Diagnosis of Benign and Malignant Breast Nodules by Conventional Ultrasound in Combination with S-Detect Technology and Elastic Imaging

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ABSTRACT

Objective: To determine the diagnostic value of conventional ultrasound combined with S-Detect and elastic imaging technology in differentiating between benign and malignant breast nodules.

Study Design: Observational study.

Place and Duration of the Study: Department of Ultrasound Imaging, Yichang Central People's Hospital, Yichang, China, from October 2019 to October 2022.

Methodology: The study included all breast nodules diagnosed using ultrasound, with patients undergoing conventional ultrasound for BI-RADS classification, elasticity score, and S-Detect examination. Benign and malignant breast nodules were classified according to the three tests and their combinations. The diagnostic sensitivity, specificity, accuracy, positive predictive value, negative predictive value, and area under curve (AUV) of those alone and combinations were calculated and compared.

Results: Of the three methods, BI-RADS, elasticity score, and S-Detect, BI-RADS had the highest accuracy (89.29%), elasticity score had the highest specificity (96.20%), and S-Detect had the highest sensitivity (93.92%). The accuracy of combined groups were higher than that of the single group. When combined with elasticity score, the AUC of the new BI-RADS increased from 0.882 to 0.917 ($p < 0.001$); and combined with S-Detect, the AUC of the new BI-RADS increased from 0.882 to 0.927 ($p < 0.001$).

Conclusion: The combination of conventional ultrasound BI-RADS classification with elasticity score or S-Detect technology has a higher diagnostic efficacy for breast nodules, which can improve breast cancer detection and provide valuable diagnostic evidence for clinical practice.

Key Words: *S-Detect technology, Ultrasound elastic imaging, Elasticity scoring, Elasticity strain ratio value, Breast tumour.*

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INTRODUCTION

Breast cancer represents a prevalent malignancy among women with approximately 2.26 million new cases reported globally in 2020, significantly impacting female health.[1] Early detection, diagnosis, and treatment are crucial, as patients diagnosed at early stage have a 5-year survival rate exceeding 90%.[2] Ultrasound (US) has been regarded as an important imaging modality for breast masses classification. The Breast Imaging Reporting and Data System (BI-RADS) standardises breast ultrasound diagnosis, facilitating clinical evaluation of lesions.[3]

Elastography objectively assesses nodular hardness, enhancing the differentiation between benign and malignant nodules.[4] S-Detect, an AI-assisted diagnostic tool, evaluates breast nodules based on their shape, orientation, margins, echo patterns, and other relevant factors, reducing subjective errors in human examination.[5]

Given the diverse manifestations of breast cancer in sonograms, this study aimed to explore the combined use of ultrasound, S-Detect technology, and elastography to improve the accuracy of benign and malignant nodule assessment, minimise unnecessary biopsies, alleviate patients' psychological and financial burdens, and provide valuable insights for developing clinical treatment plans.

METHODOLOGY

This study involved patients with breast nodules who visited the Ultrasonography or Breast and Thyroid Surgery Departments at Yichang Central People's Hospital from October 2019 to October 2022. Inclusion criteria were: Presence of one or more definite breast nodules, age 18 years or older, and scheduled for core needle biopsy or surgery. Exclusion criteria included prior breast surgery or biopsy and the inability to obtain a definitive pathological result.

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Patients were examined using the Samsung RS80A ultrasound machine with an L3-12A probe, assessing both breasts and axillary lymph nodes. Ultrasound elastography analysed the nodules' relationship with surrounding tissues, scoring elasticity images and calculating strain ratios. The S-Detect mode automatically classified nodules as likely benign or malignant. Diagnostic criteria followed the 2013 BI-RADS-US guidelines, focusing on nodule morphology, orientation, and boundaries.[6-8] Elastic imaging analysis and assessment criteria were based on the modified 5-point scoring system for elastic imaging.[9] Combined Group 1 underwent conventional ultrasound BI-RADS combined with elasticity score. Combined Group 2 underwent conventional ultrasound BI-RADS combined with S-Detect technology.

Statistical analysis was conducted using SPSS 23.0 software. Surgical or biopsy pathological results were considered as the gold standard. The sensitivity (SE), specificity (SP), accuracy (ACC), positive predictive value (PPV), and negative predictive value (NPV) for diagnosing nodules were calculated, and ROC curves assessed diagnostic performance. A p-value <0.05 indicated statistically significant differences.

RESULTS

This study utilised pathological results as the gold standard and analysed 411 breast nodules, comprising 148 malignant and 263 benign cases. Malignant nodule patients were of 52.58 ± 11.67 years, while benign nodule patients were of 42.50 ± 11.09 years, with a significant difference (p <0.001). Malignant nodules had an average maximum diameter of 1.88 ± 0.86 cm, compared to 1.39 ± 0.73 cm for benign nodules (p <0.001).

Ultrasound BI-RADS classification diagnosed 146 malignant nodules and 265 benign nodules, with 44 diagnoses that did not match pathology. The SE, SP, ACC, PPV, and NPV of ultrasound BI-RADS classification for diagnosing benign and malignant breast nodules were 88.46%, 92.02%, 89.29%, 85.62%, and 91.32%, respectively. Elasticity scoring diagnosed 108 nodules as malignant and 303 as benign, with 60 diagnoses that did not match the pathology. The elastography scores for SE, SP, ACC, PPV, and NPV of breast benign and malignant nodules were 66.22%, 96.20%, 85.40%, 90.74%, and 83.50%, respectively (Table I). The elastic strain ratio (ESR) values of benign and malignant breast nodules in different axes were examined. In the long and short axis, malignant nodules had significantly higher ESR values than benign nodules (p <0.001). Using a long-axis ESR cut-off of 2.12, the sensitivity was 90.5%, specificity 70.0%, and AUC 0.922 (95% CI: 0.897 - 0.947). With a short-axis ESR cut-off of 2.46, the sensitivity was 75.7%, specificity 61.3%, and AUC 0.890 (95% CI: 0.858 - 0.921, Figure 1). S-Detect technology diagnosed 208 benign nodules and 55 malignant nodules with SE, SP, ACC, PPV, and NPV of S-Detect technology for benign and malignant breast nodules were 93.92%, 79.09%, 84.43%, 71.65%, and 95.85%, respectively (Table II).

Combined Group 1 diagnosed 147 malignant nodules and 264 benign nodules, with 31 of them were inconsistent with pathology. Among them, 16 malignant cases were misdiagnosed as benign, and 15 benign cases were misdiagnosed as malignant. The SE, SP, ACC, PPV, and NPV of benign and malignant breast nodules in the Combined Group 1 were 89.19%, 94.30%, 92.46%, 89.80%, and 93.94%, respectively. Combined Group 2 diagnosed 153 malignant nodules and 258 benign nodules, with 29 diagnoses that did not match pathology. Among them, 12 malignant nodules were misdiagnosed as benign and 17 benign nodules were misdiagnosed as malignant. The SE, SP, ACC, PPV, and NPV of the benign and malignant breast nodules in Combined Group 2 were 91.89%, 93.54%, 92.94%, 88.89%, and 95.35%, respectively.

Table I: Comparison of diagnostic performance for breast lesions between individual applications and combined groups.

Methods	SE	SP	ACC	PPV	NPV	AUC	95% CI
US BI-RADS classification	84.46	92.02	89.29	85.62	91.32	$0.882^{*\#}$	0.847 - 0.912
Elasticity score	66.22	96.20	85.40	90.74	83.50	$0.812^{*\#}$	0.771 - 0.849
S-Detect group	93.92	79.09	84.43	71.65	95.85	$0.865^{*\#}$	0.828 - 0.897
Combined Group 1	89.19	94.30	92.46	89.80	93.94	0.917	0.886 - 0.942
Combined Group 2	91.89	93.54	92.94	88.89	95.35	0.927	0.898 - 0.950

*Note: Compared to combination Group 1, the difference is statistically significant at *p <0.05; compared to combination Group 2, the difference is statistically significant at $^{\#}$p <0.05.*

Table II: Standalone and combined use with pathological comparison.

Pathology	BI-RADS Classification		Elasticity Score		S-Detect		Combined Group 1		Combined Group 2		Total
	Malignant	Benign	Malignant	Benign	Malignant	Benign	Malignant	Benign	Malignant	Benign	
Malignant	125	23	98	50	139	9	132	16	136	12	148
Benign	21	242	10	253	55	208	15	248	17	246	263
Total	146	265	108	303	194	217	147	264	153	258	411

Table III: Conventional BI-RADS classification and BI-RADS classification adjusted with the application of combined groups.

Pathology	BI-RADS Classification					BI-RADS Classification After Adjustment in Combined Scheme One					BI-RADS Classification After Adjustment in Combined Scheme Two					Total
	3	4a	4b	4c	5	3	4a	4b	4c	5	3	4a	4b	4c	5	
Malignant	2	22	67	49	8	4	12	32	65	35	7	5	24	61	51	148
Benign	44	198	20	1	0	186	63	9	5	0	194	52	9	8	0	263
Total	46	220	87	50	8	190	75	41	70	35	201	57	33	69	51	411

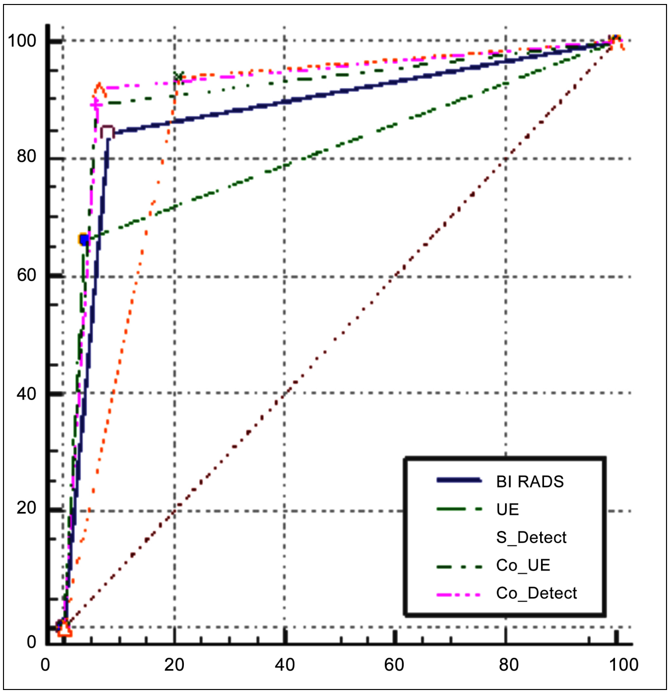

Figure 1: ROC curves for the diagnosis of breast lesion malignancy using a single and combined approach.

The AUC for the diagnosis of benign and malignant breast nodules using conventional ultrasound BI-RADS classification, elasticity score, S-detect technology, Combined Group 1, and Combined Group 2 were 0.882, 0.812, 0.865, 0.917, and 0.927, respectively. The AUC for both Combined Group 1 and Combined Group 2 was higher than that of the other three diagnostic methods, and the difference was statistically significant ($p < 0.05$, Table III and Figure 1).

DISCUSSION

In this study, 411 breast nodules were collected, and the benign or malignant tumours were identified by using 5 methods: US BI-RADS classification, elastic score in elastography, S-Detect, BI-RADS combined with elastic score, and BI-RADS combined with S-Detect. The results showed that the SE, SP, ACC, PPV, NPV, and AUC of the combined group were significantly higher than those of the other three methods. The findings suggested that the combined technique can achieve complementary advantages, improve diagnostic efficacy, and significantly reduce the biopsy rate of BI-RADS without affecting the malignant rate of biopsy.

Ultrasonic elasticity imaging has evolved into an objective method for assessing tissue hardness. By comparing the difference in elastic coefficients between lesion tissues, the hardness ratio can be reflected, enabling a more objective diagnosis.[10,11] The application of ESR in breast disease diagnosis has shown promising results. Preliminary studies by domestic and foreign scholars have indicated relatively high sensitivity and specificity.[12-14] This study suggests that the elasticity strain ratio has a good predictive ability for diagnosing benign and malignant breast nodules, but the lower specificity compared to the regular ultrasound BI-RADS classification indicates that it should not be used as a standalone clinical tool.

Ultrasound S-Detect technology utilises a convolutional neural network deep learning algorithm to analyse breast examinations. This computer-aided diagnostic tool evaluates breast nodules based on the BI-RADS dictionary, automatically detecting and analysing the internal structure, edge, direction, and morphology of the nodule. It then determines whether the nodule is benign or malignant, overcoming the subjective errors of the examiner.[15,16] The result of this study indicated that S-Detect technology has high diagnostic specificity and accuracy. The result consistent with previous research findings.[17] The approach of selecting the malignant result when the diagnosis of cross-sectional and longitudinal sections is inconsistent reduces the number of missed diagnoses but may also lead to an overestimation of malignant diagnoses, increasing the misdiagnosis rate.

In this study, the use of ultrasonic elasticity imaging combined with BI-RADS can significantly improve the diagnostic sensitivity and negative predictive value. It is important to reduce the burden of patients and improve the efficiency of diagnosis. In the other combined group, S-Detect technology was used to adjust the BI-RADS scores assigned by conventional US. This suggests that the S-Detect technology assists in correctly upscaling or downscaling the BI-RADS classification. The study found a statistically significant difference in AUC between Combined Group 2 and other groups, indicating that the diagnostic effectiveness of sonographers can be significantly improved with the assistance of S-Detect.

Limitations of this study need to be considered. This study employed stress-based elasticity imaging, which relies on the experience of the examiner and the scoring of the same lesion might vary due to subjective factors. In addition, S-Detect technology lacks integration with nodule blood flow and elastic imaging. The small sample size and single pathological results may bias the statistical findings, necessitating further verification.

CONCLUSION

Combined use of regular ultrasound, S-Detect technology, and elasticity imaging can complement each other's advantages, enhancing diagnostic efficacy and significantly reducing the misdiagnosis rate of benign and malignant breast nodules.

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ETHICAL APPROVAL:

This study was conducted after obtaining approval from the Ethics Committee of Yi Chang Central People's Hospital (Approval No. PJ-KY2019-11).

PATIENTS' CONSENT:

Written informed consent was taken from all the patients.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

BX: Concept of the study, design, data analysis, and data interpretation.

CF: Recollected patient information.

ZY: Revision for intellectual content.

All authors approved the final version of the manuscript to be published.

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