Egyptian Journal of Radiology and Nuclear Medicine

RESEARCH

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Automated breast ultrasound in breast cancer screening of mammographically dense breasts: added values

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Abstract

Background Full-field digital mammography (FFDM) is the primary screening method for breast cancer, yet the number of cancers that can be missed with mammography is considerable, notably in female with dense breast. In this study, we compared the diagnostic yield and the clinical significance of FFDM for breast cancer detection in female with dense breasts versus its performance when complemented by automated breast ultrasound (ABUS).

Results This retrospective study was performed during the period between January 2022 and December 2022 including 500 females with dense breast (ACR C&D), who underwent screening using FFDM and ABUS. The images were retrospectively interpreted, and statistical assessments were done comparing the FFDM results alone and after complemented with ABUS. Significance was considered at a p value less than 0.05. The use of FFDM with supplemental ABUS has reduced the numbers of recall and showed improved breast cancer detection with increased positive predictive value (from 74.5 to 83.5%). In comparison, using FFDM alone and associated with ABUS, there was moderate agreement with a kappa test of 0.51; $p < 0.001$.

Conclusion ABUS can be a useful and powerful diagnostic imaging tool when adjunct to FFDM for screening of dense breast. In this study, ABUS showed less false-negative results and improved the sensitivity of cancer detection.

Keywords Dense breast, Mammography, Screening, Automated breast ultrasound

Background

In spite of the advancement in identifying of breast cancer-related risk factors and genetic markers, approximately 70% of women developing breast cancer show no major predictors [1]. Therefore, the prime strategy for breast cancer early diagnosis and reducing its mortality is the screening [2, 3].

Mammography is considered the primary breast cancer screening method [4, 5] that has significantly reducing breast cancer mortality. Yet in dense breast mammographic screening sensitivity is reduced to 30–48% [6]. The odds for interval cancers diagnosis in dense breasts was about 17.6-fold higher compared with fatty breasts [6–9].

Mammography is a summation of images, resulting in overlying of all breast tissues in each view that may obscuring masses, which subsequently reduce the mammography performance in dense breasts [10]. Posterior cancer locating far at the retromammary space can also be missed by mammography [11].

That is why The American Cancer Society (ACS) has recently recommended screening MRI for young females

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with high risk for developing breast cancer [12, 13]. MRI improves the sensitivity of early cancer detection; however, it shows the disadvantages of being costly and risks of its contrast media [14, 15]. Also, breast cancer screening using MRI has shown lower sensitivity and higher rate of false-positive results compared to mammography, which requiring further follow-up and/or biopsy [16–18].

MRI also showed lower specificity (82%) compared to mammography (94%) as it increases the recall rate four times compared to mammography and about 70% of these recalls proved to be negative for cancer [19, 20].

Ultrasound is a valuable supplemental tool to mammography due to its wide availability and relatively low cost, and it is well-tolerated by patients [20, 21]. It is also used for scanning all breast parenchyma till the chest wall without tissue overlap. Early studies showed promising results using complementary high-resolution ultrasound for screening [22–28], but handheld imaging always requires time and expertise for small mass detection, which has discouraged its widespread use [29].

The FDA (Food and Drug Administration) approved automated breast ultrasound as a complementary tool for breast cancer screening in 2012. It shows the advantage of creation of standardized image sets obtained by less experienced personnel and also allows more efficient, time-saving interpretation by physicians. Previous studies also supported the usage of 3D AWBU for breast cancer screening [29–32].

This study aimed to determine whether there is improvement of the screening mammography diagnostic accuracy when complemented by AWBU.

Methods

Study design and population

From January 2022 to December 2022, women with BI-ACR density D or C (heterogeneously or extremely radiographically dense breasts) that underwent ABUS examinations at presentation for routine mammography were retrieved from the database. The examinations included were acquired for screening purposes.

A consent was approved by the academic research department of the hospital. It specifically clarified that ABUS is a procedure used as a complement for mammography and not replacing it.

FFDM was performed combined with DBT as a routine protocol for our department for women with dense breast (ACR C&D). ABUS and HHUS (handheld ultrasound) were performed independently in the same session.

Breast density was classified by two radiologists based on Breast Imaging-Reporting and Data System (BI-RADS) and classified into: almost fatty (A); have scattered fibroglandular densities (B); heterogeneously dense (C) or be extremely dense (D).

A total of 500 mammograms with ACR C&D and AWBU examinations are enrolled in the study. Patients with BIRDS 3 (requiring short-term follow-up) are excluded from the study.

Image acquisition

Mammography was obtained for each breast in the mediolateral oblique and craniocaudal views using GE machine.

The ABUS was performed with an Invenia System 2.0. Images were obtained by a trained radiographer, to ensure the examination was done correctly. The patients lie in the supine position raising the arm up.

Anteroposterior, medial and lateral views are obtained; additional superior and inferior views were acquired in large breasts.

HHUS was performed by two radiologists using a GE LOGIQ 9 machine.

Image review

Independent and sequential interpretation of all examinations was made by two radiologists for 15 years and get a specific training on the Invenia 2.0 ABUS system.

AWBU system is a computer-aided unit used to perform and record whole breast ultrasound images (SonoCine, Reno, NV). These images are acquired by multi-frequency transducers with at least 7–12 mHz range. A computer-guided mechanical arm is attached to the transducer and images acquired with 7–10 mm overlap to ensure whole breast scan. The surface of the transducers measured about 5.2 cm in more than 95% of the studies so the width of the rows was about 4.2–4.5 cm without the overlap, and for each breast, the number of rows varied from 4 to 7. The scans were performed by trained ultrasound technologists that maintain skin vertical orientation and good contact pressure. Speed and position of the transducer are controlled by a mechanical arm. The images are demonstrated immediately on the monitor of the ABUS system with about 150 to 300 images displayed per row and then stored. Imaging time for each participant was about 10–20 min with an additional 5–10 min for patient preparation.

A cine images are created by ABUS software containing about 2000–5000 images based on the size of the breast (average: 3000 images). The interpretation and lesions detection are enhanced by reviewing the cine images.

Using spatial registration recorded as images acquired any point on an image can be described as a distance from the nipple in a specific radius. Then, image revision is performed using a high-resolution monitor to optimize image review allowing image size compression,

three-dimensional reconstruction and adjustment of brightness, contrast and the speed of review.

Breast Imaging-Reporting & Data System (BI-RADS) assigns one of six assessment categories (0: incomplete, needs additional assessment; 1: negative; 2: benign findings; 3: probably benign; 4: suspicious for malignancy; 5: highly suggestive of malignancy) [33, 34], which was used for image interpretation.

Reference standard

Our reference standard was histopathological result for the lesions that required biopsy and the typical benign features of other non-biopsied lesions based on the BI-RADS calcifications (cysts, intramammary lymph node).

Statistical analysis

Collection, tabulation and analysis of data were performed by the use of SPSS (Statistical Package for Social Science) version 20.0 on IBM compatible computer (SPSS Inc., Chicago, IL, USA).

Categorical data were described as number and percentage and compared by *Z* test and Chi-square test accordingly. The agreement in the results of the two imaging modalities was assessed using Kappa agreement analysis (0.01–0.2: slight agreement, 0.21–0.4: fair agreement, 0.41–0.6: moderate agreement, 0.61–0.8: substantial agreement and 0.81–0.99: almost perfect agreement). Positive predictive value was calculated for each modality (as the ratio of patients truly diagnosed as positive to all those who had positive test results). There is significance when p value < 0.05.

Results

Study population

Five hundred women with dense breast (ACR category C&D) were included in this study with an average age of 48.45 ± 7.06 and ranged from 40 to 60 years.

The total number of recalls (BI-RADS 0 + 4 + 5) based on FFDM mammography alone was 202 (40.4%), which had been reduced to 131 (26.2%) after the supplementation of ABUS. The number of cases with BI-RADS 0 deferrers as shown in Table 1. Using ABUS images as a complement to FFDMs, only 10 patients needed additional imaging evaluation. These cases show non-specific thickened skin complex with edema caused by systemic illness with diffuse body anasarca, which totally regress after 1-month follow-up (Table 2).

While the recommended biopsies (BI-RADS 4 + 5) were 141 based on FFDM alone and reduced to 121 suspicious lesions with 111 (22.2%) patients had been confirmed malignant breast lesions (Figs. 1, 2, 3, 4, and 5) by ultrasound-guided biopsy (invasive ductal carcinomas, no special type; forty luminal A subtypes, and seventy-one luminal B subtypes).

Table 1 BI-RAD of the two estimated imaging modalities (mammography—mammography with ABUS) among the studied cases

	Mammography	Mammography with ABUS	*Z* test	*p* Value
BI-RAD				
0	61 (12.2)	10 (2.0)	6.16	< 0.001
1	88 (17.6)	139 (27.8)	3.77	< 0.001
2	210 (42.0)	230 (46.0)	1.21	0.23
4	70 (14.0)	70 (14.0)	0.09	0.93
5	71 (14.2)	51 (10.0)	1.84	0.07

Table 2 Percentage of recall of the two estimated imaging modalities (mammography—mammography with ABUS) among the studied cases

	Mammography	Mammography with ABUS	*X2* test	*p* Value
Recall				
No	298 (59.6)	369 (73.8)	22.7	< 0.001
Yes	202 (40.4)	131 (26.2)		

X^2 = Chi-squared test

Table 3 demonstrates the diagnostic performance of FFDM and FFDM + ABUS in the form of positive predictive value.

Table 4 shows moderate agreement between FFDM and FFDM complemented with ABUS.

Discussion

Screening mammography for breast cancer detection consumes much time and considers a challenging task owing to the large numbers of examinations and low cancer yield [5]. Females with dense breast show the greatest percentage of female with intermediate risk and show up to 20% risk to develop cancer. The use of an additional supplemental imaging modality is currently recommended for screening of dense breast to reduce the number of occult cancer that can be missed by mammography [6]. Complementary ultrasound has showed a substantial improvement in the diagnosis of cancer breast, which were missed on mammography in female having dense breasts with or with increased risk for cancer breast [11, 13, 14].

Our study compared FFDM diagnostic performance for screening when used alone and its performance if combined with ABUS in female with dense breast. Our results clarify that the implantation of ABUS with FFDM

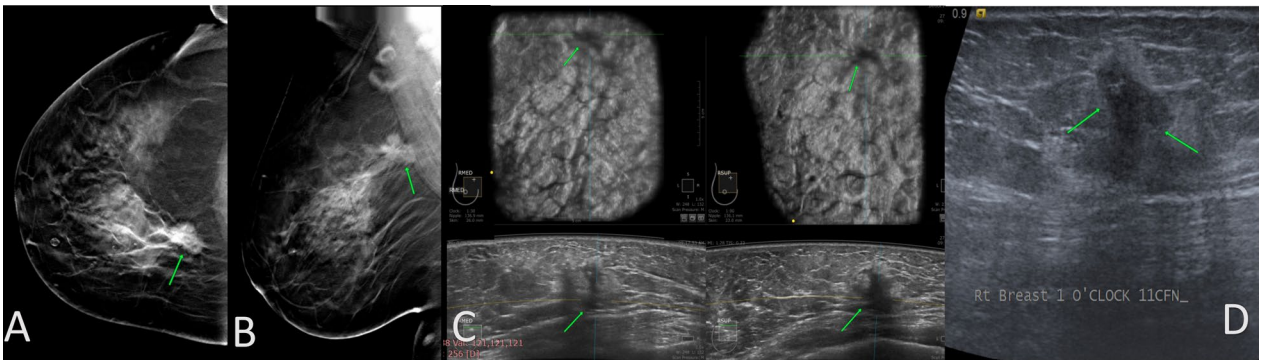

Fig. 1 Female patient of 54y old. Dense breast (ACR class c) with an irregular speculated dense mass was seen at the right upper inner quadrant on mammography (arrows **A**, **B**). On ABUS (**C**), an irregular hypoechoic mass with posterior shadowing was seen at 1 O`clock which was seen on HHUS (**D**). This was confirmed invasive ductal carcinoma

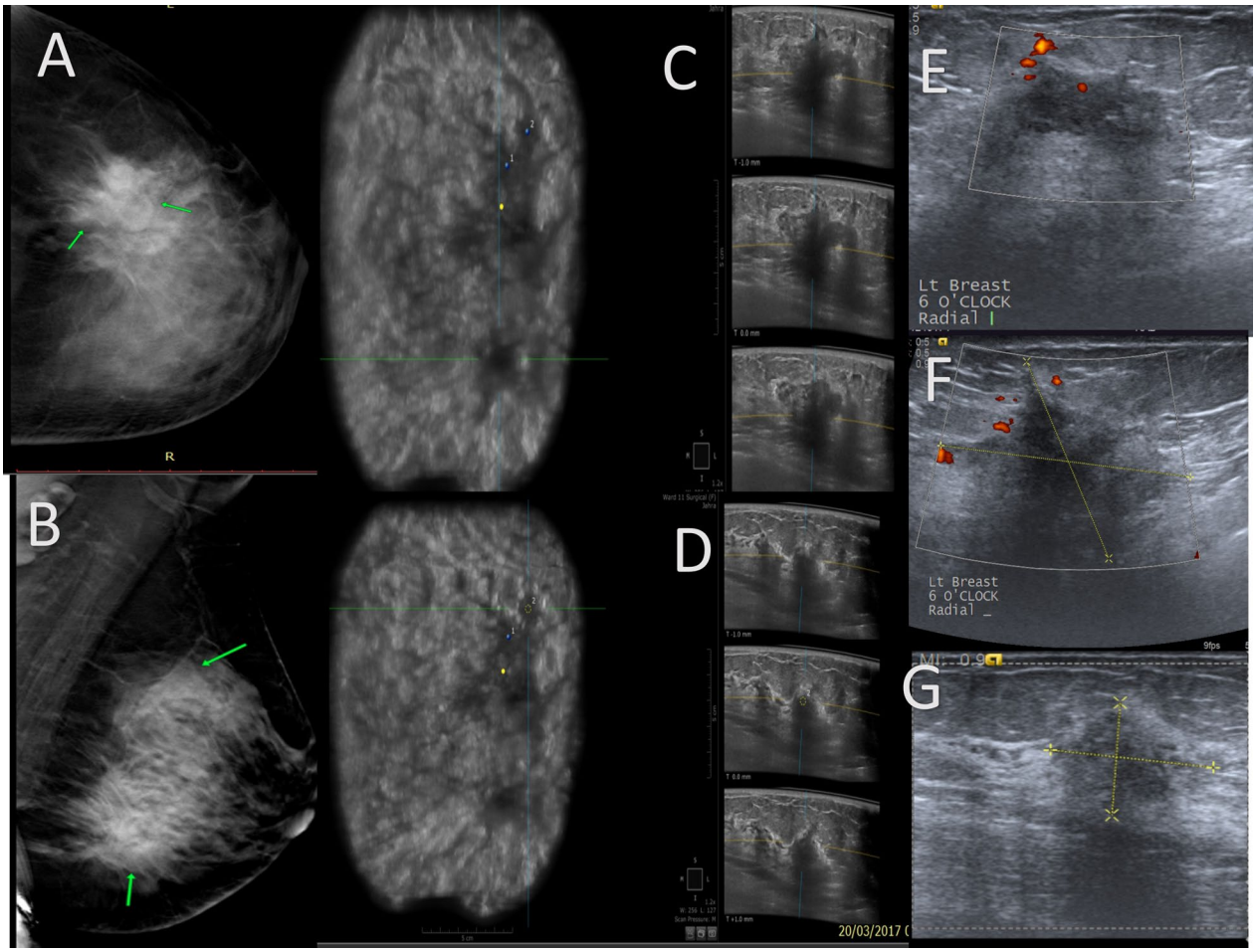

Fig. 2 Female patient of 35y old of high-risk breast ca. heterogeneous dense breast (ACR class d) showed two irregular speculated dense mass that were seen at the left upper inner quadrant and the deep central breast on mammography (arrows **A**, **B**). On ABUS (**C**, **D**), two irregular hypoechoic mass with posterior shadowing was seen at 2 O`clock & 6 O`clock, which was seen on HHUS (**E**–**G**). This was confirmed multifocal invasive ductal carcinoma

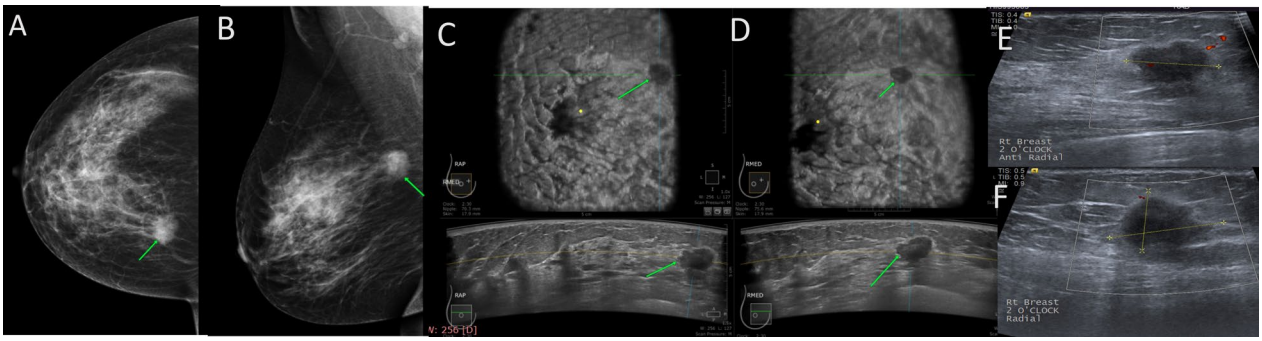

Fig. 3 Female patient of 40y old. Dense breast (ACR class c) with lobulated dense mass was seen at the right upper inner quadrant on mammography (arrows **A**, **B**). On ABUS (**C**, **D**), lobulated hypoechoic mass with posterior shadowing was seen at 2 O`clock, which was seen on HHUS (**E**, **F**). This was confirmed invasive ductal carcinoma

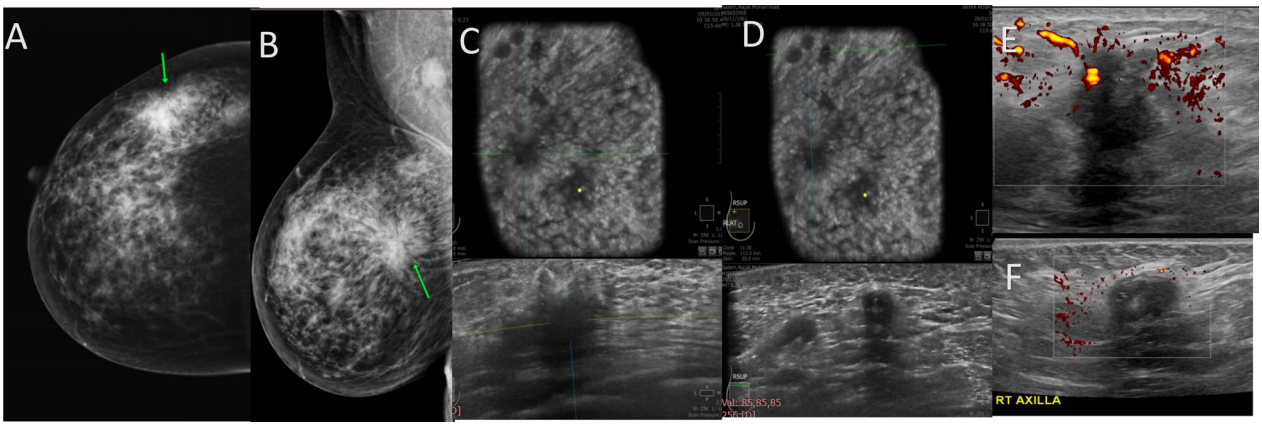

Fig. 4 Female patient of 57y old. Dense breast (ACR class c) with irregular speculated dense mass with pleomorphic microcalcifications was seen at the right upper outer quadrant on mammography (arrows **A**, **B**) with rounded axillary lymph node. On ABUS (**C**, **D**), a large irregular hypoechoic mass with posterior shadowing was seen at 9 O`clock (c) with pathological rounded axillary lymph node showing loss of normal architecture (**D**), HHUS (**E**, **F**) showed the mass with high vascularity and pathological axillary lymph node. This was confirmed invasive ductal carcinoma with malignant lymph nodes

significantly improved the readers' ability to identify true-negative and true-positive cancers in dense breasts.

Friedewald et al. [10] found that supplementing FFDM with ABUS improved the rate of breast cancer detection from 2.9/1000 to 4.1/1000 along the screened patients without significant modification in the diagnosis of cases with ductal carcinoma in situ (DCIS), signifying that the use of supplemental ABUS may show more clinical significance in breast cancer detection.

Our study showed that the use of mammography combined with ABUS increased positive predictive value for cancer detection from 74.5 to 83.5%. This is similar to the results of another earlier study adding handheld ultrasound as complementary for mammography (sensitivity 87.8%) [23].

However, the use of AWBU has some advantages compared to the handheld ultrasound: (1) it is reproducible, including the whole breasts; (2) it has higher image definition, sharpness and contrast; (3) it provides smaller images for revision by the use of a high-resolution 2,000-line reading monitor 3D; (4) it optimizes the reading environment by allowing delayed interpretation at monitor-based computer stations with non-real-time review. Other previous studies [11, 35] showed higher sensitivity (about 95%) similar to the MRI sensitivity, but with high difference in cost.

Waldherr et al. [13] described comparable sensitivity of FFDM + ABUS (91.9%), but a higher specificity of 90.5% (our study showed 71.97% specificity). A prospective study including 7292 asymptomatic female by Houssami et al. [12] with aged over 48 years and an average risk showed 85% sensitivity and 97% specificity. Another study done on 113 females showed different results by identifying 119 breast lesions with the three readers (with 8–14 years' experience); average sensitivity and specificity were 97.3 and 44.7%, respectively [16].

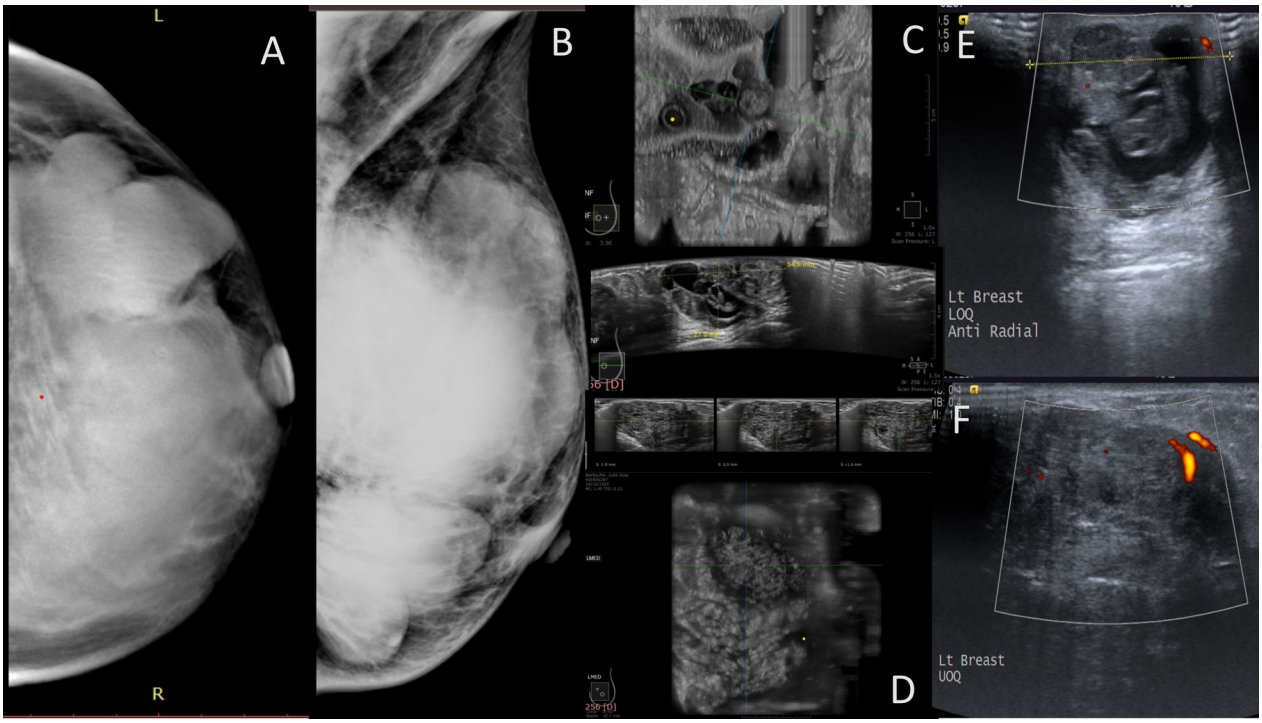

Fig. 5 Female patient of 51y old. Heterogeneously dense breast (ACR class d) with large lobulated dense mass was seen involving the whole left breast on mammography (**A**, **B**). On ABUS (**C**, **D**), a large complex mass with cystic and soft tissue components and thick septation. HHUS (**E**, **F**) was done. This was confirmed phyllodes tumor

Table 3 Diagnostic performance of the imaging technique

	Mammography	Mammography with ABUS
Positive predictive value	74.5%	83.5%

Table 4 Agreement between mammography and mammography with ABUS BI-RAD results

	Mammography		Kappa test	*p* Value
	1&2	0, 4&5		
Mammography with ABUS 1&2	278 (93.3)	91 (45.0)		
0, 4&5	20 (6.7)	111 (55.0)	0.51	< 0.001

Kappa agreement

Additional analytic data were performed by Rafferty et al. [11], showing that the use of complementary ABUS improved the detection rate of breast cancer in female with heterogeneously or extremely dense breasts and reducing the rate of recall.

Our study reported similar results and clarified that complementary ABUS significantly reduced the recall rate from 40.4 to 26.2%. The interpreted BI-RADS 0 also was significantly reduced from 60 by the use of FFDM alone to only 10 by the use of supplemental ABUS. Twenty of them were scars for previous benign lesion excisions, 40 cases with apparent focal asymmetries and small lesion with slight angulated borders that are demonstrated as simple cysts by ABUS.

Our findings are also comparable to previous studies [14, 16, 19] that using complementary screening ultrasound that resulted in the diagnosis of additional cancers that were missed by the use of mammography alone. Through our study, 10 cases with small lesions (range 4–8 mm) were missed along the FFDM, which appeared normal and reported as BI-RADS 1 while breast scanning using ABUS detects small specious lesions upgrading the diagnosis to BI-RADS 4 (Fig. 6) and 6 of these cases proved by invasive ductal carcinoma by histopathology.

Previous study [26, 31] similarly showed that the supplemental ABUS could lead to detection of additional small cancers that were not be detected by DBT (not seen even retrospectively), but unlike our study they showed that supplemental ABUS was associated with increased recall rate.

Other studies [26, 28] used the ABUS as an individual screening modality and compared it to mammography and also showed increased the recalls number for performing additional imaging or handheld ultrasound,

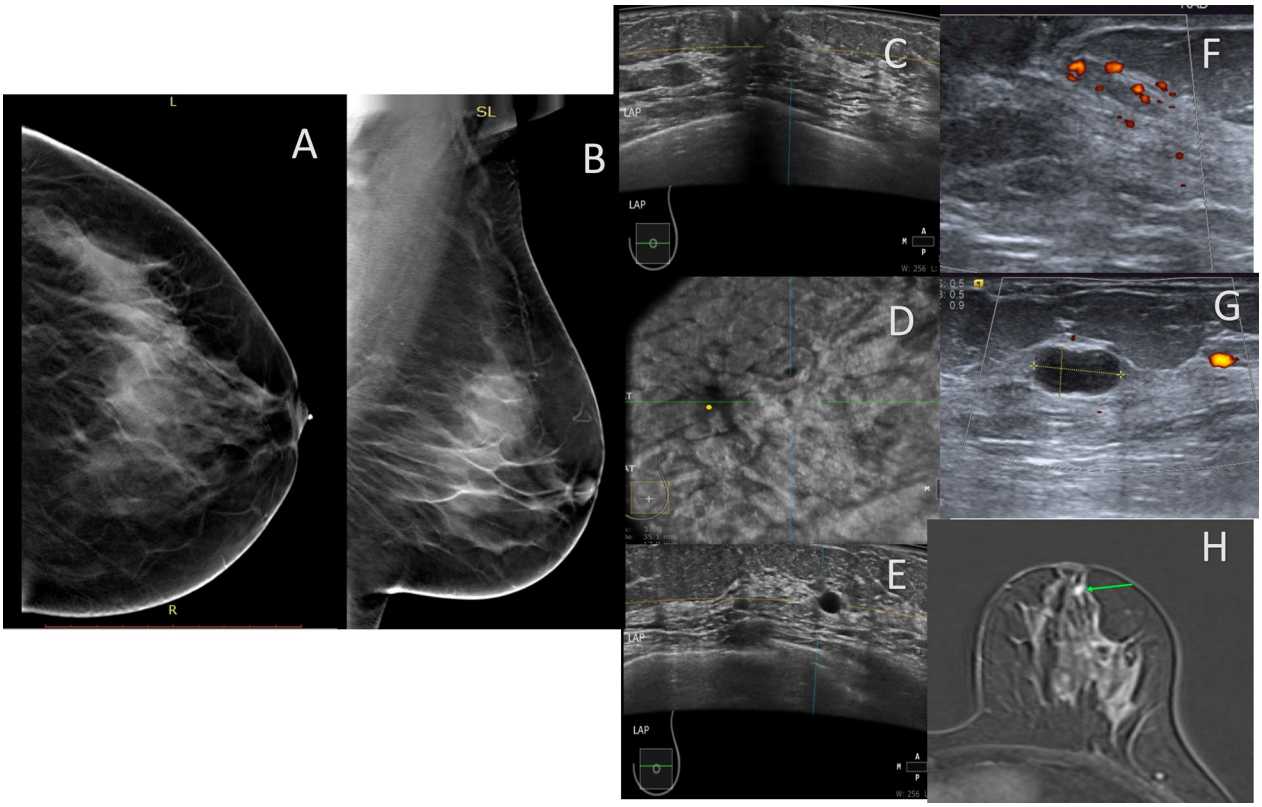

Fig. 6 Female patient of 44y old. Dense breast (ACR class c) with normal mammography (arrows **A**, **B**). On ABUS (**C**–**E**), there was focal retroareolar dilated duct with echogenic content (**C**) and scattered anechoic cysts (**D**, **E**). HHUS (**F**, **G**) showed the dilated duct (**F**) and anechoic cyst (**G**). MRI (**H**) showed small enhancing intraductal lesion (arrow). This was confirmed intraductal papilloma

which considered one of the drawbacks of this technology. This can be explained by the higher detection rate of cancer when using supplemental ABUS compared with mammography and by the availability of comparison of ABUS examinations for only 31% of the studies. Almost all mammograms also had previous studies for comparison. These studies also showed similar PPV of the recommended biopsy based on ABUS compared with mammography findings so although the ABUS can increase the recall rate, it does not increase the rate of false-positive biopsies.

The number of false-positive cases after the use of FFDM + ABUS in our study was 10 cases of BI-RADS 4 (which are proved by ultrasound-guided biopsies as 3 cases focal adenosis, 5 cases atypical fibroadenomas and 2 cases granulomatous mastitis).

Previous study [19] showed substantial agreement of HHUS compared to ABUS ($k = 0.76 \pm 0.14$) for lesions characterization (regarding: outline, border, parallel or not, echotexture, acoustic features, calcifications and associated features). Lesions orientation was the most concordant ones (parallel or not parallel to the skin, $k = 0.61 \pm 0.23$), while the presence of posterior shadowing was the most discordant features ($k = 0.35 \pm 0.26$). Golatta et al. [27] also showed that a study performed on 913 women had a good agreement comparing the two ultrasound methods, $k = 0.31$ (95% CI [0.27; 0.35]).

Our results reported 83.5% PPV and that was significantly higher than the 41% PPV yielded by the ACRIN Trial [32] for the biopsy prompted by the handheld ultrasound, and the 63% PPV showed by the breast cancer surveillance consortium (BCSC) report [34] for the ABUS. This may be because BI-RADS 3 lesions that need long-term follow-up were initially excluded from our study and the final interpretation for woman with suspicious findings was based on the mammography complemented by ABUS and these women were treated as recall patients. The recalled female that were not assigned for biopsy was interpreted as BI-RADS 1 (negative) or 2 (benign findings).

ABUS was well accepted by participants and easily used in the breast imaging. Effective screening is more beneficial for female with high breast cancer risk and does not matching the criteria of ACS for annual MRI than mammography alone. Because of the easy use and low-cost AWBU, it become a good alternative modality to MRI for

female with dense breasts or has risk factors like personal or family breast cancer history. Compared to mammography, less breast compression, lack of ionizing radiation exposure and no need to contrast medium make ABUS well tolerated by the participants.

Our limitation in this study was lacking long-term follow-up; previous studies show about 42% of cancers diagnosed clinically before the time of next screening and are visible retrospectively on previous ABUS scanning. It is postulated that improving the experience of readers can increase cancer detection. In addition, the availability of previous studies for comparison may lead to better sensitivity, fewer recalls and reducing the number of AWBU "missed" cancers.

Conclusions

We concluded that supplemental ABUS to FFDM in female having dense breasts may improve the diagnostic accuracy with detection of more cancers not visible on FFDM even retrospectively.

Abbreviations

FFDM	Full-field digital mammography
ABUS	Automated breast ultrasound
ACR	American College of Radiology
ACS	The American Cancer Society
AWBU	Automated whole breast ultrasound
BI-RADS	Breast Imaging-Reporting and Data System
HHUS	Handheld ultrasound
DBT	Digital breast tomosynthesis
MLO	Mediolateral oblique
CC	Craniocaudal
FDA	Food and Drug Administration
PPV	Positive predictive value
BCSC	Breast Cancer Surveillance Consortium
DCIS	Ductal carcinoma in situ
MRI	Magnetic resonance imaging

Acknowledgements
We would like to thank all people who helped us in this work including the clinicians and technicians.

Author contributions
WG, RY, MIY, and SO have equal sharing between authors as regarding writing of the manuscript, the collection and analysis of data and revising the final manuscript. All authors have read and approved the manuscript.

Funding
Self-funding.

Availability of data and materials
All data and material are available.

Declarations

Ethics approval and consent to participate
The study protocol was approved by the local Ethics Committee (HSC Ethical Committee). All study procedures were performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. No available ethics committee's reference number. A written consent was taken from all patients prior to the study to be included in our study.

Consent for publication
A written consent was taken from all patients prior to the study for publication.

Competing interests
No competing interests.

Received: 5 January 2024 Accepted: 9 April 2024
Published online: 30 April 2024

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