ROLE OF INTERNATIONAL OVARIAN TUMOR ANALYSIS SIMPLE RULES, ASSESSMENT OF DIFFERENT NEOPLASIAS IN THE ADNEXA MODEL AND OVARIAN-ADNEXAL REPORTING AND DATA SYSTEM IN DISCRIMINATING ADNEXAL LESIONS

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Abstract:

Prediction of malignancy risk in adnexal masses is very important to provide the best managment for the patients. Using IOTA SR,ADNEX model and O-RADS can predict malignancy risk of an adnexal mass. Moreover, O-RADS provides a mangment strategy.

Keywords: IOTA, Adnexal Lesions, ADNEX model, O-RADS.

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Role of International Ovarian Tumor Analysis Simple Rules, Assessment of Different Neoplasias in The Adnexa Model and Ovarian-Adnexal Reporting and Data System in Discriminating Adnexal Lesions

Section A -Research paper

Introduction:

Adnexal lesions are commonly encountered in daily radiology practice with an estimated prevalence of 4–18% in the general population. The etiology of adnexal masses ranges from physiologically normal luteal cysts to ovarian cancer **(1).**

Ultrasonography (US) continues to be the primary imaging modality used to identify and characterize adnexal masses **(2).**

Adequate characterization of an adnexal mass is important for both of the following, to determine which patients need surgery and to help defining the type of surgery and whether a surgical subspecialist is needed **(3).**

Therefore, predicting the risk of malignancy in adnexal masses is important. By this way,we can diagnose ovarian cancer earlier and provide the best mangment for women with adnexal masses. As some adnexal lesions could be treated expectantly, others are treated by surgical or laparoscopic removal. On the other hand, malignant adnexal masses are best managed by a specialized team including a gynecologic oncologist thus improving survival **(4).**

In response to these concerns, Various ultrasound-based approaches for characterizing adnexal masses have been used in order to improve preoperative characterization of an ovarian pathology, These approaches include the following:

1) Simple rules(SR) developed by the International Ovarian Tumor Analysis [IOTA] group but its main disadvantage is that it is inconclusive in about 25% of cases.

2) **A**ssessment of **D**ifferent **NE**oplasias in the adne**X**a (ADNEX) model that provides risk predicton without management.

3) The Ovarian-Adnexal Reporting and Data System (O-RADS) that provides both risk prediction and recommended management **(5).**

International Ovarian Tumor Analysis (IOTA)

The IOTA group has provided a three-step strategy to improve the adnexal mass (AM) evaluation. First step is using Simple Descriptors by pattern recognition. Second step is the IOTA Simples Rules and third step is a subjective assessment of an expert radiologist ***(6).***

IOTA (Simple Descriptors)

It is formed of specific Ultrasonographic patterns that correspond to specific adnexal pathologies ***(6).***

IOTA (Simple Rules)

The Simple Rules were developed at 2008 by IOTA group. They are a preoperative classification system for ovarian tumors, consisting of five sonographic features typical for benign tumors (B-features) and five sonographic features typical for malignant tumors (M-features) as shown in (Fig.1). Based on which of the B- and M-features that apply, tumors are classified as Benign, Malignant or Inconclusive. Benign lesions apply only B-features, Malignant lesions only apply M-features & Inconclusive lesions no features applied, or both B- and M-features are applied ***(7).***

Classification	Malignant Characteristics
M1	Irregular solid tumor
M2	Presence of ascites
M3	At least 4 papillary structures
M4	Irregular multilocular solid tumor with largest diameter ≥100 mm
M5	High Doppler blood flow (color score 4)
	Benign Characteristics
B1	Unilocular
B2	Presence of solid components with largest component < 7 mm
B3	Presence of acoustic shadows
B4	Smooth multilocular tumor with largest diameter < 100 mm
B5	No Doppler blood flow (color score 1)

Fig.1: showing B&M features of simple rules developed by IOTA group (***7).***

Pitfalls of IOTA: ***(8)***

1-The IOTA simple rules are unable to classify all adnexal masses as either benign or malignant because another diagnostic method (such as evaluation by an expert US examiner) is required to categorize inconclusive masses in about 20% of patient cases, limiting its usefulness.

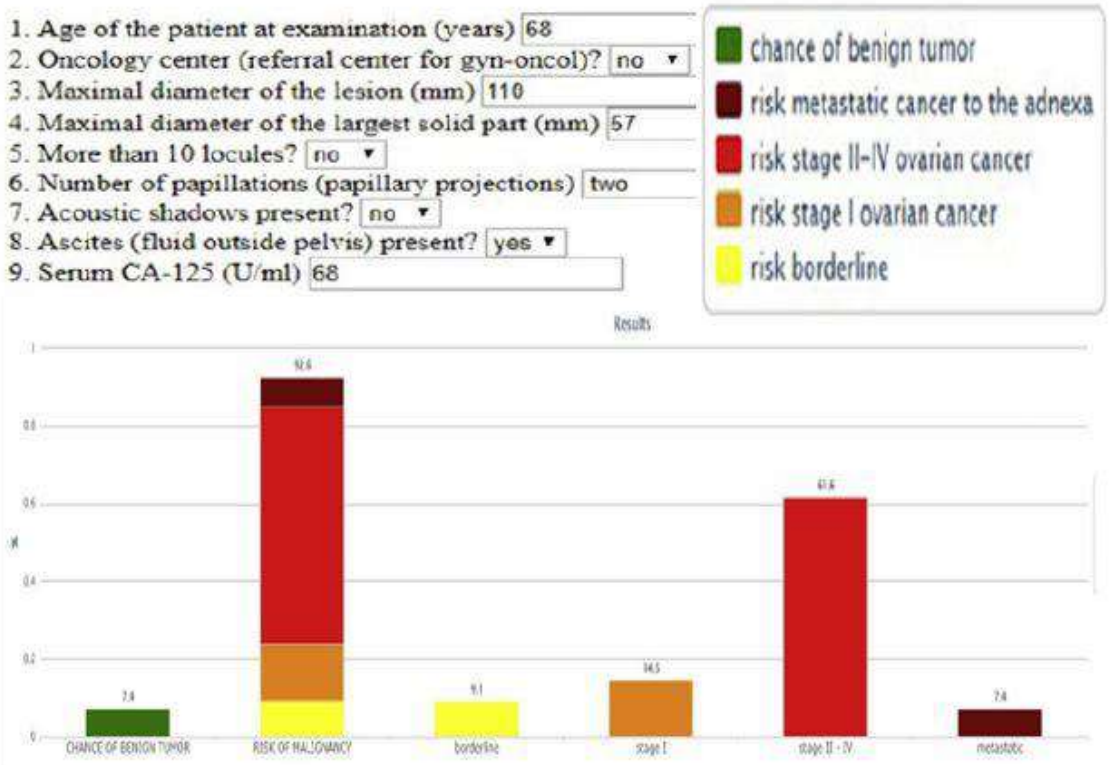
2-Limitation of their application in clinical practice is due to the preference for a so-called pattern recognition approach rather than a mathematical model (ADNEX Model).

3- Their application is also limited due to the absence of more

Detailed guidance in the evaluation of many lesions that are almost certainly benign.

The ADNEX model

The ADNEX model is a risk prediction model that can reliably distinguish between benign, borderline, stage I invasive, stage II-IV invasive, and secondary metastatic adnexal ovarian tumors .it has three patient parameters and six ultrasound parameters as shown in (figure 2) ***(9).***



	Patient Specific Risk	Relative Risk	Baseline Risk
CHANCE OF BENIGN TUMOR	7.4 %	0.1	68.2%
RISK OF MALIGNANCY	92.6 %	2.9	31.8 %
->Risk borderline	9.1 %	1.4	6.3 %
->Risk stage I ovarian cancer	14.5 %	1.9	7.5 %
->Risk stage II-IV ovarian cancer	61.6 %	4.4	14.1 %
->Risk metastatic cancer to the adnexa	7.4 %	1.8	4.0 %

Fig.2: showing ADNEX model ***(9).***

Ovarian-Adnexal Reporting and Data System (O-RADS)

In the summer of 2015, the Ovarian-Adnexal Reporting and Data System (O-RADS) Committee was created under the direction of the ACR, with the target of creating an integrated lexicon that would allow the emergence and development of a practical, effective &uniform vocabulary for characterizing the different imaging features of different adnexal masses ***(8).***

The Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon was published in 2018, giving an integrated lexicon that involves all descriptors and definitions of the distinctive US looking of normal ovaries and ovarian or other adnexal masses ***(10).***

The O-RADS lexicon provides a two complementary step strategy as shown in (Fig.3) to characterize normal ovaries and adnexal lesions (***8).***

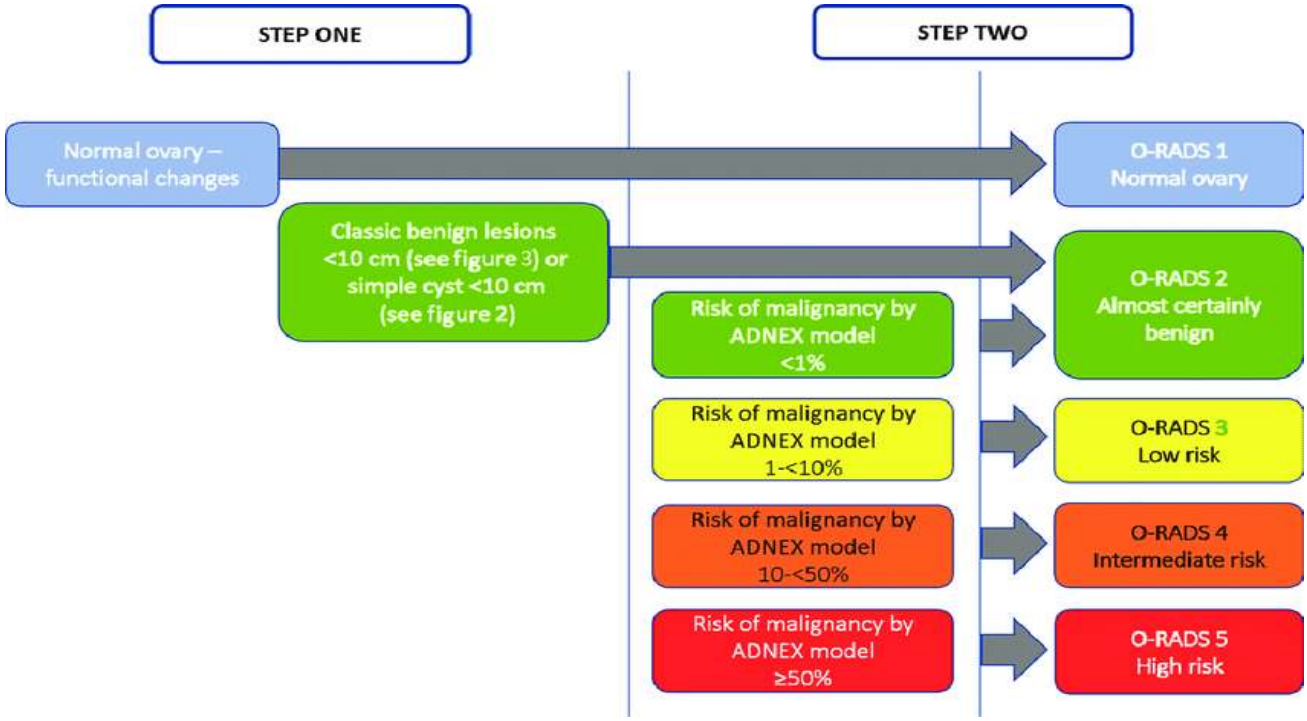


Fig. 3: Diagram showed the incorporation of assessment of different masses in the Adnexa (ADNEX) model into Ovarian-Adnexal Reporting and Data System risk classification system (8).

O-RADS Score	Risk Category [IOTA Model]	Lexicon Descriptors		Management	
				Pre-menopausal	Post-menopausal
0	Incomplete Evaluation [N/A]	N/A		Repeat study or alternate study	
1	Normal Ovary [N/A]	Follicle defined as a simple cyst ≤ 3 cm		None	N/A
		Corpus Luteum ≤ 3cm			
2	Almost Certainly Benign [< 1%]	Simple cyst	≤ 3 cm	N/A	None
			> 3 cm to 5 cm	None	Follow up in 1 year. *
			> 5 cm but < 10 cm	Follow up in 8 - 12 weeks	
		Classic Benign Lesions	See **Figure 3** for separate descriptors	See **Figure 3** for management strategies	
		Non-simple unilocular cyst, smooth inner margin	≤ 3 cm	None	Follow up in 1 year * If concerning, US specialist or MRI
			> 3 cm but < 10 cm	Follow-up in 8 - 12 weeks If concerning, US specialist	US specialist or MRI
3	Low Risk Malignancy [1-<10%]	Unilocular cyst ≥ 10 cm (simple or non-simple)		US specialist or MRI Management by gynecologist	
		Typical dermoid cysts, endometriomas, hemorrhagic cysts ≥ 10 cm			
		Unilocular cyst, any size with irregular inner wall <3 mm height			
		Multilocular cyst < 10 cm, smooth inner wall, CS = 1-3			
		Solid smooth, any size, CS = 1			
4	Intermediate Risk [10- < 50%]	Multilocular cyst, no solid component	≥ 10 cm, smooth inner wall, CS = 1-3	US specialist or MRI Management by gynecologist with GYN-oncologist consultation or solely by GYN-oncologist	
			Any size, smooth inner wall, CS = 4		
			Any size, irregular inner wall and/or irregular septation, any color score		
		Unilocular cyst with solid component	Any size, 0-3 papillary projections, CS = any		
		Multilocular cyst with solid component	Any size, CS = 1-2		
		Solid	Smooth, any size, CS = 2-3		
5	High Risk [≥ 50%]	Unilocular cyst, any size, ≥ 4 papillary projections, CS = any		GYN-oncologist	
		Multilocular cyst with solid component, any size, CS = 3-4			
		Solid smooth, any size, CS = 4			
		Solid irregular, any size, CS = any			
		Ascites and/or peritoneal nodules**			

Fig.4: This figure demonstrated the different categories of the O-RADS US risk stratification and management system. At a minimum, at least 1-year follow-up showing stability or decrease in size is recommended with consideration of annual follow-up of up to 5 years, if stable. However, there is currently a little evidence for determining adequate duration or interval of timing for surveillance. ** = Presence of ascites with category 1-2 lesions, must consider other malignant or nonmalignant etiologies of ascites. CS =color score, GYN gynecologic, N/A = not applicable ***(8).***

O-RADS Categories

O-RADS 0:
It is an incomplete evaluation due to technical factors such as bowel gas, large size of the lesion, location of the adnexa, or inability to tolerate endovaginal imaging (***8)***
O-RADS 1:
It involves the physiologic category that is relevant only in premenopausal patients, which are the follicle and corpus luteum ***(8).***

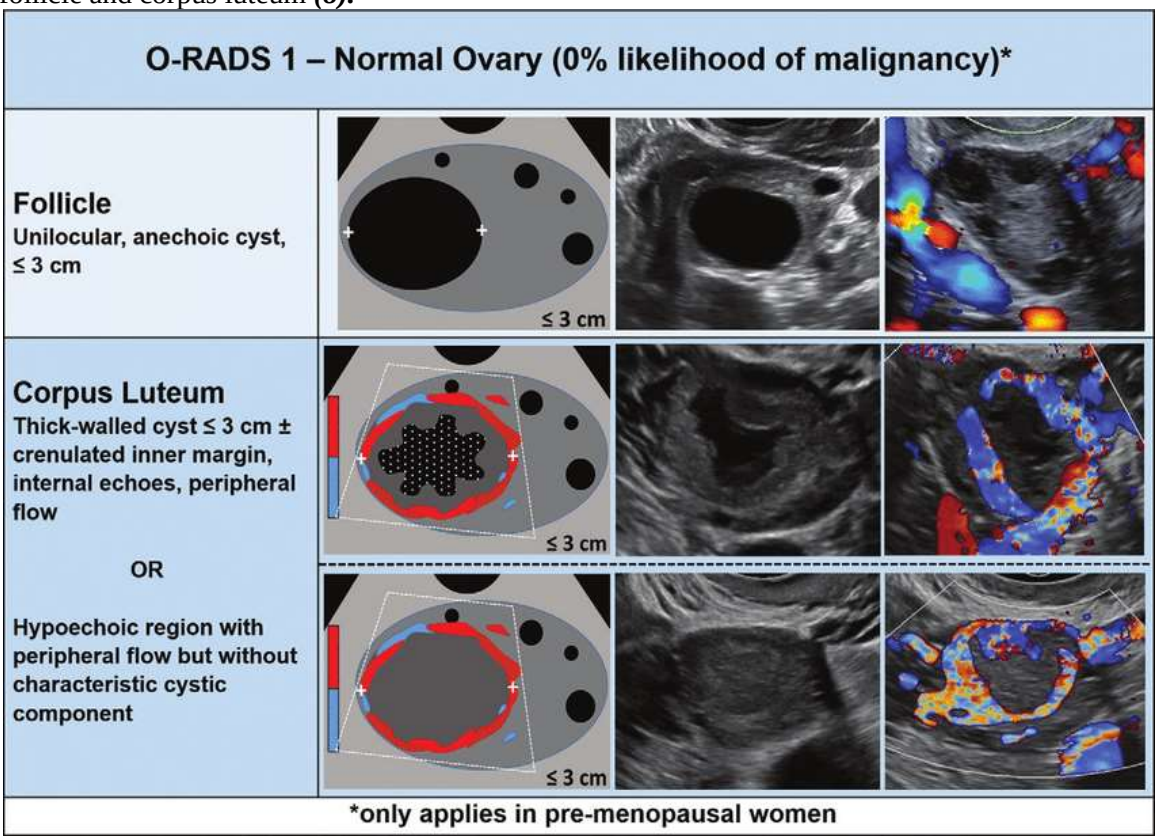


Fig. 5: Image showed the O-RADS category 1(normal ovary) ***(8).***
O-RADS 2:
It represents the majority of unilocular cysts less than 10 cm This group includes simple cysts ,and non-simple unilocular cysts with smooth walls as shown in (Fig.6) and cysts that may be described by using classic benign lesions and their descriptors if less than 10 cm in maximal diameter as shown in (Fig.7) (8).

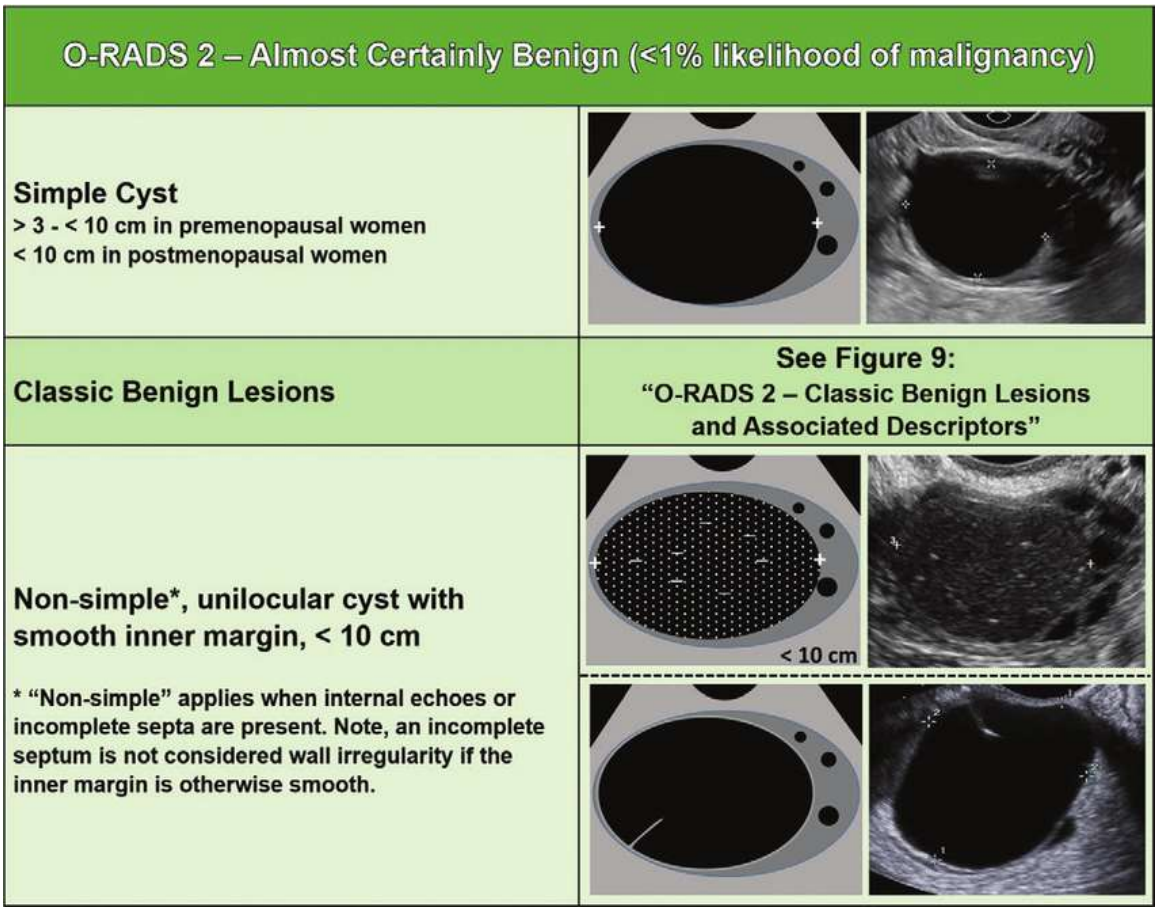


Fig. 6: Image illustrated the simple cyst and non simple cyst . (8).

Non-simple, unilocular cyst with smooth inner margin, < 10 cm

"Non-simple" applies when Internal echoes or Incomplete septa are present. Note, an incomplete septum is not considered wall irregularity if the inner margin is otherwise smooth.

Classic benign lesions are those which may be confidentially diagnosed when one or more specific O-RADS US lexicon descriptors are seen without any concerning features as shown in (Fig.7) (8).

Lexicon Term	Definition	Suggested Management Premenopausal	Suggested Management Postmenopausal
Typical hemorrhagic cyst	Reticular pattern: Fine thin intersecting lines representing fibrin strands Retracting clot: An avascular echogenic component with angular, straight, or concave margins	≤ 5 cm None	US specialist, gynecologist or MRI
		>5 cm but < 10 cm Follow up in 8-12 weeks If persists or enlarges, referral to US specialist, gynecologist, or MRI	US specialist, gynecologist or MRI
Typical dermoid cyst < 10 cm	• Hyperechoic component with acoustic shadowing • Hyperechoic lines and dots • Floating echogenic spherical structures	Optional initial follow up in 8-12 weeks based upon confidence in diagnosis If not removed surgically, annual US follow up should then be considered * US specialist or MRI if there is enlargement, changing morphology or a developing vascular component	US specialist, gynecologist, or MRI With confident diagnosis, if not removed surgically, annual US follow up should then be considered * MRI if there is enlargement, changing morphology or a developing vascular component
Typical endometrioma < 10 cm	Ground glass/homogeneous low-level echoes		
Simple paraovarian cyst/any size	Simple cyst separate from the ovary that typically moves independent of the ovary when pressure is applied by the transducer	None If not simple, manage per ovarian criteria	Optional single follow up study in 1 year
Typical peritoneal inclusion cyst/any size	Follows the contour of the adjacent pelvic organs or peritoneum, does not exert mass effect and typically contains septations. The ovary is either at the margin or suspended within the lesion.	Gynecologist	Gynecologist
Typical hydrosalpinx/ any size	• Incomplete septation • Tubular • Endosalpingeal folds: Short round projections around the inner wall of a fluid distended tubular structure	Gynecologist	Gynecologist

Fig. 7: Image illustrated the O-RADS US risk stratification and management system there for (CBLS) classic benign lesions and associated descriptors (O-RADS 2). * = is currently a little evidence for determining adequate period or interval of timing for surveillance. Evidence does support an increasing

Increasing risk of malignancy in endometriomas following menopause. Adapted, with permission, from the American College of Radiology (***8)***

O-RADS 3:

It involves lesions in O-RADS US category 2 that are large in size and other lesions where descriptors applied predict a slightly higher risk of malignancy ***(8).***

This involves both simple cysts, unilocular smooth non smile cysts, and lesions with classic benign descriptors that are larger than or equal to 10 cm ***(11).***

Also included are unilocular cysts with wall irregularity, multilocular cysts less than 10 cm without solid component, with a color score less than 4 and avascular solid or solid-appearing lesions with a smooth external contour of any size ***(8).***

O-RADS 4:

It involves descriptors found to be predictive of a higher risk of malignancy. This category involves multilocular cysts that are ≥10 cm, or have an irregular inner wall or septal irregularity (<3 mm in height), unilocular and multilocular cysts of any size with a solid part or color score up to 4, and smooth solid lesions (≥80% solid) with color score 2 or 3. It should be recognized that a papillary

projection is a type of solid component with height ≥3 mm that emerge from the cyst wall or septations and juts into the cyst lumen ***(8).***

O-RADS 5:

It involves descriptors that are highly predictive of malignancy such as irregular solid lesions and multilocular cysts with a solid component and high color score. The presence of ascites and/or peritoneal nodules would also be a reference for an O-RADS 5 score except when there is ascites in association with a physiologic cyst or almost certainly benign lesion, at which time other etiologies for ascites should be considered (***8).***

Management of different US O-RADS category:

The O-RADS US system should help the health care provider in determining which lesions need no follow-up or conservative follow-up, often with the help of a US specialist or doing an MRI study ***(12***), for adequate description, versus lesions that need d to be consulted by a gynecologist or gynecologic oncologist ***(13)***.

This classification that involves a clinical management strategy accepted on by the gynecologists, gynecologic oncologists, and radiologists in the O-RADS US working group ***(8).***

O-RADS 0, Incomplete Evaluation: (***8)***

Generally, repetition of US study is recommended, although an alternate imaging study such as MRI may be appropriate in selected cases.

O-RADS 1, Normal Ovary: ***(8)***

No additional imaging or follow-up is necessary.

O-RADS 2, Almost Certainly Benign (<1% Risk of Malignancy): ***(8)***

Generally, either no follow-up or surveillance is the recommendation for lesions that are almost certainly benign. Further characterization by a US specialist or performance of an MRI study, as well as management by a gynecologist, may be advised in some subgroups.

O-RADS 3 (1% to <10% Risk of Malignancy): ***(8)***

The majority of O-RADS US category 3 masses (>90%) are benign and the committee accepted that there is no need for consultation with a gynecologic oncologist. Patients with this group of masses should be managed by a general gynecologist, although it is important that adequate imaging evaluation be performed. Thus, consultation with an US specialist or doing of an MRI examination to decrease the risk of overlooking more suspicious features is encouraged by the O-RADS US management scheme.

O-RADS 4 (10% to <50% Risk of Malignancy):

O-ARDS US category 4 findings (intermediate-risk lesions) need either consultation with gynecologic oncology prior to removal or referral for management ***(8).***

Menopausal status, US specialist evaluation, MRI characterization, and serum biomarkers (most commonly, CA-125) may play a role in deciding which of these lesions should be referred for management by a gynecologic oncologist.If a surgical procedure is to be done by a general gynecologist, then it is recommended that the facility has the necessary support and consultative services to optimize patient outcomes ***(8)***

O-RADS 5 (50%–100% Risk of Malignancy): The system states that category 5 US findings (high-risk lesions) should be directly referred to a gynecologic oncologist for management.

Advantages of O-RADS lexicon over other systems:(8)

1-O-RADS lexicon provides consistent interpretations, to decrease or eliminate ambiguity in US reports resulting in a higher probability of accuracy in assigning risk of malignancy to ovarian and other adnexal masses.

2-It provides a management recommendation for each risk category.

3-O-RADS US is the only lexicon and classification system that encompasses all risk categories with their associated management schemes.
4-The ultimate goal of O-RDAS lexicon is to optimize ovarian cancer outcomes.

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