

CASE REPORT

Percutaneous thrombectomy of Impella-associated iliac artery thrombosis using the FlowTrievers system

Ahmad Said^{1,2}  | Luay Sayed³

¹Department of Internal Medicine,
Beaumont Health, Troy, MI, USA

²Oakland University William Beaumont
School of Medicine, Rochester, MI, USA

³Department of Cardiovascular Medicine,
Beaumont Health, Troy, MI, USA

Correspondence

Ahmad Said, Beaumont Health System,
44201 Dequindre Rd, Troy, MI 48085,
USA.

Email: ahmad.said@beaumont.org

Abstract

Percutaneous thrombectomy using the FlowTrievers system is a potentially safe and effective alternative to surgery in cases of Impella-associated peripheral arterial thrombosis.

KEYWORDS

acute limb ischemia, acute myocardial infarction, cardiogenic shock, percutaneous coronary intervention, vascular access complications, ventricular assist device

1 | INTRODUCTION

Cardiogenic shock (CS) is the deadliest complication of acute myocardial infarction (AMI), with a mortality rate close to 50%.¹ The Impella Ventricular Support Systems are a class of percutaneous ventricular assist devices (pVAD), described as a transvalvular axial flow pumps that can be inserted via a standard catheter-based procedure through the femoral artery, into the ascending aorta, across the valve and into the left ventricle. The use of the Impella in the setting of CS and high-risk percutaneous coronary interventions (PCI) has been on the rise, with the intention of unloading the ventricle thus reducing myocardial oxygen demand, in addition to providing the circulatory support necessary for myocardial recovery, weaning from toxic vasoactive medications that might result in higher myocardial oxygen consumption and worsening of refractory shock, and early assessment of residual myocardial function. Despite the increasing popularity of these devices, there are limited data regarding the management of their associated complications.

2 | CASE PRESENTATION

A 65-year-old man presented to the hospital with acute on chronic abdominal pain and bloating. The patient's past medical history was significant for hypertension, hyperlipidemia, hypothyroidism, nephrolithiasis, and chronic abdominal pain. Physical examination was unremarkable. Electrocardiogram was obtained as part of the workup, and it revealed diffuse ST segment depression in all leads except for lead aVR which showed ST segment elevation. Troponin I level was significantly elevated in the blood at 7.2 ng/mL (normal value < 0.03 ng/mL). The patient was admitted to the hospital with a diagnosis of non-ST segment elevation myocardial infarction (NSTEMI). He received aspirin and was started on intravenous (IV) heparin and nitroglycerin infusions. A few hours later, the patient developed acute hypoxic respiratory failure while on the floor and was placed on oxygen therapy via a nonrebreather mask. Chest radiograph was consistent with acute pulmonary edema. The patient was evaluated by cardiology and was emergently taken

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2020 The Authors. *Clinical Case Reports* published by John Wiley & Sons Ltd

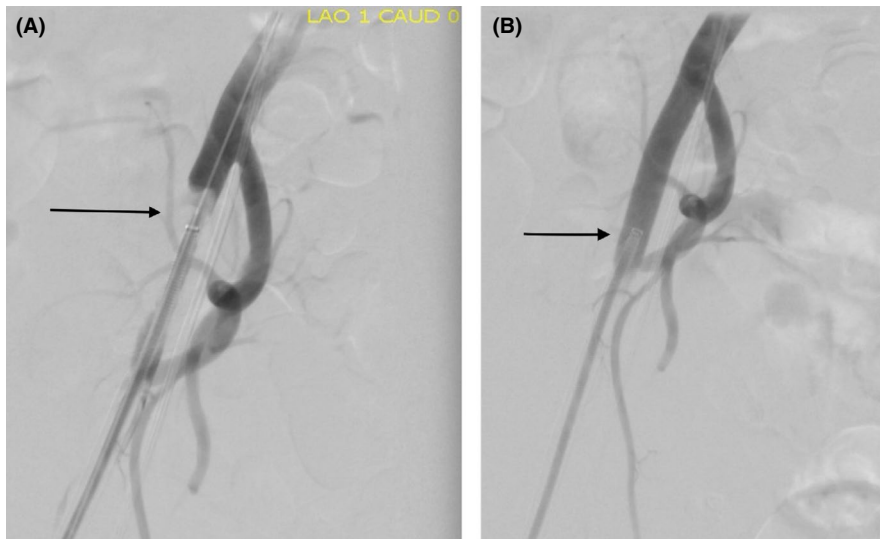


FIGURE 1 Angiography of the right iliac artery. Panel A: Thrombus in the external iliac artery (arrow). Panel B: Thrombus removed, and flow restored after thrombectomy



FIGURE 2 The FlowTrieve thrombectomy device, including the catheters and the self-expanding disks

to the catheterization laboratory for coronary angiography which revealed total occlusion of the left main artery (LM). Left ventriculography revealed an ejection fraction (EF) of 25% and anterior wall hypokinesis. A Swan-Ganz catheter was inserted in the pulmonary artery for hemodynamic assessment. The pulmonary capillary wedge pressure (PCWP) was elevated at 25 mm Hg, and the cardiac output was low at 3.5 L/min. The clinical picture was consistent with cardiogenic shock and pulmonary edema secondary to AMI. As the patient's hemodynamic and respiratory status were acutely deteriorating in the catheterization laboratory, he was deemed

unstable to await a surgical consultation for emergent coronary artery bypass graft surgery (CABG). The decision was made to proceed with performing a high-risk percutaneous coronary intervention (PCI) of the LM artery in conjunction with Impella CP support. The Impella sheath was inserted into the right common femoral artery (CFA), and PCI using a drug eluting stent (DES) was performed in the LM artery achieving complete perfusion with TIMI 3 flow. The patient was transferred to the coronary intensive care unit (CICU) for monitoring and Impella management. He remained on IV heparin for anticoagulation with therapeutic partial thromboplastin time (PTT). Over the following 3 days, the patient's hemodynamic status improved with IV diuretics and Impella support which was weaned off. Subsequently, the patient was taken back to the catheterization laboratory for Impella removal. However, drawing blood from the Impella sheath was not achievable raising the suspicion for sheath thrombosis. A right iliac artery angiogram showed a thrombus located in the external iliac artery just above the tip of the Impella sheath (Figure 1A). Aspiration of the thrombus was attempted using an 8-, 10-, and 12-French sheaths which were introduced into the Impella sheath. However, only minimum fragments of the clot were retrieved. Another technique was tried to externalize the thrombus via advancing a 5.0 mm balloon past the thrombus site then pulling back. Nonetheless, this was also unsuccessful in extracting the thrombus. As a result, the decision was made to attempt percutaneous thrombectomy using the FlowTrieve (Inari Medical) system disks as a last resort prior to seeking a surgical consultation. To avoid the risk of femoral artery dissection, upsizing to the 20-French FlowTrieve sheath was not performed. Instead, the FlowTrieve system was advanced through the 14-French Impella sheath to the proximal common iliac artery and the mesh disks were expanded to disrupt the thrombus (Figure 2). This was followed by eight slow passes from the external iliac artery and distally resulting in complete extraction of



FIGURE 3 Fragments of the thrombus removed using the FlowTriever

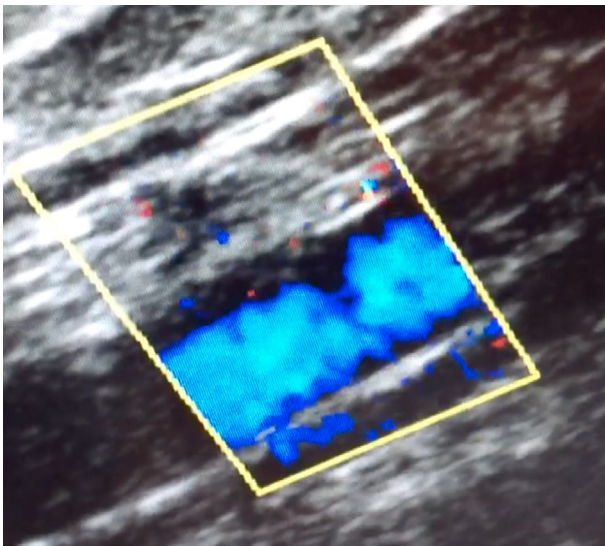


FIGURE 4 Duplex ultrasonography revealing good blood flow in the superficial femoral artery

the thrombus (Figure 3) (Video S1). Repeat angiogram confirmed the absence of a residual thrombus in the iliac artery (Figure 1B). Balloon angioplasty of the right common iliac artery was performed to achieve tamponade and facilitate the removal of the Impella sheath after which two Perclose sutures were deployed. There was good hemostasis at the end of the procedure without any evidence of a hematoma. Arterial duplex ultrasonography was performed, while the patient was still on the table and it revealed good blood flow

in the proximal superficial femoral artery (SFA) (Figure 4). The patient had a strong dorsalis pedis pulse indicating no distal embolization. Following the procedure, the patient was monitored in the hospital for three more days before he was safely discharged home with no further complication. At a follow-up visit in the office 4 months later, the patient's pedal pulses remained strong and the right groin access site was free of local complications.

3 | DISCUSSION

Acute myocardial infarction (AMI) is responsible for about 80% of cases of cardiogenic shock (CS).² Although prompt revascularization with PCI has significantly reduced the incidence of CS and improved survival in the setting of AMI, CS continues to be a highly fatal complication of AMI.^{3,4} When high-risk PCI is indicated, the early initiation of hemodynamic support with Impella was found to be associated with more complete revascularization and improved survival in the setting of refractory CS complicating an AMI.³ Vascular access site complications are a major concern related to the use of pVADs as these usually incorporate large-bore sheaths that are introduced into the vasculature and sometimes left in place for few days. Access site complications can either be hematological, neurological, infectious, or thrombotic in nature. The incidence of Impella-associated access site bleeding or hematoma was reported in few studies and ranged from 30% to 40%.^{5,6} Although anticoagulation is used in conjunction with pVADs, vascular thrombotic complications still occur including those related to the development of clots in the accessed blood vessels, commonly the right femoral artery. These thrombi have the potential to embolize and settle in distal arterial branches raising the risk for acute limb ischemia (ALI). The rate of arterial thrombosis in patients with CS who underwent Impella placement was reported to be 3.4% in a small retrospective study that compared the outcomes following either Impella or extracorporeal life support in CS.⁷ ALI was reported in 3% of patients who underwent Impella placement for AMI-induced CS according to another retrospective study that described the 12-year experience from a European medical center. All patients in the latter study required surgical intervention.⁸ The PROTECT II trial reported 9.7% vascular complications requiring surgery and 3.9% ALI in those who underwent Impella-supported high-risk PCI.⁹ Although these complications are not at all infrequent, there are no guidelines to aid in their management and most data in the literature are based on case reports. Flottman et al described a case of Impella-associated ALI that was treated with perfusion adapter.¹⁰ Bhat et al described a patient who underwent high-risk PCI with the support of the Impella 2.5 system

which was inserted in the left common femoral artery. The Impella was removed at the end of the procedure; however, the patient was noted to have signs of limb ischemia and an angiogram revealed thrombosis along the superficial femoral artery. This was treated with aspiration thrombectomy via the Pronto extraction catheter device with restoration of peripheral flow.¹¹ Succar et al reported 5 patients with suspected Impella thrombosis treated successfully with systemic tissue plasminogen activator (tPA).¹² The patient in our case report developed right external iliac artery thrombosis just above the Impella sheath which had been kept in place for 3 days due to the patient's severe CS state. Despite multiple attempts to extract the thrombus via conventional approaches, only small fragments were retrieved. Surgical intervention is usually the next step in similar scenarios. However, this was avoided in our case by performing an off-label thrombectomy using the FlowTriever Retrieval/Aspiration System, which is a single-use mechanical thrombectomy device approved by the United States Food and Drug Administration (U.S FDA) for use in the pulmonary arteries.¹³ This technique was successful in removing the whole thrombus and completely restoring the arterial blood flow to our patient's right lower extremity. The FlowTriever system has been used outside the scope of PE. Nezami et al reported its use once for an off-label thrombectomy of inferior vena cava thrombosis¹⁴ and in another case to retrieve a clot in transit from the right atrium under real time transthoracic echocardiography guidance.¹⁵ Our patient represents the first reported case of successful percutaneous thrombectomy of an arterial thrombus using the FlowTriever catheter. The approach we took was effective in preventing a detrimental limb ischemia and spared the patient from requiring a surgical intervention. The technique was also safe as the patient did not experience any significant early or late vascular access site complications and was observed over a period of 4 months.

4 | CONCLUSION

Impella-associated vascular access site thrombosis has become more frequently encountered in practice due to the growing popularity of these devices, especially in the setting of CS and high-risk PCI. We present the first case of Impella-related external iliac artery thrombosis successfully treated with the FlowTriever thrombectomy system. This approach was effective and safe in our experience and thus has the potential to be an alternative to surgical interventions.

CONFLICT OF INTEREST

The authors have no competing conflict of interest to declare.

AUTHOR CONTRIBUTIONS

Both authors have made significant contributions to the manuscript. AS: reviewed the literature thoroughly, drafted the manuscript in full, and performed revisions. LS: performed the described procedure in the manuscript and critically revised the manuscript. AS: is the corresponding author.

ORCID

Ahmad Said  <https://orcid.org/0000-0003-2629-592X>

REFERENCES

1. Bonello L, Delmas C, Gaubert M, Schurtz G, Ouattara A, Roubille F. Trials of mechanical circulatory support with percutaneous axial flow pumps in cardiogenic shock complicating acute myocardial infarction: Mission impossible? *Arch Cardiovasc Dis.* 2020;113(6-7):448-460.
2. Kapur NK, Thayer KL, Zweck E. Cardiogenic shock in the setting of acute myocardial infarction. *Methodist Debaque Cardiovasc J.* 2020;16(1):16-21.
3. O'Neill WW, Schreiber T, Wohns DH, et al. The current use of Impella 2.5 in acute myocardial infarction complicated by cardiogenic shock: results from the USpella Registry. *J Interv Cardiol.* 2014;27(1):1-11.
4. Levine GN, Bates ER, Blankenship JC, et al. ACCF/AHA/SCAI guideline for percutaneous coronary intervention. a report of the American college of cardiology foundation/American heart association task force on practice guidelines and the society for cardiovascular angiography and interventions. *J Am Coll Cardiol.* 2011;58:e44-e122.
5. Dixon SR, Henriques JP, Mauri L, et al. A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention (The PROTECT I Trial): initial U.S. experience. *JACC Cardiovasc Interv.* 2009;2(2):91-96.
6. Lemaire A, Anderson MB, Lee LY, et al. The Impella device for acute mechanical circulatory support in patients in cardiogenic shock. *Ann Thorac Surg.* 2014;97(1):133-138.
7. Lamarche Y, Cheung A, Ignaszewski A, et al. Comparative outcomes in cardiogenic shock patients managed with Impella microaxial pump or extracorporeal life support. *J Thorac Cardiovasc Surg.* 2011;142(1):60-65.
8. Ouweneel DM, De Brabander J, Karami M, et al. Real-life use of left ventricular circulatory support with Impella in cardiogenic shock after acute myocardial infarction: 12 years AMC experience. *Eur Heart J Acute Cardiovasc Care.* 2019;8(4):338-349.
9. 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.
10. Flottmann C, Braun M, Köster M, Rudolph V. Treatment of acute limb ischemia in an Impella CP patient. *Int J Artif Organs.* 2019;42(9):525-527.
11. Bhat TM, Waked A, Teli S, Lafferty J, Gala B. Acute complication due to Impella 2.5 device (superficial femoral artery thrombosis): managed successfully with novel aspiration thrombectomy catheter (pronto v3). *Clin Med Insights Cardiol.* 2011;5:17-21.

12. Succar L, Donahue KR, Varnado S, Kim JH. Use of tissue plasminogen activator alteplase for suspected Impella thrombosis. *Pharmacotherapy*. 2020;40(2):169-173.
13. Tu T, Toma C, Tapson VF, et al. A prospective, single-arm, multicenter trial of catheter-directed mechanical thrombectomy for intermediate-risk acute pulmonary embolism: the FLARE study. *JACC Cardiovasc Interv*. 2019;12(9):859-869.
14. Murali N, Nezami N, Latich I, Brown J, Mojibian H. Simultaneous proximal embolic protection and inferior vena cava mechanical thrombectomy using the FlowTrieve system. *Diagn Interv Radiol*. 2020;26(4):345-348.
15. Nezami N, Latich I, Murali N, et al. Right atrial and massive pulmonary artery mechanical thrombectomy under echocardiography guidance using the FlowTrieve system. *EJVES Short Rep*. 2019;45:22-25.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Said A, Sayed L. Percutaneous thrombectomy of Impella-associated iliac artery thrombosis using the FlowTrieve system. *Clin Case Rep*. 2020;8:2645–2649. <https://doi.org/10.1002/ccr3.3226>