Research Article

Interventional Cardiology

Impella-Supported Cardiac Surgery

Paolo Masiello[1*], Generoso Mastrogiovanni[1], Mario Colombino[1], Francesco Cafarelli[1], Francesco Frunzo[2], Marco Padula[2], Donato Triggiani[1], Gerardo Del Negro[1], Emanuele Fiore[2], Severino Iesu[1].

[1]Emergency Cardiac Surgery division
[2]Cardiothoracic Anesthesia and Intensive Care division A.O.U. San Giovanni di Dio e Ruggi D'Aragona-Salerno-Italy

*Author for correspondence:
E-mail: paolo.masiello1@virgilio.it
Received date: 20-03-2020
Accepted date: 04-04-2020
Published date: 10-04-2020

Abstract:

Background: Impella left ventricular assist devices are useful tools for the treatment of cardiogenic shock. The peri-operative use of Impella in patients with low left ventricular ejection fraction (LVEF) undergoing cardiac surgery, can be valuable for cardiac surgeons to prevent postcardiotomy cardiogenic shock.

Methods: From September 2018 to June 2019, 10 patients underwent cardiac surgery supported by Impella 5.0. Five patients underwent off-pump coronary artery bypass (OPCAB), two had OPCAB and mitral valve repair (MVR), and one each had aortic valve repair (AVR) plus MVR, OPCAB plus AVR, and left ventricular aneurysmectomy plus MV replacement. The Impella 5.0 was inserted surgically one day before the operative procedure via a side conduit through the left femoral artery in 8 cases and right axillary artery in 2 cases. The mean age of patients was 63 ± 7 years. Mean LVEF at baseline was 27.5% (20-32%) and mean duration of Impella support was 7 days (4-12 days).

Results: Hemodynamics improved immediately after the initiation of mechanical support. The cardiac surgical procedures were conducted in the usual manner. All patients received low dose of postoperative inotropes. Cardiac-related mortality was 10% (1/10), due to multiorgan failure (MOF) in 1 patient who underwent OPCAB. Major intracranial bleeding occurred in 2 patients who received extracorporeal circulation (ECC). Impella support was weaned in all patients after hemodynamics was optimized without inotropes, except the patient with MOF. The survivors had no major complications and were discharged to medical therapy at mean of 21 days.

Conclusion: Impella support is feasible for preconditioning before surgery and in the postoperative period. It enables cardiac surgery in patients with low EF using a low dose of inotropes and helps to prevent postcardiotomy cardiogenic shock. Impella support during OPCAB allows for easier positioning and unloading the heart. The underlying cause for intracranial bleeding in two cases despite successful weaning from Impella support remains to be understood.

Keywords: Mechanical cardiac support▪Cardiogenic shock▪Cardiac surgery▪ OPCABG

Introduction

Studies report that 0.2-9% of the patients undergoing cardiac surgery, irrespective of the type of surgery, experience postcardiotomy cardiogenic shock (PCCS), thereby contributing to the high overall mortality [1,2]. Mortality with PCCS is higher than cardiogenic shock (CS) due to other etiologies and is the most common indication for receiving a short term mechanical circulatory support (MCS), albeit with the lowest survival to discharge [3]. PCCS was also found to be an independent predictor of mortality in CS.

Patient- or procedure-related causes are potential risk factors with low preoperative left ventricular ejection fraction (LVEF) being the top independent predictor of CS [2]. Until recently, IABP was the most used mechanical support device. However, its use has declined since the publication of the results of the IABP-Shock II randomized trial showing limited effects in CS [4-6]. The ESC guidelines for myocardial revascularization indicate the routine use of IABP in acute myocardial infarction (AMI) with CS [7] is not useful or effective and in some cases may be harmful.

Left-sided Impella heart pumps include Impella 5.0®, which is a trans-aortic, micro axial, non-pulsatile mechanical pump that provides flows up to 5.0 L/min. Impella 5.0 provides temporary, partial, or full mechanical circulatory support and has been reported to be feasible and safe in bridging PCCS patients to recovery, durable VAD or transplantation [8].

In contrast to IABP, which decreases LV afterload and increases stroke volume, Impella devices aspire blood from the LV and deliver it directly into the aorta above the aortic valve, thus unloading the LV and consequently reducing myocardial oxygen consumption and increasing coronary blood flow. In other words, Impella pumps decrease LV pressures and volumes, thereby reducing the cardiac workload.

The approved indications for Impella 5.0 support include patients with cardiogenic shock, low cardiac output syndrome during or after cardiac interventions, or as a bridge to transplant or ventricular assist device.

One of the important considerations for MCS therapy in PCCS is the timing of initiation. While early initiation of support is associated with improved in-hospital and 1-year outcomes, late support is often associated with high mortality (9). Delays in the initiation of MCS may be due to the need for qualified staff available on-demand and the concerns related to potential complications such as bleeding [10].

We report the use of Impella 5.0 peri-operatively as a planned support for high-risk patients undergoing cardiac surgery to unload the heart before the procedure, overcome shock related to surgical injury, and aid beating heart myocardial revascularization by reducing the occurrence of myocardial ischemia related to the heart positioning.

Materials and Methods

Study design

A retrospective review of 10 patients with low LVEF (<30%, mean 27.5%) and high Euroscore II (mean 17.4%) who underwent elective cardiac surgery from September 2018 to September 2019 was performed. The baseline characteristics of patients are reported in Table 1.

Table 1: Preoperative characteristics.

Preoperative characteristics	10 Patients
Mean Age	63 ± 7 y-o
Baseline LV mean EF	27.50%
Male	8 (80%)
EUROSCORE II (mean)	17.4% (8-23)
Preoperative cardiac index (mean)	1.9 L/min/m2
Risk factors	
Heart failure on medications	5 (50%)
Unstable angina	1 (10%)
Chronic renal failure	2 (20%)
Diabetes on insulin	7 (70%)
Long standing hypertension	6 (60%)
Peripheral vascular disease	5 (50%)
Pulmonary hypertension	4 (40%)
Atrial fibrillation	4 (40%)
NYHA III-IV	8 (80%)

The Impella 5.0 was implanted one day before the surgical procedure in the cat lab under fluoroscopy via the femoral (n=8) or axillary artery (n=2), using a side surgical 10 mm vascular graft. At the same time, a full dose of Levosimendan was slowly administered to all patients. No other inotropes were administered before surgery.

Maximal Impella support was started immediately after implantation to unload the heart and improve cardiac output and maintained until the initiation of extracorporeal circulation (ECC). Impella support was reduced to P2 during ECC and aortic valve replacement while full support was maintained during off-pump coronary artery bypass surgery (OPCAB). Impella support was continued in the postoperative phase for at least 72 hours until hemodynamic stability was achieved. Activated clotting time was maintained around 160 seconds. Whenever possible, patients were extubated and mobilized as tolerated, particularly in cases with axillary Impella implants. The postoperative infusion of inotropic drugs was kept as low as possible (<0.1 µg/ml/min), and the heart contractility was monitored daily with transthoracic (TT) or transesophageal (TE) echocardiography.

Following hemodynamic stabilization, Impella flow was slowly reduced to assess if weaning could be initiated. The criteria

for weaning were cardiac index (>2 L/min), lactate levels (<3 mmol/L), and adequate mixed venous saturation. Weaning was started in a stepwise fashion by reducing the pump flow by two speeds daily until P2, along with monitoring by TTE. Once the assessment results were acceptable, Impella was removed at the bedside by retracting the pump into the vascular graft (which was clipped and stapled at the base).

Procedure

Five patients had off-pump coronary artery bypass surgery (OPCAB), and 5 had other surgical procedures using extracorporeal circulation (ECC) (Table 2). In patients undergoing concomitant surgeries, OPCAB was performed first. Myocardial viability was preoperatively documented by stress echocardiography.

Table 2: Operative characteristics.

Operative procedures	
OPCAB	5 patients
OPCAB + MVRepair	2 patients
OPCAB + AVR	1 patient
AVR + MVRepair	1 patient
LVAneurysm+ MVReplacement	1 patient
Number of grafts (mean)	3.1/pts (Isolated OPCAB)
Number of grafts (mean)	2.3/pts (Concomitant OPCAB)
Impella via femoral artery	8 patients
Impella via axillary artery	2 patients
Impella duration (days)	7 (4-12)

*AVR: Aortic Valve Replacement; MVR: Mitral Valve Replacement/Repair; LVAneurysm: Left Ventricular Aneurysmectomy

The mean number of grafts to achieve complete revascularization in OPCAB patients was 3.1. In all cases, the left mammary artery and left radial artery were used to revascularize the left coronary system in "Y" or "double Y" shaped fashion. The saphenous vein was used to graft the right coronary system in four patients. Three patients undergoing concomitant surgeries received a mean of 2.3 grafts, with arterial conduits to the left coronary system. Also, two mitral valve repairs plus one replacement, two aortic valve replacements and one left ventricular aneurysmectomy were performed. The mean ECC and cross-clamp time was 82 and 67 mins, respectively. The mean preoperative cardiac index was 1.9 l/min.

Results

The cardiac-related 30 days mortality was 10% (1/10). Impella could not be weaned in one patient who developed severe multiorgan failure (MOF) and died on the 5th postoperative day (POD). A major cerebral hemorrhage occurred in 2 patients having ECC on 2nd and 5th POD. Impella support was successfully weaned in these patients on day 4th and 6th following satisfactory cardiac function. Of note, one of the patients had suffered a cerebral hemorrhage two years before as well. Among the survivors, acute renal insufficiency developed in 2 patients receiving veno-venous ultrafiltration and resolved after 8-10 days. In one case Impella malfunction resulted in urgent removal during the weaning process. Late sepsis that resolved with appropriate antibiotic therapy occurred in one patient. No device-related heart injury, significant hemolysis, embolic stroke, or reoperation for bleeding occurred. The mean postoperative cardiac index was 2.55 l/min.

Adrenaline dose > 1 µg/kg/min for a short duration (mean 11 hours) was needed in two patients. The mean duration of Impella support was 7 days (4-12). Among the survivors, follow-up echocardiography at 3 months showed an improved LVEF (34% mean) with no signs of heart failure. Results are summarized in Table 3.

Table 3: Operative results.

Clinical data	Clinical data	Clinical data
Cardiac-related mortality	1 (10%)	
MOF	1(10%)	OPCAB
Cerebral Hemorrage	2 (20%)	OPCAB+AVR LVAn+MVRepl
Preoperative cardiac index (mean)	1.9 L/min/m2	
Cardiac index at discharge from ICU (mean)	2.55L/min/m2	
Adrenaline < 0,1 mcg/Kg/min	8 (80%)	
Noradrenaline < 0,1 mcg/Kg/min	4 (40%)	
Dobutamine < 6 mcg/Kg/min	100%	
Temporary Acute Renal Failure	2 (20%)	
Device malfunction	1 (10%)	
LVEF (mean)	34%	

Discussion

The indications for MCS use have changed drastically in recent years. The "LV unloading" concept with the Impella

micro-axial flow pumps have gained popularity, given their ability to reduce LV wall stress and the resulting decrease in myocardial oxygen consumption. The Impella heart pumps are easy to implant and explant, associated with a low incidence of complications, allow for early patient mobilization with axillary implantation, and have only few contraindications. The ease of management among nursing staff is an added value, particularly in high volume centers. On the opposite its use can be affected by complications like limb ischemia, vascular injury, stroke and bleeding requiring blood transfusion. Hemolysis due to mechanical erythrocyte shearing stress has been reported, sometimes associated with acute kidney injury.

Experimental animal studies report that LV unloading reduces ischemia-reperfusion injury and infarct size expansion in AMI. This effect is related to both the degree and early initiation of LV unloading [11-14]. Lazkani et al. reported an improved one-year outcome in "all-comers" receiving early support with Impella compared with its use as a bailout [9].

Intra-aortic balloon pump (IABP) was the extensively used MCS for cardiogenic shock, before the introduction of Impella heart pumps. IABP reduces left ventricular (LV) afterload and improves coronary flow, but its effects are modest compared to Impella devices. Alushi et al. recently reported improvement in parameters of shock severity and LVEF at 30 days with Impella use in AMI-CS patients compared to IABP, although no difference in mortality was observed [15]. Given the substantial evidence of the ineffectiveness of IABP, it is not used as MCS for PCCS at our hospital.

During "on-pump" surgery, cardiac ischemia typically occurs during cross-clamping despite optimal cardioplegic protection. While in OPCAB, temporary myocardial ischemia can be due to heart displacement, temporary interruption of coronary blood flow or blood loss. Patients with low ventricular EF may have additional complications resulting in failure to wean from ECC or development of PCCS that could be fatal. Based on these considerations, we developed the concept of using Impella as prophylactic therapy in high-risk cardiac surgery to prevent PCCS. This strategy may enable to perform surgery in patients suffering from severe LV dysfunction, usually turned down by the surgeons despite having a long-life expectancy.

Until 2018, only 5 case studies of Impella-supported high-risk cardiac surgery were reported [16-19]. Recently, three new reports were published, leading to a total of 18 cases, all demonstrating the successful adoption of this concept [20-22]. Ranganath et al. reported the largest series of prophylactic Impella use in 13 patients with low LVEF undergoing on-pump CABG [20]. They used Impella LD that was inserted in ascending aorta via a side graft and required surgical removal after weaning. No mortality and low rate of major complications (hemolysis, displacement, and renal insufficiency) were reported so they concluded that prophylactic use of the Impella is safe and effective in patients with severe LV dysfunction.

In our study, a low rate of major complications was observed with Impella use during high-risk surgery in line with the results of Ranganath et al. [20], except for the occurrence of cerebral hemorrhage cases that remains unexplained. We avoid the Impella LD use because of the surgical removal risks.

In our experience, implantation of a left-sided Impella is easy and involves a short learning curve. Initially, we placed the Impella via the femoral artery mainly due to our comfort and experience level with the procedure. Recently (since the last two cases herein reported) we transitioned to positioning the Impella via the axillary artery. When the Impella device is implanted before surgery, support can be initiated immediately after the operation without the need for a hybrid operative room or transfer of the patient to the cath lab. The axillary implantation of Impella allows early patient mobilization and has a low rate of pump displacement, which is beneficial, particularly when prolonged support is needed.

Previously, we used the Impella 2.5 and Impella CP and found that higher cardiac output was required in PCCS requiring escalation, so Impella 5.0 was used for all cases in this study. No pump displacement, major renal dysfunction, or hemolysis was observed in this study. Also, the overall complication rate and device malfunction were low, which is typically higher in this subset of patients undergoing high-risk cardiac surgery.

The in-hospital major morbidity was mainly due to cerebral hemorrhages, which were likely not related to the use of Impella. All but one patient were weaned off Impella with low myocardial stress.

Conclusion

This study demonstrates that planned prophylactic use of Impella, rather than bail out strategy after the occurrence of PCCS, is safe and effective when utilized as a bridge-to-recovery and enables high-risk cardiac surgery in patients with low LVEF while using a low dose of inotropes. LV

unloading with Impella decreases wall tension and improves coronary perfusion favoring myocardial recovery, thereby preventing PCCS. Impella support during OPCAB allows for easier positioning and unloading of the heart, enabling complete revascularization. The favorable results of this study are encouraging. However, the occurrence of intracranial bleeding in 2 cases despite successful weaning remains to be explained.

Considering the observational nature of this study, the results should be considered hypothesis-generating and additional studies are required to evaluate the prophylactic use of Impella support in patients undergoing high-risk cardiac surgery.

Acknowledgements

Author contributions: Dr. Masiello developed the concept and designed the study. Drafting the article was made by Dr. Masiello and Dr. Mastrogiovanni, Critical revision was made mainly by Dr. Iesu. All other authors contributed to data analysis collection, statistics, critical revision and approval of the article.

Conflict of interest

All authors have no financial/proprietary interest in the subject matters of manuscript

Funding

Open Access publication was supported by Abiomed, Europe GmbH

References

1. Pae Jr WE, Miller CA, Matthews Y, et al. Ventricular assist devices for postcardiotomy cardiogenic shock. A combined registry experience. J Thorac Cardiovasc Surg. 104(3): 541-552 (1992).
2. Samuels LE, Kaufman MS, Thomas MP, et al. Pharmacological criteria for ventricular assist device insertion following postcardiotomy shock: experience with the Abiomed BVS system. Card Surg. 14(4): 288-293 (1999).
3. Fléchera E, Anselmi A, Corbineaua A, et al. Current aspects of extracorporeal membrane oxygenation in a tertiary referral centre: determinants of survival at follow-up. Eur J Cardiothorac Surg. 46(4): 665-671 (2014)
4. Thiele H, Zeymer U, Neumann FJ, et al. Intraaortic balloon support for myocardial infarction with cardiogenic shock. N Engl J Med. 367(14): 1287-1296 (2012).
5. Thiele H, Zeymer U, Neumann FJ, et al. Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomized, open-label trial. Lancet. 382(9905): 1638-1645 (2013).
6. Unverzagt S, Buerke M, de Waha A, et al. Intra-aortic balloon pump counterpulsation (IABP) for myocardial infarction complicated by cardiogenic shock. Cochrane Database Syst Rev (2015).
7. The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS). 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. 40(2): 87-165 (2019).
8. Griffith B, Anderson M, Samuels L, et al. The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. J Thorac Cardiovasc Surg. 145: 548-54 (2013).
9. Lazkani M, Murarka S, Kobayashi A, et al. A retrospective analysis of Impella use in all-comers: 1-year outcomes. J Interven Cardiol. 30(6): 1-7 (2017).
10. Fukuhara S, Takeda K, Reshad GA, et al. Contemporary mechanical circulatory support therapy for postcardiotomy shock. Gen Thorac Cardiovasc Surg. 183-191 (2016).
11. Meyns B, Stolinski J, Leunens V, et al. Left ventricular support by catheter-mounted axial flow pump reduces infarct size. J Am Coll Card. 41(7): 1087-1095 (2003).
12. Esposito M, Zhang Y, Qiao X, et al. Left Ventricular Unloading Before Reperfusion Promotes Functional Recovery After Acute Myocardial Infarction. J Am Coll Cardiol. 72(5): 501-14 (2018).
13. Kapur N, Reyelt L, Swain L, et al. Mechanical Left Ventricular Unloading to Reduce Infarct Size During Acute Myocardial Infarction: Insight from Preclinical and Clinical Studies. J Cardiovasc Transl Res. 87-94 (2019).
14. Saku K, Kakino T, Arimura T, et al. Left Ventricular Mechanical Unloading by Total Support of Impella in Myocardial Infarction Reduces Infarct Size, Preserves Left Ventricular Function, and Prevents Subsequent Heart Failure in Dogs. Circ Heart Fail. 11: e004397 (2018).
15. Alushi B, Douedari A, Froehlig G, et al. Impella versus IABP in acute myocardial infarction complicated by cardiogenic shock. Open Heart. 6: e000987 (2019).
16. Pepino P, Coronella G, Oliviero P, et al. Successful use of the Impella Recover LP 5.0 device for circulatory support during off-pump coronary artery bypass grafting. Int J Surg Case Reports. 5: 803-805 (2014).
17. Yildiz CE, Sayin M, Yerebakan H, et al. First Turkish experiences of assisted beating-heart coronary artery bypass graft with the Impella Microaxial Ventricular Assist Device. Heart Surg Forum. 13(1): E60-2 (2013).
18. Szafron B, Smoczyński R, Drobiński D, et al. Impella LD microaxial pump supporting combined mitral and coronary surgery in a patient with dilated cardiomyopathy. A short bridge to recovery? J Thorac Cardiovasc Surg. 12(1): 56-59 (2015).
19. Akay M, Frazier O. Impella Recover 5.0 Assisted Coronary Artery Bypass Grafting. J Card Surg. 25(5): 606-607 (2010).
20. Ranganath N, Nafday H, Zias E, et al. Concomitant temporary mechanical support in high-risk coronary artery bypass surgery. J Card Surg. 34(12): 1-4 (2019).
21. Osswald A, Schmack B, Ruhparwar A. Impella 5.0 as short-term mechanical circulatory support following mitral valve surgery in high risk patients. Artificial Organs. Letter to the editor.
22. Takahashi K, Nakata J, Kurita J, et al. Impella-assisted coronary artery bypass grafting for acute myocardial infarction. Asian Cardiovasc Thorac Ann. 28(2) (2020).