Prognostic Significance of CA125 Dynamic Change for Progression Free Survival in Patients with Epithelial Ovarian Carcinoma

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Background: This study aimed to investigate the value of CA125 dynamic change in PFS prediction for patients with epithelial ovarian carcinoma (EOC).

Material/Methods: Data analysis was performed using SPSS 24.0 statistical software with progression-free survival (PFS) as an outcome measure. Kaplan-Meier method was used to analyze the relationship between PFS and preoperative and postoperative NLR, PLR and CA125 levels, CA125 half-life, CA125-negative time, age, FIGO stage, histopathology, differentiation, vessel carcinoma embolus, and ascites. The survival curves were compared by the log-rank test. Based on the results of single-factor analysis, the Cox model was used for multivariable analysis to analyze independent risk factors affecting the PFS of epithelial ovarian carcinoma.

Results: A total of 117 patients with EOC were selected from January 2012 to January 2019 to carry out a retrospective study. Univariate analyses showed that PFS of the patients with EOC was associated with differentiation, vessel carcinoma embolus, FIGO stage, CA125 half-life, CA125-negative time, and preoperative NLR (P<0.05). Multivariate analysis by the Cox model showed that vessel carcinoma embolus, CA125 half-life, differentiation, and preoperative NLR are the independent risk factors for PFS in patients with EOC.

Conclusions: The serum CA125 dynamic as reflected by CA125 half-life is the most important independent prognostic factor in patients with EOC. The simplicity of CA125 monitoring and its correlation with EOC patient survival can identify patients with poor prognosis through monitoring CA125 half-life, which can provide a reference value for use in clinical practice.

MeSH Keywords: CA-125 Antigen • Disease-Free Survival • Ovarian Neoplasms

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Background

Among gynecologic malignancies, ovarian carcinoma had the highest rate of morbidity, and about 75% of these patients have advanced to the late stage by time of diagnosis (FIGO IIb-IV) [1]. Among them, EOC is the most common, occurring primarily in women aged 50–60 years and accounting for 85–90% of ovarian carcinoma cases. The main treatment options for ovarian carcinoma are tumor cytoreductive surgery and postoperative adjuvant chemotherapy. After satisfactory tumor cytoreductive surgery and chemotherapy, the complete remission rate can be more than 70%, but the recurrence rate is as high as 80% [2]. Although the relapsed patients may achieve clinical remission after re-treatment, the overall prognosis is still poor and the 5-year survival rate generally does not exceed 30% [3]. Study results show that a longer remission period of ovarian carcinoma recurrence is associated with longer survival time [4]. Therefore, it would be useful to be able to predict and evaluate the prognosis early and correctly in patients with clinically complete remission (CCR) after standard treatment, which would assist clinically stratified treatment and ultimately improve prognosis.

In 1981, Bast et al. reported the identification of CA125 monoclonal antibodies produced by mice immunized with ovarian carcinoma cell lines [5]. Subsequently, radioimmunoassay was developed against the target antigen, CA125, and ovarian carcinoma patients showed elevated serum CA125 levels in 82% of cases, compared to 1% in healthy controls [6]. Also, many investigators have noted that elevated or decreased CA125 levels are associated with progression or regression of the disease, suggesting that CA125 is important for monitoring treatment response in patients with EOC. Serum CA125 has important clinical value in monitoring chemotherapy response and predicting recurrence [7].

However, the specificity of serum CA125 is poor. As the incidence of epithelial ovarian cancer increases and patients tend to be younger, fertility-preserving surgery and treatment methods are becoming more common, and finding more sensitive and specific prognostic indicators is becoming more and more important [8,9]. In patients with ovarian carcinoma, tumor burden can be significantly reduced by tumor cytoreductive surgery, and the decrease in serum CA125 is associated with fewer tumor cells. If epithelial ovarian cancer tissue is cleared, CA125 will turn negative. It is expected that the dynamic monitoring of CA125 during treatment will be of great value in the evaluation of treatment effects and prognosis. Serum CA125 dynamic changes are associated with decreased CA125 levels during treatment, and a rapid decline predicts a favorable prognosis, which can be expressed as the half-life and CA125-negative time [10]. Several multivariate analyses showed that the half-life and lowest concentration of CA125 during neoadjuvant chemotherapy were independent prognostic factors in EOC patients [11–14]. Other research suggests that serum CA125 concentrations are a strong independent predictor of the first 2 platinum-based chemotherapy cycles after suboptimal late ovarian cancer cytoreductive surgery [15]. Finally, research showed that the baseline CA125 serum level before the onset of first-line chemotherapy and maintenance chemotherapy after cytoreductive surgery were independent risk factors of recurrence and survival [15].

Although the prognostic significance of elevated CA125 levels before, during, and after comprehensive treatment of patients with EOC is clear, there is limited understanding of serum CA125 dynamic changes. Due to the complex dynamics of CA125, mainly due to factors such as surgical trauma and residual tumor burden of CA125-secreting cells, there is less concern about dynamic changes in CA125. Some studies reported that perioperative CA125 levels are associated with the size of residual lesions after tumor cell depletion [16–18]. Others have observed that use of CA125 improves accuracy in predicting residual disease [19,20]. Therefore, the clinical value of serum CA125 dynamics in the treatment of EOC patients needs further research. Based on this background, the present study was designed to investigate and evaluate the value of CA125 dynamics change in PFS in patients with EOC.

Material and Methods

Patients

Clinical data of patients with EOC who underwent treatment at Zhongda Hospital, Southeast University, and Jiangsu Cancer Hospital, Nanjing Medical University, were retrospectively collected from January 2012 to January 2019. All patients were diagnosed as having EOC by surgical pathology.

Case inclusion criteria were: 1) initial cytoreductive surgery; 2) satisfactory cytoreductive surgery, residual tumor maximum diameter < 1 cm; 3) postoperative platinum-based combined first-line chemotherapy regimen; 4) patients who were evaluated for tumor progression after clinical complete remission (CCR) after treatment; 5) complete clinical and pathological data. Case exclusion criteria were: 1) incomplete clinical and pathological data; 2) evidence of acute/chronic infection or severe bleeding before surgery; 3) with hematological malignancies; 4) perioperative death due to surgical complications.

Follow-up and data collection

The patient or family members were followed up by regular telephone calls, and the patient’s condition, treatment status, and current living status were recorded. The patient’s
previous medical examination, diagnosis, and treatment were reviewed through the hospital’s electronic medical record system. The starting point of follow-up was the patient’s first admission time. From the follow-up date to January 2019, patients who failed to follow-up were excluded. Demographic and clinical data were retrospectively collected from personal medical records.

The data collected included: preoperative and perioperative CA125 levels, the first normal CA125 value and time (if CA125 did not fall to normal within 3 months after the start of chemotherapy, we used the lowest value within 3 months). At the same time, the information on the patient’s age, pathological type, FIGO stage, degree of differentiation, presence or absence of ascites, perioperative blood routine examination report, and vascular tumor thrombus were collected. All these patients were pathologically diagnosed or confirmed according to the WHO classification guidelines by expert pathologists. Multidisciplinary assessments were performed by gynecologic oncologists, surgeons, and pathologists based on the 2014 revised FIGO staging criteria. During the treatment or review follow-up, disease progression was confirmed by clinical imaging or pathology, and the time of disease progression and the cause of disease progression were recorded in detail.

The calculation formula [10] for the half-life of CA125 is (t2-t1)/log (c1/c2), in which c1 is the level of CA125 before surgery, c2 is the first normal level after surgery (if the normal value is not restored within 3 months postoperatively, the lowest value after surgery is taken), and t1 and t2 are the corresponding time-points. CA125-negative time refers to the time required for postoperative serum CA125 level to fall to normal.

Statistical analysis

All data were analyzed using IBM SPSS Statistics (Version 24.0; IBM Corp., Armonk, NY, USA). Differences between clinical characteristics and response rates were analyzed with the χ² test or one-way analysis of variance (ANOVA). The critical value of preoperative NLR and preoperative PLR was determined by the ROC curve. Survival analysis was performed by Kaplan-Meier method, and prognostic factor analysis was performed using the Cox regression model. p < 0.05 was considered statistically significant.

Results

Clinicopathological characteristics

Clinicopathological characteristics are listed in Table 1. A total of 195 patients with complete clinical data and follow-up records were included in the inclusion criteria. PFS refers to the time from the initial treatment to the time of tumor progression. We included 117 patients with PFS (1.3 to 59.7 days) in the study. The half-life of CA125 was calculated according to the calculation formula provided by Buller [10]. Using ROC curve analysis, when NLR=2.96, the Youden index was at most 0.41, and the critical point of NLR was determined to be 2.96. The sensitivity of evaluating ovarian cancer patients without disease progression was 64.1%, and the specificity was 76.9%. The area under the curve (AUC) was 0.667. The same method calculated that when the critical point of PLR was 221, the Youden index of 0.547 was the largest, and the sensitivity of evaluating ovarian cancer patients without disease progression was 70.1%, the specificity was 84.6%, and the AUC was 0.777 (Figure 1).

Prognostic factors analyses

Univariate analyses showed that PFS of the patients with EOC was associated with differentiation, vessel carcinoma embolus, FIGO stage, CA125 half-life, CA125-negative time, and preoperative NLR (P<0.05) (Table 1). According to the results of univariate analysis, the survival curves of the 2 exposure levels of each risk factor were performed by Kaplan-Meier method (Figure 2). If the survival curves existed, the Cox survival analysis could not be applied. The results showed that the relevant factors could be included in the Cox survival analysis. Multivariate analysis by the Cox model showed that vessel carcinoma embolus, CA125 half-life, differentiation, and preoperative NLR were the independent risk factors for PFS in patients with EOC (Table 2). The serum CA125 dynamic as reflected by CA125 half-life is the most important independent prognostic factor in patients with EOC. The relative risk of disease progression in EOC patients with a serum CA125 half-life >20 days was 1.766 times that of EOC patients ≤20 days.

Discussion

EOC is the second most common gynecological cancer in the world. Globally, there were approximately 230 000 new cases in 2012 and the death toll was 150 000 [21]. Primary cytoreductive surgery and platinum-based adjuvant chemotherapy are still the criterion standard treatment for EOC patients [22]. However, most of these patients were diagnosed in the advanced stage, and half of the patients relapsed within 16 months, with a 5-year overall survival rate of less than 50% [23–26]. The International Federation of Obstetrics and Gynecology (FIGO) has identified some survival predictors for EOC patients [22]. However, most of these patients were diagnosed in the advanced stage, and half of the patients relapsed within 16 months, with a 5-year overall survival rate of less than 50% [23–26]. The International Federation of Obstetrics and Gynecology (FIGO) has identified some survival predictors for EOC patients, including age at diagnosis, stage, histological grade, residual tumor, ascites, functional status score (PS), and CA125 levels [27–29]. However, biomarkers that are effective for individualized prediction of treatment outcomes and prognosis are still urgently needed [24].

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### Table 1. Clinicopathological characteristics and Univariate analyses of the factors for progression-free survival.

| Clinicopathological characteristics | Cases | Mean PFS (95% CI) | \( \chi^2 \) | P |
|-------------------------------------|-------|-------------------|----------|---|
| **Age (y)**                         |       |                   |          |   |
| <55                                 | 54    | 21.44 (17.79–25.08) | 0.947    | 0.331 |
| ≥55                                 | 63    | 19.62 (16.37–22.87) |          |   |
| **Histopathology**                  |       |                   | 1.101    | 0.294 |
| Serous carcinoma                    | 86    | 21.33 (18.41–24.25) |          |   |
| Others                              | 31    | 18.58 (14.02–23.15) |          |   |
| **Differentiation**                 |       |                   | 8.643    | 0.003 |
| Well                                | 67    | 23.79 (12.93–19.71) |          |   |
| Poor, others                        | 50    | 16.32 (12.93–19.71) |          |   |
| **Ascites**                         |       |                   | 0.475    | 0.491 |
| Yes                                 | 60    | 19.76 (16.44–23.10) |          |   |
| No                                  | 57    | 21.48 (17.81–25.13) |          |   |
| **Vessel carcinoma embolus**        |       |                   | 10.930   | 0.001 |
| Yes                                 | 59    | 16.62 (13.59–19.66) |          |   |
| No                                  | 58    | 24.65 (21.02–28.28) |          |   |
| **FIGO stage**                      |       |                   | 9.782    | 0.002 |
| I–II                                | 45    | 25.74 (21.55–29.93) |          |   |
| III–IV                              | 72    | 17.39 (14.59–20.19) |          |   |
| **Preoperative serum CA125 (U/mL)** |       |                   | 1.113    | 0.291 |
| ≤500                                | 69    | 21.88 (18.70–25.06) |          |   |
| >500                                | 48    | 18.76 (14.89–22.64) |          |   |
| **Postoperative CA125 decline**     |       |                   | 3.741    | 0.154 |
| 0.0–49.9%                           | 6     | 15.88 (15.57–16.20) |          |   |
| 50.0–75.0%                          | 48    | 18.64 (14.77–22.51) |          |   |
| >75.0%                              | 63    | 22.55 (19.10–25.99) |          |   |
| **CA125 half-life (d)**             |       |                   | 8.302    | 0.004 |
| ≤20                                 | 63    | 23.95 (20.56–27.35) |          |   |
| >20                                 | 54    | 16.68 (13.38–19.99) |          |   |
| **CA125 negative time (w)**         |       |                   | 8.506    | 0.004 |
| ≤8                                  | 60    | 24.15 (20.58–27.72) |          |   |
| >8                                  | 57    | 16.87 (13.74–19.99) |          |   |
| **Preoperative NLR**                |       |                   | 21.445   | 0.000 |
| ≤2.96                               | 66    | 25.43 (22.18–28.69) |          |   |
| >2.96                               | 51    | 14.34 (11.33–17.37) |          |   |
CA125 is currently the most widely used tumor marker for the diagnosis of EOC [7,30–32]. It is a glycoprotein with a molecular weight of 200,000, encoded by the MUC16 gene. It originates from the fetal body cavity epithelial tissue and is widely distributed in mesothelial cells (including peritoneum, pleura, pericardium), Miller tube epithelium (including fallopian tubes, endometrium, and endocervix), and tumors (including ovarian epithelial cancer, fallopian tube cancer, endometrial cancer, cervical cancer, and mesothelioma). CA125 rarely exists in normal clinical tissues, but serum CA125 levels are elevated in patients with EOC.

CA125 is widely used in the diagnosis and follow-up of ovarian carcinoma due to its low cost and simple operation. Clinically, routine measurement of serum CA125 levels is used to monitor tumor response in chemotherapy. Studies have shown that longer patient survival is associated with decreased CA125 levels [33]. In patients with ovarian carcinoma, tumor burden can be significantly reduced by tumor cytoreductive surgery, and the decrease in serum CA125 level is consistent with the decrease in the number of tumor cells. If epithelial ovarian cancer tissue is cleared, CA125 turns negative. The dynamic monitoring of CA125 during treatment is expected to be of great value in the evaluation of treatment effects and prognosis. A study investigated the relationship between perioperative changes in serum CA125 levels and PFS, and results showed that decrease of serum CA125 levels ≥80% after surgery is an independent prognostic factor for PFS [34]. Markman et al. [35] studied 101 patients with advanced EOC to investigate the correlation between CA125 and prognosis, finding that the patients with a reduction of serum CA125 >50% after 2 cycles of chemotherapy had a more favorable prognosis. Another study showed that in both the postoperative intravenous chemotherapy group and the postoperative intraperitoneal chemotherapy group, the CA125 value above 35 U/mL after the first-line chemotherapy indicated that the condition was not controlled [36]. A study of patients with advanced EOC who achieved CCR after treatment confirmed that CA125 was related to prognosis [37]. Groups with CA125 greater than 10 U/mL had significantly shorter PFS than those with less than 10 U/mL [15]. Rocconi et al. [38] found that after 3 cycles of chemotherapy, patients with CA125 levels that did not fall to normal values had a significantly worse prognosis than patients with normal values. Nyvang et al. [39] reported that serum CA125 level after 3 chemotherapy cycles is the most important prognostic predictor for patients with EOC.

CA125 is secreted by ovarian carcinoma cells, and its level is related to tumor size. After the cancerous tissue is removed, CA125 should be negative. Therefore, the dynamic detection of CA125 can determine treatment efficacy and monitor

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**Table 1 continued.** Clinicopathological characteristics and Univariate analyses of the factors for progression-free survival.

| Clinicopathological characteristics | Cases | Mean PFS (95% CI) | £² | P |
|------------------------------------|-------|------------------|----|---|
| Postoperative NLR change           |       |                  |    |   |
| Increase                           | 54    | 19.16 (15.70–22.61) | 1.282 | 0.257 |
| Decrease                           | 63    | 21.84 (18.36–25.32) | 2.674 | 0.102 |
| Preoperative PLR change            |       |                  |    |   |
| ≤221                               | 35    | 17.17 (12.59–21.75) | 0.890 | 0.345 |
| >221                               | 82    | 22.07 (19.18–24.95) |       |     |

**Figure 1.** The ROC curve of preoperative NLR and PLR optimal cut-off points.

CA125 is currently the most widely used tumor marker for the diagnosis of EOC [7,30–32]. It is a glycoprotein with a molecular weight of 200,000, encoded by the MUC16 gene. It originates from the fetal body cavity epithelial tissue and is widely distributed in mesothelial cells (including peritoneum, pleura, pericardium), Miller tube epithelium (including fallopian tubes, endometrium, and endocervix), and tumors (including ovarian epithelial cancer, fallopian tube cancer, endometrial cancer, cervical cancer, and mesothelioma). CA125 rarely exists in normal clinical tissues, but serum CA125 levels are elevated in patients with EOC.
disease progression. Serum CA125 dynamic is a rate of decrease of CA125 levels during treatment, and a rapid decline predicts a favorable prognosis, which can be expressed as the half-life [10]. In this study, we investigated the connection between PFS in patients with EOC and preoperative CA125 values, postoperative CA125 changes, CA125 half-life, CA125-negative time, CA125 level, and CA125 half-life. CA125-negative time was associated with better PFS in patients with EOC (P<0.05). Multivariate analysis of the Cox hazard model of factors of progression-free survival in patients with EOC showed that CA125 half-life was the independent risk factor. The relative risk of disease progression in ovarian cancer patients with a CA125 half-life of >20 days is 1.766 times that of ovarian cancer patients with a CA125 half-life of ≤20 days. The best correlation between CA125 half-life and survival was obtained using the formula provided by Buller et al. [10], who found that a long half-life of CA125 predicted a lack of disease progression and a response to chemotherapy. Van der Burg et al. [11] found that patients with a CA125 half-life of >20 days had a 3.2-fold higher rate of progression compared to those with a CA125 half-life of fewer than 20 days (p=0.01) and had a significantly shorter median PFS (11 months vs. 43 months).

Table 2. Multivariate Cox hazard model analysis of factors associated with progression-free survival in patients with epithelial ovarian carcinoma.

| Factors                        | B     | Wald | HR (95% CI)       | P     |
|-------------------------------|-------|------|-------------------|-------|
| Vessel carcinoma embolus      | 0.544 | 7.368| 1.722 (1.163–2.550)| 0.007 |
| Differentiation               | 0.760 | 14.185| 2.139 (1.440–3.178)| 0.000 |
| CA125 half-life               | 0.569 | 7.981| 1.766 (1.190–2.620)| 0.005 |
| Preoperative NLR              | 0.635 | 9.469| 1.887 (1.259–2.828)| 0.002 |

Figure 2. Kaplan-Meier curves depicting PFS according to vessel carcinoma embolus (A), differentiation (B), FIGO stage (C), CA125 half-life (D), CA125-negative time (E), and preoperative NLR (F).
Conclusions

EOC patients often have no specific symptoms and signs in the early stage, so most of them have reached the advanced stage when diagnosed. Although the treatment of EOC has been gradually standardized, the recurrence rate of advanced-stage patients is still high. Therefore, evaluating the curative effect and finding signs of recurrence as soon as possible are important parts of the treatment process. This study assessed the value of serum CA125 dynamic changes in evaluating the PFS of EOC patients. The results show that the dynamic change in serum CA125, reflected by the half-life of CA125, is the most important independent prognostic factor in EOC patients. Dynamic monitoring of CA125 levels can predict recurrence, allows timely adjustment of the individualized treatment plan, and could ultimately improve the prognosis of EOC patients. It is simple, inexpensive, and is suitable for clinical use.

Conflict of interest

None.

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