





High sensitivity of O-RADS ultrasound for predicting malignant ovarian lesions in female pediatric patients: a 10-year review

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ABSTRACT

Introduction: The Ovarian-Adnexal Reporting and Data System (O-RADS) has been useful for risk stratification of malignancy in adult women. However, reports in female pediatric patients are scarce. This study evaluated the diagnostic performance of O-RADS ultrasound (US) in predicting malignant ovarian lesions in female pediatric patients. **Material and methods:** This cross-sectional study included female pediatric patients aged 0 to 17 years with ovarian lesions evaluated by US and histopathology. The O-RADS category, Color score, tumor markers, tumor size, and histological diagnosis were recorded. The diagnostic performance of O-RADS US was analyzed. **Results:** Seventy ovarian lesions in 66 female pediatric patients with a mean age of 12.6 ± 3.5 years were included. Most ovarian lesions were benign ($n = 53, 75.7\%$) while 17 (24.3%) were malignant. O-RADS categories ≥ 3 showed a sensitivity of 94.1% (95% CI, 71.3-99.8) and negative predictive value of 96.0% (95% CI, 78.0-99.4) for detecting malignant lesions. The Doppler Color score ≥ 2 achieved a sensitivity of 100% (95% CI, 80.4-100) and a negative predictive value of 100% (95% CI, 92.2-100) for detecting malignancy. One (5.9%) O-RADS category 3, three (17.6%) category 4, and twelve (70.6%) category 5 lesions were malignant. Among 21 category 4 lesions, three (37.5%) malignant ovarian lesions were subcategory 4B, while none were subcategory 4A. In contrast, among benign ovarian lesions, 13 (100%) were classified as O-RADS subcategory 4A and 5 (62.5%) as 4B. **Conclusion:** O-RADS US categories ≥ 3 as well as Doppler Color scores ≥ 2 showed high sensitivity for differentiating malignant from benign ovarian lesions in female pediatric patients.

Keywords: Ovarian-Adnexal Reporting and Data System. Ovarian neoplasms. Female. Pediatric. Doppler Color. Ultrasound.

INTRODUCTION

Ovarian lesions are rare in the pediatric population, with an estimated incidence of 2.6 cases per 100,000 per year^{1,2}. Although most lesions are benign (75% to 90%), early diagnosis is essential to ensure timely management of malignant cases (10% to 25%)³. Symptoms, such as abdominal pain, abdominal distension, and a palpable mass, are usually nonspecific⁴. Ultrasound (US) is the initial imaging modality of choice due to its accessibility, the absence of ionizing radiation, and

excellent resolution for pelvic structures, especially in children⁵. Color and spectral Doppler US provide additional information about vascularization, helping differentiate benign and malignant lesions⁶. Modalities such as computed tomography and magnetic resonance imaging are reserved for further characterization or staging of ovarian lesions⁷.

Ovarian-Adnexal Reporting and Data System (O-RADS) US⁸ has become a widely validated risk stratification tool for ovarian lesions in adult women⁹⁻¹¹.

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In a clinical decision analysis, O-RADS provided significant benefits for identifying high-risk lesions. Additionally, O-RADS shows a high level of inter-reader agreement ($\kappa = 0.77-0.83$), regardless of radiologists' training level or practical experience^{9,12-14}. Reports regarding the diagnostic performance of O-RADS US in female pediatric patients are scarce^{15,16}. The sensitivity of O-RADS categories 4 and 5 for predicting malignant ovarian lesions has been reported at 94.4%, suggesting that O-RADS is a good tool for differentiating benign from malignant lesions in female pediatric patients^{15,16}. This study evaluated the diagnostic performance of O-RADS US in predicting malignancy in ovarian lesions confirmed histopathologically in female pediatric patients.

MATERIAL AND METHODS

This cross-sectional, retrospective study was conducted from January 2013 to December 2023 in the Department of Radiology and Imaging at the Instituto Nacional de Pediatría, a referral center in Mexico City, Mexico. Female pediatric patients (0-17 years) who underwent US examination with a confirmed diagnosis of ovarian lesion by histopathology were included. Patients with prior pelvic surgery, chemotherapy, radiotherapy, a poor-quality US examination, or incomplete clinical records were excluded. Informed consent was not required, as this was an observational study using information obtained from routine clinical practice. The study was approved by the Institutional Research and Ethics Committees.

Study development and variables

The variables obtained from clinical records included age, and signs and symptoms such as abdominal pain, abdominal distention, heavy menstrual bleeding, and constipation. Laterality, size, and volume of the ovarian lesion; tumor markers, including lactate dehydrogenase (LDH), alpha-fetoprotein (AFP), and the beta subunit of human chorionic gonadotropin (β -hCG), and the surgical specimen pathology result were recorded. US findings were reported according to O-RADS categories and Color score⁸. Histopathologic diagnoses were also reported.

Imaging acquisition and analysis protocol

Pelvic US examination was performed using Philips EPIQ 7G (Philips Healthcare, Amsterdam, The Netherlands)

or General Electric LOGIQ (GE, Milwaukee, WI, USA) scanners with a 3-6 MHz convex transducer following grayscale and color Doppler protocols^{17,18}. Ovarian lesions were classified according to the characteristics defined by the O-RADS US lexicon⁸: categories 3, 4, and 5 were grouped as categories ≥ 3 to differentiate malignant from benign ovarian lesions. Vascularization of the lesion was classified using a qualitative O-RADS Color score as follows: 1, no flow; 2, minimal flow; 3, moderate flow; and 4, abundant or marked flow. Color scores 2, 3, and 4 were grouped as categories ≥ 2 to differentiate malignant from benign ovarian lesions. US images were retrospectively reviewed by a pediatric radiologist (SSM) with 20 years of experience and, under supervision, a specialist pediatric radiology resident (DNG) with 4 years of experience.

Ovarian tumor markers

LDH, AFP, and β -hCG determinations were performed in blood. The procedures were carried out according to the manufacturer's recommendations and the standardized protocols of the institution's laboratory.

Histopathologic analysis

The pathology records were reviewed to identify ovarian lesions in female pediatric patients and to determine the diagnosis according to the WHO classification¹⁹. Pathologic examination was performed by a pediatric pathologist (ARR) with 7 years of experience.

Statistical analysis

Descriptive statistics summarized quantitative variables using measures of central tendency. Qualitative variables were reported as frequency and percentage. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of O-RADS US categories ≥ 3 and the Color score ≥ 2 for predicting malignant ovarian lesions, were calculated. Statistical analysis was performed using SPSS version 25 (IBM Corp., Armonk, NY, USA).

RESULTS

Seventy ovarian lesions in 66 female pediatric patients with a mean age of 12.6 ± 3.5 years (range, 1 to 17) were included (Table 1). The presenting signs and symptoms were abdominal pain in 66.6% ($n = 44$),

Table 1. Characteristics of 66 female pediatric patients with ovarian lesions

Description	Parameter
Age, years, mean \pm SD (min-max)	12.6 \pm 3.5 (1-17)
Signs and symptoms, n (%)	
Abdominal pain	44 (66.6)
Hypermenorrhea	10 (15.2)
Abdominal distention	10 (15.2)
Constipation	2 (3.0)
Laterality of ovarian lesion, n (%)	
Right	38 (57.5)
Left	24 (36.3)
Bilateral	4 (6.2)
Tumor markers, n (%)	
Positive	9 (13.6)
Negative	57 (86.4)
Surgical specimen pathology result, n (%)	
Ovary	57 (81.4)
Cyst	12 (17.2)
Capsule cyst	1 (1.4)
Diameter (cm), mean \pm SD	
Benign ovarian lesion n = 53	
Longitudinal	10.9 \pm 5.8
Anteroposterior	6.7 \pm 4.0
Transverse	7.2 \pm 3.2
Malignant ovarian lesion n = 17	
Longitudinal	14.2 \pm 5.3
Anteroposterior	10.9 \pm 2.5
Transverse	9.1 \pm 4.2
Ovarian lesion volume (cc), mean \pm SD	
Benign lesion	465 \pm 836
Malignant lesion	899 \pm 694.1

SD: standard deviation; cm: centimeter; cc: cubic centimeter.

hypermenorrhea and abdominal distension in 15.2% (n = 10) each, and constipation in 3.0% (n = 2). The lesion was most commonly located on the right in 57.5% (n = 38), on the left in 36.3% (n = 24), and bilateral in 6.2% (n = 4) of cases. Tumor markers were positive in 13.6% (n = 9) of cases. The surgical specimen was the ovary in 81.4% (n = 57) of cases, followed by cysts in 17.2% (n = 12), and the cyst capsule in 1.4% (n = 1). Among the histopathologic results, 75.7% (n = 53) were benign, and 24.3% (n = 17) were malignant ovarian tumors. The mean diameter of benign ovarian

lesions was 10.9 \pm 5.8 cm in the longitudinal axis, 6.7 \pm 4.0 cm in the anteroposterior axis, and 7.2 \pm 3.2 cm in the transverse axis. In contrast, malignant ovarian lesions measured 14.2 \pm 5.3 cm in the longitudinal axis, 10.9 \pm 2.5 cm in the anteroposterior axis, and 9.1 \pm 4.2 cm in the transverse axis. Both the transverse and anteroposterior diameters were significantly associated with malignancy (p = 0.001 and p = 0.003, respectively). The mean volume of benign lesions was 465 \pm 836 cc, and 899 \pm 694 cc for malignant lesions.

Comparison of O-RADS US findings between benign and malignant ovarian lesions

Benign lesions (n = 53) by O-RADS were most commonly, a unilocular cyst, solid component (n = 18, 34.0%), followed by a multilocular cyst, no solid component (n = 12, 22.6%), and a typical dermoid cyst (n = 12, 22.6%) (Table 2); a multilocular cyst with a solid component, unilocular cyst with a solid component, and endometriomas were less frequent. In contrast, malignant ovarian lesions (n = 17) were most commonly solid or solid-appearing (n = 14, 82.3%), followed by multilocular cyst with a solid component (n = 2, 11.8%) and a multilocular cyst, no solid component (n = 1, 5.9%).

Benign ovarian lesions showed no differences between lesions \leq 10 cm and those $>$ 10 cm in diameter (n = 26 and n = 27, respectively). In contrast, malignant ovarian lesions (n = 10, 58.8%) commonly had a greater diameter ($>$ 10 cm). The external contour was smooth in all benign ovarian lesions (n = 53, 100%). In contrast, most malignant ovarian lesions had an irregular external contour (n = 12, 70.6%). The color Doppler flow showed that most benign ovarian lesions were Color score 1 (n = 46, 86.8%), whereas none of the malignant ovarian lesions were classified as Color score 1. In contrast, malignant ovarian lesions were classified as Color score 2 (n = 4, 23.5%), Color score 3 (n = 9, 53.0%), or Color score 4 (n = 4, 23.5%). Among the extraovarian findings, fluid was present in 3 (17.6%) of 17 malignant ovarian lesions. No patient had peritoneal thickening or nodules.

Benign or malignant histopathologic diagnoses of 70 ovarian lesions in relation to O-RADS US categories and tumoral markers

The histopathologic diagnoses of benign ovarian lesions were mature teratoma (n = 20), serous

Table 2. Comparison of O-RADS US findings of benign and malignant ovarian lesions

Description	Total, n	Benign lesions, (n = 53)	Malignant lesions, (n = 17)
Lesion category, n (%)			
Unilocular cyst, no solid components	18	18 (34.0)	-
Unilocular cyst with solid component(s)	4	4 (7.5)	-
Multilocular cyst, no solid component(s)	13	12 (22.6)	1 (5.9)
Multilocular cyst with solid component(s)	5	3 (5.7)	2 (11.8)
Solid or solid-appearing (≥ 80%)	15	1 (1.9)	14 (82.3)
Typical dermoid cyst	12	12 (22.6)	-
Typical endometrioma	3	3 (5.7)	-
Diameter, n (%)			
≤ 10 cm	33	26 (49.1)	7 (41.2)
> 10 cm	37	27 (50.9)	10 (58.8)
External contour, n (%)			
Smooth	58	53 (100)	5 (29.4)
Irregular	12	-	12 (70.6)
Color score, n (%)			
1	46	46 (86.8)	-
2	11	7 (13.2)	4 (23.5)
3	9	-	9 (53.0)
4	4	-	4 (23.5)
Extra ovarian findings, n (%)			
Fluid	3	-	3 (17.6)

No female pediatric patient with peritoneal thickening or nodules. O-RADS: Ovarian Reporting and Data System; US: ultrasound.

cystadenoma (n = 18), cystadenofibroma (n = 7), mucinous cystadenoma (n = 5), endometrioma (n = 1), dermoid cyst (n = 1), and necrosis (n = 1) (Table 3). Figures 1 and 2 show benign ovarian lesions. The histopathologic diagnoses of malignant ovarian lesions were dysgerminoma (n = 6), yolk sac tumor (n = 4), mixed germ cell tumor (n = 2), mature and immature teratoma (n = 1), juvenile granulosa cell tumor (n = 2), and leukemic infiltration (n = 2). Figures 3 and 4 show malignant ovarian lesions.

Twenty-four lesions (96.0%) of 25 O-RADS category 2 and 11 lesions (91.6%) of 12 O-RADS category 3 were benign ovarian lesions, whereas only 1 (4.0%) of 21 O-RADS category 4 was benign. In contrast, malignant ovarian lesions were commonly O-RADS categories 4 (n = 3, 17.6%) and 5 (n = 12, 70.6%). All O-RADS category 5 lesions were malignant (n = 12). Tumor markers were negative in all benign ovarian cases and positive in 5 malignant cases.

O-RADS 4 subcategories in relation to benign and malignant ovarian lesions

Twenty-one (30.0%) of 70 ovarian lesions were classified as O-RADS category 4 (Table 4). Three (37.5%) malignant ovarian lesions were in subcategory 4B, while none were in subcategory 4A. In contrast, among benign ovarian lesions, 13 (100%) were classified as O-RADS subcategory 4A and 5 (62.5%) as 4B.

Diagnostic performance of O-RADS US categories and Color score for predicting malignant lesions

The O-RADS categories ≥ 3 showed high sensitivity at 94.1% (95% CI, 71.3-99.8) and a negative predictive value of 96.0% (95% CI, 78.0-99.4) for predicting malignant ovarian lesions (Table 5). However, specificity (45.3%, 95% CI, 31.5-59.5) and positive predictive

Table 3. Benign or malignant histopathologic diagnosis of 70 ovarian lesions in relation to O-RADS US categories and tumor markers

Description	n	O-RADS category				Tumor markers
		2	3	4	5	
Benign ovarian lesions, n						
Mature teratoma	20	12	1	7	-	Negative
Serous cystadenoma	18	8	6	4	-	Negative
Cystadenofibroma	7	1	4	2	-	Negative
Mucinous cystadenoma	5	1	-	4	-	Negative
Endometrioma	1	1	-	-	-	Negative
Dermoid cyst	1	1	-	-	-	Negative
Necrosis	1	-	-	1	-	Negative
Subtotal, n (%)	53	24	11	18	-	
Malignant ovarian lesions, n						
Dysgerminoma	6	-	-	-	4	Positive
		-	-	-	2	Negative
Yolk sac tumor	4	-	1	-	3	Positive
		-	-	-	-	Negative
Mixed germinal tumor	2	-	-	1	-	Positive
		-	-	-	1	Negative
Mature and immature teratoma	1	-	-	-	1	Positive
		-	-	-	-	Negative
Juvenile granulosa cell tumor	2	-	-	-	-	Positive
		1	-	-	1	Negative
Leukemic infiltration	2	-	-	2	-	Positive
		-	-	-	-	Negative
Subtotal, n (%)	17	1	1	3	12	
Total, n (%)	70	25	12	21	12	

O-RADS: Ovarian Reporting and Data System; US: ultrasound.

value (35.2%, 95% CI, 29.2-41.6) were lower. There were 16 true positives for malignant lesions and 24 true negatives. In contrast, there were 29 false positives and only one false negative ovarian lesion.

The Color score ≥ 2 showed better diagnostic performance for all evaluated parameters, with a sensitivity of 100% (95% CI, 80.4-100) and a negative predictive value of 100% (95% CI, 92.2-100). The specificity was 86.8% (95% CI, 74.6-94.5) and the positive predictive value was 70.5% (95% CI, 54.5-82.6). There were 17 true positive results for malignant lesions and 46 true negatives. In contrast, there were 7 false positives and no cases with a false negative result.

DISCUSSION

Our study showed that O-RADS categories ≥ 3 and Color scores ≥ 2 were useful for risk stratification of

ovarian lesions in female pediatric patients, with high sensitivity for predicting malignant ovarian lesions. This is the first study in Mexico to evaluate the diagnostic performance of O-RADS and demonstrate that it is a useful tool for predicting malignant ovarian lesions in female pediatric patients.

Knowledge of ovarian lesion characterization has historically been based on studies in adult populations, where O-RADS has proven to be a reliable diagnostic tool for malignancy risk stratification. Recently, Wang et al.¹⁵ retrospectively examined 163 histopathologically confirmed ovarian lesions from 159 female pediatric patients in China. Of these lesions, 89% (n = 145) were benign, and 11% (n = 18) were malignant. In O-RADS categories 4 and 5, the malignancy rates were 23.1% and 62.5%, respectively. O-RADS category > 3 had a sensitivity of 94.4% and specificity of 86.2% for

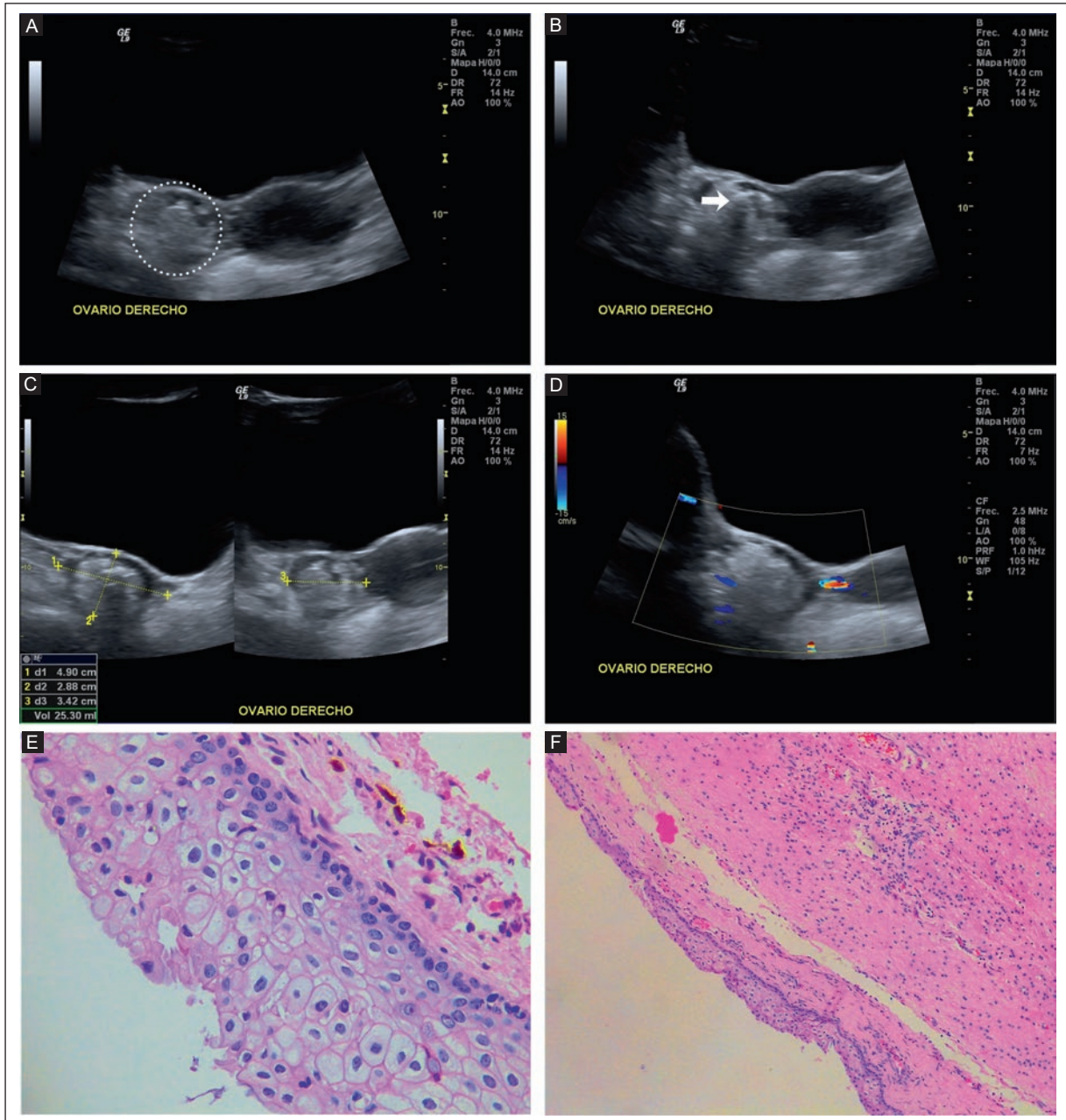


Figure 1. Pelvic US from a 16-year-old girl with hypermenorrhea. **A:** transverse view shows an ovoid, heterogeneous lesion with a hyperechoic center toward the right ovary (dotted circle). **B:** transverse view shows hyperechoic component with acoustic shadowing (arrow). **C:** the longitudinal axis measures 4.9 cm, the transverse axis 3.4 cm, and the anteroposterior axis 2.8 cm. Ovarian lesion volume is 25.3 cc. **D:** Doppler US shows no vascularity. Color score 1, O-RADS category 2. **E:** H&E stain (40x). Monodermal squamous epithelium without atypia or somatic (malignant) transformation. Some hemosiderin is observed in the underlying stroma. **F:** H&E stain (4x). Cystic wall layered beneath by stratified squamous epithelium; glial tissue, smooth muscle, and an inflammatory infiltrate are identified. The histopathologic diagnosis was mature teratoma.

US: ultrasound; H&E: hematoxylin and eosin.

predicting malignancy. Wu et al.¹⁶ analyzed 375 ovarian lesions in 364 female pediatric patients (≤ 17 years) in China and found a malignancy rate of 2.1% ($n = 8$). The O-RADS system achieved an AUC of 0.989, with 100% sensitivity and 96.5% specificity for lesions in category

≥ 4 , and specificity ranging from 92% to 100%. In our study, the malignancy rates were 5.9% for O-RADS category 3, 17.6% for category 4, and 70.6% for category 5. O-RADS categories ≥ 3 showed high sensitivity (94.1%) for predicting malignant ovarian lesions.

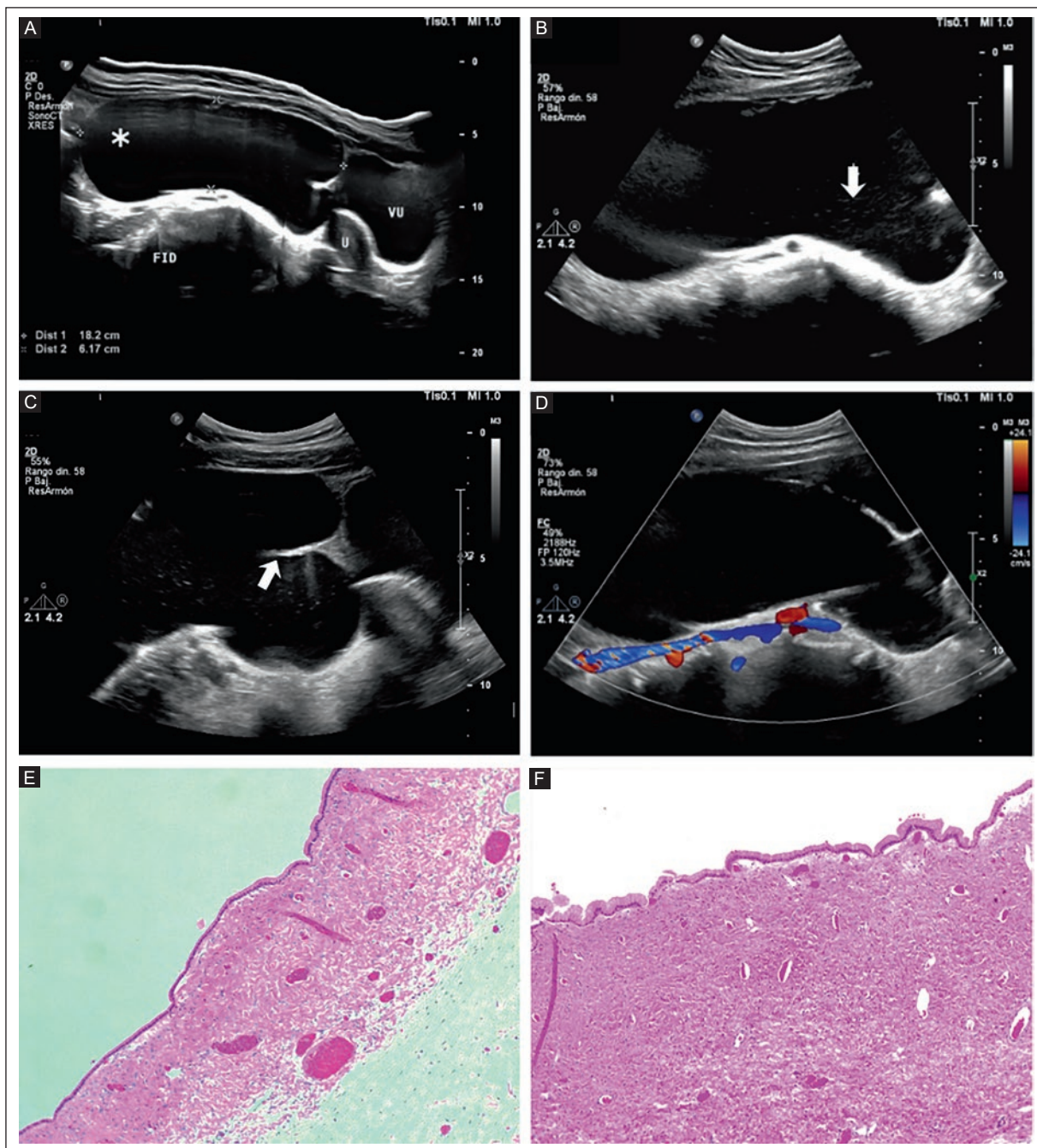


Figure 2. Pelvic US of an 11-year-old girl with hypermenorrhea. **A:** panoramic grayscale US of the right iliac fossa shows a cystic-appearing lesion at the anatomical site of the right ovary (star), measuring 18.2 cm (longitudinal axis), 15.9 cm (transverse axis, not shown), and 6.1 cm (anteroposterior axis). Ovarian lesion volume is 923 cc. **B:** a predominantly anechoic ovarian tumor in transverse view with a few internal floating spots (arrow). **C:** transverse view of a non-simple unilocular cyst shows incomplete septa (arrow), but no solid component. **D:** color Doppler US shows no vascularity. Color score 1, O-RADS category 3. **E:** H&E stain (10x). A cyst wall of fibrovascular tissue lined by simple epithelium. **F:** H&E stain (40x). The cyst inner lining consists of simple columnar epithelium with apical vacuoles. The histopathologic diagnosis was serous cystadenoma.

US: ultrasound; H&E: hematoxylin and eosin.

These results are comparable with previous reports^{15,16}. In our study the addition of Color score showed higher diagnostic performance in all parameters for predicting malignant ovarian lesions. However, the specificity of

O-RADS categories ≥ 3 was low (45.3%), with 29 (41.4%) false positives, possibly due to the inclusion of category 3 cases which had a lower frequency of malignancy (5.9%). In contrast, the studies by Wang¹⁵ and

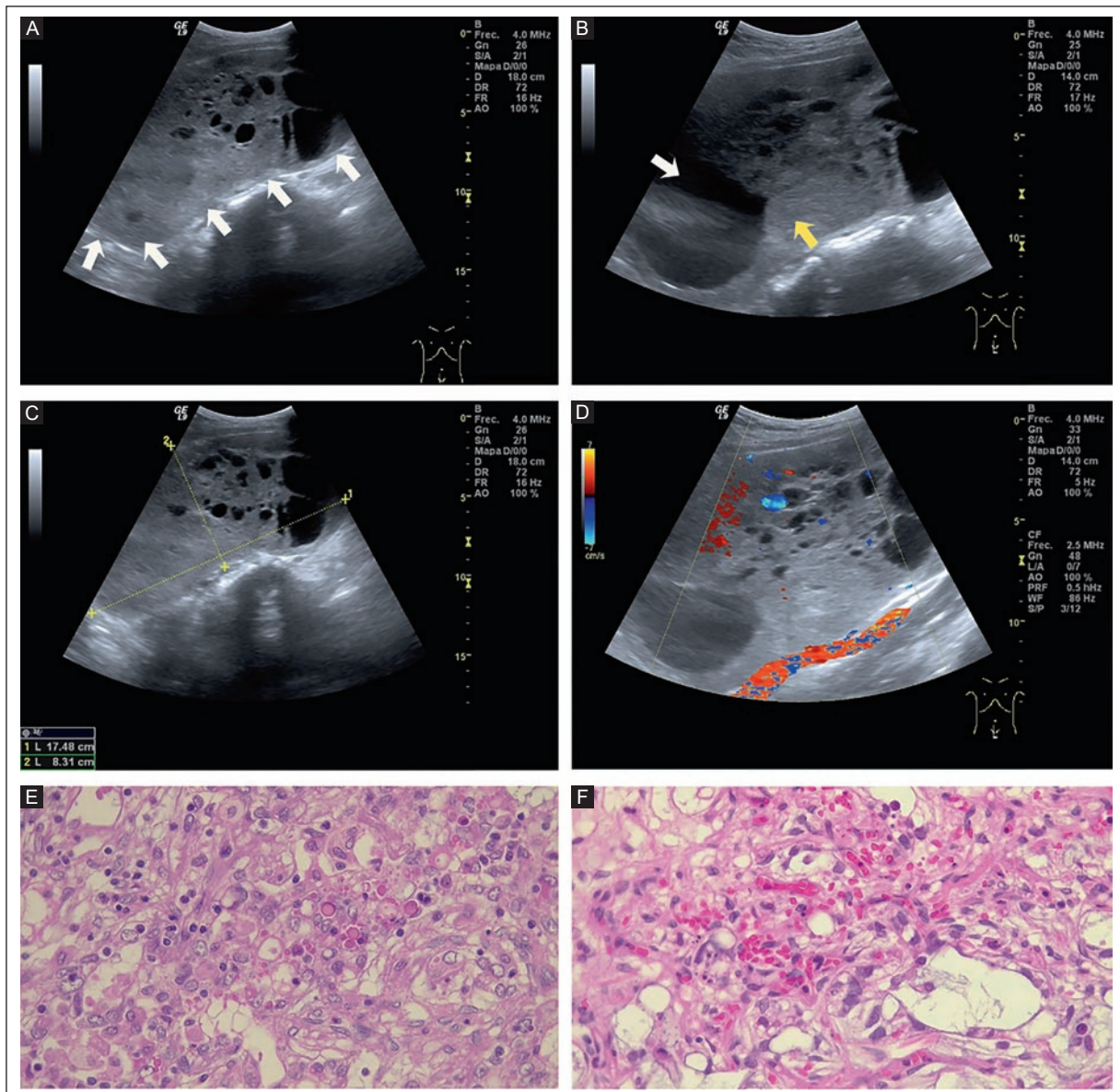


Figure 3. Pelvic grayscale US of a 12-year-old girl with hypermenorrhea and increased abdominal volume. **A:** longitudinal view of the pelvic cavity shows a large heterogeneous ovarian lesion with a solid component greater than 80% and some cystic areas with a smooth contour (arrows). **B:** longitudinal view shows cystic areas (white arrow) with solid portions (yellow arrow). **C:** longitudinal view of the ovarian lesion extends from the hypogastrium to the mesogastrium with a longitudinal axis of 17.4 cm, a transverse axis (not shown) of 9.0 cm, and an anteroposterior axis of 8.3 cm. Ovarian lesion volume is 683.6 cc. **D:** color Doppler US longitudinal view revealed internal vascularity with moderate flow. Color score 3, O-RADS category 4. **E:** H&E stain (40x). A heterogeneous neoplasm with solid growth, moderate nuclear atypia, and hyaline globules, with a focal myxoid background. **F:** H&E stain (40x). Cells with moderate nuclear atypia and a clear microcystic pattern. The histopathologic diagnosis was yolk sac tumor.

US: ultrasound; H&E: hematoxylin and eosin.

Wu¹⁶ included only categories ≥ 4 , with specificity ranging from 86.2% to 100%. O-RADS is a useful and reproducible tool for risk stratification in predicting malignant ovarian lesions in female pediatric patients.

A significant association between tumor size and ovarian malignancy has been reported. In the study by Wang et al.¹⁵ the median diameter of malignant lesions

was 11.5 cm, significantly larger than that of benign lesions (6.5 cm, $p = 0.012$), suggesting that accelerated tumor growth may be associated with malignant behavior. However, the authors emphasize that, although size is an important indicator, it is not sufficient on its own to accurately differentiate benign from malignant lesions, as certain benign lesions – such as mature

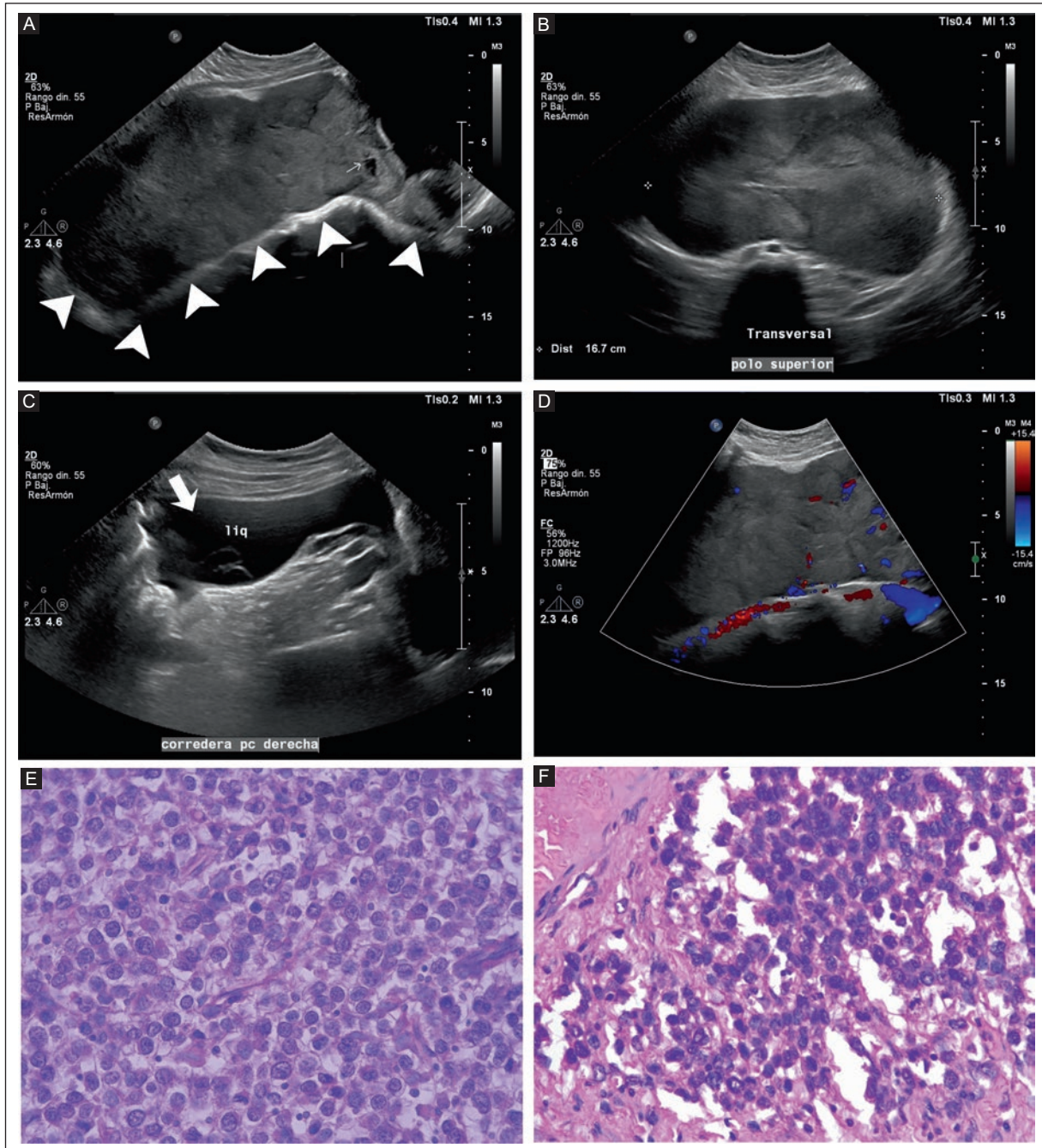


Figure 4. Pelvic grayscale US of a 15-year-old girl with asymptomatic abdominal distention. **A:** longitudinal view shows, in the topography of the left ovary, a large hypoechoic solid lesion with few cystic areas and irregular contour (arrowheads). **B:** transverse view, with dimensions of 25 cm (longitudinal axis, not shown), 16.7 cm (transverse axis), and 10.6 cm (anteroposterior axis, not shown). Ovarian lesion volume is 2,314.5 cc. **C:** longitudinal view at the level of the left parietocolic gutter shows anechoic fluid (arrow). **D:** a color Doppler US in longitudinal view shows moderate peripheral and internal vascularity. Color score 3, O-RADS category 5. **E** and **F:** H&E stain, 40x. Medium-sized cells with an eosinophilic cytoplasm, regular ovoid nuclei, granular chromatin, and moderate nucleoli. Septal infiltrating lymphocytes are seen. The histopathologic diagnosis was dysgerminoma.

US: ultrasound; H&E: hematoxylin and eosin.

teratomas or cystadenomas – can reach similar dimensions. In the study by Wu et al.¹⁶, the median diameter of the lesions was 4.2 cm (interquartile range 3.4-5.7 cm), most ovarian lesions were benign, and only 2.1%

were malignant. In our study, larger size was associated with a higher frequency of ovarian malignancy. Both the transverse and anteroposterior diameters were significantly associated with a higher frequency

Table 4. O-RADS US subcategories 4A and 4B associated with benign or malignant ovarian lesions

Description	Total (n = 21)	O-RADS 4A (n = 13)	O-RADS 4B (n = 8)
Benign ovarian lesion, n (%)	18	13 (72.2)	5 (27.8)
Malignant ovarian lesion, n (%)	3	-	3 (100)

O-RADS: Ovarian Reporting and Data System; US: ultrasound.

Table 5. Diagnostic performance of O-RADS US predicting malignant ovarian lesions in female pediatric patients

Parameter	Categories ≥ 3 % (95% CI)	Color score ≥ 2 % (95% CI)
Sensitivity	94.1 (71.3-99.8)	100 (80.4-100)
Specificity	45.3 (31.5-59.5)	86.8 (74.6-94.5)
Positive predictive value	35.2 (29.2-41.6)	70.5 (54.5-82.6)
Negative predictive value	96.0 (78.0-99.4)	100 (92.2-100)
Accuracy	57.0 (44.6-68.7)	89.9 (80.4-95.8)

O-RADS: Ovarian Reporting and Data System; US: ultrasound.

of malignancy ($p = 0.001$ and $p = 0.003$, respectively). In our cases, some benign tumors, especially teratomas, were large, which can limit the accuracy of image classification, particularly in standardized systems like O-RADS, where increased size can raise suspicion without necessarily implying malignancy. Diameter should not be used as an isolated risk criterion for ovarian malignancy in female pediatric patients.

O-RADS subcategories 4A and 4B, associated with benign and malignant ovarian lesions, respectively, have been proposed to improve risk stratification for malignancy based on morphological patterns by O-RADS¹⁵. Unilocular cysts with a solid component and multilocular cysts, no solid components are classified as O-RADS subcategory 4A. In contrast, the remaining cystic lesions with solid components are classified as O-RADS subcategory 4B. This classification showed a 10% risk of malignancy (1 out of 10 patients) for O-RADS subcategory 4A and a 50% risk (8 out of 16 patients) for O-RADS subcategory 4B¹⁵. Classification into subcategories 4A and 4B significantly improved risk stratification, differentiating groups with low versus high probability of malignancy ($p = 0.037$)¹⁵. In our study, among 21 lesions O-RADS category 4, all three (37.5%) malignant ovarian lesions were subcategory 4B, while none were subcategory 4A. Among benign ovarian lesions, 13 (100%) were classified as O-RADS

subcategory 4A and 5 (62.5%) as subcategory 4B. Subdividing O-RADS into subcategories 4A and 4B could enhance diagnostic precision and clinical decision-making, particularly in age groups where ovarian preservation is a priority.

Tumor markers (such as LDH, AFP, and β -hCG) can provide complementary information when evaluating pediatric ovarian lesions. Wang et al.¹⁵ showed that these markers are not specific enough to differentiate benign from malignant ovarian lesions on their own. Their usefulness lies in integrating them with a structured evaluation using O-RADS US, which improves preoperative stratification and guides therapeutic decisions aimed at preserving ovarian function. In germ cell tumors, these markers are relevant for monitoring and detecting recurrences. In our study, 53 benign lesions were negative for tumor markers; among the 17 malignant lesions, 29.4% (5 patients) were negative for tumor markers. Our results confirm that the absence of tumor markers does not exclude malignancy and that these markers should be considered only a complementary tool with limited diagnostic utility in female pediatric patients.

The strengths of this study include the use of a validated classification system for ovarian lesions, the O-RADS lexicon. All cases underwent histopathologic examination, and US findings were reported without knowledge of the histological results, ensuring blinded evaluation and reducing interpretation bias. Limitations include the retrospective design and small sample size. The number of cases with malignant results was small, so the specificity of O-RADS categories ≥ 3 for predicting malignancy was low. Including cases with O-RADS category 3 to differentiate malignant from benign ovarian lesions increased the number of false positives. Interobserver agreement was not evaluated in our study, although previous reports have demonstrated high consistency in the application of O-RADS descriptors regardless of the radiologist's experience¹⁵.

CONCLUSION

O-RADS US categories ≥ 3 showed high sensitivity and negative predictive value in distinguishing malignant from benign ovarian lesions in female pediatric patients. Adding a Color score ≥ 2 improved diagnostic performance for predicting malignant ovarian lesions across all parameters. Subclassifying category 4 into 4A and 4B appears promising for refining malignancy risk stratification in this population. Incorporating O-RADS US categories and Color score parameters into risk stratification for ovarian lesions in female

pediatric patients is recommended. Future studies with larger sample sizes are needed to validate these findings and optimize specific O-RADS adjustments for female pediatric patients.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical considerations

Protection of Individuals. The authors declare that this study complied with the Declaration of Helsinki (1964) and subsequent amendments.

Confidentiality, informed consent, and ethical approval. The authors declare that they followed their center’s protocol for sharing patient data. Informed consent was not required for this observational study of information collected during routine clinical care.

Declaration on the use of artificial intelligence. The authors declare that not use generative artificial intelligence to prepare this manuscript or to create tables, figures, or figure legends.

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