

ACR O-RADS US v2022

Updates with rationale



O-RADS US (v2022) - Rationale

- Updates to the O-RADS US Risk Assessment and Management system were made in order to:
 - Provide additional guidance and clarification
 - Resolve discrepancies with O-RADS MRI and SRU Consensus on Adnexal Cysts
 - Allows incorporation of O-RADS US to pelvic US report templates for all patients *(if desired)*
 - Improve specificity of certain lower risk lesion groups
 - Strengthen management recommendations to be more in line with validation studies, gyn-oncology and clinical input

O-RADS US (v2022) - **Outline**

- This tutorial is organized as follows:
 - Side-by-side presentation of original and updated Governing Concepts and Assessment Categories Tables
 - Detailed review and discussion of updates within the following categories:
 - Governing concepts
 - Lexicon terminology and definitions
 - Assessment categories
 - Management recommendations



Specific **changes**
highlighted in **gold**

Governing Concepts

Version 2019

O-RADS Ultrasound Risk Stratification – Governing concepts:

1. Recommendations should function as guidance rather than requirements for the management of patients with ovarian/adnexal masses. Individual case management may be modified by professional judgment, regardless of the O-RADS US recommendations.
2. The management system is based upon an average risk patient with no acute symptoms and no substantial risk factors for ovarian cancer such as a significant family history of ovarian cancer or BRCA gene mutation. If these factors are present, management may vary from this system.
3. The involvement of an "ultrasound specialist," denoted as a physician whose practice includes a focus on ultrasound assessment of adnexal lesions has been added to the O-RADS US System.⁵ However, at this time, there are no mandated requirements or guidelines that define such a specialist.
4. Each patient will be categorized as pre- or postmenopausal with the post-menopause category defined as amenorrhea of ≥ 1 -year.
5. The size of the lesion, an important element in risk assessment, should be obtained by measuring the largest diameter of the lesion regardless of the plane in which that diameter appears.
6. O-RADS applies only to lesions involving the ovaries and/or fallopian tube. If a pelvic lesion origin is indeterminate but suspected to be ovarian or fallopian in origin, the O-RADS system may apply. If a pelvic lesion is clearly identified as non-ovarian/tubal in origin then the O-RADS system would be appropriate only in the case of a paraovarian cyst or peritoneal inclusion cyst and, otherwise, does not apply.
7. Recommendations are generally based upon transvaginal sonography although may be augmented by transabdominal or transrectal sonography as needed.
8. In cases of multiple or bilateral lesions, each lesion should be separately characterized, and management driven by the lesion with the highest O-RADS score.

Version 2022

O-RADS™ Ultrasound v2022 — Governing Concepts

1. O-RADS Ultrasound (US) applies to the ovaries, lesions involving (or suspected to involve) the ovaries and/or fallopian tubes, and paraovarian cysts, when the intent is to stratify risk of malignancy. Scenarios when O-RADS does not apply include (but are not limited to): pelvic inflammatory disease, ectopic pregnancy, torsion of a normal ovary, and those lesions clearly identified as non-ovarian/non-tubal in origin (eg, an exophytic or broad ligament myoma). If the origin of a lesion is indeterminate, options include CT and MRI.
2. Most nonvisualized and all absent ovaries are classified as "O-RADS: not applicable". When only one ovary is visualized, it may be assessed per lexicon descriptors to obtain an O-RADS score. An exam may be considered "O-RADS 0: technically inadequate" when ovarian visualization is expected based on the indication for the exam but is not seen.
3. In cases of multiple or bilateral lesions, each lesion should be separately characterized, and management driven by the lesion with the highest O-RADS score. Separate recommendations should be provided when management of one lesion is independent of the other.
4. When menopausal status is relevant for risk stratification or management, patient should be categorized as pre- or postmenopausal. The postmenopausal category is defined as amenorrhea ≥ 1 year; (early = postmenopausal for <5 years, late = postmenopausal for ≥ 5 years). If uncertain or the uterus is absent, manage as per the postmenopausal status if age is >50 ; (early = >50 but <55 , late = ≥ 55).
5. Some O-RADS US management recommendations include the involvement of a physician whose practice includes a focus on ultrasound assessment of adnexal lesions, denoted as an "ultrasound specialist". While there are no mandated requirements or guidelines that define such a specialist, potential qualifications include sufficient experience with the appearance of adnexal pathology on US to improve the likelihood of correct diagnoses and participation in quality assurance activities related to adnexal imaging.
6. Imaging assessment of a lesion is generally based on transvaginal technique. Transabdominal imaging may add characterization and may suffice when transvaginal technique is not feasible or limited. When possible, orthogonal cine clips are strongly encouraged.
7. Single largest diameter of a lesion is used for risk stratification (scoring) and management. Reporting 3 dimensions is helpful to assess interval change, for which average linear dimension $(L + W + H/3)$ should be used.
8. Lexicon terminology and lesion characterization apply to most lesions regardless of risk or symptoms. When uncertain about feature selection, (eg, smooth versus irregular, color score, etc.) use the higher risk category to score the lesion.
9. Management recommendations should serve as guidance rather than requirements and are based on average risk and no acute symptoms. Individual case management may be modified by risk (eg, personal or family history of ovarian cancer, BRCA mutation, etc.), symptoms, other clinical factors, and professional judgement, regardless of the O-RADS score.

Table 1 – Assessment Categories

Version 2019

| O-RADS Ultrasound Risk Stratification and Management System | | | | | |
|---|------------------------------------|---|---|---|---|
| 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 Corpus Luteum ≤ 3cm | | None | N/A |
| 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** | | | |

CS=color score; GYN = gynecologic; IOTA = International Ovarian Tumor Analysis; N/A = not applicable
 * At a minimum, at least one-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.
 **Presence of ascites with category 1-2 lesion, must consider other malignant or non-malignant etiologies of ascites

Version 2022

| O-RADS™ US v2022 — Assessment Categories | | | | | | |
|--|------------------------------------|---|-----------------------------|--|----------------------------|------------------------------|
| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | | Management | | |
| | | | | Pre-menopausal | Post-menopausal | |
| 0 | Incomplete Evaluation [N/A] | Lesion features relevant for risk stratification cannot be accurately characterized due to technical factors | | Repeat US study or MRI | | |
| 1 | Normal Ovary [N/A] | No ovarian lesion Physiologic cyst: follicle (≤3 cm) or corpus luteum (typically ≤3 cm) | | None | | |
| 2 | Almost Certainly Benign [$<1\%$] | Simple cyst | ≤3 cm | N/A (see follicle) | None | |
| | | | >3 cm to 5 cm | None | Follow-up US in 12 months* | |
| | | | >5 cm but <10 cm | Follow-up US in 12 months* | Follow-up US in 12 months* | |
| | | Unilocular, smooth, non-simple cyst (internal echoes and/or incomplete septations) ----- Bilocular, smooth cyst | | ≤3 cm | None | Follow-up US in 12 months* |
| | | | | >3 cm but <10 cm | Follow-up US in 6 months* | |
| | | Typical benign ovarian lesion (Table 2) | <10 cm | See Table 2 (Classic Benign Lesions) for descriptors and management | | |
| | | Typical benign extraovarian lesion (Table 2) | Any size | | | |
| 3 | Low Risk Malignancy [1- $<10\%$] | Typical benign ovarian lesion (Table 2), ≥10 cm | | Imaging: • If not surgically excised, consider follow-up US within 6 months** • If solid, may consider US specialist (if available) or MRI (with O-RADS MRI score)*** Clinical: Gynecologist | | |
| | | Uni- or bilocular cyst, smooth, ≥10 cm | | | | |
| | | Unilocular cyst, irregular, any size | | | | |
| | | Multilocular cyst, smooth, <10 cm, CS <4 | | | | |
| | | Solid lesion, ± shadowing, smooth, any size, CS = 1 | | | | |
| | | Solid lesion, shadowing, smooth, any size, CS 2-3 | | | | |
| 4 | Intermediate Risk [10- $<50\%$] | Bilocular cyst without solid component(s) | | Imaging: Options include: • US specialist (if available) or MRI (with O-RADS MRI score)*** or Per gyn-oncologist protocol Clinical: Gynecologist with gyn-oncologist consultation or solely by gyn-oncologist | | |
| | | Multilocular cyst without solid component(s) | Irregular, any size, any CS | | | Smooth, ≥10 cm, CS <4 |
| | | | Smooth, any size, CS 4 | | | Irregular, any size, any CS |
| | | Unilocular cyst with solid component(s) | | | | <4 pps or solid component(s) |
| Bi- or multilocular cyst with solid component(s) | | Any size, CS 1-2 | | | | |
| | | Solid lesion, non-shadowing | | Smooth, any size, CS 2-3 | | |
| 5 | High Risk [≥50%] | Unilocular cyst, ≥4 pps, any size, any CS | | Imaging: Per gyn-oncologist protocol Clinical: Gyn-oncologist | | |
| | | Bi- or multilocular cyst with solid component(s), any size, CS 3-4 | | | | |
| | | Solid lesion, ± shadowing, smooth, any size, CS 4 | | | | |
| | | Solid lesion, irregular, any size, any CS | | | | |
| | | Ascites and/or peritoneal nodules**** | | | | |

GLOSSARY
 Smooth and irregular: refer to inner walls/septation(s) for cystic lesions, and outer contour for solid lesions; irregular inner wall for cysts = <3 mm in height
 Solid: excludes blood products and dermoid contents; solid lesion = ≥80% solid; solid component = protrudes ≥3 mm (height) into cyst lumen off wall or septation
 Shadowing: must be diffuse or broad to qualify; excludes refractive artifact
 pp = papillary projection; subtype of solid component surrounded by fluid on 3 sides
 CS = color score; degree of intralésional vascularity; 1 = none, 2 = minimal flow, 3 = moderate flow, 4 = very strong flow
 Bilocular = 2 locules; multilocular = ≥3 locules; bilocular smooth cysts have a lower risk of malignancy, regardless of size or CS
 *Shorter imaging follow-up may be considered in some scenarios (eg, clinical factors). If smaller (≥10-15% decrease in average linear dimension), no further surveillance. If stable, follow-up US at 24 months from initial exam. If enlarging (≥10-15% increase in average linear dimension), consider follow-up US at 12 and 24 months from initial exam, then management per gynecology. For changing morphology, reassess using lexicon descriptors. Clinical management with gynecology as needed.
 **There is a paucity of evidence for defining the optimal duration or interval for imaging surveillance. Shorter follow-up may be considered in some scenarios (eg, clinical factors). If stable, follow-up at 12 and 24 months from initial exam, then as clinically indicated. For changing morphology, reassess using lexicon descriptors.
 ***MRI with contrast has higher specificity for solid lesions, and cystic lesions with solid component(s).
 ****Not due to other malignant or non-malignant etiologies; specifically, must consider other etiologies of ascites in categories 1-2.

Table 2 – Classic Benign Lesions

Version 2019

| O-RADS Ultrasound Risk Stratification and Management System Classic Benign Lesions (O-RADS 2) | | | |
|--|---|---|---|
| Lexicon Descriptor | Definition | Management | |
| | | Premenopausal | Postmenopausal |
| Typical hemorrhagic cyst | Reticular pattern: Fine thin intersecting lines representing fibrin strands | ≤ 5 cm None | US specialist, gynecologist or MRI |
| | Retracting clot: An avascular echogenic component with angular, straight, or concave margins | >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 | <ul style="list-style-type: none"> • 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, gynecologist, or MRI With confident diagnosis, if not removed surgically, annual US follow up should then be considered * |
| Typical endometriomas < 10 cm | Ground glass/homogeneous low-level echoes | US specialist or MRI if there is enlargement, changing morphology or a developing vascular component | MRI if there is enlargement, changing morphology or a developing vascular component |
| 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 | <ul style="list-style-type: none"> • 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.

Version 2022

| O-RADS™ US v2022 — Classic Benign Lesions | | |
|---|---|---|
| Lesion | Descriptors and Definitions For any atypical features on initial or follow-up exam, use other lexicon descriptors (eg, unilocular, multilocular, solid, etc.) | Management If sonographic features are only suggestive, and overall assessment is uncertain, consider follow-up US within 3 months |
| Typical Hemorrhagic Cyst | Unilocular cyst, no internal vascularity* , and at least one of the following: <ul style="list-style-type: none"> • Reticular pattern (fine, thin intersecting lines representing fibrin strands) • Retractable clot (intracystic component with straight, concave, or angular margins) | Imaging: <ul style="list-style-type: none"> o Premenopausal: <ul style="list-style-type: none"> • ≤5 cm: None • >5 cm but <10 cm: Follow-up US in 2–3 months o Early postmenopausal (<5 years): <ul style="list-style-type: none"> • <10 cm, options to confirm include: <ul style="list-style-type: none"> • Follow-up US in 2–3 months or • US specialist (if available) or • MRI (with O-RADS MRI score) o Late postmenopausal (≥5 years): <ul style="list-style-type: none"> • Should not occur, recategorize using other lexicon descriptors. Clinical: Gynecologist** |
| Typical Dermoid Cyst | Cystic lesion with ≤3 locules, no internal vascularity* , and at least one of the following: <ul style="list-style-type: none"> • Hyperechoic component(s) (diffuse or regional) with shadowing • Hyperechoic lines and dots • Floating echogenic spherical structures | Imaging: <ul style="list-style-type: none"> • ≤3 cm: May consider follow-up US in 12 months*** • >3 cm but <10 cm: If not surgically excised, follow-up US in 12 months*** Clinical: Gynecologist** |
| Typical Endometrioma | Cystic lesion with ≤3 locules, no internal vascularity* , homogeneous low-level/ground glass echoes, and smooth inner walls/septation(s) <ul style="list-style-type: none"> • ± Peripheral punctate echogenic foci in wall | Imaging: <ul style="list-style-type: none"> o Premenopausal: <ul style="list-style-type: none"> • <10 cm: If not surgically excised, follow-up US in 12 months*** o Postmenopausal: <ul style="list-style-type: none"> • <10 cm and initial exam, options to confirm include: <ul style="list-style-type: none"> • Follow-up US in 2–3 months or • US specialist (if available) or • MRI (with O-RADS MRI score) Then, if not surgically excised, recommend follow-up US in 12 months*** Clinical: Gynecologist** |
| Typical Paraovarian Cyst | Simple cyst separate from the ovary | Imaging: None Clinical: None |
| Typical Peritoneal Inclusion Cyst | Fluid collection with ovary at margin or suspended within that conforms to adjacent pelvic organs <ul style="list-style-type: none"> • ± Septations (representing adhesions) | Imaging: None Clinical: Gynecologist** |
| Typical Hydrosalpinx | Anechoic, fluid-filled tubular structure <ul style="list-style-type: none"> • ± Incomplete septation(s) (representing folds) • ± Endosalpingeal folds (short, round projections around inner walls) | Imaging: None Clinical: Gynecologist** |

*Excludes vascularity in walls or intervening septation(s)
**As needed for management of clinical issues
***There is a paucity of evidence for defining the need, optimal duration or interval of timing for surveillance. If stable, consider US follow-up at 24 months from initial exam, then as clinically indicated. Specifically, evidence does support an **increased risk of malignancy in endometriomas following menopause and those present greater than 10 years.**

Governing Concepts

Governing Concepts – Updates

- There are **now 9** governing concepts (previously 8) to enhance guidance.
- The **order** of presentation has been **changed** to improve flow as follows:
 - GC # 1-3: Applicability criteria – when to use and not use, ovary not visualized or absent, multiple/bilateral lesions
 - GC # 4-5: Important definitions - menopausal status, US specialist
 - GC # 6: Technique – TVS vs TAS, use of cines
 - GC # 7-8: Lexicon terms – size, rules
 - GC # 9: Management – rules and caveats

Governing Concepts – Updates | Applicability Criteria

- O-RADS US applies to the ovaries, lesions involving (or suspected to involve) the ovaries and/or fallopian tubes, and paraovarian cysts, when the intent is to stratify risk of malignancy
- Scenarios when O-RADS does not apply include (*but are not limited to*):
 - Pelvic inflammatory disease, ectopic pregnancy, torsion of a normal ovary
 - Lesions clearly identified as non-ovarian/non-tubal in origin (eg, an exophytic or broad ligament myoma)
- If the origin of a lesion is indeterminate, imaging options include CT and MRI

Rationale: Clarifies O-RADS intent with examples of when the system does not apply. Allows O-RADS use for the normal ovary (previously only applicable to lesions) and provides imaging suggestions when lesion origin is unclear.

Governing Concepts – Updates | Applicability Criteria

- Ovary not seen or surgically absent
 - O-RADS US: Not applicable
 - Applies to most scenarios
 - O-RADS US 0: Technically inadequate
 - Ovarian visualization expected and required based on exam indication but not seen, eg:
 - US follow-up of ovarian lesion previously seen or on another modality
 - High-risk patient (BRCA, etc.), screening US for ovarian cancer

Rationale: Added to allow one to incorporate O-RADS to their pelvic US templates for use in all patients (*if desired*) with guidance for use in scenarios of surgically absent and nonvisualized ovaries.

Governing Concepts – Updates | Applicability Criteria

- Multiple or bilateral lesions
 - Each lesion should be separately characterized
 - Management driven by the lesion with the highest O-RADS score
 - Separate recommendations should be provided when management of one lesion is independent of the other

Rationale: In some scenarios, it is prudent to provide separate management recommendations; eg, surgical management of one lesion and US surveillance of a second lesion.

Governing Concepts – Updates | Menopausal status

- Patient should be categorized as pre- or postmenopausal
 - When menopausal status is relevant for risk stratification or management
 - Postmenopausal defined as amenorrhea ≥ 1 year
 - Early = < 5 years
 - Late = ≥ 5 years
 - If uncertain or uterus is absent, manage as postmenopausal if age is > 50
 - Early = > 50 but < 55
 - Late = ≥ 55

Rationale: Provides guidance when menopausal status is uncertain, or uterus is removed. Early and late post-menopause added to align management of hemorrhagic cysts with that provided in the SRU Consensus on Adnexal Cysts.

Governing Concepts – Updates | Ultrasound Specialist

- “Ultrasound specialist”:
 - Physician whose practice includes a focus on ultrasound assessment of adnexal lesions
 - No mandated requirements to define such a specialist
 - Potential qualifications include:
 - Sufficient experience with the appearance of adnexal pathology on US to improve the likelihood of correct diagnoses
 - Participation in quality assurance activities related to adnexal imaging

Rationale: Provides additional guidance on ultrasound specialist status emphasizing the importance of experience and involvement in the appropriate assessment of adnexal lesions; eg, multidisciplinary and QA conferences, tumor boards, etc.

Governing Concepts – Updates | Ultrasound Technique

- Imaging assessment of a lesion is generally based on transvaginal technique
 - Transabdominal imaging may augment characterization, and **may suffice when transvaginal technique is not feasible or limited**
 - **When possible, orthogonal cine clips are strongly encouraged**
- NOTE: Transrectal imaging eliminated due to low prevalence of use

Rationale: Clarifies that an exam limited to only transabdominal technique may suffice when characterization is adequate. Encouragement of cine clips added to emphasize the importance of near real-time assessment in thoroughly evaluating a lesion; not a requirement but a strong suggestion.

Governing Concepts – Updates | Lesion Size

- For risk stratification (scoring) and management:
 - Single largest diameter should be used
- For interval change:
 - Average linear dimension should be used $(L+W+H/3)$
 - Reporting 3 dimensions is helpful to assess interval change on follow-up

Rationale: Growth parameters added to help direct management. Evidence supports the use of **average linear dimension** to account for differences in technique, such as probe pressure, which may deform cystic lesions limiting the use of maximum diameter on serial exams. This also aligns with SRU Consensus on Adnexal Cysts.

Governing Concepts – Updates | Lexicon Application

- Lexicon terminology and lesion characterization (scoring) apply to most lesions regardless of risk or symptoms
- When uncertain about feature selection, (eg, smooth versus irregular, color score, etc.) use the higher risk category to score the lesion

Rationale: Clarifies that O-RADS lexicon and scoring may apply to high-risk patients or those with acute symptoms, as all patients were included in supporting IOTA trials. Provides guidance for lesions with uncertain or overlapping imaging features with recommendation for using the more concerning features to optimize sensitivity.

Governing Concepts – Updates | Management Recommendations

- Management recommendations serve as guidance rather than requirements and based on average risk and no acute symptoms
- **Individual case management may be modified**, regardless of the O-RADS score, by factors, including (but not limited to):
 - Risk for cancer (eg, personal or family history, BRCA mutation, etc.)
 - Presenting symptoms
 - Other clinical factors
 - Professional judgement

Rationale: Clarifies that management may differ in some scenarios such as high risk or acute symptoms. Takes into consideration that clinical factors may also modify management (eg, shorter follow-up due to anxiety, infertility treatment, etc.).

Lexicon Terminology and Definitions

Lexicon Terminology and Definitions – Updates | O-RADS 0

Version 2019

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors |
|--------------|-----------------------------|---------------------|
| 0 | Incomplete Evaluation [N/A] | N/A |

Version 2022

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors |
|--------------|-----------------------------|--|
| 0 | Incomplete Evaluation [N/A] | Lesion features relevant for risk stratification cannot be accurately characterized due to technical factors |

Rationale: Definition added to emphasize use of O-RADS 0 for technical factors limiting evaluation and not when lesion characterization is uncertain. As stated in GC#2, use of O-RADS 0 may be considered when the exam indication requires visualization (eg, high-risk screening, previously seen lesion, etc.) and visualization is expected (eg, pre-menopausal).

Lexicon Terminology and Definitions – Updates | O-RADS 1

Version 2019

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors |
|--------------|----------------------------|---|
| 1 | Normal Ovary [N/A] | Follicle defined as a simple cyst ≤ 3 cm |
| | | Corpus Luteum ≤ 3 cm |

Version 2022

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors |
|--------------|----------------------------|--|
| 1 | Normal Ovary [N/A] | No ovarian lesion |
| | | Physiologic cyst: follicle (≤ 3 cm) or corpus luteum (typically ≤ 3 cm) |

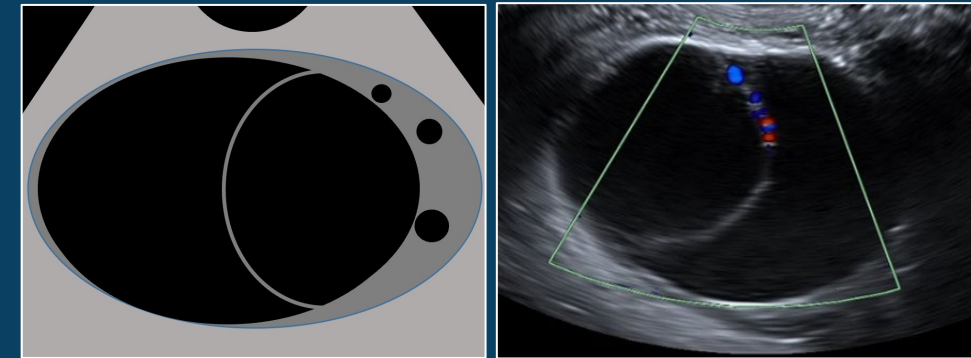
Rationale: “No lesion” added to O-RADS 1 to align with O-RADS MRI and allow incorporation of O-RADS US in pelvic US report templates for all patients (*if desired*). Added “typically” to size of a corpus luteum to encourage emphasis on morphologic and Doppler features and not a discriminatory size cutoff as most, but not all, corpora lutea measure ≤ 3 cm.

Lexicon Terminology and Definitions – Updates | O-RADS 2 - 5

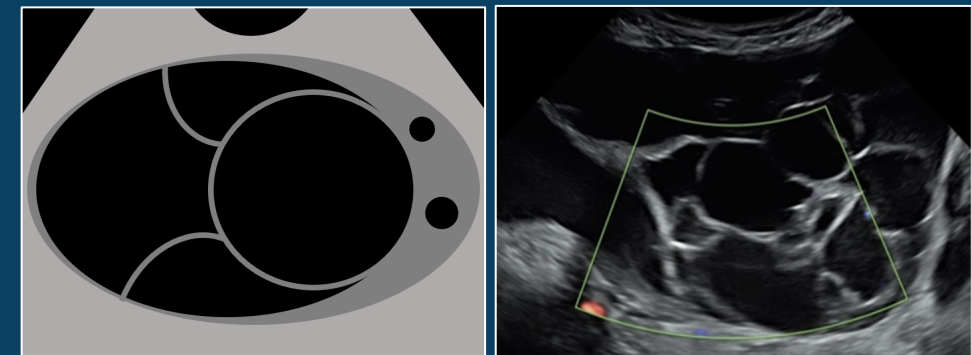
- “Bilocular” added for cystic lesions
 - Defined as 2 locules (1 complete septation)
- Multilocular now defined as ≥ 3 locules

Rationale: Added bilocular for a cyst with a single smooth septation to align with management recommendations by the SRU Consensus on Adnexal Cysts. Evidence supports improved specificity when differentiating bilocular and multilocular, as the former carries a lower risk of malignancy.

Bilocular



Multilocular



Lexicon Terminology and Definitions – Updates | Bilocular

Version 2019

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | |
|---|--|---|--|
| 2 | Almost Certainly Benign [$< 1\%$] | Simple cyst | ≤ 3 cm |
| | | | > 3 cm to 5 cm |
| | | | > 5 cm but < 10 cm |
| | | Classic Benign Lesions | See table on next page for descriptors and man |
| Non-simple unilocular cyst, smooth inner margin | ≤ 3 cm | | |
| | > 3 cm but < 10 cm | | |
| 3 | Low Risk Malignancy [1- $<10\%$] | Unilocular cyst (simple or non-simple) ≥ 10 cm | |
| | | 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 |
| | | | Smooth inner wall, any size, CS = 4 |
| | | | Irregular inner wall \pm 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 [$\geq 50\%$] | Unilocular cyst, ≥ 4 papillary projections, any size, CS = any | |
| | | 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** | |

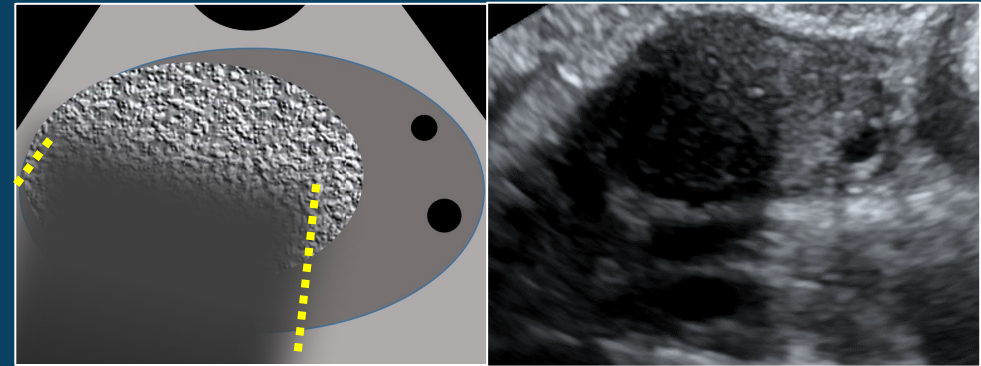
Version 2022

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | |
|--|------------------------------------|--|--|
| 2 | Almost Certainly Benign [$<1\%$] | Simple cyst | ≤ 3 cm |
| | | | >3 cm to 5 cm |
| | | | >5 cm but <10 cm |
| | | Unilocular, smooth, non-simple cyst (internal echoes and/or incomplete septations) | ≤ 3 cm |
| | | | >3 cm but <10 cm |
| | | Bilocular, smooth cyst | <10 cm |
| Typical benign ovarian lesion (Table 2) | Any size | | |
| Typical benign extraovarian lesion (Table 2) | Any size | | |
| 3 | Low Risk Malignancy [1 – $<10\%$] | Typical benign ovarian lesion (Table 2), ≥ 10 cm | |
| | | Uni- or bilocular cyst, smooth, ≥ 10 cm | |
| | | Unilocular cyst, irregular, any size | |
| | | Multilocular cyst, smooth, <10 cm, CS <4 | |
| | | Solid lesion, \pm shadowing, smooth, any size, CS = 1 | |
| | | Solid lesion, shadowing, smooth, any size, CS 2–3 | |
| 4 | Intermediate Risk [10 – $<50\%$] | Bilocular cyst without solid component(s) | Irregular, any size, any CS |
| | | Multilocular cyst without solid component(s) | Smooth, ≥ 10 cm, CS <4 |
| | | | Smooth, any size, CS 4 |
| | | | Irregular, any size, any CS |
| | | Unilocular cyst with solid component(s) | <4 pps or solid component(s) not considered a pp; any size |
| | | Bi- or multilocular cyst with solid component(s) | Any size, CS 1–2 |
| Solid lesion, non-shadowing | Smooth, any size, CS 2–3 | | |
| 5 | High Risk [$\geq 50\%$] | Unilocular cyst ≥ 4 pps, any size, any CS | |
| | | Bi- or multilocular cyst with solid component(s), any size, CS 3–4 | |
| | | Solid lesion, \pm shadowing, smooth, any size, CS 4 | |
| | | Solid lesion, irregular, any size, any CS | |
| Ascites and/or peritoneal nodules**** | | | |

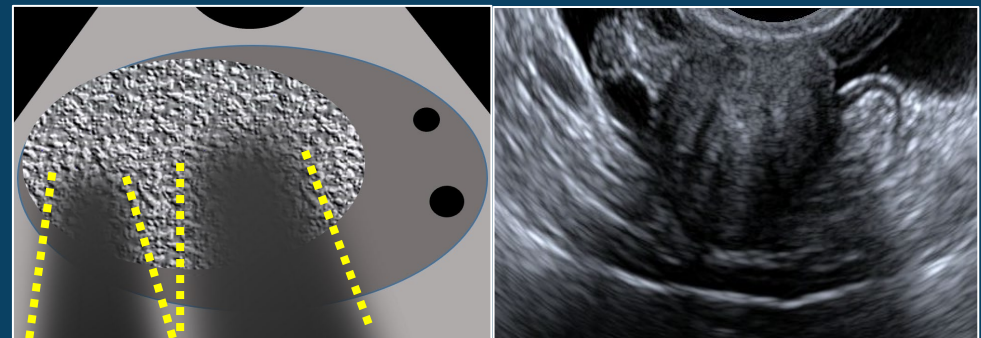
Lexicon Terminology and Definitions – Updates | O-RADS 3 - 5

- “Shadowing” added for solid lesions
 - Descriptor of posterior hypoechogenicity due to attenuation of the acoustic beam
 - Must be diffuse or broad to qualify (not refractive/edge artifact)

Diffuse shadowing



Broad shadowing



Rationale: The presence of shadowing may be seen with fibromatous lesions. Including shadowing as a descriptor improves specificity of solid lesions when the outer contour is smooth.

Lexicon Terminology and Definitions – Updates | Shadowing

Version 2019

| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | |
|--------------|--|---|--|
| 3 | Low Risk Malignancy [1-<10%] | Unilocular cyst (simple or non-simple) ≥ 10 cm | |
| | | 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 |
| | | | 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 | |
| | | 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** | |

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| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | |
|--------------|--------------------------------|--|--|
| 3 | Low Risk Malignancy [1 – <10%] | Typical benign ovarian lesion (Table 2), ≥10 cm | |
| | | Uni- or bilocular cyst, smooth, ≥10 cm | |
| | | Unilocular cyst, irregular, any size | |
| | | Multilocular cyst, smooth, <10 cm, CS <4 | |
| | | Solid lesion, ± shadowing, smooth, any size, CS = 1 | |
| | | Solid lesion, shadowing, smooth, any size, CS 2–3 | |
| 4 | Intermediate Risk [10 – <50%] | Bilocular cyst without solid component(s) | Irregular, any size, any CS |
| | | | Smooth, ≥10 cm, CS <4 |
| | | Multilocular cyst without solid component(s) | Smooth, any size, CS 4 |
| | | | Irregular, any size, any CS |
| | | Unilocular cyst with solid component(s) | <4 pps or solid component(s) not considered a pp; any size |
| | | Bi- or multilocular cyst with solid component(s) | Any size, CS 1–2 |
| | | Solid lesion, non-shadowing | Smooth, any size, CS 2–3 |
| 5 | High Risk [≥50%] | Unilocular cyst, ≥4 pps, any size, any CS | |
| | | Bi- or multilocular cyst with solid component(s), any size, CS 3–4 | |
| | | Solid lesion, ± shadowing, smooth, any size, CS 4 | |
| | | Solid lesion, irregular, any size, any CS | |
| | | Ascites and/or peritoneal nodules**** | |

Lexicon Terminology and Definitions – Updates | Classic Benign Ovarian Lesions

- For all **ovarian classic benign lesions**, the following additions have been made:

- No internal vascularity*

*Excludes flow in wall and intervening septa (if present)

Rationale: Clarifies that no intralesional flow is a requirement to qualify as a typical classic benign ovarian lesion.

-
- # of locules

- Hemorrhagic cyst: 1 (unilocular); dermoid cyst and endometrioma: ≤ 3

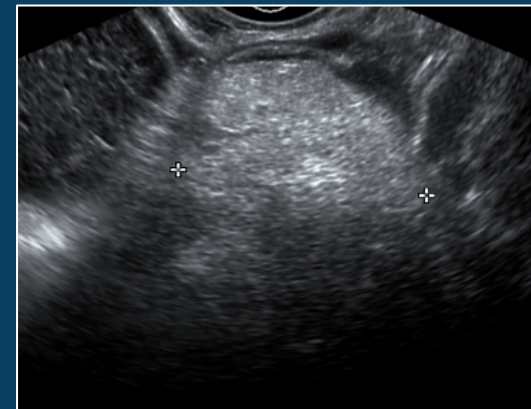
Rationale: Recognizes that a typical dermoid cyst and endometrioma may have ≤ 3 locules. (NOTE: ≥ 4 locules is atypical and warrants re-characterization as a multilocular lesion using lexicon descriptors.)

Lexicon Terminology and Definitions – Updates | Classic Benign Ovarian Lesions

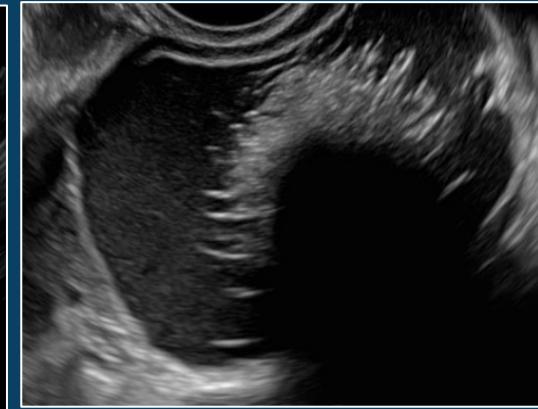
- For **dermoid cyst**, feature modification as follows:
 - Hyperechoic component (**diffuse or regional**) with shadowing

Rationale: Clarifies that the hyperechoic component may occupy the entire lesion.

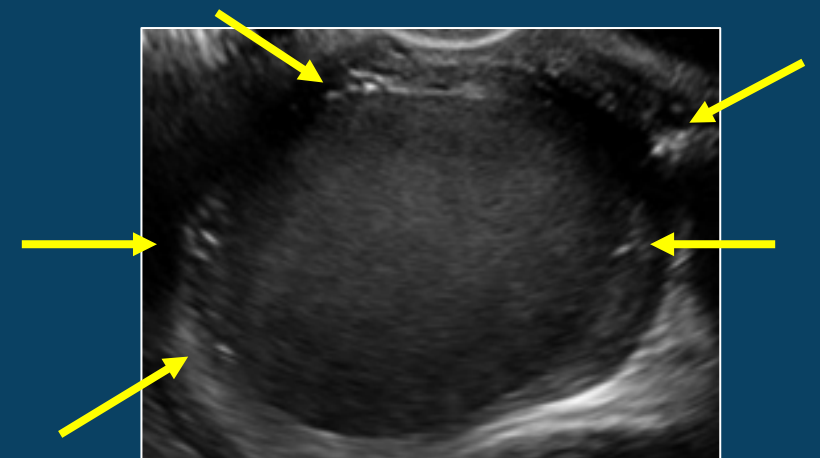
Diffuse



Regional



- For **endometrioma**, following optional feature added:
 - \pm peripheral punctate echogenic foci



Lexicon Terminology and Definitions – Updates | Classic Benign Extra-Ovarian Lesions

- For **hydrosalpinx**, typical features are clarified as follows:
 - **Anechoic, fluid-filled**, tubular structure
 - ± incomplete septations
 - ± endosalpingeal folds

Anechoic



Rationale: Distinguishes required vs. optional (\pm) features. Added “anechoic, fluid-filled” to differentiate from “hematosalpinx” which is in a separate risk category in O-RADS MRI.

Assessment Categories

Assessment Categories – Updates

- Bilocular cyst with smooth inner walls/septation, < 10 cm
 - NEW: O-RADS 2
 - OLD: O-RADS 3

NOTE: This category includes cysts with and without internal echoes or incomplete septation(s)

Rationale: A single complete septation was previously considered multilocular; however, a cyst with a single smooth septation has a ROM <1%, warranting a downgrade from O-RADS 3 to O-RADS 2

Assessment Categories – Updates

- Bilocular cyst with smooth inner walls/septation, ≥ 10 cm
 - NEW: O-RADS 3
 - OLD: O-RADS 3 or 4

NOTE: This category includes cysts with and without internal echoes or incomplete septation(s)

Rationale: Previously, bilocular cysts were considered multilocular and color score (internal vascularity) was relevant for distinguishing multilocular smooth cysts ≥ 10 cm as O-RADS 3 vs. O-RADS 4. For smooth cysts of this size with a single smooth septation, the ROM is $< 10\%$ (O-RADS 3), regardless of the CS.

Assessment Categories – Updates

- Solid lesions with shadowing, smooth outer contour and CS <4
 - NEW: O-RADS 3
 - OLD: O-RADS 3 or 4

NOTE: All solid lesions with a CS 4 (very strong flow) or irregular outer contour remain in O-RADS 5 (high risk), regardless of the presence of shadowing

Rationale: Solid lesions with a smooth outer contour and shadowing suggest fibromatous elements with a ROM <10% (O-RADS 3). Previously, solid smooth lesions with a CS of 2 - 3 (mild to moderate flow) were O-RADS 4.

Assessment Categories – Updates

- As scoring of a classic benign lesions is affected by the presence of any atypical features, the following guidance has been added to Table 2:
 - “For any atypical features on initial or follow-up exam, one should use other lexicon descriptors (eg, uni/multilocular, solid lesion, etc.)”

NOTE: Growth alone has been excluded as an atypical feature as benign lesions can grow in the absence of malignant change. Growth does however require critical evaluation for imaging features that increase the risk of malignancy to ensure lexicon descriptors for a typical classic benign lesion still apply

Management

Management – Updates | O-RADS 0 – O-RADS 1

- Management recommendations are now **divided into “imaging” and “clinical”** to better clarify their respective roles. Additional changes will be presented by O-RADS category for Table 1, then Table 2.
-

- O-RADS 0 – Imaging

- **NEW:** Repeat US or MRI
- **OLD:** Repeat study or alternate study

Rationale: Provides more specific guidance. A repeat US may be attempted if technical factors are believed likely to resolve. Otherwise, MRI may be considered

- O-RADS 1

- No changes

Management – Updates | O-RADS 2

- O-RADS 2 – Imaging
 - Premenopausal simple cyst, > 5 cm but < 10 cm
 - NEW: Follow-up US at 12 months*
 - * *Shorter f/u may be considered in some scenarios (eg, clinical factors)*
 - OLD: Follow-up US at 8-12 weeks

Rationale: Given very low ROM, follow-up in 1 year is reasonable although there may be clinical scenarios when shorter follow-up is prudent. Aligns with SRU Consensus on Adnexal Cysts.

Management – Updates | O-RADS 2

- O-RADS 2 – Imaging
 - Postmenopausal non-simple cyst (\pm internal echoes, \pm incomplete septation(s)) and bilocular cyst with smooth inner walls, ≤ 3 cm
 - NEW: Follow-up US in 12 months
 - OLD: Follow-up US in 1 yr, if concerning, US specialist or MRI

Rationale: Bilocular cyst added to non-simple cyst category given equivalent low ROM (per IOTA 5). Removed “if concerning, US specialist or MRI” as one will reassess using other lexicon terms.

Management – Updates | O-RADS 2

- O-RADS 2 – Imaging
 - Postmenopausal non-simple cyst (\pm internal echoes, \pm incomplete septation(s)) and bilocular cyst with smooth inner walls, > 3 cm but < 10 cm
 - NEW:
 - Pre- and postmenopausal: Follow-up US in 6 months
 - OLD:
 - Premenopausal: Follow-up US in 8-12 weeks
 - Postmenopausal: US specialist or MRI

Rationale: Given low ROM (per IOTA 5) in both pre- and postmenopausal groups, timing of initial follow-up exam is lengthened to 6 months.

Management – Updates | O-RADS 2

Version 2019

| | | | | | | |
|---|-------------------------------------|---|--|---|--|--|
| 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 | |

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| | | | | | | |
|---|-------------------------------------|---|------------------------|---|----------------------------|--|
| 2 | Almost Certainly Benign [$< 1\%$] | Simple cyst | ≤ 3 cm | N/A (see follicle) | None | |
| | | | > 3 cm to 5 cm | None | Follow-up US in 12 months* | |
| | | | > 5 cm but < 10 cm | Follow-up US in 12 months* | | |
| | | Unilocular, smooth, non-simple cyst (internal echoes and/or incomplete septations) ----- Bilocular, smooth cyst | ≤ 3 cm | None | Follow-up US in 12 months* | |
| | | | > 3 cm but < 10 cm | Follow-up US in 6 months* | | |
| | | Typical benign ovarian lesion (Table 2) | < 10 cm | See Table 2 (Classic Benign Lesions) for descriptors and management | | |
| | | Typical benign extraovarian lesion (Table 2) | Any size | | | |

Management – Updates | O-RADS 2

- O-RADS 2 – Imaging surveillance
 - **NEW:** Guidance on timing of initial & follow-up US exams added as follows:
 - If smaller ($\geq 10\text{-}15\%$ ↓ in average linear dimension): No further surveillance
 - If stable: Follow-up US at 24 months from initial exam
 - If enlarging ($\geq 10\text{-}15\%$ ↑ in average linear dimension): Follow-up US at 12 and 24 months from initial exam; then manage per gynecology
 - For changing morphology: Reassess using lexicon descriptors.

NOTE: Included in footnote on bottom of Table 1 corresponding to asterisk (*)

Rationale: Clarifies surveillance parameters to align with SRU Consensus on Adnexal Cysts. This includes a 10-15% threshold in average linear dimension for size changes and shortening the suggested endpoint from 5 to 2 years.

Management – Updates | O-RADS 2

- O-RADS 2 – Clinical
 - NEW: Gynecology as needed to address clinical issues

NOTE: Also included in footnote at bottom of Table 1 corresponding to asterisk (*)

*Shorter imaging follow-up may be considered in some scenarios (eg, clinical factors). If smaller ($\geq 10\text{--}15\%$ decrease in average linear dimension), no further surveillance. If stable, follow-up US at 24 months from initial exam. If enlarging ($\geq 10\text{--}15\%$ increase in average linear dimension), consider follow-up US at 12 and 24 months from initial exam, then management per gynecology. For changing morphology, reassess using lexicon descriptors **Clinical management with gynecology as needed.**

**There is a paucity of evidence for defining the optimal duration or interval for imaging surveillance. Shorter follow-up may be considered in some scenarios (eg, clinical factors). If stable, follow-up at 12 and 24 months from initial exam, then as clinically indicated. For changing morphology, reassess using lexicon descriptors.

***MRI with contrast has higher specificity for solid lesions, and cystic lesions with solid component(s).

****Not due to other malignant or non-malignant etiologies; specifically, must consider other etiologies of ascites in categories 1–2.

Rationale: Management now divided into “imaging” and “clinical” for all lesion groups. Clarifies that some O-RADS 2 lesions in Table 1 may require clinical management by a gynecologist.

Management – Updates | O-RADS 3

- O-RADS 3 – Imaging
 - NEW: If not surgically excised, consider follow-up US within 6 months. If solid, options include US specialist (if available) or MRI (with O-RADS MRI score)*
 - *MRI has higher specificity for solid lesions and cystic lesions with solid component(s)*
- OLD: US specialist or MRI

Rationale: Some women will elect surgical excision. If not excised, US surveillance is reasonable given ROM of O-RADS 3 lesions in validation studies are at the low end of 1-10% range. MRI is not necessary for all low-risk lesions, but MRI characterization of lesions with solid tissue does improve specificity.

Management – Updates | O-RADS 3

- O-RADS 3 – Imaging surveillance
 - As US surveillance is now an option, guidance on **timing of follow-up US exams** has been added as follows:
 - If following, US should be obtained at 12 and 24 months from initial exam, then as clinically indicated.
-

- O-RADS 3 – Clinical
 - No change (Gynecology)

Management – Updates | O-RADS 4

- O-RADS 4 – Imaging
 - NEW: Options include:
 - US specialist (if available) or
 - MRI (with MRI score)* or
 - Per Gyn-oncologist protocol
 - *MRI has higher specificity for solid lesions and cystic lesions with solid components*
 - OLD: US specialist or MRI

- O-RADS 4 – Clinical
 - No change (Gyn-oncologist or gynecology with consultation by gyn-oncologist)

Management – Updates | O-RADS 5

- O-RADS 5 – Imaging
 - Imaging: Per Gyn-oncologist protocol
- O-RADS 5 – Clinical
 - No change (Gyn-oncologist)

Rationale: Clarifies that additional imaging may be included in the management for high-risk lesions. However, this should be directed by the gyn-oncologist who may order an MRI or CT (eg, for staging).

Management – Updates | O-RADS 3 - 5

Version 2019

| | | |
|---|-------------------------------|---|
| 3 | Low Risk Malignancy [1-<10%] | US specialist or MRI Management by gynecologist |
| 4 | Intermediate Risk [10- < 50%] | US specialist or MRI Management by gynecologist with gyn-oncologist consultation or solely by gyn-oncologist |
| 5 | High Risk [≥ 50%] | Gyn-oncologist |

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| | | |
|---|--------------------------------|---|
| 3 | Low Risk Malignancy [1 – <10%] | <p>Imaging:</p> <ul style="list-style-type: none"> If not surgically excised, consider follow-up US within 6 months** If solid, may consider US specialist (if available) <u>or</u> MRI (with O-RADS MRI score)*** <p>Clinical: Gynecologist</p> |
| 4 | Intermediate Risk [10 – <50%] | <p>Imaging:</p> <p>Options include:</p> <ul style="list-style-type: none"> US specialist (if available) <u>or</u> MRI (with O-RADS MRI score)*** <u>or</u> Per gyn-oncologist protocol <p>Clinical: Gynecologist with gyn-oncologist consultation <u>or</u> solely by gyn-oncologist</p> |
| 5 | High Risk [≥50%] | <p>Imaging: Per gyn-oncologist protocol</p> <p>Clinical: Gyn-oncologist</p> |

**There is a paucity of evidence for defining the optimal duration or interval for imaging surveillance. Shorter follow-up may be considered in some scenarios (eg, clinical factors). If stable, follow-up at 12 and 24 months from initial exam, then as clinically indicated. For changing morphology, reassess using lexicon descriptors.

***MRI with contrast has higher specificity for solid lesions, and cystic lesions with solid component(s).

Management – Updates | Classic Benign Lesions (Table 2)

- The following has been added for all classic benign lesions:
 - If sonographic features are only suggestive, and overall assessment is uncertain, may consider follow-up US within 3 months
-
- Menopausal status now only relevant for hemorrhagic cysts and endometriomas
 - Previously also relevant for dermoid cysts which may now be managed the same for pre- and postmenopausal groups

Management – Updates | Classic Benign Lesions (Table 2)

- Hemorrhagic cyst, < 10 cm, postmenopausal – Imaging
 - NEW:
 - Early postmenopausal (< 5 years), options to confirm include:
 - Follow-up US in 2-3 months or
 - US specialist (if available) or
 - MRI (with O-RADS MRI score)
 - Late postmenopausal (> 5 years): Should not occur; must reassess using lexicon descriptors
 - OLD: US specialist, gynecologist or MRI

Rationale: Aligns with management in SRU Consensus on Adnexal Cysts.

Management – Updates | Classic Benign Lesions (Table 2)

- Endometrioma, < 10 cm, postmenopausal – Imaging
 - NEW: If initial exam, recommend follow-up US in 2-3 months or US specialist or MRI (with O-RADS MRI score) to confirm. Then, if not surgically excised, follow-up US in 12 months
 - OLD: Optional 8 -12 wk US based on confidence in diagnosis. If If not removed surgically, annual US follow-up should then be considered. US specialist or MRI if there is enlargement, changing morphology or developing vascular component

Rationale: Recognizes less common occurrence of endometriomas in post-menopause and that appearance may overlap with neoplasia. Guidance for atypical features, and when features are only suggestive and overall assessment is uncertain, now provided for all classic benign lesions.

Management – Updates | Classic Benign Lesions (Table 2)

- Dermoid cysts, ≤ 3 cm – Imaging
 - May consider follow-up US in 12 months

Rationale: Added as surveillance of small typical-appearing dermoid cysts is less clear and may not be warranted.

- Dermoid cysts, > 3 cm but < 10 cm – Imaging
 - NEW: If not surgically excised, follow-up US in 12 months
 - OLD: Optional 8-12 wk US based on 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 developing vascular component

Rationale: Guidance for atypical features, and when only suggestive and overall assessment is uncertain, now provided for all classic benign lesions.

Management – Updates

Version 2019

| Lexicon Descriptor | Management | |
|-------------------------------|---|---|
| | Premenopausal | Postmenopausal |
| Typical hemorrhagic cyst | ≤ 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 | 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, gynecologist, or MRI With confident diagnosis, if not removed surgically, annual US follow up should then be considered * |
| Typical endometriomas < 10 cm | US specialist or MRI if there is enlargement, changing morphology or a developing vascular component | MRI if there is enlargement, changing morphology or a developing vascular component |

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| Lesion | Management If sonographic features are only suggestive, and overall assessment is uncertain, consider follow-up US within 3 months |
|--------------------------|---|
| Typical Hemorrhagic Cyst | Imaging: <ul style="list-style-type: none"> Premenopausal: <ul style="list-style-type: none"> ≤ 5 cm: None >5 cm but <10 cm: Follow-up US in 2–3 months Early postmenopausal (<5 years): <ul style="list-style-type: none"> <10 cm, options to confirm include: <ul style="list-style-type: none"> Follow-up US in 2–3 months <u>or</u> US specialist (if available) <u>or</u> MRI (with O–RADS MRI score) Late postmenopausal (≥5 years): <ul style="list-style-type: none"> Should not occur; recategorize using other lexicon descriptors. |
| | Clinical: Gynecologist** |
| Typical Dermoid Cyst | Imaging: <ul style="list-style-type: none"> ≤3 cm: May consider follow-up US in 12 months*** >3 cm but <10 cm: If not surgically excised, follow-up US in 12 months*** |
| | Clinical: Gynecologist** |
| Typical Endometrioma | Imaging: <ul style="list-style-type: none"> Premenopausal: <ul style="list-style-type: none"> <10 cm: If not surgically excised, follow-up US in 12 months*** Postmenopausal: <ul style="list-style-type: none"> <10 cm <u>and initial exam</u>, options to confirm include <ul style="list-style-type: none"> Follow-up US in 2–3 months <u>or</u> US specialist (if available) <u>or</u> MRI (with O-RADS MRI score) <p>Then, if not surgically excised, recommend follow-up US in 12 months***</p> |
| | Clinical: Gynecologist** |

Management – Updates | Classic Benign Lesions (Table 2)

- Dermoid and Endometrioma - Imaging surveillance
 - **NEW:** Added parameters for **duration** of follow-up as follows:
 - Follow-up US at 24 months from initial exam, then as clinically needed
 - Specifically, evidence does support an increasing incidence of malignancy in endometriomas following menopause **and those present > 10 years.**

NOTE: Included in footnote on bottom of Table 2 corresponding to asterisk

***There is a paucity of evidence for defining the need, optimal duration or interval of timing for surveillance. If stable, consider US follow-up at 24 months from initial exam, then as clinically indicated. Specifically, evidence does support **an increased risk of malignancy in endometriomas following menopause and those present greater than 10 years.**

Rationale: Guidance updated regarding end point for surveillance with further imaging based on clinical parameters. Now includes caution regarding long-standing endometriomas.

Management – Updates | Classic Benign Lesions (Table 2)

- Clinical
 - For all ovarian and extra-ovarian* classic benign lesions
 - NEW: Gynecology as needed for management of clinical issues
- *Exception: paraovarian cyst

Rationale: While malignancy is not of concern, reflects the clinical implications which may exist with some of these lesions (eg, endometriosis, risk of torsion, infertility, pain, etc.)

Management – Updates

Version 2019

| Lexicon Descriptor | Management | |
|-------------------------------|---|---|
| | Premenopausal | Postmenopausal |
| Typical hemorrhagic cyst | ≤ 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 | 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, gynecologist, or MRI With confident diagnosis, if not removed surgically, annual US follow up should then be considered * |
| Typical endometriomas < 10 cm | US specialist or MRI if there is enlargement, changing morphology or a developing vascular component | MRI if there is enlargement, changing morphology or a developing vascular component |

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| Lesion | Management If sonographic features are only suggestive, and overall assessment is uncertain, consider follow-up US within 3 months |
|--------------------------|--|
| Typical Hemorrhagic Cyst | <p>Imaging:</p> <ul style="list-style-type: none"> Premenopausal: <ul style="list-style-type: none"> ≤ 5 cm: None >5 cm but <10 cm: Follow-up US in 2–3 months Early postmenopausal (<5 years): <ul style="list-style-type: none"> <10 cm, options to confirm include: <ul style="list-style-type: none"> Follow-up US in 2–3 months <u>or</u> US specialist (if available) <u>or</u> MRI (with O–RADS MRI score) Late postmenopausal (≥5 years): <ul style="list-style-type: none"> Should not occur; reclassify using other lexicon descriptors. <p>Clinical: Gynecologist**</p> |
| Typical Dermoid Cyst | <p>Imaging:</p> <ul style="list-style-type: none"> ≤3 cm: May consider follow-up US in 12 months*** >3 cm but <10 cm: If not surgically excised, follow-up US in 12 months*** <p>Clinical: Gynecologist**</p> |
| Typical Endometrioma | <p>Imaging:</p> <ul style="list-style-type: none"> Premenopausal: <ul style="list-style-type: none"> <10 cm: If not surgically excised, follow-up US in 12 months*** Postmenopausal: <ul style="list-style-type: none"> <10 cm <u>and initial exam</u>, options to confirm include <ul style="list-style-type: none"> Follow-up US in 2–3 months <u>or</u> US specialist (if available) <u>or</u> MRI (with O-RADS MRI score) <p>Then, if not surgically excised, recommend follow-up US in 12 months***</p> <p>Clinical: Gynecologist**</p> |

**As needed for management of clinical issues

Summary of Updated Tables

Table 1 Updates - Summary

- “Bilocular” added
- “Shadowing” added
- Management: divided into imaging and clinical; more in line with SRU Consensus on Adnexal Cysts; US surveillance allowed for low-risk lesions
- New glossary with guidance/definitions
- All asterisks listed at bottom with new guidance for timing of follow-up and increased MRI specificity for lesions with solid tissue
- *Overall, more instructive, and clear*



| O-RADS Score | Risk Category [IOTA Model] | Lexicon Descriptors | | Management | |
|---|------------------------------------|--|-----------------------------|--|----------------------------|
| | | | | Pre-menopausal | Post-menopausal |
| 0 | Incomplete Evaluation [N/A] | Lesion features relevant for risk stratification cannot be accurately characterized due to technical factors | | Repeat US study or MRI | |
| 1 | Normal Ovary [N/A] | No ovarian lesion Physiologic cyst: follicle (≤3 cm) or corpus luteum (typically ≤3 cm) | | None | |
| 2 | Almost Certainly Benign [$<1\%$] | Simple cyst | ≤3 cm | N/A (see follicle) | None |
| | | | >3 cm to 5 cm | None | Follow-up US in 12 months* |
| | | | >5 cm but <10 cm | Follow-up US in 12 months* | Follow-up US in 12 months* |
| | | Unilocular, smooth, non-simple cyst (internal echoes and/or incomplete septations) | ≤3 cm | None | Follow-up US in 12 months* |
| | | | >3 cm but <10 cm | Follow-up US in 6 months* | |
| Typical benign ovarian lesion (Table 2) | <10 cm | See Table 2 (Classic Benign Lesions) for descriptors and management | | | |
| Typical benign extraovarian lesion (Table 2) | Any size | | | | |
| 3 | Low Risk Malignancy [1 – <10%] | Typical benign ovarian lesion (Table 2), ≥10 cm | | Imaging: • If not surgically excised, consider follow-up US within 6 months** • If solid, may consider US specialist (if available) or MRI (with O-RADS MRI score)*** Clinical: Gynecologist | |
| | | Uni- or bilocular cyst, smooth, ≥10 cm | | | |
| | | Unilocular cyst, irregular, any size | | | |
| | | Multilocular cyst, smooth, <10 cm, CS <4 | | | |
| | | Solid lesion, ± shadowing, smooth, any size, CS = 1 | | | |
| Solid lesion, shadowing, smooth, any size, CS 2–3 | | | | | |
| 4 | Intermediate Risk [10 – <50%] | Bilocular cyst without solid component(s) | | Imaging: Options include: • US specialist (if available) or • MRI (with O-RADS MRI score)*** or • Per gyn-oncologist protocol Clinical: Gynecologist with gyn-oncologist consultation or solely by gyn-oncologist | |
| | | Multilocular cyst without solid component(s) | Irregular, any size, any CS | | |
| | | | Smooth, ≥10 cm, CS <4 | | |
| | | Unilocular cyst with solid component(s) | Smooth, any size, CS 4 | | |
| | | | Irregular, any size, any CS | | |
| Bi- or multilocular cyst with solid component(s) | | <4 pps or solid component(s) not considered a pp; any size | | | |
| Solid lesion, non-shadowing | | Any size, CS 1–2 | | | |
| 5 | High Risk [≥50%] | Unilocular cyst, ≥4 pps, any size, any CS | | Imaging: Per gyn-oncologist protocol Clinical: Gyn-oncologist | |
| | | Bi- or multilocular cyst with solid component(s), any size, CS 3–4 | | | |
| | | Solid lesion, ± shadowing, smooth, any size, CS 4 | | | |
| | | Solid lesion, irregular, any size, any CS | | | |
| | | Ascites and/or peritoneal nodules**** | | | |

| GLOSSARY | |
|---|--|
| Smooth and irregular: refer to inner walls/septation(s) for cystic lesions, and outer contour for solid lesions; irregular inner wall for cysts = <3 mm in height | Solid: excludes blood products and dermoid contents; solid lesion = ≥80% solid; solid component = protrudes ≥3 mm (height) into cyst lumen off wall or septation |
| Shadowing: must be diffuse or broad to qualify; excludes refractive artifact | pp = papillary projection; subtype of solid component surrounded by fluid on 3 sides |
| CS = color score; degree of intralésional vascularity; 1 = none, 2 = minimal flow, 3 = moderate flow, 4 = very strong flow | Bilocular = 2 locules; multilocular = ≥3 locules; bilocular smooth cysts have a lower risk of malignancy, regardless of size or CS |

*Shorter imaging follow-up may be considered in some scenarios (eg, clinical factors). If smaller (≥10–15% decrease in average linear dimension), no further surveillance. If stable, follow-up US at 24 months from initial exam. If enlarging (≥10–15% increase in average linear dimension), consider follow-up US at 12 and 24 months from initial exam, then management per gynecology. For changing morphology, reassess using lexicon descriptors. Clinical management with gynecology as needed.

**There is a paucity of evidence for defining the optimal duration or interval for imaging surveillance. Shorter follow-up may be considered in some scenarios (eg, clinical factors). If stable, follow-up at 12 and 24 months from initial exam, then as clinically indicated. For changing morphology, reassess using lexicon descriptors.

***MRI with contrast has higher specificity for solid lesions, and cystic lesions with solid component(s).

****Not due to other malignant or non-malignant etiologies; specifically, must consider other etiologies of ascites in categories 1–2.

Table 2 Updates - Summary

- New guidance for atypical features and when assessment uncertain
- “No internal vascularity” and # of locules permitted added
- New/modified lexicon terms: hyperechoic component (diffuse or regional) with shadowing, peripheral punctate echogenic foci, anechoic fluid-filled structure
- Management more in line with SRU Consensus on Adnexal Cysts and more directed postmenopause management
- New surveillance and clinical management guidance

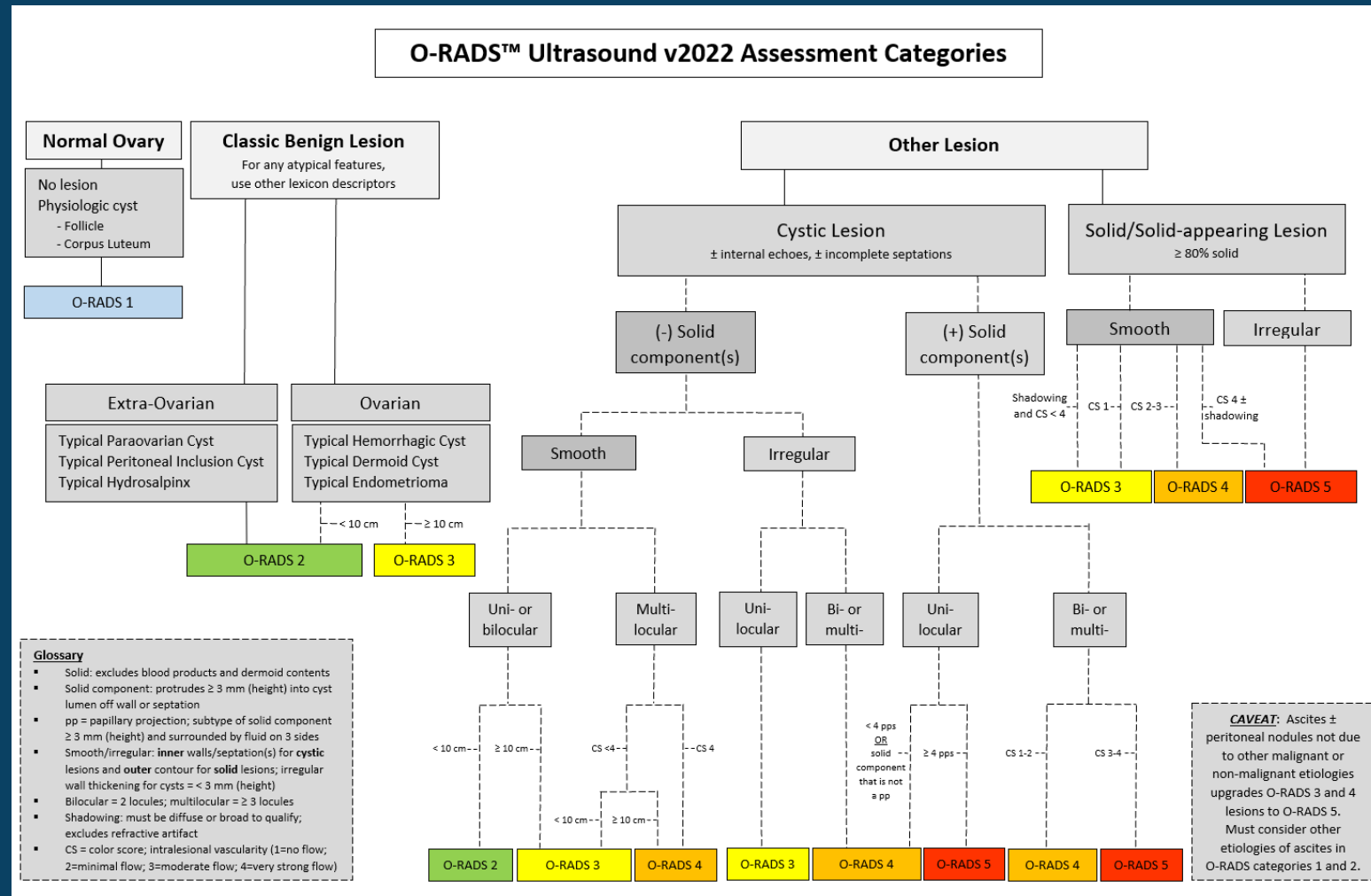


| Lesion | Descriptors and Definitions For any atypical features on initial or follow-up exam, use other lexicon descriptors (eg, unilocular, multilocular, solid, etc.) | Management If sonographic features are only suggestive, and overall assessment is uncertain, consider follow-up US within 3 months |
|-----------------------------------|--|---|
| Typical Hemorrhagic Cyst | Unilocular cyst, no internal vascularity*, and at least one of the following: <ul style="list-style-type: none"> • Reticular pattern (fine, thin intersecting lines representing fibrin strands) • Retractable clot (intracystic component with straight, concave, or angular margins) | Imaging: <ul style="list-style-type: none"> o Premenopausal: <ul style="list-style-type: none"> • ≤5 cm: None • >5 cm but <10 cm: Follow-up US in 2–3 months o Early postmenopausal (<5 years): <ul style="list-style-type: none"> • <10 cm, options to confirm include: <ul style="list-style-type: none"> ▪ Follow-up US in 2–3 months or ▪ US specialist (if available) or ▪ MRI (with O-RADS MRI score) o Late postmenopausal (≥5 years): <ul style="list-style-type: none"> • Should not occur; recategorize using other lexicon descriptors. Clinical: Gynecologist** |
| Typical Dermoid Cyst | Cystic lesion with ≤3 locules, no internal vascularity*, and at least one of the following: <ul style="list-style-type: none"> • Hyperechoic component(s) (diffuse or regional) with shadowing • Hyperechoic lines and dots • Floating echogenic spherical structures | Imaging: <ul style="list-style-type: none"> • ≤3 cm: May consider follow-up US in 12 months*** • >3 cm but <10 cm: If not surgically excised, follow-up US in 12 months*** Clinical: Gynecologist** |
| Typical Endometrioma | Cystic lesion with ≤3 locules, no internal vascularity*, homogeneous low-level/ground glass echoes, and smooth inner walls/septation(s). <ul style="list-style-type: none"> • ± Peripheral punctate echogenic foci in wall | Imaging: <ul style="list-style-type: none"> o Premenopausal: <ul style="list-style-type: none"> • <10 cm: If not surgically excised, follow-up US in 12 months*** o Postmenopausal: <ul style="list-style-type: none"> • <10 cm and initial exam, options to confirm include: <ul style="list-style-type: none"> ▪ Follow-up US in 2–3 months or ▪ US specialist (if available) or ▪ MRI (with O-RADS MRI score) Then, if not surgically excised, recommend follow-up US in 12 months*** Clinical: Gynecologist** |
| Typical Paraovarian Cyst | Simple cyst separate from the ovary | Imaging: None Clinical: None |
| Typical Peritoneal Inclusion Cyst | Fluid collection with ovary at margin or suspended within that conforms to adjacent pelvic organs <ul style="list-style-type: none"> • ± Septations (representing adhesions) | Imaging: None Clinical: Gynecologist** |
| Typical Hydrosalpinx | Anechoic, fluid-filled tubular structure <ul style="list-style-type: none"> • ± Incomplete septation(s) (representing folds) • ± Endosalpingeal folds (short, round projections around inner walls) | Imaging: None Clinical: Gynecologist** |

*Excludes vascularity in walls or intervening septation(s)
 **As needed for management of clinical issues
 ***There is a paucity of evidence for defining the need, optimal duration or interval of timing for surveillance. If stable, consider US follow-up at 24 months from initial exam, then as clinically indicated. Specifically, evidence does support an increased risk of malignancy in endometriomas following menopause and those present greater than 10 years.

New Algorithm – Assessment Categories

- The updates allow for a revised algorithmic approach to risk stratification and serves as the basis for changes in the smartphone app
 - Remember to update/download the O-RADS US v2022 calculator app on your iPhone or Android*
- This algorithm is available on the ACR O-RADS website



*Thank you for your
interest in O-RADS US*

