Original Article

Evaluation of Ovarian Lesions on Ultrasound Staged by ORADS

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ABSTRACT

Introduction: Adnexal lesions are common among women of all age groups. These vary from benign lesions like functional cysts to malignant ones like ovarian cancer. To eliminate the ambiguity and inconsistency in reports, American College of Radiology (ACR) developed Ovarian-Adnexal Reporting and Data System Ultrasound (ORADS-US) based risk stratification system. It provides the management recommendations in each category and has a higher probability of accurately assigning risk of malignancy, thus, decreasing unnecessary surgical interventions and optimizing management. The aim of the present study was to study the various morphological characteristics of adnexal lesions on ultrasound, classify them based on ORADS, formulate a standardized reporting system to facilitate management, and to determine accuracy of ORADS in differentiating benign and malignant lesions.

Methodology: A prospective study was conducted with 63 patients suspected of adnexal lesion or incidental detection. Females of more than 12 years of age were included while patients with ORADS 1 category and lost to follow-up were excluded. The transabdominal scan was done using HS70A ultrasound machine and lesion categorized and followed-up according to the ACR-ORADS guidelines.

Results: Amongst 63 patients, 11 (17.4%) turned out malignant and 52 were (82.53%) benign. Among the premenopausal women, only 3 out of 50 (6%) had malignant lesions. Among postmenopausal women, 8 out of 13 (61.5%) had malignant lesions. All ORADS 2 and ORADS 3 lesions were benign. Four cases categorized as ORADS 4 (36.3%) and all lesions categorized as ORADS 5 (100%) turned out malignant.

Conclusion: ORADS is an accurate risk stratification system for classifying benign and malignant ovarian neoplasm. It standardizes the reporting system and guides further management.

Keywords: American College of Radiology, colour score, histopathological examination, ORADS, USG.

INTRODUCTION

Adnexal lesions are common among women of all ages and most common in reproductive age groups. These lesions can vary from benign lesions like functional cysts to malignant lesions like ovarian cancer.

As malignant ovarian lesions have unobvious early symptoms and are prone to spread, approximately 60-70% cases when diagnosed are already in the advanced stage. The 5-year survival rates of stage III and IV patients are also low, making ovarian lesions the first among all female malignant tumors in terms of mortality rate. However, since surgeries are performed merely for suspected ovarian cancers with 1/3 being benign masses, it is important to elevate the diagnostic accuracy in order to decrease the treatment costs as well as to enhance the efficacy and decrease the mortality rates.[1,2]

Adnexal lesions pose a unique diagnostic challenge. Determination of a degree of suspicion of malignancy is critical and is based chiefly on imaging appearance. Ultrasound is the modality of choice for imaging the suspected adnexal lesions, but the lack of standardized terms in imaging related to adnexal pathology is a cause for concern. Inconsistency of morphologic imaging descriptors and definitions internationally, nationally, and among local institutions often results in significant differences in interpretations of the ultrasonography report. To increase the diagnostic rate and sensitivity, various systems have been proposed, like International Ovarian Tumor Analysis Simple Rules (IOTA-SRs) and Gynecologic Imaging Reporting and Data System (GI-RADS).

In 2015, under the supervision of the ACR (American

College of Radiology), the Ovarian-Adnexal Reporting and Data System (ORADS) committee was formed to create a standardized lexicon that would lead to the development of a uniform, practical vocabulary for describing the imaging characteristics of ovarian lesions. The Ovarian-Adnexal Reporting and Data System (ORADS) is a lexicon and risk stratification tool designed for the accurate characterization of adnexal lesions and is essential for optimal patient management. Since most ovarian or adnexal lesions are first detected with the USG, ORADS-US is considered the primary assessment tool.[3,4]

This study aimed to analyze the various features of ovarian-adnexal lesions and group them into different categories based on ORADS and then correlate it with follow-up ultrasonography reports for resolution of the lesion or with the MRI and HPE and followed up as needed.

METHODS

This was a prospective observational study. The study included 63 patients referred to the Department of Radiodiagnosis at JLN Medical College, Ajmer, Rajasthan, for evaluation of adnexal lesion or with incidental detection of the adnexal lesion. The study was conducted from July 2021 to December 2021. All females more than 12 years of age were included in the study and patients with ORADS 1 category lesion and patients who were lost to follow-up were excluded.

ORADS lexicon outline[3,4,5]

In ORADS, the lesions are described under these headings and categorized accordingly.

- **Category**: It is assigned as either 'Physiological,' or the term 'Lesion' is used.
    - Physiological consists of follicles and corpus luteum. Follicles are defined as anechoic well-defined cysts measuring ≤ 3 cm in maximum dimensions in the premenopausal age group. Corpus luteum is a thick walled cyst ≤ 3 cm that may have crenulated inner margins, internal echoes, and peripheral vascularity on color doppler.
    - Lesion consists of:
        a. Unilocular without any solid content
        b. Unilocular with solid content
        c. Multilocular without any solid content
        d. Multilocular with solid content
        e. Solid (>80% of the lesion is solid)
- **Size:** The maximum dimension in all three planes and the maximum dimension of the solid component is represented.
- **Solid/solid appearing lesion:** External contour can be smooth or irregular. Internal content may be calcified or fibronatous.
- Cystic lesions can be regular or irregular inner margins.

  Internal content may be cystic component, solid component, and the presence of septations (even single complete septation is considered multilocular).
- **Vascularity**: It is shown by color score 1 to 4. Colour score 1= no vascularity; colour score 2 = mild vascularity; colour score 3 = moderate vascularity; colour score 4 = very strong vascularity.
- **Extraovarian findings:** It may include para ovarian cyst, fallopian tube descriptors, peritoneal inclusion cyst fluid descriptors, peritoneal thickening, nodules, adenopathy, ascites.

ORADS 1 is the normal ovary (physiological category) consisting of the follicles defined as simple cyst < 3 cm and the corpus luteum with the largest dimension less than 3 cm. We excluded the patients with ORADS 1 category.

ORADS 2 is almost benign (<1% malignancy risk):

- Unilocular cystic lesion with the largest dimension <10 cm with smooth inner margin.
- Classic benign descriptors-

  -Hemorrhagic cyst, dermoid, endometrioma (less than 10 cm).

  -Para ovarian cyst, peritoneal inclusion cyst, and hydrosalpinx (any size).

ORADS 3 is the low risk malignancy (1-10%):

- Unilocular cysts with smooth inner margin >10 cm
- Classic benign descriptors >10 cm
- Unilocular lesion with an irregular inner wall (any size)
- Multilocular lesion with smooth inner margin or septations < 10 cm CS 1-3
- Solid lesion with smooth outer contour (any size) CS-1

ORADS 4 is the intermediate risk malignancy (10-50%):

- Unilocular cystic lesion with solid component (1-3 papillary projection) CS any
- Multilocular cystic lesion with smooth inner margin > 10 cm CS 1-3 or any size CS 4

- Multilocular cystic lesion with irregular inner margin or septations (any size) any CS
- Multilocular cyst with solid component (any size) CS 1-2
- Solid lesion with smooth outer contour (any size) CS 2-3

ORADS 5 is the high risk malignancy (51-100%):

- Unilocular cystic lesion with >4 papillary projection, any size, CS any
- Multilocular cystic lesion with solid component, any size, CS any
- 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

The patient's age and menstrual history were taken and the transabdominal scans were done using the HS70A ultrasound machine. The lesion was described and categorized according to the ACR-ORADS descriptors and followed-up according to the assigned ORADS category defined under the ACR-ORADS management guidelines. Statistical analysis was performed and findings depicted in pie charts, and graphs.

RESULTS

The study was conducted on 63 patients with suspected or incidentally detected adnexal lesions. The majority of cases belonged to the premenopausal age group accounting for 79.36% of cases (50 of 63) and 20.6% (13) belonged to the postmenopausal age group.

The majority of cases studied were benign, accounting for 82.53% of cases (52) and 17.4% (11) were malignant, confirmed by the histopathological reports. Among the premenopausal women who formed the major part of the study, only 3 out of 50 (6%) were malignant (Table 1). Two turned out to be immature teratoma on histopathological examination and one was borderline malignant teratoma. Among the postmenopausal women, 8 out of 13 (61.5%) were found to have malignant lesion.

Regarding lesion characterization on ultrasound according to the ACR-ORADS, 31 were categorized as ORADS 2, 14 as ORADS 3, 11 as ORADS 4, and 7 as ORADS 5, as shown in figure 1.

All the 31 lesions assigned to the category of ORADS 2 were benign, with 18 lesions showing complete resolution of the lesion or reduction in dimension on follow-up ultrasound scan, and 13 lesions were proven to be of benign nature by additional imaging modalities (MRI P+C). Fourteen lesions were categorized as ORADS 3, and all were proven to be of benign nature on MRI (P+C) or HPE. Eleven lesions were categorized as ORADS 4. Four amongst them were proven malignant on histopathological examination accounting for 36.3% of ORADS 4 categorized cases. Among the lesions assigned to the category of ORADS 5, all were proven malignant, accounting for 100% of ORADS 5 categorized cases (Figure 2).

Table 1: Nature of lesions according to the menstrual status

Nature	Premenopausal (50)	Postmenopausal (13)
Benign (52)	47	5
Malignant (11)	3	8

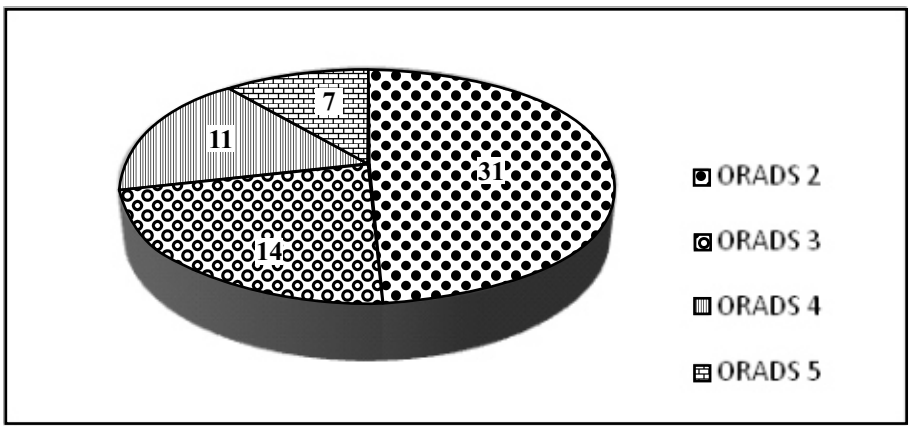

Figure 1: Lesions characterization by ORADS.

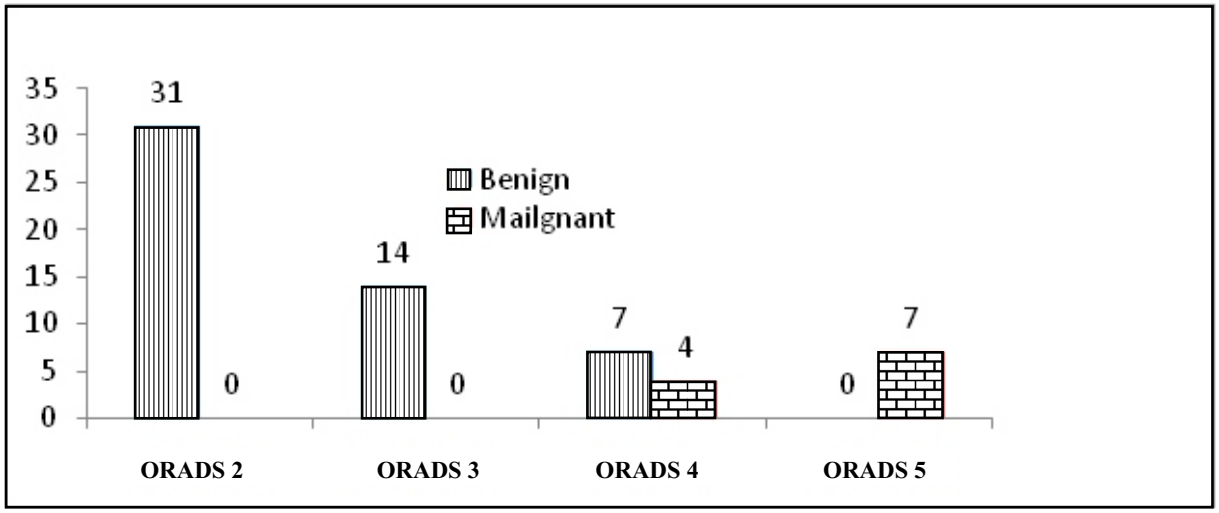

Figure 2: Nature of lesion according to ORADS category.

Table 2: Lesion characteristics on B mode Ultrasonography

Category	Without solid component (all benign)	With solid component		
			Benign	Malignant
Unilocular (44)	38	6	3	3
Multilocular (14)	12	2	-	2
Solid (5)				

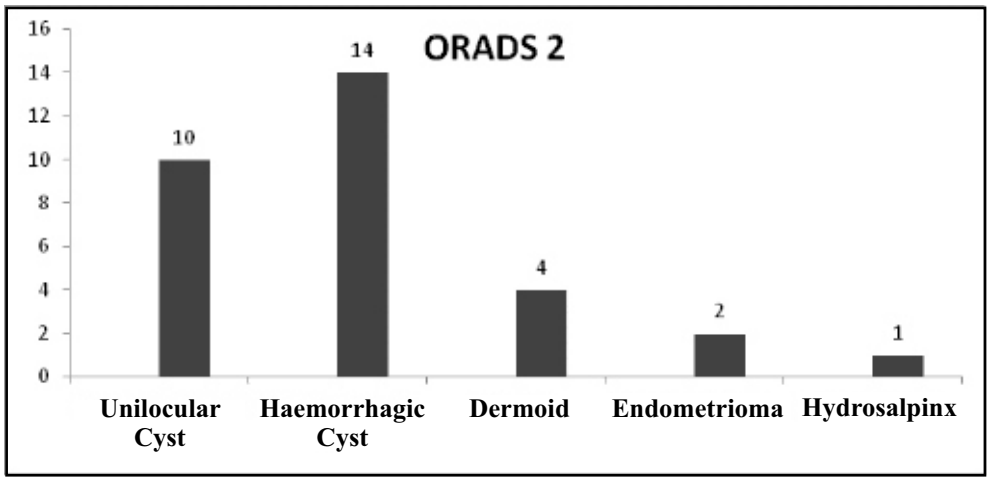

Figure 3: Characterization of lesions of ORADS 2 category.

On B mode ultrasonography, 44 (69.8%) were unilocular lesions, with 6 of them showing solid components, 14 (22.2%) were multilocular with 2 showing solid components, and 5 (7.9%) were predominantly solid lesions (Table 2). Three out of six unilocular lesions with solid component and two multilocular lesions with solid component and one multilocular lesion with irregular inner margins and the five predominantly solid lesions were proved malignant on HPE.

In the present study, 31 cases were assigned ORADS 2 category as shown in figure 3. 14 cases were assigned the category of ORADS 3, among which 5 were unilocular cysts with smooth inner margin >10 cm, one dermoid, one endometrioma, and 7 multilocular lesions with smooth inner margin or septations <10 cm CS 1-3. All were proven benign (Figure 4). 11 cases were categorized as ORADS 4 as shown in table 4 and figure 5.

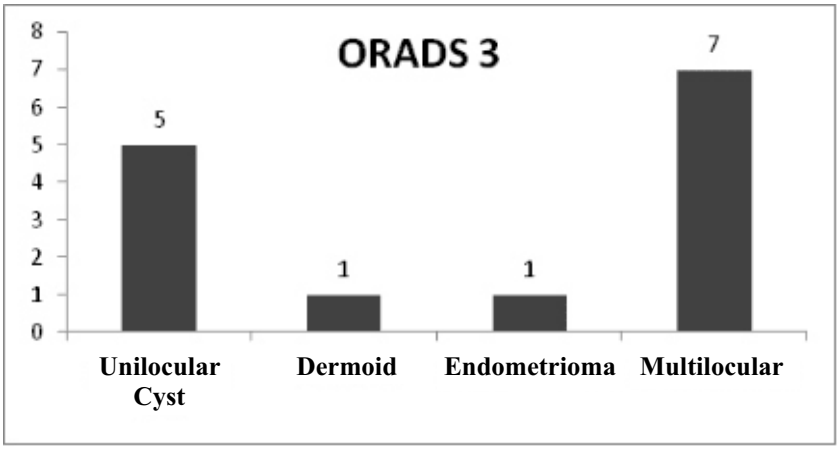

Figure 4: Characterization of lesions of ORADS 3 category.

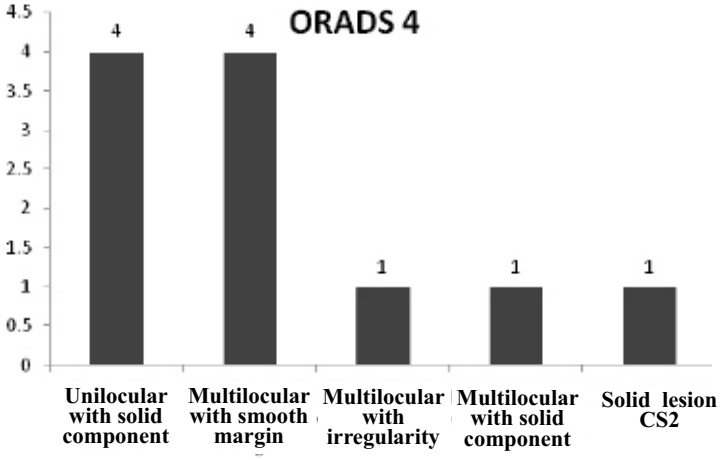

Figure 5: Characterization of lesions of ORADS 4 category.

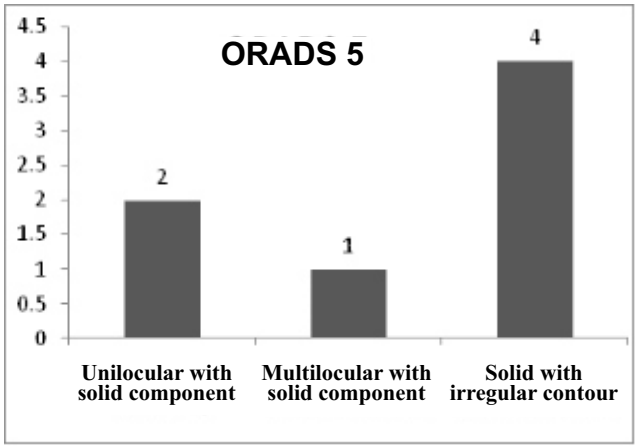

Figure 6: Characterization of lesions of ORADS 5 category.

Table 4: Characterization of ORADS 4 lesion into benign and malignant

Characteristics of the lesion (ORADS 4)	Cases	Benign	Malignant
Unilocular lesion with solid component	4	3	1
Multilocular lesion with smooth margin	4	4	–
Multilocular lesion with irregular margin	1	–	1
Multilocular lesion with solid component	1	–	1
Solid lesion with smooth outer contour CS 2	1	-	1

Table 5: Prediction of malignant lesions by ORADS in the study

USG	Reference standard (follow up/MRI/ HPE)- Benign	Reference standard (follow up/MRI /HPE) -Malignant	Prediction for malignant lesions by ORADS in our study	Actual prediction for malignant lesions by ACR-ORADS
ORADS 2 31cases	31	–	0%	<1%
ORADS 3 14 cases	14	–	0%	1-10%
ORADS 4 11 cases	7	4	36.6%	10-50%
ORADS 5 7 cases	–	7	100%	50-100%

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Seven cases were categorized as ORADS 5 (figure 6).

Prediction value for malignant lesions by ORADS categorization in the present study as shown in table 5 is comparable to the ACR-ORADS described predictive value in differentiating benign and malignant lesions.

DISCUSSION

Ovarian tumors are optimally distinguished by ultra-sonography which, however, may sometimes be lacking. Accurate characterization of ovarian lesions is essential for optimal patient management strategies. Conservative management is more appropriate for benign lesions. On the other hand, when malignancy is suspected, patients should be referred to a gynecologist oncologist because this is known to result in better outcomes.[6-8]

A study done on patients with asymptomatic tumors classified as benign by using ultrasound supports the use of conservative management as a valid option, reducing surgical complications.[9] A consensus report published in 2017 by a multidisciplinary panel of experts regarding the management of adnexal masses[10] also concluded that surgical procedures for benign lesions can be avoided, and this will lead to a reduction in complications with improved preoperative assessment.

Expert consensus and the published studies support the use of pattern recognition by ultrasound as the most accurate method of discriminating between benign and malignant adnexal lesions.[11-15] However, the level of expertise of clinicians who perform and interpret sonograms varies widely. Thus, there is a need to improve risk stratification by establishing standardized and evidence-based risk assessment algorithms.

The ACOG recommendations[16] encourage detailed use of ultrasound risk assessment by all practitioners, which includes one of the ultrasound based risk classification systems developed by the International Ovarian Tumor Analysis (IOTA) group. The IOTA group has developed Simple Rules Classification System (SRS) and Assessment of Different Neoplasias in the Adnexa (ADNEX) model.[17-19]

But the drawback is that IOTA Simple Rules are unable to classify all adnexal masses as benign or malignant because there are some inconclusive masses in about 20% patients which needs another diagnostic method to classify, thus limiting its usefulness.

The IOTA Simple Rules referred to as the ten ultrasound rules were then incorporated in a mathematical model to calculate the likelihood of malignancy.[17] It was referred to as the IOTA ADNEX model.[18] It calculates the likelihood of an adnexal mass being not only simply benign or malignant but also the mass being borderline malignant (stage I) or a stage III-V primary invasive malignancy or a metastasis in the ovary from another primary tumor. Although the predictive value of these rules and models is high (and has been externally validated and is in common usage in Europe), their acceptance has been limited due to the pattern recognition approach being more preferred than a mathematical model.

Other systems have also been proposed, like the Society of Radiologists in Ultrasound Consensus Statement (SRU) and the Gynecologic Imaging Reporting and Data System (GI-RADS).[20] SRU is popular in North America. It is helpful in determining which cystic lesions require follow-up, further imaging, or a surgical procedure. Drawback is that it lacks standardized terminology and definitions and does not recommend management for higher-risk lesions.

GI-RADS also has the same drawback. Thus there was a need to come up with a universally recognized reporting tool based on common terminology, as well as a

Figure 7: An unilocular cystic lesion showing retractile clot was noted in the right adnexa measuring 7x6x6 cm (ORADS 2).

management system for all categories of risk. ACR came up with ORADS, which is an adaptation of IOTA Simple Rules.

Pi et al[21] studied 50 patients using the ORADS scoring system and concluded that the ACR-ORADS is an effective stratification tool for radiologists and supports its continued use in practice. Cao L et al[22] studied 1054 adnexal lesions, amongst which 750 were benign and 304 were malignant. The malignancy rates of ORADS 5, ORADS 4, ORADS 3, and ORADS 2 lesions were 89.57%, 34.46%, 1.10%, and 0.45%, respectively.

In the present study, 82.5% cases were benign and 17.4% were malignant. The fact that a woman after menopause has a higher risk of the adnexal mass being of the malignant nature and patients in the reproductive period more often have benign lesions was confirmed by the results of the present study.

Ten cases had unilocular anechoic cystic lesions, a smooth inner margin measuring less than 10 cm in the largest dimension. Fourteen cases had a reticular pattern that is fine thin intersecting lines representing fibrin strands and/or retracting clot that is an avascular echogenic component with angular, straight, or concave margins. These represent the classical descriptors of a hemorrhagic cyst and on follow-up scan, these showed resolution in terms of reduction in size (Figure 7). Follow up scan was advised after 6 weeks which showed the resolution of the lesion.

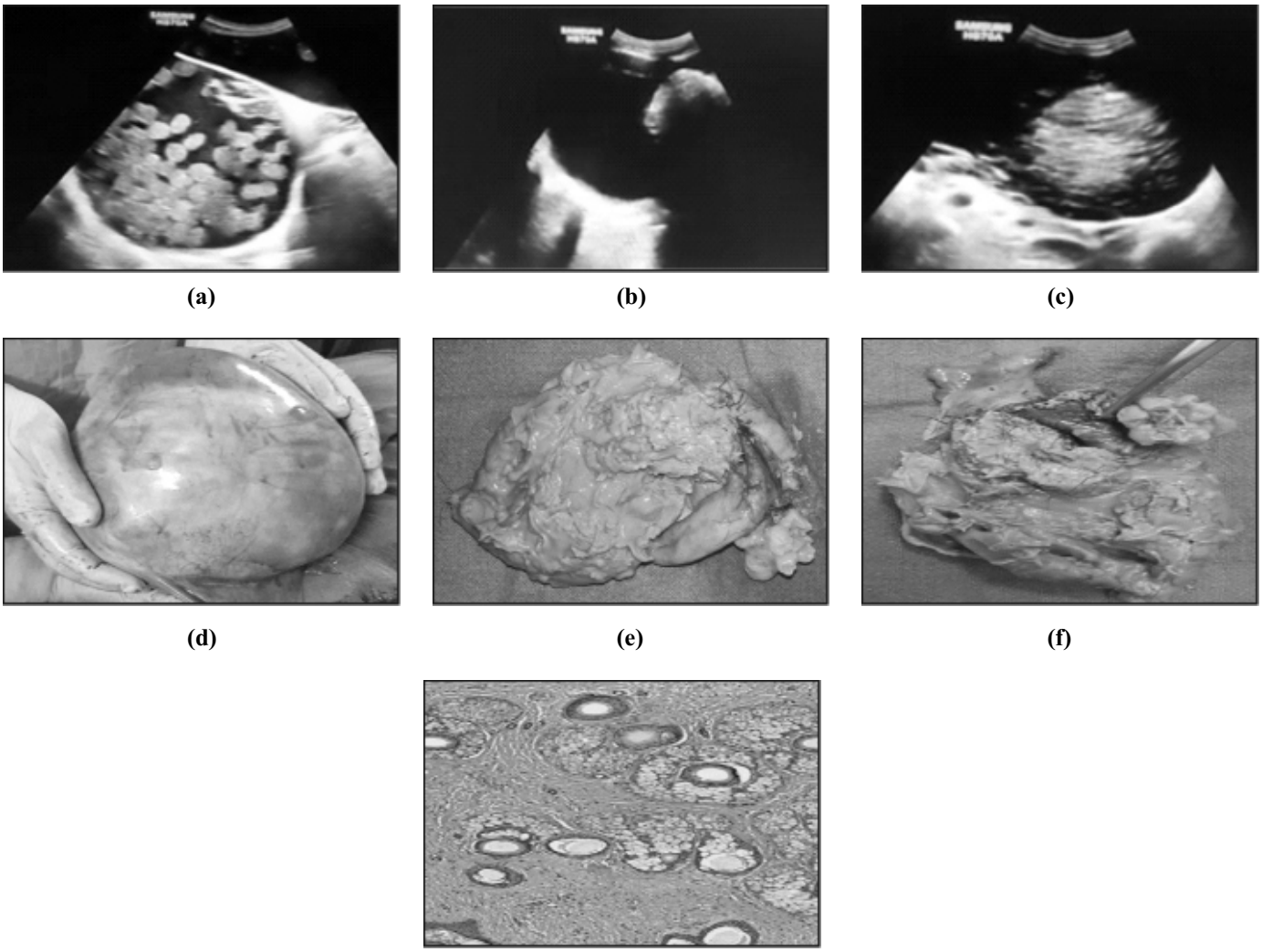
Four cases had findings consisting of either hyperechoic component with acoustic shadowing and/or hyperechoic lines and dots and/or floating echogenic spherical structures. These are the classical benign descriptors representing mature teratoma (dermoid) (Figure 8). These were proven dermoids on histopathological examination and additional imaging.

Two cases had ground glass/homogeneous low level echoes representing the classic benign descriptor for endometrioma. It was proved to be an endometrioma on MRI (Figure 9). One case showed a cystic lesion with tube-like morphology and incomplete septation and short round projections around the inner wall representing the descriptor of hydrosalpinx.

No vascularity on colour doppler (ORADS 3) was noted in multiloculated cystic lesions (Figure 10).

Four cases showed unilocular cystic lesion with solid component (1-3 papillary projection) and CS any, 4 multilocular cystic lesion with smooth inner margin > 10 cm CS 1-3 (Figure 11), one had multilocular cystic lesion with irregular septations and CS 2 (Figure 12) and one showed multilocular cyst with solid component CS 2 and one solid lesion with smooth outer contour CS 2. (Figure 13). Unilocular cyst with papillary projection and CS 3, multilocular cystic lesion with irregular septations and CS 3, multilocular cyst with solid component CS 2, and solid lesion with smooth regular contour CS 2 were malignant on histopathological examination.

Seven cases of category ORADS 5 were malignant. Out of them, three cases had ascites (Figure 14).



(a) **(b)** **(c)**

(d) **(e)** **(f)**

(g)

Figure 8: Ultrasound showing the typical dermoid descriptors in a lesion measuring 9x8x6 cm (ORADS 2). (a) floating hyperechoic spherical structures, (b) acaustic shadowing from a hyperechoic component, (c) hyperechoic lines and dot, (d) floating hyperechoic spherical structures, (e) and (f) showing hair component and fat component indicative of benign lesion (dermoid), and (g) histopathology examination shows hair follicles and stratified squamous epithelium.

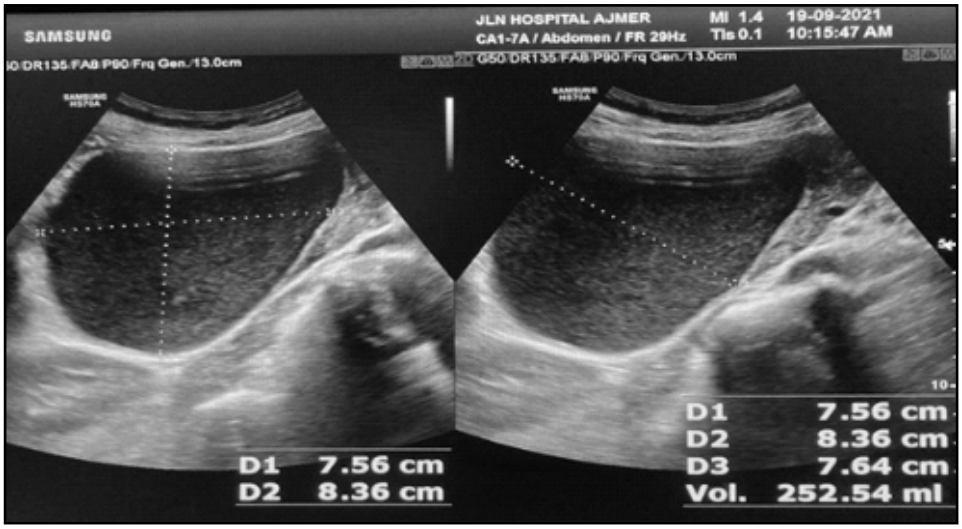
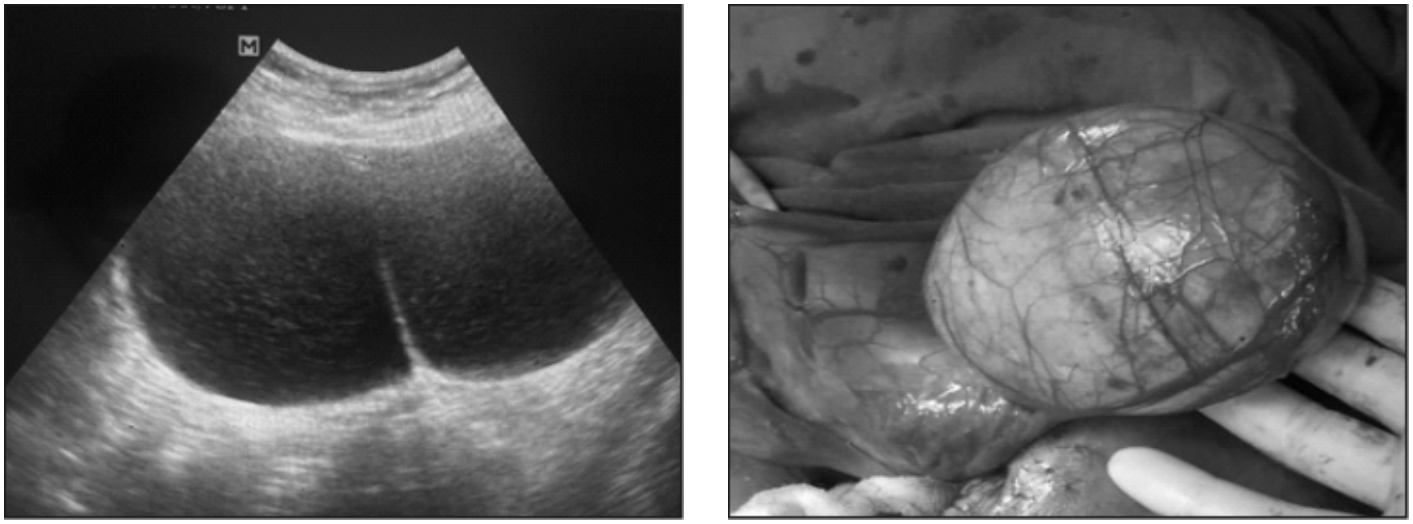
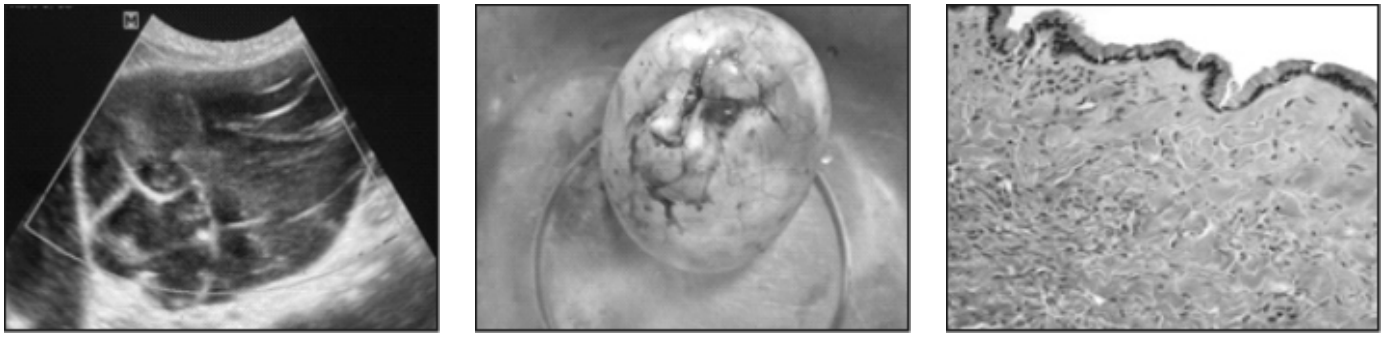


Figure 9: Unilocular lesion showing low level internal echoes measuring 9 cm in largest dimension (ORADS 2).



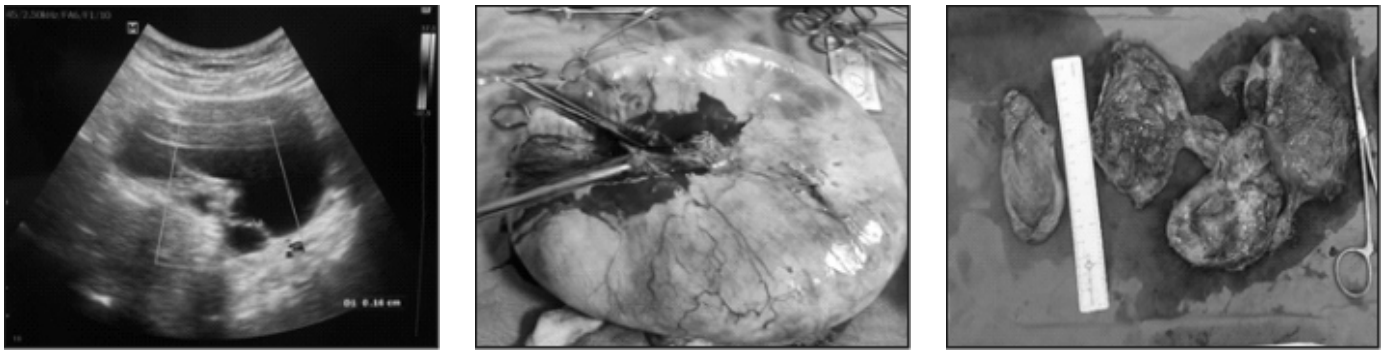
(a) **(b)**

Figure 10: (a) Multiloculated cystic lesion with single septa and smooth walls and no solid component noted measuring 9x8x6 cm, no vascularity on colour doppler (ORADS 3), (b) gross histopathological specimen of benign ovarian cystadenoma.



(a) **(b)** **(c)**

Figure 11: (a) Multiloculated cystic lesion with septae measuring 11x7 cm is noted, containing internal echoes and debris, not showing vascularity on colour doppler (ORADS 4), (b) corresponding gross histopathology specimen of benign ovarian cystadenoma. (c) histopathological examination shows cyst wall lined by a single layer of columnar epithelium containing mucin.



(a) **(b)** **(c)**

Figure 12: (a) A multiloculated cystic lesion with irregular septae without solid component of size 8x5x4cm is noted in right adnexa with septa showing vascularity colour score 2 (ORADS 4), (b) and (c) corresponding gross histopathology specimen which was proven to be malignant mucinous cystadenoma.

(a) **(b)**

Figure 13: A large predominantly solid lesion with smooth outer contour (a) showing internal vascularity on colour doppler (colour score 2), measuring 10x3x2.5 cm in right adnexa (ORADS 4), and corresponding gross specimen (b) which was proven borderline immature teratoma.

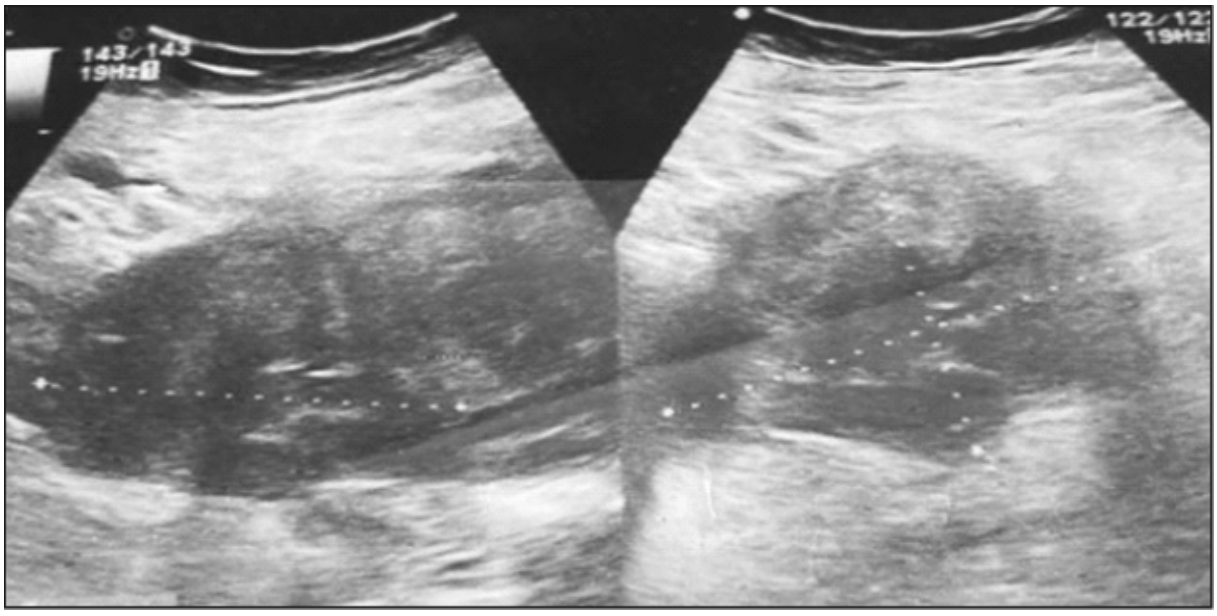


Figure 14: A large solid lesion with irregular outer contour is noted in adnexa with CS 3 (ORADS 5).

CONCLUSION

ORADS proves to be an accurate risk stratification system for classifying the benign and malignant ovarian neoplasm. It helps to standardize the reporting system and guides further management and follow-ups.

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