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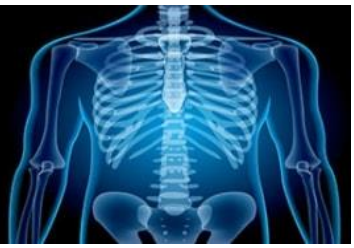

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Comparative study of the predictive value of Sonoelastography and dynamic MR Mammography for breast cancer diagnosis

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Abstract
Background & objectives: The purpose of this study is to assess the accuracy of these two imaging modalities in proposing a biopsy for BIRADS III and higher lesions, and to ascertain whether Sonoelastogram breast is a better option than Dynamic MR Mammography in this regard.
Methods: A prospective cohort study was conducted from January 2018 to January 2019 in the Out Patient Department of Radiology at Sambhram Institute of Medical Sciences and Research, Bangalore, Karnataka, India, involving 50 patients (one male and 49 female) with breast masses. All cases underwent conventional B mode ultrasound; only those categorized as BIRADS III and above had further examination using Sonoelastography and Dynamic contrast enhanced MR mammography. A Tsukuba elastographic score of 1–5 was determined based on the lesion's uptake of contrast in the introduction and twilight phases. Dynamic MR kinetic curve patterns 1–3 were examined.
Result: The HPE Final Diagnosis of the analyzed breast pathologies shows that 22 of the lesions are malignant and 28 are benign. Dynamic MR mammography curve patterns are 89.5% sensitive and 96.2% specific. Sonoelastography has a 68.4 percent sensitivty and a 92.3 percent specificity. Both the Dynamic MRI Mammogram and Sonoelastography are very accurate at diagnosing breast cancer, with 93.3% and 82.2%, respectively. Final Diagnosis of Breast Masses by HPE Compares Favorably to Curve Analysis of Dynamic MR Mammograms and Sonoelastography.
Conclusion: For evaluating breast lesions, sonoelastography and MR Mammography are both helpful techniques; the latter could reduce the number of unnecessary biopsies conducted. We discovered that in terms of both sensitivity and specificity, MR Mammography performed better than Sonoelastography.

Keywords: BIRADS, sonoelastography, MR Mammogram, kinetic curves

Introduction

Cancer and other diseases can cause breast tumors. Invasive ductal carcinoma is the most frequent malignant breast tumor, while fibroadenomas are more common benign. Despite most breast lumps being benign, Gupta *et al*. found that carcinoma breast was the most common malignancy in Indian women in 2016. The National Cancer Registry of India reports that carcinoma breast now kills more women than cervical cancer [1, 2].

India has the most breast cancer deaths, according to latest figures. Indian women's breast cancer rates rise in their 30s and peak between 50 and 64. Late-stage breast cancer is frequent in India. Breast Imaging-Reporting and Data System provides risk assessment and quality assurance for mammography, ultrasound, and MRI. Lesions with BIRADS scores of 2 or less are harmless. BIRADS grades 3 and 4 represent moderate lesions. Malignant BIRADs are grade 5 or 6 [2, 3].

Breast radiology has several imaging options. Sonoelastography, a cutting-edge sonographic tool, is being utilized to examine suspicious breast masses with B-mode ultrasound. Pressure-based sonoelastography quantifies tissue elasticity. Sonoelastogram colors show lesion size. The Tsukuba elasticity score is the most used elastography scoring method [3,4].

Breast MRI technology has advanced rapidly in the past decade. MRI's high sensitivity helps detect breast cancer that other imaging methods missed. MRI with gadolinium contrast can improve vascularity imaging of malignant breast lesions. Dynamic MR mammography may now diagnose malignant breast tumors using curve patterns [4, 5].

Several contrast-enhanced MR imaging studies have used lesion morphology or enhancing

kinetics to distinguish benign from malignant mass lesions. However, pathology classification requires kinetic and morphologic data integration. Despite non-invasive diagnostic tools, a breast biopsy is still the best technique to diagnose breast lesions and other illnesses [5, 6].

Material and Methods

Under a prospective cohort experiment, which ran from January 2018 to January 2019, participants (Male and female) over 25 who reported having breast lumps were included. Patients that attend the radiology department's outpatient clinic at the Sambhram Institute of Medical Sciences and Research in Bangalore, Karnataka, India, will make up the research population.

Inclusion criteria

1. Cases are defined as those having a BIRADS score of III or above (Determined by digital ammography and conventional B mode Ultrasound examination) and patients who are older than 20 years at the time of diagnosis.
2. Women who have breast lumps that are 5 mm or greater (Elastogram is useful only in lesions larger than 5 mm).
3. Cases with sonoelastogram and/or MR mammography imaging; cases verified histologically; cases confirmed histopathologically.

Exclusion criteria

1. Breast lesions that are graded BIRADS I or II at the time of diagnosis; lesions that develop after surgery (The fibrous alterations in the postoperative breast yields a false positive high score on elastogram).
2. Metal-implant recipients, no (Such as cochlear implants, pacemakers, defibrillators, or metallic catheters) Individuals with known sensitivities to Gadolinium-based contrast media Non-cooperative patients undergoing magnetic resonance imaging.
3. In cases when high renal parameters make Gadolinium contrast medium unsafe to employ.

Methodology

Participants in the study filled out a standard questionnaire. Information such as the patient's name, age, sex, address, education, employment, dietary habits, smoking habits, and drinking histories are included in the proforma. An extensive patient history and physical examination, as well as a thorough study and probing of the breast mass, are all included in the proforma. The study method was sanctioned by the institutional review board. After gaining each patient's consent following a thorough explanation of the process, imaging was performed.

Time-of-flight B-mode Ultrasonography was done using a GE Health care Logiq S7 scanner with a broad band linear array probe of 7.5 MHz frequency (5 - 13 MHz) and a foot print of 12.7 x 47.1 mm, after a standard clinical examination and local palpation of the breast lump.

The sonographic evaluation of the lesion's location with respect to the breast's quadrants (Upper outer, upper inner, lower outer, and lower inner), the lesion's zone, and the clock's position. Various other sonographic characteristics: Nodules along the axis Lesion margins might be well-defined, fuzzy, spiculated, or lobulated. Nodules on the axis lesions that are hypoechoic, isoechoic, or hyperechoic (Compared with the subcutaneous fat) BIRADS classification of lesions based on sonography [7, 8].

The Outpatient Service referred 170 patients who were experiencing breast mass symptoms. They both functioned in the common B mode. Ultrasound. This group was categorized by BIRADS. Both BIRADS versions were incompatible. Of the BIRADS III+ candidates, 65 were selected. Sonoelastograms were performed on 65 individuals. The dynamic contrast MRI mammography was performed on 55 people. Only fifty patients had HPE performed.

Results from 49 females and 1 male were compiled. To confirm HPE, sonoelastography and MR mammography were performed on all 45 patients within 15 days after the first imaging diagnosis, with a maximum 7-day delay between the two procedures. In all, 30 patients underwent open breast biopsies, 13 underwent core needle biopsies, and 10 underwent FNACs. Needle localization was employed in four open breast biopsies.

Standard B-mode USG of the breast was performed using a grid approach in the radial or transverse plane after a clinical history and local examination was performed with the patient supine. Lesions having a BIRADS score of 3 or above are the focus of the research. During the process of pinpointing the location of the lesion, a sonoelastogram was performed. The identical linear array transducer was utilized for both strain wave elastograms. Elastography consistently employed a 26% color enhancement, high frame rate, and a density of 2.

Results

Table 1: Age distribution in the sample population: a descriptive study (N = 50).

Parameter	Mean ±STD	Median	Min	Max	95% C.I. for EXP(B)	
					Lower	Upper
	39.95					
Age	±	38.00	22.00	75.00	37.31	44.51
	12.88					

Table 2: Age-group descriptive statistics for the sample population (N = 50).

Age Group	Frequency	Percentages
Up to 29	10	20.00%
30-39	15	30.00%
40-49	13	26.00%
50-59	9	18%
60 and above	3	6%

Table 3: Gender (N=50) descriptive statistics.

Gender	Frequency	Percentage
Female	49	98%
Male	1	2%

Table 4: Right/Left Describe the research population (N=50)

Right/Left	Frequency	Percentages
Left	22	44%
Right	21	42%
Both	7	14%

Table 5: The MRI curve was analyzed descriptively for a sample of 50 participants.

MRI curve	Frequency	Percentages
Type I	20	40.00%
Type ii	10	20.00%
Type iii	20	40.00%

Table 6: Sonoelastography Grade Descriptive Analysis (N = 50)

Sonoelastography	Frequency	Percentage
Grade-2	13	26.00%
Grade-3	20	40.00%
Grade-4	13	26.00%
Grade-5	4	8.00%

Table 7: BIRADS study population (N=50) descriptive statistics.

BIRADS	Frequency	Percentage
III	24	48%
IV	17	34%
V	7	14%
VI	2	4%

Table 8: Histopathological (HPE) diagnosis descriptions for the N=50 participants in the research.

Final Diagnosis(HPE)	Frequency	Percentage
Malignant	22	44%
Benign	28	56%

Table 9: Final Histopathological Diagnosis (HPE) and the Type of Dynamic MRI Mammogram Curve (N= 50)

MRI Curve category	Final Histopathological Diagnosis (HPE)		Chi square	P-value
	Malignant	Benign		
Malignant	18 (85.71%)	2 (6.89%)	33.537a	<0.001
Benign	3 (14.29%)	27 (93.10%)		

Table 10: Comparing the predictive validity of the curve category on dynamic MRI mammograms with Diagnosis Confirmed by Histopathology (N=50)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	89.5%	75.67%	100.0%
Specificity	96.2%	88.76%	100.0%
False positive rate	3.8%	1.00%	11.2%
False negative rate	10.5%	1.00%	24.3%
Positive predictive value	94.4%	83.86%	100.0%
Negative predictive value	92.6%	82.71%	100.0%
Diagnostic accuracy	93.3%	86.05%	100.0%

Reliability: (Kappa statistic)

	Kappa statistics	Std. Error	P-value
Measures of Agreement	0.862	0.077	<0.001

Positive likelihood ratio: -6.7 Negative likelihood ratio: 0.07

Table 11: Comparison of Sonoelastography to the Final Histopathological Diagnosis (HPE) Students' grade level (N=50) was used in the study.

Sonoelastography Grade category	Final Histopathological Diagnosis(HPE)		Chi square	P-value
	Malignant	Benign		
Malignant	14 (66.67%)	3 (10.34%)	18.219a	<0.001
Benign	7 (33.33%)	26 (89.65%)		

Table 12: The Sonoelastography's Predictive Validity Final Histopathological Diagnosis (HPE) grading vs sample size (N=50)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	67.5%	48.54%	90.4%
Specificity	93.4%	84.08%	100.0%
False positive rate	8.8%	1.00%	18.8%
False negative rate	32.7%	11.69%	53.7%
Positive predictive value	86.8%	70.47%	100.0%
Negative predictive value	82.1%	66.70%	95.4%
Diagnostic accuracy	83.3%	72.10%	94.6%

Reliability: (Kappa statistic)

	Kappa statistics	Std. Error	P-value
Measures of Agreement	0.625	0.118	<0.001

Positive likelihood ratio: -23.9 Negative likelihood ratio: 0.26

Table 13: Histopathological Diagnosis Descriptive Analysis of the Study Population (N = 50)

Histopathological Diagnosis	Frequency	Percent
Fibroadenoma	14	28%
Dcis- ductal carcinoma in situ	9	18%
Invasive ductal carcinoma	5	10%
Duct ectasia	4	8%
Phylloides	3	6%
Inflamatory carcinoma	3	6%
Granuloma	2	4%
Mastitis	2	4%
Invasive lobular carcinoma	2	4%
Ductal papilloma	1	2%
Fibroadenosis	1	2%
Hemorrhagic cyst	1	2%
Medullary carcinoma	1	2%
Mucinous carcinoma	1	2%
Nodular gynaecomastia	1	2%

Discussion

Fifty cases were included in our analysis. Almost majority of the people that took part were women (98%) with only one man (2%) contributing to the total. The average age of our sample was 39.50, with a standard deviation of 12.88 years. There was one 22-year-old and one 75-year-old (Table 1). The largest age group represented was those between 30 and 39 years old (30%), followed by those between 40 and 49 years old (26%).

According to research conducted by Sandhu *et al*. and Somdatta *et al*., the number of breast cancer diagnoses among Indian women increases considerably between the ages of 25 and 40. Our findings are consistent with this pattern. People between the ages of 35 and 50 benefit the most from contrast enhancement, per Müller-Schimpfle *et al*. Patients' contrast sensitivity seems to be independent of their age [9,10].

The left breast accounts for 44% of all cases, the right for 42%, and the right and left together for 14%. Researchers have not found any correlation between the side of the breast that is afflicted and the development of malignant tumors. Breast disorders were classified as either malignant

or benign if a definite diagnosis was confirmed (HPE). When all the diagnoses were in, 44% of the lesions were cancerous and 56% were benign [10, 11].

According to study by Schoonjans JM *et al*., invasive ductal carcinomas are the most prevalent type of malignant breast mass, while fibroadenomas are the most common type of benign breast tumor. It was also found that fibroadenomas accounted for 14 (28%) of the histological diagnoses of breast masses in this investigation. Several of the fibroadenomas were rather big, and in one case, numerous fibroadenomas against an inflammatory backdrop were first mistaken as malignant [11, 12].

Ductal carcinoma in situ is a common kind of malignant tumor (DCIS). Invasive ductal carcinoma affected 5 people, whereas in situ ductal carcinoma affected 9 others. Five cases of fibroadenosis, one of intraductal benign papilloma, one of duct ectasia, four cases of duct ectasia, three cases of phylloides tumor, two cases of chronic mastitis, two cases of granulomas, and one case of a hemorrhagic cyst were also found in our study.

Invasive and Inflammatory Lobular Carcinoma was discovered in 2 people, Medullary Carcinoma in 1, and Mucinous Carcinoma in 1. Type I curves make up 40% of all curves in a Dynamic MRI Mammogram, followed by Type II curves at 20% and Type III curves at 40% [12, 13].

When compared with the gold standard, Final Diagnosis by HPE, the sensitivity and specificity of breast mass evaluation using Dynamic MR Mammogram curve patterns are 89.5% (95% CI 75.67% 100%) and 96.2% (95% CI 88.76% 100%), respectively. Our study's sensitivity and specificity for MR Mammography are on par with those of the Liu PF *et al*. and the Mahfouz AE *et al*. investigations.

Parenchymal enhancement goes through cyclical alterations that have been linked to menstruation in studies conducted by both Delille JP *et al*. and Dean KI *et al*. Marklund M. *et al*. considered a wide range of variables, including life expectancy, HRT use, and the use of oral contraceptives. Notably absent from this article is an examination of the possible involvement of hormones in the improvement of contrast. The positive predictive value (PPV) of dynamic MRI mammography for evaluating breast masses is 94.4% (95 CI 83.86% 100%), whereas the NPPV (95 CI 82.71% 100%) is lower [13, 14].

Histological confirmation showed that MR mammography successfully identified malignant masses in 18 of 21 instances (85.71%), and benign masses in 29 of 27 cases (93.10%) in the study population. When adopting Final Diagnosis by HPE as the gold standard, the false positive rate for evaluating breast masses using Dynamic MRI Mammogram curve categories is 3.8% (95 CI 1.00%_11.2%), whereas the false negative rate is 10.5% (95 CI 1.00%-24.3%).

When we looked into MR Mammography false positives, we identified only one. In this example, several fibrodenomas developed on top of an inflammatory milieu. A common feature of the lesions in this case was an accentuated pattern of type III curves.

When MR mammography was performed on two patients with ductal carcinoma in situ, the results were false negatives due to the presence of small lesions with type II curve (Moderate) enhancement. Dynamic MRI mammography curve patterns diagnosed BIRADS III and higher-grade breast masses with a 93% (95% CI 86.05% 100%) success rate [14, 15].

Different final diagnoses for breast masses are found using the HPE and dynamic MR mammography curve analysis techniques, with the difference being statistically significant (P 0.001). Grading distribution with regard to sonoelastography looks like this: Twenty-six point seven percent got a 3, forty percent got a 4, twenty-six point seven percent got a 5, and six point seven percent got an A.

BIRADS III is present in 48% of cases, BIRADS IV in 34%, BIRADS V in 14%, and BIRADS VI in 2%. The sensitivity of sonoelastography grading is 68.4% (95 CI 47.52%_89.3%) when assessing breast masses in BIRADS categories III and above, and the specificity is 92.3% (95 CI 82.06% 100%) [15, 17].

Sonoelastography showed a positive predictive value of 86.7% (95% CI: 69.46%-100%) for evaluating breast masses in BIRADS III and above categories, and a negative predictive value of 80% (95% CI: 65.69%-94.3%). We found that Sonoelastography Grades 4 and 5 accurately discovered 13 (68.42%) histopathologically established cancers, whereas Class 2 and 3 imaging properly identified 24 (92.31%) benign breast masses.

Sonoelastography had a false positive rate of 7.7% (95% confidence interval [CI]: 1.00%-17.9%) for evaluating breast masses in BIRADS III and above categories, and a false negative rate of 31.6% (95% CI: 10.68%-52.5%). One of the men who came to see us reported feeling a lump under his chin. We identified a BIRADS IV lesion with an elastographic grade of 4 on B mode USG. Type I benign curves were seen in the dynamic MR mammography. Particularly, nodular gynecomastia was identified as the cause of the male breast growth (benign). A female patient with a large fibroadenoma and a male patient with nodular gynecomastia both had false positive cancer diagnoses after sonoelastography. Calcification may be missed on B mode USG, and fibrotic components may cause a false positive [18, 19].

Diagnostic accuracy with sonoelastography was 82.2% (95 CI 71.05% 93.4%; BIRADS III+) for all breast tumors. The HPE and Sonoelastography Grades in the Final Diagnosis are correlated quite significantly (P 0.001). We found no patients with a score of 1 or 2, indicating an uniform strain pattern indicative of a soft nature or benign lesions, which is consistent with the findings of the study by Itoh *et al*sonoelastography. It aids in avoiding invasive histological examination of these lesions when it is not essential.

The majority of malignant lesions (84% in the research by Raza *et al*.) had elasticity values of 4 or 5. Elasticity ratings of 4 or 5 were seen in 68.4% of malignant tumors and 92.3% of benign lesions. Sonoelastography was determined to have a sensitivity of 67-83% by the research teams of Thomas A. *et al*. and Lee J.H. *et al*., and a specificity of 86%-90%. Multiple investigations have demonstrated that traditional B-mode USG's sensitivity and specificity can be improved by including elastographic data into the study [20, 21].

It was found by ElSaid NA *et al*. that dynamic MR mammography had a sensitivity of 88% in detecting lesions in BIRADS grades III and higher, whereas sonoelastography had a sensitivity of 84%. Sonoelastography was shown to have a sensitivity of 84%, while MR mammography only managed 80%. Our results show that the specificity of Sonoelastography for the diagnosis of malignant breast masses is significantly higher than that shown in other investigations. In comparison to

magnetic resonance imaging (MRI), sonoelastography is more cost-effective, but it still requires the expertise of a technician.

One of the many benefits of magnetic resonance mammography is its capacity to capture images of both breasts at once (MR Mammography). High picture quality and the ability to assess masses in dense breast tissue are two other advantages. *In-vivo* breast implant research using magnetic resonance imaging is considered to be the gold standard. Although MR mammography is more costly than ultrasound, it is also less reliable in finding calcifications in the breast. Contrast enhancement in magnetic resonance mammography may be affected by hormonal fluctuations around the time of ovulation [21, 22].

Conclusion

Sonoelastogram and MR mammography both provide reliable characterizations of breast cancer masses. Integrating elastography with routine B mode USG for diagnosing breast masses improves accuracy significantly. MRI is preferable to Ultrasound when a simultaneous diagnosis of several lesions in both breasts is required. Benefits of dynamic contrast MRI include detection of in situ tumors at an early stage. Adding kinetic curve analysis to morphological analysis has improved the sensitivity and specificity of MR mammography. Sonoelastography and MR Mammography have the potential to lessen the number of invasive breast lesion biopsies that aren't necessary. Our results show that MR mammography outperforms Sonoelastography in terms of both sensitivity and specificity.

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