

EDITORIAL COMMENT

Tearing Down the Risk for Coronary Obstruction With Transcatheter Aortic Valve Replacement*



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Despite the rapid development of transcatheter aortic valve replacement (TAVR) during the past decade, several procedure-related complications still deserve rightful attention and novel solutions. Coronary artery obstruction during or after TAVR represents a rare complication (incidence of <1% in native aortic valves and 2.3% in valve-in-valve [ViV] procedures) (1,2), but its consequences are devastating, leading to high 30-day mortality (up to 50%) (1,2). Current therapeutic approaches (bailout percutaneous coronary intervention or emergency bypass surgery) are suboptimal or not always feasible, shifting attention toward the development of preventive strategies. Pre-emptive coronary protection measures have been investigated and are currently used (3,4), but they are limited by 2 major aspects: 1) the occurrence of delayed coronary obstruction after the end of TAVR (up to 30% of cases) (2); and 2) several issues associated with percutaneous coronary intervention in this setting (stent jailing with inability to retrieve it, unnecessary coronary stenting in some cases, concerns regarding suboptimal durability with the risk for fatal restenosis or thrombosis at the ostial left main coronary artery, extreme difficulty in reengaging a coronary artery after “chimney” stenting). In this context, patients who are predicted to be at high risk for coronary obstruction are frequently deprived of TAVR as a therapeutic option. Therefore, any effort to develop new preventive solutions for this TAVR complication is justified and commendable.

In this issue of *JACC: Cardiovascular Interventions*, Khan et al. (5) describe a new technique aimed to prevent coronary obstruction during and after TAVR. The BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) procedure consists of a laceration of 1 or 2 aortic valve leaflets (bioprosthetic or native) to split them before transcatheter valve implantation, thus preventing leaflet-induced coronary obstruction. The pathophysiological basis of this technique is solid, because the displacement of surgical or native aortic leaflets during transcatheter valve deployment plays a pivotal role in obstructing coronary ostia (either by directly covering the coronary ostia or by sealing the sinus of Valsalva at the sinotubular junction). This technique follows the approach of these investigators to develop novel techniques for current problems in structural interventions, using devices readily available in the catheterization laboratory, such as the transcaval approach and laceration of the anterior mitral leaflet to prevent outflow obstruction (6,7). The investigators describe the development of the technique in vitro and in animals and then report the first-in-human experience in 7 patients at high risk for coronary obstruction from TAVR and ineligible for conventional surgical aortic valve replacement. Such a pioneering study must be commended, as it represents an effort toward TAVR refinement and evolution, aiming to solve a procedure-related complication that still does not have a definitive solution. The most relevant findings of this study are as follows.

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First, in benchtop testing, the investigators demonstrated that an electrified guidewire (Astato XS 20, Asahi Intecc USA, Santa Ana, California) can perforate and lacerate the bioprosthetic valve leaflets and that subsequent transcatheter valve deployment

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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(of both balloon-expandable and self-expanding devices) results in splaying of the lacerated leaflets.

Second, in animal experiments, BASILICA was attempted in 5 pigs (3 on the left coronary cusp and 2 on both left and right coronary cusps): guidewire traversal and laceration (by means of radiofrequency energy) were effective in leaflet splitting in all animals, as demonstrated by necropsy, with no macroscopic evidence of collateral thermal damage. BASILICA resulted in severe aortic regurgitation in all pigs, and 2 animals experienced severe hemodynamic compromise after BASILICA requiring anticipated euthanasia (1 after mitral injury and the other following double BASILICA). Some major mechanical complications were observed in the first attempted procedures (mitral chord entrapment and laceration determining severe mitral regurgitation, misdirected wire traversal into the left atrium, interventricular septum, or aortic annulus); however, the technique was refined after the first procedures, with no evidence of further important complications.

Third, eventually, BASILICA was performed before TAVR in 7 patients on a compassionate basis. Included patients were considered at high risk for coronary obstruction during TAVR, on the basis of manufacturer-described geometry of the specific implanted device and currently known anatomic risk factors: ViV TAVR (particularly in patients with prior stentless bioprostheses or stented bioprostheses with externally mounted leaflets), short virtual transcatheter valve-to-coronary ostium distance, lower lying coronary ostia, or shallow sinus of Valsalva (1,2). The technical feasibility of BASILICA was demonstrated in different valve types and conditions, as the studied population was heterogeneous: 6 patients underwent ViV TAVR for failed stentless or stented bioprostheses (presenting as aortic stenosis, regurgitation, or mixed disease), whereas 1 patient underwent TAVR for native aortic stenosis; 6 patients required laceration of the left aortic cusp and 1 patient of both left and right cusps. BASILICA was technically successful in all patients (all attempted leaflets were successfully traversed and lacerated), with no cases of coronary obstruction. In this first-in-human experience, the threatened coronary arteries were protected by wiring and placing a stent mid-vessel after BASILICA; in 1 patient, the pre-positioned stent was entrapped by the transcatheter heart valve, with subsequent unnecessary deployment in the left main coronary artery (in the absence coronary obstruction). All patients experienced severe aortic regurgitation after leaflet laceration, but with no evidence of hemodynamic compromise in the 8 to 30 min between BASILICA and TAVR or afterward. There

were no major complications, and all patients survived to 30 days.

Although this new technique seems technically feasible in several scenarios (bioprosthetic or native aortic leaflets, 1- or 2-cusp laceration), data from a U.S. Food and Drug Administration-approved prospective study are eagerly awaited to confirm its safety and efficacy in a larger number of patients (NCT03381989). A definitive demonstration of safety and efficacy would provide us a valuable instrument in current TAVR practice: indications for TAVR would be expanded to patients otherwise ineligible for any therapy, and the risk for acute and delayed coronary obstruction would be mitigated among at-risk patients currently treated with TAVR. Of note, in this study, BASILICA was not attempted in patients undergoing ViV TAVR for failed TAVR devices, a scenario that will become increasingly common in the future.

Despite the enthusiasm in learning about this promising technique, a note of caution should be sounded. The procedure carries some risks and is probably not suitable in all patients and anatomic settings; hence, a few issues need to be raised.

First, acute severe aortic regurgitation is a natural consequence of leaflet laceration and may lead to hemodynamic compromise, particularly in patients with severe ventricular dysfunction or if TAVR cannot be performed immediately after BASILICA. However, it appears that the degenerated leaflet continues to move and contribute to leaflet coaptation, thus preventing rapid hemodynamic collapse. Nevertheless, the investigators were cautious by ensuring that they had access to the left ventricle with a pigtail catheter if rapid valve deployment was required.

Second, there is risk for collateral mechanical damage to surrounding structures (aortic annulus, mitral valvular apparatus, among others), particularly during wire traversal, snaring, and laceration, whose real incidence and relevance must be evaluated in larger studies.

Third, double BASILICA is more challenging from a technical point of view: 4 arterial accesses are needed (2 for each BASILICA), 2 pairs of catheters are positioned in the targeted aortic leaflets, and simultaneous laceration of both leaflets is performed by manipulating both looped guidewires; hence, there may be an increased risk for mechanical injury.

Fourth, traversal and laceration of heavy calcified aortic leaflets may be particularly difficult and may also increase the risk for periprocedural cerebral embolization.

Finally, experience is confined to the specific combination of surgical and transcatheter bioprostheses

evaluated in this study, so the safety and feasibility of BASILICA with other combinations of devices need to be tested.

These issues should be addressed in larger studies before widespread adoption of this new technique. Furthermore, the interplay between BASILICA and currently used pre-emptive coronary protection measures must be evaluated, as they may represent complementary strategies, but unnecessary maneuvers may be harmful (e.g., in the case of stent entrapment and unnecessary deployment). Although the investigators give a detailed explanation of the procedural steps, there is a significant amount of “art” to this new and technically demanding procedure, and thus we would advise readers to refrain from reproducing it without significant training or proctoring.

This new promising technique represents a potentially durable solution for a currently unsolved problem (coronary obstruction from TAVR); however, as with any new procedure, it warrants careful validation, and further efforts are required before applying it in clinical practice. We hope that future studies will follow this virtuous example of translational research (from benchtop testing to human experience) to explore innovative solutions for unresolved issues in the TAVR field, thus further refining current practice and improving patient outcomes.

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REFERENCES

1. Ribeiro HB, Webb JG, Makkar RR, et al. Predictive factors, management, and clinical outcomes of coronary obstruction following transcatheter aortic valve implantation: insights from a large multicenter registry. *J Am Coll Cardiol* 2013;62:1552-62.
2. Ribeiro HB, Rodés-Cabau J, Blanke P, et al. Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry. *Eur Heart J* 2018;39:687-95.
3. Yamamoto M, Shimura T, Kano S, et al. Impact of preparatory coronary protection in patients at high anatomical risk of acute coronary obstruction during transcatheter aortic valve implantation. *Int J Cardiol* 2016;217:58-63.
4. Abramowitz Y, Chakravarty T, Jilaihawi H, et al. Clinical impact of coronary protection during transcatheter aortic valve implantation: first reported series of patients. *EuroIntervention* 2015;11:572-81.
5. Khan JM, Dvir D, Greenbaum AB, et al. Transcatheter laceration of aortic leaflets to prevent coronary obstruction during transcatheter aortic valve replacement: concept to first-in-human. *J Am Coll Cardiol Interv* 2018;11:677-89.
6. Greenbaum AB, Babaliaros VC, Chen MY, et al. Transcaval access and closure for transcatheter aortic valve replacement: a prospective investigation. *J Am Coll Cardiol* 2017;69:511-21.
7. Babaliaros VC, Greenbaum AB, Khan JM, et al. Intentional percutaneous laceration of the anterior mitral leaflet to prevent outflow obstruction during transcatheter mitral valve replacement: first-in-human experience. *J Am Coll Cardiol Interv* 2017;10:798-809.

KEY WORDS BASILICA, coronary obstruction, TAVR, valve-in-valve