

Predictive value of ultrasound imaging in differentiating benign from malignant breast lesions taking biopsy results as the standard

Abdulkhaleq A. Binnuhaid¹, Sultan Abdulwadoud Alshoabi², Fahad H. Alhazmi², Tareef S. Daqqaq³, Suliman G. Salih², Sami A. Al-Dubai⁴

¹Department of Specialized Surgery, Radiology Section, Faculty of Medicine, Hadhramout University, Hadhramout, Republic of Yemen, ²Department of Diagnosis Radiology Technology, College of Applied Medical Sciences, Taibah University Almadinah Almunawwarah, Kingdom of Saudi Arabia, ³Department of Radiology, Faculty of Medicine, Taibah University, Almadinah Almunawwarah, Kingdom of Saudi Arabia, ⁴Joint Program of Family Medicine Postgraduate Studies, Joint Program of Preventive Medicine Postgraduate Studies, Almadinah 41311, Kingdom of Saudi Arabia

ABSTRACT

Background: Breast lesions (BLs) are abnormal swellings within the breast. The importance lies in need to exclude breast cancer. **Objective:** Due to the role of ultrasound (US) imaging in evaluating of BLs, this study was conducted to evaluate the predictive value of US imaging for differentiating benign from malignant BLs and to assess the need of biopsy in BLs. **Method:** A retrospective review of diagnostic results of 134 patients with BLs. All patients underwent breast US imaging and US-guided biopsy for cytology or histopathology. The results of both were compared. **Results:** Out of 134 patients were included in this study, the mean age was 38.45 ± 15.82 years (range, 18–90 years), and all patients were female. BLs were benign in 99 cases (73.9%) and malignant in 35 cases (26.1%). Among 98 patients with BLs diagnosed benign with US, 96.9% were confirmed benign with biopsy results and only 3.1% were malignant. The overall sensitivity of US imaging for discriminating of benign BLs was 95.95%, with a specificity of 91.42%, and positive predictive value of 96.94%. The results revealed strong compatibility between diagnoses by US imaging and biopsy results ($P < 0.001$), the measure of agreement kappa = 0.866, and the Spearman's correlation coefficient = 0.866. **Conclusion:** US imaging is a highly valuable imaging method in differentiating benign from malignant BLs. It usually predicts the benign nature of BLs with excellent diagnostic accuracy. US-guided fine-needle aspiration and core-needle biopsies are not necessary in most cases of BLs.

Keywords: Breast lesions, core-needle biopsy, fine-needle-aspiration, predictive value, ultrasound imaging

Introduction

The breast is a common site for pathologies that commonly present as masses and most of which are benign lesions (BLs).^[1] Breast cancer is the most common form of cancer among

women worldwide.^[1–4] It accounts for 25% of all cancers and a significant cause of death among women. The incidence rates vary considerably in the world. The rates of breast cancer are high in Northern America, Australia, and Northern and Western Europe countries, whereas it is lowest in Africa and Asia including Saudi Arabia and Yemen.^[2] Aging, obesity, delayed childbearing, menopause, the blood group “A + ve,” genetic, environmental, and diet factors increase the incidence of breast cancer.^[5,6]

Address for correspondence: Dr. Sultan Abdulwadoud Alshoabi, Department of Diagnosis Radiology Technology, College of Applied Medical Sciences, Taibah University, Almadinah Almunawwarah, Saudi Arabia.
E-mail: alshoabisultan@yahoo.com

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The importance of early diagnosis comes from the wide variations in the treatment of BLs from lumpectomy to mastectomy. Early and accurate diagnosis is extremely important to prevent over- or undertreatment with worse outcomes.^[7]

Detection of BL by ultrasound (US) imaging is still a challenging work in computer-aided diagnosis (CAD) as it has received more attention in medical imaging to detect and classify BLs in the recent years. The process of CAD composed of localization of the region of interest of the lesion then determine if it is benign or not.^[4,8]

Benign breast lesions (BBLs) have characteristic features on US imaging. They revealed round or oval shape, oriented parallel to the skin with well-circumscribed borders or have less than or equal three lobulations, mixed echogenicity with no posterior acoustic shadowing or the presence of posterior acoustic enhancement in some BBLs.^[9] Irregular shape, indistinct or irregular margins, homogenous marked hypoechoenicity, microcalcification, posterior acoustic shadowing, and architectural distortion of the surrounding tissue are signs of breast cancer.^[10] Spiculated margins and irregular shape have a high predictive value for malignancy.^[11]

The Breast Imaging Reporting and Data System (BIRADS) lexicon of the BLs was described by the American College of Radiology (ACR) to ensure accurate diagnosis and follow-up. BIRADS categorize the BLs as the following: BIRADS 0 refers to incomplete evaluation. BIRADS 1 refers to a negative examination, no lesions. BIRADS 2 refers to lesion with benign findings. BIRAD 3 is probably benign and risk of malignancy <2%. BIRADS 4 is a suspicious abnormality and risk of malignancy 2–10% in the subcategory-a, 10–50% in the subcategory-b, and 50–95% in the subcategory-c. BIRADS 5 is highly suspicious of malignancy (>95%). BIRADS 6 is pathology proven malignancy.^[12] BIRADS US score was also defined to use US imaging findings only.^[13]

New US imaging techniques, US-guided biopsy, and a combination of US with other imaging modalities provide effective tools for management of breast.^[10,11,13] Vascularization pattern on color Doppler increases the ability to differentiate benign from malignant BLs.^[14]

US imaging is indicated in palpable breast lump, axillary lymphadenopathy, suspicious lesions at mammography or Magnetic resonance imaging, nipple inversion, or suspicious discharge, skin retraction, breast inflammation, abnormalities of surgical scar, or breast implants. It is the first diagnostic approach for breast abnormalities in pregnant and lactating women and the method of choice before the age of 40 years.^[15]

Fine-needle aspiration (FNA) is a simple, safe, and effective procedure for diagnosis of BLs.^[16] The result of FNA is written with the use of five-stage system as the following: Code 1 = Insufficient material; Code 2 = Benign; Code

3 = Atypical, probably benign; Code 4 = Suspicious, probably *in situ* or invasive; Code 5 = Malignant.^[17] US-guided core-needle biopsy (CNB) evaluation is the standard for diagnosis of breast cancer.^[18] US-guided CNB using 14-gauge needle provided optimal diagnostic information for BLs.^[19] FNA and CNB are highly valuable techniques used in most cases of BLs. Vacuum-assisted breast biopsy is a more recent and reliable technique that could replace surgical biopsies.^[20]

The aim of this study was, first, to calculate the predictive value of US imaging in differentiating benign from malignant BLs based only on the US imaging features. Second, to determine the ability of FNA and CNB to give decision in differentiating of benign from malignant BLs, and tertiary, to evaluate the most common BLs in Hadhramout province in Yemen. The motivation to undertake such this study was the fact that US imaging is the most available imaging modality especially in remote areas in developing countries. As far our knowledge, this is the first study that deals with the efficacy of US imaging in discriminating benign from malignant BLs. Based on the ACR BIRADS lexicon, we calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of US imaging to predict the category-2 of BLs that means it is really BBLs and need no further investigation. Women of BLs often visit their primary care physicians who play an essential role in diagnosing, informing, and comanaging these patients. This study has a highly significant value for ultrasonographers, radiologists, oncologists, primary care and family physicians, and surgeons who depend on US imaging in diagnosing and follow-up of BLs to avoid unnecessary biopsies and investigations to decrease the economic burden on the patient, family, and community.

Patients and Methods

Study design

This is a retrospective study of the electronic records of 134 patients really diagnosed with BLs between Jan 2016 and Dec 2018. The study conducted at Alsafwa Consultative Medical Center (ACMC) in Al Mukalla city, Hadhramout, Republic of Yemen. The study involved the reports of 134 patients who underwent US imaging and US-guided-FNA cytology or/and histopathology of CNB using the international guidelines of the international academy of cytology (IAC).^[17] Based on the IAC standardized reporting of breast fine-needle aspiration biopsy cytology, the study included all the reports of the patients with BLs diagnosed as benign or malignant lesions by US imaging and reported in Code 2 or Code 5 by biopsy results. Exclusion criteria included: (1) patients with no clear diagnosis by US imaging, (2) patients reported in Code 1, Code 3, or Code 4 of biopsy results with no confirmation by other investigation and did not fulfill the required data.

Procedure

All patients underwent breast US imaging by a single board-qualified radiologist with 9 years' postdoctorate experience

in general US imaging. According to the breast size, 7.5 and 10 MHz linear transducer of Mindray DC30 US machine was used to assess the BL in all patients. Both real-time gray-scale US and power-Doppler imaging assessment were used in each case.

After US imaging, either US-guided-FNA or CNB was performed on BLs of 134 patients by the same radiologist. FNA was performed with a 23-gauge needle attached to a 10 ml sterilized disposable plastic syringe with targeting the solid parts of the BLs. Aspirated samples were expelled and smeared on glass slides. For each patient, six to nine slides fixed in 95% ethanol were sent to the cytopathologist. All biopsies were interpreted by a single highly qualified pathologist with 20 years' postdoctorate experience. The pathologist reported the results from Code 1 to Code 5 according to the IAC standardized reporting of breast fine-needle aspiration biopsy cytology.^[17]

CNB was performed with using a tru-cut gun with Medax or BARD disposable 14-gauge needle. Under complete aseptic condition and local anesthesia by 2% lignocaine, and after manual localization and immobilization of the BL, a skin incision was performed. A biopsy specimen was obtained by four successive insertions of the needle into the core of the lesion with different angulations. The specimen was fixed and was sent to the pathologist for interpretation.

Statistical analysis

The statistical analysis was performed using SPSS, IBM, version 23 for windows (Armonk, NY: IBM Corp. 2015). Descriptive statistics were expressed as frequencies and percentages. Sensitivity, specificity, and PPV were calculated for US imaging. A binomial test using the Chi-square test was performed to analyze the distribution of diagnoses of US imaging and biopsy. A cross-tabulation between diagnosis by US imaging and biopsy results was performed and the measure of agreement kappa and the Spearman's correlation coefficient was measured. Chi-square was assumed to be significant when < 0.05.

Results

In total, 134 patients with BLs were included in this study. All patients (100%) were females and their mean age was 38.45 ± 15.82 years (range, 18–90 years). The BLs was peaking in the 4th decade of life [Figure 1].

Figure 2 revealed statistically significant tendency of BLs to affect the left breast (*P* = 0.019).

The most common BBLs was fibroadenoma (28.4%), and the most common malignant lesion was invasive ductal carcinoma (23.9%)- [Table 1].

A cross-tabulation between diagnosis by US imaging and biopsy results was performed [Table 2] which revealed strong compatibility between diagnoses by US imaging and biopsy results (*P* < 0.001) and the measure of agreement kappa = 0.866,

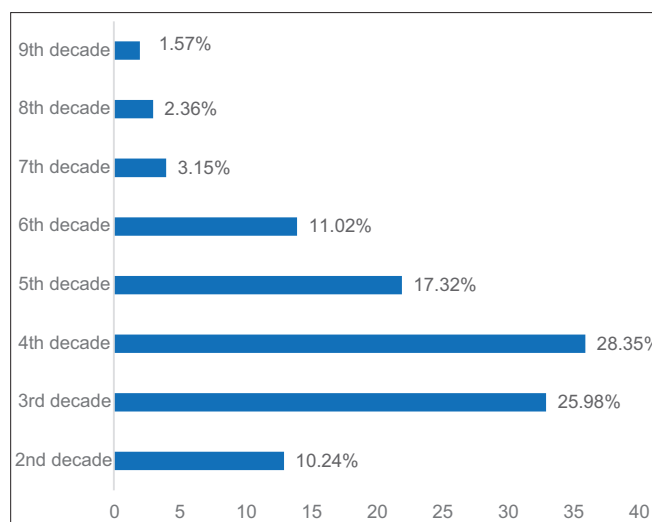


Figure 1: Diagram shows the decades of the affected patients

Table 1: Final diagnosis of BLs by biopsy results

Diagnosis	No.	Percentage
Fibroadenoma	38	28.4
Fibrocystic changes	11	8.2
Galactocele	9	6.7
Cyst	9	6.7
Mastitis	10	7.5
Inflammation	3	2.2
Phylloid tumor	2	1.5
Abscess	6	4.5
Lactating adenoma	4	3.0
Duct ectasia	5	3.7
Edema	2	1.5
Invasive ductal carcinoma (IDC)	32	23.9
Mucinous carcinoma	1	0.7
Invasive papillary carcinoma (IPC)	1	0.7
Non-Hodgkin's lymphoma (NHL)	1	0.7
Total	134	100.0

Table 2: Cross-tabulation between diagnosis by US imaging vs. biopsy results

Ultrasonography diagnosis	Biopsy results		Total no (%)
	Benign no (%)	Malignant no (%)	
Benign	95 (96.9)	3 (3.1)	98 (100)
Malignant	4 (11.1)	32 (88.9)	36 (100)
Total	99 (73.9)	35 (26.1)	134 (100)

Kappa=0.866 and *P*<0.001

and the Spearman's correlation coefficient = 0.866. BLs were benign in 99 cases (73.9%) and malignant in 35 cases (26.1%). Among 98 patients with BLs diagnosed benign with US, 95 (96.9%) were confirmed benign with biopsy results and only three (3.1%) were malignant. Among 36 patients with BLs diagnosed as malignant with US, 32 (88.9%) were confirmed malignant with biopsy results. Ultrasonography correctly predicted BBLs in 96.9% of cases. The overall sensitivity and specificity of US imaging for predict correct diagnosis of BBLs

were 95.95% and 91.42%, respectively, with 96.94% positive predictive value [Figures 3 and 4].

A cross-tabulation between detailed US-diagnosis and detailed final results of biopsy was performed [Table 3] and shows a significant compatibility between suggested diagnoses by US imaging and the results of biopsy ($P < 0.001$). The compatibility was peaking in diagnosis of carcinoma (88.6%) then fibroadenoma (86.7%).

The CNB was able to give final diagnosis in 100% of cases, whereas FNA biopsy was able to give final diagnosis in 98.68% of cases [Table 4].

Discussion

US imaging is a widely used imaging modality in diagnosing and follow-up BLs. The cornerstone in breast imaging is to exclude malignant lesions. In this study, we calculated the predictive value of US imaging for benign BLs to avoid further unnecessary interventional diagnostic work.

In this study, we reported 95.95% sensitivity with 91.42% specificity for US imaging in differentiating benign from malignant BLs. These results are compatible with Klimonda *et al.*, who

reported 93% and 88% sensitivity and specificity for US in classification of the breast changes.^[21] In this study, we reported 96.94% PPV for BBLs. In another study, Hu *et al.*, reported the sensitivity, specificity, PPV and NPV for real-time US imaging to categorize BLs in BIRADS categories as 98.9%, 58.2%, 44.8%, and 99.4%.^[22] The reported sensitivity is consistent with that in our results but the specificity was significantly low in comparison with our results. This is explained by that we calculate only the specificity of real-time US imaging to categorize BBLs (BIRADS 2), whereas Hu *et al.*, measured the specificity of real-time US imaging to classify the BLs in all categories of ACR BIRADS lexicon. Therefore, the sensitivity and PPV were low in his study.^[22]

In this study, the ability of CNB to give decision on the type of BLs was better than that of FNA (100% vs 98.68%). Ohashi *et al.* reported low diagnostic accuracy for FNA in comparison with CNB for some BLs.^[23] Our results are also consistent with Mitra and Dey who reported higher sensitivity, specificity, NPV of CNB than FNA with equivalent PPV. However, FNA is advantage in rapidity, do not require anesthesia, easy and can be done in outpatient clinic either with or without radiology guidance.^[24] CNB is a minioperation under radiology guidance and requires proper anesthesia and needs longer time. CNB have the advantage of giving enough biopsy material with lower inadequate rate. It is also better for diagnosing the gray zone lesions of the breast.

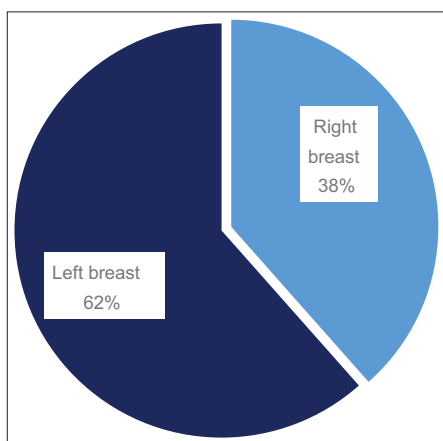


Figure 2: The side of the affected breasts

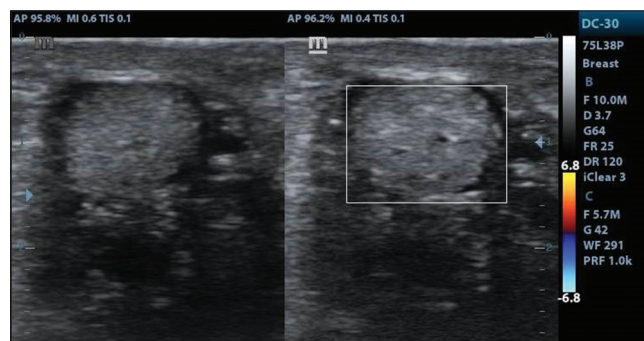


Figure 3: US image shows a well-circumscribed, homogenous, isoechoic, lesion with no blood vessels inside it on Color Doppler, suggestive of benign lesion. CNB revealed benign breast lipoma

Table 3: Cross-tabulation between detailed US-diagnosis (rows) and detailed final results of biopsy (columns)

Ultrasound diagnosis	Final biopsy result								
	Fibro adenoma No (%)	Carcinoma No (%)	Fibrocystic disease No (%)	Cyst No (%)	Galactocele No (%)	Mastitis No (%)	Abscess No (%)	Others No (%)	Total No
Fibroadenoma	39 (86.7)	1 (2.2)	2 (4.4)	0 (0)	0 (0)	0 (0)	1 (2.2)	2 (4.4)	45
Fibrocystic disease	1 (2.0)	0 (0)	3 (60)	1 (20)	0 (0)	0 (0)	0 (0)	0 (0)	5
Malignant	0 (0)	31 (88.6)	0 (0)	0 (0)	0 (0)	1 (2.9)	0 (0)	3 (8.6)	35
Cyst	0 (0)	0 (0)	2 (18.2)	8 (72.7)	0 (0)	0 (0)	1 (9.1)	0 (0)	11
Galactocele	0 (0)	0 (0)	0 (0)	0 (0)	5 (71.4)	0 (0)	0 (0)	2 (28.6)	7
Abscess	0 (0)	0 (0)	0 (0)	0 (0)	3 (37.5)	1 (12.5)	4 (50)	0 (0)	8
Mastitis	0 (0)	0 (0)	1 (16.7)	0 (0)	1 (16.7)	3 (50%)	0 (0)	1 (16.7)	6
Others	0 (0)	2 (11.8)	1 (5.9)	0 (0)	0 (0)	3 (17.6)	0 (0)	11 (64.7)	17
Total	40	34	9	9	9	8	6	19	134 (100)

Table shows significant compatibility between suggested diagnoses by US imaging and the results of biopsy ($P < 0.001$). The compatibility was peaking in diagnosis of fibroadenoma then carcinoma and so on (bold values)

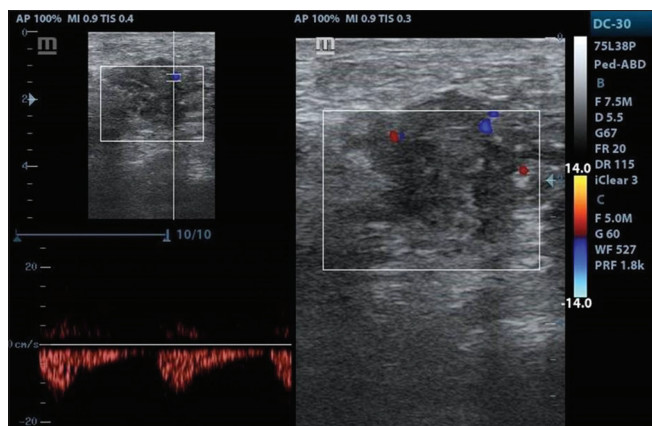


Figure 4: US image shows an ill-defined spiculated margin heterogenous hypoechoic breast lesion. Pulse-wave Doppler shows peripheral blood flow of malignant lesion. CNB revealed breast carcinoma

Table 4: Shows types of biopsy used and % of success to give final results

Type of biopsy	No. (%) of cases	% give final diagnosis
FNA	76 (56.7%)	98.68%
CNB	58 (43.3%)	100%

Our results were not consistent with the results of Al Nemer who reported 86.2% and 79.6% diagnostic accuracy of FNA and CNB, respectively.^[25]

In this study, we reported 100% diagnostic performance for CNB for deciding the nature of BLs. This result is consistent with Yang *et al.*, who reported 99.6% diagnostic accuracy of US-guided CNB for BLs.^[26] He reported that using 14-gauge CNB is a reliable and low invasive procedure for diagnosing BLs in men. In our study, we confirmed that using 14-gauge CNB is accurate, reliable, and very safe for assessing BLs in female. Moon *et al.*, reported that clinically occult benign papillary BLs diagnosed benign at US-guided 14-gauge CNB are not uniformly managed by surgical excision and the short-term follow-up is unnecessary.^[27,28] Our results also consistent with the results of Rikabi and Husaain who reported 98.2% diagnostic accuracy for tru-cut biopsy (CNB) but he reported the use of 18-gauge needle.^[29]

In this study, invasive ductal carcinoma (IDC) was the most common malignant lesion of the breast. This result is consistent with Qadri *et al.*, Özel *et al.*, and Hu *et al.*^[1,13,22] Fibroadenoma was the commonest BBL. This result is consistent with Qadi *et al.*, Özel *et al.*, Hu *et al.*, and Albasri *et al.*^[1,13,22,30]

Limitations of this study

This study is performed in a single center study and it's retrospectively nature with no available further diagnostic reference to compare the diagnostic accuracy of FNA and CNB.

Conclusion

US imaging is a highly valuable imaging method in differentiating benign from malignant BLs. It almost always predicts the benign nature of BLs with excellent diagnostic accuracy. US-guided FNA and CNB are not necessary in most cases of BLs. CNB using 14-gauge needle is almost always enough to decide the nature of BLs and to decrease the inadequate biopsies.

Significance of this study

This study recommends to conserve the principles of US diagnosis and to reduce the overuse of biopsies in masses diagnosed in category-2 of ACR BIRADS, which will be decreasing unnecessary procedures and also decrease healthcare costs. The study also recommends to use 14-gauge needle for breast CNB that giving enough biopsy material with lower inadequate results.

Ethical approval

The Institutional Ethics Committee approved this study under the protocol no. 28-7-100/2. Each patient really provided informed consent before doing biopsy. Confidentiality of the patient's information was assured during data collection and all steps of this study.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Author contributions

AAB: working ultrasound imaging reports, biopsies and collected data. SAA: Conceived and designed the study; organised and analysed data; and wrote the initial and final drafts of the manuscript. FHA: writing-review and editing. TSD: provided logistic support. SHS: review the final manuscript. SAA: review data analysis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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