ORIGINAL RESEARCH

Use of the Impella device in ambulatory heart failure and pre-heart transplant patients – one medical center's experience

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ABSTRACT

Background and objective: The prevalence of heart failure (HF) in the US has increased over several years. The American Heart Association (AHA) documents that HF has a prevalence of 6 million cases among Americans aged 20 years and older. HF is a complex syndrome that results from the structural or functional impairment of ventricular filling or ejection of blood, leading to symptoms including poor exercise tolerance, shortness of breath, and signs of HF such as edema and rales. The aim of the study was to add to the knowledge base from one medical center's experience using Impella device in ambulatory heart failure and pre-heart transplant patients.
Results: The axillary Impella enables HF patients to ambulate inside the CICU while waiting for destination therapy. RNs in our medical center's CICU can take care of these patients effectively and competently because of extensive prior experiences with the AxIABP. Nursing staff have adapted existing nursing procedures, protocols, and lessons learned from experiences with the AxIABP to manage this new patient population.
Discussion: Impella is one treatment option in advanced HF and pre-heart transplant patients. The development of an alternative insertion technique that allows patients to ambulate instead of being on bedrest continues to evolve. Our medical center's experiences with taking care of ambulatory HF and pre-heart transplant Impella patients have shown that this is a safe and effective treatment.

Key Words: Impella, Heart Failure, Ambulatory with Impella, Impella pre heart transplant

1. INTRODUCTION

The prevalence of heart failure (HF) in the US has increased over several years. The American Heart Association (AHA) documents that HF has a prevalence of 6 million cases among Americans aged 20 years and older.[1] HF is a complex syndrome that results from the structural or functional impairment of ventricular filling or ejection of blood, leading to symptoms including poor exercise tolerance, shortness of breath, and signs of HF such as edema and rales.[2]

Early in the course of the disease, HF patients are managed via guideline-directed medical therapy (GDMT). The GDMT regimen purports to improve survival and reduce adverse cardiovascular events, including HF exacerbations and hospitalizations. GDMT pharmacologic therapies such as diuretics, phosphodiesterase inhibitors (milrinone), and adrenergic agonists (dobutamine and dopamine) aim to improve contractility and forward flow of arterial blood to enhance the delivery of oxygen to tissues and organs. As the

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patient's ventricular function continues to deteriorate, however, they become more dependent and less responsive to GDMT.[3] As this occurs, the treatment options include either heart transplantation or left ventricular assist device (LVAD) implantation. The evaluation process for these destination therapies can be very lengthy; patients on the heart transplant list can wait 40 days or longer for a donor heart to become available.[4] Patients may be placed on a temporary mechanical circulatory support device while waiting for a decision on destination therapy.

2. MECHANICAL CIRCULATORY SUPPORT DEVICES

The use of short-term mechanical circulatory support (MCS) devices serves multiple roles in treating HF cardiogenic shock. Several categories of these devices exist, including intra-aortic balloon pumps (IABP), extracorporeal membrane oxygenator pumps, non-percutaneous centrifugal pumps, and non-IABP percutaneous mechanical circulatory assist devices. These devices can be further classified according to circuit configurations: 1) pumping from the right atrium (RA) or central vein to a systemic artery; 2) pumping from the left atrium (LA) to a systemic artery; or 3) pumping from the LV to a systemic artery (generally the aorta). The Impella Ventricular Support System (Impella) is one of these such latter devices.[5]

The first successful use of the IABP was reported in 1967 by Dr. Adrian Kantrowitz at Maimonides Medical Center in Brooklyn, NY, for the treatment of a patient with cardiogenic shock.[6] This technique was quickly accepted as a treatment modality for cardiogenic shock as well as for refractory angina, and its insertion quickly evolved from surgical cutdown insertion to percutaneous insertion.[7] Despite the IABP's ability to augment coronary perfusion, overall myocardial ischemic improvements were limited. Moreover, the IABP is not a forward flow pump and is instead a volume displacement device; therefore, any improvement in forward flow is accomplished by the native heart itself. Over subsequent years, with several studies suggesting unclear results regarding the IABP, attention turned to other devices, including the Impella. The Impella evolved from initial cardiopulmonary support systems introduced in the 1970s and is the latest iteration of MCS devices over the last 50 years.[8] The Impella has been in use in the USA since 2006.[9]

2.1 Impella and how it works

The Impella design is based on a miniaturized axial pump that allows for blood to be aspirated from the left ventricle into the cannula portion of the pump, then expelled into the ascending aorta (see Figure 1). There are several models with varying sizes and maximal flow capabilities, including several models for left ventricular support and the Impella RP for right ventricular support. There are three physiological mechanisms through which the left ventricular devices provide support: 1) the Impella unloads the left ventricle, reducing LV end-diastolic pressure and LV wall tension and, consequently, decreasing LV work and myocardial oxygen demand; 2) the Impella operation results in an increase in mean arterial pressure (MAP), diastolic pressure, cardiac output leading to improved systemic perfusion, and increased coronary flow; and 3) the Impella leads to a decrease in pulmonary capillary pressure and a secondary reduction in right ventricular afterload.[10]

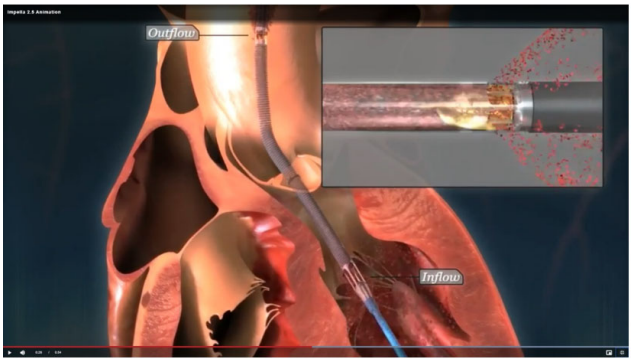


Figure 1. Impella Inflow and Outflow

The blood from the left ventricle (LV) is drawn into the inflow port of the Impella and pumped to the outflow port into the aorta. This decreases blood volume strain on the LV. The coronary arteries ostia located at the base of the aorta above the aortic valve benefits from the increased blood flow, thereby increasing coronary arteries perfusion. (Image taken from Impella video).

The Impella is an axial flow pump, with some versions capable of pumping up to 5 L/minute of blood from the left ventricle, across the aortic valve, and into the aorta. The cannula portion of the device sits across the aortic valve, and the catheter is powered by the Automated Impella Controller (AIC). A purge system is also incorporated into the device, keeping blood from entering the motor compartment via a pressure barrier. The Impella does not require synchronization with ventricular activity to function properly; therefore, there is no need for EKG or pressure triggering, both of which deteriorate with clinical worsening, seen with the IABP.

Unlike the IABP, the Impella is load dependent rather than rhythm dependent, which leads to several physiologic and bedside ramifications. The device is afterload sensitive as well as preload sensitive. Afterload sensitivity affects forward flow such that with increasing ventriculo-aortic pressure gradients, forward flow through the pump decreases – this

characteristic is readily appreciated on the AIC as the phasic motor current fluctuations seen with the cardiac cycle, with the highest flow occurring during systole when the gradient between the left ventricle and the aorta is minimal. Pump flow is also preload dependent, as it needs enough volume/inflow for normal pump output. This preload dependence is particularly evident in right ventricular dysfunction, and when severe, the insertion of a right ventricular Impella device can also be entertained.

The Impella device fulfills three fundamental criteria for mechanical cardiac assist devices: (1) relatively easy placement and simplicity of use, (2) systemic hemodynamic support by increasing net cardiac output, and (3) providing myocardial protection by reducing oxygen demand and increasing oxygen supply. The Impella simultaneously provides systemic hemodynamic support and myocardial protection as blood flow is to the aortic root across the aortic valve, providing further blood flow to both the systemic and coronary circulations. The Impella also reduces left ventricular end-diastolic volume and pressure, which leads to a reduction in left ventricular mechanical work and myocardial wall tension. This, along with increased coronary flow, leads to increased myocardial oxygen supply and improves the ability of the cardiac muscle to survive acute and chronic ischemic challenges.[11] Originally indicated for short-term (less than six days) support in cardiogenic shock and high-risk percutaneous coronary intervention patients, the use of the Impella has expanded and is now being used to support pre-LVAD and pre-heart transplant HF patients in our medical center.

2.2 Impella placement

The conventional placement of the Impella device is via the femoral artery. An alternative insertion occurs via the axillary artery, which is used in our medical center and other institutions.[12,13] Currently, our medical center has treated more than 150 axillary Impella patients for whom the device was inserted for advanced HF and as a bridge to heart transplantation or LVAD.

Both the axillary Impella and axillary intraaortic balloon pump (AxIABP) are available therapy for HF patients at our medical center, allowing for patient mobility and ambulation. The advanced heart failure cardiologists determine the type of therapy for each particular patient.

If the device is inserted via the femoral artery, the patient is admitted to the Intensive Care Unit (ICU) and is placed on mandatory bed rest. Given the protracted wait time for determining destination therapy LVAD placement or heart transplantation, complications arising from bed rest and limited mobility can occur when the advanced HF patient has a femoral artery implanted device. Bedrest has a widespread deconditioning effect on multiple organs and body systems.[14] For example, patients can lose up to 30% of their muscle mass within ten days of ICU admission due to bedrest, hence the use in the axillary artery.[15]

3. AXILLARY IMPELLA INSERTION AND MEDICAL MANAGEMENT

The axillary Impella insertion is done by transplant surgeons in the operating room. A sleeve is inserted into the subclavian artery and ascending aorta and secured with sutures at the insertion site, usually exiting on the right subclavian area. The Impella is inserted through this sleeve and is guided to the aorta, through the aortic valve into the left ventricle. Proper positioning is determined primarily by intraoperative transesophageal echocardiogram.[16]

A multidisciplinary team consisting of the HF cardiologists and the Coronary Intensive Care Unit (CICU) team, made up of medical intensivists, registered nurses (RNs), clinical pharmacists, respiratory therapists, physical therapists, dietitians, case managers, and social workers, manage the patient during their admission. Multiple specialties are also involved in the pre-transplant evaluation, such as pulmonology, nephrology, infectious diseases, psychiatry, palliative care, and our ethics service. These services assess the patient's qualification for an LVAD or heart transplant. A separate multidisciplinary transplant review board determines the candidacy of each patient and the therapy that best suits their needs and situation, whether it is destination therapy LVAD implantation or heart transplantation.

3.1 Diagnostic tests

Chest X-rays (CXRs) are ordered daily, primarily to assess lung fluid status. Given that CXRs cannot clearly articulate Impella position and placement, the utility of daily CXRs warrants further exploration.

Routine laboratory tests such as complete blood count and metabolic panels are performed every other day to minimize blood loss, limit ICU-related anemia, and limit the need for blood transfusion. This is especially important for patients pending heart transplant, given the need to decrease the incidence of antibody formation.[17] Lactic dehydrogenase (LDH) levels are monitored as an early indicator for both hemolysis and suspected clotting of the Impella motor. Partial thromboplastin time (aPTT) tests are performed according to the pharmacy heparin protocol.

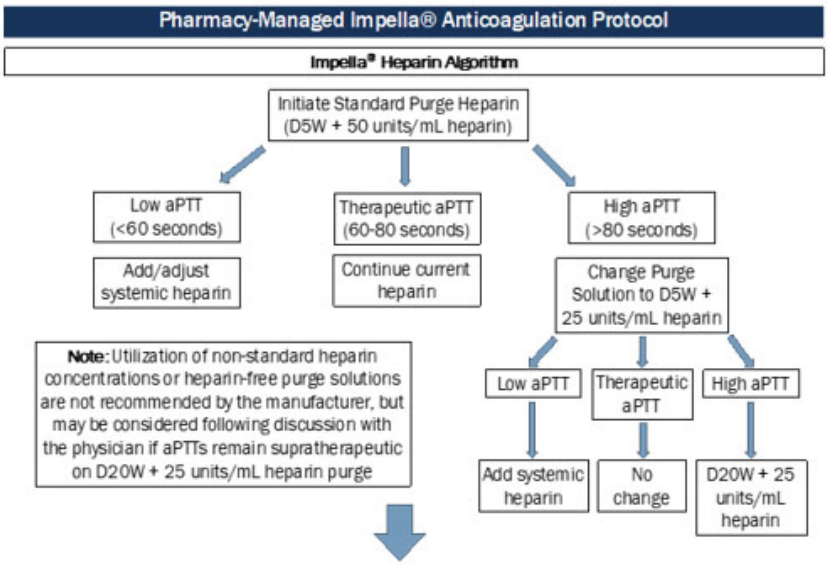
When there is a question about Impella placement, or a need to adjust the position or device speed, an echocardiogram is performed, and, when possible, changes are made in real-

time. Other diagnostic tests are performed as needed.

4. Pharmacological anticoagulation management

4.1 Heparin

Due to the risk of thrombotic complications, anticoagulation is required during Impella support. Anticoagulation is provided through a heparinized purge solution (heparin 25000 units in 500 mL Dextrose 5%-40%) that flows in the opposite direction of the patient's blood, thus, preventing blood from entering the Impella motor. The flow rates of the purge solution are automatically adjusted by the Impella device through a built-in pressure sensor and fluctuate between 2-30 mL/hr. The manufacturer recommends targeting an activated clotting time (ACT) goal of 160-180 seconds but does not provide guidance on how to achieve this goal. 16 At this medical center, a pharmacy-managed Impella anticoagulation protocol is used to guide anticoagulation. The protocol considers the heparin delivered through the purge solution and provides instructions on titration of supplemental non-purge heparin and adjustments to the purge dextrose concentration to achieve an aPTT goal of 60-80 seconds. An aPTT is obtained every 4 hours initially, and once stable, monitoring can be extended to every 24 hours (see Figure 2).



aPTT (seconds)	Hold Heparin	Rate Change	
Less than 39	None	Increase by 3 units/kg =	units/kg
40-49	None	Increase by 2 unit/kg =	units/kg
50-59	None	Increase by 1 unit/kg =	units/kg
60-80	**None**	**No change**	
81-90	None	Decrease by 1 unit/kg =	units/kg
91-110	30 minutes	Decrease by 2 unit/kg =	units/kg
111-120	1 hour	Decrease by 3 units/kg =	units/kg
Greater than 120	Stop heparin infusion and notify physician		

Figure 2. Pharmacy Managed Impella Heparin Protocol

aPTT = activated partial thromboplastin time, ABW = actual body weight, IBW = ideal body weight, DW = dosing weight

4.2 Tissue plasminogen activator

Despite anticoagulation, the risk of device thrombosis still exists and is usually diagnosed by the presence of low purge flow rates, elevated purge pressures, and markers of hemolysis. Data on the management of suspected Impella thrombosis are limited to a few case reports describing the use of tissue plasminogen activator (tPA) in the purge solution. Sorensen and colleagues reported the resolution of elevated purge pressures using tPA at a catheter-clearing dose of 2 mg in 50 mL normal saline running through the purge solution.[18] Similarly, Oetken and colleagues utilized tPA (4 mg in 100 mL dextrose 5% sterile water) in the Impella purge solution, which resulted in increased purge flow rates and decreased purge pressures.[19] Mixing tPA in sterile water

is preferred as the manufacturer recommends against the use of normal saline in the device. In a recent case series, five patients with suspected thrombosis of their Impella 5.0 device had their anticoagulation solution switched to tPA at concentrations of 0.04 or 0.08 mg/mL in sterile water, allowing for resolution of high purge pressures and low purge flow rates and delaying or preventing the need for device exchange.[20] In all cases, no major bleeding events were directly associated with tPA administration.

4.3 Other pharmacological support

Optimization of pharmacotherapy is also required in this patient population. Vasopressor and inotropic support may be utilized in conjunction with the Impella device to help support cardiac function and unloading of the right and left ventricles. Similarly, optimization of volume status is required, and patients are maintained on furosemide or receive renal replacement therapy.[21]

5. Nursing management

This medical center's CICU has extensive experience (> 200 patients) with ambulatory axillary IABPs (AxIABP); consequently, the nursing care and management of AxIABP and axillary Impella patients are very similar.[22]

5.1 Initial assessment and management

A complete and thorough nursing assessment is done upon admission to the CICU. Vital signs are recorded until the patient is deemed stable, which is generally defined as having minimal fluctuations in heart rate and blood pressure, being awake and alert, and having no bleeding from the insertion site.

Initial Impella purge pressures, purge flows, motor current, placement, and power are recorded in the electronic medical record (EMR). The right subclavian insertion site dressing is inspected for bleeding. Baseline catheter measurement markings at the insertion site are recorded in the EMR. Electrocardiogram, echocardiogram, CXR, and laboratory tests are done upon admission to establish baseline values.

Patients receive directions to avoid raising their right arm above shoulder height and to communicate with the RN in the event of bleeding at the insertion site. Switching heparin purge connections to maintenance mode with the corresponding air filter attached inhibits air from entering the purge system.

5.2 Nursing staff training and experience

All CICU nursing staff receive initial training in the maintenance and troubleshooting of the Impella system. In addition, a mandatory annual competency examination and skills return demonstrations ensure that CICU nursing staff maintain current knowledge and skills. Periodic inservices on any device or software updates are provided by representatives from the manufacturer. The increased volume of Impella patients correlates with increased RN confidence and competency due to more hands-on experience with the device and overall familiarity with the system.

5.3 Mobilization

A physical therapist (PT) determines whether patients are ready for mobilization by conducting an initial assessment and the initial ambulation. Patients are considered medically stable if they experience minimal fluctuations in heart rate, blood pressure, and oxygen saturation during the ambulation process. At this point, if the patient is both medically stable and strong, one RN and a mobility technician support the patient in ambulation.

Patients experiencing weakness receive additional ambulation support from an RN, PT, and mobility technician. If the patient's family is available, they may offer more support by pushing a wheelchair behind the patient in the event the patient needs a break from ambulation. Patients ambulate primarily inside the CICU for safety reasons.

To maximize the attention on the patient, ambulation occurs during hours with limited unit activity, such as 11-12 am or between 2-4 pm, to avoid the rush of peak unit activity. If ambulation is postponed to the evening, night shift RNs may also support ambulation. RNs track patient ambulation in the EMR with a chart that calculates distances walked by the patient relative to the hallway distances available.[23]

5.4 Monitoring

A portable transport monitor is used to monitor EKG and vital signs during patient ambulation, while the Impella controller screen displays the parameters needed to walk safely. Patient ambulation is limited to 30 minutes, which falls well within the range of Impella controller modules' battery life of 60 minutes.[16]

5.5 Impella insertion site care

Dressing changes occur every seven days and as needed based according to our medical center's protocol. The central venous catheter dressing kit used by this medical center includes adaptations specific for Impella dressing change. On the rare occasion when a patient requires bedside repositioning, surgeons utilize a nurse-developed AxIABP repositioning kit that includes the materials necessary for the procedure.[22] Afterwards, the Impella is locked at the insertion site and at the distal part of the sleeve. Insertion site markings are noted in the EMR as a reference to whether

the device has migrated. Adhesive devices secure the long, exposed area of the Impella catheter to the patient's torso, upper leg, or hips, minimizing the exposed, dangling portion. A double-strap catheter stabilization adhesive device securely fastens the red Impella plug (see Figure 3). Two daytime RNs change the controller cassette for safety and support reasons in the event problems arise. Cassette changes are performed according to the manufacturers' recommended schedule.

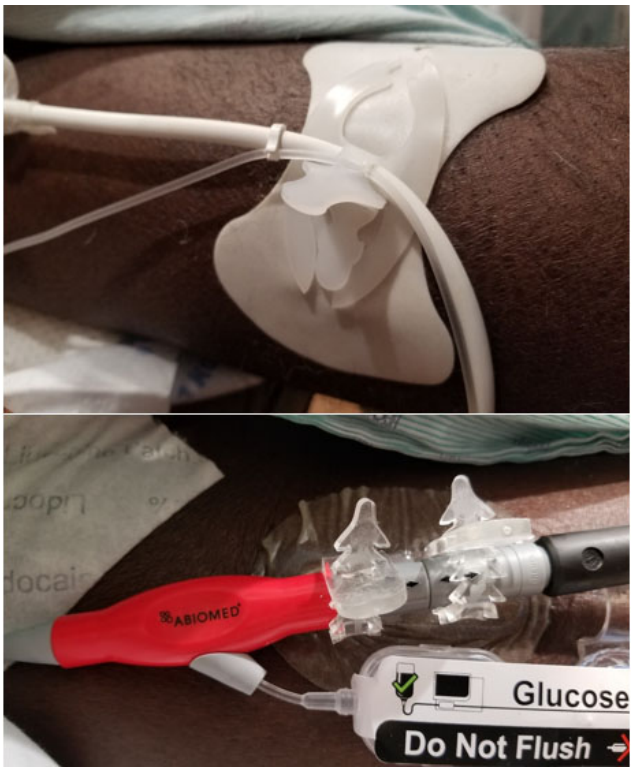


Figure 3. Impella adhesive securement product

5.6 Dietary and fluid management

Impella patients are instructed to follow a low salt, low fat, low cholesterol diet. Because meal variety is often limited due to long wait times at the hospital, home-cooked meals following the prescribed dietary restrictions are accepted. Dietitians oversee the patients' nutritional intake and prescribe high-calorie supplements to those requiring additional calories. Strict intake and output of fluid are mandatory. The combined data from fluid intake and outputs, daily weights, CXRs, and physical examinations dictate diuretic doses. Patients do not use indwelling urinary catheters to prevent urinary tract infections.

5.7 Emotional well-being

While average wait times for pre heart transplant patients vary, some wait times extend beyond forty days and may result in patients experiencing depression and helplessness.[24,25] Psychiatric evaluation is built into the pre-transplant evaluation and may be revisited if patients exhibit severe depression with a need for pharmacological intervention.

Multiple interventions for boosting morale exist. For instance, nursing staff encourage patients to bring photos of loved ones and pets or hang posters of their favorite teams. Families can decorate patient rooms with a personalized touch. Special occasions like birthdays and holidays are often celebrated with patients and families alongside their caretaking staff. External organizations such as Progressive Animal Welfare Society (PAWS) enlist trained and well-behaved dogs overseen by volunteers to visit patients. PAWS additionally evaluates patients' own pets for hospital visits.[26]

If patients consent, they also have the opportunity to visit daily with a chaplain. Patients and their families may engage in weekly prayer and music services in the CICU family lounge. Patients can request visits from music therapists and volunteer music students from a nearby university.

One particularly valuable resource for patients and families includes a stable of volunteers who have undergone a heart transplant and LVAD placement. These volunteers offer their time and personal experiences to support current patients and their families with any questions or concerns they may have with the process. This connection with others who have experienced a positive result of a heart transplant or LVAD helps boost patient morale.

Unit guidelines typically restrict visitation to those who are 13 years old and older, but special circumstances can arise when young mothers need a heart transplant or LVAD placement. In these situations, our unit grants visiting privileges to young children. Otherwise, patients usually use social media conference calls using either personal tablets or computers or hospital-supplied tablets.

5.8 Sleep and rest

Sleep and rest are critical components of patient recovery, and as such, the nursing staff allows patients to experience uninterrupted sleep within safety parameters. To support this uninterrupted rest, laboratory and radiologic tests occur after 8 am.

6. Challenges, problems, and solutions applied

Challenges unique to Impella patients occurred during patient care. See Table 1 for a list of these difficulties and subsequent solutions.

Table 1. Problems encountered with ambulatory Impella patients, and solutions applied to those problems

1. Loss of placement signal	-Occurs in majority of the patients after the Impella has been in place for a long period -Transthoracic echocardiogram (TTE) confirms the proper placement of the Impella. -Proper positioning is made in real time.
2. Crystallization at the connection site of the screwed-on filter and purge tubing preventing the Impella cassette change	-The dextrose/heparin purge solution causes crystallization and the tubing connections over time. -One RN's solution is to wrap the connection with hot washcloth thereby melting the crystals. -Use of forceps sometimes work, but there is a high probability of cracking the connection. -If unable to disconnect after all of the above interventions, the cassette change is postponed.
3. Cracks on the filter and connections	-Change the purge cassette and tubings as necessary.
4. Patient stepping on or laying on and destroying part of the catheter.	-One patient went to the bathroom without calling for assistance and in the process stepped on the dangling part of the Impella catheter. -Another restless patient broke the connection between the catheter and the filter while tossing around in bed. -Both needed emergency Impella replacement surgery.
5. Clotting of the Impella motor	-This is diagnosed when the purge pressures increase, and the purge flow decreases. -There is also an increase in the blood LDH level. -TPa is infused thru the purge system until the clotting is resolved (see pharmacological management section).
6. Impella controller stopping or malfunctioning	-Replacement Impella controllers are readily available for exchange by the perfusion department.
7. Connector cables getting tangled and twisted	-An unavoidable and eventual problem in long term Impella patients. -Since the connector cable cannot be disconnected from the controller according to the Impella representatives, this is left as it is as long as it is not interfering with the Impella function. -One patient's connector cable was so twisted and tangled, the Impella controller had to be taken off the rolling pole and turned until the connector cable was untwisted.
8. Very tiny plastic purge cassette tubing holders (see Figure 2)	-One of the Impella catheter system part that can be improved upon. It is very tedious and time consuming to insert the purge cassette tubing into all the tiny holders thereby preventing or discouraging nurses from utilizing all of the tiny holders to attach the tubing to the connector cable resulting in long hanging loops of tubing.
9. Bleeding and hematoma formation at the Impella insertion site	-Adjusting the systemic heparin flow as per pharmacy protocol. -If this does not work, the heparin purge concentration is changed. -Standard bleeding management- application of pressure dressing and hemostatic agent at the insertion site.
10. Malposition of the Impella catheter	-Repositioning is done at bedside with the use of TTE. - If unable to resolve the Impella malposition at bedside, the patient is taken to the operating room for surgical intervention.
11. Ventricular arrhythmias	-One patient had malposition-induced ventricular arrythmias. -The transplant surgery team simply loosened the lock on the insertion sleeve and twisted the catheter under TTE imaging guidance until the correct Impella position was achieved and the ventricular arrythmias resolved.
12. Very long Impella connector cable and catheter portion from the insertion site to the controller	-This becomes a problem trying to secure the catheter and leave enough slack to allow patient to move freely. -The catheter is looped in an L shape on the front torso and adhesive securing devices are used for attaching to the torso and the upper lateral thigh/leg. (see Figure 2).

7. IMPLICATIONS FOR NURSING

The axillary Impella enables HF patients to ambulate inside the CICU during the wait for destination therapy. RNs in our medical center's CICU can take care of these patients effectively and competently because of extensive prior experiences with the AxIABP. The nursing staff has adapted existing nursing procedures, protocols, and lessons learned from experiences with the AxIABP to manage this new patient population. CICU RNs must cope with this ever-evolving discipline and progress in patient care and new technology.

Proper training in conjunction with experience gained thru exposure to these new devices results in increased staff confidence and competency.

8. Conclusions

Impella is one treatment option available for use in advanced HF and pre-heart transplant patients. The development of an alternative insertion technique that allows patients to ambulate instead of being on bedrest continues to evolve. Our medical center's experiences with taking care of ambulatory HF and pre-heart transplant Impella patients have shown that this is a safe and effective treatment. Although there was no data gathered as to the efficacy and subsequent effect on post-operative recovery, the nursing, medical and pharmacological management enumerated in this article will add to the knowledge base for the treatment of this complex patient population.

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Conflicts of Interest Disclosure

The authors declare that there is no conflict of interest.

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