



The 65th ASH Annual Meeting Abstracts

ONLINE PUBLICATION ONLY

905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

A Real-World Single-Center Report on the Effectiveness and Safety of Blinatumomab Treatment on Pediatric Acute Lymphoblastic Leukemia in ChinaXiaolan Li^{1,2}, Jingliao Zhang, MD^{1,2}, Xiaofan Zhu^{3,2}, Wenyu Yang^{2,1}

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Background: Studies overseas have demonstrated blinatumomab benefits pediatric acute lymphoblastic leukemia (ALL), but the experience is limited in China.

Methods: We retrospectively collected 28 pediatric ALL patients in our center who received blinatumomab treatment since August 2021. All patients were diagnosed with B-ALL with CD19 expression on cell surface. Patients were divided into three groups: clearance of minimal residual disease (MRD) in first complete remission (MC, 18/28), supplement therapy during chemotherapy intolerance (IC, 3/28) and reinduction therapy for refractory or relapsed ALL (RR, 7/28).

Results: The age of 28 patients (16 males and 12 females) ranged from 0.6 to 16.4 years (median, 11.0 years). *BCR::ABL1* fusion was found in 6 patients in MC group and 1 patient in RR group. The reasons for chemotherapy intolerance included pancreatitis, infection, and endocarditis. The median interphase from diagnosis to blinatumomab was 3.7 (range: 0.7 to 39.8) months, 1.4 (range: 1.1 to 16.8) months and 29.0 (range: 4.9 to 62.1) months in MC, IC and RR groups, respectively. Most patients accepted 14 to 28 days of uninterrupted infusion except 1 patient in MC group received 7 days treatment for economic issue and 2 patients in MC group discontinued therapy for severe reaction in 1 or 2 days. 7 patients received 1 to 3 more cycles of blinatumomab if MRD decreased after the first cycle. In MC group, the median MRD level in bone marrow before blinatumomab, detected by flow cytometry (FC) or by real time PCR (RT-PCR) if recurrent fusion genes were positive, was 0.145% (range: 0.01% to 4.00%). MRDs were turned negative in 13 patients (72.2%) by both FC and RT-PCR, while the MRDs in the other 5 patients with *BCR::ABL1* fusion gene, of whom 3 were positive in both FC and RT-PCR and 2 were only positive in RT-PCR, were returned negative in FC but still positive in RT-PCR. In terms of safety, one patient developed grade 4 immune effector cell associated neurotoxicity syndrome on the second day of infusion. The most common reaction was fever in 9 cases in cycle 1 (9/18). In IC group, all 3 patients with negative MRD before treatment maintained their negative status, with only fever occurring (3/3) during the early stage of infusion. In RR group, the median MRD level before treatment was 8.37% (range: 0.08% to 78.3%). 4 patients (57.1%) with lower MRD (0.08% to 8.37%) by FC before blinatumomab attained MRD negativity, while 3 patients (42.9%) with higher MRD (22.64% to 78.3%) failed. The patient with *BCR::ABL1* fusion gene turned MRD negative by FC after blinatumomab, but remained positive by RT-PCR. Two patients (2/7) had cytokine release syndrome of grade 2, and 3 cases only had fever. No other severe or fetal adverse reactions were observed.

Conclusions: Blinatumomab is an effective treatment for B-ALL MRD cleanup with a good safety profile. It may, however, not benefit patients with R/R B-ALL with high tumor loads before blinatumomab, and those who carry *BCR::ABL1* fusion gene. Studies with a larger sample size are needed to confirm the results.

Disclosures No relevant conflicts of interest to declare.

OffLabel Disclosure: Blinatumomab was used for clearance of minimal residual disease (MRD) in first complete remission or supplement therapy during chemotherapy intolerance, with informed consent from the guardians of the patients.

<https://doi.org/10.1182/blood-2023-184732>