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Is there an extraclinical value of automated breast volume scanner compared with hand-held ultrasound?

A pilot study

Jia Zhan, MD, Xue-Hong Diao, PhD, Yun Pang, MBBS, Yan Wang, MBBS, Lin Chen, PhD*, Yue Chen, MBBS*

Abstract

The aim of this study was to investigate the extraclinical value of automated breast volume scanning (ABVS) in the diagnosis of breast tumor compare to hand-handle ultrasound (HHUS).

One hundred twenty-four patients with breast tumor were performed HHUS and ABVS before operation. The research focused on whether there were newly found tumors or new findings on the coronal planes by using ABVS compared with HHUS. Then, the classification adjustments of breast imaging reporting and data system (BI-RADS) were made according to new findings on the coronal planes by using ABVS.

There are totally 166 breast tumors found in 124 patients by HHUS, while 8 more were observed by ABVS, 4 of which were malignant and the rest were benign. The sensitivity and specificity of ABVS coronal plane findings were 37.0% and 92.5%, respectively. The area under receiver operating characteristic curve was 0.89 before the corrected classification versus 0.93 after the corrected classification, there were no significant differences ($P > .05$).

There was no significant extraclinical value in differentiating diagnosis of malignant tumors and benign breast tumors by ABVS comparing to HHUS. However, those minimal lesions missed diagnosis could be found by ABVS with continuously automatic scanning.

Abbreviations: ABVS = automated breast volume scanning, AUC = area under curve, BI-RADS = breast imaging reporting and data system, DCIS = Ductal carcinoma in situ, HHUS = hand-handle ultrasound, NPV = negative predictive value; PPV = positive predictive value, ROC = receiver operating characteristic, US = ultrasound.

Keywords: automated breast volume scanning, breast imaging reporting and data system, breast tumor, hand-handle ultrasound

1. Introduction

Breast cancer is the most frequent malignant tumor in Chinese women. In the past decade, its incidence had risen from 46.0[1] to 73.5 per 100,000.[2] Mammography has been used as a primary imaging investigation to diagnose a breast cancer. The results of multiple large randomized controlled trials provide evidence that supports its effectiveness in the reduction of breast cancer mortality.[3] However, mammographic sensitivity can be reduced in specific circumstances, and a dense breast is regarded as one of the important factors affecting the accuracy of mammography.[4] Recent studies have reported that hand-hold ultrasound (HHUS) can detect a substantial number of mammographically occult cancers, which encourages the supplemental use of ultrasound in Asian women with dense mammograms.[5]

HHUS is affordable and practical, but suffers from poor reproducibility and operator variability.[6] The recently developed automated breast volume scanner (ABVS) attachment, which could overcome these disadvantages, has been used in the preoperative diagnosis of breast tumors.[7] It affords additional information of morphology features on the coronal plane, which cannot be achieved with HHUS. Retraction phenomenon on the coronal plane was regarded as a high diagnostic feature in the differentiation of benign and malignant breast masses using an ABVS.[8]

Most studies revealed that ABVS shows a comparable diagnostic performance to HHUS.[9–11] However, the fact was ignored that in most cases, differential diagnosis could be made by HHUS on transverse plane or sagittal plane even without the coronal reconstruction by ABVS (Fig. 1).

Hence, the aim of the study was to assess whether there is an extraclinic value of ABVS compared with HHUS. We evaluated the extraclinic value of ABVS in 2 ways: whether there was extra benefit in differential diagnosis between benign and malignant breast masses by using ABVS, and whether ABVS can detect extra breast lesion that was ignored by HHUS.

2. Patients and methods

2.1. Patients

Informed consent was obtained from all patients and the study was performed in accordance with the ethical guidelines of the

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XHD contributed equally to this work and should be considered co-first authors.

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Department of Ultrasound Huadong Hospital, Fudan University, Shanghai, P.R. China.

* Correspondence: Lin Chen, Department of Ultrasound Huadong Hospital, Fudan University, Shanghai, P.R. China (e-mail: cl_point@126.com); Yue Chen, Department of Ultrasound Huadong Hospital, Fudan University, Shanghai, P.R. 200040, China (e-mail: ultrasound_drchen@163.com).

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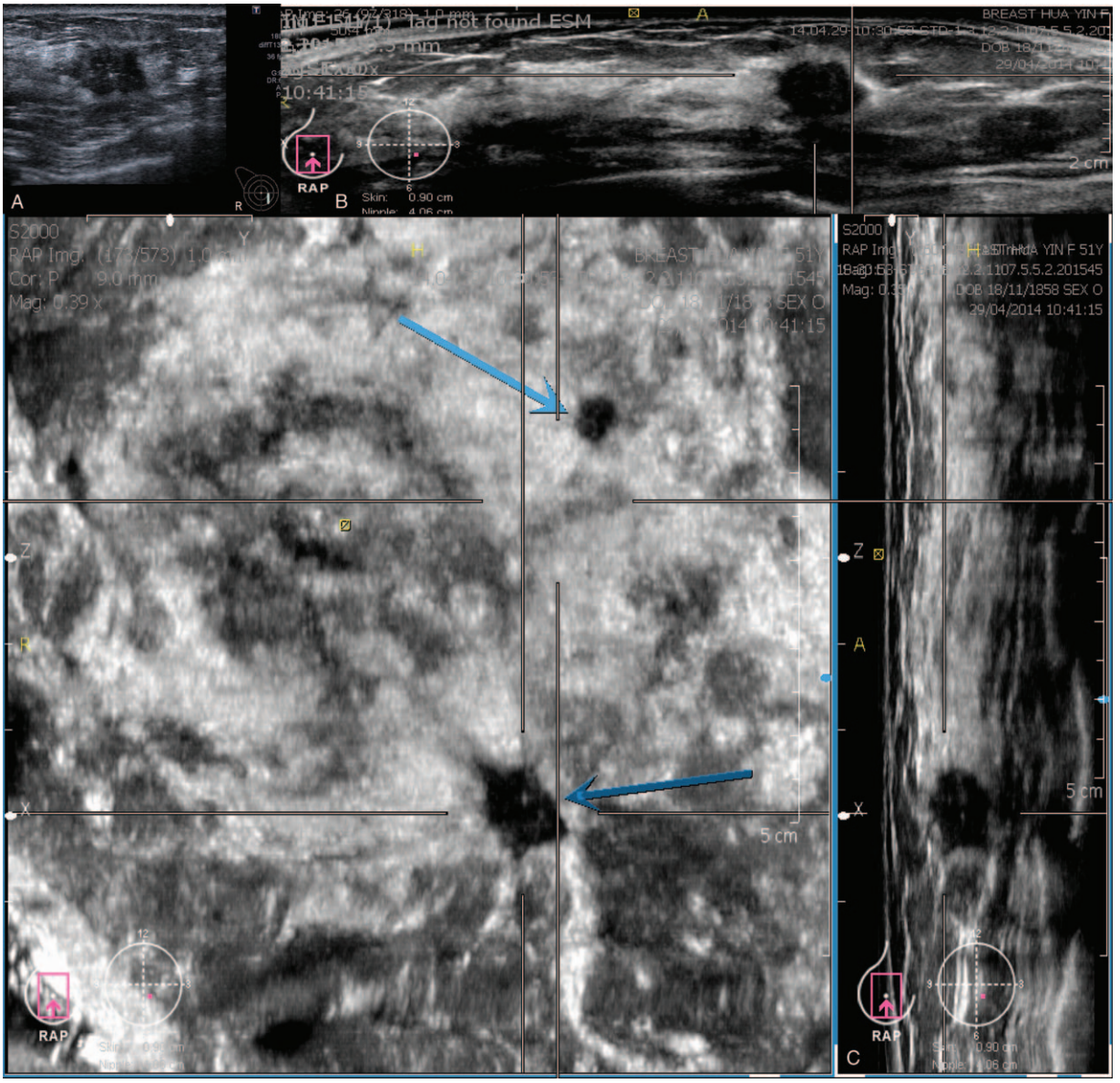

Figure 1. A 51-year-old woman with a lesion in the inner downer quadrant of right breast. (A) HHUS showed an irregular hypoechoic lesion with microcalcification. BI-RADS:4b was evaluated even without the coronal reconstruction by ABVS. (B) The transverse plane of ABVS. (C) The coronal reconstruction is lower left and the sagittal plane is lower right. There was a definitive retraction phenomenon on coronal planes by ABVS (down arrow); also, another 7 mm lesion was detected in a same plane, which was ignored by HHUS (upper arrow). Therefore, the BI-RADS lexicon of the first lesion was adjusted to 4c according to coronal planes finding. Pathologic analyses showed the first mass was an invasive ductal carcinoma, and the newly detected mass was a fibroadenoma.

Helsinki Declaration and approved by the local ethics committee. From November 2011 to November 2016, 124 patients (1 man and 123 women) with breast masses who were referred to the Breast surgery of Huadong Hospital were performed by HHUS and ABVS. The mean age of the examined patients was 50.8 ± 13.0 years (age range, 22–86 years). Median size of the masses was $2.5 \times 1.8 \times 2.0$ cm (range, $0.8 \times 0.6 \times 0.7$–$3.9 \times 2.2 \times 3.4$ cm).

The flowchart for the patient selection is present in Fig. 2. The inclusion criteria for the patients were as follows: HHUS was performed before ABVS several days ago; breast masses classified as BI-RADS category 3 or 4 on HHUS; and breast mass were pathologically confirmed after operation.

Exclusion criteria were only biopsy sample for pathological assessment; pathologically borderline tumors; patients received breast cancer-related treatments (hormonal, chemo-, and/or radiotherapy) before surgery; and obscured lesions under the nipple.

2.2. HHUS examinations

All patients were examined by using gray-scale ultrasound, 1 to 3 days before ABVS by 2 experienced sonographers (JZ and X-HD) on an Acuson S2000 ultrasound unit (SiemensMedical Solutions, Mountain View, CA) and an Aplio 500 ultrasound (US) system (Toshiba Medical Systems, Tokyo, Japan).

For US investigation, the patients were positioned. If necessary, the patient was moved into a contralateral posterior oblique position to scan the lateral and inferior parts of the breast. Ultrasound was performed in a supine position with raised arms in radial, antiradial, longitudinal, and transverse directions by experienced radiologist.

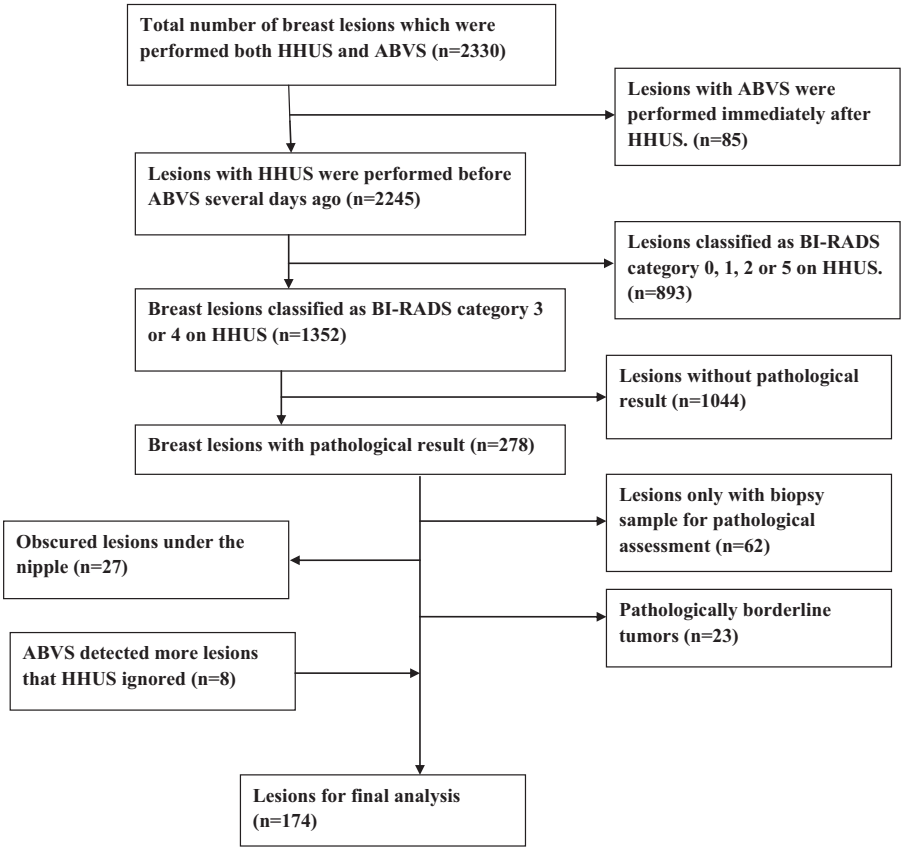

Figure 2. The flowchart for the patient selection.

Breast mass was scanned for size, volume, echogenicity, echotexture, shape, margin. JZ and X-HD assigned the BI-RADS classification.

2.3. ABVS examinations

ABVS examinations were performed after HHUS using the ABVS system integrated with the Acuson S2000 unit by the 2 technologists (YP and YW).The positioning of the patient was similar to that with HHUS. The ABVS 14L5BV probe was used after the setting (general gain, frequency, focal zone placement, and depth) and was adjusted to optimize the images. The number of scans performed on each side was selected by the examiner according to the size of the breast under observation. Smaller breasts could be fully displayed by performing medial and lateral volume scans. Larger breasts required additional views (e.g., a separate view of the apex and axillary process).

After acquisition, the volume image series was automatically sent from the ACUSON S2000 ABVS to a dedicated breast ultrasound review workstation. The workstation presents images through MPR and reconstructs secondary images from the acquisition volume in different planes. Nipple was included in each scan and labeled with a small quadrate frame to avoid confusion with hypoechoic masses and enable orientation in the subsequent assessment.

2.4. Image review and data analysis

Two independent radiologists (JZ and X-HD) respectively reviewed the 3D volume data of those patients; their HHUS was performed by himself (herself) on an ABVS workstation. They had more than 5 years of experience in ABVS image interpretation. The number of lesions detected by ABVS was compared with that of HHUS. New finding lesions were recorded and BI-RADS were made. Definitive retraction phenomenon on coronal planes was regarded as a positive finding in breast masses and whose category diagnosis would be raised 1 level (3 to 4a, 4a to 4b, 4b to 4c, 4c to 5). Suspicious retraction phenomenon on coronal planes was discussed by 3 radiologists to determine whether BI-RADS of breast lesions should be adjusted. Receiver operating characteristic (ROC) curves were drawn to compare their diagnostic accuracy.

2.5. Statistical analysis

ROC analysis was performed and performances of the before and after correction were assessed from the areas under ROC curves. The areas under ROC curve were compared with Z test. All statistical tests were performed by using commercially available software (Stata, version 10.0; StataCorp, College Station, TX). For all tests, a P value $<.05$ was considered to indicate a statistically significant difference.

3. Results

3.1. Number of lesions

One hundred sixty-six lesions were detected by both HHUS and ABVS, while ABVS detected 8 extra masses that were missed diagnosis by HHUS. Four of them were invasive ductal carcinomas, and the rest were adenosis tumors. The sizes of these

Table 1

Pathological diagnosis of 174 breast masses in 124 patients.

Pathologic diagnosis	No. of masses	Percent (%)
Malignant masses (n = 54)		
Invasive ductal carcinomas	33	18.9
Ductal carcinoma in situ (DCIS)	14	8.0
Invasive lobular carcinoma	4	2.3
Tubular carcinoma	1	0.6
Mucinous carcinoma	1	0.6
Apocrine carcinoma	1	0.6
Benign masses (n = 12)		
Fibroadenoma	62	35.6
Adenosis tumors	28	16.1
Breast intraductal papilloma	25	14.4
Mastitis	3	1.7
Cyst	2	1.2

8 breast tumors missed by HHUS are all less than 10 mm. Hence, totally 174 breast masses were confirmed by pathological result.

3.2. Pathological findings

On mastectomy, 33 of the 174 breast masses (18.9%) were diagnosed as invasive ductal carcinomas, 14 (8.0%) were diagnosed as ductal carcinoma in situ (DCIS), 4 (2.3%) as invasive lobular carcinoma, 1 (0.6%) as tubular carcinoma, 1 (0.6%) as mucinous carcinoma, 1 (0.6%) as apocrine carcinoma; 62 (35.6%) as fibroadenoma; 25 (14.4%) as breast intraductal papilloma, 28 (16.1%) as adenosis tumors, 3 (1.7%) as mastitis, and 2 (1.1%) as a cyst (Table 1).

3.3. Retraction phenomenon on coronal planes for all 174 breast masses

Totally, there were 29 retraction phenomena confirmed on coronal planes by ABVS in 174 breast masses. The coronal plane characteristics of the masses are presented in Table 2. Regarding the retraction phenomenon as the only criterion, the values to predict malignancy were sensitivity = 37.0% (20/54), specificity = 92.5% (111/120), positive predictive value (PPV) = 69.0% (20/29), negative predictive value (NPV) = 76.6% (111/145), and accuracy = 75.3% (131/174).

3.4. The adjustment of BI-RADS subcategorization of 166 breast masses

Totally, 26 breast massed were adjusted to a higher level (9 lesions from 3 to 4a, 9 from 4a to 4b, 5 from 4b to 4c, 3 from 4c to 5) (Table 3).

Table 2

Retraction phenomenon on coronal planes for 174 breast masses.

Retraction phenomenon on coronal planes	Positive findings	Negative finding
Malignant lesions	20	34
Benign lesions	9	111

The AUC was 0.926 (95% confidence interval [95% CI]: 0.888–0.964). The sensitivity = 98.0% (49/50), specificity = 72.4% (84/116), PPV = 60.5% (49/81), NPV = 98.8% (84/85), accuracy 80.1% (133/166), compared with before the adjustment was 0.891 (95% CI: 0.837–0.945), $\chi^2 = 3.28$, $P = .07$, 90.0% (45/50), 76.7% (89/116), 62.5% (45/72), 94.7% (89/94), 80.7% (134/166) (Fig. 3).

4. Discussion

The recent meta-analysis demonstrated that the diagnostic accuracy of ABVS for the differentiation of malignant and benign breast mass was high, with the pooled sensitivity and specificity being 92% (range 89.9–93.8) and 84.9% (range 82.4–87%)[12]; this result is based on images acquired by ABVS from transverse, sagittal, and coronal plane at the same time. However, the data do not reflect the extraclinical value of ABVS—as is known, the information from transverse and sagittal view can also be acquired by HHUS.

The retraction phenomenon was regarded as a especially useful feature provided by reconstructed coronal planes—which cannot be detected by HHUS. Pathologically, desmoplastic reaction of malignant breast tissue can produce contraction of the surrounding normal tissues toward the lesion and destroy normal parallel tissue planes, which might cause this special phenomenon.[13]

However, retraction phenomenon was identified to be a strong independent predictor with high PPV in differentiating benign and malignant breast masses, but not high sensitivity. Reviewing literatures, PPV of retraction phenomenon might be 98.8%,[8] and sensitivity can then only be 39.1% to 70%,[8,14] which means that most breast lesions with retraction phenomenon sign were malignant, while only partly malignant breast masses have retraction phenomenon on coronal planes. In the present study, retraction phenomenon sign on coronal planes predicted malignant breast masses with the sensitivity 37.0% (20/54) and PPV 70.0% (20/29), which caused the false-negative results.

Although single retraction phenomenon sign has not got the expected performance, combining the images acquired from

Table 3

The correction of BI-RADS category in 166 breast masses.

Pathological diagnosis	No. of masses	Before the correction of BI-RADS category				
		3	4A	4B	4C	5
Benign lesions	116	89	25	2	0	0
Malignant lesions	50	5	18	15	12	0
		94	43	17	12	0

Pathological diagnosis	No. of masses	Final BI-RADS category				
		3	4A	4B	4C	5
Benign lesions	116	84	27	4	1	0
Malignant lesions	50	1	16	17	13	3
		85	43	21	14	3

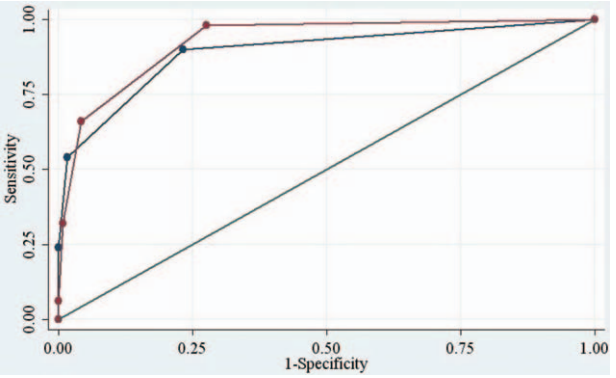

Figure 3. The comparison between ABVS (red line) and HHUS (blue line) in differential diagnosis of 166 breast lesions. The area under the ROC curve of the ABVS (0.926) was larger than HHUS (0.891) ($P > .05$).

transverse and sagittal plane, ABVS still got high sensitivity. However, there was no significant difference between HHUS and ABVS (0.926 vs 0.891, $P > .05$) (Fig. 3). Hence, it is implied that there was no extraclinic value of ABVS compared with HHUS in differential diagnosis between benign and malignant breast masses. Of course, the enlargement of sample size is a good way to improve the power of test, and more patients with retraction phenomenon sign on coronal plane by ABVS would be included in the future study. On the contrary, regarding lesion detectability by ABVS, the number of detected lesions by ABVS was not consistent with that by HHUS. ABVS detected 8 more masses, 4 of which were confirmed as invasive ductal carcinomas. It is worth emphasizing that the sizes of these 8 breast tumors are all less than 10 mm (Fig. 4). As the ABVS probe is equipped with 768 piezoelectric elements and reaches 14 MHz, we found sufficient image quality and resolution that would detect the tiny breast lesions ignored by HHUS. Meanwhile, continuous scanning and

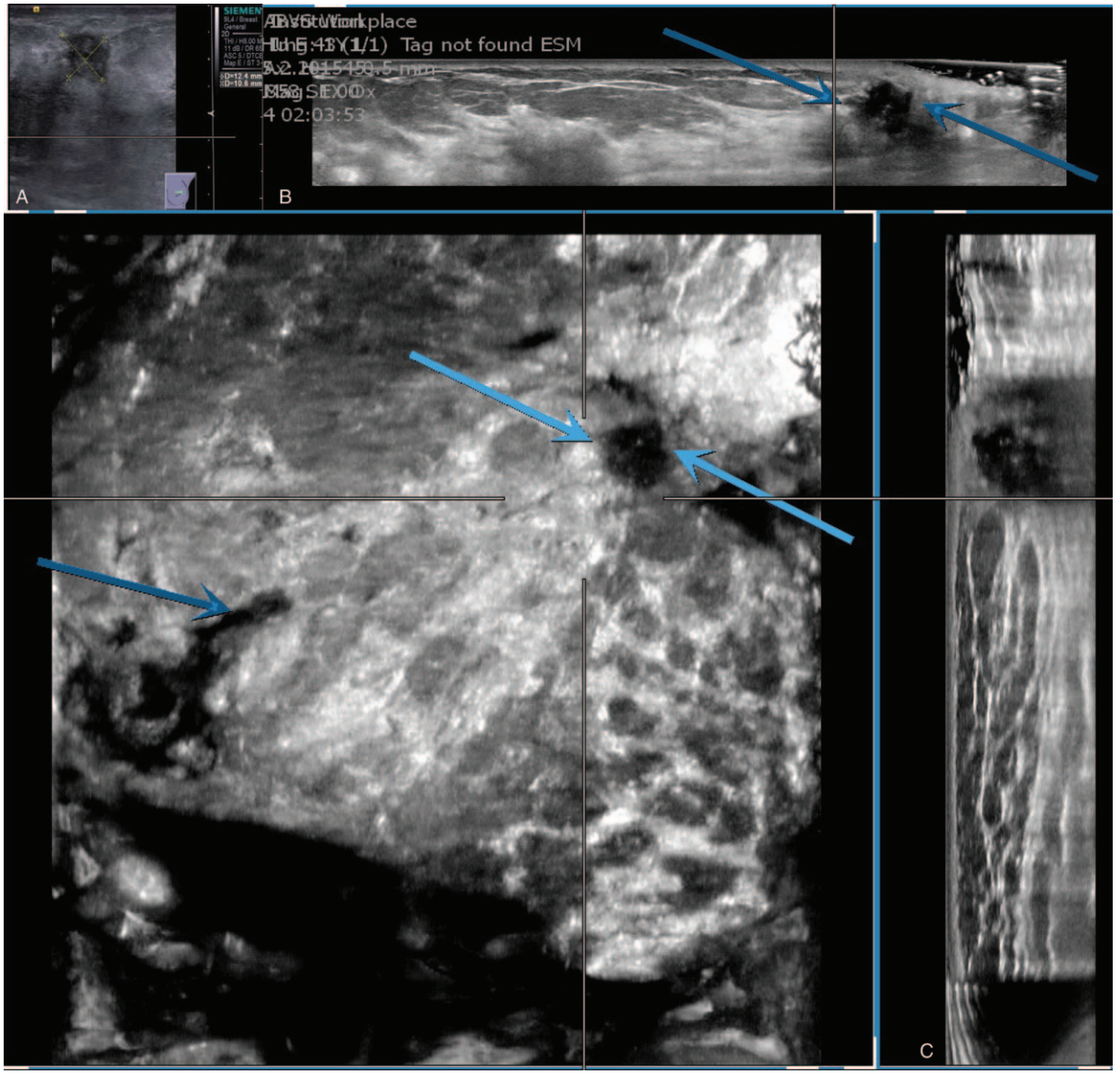

Figure 4. A 49-year-old woman with a lesion in the outer upper quadrant of left breast. (A) HHUS showed a hypoechoic oval lesion with microlobulated margin. (BI-RADS category 4c). (B) The transverse plane of ABVS. (C) The coronal reconstruction is lower left and the sagittal plane is lower right. There was no retraction phenomenon sign on coronal planes by ABVS (upper arrow); however, a dilated duct near the areola was detected in coronal plane in which an abnormal echo existed (down arrow). Therefore, the BI-RADS lexicon of the first lesion was not adjusted for the mass. Pathologic analyses showed the first mass and the dilated duct with abnormal echo were all invasive ductal carcinomas.

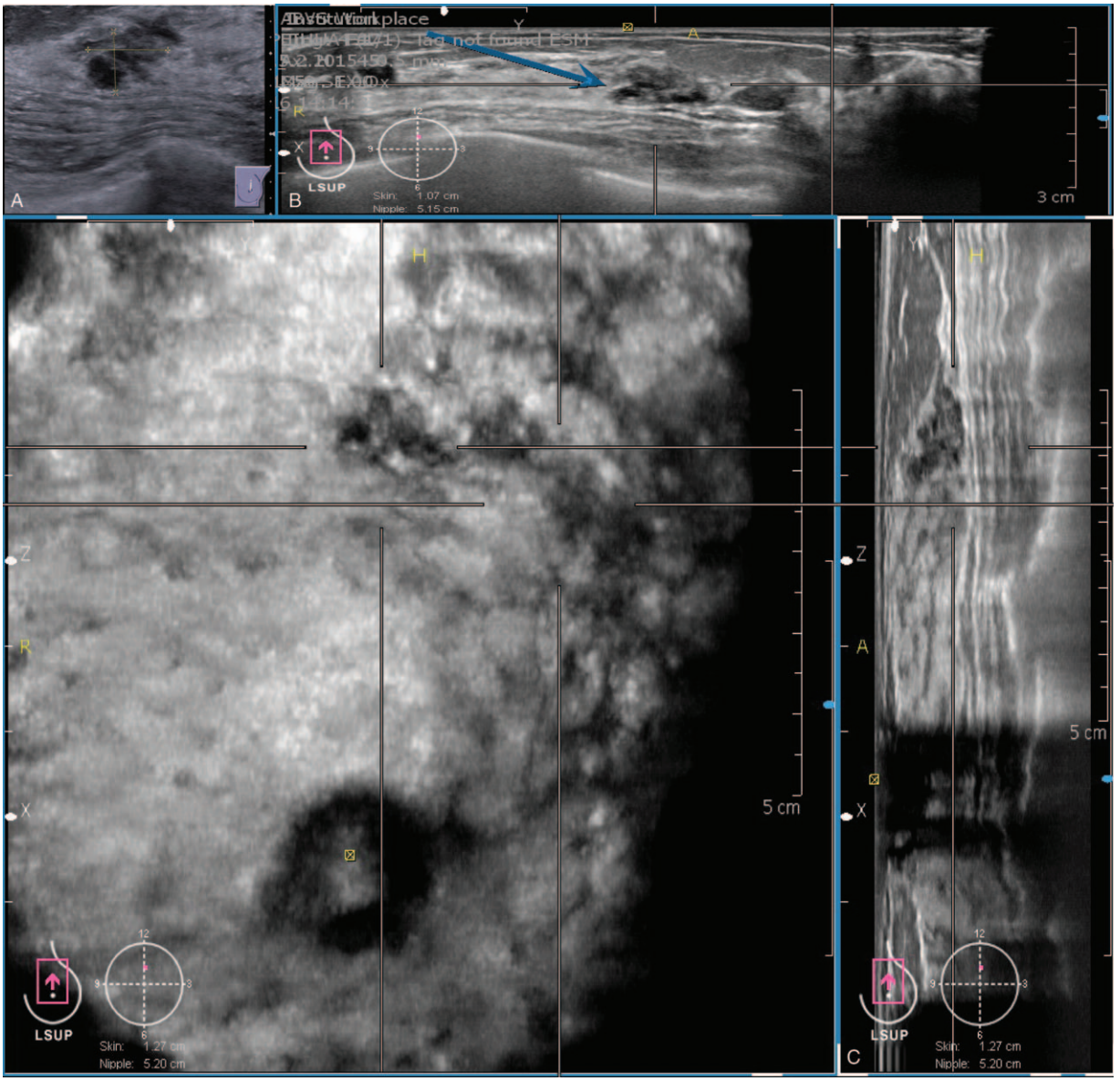

Figure 5. A 47-year-old woman with a lesion in upper quadrant of left breast. (A) HHUS showed a mixed-echoic irregular margin lesion. (BI-RADS category 4a). (B) The transverse plane of ABVS. (C) The coronal reconstruction is lower left and the sagittal plane is lower right. There was suspected retraction phenomenon sign on coronal planes by ABVS; discussion was made between 3 doctors before retraction phenomenon sign was confirmed. Therefore, the BI-RADS lexicon of the lesion was adjusted to 4b. Pathologic analyses showed it was sclerosing adenosis.

review after reconstruct the images are also considered the reasons why ABVS detected tiny lesions.

Limitations exist in present study. First, the ABVS uses focused US imaging, which constructs the image line-by-line, which means that the acquisition time is directly proportional to the width of the transducer and the line density. Because of the extraordinary width of the ABVS transducer (154 mm), and the high line density resulting from the large number of elements, the acquisition times are very long. Indeed, the examination time can initially be increased from approximately 10 to 15 minutes for a full HHUS to 20 to 30 minutes with the ABVS. Also, the large number of time-consuming second-look images reconstruction has to be taken into account. Second, participants underwent 2 different devices in HHUS examination, which may cause variability. Third, without a standard definition, retraction phenomenon has been described on the whole as convergence sign, stellate lesion, stellate margin, irregular margin, or architectural distortion by other researchers. Discrepancy may arise during identification of retraction phenomenon. And discrepancies were adjudicated by discussion with a third reviewer.

Even so, in our study, 9 benign masses (6 sclerosing adenosis and 3 fibroadenoma) also had retraction phenomenon sign (Fig. 5). Sclerosing adenosis can be confused with invasive carcinoma on clinical, imaging, and even histopathological examinations, and no typical imaging criterion is currently available for its diagnosis.[14] Thus, the application of retraction phenomenon in the differentiation of sclerosingadenosis and malignant breast masses may be limited, which may cause the false-positive results.

5. Conclusion

The ABVS may serve as an effective tool for differential diagnosis between benign and malignant breast tumor, however, without an extraclinic value than HHUS, especially in sensitivity. It is possible that this technique may manifest tiny breast, which HHUS may ignore. However, this study needs to be replicated in a larger sample of patients.

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