

# **O-RADS MRI Risk Stratification System:** Guide for Assessing Adnexal Lesions from the ACR O-RADS Committee

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MRI plays an important role as a secondary test or problem-solving modality in the evaluation of adnexal lesions depicted at US. MRI has increased specificity compared with US, decreasing the number of false-positive diagnoses for malignancy and thereby avoiding unnecessary or over-extensive surgery in patients with benign lesions or borderline tumors, while women with possible malignancies can be expeditiously referred for oncologic surgical evaluation. The Ovarian-Adnexal Reporting and Data System (O-RADS) MRI Committee is an international collaborative effort formed under the direction of the American College of Radiology and includes a diverse group of experts on adnexal imaging and management who developed the O-RADS MRI risk stratification system. This scoring system assigns a probability of malignancy based on the MRI features of an adnexal lesion and provides information to facilitate optimal patient management. The widespread implementation of a codified reporting system will lead to improved interpretation agreement and standardized communication between radiologists and referring physicians. In addition, it will allow for high-quality multi-institutional collaborations—an important unmet need that has hampered the performance of high-quality research in this area in the past. This article provides guidelines on using the O-RADS MRI risk stratification system in clinical practice, as well as in the educational and research settings.

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S is highly sensitive and specific for excluding malignancy when classic benign features are present, and the risk of malignancy when these classic features are seen approaches 0% (1–3). However, when classic sonographic imaging features of a simple or hemorrhagic cyst, dermoid, or endometrioma are not present, the potential for malignancy exists. When a lesion has indeterminate imaging features at US, the positive predictive value (PPV) of cancer can range from 7% to 50%, and when a lesion has features worrisome for malignancy, the PPV for cancer ranges from 29% to greater than 50% (1,4-7). In a study of 697 women from the general population presenting to radiology departments for pelvic US, up to one-third of lesions classified as potentially malignant with imaging criteria were nonneoplastic lesions at follow-up, onethird were benign neoplastic lesions, and one-third were borderline or invasive malignant lesions (7). MRI has the ability to increase the PPV from cancer to 71%, with a negative predictive value of 98% (8). MRI capability for providing a more specific diagnoses for sonographically indeterminate lesions reduces the level of suspicion and thus the number of surgeries performed for benign diagnoses in asymptomatic women (5,9–18).

At MRI, the presence of enhancing solid tissue in an adnexal lesion is the primary driver of risk stratification and, in the absence of solid tissue, the risk of malignancy approaches 0% (10,13,17,19-28). The ability to exclude malignancy is one of the greatest strengths of referring sonographically indeterminate adnexal lesions to MRI. In addition to excluding malignancy, the high soft-tissue resolution and ability to characterize the composition of different fluid types allows for more accurate characterization of lesion type. Furthermore, the multiplanar capabilities of MRI allow for interrogation of the entire lesion, regardless of lesion size or location. This is particularly important in the case of lesions with small papillary excrescences or soft-tissue nodules and in large adnexal lesions, both of which may be incompletely evaluated with US (5,11,13,19,29-32). MRI is also crucial in the evaluation of a large adnexal lesion of uncertain origin and allows for reclassification of the lesion as nonovarian when the ovaries can clearly be identified separate from the lesion. According to a recent prospective multicenter study, 10% of lesions referred to MRI as ovarian lesions at US were eventually found to originate from other organs and correctly reclassified with MRI with an accuracy of 97% (8). Last, the gynecologic community considers

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#### **Abbreviations**

ACR = American College of Radiology, DCE = dynamic contrast enhanced, DWI = diffusion-weighted imaging, O-RADS = Ovarian-Adnexal Reporting and Data System, PPV = positive predictive value, TIC = time-intensity curve

#### Summary

The Ovarian-Adnexal Reporting and Data System MRI risk score is a stratification system for assigning malignancy probability to adnexal lesions and can improve communication between radiologists and referring physicians to optimize treatment of women with adnexal lesions.

#### Essentials

- The Ovarian-Adnexal Reporting and Data System (O-RADS)
   MRI risk score was developed by a multi-disciplinary international
   committee of experts as a codified scoring system for MRI evaluation of ovarian and adnexal lesions.
- The O-RADS MRI risk stratification system provides a means for assigning probability of malignancy based on the composition of the lesion, the signal intensity characteristics, and the enhancement pattern of any solid tissue.
- Consistent application of the O-RADS MRI risk score has the potential to increase accuracy of lesion characterization depicted at US, improve interdisciplinary communication, and promote optimized management of adnexal lesions.

MRI the nonsurgical reference standard for adnexal lesion classification, and preoperative MRI is particularly helpful when fertility-sparing surgery is being considered (30,33–36).

Recently, the American College of Radiology (ACR) Ovarian-Adnexal Reporting and Data System (O-RADS) MRI committee published a lexicon and risk stratification system for adnexal lesions (8,37-39). This effort included a diverse multidisciplinary group of international experts on adnexal imaging and management from the fields of radiology and gynecology. The membership status of contributing authors is given in Appendix E1 (online). The ACR O-RADS MRI lexicon includes standardized terms and definitions for assessing and reporting adnexal lesions, whereas the O-RADS MRI risk stratification system provides a data-driven means for assigning probability of malignancy (8,38). The primary goal of the O-RADS MRI risk stratification system is to improve communication between radiologists and referring physicians in a reproducible fashion, so that women with benign lesions or borderline tumors can avoid unnecessary or over-extensive surgery while women with potential malignancy are promptly referred for oncologic surgical evaluation. An important secondary goal is impactful multiinstitutional outcomes research and consistent educational products, both of which are greatly facilitated with use of a codified system, as the radiology community has learned over decades using the ACR Breast Imaging Reporting and Data System.

This goal of this article is to provide guidance for using the O-RADS MRI risk stratification system in clinical practice, as well as in the educational and research setting.

# ACR O-RADS MRI Stratification System: Development and Methodology

The O-RADS MRI stratification system is based on the previously developed ADNEX MR scoring system (28). The AD-

NEX MR scoring system was developed as an algorithmic approach that incorporates the lesion characteristics experts used to make a risk assessment. This includes assessment of the fluid components (simple, hemorrhagic, proteinaceous, endometriotic, lipid) and the solid components (solid tissue, clot, debris, fat). The enhancement of any solid tissue is important because it suggests the possibility of a neoplastic lesion, while the enhancement kinetics help stratify the lesion as low, intermediate, or high risk for malignancy. The ADNEX MR scoring system integrates anatomic and functional MRI, assigning a numeric score and PPV for malignancy (21,28). Several groups have externally validated the precursor ADNEX MR 5-point scoring system, and this system was used as the template for the O-RADS MRI risk stratification system (16,40–43).

There are six risk score categories in the O-RADS MRI risk stratification system: O-RADS MRI 0 (incomplete examination), O-RADS MRI 1 (normal ovaries, including follicles and corpus luteal cysts), O-RADS MRI 2 (almost certainly benign; PPV <0.5%), O-RADS MRI 3 (low risk; PPV approximately 5%), O-RADS MRI 4 (intermediate risk; PPV approximately 50%), and O-RADS MRI 5 (high risk; PPV approximately 90%) (Fig 1). The PPVs for malignancy associated with each O-RADS MRI risk score are based on data from a large, prospective, multicenter cohort study by Thomassin-Naggara et al (8). In that study, two radiologists assigned an O-RADS MRI risk score to lesions in 1194 women and comparisons were made to the final outcome reference standard (histologic examination, 2-year follow-up imaging or clinical examination). PPVs for malignancy included both borderline tumors (histologically malignant but without destructive stromal invasion) and invasive cancers (44). The overall accuracy of the O-RADS MRI risk score in the study by Thomassin-Naggara et al was 92%, with a sensitivity of 93%, specificity of 91%, PPV of 71%, and negative predictive value of 98% (32). The ACR O-RADS MRI committee has used the data from this study to develop the current version of the O-RADS MRI risk score found on the ACR website (38). Substantial additions to the version of the risk score found on the ACR website include a non–dynamic contrast-enhanced (DCE) option for assessing enhancement of solid tissue in an adnexal lesion and a score for dermoids with a large amount of soft tissue.

#### ACR O-RADS MRI Lexicon: The Basics

To understand the terminology used in the O-RADS MRI risk stratification system, the lexicon descriptor terms for signal intensity, physiologic finding versus lesion, and fluid versus solid appearing observations will be briefly reviewed. For a more complete list of lexicon terms and definitions, please refer to the ACR O-RADS MRI lexicon table (37,39).

#### Signal Intensity

The signal intensity of both fluid and solid elements is described for all images as homogeneous or heterogeneous in nature. Homogeneous signal intensity is uniform or even in appearance. Heterogeneous signal intensity is nonuniform or uneven in appearance.

Signal intensity is described as hypointense, intermediate, or hyperintense on T2-weighted images (in relation to iliopsoas muscle and urine or cerebrospinal fluid) and T1-weighted

# O-RADS MRI Risk Stratification and Management System

O-RADS MRI Score	Risk Category	Positive Predictive Value for Malignancy^	Lexicon Description	
0	Incomplete Evaluation	N/A	N/A	
1	Normal Ovaries	N/A	No ovarian lesion  Follicle defined as simple cyst ≤ 3 cm in a premenopausal woman  Hemorrhagic cyst ≤ 3 cm in a premenopausal woman  Corpus luteum +/- hemorrhage ≤ 3 cm in a premenopausal woman	
2	Almost Certainly Benign	<0.5%^	Cyst: Unilocular- any type of fluid content  No wall enhancement  No enhancing solid tissue*  Cyst: Unilocular – simple or endometriotic fluid content  Smooth enhancing wall  No enhancing solid tissue  Lesion with lipid content**  No enhancing solid tissue  Lesion with "dark T2/dark DWI" solid tissue  Homogeneously hypointense on T2 and DWI  Dilated fallopian tube - simple fluid content  Thin, smooth wall/endosalpingeal folds with enhancement  No enhancing solid tissue  Para-ovarian cyst – any type of fluid  Thin, smooth wall +/- enhancement  No enhancing solid tissue	
3	Low Risk	~5%^	Cyst: Unilocular – proteinaceous, hemorrhagic or mucinous fluid content***  Smooth enhancing wall No enhancing solid tissue  Cyst: Multilocular - Any type of fluid, no lipid content Smooth septae and wall with enhancement No enhancing solid tissue  Lesion with solid tissue (excluding T2 dark/DWI dark) Low risk time intensity curve on DCE MRI  Dilated fallopian tube – Non-simple fluid: Thin wall /folds Simple fluid: Thick, smooth wall/ folds No enhancing solid tissue	
4	Intermediate Risk	~50%^	Lesion with solid tissue (excluding T2 dark/DWI dark)  ■ Intermediate risk time intensity curve on DCE MRI  ■ If DCE MRI is not feasible, score 4 is any lesion with solid tissue (excluding T2 dark/DWI dark) that is enhancing ≤ myometrium at 30-40s on non-DCE MRI  Lesion with lipid content  ■ Large volume enhancing solid tissue	
5	High Risk	~90%^	Lesion with solid tissue (excluding T2 dark/DWI dark)  High risk time intensity curve on DCE MRI  If DCE MRI is not feasible, score 5 is any lesion with solid tissue (excluding T2 dark/DWI dark) that is enhancing > myometrium at 30-40s on non-DCE MRI  Peritoneal, mesenteric or omental nodularity or irregular thickening with or without ascites	

^Approximate PPV based on data from Thomassin-Naggara, et al. O-RADS MRI Score for Risk Stratification of Sonographically Indeterminate Adnexal Masses. JAMA Network Open. 2020;3(1):e1919896. Please note that the PPV provided applies to the score category overall and not to individual characteristics. Definitive PPV are not currently available for individual characteristics. The PPV values for malignancy include both borderline tumors and invasive cancers.

DCE = dynamic contrast enhancement with a time resolution of 15 seconds or less

DWI = diffusion weighted images

MRI = magnetic resonance imaging

Figure 1: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) MRI risk stratification system. DCE = dynamic contrast enhanced, DWI = diffusion-weighted imaging, N/A = not applicable, PPV = positive predictive value. Reprinted, with permission, from the American College of Radiology.

<sup>\*</sup> Solid tissue is defined as a lesion component that enhances and conforms to one of these morphologies: papillary projection, mural nodule, irregular septation/wall or other larger solid portions.

<sup>\*\*</sup> Minimal enhancement of Rokitansky nodules in lesion containing lipid does not change to O-RADS MRI 4.

<sup>\*\*\*</sup> Hemorrhagic cyst <3cm in pre-menopausal woman is O-RADS MRI 1.

Table 1: Signal Intensity of Hemorrhage at T1- and T2- weighted MRI at Different Stages							
Stage	Hemoglobin	T1-weighted Signal Intensity	T2-weighted Signal Intensity				
Acute	Deoxyhemoglobin	Iso- to hypointense	Hypointense				
Early subacute	Intracellular methemoglobin	Hyperintense	Hypointense				
Late subacute	Extracellular methemoglobin	Hyperintense	Hyperintense				
Chronic	Hemosiderin	Hypointense	Hypointense				

images (in relation to the iliopsoas muscle and fat). At high b-value diffusion-weighted imaging (DWI), the signal intensity is described as low or high (in relation to urine or cerebrospinal fluid). Figure E1 (online) depicts each signal intensity descriptor.

# **Lesion Types**

A lesion is a finding associated with the ovary or adnexa that is not related to normal physiology. A lesion can be described as a cyst with or without solid components or as a a solid lesion. Cysts are fluid-containing lesions that can be unilocular or multilocular. A solid lesion is composed of at least 80% enhancing solid tissue.

# Fluid Descriptors

Fluid within a cyst can be simple or nonsimple. Nonsimple fluids are endometriotic, hemorrhagic, proteinaceous, or lipid containing. Simple fluid has the same signal intensity as cerebrospinal fluid on T1-weighted, T2-weighted, and DWI scans, exhibiting hypointense signal intensity on T1-weighted images and hyperintense signal intensity on T2-weighted images. Endometriotic fluid is homogeneous and hyperintense on T1-weighted images and hypointense or intermediate in signal intensity on T2-weighted images, also known as shading. Hemorrhagic fluid has variable signal intensity depending on the time since the hemorrhage (Table 1) (45-47). Proteinaceous fluid is variable in signal intensity and can be variably hypointense on T2-weighted images and either hypointense or hyperintense on T1-weighted images. Proteinaceous fluid includes mucin, pus, and colloid in adnexal lesions. Lipidcontaining fluid is hyperintense on T2- and T1-weighted images and can be mistaken for hemorrhagic or endometriotic fluid; however, lipid-containing fluid will show a visible decrease in signal intensity on fat-saturated images. Microscopic or intravoxel fat is best depicted on opposed-phase images and may not exhibit signal loss on fat-saturated images in the way macroscopic fat does.

#### **Solid Component Descriptors**

Solid-appearing components are any part of an adnexal lesion that is not fluid. This includes solid tissue and other solid components (ie, nonsolid tissue). Solid tissue is strictly

defined as a solid component that enhances after contrast material administration and exhibits one of the following morphologic characteristics: papillary projections, mural nodules, irregular septations or walls, and larger solid portion. Nonsolid tissue is defined as other solid components that do not fit the definition of solid tissue and includes thin or thick smooth septations or walls, blood clot, nonenhancing debris, fibrin strands, and fat. Identifying solid tissue within an adnexal lesion is important, as this raises the suspicion that the lesion may be a malignancy. Nonsolid tissue is a benign finding.

# O-RADS MRI Risk Stratification System: Classification of Adnexal Lesions

# **Governing Concepts**

On the ACR website, the ACR O-RADS MRI committee provides governing concepts for the use of the O-RADS MRI risk stratification system on adnexal lesions in clinical practice (38). The following are some important highlights from these governing concepts:

- 1. The risk assessment system should only be applied to an average-risk patient with no acute symptoms. The risk score serves as a guide for the treating physician to decide on the best clinical management.
- 2. Dermoid or mature teratomas have a very low risk of malignancy and hence are assigned an O-RADS MRI risk score of 2. Some dermoids will have a small amount of enhancing tissue (Rokitansky nodule) but would still be assigned an O-RADS MRI risk score of 2. Rarely, fat-containing lesions contain a large amount of enhancing soft tissue and can harbor malignancy, especially when this solid portion displays irregular margins. When there is a large amount of enhancing tissue, fat-containing lesion are assigned an O-RADS MRI score of 4 due to the risk of an immature teratoma or other malignant tissue in a dermoid, such as a squamous cell carcinoma.
- 3. In addition to assigning an O-RADS MRI risk score, the final diagnosis (eg, dysgerminoma, granulosa cell tumor, lymphoma, papillary serous tumors, peritoneal pseudocyst) can be reported with the score if classic imaging features are present.
- 4. DCE MRI with time-intensity curves (TICs) is preferred over non-DCE imaging for risk assessment.
- 5. If the study is technically inadequate, then the lesion should be assigned an O-RADS MRI risk score of 0.

# **MRI Technique**

Scoring an adnexal lesion is a methodical process, beginning with assessing if the MRI technique is adequate (37) (Table 2). The MRI examination should include sagittal T2-weighted images without fat saturation (section thickness,  $\leq 4$  mm), axial T2-weighted images without fat saturation (section thickness,  $\leq 3$  mm), axial T1-weighted in- and opposed-phase images (section thickness,  $\leq 4$  mm; b value >1000 sec/mm²), and postcontrast T1-weighted images with fat saturation in the plane in which adequate coverage can be obtained. For adequate assessment of any enhancing solid tissue within an

Table 2: MRI Protocol for Adnexal Mass Characterization at 1.5- or 3.0-T MRI					
Sequence	Comment				
Sagittal T2WI without fat saturation	Section thickness: 4 mm or less				
Axial T2WI without fat saturation	Section thickness: 3 mm or less				
Axial in- and out-of-phase T1WI	Section thickness: 4 mm or less				
Axial DWI	Same location as T2WI; section thickness: 4 mm or less; b value: 0–50 and 1000 sec/mm <sup>2</sup> or greater				
DCE MRI: 3D T1WI with fat saturation	Begin the scanning 30 sec before contrast material injection; injection occurs at 30 sec without interruption of scan acquisition; total imaging duration: 4 min; section thickness: 3 mm or less; minimal temporal resolution ≤15 sec; ideally in axial plane but in the case of very large masses, sagittal or coronal plane may allow lesion coverage without loss of time resolution				
Nondynamic 3D T1WI with fat saturation	Precontrast and single postcontrast phase performed at 30–40 sec after the end of the contrast material injection; section thickness: 3 mm or less				

Note.—Imaging protocol should include standard T1-weighted imaging (T1WI), T2-weighted imaging (T2WI), and diffusion-weighted imaging (DWI). The scanning parameters will vary by field strength and vendor and should be adjusted for optimum image quality. Field of view may vary between patients and should be adjusted to ensure complete coverage of the adnexal lesion. DCE = dynamic contrast enhanced, 3D = three-dimensional.

adnexal lesion, DCE MRI should be performed. The DCE MRI (three-dimensional ultrafast gradient-echo) acquisition is a dynamic T1-weighted sequence performed before and after intravenous contrast material administration (Table 2). This acquisition should have a 15-second time resolution and a minimum section thickness of 3 mm and should begin 30 seconds before contrast material injection to ensure acquisition of noncontrast time-point images to enable subtraction. The acquisition should then continue for a total scanning duration of 4 minutes.

A TIC is generated by placing one region of interest within the area of early solid tissue enhancement within the lesion and another on the outer myometrium, taking care to avoid the outer myometrial vessels or benign changes such as leiomyomas or adenomyosis. A low-risk TIC is defined as an increase in the signal intensity of solid tissue after contrast material administration, slower than that in the myometrium, without a well-defined shoulder and no plateau (Fig 2). An intermediate-risk TIC has a moderate initial rise in the signal intensity of solid tissue, with a slope slower than or equal to that of the myometrium, with a shoulder and plateau (Fig 2). A high-risk TIC has a brisk initial rise in the signal intensity of solid tissue, with a slope greater than myometrium, with a shoulder and plateau (Fig 2).

When the uterus is not present, a low-risk TIC will have a steady rate of enhancement, with no shoulder or plateau; how-ever, intermediate- and high-risk TICs will look similar and therefore confident distinction between an O-RADS MRI score 4 and 5 lesion will not be possible. If DCE MRI with 15-second time resolution is not possible, then non-DCE MRI can be performed; that is, a pre- and postcontrast three-dimensional ultrafast gradient-echo sequence can be performed 30–40 seconds after the end of the contrast material injection (section thickness, ≤3 mm). Enhancement of the solid tissue in the lesion and the outer myometrium is compared to determine if the lesion should be assigned an O-RADS MRI score of 4 or 5. Because non-DCE MRI does not allow for TIC generation, the ability to differentiate between O-RADS MRI score 3 and 4 lesions is not possible.

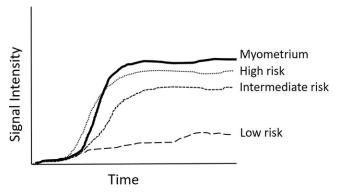


Figure 2: Graph depicts the visual differences between low-risk, intermediaterisk, and high-risk time-intensity curves (TICs). A low-risk TIC is defined as an
increase in the signal intensity of solid tissue after contrast material administration,
slower than that in the myometrium, without a well-defined shoulder and no plateau. An intermediate-risk TIC has a moderate initial rise in the signal intensity of
solid tissue, with a slope slower than or equal to that of the myometrium, with a
shoulder and plateau. A high-risk TIC has a brisk initial rise in the signal intensity of
solid tissue, with a slope greater than myometrium, with a shoulder and plateau.

# O-RADS MRI Scores: Definitions and Malignancy Risk

# O-RADS MRI Score 0

Adnexal lesions are classified as O-RADS MRI 0 when the lesion is incompletely evaluated at MRI. This may include lesions that are incompletely imaged, where portions of the lesion are not assessed. Technically inadequate MRI examinations, where all the required imaging sequences have not been performed or there is a large amount of artifact, are also included in this category.

#### O-RADS MRI Score 1

An O-RADS MRI score of 1 is assigned when the ovaries are normal, as depicted in Figure 3. In premenopausal women, when there is a physiologic observation such as follicles, hemorrhagic cysts, and corpus luteal cysts measuring 3 cm or less, the finding is not considered an adnexal lesion and can be classified as O-RADS MRI score 1. Follicles, hemorrhagic cysts, and corpus luteal cysts

O-RADS MRI 1: Normal Ovaries and Physiologic Observations							
Normal ovaries	Ovarian parenchyma (arrows): intermediate T2 and T1 signal, and high signal on DWI. Follicle with simple fluid (asterisks).						
Pre-menopausal ovaries	* Axial T2WI	Axial T1WI	Axial DWI (B-value >1000)	* Axial FS post-T1WI			
	ANIAI 12 VVI	AXIAI I I VVI	Aviai PAAI (B-Aaine >1000)	Aviai L2 host-11441			
Post-menopausal ovaries*		A	1				
Physiologic Obso	Axial T2WI	Axial T1WI	Axial DWI (B-value >1000)	Axial FS post-T1WI			
Filysiologic Obse	Follicle (arrows): hyperintense T2 signal, hypointense T1 signal and smooth wall enhancement.						
	Follicie (arrows): nyperint	ense 12 signal, nypointen	se 11 signal and smooth w	all ennancement.			
Follicle ( <u>&lt;</u> 3cm)							
	Axial T2WI	Axial FST2WI	Axial FS T1	Axial FS post-T1WI			
	Hemorrhagic cyst (arrows): hyperintense T2 and T1 signal, and no ehancement.						
Hemorrhagic cyst (≤3cm)							
	Axial T2WI	Axial T1WI	Axial FS T1	Axial FS post-T1WI			
	Corpus luteum (arrows): T2 central hyperintense signal and intermediate crenulated rim, homogenous T1 hypointense signal and an enhancing crenulated rim.						
Corpus luteum (≤3cm)	F						
	Axial T2WI	Axial T1WI	Axial FS T1	Axial FS post-T1WI			

Figure 3: Image shows examples of Ovarian-Adnexal Reporting and Data System (O-RADS) MRI 1 risk score. \* = In postmenopausal women, normal ovaries can contain very small residual follicles, and if the radiologist subjectively assesses the ovaries as normal, the ovaries can be categorized as O-RADS MRI 1. DWI = diffusion-weighted imaging, FS = fat saturated, T1WI = T1-weighted imaging, T2WI = T2-weighted imaging.

#### O-RADS MRI 2: Almost Certainly Benign (PPV for malignancy <0.5%) 3.5 cm hemorrhagic cyst with a fluid-fluid level (T2 hyperintense anteriorly/T2 hypointense dependently), intermediate to hyperintense signal on T1WI and no wall enhance Cyst: Unilocularany type of fluid content^ • No wall enhancement No enhancing solid tissue Avial T2WI Axial T1WI Axial FS pre-T1WI Axial post-T1WI Unilocular cyst with simple fluid (hyperintense on T2WI, hypointense on T1WI) and a smooth enhancing wall (arrowheads). Cyst: Unilocular simple or endometriotic Axial T2WI Coronal FS T2WI Axial FS pre-T1WI Axial post-T1WI fluid content Endometrioma: rim of dark signal and heterogeneously hypointense signal centrally (shading) on Smooth T2WI, hyperintense signal on T1WI and a smooth enhancing wall (arrowheads) enhancing wall No enhancing solid tissue Axial FS subtracted Axial FS T2WI Axial T1WI Axial FS pre-T1WI Dermoid: lipid content that decreases in signal on fat saturated images (asterisk) and no enhancement (arrow). Arrowheads: normal ovarian parenchyma Lesion with lipid content^/ No enhancing solid tissue Axial FS subtracted Axial T2WI Axial T1WI Axial FS pre-T1WI Fibroma: homogenously hypointense signal (arrows) on T2WI and DWI, intermediate signal on T1WI Lesion with homogeneous T2 dark/ DWI dark' solid tissue Axial T2WI Axial DWI (B-value >1000) Axial FS pre-T1WI Axial FS nost-T1WI Simple hydrosalpinx (arrows) with thin, smooth wall/endosalpingeal folds with enhancement. Dilated fallopian tube - simple fluid • Thin, smooth wall/ endosalpingeal folds No enhancing solid tissue Axial FS pre-T1WI Axial T2WI Axial T1WI Paraovarian cyst (asterisks): non-simple fluid (T2 hyperintense/T1 intermediate signal) and no Para-ovarian cyst any type of fluid • Thin, smooth wall +/ enhancement No enhancing solid tissue Axial T2WI Axial T1WI Axial FS pre-T1WI Axial FS post-T1WI

Figure 4: Image shows examples of Ovarian-Adnexal Reporting and Data System (O-RADS) MRI 2 risk score. ^ = Unilocular cysts with simple or hemorrhagic fluid 3 cm or smaller in a premenopausal woman would be classified as O-RADS MRI 1. ^^ = Minimal enhancement of Rokitansky nodule in lesion containing lipid does not change to O-RADS MRI 4. DWI = diffusion-weighted imaging, FS = fat saturated, PPV = positive predictive value, T1WI = T1-weighted imaging, T2WI = T2-weighted imaging.

are routinely seen in premenopausal women and, when identified, should be reported using the appropriate terminology. In postmenopausal women, normal ovaries can contain very small residual follicles, and if the radiologist subjectively assesses the ovaries as normal, the ovaries can be classified as O-RADS MRI 1. However, if the radiologist determines that an adnexal finding is not consistent with that of a normal ovary, then the finding is termed an adnexal lesion and would be scored as O-RADS MRI 2-5. The O-RADS MRI risk score does not apply to lesions found to be nonovarian or nonadnexal in origin.

# O-RADS MRI Score 2

Adnexal lesions scored as O-RADS MRI 2 are considered almost certainly benign, with a PPV for malignancy of less than 0.5% (Fig 4) (8). In both premenopausal and postmenopausal women, it is important to apply this score only to an adnexal lesion; see the O-RADS MRI Score 1 section above for findings not considered an adnexal lesion.

In the O-RADS MRI score 2 category are unilocular cystic lesions with simple and nonsimple fluid. If there is a unilocular cystic lesion with no wall enhancement, then the type of fluid is not a contributing factor. Thus, all cystic lesions with no wall enhancement are scored as O-RADS MRI 2. Proteinaceous and hemorrhagic unilocular cystic lesions (excluding physiologic findings) without enhancing walls and no solid tissue are scored O-RADS MRI 2; whereas if there is an enhancing wall, the unilocular cystic lesion with proteinaceous or hemorrhagic fluid is scored O-RADS MRI 3. Unilocular cystic lesions with simple and endometriotic fluid

#### O-RADS MRI 3: Almost Certainly Benign (PPV for malignancy ~5%) Unilocular cyst: hemorrhagic fluid (asterisks) and wall enhancement (arrowheads). Cyst: Unilocular - proteinaceous, hemorrhagic or mucinous fluid^^ Smooth enhancing wall (arrowheads) No enhancing solid tissue Axial T2WI Axial T1WI Axial FS pre-T1WI Axial FS post-T1WI Mucinous cystadenoma: variable intensity fluid (asterisks) and enhancing smooth septae Cyst: (arrowheads). Multilocular -Any type of fluid, no lipid content Smooth septae and wall with enhancement No enhancing solid tissue Axial T1WI Axial T2WI Axial FS pre-T1WI Axial FS post-T1WI Brenner tumor (arrows): hypointense signal on T2WI, heterogeneously hyperintense signal on DWI, and a low risk TIC. Lesion with solid tissue (excluding Myometrium homogenously T2 dark/ DWI dark) Low risk time Lesion intensity curve on DCE MRI Low risk Axial T2WI Axial DWI (B-value >1000) Axial FS post-T1WI time intensity curve M = myometrium L = lesion Hematosalpinx (asterisks) with enhancing walls (arrows) and adjacent normal ovarian parenchyma (arrowheads). Dilated fallopian tube -• Non-simple fluid: Thin wall / folds • Simple fluid: Thick, smooth wall/folds No enhancing solid tissue Axial T2WI Axial T1WI Axial FS pre-T1WI Axial FS post-T1WI

Figure 5: Image shows examples of Ovarian-Adnexal Reporting and Data System (O-RADS) MRI 3 risk score. ^ = Hemorrhagic cyst smaller than 3 cm in a premenopausal woman would be classified as O-RADS MRI 2. DCE = dynamic contrast enhanced, DWI = diffusion-weighted imaging, FS = fat saturated, PPV = positive predictive value, TIC = time-intensity curve, T1WI = T1-weighted imaging, T2WI = T2-weighted imaging.

and no solid tissue are classified as O-RADS MRI 2 regardless of wall enhancement. On T2-weighted images, endometriomas may exhibit a specific ancillary finding of dark (low-signal-intensity) nodules or linear foci in the wall (48,49).

Lesions with lipid content (mature teratomas or dermoids) are classified as O-RADS MRI 2. The macroscopic lipid content within the lesion will be hyperintense on T1and T2-weighted images and will decrease in signal intensity on fat-saturated images. There are usually no enhancing components within dermoids, with the exception of a Rokitansky nodule (Fig E1 [online]). Rokitansky nodules typically exhibit fat within them and may enhance. Malignant degeneration is rare, occurring in approximately 1% of dermoids (50,51). When malignant degeneration occurs in dermoids, there is more solid tissue present on MRI scans than expected for a typical Rokitansky nodule (52). When there is malignant transformation of a dermoid, the prognosis is dependent on the stage, and early detection improves long-term survival (50). Therefore, when there is a subjectively assessed large amount of tissue (especially with irregular borders) within a fatty lesion on MRI scans, the lesion is classified as O-RADS MRI 4.

Lesions that exhibit homogenously hypointense signal intensity on both T2-weighted and high-*b*-value DWI scans (hereafter, dark T2/dark DWI lesions) can be classified as O-RADS MRI 2. The enhancement pattern of homogenously dark T2/dark DWI lesions does not have an effect on the O-RADS MRI score. The term *dark T2/dark DWI* has been introduced by the ACR O-RADS MRI committee to define lesions composed of fibrous tissue, which most commonly turn out to benign ovarian fibromas and fibrothecomas.

Para-ovarian cysts without any solid tissue and dilated fallopian tubes with simple fluid and no enhancing solid tissue can both be scored as O-RADS MRI 2 lesions. In case of a hydrosalpinx, care must be taken not to mistake enhancing endosalpingial folds for papillary projections. Coronal or sagittal T2-weighted images may help confirm the tubular nature of a hydrosalpinx and can help avoid this pitfall.

# O-RADS MRI Score 3

Adnexal lesions classified as O-RADS MRI 3 are considered low risk for malignancy, with a PPV for malignancy of approximately 5% (Fig 5) (8).

This category includes unilocular cystic lesions with smooth enhancing walls and hemorrhagic or proteinaceous fluid content (eg, mucinous fluid) and no solid tissue, as well as any multilocular (nonfatty) cyst with smooth enhancing walls and septations but no enhancing solid tissue. The risk of malignancy in these multilocular cysts without solid tissue is very low (PPV < 3%); however, the malignancies discovered in this category include borderline and invasive cancers (8). As with all ovarian cancers, the expedited evaluation of women with potentially early-stage cancer is prudent to ensure the best outcome in these women (53,54). Occasionally, endometriomas may be multilocular or have the appearance of being multilocular due to ovarian parenchyma between the endometriomas mimicking septations. Endometriomas that appear multilocular should be classified as O-RADS MRI 2.

In the presence of enhancing solid tissue, the solid tissue will help guide O-RADS MRI risk score classification. If the solid tissue has homogenously low signal intensity on both T2-weighted and high-b-value DWI scans (T2 dark/DWI dark lesion), then the lesion is classified as O-RADS MRI 2. If the solid tissue does not fit the homogenously T2 dark/DWI dark pattern, then the TIC enhancement characteristics of the solid tissue relative to the outer myometrium will dictate the score. If the enhancement follows the low-risk TIC, then the lesion can be assigned a risk score of O-RADS MRI 3. Lesions with a low-risk TIC have a PPV for malignancy of 6.7%, and most lesions found to be malignant in this category are borderline tumors (8).

Dilated fallopian tubes with nonsimple fluid or thick, smooth enhancing wall and/or folds are classified as O-RADS MRI score 3. There is a paucity of data on the relative risk of cancer in women with these findings. However, given that high-grade serous carcinomas arise from the fallopian tubes and that currently the appearance of early-stage disease is not described well in the literature, the committee acknowledged that until more data are available, these types of findings should be assigned to this category. When more data are available, the PPV for malignancy will be updated and a reassignment into a different category will be made if necessary. As a reminder, if the patient has acute symptoms with findings of dilated fallopian tubes, then the O-RADS MRI score should not be used, so that pelvic inflammatory disease with pyosalpinx is not scored.

### O-RADS MRI Score 4

Adnexal lesions with an O-RADS MRI score of 4 are considered intermediate risk for malignancy, with a PPV for malignancy of approximately 50% (Fig 6).

Lesions in this category contain solid tissue (excluding T2 dark/DWI dark lesions) that exhibit the intermediate-risk TIC. Data have shown that lesions with an intermediate TIC have a PPV of 46.6% (8). If DCE MRI is not feasible, lesions with solid tissue (excluding T2 dark/DWI dark lesions) that enhance less than or equal to the myometrium at 30-40 seconds after contrast material injection on non-DCE MRI scans can be placed in this category. To our knowledge, no studies have calculated the PPV for malignancy for solid tissue that enhances less than or equal to the myometrium at 30-40 seconds at non-DCE MRI (threedimensional ultrafast gradient echo). Because the definition of intermediate-risk TIC is based on very early enhancement that is not as steep as that of myometrium, in the absence of DCE MRI, the ACR O-RADS MRI committee decided to place the lesions that enhance less than or equal to the myometrium at 30-40 seconds in the O-RADS MRI score 4 category. Although DCE MRI evaluation is the preferred method for assigning a risk score, the committee acknowledged the use of non-DCE MRI when DCE MRI is not possible. When data on the PPV for malignancy using non-DCE MRI for the evaluation of adnexal lesion become available, the PPV for malignancy will be updated.

# O-RADS MRI Score 5

Adnexal lesions classified as O-RADS MRI score 5 are considered at high risk for malignancy, with a PPV for malignancy of approximately 90% (Fig 7).

# O-RADS MRI 4: Intermediate Risk (PPV for malignancy ~50%) Lesion with solid Low-grade serous papillary tumor: solid tissue, papillary projection (arrows) and nodule (asterisks), tissue (excluding with an intermediate risk TIC. homogeneously T2 dark/DWI dark) Myometrium, Intermediate risk time intensity curve Lesion on DCE MRI Intermediate risk Axial T2WI Axial DWI (B-value >1000) Axial FS post-T1WI time intensity curve M = myometrium L = lesion Ovarian endometrioid cancer: solid tissue (arrows; L) that enhances < myometrium (M). Lesion with solid tissue (excluding homogeneously T2 dark/DWI dark) Enhancing ≤ myometrium at 30-40s on Axial T2WI Axial DWI (B-value >1000) Axial FS pre-T1WI Axial FS post-T1WI non-DCE MRI M = myometrium L = lesion Dermoid with squamous cell carcinoma: lesion with lipid content (asterisks) and a large amount of solid tissue (arrows) that was squamous cell cancer on final pathology. Lesion with lipid content • Large volume enhancing solid tissue Axial FS subtracted Axial T1WI Axial FS T1WI Axial FS pre-T1WI post-T1WI

Figure 6: Image shows examples of Ovarian-Adnexal Reporting and Data System (O-RADS) MRI 4 risk score. DCE = dynamic contrast enhanced, DWI = diffusion-weighted imaging, FS = fat saturated, PPV = positive predictive value, TIC = time-intensity curve, T1WI = T1-weighted imaging, T2WI = T2-weighted imaging.

This category includes lesions with solid tissue (excluding T2 dark/DWI dark lesions) that exhibit a high-risk TIC and/or the presence of peritoneal and/or omental deposits. Data have shown that lesions with a high-risk TIC have a PPV of 85.6% (8). If DCE MRI is not feasible, lesions with solid tissue (excluding T2 dark/DWI dark lesions) that enhances greater than that of the myometrium at 30–40 seconds after contrast material injection at non-DCE MRI can be placed in this category. To our knowledge, no studies have calculated the PPV for malignancy for solid tissue that enhances greater than the myometrium at 30–40 seconds after contrast material injection at non-DCE MRI. As the definition of high-risk TIC is based on very early enhancement steeper than that of myometrium, in the absence of DCE, the ACR O-RADS MRI committee

decided to classify lesions that enhance greater than the myometrium at 30–40 seconds as O-RADS MRI score 5. Although DCE MRI evaluation is the preferred method, the committee acknowledged the use of non-DCE MRI when DCE MRI is not possible. When data on the PPV for malignancy using non-DCE MRI for the evaluation of adnexal lesion become available, the PPV for malignancy will be updated.

# Strengths and Challenges of the O-RADS MRI Risk Stratification System in Clinical Practice

One of the major strengths of the O-RADS MRI risk score system is the ability to exclude ovarian cancer with a high degree of certainty. Thomassin-Naggara et al (8) demonstrated that when an adnexal lesion is classified as O-RADS MRI score

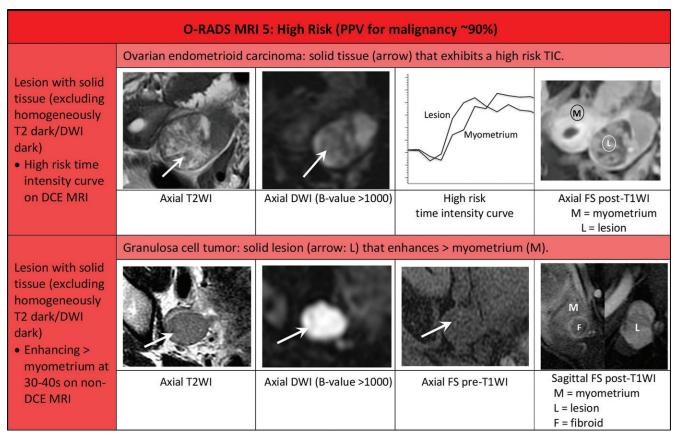


Figure 7: Image shows examples of Ovarian-Adnexal Reporting and Data System (O-RADS) MRI 5 risk score. DCE = dynamic contrast enhanced, DWI = diffusion-weighted imaging, FS = fat saturated, PPV = positive predictive value, TIC = time-intensity curve, T1WI = T1-weighted imaging, T2WI = T2-weighted imaging.

2 or 3, rather than score 4 or 5, the negative predictive value for malignancy was 98%. This is extremely reassuring to the radiologist assigning the risk score, as well as to the treating physician and, ultimately, the patient. Other strengths of the O-RADS MRI risk stratification score are that the system is based on robust clinical data rather than expert opinion. The system incorporates the methods experts use to evaluate a lesion at MRI, describing the approach in a stepwise algorithmic fashion and enabling general radiologists to perform similarly to subspecialty radiologists. The system has been tested in a prospective multicenter clinical trial, with good reproducibility between expert and nonexpert readers for the diagnosis of malignancy (38). This approach will hopefully lead to real-life performance that closely approximates the intended risk stratification categories. Furthermore, the risk score is aligned with a lexicon that standardizes the language used to describe adnexal lesions. In an ideal setting, the adoption and usage of the lexicon and risk stratification system would lead to standardized reporting to guide the referring clinician in decision making in a patient with an adnexal lesion.

As with any new approach, there are challenges to implementing and using the O-RADS MRI risk stratification system. These include implementing the appropriate MRI technique and acquiring the knowledge of tissue and fluid differentiation at MRI in practices not familiar with using MRI for adnexal lesion characterization. Developing an MRI protocol to include the necessary sequences, particularly DCE

MRI, can be a challenge in some centers. In centers where DCE is not possible due to time constraints or lack of perfusion curve analysis software, analysis of the enhancement of the solid tissue on the 30–40-second postcontrast series can be performed as a substitute. Understanding how to characterize cystic and solid components and how to differentiate enhancing tissue from other solid components at MRI are the most essential diagnostic skills that must be acquired to use this system. This takes time investment and resources, both of which can be difficult to find in a busy clinical practice. The availability of the O-RADS MRI calculator can help facilitate the integration of imaging findings and the assignment of the O-RADS MRI risk score (55).

# **Future Direction**

Future research should focus on providing more data for areas where currently there is a paucity of data. As mentioned with the O-RADS MRI score 4 and 5 categories, further research is needed to determine the PPV for malignancy when non-DCE MRI is used for the evaluation of adnexal lesions. In addition, defining the amount of solid tissue within a dermoid will be important to help radiologists move beyond subjective analysis in these lesions. Proof-of-concept evaluation using the standardized O-RADS MRI lexicon to risk-stratify lesions has been successfully performed among committee members and validated in a prospective multicenter trial in Europe (8). Further validation studies are needed, particularly in North America.

Regarding management recommendations, prospective cohort studies that assess the performance of the O-RADS MRI scoring system in a clinical practice setting are needed to guide development of future management recommendations for each O-RADS MRI risk category. There are currently two ongoing studies evaluating the effect of the O-RADS MRI 5-point score on the patient management plan. The first study is an interventional study in women with O-RADS MRI score 3 lesions, the ADNEXMR Scoring System: Impact of an MR Scoring System on Therapeutic Strategy of Pelvic Adnexal Masses, or ASCORDIA, study (ASCORDIA01, ClinicalTrials.gov identifier: NCT02664597) in France. Consenting women with a score 3 lesion are randomized to surgery or nonsurgical followup, with the number of unnecessary surgeries avoided as the primary outcome measure. A second study, the MR in Ovarian Cancer, or MROC, study (ISRCTN51246892) in the United Kingdom, evaluates the potential impact of adding MRI to standard-of-care imaging on the initial treatment decisions (either surgical and nonsurgical) in women suspected of having or confirmed to have ovarian cancer. Patient outcomes and health economic evaluations will also be performed. Once these studies are complete, we anticipate that the O-RADS MRI risk stratification system will include management recommendations and the system will evolve as additional evidence becomes available in the peer-reviewed literature.

# Conclusion

In conclusion, the Ovarian-Adnexal Reporting and Data System MRI risk score provides a stratification system for assigning the probability of malignancy to adnexal lesions based on MRI features. Its widespread implementation will improve communication between radiologists and referring physicians so that women with benign adnexal lesions can avoid unnecessary surgery while those with potential malignancies can be expeditiously referred for oncologic surgical evaluation. Furthermore, researchers will benefit from the use of this codified system, providing a means for impactful multi-institutional studies to improve outcomes in women with adnexal lesions.

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