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Correlational study of breast sonography and elastography with histopathology in patients with breast lump

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***Abstract*---**The aim is to study the correlation of Breast Sonography and Elastography findings with histopathological diagnosis in patients with palpable breast lump. This was a prospective study. All patients fulfilling inclusion criteria in Krishna Hospital & Medical Research Centre, Karad were included in the study which was conducted from December 2019 to July 2021. All patients with clinically palpable breast lump underwent breast ultrasound and breast elastography and were correlated with histopathological diagnosis. In the present study, conventional sonography had a sensitivity of 100%, specificity of 87.50%, PPV of 80% and NPV of 100% with overall accuracy of 91.67%. Elastography had a sensitivity of 100%, specificity of 90%, PPV of 83.3% and NPV of 100% with overall accuracy of 93.33%. From the present study I concluded that breast elastography when used along with conventional breast sonography can improve specificity of ultrasonography in differentiating benign and malignant lesions.

***Keywords*---**breast sonography, elastography, histopathology, breast lump.

Introduction

Breast cancer is the most frequent malignant tumour in women worldwide with about 1.5 million cases being affected. Most common cancer in Indian women is breast cancer which accounts for 27% of all cancers in women. One woman dies of every 2 women newly diagnosed with cancer.[1] Early detection for improving breast cancer outcomes is the keystone of breast cancer control. Even though ultrasonography and mammography have withstood the test of time which have

shown highest sensitivity in detecting breast cancer, both methods have some limitations. False-negative results are commonly associated with mammography done in dense breasts. However, the diagnostic sensitivity improved when ultrasound was added to screening mammography in women with dense breasts. Yet, the shortcoming was an increased false-positive rate and lower positive predictive value.

Hence, ultrasound elastography was introduced to obtain a more precise characterisation of breast lesions. By adding further information about stiffness of tissue, breast elastography can improve visualisation of tumours and enable differentiation between benign and malignant disease.

Aim and Objectives

Aim

The aim of the present prospective study is to study the correlation of breast sonography and elastography findings with histopathological diagnosis in patients with palpable breast lump.

Objectives

1. To study breast sonography findings in patients with palpable breast lump.
2. To study breast elastography findings in patients with palpable breast lump.
3. To obtain histopathological diagnosis of surgically excised breast lump/biopsy.
4. To correlate breast sonography and elastography findings with histopathological diagnosis.

Materials and Methods

Type of Study: Prospective study
Study Setting: Department of General Surgery
Study Duration: 18 months (December 2019 to July 2021)

Source of Data

This was a prospective study. All patients fulfilling inclusion criteria in Krishna Hospital and Medical Research Centre, Karad were included.

Inclusion Criteria

- All patients coming to Department of Surgery presenting with palpable breast lump
- Patients of age 18 years or more

Exclusion Criteria

- Patients who are already diagnosed and treated for breast lump.
- Patients who are previously operated for breast lump

- Patients of age less than 18 years

Sample Size

As per the reference article published by Ramona Mendez et al, on Correlation of Strain Elastography with Conventional Sonography and FNAC/Biopsy. Sample size was calculated using following formula

$$n=pq/d^2$$

where p=(true positives + True negatives/ Total cases)*100= 87
q= 100-p = 13
d= precision= 10% of p = 8.7
n=60
Hence, we have selected 60 patients as subjects for the present study.

Methods

All the cases fulfilling the set inclusion criteria, subsequent to the approval of institutional ethical committee were signed up in the present study.

- Written and informed consent was taken.
- All patients with clinically palpable breast lump underwent breast ultrasound and breast elastography and were correlated with histopathological diagnosis
- Classification method of Breast Sonography was according to BIRADS-Breast Imaging-Reporting and Data System
- Interpretation method for Elastogram was Tsukuba Elastography score
- Correlation of ultrasonography and elastography findings with histopathological diagnosis

Table no 1: Birads Classification for Breast Ultrasound

Score	Category
0	Needs additional imaging or prior examinations
1	Negative
2	Benign
3	Probably Benign
4	Suspicious
5	Highly suggestive of malignancy
6	Know biopsy proven

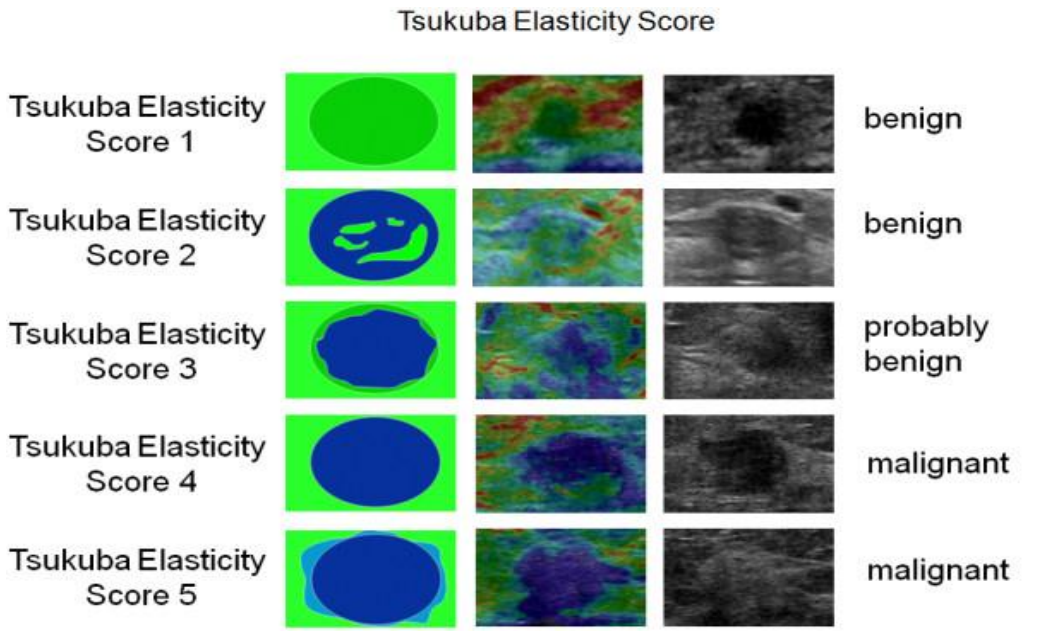


Figure No 3: Tsukuba Elasticity Score

Green: Tissue with the greatest strain (softest component) Blue: Tissue with no strain (hardest component) Red: Tissue with intermediate strain

Table No 2. Tsukuba scoring system for breast mass classification

SCORE	DENOTATION
1	mass(soft) coded in green as the adjacent breast tissue
2	blue and green (heterogeneous distribution in soft-hard internal structure)
3	: the mass coded blue in the centre surrounded by green colour (the centre of the lesion is hard)
4	the mass is completely blue (the mass is completely rigid
5	the mass and the surrounding adjacent tissue coded blue due to desmoplastic reaction in both the mass and the surrounding tissue

Statistical Analysis

- Statistical analysis was completed using SPSS 20 for Windows (SPSS Inc. Chicago, Illinois)
- $P<0.05$ was considered as significant difference.
- FNAC and Histopathology findings were compared with Age, BIRADS score, Elastography score using Fishers exact test.

Observation and Results

Table No 3: Histological Type of Tumour

HISTOLOGICAL TYPE OF TUMOUR	Fibroadenoma	26	43.3%
	Fibrocystic change	10	16.7%
	Intraductal papilloma	4	6.7%
	Infiltrating ductal carcinoma	16	26.7%
	Invasive Lobular carcinoma	4	6.7%
	Total	60	100.0%

- Among the 60 breast lesions examined, 40 were diagnosed as benign and 20 were diagnosed as malignant on pathological analysis.
- Final Pathological diagnosis is shown below

Figure No 4: Diagnosis based on Histopathology

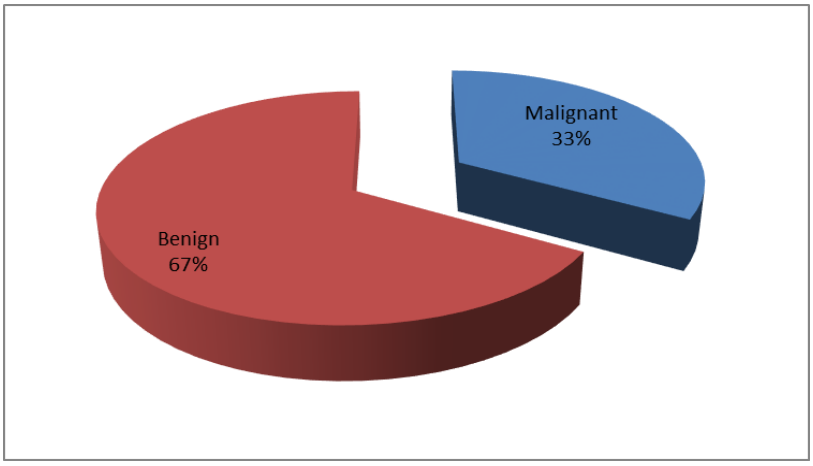


Table No 4: Age Distribution of Patients With Breast Lump

		Count	Column N%
AGE	20 and below	6	10.0%
	21 – 40	16	26.7%
	41 – 60	26	43.3%
	Above 60	12	20.0%
	Total	60	100.0%

Figure No 5: Age Distribution of Patients With Breast Lump

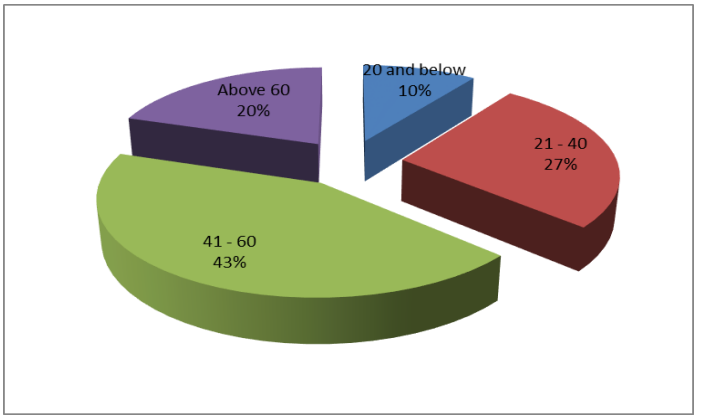
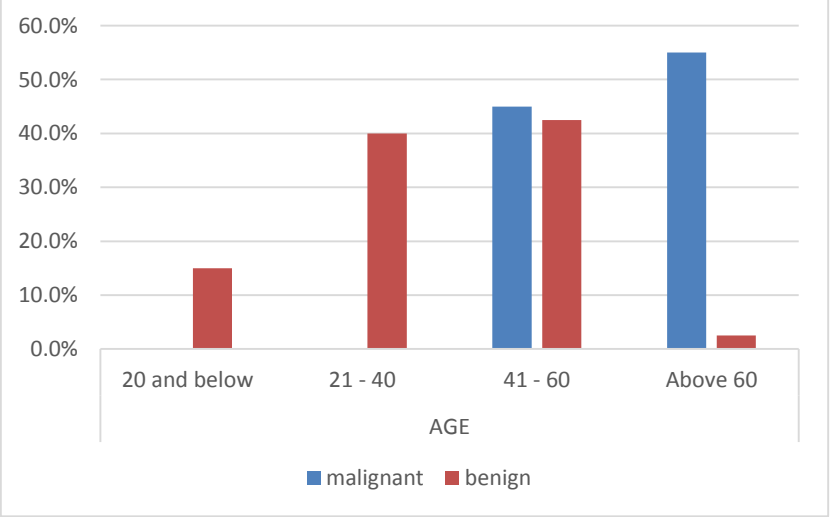


Table No 5: Association of Age With Breast Tumour

		Malignant on Histopathology		Benign on Histopathology	
		Count	Column N%	Count	Column N%
AGE	20 and below	0	0.0%	6	15.0%
	21 - 40	0	0.0%	16	40.0%
	41 - 60	9	45.0%	17	42.5%
	Above 60	11	55.0%	1	2.5%
	Total	20	100.0%	40	100.0%

Figure No 6: Association of Age With Breast Tumour



		HISTOLOGICAL TYPE OF TUMOUR									
		Fibroadenoma		Fibrocystic change		Infiltrating ductal carcinoma		Intraductal papilloma		Invasive Lobular carcinoma	
		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
AGE	20 and below	5	19.2%	1	10.0%	0	0.0%	0	0.0%	0	0.0%
	21 - 40	10	38.5%	4	40.0%	0	0.0%	2	50.0%	0	0.0%
	41 - 60	10	38.5%	5	50.0%	9	56.3%	2	50.0%	0	0.0%
	Above 60	1	3.8%	0	0.0%	7	43.8%	0	0.0%	4	100.0%
	Total	26	100.0%	10	100.0%	16	100.0%	4	100.0%	4	100.0%

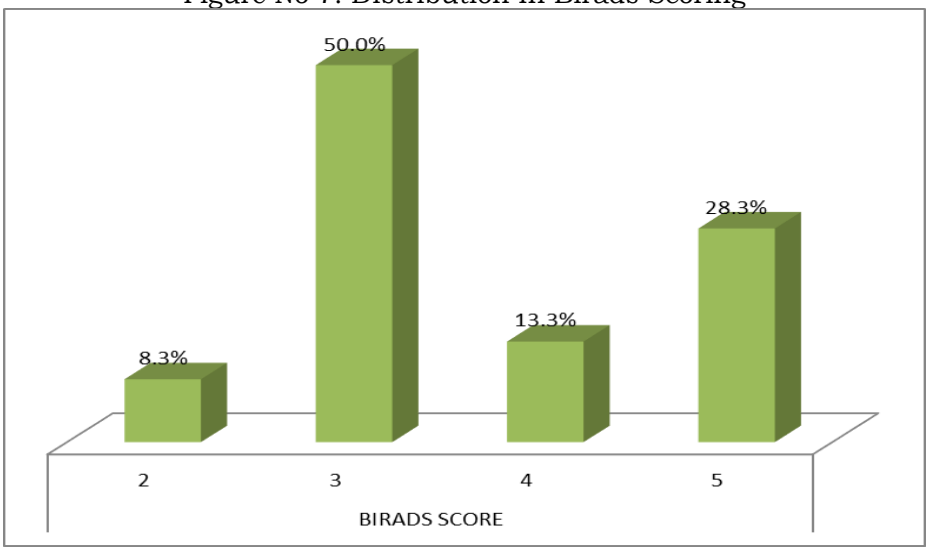
Table 6: Association Of Age With Histological Type Of Tumour

Table No 7: Distribution in Birads Scoring

		Count	Column N%
BIRADS SCORE	2	5	8.3%
	3	30	50.0%
	4	8	13.3%
	5	17	28.3%
	Total	60	100.0%

Count: Number of patients in that group

Figure No 7: Distribution In Birads Scoring



Results According to Birads

Considering the conventional cut-off between score 3 and 4 for benign and malignant.
Category 2 :5 lesions (5 benign)
Category 3 :30 lesions (30 benign)
Category 4: 8 lesions (5 benign,3 malignant)
Category 5: 17 lesions (17 malignant)

Table No 8: Correlation of Conventional Ultrasound(Bi-Rads) With Pathology Results

		Malignant on Histopathology		Benign on Histopathology	
		Count	Column N%	Count	Column N%
BIRADS SCORE	2	0	0.0%	5	12.5%
	3	0	0.0%	30	75.0%
	4	3	15.0%	5	12.5%
	5	17	85.0%	0	0.0%
	Total	20	100.0%	40	100.0%

Figure No 8: Results According to Birads

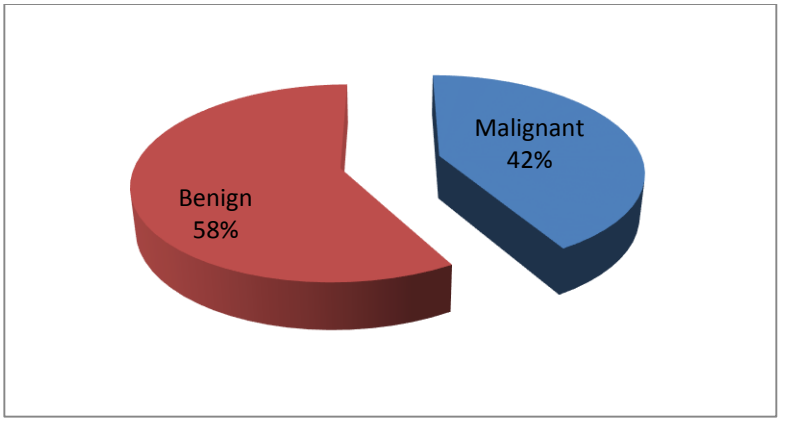


Table No 9: Distribution in Elastography Scoring

		Count	Column N%
ELASTOGRAPHY SCORE	1	6	10.0%
	2	7	11.7%
	3	23	38.33%
	4	14	23.3%
	5	10	16.66%
	Total	60	100.0%

Count: number of patients in that group

Figure No 9: Distribution in Elastography Scoring

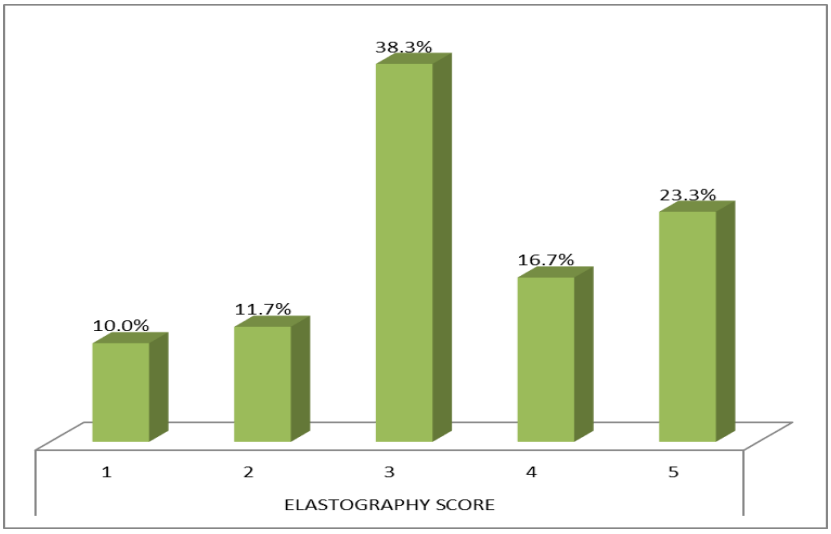


Table No 10: Correlation of Elastography Score With Pathology Results

		Malignant on Histopathology		Benign on Histopathology	
		Count	Column N%	Count	Column N%
ELASTOGRAPHY SCORE	1	0	0.0%	6	15.0%
	2	0	0.0%	7	17.5%
	3	0	0.0%	23	57.5%
	4	6	30.0%	4	10.00%
	5	14	70.0%	0	0.0%
	Total	20	100.0%	40	100.0%

- Of the 20 malignant lesions, all had a score of 4 or 5. None of these lesions had a score of 1-3
- Of the 40 benign lesions, 13 had a score of 1 or 2, 23 had a score of 3.
- 4 out of 10 lesions with a score of 4 were benign
- 0 out of 14 lesions with a score of 5 were benign

Figure No 10: Results According to Elastography Score

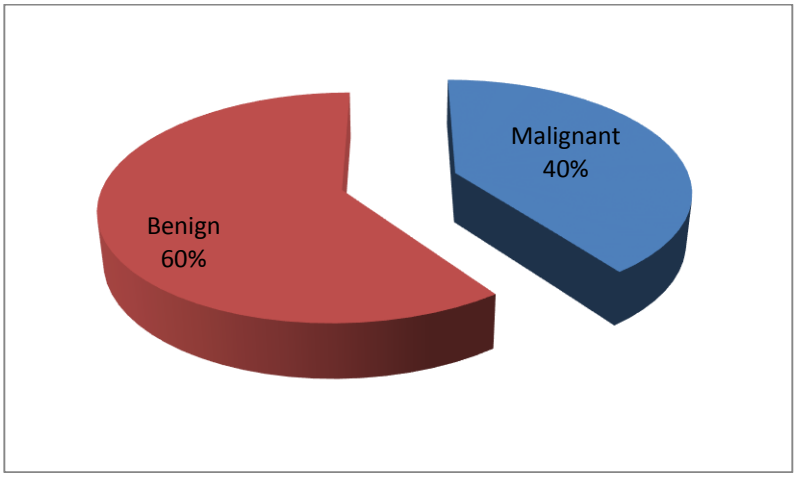


Table No 11: Correlation of FNAC Score With Pathology Results

FNAC Score	Malignant		Benign	
	Count	Column N%	Count	Column N%
C1	0	0	0	0
C2	0	0	34	85
C3	0	0	6	15
C4	6	30	0	0
C5	14	70	0	0

C1- unsatisfactory, C2 – Benign, C3- Atypical, C4- Suspicious, C5- Malignant

Results

With a conventional cut-off between BI-RADS categories 3 and 4 following values were calculated.

Table No 12: Accuracy of Breast Ultrasound

BIRADS SCORE		Confidence Interval	
		Lower	Upper
Sensitivity	100.00	100.00	100.00
Specificity	87.50	77.25	97.75
PPV	80.00	64.32	95.68
NPV	100.00	100.00	100.00
Overall accuracy**	91.67	84.67	98.66
	P=0.000, HS		

Sensitivity – 100%
Specificity – 87.50%

With a cut-off between Elastography scores 3 and 4 following values were calculated.

Table No 13: Accuracy of Elastography

ELASTOGRAPHY SCORE		Confidence Interval	
		Lower	Upper
Sensitivity	100.00	100.00	100.00
Specificity	90.00	80.70	99.30
PPV	83.33	68.42	98.24
NPV	100.00	100.00	100.00
Overall accuracy**	93.33	87.02	99.65
	P=0.000, HS		

Sensitivity – 100%
Specificity – 90.0%

Discussion

Demographic Parameters

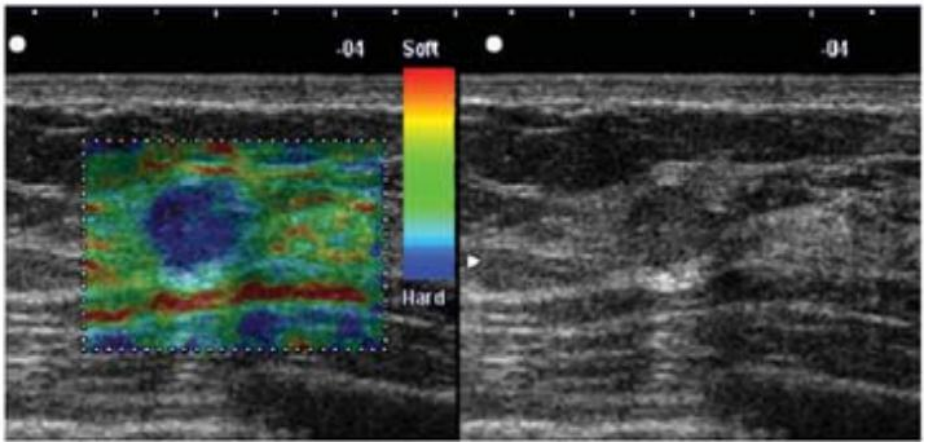
43% of patients who had breast lumps were in the age group of 40-60%. Whereas 45% of these patients turned out to have a malignant lesion.
55% of patients with malignant breast lesions were in the age group of more than 60 years.

Ultrasonography and Elastography Correlation

Conventional sonography had a sensitivity of 100% and specificity of 87.50%. Elastography had a sensitivity of 100% and specificity of 90%.

- 8 lesions were prospectively assigned as BI-RADS 4 of which 5 were found to be benign. In the benign cluster, 2 lesions had elasticity score of 2, 2 lesions had a score of 3 and 1 lesion had a score of 4.
- 1 lesion which had elasticity score of 4 was found to be fibroadenoma in dense fibroglandular tissue.
- No malignant lesions were given a score of 1,2 or 3 in elastography scoring.

Figure No 11: Real Time Elastography



Fibroadenoma in a 45 years old female. Ultrasound showed a hypoechoic lesion with an ill-defined margin interpreted as BIRADS 4A. Elastography score scored it as a 4 due to dense fibrogalndular tissue. On the account of clinical picture and BIRADS imaging, 60 lesions were subjected to FNAC and biopsy. There was a 33% biopsy positive rate. If the lesions with elasticity score of 1 and 2 were followed up, 13 biopsies would have been prevented, while not missing any malignancy at the same time. Thereby increasing specificity, elastography is likely to reduce number of invasive diagnostic procedures My study result demonstrated an exceptional value for sensitivity (100%) with conventional sonography.

My study also demonstrated a better specificity for sonographic elastography than conventional sonography with a value of 90%. It is crucial that standards used for detection of cancer be accurate, while at the same time easy to execute so as to enable inclusion into routine clinical practice. Results of my study prove that Elastography is able to differentiate benign from malignant lesions with statistical significance. My results corroborate with following studies.

- Giuseppetti et al [1] – Their study showed Elastography sensitivity and specificity of 79% and 89% respectively. They highlighted that histotype and dimensions of lesions have an effect on level of elasticity
- Rizzatto et al [2]- Their study showed high specificity with NPV of 98% in relation to the entire group of lesions and 100% in lesions less than equal to 5mm.
- Barr et al [3] – Their study showed overall sensitivity of 98.6% and specificity of 87.4%.
- Itoh et al [4]- published one of the first clinical trials aimed at evaluating the diagnostic possibilities of RTE by examining 111 nodules (59 benign, 52 malignant; confirmed by cytology/histology) dimension <30 mm in diameter. Using a cut-off value between 3 and 4, elastography achieved a sensitivity, specificity and accuracy of 86.5%, 89.8% and 88.3%, respectively. Using a BI-RADS cut-off value between 4 and 5, US reached 71.2%, 96.6% and 84.7%, respectively

- Zhi et al.[5] compared RTE, US and mammography in differentiating benign from malignant breast lesions in dense breasts. They studied 296 lesions (209 benign, 87 malignant) using the score system designed by Itoh et al.
- Yerli et al. [6] presented a study of 78 lesions (62 benign, 16 malignant; confirmed by histological analysis) submitted to US examination and RTE to evaluate if the combination of elastographic score was useful in differentiating benign from malignant lesions. Sensitivity and specificity were 80% and 95%, respectively, related to the elastographic score, 87.5% and 72.6%, respectively, related to US
- Kumm et al[7] studied 310 lesions (223 benign, 87 malignant; confirmed by biopsy) obtaining a sensitivity of 76% and 79%, specificity of 81% and 76% for elastographic score and strain ratio respectively.

Summary

The present study involved a total of 60 patients with palpable breast lump, all of which underwent breast sonography, elastography, fine needle aspiration cytology and biopsy. The results were calculated according to BIRADS scoring for conventional breast ultrasound, Tsukuba scoring for breast elastography and Yokohama system for FNAC and Histopathology for biopsy. It was found that, Conventional sonography had a sensitivity of 100%, specificity of 87.50%, PPV of 80% and NPV of 100% with overall accuracy of 91.67%. Elastography had a sensitivity of 100%, specificity of 90%, PPV of 83.3% and NPV of 100% with overall accuracy of 93.33%.

Conclusion

Breast elastography when used along with conventional breast sonography can improve specificity of ultrasonography in differentiating benign and malignant lesions.

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