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Original Article

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Risk-based Evaluation of Adjuvant Chemotherapy in Stage I Epithelial Ovarian Cancer: A Retrospective Cohort Study

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ABSTRACT

Aim: This study aims to assess the clinical utility of adjuvant chemotherapy in patients diagnosed with International Federation of Gynecology and Obstetrics (FIGO) stage I epithelial ovarian cancer (EOC), focusing on its impact on recurrence, disease-free survival (DFS), and overall survival (OS) based on patient risk stratification.

Methods: A retrospective cohort of 67 patients with FIGO stage I EOC treated at a single tertiary center between January 2006 and February 2024 was analyzed. Demographic, clinical, and pathological characteristics were reviewed. DFS and OS were evaluated using Kaplan-Meier analysis, log-rank tests, and Cox proportional hazards modeling.

Results: Among patients with low-risk stage I disease, the 10-year DFS and OS were both 100%. High-risk patients exhibited lower survival outcomes with DFS at 78% and OS at 92%. Interestingly, 10-year survival was marginally reduced among individuals who underwent adjuvant chemotherapy compared to those who were only observed. Variation in the number of administered chemotherapy cycles showed no statistically significant impact on survival rates.

Conclusion: These findings underscore the importance of risk-based therapeutic decision-making in stage I EOC. While low-risk patients may not benefit from adjuvant chemotherapy, high-risk individuals may still require tailored interventions.

Keywords: Adjuvant therapy, stage 1 epithelial ovarian cancer, chemotherapy, survival, recurrence

Introduction

Epithelial ovarian cancer (EOC) stands out as the deadliest form of gynecological malignancy. Even with the development of targeted treatments like poly (adenosine diphosphate-ribose) polymerase inhibitors, the majority of EOC is still identified at advanced stages [International Federation of Gynecology and Obstetrics (FIGO) III/IV], which adversely affects survival rates over time [1]. Earlier diagnosis has led to more cases being found at FIGO stages I-II, where five-year survival typically surpasses 70%. Still, recurrence rates within these early stages remain variable, ranging from 10% to 50% [2,3].

Management of FIGO stage I EOC typically involves total abdominal hysterectomy with bilateral salpingo-oophorectomy (TAH-BSO), lymph node dissection, omentectomy, and sampling of peritoneal fluid and tissues [4]. Precise surgical staging plays a crucial role both in diagnosis and in guiding decisions regarding additional systemic treatment [5]. Clinical studies including International Collaborative Ovarian Neoplasm trial (ICON1) and Adjuvant Chemotherapy in Ovarian Neoplasm trial (ACTION) have shown that platinum-based adjuvant chemotherapy may enhance survival, particularly for high-risk subgroups [6-8]. The necessity of such therapy in low-risk, comprehensively staged individuals remains a subject of debate.

This study investigates whether adjuvant chemotherapy provides a survival advantage in stage I EOC patients, particularly focusing on its relevance in low-risk cases.

Methods

A total of 67 FIGO stage I EOC cases treated between January 2006 and February 2023 at a single tertiary center were retrospectively reviewed. The study received ethical approval

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from the Ethics Committee of Ankara Bilkent City Hospital (decision no: TABED 1-25-1055, date: 26.02.2025). Due to its retrospective nature, informed consent was not required.

Eligible participants were women aged 18 years or older with histologically confirmed stage IA, IB, or IC EOC, or including subtypes IC1, IC2, and IC3. A minimum clinical follow-up of 12 months was required for inclusion to ensure reliable outcome evaluation [9]. Patients were excluded if they had FIGO stage II or higher disease, non-epithelial tumors, borderline histologies, or insufficient follow-up documentation.

Data extracted from medical records included patient demographics, tumor characteristics (e.g., grade, histology), menopausal status, treatment modalities, surgical procedures, recurrence, and survival outcomes. Every patient received comprehensive staging surgery, encompassing TAH-BSO, lymph node excision, omentectomy, and sampling of the peritoneum [10]. Surgical re-staging was performed in cases of incidental diagnosis.

In our cohort, all patients underwent TAH+BSO, which aligns with our institution's standard practice for earlystage EOC. This surgical strategy was selected to minimize the presence of microscopic residual disease and to avert understaging-an issue reported in up to one-third of cases when less comprehensive procedures are performed [9,11]. Fertility-sparing surgery may be considered for young, well-selected patients; however, none of the individuals in our series met the established criteria: specifically, high-risk features such as grade 3 histology or unfavorable histologic subtypes were exclusionary. Consequently, we adopted a uniform standard radical surgical approach to ensure accurate staging and oncologic safety.

For the purposes of this study, risk classification was performed using established pathological and clinical parameters. Patients were considered to have low-risk disease if they were diagnosed with FIGO stage IA or IB tumors of grade 1-2 histology without the presence of clear cell subtype. High-risk disease was defined as FIGO stage IC (IC1-IC3), grade 3 tumors, or any case of clear cell carcinoma, irrespective of tumor grade [6,9,12,13]. Therapeutic decisions were tailored according to this categorization. Women in the low-risk group were usually managed with surveillance following complete surgical staging, whereas those in the high-risk category were more frequently offered adjuvant chemotherapy. This risk-based allocation of therapy reflects evidence from large randomized clinical trials, including ICON1 and ACTION [6], subsequent analyses by the Gynecologic Oncology Group [12,13], and the recommendations of the European Society for Medical Oncology – European Society of Gynaecological Oncology consensus panel [9].

Chemotherapy regimens administered in the adjuvant setting were selected in accordance with internationally accepted oncologic protocols and tailored to individual clinical circumstances. Typically, paclitaxel (175 mg/m²) was delivered via a 3-hour intravenous (IV) infusion, followed by a 1-hour carboplatin infusion at an area under the curve of 5-6. This combination was delivered on day one of a 21-day cycle [14].

In specific clinical contexts, alternative chemotherapy schedules were employed. The FOLinic acid (leucovorin) + Fluorouracil (5-FU) + OXaliplatin (FOLFOX) regimen included oxaliplatin (85 mg/m² IV) and leucovorin (400 mg/m² IV), accompanied by 5-FU delivered initially as a 400 mg/m² bolus, followed by a continuous infusion of 2400 mg/m² over 46 hours. This protocol was implemented on days 1 and 14 of a 28-day cycle [15]. Additionally, the XELoda (capecitabine) + OXaliplatin (XELOX) regimen, consisting of IV oxaliplatin (130 mg/m² on day 1) and oral capecitabine (2000 mg/m²/day in two divided doses for 14 days), was administered every 21 days as another treatment alternativean alternative treatment [16].

The primary endpoints of this study were disease-free survival (DFS) and overall survival (OS). DFS was defined as the time interval from the initial diagnosis of FIGO stage I EOC until either the first documented recurrence or the last date the patient was known to be alive. OS was calculated from the date of diagnosis to either the date of death or the most recent follow-up.

Statistical Analysis

All statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics version 25.0. The Kolmogorov-Smirnov test was applied to assess the distribution characteristics of continuous variables. Descriptive statistics, including median, minimum, and maximum values, were used to summarize patient demographics and clinical data.

Kaplan-Meier analysis was used to determine survival, while intergroup comparisons were conducted using the Log-Rank test. To identify independent prognostic factors, variables showing significance in univariate analysis were subsequently included in a multivariate Cox proportional hazards model. Additionally, receiver operating characteristic curve analysis was performed to determine optimal cut-off values for selected parameters. A two-sided p value less than 0.05 was considered statistically significant in all analyses.

Results

A total of 67 patients diagnosed with FIGO stage I EOC were included in this study. The median age at diagnosis was 53 years. Preoperative and postoperative serum cancer antigen-125 levels had median values of 74 and 8, respectively. Most participants had an ECOG performance status of 0 or 1, reflecting favorable baseline health. While 15 patients were premenopausal, 52 were postmenopausal at diagnosis. Abdominal pain was the predominant initial symptom, followed by abdominal distension.

Histopathological subtypes included high-grade serous carcinoma (n=24), mucinous carcinoma (n=14), endometrioid carcinoma (n=13), clear cell carcinoma (n=8), and low-grade serous carcinoma (n=8). FIGO sub-staging revealed that 36 patients were classified as stage IA, 5 as stage IB, 9 as stage IC1, and 17 as stage IC2. Based on predefined clinicopathological criteria, 48 patients were categorized as high-risk and 19 as

low-risk. Tumor grading was available in 52 cases: 16 patients had grade 1 tumors, 7 had grade 2 tumors, and 29 had grade 3 tumors. In all patients, complete tumor resection was achieved with no residual macroscopic disease (Table 1).

Among all participants, 50 patients (74.6%) received adjuvant chemotherapy, while 17 (25.4%) did not undergo additional systemic treatment. The most frequently used chemotherapy regimen was carboplatin-paclitaxel, administered in 48 patients (71.6%). FOLFOX and XELOX regimens were each administered to one patient. Regarding treatment duration, 28 patients (56.0%) received six cycles of chemotherapy, 18 patients (36.0%) received four cycles, and four patients (8.0%) completed three cycles.

Adverse events associated with chemotherapy were routinely monitored during treatment and follow-up. Although mild to moderate side effects such as nausea, vomiting, and neutropenia were observed in several cases, no patients experienced grade 3 or 4 toxicities. Peripheral neuropathy, primarily related to paclitaxel use, was the most commonly reported persistent adverse effect, affecting 13 patients (26.0%).

Disease recurrence occurred in four patients (6.0%). In the relapse setting, three patients received a rechallenge with carboplatin-paclitaxel, and one patient was treated with liposomal doxorubicin (Table 2).

Table 1. Baseline demographic and clinicopathological characteristics of the study population

		Mean (±SD)	Median (min.-max.)	n (%)
Age at diagnosis		53 (10)		
preopCA125			74 (11-3396)	
postopCA125			8 (1-107)	
ECOG PS	0			31 (46.3)
	1			32 (47.8)
	2			4 (6)
Menopausal	Premenopausal			15 (22.4)
	Postmenopausal			52 (77.6)
Symptom at admission	Painless hematuria			4 (6)
	Abdominal pain			43 (64.2)
	Urination symptoms (dysuria, nocturia...)			2 (3)
	Flank pain			2 (3)
	Incidental			4 (6)
	Vaginal bleeding			3 (4.5)
	Abdominal swelling			9 (13.4)
Pathological subtype	High grade serous carcinoma			24 (35.8)
	Endometriod carcinoma			13 (19.4)
	Clear cell carcinoma			8 (11.9)
	Mucinous carcinoma			14 (20.9)
	Low grade serous carcinoma			8 (11.9)
FIGO stage	1A			36 (53.7)
	1B			5 (7.5)
	IC1			9 (13.4)
	IC2			17 (25.4)
Risk	High risk early stage			48 (71.6)
	Low risk early stage			19 (28.4)
Grade	Unknown			15 (22.4)
	1			16 (23.9)
	2			7 (10.4)
	3			29 (43.3)
Residue	No			67 (100)

preopCA125: Preoperative cancer antigen 125, postop CA125: Postoperative cancer antigen 125, ECOG PS: Eastern Cooperative Oncology Group Performance Status, SD: Standard deviation, min.-max.: Minimum-maximum, FIGO: Federation of Gynecology and Obstetrics

The 10-year median DFS (mDFS) and median OS (mOS) for the entire cohort were 84% and 94%, respectively (Figures 1A, 1B). When stratified by risk status, the 10-year mDFS was 78% for high-risk patients and 100% for low-risk patients (p=0.140, Figure 2A), while the corresponding mOS rates were 92% and 100% (p=0.366, Figure 2B).

In patients who received adjuvant chemotherapy, the 10-year mDFS and mOS were 81% and 93%, respectively. Among those who did not receive adjuvant chemotherapy, both mDFS and mOS were 100% (p=0.253, p=0.452, respectively; Figures 3A, 3B).

When comparing chemotherapy cycles, patients who received six cycles had a 10-year mDFS and mOS of 73% and 92%, respectively. These outcomes were slightly lower than those observed in patients who received three to four cycles (mDFS 95%, mOS 95%), though the differences were not statistically significant (p=0.391, p=0.776; Figures 4A, 4B).

Discussion

EOC remains one of the most frequently encountered gynecologic malignancies. Although only approximately 20% of patients present with early-stage disease, outcomes in these cases are generally favorable, with reported 5-year survival rates ranging from 80% to 93% [17]. Nonetheless, the presence of high-risk features is associated with a significantly increased likelihood of recurrence high-risk factors in early-stage EOC are commonly defined as grade 3 histology, clear cell carcinoma of any grade, and FIGO stage IC or II disease [13]. These clinical variables have been adopted as inclusion criteria in randomized trials evaluating adjuvant chemotherapy and are often used to guide clinical decision-making outside of trial settings, particularly in patients whose 5-year DFS falls between 40% and 80% depending on their risk profile [12,18,19].

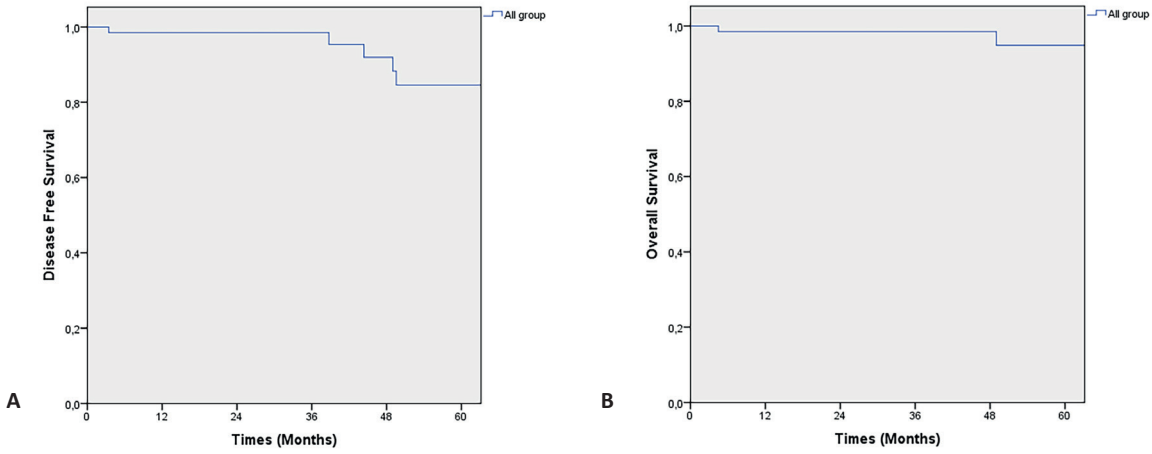

Figure 1. The 10-year median disease-free survival rate is 84% (A), and the 10-year median overall survival rate is 94% (B) for all patients

Table 2. Details of adjuvant chemotherapy, treatment-related toxicities, and relapse patterns in the study cohort

		n (%)	Column
Adjuvant therapy	Yes	50 (74.6)	74.6%
	No	17 (25.4)	25.4%
Adjuvant chemotherapy regimen	No	17 (25.4)	25.4%
	Carboplatin and paclitaxel	48 (71.6)	71.6%
	FOLFOX	1 (1.5)	1.5%
	XELOX	1 (1.5)	1.5%
Number of chemotherapy cycles	3	4 (8)	8.0%
	4	18 (36)	36.0%
	6	28 (56)	56.0%
Chemotherapy adverse effects	No	37 (74)	74.0%
	Neuropathy	13 (26)	26.0%
Relapse	Yes	4 (6)	6.0%
	No	63 (94)	94.0%
The regimen for relapses	No	63 (94)	94.0%
	Carboplatin and paclitaxel	3 (4.5)	3.0%
	Liposomal doxorubicin	1 (1.5)	1.5%

FOLFOX: FOLinic acid (leucovorin) + Fluorouracil (5-FU) + Oxaliplatin, XELOX: XELoda (capecitabine) + OXaliplatin

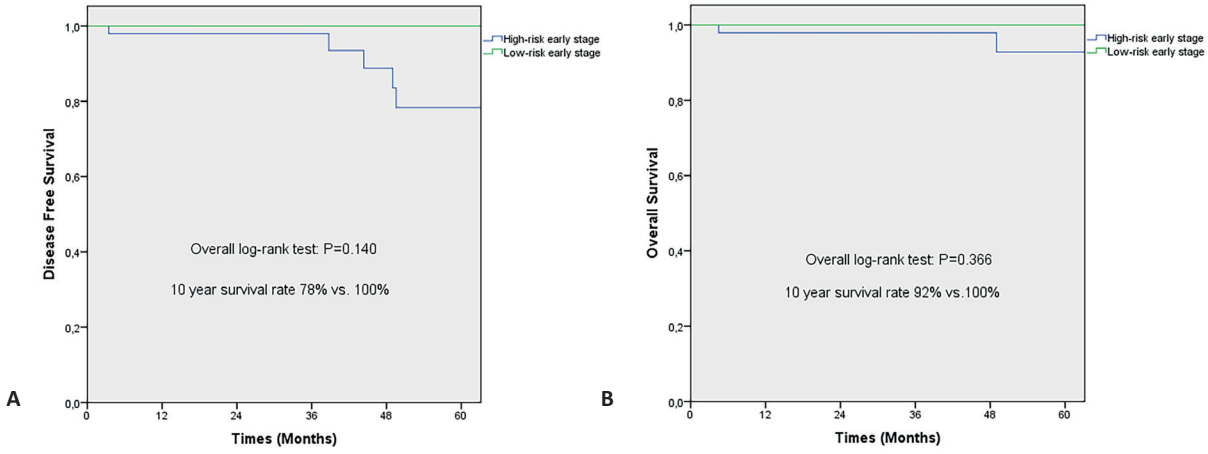

Figure 2. The 10-year median disease-free survival rate is 78% for high-risk and 100% for low-risk early-stage cases (p=0.140) (A), and the 10-year median overall survival rate is 92% and 100%, respectively, for high-risk and low-risk groups (p=0.366) (B)

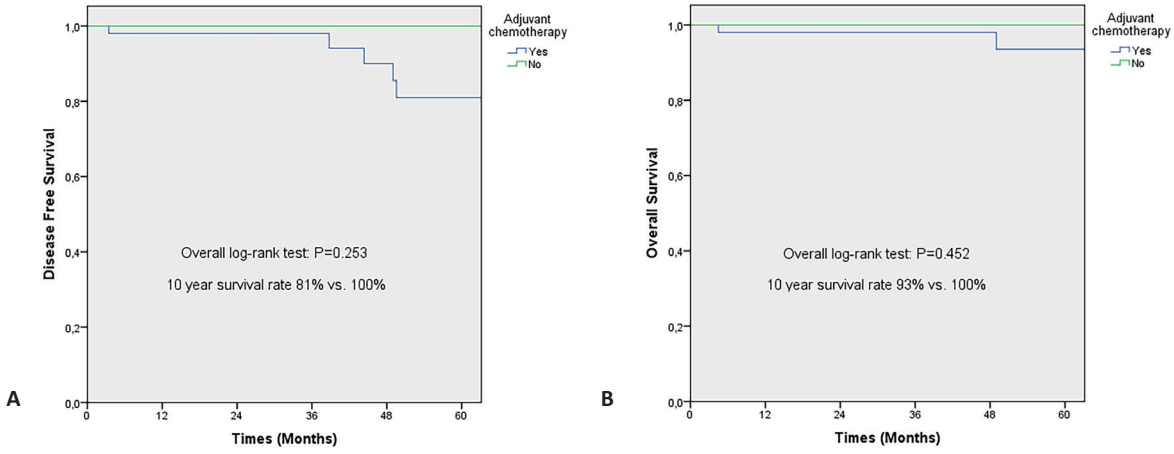

Figure 3. The 10-year median disease-free survival rates for patients with and without adjuvant chemotherapy were 81% and 100%, respectively (p=0.253) (A), while the 10-year median overall survival rates were 93% and 100%, respectively (p=0.452) (B)

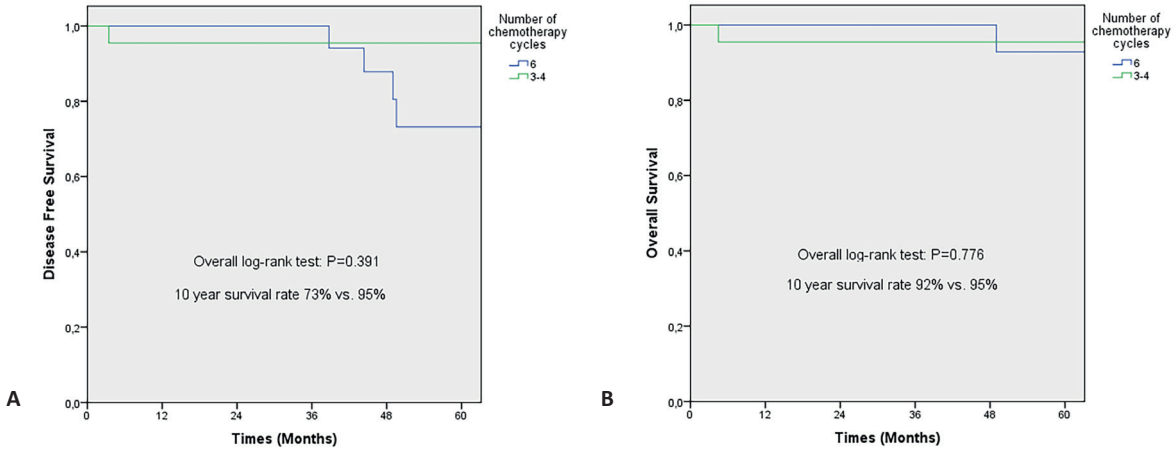

Figure 4. The 10-year median disease-free survival rates were 73% for patients who received six cycles of chemotherapy and 95% for those who received three or four cycles (p=0.391) (A). The corresponding 10-year median overall survival rates were 92% and 95%, respectively (p=0.776) (B)

In contrast, patients with low-grade tumors confined to one or both ovaries (FIGO stage IA or IB) typically demonstrate excellent long-term outcomes, with 5-year survival rates exceeding 90% [19,20]. In our cohort, low-risk patients demonstrated excellent long-term outcomes, achieving 100% 10-year DFS and OS DFS and OS, whereas high-risk patients had lower survival rates of 78% and 92%, respectively. Although this trend suggests a prognostic impact of risk stratification, the differences did not reach statistical significance, which may be attributed to the limited sample size and low recurrence rates.

The potential benefit of adjuvant chemotherapy in early-stage EOC has been explored in two meta-analyses. The first meta-analysis included 13 randomized phase III trials conducted between 1965 and 2004 of which only 8 exclusively enrolled patients with stage I disease [21]. The combined data demonstrated that patients who received adjuvant chemotherapy had significantly improved DFS and OS, particularly with platinum-based regimens. The second meta-analysis, which pooled data from five randomized trials involving 1277 patients published between 1990 and 2003, further supported the survival benefit of adjuvant chemotherapy in high-risk patients [22]. However, among those who had undergone complete surgical resection, the survival advantage of chemotherapy was less apparent. The benefit was largely restricted to patients with residual disease postoperatively, while patients with low-risk features derived minimal, if any, survival gain from systemic therapy [22]. Interestingly, patients who received adjuvant chemotherapy—most of whom were categorized as high-risk—demonstrated slightly worse survival outcomes compared to those who did not receive systemic treatment. Specifically, 10-year mDFS and mOS were 81% and 93%, respectively, among chemotherapy recipients, whereas both metrics were 100% in the observation group. This seemingly paradoxical finding likely reflects the higher baseline risk in the chemotherapy cohort rather than an adverse effect of the treatment itself.

Our analysis revealed no significant survival advantage associated with the number of chemotherapy cycles administered; patients who received six cycles had lower 10-year mDFS and mOS rates (73% and 92%, respectively) compared to those who received three or four cycles (95% for both). This observation aligns with the findings of the Gynecologic Oncology Group 157 study, which demonstrated that extending adjuvant chemotherapy from three to six cycles in high-risk early-stage EOC patients did not improve OS and instead led to increased toxicity without significantly reducing recurrence rates [23]. Paclitaxel plus carboplatin, a platinum-based duo, is recommended based on indirect evidence of significant benefit when utilized as adjuvant treatment for more progressed stages of the disease [24].

This study has several noteworthy strengths. Firstly, it presents a long-term follow-up of up to 10 years, which allows for robust evaluation of DFS and OS in a real-world cohort of patients with stage I EOC. The inclusion of both low- and high-risk patient subgroups provides valuable insight into risk-stratified treatment outcomes. Moreover, the study applied comprehensive surgical staging and utilized standardized chemotherapy regimens in accordance with international guidelines, ensuring consistency in therapeutic exposure.

In our cohort, the concept of complete resection referred to the surgical removal of all gross disease with pathologically negative margins. Even in patients with early-stage presentation, this principle was followed to minimize the risk of occult microscopic foci and to provide accurate staging information. Therefore, TAH+BSO was consistently performed, aiming to achieve both oncological safety and a uniform treatment approach. Contemporary evidence confirms that maximal cytoreduction, when no macroscopic disease is left behind, translates into improved survival outcomes and remains a fundamental goal in EOC surgery [25,26].

Study Limitations

A few limitations need to be acknowledged. The retrospective, single-center nature of the study introduces potential biases, particularly in treatment selection and risk categorization. The relatively small sample size, especially in the low-risk subgroup, may limit the statistical power to detect significant differences between treatment groups. Additionally, the absence of molecular or genomic profiling restricts the ability to correlate outcomes with underlying tumor biology. Despite these constraints, the study contributes meaningful data on the nuanced decision-making process surrounding adjuvant chemotherapy in stage I EOC and underscores the importance of individualized therapeutic strategies. Future studies should confirm current findings through larger, prospective trials. Integrating genomic profiling and patient-reported outcomes could enhance understanding of recurrence risks and guide more personalized, tolerable treatment strategies in stage I EOC.

Conclusion

This study reinforces the critical role of risk stratification in guiding adjuvant treatment decisions for patients with stage I EOC. Our findings suggest that patients classified as low-risk achieve excellent long-term survival outcomes without the need for additional systemic therapy. Conversely, individuals with high-risk features exhibit less favorable survival, underscoring the potential need for more intensive or personalized interventions. Notably, the number of adjuvant chemotherapy cycles did not significantly impact survival outcomes, indicating that extended treatment may not confer additional benefit in this setting. These insights advocate for a tailored approach to adjuvant therapy, balancing efficacy with potential toxicity. Future studies incorporating genomic and molecular profiling may further refine treatment strategies and support more individualized care.

Ethics

Ethics Committee Approval: The study received ethical approval from the Ethics Committee of Ankara Bilkent City Hospital (decision no: TABED 1-25-1055, date: 26.02.2025). **Informed Consent:** Due to its retrospective nature, informed consent was not required.

Footnotes

Authorship Contributions

Surgical and Medical Practices: D.U., Concept: İ.S., Design: S.Ö.Ç., Data Collection or Processing: S.A.E., Literature Search: İ.S., S.Ö.Ç., S.A.E., Writing: İ.S., E.A., Ö.B.

Conflict of Interest: No conflict of interest was declared by the authors.

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