

# The Use of Extracorporeal Life Support in Adult Patients With Primary Cardiac Failure as a Bridge to Implantable Left Ventricular Assist Device

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**Background.** Extracorporeal life support (ECLS) is an effective technique for providing emergent circulatory assistance, and may represent a life-saving option in patients who might not initially be considered a candidate for other forms of circulatory support (extracorporeal or implantable left ventricular assist device [LVAD]). In the setting of cardiac arrest, ECLS represents the only viable method of initiating circulatory support. However, ECLS has a number of disadvantages that include high complication rates (eg, stroke, bleeding) and a limited duration of potential support, which have prevented its widespread acceptance, particularly in the adult population. With the increased successful application of long-term implantable LVADs as a bridge to transplant, the major limitation of ECLS could be overcome by bridging patients to a long-term implantable LVAD ("bridge to bridge"), thereby reducing the reluctance to utilize ECLS when indicated. After acquisition of the HeartMate LVAD (Thermo Cardiosystems, Inc, Woburn, MA) we investigated the use of ECLS as a bridge to an implantable LVAD and subsequent transplantation in selected high-risk patients.

Extracorporeal life support (ECLS) is an effective technique for providing emergent circulatory assistance and may represent a life-saving option in patients who might not initially be considered a candidate for other forms of circulatory support (extracorporeal or implantable left ventricular assist device [LVAD]) [1–8]. In situations of cardiac arrest, ECLS represents the only viable method of initiating circulatory support. The major advantages of ECLS in these circumstances are its ease of implementation (ie, percutaneous technique), lack of need for operating room resources, and avoidance of sternotomy and general anesthesia in patients who may be in cardiac arrest or have extreme hemodynamic instability [1, 2]. However, ECLS has a number of disadvantages that include a high incidence of stroke, bleeding and infection, limited duration of support potential, and limited ability to adequately decompress the left ventri-

**Methods and Results.** From Oct 1, 1996 to Sept 30, 2000, 33 adult patients presenting with cardiac arrest or severe hemodynamic instability were placed on ECLS for the bridge to bridge indication. Of the 33 patients, 10 patients survived to LVAD implant, 1 was bridged directly to transplant, 5 weaned from ECLS, and 16 died on ECLS. Overall, 12 patients survived to discharge. One-year actuarial survival from the initiation of ECLS was 36%. One-year actuarial survival from the time of LVAD implant, conditional on surviving ECLS, was 80%.

**Conclusions.** The 1-year survival of adult patients placed on ECLS and who subsequently survived to an implantable LVAD was favorable. These data support a strategy of ECLS to implantable LVAD bridge to heart transplant in adult patients who are in need of circulatory support and who are not initially candidates for other forms of mechanical support. The favorable results of this strategy support utilization of ECLS even in situations where myocardial recovery is thought to be unlikely.

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cle in poorly functioning hearts [1, 2]. These concerns have prevented the widespread acceptance of ECLS, particularly in the adult patient with a low likelihood of having myocardial recovery. With the increased successful application of long-term implantable LVADs as a bridge to transplant, the major limitation of ECLS could be overcome by bridging patients to a long-term implantable LVAD after initial ECLS resuscitation [8–14]. This strategy could reduce the reluctance to utilize ECLS when appropriately indicated and rationalize utilization of other more expensive LVAD devices by avoiding inappropriate application. After acquisition of the HeartMate LVAD (Thermo Cardiosystems, Inc., Woburn, MA), we investigated the feasibility of utilizing ECLS as a bridge to an implantable LVAD and subsequent transplantation in selected high-risk patients.

## Material and Methods

From October 1, 1996 to September 30, 2000, 33 adult patients presenting to the University of Michigan Health System were evaluated for mechanical circulatory support for primary cardiac failure and placed on ECLS.

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Criteria for institution of ECLS included the absence of any known existing absolute contraindications to heart transplantation, age < 66 years, and either: 1) refractory cardiogenic shock and severe hemodynamic instability (CI < 2.0 L/min/m<sup>2</sup> with systolic blood pressure ≤ 75 mm Hg, pulmonary capillary wedge pressure (PCWP) > 20 mm Hg, and dependent on at least two inotropes with or without intraaortic balloon pump [IABP]); 2) cardiac arrest; or 3) risk of imminent death (minutes/hours) secondary to life-threatening recurrent ventricular arrhythmia. Patients requiring ECLS after failed transplant or planned elective ECLS-assisted coronary angioplasty were excluded from analysis.

The ECLS circuit consisted of a membrane lung (SCI Med Life Systems; Minneapolis, MN), a servo-regulated roller pump, and a heat exchanger [1, 2]. Arterial inflow to institute ECLS was obtained by right carotid artery cutdown in 10 patients, percutaneous femoral artery cannulation in 22 patients, and ascending aortic cannulation in 1 patient. Seven patients (32%; 7 of 22 patients) with percutaneous common femoral artery cannulation required arterial reinfusion of the distal extremity for limb ischemia by percutaneous or cut-down insertion of a large-bore catheter into the profunda artery or distal superficial femoral artery with perfusion from a side port of the arterial inflow canula. Venous drainage was obtained by right internal jugular cutdown in 10 patients, percutaneous femoral vein cannulation in 20 patients, and right atrial cannulation in 1 patient. Arterial and venous cannulation sites were chosen based on the urgency of establishing circulatory support. For the most urgent situations, percutaneous cannulation was the preferred technique.

Atrial septostomy, performed in the cardiac catheterization laboratory utilizing a balloon technique to achieve a trans-septal gradient less than 12 mm Hg, was the preferred method for left ventricular decompression and was performed in 7 of 33 (21%) patients placed on ECLS. Early in the experience, atrial septostomy was performed in 3 patients after the development of pulmonary hemorrhage, with 1 patient surviving ECLS to LVAD implant. Based on this experience, atrial septostomy was performed after initiation of ECLS whenever there was pulmonary hypertension (mean pulmonary artery pressure > 30 mm Hg) and echocardiographic evidence of left ventricular dilation. Using these guidelines, atrial septostomy was subsequently performed in 4 additional patients. No further episodes of pulmonary hemorrhage have occurred on ECLS utilizing our current indications for atrial septostomy.

Comparison of means was performed using one-way analysis of variance with post hoc Tukey LSD multiple comparison tests to adjust for pairwise mean comparisons between groups when more than two groups were compared. Dichotomous outcome comparisons between groups were conducted using a  $\chi^2$  or Fisher's exact test when appropriate. Statistical significance was defined as  $p < 0.05$ . Survival was determined using the Kaplan-Meier method.

## Results

Patient characteristics are shown in Table 1 for the entire sample, and separately for survivors (survival to hospital discharge) and nonsurvivors. Mean ( $\pm$  SD) age for all patients was  $47 \pm 11$  years. There was no significant difference in age between survivors and nonsurvivors. Seventy percent (22 of 33 patients) of patients were male. There were no significant differences in survival by gender. The etiology of cardiac failure was nonischemic in 30% (10 of 33 patients), ischemic in 58% (19 of 33 patients), and postcardiotomy failure to wean in 12% (4 of 33 patients). Survival for patients with ischemic cardiac failure was significantly ( $p < 0.05$ ) greater compared with either nonischemic cardiac failure or postcardiotomy failure to wean. No patient placed on ECLS after postcardiotomy failure to wean survived to hospital discharge. In 3 of 4 of these cases of postcardiotomy failure to wean, ECLS was initiated for hemodynamic deterioration or cardiac arrest occurring late (>12 hours) postoperatively in the intensive care unit. The incidence of IABP support and intubation at the initiation of ECLS was 61% (20 of 33 patients) and 100% (33 of 33 patients), respectively.

Overall, 73% of patients (24 of 33 patients) were in cardiac arrest or experienced a cardiac arrest event within 15 to 30 minutes of ECLS (Table 1). The location of the cardiac arrest included the coronary care unit ( $n = 14$ ; 4 survivors), catheterization laboratory ( $n = 3$ ; 1 survivor), electrophysiology laboratory ( $n = 1$ ; 1 survivor), labor and delivery suite ( $n = 1$ ; 1 survivor), emergency room ( $n = 4$ ; 0 survivors), and referring hospital ( $n = 1$ ; 0 survivor). Survival to discharge was significantly ( $p < 0.05$ ) decreased for patients experiencing a cardiac arrest before initiation of ECLS (29% (7 of 24 patients) versus 56% (5 of 9 patients)).

Median duration of ECLS was 65 hours (range 0 to 369 hours; mean  $\pm$  SD  $94 \pm 91$ ). Overall, 36% of patients (12 of 33) survived to hospital discharge. Survival to hospital discharge was significantly decreased when the duration of ECLS support was less than 48 hours or exceeded 168 hours (data not shown). There were 16 deaths while on ECLS. Of the 16 deaths, 1 patient died from delay in initiating ECLS due to technical difficulties at cannulation. Two patients had support discontinued within 24 hours after confirmation of intravenous cocaine use/sepsis (1) and massive pulmonary embolus (1). Seven patients had support discontinued  $\leq 48$  hours after initiating ECLS after findings of significant neurologic injury, believed attributable to the initiating cardiac event, were confirmed by clinical exam, electroencephalogram, or brain blood flow study. Six additional late deaths (>48 hours) occurred while on ECLS and were attributed to stroke (2), pulmonary hemorrhage (2), and sepsis/MSOF (multisystem organ failure, 2).

Six patients weaned from ECLS, with 3 patients surviving to discharge. Of the 6 patients that weaned from ECLS, 3 died before discharge from either stroke (1 sustained during ECLS) or ventricular arrhythmia/sepsis (2).

Ten patients placed on ECLS were bridged to an

Table 1. Patient Characteristics

	All (n = 33)	Survivors (n = 12)	Nonsurvivors (n = 21)
Age (years; mean $\pm$ SD)	47 $\pm$ 11	48 $\pm$ 12	46 $\pm$ 11
Gender			
Male	23	8	14
Female	10	4	7
Etiology			
Ischemic <sup>a</sup>	19	9	10
Nonischemic	10	3	7
Postcardiotomy	4	0	4
Cardiac arrest			
Present <sup>b</sup>	24	7	17
Absent	9	5	4
Renal function			
Serum creatinine (mg/dL)	1.9 $\pm$ 0.8	2.0 $\pm$ 1.2	1.8 $\pm$ 0.6
BUN (mg/dL)	30 $\pm$ 17	34 $\pm$ 20	28 $\pm$ 16
Urine Output (cc/24 hours)			
Day 1 <sup>c</sup>	3,082 $\pm$ 2,563	3,210 $\pm$ 1,853	3,014 $\pm$ 1,853
Day 2	3,867 $\pm$ 3,647	6,087 $\pm$ 4,261	2,159 $\pm$ 1,871
Anuria/oliguria requiring dialysis/hemofiltration after ECLS <sup>d</sup>	10 (30%)	1 (8%)	9 (43%)
Liver function			
LDH	2,091 $\pm$ 2,358	1,313 $\pm$ 1,115	2,641 $\pm$ 2,847
>5 $\times$ normal values (1,000 IU/L)	17 (52%)	7 (58%)	10 (48%)
AST	1,123 $\pm$ 2,003	684 $\pm$ 829	1,400 $\pm$ 2,461
>5 $\times$ normal values (175 IU/L)	20 (61%)	8 (67%)	13 (62%)
ALT	824 $\pm$ 1,347	526 $\pm$ 848	1,012 $\pm$ 1,577
>5 $\times$ normal values (225 IU/L)	13 (39%)	3 (25%)	10 (48%)
Serum bilirubin	1.6 $\pm$ 1.1	1.6 $\pm$ 0.8	1.7 $\pm$ 1.3
$\geq$ 3.0 mg/dL	5 (15%)	1 (8%)	4 (19%)

$p < 0.05$ .

<sup>a</sup> Survival for ischemic etiology significantly greater compared with nonischemic or postcardiotomy failure. <sup>b</sup> Presence of cardiac arrest significantly greater in nonsurvivors compared with survivors. <sup>c</sup> Urine output in survivors significantly greater compared with nonsurvivors on day 2. <sup>d</sup> Requirement for hemofiltration/dialysis significantly greater in nonsurvivors compared with survivors.

LVAD. Six patients underwent transplantation and were discharged, 2 are alive and well on LVAD support awaiting transplantation at home, and 2 patients died after LVAD implant. The 2 deaths that occurred after LVAD implantation were attributed to sepsis (1) and MSOF (1). The median duration of LVAD support after ECLS was 110 days (range 1 to 260 days). One patient placed on ECLS for cardiac failure after a postinfarct ventricular septal defect was bridged directly to transplantation and survived to discharge.

The incidence of right-sided circulatory failure (RSCF) requiring mechanical assistance (RVAD or ECLS) after LVAD implant was 40% (4 of 10 patients). For patients experiencing RSCF, survival to hospital discharge after LVAD implant was 50% (2 of 4 patients). ECLS was used as right-sided circulatory support in 2 cases (50% survival to hospital discharge [1 of 2 patients]) and an Abiomed RVAD (ABIOMED Inc, Danvers, MA) was used in 2 cases (50% survival to hospital discharge [1 of 2 patients]). The arterial outflow for the ECLS circuit when used as right-sided support in conjunction with the HeartMate LVAD was femoral artery and left atrium (1), and left atrium only (1). Left atrial access was obtained by insertion of a 20F right angle canula within the right superior pulmonary vein at the time of operation.

Initial serum creatinine, serum BUN, and urine output

in the first 24 hours were not significantly different in survivors as compared with nonsurvivors after initiation of ECLS (Table 1). Ten patients (30%) required hemofiltration/dialysis for renal failure after initiation of ECLS. This requirement was significantly more frequent among the nonsurvivors ( $p < 0.05$ ). Urine output on day 2 of ECLS was significantly ( $p < 0.05$ ) greater in survivors as compared with nonsurvivors. Initial lactic dehydrogenase (LDH), AST, alanine transaminase (ALT), and total bilirubin did not differ by survival status. However, no patient placed on ECLS with an initial LDH exceeding 4,200 IU/L, AST exceeding 2,300 IU/L, ALT exceeding 2,700 IU/L, or serum total bilirubin exceeding 3.3 mg/dL survived to hospital discharge. There was a trend towards increasing AST and ALT on day 2 of ECLS in nonsurvivors, but this was not statistically significant (data not shown). Pulmonary compliance was a significant discriminator of survival in patients on ECLS for  $\geq 5$  days ( $36 \pm 9$  cc/cm H<sub>2</sub>O in survivors vs  $22 \pm 8$  cc/cm H<sub>2</sub>O in nonsurvivors,  $p < 0.05$ ).

Median duration of follow-up was 0.4 months (range 0.03 to 36.3 months). One-year actuarial survival from the time of initiation of ECLS was  $36 \pm 8\%$  (mean  $\pm$  SE). Of those patients surviving ECLS to LVAD implant, 1-year actuarial survival was  $80 \pm 12\%$  (mean  $\pm$  SE).

## Comment

To optimize survival from cardiogenic shock, multiple mechanical circulatory support options should be available to meet unique patient needs. ECLS is a proven technology that provides circulatory support to patients presenting in cardiac arrest or in extremis [1-7]. We utilized ECLS as the initial method to establish circulatory assistance in our study based on the premise that patients were in immediate need of mechanical circulatory support and that alternative circulatory support devices (eg, extracorporeal or implantable VAD) would have required additional delay (operating room setup) and risk (general anesthesia and sternotomy). This premise was supported by the observation that there was a very high incidence of cardiac arrest, intubation, IABP use, renal failure requiring hemofiltration/dialysis, and shock liver in this group [15, 16].

There are a number of disadvantages to utilizing ECLS for resuscitation in adult patients with cardiac failure. Of these disadvantages, the very short duration of safe support and the inability to adequately decompress the left ventricle represent significant concerns. In patients experiencing acute ischemic events, decompression of the left ventricle may reduce ischemic injury and improve functional recovery of the ventricle. Thus, there are potential advantages to utilizing an extracorporeal VAD configured with left ventricular apical drainage under these circumstances. We have tried to minimize this limitation of ECLS by aggressively employing percutaneous atrial septostomy when there is evidence of left ventricular dilation by echocardiography and elevated pulmonary artery pressures. However, in patients presenting in extremis, we believe it is important to give the highest priority to timely institution of mechanical support to avoid cardiac arrest, reduce the likelihood of neurological injury, and reduce the duration of significant shock than it is to delay therapy with the goal to obtain optimal left ventricular drainage. Under conditions of extremis, many extracorporeal VADs are routinely placed utilizing left atrial drainage, frequently without cardiopulmonary bypass, and thus negate their potential benefit of affording improved left ventricular decompression. Currently, there are no data to suggest that mechanical circulatory support with an extracorporeal VAD configured with left atrial drainage is superior to ECLS. Similar considerations apply when considering an implantable LVAD, for which the potential advantages (eg, avoiding an additional operation, reducing infection risk, providing higher flow rates) are greatly outweighed by the likely consequences of the longer delay in being able to restore adequate end-organ perfusion and high operative mortality.

The most important limitation of ECLS is its inability to provide long-term support because of the high incidence of complications [1, 2]. When used as a bridge to transplant in adult patients, ECLS is associated with an unacceptably low likelihood of survival [2]. This limitation has previously prevented the use of ECLS at our institution in clinical situations where myocardial recovery was not probable [2]. This major limitation of ECLS has been circumvented by

this bridge to bridge strategy, in which ECLS provides the short-term bridge to the longer-term LVAD bridge to transplantation [8, 14].

One of the major findings in this study is our continuing observation that LVAD survival after ECLS in a cohort of high-risk patients was not different as compared with a group of patients undergoing initial support with an implantable LVAD or LVAD implant after an extracorporeal VAD [15, 16]. Previous reports by McCarthy and colleagues have demonstrated that ECLS before LVAD implant is a significant risk factor for death [14]. The reasons for the different observations between these two studies is unclear but may reflect a difference in our practice to accept longer durations of ECLS to clearly identify survivable candidates at the cost of accepting a higher attrition rate on ECLS. It is likely that as ECLS support duration increases within a reasonable time frame, more patients that are less optimal for LVAD implant can be identified. In 27% of patients (9 of 33) placed on ECLS, clear absolute contraindications to heart transplant were identified, and ECLS was terminated within 48 hours. The majority of these patients had significant neurological injury, most likely sustained at the time of the initial shock event. Thus, costly LVAD implantations in patients unlikely to be a transplant candidate or to survive LVAD implant were avoided. Thus, improved LVAD outcomes were obtained at the cost of deaths on ECLS.

After ECLS, there was a need for right-sided circulatory support in 40% of patients undergoing LVAD implant. An increased frequency of MSOF has been associated with a greater need for perioperative biventricular support [17-19]. This may be attributable to lung injury caused by the inflammatory response to ECLS [20, 21]. Alternatively, the degree of lung injury may simply have been a manifestation of the severity of the initial hemodynamic insult [20, 21].

The finding that prior ECLS is not a risk factor for death after LVAD implant should reduce the reluctance of others to utilize ECLS when the likelihood of myocardial recovery is small and transplantation will be needed for long-term survival [15, 16]. The strategy of applying ECLS followed by bridging to an implantable LVAD offers almost immediate circulatory support to patients who might not otherwise have been considered for LVAD implant, or for ECLS in the absence of a long-term support option. This strategy prompts more aggressive consideration and utilization of ECLS for patients needing circulatory support. In addition, this strategy appears to conserve LVAD resources and improve overall LVAD outcomes. Patients not surviving the initial period of ECLS would not likely have survived immediate LVAD support either.

An additional finding of this study has been the identification of clinical parameters and scenarios that predict a poor outcome after initiation of ECLS. This knowledge can be applied to optimize the timing to bridge from ECLS to an implantable LVAD. Due to the finite period of time that ECLS can be utilized without experiencing significant morbidity, it is unreasonable to expect complete resolution of all organ injury before the LVAD implant. Based on our experience, it appears that in the majority of patients with survivable degrees of end-organ

injury, reasonable recovery of organ function from the initial shock event occurs within 2 to 5 days of the initiation of ECLS. After 5 to 7 days, few patients have demonstrated significant further improvement in organ function and most begin to demonstrate progressive evidence of organ dysfunction with rising serum creatinine and BUN, decreasing urinary output, and rising bilirubin. This pattern may reflect a nonsurvivable degree of organ injury or an exacerbation of the organ injury by the inflammatory cascade initiated by extracorporeal support [21]. In the case of patients presenting with acute renal failure or who develop renal failure soon after initiating circulatory support, it is unlikely that significant renal dysfunction will recover during a short period of ECLS. In such cases, we have presumed renal function will return once pulsatile flow is established with a LVAD and have not used renal function as a criterion to assess transplant candidacy or timing of LVAD implant. However, the duration of the initial shock event, degree of organ injury, and baseline renal function before the shock event must be considered in this analysis.

Recovery of pulmonary and liver function are more important factors considered in the timing of LVAD implant. We have used an international normalized ration (INR) less than 1.5 and liver enzymes greater than five times normal as important guidelines for the timing of LVAD implant. Total bilirubin is less important an indicator of the timing of LVAD implant, as we frequently observed that the sustained elevations in bilirubin that occur during ECLS recover in a more delayed fashion after LVAD implant. In addition, pulmonary compliance appears to be an important determinant of outcome: in ECLS patients with a sustained deterioration in pulmonary compliance ( $< 25$  cc/cm H<sub>2</sub>O), ECLS and subsequent LVAD outcomes are poor. This finding is consistent with previous findings that have demonstrated that the degree of initial interstitial lung fluid is a predictor of ECLS outcome [22]. In addition, we have not achieved survival in clinical scenarios where cardiac arrest has occurred in the emergency room or has occurred in the delayed postcardiotomy setting (after return to the intensive care unit or postoperative cardiac arrest). We believe these outcomes reflect the severity of the shock event and are not a result of the type of support initiated. When feasible, our preference for postcardiotomy support is an extracorporeal VAD when it can be instituted in a timely fashion (at the time of initial operation when poor hemodynamics are evident upon weaning from cardiopulmonary bypass) before the occurrence of cardiac arrest, and when there is adequate systemic oxygenation.

In summary, ECLS to LVAD bridge to transplant therapy provides a flexible strategy of circulatory support for patients who would otherwise not be candidates for an implantable LVAD or for ECLS in the absence of a long-term support option. The observation that LVAD survival after ECLS is equivalent to survival after initial LVAD support, alone, should prompt more consideration of ECLS, even in clinical scenarios where myocardial recovery is unlikely. ECLS to LVAD bridge to heart transplant therapy improves utilization of resources by initially employing the much less expensive ECLS tech-

nology until a reasonable likelihood of implantable LVAD success can be anticipated.

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