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Ambulatory use of blinatumomab in paediatric patients with relapsed or refractory B-cell acute lymphoblastic leukaemia at a single centre in South Africa

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Acute lymphoblastic leukaemia (ALL) is the most common childhood cancer, with B-ALL comprising approximately 85% of all cases. Despite a high cure rate, those with refractory disease and/or relapsed (R/R) B-ALL have an inferior overall survival. Blinatumomab, a novel therapy, is a bispecific cluster of differentiation (CD)19-directed CD3 T-cell engager that has proven efficacy in children with R/R B-ALL. It is administered as a 28-day infusion with associated prolonged hospital admissions. To date, there are few publications on its use in paediatric B-ALL, including its use in the outpatient setting.

Contribution: This case series offers additional context and understanding in this regard.

Keywords: relapsed/refractory; B-cell acute lymphoblastic leukaemia; blinatumomab; privately funded insurance; MRD; HSCT.

Introduction

Worldwide, acute lymphoblastic leukaemia (ALL) is the most common childhood malignancy, of which B-cell ALL comprises approximately 85% of cases.[1,2] Although the 5-year survival rate for B-ALL exceeds 90% in some countries, approximately 15% – 20% of patients experience relapse after achieving remission with standard chemotherapy. Despite treatment intensification with salvage chemotherapy and subsequent haematopoietic stem cell transplantation (HSCT), overall survival (OS) in these patients remains poor with little improvement over the past few decades.[1,2,3,4,5]

Up to 20% of paediatric patients with B-ALL will demonstrate minimal residual disease (MRD) following induction and consolidation chemotherapy. Minimal residual disease is defined as the presence of leukaemic cells not detectable by microscopy but measured using standardised methods such as flow cytometry, with a sensitivity of 10^{-4} (0.01%).[1,3,4,5] Minimal residual disease is the most important risk factor, not only in predicting haematological relapse but also in predicting OS in patients with relapsed disease, highlighting its prognostic value.[1,2,3,5,6,7]

Thus, prioritising the treatment of MRD-positive disease is essential to improving OS in refractory and/or relapsed (R/R) B-ALL.[2,3,5]

One such promising therapy, which reduces MRD by eradicating the leukaemic clone, is blinatumomab, a bispecific T-cell engager construct. Blinatumomab redirects cluster of differentiation (CD)3-expressing T-cells towards CD19-expressing B-lineage cells (expressed on all B-cell leukaemic blasts), which facilitates cell lysis and eliminates leukaemic clones seemingly resistant to conventional chemotherapy.[2,3,5,8,9]

To date, there are only a few published studies on the use of blinatumomab in paediatric B-ALL in the outpatient setting.[10,11,12]

South Africa (SA) is an upper-middle-income country with a population of approximately 63.1 million people.[13] It has a two-tiered healthcare system, with privately funded insurance-based services alongside state-run care.[14] This system leads to inconsistent access to specialised medical services and novel medications such as blinatumomab. Only 15.5% of the South African (SA) population is privately funded with potential access to these agents.[13,15]

Even with medical insurance, families often face personal hardships during prolonged hospital stays, including financial strain, risk of job loss, increased stress and emotional anxiety.

Case series

All paediatric patients (< 18 years of age) with R/R B-ALL who received blinatumomab at a single privately funded paediatric oncology unit (POU) from February 2022 to April 2025 were included. February 2022 was the date of the first paediatric blinatumomab infusion.

A total of seven patients received blinatumomab from February 2022 to April 2025. Five patients had relapsed disease, and blinatumomab formed part of their salvage therapy. The remaining two patients had refractory B-ALL after induction and consolidation chemotherapy (MRD positivity) and received blinatumomab immediately thereafter (Table 1 and Figure 1).

Blinatumomab was administered as a continuous infusion over 28 days, followed by a 14-day treatment-free period. All seven patients received a minimum of two cycles. Dose incrementation was not performed. Six patients (< 45 kg) received blinatumomab at a dose of 15 mcg/m^2 per day, while one patient (> 45 kg) received a fixed dose of 28 mcg per day. A priming dose of dexamethasone (10 mg/m^2 – 15 mg/m^2) was given prior to the first infusion bag. Each infusion bag was constituted to run over 48 h. Blinatumomab was infused through an ambulatory infusion pump using either an implantable port (six patients) or a peripherally inserted central catheter in one patient. The intravenous tubing contained an in-line filter and was primed with blinatumomab prior to connection. Flushing of lines was strictly avoided when changing infusion bags, and blinatumomab was infused through a dedicated lumen.

The POU nursing staff completed comprehensive in-house training before initiating blinatumomab therapy, with a pharmaceutical sales representative available to address any questions or administration-related issues; no urgent administration-related issues were encountered.

A bone marrow (BM) biopsy was performed by a paediatric oncologist at the start of each cycle, with a lumbar puncture and intrathecal methotrexate performed twice per cycle.

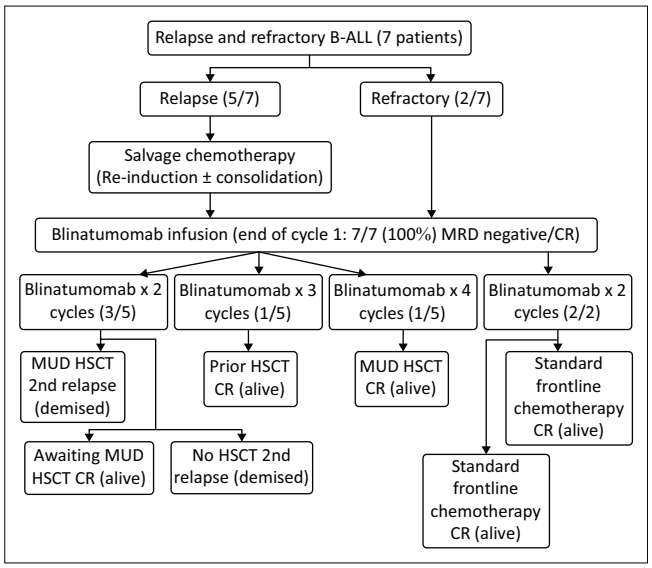
Two patients remained in hospital for the duration of their blinatumomab infusions (citing logistical and socioeconomic reasons). The remaining five patients were admitted for a median of 3 days at the start of each cycle and were then followed up every 48 h – 96 h in the POU outpatient clinic. Prior to discharge, all caregivers received intensive training to manage home infusions safely. They were provided with the POU contact numbers to call at any time for assistance with infusion-related issues.

At outpatient visits, patients were clinically assessed, any side effects were managed and additional training was provided as needed. Up to two infusion bags were dispensed per visit to facilitate home-based bag changes and to allow for the continuous infusion of the drug. Notably, no patient required hospital readmission during this period.

TABLE 1: Baseline demographics, salvage chemotherapy, response to blinatumomab, side effects and current disease status.

Number	Sex	Primary diagnosis	Relapsed versus refractory disease	Site of relapse	Time from diagnosis to relapse	Salvage chemotherapy	Pre-1st cycle blinatumomab MRD (FC)	Post-1st cycle blinatumomab MRD (FC)	Number of cycles	Toxicities	Disease progression	HSCT/type	Event/current disease status	Follow-up time
1	M	Pre-B-ALL t(12,21)	Relapse	Combined (CNS + BM)	38 months	UK ALLR3	0.4%	Negative	2	No	No	Awaiting MUD HSCT	Alive, in remission	1 month
2	F	Pre-B-ALL (iAMP 21)	Relapse	BM	24 months	Azacitidine-Venetoclax; UK ALLR3	8.6%	Negative	3	No	No	Prior MUD HSCT	Alive, in remission	16 months
3	F	Pre-B-ALL	Relapse	Combined (CNS + BM)	19 months	UK ALLR3	0	Negative	4	No	No	MUD HSCT	Alive, in remission	17 months
4	F	Pre-B-ALL (3 copies of 1q23)	Relapse	Combined (CNS + BM)	6 months	UK ALLR3	0.41%	Negative	2	Grade 1 CRS	Yes	No	Demised	N/A
5	M	Pre-B-ALL t(9;22)	Refractory	N/A	N/A	N/A	0.4%	Negative	2	Grade 1 CRS	No	N/A	Alive, in remission	7 months
6	F	Pre-B-ALL	Refractory	N/A	N/A	N/A	0.03%	Negative	2	No	No	N/A	Alive, in remission	9 months
7	F	Pre-B-ALL	Relapse	BM	25 months	UK ALLR3	1%	Negative	2	Grade 1 CRS + ICANS	Yes	MUD HSCT	Demised	N/A

MRD, minimal residual disease; FC, flow cytometry; B-ALL, B-acute lymphoblastic leukaemia; CNS, central nervous system; BM, bone marrow; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; MUD, matched unrelated donor; HSCT, haematopoietic, stem cell transplant; M, male; F, female; N/A, not applicable.



B-ALL, B-acute lymphoblastic leukaemia; MRD, minimal residual disease; CR, complete remission; MUD, matched unrelated donor; HSCT, haematopoietic stem cell transplant.

FIGURE 1: Schematic representation of patients undergoing blinatumomab infusion.

Adverse events were documented and graded using the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03.[16,17]

Three patients experienced Grade 1 cytokine release syndrome (CRS) during the first week of cycle 1. None exhibited haemodynamic instability, and all were successfully managed with oral antipyretics and additional dexamethasone.

One patient also developed Grade 1 immune effector cell-associated neurotoxicity syndrome, presenting with significant tremors and notable fatigue. Symptoms resolved following treatment for CRS. No adverse events were observed beyond cycle 1.

No patient required the temporary or permanent discontinuation of the drug as a result of an adverse event. In one instance, a patient's blinatumomab infusion bag was depleted at home without a replacement, resulting in a 4-h delay between bag changes. A repeat dose of dexamethasone was administered as an outpatient prior to restarting the new infusion bag, with no adverse effects reported.

Six patients ($n = 6/7$) had an M1 marrow (< 5% blasts), while one had an M2 marrow (5% – 25% blasts) at the start of blinatumomab. All patients were MRD negative after the first cycle.

Two of the five patients with relapsed B-ALL underwent matched unrelated donor HSCT following blinatumomab therapy. One patient experienced an isolated BM relapse within 100 days post-transplant and was not salvageable. The second patient, with relapsed infant B-ALL, received four cycles while confirming HSCT donor availability. She underwent an uneventful transplant and remains in remission.

One patient, who had previously undergone HSCT, did not proceed to a second transplant because of complications from chronic gastrointestinal graft-versus-host disease and cytomegalovirus colitis following her initial HSCT. She received three cycles of blinatumomab instead.

Another patient, while awaiting her third cycle as a bridge to transplant, experienced a combined relapse. She did not receive further blinatumomab and, despite salvage attempts, demised from her disease.

One patient is currently awaiting HSCT after completing his second cycle of blinatumomab.

The two patients with refractory B-ALL at the end of induction chemotherapy achieved MRD negativity following the first cycle of blinatumomab. Both received two cycles in total and subsequently transitioned back to standard frontline chemotherapy, without proceeding to upfront HSCT.

Discussion

This case series included privately funded paediatric patients with R/R B-ALL treated with blinatumomab at a single POU in SA.

In keeping with the published date, blinatumomab was shown to be safe and effective in children with R/R B-ALL, with all patients achieving MRD negativity and experiencing no severe adverse effects. Notably, all patients had a low pre-treatment tumour burden, which significantly reduced the risk of CRS and neurotoxicity.[3,7]

The patients with relapsed B-ALL were considered for HSCT following blinatumomab bridging therapy, in line with current standard practice.[3,4,8] The two patients with refractory B-ALL achieved MRD negativity after the first cycle of blinatumomab. They both received a further cycle and are continuing standard B-ALL chemotherapy without an upfront HSCT.

The majority of infusions were successfully administered in the outpatient setting. Outpatient treatment empowered families to take greater ownership of care, significantly reducing anxiety and improving overall well-being. It lowered hospital and chemotherapy administration costs and preserved valuable family time. Additionally, this approach provided financial benefits for both insurance providers and patient families.

Conclusion

Compared to conventional chemotherapy for R/R-ALL, which often involves prolonged hospitalisation and significant toxicity, blinatumomab is highly effective in eliminating MRD. When administered in the context of low

upfront disease burden, it offers a cost-effective, home-based treatment option with low toxicity, benefiting both patients and their families.[10,11,12]

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRediT authorship contribution

Nadia Beringer: Conceptualisation, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Validation, Visualisation, Writing – original draft, Writing – review & editing. Kate Gwynneth Bennett: Conceptualisation, Data curation, Investigation, Validation, Visualisation, Writing – original draft, Writing – review & editing. Both authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication and take responsibility for the integrity of its findings.

Ethical considerations

Ethical clearance to conduct this study was obtained from the University of the Witwatersrand, Johannesburg Human Research Ethics Committee (Medical) (No. M250649).

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Data availability

The data that support the findings of this study are available from the corresponding author, Nadia Beringer, upon reasonable request.

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