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EFFICACY AND SAFETY OF AVELUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA

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Background and importance:

The majority of patients with metastatic urothelial carcinoma experience disease progression within 9 months of initiating chemotherapy. This has led to the exploration of maintenance therapy aimed at prolonging the chemotherapy response for as long as possible.

Avelumab, a monoclonal antibody targeting the programmed death-ligand 1 (PD-L1), is approved for first-line maintenance treatment in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who have not progressed after platinum-based chemotherapy.

Aim and objectives

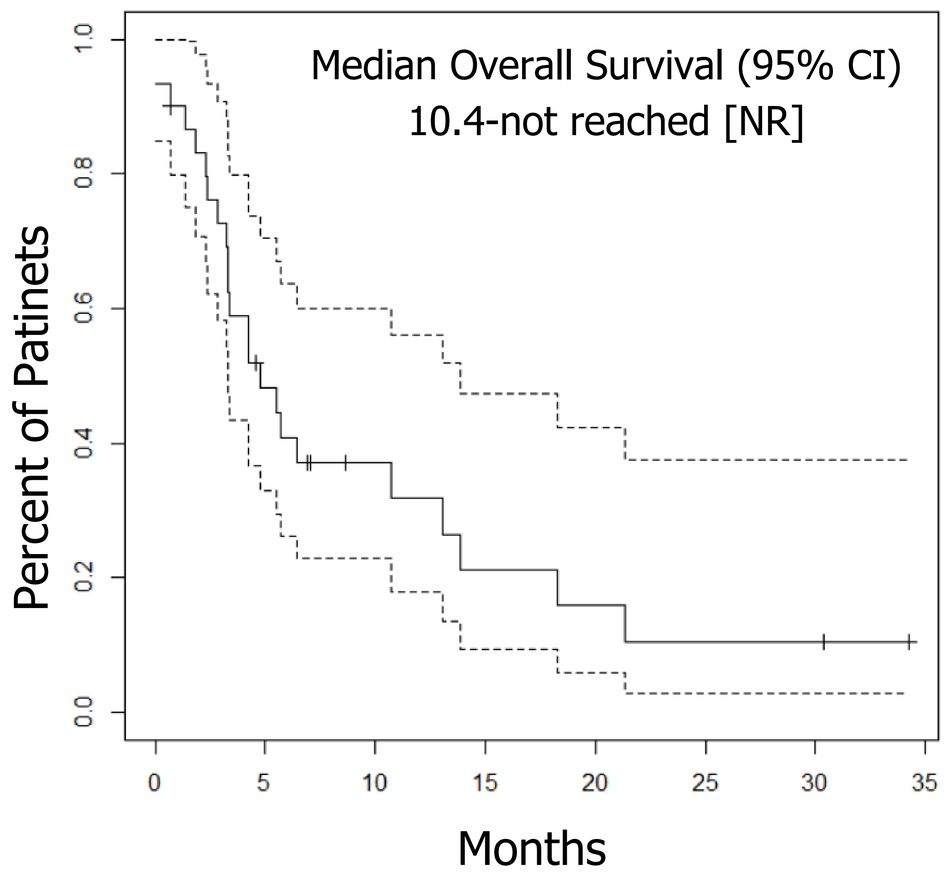
To determine the efficacy and safety of avelumab in patients with metastatic bladder cancer.

Material and methods

This was a retrospective, observational, single-center study conducted at a tertiary care hospital over 39.2 months, from January 2021 to March 2024. Efficacy endpoints included progression-free survival (PFS) and overall survival (OS), while safety endpoints included adverse events and their severity.

Results

Characteristic	Overall Population (N=30)
Age (median)	73 years
Age (range)	40-87
ECOG performance status	0 (47%) or ≥1 (53%)
First-line chemotherapy regimen	30% Gemcitabine-Cisplatin. 67% Gemcitabine-Carboplatin. 3% Both.
Best response to first-line chemotherapy	90% Complete response or partial response. 10% Stable disease.
PD-L1 status (%)	23% Positive
Metastasis before chemotherapy	43% Visceral metastases



The median OS was 21.3 months (95% confidence interval [CI]: 10.4-not reached [NR]), and the median PFS was 4.8 months (95%CI: 3.3-13.8).

23% of patients experienced adverse events of any grade related to the medication, including fatigue, dysuria, and urinary tract infection. Grade 3-4 adverse reactions were observed in 6.7% of patients, and treatment administration was delayed in 10% of cases.

Conclusion and relevance:

Clinical practice outcomes demonstrate efficacy results comparable to those obtained in the pivotal JAVELIN Bladder 100 trial, which reported a median OS of 22.1 months and a PFS of 3.7 months. Regarding safety, the toxicity profile in our study was better than that observed in the pivotal trial (98% adverse events). These findings support the use of Avelumab in clinical practice, highlighting the importance of its funding for these patients.