

Modified O-RADS Ultrasound Classification Using Qualitative Contrast-Enhanced Ultrasound Score for Borderline and Malignant Adnexal Lesions: An External Testing Study

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O-RADS Ultrasound provides a standardized framework for risk stratification of adnexal masses based primarily on morphologic and Doppler features (1). However, borderline ovarian tumors (BOTs) share characteristic features with both benign lesions and malignancies, leading to diagnostic uncertainty and potential overtreatment for O-RADS category 4 and 5 lesions (2,3). Contrast-enhanced ultrasound (CEUS) has demonstrated high accuracy in differentiating benign from malignant ovarian tumors (3). One study showed improved O-RADS Ultrasound performance when potentially modifying the category using a proposed 5-point CEUS score reflecting qualitative assessment of a lesion's enhancement time, enhancement intensity, and dynamic change in enhancement from peak intensity to clearance (4); that study had only internal testing and grouped BOTs with malignancies. The present study performed external testing of the diagnostic performance of the modified O-RADS Ultrasound classification based on the 5-point CEUS score for detection of BOTs and malignant adnexal lesions.

The institutional review board approved this retrospective study, waiving the requirement for written informed consent. The study included 357 consecutive patients (mean age, 48 years) who underwent conventional ultrasound and CEUS before surgical resection of an adnexal mass at the study institution between December 2020 and December 2024. No patients were excluded. Two radiologists (reader 1 [R1, S.Q.C.] and reader 2 [R2, Z.C.], with 19 and 14 years, respectively, of experience in gynecologic ultrasound) independently evaluated the ultrasound examinations. The readers assigned each lesion an O-RADS Ultrasound category based on morphologic and Doppler descriptors and a qualitative CEUS score using the 5-point scale described by Yuan et al. (4). Also as described by Yuan et al., O-RADS category 4 was downgraded to category 3

when the CEUS score was ≤ 2 and upgraded to category 5 when the score was ≥ 4 . The Supplemental Methods provides additional details.

Interreader agreement was assessed using weighted kappa coefficients. Diagnostic performance of original and modified O-RADS categories, both considered positive when ≥ 4 , for BOT and for malignancy was evaluated using sensitivity, specificity, accuracy, and AUC.

Table S1 summarizes characteristics of patients and lesions. A total of 129 (36%) lesions were benign, 112 (31%) were borderline, and 116 (33%) were malignant. The kappa coefficient for the initial O-RADS category was 0.984, for CEUS score was 0.975), and for modified O-RADS category was 0.971. The median CEUS score for benign, borderline, and malignant lesions was 4.0 (IQR, 4.0-4.0), 3.0 (IQR, 3.0-3.0), and 5.0 (IQR, 4.0-5.0) for R1, and 4.0 (IQR, 4.0-4.0), 3.0 (IQR, 3.0-3.0), and 5.0 (IQR, 4.8-5.0) for R2, respectively.

Table 1 reports diagnostic performance results. Sensitivity, specificity, and accuracy for BOT for R1 using original O-RADS category were 81.3%, 85.3%, and 84.0%; and using modified O-RADS category were 92.0%, 94.7%, and 93.8%; and for BOT for R2 using original O-RADS category were 80.4%, 84.5%, and 83.2%; and using modified O-RADS category were 91.1%, 93.9%, and 93.0%, respectively. Sensitivity, specificity, and accuracy for malignancy for R1 using original O-RADS category were 89.7%, 92.1%, and 91.3%, and using modified O-RADS category were 97.4%, 98.3%, and 98.0%; and for malignancy for R2 using original O-RADS category were 88.8%, 91.3%, and 90.5%; and using modified O-RADS category were 96.6%, 97.9%, and 97.5%, respectively. All metrics were significantly higher ($p < .05$) for modified than original O-RADS for both

readers. Figures 1 and S1 show representative examples of the use of the CEUS score to aid diagnosis.

The qualitative score reflects tumor perfusion behavior and can be applied during routine CEUS examinations without postprocessing or complex modeling. In this study, overall lower CEUS scores were observed in BOTs than in malignant lesions, consistent with prior pathologic and imaging studies reporting lower microvascular density in BOTs than in invasive carcinomas (5,6).

Limitations should be acknowledged. The study was performed retrospectively at one center. Additionally, the cohort included only surgically resected lesions, introducing selection bias. The impact of the CEUS score on clinical decision-making in nonoperative cases was not evaluated. Also, the original and modified O-RADS categories were assessed for the two endpoints (BOT and malignancy) using identical threshold criteria (category ≥ 4).

In conclusion, in this external testing study, a qualitative 5-point CEUS score improved both the sensitivity and specificity of O-RADS Ultrasound for detection of both BOTs and malignancies. This approach may help avoid overtreatment for benign lesions.

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Table 1. Diagnostic performance of initial O-RADS Ultrasound category and modified category based on qualitative CEUS score for outcomes of borderline ovarian tumor and malignancy (N = 357).

Diagnosis, Classification, and Reader	Sensitivity	Specificity	Accuracy	AUC
Borderline ovarian tumor				
Initial O-RADS				
Reader 1	81.3 (74.0-88.5) [91/112]	85.3 (80.9-89.7) [209/245]	84.0 (80.2-87.8) [300/357]	0.893 (0.838–0.947)
Reader 2	80.4 (73.0-87.7) [90/112]	84.5 (80.0-89.0) [207/245]	83.2 (79.3-87.1) [297/357]	0.886 (0.849–0.923)
CEUS-modified O-RADS				
Reader 1	92.0 (87.0-97.0) [103/112]	94.7 (91.9-97.5) [232/245]	93.8 (91.3-96.3) [335/357]	0.969 (0.940–0.998)
p	.03	.001	<.001	.02
Reader 2	91.1 (85.8-96.4) [102/112]	93.9 (90.9-96.9) [230/245]	93.0 (90.4-95.6) [332/357]	0.961 (0.932–0.990)
p	.03	.001	<.001	.002
Malignancy				
Initial O-RADS				
Reader 1	89.7 (84.2-95.2) [104/116]	92.1 (88.7-95.5) [222/241]	91.3 (88.4-94.2) [326/357]	0.921 (0.865–0.978)
Reader 2	88.8 (83.1-94.5) [103/116]	91.3 (87.8-94.8) [220/241]	90.5 (87.5-93.5) [323/357]	0.915 (0.858–0.972)
CEUS-modified O-RADS				
Reader 1	97.4 (94.5-100.0) [113/116]	98.3 (96.7-99.9) [237/241]	98.0 (96.6-99.4) [350/357]	0.993 (0.984–1.000)
p	.03	.002	<.001	.01
Reader 2	96.6 (93.3-99.9) [112/116]	97.9 (96.1-99.7) [236/241]	97.5 (95.9-99.1) [348/357]	0.991 (0.981–1.000)
p	.04	.002	<.001	.01

Note: Sensitivity, specificity, and accuracy reported as percentage with 95% CI in brackets and numerator and denominator in parentheses, based on classification as positive for category ≥ 3 ; AUC reported with 95% CI in parentheses. P values are for comparison with initial O-RADS.

CEUS, contrast-enhanced ultrasound

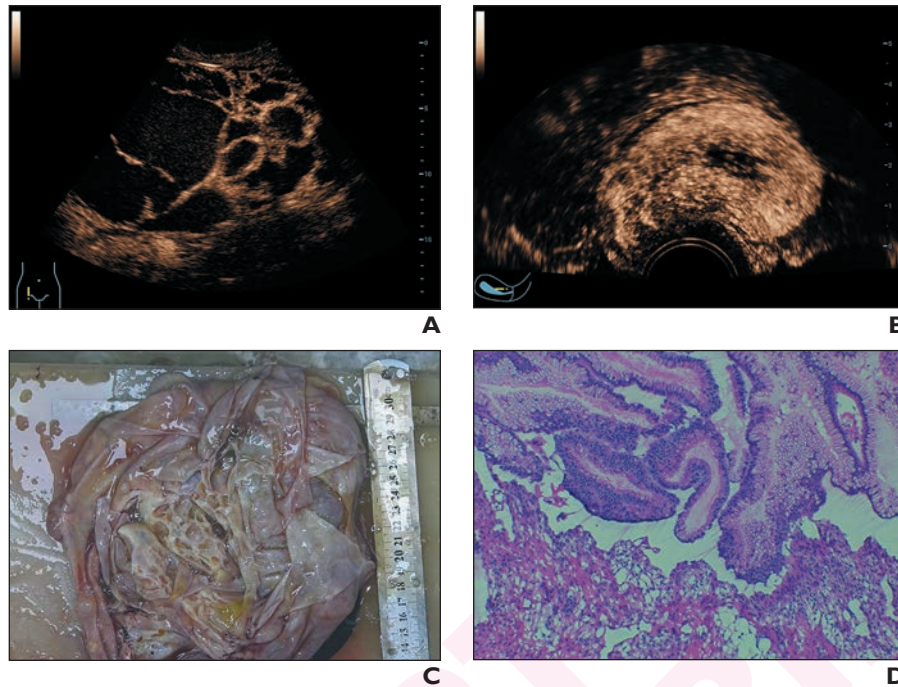


Figure 1. 57-year-old woman with adnexal lesion. (A) Contrast-enhanced ultrasound image shows right adnexal lesion. (B) Contrast-enhanced ultrasound image shows normal myometrium. Lesion shows isoenhancement relative to myometrium. Reader 1 assigned original O-RADS category of 4, qualitative CEUS score of 3, and modified O-RADS category of 4. Reader 2 assigned original O-RADS category of 3, qualitative CEUS score of 4, and modified O-RADS category of 4. (C) Sectioned surgical specimen shows cystic mass with multiple internal septations. (D) Photomicrograph (H&E stain, x100) shows fibrous cyst wall lined by mucinous columnar epithelium with epithelial stratification and mild-to-moderate cytologic atypia and absence of stromal invasion, consistent with mucinous borderline ovarian tumor.

Research Letter**Modified O-RADS Ultrasound Classification Using Qualitative Contrast-Enhanced Ultrasound Score for Borderline and Malignant Adnexal Lesions: An External Testing Study****Running Title:** Qualitative CEUS Score for Adnexal Lesions

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Declarations**Ethics approval and consent to participate**

The study was approved by the Institutional Review Board of The First Affiliated Hospital of Shantou University Medical College(B-2024-075). The requirement for written informed consent for this retrospective analysis was waived by the IRB.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article.

Author contributions

Qingzi Chen, Ju Huang and Shaoqi Chen carried out the studies, participated in collecting data, and drafted the manuscript. Qiulin Wu and Shigao Chen performed the statistical analysis and participated in its design. Zhe Chen and Liangli Hong participated in acquisition, analysis, or interpretation of data and draft the manuscript. All authors read and approved of the final manuscript.

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Conflict of interests

All authors declare that they have no any conflict of interests.

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