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Role of Ovarian Adnexal Reporting Data System (O-Rads) – Magnetic Resonance Imaging (Mri) in Assessment of Ovarian Lesions with Histopathological Correlation

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ABSTRACT:

INTRODUCTION **-** The Ovarian-Adnexal Reporting and Data System (O-RADS) - MRI scoring system estimates the likelihood of malignancy by evaluating the MRI characteristics of an adnexal lesion. This scoring system includes five categories indicating malignancy based on MRI characteristics of the lesions that effectively distinguish between benign and malignant masses [6]. This study aims to evaluate the performance of the five-point Ovarian Adnexal Reporting Data System (O-RADS) MRI score in patients with adnexal lesions using histopathological findings as a reference standard.

MATERIALS AND METHODS : All female patients fulfilling the inclusion criteria referred to the department of Radio-diagnosis were included in this study for evaluation of sonographically indeterminate adnexal lesions using Magnetic Resonance Imaging (MRI) (1.5 Tesla whole body MR systems) followed by categorization of the lesions using ORADS-MRI risk stratification system and later findings were correlated with post-surgical histopathology reports.

RESULTS : In our study ORADS-MRI risk stratification system in comparison with histopathological reports showed a sensitivity of 90.32 %, specificity of 100%, positive predictive value of 100%, negative predictive value of 90.62%. The area under the ROC curve was 0.965 (95% C.I) with a statistically significant p value ($p < 0.001$). ROC curve analysis of ORADS MRI scoring system showed cut off threshold ORADS MRI score as 3, above which ovarian lesions were classified as malignant lesions.

CONCLUSION : This study validated the effectiveness of a 5-point ORADS-MRI risk stratification scoring system and provides robust supporting evidences, leading to the introduction of this score in clinical practice could enable a personalized approach for managing sonographically indeterminate masses, helping to avoid unnecessary surgeries, minimize the extent of surgeries, or preserve fertility when suitable, while also ensuring the preoperative identification of lesions with a high risk of malignancy

***KEYWORDS*:** Ovarian-Adnexal Reporting and Data System **(ORADS), Magnetic resonance imaging (MRI), Adnexal / ovarian lesions.**

INTRODUCTION

Due to the intricate nature of their embryological and histological development, the ovaries are the origin of a diverse array of lesions [1]. Ovarian cysts are a frequent gynecological issue arising from both physiological and pathological processes [2]. Proper imaging characterization of ovarian cysts is crucial for planning appropriate therapeutic interventions and significantly impacts patient management [3].

Most of the masses remain indeterminate on trans-vaginal ultrasonography (TVUS), particularly regarding their benign or malignant status [4]. Contrast enhanced Magnetic resonance imaging (MRI) provides precise details about the characteristics and local invasion of a pelvic mass [5].

The Ovarian Adnexal Reporting and Data System (O-RADS) MRI risk stratification system created by American College of Radiology for assessing the probability of malignancy based on the MRI features of adnexal lesions, facilitating optimal patient management. The widespread implementation of this standardized reporting system aims to improve consistency in interpretation and enhances communication between radiologists and referring physicians [6].

An O-RADS MRI score was previously evaluated in a retrospective single-center study. This score categorizes malignancy risk into five levels by utilizing MRI characteristics with high positive and negative predictive values to distinguish between benign and malignant masses that are unclear on ultrasonography [6,7].

With the background knowledge of ORADS-MRI scoring system, this study mainly aims to validate the risk stratification score for women referred for MRI due to adnexal lesions that are indeterminate on sonography.

MATERIALS AND METHOD

This study was a hospital based Cross sectional study carried out in the Department of Radiodiagnosis at Sri Manakula Vinayagar Medical College and Hospital (SMVMCH), Kalitheerthalkuppam, Puducherry, India, which is located in a village 25 km west of Puducherry on National Highway (NH-45 A), from September 2022 to February 2024

All patients referred to the Radiology department with sonographically indeterminate adnexal lesion for Magnetic Resonance Imaging (MRI) for characterization of ovarian lesion and who fulfilled the inclusion criteria were selected for the study using simple random sampling method. Considering the average number of cases with ovarian lesion in the Radio-diagnosis department and based on the 95.6% prevalence of adnexal lesions in study conducted by Thomassin-Naggara et al [6] and 5% absolute precision, the sample size was calculated using the formula:

Sample size: $Z^2 \times P \times Q / d^2 = \sim 60$

Inclusion criteria :

All patients in whom ovarian lesion is clinically suspected and found to have in ultrasonography and for preoperative assessment of ovarian lesions, referred to Radio diagnosis department for Magnetic Resonance Imaging

Exclusion Criteria :

Patients who were previously operated / treated for ovarian lesions, patients with post-operative metallic implants or implanted cardiac pacemaker, claustrophobia or anxiety disorder, Magnetic Resonance (MR) – incompatible prosthetic heart valves

Brief procedure :

Patients meeting the inclusion criteria were considered for the study. After obtaining history and informed consent in the patient's native language, any questions from the patient were addressed, and information was collected through questionnaires.
The patient was subjected to Magnetic Resonance Imaging followed which findings were categorized using ORADS-MRI risk stratification system (Supplementary 1) and correlated with histopathological reports.
A magnetic resonance imaging study was performed on 1.5 Tesla whole body MR systems using standard imaging body coil. The procedure was carried out with the help of an MRI technician. Initially, imaging was done to characterize the ovarian lesions and then the image is obtained using standard MRI protocol

MRI Technique :

Patient were explained the process of MRI – T1, T1 Fat set(SPIR), T1 SPIR - post contrast, T2, T2 STIR, T2 FLAIR, DWI sequence scan.

The images were acquired in the above said sequences of MRI using 1.5 Tesla whole body MR systems using standard imaging body coil. TSE sequences were used to obtain T1WI (3500/80 [TR msec / TE msec]; axial, coronal, sagittal), T2 WI / T2 FLAIR (3500/80 [TR msec / TE msec]; axial, coronal, sagittal), STIR (1500/60/230 [TR msec/TE msec/TI msec]; axial, sagittal), DWI (3500/80 [TR msec / TE msec]; axial). All sequences involved had

matrix – 480,average slice thickness 4mm, section spacing 0.5mm, FOV 240*240, voxel size 1*1.125 and recon voxel size 0.8mm with fold over suppression.

Contrast was needed for few cases depending upon the type of lesion, in which renal function test reports were taken into consideration. In case of any renal derangements, the patient was excluded from giving contrast. **(Acquired MRI sample cases – Supplement images – 7 to 11)**

STATISTICAL ANALYSIS :

The collected data was entered into Epi Info software version 7.2.1.0 and analyzed using SPSS software version 24.0. Continuous variables such as age are reported as mean and standard deviation, while categorical variables such as gender, symptoms, and other history are expressed as percentages. Magnetic Resonance Imaging findings were also summarized in percentages. The positive predictive value (PPV) and negative predictive value (NPV) of MRI findings were calculated against cytology findings. The receiver operating characteristic (ROC) curve for the O-RADS score by MRI was plotted to determine the optimal cut-off value for malignancy. The association between study variables was assessed using the chi-square test, with a p-value of less than 0.05 considered statistically significant.

Ethical consideration :

Institutional ethics committee approval was obtained **(IEC no. EC/70/2022)** and the study was conducted fulfilling the STARD checklist. Informed consent was obtained from study participants in their native language.

RESULTS

In our study, most of the ovarian lesions were presented in the age group of 51-60 years with a mean age of 30.50 ± 14.46 years, among the study participants

Among the ovarian lesions of study participants, 90% of the lesions were cystic and only 10% of them were solid. Out of the cystic lesions, majority of them were multiloculated comprising 85.2% of cystic lesions, whereas remaining 2% were uniloculated lesions and 24.1% were non septated lesions. With respect to contents of the cystic lesion, 57.4% of them had proteinaceous contents and 28% of them had serous content.

Considering wall and septal enhancement, 25 lesions had irregular/nodular wall enhancement out of which 96% were given ORADS score of 4 or 5 and remaining 4% were given ORADS score of <3. Thus denoting significant association of irregular wall enhancement with malignancy ($p < 0.01$)

Presence of solid components with enhancement greater than that of myometrium showed strong association with malignancy, which was proved statistically significant by the chi square test, whereas presence of ascites and omental / peritoneal deposits was associated with greater risk of malignancy with metastasis and showed maximum ORADS score of 5.

Out of 60 study participants, 13.3% (n=8) were given an ORADS score of 2, 40% (n=24) were given a score of 3, 30% (n=18) were given a score of 4 and 16.7% (n=10) were given a score of 5. Most of the patients showed ORADS-MRI score of 3 among the study participants (40%). **(Supplement images – 2 to 6)**

Most of the patients included in the study underwent surgery, which aided in accurate correlation of radiological findings with that of histopathological findings.

Characteristics of the ovarian lesion as described by ACR's ORADS-MRI scoring system have been summarized in the Table 1.

Table 1 : Characteristics of ovarian lesion

CHARACTERISTICS		**PERCENTAGE (N = 60)**	**ASSOCIATION BETWEEN VARIABLE AND ORADS MRI SCORE**	
			CHI SQUARE VALUE	**p VALUE**
Type of lesion	Cystic	Multilocular – 76.7% (N=46)	19.22	0.004*

		Unilocular – 1.7 % (N=1)		
		Non septated – 12.1 % (N=7)		
		Total - 90% (N = 54)	3.28	0.35
	Solid	10% (N= 6)		
Contents of cyst	Proteinaceous	51.7 % (N=31)	15.32	0.01*
	Serous	25 %(N=15)		
	Non cystic	23.3 %(N=14)		
Wall / Septal enhancement	Smooth regular enhancement	35 % (N = 22)	51.14	0.001*
	Irregular / Nodular enhancement	41.6% (N=25)		
	No septal / wall enhancement	21.7% (N=13)		
Solid components	Present	16.7% (N=10)	20.69	0.001*
	Absent	83.3% (N=50)		
Fat contents	Present	11.7% (N=7)	9.46	0.02*
	Absent	88.3 % (N=53)		
Solid components with restriction on DWI sequences	Bright	6.7 % (N=4)	15.25	0.01*
	Dark	3.3 % (N=2)		
Solid component enhancement compared with myometrium	Heterogenous enhancement	6.7 % (N=4)	36.22	0.01*
	More than myometrium	15 % (N=9)		
	Less than myometrium	5 % (N=3)		
	No enhancement	11.7 % (N=7)		
	No solid components	61.7 % (N=37)		
Associated ascites	Present	6.7 % (N=4)	21.42	0.001*
	Absent	93.3 % (N=56)		
Peritoneal / omental deposits	Present	6.7 % (N=4)	21.42	0.001*
	Absent	93.3 % (N=56)		
ORADS MRI SCORE		**PERCENTAGE (N = 60)**		
2		13.3 % (N=8)		
3		40.0 % (N=24)		
4		30.0 % (N=18)		
5		16.7 % (N=10)		

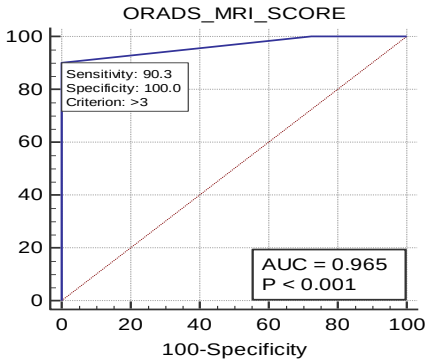
*- statistically significant by Chi square test

On correlation with the histopathological findings, lesions which were given an ORADS-MRI score of 2, 100% of them turned out to be benign. Lesions with a score of 3, 87.5% of them turned out to be benign and remaining 12.5 % came out to be malignant; whereas lesions with score of either 4 or 5, 100% of them turned out to be malignant. The association between the ORADS-MRI score and histopathological findings were found to be **statistically significant by Chi square test with p value 0.001* (Histopathological images – Supplement – 7 to 11)**

Condition		**HPE diagnosis (In %)**	**ORADS – MRI score**					**Association between ORADS MRI and histopathological diagnosis**	
			2	**3**	**4**	**5**	**Total**	**Chi Square test**	**P value**
Benign	Mucinous Cystadenoma	21.7 % (N=13)	27.6% (N=8)	72.4% (N=2)	0	0	100% (N=29)	49.49	**0.001***
	Serous Cystadenoma	8.4 % (N=5)							
	Dermoid Cyst	11.7 % (N=7)							
	Ovarian Fibroma	3.3 % (N=2)							
	Others	3.3% (N=2)							
Malignant	Mucinous Cystadeno -carcinoma	26.7 % (N=16)	0	9.7% (N=3)	58.1% (N=18)	32.3% (N=10)	100% (N=31)		
	Serous Cystadeno -carcinoma	18.3 % (N=11)							
	Others	6.8 % (N=4)							

*- statistically significant by Chi square test

Chart 1. ROC for ORADS MRI score among the study participants



The Receiver Operating Characteristic (ROC) curve analysis of ORADS MRI score showed cut-off threshold value as 3, with a sensitivity of 90.3%, and a specificity of 100%. The area under the curve (AUC) was 0.965 (95% C.I = 0.882-0.995) with a statistically significant p value ($p < 0.001$).

ROC for ORADS MRI score among the study participants

ORADS MRI score	Area under the curve (AUC)	Younden index	Sensitivity	Specificity	Positive LR	Negative LR
> 3	0.965 (95% CI - 0.882 to 0.995)	0.903	90.32% (74.2 to 98%)	100% (88.1 to 100%)	1.38	0.09

ORADS MRI score had a Sensitivity of 90.3%, Specificity of 100%, Positive Predictive Value (PPV) of 100% and Negative Predictive Value (NPV) of 90.62%.

DISCUSSION :

The American College of Radiology (ACR) ORADS-MRI risk stratification system standardizes terms and definitions for the assessment and reporting of adnexal lesions, whereas on the other hand its risk stratification model estimates a calculated probability of malignancy in an empirical manner [6,8].

Our study demonstrated that the O-RADS MRI risk stratification score has high sensitivity (90.32%) and specificity (100%), with a positive likelihood ratio of 1.38 and a negative likelihood ratio of 0.09, indicating strong potential for detecting ovarian malignancies while avoiding unnecessary interventions in benign cases. These results are comparable to those from studies by Isabelle Thomassin-Naggara et al., which reported a sensitivity of 93% and specificity of 91% [6] , and Serdar Aslan et al., with a sensitivity of 96.3% and specificity of 95.2% [9] for the O-RADS MRI scoring system.

The study found that the ORADS-MRI risk stratification system has high diagnostic accuracy, with 90.32% sensitivity and 100% specificity for detecting ovarian malignancies, making it valuable in clinical settings. It accurately identifies benign lesions, reducing unnecessary surgeries and preserving fertility in younger women. The system also improves communication between radiologists and clinicians and also aligns with previous studies, thus boosting confidence in its clinical use. However, the study's specific patient population limits generalizability, and the absence of Dynamic Contrast Enhanced (DCE-MRI) analysis and documented Negative Predictive Value (NPV) for screening are notable limitations.

Due to paucity of data and research, there is no properly defined Positive Predictive Value (PPV) for non-DCE MRI in evaluation of ovarian lesions, future researches should be focused on providing accurate data such as sensitivity, specificity and positive predictive value for non-DCE MRI in evaluation of ovarian lesion, which in turn aids in accurate diagnosis of ovarian lesion using ORADS-MRI scoring system and its further validation.

CONCLUSION

Ovarian malignancies remain a leading cause of death in gynecological cancers despite advancements in chemotherapy regimens and improved surgical techniques. Inadequate pre-operative radiological assessment has led to unnecessary surgeries for benign lesions, highlighting the need for an accurate risk stratification system, which ensures proper treatment plan. The O-RADS MRI risk score provides a standardized algorithmic approach to assess malignancy in adnexal lesions, offering codified global uniformity in reporting ovarian lesions, high specificity that enables accurate diagnosis, early recognition of malignancies, and the prevention of unnecessary interventions for benign cases

ABBREVIATIONS AND ACRONYMS

ACR	**American College of Radiology**
CE-T1WI	**Contrast-enhanced T1 Weighted Imaging**
DCE	**Dynamic contrast enhanced imaging**
DWI	**Diffusion weighted imaging**
FLAIR	**Fluid Attenuated Inversion Recovery**
FS	**Fat Saturated**
MRI	**Magnetic Resonance Imaging**

NPV	**Negative predictive Value**
ORADS	**Ovarian Adnexal Reporting and Data System**
PPV	**Positive predictive Value**
ROC	**Receiver Operating Characteristics**
SPAIR	**Spectral Adiabatic Inversion Recovery**
STIR	**Short Time Inversion Recovery**
T1WI	**T1 Weighted Imaging**
T2WI	**T2 Weighted Imaging**
TIC	**Time Intensity Curve**
TVUS	**Transvaginal Ultrasonography**

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