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## Risk stratification and validation of ultrasound ovarian & adnexal reporting data system: Correlation with clinical follow-up and histopathology

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### Abstract

**Purpose:** Diseases pertaining to the reproductive system of the women are becoming increasing common. The first and foremost system in a female body to show systemic dysfunction is the Endocrine system, which in turn affects the menstrual cycle. Thus menstrual abnormalities are becoming increasingly common. Most common gynaecological problems include ovarian cysts, adnexal masses, fibroids, polycystic ovarian disease. Ovarian cancer is the second most common malignancy in women, accounting for 4% of all cancers in the female population.

Adnexal masses (mass of the ovary, fallopian tube, or surrounding connective tissues) are a common gynaecological problem. They account for 80% of all gynaecological problems. These masses may be found in females of all ages.

**Aim:** To stratify and assess the risk stratification of adnexal masses on the basis of ORADS and to calculate statistical measures of performance of ORADS with the help of clinical follow up and histopathology.

**Materials and Methods:** Suspected patients with ovarian/adnexal lesions were referred to Radiology department for Ultrasonography. Transabdominal and/ or transvaginal sonography was performed. The lesions were assessed based on ORADS grading system. Subsequently, the lesions were correlated with the HPE reports.

**Results:** This is a prospective observational study conducted in 166 patients. There was a significant positive correlation between the distribution of benign and malignant tumours across ORADS grades and p value of 0.000 was derived indicating extremely significant statistical difference.

**Conclusions:** Ovarian-Adnexal Reporting and Data System US risk stratification and management system had higher sensitivity and specificity for detection of adnexal malignancy in our study. Higher ORADS Grades were had loculated tumours, irregular margins, septations, solid component, and higher echogenicity. In the ORADS Grade 1, 2 and 3, did not have any malignancy. ORADS grade 4 and 5 had higher prevalence of malignancy.

**Keywords:** Ovarian and adnexal reporting data system

### Introduction

Adnexal mass is defined as a growth that develops in the female pelvic region. They occur near the uterus, usually in the ovaries, fallopian tubes, or connecting tissues. A variety of gynaecological and nongynecological illnesses make up these masses <sup>[1]</sup>. They could be cancerous or benign. Cervical cancer, endometrial cancer, and ovarian cancer are examples of gynecologic malignancies. The most common gynecologic cancer-related cause of death is ovarian cancer. With 15,280 fatalities in 2007 <sup>[2]</sup>, it is the seventh most common cancer-related cause of death in women in the country. Risk factors for ovarian cancer include age older than 60 years; early menarche; late menopause; nulliparity; infertility; personal history of breast or colon cancer; and family history of breast, colon, or ovarian cancer. While females using oral contraceptives, having a higher parity, tubal ligation and oophorectomy are associated with lower risks. Its late detection, due to the fact that early ovarian cancer is usually asymptomatic, causes advance disease and high mortality rates <sup>[1]</sup>. The lifetime risk of having ovarian cancer accounts for 1.3% which is 1 in 78 women. They are mostly associated with the females of childbearing ages.

The proper discrimination between benign and malignant lesions is the most important crucial point for a correct and optimal management.

Therefore, early detection and characterization of ovarian lesions is of utmost importance for adequate management [2]. The precise description of ovarian and other ovarian and adnexal masses is necessary for the best patient care. The aim of an early diagnosis is to minimize unnecessary surgical procedures and unfavourable ovarian cancer outcomes. Unlike other neoplasms, adnexal masses should not be biopsied, thus making imaging findings is crucial for diagnosis and management. Ultrasonography is considered the initial assessment tool. In most cases, the risk of malignancy of an adnexal mass can be assessed effectively by transabdominal or transvaginal sonography. The Ovarian-Adnexal Reporting and Data System (O-RADS) Committee was established under the direction of the ACR with the aim of developing a standardised lexicon that would enable the development of a useful, consistent vocabulary for describing the imaging characteristics of ovarian masses. In order to provide consistent follow-up and

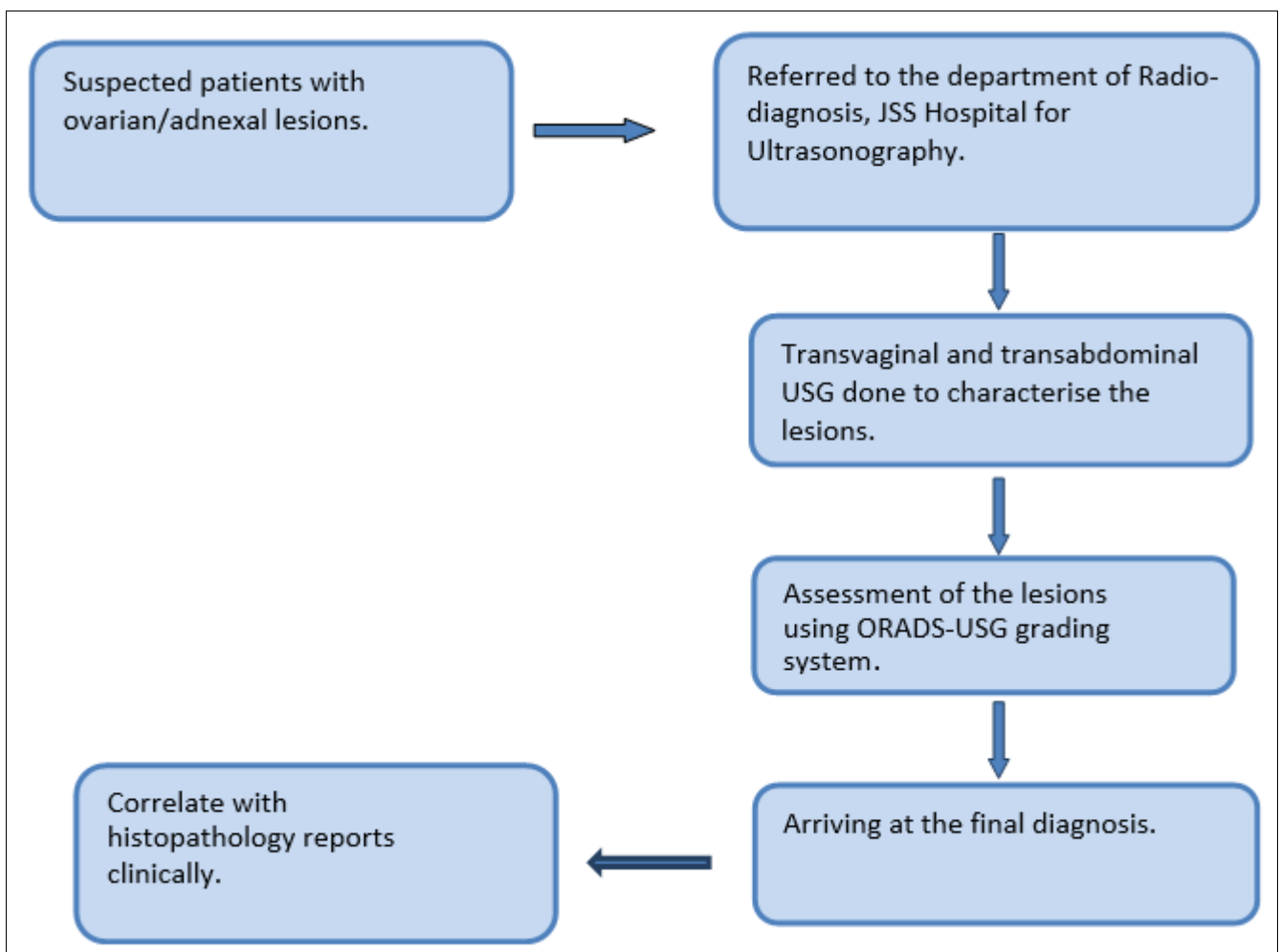
care in clinical practise, the lexicon will ultimately be applied to a risk stratification categorization [3]. Although these models have a high level of predictability, normal clinical practise in the US and Canada has not generally adopted them. Hence in this study, we aim to stratify and assess the risk stratification of adnexal masses on the basis of ORADS that will further help in clinical management and correlate it with the histopathological changes.

**Materials and Methods**

**Study Design:** Prospective observational study.

**Data collection**

The study will be a prospective study conducted on a minimum of 166 patients over a period of 18 months at the Department of Radiodiagnosis, JSS Hospital, Mysuru. After obtaining relevant clinical history and consent from the patient, they are subjected to ultrasonography imaging.



**Selection Criteria**

**Inclusion criteria**

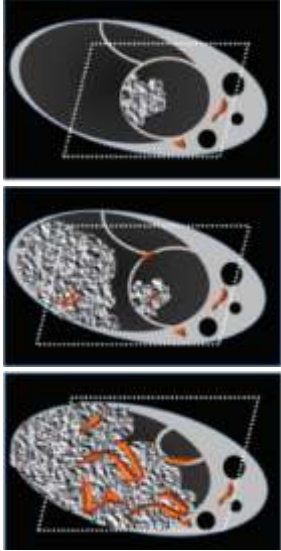
- Patients presenting with gynecological symptoms pertaining to the adnexal masses.
- Adnexal masses found incidentally by routine ultrasonography of abdomen & pelvis.
- Patients of all age groups.


**Exclusion criteria**

- Pathologically proven cases of ovarian malignancy.

**Imaging Protocol**

Patients were selected according to inclusion criteria, they were subjected to B-Mode Ultrasonography. The instruments used were: GE Health Care LOGIC QP6 colour Doppler, Philips HD 11XE9 3D (colour Doppler), Philips IU22 (4D) with colour Doppler, Philips HD 11XE (3D) with colour Doppler. The images were captured and documented for study.

Category	Term	Definition	Comments
1	<b>Major Categories</b>		
	<b>Physiologic Category (Consistent with normal ovarian physiology)</b>		
	Follicle	Simple cyst < 3cm in premenopausal group	
	Corpus luteum	Thick walled cyst < 3cm that may have crenulated inner margins, internal echoes and intense peripheral enhancement.	It can appear as hypechoic region in the ovary with peripheral vascularity without a characteristic cystic component.
	<b>Lesion Category (not consistent with normal ovarian physiology)</b>		
	Unilocular, no soild component	Cystic lesion that contains: a single compartment. May contain > 1 incomplete septum. wall irregularity. <3 mm height. Internal echoes.	Simple cyst is a subset of unilocular cyst with a smooth, thin wall, acoustic enhancement & no internal elements.
	Unilocular, with soild component	As above but includes solid components >3mm in height.	
	Multilocular cyst, no solid elements	Cystic lesion with more than one compartment (at least one incomplete septum) but no solid components >3mm in height.	
Multilocular cyst, with solid elements	As above but includes >1 solid components		
2	<b>Size</b>		
	Maximum diameter	Maximum diameter of the lesion in any plane	
3	<b>Solid or Solid Appearing Lesions</b>		
	<b>External Contour</b>		
	Smooth	Regular outer margin	
	Irregular	Non-uniform outer margin	
	<b>Internal Contour</b>		
Acoustic shadowing	Artifact produced by attenuated echoes behind a sound absorbing structure.	Commonly associated with calcifications or fibromatous type lesion	
4	<b>Cystic Lesions</b>		
	<b>Inner margin or walls including solid component</b>		
	Papillary projection or nodule	Solid component whose height $\geq 3$ mm, arises from the cyst wall or septations and protrudes into the cyst cavity.	Number of papillary projections should be included
	Smooth	Regular, uniform inner margin	
	Irregular	Irregular, non-uniform inner margin. Wall irregularities due to incomplete septations, solid component <3mm height, papillary projections.	
	<b>Internal Content, Cystic Component</b>		
	Anechoic fluid	No internal echoes or structures of any kind.	
Hyperechoic components	Area of increased echogenicity with respect to normal ovarian parenchyma.	Descriptor associated with dermoid and haemorrhagic cysts.	
5	<b>Vascularity</b>		
	<b>Colour score 1-4</b>		
			<p>Colour score = 1(no flow)</p> <p>Colour score = 2(minimal flow)</p> <p>Colour score = 3(moderate flow)</p>

			Colour score = 4(severe flow)
5	<b>General and extra-ovarian findings</b>		
	Classic benign descriptors Paraovarian cyst		
	Peritoneal inclusion cyst		
Fluid descriptors	Ascites	Fluid extending above uterine fundus beyond the POD.	

**Statistical Analysis**

SPSS (Statistical Package For Social Sciences) version 20. (IBM SPASS statistics [IBM corp. released 2011] was used to perform the statistical analysis

Data was entered in the excel spread sheet.

Descriptive statistics of the explanatory and outcome variables were calculated by frequencies and percentages for qualitative variables.

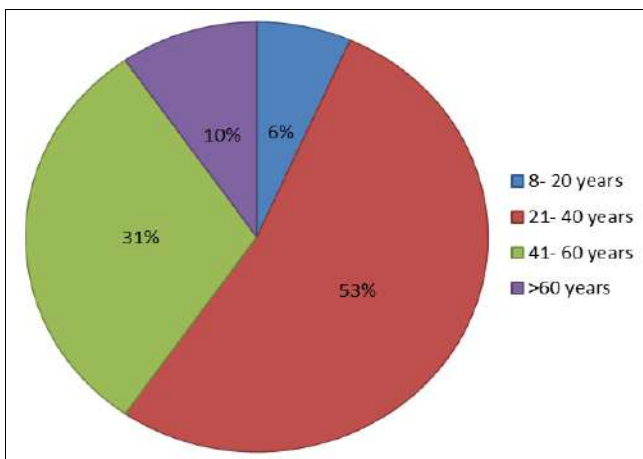
Inferential statistics like Chi-square test was applied for qualitative variables. The level of significance is set at 5%

**Results**

**Table 1:** Age distribution of subjects

Age groups	Number of cases	Percentage
8- 20 years	11	6.6%
21- 40 years	88	53.0%
41- 60 years	51	30.7%
>60 years	16	9.6%
Total	166	100%

Out of 166 subjects, majority of the subjects were in age group of 21-40 yrs with a maximum percentage of 53.0%, followed by 30.7% in 41-60 yrs age group, 16(9.6%) subjects were in age group of >60yrs. Age ranged from 8 years to 76 years. Mean age of the study group was 46 years.

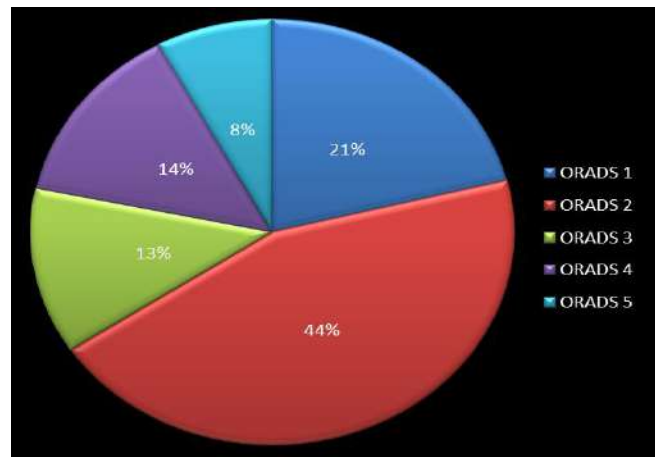


**Fig 1:** Age distribution of cases

After performing transabdominal and /or transvaginal ultrasound, the subjects depending on the characters of adnexal/ ovarian lesions were categorized into various groups of ORADS. Highest cases were in ORADS-2 with 44.6%, followed by 21.1% in ORADS-1 grade. Lowest cases were in ORADS-5 with 7.8% followed by ORADS-3 with 12.7%.

**Table 2:** Distribution of cases according to orads gradings

Orads grading	Number of cases	Percentage
Orads 1	35	21.1%
Orads 2	74	44.6%
Orads 3	21	12.7%
Orads 4	23	13.9%
Orads 5	13	7.8%
Total	166	100%

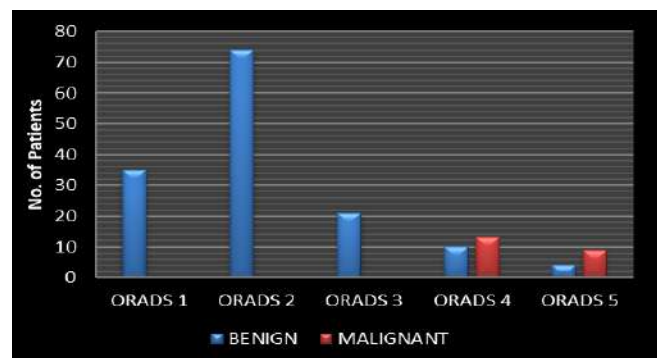


**Fig 2:** Distribution of cases according to orads gradings

Highest cases were in ORADS-2 with 44.6%, followed by 21.1% in ORADS-1 grade. Lowest cases were in ORADS-5 with 7.8% followed by ORADS-3 with 12.7%.

**Table 3:** Association between Orads score and HPE

Orads Grades	Benign (n=144)		Malignant (n=22)		Total count	Analysis
	Count	Percentage	Count	Percentage		
ORADS 1	35	100.00%	0	0.00%	35.00	Chi-square value- 92.75 P value – 0.000
ORADS 2	74	100.00%	0	0.00%	74.00	
ORADS 3	21	100.00%	0	0.00%	21.00	
ORADS 4	10	43.48%	13	56.52%	23.00	
ORADS 5	4	30.77%	9	69.23%	13.00	



**Fig 3:** Association between orads score and hpe

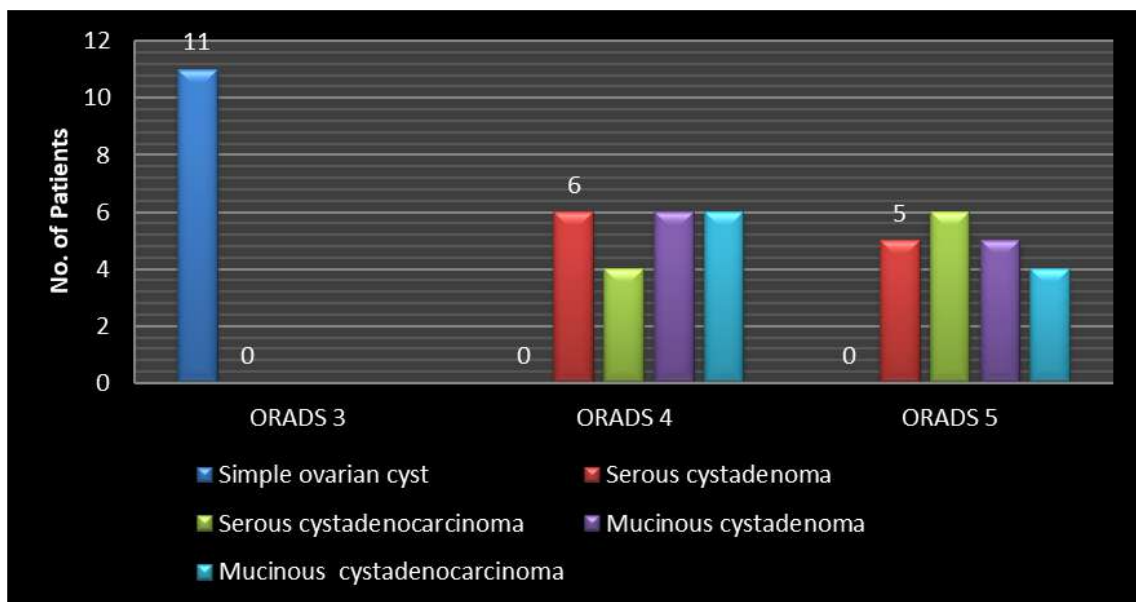
Overall 13.25% cases were malignant and 86.75% were benign. ORADS 1,2, and 3 had no malignant cases. Percentage of malignancy increased from ORAD-4 to ORAD-5. Percentage of benign cases decreased from ORAD-1 to ORAD-5 with ORADS 1,2 and 3 having only

benign cases. Chi square test was applied and p value of 0.000 was derived indicating extremely significant statistical difference between the distribution of benign and malignant tumours across ORADS grades.

**Clinical follow up**

**Table 4:** Histopathological reports of orads 3, 4 and 5

ORADS	Simple ovarian cyst	Serous cystadenoma	Serous cystadenocarcinoma	Mucinous cystadenoma	Mucinous cystadenocarcinoma	Total
ORADS 3	11	0	0	0	0	11
ORADS 4	0	6	4	6	6	22
ORADS 5	0	5	6	5	4	20
Total	11	11	10	11	10	53



**Fig 4:** Histopathological reports of ORADS 3, 4 and 5

Simple ovarian cysts were most prevalent in ORADS-3. ORADS 4 and 5 had all Serous cystadenocarcinoma, Mucinous cystadenoma and Mucinous cystadenocarcinoma. 53 patients who underwent surgery, following were their histopathological reports. These patients were further referred to the Department of Clinical Oncology for further management.

**Discussion**

The present study titled “Risk Stratification And Validation Of Ultrasound Ovarian & Adnexal Reporting Data System- Correlation With Clinical Follow - Up and Histopathology” was conducted at JSS Medical College, Mysuru, Karnataka for 18 months. This study is a prospective observational study on 166 patients presented with suspected adnexal masses.

Ultrasound imaging is the first choice to describe ovarian adnexal masses and estimate their malignancy risk. Ultrasound is low-cost and easily accessible, but highly operator-dependent. To improve the malignancy risk estimate and the management of adnexal masses, many guidelines and structured reporting systems have been established, using subjective assessments, simple scoring, or statistically derived scoring.

The Ovarian-Adnexal Reporting and Data System (O-RADS) ultrasound risk stratification and management

system is the only lexicon and classification system encompassing all risk categories of adnexal masses, with a management recommendation for each risk category. It may be the most complex adnexal masses diagnosis system, including six categories (O-RADS 0-5) and at least 21 detailed combined lexicon descriptors for scoring. However, various studies on external validation of ORADS have stated that it is to be the most effective ultrasound system, as it improved the accuracy of assessments of the malignancy risk of adnexal masses by providing a standardized reporting tool describing masses in terms of echogenicity, size, cystic wall, internal septum, boundary, shape, and blood flow.

In this context, our study sought to compare the O-RADS with histopathology and clinical follow ups.

**Demographic characteristics**

Our study included the subjects with age group ranging from 8 years to 76 years with mean of 46.7 years. Out of 166 subjects, majority of the subjects were in age group of 21-40 years with a maximum percentage of 53.0%, followed by 30.7% in 41-60yrs age group, 16 (9.6%) subjects were in age group of > 60yrs. In a study by Matuloni *et al.*, mean age was 63 years. Kheri *et al.* noted that only few cases (14%) of ovarian cancers were reported before 40 years of age, and after the age of 50 is a sharp increase in the

incidence of a tumour. The mean age at presentation was  $52.36 \pm 14.210$  year. In our observations, though the mean age was lesser than other studies, is consistent with the hypothesis that per menopausal age increases the ovarian malignancies.

#### Association between ORADS score and Histopathology

In our study, 21.1% had ORADS 1 grade, 44.6% had ORADS 2 grade, 12.7% had ORADS 3 grade, 13.9% had ORADS 4 grade and 7.8% had ORADS 5 grade.

In our study, 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. Results of our study is consistent with observations of other studies of external validation.

Cao *et al.* [12] compared the O-RADS with histopathology. The malignancy rates of O-RADS 5, O-RADS 4, O-RADS 3, and O-RADS 2 lesions were 89.57%, 34.46%, 1.10%, and 0.45% respectively. In a study by Hack *et al.*, the proportion of malignancy was 0% (0 of 100) for O-RADS 2, 3% (one of 32) for O-RADS 3, 35% (22 of 63) for O-RADS 4, and 78% (52 of 67) for O-RADS 5. Jha *et al.* observed that the frequency of malignant neoplasm for O-RADS US 2 was 0.5% (3 of 657 lesions; <1% expected); O-RADS US 3, 4.5% (5 of 112 lesions; <10% expected); O-RADS US 4, 11.6% (18 of 155; 10%-50% expected); and O-RADS 5, 65.6% (59 of 90 lesions; >50% expected).

Timmerman *et al.* [10] also observed that using the O-RADS lexicon resulted in 1.1% (24 of 2196) observed prevalence of malignancy in O-RADS 2, 4% (34 of 857) in O-RADS 3, 27% (246 of 904) in O-RADS 4, and 78% (732 of 939) in O-RADS 5.

Further, our study observed that the sensitivity and specificity of O-RADS 3 for malignancy was 81.2% and 97% respectively. The area under ROC was 0.933. Other studies which sought the external validation of ORADS gradings also concurred with our observations.

Hack *et al.* [11] observed that the use of O-RADS 4 as a threshold yielded a sensitivity of 99% (74 of 75; 95% CI: 96, 100) and a specificity of 70% (131 of 187; 95% CI: 64, 77).

Cao *et al.* [12] noted that the optimal cut-off value for predicting malignancy was >O-RADS 3 with a sensitivity and specificity of 98.7% (95% CI, 0.964-0.996) and 83.2% (95% CI, 0.802-0.858) respectively. Ahmed *et al.* highlighted that the O-RADS scoring system showed a high sensitivity 94.12%, specificity 68.75%, and accuracy 86% with 86.49% PPV & 84.62 NPV.

In the study by Jha *et al.* [13], O-RADS 4 was the optimum cut-off for diagnosing cancer with sensitivity of 90.6% (95% CI, 82.3%-95.9%), specificity of 81.9% (95% CI, 79.3%-84.3%), positive predictive value of 31.4% (95% CI, 25.7%-37.7%) and negative predictive value of 99.0% (95% CI, 98.0%-99.6%).

Solis *et al.*, in their study on external validation of ORADS, measured sensitivity for detection of ovarian cancer is 52%, a specificity of 84%, a negative predictive value of 79%, and a positive predictive value of 60%, with an accuracy of 73%.

As the ORADS 4 refers to the intermediate-risk category (10% to <50% risk of malignancy) that includes all descriptors found to be predictive of a higher risk of malignancy. This includes multilocular cysts that are greater

than or equal to 10 cm, or have an irregular inner wall or septal irregularity. As implicated in earlier studies, significant correlation was observed between multilocularity, size of the tumour and irregular margins with malignancies.

O-RADS 5, the high-risk category ( $\geq 50\%$  risk of malignancy), is comprised of descriptors that are highly predictive of malignancy such as irregular solid lesions and multilocular cysts with a solid component and high colour score. As with the ORADS 4 grade, previous studies have highlighted the association between solid lesions, high colour flow and chances of malignancy. Hence, it is intuitive as well as empirical for ORAD grade 4 and 5 to have higher specificity for malignancies.

**Table 5:** Comparison of various studies for the malignancy rates according to ORADS.

Grades	Current study	Cao <i>et al.</i>	Hack <i>et al.</i>	Jha <i>et al.</i>	Timmerman <i>et al.</i>
ORADS 1	0	-	0	0	0
ORADS 2	0	0.45%	0	0.5%	1.1%
ORADS 3	0	1.1%	3%	4.5%	4%
ORADS 4	56.52%	34.46%	35%	11.6%	27%
ORADS 5	69.23%	89.57%	78%	65.6%	78%

#### Prognosis and clinical follow up

In ORADS 4 and 5, 10 and 5 cases had TAH with BSO respectively. In ORADS 4, 12 cases of Oophorectomy were performed and in ORADS 5, 8 cases of staging Laparotomy with Debulking were performed.

Higher percentages of TAH was performed in ORADS grade 4 and 5 consistent with higher rates of malignancy. In contrast, among ORADS Grades 1,2 and 3, no major surgical procedure was carried out. Our observation was similar to observations by Jha *et al.* [13] and Ahmed *et al.* [14] who noted that patients with higher grades of ORADS had underwent invasive surgical procedures.

In the past, several attempts have been made to develop more objective ultrasound-based approaches for discriminating between benign and malignant adnexal tumours. These include the risk of malignancy index (RMI), a scoring system based on menopausal status, a transvaginal ultrasound score and serum cancer antigen 125 (CA 125) level. The IOTA model was the most studied one till the advent of ORADS system.

Basha *et al.* [14], Determined the malignancy rates, validity and reliability of the O-RADS approach when applied to a database of 647 adnexal masses collected before the development of the O-RADS system. In this retrospective study, the O-RADS system had significantly higher sensitivity than did the GI-RADS system and the IOTA Simple Rules, with a non-significant slightly lower specificity compared with both GI-RADS and IOTA Simple Rules, and with similar reliability.

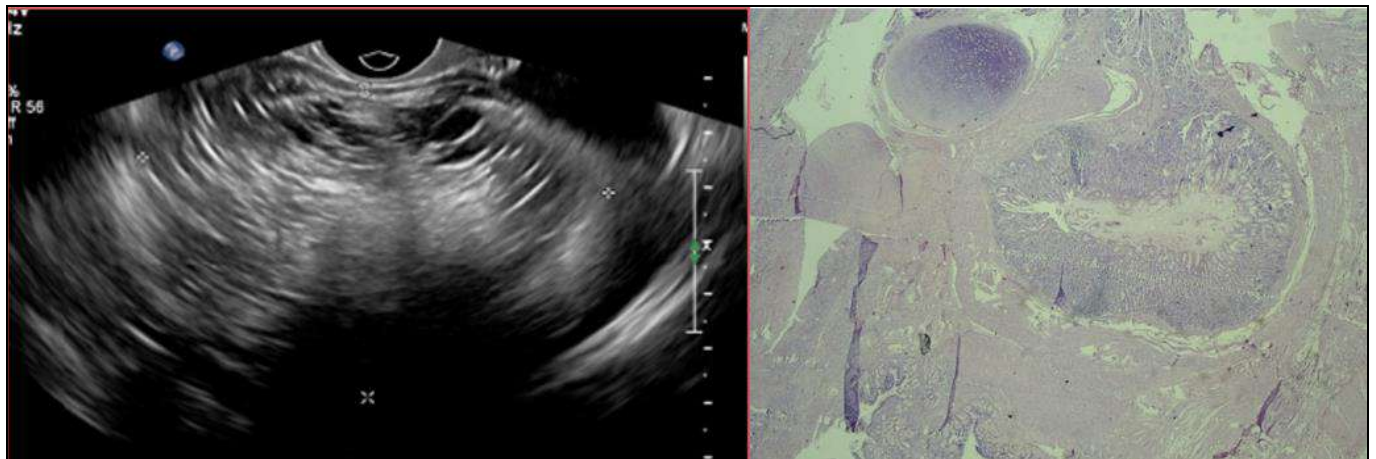
However, there are certain limitations in the ORADS system. Although serum markers do play a role in evaluation, the ORADS US committee purposely did not advocate for their routine use in the assessment based on lesion category, and they are not included in our risk stratification system. The committee felt that tumour marker evaluation should be individualized for each patient.

The authors of ORADS also emphasizes that the O-RADS classification is not a substitute for performing a thorough history and physical examination and assessing the patient's

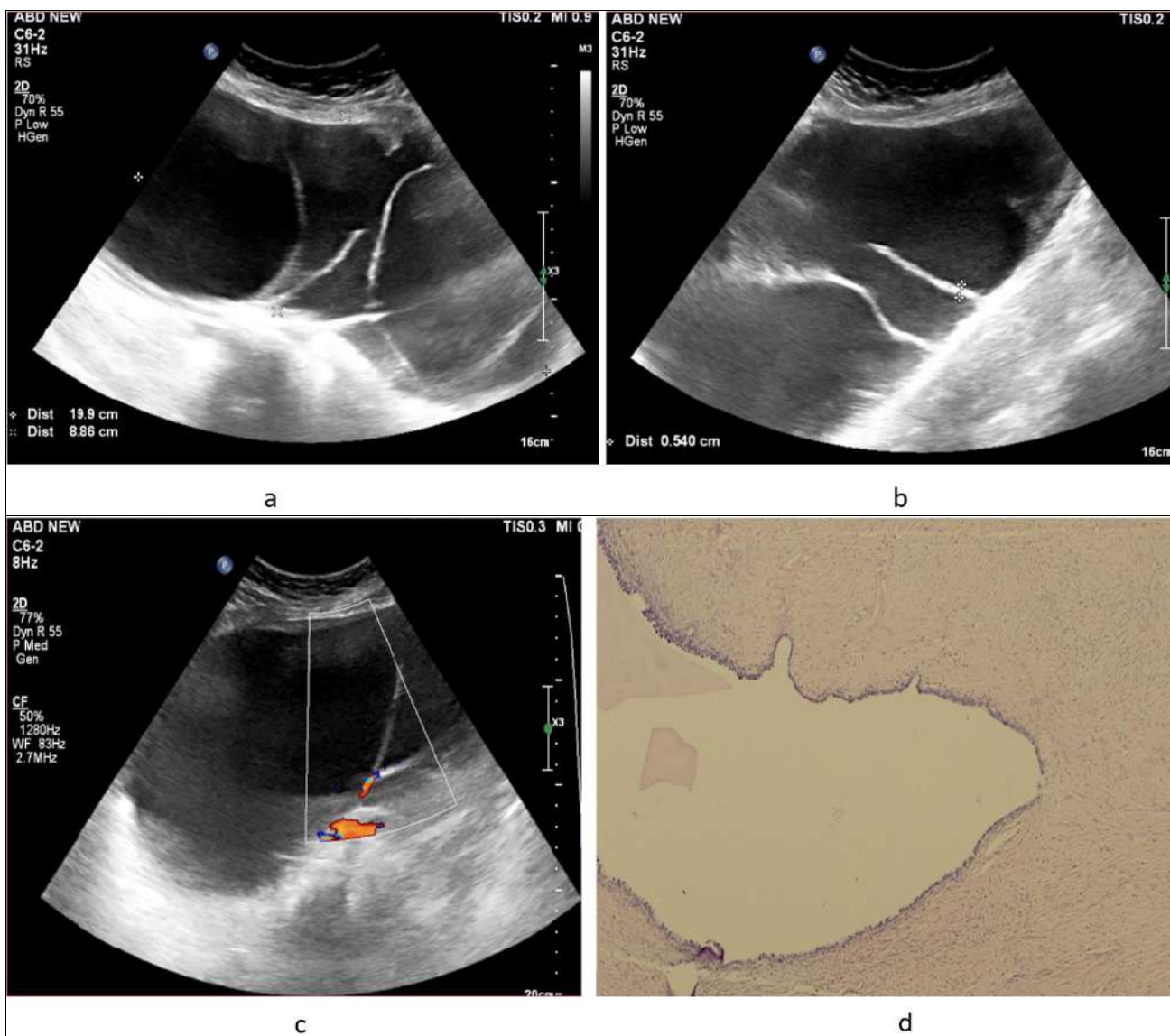
need for additional testing. Although no classification system can completely encompass all aspects of the

management of each patient with an adnexal lesion, O-RADS gradings more clearly defines referral criteria.

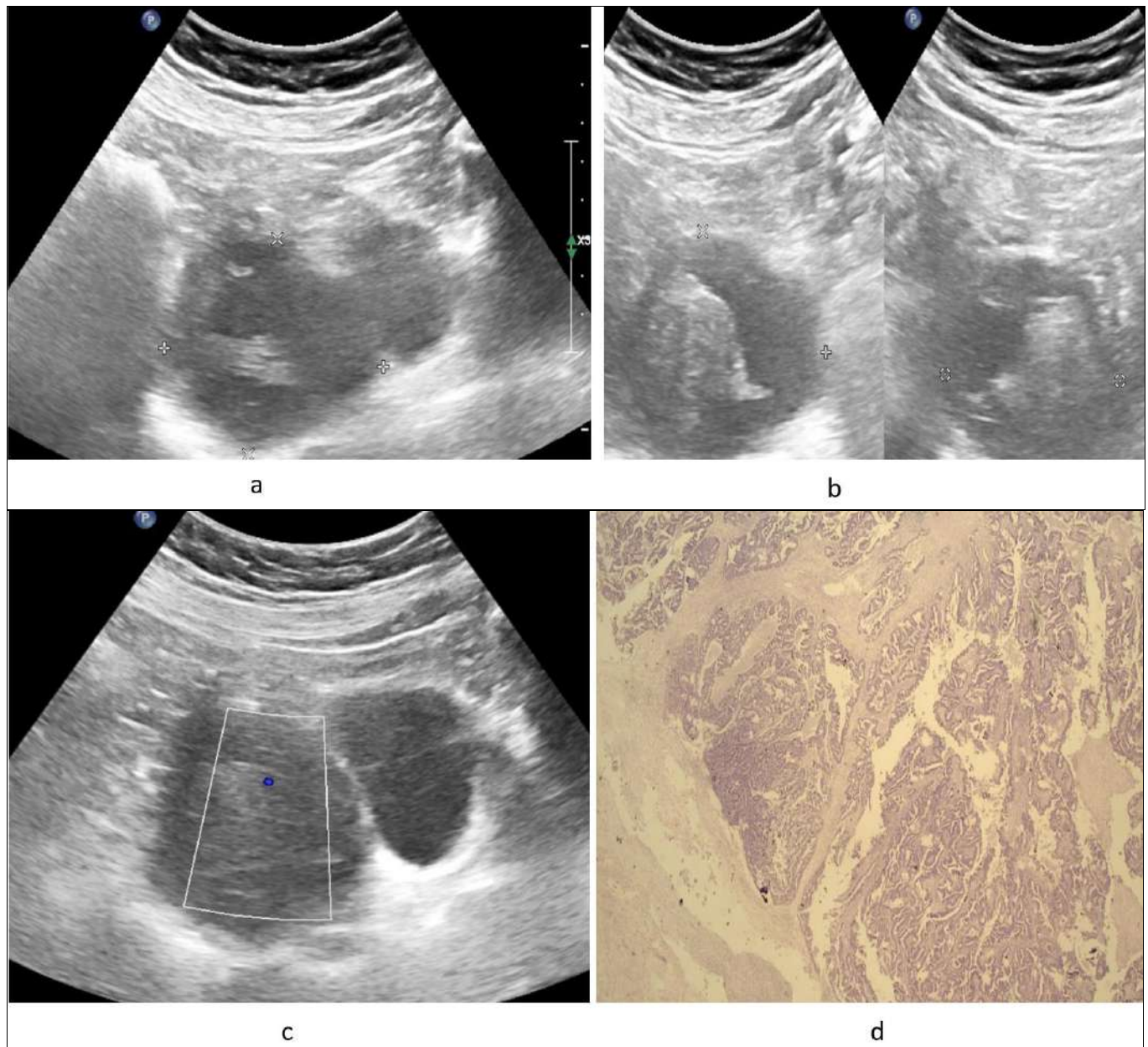
**Representative Images**



**Fig 5:** A 24yr old female came with chief complaints of abdominal pain. USG shows a well defined smooth walled solid ovarian cyst measuring ~ 6-7cm in the right ovary with reticular pattern as its content. ORADS – 2 was given. HPR shows features of dermoid.



**Fig 6:** A 44yr old female came with chief complaints of menorrhagia. USG shows a well defined irregularly margined multiloculated cystic lesion measuring~ 11.2 x 11.0cm with irregular thick septations. No solid component noted within. ORADS 4 - Serous cystadenoma. HPE - Benign, Serous cystadenoma



**Fig 7:** A 64yr old female came with mass per abdomen. USG shows a well defined cystic lesion measuring ~ 13.4 x 12.0cm with solid component within. Moderate internal vascularity noted within. Ascites was also present. ORADS 5 - Serous Cystadenocarcinoma. HPE - Benign, Serous Cystadenocarcinoma

**Conclusion**

Ovarian-Adnexal Reporting and Data System US risk stratification and management system had higher sensitivity and specificity for detection of adnexal malignancy in our study. Lower ORADS Grades were had loculated tumours, irregular margins, septations, solid component, and higher echogenicity. In the ORADS Grade 1,2 and 3, did not have any malignancy. ORADS grade 4 and 5 had higher prevalence of malignancy.

Ovarian-Adnexal Reporting and Data System US risk stratification and management system enabled accurate distinction of benign from malignant ovarian and adnexal lesions. Ovarian-Adnexal Reporting and Data System US risk stratification and management system can be relied upon for referral of the patients for Onco-Gynaecological references.

However, there is a need for a larger interobserver variability study to validate the use of the system by expert as well as less experienced observers, since initial lesion

characterization is key to risk stratification.

**List of abbreviations**

**Usg:** Ultrasonography

**Orads:** Ovarian and adnexal reporting data system

**Tas:** Transabdominal sonography

**Tvs:** Transabdominal sonography

**Girads:** Gynecologic imaging-reporting and data system

**Iota:** International ovarian tumor analysis

**Hpe:** Histopathological examination

**Conflict of Interest**

Not available



**Financial Support**

Not available

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