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REAL-WORLD EVIDENCE ON CLINICAL USE OF A NOVEL ORAL ANTICOAGULANT FOR THE TREATMENT OF ATRIAL FIBRILLATION

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Introduction: Atrial fibrillation (AF) is a common cardiac arrhythmia. Apixaban is one of the new oral anticoagulant drugs (NOACs) being used in non-valvular AF (NVAF). Currently the real-world data on patients population who used apixaban in clinical practice is still limited and available data refer mostly to administrative or insurance databases.

Objectives: This study was aimed to examine the clinical characteristics of patients with NVAF treated with apixaban in a real-world setting.

Methods: In this multi-centre, retrospective, observational study we collected data from clinical database on consecutive patients with a diagnosis of NVAF, aged 18 years or older who were newly prescribed with in the period from 1st of January 2014 till 31st of March 2016

The follow-up began at the first visit of the and underwent up to 3 follow-up visits. Each patient had to attend at least one follow-up visit during the observation period, the maximum length of follow-up was 3 years.Patients were excluded if they had been treated with apixaban in the 12 months before the beginning of the study or if they were diagnosed with valvular AF (with a prosthetic heart valve or with mild/severe mitral stenosis). The study protocol and CRF developed specifically for this study were approved by the Ethics Committee of each study centre. Several patients' characteristics were collected including apixaban dosage, previous comorbidities and co-treatments. Descriptive statistics of patients' characteristics were carried-out by University of Milan-Bicocca; in particular frequency and percentage were reported for the categorical variables.

Results: The analysed sample consisted of 766 patients affected by NVAF from five Italian Centres. Overall, 53.3% of the patients were female; mean age was 74.2 years (SD 11.1). Median $CHADS_2$ and CHA_2DS_2-VASc scores were 2.0 and 4.0, respectively, and median HAS-BLED score was 2.0 (SD 1.1).

The follow up duration was up to 3 years with different timespan: 750 patients completed the first follow up visit (V1), at median time from the baseline 339.5 days, 253 completed the second follow up visit (V2) at median time from V1 of 110.9 days and only for 84 patients the third visit was recorded (V3) at median time from V2 of 241.5 days.

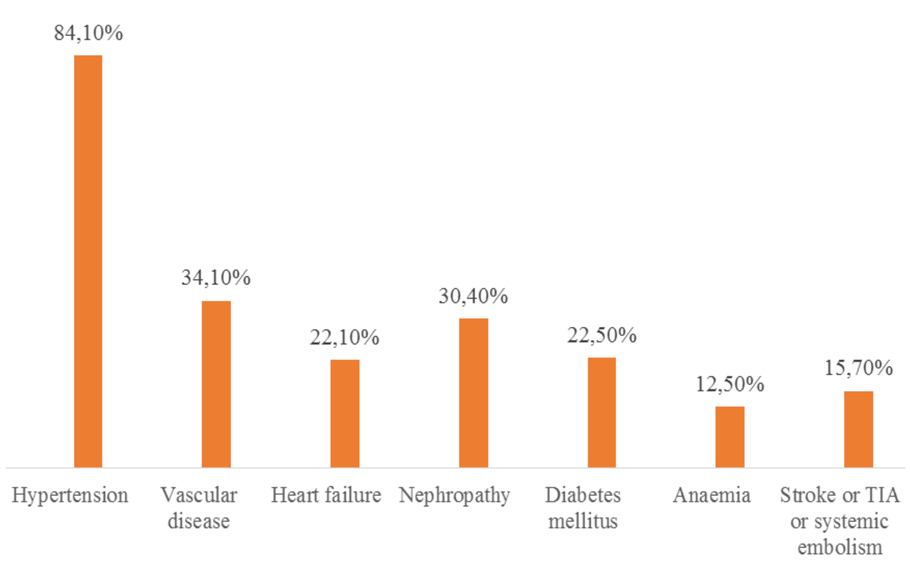

Figure 1. Co-morbidities affecting patients at baseline.

The most frequent co-morbidities were cardiovascular diseases (hypertension – affecting 84.1% of patients; previous vascular disease [34.1%]; heart failure [22.1%]), renal impairment (30.4%), diabetes mellitus (22.5%) and anaemia (12.5%). At baseline (V0), 15.7% of patients had recorded at least one event among stroke, transient ischemic attack or systemic embolism (Figure 1).

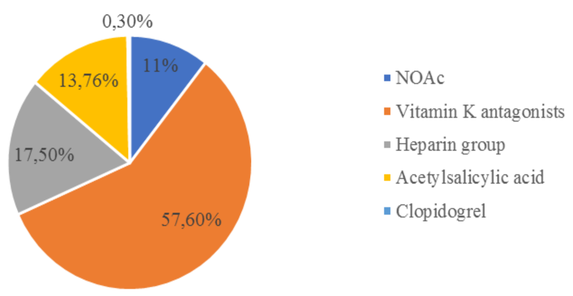

Figure 2. Use of anticoagulant drugs during the year preceding study

In the whole cohort, the 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) (Figure 2).

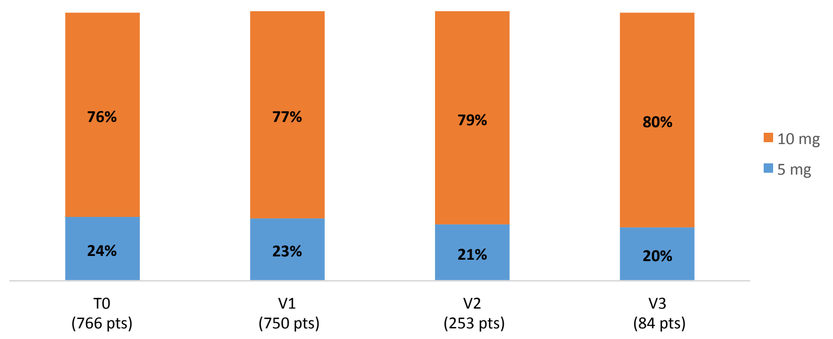

Figure 3. Dosage distribution (mg/die)

At treatment initiation, 76.5% of patients was prescribed apixaban at the recommended daily dose of 10 mg, while the remaining patients (23.5%) received the reduced daily dose of 5 mg. During the follow-up period, apixaban dose was reduced only in 2.0% of patients at V1, in 3.2% at V2 and in 4.8% at V3, but in exchange a similar proportion of patients increased the dose (Figure 3).

Switching to another anticoagulant N (%)	V1	V2	V3
Yes	40 (5.3)	21 (8.3)	8 (9.5)
No	710 (94.7)	232 (91.7)	76 (90.5)
If yes, N(%)			
dabigatran	4 (10.0)	0 (0.0)	0 (0.0)
rivaroxaban	6 (15.0)	1 (4.8)	0 (0.0)
vitamin K antagonist	17 (42.5)	5 (23.8)	0 (0.0)
heparin	13 (32.5)	15 (71.4)	8 (100.0)
acid acetylsalicylic	0 (0.0)	0 (0.0)	0 (0.0)

Table 1. Switching to another anticoagulant during the follow up

Switching to another anticoagulant occurred in 5.3% of patients at V1, in 8.3% at V2 and in 9.5% at V3 (Table 1).

Conclusions: Patient characteristics observed in this study were very similar compared to clinical trial population, while the use of the reduced daily dose of 5 mg seemed to be higher in real practice.