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Percutaneous mechanical devices for supporting the left ventricular failure

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ABSTRACT This article reviews the indications, contraindications, functionality, and complications for various percutaneous devices that can be used to support the left ventricular failure. We also reviews the anesthetic effect for these devices. A literature review was performed using PubMed. When the heart experiences end-stage systolic ventricular failure, it is generally unable to restore its practical function with pharmacological therapy alone. Percutaneous ventricular support devices have been introduced and used successfully to support a failing ventricle in a variety of settings. These devices include intra-aortic balloon pump, TandemHeart, and Impeller, as well as veno-arterial extracorporeal membrane oxygenation for left ventricular support. These devices are typically accessed percutaneously through the femoral vessels and/or the jugular vein(s), although other sites are possible in unique cases.

KEY WORDS heart failure; percutaneous ventricular assist device; intra-aortic balloon pump; Impeller; extracorporeal membrane oxygenation; TandemHeart

支持左心衰的经皮机械装置

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[摘要] 本文综述了各种可用于支持左心衰的经皮装置的适应证、禁忌证、并发症、功能性和其他特征；并回顾了这些装置对某些手术麻醉的影响。使用PubMed对相关文献进行了回顾。当心脏出现终末期收缩期心室衰竭时，单凭药物治疗通常无法恢复其实际功能。经皮心室支持装置已被引进并成功地用于在各种环境中支持衰竭的心室，包括主动脉内球囊泵、TandemHeart、叶轮、静脉-动脉体外膜肺氧合，这些装置通常是通过股动、静脉和/或颈静脉经

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皮进入的，尽管在特殊情况下可能有其他部位。

[关键词] 心力衰竭；经皮心室辅助装置；主动脉内球囊泵；叶轮；膜肺氧合；TandemHeart

The heart can be thought of as two distinct pumps that deliver blood to the pulmonary and systemic circulation[1]. There are a variety of situations that could lead to the failure of one or both of these systems, bringing about the need for exogenous support. There are several devices available that may be appropriate in providing support for the left or right heart[2-3]. Some of these devices provide long-term support ("durable" devices) and require open surgery for placement, as well as long-term care, and others may be placed percutaneously and are generally used for emergent and/or short-term support[4-5]. In this article, we will review the indications, contraindications, functionality, complications, and other characteristics of the different percutaneous devices that can be used to support the left ventricular failure. We will also review the implications these devices may have for anesthesia.

1 Indications

These devices are used to support a failing heart primarily in the setting of cardiogenic shock or in patients requiring percutaneous coronary intervention (PCI) who are considered "highrisk". They use different mechanisms to improve ventricular pump function and end-organ perfusion. Because they are temporary, generally intended for no more than 14 days of use, they are primarily a short-term bridge to a more permanent solution such as permanent ventricular assist device (VAD) placement, transplant, or weaning to recovery[6–9].

2 Cardiogenic shock

Cardiogenic shock is the most common cause of death in patients with acute myocardial infarction and is defined by several qualitative and quantitative criteria (Table 1) that are suggestive of inadequate end-organ perfusion in the setting of cardiac dysfunction. This includes hypotension, elevated pulmonary capillary wedge pressure, and diminished cardiac output/index[3, 10-19].

In the setting of myocardial infarction, timely coronary revascularization is critical, but this may not result in dramatic improvement right away. Although pharmacologic vasopressors and inotropic medications may be helpful, recent data indicate that excessive use of these medications may further impair myocardial function and recovery[20]. For this reason, temporary mechanical circulatory support (MCS) devices are being used with regularity to improve these hemodynamic parameters, limit the use of vasoactive medications, and improve myocardial recovery.

Table 1 Cardiogenic shock

Clinical criteria	Parameters
Hypotension	SBP<90 mmHg for >30 min*
Increased LV filling pressures	PCWP>15 mmHg
Impaired cardiac function	Cardiac index<2.2 L/(min·m^2)

*Or requiring vasopressors to maintain SBP>90 mmHg. SBP: Systolic blood pressure; LV: Left ventricle; PCWP: Pulmonary capillary wedge pressure. 1 mmHg=0.133 kPa

3 High-risk PCI

Patients requiring revascularization by PCI who are more likely to have an adverse outcome from stent deployment are considered "high-risk". These patients may be less able to tolerate episodes of hemodynamic instability that may occur during the procedure or more likely to acutely decompensate during the procedure. A variety of patient characteristics may be used to identify these patients, including cardiac function, number of vessels involved, complexity of lesions, and clinical comorbidities[21]. Some of these patients may benefit from the placement of temporary MCS to help preserve hemodynamic stability during their PCI procedure.

In high-risk patients undergoing PCI, the interventionalist may wish to consider the placement of a percutaneous mechanical support device to decrease the likelihood of circulatory collapse during the procedure. The 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention states that "Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully-selected high-risk patients". This is based on Class IIb evidence,

Level C[22]. When making this decision, each patient should be thoroughly evaluated on a case-by-case basis to determine the risks and benefits of the placement of such a device. The 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care details a schema to help clinicians evaluate when to consider placing one of these devices based on the likelihood of hemodynamic compromise during the PCI procedure[23].

4 Other suggested uses

The 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care makes other suggestions for potential uses of these devices as well. They may be helpful in other settings such as non-ischemic cardiomyopathy, dysrhythmias refractory to conventional treatment, difficulty weaning from cardiopulmonary bypass (CPB), or high-risk percutaneous valve procedures. Additionally, there may be value in these devices for temporary support in heart transplantation, such as in the event of acute allograft failure secondary to organ rejection, prolonged ischemic time, inadequate protection of the organ from donation time to implantation, or post-transplant failure of the right ventricle (RV). Although it may not always be feasible to do this routinely in these situations, it is reasonable to consider in the event that additional temporary circulatory support is needed or expected to be needed[23].

5 Percutaneous MCS of LV

There are currently 4 commonly used devices that can be placed percutaneously to support LV circulatory function[10, 24-32]: Intra-aortic balloon pump (IABP), extracorporeal membranous oxygenation (ECMO), Impella (Abiomed Inc., Danvers, MA, USA), TandemHeart (Cardiac Assist Inc., Pittsburgh, PA, USA).

5.1 IABP

5.1.1 Device characteristics

The IABP has been in use for over 40 years, and was initially used in the setting of cardiogenic shock[33]. The device can inflate the balloon with helium at appropriate times during the cardiac cycle to create counterpulsation to augment cardiac output. Helium is used for two reasons: Its low viscosity, which allows for rapid inflation and deflation of the balloon, and it is rapidly absorbed in the blood, making it safer in the event of balloon rupture[34]. With current IABP use, there is a fiberoptic pressure sensor used in timing of the inflation and deflation. It is notable that, while the femoral artery is the most common access site for placement, the device can also be placed by accessing the subclavian, axillary, or brachial arteries, although these are more technically challenging procedures and may require surgical cut-down[35]. The distal end of the catheter is placed 2 to 3 cm below left subclavian artery where the balloon can inflate without impeding flow to the extremities or visceral organs. Transesophageal echocardiography (TEE) may be performed to confirm placement of the device[36-37].

5.1.2 Device function and hemodynamic effects

After confirming proper placement, the computer associated with the device senses the phases of the cardiac cycle, quickly inflates the balloon at the onset of diastole (closure of the aortic valve), and deflates it at the onset of systole (prior to opening of the aortic valve)[35-38]. This correlates with the middle of the T-wave and the peak of the R-wave on the ECG, or the dicrotic notch and start of the upstroke of the aortic pressure waveform. Properly timed inflation and deflation augments diastolic pressure and decreases afterload, which decreases LV wall tension and cardiac oxygen demand, and increases coronary perfusion pressure, resulting in improved cardiac output[39].

There must be some level of LV and RV function for the IABP to be effective. Additionally, in the setting of electrical interference, dysrhythmia, the timing of the device can become impaired, leading to ineffective augmentation. Modern fiberoptic devices and pressure transduction can help to mitigate device dysfunction from these complications.

5.1.3 Complications

The most common complication of IABP use is thrombocytopenia which may be due to the interaction between the IABP membrane and the platelets, and may also be related to heparinization while the device is in use[6]. Although this is a commonly accepted complication, it has not generally been shown to result in severe adverse consequences in this setting[40].

The second-most common complication of IABP placement is fever[40]. Vascular injury, including aortic dissection, thromboembolism, limb ischemia, bleeding, device retention/entrapment, and balloon rupture have also been described in association with IABP placement[41]. When considering removal of the device, the resources to repair a vascular injury to the femoral artery may be needed and should be readily available.

5.1.4 Contraindications

Absolute contraindications to IABP use include aortic insufficiency graded as moderate or worse, aortic aneurysm, aortic dissection, severe sepsis, or uncontrolled coagulopathy. Relative contraindications include any contraindications to anticoagulation, which is generally required to use the device safely, significant peripheral arterial disease at the access site that makes safe placement of the device difficult, and LV outflow tract obstruction, which could be worsened with IABP use due to the functional afterload reduction of the device[16, 23, 42].

5.1.5 Anesthetic implications

As with any patient with cardiac disease who requires non-cardiac surgery, the risks of surgery and anesthesia must be weighed against the risks of delaying the procedure for further optimization of the chronic disease or foregoing the procedure altogether[43].

IABP counterpulsation has been used successfully to support cardiac function in high-risk cardiac patients requiring non-cardiac surgery. For example, Masaki et al[44] described the successful use of the IABP in a patient with severe three-vessel disease requiring a sigmoid colectomy, and another patient, also with extensive three-vessel disease, requiring a gastrectomy. These patients both completed their hospital courses without any reported cardiac complications. The use of perioperative IABP counterpulsation has also been described extensively in cardiac surgery. Christenson et al[45] have discussed the utility of preoperative IABP placement in certain high-risk patients undergoing redo coronary artery bypass grafting (CABG). They demonstrated that these patients had lower hospital mortality, better cardiac function, and shorter ICU stay than patients without preoperative IABP placement. In another study, Kim et al[46] described the use of IABP counterpulsation to assist cardiac function in high-risk patients undergoing posterior vessel off-pump CABG, showing that their outcomes were similar to those of lower-risk patients undergoing a similar procedure. Gong et al[47] have described the potential benefits of perioperative IABP placement in high-risk patients undergoing first-time CABG, either with or without the use of CPB, in a retrospective review.

For hemodynamic monitoring of a patient with an IABP in place, it should be noted that the pressures displayed on the console represent unaugmented pressures, whereas the augmented pressures will be reflected on the arterial line tracing. Additionally, any cardiac monitoring system that relies on the morphology of the arterial line tracing, such as a FloTrac, are not reliable. For patients requiring femoral IABP placement, patients may require postoperative sedation, as any movement of the hips could lead to device migration and malposition.

5.2 Impella

5.2.1 Device characteristics

The Impella utilizes the design of the Archimedes screw pump to augment cardiac output. An Archimedes screw pump is typically a cylindrical structure that encloses a helical column. Originally attributed to Archimedes, who lived in the 3rd century B.C., the device operates by rotating the cylinder on its longitudinal axis, causing fluid to be propelled from the bottom of the column to the top[48].

There are currently four variants of the Impella in use today: The Impella 2.5, which can increase cardiac output by up to 2.5 L/min, the Impella CP, which can increase cardiac output by up to 4.0 L/min, the Impella 5.0, which can increase cardiac output by up to 5.0 L/min, and the Impella RP, which is designed for use in the RV. Of the LV devices, the Impella 2.5 and Impella CP can be placed percutaneously, whereas the Impella 5.0 requires a femoral cut-down or axillary access for proper placement[49].

5.2.2 Device function and hemodynamic effects

Most often, the Impella device is placed by accessing the femoral artery with a 13-French sheath. A guidewire and catheter are advanced into the aorta and through the aortic valve into the LV. The catheter is then exchanged for the manufacturer-supplied guidewire, and the device is loaded onto this wire and advanced until it crosses the aortic valve, with the inlet portion of the device in the LV and the outlet portion of the device in the ascending aorta. TEE and/or fluoroscopy can be used to assist in proper device placement. The device is attached to a computer console, which can be used to control device function[10, 50].

The Impella device functions by aspirating blood from the LV into the inlet and expelling it from the outlet into the ascending aorta and systemic circulation. This serves to reduce LV preload, thus decompressing the ventricle, decreasing myocardial wall tension and oxygen demand, as well as improving overall cardiac output and systemic perfusion[13].

5.2.3 Complications

Complications associated with the Impella include vascular injury or thrombosis leading to cerebrovascular accident or limb ischemia, bleeding, coagulopathy, and injury to the aortic valve. Hemolysis has also been described as a complication. Furthermore, if the device is improperly positioned, it can cause LV volume overload and/or worsening cardiac function, thus putting the patient at risk for decompensation. Due to the positioning of the device, it may also provoke dysrhythmia. Because anticoagulation is required to use this device, complications relating to heparin use may also be seen, such as bleeding. It is also noteworthy that the device may need to be repositioned periodically to ensure proper function. This must usually be done with TEE or transthoracic echography (TTE) guidance, and skilled personnel must be readily available to perform these adjustments, when necessary. The device itself, like any mechanical device, is also susceptible to malfunction[51-52].

5.2.4 Contraindications

The Impella is contraindicated in patients with a prosthetic aortic valve, a severely calcified aortic valve, grade 2 or greater aortic insufficiency, and/or severe peripheral arterial disease. Relative contraindications include aortic disease such as aortic dissection or aneurysm, or the presence of femoral-popliteal bypass grafts, which could be damaged during device placement[53]. While severe aortic stenosis was previously considered a contraindication, the device has now been used successfully in these patients[54]. In patients who have had aortobifemoral bypass grafts, it may be prudent to consult a vascular surgeon prior to use or to place the device at an alternative access site such as the subclavian or axillary arteries.

5.2.5 Anesthetic implications

For hemodynamic monitoring of patients with these devices, it should be noted that blood flow is non-pulsatile[6]. An arterial catheter would likely be required for monitoring mean arterial pressure. Intraoperatively, TEE, TTE, and/or fluoroscopy should be available to evaluate the positioning of the device, particularly when transferring the patient to different location.

5.3 TandemHeart

5.3.1 Device characteristics

The TandemHeart consists of a 21-French inflow cannula, a centrifugal pump and control console, and a 15- to 19-French outflow cannula. In contrast to other devices, the TandemHeart is placed by accessing the venous circulation by way of the femoral vein, into the right atrium, and then placing the inflow cannula into the left atrium by trans-septal puncture. The outflow cannula is placed in the femoral artery, where it returns blood to the systemic circulation[55].

5.3.2 Device function and hemodynamic effects

By aspirating blood from the right atrium and returning it to circulation peripherally, the TandemHeart is able to augment cardiac output by up to 4.0 L/min of flow. However, because it is returning blood to the peripheral arterial circulation, it can increase afterload, thus the myocardial oxygen supply/demand balance may not be improved upon by TandemHeart as much as with some other devices. One advantage of TandemHeart is that the device bypasses the LV and can be used in the case of LV thrombus[56].

5.3.3 Complications

Use of the TandemHeart is limited due to the difficulty of placement. It requires considerable technical skill to properly position it. Additionally, as with most invasive vascular procedures, vascular injury and bleeding are potential complications. There have been reports of peripheral arteriovenous fistula at the puncture site, where communication between the femoral artery and femoral vein is created, which could ultimately lead to compartment syndrome and limb ischemia. Cannula dislodgement may occur with patient transfer as well, so care must be taken to properly secure the device[57]. Thrombus formation leading to cannula thrombosis or embolization is another risk with this device, and proper anticoagulation and anticoagulation monitoring must be utilized. Typically, an activated clotting time of 300 seconds is desirable for the safe use of this device. Unfractionated heparin is the most commonly used agent, but in patients unable to receive heparin, bivalirudin or argatroban may be substituted[58-59]. Other complications that have been described are wound

infection, limb ischemia, and lymphocele[60].

5.3.4 Contraindications

Because systemic anticoagulation is required, any contraindication to anticoagulation would preclude the use of the TandemHeart device. Additionally, patients with severe peripheral arterial disease maynot be able to safely have the device placed. Also of note, because the functionality of this device requires adequate left atrial volume, the RV must function well enough to provide this volume. Pharmacological or additional mechanical support may be necessary in patients with depressed RV function. Finally, because the inflow cannula is situated in the left atrium, a left atrial thrombus is another contraindication for the use of this device[61].

5.3.5 Anesthetic implications

TandemHeart has been successfully used as a rescue device in patients with critical aortic stenosis, as a bridge to aortic valve replacement[62]. It has also been used in a variety of other rescue situations, such as left main occlusion in a transcatheter aortic valve replacement where the vessel was occluded following valve deployment[63], and it has also been described in supporting a failing heart during the transcatheter aortic valve replacement procedure itself[64].

For hemodynamic monitoring of a patient with a TandemHeart device, it should be noted that this is a continuous flow device and may require invasive blood pressure monitoring to assess hemodynamics. As mentioned previously, cannula migration is a common complication of this device, and it may need to be re-positioned in the catheterization lab.

5.4 ECMO

5.4.1 Device characteristics

One of the more versatile circulatory support devices, ECMO can serve a variety of purposes depending on the type of ECMO device used and the location of cannula placement. Veno-venous (V-V) ECMO provides oxygenation/ventilation support only, as it aspirates blood from the venous circulation, passes it through a membrane oxygenator for gas exchange, and returns it to the patient's venous circulation through another cannula. Alternatively, the Avalon device uses a single, dual-lumen cannula that performs the same function with a single puncture site[65].

Veno-arterial (V-A) ECMO provides circulatory support, as well as oxygenation, and can be used as MCS when such a device is indicated. It functions in essentially the same way as a miniaturized version of a CPB circuit, without the additional functions such as cardioplegia administration, which would not be useful in this setting. For V-A ECMO, a cannula placed in the venous circulation drains deoxygenated blood, passes it through a membrane oxygenator for gas exchange, and returns it to the patient's circulation through an arterial cannula[66].

5.4.2 Device function and hemodynamic effects

In patients requiring assistance with gas exchange without circulatory support, V-V ECMO may be a viable intervention. V-V ECMO is frequently used for temporary support in patients with acute respiratory distress syndrome and occasionally in other disorders of pulmonary gas exchange.

In patients requiring MCS, V-A ECMO is the more appropriate intervention. The outflow from the aortic cannula can augment cardiac output by up to 6 L/min, or in some cases, greater[67]. Similar to TandemHeart, however, due to increased volume and filling pressures, ventricular stress and the myocardial oxygen supply/demand balance may not be improved. For some patients, additional measures may need to be taken to help unload the LV, such as an additional MCS device or placement of an LV vent. The Impella 2.5 has been used successfully for this purpose[68].

5.4.3 Complications

Similar to TandemHeart, thrombosis of the pump or cannulae may occur, causing malfunction of the device and a reduction in effectiveness. There may also be risk of embolization leading to end-organ ischemia, including cerebrovascular accident. To help prevent this, systemic anticoagulation, typically with unfractionated heparin, is required to a suggested activated clotting time of at least 180 seconds[69]. If unfractionated heparin is contraindicated, alternative agents such as argatroban and bivalirudin may be substituted[70-71]. Bleeding complications are also possible, as is vascular injury at the site of cannula placement.

5.4.4 Contraindications

The ECMO system requires continuous monitoring, and as such, should not be placed if properly trained personnel, frequently perfusionists, are not available to manage this. Some contraindications may include severe aortic insufficiency, LV thrombus, and an uncontrolled bleeding disorder[72]. Additionally, procedural

modifications may be required in patients with severe peripheral arterial disease, central cannulation may be necessary, or the device may not be able to be safely placed at all[73].

5.4.5 Anesthetic implications

Several things must be considered when administering an anesthetic to a patient on ECMO. Each institution may have specific guidelines for anticoagulation, as well as antimicrobial therapy, which should be followed by the anesthesiologist. As with any patient with severe cardiopulmonary disease, vasoactive medications for hemodynamic support may be required and should be used appropriately. Additionally, the volume of the ECMO circuit, as well as diminished levels of plasma proteins, may affect the volume of distribution and availability of some medications. The materials found in the ECMO circuit itself may also interact with some medications, affecting volume of distribution[74].

It has been suggested that ventilation of patients on ECMO should have tidal volumes limited to less than 6 mL/kg of predicted body weight and also a maximum peek end-inspiratory plateau pressure to a maximum of 29 cmH_2O (1 cmH_2O=0.098 kPa), and additional carbon dioxide removal by the ECMO circuit may also be beneficial. This ventilatory strategy may reduce the release of inflammatory mediators that can cause lung injury[75].

6 Choosing the appropriate MCS device

When deciding whether to place a MCS device, many factors should be considered. The clinician should evaluate the condition of the patient, device indications and contraindications, as well as the hemodynamic effects of the devices available for a given indication. The comfort level of the individuals placing the device and the ancillary staff who will be monitoring its function should be considered as well. As these are temporary devices, it is also important to consider what the next stepwill be in managing the patient. And finally, device cost should be considered.

As the IABP is generally the easiest of the devices to place and the least expensive of the devices, it is frequently the first one chosen, assuming it is appropriate for the patient. It has also been shown, in a Meta-analysis by Cheng et al[76], that although the other MCS devices may provide greater hemodynamic support, no benefit in 30-day mortality was demonstrated when comparing the these other devices to IABP. It should also be noted that the authors of this Meta-analysis believe it to be under-powered due to the small sample size of the studies available for inclusion.

7 Conclusions

With a variety of MCS devices available, useful in a variety of different settings, the clinician will have a multitude of options for supplemental support of cardiac function that go beyond the traditional pharmacologic inotropic therapies. These devices can be used to treat cardiogenic shock or during high-risk PCI, in other high-risk cardiac procedures, to assist in weaning from CPB, and in some situations, may be useful for hemodynamic support during non-cardiac surgery.

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