



Bridge to transplantation from mechanical circulatory support: a narrative review

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Objective: To highlight recent developments in the utilization of mechanical circulatory support (MCS) devices as bridge-to-transplant strategies and to discuss trends in MCS use following the changes to the United Network for Organ Sharing (UNOS) heart allocation system.

Background: MCS devices have played an increasingly important role in the treatment of heart failure patients. Over the past several years, technological advancements have led to new developments in MCS devices and expanding indications for MCS use. In October of 2018, the UNOS heart allocation policy was revised to prioritize higher-urgency patients, including those supported with temporary MCS devices. Since then, changes in trends of MCS utilization have been observed.

Methods: Articles from the PubMed database regarding the use of MCS devices as bridge-to-transplant strategies were reviewed.

Conclusions: Over the past decade, utilization of temporary MCS devices, which include the intra-aortic balloon pump (IABP), percutaneous ventricular assist devices (pVADs), and extracorporeal membrane oxygenation (ECMO), has become increasingly common. Recent advancements in MCS include the development of pVADs that can fully unload the left ventricle (LV) as well as devices designed to provide right-sided support. Technological advancements in durable left ventricular assist devices (LVADs) have also led to improved outcomes both on the device and following heart transplantation. Following the 2018 UNOS heart allocation policy revision, the utilization of temporary MCS in advanced heart failure patients has further increased and the proportion of patients bridged directly from a temporary MCS device has exponentially risen. However, following the start of the COVID-19 pandemic, the trends have reversed, with a decrease in the percentage of patients bridged from a temporary MCS device. As long-term data following the allocation policy revision becomes available, future studies should investigate how trends in MCS use for patients with advanced heart failure continue to evolve.

Keywords: Mechanical circulatory support (MCS); heart failure; transplantation; ventricular assist device (VAD)

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Introduction

Heart transplantation continues to be the gold standard for patients with end-stage heart failure. However, due to increased prevalence of end-stage heart disease and the limited number of donor hearts available, the last decade has seen a 39.7% increase in the number of candidates actively awaiting transplantation (1). As a result, alternative definitive or temporizing treatment approaches utilizing various mechanical circulatory support (MCS) devices have emerged as a viable alternative in the surgical armamentarium to treat heart failure patients.

MCS devices are designed to provide hemodynamic support and help patients maintain adequate end-organ perfusion. Temporary MCS devices are intended to provide support for a number of indications, including cardiogenic shock refractory to medical therapy, high-risk percutaneous coronary interventions, myocardial recovery, and as a bridge to definitive therapy (durable MCS devices or heart transplantation). On the other hand, durable MCS devices are designed to provide long-term support and are commonly used in advanced heart failure patients as a bridge to transplantation (BTT), destination therapy (DT), or as a “bridge to decision”.

In 2018, the United Network for Organ Sharing (UNOS) adult heart allocation policy was changed from a three-tier to a six-tier system, and patients supported with temporary MCS devices were assigned a higher priority status (2). Given this change, the field of MCS use has been rapidly evolving (3,4). This review discusses recent developments in temporary and durable MCS devices as BTT strategies, trends in MCS utilization and outcomes over the past decade, and changes in practice following the 2018 allocation policy revision.

We present the following article in accordance with the Narrative Review reporting checklist (available at <https://dx.doi.org/10.21037/jtd-21-832>).

Methods

The PubMed database was searched using combinations of the following terms: “mechanical circulatory support”, “bridge to transplant”, “intra-aortic balloon pump”, “extracorporeal membrane oxygenation”, “percutaneous ventricular assist devices”, “ventricular assist devices”, “total artificial heart”, “temporary mechanical circulatory support”, and “durable mechanical circulatory support”. Following the initial search, additional articles were added

based on manual searches of the references of retrieved literature. Original articles and letters to editors containing original data published between 2005 and February of 2021 were included. Articles written in non-English were excluded.

Temporary MCS devices

Currently available temporary MCS devices include the intra-aortic balloon pump (IABP), percutaneous ventricular assist devices (pVADs), venoarterial extracorporeal membrane oxygenation (VA-ECMO), and surgically placed temporary ventricular assist devices (VADs). Device characteristics, indications for use, major contraindications, and major adverse events associated with these devices are summarized in *Table 1*.

IABP

IABP was the earliest developed and currently the most commonly utilized form of temporary MCS (7). IABPs were initially inserted through the femoral artery and placed in the proximal descending aorta. IABP counterpulsation increases cardiac output by about 0.5 L/min and allows for increased coronary perfusion, reduced afterload, and reduced myocardial oxygen consumption (8). Compared to more recent types of percutaneous MCS devices, the IABP provides lower hemodynamic support and does not significantly improve peripheral perfusion.

The IABP remains the most commonly used MCS device due to its low cost and ease of insertion. However, published outcomes of the IABP-SHOCK II trial, a randomized controlled trial of 600 patients with cardiogenic shock, found that the IABP resulted in no significant reduction in 30-day, 12-month, or 6-year mortality compared to medical therapy alone (9-11). The results of this trial, along with an increase in the use of other MCS devices, have led to a decrease in the use of IABPs for cardiogenic shock treatment and as a BTT therapy over the last decade (12-14).

Recently, there has been increased interest in IABPs inserted percutaneously through the axillary or subclavian arteries. This configuration allows patients to ambulate and undergo physical rehabilitation as they await transplantation. Reports have found that end-stage heart failure patients with upper-extremity IABPs have high rates of successful transplantation with significant increases in ambulatory distances following axillary insertion (15,16), but no studies have directly compared outcomes in patients

Table 1 Currently available temporary mechanical circulatory support devices

Characteristic	IABP	Impella 2.5	Impella 5	Impella 5.5	TandemHeart	Impella RP	TandemLife Protek Duo	VA-ECMO	Centrimag	Syncardia TAH
Insertion method	Percutaneous	Percutaneous	Surgical cutdown	Surgical cutdown	Percutaneous	Percutaneous	Percutaneous	Percutaneous	Surgical	Surgical
Ventricular support	Left	Left	Left	Left	Left	Right	Right	Left, right, or both	Left, right, or both	Both
Hemodynamic support	0.5 L/min	2.5 L/min	5.0 L/min	6.2 L/min	4.0 L/min	4.0 L/min	4.5 L/min	Up to 10 L/min	Up to 10 L/min	Up to 9.5 L/min
Pump mechanism	Pneumatic	Axial	Axial	Axial	Centrifugal	Axial	Centrifugal	Centrifugal	Centrifugal	Pneumatic
Insertion location	Femoral artery	Femoral or axillary artery	Femoral or axillary artery	Axillary artery or directly into aorta	Femoral vein	Femoral vein	Right internal jugular vein	Femoral artery, femoral vein, internal jugular vein, or central (right atrium and aorta)	Right superior pulmonary vein or LV and aorta	Atria
Location of device	Proximal descending aorta	Across aortic valve	Across aortic valve	Across aortic valve	Left atrium via transseptal puncture	Pulmonary artery	Right atrium and pulmonary artery	Extracorporeal	Extracorporeal	Attached to atria
Cardiac synchronization	Yes	No	No	No	No	No	No	No	No	No
Oxygenation	No	No	No	No	No	No	Yes	Yes	Yes (with oxygenator)	No
FDA status	510(k) cleared	PMA approved	PMA approved	PMA approved	510(k) cleared	PMA approved	510(k) cleared	510(k) cleared	510(k) cleared	PMA approved
Off-label durability	Days	Days	Days	Days	Weeks	Days	Weeks	Weeks	Weeks	Years

Table 1 (continued)

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Characteristics	IABP	Impella 2.5	Impella 5	Impella 5.5	TandemHeart	Impella RP	TandemLife Protek Duo	VA-ECMO	Centrimag	Syncardia TAH
Major contradictions	Significant aortic regurgitation, aortic dissection, aortic insufficiency, significant peripheral vascular disease	Significant peripheral vascular disease, significant aortic stenosis or insufficiency, ventricular septal defect, metallic aortic valve	Significant peripheral vascular disease, significant aortic stenosis or insufficiency, ventricular septal defect, metallic aortic valve	Significant peripheral vascular disease, aortic stenosis or insufficiency, ventricular septal defect, metallic aortic valve	Ventricular septal defect, significant peripheral vascular disease, aortic insufficiency	Disorders of pulmonary artery wall, mechanical right heart valves, severe pulmonary or tricuspid valvular stenosis or regurgitation, severe peripheral vascular disease	Severe pulmonary or tricuspid valvular stenosis or regurgitation, RV thrombus, mechanical right heart valves	Aortic regurgitation, aortic insufficiency, aortic dissection, left ventricular thrombus, significant peripheral vascular disease (for peripheral cannulation)	Unable to be treated with anticoagulation	Unable to be treated with anticoagulation, patients without sufficient space in chest area vacated by the natural ventricles
Major adverse events	Limb ischemia, puncture site bleeding, vessel injury, aortic rupture, thrombocytopenia	Limb ischemia, valve injury, hemolysis, puncture site bleeding, ventricular arrhythmia	Limb ischemia, valve injury, hemolysis, puncture site bleeding, ventricular arrhythmia	Limb ischemia, valve injury, hemolysis, puncture site bleeding, ventricular arrhythmia	Vascular injury, limb ischemia, stroke, intracranial hemorrhage	Bleeding, vascular complication, hemolysis, thrombus, valve injury	Bleeding, stroke, renal failure	Access site bleeding, pump-induced hemolysis, thromboembolic events, limb ischemia, left ventricular dilatation	Thromboembolic events, air embolism, bleeding, hemolysis, cardiac arrhythmias, limb ischemia	Renal failure, infections, bleeding, thrombosis, liver failure, neurologic events
Major prospective clinical trials	IABP-SHOCK II	ISAR-SHOCK	RECOVER I	-	Thiele <i>et al.</i> 2005 (5) Burkhoff <i>et al.</i> 2006 (6)	RECOVER RIGHT	-	ECLS-SHOCK	-	-

IABP, intra-aortic balloon pump; VA-ECMO, venoarterial extracorporeal membrane oxygenation; TAH, total artificial heart; LV, left ventricle; FDA, US Food and Drug Administration; PMA, premarket approval; RV, right ventricular; ISAR-SHOCK, Impella LP2.5 vs. IABP in Cardiogenic SHOCK; ECLS, extra-corporeal life support.

bridged with upper-extremity IABPs to those bridged with femoral IABPs.

pVAD

pVADs, such as the Impella (Abiomed, Danvers, MA, USA) and the TandemHeart (CardiacAssist, Pittsburgh, PA, USA), offer circulatory support through continuous flow pumps that can be placed either through a truly percutaneous approach or through small cut downs with short grafts. Compared to the IABP, these devices lead to greater increases in mean arterial blood pressure, more significant reductions in pulmonary capillary wedge pressure, and greater improvements in cardiac index (6,17).

The Impella is a micro-axial flow device consisting of an impeller pump on a catheter. This device is placed across the aortic valve into the left ventricle (LV) and delivers non-pulsatile flow from the LV to the ascending aorta. The commonly used left ventricular support devices include the Impella 2.5, Impella CP, and Impella 5.0, which provide up to 2.5, 4.0, and 5.0 L/min of flow, respectively. The Impella 2.5 and Impella CP are typically placed percutaneously through the femoral artery, while the larger Impella 5.0 is placed through a surgical cut-down. These devices provide support by unloading the LV and decreasing myocardial oxygen consumption while improving systemic and coronary perfusion.

Recently, the Impella 5.5 with SmartAssist device was developed. This device improves upon the Impella 5.0 by providing up to 6.2 L/min of flow, enough to fully unload the LV. In addition, the tip of the Impella 5.5 device does not have the pigtail-shaped feature of the previous Impella devices, which reduces the risk of thrombus accumulation and allows for a longer duration of implant. The SmartAssist component of the device also allows for remote monitoring and real-time calculation and display of hemodynamic parameters, such as left ventricular end-diastolic pressure, mean arterial pressure, and cardiac power output, that enable monitoring of patient status during weaning and escalation of therapy. The first experience with the Impella 5.5 was reported in 2019 when Bernhardt *et al.* (18) placed the device into two critically ill patients with no observed pump-related adverse events. In 2020, Ramzy *et al.* (19) reported on the outcomes of the first 55 patients in the United States to receive the Impella 5.5, of which 46 (83.6%) survived to explant and 5 (9.1%) underwent heart transplantation. Further studies on the outcomes of patients with the Impella 5.5 should be performed to better understand the

effectiveness of this device as a BTT therapy compared to other temporary MCS devices.

The TandemHeart is a centrifugal-flow percutaneous VAD that delivers up to 4.0 L/min of continuous flow by removing blood from the left atrium through a transseptal puncture and transferring it to the femoral artery. The pump consists of an electromagnetic motor with a maximum speed of 7,500 rpm. Randomized controlled trials have found that the TandemHeart, compared to the IABP, provides greater hemodynamic support, but results in greater complication rates and no difference in 30-day mortality (5,6). One benefit of the TandemHeart over the Impella is that the device can be repositioned to a right-atrium-to-iliofemoral-artery configuration and a membrane oxygenator can be added to provide biventricular support if the patient progresses to right ventricular (RV) failure. In practice, however, the TandemHeart is infrequently used because of the technical challenge of the transseptal puncture (20). Small case series have validated the use of TandemHeart as a BTT strategy, but more studies should be done to better understand the long-term outcomes of these patients.

Recent advancements in pVADs include the development of two devices specifically designed to provide RV support—the Impella RP (Abiomed, Danvers, MA, USA) and the Protek Duo (TandemLife, Pittsburgh, PA, USA). The Impella RP device provides RV support by pumping >4.0 L/min of blood from the inferior vena cava to the pulmonary artery. The prospective RECOVER RIGHT study found that the Impella RP was safe and provided RV failure patients with immediate hemodynamic support (21). Recent case studies have reported on the concurrent use of the Impella RP with left-sided assist devices as BTT strategies. Varian *et al.* (22) successfully used the Impella 5.0 and the Impella RP as a BTT therapy in a patient with rapidly progressive cardiac sarcoidosis. Randhawa *et al.* (23) reported on the first extended use of the Impella RP in a patient with a durable left ventricular assist device (LVAD) as a BTT strategy. The patient was supported by the Impella RP for 37 days and was successfully bridged to transplantation without any device-related complications.

The Protek Duo is a dual-lumen cannula that provides up to 4.5 L/min of flow. This device is placed through the right internal jugular vein, which allows for the potential for patient ambulation. When the Protek Duo is used with an extracorporeal centrifugal-flow pump, blood is removed from the right heart and reintroduced at the pulmonary artery bifurcation. A single-center retrospective

review of 27 patients receiving the Protek Duo after LVAD implantation found a low rate of adverse events and a 1-year cohort survival of 81% (24), which compares well against the overall survival rate of 60% in LVAD patients requiring biventricular support (25). However, no studies have reported on the use of the Protek Duo as a bridge to transplant strategy.

ECMO

ECMO can be utilized in a veno-venous configuration for lung failure but can also provide hemodynamic support when utilized in the veno-arterial (VA) configuration. It can provide >6 L/min of biventricular support in addition to oxygenation and ventilation capabilities. Indications for VA-ECMO support include cardiogenic shock, extracorporeal cardiopulmonary resuscitation, and post-cardiotomy shock. In general, VA-ECMO is initiated via peripheral cannulation, with deoxygenated blood being removed from the femoral or internal jugular vein and oxygenated blood returned to circulation via the femoral artery. Unlike IABP and other percutaneous MCS devices, VA-ECMO increases afterload of the LV secondary to the arterial return of blood, which can increase LV end-diastolic pressure and lead to significant distention of the LV and hence myocardial ischemia. As a result, VA-ECMO may require venting of the LV to avoid worsening of LV function in those that are in severe shock or are unlikely to recover. In recent years, a number of strategies have been developed in order to vent and hence reduce LV end-diastolic pressure and distention, including concomitant use of IABP (to reduce afterload) or Impella (to reduce preload). Studies have found that treatment of cardiogenic shock with VA-ECMO and Impella to unload the LV has led to improved survival in a configuration termed “Ec-pella” (26). However, some controversy exists over whether concomitant use of IABP or Impella improves BTT outcomes in patients supported with VA-ECMO (27).

In recent years, there has been a sharp increase in the proportion of patients who are directly bridged from ECMO to heart transplantation (28). However, despite advancements in LV unloading techniques, VA-ECMO as a BTT strategy is still associated with greater rates of complications and increased early/mid-term post-transplant mortality when compared with other temporary MCS devices (20,29,30). Further studies should be done to optimize LV unloading strategies and better identify patients who would benefit most from VA-ECMO as a BTT therapy.

Surgically-implanted temporary VADs

Aside from percutaneous temporary MCS devices, there are also surgically implanted devices that are placed via a median sternotomy. The most common surgically implanted temporary device is the CentriMag (Abbott Laboratories, Abbott Park, IL, USA), which is composed of a magnetically levitated pump and can provide LV, RV, or biventricular support. The CentriMag can provide up to 10 L/min of flow and allows for patient mobility after implantation. However, implantation of the CentriMag typically requires a median sternotomy and the use of cardiopulmonary bypass, which limits its emergent use. Additionally, the CentriMag has been associated with major complications, including stroke, bleeding, and infection (31).

Recently, Takeda *et al.* (32) reported on a new minimally invasive technique that combines the CentriMag with ECMO and circumvents the need for a sternotomy and cardiopulmonary bypass. Compared to the conventional CentriMag biventricular assist device (BiVAD) implantation strategy, this minimally invasive technique resulted in equivalent mortality rates and decreased major bleeding events. However, no significant differences were found in rates of stroke, which remains a major complication of the CentriMag.

Durable MCS devices

LVAD

LVADs are the most widely used form of durable MCS. The first generation of LVADs were pulsatile devices, which provided patients with hemodynamic support but were limited by the need for extensive surgical dissection, frequent device exchanges, and large recipient body habitus (33). Subsequent generations of LVADs were continuous-flow devices (CF-LVAD) that contained just one moving part, which allowed for a smaller pump size and greater mechanical reliability (34). CF-LVADs currently make up over 95% of all implants and have essentially replaced all other forms of durable univentricular support (35). Compared to the second generation axial-flow LVADs, the third generation devices contain centrifugal-flow pumps and are designed to be smaller and more durable. As LVADs have become more compact, there has been increasing interest in minimally invasive and sternal-sparing implantation techniques to improve patient outcomes (36-38).

Recently, the most widely used LVADs have been the HeartWare HVAD (Medtronic, Minneapolis, MN, USA)

and the HeartMate 3 (Abbott Laboratories, Chicago, IL, USA), both of which are third-generation, centrifugal-flow LVADs. The HeartWare HVAD was FDA approved for BTT in 2012. Compared to the HeartMate II, the most widely used second-generation LVAD, the HeartWare device is smaller, lies completely within the pericardial space, and has contact-free rotation of the impeller (39). At the time of FDA approval, a randomized clinical trial investigating survival following device implantation found that the HeartWare device was noninferior to the HeartMate II device with respect to death or disabling stroke (40). The HeartMate II was found to be associated with an increased need for device replacement, explantation, and urgent transplantation, while the HeartWare device was associated with increased rates of sepsis, stroke, and heart failure (40). However, since its approval, the FDA has issued a series of Class I recalls after complaints of delayed or failure to restart after the pump stopped (41). In June of 2021, the HeartWare HVAD system was pulled from the market after evidence demonstrated higher rates of neurological adverse events and mortality relative to other LVAD systems, and patients were encouraged by Medtronic to use alternatives, such as the HeartMate 3 device (42,43).

The HeartMate 3 was approved by the FDA in 2017, making it the most recent durable BTT device approved. Similar to the HeartWare, the HeartMate 3 is smaller than the previous generation of LVADs and can be fully placed within the pericardial space. The HeartMate 3 uses a magnetically levitated rotor and wide blood-flow gaps to minimize shear stress (44). In the randomized MOMENTUM 3 trial, the HeartMate 3 was found to be superior to the HeartMate II with respect to survival free of disabling stroke or device removal (45), even when looking specifically at the cohort of BTT or bridge to transplant candidacy patients (46). Compared with patients who received the HeartMate II, those who received the HeartMate 3 spent fewer days in the hospital and had lower rates of bleeding during the two years following device implantation (45). However, studies of early post-transplant outcomes in patients bridged from the HeartMate 3 found no difference in short-term survival compared with patients bridged from HeartMate 2 (47,48).

Right ventricular assist device (RVAD), BiVAD, and total artificial heart (TAH)

Patients requiring biventricular support have poor rates of survival to transplantation (25). The current BTT

therapy options for these patients include BiVADs or TAHs. BiVADs, which consist of the simultaneous use of an RVAD with an LVAD, are used in LVAD patients who develop RV failure. Currently, there are no continuous flow centrifugal pump VADs designed for right-sided use. However, there are a few pulsatile paracorporeal devices that can provide RVAD and BiVAD support, including the Thoratec Paracorporeal Ventricular Assist Device (PVAD) (Abbott Laboratories, Pleasanton, CA, USA), FDA approved in 1995 for BTT, and Abiomed AB5000 (Abiomed Inc., Danvers, MA, USA), FDA approved in 2003 (49). BiVAD strategies have also utilized off-label placement of continuous flow LVADs in a right atrial or RV position. A systematic review of right-sided use of the HeartWare found that right atrial VAD placement results in a survival advantage compared to RV VAD placement (50). Overall, BiVAD support remains infrequent and is only utilized in approximately 5% of patients with MCS devices (35).

In patients with biventricular heart failure identified pre-operatively, a TAH implantation may also be used. The only TAH currently FDA approved for BTT is the SynCardia TAH (SynCardia Systems, Inc., Houston, TX, USA), a four-chambered, pulsatile device. Recent developments in the SynCardia include the Portable Freedom Driver, which allows patients to be discharged (51). The CARMAT TAH (CARMAT SA, Vélizy-Villacoublay, France) is another TAH device that is commercially available in Europe and currently being tested in clinical trials in the US. The CARMAT TAH utilizes bioprosthetic materials and sensor-based autoregulation to minimize thromboembolism and hemorrhage. Netuka *et al.* (52) recently reported on the successful bridge-to-transplantation of 5 patients supported with CARMAT TAH after a median support time of 243 days. Overall, however, mortality rates for TAH patients remain high, with a one-year survival of less than 60% (35). TAH continues to be infrequently utilized, with just 373 implantations reported in the INTERMACS database between 2006 and 2016, compared to 17,016 continuous flow LVADs implanted during the same time period (35).

Bridge-to-bridge patients

Patients receiving temporary MCS devices who are not directly bridged to transplantation may instead be bridged to a durable MCS device. In the context of cardiogenic shock, utilization of temporary MCS devices may provide patients with hemodynamic support, which allows more time for clinical evaluation and a decision to be made,

as well as time to correct end-organ injury secondary to cardiogenic shock. However, a study by Shah *et al.* (53) on post-LVAD implantation outcomes found that patients bridged from a temporary MCS device had improved hemodynamics and reversal of cardiogenic shock, but only partial end-organ recovery. Additionally, the use of a temporary MCS device was associated with a twofold increase in post-LVAD mortality, likely due to the acutely ill patient population that requires temporary MCS. A recent study by Hernandez-Montfort *et al.* (54) of the International Society for Heart and Lung Transplantation (ISHLT) Registry found that patients bridged to durable VADs from ECMO, in particular, resulted in lower longitudinal survival compared with patients bridged to durable VADs from other temporary MCS devices. In this study, 78% of ECMO patients had INTERMACS Profile 1 status prior to LVAD implantation, compared to just 45% in patients supported with other forms of temporary MCS. This suggests that ECMO patients are sicker prior to LVAD implantation than patients supported with other types of temporary MCS, which could explain the worse post-LVAD outcomes observed in ECMO patients.

Karamlou *et al.* (55) studied heart transplant outcomes in patients in the UNOS database who were double bridged to transplantation between 2000–2010. Patients who were bridged directly from an LVAD were found to have better post-transplant survival than patients who were bridged from ECMO, RVAD, or BiVAD. Meanwhile, patients who were bridged from ECMO or BiVAD to LVAD prior to transplantation experienced recovery in survival and were found to have equivalent post-transplant outcomes as those bridged from LVAD-only. No reports of a contemporary cohort of double-bridged patients have been published, and patients being double bridged from percutaneous VADs, such as the Impella or TandemHeart, have not been studied.

Trends prior to the new heart allocation system

Technological developments and advancements in the management of heart failure patients led to improvements in long term survival of patients supported with durable LVADs, particularly when comparing the 2008–2012 era with more recent years (35). Since 2013, however, LVAD survival outcomes have remained relatively unchanged. Currently, 12-month survival is 82% and 24-month survival is 72% (56). Post-transplant outcomes in patients bridged from an LVAD have also improved significantly. In a contemporary cohort of patients, LVAD prior to

transplantation resulted in no differences in long term post-transplant outcomes when compared to patients undergoing *de novo* heart transplantation (57). In addition, the duration of LVAD support does not affect post-transplant outcomes (58).

As long-term outcomes of LVADs have improved, there has been increased interest in the use of LVADs as an alternative to heart transplantation for those who are ineligible for candidacy. According to the eighth annual INTERMACS report published in 2018, the number of patients receiving durable LVAD implantations increased from 4,722 in 2008–2011 to 5,400 in 2015–2016, with a significant increase in the percentage of those receiving LVADs intended for destination therapy (DT) from 28.5% (n=1,347) to 49.8% (n=2,687). Meanwhile, the percentage of LVAD patients intended for BTT decreased from 32.3% (n=1,525) in 2008–2011 to 26.4% (n=1,427) in 2015–2016 (35). At the same time, there was an increase in the use of temporary MCS devices. The percentage of patients who received temporary MCS prior to an LVAD increased from 23.1% in the 2008–2011 era to 28.5% in the 2012–2017 era (59).

Trends following the new heart allocation system

The UNOS heart allocation policy was revised in 2018 with the goal of better prioritizing waitlist candidates based on medical urgency, reducing clustering of candidates assigned the top-tier status, decreasing waitlist times, and providing more equitable geographic access to donors. Under the previous allocation system, patients receiving both temporary and durable VADs were equally prioritized with the highest status. However, given the increase in the number of patients supported with LVADs and the improvements in long-term LVAD outcomes, 45% of patients were listed as the highest priority status under the old allocation system (60). With the 2018 heart allocation policy change, the previous 3-tiered system was replaced with a new 6-tiered system. The prior status 1A patients were stratified into status 1–3, and the prior status 1B corresponds to the new status 4. Under the new system, patients supported by ECMO are assigned status 1, while patients receiving IABPs and other percutaneous VADs are assigned status 2. LVAD-supported patients who have complications or are within the 30-day discretionary period are assigned status 3, and all other LVAD-supported patients are assigned status 4 (2).

Early studies investigating the impact of the allocation policy revision using the UNOS database have all demonstrated a decrease in time spent on the waitlist and an increase in recipient graft ischemic times due to the broader geographic distribution policy adopted (3,4,61). Additionally, some studies have also found a decrease in waitlist mortality, likely attributable to the decrease in time spent on the waitlist. When looking at post-transplant outcomes following the policy revision, however, results have been inconsistent, with some studies demonstrating increased post-transplant mortality, attributed to increased transplantation of more hemodynamically unstable patients (3,4,62), and other studies finding no difference in post-transplant mortality (61,63). Although these studies used the UNOS database, the disparate findings may be attributed to differences in study population, time periods, and follow-up time included in the investigations. Additional studies with greater follow-up time and a larger study population should be performed to draw more definitive conclusions on the impact of the policy revision on post-transplant survival.

Under the new allocation system, patients with temporary MCS devices are assigned a higher priority status than those with durable MCS devices. Unsurprisingly, reports on transplant practices following the 2018 policy change have found an increase in patients bridged directly from temporary MCS devices and a decrease in patients bridged from an LVAD (3,64). A single-center analysis by Liu *et al.* (65) found that patients were significantly more likely to be bridged from IABP and significantly less likely to be bridged from a durable LVAD after the policy change. Additional single-center studies have found increases in the number of patients bridged to heart transplantation from axillary IABP (66) and Impella 5.0 (67). A national analysis using the UNOS registry conducted by Jawitz *et al.* (61) found similar results, with the percentage of patients bridged to transplantation with a temporary MCS device increased from 13.5% to 44.5%, while the percentage of patients bridged to transplantation from a durable LVAD decreased from 41.8% to 21.2%, despite an increase in LVAD implantations from 2,994 in 2018 to 3,198 in 2019 (61,68). Other national retrospective reviews using the UNOS database found similar results, with the increase in temporary MCS BTT rates mostly due to more frequent bridging from ECMO and a >3× increase in bridging from IABP (60,64,65,69,70).

While the increase in temporary MCS BTT was not unexpected, concerns have been raised over whether this trend reflects the new prioritization of patients or whether

treatment practices have changed. In the analysis by Jawitz *et al.* (61), rates of temporary MCS utilization in listed candidates, regardless of whether they were ultimately transplanted, were found to have doubled following the allocation policy revision, suggesting that some programs may have modified their practices to provide patients with higher priority status. A study by Parker *et al.* (60) retrospectively compared a pre-policy cohort and a post-policy cohort of heart transplant candidates. Results from this study identified changes in the distribution of statuses that could be not explained by patient baseline characteristics alone. Specifically, more ECMO and IABP candidates were listed than expected, which led to more high-priority listings than anticipated. The authors of this study also found a significant difference between cardiac index measurements on the justification and registration forms, which could explain the increase in IABP listings. Additionally, Varshney *et al.* (71) compared practices in temporary MCS use between US transplant centers and other cardiac intensive care units (ICUs). US transplant centers in the post-revision period were found to have an increase in temporary MCS use in advanced heart failure patients complicated by cardiogenic shock. This shift in practice was not found in other cardiac ICUs, suggesting that the new UNOS allocation system may be influencing treatment practices. Based on these results, it is possible that US transplant programs have favored the utilization of IABPs over inotropes and durable VADs in order to provide patients with higher priority status. Further studies should be conducted to fully understand the effects of this shift in practice.

Interestingly, the trends seen following the 2018 allocation policy change have reversed during the COVID-19 pandemic. In the period of time immediately following the pandemic, there was a decrease in heart transplants and waitlist additions (72). At the same time, there was a decrease in the proportion of patients bridged from IABP and ECMO (73). Even eight months after the start of the pandemic when heart transplant volume and waitlist additions recovered, the percentage of patients bridged from a temporary MCS device was still lower than prior to the pandemic and decreasing steadily (74). The reversal in trends could be due to the diversion of health care resources towards patients with COVID-19 or apprehension associated with hospital visits for fear of exposure. The decrease in temporary MCS BTT may also be due to a reduction in heart failure hospitalizations

observed during the pandemic (75).

Conclusions

The field of MCS devices as BTT therapies has been rapidly evolving. The IABP was traditionally the most commonly used form of temporary MCS. However, the development of percutaneous VADs, such as the Impella and the TandemHeart, has led to a decrease in the use of IABPs. Recent technological advancements have led to the development of percutaneous VADs that can fully unload the LV, as well as temporary MCS devices that can provide support in the setting of RV heart failure. Advancements in durable LVADs have led to improved long-term survival both on the device and after transplantation in BTT patients.

Since the 2018 UNOS heart allocation policy change, the use of temporary MCS devices as BTT strategies has increased due to both the new prioritization guidelines and changes in treatment practices. Following the policy change, the greatest increase was seen in the proportion of patients bridged using an IABP or ECMO. Interestingly, since the start of the COVID-19 pandemic, a reversal in trends was observed, and the proportion of patients bridged from an IABP or ECMO is now decreasing. Future studies should be done to determine how the trends in MCS use continue to evolve. The effects of these changes on long term outcomes should be further elucidated in order to improve practices in the management of heart failure patients.

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