# The Ovarian/Adnexal Reporting and Data System for Ultrasound: From Standardized Terminology to Optimal Risk Assessment and Management

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## Abstract

The American College of Radiology (ACR) Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon and risk assessment tool for ultrasound (US) provides a framework for characterization of ovarian and adnexal pathology with the ultimate goal of harmonizing reporting and patient management strategies. Since the first O-RADS US publication in 2018, multiple validation studies have shown O-RADS US to have excellent diagnostic accuracy, with the majority of these studies using O-RADS 4 as the optimal cut-off for detecting ovarian cancer. Most of the existing validation studies include a dedicated training phase and confirm that ORADS US categories and lexicon descriptors are associated with high level inter-read agreement, regardless of radiologist training level or practice experience. O-RADS US has a similar inter-reader agreement when compared to Gynecologic Imaging Reporting and Data System (GIRADS), Assessment of Different Neoplasias in the adnexa (ADNEX), and International Tumor Analysis Group (IOTA) simple rules. System descriptors have been shown to correlate with expected malignancy rates and the O-RADS US risk stratification system has been shown to perform in the expected range of malignancy risk per category. Further directions will focus on clarifying governing concepts and lexicon terminology as well as further refining risk stratification categories based on data from published validation studies.

## Résumé

**Résumé** L'outil d'évaluation du risque et le lexique du système O-RADS (Ovarian-Adnexal Reporting and Data System) de *l'American College of Radiology* (ACR) pour l'échographie (US) procurent un cadre de définitions de la pathologie ovarienne et annexielle dans le but ultime d'harmoniser les rapports et les stratégies de gestion des patientes. Depuis la première publication de l'O-RADS US en 2018, de nombreuses études de validation ont montré que la précision diagnostique de ces outils était excellente, la majorité des études utilisant O-RADS 4 comme seuil optimal de détection du cancer de l'ovaire. La plupart des études de validations existantes incluent une phase de formation qui lui est consacrée et confirment que les catégories de l'O-RADS US et les termes descriptifs de son lexique sont associés à un taux élevé de concordance entre lecteurs, indépendamment du niveau de formation ou d'expérience professionnelle des radiologistes. Le niveau de concordance entre lecteurs avec l'O-RADS US était comparable aux règles simples du GI-RADS (Gynecologic Imaging Reporting and Data System), le système de données et de rapports d'imagerie en gynécologie, d'ADNEX (Assessment of Different Neoplasias in the adnexa) pour l'évaluation des différentes néoplasies des annexes et d'IOTA (International Tumor Analysis Group), le groupe international d'analyse des tumeurs. Il a été démontré que les descripteurs du système sont en corrélation avec les taux attendus de malignité et les performances du système de stratification du risque de l'O-RADS US se sont avérées être dans la plage attendue du risque de malignité par catégorie.

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D'autres consignes se concentreront sur la clarification des concepts clés et de la terminologie du lexique, ainsi que sur un affinement plus poussé des catégories de stratification du risque sur la base de données publiées dans des études de validation.

## Introduction to O-RADS Ultrasound: Genesis and Structure

The Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon for ultrasound (US) was published in 2018 and provides a standardized reporting framework and definitions of the US appearance of normal ovaries as well as ovarian and other adnexal lesions.[1] This work was a response to the need for a universally recognized standard reporting vocabulary for ovarian and adnexal pathology that was specific, clinically useful, and inclusive of relevant morphologic descriptors and definitions that are supported by evidence in determining risk of malignancy (ROM). A 2020 paper from the group outlined the risk stratification categories and corresponding ROM and management recommendations.[2] This system represents a collaborative effort of an international group of experts both in gynecologic imaging and clinical practice, with the ultimate goal of providing a harmonized approach to reporting and managing patients based on imaging findings.

The three main components of the O-RADS system include the lexicon terms, O-RADS risk categories, and suggested management.

### Lexicon

Prior to O-RADS US, Timmerman et al,[3] as part of International Tumor Analysis Group (IOTA), published a group of terms, measurement techniques, and definitions for characterizing adnexal masses. These terms led to the evidence-based vocabulary implemented in the "Simple Rules" based on 10 specific ultrasound features, and the "IOTA ADNEX" model, which is the preferred IOTA group mathematical model to differentiate malignant from benign adnexal masses.[4-6] During the genesis of O-RADS US, the IOTA group US descriptors

were felt to be the most robust and evidence-based terms available, and the phrases "unilocular cyst ± solid components," "multilocular cyst ± solid components," and "mostly solid" were incorporated as the scaffolding for the major categories of adnexal lesions in O-RADS. These categories are further divided based on additional grayscale features, lesion size and/or color Doppler characteristics.

### O-RADS Risk Assessment Categories

There are 6 O-RADS US risk stratification categories, 0 for the technically inadequate exam and 1–5, which range from normal to high risk of malignancy (Table 1).[2] These categories harmonize the pattern-based approach commonly used in North America with the statistics used in the IOTA models and are based on malignancy prevalence identified from IOTA phase 1–3 studies, which included almost 6000 patients with pathologically proven adnexal lesions.[4,7,8] By design, the O-RADS US terms were matched with the most predictive descriptors in the IOTA data, placed within risk categories, and tied to management recommendations. The goal of this standardized approach was to optimize management of higher risk lesions by the gynecologic-oncologist and enable conservative management for non-neoplastic findings and those lesions with a lower probability of malignancy. O-RADS descriptors and risk assessment categories are designed to be applied to all lesions incorporated in the IOTA 1-3 studies including high-risk and symptomatic patients, although management recommendations in these patients may differ. Since the system includes a general population with a low prevalence of malignancy, O-RADS US optimizes sensitivity at the expense of specificity to avoid false negatives results and missing ovarian cancer, an often-lethal disease.

**Table 1.** Ovarian-Adnexal Reporting and Data System for Ultrasound assessment categories and risk of malignancy.

| Category | Assessment | Risk of Malignancy (%) |
|---|---|---|
| 0 | Incomplete | NA |
| 1 | Normal, physiologic | 0 |
| 2 | Almost certainly benign | <1 |
| 3 | Low risk | 1 to <10 |
| 4 | Intermediate risk | 10 to <50 |
| 5 | High risk | ≥50 |

Modified from Strachowski LM, Jha P, Chawla TP et al. O-RADS for Ultrasound: A User's Guide, From the *AJR* Special Series on Radiology Reporting and Data Systems. AJR Am J Roentgenol. 2021 May; 216 (5):1150-1165.[9]
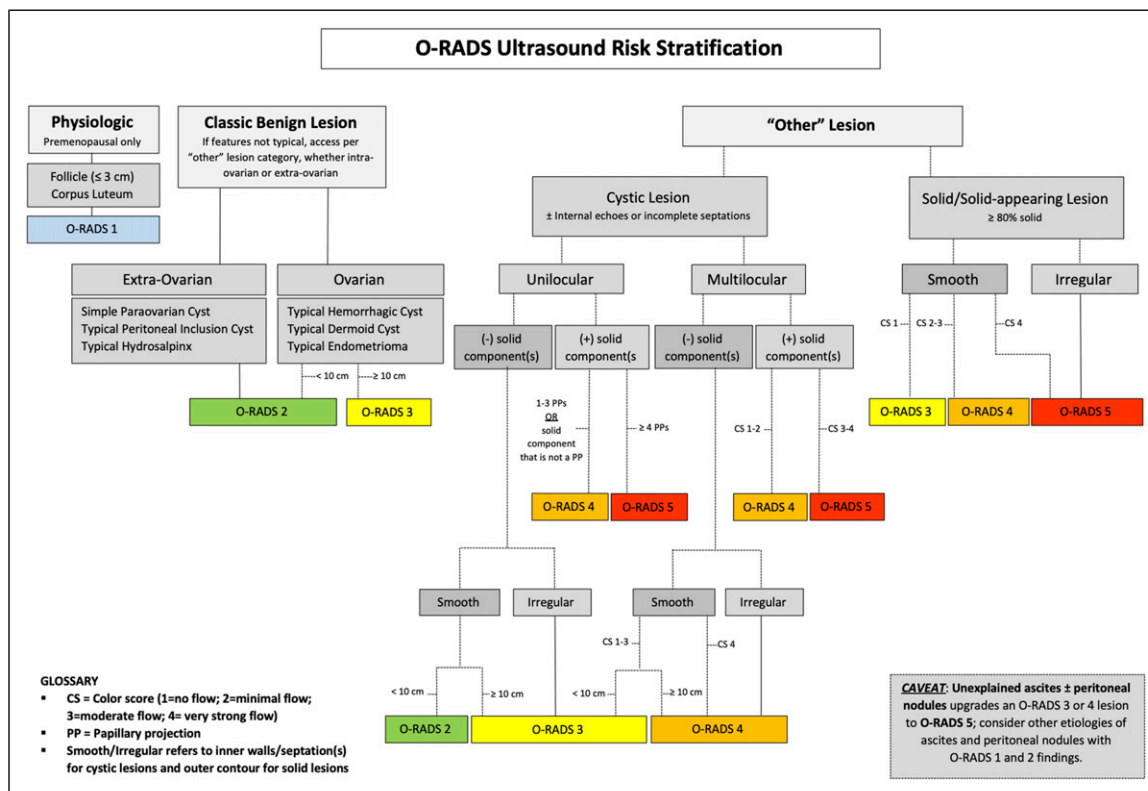
**Figure 1.** Streamlined American College of Radiology Ovarian-Adnexal Reporting and Data System (O-RADS) risk stratification algorithm, differentiating physiologic and classic benign lesions from non-physiologic, non-classically benign solid and cystic lesions.

Appropriate risk categorization of a finding is reliant on accurate recognition of lesion-specific features and proper use of lexicon terminology. Normal physiologic findings, including follicle and corpus luteum, are applicable to premenopausal women only. If a finding is not physiologic or the patient is postmenopausal, the next step is to determine whether lesion characteristics are consistent with typical features of one of the classic benign lesions including hemorrhagic cyst, dermoid cyst, endometrioma, paraovarian cyst, hydrosalpinx, or peritoneal inclusion cyst. If so, risk assessment is complete and menopausal status and lesion size are taken into consideration to determine management. If a finding is not physiologic nor a typical classic benign lesion, the lesion is placed into one of 5 subcategories:

1. Unilocular cyst without solid component
2. Unilocular cyst with solid component
3. Multilocular cyst without solid component
4. Multilocular cyst with solid component
5. Solid or solid-appearing lesion.

Unexplained ascites and peritoneal nodules should be considered before assigning a risk category as these findings may upgrade a lesion. Resources including a user's guide,[9] ACR color-coded scorecards, and O-RADS US smartphone app streamline O-RADS US categorization and subsequent management decisions in daily clinical practice. New schematics have been proposed to facilitate stratification (Figure 1).

## Suggested Management

The O-RADS US classification system is designed to assist health care providers in differentiating lesions that require no or conservative follow-up (sometimes necessitating the use of an ultrasound specialist or MRI study), from those lesions that require gynecologic or gynecologic-oncologic supervision ± surgical intervention. The proposed management strategies are a result of ACR O-RADS US committee members' consensus based on literature and expert opinion. There are a variety of management strategies in the O-RADS US 2 category (almost certainly benign), which occasionally depend upon lesion size and menopausal status, with post-menopause status defined as ≥ 1 year without menses (Tables 2 and 3). When menopausal status is uncertain, the postmenopausal management strategy should be the default recommendation. In O-RADS US categories 3–5 (low to high-risk groups), there is a single management recommendation for each group that is independent of menopausal status. Currently, O-RADS US is the only lexicon and classification system that includes all risk assessment categories and their associated management schemes.

**Table 2.** American College of Radiology Ovarian-Adnexal Reporting and Data System (O-RADS) Ultrasound Risk Stratification and Management System. Chart shows color-coded management scheme for O-RADS assessment categories, associated descriptions and management recommendations based on menopausal status when relevant.[2]

| 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 table on next page for descriptors and 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 (simple or non-simple) ≥ 10 cm | | US specialist or MRI Management by gynecologist | |
| | | Typical dermoid cysts, endometriomas, hemorrhagic cysts ≥ 10 cm | | | |
| | | Unilocular cyst, with irregular inner wall (<3 mm height), any size | | | |
| | | Multilocular cyst with smooth inner walls/septations, < 10 cm, CS = 1-3 | | | |
| | | Solid lesion with smooth outer contour, any size, CS = 1 | | | |
| 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 | | |
| 5 | High Risk [≥ 50%] | Unilocular cyst, ≥ 4 papillary projections, any size, CS = any | | Gyn-oncologist | |
| | | Multilocular cyst with solid component, any size, CS = 3-4 | | | |
| | | Solid lesion with smooth outer contour, any size, CS = 4 | | | |
| | | Solid lesion with irregular outer contour, any size, CS = any | | | |
| | | Ascites and/or peritoneal nodules** | | | |

[a]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 the optimal duration or interval of timing for surveillance.
[b]Presence of ascites with category 1-2 lesion, must consider other malignant or non-malignant etiologies of ascites.
CS = color score, GYN = gynecologic, IOTA = International Ovarian Tumor Analysis, N/A = not applicable. This has been reprinted with permission and without adaptation from the American College of Radiology.

**Table 3.** American College of Radiology Ovarian-Adnexal Reporting and Data System (O-RADS) lexicon descriptors and management recommendations for classic benign lesions.[2]

| Lexicon Descriptor | Definition | Management | |
|---|---|---|---|
| | | Premenopausal | 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 than be considered* MRI if there is enlargement changing morphology or a developing vascular component |
| Typical endometriomas < 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 |

*There is currently a paucity of evidence for defining the optimal duration or interval of timing for surveillance. Evidence does support an increasing risk of malignancy in endometriomas following menopause.
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## Response and Validation

### Response

The publication of the O-RADS US risk stratification and management system in 2020 prompted much discussion. In a letter to *Radiology*, Suh-Burgmann et al[10] raised reservations regarding the recommendation to use MRI for evaluation of low to intermediate risk masses, questioned the omission of repeat US as a management option for O-RADS 3 and 4 lesions, and sought to clarify the definition of low cancer risk and revisit the population from which O-RADS was developed. In their response, Andreotti et al clarified that the O-RADS US system does not advocate MRI use over US but endorses a conservative approach using US and the selective use of MRI to avoid unnecessary surgical procedures and improve preoperative triage to

gynecologists vs gynecologic oncologists. They acknowledged that repeat US is ideal for transient or benign lesions, however surveillance is not a specific recommendation for low risk (O-RADS 3) or moderate risk (O-RADS 4) categories because these lesions have features deemed unlikely to be transient or benign. The group clarified that O-RADS risk assessment is not related to a patient's lifetime risk of malignancy, but risk of malignancy based on lesion characteristics. They also emphasized that half of the IOTA project study subjects were not high-risk referral populations, and thus, O-RADS was developed for patients at high and average risk.

Since this response however, adding US follow-up as a management option is now being considered due to recent validations that have demonstrated some low risk (O-RADS 3) lesions at the lower range of the 1–10% risk category[11-14] when applied to the general population. This lower risk may

**Table 4.** Summary of Ovarian-Adnexal Reporting and Data System ultrasound Validation Literature.

|  | | | | Manuscripts | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| variables | Cao[11] | Pi[15] | Zhou[22] | Lai[12] | Basha[19] | Hiet[20] | Guo[13] | Jha[14] | Hack[17] |
| Authors | Sonologists | Abdominal Radiologists with US experience | Sonologists | Sonologists trained residents | Radiologists with pelvic imaging experience | MFM Sonologists IOTA certified | Sonologists | Abdominal Radiologists with US experience | Radiologists with GYN US experience |
| Sample size | 1054<br><br>750 benign and 304 malignant | 50<br><br>(+30 training cases) | 100<br><br>52 benign, 48 malignant | 734<br><br>564 benign, 69 borderline, 101 malignant | 647<br><br>469 benign 178 malignant | 150<br><br>23 Benign 40 Malignant | 25<br><br>23 Benign 2 Malignant | 1014<br><br>930 benign 84 Malignant | 262<br><br>187 benign 75 Malignant |
| Number of readers | 2 first year residents reviewed all 1054 cases. Third expert radiologist reviewed 200 randomly chosen cases | 3 Abdominal fellowship trained board cert radiologists with 6-30+years US experience | 2 experienced trainers (10+years experience) 46 trainees (26 level I practitioners, 17 level II and II experienced leve II) | 2 Residents, trained by sonologists with 20 lesions/ day x 10 days prior to the study | 5 Radiologists with 15+ years experience in pelvic imaging | 2 sonologists with 25+ years US experience | 2 sonologists with 10+ years experience | 8 Abdominal fellowship trained radiologists with 1-20 years experience | 2 subspeciality Radiologists with 9-30 yrs experience |
| Malignancy rate (2,3,4 & 5) | .45%, 1.10%, 34.46%, and 89.57% | NA | NA | 1.4%, 4.4%, 58%, and 94.5% | .4%, 2.8%, 30.6%, and 95.3% | 0, 0, 21%, and 78.8% | 0, 0, 4%, 4% | .5%, 4.5%, 11.6%, and 65.6% | 0, 3%, 35%, and 78% |
| Optimal cut off value | O-RADS 3 Sn of 98.7% Sp of 83.2% AUC=.96 | O-RADS 4 and 5 Sn of 72-100% Sp of 92-100% NPV of 92-100% PPV of 66-100% AUC of .94-.98 *for 3 readers | NA | O-RADS 4 and 5 Sn of 88% (ADNEX, 95%) PPV of 98% (ADNEX, 96%) AUV of .91, similar to GI-RADS and ADNEX | O-RADS 4 and 5 Sn of 96.6% SP of 92.8% PPV of 83.5% NPV of 98.6% | O-RADS 4 Sn of 100% SP of 46.4% | O-RADS 4 and 5 Sn of 100% SP of 32% | O-RADS 4 Sn of 90.6% SP of 81.9% PPV of 31.4% NPV of 99.0% AUC of .92 (95% CI: .89-.95, P<.001) | O-RADS 4<br><br>Sn of 99% SP of 70% |
| Inter-observer agreement | Good (K = .714) between first year consensus and the experts in evaluating 200 lesions | Very good (k = .82) inter-reader agreement for all 3 readers Very good (k = .86-.92) Pair-wise agreement between readers | The trainer inter-rater agreement was .95. No significant difference between groups 1, 2 and 3 | Very good (k = .830), similar to GI-RADS (821) and ADNEX (.861) | Good (k = .77), similar to GI-RADS (k = .69) and IOTA (k = .63) | NA | NA | Alomost perfect: .81 for assessment of lesion type, .90 for presence of solid components, and .90 for the presence of vascularity. Substantial agreement: .70 for assessment of presence of septations, .68 for the number of septations, .71 for the number contour of solid components, and .74 for the assessment of color score | Almost perfect: .99 |
| Main findings | O-RADS providers effective malignancy risk stratification for adnexal lesions with high reliability for radiologists with different experience | Excellent diagnostic accuracy and high inter-reader reliability can be achieved with independent guideline and case-based review | After training, junior doctors at different levels can reach a coincident O-RADS US risk stratification, No improvement in the learning curve with 5 tests | No significant difference among the 3 systems. O-RADS had a higher PPV than ADNEX | O-RADS had higher sensitivity than GI-RADS and IOTA simple rules with relatively similar specificity and reliability. Among 3, O-RADS performed the best | The IOTA SR, SRR assessment and ADNEX models and O-RADS have similar sensitivity in the preoperative discrimination of malignant and benign pelvic tumors; however, the IOTA models have higher specificity | The O-RADS system was able to detect malignant tumors in this series of collision tumors | O-RADS US risk stratification system performs within the expected range as published by the ACR O-RADS US commitee. The frequency of malignancy is at the lower end of the published range | O-RADS US risk stratification system accurately distinguished benign from malignant lesions. Adding acoustic shadowing as a descriptor improved diagnostic performance |

make surveillance of some O-RADS 3 lesions a reasonable option over surgery.

In another letter, Wilson et al raised the point that solid hypoechoic lesions with acoustic shadowing, which typically represent fibromas or pediculated/broad ligament fibroids, warrant a separate category and an MRI recommendation in the O-RADS US risk assessment and management system. Their concern was that these benign lesions would be classified as O-RADS US 3 at a minimum, and more likely O-RADS US 4 or 5 with referral to a gynecologic-oncologist.[15] In response, Andreotti et al acknowledged that omitting separate categories of solid/solid-appearing lesions with acoustic shadowing would result in a higher O-RADS US score, however only in a limited few. They felt improved sensitivity was prudent, and that most of these lesions would be classified as O-RADS US 3/4 leading to an accurate diagnosis by an US specialist or at MRI, while an O-RADS US 5 categorization would be rare. Appropriate risk reduction may also be obtained by using the IOTA ADNEX mathematical model, the alternative approach to O-RADS US risk assessment.[2,5]

## Validation

Strong interest in the O-RADS US system prompted quick validation. Follow-up studies have evaluated the diagnostic performance including area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), inter-reader agreement and comparison with other existing classification systems including IOTA simple rules, Gynecologic Imaging Reporting and Data System (GI-RADS), and Assessment of Different Neoplasias in the adnexa (ADNEX) systems (Table 4).

*Diagnostic accuracy.* The reported diagnostic accuracy of O-RADS US was generally excellent with the AUC ranging from .91 to .98,[11,12,14,16,17] with a single study reporting only fair accuracy at .73.[18] Lai et al[12] reported similar excellent diagnostic accuracy of O-RADS (.91) compared to GI-RADS (.91) and ADNEX (.90). Basha et al[19] found that O-RADS had a significantly higher AUC (.98) compared to GI-RADS (.97) and IOTA simple rules (.94) and performed the best among the three systems. Hack et al[17] found similar AUCs for O-RADS and ADNEX, .91 and .95, respectively.

Among nine published studies, two (22.2%) used O-RADS 3 and above as the optimal cut-off for detecting ovarian cancer,[11,18] while seven (77.8%) considered O-RADS 4 and above as the optimal cut off.[12-14,16,17,19,20] Basha et al reported a similar malignancy rate for each O-RADS category when assessing 647 lesions (27.5% malignant, 178/647). Cao et al assessed the diagnostic performance of O-RADS US in 1054 adnexal masses (28.8% malignant, 304/1054). They found that the malignancy rate in each category was comparable to that predicted by the O-RADS US system, though the malignancy rate for the O-RADS 3 category was in the lower end of the malignancy range at 1.1%.[11] Jha et al's[14] cohort of 1014 adnexal lesions with a malignancy rate of 8.4% (85/1014) also found that the

malignancy rate in each category was comparable to the predicted risk, although O-RADS 4 lesions were at the lower limit of the category at 11.6%. Smaller cohort studies have reported similar low malignancy rates for the O-RADS 3 category including Basha et al at 2.8% (5/179 O-RADS 3 malignant; overall malignancy rate of 27.5%), Hiett et al at 0% (0/40 O-RADS 3 malignant; overall malignancy rate of 26.7%), and Guo et al at 0% (0/2 O-RADS 3 malignant; overall malignancy rate of 8%).[13,19,20]

*Sensitivity, specificity, positive predictive value and negative predictive value.* The reported sensitivity of O-RADS US ranged from 72% to 100%,[13,16] except for one study with a reported sensitivity of 52%.[18] The specificity ranged from 81.9% to 100%,[14,16] except for 1 study that reported 46.4%[20] and another that reported 32%.[13] Basha et al[19] found that O-RADS US had significantly higher sensitivity (96.8%) than GI-RADS (92.7%) and IOTA simple rules (92.1%), with non-significant, slightly lower specificity (92.8% vs 93.6% vs 93.2%). Cao and Jha et al reported relatively lower specificity of 83.2% and 81.9%, respectively, compared to their sensitivity of 98.7% and 90.6%, respectively.[11,14] Cao proposed a sub-classification method by further dividing the O-RADS 4 lesions into 4A and 4B subgroups, which may potentially improve the specificity.[11] Hiett et al[20] found similar sensitivity among IOTA simple rules (SR), simple rules risk (SRR) assessment and ADNEX model, while the IOTA models had higher specificity (63.6% for ADNEX and 51.8% for SRR model) than O-RADS (46.4%). Other studies also reported a higher PPV of O-RADS (.96) than ADNEX (.96).[12] NPV for O-RADS US has been very high, ranging from 98.6 to 99.3.[11,14,19]

*Inter-reader agreement.* Several studies have demonstrated that the inter-reader agreement of O-RADS US is similar to GI-RADS, ADNEX, and IOTA simple rules.[12,19] Some have shown substantial agreement in O-RADS US assessments regardless of clinical practice experience, including when a first-year radiology resident was compared to an expert radiologist with 9 years' experience in gynecological US ($\kappa$ = .714)[11] and between cohorts of expert radiologists with over 15 years of experience in pelvic imaging ($\kappa$ = .77).[19] Other studies showed very good/almost perfect agreement when abdominal fellowship trained, board certified radiologists with 6–30+ years of ultrasound experience were compared ($\kappa$ = .82-.99),[16,17,21] when two resident sonologists with 5 years' experience were compared ($\kappa$ = .83),[12] and between two experienced radiologists with over 10 years of gynecological US experience ($\kappa$ = .95).[22] The inter-reader agreement of O-RADS US was similar to GI-RADS, ADNEX, and IOTA.[12,19] Overall, existing studies have validated the ability of radiologists to use O-RADS US, regardless of their level of training and practice experience.

It is worth noting that most studies contained a training phase to ensure the participants' knowledge and familiarity with O-RADS US and the other systems when included. Nevertheless, Pi et al[16] found that O-RADS US was an effective stratification tool for radiologists with high inter-reader

reliability, even without specific training. These findings are similar to those of Zhou et al[22] who studied the learning curve for O-RADS US amongst 3 groups of 54 trainees with varying levels of experience, including residents, first year attendings and experienced attendings. After initial training by senior doctors with 10+ years' experience, no improvement was observed among the three groups on the between subjects' effects tests.

Jha's et al showed almost perfect agreement using Fleiss's multirater kappa for assessment of lesion type ($\kappa = .81$), presence of solid components ($\kappa = .90$), and presence of vascularity ($\kappa = .90$) with substantial agreement for assessment of presence of septations ($\kappa = .70$), the number of septations ($\kappa = .68$), the number and contour of solid components ($\kappa = .71$), and the assessment of color score ($\kappa = .74$).[14] There was moderate inter-reader agreement for the type of septation ($\kappa = .56$). Large scale multi-institution, multi-reader studies are being undertaken to study the inter reader performance in varying settings.

*Lexicon descriptors, false positive, and false negative cases.* Multiple validation studies addressed the use of specific descriptors and their accuracy in differentiating benign and malignant lesions. Cao et al found that system descriptors (category, size, contour, color, and ascites) correlated with malignancy ($P < .05$), and slight discrepancy in subjective evaluation did not change final O-RADS US score. In their study, only 1 in 34 (2.9%) masses with acoustic shadowing was malignant, suggesting that acoustic shadows could be a key feature in differentiating benign and malignant tumors especially in solid lesions. They also found that the category 4 lesions of "multilocular cyst, no solid component" and "smooth solid lesions" have lower risks of malignancy when compared to "other cystic lesions with solid components" in category 4.[11] Lai et al[12] reported that among the false positive cases, multilocular cystic lesions with no solid component and largest diameter >10 cm were the most common subtype (33 out of 65). Hiett et al[20] reported the most common false positive lesions were benign mucinous and serous cystadenomas. The other reported common errors were related to assessment of classic benign lesions, color score and solid-appearing masses.

## Future Directions

With the data from the IOTA 5 study and validation papers published following the release of the O-RADS US risk stratification system, future iterations of O-RADS US will seek to clarify the governing concepts and lexicon terminology, as well as refine risk stratification categories.

### Governing Concepts

Clarification of O-RADS US governing concepts is underway. The definition of an ultrasound specialist has gathered interest and the committee plans to revisit and provide additional guidance on this designation. Potential qualifications of an US



**Figure 2.** Transvaginal grayscale ultrasound (US) of the right adnexa in a 32-year-old woman demonstrating an incidental homogeneously echogenic mass with posterior acoustic shadowing. Sonographic appearance is typical for a dermoid cyst, O-RADS US 2.
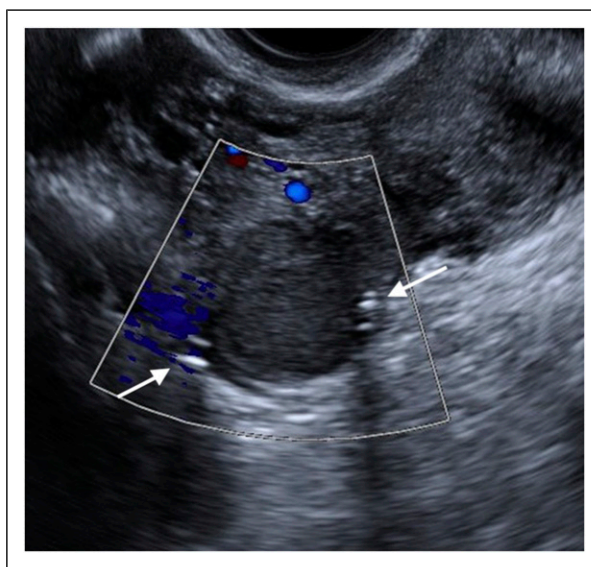


**Figure 3.** Transvaginal color Doppler US from a 38-year-old woman with infertility shows a unilocular right ovarian cyst containing homogeneous low level internal echoes and peripheral punctate echogenic foci (arrows). No internal flow was seen on color Doppler. Sonographic appearance is consistent with an endometrioma, O-RADS US 2.

specialist could be one who has sufficient experience with adnexal pathology to improve the likelihood of accurate characterization, and who participates in ongoing quality assurance programs including continued medical education in accordance with current guidelines in one's local practice. Fellowship training, including a curriculum dedicated to ultrasound of adnexal lesions, is another possible benchmark that could be clearly defined with pathways for achievement.

Further clarification of the governing concepts may emphasize that lexicon terminology and lesion categorization still apply
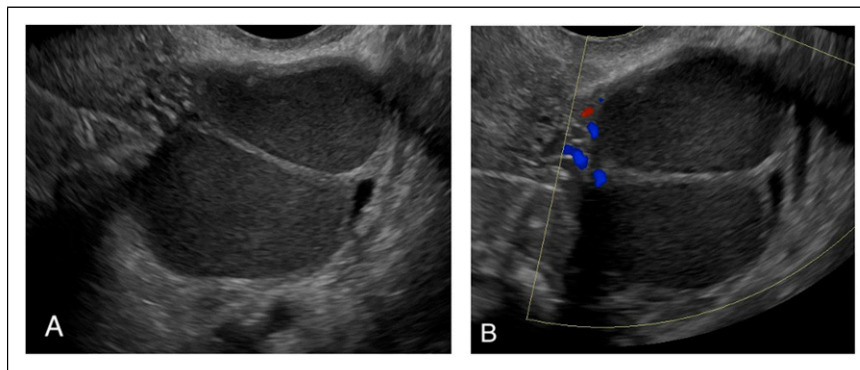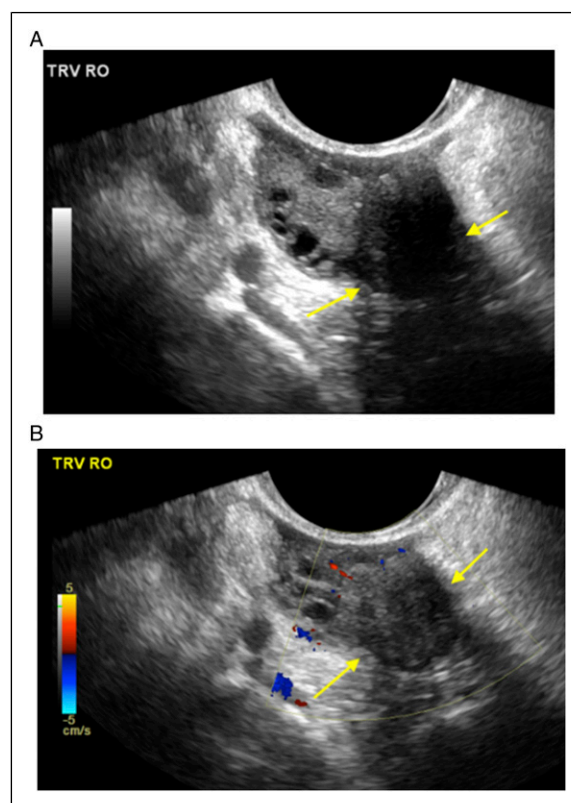
**Figure 4.** Transvaginal grayscale (A) and color Doppler (B) US images demonstrating a left ovarian multilocular cyst with homogeneous low level internal echoes, smooth inner walls, and no internal vascularity in 48-year-old woman with chronic pelvic pain. Maximum size measured less than 10 cm. Sonographic appearance is consistent with a multilocular endometrioma, O-RADS US 2.

to patients with acute symptoms and to patients at higher-than-average risk for ovarian cancer although management may vary from that proposed by O-RADS US management system. Updates may also incorporate guidance for management of multiple or bilateral lesions with different risks of malignancy, particularly when management of one lesion is independent of the other. Additionally, it may be helpful to clarify categorization pathways when a lesion is not definitively tubal or ovarian in origin, that is, is suspected to arise from the broad ligament, appendix, etc., but is located within the adnexa.

## Lexicon

Lexicon clarification addressing descriptors for O-RADS US 1 and 2 lesions is expected shortly as part of a system update. The use of additional descriptors for dermoid cysts, hemorrhagic cysts, and endometriomas will be addressed based on need for further instruction established by validations studies.[23] This would provide greater consistency with the more subjective approach of the IOTA group. For example, typical features of a dermoid cyst in the present version do not include those commonly encountered in clinical practice including fat-fluid levels and the completely hyperechoic lesion with posterior acoustic shadowing (Figure 2). Although represented in figures within the O-RADS US risk stratification and management publication,[2] the current lexicon terminology for typical features of an endometrioma do not include punctate echogenic mural foci (Figure 3) and multiloculated components (Figure 4), common features of benign endometriomas. Additionally, further clarification that hemorrhagic cysts are unilocular and avascular, regardless of an internal reticular pattern and/or retractile clot, would be instructive.

There has also been discussion that size should not be one of the defining criteria for a physiologic corpus luteum (CL) when the appearance is characteristic. While a CL is typically less than or equal to 3 cm, the current maximum dimension allowed in the physiologic (O-RADS US 1) category, it occasionally is slightly larger than 3 cm. The committee plans to
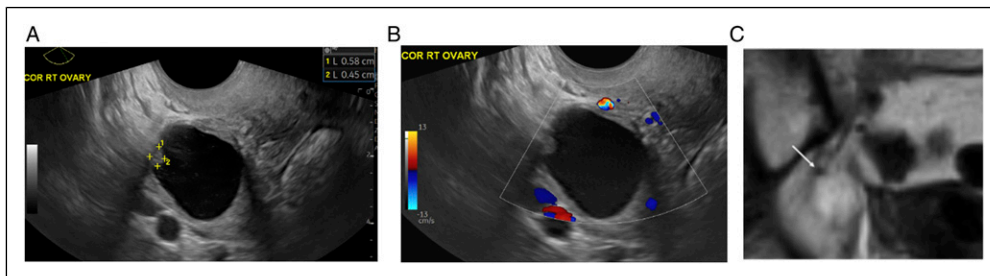


**Figure 5.** Transvaginal grayscale (A) and color Doppler (B) US images of a 29-year-old woman showing an incidental 1.7 cm right adnexal solid hypoechoic mass (arrows) with smooth outer contour, posterior acoustic shadowing and no internal flow. This lesion was felt to represent a fibroma and was managed with surveillance. It remained stable in size and appearance on 1 year follow-up.

clarify this definition considering feedback from experts who feel obligated to categorize a classic CL measuring >3 cm as an O-RADS US 2 or higher lesion under the current risk assessment system.
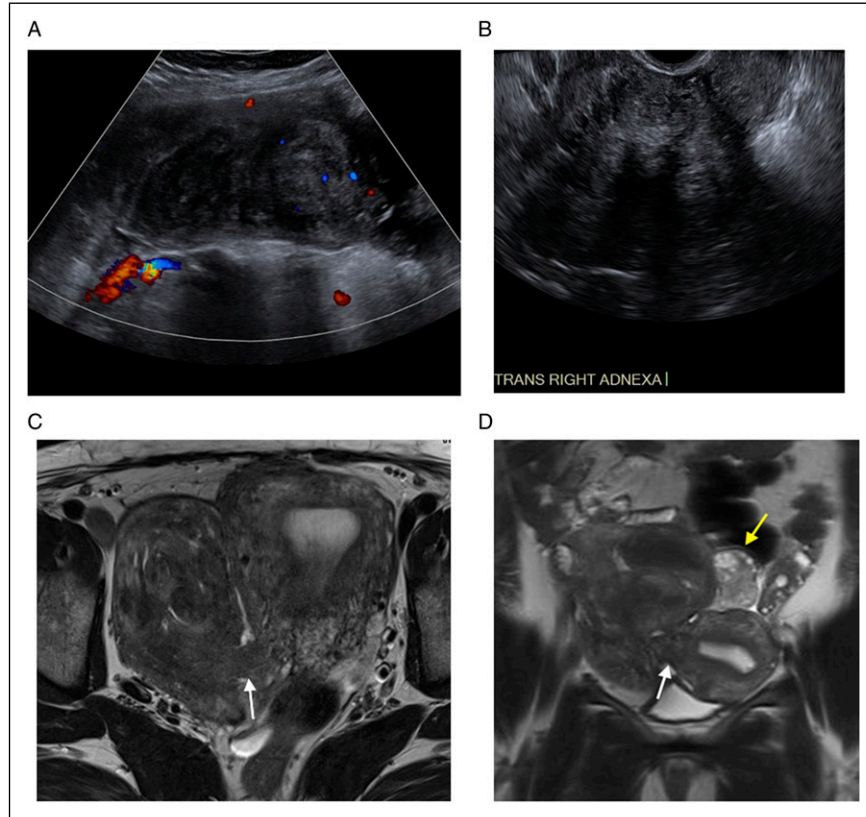
**Figure 6.** Transabdominal US (A) shows a heterogeneously hypoechoic solid lesion with smooth outer contour in the right adnexa of a 39-year-old woman with a palpable mass. Minimal flow on color Doppler and posterior acoustic shadowing is seen on transvaginal US (B). As neither a right ovary nor connection to the uterus was identified, this was presumed ovarian and given an O-RADS US 4. Axial (C) and coronal (D) T2 MRI images show the lesion is heterogeneously isointense with a band of connecting tissue to the right lower uterine segment (white arrow). The right ovary (yellow arrow) is seen medially displaced, confirming the lesion is an exophytic fibroid.



**Figure 7.** Transvaginal grayscale (A) and color Doppler (B) US images in a 68-year-old woman show a right ovarian unilocular cyst with a single 6 mm papillary projection and no internal flow, O-RADS US 4. Coronal T2-weighted MRI (C) shows a unilocular right ovarian cyst with a tiny 4 mm homogeneously T2 hypointense nodule (arrow). Axial high b-value (b = 1000 sec/mm$^2$) diffusion weighted image (DWI) (D) demonstrates the tiny mural nodule to be homogeneously hypointense (arrow), O-RADS MRI 2. Pathology showed a benign serous cystadenofibroma.

Further refining the definition of typical hydrosalpinx may be considered to bring O-RADS US in line with O-RADS MRI. Currently, O-RADS US defines a typical hydrosalpinx by features of incomplete septations, tubular configuration, and endosalpingeal folds,[2] with no stratification based on internal contents. In contrast, O-RADS MRI places the dilated fallopian tube containing simple fluid into O-RADS MRI 2 category with PPV for malignancy of .5% and dilated fallopian tubes containing non-simple fluid into O-RADS MRI 3 category with a PPV for malignancy of ~5%.[24]
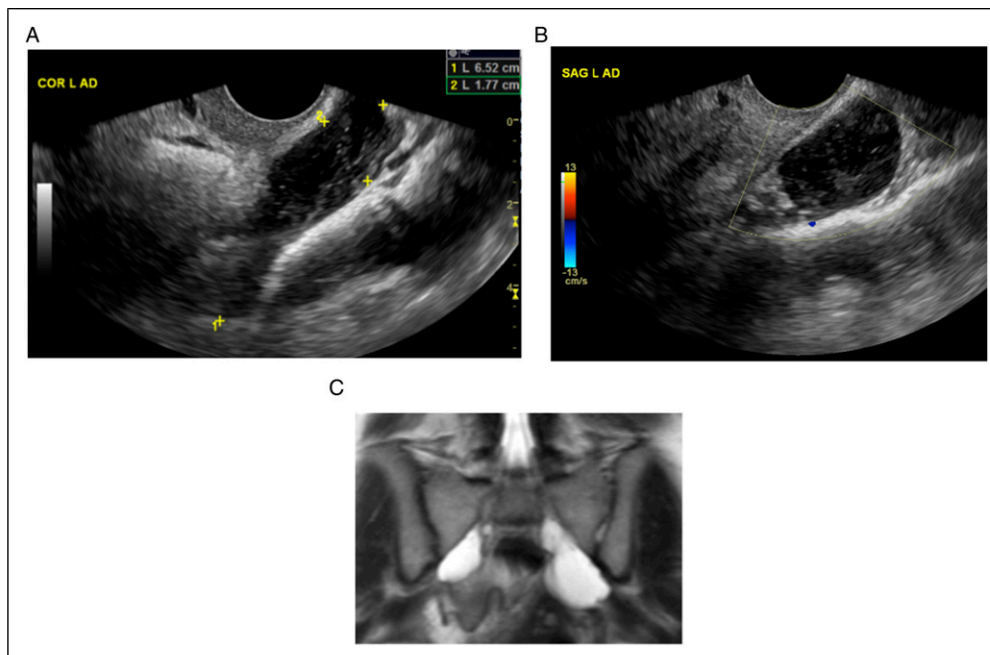
**Figure 8.** 52-year-old woman presenting with bloating, enlarging uterus, and abnormal bleeding. Transvaginal grayscale (A) and color Doppler (B) US images from the left adnexa demonstrate an avascular, multilocular cystic lesion with irregular septations measuring <10 cm. A normal left and right ovary as well as a similar appearing right adnexal lesion were identified (not shown). Given their elongated appearance, tubal pathology was suspected (O-RADS US 4) and MRI was performed for further characterization. Coronal T2-weighted MRI (C) demonstrates bilateral, left larger than right, homogeneously hyperintense unilocular cystic structures arising from the neural foramina, consistent with Tarlov cysts.

## Risk Stratification and Management System

Based on the current literature and consensus, the committee will assess if the evidence supports O-RADS US risk stratification modification in terms of malignancy risk and diagnostic performance. This will include reassessing the current O-RADS US categories and their content as well as management recommendations. Updated data from the IOTA 5 study, the largest multicenter prospective cohort study including patients selected for surgical procedures and conservative management, will affect the scope of these changes. When published, this data will be used in conjunction with other validation studies to identify features that may alter the risk category.

For instance, a recently published validation from a tertiary referral oncology center supported the use of acoustic shadowing as a benign finding that improved the diagnostic accuracy from .91 to .94, P = .01.[17] Another validation study has shown that a solid lesion with acoustic shadowing (O-RADS 4 or 5 depending on the outer contour) was often a benign fibrous tumor rather than malignancy.[11] These studies suggest that shadowing could be a feature to differentiate solid benign from malignant lesions and a potential "downgrading feature," especially for smooth solid lesions (Figures 5 and 6). Cao et al[11] also found that there was a lower risk of malignancy for the O-RADS US 4 lesions of "multilocular cyst, no solid components" and "smooth solid lesion" compared to the other O-RADS US 4 intermediate risk lesions, suggesting that a subcategorization of O-RADS US 4 (4A and 4B) with potentially different management guidelines is in order to improve specificity of this category.

The committee may also re-evaluate the management of a cyst with a smooth inner walls and single thin septation, also known as a "bilocular cyst." If less than 10 cm, the current O-RADS US system categorizes these lesions as multilocular, O-RADS 3, because the IOTA data which was used to determine O-RADS US risk stratification, did not differentiate between 1 or more septations. Management of such lesions differs from that proposed by the SRU consensus, which suggests the same management for bilocular cysts and simple cysts.[25] In practice, management of a bilocular cyst using O-RADS US includes further characterization by an US specialist or with an MRI study, which would likely support the same conclusion of a benign cyst. Therefore, the committee could consider harmonizing this management with SRU to eliminate the need for additional characterization.

## O-RADS MRI

While US is the first-line imaging modality for adnexal lesions, MRI has an important role as a problem-solving tool in O-RADS US categories 3, 4, and occasionally 2. MRI can depict the enhancement pattern of solid tissue and diagnose or
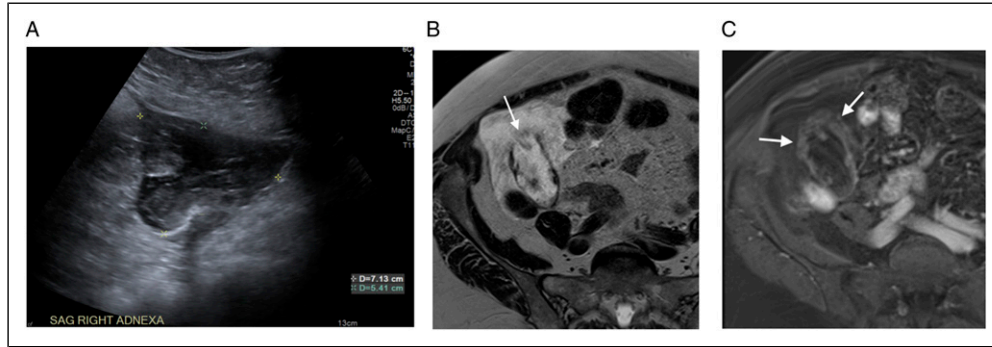
**Figure 9.** 68-year-old woman presenting for follow-up of a right adnexal cyst seen at an outside institution. Transabdominal grayscale US (A) of the right adnexa demonstrates a cystic lesion separate from the right ovary (not shown). As not suspected to be ovarian or tubal, MRI was performed to determine the origin of this lesion. Axial T2-weighted MRI (B) demonstrates a right adnexal hyperintense cystic structure arising from a dilated appendix, which is discontinuous (arrow). Post-contrast axial T1 fat-saturated MRI (C) shows the enhancing walls of the appendix to be irregular and thickened (arrows). Pathology revealed a low-grade mucinous neoplasm of the appendix.

exclude malignancy with a high positive predictive value (71% vs 50% with US) and very high negative predictive value (98% vs 99% with US).[14,26] More specific diagnoses by MRI may reduce the level of suspicion and decrease the number of unnecessary surgeries performed for benign diagnoses in asymptomatic women.[27-30] Recently, the ACR O-RADS MRI Committee published a lexicon and risk stratification systems for adnexal lesions with additional publications providing guidance for using O-RADS MRI risk stratification system in clinical practice.[27,31-33]

The O-RADS MRI system is based on a lexicon and robust clinical data, which aid in characterizing lesions into O-RADS MRI 1-5 categories with risk of malignancy ranging from 0 to ~90%,[3,29] compared to O-RADS US 0 to ≥50%.[2] Similar to O-RADS US, by describing the stepwise algorithmic approach to lesion evaluation and incorporating methods used by experts, O-RADS MRI enables general radiologist to perform similarly to subspecialty radiologists. This has been tested in a prospective multicenter clinical trial, which demonstrated good reproducibility between expert and nonexpert readers.[26] Currently, no management strategies are provided although clinical triage could be performed according to the O-RADS US risk assessment categories. Clinically, MRI can be helpful for O-RADS US 0 lesions when US evaluation is technically inadequate and repeat US is unlikely to result in sufficient characterization. It can also be utilized to further characterize O-RADS US 3 and 4 low to intermediate risk lesions. This is particularly useful when patients are poor surgical candidates or in patients wishing to preserve fertility. If MRI downgrades the lesion, these patients can be treated with surveillance or undergo less extensive surgery (Figure 7). MRI also provides more comprehensive evaluation of the pelvis and enables radiologists to confidentially identify the site of origin of a pelvic mass (Figures 8 and 9). In one study, MRI correctly reclassified the origin of presumed adnexal lesions in up to 10% of cases.[27]

## Future Research Directions

Although several validation studies[11-14,16,17,19,20] have assessed the diagnostic accuracy and interobserver variability of the O-RADS US risk stratification system, these were retrospective and therefore subject to patient selection bias as indicated by the high prevalence of cancers in some studies.[19,22] A prospective multi-center trial is needed to further validate the diagnostic performance and accurately measure the impact of the O-RADS US risk stratification system on patient management in various clinical settings. Additional research is required to better define the categories/subcategories where O-RADS MRI can add the most value due to its superior PPV/NPV, with the goal to avoid unnecessary and over extensive surgery for benign or borderline lesions, while expeditiously referring patients with a high likelihood of malignancy for gynecologic oncological consultation. Similar to other RADS classification systems, O-RADS US will undoubtedly evolve as additional evidence becomes available in the peer-reviewed literature, allowing for iterative and continual refinement of the system.

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