Med. J. Cairo Univ., Vol. 93, No. 2, Accepted 9/3/2025
DOI: 10.22608/MJCU. 493-503, June 2025
www.medicaljournalofcairouniversity.net

Accuracy Measures of 3D Automated Breast Ultrasound in Detection of Breast Lesions in Comparison to 2D Ultrasound and Digital Mammography

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Abstract

Background: Breast screening imaging tools have animportant role in prevention as well as early detection of breast cancer. Despite that mammography is the first screening tool, its sensitivity decreased by higher breast density resulting in increasing breast cancer risk by 15-25%. In addition that handheld ultrasound screening can determine early-stage cancer breast than mammographic screening alone, however screening with HHUS alone is time consuming and has a high false positive results. Automated breast ultrasound is one of the latest break throughs in detecting breast lesions and as well high resolution images production.

Aim of Study: To study better accuracy measures of ABUS in diagnosis and characterization of different breast lesions than HHUS and digital mammography.

Patients and Methods: This prospective study was performed in the Female Imaging Unit, Radiology Department, Faculty of Medicine, Cairo University and approved by its Research and Ethical committee; all the included cases gave informed consent. The study was conducted on 42 patients presented from surgery clinic and early screening clinic with either: Annual screening or Breast lump. Was done between January 2022 and January 2023. Their ages ranged from 27 to 66 years (mean age: 48.48±11.526 SD years). All of the cases (n=42) will be examined with mammography and sonography, and further analyzed with ABUS.

Results: Digital mammography accuracy measures in detecting breast lesions were 86.7% sensitivity, specificity 88.9%, 80% NPV, 92.9% PPV, and accuracy of 87.5%. Mammography was under estimated in about 13.3% of the lesions in the breast and overestimated in 11.1% of breast lesions while Handheld ultrasound sensitivity in detecting breast lesions was about 93.3%, 94.4% specificity, NPV 89.5%, 96.6% PPV, and 93.7% accuracy. Handheld ultrasound was under estimated in 6.6% of breast masses and overestimated in 5.5% of breast lesions. As well as the specificity of Automated breast ultrasound was 88.9%, sensitivity was 96.7%, 93.5% PPV, 94.1% NPV and 93.7% accuracy. Automated ultrasound was over estimated in about 11.1% of cases and under estimated in 1.1% of cases.

Conclusion: Automated breast ultrasound is a promising imaging modality that can be used in addition to mammography and instead of HHUS, in screening as well as early breast cancer detection, to reduce the patient radiation exposure eliminate human factor, save scan time and provide 3D images.

Key Words: *Handheld ultrasound – Dense breast – Automated breast ultrasound.*

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Introduction

BREAST cancer is the most common cancer worldwide and as well as responsible of about 10 million neoplasms detected each year **[1]**.

Despite that mammography is the main breast imaging screening tool, however increasing the mammographic breast density in some patients can hide breast cancer and increases the risk of breast cancer by about 15-25%. On the other hand, HHUS can determine the presence of early breast cancer than mammography, but it is time consuming, operator dependent, and increases the false positive results, while ABUS reduces the time of the examination, the false positives and produces high resolution images **[1]**.

Automated breast ultrasound (ABUS) is one of the latest imaging tools that can be used as an alternative in breast screening as it is painless, safe, radiation free as well as non-invasive technology. It is a 3D ultrasound technology allowing whole breast imaging and high resolution breast imaging production **[3]**.

Abbreviations:

ABUS: Automated breast ultrasound.
HHUS: Handheld ultrasound.
BIRADS: Breast imaging reporting and database system.

Patients and Methods

Patients:

This prospective study was done in the Female Imaging Unit, Radiology Department, Faculty of Medicine, Cairo University and approved by its Research and Ethical Committee; all the included cases gave informed consent. The study included 42 cases coming from surgery clinic and early screening clinic with either annual screening or breast abnormality in the period from January 2022 to July 2023. Their ages ranged between 27 to 66 years (mean age: 48.48±11.526 SD years).

Methods:

All the patients (n=42) examined by both mammography, HHUS, and further analyzed with ABUS.

Mammography:

All the patients underwent MLO and CC views.

2D ultra-sonography:

Both breasts 2D ultra-sonography was done in the radial and anti-radial directions by using Philips eL18-4 ultra-broadband linear array transducer with frequency range 22-2 MHz over the breast.

Automated breast examination protocol design:

The ACUSON S2000 ABUS (GE Invenia ABUS system. GE Healthcare) was used in our study. The patient is placed in the same position as for the HHUS then a gel layer is placed upon all the breast to makeperfect contact between the skin and device. Then The 14L5BV transducer is hanged over the breast and presses the tissue against the body. Images were done to the entire breast volume in 1min with a maximum depth of up to 6cm.

Three image acquisitions, typically in the antero-posterior, lateral and medial planes are usually adequate to image all the breast tissue during the automatic collection of 3D data, covering 16.8cm distance and acquiring 318 high-resolution slices for post-processing (resolution: Axial 0.09mm, lateral 0.16mm, and sagittal 0.44mm).

Image interpretation:

All the images were evaluated by two different experienced radiologists and they donot know pathological diagnosis of each patient.

Mammography images:

We have to access the breast density, the mass's shape and margin, focal or global symmetry, skin retraction and thickening as well as if there is architectural distortion, BIRADS classification.

2D ultra-sonography:

Assessment of the shape and margin of the lesion, extension, focal asymmetry skin thickening and retractionas well as architectural distortion, classification of the BIRADS.

Automated ultrasound images:

Evaluation of lump characteristics, global or focal asymmetry, mass extension, skin retraction and thickening as well as architectural distortion in both axial and coronal planes and the final BIRADS classification.

The Pathological final results were taken as a reference mark for 36 lesions out of the 48 breast lesions, while the rest 12 breast mass lesion, these lesions were proved to be cysts or fibro adenomas (BIRADS II or BIRADS III on follow-up by ultrasound), Samples were made using either fine needle aspiration cytology (FNAC), true cut needle core biopsy), surgical biopsy and then pathological analysis of these samples was performed.

Statistical analysis:

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 24, then it was summarized using frequency (count) and relative frequency (percentage) for categorical data. Standard diagnostic indices including sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV). For comparing categorical data, Chi square ($\chi 2$) test was used. Exact test was done instead when the expected frequency is less than 5.

p-value less than 0.05 was considered as statistically significant.

Results

This study was prospective study that had 42 female cases with either breast symptoms or as early screening program, their mean age was 48.48.

Table (1): Age distribution.

	Mean	Standard deviation	Minimum	Maximum
Age	48.48	11.526	27	66

Out of 42 patients 48 breast lesions were detected, 18 lesions were proved to be benign while the rest, 28 lesions were malignant and the last 2 breast lesions were border line malignancy.

Pathological results were taken as a the main reference for about 36 lesions out of the 48 masses, and as for the rest 12 masses, were proved by radiology to be fibrocystic changes (n=2)/fibro adenomas (n=7); duct ectasia (n=1); and abscesses (n=2).

Tissue diagnosis of the lesions was performedby different procedures as FNAC, core biopsy, and surgical biopsy.

Table (2): The histological diagnosis in the patients n our study.

	Count	%
Pathology:		
Benign	18	37.5
Border line malignancy	2	4.16
Malignant	28	58.3
Pathology details:		
Benign phyllodes tumor	1	2.08
Border line phyllodes tumor	2	4.16
Atypical lymphoid infiltrate	1	2.08
Duct carcinoma insitu	1	2.08
Fibroadenoama	11	22.9
Fibrocystic changes	2	4.16
Duct ectasia	1	2.08
Invasive duct carcinoma with DCIS	1	2.08
Invasive duct carcinoma	23	47.9
Invasive lobular carcinoma	2	4.16
Inflammatory mastitis (abscess)	2	4.16
Periductal granulomatous mastitis	1	2.08

All breast masses were interpreted by the BI-RADS score system.

88.9% of BIRADS II lesions proved to be benign and 77.8% of BIRADS III lesions proved to be benign.

While 100% of BIRADS V lesions proved to be malignant and 84.2% of BIRADS IV lesions proved to be malignant.

100% of BIRADS II lesions proved to be benign and 80% of BIRADS III lesions proved to be benign. While 100% of BIRADS V lesions proved to be malignant and 76.9% of BIRADS IV lesions proved to be malignant.

100% of BIRADS II lesions proved to be benign and 90% of BIRADS III lesions proved to be benign. While 100% of BIRADS V lesions proved to be malignant and 71.4% of BIRADS IV lesions proved to be malignant by ABUS.

Mammography and ABUS show agreement in 26 breast lesions; 66.66% agreement in BIRADS II benign lesions, 55.55% agreement in BIRADS III lesions, 37% agreement in BIRADS IV lesions and 89% agreement in malignant BIRADS V.

ABUS and Conventional u/s show agreement in 36 (75%) breast lesions; 6 were BIRADS 2, 7 of the lesions were BIRADS 3, 9 of the lesions were BIRADS IV as well as 14 lesions were BIRADS V.

Mammography was underestimated in about 13.3% of the breast lesionsdone and overestimated in 11.1% of the performed breast lesions.

The sensitivity was 86.70% with specificity 88.9% in characterization and detection of the lesions.

HHUS was underestimated in 6.6% of the performed breast lesions and overestimated in about 5.5% of the breast mass lesions.

Sensitivity was 93.3% with specificity 94.4%.

Automated ultrasound (ABUS) was overestimated in 11.1% of the done cases and underestimated in about 1.1% of the performed cases.

Specificity of automated ultra sound images was 88.9% with 96.7% sensitivity.

Table (3): Relation between mammography BIRADS and pathology result.

	Final diagnosis						*p*-value
	Benign		Border line malignancy		Malignant		
	Count	Row N %	Count	Row N %	Count	Row N %	
Mammography BIRADS:							
BIRADS I	1	50.00	0	0.00	1	50.00	<0.001
BIRADS II	8	88.90	0	0.00	1	11.10	
BIRADS III	7	77.80	1	11.10	1	11.10	
BIRADS IV	2	10.50	1	5.30	16	84.20	
BIRADS V	0	0.00	0	0.00	9	100.00	

Table (4): Relation between HHUS BIRADS and pathology result.

HHUS BIRADS	Final diagnosis						p-value
	Benign		Border line malignancy		Malignant		
	Count	Row N %	Count	Row N %	Count	Row N %	
BIRADS I	1	100.00	0	0.00	0	0.00	<0.001
BIRADS II	8	100.00	0	0.00	0	0.00	
BIRADS III	8	80.00	0	0.00	2	20.00	
BIRADS IV	1	7.70	2	15.40	10	76.90	
BIRADS V	0	0.00	0	0.00	16	100.00	
BIRADS VI	0	0.00	0	0.00	0	0.00	

Table (5): Relation between BIRADS given by automated and pathology results.

	Final diagnosis						p-value
	Benign		Border line malignancy		Malignant		
	Count	Row N %	Count	Row N %	Count	Row N %	
ABUS BIRADS:							
BIRADS I	0	0.00	0	0.00	0	0.00	<0.001
BIRADS II	7	100.00	0	0.00	0	0.00	
BIRADS III	9	90.00	0	0.00	1	10.00	
BIRADS IV	2	14.30	2	14.30	10	71.40	
BIRADS V	0	0.00	0	0.00	17	100.00	
BIRADS VI	0	0.00	0	0.00	0	0.00	

Table (6): Relation between automated versus mammography modalities regarding BIRADS.

ABUS	MAMMO										p-value
	BIRADS 1		BIRADS 2		BIRADS 3		BIRADS 4		BIRADS 5		
	Count	%	Count	%	Count	%	Count	%	Count	%	
BIRADS 1	0	0	0	0	0	0	0	0	0	0	<0.001
BIRADS 2	1	50	6	66.66	0	0	0	0	0	0	
BIRADS 3	0	0	2	22	5	55.55	3	16	0	0	
BIRADS 4	1	50	1	11.11	4	44.44	7	37	1	11.11	
BIRADS 5	0	0	0	0	0	0	9	47	8	89	

Table (7): Relation between automated versus HHUS modalities regarding BIRADS.

ABUS	HHUS										p-value
	BIRADS 1		BIRADS 2		BIRADS 3		BIRADS 4		BIRADS 5		
	Count	%	Count	%	Count	%	Count	%	Count	%	
BIRADS 1	0	0	0	0	0	0	0	0	0	0	<0.001
BIRADS 2	1	100	6	75.00	0	0	0	0	0	0	
BIRADS 3	0	0	2	25	7	70.00	1	8	0	0	
BIRADS 4	0	0	0	0.00	3	30.00	9	69	2	12.50	
BIRADS 5	0	0	0	0	0	0	3	23	14	87.5	

Table (8): Mammography Sensitivity and specificity.

Mammography	Pathology				*p*-value
	Malignant		Benign		
	Count	%	Count	%	
Possible diagnosis:					
Malignant	26	86.7	2	11.1	<0.001
Benign	4	13.3	16	88.9	

Table (9): Sensitivity and specificity of ultrasound.

	Pathology				*p*-value
	Malignant		Benign		
	Count	%	Count	%	
2D u/s possible diagnosis:					
Malignant	28	93.3	1	5.5	<0.001
Benign	2	6.6	17	94.4	

Table (10): ABUS sensitivity and specificity.

	Pathology				*p*-value
	Malignant		Benign		
	Count	%	Count	%	
Automated possible diagnosis:					
Malignant	29	96.7	2	11.1	<0.001
Benign	1	3.3	16	88.9	

Table (11): Comparison between accuracy measures of 3 modalities.

	Mammography	U/S	ABUS
Sensitivity	86.70%	93.30%	96.70%
Specificity	88.90%	94.40%	88.90%
PPV	92.90%	96.60%	93.50%
NPV	80%	89.50%	94.10%
Accuracy	87.50%	93.70%	93.70%

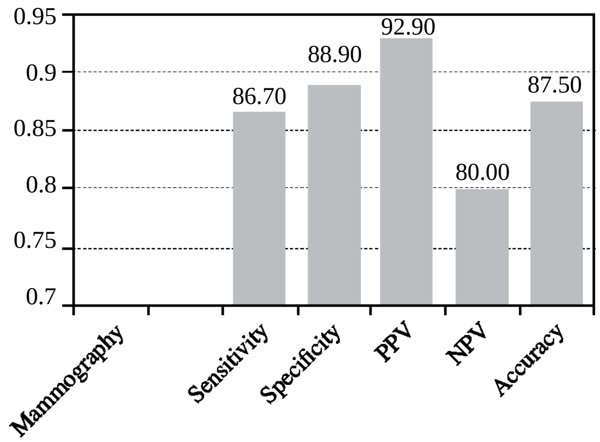

Fig. (1): Mammography images of accuracy measures.

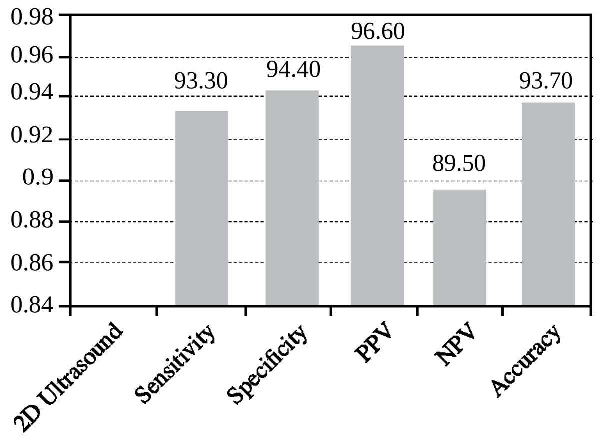

Fig. (2): HHUS images about the accuracy measures.

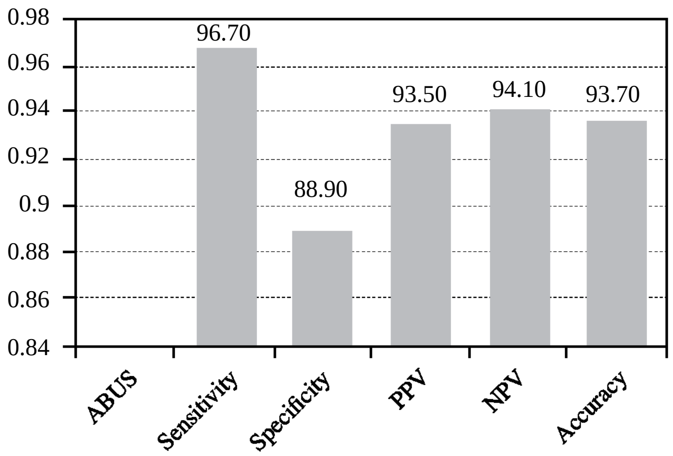

Fig. (3): Automated ultrasound images sensitivity, specificity, PPV, NPV.

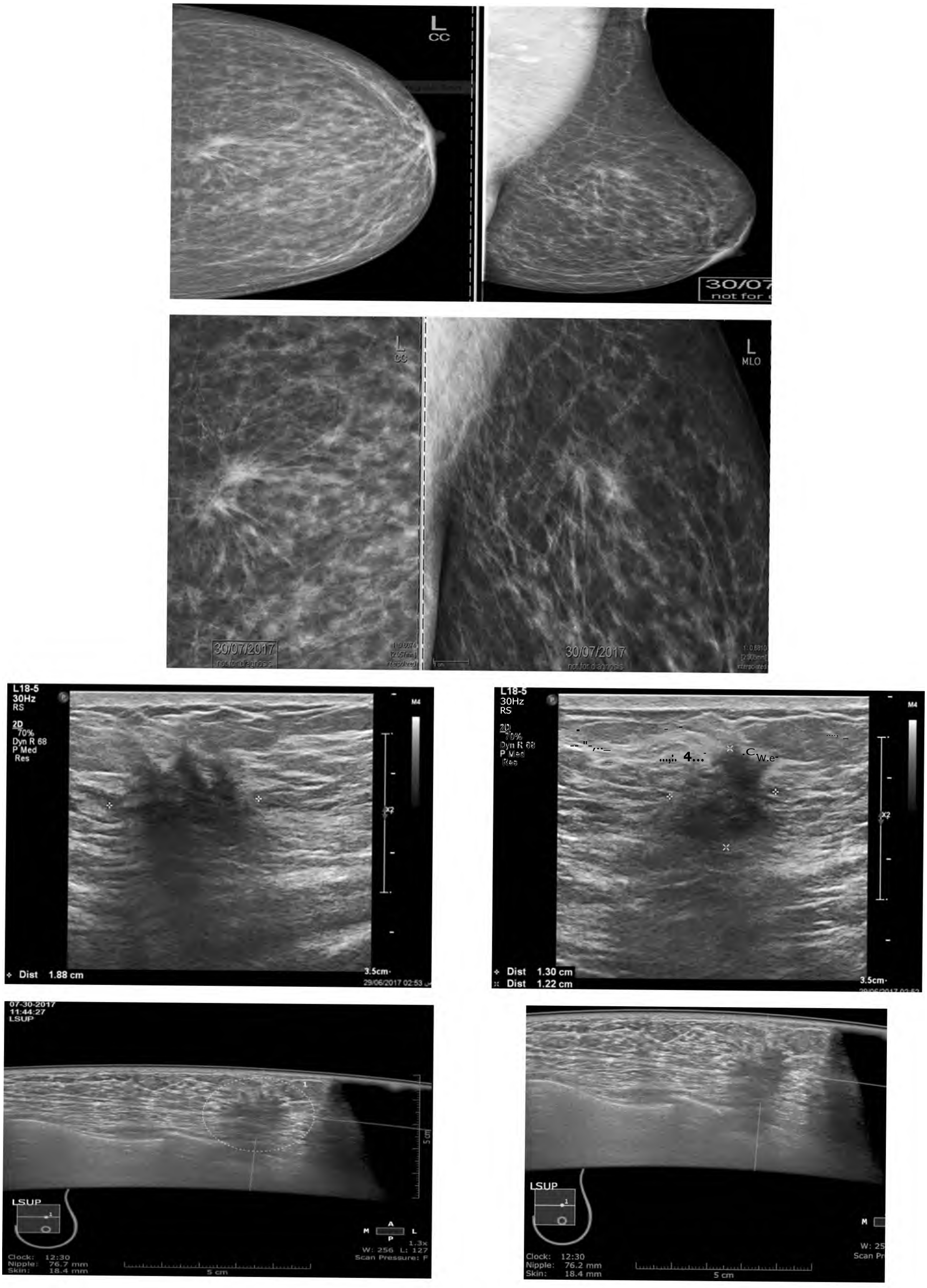
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Fig. (4)

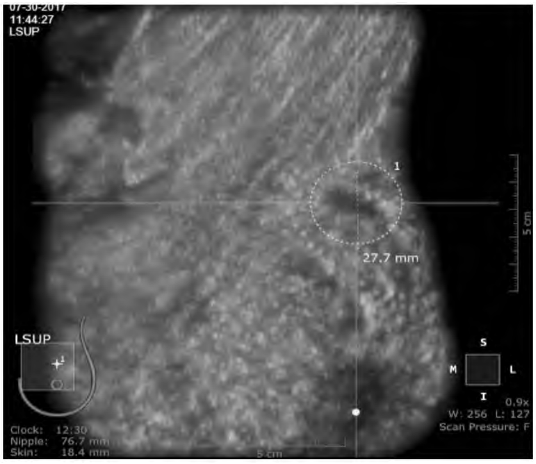


Fig. (4): Mammographic CC & MLO views of the left breast show: Left upper central two adjacent illdefined speculated dense lesions. BIRADS 5. HHUS: Two adjacent ill defend irregular shaped hypo echoic lesions with posterior acoustic shadowing. BIRADS 5 ABUS with left coronal image showed two irregular shaped spiculated hypoechoiclesionsshowed retraction phenomena. (BIRADS V). Core biopsy showed invasive lobular carcinoma.

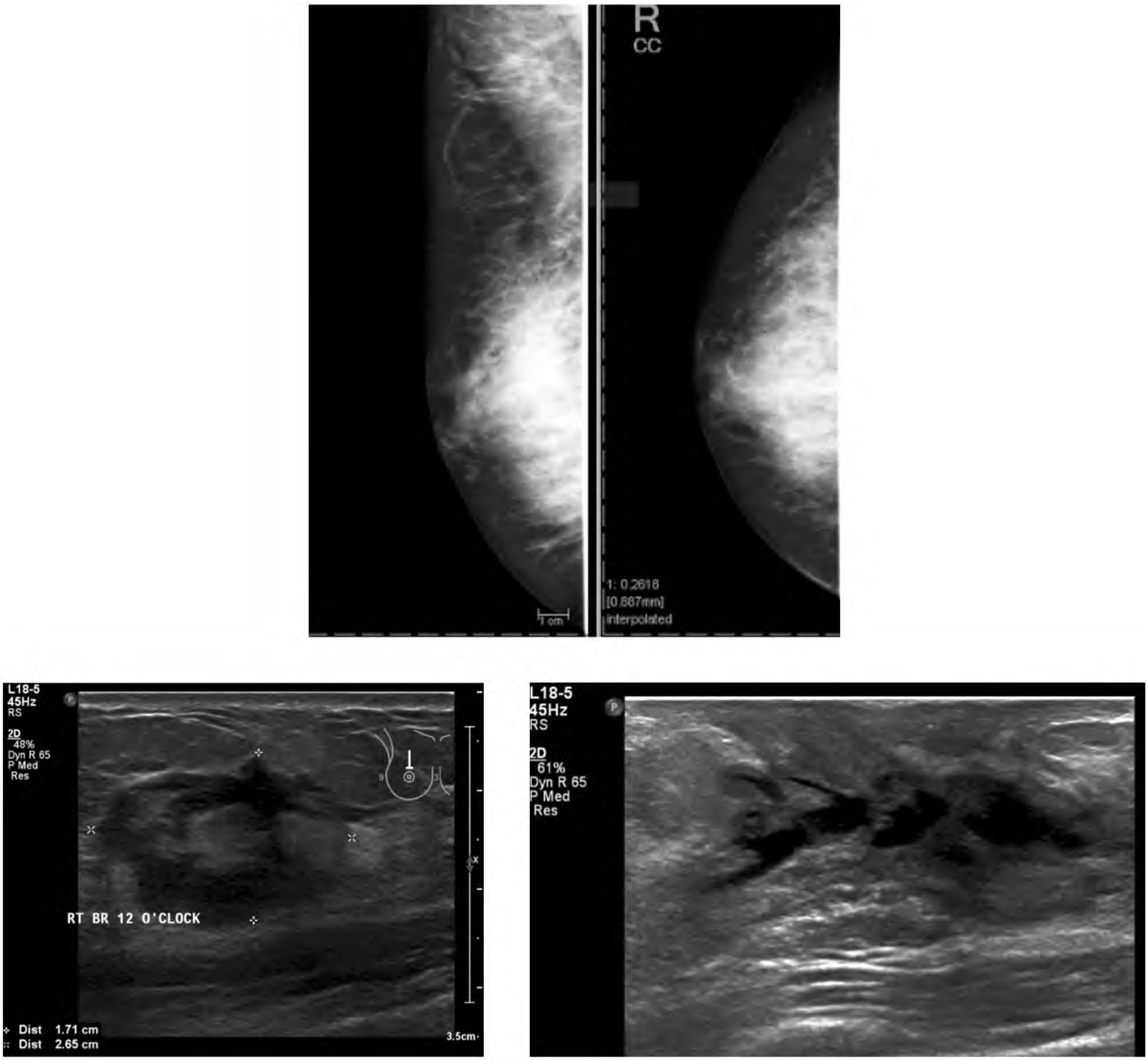


Fig. (5)

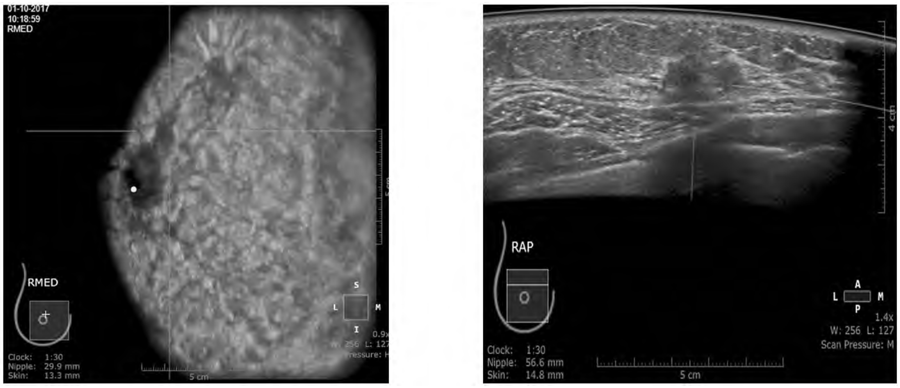
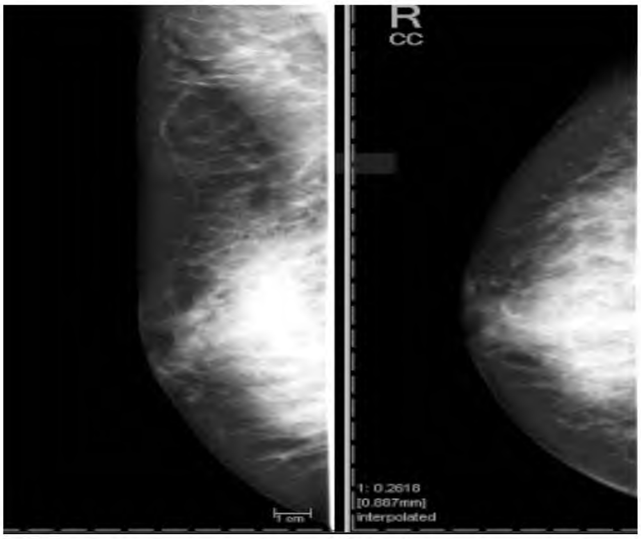
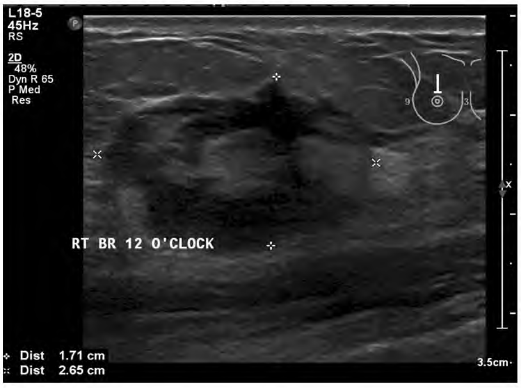
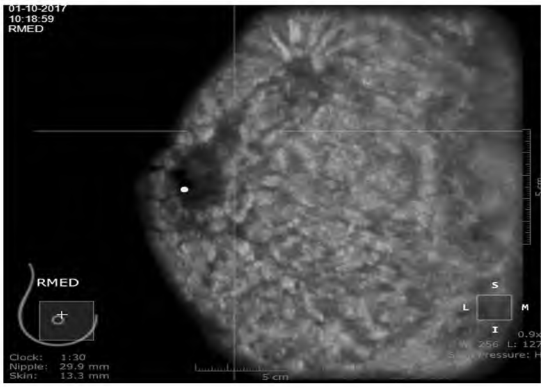


Fig. (5): Digital CC & MLO views showed left dense breast with no underlying lesions could be detected. HHUS: Irregular shaped spiculated hypoehoic lesion with posterior acoustic shadowing, BIRADS 4. ABUS: Left AP coronal image showed irregular shaped illdefined spiculated hypoechoic defect with retraction phenomena and ductal extension. BIRADS 5. Core biopsy detected Invasive duct carcinoma.







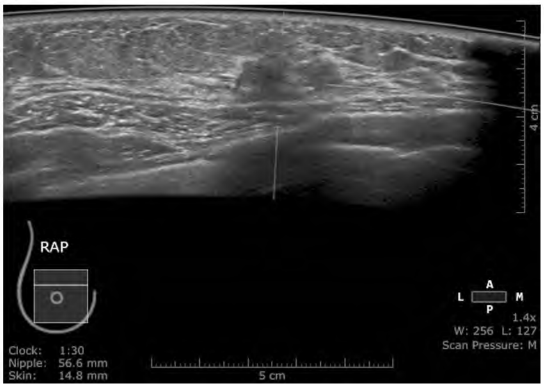


Fig. (6): Digital CC & MLO views of the left breast show Very dense breast with no definitive mass lesion could be seen. By conventional ultrasound, Ill-defined irregular hypo-ehoic mass lesion with posterior shadowing and non parallel orientation. It show multiple speculations with ductal extension. BIRADS V.Automated ultrasound left AP coronal image show irregular focal defect with retraction phenomena. Automated ultrasound image shows ill defined speculated hypo echoic mass lesion with several ductal extension. BIRADS V. Core biopsy proved Invasive duct carcinoma. ABUS and HHUS are superior on mammography in detection and characterization of breast masses.

Discussion

Breast cancer is the most well known female neoplasm in both developing and developed countries [4]. Detection of the breast cancer and its early treatment of cancer breast are our essential aim. X-ray digital mammography is the “gold standard” in both screening as well as detection of breast lesions, however dense breast is a great obstacle about detection and characterization of the lesions in mammography [5].

Moreover, some breast cancers are usually associated with false negative mammogram results including both non calcified duct carcinoma insitu and lobular carcinoma that grows in a linear pattern, therefore, may not form a discrete mass. Sometimes, tiny non speculated lesions are sometimes common mammographic false-negative results and also the oval shaped circumscribed masses may be misdiagnosed as benign [6].

Despite that, mammogram is widely available and inexpensive, its sensitivity is about 70% to 85% and dropped to 30% to 50% in high-risk women with dense parenchyma [6].

Many researches studied the ability of both ABUS in addition to mammography in breast cancer detection and proved that it was of clinical value as the automated process for ABUS showed greater consistency, reproducibility of quality images as well as eliminated operator variability [3].

On the other hand; Chou et al. [7] reported in his study review about ABUS in the past and presented that ABUS may be used as an adjunct to MG or as base line US examination of the breast, however ABUS couldnot replace mammogram as the small ductal calcified lesions or DCIS less than 1cm with no invasive component arenot shown in ABUS, as well as microcalcifications cannot be detected in ABUS.

HHUS is a complementary technique to mammography, mostly for breasts with dense parenchyma, however HHUS examinations are operator depended and time- consuming [8].

This research was a prospective researchwas done at radio-diagnosis department on 42 patients presenting with breast symptoms. They were evaluated by digital mammography; HHUS and ABUS.

Image data from conventional u/s; ABUS and mammography was evaluated by two consultantsevery one on his own and the findings were written according to the BIRADS Lexicon. The data were reported including the margin, shape, mass number, skin thickening and retraction, extension of the lesion, skin thickening and retraction, and then the final score was reported depending upon the BIRADS lexicon. Also, Then the sensitivity and specificity of every modality in the assessment of breast masslesions were calculated.

A study retrospectively evaluated the performance of ABUS in detection of both benign and malignant breast lesions resulting in high performance in the diagnosis of irregular shaped malignant lesions as well as s the benign, small, or round/oval masses [9].

Giger et al., also in 2016 compared the performance of the radiologists in detecting breast cancer using both FFDM with ABUS FFDM alone, so when comparing with mammography alone, ABUS resulted in improved readers’ detection of malignant lesions in cases with dense breast without affecting specificity [10].

Another study reported the differences between ABUS and HHUS, proved that ABUS showed superior diagnostic accuracy over HHUS [11]. Wang et al., reported that ABUS had superior sensitivity to HHUS in detecting masses less than 1cm [12].

Also, Lin et al., [13] studied the difference between ABUS and HHUS in diagnosing and detecting breast mass lesions, both showed 100% sensitivity and a high specificity (HHUS 85% and ABUS 95.0%). ABUS had a higher diagnostic accuracy (97.1%) than HHUS (91.4%) for breast lesions.

In this study; Mammography showed diagnostic accuracy 87.5% with sensitivity of 86.7% in detection and characterization of malignant masses and specificity of 88.9% in benign masses. Mammography was underestimated in 13.3% of breast masses and overestimated in 11.1% of breast lesions with NPV of 80% and positive predictive value 92.9%.

HHUS showed diagnostic accuracy 93.7% with sensitivity 93.3% in detection and characterization of malignant masses and 94.4% specificity in benign masses. It was underestimated in 6.6% of the lesions and overestimated in about 5.5% of lesions with PPV 96.6% and NPV 89.5%.

ABUS showed sensitivity 96.7% in characterization of malignant masses and specificity 88.9% in benign masses with diagnostic accuracy 93.7%. PPV of ABUS is 93.50% as well as the NPV is 94.10%. ABUS was over estimated in 11.1% of cases and under estimated in 1.1% of Cases and this is similar to Meng et al., study that showed that ABUS had high diagnostic accuracy in differentiating between benign and malignant lesions, with the sensitivity 92% and specificity 84.9% [14].

On the other hand; Wojcinski et al., [15] study reported that ABUS had a diagnostic accuracy of 66.0% with 100% sensitivity. And as second look ultrasound was highly requested, specificity was 52.8%.

Also the analysis of 107 breast mass lesions with ABUS and its comparison with manual ultrasound and mammography by Kotsianos-Hermle **[16]** concluded that the axial whole breast image plane by ABUS corresponds to CC mammogram, might give more information about the lesion differential diagnosis. Despite that the image quality was sufficient, ABUS was not good enough in replacing HHUS at this time.

Both ABUS and HHUS had the same diagnostic accuracy 93.7% and this result is similar to a study done by Chen et al., **[17]** that was performed on 175 cases and it evaluated the differences between the HHUS and ABUS diagnostic values for benign and malignant lesions with comparison to the final pathologic results. It resulted in that both HHUS and ABUS do not differ in their diagnostic accuracy measures for differentiation between malignant and benign lesions.

Conclusion:

Automated breast ultrasound can be used in addition to full field digital mammography as well as instead of hand held ultrasound in detecting and characterizations of different breast masses as its sensitivity, specificity, NPV and PPV were very close to HHUS with saving time for scan, eliminating human factor, proving 3D images and reducing the patient's exposure to radiation.

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مقاييس الدقة لتقنية التصوير بالموجات فوق الصوتية ثلاثية الأبعاد التلقائية فى الكشف عن آفات الثدى مقارنة بالموجات فوق الصوتية ثنائية الأبعاد والتصوير الشعاعى الرقمى للثدى (الماموغرافى)

الخلفيـة: يُعتبر سرطان الثدى أكثر أنواع الأورام الخبيثة شيوعًا لدى النساء عالميًا، ويأتى فى المرتبة الثانية بعد سرطان الرئة من حيث معدل الانتشار. لا يزال التصوير الشعاعى للثدى (الماموغرافى) هو الفحص الوحيد المثبت فعاليته فى الكشف المبكر عن سرطان الثدى. ومع ذلك، هناك تزايد مستمر فى التجارب والأبحاث لمعرفة الأسباب وراء المطالبة بالحلول الأفضل خصوصًا لدى النساء ذوات الأنسجة الكثيفة، نظرًا لانخفاض دقة التصوير الإشعاعى لدى هذه الفئة، مما يؤدى إلى طلبات متكررة وفحوصات غير ضرورية وزيادة فى التكلفة والتعرض للأشعة.

تهدف التكنولوجيا الحديثة إلى تحسين أدوات الكشف المبكر عن أورام الثدى. من بين هذه التقنيات جهاز التصوير بالموجات فوق الصوتية ثلاثى الأبعاد التلقائى (ABUS) والذي يتميز بدقة أكبر فى توصيف الأورام وفحص الثدى بزمن أقل دون الاعتماد على خبرة المشغل البشرى. تم فى هذه الدراسة فحص ٤٢ مريضة يعانين من أورام بالثدى، حيث تم إجراء فحوصات ماموغرافى، وموجات فوق صوتية ثنائية الأبعاد، بالإضافة إلى الفحص بجهاز ABUS.

النتائـج: أظهرت النتائج أن جهازى الموجات فوق الصوتية الثنائية والثلاثية الأبعاد متقاربان فى القدرة التشخيصية للكشف عن الأورام الخبيثة والحميدة. ومع ذلك، أوضحت الدراسة أن الاعتماد على جهاز ABUS يوفر الوقت ويقلل من الاعتماد على خبرة الفاحص، ويُعد أداة دقيقة ومبكرة لتشخيص أورام الثدى المختلفة.

الاستنتاج: نقترح فى هذه الدراسة إمكانية الاعتماد على جهاز التصوير بالموجات فوق الصوتية ثلاثى الأبعاد التلقائى كأداة تشخيصية فعالة ودقيقة فى تمييز الأورام، مما يسهم فى تحسين نتائج الكشف المبكر ويقلل من التكاليف والتعرض غير الضرورى للأشعة.