Hybrid Academic/Community Cellular Therapy Program, Adverse Events, and Outcomes After CAR-T Therapy in Hematological Malignancies, Including Outpatient Experience

A Retrospective Chart Review

Haven Curtis[2]; Cheryl Martinez, MS, RN, AGACNP-BC[1]; Virginia Simmons, MPH, MS[1]; Bhumika Patel, MD[1,2]; Saeeda Chowdhury, MD[1,2]; Elizabeth Cull, MD[1,2]; Megan Christmas, RN, MSN, BMTCN[1]; Suzanne Fanning, DO[1,2]

[1]Prisma Health Cancer Institute, [2]University of South Carolina School of Medicine Greenville

Introduction

CAR-T therapy has revolutionized the treatment of hematological malignancies and improved responses. With increasing use of CAR-T therapy, there is a need to increase knowledge regarding patient safety related to therapy and its adverse effects (AEs), like cytokine release syndrome (CRS) and immune-effector cell-mediated neurotoxicity syndrome (ICANS), especially in the community setting. As more therapies move to the outpatient setting, there is a need to understand if certain trends can predict the incidence of these toxicities and their impact on disease outcomes.

Purpose

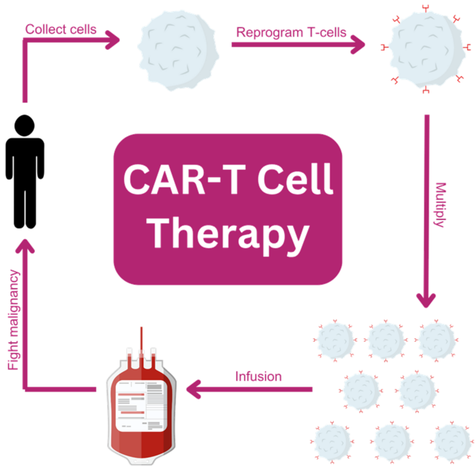
The purpose is to contribute to existing knowledge about patient AEs and clinical outcomes related to CAR-T therapy at a single academic/community institution's CT program.

Methods

A retrospective secondary data analysis will be performed. AEs to treatment, trends in laboratory results, treatment response, and clinical outcomes/survival rates at different time points are of interest. Statistical analyses will evaluate trends of adverse reactions and outcomes, including descriptive statistics and logistic regressions.

Patient Characteristics

All	N=47
Sex	
Male	56%
Female	44%
Race	
Black or African American	21%
Hispanic	8%
White or Caucasian	67%
Other	4%
Ethnicity	
Hispanic or Latino	8%
Not Hispanic or Latino	90%
Other	2%
Diagnosis	
Acute lymphocytic leukemia (ALL)	2%
Diffuse large B-cell lymphoma (DLBCL)	47%
Mantle cell lymphoma (MCL)	9%
Multiple myeloma (MM)	40%
Relapsed follicular lymphoma (FL)	2%



Results

In the preliminary assessment of data, 47 relapsed/refractory patients received CAR-T therapy at Prisma Health's CT program, 72% were infused outpatient and 28% inpatient. The cohort included patients diagnosed with diffuse large B-cell lymphoma (47%), multiple myeloma (40%), mantle cell lymphoma (9%), acute lymphoblastic leukemia (2%), and follicular lymphoma (2%).

Only 2% of patients experienced grade IV CRS toxicity within the first 30-days of treatment. 60% of patients experienced grade I or II as their highest CRS toxicity. No patients experienced grade III CRS toxicity. 11% of patients experienced grade IV ICANS, 2% grade III, and 15% grade I or II. At 100 days, 38% of patients achieved a complete response, 21% very good partial response, 17% progressive disease, and 9% deceased. Almost 51% of patients at 100 days and 36% of patients within 6-months to 1-year mark from infusion had experienced at least one infectious complication including upper respiratory, urinary tract, integumentary, and gastrointestinal infections. Data collection is ongoing.

Highest Grade Toxicities within 30 Days

All	N=47
CRS Toxicity	
Grade I	40%
Grade II	19%
Grade III	0%
Grade IV	2%
ICANS	
Grade I	11%
Grade II	4%
Grade III	2%
Grade IV	11%

Response to Therapy at 100 Days

All	N=47
Response	
Complete Response	38%
Very Good Partial Response	21%
Progressive Disease	17%
Deceased	9%

Conclusion

Ongoing data collection and analysis allows the program to evaluate the quality of patient care and safety and will add to the real-world knowledge of trends of clinical outcomes in CAR-T treatment.

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UNIVERSITY OF SOUTH CAROLINA School of Medicine Greenville

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