

The increasing importance of percutaneous mechanical circulatory assist device therapy in heart failure management

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ABSTRACT

Introduction: Advances in medical and surgical care have made it possible for an increasing number of patients with Congenital Heart disease (CHD) to live into adulthood. Transposition of the great vessels (TGV) is the most common cyanotic congenital cardiac disease where the right ventricle serves as systemic ventricle. It is not uncommon for these patients to have systemic ventricular failure requiring transplantation. **Study Design:** Hemodynamic decompensation in these patients can be swift and difficult to manage. Increasingly percutaneous LVAD's such as the Impella (Abiomed, Mass, USA) are gaining popularity in these situations owing to their relative ease of placement, both in and outside of the operating room. **Conclusion:** In this paper we demonstrate that Impella (IMP) CP placement through the axillary artery approach shows to be suitable option for short term cardiac support and improvement of end organ perfusion in anticipation of cardiac transplantation.

Key words: Congenital heart disease; Hemodynamic decompensation; Impella; Percutaneous left ventricular assist device's; Transposition of the great vessels

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INTRODUCTION

As a direct result of advances in medical therapies, corrective cardiac surgery techniques, as well as improved perioperative and critical care more patients with congenital heart disease outlive into adulthood. Unfortunately, many of them will progressively deteriorate in cardiac function resulting in symptomatic heart failure^[1,2] requiring advance cardiac care as they age.^[3]

Transposition of the great vessels is the most common cyanotic congenital heart defect^[4] with several variants, the most common being dextro-transposition of the great arteries (DTGA). In DTGA, the aorta tends to lie on the right, and the great arteries run parallel. The right ventricle (RV) serves as the systemic ventricle by pumping blood directly into the aorta and bypassing the pulmonary system. The left ventricle (LV) pumps blood into the lungs via the pulmonary artery

resulting in cyanosis as a consequence of parallel circulation.^[5,6]

One of the methods for anatomic correction in TGA includes the atrial switch procedure (ASP). In the ASP for DTGA, the two atria are baffled, referred to as the Mustard or Senning

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procedures.^[5-7] They differ in that the Senning operation uses right atrial and inter-septal flaps of the patient's native tissue to form the conduit while the Mustard operation utilizes prosthetic tissue for baffle creation. This allows for direct venous drainage to the left atrium so that the LV takes on the responsibility of the venous ventricle, and the RV takes on the role as systemic ventricle.^[7]

Device description

An intramyocardial pressure (IMP) is an axial flow pump placed percutaneously, retrograde through a central or peripheral artery, across the aortic valve and ultimately into the LV. It is capable of producing anywhere from 2.5 to 5 L of flow/min depending on the model type, with the inflow area residing in the left ventricular chamber and the outflow area projecting into the ascending aorta. Blood is ejected from the outflow portion to the ascending aorta for systemic organ perfusion.^[8-10] The device has a differential pressure sensor that allows the provider to position it correctly based on the pressure gradient difference between intraluminal and environmental hemodynamic pressures.^[11]

The IMP devices are used for mechanical circulatory support in patients with cardiogenic shock thanks to their design and hemodynamic effects including direct unload of the left (in our case systemic) ventricle, myocardial workload, oxygen consumption reduction, and increase coronary perfusion and as result improve myocardial oxygen supply/demand ratio, increase cardiac output and index, decrease pulmonary capillary wedge pressure, and increase end organ perfusion^[8,12,13] [Figures 1 and 2]. In most Cardiac Catheterization Labs as well as cardiac operating rooms

worldwide, the intra-aortic balloon pump (IABP) is now being gradually replaced by the new generation of percutaneous left ventricular assist device LVADS's owing to their greater efficacy in hemodynamic support in critically ill patients.

Although the IMP devices used in our report include the IMP CP (3.5) and 5.0, the mechanics of the different devices remain similar. Two of the main differences are the size of the motor housing and the maximal flow reach by each individual device. The IMP 2.5 comes equipped with a 12 French (Fr) motor housing enabling a pump flow rate of 2.5 L of blood/min into the systemic circulation, as opposed to the IMP CP with a 14 Fr motor housing and an output of 3.5 L of blood/min. In regard to the IMP 5.0, it has a 21 Fr motor housing size, and it reaches a flow rate of 5 L of blood/min.^[13-15]

The pump is usually used as a temporary measure to support systemic ventricular function with the Food and Drug Administration approval for partial circulatory support for periods up to 6 h for cardiac procedures not requiring cardiopulmonary bypass.^[14] The literature describes many cases of prolonged off-label use of this describing its use for up to 18 days,^[13] another case reported use for 35 days^[16] and in an experience with IMP LP 5.0 in 9 patients in the Intensive Care Unit, Impella usage extended for 23 days^[17] without a description of any major complication.

Although IMP assist devices are usually inserted through the femoral artery, there are numerous articles increasingly reporting the successful use of the axillary and subclavian approaches.^[16-21] All these articles

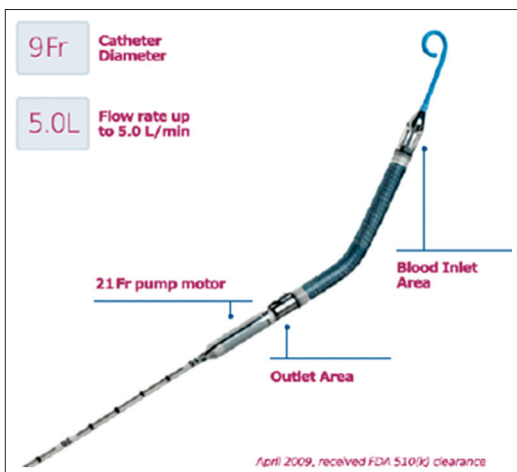


Figure 1: Impella 5.0: Courtesy of Abiomed

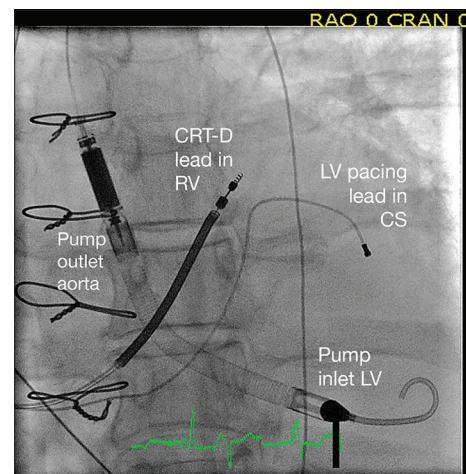


Figure 2: Standard impella placement with pump inlet in left ventricle and outlet in ascending aorta

acknowledge the advantages of the utilization of this access over the femoral emphasizing the more rapid and earlier mobilization and rehabilitation, the avoidance of vascular complications due to femoral and aortoiliac disease such as ischemia of the limb, and reduced risk of infection. In addition, there is also no need to place the IABP “on pause mode” to inset the IMP through a femoral artery.

What follows below is the index case of a patient with history of transposition of great vessels status postMustard procedure implanted with a ventricular assist device (IMP CP) as bridge to orthotopic heart transplant through the left axillary artery due to the failure of anatomic right (systemic) ventricle.

Illustrative case

A 37-year-old male with end-stage systemic ventricular dysfunction having a medical history significant for DTGA status postMustard procedure at the age of 9 months old was admitted to our institution with symptoms of worsening decompensation of his heart failure unsuccessfully treated with high dose dual inotropic support with dobutamine and milrinone and an IABP for the augmentation of ventricular function.

His echocardiogram main findings were consistent with DTGA with intact Mustard conduit, severe systemic ventricular dysfunction and pulmonary hypertension, common atrium with absent interatrial septum and well defined atrial baffle connecting inferior vena cava and superior vena cava to venous ventricular annulus, systemic ventricular cardiac output 2.37 L/min and cardiac index of 1.27 L/min/m², his estimated right ventricular (systemic ventricle) ejection fraction was 10%, pulsus alternans was present on aorta Doppler wave form in addition to, situs solitus, levocardia,

A-V concordance, V-A discordance, and severe tricuspid valve regurgitation (systemic atrio-ventricular valve) [Figures 3 and 4].

Unfortunately, despite all of the cardiac support the patient’s hemodynamics did not improve, he progressed to cardiogenic shock developing multisystem organ failure significant for lactic acidosis with a lactate level reaching 2.7 mmol/L, saturation from mixed venous blood (SVO₂) continued to decrease to 37%, with thrombocytopenia, coagulopathy and elevated transaminases secondary to congestive hepatopathy, hyponatremia secondary to congestive hypervolemic free water excess and acute renal failure secondary to cardiogenic shock with a creatinine elevation at 1.6 mg/dl and an estimated glomerular filtration rate of 48 mL/min.

An emergent multidisciplinary meeting led by the heart failure and cardiothoracic surgery services determined that an IMP 5.0 assist device placement would provide additional support.

The patient was emergently taken to the Cardiac Catheterization Lab with all the standard American Society of Anesthesiologist monitors, central venous pressure, and arterial line and positioned on the procedural table. On arrival to the Cath Lab, his systemic blood pressure was 78/53 mmHg., central venous pressure 31 mmHg., heart rate 120 beats/min. and sinus tachycardia, with dobutamine 15 mcg/kg/min, milrinone 0.5 mcg/kg/min, and IABP for hemodynamic support.

After induction of general anesthesia with fentanyl, etomidate, and rocuronium endotracheal intubation was achieved and transesophageal echo probe placed.

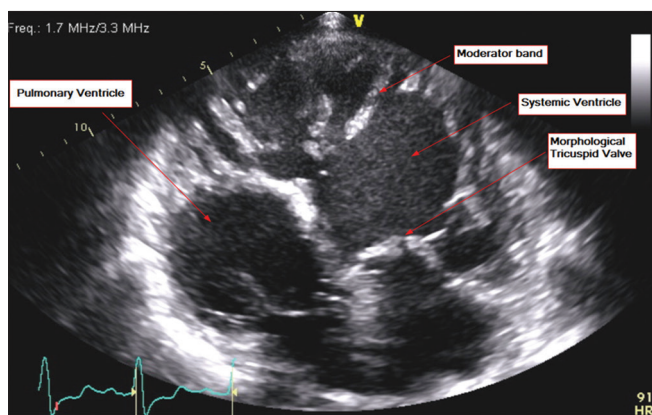


Figure 3: Transthoracic Apical 4 chamber view depicting abnormal cardiac anatomy

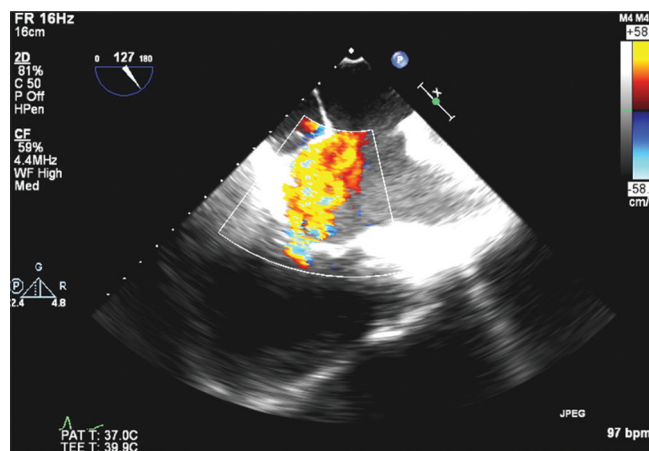


Figure 4: Transesophageal modified bicaval view showing tricuspid regurgitation

Standard sterile surgical prep and drape was performed, and a left infraaxillary 2 inch incision was made, carried down through the subcutaneous tissue and the pectoralis fascia opened. The pectoralis muscle was opened in line of the fibers and pectoralis minor muscle was partially divided. Dissection was carried down, and the left axillary artery was identified and proximal and distal control of the artery was obtained with vessel loops. The branches of the brachial plexus were identified and preserved. Because of concerns for heparin-induced thrombocytopenia, he was anticoagulated with a loading dose of 50 mg and an infusion of 1.75 mg/kg/h of bivalirudin. Once the prolongation of the activated clotting time was achieved, the vessel loops were adjusted to gain proximal and distal control. The axillary artery was incised and subsequently beveled end-to-side anastomosis of an 8 mm Dacron graft was performed with a 5-0 prolene suture and reinforced with biological glue and air evacuated from the graft and vessel.

In addition, a subcutaneous tunnel was prepared from the incision to the anterior axillary line just inferior to the left nipple line to allow us subsequently to tunnel the IMP left assist device once it had been appropriately placed.

Subsequently, through the 8 mm graft and under fluoroscopic guidance, a wire was placed across the aortic valve, then an exchange catheter was passed over the wire, and an Amplatz Extra-Stiff wire were placed through the exchange catheter into the LV after appropriately shaping the wire tip to prevent ventricular injury.

Afterward, the IMP 5.0 was introduced over the Extra-Stiff wire. Unfortunately, the 21 Fr diameter of the 5.0 catheter was too large for the patient's native vessels. The wire and the device were removed, and a 14 Fr tear-away sheath was inserted into the 8 mm graft using Seldinger technique over a wire positioned through the side of the graft. This 14 Fr sheath was then introduced through the graft across the axillary anastomosis. The wire was then positioned appropriately across the aortic valve using fluoroscopic and echocardiographic guidance and an exchange catheter.

Once this was completed, the IMP CP was advanced through the 14 Fr catheter tear-away sheath across the anastomosis and ultimately positioned properly into the patient's RV (systemic) and the device was deaired [Figure 5].

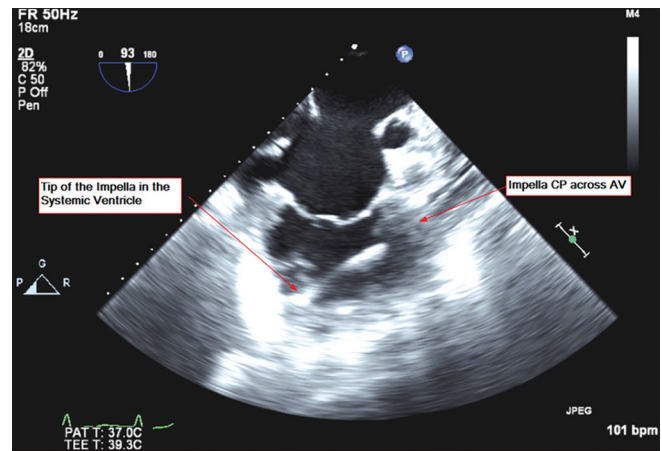


Figure 5: Transesophageal modified long axis view depicting impella final placement

Appropriate positioning was then confirmed between fluoroscopic, echocardiographic guidance, and pressure gradient difference recorded on the device console.

The IMP CP and sheath were secured over the insertion sheath after drawing the device and 8 mm Dacron graft through the subcutaneous tunnel to allow the graft to exit inferio-lateral to the left nipple in the left anterior axillary line and secured.

The IMP was initiated and ultimately was run at 3.3 L/min of flow. At the end of the procedure, the patient was taken back to the Intensive Care Unit hemodynamically stable with the dobutamine and milrinone support weaned, the IABP at 1 to 2 and the IMP running at 3.3 L/min, intubated aiming for slow wean and extubation.

He continued to demonstrate significant hemodynamic improvement in the immediate postoperative period with progressive normalization of the SVO_2 , creatinine, and lactate levels.

Twenty-four hours following IMP placement he underwent successful orthotopic heart transplantation at our center had an uneventful intraoperative and postoperative course and twenty days later, he was discharged home in stable condition.

DISCUSSION AND REVIEW OF THE LITERATURE

As the RV serves as the systemic circulation in patients undergoing Mustard procedure, it is not uncommon for these patients to have systemic ventricular failure requiring transplantation.^[1,22,23] If cardiac function deteriorates rapidly before a donor heart is available,

the use of a ventricular assist device may be the only suitable remaining option.

Three case reports in the literature describe the implantation of left ventricular assist devices through sternotomies and on cardiopulmonary bypass in patients with transposition of the great vessels after surgical repair, two of them favored heart mate^[24,25] and the third one selected a as bridge to orthotopic heart transplant. The need for assist devices in this population could be a surgical challenge. The morphology of the anatomic RV is characterized by intense trabeculations, papillary muscles, and moderator band all of which make the insertion of a left ventricular assist device inflow cannula more difficult than in an anatomic LV, the placement of the device in the upper right abdomen could also be problematic with risk of liver compression,^[24] the aorta is anterior to the pulmonary artery and the graft has to communicate with the ascending aorta bringing the graft right under the sternum that would also complicate a re-operation.^[23]

An IMP is a suitable option for short-term cardiac support in anticipation of cardiac transplantation. IMP placement doesn't require sternotomy, thoracotomy, or cardiopulmonary bypass, thus minimizing the complexity and cost with documented safety.^[21] Only one case was reported in the literature by Fishberger *et al.*, of a successful use of and IMP LP 2.5 placed percutaneously through the right femoral artery during ablation of intra-arterial reentrant tachycardia in an adult with a Mustard baffle for transposition of the great arteries to provide hemodynamic stability that was removed right after the procedure.^[26]

In this case, the patient required support with two inotropes and IABP without improvement of his status. A multidisciplinary discussion concluded that an improved mechanical support with the placement of an IMP would provide an additional circulatory support and help correct the multi-organ failure.

Placement of an IMP 5.0 was technically challenging, and thus the smaller size IMP CP was successfully inserted. This device, the newest member of the family, develops 3.5 L/min of flow rate with a motor housing size of 14 Fr.^[14,27] Its use was just reported once in the literature by Chan and Seidelin who placed it to assist in a high-risk percutaneous coronary intervention.^[28]

In our case, a multidisciplinary approach led to a successful outcome in this individual as the device displayed a great performance, showing immediate improvement of the hemodynamics and soon after also correcting the signs of the end organ hypoperfusion, making the IMP CP an appropriate tool to stabilize and optimize patients with decompensated heart failure^[27] waiting for heart transplant. A suitable heart became available to him the following day.

Anesthetic approach to these cases can be challenging owing to the unique pathophysiology of these patients,^[29] type of procedure, ongoing comorbidities,^[30] and the location in the Cath Lab. There is no evidence-based guidance for anesthetic management of patients with coronary heart disease, and there is no sole anesthetic technique to manage these patients.^[31] Anesthesiologists taking care of patients postASP should be familiar and prepared to address the risks and complications that can affect their anesthetic management, including sinus node dysfunction, atrial arrhythmias, baffle stenosis and thrombosis, pulmonary hypertension, tricuspid valve regurgitation, and right ventricular failure.^[6,29,30] Arterial and venous access may be challenging due to scarring, stenosis and obstruction,^[31,32] pulmonary artery catheters, and pacemakers may be difficult or impossible to place due to the complex anatomy^[31] and may require external pacing and defibrillation, intra and postoperative hemorrhage with the need of available blood products^[29] what warrant invasive monitoring with arterial-access, central venous pressure as well as transesophageal echocardiography to allow direct visualization of the anomalous anatomy and guide and confirm correct IMP placement. On the other hand, procedures performed in the Cath Lab have their own anesthetic implications, including being an isolated and cramped environment, with many distractions, staff unfamiliar with general anesthesia, limited access to the airway due to the C-arm of the fluoroscopy, need of extended ventilation circuit, pressure lines, IV tubing, and risk of dislocation with the manipulation of the C-arm.^[33]

Although our case demonstrates the advantages of the left axillary approach to place the IMP 3.5 and the successful application of this device to improve the status of our patient with transposition of great vessels in decompensated systemic ventricular failure, further experience is needed in the utilization of this specific device and other axial flow assist devices in the setting of heart failure in patients with congenital heart disease.

CONCLUSION

The transaxillary approach to place an IMP assist device can be expeditiously used to achieve adequate temporary mechanical support in high risk, even unstable patients, this case, being an illustrative example of insertion of the device in the systemic ventricle of a patient with dextro-transposition of the great arteries (DTGA) status postMustard procedure in decompensated heart failure. A multidisciplinary team approach and discussion led to the successful operation and outcome for the patient. Given the increasing use and more widespread availability of percutaneous VAD's in Cath Labs worldwide, cardiovascular anesthesiologists can expect to see more critically ill patients being supported temporarily with these, either as bridges to recovery, transplantation, revascularization, or long-term device therapy. Choice of the percutaneous device can be difficult and varies by the clinical situation as well as operator familiarity. In acute situations, the IABP is the device most widely available worldwide and has the advantages of familiarity and reduction of myocardial oxygen demand but does not reduce the need for concomitant vasopressor/inotropic support. There have been recent publications assessing its efficacy in acute settings.^[34] The IMP does have the innate advantage of improving systemic perfusion and lower the need for simultaneous pharmacologic support. The choice of more than one pump option with this device (2.5 and above) is another advantage that can be used based on the severity of hemodynamic instability. Complete collapse usually mandates the need for more definitive longer term support as the case may be.

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Conflicts of interest

There are no conflicts of interest.

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