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Percutaneous Thrombectomy of Impella-Associated Iliac Artery Thrombosis Using the FlowTriever System

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Abstract

We present a patient with myocardial infarction and cardiogenic shock who underwent high-risk percutaneous coronary intervention with Impella support, and developed iliac artery thrombosis at the Impella access site. Percutaneous thrombectomy was accomplished using the FlowTriever system, highlighting this approach as a potentially safe and effective alternative to surgery.

Title:

Percutaneous Thrombectomy of Impella-Associated Iliac Artery Thrombosis Using the FlowTriever System

Running Head: Impella Thrombosis Treated with FlowTriever

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Key Clinical Message:

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

Word Count: 2,167

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 is limited data regarding the management of their associated complications.

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 work up 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. The patient was admitted to the hospital with a diagnosis of non-ST segment elevation myocardial infarction (NSTEMI). He was recieved aspirin and was started on intravenous (IV) heparin and nitroglycerin drips. A few hours later, the patient developed acute hypoxemic respiratory failure while on the floor and was placed on oxygen therapy via a non-rebreather mask. Chest radiograph was consistent with acute pulmonary edema. The patient was evaluated by cardiology and was emergently taken to the catheterization lab 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 mmHg and the cardiac output was below normal. As the clinical picture was consistent with cardiogenic shock with pulmonary edema secondary to AMI, the decision was made to perform a high risk percutaneous coronary intervention (PCI) 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 continuing Impella management. Over the following three 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 lab for Impella removal. However, drawing blood from the Impella sheath was not achievable which raised 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 using a 10-French sheath inserted into the Impella sheath was attempted; 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. However, this was also unsuccessful in extracting the thrombus. The decision was made to attempt percutaneous thrombectomy using the FlowTriever system as a last resort before taking the patient to the operating room. The FlowTriever (Inari Medical) catheter was advanced to the proximal common iliac artery and the mesh disks were expanded to disrupt the thrombus (Figure 2). This was followed by eight passes from the external iliac artery and distally resulting in complete extraction of the thrombus (Figure 3) (Supplemental video). 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

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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.

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 largest registry for patients with CS reported 9.7% vascular complications requiring surgery and 3.9% ALI in those who underwent Impella placement[(9)]. Although these complications are not at all infrequent, there are no guidelines to aid in their management and most data in the literature is 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 three 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 thrombosis[(14)], 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 four months.

Conclusion:

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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.

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Author Contribution:

Both authors have made significant contributions to the manuscript. Ahmad Said reviewed the literature thoroughly, drafted the manuscript in full, and performed revisions. Luay Sayed critically revised the manuscript. Ahmad Said is the corresponding author.

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Figure Legends:

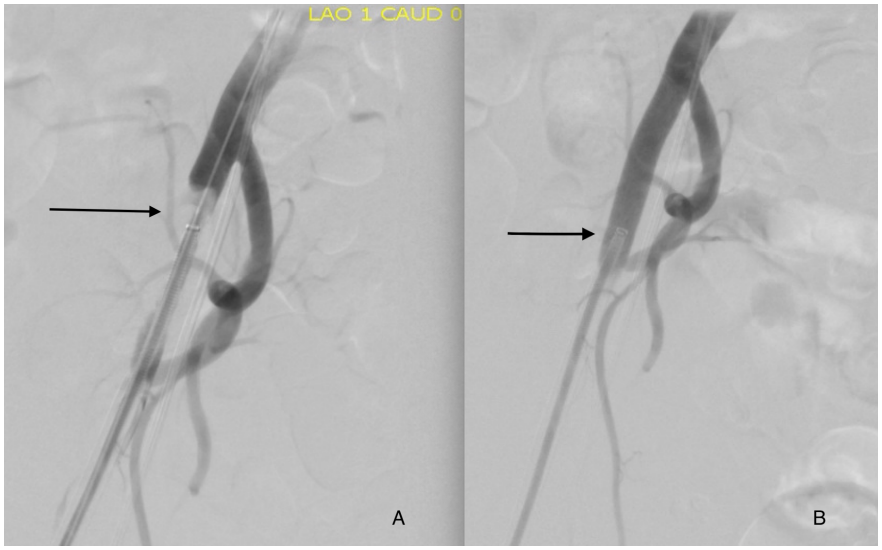
Figure 1. Angiography of the right iliac artery. Panel A: thrombus in the external iliac artery (arrow). Panel B: Thrombus removed, and flow restored after thrombectomy.

Figure 2. The FlowTriever thrombectomy device, including the catheters and the self-expanding discs.

Figure 3. Fragments of the thrombus removed using the FlowTriever.

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

Supplemental video. Angiography of the iliac artery showing mechanical thrombectomy using of the FlowTriever system to extract the thrombus from the external iliac artery.



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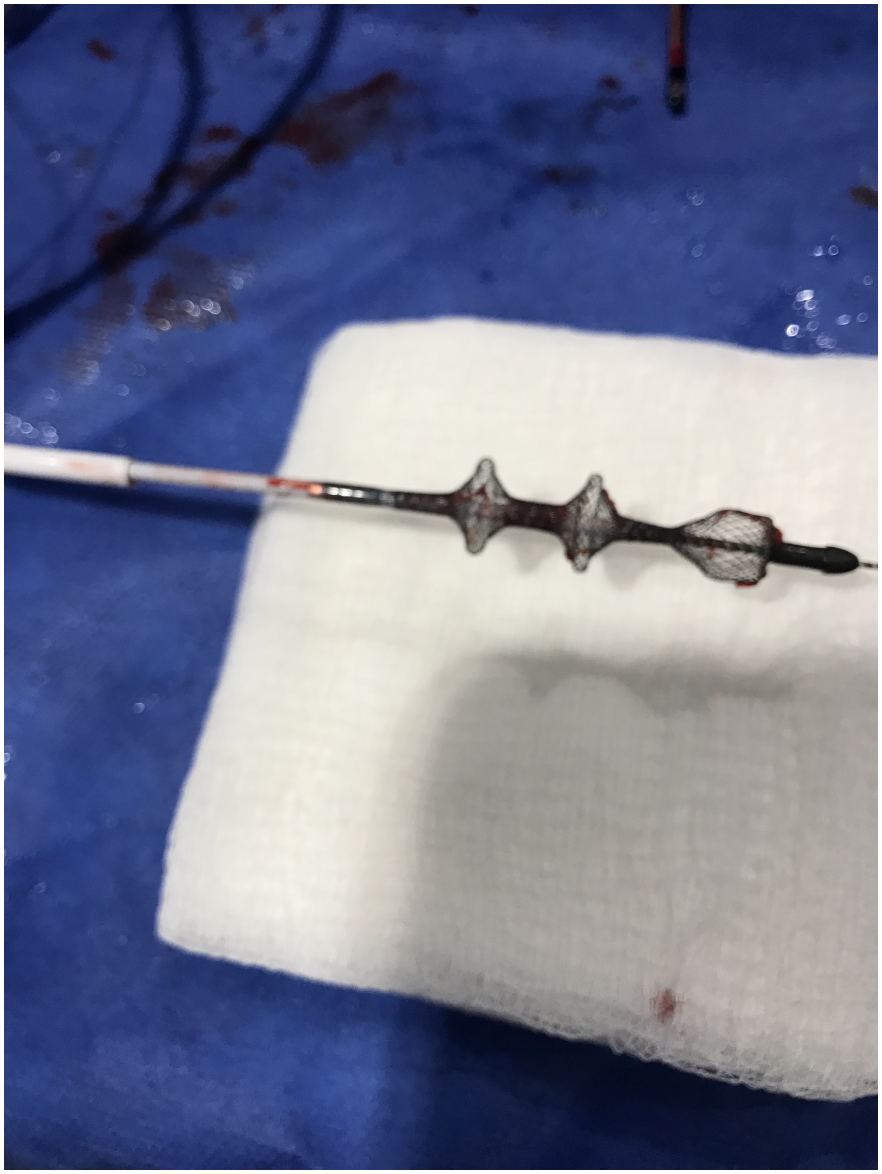

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