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Original Research

# Feasibility and Safety of Impella-Assisted High-Risk PCI Before TAVR in Patients With Severe Aortic Stenosis

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## ABSTRACT

**Background:** There are limited data on the feasibility of Impella-assisted percutaneous coronary intervention (PCI) in patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR).

**Methods:** To assess the feasibility of the Impella-assisted PCI in patients with severe symptomatic AS, we retrospectively reviewed the medical records to identify patients who were electively admitted for Impella-assisted PCI with a subsequent TAVR at Weill Cornell Medical Center from 2016 to 2021.

**Results:** During the study period, 15 patients were identified to be eligible for the study, but the Impella failed to cross the aortic valve in 1 patient despite a concomitant balloon aortic valvuloplasty requiring a switch to an intra-aortic balloon pump to assist PCI. A total of 14 patients underwent successful PCI with the Impella CP and were included in the analysis. The median age was 89 years, and women accounted for 43% of the cohort. The median aortic valve area and mean gradient were 0.85 $cm^2$ and 40 mm Hg, respectively, with a median left ventricular ejection fraction of 51%. The median SYNTAX score was 13. The left main stent was placed in 6 patients (43%), with a rotational atherectomy performed in 10 patients (71%). The balloon aortic valvuloplasty was performed in 2 patients before Impella placement. The TAVR was performed in all 14 patients on a median post–Impella-assisted PCI day of 25. No procedural complications were noted post-TAVR with no in-hospital or 30-day death.

**Conclusions:** In this single-center study of patients with severe AS, the elective Impella-assisted high-risk PCI was feasible and safe before TAVR in selected patients.

## Introduction

Rapid growth of the elderly population has been paralleled by the recent dramatic increase in the utilization of transcatheter aortic valve replacement (TAVR) to treat symptomatic severe aortic stenosis (AS).[1] Concurrent significant coronary artery disease (CAD) is common and might be associated with worse long-term survival in patients with severe AS undergoing TAVR.[2,3] Various strategies are available for the management of significant CAD in patients undergoing TAVR, and selective percutaneous coronary intervention (PCI) before TAVR has been shown to be a safe option.[4]

The Impella device (Abiomed) is a transvalvular microaxial flow pump ventricular assist device that provides hemodynamic support during high-risk PCI by improving cardiac output, coronary blood flow, and peripheral tissue perfusion. However, severe AS has been considered a contraindication to the Impella, and patients with severe AS have been excluded in the clinical trials for Impella-assisted high-risk PCI.[5,6] Therefore, the data on the feasibility of Impella use for PCI in severe AS patients prior to TAVR are limited.[7–9] We present a single-center case series of Impella-assisted PCI (IA-PCI) in patients with severe AS before TAVR.

## Methods

### *Study cohort*

In this retrospective observational study, we included all consecutive patients who underwent IA-PCI prior to a scheduled TAVR at Weill

*Abbreviations:* AS, aortic stenosis; CAD, coronary artery disease; IA-PCI, Impella-assisted percutaneous coronary intervention; PCI, percutaneous coronary intervention; TAVR, transcatheter aortic valve replacement.

*Keywords:* Impella-assisted percutaneous coronary intervention; obstructive coronary artery disease; severe symptomatic aortic stenosis; transcatheter aortic valve replacement.

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**Table 1.** Baseline characteristics of the study cohort.

| Characteristics | Study cohort (n = 14) |
|---|---|
| Age, y | 88.5 (74-90) |
| Female | 6 (42.9%) |
| Hypertension | 12 (85.7%) |
| Diabetes | 3 (21.4%) |
| Aortic valve area, $cm^2$ | 0.85 (0.68-0.98) |
| Aortic valve mean gradient, mm Hg | 40 (32-47) |
| Left ventricular ejection fraction, % | 51 (35-60) |
| Heart failure with reduced ejection fraction | 5 (35.7%) |
| SYNTAX score | 16 (11-27) |
| STS score | 8.3% |
| Creatinine, g/dL | 1.13 (0.70-1.59) |
| Rotational atherectomy | 10 (71.4%) |
| Left main stent | 6 (42.9%) |
| No. of vessels treated with DES | 2 (1-2) |
| Days between Impella and TAVR | 25 (10-35) |
| Impella-assisted PCI, n | |
| Balloon aortic valvuloplasty | 2 |
| Impella CP | 14 |
| Femoral access | 14 |
| Complications | 0 |
| TAVR | |
| Balloon-expandable/self-expandable, n | 14/0 |

Values are median (IQR) or n (%), unless otherwise noted.
DES, drug-eluting stent; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.

Cornell Medical Center and NewYork-Presbyterian Queens Hospital from June 2016 to October 2021. The institutional review board at NewYork-Presbyterian Hospital approved this research (approval #14221221).

### *Data collection*

Data on demographics, comorbidities, laboratory results, echocardiographic findings, procedural details of IA-PCI and TAVR, and outcomes were manually abstracted from each patient's electronic health record. Primary outcome was post–IA-PCI complications, defined as mortality, any vascular complication, stroke/transient ischemic attack (TIA), or composite of Bleeding Academic Research Consortium 2, 3, and 5 bleeding.[10]

### *Procedure*

IA-PCIs were performed under conscious sedation. Bilateral common femoral arteries were accessed with micropuncture kits followed by placement of 2 preclose sutures (Perclose ProGlide, Abbott Vascular), a dedicated 14F Impella sheath was advanced into the femoral artery percutaneously. The use of ultrasound to guide vascular access was left to the discretion of the operator. Following placement of a 0.018″ placement guide wire across the aortic valve, the Impella device was advanced into the left ventricle under fluoroscopic guidance. Two patients required balloon valvuloplasty to facilitate Impella placement. After confirmation of Impella placement under fluoroscopy, IA-PCI was performed using drug-eluting stents. The Impella access site was closed with 2 preclosed Perclose devices, and the PCI access site was closed with 1 Perclose device in all patients.

After IA-PCI, the patients were mostly discharged and brought back to the cardiac catheterization laboratory for TAVRs as a separate staged procedure, except for 1 patient who underwent TAVR 2 days after IA-PCI during the same hospitalization. A 6F sheath was placed in the femoral vein for temporary pacer access. The temporary pacer was advanced under fluoroscopic guidance into the right ventricle, and thresholds were confirmed. Arterial access was obtained in bilateral common femoral arteries with 6F and 7F sheaths. The access site chosen for TAVR access was preclosed with 2 Perclose devices and then upsized to an Edwards 14F sheath. A cerebral protection device was deployed in 1 patient via the radial artery because most of these cases were done prior to Food and Drug Administration approval of Sentinel Cerebral Protection System (Boston Scientific). All patients received a SAPIEN 3 valve (Edwards Lifesciences). Once a SAPIEN 3 had been advanced across the native aortic valve and the valve position was confirmed with an aortogram, it was deployed during right ventricular pacing at a rate of 170 bpm. Paravalvular regurgitation and mean gradients across the valve were immediately assessed mostly by echocardiography. After the TAVR access site was closed with the preclosed Perclose devices, protamine was administered. The contralateral arterial access site was closed with a single Perclose device. After removal of the temporary pacer wire, the femoral venous sheath was subsequently removed with manual compression for hemostasis.

### *Statistical analysis*

For descriptive analyses, categorical variables are reported as total count and percentage of patients, and continuous variables are presented as median with IQR on the basis of the distribution of data.

## Results

During the study period, 15 patients had an attempt at IA-PCI, with 1 patient having a failed crossing of the Impella despite a concomitant balloon aortic valvuloplasty (BAV), requiring a switch to an intra-aortic balloon pump-assisted PCI. A total of 14 patients underwent successful PCI using the Impella CP and were included in the analysis. The baseline characteristics of the study cohort are presented in Tables 1 and 2. The median age was 89 years, and 43% of the cohort were women. The median SYNTAX score was 16, and the STS score was 8.3%. On transthoracic echocardiogram before IA-PCI, the median aortic valve area and mean gradient were 0.85 $cm^2$ and 40 mm Hg, respectively, with a median left ventricular ejection fraction of 51%. The median left ventricular end-diastolic pressure was 19 mm Hg, and the median pulmonary capillary wedge pressure was 17 mm Hg. A BAV was performed in 2 patients to place the Impella before IA-PCI. The Impella CP was used with femoral access for all patients. For PCI, 8 patients (57%) underwent multivessel PCI, and 6 patients (43%) underwent left main PCI (2 with ostial left main lesion, 4 with distal left main bifurcation lesion), with rotational atherectomy being performed in 10 patients (71%). There were no IA-PCI–related complications, including mortality, bleeding, stroke/TIA, or vascular complications (Central Illustration). The TAVR was performed in all 14 patients with a median time from IA-PCI to TAVR of 25 days. The femoral access was utilized for all TAVR procedures, and the ipsilateral side was used for femoral access for Impella and TAVR in 36% of the cohort. All patients received a balloon-expandable SAPIEN valve for their TAVR. Post-TAVR, there was no in-hospital or 30-day mortality, although 1 patient, whose prior IA-PCI access was on the contralateral side, required a percutaneous transluminal angioplasty of the common femoral artery after TAVR due to dissection. There were no major access site bleeding complications.

## Discussion

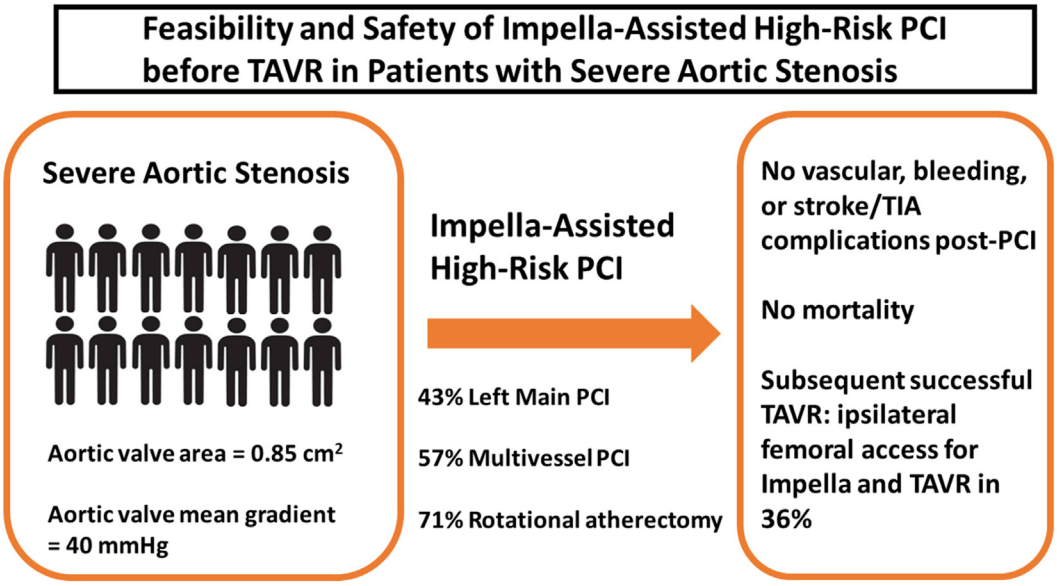
This series represents a cohort of patients with severe AS and concomitant obstructive CAD undergoing IA-PCI prior to a staged TAVR. The IA-PCI was successful in 14 out of 15 patients, who

**Table 2.** Individual clinical characteristics of the study cohort.

| Cases | Age | Sex | Comorbidities | AV area, $cm^2$ | AV mean pressure gradient, mm Hg | LVEF, % | SYNTAX score | No. of vessels for PCI | Vessel anatomy for PCI | PCI | Rotational atherectomy | TAVR | Complication | Baseline hemodynamic data | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | BP[a] | LVEDP | PAP[b] | PCWP |
| Case 1 | 59 | M | Hypertension | 0.68 | 50 | 60 | 10 | 1 | Distal LM 70% | LAD into LM | Yes | 26 mm SAPIEN 3 | None | 118/68 | 30 | 25/10 (15) | 8 |
| Case 2 | 90 | M | Hypertension | 0.98 | 32 | 56 | 13 | 2 | LAD 70%, RCA 95% | mid LAD, ostial RCA | No | 26 mm SAPIEN 3 | None | 123/67 | 19 | 67/20 (40) | 20 |
| Case 3 | 92 | M | Hypertension | 1.3 | 39 | 42 | 13 | 2 | LAD 80%, LCx 80% | mid LAD, mid LCx | No | 29 mm SAPIEN 3 | None | 147/60 | 13 | n/a | n/a |
| Case 4 | 51 | F | — | 0.79 | 30 | 65 | 11 | 1 | Ostial LM 60% | Ostial LM | Yes | 23 mm SAPIEN 3 | None | 113/75 | n/a | 20/12 (17) | 12 |
| Case 5 | 90 | F | Diabetes | 0.51 | 62 | 37 | 10 | 2 | RCA 90%, LCx 80% | BAV, ostial RCA, ostial LCx | No | SAPIEN 3 | None | 106/63 | n/a | 45/20 (33) | 25 |
| Case 6 | 89 | M | Hypertension | 0.75 | 42 | 35 | 30 | 1 | Distal LM 60%, LAD 80% | LAD into LM, mid LAD | Yes | 23 mm SAPIEN 3 | None | 99/53 | n/a | 30/10 (15) | 6 |
| Case 7 | 88 | M | Hypertension | 0.84 | 41 | 59 | 11 | 1 | LAD 95% | Ostial LAD | No | 29 mm SAPIEN 3 | None | 163/54 | 18 | 30/14 (20) | 13 |
| Case 8 | 97 | F | Hypertension | 0.86 | 39 | 47 | 12 | 2 | RCA 90%, LAD 90% | Ostial RCA, mid LAD | No | 23 mm SAPIEN 3 | None | 126/51 | n/a | 54/25 (38) | 28 |
| Case 9 | 68 | M | Hypertension, diabetes | 0.86 | 33 | 55 | 28 | 1 | Distal LM 80% | Distal LM | Yes | 26 mm SAPIEN 3 | None | 155/60 | 15 | 33/8 (17) | 8 |
| Case 10 | 89 | F | Hypertension | 0.59 | 44 | 63 | 25 | 3 | RCA 95%, Distal LM 75%, LAD 80% | Ostial RCA, distal LM, mid LAD | Yes | 26 mm SAPIEN 3 | PTA for CFA dissection[c] | 122/69 | 20 | 55/21 (25) | 15 |
| Case 11 | 85 | F | Hypertension | 0.63 | 25 | 32 | 19 | 2 | LAD 90%, LCx 80% | Prox-to-mid LAD, mid LCx | No | 26 mm SAPIEN 3 | None | 105/64 | 20 | 30/15 (22) | 18 |
| Case 12 | 74 | M | Hypertension | 0.86 | 47 | 25 | 27 | 2 | LAD 90%, LCx 80% | Prox LAD, ostial LCx | No | 23 mm SAPIEN 3 | None | 114/69 | n/a | 44/21 (32) | 23 |
| Case 13 | 89 | M | Hypertension, diabetes | 1.1 | 14 | 25 | 36 | 2 | LAD 80%, Diag1 80% | BAV, prox-to-mid LAD, ostial Diag1 | No | 26 mm SAPIEN 3 | None | 124/59 | 10 | 60/23 (40) | 24 |
| Case 14 | 83 | F | Hypertension | 0.99 | 48 | 70 | 13 | 1 | Ostial LM 90% | Ostial LM to prox LAD | Yes | 26 mm SAPIEN 3 Ultra/ femoral | None | 128/53 | 22 | n/a | n/a |
| Case 15[d] | 92 | F | Hypertension | 0.83 | 50 | 75 | 32 | 3 | LAD 95%, LCx 75%, RCA 80% | Ostial LAD, mid LCx, ostial RCA | Yes | 26 mm CoreValve Evolut R | None | 147/53 | 23 | 26/8 (16) | 9 |

AV, aortic valve; BAV, balloon aortic valvuloplasty; BP, blood pressure; CFA, common femoral artery; Diag1, 1st diagonal branch; F, female; LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main artery; LVEDP, left ventricular end-diastolic pressure; LVEF, left ventricular ejection fraction; n/a, not available; M, male; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; PCWP, pulmonary capillary wedge pressure; PTA, percutaneous transluminal angioplasty; RCA, right coronary artery; TAVR, transcatheter aortic valve replacement.

[a] BP: systolic/diastolic, mm Hg. [b] PAP: systolic/diastolic (mean), mm Hg. [c] PTA performed for CFA dissection post-TAVR. [d] Impella failed to cross the aortic valve; thus, the case was not included in the analysis.




**Central Illustration.**
Summary of study cohort with severe aortic stenosis who underwent impella-assisted high-risk percutaneous coronary intervention before transcatheter aortic valve replacement.

subsequently underwent TAVR, on average, within 25 days after IA-PCI. None of the patients had IA-PCI–associated mortality, stroke/TIA, or any vascular or bleeding complications, suggesting feasibility and safety of IA-PCI in patients with severe AS.

The 2020 American College of Cardiology/American Heart Association (ACC/AHA) valve guideline recommends coronary angiography prior to TAVR in patients with CAD risk factors.[11] Therefore, coronary angiography is performed in nearly all adult patients, and significant CAD is commonly found with its prevalence ranging between 15% and 80%.[12] Although patients enrolled in the trials comparing TAVR and surgical aortic valve replacement underwent PCI based on the protocol, either as a staged procedure before TAVR or concomitantly at the time of TAVR,[13,14] the optimal timing of the PCI in patients with severe AS remains the subject of ongoing clinical trials. A meta-analysis of 11 observational studies found no significant difference in all-cause mortality at 1 year between patients undergoing TAVR with and without PCI. Furthermore, the ACTIVATION trial failed to demonstrate the noninferiority of PCI prior to TAVR compared with no PCI in patients with significant CAD.[15] Nonetheless, the current ACC/AHA guidelines state that PCI before TAVR is reasonable for significant left main or proximal CAD based on limited data.[11] Accordingly, it is a common practice to perform PCI of significant CAD before TAVR based on the individualized approach. For instance, it would be reasonable to consider PCI before TAVR in patients with CAD in proximal segments of major epicardial arteries or with anatomical characteristics associated with difficult coronary access post-TAVR.[16]

Coronary lesions undergoing PCI before TAVR are frequently complex and high-risk.[4] The complex or high-risk CAD encompasses anatomically complex lesions and clinical parameters including reduced ventricular function and concomitant valvular disease.[17] Although the PROTECT II (Prospective, Multicenter, Randomized Controlled Trial of the Impella Recover LP 2.5 System Versus Intra-Aortic Balloon Pump in Patients Undergoing Non-Emergent High-Risk PCI II) trial failed to demonstrate benefits in the primary end point of major adverse cardiac event compared with intra-aortic balloon pump, the Impella can provide hemodynamic support by providing active forward flow leading to an effective increase in mean arterial pressure, increased cardiac output, and augmented coronary flow in select patients during complex PCI.[6,18] Accordingly, the 2021 ACC/AHA/SCAI guideline for coronary artery revascularization states that in selected high-risk patients, elective use of a hemodynamic support device as an adjunct to PCI may be reasonable to prevent hemodynamic decompensation during PCI.[19] However, severe AS is a relative contraindication for using Impella, which is placed across the aortic valve, and patients with severe AS have been excluded from the trials, including the ongoing PROTECT IV trial.[20] Therefore, there are scarce data on IA-PCI before TAVR in patients with severe AS, limited to case reports.[7,8] A series of 5 patients with severe AS received attempts at IA-PCI where the Impella failed to traverse the aortic valve in 4 patients, requiring BAV prior to IA-PCI.[7] Another study of 7 pre-TAVR patients with severe AS demonstrated the feasibility of BAV followed by IA-PCI of the left main coronary artery without periprocedural complications.[8] In our study, Impella failed to cross in 1 out of 15 patients despite a concomitant BAV. Although 2 of 14 patients required BAV before Impella insertion, all 14 consecutive patients eventually received successful IA-PCI without any periprocedural complications. The Impella provided adequate hemodynamic support whereby it facilitated the safe performance of complex, high-risk PCI without hemodynamic decompensation, including left main PCI in patients with severe AS. Of note, there were no major vascular complications or bleeding complications post–IA-PCI. Furthermore, although 36% of the cohort had femoral accesses on the ipsilateral side for IA-PCI and TAVR, no post-TAVR major vascular or bleeding complications were noted. This highlights the procedural safety of IA-PCI with large-bore access prior to TAVR. Our study adds to the extant body of literature by demonstrating the feasibility and safety of IA-PCI in selected patients with severe AS pre-TAVR.

### *Limitations*

Our nonrandomized, single-center study has several important limitations to consider in the interpretation of the data. This study of case series is subject to selection bias, and thus, the findings of our study cannot be generalizable. Although our study is hypothesis-generating, we could not test any hypothesis owing to the study's nature as a case series based on a small sample size.

## Conclusion

In appropriately selected patients with severe AS and concomitant significant CAD, IA-PCI was feasible and safe prior to TAVR, based on a case series of consecutive patients.

## Declaration of competing interest

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

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## Ethics statement and patient consent

This study was approved by the institutional review board at New-York-Presbyterian Hospital and adhered to relevant ethical guidelines. No patient consent was required because all data were retrospective.

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