



Peer-Reviewed Case Report

## Removal of Impella in the Setting of Left Ventricular Thrombus: A Potential Indication for Cerebral Embolic Protection Devices

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Citation: Asadourian M, et al. Removal of Impella in the Setting of Left Ventricular Thrombus: A Potential Indication for Cerebral Embolic Protection Devices. *The VAD Journal*. 2021; 7(1):e2021714. <https://doi.org/10.11589/vad/e2021714>

**Keywords:** acute heart failure, mechanical circulatory support, left ventricular thrombus

### Abstract

Successful percutaneous mechanical circulatory support (MCS) has been used for acute stabilization of cardiogenic shock (CS). Improved survival outcomes have been observed in patients with CS from an acute myocardial infarction (AMI) who undergo implantation of left ventricular (LV) to ascending aorta rotodynamic pumps, such as the Impella® device (Abiomed). However, thrombotic events are a known complication of such devices in poor flow states such as CS. There is limited evidence regarding the management of patients who develop an LV thrombus after Impella insertion. Currently, the Sentinel cerebral protection system (SCPS, Boston Scientific) is the only FDA-approved device for cerebral embolic protection during transcatheter aortic valve replacement procedures. While the use of a cerebral embolic protection device (CEPD) has a theoretical benefit, no current CEPD is approved for use in conjunction with Impella device removal or other MCS devices. We present a case describing the use of the SCPS during the removal of the Impella CP device in a patient who developed an LV thrombus after CS from AMI. Our case highlights a potential role for the expanded use of CEPDs in similar clinical scenarios.

Editor-in-Chief: Maya Guglin, University of Indiana

Received: March 23, 2021

Accepted: April 14, 2021

Published Online: May 4, 2021

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Funding: Not applicable

Competing interests: None

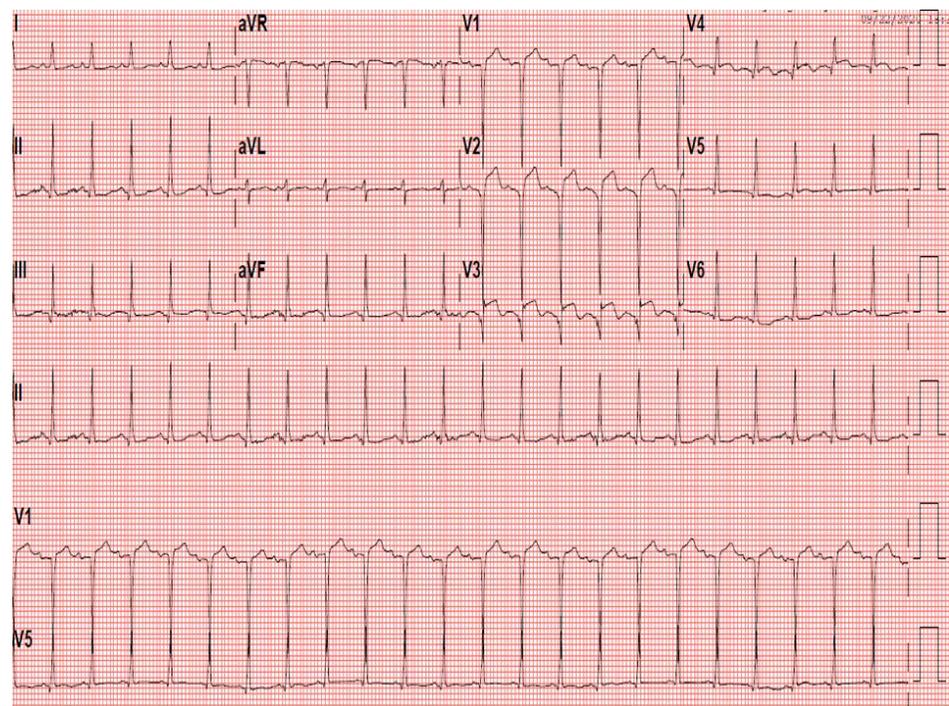


## Background

Several forms of percutaneous mechanical circulatory support (MCS) exist and include counterpulsation devices (intra-aortic balloon pumps) and continuous-flow devices. MCS also includes axial flow devices (Impella [Abiomed]) to advanced centrifugal flow devices (TandemHeart [LivaNova]) and veno-arterial extracorporeal membrane oxygenation (V-A ECMO). Device selection is dependent on several factors, and the potential complications vary from one device platform to another. The use of Impella is contraindicated in patients with known left ventricular (LV) thrombus due to the increased risk of thromboembolism.<sup>1</sup> There is an obvious challenge to minimize the risk of embolic events in patients with LV thrombus that form after Impella implantation. To the best of our knowledge, literature addressing such a dilemma is scarce. We, therefore, highlight such a case to share our experience with off-label use of the Sentinel cerebral protection system (SCPS, Boston Scientific) to minimize embolic adverse outcomes.

## Case Report

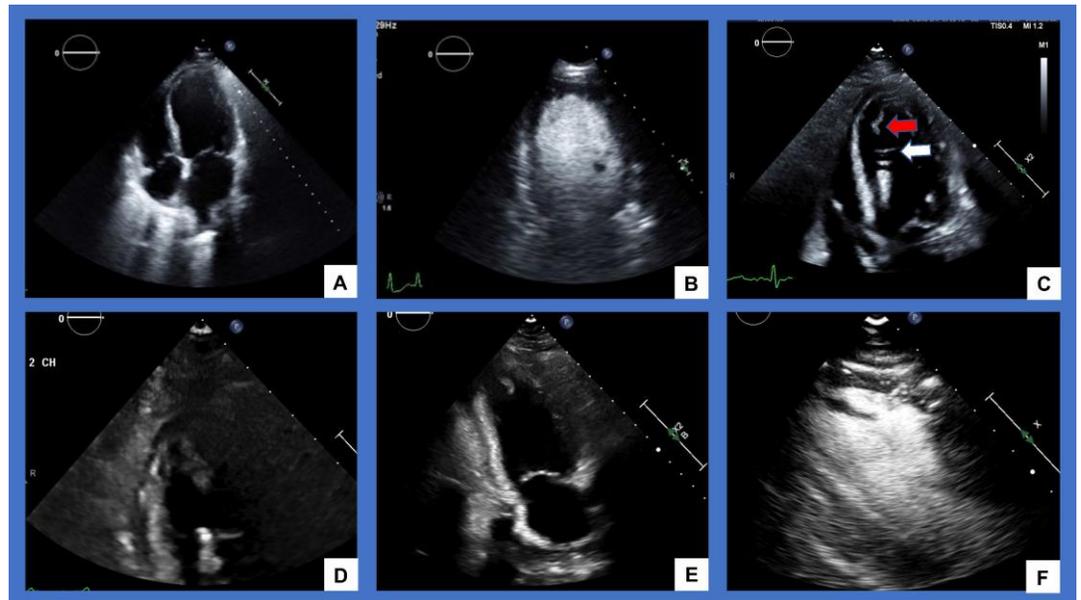
A 47-year-old male with no known medical history presented with two days of dyspnea on exertion and typical chest pain. On arrival, electrocardiogram was significant for anterior ST-elevation myocardial infarction (Figure 1).



**Figure 1.** Presenting electrocardiogram shows ST elevation and Q waves in precordial leads.



The patient was promptly taken to the cardiac catheterization lab. Emergent bedside transthoracic echocardiogram (TTE) was significant for severely reduced LV systolic function with an ejection fraction of < 20% and global hypokinesis (Figure 2A & B). Left heart catheterization revealed severe two-vessel disease with subtotal occlusion of the left anterior descending artery and mid-right coronary artery along with significant left main coronary artery disease. Hemodynamics (Table 1) were significant for left ventricular end diastolic pressure (LVEDP) at approximately 50 mmHg, along with elevated filling pressures.



**Figure 2.** A) This is an Apical 4 chamber view of transthoracic echocardiogram (TTE) before deployment of the Impella CP. No left ventricular (LV) thrombus is seen. B) Definity® ultrasound contrast is used in this view and again demonstrates absence of LV thrombus. C) The tip of the Impella (white arrow) and apical mobile LV thrombus (red arrow) are identified. D) This is a close up image of the LV thrombus and tip of Impella. E) This TTE is 48 hours after Impella removal and F) is the same image with Definity ultrasound contrast. There was a similar finding six days post-Impella removal prior to discharge.

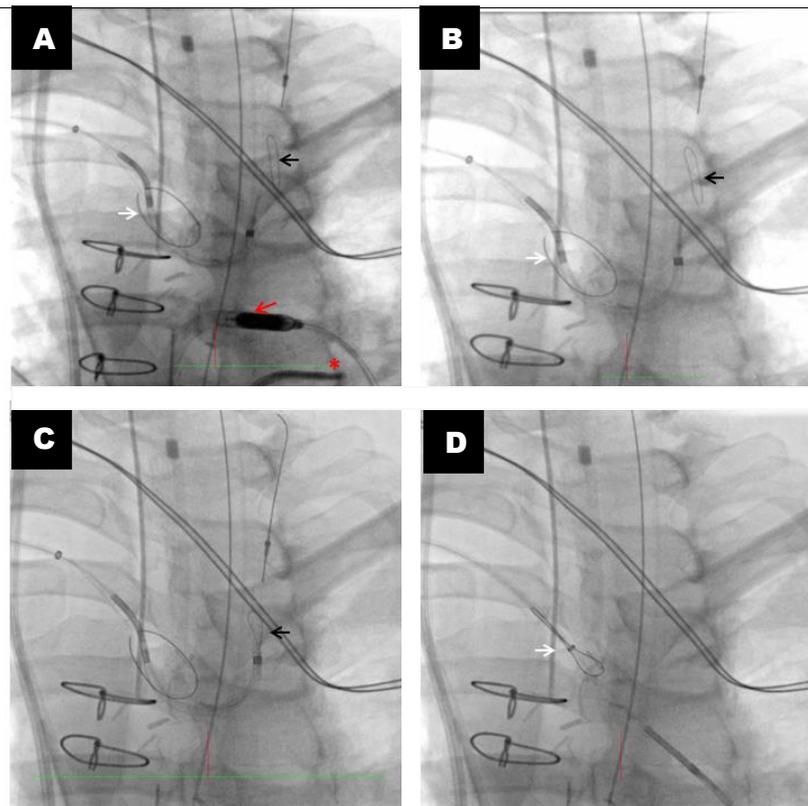
**Table 1. Hemodynamics.** Pressures were attained from transthoracic echocardiogram and right heart catheterization. The cardiac output and index were calculated by the Fick calculation.

Measure	Value Upon Presentation
Left ventricular end diastolic pressure	~50 mmHg
Right atrial pressure	21 mmHg
Right ventricular pressure	61/21 mmHg
Pulmonary arterial systolic pressure/pulmonary arterial diastolic pressure	61/44 mmHg
Mean pulmonary arterial pressure	53 mmHg
Pulmonary capillary wedge pressure	42 mmHg
Cardiac output	2.39 L/min
Cardiac index	1.4 L/min/m <sup>2</sup>



Emergent bedside echocardiogram done in the cath lab with DEFINITY® ultrasound contrast (Lantheus) showed no evidence of LV thrombus. Given the clinical picture of acute myocardial infarction complicated by CS, the decision was made to stabilize the patient with MCS, using an Impella CP and to undergo emergent surgery with coronary artery bypass grafting (CABG). Unfortunately, the bypass surgery was complicated by circulatory collapse attributed to a protamine reaction which required emergent cannulation for VA-ECMO with average flow of 3 L/min. 48 hours after Impella implantation and post-CABG, a TTE was significant for a 2.6 x 0.5 cm size mobile thrombus in the LV apex (Figure 2C, D). Initially heparin was used for anticoagulation; however, due to progressive thrombocytopenia and concern for heparin induced thrombocytopenia (HIT), anticoagulation therapy was switched to argatroban. The combination of inotropes and MCS as well as volume optimization with intravenous diuresis, resulted in clinical improvement. The patient was able to be decannulated from V-A ECMO after three days. He continued to improve, and after approximately five more days of Impella support, the device was decreased to lower performance levels using inotropes and medical management to stabilize him. Given the interval development of his LV thrombus, and to reduce the risk of any catastrophic cerebral events in a young patient with no current neurologic deficits, the heart team (interventional cardiologists, cardiovascular surgeons, heart failure specialists) decided to remove the Impella in a hybrid operating room setting with the presence of vascular surgery and interventional cardiology teams. The multidisciplinary team was needed in part due to the need for immediate femoral artery hemostasis after Impella is removed. The extraction of the 14 French sheath while the patient remained on active anticoagulation with argatroban for LV thrombus and HIT represented a significant risk. We elected to utilize the SCPS to minimize the risk of cerebral embolization during the Impella removal procedure (Figure 3).

SCPS was deployed via the right radial artery catheterization prior to the Impella removal, which was performed via a femoral artery cutdown by the vascular surgeons. Once a femoral artery window with good visualization of the Impella insertion site and encircled vessel loops were established around the arteriotomy, support was decreased from performance level 4 to level 2. The Impella was then removed and swift hemostasis was achieved with vessel clamps and interrupted 5-0 prolene suturing. Prior to closure, a thrombus was noted on the femoral artery posterior wall, which was removed and irrigated. A soft clot was also found in the Impella blood outlet area (Figure 4). The SCPS was then removed, and radial artery hemostasis was achieved via a TR band® (Terumo). There were no post-procedure complications. TTE after Impella removal showed the same, large (2.6 x 0.5 cm), mobile thrombus attached to the LV apex (Figure 2E, F). During recovery, the patient did well; no neurologic symptoms or deficits were noted. The patient experienced complete resolution of his initial presenting symptom of chest pain. He was discharged on warfarin, insulin for newly diagnosed diabetes mellitus, and guideline-directed medical therapy for new onset heart failure and coronary artery disease with cardiology follow-up.



**Figure 3:** Sentinel cerebral protection device deployment during Impella removal. A: Prior to Impella removal with deployment of left carotid artery (black arrow) and right brachiocephalic artery (white arrow) Sentinel filters were introduced via right radial access. Distal Impella CP pump near blood outlet area appreciated (red arrow) and pulmonary artery catheter (\*). B: Impella removed via right femoral artery cutdown with both filters in place (arrows). Subsequent retrieval of left carotid filter (C) and right brachiocephalic filter (D).



**Figure 4:** This is the Impella CP (Abiomed) device after removal. A soft clot is noted in the Impella blood outlet area as pointed out by the arrow.



## Discussion

Our case demonstrates several clinical dilemmas that physicians often face in CS patients supported by percutaneous MCS. Our patient's clinical presentation was significant for CS including severely elevated LVEDP with acute respiratory failure and pulmonary edema from his acute MI (Table 1). The Impella CP (Performance level 4 and 2 L/min flow) was sufficient to unload his severely hypokinetic LV and provide adequate hemodynamic support until revascularization with CABG. However, due to circulatory collapse from protamine use during CABG, our patient required emergent extracorporeal life support with V-A ECMO. This event resulted in further myocardial stunning in an already poorly contracting LV. The resultant turbulent blood flow within the LV cavity and potential stasis significantly increased the risk of developing an intra-cardiac thrombus.<sup>2</sup> Despite adequate anticoagulation, the risk of intra- or extra-cardiac thrombus formation is reported to be 3.9% in patients with impaired LV function who undergo femoral V-A ECMO with LV unloading.<sup>3</sup>

Concomitant use of V-A ECMO and Impella is an often-used technique to vent the failing LV. By offloading the LV, the Impella device lowers LVEDP in the setting of increased afterload due to the presence of the V-A ECMO outflow catheter in the aorta.<sup>2</sup> Our patient required full circulatory support with V-A ECMO due to vasodilatory, distributive shock after protamine during CABG, which resulted in circulatory collapse. On the platform of V-A ECMO, the addition of an Impella device to reduce ventricular loading results in improved survival and recovery of ventricular performance in the setting of CS.<sup>2</sup> However, there is an increased risk of complications related to the thrombogenic nature of MCS devices in the LV. The risk of cerebrovascular accidents in such patients are reported to be as high as 10%.<sup>2,4</sup> In the case of our patient, several factors, such as decreased flow due to CS, a severely akinetic apical segment, and multiple MCS devices, led to an overall increased risk for thrombotic events. Management strategies for patients with femoral V-A ECMO support and severely impaired LV function must be reassessed to avoid insufficient LV unloading at an early stage of ECMO therapy. Adjusting the flow rate of ECMO and Impella, as well as inotropic support and diuresis should be considered in patients with insufficient unloading of the LV to prevent intra-cardiac thrombus formation and reduce LV distention. Despite all these measures, our patient had thrombotic complications.

The SCPS is FDA-approved and indicated for use during TAVR procedures to protect against embolic events.<sup>5,6</sup> Herein, we demonstrate the application of this device in a relatively unique clinical dilemma. We understand its use in our scenario may not eradicate cerebral embolic events; however, we believe it provided an overall clinical benefit to our patient compared to the potential ramifications of Impella removal without SCPS. Therefore, the use of SPCS during MCS removal, such as Impella, in patients with an intra-cardiac thrombus may be a future indication for this device. Further investigation is necessary to understand the applicability to the general population prior to its widespread use.



## Conclusion

As the utilization of percutaneous MCS continues to increase, related complications will need to be carefully monitored. A multi-disciplinary approach, including interventional cardiologists, heart failure subspecialists and cardiovascular surgeons, will be crucial in managing such events. Current conventional options, such as the SCPS to prevent cerebral embolic events, as well as other emerging therapies will need to be adapted to address these issues going forward.

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