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Review Article

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Our Center Experience in Impella Insertion Through Axillary Artery Via Vascular Graft

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Abbreviation

Left ventricle (LV), Cardiogenic **shock** (**CS**), mechanical circulatory support (**MCS**), acute myocardial infarction (**AMI**), coronary artery bypass grafting (**CABG**) and percutaneous coronary intervention (**PCI**), left ventricular assist device (**LVAD**), percutaneous LVAD (**pLVAD**), activated clotting time (**ACT**), post-cardiotomy cardiogenic shock (**PCCS**), transesophagal echocardiography (**TEE**), VenoArterial Extracorporeal Life Support (**VA-ECLS**), peripheral ECLS (**ECMELLA**), left ventricular (**LV**), intra-aortic balloon counter pulsation (**IABP**).

Background

A Journey from Ancient ***Greece*** and ***Egypt*** to develop the mechanism of Impella Device pumps blood directly from the left ventricle (**LV**) to the aorta is based on a machine developed by the Greek mathematician Archimedes (282–212 BC) while he was living in Alexandria, Egypt. This machine, known as Archimedes' screw which is a type of pump used for raising water up. The screw is a helical surface surrounding a central cylindrical shaft and is placed inside a hollow tube. The screw used to lift water up [1].

Introduction

Cardiogenic shock (CS) is a leading cause of the death among hospitalized patients, and has a greater than 50% mortality rate. A wide variety of mechanical circulatory support (**MCS**) devices have been utilized to manage those cases [2].

CS is characterized by inadequate tissue perfusion due to cardiac dysfunction due to acute myocardial infarction (**AMI**). Mortality from CS still remains exceedingly high, and reaches 50% - 80% in those treated conservatively. Early revascularization by coronary artery bypass grafting (**CABG**) and percutaneous coronary intervention (PCI) is the cornerstone treatment of **AMI** complicated by **CS** [3].

The left ventricular assist device Impella 5.0 (Abiomed Inc, Danvers, MA) has become widely accepted as a temporary mechanical circulatory support (**MCS**) for patients in cardiogenic shock (**CS**) [4].

Mechanical circulatory support (**MCS**) devices have been increasingly used in this setting for hemodynamic support. The Impella device (*Abiomed Inc, Danvers, MA*) is a microaxial left ventricular assist device (**LVAD**) that can be inserted using a less invasive technique, and called percutaneous **LVAD** (**pLVAD**). It can be initiated quickly and do not necessarily require a sternotomy. The Impella devices are designed to directly unload the LV and reduce myocardial workload and oxygen consumption while increasing cardiac output and coronary and end-organ perfusion [5].

The Impella 5.0 (Abiomed Inc, Danvers, MA) is placed through an anastomosed graft. It is usually placed through a graft surgically sewn to the right axillary artery. It has especially become widely accepted as a temporary **LVAD** for patients in cardiogenic shock owing to its sufficient flow support and durability. Previous studies have shown that the use of Impella as a bridge to bridge or bridge to cure [4].

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An activated clotting time (**ACT**) of between 250 and 500 seconds is required during Impella pump insertion intraoperatively. After the pump is inserted and positioned, **ACT** of between 160 and 180 seconds is required to prevent clot formation in the motor. A continuous intravenous infusion of heparin is recommended on postoperative day 1 to achieve a partial thromboplastin time of between 40 and 50 seconds when the chest tube drainage decreases to less than 50 mL/h.

The **indication** for placement of the Impella device included post-cardiotomy cardiogenic shock (**PCCS**), acute myocardial infarction complicated with cardiogenic shock in, acute decompensated ischemic cardiomyopathy, and myocarditis with cardiogenic shock [3].

Right ventricular dysfunction or failure after the placement of LVAD is well known. Medical management of this entity is often ineffective. Mechanical circulatory support options may be invasive. We describe the novel use of a microaxial ventricular assist device for right ventricular support after LVAD placement [6].

As a ventricular unloading catheter, the Impella Recover LP 5.0 (*Abiomed, Danvers, MA*) is appropriate for temporary circulatory assistance in severe left ventricular dysfunction. Axillary implantation through a graft interposition has been previously described for ambulatory intra-aortic balloon pump use, allowing increasing patient rehabilitation. That new implantation approach to the right axillary artery aims of avoiding vascular problems due to atherosclerosis of the peripheral arteries and improving patient mobility and rehabilitation during mechanical support [7].

Numerous reports have appeared in the literature attesting to the safety and efficacy of the Impella device. As our group gained experience with the Impella for left heart support we considered its use on the right side. It was our belief that the same benefits could be achieved on the right. When we considered the anatomic constraints of placement, it was clear that peripheral insertion (*femoral vein*) would not be possible. The Impella Recover LP 5.0 (*Abiomed*) is a miniaturized rotary blood pump (**21 French**). The pump incorporates a rotor driven by an electric motor with an inflow tip. The pump is placed through the aortic valve and aspirates blood from the left ventricle cavity and expels the blood into the ascending aorta [8].

Patient and Methods

Most of patients had medical history of hypertension, hyperlipidemia, peripheral vascular disease, atrial fibrillation and coronary stenting in the past. The patient had presented with symptoms and signs of heart failure with reduced ejection fraction not responses to maximized medical medication. Echocardiography performed in the office revealed a dilated, severely impaired left ventricle, reduction of right ventricular function, global hypokinesia, pulmonary hypertension, and moderate mitral and tricuspid regurgitation. In some cases, there were three cases with mitral clip and five cases with previously biological mitral valve replacement.

Under general anesthesia and heparinization (*1 mg/kg*), the right axillary artery is exposed below the clavicle. An *8-mm* vascular graft is sutured end-to-side and clamped closed to the anastomosis. A guidewire is introduced in the device through a specific lumen to the distal pigtail. The device is then introduced into the graft, and an occluding plug around the *9-French* driving cable is tied to prevent blood loss through the graft during the implantation maneuvers. The occluding plug allows the driving of the cable and sliding of the guidewire. The clamp is removed. The guidewire is introduced into the axillary artery to the **LV** cavity, crossing the aortic valve, under fluoroscopic guidance or transesophagal echocardiography (**TEE**). After the guidewire is introduced, the device is then progressively pushed into the graft and introduced into the axillary artery to **LV** cavity. The correct position of the device is confirmed by fluoroscopy or **TTE** and the pressure signal at the console. The guidewire is then removed. The device is turned on. The graft around the cable is tied, closed to the anastomosis, cut off 1 cm farther, and removed as the occluding plug. The cable sheath is pushed into the remaining graft to the ties to complete hemostasis. The sheath is blocked distally and fixed at the skin to secure the driving cable and pump into position. The surgical approach is closed and the driving cable with the sheath is allowed to exit from the subclavicular axillary wound. To remove the device, the same approach is used. Only the remaining graft is controlled; the ties around are removed and the device is gently pulled back and out. The graft removed and axillary artery repaired then the surgical approach is closed. Distal pulsation was confirmed by Doppler and saturation probe.

During removal of the Impella 5.0, dislodgement and embolism of these blood clots can lead to extremity ischemia and may require embolectomy. To prevent this complication when removing the device, we have developed a simple, inexpensive, and effective surgical technique as a setup when implanting the Impella 5.0. When reopening the wound for removing the Impella 5.0, adhesions or hematoma can sometimes make it complicated to distinguish the surrounding anatomic structures, such as the axillary nerve or vein. The wound is well irrigated. Before removing the Impella 5.0, a regular tourniquet is passed through the vessel loop. First, the distal tourniquet is cinched down to "snare" and occludes the distal axillary artery. Then, the Impella 5.0 is removed through the graft. The graft is well flushed to remove any major clots. Then, the graft is clamped with a Satinsky clamp and trimmed short. The graft stamp is oversewn for hemostasis. Finally, the distal vessel loops are removed. The wound is closed after confirming the radial artery Doppler pulse.

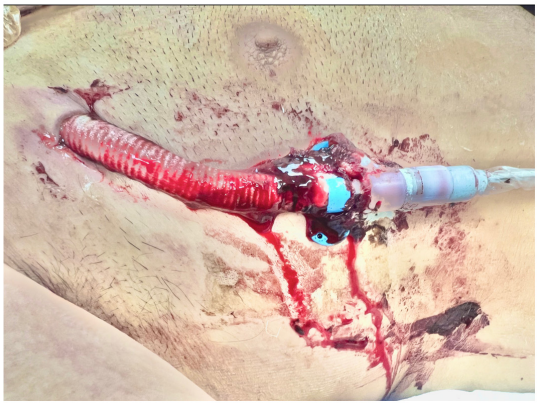

Figure 1: EMPILA connected via vascular graft to axillary artery

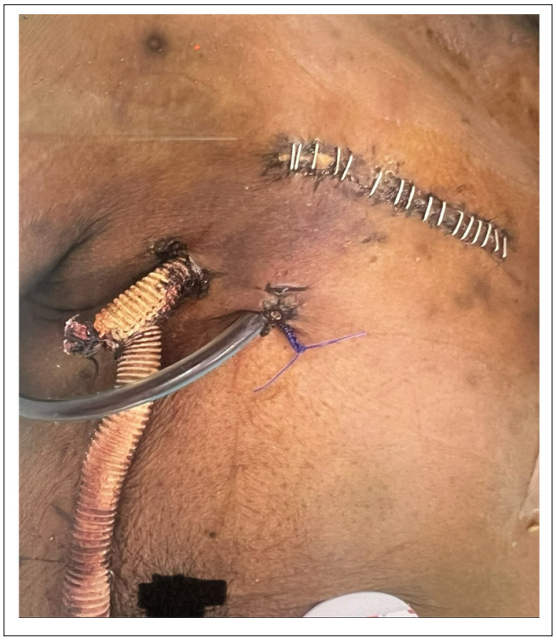

Figure 2: axillary vascular graft connected with EMPILA and another arm cut after ECMO weaning

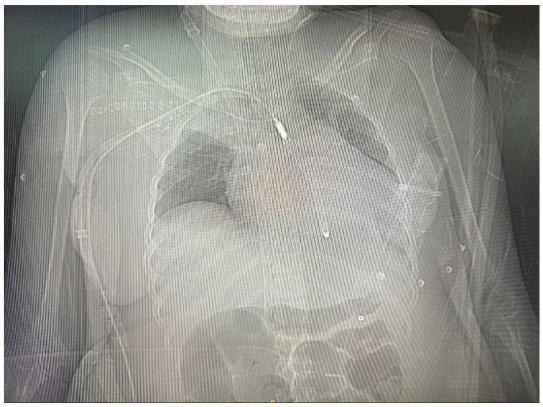

Figure 3: CXR is showing EMPILLA inserted through axillary artery with vascular graft

Also we used a combination of the Impella 5.0/5.5 (*Abiomed Inc, Danvers, MA*) and peripheral **ECLS** (**ECMELLA**) using a single arterial access in three cases. The arterial cannula was inserted through the same axillary artery interposition graft.

The weaning protocol consists of monitoring of hemodynamic and laboratory values. Once the patients have been appropriately weaned from inotropes and vasopressors and maintain stable vital signs, they then undergo assessment by transesophageal echocardiogram (**TEE**). Weaning is initiated in a stepwise fashion by decreasing the pump performance in decrements of 2 levels and then assessing the patient for 2 hours. Once the performance level of the device is reduced to level P1 (P1 = no forward flow) for 2 hours and recovery of **LV** function is achieved, the device is removed in the operating room in the presence of **TEE** probe and heart function is assessed in the operating room. If there is recovery of the **LV**, the Impella is removed. The pump is retracted into the vascular graft.

Result

We used axillary approach for Impella and **ECMELLA** in thirty cases. Most of cases had peripheral vascular diseases, systemic lupus erythromatousus, and amputated limb. We faced oozing a lot from interposition graft at intensive care unit under complete aseptic condition. Easily removal of interposition graft during weaning from Impella or **ECMELLA**. We faced two case with hematoma at axillary site needed re-exploration and drainage. We had one case of mortality due to septicemia. Later on, **LVAD** inserted through left thoracotomy approach. The result in our study demonstrates that the use of axillary approach for Impella device in patients with **CS** especially associated with peripheral vascular diseases. The axillary interposition approach has less blood loss, easily mobilization, easily removal, avoiding vascular lower limb complications. Finally, the results from our study demonstrate that the Impella device is effective improving survival in patients in cardiogenic shock.

Discussion

The operative mortality and complication rate was acceptable in these critically ill patients with **CS**. Implantation of **VADs** and Impella device can assist or completely supplement the patient's own cardiac output may support the patients until the stunned myocardium recovers (bridge to recovery) [5]. We inserted Impella as a bridge or recovery in cases of CS in our centers as a mechanical support with decreasing mortality rate and increasing survival.

The axillary approach for Impella LP 5.0 implantation is advantageous to avoid the problem of peripheral vascular access in patients with atherosclerosis. It allows early mobilization of the patient during the mechanical support. In post-cardiotomy low-output syndrome, this approach has to be considered to avoid resternotomy to remove the device [3]. We used axillary approach in cases of peripheral vascular disease with early ambulation.

Veno-Arterial Extracorporeal Life Support (VA-ECLS) with a peripheral vascular access represents a universal, fast, and very powerful tool. However, **VA-ECLS** increases left ventricular (**LV**) afterload with the subsequent risk of LV dilatation and **LV** stasis, eventually resulting in pulmonary edema. A persistently increased **LV** end-diastolic pressure with incomplete **LV** unloading inhibits myocardial recovery. Unloading the **LV** with a microaxial blood pump (*Impella, Abiomed Inc, Danvers, MA*) appears to be safe in patients on **VA-ECLS** and may be associated with improved outcomes compared with **VA-ECLS** support alone. A combination of the Impella 5.0/5.5 (*Abiomed Inc, Danvers, MA*) and peripheral **ECLS** (**ECMELLA**) using an axillary approach [6].

There is increased risk for vascular **complications** during removal of the Impella 5. One major complication is a distal extremity embolism, which can lead to ischemia [2].

Peri-graft seroma is a known complication of arterial artificial prosthesis of an Impella RD RVAD (Impella Cardiosystems GmbH) observed after implantation because of a cardiac graft failure. At this time the patient was still dependent on the device. So, bovine pericardial patch wrapped the entire prosthesis with a sutured with Prolene 5-0 and tightly (proximally and distally) as well as approximately every centimeter around the prosthesis with Mersilene or silk ligatures. The cavity between the patch

and the PTFE prosthesis was filled with fibrin glue [9].
The most common complication of axillary approach is oozing needed repeating dressing under complete aseptic condition.

Conclusion

The technique with single arterial approach for **Impella** or **ECMELLA** avoids peripheral vascular complications, encourage early mobilization, and help reduce the complications of multiple device therapy for the treatment of cardiogenic shock.

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