

Original Article

Resource-adapted immunotherapy bridging to achieve measurable residual disease negativity before allogeneic hematopoietic stem cell transplantation in high-risk acute lymphoblastic leukemia: A single-center real-world experience

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ABSTRACT

Objectives: The objective of the study is to describe the feasibility, toxicity, and early transplant outcomes of a structured resource-adapted immunotherapy bridging program using blinatumomab and/or inotuzumab ozogamicin (InO) to achieve measurable residual disease (MRD)-negative status before allogeneic hematopoietic stem cell transplantation (allo-HSCT) in high-risk acute lymphoblastic leukemia (ALL).

Material and Methods: This was a retrospective single-center analysis of consecutive high-risk patients with ALL who underwent allo-HSCT between December 2023 and September 2025 (data cutoff: December 14, 2025). Bridging feasibility measures were predefined. Blinatumomab was delivered using a label-supported multi-day infusion with the 7-day bag option, prepared with bacteriostatic 0.9% sodium chloride under pharmacy-supervised aseptic conditions in eligible patients, and age-adapted step-up dosing was used. InO was dose-capped at 0.3 mg/m²/dose, same-day scheduling was used, when possible, to facilitate vial sharing, and a planned washout of at least 6 weeks was maintained before allo-HSCT to mitigate sinusoidal obstruction syndrome/veno-occlusive disease (SOS/VOD) risk. End points included feasibility, blinatumomab utilization, toxicity, relapse, overall survival (OS), leukemia-free survival (LFS), non-relapse mortality (NRM), SOS/VOD, transplant-associated thrombotic microangiopathy (TMA), and graft failure.

Results: Nine patients underwent allo-HSCT after MRD-negative bridging. Donors were haplo-identical related in 7 patients and matched siblings in 2. Blinatumomab was used in 6/9 patients (1 cycle in 5; 2 cycles in 1) and InO in 4/9 patients (3 doses each; dose-capped). One multiply relapsed Philadelphia chromosome-positive patient after CAR-T therapy received ponatinib plus asciminib plus InO before transplantation. Median blinatumomab utilization was 14.5 vials/cycle (38.5 mcg), range 6–16. All blinatumomab recipients developed grade 1 cytokine release syndrome, and 1 patient developed grade 3 immune effector cell-associated neurotoxicity syndrome with seizure. At the cutoff, relapse occurred in 2/9 patients, with 1 death after relapse. The estimated 1-year Kaplan-Meier OS was 100%, and the estimated 1-year Kaplan-Meier LFS was 70%. NRM, SOS/VOD, and graft failure were each 0%, and TMA occurred in 1/9 patients.

Conclusion: A structured feasibility-focused bridging program combining label-supported 7-day blinatumomab infusion bags, age-adapted step-up dosing, and dose-capped InO with vial sharing and a transplant washout strategy enabled MRD-negative allo-HSCT in all transplanted patients in this small real-world high-risk ALL cohort. The approach showed encouraging early survival with no NRM or SOS/VOD and supports prospective evaluation of resource-conscious immunotherapy implementation in transplant-eligible ALL.

Keywords: Acute lymphoblastic leukemia, Allogeneic hematopoietic stem cell transplantation, Blinatumomab, Inotuzumab ozogamicin, Measurable residual disease, Pharmacoeconomics, Resource-adapted care

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INTRODUCTION

High-risk acute lymphoblastic leukemia (ALL) remains a major therapeutic challenge when relapse biology, persistent measurable residual disease (MRD), prior cellular therapy, or donor limitations complicate the path to allo-HSCT. Achieving the deepest possible remission before transplantation is clinically relevant because lower disease burden at allogeneic hematopoietic stem cell transplantation (allo-HSCT) is associated with improved post-transplant disease control and survival. Blinatumomab and inotuzumab ozogamicin (InO) have therefore become important remission-deepening tools in B-lineage ALL, particularly when the aim is to bridge patients to transplant in better biologic condition.^[1-4]

However, the adoption of these agents in resource-constrained settings is limited not only by acquisition cost but also by delivery complexity. Blinatumomab requires continuous infusion, infusion pumps, trained nursing support, and early toxicity monitoring. InO is operationally easier to administer but may be constrained by fixed vial size, financial burden, and concern regarding sinusoidal obstruction syndrome/veno-occlusive disease (SOS/VOD) before transplantation.^[3-6]

In this context, the practical question is not simply whether immunotherapy works, but whether it can be delivered safely, affordably, and with acceptable waste. Published pharmacoeconomic studies suggest that the cost profile of blinatumomab and InO is strongly shaped by hospitalization, administration design, and downstream transplant effects, rather than by drug price alone.^[7-10]

We therefore implemented a structured resource-adapted bridging program using blinatumomab and/or InO with operational modifications intended to reduce avoidable waste while preserving transplant safety. This manuscript expands our conference abstract into an IJMIO-style original article and places the findings within the published literature on cost-conscious immunotherapy use in ALL.

MATERIAL AND METHODS

Study design and patients

This was a retrospective single-center analysis of consecutive patients with high-risk ALL who underwent allo-HSCT between December 2023 and September 2025, with data cutoff on December 14, 2025. The present manuscript is based on finalized aggregate data available from the submitted abstract dataset. All reported outcomes, therefore, reflect cohort-level summary data.

Treatment objective

The bridging strategy was designed to achieve MRD-negative status before allo-HSCT while maintaining operational feasibility in a cost-sensitive environment.

Resource-adapted blinatumomab pathway

Blinatumomab was prepared according to label-supported procedures. The 7-day infusion bag option using bacteriostatic 0.9% sodium chloride was used in eligible patients to reduce bag changes and minimize wastage. Pediatric patients received body surface area-based step-up dosing (5–10 mcg/m²/day), whereas adults underwent weekly fixed-dose escalation (9–15 to 21–28 mcg/day) over a 28-day continuous infusion, with cytokine release syndrome and neurotoxicity monitoring.^[5]

Resource-adapted InO pathway

InO was dose-capped at 0.3 mg/m²/dose. Same-day scheduling was used when feasible to facilitate vial sharing among 2–3 patients from the same vial. A planned washout interval of at least 6 weeks between the last InO dose and allo-HSCT was maintained to mitigate transplant-related SOS/VOD risk.

End points

The endpoints were the feasibility of MRD-negative bridging and transition to allo-HSCT, blinatumomab utilization, treatment-emergent toxicity, relapse, overall survival (OS), leukemia-free survival (LFS), non-relapse mortality (NRM), SOS/VOD, thrombotic microangiopathy (TMA), and graft failure.

Statistics

Owing to the small cohort size, the analysis was descriptive. Survival outcomes are reported as Kaplan–Meier estimates as provided in the abstract dataset.

RESULTS

Nine patients underwent allo-HSCT after MRD-negative bridging. The donor source was haploidentical related in 7 patients and a matched sibling in 2. All transplanted patients achieved MRD-negative status before allo-HSCT.

Blinatumomab was used in 6 of 9 patients. Five patients received 1 cycle, and 1 patient received 2 cycles. InO was used in 4 of 9 patients, with 3 doses per patient using the dose-capped strategy. One Philadelphia chromosome-positive multiply relapsed patient after chimeric antigen receptor T-cell therapy received ponatinib plus asciminib plus InO before transplantation.

Median blinatumomab utilization was 14.5 vials per cycle, corresponding to 38.5 mcg, with a range of 6–16 vials per cycle. All blinatumomab recipients developed grade 1 cytokine release syndrome. One patient developed grade 3 immune effector cell-associated neurotoxicity syndrome with seizure.

At data cutoff, relapse had occurred in 2 of 9 patients, with 1 death after relapse. The estimated 1-year Kaplan–Meier OS was 100%, and the estimated 1-year Kaplan–Meier LFS, defined by relapse or death, was 70%. NRM was 0%. No patient developed SOS/VOD, and no graft failure occurred. TMA occurred in 1 of 9 patients [Table 1].

The principal feasibility signal was that all transplanted patients in this high-risk cohort could be brought to MRD-negative allo-HSCT despite cost and delivery constraints, without an apparent early penalty in transplant safety.

DISCUSSION

This study addresses a question that is particularly relevant in India and other resource-limited settings: Can modern

immunotherapy be adapted in a way that preserves efficacy while reducing avoidable cost and waste? In this cohort, the answer appears encouraging. All transplanted patients achieved MRD-negative status before allo-HSCT, and early transplant outcomes were favorable, with 0% NRM, 0% SOS/VOD, and 0% graft failure.

The present findings must be interpreted cautiously because the cohort is small, retrospective, and limited to aggregate abstract-level data. Nonetheless, the study is clinically meaningful because it focuses on implementation – an area often underreported in conventional efficacy manuscripts. In practice, barriers to blinatumomab and InO are frequently operational: Prolonged infusion logistics, wastage from fixed vial sizes, repeated bag changes, hospital bed occupancy, and clinician concern about hepatotoxicity before transplant.

Our blinatumomab strategy rested on a label-supported operational modification. The current prescribing information specifically allows use of 7-day infusion bags prepared with bacteriostatic 0.9% sodium chloride in appropriate patients.^[5]

This matters pharmacoeconomically because more frequent bag changes increase pharmacy workload, nursing contacts, and the risk of avoidable wastage. Consistent with this, a Children’s Oncology Group survey showed that only a minority of centers hospitalize children for the full 28-day infusion, whereas most programs use shorter inpatient monitoring with substantial outpatient or home-based administration.^[11]

A pharmacist-driven home-infusion pathway study from the United States reported actual inpatient drug acquisition savings of US\$178,010 across 14 admissions, with average savings of US\$12,715 per cycle and US\$29,668 per patient.^[12]

These data do not directly prove cost savings in our setting, but they strongly support the principle that administration design is a major determinant of blinatumomab affordability.

The wider pharmacoeconomic literature also supports the value proposition of blinatumomab, although the economic frame matters. In a US payer analysis comparing blinatumomab with salvage chemotherapy, the incremental cost-effectiveness ratio was estimated at US\$110,108 per quality-adjusted life-year (QALY), with a 74% probability of cost-effectiveness at a US\$150,000/QALY threshold.^[13]

In another US analysis comparing blinatumomab with InO in adults with relapsed/refractory B-cell precursor ALL, incremental costs for blinatumomab versus InO ranged from US\$7,023 to US\$36,244 and incremental QALYs ranged from 0.54 to 1.78, producing incremental cost-effectiveness ratios of US\$4,006 to US\$20,737 per QALY gained.^[7]

Pediatric data show a similar trend toward favorable long-term value: A French analysis estimated an incremental

Table 1: Cohort-level summary of the bridging program and outcomes.

Variable	Summary
Study period	December 2023–September 2025; data cutoff December 14, 2025
Patients undergoing allo-HSCT	9
Donor type	Haploidentical related: 7; matched sibling: 2
Pre-transplant MRD status	MRD-negative in all transplanted patients
Blinatumomab exposure	6/9 patients; 1 cycle in 5, 2 cycles in 1
InO exposure	4/9 patients; 3 doses each; dose-capped
Special case	One Ph-positive multiply relapsed post-CAR-T patient received ponatinib+asciminib+InO
Median blinatumomab utilization	14.5 vials/cycle (38.5 mcg), range 6–16
Blinatumomab toxicity	Grade 1 CRS in all recipients; grade 3 ICANS with seizure in 1
Relapse	2/9
Death after relapse	1
Estimated 1-year OS	100%
Estimated 1-year LFS	70%
NRM	0%
SOS/VOD	0%
Graft failure	0%
TMA	1/9

Allo-HSCT: Allogeneic hematopoietic stem cell transplantation, MRD: Measurable residual disease, InO: Inotuzumab ozogamicin, CAR-T: Chimeric antigen receptor T-cell therapy, CRS: Cytokine release syndrome, ICANS: Immune effector cell-associated neurotoxicity syndrome, NRM: Non-relapse mortality, SOS/VOD: Sinusoidal obstruction syndrome/veno-occlusive disease, TMA: Transplant-associated thrombotic microangiopathy, LFS: Leukemia-free survival, OS: Overall survival

cost-effectiveness ratio (ICER) of EUR 7,308/QALY for blinatumomab versus high-risk consolidation chemotherapy, and a Mexican analysis likewise concluded that blinatumomab was cost-effective in pediatric high-risk first-relapse disease.^[9,14]

The InO component of our program was driven by a different economic logic. InO is easier to administer than blinatumomab because it does not require continuous infusion, but pre-transplant hepatotoxicity remains a major concern. The pivotal INO-VATE trial showed superior remission and MRD-negativity rates with InO compared with standard therapy, but VOD was an important adverse event.^[3,4]

More recent transplant-focused real-world data have shown that SOS/VOD risk after allo-HSCT remains clinically relevant in patients exposed to InO, particularly with high-risk conditioning approaches.^[6]

Our use of dose capping, same-day vial sharing, and a planned washout interval before allo-HSCT was therefore designed to balance access with caution.

From a pharmacoeconomic perspective, published studies suggest that InO can be cost-effective versus standard

chemotherapy but may also appear less expensive than blinatumomab in short-term real-world claims data because the hospitalization burden is lower. In a Norway/Sweden analysis, base-case ICERs for InO versus standard of care were EUR 16,219/QALY in Sweden and EUR 44,405/QALY in Norway, with all modeled estimates remaining below approximate willingness-to-pay thresholds.^[8]

In a US real-world analysis, total ALL-related monthly costs were 43% lower for InO than for blinatumomab (US\$93,767 vs. US\$163,470), driven in part by shorter hospitalization patterns.^[10]

The published literature informing cost-conscious use of blinatumomab and InO is shown in Table 2.^[7-12,15]

These findings help explain why blinatumomab and InO should not be framed as universal economic winners or losers. Long-term value, short-term budget impact, administration burden, and transplant intent are different economic questions.

Our study also aligns with the broader implementation literature in low- and middle-income countries. Duffy *et al.* argued that expanding blinatumomab access in low- and medium-income countries requires workflow redesign,

Table 2: Published literature informing cost-conscious use of blinatumomab and InO.

Study	Setting/comparator	Key economic or operational finding	Relevance to the present study
Delea <i>et al.</i> , 2019 ^[7]	US model; blinatumomab versus InO	Blinatumomab versus InO ICERs ranged from US\$4,006 to US\$20,737/QALY gained.	Shows that long-term value depends on survival benefit, not acquisition cost alone.
Van Oostrum <i>et al.</i> , 2022 ^[8]	Norway/Sweden; InO versus standard chemotherapy	Base-case ICERs for InO were EUR 16,219/QALY in Sweden and EUR 44,405/QALY in Norway.	Supports the view that InO can be cost-effective when remission and transplant gains are considered.
Caillon <i>et al.</i> , 2023 ^[9]	France; pediatric blinatumomab versus consolidation chemotherapy	ICER for blinatumomab was EUR 7,308/QALY.	Supports blinatumomab as a high-value bridge in pediatric high-risk relapse.
Russell-Smith <i>et al.</i> , 2024 ^[10]	US real-world claims; InO versus blinatumomab	ALL-related monthly costs were 43% lower for InO than blinatumomab, partly because the hospitalization burden was lower.	Highlights the importance of the administration pattern and bed utilization.
Withycombe <i>et al.</i> , 2024 ^[11]	COG institutional survey	Most centers use short inpatient monitoring with subsequent outpatient/home administration; full 28-day hospitalization is uncommon.	Supports reduced inpatient exposure for blinatumomab where feasible.
Seago <i>et al.</i> , 2025 ^[12]	Pharmacist-driven home infusion pathway	Actual inpatient drug acquisition savings were US\$178,010 across 14 admissions; US\$12,715/cycle.	Illustrates how workflow redesign can substantially reduce blinatumomab delivery cost.
Duffy <i>et al.</i> , 2022 ^[15]	LMIC implementation science protocol	Successful access requires structured workflow, training, and monitoring systems.	Conceptual framework for resource-adapted implementation in lower-resource settings.

InO: Inotuzumab ozogamicin, ICER: Incremental cost-effectiveness ratios, QALY: Quality-adjusted life-years, COG: Children's oncology group, LMIC: Low- and medium-income countries, ALL: Acute lymphoblastic leukemia

training, monitoring systems, and implementation science rather than drug availability alone.^[15]

The present series provides a practical example of that concept. The program was not based on compromising care, but on removing avoidable waste from high-cost care.

Several limitations must be acknowledged. This is a small retrospective single-center series. The manuscript is built from aggregate abstract data and therefore lacks granular patient-level biology, conditioning details, supportive care utilization, exact cost capture, and formal comparative statistical analysis. No within-cohort pharmacoeconomic analysis was performed, so the discussion on cost is contextual rather than primary data-driven. These limitations should restrain causal interpretation.

When the clinical objective is transplant in MRD-negative remission, the most relevant measure of value is not the drug price alone but whether a patient can reach allo-HSCT safely, on time, and in deeper remission. Resource-adapted delivery may therefore serve not as a compromise, but as a clinically meaningful pathway to equity in advanced leukemia care.

CONCLUSION

A structured resource-adapted bridging program using blinatumomab and/or InO enabled MRD-negative status and successful allo-HSCT in all transplanted patients in this small high-risk ALL cohort. The combination of label-supported blinatumomab delivery optimization, InO dose capping, vial sharing, and a planned transplant washout strategy was associated with encouraging early survival and no observed SOS/VOD or NRM. Prospective multicenter studies with formal cost capture are warranted.

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Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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