Diagnostic Efficacy of Ovarian-Adnexal Reporting and Data System (ORADS) in Evaluation of Ovarian Lesions

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Abstract:

Background: The findings of this study suggest that the Ovarian-Adnexal Reporting and Data System (O-RADS) ultrasound risk stratification system are scoring algorithm that can be applied to a non-selected population of women undergoing ultrasonography examinations in radiology departments with similar diagnostic performance compared with previously studied populations.

Aim of study: The study aimed to evaluate the ovarian lesions as regarding malignancy rate, the validity and reliability through different pathological results and other imaging modalities mainly the MRI.

Patients and Methods: This study is a prospective study included seventy seven patients (fifty pre and twenty seven postmenopausal) referred from out-patient oncology clinics or in-patients at departments of South Egypt Cancer Institute (SECI) for assessing a suspicious adnexal mass lesion. Their ages ranged from 16- 75 years.

Results: The studied lesions were as following as regard (the ORADS) 15 (16.7%), 38 (42.2%), 5 (5.6%), 4 (4.4%) and 28 (31.1%) lesions were classified as ORADS caterory-1, 2, 3, 4 and 5, respectively. The main findings in the current study were that O-RADS at cutoff point> 4; it has 96.6% overall accuracy in diagnosis of nature of ovarian lesions with area under curve (AUC) was 0.986.

Conclusion: the ultrasound O-RADS classification system provide a crucial non-invasive diagnostic tool for suspected ovarian tumors to distinguish between benign and malignant neoplastic lesions,

Keywords: Ovarian-Adnexal Reporting, Ovarian Lesions

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Introduction:

US is the initial imaging modality of choice for evaluating adnexal abnormalities in women of all age groups, and accurate lesion characterization is crucial for appropriate patient care. [1,2]

Ultrasonography plays a significant role in evaluating ovarian pathology. Sonography is widely accepted as the primary radiological investigation for suspected ovarian pathology. Sonography is non-invasive, radiation-free, cost effective and widely available. Trans-abdominal (TA) and trans-vaginal (TV) ultrasound are the most commonly used approaches for performing pelvic ultrasound. [3]

In 2008, the International Ovarian Tumor Analysis (IOTA) group proposed the use of US simple rules for the diagnosis of ovarian malignancy; These are based on a set of five US features indicative for a benign tumor (B features), and five US features indicative for a malignant tumor (M features). [4]

In 2009, Amor et al designed the Gynecology Imaging Reporting and Data System (GI-RADS) as an attempt allowing standardized reporting of AM. This system is based on recognition patterns and criteria provided (IOTA). [5]

The American College of Radiology (ACR) [6] published the Ovarian-Adnexal Reporting and Data System (O-RADS), which provides an up-to-date suggestion to stratify the AM according to sonographic features. The O-RADS offers a comprehensive algorithm that categorizes AM by their possibility of

being normal (O-RADS 1), to high risk of malignancy (O-RADS 5). [7]

Aim of work:

To study the added value of O-RADS in evaluation of ovarian lesions as regarding malignancy rate, the validity and reliability through different pathological results and other imaging modalities mainly the MRI.

Patients and Methods:

Ethical consent

Academic and Ethical Committee approved the research (Approval code 17101352) All participants agreed to participate in the research after signing an informed written permission form. The Declaration of Helsinki, a global standard for the ethical conduct of medical research involving human participants, has been followed throughout this project.

This study is a prospective study done at SECI Assiut university from January 2021 to December 2022 including 77 patients referred from out-patient oncology clinics or in-patients for assessing a suspicious adnexal mass lesion. Their ages ranged from 16- 75years. Study ethics committee approvals code was obtained for this work.

Inclusion criteria:

a. All patients enrolled in the study were referred to radiology department for evaluation of suspicious adnexal mass lesions by trans-vaginal (TV) or trans-abdominal US examination, or both. All patients were compared with histopathological results and/or other modalities mainly MRI as a gold standard.

Exclusion criteria:

1-Patients refuse to be part of study and undergo examination.

2- Obese patients not allowing accurate and conclusive ultrasound evaluation of the ovaries

U/S protocol and technique

All US tests were done using the same system (Logiq 9, GE Healthcare Digital Color Doppler ultrasound system) using transabdominal probe of frequency 2.5□5 MHz and trans vaginal probe of frequency 5MHz to rule out the probability of system-to-system variations in the ultrasound imaging, a trans-abdominal ultrasound was performed with a full bladder, or a trans-vaginal ultrasound was performed after UB evacuation. The vascularity of the lesion were evaluated using Power or color Doppler US, and to ensure the presence or absence of a solid component with doppler parameters as following (Color follow 2.5MHz, Gain 21, PRF0.7 KHz, AO 100%). Using the US O-RADS categorization system, we gave each lesion a score.

The ultrasound findings were interpretated using O-RADS lexicon as following:

Table 1 [8]

O-RADS score	Risk category	Lexicon descriptors
0	Incomplete evaluation	N/A
1	Normal ovary (N/A)	• physiologic category (normal premenopausal ovary) ovarian follicle (<3 cm) • corpus luteum (<3 cm)
2	Almost certainly benign category (<1% risk of malignancy)	• Simple cyst 3-5 cm • Simple cyst 5-10 cm • Non-simple but unilocular cyst with smooth margins <3 cm • Non-simple but unilocular cyst with smooth margins 3-10 cm • Typical hemorrhagic cyst dermoid cyst endometrioma para-ovarian cyst peritoneal inclusion cyst hydrosalpinx less than
3	Low risk of malignancy (1% to < 10%).	• Unilocular >10 cm (simple or non-simple) • Lesions looking like typical dermoids, endometriomas or hemorrhagic cysts >10 cm • Solid smooth lesion of any with color score 1 4-multilocular cyst <10 cm smooth inner wall with color score 1-3
4	Lesions with an intermediate risk of malignancy (10 % to < 50%)	• Unilocular cyst with a solid component, any size, 1-3 papillary projections, any color score • Multilocular cyst with solid component, any size, color score 1-3 • Multilocular cyst without solid component: ->10 cm, smooth inner wall with color score 1-3 • Any size smooth inner wall with color score of 4 / any size with an irregular inner wall or irregular septations of any color score • Solid smooth lesion of any with color score 2-3
5	Lesions with a high risk of malignancy (≥50%)	• Presence of ascites / peritoneal nodularity • Unilocular cyst with papillary projections • Multilocular cyst with a solid component • Solid lesion - some criteria apply - color score 4 5-solid irregular

lesion of any size

Reference standard

The US findings using the O-RADS classification system were correlated with pathology findings and/or MRI for suspicious masses. We used follow up in O-RADS 1&2 lesions, MRI in indeterminate lesions (O-RADS 3) and pathology results in lesions with (ORADS 4&5)

Statistical analysis

Statistical analysis was performed by SPSS version 20 (USA). Categorical variables were expressed as frequency (percentage) while continuous data were expressed as mean and SD. Diagnostic accuracy of O-RADS in diagnosis of nature of ovarian lesions was determined by receiver operator characteristics (ROC) curve. All calculated P values were 2-sided and P values less than 0.05 were considered statistically significant and level of confidence was kept at 95%.

Results:

Mean age of the studied patients was 41.08 ± 12.95 years with range between 16 and 75 years old. As regard laterality of lesion; 36 (47.4%) and 26 (34.2%) patients had right and left ovarian lesion, respectively. Meanwhile, 14 (18.4%) women had bilateral ovarian lesions. (table 1).

A total of 90 ovarian lesions were studied in these women (14 women had bilateral lesions and 62 women had unilateral lesions). Mean size of lesion was 6.28 ± 4.11 (cm) with range between 2 and 20 (cm). As regard vascularity of the lesions; 9 (10%), 17 (18.9%) and 5 (5.5%) lesions had minimal, moderate and marked vascular flow, respectively. Majority (65.6%) of lesions had no flow at all. As regard Echopattern; 50 (55.5%), 13 (14.4%), 5 (5.6%) and 22 (24.4%) lesions had anechoic, hypoechoic, hyperechoic and heterogeneous lesions, respectively. Majority (67.8%) of the lesions had smooth outline while the other 29 (32.2%) lesions had irregular outline. Sixty (66.7%) lesions were cystic in nature, 8 (8.9%) lesions were solid and 22 (24.2%) lesions had mixed lesions. Twenty-three (25.5%) patients had abdominal lymphadenopathy and 41 (45.6%) women had ascites. Peritoneal deposits were detected in 18 (20%) patients (table 2).

Out of the studied lesions; 15 (16.7%), 38 (42.2%), 5 (5.6%), 4 (4.4%) and 28 (31.1%) lesions were classified as ORADS caterory-1, 2, 3, 4 and 5, respectively. (table 3).

It was found that O-RADS at cutoff point> 4; it has 96.6% overall accuracy in diagnosis of nature of ovarian lesions with area under curve (AUC) was 0.986. (table 5).

Majority of benign lesions had ORADS-1 (63.8%) while the malignant lesions had ORADS-5 (87.5%) (table 8).

Table 2: Characteristics of the ovarian lesions in the studied patients

	N= 90
Diameter (cm)	6.28 ± 4.11
Range	2-20
Vascularity of the lesion	
No flow	59 (65.6%)
Minimal flow	9 (10%)
Moderate flow	17 (18.9%)
Marked flow	5 (5.5%)
Echopattern	
Anechoic	50 (55.5%)
Hypoechoic	13 (14.4%)
Hyperechoic	5 (5.6%)
Heterogeneous	22 (24.4%)
Outline	
Smooth	61 (67.8%)
Irregular	29 (32.2%)
Nature	
Cystic	60 (66.7%)
Solid	8 (8.9%)
Mixed	22 (24.2%)
Abdominal lymphadenopathy	23 (25.5%)
Ascites	41 (45.6%)
Nodules	18 (20%)

Data expressed as frequency (percentage), mean (SD), range

Table 3: O-RADS in the studied lesions

	N= 90
O-RADS category	
Category-1	15 (16.7%)
Category-2	38 (42.2%)
Category-3	5 (5.6%)
Category-4	4 (4.4%)
Category-5	28 (31.1%)

Data expressed as frequency (percentage)

Table 4: Final diagnosis in the studied lesions

	N= 90
Final diagnosis	
Malignant lesion	32 (35.6%)

Benign lesion	58 (64.4%)

Data expressed as frequency (percentage)

Table 5: Accuracy of O-RADS in diagnosis nature of ovarian lesions

	O-RADS
Sensitivity	96.8%
Specificity	96.6%
Positive predictive value	93.9%
Negative predictive value	98.1%
Accuracy	96.6%
Cutoff point	≥ 4
Area under curve	0.986
P value	< 0.001

P value was significant if < 0.05

Table 6: Cross-tabulation between final diagnosis and O-RADS category (≥ 4)

O-RADS	Final diagnosis (malignant lesions)		Total
	Positive	Negative	
Positive	31	2	33
Negative	1	56	57
Total	32	58	

False discovery rate= false results/total number= 3/90= 3.3%

False positive rate = (100*false positive)/ (false positive + true negative) = (100*2)/(2+56)= 3.4%

False positive rate = (100*false positive)/ (false positive + true negative) = (100*2)/(2+56)= 3.4%

Table 8: Characteristics of the ovarian lesions in the studied patients

	Being lesions (n= 58)	**Malignant lesions (n= 32)**	***P* value**
Diameter (cm)	4.45 ± 2.71	9.60 ± 4.16	< 0.001(*)
Vascularity			
No flow	56 (96.6%)	3 (9.4%)	
Minimal flow	2 (3.4%)	7 (21.9%)	< 0.001(*)
Moderate flow	0	17 (53.1%)	
Marked flow	0	5 (15.6%)	
Echopattern			
Anechoic	43 (74.1%)	7 (21.9%)	
Hypoechoic	9 (15.5%)	4 (12.5%)	< 0.001(*)
Hyperechoic	0	5 (15.6%)	
Heterogenous	6 (10.3%)	16 (50%)	
Outline			
Smooth	55 (94.8%)	6 (18.8%)	< 0.001(*)
Irregular	3 (5.2%)	26 (81.3%)	
Nature			
Cystic	58 (100%)	2 (6.3%)	< 0.001(*)
Solid	0	22 (68.8%)	
Mixed	0	8 (25%)	
Abdominal LNs	2 (3.4%)	21 (65.6%)	< 0.001(*)
Ascites	21 (36.2%)	20 (62.5%)	0.01(*)
Nodules	18 (20%)	18 (100%)	< 0.001(*)
O-RADS category			
Category-1	15 (25.9%)	0	
Category-2	37 (63.8%)	1 (3.1%)	< 0.001(*)
Category-3	4 (6.9%)	1 (3.1%)	
Category-4	2 (3.4%)	2 (6.3%)	
Category-5	0	28 (87.5%)	

Data expressed as frequency (percentage), mean (SD), range

(*) level of confidence and statistically significant value

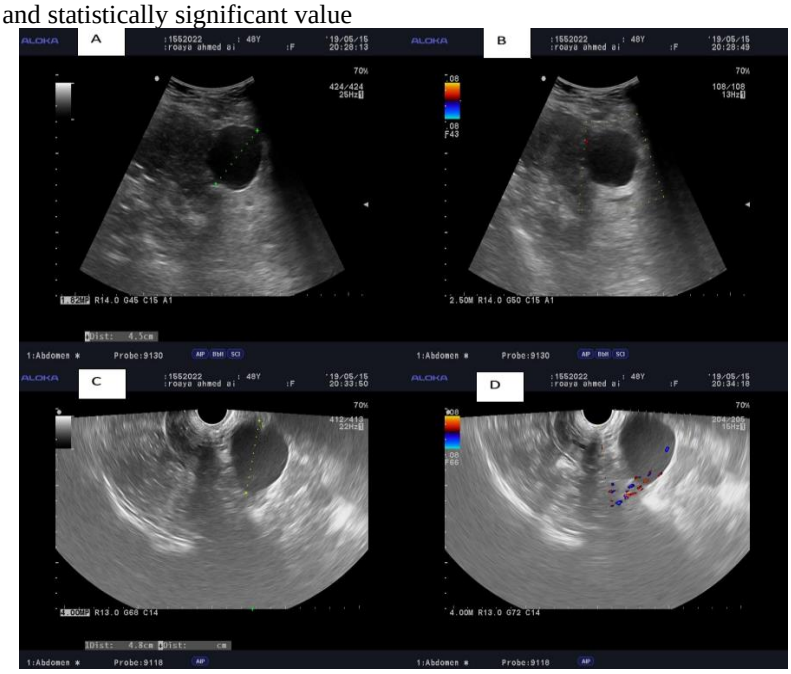

Figure 1: 48 years old patient with history of operated breast cancer on regular follow up presented with abdominal pain and distension (1) Trans-abdominal (a&b) and trans vaginal (c&d) was done showing left ovarian cystic lesion anechoic in nature measures +/- 4.5 cm in maximum dimensions with no vascularity on color mapping (CS:1), (2) Follow up was done after 10 weeks showing the same left ovarian anechoic cyst with no vascularity on color Doppler. Diagnosis: Left ovarian simple cyst O-RADS 2

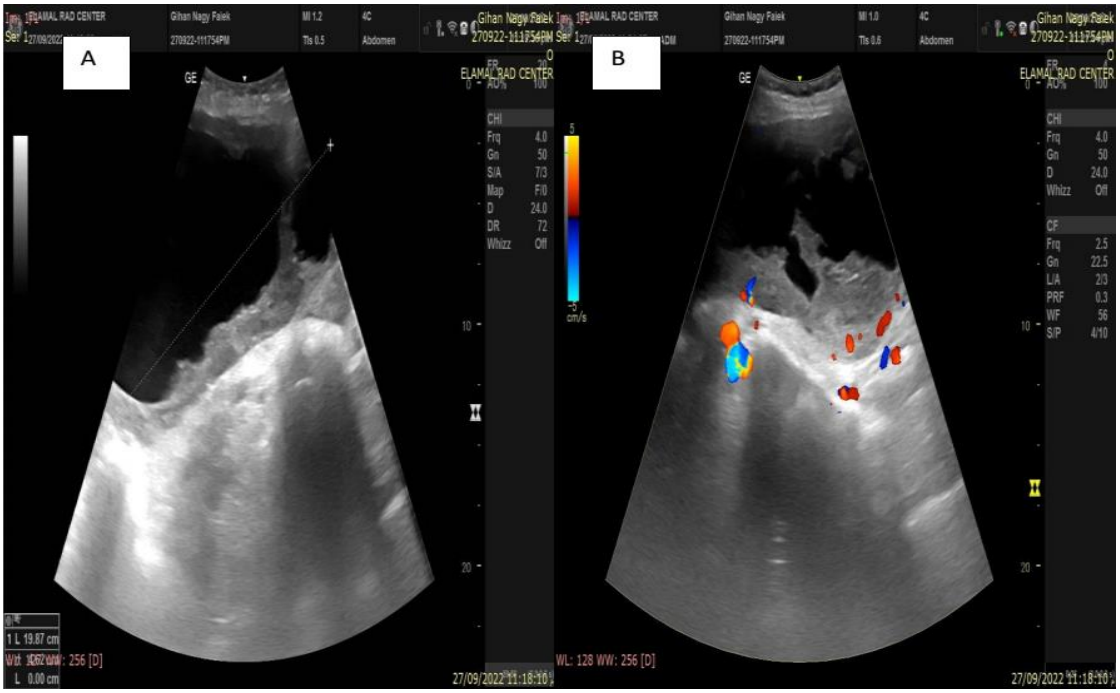

Figure 2;36 years old female patient presented with abdominal pain and distension: Trans-abdominal ultrasound was done (a&b images) showing right ovarian cystic lesion with peripheral solid component measures +/- 18 cm in maximum dimensions with moderate vascularity on color mapping (CS:3) with mild ascites and peritoneal nodules,

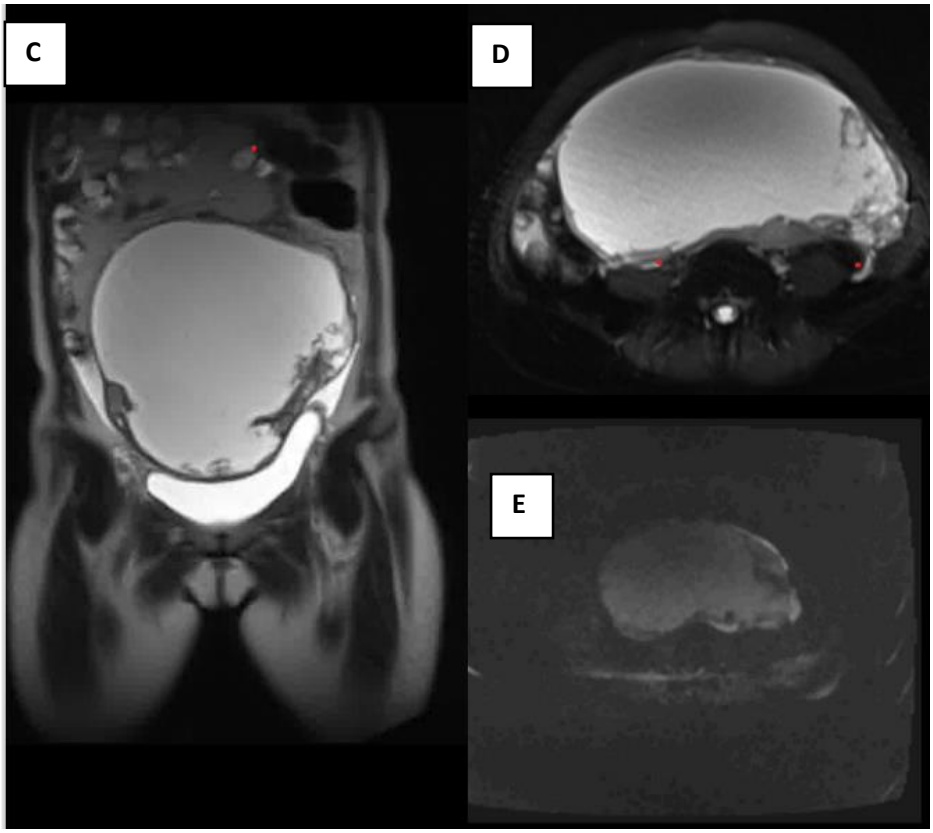

Figure3: MRI images (c&d) showing right ovarian predominant cystic lesion with peripheral solid component that showing restricted diffusion on DWI(e), associated with mild ascites and restricted peritoneal nodules
Diagnosis: Right ovarian mixed cystic solid lesion mostly malignant featuring →O-RADS 5

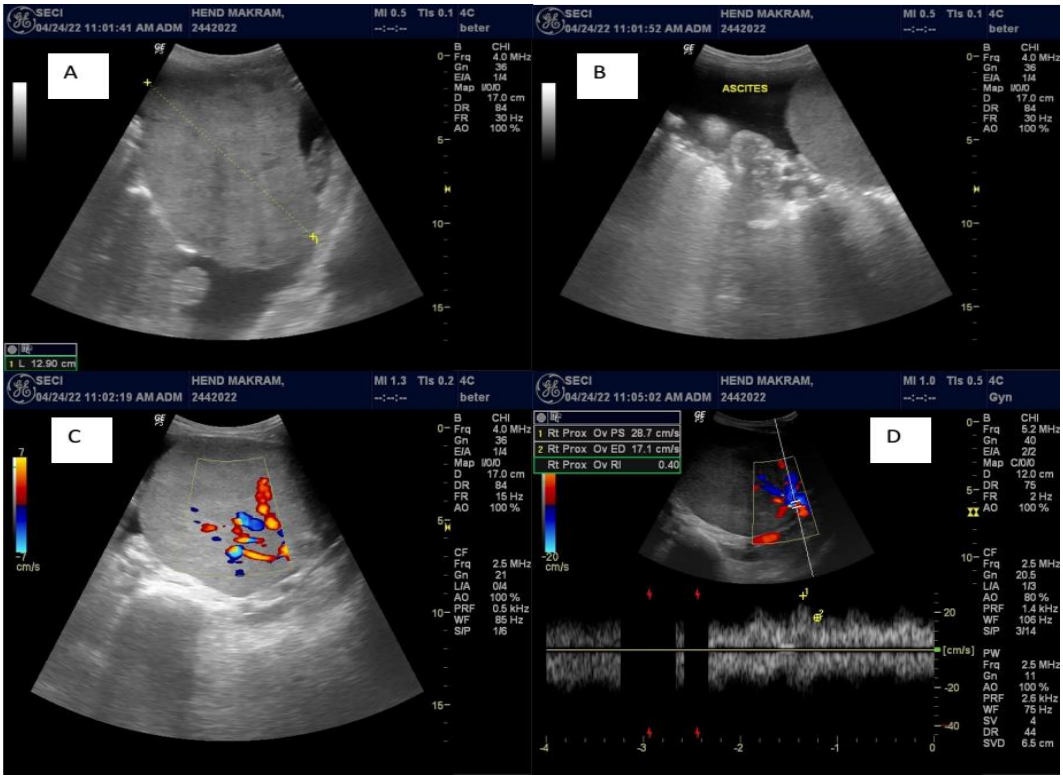

Figure 4: 31 years old female patient with abdominal pain, vomiting & distension
(1) Trans-abdominal US was done showing left ovarian solid lesion with smooth outline measures +/- 13 cm in maximum dimensions (a) with marked vascularity on color mapping (CS:4) (c&d) with moderate ascites(b), peritoneal nodules and abdominal LNS, (2) Aspiration cytology of the ascites was done showing malignant glandular epithelial neoplasm consistent with adenocarcinoma. Diagnosis: Left ovarian solid lesion malignant featuring O-RADS 5

Discussion:

Adnexal lesions are commonly encountered in daily clinical practice. Imaging plays an important role in characterizing and risk-stratifying adnexal lesions, facilitating clinical decision-making. The vast majority of these lesions are benign and can be managed conservatively, avoiding unnecessary surgeries, healthcare costs, and patient anxiety. [9]

Ovarian cancer is known to be the most lethal gynecologic malignancy, with almost 60% of patients diagnosed in advanced stages with regional or distant spread, corresponding with an unfavorable long-term prognosis. Five-year survival depends on the stage of the disease: 46% for all stages, but ranging from 90% at stage I to 4% at stage IV disease. [10]

With the aim of detecting the disease in early stages, several large ovarian cancer screening trials have been conducted. Till now, none of them has proven any clear benefit in terms of survival, when asymptomatic postmenopausal women are screened by means of serum testing with or without ultrasound examination. Moreover, because ultrasound-based screening algorithms have a high sensitivity for benign lesions, many patients would undergo surgical treatment for asymptomatic and innocent neoplasms, exposing them to possible surgical complications. [10]

Pelvic ultrasound is commonly used as part of the routine gynecologic exams, resulting in diagnosis of adnexal masses, the majority of which are functional or benign. However, due to the possible complications involving benign adnexal cysts (i.e., adnexal torsion, pelvic pain) and the importance of early diagnosis and treatment of ovarian cancer, the correct ultrasound diagnosis of adnexal masses is essential in clinical practice. [11]

The current trend is seeking to minimize unnecessary surgical procedures on low-malignancy cases, thus minimizing surgical morbidity and preserving ovarian function in patients with low malignancy risk. The need for universally accepted terminology in ultrasound reporting for ovarian and adnexal masses is essential for this goal. [8,17]

Several ultrasound classification systems have been developed for adnexal mass assessment, including the International Ovarian Tumor Analysis (IOTA) and the Gynecology Imaging Reporting and Data System (GI-RADS) More recently, the ACR released the Ovarian-Adnexal Reporting and Data System (O-RADS) for ultrasound (US). [8,18]

The Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon for ultrasound (US) was published in 2018 and provides a standardized reporting framework and definitions of the US appearance of normal ovaries as well as ovarian and other adnexal lesions. [14]

This lexicon was created to create uniformity in describing these lesions in ultrasound categorize these lesions based on their risk for malignancy and recommend appropriate management for these lesions

Applying the O-RADS US risk classification system allows accurate characterization of most adnexal lesions; however, between 5 and 25% of masses remain indeterminate at the level of ultrasound. For example, when sonographic imaging features of a classic benign lesion such as a simple or hemorrhagic cyst, endometrioma, or dermoid are absent, there is a potential for malignancy. Studies show that the positive predictive value for malignancy varies from 7 to 50% for lesions indeterminate at US. [15]

Andreotti et al., outlined the risk classification categories and corresponding risk of malignancy (ROM) and management recommendations [8] by the collaborative effort of an international group of experts both in gynecologic imaging and clinical practice, with the ultimate goal of providing a harmonized approach to reporting and managing patients based on imaging findings. [8]

Here, we conducted a prospective study on total of 90 ovarian lesions in Radiology Department of South Egypt Cancer Institute, Assiut University in the period between January 2021 and December 2022.

The O-RADS working group defined six categories for classifying malignancy risk: O-RADS 0 for unsatisfactory or inconclusive data, O-RADS 1 for normal pre-menopausal ovaries, O-RADS 2 for benign findings (<1% malignancy risk), O-RADS 3 for low malignancy risk (1%-10%), O-RADS 4 for intermediate-risk (10%-50%), and O-RADS 5 for high malignancy risk (≥50%). [8]

A total of 90 ovarian lesions were studied in our patient study group (N 76) (14 women had bilateral lesions and 62 women had unilateral lesions).

Out of the studied lesions in the current study; 32 (35.6%) lesions were malignant lesions while the other 58 (64.4%) lesions were benign lesions. This final diagnosis was based on histopathological or /and radiological full evaluation by MRI or with another modality staging by MSCT. Some lesions resolved spontaneously or after conservative medical treatment during follow-up and were considered to be benign.

Mean age of the studied patients was 41.08 ± 12.95 years with range between 16 and 75 years old. As regard laterality of lesion; 36 (47.4%) and 26 (34.2%) patients had right and left ovarian lesion, respectively. Meanwhile, 14 (18.4%) women had bilateral ovarian lesions.

In agreement with the current study, Basha et al., studied 609 women with at least one adnexal mass on US examination were collected. A total of 647 adnexal mass from 609 women (38 women (6.2%) had bilateral masses) were included in final analysis. Mean age, 48± 13.7 years with range between 18–72 years. [16]

Another study Lai et al., included a total of 734 patients with adnexal mass, aged 15 to 82 years, were enrolled in their study, including 604 premenopausal patients (82.3%) and 130 postmenopausal patients (17.7%). Out of those patients; 603 (82.2%) patients had unilateral lesion and the other 130 (17.8%) patients had bilateral lesions. [17]

Age has been described as a predisposing factor for the development of adnexal mass and ovarian cancer. Increasing risk of malignant ovarian mass has been observed in patients with a larger number of ovulatory

cycles like patients with younger age at menarche and late age of menopause. Increasing the number of ovulatory cycles increases cellular divisions predisposing to the development of malignant neoplasms. [18]

Malignant ovarian mass is considered mainly postmenopausal disease, an older age increases the risk of a more aggressive type of tumor, the median age for the diagnosis is 50–79 years. [19]

Asae et al. made a comparison between patients had benign and patients had malignant lesions in demographic characters, history, and ultrasound examination. There was a statistically significant increase in mean age and frequency of post menopause among females who had malignant lesions compared to females who had benign lesions. [20]

As regard Echopattern; 50 (55.5%), 13 (14.4%), 5 (5.6%) and 22 (24.4%) lesions had anechoic, hypoechoic, hyperechoic and heterogeneous lesions, respectively. Majority (67.8%) of the lesions had smooth outline while the other 29 (32.2%) lesions had irregular outline. As the anechoic denoting simple cyst (figure 1), the hypoechoic denoting hemorrhagic cysts, the hyperechoic denoting solid masses, the heterogeneous denoting malignant featuring mixed masses (figure 2) and dermoid cysts. Sixty (66.7%) lesions were cystic in nature, 8 (8.9%) lesions were solid and 22 (24.2%) lesions had mixed lesions. Twenty-three (25.5%) patients had abdominal lymphadenopathy and 41 (45.6%) women had ascites. Peritoneal deposits were detected in 18 (20%) patients (figure 3).

Asae et al. stated that the most frequent echogenicity among the lesions was heterogeneous and anechoic (42.4% and 33.3%, respectively). Regarding wall and composition, 69.7% of the lesions had thin walls and 57.6% had cystic components. Approximately 27.3% of the adnexal masses were multilocular. Septations were found in 15.2% of the lesions and ascites in 12.1%. The lesion size ranged from 0.097 to 224 cm with a mean of 54.40±60.19. [20]

Although cysts containing malignant neoplasms of epithelial origin are rare, their timely diagnosis is of the utmost importance since early diagnosis and treatment of ovarian cancer is the most important factor in determining survival., Ultrasound features suggestive of epithelial malignancy include thick septations, solid components, and cyst wall thickening. [11]

The solid areas may vary in size, from small nodules or appellations to larger areas. The diameter of the mass appears to be less predictive of malignancy than the features described above. Moreover, malignancies have been described even in relatively small cysts of 3–4 cm in diameter. [11,21]

The addition of Doppler flow measurements to the gray-scale parameters may provide additional information in suspicious cases, and has been thought to increase the sensitivity, specificity, and positive predictive value of ultrasound in diagnosing ovarian mass. This modality is used to detect abnormal blood vessels which arise from the neovascularization process induced by the malignant lesion. These blood vessels are characterized by abnormal blood flow patterns, typically low resistance to flow, which translates to abnormal pulsed Doppler parameters. [11] Sokalska et al., Concluded that use of gray scale ultrasound combined with Doppler measurements, when necessary, allows the experienced radiologist to reliably diagnose functional, benign, and malignant adnexal masses. The information obtained from the pelvic ultrasound, combined with patient's history and gynecologic exam, will guide recommendations from treatment, primarily the decision for conservative follow-up versus surgery. [22]

As regard vascularity of the lesions at the current study; 9 (10%), 17 (18.9%) and 5 (5.5%) lesions had minimal, moderate and marked vascular flow, respectively. Majority (65.6%) of lesions had no flow at all. The presence of vascularity increases the risk of malignancy.

The most frequent benign lesions were simple cyst (29/58; 50%), meanwhile the most frequent malignant lesion was serous cyst adenocarcinoma (10/32; 31.3%).

Similar findings were reported by Asae et al. who noticed that 75.8% of the adnexal masses were benign and 24.2% were malignant. The most frequent benign lesions were hemorrhagic cysts, mucinous cystadenomas and dermoid cysts (18.2%, 15.2%, and 15.2%, respectively) whereas serous cyst-adenocarcinoma was the most frequent malignant lesion was (12.2%). [20]. Also Basha et al. found that the most frequent malignant adnexal mass was serous cyst-adenocarcinoma (29.8%). [16]

Similar findings were reported by Surbramaniam et al. Evaluated 73 women with adnexal masses, based on histopathological reports or follow up imaging data; 20/73 (27.4%) patients had malignant lesions while the other 53/73 (72.6%) patients had benign lesions. [23]

While another study Lai et al. enrolled 734 adnexal masses and based on final diagnosis; there were 564 benign masses (76.8%) and 170 malignant masses (23.2%). Epithelial ovarian cancer was the most frequent malignant lesion (38.9%) while simple cyst was the most frequent benign lesion (28.3%). [17]

The studied lesions were as following as regard (the ORADS) 15 (16.7%), 38 (42.2%), 5 (5.6%), 4 (4.4%) and 28 (31.1%) lesions were classified as ORADS caterory-1, 2, 3, 4 and 5, respectively.

Similarly, a previous study Asae et al. which was analyzing the O-RADS score among the studied patients, 24.2% of adnexal masses were classified as score 2, 33.3% as score 3, 21.2% as score 4 and 21.2% as score 5. [20]. While Hack et al., found number of lesions within each O-RADS risk category were as follows: 100 (38%) for O-RADS 2, 32% for O-RADS 3, 24% for O-RADS 4, 27% for O-RADS 5, and 26% for ORADS 5. [24]

The variation may be explained by different sample size, studied population and selection bias. In addition, characteristics of studied patients are considerable reason for such variation.

The main findings in the current study were that O-RADS at cutoff point> 4; it has 96.6% overall accuracy

in diagnosis of nature of ovarian lesions with area under curve (AUC) was 0.986.

In accordance with the current study, recent study Asae et al. concluded that concerning O-RADS 5 adnexal masses, the O-RADS had a sensitivity of 62.5%, specificity of 92.5%, positive predictive value (PPV) of 71.4%, negative predictive value (NPV) of 88.5%, and accuracy of 84.8% for predicting malignancy of adnexal masses. The sensitivity, specificity, PPV, NPV, and accuracy of determining whether or not adnexal masses are malignant using a combination of O-RADS 4 and 5 were 87.5%, 72%, 50%, 94.7%, and 75.8%, respectively. [20]

This appears more compared to study conducted by Timmerman et al., in their study sensitivity, specificity, PPV, and NPV in their study were 52%, with a specificity of 84%, negative predictive value of 79%, and positive predictive value of 60% even though sample size of the both study is same. [25]

Regarding the results of Jha et al. with a sensitivity of 90.6%, specificity of 81.9%, positive predictive value (PPV) of 31.4%, and negative predictive value (NPV) of 99.0%, the RADS US 4 cutoff was the best for making a cancer diagnosis. [14]

With O-RADS US 4 and 5 as the malignant categories, the ROC analysis showed a sensitivity and specificity of 98.7% and 83.2% in Cao et al., and 96.6% and 92.8%, respectively in Basha et al. [16]

The basic examination to assess the malignancy rate of adnexal mass is the US. However, to date, few studies have discussed the recommended malignancy rate of adnexal mass by various US classification systems. We assessed the malignancy rates of adnexal mass in our study and found it increased with increasing suspicious sonographic patterns based on the O-RADS categories. The malignancy rates were comparable to the recommended rates in O-RADS categories [8,26].

Limitations

First, we conducted our study in single center with relatively small sample size and the analysis was based on static operator-dependent images instead of real practice, which result in unavoidable bias.

Second, all US examinations were performed by using different transducers of different vendors in spite that we tried to apply a fixed parameters as discussed in methodology.

Finally, these US-based classification systems can operate differently in different populations and practice conditions.

Conclusion:

The ultrasound O-RADS classification system provide a crucial non-invasive diagnostic tool for suspected ovarian tumors to distinguish between benign and malignant neoplastic lesions.

List of abbreviations

IOTA: International Ovarian Tumor Analysis
O-RADS: Ovarian-Adnexal Reporting and Data System
SECI: South Egypt Cancer Institute
TA: Trans-abdominal
TV: T rans-vaginal
US: Ultrasound
ACR: The American College of Radiology
AM: Adnexal Masses
PPV: Positive predictive value
B features: Benign features
M Features: Malignant features
ROC: Receiver operator characteristics
AUC: Area under curve

Competing interest: None

Author's contributions:

All authors made substantial contributions to the conception or design of the work, acquisition, analysis, or interpretation of data.

Acknowledgement: None.

Conflict of Interest:

The authors declare that they have no conflict of interest.

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