Impact of loss of B-cell aplasia on clinical outcomes following talicabtagene autoleucel in patients with relapsed/refractory B-cell malignancies: a single-centre real-world experience.

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INTRODUCTION

- B-cell aplasia (BCA) is the most accessible surrogate of functional CAR T-cell persistence.
- Loss of B-cell aplasia (LBCA) can therefore be a harbinger of relapse.
- Published CD19-directed CAR T-cell series link early B-cell recovery to inferior outcomes.
- We retrospectively evaluated the clinical outcomes associated with loss of B-cell aplasia (LBCA) and subsequent treatment approaches in patients receiving Talicabtagene autoleucel -a CD19-directed CAR T-cell therapy.

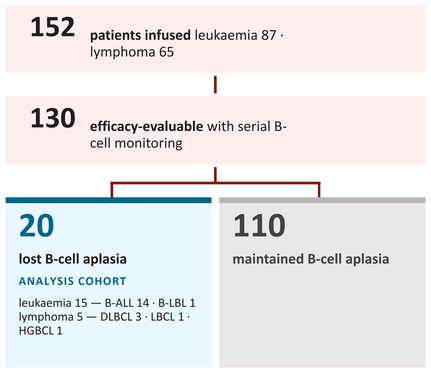
AIM

To evaluate the impact of of loss of B-cell aplasia (LBCA) in patients with relapsed/refractory B-ALL nad B cell lymphoma treated with talicabtagene autoleucel, a CD19-directed CAR T-cell therapy.

METHODS

- Retrospective, analysis of the 20 patients who lost B-cell aplasia after talicabtagene autoleucel, infused between December 2023 and October 2025.
- **LBCA** was defined as no CD19-positive marrow disease with a peripheral B-cell count ≥10 cells/µL, with counts monitored monthly to 6 months and at months 9 and 12.
- The **primary analysis** treated the interval from infusion to B-cell recovery as a **continuous** covariate in a Cox model, with confidence intervals and P values from the profile likelihood rather than the Wald statistic.
- A **descriptive** 6-month landmark cut off was taken based on existing literature on CD19 CAR-T. Survival was estimated by Kaplan–Meier and compared by log-rank; all tests were two-sided.

Figure 1. Patient flow and study population



RESULTS

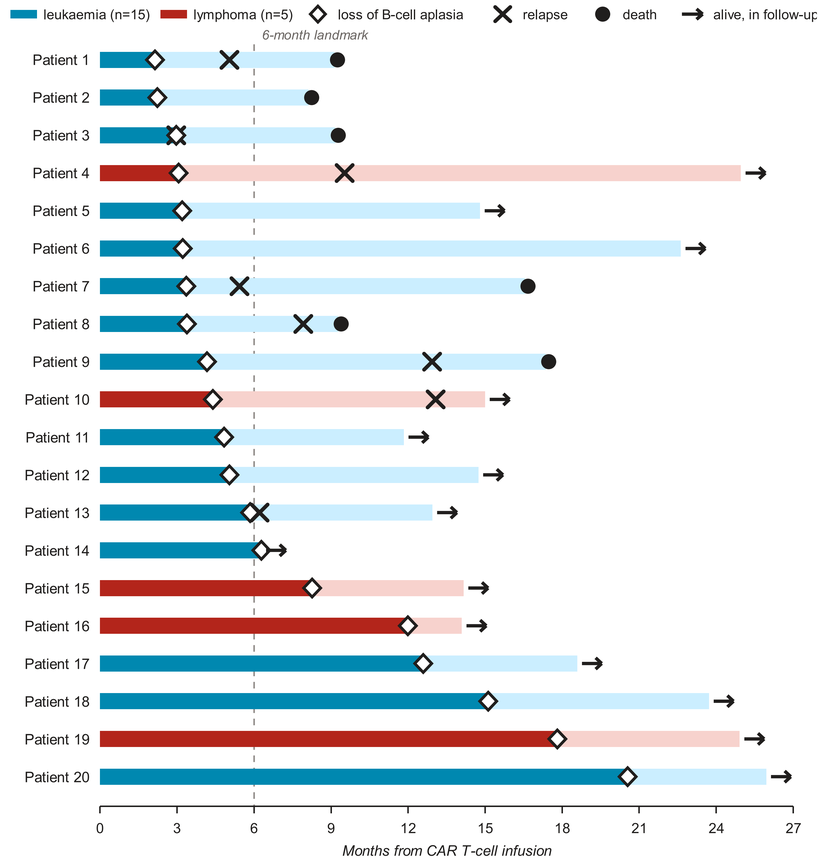
Table 1. Baseline characteristics (n = 20)

Characteristic	B-ALL (n=15)	Lymphomas (n=5)
DEMOGRAPHICS & DISEASE		
Age, years, median (range)	25.5 (15.6–54.4)	46.4 (21.2–62.2)
Male sex	12 (80)	2 (40)
Diagnosis	B-ALL 14 · B-LBL 1	DLBCL 3 · LBCL 1 · HGBCL 1
Cytogenetics — Ph+ / Ph− / Ph-like / NA	5 / 7 / 2 / 1	—
PRIOR THERAPY		
Primary refractory / relapsed	9 (60) / 6 (40)	3 (60) / 2 (40)
Prior lines, median (range)	1 (1–3)	2 (1–3)
Prior inotuzumab	3 (20)	–
DISEASE BURDEN BEFORE LYMPHODEPLETION		
Marrow blasts, %, median (range)	2 (0–32)	—
High burden (≥5% blasts) / stage III–IV · bulky ≥5 cm	2 (13)	5 (100) / 2 (40)
Extramedullary / active CNS disease	1 (7) / 1 (7)	—
Extranodal involvement	—	4 (80)
DISEASE STATUS AT INFUSION		
Morphologic / radiologic response	CR 13 (87) · no CR 2	CR 3 · PR 1 · NA 1 (PET)
MRD-negative by flow, of those assessed	7/14 (50)	—
CAR T-CELL THERAPY AND RESPONSE		
CAR-T dose, $\times 10^6$/kg, median (range)	9 (5–13)	12 (6–15)

KEY OUTCOMES

- B cells recovered a median of **4.6 months** after infusion (20.1 weeks; range 9.3–89.3), and **13 of 20 patients (65%)** recovered within 6 months.
- Relapse followed loss of aplasia in **8 of 20 patients (40%)** at a median of **16.1 weeks.**
- After a median follow-up of 15 months, the 1-year PFS and OS were 68.6% (95% CI, 43–84) and 84.2% (95% CI, 59–95), respectively in the patients with LBCA
- The cumulative incidence of relapse is 26.8% at 6 months.
- The earlier the B cells recover, the higher the hazard of progression (HR 0.65 per additional month to recovery, p = 0.014)
- At the 6-month landmark, **6 of 10** patients who had already lost B-cell aplasia progressed against **none of the 7** who remained aplastic (P = 0.019); for death the contrast was 6 of 13 against 0 of 7 (P = 0.038).

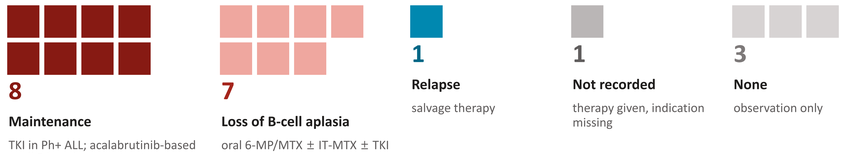
Figure 2. Swimmers plot showing Individual patient course after CAR T-cell infusion, ordered by time to B-cell recovery



Solid bar, infusion to B-cell recovery; pale bar, subsequent follow-up. Diamonds mark recovery, crosses relapse, filled circles death; arrows, alive and in follow-up. Patients are identified by initials only.

Figure 3. Therapy after CAR T-cell infusion

Each square = 1 patient (n = 20)



17/20 (85%) received systemic therapy after infusion, including 2 CAR T-cell reinfusions.

Figure 4. Progression-free and overall survival by B-cell status 6 months after infusion (landmark analysis)

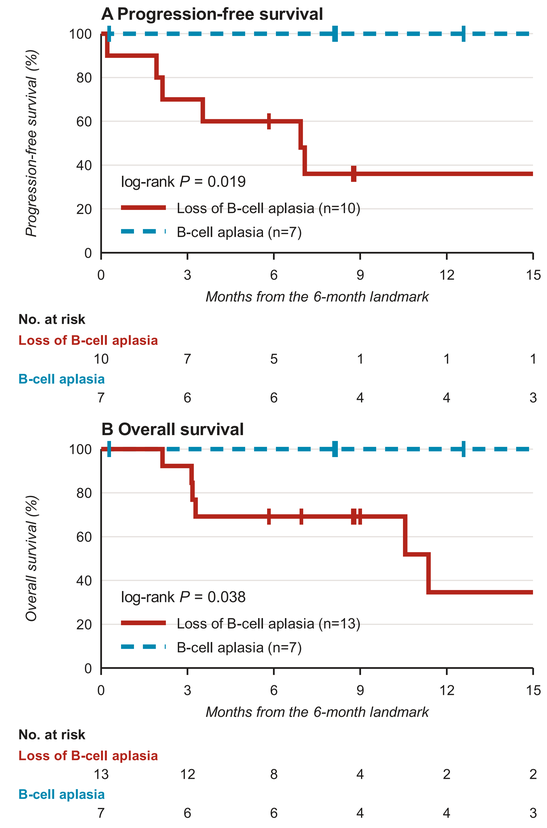
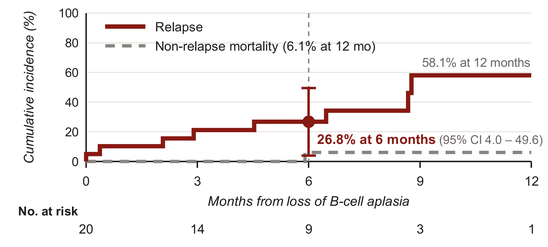


Figure 5. Cumulative incidence of relapse after loss of B-cell aplasia



CONCLUSIONS

1. Loss of B-cell aplasia following talicabtagene autoleucel infusion is associated with a significant risk of relapse.

2. This highlights the need for routine B-cell monitoring and developing appropriate maintenance strategies.

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