Role of three-dimensional automated breast ultrasound as a breast screening tool in additional to mammography

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Background
The biggest cause of cancer-related deaths among women globally is breast cancer. Breast cancer outcomes are improved by early identification; hence, survival rates are generally favorable when these tumors are found early. Radiologists play a crucial role in breast imaging. The 'gold standard' for screening and early detection of breast cancer at the moment is radiograph mammography. The majority of 'intermediate risk' women – those with a 15–25% lifetime risk of breast cancer – are women with thick breast tissue. The 'perfect storm' of reduced mammographic sensitivity and elevated breast cancer risk affects them.

Patients and methods
This is a prospective diagnostic study done from May 1, 2021 to May 30, 2022. Patients were recruited from those who had undergone screening using ultrasound examination [handheld ultrasound and automated breast ultrasound (ABUS)], and some of them had undergone mammography.

Results
In our investigation, 60 female patients had 60 findings that were validated by histopathological biopsy or at least 6 months of follow-up; 16 of the 60 findings were benign abnormalities and 44 were malignant lesions.
The gold standard for lesion categorization, biopsy or 6-month follow-up, was used to determine the diagnostic accuracy of the ABUS test.
In comparison to the reference index, the diagnostic accuracy metrics for ABUS were 90% accurate but with 88% sensitivity and 91% specificity. Positive predictive value was 78%, whereas negative predictive value was 95%. Positive likelihood ratio was 9.63, whereas negative likelihood ratio was 0.14, with relative risk being 16.33. False-positive rate was 9% and false-negative rate was 13%, with prevalence of 27%.

Conclusions
When used as a supplemental scan to mammography in a screening program for breast cancer, the automated breast ultrasound performs diagnostically similarly to handheld ultrasound. More imaging and interpretation training can increase the specificity of ABUS.

Keywords:
breast cancer screening, breast density, handheld ultrasound, mammogram, three-dimensional automated breast ultrasound

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Background

There has been a rise in the prevalence of breast cancer in recent years. Each year, there are more than 450 000 fatalities and one million new cases globally [1].

Mammography is regarded as the primary test for detecting breast cancer. The limited sensitivity of screening in women with dense breasts is seen as a drawback that necessitates a supplemental scan to increase the rate of finding any breast tumors [2].

In 1951 [the start of using of handheld ultrasound (HHUS)], HHUS provided coverage of the underperformance of mammography in dense breast, which led to better breast mass screening and increased breast cancer detection rate [3,4].

Despite having an advantage over mammography in clinical settings, HHUS has some performance flaws, such as lack of standardization, reliance on human experience, and a lengthy process with a limited field of view. To fix these flaws, a new scanning gadget was created.

Three-dimensional (3D) automated breast ultrasound (ABUS) is a brand new scanner that offers automation, eliminating the need for a well-trained physician to use it. Volumes are automatically applied under technician control, and more than one doctor can read them on a workstation [5]. It also offers 3D reconstruction of volumes for improved breast anatomy assessment, accurate lesion margin observation, speculations, and anatomical relationships. It covers the whole breast scan in three to five different volumes, depending on breast size, and is built with a broad linear transducer that provides a big scanned area in each [6,7].

Aim

The objective of this study was to demonstrate the diagnostic efficacy of 3D ABUS in detecting breast tumors in the screening program, taking into account its advantages and drawbacks.

Patients and methods

(1) Type of study: this was a cross-sectional (prospective) study.
(2) Study setting: the study was conducted in Radiology Department at Al Sheikh Zayed Al Nahian Hospital. The patients underwent HHUS examination by Philips affinity 50, ABUS examination by GE, Invenia, and mammography scan by Fujifilm.
(3) The study period was 2 years.
(4) Study population: the study included 60 individuals with breast masses by clinical evaluation during screening programs. All of the included patients were recruited from the surgical department and outpatient clinic.

Inclusion criteria

The following were the inclusion criteria:

(1) Patients accepting to participate in the study.
(2) Women who came for annual screening.

Exclusion criteria

The following were the exclusion criteria:

(1) Male patients.
(2) Pregnant/lactating women are excluded for mammography.
(3) Patients with breast implants.
(4) Postoperative changes in breast.

Sampling method: this study employed convenience nonrandom sampling.

Sample size: a total of 60 patients with breast masses were included.

Ethical considerations

(1) The Radiology Department of Al Sheikh Zayed Al Nahian Hospital granted official approvals.
(2) The scientific ethical committee of the hospital approved the study.
(3) Written consent was acquired after informing each participant about the study's purpose.

Study tools

All included patients were subjected to the following:

(1) Full history taking.
(2) Full clinical examination by the referring clinician.
(3) HHUS and ABUS examinations.
(4) 2D mammography in addition in some cases above 35 years old.
(5) Correlation for the suspicious masses with histopathological results (as a gold standard) obtain from ultrasound guided core needle biopsy or after surgery.
(6) Follow-up after 6 months for benign looking lesions.

Study procedures

Two-dimensional mammography

MLO and CC images of both breasts were performed during a two-view digital mammography on participants over the age of 40 years. The tools used were Fujifilm mammography.

Women under the age of 40 years who had a personal or family history of breast cancer had mammography as well as.

Automated breast ultrasound

Every participant underwent an ABUS examination. An ABUS system was used to acquire all ABUS tests (GE Health Care, Invenia ABUS).

The patient was examined while lying flat on their back with their nipple facing upward. On the breast, a hypoallergenic lotion was applied evenly, with more going on the nipple area. To spread out the breast equally for the best picture quality and patient comfort, a disposal membrane was used to assist with an acoustic connection. Continuous and automatic ABUS scanning was used. Women were instructed to remain still and breathe naturally throughout the acquisition. With coronal and sagittal reconstruction, volume acquisitions were made in the axial plane

beginning at the inferior region of the breast. A 15.4 cm×17.0 cm volume with a slice thickness of 0.2 mm was automatically collected from the skin to the chest wall. Three volumes were obtained for each breast: a central (anteroposterior) volume with the nipple in the foot print's donut-shaped center, a lateral volume with the upper outer part of the breast tissue and the nipple in the inferior-medial corner, and a medial volume with the inner and inferior portions of the breast tissue. Each inspection included a nipple marker to ensure precise co-ordination. Three different breast sizes were chosen for the best image quality. To prevent tissue exclusion, extra images were acquired of women with bigger breasts. When the picture data were finished being processed, the volumes were sent to a special workstation for analysis.

In each case, the entire time required for patient preparation and ABUS acquisition was noted, and it often fell between 10 and 15 min.

Handheld breast ultrasound

Following ABUS, all women had HHUS (Philips, affinity 50) using a linear transducer at 10–15-MHz gray scale. The breast was divided into four parts for scanning; each segment was scanned in two planes, sagittal and axial, and then the region around the nipple and the axilla.

Statistical analysis

Statistical package for the Social Sciences was used to update, code, tabulate, and introduce the acquired data into a computer (SPSS 20.0.1 for Windows; SPSS Inc., Chicago, Illinois, USA). Depending on the distribution of the data, quantitative variables are reported as mean, SD, or median and interquartile range. Frequencies and percentages are used to convey qualitative characteristics. A continuous variable between two research groups was compared using the Student *t* test and the Mann–Whitney test. The χ^2 test was used to look at how categorical variables relate to one another. Statistical significance was defined as *P* value of 0.05.

Results

This study included 60 female patients, aged above 25 years old, with mean age of 43±15 years.

A total of 42 patients who underwent mammographic scan were first categorized according to breast composition as follows: four patients of category A, 14 of category B, 18 of category C, and six of category D. Generally 18 patients had homogenous parenchymal density with predominance of fatty element, and 42 patients had dense parenchyma. Then, they were categorized according to BIRADS classification as follows: four patients of BIRADS 0, 12 patients of BIRADS I, 8 patients of BIRADS II, four patients of BIRADS III, eight patients of BIRADS IV, and six patients of BIRADS V (Table 1).

After that, patients underwent ABUS and HHUS examinations. Both studies' examination times were compared, and it was shown that ABUS' examination time was lower than that of HHUS (mean±SD: 4.1 ±0.9 vs. 9.2±2.0). Statistics showed that there was a difference between the two groups ($P>0.0001$) (Table 2).

Diagnostic accuracy for both ultrasound techniques was assessed in relation to the reference index and we found the following: in comparison to the reference index, the diagnostic accuracy metrics for ABUS were 90% accurate but with 88% sensitivity and 91%

Table 1 Results of mammographic examination in eligible participants

Variables	*n* (%)
Breast composition	
A	4 (9.5)
B	14 (33.3)
C	18 (42.9)
D	6 (14.3)
Breast composition grade	
A/B	18 (42.9)
C/D	24 (57.1)
BIRADS class by mammography	
BIRADS 0	4 (9.5)
BIRADS I	12 (28.6)
BIRADS II	8 (19.0)
BIRADS III	4 (9.5)
BIRADS IV	8 (19.0)
BIRADS V	6 (14.3)
Lesion classification by mammography	
Probably benign (BIRADS I–III)	24 (66.7)
Probably malignant (BIRADS IV–V)	14 (33.3)

Table 2 Comparison of examination time for handheld ultrasound or automated breast ultrasound

Variables	HHUS		ABUS		Paired differences			
	Mean	SD	Mean	SD	Mean	SD	95% CI	*P* value*
Examination time (min)	9.2	2.0	4.1	0.9	−5.1	1.8	−5.7 to −4.4	<0.0001

ABUS, automated breast ultrasound; CI, confidence interval; HHUS, handheld ultrasound. *Paired *t* test.

specificity. Positive predictive value was 78%, whereas negative predictive value was 95%. Positive likelihood ratio was 9.63, whereas negative likelihood ratio was 0.14, with relative risk of 16.33. False-positive rate was 9% and false-negative rate was 13%, with a prevalence of 27% (Table 3).

Regarding lesion categorization, there was near-perfect agreement between HHUS and ABUS (benign and malignant). Bennet's prevalence-adjusted and bias-adjusted kappa (PABAK) was 0.87, Scott's bias-adjusted kappa (BAK) was 0.85, and Cohen's kappa was 0.85 (Table 4).

Table 3 Diagnostic accuracy of automated breast ultrasound tested versus the ultimate diagnosis made by biopsy or follow-up for 6 months as the gold-standard for lesion classification

Lesion classification by ABUS	Ultimate diagnosis (biopsy or follow-up)		Total
	Malignant	Benign	
Probably malignant (BIRADS IV–V)	14	4	18
Probably benign (BIRADS I–III)	2	40	42
Total	16	44	60
Statistic	Value	Lower bound (95%)	Upper bound (95%)
Correct classification	90%	79%	100%
Misclassification	10%	0%	21%
Sensitivity	88%	51%	99%
Specificity	91%	71%	98%
False positive rate	9%	0%	20%
False negative rate	13%	0%	31%
Prevalence	27%	11%	42%
Positive predictive value	78%	51%	100%
Negative predictive value	95%	86%	100%
Positive likelihood ratio	9.63	2.50	37.02
Negative likelihood ratio	0.14	0.02	0.86
Relative risk	16.33	3.37	79.14
Odds ratio	70.00	7.83	625.61

Data in cross-tables are counts. ABUS, automated breast ultrasound.

Table 4 Agreement between handheld ultrasound and automated breast ultrasound regarding lesion classification as probably malignant or probably benign

HHUS	ABUS		Total
	Probably malignant (BIRADS IV–V)	Probably benign (BIRADS I–III)	
Probably malignant (BIRADS IV–V)	18	4	22
Probably benign (BIRADS I–III)	0	38	38
Total	18	42	60
Agreement statistics			
Cohen's kappa (κ)			0.85
Scott's bias-adjusted kappa (BAK, π)			0.85
Bennet's prevalence-adjusted and bias-adjusted kappa (PABAK)			0.87[a]

Data in cross-tables are counts. ABUS, automated breast ultrasound; HHUS, handheld ultrasound. [a]Nearly perfect agreement.

Table 5 Agreement between mammography and automated breast ultrasound regarding lesion classification as probably malignant or probably benign

Mammography	ABUS		Total
	Probably malignant (BIRADS IV–V)	Probably benign (BIRADS I–III)	
Probably malignant (BIRADS IV–V)	12	2	14
Probably benign (BIRADS I–III)	6	22	28
Total	18	24	42
Agreement statistics			
Cohen's kappa (κ)			0.60
Scott's bias-adjusted kappa (BAK, π)			0.60
Bennet's prevalence-adjusted and bias-adjusted kappa (PABAK)			0.62a

Data in cross-tables are counts. ABUS, automated breast ultrasound. [a]Substantial agreement.

There was near-perfect agreement between ABUS and mammography for the classification of lesions (benign or malignant). Bennet's prevalence-adjusted and bias-adjusted kappa (PABAK) was 0.62, Scott's bias-adjusted kappa (BAK) was 0.60, and Cohen's kappa was 0.60 (Table 5).

Regarding BIRADS categorization, there was fair agreement between ABUS and mammography. with a weighted kappa of 0.39, a SE of 0.122, and a 95% confidence interval of 0.157–0.637 (Table 6).

Regarding BIRADS categorization, ABUS and HHUS demonstrated near-perfect agreement, with weighted kappa of 0.824, SE of 0.057, and 95% confidence interval of 0.712–0.937 (Table 7).

Discussion

Although mammography is regarded as the gold standard for breast cancer screening, it has some limitations, including low sensitivity in women with dense breasts; high false-positive rates in these patients, which result in unnecessary histopathological biopsies; high call-back rates; and increased radiation dose. Additionally, mammographic radiation exposure may be a factor in the increased incidence of breast cancer in high-risk populations [8].

Therefore, ultrasonography (HHUS) came as a complimentary scan to overcome the underperformance of mammography in dense breast, which led to better breast masses screening and increased breast cancer detection rate [3,4].

On clinical use, HHUS shows some limitation too, so many radiologists are considering ABUS as a future screening tool.

ABUS has come up as a new scanner [9], providing automation, no need for well-trained physician to apply it as it is automatically applied under control of technician then volumes are read on workstation by more than one doctor [5], offering 3D reconstruction of volumes as well for improved lesion margin, spiculation, and anatomical relationship observation

Table 6 Agreement between mammography and automated breast ultrasound as regards the BIRADS classification

BIRADS class by ABUS	BIRADS class by mammography						
	BIRADS 0	BIRADS I	BIRADS II	BIRADS III	BIRADS IV	BIRADS V	Total
BIRADS 0	0	0	0	0	0	0	0
BIRADS I	0	2	2	0	0	0	4 (9.5)
BIRADS II	0	4	6	2	0	0	12 (28.6)
BIRADS III	2	4	0	0	2	0	8 (19.0)
BIRADS IV	2	2	0	2	4	2	12 (28.6)
BIRADS V	0	0	0	0	2	4	6 (14.3)
Total	4 (9.5)	12 (28.6)	8 (19.0)	4 (9.5)	8 (19.0)	6 (14.3)	42
Measure of agreement							
Weighted kappa				0.397a			
SE				0.122			
95% CI				0.157 to 0.637			

Data in cross-tables are counts. ABUS, automated breast ultrasound; CI, confidence interval. [a]Fair agreement.

Table 7 Agreement between handheld ultrasound and automated breast ultrasound as regards the BIRADS classification

BIRADS class by ABUS	BIRADS class by HHUS					
	BIRADS I	BIRADS II	BIRADS III	BIRADS IV	BIRADS V	
BIRADS I	6	0	0	0	0	6 (10.0)
BIRADS II	0	26	0	0	0	26 (43.3)
BIRADS III	0	4	2	4	0	10 (16.7)
BIRADS IV	0	0	0	8	4	12 (20.0)
BIRADS V	0	0	0	2	4	6 (10.0)
	6 (10.0)	30 (50.0)	2 (3.3)	14 (23.3)	8 (13.3)	60
Measure of agreement						
Weighted kappa			0.824a			
SE			0.057			
95% CI			0.712–0.937			

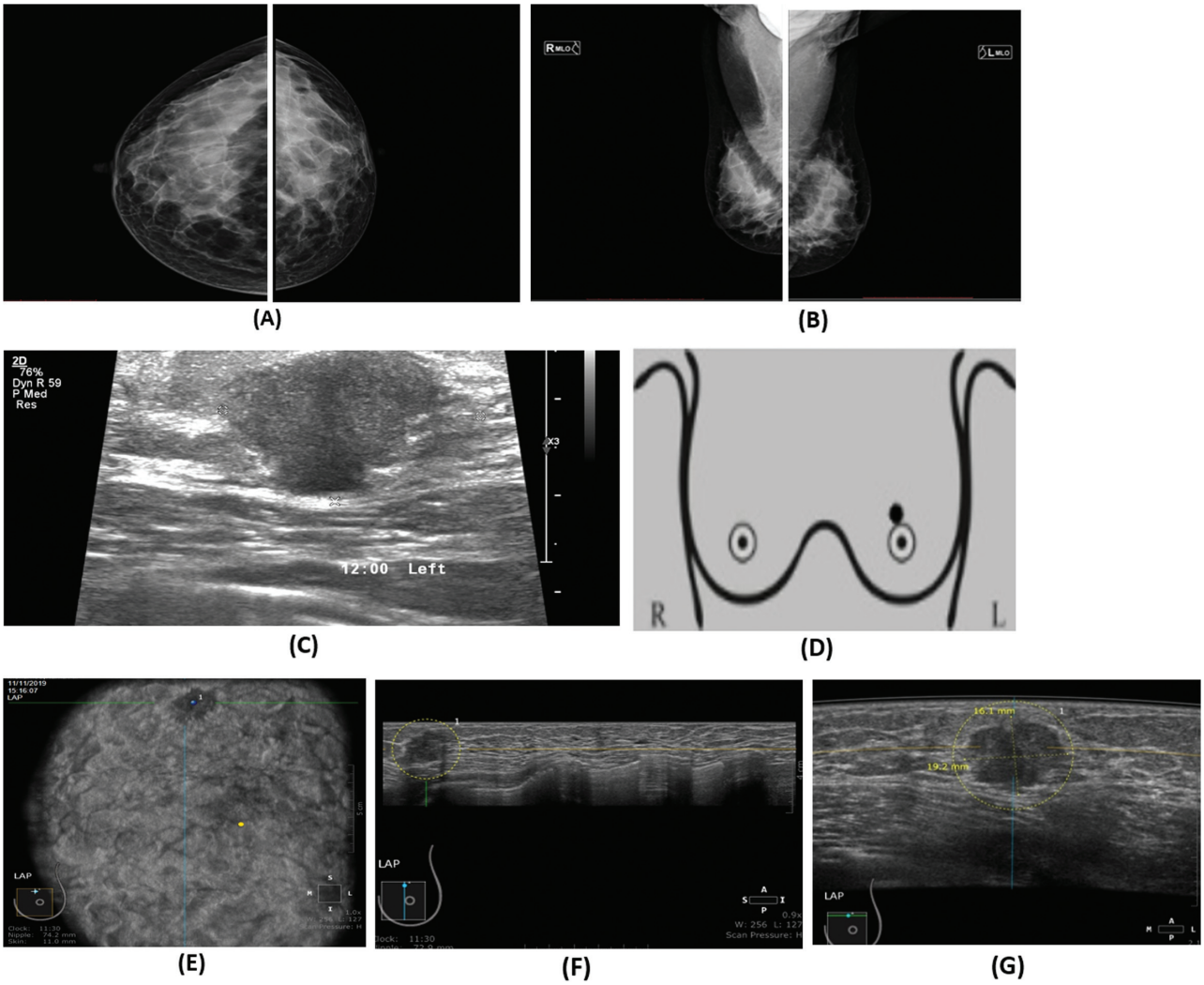
Data in cross-tables are counts. ABUS, automated breast ultrasound; CI, confidence interval; HHUS, handheld ultrasound. [a]Near perfect agreement.

as well as breast anatomy evaluation. It covers the whole breast scan in three to five distinct volumes depending on breast size and is built with a broad linear transducer that provides a big scanned area in each [6,7].

Given that the mean±SD ABUS time of examination was 4.1±0.9 and the mean±SD HHUS time of examination was 9.2±2.0, our study's comparison between ABUS and HHUS time of examination revealed a statistically significant difference in favor of ABUS, with *P* value more than 0.0001 and 95% confidence interval=5.7–4.4. It is consistent with Vourtsis and Kachulis [2] and Golatta *et al.* [5], as ABUS demonstrated faster scanning times than HHUS because it is operator independent, produces high-resolution pictures, covers a vast region of the breast in a single sweep, and features computer-aided detection software that speeds up interpretation.

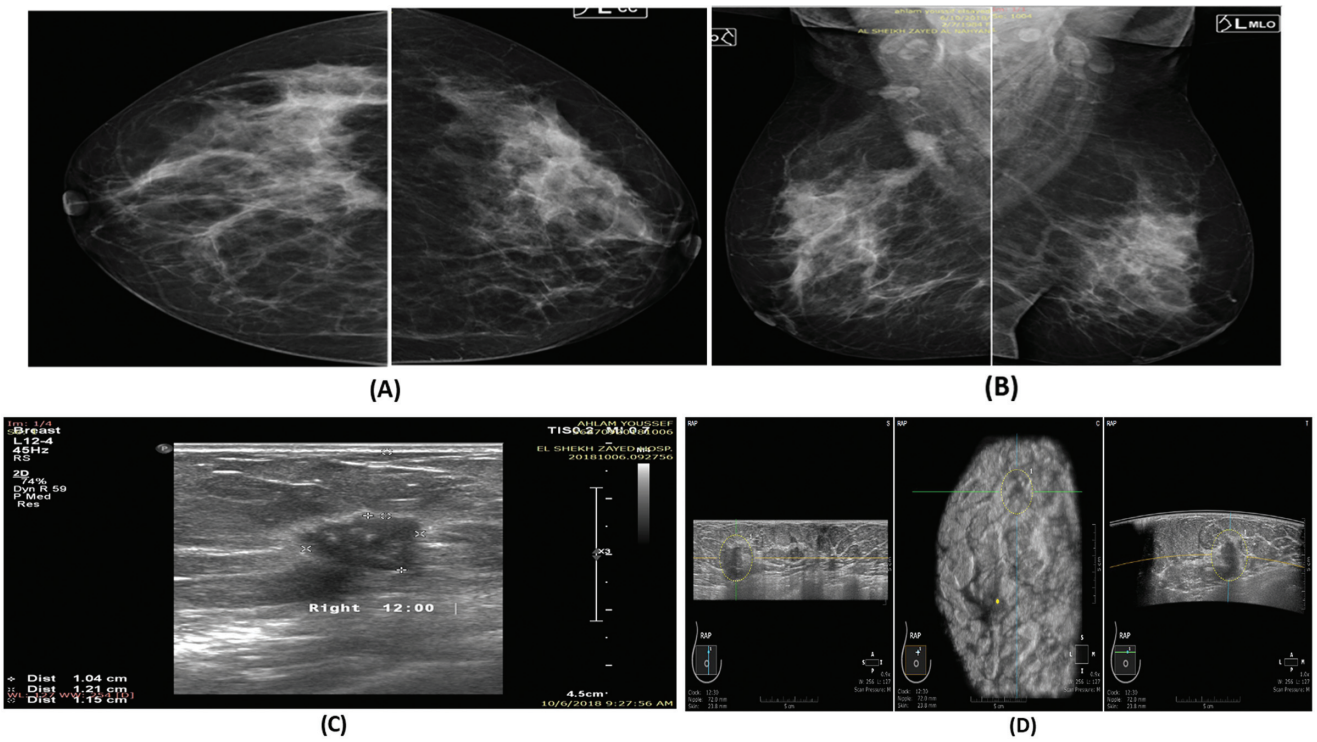
In our investigation, 60 female patients had a total of 60 findings that were validated by histopathological biopsy or at least 6 months of follow-up; 16 of the 60 findings were benign abnormalities and 44 were malignant lesions. The sensitivity, specificity, positive predictive value, and negative predictive value metrics for the HHUS were all 100%. The diagnostic accuracy parameters for ABUS were as follows: sensitivity 88%, specificity 91%, positive predictive value 78%, and negative predictive value 95%. There were notable differences in sensitivity in favor of HHUS (100% vs. 88%), which may be explained by ABUS's failure to assess vascularity or axillary lymph nodes.

Figure 1



Case 1: a 42-year-old female patient came for screening with no abnormality detected by mammography (a) cc view and (b) MLO view. Complementary HHUS (c) and ABUS (d scout, e coronal, f sagittal, g axial) show left hypoechoic irregular solid mass lesion at 12 o'clock position (BIRADS IV). It was confirmed by histopathology as invasive duct carcinoma grade III. ABUS, automated breast ultrasound; HHUS, handheld ultrasound.

Figure 2



Case 2: a 32-year-old female patient, came for screening presenting with right breast painful lump, with known positive family history. Mammography (a) CC view and (b) MLO view show right upper central irregular spiculated mass of high density with associated parenchymal distortion and no associated calcification. HHUS (c) shows right breast with hypoechoic well-defined mass with irregular margin, showing internal hyperechoic foci, associated with posterior shadowing, surrounding parenchymal distortion, and enlarged nonspecific axillary lymphadenopathy (BIRADS IV). ABUS (d) 3D (sagittal, coronal, and axial) views show right breast with hypoechoic well-defined area with irregular margin, showing internal hyperechoic foci, associated with posterior shadowing, and surrounding parenchymal distortion. It was confirmed by histopathology as invasive duct carcinoma grade II. ABUS, automated breast ultrasound; HHUS, handheld ultrasound.

This came in agreement with Schmachtenberg *et al.* [10] who reported that ABUS and HHUS showed sensitivity of 93.3 and 100%, respectively; specificity of 83.3 and 83.3%, respectively; positive predictive value of 77.8 and 78.9%, respectively; and negative predictive value of 95.2 and 100%, respectively.

It agreed as well with Xiao *et al.* [8] who reported that sensitivity and specificity of ABUS relative to biopsy (gold standard) were 28.95 and 100%, respectively, whereas the sensitivity and specificity of HHUS relative to biopsy were 43.06 and 98.36%, respectively, with higher sensitivity in favor of HHUS.

However, our study disagreed with Niu *et al.* [11] who reported significant differences in sensitivity between HHUS and ABUS (82.52 vs. 92.23%) in favor of ABUS.

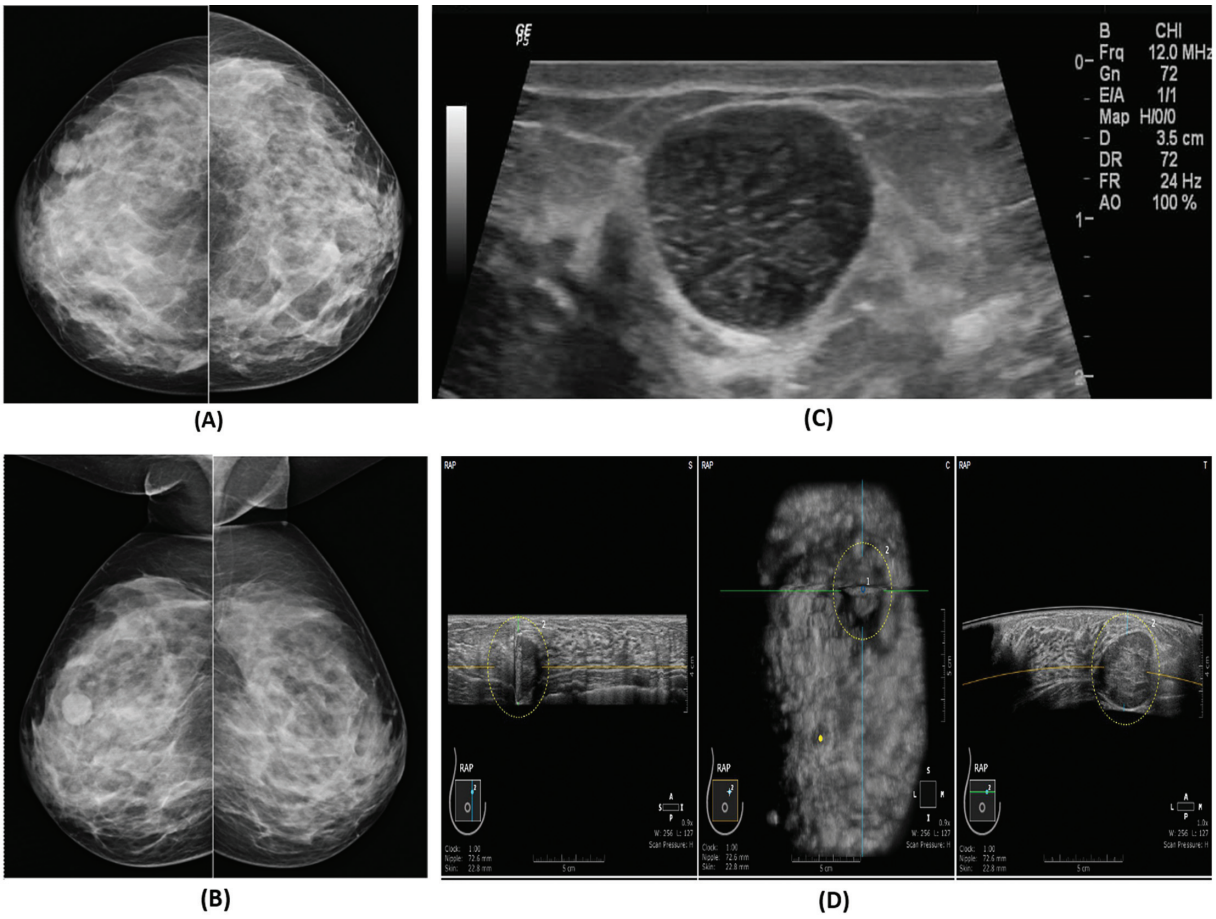
According to our study, there was near-perfect agreement between HHUS and ABUS about lesion categorization (benign and malignant), as well as with BIRADS classification. This is in line with Choi *et al.* [1], who claimed that ABUS and HHUS demonstrated moderate to good agreement (0.53–0.67 and 0.55–0.70, respectively); this resulted in agreement.The diagnostic performance of the ABUS was similar to that of HHUS in differentiating benign from malignant breast lesions, according to Wang and Qi [12], and it concurred with Vourtsis and Kachulis [2], who found a 99.8% overall agreement between HHUS and ABUS (kappa=0.994, *P*=0.0001).

In our study, regarding lesions classification (benign and malignant), both HHUS and mammography, as well as ABUS and mammography, demonstrated significant agreement.

However, regarding BIRADS classification, HHUS and mammography showed moderate agreement regarding BIRADS and also ABUS and mammography showed fair agreement.

This explains why mammography is widely regarded as the gold standard for the early detection of breast cancer, but it still requires ultrasonography as a complementary scan because both handheld and

Figure 3



Case 3: a 35-year-old female patient presented with right breast lump. Mammography (a) CC view and (b) MLO view show right well-circumscribed round-shape mass of high density seen in upper outer quadrant, no associated asymmetry, parenchymal distortion, and calcification. Complementary HHUS (c) and ABUS (d) 3D dimentions (sagittal, coronal, and axial views) show well-circumscribed rounded hypoechoic soft tissue mass noted opposite 1 o'clock position (BIRADS III). It was confirmed by histopathology as fibroadenoma. ABUS, automated breast ultrasound; HHUS, handheld ultrasound.

automated ultrasonography are effective at finding cancer that would not be visible on mammography in women with dense tissue.

That came in agreement with data reported in a systematic review of Sood *et al.* [13].

There are certain limitations in this study:

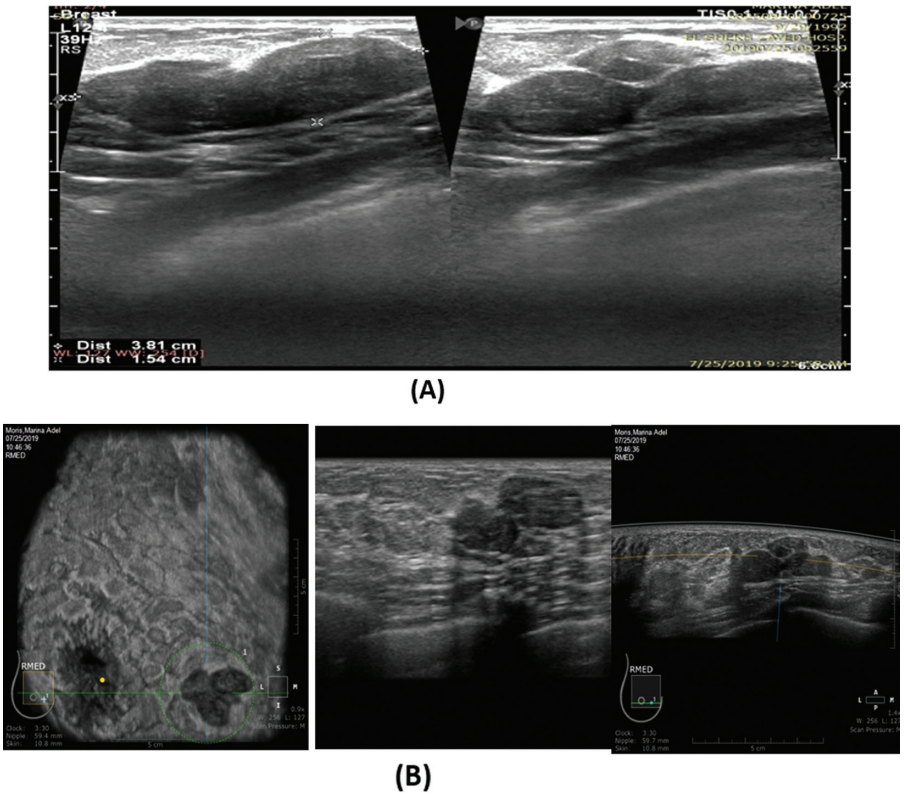
(1) The number of study participants was relatively small in the context of other related trials.
(2) The study was not designed to include pregnant women.
(3) The study was not designed to detect mortality, which prevented us from analyzing a potentially beneficial effect of the enhanced cancer detection.
(4) All breast specialists had to take enough orientation sessions before the start of the study to improve the result of the study.

Conclusions

The 3D ABUS shows comparable diagnostic performance to HHUS as a complimentary tool in the screening program of breast cancer in detecting breast tumors.

(1) More imaging and interpretation training can lead to better outcomes.
(2) In our investigation, 60 female patients had 60 findings that were validated by histopathological biopsy or at least 6 months of follow-up; 16 of the 60 findings were benign abnormalities and 44 were malignant lesions. We present some of our cases of breast tumor confirmed by histopathological as malignant tumors invasive ductal carcinoma grade III, as in Fig. 1 , and invasive ductal carcinoma grade II, as in Fig. 2, and benign tumor fibroadenomas, as in Figs 3 and 4.

Figure 4



A 25-year-old female patient presented with right breast. HHUS (a) and ABUS (b) 3D dimensions (coronal, axial, and sagittal views) show well-defined hypoechoic macro-lobulated mass (BIRADS III). It was confirmed by histopathology as fibroadenoma. ABUS, automated breast ultrasound; HHUS, handheld ultrasound.

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Conflicts of interest
There are no conflicts of interest.

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