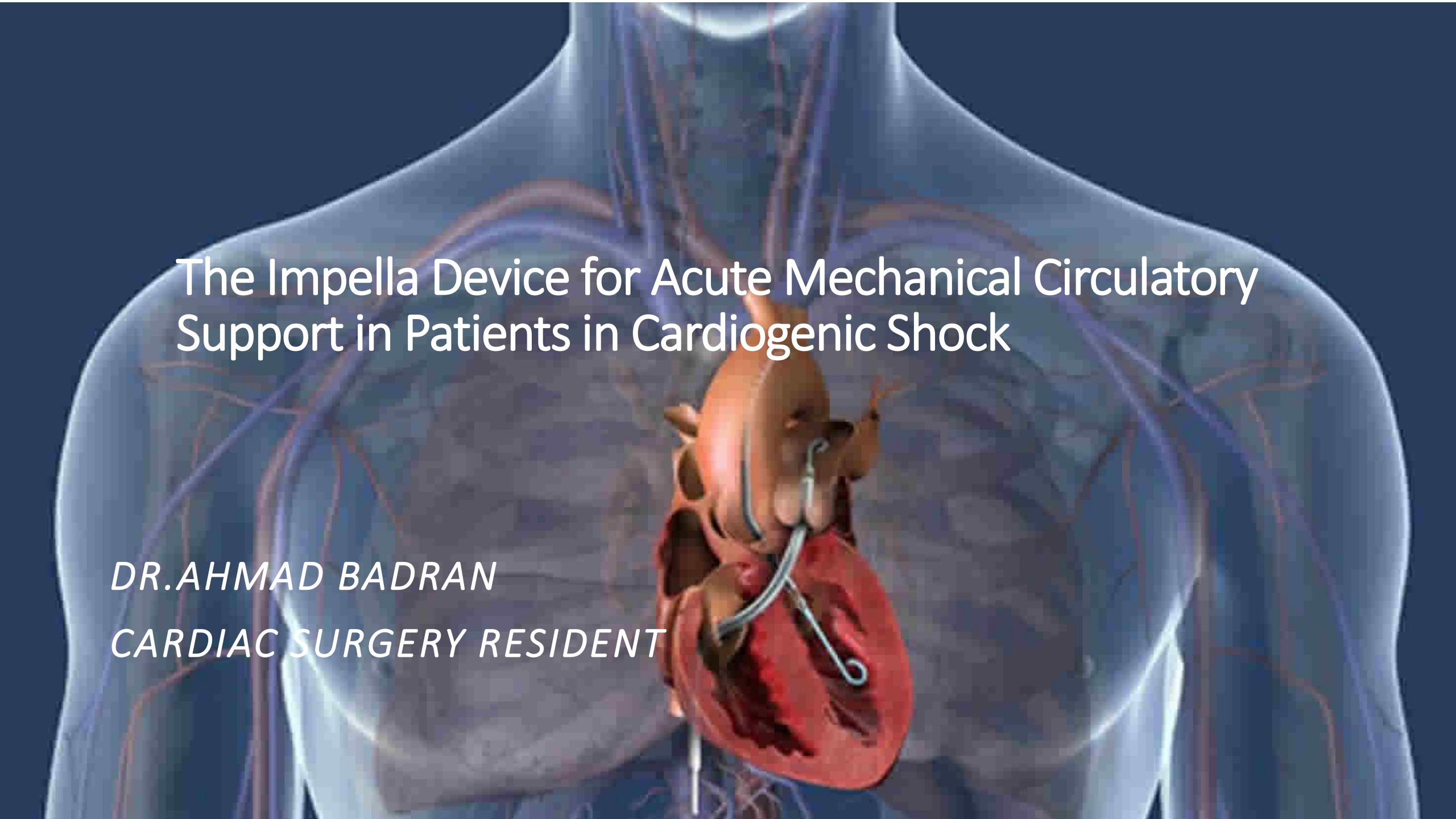

The Impella Device for Acute Mechanical Circulatory Support in Patients in Cardiogenic Shock

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Abstract

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.

Mortality from cardiogenic shock still remains exceedingly **high**, and reaches 50%.

Early revascularization by coronary artery bypass grafting and percutaneous coronary intervention is the cornerstone treatment of acute myocardial infarction complicated by cardiogenic shock.

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.

They can be initiated quickly and do not necessarily require a sternotomy.

Abstract

The Impella devices, 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.

Short-term ventricular assist devices (VADs) have been become a widely accepted treatment option for acute cardiogenic shock.

Material and Methods

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

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.

Impella System

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.

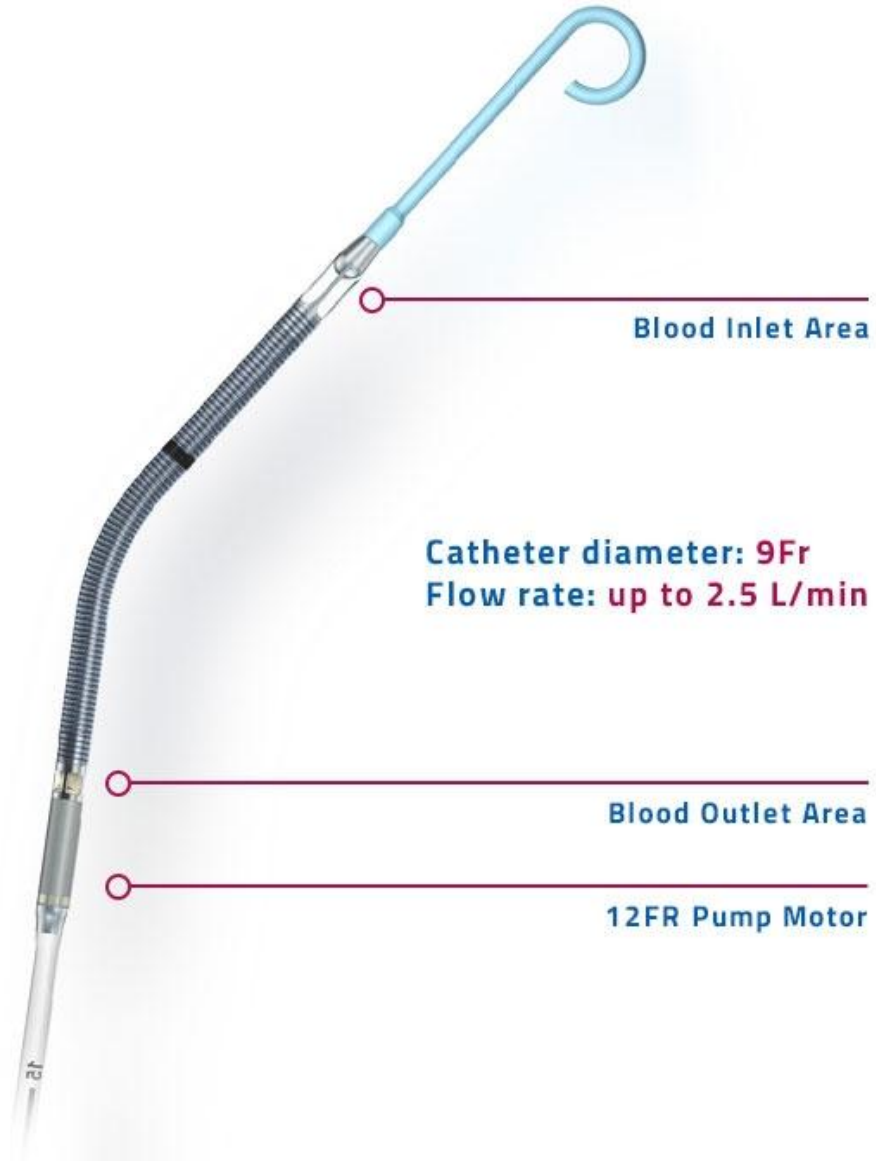
Both Impella pumps are powered and controlled by the same Impella console.

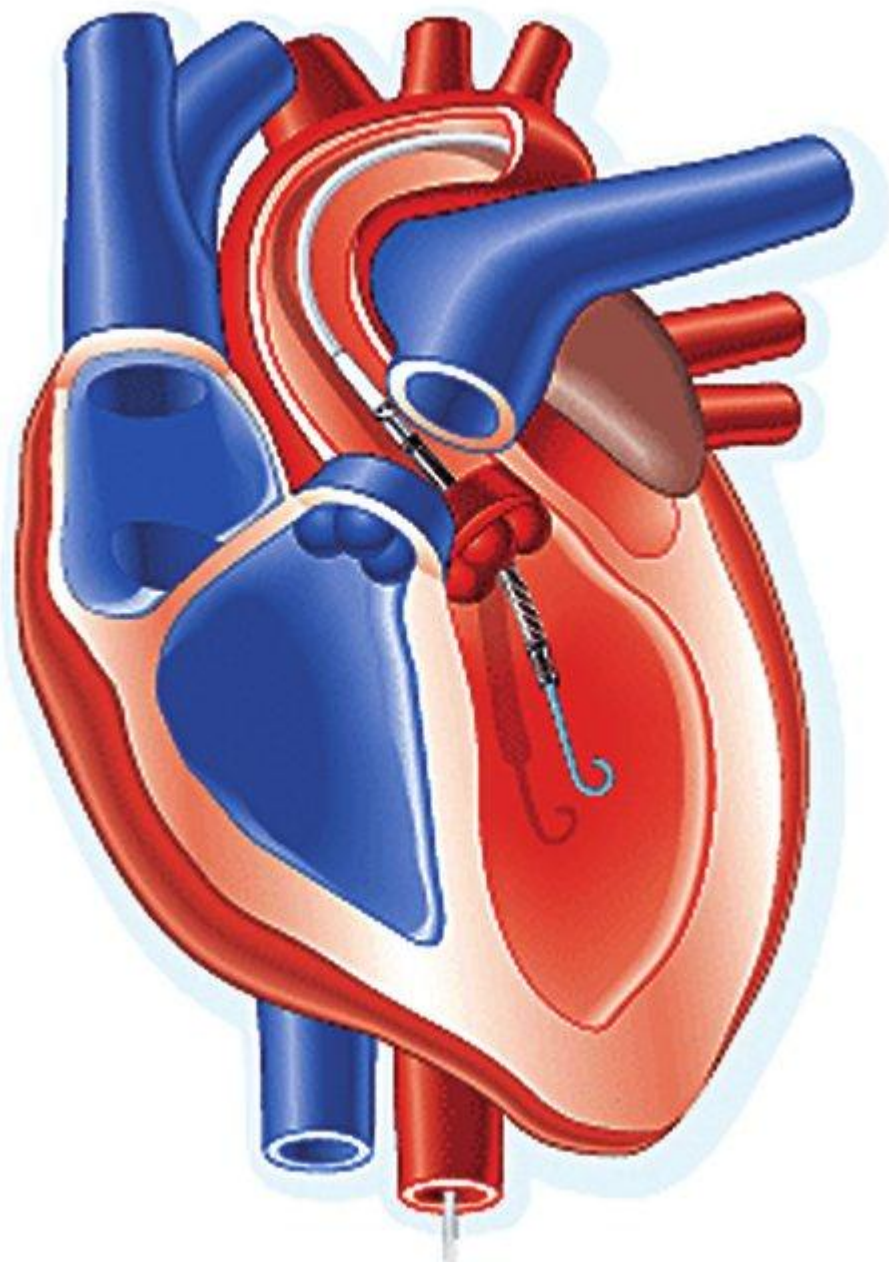
The console allows management of the pump speed (by 9 gradations) and displays the pressure difference between the inflow and outflow outlets.

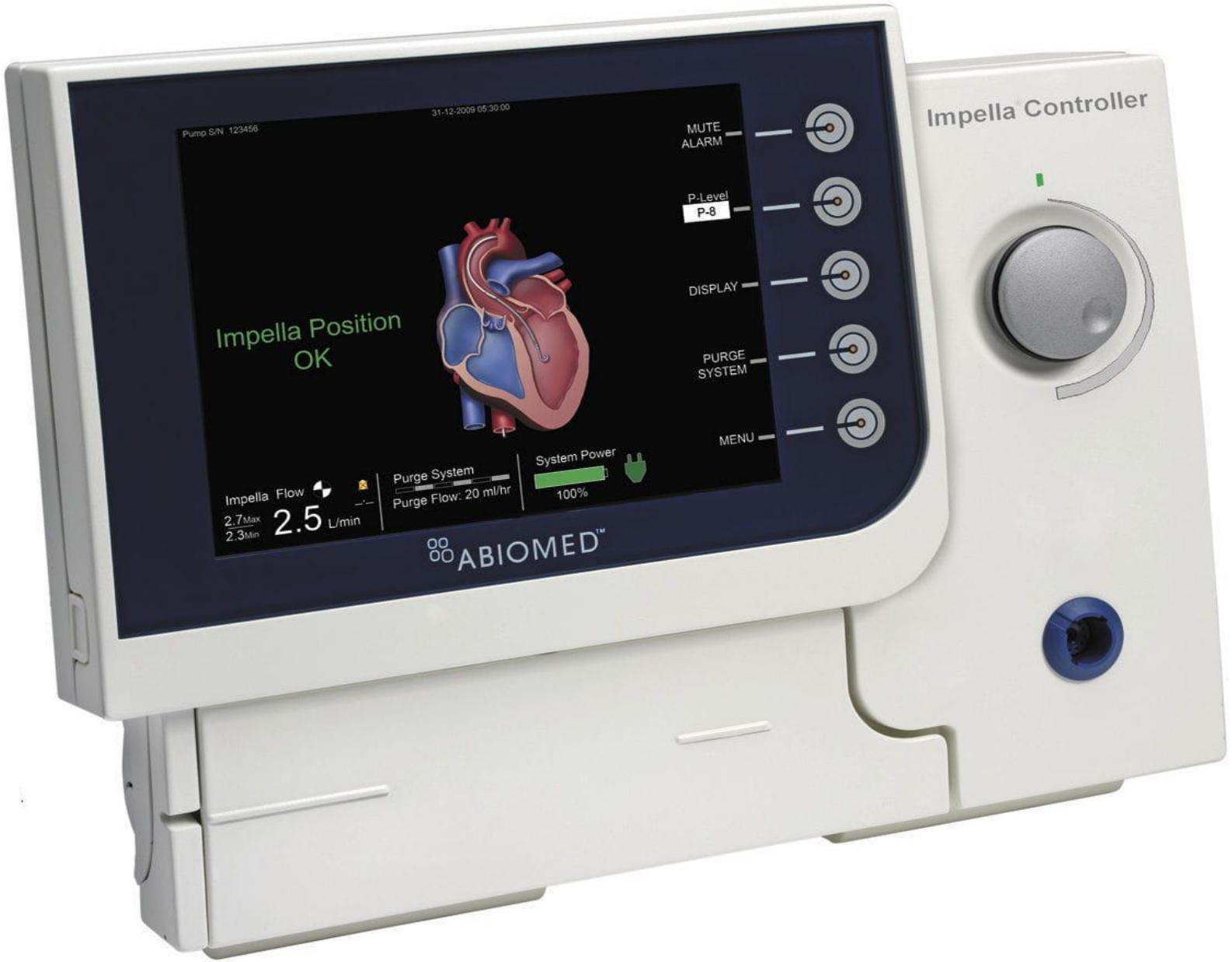
An *activated clotting time of between 250 and 500 seconds* is required during Impella pump insertion **intraoperatively**.

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 .


Blood Inlet Area
Catheter diameter: 9Fr
Flow rate: up to 2.5 L/min
Blood Outlet Area
12FR Pump Motor




Impella Controller
Pump S/N 123456
31-12-2009 05:30:00
MUTE ALARM
P-Level
P-8
DISPLAY
PURGE SYSTEM
MENU
Impella Position OK
Impella Flow
2.7Max
2.3Min
2.5 L/min
Purge System
Purge Flow: 20 ml/hr
System Power
100%
ABIOMED™

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 years.

The patients presented with multiple comorbidities.

Operations included coronary artery bypass grafting (CABG) in 24 patients (51%).

CABG and valve replacement/repair in 7 (14%).

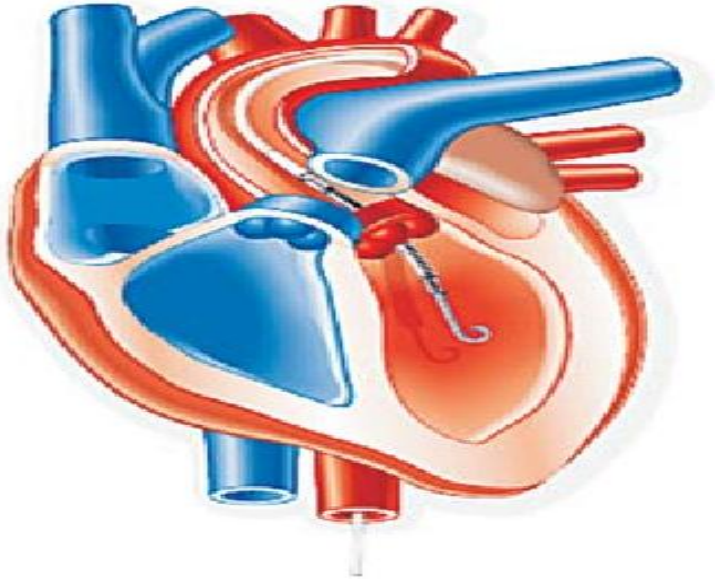
valve repair in 6 (12%).

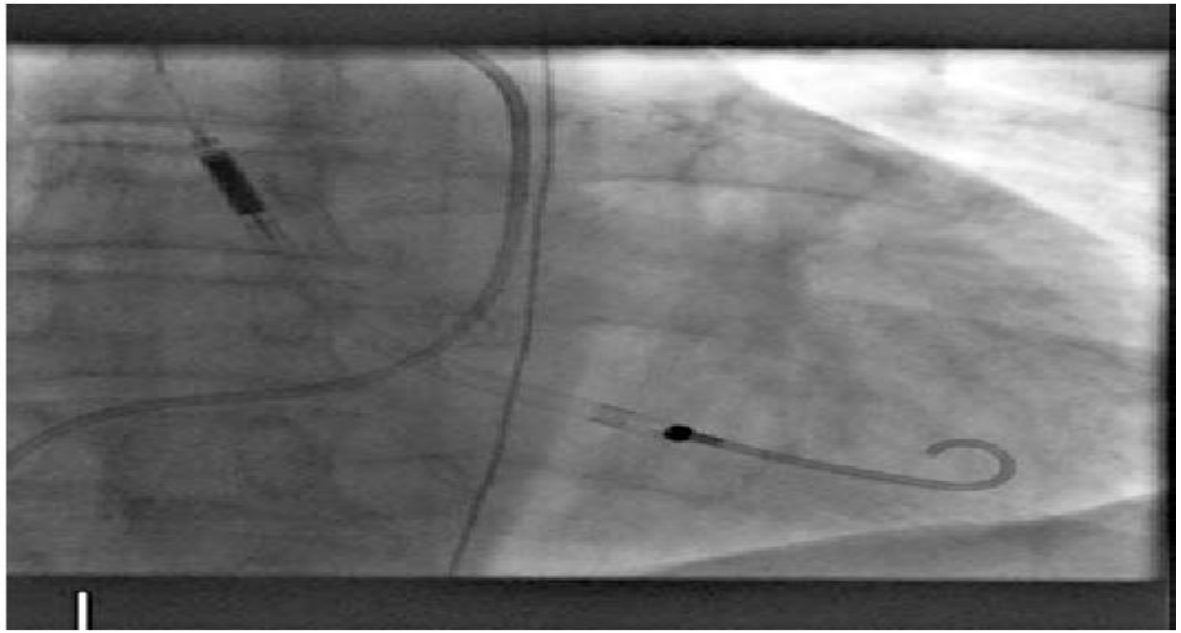
emergent percutaneous coronary intervention in 2 (4%).

ventricular septal defect repair and tetralogy of Fallot repair in 1 patient each.

Six patients (12%) only underwent Impella placement.

A





B

Figure 1. A: Schematic diagram and angiographic view of the Impella 2.5 pump in its final position across the aortic valve. B: Overview of the Impella 2:5 system, with its distal pigtail end and the proximal catheter plug with the integrated electrical and purging connections. The first figure is from Abiomed Europe GmbH (used with permission).

Results

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%).

Myocarditis with cardiogenic shock in 1 (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).

Complications occurred in 14 patients (30%) and consisted of device malfunction, high purge pressures, tube fracture, and groin hematoma.

The reason for the PCCS in these patients varied and included poor myocardial protection and insufficient myocardial revascularization.

Table 2. Indications for Impella Support

Indication	No. (%)
Postcardiotomy cardiogenic shock	32 (68)
Acute myocardial infarction complicated by cardiogenic shock	11 (23)
Acute decompensated ischemic cardiomyopathy	3 (6)
Myocarditis with cardiogenic shock	1 (2)

Contraindications

Mechanical aortic valve.

Aortic stenosis / calcification .

Moderate to sever aortic insufficiency .

Sever peripheral arteries obstructive disease .

Aneurysm of the ascending aorta and / or arch .

Mural thrombus in the left ventricle.

Results

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 ¼ 31), and the remaining Impella 5.0 devices were placed through the transfemoral or transaxillary method (n ¼ 6).

Placement of the Impella 2.5 was through the transfemoral or axillary method.

Ventricular function recovered in 34 of 47 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).

The 30-day, 90-day, and 1-year survival was 72.3%, 65.9%, and 63.8%, respectively.

Results

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.

The second most common complication was high purge pressures, which occurs when the pressure within the purge line increases.

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.

Although none of the complications were minor, no patient died as a result of these complications.

Complication

Malfunction

High purge pressures

Tube fracture/postoperative groin bleeding

Gastrointestinal bleeding

Comment

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 postcardiotomy patients both had a survival advantage when the Impella device was implanted.

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 longterm VADs such as the HeartMate II.

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.

Weaning off ..

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.

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.

CONCLUSION

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 significan.

THANKS FOR LISTENING