HOSPITAL REGIONAL
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SAFETY OF AXICABTAGENE CILOLEUCEL IN CLINICAL PRACTICE FOR THE TREATMENT OF DIFFUSE LARGE B-CELL LYMPHOMA AFTER ≥ 2 LINES OF SYSTEMIC THERAPY

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Background and importance

Diffuse large B-cell lymphoma (DLBCL) is the most common lymphoproliferative neoplasm (non-Hodgkin), characterized by clinical aggressiveness and biological heterogeneity. Autologous Chimeric Antigen Receptor (CAR) T-cell therapies targeting CD19, such as **Axicabtagene ciloleucel** (axi-cel), have emerged as a promising treatment option. However, evidence on their **safety** in real-world settings remains limited.

Aim and objectives

To evaluate the **safety** of axi-cel as third-line or later therapy in patients with relapsed/refractory DLBCL.

Materials and methods

Observational, retrospective, descriptive and multicenter study: between April 2019 to May 2025.

Variables:

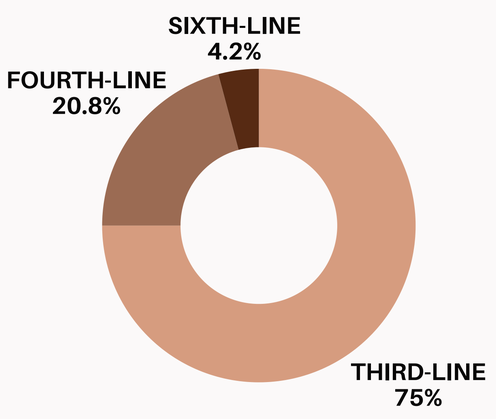
- **Demographic** (age, sex).
- **Clinical** (disease type, ECOG, transplant previous, treatment line, time to infusion, therapy follow-up).
- **Safety**: adverse events (Cytokine-Release-Syndrome [CRS]*, Immune-effector Cell-Associated Neurotoxicity Syndrome [ICANS]*, plasma alterations, infections, secondary-malignancies, mortality).

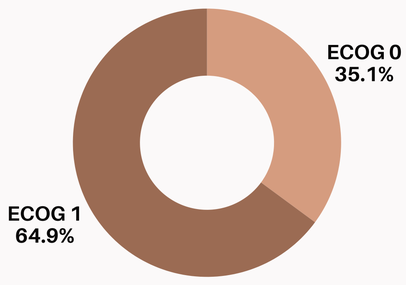
Data were obtained from medical records and prescription systems, and analyzed using descriptive statistics

** Stratified according to the American Society for Blood and Marrow Transplantation consensus of 2018.*

Results

37 patients: mean age 54.1±15.8 years; 59.7% male. 83,78% DLBCL, 6 patients withtransformed follicular lymphoma. Seven had prior transplants: 5 autologous. Median of 2.7 months sincelast relapse.





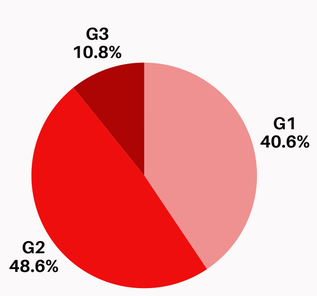
Median therapy follow up

14.7 months

[0.4 - 62.2]

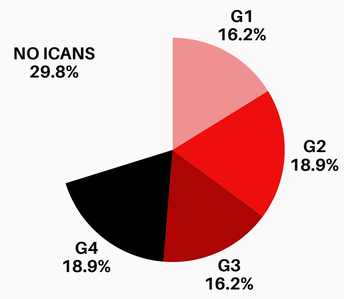
Infections: **virals** (48.6%), **bacterials** (48.6%), **fungals** (8.1%), **parasitics** (2.7%). Notably: COVID-19 (33.3%), CMV reactivation (27.8%), Clostridium difficile (38.9%).

Secondary malignancies: 5.4% (therapy-related myelodysplastic syndromes).



CRS: 100%. Median onset 1; median duration 5 days. 37.8% required corticosteroids and 73% tocilizumab (median: 2 doses; max: 4 doses).

ICANS: 70.3%. Median onset 6 days; median duration 5 days. Treatment: dexamethasone (20 patients), methylprednisolone (6), anakinra (10; median: 7 doses), and siltuximab (2).



Tumor lysis: 0%.

Macrophage activation syndrome: 0%.

Plasma alterations: 13.5% hypofibrinogenemia and 48.6% hypogammaglobulinemia, with corresponding supportive therapies.

ICU admission (37.8%)

Mortality (35.1%, 13)

Progression (6)
Early Complications (4)
Late Complications (3)

Conclusion and relevance

In this real-world cohort, axi-cel showed predictable but significant toxicity, including universal CRS and cytopenias, frequent ICANS and infections, and substantial supportive care needs. These results highlight the importance of close monitoring, multidisciplinary management, and long-term follow-up for patients undergoing CAR-T therapy.

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