

# Diagnostic Accuracy of Strain Elastography in Differentiation of Malignant and Benign Breast Lesions Taking Histopathology as Gold Standard

Elastography in Differentiation of Malignant and Benign Breast Lesions

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## ABSTRACT

**Objective:** To assess the diagnostic accuracy of strain elastography to differentiate malignant and benign breast lesions, taking histopathology as gold standard modality.

**Study Design:** Descriptive cross-sectional study.

**Place and Duration of Study:** This study was conducted at the Department of Radiology, Sahiwal Teaching Hospital, Sahiwal from 14th September 2019 to 13th March 2020.

**Materials and Methods:** 115 female patients between 22-65 years of age, with suspicion of hypoechoic or isoechoic focal solid breast lesion which was less than 30 mm in size were included in the study. We excluded patients having mastitis and indecisive histopathologic diagnosis. Ultrasound Strain elastography was carried out using My Lab twice with by Esaote. The biopsy of all cases was performed and the lesions were labeled as malignant or benign. Data was analyzed using SPSS version 22.0. Mean and SD were analyzed for variables like age, duration of disease and size of lesion. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy of ultrasound strain elastography to differentiate malignant from benign breast lesions were calculated keeping histopathology as gold standard.

**Results:** In 70 patients that were malignant on ultrasound strain elastography, 62 were true positive and 08 were false positive. Among, 45 patients that were benign on strain elastography, 05 were false negative while 40 patients were true negative. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of strain elastography in detection of malignant from benign breast lesions, keeping histopathology as gold standard was 92.54%, 83.33%, 88.57%, 88.89% and 88.70% respectively. Association between ultrasound strain elastography and histopathology in differentiating malignant and benign breast lesions were found to be statically significant (p-value 0.001).

**Conclusion:** We concluded from our study that ultrasound strain elastography is a highly sensitive and accurate modality for diagnosing malignant breast lesions.

**Key Words:** Breast lesions, ultrasound, strain elastography.

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## INTRODUCTION

Oncogenesis is a diverse process that involves both genetic and environmental factors. Breast cancer is among the highest prevalent cancers in females worldwide, with about 2.3 million new cases presenting every year and is fifth common cause of death due to cancers.<sup>1</sup>

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In Pakistan, the most commonly diagnosed cancer in females is breast cancer, accounting for about one in nine females.<sup>2,3</sup>

Patients of breast cancer commonly present with palpable breast lump and pain.<sup>4</sup> Screening test for breast cancer is mammography and ultrasonography (US), both of which are highly sensitive in detecting them. It would be patient friendly to utilize less invasive and cost effective method(s) of diagnosis without giving any pain to the patient by invasive surgical biopsy as histopathological diagnosis requires invasive procedure to get biopsy specimen.<sup>5</sup> In situation of a potential malignancy, imaging studies are beneficial to find the extent of the of disease and to identify other small masses within the breasts.

Breast ultrasound (US) is an inexpensive modality, without ionizing hazards. It is helpful in differentiating solid-cystic lesions detected on mammography, especially in dense breasts.<sup>6</sup> Despite high diagnostic

accuracy of ultrasound, it is often difficult to differentiate benign and malignant breast tumors sonographically and biopsy is often needed for these lesions. This causes discomfort to the patients. Hence, non-invasive techniques are needed to minimize biopsy of benign breast lesions.<sup>5</sup>

Recently, role of elastography has emerged to differentiate between benign and malignant breast lesions based on the tissue elasticity. Malignant lesions are stiffer than benign ones, thus elastography is considered a highly specific method for distinguishing benign and malignant lesions and it is reducing the number of benign breast biopsies.<sup>7</sup> The strain elastography was found to be a highly specific and sensitive method with a high diagnostic accuracy to differentiate benign and malignant breast lumps.<sup>8</sup> We planned this study to find the diagnostic accuracy of ultrasound strain elastography in differentiating malignant from benign breast lumps in our area so that timely diagnosis and management through non-invasive technique can be offered to our patients.

## MATERIALS AND METHODS

This descriptive, cross-sectional study was carried out in Department of Radiology, Sahiwal Teaching Hospital, Sahiwal, from 14th September 2019 to 13th March 2020. After taking permission from ethical review committee, we enrolled 115 cases in total with 95% confidence level. Patients falling between 22-65 years of age having hypoechoic or isoechoic focal solid lesion with size of less than 30 mm and definite histopathologic diagnosis were included in the study. Patients having mastitis and indecisive histopathologic diagnosis were excluded. After taking informed consent, demographic details were noted. Ultrasonography was done before going through any kind of intervention. Ultrasound strain elastography was performed with My Lab twice by Esaote. Criteria used for suspicion of malignant lesion was strain ratio greater than 3.5 and elastographic score of 4-5. To reduce the bias, all procedures were performed by a single radiologist. The biopsy specimen was performed of all cases and all the cases were reported by a single histopathologist. The lesions were labeled as malignant and benign lesions according to functional definitions. Data was analyzed using SPSS 22.0. Mean and SD were analyzed for variables like age, duration of disease and size of lesion. Frequency and percentage was calculated for menopausal status. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy of ultrasound strain elastography to differentiate malignant from benign lesions were calculated keeping histopathology as gold standard. Association between ultrasound strain elastography and histopathology was also analyzed. P-value <0.05 was considered as significant. Stratification of diagnostic accuracy of

ultrasound strain elastography for various variables such as age, duration of disease, menopausal status and size of lesion was done.

## RESULTS

The age range of our subjects was 22-65 years with mean age of  $42.35 \pm 11.61$ . The mean duration of disease was  $6.30 \pm 2.62$  months. 60 % of subjects were having disease duration < 6 months while 40 % were having > 6 months of duration. Figure No. 1.

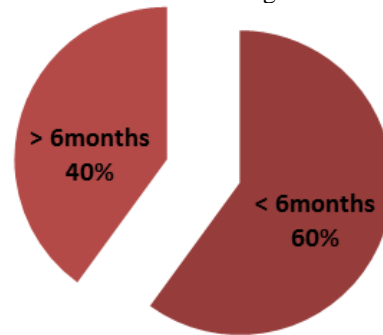


Figure No. 1: Duration of the disease

The mean size of lesion in our patients was  $17.11 \pm 6.30$  mm. 46.96 % (54) cases showed < 15 mm size of lesion whereas 53.04 % (61) cases showed 16-30 mm size of lesion. Figure No. 2.

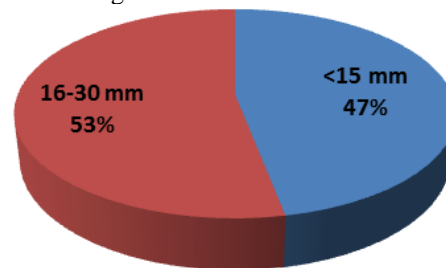


Figure No. 2: Size of the Lesion

Our study showed, 76.52 % cases were pre-menopausal while 23.48 % cases were post-menopausal. Figure 3.

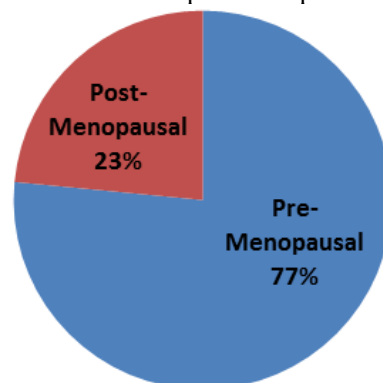


Figure No. 3: Distribution according to menopause status

In our patients, histopathology confirmed malignancy in 67 (58.26%) cases. Ultrasound strain elastography supported the diagnosis of malignant breast lesions in

70 (60.87%) patients. Among 70 patients, that were found to be malignant on strain elastography, 62 were true positive, i.e. they were found to be malignant on histopathological examination as well. 08 cases were false positive i.e., they turned out to be benign on histopathological examination. Among 45 patients that were found to be benign on strain elastography, 05 were false negative i.e. they were labeled as malignant on histopathology, whereas 40 patients were found to be true negative) i.e. they were reported as benign on histopathology as well. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of ultrasound strain elastography in differentiation of malignant from benign breast lesions, keeping histopathology as gold standard was 92.54%, 83.33%, 88.57%, 88.89% and 88.70% respectively.

Association between ultrasound strain elastography and histopathology in differentiating malignant and benign breast lesions were found to be statically significant (p-value 0.001). Table No. 1.

**Table No.I. Association between ultrasound strain elastography and histopathology**

	Malignant on Histopathology	Benign on Histopathology	P value
Malignant on strain elastography	62	08	0.001
Benign on strain elastography	05	40	

Diagnostic accuracy with respect to different variables like age, duration of disease, size of the lesion and menopausal status groups is given in Table No. 2.

**Table No.2: Stratification of diagnostic accuracy considering age, duration of the disease, size of the lesion and menopausal status.**

Variables	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Diagnostic Accuracy
<b>Age</b>					
22-45 years ( n= 71 )	90.91%	88.89%	93.02%	85.71%	90.14%
46-65 years ( n= 44 )	95.66%	76.19%	81.48%	94.12%	86.36%
<b>Duration of the Disease</b>					
≤ 6 month (n=69)	92.31%	80.0%	85.71%	88.89%	86.96%
>6 month (n= 46)	92.86%	88.89%	92.86%	88.89%	91.30%
<b>Size of The Lesion</b>					
≤15 mm (n=54)	94.12%	90.0%	94.12%	90.0%	92.59%
16-20 mm (n=61)	90.91%	78.57%	83.33%	88.0%	85.25%
<b>Menopausal Status</b>					
Pre-menopausal women (n=88)	92.59%	82.35%	89.29%	87.50%	88.64%
Postmenopausal women (n=27)	92.31%	85.71%	85.71%	92.31%	88.89%

**DISCUSSION**

Our study showed that ultrasound strain elastography is a highly sensitive and specific latest modality with high diagnostic accuracy that can be used along with B-mode ultrasound for the management of breast masses. These findings were also supported by a study conducted by Farooq F et al.<sup>8</sup> A study conducted by Rehman H et al, demonstrated the sensitivity, specificity and diagnostic accuracy of strain elastography to diagnose malignant breast lumps to be 88.57%, 90.20% and 89.78% respectively, which is closely related to our results.<sup>9</sup>

While a study conducted by Dinc Elibol F et al, showed it a user dependent method with sensitivity and specificity being 59.1% and 65.1% respectively.<sup>10</sup> Another study by Yildiz MS et al, favors the use of strain elastography as it reduces the unnecessary biopsies to be performed.<sup>11</sup> Ultrasound elastography was considered to be more sensitive to differentiate benign and malignant breast masses as compared to mammography in a study by Thomas R et al.<sup>12</sup>

A study by Pastor N et al, found elastography a good technique to diagnose and differentiate malignant breast lumps.<sup>13</sup> A study conducted by Joshi R demonstrated the diagnostic accuracy of ultrasound elastography in differentiating malignant breast lesions to be 93.33%.<sup>14</sup> There were certain limitations to our study. One of them was non-availability of shear wave elastography software in our ultrasound machine and second was small sample size. Hence, more studies including large number of patients with addition of shear wave elastography must be done in future.

**CONCLUSION**

This study concluded that strain elastography is a highly sensitive and accurate modality for differentiating malignant from benign breast lesions. So, we recommend that strain elastography should be used as a primary screening tool for accurate screening and pre-operative identification of breast lesions in order to reduce morbidity and mortality of these patients.

**Author's Contribution:**

Concept & Design of Study: Javaria Akhtar  
 Drafting: Muhammad Rafi Abbas  
 Data Analysis: Muhammad Saleem Akhter  
 Revisiting Critically: Javaria Akhtar,  
 Muhammad Rafi Abbas  
 Final Approval of version: Javaria Akhtar

**Conflict of Interest:** The study has no conflict of interest to declare by any author.

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