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" Validity of the MRI O-RADS Scoring system in improving diagnostic confidence for adnexal pathologies"

Authors

Khaled Abd El-Baky Ahmed [1] Carmen Ali Zarad [1], Asmaa M Yussif [2] , Mohamed Elrakhawy [3], Waleed S Abo Shanab [1]

[1] Diagnostic and interventional radiology department, faculty of medicine, Port Said University

[2] Department of radiology Sinbellawin general hospital, Ministry of health, Egypt.

[3] Diagnostic and interventional radiology department, Faculty of medicine Mansoura University

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https://muj.journals.ekb.egdean@med.psu.edu.eg

vice_dean_postgraduate@med.psu.edu.eg

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ABSTRACT:

Background: Ovarian masses represent the most frequent variety of adnexal masses. Characterization of different lesion types is crucial for better management.

Aim of study: This study aims to value the diagnostic reliability of the magnetic resonance imaging (MRI)-based ovarian adnexal reporting and data system (O-RADS) scoring in the description and risk stratification of adnexal masses, with the objective of determining its accuracy in differentiating benign from malignant lesions.

Patients and methods: This study included adnexal masses which show indeterminate criteria by ultra-sound (US) at different age group. We excluded patients who had contraindications for MRI. Conventional MRI, diffusion, apparent diffusion coefficient (ADC) value and dynamic contrast study were done for all patients.

Results: Regarding ORADS categorization of our studied population, 23.9 % were ORADS 2 indicating that they were almost benign, 53.4 % were ORADS 3 indicating low risk malignancy, 13.6% were ORADS 4 indicating intermediate risk malignancy, 9.1 % were ORADS 5 suggesting elevated risk of malignancy.

The sensitivity of O-RADS MRI score system for detection of malignancy was 90%, 85 % specificity, 91.2 % positive predictive value, 85 % negative predictive value and accuracy 86.4.

Conclusion:

Our findings showed that the MRI based ORADS score is a useful tool that differentiates between ambigous benign and malignant adnexal masses. It can be used clinically in cases of sonographic indeterminate ovarian masses to reduce invasive surgeries and preserve fertility.

Keywords:

Adnexal masses, ORADS, Diffusion, time intensity curve.

Introduction:

Adnexal masses are lesions that arise from the ovaries, fallopian tubes, and nearby structures, affecting women with different ages. The adnexal mass can arise from functional or physiological alterations, inflammatory conditions, endometriosis, as well as benign and malignant tumors **(1).**

Ovarian masses are the most prevalent form of adnexal mass, seen in roughly 8 to 35% of women in premenopausal stage and 3 to 17% of women in postmenopausal stage **(2).**

US couldn't not adequately describe ovarian masses in about 20% of cases. So; MRI is the preferred imaging method for further characterization because of its superior contrast resolution, which facilitates the identification of various lesion types **(3).**

The O-RADS MRI score is a global classification system that assists in categorizing adnexal masses according to an alternative evaluation of the key features most indicative of malignancy. O-RADS MRI distinguishes five risk levels, demonstrating a reported sensitivity and specificity greater than 90% in identifying malignancies **(4).**

O-RADS MRI risk classification system provide the advantage of better connection between the radiologists and the referring clinicians, aiming to decrease the instances of non indicated extensive surgeries on females diagnosed with either benign masses or borderline masses, while directing suspected females with malignancy for surgical evaluation **(5).**

This study aims to value the diagnostic reliability of the MRI-based O-RADS scoring system in the description and risk stratification of adnexal masses, with the objective of determining its accuracy in differentiating benign from malignant lesions.

Patients and methods :

Our study was a cross sectional prospective study that was conducted in the period from January 2023 to December 2024 and was approved by ethical committee (ERN: MED,

4/12/2022s.no (76) RAD922_004) of our institute. The study was in accordance with the Declaration of Helsinki.

Inclusion Criteria

This study included indeterminate adnexal masses diagnosed by US at any age group.

Exclusion Criteria

- General contraindications for MRI scan like cardiac pacemaker, metallic foreign body in the eye, or bed general condition.

Written informed consents were obtained from all participants.

The subsequent measures were fulfilled for all patients:

  - Full history including name, age, history of previous operations, hormonal intake, diabetic or hypertensive, duration of symptoms, is there menstrual irregularities, history of previous pregnancy & delivery and is there a similar condition in the family.

- **Clinical examination**
  - Females were assessed clinically as detection of pelvic masses.
  - Laboratory tests including estimation of serum levels of cancer antigen (CA)-125.
  - Pelvic ultrasound examinations were conducted utilizing transducers with different frequencies between 2.5 and 8 MHz (us done via trans abdominal method when the bladder is full, or via trans vaginal method following bladder emptying).

MR imaging

MR imaging was performed on a 1.5-Tesla system (Philips ingenia Medical Systems, Philips Electronics MRI machines United States of America).

Patient preparation.

Patient are prepared by fasting for about 4-6 hours before the MRI examination, using of an anti-peristaltic agent to decrease intestinal motility and informing the patient to void within 30 minutes prior to the examination.

All patients are requested to remove any metallic objects from their bodies and are questioned about any conditions that might interfere with an MRI like cardiac pacemaker, metallic foreign body in the eye, artificial heart valve and metallic stents.

All patients underwent imaging while in the supine position with a pelvic phased-array torso coil.

MRI imaging protocol

- Pictures in different planes including axial, coronal, and sagittal.
- We performed fast spin echo (FSE) T1-weighted echo with a field of view (FOV) of 240 mm, an interslice gap of 1–2 mm, slice thicknesses of 3 to 4 mm and a flip angle of 90 Time to repeat (TR) 500 ms, time to echo (TE) 10 ms, matrix 320 512).
- Axial and sagittal FSE T2-weighted images, TE 100 ms, TR 3000 ms, field of view (FOV) 240 mm, flip angle 90, slice thickness: 3–4 mm with an interslice gap of 1–2 mm and matrix 256 × 512,)
- Fat saturated sequence either T1-weighted or T2-weighted images is done in order for detection of fat within the lesion.

Diffusion Weighted Imaging (DWI)

-DWI was done in axial sequence, multi-section, multi-shot echo-planar imaging.

-Each patient underwent diffusion-sensitizing gradients with a b factor between 0 and 500 s/mm and a b factor from 0 to 1000 s/mm2.

- 128 x 128 acquisition matrix; thickness of 5 mm; interslice gap of 1 mm; FOV of 25 cm; high TR of 2635 ms; short TE of 75 ms. About 1 minute and 45 seconds was the acquisition time.

-ADC maps were reconstructed mechanically and utilized in the calculating ADC value. Measurement of ADC values was done manually by placing the region of interest (ROI) on

the solid components of the masses. Placing ROI at bright signal intensity areas which appear on DWIs.

- The mean ADC value was determined automatically by the system's software when ROIs were determined.

- ADC value was determined using b values of 500 and 1000 s/mm^2. Square millimeters per second (mm^2/s) is used to express the ADC values.

Dynamic contrast-enhanced MRI:

- We use gadolinium chelate (dimeglumine gadopentetate) as contrast agent and it's dose is 0.2 ml per kilogram of body weight injected by a power injector with at an average of 2 ml/s, after that flush the tubing by normal saline by about 20 ml.
- After contrast administration we obtain images in two planes axial oblique and sagittal T1 images with fat suppression: Dynamic contrast-enhanced images including axial oblique T1WI fat-suppressed that are usually obtained at 30, 60, and 120 seconds post-contrast and after 3-4 minutes delayed images are taken along the uterine axis. Dynamic contrast series must be obtained in a plane that includes both the suspicious enhanced solid tissue present in the ovarian lesion and the uterine enhanced myometrium.
- The dynamic curve of malignant tissue, in contrast to normal myometrial tissue, shows a sudden and intense increase followed by a fairly rapid decline.
- From perfusion series we creates time intensity curves for the lesion and the myometrium.

Statistical analysis:

Data analysis was conducted using statistical package of social science (SPSS) software, version 26 (SPSS Inc., predictive analysis software (PASW) statistics for Windows version 26). Chicago: SPSS Incorporated. Qualitative data were represented using numbers and percentages. Quantitative data were summarized with the median (minimum and maximum)

for non-normally distributed data and mean± standard deviation for normally distributed data, following normality testing through the Kolmogorov-Smirnov test. The importance of the results obtained was evaluated at the (0.05) level

Results :

This study included 70 women diagnosed by US with 88 adnexal masses requiring an additional MRI examination that was performed subsequently.
The patients age ranged between 16-80 years with mean value of 40.87±17.04 (Table 1).
The majority of our patients 71.5 % presented with pelvic and abdominal pain, 25.7 % presented with pelvic swelling, 18.6 % complain of fever, 12.9 % primary infertility, while 8.6 % presented with vaginal discharge, dysuria and vaginal bleeding and 2.9 % of the studied females complain from dysmenorrhea. 7.1 % of the studied patients were diabetics (Table 1).

Table (1): age and complaint among studied cases

	N=70	%
Age (years)	40.87±17.04 (16-80)	
Complaint		
Vaginal bleeding	6	8.6
Primary infertility	9	12.9
Pelvic swelling	18	25.7
Dysmenorrhea	2	2.9
Fever	13	18.6
Abdominal and Pelvic pain	50	71.5
Vaginal discharge	6	8.6
DM	5	7.1
Dysuria	6	8.6

Women with malignant masses were older than those with benign masses (mean age, 42.13±16.54 vs. 40.50±17.32 years) (Table 2).

Table (2): Comparison of age between benign , borderline versus malignant among studied cases

	Benign & borderline N=54	Malignant N=16	Test of significance
Age (years)	40.50±17.32	42.13±16.54	t=0.333 p=0.740

t:Student t test

Regarding MRI features of studied lesions tubo-ovarian abscess (TOA) more frequently showed indistinct margins (p <0.001). Association with tubal dilatation was more common in TOA than in ovarian malignancy (83.3% vs. 20%, respectively; p <0.001). However, there were no significant differences for fluid-fluid level, thickened wall and septea

Among our cases, 20 patients (22.7%) had inflammatory adnexal lesions like TAO, 30 patients have benign adnexal lesions (34%), 10 (11.3%) patients had border line adnexal lesions and 28 (31.8%) patients had malignant adnexal lesions (Table 3).

Table (3): Pathology of lesions in participating subjects (no. 88).

	N=88	
Lesion type	N	%
Inflammatory	20	22.7 %
Benign	30	34 %
Border line	10	11.3 %
Malignant	28	31.8 %

Regarding dynamic contrast study of the studied lesions time intensity curve (TIC) revealed, 42 % were low risk TIC , 36.3 % were intermediate risk TIC while the remaining 21.5 % were high risk TIC (Table 4).

Table (4): Dynamic contrast study findings .

	N=88	%
Curve		
Low risk TIC	37	42
Intermediate risk TIC	32	36.3
High risk TIC	19	21.5

Regarding time-signal intensity curve, low risk TIC associated with benign and border line cases (35/ 60 benign tumors) compared with high risk TIC which is associated strongly with malignant disease (18/28 malignant tumors) (Table 5).

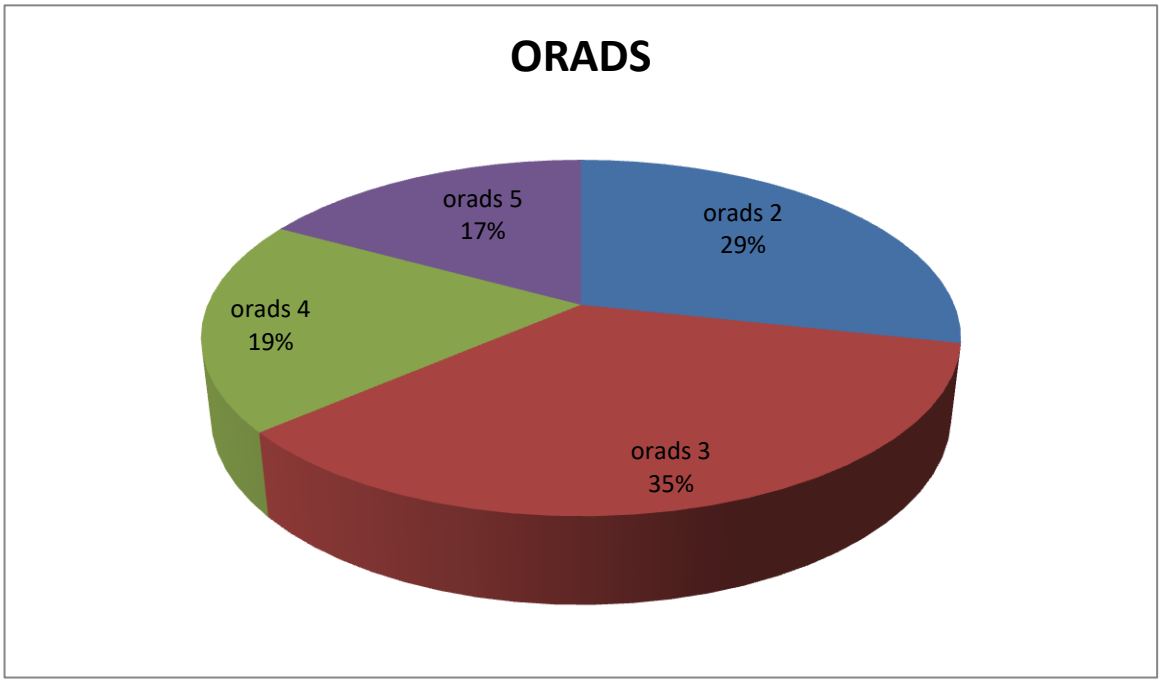
Table (5): Type of time-signal intensity curve between benign , borderline versus malignant among studied lesions

	Benign N=50	Borderline N=10	Malignant N=28
Curve			
Low risk TIC	35 (70%)	2 (20%)	0
Intermediate risk TIC	15 (30%)	7 (70%)	10 (35.7%)
High risk TIC	0	1 (10%)	18 (64.2%)

Regarding ORADS categorization of our studied population, 28.4% were ORADS 2, 35.2% were ORADS 3, 19.3% were ORADS 4, 17% were ORADS 5 (Table 6 and figure 1).

Table (6): ORADS score classification of the studied lesion

	N=88	%
ORADS		
2	25	28.4
3	31	35.2
4	17	19.3
5	15	17



Regarding ORADS categorization in differentiating between benign and malignant tumors with 90 % sensitivity and 85 % specificity 91.2 % positive predictive value, 85 % negative predictive value and accuracy 86.4 (Table 7).

Table (7): Validity of ORADS in differentiating between benign versus malignant adnexal lesions

	Sensitivity%	Specificity%	PPV%	NPV%	Accuracy%
ORADS	90	85	91.2	85	86.4

Discussion:

O-RADS: O-RADS was established by the American College of Radiology (ACR) to develop a risk stratification and management approach that help those who explain pelvic ultrasound examinations by offering a framework for fixed interpretations that avoid confusion in assessment of malignancy danger **(6).**

Malignancy comprises low grade tumors, border line tumors and high-grade tumors within the scoring system and all other ovarian and adnexal masses are supposed to be benign **(7).**

The T2 signal intensity, high B-value DW signal and the perfusion curve criteria is significant to be evaluated in presence of solid tissue within the adnexal masses **(7).**
Regarding to age, the mean age was 40.87±17.04 years, ranged between 16 to 80 years which near to the results in the study done by **Hassan et al., (8)** found that among the 72 patients mean age of 42.9±13.01 years (range: 16–62 years).

In our study patients with benign masses were younger than those with malignant masses (mean age, 42.13±16.54 vs. 40.50±17.32 years) which near to the findings in the research conducted by **Moradi et al., (9)** found that patients with cancerous tumors were significantly older than those with non cancerous tumors (40.89 years, whereas for 46.30 years).
In the current study, we found that 71.5% patients presented with pain, 25.7% presented with pelvic swelling, 18.6 % complain of fever, 12.9% primary infertility, while 8.6% presented with vaginal discharge, dysuria and vaginal bleeding and 2.9% of the studied females

complain was dysmenorrhea. 7.1% of the studied patients were diabetics. This aligns with the research conducted by **Hassan et al., (8)** which reported that all 72 patients experienced pain, with over half (63.9%) experiencing irritable bowel by either constipation or diarrhea, 44.4% displaying fever, 41.7% presenting a palpable mass or enlarged abdomen, 22.2% having dysfunctional uterine bleeding, and 19.4% reporting urinary symptoms either frequency or dysuria.

This aligned with **Bhagde et al., (10)** who reported that abdominal discomfort occurred in about 92% of patients while numerous adnexal masses are asymptomatic.

In another research conducted by **Wagh G., (11)** 100 sequential patients with adnexal masses were examined, with the primary complaint being pain (68%), followed by no complaints (15%) and abdominal distension (7%). Additional symptoms encompass a mass in the abdomen, as well as nausea and vomiting.

The current study revealed that the O-RADS based MRI score categorized 28.4% of adnexal masses as O-RADS 2, suggesting they were most likely benign; 35.2% of adnexal masses were rated as O-RADS 3, indicating low risk for malignancy; 19% of adnexal masses were designated as O-RADS 4, signifying intermediate risk for malignancy; and 17% of adnexal masses were identified as O-RADS 5, reflecting high risk for malignancy.

Our research results agree with **Hottat et al. (12),** which found that in a their study which included 402 women evaluated by transvaginal US revealed indeterminate adnexal masses and underwent further assessment using MRI. In 27 patients, there were 32 lesions rated as 2, 88 lesions rated as 3, 32 lesions rated as 4, and in 31 individuals, 39 lesions were rated as 5. A total of 201 lesions were identified, with 58 (28.9%) being malignant and the remaining classified as benign.

In the present study, we showed that using pathology results as the reference standard, 31.8% of all adnexal masses were cancerous.

Pereira et al. (13) claimed a notable malignancy rate in their study done, from 190 masses 90 mass (47.37%) categorized as malignant in the pathological correlation, which is aligning with our research findings.

Also in the research done by **Hassan et al., (8)** they claimed that of the total studied adnexal masses 36.1% were malignant according to their pathology results as a reference criterion.

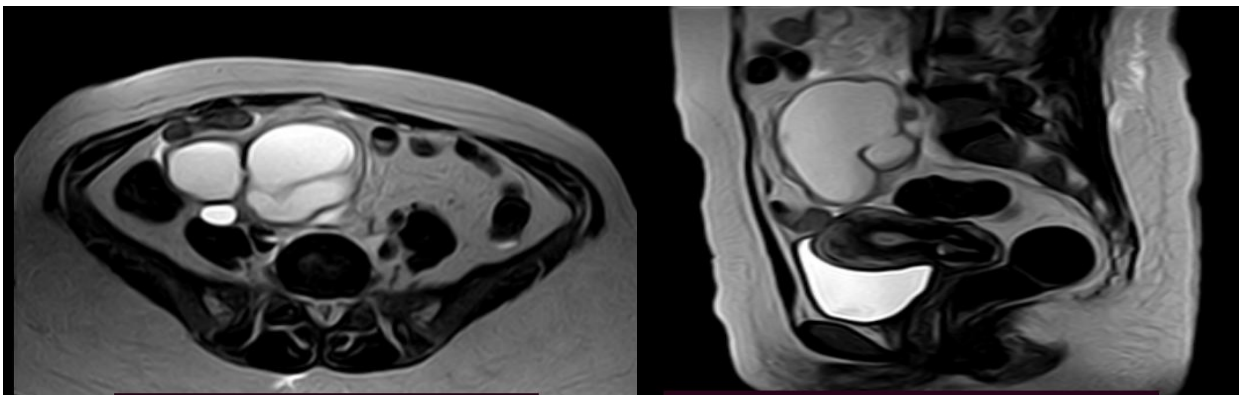
The sensitivity and specificity of the ORADS in our study were determined to be 90% and 85%, respectively and accuracy was 86.4 %.

Furthermore, **Aslan et al., (14)** demonstrate that the O-RADS MRI score give quite elevated sensitivity, specificity, and accuracy in distinguishing benign from malignant adnexal masses. The sensitivity rate stood at 96.3%, the specificity rate was 95.2%, and the accuracy rate reached 95.8%.

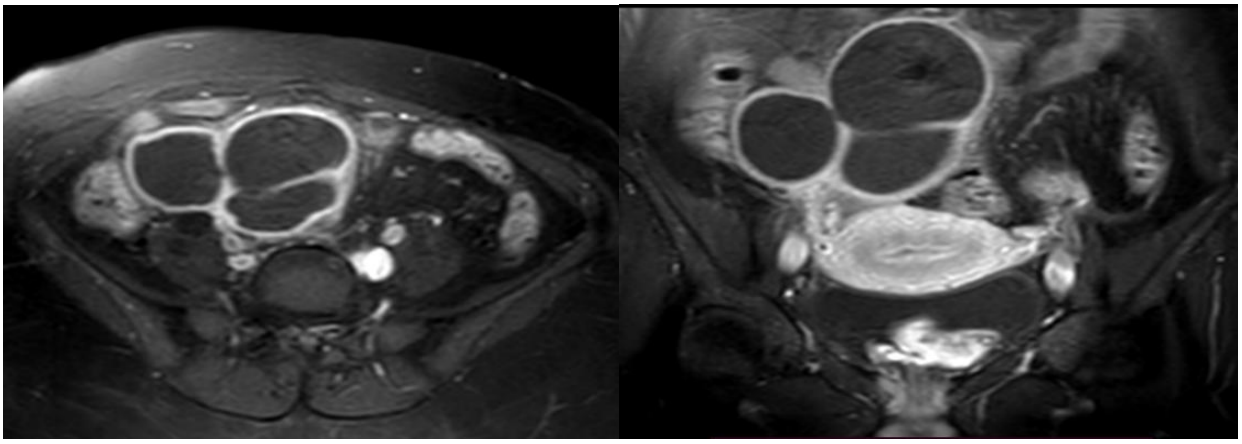
As per **BASU et al., (15, 16)** the O-RADS MR demonstrates a considerable sensitivity and specificity, showing values of 92.3% and 87.8%, respectively.

In our study we observed the mean ADC at b = 1000 was **1.81± 0.48** in benign lesions but in malignant lesions it was **0.994± 0.39** with a statistically significant difference in between $P<0.001$.

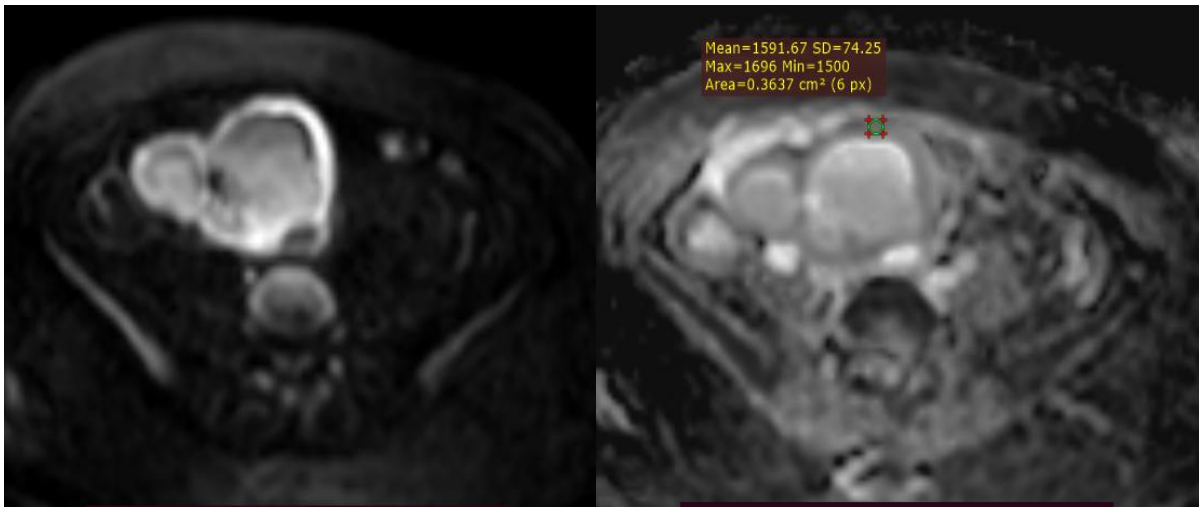
In study done by **Manganaro et al., (17)** the submitting of two ADC cut-off values, 1.411 × 10^-3 mm²/sec for O-RADS categories 3–4 and 0.849 × 10^-3 mm²/sec for and O-RADS categories 4–5, permitted the reclassification of certain adnexal masses initially placed in categories 3 (low risk) and 4 (intermediate risk).



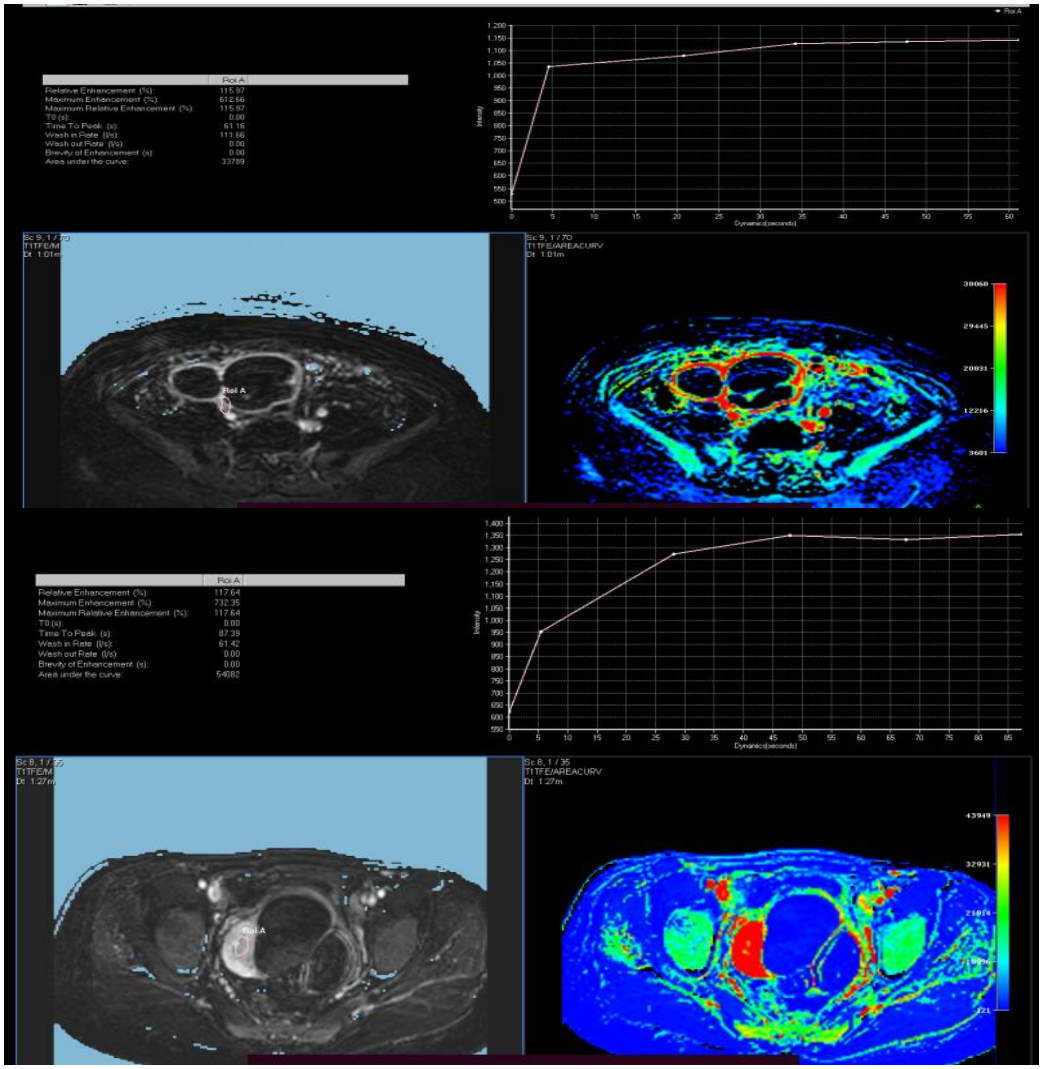
- **(A) axial and sagittal T2 WI**



(B) axial and coronal post contrast T1 Short Tau Inversion Recovery (STIR)

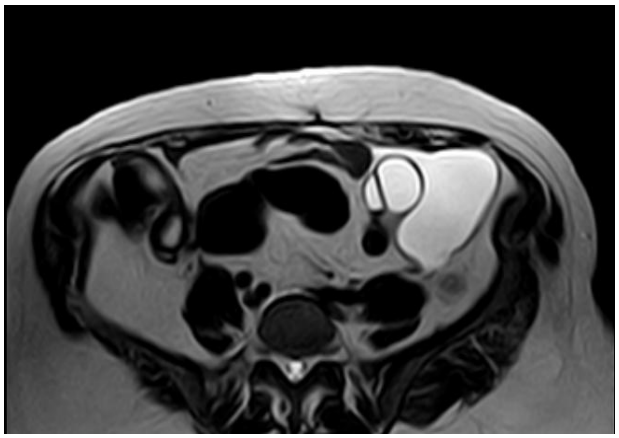
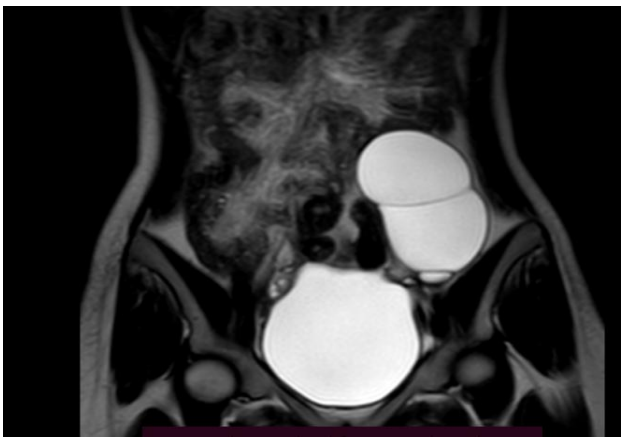


- **(C) diffusion, ADC map and ADC value**

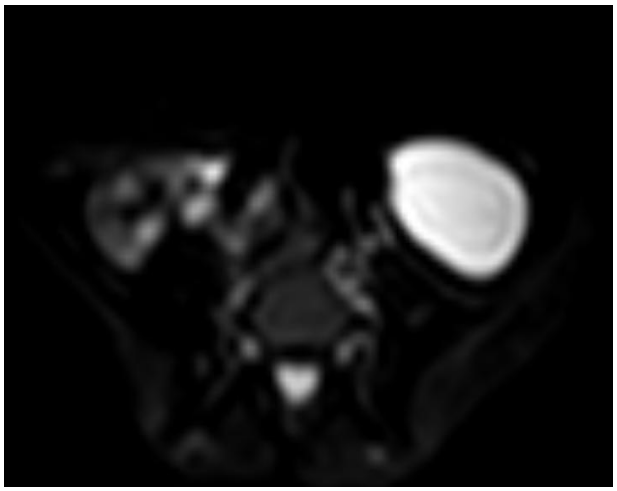
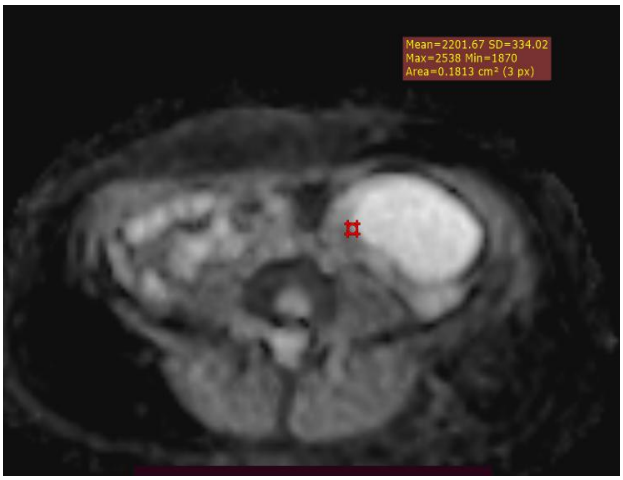


- **(D) TIC in adnexal lesion and adjacent myometrium**

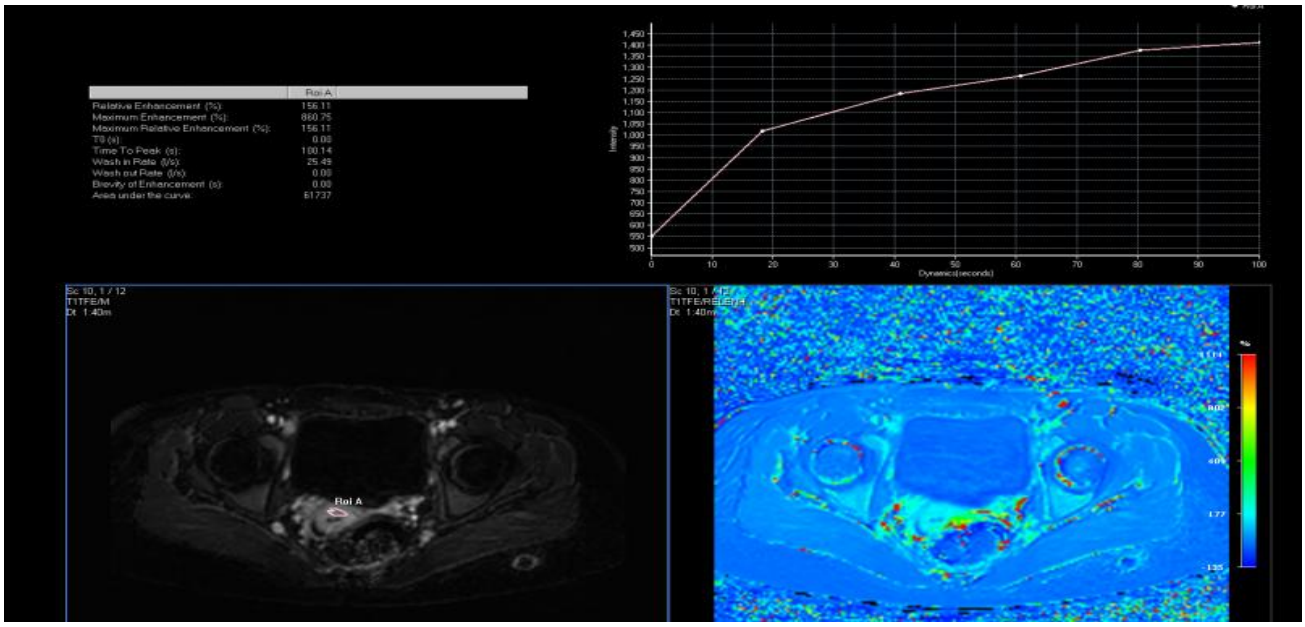
Figure 2: A 40-year-old woman with intermittent fever, pelvic pain and urinary symptoms showing right-sided multilocular cystic adnexal mass indeterminate in transvaginal ultrasound. **(A)** Axial and sagittal T2 WI confirmed high signal intensity multilocular cystic lesion in the left side of the pelvic cavity 6 x 7.5 x 9 cm with mild ascites. **(B)** MR axial post contrast-enhanced image shows a thick walled multilocular cystic lesion presenting marked rim-enhancement. **(C)** Axial DW image shows enhancing solid component on DW image show high signal intensity with a relatively high ADC value = 1.6×10^{-3} mm2. **(D)** Time intensity curve revealed intermediate risk type curve. Based on excluding dark DWI dark signal and intermediate risk TIC ORADS MR score was 4.
Pathology confirmed chronic suppurative inflammatory lesion TOA.

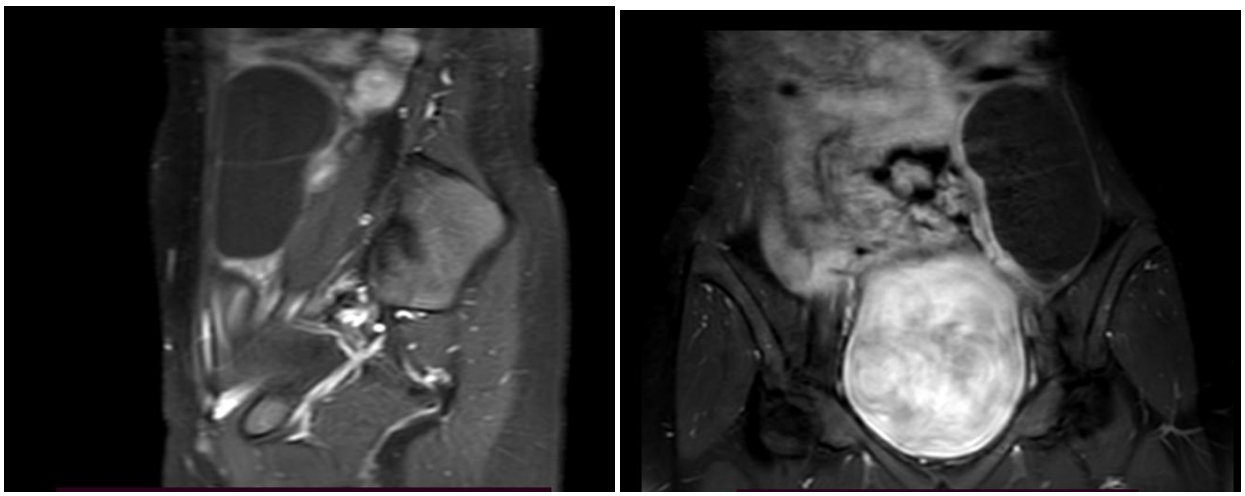
- **(A) Axial and coronal T2**

- **(B) Axial diffusion** **(C) ADC value**



- **(D) Dynamic contrast study and TIC in adnexal lesion and myometrium**



- **(E) Sagittal and coronal post contrast T1 STIR**

Figure 3: Young female aged 24-year-old complain of pelvic pain and dysfunctional uterine bleeding, transabdominal ultrasound revealed left adnexal bilocular indeterminate cystic lesion. **(A)** Axial and coronal T2-weighted MRI images show left adnexal bilocular cystic lesion with largest diameter of 6.5 x 4 x 10 cm. **(B and C)** Axial DWI showing high signal intensity at b 1000 and high ADC value 2 x 10^{-3} mm2/s. **(D)** DCE-MRI revealed low risk TIC in comparison with adjacent external myometrium. **(E)** Subjective assessment delayed post contrast sagittal and coronal T1WI STIR confirming smooth mural marginal enhancement less than external myometrium. This lesion was classified as ORADS score 3 based low risk TIC.
Pathology confirmed benign serous cystadenoma.

Conclusion:

Our findings showed that the O-RADS MRI score is a useful tool that differentiates between ambigous benign and malignant adnexal masses. It can be used clinically in cases of sonographic indeterminate ovarian masses to reduce invasive surgeries and preserve fertility.

Abbreviations:

ACR : American College of Radiology

ADC: Apparent diffusion coefficient

DCE: Dynamic contrast enhanced

DWI: Diffusion-Weighted MRI Imaging

FOV: Field of view

FSE: Fast spin echo

mm2/s: Square millimeters per second

MRI: Magnetic resonance imaging

ORADS : Ovarian-Adnexal Reporting and Data System

PASW: Predictive analysis software

ROI: Region of interset

SI: Signal intensity

SPSS: Statistical package of social science

STIR: Short Tau inversion recovery

TE: Echo time

TIC: Time intensity curve

TOA: Tubo-ovarian abscess

TR: Repetition time

TVUS: Transvaginal ultrasound

US: Ultrasound

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