Extracorporeal Life Support Outcome for 128 Pediatric Patients With Respiratory Failure

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Purpose: The aim of this study was to describe a single-center experience with pediatric extracorporeal life support (ECLS) and to determine variables predictive of outcome in pediatric patients, both before the institution of ECLS and while on support.

Methods: From October 1985 to September 1998 the authors supported 128 children with severe acute hypoxemic respiratory failure (n = 121, PaO_2/FIO_2 ratio = 58 ± 29) or acute hypercarbic respiratory failure (n = 7, $PaCO_2$ = 128 ± 37), despite maximal conventional ventilation. Mode of access included venoarterial bypass (VA, n = 64), venovenous bypass (VV, n = 53), and VV to VA bypass (n = 11). The techniques used included lung rest, pulmonary physiotherapy, diuresis to dry weight using hemofiltration if needed, minimal anticoagulation, and optimal systemic oxygen delivery.

Results: The median age was 1.4 years (range, 2 weeks to 17 years). The mean duration of ECLS was 288 ± 240 hours (range, 4 to 1148 hours or 0.2 to 47.8 days). Lung compliance increased from 0.32 ± 0.02 mL/cm H_2O/kg to 0.59 ± 0.03 mL/cm H_2O/kg in survivors, but only increased from 0.34 ± 0.02 mL/cm H_2O/kg to 0.35 ± 0.02 mL/cm H_2O/kg in nonsurvivors ($P < .002$ comparing change between survivors and nonsurvivors). Mean body weight decreased from 9% ± 2% over dry weight to 4% ± 2% in survivors, whereas in nonsurvivors the mean body weight increased from 25% ± 5% over dry weight to 35% ± 7% ($P < .001$). Outcome results by diagnosis were pneumonia, 73%; acute respiratory distress syndrome, 67%; and airway support, 60%, with overall lung recovery occurring in 77%, and hospital survival in 71%. Multivariate logistic regression modelling of patients with hypoxemic respiratory failure found the only pre-ECLS variable significantly associated with outcome to be pH ($P < .05$). Variables during the course of ECLS significantly associated with decreased survival were the presence of creatinine greater than 3.0 ($P < .01$), the need for inotropes ($P < .04$), failure to return the patient to dry weight ($P < .04$), and lung compliance that did not improve significantly. ($P < .01$).

Conclusions: ECLS provides life support in severe respiratory failure in children, allowing time for injured lungs to recover. Pre-ECLS predictors, such as pH and variables during ECLS, such as presence of renal failure, improvement in compliance, return to dry weight, and the need for inotropes on ECLS, may be useful for predicting outcome.
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INDEX WORDS: Extracorporeal life support, extracorporeal membrane oxygenation, respiratory failure, acute respiratory distress syndrome, lung compliance, outcomes, predictive factors.

ACUTE RESPIRATORY FAILURE (ARF) in the pediatric population occurs relatively infrequently but is associated with a high mortality rate.[1-3] Various ventilation strategies have been used to manage patients with pediatric acute respiratory distress syndrome (ARDS), including the application of high positive end-expiratory pressure (PEEP),[4] high-frequency ventilation,[5] and permissive hypercapnea.[6,7] However, the mortality rate in severe ARDS in the pediatric population remains over 40%.[8]

Extracorporeal life support (ECLS) has become standard treatment for neonates with respiratory failure unresponsive to conventional management, and is becoming more widely used for pediatric patients. The Extracorporeal Life Support Organization (ELSO) International Summary of the ECLS Registry reports 1,604 pediatric respiratory failure patients supported internationally from 1986 until 1997 with an overall survival rate of 54%.[9] In a multicenter, retrospective study of pediatric acute respiratory failure, Timmons et al[3] found that ECLS was associated with improved survival rates. Green et al[4] conducted a matched pairs analysis from this database and found improved survival rates in the ECLS treated patients.[4]

We previously have reported our experience with ECLS in children.[10-15] In this report we intend to update the experience at the University of Michigan Hospitals with ECLS in over 100 pediatric patients and to specifically outline the outcomes of pediatric ECLS and the factors predictive of survival.

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MATERIALS AND METHODS

The records of 128 consecutive nonneonatal pediatric patients on ECLS from October 1985 to September 1998 were reviewed retrospectively. These patients had either severe acute hypoxemic respiratory failure (n = 121) or severe acute hypercarbic respiratory failure (n = 7) that was unresponsive to maximal conventional management. The demographic data, mode of access, presence of organ system failure, need for inotropes, and lung compliance also were documented.

Inclusion Criteria

Patients were considered if they had a Pa_{O_2} to F_{IO_2} ratio ≤100 or refractory hypercarbia with pH ≤ 7.0 despite maximal ventilator management. The algorithm used at our institution for pediatric patients with ARF has been reported previously[10,12,16,17] and includes pressure-controlled inverse-ratio ventilation limiting peak inspiratory pressures to below 35 to 40 cm H_2O; optimization of systemic oxygen delivery including transfusion to keep hematocrit greater than 40%, minimizing oxygen consumption by sedation or pharmacological paralysis; restoration to dry weight; adequate nutrition; prone positioning; permissive hypercapnia; and ECLS when conventional methods show no improvement in patient status.

Exclusion Criteria

Patients were excluded from consideration for ECLS based on poor neurological status, incurable underlying disease, or prolonged pre-ECLS ventilation, initially considered to be 7 days but later extended to 10 to 14 days.[18]

Methods of Extracorporeal Support

Vascular access for cannulation was performed by 1 of 2 methods: Venoarterial support (VA, n = 64) was provided by cannulating the right internal jugular vein and the right common carotid artery, and veno-venous support (VV, n = 53), which was maintained using either a dual-lumen catheter in the right internal jugular vein or 2 single-lumen catheters, 1 in the right internal jugular vein and the other in either femoral vein. In the other 11 patients, support was maintained initially in a VV fashion but later converted to VA support because of hemodynamic instability. Some of the venous cannulae were placed percutaneously, simplifying the access technique and avoiding ligation of the veins. No drains were placed in the cephalad internal jugular veins. The circuit consisted of an occlusive roller pump; a solid silicone rubber membrane lung coiled in a spiral, the surface area of which depended on the weight of the patient; a heat exchanger; and a servo regulator. Monitors included pre- and postoxygenator pressure transducers and an oximetric venous saturation probe. Patients who required renal replacement therapy had a hemofilter placed in line for hemofiltration or hemodialysis.

Patient Management

Once on bypass, a technique of ''lung rest'' was followed using inverse-ratio ventilation. Ventilator settings were decreased to F_{IO_2} ≤ 50%; end-inspiratory pressure less than 35 cm H_2O; PEEP, 5 to 10 cm H_2O; and respiratory rate less than 10 bpm. ECLS flow was maintained to keep the mixed venous saturation (Sv_{O_2}) 70% to 80% on VA bypass, or arterial saturation (Sa_{O_2}) greater than 90% on VV bypass (about 100 mL/kg/min flow), and the sweep gas rate adjusted to keep the Pa_{CO_2} level at 35 to 45 mm Hg. Blood products were administered to keep the hematocrit level between 40% and 45% to maximize oxygen delivery, platelet count ≥100,000, and fibrinogen ≥100 g/dL. Activated clotting time was maintained between 180 and 200 seconds. Diuresis was induced as hemodynamically tolerated until dry weight was achieved using loop diuretics either intermittently or as a continuous infusion. If diuretic response was inadequate or renal failure precluded induction of diuresis, a hemofilter was placed in parallel to the circuit for continuous hemofiltration. Daily weights were documented, as was daily fluid balance.

Nutritional support was initiated early in the ECLS course, providing age-appropriate caloric and protein requirements, using the enteral route if possible. Prone position was used intermittently to optimize ventilation-perfusion matching and alveolar recruitment.

Weaning and Decannulation

Native lung oxygen consumption and carbon dioxide removal were monitored as well as pulmonary compliance. Once lung recovery had progressed to the point at which the lungs could support adequate gas exchange, a trial off ECLS was performed, which, if successful, was followed by decannulation. In the case of percutaneously placed cannulas this required withdrawal of the catheter with the application of digital pressure for 20 to 30 minutes. Catheters placed by the open technique were removed by operation, with ligation of the jugular vein and common carotid artery.

Data Analysis

Survival was defined by hospital discharge. Lung recovery was defined as improvement in lung function so that ECLS support was no longer required. Lung compliance was measured using the dividend of the tidal volume (V_t) and the difference between the end inspiratory pressure (EIP) and the PEEP. The compliance was then normalized to dry weight, and the change in compliance between the beginning of the ECLS course and the end was reported as a percentage of the initial compliance. To account for the large differences in dry weight of the patients, body weight was normalized to dry weight and expressed as a percentage relative to dry body weight. Change in compliance and percent body weight above dry weight between survivors and nonsurvivors was compared by independent *t* test with significance of *P* less than .05. Stepwise logistic regression was used to determine variables predictive of outcome both in the period before ECLS as well as during ECLS; these included the presence of renal failure, need for inotropes, failure to return the patient to dry weight, improvement in lung compliance, presence of liver failure, duration of ECLS, age, ventilator days before ECLS, and Pa_{O_2} at initiation of ECLS; only those variables with *P* less than .05 were included in the regression model.

RESULTS

There were 56 girls and 72 boys with ages that ranged from 2 weeks to 17 years, (median, 1.4 years). The median duration of conventional ventilation before the institution of ECLS was 4.7 days, ranging from 1 to 24 days. Of the 128 patients, 25 were transported to our institution from other hospitals while on ECLS. The number of patients placed on ECLS for respiratory failure by year is shown in Fig 1.

Pre-ECLS physiological, demographic, and outcome data are shown in Table 1. The pH ranged from 6.88 to 7.62. None of the patients with pH less than 7.0 at institution of ECLS survived. The survival rate of patients with an initial pH less than 7.3 was 63% and among those with an initial pH less than 7.2 was 53%. Acute

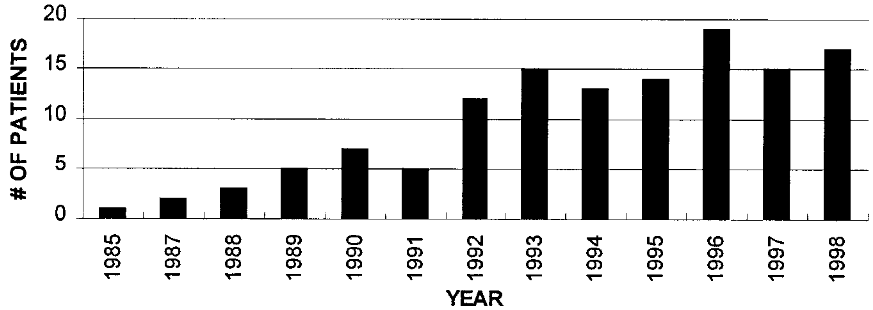

Fig 1. Number of patients placed on ECLS for respiratory failure by year.

hypoxemic respiratory failure was present in 121 patients, with a mean PaO_2 to FIO_2 ratio of 58 ± 29. Acute hypercarbic respiratory failure was present in 7 patients, with a $PaCO_2$ of 128 ± 37.

Renal failure requiring renal replacement therapy was present in 14% of patients (18 of 128) and 10 of 18 died (55%). Liver compromise or failure as evidenced by elevated aspartate and alanine transaminase levels was present in 23% (30 of 128). Of those with hepatic compromise 40% died (12 of 30) during their hospital stay.

Overall survival to the point at which lung recovery was such that ECLS was no longer required was 77%, whereas survival to hospital discharge was 71% (Table 1 and 2). The mean duration of ECLS support was 288 ± 240 hours (12 ± 10 days; median, 9.5 days; range, 0.2 to 47.8 days). The longest ECLS run of 47.8 days involved a nonsurvivor with ARDS of unknown etiology, and the second longest ECLS run of 47 days involved a survivor with viral pneumonia. Outcome by diagnosis is shown in Table 2.

In survivors, the lung compliance improved from 0.32 ± 0.03 mL/cm H_2O/kg to 0.59 ± 0.03 mL/cm H_2O/kg, a mean increase of 85 ± 10% (Table 3). In nonsurvivors, the compliance increased only from 0.34 ± 0.02 mL/cm H_2O/kg, to 0.35 ± 0.02 mL/cm H_2O/kg, a mean increase of 3% ± 1% ($P < .002$ when increase in survivors and nonsurvivors is compared using the independent *t* test). The mean body weight of survivors decreased from a mean of 9% ± 2% over dry weight to 4% ± 2%, a decrease of 5% ± 2%, whereas the mean body weight of nonsurvivors increased from 25% ± 5% over dry weight to 35% ± 7%, an increase of 11% ± 5% ($P < .001$, when change in weight in survivors compared with nonsurvivors by independent *t* test).

Multivariate logistic regression was used to identify independently significant variables for outcome both before and after institution of ECLS. The only pre-ECLS variable significantly associated with outcome was pH ($P < .05$). Variables during the course of ECLS significantly associated with mortality were the presence of renal failure ($P = .007$), the need for inotropes ($P = .04$), the failure to return the patient to dry weight ($P = .04$) and an absence of improvement in lung compliance ($P = .007$). The presence of liver failure, duration on bypass, age, time on the ventilator before ECLS and PaO_2 at initiation of ECLS were not significantly predictive of outcome. Survival as a function of time on ECLS is shown in Fig 2.

The causes of death in the 37 patients were multiorgan

Table 1. Patient Characteristics for Pediatric Respiratory ECLS

Demographics and outcomes (n = 128)	
Survival to hospital discharge	71%
Lung Recovery	77%
Male/Female (%)	56/44
Median age (yr)	1.4 (range, 2 wk to 17 yr)
Physiological data	
Pre-ECLS ventilator days	4.7 ± 3.7
Duration of ECLS (h)	288 ± 240
Pre-ECLS PaO_2 to FIO_2 ratio	58 ± 30
Last pre-ECLS ABG	
PaO_2 (hypoxemic)	58 ± 29
$PaCO_2$ (hypercarbic)	128 ± 37
Last pre-ECLS ventilator settings:	
FIO_2	1.0 ± 0.1
PIP	25 ± 15
PEEP	5.0 ± 2

Table 2. Patient Distribution by Diagnosis

Diagnoses	Percent Lung Recovery (survived/total)	Percent Survival to Hospital Discharge (survived/total)
Pneumonia	81 (60/74)	73 (54/74)
Viral	88 (43/49)	78 (38/49)
Aspiration	86 (12/14)	79 (11/14)
Fungal	0 (0/2)	0 (0/2)
Bacterial	55 (5/9)	55 (5/9)
ARDS	69 (34/49)	67 (33/49)
Trauma	78 (14/18)	78 (14/18)
Sepsis	33 (3/9)	33 (3/9)
Other	77 (17/22)	73 (16/22)
Airway support	80 (4/5)	80 (4/5)
Status asthmaticus	100 (2/2)	100 (2/2)
Tracheal obstruction	67 (2/3)	67 (2/3)
Overall	77 (98/128)	71 (91/128)

NOTE. Lung recovery is defined as improvement in lung function so that ECLS support is no longer required.

Table 3. Patient Characteristics of Survivors and Nonsurvivors

	Survivors (n = 92)	Nonsurvivors (n = 36)	Overall (n = 128)
Age (yr)	4.6 ± 6	4.9 ± 6	4.68 ± 6
PaO_2 to FIO_2 ratio	58 ± 30	58 ± 29	58 ± 2.6
pH	7.34	7.29	7.33
Pre-ECLS ventilator days	4.32 ± 3	5.8 ± 4	4.74 ± 3
Duration of ECLS (h)	254 ± 200	367 ± 304	288 ± 240
Change in compliance (%)	85 ± 10	3 ± 1	83 ± 20
Change in body weight (%)	−4	+11	1 ± 20

failure syndrome in 12 patients, neurological injury in 11, pulmonary fibrosis in 5, hemodynamic instability in 5, bleeding in 2, and unknown etiology in 2 patients.

DISCUSSION

Extracorporeal life support for pediatric respiratory failure is a reasonable option for patients with severe respiratory failure in whom maximal conventional ventilator management has been attempted without response. In this review, we have outlined our experience in supporting pediatric patients with respiratory failure with ECLS since October 1985. These data show a 71% survival overall with increased mortality in those with low pH pre-ECLS and creatinine level greater than 3.0, inotrope requirement, persistently elevated body weight, and lack of improvement in pulmonary compliance during ECLS.

In 1991 we participated in a multicenter review of 331 pediatric patients with severe respiratory failure.[3] ECLS was compared with conventional management strategies and was the only intervention that correlated positively with survival.[8] In contrast, Fackler et al[19] attempted to perform a prospective randomized trial of ECLS and conventional mechanical ventilation in pediatric ARDS but were unsuccessful because of the paucity of pediatric patients with severe ARDS, especially those without additional organ system disease or failure. Most patients in the current review had little or no native lung function before and during ECLS and, therefore, had a high predicted mortality rate. A survival rate of 71% among 128 of such patients suggests that the institution of ECLS is effective at enhancing survival among pediatric patients with severe ARDS.

We have applied an algorithm for the pre-ECLS management of severe pediatric respiratory failure which attempts to resolve the failure of gas transport from several approaches. To minimize the development of ventilator-induced lung injury, pressure-controlled ventilation is used, limiting peak airway pressure to less than 30 to 40 cm H_2O. At the same time, oxygenation is maximized along with lung protection by applying PEEP of 6 to 14 cm H_2O and by inversing the inspiratory to expiratory phase. This approach may lead to hypercapnia, which is well tolerated as long as the pH remains greater than 7.2.[20] To maximize oxygen delivery, the patient may undergo transfusion to a hematocrit level of greater than 40%. Sedation and pharmacologic paralysis often are used to decrease oxygen consumption. The patient's volume status is monitored closely, and efforts are directed toward achieving diuresis to dry weight, which in some instances requires renal replacement therapy. Underlying causes of ARDS are determined and treated if possible. It is only when this approach has failed, such that the PaO_2 to FIO_2 ratio remains less than 100, but frequently less than 60 to 70, or $AaDO_2$ greater than 600, that a patient is placed on ECLS. If there is little hemodynamic instability, VV bypass is instituted. Otherwise the patient is placed on VA bypass.

Of the group of 128 patients, 52 (41%) weighed more than 10% above their dry weight at the initiation of ECLS. There was an association between the ability to return patients to their dry weight and survival rate. Several findings have shown a negative correlation between outcome in patients with ARDS and fluid weight gain; our own experience in adults with ARDS has suggested that excess weight gain in such patients greater than 10% above dry weight correlates poorly with survival.

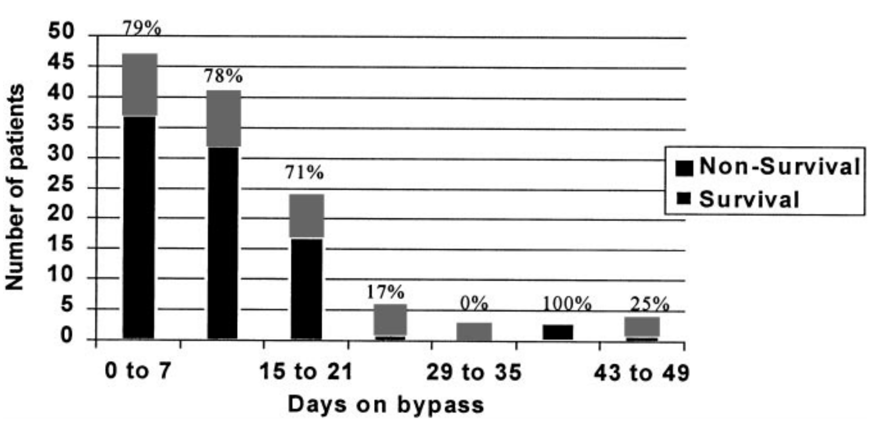

Fig 2. Survival (hospital discharge) by days on bypass.

Of the 128 patients placed on ECLS, 91 survived. The only pre-ECLS variable that correlated with survival was pH. We were surprised that the pre-ECLS period of mechanical ventilation was not predictive of outcome as it is for the adult population.[21,22] Because of our exclusion criteria, there was only 1 patient who was placed on support after greater than 14 days on the conventional ventilator. However, the pre-ECLS period of mechanical ventilation was not predictive of survival for the remaining 127 patients who were on the ventilator for between 0 and 14 days. There were also no independent predictors of outcome among several other variables: age, pre-ECLS compliance, percent of pre-ECLS weight over dry weight, nor VV versus VA ECLS.[23]

The institution of ECLS presupposes that either the underlying condition can be treated, allowing for lung recovery, or that the lungs, given the opportunity to ‘‘rest’’ will recover. In our experience lung recovery did occur even in patients on ECLS for prolonged periods, so that the number of hours on bypass did not correlate with survival rate. Factors that were associated with survival on ECLS included the presence of renal failure and the need for inotropes, both of which indicate worsening multiorgan system failure. Other predictive variables included improvement in compliance and a return to dry weight. The predictive variables outlined in this review may provide some guidance in determining whether to continue with ECLS if other indicators provide doubt as to the potential for meaningful lung recovery.

Predictive scoring systems for mortality rate are not readily available in the pediatric population for isolated respiratory failure, although there have been several articles advocating use of the PRISM scoring system, the ventilation index, the oxygenation index and the PaO_2 to FIO_2 ratio in this capacity.[3,24] However, none of these have been validated for use in predicting mortality in the setting of pediatric ARDS, either at admission or at initiation of ECLS.

This report does not attempt to measure other outcomes such as 28-day ventilator-free days, pulmonary function post-ECLS, cost, or quality of life. These questions are being addressed by others and are the next step in the evaluation of ECLS as an intervention in pulmonary failure.

We have shown a 71% survival among pediatric patients with severe respiratory failure treated with ECLS. Predictive criteria for ultimate survival, both before and during ECLS, may be helpful in guiding implementation and persistence during use of this intervention.

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