Ref: Ro Med J. 2021;68(Suppl6)
DOI: 10.37897/RMJ.2021.S6.13

Application of the new classification criteria in ovarian pathology (IOTA – O-RADS)

Gina Calinescu[1], Roxana Elena Bohiltea[2,3], Andra Magdalena Balan[1], Tiberiu Augustin Georgescu[4], Nicolae Bacalbasa[2], Irina Balescu[5], Bianca Margareta Mihai[3], Vlad Dima[3], Ioana Teodora Vladareanu[6], Corina Grigoriu[1,2]

[1]Department of Gynecology and Obstetrics, Emergency University Hospital, Bucharest, Romania
[2]Department of Gynecology and Obstetrics, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania
[3]Filantropia Clinical Hospital, Bucharest, Romania
[4]Department of Pathology, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania
[5]Department of Visceral Surgery, Ponderas Academic Hospital, Bucharest, Romania
[6]Faculty of Medicine, "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania

ABSTRACT

The Ovarian-Adnexal Reporting and Data System (O-RADS) risk stratification and management system is designed to provide consistent interpretations, to decrease or eliminate ambiguity in ultrasound (US) reports, resulting in a higher accuracy in assigning the risk of malignancy for ovarian and other adnexal masses, and to provide accurate management recommendations for each risk category. It was developed by experts in radiology, gynecology, pathology and gynecologic oncology from the United States, Canada and Europe, under the supervision of the ACR (American College of Radiology). This unique system represents a collaboration between the pattern-based approach, commonly used in North America, and the widely used, European-based, algorithmic-style of the International Ovarian Tumor Analysis (IOTA) Assessment of Different Neoplasias in the Adnexa model system, a risk prediction model that has undergone successful prospective and external validation. The Ovarian-Adnexal Reporting and Data System US risk stratification and management system for evaluation of ovarian and other adnexal masses is based on a standardized lexicon, incorporates all classes of risk, and offers an associated management strategy for each risk category. US is widely considered the primary imaging modality in the evaluation of women with suspected adnexal pathology. Standardized terms and definitions to describe the sonographic features of adnexal lesions have been proposed, and several US reporting models can aid in differentiating benign from malignant adnexal masses. However, approximately 20% to 25% of adnexal masses remain indeterminate after the initial sonographic evaluation. Furthermore, studies have demonstrated variable positive predictive values for the detection of ovarian cancer using US, with certain studies showing low positive predictive values in the general population in which the incidence of ovarian cancer is low. Secondary tests such as MRI could help decrease the number of false-positive lesions when using US in certain settings and avoid unnecessary surgery in benign lesions. The ACR Ovarian-Adnexal Reporting and Data Systems (O-RADS) MRI Committee has developed an evidence-based lexicon and risk stratification system for MRI evaluation of adnexal lesions.

Keywords: ultrasound, adnexa, ovary, cancer risk, O-RADS

INTRODUCTION

Adnexal masses are common gynecologic pathologies, being discovered either due to symptomatology (pelvic pain or pressure or abnormal uterine bleeding) or incidentally (during pelvic examination or imaging). Most adnexal masses are of ovarian origin, followed by tubal pathology and para-ovarian or para-tubal origin (1). Pelvic exam, patient's age, family history, patient's history (menstrual, sexual, fertility history) and other biological examinations (blood analysis) are fundamental (2). But the most important tool that clinicians have are

Corresponding author:
Roxana Elena Bohîlțea
E-mail: r.bohiltea@yahoo.com

Article History:
Received: 27 November 2021
Accepted: 22 December 2021

the imaging studies, ultrasound (US) being of utmost interest. Pelvic US (transvaginal and abdominal) comprises beyond gray-scale examination the color Doppler evaluation (which should be considered part of the routine examination, and not an additional test) (3).

The Ovarian-Adnexal Reporting and Data System US risk stratification and management system for evaluation of ovarian and other adnexal masses is based on a standardized lexicon, incorporates all classes of risk, and offers an associated management strategy for each risk category (4). The accurate characterization of ovarian and other adnexal masses is essential for optimal patient management. Conservative and less aggressive management is more appropriate for lesions that are likely benign. On the other hand, when malignancy is suspected, patients should be referred to a gynecologic oncologist (5).

One of the most solid attempts to develop a standardized terminology regarding adnexal tumoral pathology was realized by the International Ovarian Tumor Analysis (IOTA) group, the first consensus being published in 2000. They studied over 5,000 patients applying a set of sonographic features (the so-called "simple rules"), to describe benign tumors (the five B-features) and to characterize malignant tumors (the five M-features) (6).

The O-RADS Ultrasound Steering Committee then developed a preliminary set of terms and definitions (Table 1) with recommendations for inclusion or omission based upon their analysis of pertinent descriptors and the evidence underlying their usage (5). They concluded that the US terms developed by the IOTA Group were the most robust evidence-based available in the literature, leading to a steering committee recommendation to incorporate these terms as a package. The terms included the following five major descriptors: unilocular cyst ± solid components; multilocular cyst ± solid components; and mostly solid (> 80%) (7). This permitted to continue with evidence-based standardized terminology for major categories of adnexal lesions, which could then be modified by additional descriptors of their gray scale and color Doppler findings (8).

These are general concepts that should be understood to correctly use terms in the subsequent lexicon categories beginning with a few basic definitions followed by classes of descriptors for the characterization of any mass (8-10).

We will present shortly the descriptions of O-RADS categories.

O-RADS 0 is an incomplete evaluation due to technical factors such as bowel gas, large size of the lesion, location of the adnexa, or inability to tolerate transvaginal imaging, so, generally, a repeat US is recommended, although an alternate imaging study such as MRI may be appropriate in selected cases (5).

O-RADS 1 is the physiologic category that is relevant only in premenopausal patients, includes the follicle and corpus luteum, has a normal ovary and no additional imaging or imaging follow-up is necessary (8,9).

O-RADS 2 is the category that comprises lesions almost certainly benign (<1% risk of malignancy), majority of unilocular cysts < 10 cm. This group includes simple cysts, non-simple unilocular cysts with smooth walls, and cysts that may be described by using classic benign lesions and their descriptors if < 10 cm in maximal diameter. These include the typical hemorrhagic cyst, dermoid cyst, endometrioma, para-ovarian cyst, peritoneal inclusion cyst and hydrosalpinx (8). Generally, either no follow-up or surveillance is the recommendation for lesions that are almost certainly benign. Further characterization by a US specialist or performance of an MRI study, as well as management by a gynecologist, may be advised in some subgroups (9).

O-RADS 3 is a low-risk category (1-10% risk of malignancy). This category includes lesions in the almost certainly benign category that are larger, and other lesions where descriptors apply that denote a slightly higher risk of malignancy. This includes simple cysts, unilocular smooth non-simple cysts, and lesions with classic benign descriptors that are ≥ 10 cm (11). Also included are unilocular cysts with wall irregularity, multilocular cysts < 10 cm without solid component(s) with a color score <4, and avascular solid or solid-appearing lesions with a smooth external contour of any size. The presence of Doppler flow is diagnostic of solid tissue, but its absence is less informative, and the lesion should then be considered solid appearing as described in the abbreviated lexicon. Beginning with the O-RADS 3 category, the color score becomes incorporated into the risk stratification system (8). Over 90% of O-RADS 3 lesions are benign. A general gynecologist should manage patients with this group of lesions, although it is important that optimal imaging evaluation be performed. Consultation of an US specialist or performance of an MRI examination is encouraged by the O-RADS US management scheme to minimize the risk of overlooking more suspicious features (6).

O-RADS 4 refers to the intermediate-risk category (10-50% risk of malignancy) that includes descriptors found to be predictive of a higher risk of malignancy. This includes multilocular cysts that are ≥10 cm, or have an irregular inner wall or septal irregularity (< 3 mm in height), unilocular and multilocular cysts of any size with a solid component or color score up to 4, and smooth solid lesions (> 80%

TABLE 1. Working lexicon categories, terms & definitions of O-RADS Committee (6)

Category	Term	Definition
1	**Major categories**	
1a	**Physiologic category** (consistent with normal ovarian physiology)	
	Follicle	Simple cyst ≤ 3 cm in premenopausal group
	Corpus luteum (CL)	Thick-walled cyst ≤ 3 cm that may have crenulated inner margins, internal echoes and intense peripheral color Doppler flow.
1b	**Lesion category (not consistent with normal physiology)**	
	Unilocular, no solid component	Cystic lesion that contains 1 compartment. May contain ≥1 incomplete septum, wall irregularity <3mm height or internal echoes.
	Unilocular cyst with solid component(s)	As above but includes solid component(s) ≥ 3mm in height.
	Multilocular cyst, no solid elements	Cystic lesion with more than one compartment (at least one complete septum) but no solid component(s) ≥3mm in height.
	Multilocular cyst with solid component(s)	As above but includes ≥1 solid component(s) ≥3 mm in height.
	Solid (≥80%)	Lesion with echogenicity suggestive of tissue without characteristics of a cyst. Lesion is at least 80% solid when assessed in orthogonal 2-dimensional planes.
2	**Size**	
	Maximum diameter	Maximum diameter of a lesion in any plane.
	Maximum diameters	Largest 3 diameters in 2 perpendicular planes. One of these will be the maximum diameter of the lesion.
	Maximum diameter of the largest solid component	Maximum diameter of the largest solid component in any plane.
3	**Solid or solid-appearing lesions**	
	Smooth	Regular outer margin
	Irregular (Not Smooth)	Non-uniform outer margin
3b	**Internal contents**	
	Hypoechoic/ isoechoic/ hyperechoic	Decreased/similar/increased echogenicity when compared to the internal reference of normal ovarian stroma.
	Calcification(s)	High-level echogenic component with associated acoustic shadowing within the solid appearing portion of the lesion.
	Acoustic shadowing	Artifact produced by attenuated echoes behind a sound absorbing structure.
4	**Cystic lesions**	
4a	**Inner margin or walls**	
	Smooth	Regular, uniform inner margin
	Irregular (not smooth)	Irregular, non-uniform inner margin. May include wall irregularities due to incomplete septations, solid components <3mm height or papillary projections (solid components ≥3mm in height)
	Calcification(s)	High-level echogenicity within wall which is curvilinear or plaque-like and may demonstrate associated acoustic shadowing
4b	**Internal content, cystic component**	
	Anechoic fluid	No internal echoes or structures of any kind
	Hyperechoic components	Area of increased echogenicity with respect to normal ovarian parenchyma without acoustic shadowing
	Scattered low-level echoes	Scattered or heterogeneously dispersed echoes within a cyst
	Fluid/fluid level	Nondependent portion that is relatively hypoechoic with respect to the dependent portion with horizontal delineation
		Nondependent portion that is relatively echogenic to the dependent portion with horizontal delineation
Endometrioma descriptor	Ground glass or homogeneous low-level echoes	Homogeneously evenly dispersed echoes within a cyst

Category	Term	Definition
Dermoid descriptors	Echogenic component with acoustic shadowing	Attenuation of the acoustic beam distal to a hyperechoic component
	Hyperechoic lines and dots	Bright linear echoes and foci representing linear echoes seen en face
	Floating echogenic spherical structures	Non-dependent echogenic spheres that may be associated with posterior acoustic shadowing and have been called dermoid balls
Hemorrhagic cyst descriptors	Reticular pattern	Fine thin intersecting lines representing fibrin strands that should not be confused with septations
	Retractile clot	Avascular echogenic component with angular, straight, or concave margins
Septations	Complete	Strand of tissue extending across the cyst cavity from one internal wall to another in all scanning planes
	Incomplete	Strand tissue not completely extending from one internal wall to another in all planes
4c	**Solid or solid/appearing component**	
	Papillary projection or nodule	Solid component whose height ≥3 mm, arises from the cyst wall or septation and protrudes into the cyst cavity.
Outer contour	Smooth	The contour of the solid component within a cyst demonstrates no irregularities
	Irregular (not smooth)	The contour of the solid component or of any internal cystic area within the solid component demonstrates irregularities
5	**Vascularity**	
	Circumferential color Doppler wall flow	Color Doppler flow is restricted to the wall and includes the majority of the circumference of the wall
	Internal color Doppler flow	Color Doppler flow is detected internally within a solid component/mural nodule or in a septation of the lesion with or without peripheral (wall) flow.
	Color score 1-4	Overall subjective assessment of color Doppler flow within the entire lesion (wall and/or internal component) Color score 1 = No flow Color score 2 = Minimal flow Color score 3 = Moderate flow Color score 4 = Very strong flow
6	**General and extra-ovarian findings**	
Cysts	Peritoneal inclusion cyst	Cyst with no mass effect conforming to contours of pelvic structures typically contains fine septations. The ovary is either at the margin or suspended within the lesion.
	Paraovarian cyst	Simple cyst exists separate from ovary and moves independent of the ovary
Fallopian tube descriptors (abnormal)	Incomplete Septation	Non-continuous tissue is seen extending across the cystic cavity due to the wall of the distended fallopian tube folded upon itself
	Tubular	Substantially longer in one dimension than in the two perpendicular dimensions.
	Endosalpingeal folds	Short round projections around the inner wall of a fluid distended tubular structure
Fluid sescriptors	Cul-de-sac fluid	Confined to pouch of Douglas as defined by remaining below uterine fundus or between uterus and bladder when uterus retroverted/retroflexed
	Ascites	Fluid extending above uterine fundus beyond the pouch of Douglas or cul-de-sac when anteverted/anteflexed, and anterior/superior to uterus when retroverted/retroflexed
	Anechoic	Simple fluid
	Fluid containing internal echoes	Not simple fluid
Other	Peritoneal thickening or nodules	Nodularity or diffuse thickening of the peritoneal lining(s) or along the bowel serosal surface or peritoneum associated with peritoneal carcinomatosis
	Adenopathy	Lymph nodes measured in short axis

solid) with color score of 2–3 (11,12). It should be noted that a papillary projection is a type of solid component with height ≥3 mm that arises from the cyst wall or septation and protrudes into the cyst cavity (8). This are intermediate-risk lesions, so US specialist evaluation, MRI characterization, menopausal status and serum biomarkers (CA-125) have a role in deciding which of these lesions should be referred for management by a gynecologic oncologist (12). If a surgical procedure is to be performed by a general gynecologist, then it is recommended that the facility has the "necessary support and consultative services to optimize patient outcomes" (which means an oncologist) (10).

O-RADS 5 is the high-risk category (≥ 50% risk of malignancy). This is comprised of descriptors that

are highly predictive of malignancy such as irregular solid lesions and multilocular cysts with a solid component and high color score (12,13). The presence of ascites and/or peritoneal nodules would also indicate an O-RADS 5 score except when there is ascites in association with a physiologic cyst or almost certainly benign lesion (see O-RADS 2), at which time other etiologies for ascites should be considered (8). They are high-risk lesions and should be directly referred to a gynecologic oncologist for management. The serum markers are not included in our risk stratification system, although they play a role in evaluation. The O-RADS US committee considered that tumor marker evaluation should be individualized for each patient. For example, a premenopausal patient with an intermediate-risk lesion, a clinical scenario highly suspicious for endometriosis and an elevated level of CA-125 may unnecessarily elevate the concern for malignancy. A normal level of CA-125 for a postmenopausal woman with an intermediate- or high-risk category 4 or 5 lesion may provide false reassurance (9).

Although no classification system can completely encompass all aspects of the management of each patient with an adnexal lesion, O-RADS US more clearly defines referral criteria when compared with what has been previously published (5).

As in the mammographic report, the sonographic approach for describing an adnexal mass can be summarized as follows: 1. Is the image a simple cyst?; 2. Are the findings consistent with another physiological condition?; 3. Are the findings suggesting a specific pathologic process (endometrioma, mature teratoma, hydrosalpinx, pedunculated leiomyoma, peritoneal inclusion cyst, malignancy)?; 4. Is additional evaluation necessary (additional imaging, referral to a gynecologic oncologist, tumor markers)?

This multidisciplinary international initiative has the aim to develop standardized terminology for evaluation of ovarian and adnexal masses and to obtain consistent and accurate interpretations of malignancy risk and to determine optimal patient management strategies (4,14). The success of this first standardized reporting lexicon has led to the development of other lexicons, which have demonstrated success in improving the quality of communication among imagists, between imagists and referring clinicians, and ultimately in choosing appropriate management strategies (8,15). The committee's next step is to incorporate the O-RADS lexicon and IOTA outcomes data in the development of a system to categorize malignancy risk and provide guidelines for patient management in the different risk categories (9-11).

CONCLUSIONS

All around the world great efforts are made to better describe and classify the adnexal tumoral pathology. Nowadays, several study groups, implying multidisciplinary specialists – gynecologists, oncologists, radiologists, but also biologists and physicists are engaged in new studies, regarding better tumoral descriptors, like vascular imaging, MRI, new biomarkers and proteomics. Both IOTA and O-RADS systems contribute immensely to progress in this area.

Conflict of interest: none declared
Financial support: none declared

REFERENCES

1. Patel-Lippmann KK, Sadowski EA, Robbins JB, Paroder V, Barroilhet L, et al. Comparison of International Ovarian Tumor Analysis Simple Rules to Society of Radiologists in Ultrasound Guidelines for Detection of Malignancy in Adnexal Cysts. *AJR Am J Roentgenol.* 2020 Mar;214(3):694-700.
2. Basha MAA, Metwally MI, Gamil SA, Khater HM, Aly SA, El Sammak AA, et al. Comparison of O-RADS, GI-RADS, and IOTA simple rules regarding malignancy rate, validity, and reliability for diagnosis of adnexal masses. *Eur Radiol.* 2021 Feb;31(2):674-684.
3. Guo W, Zou X, Xu H, Zhang T, Zhao Y, Gao L, Duan W, Ma X, Zhang L. The diagnostic performance of the Gynecologic Imaging Reporting and Data System (GI-RADS) in adnexal masses. *Ann Transl Med.* 2021 Mar;9(5):398.
4. Andreotti RF, Timmerman D, Strachowski LM, Froyman W, Benacerraf BR, et al. O-RADS US Risk Stratification and Management System: A Consensus Guideline from the ACR Ovarian-Adnexal Reporting and Data System Committee. *Radiology.* 2020 Jan;294(1):168-185.
5. Pi Y, Wilson MP, Katlariwala P, Sam M, Ackerman T, Paskar L, Patel V, Low G. Diagnostic accuracy and inter-observer reliability of the O-RADS scoring system among staff radiologists in a North American academic clinical setting. *Abdom Radiol* (NY). 2021 Oct;46(10):4967-4973.
6. Stein EB, Roseland ME, Shampain KL, Wasnik AP, Maturen KE. Contemporary Guidelines for Adnexal Mass Imaging: A 2020 Update. *Abdom Radiol* (NY). 2021 May;46(5):2127-2139.
7. Ruiz de Gauna B, Rodriguez D, Olartecoechea B, Aubá M, Jurado M, Gómez Roig MD, Alcázar JL. Diagnostic performance of IOTA simple rules for adnexal masses classification: a comparison between two centers with different ovarian cancer prevalence. *Eur J Obstet Gynecol Reprod Biol.* 2015 Aug;191:10-4.
8. Andreotti RF, Timmerman D, Benacerraf BR, Bennett GL, Bourne T, et al. Ovarian-Adnexal Reporting Lexicon for Ultrasound: A White Paper of the ACR Ovarian-Adnexal Reporting and Data System Committee. *J Am Coll Radiol.* 2018 Oct;15(10):1415-1429.
9. Strachowski LM, Jha P, Chawla TP, Davis KM, Dove CK, Glanc P, Morgan TA, Andreotti RF. 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.
10. Thomassin-Naggara I, Poncelet E, Jalaguier-Coudray A, Guerra A, et al. Ovarian-Adnexal Reporting Data System Magnetic Resonance Imaging (O-RADS MRI) Score for Risk Stratification of Sonographically Indeterminate Adnexal Masses. *JAMA Netw Open.* 2020 Jan 3;3(1):e1919896.

11. Nunes N, Ambler G, Foo X, Naftalin J, Widschwendter M, Jurkovic D. Use of IOTA simple rules for diagnosis of ovarian cancer: meta-analysis. *Ultrasound Obstet Gynecol.* 2014 Nov;44(5):503-14.
12. Hiett AK, Sonek J, Guy M, Reid TJ. Performance of IOTA Simple Rules, Simple Rules Risk assessment, ADNEX model and O-RADS in discriminating between benign and malignant adnexal lesions in North American population. *Ultrasound Obstet Gynecol.* 2021 Sep 17.
13. Wilson MP, Katlariwala P, Low G. Solid Hypoechoic Adnexal Lesions with Acoustic Shadowing Warrant an MRI Recommendation in the O-RADS Risk Stratification and Management System. *Radiology.* 2020 Jul;296(1):E11-E13.
14. Sadowski EA, Maturen KE, Rockall A, Reinhold C, Addley H, Jha P, Bharwani N, Thomassin-Naggara I. Ovary: MRI characterisation and O-RADS MRI. *Br J Radiol.* 2021 Sep 1;94(1125):20210157.
15. Reinhold C, Rockall A, Sadowski EA, Siegelman ES, Maturen KE, et al. Ovarian-Adnexal Reporting Lexicon for MRI: A White Paper of the ACR Ovarian-Adnexal Reporting and Data Systems MRI Committee. *J Am Coll Radiol.* 2021 May;18(5):713-729.