Real World Incidence of Severe Inpatient Toxicity During Bispecific T Cell Engager Therapy Initiation: A 2023 National Inpatient Sample Analysis

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INTRODUCTION

Bispecific T cell engager therapies have revolutionized the treatment of relapsed or refractory hematologic malignancies. While initial trials mandated inpatient admission due to fears of systemic toxicity, the true national burden of life-threatening events during induction remains poorly defined.

AIM

To evaluate the real-world incidence of severe inpatient toxicities associated with therapy using a nationally representative database, informing risk stratified monitoring strategies.

METHOD

Design: Retrospective cross sectional observational study.

Setting: 2023 Healthcare Cost and Utilization Project National Inpatient Sample.

Population: Adult hospitalizations for BiTE therapy (teclistamab, mosunetuzumab, epcoritamab, elranatamab, glofitamab) via ICD-10-PCS codes.

CONCLUSIONS

Severe CRS and severe ICANS were uncommon during hospitalizations associated with TCE initiation (~6% overall composite rate). These nationally representative findings provide real-world estimates of serious inpatient toxicities and may help inform evolving risk-adapted monitoring strategies. Prospective studies are needed to define which patients can safely undergo outpatient step-up dosing.

RESULTS

Cohort: We identified 654 unweighted and 3,270 weighted inpatient hospitalizations. The mean patient age was 67 years, and 56% of the cohort was male.

Overall Severe Toxicity: The composite outcome (in hospital mortality, severe CRS, or ICANS ≥ Grade 3) occurred in only **6.1%** of hospitalizations (95% CI, 4.2-8.1).

Individual Severe Events:

- Severe CRS: 1.2% (95% CI, 0.5-1.9)
- ≥ Grade 3 ICANS: 1.1% (95% CI, 0.2-1.9)
- In-hospital mortality: 4.3%
- ICU admission: 2.6%
- Tumor lysis syndrome: 3.7%

Agent Comparison: Observed rates did not demonstrate clear differences among the most frequently represented agents (teclistamab at 5.5% [95% CI: 3.1–7.8], glofitamab at 5.6% [95% CI: 0.0–18.4], and epcoritamab at 3.2% [95% CI: 0.0–10.4]), although estimates for less frequently used agents were imprecise due to sample size.

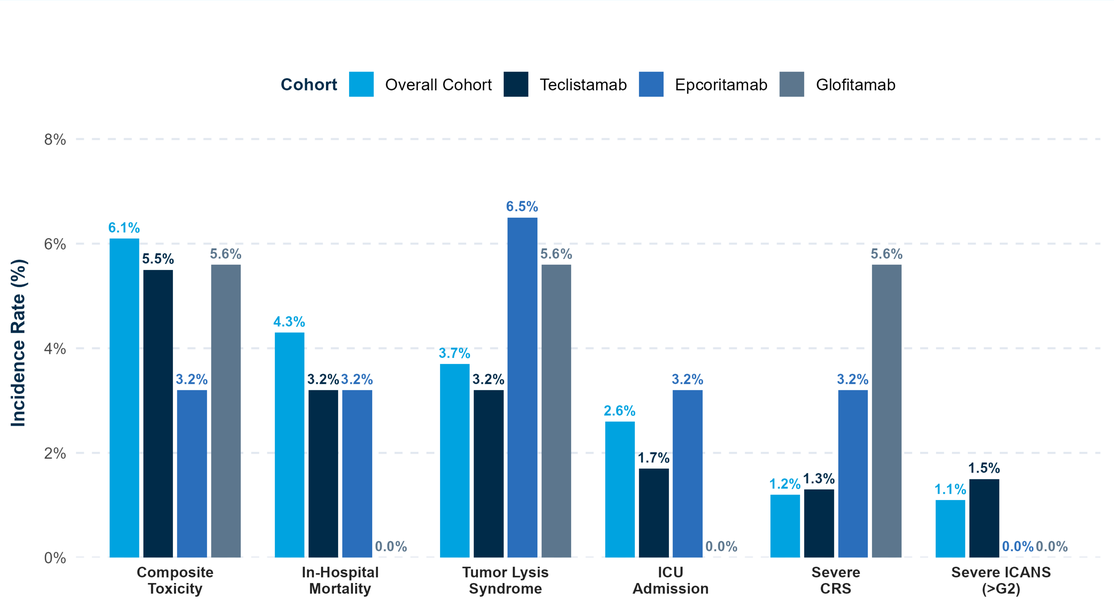

Figure 1. Real-World Incidence of Severe Inpatient Toxicity During Bispecific T-Cell Engager (BiTE) Initiation (2023 HCUP-NIS). Grouped bar chart depicting weighted incidence rates (%) across the overall national cohort ($N = 3,270$) and individual BiTE therapies: teclistamab ($n = 2,370$), epcoritamab ($n = 155$), and glofitamab ($n = 90$). The primary composite outcome includes in-hospital mortality, severe cytokine release syndrome (CRS grade $\ge$3), or severe immune effector cell–associated neurotoxicity syndrome (ICANS grade $\ge$3). Secondary endpoints include ICU admission/mechanical ventilation and tumor lysis syndrome (TLS). Values for mosunetuzumab ($n = 105$) and elranatamab ($n = 20$) yielded zero severe events and are omitted from visual comparison.

LIMITATIONS

- Retrospective Administrative Design: Relies on ICD-10-PCS/CM coding accuracy, which may be subject to misclassification or underreporting of toxicity grade.
- Sample Size Constraints: Imprecise estimates for newly approved or less frequently utilized agents (epcoritamab, elranatamab, mosunetuzumab).
- Confounding by Indication: Lacks detailed outpatient laboratory data, ECOG performance status, or prior lines of systemic therapy.

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