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Original Research Article

Correlation of ovarian adnexal reporting and data system classification with histopathological examination in diagnosis of adnexal masses

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ABSTRACT

Background: Adnexal masses are common and present significant clinical challenges related to diagnostic imaging, surgery and pathology. Ovarian adnexal reporting and data system (O-RADS) serves as both a lexicon and risk stratification tool, which is designed to accurately characterize adnexal lesions and facilitate optimal patient management. This study aimed to evaluate the diagnostic accuracy of O-RADS using histopathological examination as the gold standard.
Methods: This was a prospective observational study conducted in the department of Obstetrics and Gynaecology, Radio-diagnosis, Pathology in collaboration with the department of radio-diagnosis and pathology at Government Medical College and Hospital, Chandigarh from December 2022 to March 2024. A total of 35 women who were diagnosed with adnexal masses were included in the study.
Results: The age group of presentation of adnexal masses in our study was 14 to 62 years of age with a mean age of 31.69±11.25 years. O-RADS score 2 was 100% sensitive and 21.4% specific for detecting benign adnexal masses. ORADS score 3 was 100% sensitive and 24% specific for detecting benign masses. O-RADS score 4 was 25% sensitive and 89.47% specific for detecting malignant adnexal masses. Similarly, ORADS score 5 was 100% sensitive and 87.88% specific for detecting malignant masses using histopathology as the gold standard.
Conclusions: The ORADS classification system has a high sensitivity in differentiating between benign and malignant lesions when correlated with gold standard histopathology report.

Keywords: Histopathology report, Ovarian adnexal reporting and data system, Preoperative diagnosis, Sensitivity and specificity, Staging laparotomy

INTRODUCTION

Ovarian cancer was estimated to be the eighth most common cancer overall and third most prevalent cancer among Indian women. The incidence of ovarian cancer increases with age. It rises from 35 years of age and peaks between 55 to 64 years. It is the leading cause of cancer-related death among Indian women, accounting for 3.34% of all cancer-related fatalities in India.[1]

Adnexal masses are common and present significant clinical challenges related to diagnostic imaging, surgery and pathology. Ultrasonography is the preferred imaging modality for evaluating the pelvis, particularly the uterus and ovaries, due to its cost-effectiveness, lack of radiation exposure, and bedside availability. Detailed ultrasound evaluation is essential for identifying abnormal adnexal masses, assessing their relationship to the ovary, and determining the potential for malignancy. When

ultrasonography yields indeterminate results, magnetic resonance imaging (MRI) may be required for further assessment. Characterisation of the pelvic masses using MRI involves two steps: first to anatomically localise the mass and second to determine its morphology and tissue composition.[2]

To assess the likelihood of cancer in adnexal mass using ultrasound, several predictive techniques have been developed. A widely used method is the risk of malignancy index (RMI), which is the product of menopausal status, the morphological features seen on ultrasound and CA-125 levels.[3] The International Ovarian Tumor Analysis (IOTA) group developed logistic regression models and clear guidelines to distinguish ovarian masses as benign or malignant using ultrasonography with 10 simple rules.[4] To provide a more comprehensive evaluation of adnexal masses, IOTA group introduced the assessment of different neoplasias in adnexa (ADNEX) model in 2014. The ADNEX model employs nine predictors to differentiate between benign and malignant tumours.[5]

When evaluating the malignancy rates, reliability and validity of various adnexal lesion categorization systems including O-RADS, GI-RADS, and IOTA simple rules, O-RADS demonstrated highest sensitivity for malignancy. This increased sensitivity was attributed to well-defined management protocols, comprehensive lexicon, and descriptive criteria within the O-RADS system.[6]

Ovarian adnexal reporting and data system (O-RADS) serves as both a lexicon and risk stratification tool, which is designed to accurately characterize adnexal lesions and facilitate optimal patient management. Developed by the American College of Radiology (ACR), the O-RADS lexicon for ultrasound was published in year 2018. This classification system provides a uniform terminology encompassing all descriptions and definitions of the characteristic ultrasound appearances of normal ovaries and other adnexal lesions. By reducing ambiguity and ensuring uniform interpretations of ultrasound findings, the O-RADS US risk stratification and management system improves accuracy in assessing the risk of malignancy for ovarian and other masses, along with offering management recommendations for each risk category.[7]

Objective

This study aimed to evaluate the diagnostic accuracy of O-RADS using histopathological examination as the gold standard.

METHODS

Study place

This prospective study was conducted in the department of obstetrics and gynaecology in collaboration with the Department of Radio-Diagnosis and Pathology at Government Medical College and Hospital, Chandigarh.

Study duration

The study period was from December 2022 to March 2024.

Sample size

A total of 35 women who were diagnosed with adnexal masses were included in the study.

Inclusion criteria

All females of any age suspected of having adnexal mass, with or without symptoms presenting in OPD, indoor or in emergency and who gave consent were selected.

Exclusion criteria

All those women in whom surgery was not indicated due to benign or functional characteristics of adnexal mass were excluded from the study. Women with ectopic pregnancy. Women requiring immediate laparotomy as ORADS scoring was not possible in that case. Patients who refused to come for follow-up.

Ethical approval

Ethical approval was obtained from the Institutional Ethics Committee and informed consent was taken from all participants.

Data collection

A detailed clinical history and physical examination were done. Ultrasound examinations were conducted in the department of radio-diagnosis using the ultrasound LOGIQ S-8 X-D machine. First, transabdominal scan using probe of low-frequency 1-6 MHz followed by transvaginal ultrasound was done using Endo cavity micro convex probe of frequency 3-10 MHz. The ovarian-adnexal reporting and data system (ORADS) scoring was employed to accurately characterize the adnexal lesions and assess their risk of malignancy. After surgical removal of the mass by laparotomy or laparoscopically, the histopathological specimen was sent to the department of pathology and a histopathological diagnosis was made. So, the findings of adnexal mass on ultrasound and categorization of adnexal mass using ORADS were confirmed by the histopathological report which was the reference/gold standard.

Statistical analysis

The diagnostic value of the ORADS score was evaluated by taking ultrasonography and histopathological examination as the gold standard, taking these tests sequentially. The ultrasound parameters for all cases, including females of any age, whether premenopausal or

postmenopausal, with adnexal masses, were described using percentages across various categories. Diagnostic values of ultrasonography taking histopathological examination as gold standard were evaluated in terms of sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. Agreement between ultrasound findings and histopathological findings was tested by using Fishers exact test. Data analysis was carried out by using SPSS 20.0 software version.

RESULTS

There were 35 women enrolled in the study. Mean age of the adnexal masses were seen in the age group from 14 to 62 years of age and the mean age calculated was 31.69±11.25 years. In the study population, 71.4% of patients were married and 28.6% of patients were unmarried. According to reproductive status, 32 patients (91.4%) were premenopausal and only 3 patients (8.6%) were postmenopausal (Table 1).

There was a significant correlation between ultrasound findings of consistency, number of loculi, and color score with histopathology reports, with p values of 0.003, 0.001, and 0.042, respectively.

However, the size of the mass, the margins of the mass, the wall of the mass, and the thickness of the wall did not show any correlation with histopathological findings, with p values of 0.508, 1.000, 1.000, and 0.546, respectively (Table 2).

Table 1: Demographic characteristics of study population.

Sociodemographic characteristics		Number of cases	Percentage
Age (in years)	≤20	5	14.3
	21-30	13	37.1
	31-40	10	28.6
	41-50	5	14.3
	>50	2	5.7
Marital status	Unmarried	10	28.6
	Married	25	71.4
Reproductive status	Premenopausal	32	91.4
	Postmenopausal	3	8.6

Table 2: Correlation between benign, borderline, and malignant adnexal masses regarding ultrasound features of the studied lesions.

Ultrasound characteristics		Benign n=29 (%)	Borderline n=3 (%)	Malignant n=3 (%)	P value
Size of mass	Less than 3 cm	1 (100.0)	0 (0.0)	0 (0.0)	0.508
	3-10 cm	14 (87.5)	0 (0.0)	2 (12.5)	
	More than 10 cm	14 (77.8)	3 (16.7)	1 (5.5)	
Consistency	Purely cystic	23 (95.8)	1 (4.2)	0 (0.0)	0.003
	Cystic solid	6 (60.0)	2 (20.0)	2 (20.0)	
	Solid	0 (0.0)	0 (0.0)	1 (100.0)	
Margins	Well defined	27 (81.8)	3 (9.1)	3 (9.1)	1.000
	Irregular	2 (100.0)	0 (0.0)	0 (0.0)	
Wall of mass	Smooth	27 (81.8)	3 (9.1)	3 (9.1)	1.000
	Irregular	2 (100.0)	0 (0.0)	0 (0.0)	
Thickness of wall	Less than 3 mm	26 (83.9)	3 (9.7)	2 (6.4)	0.546
	More than 3 mm	3 (75.0)	0 (0.0)	1 (25.0)	
Locularity	Unilocular	16 (100.0)	0 (0.0)	0 (0.0)	0.001
	Multilocular	11 (91.7)	1 (8.3)	0 (0.0)	
	Multilocular with solid component	2 (33.33)	2 (33.33)	2 (33.33)	
	Solid smooth	0 (0.0)	0 (0.0)	1 (100.0)	
Color score	Color score 1	23 (88.5)	2 (7.7)	1 (3.8)	0.042
	Color score 2	6 (85.7)	0 (0.0)	1 (14.3)	
	Color score 3	0 (0.0)	0 (0.0)	0 (0.0)	
	Color score 4	0 (0.0)	1 (50.0)	1 (50.0)	

Table 3: Correlation between ORADS score and histopathology reports.

ORADS score	N	Benign (n-29)		Borderline (n-3)		Malignant (n-3)		P value
		Count	% within O-RADS	Count	% within O-RADS	Count	% within O-RADS	
ORADS 1 (normal ovary)	0	0	0.0	0	0.0	0	0.0	0.032
ORADS 2 (almost certainly benign)	7	7	100.0	0	0.0	0	0.0	
ORADS 3 (low risk of malignancy)	10	10	100.0	0	0.0	0	0.0	
ORADS 4 (intermediate risk of malignancy)	16	12	75.0	2	12.5	2	12.5	
ORADS 5 (high risk of malignancy)	2	0	0.0	1	50.0	1	50.0	

Table 4: Definitive histopathological reports of ORADS score 2, 3, 4 and 5.

HPE status	HPE report	N	ORADS score								P value
			ORADS 2		ORADS 3		ORADS 4		ORADS 5		
			F**	% within HPE	F**	% within HPE	F**	% within HPE	F**	% within HPE	
Benign	Mature cystic teratoma	8	1	12.5	3	37.5	4	50.0	0	0.0	0.541
	Endometrioma	3	2	66.7	0	0.0	1	33.3	0	0.0	
	Mucinous cystadenoma	3	0	0.0	0	0.0	3	100.0	0	0.0	
	Hemorrhagic cyst	4	2	50.0	1	25.0	1	25.0	0	0.0	
	Serous cystadenoma	5	1	20.0	2	40.0	2	40.0	0	0.0	
	Benign cyst	5	1	20.0	3	60.0	1	20.0	0	0.0	
	Paratubal cyst	1	0	0.0	1	100.0	0	0.0	0	0.0	
Malignant *	Borderline serous tumor	1	0	0.0	0	0.0	1	100.0	0	0.0	1.000
	Borderline mucinous tumor	2	0	0.0	0	0.0	1	50.0	1	50.0	
	Mucinous cystadenocarcinoma	2	0	0.0	0	0.0	1	50.0	1	50.0	
	Metastatic signet ring cell adenocarcinoma	1	0	0.0	0	0.0	1	100.0	0	0.0	

*The borderline tumors have been merged under the malignant category in this table for comparing O-RADS scoring with definitive histopathological reports. **F= Frequency of subjects

Table 5: Correlation between the ORADS score and the type of surgery performed.

ORADS	Laparoscopic cystectomy		Laparotomy with cystectomy		TAH with BSO		Staging laparotomy		P value
	F	%	F	%	F	%	F	%	
ORADS 1 (Normal ovary)	0	0.00	0	0.00	0	0.00	0	0.00	0.001
ORADS 2 (Almost certainly benign)	7	100.00	0	0.00	0	0.00	0	0.00	
ORADS 3 (Low risk of malignancy)	7	70	3	30	0	0.00	0	0.00	
ORADS 4 (Intermediate risk of malignancy)	6	37.50	0	0.00	2	12.50	8	50.00	
ORADS 5 (High risk of malignancy)	0	0.00	0	0.00	0	0.00	2	100	

In the study population, the maximum number of cases were seen in O-RADS 4 with 45.7% followed by O-RADS 3 with 28.6% of patients. 20% of cases were seen in O-RADS 2. Only 5.7% were seen in O-RADS 5 (Figure 1).

Among patients with adnexal masses scored as O-RADS 2 and 3, 100% had benign histopathology reports. For patients with adnexal masses scored as O-RADS 4, 75% were reported as benign, 12.5% as borderline, and 12.5% had malignant histopathology reports. In O-RADS 5, both borderline and malignant groups had 50% of cases each, and none of the cases were reported as benign on histopathology (Table 3).

The p value of association between the O-RADS category and definitive histopathological reports of benign cases and malignant cases was 0.541 and 1.000 respectively which is statistically nonsignificant (Table 4).

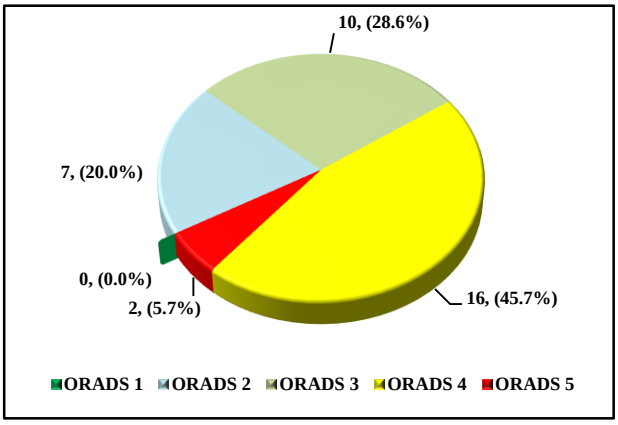

Figure 1: ORADS scoring of adnexal masses in the study population.

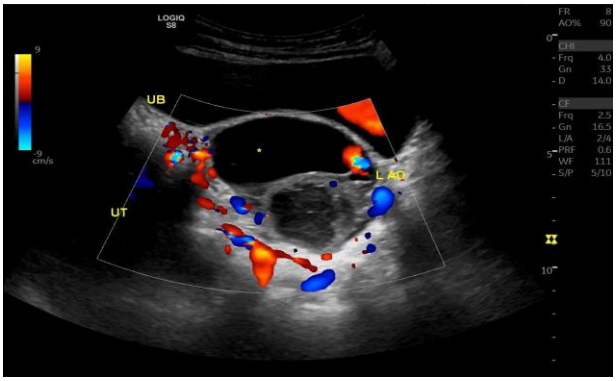

Figure 2: Observed ultrasound features of adnexal masses.

Transvaginal sonography shows solid cystic mass of 9.3*9.6*7.0 cm showing multiple loculi with thick septae with good color flow in the wall and sepate (CS=4). ORADS 5 score was given.

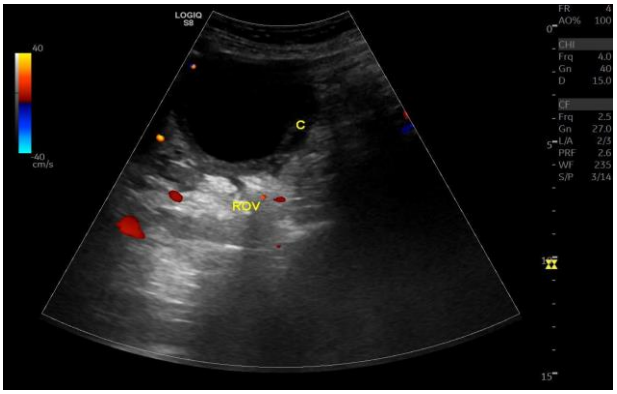

Figure 3: Observed histopathological reports of few cases.

Transvaginal sonography shows right side thin walled multilocular cystic mass of size 8.3*3.0*7.8 cm abutting right ovary with minimal color flow (CS=2). ORADS 3 score was given.

In O-RADS 2, 100.0% of cases underwent laparoscopic cystectomy. In O-RADS 3, 70% of cases had laparoscopic cystectomy whereas in 30% of cases, laparotomy with cystectomy was performed. In O-RADS 4 category, 50.0% cases underwent staging laparotomy, 37.5% of cases underwent laparoscopic cystectomy and only 12.75% cases had total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH with BSO). In O-RADS 5, 100% of cases underwent staging laparotomy (Table 5 and Figure 2).

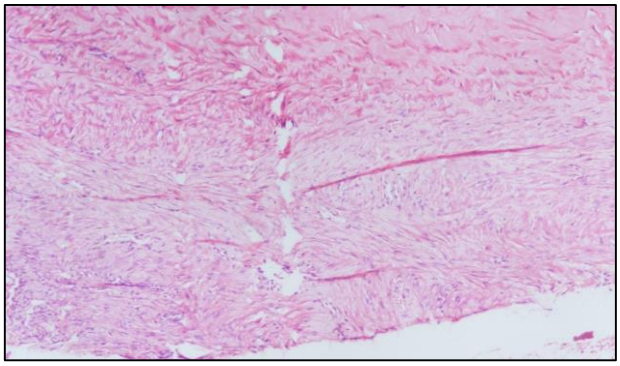

Figure 4: Photomicrograph shows benign cyst devoid of lining epithelium. Wall shows mild infiltrate (H and E X200).

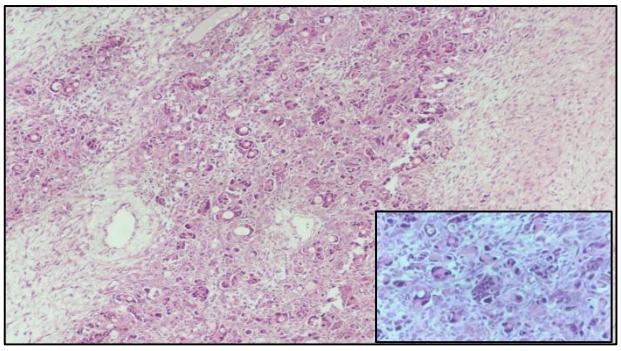

Figure 5: Photomicrograph shows tumor cells scattered within the ovarian parenchyma having vacuolated cytoplasm, pushing the nucleus to the periphery forming a signet ring suggestive of metastatic signet ring cell adenocarcinoma (H and E X10) inset (H and E X400).

DISCUSSION

Accuracy in pre-operative diagnosis of ovarian masses has become increasingly important in managing adnexal masses, especially as fertility preservation and minimally invasive surgeries have gained momentum in recent years.

Given the higher prevalence of benign cystic neoplasms and physiologic cysts compared to ovarian cancer, risk stratification based on imaging should aim for a balance between specificity and sensitivity, to accurately detect disease.[8]

It is important to note that not all ovarian-adnexal findings require evaluation using the O-RADS US system. (for example, ovarian torsion, pelvic inflammatory disease, ovarian hyperstimulation syndrome, ectopic pregnancy, or lesions identified as originating from the uterus). However, O-RADS US should be considered for non-physiologic lesions, normal ovaries in high-risk patients (such as those with BRCA mutations) undergoing ovarian cancer screening, and adnexal masses identified on other imaging modalities where further characterization with ultrasound is recommended.[9]

O-RADS is unique in offering a comprehensive lexicon and classification for all risk levels of adnexal masses, along with corresponding management recommendations.

O-RADS committee of the ACR introduced a novel system in ultrasound imaging which offers management recommendations by categorizing the risk of malignancy from benign to concerning. In January 2022, the American College of Radiology assembled a multidisciplinary team O-RADS US v2022, to enhance the O-RADS US system resulting in consensus-based outcome. Specifically, offers additional guidance and clarification to facilitate the system's practical application. Moreover, O-RADS US v2022 strengthens management recommendations and enhances specificity for certain lower-risk lesions to align with validation studies and protocols.[10]

In this context, our study compared O-RADS scoring with histopathological findings for establishing the diagnosis of adnexal masses.

We assessed various clinical and ultrasound parameters using ORADS classification supported with MRI wherever needed while evaluating adnexal masses pre-operatively. This was followed by surgical management and histopathological diagnosis.

In our study, adnexal masses were observed in individuals aged 14 to 62 years, with a mean age of 31.69±11.25 years. The highest proportion of cases (65.7%) were observed in the 21-40 age group which was like a study by Sneha et al, where adnexal masses were found in individuals aged 8 to 76 years, with a mean age of 46 years and most subjects were in the 21-40 age group, accounting for 53.0% of the cases.[11]

There were 32 premenopausal patients (91.4%) and only 3 postmenopausal (8.6%) patients enrolled in our study. Out of the total 32 premenopausal patients, 87.5% had benign adnexal mass, 9.4% patients had borderline mass and the remaining 3.1% had the presence of malignant adnexal mass. Amongst the postmenopausal patients, 66.7% patients had malignant masses and 33.3% had a benign adnexal mass. In our study, the p value was 0.030 which was statistically significant.

The results were like the study by Jha et al, where it was observed that the incidence of cancer was higher in postmenopausal women (13.8%) in comparison to premenopausal women (5.2%) (p value<0.001).[12]

Similar findings were observed, by Ahmed et al, in premenopausal women 91.7% of cases were benign and 8.3% were malignant. In postmenopausal women, only 16.7% were benign and 83.3% were malignant. The p value was <0.001 (statistically significant).[13]

Most cases were classified under O-RADS 4 in our study, comprising 45.7% of the total, while Ahmed et al. reported a higher incidence of cases falling under O-RADS 3 in their study which was 33.3%. However, in the O-RADS 2 category, our results were similar to that reported by Ahmed et al.[13]

Correlating the O-RADS scoring with histopathological diagnosis it was found that in O-RADS 2 and 3, all patients (100%) had benign histopathology reports. Within O-RADS 4, 75% of patients received benign histopathology reports, while 12.5% had borderline and an additional 12.5% had malignant histopathology reports. In O-RADS 5, both borderline and malignant groups had 50% of cases each, and nil cases were reported in the benign group. The p value of association between O-RADS score and histopathology report was 0.032 which was statistically significant, like study by Sneha et al in which all masses within ORADS 1, 2 and 3 were benign according to histopathological reports. In O-RADS 4, 56.52% of all masses were malignant whereas in ORADS 5, 69.23% of all masses were malignant (p value 0.000).[11]

In our study, in O-RADS 2, 100.0% of cases underwent laparoscopic cystectomy. In O-RADS 4 category, 50.0% cases underwent staging laparotomy, 37.5% of cases underwent laparoscopic cystectomy and 12.75% cases had TAH with BSO. In study by Sneha et al 43.4% had TAH with BSO and 52.1% had oophorectomy in O-RADS 4 category. In our study, in O-RADS 5 category, 100% of cases underwent staging laparotomy whereas in study performed by Sneha et al 61.53% cases had staging laparotomy with debulking and 38.4% underwent TAH with BSO.[11]

Therefore, higher percentages of TAH with BSO and staging laparotomy were performed in O-RADS category 4 and 5 consistent with higher rates of malignancy. In contrast, among O-RADS grades 1, 2 and 3, minimally invasive surgical procedures were carried out.

We observed that the maximum number (22.9%) of cases were mature cystic teratoma followed by benign cyst (14.3%) and serous cystadenoma (14.3%). The hemorrhagic cyst was seen in 11.4% of cases. Endometrioma and mucinous cystadenoma were each observed in 8.6% of cases. Whereas in the study by Ahmed et al. the most frequent benign lesions were hemorrhagic cysts, mucinous cystadenomas, and dermoid cysts in percentages of 18.2%, 15.2%, and 15.2%, respectively. Mucinous cystadenocarcinoma was the most frequent

malignant lesion in our study compared to serous cystadenocarcinoma in the comparison study.[13]

In our study population, O-RADS score 2 was 100% sensitive and 21.4 % specific for detecting benign adnexal masses. ORADS score 3 was 100% sensitive and 24% specific for detecting benign masses. O-RADS score 4 was 25% sensitive and 89.47 % specific for detecting malignant adnexal masses. Similarly, ORADS score 5 was 100% sensitive and 87.88% specific for detecting malignant masses. Whereas, in a study by Ahmed et al. ≥ ORADS 2 had 100% sensitivity and 0% specificity. In > ORADS 5, 0% sensitivity and 100% specificity were noted.[13] In another study by Tantawy et al at cutoff 4, the O-RADS US score for malignancy gave a sensitivity of 93.13% (95% CI 25.13-80.78), specificity of 66.72% (95% CI 34.49-76.81).[14]

A retrospective study conducted in Mexico compared the sensitivity and specificity of ultrasound using O-RADS classification with histopathological findings for ovarian cancer in 73 cases. It categorized masses into malignant O-RADS 3-5 or benign O-RADS 0-2 found an overall accuracy of 73%. The sensitivity was 52%, specificity 84%, negative predictive value (NPV) 79%, positive predictive value (PPV) was 60%. The study highlighted higher specificity than sensitivity in distinguishing malignant from benign, aiding in treatment decision-making. Specifically, ORADS 0 to 2 lesions were for conservative management, whereas ORADS 3 to 5 lesions may require surgical intervention.[15]

The main strength of this study was histopathological reference which was available for every patient for comparison. Employing a gold standard method to predict the performance of the O-RADS model offered enhanced confidence in the results. Another strength of the study is that ultrasound examination was performed by skilled experts, O-RADS scoring was assigned and wherever required, the facility of MRI was provided. The limitation of this study was the small number of patients (35 in number).

CONCLUSION

To conclude, the ORADS classification system is a valuable non-invasive diagnostic tool for adnexal masses. It helps in management planning by providing a preoperative diagnosis by giving ORADS score and thereby, selecting the option of minimally invasive surgery for benign lesions versus staging laparotomy for probable malignant lesions. It has a high sensitivity in differentiating between benign and malignant lesions when correlated with gold standard of a histopathology report.

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