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****Title: MULTIPLE SHORT-COURSE TREATMENT OF BLINATUMOMAB CONSOLIDATION THERAPY REDUCES CUMULATIVE RELAPSE RATE IN B-ALL PATIENTS WITH DAY 19 BONE MARROW MRD $\geq 1.0 \times 10^{-2}$ UNDER CCCG-ALL 2020 PROTOCOL** #**

Abstract Type: Publication Only

Topic: Acute lymphoblastic leukemia - Clinical

Background:

B-cell acute lymphoblastic leukemia (B-ALL) represents the most prevalent malignancy diagnosed in children and the 5-year overall survival (OS) rate has exceeded 90%. Early treatment response plays a pivotal role in prognosis of B-ALL. Minimal residual disease (MRD) assessment at day 19 of induction remission therapy measured by flow cytometry is crucial for risk stratification of B-ALL. In a cohort of 411 patients treated under CCCG-ALL 2020 protocol at the Children's Hospital of Soochow University, it was observed that B-ALL patients demonstrated a cumulative relapse rate (CRR) of 12%, on day 19 with bone marrow flow cytometry MRD $\geq 10^{-2}$ in contrast to a rate of 3.32% for those patients with MRD $< 10^{-2}$ ($P < 0.05$). Present treatment therapies targeting B-ALL patients who exhibit poor early treatment response have the potential to reduce relapse rates and improve the 5-year OS. Application of blinatumomab to conventional chemotherapy, either as consolidation or replacement therapy within intensified treatment regimens, have significantly improved disease-free survival in pediatric patients with B-ALL along with mitigating chemotherapy-related toxicities. However, the effect of short-course blinatumomab consolidation therapy on the prognosis of children with day 19 MRD $\geq 10^{-2}$ is currently unclear.

Aims:

To assess the effectiveness of multiple short-course (14 days) blinatumomab consolidation therapy in newly diagnosed B-ALL pediatric patients with poor early chemotherapy response.

Methods:

A retrospective analysis was conducted on 12 pediatric patients diagnosed with B-ALL and exhibiting bone marrow flow cytometry MRD levels $\geq 10^{-2}$ at day 19. Of these, 5 patients were male and 7 were female, with age ranging from 3 to 10 years. The clinical data of these B-ALL patients was collected from the Hematology Department of the Children's Hospital of Soochow University. These patients received short-course (14 days) blinatumomab consolidation as per CCCG-ALL 2020 protocol. Informed consent was obtained from the guardians of all the B-ALL patients prior to their study enrollment.

Results:

As of February 2024, all the 12 patients received multiple short-course blinatumomab consolidation therapy who were classified as intermediate risk for B-ALL. Out of the 12 patients, 8 patients underwent a single short-course of blinatumomab consolidation therapy, while 4 patients received 2 or more short-courses of blinatumomab consolidation therapy. Furthermore, 8 patients commenced blinatumomab consolidation therapy following induction, 3 patients during the consolidation phase, and 1 patient during maintenance. The average duration of follow-up was 13.1 months, with the longest follow-up period being 21 months and the shortest being 2 months. As of February 4, 2024, no instances of relapse were observed, demonstrating a CCR of 0%.

Summary/Conclusion:

The application of multiple short-course blinatumomab consolidation therapy demonstrated a potential trend in mitigating the risk of CRR among intermediate-risk pediatric B-ALL patients with poor early chemotherapy response. However, more clinical research and data are required to confirm these findings.

Keywords: relapsed/refractory, B cell acute lymphoblastic leukemia, Immunotherapy