

Assessment of Indeterminate Breast Lesions (Birads 4): Utility of Contrast Enhanced Mammography

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Abstract

Background: Breast cancer is estimated to be the most common cancer among Egyptian females and accounts for the leading cause of cancer related mortality. Contrast enhanced mammography is an emerging technique that combines intravenous iodinated contrast administration with digital mammography. CEM improves the sensitivity for breast cancer detection without decreasing the specificity owing to higher contrast and better lesion delineation.

Aim of Study: To investigate the usefulness of contrast enhanced mammography in the assessment of indeterminate (BIRADS 4) breast lesions.

Patients and Methods: The study was performed on 32 female patients discovered to have BIRADS 4 breast lesions on conventional mammography and/or breast ultrasonography. All patients were injected with non ionic contrast media. Examination was then performed on a digital mammography machine adapted for CEM.

Results: CEM correctly upgraded 22/22 histopathologically proven malignant lesions from BIRADS 4 to 5. 18/22 benign lesions were correctly downgraded from BIRADS 4 to 3, while 4 benign lesions were incorrectly upgraded to a BIRADS 5 by CEM. No malignant lesions were incorrectly downgraded to BIRADS 3 by CEM. Overall performance of CEM was a sensitivity of 100%, a specificity of 81.8%, a PPV of 84.6%, a NPV of 100% and an accuracy of 90.9%.

Conclusion: CEM is a useful and reliable tool that can increase diagnostic confidence when evaluating indeterminate breast lesions.

Key Words: Contrast enhanced mammography (CEM) – Indeterminate breast lesions.

Introduction

BREAST cancer is the most common cancer in women worldwide. In Egypt, breast cancer is estimated to be the most common cancer in women comprising 37.7% of the total number of cancers and is the leading cause of cancer-related mortality comprising 29.1% [1].

Early detection of breast cancer by X-ray mammography screening has been shown to reduce mortality; however, the method is limited by moderate sensitivity and specificity especially in dense breasts. To overcome these limitations, further workup of suspicious mammography findings may become necessary using additional mammographic views, ultrasound, and contrast enhanced breast magnetic resonance imaging (MRI) [2].

Breast cancers are known to enhance after administration of contrast agents because tumoral microvessels form rapidly and consequently often have 'leaky' basement membranes. This makes the vessels permeable to contrast agents, resulting in tumor enhancement [3]. Contrast-enhanced breast imaging techniques like CT and MRI are used for the detection of angiogenesis in suspicious tissues. However, CT has the drawback of high radiation doses, despite its reported use in the detection of breast carcinoma [4]. Contrast-enhanced MRI is currently the most sensitive breast cancer detection technique, but may have high false positive rates, higher costs, and lower availability. Also patients with pacemakers, certain aneurysm clips, other metal implants or severe claustrophobia are unable to undergo MRI [5].

Contrast-enhanced mammography (CEM) is a relatively new imaging modality among breast imaging protocols. It combines full field digital mammography (FFDM) with intravenous contrast utilization [6]. In CEM, a pair of images is acquired for each view: One low-energy image (LE), which is similar to a standard mammogram, and one high-energy image (HE), which is optimized for the detection of iodine contrast agent uptake; the two images are then combined to produce an image where glandular tissue texture is suppressed and contrast uptake is highlighted [7].

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Because the principal behind contrast-enhanced mammography is similar to breast MRI, it is to be expected that many indications for breast MRI could apply to contrast-enhanced mammography [8]. As such, CEM can serve as a valuable tool in further evaluation of extremely dense breast tissue, diagnostic assessment of suspicious lesions, surgical planning, and assessment of treatment response. It can help characterize and guide management particularly when there are multiple suspicious findings on initial screening mammogram [9].

Aim of work:

To investigate the usefulness of dual energy contrast enhanced mammography in the assessment of indeterminate breast lesions (BIRADS 4).

Patients and Methods

This study was a prospective study, conducted on 32 female patients, ages ranging from 20-63 years. All patients were referred to the Women's imaging unit at Ain Shams University Hospitals between January 2019 and March 2020. All patients were diagnosed as having BIRADS 4 breast lesions on digital mammography and/or breast ultrasound with a need for further assessment. The study was performed after approval of the Ethical committee of scientific Research, Faculty of Medicine, Ain Shams University.

Inclusion and exclusion criteria:

Inclusion criteria were female patients, 18 years and older, who were discovered to have BIRADS 4 breast lesions on digital mammography and/or breast ultrasound. Exclusion criteria were patients with renal failure or impairment, allergy to contrast media, pregnant and breast feeding patients.

Patient preparation:

A comprehensive explanation of the technique was provided and written consent was obtained. Patients were asked to provide a recent renal function test and were instructed to fast for at least 6 hours prior to the exam. A full medical history was obtained. A cannula was inserted in the antecubital fossa of the arm contralateral to the diseased breast. Non-ionic contrast media (Omnipaque 300mg/ml) was then administered manually at a dose of 1.5ml/kg body weight. After injection was complete, the cannula was left in position to allow intravenous access in case of any allergic reactions. All CEM examinations were performed by a digital mammography machine (Senographe Pristina EKB, France) with specific software and hardware adaptations to allow dual energy contrast enhanced

acquisitions and image processing. The examination started approximately two minutes after contrast injection with the diseased breast being compressed into a craniocaudal projection (CC view) followed by the non-diseased breast. A mediolateral projection (MLO view) was then obtained in the same order. For each projection, a pair of images (one low-energy and the other high-energy) was obtained. Image processing was done to obtain a subtracted image for each projection as to highlight contrast uptake.

Image analysis and interpretation:

A careful note of the location, number and type (mass, architectural distortion, breast asymmetry or suspicious microcalcifications) of the BIRADS 4 breast lesions discovered on mammography and/or ultrasound was made for accurate retrospective correlation with the CEM images.

The recombined CC and MLO CEM images were then assessed for: The presence or absence of enhancement and the morphology of said enhancements was described (whether foci of enhancement, mass enhancements or non-mass enhancements).

Foci of enhancement are enhancing breast lesions <5mm that are described according to being either:

- Unilateral or bilateral.
- Single or multiple.
- Showing faint, moderate or intense enhancement.

Mass enhancing lesions are 3-dimensional space occupying lesions described according to their:

- Shape: Round, oval or irregular.
- Margin: Circumscribed or non-circumscribed (irregular/speculated).
- Internal enhancement pattern: Homogenous, heterogeneous, with dark internal septations or rim enhancement.
- Intensity of enhancement: Faint, moderate and intense.

Non-mass enhancing lesions are non-space occupying lesions described according to their:

- Internal enhancement pattern: Homogenous, heterogeneous or clumped.
- Distribution: Focal, linear, segmental and diffuse.
- Intensity of enhancement: Faint, moderate and intense.

A benign morphology was considered if:

- No enhancement was described.
- An enhancing focus was described as being multiple, bilateral and faintly enhancing.
- An enhancing mass was described as rounded or oval, with circumscribed margins and homogenous internal enhancement or with dark internal septations.
- Non-mass enhancing lesions were described as being of a diffuse distribution and a homogenous internal enhancement.

A malignant morphology was considered if:

- An enhancing focus was described as single, unilateral with intense enhancement.
- An enhancing mass was described as irregular shaped with non-circumscribed margins (irregular or spiculated), showing heterogeneous or rim enhancement patterns, that was either moderately or intensely enhancing.
- A non-mass enhancing lesion described as having a focal, linear or segmental distribution with a heterogeneous or clumped internal enhancement pattern that was either moderate or intensely enhancing.

Each lesion was reassigned a BIRADS category according to enhancement criteria and morphology, based on the (BI-RADS) lexicon designed by the American College of Radiology (ACR) for breast MR imaging.

Lesions that were upgraded to BIRADS 5 according to CEM criteria were histopathologically assessed either by core biopsy or excision biopsy. Lesions that were downgraded to BIRADS 3 were also histopathologically assessed except for the cases that refused biopsy, follow-up was provided for 1 year, at 6 months intervals, to ascertain the stability of the lesions and to rule out underlying malignancy.

Statistical analysis:

Statistical analysis was performed using MedCalc statistical software for Windows (MedCalc Software, Mariakerke, Belgium). Data for continuous variables were expressed as either median, interquartile range and range or mean ± standard deviation and as both number and percentage for categorical data. Receiver operator characteristic (ROC) curve analysis was performed to determine the diagnostic accuracy of the various variables in distinguishing the different groups. The diagnostic accuracy of all variables was evaluated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area

under the ROC curve (AUC). CHI-squared test was used for comparison of categorical data. For all tests all *p*-values were two-tailed and a *p*-value <0.05 was considered significant.

Results

The study included 32 patients with 44 breast lesions. Ages range from 20 to 63 years with a median of 39.5 years.

Malignant and benign lesions were equally represented in our study, with 22 lesions in each group. The reference standard was histopathological tissue evaluation in 38/44 lesions which included all 22/22 malignant lesions and 16/22 benign lesions, with a scheduled follow-up for 1 year (at 6 month intervals) for the remaining 6 lesions.

Final diagnosis of breast lesions by histopathology:

Thirty eight breast lesions were biopsied, 22 lesions (57.9%) were malignant and 16 lesions (42.1%) were benign. The diagnosed malignant lesions were invasive ductal carcinoma (n=14) and invasive ductal carcinoma with foci of ductal carcinoma insitu (n=8). Benign lesions included benign fibroepithelial lesions (n=4), benign mammary lobules (n=2), benign papillomatous lesions (n=2), fibroadenoma (n=4), fibrocystic disease (n=2) and periductal and lobular mastitis (n=2).

Sono-mammographic findings:

Correlation between the appearance of the lesions on sono-mammography and their final diagnosis is seen in Table (1).

Table (1): Sono-mammographic classification of breast lesions.

Sono-mammography	Total	Benign	Malignant
Architectural distortion	4 (9.1%)	2 (4.5%)	2 (4.5%)
Asymmetry	2 (4.5%)	2 (4.5%)	0 (0%)
Mass	36 (81.8%)	18 (40.9%)	18 (40.9%)
Microcalcifications	2 (4.5%)	0 (0%)	2 (4.5%)
Total	44 (100%)	22 (50%)	22 (50%)

Contrast enhanced mammography findings:

Regarding contrast uptake, 34/44 (77.2%) lesions showed contrast uptake while 10/44 (22.7%) did not show contrast uptake. Out of the 34 enhancing lesions, 22 lesions (64.7%) were proven to be malignant and 12 lesions (35.3%) were proven to be benign. All 10 (22.7%) non-enhancing lesions were proven to be benign. Regarding the 34 enhancing lesions, the type of enhancement was as such: 2/34 (5.9%) were enhancing foci, 26/34 (76.5%) were mass enhancements and 6/34 (17.6%)

were non-mass enhancements. According to histopathology, 2/34 enhancing foci, 8/26 mass enhancing lesions and 2/6 non-mass enhancing lesions were proven to be benign while 18/26 mass enhancing lesions and 4/6 non-mass enhancing lesions were proven to be malignant. No cases presenting with enhancing foci were proven to be malignant. Distribution of the enhancing lesions according to type of enhancement into benign and malignant groups can be seen in Table (2).

Table (2): Type of enhancement in correlation with final diagnosis.

Type of enhancement	Total	Benign	Malignant
Enhancing foci	2 (5.9%)	2	0
Mass enhancement	26 (76.5%)	8	18
Non-mass enhancement	6 (17.6%)	2	4
Total	34 (100%)	12 (35.5%)	22 (64.7%)

Regarding the mass enhancing lesions, morphologic descriptors of enhancement and their correlation with final histopathology is seen in Table (3).

Table (3): Correlation of morphological characteristics of mass enhancing lesions with final pathology.

Mass enhancement characteristics	Total	Benign	Malignant	P-value
<i>Mass shape:</i>				
- Oval/round	22	8	14	0.16
- Irregular	4	0	4	
<i>Margins:</i>				
- Circumscribed	8	8	0	<0.0001 *
- Non-circumscribed	18	0	18	
<i>Internal enhancement pattern:</i>				
- Homogenous	2	2	0	<0.0001 *
- Heterogenous	16	0	16	
- Dark internal septations	6	6	0	
- Rim enhancement	2	0	2	
<i>Intensity of enhancement:</i>				
- Faint	2	2	18	0.03 *
- Intense	24	6		

*p-value <0.05 is considered significant.

Regarding the non-mass enhancing lesions, morphologic descriptors of enhancement and their correlation with final histopathology is seen in Table (4).

Table (4): Correlation of morphological characteristics of non-mass enhancing lesions with final pathology.

Non-mass enhancement characteristics	Total	Benign	Malignant	P-value
<i>Internal enhancement pattern:</i>				
- Heterogeneous	2	2	0	0.03 *
- Clumped	4	0	4	
<i>Distribution:</i>				
- Segmental	4	2	2	0.26
- Diffuse	2	0	2	
<i>Intensity of enhancement:</i>				
- Moderate	2	2	0	0.03 *
- Intense	4	0	4	

*p-value <0.05 is considered significant.

To summarize, 18/44 breast lesions were characterized by CEM as benign (BIRADS 3) and 26/44 were characterized as malignant (BIRADS 5). Correlation with final diagnosis revealed that all 18 lesions were truly benign (truly negative) while 22 lesions were truly malignant (truly positive) and 4/44 lesions turned out to be benign (false positive). When comparing the performance of CEM to that of the initial sono-mammography according to which all included lesions were BIRADS 4, 22/22 of the histopathologically proven malignant lesions were correctly upgraded from BIRADS 4 to 5 by CEM thus increasing diagnostic confidence. By CEM, 18/22 benign lesions which were incorrectly diagnosed as BIRADS 4 on the initial sono-mammography were correctly downgraded to BIRADS 3. Two cases presenting as enhancing foci on CEM and as masses on sono-mammography, were incorrectly classified as BIRADS 4 by sono-mammography and upgraded to BIRADS 5 by CEM. Both were proven to be benign papillomatous lesions. Two cases presenting with non-mass enhancement on CEM and as masses on sonomammography were incorrectly classified as BIRADS 4 lesions and as BIRADS 5 by CEM were proven by histopathology to be mastitis. On the other hand, no lesions diagnosed as suspicious by sono-mammography were incorrectly diagnosed as benign by CEM.

Analysis of the previous data revealed that CEM had a sensitivity of 100%, a specificity of 81.8%, a positive predictive value of 84.6%, a negative predictive value of 100%, an accuracy of 90.0%. The diagnostic performance of CEM is expressed in Table (5).

Table (5): Diagnostic performance of CEM in sono-mammographically diagnosed BIRADS 4 breast lesions.

CEM characterization	Total	Pathology		Sensitivity	Specificity	PPV	NPV	Accuracy	AUC
		Benign	Malignant						
Benign (BIRADS 3)	18 (40.9%)	18 (TN)	0 (FN)						
Malignant (BIRADS 5)	26 (59%)	4 (FP)	22 (TP)	100%	81.8%	84.6%	100%	90.9%	0.91
Total	44	22 (50%)	22 (50%)						

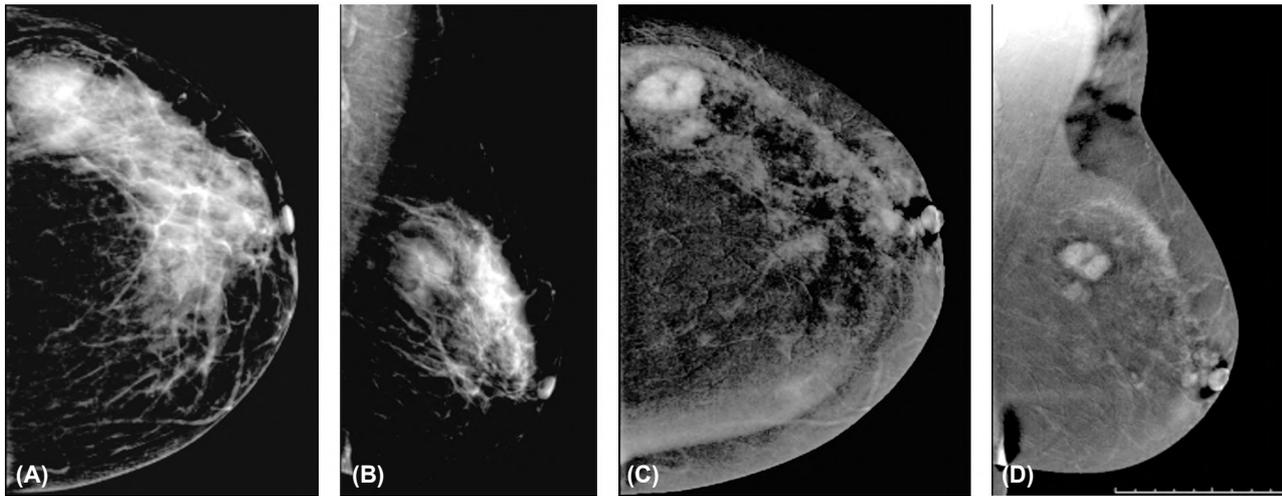


Fig. (1): A 42 year old patient came complaining of a left breast lump. Mammography CC and MLO views (A & B) revealed an upper outer isodense mass with partially well defined and partially obscured margins. Recombined CC and MLO (C & D) CEM images revealed 2 enhancing lesions with dark non-enhancing septa. Pattern of enhancement was in favor of a benign pathology (BIRADS 3). Excision biopsy revealed fibroadenomas.

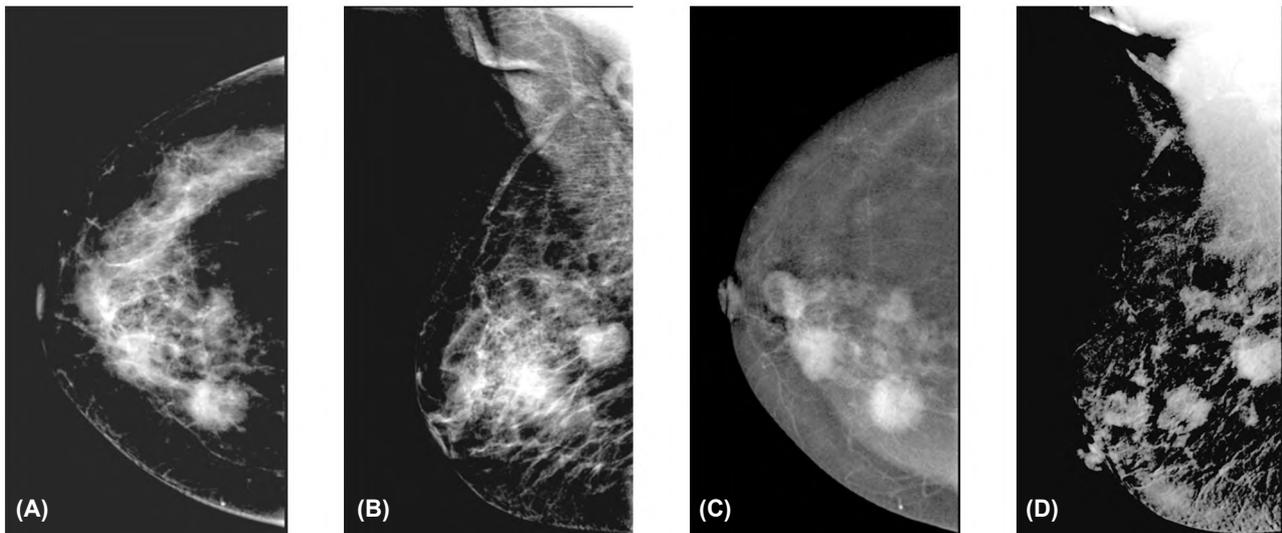


Fig. (2): A 35 year old patient came complaining of a right breast lump. CC and MLO mammography views (A&B) revealed a radio-opaque irregular mass lesion at upper inner quadrant. CC and MLO recombined CEM images (C&D) revealed 3 intensely enhancing heterogeneous lesions with other smaller lesions in the same quadrant seen to enhance intensely, a picture suggestive of multifocal malignant disease. Core biopsy of the 3 lesions revealed infiltrating duct carcinoma grade 2.

Discussion

Contrast-enhanced digital mammography (CEM) is a promising technique that uses iodinated contrast to detect tumor vascularity. It can be

performed using standard mammography equipment with addition of copper filtration and software upgrades to make the unit capable of dual-energy imaging. A CEM-specific Breast Imaging Reporting

and Data System (BIRADS) lexicon for image interpretation does not currently exist but is under development. In the meantime, the BI-RADS mammography lexicon can be used to describe morphologic findings on low-energy images and the BI-RADS MRI lexicon without kinetics to describe enhancing findings on recombined images [10]. Not all enhancing lesions on CEM are malignant, benign enhancing findings may include: Fibroadenoma, papilloma, pseudoangiomatous stromal hyperplasia, abscess, and radial scar or complex sclerosing lesions. As such we need to evaluate the enhancement criteria and morphologic descriptors to determine which descriptors are indicative of malignant pathology and which are indicative of benign lesions which is a step towards reducing the number of unnecessary biopsies [10].

The current study is a prospective study done on 32 female patients with 44 breast lesions to evaluate the utility of CESM in suspicious (BIRADS 4) breast lesions.

Patients were divided into 2 groups: Benign and malignant according to their final diagnosis based on histopathology and in those patients refusing biopsy, periodic follow-up for one year was done to assure the absence of underlying malignancy.

In our current study, the presence of contrast uptake was significantly higher in malignant breast lesions ($p=0.0004$) such that of 34 enhancing lesions, 22 of these lesions were malignant (64.7%) as opposed to only 12 were benign (35.2%). These results are comparable to Badr et al., [11], who studied 37 breast lesions and demonstrated enhancement in 27 lesions, 18 of which were malignant (67%) and 9 lesions were benign (33%). Another study by Kamal et al., [12], also demonstrated higher incidence of contrast uptake among malignant breast lesions where out of 145 enhancing breast lesions, 103 (71%) were malignant and 42 (29%) were benign.

Regarding lesions that showed mass enhancement, assessment was done according to shape, margin, internal enhancement pattern and intensity of enhancement. In lesions demonstrating mass enhancement (26/34), no significant association between mass shape and histopathology could be found; since 14/18 (77.7%) malignant lesions demonstrated a round or oval shape while only 4/18 (22.2%) malignant lesions demonstrated an irregular shape. This correlates with a study by Helal et al., [13], where only 37.5% of malignant mass enhancing lesions were irregular in shape. In a study by Kamal et al., [14], the shape that

showed that highest prediction for malignancy was the irregular shape however they concluded that malignancy could not be excluded based on a round or oval morphology alone, which only showed a NPV of 44.9%.

When considering the margins of a mass enhancing lesion we found a significant association ($p<0.0001$) between the margin and the histopathology of the mass enhancing lesions: 18/18 (100%) malignant mass enhancing lesions showed an irregular/speculated margin while 8/8 (100%) benign mass enhancing lesions showed a circumscribed margin. These results are highly comparable to the study by Kamal et al., [12], where 78/81 (96.3%) malignant mass enhancing lesions showed an irregular/speculated margin while 15/18 (83.3%) benign mass enhancing lesions showed a well-defined margin.

Internal enhancement patterns of mass enhancing lesions that showed that highest prediction for malignancy were the heterogeneous (16/18, i.e 88.8%) and the rim enhancing patterns (2/18, i.e 11.2%). Our results are comparable to the study by Helal et al., [13] which demonstrated heterogeneous enhancement in 93.8% of malignant mass enhancing lesions and ring enhancement in 6.3% of the remaining mass enhancing malignant lesions. Regarding intensity of mass enhancing lesions, the moderate and intense degrees of enhancement were strongly correlated with malignant pathology ($p=0.03$). This is in keeping with the study by Helal et al., [13] where 14/16 (87.5%) malignant mass enhancing lesions demonstrated moderate and intense uptake ($p<0.03$).

Regarding the non-mass enhancing lesions, assessment was done according to distribution, intensity and internal pattern of enhancement. In the study by Helal et al., [13], none of these parameters were significantly associated with malignancy. In our study we found a significant association between the intensity of enhancement (intense enhancement favoring malignancy while moderate enhancement favoring benignity) and pattern of enhancement (heterogenous pattern towards malignant pathology); however both our studies only included analysis of 6 non-mass enhancing lesions in contrast to a study by Kamal et al., [12], that included analysis of 46 non-mass enhancing lesions with a significant association between the above mentioned parameters and the likelihood of malignancy.

As regards the foci of enhancement pattern, all lesions in our study exhibiting this enhancement pattern were pathologically proven as benign with

no malignant counterpart so no criteria could be defined as points of differentiation between benign and malignant pathologies.

The overall performance of CESM in our study was reported as a sensitivity of 100%, a specificity of 81.8%, a positive predictive value of 84.6%, a negative predictive value of 100% and an accuracy of 90.9%. These results are highly comparable to the indices in the study by Saraya et al., [15], which demonstrated a sensitivity of 93.7%, a specificity of 91.3%, a positive predictive value of 88.2%, a negative predictive value of 95.4% and an accuracy of 92.3%.

Conclusion:

Mass enhancing lesions on CEM are more easily categorized into benign and malignant pathologies in comparison to lesions that show non-mass enhancement patterns. CEM can be a valuable tool when incorporated in the workup of indeterminate breast lesions, providing more confident assessment of patients with equivocal findings.

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تقييم آفات المشكوك بها (درجة ٤ من نظام بيرادز): فائدة الماموجرام بالصبغة

المقدمة: يعد سرطان الثدي من أكثر السرطانات شيوعاً بين السيدات في مصر ويحتل المرتبة الأولى بين أسباب الوفاة الناتجة عن الإصابة بمرض السرطان. الماموجرام بالصبغة هو فحص جديد يدمج الحقن بالصبغة مع تصوير الماموجرام التقليدي. يعتبر الماموجرام بالصبغة من الفحوصات الحساسة والدقيقة في إكتشاف سرطان الثدي لأنه يعطى صورة أوضح و أكثر شمولاً من الماموجرام التقليدي أو حتى الماموجرام المصحوب بفحص الموجات فوق الصوتية.

الهدف من البحث: تقييم مدى الافادة من الماموجرام بالصبغة فى فحص آفات الثدي المسكوك بها 0.

المرضى وطرق البحث: هذه الدراسة أجريت على ٣٢ سيدة من المترددين على وحدة المرأة بقسم الأشعة بمستشفى عين شمس الجامعى وقد تم تشخيصهم من قبل الماموجرام التقليدى أو من قبل الموجات الصوتية على أن لديهم آفات مشكوك بها وهم فى احتياج للمزيد من التقييم الطبى. تم حقن جميع الحالات بالصبغة الغير مؤينه وبعد ذلك خضعوا لفحص الماموجرام بالصبغة.

النتيجة: الماموجرام بالصبغة استطاع تأكيد ٢٢/٢٢ من الآفات المشكوك بها على أنها خبيثة مما تناسب مع تحليل الباثولوجى للأنسجة. أيضاً استطاع التأكيد على تشخيص حميد فى ١٨/٢٢ من الآفات المشكوك بيها. كان هناك التباس فى ٤ آفات تم تقييمهم على أنهم آفات خبيثة مما لم يتناسب مع تحليل الباثولوجى. لم يكن هناك آفات خبيثة تم تشخيصها على أنها حميدة من قبل الماموجرام بالصبغة.

الخلاصة: يعد الماموجرام بالصبغة من الفحوصات المفيدة بدرجة كبيرة فى تقييم آفات الثدي المشكوك بها ويزيد من الثقة فى التشخيص.