BI-RADS 4 and 5 breast lesions: correlation between sonographic findings and histopathological results following ultrasound-guided FNAC

(بيرادس 4 5) : بين مشاهدات فحص فوق الصوتية والنتائج المرضية بعد الرشف الدقيقة بـ فوق الصوتية

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خلفية البحث: التطبيق السريري لنظام البيرادس في فحص فوق الصوتية للثدي مفيد جدا في وصف عن مستوى احتمالية

الهدف: المقارنة بين مشاهدات فحص فوق الصوتية والنتائج المرضية بيرادس 4 5 ومدى التطابق بينهما. ا**لمنهجية**: دراسة مستقبلية شملت 185 مريضة من بيرادس 4 5 تم تحويلهن استشارية الثدي في مستشفى بمدينة الطب في فوق الصوتية للثدي وأجريت 2013 تم مراجعة مشاهدات

فوق الصوتية من فبل اختصاصي الاشعة اعتمادا على الطبعة الرابعة لمعجم البيرادس، بعدها تم اختيار فئة البيرادس 4 5 تتصف باحتمالية السرطان أكثر من الفئات الأخرى وفي كلا الفنتين تم إجراء الرشف بالإبرة الدقيقة لأفات الثدي الدقيقة ومقارنتها مع مشاهدات فحص فوق الصوتية لحصول على خمس احتمالات حسب درجة المطابقة بينهما ومن تم حساب معدلات

خلال فترة ثمانية أشهر تم 185 مريضة من فئة البيرادس 4 5 أعمار هن بين 20 – 73 وق فوق الصوتية للندي تم تصنيف حسب نظام البيراد 4 5 أجريت لها الرشف الدقيقة بدلالة فوق الصوتية وإجراء الفحص النسيجي فيما بعد. 65,83% يرادس 4 أظهرت نتائج حميدة و 18,99% بينت نتائج خبيثة و 12,66% أظهرت نتائج حميدة و 18,99% بينت نتائج حميدة و 18,99% بينت حميدة والنسبة الباقية تحمل خطورة عالية وبعد إجراء المقارنة بين مشاهدات فحص الأمواج فوق الصوتية والنتائج المرضية محميدة والنسبة الباقية تحمل خطورة عالية وبعد اجراء المقارنة بين مشاهدات فحص الأمواج فوق الصوتية والنتائج المرضية

18,9% لفئة البيرادس 4 بينما كان التطابق بنسبة 85.18 % لفئةَ البيرادس 5. عدم النطّابق الحميد شوهد قي 68,3% المرضى من فئة البيرادس 4 بينما وجد في 7,4% من فئة البيرادس 5 ، والصنف الأخير الذي يحمل خطورة عالية وجد في 12,6% البيرادس 4 ـ 7,4% في فئة البيرادس 5.

البيرادس 4 4,1% في ^{همه} البيرادس 5. : بينت الدراسة الحالية توافق بين النتائج المستحصلة لمعدلات مع المعدلات المذكورة في نظام البيرادس 4 5. المقارنة الدقيقة بين مشاهدات التصوير الطبي والنتائج المرضية هو جزء أساسي لفريق متعدد التخصصات ومهم جدا في تأسيس التطابق بينهما. **التوصيات**: المعرفة السابقة حول الطبعة الرابعة لمعجم البيرادس والممارسة اليومية لها في العمل ضرورية لا في تشيس التطابق بينهما. الثرى المتخصصة لتجنب أي تأخير في تشخيص الأورام الخبيئة للثري.

ABSTRACT

Background: clinical application of breast imaging reporting and data system (BI-RADS) lexicon for breast ultrasound useful to characterization of breast lesion and to inform the level of likelihood of malignancy.

Objectives: to correlate between the ultrasound findings and pathological results of BIRADS 4 and 5 lesions on the basis of the imaging-pathologic concordance or discordance.

Patients and methods: This prospective study enrolled 185 patients classified as BI-RADS-4 and BI-RADS-5, who were referred for breast ultrasound examination at breast clinic in oncology hospital-medical city complex-Baghdad that obtained between January 2013-August 2013 who had palpable breast lump on clinical examination or mass detected by mammography. Ultrasound findings were reviewed by board-certified radiologist and description of ultrasound finding bases on fourth edition BI-RADS lexicon; BI-RADS 4 and 5 was selected for breast lesions that were features suggesting malignancy, category 5 having more likelihood of malignancy than category 4. In both cases, ultrasound guided fine needle aspiration cytology (FNAC) were performed then pathological diagnoses were obtained. Finally, five possible results illustrated for ultrasound-pathology correlation according the concordance and discordance between ultrasound findings and pathological results and malignancy rates were estimated.

Results: Over a period of 8 months, 185 patients with BI-RADS 4 and 5 breast lesions were included in this study; the age at presentation ranged from 20 to 73 years. The mean age was 39 years. High resolution ultrasound with Doppler facility applied on all patient and results are categorized according breast imaging and reporting data system and category 4 and 5 were ended by fine needle aspiration cytology with ultrasound guidance and subsequently the histopathology was done. FNAC results revealed 68.35% (n=108) of BI-RADS 4 patients had

benign pathologies, 18.99% (n=30) had malignancy and just 12.66% (n=20) showing borderline or high risk lesions. The majority (85.18%) of women with BI-RADS 5 displayed malignant lesion and benign lesions were 2% and rest were borderline. following imaging-pathology correlation, the concordant malignancy in BI-RADS 4 was 18.9% versus 85.18% in BI-RADS 5 and discordant benign in BI-RADS 4 noted in 68.3% of patients while only in 7.4% in BI-RADS 5 and borderline high-risk lesion identified in 12.6% in BI-RADS 4 and 7.4% in BI-RADS 5.

Conclusion: the current study shows high agreement with the likelihood of malignancy after application of BI-RADS terminology in category 4 and 5. Careful imaging-pathologic correlation is integral part of multidisciplinary team and very important in establishing the concordance.

Recommendation: the previous knowledge about fourth edition of ACR BI-RADS lexicon and practicing it in daily work recommended for radiologist who working in dedicated breast care centers to avoid delays in diagnosis of breast malignancy.

Key wards: breast, BI-RADS, ultrasound, FNAC

INTRODUCTION

In 1993, the American college of radiology (ACR) initially introduced a breast imaging reporting and data system (BI-RADS), for lesions noticed by mammography and since 2003 the fourth edition of the system expanded to ultrasound and magnetic resonance imaging and according the degree of suspicion the sonographically detected lesions categorized into 7 divisions, category 0 (need further evaluation), category 1 (normal), category 2 (benign), category 3 (probably benign), category 4 (suspicious), category 5 (malignant) and category 6 (known malignancy). [1] The risk of malignancy in category 3 is less than 2% [2] and category 4 in last BIRADS edition divided into subcategories (4a, 4b and 4c) on the basis of the likelihood of malignancy, 2-10% for category 4a, 11-50% for category 4b and 51-95% for category 4c [3] and high suggestive in category 5 (more than 95%). [2]

Breast ultrasound is regard as essential in the evaluation of masses detected by mammogram or palpable masses from clinical examination. [4]. There are different sonographic descriptors identified to determine that a lesion is benign, malignant, or suspicious including shape, orientation, margin, echogenicity, surrounding tissue, vascularity, calcifications and posterior acoustic features. [5] Previous knowledge and practice of radiologists about BI-RADS lexicon are essential to be familiar with the sonographic features of different breast abnormalities and shrink the interobserver variability by using terminology of fourth edition of the BI-RADS to categorized lesion on breast ultrasound examination.

Imaging-pathology correlation is integral in multidisciplinary team and in establishing concordance or disconcordance between sonographic findings and pathologic results for appropriate management of patients with breast carcinoma. [6] Concordance is present when the pathology findings offer suitable explanation of breast-imaging features and discordance is present when pathology findings do not provide an acceptable explanation for the breast-imaging features. [7, 8]

Fine needle aspiration cytology (FNAC) in experienced hands achieves a very high sensitivity, specificity and low false positive or false negative rates, and the UK guidelines of complete sensitivity of more than 80%, positive predictive value of malignancy of more than 95%, false negative rate of less than 5%, false positive rate of less than 1%, inadequacy rate of

less than 25% and suspicious rate of less than 20%, confirm to the fact that FNAC can be a very good and effective diagnostic modality. [9]

The purpose of the current study is to correlate between the ultrasound findings and pathological results of BI-RADS 4 and 5 breast lesions on the basis of the imaging-pathologic concordance and discordance.

PATIENTS AND METHODS

This prospective study enrolled 185 patients classified as BI-RAD-4 and BI-RADS-5, who were referred for breast ultrasound examination at breast clinic in oncology hospital- medical city complex-Baghdad that obtained between January 2013-August 2013 who had palpable breast lump on clinical examination or mass detected by mammography.

Ultrasound examination of the breast was performed using Siemens Acuson X300 (Siemens Inc., Germany), ultrasound machines, equipped with a variable-frequency linear transducer set VF 5-13 MHz, resulting in spatial resolution of 0.1 mm at appropriate magnification. For lesions in the lateral aspect the breast, the patient was imaged in the supine-oblique position, and for other lesions, the patient was supine. Images were acquired in both radial and transverse planes and measurements were made using calipers. Additional color or power Doppler imaging were obtained to better characterization of the lesion.

Ultrasound findings were reviewed by board-certified radiologist and description of ultrasound finding bases on fourth edition BI-RADS lexicon was provide for observer to select the most appropriate description that depended on shape, orientation, margin, lesion boundary, echo pattern, posterior acoustic features, calcifications, vascularity and surrounding tissue. Typical benign features included oval shape, circumscribed margins with no more than 2-3 gentle lobulations, long axis parallel to the skin, predominantly hypoechoic homogeneous internal echotexture, abrupt interface with surrounding tissue and no features suggestive of malignancy. Criteria for malignancy included irregular shape, microlobulation, indistinct border, angularity, spiculated margins, antiparallel orientation, hypoechoic appearance or heterogeneous echotexture, echogenic halo and posterior acoustic shadowing.

Although a new recommendation in the fourth edition of BI-RADS is for category 4 to be subdivided into three subcategories (4a, 4b and 4c) according level of suspicion; however, it's optional and in our practice the subdivision not applied in view of the fact that no precise guideline regarding the risk of malignancy for each of the subcategories.

BI-RADS 4 and 5 was selected for breast lesions that were features suggesting malignancy, category 5 having more likelihood of malignancy than category 4. In both cases, ultrasound guided fine needle aspiration cytology was recommended. Ultrasound-guided FNAC performed using 22 gauge needles. Pathological diagnoses were obtained from pathology department in same hospital by subsequent biopsy.

Finally, five possible results illustrated for ultrasound-pathology correlation according the concordance and disconcordance between ultrasound findings and pathological results: *Concordant BI-RADS 5 (malignant/malignant)* indicates a lesion which demonstrated highly

suggestive findings for malignancy on ultrasound examination and is diagnosed to be malignant by pathological analysis. *Discordant BI-RADS 5 (malignant/benign)* indicates a lesion which demonstrated highly suggestive findings for malignancy on ultrasound examination and is diagnosed to be benign lesion by pathological analysis.

Concordant BI-RADS 4 (suspicious/malignant) indicates a lesion which demonstrated suspicious findings for malignancy on ultrasound examination and is diagnosed to be malignant by pathological analysis. *Discordant BI-RADS 4 (suspicious/benign)* indicates a lesion which demonstrated suspicious findings for malignancy on ultrasound examination and is diagnosed to be benign lesion by pathological analysis. *Borderline (high-risk) category* indicates a lesion which categorized BI-RADS 4 or 5 on ultrasound examination and pathological analysis revealed no definite malignancy but is increased risk for development of malignancy; however, excisional biopsy is recommended regardless of concordance due to high risk of malignancy.

Statistical analysis was performed using the Microsoft excel software-2007 and different variables were analysed. Malignancy rate according to the BI-RADS category was calculated.

RESULTS

Over a period of 8 months, 185 patients with BI-RADS 4 and 5 breast lesions were included in this study; the age at presentation ranged from 20 to 73 years. The mean age was 39 years. Majority of our patients were referred to breast clinic in the oncology hospital by consultant surgeon in same clinic following patient concern upon self-examination while the minority of the patients were referred from private clinic after clinical evaluation by their doctors or mass lesion detected on mammography followed by ultrasound examination.

Category	Benign [n (%)]	Malignant [n (%)]	Borderline [n (%)]	Total [n (%)]
BI-RADS 4	108 (68.35)	30 (18.99)	20 (12.66)	158 (85.4)
BI-RADS 5	2 (7.41)	23 (85.18)	2 (7.41)	27 (14.6)
Total	110 (59.4)	53 (28.7)	22 (11.9)	185 (100)

Table (1) malignancy rate of BI-RADS 4 and 5 breast lesions

High resolution ultrasound with Doppler facility applied on all patient and results are categorized according breast imaging and reporting data system and category 4 & 5 were ended by fine needle aspiration cytology with ultrasound guidance and subsequently the histopathology was done. 85.4% (n=158) of patients BI-RADS 4 lesion whilst 14.6% (n=27) had BI-RADS 5 lesion. FNAC results revealed 68.35% (n=108) of BI-RADS 4 patients had benign pathologies, 18.99% (n=30) had malignancy and just 12.66% (n=20) showing borderline or high risk lesions. The majority (85.18%) of women with BI-RADS 5 displayed malignant lesion and benign lesions were 7.41% and rest were borderline as shown in table (1).

FNAC finding		No.	%	Total [n (%)	
BI-RADS 4	Benign	Fibroadenoma	9	5.69	
		Fibroadenosis	4	2.53	158 (85.40)
		Fibrocystic changes	5	4.63	
		Galactocele	3	3.16	
		Intra-ductal papilloma	1	0.63	
		Chronic abscess	2	1.26	
		Ductectasia	2	1.26	
		Inflammation	21	13.29	
		Atypical lipoma	1	0.63	
		Foamy or protein	60	37.97	
	Malignant	Invasive ductal carcinoma	27	17.09	
		Lymphoma	3	3.16	
	Borderline	Atypia	20	12.65	
BI-RADS 5	Benign	Chronic abscess	1	3.70	27 (14.60)
		Adenosis	1	3.70	
	Malignant	Invasive ductal carcinoma	21	77.77	
		Lymphoma	1	3.70	
		Inflammatory carcinoma	1	3.70	
	Borderline	Atypia	2	7.40	
		Total			185 (100)

Table (2) FNAC outcomes of BI-RADS 4 and 5 breast lesions

Table (2) showed 37.9% of patients with BI-RADS 4 finding on ultrasound and benign results on FNAC analysis had no specified pathology (foamy or proteinaceous material) and 13.2% had inflammatory tissue; fibroadenoma (5.6%), fibrocystic changes (4.6%), galactocele (3.1%), fibroadenosis (2.5%), chronic abscess (1.2%), ductectasia (1.2%), and intra-ductal papilloma and atypical lipoma (0.6%). The majority of malignant lesions under BI-RADS 4 category (90%) had invasive ductal carcinoma versus 91.3% in BI-RADS 5 and only 10% of were lymphoma versus 4.3% in BI-RADS 5 category. Borderline or high risk lesions (atypia) constitute 12.6% of total number of BI-RADS 4 category versus 7.4% in BIRADS 5 lesions. Just 4.3% (n=1) of malignant lesion in BI-RADS 5 presented as inflammatory carcinoma.

Table (3) correlation between ultrasound findings and pathological results in BI-RADS 4 and 5 breast lesions

Category	Ultrasound vs. pathology	No. (%)
Concordant BI-RADS 4	suspicious vs. malignant	30 (18.99)
Discordant BI-RADS 4	Suspicious vs. benign	108 (68.35)
Concordant BI-RADS 5	Malignant vs. malignant	23 (85.18)
Discordant BI-RADS 5	Malignant vs. benign	2 (7.41)
Borderline BI-RADS 4 or 5	BI-RADS 4 or 5 vs. high risk outcome	22 (11.89)

Subsequent to imaging-pathology correlation, the concordant malignancy in BI-RADS 4 was 18.9% versus 85.1% in BI-RADS 5 and discordant benign in BI-RADS 4 noted in 68.3% of patients while only in 7.4% in BI-RADS 5 and borderline high-risk lesion identified in 12.6% in BI-RADS 4 and 7.4% in BI-RADS 5 as shown in table (3).

DISCUSSION

Breast ultrasound was proved to be useful in the evaluation of masses detected with mammography or clinical examination as ultrasound is used to distinguish cystic lesions from solid lesions and to further differentiate benign solid masses from malignant solid masses. [5, 10] However, the main purpose of BI-RADS lexicon to avoid interobserver ambiguity and inconsistency in interpretation and description of breast lesions on ultrasound examination; therefore, a standardized lexicon for sonography was published in 2003 by the American college of radiology because of increasing use of sonography in clinical practice and to provide an integrated words for sonographic reporting. [1, 11]

In fourth edition of BI-RADS, categorization of BI-RADS 4 into subgroups (4a, 4b and 4c) recommended on basis of level of suspicion of malignancy, although it's of value in our daily practice and in this current study not applied because of wide heterogeneity in observer variation in lesion recognition and classification and currently, no definite clear cut specification or guideline regarding what was the risk of malignancy fort each of the subcategories should represent and overlapping of ultrasound descriptors defined by ACR ultrasound BI-RADS and finally, the judgment depends on the knowledge and practice of radiologist about using BI-RADS terminology and determine the level of suspicion. In general the probability of malignancy in BI-RADS 4 lesions ranges from 2% to 95%. [12] However, Lazarus et al found that positive predictive value (PPV) of category 4a (6%), 4b (15%) and 4c (53%). [13]

In the current study, the overall malignancy rate of 28.6% on sampled lesions which is in agreement with published findings as in Ciatto et al [14] study over 4000 core needle biopsies of breast lesions found that about one third of the lesions were malignant and Hamy et al [15] reported 32.9% malignancy rate whilst Peters et al [16] showed higher malignancy rate in the Dutch (55%); which may be explained by using stereotactic large core needle biopsy.

BI-RADS malignancy rates per category especially in category 4 associated with a highly variable rate of cancers but in general, BI-RADS 4 lesions malignancy rates range from 2-95% [1], in this study the malignancy rate for BI-RADS 4 was 18.9%, which approached the result obtained in Hamy et al study that found 23.9% malignancy rate [15], whereas Zonderland and Pope study found a malignancy rate of 52.7% [17], and Raza et al recorded 16.2%. [18]. Rate of malignancy per subcategory BI-RADS 4 not evaluated in this study could be explained by the lack of known factors clearly and objectively defining each subdivision and also because the use of subcategories is optional and management is not standardized.

In this study, from 30 malignancy BI-RADS 4 lesion (18.9%), 90% (n=27) revealed invasive ductal carcinoma and 10% (n=3) was lymphoma whereas in Raza et al found that 80% (n=68/85) was invasive ductal carcinoma and 20% (n=17/85) was DCIS. [18].

Current study revealed that 68.3% of BI-RADS 4 had benign results which are comparable to results obtained by Raza et al was 75.2%. [18] The borderline high-risk lesions were constitute 12.6% of BI-RADS 4 lesion in contrast to results recorded by Raza et al study found only 2.1% were risk lesions, this could be explained by different biopsy program used in mentioned study.

Twenty-seven patients had categorized as BI-RADS 5; of these lesions, 85.1% were malignant, 7.4% were borderline high-risk lesions and 7.4% were benign lesions. 91.3% of malignant lesions were invasive ductal carcinoma, 4.3% were lymphoma and 4.3% were inflammatory carcinoma. Our malignancy rate of 85.1% for BI-RADS 5 category was low in comparison with supposed malignancy rate in ACR BI-RADS lexicon, which is more than 95%; however, our results were comparable with some results obtained in other studies as in Zonderland and Pope study that found malignancy rate of 85% [17] and 78.7% in Hamy et al study. [15] This is may be encountered because of the malignancy simulating lesion on ultrasound as adenosis, fibrosis and chronic abscess.

Following imaging-pathology correlation, the concordant malignancy in BI-RADS 4 was 18.9% versus 85.1% in BI-RADS 5 in which, appropriate action should be taken without any delay and discordant benign in BI-RADS 4 noted in 68.3% of patients while only in 7.4% in BI-RADS 5, which mostly demonstrated in benign lesions that show ultrasound descriptors of malignant lesions; nevertheless, the observer must give more attention to discordant benign lesions to avoid missed cancers at fine needle aspiration cytology and Liberman et al revealed that 64% of discordant benign lesion were confirmed as malignancy in subsequent surgical excisional biopsy. [19] Therefore, a surgical biopsy rather than a core needle biopsy is recommended for a repeat biopsy because of the inconclusive outcome from the first intervention. Although vacuum-assisted biopsy is of value in this category but not performed as a routine practice in our hospital.

The borderline high-risk lesions in BI-RADS 4 and 5 categories in our study were 12.6% and 7.4% respectively. The lesion in this category is not malignant but is considered to have an increased risk for the development of breast cancer as atypia or atypical ductal hyperplasia. [20] At present, there is no standardized management recommendation for high-risk category regarding surgical or medical treatment; therefore, the role of multidisciplinary team necessary for optimal management and cooperation between radiologists and pathologist as well as the surgeons and oncologists are essential is establishing radiologic-pathologic concordance. However, in our practice, the surgical excisional biopsy is usually recommended regardless of concordance, because of the relatively high-risk rate of malignancy.

CONCLUSIONS

Regarding the use of the fourth edition of ACR BI-RADS lexicon for ultrasound, the results of our study show a high agreement with the likelihood of malignancy after proper application of BI-RADS terminology in category 4 and 5. Careful imaging-pathologic correlation is integral part of multidisciplinary team and very important in establishing the concordance and special attention recommended for borderline high-risk category because of the increasing risk of malignancy.

Recommendation: although the use of assessment categories for BI-RADS, ultrasound has not been reported so far; therefore, the previous knowledge about fourth edition of ACR BI-RADS lexicon and practicing it in daily work recommended for radiologist who working in dedicated breast care centers to avoid delays in diagnosis of breast malignancy.

Acknowledgments: this study conducted in oncology hospital in Baghdad and author thankful to Dr. Sana Nadher from pathology department and staff of patients' registration unit for their cooperation.

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