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Original Research Article

Evaluation of adnexal masses: correlation of clinical examination, sonographic assessment and histopathological findings

Sreeparna Ray[1], Sanjana Halder[2], Manas K. Saha[2], Amit Kyal[2], Srijoni Chowdhury[1]*

[1]Department of Obstetrics and Gynaecology, IQ City Medical College, Durgapur, West Bengal, India
[2]Department of Obstetrics and Gynaecology, Diamond Harbour Government Medical College and Hospital, West Bengal, India

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***Correspondence:**
Dr. Srijoni Chowdhury,
E-mail: sriju.chowdhury@gmail.com

ABSTRACT

Background: Prevalence of symptomatic adnexal masses is 1:1000 in premenopausal women and 3:1000 in post – menopausal women. Benign diseases of ovaries and fallopian tube are commonest etiology. However, as risk of neoplastic lesions increases with age and further after menopause The primary goal of diagnostic evaluation of adnexal masses is to exclude malignancy.
Methods: This one-year prospective observational study was carried out on 100 female patients attending gynaecology OPD with the clinical diagnosis of adnexal mass. Female patients presenting with symptoms like lower abdominal pain, menstrual irregularity and palpable mass or asymptomatic patients with incidental finding of adnexal mass were included in the study. The aim of the study was to compare the sensitivity, specificity and predictive value of clinical examination, ultrasonography and to compare it with the histopathology.
Results: Ultrasound of pelvis was done for all patients. Laparotomy was done for all cases and the specimen was sent for histopathological examination. 70% tumours were benign and 30% tumours were malignant. As per our study, ultrasonography has the highest diagnostic accuracy (93%) followed by pelvic examination (86%) and RMI score (86%). Clinical examination has highest sensitivity of 93.33% followed by CA-125 (86.66%) and ultrasonography (83.33%).
Conclusions: Thus, ultrasound is the primary modality used for detection and delineation of pelvic masses. The study also showed that RMI has better performance than CA 125 in the prediction of malignancy. Thus, with such simple methods we can diagnose precisely without advanced radiological imaging.

Keywords: Adnexal mass, Risk of malignancy index, Cancer antigen 125

INTRODUCTION

An adnexal mass is a tissue mass in the adnexa of the uterus, which refers to that anatomical area which is adjacent to the uterus, and consists of the fallopian tube, ovary, and associated vessels, ligaments, and connective tissue. Since the fallopian tube and ovary and their mesenteries are so closely related anatomically, they are often collectively called the adnexum (plural=adnexa).[1] The most common location for this type of mass to grow is in the fallopian tube or ovary. Adnexal masses may be gynecologic or non-gynecologic in origin and are found in females of all ages with significantly variable prevalence. The differential diagnosis of adnexal masses include: Benign ovarian masses like corpus luteal cyst, follicular cyst, theca lutein cyst, serous cystadenoma, mucinous cystadenoma, polycystic ovaries and torsion of ovarian cyst, benign non-ovarian masses like- endometrioma, hydrosalpinx, leiomyoma, tuboovarian mass and ectopic pregnancy. Malignant ovarian masses-borderline tumours,

epithelial carcinoma, germ cell tumours, ovarian sarcoma, sex cord stromal tumours. Malignant non-ovarian masses-endometrial carcinoma, fallopian tube carcinoma. Non-gynecologic masses include benign masses like–appendicular abscess, diverticular abscess, pelvic kidney, nerve sheath tumour, peritoneal cyst, ureteral diverticulum, bladder diverticulum. Malignant non-gynecologic masses include gastrointestinal carcinoma, Krukenberg's tumour, metastasis from colon, breast and retroperitoneal sarcoma. The initial detection and evaluation of an adnexal mass requires a high index of suspicion, a thorough history and physical examination and careful attention to subtle historical clues. The primary goal of diagnostic evaluation of adnexal masses is to exclude malignancy. Ovarian cancer is the most lethal of the gynaecologic malignancies, with an overall 5-year survival rate of less than 40% and is the fifth commonest cause of cancer deaths inwomen.[2] Fortunately the benign ones far outnumber the malignant ones.[3] Based on the clinical findings, ultrasound and Doppler findings, a preoperative accurate identification of the nature of the mass can be done before surgical intervention. The diagnosis of ovarian tumors is based on clinical examination, sonography and measurements of CA-125 collectively known as triple diagnostic method.[4] There are various reports of the role of computerized tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) in diagnosis and management of adnexal masses, but they may not be feasible in every patient in our set up. Histopathology is still believed to be the gold standard for the evaluation of benign and malignant adnexal masses. This study was conducted with a view to find out the diagnostic value of clinical examination, ultrasonography and its correlation with histopathological diagnosis in adnexal masses.

Ultrasonogram is the preliminary study in patients with pelvic adnexal masses. The sensitivity of USG is high but the specificity is low for diagnosis of early ovarian malignancy. The International Ovarian Tumour Analysis (IOTA) group ultrasound rules for ovarian masses are a simple set of ultrasound findings that classify ovarian masses into benign, malignant and inconclusive.[5] CA 125 is the most commonly used tumor marker in screening of high risk patients with ovarian tumor. CA 125 also called cancer antigen 125, was so named because it was the 125th antibody found while testing various antibodies against ovarian tumour. Normal level is 0-35 U/ml. CA 125 was first described by Bast and colleagues in 1983. CA 125 is produced in low quantities by normal ovarian epithelial cells, peritoneal lining cells, lining cells of GIT, pancreas, breast and lung. Thus an elevated level of CA 125 is not very specific. High levels of CA 125 are frequently associated with ovarian malignancy. However due to low sensitivity and specificity, CA 125 was not useful as a screening method. CA 125 is found to be elevated besides in ovarian malignancy like breast cancer, lung cancer. various benign conditions associated with elevated CA 125 levels are more common.

Hence, the cut off value of CA 125 in postmenopausal women in predicting malignancy is 35U/ml whereas in premenopausal women, the cut off value up to 200 U/ml is not very predictive. The sensitivity of the CA 125 value was limited in early stage of the malignancy. Also, not all malignant ovarian cancer was associated with elevated CA 125 levels thus lowering the sensitivity of CA 125. Serum CA 125 levels are measured in the blood by second generation test. Due to poor sensitivity and specificity, CA 125 values are not useful in screening the general population.

In 1990, Jacob et al developed a new scoring system called risk of malignancy index (RMI).[6] RMI 1 is based on the following 3 parameters: serum CA 125 level (U/ml), and ultrasound score- the various parameters are multilocular cyst, presence of solid mass, bilateral lesions, evidence of metastasis, presence of ascites. Each parameter is given 1 point. The ultrasound score (U) of O is given if the total point is O, score of 1 if the total point is 1 and score of 3 if the total point is between 2-5. RMI is calculated with these 3 criteria. It is the product of CA 125 level (absolute value U/ml), menopausal score and ultrasound score. It is expressed as given below.

$$RMI = U \times M \times CA\,125$$

Using RMI cut off value as 200, the sensitivity is 85% and specificity is 97% in diagnosing ovarian carcinoma. Women with small (less than 50 mm diameter) simple ovarian cysts generally do not require follow up as these cysts are likely to be physiological and almost always resolve within 3 menstrual cycles. Women with simple ovarian cysts (50-70 mm in diameter) should have early ultrasound follow-up and those with larger simple cysts should be considered either for further imaging like MRI or surgical intervention due to difficulties in examining the entire cyst adequately at the time of ultrasound. In postmenopausal women, asymptomatic, simple, unilateral, unilocular ovarian cysts less than 5 cm in diameter have a low risk of malignancy. In the presence of normal CA 125 levels, these cysts can be managed conservatively, with a repeat evaluation in 4-6 months. A woman with a suspicious or persistent complex adnexal mass needs surgical evaluation. Women with RMI<200 are suitable for laparoscopic management. Laparoscopic management of ovarian cysts in postmenopausal women should comprise bilateral salpingo-oophorectomy rather than cystectomy and women should be counselled preoperatively that a full staging laparotomy may be needed if evidence of malignancy is revealed.

METHODS

This prospective observational study was performed in Eden Hospital, Department of Obstetrics and Gynecology, Medical College and Hospital, Kolkata. The study was conducted during the period of January 2018 to December 2018.

Sample size

100 cases of female patients with diagnosis of adnexal mass. From the different studies done, expected proportion of the patients, amongst the cases was assumed to be 60%). 100 patients were taken as derived from formula of sample size calculation.

Study population

The study included 100 female patients who attended OPD of Eden Hospital, Medical College Kolkata and were admitted as a case of adnexal mass.

Inclusion criteria

Female patients presenting with symptoms like lower abdominal pain, menstrual irregularity and palpable mass; and asymptomatic patients where adnexal mass detected at the time of routine pelvic examination or at the time of ultrasonography (transabdominal and transvaginal sonography) done for other diagnosis were included.

Exclusion criteria

Patients with age group of <15 years, pregnancy with adnexal masses, masses arising from urinary tract or gastrointestinal tract, women on ovulation induction drugs, and patients who do not get operated.

To evaluate the adnexal mass, an ultrasound examination consisting of either transvaginal or transabdominal sonography with colour Doppler for suspicious cases of malignancy was done. Sonographic findings regarding size of adnexal mass, laterality, locularity, solid elements, haemorrhage, presence of ascites and evidence of metastasis on Doppler studies with pulsatility index and resistance index were assessed. An ultrasound score (U) of 1 was given if none or one of the features was found, and a score of 3 was given if two or more of these features were shown. Postmenopausal status was defined as more than one year of amenorrhea or age older than 50 years for women who had undergone hysterectomy; they were scored as M=3. All other patients who did not meet these criteria were defined in a premenopausal status which scored M=1. Standard laboratory investigations of complete hemogram, fasting and postprandial blood sugar, liver and renal function tests, beta human chorionic gonadotrophin (in suspicion of pregnancy) and serum CA 125 with a cut off value of 35 U/ml were taken prior to surgery. RMI for each tumour was calculated using the following formula given below.

$$RMI\ score = Ultrasound\ score \times menopausal\ score \times CA\ 125\ level\ in\ U/ml$$

Following laparotomy, specimen was sent for histopathogical examination and the reports were correlated with preoperative clinical and imaging findings.

Categorical variables have been expressed as number of patients and percentage of patients and compared across the groups using Pearson's Chi square test for independence of attributes/Fisher's exact test as appropriate. Sensitivity, Specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy have been calculated to understand efficacy of different methods. The statistical software statistical package for the social sciences (SPSS) version 20 has been used for the analysis.

RESULTS

The mean age of the patients was 37.18±14.67, minimum age was 13 years and maximum age was 73 years (Figure 1).

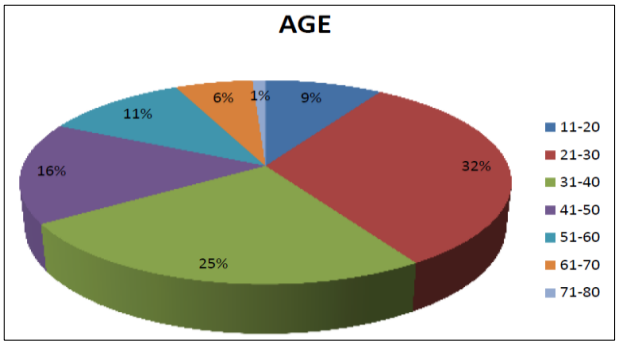

Figure 1: Age distribution in study sample.

The diagram is showing prevalence of malignancy is increasing with age (Figure 2).

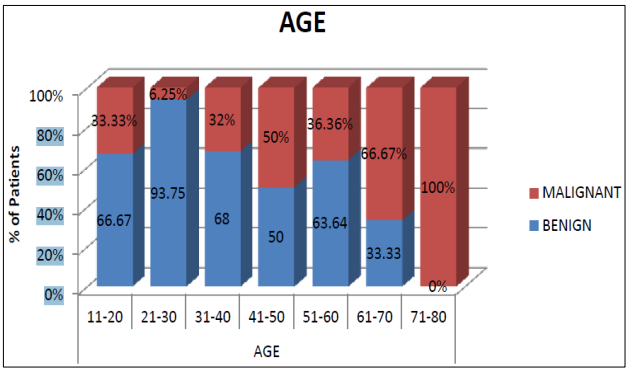

Figure 2: Age distribution versus histopathology.

Parity and menopausal status were significantly correlated with malignancy (Table 1). In context of IOTA features, in our study too all are found to be significantly associated with malignancy except bilaterality (Table 2).

USG has highest diagnostic accuracy among all, while RMI is most specific in detecting malignancy (Table 3).

Per operative finding is also very important in differentiating adnexal mass (Table 4).

Table 1: Comparison of various characteristics of study population versus histopathology.

Parameters	Benign HPE	Malignant HPE	Percentage	P value	Significance
Marital status					
Married	59	26	85	0.76	Not significant
Unmarried	11	4	15		
Education					
Illiterate	14	9	23	0.1364	Not significant
Primary	21	14	39		
Secondary	31	7	38		
Parity					
Multipara	30	24	54	0.002	Significant
Primipara	14	1	15		
Nullipara	26	5	31		
Religion					
Hindu	49	18	67	0.330	Not significant
Muslim	29	12	33		
Menstrual history					
Irregular	19	9	28	0.023	Significant
Regular	36	9	48		
Menopause	12	12	24		
H/0 surgery					
Yes	23	16	39	0.054	Not significant
No	47	14	61		
Family H/O cancer					
Yes	14	16	30	0.001	Significant
No	56	14	70		
SE status					
Lower	15	9	24	0.0438	Not significant
Lower middle	28	17	45		
Middle	27	4	31		
BMI					
18.5-24.9	57	25	82	0.82	Not significant
25-29.9	13	5	18		
Clinical suspicion					
Benign	58	2	60	<0.001	Significant
Malignant	12	28	40		

Table 2: Ultrasound features versus histopathology.

Findings	Benign	Malignant	Total	P value	Significance
Laterality					
Bilateral	11	9	20	0.102	Not significant
Unilateral	59	21	80		
Echogenecity					
Cystic	35	6	41	0.015	Significant
Cystic with calcification	5	1	6		
Complex	25	19	44		
Solid	5	4	9		
Septation					
Yes	35	24	59	0.005	Significant
No	35	6	41		
Papillary projection					
Yes	0	16	16	<0.001	Significant
No	70	14	84		
Ascites					

Continued.

Findings	Benign	Malignant	Total	P value	Significance
Yes	5	25	30	<0.001	Significant
No	65	5	70		
Vascularity					
Low	65	1	66	<0.001	Significant
Moderate	1	4	5		
High	4	25	29		
Metastasis					
Yes	0	11	11	<0.001	Significant
No	70	19	89		

Table 3: Comparison of clinical finding, CA-125 value, RMI score and ultrasonographic assessment with histopathology in the evaluation of adnexal masses.

Findings	TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic accuracy (%)
Clinical findings	28	58	12	2	93.33	82.86	70	96.67	86
CA 125	26	39	31	4	86.66	55.71	45.61	90.69	65
RMI score	27	59	3	11	71.05	95.16	90	84.29	86
USG	25	68	2	5	83.33	97.14	92.59	93.15	93

Table 4: Per-operative finding versus histopathology.

HPE	Per-op finding		Total	P value	Significance
	Benign	Malignant			
Benign	69 (98.57)	1 (3.33)	70 (70)	<0.001	Significant
Malignant	1 (1.43)	29 (96.67)	30 (30)		
Total	70 (100)	30 (100)	100 (100)		

In our study RMI is found to be significant in all age group (Table 5).

Table 5: Correlation of RMI in pre-menopausal group versus malignancy in HPE by unpaired t test.

Pre-menopausal age group	RMI>200 (25)	P value
Malignant	12	0.185 (non–significant)
Non-malignant	13	

DISCUSSION

For this study 100 cases of female patients with adnexal masses who underwent laparotomy were chosen out of which 95 (95%) cases were of ovarian origin and 5 (5%) cases were of non-ovarian origin. These are similar to studies by Radhamani et al.[7]

Among ovarian neoplasms, 65% cases were benign and 30% were malignant. These findings were similar to studies by Balbi et al (70% benign and 30% malignant) and Schutter et al (61% benign and 39% malignant) but differs from the studies by Sharadha et al (87.8% were benign, 10% malignant and 2.2% borderline), Jha et al study (83.9%were benign and 16.1% were malignant).[8-10,14]

The mean age of malignant tumour was 44.57 years in our study which is similar to other studies done by Radhamani et al and Wasim et al. Higher percentage of malignant ovarian tumours were found in postmenopausal women in the present study which is similar to other studies.[7,11-13]

Abdominal pain was the most common symptom followed by gradual swelling of abdomen. The most common ovarian neoplasm seen was surface epithelial tumours which was similar to other studies.[7,15,16] Serous cystadenoma was the most common benign tumour of ovary followed by mature cystic teratoma. Mucinous cystadenocarcinoma was the most common malignant tumour of the ovary.

In our study sensitivity of clinical examination was found to be 93.33%, specificity was 82.86% but positive predictive value of clinical examination was only 70%. This is similar to the study by Balbi et al where sensitivity of clinical examination was found to be 90%.[8]

Sonography is a sensitive method of detecting ovarian cancer. Our study showed that abdominal sonography had sensitivity of 83.33%, specificity of 97.14%, positive predictive value of 92.59%, negative predictive value of 93.15% and diagnostic accuracy of 93% which is comparable to studies by Radhamani (sensitivity of 87.5% and a specificity of 95.65% with an accuracy of 95% for predicting ovarian cancer).[7] In a study by Topaz et al sensitivity, specificity, positive predictive value and negative predictive value of ultrasonography were

calculated as 93%, 88%, 75%, and 97%, respectively.[17] Similar results were shown in a study by Pourissa et al.[18] Colour Doppler increases the diagnostic accuracy of ultrasonography.

Serum CA125 level is a valuable parameter for both diagnosis and monitoring of epithelial ovarian carcinoma. In our study the sensitivity was 86.66%, specificity was 55.71%, positive predictive value was 45.61% and negative predictive value was 90.69% which is similar to the range set by ACOG and with the study of Radhamani (sensitivity 62.5% and specificity 84.25%).[8] Comparable results were obtained in other studies.[19]

RMI score based on menopausal status, ultrasound findings and serum CA125 is an easily applicable method in the primary evaluation of patients with adnexal masses, resulting in timely referral to gynecological oncology centers for suitable surgical operations. In our study RMI had a sensitivity of 71.05%, specificity 95.16%, positive predictive value 90%, negative predictive value 84.29% and diagnostic accuracy of 86% which is similar to studies by Radhamani (sensitivity of 62.5% and a specificity of 95.65%) and Hemeda et al (sensitivity of 70.5%, specificity of 93.5%).[7,20] In previous studies using RMI 2, sensitivity and specificity were 74% and 89%, 71% and 89%. and 76% and 82%.[19,21,22]

Thus as per our results, calculation of RMI score for preoperative triage of patients with adnexal tumours is strongly recommended for post-menopausal group.

Limitations

This study used only a single tumor marker i.e. CA 125 for the study and no other markers were evaluated. The study used a single histopathology examination for concluding malignancy or negating it – observational error by a single individual could not be neutralized. The study was a cross sectional study and further follow-ups were not done.

CONCLUSION

Ovarian cancer is the leading cause of death from gynaecological malignancy. The risk of ovarian cancer increases steadily with age, the greatest occurrence is after menopause. Though there is a battery of tumour marker and scoring panel, none of them are found effective screening modality for ovarian cancer to significantly improve clinical outcomes. Thus timely detection and evaluation of an adnexal mass should be done to differentiate benign and malignant conditions. Our study shows that even though pelvic examination has a high sensitivity of 93.33% but it has a poor positive predictive value of 70%. Ultrasonography (transvaginal and transabdominal) has high specificity of 97.14% and positive predictive value of 92.59% and is the main diagnostic imaging modality prior to treatment.

Risk of malignancy index is a multimodal approach that is simple, non-invasive and easily applicable in preoperative evaluation of patients with ovarian tumor. Risk of malignancy index is a better diagnostic scoring index in discriminating benign and malignant tumor when compared to individual test of ultrasonogram or CA 125 level. The optimal cut off point that best distinguishes benign from malignant ovarian mass for RMI is 200 in the present study. In our study RMI had a sensitivity of 71.05%, specificity 95.16%, positive predictive value 90%, negative predictive value 84.29% and diagnostic accuracy of 86%.

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