



A RETROSPECTIVE STUDY SHOWING SIGNIFICANCE OF CA125 AS DIAGNOSTIC AND PROGNOSTIC MARKER IN OVARIAN LESIONS BY USING ELISA.

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ABSTRACT **Introduction:** CA-125, cancer antigen-125, also known as **MUC16** is a glycoprotein that is found at levels in most ovarian cancer cells and encoded by MUC16 gene. CA-125 is produced on the surface of cells and is released in the blood stream. CA-125 is used as a tumor marker that may be elevated in the blood of some patients with specific types of cancers. The CA-125 assay was originally developed to monitor the course of patients with epithelial ovarian cancer. Elevations were also observed with benign conditions including severe endometriosis, adenomyosis, uterine fibroids, ovarian cysts, salpingitis, peritonitis, pleuritis, pericarditis, alcoholic hepatitis, and the first trimester of normal pregnancy. Its cutoff value is 35 U/ml.

Materials and Methods: The present study was retrospective, observational, analytical type done in Department of Pathology at a tertiary care center. Estimation of serum CA 125 level was done by using Indirect Sandwich Enzyme Linked Immunosorbent Assay (ELISA).

Results: 100 samples were received out of which 30 cases were followed up postoperatively. Most common age group in our study was 41-60 year with 27% of cases were presented with ascites out of which 13 cases were diagnosed as malignant. Sensitivity for evaluating recurrent cases was found to be 64.6%.

Conclusion: Considering overall sensitivity of CA125, it should be used along with other tests for diagnosis of ovarian tumors. Serial measurement of CA125 is found useful for prognosis and monitoring recurrence in diagnosed cases.

KEYWORDS : Ovarian carcinoma, CA125, ELISA, Recurrence.

INTRODUCTION

CA-125, cancer antigen-125, also known as **MUC16** is a glycoprotein that is found at levels in most ovarian cancer cells and encoded by MUC16 gene. CA-125 is produced on the surface of cells and is released in the blood stream. The CA-125 assay was originally developed to monitor the course of patients with epithelial ovarian cancer. Elevations were also observed with benign conditions including severe endometriosis, adenomyosis, uterine fibroids, ovarian cysts, salpingitis, peritonitis, pleuritis, pericarditis, alcoholic hepatitis, and the first trimester of normal pregnancy. Its cutoff value is 35 U/ml^{1,2}. Since decades CA-125 has been used as a well-established marker for diagnosis of ovarian cancer. It is mostly over expressed in serous type of ovarian cancers and less likely to be expressed in mucinous tumors.² More than 80% of ovarian cancer patients have elevated CA-125 level during their treatment period. It has been shown that the disease progression is associated with an increase in serum CA-125 level, while a decline in serum CA-125 level is associated with response to therapy³. In another finding, it has been shown that the trend of serum CA-125 level during the first three courses of chemotherapy is a strong forecaster of re-examination findings in patients with ovarian carcinoma at the end of treatment. Interestingly, it has been shown that a normal CA-125 level by the end of second or third chemotherapy is strongly linked to the survival of patients in stage 3 or stage 4 conditions. CA-125 elevations are not related to the tumor mass volume. Serial CA-125 testing is a series of CA-125 tests repeated over a period of time^{3,4,5}. The rate at which CA-125 levels increase is a more accurate method of detecting the presence of ovarian cancer, than a single CA-125 test. When looking over serial test results check to make sure the test used in each case was the same generation, same manufacturer, and same type of assay.²

AIMS AND OBJECTIVES

To establish diagnostic and prognostic role of CA 125 in ovarian malignancy and to study its role in monitoring and recurrence of ovarian carcinoma.

MATERIALS AND METHOD

Patient's serum was taken as sample. Estimation of serum CA125 was done by using ELISA method which is Enzyme immunoassay for the quantitative determination of serum Ca125.

XEMA –ELISA kit was used. Robonik wash well and read well-ELISA instrument were used. Study was done by Indirect Sandwich ELISA method.

Study Duration: July 2020- July 2021

Sample Size: Total 100 samples

OBSERVATIONS AND RESULTS

Cases from different wards like gynecology, radiotherapy etc. presenting with adnexal mass were studied in detail including proper history. Clinical diagnosis and supportive radiological investigations were done. Confirmation of diagnosis was done by histopathological examination. Preoperative value of CA 125 was measured in all cases. Postoperative value of CA 125 was done in 30 cases.

Table – 1: Cases Of Ovarian Lesions And Age Distribution (N=100)

Sr. No.	Diagnosis	0-20	21-40	41-60	> 60	Total
1	Simple serous cyst	-	10	5	-	15
2	Benign serous cyst	-	5	6	-	11
3	Borderline serous cyst	-	2	2	-	4
4	Serous cystadenocarcinoma	-	5	6	10	21
1	Simple mucinous cyst	-	2	-	1	3
2	Benign mucinous cyst	-	2	-	-	2
3	Borderline mucinous cyst	-	2	2	-	4
4	Mucinouscystadeno carcinoma	-	-	2	3	5
3	Dermoid cyst	1	2	3	-	6
4	Hemorrhagic cyst	0	2	2	-	4
5	Other	4	7	12	2	25
	Total	5	39	40	16	100

Table-2: Overall Sensitivity In Ovary Tumor

Sr. No.	Diagnosis	No.	<35U/ml	>35U/ml	Sensitivity
1	Benign serous cystadenoma	11	7	4	36.4
2	Borderline serous cystadenoma	4	0	4	100
3	Serous cystadenoma carcinoma	21	0	21	100
4	Benign mucinous cystadenoma	2	1	1	50
5	Borderline mucinous cystadenoma	4	2	2	50

6	Mucinous cystadenoma carcinoma	5	0	5	100
7	Dermoid cyst	6	6	0	0
8	Gynandroblastoma	1	0	1	100
9	Adenocarcinoma	3	2	1	33.3
10	Thecoma fibroma	2	2	0	0
11	Endometrioid carcinoma of ovary	3	2	1	33.3
12	Granulosa cell tumor	1	0	1	100
13	Krukenberg tumor	1	0	1	100
14	Yolk sac carcinoma	1	1	0	100
	Total	65	23	42	64.6

Table-3 : Presentation Of Ascites In Ovarian Conditions

Sr. No.	Conditions	Ascites present	Ascites Absent
1	Benign	14	55
2	Malignant	13	18
	Total	27	73

- In all the 100 cases in present study preoperative CA 125 levels were measured. Post treatment values were measured in 30 cases following Surgery. Majority of patients were of 41-60 years of age group. 10 Cases with serous cystadenocarcinoma were from >60 years of age group. Overall major number of cases were from serous cystadenocarcinoma with other ovarian carcinomas. Most common presentation was adnexal mass with abdominal pain, but 27 cases presented with ascites, out of which 13 cases were diagnosed as malignant. Overall sensitivity was 64.6% while in malignant cases sensitivity was higher than benign. Out of 30 cases which were followed, few cases showed no decline in post treatment level. These cases were further diagnosed with recurrence or metastasis. Comparison study of pre-op and post-op cases was found to be statistically significant (p value < 0.0001).

DISCUSSION

- Present study has mean age group of 41-60 years and mean age for benign lesion was 34 years. These findings are in concordance with Maheshwari et al⁶, in which mean age group was 20-40 years for benign lesions. Presence of ascites was found in 27% cases which was in concordance with Frank et al (30%). Decline in post-op value was observed in >75% cases of Yoo et al⁹, which was in concordance with present study. Overall sensitivity of present study was 64.6%, which was in concordance with Brenda et al⁸ (68%) and Helzlsouer et al⁷ (57%).

CONCLUSION

- ELISA is rapid, sensitive, reliable and cost effective test for measurement of Cancer Antigen 125. CA 125 values in normal female is < 35 U/ml. values >35 U/ml are considered abnormal. CA 125 value although has definitive diagnostic value, it cannot be used as a sole diagnostic measure. It can be used with other biomarkers and radiological investigations, such as ROMA, OVA1 and RMI which can increase sensitivity for cancer detection. Higher the grade or stage of the tumor the positivity rate of tumor marker also increases. Pre and postoperative CA 125 values are important indicators & any decrease in CA125 value after surgery, radiotherapy or chemotherapy correlates with efficacy of treatment.

Ca125 is useful for ovarian surface epithelial tumors. Among them non mucinous tumors have higher sensitivity than mucinous tumors. It is also a useful marker in patients with gross ascites in which sometimes USG findings are obscured.

CA 125 is a reliable prognostic predictor for monitoring disease progression. Post operative CA 125 value has definitive prognostic value to detect any metastasis or recurrence after successful surgery or chemotherapy & should normally decrease after any therapy. For this pre-operative CA 125 measurement is necessary to correlate difference in pre operative and post operative value. Chances of recurrence are more with tumors with higher post operative value. Serial measurement of CA 125 are more important to detect recurrence or metastasis at any time after treatment.

Thus, CA 125 is an important prognostic indicator, good predictor for relapse and important for therapeutic monitoring in ovarian cancer patients.

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