Case Report

Blinatumomab as frontline therapy for B-cell precursor acute lymphoblastic leukemia in a critically ill young adult: a case report

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Contributions: (I) Conception and design: All authors; (II) Administrative support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Background: Adolescent and young adults (AYA) with acute lymphoblastic leukemia (ALL) represent a unique complex group, particularly, with respect to the therapeutic approach. The current trend is to treat AYAs with pediatric ALL treatment regimens, which has been associated with higher survival rates. Blinatumomab is a bispecific monoclonal antibody that binds to CD19 antigen on B-lymphoblasts and CD3 on T cells. Favorable outcomes regarding the utilization of blinatumomab have been obtained in both children and adults, for the treatment of relapsed/refractory (r/r) and minimal residual disease (MRD)-positive B-cell precursor ALL (B-ALL). Nevertheless, the safety and efficacy of blinatumomab in early stages of the disease as frontline therapy is not fully elucidated.

Case Description: A 20-year-old male was referred to our hospital in critical condition for untreated newly diagnosed Philadelphia chromosome-negative B-ALL (Ph-negative B-ALL) complicated with sepsis and respiratory failure. After hemodynamic and ventilatory stabilization, induction therapy with blinatumomab as a continuous intravenous infusion was initiated followed by vincristine, daunorubicin and prednisone. Chemo-immunotherapy was well tolerated and by the end of induction, the patient improved his clinical status and achieved complete remission, with MRD negativity by bone marrow (BM) flow cytometry.

Conclusions: Blinatumomab followed by chemotherapy showed favorable outcomes as frontline therapy in a newly diagnosed critically ill patient with Ph-negative B-ALL.

Keywords: Acute lymphoblastic leukemia (ALL); blinatumomab; immunotherapy; case report

Received: 05 February 2024; Accepted: 29 April 2024; Published online: 29 May 2024.
doi: 10.21037/aob-24-7
View this article at: https://dx.doi.org/10.21037/aob-24-7

Introduction

Acute lymphoblastic leukemia (ALL) is a malignant proliferation of clonal immature lymphoid cells, which invade the bone marrow (BM), blood, and extramedullary sites (1). Children under 6 years of age are predominantly affected, with a second peak in incidence in adults over 60 years old.

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It is unknown why Hispanic populations from Central and South America have the highest incidence (2). Many risk factors for the development of this disease in children have been studied, such as genetic syndromes (e.g., Down's syndrome, Fanconi anemia, etc.) and environmental factors (e.g., ionizing radiation, pesticide exposure). However, most adult patients with ALL do not exhibit any identifiable risk factor (1).

Prognosis depends on age, and clinical, molecular and cytogenetic features. Typically, patients between 1 and 10 years old have the best long-term outcomes, as they usually have low-risk characteristics such as hyperdiploidy and t(12;21). In contrast, adolescent and young adults (AYA) and adults tend to have high-risk abnormalities such as BCR-ABL1 rearrangement and Philadelphia chromosome-like disease (3-5).

AYA populations with ALL represent a unique complex group, particularly, with respect to the therapeutic approach. Despite the major differences regarding the cytogenetic and molecular features of ALL in AYAs and pediatric patients, the current trend is to treat AYAs with pediatric ALL treatment regimens. Higher survival rates have been obtained when enrolled in trials that applied pediatric-based therapy (6,7).

With greater comprehension of the genetic and molecular basis of ALL, novel drugs have been moving toward frontline and second line therapy. Blinatumomab is a bispecific T-cell engager that has been approved by the Food and Drugs Administration (FDA) for the treatment of relapsed/refractory (r/r) and minimal residual disease (MRD)-positive B-cell precursor ALL (B-ALL) (8). Several clinical trials have obtained favorable outcomes regarding the utilization of blinatumomab in various chemotherapy regimens in B-ALL, especially, during consolidation cycles (9). Nevertheless, the safety and efficacy of blinatumomab in early stages of the disease as frontline therapy is not fully elucidated. This report aims to describe a case of a young adult newly diagnosed with Philadelphia chromosome-negative B-ALL (Ph-negative B-ALL) who received treatment with blinatumomab as induction therapy in combination with chemotherapy in the context of critical illness. We present this case in accordance with the CARE reporting checklist (available at https://aob.amegroups.com/article/view/10.21037/aob-24-7/rc).

Highlight box

Key findings

- The use of blinatumomab as targeted immunotherapy showed favorable outcomes in early stages of Philadelphia chromosome-negative (Ph-negative) B-cell precursor acute lymphoblastic leukemia (B-ALL).

What is known and what is new?

- Blinatumomab is a bispecific T-cell engager currently approved for the treatment of relapsed/refractory and minimal residual disease-positive B-ALL. Its utilization as front-line therapy in early stages of the disease is not fully elucidated yet.
- Our case report showcases the use of blinatumomab as first-line therapy in a newly diagnosed critically ill young adult with Ph-negative B-ALL. The treatment showed a safe adverse-effect profile with the achievement of complete remission.

What is the implication, and what should change now?

- Blinatumomab is gaining importance as frontline therapy and may be a new standard of care for B-ALL. It is vitally important to conduct well-designed clinical trials framing the use of blinatumomab in early stages of the disease.

Case presentation

A 20-year-old male was referred to our hospital in critical condition for untreated leukemia complicated with sepsis and respiratory failure. Prior to admission to the other hospital, the patient had been suffering from fever, fatigue, malaise, and shortness of breath. He also presented with petechiae and pallor. The patient evolved unfavorably despite the administration of broad-spectrum antibiotics and antifungal coverage requiring intensive care unit (ICU) admission under invasive mechanical ventilation and hemodynamic support with vasopressors. He was then referred to our center, which had a higher resolutive capacity for diagnosis and treatment.

On admission, the white blood cell (WBC) count was 1,370/mm^3, the hemoglobin (Hb) was 10.1 g/dL and the platelet count was 42,000/mm^3. Serum albumin was measured at 2.80 g/dL. Serum lactic dehydrogenase was 542 U/L, serum fibrinogen was 893 mg/dL, prothrombin time and international normalized ratio were prolonged. Two sets of blood cultures were taken, with a negative reading at 7 days. A BM smear showed a marked proliferation of lymphoid lineage (*Figure 1*). Flow cytometry showed B-lymphoid blast infiltration of 71.50%, predominantly in Pro-B stage: CD45 +, CD34 –/++, CD19 +/++, CD38 –/+, CD123 –/+, CD66c –/+++, CD10 –/+++, CD22 +/++ and CD81 +/++; negative for CD20, cyIgM, cyCD3, cyMPO, CD7 and smCD3 (*Figure 2*). The karyotype was complex: 46, XY, del(9)(p21), der(17)t(1;17)

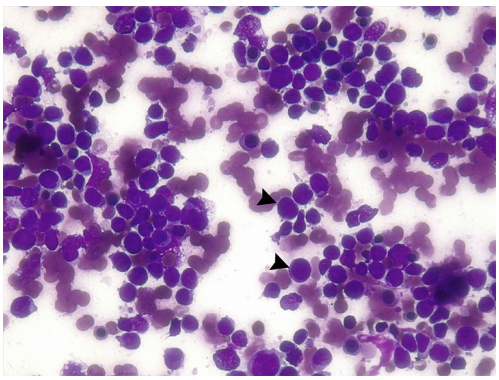

Figure 1 BM aspiration showing lymphoblasts with round nuclei, prominent nucleoli, and light blue rim of cytoplasm; findings compatible with ALL (indicated by the arrowheads, hematoxylin and eosin staining, ×1,000). BM, bone marrow; ALL, acute lymphoblastic leukemia.

(p21;p13)[23]/46, XY[07] (*Figure 3*). Molecular testing did not detect BCR-ABL1. The patient was diagnosed with Ph-negative B-ALL.

Dexamethasone at 8 mg twice daily was initiated for 4 days with tapering to 4 mg twice daily, alongside with filgrastim 300 mcg once daily for 3 days. Broad-spectrum antibiotics, antifungal coverage and prophylaxis against herpes simplex virus and *Pneumocystis jirovecii* were given. A lumbar puncture was performed to rule out lymphoblastic infiltration of the central nervous system, and flow cytometry showed no infiltration on cerebrospinal fluid. Prophylactic intrathecal chemotherapy with cytarabine 50 mg, methotrexate 12.5 mg, and dexamethasone 4 mg was administered.

Due to the patient's critical condition, we initiated targeted immunotherapy with blinatumomab followed by chemotherapy. On day 11 of hospitalization (DH11), blinatumomab 9 µg per day as a continuous infusion was initiated and was administered for seven days. Prior to immunotherapy, the WBC count was 2,430/mm^3, the Hb was 9 g/dL and the platelet count was 96,000/mm^3. C reactive protein (CRP) was 1.18 mg/dL and procalcitonin was 0.18 ng/mL. Shortly after the administration of blinatumomab, the patient presented a febrile episode with no signs or symptoms of neurological involvement. The WBC count dropped to 700/mm^3, CRP increased to 2.93 mg/dL, serum ferritin was >2,000 ng/mL and sedimentation velocity was 22 mm/h. Interleukin-6 was measured at 264.8 pg/mL and cytokine release syndrome (CRS) was suspected. Supportive measures were delivered and blinatumomab infusion was maintained with close monitorization of inflammatory markers. The WBC count increased to 2,560/mm^3 and the inflammatory markers decreased. On DH18, the dose of blinatumomab was increased to 28 mcg per day. On DH26, a BM aspiration showed complete morphologic remission and flow cytometry showed an MRD of 0.05%. Blinatumomab infusion continued until DH31. Next, the patient received intravenous chemotherapy with vincristine 2 mg on DH32, 39, 46 and 53; daunorubicin 50 mg on DH39 and 46; and oral prednisone 20 mg twice daily. On DH53, BM aspiration showed complete morphologic remission, and flow cytometry of BM showed MRD negativity by the end of chemo-immunotherapy induction. The patient then underwent consolidation treatment with chemotherapy under the HOVON 146 ALL trial protocol (10) and, currently, is under evaluation for haploidentical allograft. The complete timeline for the diagnostic tests and therapeutic agents used is illustrated in *Tables 1*,*2*.

All procedures performed in this study were in accordance with the ethical standards of the Institutional Review Board of the British American Hospital (CIEI/CAA-055-2023) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for the publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

Discussion

A 20-year-old male with newly diagnosed Ph-negative B-ALL was treated with blinatumomab in combination with chemotherapy agents as frontline therapy. The patient achieved MRD negativity after receiving blinatumomab in a continuous infusion over 21 days alongside intrathecal chemotherapy with cytarabine, methotrexate and dexamethasone, and then followed by intravenous chemotherapy with vincristine, daunorubicin and prednisone. During the early course of administration of blinatumomab, Grade 1 CRS was suspected. Supportive measures were delivered, and the infusion was continued without any further complications.

Treatment of B-ALL has evolved dramatically in recent years, as the genetic and molecular characteristics of the disease have become better understood (8). AYA populations are a unique and complex group that have been favored by the administration of pediatric-based instead of adult-based therapy regimens. Nevertheless, the outcomes are not as

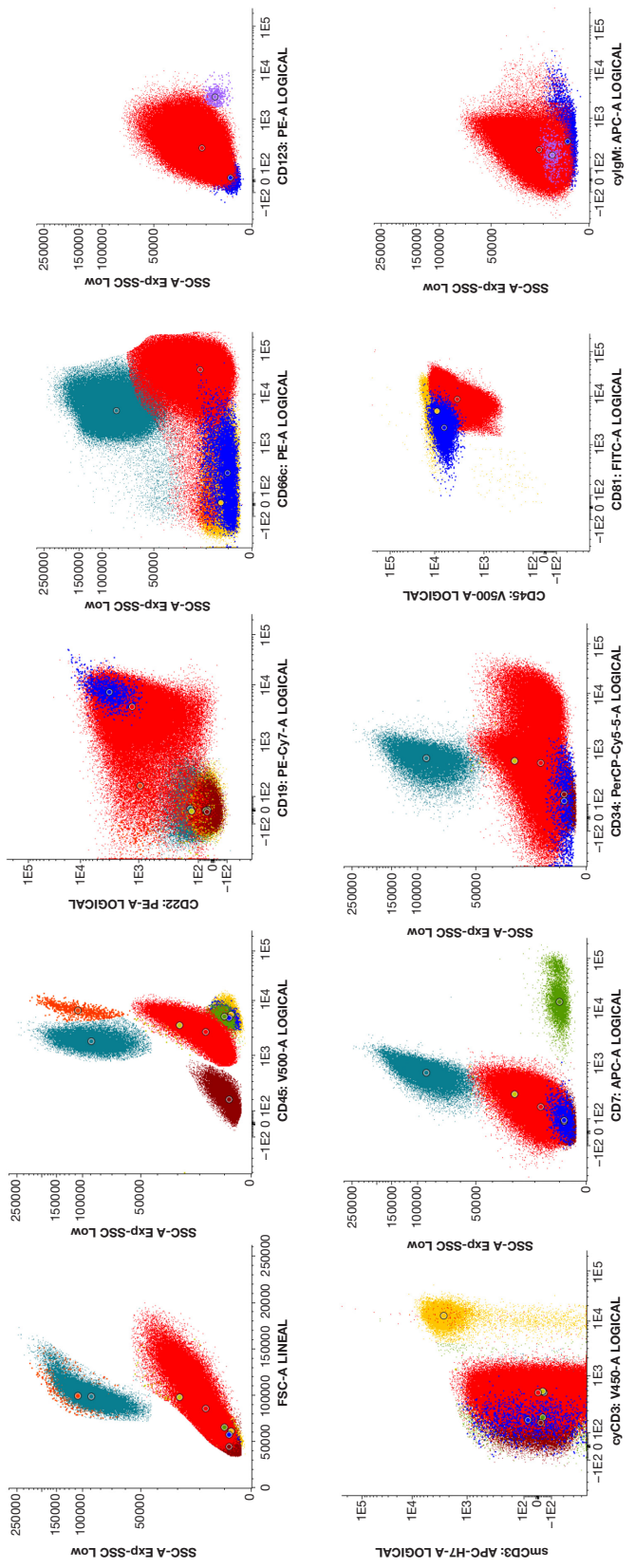

Figure 2 Flow cytometry of BM aspiration showing pathological B-lymphoid blasts expressing the following immunophenotype: CD45 +, CD34 –/++, CD19 +/++, CD38 –/+, CD123 –/+, CD66c –/+++, CD10 –/+++, CD22 +/++ and CD81 +/++; negative for CD20, cyIgM, cyCD3, cyMPO, CD7 and smCD3. BM, bone marrow.

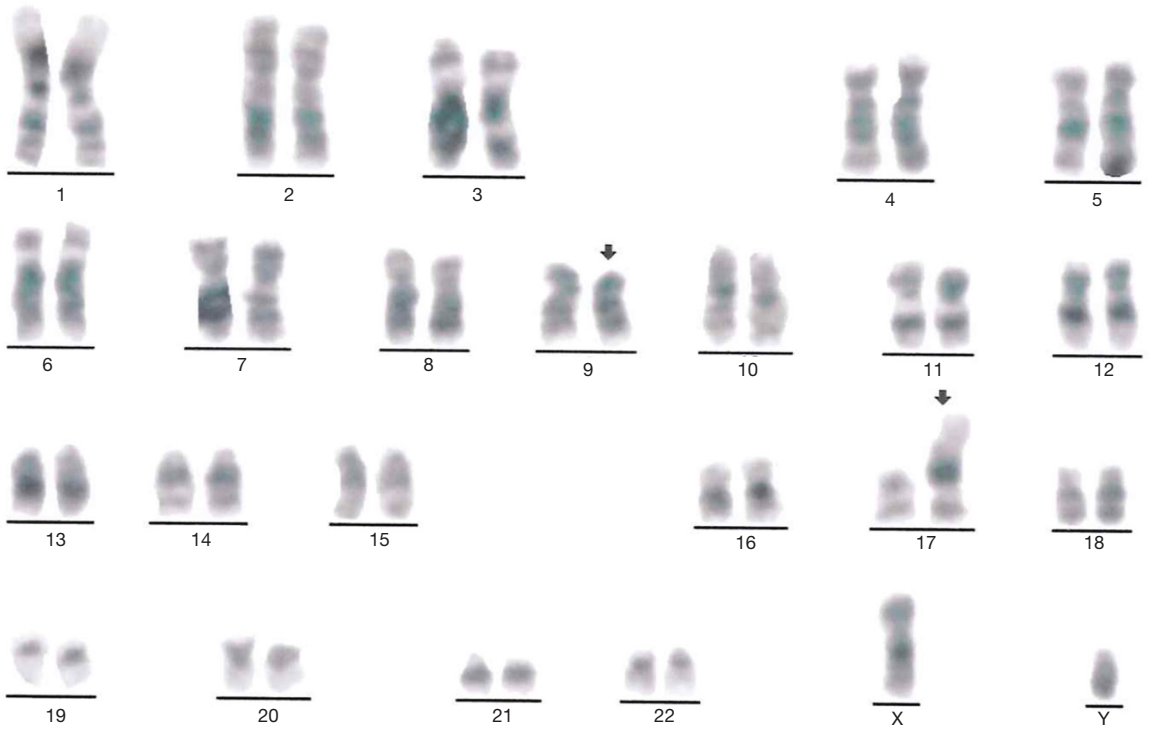

Figure 3 Male karyotype showing deletion of the short arm of chromosome 9: del(9)(p21) and a derivative chromosome 17 product of translocation between the short arms of chromosome 1 and 17: der(17)t(1;17)(p21;p13). In seven metaphases, no structural abnormalities were found.

promising as their counterparts, paving the way for novel treatments (11). Blinatumomab is a bispecific monoclonal antibody that binds to CD19 antigen on B-lymphoblasts and CD3 on T cells. It is currently approved by the FDA for the treatment of r/r and MRD-positive B-ALL (8). It has shown longer overall survival (OS) rate and higher rate of disease-free survival (DFS) in r/r B-ALL as compared with standard-of-care chemotherapy (12,13). Blinatumomab also demonstrated favorable outcomes in MRD-positive B-ALL (14).

Considering its promising activity as targeted immunotherapy and its relatively safe adverse-effect profile, blinatumomab is advancing toward a frontline position in the treatment of B-ALL. The rationale for incorporating blinatumomab in early stages of the disease is to achieve greater outcomes in comparison to late stages, where it is less likely to be curable (15). The use of blinatumomab as a chemotherapy-sparing first line agent, specially in chemotherapy-intolerant or chemotherapy-resistant B-ALL, is a novel approach currently under investigation. Blinatumomab exhibits a safer adverse-effect profile compared to conventional chemotherapy, with lower rates of myelosuppression and mucosal toxicity (16). It also has proven to be effective as a first-line therapy in chemotherapy-intolerant patients (17). The early incorporation of blinatumomab reduces the burden associated with chemotherapy, specially in critically ill patient unsuitable for intensive regimens, while attaining favorable outcomes. However, it has been called into question in which extent chemotherapy-sparing alternatives may be incorporated as frontline therapy without diminishing short- and long-term outcomes (15).

Several clinical trials support the administration of blinatumomab during consolidation cycles (9). The GIMEMA LAL2317 showed the efficacy of sequential administration of blinatumomab during early and late consolidation in increasing the MRD conversion rate, OS and DFS (18). Moreover, phase 3 ECOG-1910 trial showed longer OS and lower deaths from ALL in the blinatumomab arm (19). Clinical trials have also addressed the efficacy of blinatumomab administration during early stages of the disease for the purpose of reducing

Table 1 Therapy and diagnostic tests timeline from day of hospitalization 1 to 10

Therapy and diagnostic tests	Day of hospitalization									
	DH1	DH2	DH3	DH4	DH5	DH6	DH7	DH8	DH9	DH10
Broad-spectrum antibiotics	X	X	X	X	X	X	X	X	X	X
Antifungal therapy	X	X	X	X	X	X	X	X	X	X
HSV and *Pneumocystis jirovecii* prophylaxis	X	X	X	X	X	X	X	X	X	X
Dexamethasone 8 mg twice daily		X	X	X	X					
Dexamethasone 4 mg twice daily						X	X	X	X	X
Filgrastim 300 mcg once daily			X	X	X					
Bone marrow aspiration with flow cytometry	B-lymphoid blast infiltration of 71.5%				Complex karyotype					
Prophylactic intrathecal chemotherapy								X		
Lumbar punction with flow cytometry								No CSF infiltration		
White blood cell count (per mm^3)	1,370	1,130	790	1,540	2,060	1,950	1,830	1,590	1,830	1,790
Hemoglobin (g/dL)	10.1	9.3	8.5	10.4	10.3	9.9	9	7.7	8.9	8.9
Platelet count (per mm^3)	42,000	44,000	45,000	55,000	51,000	48,000	50,000	43,000	111,600	98,000
Serum fibrinogen (mg/dL)	893				357		252			
INR	1.5	1.3			1.4		1.4		1.3	1.5
C reactive protein (mg/dL)	23.4	16.7	8.2	3.6	1.4	1.8	1	0.7	0.7	0.4
Procalcitonin (ng/mL)	1.45	1.13	0.66				0.28			0.09

X, the patient received the drug in this day. DH, day of hospitalization; HSV, herpes simplex virus; CSF, cerebrospinal fluid; INR, international normalized ratio.

chemotherapy burden. The ALLG ALL8 study addressed blinatumomab administration following debulking chemotherapy with promising results (20). Moreover, blinatumomab has also proved to be efficient in the treatment of high-risk ALL with poor prognostic factors. The administration of blinatumomab during consolidation and maintenance in patients with KMT2A rearrangements, IKZF1 intragenic deletion or MRD-positive following induction was proved to be efficient (21). Additionally, utilization of blinatumomab as prephase therapy in patients who received pediatric B-ALL protocols proved to be safe and achieved greater complete morphologic remission and MRD negativity rates (22).

Conclusions

Blinatumomab, as targeted immunotherapy, has shown promising outcomes when administered in early stages

Table 2 Therapy and diagnostic tests timeline from day of hospitalization 11 to 53

Therapy and diagnostic tests	DH11 (DT1)	DH12 (DT2)	DH13 (DT3)	DH14 (DT4)	DH15 (DT5)	DH16 (DT6)	DH17 (DT7)	DH18 (DT8)	DH19 (DT9)	DH20 (DT10)	DH21 (DT11)	DH22 (DT12)	DH23 (DT13)	DH24 (DT14)	DH25 (DT15)	DH26 (DT16)	DH27–DH31 (DT17–DT21)	DH32–DH52 (DT22–DT42)	DH53 (DT43)
Broad-spectrum antibiotics	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Antifungal therapy	X	X	X	X	X	X	X	X	X	X									
HSV and *Pneumocystis jirovecii* prophylaxis	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dexamethasone 16 mg once daily	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Blinatumomab 9 µg—continuous infusion	X	X	X	X	X	X	X												
Blinatumomab 28 µg—continuous infusion								X	X	X	X	X	X	X	X	X	X		
Chemotherapy (intravenous vincristine and daunorubicin, and oral prednisone)																		X	X
Bone marrow aspiration with flow cytometry																MRD of 0.05%			MRD (–)
White blood cell count (per mm^3)	2,430	700	940	2,560	1,850	1,690	1,580	1,810		2,480		2,500			2,960				
Hemoglobin (g/dL)	9	10.3	9.8	9.2	9.5	8.6	8.5	8.7		8.2		8.4			10				
Platelet count (per mm^3)	96,000	98,000	100,000	93,000	103,000	102,000	115,000	140,000		149,000		140,000			143,000				
Serum fibrinogen (mg/dL)			294	404	289								210		192				
INR			1.7	1.4	1.3								1.3		1.2				
C reactive protein (mg/dL)	1.2	2.9	8.9	5.5	2.4		0.7	0.2		0.2		0.2			0.1				
Sedimentation velocity (mm/h)	23	22	49	29	21														
Procalcitonin (ng/mL)	0.18	0.33	0.35					0.03											
IL-6 (pg/mL)	14.3	264.8						5.5		5.8									

X, the patient received the drug in this day. DH, day of hospitalization; DT, day of immunotherapy of chemotherapy; HSV, herpes simplex virus; MRD, minimal residual disease; INR, international normalized ratio; IL-6, interleukin-6.

of the disease. Furthermore, blinatumomab exhibits a safe adverse-effect profile that has positioned itself as a chemotherapy-sparing agent, which is particularly important in critically ill patients unsuitable for intensive chemotherapy. Hence, it is gaining importance as frontline therapy and may be a new standard of care for B-ALL. Nevertheless, certain studies showed preliminary results in limited follow-up periods. Therefore, it is vitally important to conduct well-designed clinical trials framing the use of blinatumomab in early stages of the disease. Most of the studies assessed the administration of blinatumomab during consolidation cycles. Thus, it would be interesting to address blinatumomab in newly diagnosed patients as an induction therapy.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at https://aob.amegroups.com/article/view/10.21037/aob-24-7/rc

Peer Review File: Available at https://aob.amegroups.com/article/view/10.21037/aob-24-7/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://aob.amegroups.com/article/view/10.21037/aob-24-7/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the Institutional Review Board of the British American Hospital (CIEI/CAA-055-2023) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the patient for the publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

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doi: 10.21037/aob-24-7
Cite this article as: Mendez-Guerra C, Reyes-Farias CI, Uribe-Ramirez L, Carrasco-Yalan A. Blinatumomab as frontline therapy for B-cell precursor acute lymphoblastic leukemia in a critically ill young adult: a case report. Ann Blood 2024;9:18.

