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ORIGINAL RESEARCH

Clinical Outcomes of Avelumab Maintenance Following Full-Dose, Reduced-Dose Cisplatin, or Carboplatin-Based Chemotherapy in Advanced Urothelial Carcinoma

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Background: Avelumab maintenance therapy is a standard of care for patients with advanced urothelial carcinoma (UC) who achieve disease control following platinum-based chemotherapy. However, the influence of induction chemotherapy intensity on avelumab outcomes remains unclear.

Materials and Methods: This retrospective study included 26 patients with advanced UC who received avelumab maintenance after first-line platinum-based chemotherapy between March 2021 and June 2025. Patients were grouped by induction regimen: full-dose gemcitabine/cisplatin (GC), reduced-dose GC, or gemcitabine/carboplatin (GCarbo). Survival outcomes from the start of avelumab treatment and from chemotherapy initiation were analyzed using the Kaplan–Meier method and compared using the Log rank test.

Results: The median patient age was 72 years, with a significant difference among groups ($P < 0.01$). The objective response rates to induction chemotherapy were 60.0% (full-dose GC), 80.0% (reduced-dose GC), and 45.5% (GCarbo) (P=0.458), with respective disease control rates during avelumab maintenance of 50.0%, 100.0%, and 54.5% (P=0.188). The median progression-free survival (PFS) values from avelumab initiation were 4.0, 12.1, and 5.7 months, respectively (P=0.636). The median overall survival (OS) values from avelumab initiation were 21.7, 18.6, and 18.4 months (P=0.587), while those from chemotherapy initiation were 28.8, 28.7, and 29.0 months (P=0.496), in the respective groups. No significant differences in PFS or OS were observed among the three groups or between the GC-based and GCarbo regimens.

Conclusion: Avelumab maintenance showed comparable efficacy across the full-dose GC, reduced-dose GC, and GCarbo groups, highlighting the potential feasibility of personalized induction chemotherapy strategies. These findings may provide reassurance in clinical situations where full-dose cisplatin is not feasible due to patient frailty or renal dysfunction.

Keywords: avelumab maintenance, urothelial carcinoma, cisplatin eligibility, platinum-based chemotherapy

Introduction

The treatment landscape for advanced urothelial carcinoma (UC) has undergone significant evolution with the advent of immune checkpoint inhibitors and antibody-drug conjugates. Enfortumab vedotin (EV) in combination with pembrolizumab has recently been established in the EV-302 trial as the preferred first-line regimen, demonstrating superior survival outcomes compared with platinum-based chemotherapy.[1] Reflecting these findings, international clinical practice guidelines, such as those from the National Comprehensive Cancer Network and European Association of Urology, now recommend this combination as the preferred first-line therapy for eligible patients with advanced UC.[2,3]

Despite this paradigm shift, platinum-based chemotherapy, most commonly gemcitabine combined with either cisplatin (GC) or carboplatin (GCarbo), continues to be applied in certain real-world clinical settings, particularly where access to or

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Table 1 Baseline Patient Characteristics According to Induction Chemotherapy Regimen

Characteristics	Regimen				*p* value
	Total	Full-dose GC	Reduced-dose GC	GCarbo	
	n=26	n=10	n=5	n=11	
Age (years), median (IQR)	72 (65–77)	66 (62–70)	80 (76–81)	74 (70–79)	<0.010
Male sex, n (%)	17 (65.4)	8 (80.0)	2 (60.0)	7 (63.6)	0.318
ECOG PS score, n (%)					0.327
0	22 (84.6)	9 (90.0)	5 (100)	8 (72.7)	
≥1	4 (15.4)	1 (10.0)	-	3 (27.3)	
Primary tumor site, n (%)					0.763
Lower urinary tract	14 (53.8)	6 (60.0)	2 (40.0)	6 (54.5)	
Upper urinary tract	10 (38.5)	4 (40.0)	3 (60.0)	3 (27.3)	
Both	2 (7.7)	-	-	2 (18.2)	
Pure UC in histologic testing, n (%)	19 (73.1)	6 (60.0)	5 (100)	8 (72.7)	0.271
Visceral metastasis at start of first-line platinum-based chemotherapy, n (%)	14 (53.8)	4 (40.0)	2 (40.0)	8 (72.7)	0.268
Cycle number of first-line platinum-based chemotherapy					0.254
≤4	20 (76.9)	6 (60.0)	4 (80.0)	10 (90.9)	
≥5	6 (23.1)	4 (40.0)	1 (20.0)	1 (9.1)	

Abbreviations: IQR, interquartile range; ECOG PS, Eastern Cooperative Oncology Group Performance Status; UC, urothelial carcinoma; GC, gemcitabine and cisplatin; GCarbo, gemcitabine and carboplatin.

Table 2 Treatment Response to First-Line Platinum-Based Chemotherapy and Avelumab Maintenance Therapy in Advanced Urothelial Carcinoma Patients

	Regimen			p-value
	Full-dose GC n=10	Reduced-dose GC n=5	GCarbo n=11	
ORR to platinum-based chemotherapy, n (%)	6 (60.0)	4 (80.0)	5 (45.5)	0.458
DCR to avelumab maintenance therapy, n (%)	5 (50.0)	5 (100)	6 (54.5)	0.188

Abbreviations: ORR, objective response rate; DCR, disease control rate; GC, gemcitabine and cisplatin; GCarbo, gemcitabine and carboplatin.

eligibility for novel agents is limited. In such scenarios, avelumab maintenance therapy following disease control with platinum-based chemotherapy remains a key treatment strategy, as demonstrated by the JAVELIN Bladder 100 trial.[4]

In real-world clinical settings, the dose intensity and choice of platinum agent in chemotherapy are frequently modified according to patient-related factors, such as age, renal function, and performance status. As a result, dose-reduced cisplatin regimens or carboplatin-based alternatives are often employed.[5] While these variations are common, it remains unclear whether the efficacy of subsequent avelumab maintenance therapy is influenced by the type or intensity of the preceding chemotherapy regimen. Retrospective studies have suggested that differences in prior treatment intensity or sequence may affect the outcomes of subsequent therapies, including responses to immune checkpoint inhibitors and cytotoxic agents.[6] Notably, a multicenter study reported that patients with advanced UC who received reduced-dose cisplatin experienced lower response rates to subsequent pembrolizumab than those who were treated with carboplatin-based regimens, underscoring the potential impact of initial chemotherapy intensity on later-line immunotherapy outcomes.[7]

In this study, we aimed to evaluate the clinical outcomes of avelumab maintenance therapy in patients with advanced UC who received first-line treatment with full-dose GC, reduced-dose GC, or GCarbo. Clarifying this relationship between the intensity of first-line platinum-based chemotherapy and efficacy of subsequent avelumab maintenance therapy may support treatment decisions in patients for whom the preferred EV plus pembrolizumab regimen is not feasible.

Patients and Methods

Patient Population

This retrospective study included 26 consecutive patients with advanced UC, either metastatic or locally advanced, who received avelumab as maintenance therapy following radiologic disease control after first-line platinum-containing chemotherapy. Patients were treated between March 2021 and June 2025 at Kyushu Cancer Center, Japan.

Platinum agent selection during first-line chemotherapy was primarily guided by renal function, with the estimated glomerular filtration rate (eGFR) used as a general reference. Cisplatin was generally administered to patients with an eGFR $\geq$ 60 mL/min, whereas carboplatin was selected for those with an eGFR < 50 mL/min. For patients with an eGFR between 50 and 60 mL/min, the choice between reduced-dose cisplatin and carboplatin was made at the discretion of the treating physician. In some cases, reduced-dose cisplatin was also used for patients with an eGFR $\geq$ 60 mL/min when advanced age or poor performance status was considered. Thus, although renal function played a central role in regimen selection, other clinical factors were also considered. Avelumab was administered intravenously at a dose of 10 mg/kg every 14 days (day 1 of each cycle) and continued until radiographic or clinical disease progression or the occurrence of unacceptable toxicity.

Response Evaluation and Imaging

Tumor responses to both platinum-based chemotherapy and avelumab were assessed using the Response Evaluation Criteria in Solid Tumor, version 1.1.[8] The objective response rate (ORR) to platinum-based chemotherapy was defined as the proportion of patients achieving complete or partial response. The disease control rate (DCR) during avelumab maintenance was defined as the proportion of patients who did not develop progressive disease. Surveillance included physical examination, routine laboratory testing, and chest-abdominal-pelvic computed tomography imaging. Radiologic assessments were performed at baseline, every 4–6 cycles of avelumab, or earlier if clinically indicated. For the purposes of this study, visceral metastasis included bone metastasis and was analyzed accordingly.

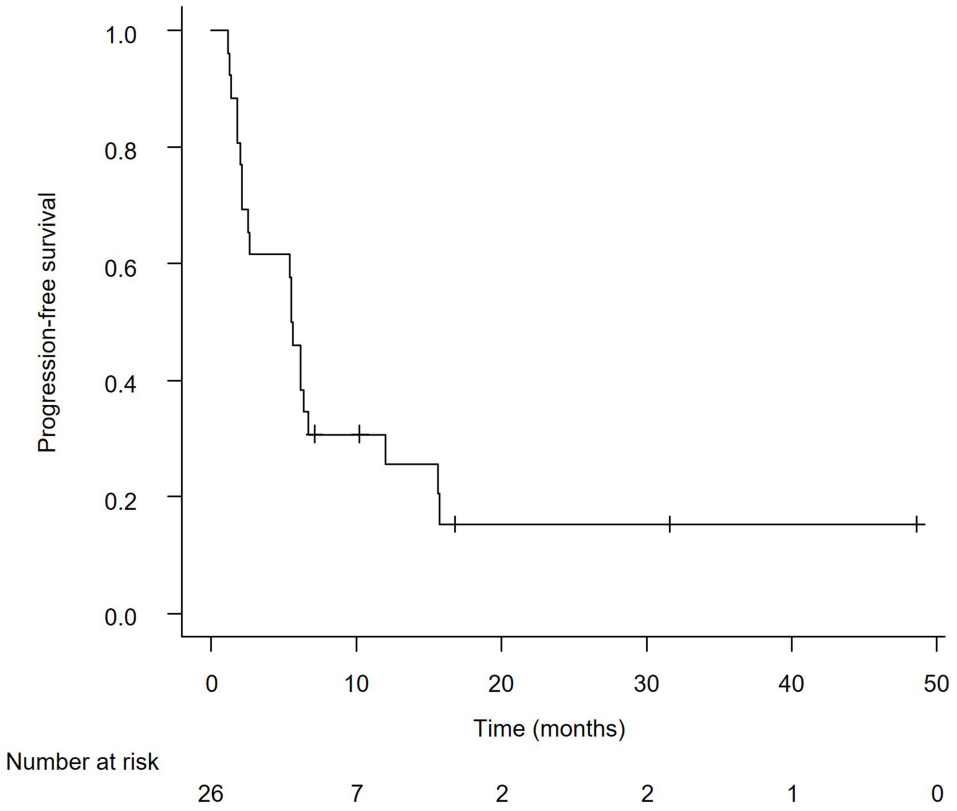

Figure 1 Progression-free survival from avelumab maintenance initiation in advanced urothelial carcinoma patients.

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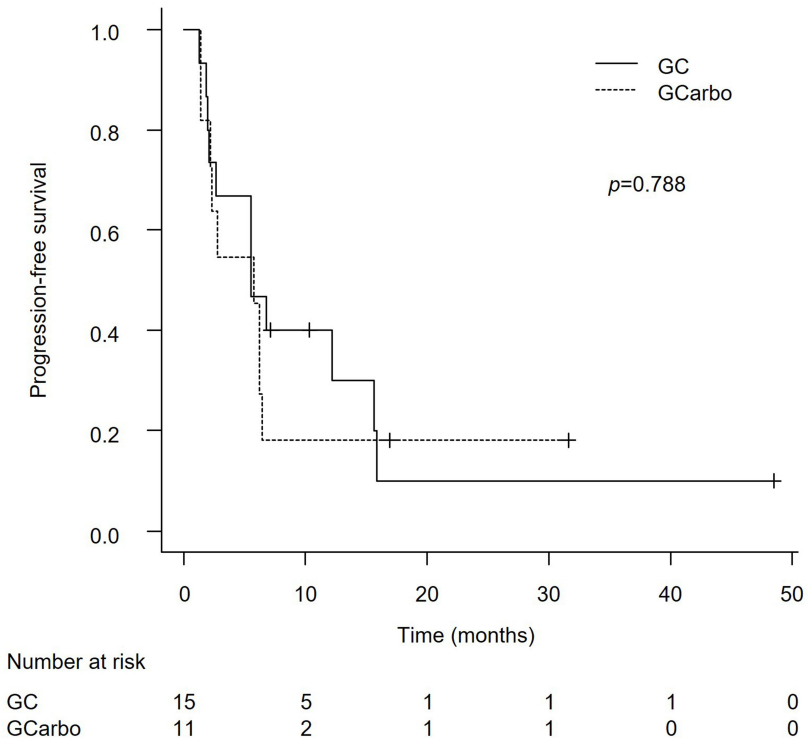

Figure 2 Progression-free survival from the start of avelumab maintenance therapy by induction regimen in advanced urothelial carcinoma patients.

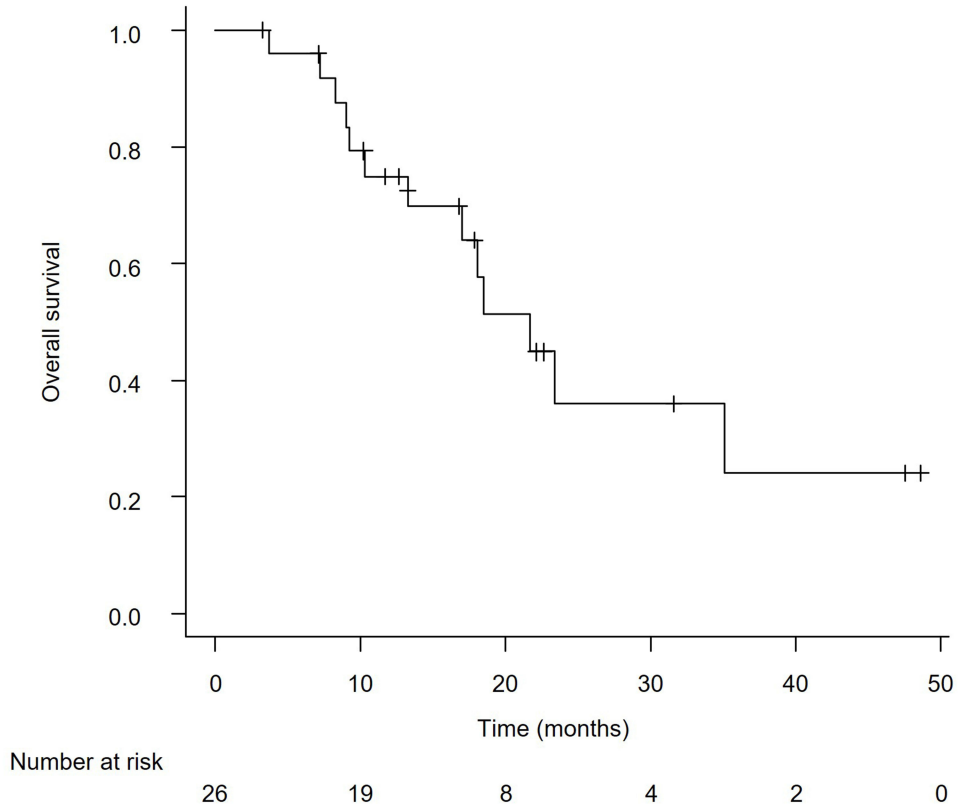

Figure 3 Overall survival from avelumab maintenance therapy initiation in advanced urothelial carcinoma patients.

Ethics

This study was approved by the Institutional Review Board of the National Hospital Organization Kyushu Cancer Center (Approval No. 2014–99). The study was conducted in accordance with the principles of the Declaration of Helsinki. Informed consent was waived using an opt-out methodology because of the retrospective design of the study.

Statistical Analysis

All statistical analyses were performed using EZR version 1.40 (Easy R; Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).[9] Continuous variables were compared using the Kruskal–Wallis test and categorical variables were compared using Fisher's exact test. Progression-free survival (PFS) was defined as the time from treatment initiation to the date of either radiographic or clinical progression, as assessed by the investigator. Overall survival (OS) was defined as the time from treatment initiation to death from any cause. Survival curves were generated using the Kaplan–Meier method, with patients without events censored at their last known follow-up. A two-tailed P-value < 0.05 was considered statistically significant.

Results

A total of 26 patients with advanced UC who received avelumab maintenance therapy following first-line platinum-based chemotherapy were included. The cohort was divided into three groups according to the induction chemotherapy regimen: full-dose gemcitabine/cisplatin (GC; n=10), reduced-dose GC (n=5), and gemcitabine/carboplatin (GCarbo; n=11).

Baseline Characteristics

The patient characteristics are summarized in Table 1. The median age was 72 years (interquartile range [IQR], 65–77 years), with significant differences among the groups (66 [62–70] years in the full-dose GC group, 80 [76–81] years in the reduced-dose GC group, and 74 [70–79] years in the GCarbo group; $P < 0.010$). Male patients comprised 65.4% of the cohort, with no significant difference between the groups (P=0.318). The Eastern Cooperative Oncology Group (ECOG) performance status was 0 in 84.6% and ≥ 1 in 15.4% of patients, with no significant intergroup difference (P=0.327). The primary tumor site was the lower urinary tract in 53.8%, upper tract in 38.5%, and both in 7.7% of patients (P=0.763). Pure UC histology was identified in 73.1% of patients, with the highest proportion in the reduced-dose GC group (100%), followed by the GCarbo (72.7%) and full-dose GC (60.0%) groups (P=0.271). Visceral metastases at the start of first-line chemotherapy were observed in 53.8% of the overall cohort, but no significant differences were found among the groups (P=0.268). Most patients received four or fewer chemotherapy cycles (76.9%), again with no significant intergroup difference (P=0.254).

Treatment Response

The treatment outcomes are shown in Table 2. The ORR to first-line chemotherapy was 60.0% in the full-dose GC group, 80.0% in the reduced-dose GC group, and 45.5% in the GCarbo group (P=0.458). The DCR during avelumab maintenance therapy was 50.0%, 100.0%, and 54.5% in these groups, respectively (P=0.188).

Survival Outcomes by GC (Full/Reduced) vs GCarbo

The median PFS from the initiation of avelumab maintenance therapy was 5.6 months (95% confidence interval [CI], 2.2–6.8) in the overall cohort (Figure 1). There was no significant difference in PFS between patients treated with GC (full or reduced dose) and those treated with GCarbo (5.5 months [95% CI, 1.9–15.6] vs 5.7 months [95% CI, 1.4–6.4]; P=0.788, Figure 2). The median OS from the start of avelumab maintenance therapy was 21.7 months (95% CI, 13.3–not estimable [NE]) in the overall cohort (Figure 3). OS did not differ significantly between the GC and GCarbo groups (21.7 months [95% CI, 21.7–NE] vs 18.4 months [95% CI, 3.8–NE]; P=0.359, Figure 4). Similarly, the median OS from the initiation of first-line chemotherapy was 28.7 months (95% CI, 16.6–41.1) in the overall cohort (Figure 5). No significant difference was observed between patients treated with GC and those treated with GCarbo (28.8 months [95% CI, 22.7–NE] vs 29.0 months [95% CI, 11.8–NE]; P=0.262, Figure 6).

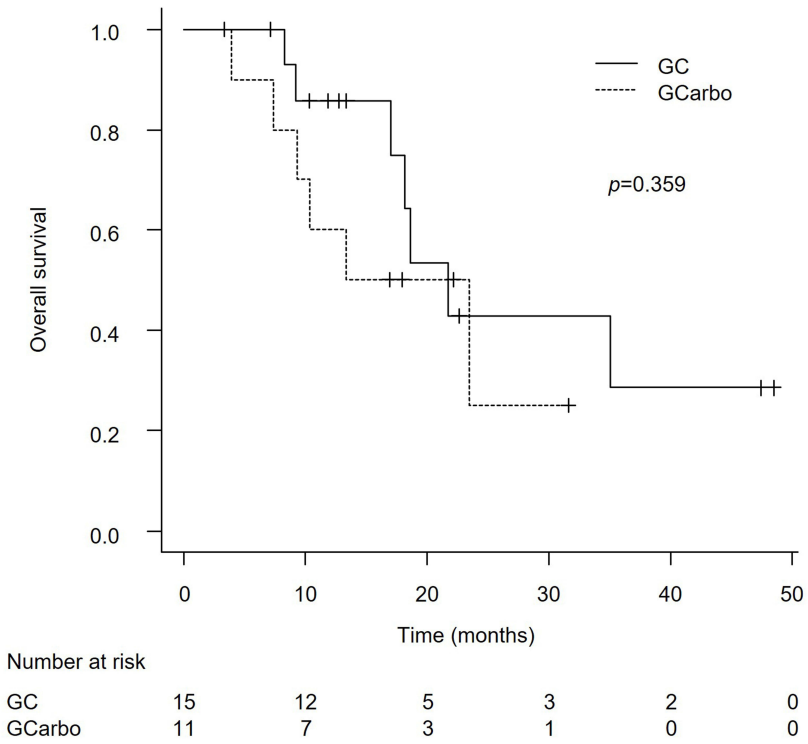

Figure 4 Overall survival from the start of avelumab maintenance therapy by induction regimen in advanced urothelial carcinoma patients.

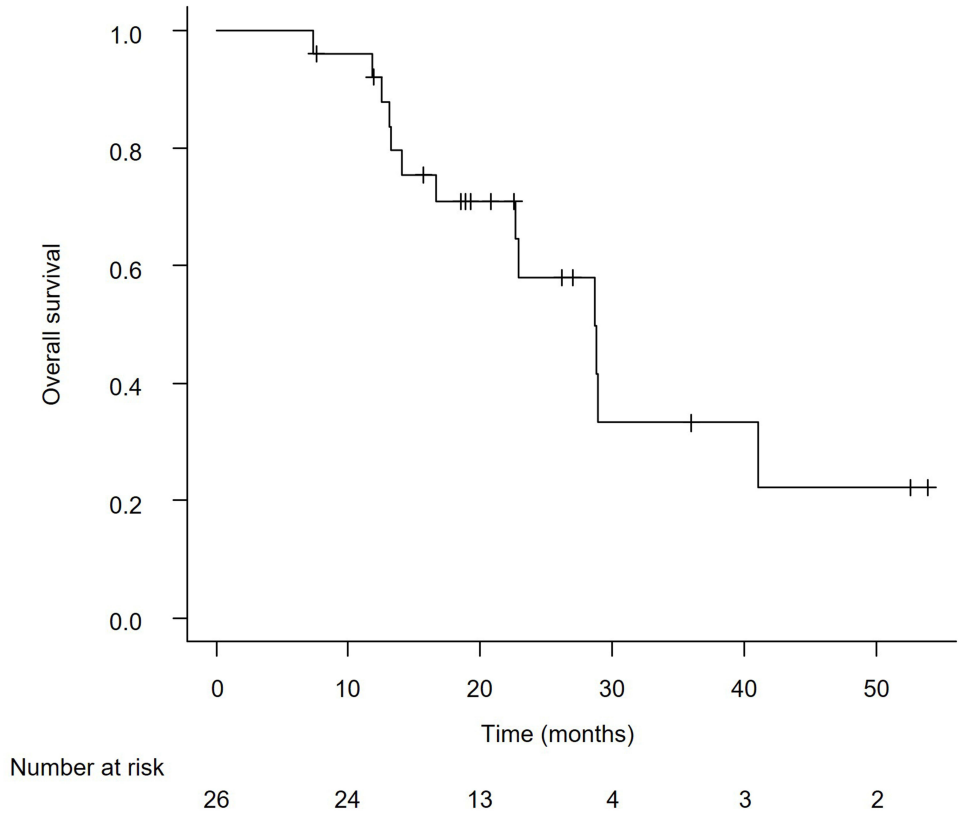

Figure 5 Overall survival from first-line platinum-based chemotherapy initiation in advanced urothelial carcinoma patients.

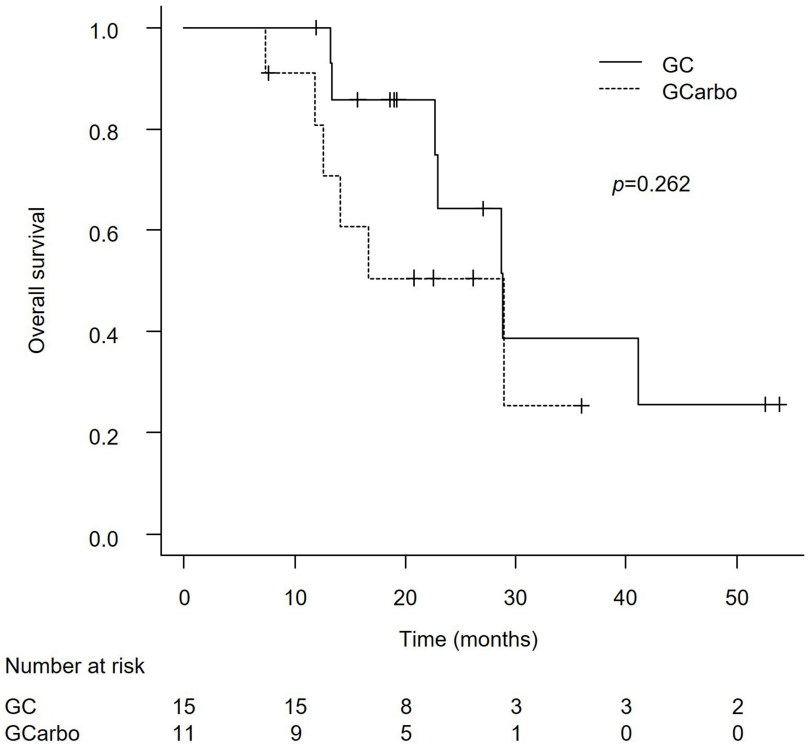

Figure 6 Overall survival from the start of platinum-based chemotherapy by regimen type in advanced urothelial carcinoma patients.

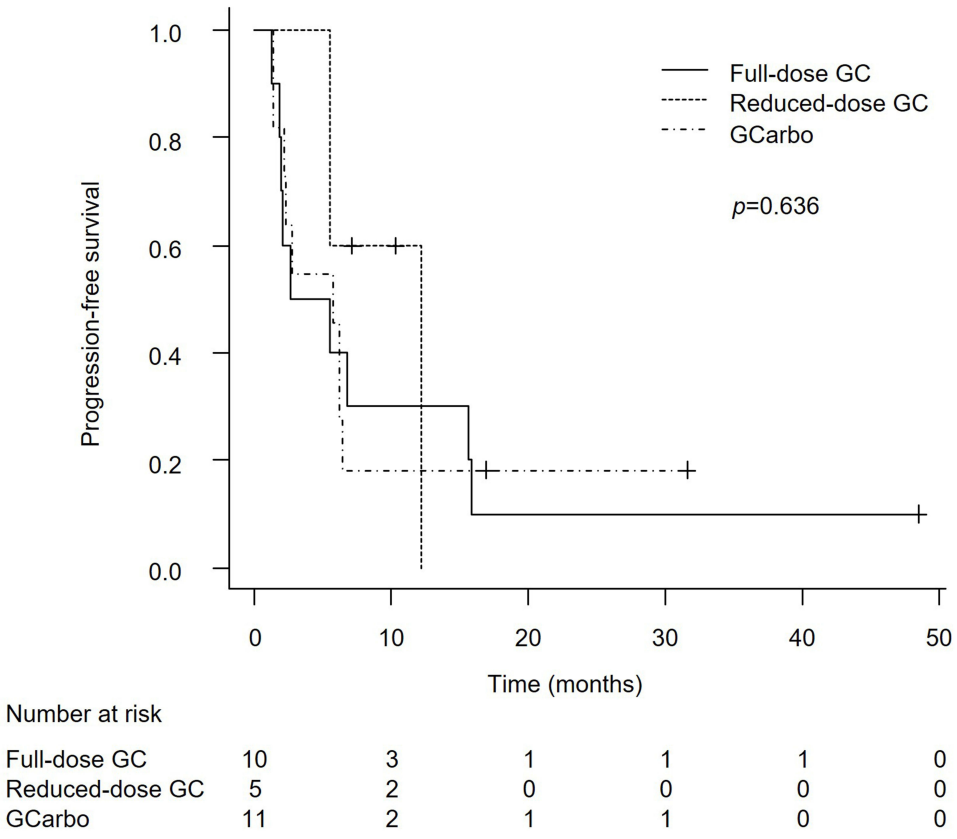

Figure 7 Progression-free survival from the start of avelumab maintenance therapy by induction regimen subgroup in advanced urothelial carcinoma patients.

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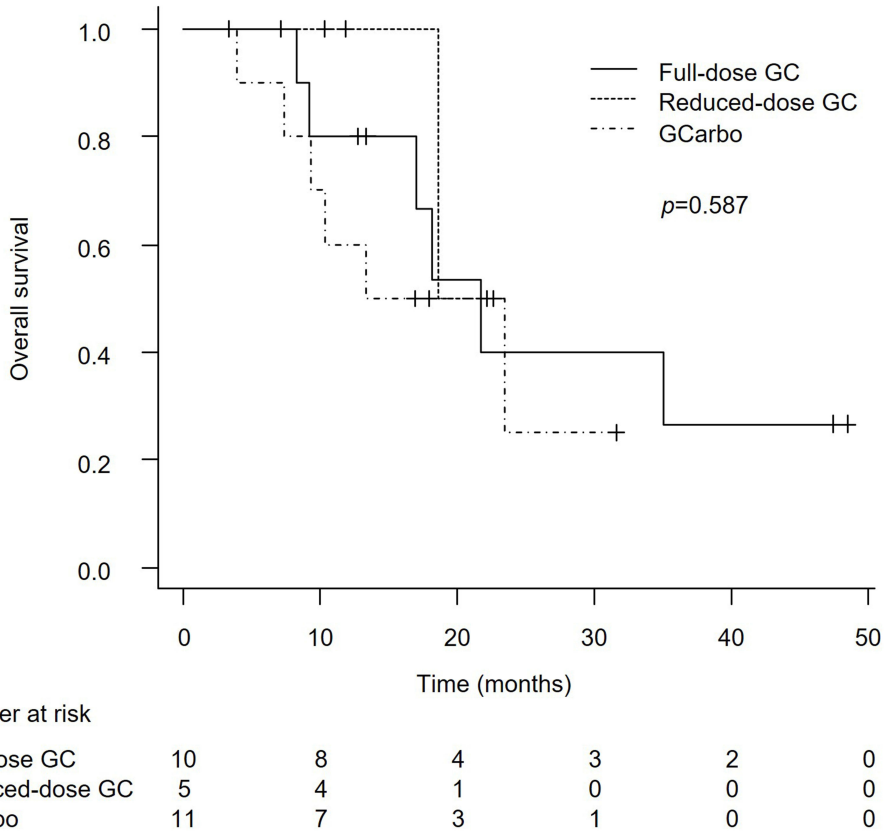

Figure 8 Overall survival from the start of avelumab maintenance therapy by induction regimen subgroup in advanced urothelial carcinoma patients.

Survival Outcomes by Individual Regimen

When analyzed by individual regimen, the median PFS from avelumab initiation was 4.0 months (95% CI, 1.2–15.6) for full-dose GC, 12.1 months (95% CI, 5.5–NE) for reduced-dose GC, and 5.7 months (95% CI, 1.4–6.4) for GCarbo. There was no statistically significant difference among the three groups (*P*=0.636, Figure 7). The median OS values from the start of avelumab maintenance therapy were 21.7 months (95% CI, 8.3–NE), 18.6 months (95% CI, 18.6–NE), and 18.4 months (95% CI, 3.8–NE) in the full-dose GC, reduced-dose GC, and GCarbo groups, respectively (*P*=0.587, Figure 8). The median OS from the initiation of first-line chemotherapy was 28.8 months (95% CI, 13.2–NE) for full-dose GC, 28.7 months (95% CI, NE–NE) for reduced-dose GC, and 29.0 months (95% CI, 11.8–NE) for GCarbo (*P*=0.496, Figure 9).

Discussion

This study investigated the clinical outcomes of avelumab maintenance therapy in patients with advanced UC who underwent first-line chemotherapy with full-dose GC, reduced-dose GC, or GCarbo. Although the JAVELIN Bladder 100 trial established the efficacy of avelumab maintenance after platinum-based induction therapy,[4] the impact of chemotherapy intensity variations, often driven by renal function or patient frailty, on avelumab effectiveness remains unclear.

Renal dysfunction is a frequent challenge in patients with UC because of factors such as advanced age, lifestyle-related comorbidities (including hypertension and diabetes mellitus), tumor-induced urinary tract obstruction, and a history of nephroureterectomy. Approximately 40% to 50% of patients are considered ineligible for cisplatin-based therapy based on renal function criteria, most commonly an eGFR < 60 mL/min.[10] This clinical limitation necessitates the use of reduced-dose cisplatin or carboplatin-based regimens in a considerable proportion of patients, particularly those who are elderly or have impaired renal function.[5] However, whether these alternative regimens provide oncologic outcomes that are similar to those of full-dose GC remains a matter of ongoing debate.[11]

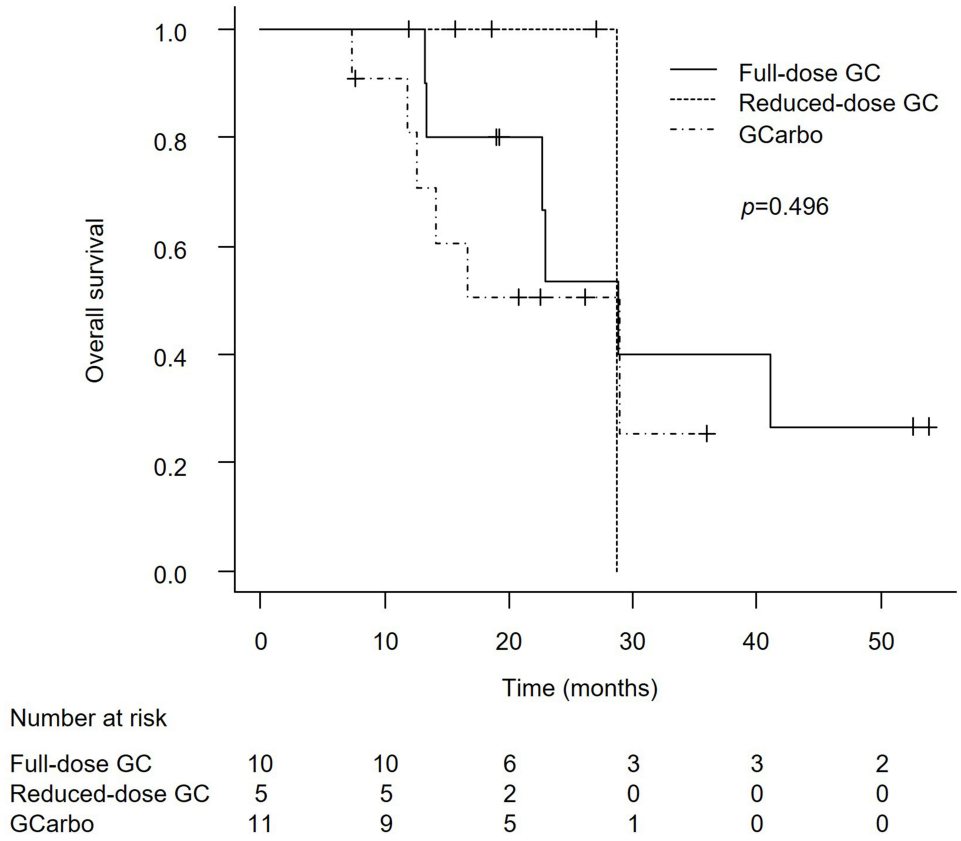

Figure 9 Overall survival from the start of platinum-based chemotherapy by induction regimen subgroup in advanced urothelial carcinoma patients.

A recent real-world study in patients with advanced UC reported no significant difference in OS, PFS, or response rate among those receiving full-dose GC, reduced-dose GC, or GCarbo as first-line therapy.[12] However, the complete response rate was quantitatively lower in the reduced-dose GC group, indicating a possible reduction in the efficacy of tumor eradication compared with standard regimens. Importantly, the study did not include data on avelumab maintenance. Therefore, our current data add to this context by demonstrating that avelumab maintenance provided comparable PFS and OS regardless of prior regimen intensity, including in patients who received reduced-dose GC. These findings indicate that attenuation of induction therapy, either because of renal or performance status considerations, does not necessarily diminish the efficacy of subsequent maintenance immunotherapy.

Interestingly, previous studies have suggested that reduced-dose cisplatin may compromise the efficacy of subsequent immune checkpoint inhibitors in the second-line setting, such as pembrolizumab, particularly in cisplatin-unfit populations.[7] However, these findings were derived exclusively from patients deemed ineligible for cisplatin using the Galsky criteria, which define cisplatin ineligibility as the presence of at least one of the following: ECOG performance status ≥ 2, creatinine clearance < 60 mL/min, grade ≥ 2 hearing loss, grade ≥ 2 peripheral neuropathy, or New York Heart Association class III heart failure.[13] In contrast, our cohort included several patients who received reduced-dose cisplatin despite preserved renal function, primarily because of advanced age or impaired performance status. Therefore, the generalizability of these previous findings to our population may be limited. Furthermore, because avelumab is administered as maintenance therapy while the disease remains under control, its clinical context and immunologic dynamics differ from those of second-line checkpoint blockade. Our findings suggest that avelumab maintenance retains its therapeutic efficacy even after attenuated cisplatin-based induction, potentially expanding its applicability across a broader spectrum of patient profiles.

Furthermore, our cohort demonstrated a statistically significant age difference among the three treatment groups, with patients in the reduced-dose GC group being the oldest. This pattern reflects real-world clinical decision-making, wherein elderly patients with preserved renal function are frequently treated with reduced-dose cisplatin out of concern for

treatment tolerability based on physician discretion.[5,14] Importantly, our findings indicate that avelumab maintenance therapy remains effective in this older subgroup, further supporting its broad applicability across diverse patient populations. Our results are consistent with real-world registry data from various studies, such as AVENANCE, J-AVENUE, and PATRIOT-II, which confirmed the feasibility and efficacy of avelumab maintenance across diverse populations, including those ineligible for cisplatin.[14–16] These findings reinforce the notion that avelumab maintenance can offer survival benefits irrespective of the preceding chemotherapy regimen. This study also underscores the relevance of shared decision-making in advanced UC management. When patients present with borderline renal function or frailty, the choice between full-dose GC, reduced-dose GC, and GCarbo often depends on balancing efficacy, toxicity, and patient preferences. Our findings can provide clinicians and patients with reassurance that choosing less intensive chemotherapy, when clinically appropriate, does not compromise the benefit of subsequent avelumab maintenance.[17–19]

Despite these insights, several limitations of this study should be acknowledged, including its retrospective design, small sample size, and single-center setting. Physician-driven treatment selection may have introduced bias, and detailed biomarker analyses were not performed. Nevertheless, the study reflects real-world practice and offers practical guidance for treatment sequencing. These findings may inform treatment decisions in settings where the preferred regimen is not feasible due to comorbidities or access limitations. Future prospective, multicenter studies with larger cohorts and integrated biomarker analyses are warranted to validate and extend these observations.

Conclusion

Avelumab maintenance therapy provided similar clinical benefits in patients with advanced UC, regardless of whether they received full-dose GC, reduced-dose GC, or GCarbo as first-line therapy. These findings support a flexible, individualized approach to induction chemotherapy, especially for patients with renal impairment or advanced age. The results may assist in shared decision-making processes by reassuring clinicians and patients that the efficacy of maintenance immunotherapy is preserved across diverse induction strategies.

Data Sharing Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of the National Hospital Organization Kyushu Cancer Center (approval number: 2014-99). The requirement for written informed consent was waived because of the retrospective nature of the study; however, an opt-out option was provided via the websites of all participating institutions.

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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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Disclosure

The authors declare that they have no conflicts of interest for this study.

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