



ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

DEPARTMENT OF RADIOLOGY AND MRT

**Intermodality concordance of O-RADS US and MRI in patients
with adnexal-ovarian lesions at St. Paul's Hospital Millennium
Medical College, Addis Ababa, Ethiopia**

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Addis Ababa, Ethiopia

June, 2024

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Abstract

Background: Ovarian cancer is a common and complex disease affecting predominantly postmenopausal women worldwide. Early disease is characterized by asymptomatic or non-specific symptoms; therefore, imaging plays a crucial role in accurate discrimination of benign vs. malignant adnexal masses, thereby early detection of ovarian cancer. For this US and MRI evaluation, the major imaging modalities with ORADS-US and MRI, which are widely accepted lexicons for accurate characterization of ovarian-adnexal lesions.

Objective: To examine the intermodality concordance of O-RADS US and MRI among patients presenting with adnexal-ovarian lesions at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia.

Methods: An institutional based retrospective cross sectional study of patients record review was conducted at selected hospital in Addis Ababa, Ethiopia. Data were entered and analyzed using Statistical Package for Social Science (SPSS) version 26. Descriptive analysis was used to generate frequencies, mean and standard deviations for background characteristics. Percent agreement and Cohen's Kappa statistic were used to quantify the level of inter-modality agreement. Additionally, Pearson's chi square test and two-tailed point-biserial correlation coefficient (ρ) were used to evaluate the association of potential factors with inter-modality agreement.

Results: A total of 225 women with adnexal masses were included in this study, with a subset of 60 women having both US and MRI. Overall, the median age was 37, with an interquartile range of 29 to 47 years. The agreement between the two approaches for assigning a specific risk group was substantial ($\kappa = 0.67$ with a percentage of agreement of 75% and weighted $\kappa = 0.79$ with a percentage agreement of 91.7%). No statistically significant association of menopausal status ($\chi^2 = 0.043$; $p = 0.836$) and lesion size ($\rho = 1.30$; $p = 0.320$) with inter-modality agreement was observed.

Conclusion: US and MRI had substantial concordance for assigning a specific risk group, with minimal disagreement. While this finding deserves further research, ultrasonographic studies may offer a reasonable diagnostic alternative when the administration of MRI is not possible.

Keywords: adnexal mass; ultrasound; MRI; concordance; O-RADS

Acronyms/Abbreviations

IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging
O-RADS	Ovarian-Adnexal Reporting and Data System
OC	Ovarian Cancer
PI	Principal Investigator
RIS	Radiologic Information System
SPHMMC	St. Paul's Hospital Millennium Medical College
SPSS	Statistical Package for Social Sciences
US	Ultrasound

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1. Introduction

1.1 Background

Ovarian cancer is a complex disease primarily observed in postmenopausal women, associated with poor survival rates. It ranks as the sixth most common cancer and the fifth leading cause of cancer-related deaths among women in developed countries. Despite representing less than one-third of all gynecologic cancers, ovarian cancer accounts for more than two-thirds of gynecologic cancer deaths. Its prevalence is higher in Western Europe and Northern America compared to Asia and Africa. Notably, sub-Saharan Africa shows considerably lower prevalence than other regions of Africa. Unlike some female cancers with early warning symptoms, ovarian cancer's symptoms are nonspecific, often leading to late-stage detection (III or IV). Major risk factors include older age, genetics, family history, hormone replacement therapy, nulliparity, and dietary fat (1–3).

Early detection of ovarian cancer is crucial for improving patient survival rates. Unfortunately, early-stage disease is often asymptomatic, or associated with nonspecific symptoms, leading to delayed presentation and diagnosis. As well, population screening remains unproven. Adnexal-ovarian masses may be incidentally detected, but most are identified through ultrasonography (US) in symptomatic patients, with characterization as benign or malignant. Unlike lesions in other body parts, biopsy is not performed in adnexal masses without evidence of peritoneal disease to avoid potential iatrogenic up-staging. Thus, accurate imaging characterization and risk stratification of adnexal masses are crucial in determining the appropriate treatment pathway (4,5).

An accurate discrimination between benign and malignant ovarian lesions is of paramount importance in gynecologic management (6). The precise characterization of adnexal lesions can significantly impact patient care and treatment outcomes. Indeed, accurate characterization helps prevent unnecessary surgical interventions in cases where the lesion is determined to be benign (7). Unwarranted surgeries can lead to increased morbidity, prolonged hospital stays, and higher healthcare costs. For women of reproductive age, preserving fertility is a critical concern. Accurate characterization allows clinicians to make informed decisions about fertility-sparing

treatments when dealing with benign lesions, thereby safeguarding the patient's ability to conceive in the future (7,8).

Therefore, imaging aims to triage patients appropriately, avoiding unnecessary or extensive surgery and expediting evaluation of potential ovarian cancer cases. Ultrasound is the primary method for diagnosing mass-forming adnexal lesions, with high sensitivity and specificity. MRI complements ultrasound, especially in cases of indeterminate or suspicious ultrasound findings and for staging such lesions. MRI exhibits higher positive predictive value compared to ultrasound in diagnosing ovarian cancer (9–11).

1.2 Statement of the problem

The prevalence of ovarian cancer rises markedly with increased age and is an insidious disease that affects one out of every 74 women worldwide. The mortality rate of OC is higher than any other female reproductive cancer. GLOBOCAN estimates indicate there were 314 000 women diagnosed with ovarian cancer in 2020 and 207 000 ovarian cancer deaths, with the disease ranking eighth in terms of both cancer incidence and mortality among women worldwide. Globally, around 428000 new ovarian cancer cases and 307000 deaths are predicted to occur in 2040, assuming no annual change in the incidence rates from the baseline year 2020 (2,3)]. A global annual decline of 2% in incidence and mortality rates would be required to reduce the burden by around 30% in 2040. Nearly 100% increase in cases and deaths is expected to occur in 2040 for the low income countries, while approximately 20% to 30% increase in cases and deaths are expected for very high countries. Ovarian cancer is also one of the most common cancers of women in sub-Saharan Africa with few population level survey (3,5).

Ovarian cancer mortality rates exhibit much less variability worldwide in part due to the relatively poor prognosis associated with ovarian cancer in transitioning economies. Ovarian cancer mortality has been decreasing over time in high income settings, but the trends are generally less pronounced relative to incidence (9). Majority of women are diagnosed with advanced stage cancer with poor prognosis, which is partly driven by delay in diagnosis and unequal access to quality care (4,5,12).

Therefore, accurate imaging assessment of complex adnexal masses is essential for timely diagnosis and appropriate treatment planning. Despite advancements in

imaging technology and the introduction of standardized reporting systems like O-RADS US and MRI, GI-RADS, ADNEX . The degree of intermodality concordance between US and MRI in adnexal-ovarian lesions remains under studied both globally and regionally. Discordance between modalities may lead to diagnostic ambiguity and impact patient management decisions (13).

1.3 Significance of this study

This study aims to evaluate the level of agreement or intermodality concordance between O-RADS US and MRI in characterizing adnexal-ovarian lesions. By doing so, it is expected to contribute significantly to the body of knowledge about O-RADS, particularly from an Ethiopian perspective. Additionally, the research will provide valuable data for interested researchers in developing countries. By contributing to the global understanding of complex adnexal-ovarian masses, this study will facilitate collaborative efforts aimed at improving diagnostic and management strategies worldwide. Shedding light on integrating O-RADS US and MRI into the daily work of radiologists is crucial for optimizing patient care. Understanding the concordance between these modalities will help streamline diagnostic workflows and improve treatment planning for patients with complex adnexal-ovarian masses.

2. Literature review

2.1 Role of O-RADS in adnexal-ovarian masses

The Ovarian-Adnexal Reporting and Data System (O-RADS) is a lexicon and risk stratification tool designed for the accurate characterization of adnexal lesions and is essential for optimal patient management (14). O-RADS is a recent addition to the American College of Radiology (ACR) reporting and data systems and consists of ultrasound (US) and MRI arm. Though other ovarian lesion characterization and management systems for US have been proposed including, O-RADS is unique given its dual US and MRI arms, common lexicon, and data-supported risk stratification that provides an ROM to providers and patients (15,16).

Since most ovarian or adnexal lesions are first detected with US, O-RADS US is considered the primary assessment tool (11). The O-RADS lexicon for US was published in 2018 and updated in 2022, providing a standardized lexicon that includes all pertinent descriptors and definitions of the characteristic US appearance of normal ovaries and ovarian or other adnexal lesions. Based on expert opinion, the O-RADS US working group defined six categories for risk classification. These include O-RADS 0, an incomplete evaluation; O-RADS 1, the physiologic category (normal premenopausal ovary); O-RADS 2, the almost certainly benign category (<1% risk of malignancy); O-RADS 3, lesions with low risk of malignancy (1% to <10%); O-RADS 4, lesions with intermediate risk of malignancy (10% to <50%); and O-RADS 5, lesions with high risk of malignancy ($\geq 50\%$) (15–17).

The ACR O-RADS MRI lexicon includes standardized terms and definitions for assessing and reporting adnexal lesions, whereas the O-RADS MRI risk stratification system provides a data-driven means for assigning probability of malignancy. There are six risk score categories in the O-RADS MRI risk stratification system: O-RADS MRI 0 (incomplete examination), O-RADS MRI 1 (normal ovaries, including follicles and corpus luteal cysts), O-RADS MRI 2 (almost certainly benign; PPV <0.5%), O-RADS MRI 3 (low risk; PPV approximately 5%), O-RADS MRI 4 (intermediate risk; PPV approximately 50%), and O-RADS MRI 5 (high risk; PPV approximately 90%) (17,18).

The overall accuracy of the O-RADS MRI risk score in the study by Sadowski et al. was 92%, with a sensitivity of 93%, specificity of 91%, PPV of 71%, and negative predictive value of 98% (11).

2.2 Diagnostic performance of ORADS US and MRI

In the literature, few studies discussed the performance of the ORADS MRI and US with emphasis on concordance, one of them a retrospective study carried out by Guo et al at Brigham and Women's Hospital, UK, with the aim of examining interreader agreement and intermodality concordance of O-RADS US and MRI in patients who received both pelvic US and MRI and had complicated adnexal masses between July 2017 and June 2020. Seven patients were postmenopausal out of 58 with complicated adnexal cysts with an average age of 37 years. A different group of radiologists examined the MRI and US. Finding: There was a significant positive correlation ($t:0.72$, $P<0.001$) between MRI and US. There was a fair interreader agreement ($k:0.31$). The highest threshold for malignancy was found using O-RADS 4. In evaluating complex adnexal lesions, the study found that both US and MRI had excellent diagnostic accuracy and moderate agreement between O-RADS US and MRI (19).

O-RADS US and MRI performance in adnexal lesions were also the subject of a systematic review and metanalysis by Qing Z et al. from AJR. Twenty-six studies totaling 9520 patients were examined; 15 of them evaluated O-RADS US, 12 evaluated O-RADS MRI, and 1 evaluated both O-RADS US and MRI. For O-RADS US, their pooled sensitivity and specificity were 95% (95% CI) and 82% (95% CI) for O-RADS US, and 95% (95% CI) and 90% (95% CI) for O-RADS MRI. They came to an end that both O-RADS MRI and O-RADS US have excellent sensitivity for ovarian or adnexal cancer. O-RADS US lacks the high specificity of O-RADS MRI (20).

In another study, Huiming W et al. conducted a retrospective study on Chinese pediatric cohorts to examine diagnostic performance and interobserver agreement with respect to O-RADS US and MRI. From O-RADS 2 to ORADS 5, they assessed 163 adnexal masses in total, all of which were verified by histopathology. They came to the conclusion that children with adnexal-ovarian lesions can be diagnosed with ORADS MRI and US (21).

In Egypt, Mansour et al. from Al-azhar University Hospital, conducted a study titled "correlation of US and MRI in patients with ovarian masses." 250 patients were involved in the trial, which ran from March 2017 to March 2018. The US has a sensitivity of 81.51% and a specificity of 93.9%. With a sensitivity of 96.43% and a specificity of 95.83%, MRI performed better. They highlighted MRIDWI, which demonstrated 100% sensitivity and 93% specificity in detecting ovarian cancerous processes (22).

3. Objective of study

3.1 General objective

- To evaluate intermodality concordance of ORADS-US and MRI in patients with complex adnexal masses at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

3.2 Specific objective

- To describe the imaging features of adnexal-ovarian lesions at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia
- To assess the concordance between ORADS US and MRI at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

4. Methods and Materials

4.1 Study area

The study was conducted at St. Paul's Hospital Millennium Medical College (SPHMMC), one of the largest government hospitals located in Addis Ababa, the capital city of Ethiopia. The college has more than 2800 clinical, academic and administrative and supporting staffs that provide medical specialty service to patients who are referred from all over the country. Built in 1969, the hospital serves about 200,000 patients annually on average, with a catchment population of more than 5 million. On top of this, this referral hospital is a teaching center for both undergraduate and postgraduate health science students. The hospital has more than 700 beds dedicated to inpatient service (23).

4.2 Study period

The study period was from March 1st, 2023 to May 31st, 2024

4.3 Study design

A facility-based, cross-sectional study was used.

4.4 Population

4.4.1 Source population

All female patients with adnexal-ovarian masses attended and recorded in RIS at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

4.4.2 Study population

All female patients with adnexal-ovarian masses imaged at the Department of Radiology of St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia during the study period with documented ORADS US and MRI.

4.5 Eligibility criteria

4.5.1 Inclusion criteria

- All female patients with adnexal-ovarian masses who undergone imaging (US and MRI) and recorded data in the RIS at SPHMMC.

4.5.2 Exclusion criteria

- Patients with radiological diagnosis imaged but incomplete recorded data in the RIS
- Pelvic lesion clearly identified as non-ovarian or tubal in origin

4.6 Sampling technique and sample size

- All female patients with adnexal-ovarian masses within the study period and who have either or both MRI and US were included in the study.

4.7 Sampling technique

The study will use all female patients with radiological imaging and recorded in RIS at SPHMMC during the study period.

4.8 Data collection tools and procedures

Data were collected by the principal investigator using data extraction format. All patients with clinical diagnosis of adnexal-ovarian masses seen at radiology US and MRI units were identified from the daily registry. Patient's card collected from archives and RIS. All data regarding demographic, clinical information and imaging result were retrieved from the chart, reports and RIS.

4.9 Operational definitions

4.9.1 O-RADS MRI:

The Ovarian-Adnexal Reporting and Data System (O-RADS) MRI is a standardized reporting system by the American College of Radiology (ACR) for evaluating ovarian and adnexal lesions using MRI. It includes a lexicon for describing imaging characteristics and a risk stratification system to estimate malignancy probability:

- 🚩 **O-RADS MRI 1:** Normal findings.
- 🚩 **O-RADS MRI 2:** Almost certainly benign (risk <0.5%).
- 🚩 **O-RADS MRI 3:** Low risk (~5%).
- 🚩 **O-RADS MRI 4:** Intermediate risk (~50%).
- 🚩 **O-RADS MRI 5:** High risk (~90%).

4.9.2 O-RADS US

The Ovarian-Adnexal Reporting and Data System (O-RADS) US is a standardized reporting system by the ACR for evaluating ovarian and adnexal lesions using

ultrasound. It also includes a lexicon for describing imaging characteristics and a risk stratification system to estimate malignancy probability:

- ✚ **O-RADS US 1:** Normal premenopausal ovaries.
- ✚ **O-RADS US 2:** Almost certainly benign (risk <1%).
- ✚ **O-RADS US 3:** Low risk (1% to <10%).
- ✚ **O-RADS US 4:** Intermediate risk (10% to <50%).
- ✚ **O-RADS US 5:** High risk ($\geq 50\%$).

4.10 Data analysis and interpretation

Data were entered and cleaned in Epi Info for windows version 3.5.1 and exported to SPSS version 26 statistical software for analysis. Frequency, proportion, mean with standard deviation were generated to describe the data used. Unweighted and weighted percent agreement and Cohen's Kappa statistic were used to quantify the level of agreement between each ORADS-US and MRI category. The level of agreement was based on the indices suggested by Cohen, as follows: values ≤ 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement. Additionally, Pearson's chi square test and two-tailed point-biserial correlation coefficient (ρ) were used to evaluate the association of potential factors with inter-modality agreement as appropriate.

4.11 Study variables

4.11.1 Dependent variable

- ORADS-MRI and ORADS-US

4.11.2 Independent variables

- Age
- Female
- Menstrual status
- Lesion characteristics such as size.
- Expertise of reviewer

- Imaging equipment and technique

4.12 Data quality management

An English version checklist was used to collect data. Brief training for the data collectors (two health professionals) about the process of data collection was given before the process of data collection. Close supervision was maintained during data collection and filled checklists were double-checked daily for consistency and completeness by data collectors and the principal investigator before proceeding to statistical analysis.

4.13 Ethical consideration

Ethical clearance was obtained from IRB of SPHMMC. A support letter was submitted to the director of the study hospitals from the Department of Radiology to proceed with the study. Following this step, the data collectors were introduced with the onsite practitioners. The collected data were kept anonymous and confidential.

4.14 Dissemination of the study findings

The findings of this study will be submitted to the Department of Radiology of SPHMMC as a partial fulfillment of the specialty certificate in Clinical Radiology. The findings will also be presented and disseminated to other concerned stakeholders through presentation in different workshops and seminars. Finally, the manuscript will be submitted to a peer-reviewed scientific journal for possible publication.

5. Results

5.1 General characteristics

The study evaluated a total of 225 women with adnexal masses. Over half of women were between the ages of 25-44yrs (n=116, 51.6%) (Fig.1). Majority (n=94, 41.8%) were from Oromia, followed by Addis Ababa (n=44, 19.6%), closely followed by Amhara and Tigray (Fig.2). More than two-thirds (n=155, 68.9%) were married, with only 22 (9.8%) were either widowed or divorced (Table 1).

A total of 171 (76%) women were premenopausal, while 54 women (24%) were postmenopausal. A little more than half (115, 51.1%) of the women had left-sided adnexal mass. Majority (128, 56.9%) of the women had small adnexal mass, with lesions ranging from 3.2cm to 20cm in size with majority of women having lesions less than 5cm(n=128, 56.9%)(Table 1).

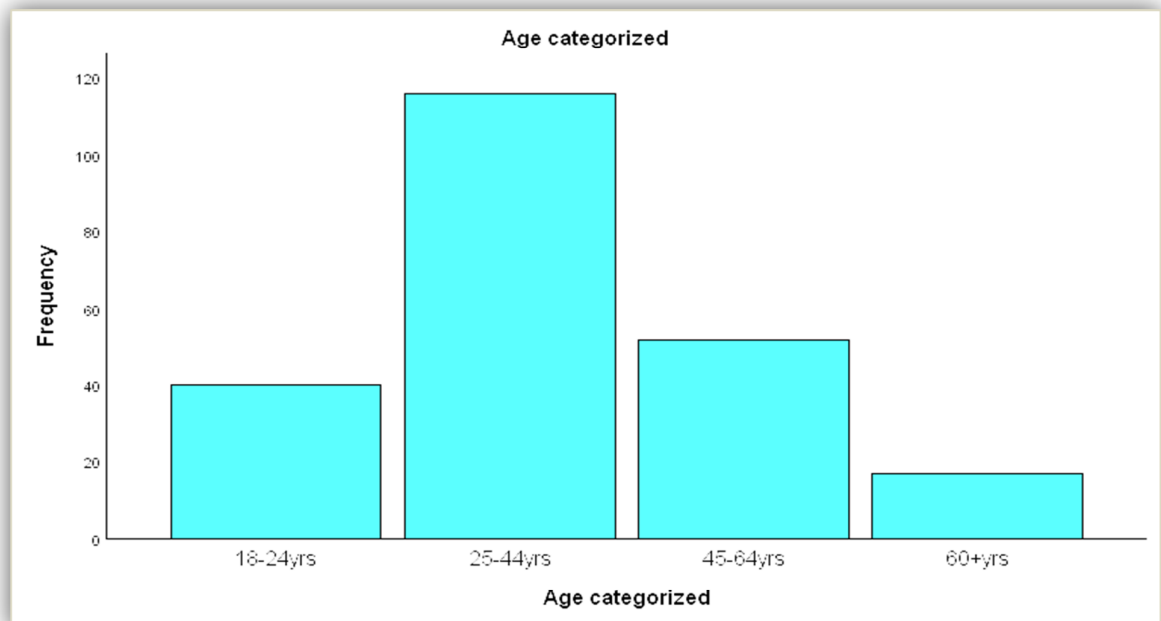


Figure1: Distribution of age groups

Table 1. General characteristics of women with adnexal-ovarian masses who underwent imaging at the Department of Radiology of St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Variable	Frequency	Percent (%)
Age group		
18-24 years	40	17.8
25-44 years	116	51.6
45-64 years	52	23.1
65+yrs	17	7.6
Residence		
Addis Ababa	44	19.6
Oromia	94	41.8
Amhara	31	13.8
Tigray	32	14.2
Others	24	10.7
Marital status		
Unmarried	48	21.3
Married	155	68.9
Widowed/Divorced	22	9.8
Menstrual status		
Premenopausal	171	76.0
Postmenopausal	54	24.0
Laterality		
Right	110	48.9
Left	115	51.1
Size		
<5 cm	128	56.9
≥5 cm	97	43.1

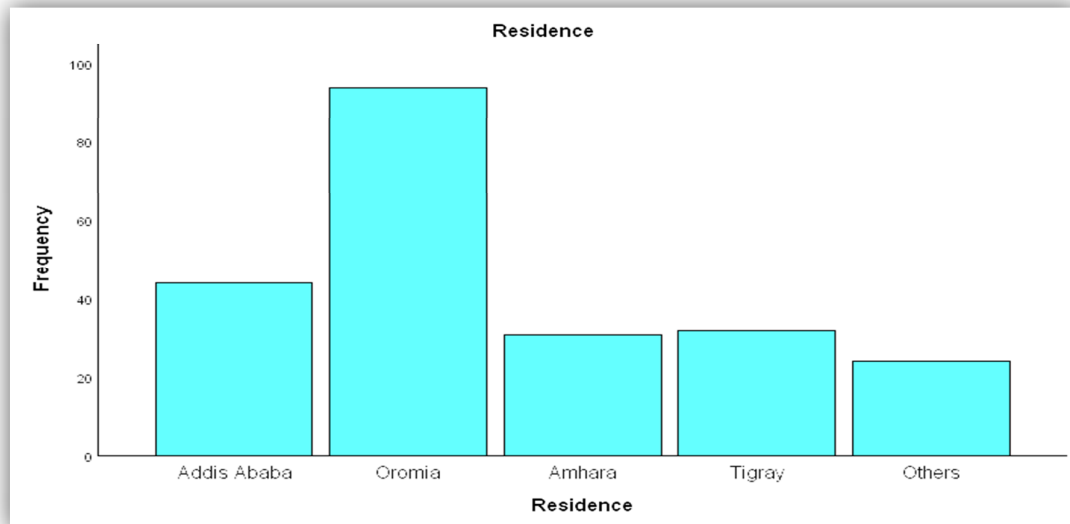


Figure 2: Distribution of residence

5.2 Intermodality concordance

Out of the 225 patients studied, a subset of 60 patients underwent both O-RADS US and MRI. Among these 60 patients, the majority of adnexal-ovarian lesions were located on the right side (n=37, 61.7%). The lesion sizes ranged from 3.6 cm to 20 cm, with a mean size of 8.7 cm. Most lesions measured between 5 cm and 10 cm (see Fig. 3).

The distribution of ORADS US scores showed that the majority of patients were classified with a score of 3(n=18, 30.0%), followed by a score of 4(n=17, 28.3%). The least frequent score was 2, assigned to 20.0% (n=12) of the patients. Likewise, the distribution of ORADS MRI scores showed that the highest proportion of patients were classified with a score of 3(n=21, 35.0%). This is followed by patients who received a score of 5(n=17, 28.3%), and 21.7 % (n=13) with a score of 2. The least frequent score was 4(n=9, 15.0%). This indicates a varied distribution of both ORADS MRI and US scores among the patients studied, with the majority of scores being 3 in both modalities.

An inter-modality reliability analysis was performed between the dependent samples of O-RADS according to ultrasonography and MRI. The agreement between the two approaches for assigning a specific risk group was substantial (Cohen's kappa statistic: 0.67), with a percentage of agreement of 75%. More interestingly, the weighted kappa statistic was even higher, indicating a near-perfect agreement between the two imaging modalities (weighted kappa statistic: 0.79), with a corresponding weighted percent agreement of 91.7% (Table 2).

Most disagreements occurred for the group O-RADS 5 (29.4% of the cases classified as O-RADS 5 by MRI were classified as ORADS 4 by US) and for the groups O-RADS 3 (28.6% of the cases classified as O-RADS 3 by MRI were classified as O-RADS 4 by US). In other words, six lesions that were assessed as ORADS-4 at US were correctly downgraded to O-RADS 3 by using findings at MRI while five lesions were upgraded from O-RADS 4 at US to O-RADS 5 by MRI (Table 2).

Table 2. Inter-modality agreement and distribution of cases of O-RADS risk group according to the modality used among women with adnexal-ovarian masses who underwent imaging at the Department of Radiology of St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

		O-RADS according to MRI			
		O-RADS 2	O-RADS 3	O-RADS 4	O-RADS 5
O-RADS according to ultrasonography	O-RADS 2	12	0	0	0
	O-RADS 3	1	15	2	0
	O-RADS 4	0	6	6	5
	O-RADS 5	0	0	1	12
Percent agreement		75.0%			
Weighted percent agreement		91.7%			
Kappa index		0.67			
Weight kappa index		0.79			
		P<0.001			
		P<0.001			

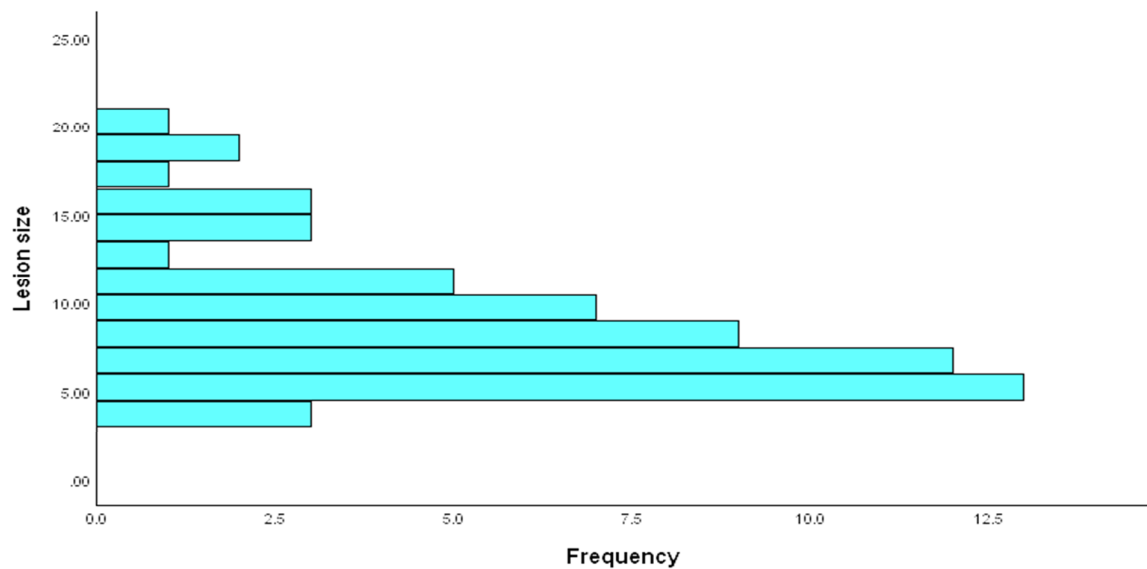


Figure 3: Distribution of lesion size

5.3 Factors associated with inter-modality concordance

Pearson's chi square test and two-tailed point-biserial correlation coefficient (ρ) were used to evaluate the association of menopausal status and lesion size with inter-modality agreement. We did not find statistically significant association of menopausal status ($\chi^2 = 0.043$; $p = 0.836$) and lesion size ($\rho = 1.30$; $p = 0.320$) with inter-modality agreement (Table 3).

Table 3. Factors associated with inter-modality agreement among women with adnexal-ovarian masses who underwent imaging at the Department of Radiology of St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Variable		Inter-modality agreement		Test value	P value
		Yes (%)	No (%)		
Menopausal status ^χ	Premenopausal	29(72.5%)	11(27.5%)	0.043	0.836
	Postmenopausal	15(75.0%)	5(25.0%)		
Size (mean±SD) [€]		7.91±2.58	9.09±4.43	1.30	0.320

χ: Chi square Test, €: Point-biserial correlation coefficient

6. Discussion

The current study was conducted to evaluate intermodality concordance of ORADS-US and MRI in women with adnexal masses. Consequently, the agreement between the two approaches for assigning a specific risk group was substantial, with an even higher level of agreement according to weighted analysis. Additionally, the agreement between the two approaches for assigning a specific risk group was independent of the patient characteristics considered.

More precisely, this study demonstrated that the agreement between US and MRI for assigning a specific risk group was substantial ($k = 0.666$). This was relatively higher than what was obtained by Guo et al. who observed a moderate agreement between the two imaging modalities, with a corresponding k coefficient of 0.58 (19). The present finding is different from the previous report in which the proportion indeterminate masses on US (O-RAD score of 4) decreased by 87.5 to 89.2% (24).

Of note, the weighted kappa coefficient (relative to the unweighted kappa statistic) demonstrated a better intermodality concordance, indicating a low level of disagreement between the two imaging techniques. In other words, the higher value of the weighted kappa statistic can be explained by the low magnitude of disagreements, which means that the disagreements are more likely to be by only one category rather than several categories (25).

The possible justifications for differences in agreement between ultrasound (US) and magnetic resonance imaging (MRI) across different studies can be attributed to several factors, and they include specific parameters being measured, the quality and resolution of the images obtained, operator experience and technique, and methodological differences. Moreover, the differences in clinical characteristics of the patients, such as maternal body mass index (BMI), may also contribute to the differences in the agreement levels.

Another pertinent finding observed in this study was that a significant proportion of patients ($n=5$) had their lesions upgraded from O-RADS 4 at US to O-RADS 5 by MRI. This upgrading means that the lesions were initially considered to have an intermediate risk of malignancy (O-RADS 4) on ultrasound but were reclassified as having a high risk of malignancy (O-RADS 5) on MRI, highlighting the added value of MRI in correctly reclassifying lesions that were initially considered suspicious but benign on ultrasound (24,26,27).

In other words, in concordance with previous reports (19), when using ORADS 4 as a cutoff for potential malignancy, findings at MRI enabled the upgrading of significant proportion of lesions to potentially malignant, confirming the value of MRI as a supplemental tool to further evaluate O-RADS US 3 or 4 lesions, which may alter the management pathway (24). The O-RADS scoring system relies on the probability of malignancy, making it useful in various clinical settings (16,24). O-RADS 4 or 5 is linked to a higher likelihood of malignancy. Therefore, patients should be directed to specialized centers for further evaluation and treatment (28).

Additionally, the level of agreement between the two diagnostic methods for assigning a specific risk group was independent of certain patient characteristics such as lesion size and menopausal status. This finding confirms the fact that the O-RADS score is designed to be a patient-independent system that focuses on the morphological features of the adnexal mass, which is why it does not depend on patient characteristics like lesion size and menopausal status for assigning a specific risk group. It is also supported by previous studies reporting that the O-RADS MRI score has high sensitivity (93%) and specificity (91%) for stratifying the risk of malignancy in adnexal masses, regardless of patient characteristics like lesion size and menopausal status (29,30).

Furthermore, this finding is supported by the fact that the presence of enhancing solid tissue is the critical factor in determining the risk level of an adnexal lesion on MRI, while size is not a primary consideration for certain cystic lesions. For instance, size does not play a role in MRI categorization of cysts with endometriotic or lipid fluid, which is considered as O-RADS MRI category 2, while classic-appearing endometrioma or dermoid cysts 10 cm or larger are considered O-RADS US 3 (31,32).

7. Strengths and Limitations

7.1 Strengths

- The study was conducted at the leading tertiary healthcare center of the country, where a relatively high number of patients with adnexal masses, with varying socio-demographic characteristics, are expected to be represented.
- The author considered weighted kappa statistic in order to account for the relative importance of disagreements and provide a more detailed and accurate assessment of inter-modality agreement.

7.2 Limitations

- The current study was conducted at a single center, making it challenging to generalize to other populations with varying socio-demographic characteristics and healthcare infrastructure.
- Being a secondary data-based study, some important particulars (specifically MRI results) in patients' clinical records were missing, and the exclusion of incomplete medical records in the inter-modality agreement analysis has resulted in a smaller sample size, which might have compromised the statistical power.
- The study did not include certain parameters such as laparoscopic observation and histopathological examination, which are considered the gold standard for the specific diagnosis of adnexal masses.

8. Conclusion and Recommendations

8.1 Conclusion

In this study, the agreement between the two modalities for assigning a specific risk group among women with adnexal masses was appreciable, ranging from substantial to near-perfect. Thus, ultrasonography studies may offer a reasonable diagnostic alternative when the administration of MRI is not possible. Additionally, the agreement between the two approaches for assigning a specific risk group was independent of certain patient characteristics such as mass size and menopausal status.

8.2 Recommendations

For radiologists,

Ultrasound can be a viable diagnostic alternative for women with adnexal masses, particularly when MRI is not possible or necessary, such as in benign adnexal masses. Moreover, for women with sonographically indeterminate to suspicious (potentially malignant) neoplasms, MRI can be used as a second-line technique and an adjunct to US for more accurate diagnosis. This will help detecting potentially malignant neoplasms, while also significantly reducing unnecessary or inappropriately extensive surgical interventions, iatrogenic fertility complications, as well as morbidity. While these findings support the current framework of the O-RADS system, additional radiologist education, particularly for US specialists, may be required to improve inter-modality agreement and overall accuracy.

For researchers,

Future researches should be multicentered, and compare imaging results against histopathological analysis to generate exact sensitivity and specificity indices of each modality.

References

1. Ali AT, Al-Ani O, Al-Ani F. Epidemiology and risk factors for ovarian cancer. *Prz Menopauzalny*. 2023;22(2):93–104.
2. Reid F. The World Ovarian Cancer Coalition Atlas 2023. 2023;2023(March):5–28.
3. Cabasag CJ, Fagan PJ, Ferlay J, Vignat J, Laversanne M, Liu L, et al. Ovarian cancer today and tomorrow: A global assessment by world region and Human Development Index using GLOBOCAN 2020. *Int J Cancer*. 2022;(March):1535–41.
4. Coburn SB, Bray F, Sherman ME, Trabert B. International patterns and trends in ovarian cancer incidence, overall and by histologic subtype. *Int J Cancer* [Internet]. 2017 Jun 1;140(11):2451–60. Available from: <https://onlinelibrary.wiley.com/doi/10.1002/ijc.30676>
5. Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2023. *CA Cancer J Clin*. 2023;73(1):17–48.
6. Jha P, Gupta A, Baran TM, Maturen KE, Patel-Lippmann K, Zafar HM, et al. Diagnostic Performance of the Ovarian-Adnexal Reporting and Data System (O-RADS) Ultrasound Risk Score in Women in the United States. *JAMA Netw Open*. 2022;5(6):E2216370.
7. Dabi Y, Rockall A, Sadowski E, Touboul C, Razakamanantsoa L, Thomassin-Naggara I. O-RADS MRI to classify adnexal tumors: from clinical problem to daily use. *Insights Imaging*. 2024;15(1).
8. Atri M, Alabousi A, Reinhold C, Akin EA, Benson CB, Bhosale PR, et al. ACR Appropriateness Criteria ® Clinically Suspected Adnexal Mass, No Acute Symptoms. *J Am Coll Radiol* [Internet]. 2019;16(5):S77–93. Available from: <https://doi.org/10.1016/j.jacr.2019.02.011>
9. Mohaghegh P, Rockall AG. Imaging strategy for early ovarian cancer: Characterization of adnexal masses with conventional and advanced imaging

techniques. *Radiographics*. 2012;32(6):1751–73.

10. Strachowski LM, Jha P, Phillips CH, Blanchette Porter MM, Froyman W, Glanc P, et al. O-RADS US v2022: An Update from the American College of Radiology's Ovarian-Adnexal Reporting and Data System US Committee. *Radiology*. 2023;308(3).
11. Sadowski EA, Stein EB, Thomassin-Naggara I, Rockall A, Nougaret S, Reinhold C, et al. O-RADS MRI After Initial Ultrasound for Adnexal Lesions: AJR Expert Panel Narrative Review. *Am J Roentgenol*. 2023;220(1):6–15.
12. Zhang S, Cheng C, Lin Z, Xiao L, Su X, Zheng L, et al. The global burden and associated factors of ovarian cancer in 1990-2019: findings from the Global Burden of Disease Study 2019. *BMC Public Health* [Internet]. 2022;22(1):1455. Available from: <https://doi.org/10.1186/s12889-022-13861-y>
13. Hiatt AK, Sonek JD, Guy M, Reid TJ. Performance of IOTA Simple Rules, Simple Rules risk assessment, ADNEX model and O-RADS in differentiating between benign and malignant adnexal lesions in North American women. *Ultrasound Obstet Gynecol* [Internet]. 2022 May;59(5):668–76. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/34533862>
14. Andreotti RF, Timmerman D, Benacerraf BR, Bennett GL, Bourne T, Brown DL, 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* [Internet]. 2018;15(10):1415–29. Available from: <https://doi.org/10.1016/j.jacr.2018.07.004>
15. Andreotti RF, Timmerman D, Strachowski LM, Froyman W, Benacerraf BR, Bennett GL, et al. O-RADS US Risk Stratification and Management System: A Consensus Guideline from the ACR Ovarian-Adnexal Reporting and Data System Committee. *Radiology* [Internet]. 2020 Jan;294(1):168–85. Available from: <http://pubs.rsna.org/doi/10.1148/radiol.2019191150>
16. Sadowski EA, Thomassin-Naggara I, Rockall A, Maturen KE, Forstner R, Jha P, et al. O-RADS MRI Risk Stratification System: Guide for Assessing

- Adnexal Lesions from the ACR O-RADS Committee. *Radiology*. 2022;303(1):35–47.
17. Elias J, de Souza LRMF. O-RADS: the evolution of the ovarian lesion classification system. *Radiol Bras*. 2022;55(4):V–VI.
 18. Strachowski LM, Jha P, Chawla TP, Davis KM, Dove CK, Glanc P, et al. O-RADS for ultrasound: A user's guide, from the AJR special series on radiology reporting and data systems. *Am J Roentgenol*. 2021;216(5):1150–65.
 19. Guo Y, Phillips CH, Suarez-Weiss K, Roller LA, Frates MC, Benson CB, et al. Interreader Agreement and Intermodality Concordance of O-RADS US and MRI for Assessing Large, Complex Ovarian-Adnexal Cysts. *Radiol Imaging Cancer*. 2022;4(5).
 20. Zhang Q, Dai X, Li W. Systematic Review and Meta-Analysis of O-RADS Ultrasound and O-RADS MRI for Risk Assessment of Ovarian and Adnexal Lesions. *Am J Roentgenol*. 2023;221(1):21–33.
 21. Wang H, Wang L, An S, Ma Q, Tu Y, Shang N, et al. American college of radiology ovarian-adnexal reporting and data system ultrasound (O-RADS): Diagnostic performance and inter-reviewer agreement for ovarian masses in children. *Front Pediatr*. 2023;11(March):1–8.
 22. Mansour TMM, Tawfik MH, El-Barody MM, Sileem SA, Okasha A. Correlation between ultrasound and Magnetic Resonance Imaging in diagnosis of Ovarian Tumors. *OPEN AIMJ* [Internet]. May; Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21477775>
 23. Wikipedia. St. Paul's Hospital Millennium Medical College.
 24. Thomassin-Naggara I, Poncelet E, Jalaguier-Coudray A, Guerra A, Fournier LS, Stojanovic S, 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;3(1):1–14.

25. Sim J, Wright CC. The kappa statistic in reliability studies: Use, interpretation, and sample size requirements. *Phys Ther.* 2005;85(3):257–68.
26. Campos A, Villerman-Lécolier C, Sadowski EA, Bazot M, Touboul C, Razakamanantsoa L, et al. O-RADS scoring system for adnexal lesions: Diagnostic performance on TVUS performed by an expert sonographer and MRI. *Eur J Radiol.* 2023;169(August).
27. Pereira PN, Yoshida A, Sarian LO, Barros RH de O, Jales RM, Derchain S. Assessment of the performance of the O-RADS MRI score for the evaluation of adnexal masses, with technical notes. *Radiol Bras.* 2022;55(3):137–44.
28. Ramadan ZA, Abdelrazek AAK, Denewar FA. Interrater reliability of the ovarian–adnexal reporting and data system magnetic resonance imaging (O-RADS MRI). *Egypt J Radiol Nucl Med.* 2024;55(1).
29. Sahin H, Panico C, Ursprung S, Simeon V, Chiodini P, Frary A, et al. Non-contrast MRI can accurately characterize adnexal masses: a retrospective study. *Eur Radiol.* 2021;31(9):6962–73.
30. Nougaret S, Lakhman Y, Bahadir S, Sadowski E, Thomassin-Naggara I, Reinhold C. Ovarian-Adnexal Reporting and Data System for Magnetic Resonance Imaging (O-RADS MRI): Genesis and Future Directions. *Can Assoc Radiol J.* 2023;74(2):370–81.
31. Bernardin L, Dilks P, Liyanage S, Miquel ME, Sahdev A, Rockall A. Effectiveness of semi-quantitative multiphase dynamic contrast-enhanced MRI as a predictor of malignancy in complex adnexal masses: Radiological and pathological correlation. *Eur Radiol.* 2012;22(4):880–90.
32. Forstner R, Thomassin-Naggara I, Cunha TM, Kinkel K, Masselli G, Kubik-Huch R, et al. ESUR recommendations for MR imaging of the sonographically indeterminate adnexal mass: an update. *Eur Radiol.* 2017;27(6):2248–57.

Figure 1. American College of Radiology (ACR) Ovarian-Adnexal Reporting and Data System (O-RADS) Ultrasound Risk Stratification Table

O-RADS Category Score [IOTA Model]	Risk	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.*
		Classic Benign Lesions	> 5 cm but < 10 cm	Follow up in 8 - 12 weeks	Follow up in 1 year.*
			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 Typical dermoid cysts, endometriomas, hemorrhagic cysts ≥ 10 cm Unilocular cyst, with irregular inner wall (<3 mm height), any size Unilocular cyst with smooth inner walls/septations, < 10 cm, CS = 1-3 Solid lesion with smooth outer contour, any size, CS = 1		US specialist or MRI Management by gynecologist	
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		
		Multilocular cyst with solid component	1-3 papillary projections (pp), or solid component that is not a pp, any size, CS = any		
			Any size, CS = 1-2		
			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	Gyn-oncologist	
			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

The table was reproduced with permission from the American College of Radiology and shows the various risk stratification scores along with respective lesion morphologic descriptors using the O-RADS lexicon and methodology.

ANNEX

O-RADS MRI Risk Stratification and Management System

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

^aApproximate PPV based on data from Thomassin-Naggers et al. O-RADS MRI Score for Risk Stratification of Sonographically Indeterminate Adnexal Masses. JAMA Network Open. 2020;3(1):191986. Please note that the PPV provided applies to the score category overall and not to individual characteristics. Definitive PPV are not currently available for individual characteristics. The PPV values for malignancy include both borderline tumors and invasive cancers.

* Solid tissue is defined as a lesion component that enhances and conforms to one of these morphologies: papillary projection, mural nodule, irregular septation/wall or other “large solid” portion.

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

*** Hemorrhagic Cyst ≤3cm in pre-menopausal woman is O-RADS MRI 1.

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

DWI = diffusion weighted images

MRI = magnetic resonance imaging

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