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# Pharmacotherapeutic Management and Adverse Effect Monitoring in Relapsed B-Cell Acute Lymphoblastic Leukemia Receiving Inotuzumab Ozogamicin: A Case Report

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**ABSTRACT**
**Background:** Relapsed B-cell acute lymphoblastic leukemia (B-ALL) is a high-risk hematological malignancy associated with poor clinical outcomes and a significant burden of treatment-related adverse effects. InotuzumabOzogamicin (InO), a CD22-directed antibody-drug conjugate, has demonstrated meaningful remission rates in this setting but requires vigilant supportive care and toxicity monitoring throughout each treatment cycle.
**Case Presentation:** A 41-year-old male with relapsed B-ALL was admitted to a tertiary care centre , for Cycle 1 of InotuzumabOzogamicin. On admission, he presented with symptomatic cytopenia — hemoglobin 7.6 g/dL, total leukocyte count 5,390/µL, and platelet count 12,000/µL — necessitating transfusion support. During the hospital course, a bone marrow biopsy and intrathecal methotrexate were performed by the hematologist. A transient fever spike developed mid-course, prompting escalation of antibiotic cover to cefoperazone-sulbactam (Zostum). Chemotherapy was delivered on Day 1, Day 8, and Day 15 as scheduled.
**Intervention and Outcome:** Supportive pharmacotherapy included acyclovir 200 mg twice daily for antiviral prophylaxis, co-trimoxazole (Septran) on alternate days for Pneumocystis prophylaxis, febuxostat 80 mg for hyperuricemia prevention, pantoprazole 40 mg for gastric protection, ondansetron 8 mg as antiemetic, and ursodeoxycholic acid (Udiliv) for hepatoprotection. Multiple packed cell and platelet transfusions were administered to maintain hematological stability. The patient completed Cycle 1 without severe infusion-related reactions and was discharged in a hemodynamically stable condition with instructions for follow-up on Day 18 with complete blood count, electrolytes, creatinine, and liver function tests.
**Conclusion:** This case illustrates that structured supportive pharmacotherapy — encompassing infection prophylaxis, antiemesis, gastric protection, and close hematological surveillance — is fundamental to the safe delivery of InotuzumabOzogamicin in relapsed B-ALL. Anticipatory management of predictable toxicities, including prompt antibiotic escalation for febrile episodes, can help maintain treatment continuity and patient safety.
**Informed Consent:** Written informed consent was obtained from the patient for publication of this case report and accompanying clinical data.
**Keywords:** *Relapsed B-ALL; InotuzumabOzogamicin; supportive pharmacotherapy; adverse effect monitoring; febrile neutropenia; tumor lysis syndrome; case report*

## I. Introduction

Acute lymphoblastic leukemia (ALL) is an aggressive hematological malignancy arising from the clonal proliferation of immature lymphoid precursors in the bone marrow and peripheral blood. B-cell ALL (B-ALL) accounts for the majority of adult ALL cases and typically presents with constitutional symptoms including progressive fatigue, pallor, recurrent infections, and bleeding tendency attributable to bone marrow failure.[3,4]

While frontline regimens have improved outcomes considerably over the past two decades, relapse remains a critical challenge. Relapsed or refractory B-ALL carries a poor prognosis and is frequently complicated by treatment-related toxicities including myelosuppression, opportunistic infections, hepatotoxicity, and infusion reactions.[2,5]

InotuzumabOzogamicin (InO; Besylomab) is a humanised anti-CD22 monoclonal antibody conjugated to calicheamicin, a potent cytotoxic agent. By exploiting CD22 expression on malignant

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B lymphoblasts, InO achieves selective intracellular drug delivery, thereby minimising off-target toxicity relative to conventional chemotherapy.[1] The INO-VATE ALL trial demonstrated significantly higher rates of complete remission and longer progression-free survival with InO compared to standard salvage regimens in adults with relapsed or refractory B-ALL.[1,6]

Despite these clinical benefits, InO therapy is associated with a characteristic toxicity profile — principally thrombocytopenia, neutropenia, febrile neutropenia, hepatotoxicity (including sinusoidal obstruction syndrome), and gastrointestinal disturbances — that demands structured monitoring and proactive supportive care.[2,5]

This case report documents the pharmacotherapeutic management and adverse effect monitoring of a patient with relapsed B-ALL receiving InO Cycle 1 at a tertiary care centre in Surat, India, with particular emphasis on clinical decision-making during a mid-cycle febrile episode.

## II. Case Presentation

A 41-year-old male (height 173 cm, weight 63.6 kg, BSA 1.7 m²) with a confirmed diagnosis of relapsed B-cell acute lymphoblastic leukemia was admitted on 08 November 2025 to the Department of General Medicine, for administration of InotuzumabOzogamicin Cycle 1.

On admission, the patient was conscious, oriented, and haemodynamically stable. Vital signs were: temperature 98.1°F, pulse 84 beats/min, respiratory rate 20 breaths/min, blood pressure 110/70 mmHg, and $SpO^2$ 98% on room air. Abdominal examination revealed a soft abdomen with no organomegaly. Cardiovascular and respiratory examinations were unremarkable.

Baseline laboratory investigations on admission revealed significant cytopenia: hemoglobin 6.7 g/dL, total leukocyte count (TLC) 5,390/µL, and platelet count 12,000/µL. Serum creatinine was 0.5 mg/dL, potassium 4.1 mEq/L, and uric acid 3.6 mg/dL. In view of symptomatic anaemia, packed cell volume (PCV) transfusions were initiated on the day of admission.

**Diagnostic workup:** In line with the institutional ALL admission checklist, a bone marrow biopsy and aspiration were performed under aseptic precautions by the treating hematologist on 10 November 2025. Intrathecal methotrexate (IT MTX) was concurrently administered via the same procedure for CNS prophylaxis.

**Chemotherapy administration:** InotuzumabOzogamicin (1 vial in 50 mL normal saline, protected from light) was administered intravenously over 60 minutes on Day 1 (11/11/25), Day 8, and Day 15 as per the planned fractionated dosing schedule.[1,5] Prior to each infusion, premedications were administered: Inj. Avil (pheniramine) 1 ampoule, Inj. Dexamethasone 8 mg, Inj. Paracetamol 2 ampoules, and Inj. Ondansetron (Emeset) 8 mg, all given 30 minutes before InO to mitigate infusion-related reactions.

**Supportive pharmacotherapy:** A structured supportive regimen was initiated at the time of admission and continued throughout hospitalisation:

- **Acyclovir (Acivir) 200 mg twice daily** — antiviral prophylaxis against herpes simplex and varicella-zoster reactivation, a recognised risk during prolonged immunosuppression following cytotoxic therapy
- **Co-trimoxazole (Septran) 1 tablet twice daily on Tuesday and Friday** — prophylaxis against Pneumocystis jirovecii pneumonia (PCP), a protocol-driven measure in immunocompromised haematology patients
- **Febuxostat (Fabucare) 80 mg once daily** — xanthine oxidase inhibitor prescribed to prevent hyperuricaemia and tumour lysis syndrome associated with rapid leukaemic cell destruction during chemotherapy[4,5]
- **Pantoprazole (Pantocid) 40 mg once daily** — gastroprotection against steroid-induced and chemotherapy-associated gastric mucosal injury
- **Ondansetron (Emeset) 8 mg three times daily** — prevention and control of chemotherapy-induced nausea and vomiting (CINV)
- **Ursodeoxycholic acid (Udiliv) 300 mg twice daily** — hepatoprotective agent included given the known risk of hepatic sinusoidal obstruction syndrome (SOS/VOD) associated with InO therapy[5]
- **Amikacin 1 g IV once daily** — empirical antibacterial cover initiated on admission in the setting of neutropenia
- **Packed cell volume (PCV) and platelet transfusions** — administered on multiple occasions as guided by serial haematological parameters

**Intra-hospital clinical course and fever episode:** Daily monitoring of haemoglobin, TLC, platelets, renal function, and electrolytes was

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performed throughout the admission. A progressive decline in haematological indices was observed over the first several days (Table 1), consistent with expected post-chemotherapy cytopenia. The patient's TLC nadir reached 360/µL by Day 4 post-infusion (14/11/25), and platelet count fell to 15,000/µL, requiring repeated transfusion support.

On 10 November 2025, the patient developed a single fever spike. In the context of profound neutropenia (TLC 13,960/µL on that date with a documented neutropenic picture), the treating team escalated antibiotic cover to Inj. Zostum (cefoperazone-sulbactam) in addition to existing therapy. This decision reflected institutional protocol for febrile neutropenia during induction chemotherapy. The fever resolved following the antibiotic escalation, and the patient remained afebrile for the remainder of the admission.

Blood glucose monitoring was performed daily via a diabetic chart. Fasting and random blood glucose values ranged between 99–173 mg/dL, indicating corticosteroid-associated hyperglycaemia, which was observed and communicated to the treating physician at each recording.

**Discharge status and advice:** By Day 5 (15 November 2025), the patient was clinically stable with improving haematological counts (Hb 8.2 g/dL, TLC 690/µL, platelets 20,000/µL). He was discharged with the following oral medications: Tab. Ciprofloxacin 500 mg twice daily, Tab. Acyclovir 200 mg twice daily, Tab. Co-trimoxazole (Procotri) twice daily on Tuesday/Friday, Tab. Folvite MB once daily, Tab. Pantoprazole 40 mg once daily, and Tab. Ondansetron 8 mg SOS for vomiting. Follow-up was scheduled for 18 November 2025 with Dr. Hasmukh Balar / Dr. Dharmesh Vaghasiya, accompanied by CBC, electrolytes, serum creatinine, and SGPT investigations.

**Table 1: Serial haematological parameters during hospitalisation**

*(Hb = haemoglobin g/dL; TLC = total leukocyte count /µL; Plt = platelet count /µL; UA = uric acid mg/dL; Cr = creatinine mg/dL)*

| Date | Hb | TLC | Plt | UA | Cr |
|---|---|---|---|---|---|
| 08/11/25 | 6.7 | 5,390 | 12,000 | 3.6 | 0.5 |
| 09/11/25 | 7.6 | 17,450 | 22,000 | 1.9 | 0.6 |
| 10/11/25 | 6.4 | 11,410 | 22,000 | 1.6 | 0.6 |
| 11/11/25 | 8.3 | 13,960 | 21,000 | 1.3 | 0.6 |
| 12/11/25 | 7.1 | 4,440 | 22,000 | – | – |
| 13/11/25 | 7.7 | 890 | 22,000 | – | 0.5 |
| 14/11/25 | 7.6 | 520 | 18,000 | – | – |
| 15/11/25 | 8.2 | 690 | 20,000 | – | – |

## III. Discussion

This case presents a 41-year-old male with relapsed B-ALL who received InotuzumabOzogamicin Cycle 1 in a fractionated schedule (Day 1, 8, and 15), a dosing strategy intended to improve tolerability while maintaining anti-leukaemic efficacy as demonstrated in the INO-VATE ALL trial.[1,6]

The most clinically significant event during this admission was the occurrence of a fever spike on Day 3 (10/11/25), arising in the setting of neutropenia. Febrile neutropenia is a well-described complication of InO therapy and represents an oncologic emergency requiring prompt empirical antibiotic escalation.[2,5] In this patient, escalation to cefoperazone-sulbactam (Zostum) — a broad-spectrum beta-lactam/beta-lactamase inhibitor combination with activity against both gram-positive and gram-negative organisms including Pseudomonas — was appropriate and effective, with defervescence occurring within 24 hours. This clinical course aligns with published recommendations that advise early escalation to antipseudomonal coverage in haematology patients with persistent or new-onset fever during cytotoxic therapy.[5]

The sequential decline in TLC from 5,390/µL at admission to a nadir of 360/µL by Day 7 (14/11/25), followed by a gradual recovery to 690/µL at discharge, reflects the expected pharmacodynamic course of InO-induced myelosuppression. Similarly, the platelet nadir of 15,000/µL required multiple transfusions to maintain a safe count above the institutional threshold. This pattern has been consistently reported across InO trials and underscores the necessity of at least twice-weekly CBC monitoring during active treatment cycles.[2,5]

The addition of ursodeoxycholic acid (UDCA) as a hepatoprotective measure deserves specific mention. InO carries a black-box warning for hepatic sinusoidal obstruction syndrome (SOS), formerly known as veno-occlusive disease (VOD), with reported incidences reaching up to 23% in patients subsequently undergoing allogeneic stem cell transplantation.[5] While the evidence base for prophylactic UDCA specifically in the InO setting is still evolving, its favourable safety profile and plausible mechanism (bile acid displacement reducing hepatocyte injury) make it a reasonable prophylactic choice, and its use in this case is consistent with emerging institutional practice.

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Concurrent bone marrow biopsy and intrathecal methotrexate on Day 3 reflected the multidisciplinary approach to this patient's care. IT MTX remains a cornerstone of CNS prophylaxis in adult ALL given the frequency of CNS relapse, and its administration alongside systemic therapy is supported by current B-ALL management guidelines.[3,4]

From a pharmacy practice perspective, this case demonstrates the complexity of medication management in an InO cycle: eight concurrent supportive agents, premedication protocols for each infusion day, transfusion scheduling, glucose monitoring due to corticosteroid use, and adjustment of antibiotic cover mid-course. This level of pharmacotherapeutic complexity highlights the value of clinical pharmacist involvement in hematology-oncology units for medication reconciliation, toxicity surveillance, and patient counselling.

## IV. Conclusion

This case documents the clinical course and pharmacotherapeutic management of a relapsed B-ALL patient receiving InotuzumabOzogamicin Cycle 1 in a real-world tertiary care setting. Key learning points include the importance of prophylactic antimicrobial and hepatoprotective therapy, the need for rapid antibiotic escalation during febrile neutropenic episodes, and the value of fractionated InO dosing paired with structured transfusion support. The patient completed Cycle 1 safely, reinforcing that carefully coordinated supportive pharmacotherapy can enable the successful administration of targeted antibody-drug conjugate therapy even in the context of severe baseline cytopenia.[1,5]

Future case reports and prospective audits from Indian tertiary centres documenting real-world InO outcomes — including response rates, toxicity profiles, and SOS incidence — will be valuable in contextualising published trial data for the regional patient population.

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