

## Ovarian Lesions Diagnosis Based on Ultrasound Ovarian-Adnexal Reporting and Data System Classification

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### ABSTRACT

**Background:** Ovarian neoplasms are the leading death cause in gynecologic cancers. The need for universally recognized standardized imaging tool yielded the US O-RADS v2022 being its latest iteration.

**Objectives:** To evaluate and integrate ultrasound Ovarian-Adnexal Reporting and Data System (O-RADS) classification system into assessment of ovarian lesions and provide a consistent interpretation for proper risk stratification and management recommendation.

**Patients and Methods:** This is a prospective study that was conducted on all female patients having ovarian lesions either incidentally discovered upon routine ultrasound examination, clinically suspected ovarian lesion or pre-operative evaluation of known ovarian masses attending at Menoufia University Hospitals over six months starting from October 2023 according to inclusion and exclusion criteria.

**Results:** Our study included 112 patients; 92% of scanned ovarian lesions were benign and 8% were malignant. The most common lesion was hemorrhagic cysts, classified as O-RADS 2 and 3, accounting for 42.9%. Mucinous cystadenocarcinoma was the most noted malignant lesion equating for 3.6%. Using  $\geq$  O-RADS 4 as cut-off point for the malignant categories demonstrates optimal diagnostic performance, ROC analysis yielded 100% sensitivity and 99.03% specificity, AUC of 0.998 (95% CI= 0.994-1.000), PPV 90%, NPV 100% and FPR 0.97%. Our high diagnostic accuracy likely reflects rigorous case adjudication.

**Conclusion:** The US O-RADS v2022 classification system achieves a standardized non-invasive approach to properly characterize ovarian lesions with high sensitivity in differentiating benign from malignant lesions. Prospective multicenter studies with larger, demographically heterogeneous cohorts are warranted to validate generalizability.

**Keywords:** Ovarian cancer, Ovarian lesions, Risk stratification system, Ultrasound O-RADS v2022.

### INTRODUCTION

Diagnosis of ovarian lesions is challenging since that benign ovarian masses greatly outnumber the malignant ones and to initially determine the degree of malignancy suspicion is critical for the fact that it's based on imaging appearance <sup>[1]</sup>.

The lack of standardized terminology in gynecologic imaging, particularly regarding ovarian pathology, has raised significant concerns about variability in interpretation. Adoption of internationally standardized descriptors is essential for ensuring uniformity in reporting, reducing ambiguity, and improving diagnostic accuracy. This not only enhances the ability to assess malignancy risk reliably but also plays a critical role in reducing unnecessary patient anxiety and guiding evidence-based management strategies for optimal clinical outcomes <sup>[2,3]</sup>.

Previous efforts have been made to improve the characterization and management of adnexal masses on ultrasound. In 2000, **Timmerman et al.** <sup>[4]</sup>, as part of the International Ovarian Tumor Analysis (IOTA) Group, proposed a standardized set of terms, definitions, and measurement techniques for research applications. These initiatives culminated in the development of evidence-based classification models, including the "Simple Rules" (SR) and "ADNEX" models <sup>[5]</sup>.

Other models were introduced, The University of Kentucky's Morphology Index, Gynecologic Imaging Reporting and Data System (GI-RADS) and Society of Radiologists in Ultrasound (SRU) consensus statement, that failed to either achieve broader recognition, rely on subjective interpretation lacking reproducibility or didn't account for solid masses limiting applicability respectively <sup>[6-8]</sup>.

The American College of Radiology (ACR) established the Ovarian-Adnexal Reporting and Data System (O-RADS) Committee in 2015 to provide a uniform practical lexicon for ovarian lesion assessment <sup>[5]</sup>. The O-RADS US score, a five-tier risk stratification system, was introduced in 2018 <sup>[9]</sup> with consecutive revisions ending with v2022 as its latest iteration providing refinements that aim to improve diagnostic accuracy, enhance clinical workflow, update evidence-based management recommendations and address discrepancies <sup>[10]</sup>.

The aim of this work was to evaluate and integrate ultrasound Ovarian-Adnexal Reporting and Data System (O-RADS) classification system into assessment of ovarian lesions and provide a consistent interpretation for proper risk stratification and management recommendation.

## PATIENTS AND METHODS

This is a prospective study that was conducted on all female patients having ovarian lesions attending at Menoufia University Hospitals over six months starting from October 2023 according to inclusion and exclusion criteria.

The inclusion criteria comprised female patients of all age groups, incidentally discovered ovarian lesions in a routine ultrasound examination, cases of clinically suspected ovarian lesions, and pre-operative evaluation of known ovarian masses.

The exclusion criteria consisted of patients lost during follow-up, incomplete initial US evaluation due to technical factors, cases under O-RADS 0, and cases of ectopic pregnancy and other adnexal extra-ovarian lesions.

After taking valid consent, cases were enrolled for the study. Each patient underwent a full detailed history and clinical examination. Ultrasound examination was performed using ultrasound machines equipped with 2-5 MHz curvilinear transducer and 9 MHz transvaginal transducer when applicable. US machines used included (SonoScape E1 Exp, SonoScape Medical Corp., Shenzhen, China) and (GE LOGIQ e, GE Medical Systems Co. Ltd., Wuxi, China). O-RADS scoring for any ovarian lesion was performed independent of any other laboratory or imaging modalities. Follow-up after medical treatment or surgical interference were conducted by ultrasound or histopathology for operated cases. Magnetic Resonance Imaging (MRI) examination was used for some patients utilizing (MAGNETOM Avanto 1.5T, Siemens Healthineers, Erlangen, Germany). Some cases underwent Computed Tomography (CT) utilizing (Aquilion Prime SP, Canon Medical Systems Corporations, Otawara, Japan). The O-RADS score was compared with histopathological data, if available, in cases that underwent surgery or tissue biopsies.

### Ethical approval:

**The study adhered to the Declaration of Helsinki and was approved by the Faculty of Medicine, Menoufia University Ethics Committees (IRB approval date and number: 10/2023-RAD23), and informed consent was obtained from all subjects and/or their legal guardians.**

### Statistical analysis

The collected data were tabulated and analyzed by SPSS software version 27 on an IBM-compatible computer. Descriptive statistics were conducted; qualitative data were expressed in number and percentage (No and %), while quantitative data were

presented as mean, standard deviation (SD), and range. Analytical statistics were also performed, The Pearson Chi-squared test ( $\chi^2$ ) was used to compare qualitative variables between groups. Fisher exact test (FE) was used to compare qualitative variables in 2x2 table if any of expected cells is less than five. Marginal homogeneity (MH) test was also applied in this study. To compare differences between two quantitative normally distributed variables, the Student-*t* test was used. *P*-value of less than 0.05 was set to be statistically significant. Values of specificity, sensitivity, diagnostic accuracy, positive predictive value (PPV), negative predictive value (NPV) and false positive rate (FPR) were calculated, and receiver operating characteristic (ROC) curve was generated with area under the curve (AUC) denoting diagnostic performance of the test.

## RESULTS

This study included 112 participants during the allocated six-month timeframe. 89.3% were premenopausal and 10.7% were postmenopausal with a mean age of  $33.64 \pm 11.10$  years. 34.8% of the participants were asymptomatic while 65.2% were symptomatic, with pelvic pain representing 50% and pain collectively equating to 61.7%.

Application of O-RADS classification system on both initial and second follow-up US study, if performed, was done. During the initial US study, 83% of the ovarian lesions studied were classified as score 2. The least score was O-RADS 4, represented by 3.6%. Other imaging parameters were also assessed including septations, calcifications, solid contents and color score. Septations were found among 50% of studied lesions. Calcifications were found in 6.3%. Intraleisional solid contents were seen in 8%.

Color score represents intraleisional color flow on color Doppler assessment. Color Score 1 (CS1) reflecting no internal color flow was the most predominant score, accounting for 92% of cases. On the second US follow-up study, O-RADS 1 represented 52.7% of the scanned ovaries including instances of no ovarian lesions. Septations were found among 10.7%. No calcifications were found among 71.4% of cases, representing all cases that underwent second follow-up ultrasound. Solid contents were seen in two cases representing 1.8% of all initially assessed participants. CS1 remained the most predominant color score equating to 69.6%. There was a statistically significant difference between initial and second follow-up US regarding O-RADS classification, calcifications, solid contents and color score (*P* value <0.05) as represented in **Table 1**.

**Table (1):** Initial and second US O-RADS among studied participants (n=112)

| Parameter             |                             | Initial US O-RADS |      | Second US O-RADS |      | Test of sig. | P value           |
|-----------------------|-----------------------------|-------------------|------|------------------|------|--------------|-------------------|
|                       |                             | No.               | %    | No.              | %    |              |                   |
| <b>O-RADS</b>         | <b>O-RADS 1</b>             | 0                 | 0.0  | 59               | 52.7 | MH=1.998     | <b>0.046*</b>     |
|                       | <b>O-RADS 2</b>             | 93                | 83.0 | 17               | 15.2 |              |                   |
|                       | <b>O-RADS 3</b>             | 9                 | 8.0  | 2                | 1.8  |              |                   |
|                       | <b>O-RADS 4</b>             | 4                 | 3.6  | 0                | 0.0  |              |                   |
|                       | <b>O-RADS 5</b>             | 6                 | 5.4  | 2                | 1.8  |              |                   |
|                       | <b>No US Study</b>          | 0                 | 0.0  | 32               | 28.6 |              |                   |
| <b>Septations</b>     | <b>Absent</b>               | 56                | 50.0 | 68               | 60.7 | MH=1.8       | 0.072             |
|                       | <b>Present</b>              | 56                | 50.0 | 12               | 10.7 |              |                   |
|                       | <b>No US Study</b>          | 0                 | 0.0  | 32               | 28.6 |              |                   |
| <b>Calcifications</b> | <b>Absent</b>               | 105               | 93.8 | 80               | 71.4 | MH=5.41      | <b>&lt;0.001*</b> |
|                       | <b>Present</b>              | 7                 | 6.3  | 0                | 0.0  |              |                   |
|                       | <b>No US Study</b>          | 0                 | 0.0  | 32               | 28.6 |              |                   |
| <b>Solid Contents</b> | <b>Absent</b>               | 103               | 92.0 | 78               | 69.6 | MH=5.51      | <b>&lt;0.001*</b> |
|                       | <b>Present</b>              | 9                 | 8.0  | 2                | 1.8  |              |                   |
|                       | <b>No US Study</b>          | 0                 | 0.0  | 32               | 28.6 |              |                   |
| <b>Color Score</b>    | <b>No internal flow CS1</b> | 103               | 92.0 | 78               | 69.6 | MH=5.53      | <b>&lt;0.001*</b> |
|                       | <b>Minimal flow CS2</b>     | 2                 | 1.8  | 0                | 0.0  |              |                   |
|                       | <b>Moderate flow CS3</b>    | 4                 | 3.6  | 0                | 0.0  |              |                   |
|                       | <b>Very strong flow CS4</b> | 3                 | 2.7  | 2                | 1.8  |              |                   |
|                       | <b>No US Study</b>          | 0                 | 0.0  | 32               | 28.6 |              |                   |

\*: Statistically significant, MH: Marginal Homogeneity test, CS: Color Score.

Cases with histopathological data (26%), whether underwent surgery or biopsies, showed that endometrioma, as a benign lesion, accounts for 13.4% of all patients, while 3.6% were deemed malignant as mucinous cystadenocarcinoma.

There was a statistically significant difference in participants with benign lesions and those with malignant lesions regarding age; age was higher in cases with malignancy. A statistically significant difference regarding O-RADS classification, solid contents and color score could also be noted as shown in **Table 2** emphasizing the value of intralesional solid content and color score as predictor for malignancy suspicion.

**Table (2):** Final diagnosis in relation to initial US O-RADS among studied participants (n=112)

| Parameter      |                      | Pathology      |       |                 |       | Test of significance | P value |
|----------------|----------------------|----------------|-------|-----------------|-------|----------------------|---------|
|                |                      | Benign (n=103) |       | Malignant (n=9) |       |                      |         |
|                |                      | No.            | %     | No.             | %     |                      |         |
| O-RADS         | O-RADS 2             | 93             | 90.3  | 0               | 0.0   | $\chi^2=101.85$      | <0.001* |
|                | O-RADS 3             | 9              | 8.7   | 0               | 0.0   |                      |         |
|                | O-RADS 4             | 1              | 1.0   | 3               | 33.3  |                      |         |
|                | O-RADS 5             | 0              | 0.0   | 6               | 66.7  |                      |         |
| Septations     | Absent               | 52             | 50.5  | 4               | 44.4  | FE                   | 1.000   |
|                | Present              | 51             | 49.5  | 5               | 55.6  |                      |         |
| Calcifications | Absent               | 97             | 94.2  | 8               | 88.9  | FE                   | 0.453   |
|                | Present              | 6              | 5.8   | 1               | 11.1  |                      |         |
| Solid Contents | Absent               | 103            | 100.0 | 0               | 0.0   | FE                   | <0.001* |
|                | Present              | 0              | 0.0   | 9               | 100.0 |                      |         |
| Color Score    | No internal flow CS1 | 103            | 100.0 | 0               | 0.0   | $\chi^2=112.00$      | <0.001* |
|                | Minimal flow CS2     | 0              | 0.0   | 2               | 22.2  |                      |         |
|                | Moderate flow CS3    | 0              | 0.0   | 4               | 44.4  |                      |         |
|                | Very strong flow CS4 | 0              | 0.0   | 3               | 33.3  |                      |         |

\*: Statistically significant, FE: Fisher exact test, CS: Color Score

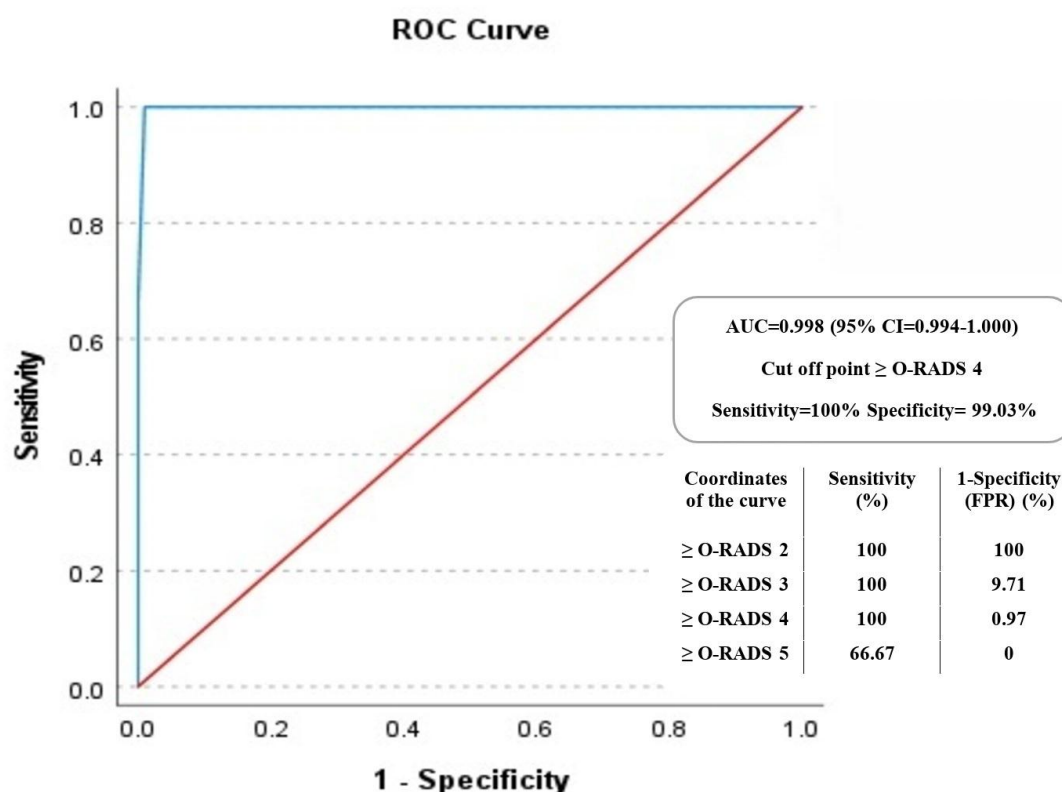
There was also a statistically significant difference between pathology (based on biopsies and clinical expertise for non-surgical benign lesions) and O-RADS classifications based on ultrasound findings. Sensitivity of 100% and specificity of 90.03% are represented in **Table 3**.

**Table (3):** Diagnostic accuracy of US O-RADS in relation to pathology (based on biopsies and clinical expertise for non-surgical benign lesions) among studied participants (n=112)

| US O-RADS        | Pathology      |                 | Test of significance | P value |
|------------------|----------------|-----------------|----------------------|---------|
|                  | Benign (n=103) | Malignant (n=9) |                      |         |
|                  | No. (%)        | No. (%)         |                      |         |
| Benign (n=120)   | 102 (99.0)     | 0 (0.0)         | FE                   | <0.001* |
| Malignant (n=10) | 1 (1.0)        | 9 (100.0)       |                      |         |
| Sensitivity      | 100%           |                 |                      |         |
| Specificity      | 99.03%         |                 |                      |         |
| Accuracy         | 99.1%          |                 |                      |         |
| PPV              | 90%            |                 |                      |         |
| NPV              | 100%           |                 |                      |         |

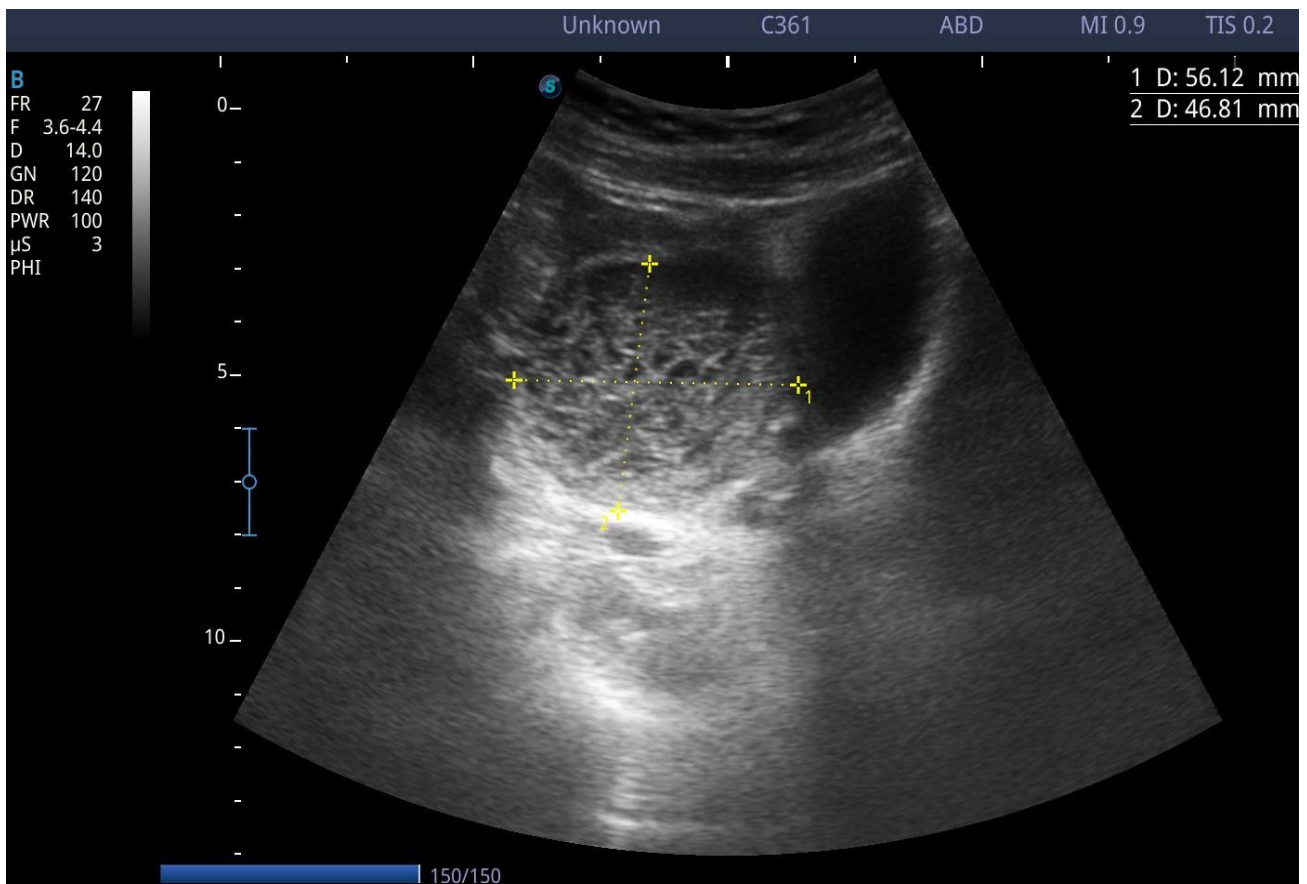
\*: Statistically significant, FE: Fisher exact test, PPV: Positive predictive value, NPV: Negative predictive value.

The ROC curve for US O-RADS malignancy prediction shown in **Figure 1** demonstrates exceptional diagnostic accuracy for the binary type AUC with  $\geq$ O-RADS 4 cutoff (AUC 0.998, 95% CI=0.994-1.000) where O-RADS 4 and 5 were considered the malignant categories. ROC curve coordinates illustrate the trade-off between sensitivity and specificity as the threshold for malignancy classification changes, with lower threshold maximizing sensitivity at the expense of higher FPR, and higher thresholds improving specificity but reducing sensitivity.  $\geq$  O-RADS 4 demonstrates optimal diagnostic performance with 100% sensitivity, 99.03% specificity and 0.97% FPR.



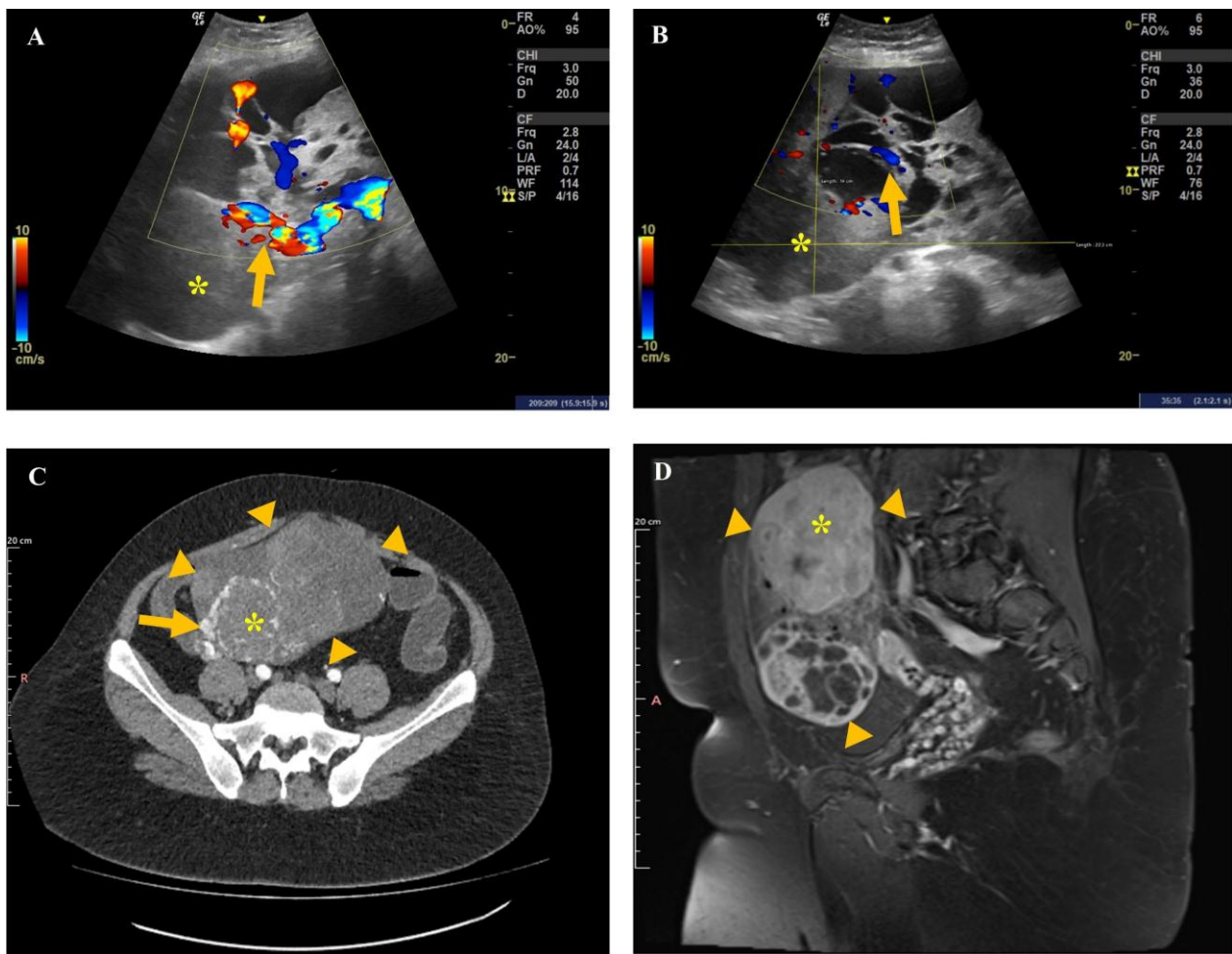
**Figure (1):** ROC curve for US O-RADS Malignancy Prediction.

Transabdominal Ultrasonography (TAUS) for a 25-year-old female patient with pelvic pain is represented in **Figure 2**. It shows a left ovarian cystic lesion measuring about 5.6x4.6 cm featuring multiple internal septations giving reticular pattern with no color flow on Doppler and no internal calcifications or solid content. Sonographic findings were classified under O-RADS score 2 and were consistent with typical hemorrhagic cyst <10 cm. Follow up shows complete resolution after 7 weeks.



**Figure (2):** Case no. 1- [TAUS for a 25-year-old female patient shows left ovarian cystic lesion measuring about 5.6x4.6 cm featuring multiple internal septations giving reticular pattern with no color flow on Doppler and no internal calcifications or solid content. Sonographic findings were classified under O-RADS score 2 and were consistent with typical hemorrhagic cyst <10 cm].

**Figure (3)** features TAUS for a 44-year-old female patient, initially presenting with pelvic pain. The first US scan (A) showed a right ovarian multilocular cystic lesion measuring about 21.2x10.9 cm with multiple internal variable sized thick septa, very strong color flow signal CS4 (arrow) and internal heterogeneous solid vascular component about 11x8.6 cm (asterisk). Sonographic findings classified under O-RADS score 5 (Multilocular cystic lesion with solid component, any size, CS 3-4). TAUS follow-up study (B) revealed increase in size of the lesion to about 22.3x14 cm. Contrast-enhanced computed tomography (CECT) (C) with mass being outlined by (arrowheads) featured heterogeneous enhancement and high internal vascularity in arterial phase. Contrast-enhanced MRI (D) illustrated solid and cystic components with heterogeneous enhancement. Imaging findings combined with increased cancer antigen-125 (CA-125) level and rising values on follow-up raised the malignancy risk prediction. US-guided Tru-Cut needle biopsy (TCNB) of the mass revealed invasive mucin secreting adenocarcinoma as pathologically reported.



**Figure (3):** Case no. 2. **A.** Initial US study showing a right ovarian multilocular cystic lesion measuring about 21.2x10.9 cm with multiple internal variable sized thick septa showing very strong color flow signal CS4 (arrow) and internal heterogeneous solid vascular component measuring about 11x8.6 cm (asterisk). Sonographic findings classified under O-RADS score 5 (Multilocular cystic lesion with solid component, any size, CS 3-4). **B.** Second follow up US study showing size progression, measuring about 22.3x14 cm. **C.** Contrast-enhanced computed tomography (CECT) in arterial phase, with mass being outlined by (arrowheads), showing heterogeneous enhancement and high internal vascularity. **D.** Contrast-enhanced MRI illustrates the structure of the lesion with solid and cystic components with heterogeneous enhancement following IV contrast administration.

## DISCUSSION

The presentation of an ovarian lesion or mass in female patients is a concerning event for the patient and the family especially in young ages. Patients are more likely to present with abdominal pain or menstrual complain<sup>[11]</sup>. Diagnosis of ovarian lesions is challenging since that benign ovarian masses greatly outnumber the malignant ones and to initially determine the degree of malignancy suspicion is critical for the fact that it's based on imaging appearance<sup>[1]</sup>.

Imaging aims for most accurate diagnosis using minimal radiation; therefore, US is the primary imaging modality for evaluating pelvic symptoms and suspected ovarian lesions, offering high sensitivity in detecting and characterizing ovarian masses<sup>[12]</sup>.

Our study included 112 female patients suspected to have ovarian lesions; most of them were symptomatic and pain was the main complaint. **Givens et al.**<sup>[13]</sup> also noted it being reported by women with

ovarian cancer. A large percentage of cases were asymptomatic which is usually accompanied by benign lesions. However, early misinterpretation and late stage ovarian cancer diagnosis is concerning since prognosis is already unpropitious<sup>[14]</sup>.

For a more uniform standardized approach to ovarian lesions in terms of description of characteristics imaging features with proper risk stratification, the American College of Radiology (ACR) established the Ovarian-Adnexal Reporting and Data System (O-RADS) Committee in 2015<sup>[5,15]</sup>.

The latest revision conducted in January 2022 provided additional guidance, addressed discrepancies while ensuring consistent implementation across ultrasound reports as well as refining the management recommendations. These refinement aims to improve diagnostic accuracy<sup>[10]</sup>.

Regarding the demographic data in our study, the median age of the patients was 32 years, ranging from 9 to 56 years and a mean of age  $33.64 \pm 11.10$



years. 89.3% were menopausal and 10.7% were postmenopausal.

In our study, 92% of the ovarian lesions scanned were benign (mostly under O-RADS 2 and 3) and 8% were malignant. The most common ovarian lesions on routine clinical radiology practice were hemorrhagic cysts, endometriomas and simple cysts (42.9%, 17% and 11.6% respectively). On the other hand, mucinous cystadenocarcinoma was the most noted malignant lesion equating for 3.8%.

**Ahmed** <sup>[16]</sup> investigated 50 patients targeting suspicious lesions in their study. Only 15 lesions, representing 30% of cases, were benign, whereas 70% were malignant. **Bhagde et al.** <sup>[17]</sup> also investigated premenopausal 50 patients; all lesions were found to be benign. **Hack et al.** <sup>[18]</sup> scanned 262 lesions, in total of 227 women in a tertiary oncology center and found 187 (71%) to be benign while 75 lesions (29%) to be malignant. **Prasad et al.** <sup>[19]</sup> studied 56 masses and that found 4 were malignant, 24 being benign masses and the rest were physiological cyst/infective process.

Regarding the O-RADS risk groups in our study, 83% of the lesions were classified as score 2, 8% as score 3, 3.6% as score 4 and 5.4% as score 5. **Hack et al.** <sup>[18]</sup> found lesions distribution as follows: 38% for O-RADS 2, 32% for O-RADS 3, 24% for O-RADS 4, and 26% for O-RADS 5.

Clinical interpretation of the coordinates on the ROC curve for different O-RADS thresholds explains that using  $\geq$ O-RADS 3 cutoff offers a more aggressive screening approach with high false positive rate leading to lower PPV (47.37%), while  $\geq$ O-RADS 5 reflects a more conservative approach with high confidence in positive results but misses 33.33% of malignancies in O-RADS 4 category. A threshold of  $\geq$  O-RADS 2 would be maximally sensitive but not specific warranting further intervention for every patient regardless of actual risk, which negates the purpose of risk stratification system. The ROC curve demonstrates optimal diagnostic accuracy using  $\geq$ O-RADS 4 as a cutoff threshold (AUC 0.998, 95% CI=0.994-1.000, 100% sensitivity, 99.03% specificity and 0.97% FPR). While these values likely reflect rigorous case adjudication, the narrow confidence intervals should be interpreted cautiously in context of the limited sample size of high-risk cases and abundance of benign lesions. The ROC analysis showed a sensitivity and specificity of 98.7% and 83.2% respectively in **Cao et al.** <sup>[20]</sup> and 96.6% and 92.8%, in **Basha et al.** <sup>[21]</sup>.

**Hack et al.** <sup>[18]</sup> retrospective study of O-RADS model implementation as well as a modified O-RADS system incorporating acoustic shadowing in distinguishing benign and malignant masses returned AUC of 0.91 and 0.94 respectively.

Our study also relied on both surgical outcome data and pathological reports as well as expert consensus as a non-surgical outcome, given that

benign-appearing lesions of the ovary are unlikely to be surgically excised <sup>[22]</sup>. 87 cases didn't undergo surgical procedures equating for 77.7% of participants. In such case, relying on surgical outcome alone may not optimally reflect the diagnostic accuracy of the O-RADS classification system.

**Jha et al.** <sup>[9]</sup> study resulted in a sensitivity of 90.6% and specificity of 81.9%, positive predictive value (PPV) of 31.4% and negative predictive value (NPV) of 99.0% with O-RADS 4 as cutoff value for cancer diagnosis. Our study yielded statistically significant data with PPV of 90% and NPV of 100% with one false positive case initially diagnosed being malignant but turned out benign on final diagnosis.

While stringent adherence to US O-RADS v2022 criteria strengthens internal validity, these results may overestimate performance in settings lacking subspecialist radiology expertise. Future prospective multicenter studies with larger sample and wider variations especially in cases with malignant lesions, false positive cases and inclusion of missed categories in current study would greatly validate the applicability of the O-RADS system as a standardized tool for diagnosis and risk stratification of ovarian lesions and assess whether results generalize across institutions with varying radiology experience while assessing diagnostic accuracy.

## CONCLUSION

O-RADS US v2022 classification system achieves a standardized, highly sensitive, non-invasive diagnostic tool to characterize and differentiate benign from malignant ovarian lesions. O-RADS 2 and 3 lesions had a very low chance of cancer, emphasizing conservative management. Larger diverse prospective multicenter studies are warranted to validate generalized applicability.

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