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Temporary Left Ventricular Assist Device Through an Axillary Access is a Promising Approach to Improve Outcomes in Refractory Cardiogenic Shock Patients

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Abstract

Cardiogenic shock (CS) causes significant morbidity and mortality and such patients can deteriorate rapidly. Temporary left ventricular assist devices (LVADs) are a promising approach to manage these patients. The following is a case series in which patients stabilized with a temporary LVAD for CS improvement were analyzed retrospectively. Between June 2011 and January 2014, 15 patients received temporary devices through an axillary approach (mean age: 53 ± 15, 93% male). Mean survival time was 317.8 ± 359.5 days (range: 6–936 days). During support there were no major bleeding events, infectious complications at the axillary access site, upper extremity edema, or emboli. The most of the patients recovered from CS (93%) were mobilized (67%) and were extubated (73%) while on temporary device support. Median times to extubation, intensive care unit discharge, and discontinuation of inotropic medications were: 1.63, 18, and 15 days, respectively. Four patients recovered to no device support and five received a long-term LVAD, all of whom remain alive. Therefore, implantation of a temporary LVAD through an axillary approach is a promising therapy for improving outcomes in patients needing mechanical circulatory support as a bridge to recovery or a definitive LVAD.

Keywords

mechanical circulatory support; cardiogenic shock; left ventricular assist device; axillary access; minimally invasive

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In patients with refractory cardiogenic shock (CS) that do not respond high doses of inotropic medications and intraaortic balloon pump counter-pulsation (IABP), therapies include support with extracorporeal membrane oxygenation (ECMO) or nondurable mechanical circulatory assistance. Crash-and-burn and acutely deteriorating CS patients (INTERMACS level 1 and 2) are a significant challenge for clinicians because they present acutely. Patients with low INTERMACS scores have a high mortality rate after permanent left ventricular assist devices (LVAD) placement, which leaves experts unsure about using long-term LVADs in this cohort.¹ Reliable short-term support is necessary while these patients are evaluated medically, socially, and financially for LVAD placement. This type of support should provide adequate circulation, avoid multiple chest entries and infection risks, and free the patient for mobilization and physical recovery. Previous reports with peripherally implantable LVADs in CS present greater than 50% early and 6 month mortality rates and increased risks of various morbidities.^{2,3} However, improved device management and implantation techniques could reduce these mortality rates.

The following discusses 15 patients who underwent salvage/emergent implantation of a temporary LVAD *via* an axillary approach. The results from this study indicate that temporary LVAD implantation is a strategy for CS patients that could help decrease morbidity and mortality.⁴⁻⁶

Methods

The Institutional Review Board of Scott&White Clinic approved the conduct of this study.

Patients

Between June 2011 and January 2014, 15 patients at Baylor Scott and White Clinic in Temple, Texas received a temporary LVAD by an axillary approach for refractory CS. Patients included in this study were in refractory CS with an INTERMACS level of 1 or 2, who would have a high risk for mortality if they proceeded to long-term LVAD implantation in their current conditions. The cardiology and cardiothoracic surgery teams determined these patients would be best managed with a mechanical circulatory support device and the axillary approach was selected by the surgical team. All but one was male; mean age was 53 ± 13 years (**Table 1**). Reasons for CS included decompensated dilated cardiomyopathy, acute myocardial infarction, and postcardiotomy syndrome (**Table 1**). Fourteen patients were INTERMACS level 1 before the implantation of their Impella 5.0 device, and one was INTERMACS level 2 declining on three inotropes. Patients were on inotropes a mean of 3.1 ± 3.0 days with a mean of 2 ± 0.6 drips and on IABP a mean of 2.0 ± 2.0 days (**Table 2**). Mean predevice right atrial pressure was 19.9 ± 5.7 mm Hg and mean tricuspid annular plane systolic excursion (TAPSE) was 15.4 ± 3.4 . No patients had peripheral edema. Patients receiving an Impella 2.5 or CP alone or a nonaxillary approaches were excluded from this study.

Cardiogenic Shock Management

Patients in CS are evaluated for multiorgan function and neurologic compromise. If a patient has a cardiac arrest with ongoing CPR, they receive veno-arterial (VA) ECMO to maintain

neurologic stability. If patient is neurologically intact, temporary circulatory support by an axillary approach followed by VA ECMO termination is considered. If a patient has CS but is stable on IV inotropes, IABP is implanted in the catheter suite or intensive care unit (ICU), followed by advancement to temporary circulatory support by an axillary approach in the operating room if continued deterioration occurs. Surgery patients are considered for temporary circulatory support if weaning from cardiopulmonary bypass fails and the cardiac index drops below 2.2 L/min/m^2 on two inotropic drips and an IABP.

Devices

Fifteen patients received an Impella 5.0 (Abiomed, Danvers, MA), all of whom were intubated and receiving inotropic therapy, one of whom previously had an Impella 2.5 (Abiomed, Danvers, MA) and 10 of whom had an IABP. No patients received VA ECMO before Impella 5.0 implantation. All patients received their device in the operating room where fluoroscopic guidance was available. Fourteen patients received their device by a right axillary approach and one had a left axillary approach. An 8 mm hemishield graft at least 20 cm in length was used for tunneling. Once the device was deployed, the distal end of the graft was snared to prevent blood loss. Transesophageal echocardiography and fluoroscopy were used to confirm placement and the graft was shortened and secured under the skin to avoid infections. Device speed was 7–9 rpm, providing 4–5 L/min flow in patients' immediate shock period. All had nonpulsatile flow postsurgically, demonstrating device dependency. Patients were anticoagulated when their Impella was in place, typically with heparin, and activated clotting time was maintained between 160 and 180 seconds. Five patients later received a HeartMate II (HMII; Thoratec, Pleasanton, CA) as definitive therapy after examination and approval by the Multi-disciplinary Heart Failure Team (including surgeons, cardiologists, social workers, financial coordinators, thoracic transplant and MCS coordinators, etc.).

Recovery

Recovery was defined as freedom from CS (cardiac index above 2.2 L/min/m^2 with systolic arterial pressure above 90 mm Hg with preserved multiorgan function) with or without a single inotrope (preferably milrinone), aortic opening with every heartbeat at Impella speeds 6, pulsatility on arterial tracing, and normal kidney and liver function tests.

Device Weaning

Patients were monitored by Swan-Ganz catheter. If the cardiac index exceeded 2.2, pump speed was decreased. If the cardiac index was greater than 2.2 with a pump speed of 3 rpm, the Impella was removed. Inotropes were weaned to a lower level so inotrope doses could be increased if necessary after device removal. Aortic valve opening and left ventricular contractility was checked by echocardiography before removal.

Outcomes

Primary outcomes included: 30 day and long-term patient survival and recovery of CS. Secondary outcomes were major bleeding, infections, time to extubation, mobility, time in the ICU, time on intravenous inotropes, and edema after Impella implantation. Patients'

creatinine, blood urea nitrogen, bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase, hemoglobin, hematocrit and lactate levels were followed for 14 days to assess organ recovery. Hemodynamic parameters were collected.

Echocardiographic Data

Echocardiography was performed within 8 hours before device insertion, 8 hours after device implantation, and 8 hours after device explantation and read by independent echocardiographers.

Statistics

Measurements were expressed as mean or median with standard deviation or range and outcome measures are means with standard errors of the mean. Mortality rates were tracked using a Kaplan–Meier curve. ANOVA and two-tailed t tests were used to evaluate biologic parameters and echocardiography respectively with a $p < 0.05$ considered significant.

Results

Outcomes

Patients had their Impella 5.0 devices implanted for a median of 9 days (range 5–30). Reasons for explantation included: non-sustained ventricular fibrillation during device therapy resulting in death ($n = 2$), withdrawal of support ($n = 2$), bridging to HMII LVAD ($n = 3$), and cardiac recovery ($n = 8$). Two of the patients who initially recovered later received an HMII roughly 3 and 9 months after implantation of their Impella 5.0. Two of the recovered patients later died from pneumonia, decompensation, and gastrointestinal tract bleeding, likely stress-induced gastritis, noted 6 days after Impella removal (**Table 3**). Only one patient experienced device failure, wherein output decreased, monitoring markers were unreliable and data follow-up was lost, and the device was unable to keep up with the patient's oxygen demands. This patient's device was replaced 6 days after the initial implantation.

Of the 15 patients receiving a temporary LVAD, 11 patients (73%) were alive after 30 days and 10 patients survived to be discharged from the hospital (67%). One of these patients died of pneumonia 88 days after his initial discharge and nine patients remain alive (60%). Mean survival time after Impella 5.0 implantation was 317.8 ± 359.5 days, with a range of 6–936 days (**Figure 1**).

On echocardiogram, Impella use for longer than 6 hours appears effective in assisting the left ventricle and maintaining the circulatory support. Only one patient had evidence of new mild aortic valve regurgitation after the removal of Impella. In addition, ejection fractions and other hemodynamic parameters improved both during LVAD support and after removal compared with before initiation (**Figure 2**). Ejection fractions improved from a mean of $17.9 \pm 2.7\%$ before Impella implantation to a mean of $35.6 \pm 3.4\%$ after Impella removal (**Figure 2A**). Furthermore, other hemodynamic parameters improved to a statistically significant degree in this cohort both during Impella support and after Impella removal compared with before Impella initiation. Cardiac output increased (Pre-Impella: 4.3 ± 0.3 L/min, with

Impella: 6.7 ± 0.3 L/min; $p < 0.0001$ postexplantation: 7.8 ± 0.8 L/min; $p = 0.0003$) and cardiac indexes improved from an initial mean of 1.9 ± 0.1 L/min/m² to 3.4 ± 0.2 L/min/m² with Impella ($p < 0.0001$) and 3.9 ± 0.4 L/min/m² after explantation ($p = 0.0001$; **Figure 2B and C**). Furthermore, pulmonary pressure measurements improved. Pulmonary artery systolic pressure decreased from a mean of 47.9 ± 2.9 mm Hg before Impella and decreasing to 36.8 ± 2.3 mm Hg with Impella ($p = 0.0069$) and 30.5 ± 3.4 mm Hg after explantation ($p = 0.0013$; **Figure 2D**). Mean pulmonary artery diastolic pressure decreased from 29.8 ± 1.8 mm Hg before Impella to 21.4 ± 1.4 mm Hg with Impella ($p = 0.0011$) and was 12.4 ± 1.6 mm Hg after Impella explantation ($p < 0.0001$; **Figure 2E**). Pulmonary capillary wedge pressure was also reduced on Impella support from a mean of 28.0 ± 1.4 mm Hg before initiation to a mean of 19.3 ± 1.4 mm Hg with Impella ($p = 0.0003$) and 11.6 ± 1.2 mm Hg after Impella removal ($p < 0.0001$; **Figure 2F**).

After receiving their Impella 5.0, patients remained intubated for a median of 1.63 days (range: 5.8 hours–14.3 days). Median ICU stay length was 18 days (range: 7–34 days). Patients were on inotropic medications for a median of 15 days (range: 0–23 days) after receiving their Impella device (**Table 2**). The first two patients were kept on bed rest but early mobilization was attempted in the remaining 13 patients. Mobilization to chair or active ambulation was achieved in 10 out of these 13 patients (77%), an improvement which represents a unique approach to this patient population. Although supported with Impella, no patients developed arm edema as measured by physical exam and checking upper extremity pulses. Some clots in the static part of the Impella were noted on explantation but no patients had evidence of embolization, ischemic complications, or loss of device function. Furthermore, evidence of end-organ damage, such as blood urea nitrogen, creatinine, aspartate aminotransferase, ALT, and bilirubin decreased in these patients although these are not statistically significant (**Table 4**). Although the medians of some of these parameters, notably creatinine and ALT, were outside the normal range before Impella implantation, they begin improving immediately after Impella support and are in the normal range by day 10 after Impella insertion. None of these data reached statistical significance, however, because of the small number of data points. One Impella was implanted in a patient already receiving hemodialysis with the hope that recovery might be possible, but this patient did not survive. In addition, patients were able to have their devices removed without general anesthesia. Five (33%) of the patient cohort had their devices removed using local anesthesia without incurring any complications.

Continuation to Durable Support

Five patients received an HMII device. For patients who bridged directly to an HMII device upon explantation of their Impella in the operating room,³ wait time was 5–9 days. Two patients received a HMII at a later time, 85 and 248 days after the implantation of their Impella 5.0. All five patients receiving a HMII remain alive at present. Two of these patients under-went heart transplantation successfully.

A multidisciplinary team evaluated patients for LVAD at a heart failure core group meeting based on medical, social, and financial factors. Three patients were approved and bridged while on temporary device support. Of the remaining two patients, one was because of the

lack of financial support and the other was for medical reasons which both resolved over time. The other 10 patients did not bridge to a long-term LVAD.

Discussion

Acute CS occurs in 8–10% of ST-elevated myocardial infarctions and decompensation and escalation to INTERMACS crash-and-burn level is common in Stage D heart failure.⁷ Early CS mortality can be as high as 50% and early intervention may benefit patients declining on inotropic support.^{8,9} Although recent ACCS&AHA guidelines consider short-term mechanical circulatory support a Class IIa recommendation, optimal management remains unclear.¹⁰ In addition, deciding to pursue definitive care takes time. Furthermore, some patients who would recover and not require circulatory support might be subjected to unnecessary risks inherent in receiving and maintaining a long-term LVAD, whereas some found too sick during the bridging phase might be denied this life-prolonging therapy. In this study, these concerns are addressed by less invasive temporary device support.

Although the Impella 5.0 is approved for 6 hours, it often takes longer to stabilize CS patients.¹¹ This work adds to other evidence that Impella 5.0 is safe for stabilizing patients.^{6,12} End-organ function improves and patients can be extubated and ambulated, making them better candidates for advanced therapies and avoiding ventilator-associated pneumonia and adult respiratory distress syndrome.^{13,14} In addition, peripheral access avoids multiple chest entries, decreasing the chance of infections and other complications.¹⁵ If patients improve, it can be removed without reintubation, unlike many LVADs and central ECMO, which require general anesthesia. In addition, patients in this study were not ideal candidates for durable support before their temporary LVAD. Outcomes after surgery are better if the patients are more stable, not intubated, on less inotropic support, have higher INTERMACS scores, and are hemodynamically stable.¹⁶ Implantation of a temporary LVAD offers a strategy to improve these parameters and patients' surgical candidacy.

Current alternatives to Impella for temporary support include IABP, ECMO, and TandemHeart percutaneous LVAD. During the IABP-SHOCK II study, IABPs failed to reduce mortality for patients with acute MI complicated by CS, although the American College of Cardiology and American Heart Association Task Force does recommend their use.^{17,18} Extracorporeal membrane oxygenation trials have shown some promise, with one study reporting 30 day, 3 month, and 1 year survival rates of 51, 35, and 29%, respectively, although ECMO can lead to significant complications.^{19,20} The survival rates for the Tandem-Heart appear to be higher than ECMO or IABP. To evaluate the TandemHeart, one study including 117 patients demonstrated 30 day and 6 month mortality rates of 40.2% and 45.3% after percutaneous VAD therapy, which was inferior to our outcomes.^{2,21} During their short-term support, the TandemHeart group also had improved hemodynamic and biological parameters. However, several complications were reported, including a femoral artery dissection, groin hematomas, bleeding at the cannula site, limb ischemia, and high infection rates.^{2,21} Therefore, temporary LVAD by an axillary approach is equivalent or superior to other available mechanical support devices.

Other groups have also placed Impella devices for CS. In France, 20 patients received an Impella by either a left axillary or femoral artery approach for a mean of 14 days and five of these patients later received LVADs.⁶ Four out of five long-term LVAD recipients remain alive. In addition, extubation and mobilization were possible earlier and kidney and liver function tests improved with Impella. Another group from New Jersey implanted Impella devices in 47 CS patients, 8% of whom transitioned to a long-term LVAD.¹² Their insertion methods were: transthoracic end-to-side anastomosis (31 patients) and femoral or right axillary (six patients). Their complication rate was higher than in this study, including bleeding events and device malfunction, which may have improved with an axillary artery implantation approach. Their survival rate was comparable with ours, with a 63.8% survival rate at 1 year. Our study represents, to the best of our knowledge, the first attempt to consistently use an axillary approach to implant temporary LVADs in patients with CS. In addition, our survival rates, patient outcomes, and complication rates are comparable with other studies on LVAD use in CS.

Limitations in this study include small sample size, short duration of follow-up, and lack of control group. Given the severity of the condition of these patients, it is unethical to withhold care because of the high mortality rate without intervention. The patients included in this study were already receiving alternative therapies, including inotropic medications and IABP therapy, and were still worsening. Therefore Impella 5.0 was selected to lengthen life and help patients recover from CS. In addition, although patients treated with ECMO could serve as a control group, this hospital system uses ECMO for sicker patients, with more evidence of right heart or biventricular dysfunction, worse neurologic condition, and peripheral vascular disease. These patients are a poor comparison because their worse initial conditions could explain worse outcomes. Although a case series cannot definitively demonstrate the effectiveness of Impella, outcomes equivalent to or better than literature values indicates that this method of stabilization warrants more study.

Conclusions

When used in patients with acute CS, temporary LVADs improve outcomes by allowing organ recovery ambulation, and shortening the duration of ventilation, facilitating patient recovery or surgical candidacy.

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Figure 1. Patient outcomes. Kaplan–Meier curves demonstrating 30 day patient survival (A) and survival to date (B).

Figure 2.

Echocardiographic data. Before, with Impella, postexplantation. ** $p < 0.01$, *** $p < 0.001$, **** $p < 0.0001$. **A:** Ejection fraction. **B:** Cardiac output. **C:** Cardiac index. **D:** Systolic pulmonary artery pressure. **E:** Diastolic pulmonary artery pressure. **F:** Pulmonary capillary wedge pressure. Represented as means with standard error of the mean.

Table 1

Patient Demographics

Parameter	Outcome
Gender	14/15 (93%) male
Age	Mean: 53 ± 15, range: 20–70
Condition causing CS	Acute MI (n = 6), acute decompensated dilated cardiomyopathy (n = 7), postcardiotomy (n = 2)
INTERMACS score before Impella	1 (n = 14), 2 (n = 1)

CS, cardiogenic shock; MI, myocardial infarction.

Table 2

Hospital Course (Median [Range])

Parameter	Time in Days; Median(Range)
Pre-Impella inotrope dependence (n = 15)	2 (0–10)
Pre-Impella IABP (n = 10)	2 (<1–7)
Time with Impella	9 (5–30)
Post-Impella inotrope dependence	15 (0–23)
Post-Impella days to extubation	1.63 (0.24–14.28)
Post-Impella ICU stay length	18 (7–34)

IABP, intraaortic balloon pump counter-pulsation; ICU, intensive care unit.

Table 3

Major Causes of Death (n = 6)

Cause of Death	Number
Ventricular fibrillation	1
Multiorgan failure	1
Sudden death	1
Gastrointestinal bleeding	1
Support withdrawn	2

Table 4

Patient Biological Parameters Before and Immediately After Impella Implantation

Outcome: Median (Range)	Before	1 Day	3 Days	7 Days	10 Days	14 Days
BUN (mg/dl)	25 (23–55)	24.5 (16–50)	27.5 (16–50)	26.5 (8–72)	28.5 (8–116)	28 (8–105)
Creatinine (mg/dl)	1.46 (0.75–3.69)	1.18 (0.74–4.93)	1.02 (0.77–5.93)	1.08 (0.67–4.27)	1.05 (0.38–7.38)	0.87 (0.7–7.19)
Bilirubin (mg/dl)	1.6 (0.3–7.8)	1.5 (0.5–5.2)	1.5 (0.4–8.4)	2 (0.7–2.9)	1.3 (0.7–2.6)	1.2 (0.7–2.2)
AST (IU/L)	84 (17–901)	49 (34–182)	54.5 (25–6572)	47 (30–83)	37 (32–78)	34 (33–63)
ALT (IU/L)	363 (0–867)	66.5 (8–255)	55.5 (11–3688)	36 (12–70)	36 (12–105)	37 (26–56)
Hemoglobin (g/dl)	10.2 (8.9–16.1)	9.0 (7.5–15.4)	8.8 (7.6–12.5)	8.8 (7.6–11.0)	9.1 (8.2–10.4)	8.85 (7.1–10.3)
Hematocrit (%)	31.75 (25.9–47.0)	28.3 (22.2–43.6)	25.6 (21.7–36.9)	25.9 (23.4–32.1)	27.1 (24.4–29.9)	28.15 (20.3–31.3)
Lactate (mmol/L)	1.7 (1–9.8)	1.7 (0.8–7.6)	0.9 (0.8–2.4)	1.4 (0.9–3.7)	1.1 (0.6–3.5)	1.2 (0.5–2.3)

BUN, creatinine, AST, ALT, bilirubin, hemoglobin, hematocrit, and lactate were measured just before surgery as well as 1, 3, 7, 10, and 14 days after Impella implantation, medians are reported; n = 8–15 for each instance. *p* values nonsignificant.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BUN, blood urea nitrogen.