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REVIEW

Complications of Temporary Percutaneous Mechanical Circulatory Support for Cardiogenic Shock: An Appraisal of Contemporary Literature

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ABSTRACT

Cardiogenic shock (CS) is associated with hemodynamic compromise and end-organ hypoperfusion due to a primary cardiac etiology. In addition to vasoactive medications, percutaneous mechanical circulatory support (MCS) devices offer the ability to support the hemodynamics and prevent acute organ failure. Despite the wide array of available MCS devices for CS, there are limited data on the complications from these devices. In this review, we seek to summarize the complications of MCS devices in the contemporary era. Using a systems-based approach, this review covers domains of hematological, neurological, vascular, infectious, mechanical, and miscellaneous complications. These data are intended to provide a balanced narrative and aid in risk–benefit decision-making in this acutely ill population.

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Key Summary Points

Many mechanical circulatory support (MCS) devices are available for the management of cardiogenic shock

There are limited data on the complications from MCS device placement in patients with cardiogenic shock

This review summarizes the complications from MCS devices in the contemporary era in a systematic fashion

Major complications include bleeding, vascular/access issues, hemolysis, cerebrovascular accidents, limb ischemia, sepsis and left ventricular distension

INTRODUCTION

Cardiogenic shock (CS) is a state of low cardiac output resulting in life-threatening end-organ hypoperfusion and hypoxia [1]. Acute myocardial infarction (AMI) with consequent left ventricular (LV) dysfunction remains the most common etiology and comprises nearly 80% of all CS [1–5]. Less frequently, CS is seen as a complication of post-cardiotomy status, end-stage heart failure, Takotsubo cardiomyopathy, acute pulmonary embolism, acute myocarditis, and septic cardiomyopathy [6–14]. Historically, CS patients were managed with the use of high-dose vasopressors/inotropes and the use of intra-aortic balloon pump (IABP) for mechanical circulatory support (MCS) [15]. The use of vasopressors and inotropes for the management of AMI-CS is associated with adverse hemodynamic effects and high myocardial oxygenation consumption, which may be associated with worsening shock [6, 16–18]. Newer percutaneous MCS, such the transvalvular axial flow pumps (Impella®), TandemHeart® and veno-arterial extracorporeal membrane oxygenation (VA-ECMO) have resulted in a paradigm shift in the management of these patients [19]. The current MCS devices improve hemodynamics and decrease the requirement for vasoactive medications [1]. In current practice, advanced percutaneous MCS devices offer attractive alternatives to IABP [19]. The physiologic rationale for MCS includes a decrease in myocardial oxygen demand, LV unloading resulting in decreased LV wall stress, facilitation of myocardial recovery by increasing microvascular flow, and weaning from toxic vasoactive medications that might result in higher myocardial oxygen consumption and worsen refractory shock [16, 20–24].

However, these newer MCS devices are associated with a higher risk of complications, which are variably reported in the literature [19, 21, 25–28]. This variability can be attributed to many factors including changes in technology and insertion techniques of devices over time, differences in patient baseline characteristics and clinical setting, and variability in operator experience based on single-center versus multicenter trials. Additionally, time to follow-up is often only until hospital discharge, but some complications are reported more frequently with longer follow-up periods [29, 30]. The various configurations, extent of support, and access for these devices have been described previously and will not be discussed in this review [1, 19, 31, 32]. The aim of this review is to assess the reported complications and complication rates reported in the literature with four common forms of temporary MCS, and to discuss risk factors that have been identified for the development of complications (Fig. 1 and Table 1).

COMPLICATIONS OF TEMPORARY PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT

Hematological Complications

Major Bleeding

Major bleeding rates are defined and reported differently across studies [21, 33–40]. For the purpose of this review, major bleeding is defined as the need for blood transfusion, or reported bleeding complication that was not defined as an access-site related bleed [33, 37, 38, 41–45]. The use of percutaneous MCS necessitates continuous anticoagulation, which often results in concomitant bleeding. Bleeding rates are affected by the activated clotting time (ACT) recommended for different devices and degree of thrombocytopenia, which is often seen due to the mechanical shear strain of these devices [19]. Early studies of percutaneous IABP insertions prior to 2000 reported bleeding rates ranging from 5 to 8% [46–49]. In a recent systematic review of complications from the IABP, de Jong et al. noted an incidence of bleeding between 0.4 and 27.7% [50]. In a comparative study of all randomized trials comparing percutaneous MCS (Impella or TandemHeart) to the IABP, Thiele et al. reported 17% bleeding rates for IABP support in AMI-CS [51]. One trial investigating IABP in combination with different thrombolytic regimens for AMI reported a moderate bleeding rate of 47%

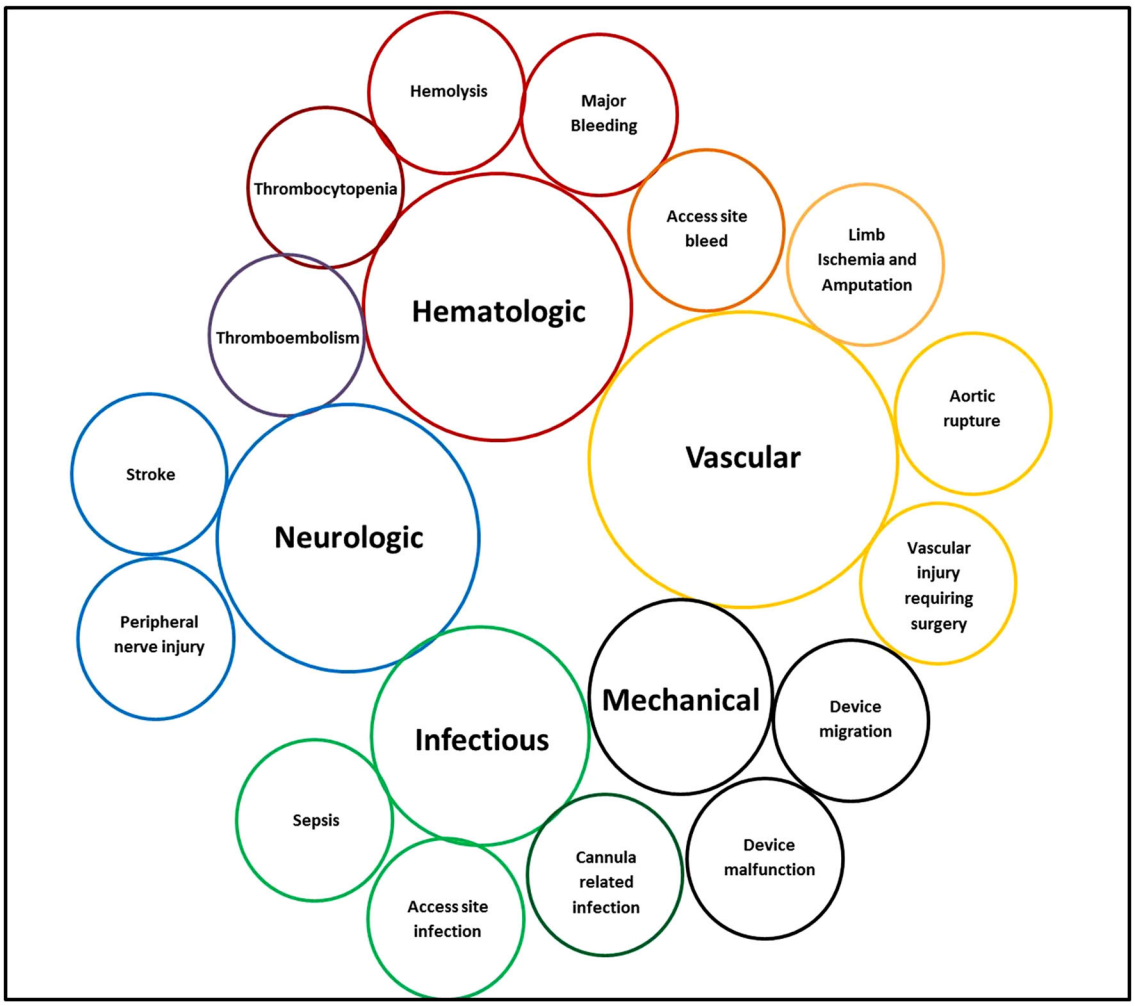

Fig. 1 Complications of MCS by category. Each *color* represents a unique complication category. Complications across more than one category are shown in a combination of colors of the two categories

and severe bleeding rate of 10% [52]. Studies of IABP to support PCI report bleeding rates of 3.3–8.4% [53–55]. More recent studies of IABP for AMI, CS, UA, and perioperative use report rates from 0.8 to 26.3% [33–35, 37, 39, 41, 56–60]. Bleeding rates for Impella® are poorly described, but range from as low as 0.05% to 54% when inserted percutaneously [21, 44, 61–64]. In a meta-analysis of randomized trials in AMI-CS, compared to the IABP, the Impella had a 2.5-fold higher risk of major bleeding [51]. TandemHeart bleeding rates are significantly higher, from 53 to 59.8% [65, 66]. This may be linked to the need for trans-septal puncture, as well as higher index of comorbidity in patients receiving TandemHeart. Rates of major bleeding in VA-ECMO have the most variability, ranging from 5 to 81% [67]. In a meta-analysis of nearly 1900 patients receiving VA-ECMO, Cheng et al. noted major bleeding in 41% (95% confidence interval 27–57%) and the need for re-thoracotomy for major bleeding or tamponade in 42% of all recipients [25].

The mechanisms for bleeding include blood loss in the device circuit, need for anticoagulation, access-site issues, hemolysis due to mechanical strain, thrombocytopenia, acquired von Willebrand syndrome and high shear stress on the circulating blood [25, 67]. Typical sites

Table 1 Prevalence of complications in patients receiving temporary mechanical circulatory support

Complication	IABP	Impella	TandemHeart	ECMO
Hematologic				
Major bleeding	0.8–47	0.05–54	53–59	5–81
Access site bleeding	2–27	2–40	8–53	6
Hemolysis	0.7–7.2	10–46	5.3	9.2–18
Thrombocytopenia	43	–	–	8.3 (HIT)
Neurologic				
Cerebrovascular accident	1–7	2.4–6.3		1.6–17.6
Neuropathy	0.4–24	–	–	–
Vascular				
Limb ischemia	0.3–42	0.07–10	3.4–11	4.3–50
Amputation	0.1–1	–	–	0–1.1
Thromboembolism	1.1–8.6	–	–	18
Aortic rupture/dissection	0.09–9	–	–	< 1
Vascular injury requiring surgery	0.01–13.3	1.3–2	0.85–13	4.7
Infectious				
Access site infection	0.5–35	1.1	16	1.1–17.7
Sepsis	1–15.7	0.16–19	29.9	12.9–31
Mechanical				
Device migration	1–8	0.05–23	8	–
Device malfunction	0.9–8.3	0.16–17	–	16.8–29

All values are expressed as percentage
ECMO extracorporeal membrane oxygenation, *IABP* intra-aortic balloon pump

for hemorrhage (beside access site) include the pulmonary and neurological systems [68, 69]. In about 5% of the population, significant gastrointestinal hemorrhage is noted in patients with pre-existing risk factors [64]. Neurological hemorrhage is often associated with catastrophic outcomes resulting in cessation of MCS use and/or withdrawal of life support [68, 69]. In patients with cardiac or respiratory pathology, such as cardiac arrest, acute respiratory distress syndrome, cardiogenic shock, and post-cardiotomy status, it is difficult to ascribe these bleeding complications to the mechanisms associated with use of MCS alone. It is possible that these patients have a higher risk of complications regardless of the type of MCS device used.

Access Site Hematoma or Bleeding

Due to the use of large-bore peripheral arterial and/or venous access, the use of advanced percutaneous MCS is often associated with access site complications [31, 43, 51]. The rates of access side-related complications vary widely by sheath size and by closure technique, which is device- and patient-dependent. Despite the use of 'safe-femoral' access in contemporary catheterization laboratories in the

contemporary era, the need for emergent access under suboptimal situations often results in higher rates of complications in these patients [70]. There appears to be a direct relationship to size of the vascular cannulae used in these patients. Furthermore, there have been recent reports of the use of more than one type of MCS concomitantly in these patients to offset the limitations of one MCS device with the other and provide incremental cardiac output support [7–10, 71]. Conceivably, this strategy may be associated with higher rates of complications and therefore needs to be carefully balanced against the realistic need for dual mechanical circulatory support [7, 8].

The IABP is complicated by access-site bleeding in 2–27% of insertions, but rates have been consistently below 10% in recent years [33, 35, 41, 47, 49, 53, 54, 59, 72–75]. Access-site complication is infrequently reported for Impella® 2.5. The PROTECT I Trial, a multi-center safety and feasibility study of the Impella® 2.5 in 20 patients undergoing high-risk PCI, has the highest reported rate at 40% [44]. This may be related to the small sample size and limited operator familiarity with the device. The PROTECT II trial of 448 patients with Impella® insertion did not report access-site complications [29]. More recent series have identified lower rates around 2%; however insertion techniques included both surgical and percutaneous approaches [76]. TandemHeart® has the highest risk of access-site-related complications, which is likely related to the large sheath required for insertion. Rates range from 8 to 53% [38, 65, 66, 77]. The highest reported rate of 53% is from a small retrospective study with only 19 TandemHeart® insertions [77]. Access-site bleeding is also very infrequently reported in the VA-ECMO literature, with a reported rate of 6% in a retrospective study of 184 insertions [40]. Lastly, there are limited comparative reports of access site bleeding related to different configurations of MCS devices such as Impella CP versus 5.0, peripheral versus central VA-ECMO, and femoral versus axillary IABP [78].

Hemolysis

The mechanism of hemolysis in patients with temporary MCS is by shear stress from axial pumping. Hemolysis is an infrequently reported complication across all forms of MCS due to challenges in determining true hemolysis. Hemolysis can be measured directly by plasma-free hemoglobin, which is more accurate [44, 79, 80], or indirectly by traditional methods of laboratory evaluation. Given the frequent need for blood transfusion in patients with temporary MCS without a clearly identified source of blood loss in many cases, the true rate of hemolysis may be higher than reported.

One small prospective multi-center study compared IABP and TandemHeart® for the treatment of cardiogenic shock and investigated plasma-free hemoglobin in seven IABP patients and nine TandemHeart® patients [80]. Rates of hemolysis were 7.2% and 5.3% respectively [80]. A larger retrospective single-center study of 3135 IABP insertions from 1985 to 2013 found a much lower rate of 0.7% [75]. In patients requiring Impella support, prior works from large registries have demonstrated hemolysis rates of 7–8% [81, 82]. In a retrospective study of 112 CS patients, Badiye et al. demonstrated a cumulative incidence of hemolysis of nearly 63% [83]. Longer duration of Impella support was associated with a continued need for blood transfusion suggestive of ongoing hemolysis [83]. Furthermore, further data are needed due to define the optimal cut-offs of laboratory parameters in patients with CS being evaluated for hemolysis due to baseline elevations in lactate dehydrogenase [84]. The differences in clinical cut-offs might explain the wide variations in the reported rates of hemolysis with the Impella device [82–84]. Hemolysis is more prevalent in VA-ECMO secondary to the inherent design of the ECMO filter and circuit that is associated with shear forces due to centrifugal pumps and high resistance flow through the oxygenator [85]. A meta-analysis of complications and mortality of ECMO including studies from 1998 to 2011 reported hemolysis rate of 18% [86], but a more recent retrospective study of ECMO cannulations at a single center from 2014 to 2018 reports a lower rate of 9.2% [40]. These data are consistent with data from the

Extracorporeal Life Support Organization data that demonstrated hemolysis in 10% and 7% of pediatric and adult patients, respectively [87]. This may be attributed to better patient selection, improved anticoagulation protocols, and improvement in ECMO circuits [85].

Thrombocytopenia

Thrombocytopenia is classified by severity (mild, moderate, or severe), but for this review will be defined as platelet count < 150,000/ml or > 50% decrease from baseline [37]. In patients with MCS, thrombocytopenia needs careful evaluation since it might be induced by heparin as against being a device-related complication. In 252 patients receiving the IABP (Roy et al.), 43% of patients developed thrombocytopenia [37]. Interestingly, thrombocytopenia did not lead to a significant increase in bleeding or change in outcomes. They also found that heparin-induced thrombocytopenia (HIT) occurred in only a small number of patients and did not significantly affect the rate of thrombocytopenia. There are limited data on thrombocytopenia with the Impella® and the TandemHeart® [88]. Rates are not reported in the ECMO literature, but it is of note that HIT is an important entity in this patient population [89, 90]. In a retrospective single-center analysis of 118 ECMO cannulations from 2009 to 2013, 74% of patients had a HIT ELISA or serotonin release assay performed within 14 days of initiating ECMO [89]. Of the 74% who were screened, 8.3% were determined to have HIT and documentation of concurrent thromboembolic events while on ECMO [89]. The authors investigated platelet count trend and time to platelet count nadir and found that the overall platelet count trend was not significantly different in patients with or without HIT, as almost all patients have a significant degree of ECMO-induced thrombocytopenia [89]. They did find that time to platelet nadir was significantly longer in the HIT-positive group, but attributed this to the longer average time on ECMO observed in this group [89]. Based on these observations, previously validated prediction scores like the 4T score are not useful in this population and it is consensus to test and treat for HIT based on high clinical suspicion [89, 90].

Neurological Complications

Cerebrovascular Accidents

Cerebrovascular accidents (CVA) are a common complication, and are frequently reported as a composite of all cerebrovascular accidents including ischemic CVA, hemorrhagic CVA, and transient ischemic attacks. In patients with CS, there is often concomitant neurological injury due to hypoperfusion, hypoxemia, hyperglycemia, or pyrexia [3, 68]. Furthermore, patients with CS often have overlapping cardiac arrest that is associated with low-flow state and ischemic-reperfusion neurological injury [3]. Therefore, the assessment of neurological injury and development of CVA is complex in this population. CVA rate in IABP is typically low, 1–10% [35, 39, 42, 49, 52, 53, 55, 56, 58, 74, 75, 91]. Impella® and TandemHeart® have rates similar to IABP, reported from 2.4 to 6.3% [29, 65, 66, 82, 88]. Rates of CVA are significantly higher in ECMO, ranging from 3.3 to 17.6% for ischemic CVA [40, 69, 86, 92–96] and 1.6–5% for hemorrhagic CVA [40, 68, 95–97]. Use of anticoagulation in these patients places them at a higher risk of hemorrhagic CVA or hemorrhagic transformation of ischemic CVA [98].

Neuropathy

Neuropathy has been described primarily as a complication downstream of lower-limb ischemia in patients with IABP. There have been isolated reports of femoral cutaneous neuropathy occurring in patients without limb ischemia [99]. Rates of persistent paresthesia and foot drop are reported from 0.4 to 4% [47, 48, 100, 101], with one study from 1987 citing a rate of 24% [102]. While this likely occurs with other forms of MCS, incidence is likely not reported due to lack of clinical significance.

Vascular Complications

Limb Ischemia

Limb ischemia is one of the most feared and most common complications across all forms of MCS, and is the most commonly reported given its clinical significance [51, 58, 82, 103]. Limb ischemia is defined as loss of pulses, Doppler signal [104] or arterial thrombus requiring thrombectomy or surgical intervention [35, 41, 105]. The mechanism of limb ischemia is most often arterial thrombus or occlusion of blood flow to the distal extremity by the MCS device [44, 50, 73, 106–108]. In many studies, the incidence of limb ischemia may or may not include patients who ultimately required amputation; however the reported rates of amputation are low [33, 35, 42, 92, 105].

The rate of limb ischemia for IABP insertion demonstrates wide variations in the literature: 0.03 to 42% [33–35, 42, 46, 48, 55, 57, 58, 73, 80, 91, 99, 100, 102, 109–111], however, more recent studies show lower rates of 0.9–12% [30, 39, 41, 75]. This can partly be attributed to improvements in sheath size, better patient selection, and shorter durations of support. Ozen et al. noted lower rates of limb ischemia (9.2% vs. 14.1%) in patients receiving the IABP without a insertion sheath [75]. In the contemporary cohort of four randomized trials evaluating IABP and Impella in CS, Thiele et al. demonstrated significantly lower rates of limb ischemia with the former (3% vs. 17%) [51]. In 112 AMI-CS patients receiving Impella support, limb ischemia was noted in 3% of the patients over 12 years at a high-volume Danish center [82]. Comparing Impella CP/5.0 to the VA ECMO in 128 patients, Karami et al. noted the Impella group to have lower rates of limb ischemia (2%) compared to the VA ECMO (5%) [64]. There are fewer data on the TandemHeart, with reported ranges of 3.4–11% [65, 66]. There is wide variability on the contemporary rates of the ischemia in patients receiving VA ECMO [40, 86, 92–95, 107, 108]. This is significantly influenced by the urgency of the cannulation, disease processing needing VA ECMO support, cannulation techniques, definition of limb ischemia, caliber of the femoral blood vessels, and the use of distal perfusion cannula [112, 113]. In patients with VA-ECMO, IABP are Impella that may be used to unload the LV to achieve myocardial recovery and decreased LV stasis [7, 8]. In such patients, the use of bilateral femoral access is associated with a higher risk of limb ischemia [113]. Careful serial monitoring of distal perfusion and a potential role for distal perfusion cannula in the ipsilateral extremity are pertinent considerations.

Amputation

Amputation is a rare but serious complication of MCS caused by prolonged limb ischemia. Rates are most frequently reported in IABP and range from 0.1 to 1% [33–35, 48, 73, 100]. Rates of amputation with VA-ECMO are 0.7–2.8% [94, 105, 106, 114–117]. There is one isolated case series of 14 VA-ECMO cannulations in which one patient required amputation for limb ischemia, however this is an outlier based on a small sample size [92]. There are no documented amputations with Impella® or TandemHeart®.

Other Thrombotic Complications

Thromboembolic events causing complications other than limb ischemia are also common. These include thromboembolism not otherwise specified, pulmonary embolism, and mesenteric ischemia. Pulmonary embolism is reported with fairly low rates of 0.1–0.5% in IABP [35, 109]. Mesenteric ischemia has been identified in three IABP studies with rates of 0.1% [35], 0.5% [109], and 1.9% [91]. Rates of other thromboembolic events range from 1.1 to 8.6% [35, 39, 47, 57, 80, 91, 109]. There is also a single case report involving spinal cord infarction [118].

Vascular Injury Requiring Surgery (Non-Access Site)

Vascular injury requiring surgery is typically access site-related, but these complications are occasionally grouped with aortic injury. Reported rates of vascular injury in IABP insertion range from 0.01 to 5.3% [35, 39, 55, 57, 74, 110, 119], with two studies citing 12–13% [91, 120]. Rates with TandemHeart® range from 0.85 to 13% [38, 45, 88].

A recent study cited vascular complications of ECMO at 4.7% [3].

Aortic Rupture or Dissection

Rates of rupture and dissection are most commonly reported with older studies of IABP, ranging from 0.09 to 4% [42, 47, 75, 91, 109, 110]. One study cited a rate of 9% based on postmortem examination, suggesting this may be more common [73]. Aortic rupture from ECMO is only documented in one study, with a rate < 1% [36].

Infectious Complications

Access Site Infection

Access site infection is most commonly reported in IABP, with rates ranging from 0.5 to 35% [47, 48, 101, 109, 110]. This may represent an underestimate, as many studies group all access site-related complications together, which includes bleeding, infection, and vascular injury. TandemHeart® rate is reported in one single-center study of 54 patients at 16% [38]. ECMO is also only reported in one study at 1.1% [40]. Cannula-related infection (CRI) in VA-ECMO has been well described with rates ranging from 3.5 to 17.7% [121]. Given the high incidence of CRI, many centers utilize prophylactic antibiotics to reduce the risk of both CRI and other nosocomial infections, however this is not standardized [122]. O'Horo, et al. performed a systematic review investigating the effects of prophylactic antibiotics to reduce the risk of nosocomial infection. They found that patients with open chest wounds and other high-risk conditions like neutropenia benefited from antibiotic prophylaxis, but there was no evidence to support antibiotic prophylaxis beyond standard surgical prophylaxis in ECMO patients who have no other indication for prophylaxis [122]. This recommendation is consistent with the Extracorporeal Life Support Organization (ELSO) Guidelines [123].

Sepsis and Bacteremia

Sepsis and bacteremia cannot always be ascribed exclusively to MCS, as patients requiring MCS are critically ill and typically have a multitude of potential sources of infection including mechanical ventilation, venous and arterial catheterization, urinary catheterization, and additional surgical intervention [122]. The overall rates of sepsis and bacteremia are similar across all types of temporary MCS with IABP at 1-15.7% [39, 47, 49, 55, 58, 74, 75, 91, 109, 110], TandemHeart ® 29.9% [38], and ECMO 12.9–31% [40, 92–94, 121].

In patients admitted with sepsis, septic cardiomyopathy is seen increasingly in contemporary practice [6, 11, 17, 124–132]. These patients typically have superimposed CS due to septic cardiomyopathy in addition to vasoplegic shock from sepsis. Such patients may benefit from the use of institution of VA-ECMO in addition to pharmacological support [133, 134]. Lastly, patients with sepsis often have frequent acute respiratory distress syndrome that might necessitate veno-venous ECMO support for poor respiratory mechanics [135–137]. Therefore, the relationship between sepsis and MCS is bidirectional and the pathophysiological course needs careful definition to understand causal relationships.

Mechanical Complications

Device Migration

Device migration is infrequently reported. Rates for IABP insertion range from 1 to 8% when monitored by serial chest X-ray [33, 111]. Migration is only reported in the initial safety studies of Impella® at 0.05% [79], and in only one TandemHeart® study at 8% [38]. Device migration is not reported for ECMO.

Device Malfunction

Device malfunction varies by type of MCS. IABP malfunction is typically defined by balloon rupture with rates ranging from 0.9 to 8.3% [34, 35, 39, 42, 46, 47, 75, 91]. Malfunction is only reported in two Impella® studies at 0.16% [79] in the initial safety studies and 17% in a more recent retrospective study comprising both medical and surgical insertions [76]. Malfunction is not reported with TandemHeart®. VA-ECMO has a relatively high rate of device

malfunction, which has increased in recent years likely secondary to increased application. Malfunction of ECMO is often related to oxygenator dysfunction. Two recent studies cite malfunction rates of 16.8% [40] and 29% [86].

Other Complications

Atrial Perforation

Atrial perforation is a complication unique to TandemHeart®, secondary to the need for transseptal puncture, and has been reported with relatively low rates of 0.85% in initial studies [65].

Left Ventricular Distension

LV distension (LVD) is a complication unique to ECMO. LVD is caused by an already-weakened ventricle pumping against an increased blood flow created by VA-ECMO [138]. It has been well described by Truby et al., with rates of subclinical LVD up to 22% and clinical LVD of 7% [139]. Subclinical LVD was defined as radiographic evidence of pulmonary edema and pulmonary artery diastolic pressure greater than 25 mmHg, while clinical LVD required immediate decompression. LVD has been addressed in many studies by attempting concurrent IABP and Impella® as a mechanism of offload the left ventricle with overall improvement in outcomes [16, 96, 140–148]. Meani et al. reviewed combinations of mechanical circulatory support and found that the most common locations for unloading were the left atrium, the aorta via IABP and trans-aortic [148]. More recent systematic reviews have determined that LV unloading via combinations of MCS can be associated with increased hemolysis, but has no increase in incidence of other major complications. Furthermore, LV unloading has been associated with decreased mortality, indicating a need for randomized trials to determine the best strategy for unloading [138].

RISK FACTORS FOR COMPLICATIONS

Many studies have investigated risk factors that predispose patients to complications of temporary MCS insertion, primarily in IABP. Factors identified include older age, female sex, body surface area (BSA) < 1.8 m [2], peripheral vascular disease, smoking history, diabetes, and hypertension [42, 47, 91, 120, 149]. A single-center study of 206 consecutive IABP insertion attempts for CS, unstable angina and cardiac arrest noted female sex and peripheral vascular disease to be significant predictors of worse complications [91]. Peripheral vascular disease was defined as symptoms of claudication, femoral bruit, or absent pedal pulses, and conferred a threefold increase in complication rates (31% vs. 10%, $p < 0.001$). Female sex was associated with a fourfold increase in complications (15% vs. 4%), which is thought to be related to smaller size of the femoral arteries. Similarly, Cohen et al. identified female sex and low BSA < 1.8 m [2] as higher risk for complication [42]. Another single-center trial of 872 IABP insertions confirmed that vascular complication rates were higher in women (32% vs. 18%, $p = 0.0001$) [47], and determined diabetes and hypertension contributed to risk of vascular injury. Risk of infection was only associated with duration of IABP use, and not patient-specific factors. Wasfie et al. demonstrated that diabetic patients have higher overall complication rates when undergoing IABP insertion, specifically if they are insulin dependent (34% vs. 14%) [149]. Most of the increase in complication rate was attributable to minor vascular complications and infection. Smoking history ($p < 0.05$) and peripheral vascular disease as determined by ankle-brachial index (ABI) ($p < 0.01$) have also been identified as significant risk factors for development of limb ischemia [73]. Given the identified risk of vascular complications including limb ischemia in patients with PVD, recent studies have investigated axillary approach for IABP and Impella® given low prevalence of atherosclerosis in this area and the benefit of increased patient mobility with positive outcomes [78, 150].

ECMO literature has also cited PVD as a significant risk factor for both early and late vascular complications citing odds ratios of 3.1 and 6.95 [114, 116]. Contemporary datasets detailing patient- and procedure-specific risk factors are limited, and further work is needed to identify subpopulations of patients who may be at higher risk of complication. Lastly, though not the focus of this topic, prevention of complications remains a crucial aspect in the management of these patients. Using MCS devices for the shortest duration, daily protocols for device weaning, limb assessment, and review of clinical progress is crucial. Furthermore, specific measures as such 'safe femoral practices', use of prophylactic antibiotics, multidisciplinary team management, selection of appropriate anticoagulation targets and LV unloading for ECMO are crucial to achieve optimal outcomes [2, 4, 7, 8, 70, 122, 151].

CONCLUSIONS

Complications of temporary mechanical circulatory support are associated with worse short- and long-term outcomes [51, 68, 86, 105, 124]. Rates vary widely by study and are affected by timing of the study, single versus multicenter, operator experience, type of MCS, and indication for MCS insertion. Furthermore, true rates of complication are difficult to discern due to variability in reporting and clinical application of each type of support. Additionally, given very few studies have directly compared different types of MCS, comparison of complications and complication rates between devices is challenging.

Trends discussed in this review include highest risk of limb ischemia leading to amputation with IABP insertion, and higher risk of major bleeding with Impella® and TandemHeart®, which is balanced by higher overall blood flow rate and improved hemodynamics [30, 39, 41, 51, 65, 66, 75]. VA-ECMO has the highest overall complication rate including limb ischemia and CVA, however, it offers the highest level support and often represents the most critically ill patient population [40, 93, 105, 121]. Recent studies have investigated combinations of IABP and Impella® with VA-ECMO as a way to improve overall hemodynamics with significant increase in rates of hemolysis, but without significant increase in incidence of limb ischemia or vascular complications [16, 96, 141, 142, 144–147].

This review is limited by selection of available studies with reported complication rates. Studies selected range in time from 1971 to 2019, with the majority of literature published after 2010. Indications for mechanical circulatory support were limited to high-risk PCI, acute myocardial infarction, cardiogenic shock, and failure to wean from cardiopulmonary bypass. As mentioned previously, given disparities in study type, time, center, clinical indication for MCS, and operator experience, it is challenging to make direct comparisons across studies or types of MCS.

In summary, complications of MCS are prevalent and vary based on type of device and indication. Due to variability in reporting and study design, true rates of complication and predisposing factors leading to complication are difficult to discern. Review of existing registries including the National Inpatient Sample may be helpful in elucidating these gaps. As such, further work is needed to determine complication rates for specific types and combinations of temporary MCS by clinical application and to identify patient-specific factors that increase risk for complications in this critically ill patient population.

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