

Clinical application and management of temporary mechanical circulatory support: A clinical consensus

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Temporary mechanical circulatory support (tMCS) plays a pivotal role in managing severe or refractory cardiogenic shock (CS), furnishing essential hemodynamic support, and sustaining organ perfusion from hours to weeks, or to even months. In the past decade, the utilization of tMCS has witnessed a significant increase in American and European countries. Meanwhile in Asia, the newly developed concepts and devices constituting tMCS have also made rapid progress. Nevertheless, the absence of a consensus or standardized guidelines, especially for the Asian population considering inherited polymorphism, is evident. To address this knowledge gap, eight associations/societies and experts in this field came up with the present consensus after repeated discussions, more specifically for the Asian population. It comprehensively elucidates the commonly employed tMCS devices, criteria for patient selection, indications and contraindications, clinical management, and the optimal timing for implantation and weaning. The goal of this statement is to promote the standardized application of tMCS and make reasonable decisions in clinical practice. Full-length version of the consensus can be seen in supplementary file, <http://links.lww.com/CM9/B883>.

tMCS Devices

The primary tMCS devices include the intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO), the CentriMag pump, and various percutaneous ventricular assist devices (pVADs) such as the TandemHeart, the extracorporeal ventricular assist device (Extra-VAD), and the Impella system.

IABP

The IABP's fundamental principle involves the insertion of an intra-aortic balloon into the thoracic aorta. During diastole, the balloon inflates, thereby enhancing diastolic pressure and coronary perfusion. In contrast, during systole, the balloon rapidly deflates, reducing aortic pressure and mitigating the left ventricular afterload. Consequently, the IABP has the potential to elevate cardiac output by 10–20% above baseline levels.

ECMO

ECMO operates through two principal modalities: veno-veno extracorporeal membrane oxygenation (VV-ECMO) and veno-arterial extracorporeal membrane oxygenation (VA-ECMO).^[1] The VV-ECMO caters to patients requiring solely respiratory support, while the VA-ECMO can furnish both respiratory and circulatory assistance. The VA-ECMO functions by employing a centrifugal pump to draw venous blood from the body, pass it through a membrane oxygenator situated externally, and subsequently return it to the arteries. The preferred access for VA-ECMO often involves femoral arterial/venous cannulation or open right atrium/ascending aorta cannulation. To alleviate left heart congestion, it is conceivable to consider a combination of IABP, atrial shunt device (e.g., D-shunt), left ventricular Impella, or the implantation of a left atrial tube *via* the pulmonary vein.

Axial tMCS (Impella)

The Impella system encompasses a range of continuous axial flow tMCS devices, including Impella 2.5, Impella CP, Impella 5.0/LD, and Impella 5.5. These devices actively transport blood from the left ventricle to the aorta. The inflow section resides in the left ventricular outflow tract, while the outflow section connects to the aorta. Impella 2.5 and Impella CP are percutaneously inserted through the femoral artery, offering low (1.5–2.5 L/min) to intermediate (2.0–4.0 L/min) blood flow rates. The larger Impella 5.0 and 5.5 can be cannulated through the axillary or subclavian artery using sutures to connect to artificial blood vessels, providing blood flow rates of up to 5.0 L/min. Impella RP is designed for right ventricular support and can be percutaneously implanted through the inferior vena cava into the pulmonary artery, delivering up to 4.0 L/min of flow.

Centrifugal pump

The CentriMag (Abbott, Abbot Park, IL, USA) represents a centrally cannulated tMCS, featuring a third-generation blood flow pump that can deliver up to 10 L/min of blood flow for a period of up to 30 days. Utilizing a magnetically levitated rotor minimizes damage to red blood cells and reduces hemolysis. Several studies have demonstrated that CentriMag is a versatile, dependable, and straightforward tMCS. It can offer single or biventricular support and facilitate the transition of patients with advanced heart failure (HF) toward transplantation, decision-making, and recovery, with minimal impact on complications and mortality.

The TandemHeart centrifugal pump represents a peripherally cannulated continuous flow centrifugal pump designed for left atrial-to-aortic assistance. This mechanism entails the insertion of a catheter into the left atrium (LA) through a septal puncture, facilitating the redirection of blood from the LA into the aorta to aid in cardiac function. The device is capable of delivering a flow rate of up to 4 L/min, with the duration of assistance spanning from a few hours to 14 days. Similar to CentriMag, TandemHeart can be centrally cannulated to provide assistance to a single ventricle or both ventricles.

MoyoAssist serves as a centrally or peripherally cannulated tMCS, featuring a magnetically levitated Extra-VAD capable of providing left/right/biventricular support with a maximum blood flow of 10 L/min. This system comprises a single-use centrifugal pump head, a maglev motor, and a console, achieving comparable pressure and flow at a significantly lower pump speed than CentriMag. Currently, two common types of Extra-VAD cannulation are employed: one involves output cannulation through the femoral artery and input cannulation through the internal jugular vein, traversing the interatrial septum into the LA. The other method entails output cannulation through the axillary artery and input cannulation through the internal jugular vein, similarly passing through the interatrial septum into the LA.^[2]

tMCS Indication/Scenario

The primary indications for tMCS predominantly encompass acute myocardial infarction-induced CS and acute decompensated HF-induced CS. The diagnosis hinges on the presence of persistent hypotension (systolic blood pressure <90 mmHg or mean arterial pressure [MAP] <65 mmHg), a cardiac index $\leq 2.2 \text{ L}\cdot\text{min}^{-1}\cdot\text{m}^{-2}$, pulmonary capillary wedge pressure $\geq 15 \text{ mmHg}$, and indicators of end-organ hypoperfusion (e.g., urine output <30 mL/h, altered mental status, cool extremities, lactate >2.0 mmol/L).

Recommendations

- (1) tMCS may provide hemodynamic benefits for patients with CS.
- (2) tMCS can be used for the treatment of CS prior to acute and critical cardiac surgery.
- (3) tMCS can be applied to treat postcardiac surgery CS and perioperative circulatory failure.
- (4) tMCS can be used in reversible acute refractory HF (fulminant myocarditis, perinatal cardiomyopathy, etc.) to gain time for cardiac function recovery.
- (5) tMCS can be applied as a bridging therapy for subsequent decision-making in the management of CS occurring in end-stage HF.

tMCS Preoperative Evaluation and Device Selection

Forming a team

Recommendation

It is recommended to form a multidisciplinary tMCS team including physicians specializing in cardiovascular surgery, cardiovascular medicine, intensive care medicine, respiratory medicine, anesthesiology, extracorporeal circulation, ultrasound imaging, and other relevant fields, along with nursing and engineering personnel,^[3] who are primarily responsible for determining the timing of tMCS placement, selecting the appropriate device, involving in preoperative preparation, device operation and management, and addressing potential complications.

Preoperative assessment and timing

Recommendations

- (1) Comprehensive evaluation of tMCS implantation, including indications, contraindications, timing of implantation, and cost-effectiveness, should be conducted by the multidisciplinary tMCS team. The final decision should respect the preferences of the patients and their families.
- (2) The timing of tMCS implantation should be guided by the underlying etiology. In cases where the clinical prognosis is poor after intensive treatment, tMCS initiation should be considered as early as possible.

tMCS device selection

In emergency situations, the IABP is a mature and relatively uncomplicated option that may be considered first. If IABP is insufficient to maintain circulation, alternatives such as ECMO, Impella, or Extra-VAD can be explored. Patients with right HF may benefit from right ventricular assist devices like Impella RP, TandemHeart, VA-ECMO, or Extra-VAD, particularly when drug therapy is ineffective. In cases of HF accompanied by respiratory failure, ECMO is generally preferred. When utilizing VA-ECMO, a combination of Impella, left atrial drainage, and atrial septal opening may be considered to alleviate left ventricular pressure.^[4]

Recommendations

- (1) Device selection should take into account the clinical context, etiology of CS, device characteristics, ease of operation, and treatment goals.
- (2) Whenever possible, tMCS placement should be guided by X-ray, ultrasound, or other imaging modalities. If bedside placement is necessary, ultrasound guidance is recommended due to its minimally invasive puncture technique.
- (3) Initial support with IABP, LV Impella, Extra-VAD, or TandemHeart may be suitable for patients primarily affected by left HF in the setting of CS. The option of ECMO combined with left heart decompression should also be considered.
- (4) Patients with acute decompensated HF and significant right heart dysfunction, hypoxemia, or severe shock may be candidates for VA-ECMO.

tMCS Clinical Management

Anticoagulation management

Recommendations

- (1) Anticoagulation is required throughout all tMCS assistance periods, with continuous heparin micro-pump infusion being the preferred method, with activated coagulation time (ACT) monitoring.^[5]
- (2) For IABP, the target ACT during insertion is 250 s, and it ranges from 150 s to 180 s for the maintenance period.
- (3) For Impella, the target ACT during insertion should exceed 250 s, while it ranges from 150–180 s during the maintenance period.
- (4) For TandemHeart and Extra-VAD, the target ACT during insertion is 250–300 s, and it ranges from 160–220 s during the maintenance period.
- (5) For CentriMag, the target ACT during insertion is 200–250 s, and it ranges from 160–180 s during the maintenance period.
- (6) In the case of ECMO, patients treated with VA-ECMO, central intubation carries a higher risk of bleeding and in-hospital mortality compared to peripheral intubation. The recommended ACT range is 160–200 s.

Anti-infective treatment

Recommendations

- (1) For tMCS with peripheral cannulation, routine prophylactic use of third-generation cephalosporins is not recommended.
- (2) For tMCS with central cannulation, it is advisable to administer routine perioperative prophylactic antibiotics (cefazolin).

Circulatory management and monitoring

Recommendations

- (1) Target an MAP of 60–80 mmHg for most tMCS patients in terms of hemodynamics.
- (2) Early implantation of pulmonary artery catheters is recommended, as they provide essential hemodynamic parameters.
- (3) Regular echocardiographic and chest radiographic assessments should be conducted during tMCS. The focus of echocardiography may vary for different tMCS devices, including assessing left ventricular decompression and monitoring aortic valve behavior in VA-ECMO management.

Complications and precautions

Recommendations

- (1) Given the high incidence of tMCS-related complications, a heightened focus on prevention and management is necessary.
- (2) During IABP use, vigilance for thrombocytopenia, hemorrhage, and lower extremity arterial ischemia is essential, and preventive measures should be applied accordingly.
- (3) Peripheral cannulation for VA-ECMO implantation may increase the risk of distal limb ischemia due to mismatched circuits. To mitigate this risk, the placement of a distal perfusion line should be considered. Furthermore, the use of peripheral VA-ECMO may lead to increased afterload, potentially resulting in left ventricular dilatation. In such cases, placement for left heart decompression is typically recommended.
- (4) Hemolysis is a common complication associated with Impella use. Continuous monitoring of urine color, lactate dehydrogenase, plasma free hemoglobin, and hemoglobin levels is advised.
- (5) When using TandemHeart and Extra-VAD, precise catheter positioning is critical to prevent catheter displacement, which could result in unoxygenated blood entering the circulatory system.

Weaning off Strategy of tMCS

Timing of weaning

Commencement of the weaning process should be based on the resolution of cardiac dysfunction, evidence of at least partial myocardial recovery, and improved end-organ

perfusion. Cardiac function serves as the primary indicator for weaning success, with successful weaning more likely when CI exceeds $2.4 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$, LVEF surpasses 20–25%, and parameters like aortic time velocity integral (VTI) $\geq 12 \text{ cm}$, and peak systolic velocity (S') measures $\geq 6 \text{ cm/s}$ in the posterior mitral leaflet of tissue Doppler imaging (TDI). Invasive hemodynamic monitoring indicators should also be considered, with RA pressure below 10 mmHg and PCWP less than 18 mmHg. Maintaining MAP at or above 65 mmHg with minimal vasoactive support, venous oxygen saturation over 65%, and lactate levels $\leq 2 \text{ mmol/L}$ for 24 h can be viewed as successful weaning markers.

Recommendations

- (1) The timing of tMCS weaning should be determined by the tMCS team and initiated as soon as the patient's condition allows.
- (2) In cases of preoperative transitions or bridging, tMCS withdrawal can be considered after the procedure is successfully completed without any special circumstances.

Program of weaning

Recommendations

- (1) Daily assessment of circulatory status, cardiac function, and vital organ perfusion is crucial during the tMCS weaning process.
- (2) Gradual reduction of support flow should be the approach for tMCS weaning. In cases where ECMO is combined with other tMCS adjuncts, ECMO should be weaned first, followed by an evaluation of the other tMCS devices.

Unsuccessful weaning

Recommendation

- (1) Long-term therapeutic strategies, such as transplantation or long-term VAD implantation, should be pursued when myocardial function cannot be restored or tMCS weaning is unsuccessful.

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Conflicts of interest

None.

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