Clinical Outcomes Following Ibrutinib Withdrawal in Mantle Cell Lymphoma: A TriNetX Analysis

SOHO 2026 Annual Meeting | Poster MCL-1233 | September 9-12, 2026 | Houston, TX

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INTRODUCTION

Ibrutinib received accelerated approval in 2013 for previously treated mantle cell lymphoma (MCL), based on response data from a single-arm study. Continued approval required confirmation of clinical benefit.

The 2022 SHINE trial improved progression-free survival but showed no overall-survival benefit and greater toxicity. The MCL indication was voluntarily withdrawn in April 2023.

AIM

To compare 1-year all-cause mortality and hospitalization-free survival among adults with MCL initiating a BTK inhibitor before versus after withdrawal of the ibrutinib MCL indication.

METHOD

Design: Retrospective new-user cohort study

Setting: TriNetX Research Network; 112 healthcare organizations

Population: Adults ≥18 years with ≥2 MCL diagnoses

Index: First BTKi prescription; follow-up days 1-365

Cohorts: Pre-withdrawal n=952; post-withdrawal n=1,107

Outcomes: Mortality and inpatient encounter-free survival

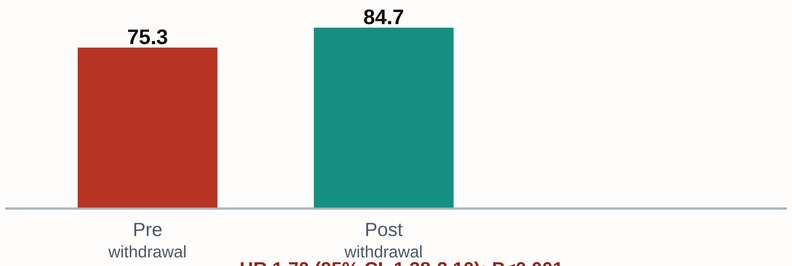
RESULTS

Mortality analysis: 918 pre-withdrawal vs 1,073 post-withdrawal patients. Hospitalization analysis: 906 propensity-matched patients per cohort.

Matching included demographics, race/ethnicity, comorbidities, laboratory measures, and bendamustine/rituximab exposure. All displayed standardized differences were <0.10 except LDH (0.131).

One-year overall survival

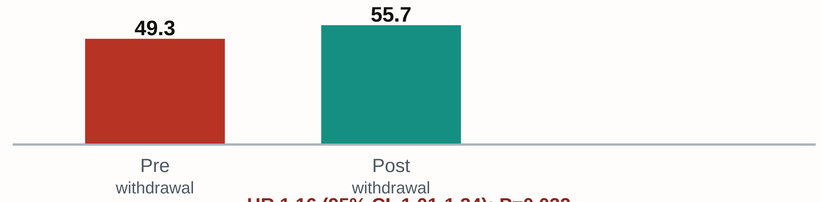
Deaths: 219/918 vs 143/1,073



HR 1.70 (95% CI, 1.38-2.10); P<0.001

One-year hospitalization-free survival

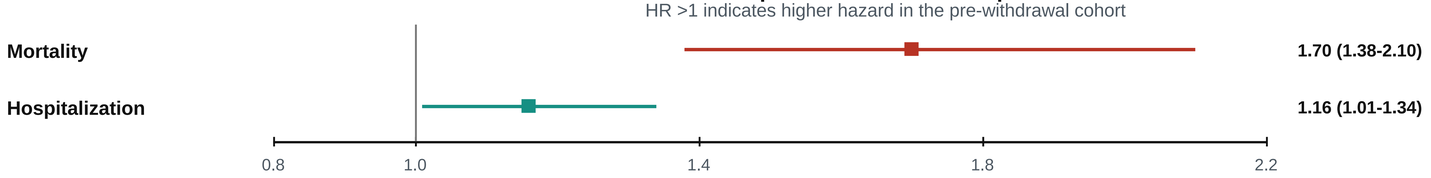
Admissions: 433 vs 366



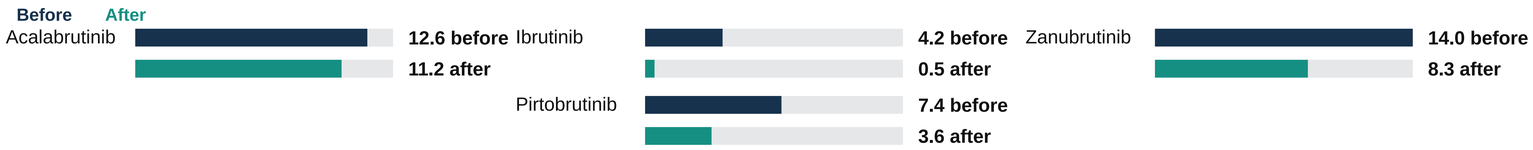
HR 1.16 (95% CI, 1.01-1.34); P=0.032

Hazard ratios: pre-withdrawal versus post-withdrawal

HR >1 indicates higher hazard in the pre-withdrawal cohort



Monthly BTKi initiations before versus after April 2023



Ibrutinib initiation declined 88%; acalabrutinib remained the most-used BTKi after withdrawal.

CONCLUSIONS

1. Post-withdrawal BTKi initiation was associated with higher 1-year overall survival.
2. Hospitalization-free survival also improved after propensity matching.
3. The shift coincided with sharply reduced ibrutinib initiation and continued use of newer BTK inhibitors.
4. These temporal associations do not establish causation.

LIMITATIONS

- Retrospective EHR data permit residual confounding and misclassification.
- Supportive care and treatment selection changed over time.
- Utilization figures are network-level monthly averages.

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ACKNOWLEDGEMENTS

No external funding.

Data source: TriNetX Research Network (112 healthcare organizations). Follow-up: days 1-365 after index BTKi prescription.

Wang et al., NEJM 2013; Wang et al., NEJM 2022 (SHINE); FDA withdrawn accelerated approvals.