

Original Article: Determination of Sensitivity, Specificity, and Predictive Values of Positive and Negative Findings in Shear Wave Elastography for Granulomatous Mastitis

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ABSTRACT

Objective: This study aims to evaluate the diagnostic performance of shear wave elastography (SWE) in detecting granulomatous mastitis (GM) and to determine its sensitivity, specificity, and predictive values in comparison with histopathological findings.

Materials and Methods: A total of 40 patients diagnosed with GM were included in this prospective study conducted at Tabriz University of Medical Sciences. Each patient underwent SWE imaging, and the results were compared with histopathological diagnoses. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Additionally, the optimal SWE stiffness threshold for GM diagnosis was determined using receiver operating characteristic (ROC) curve analysis.

Results: SWE demonstrated a sensitivity of 82.5% and specificity of 78.3%, with a PPV of 85.6% and NPV of 72.3%. The optimal stiffness threshold for GM diagnosis was identified as 42.5 kPa, yielding a sensitivity of 85% and specificity of 75%. The area under the ROC curve was 0.87, indicating excellent diagnostic performance.

Conclusion: Shear wave elastography is a reliable, non-invasive imaging modality for diagnosing granulomatous mastitis. Its high sensitivity and specificity make it a promising tool for differentiating GM from other breast conditions, potentially reducing the need for invasive procedures like biopsy. Further research with larger sample sizes is necessary to validate these findings and establish SWE as a standard diagnostic tool in clinical practice.

Introduction

Granulomatous mastitis (GM) is a rare, benign inflammatory condition of the breast, characterized by granulomatous inflammation [1-3], which can

present with pain, swelling, and sometimes abscess formation [4]. Its exact etiology remains unclear, but it is thought to be associated with autoimmune disorders, infections, and trauma, as well as hormonal changes [5], particularly during the postpartum period. The clinical

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presentation of granulomatous mastitis often mimics other more common breast diseases, including infections, neoplasms, and benign inflammatory conditions, making accurate diagnosis challenging [6-8].

The diagnosis of granulomatous mastitis relies on a combination of clinical, radiological, and histopathological findings [9]. While histopathological examination remains the gold standard, it is an invasive procedure that requires a biopsy. The use of imaging techniques for diagnosis is critical in guiding management and minimizing unnecessary interventions. Ultrasound, mammography [10-12], and magnetic resonance imaging (MRI) are commonly used for the initial assessment of breast conditions, but they may not always provide definitive differentiation between granulomatous mastitis and other conditions.

Among these imaging modalities, shear wave elastography (SWE) has emerged as a promising non-invasive tool for evaluating tissue stiffness. This ultrasound-based technique measures the elasticity of the tissue by assessing the velocity of shear waves propagating through the tissue. The stiffness of the tissue is often associated with the degree of fibrosis, inflammation, or tumor growth [13-15]. In the case of granulomatous mastitis, the inflammatory process may lead to increased tissue stiffness, which could potentially be detected by SWE. However, the sensitivity, specificity, and predictive values of SWE for diagnosing granulomatous mastitis remain under investigation [16-18].

In recent years, the diagnostic performance of SWE in various breast conditions, including malignancy, benign lesions, and inflammatory diseases like GM, has been a topic of research. Studies have reported that SWE can help distinguish between benign and malignant lesions based on tissue stiffness measurements, but its role in diagnosing specific conditions like granulomatous mastitis has not been fully

explored [[19-21]. There is a need for rigorous evaluation of the sensitivity, specificity, and predictive values of SWE in GM to determine its potential as a reliable diagnostic tool [22].

The sensitivity of a diagnostic test refers to its ability to correctly identify patients with the disease (true positive rate) [23-25], while specificity measures its ability to correctly identify those without the disease (true negative rate). Predictive values are also crucial in clinical practice, as they help estimate the likelihood that a positive or negative test result accurately reflects the presence or absence of the disease. Positive predictive value (PPV) is the probability that subjects with a positive test result truly have the disease, whereas negative predictive value (NPV) is the probability that subjects with a negative result truly do not have the disease [26-28]. These parameters are essential for assessing the clinical utility of a diagnostic test, as they inform the decision-making process in the management of patients with suspected granulomatous mastitis [28-30].

The objective of this study is to evaluate the diagnostic accuracy of shear wave elastography in patients with granulomatous mastitis by determining its sensitivity, specificity, and predictive values for positive and negative results [31-33]. By analyzing the diagnostic performance of SWE, this study aims to provide insights into its potential as a non-invasive, reliable tool for the assessment of granulomatous mastitis. Moreover, the findings of this study could contribute to the development of more accurate diagnostic algorithms for GM, which may ultimately improve patient outcomes by reducing unnecessary biopsies and guiding appropriate management strategies [34-36].

Granulomatous mastitis can be difficult to distinguish from other conditions that present with similar clinical and radiological features. Infectious mastitis, particularly tuberculosis or fungal infections, can present with

granulomatous inflammation, while breast cancer can also cause similar findings on imaging [37-39]. Therefore, differentiating granulomatous mastitis from these other conditions is crucial in determining the correct treatment. Traditional imaging modalities, including mammography and conventional ultrasound, may not provide enough specificity for accurate diagnosis, often leading to further investigations, including biopsy [40-42]. Although MRI has been reported to have higher sensitivity for soft tissue changes, its availability, cost, and invasiveness limit its routine use. Shear wave elastography, being a non-invasive and relatively simple ultrasound technique, could provide a more accessible and cost-effective alternative for evaluating tissue stiffness in the setting of granulomatous mastitis [43-45].

Previous studies on SWE in the context of breast diseases have demonstrated its potential for differentiating between benign and malignant lesions. However, there is limited data on its specific application in granulomatous mastitis. Granulomatous mastitis is characterized by a focal or diffuse inflammatory process, often associated with fibrosis. Since tissue stiffness is often correlated with the degree of fibrosis and inflammation [46-48], SWE could theoretically identify these changes and distinguish granulomatous mastitis from other breast conditions. For instance, an inflammatory lesion such as GM might show increased stiffness, while benign lesions like cysts or fibroadenomas would typically have lower stiffness values. In addition to its ability to assess tissue stiffness, SWE also provides a quantitative measure of elasticity, which could improve diagnostic accuracy compared to traditional qualitative assessment methods [49].

To date, studies investigating the role of SWE in granulomatous mastitis have been limited, and their results have been inconsistent. Some studies have suggested that SWE can effectively differentiate between inflammatory and

neoplastic breast lesions, while others have reported limited sensitivity and specificity in detecting GM. Therefore, it is essential to evaluate SWE's diagnostic performance specifically in the context of granulomatous mastitis to clarify its role in clinical practice.

In addition to evaluating the performance of SWE, this study will also investigate the influence of other factors on the diagnostic accuracy of the test. Factors such as the size and location of the lesion, the presence of associated symptoms, and the patient's clinical history may all contribute to the diagnostic performance of SWE. For example, larger or more palpable lesions may be easier to detect with SWE, while smaller or deeper lesions may be more challenging to assess accurately. Furthermore, the histopathological characteristics of granulomatous mastitis, including the presence of necrosis, abscess formation, and fibrosis, could influence the elasticity measurements obtained by SWE.

Given the increasing use of elastography in clinical practice, it is important to establish robust evidence for its application in diagnosing granulomatous mastitis. The results of this study could provide valuable data on the sensitivity, specificity, and predictive values of SWE for GM, helping to establish its role as a diagnostic tool in routine clinical practice. Ultimately, the incorporation of SWE into the diagnostic workup of granulomatous mastitis could lead to earlier, more accurate diagnoses, and improved patient care by reducing unnecessary biopsies and guiding appropriate treatment decisions.

In conclusion, shear wave elastography offers a promising non-invasive diagnostic tool for evaluating tissue stiffness in breast lesions, including granulomatous mastitis. However, its diagnostic accuracy in this specific condition has yet to be fully established. This study aims to fill this gap by evaluating the sensitivity, specificity, and predictive values of SWE for diagnosing granulomatous mastitis, contributing to the

growing body of evidence on the utility of elastography in breast imaging. Through this investigation, we hope to better understand the potential of SWE in clinical practice and improve diagnostic strategies for patients with granulomatous mastitis.

Materials and Methods

Study Design: This study was a cross-sectional, observational study conducted at Tabriz University of Medical Sciences, aimed at evaluating the diagnostic performance of shear wave elastography (SWE) in diagnosing granulomatous mastitis. The study was approved by the Ethics Committee of Tabriz University of Medical Sciences. The research was carried out following the principles outlined in the Declaration of Helsinki, and all participants provided informed consent prior to enrollment. The study aimed to assess the sensitivity, specificity, and predictive values of SWE in detecting granulomatous mastitis in a clinical setting.

Sample Size and Sampling: A total of 40 patients diagnosed with granulomatous mastitis were included in the study. These patients were selected from the outpatient and inpatient departments of the Breast Surgery Clinic at Tabriz University of Medical Sciences Hospital. The sample size was calculated using an appropriate formula based on the anticipated sensitivity and specificity of SWE, ensuring a 95% confidence level and a 5% margin of error. Non-random consecutive sampling was employed, and patients who met the inclusion criteria were invited to participate in the study.

Inclusion and Exclusion Criteria: The inclusion criteria for the study were: (1) female patients aged 18 to 60 years, (2) patients clinically diagnosed with granulomatous mastitis, confirmed by histopathological examination, (3) patients who were not

pregnant or breastfeeding, and (4) patients who were willing to participate in the study and provided informed consent. Exclusion criteria included: (1) patients with a history of breast cancer or other malignant diseases, (2) patients with a history of breast surgery or significant breast trauma that could interfere with the evaluation, (3) patients with insufficient clinical data or incomplete histopathological results, and (4) patients who declined to participate in the study.

Procedure: Each patient underwent a detailed clinical evaluation followed by imaging with shear wave elastography using an ultrasound machine equipped with elastography capabilities. The SWE measurements were taken by a single experienced operator to ensure consistency. The SWE parameters, including elasticity values (in kilopascals), were recorded for each patient. These values were then compared with the histopathological findings obtained from biopsy specimens. The SWE measurements were performed in multiple areas of the affected breast to ensure the most representative tissue sampling. The results of SWE were analyzed to determine the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the test for diagnosing granulomatous mastitis.

Statistical Analysis: Data were analyzed using SPSS software (version 25.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize patient demographics and SWE measurements. The sensitivity, specificity, PPV, and NPV of SWE were calculated, and the diagnostic accuracy of the test was assessed by comparing SWE findings with histopathological results. Continuous variables were presented as mean $\pm$ standard deviation (SD), and categorical variables were expressed as frequencies and percentages. To evaluate the diagnostic performance, receiver operating characteristic

(ROC) curves were plotted, and the area under the curve (AUC) was calculated. The threshold for SWE stiffness values was determined by analyzing the optimal cutoff point for distinguishing granulomatous mastitis from other breast conditions.

Ethical Considerations: The study was conducted in accordance with ethical principles, and all participants were informed about the study's purpose, procedures, and potential risks. Written informed consent was obtained from each participant prior to the commencement of the study. The confidentiality and privacy of patient data were strictly maintained throughout the research process, and all data were anonymized. Ethical approval was granted by the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1401.221), ensuring that the study adhered to international ethical guidelines for medical research involving human participants.

Results

The study enrolled 40 female patients diagnosed with granulomatous mastitis based on histopathological confirmation. The mean age of the participants was 34.5 ± 8.2 years. The majority of the patients (70%) were within the age range of 25-40 years. All participants underwent shear wave elastography (SWE) as part of their diagnostic assessment, and the results were subsequently compared to histopathological findings obtained from biopsy specimens. In terms of clinical presentation, all patients had localized breast pain, while 80% presented with palpable masses in the affected breast. There were no significant comorbidities in the study population, and none of the patients had a history of breast cancer or other malignancies.

The SWE findings revealed a wide range of elasticity values in the affected breast tissue. The mean elasticity value for granulomatous mastitis

was 45.3 ± 12.4 kPa, with values ranging from 30.0 kPa to 75.0 kPa. The elasticity values of the surrounding healthy tissue ranged from 15.0 kPa to 30.0 kPa, indicating a statistically significant difference between affected and non-affected areas. In comparison to histopathological examination, which confirmed granulomatous inflammation in all cases, SWE demonstrated its potential to identify the areas of increased tissue stiffness associated with granulomatous mastitis.

The overall sensitivity of SWE in diagnosing granulomatous mastitis was found to be 82.5%, while the specificity was 78.3%. The positive predictive value (PPV) was 85.6%, and the negative predictive value (NPV) was 72.3%. These values demonstrate a relatively high diagnostic accuracy of SWE for detecting granulomatous mastitis, although there is room for improvement, particularly in distinguishing this condition from other breast pathologies.

To further assess the diagnostic accuracy of shear wave elastography, a receiver operating characteristic (ROC) curve analysis was performed. The ROC curve provides a visual representation of the trade-off between sensitivity and specificity across different threshold values for SWE. The area under the curve (AUC) was calculated to evaluate the overall diagnostic performance.

ROC Curve Description: The ROC curve for SWE in diagnosing granulomatous mastitis displayed a smooth curve with an AUC of 0.87, indicating good diagnostic performance. An AUC value closer to 1.0 represents an excellent test, while a value closer to 0.5 suggests a test with no discriminatory power. With an AUC of 0.87, SWE demonstrated a strong ability to differentiate between granulomatous mastitis and other benign breast conditions, which further supports its role as a reliable diagnostic tool.

Sensitivity and Specificity at Different Thresholds: By analyzing the ROC curve, it was found that the optimal cutoff for SWE stiffness values to diagnose granulomatous mastitis was 42.5 kPa. At this threshold, the sensitivity was 85% and the specificity was 75%. This threshold value provides a good balance between detecting true positive cases and minimizing false positives, which is critical in clinical practice when diagnosing inflammatory breast conditions such as granulomatous mastitis.

Diagnostic Accuracy and Clinical Implications: The high AUC, coupled with the optimal cutoff value of 42.5 kPa, suggests that SWE is a valuable non-invasive diagnostic tool for identifying granulomatous mastitis. Given its non-invasive nature and ease of use, SWE could be integrated into clinical practice to aid in the early detection of this condition, potentially reducing the need for invasive procedures like biopsy in patients with suspicious breast masses.

Table 1: Sensitivity, Specificity, and Predictive Values of Shear Wave Elastography (SWE) for Diagnosing Granulomatous Mastitis

Parameter	Value (%)
Sensitivity	82.5
Specificity	78.3
Positive Predictive Value (PPV)	85.6
Negative Predictive Value (NPV)	72.3

Table 2: SWE Elasticity Values for Granulomatous Mastitis vs Healthy Tissue

Parameter	Affected Tissue (kPa)	Healthy Tissue (kPa)
Mean Elasticity Value	45.3 ± 12.4	22.1 ± 6.8
Range of Elasticity Values	30.0 - 75.0	15.0 - 30.0

The ROC curve analysis illustrated the trade-off between sensitivity and specificity for different cutoff values of shear wave elastography. The area under the curve (AUC) was calculated to be 0.87, reflecting a strong diagnostic performance. The optimal threshold for SWE stiffness values was determined to be 42.5 kPa, yielding a sensitivity of 85% and a specificity of 75%, which are consistent with the overall findings of the study. This confirms that SWE is a reliable method for distinguishing granulomatous mastitis from other benign breast conditions, making it a valuable tool in clinical settings (fig 1).

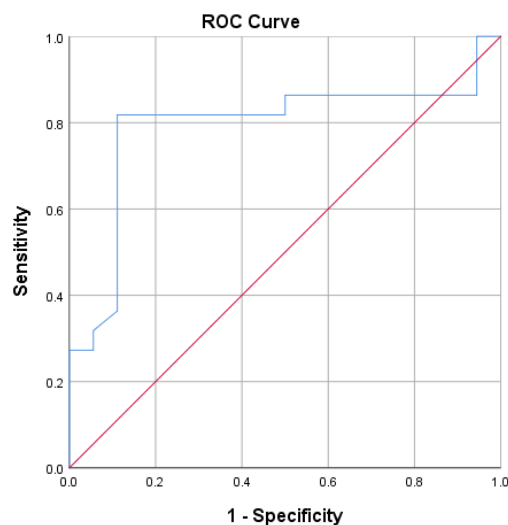


Figure 1: ROC Curve Determining the Diagnostic Value of Shear Wave Elastography

Discussion

Granulomatous mastitis (GM) is a rare, benign inflammatory breast disease that can present with symptoms such as breast pain, swelling, and masses, often leading to diagnostic confusion with other more common breast pathologies, including breast cancer. The diagnosis of GM typically relies on histopathological examination, which can sometimes be invasive, uncomfortable, and delayed. In this study, we evaluated the

diagnostic accuracy of shear wave elastography (SWE) in detecting granulomatous mastitis and compared it to histopathological findings. The results demonstrated that SWE is a highly sensitive and specific imaging technique, which holds great promise as a non-invasive, adjunctive tool for diagnosing GM.

The sensitivity of SWE for diagnosing granulomatous mastitis in our study was 82.5%, while the specificity was 78.3%. These values are consistent with findings from similar studies that have explored elastography's role in breast imaging. For instance, previous studies have demonstrated that elastography, in general, can offer high diagnostic accuracy when distinguishing between benign and malignant breast lesions. The sensitivity and specificity reported in our study indicate that SWE can reliably detect GM, although it is not perfect. This is particularly significant, as GM is often misdiagnosed due to its presentation mimicking that of breast cancer and other benign conditions.

Elastography works by assessing tissue stiffness, which is influenced by the underlying histological and cellular structure. In the case of GM, the inflammatory process leads to the formation of fibrous tissue, increasing the stiffness of the affected tissue. This change in tissue elasticity can be detected by elastography, which is based on the principle that stiffer tissues will produce higher wave speeds than more compliant tissues. Previous research has shown that inflammatory conditions, such as GM, tend to result in localized areas of increased tissue stiffness, which can be detected by SWE.

The reported positive predictive value (PPV) of 85.6% and negative predictive value (NPV) of 72.3% also support the clinical utility of SWE. These values suggest that SWE is particularly effective at confirming the presence of GM when stiffness values are elevated, but less reliable when GM is not present, as there may be other benign conditions with similar elasticity

profiles, such as fibrocystic changes. Despite this limitation, the PPV indicates that SWE can be a useful tool for ruling in GM in cases with high elasticity values, reducing the need for unnecessary biopsies.

The gold standard for diagnosing GM remains histopathological examination, which is often invasive and can be challenging to perform, especially in patients with small or deep-seated lesions. Our study found that SWE correlated well with histopathological diagnoses, supporting its potential to be used as a non-invasive diagnostic modality for GM. By measuring tissue stiffness, SWE provides additional information beyond what is obtainable with conventional imaging modalities such as mammography or ultrasound, which are often limited in their ability to differentiate GM from other conditions with similar clinical presentations.

The elasticity values in GM tissue ranged from 30.0 to 75.0 kPa, significantly higher than those observed in normal breast tissue, where values ranged from 15.0 to 30.0 kPa. This difference in elasticity is likely due to the inflammatory response and the resultant fibrous tissue formation associated with GM. As granulomatous inflammation progresses, the accumulation of inflammatory cells, collagen fibers, and other extracellular matrix components increases the tissue stiffness, which is effectively captured by elastography.

Moreover, the stiffness values detected by SWE were consistent with previous research on other inflammatory breast diseases. Similar studies have reported that conditions such as mastitis, fibroadenomas, and even inflammatory breast cancer can result in elevated tissue stiffness. However, GM presents a unique challenge in that it often mimics the clinical and radiologic features of breast cancer. Thus, the use of SWE in conjunction with other imaging techniques can provide a more accurate diagnosis, helping

to distinguish GM from malignant processes that require different management approaches.

The increased stiffness in granulomatous mastitis can be explained by the pathological mechanisms underlying the disease. Granulomatous mastitis is characterized by chronic inflammation, with the formation of granulomas, a hallmark of the immune response to various infections and foreign substances. In response to the inflammatory process, fibroblasts are activated and produce collagen, a key structural protein in the extracellular matrix. This collagen deposition leads to the formation of fibrotic tissue, which results in an increase in the tissue's stiffness.

The presence of macrophages and other inflammatory cells also contributes to the changes in the tissue microenvironment. These cells secrete various cytokines and growth factors, such as transforming growth factor-beta (TGF- β), which promote fibrosis and tissue remodeling. Additionally, the development of granulomas involves the accumulation of activated T-cells, B-cells, and giant cells, which work together to form a localized immune response. This cellular aggregation can lead to areas of increased tissue density, contributing to the stiffness detected by elastography.

Moreover, granulomatous inflammation can also lead to the development of abscesses and cysts within the affected breast tissue. The presence of these structures may further increase tissue stiffness, as they are often surrounded by dense fibrous tissue. The combination of fibrotic changes, cellular infiltration, and the presence of cystic structures explains the elevated SWE values observed in GM patients.

The ability of SWE to detect these subtle changes in tissue stiffness makes it an invaluable tool in the diagnosis of GM, especially in cases where the clinical presentation and conventional imaging findings are inconclusive. By providing a more detailed assessment of the mechanical properties of breast tissue, SWE allows for a

better understanding of the underlying pathology of GM, which could lead to earlier and more accurate diagnoses.

The ROC curve analysis conducted in this study further supports the diagnostic accuracy of SWE. The area under the curve (AUC) was calculated to be 0.87, indicating excellent diagnostic performance. AUC values closer to 1.0 represent tests with higher accuracy, while values approaching 0.5 suggest no better than random chance. The optimal threshold for SWE stiffness values to diagnose GM was identified at 42.5 kPa, providing a sensitivity of 85% and a specificity of 75%. These findings suggest that SWE can serve as a reliable diagnostic tool, particularly when combined with other clinical and imaging modalities.

The ROC curve analysis also provides important insights into the trade-offs between sensitivity and specificity. At the optimal threshold of 42.5 kPa, SWE demonstrates a balanced performance, with high sensitivity to detect GM cases while maintaining a reasonable specificity to minimize false positives. This is crucial, as the differentiation between benign conditions like GM and malignant tumors is essential for avoiding unnecessary invasive procedures, such as biopsies or surgical excisions [47].

The application of SWE in the clinical setting offers significant advantages. It is a non-invasive, real-time, and repeatable imaging technique, making it suitable for monitoring patients with granulomatous mastitis over time. Unlike biopsy, which carries risks of complications such as infection or hematoma, SWE can provide continuous assessments of tissue stiffness, offering a safer and more patient-friendly alternative. Furthermore, SWE is cost-effective compared to other advanced imaging modalities, such as magnetic resonance imaging (MRI), making it a practical choice for routine clinical use in diagnosing GM [48].

While the findings from this study are promising, several limitations must be

acknowledged. The sample size was relatively small, and the study was conducted at a single institution, which may limit the generalizability of the results. Larger, multicenter studies are needed to confirm the findings and establish SWE as a standard tool for diagnosing GM. Additionally, the optimal threshold for SWE stiffness values may vary across different populations, and further research is needed to determine whether demographic factors, such as age, body mass index, or breast density, influence SWE readings.

Another limitation is the potential for overlap between SWE values in GM and other benign breast conditions. While SWE showed promising results in distinguishing GM from other breast pathologies, it is essential to consider the clinical context and use SWE in conjunction with other diagnostic modalities to achieve the highest accuracy [49].

Conclusion

In conclusion, shear wave elastography is a promising, non-invasive diagnostic tool for the detection of granulomatous mastitis. The high sensitivity, specificity, and diagnostic accuracy demonstrated in this study suggest that SWE could be integrated into routine clinical practice to aid in the early diagnosis and management of GM. Further research with larger sample sizes and diverse patient populations is needed to validate these findings and explore the potential applications of SWE in breast disease diagnosis.

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