Real world evidence: Is ibrutinib as safe as evidence tells?

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BACKGROUND AND IMPORTANCE

Ibrutinib is a Bruton tyronsin-kinasa's inhibitor used in first and subsequent lines of treatment of chronic lymphocythic leukemia (CLL). Ibrutinib has demonstrated its efficacy and security in many studies published until now. There is also experience available about these topics in real world practice. However, the safety's evidence is different between both scenarios. Because the use of ibrutinib may vary among different countries and hospitals in the same country, we wonder if safety's information in our patients is according to real world evidence.

AIM AND OBJECTIVES

To analyze the safety profile of ibrutinib in CLL all-lines treatment, and the management of its toxicity.

Secondary endpoints: to determine ibrutinib's type responses.

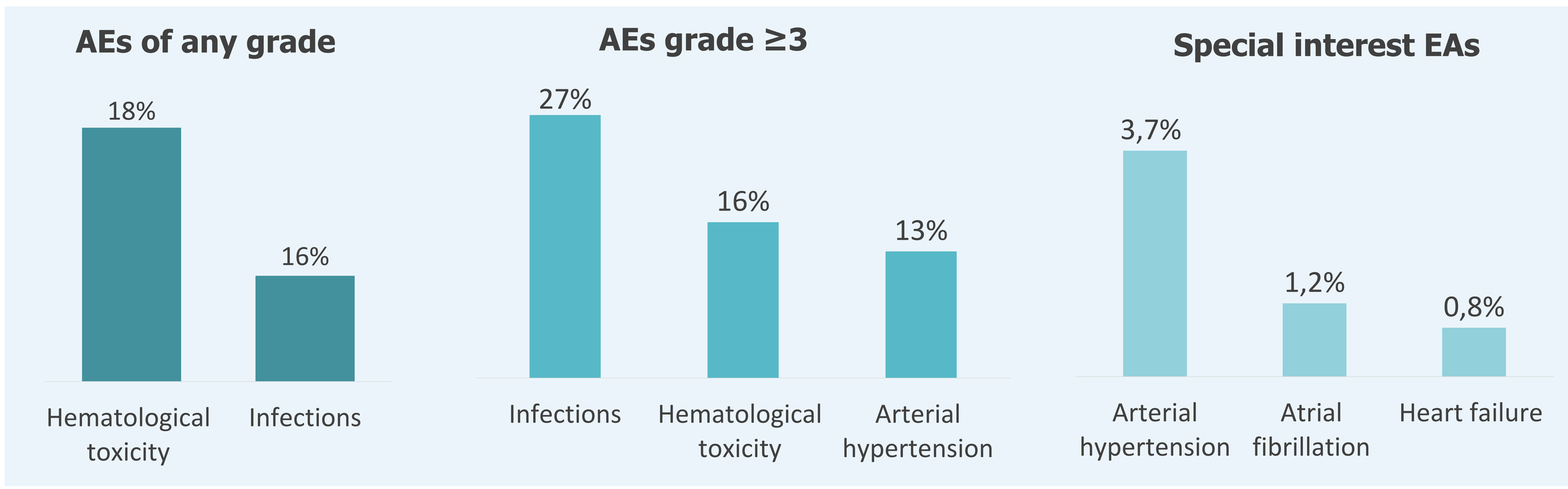
MATERIALS AND METHODS

Observational, descriptive, single-center, retrospective and longitudinal study.	*Inclusion criteria:* patients CLL diagnosed who started single-agent ibrutinib treatment from January-2016 to December-2022, aged ≥18 years-old. *Exclusion criteria:* patients treated in clinical trials and compassionate use contexts.	*Quantitative variables:* means or medians (ranges) *Qualitative variables:* absolute and relative frequencies.

RESULTS

60 patients
35% received ibrutinib in first line setting.

642 adverse events (AEs) were described.
Average: 10,7 (2-32) AEs/patient



- Five patients died during ibrutinib treatment.
- 68% of patients temporarily interrupted treatment, mostly because AEs (69%) and surgical procedures/diagnostics tests.
- 27% of patients needed dose reductions for toxicity management.
- Main reasons for treatment end were AEs (32%), disease progression (19%) and death (19%).

Treatment response	N= 51 patients
Complete response	56%
Partial response	20%
Stable disease	7%

CONCLUSION AND RELEVANCE

Despite the elevate number of AEs detected, none of special of interest not previously described have been found. Safety profile shown by ibrutinib in our treated population is comparable to that described in previous published studies. Surprisingly, complete response frequency detected is higher than reported in other studies.