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ORIGINAL RESEARCH

A Prospective Observational Study To Correlate Clinical Findings With Cytohistology For Diagnosis Of Ovarian Tumor

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ABSTRACT

Background-A pre-operative suggestion of malignancy can guide the gynecologist to refer women with suspected pelvic mass to a trained gynecological oncologist for appropriate therapy and optimized treatment, which is known to improve survival. This study was therefore conducted to evaluate the role of clinical findings in predicting the nature of the ovarian tumor.

Methodology-This study was conducted as an observational study on patients presenting with ovarian masses at tertiary care center, Rohtak during the study period of 12 months (1st April 2020 to 31st March 2021). All the patients were subjected to detailed history taking and perabdominal and bimanual examination along with necessary investigations. Histopathological and FNAC assessment was done for operable and inoperable cases respectively.

Results-This study included 40 cases with ovarian masses with mean age of 48.85±15.43 years. Clinical diagnosis based on combined per-abdominal and bimanual examination showed benign ovarian mass in 40% and malignant ovarian mass in 60% women. Majority of ovarian masses were malignant (65%) on histopathology/FNAC. We found a significant association of malignant ovarian masses on histopathological examination with age advancing age and postmenopausal status ($p<0.05$). The sensitivity of clinical diagnosis was 66.6% (95% C.I. 60%-72%), specificity was 90.9% (95% C.I. 88%-94%), positive predictive value was 85.7% and negative predictive value was 76.9%.

Conclusions-Clinical examination including abdominal and bimanual examination of women with ovarian mass play a significant role in diagnosing ovarian tumors and also in differentiating benign and malignant pathology. Histopathological diagnosis remains the gold standard method, however, preoperative timely detection of ovarian malignancy is an important factor which affects the survival of patient significantly.

Keywords- Histopathology, cytology, ovarian masses, malignancy, tumors, sensitivity.

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INTRODUCTION

Ovarian masses are common forms of neoplasm in women and represent 2/3rd of gynaecological malignancies.[1] According to data of Globocan 2020, ovarian cancer are 7th most common cancer among women worldwide and in 2020, a total of 313959 new cases of ovarian cancers were diagnosed with mortality in 207252 women.[2,3]Due to lack of availability of effective screening methods for early detection of ovarian cancer, most women present in advanced stage (70% present in stage III or IV). Even in developed countries ovarian cancer causes more deaths than all other gynecological cancers put together.[3] In India, ovarian cancer is the third most common gynaecological cancer among women (first being breast, followed by cervical) attributing to 6.6% of all cancers among women.[4]

Ovarian tumors are insidious in onset and are usually diagnosed at late stage, only when they attain big size and become clinically symptomatic. Ovarian tumors, that are present in reproductive age groups are mostly benign, 7% in premenopausal while about 30% in postmenopausal age group are malignant. Out of which, metastatic tumors to the ovaries are most frequently from the breast and gastrointestinal tract. It is important in a case of ovarian mass and to

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differentiate between a benign and malignant tumor to plan for its proper management.[5]

Early diagnosis of ovarian tumor which is likely to be missed on physical examination, poses a diagnostic challenge.[1] The complex nature, unpredictable behavior, prognosis and controversial management make the ovarian tumor a difficult problem for gynaecologists. They present themselves in various clinical forms and surprisingly many times as vague, non gynaecological complaints. Clinical presentation may resemble those of other conditions such as premenstrual syndrome, irritable bowel syndrome, temporary bladder problem, lower abdominal pain, abdominal lump, menstrual irregularities. Low parity, genetic factors (e.g. family history of carcinoma ovary, BRCA mutation), environmental factors (industrialized countries, medium-high socioeconomic level, exposure to talc or radiation, smoking, obesity), use of hormone replacement therapy, infertility, breast cancer, gastrointestinal cancer are associated with an increased risk factors of ovarian cancer.[6] The differentiation between benign and malignant tumors is an important step in the clinical diagnosis as 30% of all ovarian tumors are malignant.[6,7]Histoopathology is the gold standard method for confirmatory diagnosis of ovarian masses.

A pre-operative suggestion of malignancy can guide the gynecologist to refer women with suspected pelvic mass to a trained gynecological oncologist for appropriate therapy and optimized treatment, which is known to improve survival. At the same time a benign mass can be dealt by a gynaecologist only. In Literature, there are not many studies correlating clinical findings with histopathological findings. This study was therefore conducted at tertiary care centre to evaluate the role of clinical findings inpredicting the nature of the ovarian tumor. This pre-operative clinical diagnosis was correlated with cyto/histopathological reports to find the diagnostic accuracy of clinical diagnosis in the case of ovarian tumors.

METHODOLOGY

This study was conducted as an observational study on patients presenting with ovarian masses, in the Department of Obstetrics and Gynaecology, Pt. B.D. Sharma, PGIMS, Rohtak during the study period of 12 months i.e. from 1st April 2020 to 31st March 2021. All women with diagnosis of ovarian mass seeking care at our hospital were included whereas women with functional cysts and extra ovarian masses were excluded from the study.

A total of 40 patients with a diagnosis of ovarian mass admitted in the Gynaecology ward were enrolled. After obtaining ethical clearance from Institute's ethical committee, all the patients fulfilling the inclusion criteria were enrolled and written consent was obtained from all of them. All the patients were subjected to detailed history taking using proforma. Detailed data regarding sociodemographic variables such as name, age, residence etc. was obtained and entered in proforma. Detailed history regarding mode of presentation, parity and menopausal status was obtained and documented. All the patients were then subjected to thorough general and systemic examination. Ovarian masses were assessed thoroughly clinically using per abdominal examination and pelvic examination (bimanual examination).

All necessary investigations (complete haemogram, renal function test, liver function test, prothrombin time, bleeding time, clotting time, viral markers, complete urine examination) ultrasonography and color Doppler was performed on all the cases. MRI/CT scan abdomen and pelvis was done in cases where tumors were inconclusive. Patients were then subjected to surgery and specimen was sent for histopathological assessment. Histopathology report was corroborated with the pre-operative diagnosis and correlated with clinical findings. In inoperable cases, FNAC was done and a cytology report was obtained and corroborated with pre-operative diagnosis. In these cases, neoadjuvant chemotherapy was given, followed by surgery in our institute.

STATISTICAL ANALYSIS

Data collected in proforma was entered in MsExcel and analysed using IBM SPSS (Statistical Package for Social Sciences, IBM Corp. Illinois Chicago) software version 20. The data was analyzed by descriptive and inferential measures. Descriptive measures were described as mean and standard deviation and analysed using Student t-test was applied and the proportion was analyzed by applying the chi-square test. P value of less than 0.05 was considered statistically significant. Diagnostic accuracy of clinical diagnosis was described in terms of sensitivity, specificity, negative predictive value, positive predictive value and expressed in percentage.

RESULTS

This study included 40 cases with ovarian masses who got admitted from OPD for further evaluation. Mean age of patients enrolled in our study was 48.85±15.43 (Range 18-75) years and majority of patients belonged to 56 to 75 years of age (40%). Out of 40 cases, majority of cases were third parity (37.5%). More than half of the cases were postmenopausal (52.5%) and 42.5% cases presented with multiple complaints (Table 1).

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Table 1- Distribution of cases according to baseline variables

Baseline variables		Frequency (n=40)	Percentage
Age (years)	15-35	9	22.5
	36-55	15	37.5
	56-75	16	40.0
Parity	P0	4	10
	P1	1	2.5
	P2	9	22.5
	P3	15	37.5
	P4	3	7.5
	>P5	8	20
Menopausal status	Premenopausal	19	47.5
	Postmenopausal	21	52.5
Complaints	Pain abdomen	11	27.5
	Abdominal distension	9	22.5
	Abdominal lump	2	5
	Postmenopausal bleeding	1	2.5
	Multiple complaints	17	42.5

Table 2 represents findings on perabdominal examination, bimanual examination and per rectal examination. Ascites was present in 22.5% cases and mass was palpable in 50% cases. Tenderness could be elicited in 15% cases. Due to gross ascites and no gross abdominal findings in 14 cases, further abdominal examination could be done in 26 cases. Out of 40 patients 2 were unmarried females so vaginal examination was not done and in 6 patients exact size and surface could not be made out due to massive ascites. In present study, we found that nodularity was felt in pouch of douglas in 12 (30%) women and in 28(70%) women nodularity was not felt on per rectal examination.

Table 2- Distribution according to findings of clinical examination

Clinical examination		Per-abdominal examination (n=40)		Bimanual examination (n=38)	
		n	%	N	%
Gross findings	Ascites	9	22.5	-	-
	Ascites with palpable mass	6	15	-	-
	Mass palpable	20	50	-	-
	None	5	12.5	-	-
Size in cm	≤10	7	26.9	9	23.7
	11-15	6	23.1	10	26.3
	16-20	9	34.6	10	26.3
	>20	4	15.3	3	7.9
	Inconclusive	0	0	6	15.8
Surface	Smooth	18	69.2	20	52.6
	Irregular	8	30.8	12	31.6
	Inconclusive	0	0	6	15.8
Consistency	Cystic	14	53.8	17	44.7
	Solic cystic	8	30.8	15	39.5
	Solid	4	15.4	6	15.8
Mobility	Present	11	42.3	16	42.1
	Restricted	15	57.7	22	57.9
Tenderness	Present	6	15	7	18.4
	Absent	34	85	31	81.6
Laterality	Unilateral	-	-	18	47.4
	Bilateral	-	-	20	52.6

In the present study, on combining per abdominal examination and bimanual examination we made provisional diagnosis of benign ovarian mass in 16 (40%) women and malignant ovarian mass in 24 (60%) women (Figure 1).

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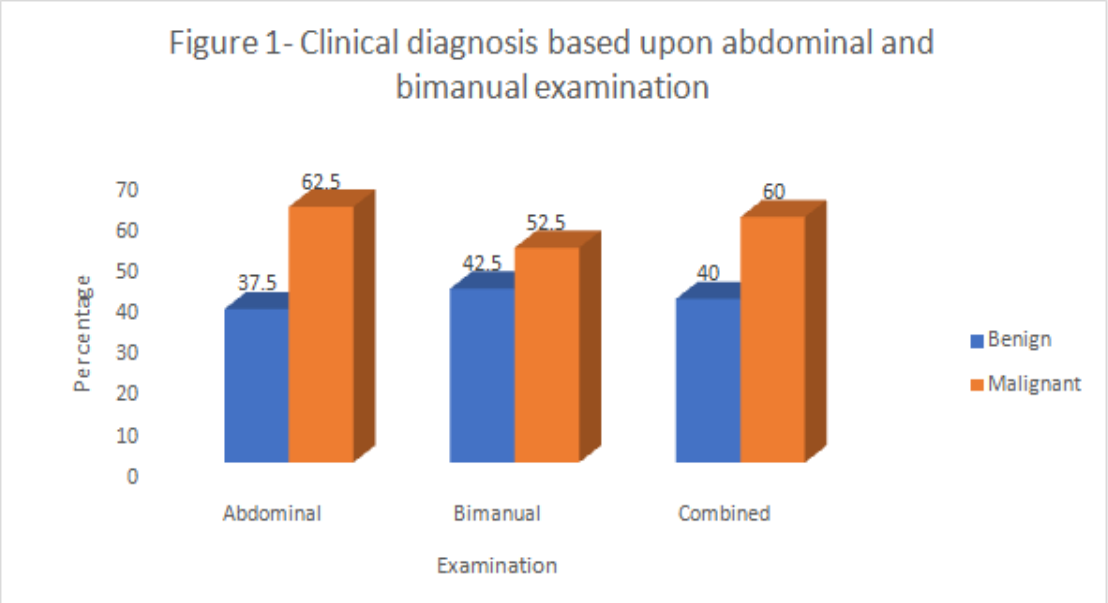

Table 3- Distribution according to findings and diagnosis on histopathology/cytology

Histopathology/ Cytology		Frequency (n=40)	Percentage
Benign	Simple benign cyst	2	5
	Dermoid cyst	1	2.5
	Mucinous cystadenoma	7	17.5
	Mature cystic teratoma	1	2.5
	Dysgerminoma	1	2.5
	Tubercular lesion of ovary	2	5
	Total	14	35
Malignant	Mature cystic teratoma + adenocarcinoma	1	2.5
	Papillary adenocarcinoma	10	25
	Adenocarcinoma ovary	7	17.5
	Papillary serous adenocarcinoma	4	10
	Clear cell carcinoma	1	2.5
	Mucinous cystadenocarcinoma	2	5
	Serous adenocarcinoma	1	2.5
	Total	26	65

Diagnosis was established by cytology in 19 (47.5%) women and by histopathology report in 21 (52.5%) women.Majority of ovarian masses were malignant (65%), and most common malignant and benign ovarian masses were papillary adenocarcinoma (25%) and mucinous cystadenoma (17.5%) respectively (Table 3).

Table 4- Association of baseline variables and clinical diagnosis with histopathological diagnosis

Variables		Benign		Malignant		P value
		n	%	n	%	
Age (years)	15-35	7	17.5	2	5	0.004
	36-55	5	12.5	10	25	
	56-75	2	5	14	35	
Parity	P0	1	2.5	3	7.5	0.75
	P1	0	0	1	2.5	
	P2	4	10	5	12.5	
	P3	5	12.5	10	25	
	P4	2	5	1	2.5	
	>P5	2	5	6	15	
Menopausal status	Premenopausal	9	22.5	8	20	0.001
	Postmenopausal	5	12.5	18	45	

We found a significant association of malignant ovarian masses on histopathological examination with age advancing age and postmenopausal status ($p<0.05$) as shown in table 4.

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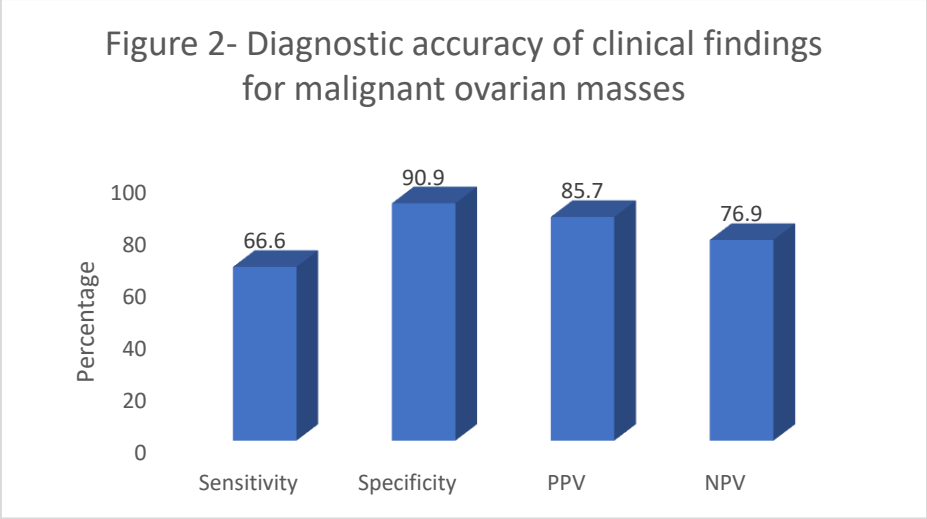

Taking Histopathology/cytology as gold standard, we found that sensitivity of clinical diagnosis was 66.6% (95% C.I. 60%-72%), specificity was 90.9% (95% C.I. 88%-94%), positive predictive value was 85.7% and negative predictive value was 76.9% (Figure 2).

DISCUSSIONS

Ovarian tumors are one of the leading causes of death in women involving a wide spectrum of clinical morphological and histopathological diagnosis. They pose the greatest clinical challenge because they frequently do not result in symptoms until the tumor has spread extensively. It was suggested that the thorough clinical examination along with standardized sonographic features can be used as a simple and effective method in making an accurate preoperative diagnosis of ovarian masses thus minimizing the time and money spent on establishing a diagnosis. A preoperative suggestion that the mass is malignant can guide a gynaecologist to refer the patients to oncosurgeon for further diagnosis or staging followed by optimized debulking surgery or administration of systemic therapy thus improving survival. At the same time, benign masses can be managed expectantly or by conservatively, laparoscopically or by open surgery by a trained gynaecologist only avoiding unnecessary cost and time and reduced morbidity and fertility preservation.[8]

This study was conducted on 40 cases with ovarian mass and the final diagnosis was established based upon histopathology or FNAC report. According to the protocol of our institute, in the patients of ovarian malignancies who presented in advanced stage (III or IV) and according to the report, neoadjuvant chemotherapy is given followed by surgery. So in many cases after surgery, the histopathology does not reveal any malignancy. In such cases, we have taken FNAC as the gold standard for comparison with clinical findings. On the basis of histopathology/cytology report in our study, 65% cases were malignant. Out of 14 cases of benign tumor, maximum were of mucinous cystadenoma (17.5%) and out of 26 cases of malignant tumor, most of the tumor were of papillary adenocarcinoma (25%). Our findings were similar to findings of Firoozabadi et al where they found benign tumors in 62(44%) and malignant in 77(55.4%) cases. Similarly, Amin et al in found that most common benign tumor was mature cystic teratoma (n=25) and most common malignant tumor was papillary adenocarcinoma (6 cases).[10] Khan et al observed in their study that 54% cases to be of papillary cystadenocarcinoma.[11]

In our study, majority of patients with ovarian masses belonged to age ranged of more than 55 years (40%). However, advanced age (35% cases with malignancy belonged to more than 55 years of age) was significantly associated with ovarian malignancy. Our study findings were supported by the findings of Karimi et al[12] and Shradha et al[13], in which the authors found a significant association of age with ovarian malignancy.

Ovarian cancer is associated with low parity and infertility because parity is inversely related to the risk of ovarian cancer. Patient having at least one child is protective for the disease with a risk reduction of 0.3 to 0.4.[5] In our study, it was observed that patient with parity 3 had more incidence of an ovarian mass (37.5%). However, we found no significant association of parity with ovarian malignancy ($p>0.05$). Our study findings were similar to the studies of Yashi et al[14] and Sharadha et al[13] where maximum cases were of parity 1-3 (75%) and 1-2 (63%) respectively.

In our study ovarian tumors were more commonly seen in the postmenopausal (52.5%) and we found a significant association of postmenopausal status with ovarian malignancy ($p<0.05$). Our study findings were supported by findings of Nunes et al (45% postmenopausal women had malignancy)[15] and Meys et al (42.4% cases were malignant in postmenopausal stage)[16].

In our study most of the women with ovarian mass presented with pain abdomen (27.5%), followed by abdominal distension. Our study findings correlated

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well with the studies of Agrawal et al[17] and Khan A et al[11] in which pain abdomen was the chief complaint in 50.9% and 57.3%cases respectively.

Per abdominal examination and bimanual examination was done in all the cases. On bimanual examination, findings were found to slightly different from abdominal examination alone and it further helped in establishing a tentative diagnosis. The bimanual examination was done in 38 patients out of 40 because 2 were unmarried girls, so bimanual examination was not done.Clinical diagnosis can be established on the basis of abdominal and bimanual examination. We found in our study, that on abdominal examination 15 patients were suspected of having benign tumor i.e. 37.5% and 25 (62.5%) patients suspected to be malignant. On bimanual examination42.5% patients were suspected to have benign ovarian tumor 52.5% to have malignant tumor. However, on combining abdominal and bimanual examination it gives more clear anatomy, morphology and extension of the ovarian masses to make the diagnosis and to differentiate between benign and malignant tumor. In a study of Madria et al, clinical diagnosis based upon combined clinical examination, radiological assessment and CA125 measurement had good diagnostic accuracy for predicting benign as well as malignant tumors as compared to histopathological examination.[18] In past, there is not enough literature present on clinical findings of ovarian tumors so comparative studies are less. Even though clinical examination plays a vital role in diagnosing ovarian tumor most of them are missed due to many confounding factors like obesity, ascites.

The main limitation of our study was less sample size. Further studies can be done on larger scale so that clinical diagnosis of ovarian tumor can be included in routine clinical practices for early diagnosis and management of ovarian tumors; thereby, improving the prognosis of women with ovarian malignancy.

CONCLUSIONS

Clinical examination including abdominal and bimanual examination of women with ovarian mass play a significant role in diagnosing ovarian tumors and also in differentiating benign and malignant pathology. Histopathological diagnosis remains the gold standard method, however, preoperative timely detection of ovarian malignancy is an important factor which affects the survival of patient significantly.

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