Abstract

Monitoring Toxicities in Patients Undergoing Chimeric Antigen Receptor T-Cell Therapy: A Prospective Observational Study

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Introduction. Chimeric antigen receptor T-cell (CAR-T) therapy has improved outcomes in relapsed/refractory hematologic malignancies, but it is associated with severe toxicities, including cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), cytopenias, and infections. Early monitoring of toxicities and patient-reported outcomes (PROs) during hospitalization remains poorly described. The aim of this study was to assess treatment-related toxicities and patient-reported outcomes in patients receiving CAR-T-cell therapy.

Methods. A prospective, single-center, observational study was conducted in patients treated with CAR-T-cell therapy between April 2022 and April 2025. Major complications and PROs were assessed during hospitalization at baseline (T0), day 7 (T1), and day 14 (T2). The tools used included the ICE score, EuroQol-5D (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Patient-Generated Subjective Global Assessment (PG-SGA), and Cancer Linear Analogue Scale (CLAS). Hematologic risk was stratified using the CAR-HEMATOTOX score. Statistical analysis included descriptive statistics and longitudinal analyses across time points, with statistical significance set at $p < 0.05$.

Results. Fifty-seven patients were included; 59.6% were male, with a median age of 59.4 years. Mean hospital stay was 20.65 days, and 7% required intensive care. Severe grade 3-4 ICANS occurred in 3.6% of patients, while CRS developed after a mean of 2.69 days and was grade 3-4 in 5.3% of cases. Anxiety decreased over time ($p = 0.038$; T0-T2 $p = 0.020$), whereas depression remained stable. CLAS scores for mobility, energy, and daily activities did not change significantly, while overall quality of life improved between T1 and T2 ($p = 0.025$). PG-SGA scores worsened from T0 to T1 and improved from T1 to T2 (both $p < 0.001$). Overall, 33.3% of patients were classified as high risk according to CAR-HEMATOTOX.

Discussion. CAR-T-cell-related toxicities were overall manageable. Validated assessment scales supported the early recognition of complications and the identification of patient needs. Integrating patient-reported outcomes into clinical monitoring may enhance individualized care, patient safety,

and continuity of care.

Keywords: CAR-T Therapy, Toxicities, Patient-Reported Outcomes

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