https://doi.org/10.29309/TPMJ/2024.31.06.7801

The Professional Medical Journal
www.theprofesional.com
2024, Volume, 31 Issue, 06

ORIGINAL ARTICLE

Diagnostic accuracy of Non Invasive Imaging "Ultrasound Elastography" in breast carcinoma in patients with pathological nipple discharge taking histopathology as gold standard.

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Article Citation: Jesrani A, Nayab S, Awan RH, Jesrani EK, Kumar A. Diagnostic accuracy of Non Invasive Imaging "Ultrasound Elastography" in breast carcinoma in patients with pathological nipple discharge taking histopathology as gold standard. Professional Med J 2024; 31(06):1004-1008. https://doi.org/10.29309/TPMJ/2024.31.06.7801

ABSTRACT… Objective: To evaluate the diagnostic accuracy of Strain Elastography in detection of breast carcinoma taking histopathology as gold standard. **Study Design:** Cross sectional study. **Setting:** Department of Radiology, Liaquat University of Medical and Health Sciences, Jamshoro. **Period:** June 2021 to May 2022. **Methods:** Patients aged 25 to 65 years with clinically palpable breast lump of any size with pathological nipple discharge. This study was conducted from June 2021 to May 2022 in department of radiology. Each patient will be subjected to sonoelastography followed by ultrasound guided trucut biopsy. The strain ratio cut off value of 4.8 will be used to differentiate benign from malignant lesion. Results of Strain Elastography will be compared with histopathology reports. **Result:** Mean age was 37.40 ±11.54 years. The sonoelastography showed sensitivity of 88.57%, specificity of 90.20%, positive predictive value of 75.61% and negative predictive value of 95.83%. So diagnostic accuracy of sonoelastography was 89.78% in diagnosis of malignant breast lesions. **Conclusion:** Sonoelastography has good sensitivity and specificity in diagnosis of malignant breast lesions.

Key words: Histopathology, Malignant Breast Mass, Strain Ratio, Strain Elastography, Trucut Biopsy, Ultrasound.

INTRODUCTION

Breast carcinoma is attributed to be one of the most common malignancies, responsible for over 22% of cancers amongst the female population globally. Patients tend to be less inclined towards biopsies, as not only are they painful and invasive but according to pathologic report, they also account for 75% of benign cases.[1-4] Consequently, it is imperative that more accurate and less invasive procedures be undertaken for cases of suspicious breast lesions.[5] In order to determine whether breast masses are malignant or benign, imaging features on ultrasonography may be useful and consequently, may reduce the reliance on diagnostic biopsies overtime.[6] Therefore, another procedure to come forth as a sonographic parameter to ascertain if the breast masses are malignant or benign is elastography.[7] True cut needle biopsy with the help of non-invasive ultrasound is often used in the replacement of surgical biopsy. The advanced b-mode ultrasonic technique now used to demonstrate size and elasticity of breast lesions. The characterization of calcification, echo pattern, posterior acoustic features were generated by breast imaging recording and data system (BIRADS), depending on scores ranges from 2 to 5, and interprets benign and malignant lesions (score 2 and 3 for benign,4 and 5 for malignant). Nevertheless, on occasion, BIRADS category remains in question as ultrasound characteristics of a lesion tend to overlap.[7,8] The Displacement caused by tissue compression is produced by a pressure that can be easily calculated by sonoelastography. The calculated value of tissue elasticity is higher for soft tissues compared with hard tissues. Hence, another technique to distinguish between benign and malignant breast lesions is Sonoelastography.[8,9] the specificity of cut off value lie between 3 and 4.[10] this study

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Article received on: 29/08/2023
Accepted for publication: 06/05/2024

was conducted to identify the strain ratio cut off value in patients having breast malignancy by using non-invasive sonoelastographic technique. However, Pathologic nipple discharge resulting from both benign and malignant causes tends to occur unilaterally and spontaneously from a single duct orifice and is usually clear or blood-stained.[18] Ultrasound displays low specificity, thereby leading to unnecessary benign biopsies.[20]

METHODS

The cross sectional study was conducted from June 2021 to May 2022 in department of radiology with the approval of ethical committee (LUMHS/REC/-99)31-05-21 at Liaquat University of medical and health science, Jamshoro.

Any size of palpable breast lump is included in the study of patients aged between 25 to 65 years with the time period of atleast one month. The exclusion criteria of the study is based on patients with cystic breast lesions, chemotherapy and hormonal therapy. Differentiation between benign lesions from malignant lesion with the help of strain elastography were subjected with the comparison of histopathology reports. Conventional ultrasonic probes with the frequency of 10.5 MHz were selected to performed sonoelastography on Toshiba. With the help of graphical patterns on the screen, an elasticity images was obtained by using Elastography mode. An acceptable elastography images was produced by using accurate techniques, which shows uniformity of graphic patterns on a screen. Different color coded images were generated by automatic construction involving softest and hardest components (Red color for softest, blue for hardest lesions) which ultimately produces elasticity images of multiple frames. The ITOH color scoring system was used to create color score.[3]

Tru cut biopsy with 18G biopsy needle were standarized for all lesions. Specific software was used to calculate fat/lesion ratio (strain ratio) with the cut off value as 4.8. The statistical analysis was performed on SPSS version 16 by entering mean standard deviation of different variables including age, duration and lesion size. The comparison of malignant lesion with the lesion size and duration was set on the basis of chi-square test with its significant value $p \leq 0.05$. An accuracy of non-invasive ultrasound elastography in ca breast patients having malignant lesion was calculated with proper statistical parameters including its sensitivity, specificity, positive and negative predictive values.

RESULTS

A total of 274 female patients were studied. Out of the total, 82 (29.9%) lesions were labelled malignant on sonoelastography while the actual number of malignant lesions on histopathology were 70 (25.5%). The results of sonoelastography and histopathology were cross-tabulated in order to assess sensitivity, specificity. There were 62 true positive, 8 false negative, 20 false positive, and 184 true negative cases. It yielded 88.57% sensitivity, 90.20% specificity, and 75.61% positive predictive value (PPV), 95.83% negative predictive value (NPV), and 89.78% accuracy for sonoelastography in the diagnosis of malignant breast lesion taking histopathology as gold standard with an observed prevalence of malignant breast mass to be 25.55%. Figure-1 showed strain elastography in a patient with suspected malignant breast lesion which is characterized by predominant blue colour codding indicating harder area and thus malignancy. The strain ratio was 4.9 which also favour malignancy. Figure-2 of histopathology showed cords of tumor cells arranged in linear fashion forming characteristic Indian filling pattern. The cells lack cohesion and appear individually dispersed in a fibrotic stroma suggests invasive lobular carcinoma.

DISCUSSION

These studies encompassed various diagnostic methods, including resistive index, color Doppler, power Doppler, and sonoelastography.[6] Out of these modalities Sonoelastography was focused in this study as possible alternative non-invasive way to diagnose breast malignancies.

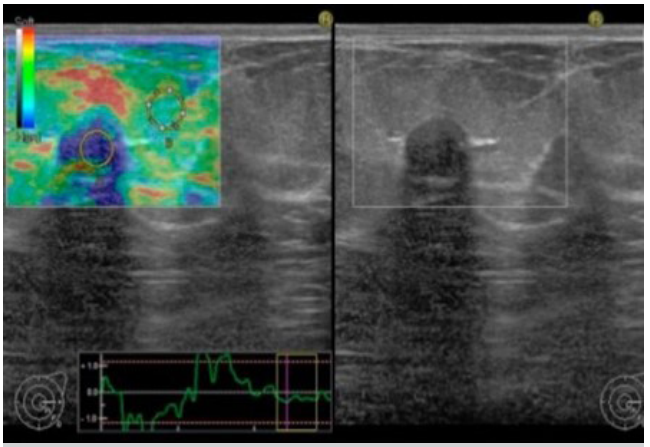

Figure-1. Strain Elastography showing malignant breast lesion

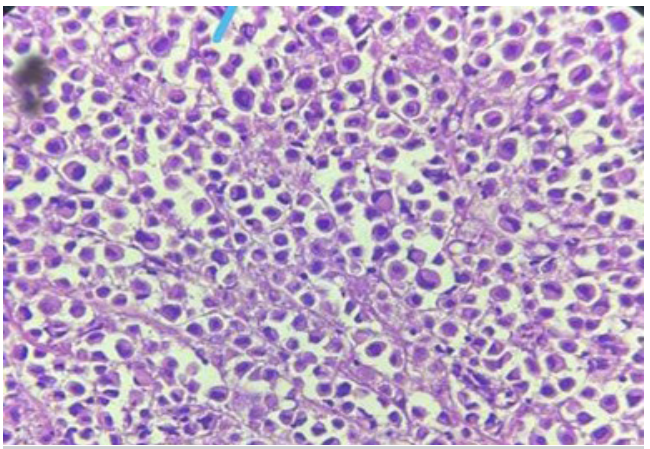

Figure-2. Histopathology showing invasive lobular carcinoma

Notably, Scaperrotta in Italy (2008) conducted a study that reported prevalence, sensitivity, and specificity. Additionally, researchers such as Yerli et al.[7] in Turkey and Aly et al. and Shakweer et al.[10,14] in Egypt have also undertaken similar investigations. The likelihood of malignancy varies significantly based on age, ranging from 2.4% for individuals aged 20 to 30 years to a much higher 77.3% for those aged 51 to 60 years. Similarly, the size of the lesion is a crucial factor, with a 2.0-3.0 cm lesion carrying a 4.9% risk of malignancy compared to a substantially higher risk of 55.3% for lesions measuring between 5.1-6.0 cm. These factors can be effectively utilized to estimate the pre-test probability of malignancy. For instance, a 55-year-old woman (with an age-related risk of 77.3%) presenting with a lesion duration of 20 weeks (associated with a risk of 37.5%) and having a lesion size of 5.5 cm (with a risk of 55.3%) may be estimated to have an average combined pre-test probability of malignancy of approximately 56.6%.In 2014, Ghajarzadeh et al. reported that sonoelastography exhibited a sensitivity of 86.0% and specificity of 66.7% in the context of diagnosing thyroid malignancies.[15] Likewise, Seo et al. in 2014 found that sonoelastography achieved a sensitivity of 95.6% and specificity of 87.5%, resulting in an overall accuracy of 91.1% when applied to diagnose fatty degeneration of the supraspinatus.[16] Furthermore, several studies have demonstrated the effectiveness of sonoelastography as a sensitive tool for the detection of malignant breast lesions.[1,7,13,14-16] Regarding the prevalence of malignant breast lesions within the sampled population, Yerli et al. observed a relatively lower occurrence of 18.3% among the Turkish population in 2013.[7] In contrast, Shakweer et al. documented a notably higher prevalence of 87.5% in Egypt. These results, nonetheless, harmonize with another local investigation conducted by Mamoon et al., which identified a 22% frequency of malignancy among breast masses in the Pakistani population.[2] These discrepancies are likely due to variations in the characteristics of the populations examined in the respective studies. Malignancy (defined as values exceeding a threshold of 4.8) while considering the initial probability before testing.

The capacity to effectively diagnose and treat clinically detectable breast cancer begins with clinical breast assessment by taking a medical history and performing a focused physical examination, including clinical breast examination (CBE).[17]

With the intension of eliminating bias single radiologist interpreted all the studies which can be considered as important limitation of this study. To achieve diagnostic accuracy and to ensure inter-observer reliability scans can be carried out by various operators as sonoelastography depends upon operator's personal skill and expertise.

BI-RADS classification system incorporated ultrasound elastography, either SE or SWE, as one of the associated features to assess the risk

of malignancy.[18,19]

In a characterization of breast lesions, as cancerous lesions tend to be stiffer than benign lesions [(20, 21).]The strength of sonoelastography in diagnosing malignant breast lesions this was first of its kind of study in local population. Keeping in view results of this study women presenting with breast mass can be first investigated with sonoelastogram followed by biopsy if ultrasound elastogram findings are suggestive of malignancy (i.e. above a cut off of 4.8 and taking pre-test) probability into account which can potentially reduce the number of biopsies carried out for investigating breast masses.

This study further suggests remarkable improvement in differentiation of malignant from benign breast lesions with concomitant use of conventional ultrasound and strain imaging. In carrying out selection of patients for breast biopsies strain imaging can be useful aid in better decision- making.

CONCLUSION

Strain elastography has good sensitivity and specificity in diagnosis of malignant breast lesions and can minimize the use of invasive biopsies for diagnosis.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
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2	Seema Nayab	Drafting of the article and shares expert research opinion in finalizing the manuscript.	
3	Riaz Hussain Awan	Contributed to conception and designing, acquisition and review of data.	
4	Eshika Kumari Jesrani	Revision and corresponding author data collection and analysis.	
5	Aneel Kumar	Contributed and conception and interpretation of data and gives its expert for manuscript designing.	