Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 101113

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Editorial

Pushing Past Boundaries: Impella Use in Severe Aortic Valve Stenosis

Kristina Gifft, DO, Arun Kumar, MD *

Division of Cardiovascular Medicine, Department of Medicine, University of Missouri School of Medicine, Columbia, Missouri

The proportion of the global population aged 65 years or above continues to rise.[1] As a result, the prevalence of severe, symptomatic aortic stenosis (AS) will also increase, leading to a higher volume of aortic valve replacements performed as definitive therapy for this invariably progressive disease. Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry data demonstrate increasing use of transcatheter aortic valve replacement (TAVR) as the therapeutic modality of choice for severe AS, and since 2018 to 2019, TAVR volumes have exceeded that of surgical aortic valve replacement.[2]

Over 50% of TAVR candidates are found to have concomitant obstructive coronary artery disease (CAD).[3] While there is no clear consensus on the extent of percutaneous coronary revascularization required prior to TAVR, the practical approach has generally been to perform percutaneous coronary intervention (PCI) on severe left main and proximal coronary lesions before valve intervention. Pre-TAVR PCI can also help minimize procedural challenges from difficult coronary access encountered once the prosthetic valve is in place. The current American College of Cardiology/American Heart Association valve guidelines deem PCI for severe CAD before TAVR as safe and feasible and recommend an individualized approach.[4]

PCI is performed in approximately 25% of patients destined to undergo TAVR, of whom approximately half are noted to have multivessel CAD.[5] In the context of complex PCI prior to TAVR, particularly cases incorporating atherectomy, temporary hemodynamic support may be necessary to reduce the risk of hemodynamic compromise. Several choices for temporary hemodynamic support devices currently exist. While counterpulsation with intra-aortic balloon pump (IABP) is familiar, widely available, and avoids interaction with the stenotic aortic valve, the modest degree of fractional cardiac output augmentation offered by an IABP is often inadequate to provide meaningful protection during a high-risk intervention. The TandemHeart percutaneous ventricular assist device (LivaNova), as a left atrial–femoral arterial circuit, offers a high degree of hemodynamic support with direct unloading of the left ventricle and avoids interaction with the aortic valve; however, it is limited to use in centers with significant experience with transseptal puncture and familiarity with the system. Over the past decade, the Impella 2.5 and CP transvalvular flow pumps (Abiomed) have emerged as a technically less demanding approach to left ventricular unloading, reliably providing 2.5 to 4 L/min of circulatory support. Severe aortic valve stenosis, however, is a contraindication to Impella insertion and was part of the exclusion criteria in the pivotal PROTECT II trial.[6] The resulting paucity in data creates a challenge for clinicians wanting to safely perform high-risk PCI with Impella support in the setting of severe AS.

In this issue of *JSCAI*, Yeo et al[7] evaluated 15 patients with severe AS who underwent Impella-assisted high-risk PCI prior to TAVR. This single-center retrospective case series evaluated an older population with a median age of 89 years and with severe aortic valve stenosis with an average aortic valve area of 0.85 cm^2 and mean aortic gradient of 40 mm Hg. The CAD was indeed complex: 43% of patients underwent left main PCI, 57% of patients underwent multivessel PCI, and 71% required atherectomy. In 1 of the 15 consecutive patients eligible for the study, the aortic valve could not be crossed with Impella despite balloon aortic valvuloplasty (BAV). This patient underwent IABP-assisted PCI. A total of 14 patients underwent successful Impella-assisted PCI before TAVR, with 2 of the 14 patients requiring BAV to facilitate Impella crossing before PCI. There were no Impella-assisted PCI-related complications (primary end point), which included mortality, bleeding, stroke or transient ischemic attack, or vascular complications. On subsequent TAVR, there were no in-hospital or 30-day mortalities. Moreover, in 36% of the patients, the ipsilateral femoral artery used for Impella was later used for TAVR large bore access, ostensibly without any adverse effects.

The results of Yeo et al's[7] study are both thought-provoking and encouraging, forcing us to re-examine whether severe aortic valve stenosis is truly a contraindication for Impella insertion. The authors have provided a detailed table with individual clinical characteristics of the study cohort, which helps the reader further examine the type of patients who may be potentially eligible for such an approach. Furthermore, this study provides important technical insight and adds meaningfully to the small existing body of evidence on this increasingly important patient subset. In order to expand the feasibility and safety of

DOI of original article: https://doi.org/10.1016/j.jscai.2023.101061.

Keywords: aortic stenosis; coronary artery disease; mechanical circulatory support; percutaneous coronary intervention; transcatheter aortic valve replacement.

* Corresponding author: kumararun@health.missouri.edu (A. Kumar).

https://doi.org/10.1016/j.jscai.2023.101113
Received 6 July 2023; Accepted 16 July 2023
Available online 4 August 2023

Impella-assisted high-risk PCI before TAVR, the following areas of further study are required:

1. Further clarification on which patients truly benefit from PCI prior to TAVR. Until such data are available, most interventional cardiologists will likely continue to pursue an individualized approach based on a combination of clinical and anatomic factors.
2. Gain a better understanding of which patients require hemodynamic support for PCI in the setting of severe AS. Studies exploring use of data derived from right heart catheterization and measurement of left ventricular end diastolic pressure, left ventricular ejection fraction, and systolic and diastolic blood pressure may provide further insight.
3. Granular technical considerations for Impella placement, vis-à-vis pretreatment of the valve with BAV prior to Impella placement, parameters to guide duration of LV support post-PCI and consideration of proceeding with TAVR in the same setting as PCI.

Future clinical trials and technological advancements, especially in the field of transvalvular catheter pumps, will help us understand how best to match the right level of support with the right patient, in the context of high-risk PCI performed prior to TAVR.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding sources

This work did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. *World Population Prospects 2022. Summary of Results*. United Nations Department of Economic and Social Affairs; 2022.
2. Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT registry of transcatheter aortic valve replacement. *Ann Thorac Surg*. 2021;111(2):701–722. https://doi.org/10.1016/j.athoracsur.2020.09.002
3. Gasparetto V, Fraccaro C, Tarantini G, et al. Safety and effectiveness of a selective strategy for coronary artery revascularization before transcatheter aortic valve implantation. *Catheter Cardiovasc Interv*. 2013;81(2):376–383. https://doi.org/10.1002/ccd.24434
4. Writing Committee Members, Otto CM, Nishimura RA, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *J Am Coll Cardiol*. 2020;77(4):e25–e197. https://doi.org/10.1016/j.jacc.2020.11.018
5. Faroux L, Campelo-Parada F, Munoz-Garcia E, et al. Procedural characteristics and late outcomes of percutaneous coronary intervention in the workup pre-TAVR. *JACC Cardiovasc Interv*. 2020;13(22):2601–2613.
6. O'Neill WW, Kleiman NS, Moses J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. *Circulation*. 2012;126(14):1717–1727. https://doi.org/10.1161/CIRCULATIONAHA.112.098194
7. Yeo I, Wong SC, Mack CA, et al. Feasibility and safety of Impella-assisted high-risk PCI before TAVR in patients with severe aortic stenosis. *J Soc Cardiovasc Angiogr Interv*. 2023, 101061. https://doi.org/10.1016/j.jscai.2023.101061