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Evaluating Risk of Complications in CAR-T Cell Therapy Among Patients With Acute Lymphocytic Leukemia

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Introduction

CAR-T cell therapy is an emerging and potentially life-saving final treatment option for patients with treatment-resistant acute lymphocytic leukemia (ALL). However, this therapy does not come without consequences; patients who undergo CAR-T are at risk of major health complications.[1,2]

Objective

The objective of this study is to identify the risk of complications of CAR-T. This study investigates differences in biochemical lab data between patients treated with CAR-T and those treated with standard chemotherapy.

Methods

Study Design

- This retrospective cohort study, conducted for the period of January 1, 2021, through December 31, 2022, leveraged Komodo's Healthcare Map™, a claims database that encompasses medical, laboratory, and pharmaceutical encounters of over 330 million patients in the US.

Inclusion/Exclusion Criteria

- These cohorts included patients of all ages and genders with a diagnosis of ALL during the study period (using ICD-10-CM codes) and a history of chemotherapy or CAR-T (using NDC, HCPCS, CPT, and ICD-10-PCS codes).

Key Study Variables

- Lab values for bilirubin (mg/dL), hematocrit (percent), and hemoglobin (g/dL) were recorded and compared for each cohort.

Results

7,789 patients with lab data were diagnosed with ALL within the study period. Of these, 45.8% were treated with chemotherapy and 1.5% with CAR-T. The average levels of bilirubin, hematocrit, and hemoglobin in each treatment cohort were compared with the average levels of ALL patients (the baseline cohort).

Hematologic levels of patients in the baseline cohort, patients treated with chemotherapy, and patients treated with CAR-T were found to lie outside the normal range of results; these patients had high bilirubin levels, low hematocrit levels, and low hemoglobin levels. Abnormal results in these measurements are likely to indicate risk of anemia, making patients undergoing cancer treatments more at risk when results are further away from normal ranges.

Figure 1. Sample Selection

Patients with ≥1 acute lymphocytic leukemia (ALL) diagnosis codes and lab data during identification period
(January 1, 2021, through December 31, 2022)
Index date: First ALL diagnosis
N = 7,789

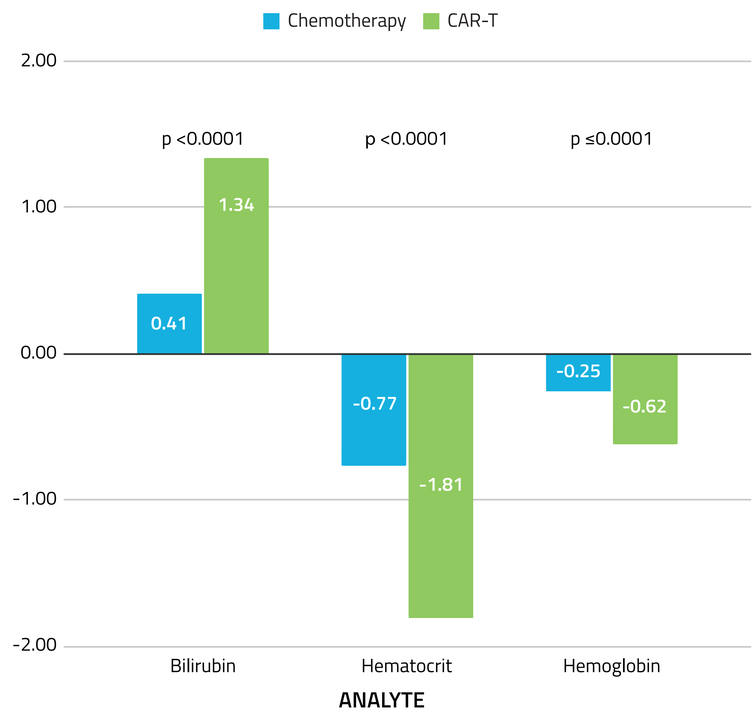
Patients treated with chemotherapy
N = 3,571 (45.8%)

Patients treated with CAR-T therapy
N = 114 (1.5%)

Chemotherapy patients had bilirubin levels that were, on average, 0.41 mg/dL higher than the baseline cohort, hematocrit levels that were 0.77 percentage points lower, and hemoglobin levels that were 0.25 g/dL lower. Conversely, CAR-T patients had bilirubin levels that were, on average, 1.34 mg/dL higher than the baseline cohort, hematocrit levels that were 1.81 percentage points lower, and hemoglobin levels that were 0.62 g/dL lower. All observed differences were statistically significant.

Although the results from both treatment cohorts were abnormal compared to the baseline cohort, patients who had undergone CAR-T experienced a larger difference in hematologic levels than those who had undergone chemotherapy.

Figure 2. Hematological Differences From Baseline Cohort by Treatment Type



Conclusion

- The magnitude of all observed hematologic differences in ALL patients treated with CAR-T therapy was larger than in those treated with chemotherapy.
- These differences must be considered by patients undergoing such treatments and their providers.

References

[1] Sheykhhasan, M., Manoochehri, H., Dama, P. Use of CAR T-cell for acute lymphoblastic leukemia (ALL) treatment: a review study. Cancer Gene Ther. 2022 Jan;29:1080-1096.

[2] Cappell, K.M., Kochenderfer, J.N. Long-term outcomes following CAR T cell therapy: what we know so far. Nat Rev Clin Oncol. 2023 Apr;20:359-371.

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