Original Research Article

Diagnostic Validity of Ultrasound Elastography and B Mode Ultrasound with Mammography in Solid Breast Masses in Correlation with Histopathological Examination

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Abstract

Background: Global breast cancer incidence increases at an annual rate of 3·1%. Over 100,000 new breast cancer patients are estimated to be diagnosed annually in India. Early, sensitive and accurate diagnosis lead to better prognosis and reduce the risk of death caused by breast cancer by 40% or more. **Objective:** To compare the diagnostic validity of mammography combined with B mode ultrasound and ultrasound elastography in detection of the nature of breast lesions (benign or malignant) separately and in combination with histopathology (HPE) as the gold standard. **Methods:** This prospective study conducted in a tertiary care teaching hospital included 100 female patients who came for screening or diagnostic mammography and had solid breast lesions of BIRADS category 3 and above. Patients with simple and complicated cystic lesions were excluded from the study. Socio demographic details and family history details were collected from the study participants and then subjected to mammography and B mode ultrasonography and further analysed with Ultrasound Elastography. Patients who have all the above examination findings were subjected to fine needle aspiration cytology (FNAC) / Biopsy / surgery to obtain the histopathology examination findings. The data collected were entered in MS Excel and analysed using SPSS software version 21. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of the investigations were determined. **Results:** Among the 100 cases, 75 cases were diagnosed as malignant and 25 cases as benign by histopathological diagnosis. Of the 75 malignant cases, 73 were found to be infiltrating ductal carcinoma and one case of malignant phylloides tumour and papillary carcinoma each. The Ultrasound along with mammography had a sensitivity of 98.6% and specificity of 68% in diagnosing malignant breast carcinomas with accuracy of 91% (83.7% - 95.2%). The Elastography had a sensitivity of 97.3% and specificity of 64% with accuracy of 89% (81.3% - 93.7%). The Elastography combined with Ultrasound and mammography findings, had a sensitivity of 97.3% and specificity of 84% with accuracy of 94% (87.5% - 97.2%). **Conclusions:** Ultrasound Elastography and mammography combined with B mode ultrasound in evaluation of solid breast lesions for predicting malignancy had a good sensitivity and predictive values of which USG with mammography had a slightly higher validity than USG Elastography. When combined USG with mammography and Elastography, the specificity is very much increased and the accuracy of prediction is higher than compared to the investigations conducted individually.

Keywords: Breast carcinoma, Ultrasound, Elastography, Mammography, Histopathology

Introduction

Breast cancer is the most frequent cancer among women in the world and its incidence increases 3·1% annually worldwide[1]. The health care burden related to breast cancer in India has been steadily mounting. In India, approximately one lakh new breast cancer patients are diagnosed annually[2]. Early, sensitive and accurate diagnosis lead to better prognosis and reduce the risk of death caused by breast cancer by 40% or more[3]. An approximate 15-20 % and 16-35 % reduction in breast cancer mortality is associated with mammography screening for women aged 40-49 years and 50-69 years respectively[4].

A mammography is an x-ray of the breast that uses very low levels of radiation. The images capture calcifications and masses, which include benign cysts that are fluid-filled, benign solid tumors and cancer. To confirm that an abnormal mass is cancer, a biopsy is undertaken and may be a fine-needle biopsy, core biopsy or surgical biopsy. Ultrasound elastography is a non-invasive imaging technique that can be used to depict relative tissue stiffness or displacement (strain) in response to an imparted force (stress)[5].

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Breast Ultrasonography is a useful diagnostic adjunct to mammography[6]. Breast ultrasound offers the advantage of distinguishing cystic lesions from solid lesions and can be used to determine whether partially obscured or indistinct lesion borders at mammography are caused by surrounding fibrous tissue or mass infiltration. Breast ultrasound is also helpful in determining whether mammographic abnormalities such as focal asymmetry are true lesions or summations. Breast ultrasound also serves as guiding tool in doing fine needle aspiration or trucut biopsy of breast lesions for histopathological confirmation[7,8].

Ultrasound elastography is a novel modality that is the subject of active research for clinical applications, that maps relative tissue stiffness[9]. Ultrasound elastography is a non-invasive imaging technique that can be used to depict relative tissue stiffness or displacement (strain) in response to an imparted force (stress). Ultrasound elastography is based on the comparison of signals acquired before and after tissue displacement. Stiff tissues deform less and exhibit less strain than compliant tissues in response to the same applied force[10].

Only few studies have studied the diagnostic validity of ultrasound in diagnosing breast cancer. This study aims to compare the diagnostic accuracy of mammography combined with B mode ultrasound (USG), ultrasound Elastography (UE) in detection of the nature of breast lesions (benign or malignant) separately and in combination with histopathology (HPE) as the gold standard.

Materials & methods

Study Setting

This cross-sectional study was conducted at a tertiary care teaching hospital. All female patients who came for screening or diagnostic mammography and had solid breast lesions of BIRADS category 3 and above were included in the study. Patients with simple and complicated cystic lesions were excluded from the study. After getting Institutional Ethics Committee clearance, the study was conducted after getting informed consent from all participants. Socio demographic details and family history details were collected from the study participants and then subjected to mammography and B mode ultrasonography and further analysed with Ultrasound Elastography. All the examinations were performed before any fine-needle aspirations or biopsy or surgery.

Sampling & Sample Size

According to Hui Zhi et al[11] study, considering the specificity (Sp) of Ultrasound Elastography and Mammography with B mode ultrasound combined as 95.7%, with a precision (d) of 4%, with 95% confidence interval ($Z_{1-\alpha/2} = 1.96$) and prevalence (p) of Breast Cancer of 1%, the sample size is calculated as $N = Z^2_{1-\alpha/2} * Sp * (1 - Sp) /(1 - p) * d^2 = 99.8$. Taking into account a 5% non-response rate, the sample size is estimated to be 105. Those subjects fulfilling the inclusion criteria were recruited consecutively till the sample size is achieved.

Study Procedure

Mammography was initially performed using a MAMMOMAT INSPIRATION DIGITAL MAMMOGRAPHY equipped with amorphous selenium detectors. Two standard views, mediolateral oblique and craniocaudal were acquired for each breast. Additional spot compression magnification images were acquired for suspicious areas or mass lesions.

Then they were examined with a VOLUSON E8 ultrasound machine and the B mode Ultrasound findings were noted and BIRADS score was given combining findings from both Mammography and B mode Ultrasound according to BIRADS lexicon[12]. The classification of BIRADS criteria for breast mass characterization is detailed as follows:

Category 1: negative findings
Category 2: benign findings
Category 3: probably benign findings
Category 4: findings suspicious for malignancy
Category4a: low level suspicious for malignancy
Category4b: intermediate level suspicious for malignancy
Category4c: moderate suspicious for malignancy
Category 5: findings highly suggestive of malignancy

Patients with solid lesions and BIRADS score of 3 and above were subjected to ultrasound Elastography. BIRADS 3, 4a (Well-defined lesion with macrolobulated margins with typical features of fibroadenoma) were considered as benign on mammography and B mode ultrasound. BIRADS category 4 b or c with features suspicious of malignancy like ill-defined margins, angular margins and BIRADS 5 (lesion with spiculated margins) were considered malignant. BIRADS 6 were HPE proven cases of malignancy.

Ultrasound Elastography was performed at the same sitting as the B mode sonography since the same machine was equipped with Elastography unit also. Dual display was used to assess Elastography score of the lesion. On one side the B mode ultrasound image was seen and on the other side Elastography image was obtained by placing the ROI over the solid lesion. Importantly to obtain images that were appropriate for analysis, we applied the probe with only light pressure, with the pressure indicator (green colour in the side bar indicates optimal compression) displayed on the right side of the screen. The target lesion was scored as 1 to 5, using the scoring system and classified as proposed by Itoh et al[10]. The lesions scored as 1 to 3 was considered benign and lesion scored as 4 or 5 was considered malignant.

Score 1: The entire hypoechoic lesion had an even strain (ie, the entire lesion was evenly shaded in green).

Score 2: Indicated a high and low strain mixed over the hypoechoic lesion (ie, the hypoechoic lesion had a mosaic pattern of green and blue).

Score 3: The periphery of the hypoechoic lesion had a high strain, with low strain in the centre of the lesion (ie, the peripheral part of lesion was green, and the central part was blue).

Score 4: The entire hypoechoic lesion had no strain (ie, the entire lesion was blue, but its surrounding area was green which is not included).

Score 5: The entire hypoechoic lesion or its surrounding area indicated no strain (ie both the entire hypoechoic lesion and its surrounding area were blue).

Patients who have all the above examination findings and who were subjected to fine needle aspiration cytology (FNAC) / Biopsy / surgery were only included in the study and histopathology examination findings were considered as the gold standard. Findings from Ultrasound with mammography and Ultrasound Elastography were compared with the histopathology separately and in combination. When combining the findings of USG with mammography and Elastography, only those cases who were identified as malignant in both investigations were considered malignant and all other cases were considered benign.

Statistical Analysis

The data collected were entered in MS Excel and analysed using SPSS software version 21. Categorical variables like age, HPE diagnosis, BIRADS score and Elastography scores were represented in frequencies and percentages. Those cases who were detected by the diagnostic test as well as by the HPE as malignant were considered true positives and detected by both as benign were true negatives. The validity of the diagnostic tests was determined by sensitivity (true positivity rate) and specificity (true negativity rate). The prediction of the investigation was represented by positive predictive value and negative predictive value. The accuracy of the diagnostic tests was determined as the ratio of sum of true positive and true negative cases to all the cases.

Results

Among the 105 subjects enrolled in the study, 5 patients had an inconclusive biopsy report or the report was not available. After excluding those subjects, 100 patients with solid breast lesion subjected to mammography, B mode Ultrasonography and Ultrasound Elastography and finally with histopathological analysis findings by either FNAC or excision Biopsy.

The age of the participants ranged from 29 to 80 years with a mean of 52.3 (±10.1) years. Most of the participants were in the 41 – 50 years age group (37%) followed by 51 – 60 years age group (35%) and 18% in more than 60 years. (Fig 1.)

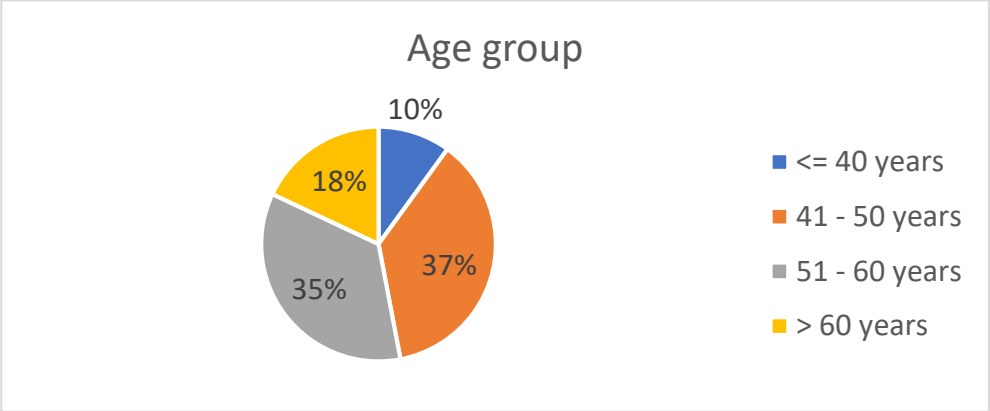

Fig. 1: Distribution of age group of the study population

Among the 100 cases, 75 cases were diagnosed as malignant and 25 cases as benign by histopathological diagnosis. Of the 75 malignant cases, 73 were found to be infiltrating ductal carcinoma and one case of malignant phylloides tumour and papillary carcinoma each. Of the 25 benign cases, 20 cases were found to be proliferative breast disease, 2 cases of fibrocystic disease and granulomatous inflammation each and one case of myofibroblastoma.

Table 1. Distribution of Diagnosis of Histopathological Examination findings.

Histopathological Diagnosis	Frequency
Benign	
Proliferative Breast Disease	20
Fibrocystic Disease	2
Granulomatous Inflammation	2
Myofibroblastoma	1
Malignant	
Infiltrating Ductal Carcinoma	73
Malignant Phylloides Tumour	1
Papillary Carcinoma	1
Total	100

Table 2. Distribution of Diagnosis of Histopathological Examination findings with BIRADS and Elastography scores.

	Histopathological Diagnosis		Total
BIRADS Score	**Benign**	**Malignant**	
3	3	0	3
4a	14	1	15
4 b & c	8	37	45
5	0	37	37
Elastography Score			
1	2	0	2
2	6	1	7
3	8	1	9
4	3	34	37
5	6	39	45

Considering the BIRADS score distribution, 3 cases had score 3 and all were benign. 15 cases had score 4a and 14 of them were benign. 45 cases had score 4 b & c and 37 of them were malignant and 8 were benign. 37 cases had score 5 and all of them were malignant. Considering the Elastography score, 2 cases had score 1 and both were benign. 7 cases had score 2 and 9 cases had score 3 in which 1 case from each were malignant and others were benign. 37 cases had score 4 out of which 34 were malignant and 45 cases had score 5 out of which 39 were malignant.

Based on the findings of Ultrasound BIRADS score along with mammography, of the 100 subjects, 82 cases were diagnosed as malignant and 18 cases as benign. On following up the 82 malignant diagnosed cases with histopathological examination, only 74 cases were found to be malignant and among the 18 benign diagnosed cases, 17 were found to be benign and one was malignant. The Ultrasound along with mammography had a sensitivity of 98.6% and specificity of 68% in diagnosing malignant breast carcinomas. It had 90% positive predictive value (PPV) and 94% negative predictive value (NPV). The accuracy of the investigation for predicting malignancy was 91% with a range of 83.7% to 95.2%.

Based on the findings of Ultrasound Elastography of the 100 cases, 82 cases were diagnosed as malignant and 18 cases as benign. On follow up with histopathological examination, only 73 out of 82 malignant diagnosed cases were found to be malignant and 16 out of 18 benign diagnosed cases were benign. The Elastography had a sensitivity of 97.3% and specificity of 64% in diagnosing malignant breast carcinomas. It had 89% positive predictive value (PPV) and 88% negative predictive value (NPV). The accuracy of the investigation for predicting malignancy was 89% with a range of 81.3% to 93.7%.

Table 3: Distribution of diagnostic validity and accuracy of USG (with mammography) and Elastography findings with HPE.

Investigation	Histopathology Diagnosis		Total	Sensitivity	Specificity	PPV	NPV	Accuracy
	Malignant	Benign						
Ultrasound (with Mammography)				98.67% (92.8 - 99.7)	68% (48.4 - 82.8)	90.24% (81.9 - 94.9)	94.44% (74.2 - 99.1)	91% (83.7 - 95.2)
Malignant	74	8	82					
Benign	1	17	18					
Total	75	25	100					
Elastography				97.33% (90.8 - 99.3)	64% (44.5 - 79.7)	89.02% (80.4 - 94.1)	88.89% (67.2 - 96.9)	89% (81.3 - 93.7)
Malignant	73	9	82					
Benign	2	16	18					
Total	75	25	100					
Ultrasound (with Mammography) & Elastography				97.33% (90.8 - 99.3)	84% (65.3 - 93.6)	94.81% (87.4 - 97.9)	91.3% (73.2 - 97.5)	94% (87.5 - 97.2)
Malignant	73	4	77					
Benign	2	21	23					
Total	75	25	100					

Combining the findings of Ultrasound Elastography along with Ultrasound and Mammography findings, of the 100 cases, 77 cases were diagnosed as malignant and 23 cases as benign. On follow up with histopathological examination, 73 out of 77 malignant diagnosed cases were found to be malignant and 21 out of 23 benign diagnosed cases were benign. The Elastography combined with Ultrasound and mammography findings, had a sensitivity of 97.3% and specificity of 84% in diagnosing malignant breast carcinomas. It had 94% positive predictive value (PPV) and 91% negative predictive value (NPV). The accuracy of the investigation for predicting malignancy was 94% with a range of 87.5% to 97.2%.

Discussion

The present study compared two investigations, Ultrasound with mammography findings and Ultrasound Elastography in predicting the malignancy of solid breast lesions with the histopathological examination findings as gold standard. The two investigations were compared individually and combined in parallel.

In Ultrasound with mammography, the study reported 18 cases as benign out of which 17 cases turned out to be benign on histopathology. These 17 true negative cases included 14 cases of BIRADS category 4A and 3 cases of BIRADS category 3. All these 17 cases had well defined margins or macrolobulated margins on ultrasound. Most of the cases were predominantly hypoechoic. None of these lesions had ductal extension, spiculated margins, ill-defined margins or posterior features. One false negative case which had BIRADS score of 4A which had macrolobulated margins turned out to be case of malignant phylloide's tumour. Differentiation of phylloide's tumour from a fibroadenoma is very difficult based on ultrasound morphology alone[13].In Ultrasound with mammography, the study reported 82 cases as malignant out of which 74 turned out to be malignant on histopathology. These 74 true positive cases included 37 cases of BIRADS category 4 (B or C), 37 cases of BIRADS category 5 and 8 cases of BIRADS category 4a. All 37 BIRADS category 4 (B or C) cases had ill-defined or angular margins and appeared hypoechoic on ultrasound. Few of them had microcalcifications within. Some of them were taller than wide. All BIRADS category 5cases had spiculated or ill-defined margin, were taller than wide and had posterior features (posterior acoustic shadowing). 8 cases which were reported as malignant on mammography and ultrasound turned out to benign on histopathology. These 8 false positive cases were under the category BIRADS 4 (B or C). These 8 cases had lesions with ill-defined or angular margins, ductal extension making them suspicious for malignancy. However, these turned out to be benign on histopathology which included 6 cases of proliferative breast disease and 2 cases of granulomatous inflammation like tuberculous mastitis.

The first important point to be noted is margin of the lesion is one of the ultrasound morphology with high positive predictive value in detection of benign and malignant solid lesions of breast. Macrolobulated lesions are usually benign. Lesions with spiculated margins are usually malignant. Lesions with ill-defined or angular margins are suspicious for malignancy and should always be confirmed with histopathology. The second most important morphology with high positive predictive value for characterization of benign versus malignant lesion is whether the lesion is taller than wide or not, if it is then the lesion is most probably malignant. Next in the order is posterior feature which also point towards a possibility of malignancy. Echogenicity as such is not so useful in characterization of the breast lesions since more than 90% of the lesions in our study (both benign and malignant) were hypoechoic on ultrasound.

In our study we obtained sensitivity, specificity, positive predictive value and negative predictive value of Ultrasound with mammography in diagnosis of breast lesions as 98.6%, 68.0%, 90.2% and 94.4% respectively. These results were comparable to the previous studies on characterization of breast masses based on ultrasound like Stavros AT et al[7] and Maniero MB et al[8]. The false positive cases on Ultrasound with mammography included 6 cases of proliferative breast disease and 2 cases of tuberculous mastitis. Tuberculous mastitis appeared to be suspicious of malignancy on B mode ultrasound and other 6 cases of proliferative breast disease were also suspicious on ultrasound. Hence diagnosis of all suspicious lesions should be confirmed with histopathology.

In ultrasound elastography we reported 18 cases as benign out of which 16 cases were benign on histopathology. Among these 16 true negative cases 2 had elastography score of 1, 6 had elastography score of 2 and 8 had elastography score of 3. 2 cases which were reported as benign on ultrasound elastography turned out to be malignant on histopathology. These two false negative cases include a case of papillary carcinoma of the breast and malignant phylloide's tumour. On elastography papillary carcinoma had an elastography score of 3 and malignant phylloide's tumour had a score of 2.

In ultrasound elastography we reported 82 cases as malignant out of which 73 cases were malignant on histopathology. Among these 73 true positive cases 34 cases had an elastography score of 4 and 39 cases had an elastography score of 5. 9 cases which were reported as malignant on ultrasound elastography turned out to be benign on histopathology. These 9 false positive cases included 6 cases of proliferative breast disease (score of 4 and 5), 1 case of fibrocystic disease (score 5), 1 case of myofibroblastoma (score 4) and 1 case of granulomatous inflammation like tuberculosis (score 5).

One can conclude from the above discussion that lesions with elastography score 1, 2 and 3 are most probably benign. Lesions with elastography score of 4 and 5 are most probably malignant. The false positivity / high elasticity score (4 or 5) in 6 cases of benign proliferative breast disease can be attributed to the abundance of fibrous stroma in these cases on histopathology. Abundant fibrous stroma makes the lesion stiffer resulting in a high elasticity score on

ultrasound elastography[13]. The same reason can also be attributed to the false positive case of myofibroblastoma. In our study we obtained sensitivity, specificity, positive predictive value, and negative predictive value of ultrasound elastography in diagnosis of breast lesions as 97.3%, 64.0%, 89.0% and 88.8% respectively. The sensitivity of ultrasound elastography in our study (97.3%) was more compared to the sensitivity obtained in Hui Zhi et al (70%) (50). However, the specificity (64%) was low compared to them. Our results were comparable to the results obtained in a similar study by Beatriz Navarro et al[14] and Smajlovic F et al[15].

Combining Ultrasound with mammography and ultrasound elastography, we reported 77 cases as malignant out which 73 turned out to be malignant on histopathology (True positives). The 4 cases which was reported as malignant turned out to be benign on histopathology (False positives) which includes 3 cases of proliferative breast disease and 1 case of granulomatous inflammation like tuberculosis. Among the 8 false positive cases on Ultrasound with mammography 4 cases were reported as benign on ultrasound elastography which includes 3 cases of proliferative breast disease and 1 case of granulomatous inflammation like tuberculosis. Thus the use of the ultrasound elastography in combination with ultrasound would have helped in diagnosis of these lesions non-invasively. Among the 2 false negative cases on elastography (i-e malignant phylloide's tumour and papillary carcinoma of breast) papillary carcinoma showed malignant features on Ultrasound with mammography. Malignant Phylloide's tumour appeared benign on both ultrasound and elastography. Among the 9 false positive cases on ultrasound elastography 5 cases were reported as benign on Ultrasound with mammography which includes 3 cases of proliferative breast disease, 1 case of myofibroblastoma and 1 case of fibrocystic disease of the breast. Thus the use of the Ultrasound in combination with ultrasound elastography would have helped in diagnosis of these lesions non-invasively. Malignant phylloide's tumour was appearing benign on B mode ultrasound (BIRADS 4A) and Ultrasound elastography. Thus the diagnosis of malignant phylloide's tumour with imaging alone is not possibly and needs histopathology examination. Among the 2 cases of granulomatous inflammation like tuberculosis, elastography showed a score of 2 in one case and score of 5 in other case. Thus tuberculous mastitis can appear as benign or malignant on ultrasound elastography and needs histopathological confirmation. This needs further evaluation with studies on a larger population.Combining mammography, B mode ultrasound and ultrasound elastography we obtained sensitivity, specificity, positive predictive value and negative predictive value in diagnosis of breast lesions as 97.3%, 84.0%, 94.8% and 91.3% respectively. Though the combination of these modalities did not yield much improvement in sensitivity however shows a significant increase in specificity. In a similar study by Hui Zhi et al[11] the sensitivity, specificity, positive predictive value and negative predictive value of combined B mode ultrasound and ultrasound elastography in diagnosis of breast lesions was 89.7%, 95.7%, 89.7% and 95.7% respectively. The Ultrasound along with mammography findings had a better sensitivity and specificity compared to Elastography and also predictive values were higher compared to it. The accuracy of USG with mammography was 91% which was higher compared to 89% in Elastography. When combined USG with mammography and Elastography findings, the sensitivity, specificity and predictive values were higher compared to the individual investigations. The accuracy of the combined investigation was as high as 94%.

Conclusion

Ultrasound Elastography and mammography combined with B mode ultrasound in evaluation of solid breast lesions for predicting malignancy had a good sensitivity and predictive values of which USG with mammography had a slightly higher validity than USG Elastography. When combined USG with mammography and Elastography, the specificity is very much increased and the accuracy of prediction is higher than compared to the investigations conducted individually.

Conflict of Interest: Nil Source of support: Nil

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