Extracorporeal Life Support as a Bridge to Lung Transplantation: A Single-Center Experience With an Emphasis on Health-Related Quality of Life

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BACKGROUND: Extracorporeal life support (ECLS) as a bridge to lung transplantation is increasingly used, but information on long-term outcome is scarce. We aim to summarize our experience with an emphasis on health-related quality of life. Secondary outcomes include ICU and hospital stay and pre- and post-transplant mortality. METHODS: A retrospective cohort study of all adult subjects receiving ECLS as a bridge to lung transplantation from 2010 to 2014 was reviewed and compared with all adult subjects who underwent bilateral lung transplantation in the same period. For the ECLS group, the general health status was assessed with the use of the EuroQol Group 5-Dimension Self-Report Questionnaire. RESULTS: A total of 130 bilateral transplants were performed, 9 transplants were performed after ECLS therapy. Another 11 subjects died on the waiting list while receiving ECLS. Quality of life, at 12 months after surgery, from a subject's perspective was comparable in both groups with a median score of 80 on the visual analog scale. The median (interquartile range [IQR]) EuroQol Group 5-Dimension Self-Report Questionnaire 3L score from the societal perspective in the ECLS group was 0.73 (0.5–0.9). Median (IQR) ICU stay was 25 d (9–68 d) for the ECLS group versus 7 d (4–18 d) for the control group ($P = .001$), and in-hospital stay was 66 d (40–114 d) versus 42 d (29–62 d) ($P = .004$). CONCLUSIONS: ECLS can be used as a bridge to lung transplantation. A significant number of subjects were not bridged successfully due to different reasons. Outcomes after successful transplantation after ECLS might be comparable with the general population undergoing lung transplantation in terms of quality of life, lung function, performance tests, and mortality, although ICU and hospital stay are longer. *Key words: lung transplantation; extracorporeal life support; health-related quality of life; quality of life.* [Respir Care 2017;62(5):588–594. © 2017 Daedalus Enterprises]

Introduction

The indication for extracorporeal life support (ECLS) by means of extracorporeal membrane oxygenation is acute, potentially reversible cardiac or respiratory failure, when conventional therapy has been insufficient.[1] In addition, ECLS can also be used in patients with chronic respiratory or cardiac failure as a bridge to transplant or to support

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cardiopulmonary resuscitation.[2] More than 3 decades ago, ECLS was introduced to manage patients on the waiting list for lung transplantation with a high risk of dying of acute respiratory failure refractory to mechanical ventilation.[3] More recently, ECLS has become a treatment option for hemodynamic support of right-ventricular failure in patients with pulmonary hypertension awaiting lung transplantation as well.[4] However, many centers had reservations to transplant patients from ECLS. This reluctance faded after it was shown that outcomes of patients receiving mechanical ventilation before transplantation were comparable with outcomes of patients without mechanical ventilation before transplantation, although postoperative mechanical ventilation duration and ICU stay were longer.[5] A registry study from the United States demonstrated that the survival after lung transplantation was markedly reduced when preoperative mechanical support was used.[6]

With the introduction of the lung allocation score, organs are now allocated to patients who have the greatest need, such as those who are receiving ECLS but are also still likely to benefit from transplant.[7] With this approach, the transplantation rates may increase for patients waiting for transplantation while receiving ECLS. A retrospective study of all lung transplantation recipients (N = 12,458) in the United Network for Organ Sharing database between 2000 and 2011 showed that 119 subjects were transplanted while receiving pre-transplant ECLS support. The 1-y survival for those subjects supported with ECLS was significantly lower than in subjects with lung transplantation without ECLS, but survival progressively increased over time, as did the number of subjects using ECLS as a bridge.[8]

In a systematic review with 14 retrospective studies, sample size ranged from 11 to 122, totaling 441 adult subjects who were supported with ECLS to lung transplantation in the period from 2000 to June 2014. This cohort had an acceptable 1-y survival, with a wide range of 50–90%.[9] Information focusing on quality of life (QOL) after ECLS therapy as a bridge to lung transplantation is lacking in the literature. The aim of our study was therefore to summarize our institutional experience with ECLS as a bridge to lung transplantation with an emphasis on generic health-related QOL (HRQOL).

QUICK LOOK

Current knowledge

Extracorporeal life support (ECLS) as a bridge to lung transplantation has been used more frequently in the last decade. The 1-y survival rates are acceptable. Health-related quality of life (HRQOL) is a very broad concept that refers to quality of life that is directly related to health or illness. To assess general health status, we used of the EuroQol Group 5-Dimension Self-Report Questionnaire. The impact of ECLS on HRQOL after lung transplantation is unclear, but it is important to focus on HRQOL as an outcome parameter after lung transplantation.

What this paper contributes to our knowledge

Nine of the 20 subjects were successfully transplanted after ECLS as a bridge, with 2 subjects dying within the first 40 d post-transplant. The 7 survivors all had a 1-y survival and a generic HRQOL and lung function comparable with other lung transplantation subjects, with a longer stay in the ICU and in the hospital.

Methods

Approval of the medical ethical committee of our institute was received before the study (METc 2014/011). We performed a retrospective cohort study in which the clinical course of all adult subjects who were receiving ECLS as a bridge to lung transplantation (ECLS group) was compared with that of all other adult subjects who underwent bilateral lung transplantation without ECLS (control group) between 2010 and 2014. All pre-transplant screenings, waiting list visits, preoperative hospital admissions, and postoperative follow-up visits took place in our hospital. Recipients were considered eligible for lung transplantation according to standard criteria. ECLS support, venovenous (VV) or venoarterial, was initiated in the presence of severe hypoxia or hypercapnia despite maximal ventilation support or, in subjects with pulmonary hypertension, in cases of hemodynamic deterioration despite maximal support at instructions of the team consisting of the intensivist, anesthesiologist, cardiothoracic surgeon, and transplantation physician. ECLS therapy was performed in all cases with the Cardiohelp HLS module 7.0 (Maquet, Wayne, New Jersey) with percutaneous inserted cannulas. Anticoagulation strategy while receiving ECLS consisted of unfractionated heparin targeted at a partial thromboplastin time between 60 and 80 s. Post-transplant immunosuppression consisted for all subjects of induction with basiliximab, 20 mg on the day of transplantation with a repeated dose on day 4 and additional triple therapy consisting of tacrolimus, mycophenolate mofetil, and prednisolone. Primary graft dysfunction was scored 0–3 according to International Society for Heart and Lung Transplantation guidelines at 0, 24, 48, and 72 h post-transplant. Severe primary graft dysfunction was defined as a score of 3 at 48 and/or 72 h.[10]

For patients in our lung transplantation program, it is standard follow-up to collect a visual analog scale score on HRQOL. For patients treated with ECLS in our hospital, it is standard to assess general health status once at 12 months

Table 1. Baseline Characteristics

Variable	ECLS as Bridge (n = 20)	Control Group (n = 121)	P
Age, median (IQR) y	42 (25–48)	52 (42–58)	.003
Male sex, n (%)	9 (45)	65 (54)	.48
BMI, median (IQR) kg/m^2	22 (18–25)	22 (19–25)	.29
Underlying pulmonary disease, n (%)			.002
COPD	1 (5)	38 (31)	.01
CF	8 (40)	25 (21)	.08
COPD alpha-1 antitrypsin deficiency	0	22 (18)	.043
Lung fibrosis	7 (35)	14 (12)	.01
IPAH	3 (15)	9 (7)	.38
Other	1 (5)	13 (11)	.69
Time on waiting list, median (IQR) d	20 (10–130)	443 (137–910)	<.001
High urgency status, n (%)	20 (100)	51 (42)	<.001
Pre-LTx mechanical ventilation, n (%)	19 (95)	7 (6)	<.001

ECLS = extracorporeal life support
IQR = interquartile range
BMI = body mass index
CF = cystic fibrosis
IPAH = idiopathic pulmonary arterial hypertension
LTx = lung transplantation

after surgery with the use of the EuroQol Group 5-Dimension Self-Report Questionnaire 3L (EQ-5D) (see the supplementary materials at http://www.rcjournal.com). Subjects were interviewed by telephone. The EQ-5D measure of HRQOL consists of a descriptive system with 5 domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), with 3 possible levels on each, which can be converted into a single summary index score ranging from −0.594 (Worst imaginable health state) to 1 (Best imaginable health state), which represents the societal perspective on QOL, and a score on a visual analog scale, ranging from 0 (worst possible health) to 100 (best possible health), which represents the patient's perspective on QOL.[11] For both the index score of the EQ-5D and the visual analog scale, higher scores indicate a better quality of life. For comparison with the control group, only the subject's perspective on QOL (visual analog scale) was used because the full EQ-5D was not part of the standard follow-up in this group. Secondary outcomes were ICU and hospital stay (length of stay [LOS]), use of blood products, primary graft dysfunction, lung function and performance testing at 12 months after lung transplantation, and mortality.

For statistical analysis, continuous variables are shown as median (interquartile range). Outcomes between subjects with and without ECLS before lung transplantation were compared with the Mann-Whitney U test, chi-square test, or Fisher exact test where methodologically appropriate. A P value of <.05 was considered statistically significant.

Results

During the study period, 20 subjects underwent ECLS as bridge to lung transplantation; of these, 9 subjects were transplanted, and 11 subjects died before lung transplantation was performed. This study population (ECLS group) was compared with 121 subjects who had lung transplantation without prior ECLS (control group). Baseline characteristics are shown in Table 1. ECLS subjects were younger, more likely to have lung fibrosis, and less likely to have COPD as an underlying diagnosis. Their time on the waiting list was shorter ($P < .001$); only 6 subjects received ECLS therapy due to clinical deterioration after a long time on the waiting list, and the other 14 subjects were urgently screened and put on the waiting list at Eurotransplant after the initiation of ECLS treatment. All subjects receiving ECLS therapy were listed as high urgency versus 51 subjects (42%) in the control group ($P < .001$). ECLS subjects depended more on mechanical ventilation (95%) than did controls (6%, $P < .001$). VV ECLS was used as the ECLS modality in 17 subjects: bi-caval dual lumen cannula in the jugular vein in 8 subjects, double lumen cannula in the femoral vein in 3 subjects, femoral-femoral vein in 3 subjects, and femoral-jugular vein in 3 subjects. Venoarterial ECLS, peripherally inserted in the groin, was used in 3 subjects with primary pulmonary hypertension. Reasons for death during ECLS support before lung transplantation were development of multi-organ failure ($n = 5$), bleeding complications ($n = 3$), and right-ventricular heart failure on VV ECLS ($n = 3$). Subjects who died while receiving ECLS were more likely

Table 2. Recipient Characteristics Among Subjects With and Without Survival to Lung Transplantation

Variable	Successful LTx after ECLS as Bridge (n = 9)	Died while on ECLS as Bridge to LTx (n = 11)	P
Age, median (IQR) y	44 (19–55)	41 (39–48)	.77
Male sex, n (%)	6 (67)	3 (28)	.18
BMI, median (IQR) kg/m^2	21 (18–25)	23 (19–24)	.66
Underlying pulmonary disease, n (%)			.10
COPD	1 (11)	0	
CF	2 (22)	6 (55)	
Lung fibrosis	5 (56)	2 (18)	
IPAH	1 (11)	2 (18)	
Other	0	1 (9)	
Time on waiting list, median (IQR) d	16 (6–24)	57 (11–183)	.15
Urgently screened, n (%)	8 (89)	6 (55)	.16
ECLS duration until death or LTx, median (IQR) d	10 (6–12)	8 (6–12)	.66
Mode of ECLS, VV, n (%)	8 (89)	9 (82)	>.99

LTx = lung transplantation
ECLS = extracorporeal life support
IQR = interquartile range
BMI = body mass index
CF = cystic fibrosis
IPAH = idiopathic pulmonary arterial hypertension
VV = venovenous

Table 3. Outcome

Variable	ECLS as Bridge (n = 9)	Control Group (n = 121)	P
Number of RBC transfusions in first postoperative day, median (IQR)	16 (10–23)	3 (2–10)	.001
Number of FFP transfusions in first postoperative day, median (IQR)	10 (5–19)	3 (0–6)	.007
Number of platelet transfusions in first postoperative day, median (IQR)	1 (1–3)	0 (0–2)	.006
Total ICU length of stay, median (IQR) d	25 (9–68)	7 (4–18)	.001
Total hospital length of stay, median (IQR) d	66 (40–114)	42 (29–62)	.004
ICU mortality, n (%)	1 (11)	10 (8)	.56
Visual analog scale, median (IQR)	80 (12–87)	80 (72–95)	.34
FEV_1 at 12 months, median (IQR) % predicted	90 (79–96)	85 (69–95)	.68
6MWT at 12 months, median (IQR) % predicted	81 (66–84)	72 (64–80)	.20
Severe PGD, n (%)	2 (25)	26 (25)	>.99

ECLS = extracorporeal life support
RBC = red blood cells
IQR = interquartile range
FFP = fresh frozen plasma
6MWT = 6-min walk test
PGD = primary graft dysfunction

to be female and had spent more time on the waiting list, although this was not statistically significant compared with subjects who survived to lung transplantation (see Table 2). The pre-transplant ECLS support had a median duration of 10 d in the 9 subjects who were transplanted. In 5 ECLS subjects (89%), transplantation was assisted with a cardiopulmonary bypass because of hemodynamic instability or inability to collapse the lungs. Cardiopulmonary bypass was used in 47 subjects (39%) from the control group. We chose to continue ECLS in all subjects for 1–2 d into the postoperative period to provide a smooth transition to the transplanted lung and remove the cannulas in the ICU. The subjects receiving ECLS had significantly more red blood cell, plasma, and platelet transfusions within the first 24 h after transplantation compared with standard bilateral lung transplants (see Table 3). The total ICU and hospital LOS was significantly longer in ECLS subjects (even when the pre-transplant ICU and hospital LOS is not included). In the ECLS group, 2 subjects (22%) died postoperatively; one subject died within 1 h upon arrival on the

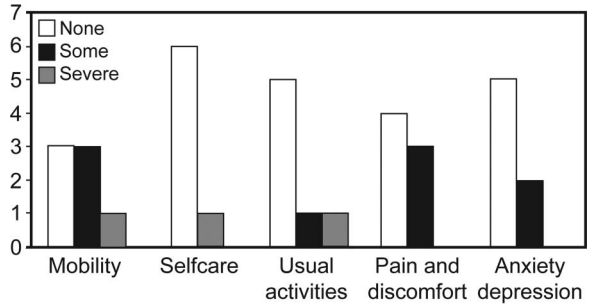

Fig. 1. The EuroQol Group 5-Dimension Self-Report Questionnaire measure of health-related quality of life. $n = 7$.

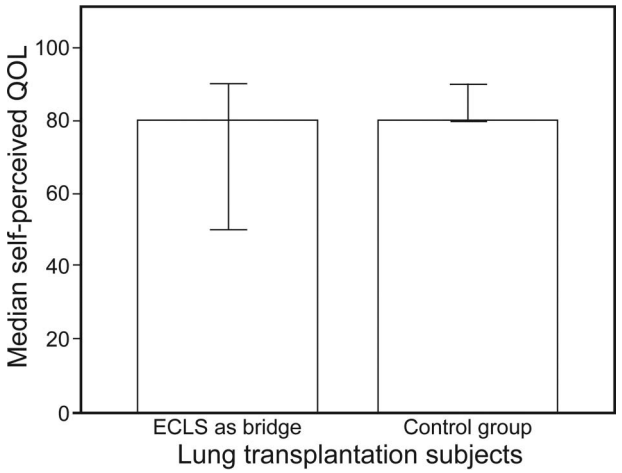

Fig. 2. Subject perspective of quality of life (QOL) as assessed by the visual analog scale, where 100 represents perfect health. ECLS = extracorporeal life support. Error bars show 95% CI.

ICU of massive blood loss after retransplantation, and the other subject died after 40 d due to respiratory insufficiency, most likely due to nonadherence to immunosuppressive medication during her stay at home. Hospital mortality was one subject (11%) in the ECLS group and 10 (8%) in the control group, which is not significantly different. After hospital discharge, another 9 subjects died in the control group, resulting in a 1-y mortality for the control group of 15%. Severe primary graft dysfunction in the first 72 h was similar in both groups, as was lung function and performance tests after 12 months.

HRQOL at 12 months after lung transplantation was available for all 7 surviving subjects in the ECLS group. The 5 EQ-5D domains of these subjects are shown in Figure 1. The 2 deceased subjects were excluded from this analysis. One subject scored "worse than dead" from a societal perspective; he underwent urgent lung transplant after an exacerbation of his mild lung fibrosis after a diagnostic wedge resection with video-assisted thoracoscopy and remained dialysis-dependent. The median (IQR) summary index score of the ECLS group was 0.73 (0.5–0.9).

The subject perspective on QOL assessed with the visual analog scale is shown in Figure 2. The visual analog scale was prospectively scored from 2012 onward and available from 77 subjects of the control group and all 7 survivors from the ECLS group. The median (IQR) visual analog scale was 80 (65–82) in the ECLS group, similar to the control group, 80 (72–95) ($P = .33$).

Discussion

The main findings of our study are that only 9 of 20 of the subjects (45%) were successfully transplanted after ECLS as bridge, with 2 subjects dying within the first 40 d post-transplant. The 7 survivors all had a 1-y survival and a generic HRQOL and lung function comparable with other lung transplantation subjects.

The mortality rate of 55% of subjects receiving ECLS who did not make it to lung transplantation was relatively high compared with the 17–50% mortality rate reported in other studies.[12-21] The most frequent causes of death in this group (multi-organ failure and bleeding complications) are the same as described in the literature.[13,21] In the study with the highest reported mortality, liver failure was an important phenomenon.[21] We did not see liver failure in our population. For the 3 subjects who died while receiving VV ECLS due to right-ventricular heart failure, the mode of support was ultimately insufficient. Compared with other studies that showed a mean waiting time of 6–7 d, our period receiving ECLS as a bridge was relatively long.[12-15] A relationship between increasing mortality and an increasing number of days spent waiting for transplantation while on ECLS with a hazard ratio of 1.12/d has been reported.[16] With the implementation of the lung allocation score, the waiting time while receiving ECLS might shorten, which could improve the waiting list outcome in the future.

When lung transplantation was performed, the ICU mortality in the ECLS group was comparable with lung transplants in the control group. The ICU and hospital LOS were significantly longer in the ECLS group than for the subjects in the control group. Although in some studies only LOS after lung transplantation is reported, our ICU and hospital LOS of our ECLS group were relatively long compared to other studies. This is partly explained by the longer time our subjects spent on the waiting list.[12,13,17,19] Furthermore, we have a large catchment and most of our subjects are discharged directly to their home and are not transferred to their regional hospitals.

For lung transplantation in general, it is well known that it can improve generic HRQOL. In a Dutch cohort of 24 subjects, it was shown that as early as 4 months after transplantation, the domains of mobility, energy, sleep, activities of daily living dependence level, and shortness of breath are positively affected. These improvements were

maintained in the follow-up.[22] Also, in a 2001 study of generic HRQOL described with the EuroQol questionnaire in the United Kingdom, a mean utility value of 0.31 for subjects ($n = 87$) on the waiting list was assessed, which improved to 0.83 7–18 months after bilateral lung transplantation.[23] Our ECLS group scored a median summary index score of 0.73, which seems comparable and acceptable.

Because of the retrospective nature of our study, the visual analog scale score was only available in two thirds of the control group, and the EQ-5D questions were not available at all. We therefore were only able to compare the subject's perspective on QOL with a score on the visual analog scale. However, the use of the visual analog scale score strongly agrees with the EQ-5D states.[24]

For intensive care patients in general, recovery after critical illness is achieved by measures applied during their stay in the ICU (eg, less sedation and awake ECLS). Specifically focusing on all of the 5 (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) will enhance HRQOL after lung transplantation. We think that physical rehabilitation plays a great part in early recovery of HRQOL in patients after lung transplantation, and even more after bridge with ECLS because of their longer hospital stay and muscle weakness and wasting.

In subjects who underwent bilateral lung transplantation, the FEV_1 6–9 months post-transplant is on average 78–85% of predicted, as it was in our control group.[25,26] There are few available data on pulmonary function in subjects who have undergone lung transplantation after ECLS. In our cohort, the pulmonary function tests showed a FEV_1 of 90% of predicted after 12 months. One study showed that 1 y after transplant, lung function did not differ between subjects requiring ECLS before lung transplant and those who did not.[12] In a Scandinavian cohort of 10 subjects receiving ECLS as a bridge, the mean FEV_1 was 2.0 ± 0.7 L (62% of predicted), and 6-min walk distance was 584 m; however, the timing of these pulmonary function tests was not clearly defined.[18]

Our study has several limitations. First, it is a single-center retrospective study of limited size. For this reason, we cannot exclude a possible confounding role of some relevant factors, such as diagnosis and comorbidity at the beginning of ECLS therapy, donor variables, or intra-operative findings (eg, bias by indication). Furthermore, when analyzing the overall population survival, the sample size did not allow meaningful use of statistics. This is also true for the QOL measure with incomplete data, and the EQ-5D questionnaire was not developed for specific ECLS-related issues. Finally, we started to use ECLS as a bridge to lung transplantation in 2010, so a learning curve bias effect cannot be excluded. Considering our results, we are convinced that ECLS support to lung transplantation is feasible and is a useful addition to our intensive care treatment; since the writing of this paper, we have already transplanted 3 patients who were receiving ECLS support.

Conclusions

ECLS can be used as a bridge to lung transplantation, but it remains a challenge. A significant number of subjects were not bridged successfully due to different reasons (multi-organ failure, bleeding complications, and right-ventricular heart failure on VV ECLS), for which a long period on the waiting list might be responsible. Outcomes after ECLS as a bridge to transplantation might be comparable with the general population undergoing lung transplantation in terms of primary graft dysfunction, lung function, performance tests, quality of life, and mortality. However, multi-center studies with larger subject cohorts are necessary to confirm our results.

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