New Surgical Circulatory Support System Outcomes

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We report the first U.S. experience of the recently approved micro-axial surgical heart pump for the treatment of ongoing cardiogenic shock following acute myocardial infarction (AMICGS), postcardiotomy cardiogenic shock (PCCS), cardiomyopathy including myocarditis, high-risk percutaneous coronary intervention (HRPCI), and coronary artery bypass surgery (HRCABG). Demographic, procedural, hemodynamic, and outcome data were obtained from the manufacturer's quality database of all Impella 5.5 implants at three centers. Fifty-five patients underwent an Impella 5.5 implant for cardiomyopathy (45%), AMICGS (29%), PCCS (13%), preop CABG (5%), OPCAB (4%), and other (4%). Thirty-five patients (63.6%) were successfully weaned off device with recovery of native heart function. Eleven patients (20.0%) were bridged to another therapy, two patients (3.6%) expired while on support, and in seven patients (12.7%) care was withdrawn. Overall survival was 83.6%. There were no device-related strokes, hemolysis, or limb ischemia observed. Four patients experienced purge sidearm damage, resulting in a pump stop in two patients. The new micro-axial surgical heart pump demonstrated successful clinical and device performance in providing both full hemodynamic support and ventricular unloading for patients with AMICGS, decompensated cardiomyopathy, and high-risk cardiac procedures. In this early U.S. experience, 83.6% of patients survived to explant with 76.1% of these patients recovering native heart function. *ASAIO Journal* 2020; 66:746–752.

Key Words: mechanical circulatory support, pump, surgery

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Abiomed provided clerical and statistical support for the manuscript. Specifically, analysis of log data and preparation of figures. The authors had free access to all clinical and device data including all the explant analyses and Automated Impella Controller (AIC) log information.

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Acute mechanical circulatory support is increasingly used for the treatment of cardiogenic shock from a variety of causes as well as acute decompensated heart failure.[1–6] These short-term devices can be used as a bridge to decision, native heart recovery, or next therapy, such as a durable left ventricular assist device (LVAD) or cardiac transplantation.[1,6,7] Additionally, given the historically low rates of survival following post-cardiotomy cardiogenic shock (PCCS),[8] Impella technology is increasingly being used in the setting of higher risk, low left ventricular ejection fraction (LVEF) cardiac surgery for the prevention of low cardiac output syndrome (LCOS).[9–11]

The Impella 5.5 with SmartAssist system is a temporary ventricular support device approved by the Food and Drug Administration (FDA) on September 24, 2019. It is intended for use up to 14 days and indicated for the treatment of ongoing cardiogenic shock that occurs immediately following acute myocardial infarction or open heart surgery or in the setting of decompensated cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure unresponsive to optimal medical management and conventional treatment measures. The intent of the Impella 5.5 with SmartAssist System is to unload the left ventricle (LV), reduce ventricular work, and provide the circulatory support necessary to allow native heart recovery and early assessment of residual myocardial function. The Impella 5.5 pump is capable of full circulatory support, delivering up to 6.2 L/min and can be inserted *via* the left or right axillary artery or directly into the ascending aorta. In this report, we present the outcomes of the first 55 patients who received an Impella 5.5 at three centers in the United States.

Materials and Methods

The Impella 5.5 with SmartAssist System

The Impella 5.5 System (Abiomed, Danvers, MA) is a 19Fr micro-axial pump and 21Fr cannula mounted on a 9Fr driveline/bearing purge delivery catheter (**Figure 1**).[12] The pump is placed across the aortic valve and pulls blood from the LV through an inlet area near the tip and expels blood from the catheter into the ascending aorta and systemic circulation (**Figure 2**). It is designed to fully unload the LV up to a flow rate of 6.2 L/min. The Automated Impella Controller (AIC) is the primary user control interface for system performance, monitoring for alarms and displaying real-time hemodynamic and catheter position information. Optical sensor technology provides a measurement of the aortic pressure (AoP), while the micro-axial motor, acting also as a sensor, provides the pressure differential between the aorta and the LV. Real-time *in-vivo* pump flow is thereby displayed based on these measurements. Based on a reference cardiac output (CO) for calibration, algorithms use the pulse pressure to estimate the real-time CO and cardiac power output (CPO). The AIC home screen (**Figure 3A**)

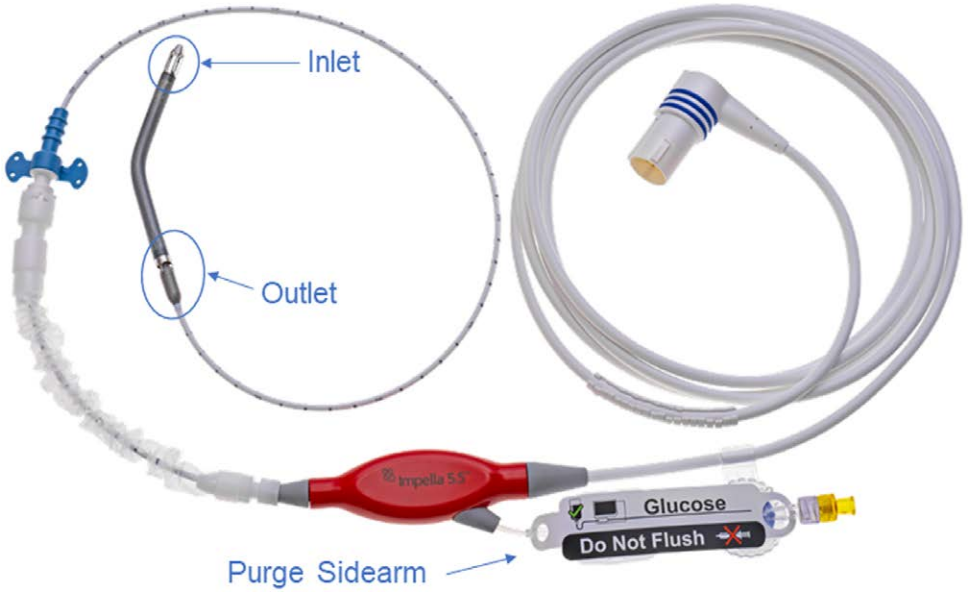

Figure 1. The Impella 5.5 with SmartAssist.

and AIC trend screen (**Figure 3B**) display the mean arterial pressure (MAP), a left ventricular end diastolic pressure (LVEDP) trend, total CO, native CO, Impella flow and calculates and displays the CPO (CPO = MAP × CO/451). These metrics can be useful for patient management and during the weaning process. The optical sensor technology also allows for precise catheter placement across the aortic valve. During operation, the pump requires an anticoagulation with a target activated clotting time (ACT) of 160–180 seconds. Impella Connect is a real-time remote viewing and collaborative patient management platform that is monitored 24/7 by the manufacturer's support center and enables clinicians to view the Impella control screen through a secure, Health Insurance Portability and Accountability Act (HIPAA) compliant website to track and review cases at any time from any internet-connected device.

Implant Technique

In the transaxillary approach to inserting the Impella 5.5, the left or right axillary artery is exposed through a small cut-down incision (**Figure 4**). Exposing the axillary artery more medially will expose a slightly larger, deeper artery. Conversely, a more lateral incision exposes a somewhat smaller, superficial artery. It is important to note that the fibers of the brachial plexus tend to be more closely involved with the artery as it courses laterally. In this case, extra caution must be taken not to apply pressure to the nerves that might result in a brachial plexopathy. A detailed review of 11 steps recommended by the manufacturer for inserting the Impella 5.5 using the trans-axillary approach is provided in Supplement, http://links.lww.com/ASAIO/A504.

Explant of the device takes place in the operating room (OR) or in the intensive care unit (ICU) using conscious sedation. In brief, explant of the Impella 5.5 placed trans-axillary consists of reaccessing the incision and gaining control of the axillary artery both proximal and distal to the anastomosis. Leaving the silastic vessel loops in place at implant may provide easier access and control of the artery during explant. Occlusion of the axillary artery distally before removal of the device is important to allow any potential thrombus or debris sitting in the axillary graft to exit the end of the graft and not down the arm. The graft is then overseen or stapled close to the native axillary artery and the incision closed.

Data Collection

This is a retrospective study of prospectively collected data from the manufacturer's FDA-mandated quality database on all consecutive patients undergoing implant of the Impella 5.5 at three major cardiovascular centers as part of a limited market release. Demographic, procedural, hemodynamic, and outcome data were obtained. Device performance was evaluated from both physician case review and device performance log data provided by the device manufacturer. Controller log data was downloaded retrospectively at the end of each case. Pump metrics were processed using LabView (National Instruments, Austin, TX) and further analysis of usage and metrics were completed with Visual Basic Applications *via* Excel (Redmond, WA). All statistical assessments and visuals were generated using Minitab (MiniTab Inc., State College, PA). The data are expressed as the mean ± standard deviation, median (range), or proportions, as appropriate. All investigators had access to study data.

Results

From October 16, 2019 to March 4, 2020, 55 patients underwent successful implantation of the Impella 5.5 with SmartAssist at three centers as part of a limited market release. Forty-eight (87%) of the patients were male with a mean age of 59 years (18–78 years). Indications for support included cardiomyopathy (45%), AMICGS (29%), PCCS (13%), peri-operative cardiac surgery (5%), off-pump coronary artery bypass (OPCAB) (4%), one patient undergoing high-risk percutaneous coronary intervention (PCI) and one patient undergoing

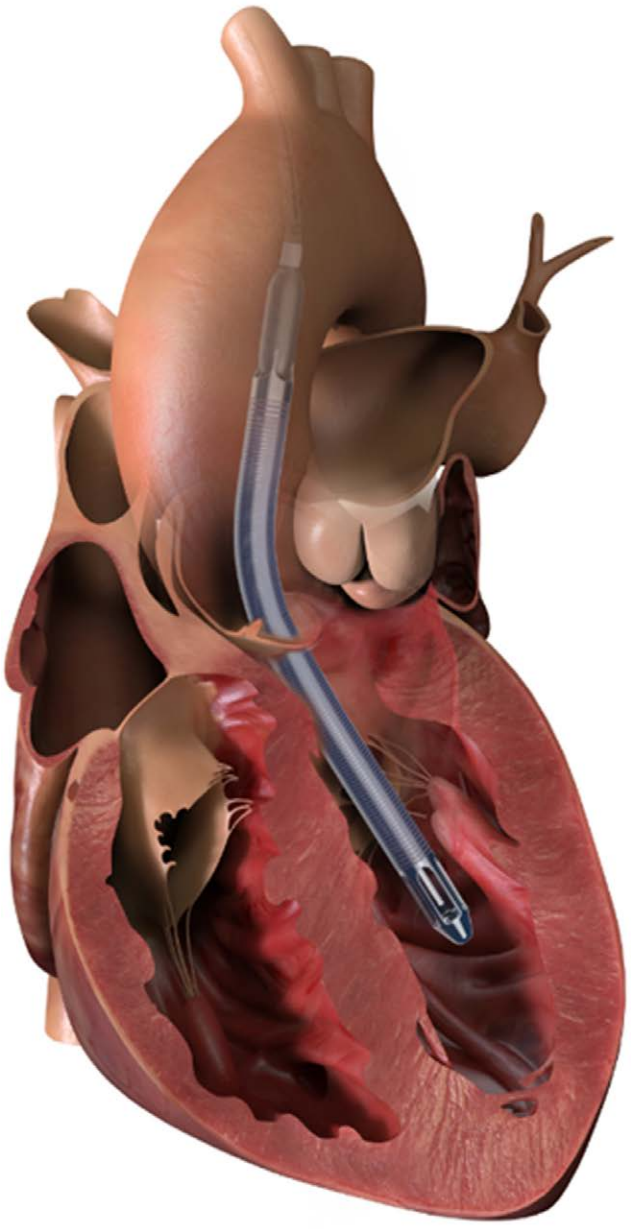

Figure 2. The Impella 5.5 in the left ventricle.

ventricular ablation. Eight patients (14.5%) were mechanically ventilated upon presentation before the Impella implant procedure.

The access site for the Impella 5.5 consisted of the right axillary in 44 (80%) patients, the left axillary artery in 8 (14.5%) and directly into the ascending aorta in three patients (5.5%). The system was successfully implanted in 98.2% (54/55) of patients. While the size of the axillary artery was not routinely measured in all cases, there were several cases successfully implanted through a healthy, atheromatous-free 6mm axillary artery. The one unsuccessful device insertion was an attempt to insert into a 5.5 mm vessel and not device related. In approximately half the patients, the Impella insertion time was recorded with 70% of cases requiring less than 10 minutes and only one case beyond 30 minutes.

Overall survival was 83.6%. The mean Impella support time was 14 ± 13.4 days (range 0.5–54.3). Thirty-five patients (63.6%) were successfully weaned off device with recovery of native heart function with mean length of support to recovery of 9.7 ± 8.7 days (range 1.6–25.9). Eleven patients (20.0%) were bridged to another therapy with mean support to bridge to next therapy of 32.0 ± 13.0 days (range 7–54). Two patients (3.6%) expired while on support, and in seven patients (12.7%) care was withdrawn. The mean duration of support for patients who eventually underwent orthotopic heart transplantation (OHT) was 35.4 ± 12.1 days (range 13.5–46.6) and MCS (LVAD, BIVAD, TAH) was 30.5 days ± 22.9 (range 11.5–54.3). The survival status of all 55 patients in shown in **Figure 5**.

In 11 cases (20.0%), the Impella 5.5 was used in combination with peripheral venous-arterial extracorporeal membrane oxygenation (VA-ECMO) in patients who presented with acute decompensated CM (5), AMI-CGS (4), and PCCS (2). All but one of these patients was on peripheral VA-ECMO before implanting the Impella 5.5. Eight of the 11 patients were first weaned from ECMO followed by successful weaning of Impella to no mechanical support (5) and cardiac transplantation (3). Care was withdrawn in the remaining three patients.

Of the total cohort of 55 Impella 5.5 patients, one patient experienced bleeding with a hematoma at a previously placed femoral intra-aortic balloon pump (IABP). There were no occurrences of aortic valve injury, stroke, clinically significant hemolysis (no patients with a plasma-free hemoglobin above 20 mg/dl), or limb ischemia observed. Four patients experienced purge sidearm damage, resulting in a pump stop with an inability to restart in two patients. In these two patients, one was transitioned to a durable LVAD and one patient no longer required mechanical circulatory support. The mean duration to first observation of purge sidearm damage was 17 days. The device manufacturer instructions for use (IFU) specifies not to use isopropyl alcohol (IPA) to wipe any of the pump components, however, one patient's pump was cleaned with IPA resulting in damage. The other patients experienced sidearm damage during ambulation or broad patient movement, which exposed the sidearm to a mechanical breakage. The device manufacturer subsequently provided additional training and guidance on best practices and no additional sidearm damages occurred after institutional adoption of these practices. Complete AIC case data were available from 20 implants, of which 17 patients recovered, 2 bridged to next therapy and 1 expired. The change in MAP and pulse pressure (PP) within the first hour of support and one hour before device explant for the recovered patients (**Figures 6A and B**).

Pump Explant Data

As part of the limited market release of Impella 5.5, 16 of 56 (29%) of the implanted pumps, including one aborted implant, were returned to the manufacturer for routine analysis. Analysis of the pumps included microscope-aided visual inspection, optical sensor characterization and accuracy testing, and motor resistance and leakage current testing.

There was no evidence of thrombus formation within any of the pumps. It was determined using data logs and histology that thrombus was caught in one pump when explanted through the graft. There was no evidence of motor corrosion or motor leakage in any pumps tested. The optical sensors were

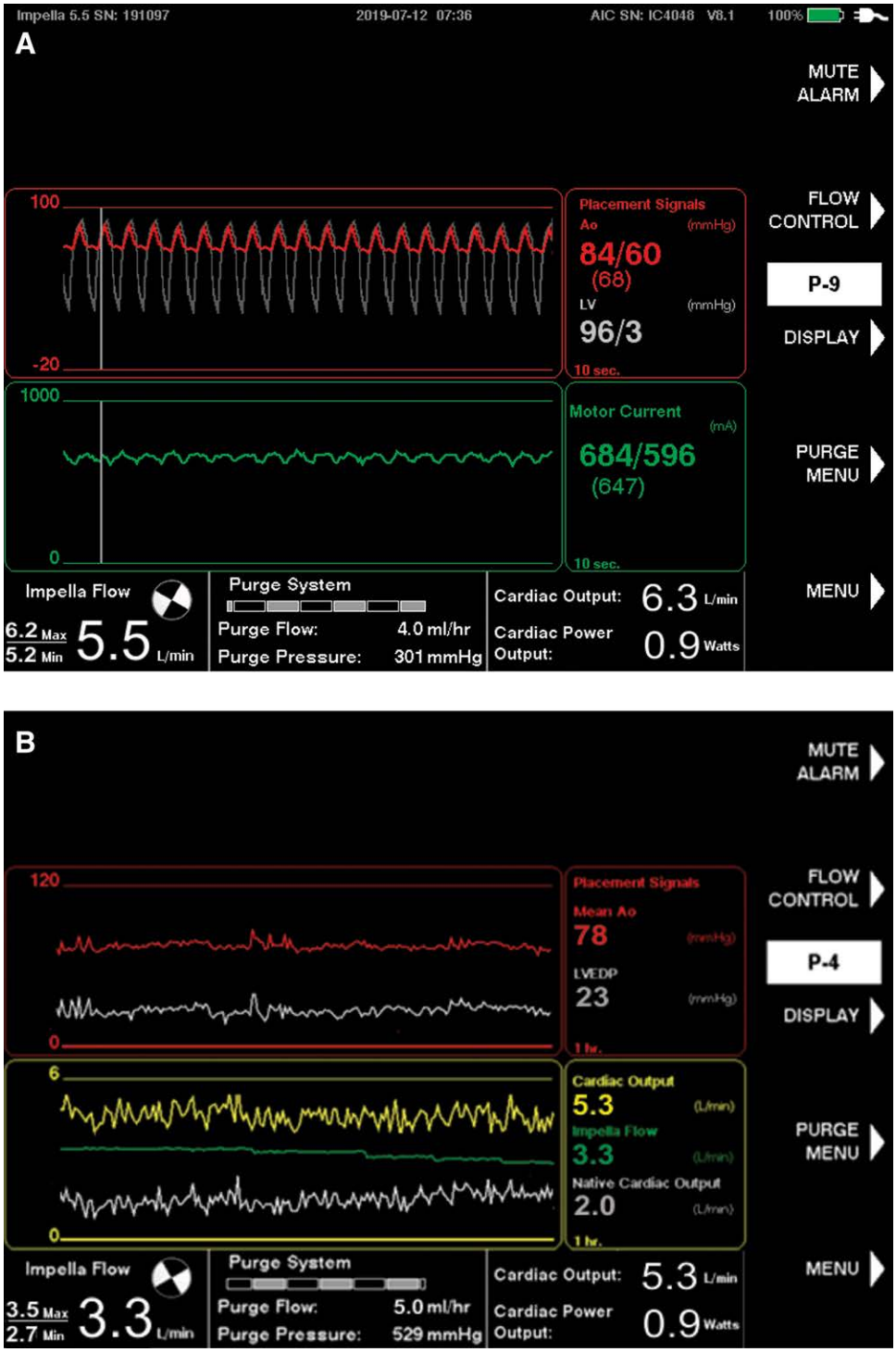

Figure 3. A: Automated Impella Controller (AIC) Home Screen. **B**: AIC Trend Screen (showing mean arterial pressure [MAP], left ventricle [LV] waveform, cardiac output [CO], cardiac power output [CPO], pump flow [mean, max, min], purge pressure and flow).

tested for accuracy and all passed the manufacturer's qualification specifications.

Discussion

Cardiogenic shock is characterized by end-organ dysfunction as a result of inadequate CO due to LV, RV, or biventricular failure.[13] Multiple types of cardiogenic shock can benefit from percutaneous mechanical support. In broad terms, these include AMICGS, PCCS, and myocarditis.[1,3,4,7,9,11,14] Matching the optimal therapy in a timely fashion to the right patient requires an understanding of the capabilities of support systems and an accurate assessment of the patient's current hemodynamic and metabolic state. A meta-analysis of six studies totaling 163 patients using Impella 5.0 for cardiogenic shock showed a high survival rate to discharge, 30, 180, and 365 days across all

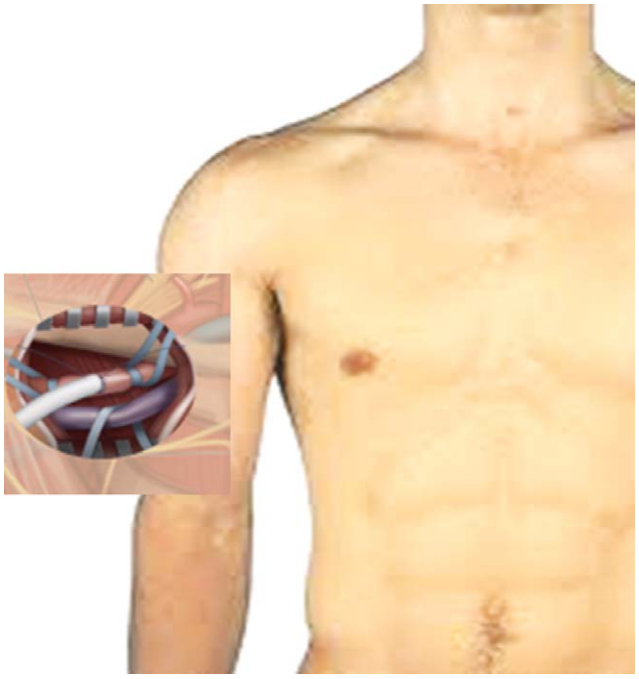

Figure 4. Axillary access approach.

etiologies achieving 73.5%, 72.6%, 62.7%, and 58.4%, respectively.[15] Additionally, a high myocardial recovery rate was observed in patients supported for PCCS or AMICGS, reaching 73.8% in those who survived to device removal.

In addition to most forms of cardiogenic shock, percutaneous mechanical support can also benefit patients with acute decompensation of advanced heart failure from a variety of etiologies.[1,6,16] In this case, acute mechanical circulatory support (MCS) is a therapeutic bridge to recovery or baseline, a bridge to decision, candidacy, or next therapy, such as durable LVAD or cardiac transplantation.[17] Hall *et al.* described their experience of 58 inotrope dependent, advanced heart failure patients who acutely decompensated and received the Impella 5.0 for bridge to decision (BTD).[18] In their experience, 67% of patients survived to next therapy with a 1-year survival of 65%. For a similar indication, survival rate to next therapy was 73.5% when the device was used as a bridge to decision in ADHF.[15] Chung *et al.* recently reported their contemporary experience of 100 patients undergoing insertion of an axillary Impella 5.0.[6] In this report, over half the patients were INTERMACS 1 with an average LEVF of the entire cohort of 16%. In this very ill patient population, overall survival to explant was 64% and 50%, 48%, and 81% for bridge to recovery (BTR), bridge to decision (BTD), and bridge to transplant (BTT), respectively. Survival to explant improved significantly during their experience and was 90% overall in the most recent 30 patients.

Bridging patients in refractory cardiogenic shock with the Impella 5.0 has shown excellent hemodynamic support, and the potential for both native heart recovery and the reversal of end organ.[6,7] In a recent report by Seese *et al.*,[19] 57 patients undergoing a direct bridge from an Impella 5.0 to OHT had survival of 96.5% at 30-days, 93.8% at 90-days, and 90.3% at 1-year follow-up.

Finally, acute percutaneous mechanical support is a useful tool in performing complex and high-risk cardiac intervention and cardiac surgery.[20–24] The RECOVER I study sought to address the unmet need of supporting postoperative cardiac surgery patients in need of additional circulatory support.[9] The study was a prospective, single-arm, clinical trial designed under U.S. FDA guidance to investigate the safety and feasibility of Impella support (Impella 5.0 and LD devices) in 16 patients experiencing PCCS or LCOS after cardiac surgery. The results demonstrated that the use of the Impella 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. Given the high mortality of PCCS,[25] there has been a gradual trend to consider planned, rather than reactive, temporary mechanical support with Impella. Small series have shown Impella 5.0 to be an effective strategy to bridge-to-recovery following high-risk and low LVEF cardiac surgery. potentially avoiding the development of PCCS or LCOS.[15,26] Ranganath *et*

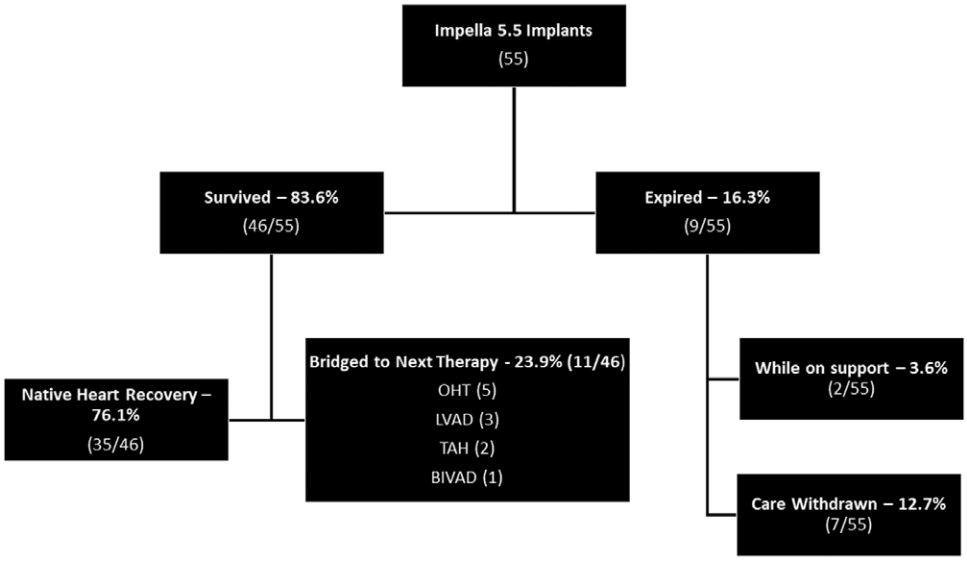

Figure 5. Survival status of all patients. OHT, orthotopic heart transplantation; LVAD, left ventricular assist device.

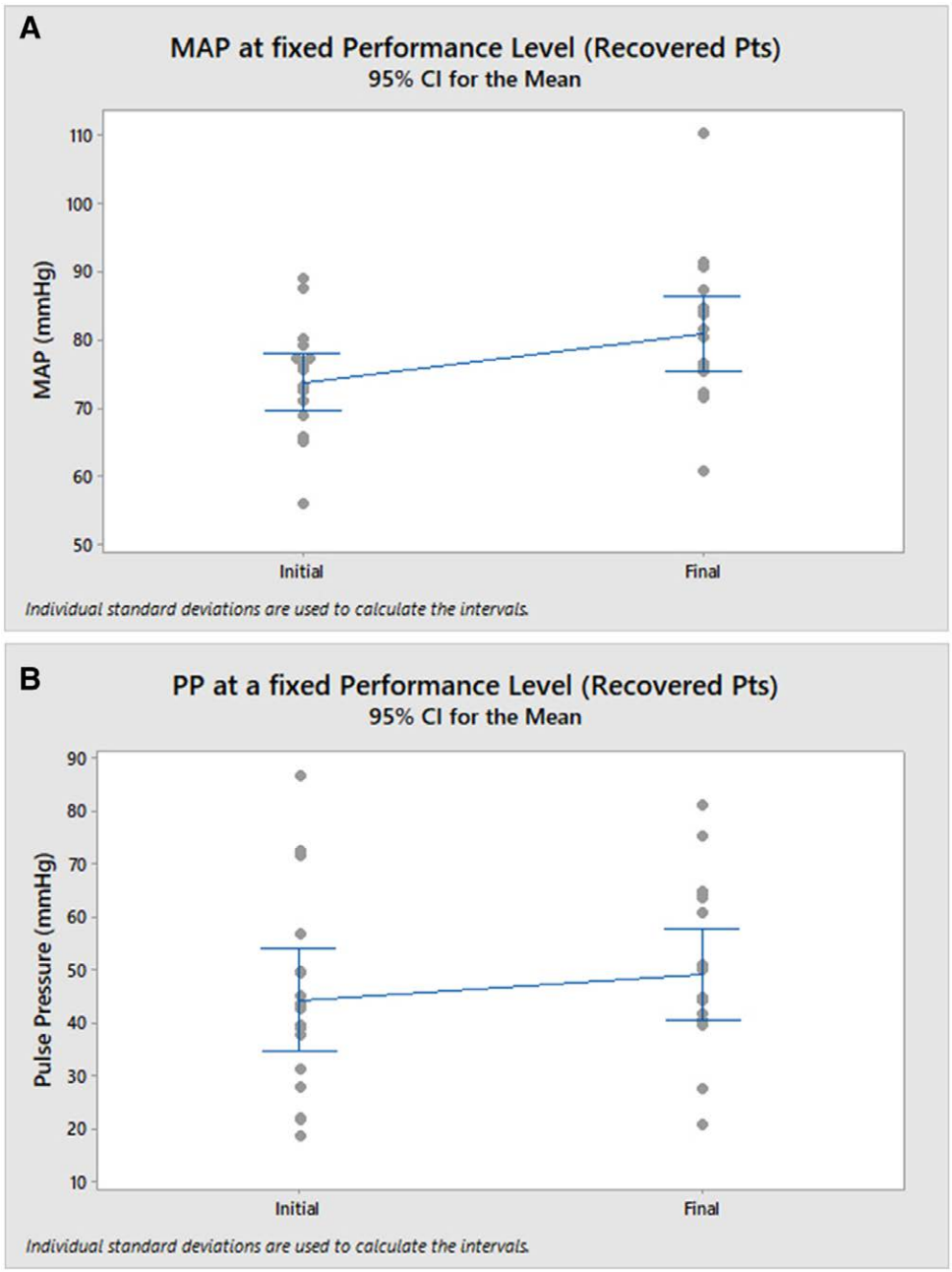

Figure 6. (**A**) Mean arterial pressure (MAP) and (**B**) pulse pressure (PP) at fixed performance level in 17 recovered patients. full color online

al. reviewed their early experience of 13 patients undergoing high-risk CABG with an LVEF of <30% and a mean predicted risk of mortality of 4.6%.[26] Using the Impella "prophylactically" in these patients yielded no postoperative myocardial infarctions or death, and more than 60% of the patients were extubated within 48 hours.

In comparison to the Impella 5.0, the Impella 5.5 has several improvements that address deliverability, durability and patient management. There is no pigtail on the Impella 5.5 to allow for longer implant duration without the concern of potential thrombus accumulation. The absence of the pigtail also makes steering and torqueing the pump within the LV easier and without the risk of catching mitral valve chordae tendineae. The cannula of the Impella 5.5 is more rigid than the Impella 5.0 and this change has resulted in improved catheter pushability and less buckling. Additionally, the motor section of the system is 45% shorter, allowing for easier maneuvering, particularly in challenging vascular anatomy. Improved deliverability as measured by procedural time and success appears to be supported with this early experience.

Although this report is an early experience in a heterogeneous patient population, it is encouraging that 83.6% of patients survived to explant with 76.1% of these patients recovering native heart function. The main findings can be summarized as follows: (a) the system can be implanted with a high degree of success down to an axillary artery diameter of

6 mm; (b) the system is safe and effective for a variety of challenging clinical scenarios including all forms of cardiogenic shock, ECMO unloading and weaning, acute decompensated heart failure, and perioperative high-risk PCI and cardiac surgery; and (c) clinical outcomes to explant are very encouraging with a favorable risk/benefit profile.

Limitations

This is an early experience in a heterogeneous patient population and additional data are needed to evaluate clinical outcomes in specific patient cohorts. Although the data for Impella 5.5 are being collected prospectively, this is a retrospective study and subject to the limitations and biases associated with it. The data provided in this manuscript were obtained from a manufacturer's quality database that gathers information from implant to explant only. Therefore, important baseline characteristics, such as risk factors, the degree of cardiogenic shock, and timing of implant were not captured. Given the observational design of the study, centers were not mandated to perform specific imaging tests, invasive procedures, such as as a right heart catheterization or routinely check certain lab values, such as plasma-free hemoglobin (PfHb). However, it is standard practice to obtain a level when there is clinical suspicion of hemolysis. Capturing baseline data and longer-term clinical outcomes of Impella 5.5 are currently the focus of an ongoing prospective study.

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