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Original Article

Radiology Section

# Diagnostic Performance and Accuracy of Ovarian-Adnexal Reporting and Data System Ultrasound Risk Score-A Prospective Cohort Study

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## ABSTRACT

**Introduction:** Adnexal malignancies are a leading cause of mortality in gynaecologic cancers, posing significant diagnostic challenges. Ultrasonography (USG) is the primary imaging modality, and the development of the Ovarian-Adnexal Reporting and Data System Ultrasound (O-RADS US) aims to provide standardised interpretations to assist in management decisions.

**Aim:** To evaluate the effectiveness of using the O-RADS classification system in diagnosing and characterising adnexal lesions.

**Materials and Methods:** This single-centre prospective cohort study was conducted at the Department of Radiodiagnosis, Sri Guru Ram Das Charitable Hospital attached to Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar, Punjab, India from January 1, 2023, to March 31, 2024. The study included 50 patients with adnexal mass lesions from all age groups. All participants underwent transabdominal/transvaginal ultrasonographic examinations, with Colour Doppler assessment included. The O-RADS classification system was employed to assess and characterise the adnexal mass lesions. The diagnostic accuracy of the O-RADS US risk score was determined. Statistical analysis was conducted using Statistical Packages for Social Sciences (SPSS) version 24.0 to calculate the sensitivity, specificity, accuracy, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) for O-RADS US results in diagnosing ovarian masses.

**Results:** The patients' ages ranged from 18 to 83 years, with a mean age of 41.68±15.51 years. The cohort included 35 premenopausal and 15 postmenopausal individuals. The most common indication for USG was pelvic pain, observed in 15 out of 50 patients, representing 30% of the study cohort. The O-RADS sensitivity for the detection of ovarian cancer was 88.89%, with a specificity of 93.75%, NPV of 93.75%, and PPV of 88.89%, with an accuracy of 92%. These results were achieved by keeping O-RADS score of 4 as the cutoff for malignancy.

**Conclusion:** The O-RADS US is effective in the risk stratification of ovarian lesions and has a high diagnostic performance. Implementing these guidelines in clinical practice could be beneficial for managing adnexal lesions.


**Keywords:** Adnexa, Gynaecologic malignancy, Ovarian masses, Ultrasonography

## INTRODUCTION

Ovarian cancer is a major health concern due to its poor prognosis and high mortality rates, often caused by non specific initial symptoms that lead to delayed diagnosis [1,2]. Adnexal lesions can have various origins, including functional changes, inflammation, benign tumours, and malignant neoplasms [3]. Accurately characterising ovarian mass lesions is crucial to reduce anxiety and enable informed management decisions [4], ultimately improving survival rates for patients with ovarian malignancies through timely intervention. Diagnosing adnexal masses poses a particular challenge due to the higher prevalence of benign lesions compared to malignant ones.

On USG imaging, the majority of adnexal lesions are typically benign and fall into categories such as simple cysts, haemorrhagic cysts, endometriomas, and dermoids [5-9]. The likelihood of malignancy in these lesions is very low. It is crucial to assess the imaging features of the mass to determine the level of suspicion for malignancy accurately [10]. Ultrasound assessment is widely regarded as the primary imaging modality for evaluating the female pelvis, providing a comprehensive evaluation of most adnexal lesions using both transvaginal and transabdominal techniques [11].

Accurate imaging and risk stratification are crucial elements in effective management strategies, with O-RADS representing a significant advancement in this area. The O-RADS guidelines offer standardised protocols for interpreting and reporting ovarian and adnexal imaging findings, aiming to enhance diagnostic consistency, improve risk assessment, and enable early detection of ovarian malignancies. In 2018, the American College of Radiology (ACR) O-RADS US committee released a white paper focusing on standardising the description of adnexal masses using established US features. This effort led to the development of a risk stratification classification system (O-RADS 0 to 5) based on an analysis of the International Ovarian Tumour Analysis (IOTA) database [12-16].

The recent update to the O-RADS US system, known as O-RADS US v2022, has resulted in modifications across related documents such as tables, lexicon entries, and governing concepts. These changes ensure alignment with the latest advancements and standards in adnexal lesion assessment, aiming to optimise patient outcomes through improved imaging and clinical management recommendations.

The present study aimed to evaluate the usefulness of using the O-RADS classification system in the US diagnosis of suspicious ovarian mass lesions.

## MATERIALS AND METHODS

This single-centre prospective cohort study was conducted at the Department of Radiodiagnosis, Sri Guru Ram Das Charitable

Hospital, attached to Sri Guru Ram Das Institute of Medical Sciences and Research, in Sri Amritsar from January 2023 till March 2024. The study included 50 patients, with 35 premenopausal and 15 postmenopausal females, who were referred to the Department of Radiodiagnosis for ultrasonographic assessment of adnexal lesions. The study was approved by the Institutional Ethical Committee (IEC) with letter number (SGRDU/cont/23-946).

**Inclusion criteria:** The inclusion criteria encompassed patients aged 18 years and above with clinically suspected adnexal masses diagnosed via US. Diagnostic criteria for adnexal lesions included clinical symptoms such as pelvic pain and abnormal bleeding, as well as physical examination findings of palpable masses. USG confirmed adnexal lesions by assessing their location, size, internal consistency, border definition, vascularity, and the presence of solid components.

**Exclusion criteria:** The exclusion criteria comprised known cases of gynaecological malignancy, patients lost to follow-up, and those who refused biopsy and further investigation. Additionally, patients with simple ovarian follicles (defined as simple cysts <3 cm in premenopausal women), corpus luteal cysts, and cystic lesions smaller than 1 cm in postmenopausal women were excluded from the study.

After obtaining informed written consent and relevant history, patients underwent USG and were scored according to the O-RADS system.

### Study Procedure

The USG utilised machines like Voluson E8 with either a curvilinear transducer (2-6 MHz) or a transvaginal probe (4-9 MHz). A single experienced radiologist, with over 15 years of expertise in USG, conducted the scoring process for adnexal lesions. This radiologist underwent extensive training in utilising the established lexicon for precise scoring and employed the ACR O-RADS calculator to maintain standardised risk assessment protocols. To minimise intraobserver variability, all measurements and evaluations were consistently performed by the same radiologist, ensuring uniform interpretation of US findings. Given the study's design, no interobserver variability measures were required as it was conducted under the supervision of this highly experienced observer.

During US examinations, static images and cine clips of various pelvic structures were routinely captured. Grey scale and Doppler imaging were employed to assess any identified ovarian, adnexal, or pelvic lesion.

Adnexal lesions were categorised based on their size, location, internal consistency, and definition of borders. Additionally, Colour or power Doppler US was utilised to evaluate lesion vascularity and confirm the presence of any solid component. Each mass received an O-RADS US score [6].

Patient demographics such as age, symptoms, and menopausal status were documented. Surgical patients had their final pathological results recorded, serving as the reference standard for histopathology and final clinical diagnosis. For patients without surgery, follow-up imaging details and any changes over time were noted if available. Lesions were classified as benign if they remained the same size or decreased during follow-up imaging or exhibited typical benign imaging characteristics.

The US findings using the O-RADS classification system were compared with surgical excision and pathology results for 18 suspicious masses, while the remaining 32 benign lesions were monitored for 6-12 months until their final clinical diagnosis was determined. Patients were followed up with USG every 3 to 6 months, depending on the initial risk assessment and clinical judgment, to ensure timely detection of any changes while minimising unnecessary frequent imaging. The selection of O-RADS score 4 as a cutoff is endorsed by the American College of Radiology guidelines (Andreotti RF et al.,) and reinforced by recent studies validating its effectiveness in stratifying risks and managing adnexal masses (Jha P et al.,) [6,17].

## STATISTICAL ANALYSIS

Statistical analysis was conducted using SPSS version 24.0 to calculate the sensitivity, specificity, accuracy, PPV, and NPV for O-RADS US results in diagnosing ovarian masses.

## RESULTS

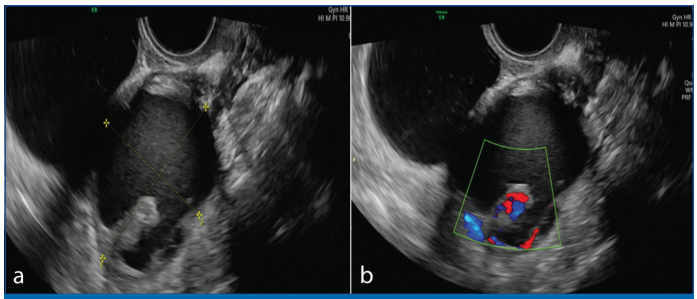
In the study, 50 patients with 50 suspicious adnexal mass lesions were included, with 35 being premenopausal and 15 postmenopausal. The patients' ages ranged from 18 to 83 years, with a mean age of 41.68±15.51 years. The most common presenting complaint among patients was pelvic pain 15 (30%), followed by dysmenorrhoea 10 (20%), vaginal discharge 9 (18%), abdominal mass 8 (16%), amenorrhoea 5 (10%), and weight loss 3 (6%).

The study's US O-RADS diagnosis results for 50 adnexal lesions revealed that 18 lesions were scored as O-RADS 2 (36%), 14 lesions as O-RADS 3 (28%), 14 lesions as O-RADS 4 (28%), and four lesions as O-RADS 5 (8%), based on the analysis of lesion morphology, including size, consistency, and vascularity, using the O-RADS US scoring system [Table/Fig-1].

| O-RADS US score | No. of lesions |
|---|---|
| 2 | 18 |
| 3 | 14 |
| 4 | 14 |
| 5 | 4 |

**[Table/Fig-1]:** Distribution of no of lesions according to O-RADS US risk score.

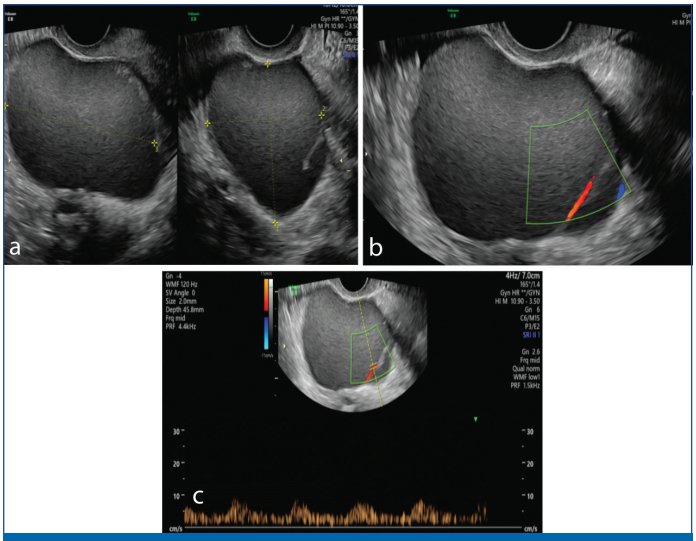
Eighteen out of 50 lesions were malignant (36%). The most common malignant pathology was mucinous cystadenocarcinoma 8 (44%) [Table/Fig-2a,b,3a-c], followed by serous cystadenocarcinoma (4/18; 22%) [Table/Fig-4a,b]. Two lesions initially scored as benign (Score 3) grew in size on follow-up imaging and were diagnosed as low-grade borderline cystadenocarcinoma on histopathology. Additionally, two lesions given a score of 4 on imaging evaluation revealed inflammatory smears on Fine Needle Aspiration Cytology (FNAC) and were diagnosed as chronic tubo-ovarian inflammatory lesions (benign) [Table/Fig-5a,b].



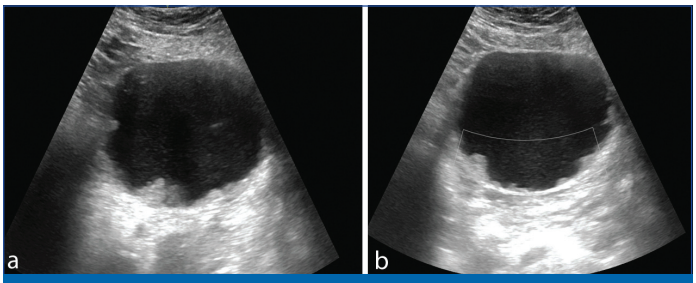

**[Table/Fig-2a,b]:** Grey scale and colour Doppler transvaginal images in a patient presenting with subacute pelvic pain shows a unilocular cystic lesion with peripheral solid component (colour score 2-3). This was given O-RADS US score 4 and was diagnosed as mucinous cystadenocarcinoma on histopathology.

The remaining 30 lesions, which were determined to be of benign aetiology, included serous and mucinous cystadenomas 4 (13%), haemorrhagic cysts 8 (26%) [Table/Fig-6a,b], endometrioma [Table/Fig-7a-c] 4 (13%), hydrosalpinx 2 (6.6%), dermoid (4/30; 13%), parovarian cyst 2 (6.6%), and follicular/simple cyst (6/30; 20%). The final diagnosis based on histopathology or follow-up of all lesions is presented in [Table/Fig-8].

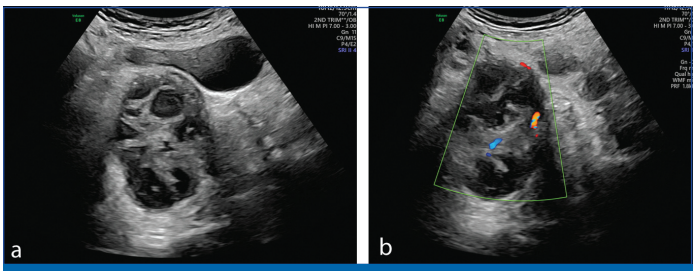
Keeping O-RADS score 4 and above as the cutoff for malignant lesions, 30 lesions were true negative and 16 were true positive, while two lesions were false positive and two lesions were false negative [Table/Fig-9].



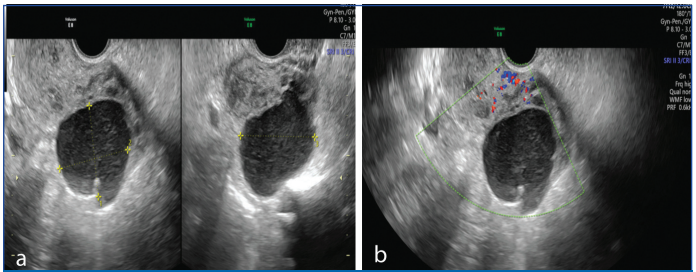
**[Table/Fig-3a-c]:** Grey scale and colour doppler transvaginal images in a patient presenting with abdominal fullness and dysmenorrhoea shows a unilocular cystic lesion with dense internal echoes and irregular septa showing intense vascularity (colour score 3) and arterial spectral waveform. Ascites was also noted. This was given O-RADS US score 5 and was diagnosed as mucinous cystadenocarcinoma on histopathology.



**[Table/Fig-4a,b]:** Grey scale transabdominal images in a patient shows a unilocular cystic lesion with multiple peripheral papillary projections (>4). On colour doppler no demonstrable vascularity was noted in the solid component. O-RADS US score 5 was given and histopathology showed features of serous cystadenocarcinoma.

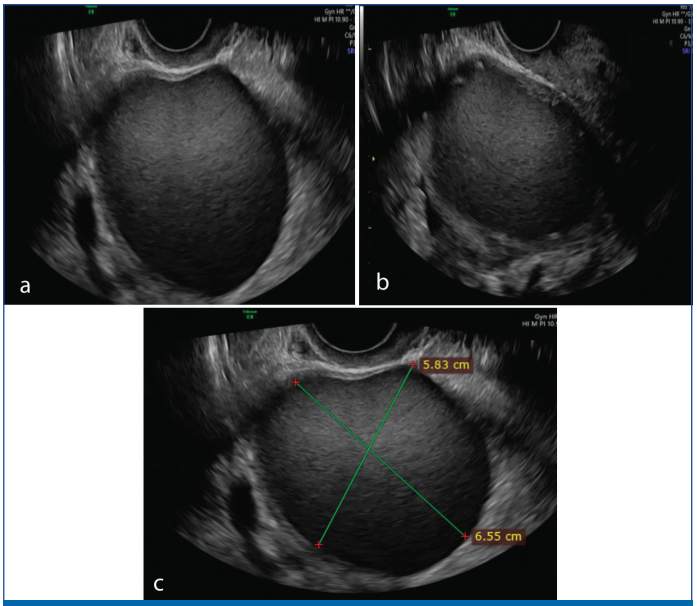


**[Table/Fig-5a,b]:** Grey scale and colour doppler imaging in patient presenting with acute pelvic pain shows a multiloculated cystic lesion with solid component showing vascularity consistent with colour score 2. Based on imaging this was graded as score 4 lesion. However, on FNAC inflammatory smears was found, consistent with diagnosis of tubo-ovarian abscess.



**[Table/Fig-6a,b]:** Transvaginal ultrasonographic images show a unilocular cystic lesion with multiple internal reticulation representing haemorrhagic cyst. This was graded as O-RADS US score 2 and resolved on follow-up imaging.

The present study showed a high sensitivity of 88.89%, specificity of 93.75%, accuracy of 92%, PPV of 88.89%, and NPV of 93.75%. The Receiver Operating Curve (ROC) curve was calculated keeping O-RADS 4 as the cutoff for malignancy with an area under the curve of 0.91 [Table/Fig-10].




**[Table/Fig-7a-c]:** Transvaginal US images show a left adnexal cyst with low level dense internal echoes with peripheral echogenic foci and nonvascular nodules representing endometrioma. This was categorised as O-RADS US category 2 lesion (size <10 cm).

| O-RADS score | No. of lesions | Final diagnosis on histopathology/ follow-up | No. of lesions |
|---|---|---|---|
| 2 | 18 | Haemorrhagic cyst | 8 |
| | | Endometrioma | 1 |
| | | Follicular/simple cyst | 6 |
| | | Dermoid | 1 |
| | | Parovarian cyst | 2 |
| 3 | 14 | Endometrioma | 3 |
| | | Hydrosalpinx | 2 |
| | | Dermoid | 3 |
| | | Serous cystadenoma | 2 |
| | | Mucinous cystadenoma | 2 |
| | | Borderline serous tumours | 2 |
| 4 | 14 | Endometriod carcinoma | 2 |
| | | Dysgerminoma | 1 |
| | | Mucinous cystadenocarcinoma | 7 |
| | | Serous cystadenocarcinoma | 2 |
| | | Tubo-ovarian abscess | 2 |
| 5 | 4 | Adenocarcinoma | 1 |
| | | Mucinous cystadenocarcinoma | 1 |
| | | Serous cystadenocarcinoma | 2 |

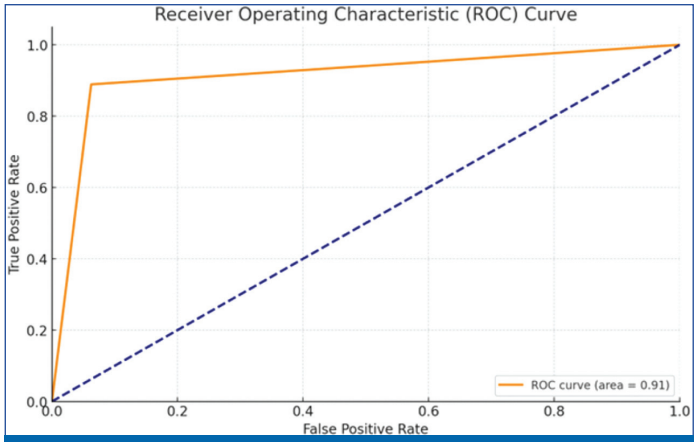
**[Table/Fig-8]:** Final diagnosis based on histopathology/follow-up of all lesions.

| Ultrasound result | Malignancy positive (n) | Malignancy negative (n) |
|---|---|---|
| Positive | 16 (True positive) | 2 (False positive) |
| Negative | 2 (False negative) | 30 (True negative) |

**[Table/Fig-9]:** Diagnostic accuracy of O-RADS US with cut-off score 4 and above.

## DISCUSSION

Accurate characterisation of adnexal lesions on imaging is paramount due to the asymptomatic nature of these lesions until late stages, contributing to ovarian malignancy ranking as the fifth most common cause of cancer-related deaths in women [18]. Late-stage presentations further complicate management, highlighting the importance of precise imaging-based characterisation. This approach aids in avoiding unnecessary surgeries for benign lesions, minimising complications and financial strain on patients. Furthermore, it facilitates timely referral of suspected malignant cases to gynaecological oncologists, ensuring prompt initiation of treatment and potentially improving patient outcomes [19-21].




**[Table/Fig-10]:** The ROC curve illustrates the diagnostic performance of the O-RADS scoring system with a cut-off score of 4 for identifying malignancy. The true positive rate (sensitivity) is plotted against the false positive rate (1- specificity). An AUC of 0.91 demonstrates excellent discriminative ability of the O-RADS system to differentiate between benign and malignant adnexal lesions.

The study comprised 50 patients with suspected ovarian masses, with most being asymptomatic. However, pain was reported as the primary complaint in some patients. This was in agreement with Bhagde AD et al., who stated that many adnexal masses are asymptomatic, while abdominal pain was seen in about 92% of patients. Also, Givens V et al., stated that pelvic or abdominal pain was the predominant symptom reported by women with ovarian cancer [22,23].

Ultrasound is crucial as the primary diagnostic imaging modality for evaluating adnexal lesions. The structured terminology of the O-RADS US plays a pivotal role in accurately characterising ovarian masses. This precise description is essential for developing customised management strategies based on each patient's condition [24,25].

In present study, including 35 premenopausal and 15 postmenopausal patients with adnexal masses scored based on O-RADS US classification system revealed that 32 lesions were scored benign (O-RADS 2-3), while 18 lesions scored as O-RADS US 4-5 that are considered to be likely of malignant aetiology, with a significant proportion of them being in the postmenopausal age group. This was in coincidence with Zhang T et al., a study in 2017, which analysed 263 masses using U/S GI-RADS, found 86 benign neoplasms (GI-RADS 3), 101 GI-RADS 4 lesions, and 28 GI-RADS 5 lesions. Additionally, the study noted that cancer patients tended to be older than those with benign tumours [26].

The final diagnosis revealed that the majority of cases were of benign origin (32/50; 64%), with a 36% malignancy rate. This finding aligns with Zhang T et al., a study of 242 patients, which included 153 benign and 110 malignant tumours. Additionally, Prasad S et al., studied 56 masses, identifying four malignant masses, 24 benign masses, and others related to physiological cysts or infective processes [26,27].

The present study's results using the O-RADS US score classification system, keeping score 4 as the cut-off for malignancy, showed sensitivity of 88.89%, specificity of 93.75%, with a PPV and an NPV of 88.89% and 93.75%, respectively. In comparison, Solis Cano DG et al., a study had lower sensitivity (52%) and specificity (84%) for detecting ovarian cancer using O-RADS, with varying NPV, PPV, and accuracy. These differences could be due to different proportions of malignant lesions in the study populations [28]. The comparison of diagnostic performance of the O-RADS US risk score between the current study and previously published studies has been depicted in [Table/Fig-11] [17,29-32]. The present study benefits significantly from the involvement of a highly experienced radiologist with over 15 years of expertise in USG, ensuring consistent and reliable interpretation of adnexal lesions using the O-RADS US system. The standardised risk assessment facilitated by the American College of Radiology (ACR) O-RADS calculator and adherence to established lexicon guidelines further enhance the study's methodological rigour. By minimising intraobserver variability through the consistent handling of measurements and evaluations by the same radiologist, the study ensures robust and dependable US findings.

| Authors name | Year of study | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|---|
| Chen H et al., [29] | 2019 | 92 | 89 | 76 | 96 |
| Guo Y et al., [30] | 2017-2021 | 91 | 82 | 62 | 97 |
| Jha P et al., [17] | 2011-2014 | 90.6 | 81.9 | 31.4 | 99 |
| Basha MA et al., [31] | 2020 | 96.6 | 92.8 | 83.5 | 98.6 |
| Cao L et al., [32] | 2021 | 98.7 | 83.2 | 70.4 | 99.3 |
| Present study | 2023-2024 | 88.89 | 93.75 | 88.89 | 93.75 |

**[Table/Fig-11]:** Comparison of diagnostic performance between the current study and previously published studies using the O-RADS US risk score [17,29-32].

Future studies should validate findings across diverse settings and populations to enhance generalisability. Collaboration with multiple centres could increase the sample size and diversity, strengthening study outcomes. Extending follow-up for benign lesions and integrating O-RADS into routine practice would improve long-term management, supported by educational initiatives to enhance system adoption among clinicians.

### Limitation(s)

The present study had some limitations and pitfalls, such as the relatively low number of lesions included and reliance on follow-up clinical diagnosis for most benign lesions.

## CONCLUSION(S)

In conclusion, the study validated the effective diagnostic performance and reliability of O-RADS US for diagnosing ovarian and adnexal masses. The O-RADS-US system proved to be an efficient method for risk stratification with high diagnostic performance and less complexity compared to other systems. It contributed to reducing unnecessary surgical interventions for benign lesions and facilitated planning for further evaluation and management of malignant lesions.

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- Plagiarism X-checker: May 25, 2024
- Manual Googling: Jul 02, 2024
- iThenticate Software: Jul 06, 2024 (10%)

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- Financial or Other Competing Interests: None
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