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ORIGINAL RESEARCH • STATEMENTS AND GUIDELINES

O-RADS US Risk Stratification and Management System: A Consensus Guideline from the ACR Ovarian-Adnexal Reporting and Data System Committee

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The Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system is designed to provide 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, and to provide a management recommendation for each risk category. It was developed by an international multidisciplinary committee sponsored by the American College of Radiology and applies the standardized reporting tool for US based on the 2018 published lexicon of the O-RADS US working group. For risk stratification, the O-RADS US system recommends six categories (O-RADS 0–5), incorporating the range of normal to high risk of malignancy. This unique system represents a collaboration between the pattern-based approach commonly used in North America and the widely used, European-based, algorithmic-style International Ovarian Tumor Analysis (IOTA) Assessment of Different Neoplasias in the Adnexa model system, a risk prediction model that has undergone successful prospective and external validation. The pattern approach relies on a subgroup of the most predictive descriptors in the lexicon based on a retrospective review of evidence prospectively obtained in the IOTA phase 1–3 prospective studies and other supporting studies that assist in differentiating management schemes in a variety of almost certainly benign lesions. With O-RADS US working group consensus, guidelines for management in the different risk categories are proposed. Both systems have been stratified to reach the same risk categories and management strategies regardless of which is initially used. At this time, O-RADS US is the only lexicon and classification system that encompasses all risk categories with their associated management schemes.

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The accurate characterization of ovarian and other adnexal masses is essential for optimal patient management. Conservative and less aggressive management is more appropriate for lesions that are likely benign. On the other hand, when malignancy is suspected, patients should be referred to a gynecologic oncologist because this is known to result in better outcomes (1–3). The ultimate goal is to optimize ovarian cancer outcomes while minimizing unnecessary surgical procedures in patients at low risk of malignancy. Consideration should be given to minimizing surgical morbidity and maintaining hormonal competency for patients at low risk for malignancy. A recent study (4) of patients with asymptomatic tumors classified as benign by using US supports the use of expectant management as a valid option, which may reduce the number of surgical complications while minimizing health care costs. A consensus report by a multidisciplinary panel of experts regarding management of adnexal masses published in 2017 (5) also concluded that surgical procedures for benign lesions may be avoided with improvement in the preoperative assessment of these lesions.

Published studies, as well as expert consensus, support the use of pattern recognition by an experienced US examiner as the most accurate US method of discriminating between benign and malignant adnexal lesions (6–10). However, the level of expertise of practitioners who perform and interpret sonograms varies widely (5). Recognizing this offers an opportunity to improve risk stratification by establishing standardized and evidence-based risk assessment algorithms.

The American College of Obstetricians and Gynecologists recommendations (11) now encourage more detailed use of US risk assessment by all practitioners, incorporating an elevated score on a formal risk assessment test that includes one of the US-based risk classification systems developed by the International Ovarian Tumor Analysis

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Abbreviations

ADNEX = Assessment of Different Neoplasias in the Adnexa, CA-125 = cancer antigen 125, IOTA = International Ovarian Tumor Analysis, O-RADS = Ovarian-Adnexal Reporting and Data System

Summary

The Ovarian-Adnexal Reporting and Data System US risk stratification and management system for evaluation of ovarian and other adnexal masses is based on a standardized lexicon, incorporates all classes of risk, and offers an associated management strategy for each risk category.

Key Results

- The Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system offers a means to provide consistent interpretations and decrease ambiguity in US reports in assigning risk of malignancy.
- These recommendations function as guidance in the management of average-risk patients without acute symptoms who demonstrate adnexal lesions. Individual case management may be modified based on professional judgment, regardless of the O-RADS US recommendations.
- The guidelines include a condensed lexicon containing only required descriptors that facilitate the application of lexicon terms to the risk stratification system.

(IOTA) group. The IOTA group has developed evidence-based terms and definitions (12) used in the Simple Rules classification system and Assessment of Different Neoplasias in the Adnexa (ADNEX) model to differentiate benign from malignant adnexal masses (13–15). 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. However, the 10 US features referred to when applying the IOTA Simple Rules have now been incorporated in a mathematical model to calculate the likelihood of malignancy (14). The preferred IOTA group mathematical model, the IOTA ADNEX model (15), calculates the likelihood not only of an adnexal mass being simply benign or malignant but also the likelihood of a mass being borderline malignant, a stage I primary invasive malignancy, a stage II–IV primary invasive malignancy, or a metastasis in the ovary from another primary tumor. Although the predictive value of these rules and models is high (and has been externally validated and in common usage in Europe), their acceptance has been limited in clinical practice in the United States and Canada to date. This may be related to the preference for a so-called pattern recognition approach rather than a mathematical model (ADNEX), as well as the absence of more detailed guidance in the evaluation of many lesions that are almost certainly benign.

Other ovarian mass characterization and management systems have been proposed, including the Society of Radiologists in Ultrasound consensus statement (6); the University of Kentucky morphology index (16–18); and the Gynecologic Imaging Reporting and Data System, or GI-RADS (19). The Society of Radiologists in Ultrasound consensus statement, popular in North America, is helpful in determining which cystic lesions require follow-up, further imaging, or a surgical procedure. However, the statement does not include standardized terminology and definitions, and does not recommend management for higher-risk lesions. GI-RADS also does not provide objective criteria for all lesions. The morphology index by the University of Kentucky group defines objective morphology terms which, when combined with tumor volume, demonstrates good prediction of malignancy in ovarian tumors from an ovarian cancer screening population, but it has not been validated outside a single institution and is without widespread acceptance. This leaves an opportunity to create a universally recognized reporting tool based on common terminology, as well as a management system for all categories of risk.

The Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon for US (20) was published in 2018, providing a standardized lexicon that includes all pertinent descriptors and definitions of the characteristic US appearance of normal ovaries and ovarian or other adnexal lesions. The lexicon is based on consensus of the committee. Taking into consideration supporting evidence for the performance of different terminology used in the literature for the classification of a mass as benign or malignant, the committee members agreed on terms similar to those used in the IOTA models. We have now tested the descriptors used in the O-RADS lexicon on the large data set from phases 1–3 of the IOTA study to assign a risk of malignancy to each of them. Those terms that were found to be useful in assigning risk of malignancy have been placed in a condensed lexicon table to facilitate risk stratification (Fig 1). Finally, with the use of other evidence-based supporting studies in the literature that offer additional guidance differentiating management schemes in a variety of almost certainly benign lesions that include simple cysts, hemorrhagic cysts, dermoid cysts, endometriomas, paraovarian cysts, peritoneal inclusion cysts, hydrosalpinges, and O-RADS US working group consensus, we offer guidelines for management in the different risk categories. The proposed guidelines are a collaborative, multidisciplinary, international approach incorporating both the common European and North American approaches. The guidelines include all risk categories with their attendant management strategies, which have not been included within any of the prior systems.

Risk Stratification Methodology

Based on expert opinion, the O-RADS US working group defined six categories for risk classification. These include O-RADS 0, an incomplete evaluation; O-RADS 1, the physiologic category (normal premenopausal ovary); O-RADS 2, the almost certainly benign category (<1% risk of malignancy); O-RADS 3, lesions with low risk of malignancy (1% to <10%); O-RADS 4, lesions with intermediate risk of malignancy (10% to <50%); and O-RADS 5, lesions with high risk of malignancy (≥50%).

We performed a retrospective analysis of prospectively collected data from IOTA phase 1–3 to classify lesion risk. In these multicenter prospective cohort studies, patients with an adnexal lesion were consecutively recruited from 24 centers in 10 countries between 1999 and 2012 as follows: phase 1 (21) between 1999 and 2002, phase 1b (22) between 2002 and 2005, phase 2 (23) between 2005 and 2007, and phase 3 (24) between 2009 and 2012. All patients underwent a standardized US examination using IOTA terms and definitions (12) and were scheduled

Category	Term	Definition	Comments
1	**Major Categories**		
	Physiologic Category (consistent with normal ovarian physiology)		
	Follicle	Simple cyst ≤ 3 cm in premenopausal group	
	Corpus luteum (CL)	Thick walled cyst ≤ 3 cm that may have crenulated inner margins, internal echoes and intense peripheral color Doppler flow	CL can sometimes appear as a hypoechoic region in the ovary with peripheral vascularity without a characteristic cystic component
	Lesion Category (not consistent with normal physiology)		
	Unilocular, no solid component	Cystic lesion that contains a single compartment. May contain ≥ 1 incomplete septum, wall irregularity < 3mm height or internal echoes	***Simple cyst is a subset of unilocular cyst with a smooth, thin wall, acoustic enhancement and no internal elements, thus anechoic**
	Unilocular cyst with solid component(s)	As above but includes solid component(s) ≥ 3mm in height	
	Multilocular cyst, no solid elements	Cystic lesion with more than one compartment (at least one complete septum) but no solid component(s) ≥ 3mm in height	
	Multilocular cyst with solid component(s)	As above but includes ≥ 1 solid component(s) ≥ 3 mm in height	
	Solid or solid appearing (greater than or equal to 80%)	Lesion with echogenicity suggestive of tissue without characteristics of a cyst. Lesion is at least 80% solid when assessed in orthogonal 2-dimensional plane	Confirmed with color or spectral Doppler with absence of color Doppler flow less informative. Lack of internal motion with transducer pressure is helpful.
2	**Size**		
	Maximum diameter	Maximum diameter of a lesion in any plane	
3	**Solid or Solid-Appearing Lesions**		
	External contour		
	Smooth	Regular outer margin	
	Irregular (Not Smooth)	Non-uniform outer margin	A lobulated outer margin is considered irregular
	Internal contents		
	Acoustic shadowing	Artifact produced by attenuated echoes behind a sound absorbing structure	Descriptor is commonly associated with calcification(s) or fibromatous type lesion
4	**Cystic Lesions**		
	Inner Margin or Walls Including Solid Component		
	Papillary projection or nodule	Solid component whose height ≥ 3 mm, arises from the cyst wall or septation and protrudes into the cyst cavity	Number of papillary projections should be included
	Smooth	Regular, uniform inner margin that may include inner margin of a solid component that is not a papillary projection	
	Irregular (not smooth)	Irregular, non-uniform inner margin. May include wall irregularities due to incomplete septations, solid components < 3mm height, papillary projections, the contour of the solid component or the margin of any internal cystic area within the solid component	

Figure 1: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) key US lexicon terms for risk assessment. IOTA = International Ovarian Tumor Analysis. Adapted, with permission, from the American College of Radiology. *(Fig 1 continues)*

for surgical procedures as judged by the clinician. Among all 6169 patients recorded in the databases for phases 1, 1b, 2, and 3, we excluded 255 patients (4.1%) (15). For details on inclusion and exclusion criteria as well as data collection, we refer to the original publications of the respective study phases (15,21–24). Additionally, nine patients were excluded because the US investigator did not specify the tumor type. The resulting group of 5905 patients represents the largest available data set of adnexal masses that have undergone surgical procedures and have histologic findings available as a reference standard (15).

Based on expert opinion of the committee members, lexicon features were combined to represent clinically relevant groups of tumors and were placed in the different prespecified risk categories based on their corresponding prevalence of malignancy as found in the IOTA database (Table). These groups of terms incorporate descriptors that can be used to categorize the vast majority of ovarian and other adnexal lesions imaged with sonography. This classification that includes a clinical management scheme agreed on by the gynecologists, gynecologic oncologists, and radiologists in the O-RADS US working group formed the basis for the O-RADS US stratification system (Figs 2, 3).

To categorize a specific lesion, there are two complementary strategies. One can apply the US descriptors to assess the lesion, recognized as the most accurate method of discriminating

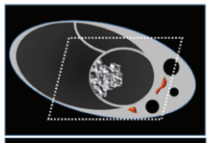
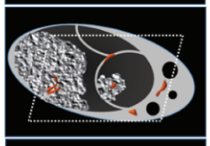
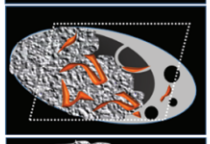
	Internal Content, Cystic Component		
	Anechoic fluid	No internal echoes or structures of any kind	
	Hyperechoic components	Area of increased echogenicity with respect to normal ovarian parenchyma without acoustic shadowing	Descriptor associated with dermoid cysts or hemorrhagic lesions
"Classic" Benign Descriptors- See Figure 3 definitions ○ **Hemorrhagic cyst** ○ **Dermoid cyst** ○ **Endometrioma**			
5	**Vascularity**		
	Color score 1-4	Overall subjective assessment of color Doppler flow within the entire lesion (wall and/or internal component) Color Score = 1 No flow  Color Score = 2 Minimal Flow  Color Score = 3 Moderate flow  Color Score = 4 Very Strong Flow 	IOTA Group criteria using vendor recommended settings Spectral Doppler may be needed to distinguish vascular flow from artifact
6	**General and Extra-Ovarian Findings**		
"Classic" Benign Descriptors- See Figure 3 definitions ○ **Paraovarian cyst** ○ **Peritoneal inclusion cyst** ○ **Fallopian tube (fluid distended)**			
Fluid Descriptors	Cul-de-sac fluid	Confined to pouch of Douglas as defined by remaining below uterine fundus or between uterus and bladder when uterus retroverted/retroflexed	
	Ascites	Fluid extending above uterine fundus beyond the pouch of Douglas or cul-de-sac when anteverted/anteflexed, and anterior/superior to uterus when retroverted/retroflexed	
Other	Peritoneal thickening or nodules	Nodularity or diffuse thickening of the peritoneal lining(s) or along the bowel serosal surface or peritoneum associated with peritoneal carcinomatosis	

Figure 1: *(continued).*

benign from malignant lesions in the hands of expert sonographers as presented in the O-RADS US lexicon. Alternatively, one can use the risk prediction given by using the IOTA ADNEX model (Fig 4), a mathematical model consisting of three clinical variables (patient age, oncology or nononcology center, and serum cancer antigen 125 [CA-125] level) and six US variables (Fig 5). Results from the logistic regression formula can be obtained by using a calculator freely available online (*https://www.iotagroup.org/adnexmodel/* or *https://www.evidencio.com/models/show/946*), in applications for smartphones, or integrated in the US systems. The ADNEX model has undergone successful prospective and external validation (25–27), including in the hands of less-experienced examiners (26).

Synopsis of American College of Radiology O-RADS US RISK Stratification and Management Strategy

Governing Concepts

1. Recommendations should function as guidance rather than requirements for the management of patients with ovarian and other adnexal masses. Individual case man-

agement may be modified by professional judgment, regardless of the O-RADS US recommendations.

2. The management system is based on an average-risk patient with no acute symptoms and no substantial risk factors for ovarian cancer, such as a significant family history of ovarian cancer or *BRCA* gene mutation. If these factors are present, then management may vary from this system.

3. The involvement of a US specialist, denoted as a physician whose practice includes a focus on US assessment of adnexal lesions, has been added to the O-RADS US system (5). However, at this time, there are no mandated requirements or guidelines that define such a specialist.

4. Each patient will be categorized as pre- or postmenopausal with the postmenopause category defined as amenorrhea of greater than or equal to 1 year.

5. The size of the lesion, an important element in risk assessment, should be obtained by measuring the largest diameter of the lesion regardless of the plane in which that diameter appears.

Table: IOTA Phase 1–3 Data Used to Define O-RADS Categories

Description	Fulfill Criterion	Malignant
<1%	1452 (24.6)	7 (0.5)
Classic hemorrhagic cyst ≥5 cm to <10 cm	11 (0.2)	0 (0)
Classic dermoid cyst <10 cm	321 (5.4)	0 (0)
Classic endometrioma <10 cm	583 (9.9)	4 (0.7)
Unilocular smooth cyst ≤3 cm	54 (0.9)	0 (0)
Other unilocular smooth cyst >3 cm to <10 cm	483 (8.2)	3 (0.6)
1% to <10%	945 (16.0)	34 (3.6)
Unilocular smooth ≥10 cm	185 (3.1)	5 (2.7)
Unilocular irregular wall	101 (1.7)	4 (4.0)
Multilocular smooth CS 1–3 <10 cm	577 (9.8)	19 (3.3)
Solid smooth CS 1	82 (1.4)	6 (7.3)
10% to <50%	1734 (29.3)	516 (29.8)
Multilocular smooth ≥10 cm CS 1–3	227 (3.8)	41 (18.1)
Multilocular smooth CS 4	22 (0.4)	3 (13.6)
Multilocular irregular	182 (3.1)	35 (19.2)
Unilocular-solid no papillary projection	198 (3.4)	58 (29.3)
Unilocular-solid 1–3 papillary projections	338 (5.7)	98 (29.0)
Multilocular-solid CS 1–2	405 (6.9)	126 (31.1)
Solid smooth CS 2–3	362 (6.1)	155 (42.8)
50%–100%	1774 (30.0)	1374 (77.5)
Unilocular-solid with ≥4 papillary projections	94 (1.6)	64 (68.1)
Multilocular-solid CS 3–4	619 (10.5)	372 (60.1)
Solid smooth CS 4	135 (2.3)	104 (77.0)
Solid irregular	206 (3.5)	178 (86.4)
Ascites or metastases	720 (12.2)	656 (91.1)

Note.—Data are the number of lesions that fulfill each criteria, with percentages in parentheses. Source.—References 14, 15. CS = color score, IOTA = International Ovarian Tumor Analysis, O-RADS = Ovarian-Adnexal Reporting and Data System.

6. O-RADS applies only to lesions involving the ovaries or fallopian tube. If a pelvic lesion origin is indeterminate but suspected to be ovarian or fallopian tube in origin, then the O-RADS system may apply. If a pelvic lesion is clearly identified as not ovarian or tubal in origin, then the O-RADS system would be appropriate only in the case of a paraovarian cyst or peritoneal inclusion cyst and, otherwise, does not apply.

7. Recommendations are generally based on transvaginal sonography, although they may be augmented by transabdominal or transrectal sonography as needed.

8. In cases of multiple or bilateral lesions, each lesion should be separately characterized, and management driven by the lesion with the highest O-RADS score.

The risk stratification algorithm is divided into six basic categories (O-RADS 0–5), with risk categories developed by the committee based on IOTA data as described in the prior section entitled "Risk Stratification Methodology." These categories are described next.

O-RADS Categories

O-RADS 0 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 (Figs 2,3)

O-RADS 1, the physiologic category that is relevant only in premenopausal patients, includes the follicle and corpus luteum as defined in Figure 1 (also see Figs 6, 7). To prevent misunderstanding by patients, it is recommended that the US report describe these as a follicle and corpus luteum rather than a cyst. Although the study would be categorized as O-RADS 1 (a normal ovary), some patients, on seeing the term *cyst* in a report, may have difficulty understanding that there is no abnormality.

O-RADS 2, the almost certainly benign category (<1% risk of malignancy), comprises the majority of unilocular cysts less than 10 cm (Fig 8). This group includes simple cysts, nonsimple unilocular cysts with smooth walls, and cysts that may be described by using classic benign lesions and their descriptors if less than 10 cm in maximal diameter (Fig 9). Classic benign lesions are those that may be accurately diagnosed when one or more specific O-RADS US lexicon descriptors are seen without any concerning features. These include the typical hemorrhagic cyst (28,29) (Fig 10), dermoid cyst (30–33) (Fig 11), endometrioma (29,34–37) (Fig 12), paraovarian cyst (37), peritoneal inclusion cyst (37,38), and hydrosalpinx (39) (Fig 9). When possible, the diagnosis of classic benign lesions using their associated specific descriptors should always take precedence over less specific or more generic descriptors in classifying a lesion in this category. Although the color score described in Figure 1 (the abbreviated lexicon) is not included in the evaluation of lesions in the

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**			

Figure 2: Image shows Ovarian-Adnexal Reporting and Data System (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 paucity of evidence for defining optimal duration or interval of timing for surveillance. ** = Presence of ascites with category 1–2 lesion, must consider other malignant or nonmalignant etiologies of ascites. CS = color score, GYN = gynecologic, IOTA = International Ovarian Tumor Analysis, N/A = not applicable. Adapted, with permission, from the American College of Radiology.

O-RADS 2 category, it is an important part of evaluation of lesions in the higher-risk categories. A complete definition of the color score with associated illustrations of each score is found in the "Vascularity" category of Figure 1.

O-RADS 3, the low-risk category (1% to <10% risk of malignancy), includes lesions in the almost certainly benign category that are larger, and other lesions where descriptors apply that denote a slightly higher risk of malignancy (Fig 13). This includes both simple cysts, unilocular smooth nonsimple cysts, and lesions with classic benign descriptors that are greater than or equal to 10 cm. A cutoff of 10 cm was used in view of a considerable increase in risk of malignancy found using this threshold by applying IOTA 1–3 data, as well as supportive literature (4,6,7,11,42,46). Also included are unilocular cysts with wall irregularity, multilocular cysts less than 10 cm without solid component(s) with a color score less than 4 (Fig 1), and avascular solid or solid-appearing lesions with a smooth external contour of any size. The presence of Doppler flow is diagnostic of solid tissue but its absence is less informative, and the lesion should then be considered solid appearing as described in the abbreviated lexicon (Fig 1). Beginning with the O-RADS 3 category, the color score becomes incorporated into the risk stratification system. The individual O-RADS 3 descriptors are listed in Figure 2.

O-RADS 4 refers to the intermediate-risk category (10% to <50% risk of malignancy) that includes descriptors found to be

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

Figure 3: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system for classic benign lesions and associated descriptors (O-RADS 2). * = There is currently a paucity of evidence for defining optimal duration or interval of timing for surveillance. Evidence does support an increasing risk of malignancy in endometriomas following menopause. Adapted, with permission, from the American College of Radiology.

predictive of a higher risk of malignancy (Fig 14). This includes multilocular cysts that are greater than or equal to 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 component or color score up to 4, and smooth solid lesions (>80% solid) with color score of 2–3. It should be noted that a papillary projection is a type of solid component with height greater than or equal to 3 mm that arises from the cyst wall or septation and protrudes into the cyst cavity. The individual O-RADS 4 descriptors are listed in Figure 2.

O-RADS 5, the high-risk category (≥50% risk of malignancy), is comprised of descriptors that are highly predictive of malignancy such as irregular solid lesions and multilocular cysts with a solid component and high color score (Fig 15). The presence of ascites and/or peritoneal nodules would also indicate an O-RADS 5 score except when there is ascites in association with a physiologic cyst or almost certainly benign lesion (see O-RADS 2), at which time other etiologies for ascites should be considered. The individual O-RADS 5 descriptors are listed in Figure 2.

Management

The O-RADS US classification system should aid the health care provider in deciding which lesions require no follow-up or conservative follow-up, often with the aid of a US specialist or the performance of a MRI study (10,40) for optimal characterization, versus lesions that mandate consultation with a gynecologist or gynecologic oncologist (41). General agreement of committee members based on the literature and expert opinion was achieved through discussion during multiple conference calls following e-mail distributions in determining management strategies in each category (Fig 2). These are described in detail below.

O-RADS 0, Incomplete Evaluation

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

O-RADS 1, Normal Ovary

No additional imaging or imaging follow-up is necessary.

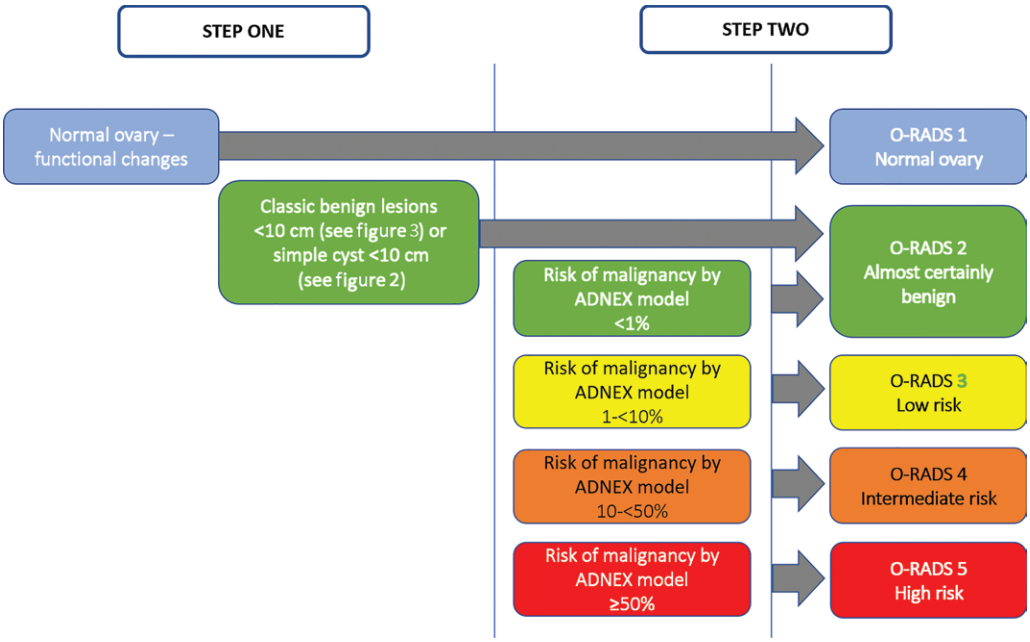


Figure 4: Image shows incorporation of Assessment of Different Neoplasias in the Adnexa (ADNEX) model into Ovarian-Adnexal Reporting and Data System (O-RADS) risk classification system.

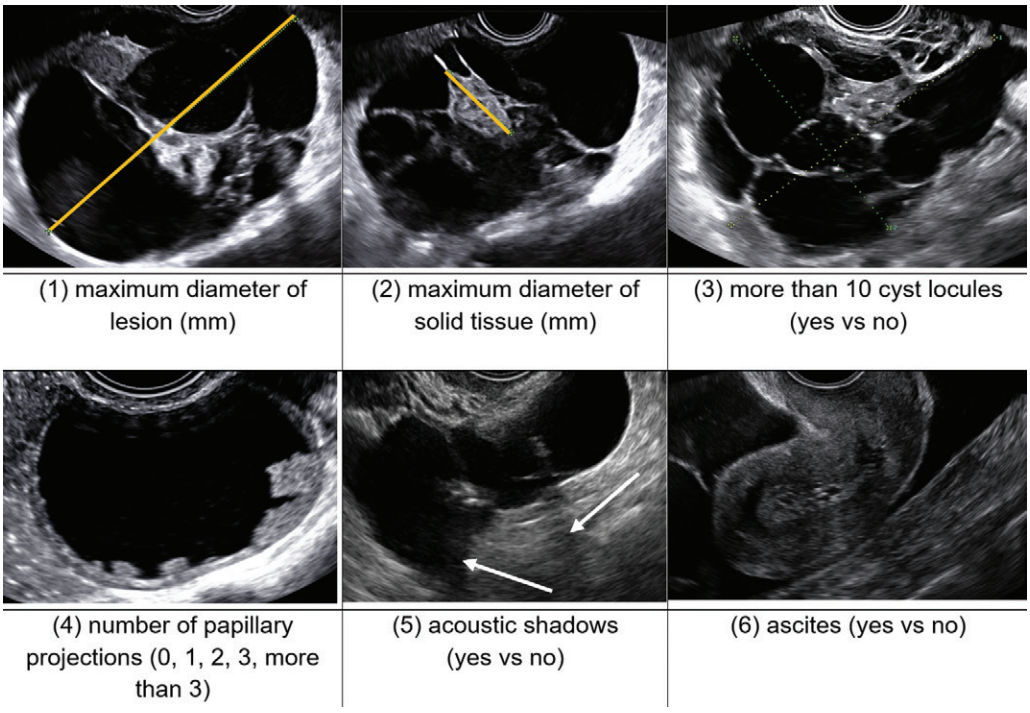


Figure 5: Images show US features used in Assessment of Different Neoplasias in the Adnexa model.

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

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.

Simple Cysts

The simple cyst is a subset of unilocular cysts with a smooth thin wall, acoustic enhancement, and no internal elements (thus anechoic), as stated in the O-RADS US lexicon (20). Although simple cysts are not a separate category in the IOTA group data, there is strong support for a benign etiology in the literature. In a recent nested case-controlled study by Smith-

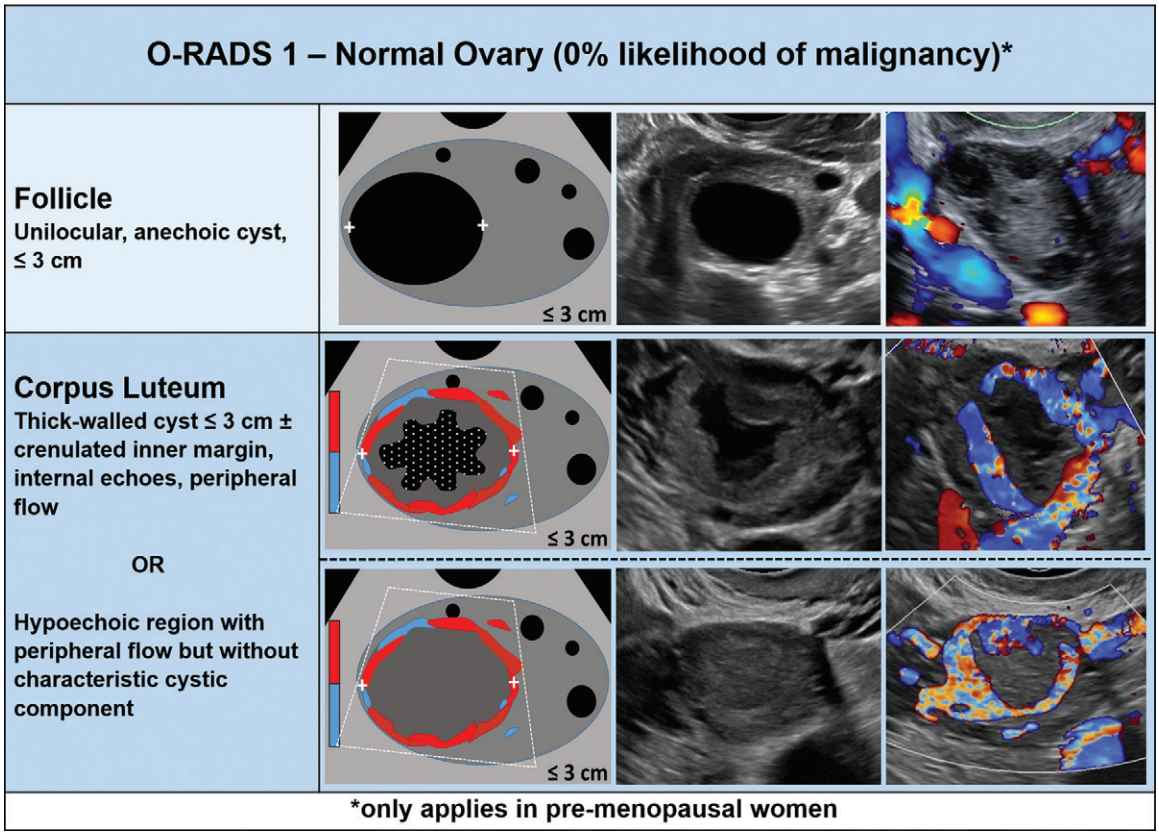


Figure 6: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 1, normal ovary.

Bindman et al (42) of 72 093 women who underwent pelvic sonography from 1997 to 2008, no simple cysts were diagnosed as cancer in women younger than 50 years (0 of 12 957 cysts), and only a single simple cyst was ultimately diagnosed as a malignancy in women over 50 years (one of 2349 simple cysts) at 3 years following US. Other large populations of patients with simple cysts have also been studied with similar findings, albeit predominantly in the ovarian cancer screening populations in postmenopausal women (43–47). A recent meta-analysis of surgically removed unilocular cysts by Parazzini et al (48), reviewing articles published after 2000, suggested a limited risk of malignancy in anechoic cysts among premenopausal women of approximately 0.5% (three of 657) versus postmenopausal women of 1.5% (seven of 469). Major limitations of this meta-analysis were the heterogeneity among studies. In particular, the definition of a unilocular anechoic cyst that may not meet the strict definition of a simple cyst, while including only masses that had been selected for surgical procedures, is likely to have included patients with higher risk, potentially overestimating risk. Based on the data supporting the low risk of malignancy of simple cysts, the American College of Obstetricians and Gynecologists Committee on Practice Bulletins—Gynecology, has recommended that "Simple cysts up to 10 cm in diameter on transvaginal ultrasonography performed by experienced ultrasonographers are likely to be benign and may be safely monitored using repeat imaging without surgical intervention, even in postmenopausal patients" (11).

The committee agreed that no additional management is required for simple cysts less than or equal to 5 cm in diameter in premenopausal patients, and those less than or equal to 3 cm should be considered physiologic (consistent with normal physiology, ie, follicles). Because of the challenge of performing a consistently high-quality study in larger cysts and keeping in mind that the vast majority of these cysts are functional, the committee agreed that it is reasonable in the premenopausal patient to recommend a follow-up in 8–12 weeks for cysts greater than 5 cm but less than 10 cm to confirm its functional nature or to reassess for cyst wall abnormalities (more easily missed in cysts approaching 10 cm). In general, the proliferative phase is the optimal time for reevaluation, allowing involution of functional cysts to occur following menstruation. If the cyst persists or enlarges, then management by a gynecologist is suggested. At times, larger cysts may be incompletely evaluated by transvaginal US, and in these cases, it is important to perform a transabdominal examination or to indicate an incomplete evaluation due to size, location, or both, thus reverting to category 0.

Because data confirm only the rare occurrence of malignancy in the sonographically demonstrated postmenopausal simple cyst (42–47), no further management is suggested in cysts up to 3 cm. For cysts greater than 3 cm but less than 10 cm, at least 1-year follow-up showing stability or decrease in size is recommended with consideration of annual follow-up for up to 5 years, if stable (47). If the cyst enlarges, then management by a

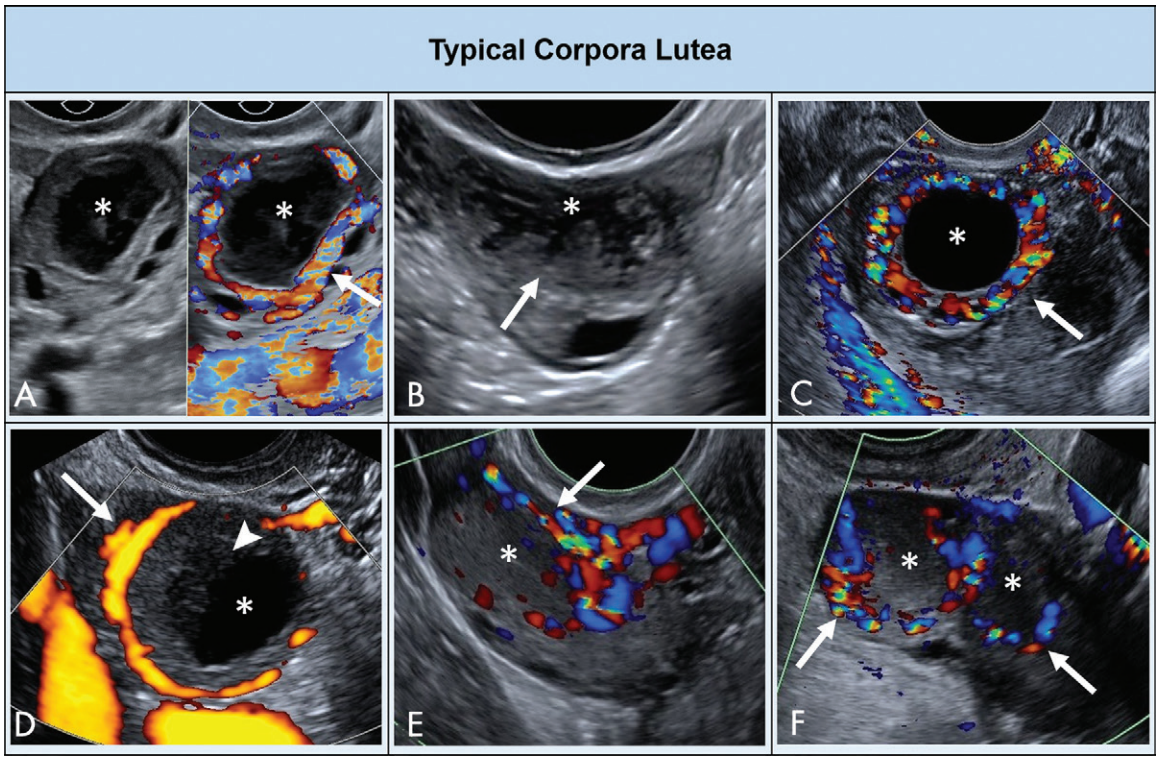


Figure 7: Images show typical corpora lutea. *A*, Corpus luteum with color Doppler and without color Doppler demonstrates central cystic component (asterisks) with smooth thickened wall, avascular internal echoes, and peripheral vascularity (arrow). *B*, Corpus lutea with central component, thickened wall, and crenulated inner margin (arrow). *C*, Anechoic thick-walled cyst (asterisk) with intense peripheral vascularity (arrow). *D*, Color Doppler energy demonstrates peripheral vascularity (arrow) in this cystic (asterisk) corpus luteum with retracting clot (arrowhead). *E*, Corpus luteum as hypoechoic region (asterisk) without central cystic component but with peripheral flow (arrow) at color Doppler. *F*, Two corpora lutea in setting of dual ovulation manifest by two hypoechoic regions (asterisks) with peripheral flow (arrows).

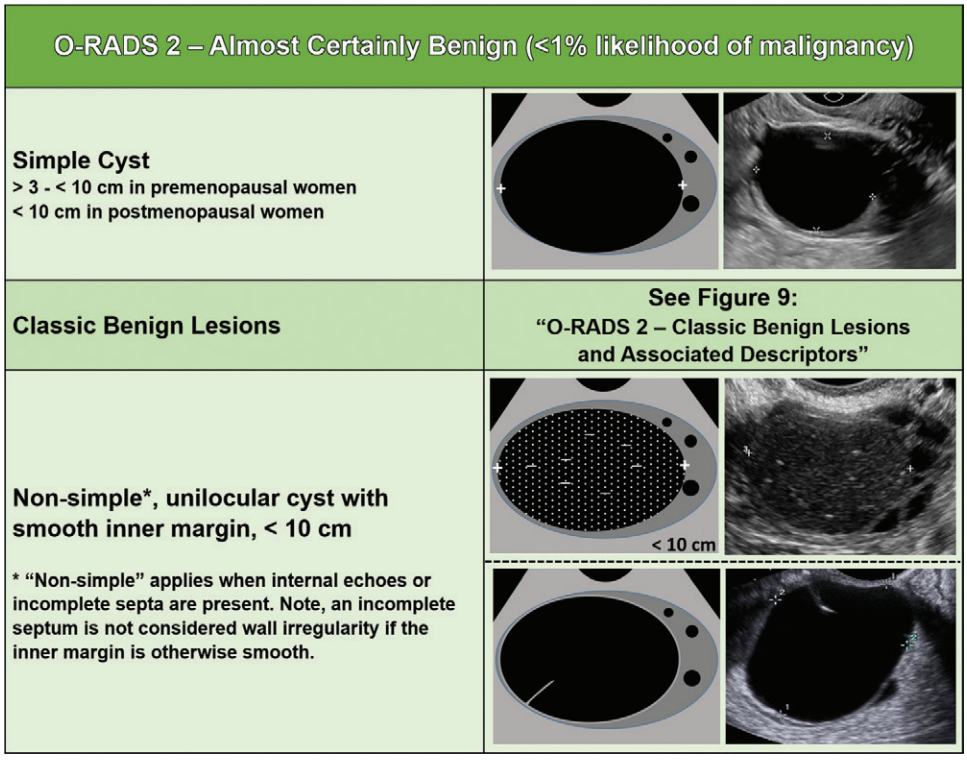


Figure 8: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 2, almost certainly benign.

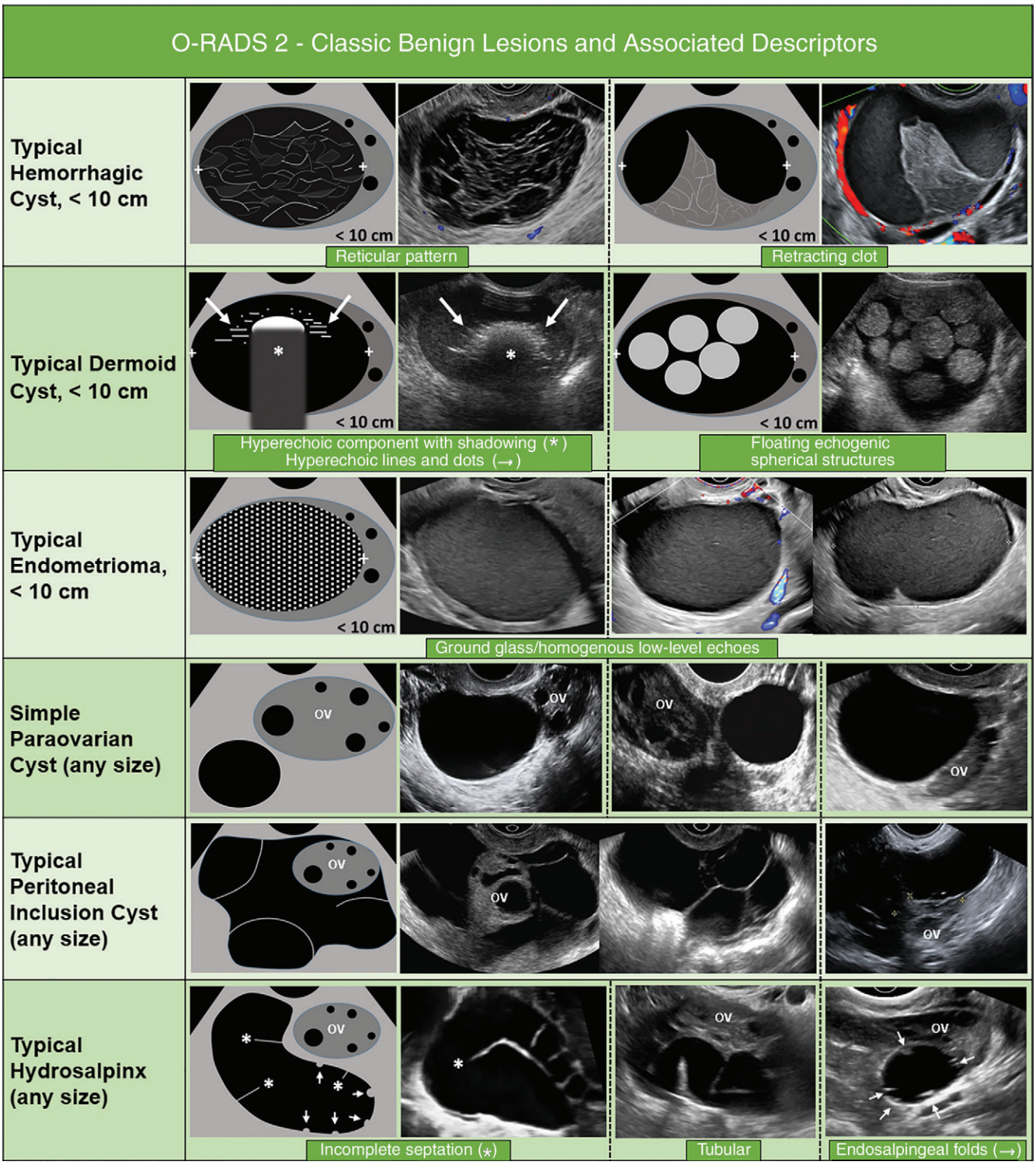


Figure 9: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 2, classic benign lesions and associated descriptors. Ov = ovary.

gynecologist is suggested. However, there is currently a paucity of evidence for defining the optimal duration or time interval for surveillance.

Classic Benign Lesions and Associated Descriptors

Once again, when certain classic benign features cited in the literature are encountered, one should use them to make a specific diagnosis. Trying to use other, more generic descriptors may lead to an incorrect diagnosis and inappropriate management. If these almost certainly benign lesions are not classic, then some may fall into risk categories that would require further characterization by referral to a US specialist or by performance of an MRI study. However, through this process, the correct diagnosis should be reached and these patients not overtreated. An example would be

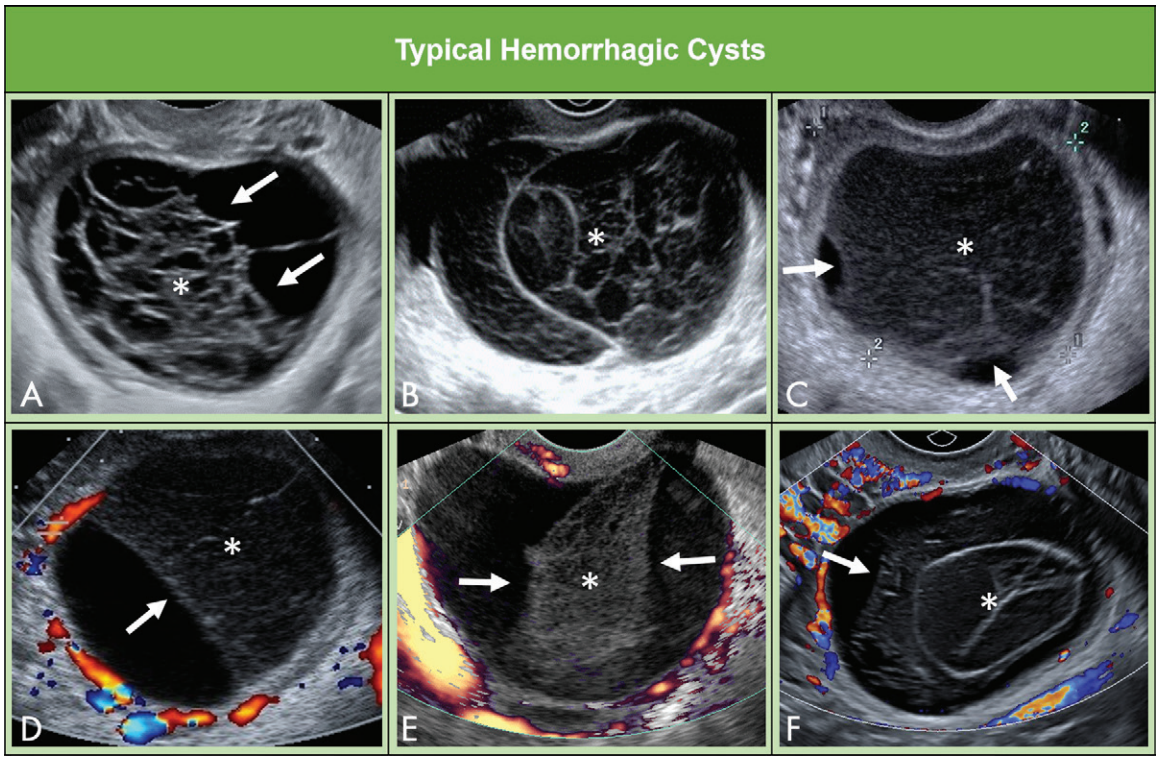


Figure 10: Images show typical hemorrhagic cysts. *A*, Ovarian hemorrhagic cyst with retracting clot demonstrates concave margins (arrows) and internal reticular pattern (asterisk). *B*, Hemorrhagic cyst with reticular pattern (asterisk) throughout. *C*, Reticular pattern (asterisk) with fine discontinuous linear echoes and early retraction of clot at periphery (arrows). *D*, Retracting clot with reticular pattern (asterisk) and concave margin (arrow). Color Doppler flow is seen in surrounding ovarian tissue; however, it is absent within blood products. *E*, Reticular pattern (asterisk), straight and concave margins (arrows), and no flow at color Doppler energy differentiates retractile clot from solid tissue. *F*, Avascular hemorrhagic cyst with reticular pattern (asterisk) and concave margin of retractile clot (arrow).

in the setting of a hydrosalpinx that may demonstrate the presence of what appears to be a complete septation or endosalpingeal fold misinterpreted as a solid component (see Fig 3).

Hemorrhagic cysts.—Typical hemorrhagic cysts in the premenopausal age group that are less than or equal to 5 cm require no further management. When greater than 5 cm but less than 10 cm, follow-up in 8–12 weeks is recommended. If the cyst persists or enlarges, then referral for additional expertise to a US specialist or gynecologist, or the recommendation of an MRI study, is suggested. Hemorrhagic cysts should not occur in the postmenopausal population. Thus, when typical hemorrhagic cysts less than 10 cm in size are encountered in the postmenopausal age group, further evaluation by a US specialist, referral to a gynecologist, or performance of an MRI study is suggested.

Dermoid cysts and endometriomas.—Typical dermoid cysts and endometriomas that are less than 10 cm are managed similarly. In the premenopausal patient, an optional initial follow-up at 8–12 weeks may be helpful based on the confidence in the diagnosis and, if not removed surgically, annual US surveillance should be considered. These patients are usually under the care of a gynecologist. In the postmenopausal group, patients with a confident diagnosis of a dermoid cyst or endometrioma may be considered for annual US follow-up when not surgically excised. However, in postmenopausal patients, the risk of malignancy and the risk of malignant transformation (ie, clear cell and endometroid carcinomas) are higher in endometriomas, so this risk should be considered when deciding management (34). If there is changing morphology or a developing vascular component within the lesion, then referral to a US specialist or performance of an MRI study is recommended in the premenopausal age group and direct referral to MRI is recommended in the postmenopausal group. Similar to surveillance of postmenopausal simple and nonsimple smooth cysts, the optimal duration or interval of timing for surveillance has not been established.

Extraovarian cysts.—These include the paraovarian cysts, typical peritoneal inclusion cysts, and the typical hydrosalpinges of any size. Generally, no further follow-up is needed for simple paraovarian cysts with an optional follow-up at 1 year in the postmenopausal age group based on confidence in the diagnosis. If not simple, then the cyst should be managed according to O-RADS US ovarian cyst criteria. Management by a gynecologist is recommended for typical peritoneal inclusion cysts or hydrosalpinges.

Nonsimple Unilocular Smooth Cysts

Unilocular cysts with smooth inner margins that are not simple and do not fall into any of the categories of classic benign lesions require no management in the premenopausal

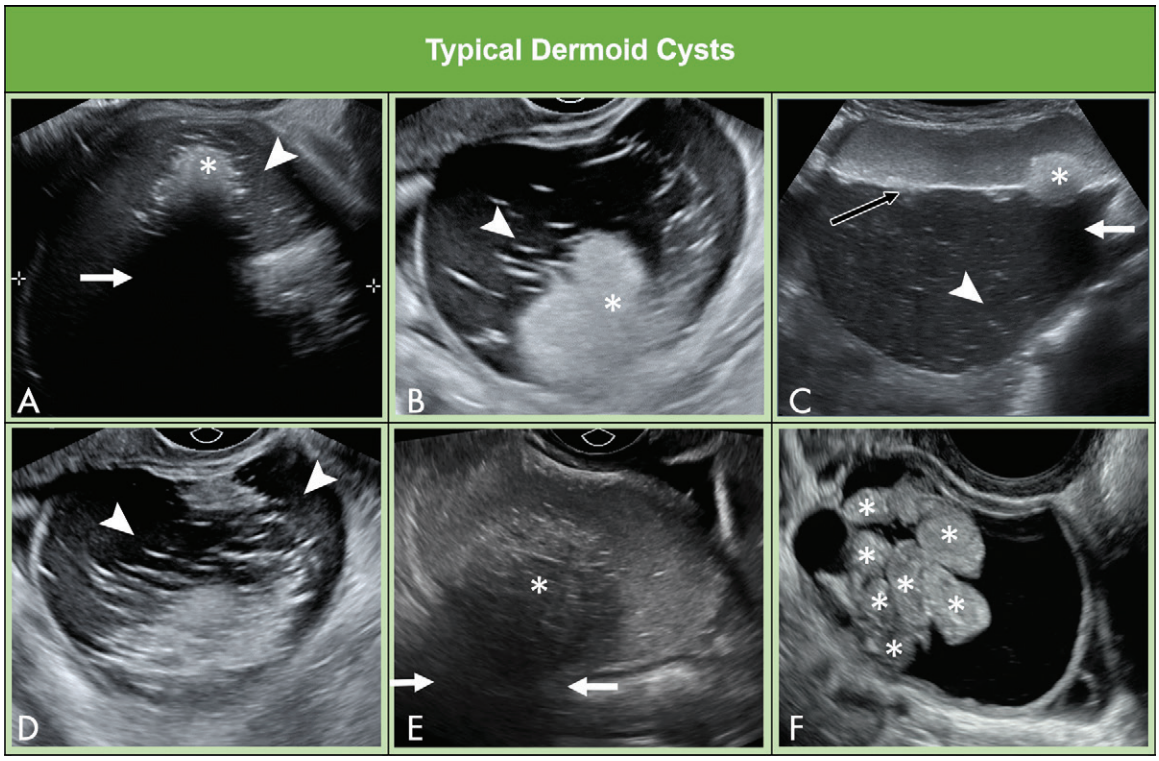


Figure 11: Images show typical dermoid cysts. *A,* Dermoid cyst with hyperechoic component (asterisk) with acoustic shadowing (arrow) and hyperechoic lines and dots (arrowhead). *B,* Hyperechoic lines and dots and hyperechoic component in another dermoid cyst. *C,* Transabdominal image of dermoid cyst demonstrates fluid-fluid level (black arrow) with nondependent hyperechogenicity consistent with floating liquid 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 coiled hair in dermoid cyst. *E,* Hyperechoic component (asterisk) with acoustic shadowing (arrows) in dermoid cyst containing internal echoes. *F,* Floating echogenic spherical structures (asterisks) are not common but are pathognomonic of dermoid cyst.

age group when less than or equal to 3 cm. A follow-up US in 8–12 weeks, in the proliferative phase if possible, is recommended for cysts greater than 3 cm and less than 10 cm. If the cyst persists or enlarges, then referral to a US specialist or performance of an MRI study should be considered for further characterization. In the postmenopausal age group, although follow-up in 1 year is an option if the cyst is less than or equal to 3 cm, additional characterization of the fluid and inner margins of the cyst may be accomplished by a US specialist or an MRI study and should be considered for these cysts irrespective of the size. Management by a gynecologist is suggested for the larger premenopausal cysts greater than 3 cm and all postmenopausal nonsimple unilocular smooth cysts.

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

The vast majority of O-RADS 3 lesions (>90%) are benign and the committee agreed that there is no need for consultation with a gynecologic oncologist. Patients with this group of lesions should be managed by a general gynecologist, although it is important that optimal imaging evaluation be performed. Thus, consultation with a US specialist or performance of an MRI examination to minimize 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)

Category 4 US findings (intermediate-risk lesions) warrant either consultation with gynecologic oncology prior to removal or referral for management (2). 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 (49). If a surgical procedure is to be performed by a general gynecologist, then it is recommended that the facility has the "necessary support and consultative services to optimize patient outcomes" (11).

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.

Although serum markers do play a role in evaluation, the O-RADS US committee purposely did not advocate for their routine use in the assessment based on lesion category, and they are not included in our risk stratification system. The committee felt that tumor marker evaluation should be individualized for each patient. For example, an elevated level of CA-125 in a premenopausal patient with an intermediate-risk lesion and a clinical scenario highly suspicious for endometriosis may unnecessarily elevate the concern for malignancy. Likewise,

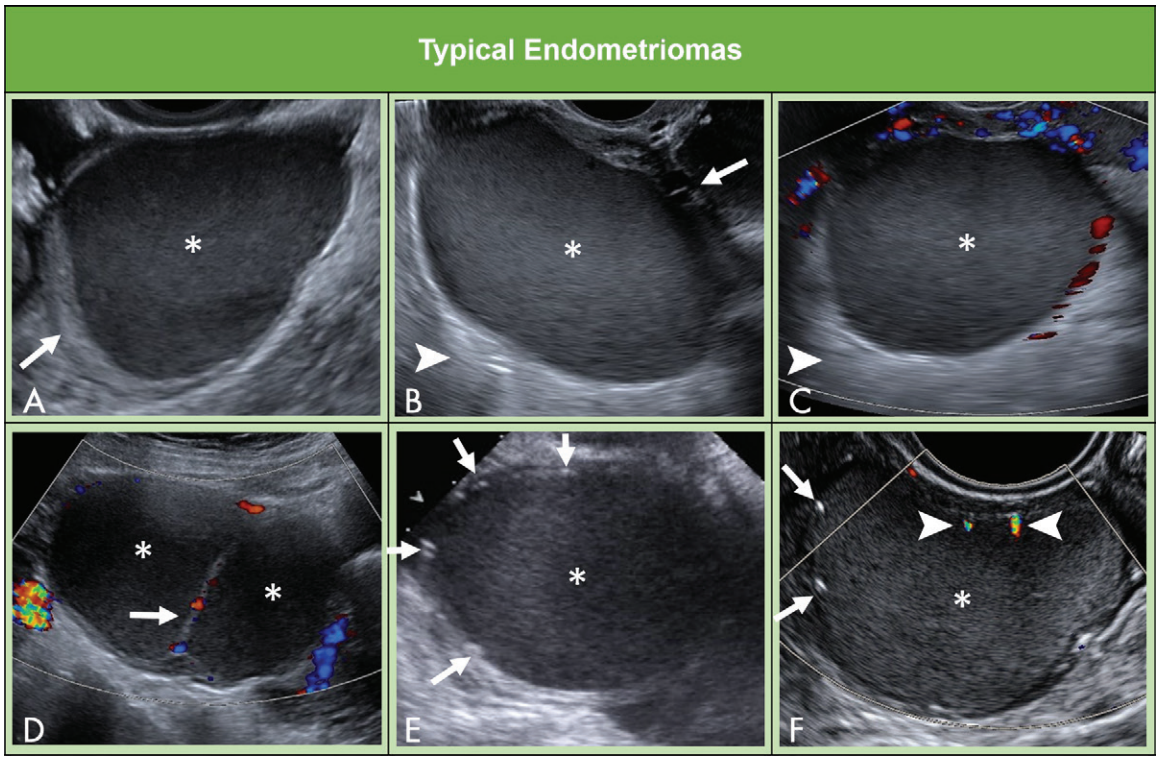


Figure 12: Images show typical endometriomas. *A*, Common appearance of endometrioma demonstrates homogenous low-level or ground glass internal echoes (asterisk); surrounding ovarian parenchyma (arrow) is seen. *B*, Similar features of homogenous low-level or ground glass echoes (asterisk) with surrounding ovarian tissue (arrow) and posterior acoustic enhancement (arrowhead). *C*, No internal flow at Doppler imaging should be observed in endometriomas; homogenous low-level echoes (asterisk) and posterior acoustic enhancement (arrowhead). *D*, Multiloculated endometrioma with homogenous low-level echoes (asterisks) in each component; flow may be observed in intervening septum (arrow). *E*, Occasionally, peripheral punctate echogenic foci (arrows) are seen with endometriomas; however, homogenous low-level echoes (asterisk) are most specific feature. *F*, Although shadowing is typically not associated with peripheral punctate echogenic foci (arrows) surrounding endometrioma (asterisk), twinkling artifacts may be appreciated with Doppler imaging (arrowheads).

a normal level of CA-125 may provide false reassurance in a postmenopausal woman with an intermediate- or high-risk category 4 or 5 lesion. Serum CA-125 levels are optional in the ADNEX model because they do not improve the overall model performance to distinguish between benign and malignant lesions. However, CA-125 improves subclassification of malignant lesions (eg, stage 2–4 invasive malignancies vs metastatic lesions). The committee also emphasizes that the O-RADS classification is not a substitute for performing a thorough history and physical examination and assessing the patient's need for additional testing. Although no classification system can completely encompass all aspects of the management of each patient with an adnexal lesion, O-RADS US more clearly defines referral criteria when compared with what has been previously published (50).

Discussion

The American College of Radiology Ovarian-Adnexal Reporting and Data System (O-RADS) committee believes that the objective has been met to provide a system previously unavailable using US that is based on a common lexicon to categorize malignancy risk throughout the spectrum of benign and more suspicious lesions and provide guidelines for management. The new system incorporates European as well as North American management preferences that include the choices of referring to a US specialist or performing an MRI examination for lesion characterization, and the complementary use of lesion descriptors or a mathematical model to reach the same management scheme.

Initially, it may appear disappointing that the specificity of the O-RADS US system is low compared with some of the other American College of Radiology Reporting and Data Systems such as the Liver Imaging Reporting and Data System (or LI-RADS) (51), which offers extremely high specificity. This is related to the differing populations. Whereas LI-RADS applies only to patients at high risk for hepatocellular cancer, the O-RADS system has been developed for the patient at average risk. This maximizes sensitivity rather than specificity in order not to miss an ovarian cancer, which is of low prevalence but a potentially highly lethal disease. As designed, the system performs well in assigning appropriate management to patients based on risk assessment with more conservative management for benign-appearing lesions and referral to a gynecologic oncologist when the lesion is more suspicious. Thus, patients with ovarian cancer will benefit from improved survival by referral for specialized gynecologic oncology care, while a false-positive diagnosis will not harm survival.

The committee also understands that a limitation of the present risk stratification categories is its foundation on a database only including lesions with surgical procedures as the

reference standard. This may lead to the risk of malignancy being overestimated in the more benign categories. For this reason, although the International Ovarian Tumor Analysis (IOTA) data address all unilocular smooth cysts as a group, we have separated the category of simple from non-simple unilocular cysts. There is a plethora of non-IOTA data that supports the rarity of malignancy in this group (42–47). Another limitation is the retrospective, rather than prospective, testing of descriptors using IOTA phase 1–3 data.

In the process, the committee did find that a number of terms in the original O-RADS US lexicon (20) are not necessary in the risk stratification process. Accordingly, we have included a condensed lexicon containing only required descriptors to facilitate the application of lexicon terms to risk stratification (Fig 1).

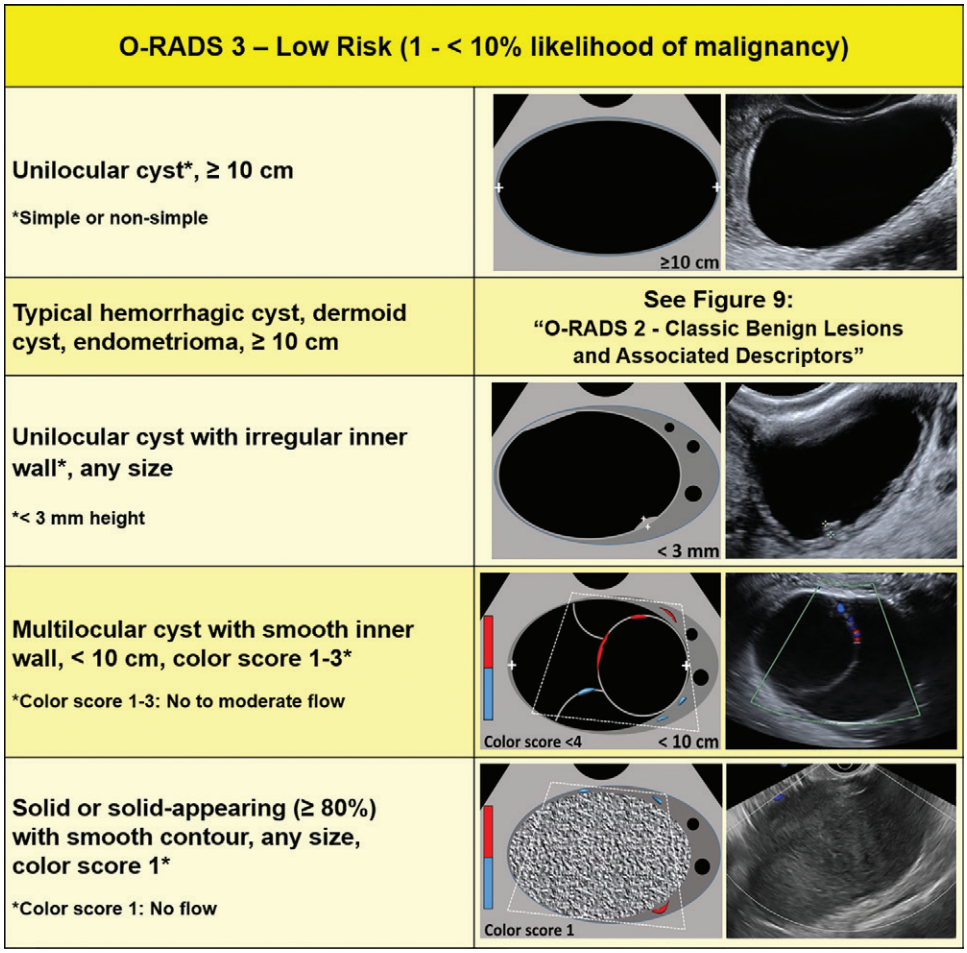


Figure 13: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 3, low risk of malignancy.

Future Directions

With results from the IOTA 5 study, the largest multicenter prospective cohort study not only including patients selected for surgical procedures but also for conservative management, we plan to validate the O-RADS US risk stratification and management system on this large cohort of patients. This will demonstrate its validity on a broader population, including all types of adnexal pathologic features (4).

Informal lesion evaluation using the terminology to risk-stratify lesions has been successfully performed among committee members. However, there is a need for a larger interobserver variability study in North America to validate the use of the system by expert as well as less experienced observers, since initial lesion characterization is key to risk stratification and prior validations of the IOTA data were based on a predominantly European population. After future validation, it is the intention of the committee that this management tool will be accepted as an international reference for the management of patients with adnexal lesions. We anticipate that this risk stratification system may evolve with additional evidence-based literature.

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Disclosures of Conflicts of Interest: R.F.A. Activities related to the present article: received support for travel to meetings for the study or other purposes

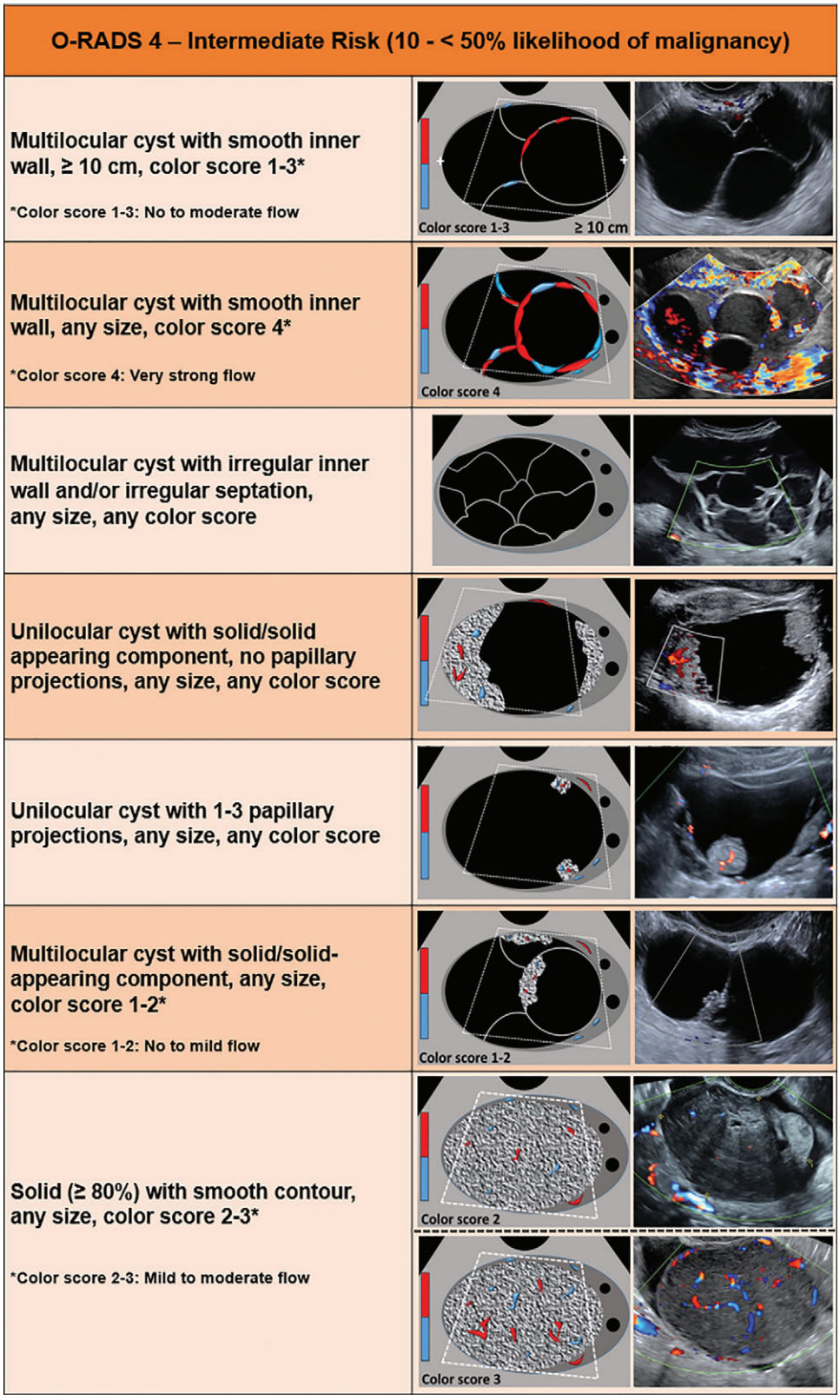


Figure 14: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 4, intermediate risk of malignancy.

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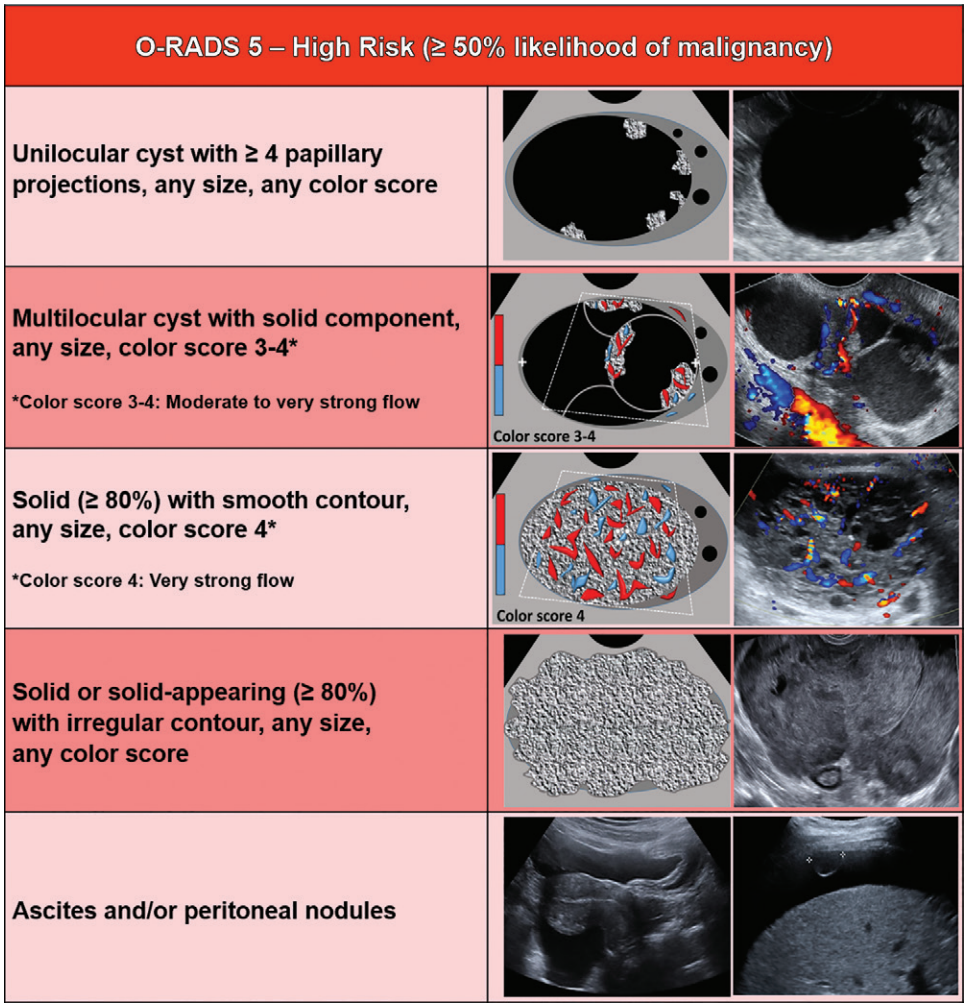


Figure 15: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US category 5, high risk of malignancy.

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