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BACKGROUND & OBJECTIVE

- Enfortumab vedotin with pembrolizumab (EVP) was approved by NICE in September 2025.
- In the EV-302 trial, EVP doubled both progression-free and overall survival versus platinum-based therapy — gemcitabine with cisplatin or carboplatin (GemCisCarbo) — in previously untreated advanced urothelial carcinoma.
- This study reports real-world outcomes and the safety profile of EVP at Oxford University Hospitals NHS Foundation Trust (OUH) against a retrospective GemCisCarbo control group.

METHODS

- All patients started on EVP for advanced urothelial cancer at OUH between October 2025 and April 2026 (n = 21).
- Comparator: a similar cohort treated with gemcitabine plus cisplatin or carboplatin before EVP approval, July to October 2025 (n = 15).
- Progression point for both groups based on the latest scan as of April 2026.

LIMITATIONS & NEXT STEPS

- Small sample size and immature follow-up, reflecting the recency of EVP approval in the UK; female-to-male ratio 1:4.
- Next steps: long-term follow-up to obtain 5-year survival rates, and compiling data across multiple UK centres.

OBJECTIVE RESPONSE

57%

EV-Pembro
vs 13% GemCisCarbo
RR 4.3 · p = 0.014

MORTALITY

4.8%

EV-Pembro
vs 40% GemCisCarbo
RR 0.12 · p = 0.013

DISEASE PROGRESSION

14%

EV-Pembro
vs 87% GemCisCarbo
RR 0.16 · p < 0.001

Outcome comparison — EV-Pembro vs GemCisCarbo

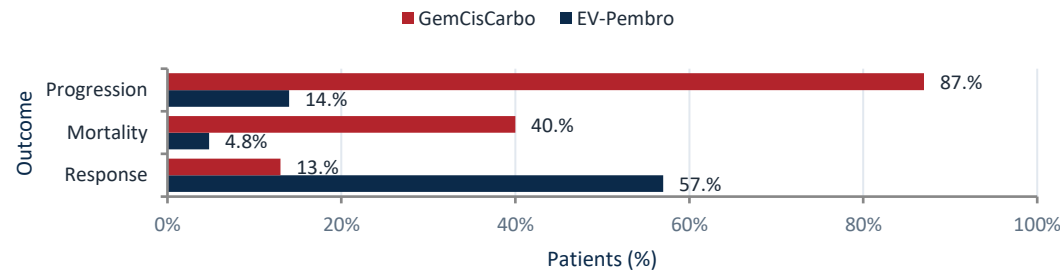


Figure 1. Progression, mortality, and response by cohort — EV-Pembro (n = 21) vs GemCisCarbo (n = 15).

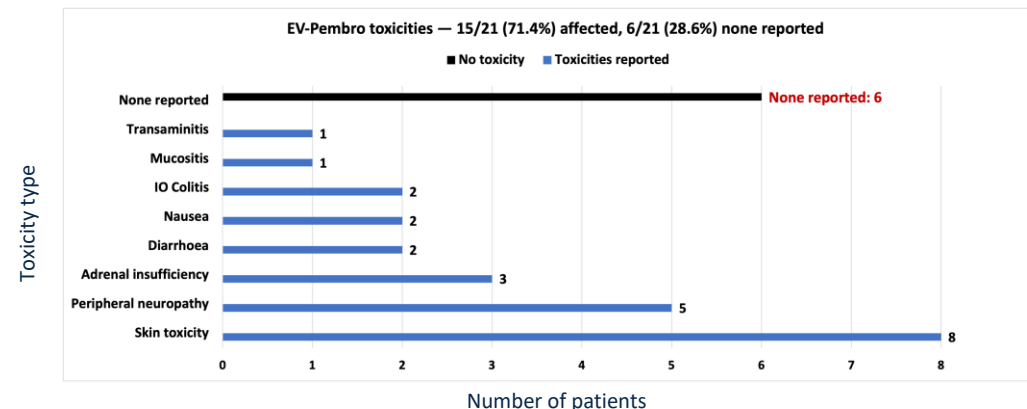


Figure 2. Toxicity burden in the EV-Pembro cohort.

SAFETY PROFILE

- 15 of 21 patients (71%) experienced at least one toxicity, with 24 total toxicity occurrences recorded; 6 patients (29%) had none reported.
- Skin toxicity was most common at 8 patients (38%), followed by peripheral neuropathy (5, 24%) and adrenal insufficiency (3, 14%).
- Most events were low-grade (Grade 1–2) and many patients had overlapping toxicities, with only isolated higher-grade events — one Grade 3 immune-related skin toxicity.

Distribution of toxicity types (24 occurrences)

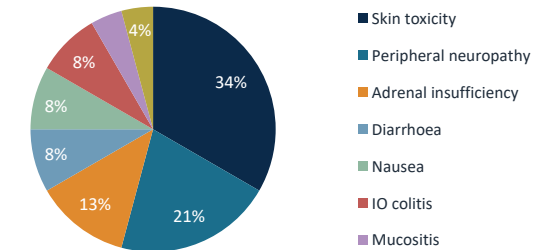


Figure 3. Distribution of toxicity types.

CONCLUSIONS

EVP demonstrates significantly better response, survival and progression outcomes than GemCisCarbo across a well-matched population in our experience. Toxicity was common but largely low-grade and manageable, dominated by skin and neuropathy effects, with roughly a third of patients experiencing no toxicity at all.