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# A Comparative study between New Ultrasound Gynecological Reporting Data System (GIRADS) and Ovarian Reporting Data System (ORADS) in Evaluating Ovarian Lesions

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## ABSTRACT

**Background:** Adnexal masses are a frequent cause of patient complications that necessitate diagnostic imaging, surgical intervention, and postoperative pathology. No large-scale clinical investigation had previously explored the wide variation in GI-diagnostic RADS's performance among trials.

**Objective:** The aim of the current study was to highlight the role of Gynecological Reporting Data System (GIRADS) and Ovarian Reporting Data System (ORADS) in differentiating ovarian lesions and determine which of them a higher accuracy has based on biopsy result and short interval follow up.

**Patients and methods:** A cross-sectional study was conducted on 100 female patients with ovarian mass, attending at Radiodiagnosis Department of Zagazig University Hospitals from March 2020 to March 2021.

**Results:** With an AUC of 0.983, 100% sensitivity, 96% specificity, 82% positive predictive value (PPV), 100% negative predictive value (NPV), and 97% accuracy, GIRAD can distinguish between benign and malignant lesions. ORAD has a high area under the curve (AUC) for distinguishing between benign and malignant lesions; its sensitivity is 92.9%, specificity is 91.9%, PPV is 65%, and NPV is 98.8%. Kappa (κ) = 0.834 indicates moderate agreement between GIRAD and ORAD in determining whether lesions are benign or malignant.

**Conclusion:** Clinical decision-making appears to be aided by the GI-RADS categorization of adnexal masses, in comparison to the GIRADS, the ORADS classification system for ovarian masses is a useful non-invasive diagnostic tool with excellent sensitivity in differentiating between benign and malignant neoplastic lesions. When compared to the ORADS simple rules, the GIRADS was more sensitive while maintaining equivalent specificity as well as reliability.

**Keyword:** Gynecological Reporting Data System (GIRADS), Ovarian Reporting Data System (ORADS), Ovarian Lesions.

## INTRODUCTION

Adnexal masses can have gynecologic or non-gynecologic origins and can range from benign luteal cysts to malignant ovarian tumors [(1)]. Ovarian cancer is the second most frequent form of gynecologic cancer, with an estimated 22,000 new cases identified annually in the United States in 2010 alone [(2)].

Age, a family history of breast or gynecologic cancer, the existence of the breast cancer gene "BRCA" or other genetic cancer syndromes, infertility treatments, obesity, and a lack of children are all risk factors for ovarian cancer. The patient's contraceptive method and reproductive state also play an influence [(3,4)].

When performed by an experienced clinician, transvaginal sonography (TVS) achieves great affectability for identifying ovarian disease and has been shown to be useful for selecting the most cautious treatment option for ovarian masses [(5)]. TVS has come a long way in terms of its diagnostic accuracy, however a recent large multicenter study found that it has a potentially alarmingly high false positive rate of about twenty-four percent [(6)].

Randomized research has shown that administrator experience may be to blame for the high proportion of false positives. Another possibility is that the sonographer's findings were not properly communicated to the practitioner. It's true that descriptions of sonographic findings in reports aren't always clear [(7)]. Recently many reporting systems are developed to increase the accuracy in diagnosing ovarian masses as GIRADS, ORADs and IOTA (International ovarian tumor analysis group) [(8)].

The aim of the current study was to highlight the role of Gynecological Reporting Data System (GIRADS) and Ovarian Reporting Data System (ORADS) in differentiating ovarian lesions and determine which of them a higher accuracy has based on biopsy result and short interval follow up.

## PATIENTS AND METHODS

A cross-sectional study was conducted on 100 female patients with ovarian mass, attending at Radiodiagnosis Department of Zagazig University Hospitals from March 2020 to March 2021.

**Sample size:** A Comprehensive sample was taken including all female patients with ovarian mass, attending at Radiodiagnosis Department Zagazig University Hospitals for 6 months. The sample was 100 cases.

**Inclusion criteria:**

- Any female patient with ovarian cyst or mass during routine trans-abdominal or pelvic US.
- Available pathologic report or regular follow-up.



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**Exclusion criteria:**

- Refusal of patients to filling consent.
- Patient with a previous history of the operated ovarian lesion.
- Patient missed during follow-up or not provided pathology report.
- Vaginitis.

**Methods:**

**All patients were subjected to:**

1. **Complete history taking** (age, Family history for ovarian cancer, menstrual cycle).
2. Conditions such as diabetes, organ failure, or a recent inflammatory or infectious state are also considered to be co-morbidities.
3. **Clinical examination** (blood pressure, heart rate, breath)**.**
4. **Laboratory investigation.**
5. Complaints as severe abdominal pain, vaginal discharge or bleeding.
6. **Imaging** including ***Transvaginal (TV) ultrasound (US) for morphologic evaluation*****.**

**Ultrasound examination:**

Every woman had an ultrasound, either a TV or a transabdominal one. Adjustments were made by hand to the primary b-mode parameters of the US machines in order to achieve consistent subjective assessments of image quality. Filling the bladder to the proper height (1-2 cm above the uterine fundus) was necessary for the examination. Sagittal and transverse images were taken (oblique image may be needed).

We panned the transducer from side to side to check out the adnexa. To reduce discomfort and bring the uterus and ovaries within the focus zone, a transvaginal sonogram (TVS) was conducted using a 4-8 MHz endoluminal probe after the patient had emptied their bladder. The transducer head was prepared with US gel and a condom was used after the probe was sterilized. Pelvic imaging was performed in both the anterior-posterior and transverse planes. Color and power Doppler was performed on all instances to identify vascularity and discriminate between solid components of worrisome lesions and benign ones.

**Color Doppler to identify vascular state within the mass:**

Post-operative biopsy or cytology for histopathological confirmation of imaging findings.

**GI-RADS:**

The lesions were analyzed for morphology and color Doppler. Location, size, echo pattern, associated solid component, and septa or papillary projections were some of the morphological criteria. High or low vascularity, as well as central or peripheral vessel layout, were detected using color Doppler. Lesion suspicion was raised when central vascularity was aberrant and peripheral vascularity was absent or weak.

For adnexal masses, we utilized the GI-RADS classification system, wherein grades 1 and 2 were deemed definitely benign, grades 3 and 4 were considered probably malignant, and grades 4 and 5 were considered very probably malignant.

When color or power microscopy revealed vascularization within solid areas, papillary projections, or the center area of a solid tumor, a malignant diagnosis was considered likely. The criteria established by the International Ovarian Tumor Analysis Consortium for Doppler assessment of ovarian tumors.

**O-RADS:**

O-RADS was used to categorize the results of transvaginal ultrasounds into two categories: benign (O-RADS 0-2) and suspicious for malignancy (O-RADS3-5). Two expert pathologists reviewed the histology reports and compared them to the diagnoses, determining whether or not the features are benign or malignant and ruling out conditions such immature teratoma, serous cystadenoma, and mixed carcinoma. Histological analysis and O-RADS diagnosis were feasible thanks to a high degree of correlation between pathology slides and ultrasound scans.

**Ethical approval:**

**This study was ethically approved by the Institutional Review Board [IRB] of the Faculty of Medicine, Mansoura University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.**

***Statistical analysis***

For this study, we used IBM SPSS Version 27.0. Numerical information was summarized using minimum and maximum values, as well as means, standard deviations, medians, and interquartile ranges. The results were considered significant if they fell within a 95% confidence interval. Qualitative data were defined as numbers and percentages. There was a Chi-square test performed. Over twenty percent of the cells had an estimated count of less than 5, necessitating Chi-square adjustment for categorical variables. P value $\leq 0.05$ was considered to be statistically significant.

**RESULTS**

Table 1 summarizes the sociodemographic characteristics and complaints of the participants.

**Table (1): Demographics and complaints of the studied cases.**

| Demographic data | Cases (n = 100) | |
|---|---|---|
| Age (Years) | | |
| Min. – Max. | 23.0 – 57.0 | |
| Mean ± SD. | 39.42 ± 11.55 | |
| Menopause | **No.** | **%** |
| No | 83 | 83 |
| Yes | 17 | 17 |
| Family history for ovarian cancer | **No.** | **%** |
| +ve | 16 | 16 |
| -ve | 84 | 84 |
| Complaint | | |
| Severe abdominal pain | 54 | 54 |
| Vaginal discharge | 22 | 22 |
| Screening | 11 | 11 |
| Check-up | 6 | 6 |
| Bleeding | 7 | 7 |

Table 2 shows GIRADS lesion classification and stages.

**Table (2): GIRADS examination results of the studied cases.**

| Variable | Cases | |
|---|---|---|
| GIRADS | **No.** | **%** |
| I | 0 | 0.0 |
| II | 57 | 57 |
| III | 26 | 26 |
| IV | 13 | 13 |
| V | 4 | 4 |
| GIRADS lesion classification | No. | % |
| Probable- benign (GIRADS I-III) | 83 | 83 |
| Probable- malignant (GIRADS IV-V) | 17 | 17 |

Table 3 shows ORADS examination of the participants with GIRADS and lesion classification.

**Table (3): ORADS examination results of the studied cases.**

| Variable | Cases | |
|---|---|---|
| GIRADS | **No.** | **%** |
| I | 0 | 0.0 |
| II | 51 | 51 |
| III | 29 | 29 |
| IV | 15 | 15 |
| V | 5 | 5 |
| ORADS lesion classification | No. | % |
| Probable- benign (ORADS I-III) | 80 | 80 |
| Probable- malignant (ORADS IV-V) | 20 | 20 |

Table 4 shows that there were 86 (or 86%) benign lesions and 14 (or 14%) malignant ones.

**Table (4): Reference Index of the study population**

| Variable | Cases | |
|---|---|---|
| Lesion classification (final diagnosis) | **No.** | **%** |
| Benign | 86 | 86 |
| Malignant | 14 | 14 |

With an AUC of 0.983, 100% sensitivity, 96% specificity, 82% positive predictive value (PPV), 100% negative predictive value (NPV), and 97% accuracy, GIRAD has been proven to distinguish between benign and malignant lesions. ORAD was demonstrated to be able to distinguish between benign and malignant lesions with an area under the curve (AUC) of 0.924, sensitivity 92.9%, specificity 91.9%, positive predictive value (PPV) 65%, negative predictive value (NPV) 98.8% and accuracy 92%.

**Table (5): Comparison of GIRAD and ORAD's ROC curves for detecting malignant and benign lesions.**

| Variable | AUC | Sens% | Spec% | PPV% | NPV% | Accuracy % |
|---|---|---|---|---|---|---|
| GIRAD | 0.983 | 100 | 96.5 | 82.4 | 100 | 97 |
| ORAD | 0.924 | 92.9 | 91.9 | 65 | 98.8 | 92 |

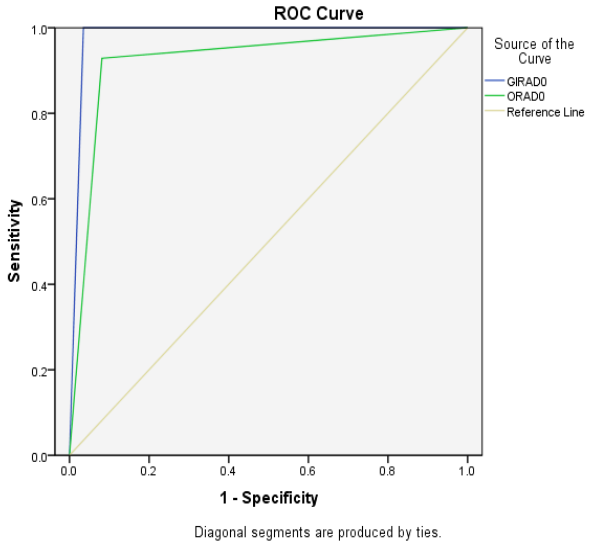



**Figure (1):** Comparison of GIRAD and ORAD's ROC curves for detecting malignant and benign lesions.

Kappa (κ) between GIRAD and ORAD for determining whether lesions were benign or malignant was 0.834, indicating fair significant agreement (**Table 6**).

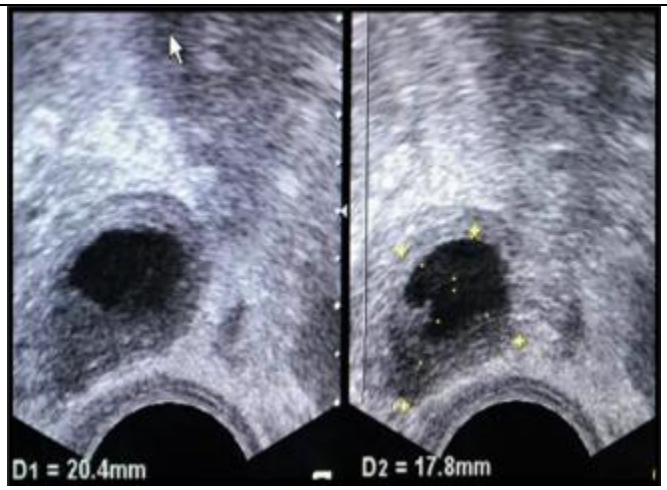
**Table (6): The GIRAD and ORAD agree on whether a lesion is more likely to be malignant or benign.**

| GIRAD | | | | | |
|---|---|---|---|---|---|
| ORAD | Benign | | Malignant | | Kappa (κ) |
| | No. | % | No. | % | |
| Benign | 79 | 79.0 | 1 | 1.0 | 0.834 |
| Malignant | 4 | 4.0 | 16 | 16.0 | |

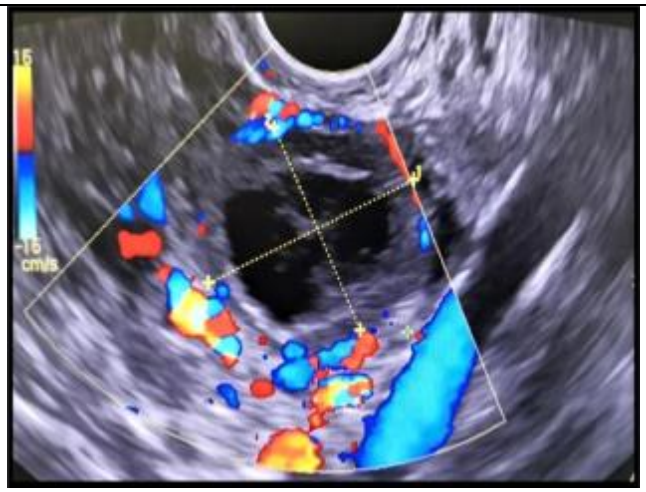
GIRAD and ORAD showed good substantial agreement regarding Histological lesions classification (**Table 7**).

**Table (7): Agreement between Specific Histopathology and classification of lesions according to GIRADS and ORADS among 73 cases.**

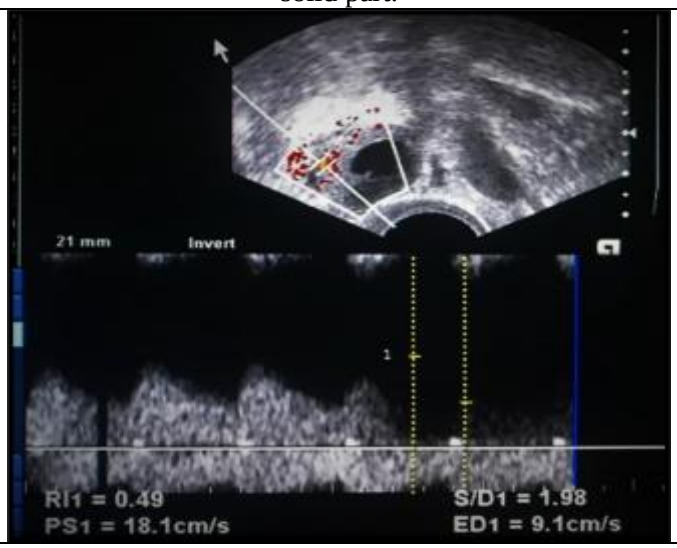
| Histopathology | GI-RAD | | | | N | % | O-RADS | | | | N | % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2 | 3 | 4 | 5 | | | 2 | 3 | 4 | 5 | | |
| Serous cyst adenoma | 19 | 2 | 0 | 0 | 21 | 15.3 | 21 | 0 | 0 | 0 | 21 | 15.3 |
| Endometriotic cyst | 11 | 0 | 0 | 0 | 11 | 8.3 | 11 | 0 | 0 | 0 | 11 | 8.3 |
| Simple serous cyst | 3 | 0 | 0 | 0 | 3 | 2.1 | 1 | 0 | 0 | 0 | 3 | 2.1 |
| Mucinous cystadenoma | 0 | 12 | 0 | 0 | 12 | 8.7 | 0 | 12 | 0 | 0 | 12 | 8.7 |
| Cyst adeno fibroma | 0 | 4 | 0 | 0 | 4 | 2.9 | 0 | 4 | 0 | 0 | 4 | 2.9 |
| Benign cystic Teratoma | 0 | 3 | 0 | 0 | 3 | 2.1 | 0 | 3 | 0 | 0 | 3 | 2.1 |
| Malignant Teratoma | 0 | 0 | 2 | 0 | 2 | 1.4 | 0 | 0 | 2 | 0 | 2 | 1.4 |
| Malignant fibrothecoma | 0 | 0 | 1 | 0 | 1 | 0.7 | 0 | 0 | 1 | 0 | 1 | 0.7 |
| Mucinous cystadenocarcinoma | 0 | 0 | 2 | 0 | 2 | 1.4 | 0 | 0 | 2 | 0 | 2 | 1.4 |
| Serous cystadenocarcinoma | 0 | 0 | 5 | 7 | 12 | 8.7 | 0 | 0 | 5 | 7 | 12 | 8.7 |
| Tubo ovarian abscess | 0 | 2 | 0 | 0 | 2 | 1.4 | 0 | 2 | 0 | 0 | 2 | 1.4 |




(A) Right side slight thick wall ovarian cyst measuring 17x20 mm with anechoic center. No calcification, nor solid part.

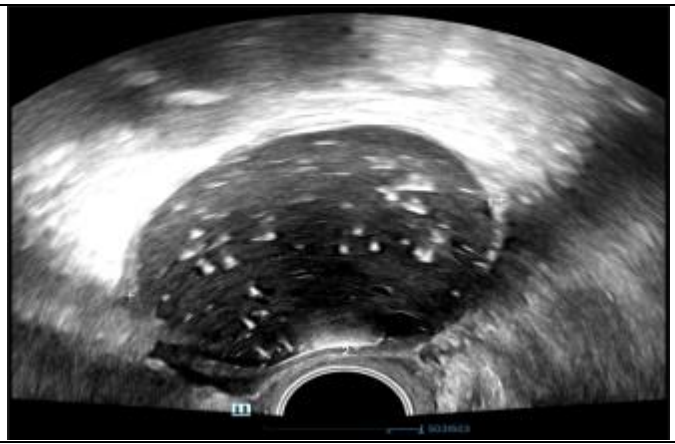



(B) Color Doppler shows vascularity at the periphery gives the appearance of Ring of fire sign.

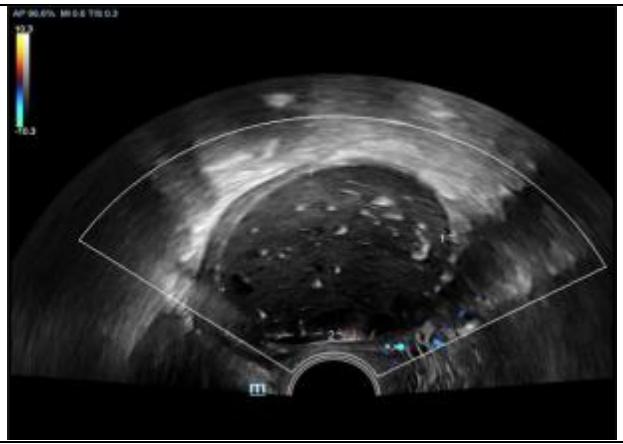



(C) Pulsed Doppler shows the RI=0.49 (Low Resistant arterial flow).

**Figure (2):** A 33-year-old female case complaint: Mild right side pelvic pain. This cyst was diagnosed as Corpus luteum and classified as GI-RAD 2 & ORADS 1. After follow up, the corpus luteum has resolved spontaneously.

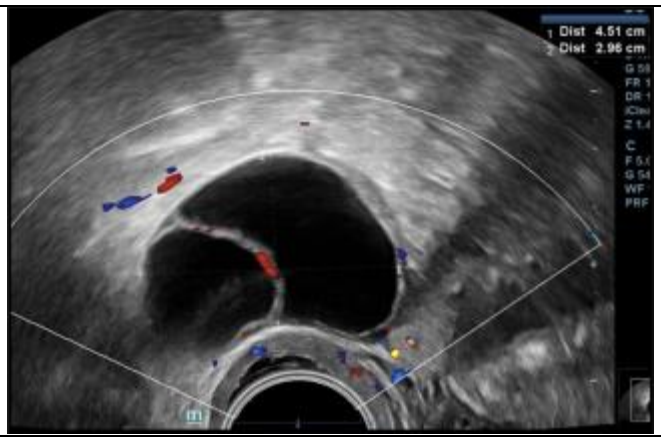


(A) A well-defined large left adnexal cystic mass measuring 67x51mm with non-shadowing echogenic foci with posterior enhancement.

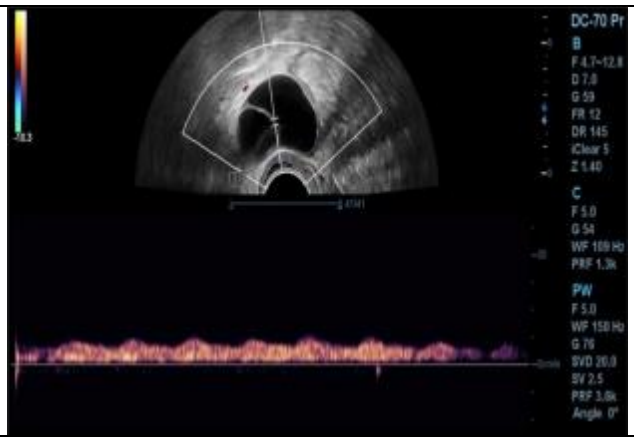


(B Color Doppler There is no vascularity is seen.

**Figure (3):** A 26-year-old female patient complaint: Irregular menses & pelvic pain, The mass was diagnosed as Dermoid cyst and classified as GI-RAD3 &ORADS2, the mass was removed and the diagnosis was confirmed by Histopathology.

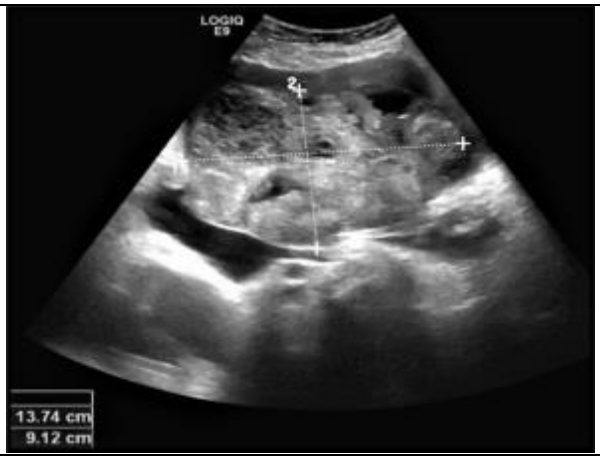



(A) There is a right side bilocular cystic adnexal lesion measuring 45x29 mm appears smooth, of thin walls with anechoic fluid, no internal echoes (denoting clear contents), just thick complete internal septum but no papillary projection, calcification nor solid elements.

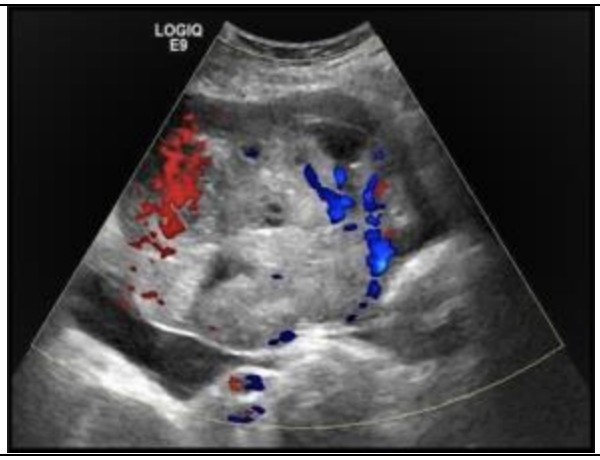


(B) Pulsed Doppler shows no pulsatile venous flow along the middle of the septum.

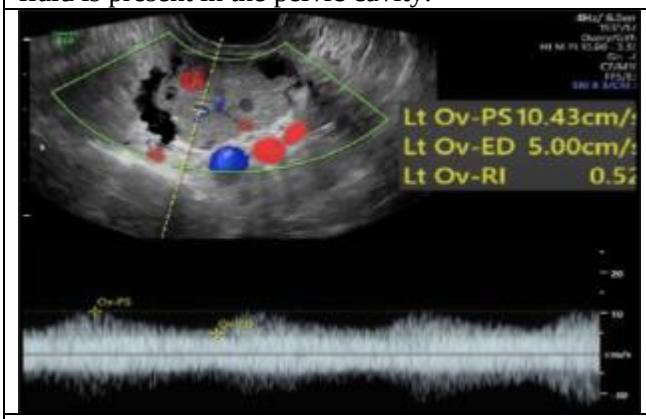
**Figure (4):** A 44-year-old female patient complain: Lower back & pelvic pain, this lesion was diagnosed as benign lesion and classified as GIRADS 3 & ORADS 3, the mass was removed and diagnosed as Serous cystadenoma by histopathology.




(A) A lobulated, 137 mm x 90 mm, mixed solid and cystic ovarian lesion is present on the patient's left side. There were no calcifications found. Internal echoes are very loud and the fluid is murky. Mild free fluid is present in the pelvic cavity.




(B) According to color Doppler, the lesion's solid area contains vascularity.




(C) Pulsed doppler image show RI =0.52 (Low Resistive arterial flow pattern).

**Figure (5):** A 51-year-old female case complaint: Disturbed menstrual bleeding and stomach pain, according to the GIRADS and High Risk ORADS classification systems, the mass represents a malignant neoplastic lesion. Ovarian germ cell tumor was found after surgical removal of the tumor.

## DISCUSSION

Amor F created the Gynecologic Imaging Reporting and Data System (GI-RADS) to standardize the gynecologic ultrasound report. A higher GI-RADS score suggests that the mass is more likely to be malignant. The scale ranges from 1 to 5. Previous research found that the kappa coefficients for GI-RADS categorization were 0.896 (95% CI: 0.775 to 1.0). No large-scale clinical investigation had previously explored the wide variation in GI-diagnostic RADS's performance among trials [(9)].

Mean age of patients among our study was 39.42 (SD 11.55). A total 17 (17%) females had menopause and there were 16 (16%) with positive family history for breast cancer.

**Ahmed** [(10)] revealed that ultrasonography was found to be beneficial in diagnosing 50 patients with 50 lesions suspected to be ovarian tumors using the O-RADS categorization system. The ages of the patients ranged from 19 to 67, with 15 being premenopausal and 35 being postmenopausal.

In this thesis we illustrated that among the studied cases there were 54 (54%) with severe abdominal pain, 22 (22%) with vaginal discharge, 11 (11%) admit for screening, 6 (6%) to do check-up and 7 (7%) with vaginal bleeding.

This was in agreement with **Givens *et al.*** [(3)] who reported that the most common sign of ovarian cancer in women was discomfort in the pelvis or abdomen. **Ahmed** [(10)] discovered that 29 out of 35 postmenopausal patients had no symptoms, while 13 out of 15 premenopausal patients did.

**Hamed *et al.*** [(11)] found that 60% of women with ovarian lesions reported abdominal pain, 20% reported abdominal pain and enlargement, 14% reported menstrual abnormalities, vaginal bleeding, and infertility, and 60% reported no symptoms at all, according to a study evaluating the utility of ultrasound for this purpose.

In this study, we demonstrated that among the cases examined by mammography, none had GIRADS of I, 57% had GIRADS of II, 26% had GIRADS of III, 13% had GIRADS of IV, and 4% had GIRADS of V; 83% of lesions were classified as benign, and 17% as malignant.

**Amor *et al.*** [(12)] concluded that 92 (21%) of the 432 masses evaluated were GI-RADS 2, 184 (43%) were GI-RADS 3, 40 (9%) were GI-RADS 4, and 116 (27%) were GI-RADS 5. Cases with GI-RADS scores of 2 and 3 had considerably smaller tumor volumes than those with GI-RADS scores of 4 and 5, while scores of 2 and 3 and 4 and 5 did not vary.

**Abd elsalam *et al.*** [(13)] who analyzed GIRADS classification for 112 lesions found that 32.1% of lesions were GI-RADS 2, 28.6% of lesions were GI-RADS 3, 11.6% of lesions were GIRADS 4, and 27.7% of lesions were GI-RADS 5, with 49.1% being ovarian neoplastic.

In our study we observed that among the cases analyzed, 80% were classified as benign and 20% as malignant based on mammography findings; 0% had ORADS of I, 51% had ORADS of II, 29% had ORADS of III, 15% had ORADS of IV, and 5% had ORADS of V.

**Ahmed** [(10)] imaging results determined that 13 lesions were classified as ORADS 3, which indicates a benign etiology, 18 lesions were classified as O-RADS 4, and 19 lesions were classified as O-RADS 5, which indicates a malignant etiology.

Our results showed that regarding lesion classification (Doppler and biopsy) there were 86 (86%) benign and 14 (14%) malignant. **Prasad *et al.*** [(14)] analysed 56 tumours and discovered just 4 to be cancerous, 24 to be noncancerous, and the rest to be physiological cysts or infectious processes. Our results were in contrast to **Ahmed** [(10)] discovered that 15 of the tumors (or 30%) were benign, but that malignancy was the cause in 70% of the cases.

In this study we found that according to final diagnosis there were 3 (3%) benign mature cystic teratoma, 9 (9%) corpus luteum cyst, 4 (4%) cystadenofibroma, 14 (14%) endometriotic cyst, 7 (7%) high grade malignant serous cytadenocarcinoma, 5 (5%) low grade malignant serous cytadenocarcinoam, 3 (3%) malignant teratoma, 2 (2%) mucinous cystadenocarcinoma, 11 (11%) mucinous cystadenoma, 30 (30%) serous cystadenoma, 1 (1%) simaosio cystadenoma and 11 (11%) simple serous cyst. **Migda *et al.*** [(15)] observed a significant rate of cancerous tumors in our research (24.7%). Adenocarcinoma was the most common malignant tumors type (44 instances), accounting for almost 83% of all malignant tumors.

With an AUC of 0.983, 100% sensitivity, 96% specificity, 82% PPV, 100% NPV, and 97% accuracy, GIRAD has been proven to distinguish between benign and malignant lesions.

**Khalaf *et al.*** [(16)] observed a highly significant AUC of 0.96 for the GI-RADS in predicting malignant ovarian masses (P=0.002) in their diagnostic performance. **Abd elsalam *et al.*** [(13)] revealed that US GI-RADS studies showed 97% sensitivity, 73% specificity, 84% PPV, 94% NPV, and 87% accuracy. While **Prasad *et al.*** [(14)] revealed that sensitivity of 100%, specificity of 80%, PPV of 36%, and NPV of 100% were reported between histology and US GI-RADS in the diagnosis of benign and malignant ovarian cancers.

**Zhou *et al.*** [(17)] discovered that GI-RADS classification has a sensitivity of 99.1%, specificity of 85.9%, PPV of 71.1%, and NPV of 99.6%.

**Guo *et al.*** [(9)] revealed that GI-RADS was found to have a good diagnostic value, with an AUC of 0.9806 suggesting excellent performance. These findings demonstrated that the GI-RADS could distinguish adnexal masses from gynecological adnexal cancer.

ORAD was demonstrated to be able to distinguish between benign and malignant lesions with an AUC of

0.924, sensitivity of 92.9%, specificity of 91.9%, PPV of 65%, NPV of 98.8%, and accuracy of 92%.

**Ahmed** [10] found that the results showed a 96.4% sensitivity, an 84.3% specificity, an 18.5% false-positive rate, a 3.0% false-negative rate, and an 89.3% accuracy.

In this study we illustrated Kappa (κ) between GIRAD and ORAD for determining whether lesions were benign or malignant was 0.834, indicating fair significant agreement.

**Basha *et al.*** [8] found that the overall IRA agreement between O-RADS and GI-RADS was quite similar (P values 0.77 and 0.69, respectively), with a trend toward greater IRA with O-RADS than with GI-RADS. For O-RADS, the IRA varied from -0.90 to 0.59. For GI-RADS, the IRA was in the -0.90 to 0.53.

**Amor *et al.*** [12] observed a high level of agreement between observers using GI-RADS to categorize adnexal masses (weighted kappa index= 0.846).

Our study had several limitations and pitfalls, including the small number of lesions included and the reliance on a follow-up clinical diagnostic evaluation for the accurate classification of some lesions, so definitive confirmation of our findings requires additional research with a larger sample size and longer follow-up period.

## CONCLUSION

Clinical decision-making appears to be aided by the GI-RADS categorization of adnexal masses, in comparison to the GI-RADS, the O-RADS classification system for ovarian masses is a useful non-invasive diagnostic tool with excellent sensitivity in differentiating between benign and malignant neoplastic lesions. When compared to the O-RADS simple rules, the GI-RADS was more sensitive while maintaining equivalent specificity as well as reliability.

**Sponsoring financially:** Nil.
**Competing interests:** Nil.

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