

# Staged High-Risk Percutaneous Coronary Intervention

with Impella Support after On-Pump Transcatheter Aortic Valve Replacement

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*The management of concomitant obstructive coronary artery disease and severe aortic stenosis in poor surgical candidates is an evolving topic. Although the typical current practice is to perform percutaneous revascularization before transcatheter aortic valve replacement (TAVR), some data have emerged regarding revascularization after performing TAVR. We present the case of a 90-year-old man with multivessel coronary artery disease who was at prohibitive risk for surgical aortic valve replacement. We first performed TAVR with use of hemodynamic support, then Impella-assisted multivessel percutaneous coronary intervention on the patient's unprotected left main coronary artery. We describe this complex case and review the medical literature on percutaneous coronary intervention after TAVR. (Tex Heart Inst J 2016;43(5):423-7)*

**Key words:** Aged, 80 and over; aortic valve stenosis/ complications/therapy; heart valve diseases/complications; heart valve prosthesis implantation/instrumentation/methods; percutaneous coronary intervention/instrumentation/methods; risk assessment; treatment outcome

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**D**ebate continues about the optimal management of concomitant severe aortic stenosis and coronary artery disease (CAD). The typical practice, revascularization before transcatheter aortic valve replacement (TAVR), is based on sparse data.<sup>1</sup> For example, in the Placement of AoRTic TraNscathetER Valve (PARTNER) trial (the original landmark trial examining TAVR), the investigators excluded patients who had indications for revascularization, and higher mortality rates were not found in patients who had underlying CAD.<sup>2</sup> Other investigators have not found higher mortality rates in patients with underlying CAD who underwent TAVR.<sup>3,4</sup> Dewey and colleagues<sup>5</sup> reported poorer outcomes in TAVR patients who had coexisting CAD; however, lack of data on the degree of CAD was a major limitation of that study. The Percutaneous Coronary Intervention prior to transcatheter aortic Valve implantation (ACTIVATION) trial is an ongoing randomized trial whose investigators are comparing results between pre-TAVR percutaneous coronary intervention (PCI) and unrevascularized TAVR; however, no results have yet been reported. Given the sparse current data, the necessity of performing PCI before TAVR comes into question. Residual CAD preceding surgical aortic valve replacement is an independent risk factor for death<sup>6-8</sup>; conversely, the percutaneous technique exposes patients to an entirely different set of intraoperative hemodynamic factors not comparable with those during surgical valve replacement. Despite these considerations, revascularization of severe coronary stenosis before TAVR is still the standard of care, typically out of concern for ischemic arrhythmias induced by rapid pacing during valve deployment.<sup>9</sup>

We describe the case of an elderly patient in whom we first performed TAVR with use of hemodynamic support, and, later, device-assisted PCI. We discuss our reasoning and the existing medical literature.

## Case Report

In February 2014, a 90-year-old man with a history of hypertension, chronic kidney disease, and sinus node dysfunction after pacemaker implantation presented with New York Heart Association functional class III dyspnea and fatigue on exertion. A late-peaking systolic ejection murmur was consistent with severe aortic stenosis. Echocardiograms revealed a left ventricular ejection fraction (LVEF) of 0.25 to 0.30 and severe aortic stenosis: calculated valve area, 0.63 cm<sup>2</sup>; mean gradient, 23.2 mmHg; and peak velocity, 2.41 m/s. During the patient's 8-day hospitalization, his heart fail-

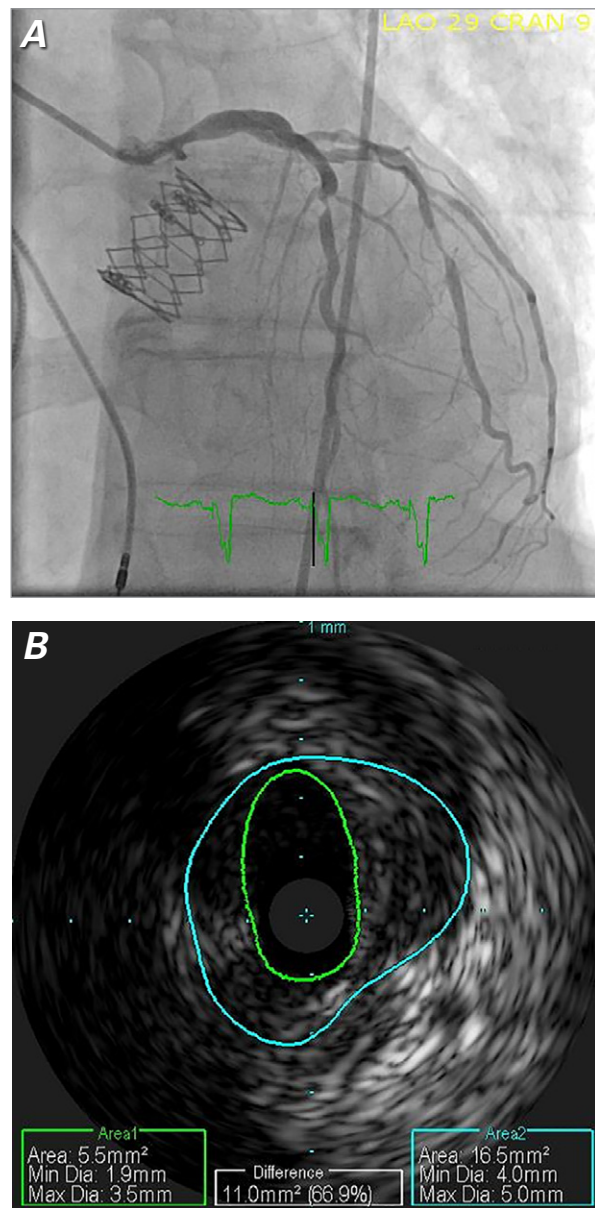
ure progressed rapidly, and the cardiac team thought that urgent intervention for his aortic stenosis was his only chance for survival. His age, frailty, and comorbidities put him at prohibitive risk for surgical aortic valve replacement, so he was referred for TAVR. Pre-TAVR coronary angiograms revealed stenoses as follows: 50% of the ostial left main coronary artery (LMCA), 90% of the mid left anterior descending coronary artery (LAD), 90% of the distal left circumflex coronary artery (LCx), 60% of the 2nd obtuse marginal branch (OM), and a chronically occluded right coronary artery. The patient was taken to the operating room for TAVR, via the transfemoral approach, with use of the Edwards SAPIEN XT system (Edwards Lifesciences LLC; Irvine, Calif).

The patient's poor biventricular function and severe CAD led us to perform TAVR without revascularization and with use of cardiopulmonary bypass (CPB). Balloon aortic valvuloplasty was performed with use of a 23-mm × 4-cm Edwards balloon and rapid ventricular pacing at a rate of 160 beats/min, with pump flow decreased to lower the patient's blood pressure to <50 mmHg. A 26-mm Edwards SAPIEN XT prosthesis was positioned across the aortic valve. The ideal landing zone was identified on the basis of aortic angiography, performed with a pigtail catheter in the right coronary sinus. The valve was then deployed in the intended position with an 80:20 split above and below the plane of the annulus. The patient was weaned from CPB and mechanical ventilation. He recovered uneventfully, had marked improvement in his symptoms, and was discharged from the hospital after 7 days.

Two months later, the patient followed up with his primary cardiologist for the known residual CAD. An echocardiogram showed significant improvement in cardiac function (LVEF, 0.55–0.60). An angiogram revealed worsening of the LMCA stenosis (Fig. 1A), and an intravascular ultrasonogram showed a minimal luminal area of 5.5 mm<sup>2</sup> (Fig. 1B). Plans were made for staged LMCA intervention with use of an Impella® 2.5 LP Circulatory Support System (ABIOMED, Inc.; Danvers, Mass) for hemodynamic support.

During the scheduled procedure, left common femoral artery access was attained by using the modified Seldinger technique and a 6F sheath. Two Perclose ProGlide® Suture-Mediated Closure Systems (Abbott Vascular; Redwood City, Calif) were then deployed in a preclose technique. A 13F Impella sheath was placed in the left common femoral artery after serial dilation with 8F and 10F dilators. The Edwards SAPIEN valve was successfully crossed with use of a 4F catheter and a 0.035-in Wholey wire. The Wholey wire was then exchanged for a 0.018-in Impella wire. An Impella 2.5 LP catheter was advanced over the wire and placed across the valve in the left ventricle under fluoroscopic guidance (Fig. 2).

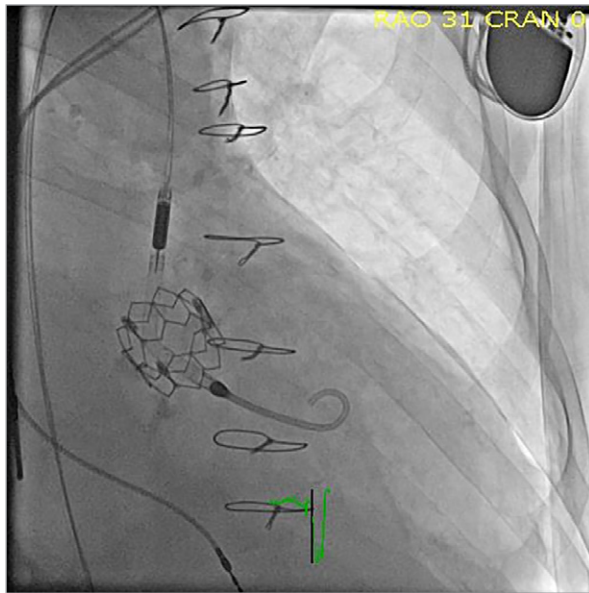
After the Impella was deployed, access to the right common femoral artery was attained, and a 6F Voda



**Fig. 1 A)** Angiogram shows significant left main coronary artery stenosis. **B)** Intravascular ultrasonogram of left main stenosis shows a substantially reduced luminal area.

left 3.5 guide catheter was used to cannulate the LMCA with some difficulty. Coronary angiograms revealed the previously known focal 80% stenosis in the ostial LMCA. There was a 90% focal stenosis in the mid segment of the LAD, the proximal LCx had a 50% stenosis, the 2nd OM branch had an 80% segmental narrowing, and the right coronary artery remained occluded.

After initiating intravenous bivalirudin for anticoagulation and guidewire placement across the LAD and OM, we deployed a 3 × 28-mm Promus PREMIER™ drug-eluting stent (Boston Scientific Corporation; Natick, Mass) across the OM lesion after predilation

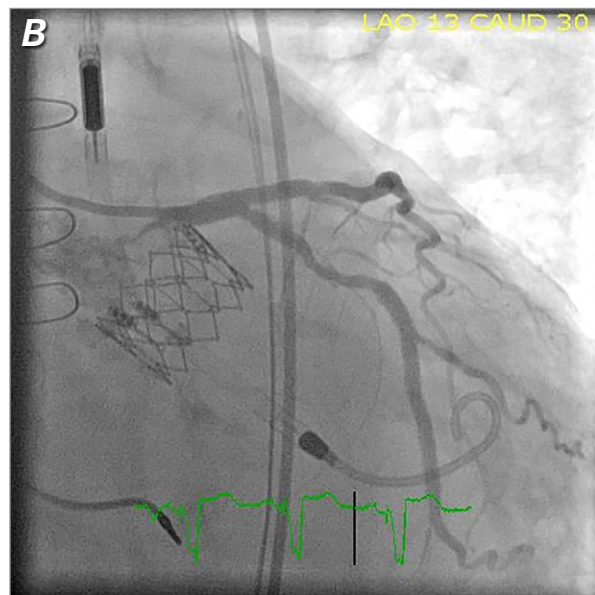
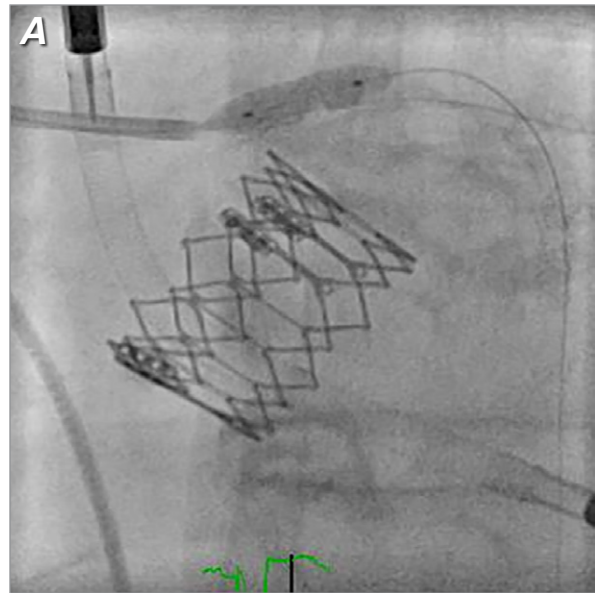


**Fig. 2** Angiogram shows placement of the Impella 2.5 across the EDWARDS SAPIEN aortic valve.

with a 2.5 × 12-mm Emerge™ PTCA Dilatation Catheter (Boston Scientific). This was followed by deployment of a 3 × 15-mm Promus PREMIER stent in the LAD. Next, a 4 × 8-mm Emerge balloon was used to predilate the ostial LMCA under continuous hemodynamic support, and a 4 × 8-mm Promus PREMIER stent was deployed. The lesion was then postdilated with a 4.5 × 8-mm noncompliant Quantum Apex™ PTCA Dilatation Catheter (Boston Scientific) at a pressure of 19 atm (Fig. 3A). An intravascular ultrasonogram revealed poor stent apposition, so the lesion was again postdilated, this time with a 5 × 12-mm noncompliant Quantum balloon inflated to a pressure of 19 atm. Intravascular ultrasonographic and angiographic images revealed optimal stent expansion and apposition without significant residual stenosis and with Thrombolysis in Myocardial Infarction-3 flow into the distal vessel (Fig. 3B). The Impella device was removed, and the Perclose sutures were tightened to achieve hemostasis. The patient tolerated the procedure well and was discharged from the hospital the next day in stable condition. He died in September 2015 of injuries from a fall.

## Discussion

Since the initial description of PCI after TAVR,<sup>10</sup> data have remained sparse.<sup>11-16</sup> There have been isolated reports of emergency deployment of the Impella through TAVR valves with consistently good results.<sup>17,18</sup> As patients with aortic stenosis age, the incidence of CAD needing revascularization in this population will increase. In a single-center study evaluating the ease of angioplasty in TAVR patients with use of a standard



**Fig. 3** Angiograms show **A**) stent deployment in the left main coronary artery and **B**) final results of the procedure.

diagnostic catheter,<sup>19</sup> angioplasty was successful in all 16 patients who were given an Edwards SAPIEN XT valve but in only 1 of 10 patients who received a CoreValve® (Medtronic, Inc.; Minneapolis, Minn). Authors have described the first cases of PCI in patients who were given an Edwards SAPIEN valve<sup>10</sup> and a CoreValve.<sup>11</sup> Although the procedures were considered feasible and safe in these cases, positioning of the prosthesis was thought to be an important determinant of successful PCI. Multiple previous reports of acute coronary occlusion after TAVR have been noted, which makes the realistic prospect of this sequela impossible to ignore.<sup>20-22</sup> Recently, investigators sought to determine the effects when the coronary ostia are covered by the Edwards SAPIEN

frame; they measured troponin T release after TAVR and after post-PCI TAVR. There was no significant difference between the control group and the group whose prostheses covered the coronary ostia.<sup>23</sup> However, the study's small sample size and the sole use of troponin elevation to determine myocardial injury severely limited the ability to draw conclusions. The effect of valve position on potential coronary occlusion is well known; however, whether valves that cover the coronary ostia lead to difficult revascularization has only been hypothesized, except in isolated cases. Murarka and Pershad,<sup>16</sup> intervening on an occlusion, had trouble traversing the stent struts of a CoreValve prosthesis when trying to engage the coronary ostia. Blumenstein and colleagues<sup>19</sup> faced similar difficulties with the CoreValve prosthesis.

Most operators prefer revascularization before TAVR, but no relevant formal guideline or recommendation exists. In our patient, we departed from current convention by performing TAVR before revascularization. The cardiac team conferred and thought that the patient's symptoms and heart failure were predominantly caused by aortic stenosis rather than ischemic disease. Because the patient would probably not survive complex PCI without improving his hemodynamic status, we decided to perform TAVR first. Considering the literature on revascularization after TAVR, we thought that post-TAVR revascularization would be technically less challenging after placing a SAPIEN valve than a CoreValve. However, the SAPIEN system requires rapid pacing during implantation, so there was a very high risk of ventricular arrhythmia. We considered this and used CPB during TAVR to provide a safety margin if ventricular arrhythmia were to occur.

This case shows that TAVR might be considered before revascularization in patients whose valvular disease predominates their CAD. However, TAVR before PCI requires careful planning and adequate hemodynamic support to guard against potentially fatal arrhythmias during rapid pacing.

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