ORIGINAL ARTICLE

Venoarterial Extracorporeal Membrane Oxygenation for Refractory Cardiogenic Shock and Cardiac Arrest: An Initial 7-Year Experience in an Adult Cardiology Center

Utilización de oxigenación por membrana extracorpórea venoarterial en el shock cardiogénico y paro cardiorrespiratorio refractarios: experiencia inicial de 7 años en un centro de cardiología de adultos

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ABSTRACT

Background: Venoarterial extra corporeal membrane oxygenation (VA-ECMO) is a rescue intervention used in patients with cardiogenic shock (CS) or cardiac arrest (CA) refractory to conventional medical therapies.
Objective: The aim of the present study is to describe the characteristics and summarize our 7-year experience in patients with CS or CA supported with VA-ECMO.
Methods: We conducted a single-center retrospective study analyzing consecutive adult patients requiring VA-ECMO due to refractory CS or CA at ICBA, Instituto Cardiovascular between January 2014 and December 2020.
Results: A total age 54 patients were included (54 ±12 years), 36.5% presented ischemic cardiomyopathy and 23.1% significant valvular heart disease. The indications for VA-ECMO implantation were post-cardiotomy (43.4%), refractory CS (28.3%) and primary graft dysfunction (20.8%). Cardiopulmonary resuscitation before VA-ECMO occurred in 18.5% of the cases. Peripheral cannulation was performed in 81.5% o the cases, 83.3% had INTERMACS profile 1 and 87% were on intraaortic balloon pump. Duration of ventricular assistance on VA- ECMO was 5.5 days (IQR 2.8-10). Survival rate on ECMO VA was 63% (37% as a bridge to cardiac transplantation and 26% as a bridge to recovery) and survival to discharge was 42.6%. The most common complications were hemorrhage (61.1%), infections (51.9%), and thromboembolic complications (46.3%).
Conclusion: In our center, VA-ECMO as a treatment for refractory CS or CA showed acceptable survival during ventricular support and on hospital discharge. It is an effective life support treatment to rescue critically ill patients when conventional therapies fail, is apparently useful and can be implemented in a country with limited resources and access to complex ventricular assist devices.

Key words: Extracorporeal Membrane Oxygenation – Cardiogenic shock – Postcardiotomy shock – Ventricular assist devices

RESUMEN

Antecedentes: La oxigenación por membrana extracorpórea venoarterial (ECMO VA) es una intervención de rescate en pacientes con shock cardiogénico (SC), y paro cardiorrespiratorio (PCR) refractarios a las terapias convencionales.
Objetivo: Describir las características, y resumir nuestra experiencia inicial de 7 años de pacientes que requirieron ECMO VA por SC o PCR.
Material y métodos: Se realizó un estudio de cohorte unicéntrico. Se analizaron retrospectivamente los pacientes adultos consecutivos que fueron asistidos con ECMO VA por SC o PCR refractarios entre 2014 y 2020 en el ICBA Instituto Cardiovascular.
Resultados: Se incluyeron 54 pacientes, (54 ± 12 años). El 36,5% presentó miocardiopatía isquémica, y el 23,1% enfermedad valvular significativa. Las indicaciones para ECMO VA fueron: poscardiotomía (43,4%), SC refractario (28,3%), y falla primaria del injerto (20,8%). La reanimación cardiopulmonar previa a la ECMO VA se realizó en el 18,5%. La canulación fue periférica en el 81,5%, el 83,3% se asistió en INTERMACS 1, y el 87% presentaba balón de contrapulsación intraaórtico. La duración de asistencia en ECMO VA fue de 5,5 días (RIC 2,8-10). La tasa de supervivencia en ECMO VA fue del 63% (37% puente a trasplante cardíaco, y 26% recuperación), y al alta del 42,6%. Las complicaciones más frecuentes fueron: sangrado (61,1%), infección (51,9%), y complicaciones tromboembólicas (46,3%).
Conclusión: La ECMO VA como tratamiento del SC o PCR refractarios en nuestro centro presentó una sobrevida aceptable al alta hospitalaria. La ECMO VA es un tratamiento efectivo cuando las terapias convencionales fallan, siendo aparentemente útil y aplicable en un país donde existe acceso limitado a los dispositivos de asistencia ventricular compleja.

Palabras claves: Oxigenación por membrana extracorpórea - Shock cardiogénico - Shock postcardiotomía - Dispositivos de asistencia ventricular

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Abbreviations

VA-ECMO	venoarterial extracorporeal membrane oxygenation	**CS**	cardiogenic shock
CA	cardiac arrest		

INTRODUCTION

Venoarterial extracorporeal membrane oxygenation (VA-ECMO) is a form of continuous-flow left ventricular assist device that provides vital support for patients experiencing both pulmonary and cardiac failure unresponsive to conventional therapy. (1) Compared to other ventricular assist devices, the main advantages of VA-ECMO are that it is one of the less expensive devices and provides respiratory support and single or biventricular support. (2) Nevertheless VA-ECMO is used for short-term cardiac support not exceeding 7 days.

Generally, VA-ECMO is a rescue intervention used in patients with cardiogenic shock (CS) or cardiac arrest (CA) refractory to conventional medical therapies, as a bridge to cardiac transplantation, myocardial recovery, decision, or long-term cardiac support. (3)

In recent years VA-ECMO has become a valuable tool, and its use has spread worldwide. Along with the expansion and greater experience, there are more professionals trained, the understanding of this type of assistance has increased, and the technology of the equipment has improved. In addition, the creation of multidisciplinary teams known as "ECMO Teams" has allowed for a holistic approach to these complex patients and their appropriate selection, which is reflected in the optimization of results. (4,5)

While there are specific international data provided by the Extracorporeal Life Support Organization (ELSO) registry, in Argentina there are currently no registries or cohorts providing data on adult patients assisted by VA-ECMO for CS or CA. (6)

The aim of the present study is to analyze our 7-year experience in patients with CS or CA supported with VA-ECMO, describe the characteristics of these patients, device-related complications and associated clinical events.

METHODS

We conducted a retrospective and single-center cohort study.

Database

We retrospectively analyzed a prospective database of patients on ventricular assist device at ICBA, Instituto Cardiovascular, between 2014 and 2020. The main variables include demographic characteristics, type of ventricular assist device, complications, relevant clinical events, and clinical, biochemical and echocardiographic predictors of prognosis.

Population study

The cohort was made up of consecutive adult patients requiring VA-ECMO due to CS or CA refractory to treatment at ICBA, Instituto Cardiovascular between January 2014 and December 2020.

Patients who had venovenous ECMO implanted for respiratory support only, and those who had another type of ventricular assist device (e.g., Centrimag) were excluded.

Definitions

CS or CA refractory to treatment in patients with VA-ECMO implanted were defined as follows:

- Refractory CS: Shock due to cardiac causes requiring 2 or more inotropic drugs at intermediate/high doses (e.g., norepinephrine > 0.5 mcg/kg/min).
- Refractory CA: witnessed CA due to presumed cardiac cause (mainly with ventricular tachycardia or ventricular fibrillation as the onset rhythm), lasting > 20 minutes, even with adequate cardiopulmonary resuscitation from the beginning.

Relevant clinical events:

- Survival on ECMO: survival during ECMO support and within 24 hours after ECMO weaning. In this case, the reasons for ECMO weaning are recovery of cardiac function or cardiac transplantation.
- Survival to discharge: includes hospital discharge or referral to other health care center (e.g., tertiary rehabilitation center).
- Survival during follow-up: evaluates survival until the last patient was included.

Major complications of the patient on ECMO and of the device were considered according to the definitions of the ELSO:

- Mechanical complications: defined as those requiring intervention, such as change of equipment or circuit components. These complications include oxygenator failure, pump failure, tubing rupture, circuit change due to clots or air in the circuit and heat exchanger malfunction.
- Hemorrhagic complications: bleeding requiring whole blood transfusion >20ml/kg/day or packed red blood cell >3U/day.
- Neurologic complications: include brain death (irreversible loss of the capacity for consciousness combined with the irreversible loss of all brainstem functions, including the capacity to breathe), and stroke (signs of acute ischemia and brain CT scan showing new ischemic changes or hemorrhage).
- Infections: those that occur prior to and on ECMO, with or without positive cultures, with requirement of antibiotic therapy.
- Thromboembolic complications: presence of clots or air in the patient (either clinical or in imaging tests) or in the ECMO device.
- Renal complications: kidney failure is defined as change in creatinine level ≥ 1.5 mg/dL after ECMO implant or requirement of dialysis.

Statistical analysis

The normality of quantitative variables was evaluated using the Kolmogorov-Smirnov test or the Shapiro-Wilk test, as applicable. Parametric variables were expressed as mean ± standard deviation (SD) and non-parametric variables as median and interquartile range (IQR). Qualitative variables were presented as percentages. The differences between the groups were compared using the Student's t test, Mann Whitney test and chi-square test, as applicable. Survival during follow-up was evaluated using the Kaplan-Meier curve and Cox proportional hazards model.

Statistical analysis was performed using SPSS 22.0 statistical package (SPSS, IBM Corporation, Armonk, New York).

Ethical considerations

The study was conducted following the recommendations of the Declaration of Helsinki and was approved by the institutional review board. All the patients signed an informed consent form during hospitalization authorizing the anonymous use of their information for research purposes.

RESULTS

A total of 54 patients on ECMO due to refractory CS or CA were included. The number of patients on ECMO increased over the years, with the maximal peak in 2019 (n = 15). Figure 1 shows the increase and indicates two relevant events as the creation of the multidisciplinary ECMO team in 2019 and the pandemic of coronavirus disease 2019.

Mean age of patients was 54 ± 12 years and 64.8% were men. The baseline characteristics of the population are shown in Table 1: 22.2% were diabetics, 37% had a history of coronary artery disease, 47.2% had previous valvular heart disease and 20.4% had previous kidney failure. (Table 1).

The main diagnoses of myocardial damage at the time of implantation of the assist device were ischemic cardiomyopathy (36.5%), significant valvular heart disease (23.1%) and myocarditis (5.8%). (Table 2). The main indications for VA-ECMO implantation were post-cardiotomy (43.4%), refractory CS (28.3%) and primary graft dysfunction (20.8%). Cardiopulmonary resuscitation before VA-ECMO occurred in 18.5% of the cases. The INTERMACS profile 1 (7) was found in 83.3% of the patients and 87% were on intraaortic balloon pump. (Table 3)

The cannulation site was peripheral in 81.5% of the cases, mostly femoro-femoral. Pulmonary venting was necessary for left ventricular decompression in 7.4% of the cases. Median duration of life support on VA-ECMO was 5.5 days (IQR 2.8-10). Median time to death on VA-ECMO was 7 days (IQR 2-22). (Table 3)

The survival rate on ECMO VA was 63%, 37% as a bridge to cardiac transplantation and 26% as a bridge to recovery. Survival on hospital discharge was 42.6%. In survival to discharge was 90% after a median follow-up of 22 months (IQR 6-30). (Figure 2)

The most common complications during VA-ECMO support were hemorrhage (61.1%), infections (51.9%), thromboembolic complications (46.3%), acute kidney failure (44.4%), and prolonged mechanical ventilation requiring tracheostomy (35.2%). (Table 3)

Most bleeding events were medically treated and only 11.1% required surgery; 37% occurred at the implant site of the device and 11% were gastrointestinal bleeding.

Most infections (39%) occurred in the device, 34% in the respiratory system and the site was not clear in 17%. In all the infections with microbiological confirmation were due to bacteria, and Pseudomona aeruginosa was the most common microorganism. There were no infections due to fungi.

Most thromboembolic complications did not require intervention and were associated with the ECMO circuit or due to the site of femoral cannulation, with clinical signs of arterial ischemia. One patient (1.9%) required amputation of the lower extremity and 7.4% underwent fasciotomy.

Stroke occurred in 13% of the cases and was ischemic in 75% of them. One patient developed seizures (1.9%) and another patient (1.9%) presented brain death during VA-ECMO support.

There were no mechanical complications in any of the device components (oxygenator failure, pump failure, tubing rupture, or heat exchanger malfunction).

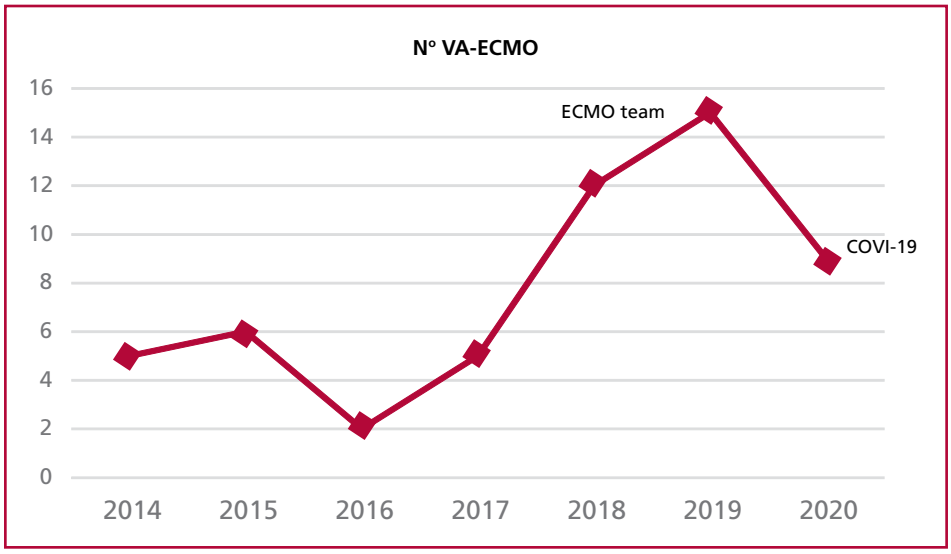

Fig. 1. Number of VA-ECMO devices implanted per year

COVID-19: coronavirus disease 2019, VA-ECMO: venoarterial extracorporeal membrane oxygenation

Table 1. Baseline characteristics of the population (n = 54)

Age in years (mean, SD)	54 (12)
Male gender (n, %)	35 (64.8)
BMI in kg/m² (mean, SD)	26 (4.6)
HTN (n, %)	20 (37)
Diabetes (n, %)	12 (22.2)
Dyslipidemia (n, %)	29 (53.7)
Current smoking (n, %)	5 (9.2)
Previous coronary artery disease (n, %)	20 (37)
Moderate/severe valvular heart disease (n, %)	25 (47.2)
Previous cardiovascular surgery (n, %)	9 (16.7)
Stroke/TIA (n, %)	2 (3.7)
COPD (n, %)	2 (3.7)
CKD (n, %)	11 (20.4)
Anemia (n, %)	9 (16.7)
Atrial fibrillation (n, %)	12 (22.2)
Previous LVEF < 40% (n, %)	31 (57.4)

SD: standard deviation. HTN: hypertension. BMI: body mass index. TIA: transient ischemic attack. COPD: chronic obstructive pulmonary disease. CKD: Chronic Kidney Disease. LVEF: left ventricular ejection fraction.

Table 2. Clinical characteristics at the moment of circulatory support

	n = 54
Type of cardiac disease (n, %)	
Idiopathic dilated cardiomyopathy	5 (9.6)
Ischemic cardiomyopathy	19 (36.5)
Valvular heart disease	12 (23.1)
HCM	3 (5.8)
Myocarditis	3 (5.8)
LVNC	2 (3.8)
Other	5 (9.6)
Chagas disease	3 (5.9)
Indications for implantation (n, %)	
Post-cardiomyopathy	23 (43.4)
Cardiogenic shock	15 (28.3)
Primary graft dysfunction	11 (20.8)
CA	3 (5.7)
Other	1 (1.9)
ECMO in CA (n, %)	(18.5)
INTERMACS (n, %)	
1	45 (83.3)
2	8 (14.8)
3	1 (1.9)
Strategy for implantation (n, %)	
Bridge to heart transplantation	13 (24.1)
Bridge to recovery	37 (68.5)
Bridge to decision	4 (7.5)
Bridge to graft	0 (0)
IABP on ECMO (n, %)	47 (87)
Previous Levitronix® CentriMag (n, %)	2 (3.7)

HCM: hypertrophic cardiomyopathy, LVNC: left ventricular noncompaction, CA: cardiac arrest, ECMO: extracorporeal membrane oxygenation, IABP: intraaortic balloon pump.

DISCUSSION

In our center, VA-ECMO as a treatment for refractory CS or CA showed acceptable survival during ventricular support and on hospital discharge.

We have not found any papers or registries in the national literature dealing with adult patients requiring VA-ECMO. However, at the international level, the ELSO registry annually updates data on all ECMO patients from the affiliated centers. Based on the information updated by July 2020 of 27,004 adult patients, survival on VA-ECMO was 59%, and survival to discharge was 44%, which is similar to that of our study (63% and 42.6%, respectively). We should consider that we also included in our cohort patients with refractory CA, who usually have lower survival rate (41% on ECMO, and 29% to discharge). (6) In a meta-analysis, Xie et al. reported a high survival of 40.2%, similar to our finding. (8) Of importance, as there are no randomized studies in this clinical scenario and most of the results emerge from registries or observational studies. (9-12)

Besides including patients after CA, our patients had worse prognosis as in most of them the device was implanted post-cardiotomy. According to the review by Lorusso et al. survival on ECMO in this population ranges between 31% and 76%, and in half of the cases is near 50% (lower than in our experience, which was 63%). (13) According to this study, survival to discharge varies between 16% and 52%, and was < 40% in two-thirds of the centers (in our case it was 42.6%). In the ELSO registry, post-cardiotomy patients had survival rates slightly lower than in those of our study (56.4% on ECMO, and 41.7% to hospital discharge). (14) Kowalewski et al. recently published a meta-analysis including 13,000 patients; 44% were post-cardiotomy patients and 20.7% were in CS due to acute myocardial infarction (like in our study). The survival rate was almost like ours (42.8%), with better outcomes in centers with heart transplantation programs. (15)

There is not sufficient evidence on mid-term survival in the current literature. Recently, Biancari et al. published the 5-year follow-up of 665 post-cardiotomy patients treated with VA-ECMO. Survival to discharge was high, 36.1% (less than in our study), and was 27.7% at 5 years. (16) In our experience, this figure was higher: 90% of the patients discharged from hospital were alive at 5 years, representing 38.9% of the total number of patients.

The sample size in our study was small, as we included 54 patients. Yet, our study is still original, since it would be the first study performed in Argentina analyzing adult patients on VA-ECMO due to refractory CS or CA. In addition, most international observational studies evaluated between 81 and 172 patients. (11,12) An analysis of the ELSO Latin America registry shows that the median number of VA-ECMO implants in adults is only 4 per year per center. (6) In

contrast, 54 VA-ECMO devices were implanted in our center over a 7-year period, and the number increased to 15 in 2019, and 9 in 2020, even during the pandemic and with a 54% reduction in cardiovascular surgeries.

Median VA-ECMO duration was 7.3 days in the ELSO registry, higher than the 5.5 days in our study. (6) In those studies that considered only post-cardiotomy patients treated with VA-ECMO, median duration was similar, between 5 and 7 days. (17-19) In these studies, peripheral cannulation was also predominant in 65.1% to 85.3% of the cases. This type of cannulation is endorsed by recent intersociety guidelines on post-cardiotomy ECMO, which recommend peripheral implantation as the first option (class IIa, level of evidence B). (20)

Table 3. Characteristics and complications of VA-ECMO

	n = 54
Peripheral cannulation (n, %)	44 (81.5)
Pulmonary venting (n, %)	4 (7.4)
Duration in days (median, IQR)	5.5 (2.8-10)
Weaning (n, %)	34 (63)
Survival on ECMO (n, %)	34 (63)
In-hospital survival (n, %)	23 (42.6)
Clinical complications (n, %)	
Bleeding	33 (61.1)
Bleeding in surgical site	6 (11.1)
Acute kidney failure	24 (44.4)
Cardiac tamponade	9 (16.7)
Infection	28 (51.9)
Ischemic stroke	7 (13.0)
Peripheral artery ischemia	13 (24.1)
Embolism	25 (46.3)
Tracheostomy	19 (35.2)
Mechanical complications (n, %)	0 (0)

ECMO: extracorporeal membrane oxygenation, IQR: interquartile range.

The incidence of complications in patients on VA-ECMO varies greatly according to the different series, and in some cases the information is limited.

In our study, bleeding was the most common complication, occurring in 61.1% of the cases. In the Latin America ELSO registry, bleeding was reported in 44.7% of the cases; our population was made up mainly of post-cardiotomy patients. (6) This population usually has a higher rate of bleeding due to coagulopathy associated with extracorporeal circulation and ECMO, and with the need for immediate anticoagulation in the postoperative period after cardiovascular surgery. In the study by Lorusso et al. evaluating post-cardiotomy patients, the major bleeding rate was 90%. (13)

In our population, infections were observed in 51.9% of the cases, a higher incidence than those described in the ELSO registry and in the meta-analysis by Xie et al. (25.1%). (6,8) Obviously, these are vulnerable and critically ill patients, with prolonged mechanical ventilation, multiple vascular accesses, and on extracorporeal membrane. Unlike other studies in which Candida is the most common microorganism, we did not observe any fungal infections in our study, probably due to the routine use of antifungal prophylaxis. (21)

The prevalence of thromboembolic complications was 46.3% in our cohort. The rate was higher than that described in the ELSO registry, since we included visible clots in the oxygenator and circuit without clinical relevance, whereas the ELSO registry only considered those requiring an active action as oxygenator change. (6) In other series, clots in oxygenator were observed in 51% of cases. (21,22)

Although VA-ECMO is not free of complications, its use in an experienced center and by a multidisciplinary team improves the survival of patients with refractory CS or CA. (4,5)

Our study has some limitations. Firstly, it is a descriptive observational study with its associated biases. The small number of patients included is another

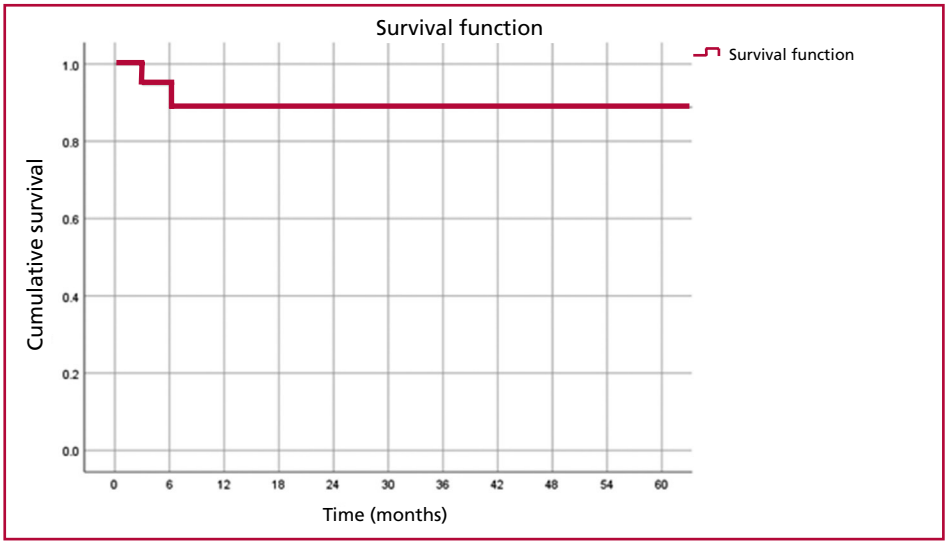

Fig. 2. Survival after hospital discharge.

limitation to consider. In any case, since the inclusion criteria were very strict, with the inclusion of only those patients who were treated with VA-ECMO for refractory CS or CA, this figure is significant if we compare it with the experience of other similar centers in Latin America or international cohorts. Finally, since it was a single-center study and was carried out in a high-complexity cardiovascular center, the results may not be extrapolated to other institutions in the region. Therefore, our experience may not be representative of the current national reality.

In conclusion, in our center VA-ECMO as a treatment for refractory CS or CA had an acceptable survival rate similar to the international experience during vital support and at hospital discharge. It is an effective life support treatment to rescue critically ill patients when conventional therapies fail, is apparently useful and can be implemented in a country with limited resources and access to complex ventricular assist devices.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web/Additional material.)

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