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REAL-WORLD TOXICITY AND MANAGEMENT OF CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPIES TARGETING CD19 IN PATIENTS WITH HEMATOLOGICAL MALIGNANCIES.

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Background and importance

Chimeric antigen receptor-T (CAR-T) have demonstrated clinical efficacy in hematologic malignancies, however they also have a relevant toxic side effect profile.

Aim and objectives

To describe toxicity and management of CAR-T cell therapies(CARTs) (Tisagenlecleucel(Tisa-cel)and axicabtagene ciloleucel(Axi-cel)) in "real world" population with hematological malignancies

Material and methods

Retrospective study that included all patients treated with CARTs in our hospital (August 2019-September 2020).

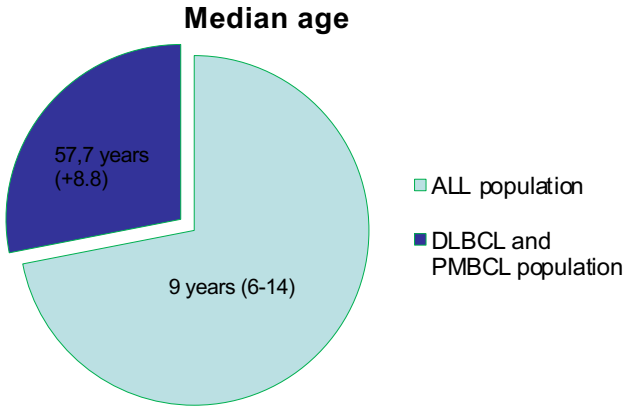
Data collected included age, gender, diagnosis, hospital stay, admission to intensive care unit (ICU), lenght of ICU stay and the main adverse events (AE) detected: (cytokine release syndrome(CRS), neurologic toxicity, hypogammaglobulinemia, febrile neutropenia and infections) and tocilizumab and/or corticosteroids given to treat these AE.

Statistical analysis was performed using SPSS V.21.0.

Results

32 patients, 53.1% men. Axi-cel was administered in 53.1% of patients, of which 70.6% had Diffuse Large B-Cell Lymphoma(DLBCL) and the remaining, Primary Mediastinal Large B-cell Lymphoma(PMBCL). The rest were treated with tisa-cel, 60.0% had DLBCL and the others B-cell precursor Acute Lymphoblastic Leukemia (ALL).

CRS and febrile neutropenia rates were similar in patients treated with tisa-cel and axi-cel (73.7% vs 88.2% and 80.0% and 76.5%, respectively). Neurological toxicity was more frequent with axi-cel (52.9% vs 20%).



	Patients (n=32)
Median hospital stay	
- **Days**	**46,8% (n=15)**
Admission to ICU	**15,6% (n=5)**
AE	
- **Mild Hipersensitivity Reaction**	**6,25% (n=2)**
- **CRS**	**81,3% (n=26)**
- **Neurologic toxicity**	**37.5% (n=12)**
- **Febrile neutropenia**	**78.1% (n=25)**
- **Active infections**	**15.6% (n=5)**
- **Hypogammaglobulinemia**	**9,4% (n=3)**
Administration	
- **Tocilizumab and Corticosteroids**	**21.9% (n=7)**
Dead patients during admission	**6,25% (n=2)**

Conclusion and Relevance

CAR T-cell therapy was generally well tolerated with a low rate of severe or life-threatening AE.CRS was the most frequent AE, no differences were found between axi-cell and tisa-cel. The needs of neurological toxicity rates was similar to observed in clinical trials with tisa-cel and lower with axi-cel. The needs of tocilizumab and/or corticosteroids in axi-cel patients were lower than in clinical trial.