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EDITORIAL COMMENT

Management of Massive Thrombosis of a Tendyne Valve

The Importance of Heart Valve Centers

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Transcatheter mitral valve replacement (TMVR) therapies have rapidly evolved with the development of new dedicated devices. These procedures present distinctive challenges, both in the planning of the procedure and the management of early and late complications.

Among these complications, valve thrombosis stands out as a noteworthy concern.[1]

The rate of thrombosis of mitral transcatheter heart valves (THV) varies based on the type of imaging test used (computed tomography [CT] and transthoracic and transesophageal echocardiography) and the prosthesis design. The risk is particularly high in the early perioperative period, remaining high within the first 3 months after the procedure and decreasing after the first year.[2] Although mitral THV thromboses are mostly subclinical, they can result in heart failure and thromboembolic complications.[2,3] In addition, valve thrombosis might represent an early phase of the process leading to valve degeneration.[1] Nonetheless, most evidence on mitral THV thrombosis is from valve-in-valve or valve-in-ring using aortic THVs, and little is known about the risk of valve thrombosis of new dedicated THV for mitral valve. In addition, these devices have larger and, frequently, double-frame stent, and more synthetic material than aortic valves, which might increase the risk of valve thrombosis. In this issue of *JACC: Case Reports*, Dohle et al[4] present a patient with massive valve thrombosis of a Tendyne THV resulting in severe mitral stenosis and refractory heart failure. This case underscores the challenges in managing these patients.

One of the challenges in cases suggestive of valve thrombosis is distinguishing it from valve endocarditis, especially in the context of sepsis, as in this case. As for valve thrombosis, the design of devices might also affect the risk of valve endocarditis.[5] The present case effectively illustrates the diagnostic approach required to differentiate both entities.

Even if the clinical experience with TENDYNE TMVR is the largest in the field, little is known about the specific risk of valve thrombose and endocarditis. Prior studies reported a 2% risk of valve endocarditis[6] and 6% risk of valve thrombosis, all occurring within the first year after valve implantation.[3] However, in these early experiences with Tendyne, patients did not undergo systematic CT examinations on follow-up; thus, the rate of THV thrombosis, in particular subclinical thrombosis, might have been underestimated. Indeed, a case of subclinical valve thrombosis in a Tendyne THV identified through CT has been reported.[7]

It is noteworthy that in this reported case, patient noncompliance with anticoagulation was the strongest factor associated with valve thrombosis. Furthermore, patient noncompliance or the absence of warfarin prescription were confirmed in all patients with Tendyne THV thrombosis previously reported.[3,6,7] Although it is widely acknowledged that anticoagulation therapy is essential in these patients, data on the best anticoagulant regime (type and duration of anticoagulation therapy) remain limited. Current recommendations suggest prescribing vitamin K antagonists after TMVR. However, practices vary across centers, as evidenced by the European registry on Tendyne, in which 83% of patients were discharged with a vitamin K antagonist, 17% received non-vitamin K antagonist anticoagulation therapy,

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and 38% had combined anticoagulant and antiplatelet therapy.[8] Ensuring proper adherence to antivitamin K antagonists can be challenging. Recently, the use of new oral anticoagulants (DOAC) after valve-in-valve and valve-in-ring TMVR when has been proposed. The use of DOAC was associated with a lower risk of bleeding without an increased risk of thrombosis compared with antivitamin K agents.[9] Although the efficacy of DOACs in preventing valve thrombosis in these patients has yet to be fully demonstrated, this strategy might be particularly relevant for patients who are noncompliant with antivitamin K therapy.

Importantly, in this case reported here, the heart team played a crucial role in the successful management of the patient, perfectly illustrating the value of experienced heart valve centers for handling these complications. An early diagnosis and a prompt surgery performed by experienced surgeons allowed the patient's recovery without any thromboembolic complications.

Little is known about reintervention after the implantation of a Tendyne valve. In prior studies, 5 patients required reintervention to reduce the tether length or percutaneous implantation of a plug for treating perivalvular leak.[3] In the present case, the valve was explanted, demonstrating the feasibility of explantation of the valve followed by mitral valve replacement years after initial implantation. Although Tendyne THV has been treated successfully with valve-in-valve implantation of transcatheter aortic valve in animals, the safety and efficacy has yet to be demonstrated in humans cases.[10] In addition, in patients with massive thrombosis, valve-in-valve procedures are contraindicated because of the thromboembolic risk.

In conclusion, the long-term management of patients undergoing TMVR with dedicated devices poses unique challenges. A multidisciplinary approach involving the heart team in heart valve centers with experienced operators is crucial for successful management of patients facing valve-related complications.

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