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ORIGINAL ARTICLE

Correlation between Serum CA-125 Levels and FIGO Stage of Epithelial Ovarian Cancer

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ABSTRACT

Background: Epithelial ovarian cancer is one of the most common types of gynecological cancer that is often diagnosed at late stages due to its nonspecific clinical features and the lack of a reliable screening test. The serum cancer antigen 125 (CA-125) is widely accepted as a marker for the assessment of ovarian cancer but its correlation is different for each patient.

Objective: To determine the correlation between pretreatment serum CA-125 levels and FIGO stage among patients with epithelial ovarian cancer.

Materials and Methods: This hospital-based analytical cross-sectional study was designed to include 140 patients with histopathologically confirmed epithelial ovarian cancer from January 2022 to January 2023. The demographic characteristics, histopathological findings, pretreatment serum CA-125 levels, and FIGO stages were assessed. The Kruskal–Wallis test was used to compare the levels of CA-125 between FIGO stages, which are presented in U/mL. Spearman's rank correlation was employed to study the correlation between the CA-125 levels and the stage of the disease. A p value of < 0.05 was deemed significant.

Results: In the 140 patients, the mean age was 52.39 ± 10.74 years. High-grade serous carcinoma was the predominant histological subtype (57.9%), and 62.1% of patients had advanced-stage disease. Median CA-125 concentrations increased progressively from 64.00 U/mL in stage I to 164.80 U/mL in stage II, 449.40 U/mL in stage III, and 768.65 U/mL in stage IV. Differences across stages were statistically significant ($p<0.001$), with a strong positive correlation between CA-125 and FIGO stage ($rho=0.755$, $p<0.001$).

Conclusion: The analysis demonstrated a positive association between pretreatment serum CA-125 concentrations and advancing FIGO stage. CA-125 may provide supplementary information regarding disease extent but cannot independently determine ovarian cancer stage.

Keywords: CA-125; epithelial ovarian cancer; FIGO stage; tumor marker; gynecological oncology; disease progression.

INTRODUCTION

Ovarian cancer is a significant cause of morbidity and mortality in women globally, and one of the most difficult malignancies for gynecological oncologists. Ovarian cancer is a significant public health problem with global estimates for 2020 projecting about 314,000 new cases and over 207,000 deaths. It is not uncommon for the disease to present itself without any formal signs or symptoms in the early stages, with clinical signs and symptoms, including abdominal distention, discomfort in the pelvis, early satiety and gastrointestinal disturbances, mimicking non-toxic disease. For this reason, diagnosis often can be delayed until the cancer has spread from where it began. Epithelial ovarian cancer represents the majority of ovarian cancers, and there are a number of histological subtypes of ovarian cancer that are characterized by different biological features, clinical presentations and prognosis. Reliable methods of clinical assessment and disease characterization are crucial in treatment planning and prognosis, as the degree of disease at diagnosis is important[1-3].

Epithelial ovarian cancer (EOC) is a heterogeneous disease including high-grade serous, low-grade serous, endometrioid, mucinous and clear cell carcinoma. These histological subtypes have distinct molecular alterations, patterns of progression, clinical properties, and responses to treatment. The most common is high grade serous carcinoma, which typically presents with widespread peritoneal involvement. The International Federation of Gynecology and Obstetrics (FIGO) staging system offers a standard method for describing the extent of the disease, which is from malignancy limited to the ovary or fallopian tubes to extensive disease spread to the peritoneum or somewhere else. Appropriate clinical assessment, imaging, operative findings and histopathological evaluation is necessary in making the appropriate staging. Imaging and surgical evaluation continues to be the mainstays for disease staging, however, levels of circulating tumor markers may offer further insights into biological activity and clinical burden of malignancy[4-6].

One of the most widely studied biomarkers in epithelial ovarian cancer is the serum cancer antigen 125 (CA-125). It is a circulating glycoprotein that is linked to MUC16 and may be shed from malignant epithelial cells and stimulated mesothelial tissue. It is used in the diagnosis of suspicious adnexal masses, before treatment, to assess response to treatment, and to follow for recurrence. High serum CA-125 may also be seen in the setting of high tumour burden, involvement of the peritoneum, ascites and advanced malignancy. But the usefulness of CA-125 as a diagnostic marker depends on a number of factors, including menopausal status, the histopathological subtype and the presence of coexisting benign gynecological or inflammatory diseases. In addition, a significant number of patients with early stage ovarian cancer may have either normal or only slightly elevated CA-125 levels. Thus, CA-125 should not be viewed as an independent diagnostic tool or to determine the stage of the disease and should only be used in conjunction with the clinical examination, radiological and histopathological data[7-9].

Understanding the relationship between pretreatment CA-125 concentrations and FIGO stage may contribute to improved clinical interpretation of this routinely available tumor marker. Assessing variations in serum CA-125 across different stages can help clarify its association with disease extent and its potential role in pretreatment risk assessment. This is particularly relevant in clinical settings where accessible and cost-effective laboratory investigations are needed to complement specialized imaging and oncological evaluation. Nevertheless, tumor heterogeneity and differences in biomarker expression make it necessary to investigate CA-125 concentrations within defined patient populations. Further evaluation of the relationship between CA-125 and FIGO stage may provide useful evidence regarding the clinical relevance and limitations of this biomarker in epithelial ovarian malignancies. The present study was designed to determine the

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correlation between pretreatment serum CA-125 levels and FIGO stage among patients with histopathologically confirmed epithelial ovarian cancer[10].

MATERIALS AND METHODS

This hospital-based analytical cross-sectional study was conducted in the Department of Gynecology and Oncology at tertiary care hospital of Pakistan over twelve months, from January 2022 to January 2023. The study aimed to determine the relationship between pretreatment serum cancer antigen 125 (CA-125) concentrations and the International Federation of Gynecology and Obstetrics (FIGO) stage among patients diagnosed with epithelial ovarian cancer. The primary outcome was the correlation between serum CA-125 levels and FIGO stage, while secondary outcomes included the association of CA-125 levels with histopathological subtype, ascites, and other clinicopathological characteristics.

The proposed sample size was calculated using Fisher's Z-transformation for correlation analysis. An anticipated correlation coefficient of 0.25 between pretreatment serum CA-125 levels and FIGO stage was assumed, considering a 95% confidence level, 80% statistical power, and a 5% level of significance. The minimum estimated sample size was 124 patients. After allowing approximately 10% for incomplete clinical or laboratory records, the target sample size was rounded to 140 patients. The anticipated relationship was supported by previous research demonstrating increasing CA-125 concentrations with advancing stages of ovarian carcinoma[11].

Eligible were patients over 18 years of age who had histopathologically confirmed epithelial ovarian carcinoma, a pretreatment serum CA-125 measurement, and a known FIGO stage. Epithelial ovarian cancer, borderline and metastatic tumor from other primary sites were excluded. Patients that were treated with chemotherapy, radiotherapy, or any other type of anticancer therapy prior to the base line CA-125 measurement were also excluded. Incomplete essential clinical data, unavailable CA-125 levels or lack of data for FIGO staging were not included in the final analysis.

After the assessment of eligibility, the following relevant demographic, clinical, laboratory and histopathological data was collected through a structured data collection proforma. Demographic variables were age, age group and menopausal status. Clinical variables were abdominal symptoms, ascites, and laterality of ovarian tumor, and documented lymph node involvement. Histopathological data was comprised of the epithelial carcinoma type, tumor characteristics and the disease stage. The available histopathological reports were used to classify the histological subtypes as high-grade serous, low-grade serous, mucinous, endometrioid, and clear cell carcinoma.

The hospital laboratory records were used to obtain serum CA-125 concentrations and the results were reported in units per milliliter (U/mL). The impact of therapeutic interventions on biomarker concentrations was minimized by using the pretreatment CA-125. An upper reference limit of 35 U/mL was adopted. Patients were divided into four groups for descriptive analysis: ≤35 U/mL, 36–200 U/mL, 201–500 U/mL and >500 U/mL. The values of continuous CA-125 were not discarded because of the loss of information.

The FIGO stage of epithelial ovarian cancer was established based on the documented clinical, operative, imaging and pathological data (where available). Patients were classified into FIGO stage I, II, III and IV ovarian cancer. Stage I was disease limited to the ovary or fallopian tube; stage II was disease in the pelvis; stage III was extrapelvic peritoneal disease and/or retroperitoneal lymph node involvement; stage IV was metastatic disease elsewhere in the body. To facilitate further comparison, stages I and II were considered as early-stage disease while stages III and IV were considered as advanced-stage disease. Serum CA-125 level was compared between the 4 stages of FIGO to assess the difference in the level of the biomarker depending on the extent of disease.

Data collected were inputted and analyzed with IBM SPSS Statistics version 25.0. Continuous variables were summarized using the mean and standard deviation for approximately normally distributed variables, skewed variables, especially CA-125 levels in serum were presented as median and interquartile range. Categorical variables were presented in frequencies and percentages. Continuous variables were assessed graphically and by the use of suitable normality tests. The Kruskal–Wallis test was used to evaluate differences in CA-125 levels in the 4 FIGO stages. Mann–Whitney U test was used to compare the CA-125 level in early-stage disease and advanced-stage disease and in patients with and without ascites. Spearman's rank correlation coefficient was used to assess the association's strength and direction between serum CA-125 concentrations and FIGO stage (ordinal). Association between categorical variables, when appropriate, was tested using chi square or Fisher's exact test. Two sided p-values < 0.05 were considered statistically significant.

RESULTS

A total of 140 patients were included in the analysis. The mean age was 52.39 ± 10.74 years and the highest number was in the 51-60-year age group (36.4%). A majority of patients were post menopausal (57.9%). Bilateral ovarian involvement and lymph node involvement were seen in 46.4% and 27.1% of patients, respectively, and ascites was noted in 56.4%.

The most common histological type was high-grade serous carcinoma (57.9%) followed by mucinous carcinoma (13.6%) and endometrioid carcinoma (11.4%). The most common stage represented was stage III (45.0%). In all, 87 patients (62.1%) were in advanced stage of disease (FIGO III–IV) and 53 (37.9%) were in early stage of disease (FIGO I–II).

The overall median serum CA-125 concentration was 357.45 U/mL (IQR: 154.38–590.28 U/mL). One hundred thirty-seven patients (97.9%) had elevated levels (more than 35 U/mL). Around one third of patients had concentrations more than 500 U/mL and only three patients had CA-125 levels within the normal range.

Increased serum CA-125 levels were seen as the disease progressed (with advancing FIGO stage). The median CA-125 concentration increased from 64.00 U/mL in stage I to 164.80 U/mL in stage II, 449.40 U/mL in stage III, and 768.65 U/mL in stage IV. This was statistically significant (Kruskal-Wallis H=83.46, p<0.001) and showed a strong association between increased CA-125 levels and disease stage.

Spearman's rank correlation analysis showed a high positive correlation between serum CA-125 levels and FIGO stage (rho=0.755, p<0.001). Median CA-125 levels in patients with advanced and early stage disease were significantly higher at 499.80 and 106.30 U/mL, respectively (p<0.001). Patients with ascites also had higher levels of CA-125 compared to patients without ascites (437.40 vs 156.10 U/mL; p<0.001).

Table 1. Demographic and clinical characteristics of patients with epithelial ovarian cancer (n=140)

Variables	Frequency (%) / Mean ± SD
Age (years)	52.39 ± 10.74
≤40 years	19 (13.6%)
41–50 years	38 (27.1%)
51–60 years	51 (36.4%)
>60 years	32 (22.9%)
Premenopausal	59 (42.1%)
Postmenopausal	81 (57.9%)
Ascites present	79 (56.4%)
Ascites absent	61 (43.6%)
Bilateral ovarian involvement	65 (46.4%)
Unilateral ovarian involvement	75 (53.6%)
Lymph node involvement	38 (27.1%)
No lymph node involvement	102 (72.9%)

Table 2. Histopathological characteristics and FIGO stage distribution (n=140)

Variables	Frequency (%)
Histopathological subtype	
High-grade serous carcinoma	81 (57.9%)
Low-grade serous carcinoma	12 (8.6%)
Mucinous carcinoma	19 (13.6%)
Endometrioid carcinoma	16 (11.4%)
Clear cell carcinoma	12 (8.6%)
FIGO stage	
Stage I	25 (17.9%)
Stage II	28 (20.0%)
Stage III	63 (45.0%)
Stage IV	24 (17.1%)
Disease stage grouping	
Early stage (I–II)	53 (37.9%)
Advanced stage (III–IV)	87 (62.1%)

Table 3. Distribution of pretreatment serum CA-125 levels among patients (n=140)

Serum CA-125 level	Frequency (%)
Overall CA-125, median (IQR), U/mL	357.45 (154.38–590.28)
≤35 U/mL	3 (2.1%)
36–200 U/mL	41 (29.3%)
201–500 U/mL	51 (36.4%)
>500 U/mL	45 (32.1%)
Elevated CA-125 (>35 U/mL)	137 (97.9%)

Table 4. Comparison of serum CA-125 levels according to FIGO stage

FIGO stage	n (%)	Median CA-125 (IQR), U/mL
Stage I	25 (17.9%)	64.00 (44.70–92.40)
Stage II	28 (20.0%)	164.80 (111.53–271.08)
Stage III	63 (45.0%)	449.40 (343.65–724.15)
Stage IV	24 (17.1%)	768.65 (419.90–980.38)
Overall comparison	140 (100%)	p<0.001

Statistical test: Kruskal–Wallis test.

Table 5. Association of serum CA-125 levels with disease stage and clinical characteristics

Comparison	Statistical result	p-value
CA-125 vs FIGO stage I–IV	Spearman rho = 0.755	<0.001
Early vs advanced stage	Median 106.30 vs 499.80 U/mL	<0.001
Ascites absent vs present	Median 156.10 vs 437.40 U/mL	<0.001
CA-125 comparison across four FIGO stages	Kruskal–Wallis H = 83.46	<0.001

Statistical tests: Spearman's rank correlation, Mann–Whitney U test and Kruskal–Wallis test, as appropriate.

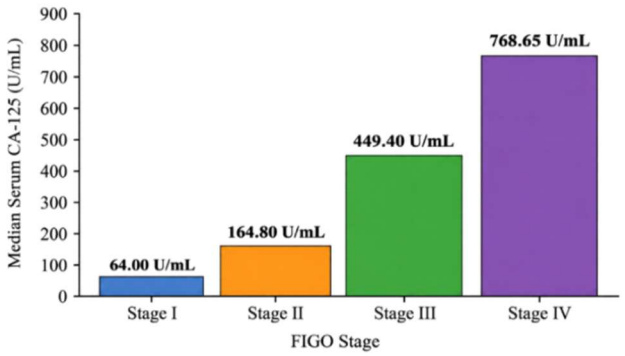


Figure 1. Comparison of median pretreatment serum CA-125 levels across FIGO stages of epithelial ovarian cancer, demonstrating a progressive increase from Stage I (64.00 U/mL) to Stage II (164.80 U/mL), Stage III (449.40 U/mL), and Stage IV (768.65 U/mL).

DISCUSSION

Epithelial ovarian cancer remains one of the most challenging gynecological malignancies because of its heterogeneous biological behavior, nonspecific clinical manifestations, and frequent diagnosis at advanced stages. The relationship between serum cancer antigen 125 (CA-125) concentrations and disease stage is clinically important because tumor burden and the extent of peritoneal involvement may influence circulating biomarker concentrations. CA-125, a high-molecular-weight glycoprotein associated with MUC16, is widely used in the clinical evaluation and monitoring of epithelial ovarian cancer. Increasing serum concentrations may reflect greater tumor activity, peritoneal irritation, and metastatic dissemination. However, individual CA-125 values are influenced by multiple biological and pathological factors, making interpretation within the broader clinical context essential. The FIGO staging system provides a standardized assessment of disease extent, while CA-125 offers complementary biochemical information that may assist in pretreatment evaluation and subsequent clinical monitoring[12-14].

The correlation of increasing CA-125 concentration with increasing stage of ovarian cancer may be due to the progressive involvement of the ovarian tissue, pelvic structures, peritoneal surfaces and distant anatomic sites. Higher levels of CA-125 expression and shedding may lead to higher blood levels as malignant epithelia proliferate and spread. The presence of extensive peritonitis and ascites may also affect the elevation of the biomarkers due to activation of the mesothelial cell and inflammatory response. However, expression of CA-125 is not identical among all the different subtypes of epithelial ovarian cancer. Generally, serous carcinomas express higher levels of CA-125, whereas mucinous and some other histological variants may show a relatively low expression of CA-125 and clinically significant disease. Thus, the level of CA-125 should not be considered as a standalone indicator of tumor burden or tumour distribution. Biomarker concentration can vary by individual patient and the histopathological subtype, differentiation, inflammatory conditions, and menopausal status are pertinent factors to consider[15-17].

CA-125 is not just a marker of tumour stage. Pretreatment measurement could be helpful in the initial assessment of the patient with a suspicious adnexal mass, in combination with ultrasonographic evaluation, clinical examination, menopausal status, and other appropriate tumor markers. CA-125 is also frequently used for serial measurement during treatment and follow-up for biochemical response assessment and for detection of possible disease progression. A single raised CA-125 has not proven to be sufficient to establish malignancy, however, a normal CA-125 does not reliably exclude epithelial ovarian cancer, especially in cases with early stage disease or certain histological types. Other nonmalignant processes, such as benign gynecological conditions, inflammatory disorders, and the like can result in raised levels of CA-125. Therefore, the ideal clinical use for CA-125 is in conjunction with other imaging, histopathological, surgical, and defined staging criteria, and not as a standalone diagnostic or staging tool[18,19].

This association of CA-125 to FIGO stage is significant in gynecological oncology practice, especially in healthcare facilities where there may be limited availability of specialized facilities for diagnosis. A serum biomarker that is easily obtainable could be helpful as an additional measure in initial evaluation, to set a baseline before treatment and to monitor over time. However, there is biological variability among ovarian cancer patients, as well as different methods of laboratory measurement and blood collection time, which can affect the accuracy of the biomarker assessments. There are also constraints on the conclusions that can be drawn about causality, survival, recurrence, and treatment response due to the analytical cross-sectional design. Further prospective multicenter studies, which include histological subtypes, tumor load, molecular features, serial levels of CA-125 and long-term clinical outcomes, may give a more complete picture of the diagnostic and prognostic relevance of the biomarker. The use of CA-125 in

addition to other biomarkers and imaging based assessments could further enhance clinical risk stratification and individualized patient management[20].

CONCLUSION

Pretreatment serum CA-125 is an important supplementary biomarker in the clinical evaluation of epithelial ovarian cancer. Its concentration may increase with advancing FIGO stage, reflecting differences in disease burden, peritoneal involvement, and tumor biology. Nevertheless, CA-125 values vary across histological subtypes and may be influenced by benign and malignant conditions. Therefore, CA-125 should be interpreted alongside clinical assessment, imaging, histopathological findings, and established FIGO staging criteria rather than being used independently to determine disease stage. Further prospective investigations are required to establish the clinical utility of CA-125 in disease assessment, risk stratification, and long-term monitoring.

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