Temporary Mechanical Circulatory Support for Refractory Cardiogenic Shock Before Left Ventricular Assist Device Surgery

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Background—There are limited data on the role of temporary mechanical circulatory support (MCS) devices for cardiogenic shock before left ventricular assist device (LVAD) surgery. This study sought to evaluate the trends of use and outcomes of MCS in cardiogenic shock before LVAD surgery.

Methods and Results—This was a retrospective cohort study from 2005 to 2014 using the National Inpatient Sample (20% stratified sample of US hospitals). This study identified admissions undergoing LVAD surgery with preoperative cardiogenic shock. Admissions for other cardiac surgery and heart transplant were excluded. Temporary MCS was identified using administrative codes. The primary outcome was hospital mortality and secondary outcomes were hospital costs and lengths of stay in admissions with and without MCS use. In this 10-year period, 9753 admissions were identified with 40.6% requiring pre-LVAD MCS. There was a temporal increase in the frequency of cardiogenic shock associated with an increase in non–intra-aortic balloon pump MCS devices. The cohort receiving MCS had greater in-hospital myocardial infarction, ventricular arrhythmias, and use of coronary angiography. On multivariable analysis, older age, myocardial infarction, and need for MCS devices were independently predictive of higher in-hospital mortality. In 696 propensity-matched pairs, use of MCS was predictive of higher in-hospital mortality (odds ratio 1.4 [95% confidence interval 1.1–1.6]; P=0.02) and higher hospital costs, but similar lengths of stay.

Conclusions—in patients with cardiogenic shock bridged to LVAD therapy, there was a steady increase in preoperative MCS use. Use of MCS identified patients at higher risk for in-hospital mortality and greater resource utilization. (J Am Heart Assoc. 2018;7:e010193. DOI: 10.1161/JAHA.118.010193.)

Key Words: cardiogenic shock • critical care • destination therapy • left ventricular assist device • mechanical circulatory support

Heart failure is a leading cause of cardiovascular mortality and morbidity that currently affects 5.7 million American adults and is projected to increase by 46% in the next 15 years. Stage-D or end-stage heart failure constitutes <1% of the total heart failure burden, but is associated with the highest hospital costs and short-term mortality. Patients with end-stage heart failure had 75% 1-year mortality and nearly 100% 2-year mortality despite optimal medical therapy in the landmark Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure trial. Despite the advances in the medical therapy for heart failure, these patients frequently require more advanced therapy in the form of a durable left ventricular assist device (LVAD) or orthotopic heart transplantation. However, because of the critical shortage of donor hearts, LVAD therapy has been increasingly used in modern practice for end-stage heart failure as either destination...
Clinical Perspective
What Is New?
- In patients with cardiogenic shock bridged to left ventricular assist device therapy, there was a steady increase in preoperative mechanical circulatory support use.
- Use of mechanical circulatory support identified patients at higher risk for in-hospital mortality and greater resource utilization.

What Are the Clinical Implications?
- Careful study of risk factors and predictors of outcomes in this population is necessary to optimize clinical outcomes in this critically ill population.

Other researchers for purposes of reproducing the results or replicating the procedure. Please refer to Tables 1 and 2 for detailed International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes used in this study.

Study Database
The Nationwide/National Inpatient Sample (NIS) is the largest all-payer database of hospital inpatient stays in the United States. NIS contains discharge data from a 20% stratified sample of community hospitals and is a part of the Healthcare Quality and Utilization Project (HCUP), sponsored by the Agency for Healthcare Research and Quality. Information regarding each discharge includes patient demographics, primary payer, hospital characteristics, principal diagnosis, up to 24 additional secondary diagnoses, and procedural diagnoses. No institutional review board approval or informed consent was sought because of the publically available de-identified data set used in this research.

Study Population, Variables, and Outcomes
Using the HCUP-NIS data from 2005 to 2014, a retrospective cohort of admissions including patients >18 years undergoing LVAD placement (ICD-9-CM 37.66 in the primary procedure field) were included. Since the ICD-9-CM codes were re-defined in 2005 to distinguish between permanent MCS devices (ICD-9-CM 37.66) and nonimplantable paracorporeal devices (ICD-9-CM 37.62 and 37.65), procedures performed before 2005 were excluded from this study. Preoperative cardiogenic shock was identified using an ICD-9-CM code of 785.51 timed using the date of LVAD and date of temporary MCS insertion. Cardiogenic shock, per the ICD-9-CM classification, was defined as shock resulting from diminution of cardiac output in heart disease, shock resulting from primary failure of the heart in its pumping function, as in myocardial infarction, severe cardiomyopathy, or mechanical obstruction or compression of the heart or shock resulting from the failure of the heart to maintain adequate output. Validation studies have shown a specificity of 99.3%, a sensitivity of 59.8%, a positive predictive value of 78.8%, and a negative predictive value of 98.1% for the ICD-9-CM code 785.51 to identify cardiogenic shock. Admissions for orthotopic heart transplants (ICD-9-CM 37.5, 37.51, or 33.6), valve repair (ICD-9-CM 35.10–35.14), valve replacement (35.20–35.28), and bypass surgery (36.1–36.2) were excluded. Short-term MCS was defined using ICD-9-CM codes for IABP (ICD-9-CM 37.61), percutaneous MCS (Impella/TandemHeart) (ICD-9-CM 37.68), nonpercutaneous MCS (ICD-9-CM 37.60, 37.62, 37.65), extracorporeal membrane oxygenation (ECMO) (ICD-9-CM 39.65), and percutaneous cardiopulmonary support (ICD-9-CM 39.66).

Material and Methods
The data used for this study are publicly available with the Agency for Healthcare Research and Quality. The data, analytic methods, and study materials have been made available to

therapy or bridge-to-transplant. LVADs are used in 15% of patients with cardiogenic shock, but the use of LVADs in patients with ongoing cardiogenic shock is associated with higher postimplant mortality as noted in the recent report from the INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support). Despite the advances in cardiovascular medicine, patients with INTERMACS Class 1 (critical cardiogenic shock) continue to have a mortality of 35% to 45% without LVAD therapy. In addition to optimal medical therapy with high-dose vasopressors and inotropes, these patients frequently require temporary mechanical circulatory support (MCS) devices for hemodynamic stabilization. Historically, the intra-aortic balloon pump (IABP) was the most commonly used temporary device; however, the advent of newer devices providing more robust circulatory support has resulted in a paradigm shift in modern practice. The role of temporary MCS has been studied extensively in cardiogenic shock in the setting of acute coronary syndromes and as an adjunct to high-risk intervention. The clinical profiles and outcomes of patients with cardiogenic shock needing preoperative MCS before LVAD surgery are infrequently reported. This study sought to evaluate the characteristics of patients admitted with cardiogenic shock who were bridged to LVAD therapy with and without the use of temporary MCS. The primary outcome was in-hospital mortality and secondary outcomes included trends, hospital costs, and lengths of stay associated with admissions with and without the use of temporary MCS.
Table 1. Baseline Characteristics of Patients With and Without MCS

| Variable                              | MCS (n=3958) | No MCS (n=5795) | Overall (n=9753) | P Value |
|---------------------------------------|--------------|-----------------|------------------|---------|
| Age, y                                | 53.3±0.5     | 55.9±0.4        | 54.0±0.3         | <0.001  |
| Female sex                            | 23.8         | 24.8            | 24.4             | 0.23    |
| Race                                  |              |                 |                  | <0.001  |
| White                                 | 57.0         | 57.5            | 57.3             |         |
| Nonwhite                              | 36.5         | 29.4            | 32.3             |         |
| Missing                               | 6.5          | 13.1            | 10.4             |         |
| Cardiac morbidity during admission    |              |                 |                  |         |
| Myocardial infarction                 | 25.1         | 13.4            | 18.2             | <0.001  |
| Coronary angiography/percutaneous coronary intervention | 23.6 | 15.6 | 18.9 | <0.001 |
| Ventricular tachycardia/fibrillation  | 14.4         | 7.2             | 10.1             | <0.001  |
| Pathogenesis                          |              |                 |                  |         |
| Acute myocardial infarction           | 25.1         | 13.4            | 18.2             | <0.001  |
| Heart failure                         | 94.5         | 93.7            | 94.0             | 0.09    |
| Acute myocarditis                     | 3.3          | 1.6             | 2.3              | <0.001  |
| Charlson Comorbidity Index            |              |                 |                  | 0.02    |
| 0–1                                   | 30.1         | 31.2            | 30.8             |         |
| ≥2                                    | 69.9         | 68.8            | 69.2             |         |
| Primary expected payer                |              |                 |                  | <0.00   |
| Nonprivate insurance                  | 51.5         | 55.1            | 53.6             | 1       |
| Private insurance                     | 48.5         | 44.9            | 45.8             |         |
| Median household income category for zip code |          |                 |                  | <0.001  |
| 0–25th percentile                     | 24.3         | 25.8            | 25.7             |         |
| 26th–50th percentile                  | 25.2         | 25.2            | 25.2             |         |
| 51st–75th percentile                  | 22.0         | 25.7            | 24.2             |         |
| 76th–100th percentile                 | 26.8         | 21.9            | 23.9             |         |
| Hospital bed size                     |              |                 |                  | 0.36    |
| Small                                 | 0.9          | 1.2             | 1.1              |         |
| Medium                                | 9.6          | 10.0            | 9.9              |         |
| Large                                 | 89.5         | 88.7            | 89.0             |         |
| Urban location                        | 99.6         | 99.8            | 99.8             | 0.10    |
| Teaching hospital                     | 96.4         | 96.8            | 96.6             | 0.35    |
| Hospital region                       |              |                 |                  | <0.001  |
| Northeast                             | 19.4         | 14.6            | 16.5             |         |
| Midwest                               | 18.9         | 23.9            | 21.9             |         |
| South                                 | 26.5         | 23.5            | 24.7             |         |
| West                                  | 12.1         | 16.6            | 14.8             |         |
| Weekends admission                    | 17.9         | 13.9            | 15.5             | <0.001  |
| Obesity                               | 10.8         | 12.8            | 12.0             | 0.003   |
| Hypertension                          | 34.7         | 37.9            | 36.6             | 0.002   |
| Diabetes mellitus, type 2             | 24.0         | 28.3            | 26.6             | <0.001  |
| Smoking                               | 4.6          | 4.4             | 4.5              | 0.61    |

Continued
Table 1. Continued

| Variable                        | MCS (n=3958) | No MCS (n=5795) | Overall (n=9753) | P Value |
|--------------------------------|--------------|----------------|-----------------|---------|
| Coronary artery disease        | 34.2         | 34.5           | 34.4            | 0.78    |
| Family history of coronary artery disease | 2.0         | 2.2            | 2.1             | 0.37    |
| Previous myocardial infarction | 8.6          | 11.6           | 10.4            | <0.001  |
| Previous percutaneous coronary intervention | 7.1          | 6.8            | 6.9             | 0.64    |
| Previous coronary artery bypass grafting | 5.2          | 8.1            | 6.9             | <0.001  |
| Previous cardiac arrest        | 1.3          | 1.0            | 1.1             | 0.10    |
| Atrial fibrillation            | 35.5         | 38.1           | 37.1            | 0.01    |
| Congestive heart failure       | 94.5         | 93.7           | 94.0            | 0.09    |
| Chronic pulmonary disease      | 14.2         | 18.5           | 16.8            | <0.001  |
| Pulmonary circulation disorders | 0.1          | 0.3            | 0.2             | 0.21    |
| Peripheral vascular disease    | 9.3          | 6.7            | 7.8             | <0.001  |
| Chronic renal failure          | 35.2         | 35.5           | 35.4            | 0.80    |
| Fluid and electrolyte disorders | 70.4         | 62.7           | 65.8            | <0.001  |
| Neurological disorder          | 6.7          | 6.5            | 6.6             | 0.74    |
| Anemia                         | 18.7         | 19.0           | 18.8            | 0.73    |
| Coagulopathy                   | 45.2         | 37.9           | 40.8            | <0.001  |
| Hematological/solid malignancy | 1.3          | 2.0            | 1.7             | 0.007   |

All values represented as percentage or mean±standard error. MCS indicates mechanical circulatory support.

region) and primary payer associated with each discharge were identified from the HCUP-NIS database. The hospitals were divided into tertiles based on the annual volume of LVAD discharges. The Deyo’s modification of Charlson Comorbidity Index was used to identify the burden of comorbid diseases.15

The primary outcome was in-hospital mortality in patients with and without the use of MCS for cardiogenic shock pre-LVAD surgery. Secondary outcomes included incidence and trends of MCS use in pre-LVAD surgery and the hospital costs and lengths of stay for these admissions.

Statistical Analysis

As recommended by HCUP-NIS, survey procedures using discharge weights provided with HCUP-NIS database were used to generate national estimates.16 Chi-square and t tests were used to compare categorical and continuous variables, respectively. Linear regression was used to analyze trends over time. The inherent limitations of the HCUP-NIS database were reviewed and addressed during the statistical analysis and interpretation of these data.17

Univariate analysis for trends and outcomes was performed and were represented as odds ratio with 95% confidence interval or mean±standard error. Multivariate regression analysis incorporating age, sex, race, myocardial infarction, coronary angiography, and/or percutaneous coronary intervention, median household income, hospital characteristics, and comorbidities was performed for in-hospital mortality using MCS as the dependent variable. For the multivariate modeling, regression analysis with purposeful selection of statistically and clinically relevant variables was conducted. Further propensity-matched cohorts were generated using 1:1 nearest neighbor matching (with 0.01 calipers and without replacement) to match patients with MCS use to those without. Propensity-matched sample has standardized differences <10% for all baseline characteristics. Two-tailed P<0.05 was considered statistically significant. All statistical analyses were performed using STATA 14.0 (StataCorp, College Station, TX).

Results

In the 10-year period from 2005 to 2014, there were a total of 9753 estimated admissions for LVAD surgery that were complicated by preoperative cardiogenic shock. Temporary MCS was used in 3958 (40.6%) of these admissions. During this 10-year period there was a 4.6 times temporal increase in the incidence of cardiogenic shock pre-LVAD surgery that was associated with a 5.5 times concomitant increase in the use of temporary MCS devices (Figure 1). There was a significant increase in the
Table 2. Multivariate Analysis of In-Hospital Mortality*

| Parameter                                                                 | Odds Ratio | 95% Confidence Interval | P Value |
|---------------------------------------------------------------------------|------------|-------------------------|---------|
| Age                                                                       | 1.1        | 1.1                     | 1.1     | 0.003   |
| Female sex                                                                | 1.0        | 0.9                     | 1.3     | 0.67    |
| Race                                                                      |            |                         |         |         |
| White                                                                     | Reference  |                         |         |         |
| Nonwhite                                                                  | 0.7        | 0.6                     | 0.9     | 0.003   |
| Missing                                                                   | 2.6        | 1.7                     | 4.0     | <0.001  |
| Mechanical circulatory support                                            | 1.6        | 1.3                     | 1.9     | <0.001  |
| Cardiac morbidity during admission                                        |            |                         |         |         |
| Myocardial infarction                                                     | 1.7        | 1.4                     | 2.1     | <0.001  |
| Coronary angiography/percutaneous coronary intervention                   | 0.6        | 0.5                     | 0.8     | <0.001  |
| Ventricular tachycardia/fibrillation                                      | 1.1        | 0.9                     | 1.5     | 0.39    |
| Primary expected payer                                                    |            |                         |         |         |
| Nonprivate                                                                | Reference  |                         |         |         |
| Private                                                                   | 0.6        | 0.5                     | 0.8     | <0.001  |
| Median household income category for patient’s zip code                   |            |                         |         |         |
| 0–25th percentile                                                         | Reference  |                         |         |         |
| 26th–50th percentile                                                      | 1.7        | 1.3                     | 2.2     | <0.001  |
| 51st–75th percentile                                                      | 1.4        | 1.1                     | 1.8     | 0.03    |
| 75th–100th percentile                                                     | 1.9        | 1.4                     | 2.4     | <0.001  |
| Hospital region                                                           |            |                         |         |         |
| Northeast                                                                 | Reference  |                         |         |         |
| Midwest                                                                   | 0.5        | 0.2                     | 1.3     | 0.17    |
| South                                                                     | 0.6        | 0.3                     | 1.5     | 0.29    |
| West                                                                      | 1.3        | 0.5                     | 3.5     | 0.55    |
| Weekends admission                                                        | 1.7        | 1.3                     | 2.1     | <0.001  |
| Obesity                                                                   | 1.1        | 0.9                     | 1.5     | 0.40    |
| Hypertension                                                              | 0.9        | 0.7                     | 1.1     | 0.32    |
| Diabetes mellitus, type 2                                                 | 1.2        | 0.9                     | 1.4     | 0.44    |
| Previous myocardial infarction                                            | 0.7        | 0.5                     | 0.9     | 0.01    |
| Previous coronary artery bypass grafting                                  | 0.8        | 0.6                     | 1.2     | 0.29    |
| Atrial fibrillation                                                       | 0.4        | 0.3                     | 0.5     | <0.001  |
| Chronic pulmonary disease                                                 | 0.5        | 0.4                     | 0.7     | <0.001  |
| Peripheral vascular disease                                               | 1.5        | 1.1                     | 2.0     | 0.01    |
| Fluid and electrolyte disorder                                            | 1.1        | 0.9                     | 1.3     | 0.58    |
| Coagulopathy                                                              | 2.7        | 2.3                     | 3.3     | <0.001  |

*All variables listed in Table 2 were used in a multivariable analysis for in-hospital mortality.

The proportion of cases receiving temporary MCS, primarily because of an increase in the use of non-IABP devices (all $P<0.001$) (Figure 2). Baseline characteristics of patients with and without the use of temporary MCS are detailed in Table 1. End-stage heart failure was the predominant cause of cardiogenic shock without any differences between cohorts with and without MCS use (94.5% versus 93.7%; $P=0.09$). Patients receiving MCS were more likely to be younger, of nonwhite race, have acute myocardial infarction and acute myocarditis as cause, using private insurance, and had greater comorbidity burden. Greater rates of in-hospital cardiac events such as myocardial infarction, ventricular tachycardia/fibrillation, and need for coronary...
angiography/percutaneous coronary intervention were noted in the patients receiving MCS. The cohort that received MCS had higher in-hospital morbidity such as acute kidney injury (69.5% versus 57.9%; \(P<0.001\)), stroke (5.9% versus 4.6%; \(P=0.004\)), and invasive mechanical ventilation (40.2% versus 36.5%; \(P<0.001\)). Trends of MCS use in patients with cardiogenic shock before LVAD surgery stratified by patient age, sex, race, and median household income for zip are shown in Figure 3A through 3D.

Mortality, Lengths of Stay, and Hospital Costs

Unadjusted mortality for admissions with and without the use of MCS was 19.7% versus 14.2%; \(P<0.001\). The unadjusted mortality trends over this 10-year duration are presented in Figure 4. In a multivariate model, older age, concomitant myocardial infarction, higher median household income, weekend admission, and use of temporary MCS were predictive of higher in-hospital mortality in this population (Table 2). Using propensity matching for baseline clinical and demographic variables, 696 pairs (total 1392 admissions) were generated for further analysis (Table 3). Use of MCS was predictive of higher in-hospital mortality—odds ratio 1.4 (95% confidence interval 1.1–1.6); \(P=0.02\), higher hospital costs ($277 803±5199 versus $232 707±4561; \(P<0.001\)) but similar lengths of hospital stay (43±1.2 days versus 40±1.3 days; \(P=0.11\)).

Discussion

In this large nationally representative cohort of patients, this study noted a temporal increase in cardiogenic shock that previously received LVAD surgery. There was a concomitant increase in the use of temporary MCS before LVAD surgery between 2005 and 2014. Despite the IABP being the predominant device of choice, there was a steady increase in non-IABP temporary MCS. Older age, concomitant myocardial infarction, and use of MCS were independent predictors of higher in-hospital mortality. In 696 propensity-matched pairs, use of MCS was associated with higher hospital costs but no difference in length of hospital stay, suggestive of the role of higher morbidity and mortality in this population.

Consistent with the most recent INTERMACS data, this study noted a steady increase in LVAD volumes for cardiogenic shock since the approval of the continuous-flow LVADs in 2008.4 As noted in the literature, end-stage cardiomyopathy was the leading cause of cardiogenic shock in patients receiving LVAD therapy in this study as compared with acute myocardial infarction or fulminant myocarditis.10,18 Patients with cardiogenic shock frequently require temporary MCS to aid in hemodynamic stabilization in addition to high doses of vasodilative medications.6 Prior literature has demonstrated favorable hemodynamic effects and improvement of candidacy for LVAD using percutaneous MCS before LVAD implantation.18,19 This is of crucial importance since the use of emergent durable LVAD in cardiogenic shock patients is associated with unacceptably high mortality of nearly 60% to 80%.18 In the background of this information, this study serves to highlight an important gap in the literature examining the role of short-term MCS in cardiogenic shock that are bridged to LVAD therapy in a large nationally representative cohort. Other international registries such as the INTERMACS and Extracorporeal Life Support Organization registries report durable MCS and ECMO, respectively, without any data on other forms of temporary MCS.

Figure 1. Trends in the incidence of pre-LVAD surgery cardiogenic shock and the use of mechanical circulatory support. \(P\) value for trends for all categories \(P<0.001\). CS indicates cardiogenic shock; LVAD, left ventricular assist device; MCS, mechanical circulatory support.
There are limited contemporary data on percutaneous and nonpercutaneous MCS devices in patients with cardiogenic shock before LVAD surgery. Consistent with literature in other causes of cardiogenic shock, this study demonstrated a decrease in the use of IABP in these patients with a concomitant increase in non-IABP MCS devices.\textsuperscript{8,20} Importantly, between 2012 and 2014, nearly 8% to 10% of admissions received preoperative ECMO support, which highlights a paradigm shift in care of patients with cardiogenic shock, which is significantly higher than the use of ECMO in acute coronary syndromes.\textsuperscript{8} This can be postulated to be because of greater operator comfort with ECMO technique in cardiac surgery, need for higher cardiac output (flows), and a higher incidence of biventricular failure in this population of end-stage heart failure. Conversely, this could also represent lesser elective use of IABP before LVAD surgery and limiting the use of MCS to only emergent cases.\textsuperscript{21} Despite a higher overall proportion of nonprivate insurance patients, this study

**Figure 2.** Trends in the percentage of admissions with mechanical circulatory support for pre-LVAD surgery cardiogenic shock. \(P\) value for trends for all categories \(P<0.001\). CS indicates cardiogenic shock; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support; npMCS, nonpercutaneous mechanical circulatory support; PCPS, percutaneous cardiopulmonary support; pMCS, percutaneous mechanical circulatory support.

**Figure 3.** Trends in the use of mechanical circulatory support stratified by age (in years) (\(A\)), sex (\(B\)), race (\(C\)), and median income for zip code (\(D\)). \(P\) value for trends for all categories \(P<0.001\). CS indicates cardiogenic shock; LVAD, left ventricular assist device.
noted greater use of MCS in patients with private insurance compared with those on nonprivate insurance. Prior literature from the HCUP-NIS database has alluded to the role of insurance in patient outcomes. Given the high costs associated with care for both LVAD surgery and MCS patients, these considerations are worthy of careful evaluation in subsequent studies to ensure equitable care across the United States. Importantly, there were no differences in MCS use before LVAD surgery when hospitals were stratified by size and location. Prior data from the HCUP-NIS database have shown that the use of MCS is lesser in rural and nonacademic hospitals. It is possible that given the differences in population and the limited centers in the United States that perform LVAD implantation, we were unable to replicate these findings. There was significant geographic variation in the use of MCS, with the highest in southern United States; however, this did not influence hospital mortality. It is pertinent to note that the time period of this study preceded the most recent guidelines on MCS use; hence the practice variability could potentially be explained by the lack of uniform consensus on the indication, duration, and type of MCS device use.

Mortality Outcomes

Despite advances in the management of cardiogenic shock of all causes, the mortality in this population has remained high at 30% to 40%.[6,24] In patients with cardiogenic shock, den Uil et al reported a hospital mortality of 33% to 55% depending on the type of MCS used.10 In contrast, LVAD surgery is associated with only 7% to 8% mortality across all INTERMACS classes.25 In comparison, our study noted overall mortality of 20% in patients with cardiogenic shock before LVAD surgery. The results of this study are in contrast to smaller single-center studies that did not demonstrate any differences in outcomes in patients with and without preoperative MCS support.19,26–30 This can likely be explained by the multicenter, nationally representative nature of our study and the inability to correct for the indication for temporary MCS device placement. Additionally, this study considered all forms of temporary MCS as compared with prior studies looking at specific types of MCS. It is possible that a certain portion of the IABP MCS devices used in this study were implanted electively, consistent with national practice, and the remainder of the devices were used as salvage therapy.21 Importantly, given the inherent limitations of the NIS database, these results should be perceived as trends and estimates, given the inability to control for all types of confounding, and need further validation in carefully controlled prospective trials. As noted in this study, the overall mortality for patients with cardiogenic shock receiving LVAD therapy has significantly decreased over this 10-year period, with a sharp inflection point in 2008. This can be explained by multiple reasons: (1) the US Food and Drug Administration approval for continuous-flow pumps in 2008 in conjunction with improved patient-selection strategies; (2) a steady increase in non-IABP MCS devices to support cardiogenic shock since 2007, which could influence mortality in this

Figure 4. Trends of in-hospital mortality in patients with and without the use of mechanical circulatory support. P value for trends for all categories P<0.001. MCS indicates mechanical circulatory support.
Table 3. Baseline Characteristics of Propensity-Matched Patients*

| Variable                                           | MCS (n=696) | No MCS (n=696) | P Value |
|----------------------------------------------------|-------------|----------------|---------|
| **Age, y**                                         | 54±0.5      | 54±0.5         | 0.92    |
| **Female sex**                                     | 23.9        | 24.4           | 0.80    |
| **Race**                                           |             |                | 0.58    |
| White                                              | 56.9        | 59.6           |         |
| Nonwhite                                           | 36.2        | 34.1           |         |
| Missing                                            | 6.9         | 6.3            |         |
| **Cardiac morbidity during admission**             |             |                |         |
| Myocardial infarction                              | 20.1        | 19.4           | 0.95    |
| Coronary angiography/percutaneous coronary intervention | 19.1        | 19.3           | 0.94    |
| Ventricular tachycardia/fibrillation               | 10.8        | 10.3           | 0.79    |
| **Charlson Comorbidity Index**                     |             |                | 0.89    |
| 0                                                  | 1.4         | 1.2            |         |
| 1                                                  | 30.8        | 30.6           |         |
| ≥2                                                 | 67.8        | 68.3           |         |
| **Primary expected payer**                         |             |                | 0.96    |
| Nonprivate insurance                               | 53.6        | 53.5           |         |
| Private insurance                                  | 46.4        | 46.6           |         |
| **Median household income category for zip code**  |             |                | 0.91    |
| 0–25th percentile                                  | 25.3        | 24.4           |         |
| 26th–50th percentile                               | 25.2        | 25.1           |         |
| 51st–75th percentile                               | 22.6        | 21.4           |         |
| 76th–100th percentile                              | 25.6        | 27.2           |         |
| **Hospital bed size**                              |             |                | 0.64    |
| Small                                              | 1.2         | 1.3            |         |
| Medium                                             | 8.9         | 10.3           |         |
| Large                                              | 89.9        | 88.4           |         |
| **Teaching hospital**                              |             |                | 0.77    |
| 96.6                                               | 96.3        |                |         |
| **Hospital region**                                |             |                | 0.94    |
| Northeast                                          | 18.7        | 18.4           |         |
| Midwest                                            | 19.4        | 17.8           |         |
| South                                              | 25.9        | 26.0           |         |
| West                                               | 12.8        | 13.7           |         |
| **Weekends admission**                             |             |                | 0.73    |
| Obesity                                            | 11.6        | 11.2           | 0.80    |
| **Hypertension**                                   | 35.3        | 35.6           | 0.91    |
| Diabetes mellitus, type 2                          | 25.0        | 25.0           | >0.99   |
| **Smoking**                                        | 4.6         | 4.3            | 0.80    |
| Coronary artery disease                            | 32.9        | 31.9           | 0.69    |
| Family history of coronary artery disease          | 2.2         | 2.0            | 0.85    |
| Previous myocardial infarction                     | 9.3         | 8.6            | 0.64    |
| Previous percutaneous coronary intervention        | 6.9         | 6.9            | >0.99   |

Continued
population; (3) improved patient selection strategies over time; and (4) the evolution and maturation of the field of critical care cardiology that could potentially have influenced the management of the acute postoperative course.31

Limitations

This study has several limitations, some of which are inherent to the analysis of a large administrative database. There are limited data available in the NIS on the type, location, and operative and mechanistic characteristics of the LVAD, all of which are known to influence short-term outcomes.32 Importantly, this study only evaluated use of temporary MCS before LVAD surgery, and therefore is unable to comment on postoperative right ventricular failure and the need for subsequent MCS.33 These administrative codes cannot be used to distinguish between similar devices with improvements in technology (such as improving circulatory support with the percutaneous LVAD). This study did not evaluate patients with temporary MCS that recovered ventricular function or those who were not candidates for durable LVAD therapy and is therefore unable to comment on these important subgroups. Coding errors, misrepresentation of procedural volumes, and underreporting of comorbidities are potential limitations of using ICD-9-CM codes.34 The HCUP-NIS attempts to mitigate potential errors by using internal and external quality-control measures. This study was limited to in-hospital costs and was unable to account for long-term costs of care for these patients. However, the HCUP-NIS sampling design has been widely used for research in the past and represents a large nationally representative sample for a detailed outcome analysis.34

Additionally, the incorporating of newer MCS devices in clinical care could potentially have resulted in greater use in patients over more recent years because of greater availability. Finally, because of the limitations of the HCUP-NIS database, it is not possible to ascertain whether these patients received an LVAD as destination therapy or bridge-to-transplant, which may represent 2 different populations.4 Despite these limitations, this study addresses an important knowledge gap highlighting the national prevalence and trends of MCS in cardiogenic shock pre-LVAD implantation and defining the hospital outcomes including mortality, costs, and lengths of stay in this sick population.

Conclusions

Preoperative use of temporary MCS for management of cardiogenic shock is seen in nearly 40% of all admissions for LVAD surgery, with the IABP being the most commonly used device. There has been a steady increase in non-IABP devices over this 10-year study period. Patients requiring MCS had higher in-hospital mortality and hospital costs, likely reflecting higher overall severity of illness in this population. Further research on optimal patient, device, and surgical factors are required to improve clinical outcomes in this high-risk population.

Author Contributions

Vallabhajosyula, Prasad, and Deshmukh were involved in study design and literature review; Vallabhajosyula, Arora, Vallabhajosyula et al

Table 3. Continued

| Variable                        | MCS (n=696) | No MCS (n=696) | P Value |
|--------------------------------|-------------|----------------|---------|
| Previous coronary artery bypass grafting | 5.5         | 4.7            | 0.54    |
| Previous cardiac arrest        | 1.0         | 1.2            | 0.80    |
| Atrial fibrillation            | 36.8        | 37.6           | 0.74    |
| Congestive heart failure       | 94.5        | 94.7           | 0.91    |
| Chronic pulmonary disease      | 15.1        | 14.2           | 0.65    |
| Pulmonary circulation disorders| 0.1         | 0.1            | >0.99   |
| Peripheral vascular disease    | 8.2         | 8.8            | 0.70    |
| Chronic renal failure          | 35.8        | 36.5           | 0.78    |
| Fluid and electrolyte disease  | 69.0        | 69.0           | >0.99   |
| Neurological disorder          | 6.9         | 6.6            | 0.83    |
| Anemia                         | 19.0        | 18.3           | 0.73    |
| Coagulopathy                   | 43.7        | 43.4           | 0.91    |
| Hematological/solid malignancy | 1.4         | 1.7            | 0.67    |

All values represented as percentage or mean±standard error. MCS indicates mechanical circulatory support.

*All variables listed in Table 3 were used in the generation of the propensity-matched cohorts.
Lahevala, Kumar, and Shantha were involved in data extraction, management, and analysis; Vallabhajosyula and Deshmukh were involved in manuscript drafting; and Jentzer, Stulak, Gersh, Gulati, Rihal, Prasad, and Deshmukh were involved in manuscript revision, intellectual revisions, and mentorship.

Disclosures
None.

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