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Costs and Effects of Left Atrial Venous Drainage Cannula Placement in Venous-Arterial Extracorporeal Membrane Oxygenation (LAVA ECMO) Via Transeptal Puncture for Left Heart Decompression – A Single Institution Case Series

By Aurelie Merlo, MD, Panagiotis Tasoudis, MD, Lavinia Kolarczyk, MD,
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Methods: We performed a retrospective single-institution case series of fifteen patients who underwent left atrial venous drainage venous-arterial ECMO. The venous drainage cannula was a multistage single venous drainage cannula that was placed with fluoroscopic and echocardiographic guidance across the inter-atrial septum. The primary outcome of interest was six-month survival. Secondary outcomes included echocardiographic indices of left ventricular distention, platelet and bilirubin trend post cannulation, survival on ECMO, and surgical outcome.

Keywords: ECMO, cardiogenic shock, myocardial recovery.

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A Trial Decompression on VA ECMO

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Abstract- Background: Peripherally cannulated patients on veno-arterial extra corporeal membrane oxygenation support may require left heart venting to offload the left ventricle and allow for myocardial rest and recovery. Which venting strategy is optimal is currently not known.

Methods: We performed a retrospective single-institution case series of fifteen patients who underwent left atrial venous drainage veno-arterial ECMO. The venous drainage cannula was a multistage single venous drainage cannula that was placed with fluoroscopic and echocardiographic guidance across the inter-atrial septum. The primary outcome of interest was six-month survival. Secondary outcomes included echocardiographic indices of left ventricular distention, platelet and bilirubin trend post cannulation, survival on ECMO, and surgical outcome.

Results: Fifteen patients were cannulated using LAVA ECMO between January 2018 and June 2022. At six months, four patients were still alive. Echocardiographic assessment of left ventricular decompression was difficult to interpret. There were no cases of heparin induced thrombocytopenia, hemolysis, or residual patent foramen ovale at decannulation. 3 patients died while on ECMO and the remainder survived to decannulation, transplant or LVAD implantation. In this case series of 15 patients on LAVA ECMO, while twelve patients survived to decannulation, transplant or LVAD implantation, only 4 were still alive at six months.

Conclusions: This is the first case series to present a majority of patients who underwent LAVA ECMO as their initial cannulation strategy. There were no cases of heparin induced thrombocytopenia, or hemolysis or residual patent foramen ovale after decannulation. While 80% of patients survived to decannulation, only 27% survived 6 months underscoring the prolonged period of high risk of mortality associated in these patients.

Keywords: ECMO, cardiogenic shock, myocardial recovery.

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I. INTRODUCTION

Veno-arterial extracorporeal membrane oxygenation (VA ECMO) is a method of temporary mechanical circulatory support that is increasingly being used in the setting of cardiogenic shock¹. The role of the ECMO circuit is to circulate blood in order to provide end organ perfusion all while decreasing myocardial work load². The ultimate goal is to achieve either myocardial recovery and weaning from circulatory support or, if that is not possible, transition to transplant or durable mechanical circulatory support (such as with an intracorporeal left ventricular assist device). In order to allow myocardial recovery, myocardial work load must be decreased and that occurs by maintaining the left ventricle decompressed³. When centrally cannulated placement of a left ventricular vent is not so arduous (typically via the right superior pulmonary vein), but in a peripheral cannulation strategy it is more complicated to “unload” the left ventricle. While unloading the left ventricle might be complicated, it is necessary. A growing body of literature suggests that early left ventricular venting may improve outcomes on ECMO.⁴⁻⁶ There are several ways to achieve left ventricular decompression while on peripheral VA ECMO. These include the placement of an extra cardiac devices such as an intra-aortic balloon pump⁵, as well as the placement of intracardiac devices such as an impella⁷. Vents can also be placed either directly across the aortic valve with a trans aortic valve pigtail percutaneously⁸ or through a minimally invasive transthoracic approach such as video-assisted thoracoscopic surgical placement of a pigtail in the pulmonary vein⁹ leading into the left atrium or a direct approach to the LV apex¹⁰. Even an interatrial septostomy can be performed to allow for decompression of the left side of the heart¹¹. Finally, the venous drainage cannula to the ECMO circuit can serve as an LV vent as well if it is placed across the interatrial septum to act as a drainage

cannula of both the left atrium and the right atrium¹². Currently no studies exist to show benefit of one venting strategy over another.

The purpose of this study is to describe a single institution case series of fifteen consecutive patients who were placed on LAVA ECMO. We describe both echocardiographic outcomes such as change in ventricular size, as well as clinical outcomes such as discharge disposition and ultimate cardiac outcome. The primary outcome of interest is six month survival. As a non-comparison study this study will not provide information regarding the superiority of this venting strategy over other strategies, but rather will be an important addition to the physiologic changes and potential clinical outcomes of using LAVA ECMO.

II. METHODS

a) Description of the procedure

An 8Fr sheath is placed in the common femoral vein using ultrasound guidance. Heparin is given for a goal activated clotting time of approximately 250 seconds. A Baylis trans-septal sheath is placed in to the right atrium. A Baylis needle is inserted through a LAMP sheath and then used to puncture the interatrial septum about 1cm superior to the fossa ovalis and the sheath is advanced over the needle. The location of the puncture is identified using fluoroscopy and trans-esophageal echocardiography. Left atrial pressures are measured. The Baylis sheath is exchanged over an Amplatz guide wire and the ECMO cannula is placed. The cannula itself is a multistage cannula the possible sizes include 21-25Fr with a length of 65cm.

b) Patient Population

This is a case series of all patients who underwent ventricular decompression with placement of a trans-atrial septal venous drainage cannula while on peripheral VA ECMO between January 2018 and June 2022. All consecutive patients were included. Patients were included both if they were initially cannulated using the LAVA ECMO technique and if they were cannulated peripherally with no left atrial cannula and subsequently were converted to LAVA ECMO. The Institutional Review Board of our institution reviewed this study and granted an exemption from informed consent due to the de-identified nature of the research. The IRB number is 21-0054.

c) Statistical Analysis

The primary outcome measure was six month survival. Additional outcome measures included echocardiographic data such as degree of mitral regurgitation, right ventricular dysfunction, and left ventricular end diastolic diameter, hemolysis laboratory data, and clinical outcomes such as length of stay, and ultimate cardiac outcome (transplantation, decannulation, etc.). In addition, cost information is

provided regarding LAVA ECMO. Left ventricular end diastolic diameter was measured by transthoracic echocardiogram (TTE) pre ECMO and by transeopshageal echocardiogram (TEE) post ECMO. The posterior to anterior dimension was used in TEE to measure LVEDD to more accurately correlate to TTE LVEDD. Descriptive statistical analysis was performed using Excel.

III. RESULTS

Fifteen patients were cannulated for VA ECMO at our institution between January 2018 and June 2022. Baseline demographics of the study population are detailed in Table 1. The majority of patients were cannulated with an initial cannulation strategy of LAVA ECMO. Three patients were converted to LAVA ECMO after initial ECMO cannulation. Two patients were transferred from another institution and were converted to LAVA ECMO in the days following transfer. One patient was peripherally cannulated at the time of cardiac arrest and was subsequently converted to LAVA ECMO. The majority of patients had few significant comorbidities such as vascular disease, chronic obstructive pulmonary disease, and diabetes. Two patients presented with frozen mechanical bioprosthetic valves in the setting of not taking coumadin. Four patients (27%) were alive six months post decannulation.

The echocardiographic data obtained from the study patients pre and post cannulation for LAVA ECMO is listed in Table 2. A total of six patients (40%) were missing data that resulted in the inability to calculate a change in left ventricular end diastolic diameter. Of the patients who had echocardiographic assessment of LVEDD (8 total), the majority of patients did not have a change in LVEDD that was greater than 1.0cm (N=6, 75%). Only two patients had a decrease in ventricular diameter that was greater than 1.0cm (25%). The degree of mitral regurgitation significantly improved in 9 out of 12 patients (75%) and stayed the same in the remaining three patients. Regarding laboratory data, there were no cases of heparin induced thrombocytopenia or of hemolysis leading to circuit change. Trends in total bilirubin and platelet count are graphically represented in Figures 1 and 2. The median change in platelets went from 140,000 to 70,000 by the fifth day of ECMO. The median change in total bilirubin was 1.3 to 2.4 mg/dL. On average patients received 1.7 units of packed red blood cells in the first five days on ECMO. Half of the patients (N=8, 53%) did not require any blood transfusion the first five days on ECMO.

Clinical outcomes of the case series are detailed in Table 3. The most common complication was vascular complications (deep vein thrombosis or limb ischemia). Three patients (20%) died on ECMO and the remainder survived to decannulation, left ventricular

assist device placement, or heart transplant. A total of six patients (three additional patients) died prior to discharge. For those who did not undergo transplant or LVAD there was no residual patent foramen ovale seen on subsequent echocardiographic assessment. For patients who underwent LVAD placement, the patent foramen ovale was closed at the time of LVAD implant.

The cost of LAVA ECMO initiation at our institution is \$4,446 which is the cost of the supplies used to perform the atrial septostomy in the catheterization laboratory. This does not include the cost of the ECMO pump or ECMO personnel or cost of the catheterization laboratory operation costs.

IV. DISCUSSION

This single institution case series of fifteen patients who were on LAVA ECMO presents valuable clinical information to the mechanical circulatory support community. First, it consists of a case series of a patients who presented in cardiogenic shock of several etiologies and suggests that this cannulation strategy can be used as the go-to cannulation strategy for peripheral VA-ECMO. Indeed, it was the initial cannulation strategy for 12 out of the 15 patients. Second, it provides the first trend in data on platelet count and bilirubin in patients on LAVA ECMO. Importantly, these trends show downward trend in platelets and upward trend in bilirubin, but these changes are not dramatic and do not compromise end organ function or circuit integrity. This would be interesting to compare to patients with an Impella device as their venting strategy. Third, it provides short and medium term clinical outcomes of LAVA ECMO patients in granular detail not previously published. While the majority of patients survived the course on ECMO, only 60% survived until discharge and only 27% were alive at six months. The continued high mortality after decannulation points to an important opportunity for outcomes improvement.

Other authors have reported case series in LAVA ECMO. The largest case series to date by far is by the Kim et al group from the University of Ulsan in Korea¹³, who compared their outcomes in 62 patients who underwent LAVA ECMO with 62 patients at their institution who were on ECMO with no venting strategy. They describe 60% of their patients were weaned from ECMO and 30% survived to heart transplantation. These patients were cannulated peripherally initially and percutaneous drainage was initiated if pulmonary edema was noted on chest x-ray. While our study is not a comparison study like theirs between LV venting and no LV venting, we do report similar short-term results. Our results also provide additional data on patients who were cannulated with LAVA ECMO as the *initial* cannulations strategy as well as information regarding hemolysis (which is important when comparing to other

venting strategies such as Impella) and medium-term outcomes (six month survival). This adds to a recently published case series from the University of Kentucky describing 33 patients who were placed on LAVA ECMO¹⁴, the majority of which were cannulated using LAVA ECMO as their initial cannulation strategy.

Other smaller case series exist: Alkhouli et al describe a case series of four patients¹⁵ in whom atrial decompression was needed after initial ECMO cannulation; Na et al describe a case series of all ECMO patients, of which 15 patients were placed on LAVA ECMO after initially being cannulated for VA-ECMO; Dulnuan et al describe a case series of four patients who were placed on peripheral VA ECMO and had signs of pulmonary congestion who then underwent transseptal cannula placement that was “Y’d” into the drainage system, but who continued to have persistent pulmonary edema. They exchanged the smaller transseptal cannula for a single venous drainage cannula. They are the first group, to our knowledge, to use the term LAVA ECMO. In summary, while many case reports exist describing transseptal puncture for LAVA ECMO in the setting of pulmonary edema once already being cannulated for peripheral VA ECMO, our study is the first to describe a case series with the majority of patients who were placed on LAVA ECMO as the initial cannulation strategy and to include laboratory data regarding hemolysis.

Another common venting strategy is the use of Impella (a percutaneous device that traverses the aortic valve) and provides left ventricular decompression. Some meta-analyses exist attempting to compare venting strategies such as Impella (when combined with ECMO this is often called ECPELLA)¹⁶ and have found that ECPELLA is associated with reduced mortality when compared to non LV venting.¹⁶ However direct comparison between LV venting strategies is not possible without a controlled randomized trial which is not likely to occur. Animal models may provide some answers, at least regarding hemodynamic data and interesting work is being done by Meani et al¹⁷ and Stephens et al¹⁸ to show both the benefit of venting as well as which strategy “unloads” the ventricle optimally. One concern our group, and many others have, with ECPELLA is that the device may be associated with increased risk of hemolysis. A study by Nakamura et al shows that up to 48% of patients cannulated with an ECPELLA strategy develop signs of hemolysis. The Impella type was not included in Nakamura’s analysis, and the newest Impella iterations (Impella CP) purportedly cause less cell lysis. It would be interesting to see a direct comparison in hemolysis labs between a cohort of patients cannulated with ECPELLA and with LAVA ECMO.

An additional point of comparison between ECPELLA and LAVA ECMO is cost. Both require use of the catheterization laboratory for placement and both

require use of ECMO pumps and ECMO personnel. The biggest difference in cost exists between the instruments used for the transeptal puncture for LAVA ECMO and the Impella device. This cost difference is significant. At our institution the instruments for LAVA ECMO cost \$4,446 and the cost of an Impella device is \$28,830. This cost combined with increased risk of hemolysis may provide further evidence that LAVA ECMO can be the primary LV venting strategy in select patients.

While we attempt to answer the question of whether or not venting is beneficial, we will have to decide what outcome measure is the best to reflect adequate venting and whether that outcome measure has an impact on clinical outcome. One parameter we chose to evaluate was left ventricular end diastolic diameter because it can be calculated both on transthoracic echocardiography and transesophageal echocardiography. In this study the majority of the post-cannula placement echocardiograms were done transesophageally and this value was compared to a value obtained on a transthoracic echocardiogram. We did use the inferior to anterior dimensions, which is most consistent with transthoracic quantification to attempt to mitigate this difference. Nonetheless, using only two dimensions limits a truly accurate assessment of left ventricular size. Perhaps a better measurement would be LV-end diastolic and systolic area rather than diameter, however this is obtained on three dimensional views which are not routinely obtained on routine echocardiography. Furthermore, venting is not the only parameter contributing to LV dimension – other factors are at play such as afterload, valvular dysfunction, and volume status. Indeed, LVEDD may not be the best assessment of LV venting, but it is a commonly measured value pre and post cannulation and can provide an additional data point, albeit imperfect, to help assess impact of cannulation strategy on LV size.

In our study only two patients had a greater than 1.0cm decrease in their LVEDD. Importantly no patients had an increase of greater than 0.8cm. Does this suggest that only two patients needed venting? We think likely not. Unfortunately, we had significant missing variables for the primary outcome measure which limits its interpretation. Furthermore, most commonly the first echocardiographic assessment of the patient on ECMO was performed at the time of decannulation, LVAD, or transplantation, that is to say at a point that the heart has either recovered or been stabilized with LAVA ECMO. We have missed a more dramatic change in LVEDD that would have been better evaluated with bedside TTE on the first or second day after cannulation.

The limitations of this study are those of a retrospective single-institution case series. The sample size is limited which may impact both internal and external validity. A small sample size does make generalizability of results difficult. As discussed, LVEDD

is a problematic surrogate of LV size and myocardial rest, although better surrogates are difficult to measure. Furthermore, we had several missing variables with echocardiographic data limiting interpretation of results. This patient sample was not controlled and so selection bias is inherent to this study. We included all patients who underwent LAVA ECMO, but other patients (post-cardiotomy, central cannulation, transfers) were on ECMO and LAVA ECMO was not used. Despite these limitations, this is the first case series of patients who underwent LAVA ECMO, with the majority having LAVA ECMO as their first cannulation strategy and this study provides new echocardiographic and laboratory data not previously published.

In summary we present a case series of fifteen patients cannulated for peripheral VA ECMO using a left atrial venous drainage cannula (LAVA ECMO). There were no instances of hemolysis or heparin induced thrombocytopenia and no requirements for circuit change. Ultimately twelve patients were decannulated, transplanted or underwent LVAD implantation from LAVA ECMO, but only four patients were still alive six months after decannulation. The low six-month survival warrants further investigation and underlines an important opportunity for clinicians to improve outcomes.

Conflicts of interest: none declared

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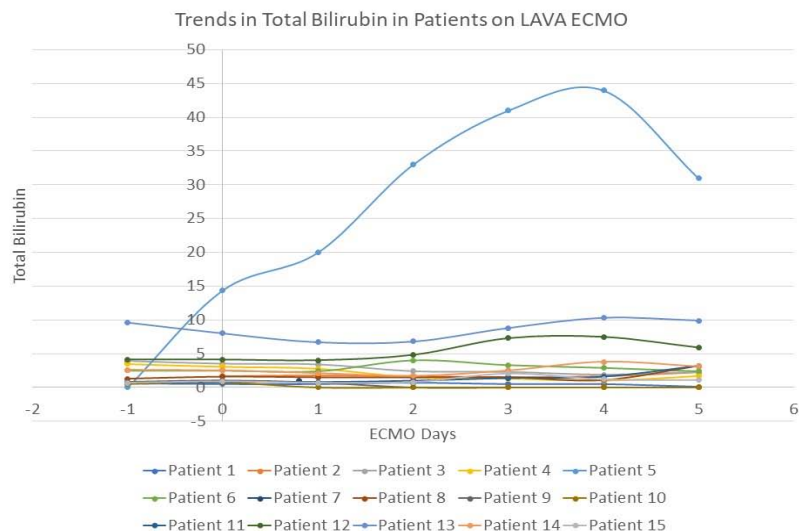


Figure 1: Trends in Total Bilirubin in Patients on LAVA ECMO

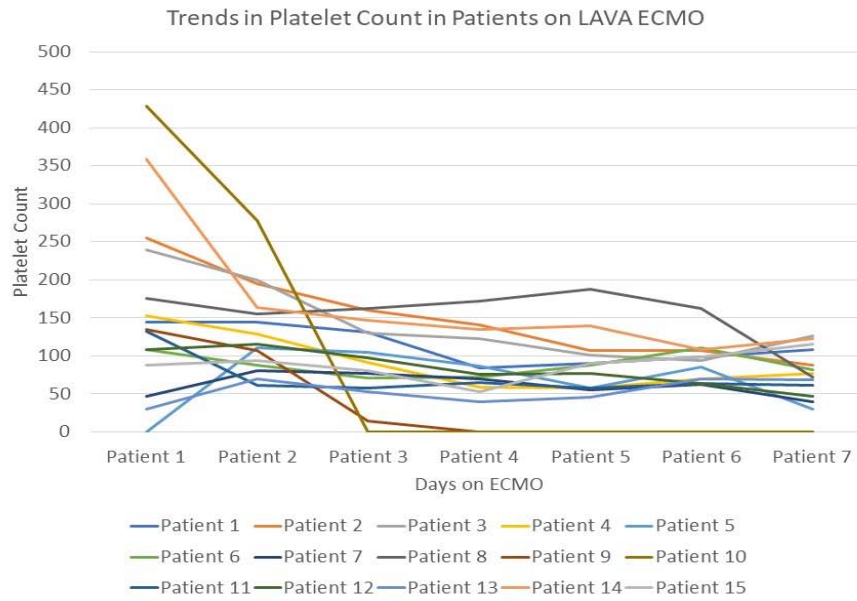


Figure 2: Trends in Platelet Count in Patients on LAVA ECMO

Table 1: Demographic Data

Table 1. Demographic data		
	Median/N	IQR/%
Age (years)	49	25
Female	6	40%
Renal Disease	3	20%
COPD	1	7%
Vascular disease	1	7%
Diabetes Mellitus	5	33%
Infection	2	14%
Independent	14	93%
Ischemic cardiomyopathy	4	26%
Initial cannulation strategy	12	80%
Timing HF < 1 week	4	26%
Timing HF > 2 years	7	46%
Home inotrope	1	7%
AICD	8	53%
Abbreviations: AICD: automatic implantable cardioverter-defibrillator; HF: heart failure		

Table 2: Echocardiographic data

Table 2. Echocardiographic Data								
	PRE				POST			
	LVEDD	LVESD	MR	RV dysfunction	LVEDD	LVESD	MR	RV dysfunction
Patient 1	4.5	3.9	mild	mild	NA	NA	none	Mild
Patient 2	5.5	5.2	none	moderate	5.9	5.6	none	severe
Patient 3	6.5	5.7	severe	none	6.9	6.5	mild	moderate
Patient 4	10.4	9.4	severe	moderate	8	7.6	trace	severe
Patient 5	NA	NA	severe	severe	NA	NA	NA	NA
Patient 6	8.5	7.9	severe	moderate	7.9	7.9	mild	moderate
Patient 7	NA	NA	NA	severe	NA	NA	NA	NA
Patient 8	6.2	4.5	severe	moderate	NA	NA	moderate	mild
Patient 9	7.4	6.7	mild	mild	NA	NA	NA	NA
Patient 10	7.3	6	mild	none	NA	NA	NA	NA
Patient 11	3.8	2.6	none	mild	4.6	3.7	none	mild
Patient 12	6.6	6.1	moderate	moderate	5.4	3.7	mild	mild
Patient 13	6.5	6.1	moderate	moderate	NA	NA	mild	severe
Patient 14	6.4	6	moderate	severe	6.9	6.5	mild	mild
Patient 15	6.7	6.1	trace	mild	6.5	6.5	trace	mild
Total	6.5	6			6.7	6.5		

Abbreviations: LVEDD: left ventricular end diastolic dimension; LVESD: left ventricular end systolic dimension; MR: mitral regurgitation; RV: right ventricle; NA not available

Table 3: Outcomes of LAVA ECMO patients

Outcomes	n	%
Death	6	40%
Length of ECMO	9	6
Length of stay	56	38
Adverse events		
Neurologic	3	20%
Renal failure	5	33%
Respiratory failure	6	40%
Vascular complication	8	53%
Cardiac outcome		
Decannulation	5	33%
Transplantation	3	13%
LVAD	4	33%
Death on ECMO	3	20%
Discharge disposition		
Died in hospital	6	40%
Rehab	4	27%
Transfer	2	13%
Home	2	13%
ASD	0	0%
Alive at 6 months	4	27%

