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Real-World Outcomes of Second-Line Pembrolizumab in Urothelial Cancer: Campania Network Analysis

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Background: Platinum-based chemotherapy followed by immunotherapy is standard for locally advanced/metastatic urothelial cancer (La/mUC). Despite advances, La/mUC remains aggressive with poor prognosis. Real-world outcomes may differ from clinical trials. Oncology networks generating real-world data (RWD) are crucial to guide treatment. We retrospectively analysed La/mUC patients treated with second-line pembrolizumab within the Campania Oncological Network (ROC).

Methods: This multicenter retrospective study included patients (≥ 18 years) with histologically/cytologically confirmed La/mUC, previously treated with chemotherapy, who received pembrolizumab (200 mg every 3 weeks) across six ROC centres. Primary endpoints were progression-free survival (PFS) and overall survival (OS); secondary endpoints included objective response rate (ORR), disease control rate (DCR) and safety.

Results: From January 2021 to November 2023, 132 patients received pembrolizumab. Median age was 67 years (range 30–88); 73.5% were male. Eastern Cooperative Oncology Group (ECOG) performance status was 0–1 in 82.6%. Most had pure urothelial carcinoma (87.1%), and 12.9% had rare variants. At diagnosis, 34.1% had metastatic disease, and 54.5% underwent cystectomy. Common metastatic sites were lymph nodes (74.2%), lung (38.6%), bone (34.1%), and liver (15.9%). After a median follow-up of 8.5 months, 81.8% experienced progression or death. Median PFS and OS were 3.75 (95% CI: 3.4 to 4.7) and 7.3 (95% CI: 6.05–9.33) months, respectively. ORR was 13.5% (95% CI: 7.4% - 19.7%), DCR 33.9% (95% CI: 25.6%–42.0%), and ORR in rare subtypes was 23.5% (95% CI: 3.3% to 43.7%).

Metastatic disease at diagnosis (HR=2.01, $p=0.02$) and liver metastases (HR=2.11, $p=0.02$) were associated with worse OS. Lymph node-only metastases predicted better PFS (HR=0.46, $p=0.004$) and OS (HR=0.52, $p=0.02$). Prior cystectomy improved PFS (HR=0.67, $p=0.04$) and OS (HR=0.54, $p=0.003$) in univariate analysis.

Among 114 treatment-related adverse events (AEs), 79.8% were grade 1–2, and 20.2% grade 3–4. No treatment-related deaths occurred. Pembrolizumab was discontinued in 7.6% due to AEs; the most frequent were asthenia (20%), pruritus (10%), and myalgia (7%).

Conclusions: Second-line pembrolizumab showed clinical activity and acceptable safety in this real-world La/mUC cohort. Prognostic factors such as metastatic sites and prior cystectomy significantly influenced outcomes. These data support the role of oncology networks in guiding real-world treatment strategies.