ORIGINAL ARTICLE

Positive Predictive Value of Ultrasonography for Detection of Ovarian Masses Taking Magnetic Resonance Imaging as a Gold Standard

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ABSTRACT

Aim: To determine the efficacy of ultrasonography in the detection of ovarian masses considering MRI a Gold standard. Study design: Prospective analytical cross-sectional study

Place and duration of study: Dow Institute of Radiology, Dow University of Health Sciences Karachi, Pakistan from 1st June 2018 to 30th November 2019.

Methodology: One hundred and forty eight ovarian cancer patients were enrolled.

Results: The mean age of the patient was 41.87±16.30 years. The majority of the patients were age ≥20 years (29.10%) and obese (33.1%). Malignant tumors were 56.1% (n=83) and 64.2% (n=95) respectively on ultrasound and magnetic resonance imaging. Ultrasound had a positive predictive value of 80%, sensitivity of 98.11%, and specificity of 86.32 % for the diagnosis of ovarian masses. Overall diagnostic accuracy of ultrasonography was 90.54%. There was an excellent agreement between the ultrasonography and magnetic resonance imaging (kappa=0.84, p-value <0.001) and area under the curve was 92.2%. **Conclusion:** Ultrasonography has excellent diagnostic accuracy in the detection of ovarian masses.

Keywords: Ovarian mass/tumor, Ultrasonography, MRI, Positive predictive value, Benign, Malignant

INTRODUCTION

Tumors of the ovary are considered the common gynecological problem with a prevalence of about 12%; small numbers are reported to be malignant¹. Ovarian cancer is one of the most aggressive gynecological tumors and has a five-year survival rate of almost 40%². Survival and the prognosis over the years have not improved significantly because about 70% of females present when tumor is in advanced stage e.g. tumor has metastasized or found incidentally on imaging³. Tumor's location deep in the pelvis and the asymptomatic nature till late stages are the most common features attributed to its late detection. The ones who present with symptoms are easily confused with tumors of the gastrointestinal tract; therefore, the timely and correct diagnosis along with the proper characterization of ovarian mass will improve management, prevent unnecessary delays and avoid unwarranted therapy^{5,6}.

modalities, Among the various existing imaging ultrasonography (US) is the initial choice for investigating⁷⁻¹⁰. It is an easily available, non-invasive, and cost-effective technique that poses no discomfort or risk to the patient. It is one of those imaging techniques which have the advantage of providing a dynamic and interactive examination that gives information on the relative movement of pelvic and abdominal structures^{11,12}. Massive technical improvements witnessed over the past decade in ultrasonography have increased its efficacy. If performed by an expert/experienced sonographer; it provides significant information in the primary diagnosis of ovarian tumors¹³.

Testa et al¹⁴ reported that all the cases (17/17) of recurrent ovarian cancer without clinical or serological signs of disease were recognized upon imaging with ultrasonography. Besides being used as a tool for diagnosis, it can help in assessing the extent of the tumor in the abdomen and pelvic cavity; can also provide valuable information in evaluating the effectiveness of treatment using RECIST criteria (Response Evaluation American Joint Committee on Cancer Criteria in Solid Tumors) and in follow-up^{15,16}

Being an initial and primary imaging choice of US it has high sensitivity in identification of ovarian masses and specificity between 60 to 95%. Almost 20% of these masses are reported to be indeterminate. Thus, at a time other imaging techniques like Magnetic resonance imaging MRI are needed to clinch the

Received on 16-08-2022 Accepted on 26-12-2022 definitive diagnosis and provide supportive information to delineate between benign and malignant ovarian masses¹⁷.

Besides histology, MRI is considered a gold standard imaging technique to characterize ovarian masses as either benign or malignant. Radiological features delineated by MRI are so detailed and advanced that a radiologist can confidently characterize the ovarian mass into a specific histological subtype^{18,19}. In keeping view with evidence provided in the literature and considering the health care expenditures in our part of the world, we have designed a study to evaluate the diagnostic efficacy and accuracy of ultrasonography pelvis for ovarian masses considering MRI pelvis as a gold standard. We aim to prove ultrasonography can use as first-line or screening imaging modality in diagnosing ovarian masses thus decreasing the health expenses at the consumer end and setting the stages to advance the radiological practices in the context of ultrasonography pelvis.

The objective of the study was to assess the efficacy of ultrasonography in terms of Positive predictive value in the detection of ovarian masses considering the MRI as gold standard.

MATERIALS AND METHODS

This prospective analytical cross-sectional study had been conducted among ovarian cancer patients at Dow Institute of Radiology, Dow University of Health Sciences, Ojha Campus Karachi from 1st June 2018 to 30th November 2019. Sample size 148 was calculated via Epi info at a 95% confidence interval with the margin of error of 6% and reported positive predictive value of US is 83.3%.14 A consecutive sampling technique has used to target 148 ovarian cancer patients who met the inclusion criteria. Subjects included in the study were: Women with the age >20yrs, suspected ovarian mass, and present with complaints of lower abdominal pain, per vaginal bleeding, vaginal discharge, or heavy menstrual bleeding of any duration and irrespective of marital status. Women with histopathological proven ovarian mass advised MRI pelvis for follow-up of an already diagnosed disease process, presented with other abdominal or pelvic mass and history of contrast allergy were excluded from the study.

Ethical approval was taken from the Institutional Review Board (IRB) of Dow University of Health Sciences, Karachi Pakistan. Informed consent had been taken from all eligible patients. U/S and MRI have been done in all selected cases. Ultrasound of pelvis has been done per abdomen with a full urinary

bladder on volusion S6 machine with a convex probe by radiologist and senior sinologist who have more than 05 years' experience. MRI pelvis was performed on GE 1.5 Tesla machine. MRI pelvis obtained with standard protocol requiring 6 hours fasting, empty bowels, and full bladder. 1.5-T MRI with a flexed body array in a supine position was used. Imaging time was 30-45 minutes, and obtained images were included: Sagittal, Coronal, and Axial T2weighted fast spin-echo images, Axial T1-weighted spin-echo images, Axial T2-weighted spin-echo images through any lesion, images with the addition of frequency-selective fat suppression, post-contrast Sagittal, Coronal, and Axial T1-weighted fatsuppressed images, and Diffusion-weighted images. Contrastenhanced images were obtained after injecting intravenous (IV) gadolinium at a dose of 0.1mmol/kg of body weight (maximum 20ml). Radiologists with 3years of experience in reporting after a fellowship in women imaging evaluated the MRI scan and described the findings indicating the location, size, and nature of mass. The nature of the mass was characterized by various factors such as wall thickness, post-contrast enhancement of walls, internal enhancement, the thickness of septae more than 3mm, presence of mural nodule and papillary projections, as well as on signal characteristics. The information regarding body mass index (BMI), marital status, menstrual status, duration of symptoms, site of mass, consistency of mass, number of mass, and size of mass have been obtained as independent variables and to find the association with the dependent variables such as benign and malignant ovarian tumors on the US as well as MRI.

SPSS-22.0 was used to analyze the data. Chi-square has been used to find the association of demographics and clinical characteristics with tumor status (benign/malignant). Contingency table was employed to evaluate positive predictive value (PPV) along with negative predicted value (NPV), sensitivity, and specificity and positive and negative likelihood ratios (LR+ and LRrespectively) of ultrasongraphy for benign and malignant ovarian masses considering the MRI as gold standard. Agreement was assessed via Cohen's kappa (k). ROC curve was run to assess the AUC, which indicate the overall diagnostic accuracy. 95% CI have been reported and p-value <0.05 considered significant.

RESULTS

The mean age and BMI of the patient were 41.87±16.30 years and 27.63±5.57 kg/m² respectively. The majority of the study population, 43 (29.1%) were reported with age group between 20 to 29 years and 138 (93.2%) patients were married; 77 (52%) and 40 (27%) respondents were reported their menstrual status normal and menopause respectively. The BMI of the patients were found to be normal range 51 (34.5%) and obese 49 (33.1%) as per WHO criteria. On radiological examination, 83 (56.1%) and 95 (64.2%) patients were found to be a malignant tumor on ultrasound and MRI respectively. On cross-tabulation, tumor status (benign/malignant) depicts a very high significant association with age, BMI, and menstrual status at p-value <0.001. Among All age groups, malignant tumors were found most commonly which were 75% (n=21/28), 63.3% (n=19/30), 90.5% (n=19/21), 73.1% (n=19/26), and 39.5% (n=17/43) for 40-49years, 30-39years, 50-59 years, and ≥60years and 20-29years old patients respectively. 63% (n=29/46), and 85.7% (n=42/47) malignant tumors were found among overweight and obese patients respectively. In contrast, most of the benign cases 54.9% (n= 28/51) were found among patients with normal BMI. Malignant tumors were found among patients with normal menstrual status 51.9% (n=40/77), Menopause 85% (n=34/40), premenopause 66.7% (n=2/3) and perimenopause 88.2% (n=15/17). Marital status was not significantly associated with tumor status (Table 1). Most of the patients, 106 (71.6%) and 23 (15.5%) reported that duration of

symptoms were 1 to 6 months and 1 to 15 days respectively. The right site mass and cystic mass identified among 70 (47.3%) and 105 (70.9%) patients respectively; second most common mass was solid cum cystic 24 (16.2%). The single mass was found among 143 (96.6%). Chi square findings showed significant association between consistency of mass and tumor status, pvalue <0.001. All of the hard 100%, (n=1/1), solid 100%, (n=6/6), solid & cystic 100%, (n=7/7), cystic complex 100%, (n=2/2), heterogeneous 100%, (n=3/3) masses were malignant. Cystic mass, 50.5% (n=53/105) and solid cum cystic mass, 95.8% (n=23/24) were malignant. Duration of symptoms, site of mass and No. of masses were not significantly associated with tumor status (Table 02). The mean size of midline anterio-posterior (AP), Transverse (T), cranio-caudal (CC) masses were larger, 15.66±5.66 × 15.60±4.66× 11.70±7.07 respectively, compared to right (7.79±5.01× 6.81±4.62 × 7.80±3.35) and left (8.37±5.96× 7.77±5.29× 10.14±5.18) tumors sizes (Table 2).

on ultrasound, mostly reported tumors were Complex ovarian cyst 50 (38%), heterogenous cystic mass 19 (12.8%), multi loculated cyst 18 (12.2%), endometriotic cyst 11 (7.4%), multi septate cyst 11 (7.4%) dermoid cyst 8 (5.4%), complex ovaries 6 (4.4%), cystic mass 8 (5.4%) and other were cyst with internal echoes 3 (2%), large ovary 2 (1.4%), suspected abdominal mass 2 (1.4%), hemorrhagic cyst 2 (1.4%), mature follicle cyst 2 (1.4%), adnexal cystic lesion 1 (0.7%), mesenteric cyst 1(0.7%), tubo ovarian abscess 1 (0.7%), polycystic ovaries 1(0.7%), necrotic mass 1 (0.7%), abnormal signals in ovary 1(0.7%). Most of the complex ovarian cyst (n=32/50), cystic mass (n=7/8), heterogenous mass (n=19/19), multi-loculated Cyst (n=16/18), and multi-septated cyst (n=7/11) were malignant; Significant association has been found between types of tumor and tumor status at p-value <0.001. Commonly reported tumors diagnosed on MRI were heterogeneous enhancing mass 20 (13.5%), complex ovarian cyst 17 (11.5%), endometriotic cyst 17(11.5%), multi-septic cyst 15 (10.1%), neoplastic cystic mass 12 (8.1%), cystic mass 11(7.4%) and dermoid cyst 10 (6.8%). MRI findings showed that all of the neoplastic cystic mass (n=12/12), complex solid cum cystic mass (n=8/8), heterogeneous cystic mass (n=4/4), multi septated cyst (n=15/15), cystic cum solid lesion (n=7/7), cyst with internal echoes (n=3/3), lobulated cystic mass (n=2/2) and tubo ovarian abscess (n=1/1) were malignant. Most of the heterogeneous enhancing mass (n=19/20), complex ovarian cyst (n=9/17), and cystic mass (n=8/11) were also malignant. Furthermore, all of the hemorrhagic cyst (n=3/3), adenexal cystic lesion (n=2/2), mature follicle cyst (n=2/2), mesentric cyst (n=1/1), para ovarian cyst (n=3/3) and 50% (n=2) multi loculated cyst as well as hematosalphinx hHydrosalphinx 50% (n=2) were benign. Types of tumor depicted very high significant association with tumor status at p-value <0.001. For the diagnosis of benign and malignant ovarian masses, findings of the study revealed that ultrasound had a PPV of 80%, 95% CI (0.70- 0.86) and NPV of 98.80%, 95% CI (0.92-0.99). In addition, sensitivity was 98.11%, 95% CI (0.89-0.99) and specificity was 86.32 %, 95% CI (0.77-0.92) respectively. Overall diagnostic accuracy of USG was found to be 90.54%, 95% CI (0.84-0.94). Disease prevalence was 35.81 and 64.19 for benign and malignant tumor respectively (Table 03).

Cohen's K was run to observe the agreement between ultrasound and MRI findings for the benign and malignant ovarian tumors. There was almost perfect agreement between the two diagnostic test, k=0.84 (95%CI, 0.70796-0.900), p-value <0.001. The graph of ROC found to be ultrasound had an excellent diagnostic accuracy in detecting benign and malignant ovarian tumors. The AUC 92.2%, 95% CI: 0.875-0.969. Diagnostic test has significant association with tumor status at p-value <0.001 (Fig. 1).

Table 1: Demographic characteristics and association with ovarian masses

Variable	Frequency (%)	Benign F (%)	Malignant F (%)	P-Value
Age (years)	· · · ·			
20-29	43(29.1)	26 (60.5)	17 (39.5)	<0.001
30-39	30 (20.3)	11(36.7)	19 (63.3)	
40-49	28(18.9)	7 (25.0)	21 (75.0)	
50-59	21(14.2)	2 (9.5)	19 (90.5)	
60 or above	26 (17.6)	7 (26.9)	19 (73.1)	
Body mass index (kg/m ²)				
Underweight "<18.50"	2 (1.4)	1 (50.0)	1 (50.0)	<0.001
Normal Range "18.50-24.99"	51 (34.5)	28 (54.9)	23 (45.1)	
Overweight "25.00-29.99"	46 (31.1)	17 (37.0)	29 (63.0)	
Obese "≥ 30.00"	49 (33.1)	7 (14.3)	42 (85.7)	
Total	148 (100)	53 (35.8)	95 (64.2)	
Marital Status				
Married	138 (93.2)	47 (34.1)	91 (65.9)	0.097
Unmarried	10 (6.8)	6 (60.0)	4 (40.0)	
Total	148 (100)	53 (35.8)	95 (64.2)	
Menstrual Status				
Normal	77 (52.0)	37 (40.0)	40 (51.9)	
Premenopause	3 (2.0)	1 (33.3)	2 (66.7)	<0.001
Perimenopause	17 (11.5)	2 (11.8)	15 (88.2)	
Menopause	40 (27.0)	6 (15.0)	34 (85.0)	
Postmenopause	11 (7.4)	7 (63.6)	4 (36.4)	
Total	148 (100)	53 (35.8)	95 (64.2)	
Radiological Findings			· · ·	
Ultrasound	148(100)	65(43.9)	83(56.1)	0.078
MRI	148(100)	53(35.8)	95(64.2)	

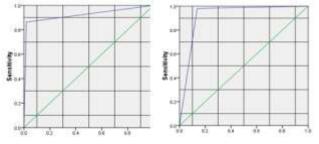
Table 2: Clinical Characteristics and association with ovarian masses

Variable	Frequency (%)	Benign F (%)	Malignant F (%)	P-Value
Duration of symptoms				
1 to 15 days	23 (15.5)	8 (34.8)	15 (65.2)	0.518
16 to30 days	9 (6.1)	5 (55.6)	4 (44.4)	
1 to 6 months	106 (71.6)	35 (33.0)	71 (67.0)	
7 to 12 months	6 (4.1)	3 (50.0)	3 (50.0)	
1 to 3 years	3 (2.0)	2 (66.7)	1 (33.3)	
> 3 Years	1 (0.7)	0 (.0)	1 (100)	
Site of mass				
Right	70 (47.3)	27 (38.6)	43 (61.4)	0.169
Left	57 (38.5)	23 (40.4)	34 (59.6)	
Right & Left	12 (8.1)	2 (16.7)	10 (83.3)	
Midline	9 (6.1)	1 (11.1)	8 (88.9)	
Consistency of mass				
Hard	1 (0.7)	0 (0)	1 (100)	<0.001
Cystic	105 (70.9)	52 (49.5)	53 (50.5)	
Solid	6 (4.1)	0 (0)	6 (100)	
Solid & Cystic	7 (4.7)	0 (0)	7 (100)	
Cystic Complex	2 (1.4)	0 (0)	2 (100)	
Solid cum cystic	24 (16.2)	1 (4.2)	23 (95.8)	
Heterogeneous	3 (2.0)	0 (0)	3 (100)	
Number of mass				
Single	143 (96.6)	53 (37.1)	90 (62.9)	0.105
Multiple	5 (3.4)	0 (0)	5 (100)	

Table 3: PPV along with diagnostic accuracy of ultrasonography for benign & malignant ovarian mass

	Benign ovarian mass% (95% CI)	Malignant ovarian mass % (95% CI)
Sensitivity	98.11 (89.93-99.95)	86.32 (77.74-92.51)
Specificity	86.32 (77.74-92.51)	98.11 (89.93-99.95)
PPV	80 (70.68-86.91)	98.80 (92.16-99.83)
NPV	98.80 (92.16-99.83	80.00 (70.68-86.91)
LR+	7.71 (4.32-11.90)	45.75 (6.55-319.32)
LR	0.02 (0.00-0.15)	0.14 (0.08-0.23)
Disease prevalence	35.81 (28.11-44.10)	64.19 (55.90-71.89)
Diagnostic accuracy	90.54 (84.64-94.73)	90.54 (84.64-94.73)

Fig. 1: ROC curve of specificity and sensitivity



DISCUSSION

The malignant ovarian tumor was found to be 56.1% and 64.2 %on USG and MRI respectively. Age, BMI and menstrual status showed highly significant (p<0.001) association with tumor status (benign/malignant). Malignant tumor most commonly found among all age groups, overweight and obese patients with normal menstrual, menopause, premenopause, and perimenopause. Similarly another Study conducted among Asian population was found the mean age of the patient was 40.95±16.54 and 53.8% (42/78) tumors were malignant.²⁰ A study was conducted among ovarian cancer patients in Maharaj Nakorn Chiang Mai hospital, Thailand from 2007 to 2012. The Mean age of the patient was 42.4±16.2 years which was depicting that risk of ovarian tumor was higher among elder age group.21 A case control study was conducted among 50 suspected ovarian cancer patients in India. Transvaginal ultrasonography has been done in all patients. The patient mean age was 42.5 years. They also found malignant tumor was more common (81.81%, n = 9/11) among older age group (56-70years) and benign tumor was more common among postmenopausal patients (66.67%, n=10/15), which are in agreement with the current study findings.²² A retrospective study

was conducted among 168 ovarian cancer patients in china. The finding of the study revealed that malignant tumor was more common (n= 107) among ovarian cancer patients. On comparison with demographic variables, they also found malignant tumor was high among patients with the age \leq 45years and married. These findings are in consistent with the current study findings.²³

In contrast to current study findings, another study shown that benign ovarian tumor was higher (59%) as compare to malignant tumor, it could be reported due to nature of study which was multicentre based study. They also found malignant ovarian tumor was more common among postmenopausal patients; they were enrolled pre and postmenopausal patients. However in this study patients were stratified in 5 categories and most of the patients were in normal menstruation and menopaus phase and majority of the malignant ovarian tumor was found among perimenaupause and menopause patients (24). Another study also contradict current study findings and found malignant ovarian tumor among 104 (46%) cases, this difference might be happened due to small sample size in current study.²⁵

In this study, cystic and solid cum cystic mass were found to be 70.9% and 16.2%. Mean size of midline anterior posterior (AP), transverse (TS), cranial cardial (CC) mass were 15.66±5.66x 15.60±4.66 x 11.70±7.07 respectively. The mean ovarian mass size for the right and left ovary was 7.79±5.01x6.81±4.62x 7.80±3.35 and 8.37±5.96x7.77±5.2x.14±5.18. Another study also found mean tumor size of the left and right ovary was 7.6±4.03x6.1±3.13 and 7.9±4.22x6.5±3.00 in tranverse and longitudinal axis respectively²⁰.

On ultrasound, most of the tumors were complex ovarian cyst, heterogenous cystic mass, multi loculated cyst, endometriotic cyst, and multi septic cyst. Most of the ovarian masses found on MRI to be hetrogenous enhancing mass, complex ovarian cyst, endometriotic cyst, multi septic cyst, neoplastic cystic mass, cystic mass and dermoid cyst. All of the hard, solid, solid & cystic, cystic complex, and heterogenous mass were malignant. MRI feature of the most of the malignant ovarian tumor were hetrogenous enhancing mass, complex ovarian cyst and cystic mass. These findings are in agreement with previous studies findings^{7,11,16,17}.

The findings of the current study are also comparable with the previous study findings; conducted at tertiary care public and private sector hospitals in Karachi from 2009 to 2011 to determine role of ultrasound in the detection of ovarian masses. In their study, PPV and NPV were 93%, 95% CI: (0.79, 0.9)] and 89%, 95% CI: (0.73, 0.96)²⁰.

A study conducted among ovarian cancer patients in Thailand also revealed high PPV (89.8%, 95% CI: 0.83-0.95), Sensitivity (82.2%, 95% CI: 0.75-0.89), specificity (95.3%, 95% CI: 0.92-0.98), LR⁺(17.2, 95% CI: 9.5-32.1) and low LR⁻ (0.19, 95% CI: 0.12-0.28) (28) which were comparable with the current study findings.

Another multicenter cross sectional study conducted among patients with ovarian masses to predict risk of malignant ovarian masses via using transvaginal ultrasound examination and histopathological findings as a gold standard. Findings of their study revealed that 48% of patients had high estimated risk and the PPV was 75.4% and NPV was 93.9%¹⁷.

A prospective cross sectional study conducted among Indian population; Authors of the study enrolled 60 eligible patients in their study to assess the role of ultrasonography in early and accurate diagnosis of ovarian masses and found 91% and 86.11% of PPV and NPV respectively²⁹. Findings of their study are also consistent with the current study findings.

Findings of the current study revealed the sensitivity and specificity of USG for benign and malignant ovarian masses were 98.11% and 86.33% and Diagnostic accuracy was 90.54%. These findings are in consistent with the result of Zhou et al study; they also found 89.47% sensitivity, 83.64% specificity and 86.61% diagnostic accuracy.²⁵ Another study also found sensitivity and specificity of USG for benign and malignant tumor was 90.7%, 95% CI (0.77, 0.96) and 91.4%, 95% CI (0.76-0.98) respectively.²⁰

Result of the study are in agreement with the previous studies findings, Literature showed higher sensitivity and specificity for malignant ovarian tumors (85 to 98%)²², which were comparable with current study finding.

In this study, ROC curve show ultrasound has an excellent diagnostic accuracy and the AUC is 92.2%, these findings are in agreement with the multicentre based diagnostic accuracy study; which was conducted among 2403 patients with benign and malignant ovarian tumor. They also found The AUC of receiver operator characteristic was 0.91.4% (0.886-0.936)²⁴.

In this study result has shown almost perfect agreement between the two diagnostic test, ultrasound and MRI at p-value <0.001. Another study also found statistically significant high level agreement on kappa analysis (k=0.323).²²

CONCLUSION

The PPV of ultrasonography for the detection of benign and malignant ovarian masses to be 80% and 98% respectively and has significant (P<0.001) association with tumor status. Thus its increasing reliability seems ultrasound is the best modality of choice for the diagnosis of ovarian masses in resources scarce country for instance Pakistan. As one of the developing country most of the patient cannot afford expenses diagnostic modality tool such as MRI. Ultrasound is the cost effective and easily available initial modality tool. Therefore, clinician/radiologist need to encourage its significance and use for the timely diagnosis of ovarian masses to decrease mortality and morbidity and improve patient's quality of life.

Conflict of interest: Nil

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