Clinical Medicine Insights: Cardiology

CASE REPORT

Acute Complication Due to Impella 2.5 Device (Superficial Femoral Artery Thrombosis): Managed Successfully with Novel Aspiration Thrombectomy Catheter (Pronto V3)

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Abstract: The Impella recover LP 2.5 is a percutaneous left ventricular assist device (LVAD) recently approved for use in patients undergoing high risk percutaneous coronary intervention (PCI) and also in cases of cardiogenic shock. There is limited evidence available in literature about its safety, especially with regards to the incidence of local vascular complications, their management and long-term implications. We report here the first case of a serious local vascular complication—superficial femoral artery thrombus formation during Impella recover LP 2.5 use in a high risk PCI which was managed successfully with novel aspiration thrombectomy catheter (Pronto V3), which in itself is the first reported use of Pronto V3 in such a vascular complication.

Keywords: impella LP 2.5, complication of impella, pronto V3, high risk PCI

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Case Report

An 86 year old lady with a past medical history of hypertension, diabetes mellitus, hypothyroidism, Bell's palsy, transient ischemic attack, hypercholesterolemia, Parkinson's disease, abdominal aortic aneurysm repair, peripheral vascular disease, stage IV chronic kidney disease, renal artery stents, coronary artery disease with a history of drug eluting stents to the right coronary and left circumflex arteries and diastolic heart failure was admitted to our hospital with severe chest pain. This was her second admission for unstable angina in the past three weeks. She also suffered two non-ST segment myocardial infarctions (NSTEMI) in the past three weeks. During all her previous admissions she was considered a high-risk candidate for any invasive therapy due to multiple co-morbidities and hence was managed medically. However, on this occasion the patient agreed to a coronary angiogram. She was found to have left main and triple vessel coronary artery disease. The coronary lesions were as follows: There was a diffuse 60% stenosis of distal third of left main coronary artery. The left anterior descending artery (LAD) revealed an 80% stenosis at the ostium followed by 70% stenosis of mid portion. The proximal left circumflex artery was medium sized with a patent previous stent. The first obtuse marginal showed tubular 70% stenosis in the middle third of the vessel segment. There was also a discrete 70% stenosis in the ostial right coronary artery (RCA) and 70% stenosis of mid RCA. The left ventricular ejection fraction by echocardiography was 35%–50% with anterior and anterolateral hypokinesis. Distal abdominal aortography with bilateral run-off revealed no significant aorto-iliac disease. Different modalities of treatment were discussed with the patient and her family. She was deemed a poor candidate for surgery and the only options were high risk PCI or medical management. The patient did not agree to surgery or PCI and was managed with aggressive medical treatment. She was readmitted within two weeks for another episode of unstable angina and acute NSTEMI. Having failed medical therapy, she agreed to undergo high risk PCI. A multi-vessel PCI of Left main into LAD and possibly of ostial right coronary artery and obtuse marginal was planned.

The Impella recover LP 2.5 LVAD was chosen for circulatory support during this high-risk procedure.

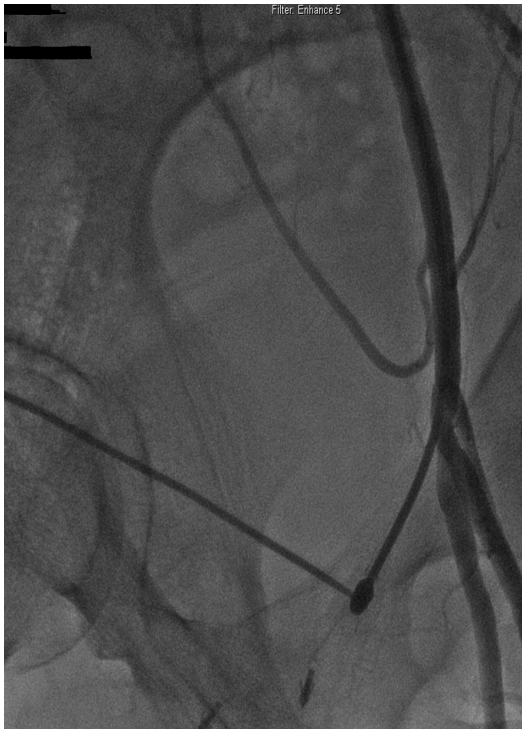

Figure 1. Pre-procedure angiogram showing patent superficial femoral artery.

After obtaining adequate arterial access and insertion of appropriate sheaths, the Impella 2.5 device was placed in the left ventricular cavity via the left common femoral artery (CFA) sheath, under fluoroscopy and adequate flow ensured. A cine run of the left ilio-femoral system was performed before and after insertion of the sheath. There was some sluggish flow noted in the left superficial femoral artery (SFA). At this time a decision was made to only perform a left main and LAD intervention and stage the other lesions. Using right CFA access, a Balloon angioplasty and bare metal stenting were performed on the left main and mid LAD lesions with excellent angiographic appearance and 0% residual stenosis. The Left circumflex ostium was not compromised angiographically. The Impella device was removed as per protocol. Another cine run of the left ilio-femoral system was performed. This revealed extremely sluggish flow in the left SFA with the appearance of multiple thrombi like lesions throughout its course. The left leg clinically appeared to be cooler than the right. The 13 French (Fr) Impella device sheath was removed and hemostasis achieved successfully with Perclose®. A 6 Fr multipurpose catheter was placed via the right CFA sheath into left common iliac and a selective

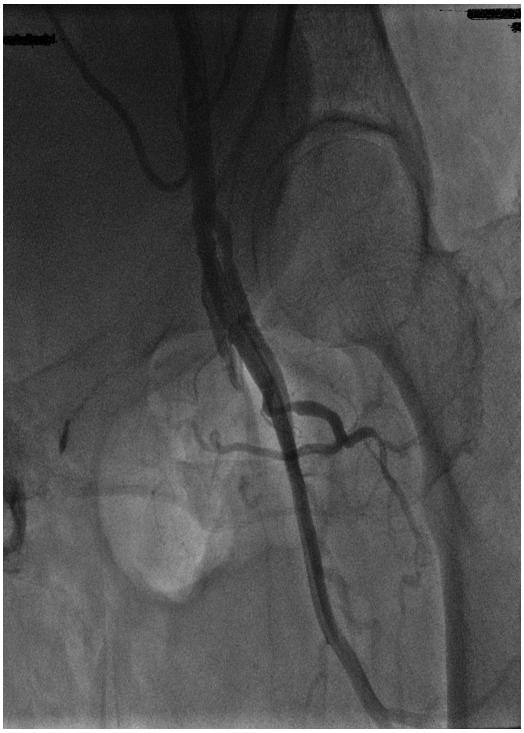

Figure 2. Post sheath removal angiogram showing absence of blood flow in superficial femoral artery.

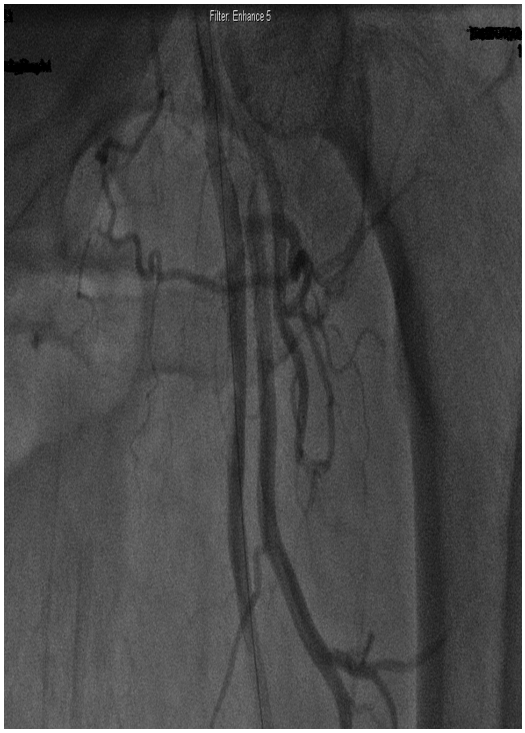

Figure 3. Post Pronto V3 device use, showing resumption of blood flow in superficial femoral artery.

angiogram of the left common iliac, external iliac and common femoral arteries was obtained. This confirmed our previous findings with better delineation of the thrombus like lesions along the length of the SFA. Two inflations of the CFA at the site of Perclose sutures was performed with a 4.0 × 20 mm Fox plus balloon with 10 atmospheres of pressure. Flow in the superficial femoral artery remained sluggish. The patient had developed an acutely ischemic limb secondary to cessation of antegrade flow down the left superficial femoral artery. Time was of the essence. We did have the angiojet device commonly used for thrombectomy procedures. However set up of this device is a little time consuming. The pronto extraction catheter is another device commonly used for thrombus extraction with very little set up time. This was readily available and in our experience has shown tremendous success in thrombus extraction in coronary cases. Hence we decided to use this device while the angiojet was being set up. An aspiration thrombectomy was then performed using Pronto V3 extraction catheter. The angiographically apparent thrombi were completely removed with 0% remaining stenosis. The flow in the left CFA returned to normal. Good peripheral circulation was confirmed clinically. Hence we decided to stop at this point and did not go ahead with use of the angiojet device. The patient was transferred to CCU for observation and did well hemodynamically. Her post procedure period was complicated by acute kidney injury in the face of chronic kidney disease, requiring hemodialysis for two sessions three days apart. The kidney function and urine output returned to baseline two weeks after the procedure. The patient was discharged in stable condition for physical rehabilitation. Four months after the procedure, the patient remains angina free and has not been readmitted since.

Discussion

Mechanical assist devices have found a growing role in high risk PCI due to an increasing patient population with complex co-morbidities, most of whom are not good candidates for surgery. Impella recover LP 2.5 is the first percutaneous left ventricular assist devices currently available. It is inserted via a 13 French sheath and placed under fluoroscopic guidance in the left ventricular cavity. The device is capable of providing 2.5 Litres/minute of blood flow and thus ensures a stable cardiac output. Successful use of the Impella as a circulatory support device in high

risk PCI was initially reported from Europe.[1] It has also been used in patients with cardiogenic shock either alone or in combination with other devices like intraaortic balloon pump.[2,3] This device can be maintained in situ for five to seven days and was recently approved for use in the USA by FDA for partial circulatory support up to six hours.

Published literature on the use of Impella device, including safety is limited. Reported complications associated with the Impella device include sensor failure, pump displacement, hemolysis and functional mitral stenosis.[2,4] It is thought that due to the use of a larger sheath (13Fr), there may be increased incidence of local vascular complications including bleeding and limb ischemia but has not been observed in the published experience. Recent large multi-centre registries from Europe and previous small feasibility trials have not reported any major local vascular complication especially limb ischemia.[5–7]

In our case, the Impella device was used in a patient with triple vessel coronary artery disease and left ventricular dysfunction, who was a poor surgical candidate and was undergoing high-risk coronary intervention including left main stenting. Our patient had mild peripheral vascular disease noted during angiography, because iliac vessels were found free of the disease, the use of Impella device was not contraindicated. After successful PCI, when the 13 Fr sheath placed for Impella device was removed, thrombus formation was noted on the same side in SFA during angiography. As acute thrombosis of SFA can be limb threatening and would required immediate surgery or thrombolytic therapy, successful thrombectomy and recovery of blood flow was achieved with the use of Pronto V3 device. The acute thrombosis was likely related to stasis and near complete occlusion of antegrade flow to the SFA secondary to a large sheath in ilio-femoral vasculature.

Pronto V3 is one of the thrombectomy devices, used with better outcomes in STEMI patients for performing thrombectomy before PCI.[8] It has been used successfully in management of acute stent thrombosis.[9] There are a few case reports of utilizing Pronto V3 in managing non-coronary vascular thrombosis.[10–12] Ours is the first documented case utilizing Pronto V3 thrombectomy device in managing acute superficial femoral artery thrombosis.

In summary, vascular complications such as bleeding, pseudo-aneurysm, infections, limb ischemia and AV fistulas are always a possibility during PCI especially when percutaneous assist devices with bigger sheaths are utilized simultaneously. Extra caution has to be adopted in high-risk patients in particular patients with peripheral vascular disease. Even though these local vascular complications have not been reported heavily, the interventionalist must be aware of their incidence and appropriate management.

Disclosure

This manuscript has been read and approved by all authors. This paper is unique and not under consideration by any other publication and has not been published elsewhere. The authors and peer reviewers report no conflicts of interest. The authors confirm that they have permission to reproduce any copyrighted material. Written consent was obtained from the patient or relative for publication of this study.

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