REVIEW ARTICLE

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OVARIAN-ADNEXAL REPORTING AND DATA SYSTEM FOR US (O-RADS US) IN OVARIAN CANCER

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ABSTRACT

OBJECTIVE: to describe the new System called Ovarian-Adnexal Reporting and Data System for US (O-RADS US) supported by the American College of Radiology to standardize the lexicon in the description of characteristics of ovarian and adnexal masses and assign risk categories for the probability of malignancy Based on the assessment of these characteristics, management recommendations are also standardized.

METHODS: Bibliographic review. For risk stratification, the O-RADS US system recommended six categories (O-RADS 0–5), incorporating the range of normal to high risk of malignancy.

RESULTS: In the studies found, the results for sensitivity, specificity, PPV, NPV and kappa of the method were significant with the use of the Ovarian-Adnexal Reporting and Data System (O-RADS) risk stratification and management system.

CONCLUSION: This system was designed to provide consistent interpretations, to decrease or eliminate ambiguity in US reports, resulting in a greater likelihood of accuracy in assigning malignancy risk to ovaries and other adnexal masses, and to provide a management recommendation for each category. of risk. O-RADS US is the only lexicon and classification system that covers all risk categories with their associated management schemes.

KEYWORDS: O-RADS, CANCER, OVARY, ULTRASOUND

INTRODUCTION

Ovarian cancer is the deadliest gynecological cancer. Less than half of patients survive for more than five years after diagnosis. Ovarian cancer affects women of all ages, but it is most commonly diagnosed after menopause. More than 75% of affected women are diagnosed at an advanced stage because early-stage disease is usually asymptomatic and symptoms of advanced-stage disease are nonspecific. Risk factors for ovarian cancer are old age and a family history of ovarian and breast cancer. Women with symptoms related to ovarian cancer should be evaluated with a physical examination, transvaginal ultrasound, and measurement of biomarkers such as cancer antigen 125 (CA-125). If the results are suspicious for ovarian cancer, the patient should be referred to a gynecological oncologist[1].

Despite the low rate of early diagnosis, guidelines do not recommend routine screening for ovarian cancer in average-risk women because screening, including routine pelvic exams, is ineffective and associated with harm. However, a recent study found a potential benefit of annual screening using an algorithm based on serial measurements of cancer antigen 125, followed by transvaginal ultrasound, for women at increased risk, as determined by the algorithm. Women with a family history of increased risk should be referred for genetic counseling and, if genetic mutations are identified (eg, BRCA mutations), bilateral salpingo-oophorectomy may be considered for risk reduction. In medium- and high-risk women, long-term use of hormonal contraceptives reduces the risk by about 50%. Treatment of ovarian cancer usually involves surgery, with or without intraperitoneal and intravenous chemotherapy[1].

When detected at stage I, ovarian cancer can be cured in up to 90% of patients. Stage II ovarian cancer is associated with a 5-year survival of 70%. However, disease that has spread beyond the pelvis (stage III-IV) has a long-term survival rate of 20% or less. Currently, only 20% of ovarian cancers are diagnosed at stage I-II. Computer simulations suggest that detecting preclinical disease at an earlier stage could improve survival by 10-30%[2].

Currently, the combination of an ultrasound examination with a cancer antigen (CA)-125 assay is the most effective diagnostic technique, but it is not yet accepted as a screening method[3]. Therefore, it is extremely important to be able to differentiate suspicious ovarian and adnexal masses from those that can safely be ignored or followed, remembering that surgery may be appropriate for some benign lesions (to remove symptomatic ones or to prevent future malignancy). To this end, the American College of Radiology (ACR) supported the development and dissemination of the Ovarian-Adnexal Reporting and Data System for US (O-RADS US) and for MRI (O-RADS MRI). By standardizing the lexicon to describe characteristics of ovarian and adnexal masses and assigning risk categories for the likelihood of malignancy based on the assessment of these characteristics, manage-

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ment recommendations are also standardized[4].

The aim of this study is to describe the new system called Ovarian-Adnexal Reporting and Data System for US (O-RADS US) supported by the American College of Radiology.

STANDARDIZATION OF O-RADS FOR OVARIES

Concept

The Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon for US was published in 2018, providing a standardized lexicon that includes all pertinent descriptors and definitions of the characteristic US appearance of normal ovaries and ovaries or other adnexal lesions. The lexicon is based on committee consensus. Taking into account the supporting evidence for the performance of different terminologies used in the literature for classifying a mass as benign or malignant, the committee members agreed on terms similar to those used in the IOTA models.

The descriptors used in the O-RADS lexicon were tested on the large dataset from phases 1-3 of the IOTA study to assign a risk of malignancy to each of them. Terms that proved useful for designating malignancy risk were placed in a condensed lexicon table to facilitate risk stratification. Finally, with the use of other supporting evidence-based studies in the literature that offer additional guidance in differentiating treatment regimens in a variety of almost certainly benign lesions that include simple cysts, hemorrhagic cysts, dermoid cysts, endometriomas, paraovarian cysts, inclusion cysts peritoneal, hydrosalpinx, and O-RADS US working group consensus, guidelines are provided for management in different risk categories. The proposed guidelines are a collaborative, multidisciplinary and international approach that incorporates common European and North American approaches. The guidelines include all risk categories with their respective management strategies, which were not included in any of the previous systems[5].

CLASSIFICATION

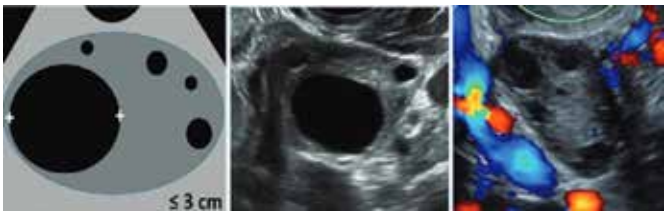
O-RADS 0 - INCOMPLETE EVALUATION

Usually due to technical difficulties, such as intestinal gas, large size of the lesion, location of the adnexa, or the patient's inability to perform an endovaginal exam.

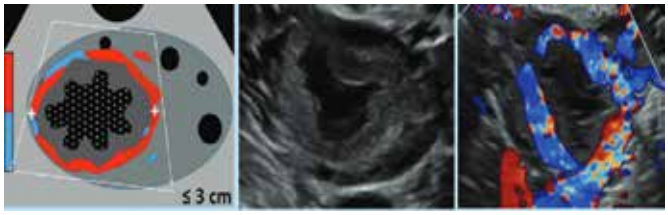
O-RADS 1 - NORMAL OVARIES

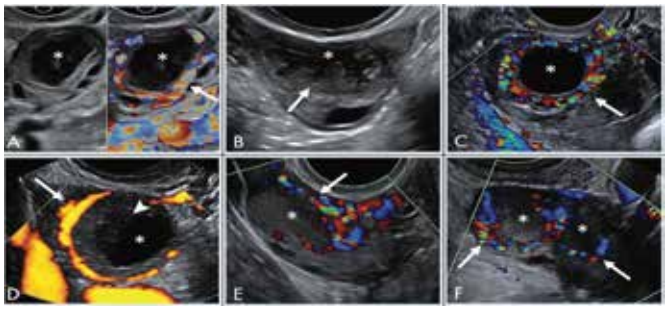
Physiological category. Relevant only in premenopausal patients as it includes the follicle and corpus luteum. One should avoid using the word cyst to describe these structures.

Follicle - anechoic unilocular cyst ≤ 3 cm



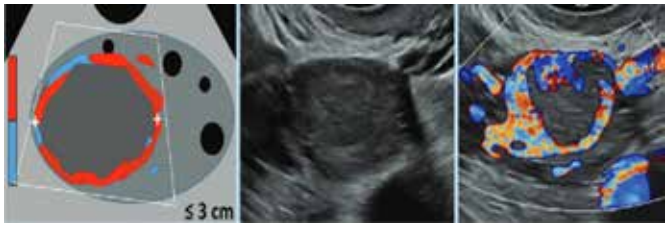
Corpus Luteum - Cyst with thick walls 3cm +-, crenulated internal margin, internal echoes, peripheral flow.





The images show typical corpora lutea. A, Corpus luteum with color Doppler and without color Doppler demonstrates a central cystic component (asterisks) with smooth thickened wall, avascular internal echoes, and peripheral vascularity (arrow). B, Corpus luteum with central component, thickened wall and crenulated inner margin (arrow). C, Thick-walled anechoic cyst (asterisk) with intense peripheral vascularization (arrow). D, Color Doppler energy demonstrates peripheral vasculature (arrow) in this cystic corpus luteum (asterisk) with retracted clot (arrowhead). E, Corpus luteum as a hypoechoic region (asterisk) without a central cystic component, but with peripheral flow (arrow) on color Doppler. F, Two corpora lutea in double ovulation configuration manifested by two hypoechoic regions (asterisks) with peripheral flow (arrows).

Hypoechoic region with peripheral flow, but without a characteristic cystic component.



O-RADS 2 - ALMOST CERTAINLY BENIGN.

Risk of malignancy < 1%

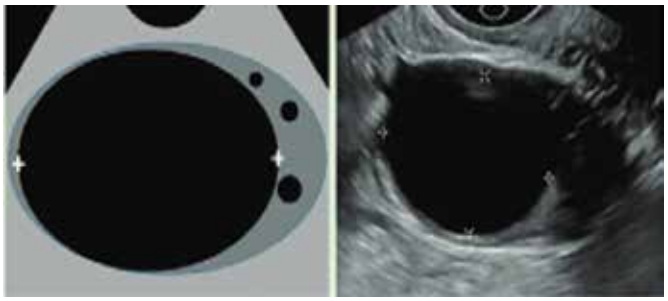
The category includes most unilocular cysts smaller than 10 cm.

Simple cysts, non-simple unilocular cysts with smooth walls and cysts that can be described using classic benign lesions and their descriptors if smaller than 10cm in maximum diameter.

Simple cyst

>3 - < 10cm in premenopausal women

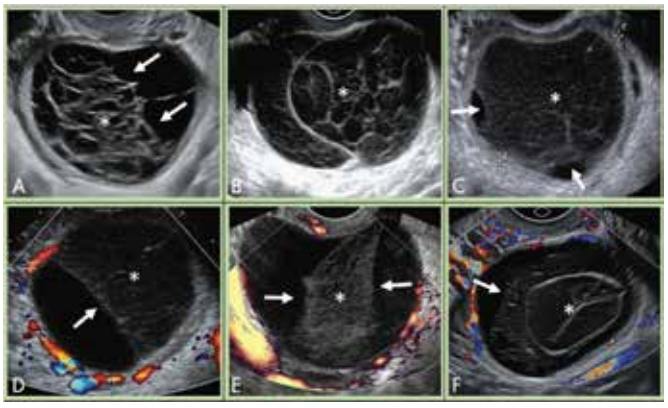
< 10 cm in postmenopausal women



Classic benign lesions – Typical hemorrhagic cyst, dermoid cyst, endometrioma, paraovarian cyst, peritoneal inclusion cyst and hydrosalpinx.

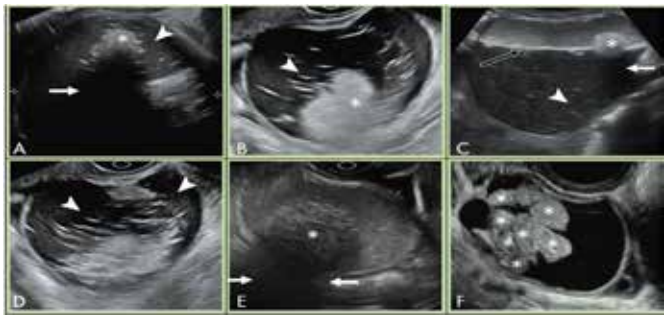
Typical hemorrhagic cyst

The images show typical hemorrhagic cysts. A, Hemorrhagic ovarian cyst with retracted clot demonstrates concave margins (arrows) and internal reticular pattern (asterisk). B, Hemorrhagic cyst with full-length reticular pattern (asterisk). C, Reticular pattern (asterisk) with fine discontinuous linear echoes and early clot retraction in the periphery (arrows). D, Retracted clot with reticular pattern (asterisk) and concave margin (arrow). Color Doppler flow is observed in the surrounding ovarian tissue; however, it is absent in blood products. E, Reticular pattern (asterisk), straight and concave margins (arrows) and no flow in color Doppler energy differentiates retractable clot from solid tissue. F, Avascular hemorrhagic cyst with reticular pattern (asterisk) and concave margin of retractable clot (arrow).



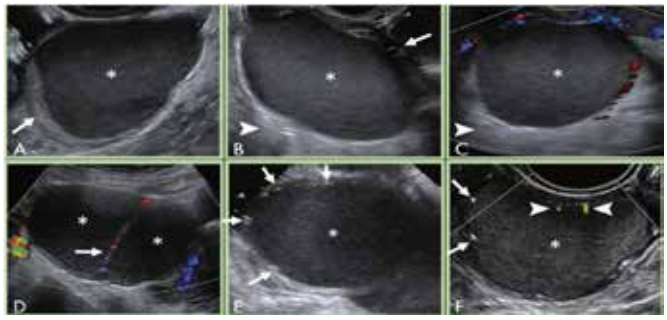
Typical dermoid cyst

The images show typical dermoid cysts. A, Dermoid cyst with hyperechoic component (asterisk) with acoustic shadow (arrow) and hyperechoic lines and dots (arrowhead). B, Hyperechoic lines and dots and hyperechoic component in another dermoid cyst. C, Transabdominal image of dermoid cyst demonstrates fluid-fluid level (black arrow) with non-dependent hyperechogenicity consistent with fluctuating fluid fat. Hyperechoic component (asterisk) with acoustic shadowing (arrow) and subtle hyperechoic lines and dots (arrowhead) are also seen. D, Cystic lesion with prominent hyperechoic lines and dots (arrowheads), which reflect the coiled hair in the dermoid cyst. E, Hyperechoic component (asterisk) with acoustic shadow (arrows) in dermoid cyst containing internal echoes. F, Floating echogenic spherical structures (asterisks) are uncommon but are pathognomonic of a dermoid cyst.



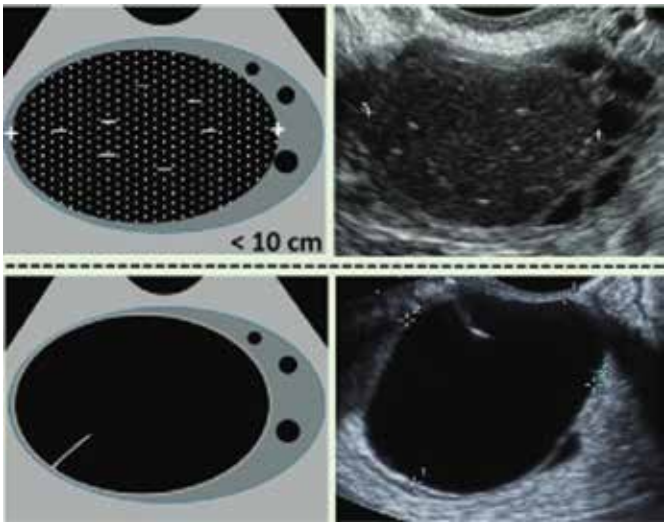
Typical endometriomas

The images show typical endometriomas. A, The common appearance of endometrioma demonstrates homogeneous low-level or ground-glass internal echoes (asterisk); The surrounding ovarian parenchyma (arrow) is observed. B, Similar features of homogeneous low-level or ground-glass echoes (asterisk) with surrounding ovarian tissue (arrow) and posterior acoustic enhancement (arrowhead). C, No inflow on Doppler imaging should be seen in endometriomas; homogeneous low-level echoes (asterisk) and posterior acoustic reinforcement (arrowhead). D, Multiloculated endometrioma with homogeneous low-level echoes (asterisks) in each component; flow can be observed in the intervening septum (arrow). E, Occasionally, peripheral punctuated echogenic foci (arrows) are seen with endometriomas; however, homogeneous low-level echoes (asterisk) are more specific features. F, Although shadowing is not normally associated with peripheral punctuated echogenic foci (arrows) around the endometrioma (asterisk), shimmering artifacts can be seen with Doppler imaging (arrows).

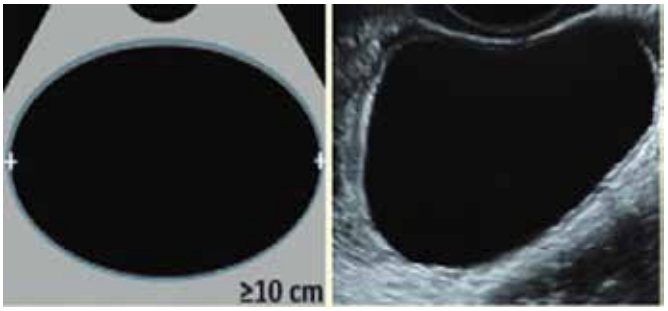


Non-simple unilocular cysts – cysts with internal echoes or incomplete septum.

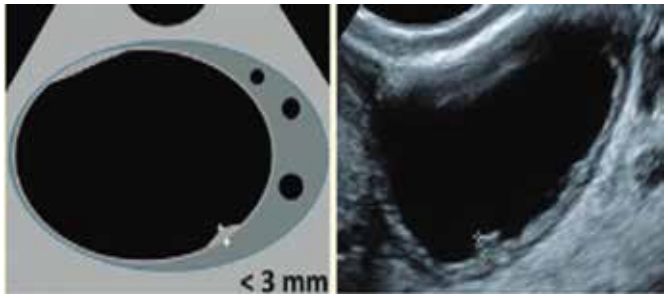
Non-Simple, unilocular cyst with smooth internal margin < 10cm - "Non-Simple" cyst applies when internal echoes or incomplete septa are present. Note that an incomplete septum is not considered a wall irregularity if the inner margin is smooth.



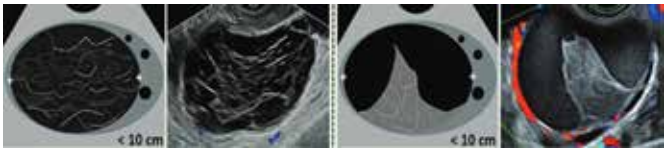
O-RADS 3 - LOW RISK OF MALIGNITY (1% TO 10%)
Simple unilocular cyst > 10 cm.



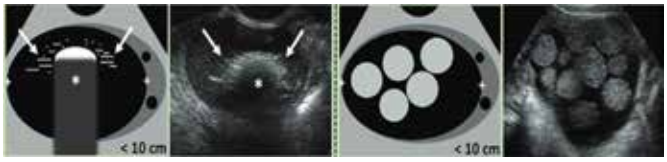
Unilocular cyst of any size, with wall irregularity < 03 mm in height.



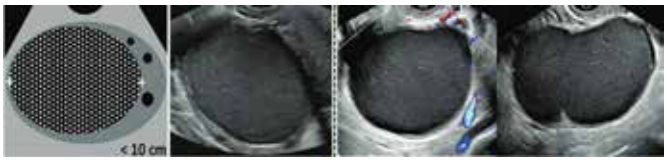
Classical benign lesions > 10 cm – Dermoid, endometriomas or hemorrhagic cysts.



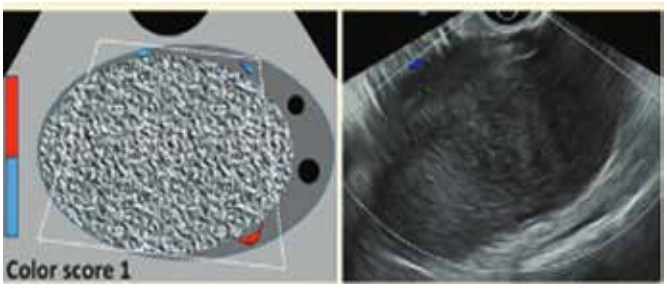
Hemorrhagic cyst



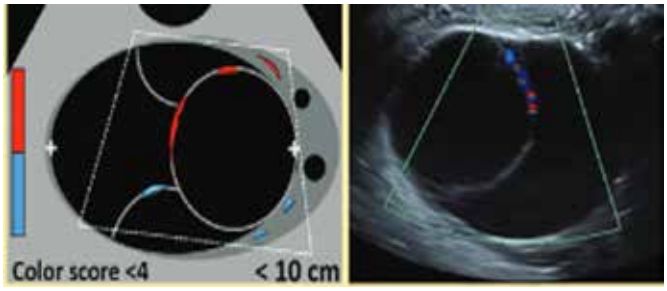
Dermoid cyst



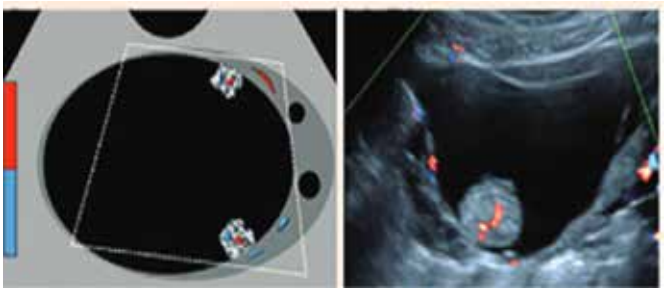
Endometriomas
Solid, smooth-edged lesion of any size, color score 1, no flow.



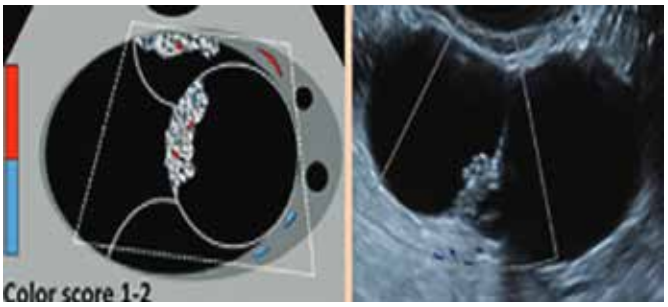
Multilocular cyst < 10 cm, with smooth inner wall, color score 1-3.



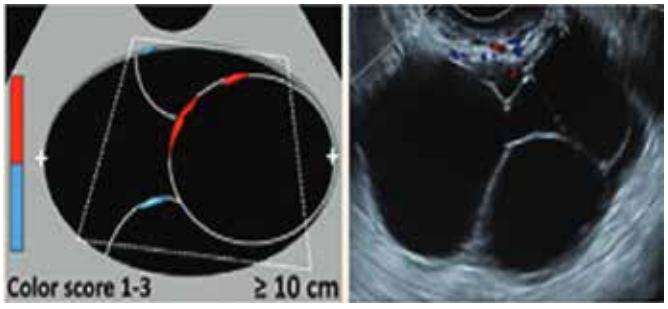
O-RADS 4 - INTERMEDIATE RISK OF MALIGNITY (10% TO 50%)
Unilocular cyst with solid component – 1-3 papillary projections (PP), or solid component that is not PP. Any size and any color score.



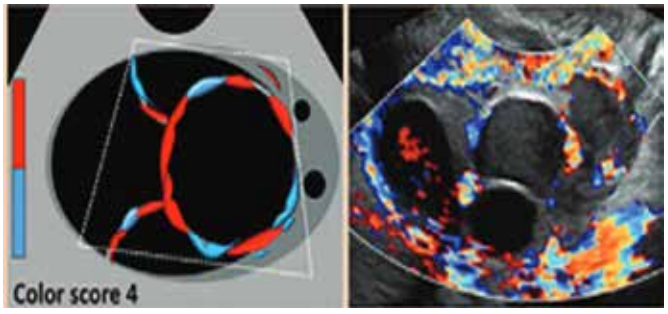
Multilocular cyst with solid component. Any size. Color Score 1-2.



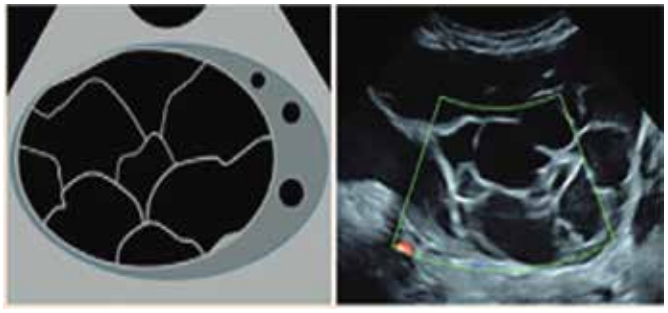
Multilocular cyst without solid component 10cm. Smooth inner wall. Color Score 1-3.



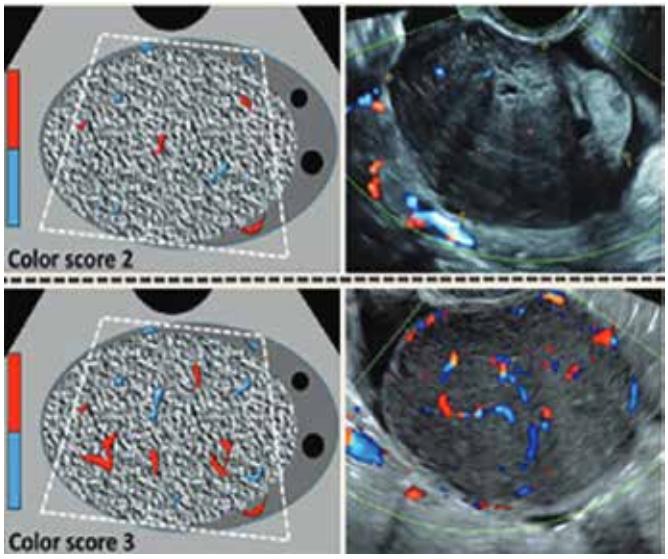
Any size. Smooth inner wall. Color score 4.



Any size. Irregular inner wall or papillary projections <03mm in height. Any color score.

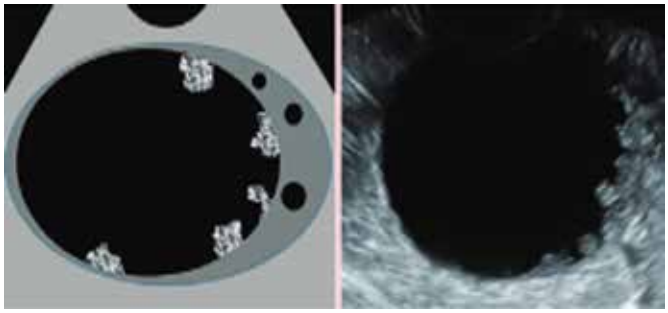


Solid lesion. Smooth outline. Any size. Color score 2-3.

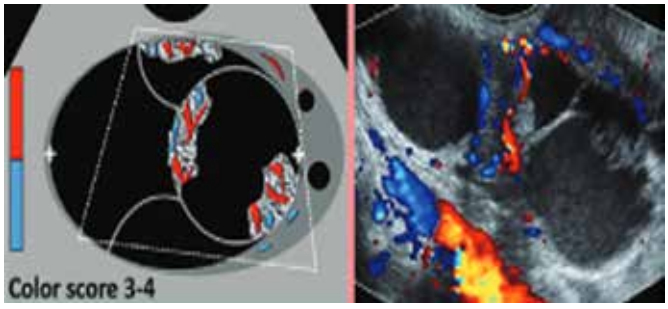


O-RADS 5 - Lesions with a high risk of malignancy (≥50%)

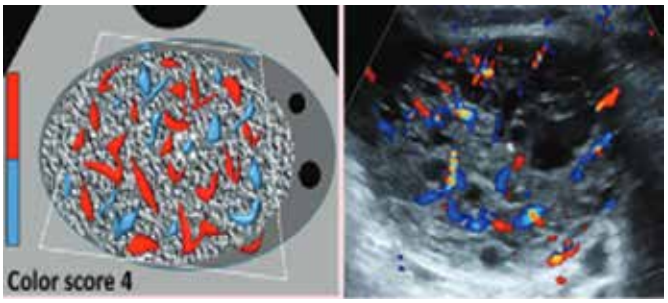
Unilocular cyst with four or more papillary projections. Any size. Color score.



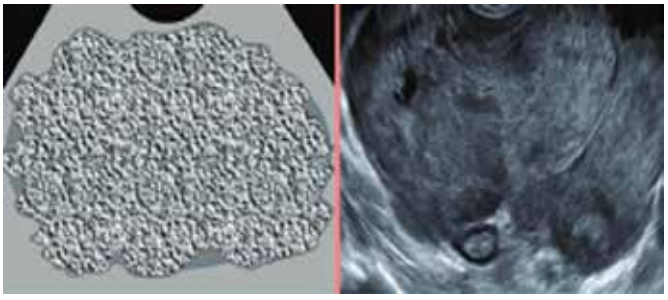
Multilocular cyst with solid component.



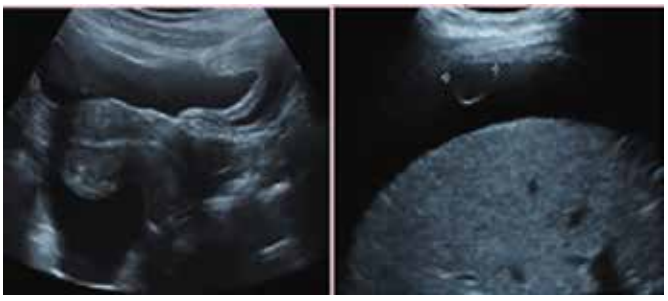
Solid lesion, Smooth outline. Any size. Color score 4.



Irregular solid lesions of any size.

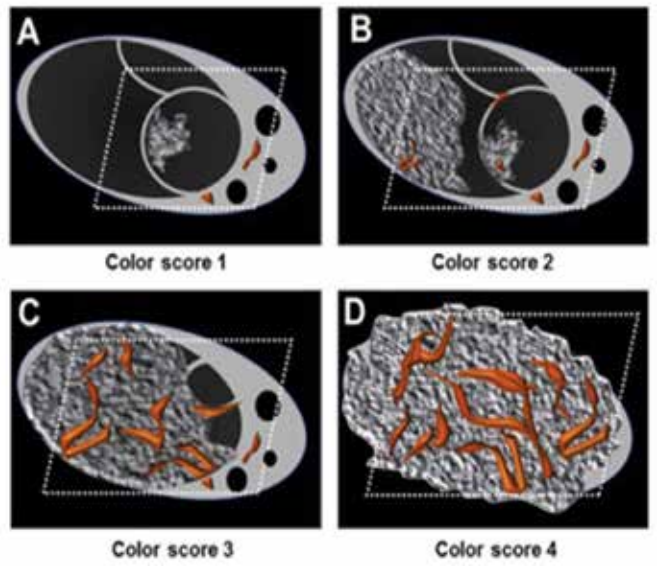


Presence of ascites or peritoneal nodularity.



Color score indicator

O-RADS: color score 1 to 4 (subjective evaluation of blood flow by the International Tumor Analysis Group adopted as part of the O-RADS Lexicon: (A) Color score 1 is given when no blood flow is detected in the tumor wall. cyst, septa or solid component. (B) Color score 2 is given when only minimal flow is detected. (C) Color score 3 is given when moderate flow is present. (D) Color score 4 is given when the adnexal lesion is highly vascularized with increased blood flow.



The presence of flow on Doppler is diagnostic of solid tissue, but its absence is less informative, and the lesion should then be considered solid in appearance.

Papillary projection (PP) is a type of solid component with a height greater than or equal to 3mm that arises from the cyst wall or septum and projects into the cyst cavity. When < 03mm in height, it should not be called PP.

Solid lesions are thus considered when they have a solid component > 80%.[5]

O-RADS MODEL TEST EVALUATION

One study evaluated the diagnostic accuracy of the ACR O-RADS scoring system among radiologists with no prior experience with the system. After being trained with thirty cases, radiologists evaluated 50 pelvic ultrasound scans using the O-RADS system. The results showed excellent specificity and negative predictive value and variability in sensitivity and positive predictive value. Individual reader AUC values ranged from 0.94 to 0.98 and overall reader agreement was "very good". The study concluded that even without specific training, radiologists can achieve excellent diagnostic performance and high reliability among readers with self-directed review of guidelines and cases. The study highlights the effectiveness of ACR O-RADS as a stratification tool for radiologists and supports its continued use in practice. However, the study identified some common errors in the system, which can be avoided with greater familiarity and training with the O-RADS system [6].

Another study assessed interobserver agreement in assigning imaging features and classifying adnexal masses using simple IOTA rules versus O-RADS lexicon and identifying causes of discrepancy. Pelvic ultrasound examinations were performed on 114 women with 118 adnexal masses who were evaluated by eight blinded radiologists for the final diagnosis, using simple IOTA rules and the O-RADS lexicon. Each characteristic category was analyzed for interobserver agreement using the intraclass correlation coefficient (ICC)

for ordinal variables and free marginal kappa for nominal variables. The two-tailed significance level was set at 0.05.) with k values of 0.80-0.82 and 0.68-0.69, respectively. Interobserver agreement was nearly perfect for two categories of benign features (B2, B3), substantial for two (B4, B5) and moderate for one (B1) with k values of 0.81-0.90, 0.69-0.70 and 0.60, respectively. For O-RADS, interobserver agreement was nearly perfect for two of the ten feature categories (ascites and peritoneal nodules) with k values of 0.89 and 0.97. Interobserver agreement ranged from fair to substantial for the remaining eight resource categories with k values of 0.39-0.61. Fellows and participants had ICC values of 0.725 and 0.517, respectively. The authors concluded that the O-RADS showed variable interobserver agreement with good overall agreement. Simple IOTA rules had more uniform interobserver agreement with excellent overall agreement. Greater reader experience did not improve interobserver agreement with O-RADS.

A diagnostic accuracy study was carried out with the aim of applying the simple rules (SR) of the International Ovarian Tumor Analysis (IOTA), the IOTA Simple Rules risk assessment (SRR), the IOTA assessment of different neoplasms in the adnex model (ADNEX) and the ovarian-adnexal data and reporting system (O-RADS) in the same cohort of US patients and compare their performance in preoperative discrimination between benign and malignant adnexal lesions. The study included 150 women with adnexal injury. Using the ADNEX model, lesions were classified prospectively, while the SR, SRR and O-RADS assessment were applied retrospectively. Surgery with histological analysis was performed up to six months after the ultrasound examination. Sensitivity and specificity were determined for each test modality and the performance of different modalities was compared [8].

Of the 150 women, 110 (73.3%) had a benign ovarian tumor and 40 (26.7%) had a malignant tumor. The mean risk of malignancy generated by the ADNEX model without CA 125 was significantly higher in malignant versus benign lesions (63.3% versus 11.8%) and the area under the curve of receptor operating characteristics (AUC) of the ADNEX model to differentiate between benign lesions and malignant adnexal masses at the time of ultrasound examination was 0.937. The mean risk of malignancy generated by the SRR assessment was also significantly higher in malignant versus benign lesions (74.1% versus 15.9%) and the AUC was 0.941. To compare the ADNEX model, SRR assessment, and O-RADS, the malignancy risk threshold was set at ≥ 10%. This cutoff differentiates low-risk O-RADS categories (Category ≤ 3) from intermediate-to-high-risk categories (Categories 4 and 5). At this cutoff point, the sensitivity of the ADNEX model was 97.5% (95% CI, 85.3%-99.9%) and the specificity was 63.6% (95% CI, 53.9%- 72.4%) and, for the SRR model, the sensitivity was 100% (95% CI, 89.1%-100%) and the specificity was 51.8% (95% CI, 42.1%-61.4%). In the 113 cases in which SR could be applied, the sensitivity was 100% (95% CI, 81.5%-100%) and the specificity was 95.6% (95% CI, 88.5%-98 .6%). If the remaining 37 cases, which were inconclusive under SR, were designated as 'malignant', the sensitivity remained at 100%, but the specificity was reduced to 79.1% (95% CI, 70.1%-86.0%). The 150 cases fell into the following O-RADS categories: 17 (11.3%) injuries in category 2, 34 (22.7%) in category 3, 66 (44.0%) in category 4 and 33 (22 .0%) in category 5. There were no histologically proven malignant lesions in category 2 or 3. There were 14 malignant lesions in category 4 and 26 in category 5. O-RADS sensitivity using a malignancy risk threshold of ≥ 10% was 100% (95% CI, 89.1%-100.0%) and the specificity was 46.4% (95% CI, 36.9%-56.1%) [8] – see data summaries in table 1 below.

Teste	Sensibilidade	Especificidade	Intervalo de Confiança (95%)
ADNEX	97,5%	63,6%	(85,3%-99,9%)
Avaliação SRR	100%	51,8%	(89,1%-100%)
RS (113 casos)	100%	95,6%	(81,5%-100%)
RS (150 casos)	100%	79,1%	(70,1%-86,0%)
O-RADS	100%	46,4%	(89,1%-100%)

Table 1. Displays the tests used with their sensitivity, specificity and confidence interval.

COMMENTS

• ADNEX and SRR Assessment have high sensitivity but low specificity.

• SR has high sensitivity and specificity when applied to all cases, but specificity is reduced when inconclusive cases are considered malignant.

• O-RADS has high sensitivity but low specificity.

The results indicate that, when IOTA terms and techniques are used, the performance of IOTA models in a North American patient population is in line with published IOTA results in other populations. The IOTA SR, SRR, ADNEX and O-RADS models have similar sensitivity in preoperative discrimination of malignant from benign pelvic tumors. However, IOTA models have higher specificity and the algorithm does not require the use of MRI [8].

The study evaluated the diagnostic performance and interobserver agreement of the American College of Radiology (ACR) Ovarian-Adnexal Reporting and Data System Ultrasound (O-RADS US) ultrasound data reporting system. Data from 1035 patients with a total of 1054 adnexal lesions categorized according to O-RADS criteria were analyzed.

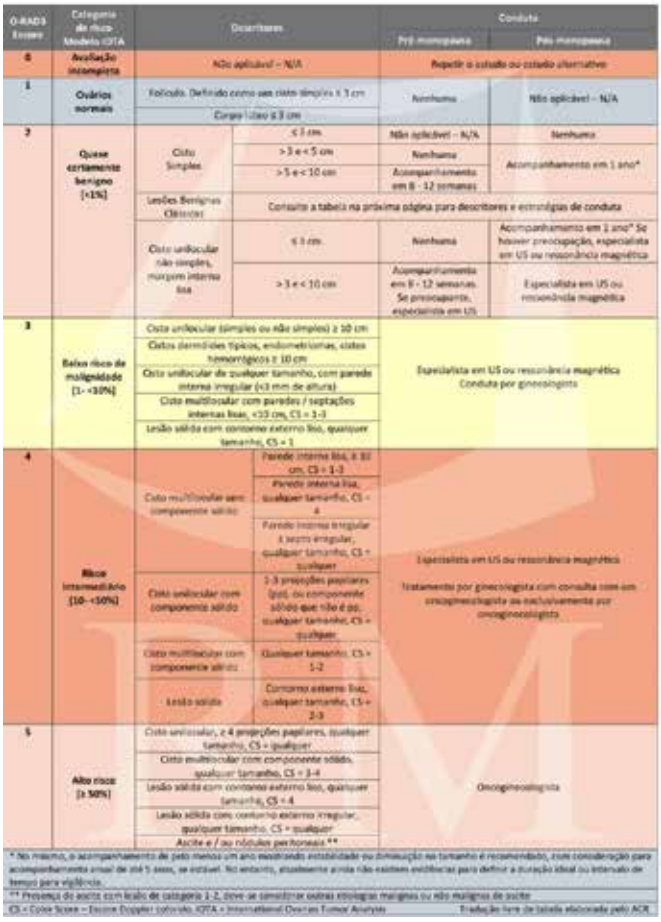
Of the 1054 adnexal lesions, 750 were benign and 304 were malignant. The malignancy rates of lesions classified as O-RADS 5, O-RADS 4, O-RADS 3 and O-RADS 2 were 89.57%, 34.46%, 1.10% and 0.45%, respectively. . The area under the receiver operating characteristic curve was 0.960, indicating a good performance of O-RADS in the diagnosis of adnexal lesions.

The ideal cutoff value to predict malignancy was > O-RADS 3, with sensitivity and specificity of 98.7% and 83.2%, respectively. The subgrouping of O-RADS 4 lesions into two groups (O-RADS 4a lesions and O-RADS 4b le-

sions) showed a malignancy rate of 17.02% and 42.57%, respectively, allowing for better risk stratification. Interobserver agreement between a less experienced radiologist and an O-RADS expert radiologist was good ($\kappa = 0.714$).

Therefore, the results indicate that O-RADS US is an effective tool for stratifying the risk of malignancy in adnexal lesions, with high reliability for radiologists with different levels of experience. Furthermore, the subclassification of O-RADS 4 lesions into two groups may facilitate a better stratification of intermediate risk [8].

Summary table



O-RADS Escore	Categoria de risco Modelo IOTA	Descritores		Conduta	
				Pré-menopausa	Pós-menopausa
0	Avaliação incompleta	Não aplicável – N/A		Repetir o estudo ou estudo alternativo	
1	Ovários normais	Folículo. Definido como um cisto simples ≤ 3 cm		Nenhuma	Não aplicável – N/A
		Corpo lúteo ≤ 3 cm			
2	Quase certamente benigno (<1%)	Cisto Simples	≤ 3 cm	Não aplicável – N/A	Nenhuma
			> 3 e < 5 cm	Nenhuma	Acompanhamento em 1 ano*
			> 5 e < 10 cm	Acompanhamento em 8 - 12 semanas	
		Lesões Benignas Clássicas	Consulte a tabela na próxima página para descritores e estratégias de conduta		
		Cisto unilocular não simples, marcam interna lisa	≤ 3 cm	Nenhuma	Acompanhamento em 1 ano* Se houver preocupação, especialista em US ou ressonância magnética
			> 3 e < 10 cm	Acompanhamento em 8 - 12 semanas. Se preocupante, especialista em US	Especialista em US ou ressonância magnética
3	Baixo risco de malignidade (1- <10%)	Cisto unilocular (simples ou não simples) ≥ 10 cm		Especialista em US ou ressonância magnética Conduta por ginecologista	
		Cistos dermóides típicos, endometriomas, cistos hemorrágicos ≥ 10 cm			
		Cisto unilocular de qualquer tamanho, com parede interna irregular (<3 mm de altura)			
		Cisto multilocular com paredes / septações internas lisas, <10 cm, CS = 1-3			
		Lesão sólida com contorno externo liso, qualquer tamanho, CS = 1			
4	Risco intermediário (10- <50%)	Cisto multilocular sem componente sólido	Parede interna lisa, ≥ 10 cm, CS = 1-3	Especialista em US ou ressonância magnética Tratamento por ginecologista com consulta com um oncoginecologista ou exclusivamente por oncoginecologista	
			Parede interna lisa, qualquer tamanho, CS = 4		
			Parede interna irregular à septo irregular, qualquer tamanho, CS = qualquer		
		Cisto unilocular com componente sólido	1-3 projeções papilares (pp), ou componente sólido que não é pp, qualquer tamanho, CS = qualquer		
		Cisto multilocular com componente sólido	Qualquer tamanho, CS = 1-2		
		Lesão sólida	Contorno externo liso, qualquer tamanho, CS = 2-3		
5	Alto risco (≥ 50%)	Cisto unilocular, ≥ 4 projeções papilares, qualquer tamanho, CS = qualquer		Oncoginecologista	
		Cisto multilocular com componente sólido, qualquer tamanho, CS = 3-4			
		Lesão sólida com contorno externo liso, qualquer tamanho, CS = 4			
		Lesão sólida com contorno externo irregular, qualquer tamanho, CS = qualquer			
		Ascite e / ou nódulos peritoneais **			

* No mínimo, o acompanhamento de pelo menos um ano mostrando estabilidade ou diminuição no tamanho é recomendado, com consideração para acompanhamento anual de até 5 anos, se estável. No entanto, atualmente ainda não existem evidências para definir a duração ideal ou intervalo de tempo para vigilância.

** Presença de ascite com lesão de categoria 1-2, deve-se considerar outras etiologias malignas ou não malignas de ascite

CS = Color Score – Escore Doppler colorido; IOTA = International Ovarian Tumor Analysis — Tradução livre de tabela elaborada pelo ACR

FINAL CONSIDERATIONS

The American Ovarian-Adnexal Reporting and Data System (O-RADS) risk stratification and management system is designed to provide consistent interpretations, to decrease or eliminate ambiguity in US reports, resulting in a greater likelihood of accuracy in assigning risk of malignancy to ovaries and other adnexal masses and provide a management recommendation for each risk category. For risk stratification, the US O-RADS system recommends six categories (O-RADS 0–5), incorporating the normal to high risk range of malignancy. O-RADS US is the only lexicon and classification system that covers all risk categories with their associated management schemes.

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