5PSQ-014

POST CART-T CELLS CRS: CLINICAL TRIALS VS REAL LIFE

E. BLAISONNEAU[1], C. HAMON[1], R. WILSON[1], N. LE BRAS[1], V. JASPART-LE DU[1], A. CHANAT[1]

1. Pharmacy department, Rennes University Hospital, Rennes, France

Background and importance

Our university hospital has been a investigator in CAR-T clinical trials since their early development. This experience positions us at the forefront of this therapeutic innovation. The pharmacists at the University Hospital are an important player in CAR-T cell therapy, both in clinical research and routine practice.

CAR-T cell therapy represents a breakthrough in treating blood cancers. However, it can cause severe side effects that require specialized management.

Cytokine Release Syndrome (CRS) is one of the most common and serious complications of CAR-T and BsAbs therapy. It occurs when:

- CAR-T cells and BsAbs trigger massive immune activation
- The body releases excessive cytokines, especially interleukin-6 (IL-6)
- This inflammatory response can rapidly lead to multiorgan failure
- Early recognition and urgent treatment are essential

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) is a potentially severe neurological toxicity associated with immune effector cell therapies, particularly CAR-T cells and some bispecific antibodies. It manifests with symptoms ranging from mild confusion and language disturbances to seizures, cerebral edema, and coma, and is thought to result from immune-mediated inflammation affecting the central nervous system.

Materials and methods

Retrospective single-center study

01 January, 2020 and 01 July, 2025

All patients who received CAR-T therapy : in clinical trials and in real-life

- Demographics (Sex, Age, ...)
- Indications
- Adverse events and their management

Aim and objectives

To compare the incidence, severity, and management of CRS after CAR-T infusion in clinical trials versus standard-of-care patients at our university hospital.

Results

Demographics

	Real-life population (n = 361)		p-value
Sexe - Male - Female	 230 131	 27 13	0.6356
Age (in years) - Median - Standard deviation	 62,7 14,2	 59,1 13,6	0.1202
Weight (inkg) - Median - Standard deviation	 69,1 14,5	 77,2 24,7	0.0481
Recovery Death	195 5	20 0	0.999

Indication

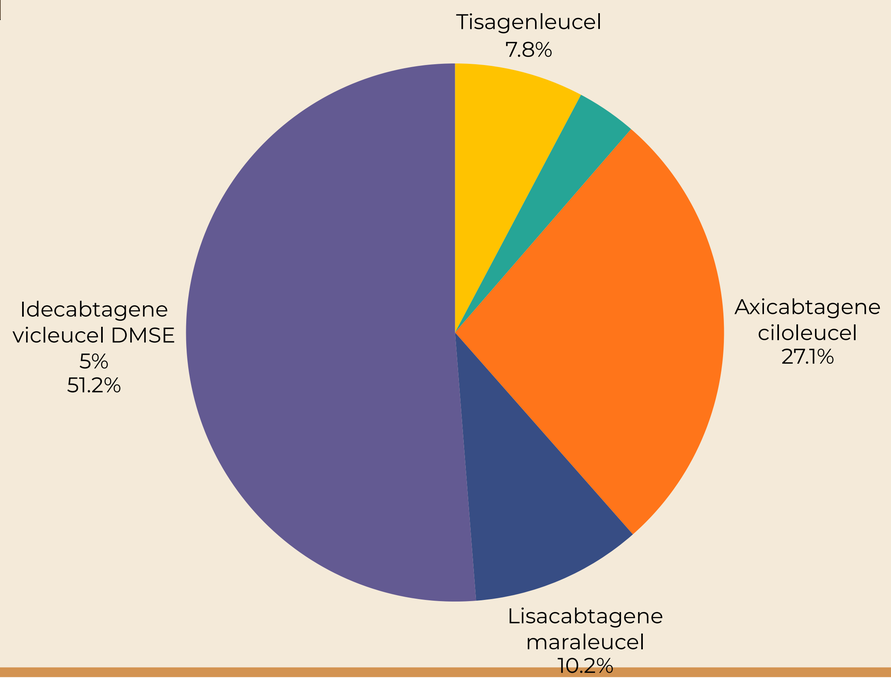
Real-life

1 - Relapsed/refractory B-cell NHL (DLBCL type ⩾ 3rd line) (150/361 - 41.6%)
2- Refractory B-cell lymphoma (DLBCL as 2nd line therapy) (78/361 - 21.6%)
3 - Multiple myeloma (71/361 - 19.7%)

Clinical trials

1 - Refractory B-cell lymphoma (DLBCL in second-line treatment) (14/40 - 35.0%)
2- Relapsed/refractory aggressive NHL (PMBCL ⩾ second-line treatment) (10/40 - 20.0%)
3 - Acute B-cell leukemia (8/40 - 20.0%)

CAR-T cells used in the general population



CRS and ICANS

CRS	Real-life population (n = 361)	Clinical trials population (n = 40)	p-value
Yes - Grade 1 - Grade 2 - Grade 3	303 255 45 3	20 13 5 2	0.0270
No	57	20	

ICANS	Real-life population (n = 361)	Clinical trials population (n = 40)	p-value
Yes -Grade 1 -Grade 2 -Grade 3 -Grade 4 Not applicable	52 6 27 17 2 113*	16 8 4 2 2 -	0.0286
No	309	32	

*use of dexamethasone alone (n = 8), use of the combination of dexamethasone and tocilizumab (n = 105)

Treatment with tocilizumab

	Real-life population (n = 361)	Clinical trials population (n = 40)	p-value
Total number of patients who received tocilizumab	200	20	0.6124
Average dose (in mg)	555.2	581.3	0.2145
Time to administration from the start of CRS (in days)	2.0	3.7	0.0001
Number of injections per patient	1.9	2.5	0.0031
Concomitant use of corticosteroids	53.5%	65.0%	0.1806

Discussion et conclusion

CRS incidence and severity after CAR-T therapy were broadly comparable between clinical trials and real-life practice, but supportive measures were implemented later outside trials. Reinforcing staff training and standardizing management pathways could improve the handling of this toxicity in routine settings.