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Article

A Simple and Effective Venoarterial Extracorporeal Membrane Oxygenation Weaning Protocol Conducted in A Community Hospital

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Abstract

Introduction: In recent years, the use of extracorporeal membrane oxygenation (ECMO) has expanded beyond university centers and is now being performed at community hospitals with limited resources. There is currently no consensus approach to weaning from venoarterial ECMO (VA-ECMO) after cardiogenic shock, with multiple different methods supported in the literature. Many of these approaches are complicated and resource-intensive, requiring equipment or personnel that are not available in the community setting. In our community hospital, we developed a simplified ECMO weaning protocol, and this study aimed to assess the feasibility and efficacy of our protocol. **Methods**: In this retrospective single-center study, we evaluated the outcomes of patients who underwent our ECMO weaning protocol between May 2021 and December 2023. To qualify for our ECMO weaning protocol, the patient needed to be well perfused with stable settings on the VA-ECMO. Our ECMO weaning protocol was as follows: Maintain anticoagulation with a partial thrombin time (PTT) goal of ~50 seconds. The ECMO flow was weaned at 0.5 L/min every 30–60 min. Once the ECMO flow reached ~2 L/min, a bolus of fluid and inotrope was started. A transthoracic echocardiogram would be obtained to evaluate the left and right ventricular functions. Then, the ECMO flow rate was further decreased to 1.5 L/min. Based on the echocardiogram findings, a discussion would be held to evaluate whether the patient was a candidate for decannulation, if the patient required an additional mechanical-assisted device, or if they should be transferred for a higher level of care. **Results**: A total of 64 patients who underwent VA-ECMO at our institution were evaluated for decannulation from ECMO using our weaning protocol. In this group, 25 eventually passed our weaning trial, while 39 failed to pass our weaning trial at any point. Of the 25 patients who passed our trial, 19 were weaned off mechanical support, four were weaned to a left ventricular assist device (LVAD), and two were weaned to a right ventricular assist device (RVAD). Of the patients who underwent successful weaning, four patients experienced post-ECMO cardiogenic shock, leading to death or reinitiation of ECMO. Our protocol had a sensitivity of 95.5% (95% confidence interval (CI): 77.2% to 99.9%) with a specificity of 87.1% (95% CI: 70.2% to 96.4%). **Conclusion**: In a community hospital with limited resources, the existence of a clear ECMO weaning protocol that optimizes the use of available resources is essential. In our experience, this protocol was predictable and produced acceptable results.

Keywords

cardiogenic shock; venoarterial extracorporeal membrane oxygenation; extracorporeal membrane oxygenation wean

Introduction

Venoarterial extracorporeal membrane oxygenation (VA-ECMO) provides circulatory support to patients in cardiogenic shock for days to weeks, serving as a bridge to cardiac recovery, definitive intervention, a durable mechanical support device, or transplantation. One of the key decision points for patients on VA-ECMO is determining whether a patient has adequate cardiac recovery to decannulate [1]. However, the optimal approach to VA-ECMO weaning has yet to be defined, with multiple different methods described in the literature.

Over the past few years, extracorporeal membrane oxygenation (ECMO) support has expanded beyond academic centers to lower-resourced community center programs. This has enabled the benefits of this crucial technology to become accessible to a larger portion of the population. Many of these approaches are complicated and resource-intensive, requiring equipment or personnel that are not readily available in the community setting. In our prior paper, we demonstrated that outcomes from our ECMO protocol at a community center program were noninferior to those at larger centers, after adjustments were made for resource limitations [2].

In this paper, we explored and evaluated our simplified approach to VA-ECMO weaning that was developed for use in our community center program. Although prior papers have defined a variety of methods for weaning, these

techniques often require equipment or staff that are not available in a community center. We believe this simplified approach holds promise for use in similarly resourced community centers, yielding comparable outcomes to those previously described.

Methods

Hospital

Our community hospital features 350 beds, including a cardiac catheterization laboratory and a busy cardiac surgery practice that serves the southern New Jersey region. Our center was not certified for durable long-term ventricular support devices (VADs) or heart transplants during the study period. Our ECMO program was established in 2021 and registered as an ECMO center in the Extracorporeal Life Support Organization center list (ID 1032). Once identified, suitable cardiogenic shock patients were cannulated via a standardized approach. We used the femoral artery with a distal perfusion catheter for our arterial cannula and the femoral vein for our venous cannula. When possible, we cannulated patients in the cardiac catheterization laboratory; however, on occasions, we would cannulate patients in the operating room or the cardiac intensive care unit. All data from ECMO patients were entered into our database, which was approved for research purposes (Internal review board certification GLL11). The details of our cannulation protocols are published in Rizvi *et al*. [2].

Equipment and Personnel

All VA-ECMO patients were managed in our dedicated Cardiothoracic Intensive Care Unit by a full-time intensivist trained in cardiothoracic surgery, supported by midlevel providers. The cardiothoracic intensivists and echocardiography technicians were on-site during the day and on call during off-hours. Transthoracic echocardiography (TTE) was available for use by either the cardiothoracic intensivists or echocardiogram technicians. However, the transesophageal echocardiogram could only be used by qualified cardiologists or cardiac anesthesiologists. The temporary percutaneous ventricular assist device (Impella CP, Abiomed, Danvers, MA, USA) was readily available in the cardiac catheterization laboratory; however, the Impella 5.5 required a trained cardiothoracic surgeon and operating room availability for use.

Patients

Between May 2021 and December 2023, 64 consecutive patients underwent VA-ECMO for longer than 24 hours due to cardiogenic shock. Cardiogenic shock was defined as a rapid decline in hemodynamics requiring multiple inotropes to achieve a cardiac index of 2 L/min per m^2. Once recovered, all patients underwent our simplified weaning protocol (Fig. 1).

ECMO Weaning Trial Protocol

To qualify for our ECMO weaning protocol, the patient needed to be well perfused with stable settings on the VA-ECMO. We defined "stable" as an ECMO flow at Body surface are (BSA) $\times$ 2.2 for 48 hours with stable vital signs (mean arterial pressure of 65 with minimum vasopressor support and minimum inotrope support (dobutamine less than 3), recovery of lung function (FiO_2 of 50% from vent and FiO_2 of 50% from ECMO support, an ECMO sweep less than 3 L/min), and resolution of lactic acidosis. The use of continuous venovenous hemodialysis (CVVHD) was not an exclusion for the wean trial. If a percutaneous ventricular assist device was used, the P-level should be set at P-5 or below. We did not use a Swan-Ganz catheter during weaning. Our weaning protcol is shown in Fig. 1.

Step 1: The patient was subjected to a mini ECMO wean, during which the ECMO flow was reduced to less than 2 L/min for fewer than 5 minutes to assess whether the patient was a candidate for a formal ECMO wean. If an echocardiography was available at the bedside, it would be performed by the intensivist to assess ventricular function. If the patient could tolerate the mini ECMO wean without significant hemodynamic instability, a formal ECMO wean would be scheduled for the next day. If the patient did not accept the mini wean trial, we would repeat the trial after 2 days.

Step 2: For the formal wean, anticoagulation would be maintained with a partial thrombin time (PTT) goal of 45–55 seconds. From the baseline ECMO flow, the ECMO flow would be weaned by 0.5 L/min every 30–60 min with a target of 2 L/min. However, if the PTT goal were not achieved, the target ECMO flow would be 2.5 L/min.

Step 3: Once the ECMO flow reached 2–2.5 L/min, a 250–500 cc bolus of fluid was administered based on central venous pressure, or the CVVHD was adjusted to reduce fluid removal, and an inotrope was started or increased (dobutamine 3–5 mic/kg/min). At this point, a TTE was performed and reviewed by the intensivist to assess LV and RV function and regurgitation from the mitral and tricuspid valves, determining whether to proceed to the next stage. If the patient continued to have severe ventricular dysfunction, the weaning trial was considered to have failed. However, moderate left ventricular dysfunction or better (defined as left ventricular ejection fraction (LVEF) 25% or greater) was acceptable as long as the patient remained hemodynamically stable during the weaning trial.

Step 4: If the patient had reached the goal for PTT, as confirmed by a TTE at the bedside, then the flow would be decreased to 1.5 L/min for 15–20 minutes and subse-

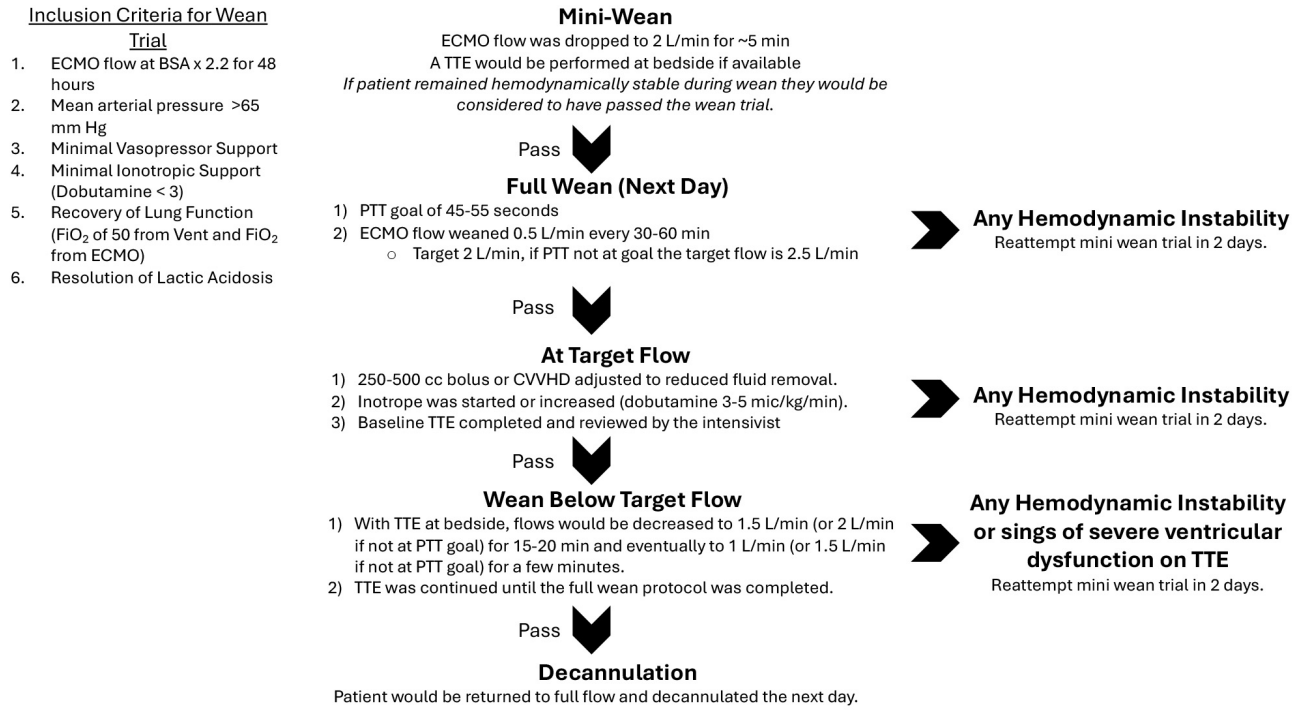

Fig. 1. Weaning protocol. PTT, partial thrombin time; TTE, transthoracic echocardiogram; ECMO, extracorporeal membrane oxygenation.

quently to 1 L/min for a few minutes. If the patient were not at goal for PTT, a bedside TTE would be performed, and the flow would be decreased to 2 L/min for 15–20 minutes, then gradually reduced to 1.5 L/min for a few minutes. TTE was continued during this stage until the full weaning protocol was completed. An arterial blood gas was used to evaluate the oxygenation and ventilation status at the end of the study.

Step 5: If the patient remained hemodynamically stable for the duration of the weaning trial, the patient would be returned to the baseline ECMO settings. The echocardiogram findings would then be discussed among cardiologists, cardiothoracic intensivists, and cardiothoracic surgeons. In general, the patient would be assessed as ready for decannulation if the LVEF was greater than 25% and the patient had no greater than moderate right ventricular dysfunction.

Decannulation: If no concerns existed, the patient would be scheduled for decannulation in the operating room later the same day or the next day. Severe ventricular dysfunction at the end of the wean protocol was considered to be wean failure. If the patient became hemodynamically unstable at any point during the weaning trial, the flows would be returned to baseline, and the patient would be considered a trial failure. The trial would be reattempted in two to three days, or the patient would be considered for transfer to a higher level of care at a transplant or permanent left ventricular assist device (LVAD) center.

If the patient showed persistent left ventricular (LV) failure with preserved right ventricular (RV) function, they would be considered for transition to a temporary LVAD or transfer to a center for placement of a permanent LVAD. Patients with preserved LV function and isolated severe RV failure would be considered for external right ventricular-assisted device (RVAD) placement to facilitate ECMO decannulation. Patients with continued biventricular failure would be discussed with a transplant center for candidacy of a biventricular assist device or cardiac transplant.

Patients who passed the weaning trial were decannulated in the operating room, assisted by a cardiac anesthesiologist and a cardiothoracic surgeon. A TEE and Swan-Ganz catheter were used for monitoring during the decannulation process.

Determination of Outcomes

To evaluate the success of our weaning trial, we utilized sensitivity and specificity measurements with a 95% confidence interval, as calculated using Microsoft Excel (Microsoft, Redmond, WA, USA). These specificity and sensitivity measurements were calculated in two different ways: First, we considered all patients who passed our trial and remained successfully ECMO-free after decannulation as true positives, patients who passed our weaning trial but either died due to cardiogenic shock post-decannulation or required decannulation onto ECMO as false positives, patients who failed our ECMO wean and died on the ECMO

Table 1. Patient demographics.

Characteristic	Wean success (n = 25)	Wean failure (n = 39)
Age (year)	57 ± 15	60 ± 13
Male sex	16 (64%)	32 (82%)
ECPR	3 (12%)	13 (33%)
Indication		
Acute myocardial infarction	12 (48%)	17 (44%)
Post-cardiotomy failure	5 (20%)	12 (31%)
Septic shock	0	1 (2.6%)
Right ventricular failure	0	1 (2.6%)
Malignant ventricular arrythmia	2 (8.0%)	3 (7.7%)
Acute on chronic heart failure	0	2 (5.1%)
Pulmonary embolism	1 (4.0%)	2 (5.1%)
Acute myocarditis	0	1 (2.6%)
Cardiomyopathy	4 (16.0%)	0
Amniotic fluid embolism	1 (4.0%)	0
Length of ECMO days	4.5 ± 2.4	6.5 ± 2.4
Pre-ECMO mean arterial pressure, mmHg	65 ± 14	60 ± 19
Pre-ECMO lactate, mmol/L	5.2 ± 3.9	6.0 ± 4.7
Maintenance ECMO flow, L/min	4.3 ± 1.0	4.3 ± 1.0

ECPR, ECMO assisted cardiopulmonary resuscitation; ECMO, extracorporeal membrane oxygenation. Data are expressed as the mean ± standard deviation or number (percentage).

were considered true negatives, and patients who were successfully decannulated after failing our weaning trial were considered false negatives. In our second calculation, we excluded all patients who were transferred out of our hospital after failing a weaning trial at our institution.

Results

A total of 64 patients underwent our simplified VA-ECMO weaning protocol, with 25 (39%) passing our trial (Table 1). Of these 25 patients, 19 experienced complete biventricular recovery, four had isolated LV failure, and two had isolated RV failure (Fig. 2). The four patients with isolated LV failure were transitioned to an external LVAD (Impella 5.5) for decannulation. The two patients with isolated RV failure were transitioned to an external RVAD (ProtekDuo, LivaNova, London, UK) for decannulation. The remaining 39 patients failed the weaning trial at our institution. These patients were discussed with outside transplant centers to evaluate the candidacy for further mechanical circulatory support (MCS) devices or cardiac transplantation. Among these 39 failed weaning trial patients (61%), 27 patients died within 30 days without successful decannulation at our institution, one patient was successfully decannulated after failing the weaning trial, and 11 patients were transferred to an outside hospital for higher levels of care for evaluation of implantable LVAD or transplantation.

Of the 19 patients who passed the weaning trial without MCS support, 17 (89%) did not suffer a repeat cardiogenic shock episode. However, only eight of these patients survived beyond 30 days. Of the patients who passed away within 30 days, five patients did not have a neurological recovery or had worsening neurological status after decannulation, two patients died due to acute respiratory distress syndrome (ARDS), one patient died due to sepsis, and one patient died after the family decided to withdraw care (Fig. 3). Of the 19 patients who passed the weaning trial without MCS support, two patients had a repeat episode of acute cardiac decompensation post-decannulation; one patient died of a sudden cardiac arrest on post-ECMO day 1, and the other required another VA-ECMO (this patient was ultimately transferred to an outside hospital on ECMO and survived decannulation without support).

Of the patients who required MCS to pass the weaning trial, four patients required an Impella 5.5 for persistent left ventricular failure, and two patients required a ProtekDuo for persistent right ventricular failure. Of the four patients who required Impella 5.5 placement for decannulation, three ultimately recovered sufficiently for temporary external LVAD removal and survived for more than 30 days. However, one patient died due to cardiac arrest on temporary external LVAD support on post-operative day one. Of the two patients requiring ProtekDuo for decannulation, one patient recovered enough for RVAD decannulation and survived for longer than 30 days. The other patient on ProtekDuo died due to sudden LV failure on post-operative day 3.

There was one patient who failed our weaning trial but was ultimately successfully decannulated in the operating room. This patient failed the trial due to a low EF of 10–15% on the low ECMO flow. We had planned for a temporary LVAD, but once in the operating room, we assessed that the ventricular function was acceptable for decannulation without an LVAD, and we were able to decannulate the patient. This patient survived beyond 30 days.

Of the 27 patients who failed the weaning trial and died at our institution while on ECMO, 11 had care withdrawn due to a failure to have significant cardiac recovery (Fig. 1). Seven of these patients had persistent biventricular failure, and care was withdrawn after discussion with a transplant center. Three patients had isolated LV failure and were not considered candidates for LVAD, or their families refused advanced therapy. One patient had isolated RV failure and was not deemed an appropriate candidate for RVAD due to their neurological status. Of the remaining patients, six had care withdrawn due to lack of significant neurological recovery or worsening neurological status on ECMO (including stroke), three patients had sepsis following gastrointestinal issue on ECMO, the families of four patients opted to withdraw care, and three patients experienced the sudden loss of ECMO flow that could not be resolved.

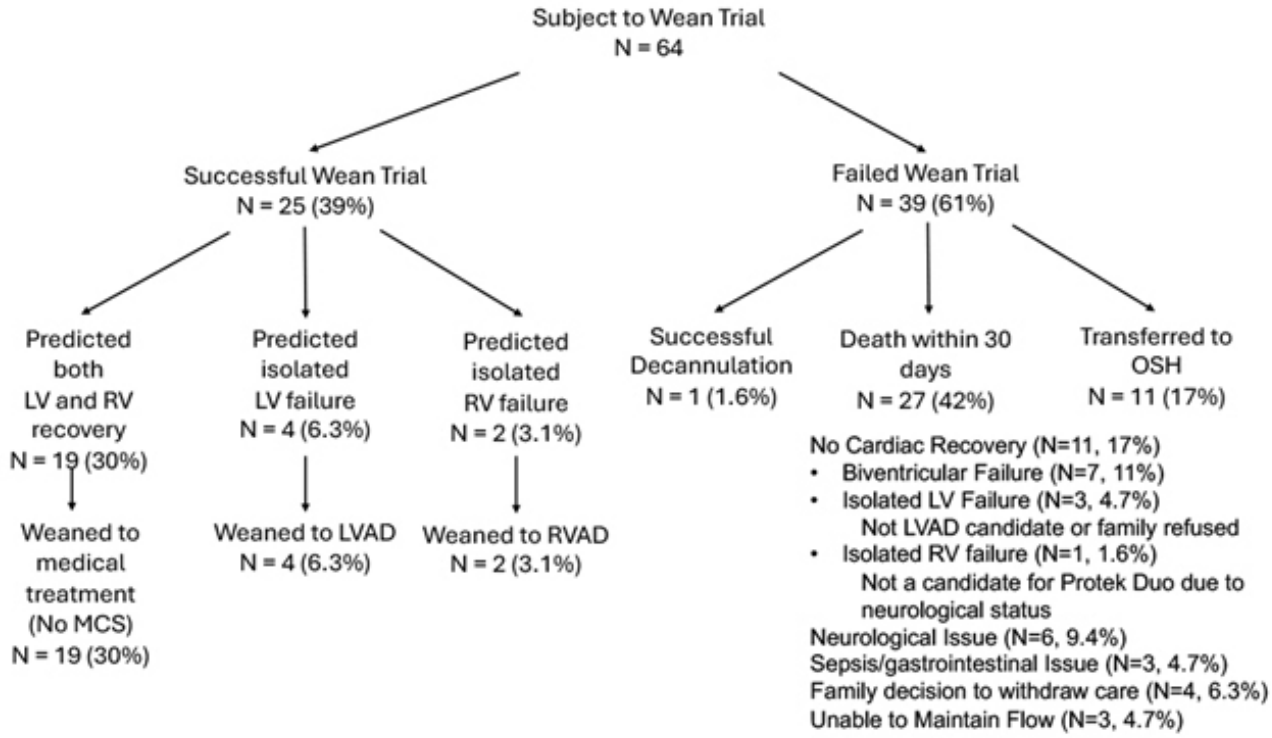

Fig. 2. The weaning protocol results. LV, left ventricle; LVAD, left ventricular assist device; RV, right ventricle; RVAD, right ventricular assist device; MCS, mechanical circulatory support; OSH, Out side hospital.

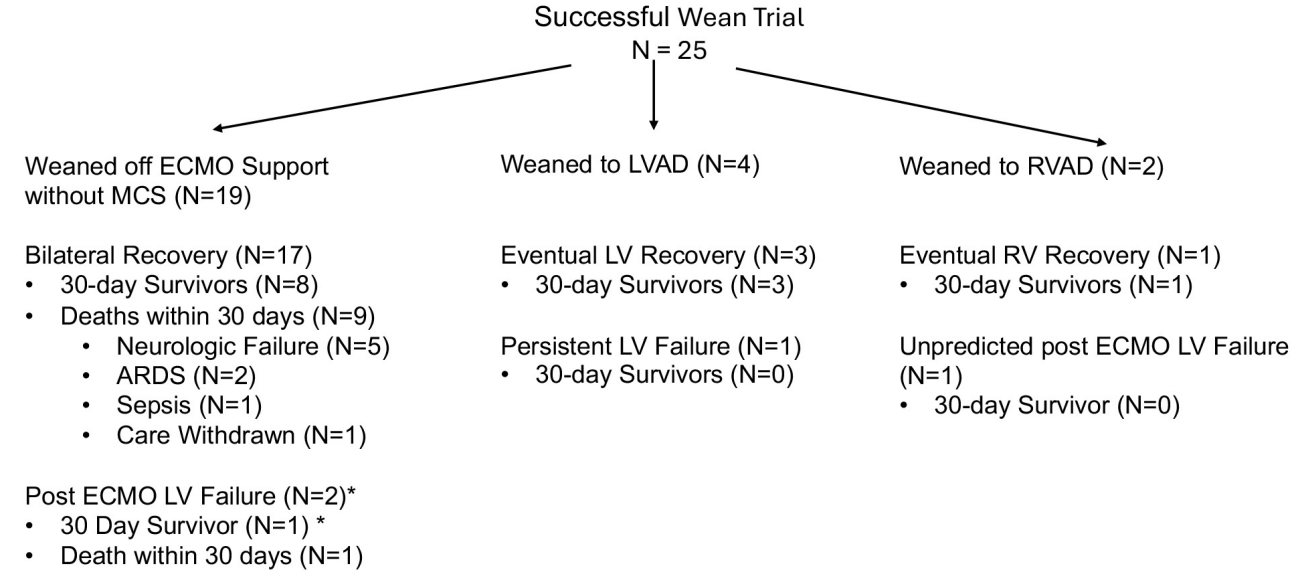

Fig. 3. Patient outcomes for those who passed the weaning trial.

The final group of 11 patients was transferred to outside institutions on ECMO after failing our weaning trial. In at least one case, the patient required a pulmonary embolectomy, which was not offered at our institution, and was decannulated postoperatively. However, most of the time it was for transplant evaluation, implantable LVAD

evaluation, or simply at the request of the family. Of these patients, nine were successfully decannulated from the ECMO, with eight not requiring implantable LVAD support, and the remaining patient was decannulated onto an external temporary LVAD.

In all our weaning trials, we predicted that 25 patients would tolerate ECMO decannulation, with only four patients dying from cardiac causes or requiring re-cannulation onto ECMO. Of the 39 patients who failed our weaning trial, only 10 were ultimately successfully weaned off ECMO. This analysis yields a sensitivity of 67.7% (95% CI: 48.6% to 83.3%) and a specificity of 87.9% (95% CI: 71.8% to 96.6%). However, it is challenging to determine whether patients who were decannulated at an outside hospital failed the weaning trial due to an issue with our methodology or because a greater amount of time was allowed for cardiac recovery with a higher level of care. If we exclude all patients transferred to an outside hospital and only include patients managed entirely at our hospital, then our analysis would calculate a sensitivity of 95.5% (95% CI: 77.2% to 99.9%) with a specificity of 87.1% (95% CI: 70.2% to 96.4%).

Discussion

In patients with cardiogenic shock or cardiac arrest, ECMO often serves as the final effort to stabilize the patient and provide a bridge to recovery or definitive treatment. However, the longer the patient remains on ECMO, the greater the exposure of patients to major ECMO-related risks, which include bleeding, thrombosis, and limb ischemia. For this reason, patients must be properly identified for decannulation promptly, while balancing the risk of failed decannulation. However, there is great heterogeneity in the approach to ECMO decannulation [3].

The ELSO Interim Guidelines for Venoarterial Extracorporeal Membrane Oxygenation in Adult Cardiac Patients, last published in 2021, provide two key recommendations. The first is that patients should be considered for weaning when the patients remain hemodynamically stable on low ECMO flow with a mean arterial pressure (MAP) $>$60 mmHg, left ventricular outflow tract velocity $>$0.12 m/s, tissue Doppler lateral mitral annulus peak systolic velocity $\geq$6 cm/sec, central venous pressure $\leq$10 mmHg, and left ventricular ejection fraction $\geq$25–30% on low dose vasoactive, inotropic support. However, these recommendations do not provide specific guidelines for conducting weaning. The second recommendation supports a pump-controlled retrograde trial off or a shunt in the ECMO circuit during weaning to simulate reduced or negligible ECMO support. However, this statement does not specifically recommend this approach [4].

In our review of the literature, two general approaches to ECMO weaning were identified. One approach was to reduce ECMO flow in 0.5 L/min increments until the patient reached minimal flow, at which point the patient would be assessed for stability, and an echocardiogram would be performed to evaluate cardiac function [3,5–7]. A slight variation in this approach involves reducing the flow to two-thirds of the baseline and eventually to one-third of the baseline, after which the patient is assessed [8,9]. The alternative approach would be a trial of pump-controlled retrograde trial off (PCRTO), where the ECMO flow would be allowed to decrease until a retrograde flow of 0.5–1 L/min is achieved, and the patient would be assessed at this point [10,11]. However, the speed at which patients were weaned varied, and the specific parameters varied widely. For example, in one review of ECMO weaning, 10 papers were examined, and each paper used different echocardiographic parameters to assess success or failure during their weaning trial [3]. This variation also reflected different levels of resources at each center, which were not always available at our community center.

In designing our weaning trial, we had to consider several key limitations inherent to community programs. Our primary investigators had used the hemodynamic transesophageal echocardiogram (hTEE) to aid in ECMO weaning previously [7], but this device was not available in our institution. Due to limited TEE availability at our hospital, we had to be considerate and limit their use with ICU patients. Instead, we had to utilize TTE, which was more readily available and easier to use. Finally, we had to rationalize our approach to ECMO weaning in relation to our role in the chain of care. In general, our view is that an effective community ECMO center should be able to identify patients who require transfer for a higher level of care without overloading tertiary care centers with patients who could easily be cared for without transfer. As ECMO expands beyond university centers, we believe that this discussion will become increasingly important.

In our study, we evaluated 64 patients who were initiated on ECMO at our institution and underwent at least one simplified ECMO weaning trial. This trial would be attempted repeatedly until the patient satisfactorily passed the trial and was decannulated from ECMO with or without support of another MCS device. From here, we could assess which patients remained free of significant cardiac failure leading to death or reinitiation of ECMO. For patients who failed our weaning trial, only one had an attempted decannulation at our institution at the request of the family and survived. This patient remained hemodynamically stable during our weaning trial and failed only due to a low EF of 10–15% on the TEE. The remaining nine patients who survived decannulation despite failing our weaning trial were decannulated at outside hospitals after transfer. For these patients, it is difficult to assess whether our weaning trial misidentified them or if they simply needed greater time for recovery. Therefore, it is not unreasonable to consider the sensitivity and specificity with and without transferred

patients as upper and lower bounds for our test. In general, we found the success rate of our protocol to be in line with that of similar protocols, even considering the adaptations we had to make at a less resourced community center.

There were several limitations to our trial, many of which are related to our status as a community center. This meant that many patients were transferred for definitive management elsewhere, often at the request of their families, and in many cases, these patients were successfully decannulated from ECMO. For these patients, we have very basic information, and it is difficult to assess what changed to allow the outside center to decannulate these patients. These transfers also represent a more favorable subset of the patients we treated. If a patient was accepted for transfer, that patient was more likely to do well. Of the 11 patients who transferred to other institutions on ECMO, nine survived more than 30 days. In contrast, only 14 of 53 patients who remained at our center survived more than 30 days. We feel this is largely due to selection bias, where transferring institutions only took patients with acceptable neurological status and a better probability of full recovery and rejected more morbid patients. There was also a significant 30-day mortality rate for patients who were decannulated from ECMO at our facility, with only 13 of 25 patients surviving beyond 30 days. However, only three of these deaths were due to cardiac causes, which could be attributed to a failure of our protocol. The largest proportion of these patients died due to worsening neurologic status or a lack of improvement from their baseline status post-cannulation; this is expected in this population, although it does limit our ability to evaluate long-term cardiac recovery.

Conclusion

It is possible to achieve strong and predictable results for ECMO weaning in a community center that lacks the resources of larger university centers. We believe that our approach holds promise and can be applied in similarly resourced centers, as the use of ECMO for cardiogenic shock expands beyond university centers.

Availability of Data and Materials

The data are available from the corresponding author upon reasonable request.

Author Contributions

DM: Data collection, writing paper. LM: Data collection, revising paper. QY: design of work, revising paper. HH: design of work, supervision, creating idea, revising paper. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

The study was carried out in accordance with the guidelines of the Declaration of Helsinki. This study was conducted in Virtua Health, Our Lady of Lourdes Hospital under internal review board approval (GLL11). As a retrospective study, it is not necessary to obtain informed consent of patients.

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Conflict of Interest

The author declares no conflict of interest. Hitoshi Hirose serves on the editorial board of this journal. Hitoshi Hirose declares that he was not involved in the processing of this article and has no access to information regarding its processing. Full responsibility for the editorial process for this article was delegated to Curt Tribble.

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