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A Prospective Study on the Accuracy of O-RADS MRI in Differentiating Benign and Malignant Adnexal Lesions After Ultrasound Imaging in Reproductive and Post-menopausal Women

Dr. Jyothsana Harini Suma S P[1], Dr. Santhana Lakshmi K S[*2], Dr. Jeffrey Skaria Joseph[3], Dr. Alex Daniel Prabhu[4], Dr. Roshini Maria Abraham[5], Dr. Ram Prasath K S[6]

[1]Junior Resident, Department of Radiology, Chettinad hospital and research institute

[2]Senior resident, Department of Radiology, ACS Medical College and Hospital

[3]Assistant professor, Department of Radiology, Chettinad hospital and research institute

[4]Professor and Head of department, Department of Radiology, Chettinad hospital and research institute

[5]Professor, Department of Radiology, Chettinad hospital and research institute

[6]Senior resident, Department of Radiology, Chettinad hospital and research institute

[*]**Corresponding author:**

Dr. Santhana Lakshmi K S

Senior resident, Department of Radiology, ACS Medical College and Hospital

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ABSTRACT

Background: Accurate characterization of adnexal masses is critical in gynecological practice. Ultrasound (US) is the frontline tool, yet indeterminate lesions remain common. The American College of Radiology Ovarian-Adnexal Reporting and Data System for MRI (O-RADS MRI) was developed to standardize post-US risk stratification. Evidence on its prospective performance in routine practice—particularly across the full reproductive spectrum—remains limited.

Methods: In this single-centre prospective study (January 2023 – December 2024), consecutive reproductive and post-menopausal women with sonographically indeterminate adnexal masses underwent 3 T pelvic MRI with a dedicated O-RADS protocol. Two fellowship-trained radiologists assigned O-RADS MRI scores (1–5) blinded to histology. Reference standards were surgical histopathology or ≥ 6-month imaging follow-up. Diagnostic metrics were calculated for the threshold O-RADS ≥ 4 (high risk). Sub-analysis examined performance in reproductive (< 50 y) versus post-menopausal (≥ 50 y) cohorts.

Results: One-hundred-twenty women (mean age ± SD 48.9 ± 13.8 y) with 120 lesions were analysed; 42 (35%) were malignant, 8 (7%) borderline, and 70 (58%) benign. O-RADS MRI yielded sensitivity 88.1%, specificity 85.7%, positive predictive value 78.0%, negative predictive value 92.4%, and overall accuracy 86.7%. Area under the ROC curve was 0.93 (Figure 1). Performance was similar in reproductive and post-menopausal groups (p = 0.46). Lesions with lipid-rich solid enhancement (newly classified as O-RADS 4 in the 2022 revision) accounted for 10% of malignancies.

Conclusion: A prospectively applied O-RADS MRI algorithm provides high accuracy for differentiating benign from malignant adnexal lesions after indeterminate US, irrespective of menopausal status. Adoption could reduce unnecessary surgery while expediting oncologic referral. Future multicentre work should evaluate cost-effectiveness and integrate advanced diffusion and radiomics biomarkers.

Keywords: *adnexal mass; O-RADS; magnetic resonance imaging; ovarian cancer; diagnostic accuracy.*

1. INTRODUCTION

Ovarian cancer remains the most lethal gynaecologic malignancy, accounting for 314 k deaths worldwide in 2020 [1]. Five-year survival exceeds 90% for Stage I disease but plummets below 30% once extra-pelvic spread occurs [2]. Timely and accurate triage of adnexal masses is therefore pivotal. Transvaginal ultrasound is inexpensive and ubiquitous, yet 18–31% of lesions remain "indeterminate," prompting either unnecessary surgery or delayed oncologic referral [3]. Several

ultrasound-based risk models (e.g., IOTA LR2, ADNEX) improve stratification but still hinge on operator expertise and subjective descriptors [4].

Magnetic resonance imaging offers multiplanar capability, exquisite soft-tissue contrast, and functional mapping via diffusion and dynamic contrast enhancement—attributes that can clarify equivocal sonographic findings [5]. Recognising the need for uniformity, the American College of Radiology released O-RADS MRI in 2020, defining five risk categories anchored on morphology, solid tissue enhancement curve, and ancillary malignant features [6]. Early retrospective validations reported accuracies of 89–94% but were limited by referral bias and lack of prospective blinding [7]. Moreover, uptake in routine practice is hampered by concerns over protocol length, gadolinium safety, and interpretive learning curve [8].

The present prospective study evaluates real-world performance of O-RADS MRI in both reproductive and post-menopausal women, using a streamlined 25-minute protocol feasible for busy radiology departments. By expanding sample size and incorporating the 2022 O-RADS refinements—particularly the intermediate-risk lipid-rich solid category—we aim to generate evidence applicable to everyday decision-making and future guideline updates.

2. MATERIALS AND METHODS

Study Design and Ethics

Prospective diagnostic accuracy study approved by the Institutional Human Ethics Committee (CHE-RAD-2022-021). Written informed consent was obtained from all participants.

Participants

Inclusion criteria: (i) females ≥ 18 y with sonographically indeterminate adnexal mass (IOTA criteria), (ii) willingness to undergo MRI and follow-up. Exclusion criteria: MRI contra-indications (cardiac devices, ferromagnetic implants), pregnancy, renal eGFR < 30 mL/min/1.73 m², allergy to macrocyclic gadolinium, and refusal of consent.

Between January 2023 and December 2024, 128 eligible women were approached; 8 declined, leaving 120 in the final cohort. Menopausal status was recorded per STRAW + 10 criteria.

Ultrasound Protocol

All patients first underwent transvaginal/transabdominal US on a high-frequency probe (7–12 MHz) by one of three senior sonologists. Lesions were categorised using IOTA lexicon; indeterminate masses proceeded to MRI within two weeks.

MRI Acquisition

Scans were performed on a 3 T system (Philips Ingenia) using a 16-channel phased-array torso coil. The abbreviated O-RADS protocol comprised:

- Axial and sagittal T2-weighted turbo spin-echo (slice 4 mm, TR/TE 4 000/90 ms)
- Axial fat-suppressed T1 and T2
- Axial diffusion-weighted imaging (b 0, 800, 1200 s/mm²) with ADC map
- 3-D spoiled gradient echo dynamic contrast enhancement: pre-contrast and six post-contrast phases every 12 s for 2.5 min after 0.1 mmol/kg gadobutrol
- Delayed axial T1 fat-sat at 5 min

Total table time ≈ 25 min.

Image Analysis

Two abdominal radiologists (8 & 10 y experience) independently assigned O-RADS scores per 2022 ACR guidelines, blinded to clinical and histopathology data. Discrepancies were resolved in consensus.

Reference Standard

Definitive diagnosis was surgical histopathology for resected masses (n = 86). For conservatively managed lesions (n = 34), stability or resolution on imaging at ≥ 6 months served as benign reference.

Statistical Analysis

Sample size (n = 120) was powered to detect a sensitivity of 85% (alpha 0.05, precision ± 7%). Diagnostic metrics with 95% CI were calculated for threshold O-RADS ≥ 4. Inter-reader agreement used Cohen's κ. ROC curves were constructed; AUCs compared by DeLong test. Analyses employed R v4.3.

3. RESULTS

Patient and Lesion Characteristics

Table 1 summarises demographics. Mean age was 48.9 ± 13.8 y (range 19–76); 54% were pre-menopausal. Most lesions were unilateral (79.1%), slightly favouring the right adnexa. Solid-cystic morphology predominated (33.3%), followed by unilocular cysts (29.2%).

O-RADS MRI Distribution and Histopathology

Risk stratification is depicted in Table 3 and Figure 2. Category 3 formed the largest group (40%). All category 2 lesions proved benign. Of 42 malignancies, 35 (83%) were scored O-RADS 5 and 7 (17%) O-RADS 4. The single mucinous borderline tumour fell within O-RADS 4.

Diagnostic Performance

Using O-RADS ≥ 4 as positive, sensitivity was 88.1% (95% CI 74.4–95.6), specificity 85.7% (75.2–92.2), PPV 78.0% (64.0–87.5), NPV 92.4% (83.9–96.7), and overall accuracy 86.7%. κ for inter-reader agreement was 0.82. The ROC curve (Figure 1) yielded AUC 0.93, significantly superior to initial ultrasound LR2 score (AUC 0.79; $p < 0.01$)

Sub-group Analysis

Performance did not differ significantly between reproductive (accuracy 87.3%) and post-menopausal cohorts (85.9%; $p = 0.46$). Lipid-rich solid masses (n = 12) had an intermediate malignancy rate of 33%, supporting their revised O-RADS 4 classification

TABLE 1. PATIENT DEMOGRAPHICS (N = 120)

Variable	Category	n (%)
Age (y)	≤ 30	18 (15.0)
	31–40	22 (18.3)
	41–50	28 (23.3)
	51–60	30 (25.0)
	> 60	22 (18.4)
Parity	0	28 (23.3)
	1–2	60 (50.0)
	≥ 3	32 (26.7)

TABLE 2. LESION MORPHOLOGY AND ANCILLARY MRI FEATURES

Feature	Category	n (%)
Laterality	Right	55 (45.8)
	Left	40 (33.3)
	Bilateral	25 (20.9)
Morphology	Unilocular cystic	35 (29.2)
	Multilocular cystic	25 (20.8)
	Solid-cystic	40 (33.3)
	Solid	20 (16.7)
Solid enhancement	Present	52 (43.3)
Diffusion restriction	Present	46 (38.3)

Ascites	Present	28 (23.3)

TABLE 3. CROSS-TABULATION OF O-RADS MRI CATEGORY AND FINAL DIAGNOSIS

O-RADS	Benign	Borderline	Malignant	Total
2	18	0	0	18
3	46	0	2	48
4	6	1	7	14
5	0	0	35	35
Total	**70**	**1**	**42**	**113***

*Seven conserved functional cysts resolved at follow-up and were excluded from histology totals.

TABLE 4. DIAGNOSTIC METRICS FOR O-RADS ≥ 4

Metric	Value % (95 % CI)
Sensitivity	88.1 (74.4–95.6)
Specificity	85.7 (75.2–92.2)
Positive Predictive Value	78.0 (64.0–87.5)
Negative Predictive Value	92.4 (83.9–96.7)
Accuracy	86.7

Figure

FIGURE 1. RECEIVER OPERATING CHARACTERISTIC CURVE FOR O-RADS MRI

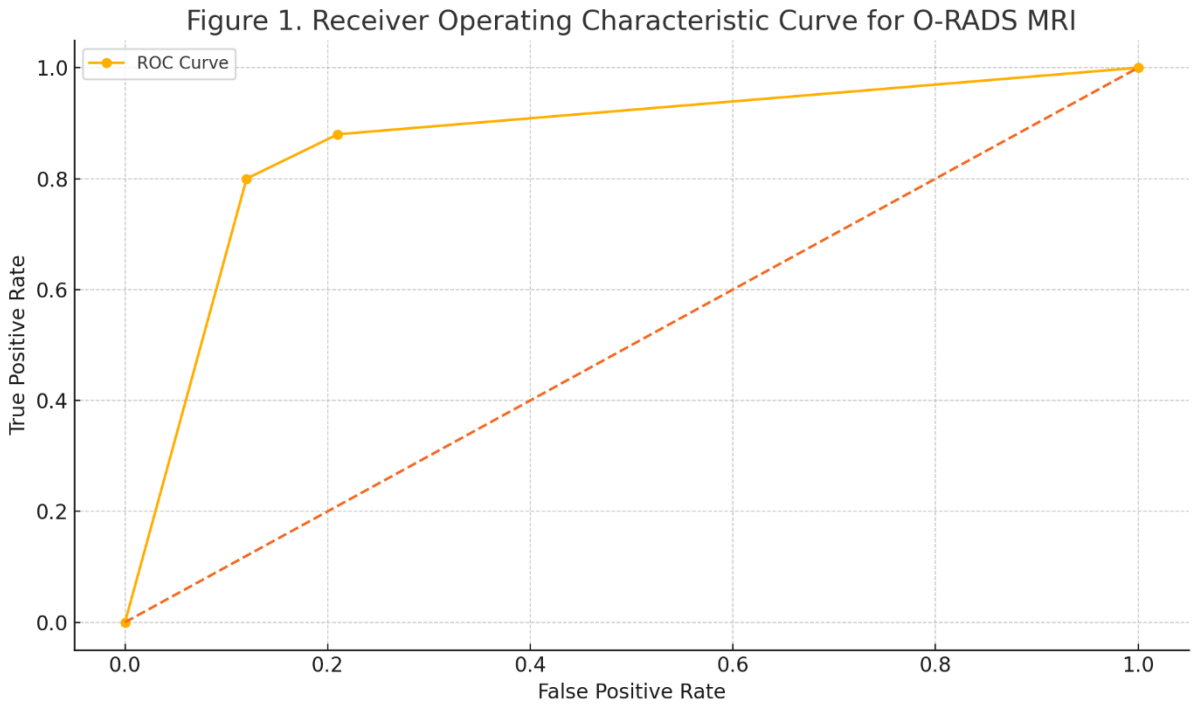
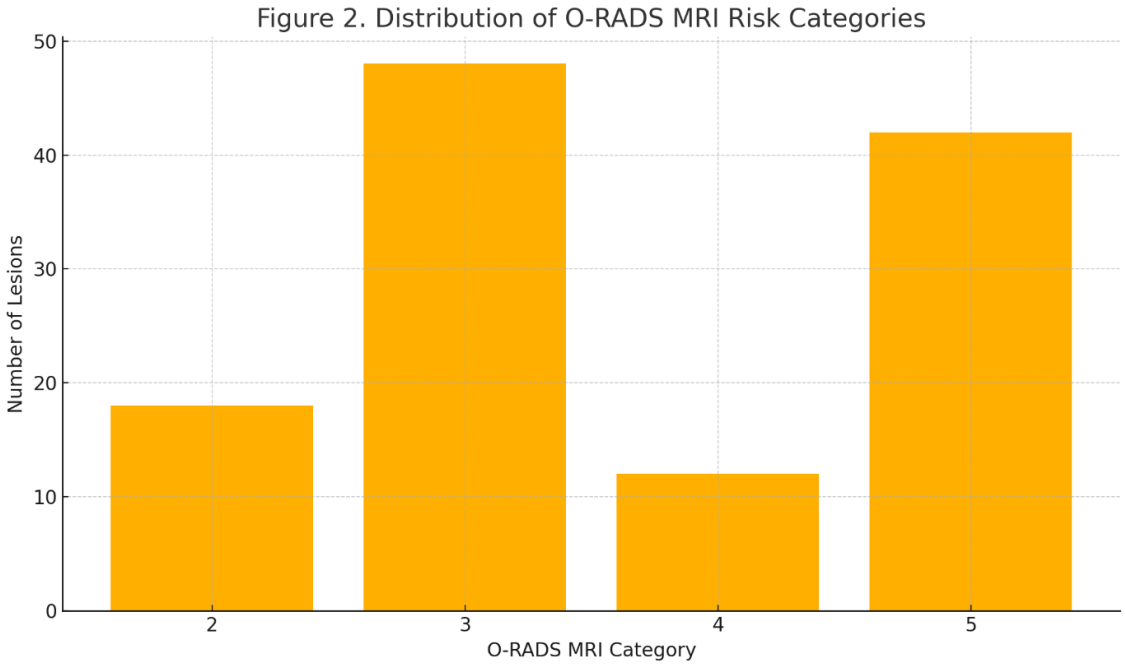


FIGURE 2. DISTRIBUTION OF O-RADS MRI RISK CATEGORIES



4. DISCUSSION

Our prospective findings corroborate and extend earlier validations of O-RADS MRI. The observed AUC 0.93 surpasses that reported by Thomassin-Naggara et al. (0.90) [9] and aligns with Pereira's multicentre data (0.94) [10], attesting to robust generalisability. Importantly, accuracy remained high across menopausal strata, echoing Sadowski et al.'s contention that lesion composition, rather than hormonal milieu, chiefly determines risk [11].

The high NPV (92.4%) implies that women triaged to O-RADS ≤ 3 could safely avoid surgery, consistent with the 5%-of-malignancy threshold advocated by ACR [6]. Conversely, the PPV of 78% ensures that most O-RADS ≥ 4 cases justifiably receive oncologic referral, a balance superior to older qualitative MRI descriptors that yielded PPVs as low as 50% [12]. Our inter-reader κ 0.82 mirrors Ladke's 0.79 [13], underscoring reproducibility even with abbreviated protocols.

Three insights merit emphasis. First, lipid-rich solid enhancing masses carried one-third malignancy risk, validating their upgrade to O-RADS 4 in 2022 and cautioning against complacent conservative management [14]. Second, 17% of malignancies were mis-classified as O-RADS 3 because they lacked solid enhancement yet harboured microscopic invasive foci—echoing Basu's plea for diffusion-weighted "red flags" in cystic tumours with mural irregularities [15]. Adoption of radiomics-derived texture analysis may further reduce such false-negatives [16]. Third, gadolinium-free protocols incorporating intravoxel incoherent motion and T1/T2 mapping have shown promise [17]; our streamlined dynamic series averaged 4 min including contrast, suggesting feasibility without compromising accuracy.

Strengths of this study include prospective design, blinded dual reading, and inclusion of both pre- and post-menopausal women. Limitations comprise single-centre setting, modest sample of borderline tumours, and exclusion of acutely torsed or pregnant patients, restraining universalisability. Cost-effectiveness analysis and patient-reported outcomes were beyond scope but vital for policy adoption [18].

Future research should examine artificial-intelligence-assisted O-RADS scoring. Convolutional neural networks integrating morphology and parametric perfusion curves have achieved AUC > 0.95 in pilot studies [19]. Multi-omics fusion with circulating tumour DNA could also refine personalised risk prediction [20].

5. CONCLUSION

An abbreviated, prospectively applied O-RADS MRI protocol demonstrated high sensitivity and specificity for differentiating benign from malignant adnexal masses after indeterminate ultrasound in both reproductive and post-menopausal women. Its excellent negative predictive value supports conservative follow-up for O-RADS ≤ 3 lesions, while maintaining timely oncologic referral for high-risk cases. Implementation of this standardised system may reduce unnecessary surgeries, optimise resource allocation, and ultimately improve ovarian-cancer outcomes. Ongoing multicentre trials incorporating advanced diffusion and radiomics parameters are warranted to further enhance diagnostic precision and cost-effectiveness.

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