Original Article

Comparison characteristic visibility of the lesions with automated whole breast ultrasound and handheld breast ultrasound in screening situation

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Abstract

Background: Screening mammography and additional ultrasound are effective in detecting occult cancer. We know that handheld breast ultrasound (HHUS) depends on the operator. In comparison, automated whole breast ultrasound (ABUS) decreases these disadvantages of ultrasound procedures and can increase its sensitivity to cancer detection rates, but the results showed such studies, especially masses' characteristics, are different. Our study wants to evaluate the features of the lesions in all aspects of the masses by using ABUS compared to HHUS to increase overall interpretation confidence.

Objective: Comparison of visible breast lesions between ABUS and HHUS.

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Materials and Methods: Retrospective analysis was conducted with 168 screening mammography cases, the undergoing ABUS and HHUS interpreted as the detected lesion, mass characteristic and BI-RADS between October 2017 to May 2018. The investigator reviewed the pathologic or the 2-year follow-up from hand-held ultrasound results. The agreement measurements were assessed, using SD, ICC, percent agreement and Cohen kappa coefficient.

Results: Comparison of the mass's details between two radiologists by using ABUS, ICCs for the location and individual size of the lesion had good reliability. Localization ($\kappa = 0.81$) and BI-RADS ($\kappa = 0.82$) showed almost perfect agreement showing substantial agreement for mass margin ($\kappa = 0.78$), moderate agreement for mass shape ($\kappa = 0.48$) as well as 95% agreement for mass orientation. Intra-rater reliability between two modalities also revealed concordance in both radiologists in important ways for breast mass interpretation.

Conclusion: ABUS can detect lesions, give accurate locations, certain mass size and a few characteristics, is acceptable for screening and monitor detected lesions.

Keywords: Automatic whole breast ultrasound, Breast cancer, Handheld breast ultrasound, Screening.

Introduction

Breast cancer is the most common diagnostic malignancy in women worldwide, including Thailand [1-2]. Multiple studies show early detection of breast cancer by screening mammography can reduce mortality. However, the sensitivity of mammography is about 85% because it is not a particularly effective tool for screening cancer in women with dense breast tissue. Moreover, its sensitivity is reduced to 47.8-64.4% in this woman group because normal breast tissue could obscure the lesion [3-5].

The dense breast is categorized by expert consensus, as heterogeneously dense breasts (BI-RADS category C) and breasts with extremely dense fibroglandular tissue (BI-RADS category D) (more than 50% dense tissue, according to the BI-RADS fourth edition) are considered dense [6-7].

There are supplemental screening modalities that include whole-breast ultrasonography (US) and magnetic resonance (MR) imaging. Because the cost of MR imaging is too expensive, ultrasound is used more prevalently. Many studies supported the idea that ultrasound could detect mammographically occult and clinically significant small invasive breast cancers [8-11].

It is commonly known that more than 50% of women in Western countries have dense breast tissue [12]; meanwhile, more than 70% of women in Eastern countries also have dense breasts [13]. Therefore, in today's clinical practice, after the radiologist interprets screening mammography and the breast tissue of the patient has dense breast tissue or the radiologist suspects something in mammographic imaging, they will do an additional ultrasound to evaluate the findings.

Although many studies are showing that screening breast ultrasound in women is effective in detecting mammographically occult cancer, the practical workflow of nearly 20 minutes for the performance of bilateral handheld breast ultrasound (HHUS) makes it a challenge for screening [14]. Besides, the HHUS is operator-dependent which makes the number of false positives.

Currently, automated whole breast ultrasound (ABUS) is being developed. The ABUS is a technology in which ultrasound scanning is performed mechanically. The operation of the automated system to acquire the scanning data does not require an ultrasound technologist; anyone can be trained to operate the equipment for scanning. The unit acquired raw data via a larger transducer. The transducer paddle is placed over the breast with a small amount of compression. Three image acquisitions of each breast are usually sufficient to image virtually all of the breast tissue, excluding the axilla, including anterior-posterior,

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medial, and lateral positions. In women with large breasts, 4 or 5 acquisitions of each breast may be needed. The total time to complete the examination is about 15 minutes [15]. The images can be reviewed on a standard workstation. One study shows the interpretation time for each examination is about 3 minutes [16]. These advantages such as image consistency, reproducibility, independence from an operator, and a short time to interpret are feasible for screening situations as an adjunct to screening mammography.

A few studies supported that ABUS significantly increased the sensitivity cancer detection rate but increased recall and false-positive biopsy rates [17-19]. Some studies have made it suspicious that ABUS actually has a significant decrease in specificity [20].

However, a few studies showed that ABUS can help radiologists increase confidence in the visualization of suspicious and benign lesions in various aspects such as size, distance from the nipple, and other characteristics. The results of these studies show no significant difference in radiologists' detection performance, sensitivity, and specificity [21-26]. But different results are shown in separate ways in such studies, especially some mass characteristics. Regarding the results in previously mentioned studies, our study strives to evaluate and confirm characteristic visibilities of the lesions in all aspects of the detected lesions, which can help radiologists increase overall interpretation confidence and specificity and decrease a false-positive biopsy rate. It is useful for both new lesions and in a long-term follow-up of known benign-appearing lesions in a screening setting.

Materials and methods

A retrospective study of 168 cases of women who came to have mammography screening and needed an additional ultrasound between October 2017 to May 2018 was recruited to this study. Each case was combined with both HHUS and ABUS.

Automated ultrasound of the breast (Acuson S2000 automated breast volume scanner (ABVS), Siemens Healthcare) was performed by technologists who had trained to use the technique. A typical examination comprised three automated scans of each breast in the anteroposterior, lateral, and medial positions. Occasional additional views were required for larger breasts. Two breast radiologists with 7 and 9 years of experience independently evaluated the 3D volume data at the automated breast ultrasound workstation. They were blinded to the findings on the corresponding mammograms and handheld ultrasound images as well as to clinical information and tissue pathologic results.

Breast ultrasound with the handheld device (Siemens Acuson S2000) equipped with two linear-array transducers with a frequency bandwidth of 4-9 MHz and 5.5-18 MHz was performed by two breast radiologists with 7 and 9 years of experience according to a standardized scanning protocol. All images, previously interpreted by those two radiologists for a clinical service, were retrieved from the hospital database.

Data obtained from ABUS and HHUS ultrasound images were interpreted in the same detail including breast tissue echogenicity, mass characteristics such as shapes, orientation, margins, echo patterns, posterior features, calcification, associated features such as architectural distortion, duct changes, skin changes, edema, vascularity.

The sequence of images was independently randomized to reduce the risk of bias.

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The investigator reviewed the pathologic result in which the suspicious masses (BI-RADS IV-V) were biopsied or the handheld ultrasonographic result in which the probably benign lesions (BI-RADS III) received a follow-up every 6 months for 2 years or until the last visit before December 2019 (The duration of the follow-ups was about 1-4 times, one time/person on average).

We used mean, (SD), and two-way interrater reliability (A,1) type of intra-class correlation coefficient (ICC) to calculate descriptive statistics such as the mass size.

Based on the 95% confident interval of the ICC, the estimated values were scored as poor (ICC< 0.5), moderate (ICC = 0.5-0.75), good (ICC = 0.75-0.9), and excellent reliability (ICC > 0.90) [27].

The agreement of detectable lesions, breast parenchymal echogenicity, and mass characteristics of each lesion between ABUS and HHUS, as well as agreement between radiologic interpretations of each modality, were compared by using percent agreement and Cohen's kappa (κ).

CI construction for the Cohen kappa coefficient was based on the asymptotic normality assumption, and Landis and Koch [28] reference intervals were used to assess the strength of agreement in terms of the Cohen kappa coefficient, where values of $\kappa \leq 0$ indicate no agreement; $0 < \kappa \leq 0.20$, slight agreement; $0.20 < \kappa \leq 0.40$, fair agreement; $0.40 < \kappa \leq 0.60$, moderate agreement; $0.60 < \kappa \leq 0.80$, substantial agreement; and $0.80 < \kappa < 1$, almost perfect agreement. A P-value of less than 0.05 is considered a statistically significant difference.

Results

The 168 women met the study criteria. Between 72 and 83 detected masses were depicted in ABUS examination, by 1st and 2nd radiologists, respectively. Also, 85 masses were results of HHUS, previously interpreted by those two radiologists from the hospital database.

All data from the 168 cases were compared between two breast radiologists using only imaging from ABUS to evaluate the inter-rate agreement. We also used the data to compare the consistency of the data obtained from each individual radiologist's interpretation of ultrasound images from hand-held ultrasound and ABUS which detect detectable lesions, localization, mass size, clock face position, mass characteristics and BI-RADS categories to evaluate inter-rater agreement of imaging interpretation by using ABUS.

A comparison between two radiologists with ABUS significantly showed good reliability for the mass size in width (ICC = 0.89), length (ICC = 0.81), and height (ICC = 0.87) as well as other important mass characteristics such as a substantial agreement for mass margin (κ = 0.78), fair agreement for posterior features (κ = 0.36) of mass and 95% agreement of mass orientation. The almost perfect agreement of the BI-RADS category assessment (κ = 0.82) by two radiologists using ABUS was also manifested.

The intra-rater reliability between the two modalities revealed concordance.

The 1st radiologist significantly showed excellent reliability for the mass size in width (ICC = 0.91) and length (ICC = 0.94), substantial agreement for mass orientation (κ = 0.65), 93% agreement for the shape of the mass*, moderate agreement for detected mass (κ = 0.52), a clock-face position (κ = 0.55), the mass size in height (ICC = 0.62), and the mass margin (κ = 0.45).

The 2nd radiologist significantly described substantial agreement for the clock-face position (κ = 0.68), the mass shape (κ = 0.78) and the margin (κ = 0.68) with

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BI-RADS categories assessment (κ = 0.76), good agreement for the mass size in width (ICC = 0.87), moderate agreement for the mass size in length (ICC = 0.6), fair agreement for detected mass (κ = 0.39) and posterior features of the mass (κ = 0.39).

**Note: Some data cannot be calculated by using Cohen's kappa statistic because when one rater's ratings have no variation, the agreement corrected for chance (κ) is considered to be zero. Furthermore, our study shows a corresponding agreement between the percent agreement and the Cohen's kappa statistics. Consequently, we used percent agreement instead of Cohen's kappa statistics if the κ could not be assessed.*

We found that 40 masses matched between the two radiologists for ABUS imaging interpretation, with 25 masses matching those found in both HHUS and ABUS between the two radiologists.

BI-RADS categories assessment for ABUS, detectable lesions by 1st and 2nd radiologists were corresponding as 2.5%, 65%, 5% and 7.5% in BI-RADS II, III, IVa and IVc, respectively. However, 2.5% discordant BI-RADS categories assessment was shown in this study; interpreted as BI-RADS II and IVa that the pathologic result was invasive ductal carcinoma grade 1 (Table 1).

Table 1. *Comparison of BI-RADS categories assigned by 1st and 2nd radiologist for ABUS.*

			1st Radiologist BI-RADS						
			I	II	III	IVa	IVb	IVc	V
2nd Radiologist	BI-RADS	I	0	0	0	0	0	0	0
		II	0	1 (2.5%)	0	1 (2.5%)	0	0	0
		III	0	0	26 (65%)	4 (10%)	0	0	0
		IVa	0	0	2 (5%)	2 (5%)	1 (2.5%)	0	0
		IVb	0	0	0	0	0	0	0
		IVc	0	0	0	0	0	3 (7.5%)	0
		V	0	0	0	0	0	0	0

A comparison of BI-RADS categories interpretation by two radiologists between ABUS and HHUS significantly reported reliability (Table 2). The pathologic results showed mostly benign such as fibroadenoma (Figure 1), intraductal papilloma, and stromal fibrosis; however, it had one malignancy as ductal carcinoma in situ (DCIS) high grade (Figure 2).

Table 2. *Comparison of BI-RADS categories assigned by 1st and 2nd radiologist between ABUS and HHUS with the pathologic result.*

		1st Radiologist		2nd Radiologist		Mean	
		ABUS (n)	HHUS (n)	ABUS (n)	HHUS (n)	ABUS	HHUS
BI-RADS	I	0	0	0	0	0	0
	II	1	1	0	0	0.5	0.5
	III	21	20	20	20	20.5	20
	IVa	3	4	4	4	3.5	4
	IVb	0	0	0	0	0	0
	IVc	0	0	1	1	0.5	0.5
	V	0	0	0	0	0	0
Total		25	25	25	25	25	25
Pathologic result		- 4 masses with BI-RADS IVa are 2 fibroadenomas, 1 Intraductal papilloma and 1 stromal fibrosis		- 4 masses with BI-RADS IVa are fibroadenomas - 1 mass with BI-RADS IVc is DCIS high grade		-	

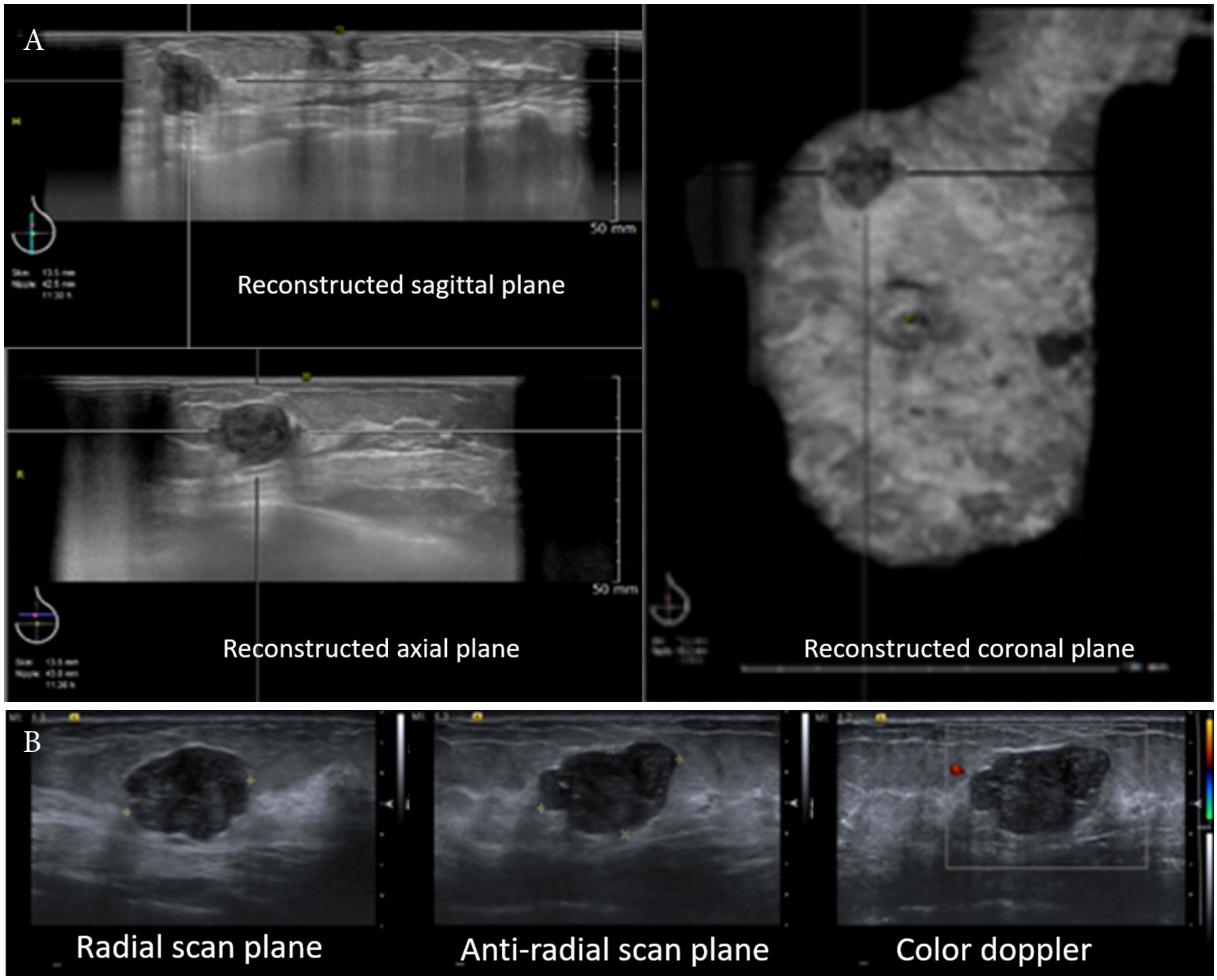

Figure 1. *Ultrasound findings in ABUS (A) and HHUS (B) showed an oval, microlobulated, heterogeneous hypoechoic mass with parallel orientation and enhancement of the posterior feature at 11-12 o'clock of the left breast. There was no vascularity. (BI-RADS IVa) The pathologic result was fibroadenoma at the left breast.*

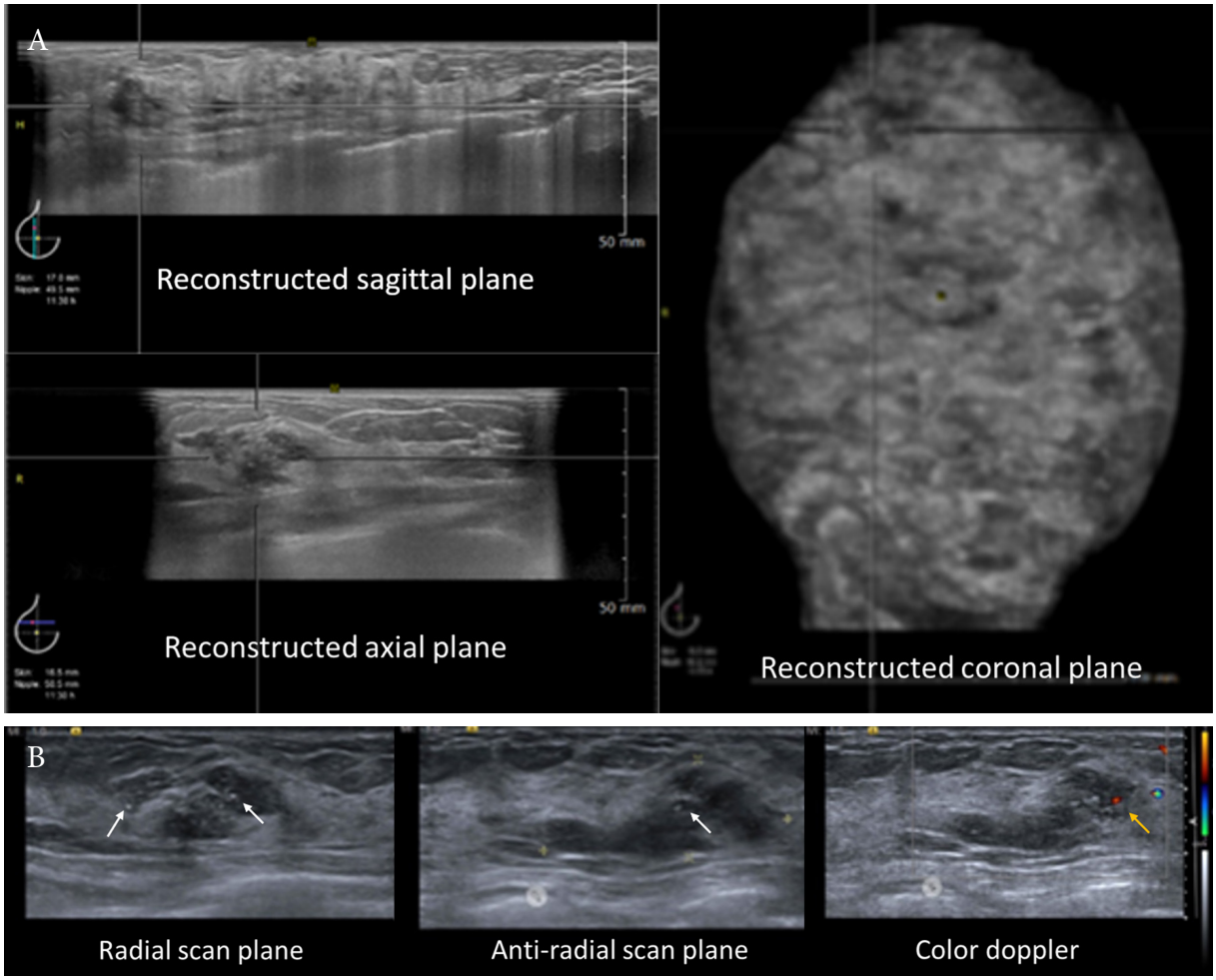

Figure 2. *Ultrasound findings in ABUS (A) and HHUS (B) showed an irregular, indistinct, hypoechoic mass with parallel orientation, the combined pattern of posterior features and internal calcification at 11-12 o'clock of the right breast (White arrow). Internal vascularity was seen at the medial portion of the mass (Yellow arrow). (BI-RADS IVc) The pathologic result was high-grade ductal carcinoma in situ (DCIS).*

Discussion

Unlike other breast imaging techniques, breast ultrasound is affected by a lack of reproducibility in lesion characterization. Also, the document data is not consistent and reproducible. ABUS has the potential for complete and standardized documentation which has several advantages over HHUS. As a matter of fact, there are a number of interesting studies showing equal efficacy between ABUS and HHUS [22-25, 29-31], but those studies were done in people with the diagnostic groups, differently from this study which was in a screening situation to assess the reliability of ABUS compared with HHUS for lesion detection, description, and interpretation, that may be useful to allow delayed interpretation both inside and outside the workplace.

Consistent reporting with reproducible localization of detected breast lesions is critical for the clinical application of ABUS. We found ICCs for the lesion localization (clock face location, distance from nipple, deep from skin) were 0.9, 0.82, and 0.8, indicating excellent and good reliability, respectively. The individual size of detected lesions (wide, long and height) was 0.89, 0.81, and 0.87, indicating good reliability. This information is consistent with previous reports in Chang et al and Shin et al, except for skin depth locations, in which our study was more reliable [21,23].

Practicable reasons for the higher rate of reliability when using ABUS could be due to readers being able to reproduce whole breast scans in multiple orientations, selecting the longest dimension plane, and measure the size, by using the 3D volume data. The reader can link the image to the coronal scan plane performed using ABUS and provide a center of the lesion to access the distance from the nipple and the depth from the skin and the workstation also has the software to help us measure automatically. Therefore, in the follow-up of multiple benign lesions or probably benign lesions in people with dense breasts and still requiring a mammogram every year, changes in size can be monitored, precisely. ABUS is also important for education hospitals where different inexperienced radiologists may perform each examination. On the other hand, like any imaging

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technique, ABUS has disadvantages and some limitations. Disadvantages regarding image acquisition are the inability to assess the axilla, the vascularization, and the elasticity of a lesion while concerning the interpretation, the disadvantages are the artifacts due to poor positioning, a lack of contact, a motion, or lesion related factors. Therefore, the technician should be aware of these aspects and scan the entire breast by obtaining supplemental acquisitions on the superior and inferior parts of the breasts. Furthermore, suspicious lesions detected with ABUS and requiring further assessment need to be reevaluated with HHUS.

The result of this study about the characteristic visibility of the breast lesions using ABUS almost resembles other studies such as Zhang et al, Shin et al, and Kim et al, in some aspects [23,25,31] (Table 3).

Table 3. *Compared results of localization, size, and characteristics of lesions between our study and other studies.*

Variable	This study	Chang et al.	Zhang et al.	Shin et al.	Kim et al.
Location (ICC)	Excellent (0.90)	Excellent (0.99)	-	Good (0.75)	Substantial (κ= 0.74)
Distance from nipple (ICC)	Good (0.82)	Excellent (0.93)	-	Good (0.89)	-
Deep from skin (ICC)	Good (0.80)	Fair (0.34)	-	Good (0.89)	-
Size(W-L-H) (ICC)	Good (0.89-0.81-0.87)	Excellent (0.98)	-	Excellent (0.94)	Moderate (κ =0.43)
Shape (κ)	Moderate (0.48)	-	Substantial (0.79)	Substantial (0.71)	Moderate (0.45)
Orientation(κ)	95% agreement	-	Substantial (0.74)	Substantial (0.72)	Moderate (0.50)
Margin(κ)	Substantial (0.78)	-	Substantial (0.76)	Substantial (0.61)	Fair (0.25)
Echo pattern(κ)	Fair (0.31)	-	Substantial (0.69)	Moderate (0.45)	Substantial (0.65)
Posterior feature(κ)	Fair (0.36)	-	Substantial (0.68)	Moderate (0.42)	Moderate (0.45)
BI-RADS (κ)	Almost perfect (0.82)	-	Substantial (0.70)	Substantial (0.63)	Substantial (0.57)

We found substantial agreement on the description of the margin (κ=0.78), moderate agreement on the description of the shape (κ=0.48), and fair agreement on the description on mass echogenicity, and posterior acoustic features (κ= 0.31 and κ= 0.36, respectively). Anywise, this study shows 95% agreement instead of Cohen's kappa value to assess the concordance of orientation due to statistic κ cannot be assessed because of no variation from most of the lesions in screening situation which were horizontal appearing masses and our study already proved concordance agreement between the percent agreement and the Cohen's kappa statistics (Table 1). Prominently, almost perfect agreement was found in BI-RADS assessment in this study (κ= 0.82), distinguished from previous studies.

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Based on the data obtained from this research together with the facts supported by other studies, this makes us certain that ABUS can be used to detect new lesions, monitor identified known lesions, localization, description, and interpretation.

However, in our study, one radiologist missed one lesion from ABUS image (Figure 3) that was malignancy from the pathologic result (invasive ductal carcinoma grade 1). Also, this lesion was a subareolar region which is a limit position for the lesion detection of ABUS.

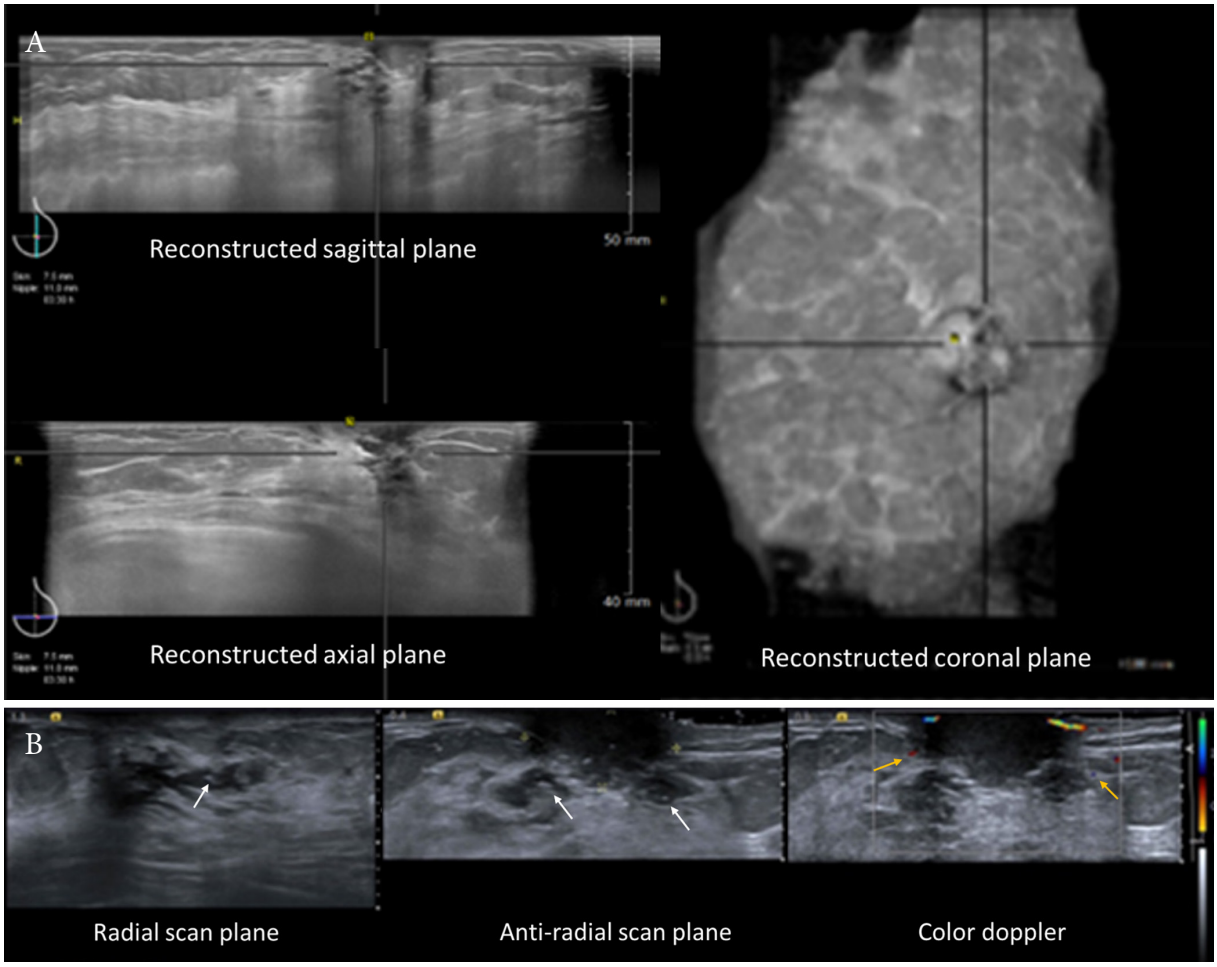

Figure 3. *Ultrasound findings in ABUS (A) and HHUS (B) showed an irregular, indistinct, hypoechoic mass with parallel orientation, the enhancement pattern of posterior features and internal calcification at 3-4 o'clock at the subareolar region (White arrow). Adjacent subareolar duct dilatation with internal echogenic content and calcification was noted. Vascularity was seen as a vessel in the rim (Yellow arrow). (BI-RADS IVc) The pathologic result was invasive ductal carcinoma grade 1 (IDC).*

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In daily practice, ABUS may have more benefits than HHUS in several respects. First, patients with multiple lesions might benefit from the faster examination time. Second, for patients with dense breast tissue, additional screening ABUS may be beneficial because of improved workflow efficiency and a lack of operator dependence. Third, to monitor the previously detected lesion might be standard and reproducible. Last, for surgical planning, surgeons who are familiar with the coronal plane may appreciate the multiplanar images obtained with ABUS.

Our study had some limitations. First, the readers were blinded to the mammographic and clinical findings, and BI-RADS categorization established only with the ultrasound features does not always reflect actual practice. Second, our study included a relatively small number of patients with malignancy, so the mass characteristics were more similar, for example, the oval mass-shaped and parallel orientation of mass which represent mostly benign lesions. Moreover, the number of associated features, such as calcification, architectural distortion, skin, or duct change as well as special finding, for example, lymph node, cluster microcyst, vascularity abnormalities or fat necrosis, were too small sample size for available interpretation. Third, our study was a retrospective study; thus, some data were incomplete. Fourth, our study including only two radiologists was small to assess the reliability agreement. A further evaluation of the interobserver agreement among multiple radiologists is needed.

Conclusion

ABUS is a useful tool for detecting lesions and providing accurate information on their locations, sizes, and key characteristics, making it ideal for screening breast lesions and monitoring any detected lesions although ABUS may have limitations related to the technique, for example, air interposition or insufficient compression which can be effectively managed with extensive training and attention to image acquisition and interpretation.

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