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Antithrombotic after TAVR: no treatment, no problem?

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Current international guidelines recommend the use of lifelong single antiplatelet therapy (SAPT), with or without an initial 3-to-6 months course of anticoagulation with vitamin K antagonists, in surgical bioprosthetic aortic valves recipients without other indications for oral anticoagulants(1,2). Strikingly, available data from the literature lack compelling evidence from large randomized studies to support these recommendations.

Transcatheter aortic valve replacement (TAVR), being of more recent introduction than its surgical counterpart in the therapeutic armamentarium of severe aortic stenosis, had to thrive in the evidence-based medicine era. Consequently, each aspect of the procedure has been, and still is, under the intense scientific scrutiny of randomized controlled trials. Therefore, the rationale behind antithrombotic therapy following TAVR has known many changes in recent years(3). It was initially believed that transcatheter aortic valves would behave similarly to coronary stents in term of rheology and thus dual antiplatelet therapy (DAPT) for up to 6 months followed by lifelong SAPT was recommended in patients with no indication for chronic oral anticoagulation. This was proven incorrect on both the patient- and device-level(4).

Although TAVR indications have been expanding toward lower risk patients, the targeted population inherently remains old and frail with an increased bleeding risk. Similarly, the risk of ischemic complications, mainly stroke, remains significant yet mostly subsequent to the TAVR procedure itself, atrial fibrillation and/or device thrombosis for which antiplatelet therapy does not provide adequate protection. Randomized controlled trials comparing dual to single antiplatelet therapy have consistently demonstrated the latter to reduce bleedings without a significant ischemic offset(5). Furthermore, bioprosthetic valves are exposed to subclinical leaflet thrombosis (SLT), a complication affecting up to a third of patients treated with antiplatelet therapy, and which may be associated with a higher risk of cerebrovascular events, particularly in the absence of oral anticoagulation(6,7). The systematic use of direct oral anticoagulant reduces the occurrence of SLT without reducing the risk of stroke, which may

come at the expense of an increased risk of life-threatening bleeding and non-cardiovascular mortality, depending on the type of direct oral anticoagulant, its dosing and association with antiplatelet therapy (8,9). Following these accumulating evidence, guidelines were recently updated to henceforth recommend lifelong SAPT after TAVR (10).

However, the rationale for the use of lifelong SAPT after TAVR may also be incorrect as supporting evidence are scarce and potentially outdated. In this issue of the journal, Kobari and coauthors describe, for the first time, outcomes following elective TAVR without antiplatelet therapy prescription at discharge in 3575 patients without oral anticoagulation or procedural complications using the OCEAN-TAVI registry(11). A total of 293 patients (8.2% of the studied population) were discharged without antiplatelet per the attending physician decision and compared with patients discharged either on SAPT or DAPT. Although this strategy was mostly motivated by the presence of patients' characteristics allegedly associated with a high bleeding risk (HBR), these patients were in fact younger, with less chronic kidney disease and anemia than those discharged with antiplatelet therapy. Interestingly, more than 90% of patients in each group were considered at HBR according to the recently published Academic Research Consortium criteria, emphasizing the difficult appreciation of the bleeding risk in this particular population for which dedicated HBR criteria are lacking(12). After 3 years of follow-up, the adjusted risk of all bleedings was significantly reduced in the absence of antiplatelet therapy compared to DAPT (adjusted Hazard ratio [aHR] 0.51 95% confidence interval [CI] 0.27-0.95) and only numerically reduced compared to SAPT (aHR 0.63 95%CI 0.33-1.19) without any significant difference in term of all-cause and cardiovascular death, stroke or myocardial infarction. The study opens up a novel and interesting perspective, which warrants further confirmation in European or North American population. Some key limitations should nonetheless be kept in mind. First, the potential target for such approach is likely to be limited, as many patients will require antithrombotic therapy for prior or new-onset of atrial fibrillation

and concomitant coronary or peripheral artery disease(13,14). Less than one-tenth of the study population received no antithrombotic at discharge and it is noteworthy from their baseline characteristics that at least 15% of patients in this group had a valid indication for an antiplatelet therapy. Second, the present study was not design to properly assess the risk of SLT in patients with or without antiplatelet therapy. Although it provides reassuring results without an alarmingly high rate of SLT in patients without antiplatelet therapy, a systematic evaluation with computed tomography scan remains necessary, particularly considering that SLT may be associated with a higher risk of symptomatic hemodynamic valve deterioration(15). Third, the present study as any other observational study is inherently vulnerable to selection bias and other usual shortcomings of this kind of design. Nonetheless, Kobari and colleagues should be commended for their thought-provoking study, which paves the way for future randomized comparisons evaluating the safety and efficacy of an abbreviated antiplatelet regimen following TAVR.

References

1. Otto CM., Nishimura RA., et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol* 2021;77:450–500.
2. Vahanian A., Beyersdorf F., Praz F., et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J* 2022;43:561–632.
3. Guedeney P., Mehran R., Collet J-P., Claessen BE., Ten Berg J., Dangas GD. Antithrombotic Therapy After Transcatheter Aortic Valve Replacement. *Circ Cardiovasc Interv* 2019;12:e007411.
4. Granger C., Guedeney P., Collet J-P. Antithrombotic Therapy Following Transcatheter Aortic Valve Replacement. *J Clin Med* 2022;11:2190.

5. Guedeney P., Sorrentino S., Mesnier J., et al. Single Versus Dual Antiplatelet Therapy Following TAVR: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *JACC Cardiovasc Interv* 2021;14:234–6.
6. Makkar RR., Fontana G., Jilaihawi H., et al. Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves. *N Engl J Med* 2015;373:2015–24.
7. Montalescot G., Redheuil A., Vincent F., et al. Apixaban and Valve Thrombosis After Transcatheter Aortic Valve Replacement: The ATLANTIS-4D-CT Randomized Clinical Trial Substudy. *JACC Cardiovasc Interv* 2022;15:1794–804.
8. Dangas GD., Tijssen JGP., Wöhrle J., et al. A Controlled Trial of Rivaroxaban after Transcatheter Aortic-Valve Replacement. *N Engl J Med* 2020;382:120–9.
9. Collet J-P., Van Belle E., Thiele H., et al. Apixaban vs. standard of care after transcatheter aortic valve implantation: the ATLANTIS trial. *Eur Heart J* 2022:ehac242.
10. Ten Berg J., Sibbing D., Rocca B., et al. Management of antithrombotic therapy in patients undergoing transcatheter aortic valve implantation: a consensus document of the ESC Working Group on Thrombosis and the European Association of Percutaneous Cardiovascular Interventions (EAPCI), in collaboration with the ESC Council on Valvular Heart Disease. *Eur Heart J* 2021;42:2265–9.
11. Kobari Y., Inohara T., Yashima F., et al. No Antithrombotic Therapy after Transcatheter Aortic Valve Replacement: Insight from the OCEAN-TAVI Registry. *JACC Cardiovasc Interv* 2022;in press.
12. Garot P., Neylon A., Morice M-C., et al. Bleeding risk differences after TAVR according to the ARC-HBR criteria: insights from SCOPE 2. *EuroIntervention* 2022;18:503–13.
13. Faroux L., Guimaraes L., Wintzer-Wehekind J., et al. Coronary Artery Disease and Transcatheter Aortic Valve Replacement: JACC State-of-the-Art Review. *J Am Coll Cardiol* 2019;74:362–72.

14. Chopard R., Teiger E., Meneveau N., et al. Baseline Characteristics and Prognostic Implications of Pre-Existing and New-Onset Atrial Fibrillation After Transcatheter Aortic Valve Implantation: Results From the FRANCE-2 Registry. *JACC: Cardiovascular Interventions* 2015;8:1346–55.
15. Hein M., Schoechlin S., Schulz U., et al. Long-Term Follow-Up of Hypoattenuated Leaflet Thickening After Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv* 2022;15:1113–22.