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Clinical Research

Comparison of Conventional Methods with Pump-Controlled Retrograde Trial off for Weaning Adults with Cardiogenic Shock from Veno-Arterial Extracorporeal Membrane Oxygenation

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Background: Pump-controlled retrograde trial off (PCRTO) is a safe, simple, and reversible method for weaning patients from veno-arterial extracorporeal membrane oxygenation (VA-ECMO). However, few studies have compared PCRTO to conventional weaning methods. This retrospective study aimed to compare PCRTO to non-PCRTO methods.
Methods: This study included patients who were weaned from VA-ECMO from January 2016 to December 2022 at our medical center. Demographic data, ECMO management, ECMO complications, survival to discharge, and cardiogenic shock after VA-ECMO weaning were compared between the 2 groups.
Results: Seventy patients who were weaned from VA-ECMO using PCRTO and 85 patients who were weaned with conventional methods were compared. Patient characteristics were not significantly different between the 2 groups. The rate of survival to discharge was significantly higher in the PCRTO group than in the non-PCRTO group (90% vs. 72%, p=0.01). The rates of freedom from all-cause mortality at 10, 30, and 50 days after weaning from ECMO were 75%, 55%, and 35% in the non-PCRTO group and 62%, 60%, and 58% in the PCRTO group, respectively (p=0.1). The incidence of cardiogenic shock after weaning from VA-ECMO was significantly higher in the non-PCRTO group (16% vs. 5%, p=0.04). In logistic regression analysis, PCRTO was a significant factor for survival to discharge (odds ratio, 2.42; 95% confidence interval, 1.29–5.28; p=0.02).
Conclusion: Compared to conventional methods, PCRTO is a feasible and reversible method, and it serves as a useful predictor of successful VA-ECMO weaning through a preload stress test.

Keywords: Extracorporeal membrane oxygenation, Weaning, Prognosis

Introduction

Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is considered one of the most favorable treatment options for patients with cardiogenic shock and cardiac arrest [1,2]. However, evidence regarding strategies for VA-ECMO weaning remains limited due to the lack of large cohorts [3-6].

Pump-controlled retrograde trial off (PCRTO) was introduced by Westrope et al. [7] in 2013 as a method for VA-ECMO weaning. PCRTO allows direct left-to-right shunt flow from the arterial to the venous system through the ECMO circuit and also enables an evaluation of the cardiopulmonary reserve during weaning from VA-ECMO [8]. A major advantage of PCRTO is that the continuous blood flow through the ECMO circuit during weaning reduces the risk of blood clot formation. This means that patients can be monitored for several hours with ECMO support temporarily halted. Recent studies on PCRTO during VA-ECMO weaning have shown that it is a safe and feasible approach [7-12]. However, few studies have focused on PCRTO in adults, and there is a lack of research comparing the PCRTO method with conventional methods traditionally used for weaning patients from VA-ECMO. Therefore,

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we retrospectively compared PCRTO and conventional weaning methods in a single center.

Methods

Ethical statement

This study was conducted in compliance with the principles of the Declaration of Helsinki. The Institutional Review Board (IRB) of the Dongsan Medical Center approved the study (IRB file number: 2023-11-017-001; November 21, 2023). The requirement for informed consent was waived due to the retrospective nature of this study.

Patient population

Patients who were weaned from VA-ECMO between January 2016 and December 2022 at Dongsan Medical Center were included in the study. Data were obtained from medical charts and electronic health records. The exclusion criteria were patients under 18 years of age, those who underwent veno-venous ECMO, those who were candidates for heart transplantation or a ventricular assist device, those transferred to other hospitals, those with a poor prognosis leading to discontinuation of ECMO with consent from their representatives, those intended for cadaveric organ harvesting, and those with trauma or malignancy. PCRTO was introduced at our center in September 2019 and has been routinely performed for ECMO weaning since early 2020.

A total of 266 patients received VA-ECMO for circulatory support, and 111 of these patients failed to be weaned from VA-ECMO. The final cohort consisted of 155 patients (58%); 70 patients (45%) were weaned from VA-ECMO using PCRTO, and 85 patients (55%) were weaned using conventional methods (Fig. 1). The severity of the patients' conditions at the time of VA-ECMO weaning was assessed using the Survival after Veno-arterial ECMO (SAVE) score and the Vasoactive-Inotropic Score (VIS) [13,14].

Veno-arterial extracorporeal membrane oxygenation management

Cannulation was performed peripherally in all patients, with the inflow cannulas being inserted into the femoral artery. Mechanical ventilation was initiated prior to VA-ECMO, tailored to each patient's condition. The Seldinger technique was employed for cannulation. In cases where pulmonary edema occurred during VA-ECMO, left atrial venting via percutaneous atrial septostomy was carried out to unload the left ventricle. A distal perfusion catheter was placed in the event of progressing limb ischemia or absence of detectable lower limb blood flow by Doppler ultrasonography. Anticoagulation therapy was administered to all patients, barring those with contraindications to anticoagulation. Daily transthoracic echocardiography (TTE) was conducted to monitor cardiac function. The implementation of VA-ECMO was guided by the most recent guidelines and literature available.

Data collection and outcomes

We collected data on patients' baseline characteristics, etiologies, comorbidities, management of VA-ECMO, complications arising during VA-ECMO, and outcomes following weaning from VA-ECMO from the ECMO database at our center.

In this study, the observation time was defined as the duration of ECMO circuit clamping in the non-PCRTO group and as the duration of PCRTO in the PCRTO group.

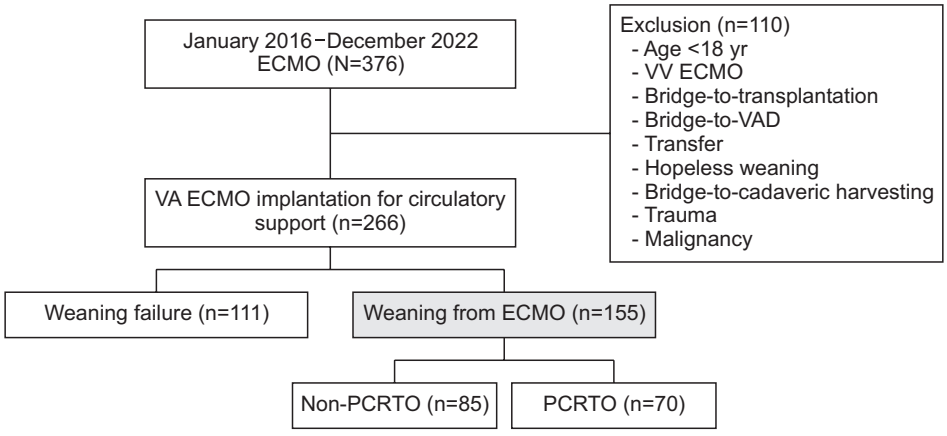

Fig. 1. Algorithm of patients managed using veno-arterial (VA) extracorporeal membrane oxygenation (ECMO). VV, veno-venous; VAD, ventricular assist device; PCRTO, pump-controlled retrograde trial off.

The primary outcome measured was the proportion of patients who were discharged alive following weaning from VA-ECMO. Secondary outcomes included the causes of mortality, the proportion of patients who experienced cardiac death, and the proportion of patients who required re-insertion of VA-ECMO after initial weaning.

Extracorporeal membrane oxygenation weaning protocol

If cardiac and pulmonary function were adequate for VA-ECMO weaning, the process was initiated. We gradually decreased the VA-ECMO flow rate by 0.5 L/min every 6 hours for all patients to evaluate their readiness for weaning [5,15]. During this time, we monitored mean arterial pressure, chest X-ray findings, TTE results, and lactate levels. Once a patient successfully maintained a VA-ECMO flow of 1 L/min for at least 8 hours with stable end-organ function, we considered decannulation using either the conventional method (non-PCRTO group) or PCRTO (PCRTO group). The weaning protocols for VA-ECMO were halted if the patient exhibited hemodynamic instability, respiratory compromise, decreased urine output, or elevated lactate levels.

Conventional weaning method (non-pump-controlled retrograde trial off)

The drain and return cannulas were clamped at the most proximal site, creating a shunt flow between them to maintain ECMO circuit flow (Fig. 2). A heparin bolus of 500–1,000 IU was administered, and the clamps were released every 5 minutes to prevent clot formation within the ECMO circuit. Stability of the patient's vital signs and arterial blood gas analysis (ABGA) results was monitored for 20 minutes to 1 hour; if stable, ECMO decannulation was then carried out.

Pump-controlled retrograde trial off

We adjusted the revolutions per minute setting to achieve an ECMO flow rate of -300 to -800 mL/min, which varied depending on the patient's weight (typically 5–10 mL/kg). Once retrograde flow was established, we discontinued the sweep gas flow to the oxygenator (Fig. 3). We conducted serial arterial and venous blood gas analyses at 30-minute intervals. The activated clotting time was maintained between 200 and 220 seconds, or alternatively, the activated partial thromboplastin time was kept at 40–60 seconds, managed with a continuous intravenous heparin infusion. Following a 60–120-minute period of observation, we began preparations for ECMO decannulation if the patient's condition had stabilized. However, for patients with marginal cardiac function, the assessment period could extend up to 8 hours. We continuously monitored parameters such as the patient's vital signs, ABGA, and lactate levels; decannulation of ECMO was carried out if these parameters remained unchanged.

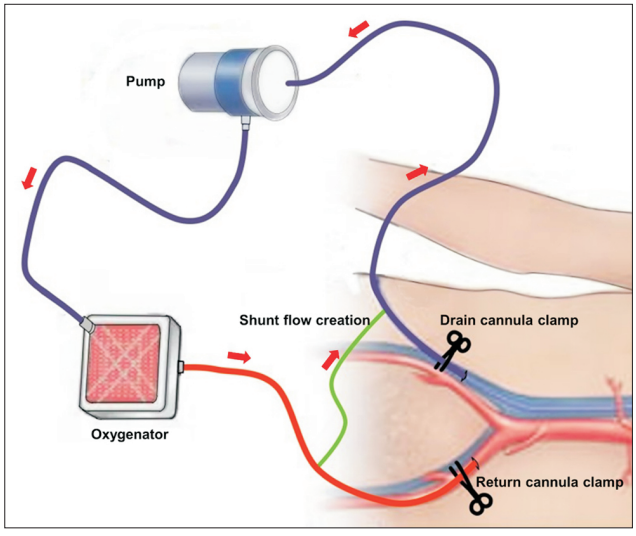

Fig. 2. Conventional weaning method (non-pump-controlled retrograde trial off).

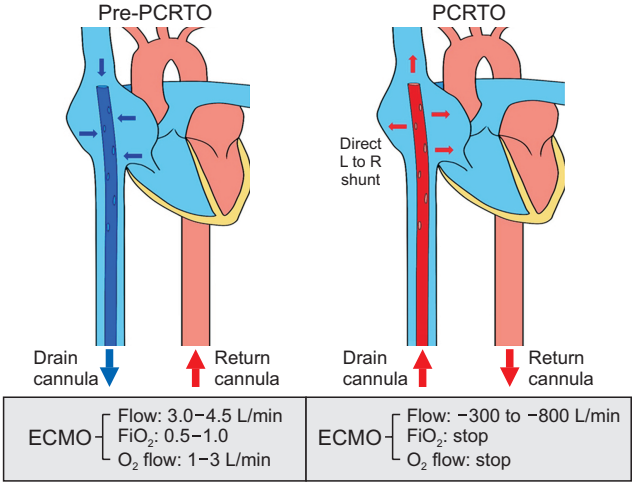

Fig. 3. Extracorporeal membrane oxygenation (ECMO) settings, parameters, and blood flow changes in pump-controlled retrograde trial off (PCRTO). L, left; R, right; FiO_2, fraction of inspired oxyge.

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Statistical analysis

Variables that followed a normal distribution were analyzed using the independent t-test and are reported as means. In contrast, categorical variables were assessed using the Pearson chi-square test or Fisher's exact test, as appropriate, and are reported as counts (percentages). All statistical tests were 2-sided, and an alpha level of 0.05 was used to determine significance.

Predictors of survival to discharge, defined as the ratio of patients free from mortality at the point of hospital discharge, were identified using logistic regression. Univariate analysis was conducted on the variables listed in Table 1. Those variables with a p-value of less than 0.2 in the univariate analysis were subsequently included in the multivariate analysis [16]. The multivariate analysis models were refined through backward elimination. The results are presented as odds ratios (ORs) with 95% confidence intervals (CIs) from the logistic regression analysis. Statistical analyses were performed using IBM SPSS software ver. 29.0 (IBM Corp., Armonk, NY, USA) and R statistical software ver. 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient characteristics

The mean ages of patients in the non-PCRTO and PCRTO groups were 60.6 years and 61.1 years, respectively, with no significant difference between the groups (p=0.8) (Table 1). The PCRTO group contained a significantly higher percentage of men than the non-PCRTO group (78% versus 62%, p=0.04). There was no significant difference in the prevalence of ischemic cardiac compromise between the PCRTO and non-PCRTO groups (70% versus 69%, p>0.99). However, the proportion of patients with dilated cardiomyopathy was significantly higher in the PCRTO

Table 1. Patient characteristics

Characteristic	Non-PCRTO (N=85)	PCRTO (N=70)	Total (N=155)	p-value
Age (yr)	60.6±13.6	61.1±12.3	60.8±13.0	0.800
Body mass index (kg/m^2)	1.7±0.2	1.7±0.2	1.7±0.2	0.962
Length of ICU stay (day)	23.2±23.5	18.5±14.8	21.1±20.2	0.127
Hospital stay after ECMO weaning (day)	33.8±30.4	42.3±47.6	37.6±39.2	0.204
Sex, male	53 (62.4)	55 (78.6)	108 (69.7)	***0.044***
Cardiac compromise cause				>0.99
Ischemic	59 (69.4)	49 (70.0)	108 (69.7)	
Non-ischemic	26 (30.6)	21 (30.0)	47 (30.3)	
Comorbidity				
Hypertension	42 (49.4)	37 (52.9)	79 (51.0)	0.791
Diabetes mellitus	20 (23.5)	22 (31.4)	42 (27.1)	0.358
Cerebral infarction	4 (4.7)	4 (5.7)	8 (5.2)	>0.99
Previous PCI	13 (15.3)	20 (28.6)	33 (21.3)	0.09
Previous CABG	3 (3.5)	2 (2.9)	5 (3.2)	0.96
Previous PCI and CABG	0	2 (2.9)	2 (1.3)	>0.99
Dilated cardiomyopathy	5 (5.9)	15 (21.4)	20 (12.9)	***0.008***
Chronic renal failure	7 (8.2)	14 (20.0)	21 (13.5)	0.058
Chronic renal failure on HD	4 (4.7)	8 (11.4)	12 (7.7)	0.209
Peripheral artery disease	1 (1.2)	3 (4.3)	4 (2.6)	0.480
ECMO running time (hr)	166.1±245.8	162.8±121.2	164.6±198.8	0.913
CPR time before ECMO (min)	12.5±15.3	13.1±16.5	12.8±15.8	0.801
ECPR	40 (47.1)	29 (41.4)	69 (44.5)	0.590
IABP before ECMO	6 (7.1)	0	6 (3.9)	0.064
Mechanical ventilation before ECMO	60 (70.6)	28 (40.0)	88 (56.8)	***<0.001***
CRRT during ECMO	47 (55.3)	49 (70.0)	96 (61.9)	0.087
Distal perfusion	7 (8.2)	21 (30.0)	28 (18.1)	***0.001***
Left atrial venting	1 (1.2)	4 (5.7)	5 (3.2)	0.257

Values are presented as mean±standard deviation or number (%). Significant p-values are shown in italics and bold.
PCRTO, pump-controlled retrograde trial off; ICU, Intensive care unit; ECMO, extracorporeal membrane oxygenation; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; HD, hemodialysis; CPR, cardiopulmonary resuscitation; ECPR, extracorporeal cardiopulmonary resuscitation; IABP, intra-aortic balloon pump; CRRT, continuous renal replacement therapy.

group than in the non-PCRTO group (21.4% versus 5.9%, p=0.008). The duration of ECMO support did not differ significantly between the PCRTO and non-PCRTO groups (162.8±121.2 minutes versus 166.1±245.8 minutes, p=0.913). Prior use of mechanical ventilation was significantly more common in the non-PCRTO group than in the PCRTO group (70.6% versus 40%, p<0.001). Additionally, distal perfusion catheter insertion was performed significantly more often in the PCRTO group than in the non-PCRTO group (30% versus 8.2%, p<0.001).

Outcomes

The rate of survival to discharge was significantly higher in the PCRTO group than in the non-PCRTO group (90% versus 72.9%, p=0.01) (Table 2). In examining the causes of death after ECMO weaning, a significantly greater proportion of patients in the non-PCRTO group succumbed to cardiogenic shock (16.5% versus 5.7%, p=0.04). The incidence of VA-ECMO reinsertion within 3 days of weaning was 3.5% in the non-PCRTO group and 1.4% in the PCRTO group, which was not a statistically significant difference (p=0.755). The SAVE score and the VIS at the time of ECMO weaning did not differ significantly between the 2 groups (SAVE: -4.4±4.4 versus -4.2±4.3, p=0.803; VIS: 5.9±5.7 versus 6.3±6.0, p=0.705).

The rates of survival free from all-cause mortality at 10, 30, and 50 days post-weaning from ECMO were 75%, 55%, and 35% in the non-PCRTO group, compared to 62%, 60%, and 58% in the PCRTO group, respectively (p=0.1) (Fig. 4). The rates of survival free from cardiac death at 10, 30, and 50 days post-weaning from ECMO were 72%, 62%, and 60% in the non-PCRTO group, versus 62%, 59%, and 58% in the PCRTO group, respectively (p=0.03). A multivariate Cox regression analysis identified age as a significant factor for long-term survival (hazard ratio, 1.044; 95% CI, 1.02–1.069; p<0.001) (Supplementary Table 1).

Multivariate predictive factor analysis for survival to discharge following weaning from VA-ECMO identified PCRTO as a significant factor (OR, 2.42; 95% CI, 1.29–5.28; p=0.02) (Fig. 5). Additionally, the VIS (OR, 0.89; 95% CI, 0.82–0.96; p=0.003) and the use of ECMO in conjunction with continuous renal replacement therapy (OR, 0.09; 95% CI, 0.03–0.28; p<0.001) were significant predictors of sur-

Table 2. Results of VA-ECMO weaning

Variable	Non-PCRTO (N=85)	PCRTO (N=70)	Total (N=155)	p-value
Survival to discharge	62 (72.9)	63 (90.0)	125 (80.6)	***0.013***
Cause of death after ECMO weaning				
Cardiogenic shock	14 (16.5)	4 (5.7)	18 (11.6)	***0.045***
Multiorgan failure	1 (1.2)	3 (4.3)	4 (2.6)	0.328
Sepsis	5 (5.9)	0	5 (3.2)	0.064
Neurological injury	3 (3.55)	0	3 (1.9)	0.252
VA-ECMO re-insertion within 3 days	3 (3.5)	1 (1.4)	4 (2.6)	0.755
VA-ECMO re-insertion after 3 days	3 (3.5)	3 (4.3)	6 (3.9)	>0.99
CRRT at the moment of ECMO weaning	29 (34.1)	8 (11.4)	37 (23.9)	***0.002***
Mechanical ventilation at ECMO weaning	78 (91.8)	64 (91.4)	142 (91.6)	>0.99
Neurologic complication before weaning	11 (12.9)	6 (8.6)	17 (11.0)	0.543
SAVE score at ECMO weaning	-4.4±4.4	-4.2±4.3	-4.3±4.4	***0.803***
VIS score at ECMO weaning	5.9±5.7	6.3±6.0	6.1±5.8	***0.705***
ECMO complication				
Limb ischemia	5 (5.8)	5 (7.1)	10 (6.4)	0.641
Cannulation site bleeding	2 (2.4)	1 (1.4)	3 (1.9)	>0.99
Gastrointestinal bleeding	4 (4.7)	5 (7.1)	9 (5.8)	0.764
Sepsis	8 (9.4)	2 (2.9)	10 (6.5)	0.185
Rhabdomyolysis	0	1 (1.4)	1 (0.6)	0.922
Intrathoracic bleeding	0	2 (2.9)	2 (1.3)	0.393
Cerebral infarction	4 (4.7)	6 (8.6)	10 (6.5)	0.518
Brain hemorrhage	2 (2.4)	0	2 (1.3)	0.564
Observation time[a] (min)	41.5±11.2	226.3±119.7	125.5±122.7	***<0.001***

Values are presented as number (%) or mean±standard deviation. Significant p-values are shown in italics and bold.
VA, veno-arterial; ECMO, extracorporeal membrane oxygenation; PCRTO, pump-controlled retrograde trial off; CRRT, continuous renal replacement therapy; SAVE score, Survival after Veno-arterial ECMO score; VIS, Vasoactive-Inotropic Score.
[a]ECMO circuit clamping time of the non-PCRTO group and PCRTO time of the PCRTO group.

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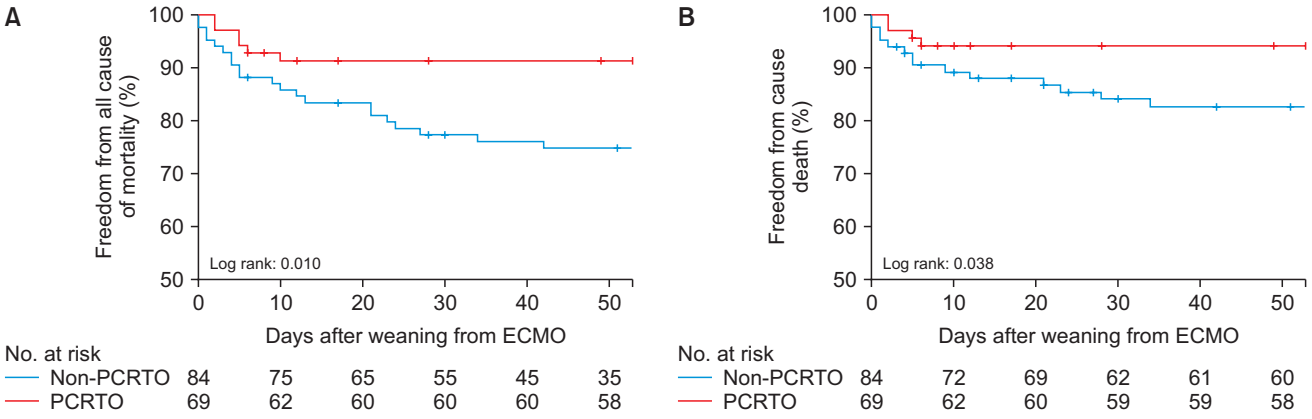

Fig. 4. (A, B) Results of pump-controlled retrograde trial off (PCRTO) and non-PCRTO methods after veno-arterial extracorporeal membrane oxygenation (VA-ECMO) weaning.

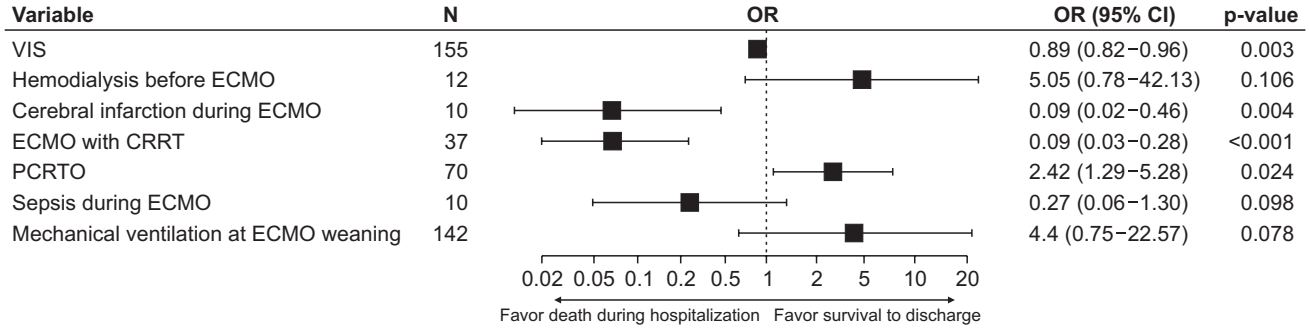

Fig. 5. Predictive factor analysis for survival to discharge after veno-arterial extracorporeal membrane oxygenation (VA-ECMO) weaning. Significant p-values are shown in italics and bold. PCRTO, pump-controlled retrograde trial off; CRRT, continuous renal replacement therapy; VIS, Vasoactive-Inotropic Score; OR, odds ratio; CI, confidence interval.

vival to discharge after weaning from ECMO.

This study compared the duration of ECMO circuit clamping in the non-PCRTO group with the PCRTO duration in the PCRTO group. The PCRTO group experienced a significantly longer observation time than the non-PCRTO group (226.3±119.7 minutes versus 41.5±11.2 minutes, p<0.001). Within the PCRTO group, the initial PCRTO did not succeed in 9 patients, requiring a return to ECMO support. The reasons for PCRTO failure included hypotension in 4 patients, the emergence of new arrhythmias in 2 patients, worsening hypoxemia in 2 patients, and increased acidosis in 1 patient. Notably, there were no thromboembolic events, such as ECMO circuit thrombosis, observed during or after VA-ECMO weaning in either the PCRTO or non-PCRTO group.

Discussion

In this study, we found that the rates of survival to discharge and freedom from cardiogenic shock after weaning from VA-ECMO were higher in the PCRTO group than in the non-PCRTO group. Typically, after VA-ECMO weaning, a range of factors such as refractory cardiogenic shock, cardiovascular comorbidities, acute kidney injury, and sepsis can contribute to the need for ECMO re-implantation and are associated with a poor prognosis [17-21]. Hence, predicting the likelihood of a patient developing cardiogenic shock post-VA-ECMO weaning is crucial due to the associated poor prognosis and the technical challenges of ECMO re-implantation, which include complications like hematoma, groin infection, pseudoaneurysm, or uncontrolled bleeding. We hypothesize that the improved survival observed in the PCRTO group in this study may be attributed to the extended observation of patient conditions using a "preload stress test," as compared to the non-PCRTO group.

PCRTO evaluates patients using a "preload stress test" that involves a direct external left-to-right shunt through VA-ECMO. Pandya et al. noted that PCRTO gauges cardiopulmonary reserve during a trial weaning period from

VA-ECMO and improves the likelihood of sustaining circulation independently of ECMO support. Furthermore, retrograde ECMO flow guarantees sufficient right ventricular (RV) filling and enables an accurate assessment of RV function [8]. For clinicians, the ability to directly and easily assess cardiac loading and the potential for ECMO weaning without additional invasive procedures in patients on VA-ECMO is important in decision-making, as the results may indicate whether patients will remain stable after VA-ECMO weaning.

Unlike the conventional method, which maintains partial shunt flow through the ECMO circuit, PCRTO preserves ECMO flow in all components of the circuit, including the cannula, even after retrograde reduction of ECMO flow. As a result, the risk of clot formation is lower with PCRTO than with conventional weaning methods [7-11]. Consequently, PCRTO allows for the assessment of a patient's condition over several hours during the weaning from VA-ECMO without increasing the risk of clot formation. In this study, there were no thromboembolic events in the PCRTO group, despite a significantly longer observation period compared to the non-PCRTO group.

PCRTO has was introduced in 2013 by Westrope et al. [7], according to whom the advantage of PCRTO is that VA-ECMO weaning can be performed without clamping or arteriovenous (AV) bridging formation. There are case series and retrospective studies of PCRTO in adults [9-11] as well as studies comparing PCRTO to AV bridging in pediatric patients [8]. The collective findings from these studies demonstrate the safety and feasibility of PCRTO. In summary, PCRTO is considered a safe method for weaning because it permits multiple weaning attempts, acts as a "preload stress test," does not increase the risk of clot formation, and eliminates the need for ECMO circuit manipulation, such as AV bridging or clamping.

There is currently no knowledge of cases where PCRTO has failed, yet the patient remained stable with the clamping method. Unsuccessful PCRTO may suggest that the patient's condition is not robust enough to withstand the "preload stress test" that PCRTO represents. To date, there are no definitive studies on whether patients who cannot tolerate PCRTO will fare well with clamping and ultimately survive. If such a scenario arises, it could be inferred, as suggested in this paper, that sufficient left ventricular recovery has not yet occurred. In this case, it would be prudent to delay ECMO weaning and allow more time for left ventricular recovery until the patient can pass the PCRTO. Additionally, the primary purpose of performing PCRTO is to avoid the need for clamp manipulation. Therefore, if a patient does not pass the PCRTO, the clamping method is not employed as an alternative; instead, PCRTO is attempted again once the patient has fully recuperated. This also implies that conducting cross-over clinical studies is challenging.

This study is limited by its retrospective, non-randomized design. Throughout the study period, there were several adjustments to the ECMO management strategy, including a decrease in intra-aortic balloon pump (IABP) insertions for patients with cardiogenic shock, an increase in distal perfusion catheter placement during VA-ECMO management, and a trend toward early awakening on ECMO (managing ECMO without the aid of mechanical ventilation). Nevertheless, other management strategies at our hospital remained largely unchanged over the course of our experience. Additionally, there were no significant differences in patient conditions at the initiation of VA-ECMO management between the 2 groups, with the exceptions of IABP use, distal perfusion, and the trend toward early awakening on ECMO. Thromboembolic events were not exhaustively assessed in all patients, as imaging studies were not routinely conducted unless there was a clinical indication. TTE was performed on all patients; however, due to the limitations of bedside TTE, precise measurements of left ventricular ejection fraction were not obtainable. Consequently, the VIS and SAVE scores were employed to adjust for the severity of the patients' conditions between the 2 groups. A randomized, prospective study in adults is warranted to confirm those results.

Conclusion

In conclusion, PCRTO is a safe, simple, and reversible weaning method that is performed prior to decannulation in patients undergoing VA-ECMO weaning. PCRTO also provides a sufficient observation period without performing additional invasive procedures on the ECMO circuit. With this "preload stress test," PCRTO is a useful predictor of successful weaning of a patient from ECMO, subsequently resulting in a lower mortality rate and cardiac death rate compared to non-PCRTO weaning methods. Further large-scale, randomized, prospective studies are warranted.

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Author contributions

KS and WSJ conceived of the presented idea. NP and JBK developed the theory and performed the computations. JJJ analyzed the data. KS verified the analytical methods. KS and YSK supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Supplementary materials

Supplementary materials can be found via https://doi.org/10.5090/jcs.23.168. **Supplementary Table 1.** Univariate and multivariate Cox regression analysis for long-term survival rate.

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