CASE SERIES

Extracorporeal Membrane Oxygenation as a bridge: No middle ground. *Folium olivae o spinam coronam*. Case Series

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Extracorporeal life support (ECLS) is a broad term that includes extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass (CPB), and extracorporeal cardiopulmonary resuscitation (ECPR). ECMO is a life support device that performs gas-exchange and continuous-flow circulation, external to the body by providing cardio-respiratory support for patients with severe respiratory and/or cardiac failure. Evolution in technology has resulted in rapid increase in the utilization of ECMO as a bridge to recovery, long term support devices (LVAD), total artificial heart (TAH) and/or transplantation. Although there is limited evidence for the use of ECMO as a bridge to advance therapies, recent improvements in technology, personnel training and ambulatory practices on ECMO have resulted in improved outcomes in patients bridged to other advance strategies. We presented a case series of ECMO as a bridge to different strategies, including bridge to a durable left ventricular assist device (LVAD), heart transplant (HT), lung transplant (LT) and heart-lung transplant (HL/T).

Key words: **ECMO, bridge; LVAD; Cardiac transplant.**

Soporte de vida extracorpórea (ECSL) es un amplio término que incluye la oxigenación de membrana extracorpórea (ECMO), bypass cardiopulmonar y resucitación cardiopulmonar extracorpórea. ECMO es un dispositivo extracorpóreo de soporte vital, que efectua intercambio gaseoso y otorga flujo circulatorio continuo , para pacientes con falla severa cardiaca y/o respiratoria La evolucion tecnológica ha desencadenado un rápido incremento en la utilización de ECMO como puente a recuperación, a soportes circulatorios mecánicos de largo plazo, corazón artificial total y/o trasplante. A pesar de que hay limitada evidencia para el uso de ECMO como puente a terapias avanzadas, recientes avances en tecnología, personal especializado y protocolos de ambulación, han determinado mejores resultados en el proceso a estas estrategias especializadas. Presentamos una serie de casos de ECMO como puente a diferentes estrategias, incluyendo puente a un soporte mecánico de larga duración, trasplante cardiaco, trasplante de pulmón y trasplante de corazón-pulmon.

Palabras clave**: ECMO, puente; LVAD; Transplante cardiaco.**

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ECMO has revolutionized the treatment of severe cardiac and respiratory failure; the number of ECMO cases has increased steadily each year with the largest growth occurring in the adult population. The miniaturization and durability of ECMO systems, as well as advances in strategies cannulation, improve postoperative care, rehabilitation, ambulation, and anticoagulation protocols; they have made it more convenient and mobile than ever. However, ECMO-related morbidity and mortality remain high [1]. The role of ECMO in the adult patient population is evolving extremely fast. ECMO is always a temporary measurement, a bridge to another stage in the evolution of the patient, it could be recovery or a bridge to decision, and in some cases, lead the patient to be a candidate to LVAD, TAH or transplant. Each one of these scenarios deserve different analysis, considerations and approaches.

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CASE SERIES

ECMO as bridge to LVAD

A 24-year-old female transferred from another hospital in cardiogenic shock (CS), possible postpartum cardiomyopathy vs. acute myocarditis. No significant past medical history. COVID neg. Required veno-arterial (VA) ECMO for 6 days and then transitioned to Impella and transferred to our hospital. On admission, the patient was significantly hemolyzing and bleeding from prior VA ECMO site on right groin and from Impella femoral access requiring emergent Impella removal, vascular repair, bilateral groin debridement and bilateral rectus femoris local flaps. She required temporary renal replacement therapy (CRRT) with some renal recovery. She was discharged on Warfarine. A month later, she is readmitted on CS, given her previous groin surgeries, femoral vessels were not accessible. She underwent urgent central ECMO cannulation, and 48 hrs. later she was bridged to left ventricular assist device (LVAD) Heartware (HW) and a temporary right ventricular assist device (RVAD) from a percutaneous inflow cannulation in the right internal yugular vein and outflow with a tunnelized 8 mm dacron graft to the pulmonary artery. RVAD was explanted 3 weeks later. Post-operative course was complicated for gastrointestinal (GI) bleeding and 2 duodenal angioectasias were clipped with resolution of bleed. She was restarted on Warfarin with goal INR 2-3 without any issues. Patient remained profoundly weak, improving with aggressive rehabilitation, most recent echo with some LV recovery, LVEF 35-40%. She was hemodynamically stable on oral therapies and LVAD support. She was finally discharged with follow up in our output clinic.

ECMO as bridge to HT

A 53-year-old male with heart failure secondary to ischemic cardiomyopathy and mitral regurgitation underwent CABG and mitral valve repair 3 years prior to presentation with improvement in symptoms. He subsequently developed cardiac arrest requiring dual-chamber ICD placement. He did well for 6 months, until he presented with increased edema and decreased functional capacity. Echocardiography revealed an LVEF of 15%. Coronary angiography revealed patent bypass grafts without new focal lesions. Right heart catheterization revealed elevated filling pressures and a depressed cardiac index. He was started on intravenous inotropes and an intra-aortic balloon pump was placed; however, hemodynamic status continued to decline. The decision was made to increase level of support to VA ECMO as bridge to transplant (BTT). We decided to use a Bio-medicus NextGen multi-stage cannula for left atrial (LA)-VA ECMO in order to obtain left-sided venting and venous drainage simultaneously. Right common femoral arterial access was obtained, and a 6 French sheath was placed. Access to the superficial femoral artery (SFA) was then obtained and a 6 French x 24 cm braided sheath was inserted for antegrade perfusion. The patient was heparinized to achieve an ACT greater than 300 seconds. Next, an SL-1 sheath and BRK needle were used to perform transseptal puncture under real-time transesophageal echocardiographic guidance. The SL-1 sheath was removed, and a ProTrack™ wire (Baylis; Mississauga, ON, Canada) was advanced into the left atrium. Next, an atrial septostomy was performed using a 6 mm x 40 mm peripheral balloon. Next, the venous tract was serially dilated and a 23 French Bio-medicus NextGen cannula multistage venous cannula was inserted with 4 cm of its tip in the left atrium, leaving the first set of ports inside of the LA for LV venting and the second set of ports in the IVC for venous drainage (**Fig. 1**). Next, a 17 Fr arterial cannula was placed in the right common femoral artery, and the patient was initiated on LA-VA ECMO. The arterial return cannula was connected to the antegrade perfusion sheath to provide flow to the right lower extremity. The patient remained stable after the procedure without signs

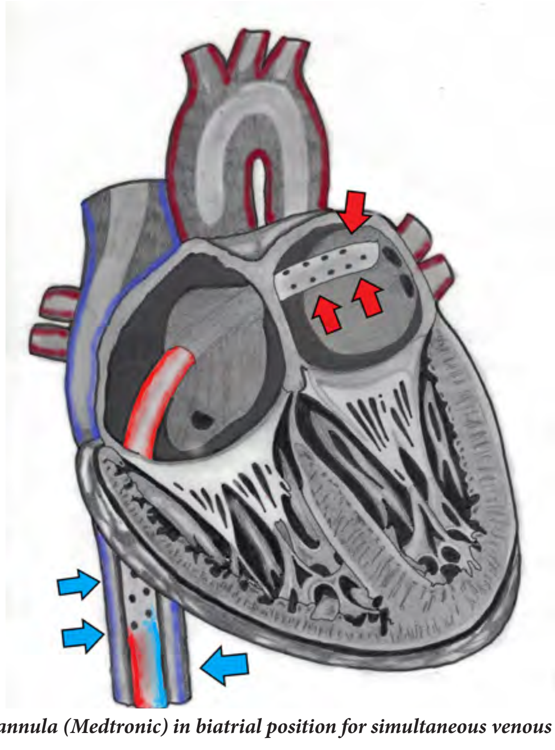

Figure 1. Biomedicus NextGen Cannula (Medtronic) in biatrial position for simultaneous venous drainage and left-side venting.

of left ventricular distension and no other complications. A suitable donor was available three days later, and he underwent successful HT.

ECMO as a bridge to LT

A 50-year-old female with past medical history of interstitial lung disease, chronic respiratory failure, anemia and polymyositis was admitted with increasing O2 requirements and lung transplant evaluation. She developed severe hypoxemia and hypercapnia with respiratory acidosis; she was intubated and placed on venous-venous (VV ECMO) via right internal jugular vein with a 32 Fr double lumen MC3 crescent cannula (**Fig. 2**), and epoprostenol as bridge to transplant. After ECMO placement, she was extubated in order to optimize her physical condition. Her rehabilitation was focused on nutrition and ambulation. A multidisciplinary team guided and monitored the patient during bed mobility, transfers and ambulation. Hospital course was complicated by epistaxis, atrial fibrillation, hypotension, leukocytosis and bacteremia. She remained on the waiting list for a long time, given her advanced restrictive disease and small lungs, with difficult suitable size mismatch donor. After almost 100 days on ECMO, she underwent to bilateral lung transplant, total ischemic time: 6 hrs. Twenty-four hours later, the sternum was closed, and ECMO was decannulated. ID consulted for antibiotic recommendation for donor lung positive for MSSA and P. agglomerans. She was extubated and subsequently reintubated several hours later for hypercapnic respiratory failure, and a tracheostomy was performed. The cannula was exchanged in operating room, and using intraoperative fluoroscopy and esophagogastroduodenoscopy scope, a Dobhoff feeding tube was placed into the fourth segment of the duodenum. The postoperative course was long and complicated, with development of pneumonia, dyspnea for severe deconditioning, muscle wasting, diaphragmatic weakening, frequent anxiety attacks and difficult pain control. She eventually recovered and was discharged almost 1 month after the LT.

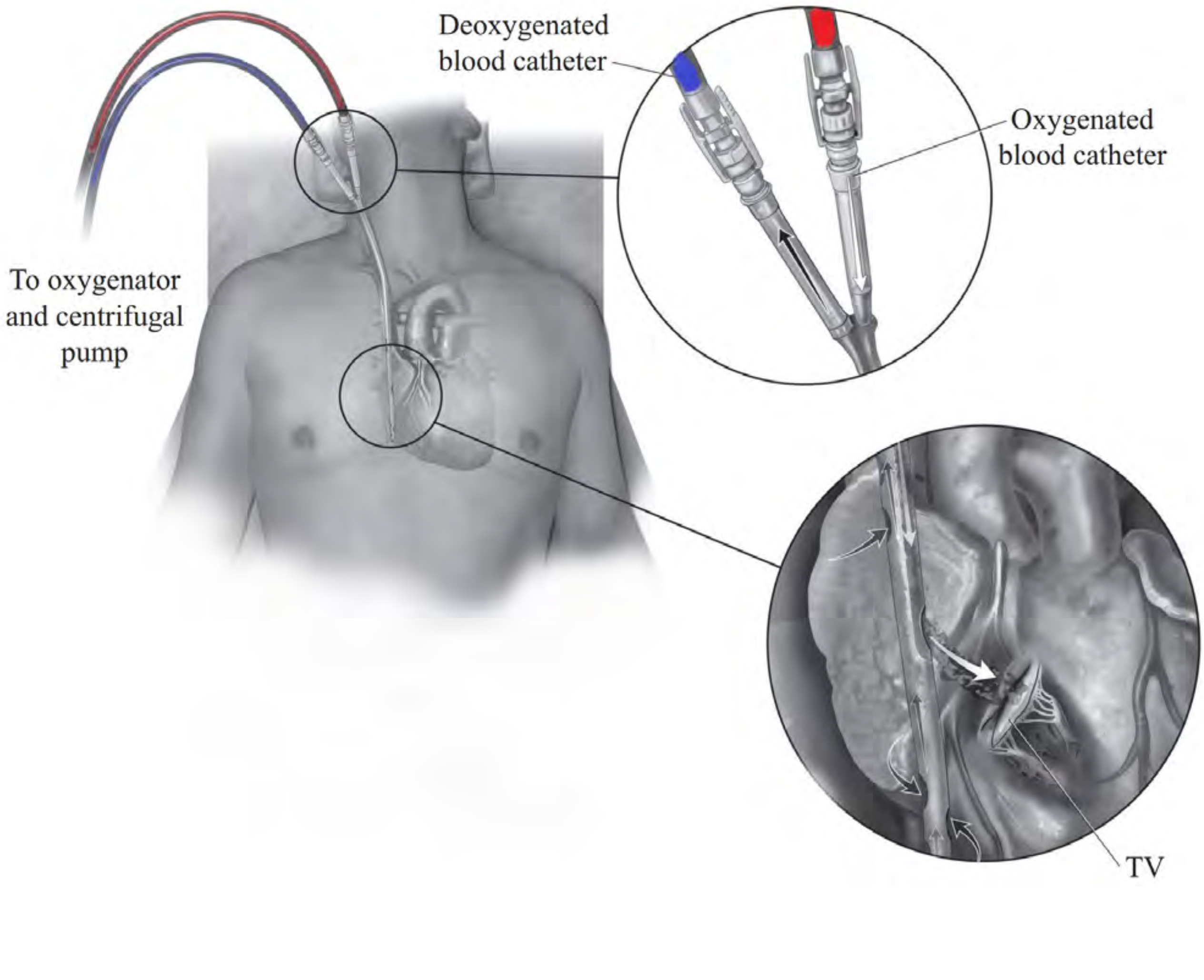

Figure 2. Dual-lumen cannulation (DLC) for veno-venous (VV) ECMO (Adapted from [26]).

ECMO as bridge to HLT

A 56-year-old male with pulmonary hypertension secondary A 56-year-old male with pulmonary hypertension secondary to hypoxia and vasculopathy from interstitial lung disease. He required supplemental oxygen therapy at home and was managed with an immunosuppressive regimen. He was admitted with congestive heart failure. Transthoracic echocardiogram (TTE) indicated a LVEF of 40% and reduced right ventricular function (RVF). Right and left heart catheterization noted an elevated pulmonary artery pressure of 68/31, pulmonary capillary wedge pressure (PCWP) of 23 and Fick cardiac index (CI) of 1.77. Left heart catheterization was unremarkable. Cardiac MRI was notable for LVEF of 25.2%, pulmonary hypertension (pulmonary artery dilated) with right ventricular ejection fraction of 24.2% and severe tricuspid regurgitation. While undergoing additional pre-operative workup, his clinical status deteriorated with worsening hemodynamics, hypotension, frequent premature ventricular contractions, episodes of ventricular tachycardia and atrial fibrillation. He was urgently taken to the operating room and successfully placed on peripheral femoral VA ECMO. He was extubated the same day, and his rehabilitation was focused on nutrition and ambulation. A multidisciplinary team composed of perfusion specialists, nurses and physical therapists (PT) guided and monitored the patient during bed mobility, transfers and ambulation. Physical exercise included assisted active bed and chair exercises, sitting, standing and walking. Hemodynamics, comfortable respiratory status and safety were the highest priorities. Five days later, he needed only minimal assist to transfer from bed to chair and started ambulating. Prior to transplant he was able to walk almost 700 ft. He did not develop any complications related to ambulation.

On ECMO day 11, a suitable donor became available (**Fig.3)**. He was taken to the operating room for heart-lung block transplant, ECMO decannulation and femoral vessel repair. The chest was left open secondary to coagulopathy and closed the next day. The peri-operative course included atrial fibrillation. Samples from the donor lungs were positive for Candida albicans, which was treated with itraconazole and inhaled amphotericin B. Blood cultures grew Klebsiella oxytoca. He was treated with meropenem, vancomycin, transitioned to ceftriaxone, and follow up blood cultures were without growth. He was discharged from the hospital on post-operative day twenty-one. He is stable on New York Heart Association functional class I status.

DISCUSSION

Extracorporeal life support (ECLS) is a broad term that includes extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass (CPB), and extracorporeal cardiopulmonary resuscitation (ECPR).

ECMO has revolutionized the treatment of severe cardiac and respiratory failure. Evolution of this technology arose in the 1970 [2]. ECMO has been rapidly expanding over

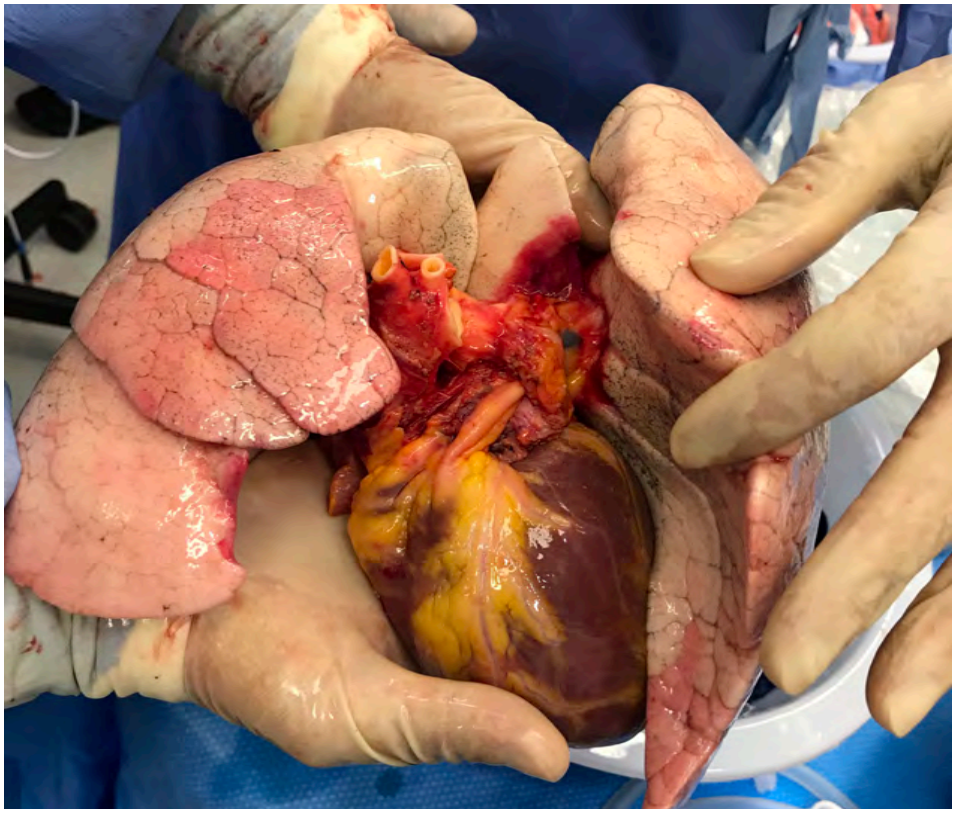

Figure 3. Heart-Lung Block

the last 10 years. The number of ECMO cases has increased steadily each year specially in the adult population. However, ECMO-related morbidity and mortality remain high [3]. As the same time that the ECMO cases are increasing, the role of ECMO in the adult patient population is extending and evolving.

Indications typically are classified by respiratory or cardiac failure. ECMO for bridge to another therapy is increasing, including the bridge to a durable left ventricular assist device (LVAD), heart transplant (HT), lung transplant (LT) or heart-lung transplant (HL/T).

ECMO as bridge to LVAD

ECMO is increasingly used as a bridge to decision in patients with refractory acute cardiogenic shock (CS). Although there is no strong current evidence to completely justify the use of ECMO as temporary mechanical support: does ECMO does alter the natural history of disease or simply optimize physiology and delay the time to death? ECMO –as it is currently used– is not therapeutic, it normalizes the physiologic consequences of underlying illness. Nonetheless, ECMO is the most common short mechanical circulatory support (MCS) in patients with CS and refractory acute respiratory failure. However, once on ECMO, subsequently, these patients might be bridged to durable MCS either as a bridge to candidacy/transplantation, or as destination therapy and sometimes, to recovery [4].

ECMO has become a realistic and cost-effective option to reverse shock [5]. In this way, time can be taken to assess and ameliorate secondary organ failures and to predict the chance of cardiac recovery ('bridge to recovery and decision') [6]. When recovery is not possible, a decision must be made to heart transplantation (HTX), LVAD or unfortunately, withdrawal support [7]. Due to limited suitable donor hearts and good long-term results of LVADs, the number of patients bridged to a LVAD is increasing, either as destination therapy or as a bridge to candidacy or transplantation [4]. However, the extent and optimal timing of bridging towards recovery or LVAD in patients with cardiogenic shock being supported with ECMO is currently unclear.

Between all the short-term MCS devices, ECMO shows the highest mortality in all studies. An IMACS registry analysis provides a useful, real world information about the results of short-term MCS as bridge to LVAD. ECMO showed the lowest associated longitudinal survival, highest rate of biventricular failure with increased intensive care unit LOS, as compared with IABP, other MCS and non-MCS [8]. For this reason, extreme caution is required when considering transition of CS patients on ECMO to LVAD. Potential explanations to this result are that the patients with pre-LVAD ECMO were found to be predominantly ischemic in etiology with a higher proportion of high-risk, pre-operative features, including cardiac arrest, chronic liver dysfunction and other abnormal hemometabolic indices. Given this lower survival with ECMO before LVAD, an extensive research is necessary to further understand these differences.

The mortality of patients supported with VA-ECMO for cardiac failure remains high with 40% to 50% of patients surviving to hospital discharge [3,9]. This survival was heterogeneous; however, this was probably primarily caused by the fact that the studies included different patient populations.

Patients receiving low-level support (IABP, Impella, Tandem-Heart) were less sick as compared to patients receiving ECMO. It is possible this explains the differences in outcomes. Timing and the possibility of durable LVAD implantation depends primarily on the underlying cardiac disease, the severity of other organ failure as well as in possible recovery. At this point in history, it is currently impossible to provide evidence-based recommendations on best timing to durable LVAD. Although, some authors suggest a possible timing or duration of ECMO towards LVAD, recovery or HT, depending of the cardiac disease [4] (**Table 1**).

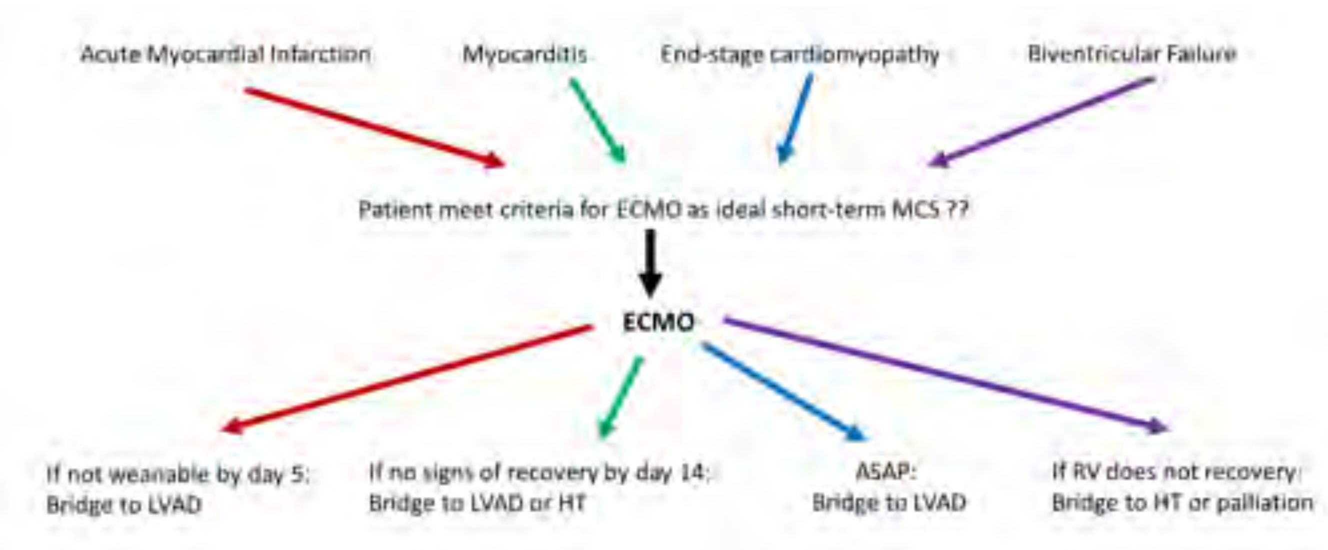

Table 1. ECMO and possible timing to advances therapies.

ECMO as a bridge to HT

Advanced heart failure (AHF) complicated by CS is a complex and time-sensitive disease and a worldwide challenge to all health care systems [8]. Short -term MCS is a common strategy in the treatment and approach of CS. MCS could be a therapeutic bridge strategy that can help transition eligible patients to a LVAD, total artificial heart, or heart transplantation [10,11]. Outcomes in VA ECMO used as a bridge to heart transplant is extremely infrequent in adults. Analysis of United Network of Organ Sharing identified 25,168 adult recipients between 2003 and 2016. Of these, 107 (0.4%) were bridged with ECMO and 6148 (24.4%) were bridged with a LVAD. Bridge to transplant with ECMO was associated with increased early/mid-term mortality. Post-transplant survival results are the following: 73.1% versus 93.1% at 90 days (P<.001) and 67.4% versus 82.4% at 3 years (P<.001) in ECMO and LVAD, respectively [12]. As we exposed before, there are many possible reasons to explain this outcomes: patients in the ECMO group were more likely to have severely disabled functional status, shorter waitlist time, and were more frequently mechanically ventilated than the patients in the continuous-flow left ventricular assist device group. However, the extent and optimal timing of bridging towards recovery, heart transplant or LVAD in patients with cardiogenic shock being supported with ECMO is currently unclear. Bridge to LVAD occurred more frequently in patients with end stage cardiomyopathy than in patients with acute myocardial infarction or myocarditis; heart transplant is more related with myocarditis and biventricular failure [4]. As with bridge to LVAD, the exact duration of the ECMO before the HT is unknown; there are some recommendations, but further and extensive research is necessary to clarify those criteria.

ECMO as a bridge to LT

ECMO has revolutionized the treatment of severe cardiac and respiratory failure. ECMO has been rapidly expanding over the last 10 years, particularly in lung transplantation [2]. Lung transplantation is the treatment of choice for end-stage lung disease (ESLD) in selected patients. ECMO use in LT has expanded to the following scenarios: pre-transplantation rescue for acute cardiopulmonary failure, facilitate ambulation for pre-transplantation rehabilitation, intraoperative cardiopulmonary support, rescue for post-operative infection or primary graft dysfunction, and bridge to re-transplantation [13]. Although there is limited evidence for the use of ECMO as BTT, this strategy has increased and with excellent results [14]. The introduction of the lung allocation score in 2005 changed organ allocation to a system based on medical urgency rather than time on the waiting list [15]. Before the revision, outcomes for ECMO as BTT were poor. Since the revision, patients on ECMO as BTT receive a higher urgency, greatly increasing the chances of identifying a suitable organ in a much shorter time frame. Hakim et al. showed an 87% success rate in survival to transplantation in patients placed on ECMO as BTT [16]. One-year and three-year survival in this cohort were 85% and 80% respectively, which is comparable to the nationally published lung transplantation survival data of 82% (1-year) and 69% (3-year) for bilateral lung recipients [17].

According with the ELSO database [1990-2016], 1,066 lung transplant recipients and/or patients on the transplant waitlist were supported with ECLS in the pre, peri or post-operative period with an overall ECLS survival to hospital discharge of 65% [18]. However, the overall utilization of ECLS as a bridge to lung transplant remains minuscule as compared to the total rates of lung transplantation. More recent studies analyzing the UNOS database have showed that outcomes in ECMO patients post-lung transplant may be like non-ECMO patients, especially in centers with higher transplant volumes and experience [13,19].

Increased pre-transplant frailty is a risk factor for worse post LT outcomes [20]. Critically ill patients on prolonged mechanical ventilation and/ or ECMO support are prone to developing significant neuro-muscular weakness [21]. Several studies have demonstrated that physical rehabilitation in patients on ECMO support is safe and can potentially improve post-transplant recovery and outcomes [22-24]. Usually we consider ECMO as a bridge to LT in patients already listed, the most important considerations in order to proceed to this strategy are: whether acute worsening of previous ESLD is a new problem? Whether all other options for support have been evaluated? Assess physical rehabilitation potential, contraindications to anticoagulation? Nutritional status? Is there multi-organ failure? Any new multi-drug resistant infection? High panel reactive antibodies? [13].

Ambulation can be safely achieved in patients cannulated via a double lumen cannula (Avalon, Crescent) in a VV configuration or subclavian/central VA configuration [25,26]. The use of ambulatory ECMO is based in 2 facts: patients who are ambulatory and socially interactive provide the most effective vehicle for clinical recovery or subsequent bridge to transplant, and we avoid the injury from paralysis, sedation, intubation , including pneumonia, barotrauma and profound reconditioning . This ambulatory concept on ECMO is analogous to the ventricular assist devices for patients with heart failure [27]. In patients with configurations requiring femoral cannulation, ambulation may result in cannula dislodgment and be potentially harmful [28]. However, in our institution we have a protocol for femoral ECMO ambulation, a multidisciplinary team comprising of a physician, nursing staff, perfusion, respiratory and physical therapists facilitate safe and effective physical rehabilitation on femoral ECMO.

ECMO as a bridge to HLT

Heart-Lung transplant (HLT) is a widely accepted current modality for some patients with advanced and refractory cardiopulmonary disease. Some of these patients are critically ill on the transplant waiting list, and VA-ECMO can be used as bridge to transplantation. Although the experience with ECMO as bridge to lung transplant is promising, there is limited evidence to use ECMO as a bridge to HLT. The number of HLT remained static during the last 5 years, with 59 procedures in 2017 [29]. Currently, most of the heart-lung transplants are performed on patients with severe pulmonary hypertension associated with congenital heart disease, followed by primary pulmonary hypertension (IPAH) and cystic fibrosis (CF). There is also a small trend showing an increasing number of HLT performed for idiopathic interstitial pneumonia (IIP) [30]. The evidence to support this strategy is limited, but the evaluation of the outcomes is crucial, especially with the new heart status allocation system [31].

HLT is widely accepted for some patients with advanced and refractory cardiopulmonary disease. Sometimes a double lung transplant is the procedure of choice, even with severe

RVF, in this case we think the best procedure was HLT, given the severe LV dysfunction. Although experience with ECMO as a bridge to lung transplant is encouraging and promising, there is limited evidence to use ECMO as a bridge to HLT. A previous analysis by Sertic et al. reported a 50% mortality at 30 days and 50% mortality at 1 year in patients with ECMO before the HLT. ECMO was identified as a strong predictor of mortality [31].

As a conclusion, AHF and ESLD, complicated by CS and acute pulmonary failure, are a complex and time-sensitive disease and a worldwide challenge to all health care systems. ECMO represents a real revolution in the treatment of those entities. Even with all the evidence, we cannot answer the fundamental question regarding the use of ECMO as temporary mechanical support: does ECMO alter the natural history of disease or simply optimize physiology and delay the time to death? Advances in technology have contributed to the increased utilization of ECMO. There is room for improvement in patient outcomes, likely through patient selection and ECMO management. Indication, patient risk factors, anticipated duration of support and an exit strategy should be considered. ECMO is not therapeutic; it is always a temporary bridge to the next level, from possible recovery, to LVAD or even a thoracic transplantation. Challenges arise from the ethical and legal issues of studying the use of ECMO. It is paramount to learn from experience through registries and publication of outcomes, and further and extensive research is necessary to clarify the criteria of the use of ECMO as a bridge to more advanced therapies.

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