The Impella Device for Acute Mechanical Circulatory Support in Patients in Cardiogenic Shock

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Background. Acute cardiogenic shock is associated with high mortality rates. Mechanical circulatory 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 that can be inserted using a less invasive technique. This study was conducted to determine the outcome of patients who have undergone placement of the Impella device for acute cardiogenic shock in our institution.

Methods. A retrospective record review of 47 patients who underwent placement of the Impella device was performed from January 1, 2006, to December 31, 2011. Records were evaluated for demographics, operative details, and postoperative outcomes. Operative mortality was defined as death within 30 days of the operation.

Results. The patients (33 male) were an average age of 60.23 ±13 years. The indication for placement of the Impella device included cardiogenic shock in 15 patients (32%) and postcardiotomy cardiogenic shock in 32 (68%). Of the 47 patients, 38 (80%) received the Impella 5.0 and the rest the 2.5 device. Ventricular function recovered in 34 of 47 patients (72%), and the device was removed, with 4 patients (8%) transitioned to long-term ventricular assist devices. The 30-day mortality was 25% (12 of 47 patients). Complications occurred in 14 patients (30%), consisting of device malfunction, high purge pressures, tube fracture, and groin hematoma.

Conclusions. This is one of the largest series of patients undergoing placement of the Impella device for acute cardiogenic shock. Our outcomes showed improved results compared with historical data. Myocardial recovery was accomplished in most patients. Finally, the 30-day mortality and complication rate was acceptable in these critical patients. These benefits were all achieved with the Impella device in a less invasive method.

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Cardiogenic shock is characterized by inadequate tissue perfusion due to cardiac dysfunction and is the leading cause of death in patients hospitalized with acute myocardial infarction [1]. Mortality from cardiogenic shock still remains exceedingly high, and reaches 50% to 80% in those treated conservatively [2]. Early revascularization by coronary artery bypass grafting and percutaneous coronary intervention is the cornerstone treatment of acute myocardial infarction complicated by cardiogenic shock [3]. In addition to revascularization, mechanical circulatory support devices have shown progress in improving outcomes in patients with chronic heart failure and in patients with refractory cardiogenic shock. These findings are in contrast to the lack of success of pharmacologic agents or intraaortic balloon pump (IABP), or both, demonstrated previous reports [4].

Short-term ventricular assist devices (VADs) have been become a widely accepted treatment option for acute cardiogenic shock. They can be initiated quickly and do not necessarily require a sternotomy. The Impella devices (Abiomed Inc, Danvers, MA) are minimally invasively placed, catheter-mounted, microaxial flow pumps. They are versatile and the least invasive of the left ventricular VAD (LVAD) technology available. 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.

The purpose of our study was to determine the outcome of the Impella device for acute mechanical circulatory support in the cardiogenic shock setting at a large-volume single institution. The primary end points included survival to 30 days and 1 year. The secondary end points included device-related complications.

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Drs Batsides and Anderson disclose financial relationships with Abiomed.
Material and Methods

The Institutional Review Board of Robert Wood Johnson Medical School approved the conduct of this study.

Patients

We performed a retrospective record review of 47 consecutive patients with cardiogenic shock who underwent placement of the Impella device between February 2006 and December 2011. Cardiogenic shock is defined here as a systolic blood pressure of less than 90 mm Hg and cardiac index of less than 2.2 L/min/m². Records were evaluated for data relative to patient demographics, hemodynamics, operative details, 30-day outcome, including native heart function recovery, 90-day outcome, and 1-year survival.

Impella System

At the present time, the approved Impella technology comprises the Impella 2.5 and 5.0/LD devices, which have both been described elsewhere [5, 6]. Briefly, the Impella 2.5 is a 12F microaxial pump mounted on a 9F catheter shaft housing the motor driveline and the purge line system. It is inserted through the femoral artery and positioned across the aortic valve into the LV under fluoroscopic guidance. The Impella 5.0/LD device is also mounted on the same 9F catheter shaft, and the pump is 21F in diameter. It is inserted from transthoracic or transsternal access through a 10-mm vascular graft sewn end-to-side on the ascending aorta and advanced across the aortic valve in the LV. Alternatively, it can also be inserted peripherally from the femoral artery and advanced retrograde with transesophageal echocardiography guidance across the aortic valve into the LV. A peripheral insertion through the right axillary artery through a vascular graft is also possible.

The Impella 2.5 and 5.0/LD devices are capable of generating up to 2.5 L/min and 5.0 L/min of forward flow in the systemic circulation, respectively. Both Impella pumps are powered and controlled by the same Impella console. The console allows management of the pump speed (by 9 gradations) and displays the pressure difference between the inflow and outflow outlets.

An activated clotting time of between 250 and 500 seconds is required during Impella pump insertion intraoperatively. After the pump is inserted and positioned, an activated clotting time 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.

Statistical Analysis

Continuous data are presented as mean ± standard deviation, and categoric data are presented as proportions. Survival at 30 days and 1 year is presented in Kaplan-Meier curves.

Results

Between February 2006 and December 2011, 47 consecutive patients (33 men) with cardiogenic shock received an Impella LVAD. The patients were an average age of 60.23 ±1 years. The patients presented with multiple comorbidities (Table 1.) Before Impella placement, the average ejection fraction was .235 ± .14. Operations included coronary artery bypass grafting (CABG) in 24 patients (51%), CAGB and valve replacement/repair in 7 (14%), valve repair in 6 (12%), emergent percutaneous coronary intervention in 2 (4%), and other procedures in 2 (4%), consisting of ventricular septal defect repair and tetralogy of Fallot repair in 1 patient each. Six patients (12%) only underwent Impella placement.

The indication for placement of the Impella device included postcardiotomy cardiogenic shock (PCCS) in 32 patients (68%), acute myocardial infarction complicated with cardiogenic shock in 11 (23%), acute decompensated ischemic cardiomyopathy in 3 (6%), and myocarditis with cardiogenic shock in 1 (2%; Table 2). Of the 47 patients, the Impella 5.0 was placed in 38 (80%) and the rest had the 2.5 device. Ventricular function recovered in 34 patients (72%), and the device was removed, with 4 patients (8%) transitioned to long-term VADs. The 30-day mortality was 25% (12 of 47 patients; Table 3). Complications occurred in 14 patients (30%) and consisted of device malfunction, high purge pressures, tube fracture, and groin hematoma (Table 4).

The 32 patients (68%) with PCCS demonstrated an increased requirement for pharmacologic support and worsening clinical condition. One patient was brought back to the operating for placement of the Impella device after the patient’s condition worsened postoperatively in the intensive care unit. Of the 32 PCCS patients, 18 (56%) underwent CABG, 8 (26%) underwent combined CABG and valve replacement/repair, 5 (17%) underwent isolated

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<th>Table 1. Baseline Characteristics</th>
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<tr>
<td>Ejection fraction</td>
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<td>Coronary artery disease</td>
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<td>Congestive heart failure</td>
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COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; SD = standard deviation.
valve repair, and 1 (3%) underwent tetralogy of Fallot repair. The reason for the PCCS in these patients varied and included poor myocardial protection and insufficient myocardial revascularization.

The overall average duration of support with Impella devices was 5.4 ± 4.5 days (range, 1 to 18 days) for the entire cohort. A variety of methods were used to implant the devices. The transthoracic end-to-side anastomosis was the most common approach for the Impella 5.0 device (n = 31), and the remaining Impella 5.0 devices were placed through the transseptal or transaxillary method (n = 6). Placement of the Impella 2.5 was through the transseptal or axillary method.

Ventricular function recovered in 34 of 47 patients (72%), and the device was removed, with 4 patients (8%) transitioning to long-term VADs. The 30-day mortality was 25% (12 of 47 patients). The 30-day, 90-day, and 1-year survival was 72.3%, 65.9%, and 63.8%, respectively (Fig 1).

The placement of the Impella device resulted in a relatively low complication rate, with only 14 complications occurring in the 47 patients. The complications, although not insignificant, did not cause any deaths. The most common complication was device malfunctions, which in some patients were due to device kinking and in others from an unclear etiology. In 3 of the 5 patients the Impella device was removed, and the device in 2 patients was exchanged for a new device.

Table 2. Indications for Impella Support

<table>
<thead>
<tr>
<th>Indication</th>
<th>No. (%)</th>
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<tr>
<td>Postcardiomyopathy cardiogenic shock</td>
<td>32 (68)</td>
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<tr>
<td>Acute myocardial infarction complicated by</td>
<td>11 (23)</td>
</tr>
<tr>
<td>cardiogenic shock</td>
<td></td>
</tr>
<tr>
<td>Acute decompensated ischemic cardiomyopathy</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Myocarditis with cardiogenic shock</td>
<td>1 (2)</td>
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The second most common complication was high purge pressures, which occurs when the pressure within the purge line increases. The most likely reason for this is catheter kinking, which might be visualized on a roentgenogram. The kinking of the catheter was related to design issues; however, the manufacturer has reinforced the catheter, and most of these issues are now resolved. In 2 patients with high purge pressures, the device was removed, and the Impella device was exchanged in the other patient. Another complication was gastrointestinal bleeding, which occurred in 1 patient and was determined to be from an upper gastrointestinal source. The patient underwent upper endoscopy, and the bleeding ulcer was coagulated. Although none of the complications were minor, no patient died as a result of these complications.

Comment

This is the largest series of patients undergoing placement of the Impella device for acute cardiogenic shock. The outcomes from our study have results that are improved over historical data. Myocardial recovery was accomplished in most patients. Moreover, the 30-day mortality and complication rates were acceptable in these critical patients. Our results are more impressive when one considers the gravity of the clinical problem that these patients have experienced. Traditionally, a significant reduction of the mortality rate for patients with cardiogenic shock has not been observed despite early revascularization, advances in medical therapy, and mechanical hemodynamic support technology. The findings from our study are unique in that we show the success of the Impella device in these critically ill patients.

The results in this study demonstrate that the use of the Impella device in patients with cardiogenic shock has been very successful. The patients with acute cardiogenic shock from acute myocardial infarction and the post-cardiomyopathy patients both had a survival advantage when the Impella device was implanted (Fig 2). Most of the patients, 34 of 47 (72%), were successfully weaned from the Impella device, and the patients that could not be weaned often were transitioned to more durable long-term VADs such as the HeartMate II (Thoratec, Pleasanton, CA).

The weaning protocol at our institution consists of vigilant 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. For the patients who are being considered for Impella removal, the devices are weaned in the presence of a transesophageal probe and their heart function is assessed in the operating room. If there is recovery of the LV, the Impella is removed.

The weaning protocol at our institution is the following: once vigilant monitoring of hemodynamic and laboratory values shows patients are hemodynamically stable, 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. The pump is retracted into the vascular graft which is then ligated flush with the ascending aorta or is oversewn, followed by standard closure of the sternotomy in the case of direct insertion into the ascending aorta. If the device is retrieved from the femoral or axillary artery insertion site, then manual compression at the groin or the axillary site that was used to achieve hemostasis.

Historically, the operative mortality of patients with shock can be at a minimum of 50%. The 30-day mortality

**Fig 1. Survival curve of patients who underwent placement of the Impella device.**

**Fig 2. Survival curve of patients with postcardiotomy cardiogenic shock (PCCS) and those with acute myocardial infarction complicated by cardiogenic shock (AMICS) or acute decompensated ischemic cardiomyopathy (DICM) who underwent placement of the Impella device.**
in our study was only 25%. In addition to the survival benefit, the Impella device has other advantages over traditional devices. It is easily placed, and as an internal device, can be placed minimally invasively through a transaxillary or transfemoral approach. Furthermore, for patients who undergo a traditional full sternotomy, the device can serve as a tool for transitioning off the cardiopulmonary bypass machine. It provides upwards of 5.0 L/min of support and LV decompression. In the setting of severe LV dysfunction, the Impella provides decompression of the LV necessary to reduce wall stress and increases the likelihood of myocardial recovery. The circulatory support provided by the Impella device is only a portion of the benefit because the ability to unload the LV is very significant [7].

Several studies have demonstrated that the combined use of revascularization therapy (ie, CABG or angioplasty) and counterpulsation may improve the prognosis in patients with myocardial infarction complicated by cardiogenic shock [8]. These two treatment methods both interrupt the vicious cycle in cardiogenic shock by stabilizing hemodynamics and the metabolic situation.

Multiple counterpulsation devices are available for both cardiologists and cardiac surgeons. These include the IABP, implantable turbine-pump (Hemopump; Medtronic Inc, Minneapolis, MN), percutaneous cardiopulmonary bypass support, and right heart, left heart, or biventricular assist devices. Another commonly used device is the TandemHeart Assist device (Cardiac Assist, Pittsburgh, PA), an LVAD designed for percutaneous insertion in the cardiac catheterization laboratory. This device can provide temporary left atrial-to-femoral artery bypass [9], with flow rates of up to 5 L/min [10, 11]. High-risk percutaneous coronary intervention with percutaneous LV assist with TandemHeart is a viable therapeutic strategy for the highest-risk subset of patients with severe coronary artery disease and profound LV dysfunction, and who are at very high risk for standard percutaneous or surgical revascularization. The literature is controversial in its support of these devices. Specifically, the IABP showed no survival benefit in a recently performed meta-analysis of IABP usage in ST segment elevation myocardial infarction [12].

To our knowledge, this is the largest series of patients undergoing placement of the Impella device for acute mechanical circulatory support. The outcomes from our study have results that are improved over historical data. The findings from our study are supported by previously published data. Indeed, the recently published RECOVER I study, a multicenter prospective single arm clinical trial designed under the U.S. Food and Drug Administration, to investigate the safety and feasibility of the Impella 5.0/LD in patients experiencing cardiogenic shock or low cardiac output syndromes after cardiac operations, corroborates our results. In this trial, the device was successfully inserted in 16 patients (100%). Hemodynamic indexes improved immediately once support was initiated. In addition, the use of Impella 5.0/LD enabled immediate restoration of hemodynamics with a gradual reduction in the need of inotropic support. Overall, 94% of patients survived to 30 days, and of those, 93% were weaned off mechanical support [13].

In this study, the operative mortality and complication rate was acceptable in these critically ill patients. The mortality rate of patients with cardiogenic shock is often exponentially higher with medical therapy or other mechanical devices. The goals expected from the implantation of VADs are alleviation of the strained cardiac muscle and immediate restoration of cardiac output with physiologic organ perfusion, thus breaking the vicious cycle of harmful neurohumoral responses and cytokine production. Interventions such as the Impella device that can assist or completely supplement the patient's own cardiac output may support the patients until the stunned myocardium recovers (bridge to recovery). Finally, the results from our study demonstrate that the Impella device is effective improving survival in patients in cardiogenic shock.

References

INVITED COMMENTARY

Lemaire and colleagues [1] report their experience with the Impella (Abiomed Inc, Danvers, MA) microaxial-flow left ventricular assist device (LVAD) in the setting of cardiogenic shock. The authors reported successful removal of the device in 34 of 47 patients (72%), with only 4 patients requiring transition to long-term LVAD support. The 30-day, 90-day, and 1-year survival was 72%, 66%, and 64%, respectively.

The historical context of this report is noteworthy. Minimally invasive mechanical circulatory assist began in the 1960s with the intraaortic balloon pump (IABP) [2] and in the 1970s with the Hemopump (Medtronic Inc, Minneapolis, MN). In 1989 Frazier and colleagues [3] reported the use of the Hemopump in 12 patients: 6 of the 12 survived 30 days. Although the Hemopump is no longer used, the template of a minimally invasive LVAD was forged.

preceding this study, other multicenter trials validated Impella use in high-risk percutaneous coronary intervention (ie, A Prospective, Multi-center, Randomized Controlled Trial of the IMPELLA RECOVER LP 2.5 System Versus Intra Aortic Balloon Pump [IABP] in Patients Undergoing Non Emergent High Risk PCI [PROTECT II]) and in postcardiomyocotomy shock (ie, IMPELLA RECOVER® LP/LD 5.0 Support System: A Clinical Safety and Feasibility Study [RECOVER I] [4, 5]. A continental registry (ie, EUROSHOCK Registry) tracks outcomes of acute myocardial infarction patients supported with the Impella 2.5; a recent report of 120 patients demonstrated a 64.2% 30-day mortality rate, with survival at 317 ± 526 days reported at only 28.3% [6]. Clearly, there is room for improvement.

In summary, the disease states that lead to acute cardiogenic shock have not changed in the past 50 years, but the technology to combat it has. The use of multiple and escalating doses of high-dose inotropes to treat low cardiac output is associated with unacceptable mortality and should be abandoned and replaced by mechanical circulatory support [7]. The experience reported by Lemaire and colleagues [1] is noteworthy and commendable. Impella technology and minimally invasive products like it are transforming the landscape of surgical and interventional treatment of this deadly condition.

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