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CAR-T cell therapy effectiveness and safety: real-world experience in a tertiary hospital

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Background and importance

CAR-T cell therapies have demonstrated efficacy in hematologic malignancies in pivotal trials. However, real-world evidence remains limited.

Objective

To describe real-world-clinical-outcomes and the toxicity profile of CAR T-cell therapy at a tertiary hospital.

Materials and methods

Retrospective analysis of patients treated with commercial CAR-T between July 2022 and March 2025.

Variables collected: comercial CAR-T, age, sex, diagnosis, ECOG, prior lines of therapy, disease status and prior transplantation

Outcomes analyzed:

- Response rate (**ORR**)
- Complete remission (**RC**)
- Partial remission (**RP**) and progression-free-survival (**PFS**): +30, +90 days, 6 months
- Cytokine-release-syndrome (**CRS**)
- Immune-effector-cell-associated-neurotoxicity-syndrome (**ICANS**)
- **Prolonged cytopenias** (>30 days post-CAR-T)
- Intensive Care Unit (ICU) admission
- Median stay, length of hospitalization

Descriptive statistics included percentages for categorical variables and medians with interquartile ranges (IQR) for continuous variables.

Results

34 patients received commercial CAR-T therapy. Median age: 67.5 years (IQR 58.8–72.0); 73% male.

Axicabtagén ciloleucel (Yescarta®): 80.8%, brexucabtagén autoleucel (Tecartus®): 11.5%, Tisagenlecleucel (Kymriah®): 7.7%.

Diagnoses: diffuse large B-cell lymphoma (DLBCL) in 82.4%, mantle cell lymphoma (MCL) in 14.7%, and primary mediastinal large B-cell lymphoma (LBMP) in 2.9% of patients.

ECOG performance status: 0 in 80.8%, 1 in 15.4%, and 2 in 3.8% of patients.

Number of prior lines of therapy: 1 line (11.5%), 2 lines (73.1%), and ≥3 lines (15.4%).

Progressive disease: 69.2%; relapsed disease: 30.8%. Prior transplantation: 30.8% .

Effectiveness (response rates)

- **Day +30**: ORR 92.3% (CR 57.7%, PR 34.6%), PFS 91,2%
- **Day +90**: ORR 61.5% (CR 50.0%, PR 11.5%), PFS 70,6%
- **Month +6**: ORR 50.0% (CR 46.2%, PR 3.8%), PFS 64,7%

Safety

- **CRS**: all patients (23.1% grade I, 61.5% grade II, and 15.4% grade III)
- **ICANS**: 53.8% (26.9% grade I, 7.7% grade II, 7.7% grade III, and 11.5% grade IV)
- **Prolonged cytopenias**: 28% of patients.
- **ICU admission**: 65.4% (median stay: 3 days; IQR 3–10)
- **Median length of hospitalization**: 23.5 days (IQR 17-28)

Conclusion and relevance

CAR-T cell therapy in real-world-practice achieves **high early response rates**, although **effectiveness decreases over time**.

Toxicity remains a significant challenge, particularly CRS and ICANS, underscoring the need for optimized supportive care and long-term follow-up strategies.