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Edoxaban in patients with bioprostetic valve

Abstract

Background: Nowadays the treatment with Direct Oral Anticoagulants (DOACs) and in particular with edoxaban in patients with Bioprosthetic Aortic Valve (BPAV) is unsupported by consistent data. We analyzed retrospectively our experience in this group of patients.

Methods: The data of the present study were retrospectively obtained from 24 consecutive patients with BPVA evaluated for AF in a high-volume Italian cardiological center. We analyzed the data pulled from reports of patients with Nonvalvular Paroxymal Atrial Fibrillation (NVAF), that we entered in the Italian Registry of Drugs (AIFA registry).

All patients were treated with edoxaban 60 mg for AF. At the time of the data collection, the average follow-up in valvular patients was 36 ± 3 months, with a median follow-up of 33 ± 6 months.

Results: There were no major bleedings, strokes, systemic embolisms, or cardiovascular deaths reported. A single case of transitory ischemic event (6,25%) and a case of minor bleeding (6,25%) were reported during the follow-up. The complication rate was similar in patients with BPAV compared to that of the whole group of patients with fibrillation and there were no statistical differences (2.08% vs 1.37%; p: 0.36).

Although the number is too small, transient ischemic attack appears to be more frequent in patients with BPAV than in the control group (p: 0.0046).

Conclusion: In our experience, we used edoxaban in a group of 36 subjects with BPAV and AF: the event rate of this subpopulation was not different from that of all patients with AF included in the control group. Therefore, the results suggest that the use of edoxaban for AF in patients with BPVA appears to be safe and effective.

Keywords: aortic valve, bio-prothesis, edoxaban, atrial fibrillation, safety, efficacy, complication rate

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Introduction

European and American guidelines encourage the use of Direct Oral Anticoagulants (DOACs) in patients affected by Atrial Fibrillation (AF), and many cardiologists widely use these drugs currently in clinical practice. Till now, the Italian drug agency authorizes the prescription only for Non-Valvular Atrial Fibrillation (NVAF). What should be called non-valvular atrial fibrillation has been the subject of debate in recent years in the literature.[1–6] Up to now, the Italian drug agency (AIFA) authorizes the DOAC prescription only for NVA. However, what we call non-valvular atrial fibrillation is currently under debate. From 2012 to date, numerous revisions of the European guidelines on atrial fibrillation have been published and in each of them the indication field for anticoagulation by NOAC have progressively expanding.[1–6]

However, many of the considerations in the guidelines are still based today on the opinions of experts: in fact, there are insufficient data about the use of DOAC in patients with biological valvular prosthesis and atrial fibrillation.[1–5]

In a recent study published in Heart in 2019 Malik AH performed a meta-analysis in 280 patients with a bioprosthetic heart valve and AF treated with DOACs. The data included in this meta-analysis come from both large trials and smaller studies that have be found in literature.[6] Moreover, various studies would suggest a preferability of edoxaban, apixaban or dabigatran in this group of subjects, since rivaroxaban significantly increases episodes of major bleeding episodes compared to warfarin.[3,4]

In our experience we conducted a retrospective observational study on a cohort of 36 patients treated with edoxaban for FA who underwent a BPAV implant before starting therapy.

Methods

The data of the present study were retrospectively obtained from 24 consecutive patients evaluated for AF in an high-volume Italian cardiological center. We analyzed the data pulled from reports of patients with NVA, that we entered in the Italian Registry of Drugs (AIFA registry). All selected patients received a first prescription of edoxaban between June 2016 and September 2019. The inclusion criteria were: at least one episode of documented AF of any duration in the preceding 12 months; age >18 years, a CHA2DS2-VASc [Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, previous Stroke/transient ischemic attack [double weight]–Vascular disease, Age 65–74 years, (female) Sex category] score of ≥2; any type of NVAF; a bio-prosthetic aortic valve implantation before the edoxaban administration, after the surgery.

To compare the treatment outcomes of both groups, we calculated the incidence percentage of events that occurred in each of them. All procedures performed in our study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration. The patient consent was obtained from all individual participants included in the study, who consented to the analysis and storage of their data in the AIFA registry. Due to the retrospective nature of the study, the ethical committees were retrospectively informed of the present study. Standard two-dimensional transthoracic echocardiographic examination was performed in all patients. Left ventricular end-diastolic volume, end-

systolic volume, and Left Ventricular Ejection Fraction (LVEF) were measured using the modified Simpson's rule from the apical view. Follow-up, characterized by clinical examination, Electrocardiogram and blood analysis, was performed every 6 months. None of 36 patients was lost in follow-up. The main endpoint was the incidence of major bleedings according to the International Society on Thrombosis and Hemostasis definition, or Clinically Relevant Non-Major Bleeding (CRNMB) thromboembolic events, ischemic or hemorrhagic stroke, systemic embolism, and cardiovascular death. A secondary safety endpoint was total minor bleedings. All patient follow-up data were blinded and analyzed with the SPSS® Statistics 24.0 (IBM, Armonk, NY, USA) software. We analyzed events that occurred, the main clinical and laboratory characteristics and concomitant medications.

Results

The main clinical and laboratory characteristics as well as concomitant medications for the 36 patients in the study are shown in the. All patients in both groups were treated with edoxaban by atrial fibrillation. At the time of the data collection, the average follow-up in patients with BPAV was 36±3 months, with a median follow-up of 33±6 months. There were no major bleedings, strokes, systemic embolisms, or cardiovascular deaths reported. Only one transitory ischemic event (6,25%) and one case of minor bleeding (6,25%) were reported. The results of the valvular patient group and of the control group, that included all patients with atrial fibrillation treated with edoxaban, were reported in.

The total event rate of the patients BPAV compared with the control group was similar and without any statistical differences. Although the number is too small, transient ischemic attack appears to be more frequent in patients with BPAV than in the control group ($p<0.0046$).

Discussion

The rationale for the use of DOACs in patients with BPAV is based on the fact that a risk of thromboembolism originating from the aortic valve has never been established for these patients.[1-6]

In fact, in clinical practice patients with biological implants do not require anticoagulants. In these patients, anticoagulants should only be prescribed in the presence of comorbidities such as atrial fibrillation. However, due to the high average age of these patients, association with atrial fibrillation is frequent.

According to the opinion of experts not based on scientific evidence, the European guidelines do not exclude the use of DOAC in patients with biological valves. In Italy the prescription is possible only for patients with non-atrial fibrillation valve. However, it should be noted that the definition of NVAF remains controversial in some respects.[1–6]

On this topic, a recent meta-analysis has collected all the published cases: in total 280 patients with biological valve and treated with DOAC, which were extracted from various trials and heterogeneous studies, often with a short follow-up.[6]

To help find an answer to these controversies, we thought to retrospectively analyze the data of 36 patients in treatment with edoxaban for FA who were BPVA wearers. To understand if the use of edoxaban may be safe and effective in this population, we compared the data relating to the safety and efficacy of this group with the data obtained from the whole group of patients undergoing anticoagulant therapy.

The results obtained from our study highlighted that the use of edoxaban is effective and safe in this population with an overall event index comparable in the two groups. The main limitation of the study is the small number of patients, which did not allow any sub-analysis for events.

Conclusion

In our experience, we used edoxaban in a group of 36 subjects with BPAV and AF: the event rate of this subpopulation was not different from that of all patients with AF included in the control group. Therefore, the results of our study suggest that the use of edoxaban in subjects with BPVA is safe and effective.

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