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ORAL ABSTRACTS

705.CELLULAR IMMUNOTHERAPIES: LATE PHASE AND COMMERCIALLY AVAILABLE THERAPIES

Predictors of Cytokine Release Syndrome and Neurotoxicity in Patients with Large B-Cell Lymphoma and Their Impact on Survival

Roni Shouval, MD PhD[1], Christopher Strouse, MD[2], Soyoung Kim, PhD[3,4], Temitope Oloyede, MPH[4], Sairah Ahmed, MD[5], Farrukh T. Awan, MD[6], Veronika Bachanova, MD PhD[7], Talha Badar, MD[8], Pere Barba, MD[9], Amer M. Beitinjaneh, MD MS[10], Amanda F Cashen[11], Bhagirathbhai Dholaria, MBBS[12], Mahmoud Elsawy, MD MSc[13], Siddhartha Ganguly, MD[14], Praveen Ramakrishnan Geethakumari, MD MS[15], Uri Greenbaum, MD[16], Hamza Hashmi, MD[17], Laquisa C. Hill, BS, MD[18], Michael D. Jain, MD PhD[19], Tania Jain, MD[20], Partow Kebriaei, MD[21], Adam S Kittai, MD[22], Frederick L. Locke, MD[19], Premal D. Lulla, MBBS[23], Elena Mead, MD[24], Joseph P McGuirk, DO[25], Alberto Mussetti[26], Taiga Nishihori, MD[19], Amanda L. Olson, MD[21], Martina Pennisi[27], Miguel-Angel Perales, MD[28], Peter A. Riedell, MD[29], Wael Saber, MDMS[30], Sayeef Mirza, MDMPH[19], Margarida Magalhaes-Silverman, MD[31], Elizabeth J. Shpall, MD[21], Mohamed Sorror, MDMSc[32,33], Kitsada Wudhikarn, MD[34], Cameron J. Turtle, MBBS, PhD[32,35], Marcelo Pasquini, MDMS[36,37], Amy Moskop, MD[38,39]

[1] Adult BMT Service, Memorial Sloan Kettering Cancer Center, New York, NY
[2] Division of Hematology, Oncology and Blood & Marrow Transplantation, Holden Comprehensive Cancer Center, University of Iowa Hospitals and Clinics, Iowa City, IA
[3] Division of Biostatistics, Institute for Health and Equity, Medical College of Wisconsin, Milwaukee, WI
[4] CIBMTR® (Center for International Blood and Marrow Transplant Research), Department of Medicine, Medical College of Wisconsin, Milwaukee, WI
[5] Department of Lymphoma/Myeloma and Stem Cell Transplantation, The University of Texas MD Anderson Cancer Center, Houston, TX
[6] Division of Hematology and Oncology, University of Texas Southwestern Medical Center, Dallas, TX
[7] Bone and Marrow Transplant Program, University of Minnesota Medical Center, Minneapolis, MN
[8] Division of Hematology-Oncology, Blood and Marrow Transplantation Program, Mayo Clinic, Jacksonville, FL
[9] Deparment of Hematology, Vall D'Hebron Institute of Oncology (VHIO), Hospital Universitari Vall D'Hebron, La Garriga, Spain
[10] Division of Transplantation and Cellular Therapy, University of Miami Hospital and Clinics, Sylvester Comprehensive Cancer Center, Miami, FL
[11] Washington University School of Medicine in St. Louis, St Louis, MO
[12] Division of Hematology/Oncology, Vanderbilt University Medical Center, Nashville, TN
[13] Division of Hematology, Department of Medicine, Dalhousie University, Halifax, Canada
[14] Houston Methodist Hospital and Neal Cancer Center, Houston, TX
[15] Section of Hematological Malignancies and Cellular Therapy, Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Dallas, TX
[16] Soroka University Medical Center, Beer Sheva, Israel
[17] Medical University of South Carolina, Charleston, SC
[18] Baylor College of Medicine, Center for Cell and Gene Therapy, Houston, TX
[19] Department of Blood and Marrow Transplantation and Cellular Immunotherapy, Moffitt Cancer Center, Tampa, FL
[20] Johns Hopkins University, Baltimore, MD
[21] Department of Stem Cell Transplantation and Cellular Therapy, The University of Texas MD Anderson Cancer Center, Houston, TX
[22] Division of Hematology, The Ohio State University, Columbus, OH
[23] Center for Cell and Gene Therapy, Baylor College of Medicine, Houston Methodist Hospital, Texas Children's Hospital, Houston, TX
[24] Cellular Therapy Service, Memorial Sloan Kettering Cancer Center, New York, NY
[25] University of Kansas Medical Center, Westwood, KS
[26] Clinical Hematology Department, Institut Català d'Oncologia-Hospitalet, IDIBELL, Barcelona, Spain

[27] Hematology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milano, Italy
[28] Adult Bone Marrow Transplantation Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY
[29] Department of Medicine, Section of Hematology/Oncology, University of Chicago, Chicago, IL
[30] Medical College of Wisconsin, Milwaukee, WI
[31] Holden Comprehensive Cancer Center, University of Iowa Hospital and Clinics, Iowa City, IA
[32] Fred Hutchinson Cancer Center, Seattle, WA
[33] University of Washington School of Medicine, Seattle, WA
[34] Chulalongkorn University and King Chulalongkorn Memorial Hospital, Bangkok, Thailand
[35] Faculty of Medicine and Health, University of Sydney, Sydney, Australia
[36] Froedtert & The Medical College Cancer Ctr., Milwaukee, WI
[37] Center for International Blood and Marrow Transplant Research, Medical College of Wisconsin, Milwaukee, WI
[38] Center for International Blood and Marrow Transplant Research, Department of Medicine, Medical College of Wisconsin, Milwaukee, WI
[39] Division of Pediatric Hematology/Oncology/Blood and Marrow Transplant, Department of Pediatrics, Medical College of Wisconsin, Milwaukee, WI

Background: Autologous CAR-T therapy targeting CD19 is an effective treatment for relapsed or refractory large B-cell lymphoma (LBCL). However, morbidity and mortality related to CAR-T toxicity remain significant concerns. This study aims to evaluate the patterns, risk factors, and implications of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) following CD19-CAR-T therapy in LBCL.
Methods: This retrospective analysis includes 1916 LBCL patients treated with CD19-CAR-T cell therapy (axicabtagene-ciloleucel [axi-cel] 75% and tisagenlecleucel 25%) between 2018 and 2020 and reported to the Center for International Blood and Marrow Transplant Research (CIBMTR). Patient demographics, baseline characteristics, treatment-related variables, and clinical outcomes were collected. The incidence, severity and timing of onset of CRS and ICANS (according to median time to onset) were analyzed, factors associated with these outcomes and their impact on overall survival as time dependent covariates were done using Cox Regression multivariate analyses.
Results: The median age of the patients was 64 years, with a majority having a Karnofsky performance status (KPS) below 90% (61%) and not receiving bridging therapy (67%). CRS was observed in 75.1% of patients, with 9% experiencing severe CRS (grades $\geq$ 3). Similarly, 43% of patients experienced ICANS, with 20% having severe ICANS (grade $\geq$ 3). The median time to toxicity was shorter for CRS (4 days) compared to ICANS (7 days). Nearly all the patients who developed ICANS also experienced CRS (98%;), and the correlation between these two events and respective severities are shown in the Figure 1a. In the multivariate analyses, factors associated with development of CRS were gender (women, Odds ratio [OR] 1.39, 95% confidence interval [CI] 1.10- 1.76, p=0.006), high LDH at time of infusion (OR 1.56; 95% CI 1.22 - 2.00, p=0.002) and product (axi-cel OR 4.60, 95% CI 3.56 -5.81, p<0.001). Factors associated with the development of ICANS included age (> 65 years, OR 1.83; 1.50-2.24, p<0.001), KPS (<80%, OR 2.48; 1.88-3.27, p<0.001), disease status at infusion (treatment resistant disease, OR 1.98; 1.09-3.58, p=0.024; and untreated relapse OR 2.62, 1.35-5.10, p=0.004) and product (axi-cel, OR 5.85; 4.47-7.64, p<0.0001). Factors associated with severe and early onset CRS and ICANS are listed in the table below.
The median follow-up of 14.2 months, the estimated 12-month overall survival, progression-free survival (PFS), and treatment-related mortality were 61.6% (95% CI: 59.4-63.9), 42.2% (39.9-44.5), and 4.3% (3.4-5.3), respectively. Overall CRS, early onset CRS and overall ICANS were not associated with higher mortality, however grade >3 CRS (HR 1.79; 1.41-2.28, p<0.001), grade >3 ICANS (hazard ratio [HR] 1.34; 95% CI 1.13-1.59, p=0.002) and early onset ICANS (<7 days, HR 1.23; 1.05-1.44, p=0.01) were associated with higher mortality. The impact of severe CRS on survival are shown in the landmark analysis at 30 days from infusion in the figure 1B.
Conclusion: In the largest analysis of CD19-CAR-T cell therapy toxicities to date, we observed a high burden of CRS and ICANS among LBCL patients. The CAR T cell product type was consistently associated with higher incidence, shorter onset and higher severity of both toxicities. High LDH, older age and low performance score also influence the severity and onset of these outcomes. Additionally, patients who developed higher grades of CRS/ICANS and earlier onset ICANS had a higher mortality, stressing the need to develop novel strategies to mitigate the incidence and optimize management of these patients to improve their outcomes.

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Figure 1: Relationship between CRS and ICANS severity (A). Landmark analysis at 30 days post infusion to assess the impact of CRS on survival (B).

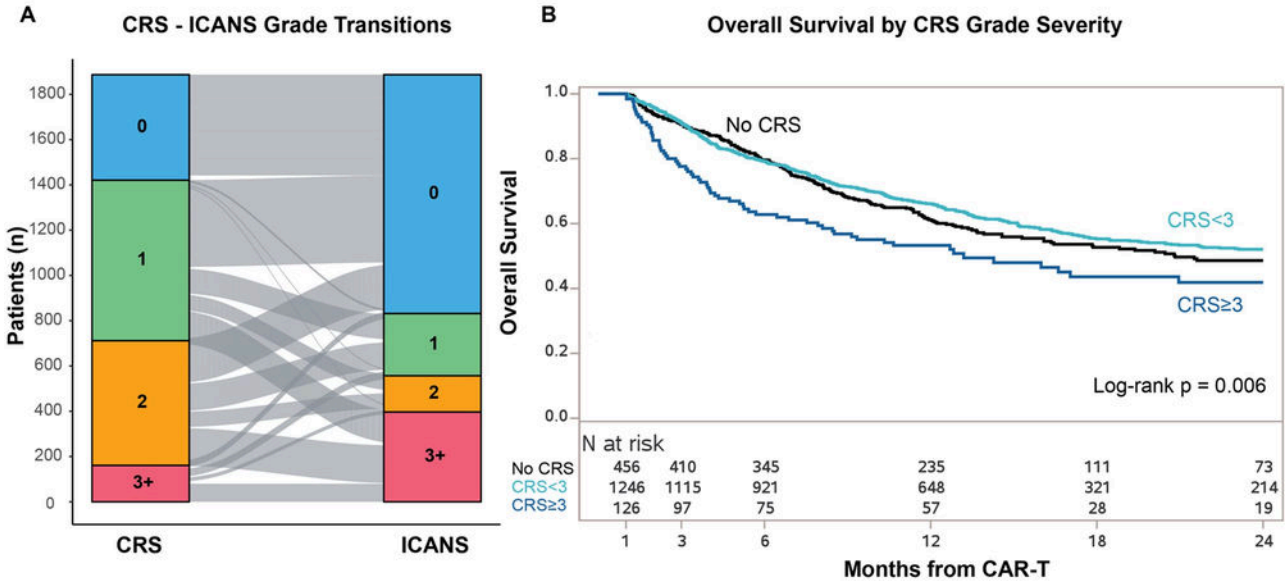

Table 1: Multivariate analysis of severity and time to onset of CRS and ICANS

	Severe CRS (Gr ≥3 vs <3 & no CRS)	Onset CRS (≤ 4 days vs > 4 days & no CRS)	Severe ICANS (Gr ≥3 vs <3 & no ICANS)	Onset ICANS (≤ 7 days vs > 7 days & no ICANS)
Age	p<0.001*		p<0.001*	p<0.001*
<65	1.0		1.0	1.0
≥65	1.6 (1.15-2.23)‡		1.55 (1.22-1.98)‡	1.73 (1.39-2.15)‡
Performance Score	p<0.001*		p<0.001*	p<0.001*
90-100%	1.0		1.0	1.0
80%	1.63 (1.05-2.54)†		1.24 (0.90-1.69)‡	1.19 (0.91-1.55)†
<80%	3.31 (2.15-5.10)‡		2.85 (2.07-3.93)‡	2.07 (1.56-2.73)†
unknown	1.53 (0.87-2.72)‡		2.76 (1.91-3.99)‡	1.45 (1.03-2.05)†
LDH at Infusion		p<0.001*	p=0.007*	p=0.005*
Normal		1.0	1.0	1.0
Elevated		1.67 (1.36-2.05)‡	1.51 (1.15-2.00)‡	1.40 (1.10=1.79)†
unknown		1.25 (0.96-1.65)	1.09 (0.77-1.55)	0.96 (0.71-1.32)
Product	p<0.001*	p<0.001*	p<0.001	p<0.001*
Tisagenlecleucel	1.0	1.0	1.0	1.0
Axicabtagene Ciloleucel	2.11 (1.36-3.29)‡	1.45 (1.17-1.81)‡	5.65 (3.92-8.35)‡	4.02 (2.95-5.49)‡

*Overall p-value, † p<0.05, ‡ p<0.001

Figure 1

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