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Research Article

Correlation Between Ultrasound Manifestations and Traditional Chinese Medicine Syndrome Differentiation of Breast Nodules

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Abstract

Background Breast nodules are a health issue that concerns women, and clinical practice entails great concern for accurate diagnosis and appropriate prevention and treatment. This study examined the correlation between ultrasound manifestations and traditional Chinese medicine (TCM) syndrome differentiation of breast nodules. *Methods* This study included 128 patients with breast nodules based on ultrasound-dependent Breast Imaging-Reporting and Data System (BI-RADS) grading and ultrasound elastography (UE) scoring. This study explored the correlation of syndrome differentiation with age, medical history, nodule size, morphology, boundary status, blood flow signals, BI-RADS grading, and UE score. *Results* Age and medical history were significantly correlated with TCM syndrome differentiation. Patients with the Chong–Ren imbalance syndrome were older, and those with the phlegm–blood stasis syndrome had the longest disease course. The maximum nodule diameter was not correlated with TCM syndrome differentiation. Furthermore, nodule blood flow signal, BI-RADS grading, and UE scoring were significantly correlated with TCM syndrome differentiation. Patients with the phlegm–blood stasis syndrome had the highest proportion of those with "blood flow signal," BI-RADS Grade 4, and UE score of four points. Furthermore, the morphology and boundary state of the nodules were not correlated with TCM syndrome differentiation. *Conclusio*n Age, medical history, ultrasound blood flow signals, BI-RADS grading, and UE scoring were correlated with TCM syndrome differentiation in patients with breast nodules, particularly for BI-RADS Grade 4 and UE 4-point nodules, the prevalence of phlegm–blood stasis syndrome is at its highest. After excluding malignant transformation, patients with breast nodules at risk of cancer can receive preventive TCM treatment.

Keywords

Breast Nodules, Bi-Rads Grading, Ue Scoring, Traditional Chinese Medicine Syndrome Differentiation, Correlation Research

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1. Introduction

Breast nodules account for 70%–80% of female breast diseases diagnosed via imaging, of which approximately 20%–30% may develop into breast cancer [1, 2]. The presence of breast nodules can cause physical and mental stress on these patients. Early diagnosis and appropriate prevention and treatment of breast nodules are of great significance. Ultrasound is currently the primary diagnostic option for breast nodules. The Breast Imaging-Reporting and Data System (BI-RADS) grading is the most commonly used method for evaluating the degree of benignancy and malignancy and risk of breast lesions. Ultrasound elastography (UE) examination scoring evaluates the risk of nodules by detecting the modulus of elasticity. According to previous studies [3, 4], the BI-RADS grading combined with UE scoring can increase the risk screening accuracy for breast nodules. In the field of traditional Chinese medicine (TCM), syndrome differentiation can contribute to determining the disease characteristics of nodules and guiding clinical treatment, which is effective for preventing and treating nodules with Chinese characteristics [5]. However, few studies have reported the correlation between ultrasound-dependent diagnosis of nodules and TCM syndrome differentiation. Accordingly, this study collected data on patients with breast nodules diagnosed using ultrasound to explore the correlation of patient age, disease duration, nodule size, morphology, boundary status, blood flow signals, BI-RADS grading, and UE scoring with TCM syndrome differentiation. The findings of this study are expected to benefit our comprehensive understanding of the pathogenesis of breast nodules, help uncover the unified inherent laws of TCM and Western medicine, and guide clinical diagnosis and treatment.

2. Data and Methods

2.1. General Data

This study included 128 female patients (average age: 39.94 ± 8.80 years; age range: 22–57 years) diagnosed with breast nodules in the Department of Ultrasound of our hospital between January 2023 and January 2024.

2.2. Diagnostic Criteria

2.2.1. BI-RADS Grading Diagnostic Criteria

According to the criteria of the BI-RADS grading (5th edition) [6], this study defined breast nodules into the following categories: Grade 0, lesions that cannot be comprehensively evaluated via ultrasound examination, thereby requiring further diagnosis using other imaging modalities; Grade 1, no abnormality in ultrasound examination; Grade 2 (benign), benign breast masses (e.g., simple cysts, mammary cysts, fibroadenomas without changes after follow-up, and fibro lipomas) and benign calcifications; Grade 3 (high possibility of benign lesions, with the possibility of malignant transformation of <2%), (1) round or oval lumps in morphology, (2) parallel to the skin or with an aspect ratio of <1, (3) clear boundaries, (4) narrow and sharp edges, (5) posterior echo enhancement or no change, (6) no changes in surrounding tissues, (7) large (≥0.5mm) calcifications, and (8) no internal blood flow (females who met the criteria of (1) and (2), in addition to the other three or more criteria, can be classified to have Grade 3 nodules); Grade 4, solid masses with the nature to be determined (malignancy rate of approximately 3%–94%, considering biopsy to confirm diagnosis), irregular morphology, blood flow signals, and edge infiltration and microcalcification clusters; Grade 5 (malignant transformation rate of >95%), (1) irregular shape, (2) not parallel to the skin with an aspect ratio of >1, (3) unclear boundaries, (4) malignant halo sign with strong echo in the surrounding areas, (5) posterior enhancement with indistinct or irregular edges on both sides, (6) changes in surrounding tissues, (7) microcalcifications (<0.5mm), and (8) internal blood flow (females who met three or more of the aforementioned criteria can be classified to have Grade 5 nodules); and Grade 6, pathologically confirmed malignant masses.

2.2.2. UE Scoring Diagnostic Criteria

Breast nodules were scored according to the Guidelines on the Clinical Use of Ultrasound Elastography [7]. The modified UE 5-point scoring system was described as follows: 1 point (the entire or most of the lesion appeared green), 2 points (the lesion appeared blue in the center and green in the periphery), 3 points (the lesion appeared green and blue in a similar proportion), 4 points (the lesion was generally blue or had a slight green color inside); and 5 points (the surrounding tissues of the lesion appeared blue, with or without a green color inside). Females with 1–3 points indicated that they have benign lesions, and those with 4–5 points indicated that they have malignant transformation.

2.2.3. TCM Syndrome Differentiation Criteria

TCM syndrome differentiation was performed according to the classification criteria of "intramammary nodules" in the 2021 edition of Traditional Chinese Medicine Surgery [8].

1) Syndrome of liver depression and Qi stagnation: Breast swelling and pain, associated with the menstrual cycle and emotions, often accompanied by painful distension in the chest and hypochondriac regions, impatience and irritability, a reddish tongue, thin yellow coating, and stringy pulses.
2) Phlegm–blood stasis syndrome: Palpable lumps in the breast, which were tough in texture and may cause stinging, with swelling or involuntary pain, without obvious relation to menstrual changes, accompanied by

menstrual irregularities or dysmenorrhea, pale dark tongue with ecchymosis, tortuous sublingual veins, white or greasy coating, and rough or slippery pulses.

3) Chong–Ren imbalance syndrome: Painful lumps without obvious relation to menstrual or emotional changes, often accompanied by menstrual disorders, dark complexion or chloasma, fatigued spirit and lack of strength, dreaminess during sleep at night, pale tongue with a whitish coating, floating and soft or deep and faint pulses.

2.3. Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) females aged ≥ 18 years; (2) patients with BI-RADS grades 2–5 and UE scores of 1–5 points; (3) patients with TCM syndromes of liver depression and Qi stagnation, phlegm–blood stasis, and Chong–Ren imbalance; and (4) patients who did not receive any relevant treatments in the month before enrollment. The exclusion criteria were as follows: (1) patients diagnosed with malignant tumors; (2) patients with chronic diseases, such as diabetes mellitus, hypertension, and coronary heart disease; and (3) pregnant or lactating women. This study was approved by the Ethics Committee of Shenzhen Hospital of Beijing University of Chinese Medicine (SZLDH2021LSYM-158).

2.4. Ultrasound-Dependent Diagnosis and TCM Syndrome Differentiation

BI-RADS grading: A senior attending physician specializing in ultrasound performed breast examinations of the enrolled patients using the Mindray R9W color Doppler ultrasound machine. Patients were notified of relevant precautions before the examination to alleviate their nervousness. During the examination, with full exposure of the patients ‘chests, an appropriate amount of coupling agent was applied to both breasts, and the breast skin was gently examined using the probe in a vertical position with the skin. Data on the nodules, including size, morphology, boundary status, echo, blood flow, and other characteristics, were recorded. The nodules were classified according to the BI-RADS grading criteria for diagnosis.

Modified UE 5-point scoring: The depth of the ultrasound probe was adjusted to optimize the TCC curve. In elastography, hard texture is presented in red, medium texture in green, and soft texture in blue. The breast lesions were searched to locate the largest section of the lesion, with adjustment of the size of the region of interest, and the skin was gently touched with the probe, without applying any pressure, while trying to keep the probe perpendicular to the skin as much as possible. Elastography was started using strain elastography, and the patients were instructed to hold their breath while the probe was slightly lifted after stabilization of the elastography image. The fat or glandular layer will appear in blue. After stabilization, the image was frozen for scoring according to the UE scoring criteria.

TCM syndrome differentiation: For patients with breast nodules detected using ultrasound as described above, related data, such as age and medical history, were recorded by two senior associate chief physicians of TCM at the Oncology Department. Syndrome differentiation of the breast nodules was performed with reference to the TCM syndrome differentiation criteria.

Based on the results of BI-RADS grading, UE scoring, and TCM syndrome differentiation of the breast nodules, the correlations of TCM syndrome differentiation with patient age, medical history, nodule size, morphology, boundary status, blood flow signals, nodule BI-RADS grading, and UE scoring were analyzed.

2.5. Statistical Analysis

All data in this study were statistically processed using Statistical Package for the Social Sciences (version 26.0). Descriptive analysis was used for general data, and quantitative data are presented as means ± standard deviations. Analysis of variance was used for data analysis of three or more groups, the chi-square (χ^2) test was used for comparison of counting data, and Kappa analysis was used for consistency analysis. Differences with p-values <0.05 were considered statistically significant.

3. Results

3.1. Correlation of Patient Age, Medical History, and Maximum Diameter of Nodules with TCM Syndrome Differentiation

As shown in Table 1, analysis of variance revealed significant correlations between patient age and medical history and TCM syndrome differentiation in patients with breast nodules (p= 0.002 and p= 0.000). In particular, patients with the Chong–Ren imbalance syndrome were the oldest in age, followed by those with the phlegm–blood stasis syndrome and those with liver depression and Qi stagnation; moreover, patients with the phlegm–blood stasis syndrome had the longest disease course, followed by those with the Chong–Ren imbalance syndrome and those with liver depression and Qi stagnation. Furthermore, no significant correlation was observed between the three TCM syndrome types and the maximum diameter of the nodules (p= 0.080).

Table 1. *Association analysis of age, medical history, and maximum diameter of nodules with TCM syndrome differentiation of patients with breast nodules.*

Age/medical history	TCM syndrome differentiation	Sample size	Average	Standard deviation	ANOVA
Age (years)	Liver *qi* stagnation	57	37.649	7.979	F=6.846 P=0.002***
	Phlegm and blood stasis	41	39.683	8.796	
	Chong-Ren imbalance	30	44.667	8.739	
	Total	128	39.945	8.805	
Medical history (month)	Liver *qi* stagnation	57	9.675	8.746	F=12.55 P=0.000***
	Phlegm and blood stasis	41	25.268	19.961	
	Chong-Ren imbalance	30	17.767	17.553	
	Total	128	16.566	16.604	
Maximum diameter of nodules (mm)	Liver *qi* stagnation	57	10.246	5.156	F=2.574 P=0.080*
	Phlegm and blood stasis	41	13.029	8.144	
	Chong-Ren imbalance	30	10.367	5.732	
	Total	128	11.166	6.463	

Note: ***, **, and * represent significance at the 1%, 5%, and 10% levels, respectively.

3.2. Correlation Between the General Morphological Features of Breast Nodules and TCM Syndrome Differentiation

The chi-square test revealed no correlation between the nodule boundary state and morphology and TCM syndrome differentiation (p= 0.166 and p= 0.407). Meanwhile, a significant correlation was observed between nodule blood flow signals and TCM syndrome differentiation (p= 0.0024). The proportions of TCM syndrome types were as follows: phlegm–blood stasis syndrome (48.78%), Chong–Ren imbalance syndrome (30.00%), and syndrome of liver depression and Qi stagnation (22.80%), as presented in Table 2.

Table 2. *Associations of the boundary, morphology, and blood flow signals with TCM syndrome differentiation of breast nodules.*

Boundary/morphology/blood flow signal	Classification	TCM syndrome differentiation			Total	X^2	P
		Chong-Ren imbalance	Phlegm and blood stasis	Liver *qi* stagnation			
Boundary	Unclear	8	13	9	30	3.595	0.166
	Clear	22	28	48	98		
Total		30	41	57	128		
Morphology	Irregular	10	16	15	41	1.8	0.407
	Regular	20	25	42	87		
Total		30	41	57	128		
Blood flow signal	Without	21	21	44	86	7.438	0.024**
	With	9	20	13	42		
Total		30	41	57	128		

Note: ***, **, * represent significance levels of 1%, 5%, and 10%, respectively.

3.3. Consistency Analysis Between BI-RADS Grading of Breast Nodules and UE Scoring

In this study, nodules with BI-RADS grades 2–3 and UE scores of 1–3 points were defined as benign lesions, whereas those with BI-RADS Grade ≥4 and UE scores ≥4 points were classified as suspected malignant lesions. Kappa analysis (Table 3) revealed good consistency between the two diagnostic methods (Kappa= 0.942, p= 0.000).

Table 3. *Consistent correlation analysis between BI-RADS grading and UE score of breast nodules.*

Diagnostic criteria	Benign	Suspicious abnormality	Total	Kappa value	Standard error	z	P
BI-RADS classification	27+79	22	128	0.942	0.011	85.726	0.000***
UE score	28+39+37	24	128				

Note: ***, **, * represent significance levels of 1%, 5%, and 10%, respectively.

3.4. Correlation of BI-RADS Grading and UE Scoring of Breast Nodules with TCM Syndrome Differentiation

The chi-square test revealed significant correlations between BI-RADS grading and UE scoring and TCM syndrome differentiation of breast nodules (p= 0.015 and p= 0.044). In particular, the proportions of BI-RADS Grade 4 nodules and UE 4-point nodules with high risk of cancer in various TCM syndrome types were as follows: 31.70% and 34.14% for the phlegm–blood stasis syndrome; 10.52% and 12.28% for the syndrome of liver depression and Qi stagnation, and 10% and 10% for the Chong–Ren imbalance syndrome (Table 4).

Table 4. *Association analysis of BI-RADS classification and UE score with TCM syndrome differentiation of breast nodules.*

Malignancy tool	Category/ score	TCM syndrome differentiation			Total	χ^2	P
		Chong-Ren imbalance	Phlegm and blood stasis	Liver *qi* stagnation			
BI-RADS classification	2	6	4	17	27	12.418	0.015**
	3	21	24	34	79		
	4	3	13	6	22		
Total		30	41	57	128		
UE score	1	5	6	17	28	12.913	0.044**
	2	12	9	18	39		
	3	10	12	15	37		
	4	3	14	7	24		
Total		30	41	57	128		

Note: ***, **, * represent significance levels of 1%, 5%, and 10%, respectively.

4. Discussion

Breast nodules are morphological breath changes found on imaging examinations, and they may indicate mammary gland hyperplasia, mastitis, cystic changes, fibroadenoma, and even breast cancer, among others. Therefore, early systematic diagnosis and targeted prevention and treatment are of great significance. Ultrasound-dependent BI-RADS grading and UE scoring can diagnose breast nodules from a microscopic viewpoint and obtain biological information about the nodules. Meanwhile, TCM can systematically classify the prevention and treatment of breast nodules based on macroscopic syndrome differentiation and treatment. Therefore, clarification of the intrinsic correlations between these modalities is essential for a comprehensive understanding of the occurrence and development of breast nodules.

In the field of TCM, breast nodules belong to the category of "intramammary nodules." For young females, it is mainly attributed to the stagnation of the liver Qi due to poor mood or mental irritation, which can lead to spleen damage, spleen dysfunction in transportation, and production of phlegm turbidity internally, causing phlegm–blood stasis to accumulate and block the breasts. Meanwhile, in middle-aged and elderly women, menstrual disorders may induce insufficient blood supply to the liver, stagnation of the liver Qi, spleen deficiency, and phlegm retention, resulting in phlegm–blood stasis, which promotes the formation of breast nodules. Consequently, from the viewpoint of TCM syndrome differentiation, breast nodules comprise three syndromes: phlegm–blood stasis, Chong–Ren imbalance, and liver depression and Qi stagnation. Furthermore, they are in line with the evolution process of TCM pathogenesis. For instance, Zhang Weiying et al. [9] reported that breast nodule classification was correlated with age and disease duration. In particular, the syndrome of liver depression and Qi stagnation was the major syndrome type in patients aged <40 years, whereas the main syndrome type in patients aged ≥40 years, particularly after menopause, was the Chong–Ren imbalance syndrome; meanwhile, the phlegm–blood stasis syndrome was more common in females aged between >40 years and before menopause. Moreover, in terms of disease duration, the average durations of the syndromes of phlegm–blood stasis, Chong–Ren imbalance, and liver depression and Qi stagnation were 28, 20, and 19 months, respectively. In this study, significant correlations were observed between patient age and medical history and TCM syndrome differentiation of breast nodules (p= 0.002 and p= 0.000). Patients with the Chong–Ren imbalance syndrome were the oldest in age, followed by those with the phlegm–blood stasis syndrome and those with liver depression and Qi stagnation. Meanwhile, patients with the phlegm–blood stasis syndrome had the longest disease course, followed by those with the Chong–Ren imbalance syndrome and those with liver depression and Qi stagnation. These findings are consistent with those of the aforementioned studies and the report by Yang Zhiguang et al. [10] Furthermore, nodule size is not an independent risk factor for malignancy but a major cause of patient anxiety. This study revealed no correlation between the maximum diameter of breast nodules and TCM syndrome differentiation (p= 0.080). However, patients with the phlegm–blood stasis syndrome had the largest diameter of breast nodules, followed by those with the Chong–Ren imbalance syndrome and those with liver depression and Qi stagnation. This finding indicates that breast nodules gradually grow with the prolongation of the disease course. Generally, the presence of "blood flow signals" in nodules may reveal the complexity of the disease. Some researchers have proposed that nodules with blood flow signals have a higher risk of malignant transformation than cysts without blood flow signals [11]. In our study, a significant correlation was observed between the presence of "blood flow signals" and TCM syndrome differentiation (p= 0.0024). The proportions of nodules with "blood flow signals" in TCM syndrome types were as follows: 48.78% for the phlegm–blood stasis syndrome, 30.00% for the Chong–Ren imbalance syndrome, and 22.80% for the syndrome of liver depression and Qi stagnation. This finding indicates that as the condition progresses, the risk of malignant transformation of breast nodules increases in females with the phlegm–blood stasis syndrome. No correlation was observed between nodule boundary and morphology and TCM syndrome differentiation (p= 0.166 and p= 0.407).

Furthermore, the BI-RADS grading has been commonly applied for evaluating the degree of benignancy and malignancy and risk of breast lesions [12, 13]. This system is widely used in various breast imaging examinations, such as mammography, ultrasound, and magnetic resonance imaging (MRI). It defines breast nodules in seven grades (0–6) based on nodule size, shape, echo, and blood flow signals, among others. In particular, nodules defined as Grade 0 cannot be diagnosed and require other imaging methods for diagnosis; grades 1–2 indicate no nodules or cystic breast lesions detected; Grade 3 nodules have a malignancy rate of <2%; Grade 4 nodules are suspected malignant lesions, with a malignancy rate of 3%–94%; Grade 5 nodules have a high possibility of malignancy (≥95%); and Grade 6 nodules are confirmed malignancies. Simultaneously, UE scoring is also a system used for determining the benign and malignant natures of breast masses. In 1991, Ophir et al. [14] proposed a UE concept based on the principle that the moduli of elasticity of different tissues have different strain rates under external forces or alternating vibrations. This concept was rapidly and widely applied to evaluate lesion hardness. At present, the modified UE 5-point scoring system is commonly used for elasticity scoring, with 1–3 and 4–5 points indicating benign lesions and possible malignant transformations, respectively. Gao LY et al. [15] explored the value of the BI-RADS grading combined with the UE scoring and MRI in the diagnosis of breast nodules. According to their study, the BI-RADS grading combined with the UE scoring exhibited higher sensitivity and specificity in distinguishing dense

breast nodules than MRI ($p< 0.01$), with clinical accessibility and cost-effectiveness superior to those of MRI. Similarly, our study revealed consistency in the two aforementioned diagnostic methods (Kappa=0.942, p=0.000), suggesting the rationality and necessity of applying the BI-RADS grading and UE scoring jointly for clinical diagnosis. Importantly, this study emphasized clarifying the correlation of the BI-RADS grading and UE scoring with TCM syndrome differentiation of breast nodules. The two diagnostic methods were significantly correlated with TCM syndrome differentiation ($p= 0.015$ and $p= 0.044$). In particular, the proportions of BI-RADS Grade 4 nodules and UE4pointnodules with high risk of malignancy were 31.70% and 34.14%, respectively, in the phlegm–blood stasis syndrome; 10.52% and 12.28%, respectively, in the syndrome of liver depression and Qi stagnation, and 10% and 10%, respectively, in the Chong–Ren imbalance syndrome. Collectively, the phlegm–blood stasis syndrome accounted for the largest part of TCM syndrome differentiation of high-risk breast nodules. Patients with breast nodules and the phlegm–blood stasis syndrome may experience a higher risk of malignancy. For the prevention of breast nodules using TCM, the Consensus of Chinese Experts in Clinical Diagnosis and Treatment of Integrated Traditional and Western Medicine [16] proposes that TCM prescriptions or traditional Chinese patent drugs can be used for treatment based on syndrome differentiation. Xiaojin Pellets or Hongjin Xiaojie tablets may be effective for treating breast nodules in patients with the phlegm–blood stasis syndrome [17, 18].

This study has several limitations. First, there may have been outcome bias due to the smaller sample size in this study. Second, technical deviations may have been unavoidable even though the medical diagnoses of the enrolled patients were made by professional ultrasound experts and TCM specialists, which may have affected the final results. In the future, our research group intends to conduct a large-scale multicenter clinical study based on consultations with more specialized diagnosticians, aiming to make up for the shortcomings of this study.

5. Conclusion

In summary, significant correlations were observed between age, disease duration, ultrasound blood flow signals, BI-RADS grading, and UE scoring and TCM syndrome differentiation in patients with breast nodules. Patients with BI-RADS Grade-4 and UE4point nodules commonly present with the phlegm–blood stasis syndrome. Preventive measures using TCM for reducing phlegm and dispersing blood stasis can be considered in suitable patients after ruling out the risk of cancer. The findings of this study may offer objective evidence for the intrinsic unity between TCM and Western medicine diagnoses and the prevention and treatment of breast nodules with TCM.

Abbreviations

TCM	Traditional Chinese Medicine
BI-RADS	The Breast Imaging-Reporting and Data System
UE	Ultrasound Elastography
MRI	Magnetic Resonance Imaging

Author Contributions

Ruo Chen: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Writing – original draft, Writing – review & editing

Jie Zhang: Formal Analysis, Investigation, Resources, Software, Supervision

Yong Dai: Data curation, Formal Analysis, Investigation, Project administration, Software

Xinhan Tan: Conceptualization, Resources, Validation, Visualization

Yufei Liu: Conceptualization, Data curation, Methodology, Software

Yuanqi Li: Formal Analysis, Project administration, Validation, Visualization

Gaofei Feng: Conceptualization, Investigation, Resources, Software, Writing – original draft, Writing – review & editing

Ethical Statement

All methods used in this study were performed in accordance with relevant guidelines and regulations and were approved by the Ethics Committee of Shenzhen Hospital, Beijing University of Chinese Medicine (SZLDH2021LSYM-158).

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Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author.

Conflicts of Interest

The authors declare that they have no competing interests.

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