Ochsner Journal 16:210–216, 2016

Using the Minimally Invasive Impella 5.0 via the Right Subclavian Artery Cutdown for Acute on Chronic Decompensated Heart Failure as a Bridge to Decision

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Background: Outcomes of traditional mechanical support paradigms (extracorporeal membrane oxygenation, intraaortic balloon pump [IABP], and permanent left ventricular assist device [LVAD]) in acute decompensated heart failure have generally been suboptimal. Novel approaches, such as minimally invasive LVAD therapy (Impella 5.0 device), promise less invasive but equivalent hemodynamic support. However, it is yet unknown whether the outcomes with such devices support widespread acceptance of this new technology. We recently started utilizing the right subclavian artery (RSA) for Impella 5.0 implantation and report our early experience and outcomes with this novel approach.

Methods: A single-center retrospective review was performed of 24 patients with acute on chronic decompensated heart failure who received the Impella 5.0 via the RSA from June 2011 to May 2014. The device was implanted via a cutdown through an 8-mm vascular graft sewn to the RSA. The device was positioned with fluoroscopy and transesophageal echocardiography.

Results: The mean age of the patients was 51.29 years, and 75% were male. At implantation, all patients were mechanically ventilated on at least 2 inotropes with persistent cardiogenic shock, and 17 (70.8%) were on IABP support. Postimplantation, 21 (87.5%) tolerated extubation, and all 17 of the patients with IABPs tolerated discontinuation of IABP support. The reduction in the Model for End-Stage Liver Disease score preimplantation vs postimplantation was statistically significant (21.17 vs 14.88, P=0.0014), suggesting improvement in end organ function. A significant decrease was also seen in creatinine levels before and after implantation (2.17 mg/dL vs 1.50 mg/dL, P=0.0043). The endpoint of support included recovery in 6 patients (25.0%), permanent LVAD in 9 (37.5%), and heart transplantation in 2 (8.3%). Death occurred in 7 patients (29.2%) as a result of multisystem organ failure, infection, or patient withdrawal of care.

Conclusion: Minimally invasive LVAD therapy using the Impella 5.0 via the RSA cutdown is an attractive option in acute on chronic decompensated heart failure. Improvement in end organ function allows for transition to recovery or to advanced surgical therapies such as permanent LVAD and heart transplantation. Significant advantages to this approach include improved left ventricular unloading, lower anticoagulation need, and the potential for ambulation and physical therapy.

Keywords: *Axillary artery, creatinine, heart-assist devices, minimally invasive surgical procedures, shock–cardiogenic*

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INTRODUCTION

Mechanical circulatory support in the setting of acute decompensated heart failure is typically associated with significant morbidity and mortality.[1-3] Adverse outcomes are often the result of further exacerbation of underlying end organ dysfunction typical of patients with chronic heart failure. Traditional treatment options include inotropes, intraaortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO), and permanent left ventricular assist device (LVAD). In the last few years, minimally invasive LVAD therapy with the Impella 5.0 (AbioMed Inc.) has emerged as a realistic option with growing experience of its use as a temporary support option.[4]

The Impella LVAD is a microaxial ventricular support device designed to provide temporary support in the setting of acute left ventricular failure. The device sits across the aortic valve with the inlet portion in the left ventricle and the outlet portion in the ascending aorta. The Impella device is

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designed for temporary support and is used as a bridge to decision, for myocardial recovery, or as a bridge to a long-term solution such as LVAD. Currently, the US Food and Drug Administration (FDA) has approved this device for 6 hours of support. In Europe, the CE-marked device is approved for short-term use of $\leq$10 days.

The Impella LVAD is available in 3 versions: 2.5, CP, and 5.0, providing support of 2.5 L/min, 3.5 L/min, and 5.0 L/min, respectively. The Impella 2.5 and Impella CP can be implanted in the cardiac catheterization laboratory via a percutaneously placed arterial sheath, while the Impella 5.0 requires a surgical cutdown. Most commonly, the femoral approach is utilized for implantation of this device, although interest in using the right subclavian artery (RSA) approach has been growing recently.

The objective of this study was to investigate the value of the Impella 5.0 implanted using the RSA approach for temporary mechanical circulatory support in patients with acute on chronic decompensated heart failure.

METHODS

After obtaining approval from the Ochsner Clinic Institutional Review Board, a retrospective review was performed of patients who underwent placement of the Impella 5.0 percutaneous LVAD for acute on chronic decompensated heart failure from June 2011 to May 2014.

All patients were being cared for in an intensive care unit and were diagnosed with acute cardiogenic shock on the basis of a cardiac index (CI) $<$1.8 L/min/m^2 as measured via a pulmonary artery catheter. At the time of implantation of the device, all patients were on at least 2 inotropes, were mechanically ventilated, and were still in persistent cardiogenic shock.

All patients underwent surgical implantation of the Impella 5.0 through the RSA via a surgical cutdown and placement of an 8-mm woven double velour vascular graft (Hemashield Platinum, Maquet Cardiovascular LLC) to the subclavian artery in an end-to-side fashion. The device was placed using standard techniques and positioned in the left ventricular outflow tract with the assistance of fluoroscopy and transesophageal echocardiography. The device was initiated at its lowest speed setting and slowly increased to maximal support with simultaneous down-titration of vasopressor and inotropic agents. Nursing staff trained in the use of the Impella 5.0 in conjunction with physicians and perfusionists provided bedside management of the device. Anticoagulation was initiated 6 hours after the surgical implantation and consisted of a continuous infusion of unfractionated heparin to achieve a partial thromboplastin time of 40-50 s.

To assess end organ function, we used the Model for End-Stage Liver Disease (MELD), a model initially developed to predict survival in patients undergoing transjugular intraheptic portosystemic shunts.[5] The United Network for Organ Sharing (UNOS) modification of the MELD score is a weighted sum of serum creatinine, bilirubin, and the international normalized ratio (INR).[6] Clinically, the score has been used to prioritize liver transplants[7] and to predict outcomes of patients with cirrhosis who undergo major surgeries.[8-11] However, because of the variables making up the score, the MELD is a marker of multisystem dysfunction and can be used to predict outcomes in other populations. We calculated the UNOS-modified MELD scores according to the following formula[6]:

$$\text{MELD} = 9.57(\log_e\text{creatinine}) + 3.78(\log_e\text{bilirubin}) + 11.2(\log_e\text{INR}) + 6.43$$

To assess hemolysis, we utilized the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) definition: a plasma-free hemoglobin value $>$20 mg/dL or a serum lactate dehydrogenase (LDH) level $>$2.5 times the upper limits of the normal range at the implanting center occurring after the first 72 hours postimplant and associated with clinical symptoms or findings of hemolysis or abnormal pump function. Major hemolysis requires the presence of one or more of the following conditions: hemoglobinuria (tea-colored urine), anemia (decrease in hematocrit or hemoglobin level that is out of proportion to levels explainable by chronic illness or usual post-VAD [ventricular assist device] state), hyperbilirubinemia (total bilirubin $>$2 mg/dL, with predominately indirect component), pump malfunction, and/or abnormal pump parameters.[12]

Demographics and operational data were compiled for presentation as mean $\pm$ standard deviation and also as percentages of the total sample group. The chi-square test was used to measure categorical outcome variables. Normality was tested for continuous variables using the Kolmogorov-Smirnov test. Because of our small sample size and the nonparametric distribution of continuous data, the Wilcoxon signed-rank test was used to compare differences in preimplantation and postimplantation variables. Kaplan-Meier methods were used to estimate the survival function for this patient population. $P<0.005$ was considered statistically significant.

RESULTS

The mean age of the 24 patients included in this retrospective review was 51.29 years, and 75% were male. Other demographic characteristics are presented in Table 1. At implantation, all patients were mechanically ventilated and on at least 2 inotropes with persistent cardiogenic shock, and 17 patients (70.8%) were on IABP support.

The mean duration of support was 17.58 days (range 1-71 days). Postimplantation, 21 patients (87.5%) tolerated extubation, and all 17 of the patients with IABPs tolerated discontinuation of IABP support (100%). A significant reduction in MELD score preimplantation vs postimplantation (21.17 vs 14.88, P=0.0014) was seen, suggesting improvement in end organ function (Figure 1). Creatinine levels (Figure 2) significantly decreased (2.17 mg/dL vs 1.50 mg/dL, P=0.0043). Liver function improved (Figure 2); however, the improvement in bilirubin was not statistically significant.

Postoperative outcomes are presented in Table 2.

Three complications were related to surgical implantation. One patient suffered from a temporary brachial plexopathy that resolved. Another patient developed a pectoral hematoma that was identified at the time of explant. Another patient had an embolic stroke at the time of explant and experienced full recovery.

All patients developed some level of hemolysis as reflected by elevated serum LDH levels; however, no patient had hemolysis significant enough to mandate discontinuation of the device.

Table 1. Demographic Characteristics of Patients Supported With the Impella 5.0 (n=24)

Characteristic	Value
Mean age, years	51.29 ± 13.85
Males, %	75
Mean body mass index	27.53 ± 5.88
Diabetes, n (%)	9 (37.5)
Lung disease, n (%)	5 (20.8)
Cerebrovascular accident, n (%)	2 (8.3)
Mean ejection fraction, %	11.46 ± 3.12
Diagnosis, n (%)	
Ischemic cardiomyopathy	14 (58.3)
Idiopathic cardiomyopathy	5 (20.8)
Postpartum cardiomyopathy	2 (8.3)
Drug-induced cardiomyopathy	1 (4.2)
Viral cardiomyopathy	1 (4.2)
Valvular cardiomyopathy	1 (4.2)
Inotropic support, n (%)	24 (100)
Mechanical ventilation, n (%)	24 (100)
Intraaortic balloon pump, n (%)	17 (70.8)
Mean left ventricular end diastolic dimension, mm	67.71 ± 10.98 (range, 39-87)

The endpoint of support included recovery in 6 patients (25.0%), permanent LVAD in 9 patients (37.5%), and heart transplantation in 2 patients (8.3%), yielding an overall bridge to success rate of 70.8% (17/24). Seven patients (29.2%) died; the causes of death are listed in Table 3. One death was not the result of the Impella device failure but was the result of withdrawal of care based on patient wishes. We chose to include this death as an event because we believe the inclusion more closely approximates real-world patient experience with the Impella device. Actuarial Kaplan-Meier survival for this group is shown in Figure 3.

The Impella 5.0 was successfully used as a bridge to transplant in 2 patients. Both patients are alive 2 years post–heart transplant.

DISCUSSION

This study reports our initial experience with the RSA approach for placement of the minimally invasive Impella 5.0 LVAD and demonstrates its efficacy in managing acute on chronic decompensated heart failure with an overall bridge to success rate of 70.8% (17/24) and a survival to discharge rate of 62.5% (15/24). Although ours is a small cohort, this step up in survival is significant compared to the traditional treatment modalities that have been associated with mortality rates in excess of 50%. Often, such patients are on maximal medical therapy, including multiple inotropes/vasopressors and an IABP. Unfortunately, such modalities of therapy are often insufficient, leaving

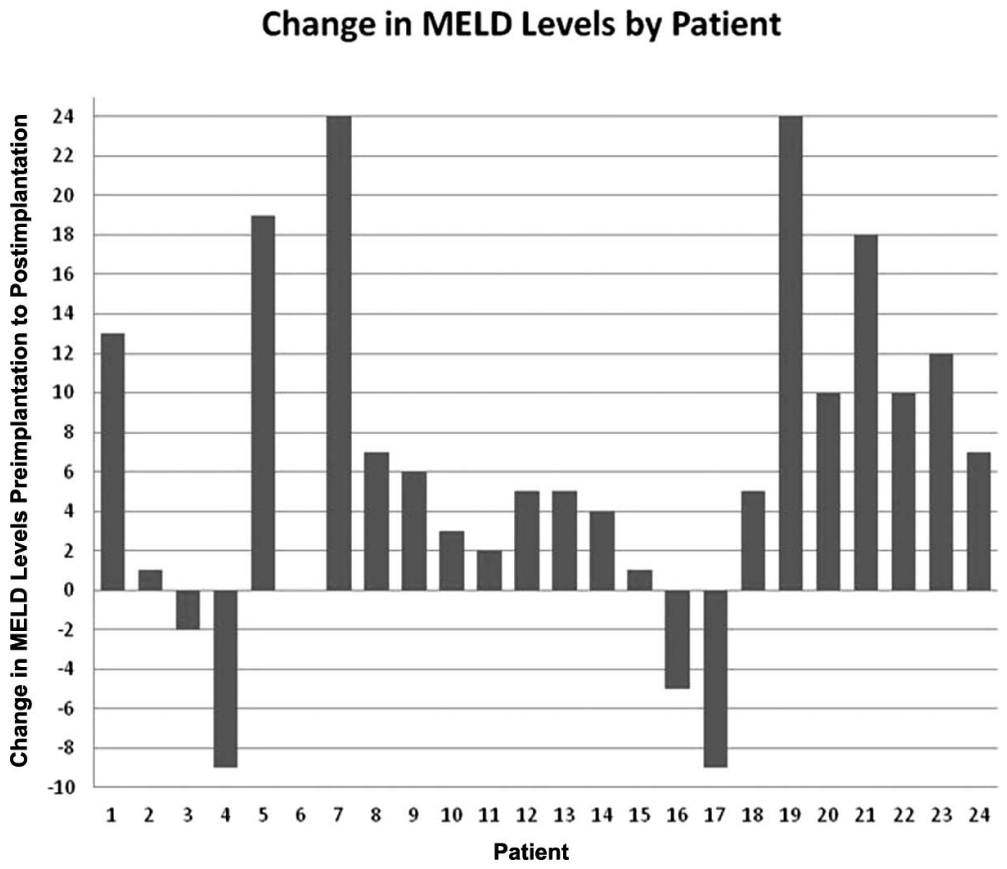

Figure 1. Changes in Model for End-Stage Liver Disease (MELD) score during duration of Impella 5.0 support.

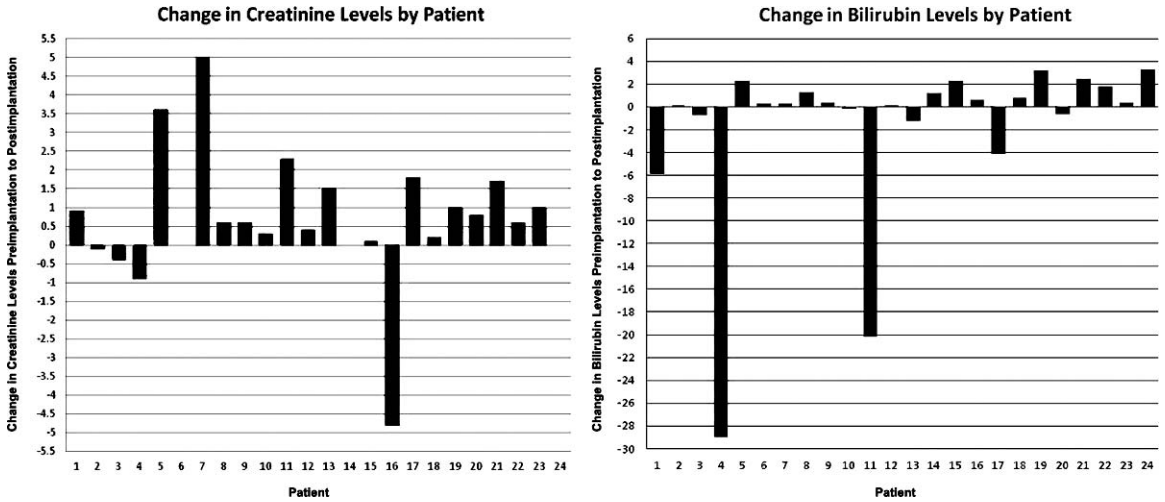

Figure 2. Changes in creatinine and total bilirubin levels during duration of Impella 5.0 support.

the patient with persistent cardiogenic shock and at significant risk for end organ failure.

Traditional treatment paradigms have focused on peripherally introduced approaches such as IABP, ECMO, or sternotomy approaches for LVAD placement. Peripheral approaches for IABP or ECMO typically are deployed via the femoral vasculature with the attendant risks of lower limb ischemia and often mandate the patient to be bed bound. Because of the usual debilitation in this population, as well as their compromised end organ function during the acute phase of decompensation, they are often deemed poor candidates for sternotomy approaches for LVAD placement. Ultimately, many succumb to multiorgan failure caused by ongoing shock. As we have demonstrated, the Impella 5.0 device mitigates many of these concerns when deployed via the RSA. Avoiding sternotomy and limb-threatening complications and providing higher levels of cardiac support (up to 5 L/min) are formidable advantages of this approach.

In addition to the Impella device, another available FDA-approved percutaneous LVAD therapy is the TandemHeart System (CardiacAssist, Inc.). This device is a continuous-flow centrifugal pump, capable of delivering flows of 3.5-4 L/min. TandemHeart utilizes a transseptal puncture for a cannula to be positioned in the left atrium to allow for direct unloading of the left heart. This system is typically inserted in the cardiac catheterization laboratory utilizing the femoral vessels for cannulation as a bridge to cardiac recovery or other treatment, such as an implantable LVAD. Although the TandemHeart has the ability to provide 3.5-4 L/min of flow, in the largest experience, which was reported by Kar et al, the mean flow rate was $<$3 L/min.[13] Additionally, the TandemHeart requires femoral veins of adequate size and is also associated with limb-related complications. Two randomized trials comparing the TandemHeart to IABP demonstrated superior improvement in hemodynamics with the TandemHeart but also higher limb complication rates.[14,15] Furthermore, the need for specialized personnel to perform the transseptal puncture for placement of the left atrial cannula and the potential for left atrial thrombus formation and stroke create significant disadvantages.

At our institution, we have utilized the Impella 5.0 as the device of choice for patients with acute decompensated heart failure. All of the patients in this series were critically sick as reflected by their MELD scores. We utilized the MELD score as a marker for end organ function as it has been shown to be a predictor of adverse events in patients undergoing VAD support.[16,17]

At the time of presentation, most of our patients were in extremis with declining end organ function and a mean MELD score of 21.17. After implantation of the Impella 5.0 device, we noticed significant stabilization of hemodynamics, decreasing inotropic dependency, and improvement in

Table 2. Postoperative Outcomes of Patients Supported With the Impella 5.0 (n=24)

Characteristic	Result
Extubated, n (%)	21 (87.5)
Intraaortic balloon pump removed, n (%) (n=17)	17 (100)
Endpoint of support, n (%)	
Recovery/device weaned	6 (25.0)
Permanent left ventricular assist device	9 (37.5)
Heart transplantation	2 (8.3)
Death on device	7 (29.2)
30 days' survival, n (%)	16 (66.7)
Survival to discharge, n (%)	15 (62.5)

Table 3. Causes of Death for Patients Supported With the Impella 5.0

Patient	Days of Support	Cause of Death
1	12	*Klebsiella pneumoniae*
2	9	Patient withdrew care
3	25	*Pseudomonas* pneumonia
4	6	Persistent shock
5	16	Renal failure
6	25	*Candida* bacteremia
7	10	Ventricular arrhythmia

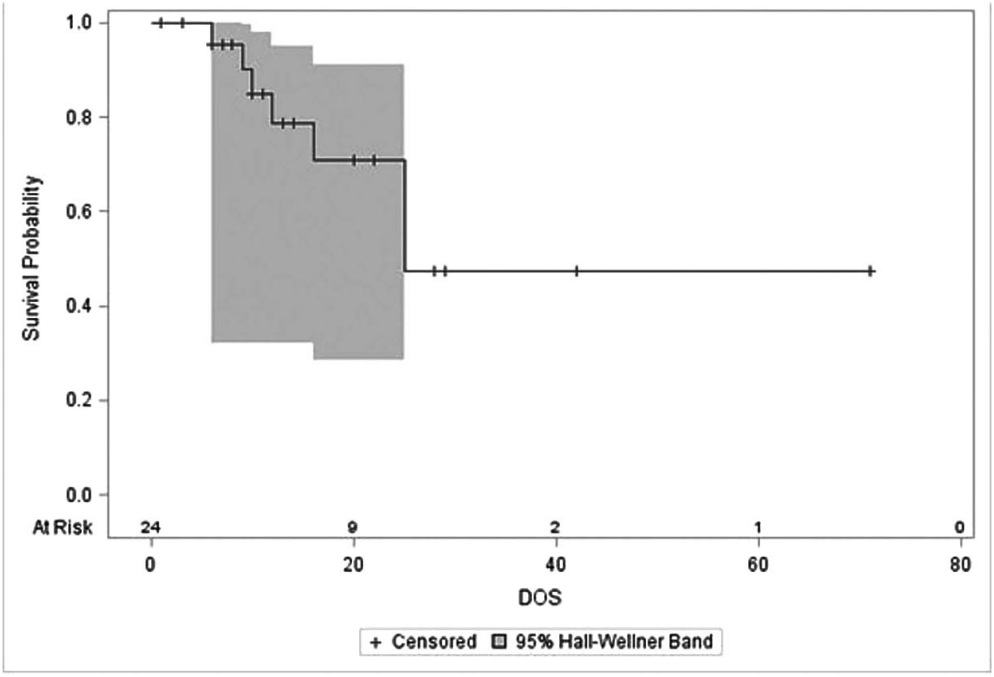

Figure 3. Kaplan-Meier survival curve. DOS, duration of support.

end organ function that were reflected by a reduction in the MELD score to a mean of 14.88. This difference was statistically significant in our analysis.

In the Bonde et al study, such a drop in MELD score equated to a 21% mortality improvement and a 15% and 18% improvement in the risk of respiratory failure and renal dysfunction, respectively, post-LVAD implant.[16]

Although improvement in hemodynamic parameters can be expected and is often seen after institution of temporary mechanical circulatory support, these changes are only relevant if they translate to improvement in end organ function. For this reason, in our practice, we have focused less on the improvement in the hemodynamics after the implantation of the device and more on how those hemodynamic changes impact end organ function as measured by the MELD score.

Creatinine levels before and after Impella 5.0 support show a statistically significant improvement in renal function. Multiple studies have demonstrated renal dysfunction as a risk factor for morbidity and mortality with the use of LVADs. Sandner et al demonstrated a significant decrease in survival in patients who progress to renal failure after implantation of a permanent LVAD.[18] This finding is even better demonstrated in the INTERMACS presentation on predicting major outcomes after mechanical circulatory support device implantation (Figure 4).[19] An extremely important highlight of this study shows that an improvement in renal function before implantation of a permanent device and in transplant patients leads to a much better survival than the usual anticipated survival in patients with poor renal function.

To our knowledge, no studies have demonstrated that strategies directed at reducing the MELD score prior to definitive management of acute decompensated heart failure can improve postoperative outcomes. Our observation, while not a direct comparison, provides a glimpse at the efficacy of this approach.

Indeed, 87.5% of our patients supported with the Impella 5.0 were extubated, and 100% of them had their IABPs removed. Because we utilized the axillary artery approach rather than the femoral approach, many of these patients were able to sit up and perform physical therapy (Figure 5) as well as involve themselves in future decision-making for permanent therapy options such as implantable device placement or transplantation. The use of the Impella 5.0 as a support to transplant needs further study.

With the RSA technique, we noticed low complication rates. Two patients had device migration requiring repositioning at the bedside utilizing echocardiography. In our experience, the axillary approach provides a more stable platform from a device migration standpoint than Impella devices placed femorally. One patient had a temporary brachial plexopathy that resolved completely within a few weeks. One patient developed a pectoralis major hematoma that was identified and evacuated at the time of explant. The patient had a full recovery with no underlying muscle weakness. One patient suffered an embolic stroke at the time of permanent LVAD placement. This patient had been supported with the Impella 5.0 for 42 days before placement of a HeartMate II LVAD (Thoratec Corporation). The stroke was identified within 2 hours of implant, and the patient underwent a successful interventional radiology–guided clot removal from the left middle cerebral artery bifurcation. He subsequently made a complete recovery.

In our practice, we have not followed LDH levels just to make a decision about discontinuation of the device; rather we focus on whether hemolysis resulted in any drop in hemoglobin requiring blood transfusion or if hemolysis impacted renal and hepatic function. We also agree with Bakker et al[20] that LDH is a nonspecific marker for hemolysis during the acute phase of cardiogenic shock,

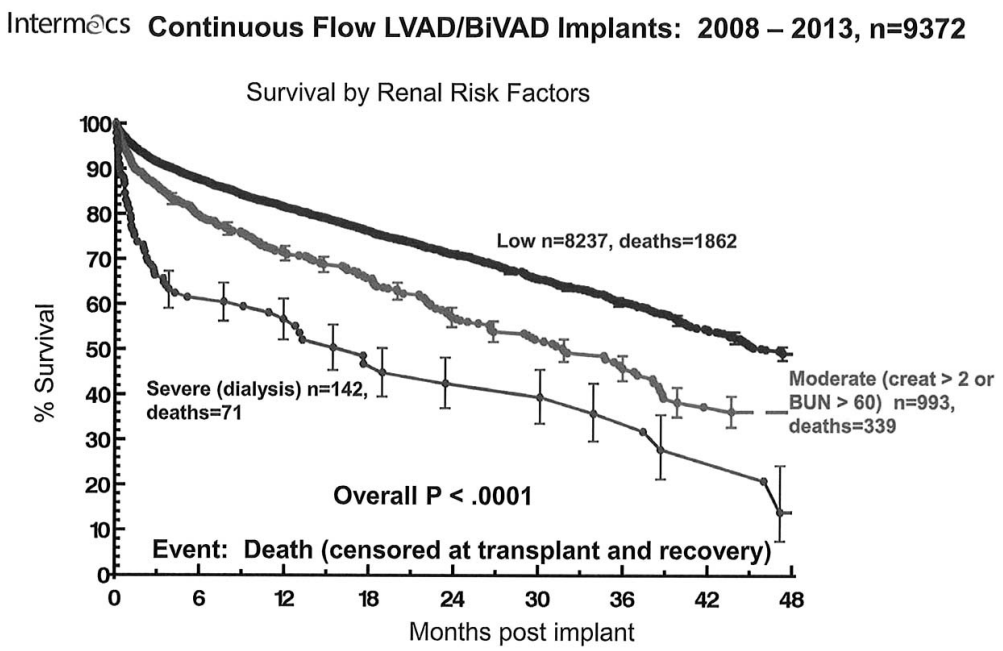

Figure 4. Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) continuous flow left ventricular assist device (LVAD) implants: survival by renal risk factors.
BiVAD, biventricular assist device; BUN, blood urea nitrogen; creat, creatinine.

and a better marker would have been plasma free hemoglobin measurements. However, because this test is a send-out for our institution, we have traditionally not used it.

This study has all the usual limitations inherent to a retrospective case series, including a small number of patients, the lack of defined parameters guiding management decisions, and no control group for comparison. Because of the small numbers, we were not able to statistically correlate reduction in MELD score with a specific improvement in survival. Further studies should focus on larger cohorts of patients with defined management guidelines, probably as part of a multicenter trial.

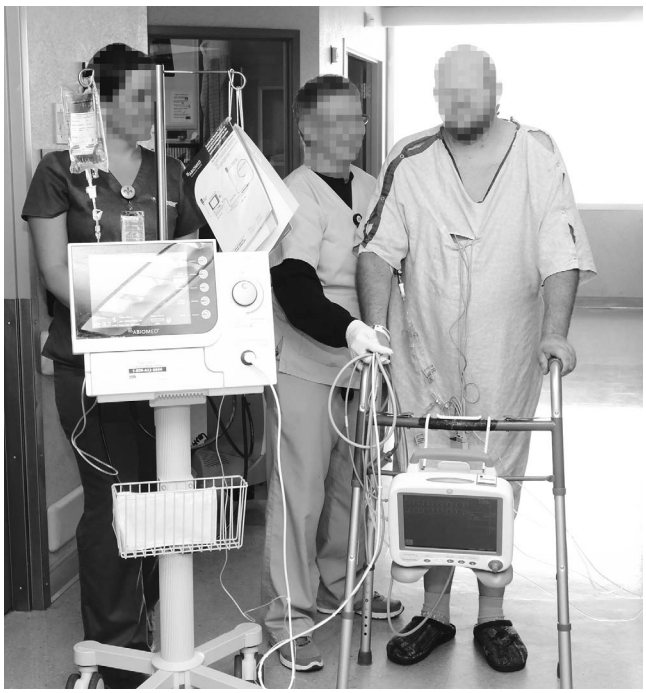

Figure 5. Patient with an axillary Impella 5.0 participating in physical therapy.

CONCLUSION

We believe the Impella 5.0 can be used as a bridge to decision for patients with acute on chronic decompensated heart failure. In this extremely sick patient population, significant hemodynamic improvement along with improvement in end organ function can be expected with a reduction in MELD score. We believe that this approach may optimize patients for durable support options such as LVAD and/or heart transplant. When compared to traditional platforms for mechanical circulatory support such as ECMO, the Impella 5.0 has many advantages including better left ventricle unloading, the potential to ambulate and perform physical therapy, better oral alimentation, and lower anticoagulation requirements. Above all, the device does not require specialized bedside personnel (ie, a perfusionist) for management, allowing for relative cost containment.

ACKNOWLEDGMENTS

Dr Aditya Bansal has received speaking honoraria from AbioMed Inc., Danvers, MA. Otherwise, the authors have no financial or proprietary interest in the subject matter of this article.

A poster presentation was made at the International Society for Heart and Lung Transplantation 33rd Annual Meeting, April 24-27, 2013, Montreal, Canada.

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