Percutaneous Coronary Intervention Under Cover of Left Ventricular Assist Device (Impella 2.5)

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ABSTRACT

Impella 2.5 is a temporary left ventricular assist device that is being increasingly used in high risk Percutaneous Coronary intervention (PCI). It reduces the cardiac workload and provides assistance to myocardium and vital organs in states of severe left ventricular dysfunction and cardiogenic shock. We report the first case of successful percutaneous coronary stenting performed in a high risk patient using impella 2.5. A 65-year old diabetic and hypertensive male with a known double vessel coronary artery disease and a reduced left ventricular function (ejection fraction, 20%) was admitted with intractable angina. He was on optimal medical treatment for 2 months. His coronary angiogram done 2 months back had revealed double vessel coronary artery disease (subtotally occluded co-dominant left circumflex and moderate 60% stenosis in left anterior descending artery and a normal co-dominant right coronary artery). He was considered a high risk both for Coronary Artery Bypass Graft (CABG) surgery and PCI due to co-morbidities and reduced left ventricular function. As he had failed a trial of optimal medical therapy and the cardiac surgeon’s reluctance for surgery, the patient and his family was counseled for high risk PCI with left ventricular assist device using the impella 2.5.

Key Words: Left ventricular assist device (LVAD). Impella 2.5. High risk percutaneous coronary intervention.

INTRODUCTION

The introduction of left ventricular assist devices has revolutionized the field of interventional cardiology especially when conducting high risk Percutaneous Coronary Intervention (PCI). Although Coronary Artery Bypass Group (CABG) surgery is considered a better option in high risk patients with coronary artery disease, PCI can be considered under cover of left ventricular assist devices.1

Intra Aortic Balloon Pump (IABP) is a left ventricular device that has been used since 1960 in high risk patients with coronary artery disease, cardiogenic shock and refractory angina.2 IABP cannot provide total circulatory support and for optimal functioning, patients must have some level of left ventricular function.

The development of percutaneous circulatory support devices such as Impella 2.5 (Abiomed Europe, GmbH) has resulted in significant improvement in outcomes due to hemodynamic stability provided by circulatory support. It aspirates 2.5 litres of blood per minute from the left ventricle into the ascending aorta, thus improving the hemodynamic status of the patient.3 Compared to IABP, Impella 2.5 causes more profound increase in cardiac output.4

Common indications of impella 2.5 include its use in patients with high risk coronary artery disease as in cardiogenic shock, severe left ventricular dysfunction and in cases of associated ventricular septal rupture.5 It is also approved as a bridge therapy in heart transplant patients.

CASE REPORT

A 65-year old gentleman, an ex-smoker, with a significant past medical history of uncontrolled diabetes mellitus (type II), hypertension and chronic kidney disease (stage-II), extensive double vessel coronary artery disease and a severely reduced left ventricular function (ejection fraction, 20%) was admitted in the coronary care unit of our hospital with intractable angina. He had complaints of severe angina symptoms (Canadian Cardiac Society Class III) despite optimal antianginal therapy. His coronary angiogram done 2 months back had revealed double vessel coronary artery disease (subtotally occluded co-dominant left circumflex and moderate 60% stenosis in Left Anterior Descending (LAD) artery and a normal co-dominant right coronary artery) [Figure 1 and 2]. The case was discussed in heart team conference. There was consensus regarding the moderate nature of LAD lesion so the patient was considered inappropriate for CABG surgery and PCI due to co-morbidities and reduced left ventricular function. As he had failed a trial of optimal medical therapy and the cardiac surgeon’s reluctance for surgery, the patient and his family was counseled for high risk PCI with left ventricular assist device using the Impella 2.5.

After taking the consent, a 6 Fr arterial sheath (Cordis) was placed in right radial artery for coronary intervention. A 6 Fr arterial access was placed in the
right femoral artery for Impella insertion. Intra-arterial heparin was administered to maintain an activated clotting time > 250 seconds. The 6 Fr arterial sheath was progressively replaced by a 13 Fr sheath for convenient handling of the device. A 0.018” exchange guide wire (Boston Scientific, Mass.) was introduced in the Left Ventricular (LV) cavity using a multipurpose catheter for retrograde Impella insertion (Figure 3). The Impella 2.5 device was placed in the LV cavity over the wire via the right femoral artery (CFA) sheath, under continuous fluoroscopy monitoring (Figure 4). Once in place, the guide wire was removed and Impella turned on at performance level P2. Impella console was continuously monitored for optimal device placement with pump inlet in LV cavity and outlet in aortic root by continuously monitoring placement signal characteristic of aortic pressure and pulsatile motor current signal. Gradually, the pump performance increased to P8 level, thus ensuring a cardiac output of 2.1 - 2.3 l/minute. Once Impella was properly inserted and functioning ensured, PCI of the left circumflex artery was done and the artery was successfully stented with 3.0 x 18 mm drug eluting stent (Figure 5 and 6).

At the end of the procedure, Impella was removed and prolonged pressure was applied for hemostasis. The device functioned smoothly during the procedure and no complication like limb ischemia, arrhythmia, or hypotension was encountered. Post-procedure, the patient had an uneventful recovery with no elevation of cardiac biomarkers, or evidence of myocardial ischemia or decline in blood pressure. The patient was discharged 48 hours after the high-risk PCI with encouragement to quit smoking, strict compliance with medical therapy and to begin a supervised exercise program. The patient was advised myocardial perfusion scan to address ischemia if any in the LAD territory.

**DISCUSSION**

Impella 2.5 is now being routinely used in high risk PCIs. The PROTECT I study was a hallmark study done to assess the safety and efficacy of device placement in patients undergoing high-risk PCI. Twenty patients were enrolled in the study and all had a reduced ventricular function (ejection fraction < 35%) and had PCI on an unprotected left main coronary artery or the last remaining patent coronary artery or graft. The device was placed for the duration of support ranging from 0.4 to 2.5 hours. No hemodynamic deterioration was encountered in any patient. Based on this study, Impella 2.5 was approved by the FDA for high risk PCI procedures.

The ISAR SHOCK trial compared IABP to Impella 2.5 in high risk PCI procedures in patients with cardiogenic shock secondary to myocardial infarction. Improvements in cardiac index were more in cases of Impella 2.5 than in IABP cases.

LV assist device supporters foresee that the growing accessibility of these devices will significantly expand the percutaneous treatment possibilities, particularly in high risk PCI. However, two important questions need to be answered. First, what is the exact indication for mechanical cardiac assist in the setting of elective PCI? Second, what is the optimal device to be used during elective high-risk PCI procedures? First, the guidelines are conservative with regard to the indications of mechanical cardiac assist in elective PCI, because they only recommend it in patients with very poor LV dysfunction or those considered at high risk of periprocedural hemodynamic collapse.

Secondly, the main reasons impeding widespread implementation of percutaneous LV assist devices for use in elective high risk PCI and other indications were...
the high complication rates and complex handling of earlier devices, such as the femoro-femoral cardiopulmonary support system.\(^1\) Three small series of periprocedural Impella 2.5 support were encouraging with respect to safety and feasibility.\(^6\) However, to-date, large series of the use of Impella 2.5 in high-risk PCI were lacking. The Europella registry\(^9\) showed that the Impella 2.5 was easy to implant and explant, and was associated with a low rate of adverse events. The observed mortality of 5.5% in the registry seems to be consistent with the rate expected for this high-risk patient group (LMCA and/or MVD). For comparison, the 30-day mortality was 10% in the PROTECT I trial.\(^6\) In addition, in the SYNTAX (Synergy between PCI with Taxus and Cardiac Surgery) registry,\(^10\) for patients undergoing elective PCI, after being refused from CABG the 1-year mortality was 7.3%. Importantly, the rate of hemorrhagic and thromboembolic complications in the Europella registry was limited. Finally, there were no cases of device malfunction.

Impella 2.5 use in Pakistan had not been initiated due to its high cost and lack of expertise involved. On the average, Impella 2.5 costs in the range of Rs 2.5 million to 3 million which is non-affordable for most of the people. One case of Impella 2.5 (older version) insertion has been reported at Armed Forces Institute of Cardiology, Rawalpindi; however, PCI was not performed.\(^8\) We at Rawalpindi Institute of Cardiology are the first to perform a successful PCI under cover of the Impella 2.5 (latest version). Being a government-run institute and the patient being poor and non-affording, the costs of the procedure are being covered through the hospital funds for the poor and deserving patients.

REFERENCES