EuroIntervention
2024;20:e733-e734
published online e-edition June 2024
DOI: 10.4244/EIJ-E-24-00029

EDITORIAL

Role of leaflet modification in TAVI: to prevent coronary obstruction only or potentially a routine practice?

Toby Rogers[1,2]*, MD, PhD; Lior Lupu[1], MD, MBA

*Corresponding author: MedStar Washington Hospital Center, 110 Irving St NW, Suite 4B1, Washington, D.C., 20010, USA. E-mail: toby.rogers@medstar.net

The authors' affiliations can be found at the end of this article.

Over the years, transcatheter aortic valve implantation (TAVI) has been increasingly offered to younger patients. The trend has been driven not only by technological advancement and rigorous clinical trials but also by patient demand for interventions that are less invasive, with lower risk and faster recovery. This is evidenced by the high proportion of patients under the age of 65 who undergo TAVI in the USA despite the guidelines recommending surgical aortic valve replacement (SAVR) in this age group[1]. Younger patients who undergo TAVI are more likely to require reintervention for bioprosthetic valve failure (BVF). If BVF occurs, treatment options are limited to surgical explant or a second TAVI inside the failed valve (redo-TAVI). Both treatment options carry risks. Explant surgery is associated with high mortality rates (with recent data showing a 30-day mortality rate of 16%[2]). Redo-TAVI risks coronary obstruction and makes future coronary access more challenging[3-5]. This is because when we perform redo-TAVI and deploy a transcatheter heart valve (THV) inside a failed THV, we push the degenerated leaflets of the first valve to the side, creating a covered stent in the aortic root which can obstruct the coronaries directly, or indirectly through sinus sequestration. The width and height of the covered stent are determined by the combination of THVs[6]. In addition to risking acute coronary obstruction, the covered stent may impede coronary access in the future, thereby limiting our ability to manage coronary artery disease, which remains prevalent in patients with aortic stenosis, even in younger low-risk cohorts[7].

Leaflet modification with BASILICA (Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction) was developed to prevent these implications by pre-emptively splitting the displaced leaflet of the native valve[8]. An electrosurgical technique initially performed using off-label catheters and guidewires, there are now several technologies in development to make on-label leaflet modification safer, easier and faster.

In this issue of EuroIntervention, Beneduce et al present the findings of a benchtop study investigating the impact of BASILICA on coronary access following redo-TAVI with a balloon-expandable THV inside a supra-annular THV. The investigators used three-dimensionally (3D)-printed models of high-risk patient anatomies to conduct *ex vivo* TAVI and redo-TAVI procedures. They examined the impact of THV selection, commissural alignment, implant depth, and BASILICA on coronary access. An initial TAVI was performed using either a 26 mm Evolut PRO (Medtronic) or size S ACURATE *neo*2 (Boston Scientific). The valves were implanted at different degrees of commissural misalignment (0°, 30°, 45°, and 60°). A redo-TAVI procedure was performed using a 23 mm SAPIEN 3 Ultra (Edwards Lifesciences) within the first THV at either a low or high implant depth. Coronary access was then attempted using fluoroscopy and standard catheters. To investigate the role of BASILICA on the ability to engage the coronaries, pairwise comparisons were conducted after adjusting for the effects of sinus height, design of the first THV, commissural alignment, and implant depth of the second THV. Overall, the feasibility of coronary access was significantly improved with BASILICA (60.9% versus 18.7%; p<0.001). The combination of BASILICA and a low redo-TAVI implant depth provided the highest likelihood of coronary access. However, coronary access was not successful, even after BASILICA, when commissural misalignment was ≥45° for the ACURATE *neo*2 valve and ≥30° for the Evolut PRO valve[9].

Article, see page e770

The study tantalises a role for BASILICA to facilitate coronary access after redo-TAVI, further establishing leaflet modification as an important tool in the arsenal of TAVI operators.

Additionally, it emphasises the importance of considering the lifetime management of patients with aortic stenosis when planning their first TAVI procedure. While the choice of THV is multifactorial, ensuring commissural alignment is imperative to enable future reintervention. In this benchtop study, BASILICA was effective when there was mild or moderate commissural misalignment but appeared ineffective in cases of severe commissural misalignment – when the THV commissural suture posts lay in front of the coronary ostia.

One important caveat: the second balloon-expandable THV was deployed with "perfect" commissural alignment in this *ex vivo* study. Almost 40% of coronary cannulations after BASILICA were only possible through the stent frame of the second THV. However, the SAPIEN 3 Ultra delivery system does not currently provide a method for commissural alignment. If this study were repeated with "random" commissural alignment of the second THV, it is likely that the success rates for coronary access following redo-TAVI would have been much lower. This underscores the need for every THV platform to offer simple and reliable commissural alignment.

At present, the generally accepted role for leaflet modification is to prevent coronary obstruction during TAVI for native aortic stenosis, valve-in-valve TAVI for failing surgical bioprostheses, and redo-TAVI. It is conceivable that leaflet splitting could be used more broadly in the future, i.e., for patients in whom coronary obstruction is not an issue but rather to facilitate coronary access. The study by Beneduce et al provides compelling evidence that leaflet splitting makes coronary access more predictable and technically simpler in challenging patient anatomies (e.g., low coronary ostia, commissural misalignment or when treating failed supra-annular THVs). Beyond the scope of this benchtop study, there are intriguing data that suggest that leaflet splitting may prevent THV thrombosis. In a benchtop pulsatile flow phantom model, BASILICA reduced stasis by improving neosinus washout[10]. In the BASILICA IDE study, THV leaflet thrombus was observed in approximately 11% of patients, but never in the neosinus adjacent to the lacerated leaflet[8]. One can therefore speculate that if we had on-label tools that made leaflet modification safe, quick and easy, why wouldn't we perform it in every patient undergoing TAVI if it makes coronary access easier and prevents leaflet thrombosis?

BASILICA was first developed to address a clinical problem: to prevent coronary obstruction in patients undergoing TAVI who were too high risk for surgery. However, one should not assume that leaflet modification is the solution to all of our problems. We must strive to identify younger patients whose anatomy makes redo-TAVI difficult before we perform the first TAVI. In such patients, surgery with excision of the native leaflets and implantation of an appropriately sized prosthesis and perfect commissural alignment remains the better initial therapy. Technology advancements that enhance the durability of THVs, guarantee commissural alignment every time, and do not jail the coronaries will further enhance our ability to offer TAVI to younger patients without compromising future reinterventions.

Authors' affiliations

1. Section of Interventional Cardiology, MedStar Washington Hospital Center, Washington, D.C., USA; 2. Cardiovascular Branch, Division of Intramural Research, National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, MD, USA

Conflict of interest statement

T. Rogers: consulting: Edwards Lifesciences, Medtronic, Boston Scientific, Abbott, Anteris, and Transmural Systems; advisory board: Medtronic, Boston Scientific; equity interest: Transmural Systems; intellectual property: co-inventor on patents, assigned to NIH, for transcatheter electrosurgery devices. L. Lupu has no conflicts of interest to declare.

References

1. Gupta T, DeVries JT, Gilani F, Hassan A, Ross CS, Dauerman HL. Temporal Trends in Transcatheter Aortic Valve Replacement for Isolated Severe Aortic Stenosis. *J Soc Cardiovasc Angiogr Interv*. 2024 April 5. Available at: https://doi.org/10.1016/j.jscai.2024.101861. (Last accessed: 22 May 2024).

2. Zaid S, Kleiman NS, Goel SS, Szerlip MI, Mack MJ, Marin-Cuartas M, Mohammadi S, Nazif TM, Unbehaun A, Andreas M, Brinster DR, Robinson NB, Wang L, Ramlawi B, Conradi L, Desai ND, Forrest JK, Bagur R, Nguyen TC, Waksman R, Leroux L, Van Belle E, Grubb KJ, Ahmad HA, Denti P, Modine T, Bapat VN, Kaneko T, Reardon MJ, Tang GHL, Explant-Tavr Registry Investigators OBOT. Impact of transcatheter heart valve type on outcomes of surgical explantation after failed transcatheter aortic valve replacement: the EXPLANT-TAVR international registry. *EuroIntervention*. 2024;20:e146-57.

3. Rogers T, Greenspun BC, Weissman G, Torguson R, Craig P, Shults C, Gordon P, Ehsan A, Wilson SR, Goncalves J, Levitt R, Hahn C, Parikh P, Bilfinger T, Butzel D, Buchanan S, Hanna N, Garrett R, Buchbinder M, Asch F, Garcia-Garcia HM, Okubagzi P, Ben-Dor I, Satler LF, Waksman R. Feasibility of Coronary Access and Aortic Valve Reintervention in Low-Risk TAVR Patients. *JACC Cardiovasc Interv.* 2020;13:726-35.

4. Forrestal BJ, Case BC, Yerasi C, Shea C, Torguson R, Zhang C, Ben-Dor I, Deksissa T, Ali S, Satler LF, Shults C, Weissman G, Wang JC, Khan JM, Waksman R, Rogers T. Risk of Coronary Obstruction and Feasibility of Coronary Access After Repeat Transcatheter Aortic Valve Replacement With the Self-Expanding Evolut Valve: A Computed Tomography Simulation Study. *Circ Cardiovasc Interv.* 2020;13:e009496.

5. Ochiai T, Oakley L, Sekhon N, Komatsu I, Flint N, Kaewkes D, Yoon SH, Raschpichler M, Patel V, Tiwana R, Enta Y, Mahani S, Kim Y, Stegic J, Chakravarty T, Nakamura M, Cheng W, Makkar R. Risk of Coronary Obstruction Due to Sinus Sequestration in Redo Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv.* 2020;13:2617-27.

6. Akodad M, Sellers S, Gulsin GS, Tzimas G, Landes U, Chatfield AG, Chuang A, Meier D, Leipsic J, Blanke P, Ye J, Cheung A, Wood DA, Khan JM, Webb JG, Sathananthan J. Leaflet and Neoskirt Height in Transcatheter Heart Valves: Implications for Repeat Procedures and Coronary Access. *JACC Cardiovasc Interv.* 2021;14:2298-300.

7. Faroux L, Guimaraes L, Wintzer-Wehekind J, Junquera L, Ferreira-Neto AN, Del Val D, Muntané-Carol G, Mohammadi S, Paradis JM, Rodés-Cabau J. Coronary Artery Disease and Transcatheter Aortic Valve Replacement: JACC State-of-the-Art Review. *J Am Coll Cardiol.* 2019;74:362-72.

8. Khan JM, Greenbaum AB, Babaliaros VC, Rogers T, Eng MH, Paone G, Leshnower BG, Reisman M, Satler L, Waksman R, Chen MY, Stine AM, Tian X, Dvir D, Lederman RJ. The BASILICA Trial: Prospective Multicenter Investigation of Intentional Leaflet Laceration to Prevent TAVR Coronary Obstruction. *JACC Cardiovasc Interv.* 2019;12:1240-52.

9. Beneduce A, Khokhar AA, Curio J, Giannini F, Zlahoda-Huzior A, Grant D, Lynch L, Zakrzewski P, Kim WK, Maisano F, de Backer O, Dudek D. Impact of leaflet splitting on coronary access after redo-TAVI for degenerated supra-annular self-expanding platforms. *EuroIntervention*. 2024;20:e770-80.

10. Hatoum H, Maureira P, Lilly S, Dasi LP. Impact of Leaflet Laceration on Transcatheter Aortic Valve-in-Valve Washout: BASILICA to Solve Neosinus and Sinus Stasis. *JACC Cardiovasc Interv.* 2019;12:1229-37.