Original Articles

Survival analysis of second-line chemotherapy in platinum-sensitive relapsed ovarian cancer patients

VINEET TALWAR, ATIKA DOGRA, VARUN GOEL, VIDYA KRISHNA

ABSTRACT

Background. Patients of ovarian cancer who respond to the initial chemotherapy (CT) regimen may respond again to the same drugs after relapse. We aimed to evaluate the survival of patients with recurrent ovarian cancer (ROC) treated with second-line CT drugs such as liposomal doxorubicin, paclitaxel/carboplatin, and/or bevacizumab.

Methods. Electronic medical records of ovarian cancer patients registered between January 2009 and December 2017 were reviewed to identify those with ROC. Data regarding demographics, clinical characteristics, treatment, recurrence, vital status at last contact, etc. were retrieved. The log-rank test was applied to compare the Kaplan-Meier curves for survival analysis.

Results. A total of 119 cases met the inclusion criteria. The median age at diagnosis and relapse was 49 and 51 years, respectively. The medians for progression-free survival (PFS) and post-relapse survival (PRS) were 19 (95% CI 10.34–21.66) months and 34 (95% CI 37.17–56.83) months, respectively. The PFS was significantly higher among premenopausal women ($p=0.025$). Patients treated with paclitaxel/carboplatin-based second-line CT had significantly higher PRS compared to those treated with liposomal doxorubicin/carboplatin ($p<0.001$). Overall survival was also significantly different between the stage groups ($p=0.003$).

Conclusions. The 5-year PFS rate in ROC treated with second-line CT is <20%. The rate of secondary recurrence is moderately high, leading to reduced survival. Paclitaxel/carboplatin-based second-line CT significantly increases PRS among ROC patients. The probability of mortality increases as the stage advances.

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INTRODUCTION

Among gynaecologic cancers, ovarian cancer has the worst outcome and the highest fatality rate.[1] Despite primary and subsequent cancer-directed treatments, most patients with advanced ovarian cancer experience disease recurrence frequently due to chemoresistance.[2] Selection of second-line chemotherapy (CT) depends on the treatment-free interval. Usually, patients with recurrent ovarian cancer (ROC) are classified into two subcategories depending upon platinum-free interval (PFI), which is calculated as the duration between platinum-based therapy completion and disease progression. The two subcategories are 'platinum sensitive' with a PFI of at least 6 months and 'platinum resistant' if the PFI is <6 months. Patients who responded to the initial CT regimen and had a fair disease-free survival (DFS) may respond again to the same drugs.[3] We evaluated the survival data in a cohort of ROC treated with second-line CT drugs such as liposomal doxorubicin/carboplatin, paclitaxel/carboplatin, and/or bevacizumab.

METHODS

The requirement for ethics approval was waived by the institutional ethics review board. The data of subjects were de-identified to preserve their confidentiality.

The selection of ROC patients was done from our previously reported dataset of ovarian cancer patients.[4] The inclusion criteria were: ovarian cancer patients that relapsed after primary treatment with a combination of surgery and carboplatin/paclitaxel-based first-line CT, and ROC patients that had received a minimum of 3 cycles of either liposomal doxorubicin/carboplatin with or without bevacizumab or paclitaxel/carboplatin with and without bevacizumab based second-line CT. The patients treated with other second-line CT regimens were excluded. Of 440 patients studied earlier, 235 (54.1%) had primary recurrence.[4] However, only 119 of 235 had received the second-line CT regimens mentioned in the inclusion criteria. Hence, these were selected for the analysis.

The detection of primary recurrence in ROC cases was based on the emergence of new symptoms, an increase in CA125, and clinical examination. Histological evaluation and computed tomography/positron emission tomography were also used to confirm the secondary recurrence wherever necessary. Comprehensive data regarding demographics,

symptoms at first presentation, co-morbid conditions, history of cancer, initial International Federation of Gynecology and Obstetrics (FIGO) staging, CA125 level at recurrence, therapy after recurrence, chemotoxicities, disease status at last follow-up, vital status, etc. were gathered from the electronic medical records (Table 1). All patients were followed up until March 2023. The primary endpoint of the study was to assess the progression-free survival (PFS) in ROC patients treated with second-line CT. Secondary endpoint included the assessment of post-relapse survival (PRS).

Treatment

The regimens of second-line CT were selected according to the National Comprehensive Cancer Network ovarian cancer treatment guidelines. Patients who did not have major peripheral neuropathy or myelosuppression and experienced a disease-free interval of >1 year after treatment with previous chemotherapy were given paclitaxel/carboplatin and/or bevacizumab. On the other hand, patients with major peripheral neuropathy and <1 year of disease-free interval were treated with liposomal doxorubicin/carboplatin and/or bevacizumab. In addition, patients who wished to avoid alopecia were also treated with liposomal doxorubicin/carboplatin-based second-line CT. The liposomal doxorubicin and paclitaxel doses were calculated according to the patients' body surface area, and those of carboplatin were planned in accordance with the area under the curve-5. Bevacizumab was administered at 7.5 mg/kg every week. Liposomal doxorubicin and paclitaxel/carboplatin were administered once every 4 weeks and on days 1 and 2, every 21 days, respectively.

Almost all patients received the prescribed doses of CT. Some patients underwent secondary debulking surgery along with second-line CT. The assessment of response was done after 3 cycles of CT. The toxicities related to CT were assessed according to the Common Terminology Criteria for Adverse Events of the National Cancer Institute (NCI CTCAE; Version 3.0, DCTD, NCI, NIH, DHHS, Bethesda, Maryland).

Response evaluation

Evaluation of treatment response was done by comparing radiological scans with previous scans and levels of serum CA125 after every 3 or 6 cycles. The response to therapy was assessed according to Response Evaluation Criteria in Solid Tumours (RECIST) 1.1.[5] Complete response refers to the complete disappearance of all target lesions; while partial response indicates a 30% decrease in the sum of the longest diameters of the target lesions.

The detection of secondary recurrence was done based on emerging symptoms, rising CA125 values, and clinical examination. In addition, it was confirmed with the findings of computed tomography/positron emission tomography and histopathological examination, where needed. Follow-up details for the entire cohort were periodically updated until March 2023. The follow-up data were collected either by reviewing patients' electronic medical records or via contacting them telephonically. The PFI was computed as the duration between the completion dates of carboplatin/paclitaxel-based first-line CT to primary recurrence/last contact or date of death, whichever happened earlier.

TABLE 1. Characteristics of patients

Characteristic (*n*)*	Frequency (%)
Age at primary diagnosis (years)	
Mean (SD)	49.6 (8.8)
Median (IQR)	49 (28–72)
Laterality	
Unilateral	16 (13.4)
Bilateral	103 (86.6)
Median (range) baseline CA125 (units/ml)	600 (13.9–9965)
Comorbid conditions	
Absent	73 (61.3)
Present	46 (38.7)
Family history of breast/ovarian cancer	
Absent	106 (89.1)
Menopausal status (104)	
Premenopausal	50 (48.1)
Postmenopausal	54 (51.9)
Staging	
I and II	8 (6.7)
III	104 (87.4)
IV	7 (5.9)
Type of histology	
Serous	110 (92.4)
Mixed	3 (2.5)
Endometroid	2 (1.7)
Mucinous	2 (1.7)
Clear-cell	1 (0.8)
Undifferentiated	1 (0.8)
Histological grade	
High grade	101 (84.9)
Response to therapy	
Complete response	34 (28.5)
Partial response	44 (37)
Stable disease	19 (16)
Progressive disease	22 (18.5)
Age at primary recurrence (years)	
Mean (SD)	51.4 (8.8)
Median (range)	51 (30–75)
CA125 level (units/ml) at primary recurrence (116)	
Increased	87 (75)
Not increased	29 (25)
Median (range)	82.3 (2–3230)
CT regimen	
Paclitaxel/carboplatin and/or bevacizumab	54 (45.4)
Doxorubicin/carboplatin and/or bevacizumab	65 (54.6)
Discontinuation of second-line CT	
Yes	17 (14.3)
Haematological toxicities	
Present	100 (84)
Non-haematological toxicities	
Present	55 (46.2)
Secondary recurrence	
Present	76 (63.9)
Disease status at last follow-up	
Disease free	22 (18.5)
Recurrent disease	97 (81.5)
Survival status	
Alive	55 (46.2)
Dead	64 (53.8)
Cause of death (64)	
Disease related	63 (98.4)

* all numbers are 119 unless mentioned in parentheses

The PFS was calculated from completion of the second-line CT to secondary recurrence or disease progression/last contact, or date of death, whichever happened earlier. The PRS was calculated from the detection of the first relapse to the last contact or death. The survival rates were compared corresponding to PFI, serum CA125 levels, menopausal status, disease stages, CT regimens, and bevacizumab.

Statistical analysis

Data were analysed using the IBM SPSS software (Version 29, SPSS Inc., Chicago, IL, USA). Continuous data were mentioned as mean (standard deviation [SD]) or median (interquartile range [IQR]), and categorical data were mentioned in numbers or percentages. The comparison between continuous variables was done using a paired T-test, and that of categorical variables was performed using a Chi-squared test. The log-rank test was used to distinguish the Kaplan–Meier curves for survival analysis. The results were considered significant at $p<0.05$.

RESULTS

Baseline characteristics

The mean (SD) and median (IQR) ages of patients at diagnosis were 49.6 (8.8) and 49 (28–72) years, respectively. An overview of the clinical features of the patients is given in Table 1. Most patients had bilateral disease at diagnosis. Family history of any cancer, and specifically breast and ovarian cancer, were present in 14.3% and 10.9%, respectively. History of smoking was present only in 2 (1.7%) patients. The most common symptoms at diagnosis were gastrointestinal (81.5%), followed by genitourinary (12.6%), and others (5.9%). Most patients were stage III at diagnosis. The most common type of histology was serous carcinoma, and most tumours were high grade.

Characteristics at relapse

The mean (SD) and median (IQR) ages at disease relapse were 51.4 (8.8) years and 51 (30–75) years, respectively. The mean and median levels of serum CA125 at disease recurrence were 214.9 (385.1) and 82.3 (2–3230) µg/ml, respectively. The mean serum CA125 level at diagnosis was significantly higher compared to that at first relapse ($p<0.001$).

Of 119 patients, 44 (37%) underwent secondary surgical cytoreduction along with CT, and 102 (85.7%) received the complete prescribed dose of second-line CT. CT related toxicities were present in 69 (58%) patients. Vomiting/nausea (23, 19.3%) was the major toxicity, followed by abdominal distension/pain (18, 15.1%), fever (15, 12.6%), weakness (15, 12.6%), and others. The second-line CT was given for 6 cycles, and therapy was changed in case of progressive disease. More than half the patients had a secondary relapse and succumbed to the disease.

Response to therapy

Fifty-three (45.4%) patients were given paclitaxel/carboplatin-based CT, and the rest (54.6%) were treated with doxorubicin/carboplatin-type CT. The group of patients treated with paclitaxel/carboplatin and/or bevacizumab had a significantly higher rate of clinical response/partial response ($p=0.003$) compared with patients receiving doxorubicin/carboplatin and/or bevacizumab (Table 2). Comparison of treatment outcomes between two second-line CT regimens revealed lower toxicity among patients treated with paclitaxel/carboplatin and/or bevacizumab, though it was not significant. In addition, the mortality rate was significantly lower in this group ($p=0.016$) compared to that treated with doxorubicin/carboplatin and/or bevacizumab (Table 2).

Seventeen (14.3%) of 119 subjects received bevacizumab along with any of two regimens (Table 3). Toxicities were reported to be lower in patients who had received bevacizumab compared to those who had not though the difference was not statistically significant ($p=0.062$). The frequency of secondary recurrence was lower among patients treated with bevacizumab in combination with second-line CT (Table 3).

Progression-free survival

The median follow-up for the ROC was 34 months. Median PFS of patients was 11 (IQR 0–150) months. Both 5- and 8-year PFS rates in the entire cohort of ROC cases were similar (19%). The comparison of PFS between patients with serum CA125 >600 U/ml levels and that with serum

TABLE 2. Chemotherapy regimen and treatment outcome in 119 patients

Characteristic	Paclitaxel/carboplatin and/or bevacizumab (*n*=54)	Liposomal doxorubicin/carboplatin and/or bevacizumab (*n*=65)	p value
Response			
Complete response	20 (37.7)	13 (20)	0.003
Partial response	24 (45.5)	20 (30.8)	
Stable disease	4 (7.5)	14 (21.5)	
Progressive disease	5 (9.4)	18 (27.7)	
Toxicity			
Absent	26 (49.1)	24 (36.9)	0.185
Present	27 (50.9)	41 (63.1)	
Secondary recurrence			
Absent	17 (32.1)	26 (40)	0.374
Present	36 (67.9)	39 (60)	
Survival status			
Alive	31 (58.5)	24 (36.9)	0.019
Dead	22 (41.5)	41 (63.1)	

TABLE 3. Outcomes in relation to administration of bevacizumab (*n*=119)

Characteristic	Received (*n*=17)	Not received (*n*=102)	p value
Toxicity			
Absent	11 (64.7)	39 (38.2)	0.062
Present	6 (35.3)	63 (61.8)	
Secondary recurrence			
Absent	12 (70.6)	49 (48)	0.116
Present	5 (29.4)	53 (52)	
Survival status			
Alive	13 (76.5)	76 (74.5)	0.999
Dead	4 (23.5)	26 (25.5)	

CA125 ≤600 U/ml at diagnosis were significantly different (p=0.026; Fig. 1a). Similarly, PFS in premenopausal women was significantly superior than in postmenopausal women (p=0.025; Fig. 1b). The difference in PFS between patients with PFI of 6–12 months and >12 months was not significant (p=0.885; Fig. 1c). Evaluation of PFS among the stages of disease displayed no significant difference (p=0.722; Fig. 1d). Similarly, there were no significant differences in the PFS based on the CT regimens (Fig. 1e) or bevacizumab-based therapy (Fig. 1f).

Post-relapse survival

The median PRS observed in our study was 34 (0–160) months. The 5- and 8-year PRS rates were 40% and 23%, respectively. Comparison of PRS corresponding to PFI did not show significant difference (p=0.096; Fig. 2a). Similarly, PRS was not different related to the menopausal status (p=0.123) and serum CA125 levels (p=0.302). The PRS at stages I and II combined was highest (62.5%), followed by stages III (46.2%) and IV (28.6%) and the comparison of PRS between disease stages was statistically significant (p=0.003). Patients who received paclitaxel/carboplatin-based second-line CT had significantly better PRS in comparison with subjects treated with liposomal doxorubicin/carboplatin (p<0.001; Fig. 2b). On the contrary, PRS between patient sets treated and not treated with bevacizumab was not significantly different (Fig. 2c).

DISCUSSION

We evaluated the PFS and PRS of 119 patients with ROC treated with liposomal doxorubicin/carboplatin, paclitaxel/carboplatin, and/or bevacizumab as second-line CT. We found that the regimens were effective in some patients; however, a considerable proportion of patients had a second relapse. The median age of 49 years at diagnosis and 51 years at first relapse indicated a short recurrence-free survival. The presence of a family history of breast and ovarian cancer among 13 (11%) patients was consistent with our previous findings.[4] It corroborates the fact that 5%–10% of cancers can be attributed to genetic defects.[4,6] The symptoms of disease at presentation were predominantly gastrointestinal and not related to the genitourinary system.[7] The stage of disease at presentation was mainly advanced, which supports the fact that early-stage disease is generally asymptomatic, and symptoms of late-stage disease are non-specific.[8] The majority of tumours were high-grade and had a serous type of tumour histology; these constitute the most aggressive histologic subtypes and have a dismal prognosis.[9] This may be the reason for the high rate of recurrence in our patients. Statistically higher serum CA125 levels at diagnosis and no increase at primary relapse in about 25% of patients may indicate that CA125 is not optimally sensitive and that some patients with normal levels may have persistent disease.[10] Secondary recurrence in 64% of patients indicates that ovarian cancer relapses frequently and leads to poor survival and quality of life for patients.[2] The majority of patients are at an advanced stage at diagnosis.

The median PFS in our cohort was higher than that reported by Ding *et al.*[11] and lower than that observed by Kim *et al*.[12] This may be due to tumour heterogeneity. The Kaplan–Meier log-rank test reflected that initial staging was not associated with PFS, which contrasts with the existing literature.[4,12] A significantly higher PFS in premenopausal women corroborates the finding that clinical outcomes are better in this group compared to those in postmenopausal women.[13] Superior PFS in the group of patients treated with paclitaxel/carboplatin compared to the other second-line CT regimen is in agreement with the findings of Mahner *et al*.[14] Patients in the paclitaxel/carboplatin group had less toxicity and better outcome compared with those in the doxorubicin/carboplatin group. In addition, those with PFI>12 months had better PRS, which may be because these patients had a good response to first-line CT, and the re-introduction of the same regimen generated a better response. The addition of bevacizumab enhanced PRS.[15]

The median PRS in our study was higher than that reported by Shimokawa *et al*.; however, it was lower than that mentioned by others.[16–18] Our 5-year PRS is higher than that reported by Soyama *et al*.[19] In congruence with the findings of our previous study and others, the PRS was strongly related to the stage of the disease.[4,20] It shows that mortality increases with advancing stage. Though not statistically significant, a better PRS in the premenopausal group reflected better outcomes in premenopausal women.[13]

The limitation of our study is that we could not assess the chemotoxicity profile in detail due to the non-availability of comprehensive data in this context.

Conclusion

The 5-year PFS rate in ROC treated with second-line CT was <20%. The rate of secondary recurrence was moderately high, leading to reduced survival. Premenopausal women have superior PFS in comparison

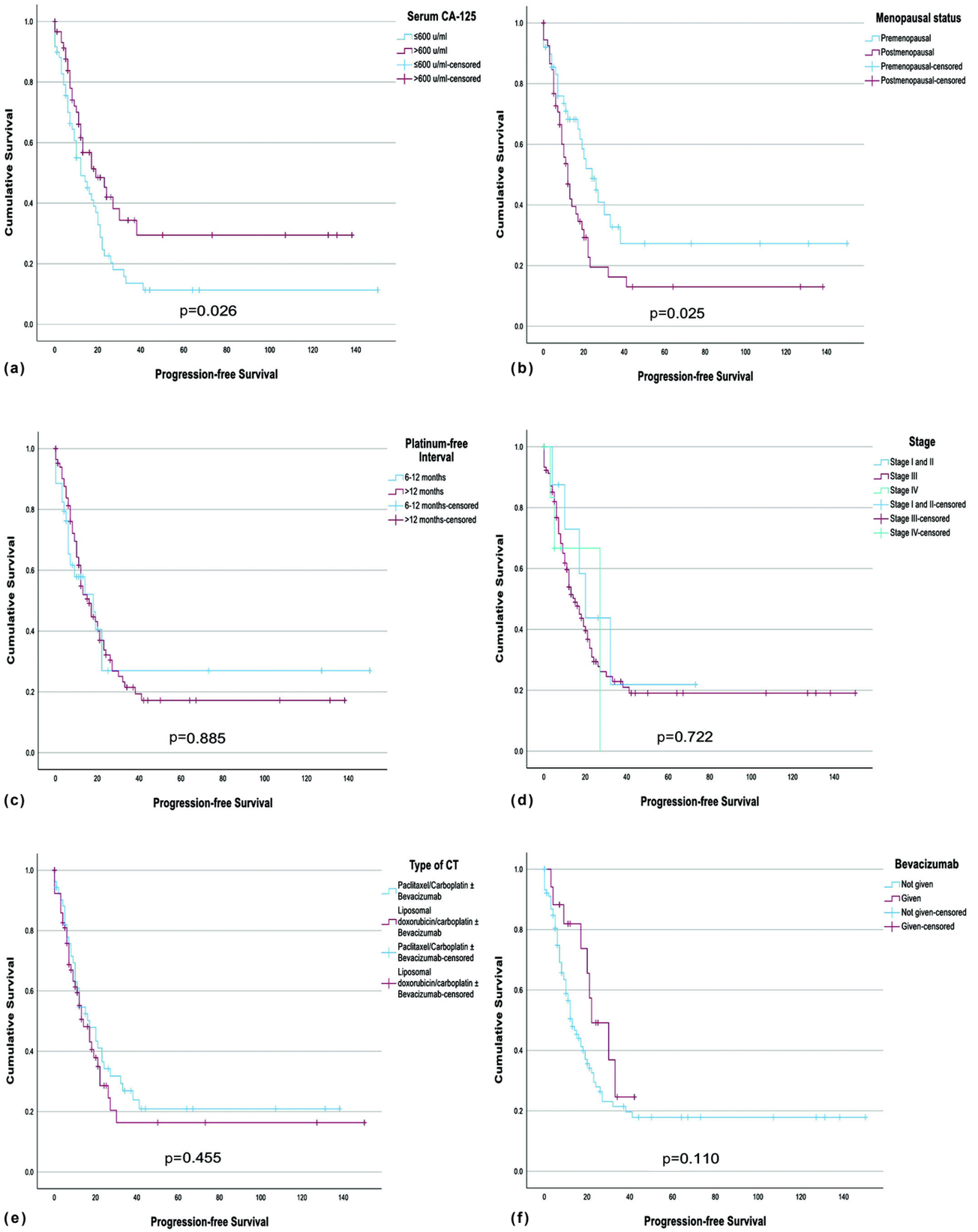

FIG 1. Kaplan–Meier survival curves for progression-free survival (a) serum CA-125 level, (b) menopausal status, (c) platinum-free survival, (d) disease stage, (e) type of chemotherapy (CT), (f) bevacizumab

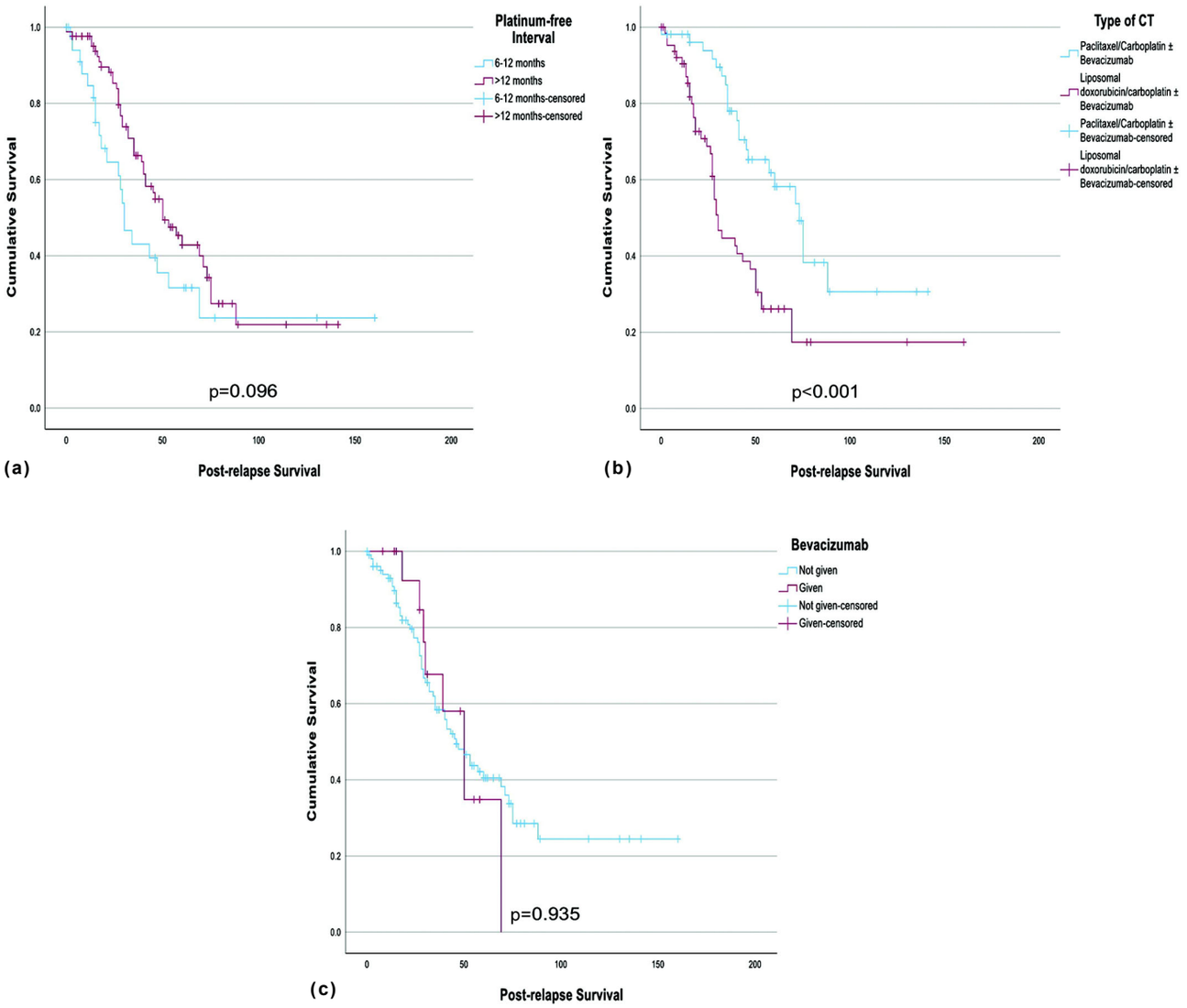

FIG 2. Kaplan–Meier survival curves for post-relapse survival corresponding to factors: (a) platinum-free interval, (b) type of chemotherapy (CT), (c) bevacizumab

with postmenopausal women. Paclitaxel/carboplatin-based second-line CT significantly increases PRS among ROC patients. The likelihood of mortality increases as the stage advances in ROC. Identification of recurrence-specific drivers and molecular targeted therapies is essential.

Conflicts of interest. None declared

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