

# VALIDITY OF ULTRASONOGRAPHIC FINDINGS BASED ON ACR-BIRADS SCORES TO DIAGNOSIS BREAST DISEASES IN SULAIMANI BREAST DISEASE TREATMENT CENTER



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Submitted: 14/5/2019; Accepted: 10/9/2019; Published: 21/12/2019

## ABSTRACT

### *Background*

Breast diseases are common in females all over the world. Breast cancer is the second common causes of concept mortality; early detection of breast cancer promotes outcomes.

### *Objectives*

To evaluate the validity of ultrasonographic findings based on American College of Radiology Breast-Imaging Reporting and Data System (ACR-BIRADS) in diagnosis of breast diseases, and determine sensitivity and specificity of ultrasonographic finding in breast and axillary lesions in Sulaimani breast disease treatment centre.

### *Materials and Methods*

This retrospective descriptive study was performed on 427 patients with different breast and axillary lesions at Sulaimani breast disease treatment center, from January 2014 till December of 2018. Ethical consideration by the regulatory bodies was followed. Information was recorded according to inclusion criteria by using a questionnaire paper. Finding of ultrasonography by using ACR-BIRADS system was compared with histopathology reports, The Chi-square test was used and the obtained results were judged statistically significant at  $P \leq 0.05$ ,  $P$ -value  $< 0.001$  is regarded as highly significant. statistical analysis was performed using statistical package for social science SPSS (version 21).

### *Results*

Age range was 22-84 years old, average age of participants with the standard deviation was  $45.32(\pm 11.763)$ . 128 (30.0%) and 125 (29.3%) of all breast lesions were in the range of BIRADS 5 and 3 respectively. Among 427 cases, most of the breast lesions 222 (52.2%) were malignant on histopathology, while 205 (47.8%) were benign on histopathology. Sensitivity; Specificity of ultrasound for breast was 87.38%, 85.85%, respectively. Also Sensitivity, Specificity of ultrasound for axilla was 78.16%, 10%, respectively. In finding correlation between ACR-BIRADS system and histopathology results using chi square  $P$ -value was  $< 0.001$  which is highly significant for both breast and axilla.

### *Conclusions*

Sensitivity and specificity of using ultrasound based on ACR-BIRADS scores in diagnosis of breast pathology were high; it makes a good way for diagnosis of breast diseases. But using BIRADS ultrasound system as sole investigation in diagnosis of breast pathology is the matter of debate. Using ultrasound based on Sensitivity and specificity for axilla didn't make it an ideal way for diagnosis of pathological lymph nodes.

**Keywords:** *Breast diseases, Ultrasound, ACR-BIRADS scores, Comparison, Histopathology .*

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## INTRODUCTION

Breast diseases are increasingly common, comprising about 30% of general surgical concomitant among women <sup>(1)</sup>. Breast cancer is the most commonly diagnosed malignancy in females and is the second common cause of cancer mortality in females. Early detection of breast cancer promotes outcomes. Screening strategies by triple assessment for detecting early staged breast cancer are now stratified <sup>(2)</sup>. Whereas breast cancer in males consider just 0.7% of all breast cancers <sup>(3)</sup>. Ultrasound has an important role in diagnostic breast imaging, it is crucial to assess the correlation of ultrasound findings to be compatible with a histopathological outcome <sup>(4)</sup>. The first breast ultrasound was conducted in 1953 by Wild and Reid, who command to see a 7 mm breast cancer by using a home-made 15-MHz transducer <sup>(5)</sup>.

Nowadays ultrasound most widely used as an accessory test in identifying lesions perceived by other imaging manner or by clinical examination. Also is the best method in the assessment of women who are younger than 30 years old mostly they had dense breast, pregnant, or lactating. Both mammography and ultrasound might have a good performance in screening high-risk populations, separations of cysts and solid tumors. Guidance of interventional procedures, consist of fine needle aspiration, core biopsy, diagnostic and therapeutic vacuum biopsy, preoperative tumor localization and axillary lymph node biopsy. Preoperative follow up describe lesion size and location for planning breast conservative surgery, mastectomy, follow-up under neoadjuvant chemotherapy. While reservation of breast ultrasound were micocalcification can be missed, fat and air can ambiguous the lesion, relatively well defined malignant masses can be labelled as benign isoechoic and multicentric lesions can be strayed <sup>(3, 6-8)</sup>.

Breast Imaging Reporting and Data System (BI-RADS) was concentrated in 1993 and announced by the American College of Radiology (ACR) to normalize reporting mammographic finding and since 2003, is the fourth edition of the system expanded to ultrasound and magnetic resonance imaging. To obtain scheme reproval consistency to get perspicuous, comprehensive and excellence language, not only between radiologists but also the physicians and surgeons. BI-RADS had 0-6 estimation classification:

BIRADS 0: Need an additional imaging analysis. BIRADS1: Normal, BIRADS 2: Benign findings, also BIRADS 3: Most likely benign finding; need

short-interval follow-up, the possibility of malignancy in category 3 is less than 2%. BIRADS 4: Indecent abnormality; biopsy should be applied. In the last BIRADS edition separated into subcategories (4a, 4b and 4c) on the ground of the likelihood of malignancy, 2-10% for category 4a, 11-50% for category 4b and 51-95% for category 4c, BIRADS 5: Extremely suggestive of malignancy (more than 95%); proper work should be taken and BIRADS 6: Known biopsy-established malignancy, BIRADS 4 and 5 lesions needs biopsy, also BIRADS 3 lesions rarely require biopsy especially, on clinical requirements <sup>(9-11)</sup>.

### Criteria for benign breast lesions on ultrasound

Creaseless and well circumscribed, hyper echoic, isoechoic or mildly hypoechoic, fine echogenic capsule, ellipsoid shape, with the supreme diameter being in the crosswise plane and three or fewer lobulations <sup>(12)</sup>.

### Criteria for suspicious breast lesions on ultrasound:

**Minor criteria:** Round form, Microlobulated, indistinct, or angular margin not parallel orientation, duct extension, complex echogenicity, and posterior shadowing.

**Major Criteria:** Irregular shape, speculated margin, punctate Microcalcifications <sup>(13)</sup>.

Triple assessments of breast lesions remain the keystone of their diagnosis. Fine Needle Aspiration Cytology (FNAC) and core needle biopsy (CNB) have been used to acquire a pathological diagnosis in part as of triple appraisal. While FNAC was the favourite style in the past with the advantage of being less painful and brilliant to bear a quick diagnosis, CNB has been steadily more used since 1980s. Core needle biopsy was used when FNAC was indecisive or if there were conflict between clinical, radiological and cytological results. It was also superior in patients planned for neoadjuvant chemotherapy for getting information on pathological subtype, grade, and receptor status before establishing the chemotherapy <sup>(14)</sup>. Nipple discharge cytology samples were collected either as air-dried or alcohol-fixed <sup>(15)</sup>.

On ultrasound normal or benign-appearing axillary lymph nodes may have an elliptical or lobulated form, gentle and unequivocal edge. The cortex should be faintly hypoechoic and consistently delicate, scaling 3 mm or less <sup>(16)</sup>. Cortical thickening and hilum were vacancy as criteria for clarification of the hazard for metastasis <sup>(17)</sup>.

The aim of this study to assess the validity of ultrasonographic finding based on ACR-BIRADS in diagnoses of benign and malignant breast diseases, Determine sensitivity and specificity of ultrasonographic finding in breast and axillary lesions.

## **MATERIALS AND METHODS**

This retrospective descriptive study was carried out in the Sulaimani breast disease treatment center. It was included 427 patients who visited Sulaimani breast disease treatment center. Who were retrieved from saved data from January 2014 till December 2018, Ethical consideration by the regulatory bodies was followed files of patients were stored, consent was taken from the patients by phone call. After acceptance was obtained from the Ethics Committee of Sulaimani medical school for this study. 420 cases were females, while only 7 cases were males. Patients demographic features like age, sex, residency, occupations were taken, also chief complain. Physical examination with breast and axilla examination were taken. Sampling technique of this study was convenient sampling.

Inclusion criteria of this study were patients either male or female who came for breast disease treatment center, regarding any complain underwent ultrasound focused on ACR-BIRADS scores and histopathological exams.

Exclusion criteria: patients who underwent fine needle aspiration cytology (FNAC) or cytology of nipple discharge but incompatible with histopathology results. Patients who took ultrasound report outside Sulaimani breast disease treatment center, and post-operative breast cancer surgery, also those who were received chemotherapy and radiotherapy, or received neoadjuvant chemotherapy.

Ultrasound examination and intervention of the breast and axilla were done by two expert sonographer in the department of radio diagnosis, using a liner transducer with a 50-mm width and a frequency of 7.5 MHz using Philips models. In current study, we considered ultrasound BIRADS categories (1, 2 and 3) to be benign, while BIRADS categories (4, 5 and 6) to be malignant, regarding all BIRADS scores 6 were BIRADS score 5 before histopathology report.

Regarding axillary ultrasound all of the lymph nodes were normal or reactionary on ultrasound considered to be benign, while those lymph nodes were suspicious on ultrasound considered to be pathological. For those patients who underwent, core needle biopsy,

(FNAC), and cytology of nipple discharge, after that results proved either by modified radical mastectomy (MMR), breast conserving surgery (BCS) with or without axillary clearance or wide local excision. Results of histopathology were verified with the help of experienced pathologists in Shorsh, and Sulaimani teaching hospitals.

Then sensitivity, specificity, positive predictive value, negative predictive value, P value of ultrasound BIRADS score was assessed against the result of histopathology. Sensitivity and specificity of ultrasound was calculated by constructing a 2 x 2 table taking histopathology as gold standard. Data have been tabulated and analysed by using statistical packages for social science (SPSS version 21). Categorical data were presented as number and percentages, whereas quantitative data were expressed as mean and standard deviation (SD). The Chi-square test, the obtained results were judged statistically significant at  $P \leq 0.05$ , P-value < 0.001 is regarded as highly significant.

## **RESULTS**

From a total of four hundred twenty seven cases were selected according to inclusion criteria, in which 420 (98.4%) cases were female and only 7(1.6%) cases were male. Average age of participants with the standard deviation was (45.32 years old $\pm$ 11.763). Age range was (22-84) years old, most of the patients 275 (64.4%) cases fall in the range age (30-49) years old. On examination large number of patients had breast lumps 400 (93.7%), as shown in (Table 1).

According to ACR-BIRADS, 128 cases (30.0%) was considered in the ACR-BIRADS category 5 the next common category comprising 125 cases (29.3%) was ACR-BIRADS category 3, most of the breast lesions 222 (52.2%) were malignant on histopathology while 205 (47.8%) were benign on histopathology as shown in (Table 2).

Among the axillary lesions only 107 (25%) were suspicious on ultrasound, in which just 87 (20.5%) were positive for malignancy on histopathology as shown in (Table 3).

Among the non-malignant lesions on histopathology accounted as 205 (47.8%) cases finding arranged as granulomatous mastitis 51 (25%), then followed by fibroadenoma 46 (22.5%) fibrocystic changes 38 (18.4%), duct ectasia 18 (8.7%), abscesses 14 (6.8%),

cysts 12 (5.8%), and others 26 (12.8%) as shown in (Table 4).

Malignant lesions on histopathology 222 (52.2%) cases in which the majority was invasive ductal carcinoma 187(84.2%) then invasive lobular carcinoma 14 (6.3%), ductal carcinoma in situ (DCIS), 9 (4.25%) and other types 12 (5.25%) as shown in (Table 5).

The sensitivity, specificity, Positive Predictive Value and Negative Predictive Value of ultrasound for breast

were 87.38%, 85.85%, 86.99% and 86.27% respectively, sensitivity, specificity, Positive Predictive Value and Negative Predictive Value of ultrasound for axilla were 78.16%, 10%, 79.06% and 9.52% respectively. Relation of the use of ultrasound and histopathological finding for breast and axillary lesions by using chi square test P-value was < 0.001 which is highly significant, as shown in (Table 6).

**Table 1. Physical examination of the breast.**

Physical examination of breast	No. (%)	
<b>Breast Lump</b>	Right breast	179 (41.9)
	Left breast	218 (51.1)
	Both breast	3 (0.7)
<b>Skin Changes</b>	Redness	6 (1.4)
	Ulceration	1 (0.3)
	Dimpling	2 (0.4)
<b>Nipple discharge</b>	Yellow	6 (1.4)
	Green	2 (0.5)
	Serous	1 (0.2)
	Blood	9 (2.1)
<b>Total</b>	427 (100)	

**Table 2. Comparison between each category of ACR-BIRADS scores of ultrasound with histopathology results.**

Ultrasound BIRADS categories	Histopathology results		Total (%)
	Benign lesions No. (%)	Malignant lesions No. (%)	
<b>Category 1</b>	2 (0.4)	0 (0.0)	2 (0.4)
<b>Category 2</b>	74 (17.3)	4 (1.0)	78 (18.3)
<b>Category 3</b>	100 (23.2)	25 (6.1)	125 (29.3)
<b>Category 4</b>	28 (6.7)	58 (13.5)	86 (20.2)
<b>Category 5</b>	1 (0.2)	127 (29.8)	128 (30.0)
<b>category 6</b>	0 (0.0)	8 (1.8)	8 (1.8)
<b>Total (%)</b>	205 (47.8)	222 (52.2)	427 (100)

Table 3. Comparison between axillary ultrasound with histopathological results.

Ultrasound of axilla	Histopathology of axilla		Total (%)
	Negative for malignancy No. (%)	Malignant lymph nodes No. (%)	
Benign lymph nodes	2 (0.4)	19 (4.4)	21 (4.8)
Malignant (pathology)	18 (4.1)	68 (16.1)	86 (20.2)
<b>Total (%)</b>	20 (4.5)	87 (20.5)	107 (25)

Table 4. The frequency and percentages of non-malignant breast lesions on histopathology results.

Non-malignant breast lesions	No. (%)
Granulomatous mastitis	51 (25)
Fibroadenoma	46 (22.5)
Fibrocystic changes	38 (18.4)
Duct ectasia	18 (8.7)
Abscess	14 (6.8)
Cysts	12 (5.8)
Fat necrosis	6 (3)
Sclerosing adenosis	6 (3)
Galactocele	5(2.4)
Breast papilloma	4 (2)
Florid hyperplasia	3 (1.4)
Hamartoma	1 (0.5)
Gynecomastia	1(0.5)
<b>Total</b>	205 (100)

Table 5. The frequency and percentages of malignant breast lesions on histopathology results.

Malignant breast lesions	No. (%)
Invasive ductal carcinoma	187(84.2)
Invasive lobular carcinoma	14(6.3)
Ductal carcinoma insitu	9(4.25)
Lobular carcinoma insitu	1(0.45)
Intraductal papillary carcinoma	5 (2.2)
Metaplastic cancer	3(1.3)
Mucinous cancer	3 (1.3)
<b>Total</b>	222 (100)

**Table 6. Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of using ultrasound ACR-BIRADS score in diagnosis of breast diseases and axillary lesions, and association between ultrasonography findings with histopathological results.**

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Chi-square test	P-value
<b>Ultrasonography of Breast</b>	87.38%	85.85	86.99%	86.27%	231	0.000
<b>Ultrasonography of Axilla</b>	78.16%	10%	79.06%	9.52%	430.7	0.000

## DISCUSSION

Ultrasound has a prohibitive indicative tool in separating breast cancer from benign lesions, in preoperative evaluation and even in the observation of early cancers that are mammographically and clinically obscure. The conveniences of breast ultrasound correlated to mammography increment with higher breast density and in young lady where the sensitivity of mammography is minor. Dense breast tissue itself is an imager of marked up liability of breast cancer in the level of 4–6 folds <sup>(18)</sup>.

In the current study a total of 427 patients, more than half of the patients 222 (52.2%) were in the range of malignant lesions, whereas 205 (47.8%) of patients were in the range of benign lesions, these results discordant with the results of the previous study Navya BN et al (2017), in which more than half of patients were with benign lesions according to BIRADS scores and histopathology results <sup>(11)</sup>. This differences can be explained by the fact in our locality there was some insufficiency in screening program, lack of awareness regarding the way of self-breast examination, and at which time needed to visit breast clinic, most of the patients present with palpable breast cancers.

In the current study majority 275 (64.4%) of patients who visit breast clinic were in the range of age (30-49) years old, this finding nearly consistent to the previous study Lalchan S et al (2015) <sup>(19)</sup> Also in the current study regarding malignant finding 222 (52.2%) on histopathology findings majority 187 ((84.2) was invasive ductal carcinoma, then invasive lobular carcinoma 14 (6.3%), it was similar to the study done by Haghighi F et al (2017) <sup>(20)</sup>.

In the current study regarding benign finding 205 (47.8%) on histopathology results Granulomatous

mastitis 51 (25%) then followed by fibroadenoma 46 (22.5%) it was conflicted to the previous study Navya BN et al (2017) in which fibroadenoma was the common benign finding <sup>(11)</sup>. This can be clear that granulomatous mastitis may mimic breast carcinoma clinico-radiologically (painful, firm, tender, ill-defined mass in the breast, can cause skin thickness, sinus and abscess formation, axillary lymphadenopathy and nipple retraction which may be clinically mistaken for breast carcinoma) <sup>(21)</sup>. On the other hand, when the lesions typically goes with typical benign features on ultrasound did not undergo histopathological exams in our breast clinic.

Sensitivity and specificity, of breast ultrasound BIRADS score of the current study was, 87.38%, 85.85%, respectively. In comparison with Wang ZL et al (2015) sensitivity, specificity, of Ultrasound BIRADS scores were 95.35%, 43.24% respectively. Regarding sensitivity somewhat higher than current study, while specificity was lower than current study, <sup>(22)</sup>.

Current study sensitivity, specificity of ultrasound BIRADS score was lower in comparison to the sensitivity and specificity of ultrasonography and mammography BIRADS score were 88%, 87.5%, by Navya BN et al (2017), and 95.65 % 95.58 % by Lalchan S et al (2015) <sup>(11, 19)</sup>. This differences can be explained by the fact that combined imaging modalities of mammography and ultrasonography plays an important role in diagnosing and characterizing of different breast lesions, especially in younger patients with dense breast in which ultrasound was more sensitive in young age group than mammography in diagnosis of breast diseases. Thus, combined imaging helps in avoidance of unnecessary surgical procedures.

Study done by Alhamami QS et al (2018) sensitivity, specificity, of Ultrasound = 60.0%, 96.0%, respectively,

in which sensitivity was lower and specificity was higher in correlate with current study results <sup>(23)</sup>.

Another study done by Khan TS (2016) Sensitivity 89.87%, specificity 66.67%, in which specificity was lower in comparison to the current study <sup>(24)</sup>.

In the current study, sensitivity, specificity of ultrasound for axilla were 78.16%, 10. In correlate to the results study done by Stachs A, et al (2015) sensitivity and specificity of ultrasonography of axilla were 66.7% and 74.6%, sensitivity was lower, while specificity was higher in compare to the current study results <sup>(25)</sup>.

According to Liu Q, et al (2018) study sensitivity, specificity, was 90.4%, 68.2%, for ultrasonography of axilla; was 66.9%, 80.8%, for mammography of axilla; was 94.9%, 62.4%, for combined mammography and ultrasonography of axilla, combination of ultrasonography and mammography revise the sensitivity in separating N0–N1 breast cancer from N2–N3 breast cancer <sup>(26)</sup>, but convince diminished specificity. Additions of mammography to ultrasonography pretend not to maintain serious assistance in suppose axillary lymph nodes status in breast cancer patients

In conclusions; ultrasonography finding in diagnosis of breast lesions had accepted sensitivity and specificity. But using BIRADS ultrasound system as sole investigation in diagnosis of breast pathology is the matter of debate. Ultrasonography finding had non accepted specificity in diagnosing axillary lesions, which didn't make it an ideal way for diagnosis of suspicious axillary lymph nodes by ultrasound. Ultrasound was inexpensive and available tool, especially for those that ages less than 40 years dense breast, but the sensitivity and specificity were become high if combined with mammography, especially for those that above 40 years old.

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