Use of Extracorporeal Life Support for Heart Transplantation: Key Factors to Improve Outcome

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Abstract

Although patients receiving extracorporeal life support (ECLS) as a bridge to transplantation have demonstrated worse outcomes than those without ECLS, we investigated the key factors in the improvement of their posttransplant outcome. From December 2003 to December 2018, 257 adult patients who underwent heart transplantation (HTx) at our institution were included. We identified 100 patients (38.9%) who underwent HTx during ECLS (ECLS group). The primary outcome was 1-year mortality after HTx. The median duration of ECLS was 10.0 days. A central type of ECLS was used in 35.0% of patients in the ECLS group. The 1-year mortality rate was 12.8%, with no significant difference between the ECLS and non-ECLS groups (16.0% versus 10.8%, $p = 0.227$). Multivariable analysis indicated that the use of ECLS was not a predictor of 1-year mortality ($p = 0.140$). Independent predictors of 1-year mortality were found to be cardiopulmonary resuscitation before HTx ($p = 0.002$) and Sequential Organ Failure Assessment (SOFA) score ($p < 0.001$). A SOFA score greater than 10 was suggested the a cutoff value for 1-year survival. Early ECLS application, sophisticated ECLS and intensive care, and liberal use of central cannulation may be important steps in achieving favorable survival after HTx.

Introduction

Venoarterial (VA) extracorporeal life support (ECLS) is a type of temporary mechanical circulatory support (MCS) for patients in cardiogenic shock¹. ECLS can be initiated for either newly diagnosed acute cardiac failure or decompensated chronic heart failure in patients already awaiting heart transplantation (HTx)². Although a durable left ventricular assist device (LVAD) is a choice of MCS for bridge to transplantation (BTT), it has several contraindications, such as intolerance for a vitamin K antagonist, poor right ventricular function, restrictive cardiomyopathy, severe intracardiac problems, and patient refusal to use long-term MCS. Furthermore, the health care system, availability of devices, patient's insurance policy, sociocultural background, and organ transplantation system vary widely by region and country³.

Although the outcomes of HTx performed directly after ECLS have been poor^{4,5}, careful patient management in an experienced center showed a favorable outcome⁶. Because the highest priority of HTx in ECLS has been established in most countries, the short waiting time may justify direct HTx from ECLS⁷⁻⁹. However, the factors that improve post-HTx survival with the liberal use of ECLS as a BTT are not well known. Hence, we reviewed our 15-year experience of HTx to determine the key factors improving outcome.

Methods

Study patients. A total of 262 adult patients underwent HTx at Samsung Medical Center from December 2003 to December 2018 (Fig. 1). All patients were on the waiting list for HTx in the Korean Network for Organ Sharing. We excluded patients who underwent repeated transplantation and those younger than 18 years. In addition, we excluded five patients who had undergone implantation of a durable LVAD before HTx. In the final cohort of 257 cases, 100 patients (38.9%) who were supported by VA ECLS or temporary

LVAD while awaiting HTx were assigned to the ECLS group. The criteria for considering ECLS as a BTT were the patient's inability to be weaned from ECLS and acute or chronic heart failure, which was included in the indications for HTx. Contraindications for HTx at our institution are severe pulmonary hypertension, irreversible renal and hepatic dysfunction, active malignancy, and active infection.

Management and cannulation strategies of ECLS. Durable LVAD was not covered by Korean National Insurance before October 2018. Therefore, most patients who failed to respond to medical therapy or intra-aortic balloon pump underwent ECLS as BTT. Patients at our institution with acute and chronic heart failure were followed by a multidisciplinary heart failure team, which was formally established in 2014. Since 2014, all patients have been provided care under the updated guidelines of modern critical care, including prevention and management of pain, agitation, delirium, immobilization, and sleep deprivation¹⁰.

The establishment of peripheral VA ECLS using Seldinger's technique at our institution was described previously¹. When the left ventricle was distended, atrial septal puncture was performed by interventionists in a catheterization laboratory (n = 17). We have not used intra-aortic balloon pump as a means for left heart decompression^{11,12}. Among the 65 patients (65.0%) in the ECLS group, peripheral cannulation was maintained until HTx. Therefore, 35 patients (35.0%) had central ECLS at the time of HTx. In 18 patients (18.0%) in the ECLS group, peripheral VA ECLS was implemented first and, after a while, converted to central ECLS. Another 17 patients (17.0%) in the ECLS group underwent central cannulation from the beginning of ECLS. Among 35 central ECLS patients, 10 (28.6%) had LVAD-type cannulation using an ECLS device. We avoided mechanical ventilation and immobilization as much as possible in accordance with the stability of the cannulation site and the patients' general condition. This strategy enables patients who are receiving ECLS to wait for HTx with a minimal risk of ventilator-associated pneumonia and peripheral cannulation-related complications.

Endpoints and follow-up. The primary outcome of the study was 1-year mortality. All patients were monitored after surgery by heart transplant physicians at Samsung Medical Center. Baseline characteristics of clinical data were collected from medical records and databases. We acquired follow-up clinical data, including vital status, through a review of medical records and telephone interviews. To complete the data, including mortality, we confirmed information by the National Registry of Births and Deaths using the unique personal identification number for each patient. The Institutional Review Board at Samsung Medical Center approved this study and waived the requirement for patient consent (IRB No. SMC 2019-09-109). The current study was carried out in accordance with the Declaration of Helsinki.

Statistical analysis. We calculated the data as the mean $\pm$ standard deviation, as the median (interquartile range), or as frequency and proportion. We used the Wilcoxon rank-sum test for skewed continuous variables. The chi-square test for categorical variables was used to compare the patient groups. We used Cox proportional hazards regression model for univariable and multivariable analyses and the forest plot based on the results of multivariable analysis to determine the independent predictors of 1-year mortality. To estimate the survival curves during the follow-up period, we used the Kaplan–Meier method, and the

survival rates of the two groups were compared using the log rank test. Statistical analysis was performed with the R programming language, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria) and SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

Baseline characteristics. The mean age of all patients was 50.3 ± 13.6 years, and the median age was 53 years (range, 18–78 years). Of the 257 patients, 79 (30.7%) were female. In the ECLS group, the mean duration of ECLS before HTx was 16.0 ± 18.9 days, and the median duration was 10.0 days (interquartile range, 7–17 days). Sixty-eight patients (68.0%) in the ECLS group were on the waiting list for HTx at the time of VA ECLS implantation. In the other 13 ECLS patients, decompensated chronic heart failure was diagnosed after hospitalization. Another 19 ECLS patients were diagnosed with irreversible acute heart failure, such as extensive myocardial infarction or irreversible myocarditis (Fig. 1). Table 1 summarizes the baseline characteristics of the patients in the ECLS and non-ECLS groups, and we found significant differences in several characteristics between the two groups.

Perioperative outcomes and predictors of 1-year mortality. Although aortic cross-clamping time and total ischemic time were similar in the two groups, postoperative complications were more frequent in the ECLS group than in the non-ECLS group. Table 2 summarizes the operative and postoperative data.

The 1-year mortality rate was 12.8% ($n = 33$). The 1-year outcomes did not differ significantly between the two groups (16.0% mortality in the ECLS group and 10.8% mortality in the non-ECLS group; $p = 0.227$). The Kaplan–Meier survival analysis also revealed a trend for a difference in overall survival after HTx (Fig. 2; log rank $p = 0.114$). Supplementary Table S1 summarizes the estimated rates of survival at 6 and 12 months.

In the multivariable analysis, the 1-year mortality rates did not differ significantly between the ECLS and non-ECLS groups ($p = 0.140$; hazard ratio 0.483; 95% confidence interval 0.184–1.270). The need for cardiopulmonary resuscitation (CPR) during the waiting period ($p = 0.002$; hazard ratio 3.574; 95% confidence interval 1.615–7.912) and the Sequential Organ Failure Assessment (SOFA) score ($p < 0.001$; hazard ratio 1.246; 95% confidence interval 1.118–1.390) were independent predictors. The receiver-operating characteristic curve showed that the SOFA score predicted 1-year mortality with an area under the curve of 0.686 ($p < 0.001$), and the cutoff value was 10 (Supplementary Fig. S1). Table 3 and Fig. 3 summarize the results of the Cox proportional hazards regression model for univariable and multivariable analyses of 1-year mortality.

Discussion

Although the best option for BTT is durable LVAD, there are a few circumstances in which ECLS can be favored. First, in some countries, a durable LVAD is still not available or is too restrictive¹³. For example, the approval process by the National Health Insurance in Korea takes a few weeks. Second, when a

patient has severe right ventricular dysfunction or restrictive cardiomyopathy, the implantation of durable LVAD is not a viable option^{14,15}. Furthermore, in most national organ-sharing systems, highest priority for HTx is given to patients on temporary MCS such as ECLS. In such transplantation systems, the waiting time on ECLS may be within the safe range, namely, less than a few weeks, if a high level of ICU and ECLS care is provided.

Although post-HTx complications were more common in the ECLS group than in the non-ECLS group, there was no statistically significant difference in 1-year mortality between the two groups. After adjusting for confounders including organ failure and cardiac arrest, pre-HTx ECLS tended to be a favorable factor for 1-year survival (Fig. 3). Although this does not mean that performing ECLS improves 1-year survival, cardiac arrest during the waiting period and high SOFA score are much stronger risk factors than ECLS. ECLS can prevent sudden cardiac arrest and organ failure caused by low cardiac output syndrome, which suggests that timely ECLS initiation is the most important step to improve outcome of HTx. The second step would be applying sophisticated ECLS and up-to-date intensive care to prevent both ECLS and intensive care–related complications. For patients who are waiting for HTx while on ECLS, the final step could be the liberal use of central cannulation. In some relatively stable patients who require a prolonged waiting time for HTx, primary central ECLS can be performed. In other patients who already had peripheral ECLS, cannulation can be stitched to a central type after careful discussion and hemodynamic stabilization. Central cannulation and circuit configurations vary according to the patient's right ventricular and pulmonary function. In general, we consider central conversion on the 14th day of peripheral cannulation. Fig. 4 shows our recent strategy.

Moonsamy et al. also reported that temporary circulatory support (TCS)-VAD had a survival advantage over ECLS and was similar to durable LVAD as a BTT in the United Network of Organ Sharing database⁷. In their study, there is no information about cannulation type or ECLS duration. In our study, the definition of ECLS includes TCS-VAD in Moonsamy's study, because 35.0% of our ECLS patients had nonperipheral cannulation, including central VA ECLS and temporary VAD with/without membrane oxygenator TCS-VAD. In other words, in an emergency setting, temporary VAD implantation cannot be placed as conveniently and quickly as ECLS. We believe that some patients in the TCS-VAD group probably had been converted from peripheral ECLS, like our patients. Therefore, we believe that various cannulation options should be offered to patients, including either direct central cannulation or peripheral ECLS first. To reduce peripheral cannulation–related complications, the timely conversion to central cannulation is critical.

Coutance et al. also compared ECLS-bridged HTx and non-ECLS-bridged HTx in their large retrospective study⁶. Although they emphasized strong ECLS care, including the prevention of ECLS complications and the application of light sedation, their selection criteria for HTx in ECLS patients seems to be quite strict. In contrast to our procedure, they performed HTx only for patients without other organ failure. Because the study by Coutance et al. included only relatively low-risk patients,⁶ it is difficult to determine how we can improve the outcome of HTx. Table 4 presents a comparison of previous studies (Coutance et al. and Moonsamy et al.) with the current study^{6,7}. Each paper showed various HTx waiting periods, and to

improve HTx outcomes, it will be important to implement the optimal settings for BTT based on the circumstances of each country.

Because we included patients with some degree of organ failure, we determined that the need for CPR during the waiting period and the SOFA score were independent predictors of 1-year mortality. We also found that a SOFA score greater than 10 is a predictor of poor clinical outcome. Thus, the timing of ECLS insertion is important, and ECLS should be deployed before cardiac arrest and severe multiorgan failure.

We used an approach to prevent the occurrence of ECLS-related complications. Most patients had a preventive distal limb perfusion catheter. For example, in the ECLS group, the rate of limb ischemia was 5.0% (Table 2). During the same period as our study, the rate of limb ischemia in all patients with VA ECLS at our institution was 5.69%. Taking into consideration that the rate of limb ischemia has been reported to be as high as 70%¹⁶, our outcome is good. Intensivists have maintained the most up-to-date ICU care, such as light sedation, minimally invasive ventilation, and aggressive mobilization. High-quality ECLS and ICU care were also emphasized in the article by Coutance et al⁶. Although post-HTx complications were more common in the ECLS group than in the non-ECLS group, they did not affect post-HTx survival.

Limitations

Because this study was retrospective and involved 257 patients at a single tertiary center, its statistical power may be limited. Although the unadjusted 1-year outcome did not differ between the two groups, there was a marginal decrease in the rate of survival in the ECLS group. ECLS itself was clearly not a predictor of mortality in the multivariate analysis. The duration of ECLS before HTx in the ECLS group was short (median: 10 days, mean: 16.0 ± 18.9 days). However, the duration was longer than in previous studies^{6,17}. We did not include patients who were listed for HTx but did not receive a transplantation. Thus, the study may have some selection bias.

Conclusion

After multivariable adjustment, the use of ECLS was not determined to be a risk factor of post-HTx survival. CPR before HTx and the degree of multiorgan failure were independent predictors of 1-year mortality. Early ECLS application, sophisticated ECLS and intensive care, and liberal use of central cannulation may be important steps in achieving favorable survival after HTx.

Declarations

Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

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Authors contributions

J.H.L, J.O.C, and Y.H.C conceived and designed the study. J.H.L, I.P, and J.Y.K performed statistical analyses and wrote the manuscript. K.S, W.S.K, D.K, J.H.Y, E.S.J, J.O.C, and Y.H.C revised the manuscript. All authors participated in drafting the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare no competing interests.

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Tables

Table 1. Baseline characteristics of all patients.

Characteristic	ECLS group (n = 100)	Non-ECLS group (n = 157)	<i>p</i> value
Age of recipient (years)	51.5 (38.5-59.5)	54 (44-61)	0.186
Female recipients	29 (29.0)	50 (31.9)	0.630
Age of donor (years)	42.5 (33-50)	42 (34-49)	0.761
Female donors	22 (22.0)	46 (29.3)	0.196
Gender mismatch	35 (35.0)	52 (33.1)	0.756
Diabetes	29 (29.0)	29 (18.5)	0.049
Hypertension	27 (27.0)	52 (33.1)	0.300
Body mass index (kg/m ²)	21.9 (19.2-24.2)	22.1 (20.4-24.5)	0.142
Previous cardiac surgery	23 (23.0)	17 (10.8)	0.009
Previous PCI or CABG	28 (28.0)	32 (20.4)	0.159
Stroke	8 (8.0)	11 (7.0)	0.767
Chronic renal insufficiency	9 (9.0)	33 (21.0)	0.011
Dialysis	30 (30.0)	13 (8.3)	< 0.001
CPR	31 (31.0)	11 (7.0)	< 0.001
LVEF (%)	20 (16-25)	23 (19-30)	0.002
DCMP	54 (54.0)	100 (63.7)	0.122
ICMP	26 (26.0)	29 (18.5)	0.151
SOFA score	7 (6-10)	3 (2-5)	< 0.001
Pre-HTx hospital day	25 (12-43)	50.5 (23-92)	< 0.001
Pre-HTx ECLS day	10 (7-17)	NA	NA
Pre-HTx ventilator day	7 (2-13)	0 (0-0)	< 0.001
WBC (10 ³ /mm ³)	10.6 (8.2-13.8)	6.5 (5.2-8.1)	< 0.001
Hemoglobin (g/dL)	9.6 (8.8-10.4)	11.9 (10.5-13.1)	< 0.001
Hematocrit (%)	28.7 (26.3-31.6)	36.3 (31.1-39.3)	< 0.001
Platelet count (10 ³ /mm ³)	97.5 (72-126)	181 (137-233)	< 0.001
Creatinine (mg/dL)	1.1 (0.7-1.7)	1.1 (0.9-1.4)	0.722
Total bilirubin (mg/dL)	2.6 (1.5-7.4)	1.3 (0.7-2.2)	< 0.001

NT-proBNP (pg/mL)	9836 (3588-23658)	4052 (2263.5-8818)	< 0.001
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Non-normally distributed numerical variables are presented as medians (interquartile ranges) and were tested using the Wilcoxon rank-sum test. Categorical variables are presented as numbers (percentages) and were tested using the chi-square test.

PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft surgery; CPR, cardiopulmonary resuscitation; LVEF, left ventricular ejection fraction; DCMP, dilated cardiomyopathy; ICMP, ischemic cardiomyopathy; SOFA, Sequential Organ Failure Assessment; HTx, heart transplantation; ECLS, extracorporeal life support; NA, not applicable; WBC, white blood cell; NT-proBNP, N-terminal prohormone of brain natriuretic peptide.

Table 2. Operative and postoperative characteristics of all patients.

Characteristic	ECLS group (n = 100)	Non-ECLS group (n = 157)	<i>p</i> value
CPB time (minutes)	143 (123.5-170)	146 (127-182.5)	0.136
ACC time (minutes)	78.5 (64-96.5)	88 (70-106)	0.005
Total ischemic time (minutes)	179.5 (146.5-237)	180 (147.5-234.5)	0.901
Cold ischemic time (minutes)	119 (85.5-179.5)	114 (81-162.5)	0.399
Warm ischemic time (minutes)	59 (49.5-70)	66 (56-79)	0.001
Postoperative ICU stay (days)	16 (11-28)	9 (6-13)	< 0.001
Total hospital stay (days)*	75 (54-125)	79 (52-128)	0.935
Ventilator support $\geq$ 3 days after HTx	37 (37.0)	14 (8.9)	< 0.001
Reoperation for bleeding control	17 (17.0)	11 (7.0)	0.012
Infection	36 (36.0)	17 (10.8)	< 0.001
Limb ischemia	5 (5.0)	NA	NA

*Total hospital stay includes pre- and post-HTx hospital stay.

Non-normally distributed numerical variables are presented as medians (interquartile ranges) and were tested using the Wilcoxon rank-sum test. Categorical variables are presented as numbers (percentages) and were tested using the chi-square test.

CPB, cardiopulmonary bypass; *ACC*, aorta cross-clamping; *ICU*, intensive care unit; *HTx*, heart transplantation; *NA*, not applicable.

Table 3. Independent predictors of 1-year mortality.

Variable	Univariable				Multivariable			
	<i>p</i> value	Hazard ratio	95% Confidence interval		<i>p</i> value	Hazard ratio	95% Confidence interval	
			Lower .95	Upper .95			Lower .95	Upper .95
Pre-HTx ECLS	0.169	1.616	0.816	3.199	0.140	0.483	0.184	1.270
Age of recipient (years)	0.156	1.020	0.992	1.049	0.486	1.010	0.982	1.040
Female recipients	0.133	1.696	0.851	3.384				
Age of donor (years)	0.530	0.991	0.963	1.019				
Female donors	0.915	1.042	0.485	2.243				
Gender mismatch	0.436	1.320	0.656	2.653				
Diabetes	0.924	0.960	0.417	2.212				
Hypertension	0.574	0.803	0.373	1.727				
Body mass index (kg/m ²)	0.586	0.976	0.893	1.066				
Previous cardiac surgery	0.980	1.012	0.391	2.622				
Previous PCI or CABG	0.339	1.436	0.684	3.017				
Stroke	0.990	0.000	0.000	NA				
Chronic renal insufficiency	0.005	2.825	1.369	5.829	0.076	2.067	0.927	4.611
CPR	< 0.001	4.576	2.292	9.136	0.002	3.574	1.615	7.912
LVEF (%)	0.055	1.023	1.000	1.047				
DCMP	0.138	0.596	0.301	1.180				
ICMP	0.604	0.791	0.327	1.917				
SOFA score	< 0.001	1.193	1.113	1.279	< 0.001	1.246	1.118	1.390
WBC (10 ³ /mm ³)	0.655	1.015	0.951	1.084				
Hemoglobin (g/dL)	0.382	0.927	0.782	1.099				
Hematocrit (%)	0.327	0.972	0.918	1.029				

Platelet count (10 ³ /mm ³)	0.118	0.996	0.991	1.001				
Creatinine (mg/dL)	0.061	1.116	0.995	1.253				
Total protein (g/dL)	0.143	0.784	0.567	1.086				
Albumin (g/dL)	0.025	0.563	0.340	0.930	0.532	1.252	0.619	2.529

HTx, heart transplantation; ECLS, extracorporeal life support; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft surgery; NA, not applicable; CPR, cardiopulmonary resuscitation; LVEF, left ventricular ejection fraction; DCMP, dilated cardiomyopathy; ICMP, ischemic cardiomyopathy; SOFA, Sequential Organ Failure Assessment; WBC, white blood cell.

Table 4. Comparison of recent and current studies.

Characteristic	The current study (n = 100)	Coutance et al. (n = 118)	Moonsamy et al. (n = 177)
Study setting	Single institution Retrospective	Single institution Retrospective	Multi-center registry Retrospective
Study period (duration)	2003-2018 (15 years)	2012-2016 (5 years)	2005-2017 (13 years)
Age of recipient (years)	48.8 ± 14.2	48.0 ± 12.4	46 ± 15
Age of donor (years)	40.9 ± 11.7	44.9 ± 15.3	32 ± 12
Previous cardiac surgery	23 (23.0)	23 (19.5)	82 (46.3)
Dialysis	30 (30.0)	1 (0.9)	32 (18.1)
ICMP	26 (26.0)	37 (31.3)	40 (22.6)
Mechanical ventilation	84 (84.0)	13 (11.0)	82 (46.3)
Total days on the waiting list	48.9 ± 94.0	18.0 ± 56.0	89 ± 214
Pre-HTx ECLS days	10 (7-17)	9 (5-15)	NA
Creatinine (mg/dL)	1.5 ± 1.6	0.8 ± 0.4	1.3 ± 0.8
Total bilirubin (mg/dL)	6.3 ± 9.7	5.6 ± 4.1	2.3 ± 3.4
Total ischemic time (minutes)	192.9 ± 62.3	199 ± 47	198 ± 60
1-year survival of ECLS group (%)	84.0	85.5	67.6
1-year survival of no support (%)	89.2	80.7	90.2

Numerical variables are presented as medians (interquartile ranges) or means ± standard deviations. Categorical variables are presented as numbers (percentages).

ICMP, ischemic cardiomyopathy; HTx, heart transplantation; ECLS, extracorporeal life support; NA, not applicable.

Figures

Figure 1

Flow diagram of patient recruitment. HTx, heart transplantation; LVAD, left ventricular assist device; ECLS, extracorporeal life support; CHF, chronic heart failure; AHF, acute heart failure; VA, venoarterial.

Figure 2

Kaplan-Meier post-heart transplantation survival curves for patients who received extracorporeal life support (ECLS; green line) and those who did not receive ECLS (Non-ECLS; blue line). ECLS, extracorporeal life support.

Figure 3

The forest plot based on the result of multivariable analysis of 1-year mortality. HR, hazard ratio; CI, confidence interval; HTx, heart transplantation; ECLS, extracorporeal life support; CPR, cardiopulmonary resuscitation; SOFA, Sequential Organ Failure Assessment.

Figure 4

The recent strategy of extracorporeal life support as bridge to transplant in our institution. VA, venoarterial; ECLS, extracorporeal life support; HTx, heart transplantation; LVAD, left ventricular assist device; BTC, bridge to candidacy; DT, destination therapy; BTT, bridge to transplantation.

Supplementary Files

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