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Conflict of Interest No conflict of interest.

5PSQ-104 REAL-WORLD EVIDENCE: IS IBRUTINIB AS SAFE AS EVIDENCE TELLS?

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Background and Importance Ibrutinib is a Bruton tyrosine-kinase inhibitor used in first and subsequent lines of treatment of chronic lymphocytic leukaemia (CLL). Ibrutinib has demonstrated its efficacy and safety in many studies published to date. There is also experience available about this topic 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 question whether safety's information in our patients is according to real-world evidence.

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

Secondary endpoints to determine ibrutinib's type responses.

Material and Methods Observational, descriptive, single-centre, 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. Patients treated in clinical trials and compassionate use contexts, were excluded. Quantitative variables will be described with means or medians (ranges); qualitative variables with absolute and relative frequencies.

Results Sixty patients were included, 35% received ibrutinib in first-line setting. 642 adverse events (AEs) were described, average: 10,7 (2–32) AEs/patient. Most common AEs of any grade were haematological toxicity (18,1%) mainly anaemia and neutropenia, and infections (15.9%). As special interest EAs, it was found arterial hypertension (3.7%), atrial fibrillation (1.2%) and heart failure (0.8%). Most frequent grade ≥ 3 AEs were: infections (27%) especially respiratory infections, haematological toxicity (16%) and arterial hypertension (13%). Five patients died during ibrutinib treatment. Temporary interruptions occurred in 68% patients, mostly because AEs (69%) and surgical procedures/diagnostics tests. 27% of patients needed dose reductions for toxicity management. Any patient required a second reduction for its management. Main reasons for treatment end were AEs (32%), disease progression (19%) and death (19%). Treatment response was evaluated in 51 patients: complete response (56%), partial response (20%) and stable disease progression (7%).

Conclusion and Relevance Despite the elevated 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.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-105 PATTERNS OF USE AND APPROPRIATENESS OF ANTICOAGULATION IN ATRIAL FIBRILLATION: AN OBSERVATIONAL STUDY AMONG GERIATRIC INPATIENTS

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Background and Importance Atrial fibrillation (AF) is a common arrhythmia, affecting nearly half of all geriatric patients. AF poses a significant ischemic stroke risk, making effective anticoagulation essential. Direct oral anticoagulants (DOACs) have emerged as effective stroke-prevention agents, yet under-utilisation remains a concern, especially in geriatric patients. To improve pharmacotherapy, including anticoagulation, a clinical pharmacy program was implemented on the geriatric units.

Aim and Objectives On that background, we sought to characterise anticoagulant utilisation patterns and inappropriateness among geriatric AF inpatients.

Material and Methods An observational study was performed at the acute geriatric units of an academic hospital. The first 90 AF patients for 2020, 2021 and 2022, who received at least one oral anticoagulant, were included. Anticoagulant use at discharge and therapy appropriateness were assessed. Determinants for underdosing were evaluated using multivariable logistic regression. Temporal associations for appropriateness (yes or no) and anticoagulant class (Vitamin K antagonist (VKA) vs. DOAC) were assessed using Fisher's exact analysis.

Results Mean age was 86.5 (± 5.3) years with median CHA₂DS₂-VASc score 5 [4–6]. At discharge, 256 (94.8%) patients used a DOAC, 9 (3.3%) used a VKA, 1 (0.4%) a DOAC-antiplatelet combination, and in 4 (1.5%) anticoagulant use was discontinued. Apixaban was most commonly prescribed (40.7%) and a majority of patients (64.4%) received a reduced DOAC dose. Thirty-nine (14.4%) patients received inappropriate therapy and for 23/39 (59.0%) no deviation rationale was documented. The year '2022' (odds ratio 0.104; 95% confidence interval, 0.012–0.878) was the only determinant for underdosing. There was no temporal association regarding appropriateness ($P=0.533$) or anticoagulant class ($P=0.479$).

Conclusion and Relevance A majority received anticoagulation at discharge, mostly reduced DOAC doses. Only a minority was managed inappropriately. The reassuring findings over the 3-year period might be explained by the success of the clinical pharmacy programme. In conclusion, on a background of said pharmacy services, most AF patients were treated according to current guidelines. However, deviation from clinical guidelines still occurred consistently, frequently without a documented rationale and largely explained by underdosing in the context of a high bleeding risk. Accordingly, more trial data on the most appropriate anticoagulation strategy are urgently needed in geriatric AF patients with (very) high bleeding risks.