



## O-RADS Ultrasound Frequently Asked Questions (FAQ's)

### **A. Descriptors**

#### **Question A1:**

What is the difference between a papillary projection and a solid component? How are they differentiated in the risk stratification table?

#### **Question A2:**

The terms “solid smooth” and “solid irregular” appear as sub-categories in risk categories 3, 4 and 5. Does this refer to a lesion or any solid component within a lesion?

#### **Question A3:**

Differentiating among types of characteristic cyst fluid (endometrioma, mucinous tumor, dermoid) can be challenging. Are there some tips that may be helpful to the user?

#### **Question A4:**

Although the benign predictive value of the descriptor, “acoustic shadowing” for solid lesions is mentioned in the original JACR lexicon publication, why was this descriptor not included in risk stratification?

#### **Question A5:**

Since the color score is a subjective evaluation, are there tips that will help to distinguish between minimal (color score 2) and moderate flow (color score 3), as well as moderate (color score 3) and strong flow (color score 4)? Does spectral Doppler play any role?

#### **Question A6:**

Would a cyst that contains a “daughter cyst” be considered multilocular?

#### **Question A7:**

How does a unilocular cyst with a wall calcification fit into the risk stratification system?

#### **Question A8:**

What is considered “ascites”? Do echoes within the fluid matter?

### **B. Comparison with Other Risk Management Systems**

#### **Question B1:**

Why does O-RADS US have a low specificity in the higher risk categories with broad ranges of risk differing from the higher specificity of other RADS?



## Questions B2- B5

### Clarification

#### **Question B2:**

Unlike the SRU Consensus Statement, why does the O-RADS management scheme differentiate between classic benign lesions and simple cysts of the ovary that are less than 10 cm and those greater than or equal to 10 cm?

#### **Question B3:**

A cyst with a smooth inner margin and a thin septation is managed like a simple cyst according to the SRU Consensus. Why is this type of cyst considered a multilocular cystic lesion by O-RADS and managed in the O-RADS 3 rather than O-RADS 2 category?

#### **Question B4:**

Why does O-RADS not incorporate the early postmenopausal period in its system as the SRU Consensus does?

#### **Question B5:**

Is there a difference in recommended management of a hydrosalpinx and peritoneal inclusion cyst in the SRU and O-RADS US systems?

## **C. Management**

#### **Question C1:**

Can lesions in high risk and symptomatic patients be included in any part of the O-RADS system?

#### **Question C2:**

Does O-RADS apply to all ovarian and adnexal lesions?

#### **Question C3:**

How do you manage the stable O-RADS 3 or 4 lesion?

#### **Question C4:**

When is a study considered O-RADS 0, an “incomplete evaluation”?

#### **Question C5:**

Can we risk stratify a changing endometrioma or dermoid?

#### **Question C6:**

Who is the ultrasound specialist?



## A. Descriptors:

### Question A1:

What is the difference between a papillary projection and a solid component? How are they differentiated in the risk stratification table?

### Answer:

A papillary projection (or nodule) is a type of solid component that protrudes from the wall or septation of a cyst and is surrounded on 3 sides by fluid. In Category 4, in order to simplify the table, we grouped the unilocular cyst with a solid component that is not a papillary projection (0 papillary projections) with the unilocular cyst that contains up to 3 papillary projections in a single sub-category. To clarify this, we have modified this subcategory in an updated risk stratification table available on the ACR website.

### Original table:

4	Intermediate Risk [10- < 50%]	Multilocular cyst, no solid component	≥ 10 cm, smooth inner wall, CS = 1-3 Any size, smooth inner wall, CS = 4 Any size, irregular inner wall and/or irregular septation, any color score	US specialist or MRI  Management by gynecologist with GYN-oncologist consultation or solely by GYN-oncologist
		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	

### New version table:

4	Intermediate Risk [10- < 50%]	Multilocular cyst, no solid component	Smooth inner wall, ≥ 10 cm, CS = 1-3	US specialist or MRI  Management by gynecologist with gyn-oncologist consultation or solely by gyn-oncologist
			Smooth inner wall, any size, CS = 4	
			Irregular inner wall ± irregular septation, any size, CS = any	
		Unilocular cyst with solid component	1-3 papillary projections (pp), or solid component that is not a pp, any size, CS= any	
		Multilocular cyst with solid component	Any size, CS = 1-2	
Solid lesion	Smooth outer contour, any size, CS = 2-3			

### Question A2:

The terms “solid smooth” and “solid irregular” appear as sub-categories in risk categories 3, 4 and 5. Does this refer to a lesion or any solid component within a lesion?

### Answer:

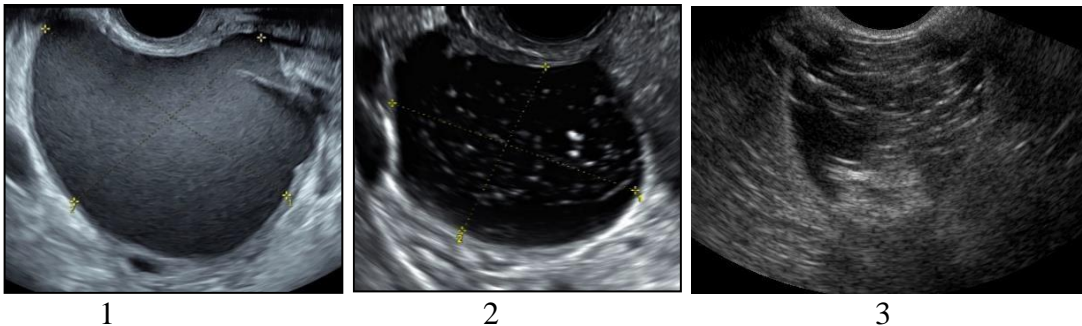
As each of the prior subcategories within each risk category refer to a unilocular or multilocular cyst, “solid smooth” and “solid irregular” refers to a solid lesion (≥ 80% solid or solid appearing) being the 5<sup>th</sup> major subcategory used in the IOTA/O-RADS system. Understanding this confusion, we have modified these terms to “solid lesion” in each of the risk groups in an [updated table](#) available on the [ACR O-RADS web page](#).

**Question A3:**

Differentiating among types of characteristic cyst fluid (endometrioma, mucinous tumor, dermoid) can be challenging. Are there some tips that may be helpful to the user?

**Answer:**

Typically, “homogeneous low level” or “ground glass” echoes are evenly dispersed tiny echoes within a cyst which represent blood products in an endometrioma (1) as opposed to “scattered” echoes of variable size and echogenicity that are heterogeneously dispersed echogenic foci within cystic contents that is more representative of mucinous material.(2) Mucinous fluid is also more likely to be mobile and show streaming when pressure is applied by the transducer or with color Doppler than the blood products with an endometrioma due to relative decrease in viscosity. Another type of cyst content to be differentiated are the “hyperechoic line and dots” representing hair within the liquified component of a dermoid cyst. The key to this diagnosis is the more linear appearance of these foci. (3) While the difference between these echoes can be challenging, the assessment category is the same (O-RADS 2) for endometrioma, dermoid cyst and (indeterminate) non-simple unilocular cyst and management is not significantly affected. Please refer to figures below.

**Question A4:**

Although the benign predictive value of the descriptor, “acoustic shadowing” for solid lesions is mentioned in the original JACR lexicon publication, why was this descriptor not included in risk stratification?

**Answer:**

Keeping the table simple, with less categories was felt to be extremely important in this first publication of O-RADS. After a careful review of the literature and IOTA 1-3 data, we also concluded that using the descriptor approach, management did not vastly change for the majority of these lesions irrespective of “acoustic shadowing”. We did recognize that the omission of separate categories of solid or solid component with acoustic shadowing will result in a higher O-RADS score in some patients but felt the benefits of table simplicity as well as sacrificing specificity over sensitivity and erring on the side of caution was prudent at that time. However, this will be included in the next revision. This sonographic risk reduction may also be obtained using the ADNEX mathematical model<sup>1</sup>, an alternative approach that is part of the O-RADS System.



REFERENCE: Van Calster B, Van Hoorde K, Valentin L, et al. Evaluating the risk of ovarian cancer before surgery using the ADNEX model to differentiate between benign, borderline, early and advanced stage invasive, and secondary metastatic tumours: prospective multicentre diagnostic study. *BMJ* 2014; 349: g5920.

**Question A5:**

Since the color score is a subjective evaluation, are there tips that will help to distinguish between minimal (color score 2) and moderate flow (color score 3), as well as moderate (color score 3) and strong flow (color score 4)? Does spectral Doppler play any role?

**Answer:**

The color score is an overall subjective assessment of color Doppler flow within the entire lesion, excluding any adjacent normal ovarian parenchyma. When color Doppler flow demonstrates only minimal flow after adjusting settings for maximum sensitivity of low blood flow states, this would be considered minimal flow, color score 2. Some vendors offer automated “low flow” settings, while others require selective adjustments of parameters including color Doppler gain, scale (4cm/sec), pulse repetition frequency and wall filters. Additional operator selections to maximize flow detection include the use of power Doppler and decreasing the size of the Doppler box to the region of interest. In contrast, when color Doppler flow is robust and easily obtained throughout the solid components of the lesion, this would be considered color score 4. Anything in between would be considered moderate flow, color score 3. Spectral Doppler is useful as an adjunct to distinguish vascularity from artifact when vessels are not clearly delineated with color Doppler, however, plays no other role in determining the color score.

**Question A6:**

Would a cyst that contains a “daughter cyst” be considered multilocular?

**Answer:**

A daughter cyst is defined as partial volume averaging of an adjacent, small support follicle that appears to project within a larger unilocular cyst or follicle on a given image however, as one scans through the lesion either in real-time time or via a cine-clip, the two can be separated. This is only applicable to premenopausal patients. A “cyst within a cyst” that can be separated from the inner wall or ovarian parenchyma is a septation and the entire cyst would be considered multilocular.

**Question A7:**

How does a unilocular cyst with a wall calcification fit into the risk stratification system?

**Answer:**

If there is a protrusion from the wall of the cyst inside the cyst cavity that is < 3 mm in height, whether it is calcified or not, it will be an irregularity of the wall. If the protrusion is  $\geq 3$  mm, it is a papillary projection or nodule. A flat wall calcification that does not protrude within the cavity would be considered a smooth inner wall. Other descriptors such as “shadowing” (ADNEX model) would also be helpful for better prediction of malignancy.

**Question A8:**

What is considered “ascites”? Do echoes within the fluid matter?

**Answer:**

For the purposes of risk stratification, ascites is defined as fluid extending beyond the cul-de-sac superior to the uterine fundus if the uterus is anteverted or anteflexed, or fluid anterior and superior to the uterus, if the uterus retroverted or retroflexed. Echoes within the fluid do not play any role in risk stratification but may change the management strategy if the patient presents with acute symptoms.

**B. Comparison with Other Risk Management Systems****Question B1:**

Why does O-RADS US have a low specificity in the higher risk categories with broad ranges of risk differing from the higher specificity of other RADS?

**Answer:**

The O-RADS management system has been developed for the patient at average risk maximizing sensitivity rather than specificity in order not to miss an ovarian malignancy, which is of low prevalence but a potentially highly lethal disease. This is in contrast to some of the other American College of Radiology (ACR) Reporting and Data Systems (RADS) such as LI-RADS, which offers very high specificity in a population already at high risk for hepatocellular carcinoma.

**Questions B2 – B5**

It has come to our attention that there are questions regarding the rationale behind O-RADS risk stratification and management recommendations that differ from the Society of Radiologists in Ultrasound (SRU) Consensus Statement guidelines of 2010. The SRU guidelines have been helpful in determining which cystic lesions require follow-up, further imaging, or a surgical procedure. However, unlike the SRU Consensus Statement, O-RADS is based on a standardized lexicon in order to categorize malignancy risk with subsequent standardization of interpretations. In addition, O-RADS standardized descriptors, based upon the IOTA model, have been tested on a large data set from phases 1–3 of the IOTA study to assign a risk of malignancy to each of them and provide recommended management strategies for each risk category. Percentile risk is not given in the SRU guidelines, nor are management strategies for higher risk lesions. The following address more specific questions, some that can be answered based upon evidence in the IOTA 1-3 data set.

**Question B2:**

Unlike the SRU Consensus Statement, why does the O-RADS management scheme differentiate between classic benign lesions and simple cysts of the ovary that are less than 10 cm and those greater than or equal to 10 cm?

**Answer:**

The IOTA 1-3 data set places benign classic ovarian lesions and all unilocular cysts (simple or non-simple) with smooth inner margins, in a <1% risk category only when the size is < 10 cm. There is other evidence supporting a higher risk of malignancy in these larger classic benign lesions, some are referenced in the SRU Consensus Statement article. As O-RADS is based upon data using surgical specimens and simple (anechoic, unilocular) cysts were not separated from other non-simple unilocular smooth cysts, we are likely overestimating risk in the  $\geq 10$  cm simple cyst. However, one should also keep in mind that sonographic characterization of simple cysts of this larger size may be more difficult resulting in missed mural irregularities or nodules. We also



plan to validate the O-RADS US risk stratification and management system using data from the IOTA 5 study, the largest multicenter prospective cohort study not only including patients selected for surgical procedures but also for conservative management.

**Question B3:**

A cyst with a smooth inner margin and a thin septation is managed like a simple cyst according to the SRU Consensus. Why is this type of cyst considered a multilocular cystic lesion by O-RADS and managed in the O-RADS 3 rather than O-RADS 2 category?

**Answer:**

While the risk of malignancy is extremely low for a cyst with a smooth inner margin and a single thin septation, the IOTA data which we used to determine our risk stratification did not differentiate between 1 or more septations. That said, the management for a single septation (if indeed smooth) would be for assessment by an US specialist or by MRI and would likely support the same conclusion of a benign lesion. What is more important than the number of septations is whether they are smooth or irregular and the amount of overall lesion flow by Doppler which does alter level of risk and was not specifically addressed by SRU.

**Question B4:**

Why does O-RADS not incorporate the early postmenopausal period in its system as the SRU Consensus does?

**Answer:**

The gynecologists on the committee felt strongly that the definition of menopause should be consistent throughout the management recommendations. In the SRU guidelines, the differentiation of early from late post menopause is only made for the specific evaluation of a hemorrhagic cyst so that short interval follow up can be recommended. In the O-RADS system, this would be further managed by referral to an ultrasound specialist, gynecologist or for an MRI study. The specific selection of management choices would likely be influenced by the number of years post-menopause.

**Question B5:**

Is there a difference in recommended management of a hydrosalpinx and peritoneal inclusion cyst in the SRU and O-RADS US systems?

**Answer:**

There is no significant difference in the management recommendation of the SRU guidelines that recommend management “as clinically indicated” and O-RADS recommendation of “management by a gynecologist”. In order to clinically evaluate the patient for necessary treatment of problems unrelated to malignancy (i.e. fertility, endometriosis, infection, etc.) in these almost certainly benign lesions, management by a gynecologist is recommended.





## **C. Management**

### **Question C1:**

Can lesions in high risk and symptomatic patients be included in any part of the O-RADS system?

#### **Answer:**

The lexicon and O-RADS categories can be applied to any lesion; however, use of the management aspect is restricted to patients of average risk. The following is the specific governing concept for our risk management system that applies to this question and can be found in the published article and on the ACR website:

*“The management system is based upon 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, management may vary from this system.”*

We specifically refer to the variation in management for these patients but do not discourage the use of lexicon descriptors to risk stratify the individual lesions. The IOTA literature and IOTA 1-3 data, upon which the system is based, consists of consecutive patients with no cited exclusions. Lesions in high as well as average risk patients were included. Ergo, it is acceptable to risk stratify any lesion using descriptors or the ADNEX model. We are scoring the appearance of the lesion, not giving a general risk of malignancy to the patient based upon other criteria. However, since other patient issues must be addressed, the management of a patient with acute symptoms or who is at high risk will likely vary from the recommended scheme.

### **Question C2:**

Does O-RADS apply to all ovarian and adnexal lesions?

#### **Answer:**

The following is the specific governing concept for our risk management system that applies to this question and can be found in the published article and on the ACR website:

*O-RADS applies only to lesions involving the ovaries and/or fallopian tube. If a pelvic lesion origin is indeterminate but suspected to be ovarian or fallopian in origin, the O-RADS system may apply. If a pelvic lesion is clearly identified as non-ovarian/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.*

### **Question C3:**

How do you manage the stable O-RADS 3 or 4 lesion?

#### **Answer:**

If a study demonstrates stability of an O-RADS 3 or 4 lesion (low risk or moderate risk), according to management recommendations, further characterization by an US specialist, that may include the use of the IOTA/ADNEX Model, or referral for an MRI study should be suggested if this has not already been performed. The ultimate management decision of whether to proceed with surgery





or continue surveillance would be made by the managing Gynecologist or Gyn-oncologist.

**Question C4:**

When is a study considered O-RADS 0, an “incomplete evaluation”?

**Answer:**

O-RADS 0 covers the situation of a technically inadequate or incomplete study. This may occur when a patient declines a transvaginal evaluation, requests to discontinue a study on the basis of discomfort or technical factors such as bowel gas artifact obscuring a lesion. In these cases, a judgement is made as to whether repeating the ultrasound study will add value or whether an MRI should be considered for exam completion. Please note this applies to an incomplete study from a technical perspective, rather than to an indeterminate or non-diagnostic study from an interpretative perspective.

**Question C5:**

Can we risk stratify a changing endometrioma or dermoid?

**Answer:**

According to the O-RADS US system an endometrioma or dermoid < 10 cm with changing morphology or developing vascular component on follow up would have a suspicious component and is no longer a “classic benign lesion” in the O-RADS 2 category but additional O-RADS scoring is not advisable. The management recommendation is referral to an US specialist or for an MRI study for further characterization.

**Question C6:**

Who is an ultrasound specialist?

**Answer:**

The following is the specific governing concept for our risk management system that applies to this question and can be found in the published article and on the ACR website:

*The involvement of an “ultrasound specialist,” denoted as a physician whose practice includes a focus on ultrasound assessment of adnexal lesions has been added to the O-RADS US System. However, at this time, there are no mandated requirements or guidelines that define such a specialist.*

This is the person at your institution or within your referral patterns who would be asked for a second opinion when the imager is faced with a challenging ovarian/adnexal lesion. Radiologists who are ultrasound specialists would usually have fellowship training that would include pelvic ultrasound. There is evidence that experts demonstrate high accuracy in evaluation of malignancy, so it is prudent to make use of available expertise rather than refer the patient for an MRI study for every O-RADS 3,4, and occasional 2 lesion that give both management options.