

# Original Article

# A PROSPECTIVE OBSERVATIONAL STUDY ON ADNEXAL MASSES -COMPARISON OF CLINICAL IMPRESSION, CA -125, ULTRASOUND FINDINGS AND HISTOPATHOLOGICAL DIAGNOSIS

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#### Key words:

Adnexal Mass, CA-125, Ultrasonogram, RMI, Histopathology

#### Abstract:

Adnexal mass may be found in women of all ages with a prevalence of 1:1000 in premenopausal group and 3:1000 in post menopausal group. The risk of malignancy increases with age. The current study was carried out in the department of Obstetrics and Gynaecology in Ad-din Women's Medical College Hospital, Maghbazar, Dhaka from Ist July 2023 to 30 th June 2024. It was a hospital based observational study which included 100 patients of adnexal masses who required surgery. The goal of the study was to compare sensitivity , specificity , predictive value of clinical evaluation , USG with colour Doppler, CA-125 ,RMI score and to compare them with histopatholoy. All cases were evaluated clinically, by Ultrasonogram with colour doppler ,CA-125 and RMI score. After surgery specimens were sent for histopathology and reports were compared with pre surgical evaluation. 93% cases were of ovarian origin and 7% were non ovarian cases. Histopathology reports showed that 68% adnexal masses were benign and 32% were malignant. The principle tool for evaluation of adnexal mass was Ultrasonogram with colour doppler which had the highest diagnostic accuracy(92%) . But clinical evaluation had the highest sensitivity(90.62%) and RMI score had the highest specificity(95.59%) .With these comparatively simple methods we can diagnose adnexal masses without expensive advanced imaging modalities.

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#### Introduction

An adnexal mass is a common issue in our gynaecological practice. It can be gynaecological or nongynaecological. The term adnexal mass is often used for the mass in the adnexa of the uterus and consists of the fallopian tube, ovary, and associated vessels, ligaments and connective tissue. Since the fallopian tubes, ovaries and their mesenteries are so closely related anatomically, they are often collectively called the adnexum (plural=adnexa).<sup>1</sup>

Adnexal masses are found in females of all ages. The differential diagnosis of adnexal masses include-Gynaecological: Ovarian origin- ovarian neoplasm ,ovarian cyst, endometrioma & tuboovarian mass. Non-ovarean origin: Uterine origin-uterine myoma, Tubal pathology-ectopic pregnancy, hydrosalpinx, tubal neoplasm. Non-gynaecological masses: GIT-appendicular mass, diverticulitis, Genitourinary-pelvic kidney. Ovarian cancer is one of the most lethal gynaecological malignancy.<sup>2</sup>

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Evaluation of an adnexal mass needs a high index of suspicion and the primary goal is to exclude malignancy. A preoperative identification of the nature of the mass can be done before surgical intervention by clinical examination, sonography and CA-125.

Computerized tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) can also be done in diagnosis of adnexal masses. But they are not suitable in every patient in low resource set up. However, histopathology is the gold standard for proper evaluation of adnexal masses.

The goal of this study was to find out the diagnostic value of Clinical Examination, ultrasonography & CA 125 and their correlation with histopathological diagnosis in adnexal masses.

Ultrasonogram is commonly used in patients with adnexal masses. Ultrasound combined with doppler measurements allows the experienced sonographer to reliably diagnose functional, benign, and malignant adnexal masses. [3] The sensitivity of USG is high but the specificity is low.

CA125 is a high molecular weight glycoprotein that has served as the main ovarian cancer biomarker for almost four decades. CA125 has played an important role in the screening, treatment, and follow-up phases of ovarian cancer management<sup>2</sup>. Normal level is 0-35 U/ml. 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. But it is found to be elevated in breast cancer, lung cancer and various benign conditions. Due to poor specificity, CA125 values are not useful in screening the general population.

RMI (risk of malignancy index) is a reliable tool in differentiating benign from malignant adnexal masses. <sup>[4]</sup> It is simple, easy to use and cost effective. The RMI is a product of the ultrasound scan score, the menopausal status and the serum CA125 level (IU/mI). RMI = U x M x CA125 . The ultrasound result is scored 1 point for each of the following characteristics: multilocular cysts, solid areas, metastases, ascites and bilateral lesions. U = 0 (for an ultrasound score of 0), U = 1 (for an ultrasound

score of 1), U = 3 (for an ultrasound score of 2 to 5). The menopausal status is scored as 1 = premenopausal and 3 = post-menopausal. The classification of 'post-menopausal' is a woman who has had no period for more than 1 year or a woman over 50 who has had a hysterectomy.

#### Methods:

This hospital based observational study was performed in the Department of Obstetrics and Gynaecology, Ad-din Women's Medical College Hospital, Dhaka. The study was conducted during the period of 1st July 2023 to 30 th June 2024. The study included 100 female patients who attended OPD of Department of Obstetrics and Gynaecology, Addin Women's Medical College Hospital, Dhaka with the diagnosis of adnexal mass.

#### Inclusion criteria

Female patients with adnexal masses who attended Gynaecological Outpatient Department, Ad-din Women's Medical College Hospital, Dhaka who required admission and operative intervention.

#### **Exclusion criteria**

- Patients who did not get operated
- Patients with masses from uterus, urinary tract or gastrointestinal tract.

An ultrasound examination with colour doppler was done to evaluate adnexal masses. Ultrasound findings regarding laterality, locularity, solid elements, presence of ascites and evidence of metastasis were assessed. Complete blood count, 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 done before surgery. RMI was calculated in the following way-

RMI score = Ultrasound Score x menopausal Score x CA125 level in U/ml

After surgery, specimen were sent for histopathology and the reports were compared with clinical, USG findings & CA 125 level.

Categorical variables were analysed using Chi square test. Sensitivity, Specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy have been calculated to evaluate various methods. SPSS version 29 was used for the analysis of various data.

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#### Results

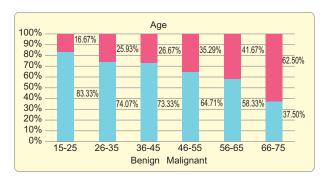
The mean age of the patients was 39.12±12.33, minimum age was 16 years and maximum age was 75 years.

**Table-I**Age distribution of Patients

Age Group	Number of Patients	Percentage
15-25	6	6
26-35	27	27
36-45	30	30
46-55	17	17
56-65	12	12
66-75	8	8
Total	100	100

The occurrence of adnexal mass was highest in 36-45 years of age group (30%).

The diagram (Figure 1) showed percentage of malignant adnexal masses increased with age.



**Figure 1**: Age distribution and histopathological Diagnosis

**Table-II**Presenting Features of Adnexal mass

Chief Complaints	Number	Percentage
Abdominal Pain	70	70
Abdominal swelling	21	21
Irregular Menstruation	16	16
Infertility	10	10
Gastrointestinal Symptoms	9	9
Others	6	6

The majority of patients had multiple symptoms. The most common clinical presentation in all adnexal masses were abdominal pain (70%) followed by abdominal swelling (21%). Other complains like irregular menstruation, infertility, gastrointestinal symptoms etc. were also found.

**Table-III**Non ovarian mass

Pathology	Number	Percentage
Ectopic pregnancy	5	5
Broad ligament tumour	1	1
Hydrosalpinx	1	1
Total	7	7

Non ovarian masses accounted for 7% of adnexal masses.

**Table-IV**Ovarian mass

Pathology	Number	Percentage
Non neoplastic	0	0
Neoplastic	93	93
Total	93	93

**Table-V**Benign ovarian tumour (histology).

Benign tumour	Number	Percentage
Serous cyst adenoma	27	27
Mucinous cyst adenoma	14	14
Mature teratoma (dermoid)	20	20
Total	61	61

The occurrence of benign tumor in the present study was 61% and the most common benign tumor was serous cyst adenoma(27%).

**Table-VI** *Malignant ovarian tumour (histology).* 

Malignant tumour (histology)	Number	Percentage
Serous cyst adenocarcinoma	20	20
Mucinous cyst adenocarcinom	6	6
Dysgerminoma	4	4
Metastatic carcinoma	2	2
Total	32	32

The occurrence of malignant tumor in the present study was 32% and the most common malignant tumor was serous cyst adenocarcinoma.

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**Table-VII**Clinical Characteristics of Study population and Histopathology

Characteristics	Benign	Malignant	Row Total	P value
Urban/Rural				
Urban	39	20	59	0.6254 <sup>ns</sup>
Rural	29	12	41	
Education				
Illiterate	14	11	25	0.1374 <sup>ns</sup>
literate	54	21	75	
Social Status				
Lower	27	12	9	0.4008 <sup>ns</sup>
Middle	31	18	3	
Higher	10	2	12	
Marital Status				
Unmarried	56	24	80	0.3912 <sup>ns</sup>
Married	12	8	20	
Parity				
Nullipara	25	4	29	0.0058s
primipara	13	3	16	
multipara	30	25	55	
Religion				
Muslim	41	19	60	0.9956 <sup>ns</sup>
Hindu	25	12	37	
Christian	2	1	3	
Menstruation				
Pre-menopausal	56	19	75	0.013 <sup>S</sup>
Menopausal	12	13	25	
Family H/O Malignancy				
Yes	11	19	30	0.00001 <sup>S</sup>
No	57	13	70	
Weight				
Underweight				
(BMI< than 18.5)	5	2	7	0.9740 <sup>ns</sup>
Normal				
(BMI18.5 - 24.9)	51	24	75	
Overweight				
(BMI 25-29.9)	12	6	18	
Clinical Diagnosis				
Benign	58	6	64	0.00001 <sup>S</sup>
Malignant	10	26	36	

P value was reached from Chi square test, s=significant, ns=not significant. Parity, menopausal status, family history and clinical diagnosis of malignancy were significantly correlated with malignancy.

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Table-VIII

Evaluation of adnexal masses - Clinical assessment, sonographic features,

CA-125 & RMI score versus histopathology

	True Positive	True Negative	False Positive	False Negative	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy
Clinical	29	57	11	3	90.62	83.82	72.5	95	86
assessment USG	27	65	3	5	84.38	94.59	90	92.86	92
CA 125	28	38	30	4	87.5	55.88	48.28	88.24	66
RMI	26	65	3	6	81.25	95.59	89.66	91.55	91

**Table-IX**Histopathology and Per-operative findings

Histopathology	Per operative finding		Total	P value	Significance
	Benign	Malignant			
Benign	65	3	68	<0.00001 s	Significant
Malignant	2	30	32		
Total	67	33	100		

P value was reached from Fisher's Exact Test. P value was < 0.00001. The result was significant at p < .05. So per operative finding was found significant in differentiating adnexal masses .

Our study showed that clinical assessment had highest sensitivity(90.62%) while RMI was most specific (95.59%)in detecting malignancy . But USG had highest diagnostic accuracy(92%) (Table 8).

### Discussion

In the present study, 100 cases of female patients with adnexal masses undergoing surgical intervention were chosen . 93% were ovarian in origin and 7% were non ovarian origin. Among the ovarian neoplasms, 61% were benign, and 32% were malignant. These findings are comparable with studies by Ray et al and Sharadha et al.  $^{5,6}$ 

The mean age of patients with malignant tumour was 45.36 years in our study which is similar to other studies done by Ray et al<sup>5</sup> and Radhamani et al<sup>7</sup>. Higher percentage of malignant ovarian tumours were found in postmenopausal women in the present study which is similar to other studies.<sup>7,8</sup>

Abdominal pain was the most common symptom followed by gradual swelling of abdomen. It was compatible with previous studies. 8

The most common benign tumor was serous cyst adenoma(27%) followed by mature cystic teratoma. Serous cystadenocarcinoma was the most common

malignant tumour of the ovary which was similar to other studies.<sup>7,8</sup>

In this study, parity, menopausal status, family history and clinical diagnosis of malignancy were significantly correlated with malignancy . These findings are comparable with studies by Ray et al.  $^5\,$ 

In our study sensitivity of clinical examination was found to be 90.62%, specificity was 83.82%, positive predictive value of clinical examination was only 72.5% but the accuracy was 86%. This is similar to the study by Balbi et al.  $^9$ 

USG had sensitivity of 84.38%, specificity of 94.59%, positive predictive value of 90%, negative predictive value of 92.86% and diagnostic accuracy of 92% which is comparable to studies by Ray et al (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%)<sup>5</sup>. Similar results were shown in a study by Pourissa et al.<sup>10</sup> Colour Doppler increases the diagnostic accuracy of ultrasonography.

Serum CA-125 level is a valuable parameter for both diagnosis and monitoring of epithelial carcinoma. The overall sensitivity of CA-125 screening in distinguishing

benign from malignant adnexal masses reportedly ranges from 61% to 90%, specificity ranges from 71% to 93%,positive predictive value ranges from 35% to 91% and negative predictive value ranges from 67% - 90%. <sup>11</sup> In our study sensitivity (87.5%) was similar, but specificity (55.88%) was low when compared to other studies. <sup>12,13</sup> But positive predictive value and negative predictive value were similar.

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 81.25%, specificity 95.59%, positive predictive value 89.66%, negative predictive value 91.55% and diagnostic accuracy of 91% which is similar to studies by Ray at al(sensitivity of 71.05% and a specificity of 95.16%)<sup>5</sup> and Hemeda et al(sensitivity of 70.5%, specificity of 93.5%)<sup>14</sup>. Thus as per our results, RMI scoring must be done in every patients with adnexal mass.

#### Limitations

The study was hospital based observational study and further follow-up were not done. Study population was small. This study used only a single tumor marker i.e.CA 125 for the study and no other markers were evaluated.

#### Conclusion

In case of adnexal mass timely appropriate diagnosis is essential to avoid malignancy related mortality. Majority of adnexal masses were of ovarian origin. Ovarian malignancy is the leading cause of death . Tumour markers are not effective screening modality for ovarian malignancy. Clinical examination has a high sensitivity but it has a poor positive predictive value. Ultrasonography has high specificity. It is the main diagnostic imaging modality prior to treatment. Risk of malignancy index is a simple, non-invasive and easily applicable diagnostic scoring index in discriminating benign and malignant lesions.

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Conflict of interest: None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

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