REAL-LIFE SAFETY AND EFFECTIVENESS OF APIXABAN IN PATIENTS WITH NON VALVULAR ATRIAL FIBRILLATION

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Introduction

Real-world data on long-term safety and effectiveness in clinical practice of novel oral anticoagulants (NOACs) play an important role in the assessment of risks and benefits of this class of drugs and in supporting decision making process. Despite this, currently, the real world evidence on NOACs is still limited and available data refer mostly to administrative or insurance databases. This study aimed to collect data from Italian hospitals on patients with non-valvular atrial fibrillation (NVAF) to evaluate the incidence of major bleeding and cardiovascular outcomes in a cohort of patients exposed to apixaban.

Objectives

Our primary objective was to evaluate the incidence of major bleedings during treatment with apixaban in patients with NVAF. As a secondary objective, we investigated the incidence of a composite endpoint of major events including all-cause death, myocardial infarction, stroke and systemic thromboembolism.

Methods

In this multi-center, retrospective, observational study we collected data from clinical database on consecutive patients with a diagnosis of NVAF who had initiated apixaban from 1 January 2014 up to March 31, 2016.

Results

We studied 766 patients with NVAF from five Italian hospitals. The mean age of patients was 74.2 years and 53.5% were women. The median CHADS2 and CHA2DS2VASc scores were respectively 2.0 and 4.0. The most frequent co-morbidities were cardiovascular diseases (hypertension in 84.1% of patients; previous vascular disease in 34.1%; heart failure in 22.1%, renal impairment in 34.4%, diabetes mellitus in 22.5% and anemia in 12.5%. At baseline, 15.7% of patients had a history of at least one major event including stroke, transient ischemic attack or systemic embolism. In the whole cohort, half of patients (50.7%) were naïve to oral anticoagulants, while 219 patients had been previously treated with warfarin, heparin (66 patients), acetylsalicylic acid (52 patients), clopidogrel (1 patient) and a novel oral anticoagulant (NOAC, 40 patients). At treatment initiation, 76.5% of patients received the recommended daily dose of 10 mg, while the remaining patients (23.5%) were treated with 5 mg daily.

Over a follow-up period of 3 years, 16 major bleedings occurred. The incidence rate of major bleedings (per 1000 person-years) was 11.9, while the cumulative incidence of major bleedings

was 8.5% (95%IC 3.8%- 18.6%). With regard to the composite outcome, 26 major events were documented, including 20 deaths for any cause, 4 myocardial infarction, 4 cerebral stroke and 1 systemic thromboembolism. The cumulative incidence of composite outcome was 6.7% (95%IC 4.4-10.1).

Conclusion

In the present study, the rate of major bleedings and major thrombotic events in real-life patients treated with apixaban was comparable to that found in randomized clinical trial.