Al-Azhar International Medical Journal

Volume 2 | Issue 10 Article 1

10-1-2021

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How to Cite This Article

Ahmed, Hoda (2021) "The usefulness of the ultrasound diagnosis of suspicious ovarian masses based on the O-RADS classification system," *Al-Azhar International Medical Journal*: Vol. 2: Iss. 10, Article 1.
DOI: https://doi.org/10.21608/aimj.2021.90943.1551

OPEN AIMJ ORIGINAL ARTICLE

Radiodiagnosis

The Usefulness of The Ultrasound Diagnosis of Ovarian Masses Based on The O-RADS Classification System

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Received *for publication August 28, 2021;* ***Accepted*** *October 01, 2021;* ***Published online*** *October 01, 2021.*

doi: 10.21608/aimj.2021.90943.1551

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ABSTRACT

Aim of the work: Ovarian malignancies represent the leading cause of mortality from gynecologic cancers and its diagnosis is a special challenge. Ultrasonography is the primary imaging modality and the Ovarian-Adnexal Reporting and Data System (O-RADS) US was made to provide consistent interpretations that can help in management recommendation. The present study aimed to evaluate the usefulness of using the O-RADS classification system US in the diagnosis of suspicious ovarian masse lesions.

Patients and methods: Fifty patients " 15 pre and 35 post-menopausal" with suspicious adnexal mass lesions, their ages ranged from 19-67 years (M=41.8±3.64 years). Trans-abdominal & trans-vaginal US with Color/Power Doppler examination were done to all patients. The US O-RADS classification system was used for evaluation of the all studied adnexal mass lesions.

Results: Lesion morphology including size, consistency and vascularity were analyzed and scored using the US O-RADS system with selected proper line of management revealed, 13 lesions as O-RADS3 (likely benign) while 18 lesions scored as O-RADS4 &19 lesions scored as O-RADS5 (likely malignant). The O-RADS scoring system showed a high sensitivity 94.12%, specificity 68.75%, and accuracy 86% with 86.49% PPV & 84.62 NPV.

Conclusion: The U/S O-RADS classification system was found to be a valuable non-invasive diagnostic tool of suspicious ovarian masses with high sensitivity in differentiation between benign and malignant neoplastic lesions.

Keywords: *Ultrasound; Suspicious ovarian lesions, O-RADS.*

Disclosure: *The authors have no financial interest to declare in relation to the content of this article. The Article Processing Charge was paid for by the authors.*
Authorship: *All authors have a substantial contribution to the article.*

INTRODUCTION

Ovarian malignancy represents the leading cause of death from gynecologic cancers with its greatest risk occurring after menopause.[1] The adnexal lesions can be of functional etiology, inflammatory changes, benign and malignant neoplasm.[2]

Adnexal masses are common health problem that lead to clinical workload that need diagnostic imaging, surgery, and pathology.[3] The characterization of ovarian mass lesions is significant both to decrease unnecessary anxiety and enable decisions regarding optimal management.[4] Adnexal mass diagnosis has a special challenge owing to that benign adnexal masses greatly outnumber the malignant ones and to determine the degree of malignancy suspicion is critical which is mainly based on imaging appearance.[5]

Ultrasound (US) is a simple and noninvasive diagnostic method that considered the primary imaging modality for identifying and characterizing of ovarian masses.[6] The US Color Doppler findings can improve the morphology assessment on ovarian cancer risk.[7]

Various approaches for adnexal masses characterizing have been used that include subjective assessment, simple scoring systems, statistically derived scoring systems or probability predictors based on logistic regression analysis.[8]

The Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system is designed to provide consistent interpretations to decrease or eliminate ambiguity in US reports resulting in a higher probability of accuracy in assigning risk of malignancy to ovarian and other adnexal masses, and to provide a management recommendation for each risk category.[9]

This study aimed to evaluate the usefulness of using the O-RADS classification system US in the diagnosis of suspicious ovarian mass lesions.

PATIENTS AND METHODS

Patients: This prospective study included 50 patients, 15 pre and 35 post-menopausal who referred to diagnostic ultrasonography unite for assessing a suspicious adnexal mass lesion. Their ages were 19-67 years (M=41.8±3.64). Study ethics committee approvals were obtained for this work.

Inclusions criteria: any patient had a suspicious adnexal mass lesion

Exclusions criteria: patients with O-RADS score1-2 classic form. Also patients who could not tolerate full bladder and whom did not come for follow up or surgical interference.

U/S protocol and technique:-

Either trans-abdominal US examination with fully distended urinary bladder or trans-vaginal US exam. After UB evacuation was done using Semen's Acuson x300 machine with transducer frequencies ranged from 2.5-8 MHz while patient lying supine and multi-directional sonograms were taken through the area of interest. Each adnexal lesion was categorized according to its:-size, location, internal consistency, and definition of borders. Color or power Doppler US was used to assess lesion vascularity and to ensure if there is any solid component. Each lesion was evaluated and scored based on the US O-RADS classification system , table I.[10]

O-RAD US score	Risk of malignancy	Descriptors
3	1 to < 10% %	Mature teratoma/hemorrhagic cyst/endometrioma ≥ 10 cm Unilocular cyst with irregular inner wall (< 3 mm height) Multilocular cyst < 10 cm with smooth inner wall, CS 1–3 Solid smooth lesion, any size, CS 1
4	10 to < 50%	Unilocular cyst with solid component (0–3 papillary projections) Multilocular cyst ≥ 10 cm with smooth inner wall, CS 1–3 Any size with smooth inner wall, CS 4 Any size with irregular inner wall and/or septation, any CS With solid component, CS 1–2 Solid smooth lesion, any size, CS 2–3
5	≥ 50%	Unilocular cyst with ≥ 4 papillary projections, any CS Multilocular cyst with solid component, CS 3–4 Solid smooth lesion, CS 4 Solid irregular lesion, any CS Peritoneal findings (ascites or nodules)

Table 1: O-RADS, US scores, 3-5 .

Histo-pathology and final clinical diagnosis as a reference standard:-The US findings with the O-RADS classification system were correlated by surgical excision and pathology results for 39 suspicious masses where the remaining 11 benign featuring lesions in young pre-menopausal patients were followed up for a period of 6-12 months until reaching the final clinical diagnosis.

Statistical analysis:-

The statistical calculations were done using Statistical Package for the Social Science in which data described in terms of range, mean ± standard deviation, (M±SD), percentages. Sensitivity, specificity, accuracy, positive predictive value and negative predictive value for US O-RADS results for ovarian masses.

RESULTS

This study included 50 patients with 50 suspicious ovarian mass lesions. Fifteen patients were pre-menopausal and 35 were post-menopause. Most post-menopausal patients were asymptomatic (29/35) while pain was the main complaint in the pre-menopausal patients (13/15), Table II.

C/O	Pre-menopausal	Post-menopausal	Total
Asymptomatic	3	29	31
Pain	13	5	18
Vaginal discharge	5	2	7
Bleeding	5	1	6
Pelvic mass	3	-	3
Diarrhea/constipation	1	2	3
Amenorrhea	2	-	2

Table 2: pt. demographic data and C/P in all patients (no=50)

US O-RADS diagnosis results of studied 50 adnexal lesions:-

Lesion morphology including size, consistency and vascularity were analyzed and scored using the U/S O-RADS scoring system with selected proper line of management. Thirteen lesions were scored as O-RADS 3 which considered likely of benign etiology while 18 lesions scored as O-RADS 4 and 19 lesions scored as O-RADS 5 that considered likely of malignant etiology according to the imaging findings. Table III.

US Lesion Morphology			CD	O-score	Management
texture	**size**	**no**			
Mature teratoma,	10.5 cm	1	-	3	Surgery
Hemorrhagic cyst	11-13 cm	3	-	3	2 Follow up 1 Surgery
Unilocular cyst with irregular inner wall < 3 mm height	4-8cm	4	CS 3/4	3	2 follow up &2 Surgery
Multilocular cyst with smooth inner wall/septae	< 10 cm	4	CS 1–3	3	3 follow up &1 surgery
Solid with smooth outer	7x6 cm	1	CS 1	3	surgery
Unilocular cyst with solid component (0–3 papillary projections	5-7 cm	2	- -	4	1 follow up & 1 surgery
Multilocular cyst with smooth inner wall	≥ 10 cm	6	-CS 1–3	4	Surgery
Cyst with thick smooth inner wall	6-11cm	5	CS 4	4	2 follow up & 3 surgery
cyst with irregular inner wall and/or septation,	5-13cm	5	CS 1–2	4	Surgery
Unilocular cyst with ≥ 4 papillary projections	4-9cm	3	- any	5	Surgery
Multilocular cyst with solid component	8-14cm	4	CS 3-4	5	Surgery
Solid smooth lesion	8x6cm	1	CS 4	5	Surgery
Solid irregular	6-15cm	7	CS3	5	Surgery
+ peritoneal findings	8-15cm	4	CS3-4	5	surgery

Table 3: Lesion US morphology with US O-RADS score 3-5 diagnosis of studied lesions (no=50)

Histopathology and final clinical diagnosis results of the studied 50 adnexal lesions:-

Our reference standard was the histopathology results for 39 surgical excised lesions while 11 lesions undergo follow up for 6- 12 months until reaching the final clinical diagnosis. Malignant lesions represented by 70% of studied lesions (35/50) with Mucinous cystadenocarcinoooma found to be the commonest pathology (36%) followed by Serous cyst-adenocarcinoma (32%) in the other hand , 15/50 lesions (30%) found to be of benign etiology with Cystadenoma-cystadenofibroma, either serous/mucinous found to be the commonest benign pathology(12%) followed by Follicular cyst (8%). There is only 1 fibroma lesion that misdiagnosed by the U/S O-RADS as a malignant lesion,. Malignancy etiology was the most prevalent pathology in elderly post-menopausal patients, 34 lesions while the all benign "15 lesions" were detected in young pre-menopausal women. Table IV.

Lesion final (Histopathology/clinical) diagnosis	Pt. age & Menopause sate	No.	Percent %
Benign lesions:-	19-47 yes (Pre-M.)	15	30%
Cystadenoma-cystadenofibroma (serous/mucinous))		6	12%
Follicular cyst		4	8 %
Hemorrhagic cyst		3	6 %
Fibroma		1	2 %
Teratoma		1	2%
Malignant lesions:-	33& ≥50ys (1Pre/34 Post M)	35	70%
Mucinous cystadenocarcinoooma		18	36%
Serous cyst-adenocarcinoma		16	32%
Endometriod carcinoma		1	2%

Table 4: Histopathology & final clinical diagnosis results of the studied 50 adexeal lesions (no=50).

Analysis of the lesion US O-RADS score in correlation with the final diagnosis of studied 50 adnexal lesions:-

According to the O-RADS score classification system in correlations to the reference standard until reaching the final diagnosis, 11 lesions were true negative and 32 were true positive while 5 lesions were false positive and 2 lesions were false negative, Table V. Fig.,1-6

Lesion number	US O-RADS score diagnosis	Final diagnosis	
		Benign	Malignant
13	Score 3 (likely benign)	11	2
18	Score 4 (likely malignant)	4	15
19	Score 5 (malignant)	1	17

Table 5: Lesion US O-RADS score in correlation with final diagnosis.

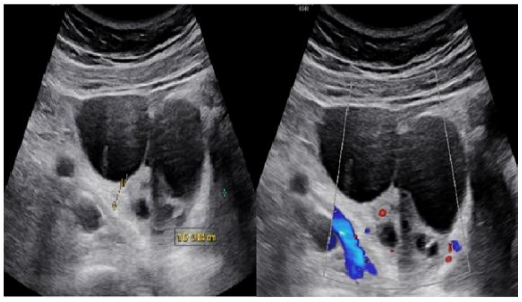

Fig. 1: A young female aged 29 years complaining of pelvic pain: a) Abd. U/S exam. revealed a sizable multi-locular cystic lesion < 10 cm with smooth inner wall b) Color Doppler exam. Showed no vascularity (CS1), O-RADS 3 (Benign featuring cystic lesion). Histopathology: Serous cystadenoma.

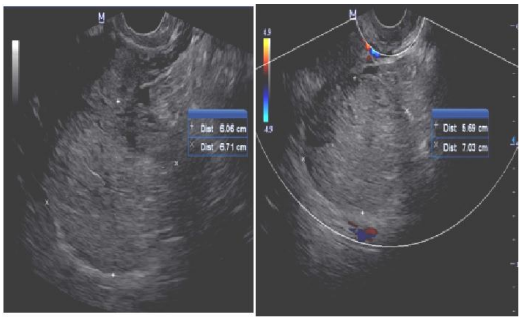

Fig. 2: A young female aged 22years with irregular vaginal bleeding a) TV U/S exam. showed a well demarcated solid lesion with smooth outlines. b) Color Doppler exam. showed no vascularity (C1), O-RADS 3. (Benign featuring ovarian cystic lesion). Histopathology: Fibroma.

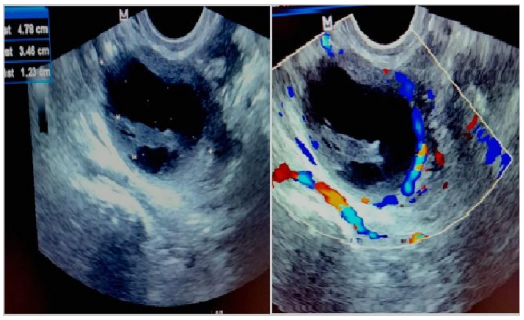

Fig. 3: Middle aged female (42 years) with history of vaginal discharge: a) TV U/S exam. revealed a unilocular cystic lesion with irregular inner walls and papillary projection. b) Color Doppler exam. showed moderate vascularity(C3) O-RADS 4 (Malignant featuring ovarian mass lesion). Histopathology: Mucinous cystadenoma.

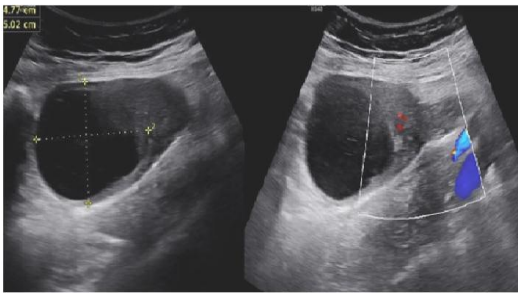

Fig. 4: Asymptomatic female aged 34 years a) Abd. U/S exam. revealed a unilocular cyst with smooth outlines and a solid component .b) Color Doppler exam. Showed minimal vascularity (C2), O-RADS 4. (Benign featuring cystic lesion). Histopathology: Endometriod ovarian carcinoma.

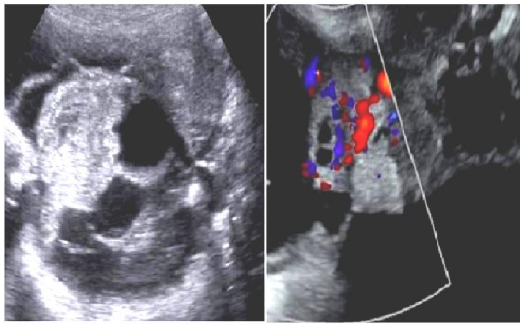

Fig. 5: An elderly female aged 60 years with history of pelvic pain: a) Abd. U/S exam. revealed a sizable multi-locular cystic lesion with solid component and ascites b) Color Doppler exam. showed marked vascularity (C4) O-RADS 5 (Malignant featuring mass lesion). Histopathology: Mucinous cyst-Adenocarcinoma.

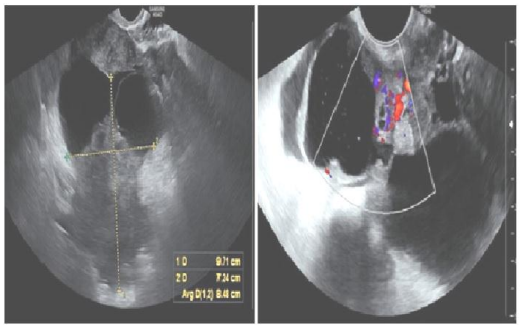

Fig. 6: A female aged 51 years with history of pelvic pain: a)TV U/S exam. revealed a sizable multi-locular cystic lesion with solid component, b) Color Doppler exam. showed moderate vascularity(C3) O-RADS 5 (Malignant featuring mass lesion). Histopathology: serous cyst-Adenocarcinoma.

Statistical results of US O-RADS in the diagnosis of the studied 50 suspicious adnexal masses:-

Applying the O-RADS scoring system to the studied 50 suspicious adnexal lesions with the histopathology & follow up clinical diagnosis as a reference standard; It showed a high sensitivity 94.12%, specificity 68.75%, and accuracy 86% with 86.49% positive predictive value & 84.62 negative predictive value, Table VI.

	Sensitivity	Specificity	Accuracy	PPV	NPP
US/O-RADS	94.12%	68.75%%	86%	86.49%	84.62 %

Table 6: Statistical results of US O-RADS in the diagnosis of the studied 50 suspicious adnexal masses.

DISCUSSION

Cancer Ovary showed a high case–fatality ratio with its diagnosis often presents diagnostic and management dilemmas.[11,12]

Our study included 50 patients with suspicion ovarian masses; the majority of them were asymptomatic while the pain was the main complaint in some patients. This was in agreement with Dipak AB et al 2009, who stated that many adnexal masses are asymptomatic while abdominal pain was seen in about 92% of patients,[13] Also, Givens V et al 2009 said that:- Pelvic or abdominal pain was the predominate symptoms reported by women with ovarian cancer.[1] In the other hand, Ebell MH et al 2016 & Goff BA et al 2004 stated that ovarian cancer presents by non-specific symptoms like irritable bowel syndrome, fatigue and unexplained weight loss.[14,15]

Ultrasound is the primary diagnostic imaging tool of adnexal lesions & the US ORADS structured terminology is used to accurately describe ovarian masses which lead to appropriate management strategies.[16,17]

Our U/S and color Doppler results of the studied 15 pre-menopause & 35 post-menopause patients based on US-ORADS classification system revealed that:- 13 lesions showed benign criteria with US O-RADS score 3 while 37 lesions scored as US O-RADS 4-5 that considered to be likely of malignant etiology that was the most prevalent pathology in elderly post-menopausal patients . This was in coincidence with Zhang T 2017 who studied 263 masses, by U/S GI-RADS and found that:- eighty sex were benign neoplasm (GI-RADS 3), one hundred and one were of GI-RADS 4 & twenty eight were of GI-RADS 5 and cancer patients were older than patients with benign tumors.[18] Also, AMOR FJ 2011 found that malignant tumors were more common in post-menopausal elderly women [19] & Li Zhou et al 2019 who retrospectively analyzed 224 patients with ovarian tumor and found that 120 were benign in patients aged 42±14.68 years & 104 were malignant in patients aged 53±12.73 years.[20] While, Mahmoud SA et al 2020 who studied 112 lesions using GI-RADS classification concluded that: 36 lesions (32.1%) were of GI-RADS 2, 32 lesions (28.6%) were GI-RADS 3, 13 lesions (11.6%) were GI-RADS 4, and 31 lesions (27.7%) were of GI-RADS 5 with 49% ovarian neoplastic lesions.[21]

Pre-operative diagnosis of ovarian lesions as benign or malignant very important for appropriate patient triage, referral, and management.[22]

According to our histopathology results for 39 lesions and final clinical diagnosis for 11 lesions:

Malignancy etiology was the most prevalent pathology " 70%" while 15 lesions "30%" were benign . Our results were in contrast to Zhang T et al 2017 results who studied 242 patients with 153 benign and 110 malignant tumors(18) & Prasad1S et al 2019, who studied 56 masses and found 4 malignant masses, 24 benign masses and rest were physiological cyst/ infective process(22). While, Bhagde DA et al 2017, studied 50 patients with the majority below 45 years found that: All studied lesions were of benign etiology(13). Some authors stated that:-Ovarian fibroma can be misdiagnosed as it often exhibits features that are suggestive of malignancy.[23,24]

The essential role of O-RADS is to improve the quality and communication between interpreting and referring physicians, to guide patient management.[25]

Our study results using the U/S O-RADS score classification system in correlations to the final histopathology/clinical diagnosis revealed 11 true negatives, 32 true positives, 5 false-positive, and 2 lesions were false negative with 94.12%, sensitivity, 68.75%, specificity and 86% accuracy, 86.49% PPV & 84.62 NPV that matched with Zhang T et al 2017 results which found 4 false-negative malignant cases that were misclassified as GI-RADS3, whereas 24 benign lesions with false-positive results that misdiagnosed as GI-RADS 4.

The sensitivity, specificity, false-positive, false-negative & accuracy, were 96.4%, 84.3%, 18.5%, 3.0%, 89.3%, respectively.[18] However Mahmoud SA et al 2020 results revealed:- A diagnostic accuracy of US GI-RADS classification results were of 97% sensitivity, 73% specificity, 84% PPV, 94% NPV and 87% accuracy.[21] While, Prasad1 S et al 2019 concluded that: Excellent agreement between histopathology and U/S GI-RADS was found for the diagnosis of benign and malignant ovarian tumors with 100% sensitivity, 80% specificity, PPV 36%, and NPV 100% [22] & Li Zhou et al 2019 found that:- The GI-RADS classification showed 99.1% Sensitivity, 85.9% specificity, 71.1% PPV and 99.6% NPV.[20]

CONCLUSION

The U/S O-RADS classification system was found to be a valuable non-invasive diagnostic tool of the suspicious ovarian masses with high sensitivity in differentiation between benign and malignant neoplastic lesions.

This study had some limitations & pitfalls due to the relatively low number of lesions included and as diagnosis of some lesions was relied on a follow-up clinical diagnosis.

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