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Original Research Article

Role of sonomammography and its diagnostic accuracy for evaluating benign and malignant breast lesions

M. Dawood Khan[1]*, Subhra Banerjee[2], Swarnadeep Tarafdar[2], Debabrata Kundu[2]

[1]Department of Urology, [2]Department of General Surgery, Medical College and Hospital, Kolkata, West Bengal, India

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***Correspondence:**
Dr. M. Dawood Khan,
E-mail: dk.onco@gmail.com

ABSTRACT

Background: Mammography and ultrasound are the best-known techniques used for screening and diagnosis of breast cancer. This study evaluated the accuracy of sonomammography in diagnosing breast lesions, both benign and malignant separately and confirmation of the findings by histopathology.
Methods: A prospective study was conducted for 18 months in women aged above 15 years with breast lesions or symptoms of breast diseases. The diagnosis protocol consisted of clinical breast examination, mammography, ultrasound and histopathological examination. Mammograms were interpreted according to the breast imaging reporting and data system (BI-RADS) diagnostic categories on a five-point scale. This was followed by ultrasound imaging of the breast and axilla with ultrasound-guided fine needle aspiration cytology (sonomammography-FNAC) from the breast lump.
Results: Among the 52 patients, three patients were divorced, 40 were married and nine were unmarried. Eight had a history of oral contraceptive pills (OCP) use and one patient had a family history of breast lesions. The mammography report revealed 31 patients suspected to be malignant and 21 patients to be benign. According to the sonomammography report, 32 patients were suspected to be malignant while 20 patients were suspected to be benign. Correlation between mammography report, sonomammography report and grade versus histopathological finding also showed significance with $p<0.0001$.
Conclusions: Sonomammography reveals good sensitivity and specificity for detecting all breast lesions. Hence it can be considered as a suitable means of investigation than mammography especially in patients less than 40 years of age.

Keywords: BI-RADS, Breast cancer, Histopathological, Mammography, Sensitivity, Specificity, Ultrasonography

INTRODUCTION

Breast cancer is the fifth leading cause of death amongst women globally. Among different cancers occurring in women, breast cancer is the commonest where the incidence rate is one in four women with cancer. As per Globocan factsheet of the year 2018, the number of deaths occurred due to breast cancer worldwide was 626,679.[1] Asia is at the top in terms of incidence rate (43.6%), mortality (49.6%) and prevalence (38.2%) of breast cancer.[2] Women with breast mass or lesions need to undergo mammography, but in certain cases heavy breast tissue particularly in young women reduces the sensitivity of mammography. In such conditions, ultrasound mammography is an appropriate diagnostic tool to detect breast cancer. Breast ultrasonography, also called as sonomammography, apart from assessing palpable breast mass, can extricate cysts from solid mass and trace anomalies in the peripheral view which is not spotted by mammography.[3,4] It is a non-invasive method, free of radiations hence very useful in lactating and pregnant women. It is a suitable method of assessment in post-surgical, irradiated breast and painful conditions where use of mammography is discouraged.[5,6]

Sonomammography has advantages but higher rate of false positive diagnosis in sonomammography is reported.[7]

In India, breast cancer is progressing rapidly every year and is the leading form of cancer surpassing other cancer types in women. Indian women hesitate to seek medical help due to orthodox society and lack of awareness.[8,9] Hence medical awareness among people is a necessity along with diagnostic screening methods like sonomammography and mammography to reduce mortality and burden on the health care system.

Therefore, the present study aimed to evaluate the accuracy of sonomammography in diagnosing breast lesions, both benign and malignant separately and confirmation of the findings by histopathology. Efforts were made to diagnose and categorize the lesions using ultrasonography and to differentiate whether a lesion is solid or cystic.

METHODS

This was a prospective, observational study conducted at out patients department (OPD) of General Surgery Medical College and Hospital, Kolkata, West Bengal. The duration of the study was 18 months, conducted from January 2017 to June 2018 in female patients aged above 15 years. The study protocol was approved by the institutional ethics committee. The study procedure was in accordance with the Declaration of Helsinki. The written informed consent was obtained from the patients prior to the study enrolment.

Inclusion criteria

Female patients with age above 15 years and those willing for follow up.

Exclusion criteria

Female patients with age less than 15 years, who have not attained menarche and those refusing to take part in the study.

The protocol of diagnosis consisted of clinical breast examination, ultrasound, mammography and histopathological examination. Detailed medical history and clinical examination were performed in all the patients with a palpable breast lump or any other features suggestive of breast diseases.

Physical examination

Clinical breast examination of the whole breasts and axillary regions were performed with the patient in the sitting position with arms both lowered and raised. In an upright position, the breasts were inspected visually, noting asymmetry, nipple discharge, obvious masses, and skin changes (such as dimpling, inflammation, rashes, and unilateral nipple retraction or inversion). The patients were made to lie down in supine position with one arm raised, and the breast tissue, axillary regions and supraclavicular areas were thoroughly palpated, assessing the size, texture, and location of any masses.

Mammography

The next diagnostic test performed in women above 35 years with a palpable breast lump was mammography. Conventional film-screen mammography was performed with at least two views per breast, medio-lateral oblique and cranio-caudal views. Additional views or spot compression views were obtained wherever appropriate. Mammograms were obtained with dedicated mammography units (Alpha RT Imaging, General Electric Medical Systems, Milwaukee). Mammograms were interpreted according to the Breast Imaging Reporting and Data system (BI-RADS) diagnostic categories on a five-point scale, with BI-RADS 1 (negative), 2 (benign finding), 3 (probably benign), 4 (suspicious abnormality), and 5 (highly suggestive of malignancy). This was followed up by ultrasound imaging of the breast and axilla with ultrasonography (sonomammography)-guided fine needle aspiration cytology (FNAC) from the breast lump. Patients with mastalgia but without any definite mass clinically were evaluated by ultrasound breast.

Sonomammography

Ultrasound examinations were performed using a high-resolution unit (Aloka SSD; Tokyo, Japan and Mindray DP Plus) with a linear array probe centred at 7.5 MHz. All ultrasound examinations were performed with the patient in a supine position for the medial parts of the breast and in a contra lateral posterior oblique position with arms raised for the lateral parts of the breast. The whole breasts were scanned. Diagnoses were scored on a five-point scale identical to the mammographic BI-RADS categories. For any suspicious lesion found on ultrasound, the sonomammography-FNAC was done besides the routine investigations. The patients who desired surgery and in those where indicated, underwent excisional biopsy and histopathological examination of the excised lump.

Histopathological examination was done among the 52 breast lesions. FNAC was done for all suspected benign lesions and trucut biopsies were done for all suspected malignant lesions. Final histologic diagnosis was obtained for all the patients who underwent surgical biopsy and verified by reviewing the histopathology report.

Statistical analysis

Statistical analysis was performed by SPSS version 24.0 and GraphPad Prism version 5. Data was presented as mean and standard deviation (SD) for numerical

variables, count and percentages for categorical variables. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. A p value <0.05 was considered statistically significant.

RESULTS

Total 52 female patients visiting the OPD were enrolled in the study. The baseline characteristics are presented in Table 1.

Tables 1: Demographics and baseline characteristics (n=52).

Characteristics	Number of patients N (%)
Age (years)	
≤30	15 (28.8)
31-40	18 (34.6)
41-50	13 (25.0)
51-60	6 (11.5)
Marital status	
Divorced	3 (5.8)
Married	40 (76.9)
Unmarried	9 (17.3)
OCP use	
Yes	8 (15.4)
No	44 (84.6)
Family history	
Yes	1 (1.9)
No	51 (98.1)
Clinical examination	
Malignant	31 (59.6)
Non-malignant	21 (40.4)
Report of mammography	
Malignant	31 (59.6)
Non-Malignant	21 (40.4)
Sonomammography	
Malignant	32 (61.5)
Non-malignant	20 (38.5)
Histopathology	
Malignant	31 (59.6)
Non-malignant	21 (40.4)
Histopathological type	
Ductal carcinoma	25 (48.1)
Fibroadenoma	5 (9.6)
Fibroadenosis	16 (30.8)
Lobular carcinoma	6 (11.5)

Data is shown as n (%). OCP, oral contraceptive pills.

The age of the patients ranged from 21-59 years with an average age of 37.8 years. Among the 52 patients, three (5.8%) patients were divorced, 40 (76.9%) were married and nine (17.3%) were unmarried. Eight (15.4%) had a history of use of oral contraceptive pills (OCP) and one (1.9%) patient had a family history of breast lesions. The mammography report revealed 31 (59.6%) patients suspected to be malignant and 21 (40.4%) patients to be benign. According to the sonomammography report, 32 (61.5%) patients were suspected to be malignant while 20 (38.5%) patients were suspected to be benign. Histopathological report revealed, 31 (59.6%) patients had malignant lesions while 21 (40.4%) had benign lesions. Majority of patients had ductal carcinomas (n=25) and fibroadenosis (n=16).

Table 2: Mammographic features in differentiation of benign from malignant masses.

Features	Benign	Malignant
Mammographic features		
Mass shape		
Oval	+ + +	+ +
Round	+	+ +
Irregular	+	+ + + +
Mass margin		
Circumscribed	+ + + +	+
Microlobulated	+ +	+ + +
Indistinct	+ +	+ +
Spiculated	+	+ + +
Calcification		
Punctate/round	+ + + +	+
Coarse	+ + + +	+
Tubular	+ + +	+ +
Microcalcification	+	+ + +
Granular/casting	+	+ + +
Mixed	+	+ + + +
Architectural distortion	+	+ + + +
Nipple retraction	+	+ + + +
Sonomammographic features		
Mass shape		
Oval	+ + +	+ +
Round	+	+ +
Irregular	+	+ + + +
Mass margin		
Circumscribed	+ + + +	+
Microlobulated	+ +	+ + +
Indistinct	+ +	+ +
Angular	+	+ + +
Spiculated	+	+ + + +
Mass orientation		
Parallel (wide than tall)	+ + + +	++
Not parallel (tall than wide)	+	+ + +
Posterior acoustic features		
No posterior acoustic features	+ + +	+
Enhancement	+ +	+
Shadowing	+ +	+ + +
Combined pattern	+ +	+ +
Lesion boundary		
Abrupt interface	+ + +	+ +
Echogenic halo	+ +	+ + +
Echo pattern		
Hyperechoic	+ + + +	+
Isoechoic	+ + +	+
Hypoechoic	+ +	+ +
Complex	+	+ + + +
Anechoic	+ +	+ +

+, Rare (<1%); ++ Low probability, (<15%); +++, Intermediate probability (16-84%); ++++, High probability (>85%).

Table 2 summarizes mammographic and sono-mammographic features in differentiation of benign and malignant masses. Additional sonomammographic features like posterior acoustic feature, lesion boundary and echo pattern show the probability of malignancy.

The obtained grades of sonomammography according to BI-RADS were as follows; 20 (38.5%) patients had BI-RADS-3, 25 (48.1%) had BI-RADS-4 and 7 (13.5%) had BI-RADS-5 (Figure 1). In case of malignant breast lesions, three (9.7%) patients were ≤30 years of age, 11 (35.5%) patients were in the range of 31-40 years of age, 11 (35.5%) patients were 41-50 years of age and six (19.4%) were >50 years of age. In non-malignant, 12 (57.1%) patients were ≤30 years of age, seven (33.3%) patients were between 31-40 years of age and 2 (9.5%) were between 41-50 years of age. Association of age and histopathological findings was statistically significant (p=0.0006).

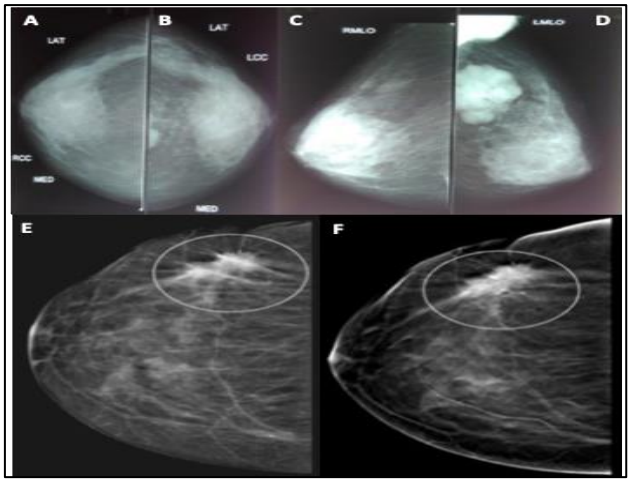

Figure 1: (A-D) BI-RADS-4 left breast and (E-F) BI-RADS-5.

Table 3: Correlation of modality versus histopathology findings.

Clinical versus HP	HP		P value
	Malignant	**Non-malignant**	
Clinical, N	28	3	<0.0001
Malignant	90.3	9.7	
Non-malignant	14.3	85.7	
Mammography, N	31	0	<0.0001
Malignant	100	0	
Non-malignant	0	100	
Sonomammography, N	31	1	<0.001
Malignant	96.9	3.1	
Non-malignant	0	100	
Sonomammography <40 years, N	17		<0.0001
Malignant	100	0	
Non-malignant	100	0	
Sonomammography >40 years, N	14	1	<0.001
Malignant	93.3	6.7	
Non-malignant	0	100	

Data is presented as %, unless otherwise specified. HP, histopathology.

Table 4: Parameters comparing breast lesions by mammography and sonomammography.

Modality	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Mammography report	100	100	100	100
Sonomammography (age <40 years)	100	100	100	100
Sonomammography (age >40 years)	100	94.7	93.3	100
Sonomammography in benign lesions	95.23	100	100	96.87
Sonomammography in malignant lesion	100	95.23	96.87	100

Data is presented as %.

Table 3 presents the correlation of different modalities versus histopathological findings. According to the report of mammography in malignancy, all the patients were malignant and association of report of mammography versus histopathological findings was statistically significant (p<0.0001).

According to histopathological type in malignant, 25 (80.6%) patients had ductal carcinoma and six (19.4%) patients had lobular carcinoma. According to histopathological type in non-malignant, five (23.8%) patients had fibroadenoma and 16 (76.2%) patients had fibroadenosis. Association of histopathological type

versus histopathology results was statistically significant (p<0.0001).

According to the grade of sonomammography in malignant, 24 (77.4%) patients had BI-RADS-4 and seven (22.6%) patients had BI-RADS-5. According to the grade of sonomammography in benign, 20 (95.2%) patients had BI-RADS-3 and one (4.8%) patients had BI-RADS-4. Association of grade of sonomammography with report of histopathology was statistically significant (p<0.0001). Table 4 presents the sensitivity, specificity and predictive values of mammography and sonomammography (younger and older patients, benign and malignant lesions). The sensitivity and specificity of sonomammography of breast for detecting all lesions (benign and malignant) are 100.0% and 95.2% respectively. The positive and negative predictive values of sonomammography are 96.9% and 100% respectively.

DISCUSSION

Breast cancer is a rapidly emerging health issue in Indian women. Awareness about its diagnosis and management among the general public has resulted in decrease of mortality rates. All women are at a risk of developing breast cancer especially in the age above 50 years. Most important factor in reducing death from breast cancer is its early detection. Patient delay in diagnosis are normally influenced by factors such as single marital status and advanced age.[10,11] Breast self-examination and clinical breast examination are low cost approaches to detect breast cancer.

The most efficient methods for diagnosis of breast cancer comprises of imaging techniques like mammography and ultrasound. Women showing symptoms like palpable breast lump, bloody nipple discharge, skin dimpling/ retraction are endorsed to undertake mammography, MRI and sonomammography as a diagnosis. There are circumstances where mammograms are unable to detect breast lesions or any anomalies and even pregnant women or those prohibited from exposure to x rays or having increased breast density are forbidden from mammography technique. Thus, in such conditions sonomammography is an ideal and reliable method for early diagnosis of breast cancer.[12]

In the present prospective study, patients were examined clinically and underwent imaging modalities like ultrasonography and mammography. Cytology/histology results were obtained by FNAC/true cut biopsy. The age of the enrolled patients ranged from 21 to 59 years. Majority of the patients (n=18) were within the age group 31-40 years followed by 15 patients below 30 years. Devolli-Disha et al reported studies with similar age range (above 30 years) for evaluation of sonomammography.13 Histopathological correlation revealed 31 patients diagnosed with malignant while 21 patients were non-malignant.

The present study revealed, 25 ductal carcinoma and 6 lobular carcinoma among 31 malignant patients that was in concordance with the reported literature.[14] Among 21 benign cases, majority of patients (n=16) had fibroadenosis and 5 patients had fibroadenoma. BI-RADS is a tool used in sonomammography, mammography and MRI for assessing and interpreting breast imaging wherein a score is given indicating the malignancy.[15] Higher the score greater is the risk of being malignant. In sonomammography, 25 (48%) patients were classified to be BI-RADS-4, and seven patients (13%) came under BI-RADS-5 which highly signifies malignancy. Twenty patients (38%) presented with BI-RADS-3 having a higher probability of being benign. Thirty-five percent patients showed malignancy in the age group between 31-40 years and 57.1% patients showed non-malignancy in age group ≤30 years. The present study reveals additional features like posterior acoustic features, lesion boundary and echo pattern using sonomammography to differentiate between benign and malignant masses that is in concordance with the results reported by Chandak et al.[14] Correlation of age (p<0.0006), clinical findings (p<0.0001) and histopathological type (p<0.0001) with histopathological findings were found to be significant.

Further mammography report, sonomammography report and grade vs histopathological finding also showed significance with p<0.0001. However, correlation of marital status (p=0.9389), use of OCP (p=0.5468) and family history (p=0.2198) showed non-significance.

The sensitivity of sonomammography in detecting benign breast lesions is 95.23% while that of malignant is 100%. Similarly, Badu-Peprah et al assessed overall sensitivity and specificity of mammography and sonomammography that was found to be 73%, 80% and 100%, 80.4% respectively.[16] Sonomammography is more sensitive than mammography for breast lumps in patients less than 40 years of age.[17-19] The reason may be the presence of denser breasts which are less fatty and tumors that are surrounded by more fatty tissue are easily visible in a mammogram.[20] Therefore, experts recommend ultrasound in younger women and mammography in older women. In the present study, comparison of mammography and sonomammography results establishes the overall accuracy of sonomammography in detecting benign and malignant lesions. So, it can be used as a routine screening investigation for breast lesions. However, Devolli-Disha et al reported higher sensitivity and specificity (72.6% and 88.5%) of sonomammography in symptomatic younger women (less than 45 years).[13] Likewise, Stavros et al have reported high sensitivities for the sonomammography (99.8%) in comparison to mammography to differentiate benign and malignant breast lesions.[21] A study conducted by Beerappa et al showed insignificant differences between sensitivity and specificity of mammography and sonomammography in assessment of breast lesions, but a significant difference was observed when mammography used alone and mammography and sonomammography combination.[22] In

the present study, the sensitivity and specificity of sonomammography was comparatively higher than the study by Gonzaga, where the sensitivity and specificity of sonomammography was 57.1% and 62.8%, respectively.[23] Authors acknowledge few limitations of this study. First, the study was limited by the small sample size. Second, the study was conducted as a single centre, hence results need to be generalized cautiously.

CONCLUSION

Sonomammography reveals good sensitivity and specificity for detecting all breast lesions. Hence it can be considered as a suitable means of investigation than mammography. It can be used as a primary screening modality for breast lumps in patients less than 40 years of age. Classification using BI-RADS is useful in understanding and management of breast lesions.

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