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ORIGINAL RESEARCH

Bevacizumab Efficacy and Tolerability in Patients with Metastatic Platinum-Sensitive Ovarian Cancer Beyond Progression

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Introduction: High recurrence rates and the emergence of resistance mechanisms in ovarian cancer necessitate exploring alternative therapeutic strategies except platinum-based chemotherapies. This has led to the development of bevacizumab, a recombinant humanized monoclonal antibody targeting VEGF. Nevertheless, the continuation of bevacizumab treatment initiated alongside chemotherapy, especially after disease progression, remains a topic of debate.

Materials and Methods: Our study involved a single-center retrospective analysis of the medical records of patients diagnosed with stage 3 and 4 epithelial ovarian cancer between June 2011 and January 2023. All patients in our study were platinum-sensitive.

Results: Patients with residual disease >1 cm following initial surgery had significantly worse median OS ($p = 0.002$). Post-progression, patients were divided into two groups based on whether bevacizumab was continued. More than half of the patients who continued treatment with bevacizumab and chemotherapy achieved a 5-year OS, which was statistically superior ($p < 0.001$). When comparing PFS between patients who did and did not receive bevacizumab in the second line following recurrence/progression, those treated with bevacizumab demonstrated a median PFS of 12.0 months (95% CI: 10.5–13.4), which was significantly better ($p < 0.001$). The hazard ratio for mortality in patients continuing bevacizumab treatment beyond progression was 0.11 (95% CI: 0.05–0.22) ($p < 0.001$).

Conclusion: Many studies have shown the effectiveness and survival benefit of bevacizumab in epithelial ovarian cancer. In contrast, the literature offers limited studies addressing the survival benefits of continuing bevacizumab beyond disease progression. However, our study indicates that continuing bevacizumab beyond progression significantly contributes to both OS ($p < 0.001$) and PFS ($p < 0.001$). As larger studies with similar results to ours are conducted in the future, current guidelines may improve, and the decision to continue bevacizumab treatment after progression may become more evidence-based.

Keywords: metastatic ovarian cancer, beyond progression, bevacizumab, efficacy and tolerability

Introduction

Epithelial ovarian cancer is one of the most prevalent gynecological malignancies, ranking as the eighth most common cancer among women globally and the fifth leading cause of cancer-related deaths in women in developed countries.[1] Alarmingly, approximately 75% of patients are diagnosed at an advanced stage, with disease recurrence observed in over 70% of cases. Due to the ovaries and fallopian tubes' deep anatomical location, early-stage symptoms are typically absent or non-specific.

The standard treatment protocol involves optimal surgical intervention followed by platinum-based chemotherapy. For metastatic patients or those unsuitable for primary surgery, platinum-based neoadjuvant chemotherapy is administered before debulking surgery. The response duration to first-line platinum-based chemotherapy is defined by the platinum-free interval (PFI), which plays a critical role in guiding subsequent treatment strategies for recurrent ovarian cancer. Patients with a PFI of less than six months are classified as platinum-resistant, while those with a PFI of six months or more are considered platinum-sensitive.[2]

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In cases of recurrent platinum-sensitive ovarian cancer, retreatment with platinum-based chemotherapy is typically the initial approach. However, high recurrence rates and the emergence of resistance mechanisms necessitate exploring alternative therapeutic strategies. Suppression of vascular endothelial growth factor (VEGF) has been demonstrated to improve survival outcomes in epithelial ovarian cancer. This has led to the development of bevacizumab, a recombinant humanized monoclonal antibody targeting VEGF. Randomized Phase III clinical trials have evaluated the efficacy and safety of combining chemotherapy with bevacizumab.[3] Nevertheless, the continuation of bevacizumab treatment initiated alongside chemotherapy, especially after disease progression, remains a topic of debate.

In our study, we assessed the effects and adverse outcomes linked to the addition of bevacizumab to chemotherapy, along with the influence of continuing bevacizumab therapy beyond progression on survival in patients with platinum-sensitive recurrent or metastatic ovarian cancer.

Materials and Methods

Our study involved a single-center retrospective analysis of the medical records of 130 patients diagnosed with ovarian cancer between June 2011 and January 2023. Pathological staging was performed by the 7th edition of the TNM staging system.[4] Patients with incomplete data, those diagnosed with more than one primary malignancy, and individuals under 18 were excluded from the analysis. Patients who received bevacizumab in adjuvant treatment were not included in the study. Patients with negative germline and somatic BRCA-1 and BRCA-2 mutations were included in the study.

Patients were categorized into three groups: those who underwent interval cytoreduction and adjuvant therapy following neoadjuvant treatment, those who underwent primary surgery followed by adjuvant therapy, and those who could not undergo surgery due to tumor characteristics or comorbidities. All patients were diagnosed with stage 3 or stage 4 epithelial ovarian cancer. Baseline characteristics at diagnosis, including age, tumor localization, disease stage, presence of ascites, and residual disease >1 cm following initial surgery, were documented.

This study focused on patients who had not received bevacizumab during neoadjuvant, and adjuvant treatment but were subsequently treated with bevacizumab in combination with chemotherapy after recurrence or disease progression. All in-operative and stage 4 patients in our study received chemotherapy with bevacizumab in the metastatic first line. Platinum sensitivity status was determined based on the time interval between the last platinum-based treatment and the recurrence or progression date, with platinum-free intervals (PFIs) calculated accordingly. All patients in our study were platinum-sensitive.

Progression-free survival (PFS) was assessed across all treatment lines, with particular attention given to the longest PFS achieved after adding bevacizumab to chemotherapy. Whether bevacizumab was continued beyond progression was also recorded. Treatment responses during chemotherapy with bevacizumab and chemotherapy alone were evaluated. Radiologic responses were assessed using the Response Evaluation Criteria in Solid Tumors (RECIST),[5] with treatment outcomes categorized as complete response (CR), partial response (PR), progressive disease (PD), or stable disease (SD).

Patients were further stratified into two groups based on residual disease status: those with and those without residual disease >1 cm following initial surgery. Overall survival (OS) was defined as the time from diagnosis to death or the last follow-up date. All neoadjuvant and adjuvant treatments were administered every 21 days. The paclitaxel dose was 175 mg/m2 and the carboplatin dose was calculated to be AUC=5. Additionally, the adverse effects of bevacizumab, including hypertension, arterial/venous thrombosis, and proteinuria, were systematically evaluated.

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki and received approval from the Sağlık Bilimleri University Prof. Dr. Cemil Taşcıoğlu City Hospital Ethics Committee (Approval date and number: January 12, 2021, 477). Informed consent was obtained from all patients.

Statistical Analysis

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics are presented as frequencies and percentages (n, %) for categorical variables, and as Mean ± Standard Deviation (SD) or Median (min-max) for continuous variables. The Kaplan-Meier method was utilized to compare survival and progression-free survival (PFS) times across clinical groups. Additionally, multivariate Cox

regression analysis was performed to evaluate the mortality risk associated with various clinical variables. A p-value of <0.05 was considered statistically significant.

Results

The median age of the patients was 58 years, with a median follow-up period of 32 months. Among the cohort, 73 patients received neoadjuvant and adjuvant chemotherapy, 43 underwent primary surgery followed by adjuvant chemotherapy, and 14 were not eligible for surgery. Table 1 summarizes the sociodemographic and clinical characteristics of the patients.

The overall median overall survival (OS) was 33.0 months (95% CI: 29.5–36.4), with a 2-year OS rate of 73.1% and a 5-year OS rate of 20.8%. Inoperable patients had a median OS of 23.0 months (95% CI: 19.3–26.7), which was

Table 1 Sociodemographic and Clinical Characteristics Data (n=130)

Variables	N	%
Age		
Mean±SD	58.17±9.46	
Median (min-max)	58.0 (34–75)	
≤65	98	75.4
>65	32	24.6
Histology		
Serous adenocarcinoma	104	80
Endometrioid adenocarcinoma	10	7.7
Clear cell adenocarcinoma	6	4.6
Mucinous adenocarcinoma	10	7.7
Tumor location		
Ovary	111	85.3
Fallopian tube	7	5.5
Primary peritoneum	6	4.6
Ovary + Fallopian tube	6	4.6
Stage at diagnosis		
3a	16	12.3
3b	17	13.1
3c	55	42.3
4a	13	10.0
4b	29	22.3
Ascite		
No	68	52.3
Yes	62	47.7
Initial surgical status		
Surgery + adjuvant chemotherapy	43	33.1
Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy	73	56.2
In-operable patients	14	10.8
>1 cm. residual disease		
No	88	76.5
Yes	27	23.5

(*Continued*)

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Table 1 (Continued).

Variables	N	%
First-line chemotherapy regimen in after recurrence/progression and in metastatic disease		
Carboplatin + gemcitabine + bevacizumab	54	36.2
Carboplatin + paclitaxel + bevacizumab	56	36.9
Carboplatin + liposomal doxorubicin + bevacizumab	10	7.7
Cyclophosphamide + bevacizumab	10	7.7
How many cycles of neoadjuvant therapy		
3	48	66.7
4	24	33.3
Mortality		
Lives	42	32.3
Exitus	88	67.7
PFS in the first line after recurrence/progression and in the metastatic first line (months)		
Median (min-max)	10.0 (3.0–24.0)	
Follow-up period (months)		
Median (min-max)	32.0 (9.0–141.0)	

Abbreviation: PFS, Progression-free survival.

significantly worse (p = 0.036). Similarly, patients with residual disease >1 cm following initial surgery had a median OS of 26.0 months (95% CI: 23.9–28.0), also significantly worse (p = 0.002).

All patients received chemotherapy combined with bevacizumab in metastatic first-line treatment and as the first-line treatment after recurrence or progression after adjuvant therapy. Post-progression, patients were divided into two groups based on whether bevacizumab was continued. More than half of the patients who continued treatment with bevacizumab and chemotherapy achieved a 5-year OS, which was statistically superior (p < 0.001). OS comparisons are detailed in Table 2.

During the first-line treatment after recurrence or progression, 23 patients (17.6%) achieved a complete response (CR), 53 (40.7%) achieved a partial response (PR), 30 (23.0%) showed stable disease (SD), and 24 (18.4%) had

Table 2 OS Comparisons of Patients

OS (Months)	2 Years %	5 Years %	Median (%95 CI)	p
General	73.1	20.8	33.00 (29.57–36.42)	
Age				
≤65	73.5	20.5	34.00 (30.52–37.47)	0.674
>65	71.9	24.7	30.00 (25.19–34.80)	
Stage at diagnosis				
3a	75.0	31.2	45.00 (22.00–67.99)	**0.011**
3b	70.5	23.5	35.00 (29.57–40.42)	
3c	69.0	19.9	34.00 (27.81–40.18)	
4a	61.3	20.0	33.00 (30.18–35.81)	
4b	48.2	–	22.00 (19.35–24.64)	
Ascite				
No	76.5	20.0	34.00 (28.32–39.67)	0.392
Yes	69.4	24.3	32.00 (27.57–36.42)	

(*Continued*)

Table 2 (Continued).

OS (Months)	2 Years %	5 Years %	Median (%95 CI)	p
Initial surgical status				
Surgery + adjuvant chemotherapy	76.7	20.3	35.00 (30.60–39.39)	**0.036**
Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy	76.7	23.9	35.00 (30.76–39.24)	
In-operable patients	42.9	-	23.00 (19.33–26.66)	
>1 cm residual disease				
No	81.8	27.6	41.00 (32.09–49.90)	**0.002**
Yes	63.0	10.6	26.00 (23.97–28.02)	
How many cycles of neoadjuvant therapy				
3	87.5	34.8	36.00 (32.30–39.69)	0.510
4	58.3	29.6	31.00 (8.54–53.45)	
Was bevacizumab continued in treatment after progression?				
No	61.5	3.2	28.00 (25.09–30.91)	**<0.001**
Yes	100.0	52.5	- (-)	

Notes: Kaplan-Meier curve was performed, and the Log rank test was applied; p<0.05 was considered statistically significant. Statistically significant results are written in bold.
Abbreviation: OS, Overall survival.

progressive disease (PD). The median progression-free survival (PFS) for this line was 10.0 months. Four patients died due to disease progression during this treatment line.

When comparing PFS between patients who did and did not receive bevacizumab in the second line following recurrence/progression, those treated with bevacizumab demonstrated a median PFS of 12.0 months (95% CI: 10.5–13.4), which was significantly better ($p < 0.001$). PFS comparisons in the second line after recurrence/progression and in the metastatic second line of treatment are shown in Table 3. In this line, 37 patients continued bevacizumab treatment after progression. Among these, the best treatment responses were categorized as CR in 5 patients (13.5%), PR in 11 (29.7%), SD in 18 (48.6%), and PD in 3 (8.1%). For patients who discontinued bevacizumab, responses included PR in 16 patients (18%), SD in 33 (37%), and PD in 40 (45%). Kaplan-Meier analysis results, illustrating OS and PFS

Table 3 PFS Comparisons Across Patients

PFS (Months)	6 Months %	1 Year %	Median (%95 CI)	p
General	38.5	11.5	6.00 (5.54–6.45)	
Age				
≤65	40.9	9.7	6.00 (5.48–6.51)	0.809
>65	31.0	3.4	5.00 (3.68–6.31)	
Stage at diagnosis				
3a	62.5	12.5	7.00 (5.08–8.92)	0.156
3b	52.9	11.7	6.00 (4.70–7.29)	
3c	38.1	10.9	6.00 (5.50–6.49)	
4a	30.7	7.6	4.00 (1.65–6.34)	
4b	13.7	–	3.00 (2.57–3.42)	
Ascite				
No	37.9	12.1	6.00 (5.35–6.64)	0.967
Yes	39.3	10.7	6.00 (5.34–6.65)	

(*Continued*)

Table 3 (Continued).

PFS (Months)	6 Months %	1 Year %	Median (%95 CI)	p
Initial surgical status				
Surgery + adjuvant chemotherapy	34.9	14.0	6.00 (5.38–6.61)	0.605
Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy	44.1	8.8	6.00 (5.33–6.66)	
In-operable patients	18.2	18.2	4.00 (-)	
How many cycles of neoadjuvant therapy				
3	41.3	6.5	6.00 (5.45–6.54)	0.846
4	52.4	14.3	7.00 (2.55–11.44)	
Was bevacizumab continued in treatment after progression?				
No	14.1	0.0	4.00 (3.00–5.00)	**<0.001**
Yes	94.6	37.8	12.00 (10.55–13.44)	

Notes: Kaplan-Meier curve was performed, and the Log rank test was applied; p<0.05 was considered statistically significant. Statistically significant results are written in bold.
Abbreviation: PFS, Progression-free survival.

curves for patients receiving and not receiving bevacizumab in the second line after recurrence/progression and in the metastatic second line, are presented in Figures 1 and 2, respectively.

Multivariate Cox regression analysis identified several factors significantly associated with increased mortality risk, including advanced stage, inoperability, residual disease >1 cm, and discontinuing bevacizumab beyond progression. The

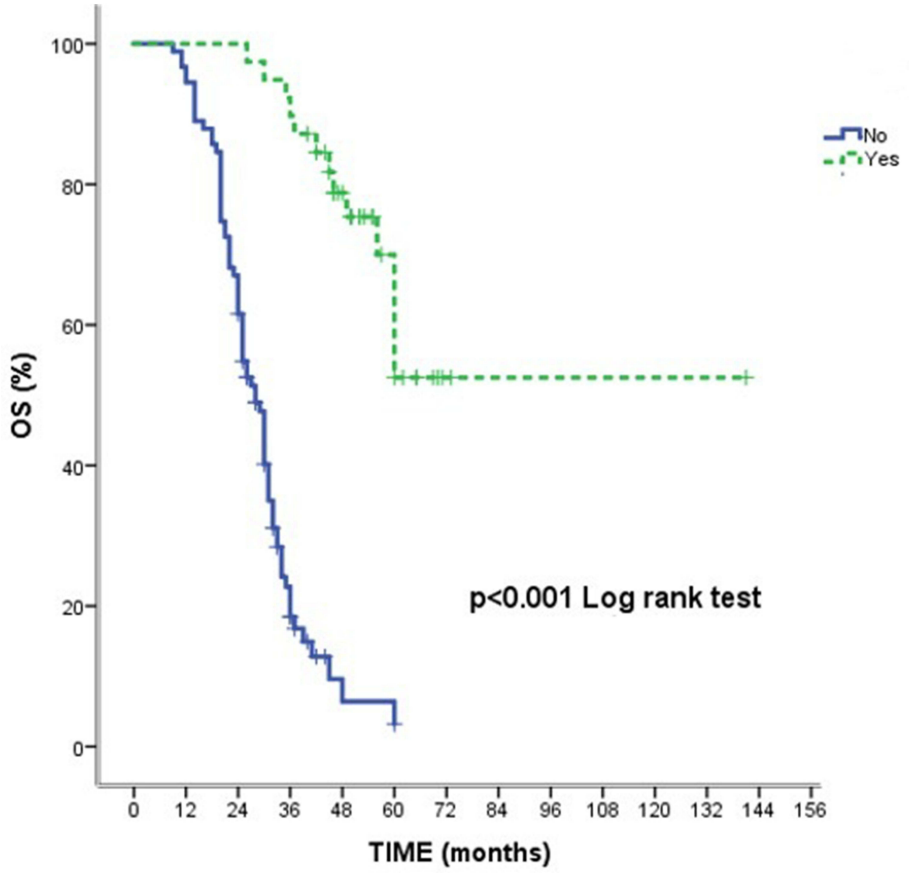

Figure 1 OS curve for patients receiving and not receiving bevacizumab in the second line after recurrence/progression and in the metastatic second line.

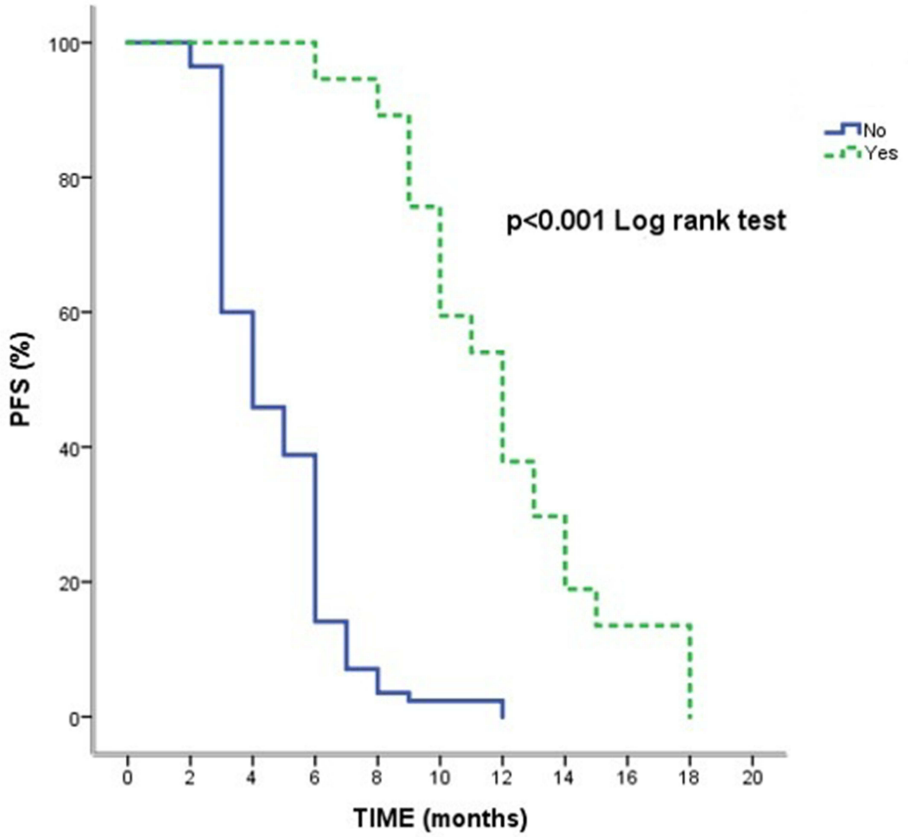

Figure 2 PFS curve for patients receiving and not receiving bevacizumab in the second line after recurrence/progression and in the metastatic second line.

hazard ratio for mortality in patients continuing bevacizumab treatment beyond progression was 0.11 (95% CI: 0.05–0.22) ($p < 0.001$). The detailed results of the multivariate Cox regression analysis are provided in Table 4.

Adverse events associated with bevacizumab treatment were also assessed. Proteinuria was observed in 7 patients, hypertension in 7, venous thromboembolism in 6, arterial thrombosis in 2, and ileus in 2. Among the cases of proteinuria, 4 were classified as grade 1 and 3 as grade 2. No significant differences in OS or PFS were observed between patients with or without these adverse events.

Table 4 Multivariate Cox Regression Results of Various Clinical Variables on Mortality Risk

OS (Months)	HR (%95 CI)	p
Stage at diagnosis		0.088
3a	Ref	
3b	1.05 (29.57–40.42)	0.891
3c	1.13 (30.18–35.81)	0.758
4a	1.61 (22.13–27.86)	0.556
4b	2.29 (19.35–24.64)	**0.043**
Initial surgical status		
Surgery + adjuvant chemotherapy	1.00 (0.76–1.24)	0.726
Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy	Ref	
In-operable patients	1.04 (0.63–1.74)	0.854

(*Continued*)

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Table 4 (Continued).

OS (Months)	HR (%95 CI)	p
>1 cm. residual disease		
No	Ref	
Yes	2.19 (1.24–3.86)	**0.006**
Was bevacizumab continued in treatment after progression?		
No	Ref	
Yes	0.11 (0.05–0.22)	**<0.001**

Notes: p<0.05 was considered statistically significant. Statistically significant results are written in bold.
Abbreviation: OS, Overall survival.

Discussion

Epithelial ovarian cancer is a major cause of mortality and morbidity for patients, which has prompted clinicians to seek alternative treatment options to platinum-based chemotherapy, a longstanding cornerstone in therapy. Angiogenesis plays a crucial role in tumor growth, invasion, and metastasis. Inhibition of angiogenesis through VEGF blockade has been explored as a treatment strategy for various cancers. Bevacizumab is a recombinant humanized monoclonal immunoglobulin G1 (IgG1) antibody that selectively binds to all isoforms of VEGF with high affinity. Apart from ovarian cancer, its effectiveness has also been proven in other malignancies. It is widely used in the treatment of metastatic colorectal cancer, non-squamous non-small cell lung cancer, central nervous system tumors, metastatic renal cell carcinoma, and recurrent or metastatic cervical cancer.

Numerous clinical trials have investigated the efficacy of bevacizumab and its survival benefits when added to chemotherapy in epithelial ovarian cancer. Some studies have demonstrated an improvement in OS. In a study in which 674 patients were randomly assigned to chemotherapy and chemotherapy+bevacizumab arms, the median OS was 42.2 months vs 37.3 months, which was at the limit of statistical significance.[6] A study in platinum-resistant patients also showed that the addition of bevacizumab to chemotherapy contributed to PFS.[7] In another study with a large number of patients and a long follow-up period, the addition of bevacizumab to chemotherapy did not show a survival benefit.[8]

The final OS analysis of the Phase 3 OCEANS study and the phase 3 ICON7 study showed that bevacizumab added to chemotherapy did not significantly contribute to OS.[9,10] Another large study with 927 patients found no statistically significant difference in OS and PFS between patients evaluated in 2 groups: those receiving 15 months and 30 months of bevacizumab treatment.[11]

In contrast, the literature offers limited studies addressing the survival benefits of continuing bevacizumab beyond disease progression. Recurrence and progression are common in advanced-stage ovarian cancer. To date, no globally accepted study has established the use of bevacizumab beyond progression as a routine practice or guideline-altering strategy. The potential benefit of continuing bevacizumab in patients with platinum-sensitive ovarian cancer was first investigated in the Japanese Gynecologic Oncology Group study (JGOG3023).[12] The studies we mentioned above are generally Phase 2 and phase 3 studies, and there is only 1 study in the literature that provides real-life data and is designed similarly to our study. This study demonstrated that continuing bevacizumab beyond progression resulted in prolonged survival.[13]

In another phase 3 study similar to our study, the PFS of patients who received standard chemotherapy and those who received bevacizumab+chemotherapy after progression was compared, and a statistically significant longer PFS was found in the bevacizumab group (hazard ratio: 0.51, 95% CI: 0.41-0.65; log-rank $p < 0.0001$). In this study, the median PFS of the bevacizumab group was almost the same as the median PFS of the same patient group in our study (11.8 months and 12.0 months, respectively).[14]

The limitations of our study are the relatively limited number of patients, the retrospective study, and its single-center nature. A larger patient cohort and multi-center study would have yielded more meaningful results. Furthermore, the quality of this paper could have been improved by investigating the basis for bevacizumab's efficacy, for example, by identifying angiogenic factors in pathological samples. Although there may be a suspicion of a possible selection bias in

patients continuing bevacizumab treatment, the patient files included in our study were completely randomly determined. Since there is currently no clear recommendation in the guidelines for the continuation of bevacizumab treatment beyond progression, we cannot say that there is bias in the patients who continued treatment in our study.

As a result, while some studies have shown survival benefits from adding bevacizumab to chemotherapy in epithelial ovarian cancer, doubts remain about the continuation of bevacizumab beyond progression. Current evidence does not yet provide a definitive conclusion. However, our study indicates that continuing bevacizumab beyond progression significantly contributes to both OS ($p < 0.001$) and PFS ($p < 0.001$). In addition, the entire cohort in our study was platinum-sensitive, and similar analyses should be performed on platinum-resistant patients to expand the literature. As additional large-scale studies are conducted in the future, current guidelines may evolve, and deciding to continue bevacizumab treatment after progression is more accessible and evidence-based.

Data Sharing Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

Statement of Ethics

The study was conducted according to the principles outlined in the Declaration of Helsinki and approved by the local Ethics Committee (Approval date and number: January 12, 2021, 477).

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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The authors declare no potential conflicts of interest.

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