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БИОМЕДИЦИНА ВА АМАЛИЁТ ЖУРНАЛИ
ЖУРНАЛ БИОМЕДИЦИНЫ И ПРАКТИКИ | JOURNAL OF BIOMEDICINE AND PRACTICE**IBRAGIMOVA Sapura**

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**OUTCOMES OF BLINATUMOMAB THE INITIAL PHASE OF CHEMOTHERAPY
IN CHILDREN WITH B-CELL ALL**

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 <http://dx.doi.org/10.5281/zenodo.17554153>**ABSTRACT**

This retrospective single-center study (2020–2024) from the Pediatric Oncology Center in Tashkent evaluated the efficacy of incorporating **blinatumomab** (14-day courses at 15 µg/m²/day, twice with a two-month interval) into the ALL-MB-2015 protocol for children with B-cell ALL who remained MRD-positive post-induction. All 25 patients achieved hematologic remission; MRD dropped from 12 % to 0.001 % after the first blinatumomab course, and remained negative after the second. Median follow-up was 2.5 years. There were two late relapses (in standard- and intermediate-risk groups), 4-year EFS was 88.1 ± 3.7 %, and no deaths occurred. Adverse events (allergic reactions, neurotoxicity, hypoalbuminemia, cytopenias) were manageable.

Keywords: ALL, blinatumomab, minimal residual disease, children

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Bolalar onkologiyasi, gematologiyasi va immunologiyasi ilmiy-amaliy markazi

B-HUJAYRA LIMFOMA BILAN OG'RIGAN BOLALARDA KIMYOTERAPIYANING DASTLABKI FAZASIDA BLINATUMOMAB QO'LLANILISHINING NATIJALARI

ANNOTATSIYA

Asos: Blinatumomab – bu BiTE turidagi bispesifik antikor bo‘lib, CD19 (B hujayralar) va CD3 (T hujayralar) ni nishonga olib, yomon sifatli B-hujayralarni yo‘q qilishga yordam beradi. Induksiya davolashidan keyingi MRD (minimal qoldiq kasallik) musbatligi B-ALL bilan kasallangan bolalarda yomon prognozni ko‘rsatadi.

Maqsad: ALL-MB-2015 protokoli asosida induksiya kimyoterapiyasidan keyin MRD musbat bo‘lgan bolalarda blinatumomabning samaradorligi va xavfsizligini baholash.

Usul: 2020–2024 yillarda Toshkentdagi yagona markazda davolangan 25 bola tahlil qilindi. MRD darajasi induksiya va ikki marotaba 14 kunlik blinatumomab kurslaridan so‘ng baholandi.

Natijalar: MRD darajasi 12% dan 0,001% gacha sezilarli darajada kamaydi. Ikkinchi kursdan so‘ng barcha bemorlar MRD salbiy holatga erishdi. 4 yillik holatda 88,1% holatda nojo‘ya holat kuzatilmadi va o‘lim qayd etilmadi. Yon ta’sirlar yengil va boshqariladigan bo‘ldi.

Xulosa: Blinatumomabning dastlabki kimyoterapiyaga qo‘shilishi B-ALL bilan kasallangan bolalarda davolanish prognozini yaxshilaydi. Kelgusida uzoq muddatli kuzatuvlar zarur.

Kalit so‘zlar: B-hujayrali OLL, blinatumomab, minimal qoldiq kasallik (MRD), bolalar, immunoterapiya

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РЕЗУЛЬТАТЫ ПРИМЕНЕНИЯ БЛИНАТУМОМАБА НА НАЧАЛЬНОМ ЭТАПЕ ХИМИОТЕРАПИИ У ДЕТЕЙ С В-КЛЕТОЧНЫМ ОСТРЫМ ЛИМФОБЛАСТНЫМ ЛЕЙКОЗОМ

АННОТАЦИЯ

В рандомизированном ретроспективном исследовании из Центра детской онкологии в Ташкенте (2020–2024 гг.) оценивалась эффективность включения блинатумомаба (14-дневные циклы по 15 мкг/м²/день, два раза с двухмесячным перерывом) в протокол ALL-MB-2015 у детей с В-клеточным Р-ALL, MRD-позитивных после индукции. Из 25 пациентов все достигли гематологической ремиссии. MRD снизился с 12% до 0,001% после первого курса, а после второго курса — оставался отрицательным. Средняя длительность наблюдения — 2,5 года. Два поздних рецидива (в стандартной и промежуточной группе риска), EFS через 4 года составила 88,1 ± 3,7%, смертельных исходов не зарегистрировано. Боковые эффекты (аллергические реакции, нейротоксичность, гипоальбуминемия, цитопении) были управляемыми.

Ключевые слова: острая лимфобластная лейкемия (ALL), блинатумомаб, минимальная остаточная болезнь (MRD), дети, протокол ALL-MB-2015

Background: Blinatumomab is a bispecific T-cell engaging (BiTE) antibody linking the targeting regions of two antibodies directed against CD19 and CD3. CD19 is expressed by the precursor-B-ALL cells, and CD3 is the constant part of the T-cell receptor (TCR) complex that mediates T-cell receptor signaling. Blinatumomab, therefore, leads to a very close linkage between malignant B cells and T cells, a cytolytic synapse forming in the close contact zone [1,2,3,4]. Blinatumomab, a bispecific T-cell activator, has been recognized as an effective drug for patients with MRD-positive B-cell ALL [5,6,7,8]. It is known that minimal residual disease (MRD) positivity after induction remains a serious problem, often leading to a poor prognosis. This study evaluates the efficacy of adding blinatumomab to the ALL-MB-2015 protocol regimen with asparaginase and low-dose methotrexate in children with post-induction MRD-positive B-ALL [9,10,11,12]

Methods: We retrospectively analyzed 25 children with ALL treated between 2020 and 2024. Patients were treated with blinatumomab for MRD positivity post-induction intensive chemotherapy (n=25) (Table 1.). Outcomes measured included MRD status post-induction and after 14-day course blinatumomab, relapse, survival, and other clinical parameters. MRD status was measured by immunophenotyping. Risk-adapted therapy: Patients are categorized into standard, intermediate, and high-risk groups based on factors like age, white blood cell count, and response to initial treatment. MRD monitoring: Monitoring minimal residual disease (MRD) using flow cytometry is an important part of the ALL-MB protocols, particularly in identifying patients who may benefit from reduced therapy intensity.

Adding 14 day course blinatumomab twice significantly improved post-induction MRD positivity (from 12% to 0,001% after blinatumomab usage).

Table 1. Patient characteristics

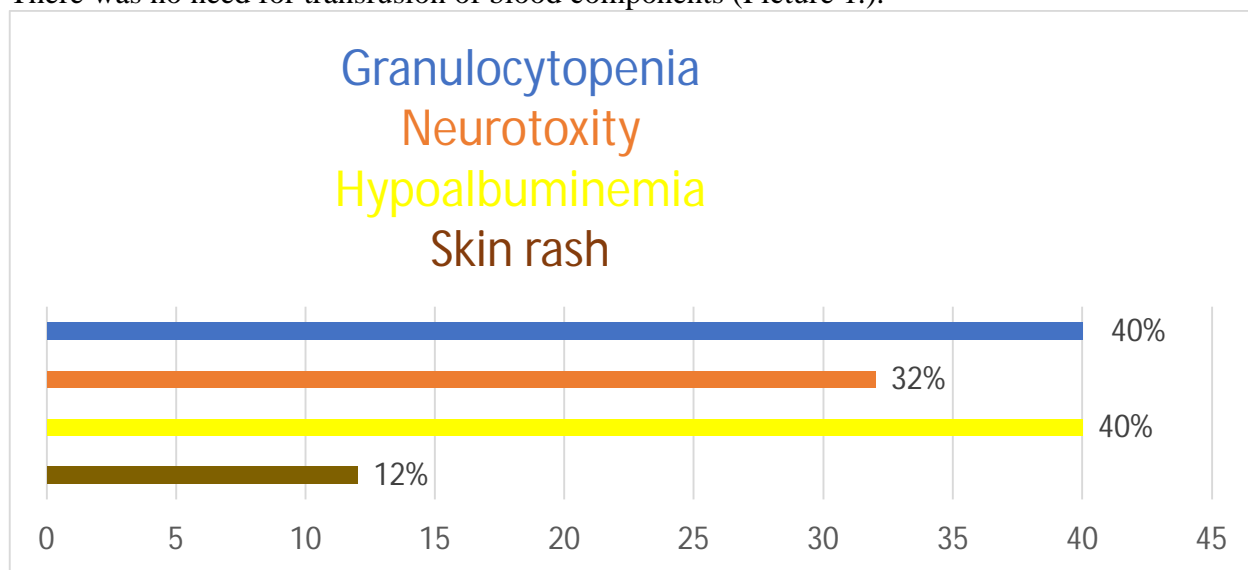
N	25
Sex, m/f	16/9
Age	4.1 years (range 4.0–17 years)
Immunophenotype by EGIL	
BI-ALL	1
BII-ALL	23
BIII-ALL	1
Chromosomal aberration	25/19 (76%)
t(12;21) (p13;q22)/ETV6::RUNX1	6
t(1;19) (q23;p13)/TCF3::PBX1	3
KMT2A rearranged	2
Hyperdiploid	6
Hypodiploid	2
Initial WBC (×10 ⁹ /L)	
<10	10
10≤WBC<30	11
≥30	4
Spleen (cm below costal margin)	
<4	20
≥4	5
Risk group	
SR	5
ImR	19
HRG	1

Results: The ALL-MB protocols are a series of treatment protocols used for childhood acute lymphoblastic leukemia (ALL) in Russia and other countries, in particular in Uzbekistan too. These protocols, developed by the Moscow-Berlin (MB) group, involve risk-adapted therapy based on factors like initial risk group, response to treatment, and minimal residual disease (MRD) levels. The protocols have evolved over time, with ALL-MB 2002, ALL-MB 2008, and ALL-MB 2015 being notable iterations [13,14,15].

The bispecific monoclonal antibody blinatumomab (CD19/CD3) is widely and successfully used to treat children with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (BCP-ALL). Advances have also led to the use of immunotherapy in children with primary BCP-ALL [15]. This paper presents the effectiveness of a 14-day courses of blinatumomab (which were held 2 times with a break of 2 months) together with consolidation chemotherapy and maintenance therapy in primary BCP-ALL patients. Patients received conventional risk-adapted induction therapy according to the ALL-MB 2015 protocol. Minimal residual disease (MRD) was measured using multicolor flow cytometry at the end of induction, then immediately after blinatumomab course. All 25 patients successfully completed induction therapy and achieved complete hematological remission. All had their MRD measured at the end of induction, showed various levels of MRD positivity (0,02 - 8%). One adolescent girl with a high MRD level after induction remained MRD positive after blinatumomab course and further received high-risk therapy with allogeneic hematopoietic stem cell transplantation.

The study included patients with morphological remission in bone marrow with blasts less than 5%, including 2 patients with incomplete induction chemotherapy. First patient received only 2 injections of vincristine, second patient received only 3 injections, then due to severe infectious complications of fungal etiology, chemotherapy was canceled. First patient had invasive fungal infection of central nervous system. These patients were transferred to consolidation therapy after the 1st course of blinatumomab.

The studies showed, adverse events are much less common under blinatumomab compared to conventional chemotherapy [9,10]. Additionally, even specific blinatumomab-related toxicities, such as CRS and neurotoxicity, only rarely necessitate the interruption of therapy [11,12,13]. In this study, during treatment with blinatumomab, all patients were premedicated with dexamethasone, allergic reactions in the form of skin rash were observed in 3 patients, transient neurotoxicity not requiring intensive care was observed in 8 patients, hypoalbuminemia was observed in 10 patients (was required correction by administration of albumin). In the 1st week of administration were observed leukopenia (leukocytes below 3 thousand), granulocytopenia (granulocytes less than 1000) without the development of infectious complications in 10 patients. There was no need for transfusion of blood components (Picture 1.).



Picture 1. Adverse events of blinatumomab.

Patients continued consolidation and reinduction courses according to the protocol with low-dose of methotrexate. After 2 months, the 14-day course of blinatumomab was repeated. All patients remain MRD-negative. At the time of analysis, 24 children had completed all therapy, including 12 months of maintenance. MRD was examined in 24 patients, and all were MRD negative. Over a 4-year study period with a median follow-up of 2.5 years, 2 late relapses were registered: 1 in the standard-risk group and 1 in the intermediate-risk group. Although the presented results are preliminary and more time is needed for definitive conclusions, a 2-week 15 µg/m²/day blinatumomab course immediately after induction and after consolidation 2 is effective in achieving and maintaining MRD negativity in children with BCP-ALL. This study showed the fundamental possibility of treating ALL by combining immunotherapy with the bispecific monoclonal antibody blinatumomab with a significant chemotherapy reduction.

Conclusion. This observation makes blinatumomab an ideal drug for selected use in vulnerable patients. The 4-year event-free survival was 88.1 ± 3.7 % for all patients. At the time of analysis, all patients were alive; no deaths were registered. The addition of blinatumomab to post-induction chemotherapy improved the prognosis of the disease in patients and allowed continuing chemotherapy according to the protocol. The addition of blinatumomab courses to initial chemotherapy requires further studies and longer observations.

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