BOSUTINIB IN SECOND-LINE AND BEYOND: A SINGLE-ARM META-ANALYSIS OF ITS EFFICACY IN CHRONIC MYELOID LEUKEMIA

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Introduction

Patients with chronic myeloid leukemia (CML) who are resistant or intolerant to first-line tyrosine kinase inhibitors (TKIs) face a greater risk of treatment failure due to disease biology and the limited efficacy and/or safety of available treatment options[1]. Bosutinib, a second-generation TKI, is approved for use in these patients; however, a comprehensive evaluation of its efficacy in second-line (2L) and later-line (≥3) settings remains lacking[2].

Aim

To assess whether bosutinib is a good choice for CML patients resistant to first-line TKIs.

Objectives

To determine the overall efficacy of bosutinib as a second-line (2L) and beyond (≥3L) therapy for CML by pooling molecular and cytogenetic response data and safety outcomes from existing trials.

Methods

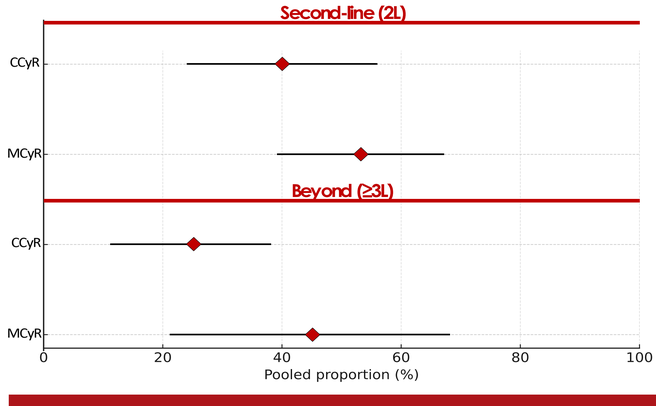
PubMed, Embase, Cochrane, clinicalTrials.gov, and WHO ICTRP were searched for records published until April 2025. Text words and controlled vocabulary for “bosutinib” and “CML” were used. Pooled prevalence of response rates was estimated using the double arcsine transformation and a random-effects model. Heterogeneity was assessed using I^2 and χ^2 statistics, with I^2>50% indicating significant interstudy variability.

Registered Protocol

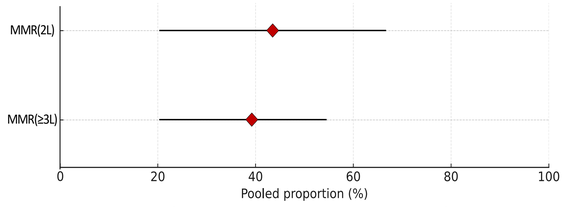
Results

A total of 2,534 records were identified from the searched sources, and 16 studies reporting data for 1,205 CML patients were included.

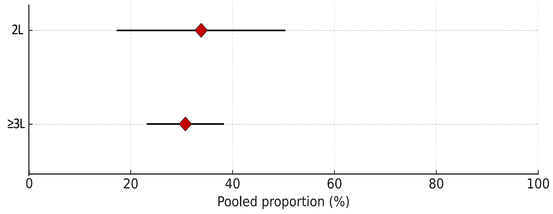
- As 2L: Pooled complete cytogenetic response (CCyR) and major cytogenetic response (MCyR) rates were 40% (95% CI: 0.24–0.56) and 53% (95% CI: 0.39–0.67), respectively.
- As ≥3L: CCyR and MCyR were 25% (95% CI: 0.11–0.38) and 45% (95% CI: 0.21–0.68), respectively.
- A significant variation was observed based on CML phase and prior treatment history.



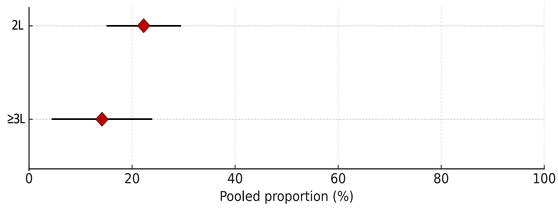
- The major molecular response (MMR) rates were 44% (95% CI: 0.21–0.66) and 38% (95% CI: 0.21–0.55), respectively, for 2L and ≥3L.



- Treatment discontinuation occurred in 34% (95% CI: 0.17–0.51) and 31% (95% CI: 0.24–0.38) of patients in 2L and ≥3L settings, respectively.



- Thrombocytopenia was reported in 23% (95% CI: 0.15–0.30) and 16% (95% CI: 0.8–0.25), of patients in 2L and ≥3L settings, respectively.



Summary

Bosutinib shows moderate efficacy in both the settings, with significantly better results as a 2L therapy.

Discussion

Bosutinib remains a viable and generally well-tolerated treatment option for CML patients resistant or intolerant to first-line TKIs. However, randomized controlled trials (RCTs) are warranted to further validate its long-term efficacy and safety across different lines of therapy.

References

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3. 3. Efficacy of Bosutinib in Second-Line and Beyond: A Single-arm Meta-Analysis in Chronic Myeloid Leukemia. PROSPERO 2025 CRD420251055028.

The author(s) declare no conflicts of interest related to this poster presentation