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Chapter

Left Ventricular Unloading in v-a ECLS Patients

Gaik Nersesian, Daniel Lewin, Pia Lanmüller, Sascha Ott and Evgenij Potapov

Abstract

The v-a ECLS is an effective approach for mechanical circulatory support, however, it is associated with several disadvantages. An increased afterload generated by a pump outflow leads to a left ventricular (LV) distension, pulmonary congestion, and lung edema on one hand and impairs myocardial perfusion on the other. In this chapter, we will discuss the rationality as well as different techniques for LV unloading during v-a ECLS support.

Keywords: ECLS, LV unloading, ECMELLA, Impella, IABP, venting

1. Introduction

V-a ECLS represents an effective rescue therapy in patients suffering circulatory failure. The mechanical circulatory support (MCS) with a v-a ECLS can be rapidly established, achieving a blood flow of up to 9.9 L/min and simultaneous blood oxygenation and decarboxylation [1]. Uncomplicated placement, reasonable costs, and the possibility to implant a v-a ECLS during an ongoing cardiopulmonary resuscitation (eCPR) have made it a widely used mobile tool for first-line MCS [2].

Despite these alluring benefits v-a ECLS is an invasive approach and has its side effects, which have to be taken into consideration [2]. One of the significant disadvantages of the system is an increased afterload of the LV generated by the pump outflow [3]. In patients with severely impaired cardiac function, this can cause LV distention and ballooning, increasing the myocardial oxygen consumption, and impairing the coronary perfusion at the same time [2]. In addition, increased left heart end-diastolic pressure leads to pulmonary congestion and edema, with the consequence of respiratory failure [3]. All these factors limit the potential benefits of the v-a ECLS and complicate circulatory weaning [3]. Temporary MCS with v-a ECLS can impair ventricular recovery regardless of the severity of myocardial damage [4].

In order to prevent an LV distention on v-a ECLS, several approaches can be established: LV unloading via passive LV venting, creation of an ASD, or with a microaxial catheter-based Impella pump. Alternatively, LV afterload can be decreased by using a combination of ECLS with an intra-aortic balloon counterpulsation (IABP).

2. Passive venting

LV venting can be achieved through the placement of an additional inflow cannula draining the left atrium or LV into the venous side of the ECLS. In the case of post-cardiotomy patients, the venting cannula is usually placed in the left ventricle via the right superior pulmonary vein and then connected by a Y-tubing to the venous drainage line of the ECLS circuit [5]. Alternatively, the venting cannula may be directly placed into LV via the left ventricular apex, with a subsequent subxiphoid tunneling and externalization [5]. Another possibility is the direct placement of the cannula into the pulmonary artery [3].

In rare cases, an iatrogenic atrial septal defect (ASD) can be created in order to achieve passive drainage of the left atrium (LA) via a venous cannula placed in the right atrium [6]. This approach can be performed both surgically or by a percutaneous blade and balloon atrioseptostomy and is considered more as rescue therapy rather than a standard approach [6].

3. Percutaneous venting

Alternatively, in patients with a closed chest on peripheral v-a ECLS left ventricular apical cannulation can be performed through a left anterolateral thoracotomy. This approach requires high surgical expertise due to potential LV damage, coronary injury, and a high risk of bleeding [5].

Furthermore, percutaneous approaches for LV unloading are available [5]. The TandemHeart system (LivaNova PLC, London, UK) uses a single-stage cannula, which can be placed percutaneously in the LA through an atrial septal puncture providing LV unloading on mechanical circulatory support [7].

The specially designed Bio-Medicus NextGen two-stage cannula (Medtronic PLC., Dublin, Ireland) can be applied in order to obtain both left-sided venting and venous drainage simultaneously. For this approach, the cannula is placed via a femoral vein with its tip advanced into the LA; the venous drainage is achieved by a second inflow positioned in the inferior vena cava [7]. The cannulation in both cases is performed in a catheterization lab or hybrid operation room under fluoroscopic and/or echocardiographic guidance. The major drawback of this method is ASD remains after decannulation. In the vast majority of cases, the iatrogenic ASD has no hemodynamic influence, however, can become relevant in patients undergoing a LVAD implantation [7].

4. LV unloading during v-a ECLS employing IABP

A combination of v-a ECLS with an intra-aortic balloon pump (IABP) can be applied for LV unloading. The use of IABP can decrease LV afterload during systole, increase diastolic blood pressure and coronary blood flow, and significantly improve survival in ECLS patients [5, 8]. However, since the publication of the IABP-SHOCK II Trial, where no survival benefit for IABP application in cardiogenic shock patients could be demonstrated, the use of IABP is decreasing [9]. The effect of the IABP on LV unloading depends on a degree of LV contractility—the less contractility, the less unloading [3]. Therefore, in patients for whom LV requires maximal unloading, the IABP does not work [9]. Nevertheless, IABP remains a feasible option for patients with mechanical aortic valves, since Impella unloading is technically not possible, and

passive LV unloading may preclude LV ejection and, therefore, carry a high risk for mechanical aortic valve thrombosis [10]. Further, in patients with mobile LV thrombus precluding Impella unloading, IABP remains a feasible alternative [10, 11].

5. ECMELLA approach

Implantation of microaxial catheter-based devices, such as Impella (Abiomed Inc., Danvers, MA, and USA), provides temporary MCS with simultaneous LV

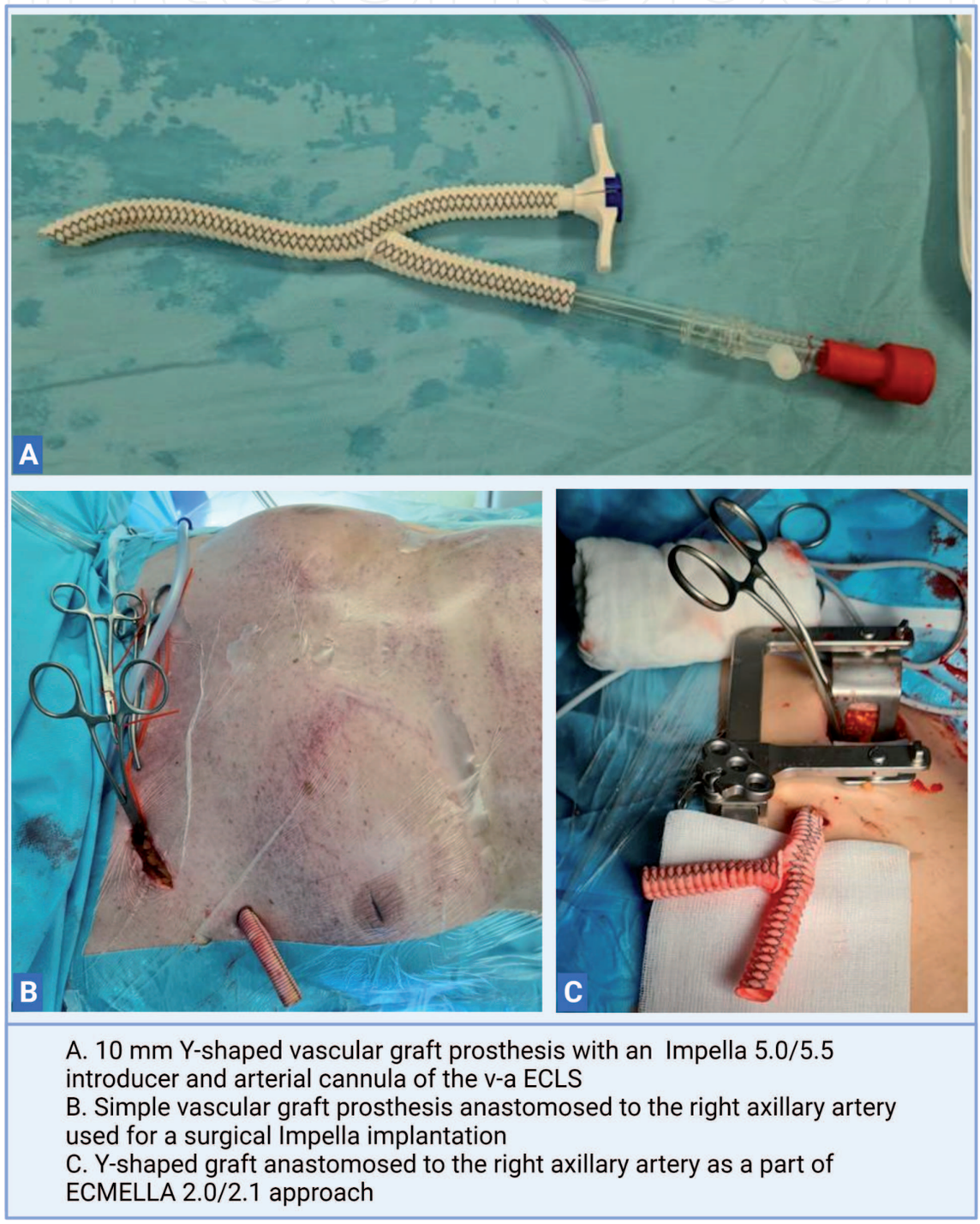

Figure 1.
Single arterial access ECMELLA cannulation.

unloading [12]. The combination of Impella and v-a ECLS, so-called ECMELLA approach provides advanced cardiopulmonary support in cardiogenic shock patients and has been demonstrated to significantly improve the outcomes compared to ECLS use alone [4, 11, 12]. Impella devices (Impella 2.5, CP, 5.0, and 5.5) are directly placed in the LV via the aortic valve, providing an anterograde blood flow and unloading in contrast to an ECLS [1, 2, 12]. Thereby, Impella within the ECMELLA approach enhances the support concept to a cardiocirculatory, rather than just a circulatory support system [13].

The Impella 2.5 and CP devices are placed percutaneously and support the hemodynamic with 2.5 up to 4.3 L/min. The surgically implanted Impella 5.0 and 5.5 models are able to generate full circulatory support with up to 5.5 L/min of blood flow. In the case of ECMELLA approach, an Impella flow of 1–2 L/min is usually enough for a sufficient LV unloading [10]. However, the application of more powerful Impella models can be beneficial, since it allows a de-escalation therapy meaning gradual ECLS weaning and explantation during increased Impella support and patients' mobilization [14].

Nevertheless, ECMELLA is associated with some vascular complications [4]. The necessity of additional arterial access increases the risk of access site bleeding, hematoma, dissections, and infections [4]. The ECMELLA 2.0 technique aims to reduce that issues, by utilization of a single arterial access technique. In this case, a Y-shaped vascular prosthesis is anastomosed to the patient's subclavian artery. One branch of the graft is used for Impella insertion, while the arterial cannula of ECLS is placed via the second side branch (**Figure 1**) [13, 15]. This method allows advanced cardiopulmonary support with flow rates above 10 L/min, providing biventricular unloading at the same time [13]. Another major advantage of this technique is the possibility for bedside de-escalation and ECLS explanation, which can be performed in local anesthesia and does not require surgical re-opening of the wound [10, 16].

Further improvement of the single-site ECMELLA approach is the ECMELLA 2.1 technique, with the percutaneous cannulation of the jugular vein for blood drainage. This approach allows patients' mobilization on ongoing support for an extended period of time (**Table 1**) [17].

Parameter	Passive vent	Percutaneous vent	ECLS + IABP	ECMELLA
Access	Sternotomy/ thoracotomy	Percutaneous	Percutaneous	Percutaneous/ surgical cut-down
Additional hemodynamic support	N/A	N/A	N/A	2.5–5.5 L/min
Size	12–18 Fr	15–21 Fr*	7.5 Fr	12–24 Fr
Costs	*	**	**	***
Mobilization	No	No	Possible (axillary cannulation)	Yes for ECMELLA 2.0/2.1
Explantation	Surgical	Surgical/ Percutaneous	Percutaneous	Surgical/ Percutaneous

**For Bio-Medicus NextGen cannulas.*

Table 1.
Comparison of different LV unloading strategies.

6. Discussion

6.1 Timing of unloading

Various studies have demonstrated the advantages of LV unloading in ECLS patients. However, the timing and patient selection still represent a point of high debate among advanced heart failure specialists [4, 10]. The propensity score matched the multicenter study from Schrage et al., which demonstrated that LV unloading (with Impella) initiated before or shortly after the v-a ECMO implantation significantly improves survival compared to v-a ECLS alone [4]. However, a subgroup analysis of those patients who underwent delayed unloading (>2 h since ECLS), revealed no significant survival benefits [4]. Still, there is a point of discussion if the LV unloading has to be performed simultaneously in ECLS or if a delayed approach is more optimal in a clinical setting. The propensity score matched the study from Grandin et al., which demonstrated that patients who undergo an upright LV unloading have no differences in regard to on-support or in-hospital mortality but a lower incidence of renal injury compared to the delayed unloading cohort [11]. Moreover, initiation of a LV unloading after a period of v-a ECLS exposure might be associated with increased procedural risk and technical difficulties with the placement of an additional device [4, 11].

6.2 System choice

Another important point of the LV unloading strategy is the choice of the system. Several important aspects should be taken into consideration during the decision-making process:

- Approximate duration of MCS, potential weaning
- Vascular access possibilities
- Complication profile
- Availability of each system and costs

The current evidence-based data have demonstrated that the LV unloading in v-a ECLS patients improve the patients' outcomes [1, 4, 11, 12, 18]. However, no general recommendation or guideline on the technique of LV unloading exists [3]. The decision-making is often based on the expertise of the performing surgeon or interventional cardiologist and the internal standardized operational protocols of each clinic [3].

Although the LV unloading via an additional inflow cannula placed through the apex of the right superior pulmonary vein represents the most cost-effective and simplified approach, it is predominantly reserved for patients with central ECLS [3]. Since it requires a sternotomy or thoracotomy, it might be associated with an increased risk for collateral surgical damage [3]. Another major disadvantage is the necessity for surgical removal of the cannula for weaning. In this constellation, the utilization of specialized percutaneous venting cannulas represents a preferable and flexible solution and has been increasingly applied in recent years [7].

Currently, the vast majority of patients receive LV unloading with either IABP or Impella devices [11]. Both approaches provide similar survival benefits, however, have different complications and hemodynamic profiles [11]. The implantation site bleeding and vascular injury remain the major disadvantage for LV unloading since the addition of extra arterial access increases the risk for complications [4, 11]. However, in the case of an IABP it is significantly lower due to the size of the used catheter (7.5 Fr compared to 14 Fr in Impella CP in devices) [3]. Finally, yet importantly, the ECMELLA therapy is associated with significantly higher costs compared to LV unloading with a venting cannula or an IABP [3].

Despite its invasiveness, the ECMELLA approach has some unique advantages which have to be taken into consideration during the decision-making process [13]. The ECMELLA provides the highest level of temporary cardiopulmonary support currently available in surgical armaments [15, 19]. In patients suffering from systemic inflammation response syndrome and consecutive vasoplegia as a sequel of, or coincidently with, severe cardiogenic shock or after CPR, optimal flow rates of up to 11 L/min or even more might be necessary [15, 20, 21]. ECMELLA allows a controlled stepwise support reduction and de-escalation strategy: v-a ECLS explantation with further Impella support, which achieves a reduction of ECLS-related complications in patients requiring prolonged support [1]. The recently developed single arterial access ECMELLA 2.1 includes advantages of high flow support, patients' mobilization, and bedside explantation, with no need for a renewed exploration of the implantation site [13, 15, 17].

6.3 Perspectives

Currently, two randomized controlled trials investigating the impact of LV unloading in v-a ECLS patients have been launched: the REVERSE (NCT03431467) trial from the University of Pennsylvania and ANCHOR (NCT04184635) trial guided by the Hôpital Pitié Salpétrière from Paris. The REVERSE trial aims to investigate the impact of Impella CP as a vent in v-a ECLS patients, while the unloading has to be initiated within 10 h after implantation of the v-a ECLS. Planning to recruit 96 patients, the first results are expected in 2025. The ANCHOR trial compares 200 patients with acute myocardial infarction-related CS (AMICS) treated with v-a ECLS + IABP vs. a control group without tMCS. The finishing is scheduled for the end of 2024. However, no prospective study investigating different LV unloading strategies is currently available.

The self-expandable catheter-based microaxial pumps represent a promising improvement in MCS [22]. This technology allows percutaneous insertion of narrow-profiled devices, which expand during support aiming to reduce the risk for vascular complications and hemolysis by minimizing the shear stress on blood cells [22]. The HeartMate Percutaneous Heart Pump (PHP, Abbott Vascular, Santa Clara, CA, and US) was the first pump that was deployed via a 14 Fr femoral arterial sheath and delivered a self-expanding 24 Fr nitinol cannula and impeller across the aortic valve [22]. However, due to a high incidence of device malfunctions, the HartMate PHP was not implemented in clinical practice [22]. The recently presented Impella ECP (Abiomed Inc., Danvers, MA, and US) device has a 9 Fr catheter and an up to 18 Fr size expandable body. Currently, the ECP trial (NCT05334784) investigating the effect of the device on patients with high-risk coronary interventions is scheduled. Both devices were originally designed for periprocedural support during high-risk interventions (max. 6–12 h); however, self-expandable Impeller pumps can be potentially used for prolonged support in cardiogenic shock patients in future (**Table 2**) [22].

Study, first author	Year	Investigated cohorts	Outcomes
Retrospective studies			
Gass et al. [8]	2014	135 v-a ECLS + IABP	Overall, in-hospital survival of 57.8%, high incidence of access site bleeding.
Pappalardo et al. [12]	2017	42 v-a ECLS vs. 21 ECMELLA*	Significantly better survival for ECMELLA, no difference in bleeding complications.
Schrage et al. [4]	2020	255 v-a ECLS vs. 255 ECMELLA*	Significantly better survival for ECMELLA, more access-related bleeding, hemolysis, and need for renal replacement therapy in ECMELLA group.
Tongers et al. [19]	2020	69 ECMELLA	Early MCS escalation (ECMELLA) rapidly stabilized patients, reducing number and doses of catecholamines, and improves hemodynamics.
Grandin et al. [11]	2022	3399 ECLS patients with LV unloading vs. 9335 without	Significantly decreased in-hospital mortality for LV unloading group at the expense of more complications, including hemolysis and cannulation site bleeding.
Prospective randomized trials			
REVERSE Trial	2018–2025	96 v-a ECLS with Impella CP as vent	Patients randomized to the experimental arm will have an Impella CP implanted in addition to v-a ECLS <10 h since the institution of v-a ECLS
ANCHOR Trial	2019–2024	200 patients v-a ECLS with IABP vs. 200 without tMCS	Experimental arm v-a ECLS + IABP instituted percutaneously as soon as possible. Control arm: Standard management of CS due to myocardial infarction, according to the current ESC guidelines. It is not recommended to use IABP support and no other tMCS devices are allowed.

**Cohorts after propensity score matching.*

Table 2.
Important studies on LV unloading in v-a ECLS patients.

7. Conclusion

Active LV unloading in v-a ECLS patients improves survival, however, the costs of more vascular complications, bleeding, and hemolysis. Prospective randomized trials comparing different LV unloading approaches are required in order to optimize the treatment. Perspective devices and equipment might reduce the complications associated with LV unloading and ease clinical management.

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