INTRODUCTION

Continuous therapy with ibrutinib has demonstrated sustained progression-free survival (PFS) with long-term follow-up in patients with ibrutinib-refractory malignant lymphoma.

Previous studies suggest that patients who continue treatment with ibrutinib experience better survival outcomes compared to those who discontinue treatment within the first few months.

Dose reduction is a potential adverse event (AE) management approach to optimize ibrutinib treatment outcomes and avoid early discontinuation.

METHODS

- Data were pooled for ibrutinib-treated patients from 10 clinical trials in patients with chronic lymphocytic leukemia/lymphoma: ibrutinib monotherapy (n=345), ibrutinib plus.Ole (n=709), or ibrutinib plus rituximab (n=131) (Supplemental Tables).
- Initial ibrutinib dose was 420 mg once daily for CLL/SLL and WM, and 840 mg once daily for MCL and MZL.
- Cardiac AEs, initial and recurrent, were identified by preferred terms within the cardiac disorders system organ class.
- Recurrence was defined as an AE of the same or a lower grade and was measured up to 30 days after the last dose of ibritinib on the date of first therapy, whenever occurred earlier.

OBJECTIVE

To evaluate the outcomes of dose reductions for any AE subsequent to first occurrence of a cardiac AE in patients with B-cell malignancies who were treated with ibrutinib.

RESULTS

- Of 222 patients with grade ≥1 cardiac AEs, 21 (9%) had dose reductions of ibrutinib.
- 44 patients had ibrutinib dose reductions for AEs per USPI recommendations: from 420 mg to 280 mg in 150 mg intervals, and from 280 mg to 140 mg (n=4)

CONCLUSIONS

Rates of recurrence of same/worse severity or serious cardiac AE were lower for Management of Cardiac AEs in Patients With an Ibrutinib Starting Dose of 420 mg (A) or By Dose Reductions For Cardiac AEs for Per USPI Recommendations (B)