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Brief Report
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High-Risk "Protected" Percutaneous Coronary Intervention with Mechanical Circulatory Support in a Non-Surgical Center – An Early Asian Experience

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High-risk "protected" percutaneous coronary intervention (PCI) using mechanical circulatory support (MCS) devices, particularly the Impella axial pump, has emerged as a viable treatment option for high-risk patients with satisfactory clinical outcomes. High-risk and complex interventions have mostly remained within the domain of surgical centers. We report on an early "protected" PCI experience using MCS with the Impella flow pump at a high-volume PCI hospital without on-site surgery.

A total of 5 patients underwent elective "protected" PCI utilizing MCS with Impella at our institution. The mean left ventricular ejection fraction was 28 ± 10% and all patients had triple vessel coronary artery disease with the majority having a high SYNTAX score. Device implantation and procedural success were achieved in all cases with no intraprocedural or access site complications. All patients were alive at 30 days and clinically well.

The Impella unloads the ventricle, improves forward cardiac output and lowers myocardial oxygen demand, thereby improving mean arterial pressure and coronary perfusion. Device insertion is relatively quick and the "learning curve" is short, centering mainly around managing large bore access. Our limited experience suggests that not only is high-risk PCI with Impella support feasible in a non-surgical center, but that it may be crucial to enable success.

Key Words: High risk • Impella device • Mechanical circulatory support device • Non-surgical center • Percutaneous coronary intervention

INTRODUCTION

Temporal trends from Western countries suggest that patients presenting to the cardiac catheterization laboratory are increasingly older, frail and have multiple comorbidities.[1] Southeast Asian countries are similarly facing an aging population[2] with increasing prevalence rates of heart failure,[3] diabetes, and renal failure,[4] giving rise to a group of patients with complex coronary anatomy that are often deemed to have a prohibitive procedural risk, be it surgical or percutaneous. High-risk "protected" percutaneous coronary intervention (PCI) using mechanical circulatory support (MCS) devices, particularly the Impella axial pump, has emerged as a viable treatment option for such high-risk patients with satisfactory clinical outcomes.[5-7] Although performing both primary and elective PCI in hospitals without on-site surgical backup has become common,[8] high-risk and complex interventions have remained within the domain of surgical centers.[9] However, there are no robust data on outcomes of patients undergoing complex PCI at high-volume non-surgical centers. Herein, we report our early "protected" PCI experience using MCS with the Impella flow pump at a high-volume PCI hospital without on-site surgery.

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CASE PRESENTATION

A total of 5 patients underwent elective "protected" PCI utilizing MCS with Impella at our institution. These cases were performed between October 2017 and August 2018. All cases were presented and discussed at Heart Team rounds and accepted for high-risk PCI after a consensus had been achieved.

Table 1 outlines the clinical characteristics of the study cohort. Among this group, the mean age was 67

Table 1. Summary table of all protected PCI cases with Impella support

Case	1	2	3	4	5
Age (years)	73	61	67	75	59
Sex	Male	Male	Male	Male	Male
Diagnosis	NSTEMI	NSTEMI	STEMI, staged PCI	Angina	Angina
TIMI risk score	6	5	10	N.A	N.A
EF (%)	25%	25%	30%	45%	17%
Baseline haemoglobin (g/dL)	12.8	9.0	16.6	12.3	12.3
Chronic kidney disease (eGFR ml/min/1.73 m^2)	Yes (39)	ESRF on hemodialysis	No	No	No
Diabetes mellitus	Yes	Yes	Yes	Yes	Yes
Severe valvular heart disease	No	No	No	No	No
Coronary angiography findings	Triple vessel disease with LAD and LCx CTO, calcified mid-RCA 80%	Mid-LM 80%, triple vessel disease with proximal LAD diffuse 80%; distal LCx 95% and proximal RCA 90% with mid-RCA CTO	Triple vessel disease s/p PCI to LCx and RCA, residual proximal LAD 85% (required IABP support for shock during initial STEMI presentation)	Distal LM 60%, CTO of proximal LCX and distal RCA, with 70% stenosis in ostial to proximal LAD	Distal LM 70%, proximal and mid LAD 90%, mid-RCA CTO, proximal OM1 80%
Target vessel	RCA (last remaining vessel)	LM, LAD	LAD	LM, LAD	LM, LAD
Syntax score	38	43	23	44	39
CABG offered	Turn down	Turn down	Turn down	Patient refused	Turn down
Rotablation	Yes	Yes	Yes	Yes	Yes
Procedure details	Rotablation to mid RCA, transient hypotension during stent deployment and post dilatation	Rotablation to LM, LAD	Angiosculpt to proximal LAD, transient hypotension due to slow flow in LAD, stabilized subsequently	Rotablation to LM, LAD	Rotablation to LM, LAD. LVEDP improved from 24 to 13 on Impella CP
Number of DES	2	3	1	1	2
Impella used	2.5	2.5	2.5	2.5	CP
Impella explanted on table	Yes	Yes	Yes	Yes	Yes
Complications	No	No	No	No	No
Duration of hospitalization after PCI (days)	16	11	11	4	3
Access site complication require intervention	No	No	No	No	No
AKI	No	ESRF	No	No	No
Procedure time (min)	75	150	90	138	155
30 day outcome	Survived	Survived	Survived	Survived	Survived

AKI, acute kidney injury (defined as > 25% rise in creatinine); CP, cardiac power; CTO, chronic total occlusion; DES, drug-eluting stents; EF, ejection fraction; eGFR, estimated Glomerular filtration rate; ESRF, end stage renal failure; IABP, intra-aortic balloon pump counterpulsation; LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main; LVEDP, left ventricular end-diastolic pressure; LVEF, left ventricular ejection fraction; NSTEMI, non ST-elevation myocardial infarction; OM, obtuse marginal; PCI, percutaneous coronary intervention; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

(± 7) years; all were male with a high prevalence of hypertension, hyperlipidemia, and diabetes. Two patients had end-stage renal failure requiring dialysis, and one patient had peripheral arterial disease. The mean left ventricular ejection fraction (LVEF) was 28 ± 10%. All of the patients had triple vessel coronary artery disease (3 had concomitant obstructive left main stenosis) with the majority having a high SYNTAX score. Four of the 5 patients were deemed to be unsuitable for coronary artery bypass grafting (CABG) due to high surgical risk, and the other patient declined surgery. Device implantation and procedural success were achieved in all cases. There were no intraprocedural or access site complications, and the Impella device was explanted on the catheterization table in all cases. All patients were alive at 30 days and clinically well. Below, we discuss two cases to illustrate the role of MCS with Impella in these very high-risk patients.

Case 2 was a 61-year-old male with hypertension, hyperlipidemia, diabetes mellitus and end-stage renal failure requiring hemodialysis. He presented to the catheterization laboratory with non-ST elevation myocardial infarction (NSTEMI) and a thrombolysis in myocardial infarction (TIMI) risk score of 5. An echocardiogram demonstrated a low EF of 25%. Angiography showed an occluded right coronary artery (RCA) filling via left-right collaterals, severe calcific left main and left anterior descending (LAD) disease as well as severe distal left circumflex (LCx) disease (Figure 1). He was offered CABG, but adamantly declined surgical revascularization. Right femoral arterial access was obtained under ultrasound guidance, and two Perclose ProGlide (Abbott Vascular, CA, USA) vascular closure devices were deployed prophylactically at the arteriotomy site. An Impella 2.5 MCS device was placed across the aortic valve which provided good hemodynamic support for this patient. Rotational atherectomy of the left main and LAD was performed, followed by intravascular ultrasound-guided stenting with three drug-eluting stents (DESs) (Figure 1). Stent placement in the LAD required the use of a Guideliner guide catheter extension. During the Guideliner introduction, there was contrast stagnation in the left coronary artery due to the loss of cardiac contraction, which persisted even after disengagement of the guiding catheter. Despite losing the pulsatile waveform from the arterial line, the moderately sedated patient remained rousable, suggesting adequate cerebral perfusion from the Impella device when the heart briefly went into pulseless electrical alternans (PEA) (Figure 2). MCS support was weaned off on the table, and the device was explanted, after which the arteriotomy site was closed using the previously deployed Perclose sutures. The patient was discharged 6 days later in a stable condition after optimizing his medication and undergoing routine dialysis.

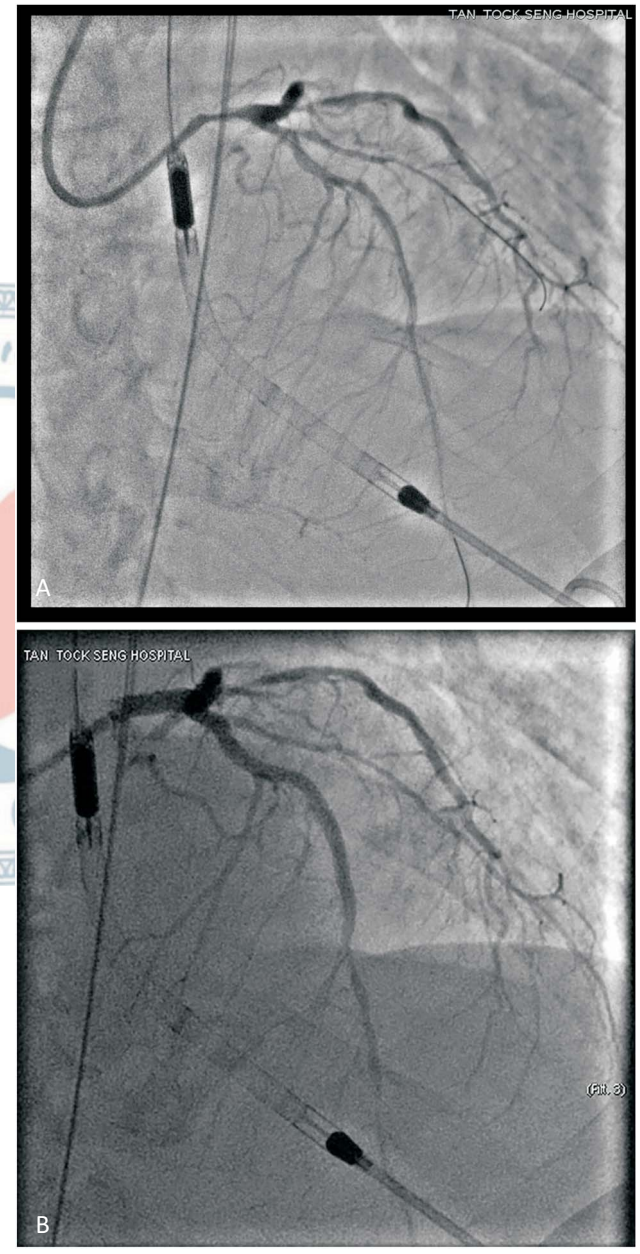

Figure 1. *(A) Initial coronary angiogram showing severe left main and mid-left anterior descending (LAD) disease. (B) Final angiographic results after implantation of 3 drug-eluting stents (DESs) from left main to mid LAD.*

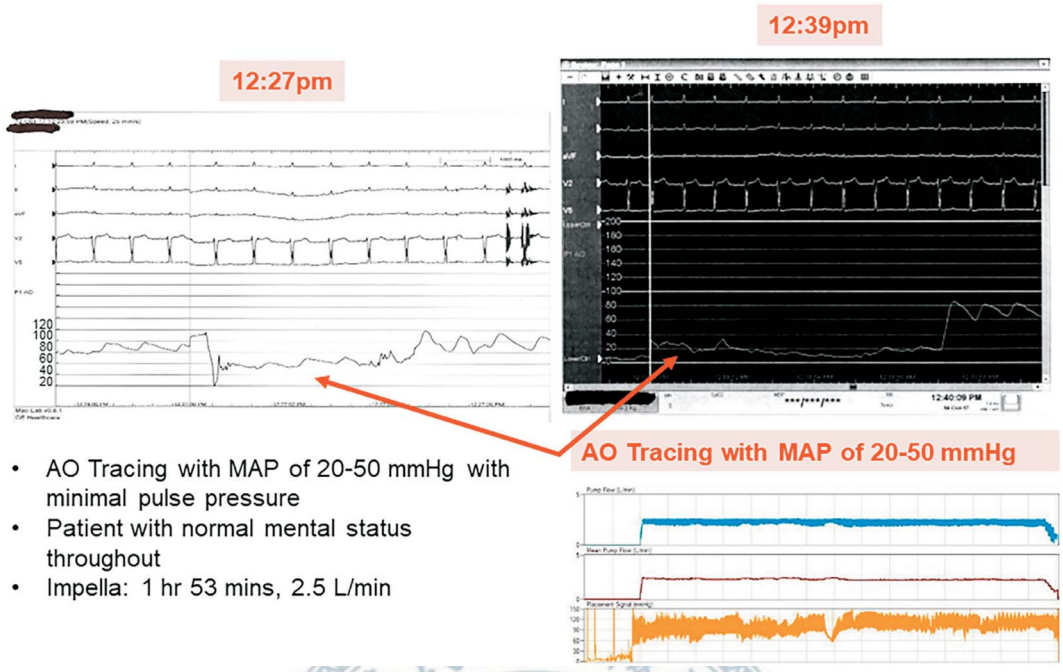

Figure 2. *Hemodynamic tracing showing blood pressure declining and complete loss of pulsatile flow yet cardic output maintained. AO, aortic; MAP, mean arterial pressure.*

Case 5 was a particularly challenging case of a 59-year-old male with hypertension, diabetes, hyperlipidemia and peripheral vascular disease who was admitted initially for NSTEMI. Coronary angiography revealed severe distal left main and calcific triple vessel disease along with an occluded RCA that filled via left-to-right collaterals (Figure 3). His LVEF was 17%. Given his severe disease, CABG was recommended, and he was referred to a surgical center. However, his risk was felt to be prohibitive by the surgeons, and he was turned down for CABG. Due to persistent symptoms, he was offered high-risk "protected" PCI. Computed tomographic angiography of the lower extremities revealed an occluded right, but patent left femoral artery. An Impella cardiac power (CP) device was inserted via the left femoral artery through a 14F sheath, and PCI was performed transradially. The baseline left ventricular end-diastolic pressure (LVEDP) was 24 mmHg. Plaque modification with rotational atherectomy from the left main to LAD with a 1.5-mm burr was performed, followed by dilatation with a non-compliant and then scoring balloons before the deployment of two long DESs (Figure 3). The patient tolerated the procedure well with no significant drop in blood pressure. The LVEDP at the end of the procedure dropped to 13 mmHg due to off-loading of the left ventricle by the Impella CP device. Normal saline (450 ml) was infused, and we were able to slowly wean off the MCS device over an hour in the laboratory. Once explanted, the femoral wound was closed with two pre-delivered ProGlide suture devices. The patient was discharged well 3 days later.

DISCUSSION

Although there is no common unifying definition of what constitutes "high-risk" PCI, the underlying principle is that low LVEF and hence poor myocardial reserve, a large territory of jeopardized myocardium and lesion complexity (including but not limited to calcification and need for atherectomy), substantially contribute to this risk.[10] In the PROTECT II trial, high-risk PCI was defined as cases with an unprotected left main, last patent coronary vessel with reduced LVEF ≤ 35%, or triple vessel disease with LVEF ≤ 30%.[7] The most commonly used MCS device is the intra-aortic balloon pump (IABP), which is easy to insert and provides modest hemodynamic support.[10] Recent trials, however, have failed to show a benefit of the IABP in high-risk PCI or cardiogenic shock.[11] Left atrial to aorta assist devices such as TandemHeart are effective but require the additional ex-

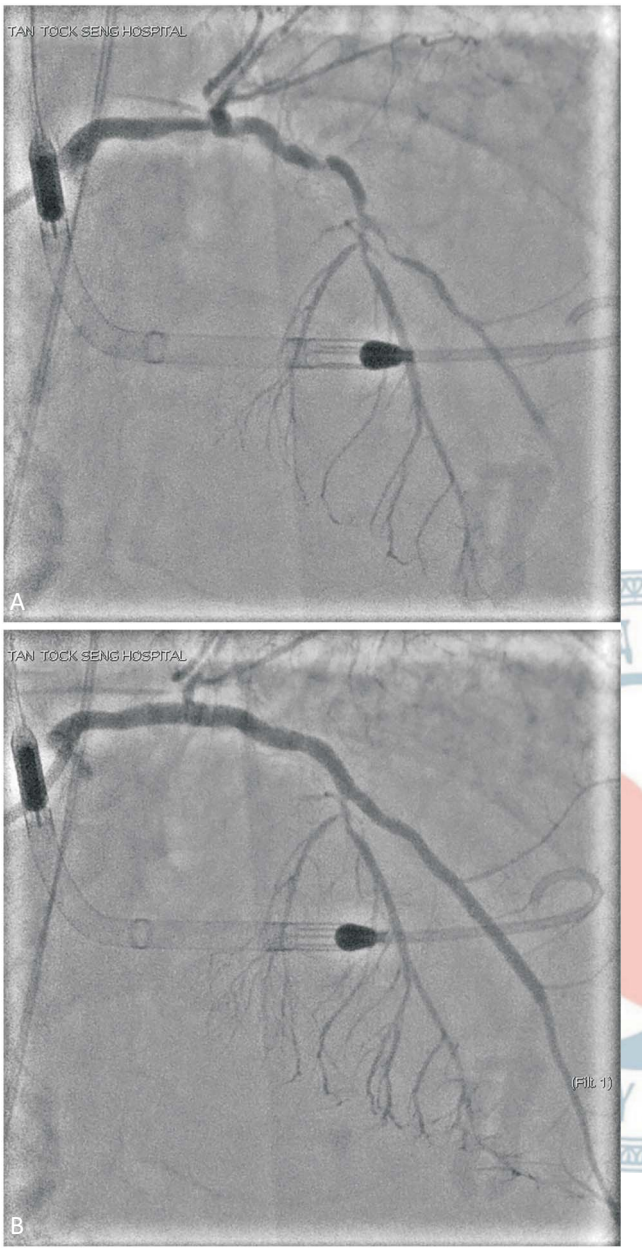

Figure 3. *(A) Coronary angiogram showing severe stenosis in proximal to mid left anterior descending (LAD). (B) Final angiogram showing implantation of two drug-eluting stents in the left main and LAD.*

pertise of trans-septal puncture, making widespread use difficult.[10] Another alternative MCS device is veno-arterial extra-corporeal membrane oxygenation or percutaneous cardiopulmonary support, which, while effective, requires the presence of a perfusionist, something that is not readily available, particularly at a non-surgical center. The Impella is a left ventricle to aorta assist device that provides non-pulsatile flow from the left ventricle to the aorta and, via either a 12F or 14F sheath, and is introduced into the left ventricle in the same manner as a pigtail catheter. The access site is most commonly the femoral artery, however subclavian and axillary artery implantations have been described. The Impella unloads the left ventricle and not only improves forward cardiac output but also lowers myocardial oxygen demand, thereby improving mean arterial pressure and coronary perfusion. The device provides a flow rate of 2.5 L/min, but with the Impella CP flow rates of 3-4 L/min can be achieved. Device insertion is relatively quick and the “learning curve” is short, centering mainly around managing large bore access. While the PROTECT II randomized trial[7] failed to meet its primary 30-day endpoint, benefits appeared to surface at 90 days, particularly in a per-protocol analysis. Although by no means conclusive, these data, as well as large registries showing a favorable effect of Impella-assisted PCI[6] suggest that perhaps the most severely ill patients (who would need MCS devices the most) may not be getting enrolled in trials. Our limited experience suggests that not only is high-risk PCI with Impella support feasible in a non-surgical center, but that it may be crucial to enable success, as seen with case 2 where all pulsatile blood flow was transiently lost.

There are several limitations of MCS-assisted PCI with Impella, particularly in the context of a non-surgical Asian center. First, it is important to note that our institution is a very high-volume PCI center, performing close to 1800 interventions annually with all operators being highly experienced. Impella-assisted high-risk PCI would not be feasible in low volume centers or with inexperienced operators because both laboratory staff and operator expertise are important to ensure a good outcome. Second, meticulous attention to vascular site management is essential to ensure a complication-free outcome, and operators/centers not experienced with this may have significant vascular complications negating potential benefits. Third, limitations to the more widespread use of Impella in most Asian countries is its prohibitive cost and lack of national or insurance coverage.

CONCLUSIONS

Patients presenting to the cardiac catheterization

laboratory have an increasing number of comorbidities and disease complexity. Increasingly, such patients are being turned down for surgical interventions, and the need for high-risk "protected" PCI is growing in most interventional cardiology practices including in Southeast Asia. Our preliminary experience suggests that high-risk "protected" PCI using MCS with Impella is feasible in a non-surgical center with excellent success and a low complication rate. Operator experience, close teamwork and laboratory volume are probably key factors for the success of such an approach.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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