CT-886 - Comparative Inpatient Outcomes Among FDA-Approved Chimeric Antigen Receptor T-Cell Products: An Analysis of the National Inpatient Sample

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Background

- Comparative national data on inpatient outcomes for individual FDA-approved CAR T-cell products remain limited.
- There exists a knowledge gap in understanding variations in severe inpatient toxicities and resource demands between different CAR-T therapies.
- Understanding these differences is significant for informing inpatient risk stratification and healthcare resource planning.
- This study aims to compare severe inpatient toxicities and resource-intensive complications among FDA-approved CAR-T products using a national inpatient sample.

Methods

- Retrospective cross-sectional analysis of the 2022-2023 Healthcare Cost and Utilization Project National Inpatient Sample.
- CAR-T hospitalizations identified via product-specific ICD-10-PCS procedure codes; toxicities and complications identified using ICD-10-CM diagnostic codes.
- The primary outcome was a composite severe inpatient toxicity including in-hospital mortality, grade ≥3 cytokine release syndrome (CRS), or grade ≥3 immune effector cell-associated neurotoxicity syndrome (ICANS).
- Secondary outcomes encompassed individual toxicity components, shock, febrile neutropenia, tumor lysis syndrome, mechanical ventilation, dialysis, and transfusion.
- Survey-weighted estimates and multivariable survey logistic regression adjusted for age, sex, Elixhauser mortality score, underlying indication, and calendar year.
- Statistical significance was set at P < .05 for the primary outcome and Bonferroni-adjusted P < .0033 for 15 secondary outcomes.

Results

Characteristic	All N=1,622; weighted N=8,110	Axi-cel N=634; weighted N=3,170	Liso-cel N=207; weighted N=1,035	Brexu-cel N=199; weighted N=995	Tisa-cel N=83; weighted N=415	Ide-cel N=267; weighted N=1,335	Cilta-cel N=232; weighted N=1,160
Age, median (IQR), y	64.3 (56.1-71.0)	61.5 (53.9-68.0)	70.4 (64.0-75.6)	61.8 (43.1-70.6)	64.5 (31.3-71.1)	67.2 (60.6-72.4)	63.6 (57.8-69.5)
Elixhauser mortality index, mean (SD)	-1.99 (9.47)	-1.86 (8.87)	-2.23 (9.85)	-2.44 (9.85)	-1.76 (10.21)	-1.76 (10.13)	-2.09 (9.35)
Underlying indication							
Follicular lymphoma	580 (7.2)	465 (14.7)	-	0 (0.0)	70 (16.9)	0 (0.0)	-
Large B-cell/aggressive B-cell NHL	3755 (46.3)	2510 (79.2)	960 (92.8)	-	235 (56.6)	-	-
Lymphoid leukemia/ALL	520 (6.4)	-	0 (0.0)	415 (41.7)	95 (22.9)	0 (0.0)	0 (0.0)
Mantle cell lymphoma	525 (6.5)	0 (0.0)	0 (0.0)	525 (52.8)	0 (0.0)	0 (0.0)	0 (0.0)
Multiple myeloma/ plasma cell neoplasm	2470 (30.5)	-	0 (0.0)	-	0 (0.0)	1315 (98.5)	1115 (96.1)
Other malignancy	260 (3.2)	160 (5.0)	-	-	-	-	-

Table 1: Patient demographics and indications across CAR-T products. Dashes (-) represent suppressed estimates under HCUP reporting requirements.

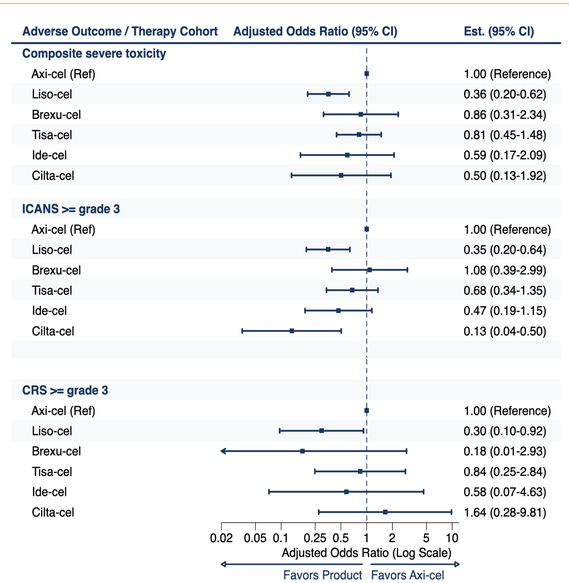

Figure 1: Comparative adjusted odds of toxicities by CAR-T product

Patient Characteristics and Composite Severe Toxicity

- Analyzed 1,622 unweighted CAR-T hospitalizations, representing 8,110 weighted hospitalizations nationally.
- Median patient age was 64.3 years (IQR, 56.1–71.0); 62.9% were male.
- Composite severe toxicity occurred in 13.5% of hospitalizations; in-hospital mortality was 1.7%.

Individual Toxicity and Complication Frequencies

- Grade ≥3 CRS occurred in 3.6%, grade ≥3 ICANS in 10.7%, shock in 3.1%, febrile neutropenia in 24.5%, tumor lysis syndrome in 1.4%.
- Mechanical ventilation was required in 2.3%, dialysis in 1.5%, and transfusion in 8.3% of weighted hospitalizations.

Adjusted Odds of Toxicities by CAR-T Product

- Compared with Axi-cel, Liso-cel had lower adjusted odds of composite severe toxicity (aOR, 0.36; 95% CI, 0.20-0.62) and grade ≥3 ICANS (aOR, 0.35; 95% CI, 0.20-0.64).
- Compared with Axi-cel, Cilta-cel also had lower adjusted odds of grade ≥3 ICANS (aOR, 0.13; 95% CI, 0.04-0.50).

Discussion

- This study provides comparative national data highlighting variability in severe toxicity among CAR T-cell therapies, underscoring differential inpatient risk profiles.
- Results advance understanding in the field by informing tailored approaches for inpatient management and resource allocation specific to CAR-T product type.
- Limitations include discharge-level NIS data, unavailable disease, treatment and post-discharge information, potential ICD-10 misclassification of CRS and ICANS, and residual confounding.
- Future validation via prospective registries is warranted to confirm these retrospective findings.

Key Findings

- Severe inpatient toxicity differed among CAR T-cell products after adjustment for measured clinical characteristics and underlying indication.
- Composite severe toxicity occurred in 13.5% of hospitalizations with in-hospital mortality at 1.7%.
- Liso-cel was associated with lower odds across composite severe toxicity and severe ICANS outcomes when compared to Axi-cel; Cilta-cel was also associated with lower odds of severe ICANS.
- Findings support the need for product-specific inpatient risk assessment and resource planning.

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