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Analysis of 60 patients with relapsed or refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma treated with CD7-targeted chimeric antigen receptor-T cell therapy

Xian Zhang [1 2], Junfang Yang [1 2], Jingjing Li [1 2], Liyuan Qiu [1 2], Jianping Zhang [1 2], Yue Lu [1 2], Yan-Li Zhao [1 2], David Jin [2], Jianqiang Li [3], Peihua Lu [1 2]

Affiliations

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[No authors listed]

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Abstract

While the use of chimeric antigen receptor-T (CAR-T) therapy for T-cell malignancies is in the early stage of clinical trials, it exhibits substantial potential to offer long-term remission for patients with refractory/relapsed (R/R) T-cell malignancies. In our phase I/II clinical trials, 65 pediatric and adult patients with R/R T-cell acute lymphoblastic leukemia and lymphoblastic lymphoma (T-ALL/LBL) were enrolled (NCT04572308 and NCT04916860). Of these, 60 participants (T-ALL 35, T-LBL 25) received a single dose of naturally selected anti-CD7 CAR (NS7CAR) T cells at three levels: a low dose (5×10^5 /kg), a medium dose (1 to 1.5×10^6 /kg), and a high dose (2×10^6 /kg). On day 28, 94.4% of patients achieved deep complete remission (CR) in bone marrow. Among the 32 patients with extramedullary disease, 78.1% showed response, with 56.3% in CR and 21.9% in partial remission. The 2-year overall survival and progression-free survival (PFS) were 63.5% (95% CI 47.7-79.4) and 53.7% (95% CI, 38.9-68.6), with no difference between pediatric and adult patients. PFS was significantly higher among the 37 CR patients who proceeded with consolidation transplant than the 10 patients who did not with 1-year PFS 67.2% (95% CI 51.9-82.4) versus 15.0% (95% CI 0-40.2), $p < .0001$. Of the 10 CR patients without transplants, eight relapsed, while two sustained CR on day 128, and day 180, respectively. Cytokine release syndrome occurred in 91.7% of patients (grade 1/2 in 80.0%, grade 3/4 in 11.7%) and 5% of patients had neurotoxicity. NS7CAR-T therapy is effective in treating R/R T-ALL/LBL patients with promising PFS while maintaining a manageable safety profile.

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