications.

Radial scars/complex sclerosing lesions (n = 12, 31.6%) are one of the most common non-malignant findings in our study. Bahl et al[19] showed that radial scars are more commonly found with DBT. Among architectural distortions detected on DBT in our study, about one-third of cases were radial scars. In a recent meta-analysis, Farshid and Buckley[28] found that the upgrade rate of radial scars without atypia from VAB by 8- to 11-gauge needles (1%) was much lower than from core-needle biopsy by 14-gauge needle (5%). Due to the low malignant upgrade rate of radial scars/complex sclerosing lesions removed with VAB, there has been a shift in management of these lesions towards close surveillance instead of surgical excision.[29,30] This is why the radial scars/complex sclerosing lesions in this study were not subjected to further surgical excision (Figure 2).

There are several advantages of tomosynthesis-guided biopsy, which can overcome some of the technical difficulties of 2D-guided biopsy. There is a higher chance of inaccurate targeting in 2D-guided biopsy of low-contrast lesions, as the operator may fail to identify the same lesion on the paired images.[12] DBT improves lesion conspicuity and provides depth information without the need for triangulation and paired images.[11] It allows accurate lesion targeting and calculation of the distance between target and skin. It facilitates better biopsy planning with a safer and easier approach to avoid complications such as skin injury. The procedural time can be reduced by faster lesion detection and hence patients' comfort can be improved. In our study, we seldom encountered difficulty in lesion targeting even though all of our targets were low-contrast lesions.

There are a few limitations of this study. First, it was a retrospective study, which has its inherent limitations. In our study, the precise record of procedural time could not be achieved in most of the cases. Second, the sample size was relatively small (n = 40). The pathological analysis of focal asymmetry was also limited due to very small sample size (n = 2). Third, the study was performed in a single institution from a breast screening programme. All diagnostic and biopsy procedures in our institution were interpreted and performed by trained breast radiologists which may not be generalisable to other practices. Fourth, there is a lack of complete follow-up data and imaging (i.e., >2 y of stability) for the benign or high-risk lesions due to short follow-up period of this retrospective study. This would potentially underestimate the malignancy rate. Lastly, tomosynthesis-guided VAB were performed in selected cases (i.e., sonographically occult non-calcified lesions) and as self-financed basis, which would introduce selection bias. Further studies (such as a prospective study with larger sample size and complete follow-up data) are suggested for confirmation of our findings. As the use of DBT becomes more popular, it is important for breast radiologists to familiarise themselves with tomosynthesis-guided biopsy techniques.

CONCLUSION

Tomosynthesis-guided VAB is a safe, minimally invasive, and cost-effective method for evaluation of sonographically occult lesions detected on DBT. The majority of DBT-detected sonographically occult non-calcified breast lesions were architectural distortion with a PPV of 7.9%.

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