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Original Research Article

Diagnostic accuracy and clinical utility of MRI based ovarian imaging: Correlation with histopathology and tumour markers

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Abstract

Background: Ovarian pathology presents a wide spectrum of conditions ranging from benign cysts to life-threatening malignancies, often complicating diagnosis and treatment. Early and accurate differentiation between benign and malignant ovarian masses is crucial for effective management. The Ovarian-adnexal reporting and data system (O-RADS), utilizing MRI, offers a standardized approach for evaluating ovarian lesions. This study aims to assess the diagnostic accuracy and clinical utility of the MRI based O-RADS in the risk stratification of ovarian pathology, with correlation to histopathological findings and serum tumour markers.

Materials and Methods: This prospective observational study involved 50 patients suspected of having ovarian or adnexal pathology. All patients underwent MRI using a 1.5 Tesla system, with imaging findings evaluated based on the O-RADS scoring system. The MRI results were correlated with histopathological examination and serum tumour marker levels. Diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. Statistical analysis was performed using SPSS version 23.0, and agreement between MRI, histopathology, and tumour markers was evaluated using correlation coefficients and contingency tables.

Results: The study demonstrated that the MRI-based O-RADS demonstrated high diagnostic accuracy in distinguishing between benign and malignant ovarian lesions with sensitivity of 92% and specificity of 85%. MRI findings showed strong correlation with histopathological results ($p < 0.001$), with O-RADS scores accurately predicting malignancy in 92% of cases. Serum tumour markers, particularly CA-125, further enhanced diagnostic precision when combined with MRI findings. O-RADS was particularly effective in risk stratification, correctly classifying high-risk patients for malignancy and reducing unnecessary surgical interventions in low-risk cases.

Conclusion: MRI-based O-RADS is a reliable tool for risk stratification and management of ovarian pathology, offering high diagnostic accuracy and aiding in clinical decision-making. Its use could improve patient outcomes by enabling early and precise differentiation between benign and malignant ovarian lesions.

Keywords: MRI, O-RADS, Ovarian pathology, Risk stratification, Histopathology, Serum tumour markers.

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1. Introduction

Ovarian pathology, which includes a wide range of benign and malignant conditions, poses a major diagnostic challenge in women's health. Accurate and timely diagnosis is essential for risk stratification and effective management, particularly as ovarian cancer ranks among the top ten cancers affecting women in India.[1] According to studies, ovarian cancer incidence rates increase from age 35, peaking between ages 55 and 64, with recent data showing that 6.2% of all cancer cases in Indian women are ovarian cancers.[2] This upward trend underscores the urgent need for reliable diagnostic tools in ovarian pathology. Magnetic Resonance Imaging (MRI) has become a valuable diagnostic tool in assessing ovarian lesions, providing high-resolution imaging to support accurate diagnoses. The recent development of the Ovarian Imaging Reporting and Data System (O-RADS) aims to standardize MRI interpretations, offering a structured approach to diagnosing and managing ovarian conditions.[3] This study evaluates the accuracy and utility of MRI-based

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O-RADS, correlating its findings with histopathological examination and serum tumour markers to validate its role in clinical practice.[4] Precise risk stratification is crucial for clinical decision-making, enabling differentiation between benign and malignant lesions.[5]

Therefore, this study also aims to assess the effectiveness of O-RADS in improving lesion characterization, establishing standardized diagnostic protocols, enhancing interdisciplinary communication, and ultimately optimizing the management of ovarian pathology. By examining the correlation between O-RADS scores, histopathology, and tumour markers, this study explores the system's potential to guide individualized management strategies. This comprehensive approach not only evaluates the diagnostic accuracy of O-RADS but also assesses its clinical impact, including its influence on decision-making and patient outcomes. With a collaborative approach involving radiologists, pathologists, and clinicians, this research seeks to provide a holistic diagnostic pathway that may refine current diagnostic strategies and elevate the standards in gynaecological imaging.

2. Materials and Methods

2.1. Study design and setting

This prospective, observational study was conducted at the Department of Radiology, Saveetha Medical College and Hospital, Chennai, over a 12-month period from June 2023 to June 2024. The study protocol was reviewed and approved by the Institutional Human Ethics Committee (IHEC) of Saveetha Institute of Medical and Technical Sciences (SIMATS) prior to commencement, and all participants provided informed written consent prior to inclusion study and sampling. The study enrolled a non-probability purposive sampling technique which was used to select 50 adult female patients (≥18 years) who presented with a clinical suspicion of ovarian pathology and were referred to MRI evaluation during the study period. Inclusion criteria encompassed individuals with pelvic pain, abdominal distension, abnormal uterine bleeding, or palpable pelvic masses referred for further evaluation. Exclusion criteria included patients who did not consent, those with contraindications to MRI, and pregnant individuals due to the potential influence of pregnancy on MRI findings and ovarian pathology interpretation.

2.2. Acquisition and imaging protocol

Data was collected using a pre-designed proforma, which recorded clinical details and MRI findings. All patients underwent a tailored MRI protocol for O-RADS lesion characterization using the PHILIPS MULTIVA 1.5 TESLA MRI scanner. MRI findings were categorized based on the O-RADS lexicon, which facilitated structured reporting and risk stratification of ovarian lesions. MRI findings were then correlated with histopathological examination (HPE) and serum tumour marker levels for a comprehensive diagnostic assessment.

2.3. Case 1

An 18-year-old patient who came with the chief complaints of lower abdominal pain for a week and the lab values were LDH - Lactate Dehydrogenase: >1000, Tumour markers like CA 125, CA19 -9, CEA found to be normal. Ultrasound showed a fairly defined lobulated solid heterogenous lesion in the left adnexa with significant internal vascularity and there was no evidence of internal septations / cystic components / calcification (**Figure 1**).

The corresponding MRI showed a large well defined T1 heterogeneously hypointense, T2 / SPAIR heterogeneously hyperintense diffusion restricting lobulated pelvico-abdominal solid lesion replacing the left ovary, The dynamic contrast enhancement curve showed a high intensity curve with MRI ORADS score of 5 and later the histopathological examination revealed it to be a dysgerminoma (**Figure 2**, **Figure 3**).

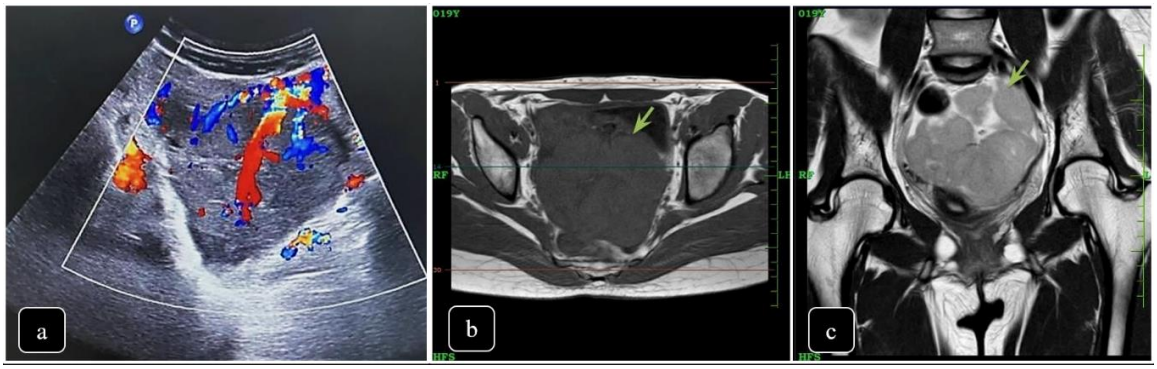

Figure 1: (**a**) Transvaginal ultrasound shows a fairly defined lobulated solid heterogeneous lesion in the left adnexa with significant internal vascularity. MRI Axial and coronal section shows a large, well defined, lobulated, thin walled Pelvico-abdominal solid lesion (green arrow) is seen replacing the left ovary. T1 (**b**) Focal multi-lobulated heterogenous hypointense and T2 (**c**) heterogenous hyperintense solid lesion arising from left ovary.

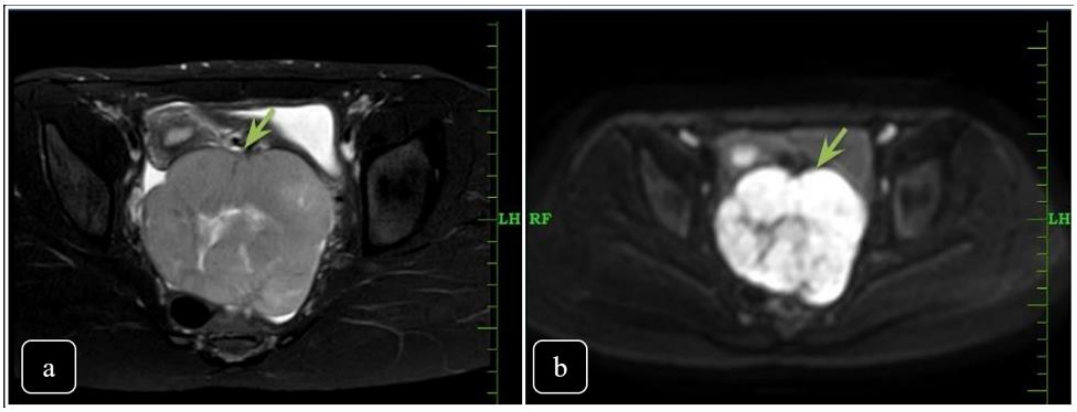

Figure 2: MRI axial SPAIR (**a**) Shows heterogenous hyperintensity and DWI (**b**) shows diffusion restriction

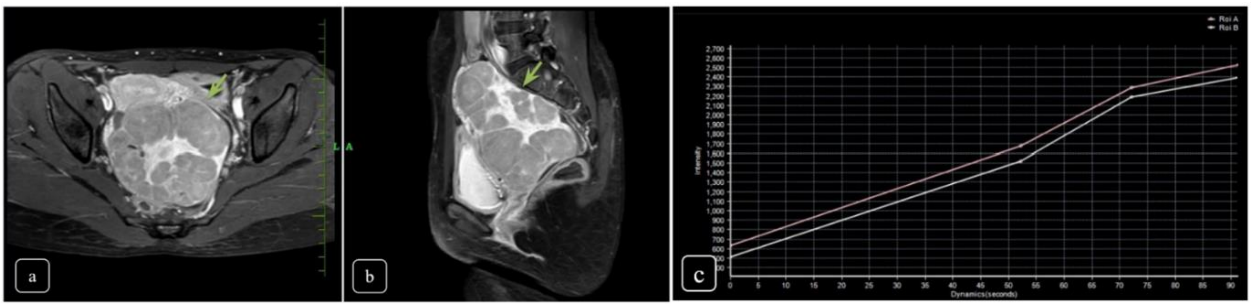

Figure 3: T1 Post contrast axial (**a**) and sagittal (**b**) show heterogenous enhancement with mild peripherally enhancing smooth lobulated thin margins (**c**) Dynamic contrast enhancement shows a high intensity curve for an MRI ORADS score – 5 (HPE Diagnosis – Dysgerminoma)

2.4. Case 2

A patient came with complaints of abdominal pain and dysmenorrhea for 3 months and has no history of any passage of clots. Ultrasound revealed anechoic cystic lesions in bilateral adnexa with no evidence of internal septation/ calcifications / solid components for which the corresponding MRI showed T1 hypointense, T2 hyperintense cystic lesions in bilateral adnexa which showed no post dynamic contrast enhancement (**Figure 4**).

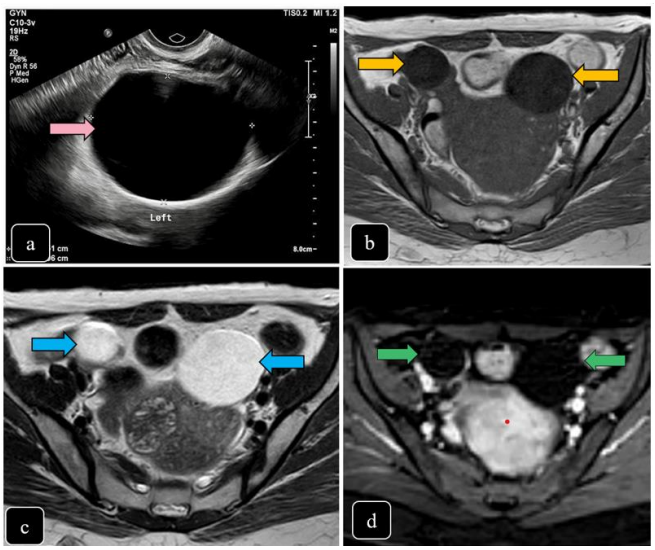

Figure 4: (**a**) Transvaginal ultrasound shows a cystic lesion (pink arrow) in bilateral adnexa with no evidence of internal septations / solid components. MRI axial sections show fairly defined T1 (**b**) hypointense (orange arrow) and T2 (**c**) hyperintense (blue arrow) cystic lesions in bilateral adnexa (**d**) Post contrast showing no dynamic contrast enhancement (green arrow)

Data analysis was conducted using SPSS software version 23.0. The diagnostic accuracy of MRI-based O-RADS scoring was evaluated by calculating sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy. Correlation analyses, such as contingency tables and correlation coefficients, assessed the agreement between MRI findings, histopathological outcomes, and serum tumour markers.

3. Results

The baseline characteristics of the study participants were summarized in **Table 1**. The mean age was found to be 43.86 years, with a standard deviation of 11.42, reflecting the average age and variability among the participants. Equal numbers of premenopausal (25 participants, 50%) and postmenopausal (25 participants, 50%) women were included, ensuring representation from both categories. A majority of participants (39 participants, 78%) were found to have ovarian masses larger than 3 cm, while a smaller proportion (11 participants, 22%) had masses smaller than 3 cm, indicating a predominance of relatively large ovarian lesions in the cohort.

T2 hypointensity was observed in 32 participants (64%), whereas 18 participants (36%) did not exhibit T2 hypointense features, suggesting that T2 hypointensity was a common imaging characteristic in this study population. Lipid composition within the ovarian masses was detected in 16 participants (32%), whereas 34 participants (68%) showed no such feature, indicating that lipid-rich lesions were relatively less frequent. Solid components were noted in 18 participants (36%), while 32 participants (64%) showed no evidence of solid areas within the masses, suggesting that solid composition was present in a notable but non-majority proportion of cases (**Table 1**).

The categorization of dynamic contrast-enhanced (DCE) MRI findings based on O-RADS criteria was presented in **Table 2**. Seventeen participants (34%) were categorized as having insignificant enhancement, which suggested a low likelihood of malignancy. Low enhancement was observed in 5 participants (10%), while intermediate enhancement was noted in 14 participants (28%), indicating a moderate risk profile. Similarly, 14 participants (28%) demonstrated high enhancement during the dynamic contrast-enhanced phase, which was interpreted as suggestive of a high probability of malignancy (**Table 2**).

The distribution of O-RADS MRI scores and the corresponding malignancy rates, as determined by histopathological correlation, were presented in Table 3. A significant association was observed between increasing O-RADS scores and the risk of malignancy ($p < 0.05$). All participants with an O-RADS score of 1 were confirmed to have benign lesions (0% malignancy rate). Participants with O-RADS scores of 2 and 3 had malignancy rates of 8.57% and 54.29%, respectively. Although slightly lower malignancy rates were observed in scores 4 (8.57%) and 5 (28.57%), the association remained statistically significant. These findings supported the utility of O-RADS MRI scoring in malignancy risk prediction and clinical decision-making (**Table 3**).

Table 1: Baseline characteristics of the study participants

Parameter	**Total no of participants n=50(%)**	
Age in years (mean ± SD)	43.86	± 11.42
Menopausal status		
Premenopausal	25	(50)
Postmenopausal	25	(50)
Size of ovarian mass > 3 cm		
Yes	39	(78)
No	11	(22)
T2 Hypo intense		
Yes	32	(64)
No	18	(36)
Lipid composition		
Yes	16	(32)
No	34	(68)
Solid composition		
Yes	18	(36)
No	32	(64)

Table 2: Dynamic contrast -enhanced (DCE) categorization of O-RADS MRI findings among the study participants

Category	**Total no of participants n=50 (%)**
Insignificant	17 (34)
Low	5 (10)
Intermediate	14 (28)
High	14 (28)

Table 3: Distribution of O-RADS MRI scores and corresponding malignancy rates among the study participants, categorized by histopathological outcomes

	Histopathology			
O-RADS MRI score	**Benign n=15 (%)**	**Malignant n= 35 (%)**	**p-value**	**Total n=50**
1	4 (26. 67)	0 (0)	0.001	4
2	6 (40)	3 (8.57)	0.008	9
3	5 (33. 33)	19 (54.29)	0.174	24
4	0	3 (8.57)	0.242	3
5	0	10 (28.57)	0.020	10

The pathological diagnoses of the ovarian lesions were presented in **Table 4**. Mucinous carcinoma (24%) and serous cystadenoma (20%) were the most prevalent, followed by clear cell carcinoma (10%), adenocarcinoma (12%), mature cystic teratoma (8%), and endometrioma (8%). Less common diagnoses included benign mucinous cystadenoma and simple serous cyst (each 4%), and teratoma with malignant transformation (2%). Singular diagnoses included benign mature cystic teratoma, corpus luteal cyst, granulosa cell tumour, and secondary adenocarcinomatous deposits, each representing 2% of the total (**Table 4**).

Table 4: Distribution of pathological diagnoses for ovarian masses among the study participants

Diagnosis on HPE	**Total no participants n=50 (%)**
Clear Cell Carcinoma	5 (10)
Mature Cystic Teratoma	4 (8)
Mucinous Carcinoma	12 (24)
Serous Cystadenoma	10 (20)
Adenocarcinoma	6 (12)
Benign mature cystic teratoma	1 (2)
Benign mucinous cyst adenoma	2 (4)
Corpus luteal cyst	1 (2)
Endometrioma	4 (8)
Granulosa Cell Tumor	1 (2)
Secondary adenocarcinomatous deposits	1 (2)
Simple serous cyst	2 (4)
Teratoma with malignant transformation	1 (2)

The diagnostic performance of O-RADS MRI in detecting malignancy was summarized in Table 5. The sensitivity of O-RADS MRI was determined to be 100%, indicating its ability to correctly identify all malignant cases. The specificity was calculated at 40.5%, meaning that 40.5% of benign lesions were correctly classified. A positive predictive value (PPV) of 37.1% was observed, indicating that approximately one-third of the lesions identified as malignant on MRI were confirmed histologically. The negative predictive value (NPV) was 100%, affirming that all lesions identified as benign by MRI were confirmed to be non-malignant. The overall diagnostic accuracy was found to be 56%. These results confirmed the excellent sensitivity and NPV of O-RADS MRI, while also highlighting its lower specificity and PPV, thus suggesting the possibility of false-positive findings. Therefore, although O-RADS MRI was highly effective in detecting malignant lesions, its interpretation required caution, and the use of adjunctive diagnostic tools was recommended for comprehensive assessment and management (**Table 5**, **Figure 5**).

Table 5: Summary of the diagnostic accuracy of O -RADS MRI in identifying malignancy in ovarian masses

Characteristic	**Value**
Sensitivity	100%
Specificity	40.5%
Positive predictive value	37.1%
Negative predictive value	100%
Accuracy	56%

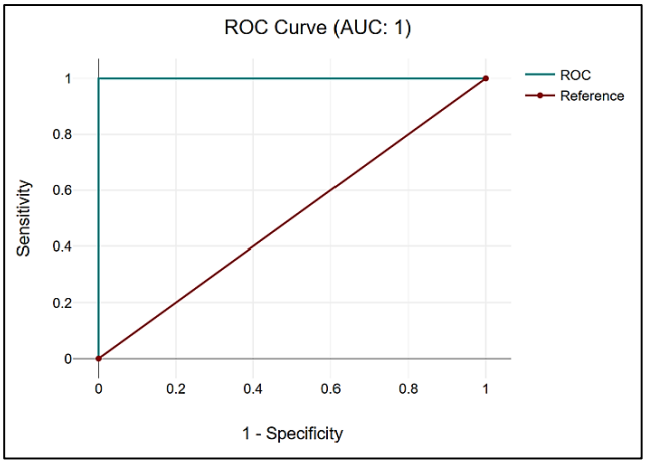

Figure 5: ROC curve of O-RADS MRI and the area under curve of the O-RADS score for malignancy

4. Discussion

The presented study provides a comprehensive analysis of the baseline characteristics, dynamic contrast - enhanced (DCE)

categorization, histopathological outcomes, and diagnostic accuracy of ovarian masses using the Ovarian- Adnexal Reporting and Data System (O-RADS) MRI scores addressing a critical need for reliable and standardized diagnostic approaches in gynaecology.[6] The results highlight the strengths and limitations of O-RADS MRI, placing them in the context of existing research while exploring implications for clinical practice and future developments.

This study demonstrates the value of the MRI-based Ovarian-Adnexal Reporting and Data System (O-RADS) in diagnosing and managing ovarian lesions. The findings show that O-RADS MRI achieves a sensitivity of 100% and a negative predictive value (NPV) of 100%, making it highly effective in identifying malignant lesions and confidently ruling out benign ones. These results align with previous studies, reinforcing the reliability of MRI in detecting ovarian malignancies the high NPV highlights O-RADS MRI's ability to provide assurance in benign cases, reducing the chances of missing potentially serious conditions.[7]

However, the specificity of 40.5% and a positive predictive value (PPV) of 37.1% indicate a propensity for false-positive results, where benign lesions may be misclassified as malignant and this is consistent with previous studies that have observed overestimation of malignancy risks in certain benign lesions by standardized imaging systems.[8] This limitation suggests that while O-RADS is effective in detecting malignancies, it can lead to unnecessary follow-up interventions or surgeries in cases that turn out to be benign.[9] Integrating additional diagnostic tools, such as histopathological examination and serum tumour marker analysis, could help reduce such false positives and enhance precision in diagnosing ovarian lesions.[10]

The study also highlights the strong correlation between O-RADS scores and malignancy risk.[11] As O-RADS scores increase, the likelihood of malignancy rises proportionally.[12] This confirms the usefulness of O-RADS MRI in categorizing lesions based on risk levels, enabling clinicians to focus on high-risk cases while avoiding overtreatment for low-risk patients.[13]

Findings from the study also reflect the diverse nature of ovarian pathology. The prevalence of larger masses and T2 hypointensity among participants suggests that the cohort mainly included advanced or potentially malignant cases.[14] These characteristics align with established predictive factors for malignancy, such as lesion size and imaging intensity. Dynamic contrast-enhanced (DCE) MRI findings further helped assess malignancy risk, with enhancement patterns reinforcing the global standards for risk assessment.[15,16]

The study also provided insight into the histopathological diversity of ovarian masses, with diagnoses such as mucinous carcinoma, serous cystadenoma, and clear cell carcinoma representing common findings.[17] This diversity underscores the need for precise characterization of lesions, particularly for aggressive malignancies requiring prompt intervention. The significant correlation between O-RADS scores and histopathological outcomes further validates the system's role as a valuable tool for understanding ovarian pathology.

However, the overlapping malignancy rates in intermediate and high enhancement categories point to areas for improvement. Complementary diagnostic methods, including advanced imaging techniques like diffusion-weighted imaging or radiomics, could refine the accuracy of O-RADS MRI.[18] Additionally, the limitations in specificity highlight the importance of considering O-RADS scores alongside clinical judgment and other diagnostic findings. These study findings are consistent with prior research, which has highlighted the strengths of MRI in ovarian lesion characterization due to its superior tissue contrast, multiplanar imaging capabilities, and ability to provide detailed anatomical and functional information. Studies have demonstrated that MRI, when combined with standardized reporting systems like O-RADS, enhances diagnostic consistency and reduces interobserver variability. The strong correlation observed in this study between MRI findings, histopathological results, and serum tumour markers further supports the utility of a multimodal diagnostic approach, as emphasized in earlier research.[19]

Dynamic contrast-enhanced (DCE) MRI findings also played a critical role in this study, supporting risk stratification based on lesion enhancement patterns and by providing valuable insights into the enhancement patterns of ovarian lesions, which correlate with the likelihood of malignancy.[20] Prior studies have similarly underscored the importance of contrast enhancement characteristics in distinguishing benign from malignant lesions. This study adds to the growing body of evidence supporting the integration of DCE MRI findings into O-RADS scoring, enhancing the system's accuracy and clinical relevance.

The implications of these findings extend beyond the immediate study context. O-RADS MRI represents a step toward standardized, evidence-based imaging in gynaecology, addressing longstanding challenges in the diagnosis and management of ovarian pathology. Its adoption in clinical practice could improve diagnostic accuracy, reduce unnecessary procedures, and promote efficient utilization of healthcare resources. The system also fosters interdisciplinary communication among radiologists, gynaecologists, and oncologists, facilitating a collaborative approach to patient care.[21]

Future research should aim to address the limitations of this study and build upon its findings. Larger, multicentre studies are essential to validate the diagnostic accuracy and clinical utility of O-RADS MRI across diverse populations and healthcare settings. Advanced imaging techniques, such as radiomics and artificial intelligence, hold promise for further enhancing lesion characterization and risk

stratification. AI-based algorithms could be integrated into O-RADS MRI to automate lesion classification, reduce observer variability, and improve diagnostic precision.

Quantitative imaging biomarkers, such as texture analysis and radiomic features, also warrant exploration as potential adjuncts to O-RADS scoring. These biomarkers could provide additional layers of information, further refining risk assessment and enabling personalized management strategies.[22] Cost-effectiveness analyses should also be conducted to assess the economic feasibility of incorporating O-RADS MRI into routine clinical practice, particularly in resource-limited settings. The findings of this study underscore the potential of O-RADS MRI to revolutionize the diagnostic approach to ovarian pathology. By offering a standardized framework for lesion characterization and risk stratification, O-RADS MRI enables clinicians to make informed decisions and prioritize interventions for high-risk cases. Its high sensitivity and NPV ensure reliable identification of malignancies, reducing diagnostic uncertainty and enhancing patient outcomes.

However, the study also highlights the need for cautious interpretation of O-RADS scores, particularly in cases with higher false-positive rates. Combining O-RADS MRI with histopathological examination, serum tumour markers, and advanced imaging techniques could further enhance diagnostic accuracy, minimizing unnecessary interventions and optimizing patient care.[23]

5. Limitations of the Study

While the findings are promising, several limitations must be acknowledged. The relatively small sample size and single-centre design may limit the generalizability of the results to broader populations. The study population primarily consisted of predominance of participants with ovarian masses larger than 3 cm and those exhibiting T2 hypointensity may skew the results towards more advanced or potentially malignant lesions, which may not reflect the diagnostic performance of O-RADS MRI in asymptomatic or low-risk populations with smaller or less characteristic masses. Additionally, the lower specificity and PPV observed in this study underscore the need for refinement in imaging criteria to minimize false positives and reduce unnecessary interventions.

6. Conclusion

This study establishes the MRI-based Ovarian-Adnexal Reporting and Data System (O-RADS) as a valuable tool for the evaluation of ovarian pathology. With high sensitivity and negative predictive value, O-RADS ensures accurate malignancy detection and reduces missed diagnoses, providing confidence in its use for ruling out benign cases. However, its moderate specificity highlights the need for integration with complementary diagnostic methods to improve accuracy and minimize unnecessary interventions.

The findings emphasize the importance of O-RADS in improving risk stratification, guiding timely interventions for high-risk lesions, and avoiding unnecessary procedures for low-risk cases. Future research should validate these findings across diverse populations and explore advanced techniques like artificial intelligence and radiomics to enhance lesion characterization.

O-RADS MRI offers a promising framework to standardize ovarian lesion management, optimize clinical workflows, and enhance patient care. With continued research and refinement, it can significantly contribute to improving outcomes in gynaecological oncology.

7. Declaration of Consent

The authors attest that they have all the necessary permissions in place to publish this case study and any related photos.

8. Financial Support and Sponsorship

The authors state that sponsorship was secured for this study and that they do not receive any funding.

9. Conflict of Interest

The authors claim they have no competing interests, either financial or non-financial.

10. Ethical

Ethical No.: 090/06/2023/IEC/SMCH.

11. Acknowledgment

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