Outcomes of Ruxolitinib in Adult Patients with Acute Lymphoblastic Leukemia After Allogeneic Hematopoietic Cell Transplantation: A Propensity Score-Matched Real-World Analysis

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INTRODUCTION

- Ruxolitinib, a JAK1/2 inhibitor, is increasingly used after allogeneic hematopoietic cell transplantation (alloHCT) for steroid-refractory graft-versus-host disease (GVHD).
- In acute lymphoblastic leukemia (ALL), transplant-related morbidity is high and GVHD is a major cause of post-transplant complications.
- Data on the impact of ruxolitinib on survival, relapse, and infection risk in this population remain limited.

AIM

To evaluate the association of ruxolitinib use with clinical outcomes in adult patients with ALL who developed GVHD after alloHCT:

- Overall survival
- Relapse or need for salvage therapy
- Chronic GVHD
- Infectious complications — severe infection or sepsis, CMV reactivation, pneumonia

METHOD

- **Source:** TriNetX Research Network (112 healthcare organizations)
- **Population:** adults with ALL who underwent alloHCT and developed GVHD within 6 months post-transplant
- **Exposure:** ruxolitinib within 1 year (n=53) vs no ruxolitinib (n=334)
- **Matching:** 1:1 propensity score matching on demographics, comorbidities, and conditioning/GVHD prophylaxis regimens → 50 matched pairs (47 for the severe-infection endpoint)
- **Outcomes:** overall survival (day +1 to +1095), relapse or salvage therapy (+100 to +730), chronic GVHD (+100 to +365), severe infection or sepsis (+1 to +365), CMV reactivation, pneumonia
- **Analysis:** Kaplan–Meier, log-rank, and Cox regression

CONCLUSIONS

- Ruxolitinib was not associated with increased relapse risk, and infection rates were broadly similar between groups.
- The higher chronic GVHD rate likely reflects selection bias — sicker patients were more likely to receive ruxolitinib. The overall survival difference should be interpreted with similar caution.
- Ruxolitinib appears usable after alloHCT in ALL without major infectious safety concerns.
- Prospective studies are needed to define its optimal role.

RESULTS

3-y OS 54.0% vs 69.9% · Relapse 32% vs 32% · Chronic GVHD 62% vs 38% · Severe infection 55% vs 55%

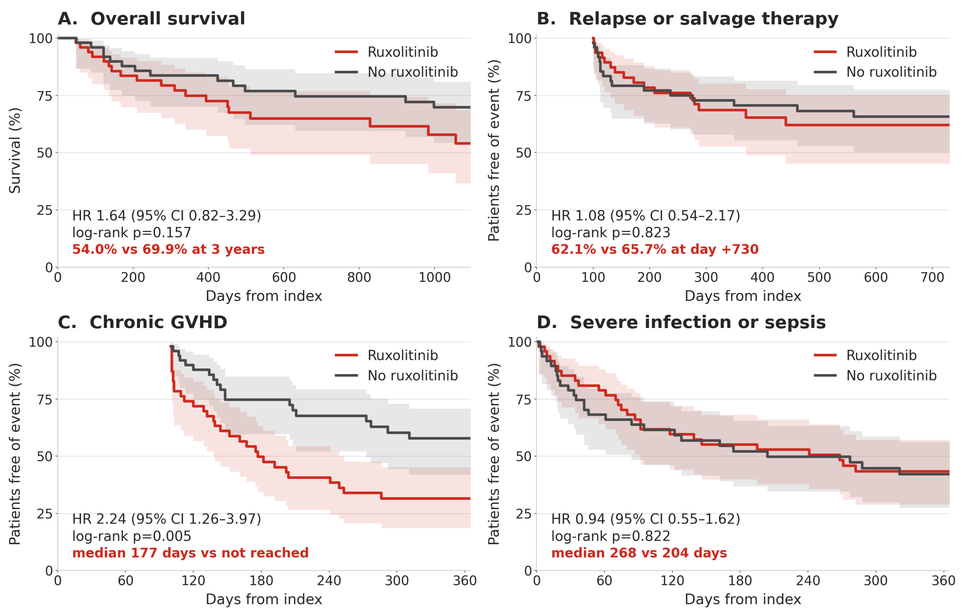

Figure 1. Kaplan–Meier curves in the 1:1 propensity score–matched cohort. Shaded bands are 95% confidence intervals. Time windows: overall survival day +1 to +1095; relapse or salvage therapy +100 to +730; chronic GVHD +100 to +365; severe infection or sepsis +1 to +365.

Outcome	Ruxolitinib	No ruxolitinib	HR (95% CI)	p
Overall survival at 3 y	54.0%	69.9%	—	—
Death	19/50 (38%)	14/50 (28%)	1.64 (0.82–3.29)	0.157
Relapse or salvage therapy	16/50 (32%)	16/50 (32%)	1.08 (0.54–2.17)	0.823
Chronic GVHD	**31/50 (62%)**	**19/50 (38%)**	**2.24 (1.26–3.97)**	**0.005**
Severe infection or sepsis*	26/47 (55%)	26/47 (55%)	0.94 (0.55–1.62)	0.822
CMV reactivation†	17/50 (34%)	14/50 (28%)	1.27 (0.62–2.57)	0.52
Pneumonia†	18/50 (36%)	16/50 (32%)	1.15 (0.58–2.25)	0.67

Table 1. Outcomes in the propensity score–matched cohort.
*47 matched pairs; all other endpoints 50 pairs. HR = hazard ratio (ruxolitinib vs no ruxolitinib); — = not estimated. p from log-rank test except †risk-difference test. Severe infection recurred less often with ruxolitinib (mean 2.85 vs 5.62 episodes; p=0.19).

BASELINE BALANCE AND CONFOUNDING
Before matching, ruxolitinib recipients were older (41.5 vs 33.8 years; p=0.006) and had more comorbidity (CKD 19% vs 3%; heart failure 19% vs 5%). After matching all measured covariates were balanced (standardized mean differences ≤0.23). GVHD severity and steroid-refractoriness could not be matched, so confounding by indication remains the most likely explanation for the excess chronic GVHD and lower survival.

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TAKE-HOME MESSAGE
In adult ALL, ruxolitinib after alloHCT was not associated with more relapse or more infection. Residual confounding by indication is the most likely explanation for the higher chronic GVHD and lower survival.