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CASE SERIES
Heart failure

Case report: management of refractory cardiogenic shock with Impella 5.5 in patients with transcatheter aortic valves

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Background Impella is a transaortic valvular pump commonly utilized in patients with cardiogenic shock. However, its use with transcatheter aortic valves (TAVI) remains rare. We present two cases where surgical Impella 5.5 was placed across both Sapien 3 Ultra and Evolute Pro+ valves.

Case summary **Patient 1**: A 74-year-old male with history of ischaemic cardiomyopathy with ejection fraction 20–25% status post-cardiac resynchronization therapy with a defibrillator, severe aortic stenosis (AS) status post-recent Sapien 3 Ultra TAVI presented with cardiogenic shock. Due to persistent unstable haemodynamic status, Impella 5.5 was placed and was utilized as a bridge to left ventricular assist device. **Patient 2**: A 74-year-old male with a history of alcoholic cirrhosis and AS underwent Evolute Pro+ TAVI at outside facility. The implantation was complicated by left main coronary artery occlusion, leading to cardiogenic shock. Patient required femoral veno-arterial extracorporeal membrane oxygenation (ECMO) support and emergent single vessel coronary bypass of a saphenous venous graft to the left anterior descending artery. Extracorporeal membrane oxygenation was decannulated on Day 20 and Impella 5.5 was placed as a bridge to recovery. In both cases, there were no procedural complications or residual aortic or perivalvular regurgitation.

Discussion Impella 5.5 implanted via the axillary surgical cutdown is safe and feasible approach to manage refractory cardiogenic shock in patients with TAVI including different types of valves, Sapien 3 Ultra, and Evolute Pro+. As it can provide full haemodynamic support, Impella 5.5 can be used as bridge to recovery or durable mechanical support.

Keywords Cardiogenic shock • Mechanical circulatory support • Transcatheter aortic valves • Case report

ESC curriculum 4.2 Aortic stenosis • 6.2 Heart failure with reduced ejection fraction • 6.4 Acute heart failure • 7.3 Critically ill cardiac patient • 4.10 Prosthetic valves

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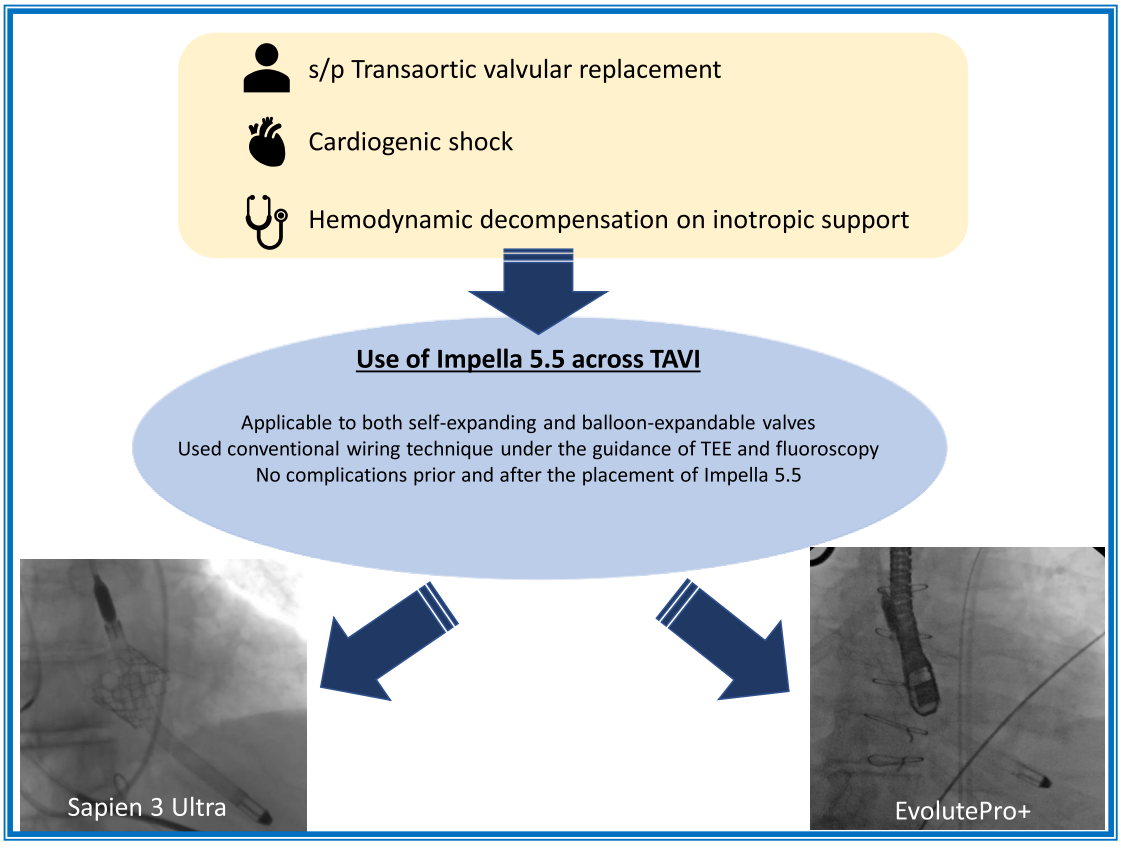
Learning points

- Impella 5.5 is a feasible and safe approach to provide full haemodynamic support in patients with transcatheter aortic valve (TAVI) and in refractory cardiogenic shock.
- A conventional technique via right axillary surgical cutdown under the guidance of transoesophageal echocardiography and fluoroscopy can be used to place Impella 5.5 across TAVIs.
- Impella 5.5 can be used as a bridge to recovery or to durable left ventricular assist device in patients with refractory cardiogenic shock.

Introduction

The Impella CP and 5.5 (Abiomed, Danvers, MA, USA) are transaortic valvular pumps that provide left ventricular support by unloading the left ventricle, increasing cardiac output, and decreasing myocardial oxygen demand. Previously, the use of Impella CP/5.5 has been described in the management of cardiogenic shock related to acute myocardial ischaemia, high-risk percutaneous coronary intervention, and acute decompensated cardiomyopathy.[1] It has also been used as an escalation or de-escalation strategy for patients with cardiogenic shock as a bridge to advanced mechanical circulatory support and/or as a bridge to recovery.[2] As a transvalvular device, it carries the theoretical risk of damaging the native valve or surgical bioprosthetic valve; in the case of transcatheter aortic valve (TAVI), it carries the risk of dislodgement and embolization. Although many patients can be supported with the smaller Impella devices (2.5, CP), some patients will require escalation to a surgical Impella device (5.0/5.5). The safety of inserting an Impella 5.5 through a TAVI valve is unknown. Herein, we present two cases where the surgical Impella 5.5 was placed across the two most utilized TAVI valves, the Sapien 3 Ultra (Edwards, Irvine, CA, USA) and Evolute Pro+ (Medtronic, Minneapolis, MN, USA) bioprosthetic valves.

Summary figure



Case presentation

Patient 1: A 74-year-old male with history of coronary artery disease, ischaemic cardiomyopathy with left ventricular ejection fraction of 20–25% status post-cardiac resynchronization therapy with a defibrillator presented with cardiogenic shock at outside facility. Patient also has history of severe aortic stenosis (AS) and underwent 26 mm Sapien 3 Ultra TAVI 5 months ago. His echocardiography prior to TAVI showed aortic

valve area 0.7 cm^2, peak velocity 3.6 m/s, mean gradient 33 mmHg stroke volume index 32 mL/m^2. At the time of cardiogenic shock presentation, the estimated aortic valve area was 1.3 cm^2 with mean gradient of 11 mmHg, peak velocity of 2.25 m/s, and stroke volume index 24 mL/m^2. He was transferred to our facility for higher level of care. On examination, patient was on supplemental oxygenation at 2 L/min saturating at 96%, elevated jugular venous distention, diminished heart sounds with regular rate and rhythm, +3 pitting oedema in bilateral lower extremities. Despite pressor support with dobutamine 8 mcg/kg/min and norepinephrine 0.08 mcg/kg/min, he remained in refractory shock with mean arterial pressure of 59 mmHg and worsening acidosis with arterial blood gas revealing metabolic acidosis of pH 7.28 and base deficit of −8.0 mmol/L. The patient was taken emergently to the operating room for implantation of an Impella 5.5. A right axillary cutdown was performed, and a 10 × 30 mm Gelweave graft was bevelled at 45° and anastomosed in running fashion after giving 5000 units of intravenous heparin. A pigtail and J wire were used to cross the bioprosthetic aortic valve, under guidance by both fluoroscopy and transoesophageal echocardiography (TEE). The Impella support was set in high thrust condition (4.3–4.9 L/min, P-level 8). His haemodynamics subsequently stabilized, and we were able to wean off vasoactive medications. There was no haemolysis or pump thrombosis noted with a prolonged course of Impella 5.5. After 13 days of support, the patient's left ventricle had failed to recover, and subsequently underwent the left ventricular assisted device (LVAD) Heartmate 3 device implantation. At the time of durable LVAD insertion, the Impella was pulled under TEE guidance without complication. There was no residual aortic or perivalvular regurgitation noted post-removal. He continues to follow-up at our clinic and is doing well on LVAD with New York Heart Association Classification Class I symptoms.

Patient 2: A 74-year-old male with history of alcoholic cirrhosis and AS underwent elective 34 mm EvolutePro+ TAVI at outside facility. Significant paravalvular leak was noted post-valve deployment and was treated with balloon valvuloplasty. However, it led to occlusion of the left main coronary artery and cardiogenic shock. Patient was evaluated by interventional cardiologists and percutaneous intervention of the left main artery was deemed to be technically non-feasible as they were unable to cross the cells of EvolutePro+ valve to engage the left main artery. In the setting of acute haemodynamic decompensation, emergent single vessel coronary bypass with a saphenous venous graft to the left anterior descending artery via sternotomy was performed. Patient was also started on femoral veno-arterial extracorporeal membrane oxygenation (ECMO). Over the next 2 weeks, he was unable to wean off from ECMO support with a persistent ejection fraction of 20% and transferred to our facility. On examination, patient appeared slightly jaundice, on mechanical ventilation with sedation, his heart with regular rate and rhythm without murmurs. His bilateral lower extremities showed +3 pitting oedema with audible pulses on Doppler. Transthoracic echocardiography at presentation revealed aortic valve area 1.64 m^2, peak velocity1.1 m/s, mean gradient 3 mmHg, and stroke volume index 16 mL/m^2. He was taken to the operating room on Day 20 of ECMO support for Impella insertion as a weaning platform from ECMO. He was supported with Impella 5.5 running at low to moderate thrust condition (1.9–3.3 L/min support, P-level 4) for 5 days and his left ventricular function recovered with resolution of pulmonary oedema. The Impella was then successfully removed with fluoroscopic and echocardiographic guidance without complications. He was discharged back to outside facility (*Table 1*).

Discussion

In cases of refractory cardiogenic shock, Impella 5.5 is implanted via a right axillary surgical cutdown and can be safely utilized and placed across TAVI. Unlike surgically replaced valves, TAVI valves rely on radial tension to maintain position until the valve scars into place. Early manipulation of the valve carries at least a theoretical risk of dislodgement and embolization. The incidence of peri-procedural valve embolization and migration based on TRAVEL registry was reported to be 0.92%.[3] The advancement of Impella 5.5 through these bioprosthetic valves can be challenging and may have a higher risk for valve dislodgement when compared with Impella CP or 2.5 because of the larger pump circumference. Both Impella CP and 2.5 have been previously used in patients with TAVI intraoperatively or for a protected coronary intervention but to our knowledge, this is the first report of Impella 5.5 placement in patients with Sapien 3 Ultra and Evolute Pro+ TAVI for management of cardiogenic shock.[4,5]

The insertion of Impella 5.5 via the right axillary artery allows patients to ambulate while receiving haemodynamic support. As both Sapien 3

Table 1 Baseline demographics of patient 1 and patient 2

Baseline characteristics	Patient 1	Patient 2
Age/sex	74/male	74/male
Type of valve prosthesis	Sapien 3 Ultra	Evolute Pro +
Ejection fraction (%)	10	20–25
Comorbidities	Coronary artery disease, cardiomyopathy s/p CRT-D, recent ECMO	Alcoholic cirrhosis
Initial central venous pressure (mmHg)	11	14
Cardiac output/Cardiac index with Impella (L/min/L/min/m^2)	5.5/2.7	6.1/2.7
Pulmonary artery pressure (mmHg) with Impella	44/16	32/13
Mean pulmonary artery pressure (mmHg) with Impella	25	19
Pulmonary wedge pressure (mmHg)	33	19
SVO_2 (%) with Impella	68	54
Systemic vascular resistance(dynes/cm^5)	1193	774
Duration of Impella (days)	13	5
Initial Cr (mg/dL)	3.14	1.77
Maximum Cr (mg/dL)	5.27	3.69
Lactic acid level pre-Impella (mmol/L)	2.3	1.8
Lactic acid level post-Impella (mmol/L)	0.7	0.3
Cardiac output/Cardiac Index post-Impella (L/min/L/min/m^2)	4.6/2.2 (HeartMate III)	4.7/2.1

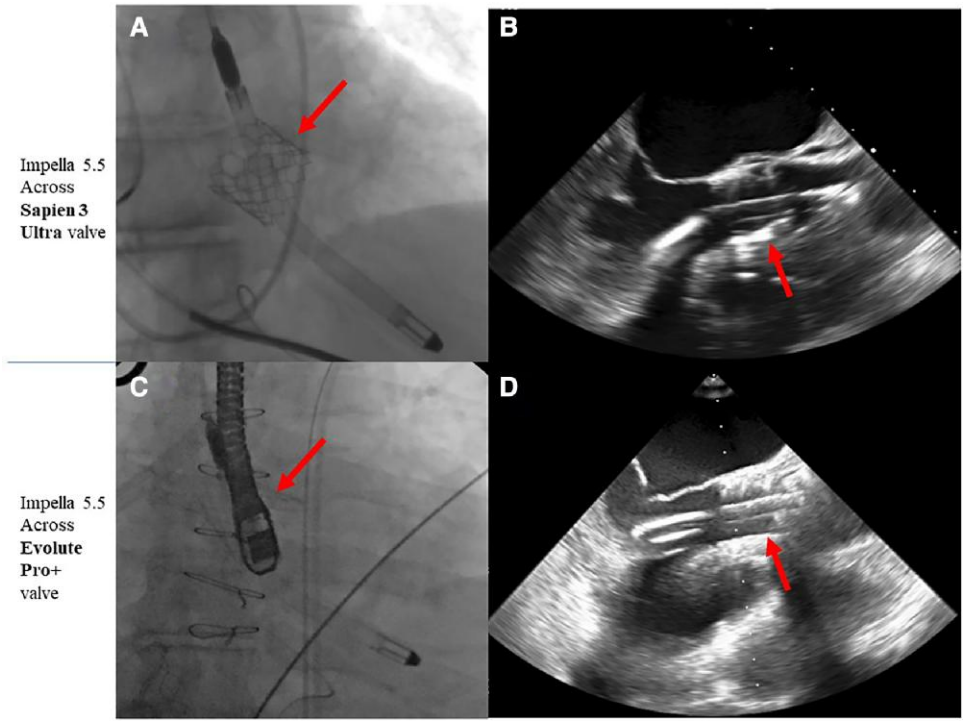


Figure 1 Fluoroscopic and echocardiographic images of Impella 5.5 placed through transcatheter aortic valve. (*A*) Fluoroscopic image and (*B*) echocardiographic image of Impella 5.5 implanted through 26 mm Sapien 3 Ultra valve. (*C*) Fluoroscopic image and (*D*) echocardiographic image of Impella 5.5 implanted through 34 mm Evolute Pro + valve.

Ultra and Evolute Pro+ valves require femoral artery access, having alternative vascular access with Impella 5.5 is useful to avoid vascular complications, especially if the valves were recently placed. The technique to place Impella 5.5 remains the same for both self-expandable valves and balloon-expandable valves. After obtaining vascular access, the pigtail catheter is introduced to secure a route across the valve. Under fluoroscopic and TEE guidance, it is ensured that the wire is not under the mitral apparatus. Then, it is exchanged with an insertion wire, followed by a careful advancement of Impella 5.5 under the guidance of transoesophageal echocardiography and fluoroscopy. The device can be advanced slowly while keeping it in the centre of the valve. The location of Impella 5.5 was confirmed with echocardiography by measuring the distance between the inlet cannula to the neo-annulus (*Figure 1A–D*). It is essential to identify any signs of new paravalvular leaks, valve embolization, or haemodynamic changes throughout the procedure. The removal of Impella 5.5 was also performed in the standard technique.

As seen in our patients, Impella 5.5 can be effectively placed in both new and old transcatheter bioprosthetic valves without dislodging the valve. The application of Impella 5.5 is safe and beneficial for the management of refractory cardiogenic shock secondary to the left ventricular failure, as it can provide haemodynamic support up to 5.5 L/min. This is ideal when considering bridging to full recovery or to durable mechanical support. Impella 5.5 is also known to shorten the time of ECMO circuit, allowing early patient mobilization and minimizing the duration of inotropy. A small retrospective study done by Zuvarevich *et al.* has reported that 40% of their patients were sitting up to chair, 21% of that were using bed bike, and 18% of that in were ambulating. There was no limb ischaemia or stroke seen in these patients and 53% of their patients were bridged to recovery.[6] In both patients, there was no echocardiographic evidence of central aortic regurgitation or paravalvular leaks noted after Impella 5.5 removal. No valvular injuries have also been reported in the small number of previously published case reports where Impella CP was used in TAVI patients.[7,8] However, further studies will be warranted to investigate the risk of valve embolization or impairment at the time of Imepla 5.5 placement.

Conclusion

The use of Impella 5.5 is a feasible approach to providing cardiac support in patients with TAVI including patients who are immediate post-TAVI implant. The device can be placed across the bioprosthetic valves with conventional techniques and can be removed without causing valve injuries.

Lead author biography

Rakushumimarika Harada completed internal medicine residency at Texas Health Presbyterian Hospital in Dallas, TX. She is a cardiology fellow at the Baylor Scott and White the Heart Hospital in Plano. She has special interest in heart failure and management of cardiogenic shock with mechanical circulatory support devices.

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Consent: Written consents for submission of the case series have been obtained by the two patients in line with COPE guidance.

Conflict of interest: None declared.

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Data availability

Data utilized in the cases are all available in the manuscript.

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