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Enfortumab Vedotin Plus Pembrolizumab as First-Line Therapy for Locally Advanced or Metastatic Urothelial Carcinoma: A Systematic Review and Meta-Analysis of Efficacy and Safety Outcomes With Meta-Regression

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Abstract

Background

Enfortumab vedotin plus pembrolizumab (EV/P) is a promising treatment for metastatic urothelial carcinoma (mUC), but a comprehensive efficacy and safety synthesis is currently lacking.

Methods

Following PRISMA 2020 guidelines, we searched PubMed, Scopus, and Web of Science for RCTs and observational studies evaluating EV/P in mUC. Random-effects meta-analyses and meta-regressions (via R) evaluated ORR, CR, DCR, progressive disease (PD), OS, grade ≥ 3 adverse events (AEs), treatment discontinuation, and skin toxicity.

Results

Twelve studies (1,939 patients) were included. Pooled rates were: ORR 64.6% (95% CI: 60.1–

68.8%; $p < 0.0001$), CR 16.1% (12.1–21.0%; $p = 0.001$), DCR 83.2% (77.9–87.3%; $p < 0.0001$), and PD 13.6% (10.6–17.2%). Overall survival significantly favored EV/P (HR: 0.60, 95% CI: 0.44–0.82; $p = 0.0028$). Regarding safety, grade ≥ 3 AEs occurred in 31.3% of patients (21.6–42.9%), skin toxicity in 53.0% (44.3–61.4%), and treatment discontinuation in 29.1% (22.3–36.8%). Heterogeneity was high across outcomes ($I^2 = 73.9–94.0\%$). Meta-regression revealed that a higher proportion of patients with ECOG PS ≥ 2 was inversely associated with CR, DCR, ORR, PD, grade ≥ 3 AEs, and treatment discontinuation, but positively associated with skin toxicity. A moderate, non-significant positive correlation was observed between skin toxicity and ORR (Spearman's $r = 0.47$, $p = 0.146$).

Conclusion

EV/P demonstrates robust efficacy in mUC, yielding high response rates and improved overall

survival. However, this is accompanied by substantial toxicity and treatment discontinuation rates. Baseline ECOG PS appears to significantly

influence both tolerability and treatment outcomes, warranting further investigation.

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