

ROLE OF 3D DIGITAL MAMMOGRAPHY IN STUDYING BREAST LESIONS IN ADULT FEMALES OF DENSE BREAST

By

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ABSTRACT

Background: Digital breast tomosynthesis (quasi three-dimensional [3D] mammography) is a relatively novel technique. It creates thin-slice reconstructions of the breast from low-dose digital mammographic images acquired at multiple angles. This evolution of mammography improves lesion visibility by reducing overlapping tissue. Hence, it has the potential to increase BC detection and to reduce false-positive (FP) findings.

Objective: To review the role of 3D Digital Mammography in Studying of dense breast Lesions in adult female.

Patients and methods: This was a retrospective study conducted on 40 patients who were eligible for examination by 3D Digital Mammography referred to WAFI center (women and fetal imaging center). The study was conducted during 12 months from January 2019 till January 2020 and was carried at Al-Azhar University Hospitals and WAFI Center (Woman and fetal imaging center).

Results: There was no statistically significant difference between ultrasound (US) and tomosynthesis (TOMO) as regarding mass detection. There was a statistically significant increase as regarding calcification detection in TOMO than US. There was a statistically significant increase as regarding asymmetry detection in TOMO than US. There was no statistically significant difference between US & TOMO as regards Arch. Distortion detection. There was no statistically significant difference between US & TOMO as regards inflammatory reactions detection. There was statistically significant increase as regarding cyst detection in US than TOMO. There was a statistically significant increase as regarding dilated ducts detection in US than TOMO. There was a statistically significant increase as regarding added value detection in US than TOMO. There was no statistically significant difference between US & TOMO as regarding Breast Imaging-Reporting and Data System (BI-RADS).

Conclusion: Both modalities were not similar in the ability to identify malignant lesions. Wide-angle digital breast tomosynthesis (DBT) was able to initially identify two more lesions <1cm in size; one more malignant focus in a patient with a multi-focal disease, and a small malignant lesion, a case with multiple benign lesions. Both lesions presented as small area of architectural distortion on DBT images (statistically, no significance despite the difference between the two modalities, $p=0.07$), also DBT has higher detection rate than US as regard calcification and focal asymmetry.

Keywords: 3D Digital Mammography, Breast lesions, Adult females, Dense breast.

INTRODUCTION

Two-dimensional full-field digital mammography (2DDM) has been the standard of care for X-ray examination of the breast in women aged 40 years presenting with breast symptoms, and for routine breast cancer screening offered to asymptomatic women aged 50 years, and to women aged from 40 years with a moderate or high risk of breast cancer (*Garcia et al., 2016*).

Mammographic surveillance may be considered for women aged 30-39 years with a high risk of breast cancer and those with a BRCA1 or BRCA2 mutation. The accuracy of 2DDM in screening is limited because of the effect of superimposition of normal breast structures and abnormal features onto a two-dimensional image. The mammographic signs of breast cancer may be partially or completely obscured, particularly in women with a dense glandular parenchymal pattern on mammography, leading to delays in the diagnosis of breast cancer (*Michell and Batohi, 2018*).

Digital breast tomosynthesis is an evolution of full-field digital mammography involving quasi-three-dimensional transformation of breast images. By acquiring projection images that are reconstructed as a series of slices through the breast, tomosynthesis has the potential to improve visualisation of breast cancer due to a reduction in the effect of tissue superimposition on standard mammography (*Houssami and Skaane, 2013*).

Tomosynthesis in the screening setting has been evaluated in prospective studies that show detection of additional cancers when tomosynthesis is added to

mammography or synthetic 2D images reconstructed from 3D acquisitions versus 2D mammography alone (*Bernardi et al., 2016*).

Ultrasonography (US) has been playing an increasingly important role in the evaluation of breast cancer. US is useful in the evaluation of palpable masses that are mammographically occult, in the evaluation of clinically suspected breast lesions in women younger than 30 years of age, and in the evaluation of many abnormalities seen on mammograms. Some breast imagers believe that US is the primary modality for the evaluation of palpable masses in women 30 years of age and older and that mammography plays an adjunctive technique. US is also useful in the guidance of biopsies and therapeutic procedures; research is currently under way to evaluate its role in cancer screening. Originally, ultrasonography was primarily used as a relatively inexpensive and effective method of differentiating cystic breast masses from solid breast masses. However, it is now well established that US also provides valuable information about the nature and extent of solid masses and other breast lesions (*Koo et al., 2017*).

Furthermore, tomosynthesis has been demonstrated to improve cancer detection in women with dense breasts, for whom cancer may be “masked” by tissue superimposition on conventional mammography given such improvements in breast cancer detection, the application of tomosynthesis to the pretreatment assessment of cancer extent is an important area for further study, particularly given the increasing adoption

of tomosynthesis into population screening practice and the availability of those screening images for breast cancer staging. More accurate measurement of tumor size at initial staging may better inform surgical management including informing decisions about eligibility for breast conservation, and planning resection to achieve clear margins (*Phi et al., 2018*).

Measurement of tumor size is inherently subjected to error. For example, the longest tumor dimension visible on imaging may not correspond to the dimension measured at pathology, resulting in underestimation of pathologic size. Conversely, imaging may overestimate size (*Luke Marinovich et al., 2018*).

Due to dense tissue being difficult to distinguish from tumor. Quasi-3D images from tomosynthesis have potential advantages over 2D mammography in reducing such measurement errors. Current guidelines for the diagnosis and evaluation of breast cancer note the potential of tomosynthesis to improve accuracy for staging, particularly for women with dense breasts, but do not yet recommend its routine use outside the screening setting (*Senkus et al., 2015*).

The present study aimed to review the role of 3D digital mammography in studying of dense breast lesions in adult female.

PATIENTS AND METHODS

This was a retrospective study conducted on 40 patients who were eligible for examination for 3D Digital Mammography referred to Al-Azhar University Hospitals and WAFI center

(women and fetal imaging center). The study was conducted during 12 months from January 2019 till January 2020.

All patients were submitted to the following:

1. Demographic and clinical data collection including patient's name, age, marital status and number of offspring's, lactating history, residence and phone number, diagnosis, past history and family history.
2. Imaging modality: Women above the age of 40 were examined with 2D mammogram + wide-angle DBT and 2D HHUS. Women below the age of 40 were initially examined by HHUS and obtained complementary wide-angle DBT mammography based on clinical necessity.
3. Written informed consent was taken from every patient for enrollment in this study.

All exams were performed for the patient at the same visit (no recalls).

Inclusion criteria: Women who are coming for screening if high risk patient with dense breast and patients complaining of breast lump or pain or discomfort with dense breast.

Exclusion criteria: Pregnant females.

Technique of 3D Tomosynthesis:

For 3D digital tomosynthesis two views (MLO and CC) were obtained. Three dimensional wide-angle DBT involved the acquisition 50° wide-angle projection exposures by a digital detector from a mammographic X-ray source which moved over a limited arc angle. The 3D volume of compressed breast was

reconstructed from the 2D projections in the form of series of images (slices) through the entire breast. Images were assessed on the workstation.

Image analysis and interpretation of 3D digital tomosynthesis:

1. After imaging analysis process, data were collected including age, breast density, type of examination and referral (screening or diagnostic).
2. Radiological abnormalities identified by wide-angle (DBT) tomosynthesis and ultrasound were detected.
3. Separate BI-RADS were given for each modality.
4. The final diagnostic results for each modality were correlated with histopathological results for BI-RADS category 4 and 5, or routine follow up images for BI-RADS category 3 (*Birads, 2013*).

Statistical analysis:

Collected data were tabulated and analyzed by SPSS (statistical package for the social sciences) version 25 (Armonk, NY: IBM Corp) on IBM compatible computer. The data were tested for normality using Kolmogorov–Smirnov test, Shapiro–Wilk tests.

Qualitative data were represented as number and percentage and quantitative data were continuous group represented by mean \pm SD. Sensitivity, specificity and accuracy was estimated.

Chi-square test (χ^2) was used to study association between two qualitative variables. Student t-test was used for comparison between two groups having quantitative variables with normal distribution (for parametric data). P-value of < 0.05 was considered statistically significant.

RESULTS

Mean of age of patients was 46.83±8.66 years and ranged from 30 to 67 years. Sixty percent of patients had no complaint, while the 40 % of patients their

complaint ranged from palpable mass 17.5%, pain 10% nipple discharge 2.5% to skin discharge 2.5% (**Table 1**).

Table (1): Demographic data and complaint of patients

	Mean±SD	Min-Max
Age (N=40)	46.83±8.661	30-67
	Frequency (N)	Percent (%)
Palpable mass	7	17.5
Pain	4	10.0
Nipple discharge	1	2.5
Skin discharges	1	2.5
No complaint(screening)	24	60.0
Pain & palpable mass	3	7.5
Total	40	100.0

There was no statistically significant difference between ultrasound and TOMO as regarding mass detection. There was a statistically significant increase as regarding calcification detection in TOMO than US. There was a statistically significant increase as regarding asymmetry detection in TOMO than US. There was no statistically significant difference between ultrasound and TOMO as regards arch. distortion detection. There was no statistically significant difference between ultrasound and TOMO as regards

inflammatory reactions detection. There was a statistically significant increase as regarding cyst detection in ultrasound than TOMO. There was a statistically significant increase as regarding added value detection in ultrasound than tomosynthesis. There was a statistically significant increase as regarding dilated ducts detection in ultrasound than TOMO. There was no statistically significant difference between ultrasound and TOMO as regarding BI-RADS (**Table 2**).

Table (2): Comparison between tomosynthesis and ultrasound investigation as regards mass, calcification, asymmetry, arch. distortion, inflammatory changes, cyst, added value, dilated ducts and BI-RADS

			Benign	Suspicious	none	Total	p-value	
Mass	TOMO	Count	20	3	17	40	0.483	
		%	50.0%	7.5%	42.5%	100.0%		
	US	Count	15	5	20	40		
		%	37.5%	12.5%	50.0%	100.0%		
Calcifications	TOMO	Count	17	2	21	40	0.001	
		%	42.5%	5.0%	52.5%	100.0%		
	US	Count	3	1	36	40		
		%	7.5%	2.5%	90.0%	100.0%		
Asymmetry	Tomo	Count	5	2	33	40	0.022	
		%	12.5%	5.0%	82.5%	100.0%		
	US	Count	0	0	40	40		
		%	0.0%	0.0%	100.0%	100.0%		
Arch. Distortion	TOMO	Count	3	7	30	40	0.207	
		%	7.5%	17.5%	75.0%	100.0%		
	US	Count	1	3	36	40		
		%	2.5%	7.5%	90.0%	100.0%		
			Edema	Skin thickening	Lymph nodes	Trabecular thickening	None	p-value
Inflammatory changes	TOMO	Count	0	2	6	1	31	0.543
		%	0.00%	5%	15%	2.5%	77.5%	
	US	Count	2	2	5	0	31	
		%	5%	5%	12.5%	0.00%	77.5%	
			Yes	No	Total	p-value		
Cyst	TOMO	Count	0	40	40	0.00		
		%	0.0%	100.0%	100.0%			
	US	Count	18	22	40			
		%	45.0%	55.0%	100.0%			
Added value	TOMO	Count	21	19	40	0.036		
		%	52.5%	47.5%	100.0%			
	US	Count	30	10	40			
		%	75.0%	25.0%	100.0%			
			Fluid	None	Total	p-value		
Dilated ducts	TOMO	Count	0	40	40	0.040		
		%	0.0%	100.0%	100.0%			
	US	Count	4	36	40			
		%	10.0%	90.0%	100.0%			
			Mean	Std. Deviation	p-value			
BI-RADS	TOMO	2.95	0.932	0.906				
	US	2.98	0.947					

Patients were distributed according to biopsy outcomes into 35(87.5%) negative and 5 (12.5%) positive. the patients were distributed according to TOMO outcomes into 30 (75%) negative and 10 (25%)

positive. Patients were distributed according to ultrasound outcomes into 33(82.5%) negative and 7 (17.5%) positive (**Table 3**).

Table (3): Distribution of the studied cases according to biopsy, TOMO, ultrasound (n = 40)

Distribution Parameters	Negative		Positive	
	No.	%	No.	%
Biopsy	35	87.5	5	12.5
TOMO	30	75.0	10	25.0
Ultrasound	33	82.5	7	17.5

Biopsy outcomes were statistically significantly related to tomosynthesis outcomes (p-value=0.001). The biopsy

were statistically significantly related to ultrasound outcomes (p-value=0.001) (**Table 4**).

Table (4): Sensitivity, specificity and accuracy for TOMO and Ultrasound

TOMO	Biopsy				Sensitivity	Specificity	PPV	NPV	Accuracy
	Negative		Positive						
	(n = 35)		(n= 5)						
	No.	%	No.	%					
Negative (n = 30)	30	85.7	0	0	100	85.7	50	100	87.5
Positive (n= 10)	5	14.3	5	100					
² (p)	17.14*(0.000*)								
Ultrasound:									
Negative (n = 33)	32	91.4	1	20	80	91.4	57.1	97	90.0 %
Positive (n= 7)	3	8.6	4	80					
² (p)	15.47*(0.000*)								

X2: Chi Square test PPV: Positive predictive value NPV: Negative predictive value

Example case:

A 66-year-old woman seen for a tender palpable mump in her right breast. Her mammogram showed heterogeneously dense parenchyma (ACR C). Complementary Right MLO

tomosynthesis showed a smoothly circumscribed mass of equal density with no associated distortion or calcifications which indicated its benign nature (**Figures 1 & 2**).

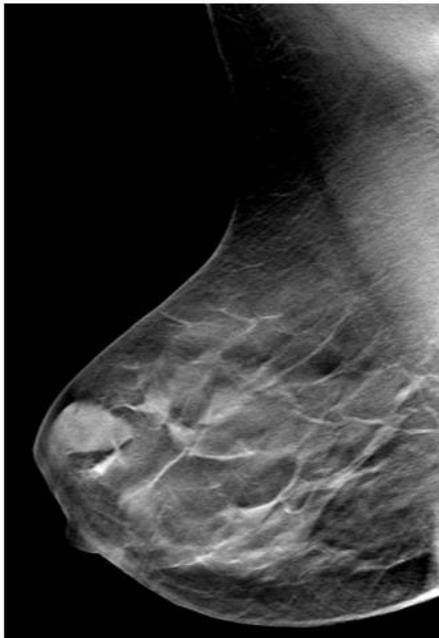


Figure (1): 3b Tomosynthesis MLO.

Complementary right MLO tomosynthesis showed a smoothly circumscribed mass of equal density with no associated distortion or calcifications, which indicated its benign nature.

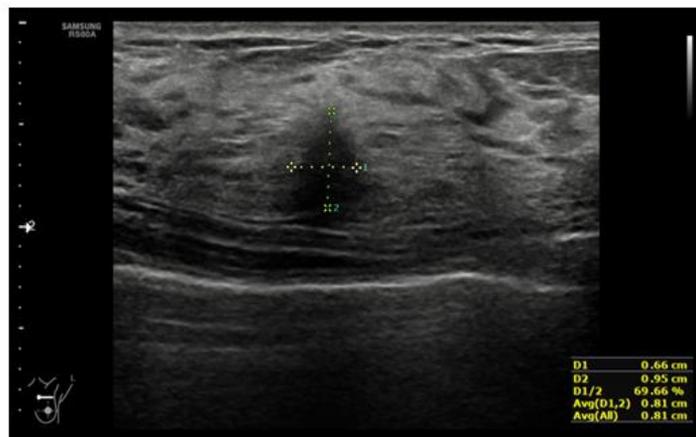
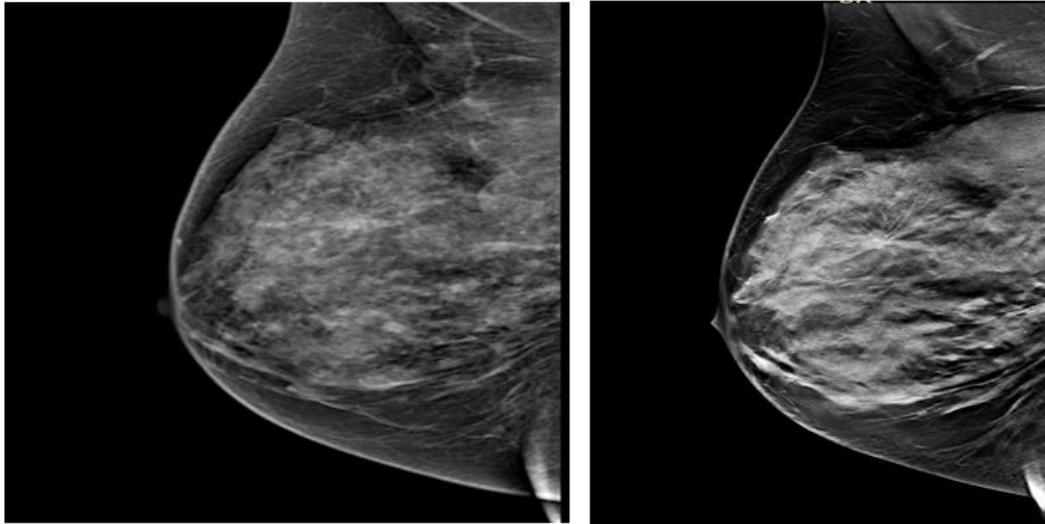


Figure (2): 2D ultrasound.

Complementary ultrasound showed a corresponding sub-dermal complex cystic lesion, tender on probing, with surrounding edematous fat lobules denting inflammatory process (sub-dermal abscess).

Short term follow up with anti-inflammatory/anti-biotic treatment showed significant resolve of the lesion.

Example case 3: a 60 year-old woman is seen for her routine annual screening mammogram



She has an extremely dense breast (ACR D) No definite abnormality was identified in the 2D mammogram. A complementary wide-angle tomosynthesis is performed and showed a definite small suspicious area of architectural distortion

seen at the UOQ of the right breast. Targeted 2D ultrasound showed a corresponding small irregular suspicious hypoechoic solid lesion (9x7 mm). Pathology confirmed early invasive malignant process.

DISCUSSION

The present study revealed that the mean age of participants was 46.83 ± 8.66 years and ranged from 30 to 67 years, compared to the study of *Tagliafico et al. (2016)* where the median age was 51 years (interquartile range, 44 to 78 years; range, 38 to 88 years).

Breast lump is the most common presenting symptom among women with breast cancer and has a relatively high predictive value for malignancy. Consequently, it has long been the focus of public health education campaigns about cancer symptom awareness (*Redaniel et al., 2015*).

The present study revealed that majority of women 60% had no complaint, 17.5% with Palpable mass, 10% had Pain, 2.5% come by nipple discharge, 2.5% Skin discharges and 7.5% had pain & palpable mass.

Koo et al. (2017) reported that breast lump was the most common symptom, recorded in about four-fifths of all women (83%). The next most commonly reported presenting symptoms were nipple abnormalities (7%), breast pain (6%), and breast skin abnormalities (2%).

The present study revealed that there was no statistical significant difference between tomosynthesis and ultra-sound investigation as regards mass detection. However, wide-angle DBT was able to initially identify two more lesions <1cm in size; one more malignant focus in a patient with a multi-focal disease, and a small malignant lesion a case with multiple benign lesions, both lesions presented as small area of architectural distortion on DBT images.

Calcifications are frequent findings in mammography, and can have a variety of causes. Specific patterns of breast calcifications have been associated with an increased positive predictive value of malignancy, whereas others portend benign pathologic abnormalities (*Burnside et al., 2012*). A lot of cases with calcifications of the breast are pointed by the images of mammography (MG), because breast screening using MG become common. Although MG is a gold standard modality for detecting calcifications, images of ultrasonography (US) are feasible to detect micro-calcifications with improvements to

ultrasound diagnostic devices (*Hashimoto et al., 2015*).

The present study revealed that there was a statistical significant difference between tomosynthesis and ultra-sound investigation as regards calcification detection. Digital breast tomosynthesis has been shown to reduce recall rates by resolving overlapping structures seen on mammography, but there is some concern that it may not depict calcifications as well as traditional mammography (*Poplack et al., 2010*).

The present study revealed that there was statistical significant difference between tomosynthesis and US as regard asymmetry detection.

Previous study of *Yang et al. (2013)* in the diagnostic environment have concluded that adjunct DBT is particularly useful for non-calcified lesions, including asymmetries and better delineates lesion margins as compared to DM alone. *Roth et al. (2014)* also made similar observations and found adjunct DBT useful as a problem-solving tool and asymmetry detection. They suggest that DBT could reduce the need for additional views due to its improved capability of analyzing lesion margins, as well as better triangulation of lesions seen on one view only.

Cluster, linear, or segmental distribution of micro-calcifications is suspicious for malignancy (*Yang et al., 2013*).

Takamoto et al. (2013) who investigated the role of DBT in the diagnosis of breast cancer reported the superiority of DBT in diagnosing mass,

focal asymmetric density and parenchymal distortion.

The present study revealed that there was no statistically significant difference between US & TOMO as regards inflammatory reactions detection, where skin thickness detected in 2 CASES in both US and TOMO and L.N 5 in US and 6 in Tomo. However, ultrasound was more accurate than TOMO in characterization of inflammatory lesions as two of the diagnostic cases presented with acute inflammatory symptoms; one showed architectural distortion in DBT, which was a false positive for DBT, and the other case presented by a circumscribed mass lesion in DBT, ultrasound showed mastitis and an abscess in these two cases respectively.

Screening breast ultrasonography has been shown to detect early stage, mammographically occult breast cancer, especially in women with dense breasts. Many studies have evaluated supplemental ultrasound screening in high risk women with dense tissue, and have shown an increased detection of small, invasive node negative cancers as compared to mammography alone (*Brem et al., 2015*).

The present study revealed that there was a statistical significant difference between US and tomosynthesis as regard cyst detection and dilated ducts detection with higher detection rate by US. In a similar study, *Lee et al. (2016)* demonstrated that diagnostic performance of DBT is superior to US in category-5 dense breasts and emphasized that DBT reduces the false positive rates and short-interval follow-up.

The present study demonstrated that there was a statistical significant difference between both US and tomosynthesis as regard added value in detection of dense breast lesions with higher value in US.

Evidence reviews of adjunct screening technologies for women with mammography-negative dense breasts have concluded that ultrasound shows substantial but heterogeneous incremental breast cancer detection (*Lauby-Secretan et al., 2015*). On the other hand, if adjunct ultrasound is not routinely performed in mammography-negative dense breasts, then our results could be taken to support use of adjunct tomosynthesis despite its lower incremental CDR relative to ultrasound. The rationale is that through tomosynthesis-based mammography (assuming that it also provided the reconstructed 2D images), a substantial proportion of the additionally detected BCs on adjunct ultrasound would be identified through the primary tomosynthesis screen (*Tagliafico et al., 2016*).

Various methods of breast density classification exist, ranging from the early classification systems of Wolfe and Tabár to the most commonly used BI-RADS classification of the ACR (*D'Orsi et al., 2013*). The BI-RADS lexicon classifies breast density on mammography according to four categories, which are mainly assessed qualitatively by subjective visual estimation of the reporting radiologist (*Wengert et al., 2018*).

Additionally, the current study revealed that there was no statistical significant difference between

tomosynthesis and ultra sound investigation as regards BI-RADS. *Emlik et al. (2017)* reported that there was no statistical significant difference between tomosynthesis and ultra sound investigation as regards BI-RADS.

The present study revealed that the patients were distributed according to biopsy outcomes into 87.5% negative, and 12.5% positive, while the patients were distributed according to tomosynthesis outcomes into 75% negative and 25% positive, and we found that according to US outcomes into 82.5% negative and 17.5% positive.

The present study found that sensitivity and specificity of tomosynthesis was 100% and 85.7% respectively for detection of cancer breast, while the sensitivity and specificity of ultrasonography was 80% and 91.4% respectively for detection of cancer breast. In comparison to the study *Emlik et al. (2017)* reported that as regard to the diagnostic performance of additional DBT and US procedures, the sensitivity was 96% and 93%; specificity was 82% and 79%; diagnostic accuracy was 84% and 81%; NPV was 99% and 98%; and PPV was 48% and 47%, respectively. Moreover, AUC value was 0.89 for DBT and 0.86 for US. Based on these outcomes, we can say that diagnostic performance is superior for DBT according to US.

CONCLUSION

Both modalities were not similar in the ability to identify malignant lesions; wide-angle DBT was able to initially identify two more lesions <1cm in size; one more malignant focus in a patient with a multi-focal disease, and a small malignant lesion

a case with multiple benign lesions, both lesions presented as small area of architectural distortion on DBT images (statistically, no significance despite the difference between the two modalities, $p=0.07$), also DBT has higher detection rate than US as regard calcification and focal asymmetry.

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دور التصوير الرقمي للثدي ثلاثي الأبعاد في دراسة آفات الثدي لدى الإناث البالغات من الثدي عالي الكثافة

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خلفية البحث: يعد فحص التصوير الشعاعي للثدي أفضل طريقة متاحة لتقليل الإصابة بسرطان الثدي والوفيات المتأخرة. يُعد تكوين الغشاء الصمغي الرقمي للثدي (أو تصوير الثدي بالأشعة ثلاثية الأبعاد) تطوراً من تصوير الثدي رقمي كامل المجال يوفر تحليلاً لبيانات التصوير الشعاعي للثدي ثلاثية الأبعاد من خلال سلسلة من شرائح الصور المقطعية من خلال الثدي مما يسمح بإعادة الإعمار في شرائح رفيعة.

الهدف من البحث: مراجعة دور التصوير بالماموجرام ثلاثي الأبعاد في دراسة إصابات الثدي في السيدات البالغات ذوي الثدي عالي الكثافة.

المريضات وطرق البحث: هذه دراسة استطلاعية أجريت على 40 مريضة مؤهلات لفحص التصوير الشعاعي للثدي الرقمي ثلاثي الأبعاد المحول إلى قسم الأشعة في المعهد الوطني للسرطان.

نتائج البحث: لم يكن هناك فرق ذو دلالة إحصائية بين السونار وتومو فيما يتعلق بالكشف الشامل. وكانت هناك زيادة ذات دلالة إحصائية فيما يتعلق بالكشف عن تكلس في التصوير بالماموجرام ثلاثي الأبعاد من السونار. وكانت هناك زيادة ذات دلالة إحصائية فيما يتعلق بالكشف عن عدم التماثل في التصوير بالماموجرام ثلاثي الأبعاد من السونار. ولم يكن هناك فرق ذو دلالة إحصائية بين الموجات الصوتية وتومو فيما يتعلق القوس. وكشف التشويه. ولم يكن هناك فرق ذو دلالة إحصائية بين السونار وتومو فيما يتعلق بالكشف عن ردود الفعل الالتهابية. وكانت هناك زيادة ذات دلالة إحصائية فيما يتعلق بالكشف عن الكيس في السونار من التصوير بالماموجرام ثلاثي الأبعاد. وكانت هناك زيادة ذات دلالة إحصائية فيما

يتعلق بالكشف عن القنوات الموسعة في السونار من التصوير بالمماموجرام ثلاثي الأبعاد. كما كانت هناك زيادة ذات دلالة إحصائية فيما يتعلق بالكشف عن مظاهر أخرى في التصوير بالمماموجرام ثلاثي الأبعاد من السونار. كذلك، كانت هناك زيادة ذات دلالة إحصائية فيما يتعلق بالكشف عن القيمة المضافة في السونار. لم يكن هناك فرق ذي دلالة إحصائية بين السونار وتومو فيما يتعلق بنظام التقارير والمعطيات عن تصوير الثدي.

الاستنتاج: لم تكن الطريقتين متشابهتين في القدرة على تحديد الأفات الخبيثة، وكان تخليق الثدي الرقمي واسع الزاوية قادراً على تحديد آفتين أخريين بحجم أقل من 1 سم، وتركيز خبيث آخر في مريضة مصابة بمرض متعدد البؤر، وآفة خبيثة صغيرة حالة ذات آفات حميدة متعددة، وتم تقديم كلا الأفتين كمنطقة صغيرة من التشويه المعماري على صور التركيب المقطعي للثدي الرقمي.

الكلمات الدالة: التصوير الرقمي ثلاثي الأبعاد، آفات الثدي، الإناث البالغات، الثدي عالي الكثافة.