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Editorial

Transcatheter Aortic Valve Implantation After Mitral Valve Replacement: Insights From the OPTIMAL Registry

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See article by Baldetti et al., pages 866–874 of this issue.

The spectacular progress of heart valve repair or replacement techniques in the past 30 years has dramatically improved the longevity and quality of life of patients with severe valvular heart disease. One of the consequences of this success is that cardiologists are often confronted by successive or concomitant heart valve diseases in the same patient. In particular, an important proportion of patients who undergo mitral valve (MV) replacement will develop severe aortic stenosis later during their lifetime and will thus require aortic valve intervention.[1] Transcatheter aortic valve replacement (TAVR) is a well validated alternative to surgical aortic valve replacement in the subset of patients with intermediate or high surgical risk, which includes those with preexisting mitral prosthesis. There are few data on the outcomes of TAVR in patients with preexisting mitral prosthesis, in large part because these patients were excluded from most previous randomized trials or registries.

In this issue of the *Canadian Journal of Cardiology*, Baldetti et al. report the results of the **O**utcome of **P**atients Undergoing **T**ranscatheter **Im**plantation of **A**ortic Valve With Previous Mitra**l** Valve Prosthesis (OPTIMAL) international multicentre retrospective registry, which included 154 patients with previously implanted mitral prosthesis who underwent TAVR for severe aortic stenosis.[2] This represents the largest registry published to date on TAVR procedures remotely after MV replacement. Most (83%) of the patients had undergone isolated MV replacement and the MV prosthesis was a mechanical valve in 70% of the patients. The TAVR was performed, on average, 11.7 ± 8.4 years after the MV replacement and the transcatheter heart valve (THV) was of first-generation in 73% of the cases, and second-generation in 37%. Transfemoral access was used in 78%, transapical in 16%, and other in 3%. The TAVR procedure was a valve-in-valve (ie, a TAVR within a degenerated bioprosthetic aortic valve) in 14% of the cases in this registry. Successful device implantation, according to Valve Academic Research Consortium-2 (VARC-2) definition, was achieved in 86% of patients; 5% had mean aortic gradient ≥ 20 mm Hg and 6% had moderate/severe aortic regurgitation. Interference between the MV prosthesis and the THV was observed in 2 patients and in both cases, the mitroaortic distance was < 5 mm. Periprocedural complications included: 2.6% stroke, 6.6% major vascular complications, 14.4% severe bleeding, and 3.2% in-hospital death. At a median follow-up of 13.5 months, all-cause and cardiovascular-related mortality rates were 16.9% and 9.7%, respectively. Late fatal MV prosthesis thrombosis occurred in 2 patients (one of whom had spontaneous discontinuation of anticoagulant therapy). Rehospitalization because of worsening of heart failure occurred in 16.2% of patients. The main limitation of the OPTIMAL registry is the absence of a matched control group of patients with no MV prosthesis.

Table 1 shows a summary of the key findings of the OPTIMAL registry as well as of the previous smaller (< 100) series of patients who underwent TAVR long after MV replacement. In the second largest series reported by Amat-Santos et al,[3] the clinical outcomes were similar overall to those of the OPTIMAL registry, except for the higher rates of THV embolization (7% vs 1%) and use of a second valve (5% vs 1%; Table 1). The third largest cohort reported by Barbanti et al. showed no embolization or second valve use.[4] The OPTIMAL registry included 154 patients from 11 centres and showed the feasibility and good outcomes of TAVR in patients with a preexisting MV prosthesis.[3,5-8] The presence of an MV prosthesis has often been considered as a relative contraindication of TAVR and/or an exclusion criteria in most TAVR trials. The novel and compelling data presented by the OPTIMAL investigators in this issue of the *Canadian Journal of Cardiology* are very reassuring with respect to the utility and safety of TAVR in this context. However, performing TAVR in a patient with preexisting MV prosthesis raises some technical challenges and risks of procedural complications. The main concerns with the performance of TAVR in this context are: (1) the risk of interference between the MV prosthesis and the THV; and (2) the risk of thromboembolic and bleeding complications.

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Table 1. Summary of the results of the studies of patients who underwent transcatheter aortic valve replacement at distance of mitral valve replacement

Reference	Centre(s), n	Patients, N • Age, years • Sex • Mean STS score	Mitral valve surgery • Type of MV device • Size, mm • Interval MV surgery to TAVR, years	TAVR procedure • Type of device • Size, mm • Transfemoral access	Procedural outcomes and complications • Embolization • Second valve • Balloon shift • Device shift Device success* Procedural success†	In-hospital outcomes • New permanent PM • Cerebrovascular event • Bleeding complication • Length of stay, days • Death	Late clinical FU • Length, months • Death
Baldetti et al.[2]	11	154 • Mean age: 77 • Female: 80% • STS: 8.7 ± 8.0	• Mech: 70%, bio: 30% • Mean size: 26 • Mean interval: 12	• BE: 48%, SE: 49%, other: 3% • Mean: 26 • TF: 78%	• Embolization: 1% • Second valve: 1% • Balloon shift: – • Device shift: – Device success: 86% Procedural success: 97%	• New permanent PM: 12% • Cerebrovascular event: 3% • Bleeding complication: 14% • Length of stay, median: 9 • Death: 3%	• Median FU: 13.5 • Death: 17%
Amat-Santos et al.[3]	10	91 • Mean age: 75 • Female: 71% • STS: 8.9 ± 7.5	• Mech: 74%, bio: 26% • Size: 27 • Median interval: 14	• BE: 56%, SE:42%, other: 2% • Size: – • TF: 79%	• Embolization: 7% • Second valve: 5% • Balloon shift: – • Device shift: – Device success: 76% Procedural success: 99%	• New permanent PM: 15% • Cerebrovascular event: 3% • Bleeding complication: 24% • Length of stay, mean: 9 • Death: 6%	• Median FU: 60 • Death: 31%
Barbanti et al.[4]	9	40 • Mean age: 76 • Female sex: 73% • STS: 13.4 ± 11.5	• Mech: 75%, bio: 25% • Size: – • Mean interval: 15	• BE :30%, SE: 70% • Size: – • TF: 58%	• Embolization: 0% • Second valve: 0% • Balloon shift: 13% • Device shift: 8% Device success: 98% Procedural success: 100%	• New permanent PM: – • Cerebrovascular event: 3% • Bleeding complication: 28% • Length of stay, mean: 14 • Death: 0%	• Median FU: 19 • Death 13%
Soon et al.[9]	1	10 • Mean age: 78 • Female: 70% • STS: 10.0 ± 4.8	• Mech: 70%, bio: 30% • Median size: 27 • Mean interval: 12	• BE: 100%, SE: 0% • Median: 26 • TF: 0% (all TA)	• Embolization: 0% (but 1 device embolization earlier via TF access) • Second valve: 0% • Balloon shift: 50% • Device shift: 40% Device success: 80% Procedural success: 100%	• New permanent PM: 20% • Cerebrovascular event: 0% (but delirium 50%) • Bleeding complication: 33% • Length of stay: – • Death: 0%	• Mean FU: 12 • Death: 40%
Bruschi et al.[15]	1	9 • Median age: 74 • Female: 78% • STS: 12.7 ± 10.0	• Mech: 78%, bio: 11%, ring: 11% • Median size: 27 • Mean interval: 13	• BE: 0%, SE: 100% • Median: 26 • TF: 78%	• Embolization: 0% • Second valve: 0% • Balloon shift: – • Device shift: – Device success: 100% Procedural success: 100%	• New permanent PM: 11% • Cerebrovascular event: 0% • Bleeding complication: 0% • Length of stay, median: 12 • Death: 0%	• Mean FU: 23 • Death: 11%
Asil et al.[16]	1	6 • Mean age: 71 • Female: 67% • STS: 9.83 ± 3.3	• Mech: 83%, bio: 17% • Size: – • Mean interval: 15	• BE: 0%, SE: 100% • Median size: 29 mm • TF: 100%	• Embolization: 0% • Second valve: 0% • Balloon shift: – • Device shift: – Device success: 83% Procedural success: 100%	• New permanent PM: 17% • Cerebrovascular event: 0% • Bleeding complication: 33% • Length of stay: – • Death: 0%	• Median FU: 12 • Death: 0%
Drews et al.[17]	1	6 • Median age: 81 • Female: 83% • STS: 43.0 ± 18.1	• Mech: 33%, bio: 50%, ring: 17% • Median size: 31 • Mean interval: 8	• BE: 100%, SE: 0% • Median: 23 • TF: 0% (all TA)	• Embolization: 0% • Second valve: 0% • Balloon shift: – • Device shift: – Device success: 100% Procedural success: 100%	• New permanent PM: 0% • Cerebrovascular event: 0% • Bleeding complication: 0% • Length of stay: – • Death: 17%	• Median FU 11 • Mean FU 10 • Death 33% (1 case of fatal endocarditis)

Sari et al.[18]	1	6 • Mean age: 71 • Female: 50% • STS: 10.5 ± 2.7	• Mech: 83%, bio: 17% • Median size: 27 • Mean interval: 10	• BE: 100%, SE: 0% • Median: 26 • TF: 100%	• Embolization: 0% • Second valve: 0% • Balloon shift: – • Device shift: – Device success: 100% Procedural success: 100%	• New permanent PM: 17% • Cerebrovascular event: 0% • Bleeding complication: 17% • Length of stay, mean: 5 • Death: 0%	• Median FU: 16 s • Death: 17%

BE, balloon-expandable transcatheter aortic valve replacement device; bio, biological prosthesis; FU, follow-up; Mech, mechanical prosthesis; MV, mitral valve; PM, pacemaker; SE, self-expandable; STS, Society of Thoracic Surgery; TA, transapical access; TAVR, transcatheter aortic valve replacement; TF, transfemoral access; VARC-2, Valve Academic Research Consortium-2.

* Device success is defined by the absence of procedural mortality and correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance of the prosthetic heart valve (no prosthesis-patient mismatch and mean aortic valve gradient < 20 mm Hg or peak velocity < 3 m/s, and no moderate or severe prosthetic valve regurgitation).

† Procedural success is defined by the implantation of a single TAVR device at the desired site without procedural mortality or surgical conversion.

MV Prosthesis-THV Interference

The interaction with the strut of the bioprosthetic MV or the outlet frame, leaflet guard, or cage of the mechanical MV might cause an upward shift of the balloon and/or THV device.[9] This might lead to THV malposition, embolization, and other associated complications such as coronary obstruction, and paravalvular regurgitation.

The distance from the MV prosthesis to the aortic annulus is one of the key factors in determining the risk of TAVR procedural complications (Fig. 1). Amat-Santos et al. indeed reported that the risks of MV prosthesis-THV interference and ensuing THV malposition or embolization increase markedly when distance from the MV prosthesis to the aortic annulus is < 7 mm.[3] The MV prosthesis-aortic annulus distance information was available in only 29% of the patients included in the OPTIMAL registry. Nonetheless, the 2 patients who experienced THV-MV prosthesis interference during the procedure had a short mitroaortic distance (≤ 5 mm).

Direct interaction between the THV stent frame and the mechanical MV occluder or bioprosthetic MV leaflets might lead to immediate or late prosthetic MV dysfunction and adverse outcomes.[10-12] However, the struts or housing of the MV prosthesis might impair THV deployment and cause deformation, especially with self-expanding devices, which might lead to significant transvalvular or paravalvular aortic regurgitation.[3,13] Hence, comprehensive imaging, including echocardiography and cinefluoroscopy, should be performed after THV implantation to assess the anatomical relation and potential interaction between the 2 devices. No significant difference in TAVR procedural success rates was found according to the type of THV (ie, balloon-expandable vs self-expanding). Thus, the choice of THV type should be made according to anatomical features and experience of operators.

Bleeding and Thromboembolic Risk

Patients with a mechanical MV require lifelong anticoagulation with vitamin K antagonists (VKAs) with a target international normalized ratio of 3.0 (class IB) in combination with single antiplatelet therapy (aspirin 75-100 mg; class IA).[14] In patients with a mitral bioprosthesis, anticoagulation with a VKA is reasonable for 3 months post MV replacement followed by lifelong single antiplatelet therapy (or lifelong VKA if anticoagulation is needed for other reasons). Hence, patients with a previously implanted MV prosthesis are at higher risk of bleeding complications during and after the TAVR procedure, and major bleeding complications are associated with increased mortality risk.[3] In the OPTIMAL registry, 79% of the patients were receiving oral anticoagulation at discharge and 14% had severe bleeding complications after TAVR.[2] Optimal antithrombotic management in the peri- and postprocedural periods is thus key to reduce the risk of bleeding and thromboembolic complications after TAVR in patients with an MV prosthesis. Further studies are needed to determine the optimal bridging antithrombotic therapy during the periprocedural TAVR period in patients with a mechanical MV prosthesis.

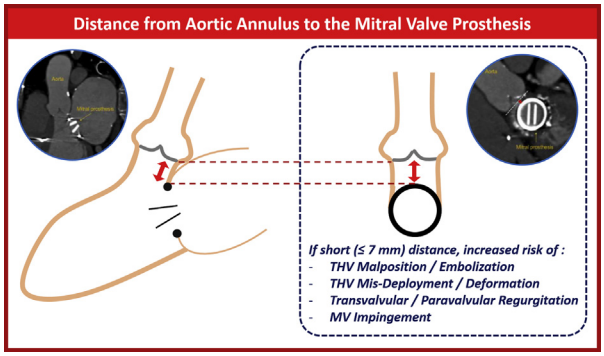

Figure 1. Effect of distance from aortic annulus to mitral valve prosthesis on outcomes following TAVR performed after mitral valve replacement. MV, mitral valve; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve.

Conclusion

The results of the OPTIMAL registry published in this issue of the *Canadian Journal of Cardiology* confirm the feasibility, high procedural success rate, and safety of the TAVR procedure in patients with previous MV replacement. However, caution is required when the mitroaortic distance is short ($\leq$ 7 mm) and antithrombotic regimens should be optimized and anticoagulation status carefully monitored during and after TAVR.

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