

## Letters to the Editor

**Antithrombotic Therapy After Percutaneous Aortic Valve Implantation: Large Gaps for a Matter of Extreme Importance****Tratamiento antitrombótico tras implante percutáneo de válvula aórtica: grandes lagunas para una cuestión de extrema importancia****To the Editor,**

We read with great interest the meta-analysis by Verdoia et al.<sup>1</sup> on antithrombotic therapy after transcatheter aortic valve implantation (TAVI) and we would like to congratulate the authors for their efforts to clarify an important issue. TAVI represents a major revolution, not only because it is a very effective and less traumatic alternative to surgery but also because it is an option for those patients who would not be candidates for surgery because of their comorbidities.<sup>2,3</sup> Although truly spectacular advances have been made since the technique first became available more than 10 years ago, certain questions still remain to be clarified, in particular regarding use of antithrombotic therapy.

Given their age and associated comorbidities, patients who are candidates for TAVI are at high risk of bleeding. Recently, bleeding events recorded in 926 patients in the Swiss TAVI registry have been reported.<sup>4</sup> After mean follow-up of 3 years and maximum follow-up of 5 years, 30.7% of patients had at least 1 bleeding event. Of these events, 24% were major or life-threatening. Mortality increased by 34% if the bleeding was associated with the access site and was doubled in those cases of bleeding of a different origin. Mortality was very high during follow-up, with bleeding once again having a substantial impact: 49% in patients without bleeding, 58% in those with an access-site bleeding complication, and 73% in those with bleeding of another origin; mortality also increased continually in these 3 groups.

In another recent article, Rodes-Cabau et al.<sup>5</sup> reported the results of the ARTE study, which randomized 222 patients implanted with an Edwards Sapien XT valve and without indication for oral antithrombotic therapy to 100 mg/day of acetylsalicylic acid either in monotherapy or combined with 75 mg clopidogrel for the first 3 months after the procedure. Although the study was terminated with 74% of the planned 300 patients enrolled, a decrease in major bleeding and life-threatening bleeding was found in the monotherapy group (10.8% versus 3.6%;  $P = .038$ ), as well as trends towards reduced mortality, myocardial infarction, and cerebrovascular accident. Although these trends were not statistically significant, they were nevertheless substantial (odds ratio, 1.78, 4.13, and 3.11, respectively). These results, along with the results from 2 previous studies with similar findings,<sup>6,7</sup> totalling 421 randomized patients, suggest that dual antithrombotic therapy does not reduce the risk of stroke and increases the risk of bleeding.

The American guidelines currently recommend dual therapy for the first 6 months while the European guidelines recommend dual

therapy for the first 3 months. In both cases, these are class IIb recommendations with level of evidence C, that is, expert consensus based on the approach in the PARTNER study. In view of the findings of the present meta-analysis, however, we believe these recommendations should be treated with caution until the results of the future POPular TAVI and CLOE studies become available. These studies are comparing monotherapy with dual antithrombotic therapy and will provide an answer to this important question.

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