Selective implantation of durable left ventricular assist devices as primary therapy for refractory cardiogenic shock

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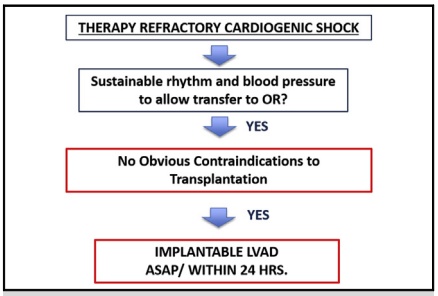
ABSTRACT

Objective: Surgical therapy for refractory primary cardiogenic shock is largely based on emergent placement of extracorporeal membrane oxygenation or short-term ventricular assist devices. We have adopted a strategy of routine implantation of durable left ventricular assist devices (LVAD) as initial therapy for refractory cardiogenic shock, in patients who are potential candidates for heart transplantation, and report our experience.

Methods: Retrospective review of 43 consecutive patients with refractory shock caused by acute myocardial infarction (n = 21) or acute decompensated heart failure (n = 22) who were treated with primary implantation of a durable LVAD in a single institution.

Results: All patients received durable LVAD (axial flow, n = 37; centrifugal, n = 4; pulsatile, n = 2), with concurrent placement of right ventricular assist device (RVAD) in 5 patients (12%). One patient had delayed RVAD implantation. Mean operative time was 362 minutes and mean cardiopulmonary bypass time was 94 minutes. Twenty patients underwent concurrent cardiac procedures. Major early adverse events included operative mortality 14% (6/43), reoperation for bleeding 7% (3/43), and stroke 4.7% (2/43). Median time on mechanical ventilation was 3.5 days, ICU stay 9 days, and hospital stay 25 days. Kaplan-Meier survival was 82.7 ± 6.0% at 6 months and 73.9 ± 8.0% at 12 months. Using competing analysis, the cumulative incidence of transplantation was 10.3 ± 5.0% at 6 months and 30.8 ± 7.9% at 1 year.

Conclusions: Our data challenge the notion that patients in refractory cardiogenic shock are best served by an initial period of stabilization with temporary devices. Primary implantation of durable LVADs in cardiogenic shock can yield good midterm outcomes and may have potential benefits. (J Thorac Cardiovasc Surg 2017;■:1-10)



Mount Sinai Algorithm for Management of Refractory Cardiogenic Shock.

Central Message

Implantation of durable LVADs as primary therapy in refractory cardiogenic shock was feasible and is associated with good outcomes in a single center.

Perspective

The recommended mechanical support therapy for patients in refractory shock with multiorgan failure is extracorporeal membrane oxygenation. In this study, we present data on an alternative strategy of direct implantation of a durable left ventricular assist device. With this approach, patients may experience shorter periods of hospitalization, fewer reinterventions, and, possibly, better outcomes.

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Traditionally, the mainstay of therapy for refractory cardiogenic shock caused by acute myocardial infarction (AMI) and acute decompensated heart failure (ADHF) has been extracorporeal membrane oxygenation (ECMO) support and temporary percutaneous left ventricular assist device (LVAD) support as a first step.[1] The 2013 International Society for Heart and Lung Transplantation guidelines for mechanical circulatory support recommend short-term mechanical devices for management of acutely decompensated patients with heart failure failing maximal medical therapy (class I, level of evidence C). The guidelines also recommend use of temporary mechanical support in

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Abbreviations

ADHF = Acute decompensated heart failure
AMI = Acute myocardial infarction
ECMO = Extracorporeal membrane oxygenation
ICU = Intensive care unit
INTERMACS = Interagency Registry for Mechanical Assisted Circulatory Support
LVAD = Left ventricular assist device
RVAD = Right ventricular assist device

patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment before placement of a long-term mechanical circulatory support device (class I, level of evidence C).[2] The rationale for this recommendation is that patients in cardiogenic shock are too sick to tolerate surgery for implantation of durable LVAD; are more likely to bleed as a result of coagulopathy; are more prone to surgical complications; are more likely to require right ventricular assist devices (RVADs); will frequently not survive the short-term, regardless of institution of circulatory support (hence resulting in unnecessary incremental cost and resource use if a durable LVAD was placed); and would be more likely to survive implantation of a durable LVAD after a period of optimization with short-term support.

We have previously reported[3] that primary use of durable LVADs may yield acceptable clinical outcomes in refractory cardiogenic shock and may reduce cost and resource use by avoiding the prolonged intensive care hospitalizations, morbidity, and repeat interventions typically associated with temporary support devices. We report an updated experience of our approach of using durable LVADs as primary therapy for patients with refractory cardiogenic shock.

METHODS

Study Design

Between 2007 and 2016, 315 patients received implantable LVADs in our center, 43 of which were placed as primary therapy for refractory cardiogenic shock caused by AMI or ADHF. This study is a retrospective study of these 43 patients who underwent LVAD implantation as primary therapy for cardiogenic shock in our center. Clinical data were extracted from our departmental cardiac surgery reporting databases. These registries are approved for use in research by the institutional review board, with patient consent waived. We defined therapy-refractory cardiogenic shock as cardiogenic shock with indication of worsening end-organ hypoperfusion (progressive hepatorenal dysfunction, declining mental status, and respiratory failure) or progressive tissue hypoxia (increasing blood lactate level and low venous oxygen saturation), concomitant with sustained hypotension, despite adequate intravascular volume and high doses of inotropes and vasopressors. Patients in cardiogenic shock requiring repeated drug boluses to maintain arterial blood pressure, patients with unstable ventricular arrhythmias, and patients requiring cardiopulmonary resuscitation were also regarded as therapy refractory. Data were abstracted from institutional databases on demographic, process, and outcome variables. The primary end point was all-cause mortality. Operative mortality was defined as any death within 30 days or at any time during the same hospital stay. Stroke was defined as a temporary or permanent new neurologic deficit with computed tomographic evidence of brain infarction or hemorrhage. Limb complications were defined as any limb ischemic complication needing surgical intervention. Potent antiplatelet drugs were defined as any of high-dose clopidogrel, prasugrel, glycoprotein IIb/IIIa inhibitors, or ticagrelor.

TABLE 1. Patient demographics

Age (y)	54.9 ± 10.8
Males	38 (88)
Acute MI	21 (49)
Decompensated heart failure	22 (51)
CPR within 24 h before operation	8 (18.6)
Unknown neurologic status	5 (11.6)
Preoperative mechanical ventilation	25 (58.1)
IABP	32 (74.4)
Percutaneous LVAD	7 (16.3)
Potent antiplatelet therapy within 48 h	16 (40)
Previous sternotomy	5 (11.6)
Creatinine (mg/dL)	2.0 ± 1.3
Bilirubin (mg/dL)	2.7 ± 3.4
Aspartate aminotransferase (U/L)	934 ± 2896
Lactate (mmol/L)	3.1 ± 3.0
Pulmonary capillary wedge pressure (mm Hg)	28.2 ± 6.8
Right atrial pressure (mm Hg)	19.4 ± 9.9
Pulmonary artery systolic pressure (mm Hg)	49.7 ± 11.2

Values are number (%) or mean ± standard deviation unless otherwise indicated. *MI*, Myocardial infarction; *CPR*, cardiopulmonary resuscitation; *IABP*, intra-aortic balloon pump; *LVAD*, left ventricular assist device.

Patients

Patient demographics are described in Table 1. Patients ranged from 33 to 78 years of age and were predominantly male (n = 38, 88%). Twenty-two patients had AMI (51%) and 21 had ADHF (49%). The 2 groups were similar in demographics other than higher bilirubin and lower platelet count in the ADHF compared with AMI group (4.5 mg vs 1 mg/dL; $P = .0003$ and 129,000 vs 194,000/μL; $P = .018$ respectively). Hemodynamics were notable for a lower mean cardiac index (1.6 l/min/m^2 vs 2.1 l/min/m^2) and higher systolic pulmonary artery pressure (55 vs 44 mm Hg) in the patients with ADHF compared with AMI respectively. Mean right atrial pressure (21 vs 18 mm Hg; $P = .5$) and pulmonary artery wedge pressure (30 vs 27 mm Hg; $P = .3$) were similar in both groups. In patients with post-AMI cardiogenic shock, the median duration from myocardial infarction to LVAD implantation was 3 days (range, 1-23 days). Seven patients had a preexisting percutaneous LVAD placed before referral to the LVAD team but yet remained in cardiogenic shock. Five had a limited flow percutaneous LVAD (Impella 2.5 heart pump [Abiomed Inc, Danvers, Mass]), whereas 2 patients had a TandemHeart percutaneous LVAD (CardiacAssist, Inc, Pittsburgh, Pa).

Treatment Strategy

Our strategy for stratification and management of patients in refractory cardiogenic shock is summarized in Figure 1. Typically, patients in