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A Cross-sectional study Comparing Performance of IOTA Simple Rules, Simple Rules Risk Assessment and O-RADS in differentiating between Benign and Malignant Adnexal Lesions in a Tertiary Care Centre, Chengalpattu District

Dr. Arun S.V [1], Dr. Harshavardhan. B[2], Dr. Jenikar Paul Raj[3], Dr. Remya.R[4*]

[1]Post Graduate, Department of Radio Diagnosis, Shri Sathya Sai medical college and Research SBV Chennai campus, Shri Sathya Sai nagar, Ammapettai, thirupporur, Chengalpattu dt-603108.

Email ID : arun.v546@gmail.com

[2]Assistant Professor, Department of Radio Diagnosis, Shri Sathya Sai medical college and Research SBV Chennai campus, Shri Sathya Sai nagar, Ammapettai, thirupporur, Chengalpattu dt-603108.

Email ID : harshavardhanb@sssmcri.ac.in

[3]Professor, Department of Radio Diagnosis, Shri Sathya Sai medical college and Research SBV Chennai campus, Shri Sathya Sai nagar, Ammapettai, thirupporur, Chengalpattu dt-603108.

Email ID : drjenikar@gmail.com

[4]Assistant professor, Department of Radio Diagnosis, Shri Sathya Sai medical college and Research SBV Chennai campus, Shri Sathya Sai nagar, Ammapettai, thirupporur, Chengalpattu dt-603108.

Email ID : drremya1986@gmail.com

[*]**Corresponding author:**

Dr. Remya. R

Email ID : drremya1986@gmail.com

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ABSTRACT

Background: Grading systems like IOTA Simple Rules and O-RADS are commonly used to assess ovarian lesions, but their comparative effectiveness in clinical practice remains underexplored.

Objective: To evaluate and compare the performance of IOTA simple rules, simple rules risk assessment and O-RADS in differentiating between benign and malignant adnexal lesions.

Methods: This was a single center, hospital based cross-sectional study conducted in the Department of Radiodiagnosis, Shri Sathya Sai Medical College and Research Institute, Kancheepuram, Tamil Nadu between July 2023 and December 2024.

Results: The study included 128 participants, of whom 96 (75%) had benign adnexal masses and 32 (25%) had malignant lesions. The mean age of participants was 48.6 years, with no significant age difference between benign and malignant groups ($p = 0.920$). The majority of participants were under 50 years of age. In terms of lesion size, the mean maximum dimension was significantly larger for malignant lesions (100.5 mm) compared to benign lesions (83.0 mm, $p < 0.001$). Solid tissue was more common in malignant lesions (87.5%) compared to benign lesions (34.4%, $p < 0.001$). When using the IOTA Simple Rules, 74.2% of lesions were classified as benign, 16.4% as malignant, and 9.4% as inconclusive. The IOTA Simple Rules Risk Assessment categorized 45.3% of lesions with a malignancy risk of less than 1%, while 21.1% were classified with a risk of 50% or higher. The O-RADS classification showed that 68.0% of lesions were O-RADS 2 (benign), and 16.4% were O-RADS 5 (high risk). The IOTA Simple Rules Risk Assessment demonstrated an AUC of 0.922 (sensitivity: 81.3%, specificity: 82.7%), while the O-RADS system showed an AUC of 0.854 (sensitivity: 90.6%, specificity: 83.7%). Both systems were statistically significant ($p < 0.001$) in predicting malignant adnexal masses.

Conclusion: Both the IOTA Simple Rules and O-RADS systems are effective in differentiating benign and malignant adnexal masses, with high diagnostic accuracy. The findings support their utility in improving clinical decision-making and patient outcomes

Keywords: *IOTA Simple Rules, Simple Rules Risk Assessment, O-RADS, Benign, Malignant, Adnexal Lesions, Risk prediction.*

1. INTRODUCTION

Ovarian and adnexal masses are common findings in clinical practice, presenting a significant diagnostic challenge. Differentiating between benign and malignant lesions is critical, as accurate diagnosis guides clinical management and treatment strategies. Ovarian cancer is the most lethal gynecological malignancy, with early detection playing a pivotal role in improving survival rates.(1) On the other hand, benign ovarian tumors, which are more common, often do not require aggressive intervention, making accurate differentiation essential for minimizing unnecessary surgeries.(2, 3) Various imaging modalities, including ultrasound, magnetic resonance imaging (MRI), and computed tomography (CT), have been employed to assess adnexal lesions. Among these, ultrasound is the most commonly used due to its accessibility, non-invasiveness, and cost-effectiveness.(4) However, the challenge lies in distinguishing malignant from benign lesions, especially in cases where the imaging findings are inconclusive.(5)

To address these challenges, several risk stratification models have been developed. The International Ovarian Tumor Analysis (IOTA) group has proposed the use of Simple Rules (SR) and the Simple Rules Risk Assessment (SRRA) model,(6, 7) which have demonstrated high diagnostic accuracy in differentiating benign from malignant ovarian tumors.(8) The IOTA SR model is a set of rules that incorporates several key ultrasound features, such as tumor size, multilocular structure, and blood flow, to predict malignancy. The SRRA model extends this approach by providing a numerical risk score based on the IOTA SR, offering further refinement in clinical decision-making.(9, 10) Another widely used system for evaluating adnexal masses is the Ovarian-Adnexal Reporting and Data System (O-RADS), developed by the American College of Radiology.(11) O-RADS classifies adnexal masses based on their sonographic and MRI features into different risk categories, which correspond to varying probabilities of malignancy.(12) O-RADS has been shown to have high sensitivity, particularly when using MRI, and may help avoid unnecessary interventions.(13) However, concerns have been raised regarding its specificity, particularly in distinguishing benign lesions from low-risk malignant ones.(14)

Given the increasing reliance on imaging systems to aid in the diagnosis of adnexal masses, it is crucial to evaluate and compare the effectiveness of different grading and risk assessment models in clinical practice. Against this background, the objective of the present study was to compare the diagnostic performance of IOTA SR, SRRA, and O-RADS in differentiating benign from malignant ovarian lesions, focusing on achieving faster and more accurate results.

2. MATERIALS AND METHODS

This was a single center, hospital based cross-sectional study conducted in the Department of Radiodiagnosis, Shri Sathya Sai Medical College and Research Institute, Kancheepuram, Tamil Nadu over a period of 18 months between July 2023 and December 2024. The study was approved by the Institutional Human Ethics Committee (IHEC) with reference number 2023/864 dated 27/07/2023. The participants were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. Patients referred to the Department of Radiodiagnosis by the Department of Obstetrics and Gynecology with symptoms/clinical features suggestive of adnexal mass were included. However, patients with pregnancy and prior history of pelvic surgery were excluded.

The sample size was calculated using the formula $n=(4\times P\times Q)/L^2$, where the prevalence (P) was 75.5%, Q was 24.5%, and the margin of error (L) was 8%. After adjusting for a 10% non-response rate, the final sample size was rounded to 128 participants. We used nonprobability sampling technique – purposive sampling/complete enumeration to enroll patients. All participants underwent abdominal ultrasound examinations using the MINDRAY DC-80 ultrasound system. A standardized imaging protocol was followed, which included grayscale imaging for the evaluation of adnexal masses and Doppler imaging for vascularity assessment. Detailed lesion characteristics such as size, shape, internal composition (solid, cystic, or mixed), wall thickness, septations, and the presence of papillary projections were documented. Doppler flow patterns and vascularity were also assessed. Each adnexal lesion was evaluated using IOTA Simple Rules, Simple Rules Risk Assessment, and O-RADS criteria to classify the lesions. Clinical data, including patient age, symptoms, and relevant medical history, were recorded.

Statistical analysis: Statistical analysis was conducted to evaluate the diagnostic performance of the grading systems, including sensitivity, specificity, positive predictive value, and negative predictive value. Receiver Operating Characteristic (ROC) curves were used to compare the effectiveness of IOTA Simple Rules, Simple Rules Risk Assessment, and O-RADS. Results were reported as mean ± standard deviation for continuous variables and as frequencies or percentages for categorical variables.

3. RESULTS

Among the 128 patients, 96 (75%) had benign and 32 (25%) had malignant adnexal masses. The mean age was similar across groups (48.6 ± 4.1 vs. 48.6 ± 3.3 years; p = 0.920), with no significant differences in age distribution (<50 years: 62.5% vs. 65.6%; p = 0.751) or menopausal status (premenopausal: 51.0% vs. 50.0%; p = 0.919). Malignant lesions, however, were significantly larger in size (100.5 ± 5.7 mm vs. 83.0 ± 5.2 mm; p < 0.001) and more frequently contained solid tissue (87.5% vs. 34.4%; p < 0.001). The maximum dimension of solid components was also markedly greater in malignant masses (61.1 ± 4.1 mm vs. 35.2 ± 3.3 mm; p < 0.001).

Among the 128 adnexal masses assessed using IOTA Simple Rules, benign features predominated, with unilocular cysts (B1) and acoustic shadows (B3) being the most frequent, observed in 53.1% and 53.9% of cases, respectively. Solid components smaller than 7 mm (B2) were noted in 25.8%, while smooth multilocular tumors (B4) and absent Doppler blood flow (B5) were relatively uncommon, present in 7.0% and 3.9% of cases, respectively. Malignant characteristics included irregular solid tumors (M1) in 23.4%, at least four papillary projections (M3) in 14.1%, ascites (M2) in 9.4%, irregular multilocular-solid tumors ≥10 cm (M4) in 7.8%, and very strong Doppler vascularity (M5) in 4.7% of patients.

IOTA Simple Rules classified 74.2% as benign, 16.4% as malignant, and 9.4% as inconclusive, with 95.8% of benign lesions correctly identified as benign and 65.6% of malignant lesions classified as malignant. Using IOTA Simple Rules Risk Assessment, 45.3% of lesions had a malignancy risk of <1%, while 21.1% were categorized as having ≥50% risk, the majority (84.4%) of which were malignant. O-RADS categorization showed that most benign lesions (90.6%) were placed in category 2, while malignant lesions were predominantly classified into category 5 (65.6%), with smaller proportions in categories 3 (9.4%) and 4 (25.0%).

The IOTA Simple Rules Risk Assessment demonstrated an AUC of 0.922 (95% CI: 0.877 to 0.968) with a cutoff of >2.5, achieving a sensitivity of 81.3% and specificity of 82.7%, with a statistically significant P value of <0.001. The O-RADS system, on the other hand, had an AUC of 0.854 (95% CI: 0.757 to 0.951) with a cutoff of >31.5, showing a higher sensitivity of 90.6% and specificity of 83.7%, also with a statistically significant P value of <0.001. Both systems were found to be statistically significant at P<0.05 in predicting malignant adnexal mass.

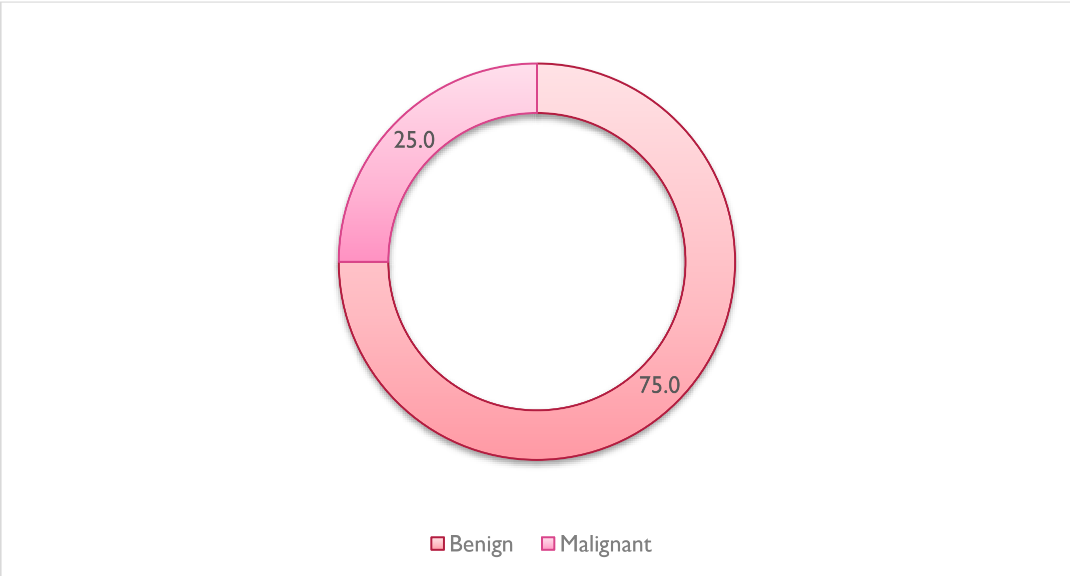

Figure 1: Distribution of patients, by type of adnexal mass

Table 1: Baseline Demographic and Lesion Characteristics of Patients with Benign and Malignant Adnexal Masses

		Benign N = 96	Malignant N = 32	Total N = 128	P value
		n (%)	n (%)	n (%)	
Age (in years), Mean (SD)		48.6 (4.1)	48.6 (3.3)	48.6 (3.9)	0.920
Age (in years)	≤50	60 (62.5)	21 (65.6)	81 (63.3)	0.751

	>50	36 (37.5)	11 (34.4)	47 (36.7)	
Menopausal status	Premenopausal	49 (51.0)	16 (50.0)	65 (50.8)	0.919
	Postmenopausal	47 (49.0)	16 (50.0)	63 (49.2)	
Maximum dimension of lesion (in mm), Mean (SD)		83.0 (5.2)	100.5 (5.7)	87.4 (9.2)	<0.001*
Solid tissue in lesion	Present	33 (34.4)	28 (87.5)	61 (47.7)	<0.001*
	Absent	63 (65.6)	4 (12.5)	67 (52.3)	
Maximum dimension of solid tissue (in mm), Mean (SD)		35.2 (3.3)	61.1 (4.1)	47.1 (13.5)	<0.001*
*Statistically significant at p<0.05 SD, Standard deviation					

Table 2: Distribution of Benign and Malignant Features Based on IOTA Simple Rules

		Number (N = 128) (n)	**Percentage (%)**
Benign	B1: Unilocular cyst (a single, simple cyst with no internal septations or solid areas)	68	53.1
	B2: Presence of solid components where the largest solid component is less than 7 mm	33	25.8
	B3: Acoustic shadows (areas of reduced sound transmission behind the mass).	69	53.9
	B4: Smooth multilocular tumor (a cyst with multiple compartments but smooth walls)	9	7.0
	B5: No blood flow on Doppler ultrasound	5	3.9
Malignant	M1: Irregular solid tumor (solid mass with uneven or irregular contours)	30	23.4
	M2: Presence of ascites (fluid in the abdomen not confined to the pelvis)	12	9.4
	M3: At least four papillary projections (solid, finger-like projections on the inner cyst wall)	18	14.1
	M4: Irregular multilocular-solid tumor with a largest diameter ≥10 cm	10	7.8
	M5: Very strong blood flow on Doppler ultrasound (indicative of vascularization)	6	4.7

Table 3: Comparison of Lesion Classification by IOTA Simple Rules, SR Risk Assessment, and O-RADS

	Benign N = 96	**Malignant N = 32**	**Total N = 128**

		n (%)	n (%)	n (%)
IOTA Simple Rules	Benign	92 (95.8)	3 (9.4)	95 (74.2)
	Malignant	0 (0.0)	21 (65.6)	21 (16.4)
	Inconclusive	4 (4.2)	8 (25.0)	12 (9.4)
IOTA Simple Rules Risk Assessment	Less than 1%	58 (60.4)	0 (0.0)	58 (45.3)
	1% to less than 10%	38 (39.6)	1 (3.1)	39 (30.5)
	10% to less than 50%	0 (0.0)	4 (12.5)	4 (3.1)
	50% and above	0 (0.0)	27 (84.4)	27 (21.1)
O-RADS	2	87 (90.6)	0 (0.0)	87 (68.0)
	3	9 (9.4)	3 (9.4)	12 (9.4)
	4	0 (0.0)	8 (25.0)	8 (6.2)
	5	0 (0.0)	21 (65.6)	21 (16.4)
IOTA, International Ovarian Tumor Analysis				

Table 4: Receiver operating characteristics (ROC) analysis showing AUC of IOTA Simple Rules Risk Assessment and O-RADS in predicting malignant adnexal mass

	AUC (95% CI)	Cut off	Sensitivity (%)	Specificity (%)	P value
IOTA Simple Rules Risk Assessment	0.922 (0.877 to 0.968)	>2.5	81.3	82.7	<0.001*
O-RADS	0.854 (0.757 to 0.951)	≥31.5	90.6	83.7	<0.001*
*Statistically significant at p<0.05 O-RADS, Ovarian-Adnexal Reporting and Data System; IOTA, International Ovarian Tumor Analysis; AUC, Area under the curve; CI, Confidence interval					

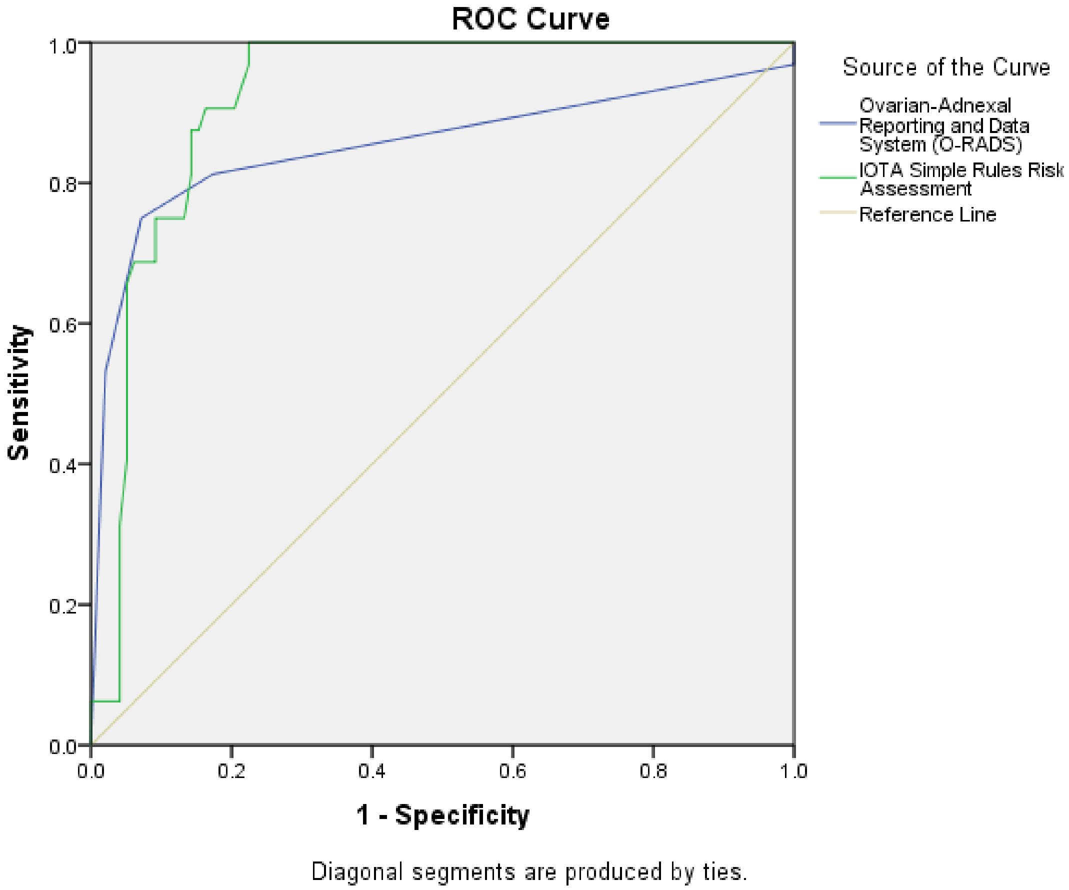

Figure 2: Receiver operating characteristics (ROC) analysis showing AUC of IOTA Simple Rules Risk Assessment and O-RADS in predicting malignant adnexal mass

4. DISCUSSION

This study aimed to evaluate and compare the performance of IOTA Simple Rules, Simple Rules Risk Assessment, and O-RADS in differentiating between benign and malignant adnexal lesions. The study found that 75.0% of the participants had benign adnexal masses, while 25.0% had malignant lesions. This distribution is consistent with previous studies in similar populations, which typically report a higher prevalence of benign lesions in women presenting with adnexal masses.(15, 16) No significant differences were observed between the benign and malignant groups with regard to age or menopausal status. The mean age of participants in both groups was 48.6 years, and the age distribution was similar across both groups. This finding is in line with earlier studies showing that adnexal masses are common in both premenopausal and postmenopausal women,(17) although certain types of lesions, such as ovarian cancer, tend to occur more frequently in postmenopausal women.(18)

A significant finding in this study was the difference in lesion size between benign and malignant masses. Malignant lesions had a mean maximum dimension of 100.5 mm, significantly larger than the benign lesions, which had a mean of 83.0 mm. This is consistent with the literature, which generally reports that malignant ovarian masses tend to be larger than benign ones, especially in cases of epithelial ovarian cancer.(19) Additionally, the presence of solid tissue was significantly more common in malignant lesions (87.5%) than in benign ones (34.4%). Solid tissue is often associated with malignancy, as it may indicate the presence of tumor tissue rather than simple fluid-filled cysts.(20, 21) The mean maximum dimension of solid tissue in the lesions was also significantly larger in malignant masses (61.1 mm) compared to benign masses (35.2 mm), further highlighting the importance of solid components in malignancy detection.

Unilocular cysts, commonly observed in benign masses, were found in 53.1% of cases, while solid components with the largest measuring less than 7 mm were present in 25.8% of cases. These findings align with those of Modesitt et al. (2003),(22) who reported that unilocular cysts and small solid components (less than 7 mm) are typically associated with benign lesions. On the other hand, malignant lesions more frequently exhibited irregular solid tumors (23.4%) and other high-risk features such as ascites (9.4%) and papillary projections (14.1%). These characteristics are consistent with those of malignant ovarian tumors, which often exhibit more complex morphology and vascularization compared to benign lesions.(23) The Doppler ultrasound findings also supported these observations, with 4.7% of malignant lesions showing very strong blood flow, indicative of vascularization, which is a known feature of malignant tumors.(24) The presence of ascites, papillary projections, and irregular tumor contours is consistent with findings from other studies, which suggest that these features increase the likelihood of malignancy in adnexal masses.(25)

The diagnostic performance of the IOTA Simple Rules was assessed by classifying lesions as benign, malignant, or inconclusive. Among the benign cases, 95.8% were accurately identified as benign, while none were misclassified as malignant. This is a notable strength of the IOTA Simple Rules, as it demonstrates high specificity for benign lesions. However, a portion of malignant lesions (25.0%) were misclassified as benign, and 4.2% of benign lesions were incorrectly labeled as inconclusive. The accuracy of IOTA Simple Rules in identifying malignant lesions was lower, with only 65.6% of malignant masses being correctly classified as malignant. This is a limitation of the IOTA Simple Rules, which, although highly effective in distinguishing benign from malignant masses in certain settings, may still result in misclassification in some cases. These findings are consistent with previous studies that have reported the IOTA Simple Rules to be highly accurate in classifying benign lesions but less reliable for identifying all types of malignant lesions.(26-28)

The IOTA Simple Rules Risk Assessment provides a stratified approach to classifying the risk of malignancy in adnexal masses. The results of this study demonstrate that the majority of benign lesions (60.4%) were classified as having a malignancy risk of less than 1%, which aligns with previous reports indicating that benign masses typically present with very low malignancy risk.(29) Additionally, none of the malignant lesions were assigned to this low-risk category, which underscores the specificity of the system for benign lesions. The risk stratification for malignant lesions demonstrated a clear pattern. A substantial proportion of malignant masses (84.4%) were classified with a malignancy risk of 50% or higher, a finding consistent with the typical clinical behavior of malignant adnexal lesions, which tend to have more aggressive features and higher malignancy risks. The specificity and sensitivity of the IOTA Simple Rules Risk Assessment in this study were 82.7% and 81.3%, respectively, with an AUC of 0.922, indicating a high level of diagnostic accuracy. These findings are consistent with previous studies that have demonstrated that IOTA Simple Rules Risk Assessment offers strong predictive value, particularly when used in conjunction with other diagnostic modalities.(30-32) While the IOTA Simple Rules Risk Assessment was effective in identifying both benign and malignant lesions, it did misclassify a small portion of malignant lesions (12.5%) in the 10% to 50% risk range, which is a limitation of the system. These misclassifications may be due to the complexity of certain malignant lesions that do not follow typical patterns seen in more advanced stages of malignancy.(33)

The O-RADS system, which uses a numerical score to categorize adnexal masses according to their likelihood of malignancy, was also evaluated in this study. A significant proportion of the lesions (68.0%) were classified as O-RADS 2, suggesting a benign nature. This classification is consistent with the majority of adnexal masses, which are benign and can be reliably classified using simple imaging techniques. Furthermore, no malignant lesions were classified as O-RADS 2, supporting the system's specificity for benign lesions. While O-RADS 3 (low risk) and O-RADS 4 (moderate risk) categories accounted for smaller proportions of the lesions, the system was effective at classifying high-risk lesions as O-RADS 5. Among malignant lesions, 65.6% were classified as O-RADS 5, which strongly correlates with the high-risk nature of these tumors. This feature is a key strength of the O-RADS system, as it helps to identify high-risk lesions that may require urgent intervention or further diagnostic evaluation. These findings support the clinical utility of O-RADS, particularly in stratifying high-risk lesions.(12) In terms of diagnostic performance, the O-RADS system demonstrated an AUC of 0.854, with a sensitivity of 90.6% and a specificity of 83.7%. While the sensitivity of O-RADS was slightly higher than that of the IOTA Simple Rules Risk Assessment (90.6% vs. 81.3%), the specificity was marginally lower (83.7% vs. 82.7%). Both systems achieved statistically significant results with a p-value < 0.001, indicating that both methods were reliable in predicting malignancy. The higher sensitivity of O-RADS suggests that it may be particularly useful in settings where a higher detection rate of malignant lesions is critical, such as in cancer screening programs or initial diagnostic workups.

The direct comparison of the IOTA Simple Rules Risk Assessment and O-RADS classification in this study highlights the strengths and limitations of each system. The IOTA Simple Rules Risk Assessment is more specific, with fewer benign lesions misclassified as malignant. However, it has a slightly lower sensitivity compared to O-RADS. The O-RADS system, on the other hand, exhibits a higher sensitivity and may be more useful in clinical scenarios where the goal is to detect as many malignant lesions as possible, even at the cost of slightly lower specificity.

One limitation of this study is its single-centre, hospital-based design, which may limit the generalizability of the results to broader populations or different healthcare settings. The reliance on ultrasound-based grading systems, such as the IOTA Simple Rules and O-RADS, may also introduce observer bias, as different clinicians could interpret ultrasound images with varying degrees of accuracy. Furthermore, the study did not include an assessment of the potential role of other diagnostic tools, such as MRI or biomarkers, in conjunction with ultrasound-based systems, which could provide a more comprehensive diagnostic approach.

5. CONCLUSION

In conclusion, the present study demonstrates that the IOTA Simple Rules, Simple Rules Risk Assessment, and O-RADS systems are effective tools for differentiating benign and malignant adnexal masses, with each system showing statistically significant performance. The IOTA Simple Rules and O-RADS systems both exhibit high sensitivity and specificity, making them valuable for clinical use in evaluating adnexal masses. While both systems showed promising results, the IOTA Simple Rules Risk Assessment had a slightly higher AUC, suggesting a marginally better ability to predict malignancy. The findings highlight the potential of these grading systems to aid in the accurate and timely identification of malignant adnexal masses, ultimately contributing to better clinical decision-making and patient management

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