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# Advanced Percutaneous Mechanical Circulatory Support Devices for Cardiogenic Shock

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## Abstract

**Objective—**To review temporary percutaneous mechanical circulatory support devices (pMCS) for the treatment of cardiogenic shock, including current evidence, contraindications, complications, and future directions.

**Data Sources—**A MEDLINE search was conducted with MeSH terms: cardiogenic shock, percutaneous mechanical circulatory support, extracorporeal membrane oxygenation (ECMO), Impella, and TandemHeart.

**Study Selection—**Selected publications included randomized controlled trial data and observational studies describing experience with pMCS in cardiogenic shock.

**Data Extraction—**Studies were chosen based on strength of association with and relevance to cardiogenic shock.

**Data synthesis—**Until recently, there were few options if cardiogenic shock was refractory to vasopressors or intra-aortic balloon pump (IABP) counterpulsation. Now, several pMCS devices, including Impella®, TandemHeart™, and ECMO, are more accessible. Compared with IABP, Impella provides greater hemodynamic support, but no reduction in mortality. Similarly, TandemHeart improves hemodynamic variables, but not survival. Comparative studies have been underpowered for mortality because of small sample size. Veno-arterial ECMO offers the advantage of biventricular circulatory support and oxygenation but there are significant vascular complications. Comparative studies with ECMO have not been completed. Despite lack of randomized controlled data, there has been a substantial increase in use of pMCS. Several ongoing prospective studies with larger sample sizes may provide answers, and newer devices may become smaller, easier to insert, and more effective.

**Conclusions—**Mortality from cardiogenic shock remains unacceptably high despite early coronary revascularization or other therapies. While evidence is lacking and complications rates are high, improvements and experience with pMCS may offer the prospect of better outcomes.

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**Keywords**

Cardiogenic shock; mechanical circulatory support; percutaneous ventricular assist device

## Introduction

Despite modern advances, cardiogenic shock still occurs in over 8% of ST-segment elevation myocardial infarction (MI) with mortality nearing 50%.[1–3] Until recently, an intensivist's armamentarium consisted of vasoactive agents and intra-aortic balloon pump (IABP) counterpulsation, neither of which have demonstrated mortality benefit in cardiogenic shock.[4–7] Although introduction of IABP counterpulsation was hailed as a major advance, there was no mortality benefit at 30-day or 12 month follow-up in a major randomized controlled trial of IABP vs. medical therapy in 600 subjects eligible for revascularization (IABP-SHOCK II).[6,8] The IABP-SHOCK II trial has been criticized because of a high cross-over rate, relatively smaller sample size, timing of IABP insertion, and lower mortality (40%) than reported earlier. Notably, there were positive trends in certain subsets, that some hypothesize could benefit from IABP support.[9] Nevertheless, the recommendation for IABP use has been downgraded from Class I to IIa in the United States (US) and European guidelines. Percutaneous mechanical circulatory support (pMCS) carries a Class IIb recommendation.[10,11]

Similar to the IABP, short-term pMCS has not shown improved outcomes in cardiogenic shock.[12] Despite this, use of percutaneous ventricular assist devices (pVADs) has increased 30-fold between 2007 and 2012, including in patients undergoing percutaneous coronary intervention (PCI) for acute MI (AMI) without cardiogenic shock.[13,14] With so many options and little data, proper guidance has been lacking for clinicians, but is being developed.[15] This review focuses on short-term advanced pMCS for cardiogenic shock, including current evidence, contraindications, complications, trends, and future directions.

## Study Design

This review describes the current use of Impella® and TandemHeart™ devices, termed pVADs, as well as extracorporeal membrane oxygenation (ECMO), collectively termed pMCS. A MEDLINE search was performed with MeSH terms cardiogenic shock, percutaneous mechanical circulatory support, extracorporeal membrane oxygenation (ECMO), Impella, and TandemHeart. Randomized controlled trial data and observational studies were selected based on use of pMCS in cardiogenic shock. The IABP has been extensively reviewed elsewhere and was excluded.

## Circulatory Support Devices

The common goal of pMCS devices is to improve cardiac function while awaiting reversal of the cause of cardiogenic shock.

## Impella®

The Impella (Abiomed, Inc., Danvers, Massachusetts) devices are intracardiac pumps (Figure 1A). They produce nonpulsatile, axial-flow designed to pump blood from the left ventricle (LV) into the ascending aorta; Impella 2.5 L/min, Impella CP (Cardiac Power), and Impella 5.0 L/min (Table 1).[15] In addition, the Impella RP (Right Percutaneous) is available for treatment of right heart failure.[16] The Impella CP provides an intermediate level of support of 3.0–4.0 L/min of blood flow and is now available in the US.[17] The smaller devices are inserted percutaneously via the femoral artery, or infrequently the axillary artery, and are advanced retrograde across the aortic valve. The larger Impella 5.0 has required a surgical cut down,[18] but transcaval access is a novel approach designed to facilitate placement of large devices in patients ineligible for femoral artery access.[19]

Unlike the IABP which decreases LV pressures and increases stroke volume (Figure 2A), Impella devices entrain blood from the LV to pump into the aorta in series, thus unloading the LV and reducing myocardial oxygen consumption and demand. The resulting decrease in LV pressures and volumes decreases cardiac workload (Figure 2B).[15,20] Since Impella is positioned in the LV, there are obvious contraindications including significant aortic valve disease, mechanical aortic valve and LV thrombus.[15,21]

There are two small randomized controlled trials comparing Impella and IABP for patients with cardiogenic shock (Table 2).[16,17,22] One study randomized patients with AMI and cardiogenic shock to Impella 2.5 (n=12) vs. IABP counterpulsation (n=13). Compared with IABP, the Impella group had higher cardiac index (0.49L/min/$m^2$ vs.0.11 L/min/$m^2$; p=0.02) at 30 minutes after implantation, but 30-day mortality was roughly 50% in each group (p=0.97).[22] More recently, Impella CP was compared with IABP in 48 patients with shock after AMI. Thirty-day mortality was about 50% in each group (p=0.92).[17] Neither study was powered to detect differences in mortality. These trial data were combined with data from a study of Impella 2.5 vs. IABP in 21 subjects with cardiogenic pre-shock.[23] The resultant meta-analysis reported no difference in mortality at 30 days (RR 0.99, [CI 0.62–1.58]; p=0.95) or 6 months (RR 1.15, [0.74–1.48]; p=0.53).[24]

In 154 consecutive “real-world” patients from the USpella Registry with cardiogenic shock undergoing PCI, those receiving Impella 2.5 pre-PCI had reduced mortality compared to those receiving the device post-PCI (40.7% vs. 65.1%; p=0.003). Almost 90% of these patients had failed inotropes and/or IABP, and about 38% of them would have been considered too ill to be included in the IABP-SHOCK II trial.[6,25]

There are few studies, mostly non-randomized trials, assessing the utility of Impella 5.0. In a retrospective single center review comparing mortality in 34 patients with cardiogenic shock who received the Impella 2.5 or 5.0, the Impella 5.0 group had higher 30-day survival (33% (3/9) vs. 24% (6/25)). However, the study was not randomized or blinded and there were crossovers to Impella 5.0.[26] Several other single center, retrospective studies have shown more favorable outcomes for cardiogenic shock when treated with Impella 5.0.[27] In a multicenter, prospective, feasibility study without a control group, Impella 5.0 was used in 16 patients with postcardiotomy cardiogenic shock with 94% survival at 30 days.[28]

### TandemHeart™

The TandemHeart (CardiacAssist, Inc., Pittsburgh, PA) is a continuous flow centrifugal extracorporeal assist device, withdrawing oxygenated blood from the left atrium and returning it to the femoral artery (Figure 1B). The inflow cannula is inserted percutaneously, via the femoral vein and advanced into the left atrium. This procedure requires a catheterization laboratory and experience in trans-septal puncture.[21] Oxygenated blood is pumped through a femoral artery cannula at blood flow rates of 3.5–5.0 L/min depending on cannula size.[29] Although TandemHeart can also support the right ventricle with placement of the inflow cannula in the right atrium and outflow cannula in the main pulmonary artery, this indication is not approved by the US Food and Drug Administration.[15]

Hemodynamic benefits include near-systemic blood flow rates, improved mean arterial pressure, and reduction in the pulmonary artery occlusion pressure.[30] In simulated models, TandemHeart provides support intermediate between Impella 2.5 and Impella 5.0.[21] Similar to Impella, TandemHeart reduces cardiac workload by decreasing LV pressures and volumes (Figure 2B),[15] although, placement high in the aorta could increase afterload and offset LV unloading,[31] especially in low cardiac output states.[21] Contraindications include intracardiac thrombus and ventricular septal defect.[15]

In a review of 117 patients with refractory cardiogenic shock despite IABP counterpulsation or high-dose vasopressor support, insertion of TandemHeart improved hemodynamics significantly, and was associated with 40.2% 30-day mortality. This was lower than anticipated given that nearly half underwent cardiopulmonary resuscitation (CPR) preceding TandemHeart insertion.[29] Two randomized studies have compared TandemHeart to IABP in patients with AMI complicated by cardiogenic shock.[32,33] Each reported improved hemodynamic parameters but more complications in TandemHeart compared with IABP. Neither study reported a statistically significant difference in 30-day mortality. A subsequent meta-analysis that included the TandemHeart studies and the first Impella 2.5 randomized trial reported no mortality difference at 30-days (RR 1.06, 95% CI 0.68–1.66).[12] The total population was small (n=100) and limited by heterogeneity in outcomes, likely due to combination of two different types of pVADs in the analyses.

### Extracorporeal Membrane Oxygenation

Initially developed in the 1970s, ECMO has experienced recent improvements in technology, as well as a rise in cardiopulmonary usage.[34] Venoarterial (VA)-ECMO (Figure 1C) includes a centrifugal (nonpulsatile) pump, heat exchanger, and membrane oxygenator allowing for full biventricular support (≥ 6 L/min) and gas exchange.[35] VA-ECMO involves peripheral cannulation via the femoral vein and artery or centrally with cannulation of the right atrium and ascending aorta. Given the large diameter of the cannulas, reperfusion lines are often placed to allow blood flow distal to the insertion sites.[36] Previously, ECMO was initiated in the operating room, but more recently, percutaneous cannulation has been performed at the bedside.[35] While standard care includes a large, multidisciplinary team, initiation has occurred safely at remote institutions before transport to ECMO centers.[37]

Removal of venous blood reduces cardiac preload. Simultaneously, reinfusion of blood through the arterial cannula increases mean arterial pressure by increasing both systolic and diastolic pressures (Figure 2C).[15] Depending on native LV function, the increase in afterload with ECMO can elevate left heart filling pressures.[35] Several strategies to assist LV decompression while on ECMO include inotropic support or implantation of an Impella device or IABP or other LV venting plan.[36,38]

The evidence for the utility of ECMO in patients with cardiogenic shock is scant and there are no randomized controlled studies comparing ECMO with pVADs. In a retrospective review comparing patients with cardiogenic shock who received a pVAD (TandemHeart or Impella 5.0, n=18) vs. ECMO (n=61), there was no significant difference in rates of long-term support, complications, or in-hospital mortality.[39] A recent meta-analysis of cohort studies found that patients treated with ECMO had a higher 30-day survival compared with IABP ($p<0.001$, NNT 13), but no difference when compared with pVADs ($p=0.70$).[40] Another retrospective case series reported lower 30-day mortality in patients with cardiogenic shock undergoing ECMO-assisted PCI vs. ECMO-unassisted PCI (39.1% vs. 72%, respectively). However, the ECMO-unassisted group was a historic control group (1993–2002) and likely received a different standard of care.[41]

With the ability to deploy at the bedside and transport, another growing use of ECMO is in refractory cardiac arrest, termed extracorporeal CPR (E-CPR). The prospective, single-center CPR, Hypothermia, ECMO, and Early Reperfusion (CHEER) trial included 26 patients with refractory in-hospital and out-of-hospital cardiac arrest. Intensivists performed ECMO cannulation. Return of spontaneous circulation and full neurologic recovery occurred in 96% and 54% of patients, respectively.[42]

## Complications

Given the large bore cannulas and need for systemic anticoagulation, there are many complications common to pMCS devices including limb ischemia, bleeding, vascular injury, infection, thromboembolic events, and hemolysis.[15] Common contraindications include severe peripheral vascular disease, significant aortic valve disease, and the inability to tolerate systemic anticoagulation.

In general, Impella devices are associated with the most hemolysis amongst pMCS. If hemolysis persists and results in acute kidney injury, device removal should be considered. Alternatively, if hemodynamically tolerable, decreasing device motor speed may reduce the degree of hemolysis.[23,43,44] Data from the USpella Registry and Impella-EUROSHOCK-registry estimate the frequency of hemolysis at 5.0–10%.[25,44] Rarely, the Impella devices have been associated with LV perforation. When proper techniques are used, arterial complications of Impella 2.5 are similar to IABP.[45] With the exception of vascular injury, complications rates for Impella CP and 5.0 are reportedly comparable with Impella 2.5.[16,17,27]

Proper placement of Impella is critically important, and requires close monitoring as migration can occur. Suction alarms suggesting inadequate blood volume for pump may

indicate migration to the LV apex, but can also occur for other reasons, including acute hypovolemia from bleeding, dehydration, or RV failure. If a suction event occurs, the patient should be assessed for hypovolemia as well as device location by echocardiogram or fluoroscopy.[45] Unique to Impella is a purge cassette with heparin solution, which is designed to prevent blood from entering the motor. Purge alarms can signal various complications along the system, including leakage, air, blood in the motor, or tube kinking.[45]

Due to cannula size, TandemHeart and ECMO are most often associated with limb ischemia, bleeding, and vascular injury.[43] In a small trial comparing TandemHeart to IABP in cardiogenic shock, the TandemHeart group had more bleeding (42.1%vs.14.3%) and limb ischemia (21.1%vs.14.3%).[32] Another study described development of disseminated intravascular coagulation in nearly all patients with TandemHeart after two or more days.[33] Unique to TandemHeart is the possibility of residual atrial septal defect due to the trans septal approach.[43] Dislodgement of the device into the right atrium can cause massive shunting, with deoxygenated blood being delivered to the arterial system.[15] In a meta-analysis of the three randomized trials (n=100) comparing pVADs (Impella 2.5 and TandemHeart) to IABP for cardiogenic shock, the pVAD group had more bleeding (RR 2.35 [1.40–3.93], $p<0.01$) and a trend towards more limb ischemia (RR 2.59 [0.75–8.97]).[12] Also, unlike ECMO, pVADs do not provide biventricular support, so in biventricular failure, LV pVAD insertion could lead to RV volume overload and worsening RV failure with a subsequent reduction in LV cardiac output.

Hemorrhage at multiple locations, including cannulation sites as well as the neurologic and pulmonary systems, remains one of the most devastating complications of ECMO.[35,46,47] In an analysis of almost 1900 patients with cardiogenic shock or cardiac arrest requiring ECMO, complication rates were 40.8% for major bleeding; 16.9% for lower extremity ischemia; 5.9% for stroke; 30.4% for significant infection; and varying rates for both venous and arterial thrombus.[47] Renal complications are also exceedingly common in patients on ECMO. Estimates of the incidence of acute kidney injury are as high as 80% with a subsequent increased mortality. Many patients progress to renal failure requiring continuous renal replacement therapy.[48] However, the relationship is complex and multiple factors may contribute to worsening renal function including concomitant therapies, overall severity of illness or ECMO itself.

Femoral artery placement of the arterial cannula directs blood flow in a retrograde direction towards the heart. If native cardiac function is poor, the ECMO output perfuses both the cerebral and coronary circulation, regardless of pulmonary function. If cardiac function is robust or recovers, a watershed mixing point can develop opposite the ECMO flow. Supplying the heart with poorly oxygenated blood from the lungs could lead to hypoxemia to the upper half of the body, also known as North-South or Harlequin Syndrome. Oxygenation of the cerebral and coronary beds can be checked by sampling the right radial artery.[35] Also, given the potential for LV over distension and worsening pulmonary edema with retrograde ECMO flow, there is increased risk of acute lung injury.[49]

## Current Trends

While studies have shown an improvement in hemodynamics with pMCS, there is no clear survival benefit.[12,16,22,32,33] There is also lack of uniformity amongst professional societal guidelines.[10,15] Nevertheless, data from the National Inpatient Sample reports that pVAD use has increased 30-fold from 2007 to 2011 (Figure 3).[13,50] Further, the number of hospitals with an annual volume of 10 or more pVADs increased from 0 in 2007 to 102 in 2011 (p for trend <0.001). When compared with IABP, this increase in pVAD use was associated with a substantially increased cost.[13] Yet, by comparison with surgically implanted hemodynamic support devices such as ECMO, analysis of a national administrative database (MedPAR) suggests that use of percutaneous VADs in cardiogenic shock are associated with lower cost ($p<0.001$).[51] They also reported better survival and shorter length of stay with pVADS, but interpretation of these results are limited by the study's observational design.

## Gaps in Knowledge

Given the absence of a properly powered study to detect discrete outcomes like mortality, the true benefit or harm of temporary pMCS is unknown. In addition to small patient sample sizes, current studies have failed to detect differences in outcomes due to variance in timing of implantation, device management, and patient selection, as well as inherent difficulties in studying this population.[23,52]

As centers increase their yearly volume of pMCS implantation and multidisciplinary teams gain experience, complications rates have decreased.[53] Analogous to door-to-balloon time, proper timing of intervention or "door-to-unloading" time has been suggested to prevent the progressive spiral of myocardial dysfunction seen in cardiogenic shock.[3,43] Finally, the utility of employing temporary pMCS to improve candidacy of more durable VADs is unclear.

## Device Selection

Once a decision to deploy mechanical support has been made for cardiogenic shock, the device should be inserted without delay to prevent progressive myocardial dysfunction. As discussed, definitive evidence for choice of device is lacking. Device selection should include assessment of familiarity, cost, consideration for right heart failure, degree of support needed, and institutional capabilities. In the absence of severe biventricular failure, the IABP remains a reasonable first option, because of lower cost, clinician familiarity, and option for bedside insertion. Consideration for pVAD becomes more practical in the setting of the cardiac catheterization laboratory. Although more expensive, with experience an Impella insertion may be as rapid as the IABP and is becoming first line for some centers.[15] For patients with biventricular failure, concomitant respiratory failure, or cardiac arrest, ECMO is the best choice in experienced centers.

## Future Directions

There are ongoing trials with higher patient enrollment, which could provide more answers. One notable trial for cardiogenic shock is the Danish Cardiogenic Shock Trial (DanShock; NCT01633502), which plans to randomize 360 patients to either the Impella CP or conventional circulatory support. Another is the ExtraCorporeal Membrane Oxygenation in the Therapy of Cardiogenic Shock (ECMO-CS; NCT02301819) trial with an estimated enrollment of 120 patients randomized to VA-ECMO or early conservative therapy.

Although great technological strides have occurred, future devices aim to be smaller and more powerful with faster insertion at the bedside and fewer complications. Currently in development, the i-cor system (Xenios AG, Heilbronn, Germany) is similar to an ECMO circuit and provides up to 8 L/min of blood flow. Novel to the i-cor device, continuous flow or diastolic augmentation with ECG-triggered pulsatile flow can be provided. The HeartMate PHP (Percutaneous Heart Pump, St. Jude, St. Paul, MN) is an axial flow circulatory device, which expands when across the aortic valve and provides up to 5 L/min of blood flow. It is currently being compared to the Impella 2.5 in high risk PCI patients. The Reitan Catheter Pump (CardioBridge GmbH, Hechingen, Germany), placed in the descending thoracic aorta distal to the subclavian artery, creates a pressure gradient similar to the IABP counterpulsation resulting in decreased afterload and increased perfusion distally. Also positioned in the descending aorta, the Aortix device (Procyrion Inc., Houston, TX) has expanding anchors and a transcutaneous charger allowing for sheath removal and potentially provides durable support.[36]

## Conclusion

The prognosis for patients with cardiogenic shock remains poor despite current therapy. Temporary pMCS offers the opportunity to improve these outcomes, but still requires large studies powered to evaluate mortality as well as continued improvements in technology to decrease complications.

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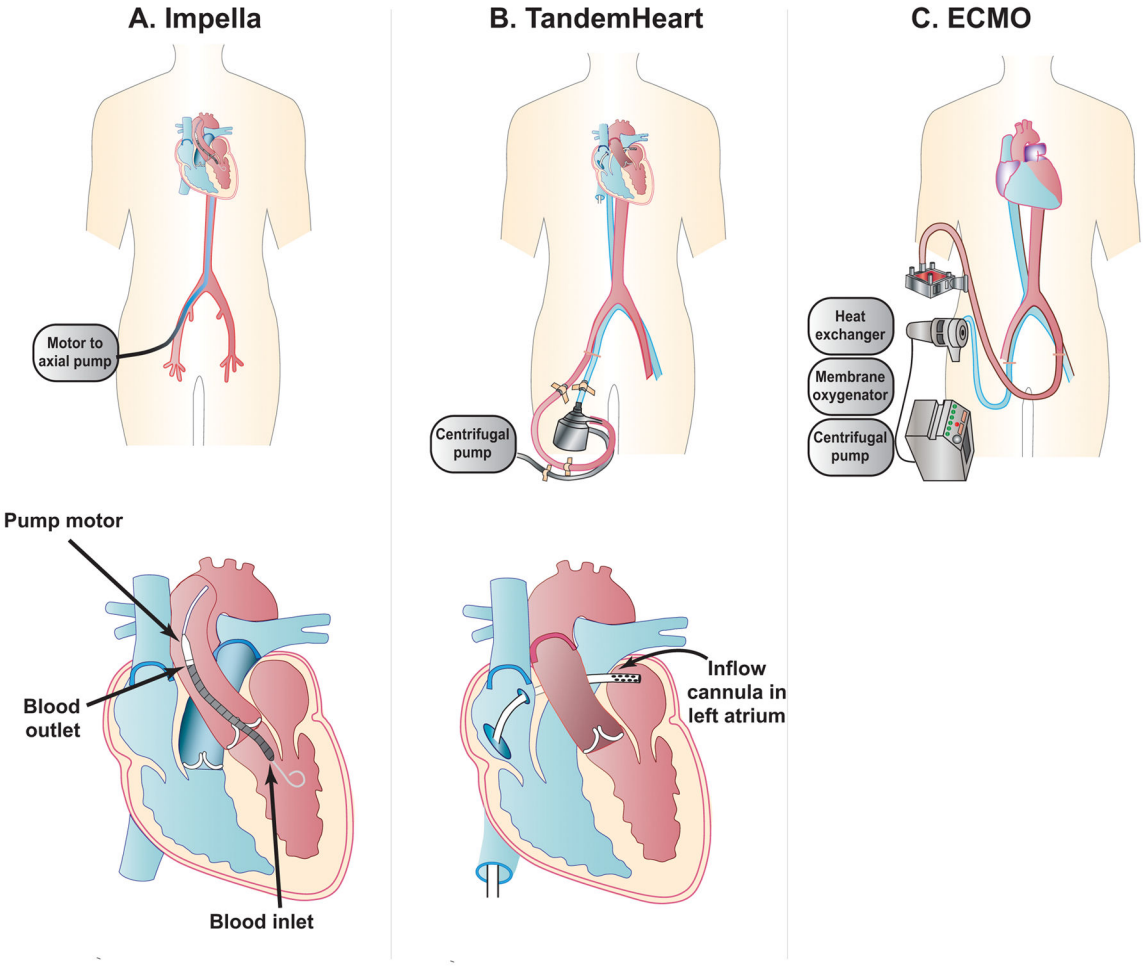


**Figure 1. Percutaneous Mechanical Circulatory Support Devices**

Schematic diagrams of percutaneous ventricular assist devices for cardiogenic shock including (A) Impella catheter; (B) TandemHeart; and (C) ECMO (extracorporeal membrane oxygenation).

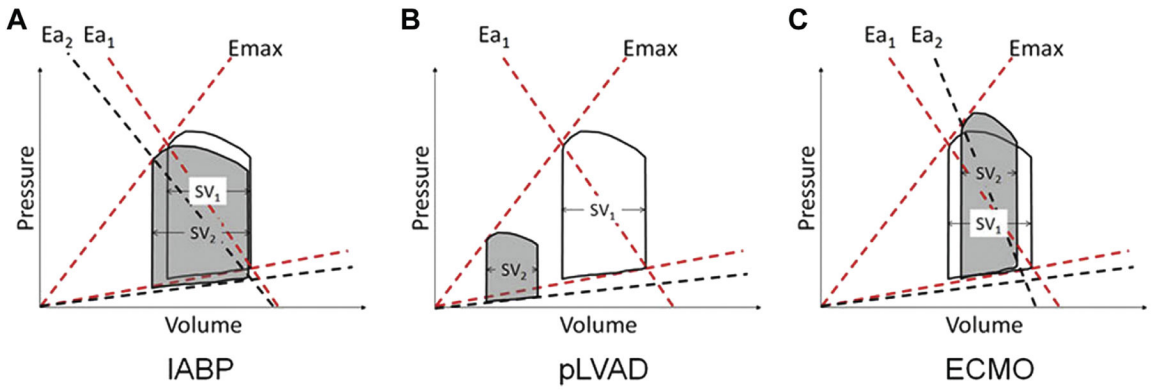


**Figure 2. Pressure Volume Loops of Percutaneous Mechanical Circulatory Support Devices**

Cardiac effects of mechanical support. Illustrations of pressure volume (PV) loops before (non-shaded loops) and after activation of device therapy (shaded loops). Emax is load-independent contractility, defined as the maximal slope of the end-systolic PV point under various loading conditions. (A) Intra-aortic balloon pump (IABP) counterpulsation reduces both peak LV systolic and diastolic pressures and increases LV stroke volume. The net effect is a reduced slope of arterial elastance (from $Ea_1$ to $Ea_2$), (B) Percutaneous LV assist devices (pLVAD: Impella and TandemHeart) significantly reduce LV pressures, LV volumes, and LV stroke volume. The net effect is a significant reduction in cardiac workload. (C) Venoarterial Extra-corporeal Membrane Oxygenation (VA-ECMO) without a LV venting strategy increases LV systolic and diastolic pressure, while reducing LV stroke volume. The net effect is an increase in arterial elastance (from $Ea_1$ to $Ea_2$).(Reprinted from *J Card Fail*; Rihal CS, Naidu SS, Givertz MM, et al: SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care. 21; 499–518, 2015 with permission from Elsevier) [15]

**Key:** Ea, arterial elastance; IABP = Intra-aortic balloon pump; ECMO = extracorporeal membrane oxygenation; pLVAD = percutaneous left ventricular assist device; SV, stroke volume.

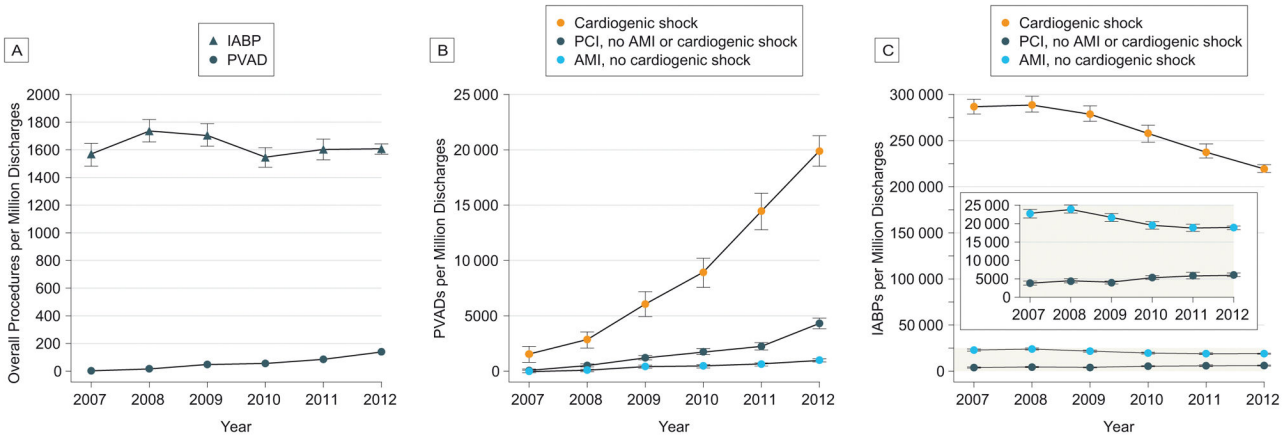


**Figure 3. Calendar Year Trends in the Use of Percutaneous Ventricular Assist Devices and Intra-aortic Balloon Pumps in the United States, 2007 – 2012**

Estimated use of PVADs and IABPs per million discharges (± standard errors). **A.** Use of PVADs increased from 4.6 per million (2007) to 138 per million (2012; *P* for trend < .001). Use of IABPs decreased from 1738 per million (2008) to 1608 per million (2012; *P* for trend = .02). **B.** Use of PVADs increased in patients with cardiogenic shock, AMI without cardiogenic shock, and PCI without AMI or cardiogenic shock (*P* for trend < .001 for all). **C.** Use of IABPs decreased in patients with cardiogenic shock and AMI without cardiogenic shock but increased in patients who underwent PCI without cardiogenic shock or AMI (*P* for trend < .001 for all).

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**Key:** AMI, acute myocardial infarction; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; PVAD, percutaneous left ventricular assist device.

**Table 1**

Characteristics of peripheral mechanical circulatory support devices.

| Parameter | IABP | Impella 2.5 | Impella CP | Impella 5.0 | TandemHeart | ECMO |
|---|---|---|---|---|---|---|
| Blood flow (L/min) | 0.5–1.0 | 2.5 | 4.0 | 5.0 | 3.5–5.0 | ≥ 6.0 |
| Cannula size (Fr) | 7.0–8.0 | 12 | 14 | 21 | 21 venous, 15–19 arterial | 17–24 venous, 16–21 arterial |
| Insertion | Percutaneous | Percutaneous | Percutaneous | Surgical cutdown† | Percutaneous | Percutaneous and surgical |
| Insertion Time | + | 2+ | 2+ | 4+ | 4+ | 2+ |
| Biventricular Support | − | − | − | − | _* | + |
| Anticoagulation | +/− | + | + | + | + | + |
| Hemolysis | 1+ | 2+ | 2+ | 2+ | 2+ | 2+ |
| Limb Ischemia | 1+ | 2+ | 2+ | 2+ | 3+ | 3+ |
| Risk of Bleeding | 1+ | 1+ | 2+ | 2+ | 3+ | 3+ |
| Vascular Injury or stroke | 1+ | 1+ | 2+ | 2+ | 2+ | 2+ |
| Management complexity | + | 2+ | 2+ | 2+ | 4+ | 3+ |

**Key:** CP, Cardiac Power; ECMO, extracorporeal membrane oxygenation; Fr, French gauge; IABP, Intra-aortic balloon pump.

*Placement in the right atrium and pulmonary artery can provide right ventricular support.

†or transcaval access if ineligible for femoral artery access.

**Table 2**

Randomized controlled trials of percutaneous ventricular assist devices (pVAD) compared to intra-aortic balloon (IABP) counterpulsation for cardiogenic shock.

| Study | Date | Condition | Device | Control | Total Sample Size | Primary Outcome | Mortality at 30 days IABP vs. pVAD |
|---|---|---|---|---|---|---|---|
| Ouweneel et al[17] | 2017 | Cardiogenic Shock | Impella CP n=24 | IABP n=24 | 48 | 30-day mortality | 50% vs. 46%** |
| Ouweneel et al[23] | 2016 | Cardiogenic Pre-Shock | Impella 2.5 n=12 | IABP n=9 | 21 | LV ejection fraction at 4 months | 11% vs. 25% ** |
| Seyfarth et al[22] | 2008 | Cardiogenic Shock | Impella 2.5 n=12 * | IABP n=13 | 26 | Cardiac index | 46% vs. 46%** |
| Thiele et al[32] | 2005 | Cardiogenic Shock | TandemHeart n=21 | IABP n=20 | 41 | Cardiac power index | 45% vs. 43%** |
| Burkhoff et al[33] | 2006 | Cardiogenic Shock | TandemHeart n=19 | IABP n=14 | 33 | Hemodynamic improvement | 64% vs. 53%** |

**Key:** CP, Cardiac Power; IABP, intra-aortic balloon pump; LV, left ventricular;

* one patient died prior to implant;

** Not significant