Evaluation of Diagnostic Accuracy of Ultrasound Elastography in Differentiating benign and Malignant Solid Breast Masses in Correlation with Mammography, Fine Needle Aspiration Cytology (FNAC) and Biopsy

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ABSTRACT

Introduction: Breast masses are common and usually benign. Study aimed to determine the diagnostic accuracy of breast ultrasound elastography in differentiating benign from malignant breast masses and to correlate between elasticity values of solid breast masses and histological findings and to determine if use of ultrasound elastography could lead to reduced number of interventional procedures for breast masses .

Material and methods: 78 female patients were considered to study the sensitivity, specificity, PPV and NPV of ultrasound elastography (USE) and in the detection and characterization of various breast masses and its correlation to mammography, USG, FNAC and HP study. Mammography was done using MAM VENUS+ machine. Ultrasound examinations was performed by using a conventional B-mode grayscale ultrasound and color Doppler equipped with real-time elastography software using Samsung HS70A ultrasound machine with a 4-18 MHz linear-array transducer .Both benign and malignant lesions were diagnosed by FNAC ± excision biopsy for histological analysis.

Results: The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), of USE is 90.47%, 100%,100%, 95%, 97.43% respectively with p value≤0.05 which is at par with HP-study and more superior to conventional USG and mammography. Hence USE makes newer approach in early identification of malignant lesions.

Conclusion: Breast elastography has recently been subject to substantial attention as it has proven to reach an adequate specificity and a high negative predictive value in combination with US. Elastography may reduce the need for biopsy in lesions classified as BI-RADS 3 on US image and postpone follow-up.

Keywords: Elastography, FNAC, Biopsy, BIRADS

INTRODUCTION

Breast masses are common and usually benign but breast cancer is most common cancer worldwide[1-3] and the second-most common cause of cancer-related mortality.[4] Early, sensitive and accurate diagnosis lead to better prognosis and reduce the risk of death caused by breast cancer by 40% or more.[5] Non- invasive diagnosis of breast cancer remains a challenge to the medical fraternity. Mammography and sonography are currently the most sensitive investigations for detecting breast cancer.[6,7] Because of various limitations of mammography and sonography and the not to miss an early diagnosis, lead to FNAC & aggressive biopsy. Out of all biopsies only 10%-30%are found to be malignant.[8,9] It suggests that 70%-90% of breast biopsies performed for benign diseases are invasive which leads to unnecessary patient anxiety.

Therefore, it clearly denotes need for the development of additional reliable methods in order to avoid unnecessary biopsy. In the early 1990s, Ophir et al[10] described a new technique called Ultrasound Elastography. The first clinical study was published in 1997 showing the potential of elastography in the detection and characterization of breast lesions. The main principle of ultrasound elastography in differentiating malignant breast lesions from that of benign is “Cancerous lesions are stiffer than non cancerous ones on compression”. USE improves early and accurate differentiation of benign from malignant breast lesions[11,12] than conventional ultrasound and mammography. It increases the specificity of conventional B-mode ultrasound by more precise characterization of breast lesions which eventually helps to reduce false-positive results (i.e, increased specificity) and therefore is useful in avoiding unnecessary breast biopsies. Study aimed to determine the diagnostic accuracy of breast ultrasound elastography in differentiating benign from malignant breast masses and to correlate between elasticity values of solid breast masses and histological findings.

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MATERIAL AND METHODS

After proper institutional ethical clearance, this prospective study was conducted in the department of Radiodiagnosis and Pathology of a tertiary care teaching hospital of eastern India from July 2017 to June 2019.

Informed consents from all participants were taken. Sociodemographic, personal, and medical history was taken from each women.The same physician performed the conventional ultrasound and sonoelastographyevaluations prior to biopsy in all patients who was blinded for initial diagnosis of the subjects. A total of 89 female patients with breast lump were enrolled for the study. Patients under 15 years of age, history of radiotherapy or chemotherapy, known histology and without informed consent were excluded.

Out of 89 female patient included in the study, 78 breast lesions were confirmed by histopathology,9 biopsy results couldn't be traced while 2 cases were deemed as inconclusive and repeat biopsy was requested.

At first Mammography was done using MAM VENUS$^+$ machine. Ultrasound examinations was performed in a fairly low lightning ultrasound room with patients in supine position by using a conventional B-mode grayscale ultrasound and color Doppler equipped with real-time elastography software using Samsung HS70A ultrasound machine with a 4-18 MHz linear-array transducer.

All cases which were found to have breast lesion on ultrasound elastography were subjected to FNAC and HP study.

Mammography of breast lump

During mammography a specially qualified radiologic technologist positioned the breast of patient in the mammography unit and gradually compress it. Patient was asked to change positions between images. Two views were used to take the X-ray film.

- Cranio-caudal view
- Medio lateral oblique view

Conventional USG of the breast lump

Initially conventional ultrasound was performed in all patients to assess the size, shape, border characteristics, posterior acoustic features, echogenicity, internal structure, and the presence of calcification in the lesion; and in the course of this, obtaining B-mode images were given priority. Subsequently, color Doppler ultrasoundwere performed in the patients with breast lumps in order to evaluate the vascularity of the mass, which was one of the BIRADS criteria for USG.

Details of BIRADS criteria for breast mass characterization is given below:-

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 levelsuspicious for malignancy
Category4c: moderate suspicious for malignancy
Category 5: findings highly suggestive of malignancy

Elastography of the breast lump

Next stage was to obtain elasticity images as motion images on the same sitting. It was performed on the patient in supine position, and with the probe oriented perpendicular to the chest wall. The probe was applied to the breast and was moved slightly inferior and superior, and normal breast tissue was included to obtain the elasticity images. The probe was applied with just a light pressure in order to obtain the images, which were appropriate for analysis and a higher level of pressure was simply passed up. Before and after soft compression of tissues, an image was taken in which color coding was used to evaluate deformation. Moderate vertical compressions were applied with the probe, three to five times, over the lump and elasticity images were displayed on a computer monitor. A chromatic scale assigns tissues that undergo strain(soft tissues) a different color (Green in Samsung machine) from those that are not deformed by the compressions(Blue in Samsung machine).The B-mode grey scale image and the elastogram are displayed side by side.

Measured variables included

A. Elasticity score(Tsukuba score): a chromatic scale was used to assign soft tissues e.g. green color for compressed/ strained and hard tissues, blue color fornon-compressible tissues. The masses were categorized based on Ueno et al.[13] Strain score where score 1 to 3 are considered benign and score 4 and 5 malignant.

1. Indicates equal strain for hypoechoic lesion (i.e., the entire lesion was displayed as green color.)
2. Indicates mixed pattern of high and low strain throughoutthe hypoechoic lesion (i.e. mosaic pattern of green and blue within the hypoechoic lesion).
3. Indicates high strain at the periphery of the hypoechoic lesion, with low strain at the center of the lesion (i.e., the peripheral part of lesion was green, and the central part was blue).
4. Indicates no strain in the entire hypoechoic lesion (i.e. the entire lesion was blue, but its surrounding area was green in color)
5. Indicates no strain in the entire hypoechoic lesion or in the surrounding area (i.e., both the entire hypoechoic lesion and its surrounding area were blue).

B. Strain ratio: Thomas et al.[14] took a cutoff of 2.455 to distinguish benign from malignant lesions using the strain ratio. Alhabshi et al.[15] took a cutoff of 5.6 to distinguish benign from malignant lesions using the strain ratio. We selected a cutoff point of ≥4.5 for malignant lesions.

C. Size ratio(E/B): The size change between the B-mode image and elastogram was evaluated. Cutoff point ≥ 1.2 was considered as malignant based on study by Hall et al.[16]

Some of our elastographicimages with Elasticity score (tsukubascore),strainratio,size ratio are given below.(Fig:1-3)

FNAC AND BIOPSY

Histopathological analysis of benign lesions were done using fine needle aspiration cytology (FNAC) or excision biopsy.

The malignant lesions were diagnosed using a combination of FNAC and excision biopsy. Histology diagnosis i.e. benign or malignant was compared to strain score and strain ratio classification and accuracy of elastography was calculated.

RESULTS

In this study, 78female patients werefinally considered to study the sensitivity and specificity of ultrasound elastography and Strain ratioin the detection and characterization of various breast masses and its role in differentiating benign and malignant breast masses and its correlation to FNAC and histopathology.

The mimimum age of presentation at our hospital is 15 year and maximum age of presentation is 72 years. Maximum cases belong to 15 to 30 years age group. Out of 78 patients studied 32(41.02%) belong to15-30 years age group, 16(20.51%) in 31-40years age group, 18 (23.07%) in 41-50 years age group,8 (10.25%)in 51-60 age group, 4 (5.12%) in ≥60 years age group (Fig:4). Out of 78 patients, 57 (73.07%) was histologically benign and,21 (26.93%) were histologically malignant (Fig:5). The final pathologic diagnosis of all breast lesions are illustrated in Fig-6.

Out of 57 benign cases 31 cases were found to be in 15-30 years of age,13 cases in 31-40 years of age group,10 cases in 41-50 years age group,2 cases in 51 to 60 years of age group,1 case in ≥60years of age group.Similarly out of 21 malignant cases 1case was found to be in ≤30 years of age,3 cases in 31-40 years of age group,8 cases in 41-50 years age group,6 cases in 51 to 60 years of age group, 3 cases in ≥ 60years of age group.(Table-1)

Elasticity score(Tsukuba score): A visual representation of how tissues deform under compression.A five point score is

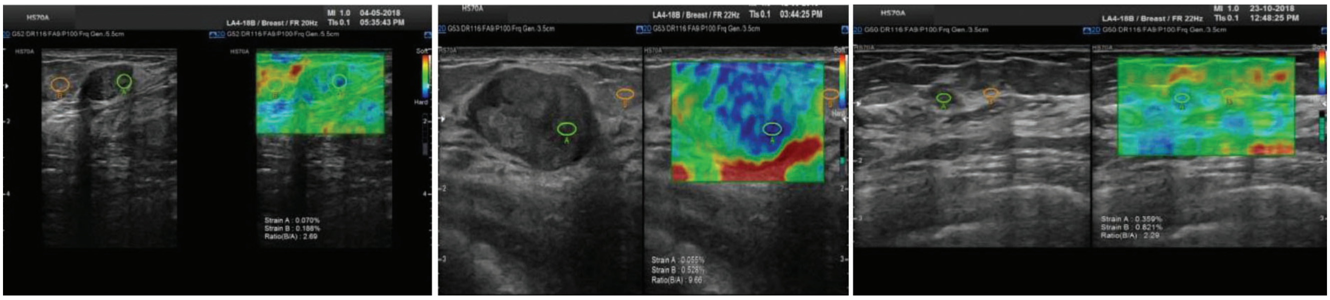

Figure-1: Elasticity Score-2; Strain Ratio-9.66; E/B Ratio- 1.53. **Figure-2:** Elastography Score-5; Strain Ratio-2.69;E/B Ratio-1
Figure-3: Elastography Score-2; Strain Ratio-2.3; E/B Ratio-0.57

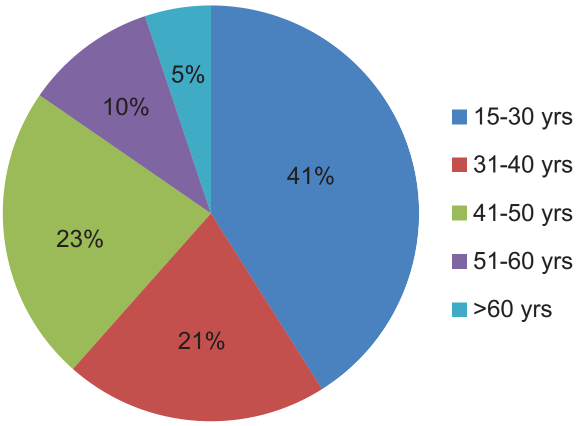

Figure-4: Age distribution

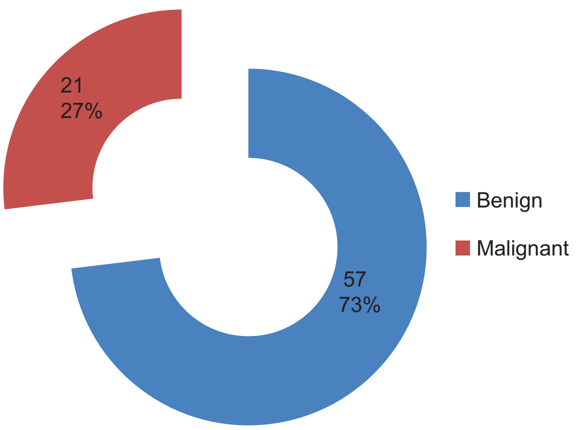

Figure-5: Number of benign and malignant lesions

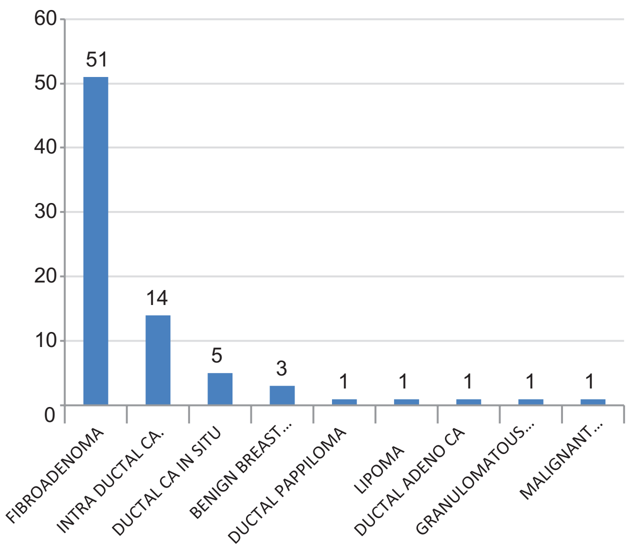

Figure-6: Histopathological diagnosis

used to categorize the mass.A strain score cut off≥4 indicates malignancy. All cases having elasticity score of 1 - 3 were benign.(Table-2)

Size ratio(E/B ratio): The size change between the elastogramand B-mode image is evaluated. Cutoffpoint≥ 1.2 is considered as malignant. All 57 benign cases had size ratio of < 1.2.outof21 malignant cases 3 had size ratio <1.2 and 18 had size ratio ≥1.2 (Table-3).

Strain ratio: used to quantify the relative stiffness between the lesion and surrounding tissue. A strain ratio of more than 4.5shows a predictive value of malignancy. All benign cases found to have strain ratio <4.5 except one. out of 21 malignant cases 2 had strain ratio <4.5 and 19 had the ratio ≥4.5(Table-4).

Of the total 78 subjects, based on USG 16 (20.5%) patients showed features of malignancy. corresponding HP- Study performed on these 16 patients, 14 showed malignant features. Based on USG, 62(79.5%) patients showed benignfeatures, corresponding HP-Study performed on these 62 patients, 55 showed benign features and 7 showed malignant features. So comparing the USG findings and the corresponding HP-Study on these 78 subjects sensitivity and specificity was 66.66% and 96.5% withan accuracy rate of 88.46% [Table-5].

Of the total 78 subjects based on BIRADS, 17 (21.79%) patients showed features of malignancy. Corresponding HP-Study performed on these 17 patients, 15 showed malignant features and 2 showed benign feature. BIRADS 1,2,3 taken as benign and BIRADS 4a,4b,4c,and 5 taken as malignant. Based on BIRADS61(78.21%) patients showed benign features, corresponding HP-Study performed on these 61 patients, 55 showed benign features and 6 showed malignant features. So comparing the BIRADS findings and the corresponding HP-Study on these 78 subjects sensitivity and specificity was 71.42% and 96.49% with an accuracy rate of 89.74% [Table-6].

Of the total 78 subjects based on elastography, 19(24.35%) patients showed features of malignancy.Corresponding FNAC performed on these 19 patients, 18 showed malignant features. Based on elastography 59 (75.64%) patients showed benign features, corresponding FNAC performed on these 57 patients showed benign features and 2 cases showed malignancy.So comparing the elastography findings and the corresponding FNAC on these 78 subjects sensitivity and specificity was 90% and 98.27% with an accuracy rate of 96.15% [Table-7].

Of the total 78 subjects based on elastographyscore (Tsukuba score), 20 (25.64%)patients showed features of malignancy. Corresponding HP Study performed on these 20 patients, 18showed malignant features. Based on elastography score (Tsukuba score),58(74.36%) patients showed benign features, corresponding HP Study performed on these 58 patients, 55 showed benign features and 3 showed malignant features.So comparing the elastography scorefindings and the corresponding HP Study on these 78 subjects sensitivity and specificity was 85.71% and 96.49% with an accuracy rate of 93.58% [Table-8].

Of the total of 78 patients, based on Strain ratio, 20 patients were malignant. CorrespondingHP Studyon these same 20 patients, 19 patients were malignant. Total 58 patients were benign based on Strain ratio and 56 were benign on HP Study and 2 were malignant. The sensitivity,specificity, PPV

Age(years)	Benign	Malignant	Total
15-30 Years	31	1	32
31-40years	13	3	16
41-50years	10	8	18
51-60 Years	2	6	8
>60 years	1	3	4
Total	57	21	78

Table-1: Age distribution of benign and malignant lesions

Elasticity score	1(one)	2(two)	3(three)	4(four)	5(five)
No.of cases	8	37	13	8	12
No.of benign cases (Histopathology)	8	37	10	2	0
No. of malignant cases (Histopathology)	0	0	3	6	12
Mean elasticity score of benign lesions: 2.10 (120/57); Mean elasticity score of malignant lesions: 4.43					

Table-2: Elasticity score wise distribution of cases

Size ratio	< 1.2	≥ 1.2
No. of cases	60	18
No.of benign cases	57	0
No. of malignant cases	3	18
Mean size ratio of benign lesions: 0.860; Mean size ratio of malignant lesions: 1.356		

Table-3: Size ratio wise distribution of cases

Strain ratio	< 4.5	≥ 4.5
No.of cases	58	20
No.of benign cases	56	1
No. of malignant cases	2	19
Mean strain ratio of benign lesions: 2.448; Mean strain ratio of malignant lesions: 6.276		

Table-4:Strain ratio wise distribution of cases

Parameters	HP study (Malignant)	HP study (Benign)	Total
USG (malignant)	14	2	16
USG (benign)	7	55	62
Total	21	57	78
Sensitivity=66.66%, Specificity=96.5%, PPV=87.5%, NPV=88.7%, Accuracy=88.46%; p-value:-<0.05			

Table-5: Sensitivity and specificity of USG Vs HP study

Parameters	HP study (Malignant)	HP study (Benign)	Total
BIRADS (malignant)	15	2	17
BIRADS (benign)	6	55	61
Total	21	57	78
Sensitivity=71.42%, Specificity=96.49%, PPV=88.23%, NPV=90.2%, Accuracy=89.74%, p-value<0.05			

Table-6: Sensitivity and specificity of BIRADSvs FNAC

Parameters	FNAC (Malignant)	FNAC (Benign)	Total
Elastography (malignant)	18	1	19
Elastography (benign)	2	57	59
Total	20	58	78
Sensitivity=90%, Specificity=98.27%, PPV=94.7%, NPV=96.61%, Accuracy=96.15%; p-value:-<0.05			

Table-7: Sensitivity and specificity of Elastographyvs FNAC

Parameters	HP Study (Malignant)	HP Study (Benign)	Total
Elastography score (malignant)	18	2	20
Elastography score (benign)	3	55	58
Total	21	57	78
Sensitivity=85.71%, Specificity=96.49%, PPV=90%, NPV=94.82%, Accuracy=93.58%, p-value<0.05			

Table-8: sensitivity and specificity of Elastographyvs HP Study

Parameters	HP Study (Malignant)	HP Study (Benign)	Total
Strain ratio (malignant)	19	1	20
Strain ratio (benign)	2	56	58
Total	21	57	78
Sensitivity=90.47%, Specificity=98.24%, PPV=95%, NPV=96.55%, Accuracy=96.15%; p-value<0.05			

Table-9: Sensitivity and specificity of strain ratio vs HP Study)

Parameters	HP Study (Malignant)	HP Study (Benign)	Total
Size ratio(E/B) (malignant)	18	0	18
Size ratio(E/B) (benign)	3	57	60
Total	21	57	78
Sensitivity=85.7%, Specificity=100%, PPV=100%, NPV=95%, Accuracy=97.43%, p-value:-<0.05			

Table-10: sensitivity and specificity of size ratio vs HP Study

Modality	Sensitivity	Specificity	PPV	NPV	Accuracy
BIRADS	71.42	96.49	88.23	90.2	89.74
Elastography score	85.71	96.49	90	94.82	93.58
Strain Ratio	90.47	98.24	95	96.55	96.15
E/B Ratio	90.47	100	100	96.61	97.42

Table-11: Correlation of BIRADS andsonoelastographywith HP –study is depicted below in

and NPV are 90.47%,98.24%,95% and 96.55%respectively (Table-9).

Of the total of 78 patients, based on Size ratio(E/B), 18 patients were malignant. CorrespondingHP Studyon these same 18 patients, 18 patients were malignant. Total 60 patients were benign based on Size ratio and 57 were benign on HP Study. The sensitivity,specificity, PPV and NPV are 85.7%,100%, 100% and 95% respectively (Table-10).

Correlation of BIRADS andsonoelastographywith HP –study is depicted in Table-11

DISCUSSION

In this study, we compared 3 interpretation criteria for elastography, i.e. elastography score, strain ratio, size ratio. The results of our study prove that each of these criteria is able to differentiate benign and malignant lesions with statistical significance.

Comparison of conventional Sonography versus Sonographic Elastography

B-mode sonography is a non invasive and cost-effective method for initial evaluation of suspected breast lesions. It determines the location, number and morphology of the lesions with great accuracy.

Ourstudy results showed an excellent value for specificity (96.5%) with conventional sonography where as on elastography the specificity increases upto 100%. Furthermore, our study showed better sensitivity for sonoelastography than conventional sonography, with a sensitivity of 90.47% when strain ratio taken as reference where as sensitivity on conventional USG is 66.66%. These results corroborate those of other studies.[17,-21] Thus elastography in conjunction with conventional sonography have potential to improve diagnostic accuracy (Table-11). Comparing sensitivity and accuracy rate, sonoelastography is far superior to BIRADS. Whereasspecificity, PPV, NPV is slightly superior with sonoelastography.

We consider BI-RADS 1,2,3 are benign, andBIRADS 4A,4B and 4C and 5 as malignant for conventional sonography.

In this study, 22 of the 27 BI-RADS 3 lesionswere benign and 5 were malignant on HP-study. Out of 5 malignant lesions, 4 were identified as malignant on sonoelastography based on the strain ratio with cutoff of≥4.5. All BIRADS 3 lesions with strain ratio <4.5 were found to be benign except one which was found to be malignant on FNAC and HP-study. Thus, these results corroborate those of other Researchers[11,17,20-22] that this group of low suspicion lesions may be the area where elastography has the most beneficial role in early detection of malignancy.

BI-RADS 4A designate lesions with a low suspicion for malignancy in which a benign pathological diagnosis is expected and would be considered concordant. Strain characteristics with a high likelihood of benignity could allow interpretation of BI-RADS 4A lesions as either BI-RADS 3 or even 2. Of particular note, out of 3BI- RADS 4A lesions 2 were assigned strain ratio <4.5 and subsequently found to be benign on HP- study, thus raising confidence level in the diagnostic performance of this technique.

5.

There were 2 prospectively assigned BI-RADS 4B lesions which were assigned strain ratio ≥4.5 and subsequently found to be malignant on HP-study. There were 6 BI-RADS 4C lesions and 6 BIRADS 5 lesions of which all were found to be malignant on HP-study. All lesions wereassigned strain score ≥4.5.

Elastography score

On the basis of clinical presentation and BI-RADS imaging, 78 lesions were subjected to FNAC/ biopsy. There was a 27% (21/78) positive biopsy rate. If all lesions with elastography scores 1 and 2 were followed up, 45(57%) biopsies would have been avoided while at the same time not missing any malignancy. Thus by improving specificity elastography has potential to decrease the number of Invasive diagnostic procedures.

The mean elasticity score is significantly higher in malignant(4.43) than benign (2.1) with a p-value of <0.001withSensitivity=85.71%,Specificity=96.49%, PPV=90%, NPV=94.82%, Accuracy=93.58%.This is in close conformity with results reported by Schnitt SJ et al[23], who found that when a cutoff point of between 3 and 4 was used, elastography had 86.5% sensitivity, 89.8% specificity, and 88.3% accuracy.

Also our results were approximately consistent with studies of Gheonea IA et al.[24] obtained a sensitivity of 86.7% and a specificity of 92.9% for elasticity score. In the study done by Thomas A et al., sensitivity and specificity of 81% and 89% for elastography were observed[25], which is similar to our study.

Strain ratio

In our study based on SR with acutoff value of 4.5, the Sensitivity = 90.47%, Specificity = 98.24%, PPV = 95%, NPV = 96.55%, Accuracy = 96.15% respectively. The mean SR was significantly higher for malignant lesions 6.276 than for benign lesions 2.448with a p-value of<0.001. This is in close conformity with results reported by Esinger F et al.[26] who had a sensitivity of 93.3% and a specificity of 92.9% for SR when a cutoff point of 3.67 was used.

Ioana A.G. et al[27] in Romania found that one lesion(3.57%) with elasticity score of 4 and one lesion(3.57%)with elasticity score 5 to be benign after FNAC and exisional biopsy. In the same study, one lesion(3.57%)with elasticity score of 1 and three(10.72%)with elasticity score of 3 turned out to be malignant. In our study 2 lesions with elastography score 4 found to be benign and all elastography score of 5 were found to be malignant.

Size ratio(E/B)

In our study based on size ratio with cutoff 1.2, all 57 benign lesionshave size ratio of <1.2. where as out of 21 malignant lesions 18 have size ratio ≥1.2 and 3 have <1.2.those 3 malignant lesions with size ratio <1.2,came out to be DCIS, necrotic IDC. For less aggressive tumors such as DCIS or mucinous or colloid cancer the ratio is close to 1. For invasive ductal cancers the ratio increases with grade and is statistically significant. The clinical utility of this finding is unclear at this time. with a cutoff value of 1.2, low-grade malignancies such as DCIS or mucinous cancers can be misclassified as benign.

In our study we have taken cutoff of size ratio as 1.2 and found Sensitivity = 90.47%, Specificity = 100%, PPV = 100%, NPV = 96.61%, Accuracy = 97.43%.

Hall et al[16] demonstrated that there was potential to use size ratiotechnique to characterize breast lesions as benign or malignant. It was noted on SE that benign lesions measure smaller in size than the corresponding B-mode image, whereas malignant lesions measured larger. They proposed using the ratio of the lesion size on elastography to the B-mode size (E/B ratio) as a diagnostic criterion for benign or malignant. They used an E/B ratio of > 1.2 for a lesion to be malignant based on the Receiver Operating Characteristics (ROC) curve of a small data set. With these criteria they found a sensitivity of 100% and a specificity of 75.4%.

Barr et al[28] in a single-center unblended trial of 123 biopsy-proven cases using an E/B ratio of < 1 as benignand ≥ 1 as malignant had a sensitivity of 100% and a specificity of 95% in distinguishing benign from malignant breast lesions.

A large multicenter, unblinded trial evaluating 635 biopsy proven cases using Barr's criteria had a sensitivity of 99% and a specificity of 87% in characterizing breast lesions as benign or malignant.In a single-center trial of 230 lesions a 99%sensitivity, 91.5% specificity, Positive Predictive Value (PPV) of 90%, and a Negative Predictive Value (NPV) of 99.2% using the E/B ratio.

Comparing all the above mentioned techniques when elastographyscore, SR and E/B ratio was combined, it increased the sensitivity to 90.4% with a specificity of 100%. Hence allthree makes newer approach in early identification of malignant lesions.

CONCLUSION

Breast elastography has recently been subject to substantial attention as it has proven to reach an adequate specificity and a high negative predictive value in combination with US. Elastography may reduce the need for biopsy in lesions classified as BI-RADS 3 on US image and postpone follow-up. Elastography has a significant role in the management of nodules <5 mm which are visible on the US image, but not on mammography, in which reduced deformability may lead to biopsy rather than monitoring as required by the current guidelines.

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