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Case Report
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First Reported Case of 'High-Risk' Protected PCI with Impella in a Very Old Patient with Multiple Comorbidities

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Abstract

Background: For a long time, high-risk and complex coronary interventions had been in the exclusive domain of cardiac surgeons. High-risk "protected" Percutaneous Coronary Intervention (PCI) using mechanical circulatory support (MCS) devices such as Impella have now emerged as a viable option particularly in high-risk patients with multiple comorbidities.

Clinical Case: Here we present the first reported case in medical literature of the use of Impella device during a unprotected Left Main (LM) and complex bifurcation Percutaneous Coronary Intervention (PCI), in a 93 year old patient with multiple comorbidities.

Conclusion: This case highlights the problems or difficulties encountered in using MCS in such patient subsets and giving some valuable lessons for its widespread use in the future.

Keywords: Impella device; Complex percutaneous coronary intervention; CAD; MVD

Introduction

Coronary Artery Disease (CAD) is a leading cause of morbidity and mortality globally, despite advances in various preventive therapies. Patients with advanced age, complex coronary anatomy, and multiple comorbidities are often unsuitable for surgical revascularization. Determining the optimal revascularization strategy in patients with Multi-Vessel Coronary Artery Disease (MVD) and severely reduced Left Ventricular Ejection Fraction (LVEF) remains a clinical challenge. Recommending Percutaneous Coronary Intervention (PCI) or coronary artery bypass grafting is based on careful assessment of the complexity of disease with consideration of patient's individual characteristics and procedural risk. With the continuing evolution of catheter-based techniques, PCI has now become an attractive alternative to treat complex coronary artery disease.

"High-risk" PCI is usually defined as unprotected left main stenosis (>50%) with reduced LVEF <35%, or triple vessel disease with LVEF <30% [1]. High-risk coronary interventions are associated with at least two-fold increase in mortality when compared to routine Percutaneous Coronary Interventions (PCIs) [2]. High-risk PCI can result in hypotension, compromised cardiac perfusion, development of cardiogenic shock and cardiac arrest [3]. High-risk PCI also requires longer procedural time and is associated with increased intra and post procedural adverse events [4].

Mechanical support during PCI in high-risk complex Coronary Artery Disease (CAD) is helpful to maintain long term hemodynamic stability, thereby enabling complete revascularization. Mechanical Circulatory Support (MCS) devices such as Impella can provide hemodynamic support over a wide range of cardiac output and is the most studied mechanical circulatory support device by the FDA, with a robust clinical data.

Here we present the first reported case in medical literature, of the use of Impella device in a 93 year old patient with reduced Left Ventricular (LV) systolic function and multiple comorbidities. She safely underwent an unprotected Left Main (LM) and bifurcation Percutaneous Coronary Intervention (PCI). The case also highlights the problems or difficulties encountered in using MCS in such very old patients.

Case Presentation

A 93 year-old female came with chief complaints of breathlessness and fatigue since last 7 days.

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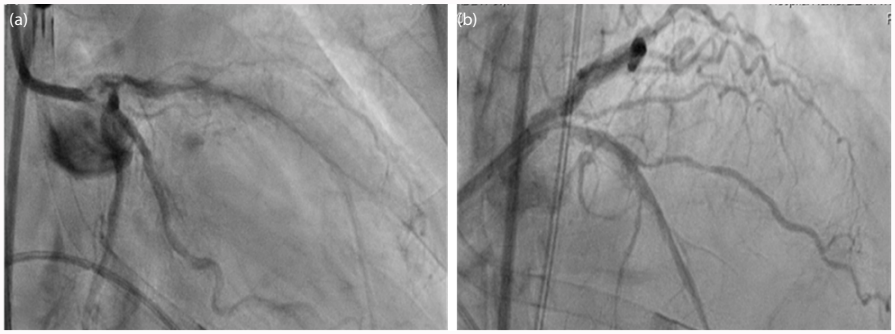

Figure 1: a, b) RAO caudal view (a), and AP cranial view (b).Coronary angiogram showing Left Main (LM) with 80% stenosis at distal bifurcation extending into the ostium of Left Anterior Descending (LAD) and dominant Left Circumflex (Lcx) arteries.

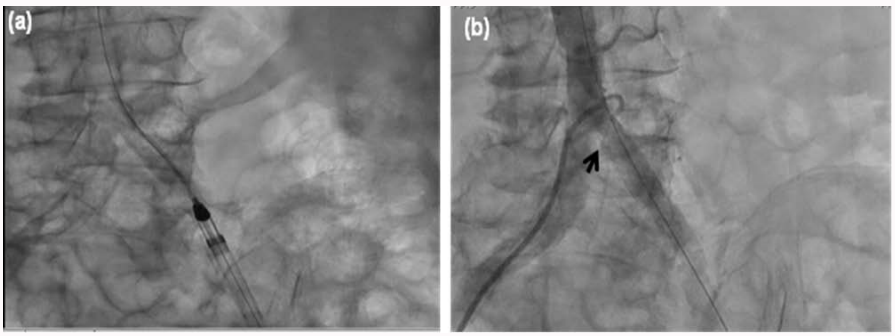

Figure 2: a, b) Angiographic image showing failure of Impella device to negotiate the narrowed left iliac artery (a) due to a plaque in the left iliac artery (arrow) (b).

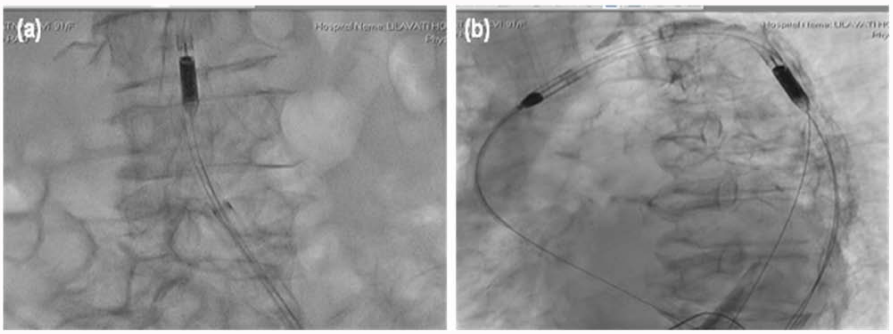

Figure 3: a, b) Angiographic image showing successful crossing of the lesion with the help of 14Fr Cook sheath (a), and passage of Impella device across heavily calcified Aorta with sustained traction maneuvre (b).

She gives history of hypertension and diabetes since the last 30 years on regular medication. On examination, blood pressure was 160/90 mmHg. On auscultation of chest, S1 and S2 were normal with a short ejection systolic murmur (grade 1) in the right second intercostal space.

Transthoracic Echocardiography (TTE) showed hypokinesia of anterior and lateral walls with preserved wall thickness. LV ejection fraction was 25%. Aortic and mitral valves were calcified with no significant gradient or regurgitation.

CAG done showed heavily calcified Left Main (LM) with 80% stenosis at distal bifurcation, extending into the ostium of Left Anterior Descending (LAD) and dominant Left Circumflex (Lcx) arteries. Mid LAD also had a tubular lesion of 70% stenosis. SYNTAX score was 34 (Figure 1a, 1b).

In view of the severity and complexity of the lesions and other comorbidities, "High-risk" protected PCI with Impella CP® mechanical support was planned by the Heart Team.

Procedure

Under local anesthesia, Impella-CP insertion was planned through Left Femoral Artery (LFA) and PCI was planned through Right Femoral Artery (RFA). However, inspite of repeated attempts, the 14 Fr sheath supplied with the Impella-CP device, could not negotiate the calcified plaque in the left iliac artery (Figure 2a, 2b). A Cook 14 Fr sheath was then taken, which crossed the lesion and Impella CP device was then negotiated across the severely calcified aorta with some difficulty and placed precisely across the Aortic valve, to give a constant 4 L/min cardiac output. PCI was then commenced through RFA (Figure 3a, 3b).

A 2.75 mm × 33 mm Xience Xpedition DES was deployed in mid LAD. Another 3.50 mm × 23 mm Xience Xpedition DES was deployed from LM into LAD. Using the T and Protrusion (TAP) technique, 3.00 mm × 12 mm Xience Xpedition DES was deployed

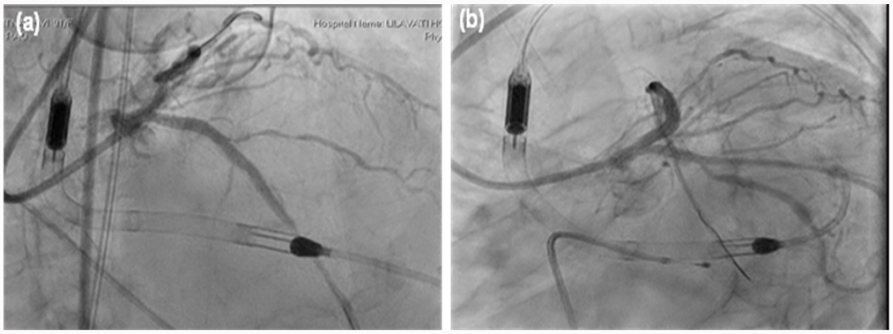

Figure 4: a, b) Angiographic image showing well deployed DES in LM and LAD (a), and TAP technique employed to stent the Lcx artery (b).

in the Lcx artery. Final Proximal Optimization (POT) was done to LM with a Accuforce 4.5 mm × 8 mm balloon (Figure 4a, 4b). Final OCT showed optimal coverage of carina, good stent apposition with no tissue prolapse or edge dissection.

After the procedure Impella-CP device was weaned off over 30 min and LFA puncture site sealed with Proglide sutures. Patient made an excellent recovery and was discharged three days later. She is on a regular follow-up and her LV ejection fraction has now improved to 45%.

Discussion

Complete revascularization is associated with significantly lower rates of major adverse cardiovascular events, myocardial infarction, and revascularization as compared with incomplete revascularization [5]. Revascularization procedures conducted in a single session result in significantly fewer major adverse cerebral and cardiovascular events and deaths compared to stage PCI procedures [6]. However, treating multiple lesions in one session can increase procedural time and is associated with increased risk of hemodynamic instability and intra or post-procedural adverse events, including kidney injury and cardiac arrest.

Use of MCS devices like the Impella has been shown to be safe and effective during high-risk PCI. Impella heart pump (Abiomed, Inc.) provides a non-pulsatile flow from the left ventricle into the aorta with flow rate ranging from 2.5 L/min to 5.5 L/min, depending on the device and selected performance level. It can be placed either percutaneously or *via* surgical cut down in the axillary or femoral artery. It assists by unloading the left ventricle, increasing the coronary perfusion pressure and means arterial pressure, thereby optimizing end-organ perfusion [7].

Europella registry demonstrated the safety and feasibility of Impella in providing good hemodynamic support during high-risk PCI. About 53% of the patients underwent LM-PCI of which 35% had LV systolic dysfunction. The 30-day mortality of patients undergoing Impella assisted high-risk PCI was 5.5% [8]. PROTECT I and II trials have shown that there was significant reduction in major adverse events when used during elective or urgent high-risk PCI [9,10]. PROTECT III preliminary results also showed that Protected PCI with Impella decreased MACCE events by 54% in the Impella cohort as compared to the IABP cohort which further validate its use.

Several limitations of using Impella device exist. Impella-assisted PCI may not be feasible in low volume centers or with inexperienced operators as it tends to give poor results. Meticulous attention to vascular anatomy (probably with a CT aortogram) and puncture site management is required to ensure complication-free outcomes. Impella has a prohibitive cost and may not be reimbursed under insurance coverage. Finally, Impella use can also lead to increased incidence of hemolysis (5% to 10%). However, the degree of hemolysis that has been observed is typically mild which usually resolves after the removal of Impella.

Conclusion

Selecting a revascularization strategy in patients with complex Multivessel Disease (MVD) and severely reduced Left Ventricular Ejection Fraction (LVEF) in the presence of multiple comorbid conditions, remains a challenge. Use of MCS devices such as Impella pump is feasible in high-risk PCI with excellent results and low complication rates. However, patient selection, operator experience and close teamwork are required to ensure optimal results. Cost of the device is also a major impediment and efforts should be made to make it more equitable for its widespread use.

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Author Contributions

All the authors were involved in the procedure and managed the patient. CRKV is involved in preparing the first draft of the manuscript. All authors have read, corrected the draft and approved the final manuscript.

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