ORIGINAL RESEARCH

Diagnostic Utility of Surrounding Tissue Hardness in Breast Masses: A Quantitative Analysis Using Shear Wave Elastography to Distinguish Malignancy Across Various Mass Sizes

Pan Yan, BS; Xiaoyan Song, BS; Wentao Fan, BS

ABSTRACT

Objective • This study aims to investigate the utility of shear wave elastography (SWE) in quantitatively assessing the surrounding tissue hardness of breast masses and its diagnostic significance in distinguishing between benign and malignant masses of varying sizes.

Methods • A retrospective analysis was conducted on 60 patients with breast masses diagnosed at our hospital between January 1, 2022, and December 31, 2022. All patients underwent standard breast ultrasound examination and SWE assessment. Masses were categorized based on diameter (≤20mm and >20mm) for comparative analysis. SWE parameters, including maximum shear wave velocity (Max SWV), mean shear wave velocity (Mean SWV), and elasticity ratio (E_{ratio}) of surrounding tissue, were recorded. Histopathological results determined mass nature. SWE parameters were correlated with pathological diagnoses for discrimination analysis.

Results • Of all patients, 37 had benign masses, and 23 had malignant masses. Malignant masses exhibited significantly higher Max SWV, Mean SWV, and E_{ratio} in surrounding tissue compared to benign masses ($P < .05$). Statistically significant differences in SWE parameters were observed between different-sized masses; smaller masses (≤20mm) showed higher SWE parameters in malignant masses compared to benign masses ($P < .05$). In masses larger than 20mm, though SWE parameters still differed between benign and malignant masses, the significance was less pronounced ($P < .05$). Receiver operating characteristic (ROC) analysis demonstrated higher diagnostic accuracy of SWE parameters in discriminating malignancy in smaller breast masses.

Conclusions • SWE parameters effectively quantify surrounding tissue hardness in breast masses and have diagnostic value in distinguishing between benign and malignant masses of varying sizes, particularly in masses ≤20mm. SWE offers crucial quantitative parameters for the clinical discrimination of breast masses, enhancing diagnostic accuracy and sensitivity. Future studies should expand sample sizes and optimize diagnostic models to enhance SWE's utility further in discriminating breast mass malignancy. (*Altern Ther Health Med.* [E-pub ahead of print.])

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INTRODUCTION

Breast tumors represent one of the most common malignancies affecting women globally. Diagnosis of breast masses typically involves ultrasound, mammography (mammogram), and magnetic resonance imaging (MRI), with confirmation of malignancy often achieved through histopathological biopsy.[1] Although conventional ultrasound (B-mode) is widely used for diagnosing breast masses, it struggles to differentiate between benign and malignant masses, particularly in young patients with smaller masses or denser breast tissue.[2,3]

The limitations of conventional ultrasound in accurately distinguishing between benign and malignant breast masses underscore the need for the development of new diagnostic technologies to enhance discriminatory capability.[3] In recent years, shear wave elastography (SWE) has emerged as a novel ultrasound technology that addresses the limitations of conventional B-mode ultrasound by assessing tissue stiffness variations. SWE, a non-invasive examination method, measures tissue response to sound waves (shear wave velocity) to determine tissue elasticity, providing additional information to differentiate between benign and malignant breast masses.[4,5] Compared to traditional ultrasound imaging, SWE offers more quantitative information to assist physicians in determining the nature of masses.[6]

Clinically, the quantitative assessment of mass hardness and surrounding tissues can provide additional insights into tumor growth patterns and invasive characteristics. For example, malignant tumors often provoke fibrotic reactions in surrounding tissues, leading to increased overall hardness, which may be reflected in higher shear wave velocity values detected by SWE.[7,8] Therefore, the quantitative evaluation of surrounding tissue hardness may play a pivotal role in distinguishing between benign and malignant masses.[9]

Existing studies suggest that SWE technology exhibits high sensitivity and specificity in diagnosing breast masses, especially in smaller lesions, offering significant clinical utility. Through the utilization of shear wave velocity as an objective parameter, SWE has the potential to enhance the differentiation and classification of benign and malignant lesions. However, further research and validation are necessary to assess the performance of SWE parameters for masses of various sizes and to determine their accuracy and feasibility in mass discrimination.[10]

This study aims to systematically analyze breast masses of varying sizes using SWE for pathological comparison. The objective was to assess the practicality and accuracy of SWE parameters in diagnosing benign and malignant masses. The study seeks to investigate the potential value of parameters such as shear wave velocity (SWV) and elasticity ratio (E_{ratio}) in distinguishing between benign and malignant breast masses by integrating clinical and pathological data. The findings of this study can offer more precise quantitative insights for clinical diagnosis and treatment decision-making.

MATERIALS AND METHODS

Study Design

This study comprised a retrospective analysis of data gathered from patients diagnosed with breast masses at our institution between January 1, 2022, and December 31, 2022. A total of 60 patients, aged between 22 and 70 years, were included in the analysis. All patients were female and consisted of individuals who either presented with initial detection of breast masses or incidentally discovered masses during routine examinations. They underwent routine B-mode ultrasound and SWE examinations, followed by subsequent histopathological tissue analysis. General patient information, including gender, age, and medical history, as well as clinical, surgical, and pathological results, were compiled into a database for comparative analysis. The study protocol received approval from the ethical committees of the participating institutions, ensuring adherence to ethical standards in research. Prior to participation, all subjects provided written, informed consent, demonstrating their understanding and agreement to take part in the study.

Inclusion and Exclusion Criteria

In this study, the inclusion criteria were as follows: (1) Female patients aged between 22 and 70 years; (2) Patients who had breast masses detected during routine ultrasound examinations; (3) Patients who underwent SWE examinations; (4) Diagnosis of mass malignancy or benignity was confirmed through subsequent histopathological examination of the breast tissue; (5) Complete medical records were required, including medical history, imaging data, and pathological diagnosis.

The exclusion criteria were as follows: (1) Male patients; (2) Individuals with incomplete medical records or lacking subsequent pathological confirmation; (3) Pregnant or lactating women; (4) Patients with a history of breast surgery or breast-related treatments; (5) Individuals suffering from inflammatory breast diseases or other benign breast conditions; (6) Patients who were unable to complete the entire examination process or for whom the nature of the mass could not be clearly diagnosed due to other medical reasons.

Imaging Techniques

The SWE and routine ultrasound examinations employed in this study were executed using the same model of ultrasound equipment provided by Mindray Medical Systems. Experienced ultrasound physicians carried out all scanning procedures to guarantee the reliability and consistency of examination results.

Patient Positioning and Initial Imaging Procedures. Before initiating the examination, ensuring correct patient positioning was crucial. The patients were positioned lying supine with the arm raised to expose the breast for examination adequately. Initially, a conventional breast ultrasound scan was conducted, and grayscale images were saved. Subsequently, the imaging mode was switched to color Doppler flow, and characteristic images of the masses' blood flow were recorded and saved.

Shear Wave Imaging Procedure. The shear wave imaging process entailed setting the Young's modulus threshold to 140 kilopascals (kPa). Adequate coupling gel was applied to the examination area to facilitate ultrasound wave propagation. The operator ensured that the probe was perpendicular to the skin surface, avoiding excessive pressure to maintain accuracy in the examination results.

After configuring the ultrasound machine to the elastography mode (Elasto), SWE was selected. The size and position of the region of interest were adjusted to ensure that the mass was centrally located within this area, encompassing a certain range of normal glandular or fatty tissue. Quality control procedures were initiated, and the patient was instructed to hold their breath to maintain stability in the examination area. Once the quality control display indicated that the mass area was fully green or achieved a reliability index of 90% or higher, the image was frozen for subsequent analysis.

Mass Delineation and Elastic Modulus Measurement. Using the trajectory ball function within the image software, the borders of the mass were accurately delineated. Elastic modulus values were measured within 1mm, 2mm, and 3mm ranges around the mass. The maximum (E_{max}), mean (E_{mean}), minimum (E_{min}), and standard deviation (E_{sd}) of elasticity modulus values were recorded within the mass itself and its surrounding different distance ranges.

Table 1. Pathological Classification and Quantity Statistics of Benign and Malignant Breast Masses

Pathologic Classifications	Total
Invasive Ductal Carcinoma	18
Ductal Carcinoma In Situ	4
Intraductal Papillary Carcinoma	3
Invasive Lobular Carcinoma	2
Mucinous Carcinoma	2
Medullary Carcinoma	1
Fibroadenoma	24
Intraductal Papilloma	3
Lipogranulomatous Lobular Mastitis	2
Sclerosing Adenosis	1

Note: The table presents the pathological classification and quantity statistics of benign and malignant breast masses included in the study.

Categorization of Ultrasound Images. Ultrasound images were classified according to the 2013 Breast Imaging Reporting and Data System (BI-RADS) classification criteria. BI-RADS categories 3 and 4a from conventional ultrasound images were deemed indicative of benign lesions, while categories 4b, 4c, and 5 were considered suspicious for malignancy.

Statistical Analysis

Statistical analysis was conducted using SPSS 20.0 software. All statistical comparisons were based on postoperative pathological diagnosis, and an independent sample *t*-test was utilized to compare the differences in SWE parameters between benign and malignant breast masses. A significance level of $P < .05$ was established to determine statistical significance. Additionally, Receiver Operating Characteristic (ROC) curve analysis was employed to evaluate the diagnostic performance of each SWE parameter in distinguishing between benign and malignant breast masses. The area under the ROC curve (AUC) was calculated to assess the diagnostic efficacy of each parameter. Based on ROC analysis, optimal diagnostic cutoff values for different parameters were determined, and specificity and sensitivity were calculated at these cutoff values.

RESULTS

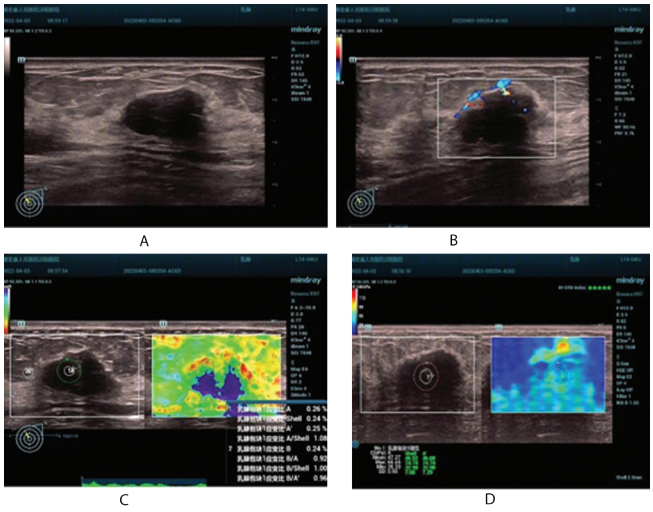
Pathological Classification of Breast Masses in All Patients

In this study, a group of 60 patients with breast masses was examined. Each participant underwent an SWE assessment, allowing for the collection of hardness parameters related to both the masses and the surrounding tissues. These findings are detailed in Table 1, Figure 1, and Figure 2.

Elastic Modulus Values of Different-Sized and Benign/Malignant Tumors

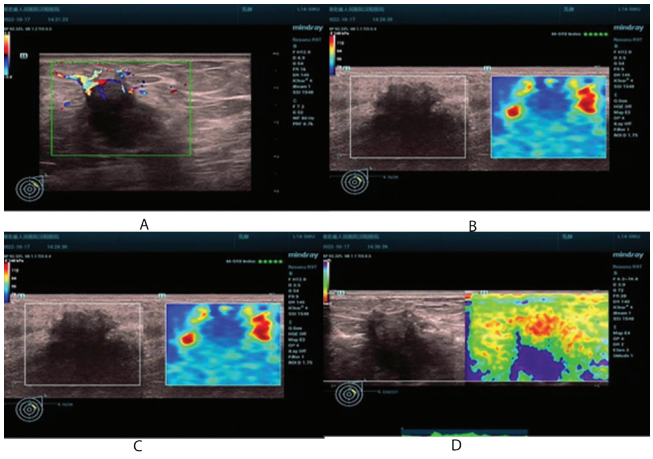
Table 2 presents the elastic modulus values of masses and their surrounding tissues measured using SWE, including maximum (E_{max}), mean (E_{mean}), minimum (E_{min}), standard deviation (E_{sd}), and elasticity ratio (E_{ratio}). Statistical analysis was conducted separately for masses with diameters greater than 20mm and those equal to or less than 20mm. The analysis revealed that for masses with a diameter greater than

Figure 1. Ultrasound Imaging and Shear Wave Elastography of Breast Mass



Note: The ultrasound examination revealed a hypoechoic mass measuring 2.3 × 1.3 × 1.9 cm, observed at 11 o'clock in the left breast. The mass has a relatively clear boundary, an irregular shape, and an uneven distribution of internal echoes. Several punctate strong echoes are visible inside, and Color Doppler Flow Imaging (CDFI) indicates blood flow signals both inside and around the mass. Ultrasound suggests an extremely hypoechoic nodule with punctate calcifications in the left breast, classified as BI-RADS category 4, pathologically diagnosed as a breast fibroadenoma. Images A and B depict conventional ultrasound images. At the same time, C showcases qualitative shear wave elastography (SWE), displaying the hardness of the mass and surrounding tissues through color coding, where different colors represent varying hardness levels—blue indicates soft tissue, and red indicates hard tissue. Image D demonstrates quantitative SWE, providing specific numerical values for the hardness of the mass and adjacent tissues.

Figure 2. Ultrasound Imaging and Shear Wave Elastography of Breast Mass



Note: The ultrasound examination reveals a hypoechoic mass measuring 1.8 × 2.5 cm, visible at the 1-2 o'clock position in the left breast. The mass exhibits an unclear boundary, an irregular crab-like shape, and a longitudinal-to-transverse ratio exceeding 1. Several patchy, strong echoes are observed inside, with Color Doppler Flow Imaging (CDFI) indicating internal blood flow signals. Ultrasound indicates a space-occupying lesion in the left breast, pathologically diagnosed as infiltrating ductal carcinoma of the breast. Image A presents a Color Doppler ultrasound illustrating the blood flow dynamics within the mass. Images B and C display quantitative analyses of the mass tissue's elasticity characteristics. The red area signifies relatively hard tissue, while the blue area signifies relatively soft tissue. Image D combines qualitative and quantitative shear wave elastography (SWE) images. The left side exhibits B-mode ultrasound images, while the right side displays corresponding SWE hardness images.

Table 2. Elastic Modulus Parameters of Breast Masses by Tumor Type and Size

		E_{max} (kPa)		E_{mean} (kPa)		E_{min} (kPa)		E_{sd} (kPa)		E_{ratio}	
Tumor Type	**n**	**≥20mm**	**<20mm**	**≥20mm**	**<20mm**	**≥20mm**	**<20mm**	**≥20mm**	**<20mm**	**≥20mm**	**<20mm**
Malignant	23	78.5 ± 15.2	50.2 ± 12.7	65.2 ± 10.4	42.3 ± 9.3	58.6 ± 14.3	38.3 ± 8.7	9.8 ± 3.5	7.9 ± 2.5	4.0 ± 1.2	3.5 ± 1.0
Benign	37	32.1 ± 6.3	28.2 ± 7.6	28.4 ± 5.2	26.1 ± 6.1	25.1 ± 8.1	22.5 ± 5.8	6.5 ± 2.2	5.4 ± 1.9	1.3 ± 0.5	1.2 ± 0.4
t	-	5.987	3.575	4.782	5.937	3.956	2.947	3.574	3.857	4.694	3.859
P value	-	.03	<.001	.02	<.001	.003	<.001	.002	<.001	.01	<.001

Note: The table presents the parameters of breast masses categorized by tumor type and size, including E_{max}: maximum elasticity; E_{mean}: mean elasticity, E_{min}: minimum elasticity; E_{sd}: standard deviation of elasticity; and E_{ratio}: elasticity ratio. The statistical significance (t) and *P*-values (P) for comparisons between malignant and benign masses are provided.

Table 3. Diagnostic Performance of Breast Mass Hardness Parameters by Tumor Size

Tumor Size	Parameter	Malignant AUC (95% CI)	Benign AUC (95% CI)	Optimal Cut-off	Sensitivity	Specificity
<20mm	E_{max}	0.950 (0.880-0.990)	0.870 (0.760-0.940)	45 kPa	88%	90%
	E_{mean}	0.930 (0.860-0.970)	0.850 (0.740-0.920)	35 kPa	84%	85%
≥20mm	E_{max}	0.720 (0.580-0.85)	0.680 (0.520-0.810)	30 kPa	75%	78%
	E_{mean}	0.700 (0.560-0.830)	0.670 (0.510-0.800)	27 kPa	72%	74%

Note: AUC: Area Under the Curve. Values represent the performance of each parameter in distinguishing between malignant and benign breast masses. Sensitivity and specificity values indicate the ability of each parameter to correctly identify malignant and benign masses, respectively. The optimal cutoff values for E_{max} and E_{mean} represent the threshold values at which the parameters achieve the highest diagnostic accuracy.

20mm, the E_{max} value for malignant masses was 78.5±15.2 kPa, whereas, for benign masses, it was 32.1±6.3 kPa, indicating a statistically significant difference (P = .03).

Comparison of Elastic Modulus Values between Malignant and Benign Masses. The E_{mean} value for malignant masses significantly exceeded that of benign masses, measuring 65.2±10.4 kPa and 28.4±5.2 kPa, respectively (P = .02). Similarly, for masses with diameters equal to or less than 20mm, the E_{max} and E_{mean} values for malignant masses were significantly higher compared to benign masses, specifically 50.2±12.7 kPa and 42.3±9.3 kPa, and 28.2±7.6 kPa and 26.1±6.1 kPa, respectively, all displaying statistically significant differences (P < .001). Statistically significant differences were also observed between malignant and benign masses regarding the E_{min} and E_{sd} parameters. Additionally, the E_{ratio} parameter exhibited significant differences between malignant and benign mass groups for diameters ≤20mm and >20mm (P < .05).

Statistical Analysis of Hardness Parameters in Diagnosing Breast Mass Malignancy

Statistical tests were conducted to analyze the efficacy of hardness parameters of malignant and benign masses in diagnosing breast mass malignancy. SWE parameters exhibited higher diagnostic accuracy in discriminating between benign and malignant breast masses with diameters <20mm, as represented in Table 3.

DISCUSSION

The findings of this study highlighted the effectiveness and reliability of SWE in evaluating breast masses and distinguishing between benign and malignant lesions. Valuable insights into the diagnostic capabilities of this imaging modality were revealed through a comprehensive analysis of elastic modulus values and other parameters obtained from SWE examinations. The hardness of breast lesions was considered to be intricately linked to variations in internal pathological structures, which highlighted differences between emerging ultrasound elastography techniques and traditional grayscale ultrasound examinations.[11] This understanding highlights the importance of investigating the comparative effectiveness of these modalities in assessing lesion hardness and diagnosing breast conditions accurately.

Currently, ultrasound elastography techniques utilize various assessment and measurement methods, primarily employing semi-quantitative approaches to determine lesion hardness. However, these measurements may be susceptible to operator subjectivity and variations in the internal tissue composition within the lesions.[11,12] SWE represents a relatively new quantitative elastography technique. SWE employs probes that emit various types of acoustic waves, generating shear waves at different depths within lesions using pulse control technology.

Shear waves, characterized as a type of transverse wave, typically propagate at speeds ranging from 1 to 10 centimeters per second, necessitating high-speed imaging techniques for shear wave imaging.[13,14] There is a direct relationship between the propagation speed of shear waves and the hardness of lesions. Through the measurement of shear wave propagation speed within tissues, SWE calculates the tissue's elastic modulus value, providing a quantitative measurement method that minimizes the influence of subjective judgment and renders the assessment of mass hardness more objective.[15]

In this study, SWE was employed to assess the hardness of 60 breast masses, encompassing both benign and malignant cases, along with their surrounding tissues. The analysis unveiled notable statistical differences in elastic modulus between benign and malignant breast masses. Specifically, the E_{max}, E_{mean}, and E_{sd} values of malignant masses consistently surpassed those of benign masses.

Among these parameters, E_{max} signifies the maximum hardness within the mass, E_{sd} indicates the dispersion of elastic modulus within different areas of the mass, assisting in quantitatively assessing mass homogeneity, and E_{mean} represents the average elastic modulus within the mass. The study observed that malignant masses demonstrated greater hardness and heterogeneity compared to benign masses, consistent with the fundamental biological characteristics of tumors.[16,17]

Breast malignancies often invade surrounding tissues, provoking an immune response that prompts reactive changes in adjacent connective tissues. These changes encompass fibrotic proliferation, lymphocytic infiltration, and heightened microvascular density, culminating in increased hardness around the tumor periphery.[18,19] This phenomenon was evident in color elastography as the presence of a rigid rim encircling the mass was recognized as one of the characteristic indicators of malignant breast masses. Quantitative indices revealed notable differences in elastic modulus between the mass interior and its surrounding tissues, particularly with a significant elevation in E_{max}, signifying the hardest region within the mass.[20,21]

Upon analyzing the entire dataset, it became apparent that malignant masses demonstrated elevated values in Max SWV, Mean SWV, and E_{ratio} in relation to the surrounding tissues compared to benign masses ($P < .05$). This finding supports previous research,[22,23] which suggests that malignant masses typically exhibit higher elastic modulus values than benign masses. Such differences reflect the fibrosis and cellular proliferation typical of malignancies, leading to denser and firmer tissue structures.[23] This inherent characteristic offers a solid biophysical foundation for the clinical application of SWE in identifying mass properties.

For masses larger than 20mm, although distinctions in SWE parameters between benign and malignant masses endure, the statistical significance is less pronounced than in the smaller mass group ($P < .05$). This phenomenon could be attributed to the more complicated biological changes occurring in the surrounding tissues of larger masses. These changes involve diverse cellular and stromal compositions, thereby complicating the use of SWE for distinguishing between benign and malignant masses. For larger masses, it may be necessary to employ a combination of other imaging modalities and clinical indicators to enhance diagnostic accuracy.[25]

Through ROC curve analysis, it was determined that for breast masses smaller than 20mm, the optimal cutoff value for E_{max} was 45 kPa. This value demonstrated excellent diagnostic efficacy, with sensitivity and specificity at 88% and 90%, respectively (AUC 0.950). Despite a lower diagnostic efficacy of Emax for masses larger than 20mm (AUC 0.720), it still underscores the diagnostic potential of SWE for larger masses.

Based on the research findings, it is evident that SWE proves effective in quantitatively assessing the hardness of surrounding tissues in breast masses. Moreover, it holds considerable diagnostic value in distinguishing between benign and malignant masses of varying sizes. Specifically, SWE shows higher diagnostic accuracy in discerning the nature of smaller masses. These results highlight the potential clinical significance of ultrasound shear wave elastography.

Clinical Implications of SWE in Breast Mass Evaluation

The clinical implications of these findings are substantial. Parameters derived from SWE, including Max SWV, Mean SWV, and E_{ratio}, offer objective and quantitative assessments of tissue stiffness. Their value aids significantly in discriminating between benign and malignant breast masses. Integrating SWE into routine breast ultrasound examinations has the potential to enhance diagnostic accuracy, particularly for smaller masses. Accurate differentiation between benign and malignant masses can lead to better treatment decisions, minimizing unnecessary invasive procedures and enabling timely interventions for malignant masses.

Study Limitations

In discussing the limitations of this study, several factors merit consideration. Firstly, the relatively small sample size of 60 patients could potentially restrict the broader applicability and generalizability of our findings. To improve the robustness of our conclusions, future investigations with larger cohorts are warranted. Additionally, as this study was a retrospective analysis conducted within a single institution, inherent biases related to patient selection may have influenced our results. A more diverse patient population across multiple centers would enhance the external validity of our findings.

Furthermore, the exclusion of certain patient cohorts, such as those with prior breast surgeries or treatments, inflammatory breast diseases, or other benign breast conditions, introduces a degree of selection bias and may limit the extrapolation of our results to these specific demographics. Acknowledging these limitations emphasizes the need for further research to confirm and expand upon our findings, ultimately advancing our understanding of the diagnostic utility of SWE in breast mass evaluation.

CONCLUSION

In conclusion, this study highlighted the diagnostic utility of SWE in differentiating between benign and malignant breast masses. Our findings emphasize the potential of SWE parameters to complement conventional ultrasound methods, particularly for smaller masses. However, to confirm these findings and refine diagnostic models, further investigations with larger sample sizes and multi-center studies are imperative. By addressing these limitations, future research endeavors can increase the application of SWE in clinical practice, enhancing diagnostic accuracy and ultimately improving patient outcomes in the assessment of breast masses.

COMPETING INTERESTS
All authors declare no competing interests.

FUNDING
None.

AUTHORS' CONTRIBUTIONS
All authors equally contributed to the study's conception, design, and operations. All authors read and approved the final manuscript.

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AVAILABILITY OF DATA AND MATERIALS
The datasets analyzed during the current study are available in the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethical committees of the participating institutions approved the study protocol. Written, informed consent for participation in the study was obtained from all the subjects. This trial was performed in accordance with the Helsinki Declaration of 1964 and its later amendments.

CONSENT FOR PUBLICATION

All authors have read and approved the submission of the manuscript.

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