















REVIEW

Impact of mechanical circulatory support modalities on outcomes in acute myocardial infarction-related cardiogenic shock undergoing early revascularization: A systematic review of survival and cardiac function outcomes

Impacto de las modalidades de soporte circulatorio mecánico en los resultados del shock cardiogénico relacionado con el infarto agudo de miocardio sometido a revascularización temprana: una revisión sistemática de los resultados de supervivencia y función cardíaca

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ABSTRACT

Introduction: cardiogenic shock complicates 5,10 % of acute myocardial infarctions and remains associated with early mortality of approximately 40 %. Mechanical circulatory support devices, including intra-aortic balloon pump, Impella, and extracorporeal membrane oxygenation, are increasingly applied, yet their effect on outcomes is uncertain.

Objective: this review aimed to systematically evaluate the impact of intra-aortic balloon pump, Impella, and extracorporeal membrane oxygenation on survival and left ventricular function in patients with acute myocardial infarction complicated by cardiogenic shock undergoing early revascularization.

Method: a systematic search of PubMed, ScienceDirect, and the Cochrane Library was conducted up to May 1, 2025. Eligible studies included randomized controlled trials and observational studies assessing intra-aortic balloon pump, Impella, or extracorporeal membrane oxygenation in acute myocardial infarction-related cardiogenic shock. Two reviewers independently screened studies, extracted data, and assessed quality using Cochrane RoB 2.0 and ROBINS-I tools. Sixteen studies encompassing more than 35 000 patients were included.

Results: across all modalities, mechanical circulatory support did not consistently improve short- or long-term survival. Randomized trials showed no benefit for intra-aortic balloon pump in survival or ventricular recovery. Impella use was associated with higher rates of bleeding and vascular complications without mortality advantage. Extracorporeal membrane oxygenation demonstrated the highest complication rates. Early Impella deployment showed limited potential for ventricular recovery in select cases, but results were inconsistent.

Conclusions: despite theoretical hemodynamic benefits, current evidence does not demonstrate consistent improvements in survival or left ventricular function with intra-aortic balloon pump, Impella, or extracorporeal membrane oxygenation in acute myocardial infarction complicated by cardiogenic shock. High complication rates, particularly with Impella and extracorporeal membrane oxygenation, offset potential benefits, underscoring the need for timely revascularization rather than reliance on mechanical circulatory support.

Keywords: Acute Myocardial Infarction; Cardiogenic Shock; Intra-Aortic Balloon Pump; Ventricular Function; Left; Extracorporeal Membrane Oxygenation; Mortality.

RESUMEN

Introducción: el shock cardiogénico complica entre el 5 y el 10 % de los infartos agudos de miocardio y se asocia con una mortalidad temprana cercana al 40 %. Los dispositivos de soporte circulatorio mecánico, como el balón de contrapulsación intraaórtico, Impella y la oxigenación con membrana extracorpórea venoarterial, se utilizan de manera creciente, aunque su beneficio clínico sigue siendo incierto.

Objetivo: evaluar la efectividad de los principales dispositivos de soporte circulatorio mecánico sobre la supervivencia y la función cardíaca en el shock cardiogénico relacionado con el infarto agudo de miocardio.

Método: se realizó una revisión sistemática siguiendo las directrices PRISMA. Se buscó en PubMed, ScienceDirect y Cochrane Library hasta mayo de 2025. Se incluyeron dieciséis estudios con más de 35 000 pacientes. Dos revisores realizaron de forma independiente la selección, extracción de datos y evaluación de calidad con las herramientas Cochrane RoB 2.0 y ROBINS-I.

Resultados: los dispositivos de soporte circulatorio mecánico no demostraron una mejoría consistente en la supervivencia a corto o largo plazo en pacientes con shock cardiogénico sometidos a intervenciones coronarias. El balón intraaórtico no mostró beneficio en ensayos clínicos aleatorizados. Impella se asoció con mayor sangrado y complicaciones vasculares sin clara ventaja de mortalidad, mientras que la oxigenación extracorpórea presentó la tasa más alta de complicaciones. El uso temprano de Impella evidenció recuperación ventricular en casos seleccionados, aunque de manera inconsistente.

Conclusiones: A pesar de los beneficios hemodinámicos teóricos, la evidencia disponible no respalda un beneficio sostenido en la supervivencia ni en la función ventricular izquierda. Las altas tasas de complicaciones limitan el impacto clínico de estos dispositivos.

Palabras clave: Infarto del Miocardio; Shock Cardiogénico; Dispositivos de Asistencia Circulatoria; Balón de Contrapulsación Intraaórtico; Oxigenación por Membrana Extracorpórea.

INTRODUCTION

Cardiogenic shock (CS) remains the most severe complication of acute myocardial infarction (AMI) and continues to be the leading cause of in-hospital mortality among patients who survive to hospital admission.^(1,2) Despite advances in reperfusion strategies and medical therapies, the prognosis of AMI complicated by CS (AMI-CS) remains poor, with early mortality rates approaching 40 % and rising to 50 % at one year.⁽²⁾ Each year, approximately 40 000 to 50 000 patients in the United States develop AMI-CS, highlighting the significant clinical and public health burden posed by this condition.⁽²⁾ Mechanical circulatory support (MCS) has emerged as a therapeutic adjunct aimed at stabilizing hemodynamics, supporting coronary perfusion, and allowing myocardial recovery in patients undergoing early revascularization. Historically, intra-aortic balloon pump (IABP) therapy dominated practice for decades following its introduction in the 1960s, based on its ability to augment diastolic coronary blood flow and reduce left ventricular afterload.⁽³⁾ However, the IABP-SHOCK II trial challenged this paradigm by demonstrating no mortality benefit of IABP use when added to optimal revascularization and medical therapy.⁽⁴⁾ More recently, percutaneous left ventricular assist devices (pLVADs), such as Impella, have been increasingly used due to their capacity to deliver substantially greater cardiac output support (2.5-5.5 L/min) compared with IABP (0.8-1.0 L/min).^(2,3) Nonetheless, randomized trials such as IMPRESS have not shown consistent survival advantages of Impella over IABP, raising questions about their true impact on outcomes.^(5,6,7)

Previous systematic reviews and meta-analyses have largely concentrated on short-term mortality endpoints, often overlooking broader dimensions of patient recovery. In particular, limited attention has been given to cardiac function recovery, complications such as bleeding or vascular injury, and the role of device timing in determining outcomes.^(8,9) These aspects are critical for guiding device selection, optimizing patient management, and informing long-term strategies in AMI-CS care. The central problem therefore lies in the uncertainty regarding the net clinical benefit of MCS in AMI-CS patients treated with early revascularization. While hemodynamic improvements are well-documented, it remains unclear whether these translate into

meaningful survival gains, improved cardiac recovery, or acceptable safety profiles. This systematic review aims to evaluate the impact of MCS modalities on outcomes in AMI-CS patients undergoing early revascularization. Specifically, it seeks to (1) assess survival outcomes, (2) examine recovery of cardiac function, (3) analyze complication rates associated with different devices, and (4) evaluate the influence of device timing. By addressing these dimensions, this review intends to provide a more comprehensive understanding of the role of MCS in AMI-CS management.

METHOD

Study Design and Registration

This systematic review was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to assess the impact of mechanical circulatory support (MCS) modalities on survival and cardiac function outcomes in patients with acute myocardial infarction-related cardiogenic shock (AMI-CS) undergoing early revascularization.⁽¹⁰⁾ The primary objective was to evaluate mortality associated with different MCS strategies. Secondary objectives included assessment of left ventricular (LV) function recovery and major complications.

Eligibility Criteria

Studies were eligible if they

- Reported on adult patients (≥ 18 years) with AMI-CS undergoing early revascularization (PCI or CABG).
- Evaluated outcomes of percutaneous MCS devices: intra-aortic balloon pump (IABP), percutaneous left ventricular assist devices (pLVAD, e.g., Impella), venovenous extracorporeal membrane oxygenation (VA-ECMO), or combined strategies (e.g., ECPELLA).
- Reported at least one of the following outcomes: short-term or long-term mortality, LV function outcomes (e.g., LVEF), or major complications (e.g., bleeding, vascular events).
- Included ≥ 10 patients per intervention group.
- They were published in English in peer-reviewed journals.

Exclusion criteria were

- Non-adult populations (studies including patients < 18 years).
- Studies of advanced therapies outside the scope (durable LVADs as destination therapy or bridge to transplant, isolated heart transplantation).
- Low-quality or non-peer-reviewed evidence (case reports, case series with < 10 patients, conference abstracts without full data).
- Language and accessibility limitations (publications not available in English).
- Duplicate or overlapping datasets, in which case the most comprehensive or recent publication was retained.

Search Strategy

A systematic search was performed in Medline (PubMed), Science direct, and Cochrane library databases from inception through May 1, 2025. Keywords and MeSH terms included combinations of “mechanical circulatory support,” “intra-aortic balloon pump,” “Impella,” “extracorporeal membrane oxygenation,” “ECMO,” “venoarterial ECMO,” “acute myocardial infarction,” “cardiogenic shock,” “revascularization,” “mortality,” and “cardiac function.” Boolean operators “AND” and “OR” were applied. Reference lists of included articles and relevant reviews were screened manually. Grey literature, preprints, and clinical trial registries were checked. Corresponding authors were contacted for missing data or clarification when necessary.

Study Selection

Full texts of potentially eligible studies were retrieved and assessed against the inclusion criteria. Discrepancies were resolved through discussion or consultation with a third reviewer.

Data Extraction

Extracted variables included study design, publication year, patient population, MCS modality (IABP, Impella, VA-ECMO, or combinations), timing of MCS relative to revascularization, 30-day and longer-term mortality, LV function outcomes (e.g., ejection fraction recovery), and major complications (e.g., bleeding, stroke, vascular injury, renal failure). Disagreements were resolved by consensus.

Quality Assessment

Methodological quality of included studies was assessed independently by two reviewers using The

methodological quality of included studies was independently assessed by two reviewers using the Cochrane RoB 2.0 tool for randomized controlled trials (RCTs) and the ROBINS-I tool for observational studies. Figures 2 and 3 illustrate the domain-specific risk of bias evaluations for RCTs and non-randomized studies, respectively. Most RCTs showed low risk of bias across all domains, whereas observational studies exhibited moderate to serious risks, mainly due to confounding and limitations in outcome measurement. Discrepancies between reviewers were resolved through discussion. These assessments provide critical context for interpreting mortality outcomes and overall study reliability.

Data Synthesis

Given expected clinical and methodological heterogeneity in study designs, patient populations, intervention protocols, and outcome measures, a qualitative narrative synthesis was performed. Key data on mortality rates, complications (e.g., bleeding, vascular events), and left ventricular recovery were extracted and descriptively summarized. Results were organized in detailed tables to enable cross-study comparisons of MCS strategies (IABP, Impella, VA-ECMO) in AMI-CS patients undergoing early PCI. Results were presented in tables to highlight variations in clinical outcomes, practice patterns, and complication profiles.

RESULTS

A total of 3,570 records were identified, with 1,267 duplicates removed, leaving 2,303 for screening. After assessing 215 full-text reports, 15 studies were included. These studies, comprising over 35,000 AMI-CS patients undergoing early revascularization with mechanical circulatory support (MCS), demonstrated in-hospital or 30-day mortality rates ranging from 24 % to 75 %. Despite varied devices—such as IABP, Impella, and VA-ECMO—no consistent survival benefit was observed. Several studies reported increased complications, particularly bleeding and vascular events with Impella or ECMO, highlighting the lack of definitive improvement in outcomes and underscoring the need for randomized trials to guide

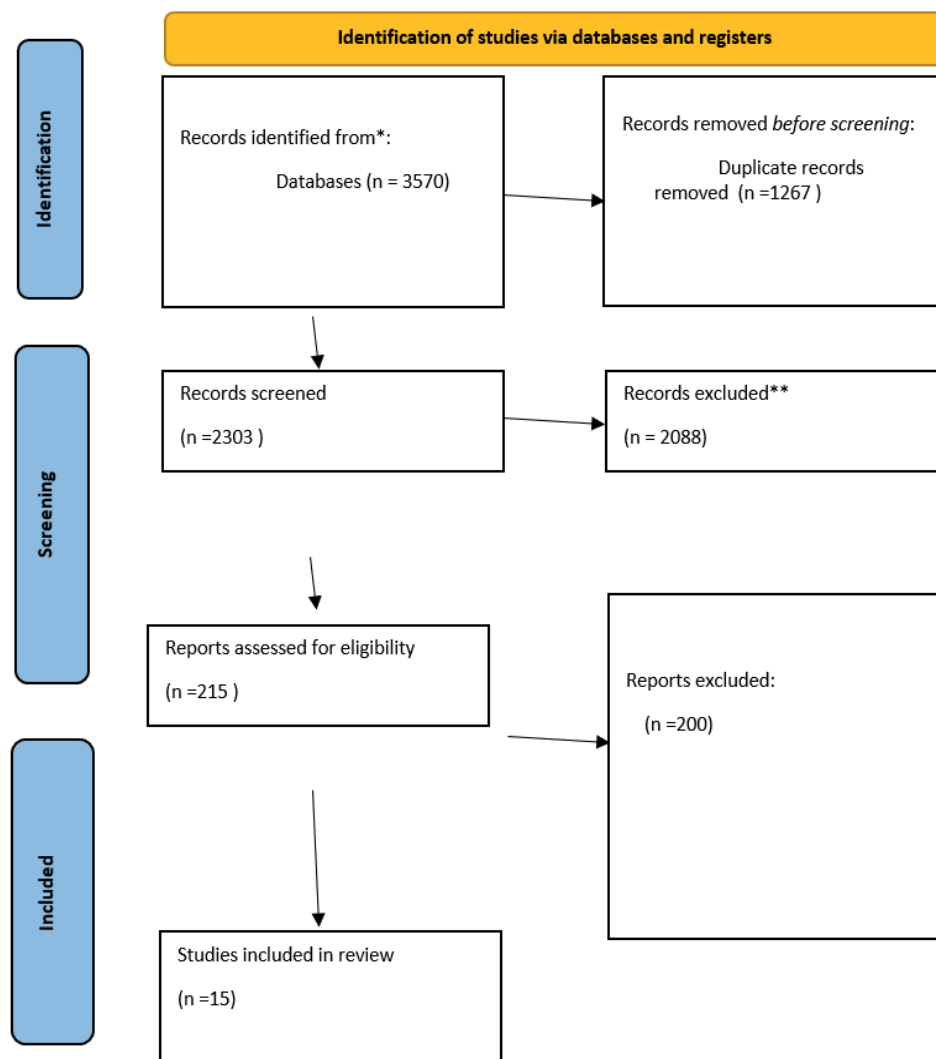


Figure 1. Prisma flow chart

Table 1. Summary of Results

Study	Study design	Population	MCS Modality	Timing of MCS	30-day Mortality	LV Function Outcomes	Major Complications	Key Findings related to my study
Holger Thiele et al. ⁽¹¹⁾	Randomised, open-label, multicenter trial	600 patients with AMI complicated by cardiogenic shock undergoing early revascularisation	Intra-aortic balloon pump (IABP)	IABP was initiated immediately after randomisation during early PCI or CABG	30-day mortality: 40 % in IABP vs. 41 % in control (no significant difference)	No significant improvement in LVEF or LV recovery at 6 or 12 months between IABP and control	Similar rates of reinfarction, recurrent revascularisation, and stroke between groups; no increase in major bleeding or stroke with IABP	IABP did not reduce short- or long-term mortality or improve cardiac function in AMI-related cardiogenic shock undergoing early revascularisation; supports downgrading routine IABP use in guidelines
Fang et al. ⁽¹²⁾	Retrospective cohort n=250	AMI with cardiogenic shock undergoing PCI	Intra-Aortic Balloon Pump (IABP)	Mostly post-PCI (85,7 % of IABP patients)	In-hospital mortality: IABP 33,8 % vs. control 33,0 % (p=0,90); 1-year mortality: IABP 48,1 % vs. control 48,0 % (p=0,99)	Indirect indicators (e.g., troponin, lactate) were worse in the IABP group at baseline, but no improvement was shown post-intervention	Longer ICU stay (median 124h vs. 83h, p=0,005); longer hospital stay (median 250h vs. 170h, p=0,009)	IABP use in AMI-CS undergoing PCI was not associated with improved short- or long-term survival; patients with IABP had significantly longer ICU and hospital stays without evidence of improved cardiac recovery.
Nishimoto et al. ⁽¹³⁾	Nationwide registry, n=12,171	Patients with ACS complicated by cardiogenic shock undergoing PCI in Japan (2019-2021)	IABP alone, Impella, VA-ECMO alone, IABP, ECPella (VA-ECMO + Impella)	Varies; devices applied before or during PCI	In-hospital mortality is highest in VA-ECMO alone (58,5 %), lowest in Impella (24,6 %); IABP alone 26,1 %, VA-ECMO+IABP 55,7 %, ECPella 46,9 %	TIMI 3 flow achieved in >95 % of cases across groups; direct LV function measures (e.g., LVEF) not reported	Bleeding requiring transfusion is most common in ECPella (8,1 % access site); cardiac tamponade is up to 2,1 % in ECPella.	IABP use declined (63,5 %→58,3 %), Impella use rose (2,1 %→8,7 %); overall mortality trended down (36,6 %→32,1 %), but adjusted analysis showed no significant mortality reduction. ECPella use rose substantially in VA-ECMO patients, but did not improve survival. Highlights shifting practice patterns without clear outcome improvement.
Vallabhajosyula et al. ⁽¹⁴⁾	Retrospective cohort, N=110,452	AMI-CS patients receiving early PCI (hospital day 0); 54,8 % received MCS	IABP (94,8 %), pLVAD (4,2 %), ECMO (1,0 %)	Early, concurrent with PCI	Higher in-hospital mortality with MCS: 31 % vs 25,8 % without MCS (adjusted OR 1,23 [1,19-1,27]; p<0,001)	Patients with pLVAD/ECMO had worse discharge outcomes and longer stays	Higher rates of organ failure, longer length of stay, fewer discharges to home; pLVAD/ECMO groups had mortality >49-54 % vs 30 % with IABP	MCS-assisted PCI identifies a sicker AMI-CS cohort with higher mortality; pLVAD and ECMO are associated with significantly worse outcomes than IABP; IABP trend declining despite lower mortality than pLVAD/ECMO

javaid et al. ⁽¹⁵⁾	Retrospective propensity-matched cohort study	17,762 AMI-CS patients undergoing PCI	Impella, IABP, Vasopressors without MCS	During hospitalization	PCI	Impella: 34,1 % (vs IABP 26,9 %), Impella: 42,3 % (vs Vasopressors 35,7 %); IABP vs Vasopressors: 25,4 % vs 33,7 % (NS)	LV function not directly assessed; no echocardiographic or hemodynamic data reported	Impella: higher major bleeding vs IABP (31,4 % vs 13,6 %; p<0,001) and vasopressors (33,9 % vs 22,7 %; p<0,001). No significant difference in major complications between IABP vs vasopressors	Impella use in AMI-CS + PCI is associated with higher mortality and bleeding compared to vasopressors alone, and higher bleeding with no mortality benefit vs IABP. IABP had comparable outcomes to vasopressors without MCS. Supports caution in routine Impella use for AMI-CS during early PCI without a clear survival benefit
Thiele et al. ⁽⁴⁾	Randomized Controlled Trial (RCT), n=600	Patients with AMI complicated by cardiogenic shock; undergoing early revascularization	Intraaortic Balloon Pump (IABP) vs. no IABP	Mostly post-PCI insertion (86,6 %), some pre-PCI (13,4 %)		39,7 % (IABP) vs. 41,3 % (control), no significant difference (RR=0,96, p=0,69)	No significant difference in LV function; LVEF recovery did improve with the IABP	Major bleeding: 3,3 % (IABP) vs. 4,4 % (control); sepsis: 15,7 % vs. 20,5 %; stroke: 0,7 % vs. 1,7 %; peripheral ischemia: 4,3 % vs. 3,4 %	Use of IABP did not reduce 30-day mortality or improve cardiac function outcomes in AMI-CS patients undergoing early revascularisation; no difference in safety endpoints
Ali ⁽¹⁶⁾	Retrospective national cohort (NRD 2016-2020)	20,950 AMI-CS patients undergoing PCI requiring MCS	Impella vs. ECMO (with E C P E L L A subgroup)	Early MCS with PCI/CABG (early revascularization)		ECMO: 51,6 % vs. Impella: 41,5 % (propensity-matched)	Inferred impaired LV function in the ECMO group due to higher mortality and complications	ECMO: ↑SCA (40,9 %), ↑stroke (9,2 %), ↑major bleeding (16 %), ↑AKI (72 %), ↑respiratory complications (90 %) compared to Impella	Despite widespread MCS use, AMI-CS mortality trends are unchanged (p-trend=0,071). ECMO w/o LV unloading had worse survival & complications; Impella alone was associated with better short-term outcomes. Prospective studies are needed.
Basir et al. ⁽¹⁷⁾	Prospective multicenter registry, single-arm, n=406	AMI-CS patients at 80 US sites; high-risk cohort (77 mmHg SBP, lactate 4,8 mmol/L)	Impella CP	Early MCS: implanted before or immediately at PCI		68 % survival at 30 days	Improved cardiac power output (0,67→1,0W) and reduced lactate (4,8→2,7 mmol/L) at 24h; LVEF not reported	Vascular complications not quantified, but procedural survival 99 %	Early Impella use is feasible in real-world AMI-CS, associated with rapid hemodynamic stabilization and high survival to discharge (71 %) and 30 days (68 %), supporting the potential benefit of an early MCS strategy pending RCT confirmation.
Schrage et al. ⁽¹⁸⁾	Retrospective matched cohort study, n=237 Impella vs. 237 IABP-SHOCK II patients	AMI-CS patients undergoing PCI treated at European tertiary centers, matched by SHOCK II criteria undergoing PCI	Impella CP vs. IABP	Early MCS: before/ at PCI		No significant difference: 48,5 % Impella vs. 46,4 % IABP mortality (P=0,64)	Not significantly different in LVEF between groups	Severe / life-threatening bleeding: 8,5 % (Impella) vs. 3,0 % (IABP); vascular complications: 9,8 % vs. 3,8 %	Impella did not reduce 30-day mortality compared to matched IABP/medical therapy controls; significantly more bleeding and vascular complications highlight the need for randomized trials on Impella efficacy in AMI-CS.

Zeymer et al. ⁽¹⁹⁾	Prospective registry n=42,317	Patients with STEMI or NSTEMI complicated by cardiogenic shock undergoing PCI in 176 centers across 33 countries (Europe, Mediterranean)	IABP	During/after PCI	In-hospital mortality: 56,9 % with IABP vs. 36,1 % without IABP; adjusted OR for mortality 1,47 (95 % CI 0,97-2,21; p=0,07) — no survival benefit	LV function not systematically assessed; no data on LVEF or recovery provided	Higher use of inotropes (72,9 % vs. 65 %), mechanical ventilation (36,3 % vs. 15,3 %), and renal failure requiring dialysis was more frequent with IABP (10,3 % vs. 5,6 %, p=0,06)	Despite guideline recommendations, IABP was used in only ~25 % of AMI-CS patients treated with PCI. No signal of improved survival with IABP in multivariate analysis, highlighting the need for RCTs. Use of IABP is associated with higher rates of organ support (ventilation, dialysis), without reduction in mortality.
Kim et al. ⁽²⁰⁾	Prospective cohort n=1359	AMI-CS patients undergoing PCI	IABP	Early: at the time of PCI decision (pre/post)	Higher mortality with IABP: 59,9 % (IABP) vs. 52,5 % (No IABP); adjusted HR 1,22 [1,02-1,47], p=0,034 (no mortality reduction after propensity matching)	No improvement in LV recovery reported	Similar rates of recurrent MI, stroke, and major bleeding in both groups; bleeding: ~4 %	IABP use did not reduce 30-day mortality in AMI-CS with cardiac arrest despite early revascularization; this supports the lack of survival benefit seen in IABP-SHOCK II and highlights worse outcomes even in higher-risk CPR patients.
Prunea et al. ⁽²¹⁾	Prospective registry subanalysis n=71	AMI-CS patients undergoing PCI (SCAI C-E)	Impella or VA-ECMO	Upfront (before PCI) vs. Procedural (during/after PCI)	Upfront: 61 % mortality; Procedural: 79 % mortality (p=0,12; not statistically significant)	No specific data on LVEF or quantitative LV recovery; study focused on survival endpoints	Vascular and ischemic complications are rare; 1 ischemic complication (upfront), 1 bleeding complication (procedural)	Timing of MCS (upfront vs. procedural) did not provide a significant survival benefit; both groups had high mortality; highlights limited efficacy of MCS timing optimization alone in AMI-CS despite early revascularization
Wilkins et al. ⁽²²⁾	Retrospective cohort, n=90	AMI-CS patients undergoing PCI at a rural community hospital without surgical backup	Impella 2,5 / CP	Median door-to-Impella: 59 min; pre-PCI in 46,6 %, post-PCI in 53,3 %	30-day survival: 60 % overall; 72,4 % if Impella started ≤48 min vs. 39,3 % if >86 min	Significant LVEF recovery: baseline 39 % → 43,6 % at discharge → 54,1 % at up to 24 months follow-up (P<0,001)	Bleeding requiring transfusion (24,7 %), hemolysis (21,5 %), rare limb ischemia (1,1 %), bleeding requiring surgery (2,25 %)	Early Impella support (≤48 min) in AMI-CS patients significantly improved survival rates and led to meaningful LV functional recovery, supporting early MCS initiation even at rural centers without surgical backup.

Jin et al. ⁽²³⁾	Retrospective observational cohort n=51,150	Adults hospitalized with AMI-CS undergoing PCI, US national data 2012-2017	IABP Impella	vs.	During hospitalization, the timing relative to PCI was not precisely recorded..	PCI Mortality significantly lower with IABP: 28,95 % vs. 49,59 % in propensity-matched cohort (P<0,01)	LV function data were not directly reported; outcomes were in-hospital endpoints without echocardiography.	Higher sepsis (12,69 % vs 6,44 %, P=0,01) and blood transfusion (14,28 % vs 8,92 %, P=0,01) rates with Impella; no significant difference in stroke or cardiac arrest after adjustment	In AMI-CS patients undergoing PCI, IABP was associated with lower in-hospital mortality and fewer complications compared with Impella, despite similar cardiac arrest and stroke rates. Supports skepticism about routine Impella use without clear benefit; highlights potential harms in real-world practice.
Klein et al. ⁽²⁴⁾	Retrospective registry cohort; Netherlands Heart Registration 2017-2021; N=1,363 AMICS post-PCI	AMI-CS patients undergoing PCI; subgroup with MCS N=332	MCS devices: IABP, Impella, ECMO ± combinations		MCS timing is not explicitly defined, but likely peri-PCI	Overall AMICS 30-day mortality was 32 %; MCS subgroup mortality was 50 % vs non-MCS 29 %; longer symptom duration (>24h) worsened mortality to 59 % vs 45 % in MCS patients	Patients with prolonged symptom duration had worse LV recovery; the MCS group had higher troponin and lactate, suggesting more severe LV dysfunction	The MCS group had higher bleeding, multiorgan dysfunction, and a greater incidence of multivessel PCI with poorer outcomes	Longer prehospital symptom duration independently predicted higher mortality; MCS use was associated with increased mortality in those with prolonged ischemia; this emphasizes the critical importance of early recognition/intervention rather than MCS alone for survival benefit in AMI-CS.

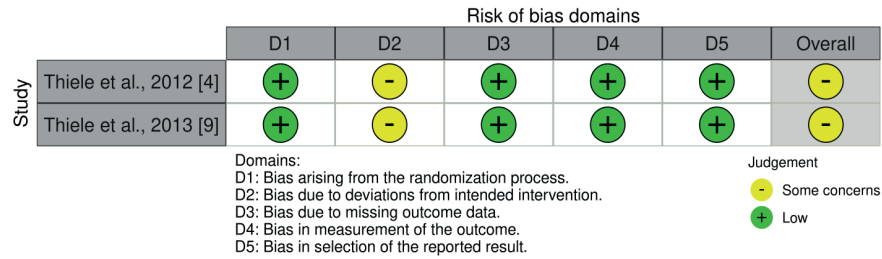


Figure 2. Quality assessment of RCTs by the Rob 2.0 tool

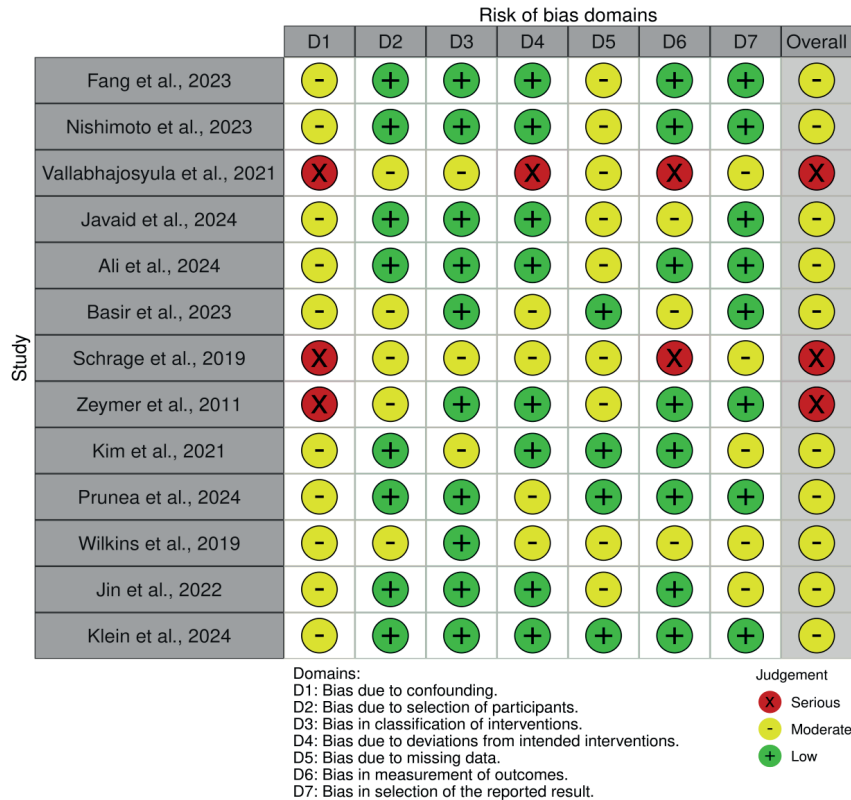


Figure 3. Quality Assessment of Non-RCTs Using the ROBINS-I Tool

Mortality Outcomes

Mortality rates across studies were consistently high, reflecting the critical severity of AMI-CS. Randomized trials such as IABP-SHOCK II reported 30-day mortality of 40 % with IABP versus 41 % in controls, with no significant survival benefit.^(4,11) Similar in-hospital (33,8 % IABP vs. 33,0 % control) and 1-year mortality (48,1 % vs. 48,0 %) in a large MIMIC-IV cohort.⁽¹²⁾ Jin et al.⁽²³⁾ observed nearly double mortality with Impella (49,6 %) compared to IABP (28,9 %) in a propensity-matched analysis of over 50000 patients. Nishimoto et al.⁽¹³⁾ reported mortality ranging from 24,6 % with Impella to 58,5 % with VA-ECMO alone; combined strategies (ECPella) showed intermediate mortality (46,9 %). Vallabhajosyula et al.⁽¹⁴⁾ found that MCS use overall increased mortality (31 % with MCS vs. 25,8 % without). Awad⁽¹⁵⁾ showed Impella mortality exceeding IABP (34,1 % vs. 26,9 %) and vasopressors (42,3 % vs. 35,7 %). Zeymer et al.⁽¹⁹⁾ observed higher mortality with IABP (56,9 % vs. 36,1 % without IABP; p=0,07). Ali et al.⁽²⁵⁾ found ECMO had the highest mortality (51,6 %) compared with Impella (41,5 %) and ECPella (46,2 %). Basir et al.⁽¹⁷⁾ demonstrated 68 % 30-day survival with early Impella use, a relatively favorable outcome in high-risk patients. Schrage et al.⁽¹⁸⁾ reported no significant difference in 30-day mortality between Impella and IABP (48,5 % vs. 46,4 %). Kim et al.⁽²⁰⁾ found worse mortality with IABP in AMI-CS after cardiac arrest (59,9 % vs. 52,5 %). Prunea et al.⁽²¹⁾ noted very high mortality regardless of timing: 61 % with upfront MCS vs. 79 % procedural (p=0,12). Wilkins et al.⁽²⁶⁾ reported improved survival with early Impella (≤ 48 min) (72,4 % vs. 39,3 % with delayed support). Klein et al.⁽²⁴⁾ found mortality of 50 % in MCS-treated patients vs. 29 % without MCS; mortality rose to 59 % if symptoms persisted >24h pre-treatment.

Left Ventricular Function Outcomes

Recovery of LV function was inconsistently assessed. Thiele et al.⁽¹¹⁾ found no LVEF improvement with IABP compared to controls. Fang et al.⁽¹⁸⁾ lacked direct LV measures but reported no indirect improvement benefit [10]. Schrage et al. showed no significant LVEF differences between Impella and IABP. Kim et al.⁽²⁰⁾ reported no LV recovery benefit with IABP in AMI-CS after cardiac arrest. In contrast, Wilkins et al.⁽²²⁾ demonstrated substantial LVEF improvement with early Impella initiation (39 %→54 % at 24 months; $p<0,001$). Basir et al.⁽²⁴⁾ showed improved cardiac power output and lactate reduction with Impella but did not report LVEF specifically.⁽¹⁷⁾ Worse LV recovery with prolonged symptom duration despite MCS. Other studies did not provide systematic LV functional outcomes, but several inferred impaired LV recovery through elevated biomarkers or prolonged organ dysfunction.^(23,13, 27,15,19,21)

Complication Profiles

Major complications were common, particularly with more invasive devices. Impella consistently demonstrated increased bleeding: Jin et al.⁽²³⁾ Awad⁽¹⁵⁾ showed significantly higher bleeding rates with Impella (14,3 %-31,4 %) vs. IABP (8,9 %-13,6 %). Schrage et al.⁽¹⁸⁾ reported severe bleeding in 8,5 % of Impella vs. 3,0 % of IABP patients; vascular complications were also higher with Impella (9,8 % vs. 3,8 %). Found that bleeding requiring transfusion was highest with ECPella (8,1 %). Reported ECMO associated with dramatically increased stroke (9,2 %), bleeding (16 %), acute kidney injury (72 %), and respiratory complications (90 %).^(13,16) Zeymer et al.⁽²¹⁾ observed higher rates of mechanical ventilation, dialysis, and inotropes in IABP groups.⁽²⁸⁾ Described rare but serious bleeding and ischemic complications. Wilkins et al.⁽²²⁾ identified frequent bleeding requiring transfusion (24,7 %) and hemolysis (21,5 %). Klein et al.⁽²⁴⁾ found elevated troponin and lactate levels, reflecting severe LV dysfunction, along with increased bleeding and multiorgan failure in MCS-treated patients. Fang et al.⁽¹²⁾ reported longer ICU/hospital stays for IABP without a survival benefit. Basir et al.⁽¹⁷⁾ did not quantify vascular complications but noted 99 % procedural survival. Kim et al.⁽²⁰⁾ found no significant bleeding difference between IABP and controls but did not report LV recovery data.

Trends in MCS Utilization

Several studies highlighted evolving device use patterns. Nishimoto et al.⁽²⁹⁾ documented declining IABP use (63,5 %→58,3 %) and rising Impella use (2,1 %→8,7 %) over three years, although adjusted mortality remained unchanged. Vallabhajosyula et al.⁽²⁷⁾ described declining IABP use despite lower mortality compared to pLVAD/ECMO. Ali et al.⁽¹⁶⁾ showed Impella was the dominant device in AMI-CS (93,7 %), with ECPella use rising but not improving outcomes. Klein et al.⁽²⁴⁾ demonstrated that delayed symptom-to-treatment time worsened outcomes regardless of MCS. Zeymer et al.⁽¹⁹⁾ highlighted IABP use in only ~25 % of AMI-CS PCI patients despite guideline recommendations, with no mortality benefit. Other studies, suggest ed early MCS use might benefit select patients, but overall survival improvements remained inconsistent.^(23,15,17,18, 21,26)

DISCUSSION

Acute myocardial infarction complicated by cardiogenic shock (AMI-CS) remains the leading cause of in-hospital mortality among patients with myocardial infarction, with 30-day death rates consistently exceeding 40 % despite early revascularization efforts.^(4,11) Across randomized trials and large cohorts, IABP consistently failed to improve 30-day or in-hospital survival compared to standard therapy, with mortality rates of ~40 % in IABP-SHOCK II^(4,11) and similar results in retrospective analyses.^(12,20) Impella showed no consistent survival benefit over IABP, with multiple studies reporting significantly higher mortality in Impella-treated patients.^(12,20,18) while only isolated registries suggested favorable outcomes with early use.^(17,22) VA-ECMO, despite potent hemodynamic support, showed the highest mortality (up to 58,5 %) with significant complications.^(13,25) Findings are consistent with systematic reviews and meta-analyses which reported that MCS did not significantly reduce mortality in AMI-CS despite advances in device technology and earlier deployment.^(30,31) While some studies noted reduced lactate and improved cardiac power with Impella these hemodynamic benefits did not reliably translate to survival gains, paralleling conclusions from meta-analysis showing improved short-term hemodynamics without mortality benefit.⁽⁵⁾

Left ventricular (LV) functional recovery was rarely assessed rigorously across included studies, with only Wilkins et al. demonstrating significant LVEF improvement at long-term follow-up in early Impella recipients,⁽²⁶⁾ while reported no LV function benefit with IABP or Impella.^(4,11,18,20) Studies reporting surrogate markers, such as lactate clearance or cardiac power, suggested transient hemodynamic stabilization⁽¹⁷⁾ but failed to show consistent downstream improvements in cardiac recovery or survival. These observations align with recent systematic reviews, Zhang et al.⁽⁹⁾ Saggi et al.⁽³²⁾ that emphasize that while MCS can improve hemodynamic parameters acutely, this rarely translates into better LV function or long-term outcomes in AMI-CS patients. Additionally, the high incidence of bleeding, vascular injuries, and end-organ complications—particularly with Impella and ECMO—compounded mortality risks, reinforcing concerns highlighted in literature analyses by Subramaniam et al. about adverse event profiles associated with percutaneous MCS devices in AMI-CS.⁽³³⁾

A major methodological limitation of this review was the heterogeneity of included studies, with wide variations in patient selection, timing of MCS initiation relative to PCI, device choice, and outcome definitions. Most studies were retrospective observational cohorts prone to confounding by indication, where sicker patients disproportionately received MCS, inflating mortality estimates. Randomized trials like IABP-SHOCK II excluded patients requiring immediate high-level support, limiting applicability to the sickest populations. Echocardiographic assessment of LV recovery was inconsistently reported or missing in most studies, preventing quantitative synthesis of cardiac function outcomes. Additionally, publication bias cannot be excluded, as negative studies may be underreported. Collectively, these methodological shortcomings underscore the need for large-scale, adequately powered randomized controlled trials with standardized protocols, robust cardiac imaging, and long-term follow-up to definitively establish the role of MCS in AMI-CS.

CONCLUSIONS

In conclusion, current evidence demonstrates that while mechanical circulatory support devices such as IABP, Impella, and VA-ECMO can provide hemodynamic stabilization in AMI-related cardiogenic shock, they have not consistently improved survival or long-term cardiac function when used during early revascularization. Studies frequently show increased complication rates, particularly with Impella and ECMO, without a clear mortality benefit compared to IABP or medical therapy alone. These findings highlight the urgent need for well-designed randomized controlled trials to determine optimal MCS strategies and identify patient populations most likely to benefit, ultimately guiding more effective and safer management of AMI-CS.

BIBLIOGRAPHIC REFERENCES

1. Hochman JS. Cardiogenic shock complicating acute myocardial infarction: Expanding the paradigm. *Circulation*. 2003 Jun 24;107(24):2998-3002.
2. Samsky MD, Morrow DA, Proudfoot AG, Hochman JS, Thiele H, Rao S V. Cardiogenic Shock after Acute Myocardial Infarction: A Review. *JAMA - J Am Med Assoc*. 2021 Nov 9;326(18):1840-50.
3. Amin AP, Spertus JA, Curtis JP, Desai N, Masoudi FA, Bach RG, et al. The Evolving Landscape of Impella Use in the United States Among Patients Undergoing Percutaneous Coronary Intervention With Mechanical Circulatory Support. *Circulation*. 2020 Jan 28;141(4):273-84.
4. Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J, et al. Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock. *N Engl J Med*. 2012 Oct 4;367(14):1287-96.
5. Ouweneel DM, Eriksen E, Sjaauw KD, van Dongen IM, Hirsch A, Packer EJS, et al. Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction. *J Am Coll Cardiol*. 2017 Jan 24;69(3):278-87.
6. O'Neill WW, Kleiman NS, Moses J, Henriques JPS, Dixon S, Massaro J, et al. A prospective, randomized clinical trial of hemodynamic support with impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: The PROTECT II study. *Circulation*. 2012 Oct 2;126(14):1717-27.
7. Thiele H, Zeymer U, Akin I, Behnes M, Rassaf T, Mahabadi AA, et al. Extracorporeal Life Support in Infarct-Related Cardiogenic Shock. *N Engl J Med*. 2023 Oct 5;389(14):1286-97.
8. Thiele H, Jobs A, Ouweneel DM, Henriques JPS, Seyfarth M, Desch S, et al. Percutaneous short-term active mechanical support devices in cardiogenic shock: A systematic review and collaborative meta-analysis of randomized trials. *Eur Heart J*. 2017 Dec 14;38(47):3523-31.
9. Zhang Q, Han Y, Sun S, Zhang C, Liu H, Wang B, et al. Mortality in cardiogenic shock patients receiving mechanical circulatory support: a network meta-analysis. *BMC Cardiovasc Disord*. 2022;22(1):1-12. <https://bmccardiovascdisord.biomedcentral.com/articles/10.1186/s12872-022-02493-0>
10. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372. <https://www.bmj.com/content/372/bmj.n71>
11. Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J, et al. Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): Final 12 month results of a randomised, open-label trial. *Lancet*. 2013;382(9905):1638-45. Available from: <https://pubmed.ncbi.nlm.nih.gov/24011548/>

12. Fang D, Yu D, Xu J, Ma W, Zhong Y, Chen H. Effects of intra-aortic balloon pump on in-hospital outcomes and 1-year mortality in patients with acute myocardial infarction complicated by cardiogenic shock. *BMC Cardiovasc Disord.* 2023;23(1). <https://pubmed.ncbi.nlm.nih.gov/37644466/>
13. Nishimoto Y, Inohara T, Kohsaka S, Sakakura K, Kawai T, Kikuchi A, et al. Changing Trends in Mechanical Circulatory Support Use and Outcomes in Patients Undergoing Percutaneous Coronary Interventions for Acute Coronary Syndrome Complicated With Cardiogenic Shock: Insights From a Nationwide Registry in Japan. *J Am Heart Assoc.* 2023;12(23). <https://pubmed.ncbi.nlm.nih.gov/38038195/>
14. Vallabhajosyula S, Prasad A, Sandhu GS, Bell MR, Gulati R, Eleid MF, et al. Ten-year trends, predictors and outcomes of mechanical circulatory support in percutaneous coronary intervention for acute myocardial infarction with cardiogenic shock. *EuroIntervention.* 2021;16(15):E1254-61.
15. Javaid AI, Michalek JE, Gruslova AB, Hoskins SA, Ahsan CH, Feldman MD. Mechanical circulatory support versus vasopressors alone in patients with acute myocardial infarction and cardiogenic shock undergoing percutaneous coronary intervention. *Catheter Cardiovasc Interv.* 2024 Jan 1;103(1):30-41.
16. Ali S, Kumar M, Badu I, Farooq F, Alsaed T, Sultan M, et al. Trends and outcomes of different mechanical circulatory support modalities for acute myocardial infarction associated cardiogenic shock in patients undergoing early revascularization. *Am Hear J Plus Cardiol Res Pract.* 2024;46:100468. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11490672/>
17. Basir MB, Lemor A, Gorgis S, Patel KC, Kolski BC, Bharadwaj AS, et al. Early Utilization of Mechanical Circulatory Support in Acute Myocardial Infarction Complicated by Cardiogenic Shock: The National Cardiogenic Shock Initiative. *J Am Hear Assoc Cardiovasc Cerebrovasc Dis.* 2023. 12(23):e031401. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC10727311/>
18. Schrage B, Ibrahim K, Loehn T, Werner N, Sinning JM, Pappalardo F, et al. Impella support for acute myocardial infarction complicated by cardiogenic shock: Matched-pair iabp-shock II trial 30-day mortality analysis. *Circulation.* 2019 Mar 5;139(10):1249-58.
19. Zeymer U, Bauer T, Hamm C, Zahn R, Weidinger F, Seabra-Gomes R, et al. Use and impact of intra-aortic balloon pump on mortality in patients with acute myocardial infarction complicated by cardiogenic shock: Results of the Euro Heart Survey on PCI. *EuroIntervention.* 2011 Aug;7(4):437-41.
20. Kim HK, Jeong MH, Ahn Y, Sim DS, Chae SC, Kim YJ, et al. Clinical outcomes of the intra-aortic balloon pump for resuscitated patients with acute myocardial infarction complicated by cardiac arrest. *J Cardiol.* 2016;67(1):57-63. <https://www.journal-of-cardiology.com/action/showFullText?pii=S0914508715001239>
21. Prunea DM, Bachl E, Herold L, Kanoun Schnur SS, Pätzold S, Altmanninger-Sock S, et al. Impact of the Timing of Mechanical Circulatory Support on the Outcomes in Myocardial Infarction-Related Cardiogenic Shock: Subanalysis of the PREPARE CS Registry. *J Clin Med [Internet].* 2024 Mar 1 [cited 2025 Jul 1];13(6):1552. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC10971213/>
22. Wilkins C, Herrera T, Nagahiro M, Weathers L, Girotra S, Sandhu F. Outcomes of Hemodynamic Support With Impella for Acute Myocardial Infarction Complicated by Cardiogenic Shock at a Rural Community Hospital Without On-Site Surgical Back-up. *J Invasive Cardiol [Internet].* 2019 Feb [cited 2025 Jul 1];31(2). <https://www.hmpgloballearningnetwork.com/site/jic/articles/outcomes-hemodynamic-support-impella-acute-myocardial-infarction-complicated-cardiogenic-shock-rural-community-hospital-without-site-surgical-back>
23. Jin C, Yandrapalli S, Yang Y, Liu B, Aronow WS, Naidu SS. A Comparison of In-Hospital Outcomes Between the Use of Impella and IABP in Acute Myocardial Infarction Cardiogenic Shock Undergoing Percutaneous Coronary Intervention. *J Invasive Cardiol.* 2022;34(2):E98-103. <https://pubmed.ncbi.nlm.nih.gov/35100554/>
24. Klein F, Crooijmans C, Peters EJ, van 't Veer M, Timmermans MJC, Henriques JPS, et al. Impact of symptom duration and mechanical circulatory support on prognosis in cardiogenic shock complicating acute myocardial infarction. *Netherlands Hear J [Internet].* 2024 Aug 1 [cited 2025 Jul 1];32(7-8):290-7. Available from: <https://link.springer.com/article/10.1007/s12471-024-01881-9>

25. Ali S, Kumar M, Badu I, Farooq F, Alsaheed T, Sultan M, et al. Trends and outcomes of different mechanical circulatory support modalities for acute myocardial infarction associated cardiogenic shock in patients undergoing early revascularization. *Am Hear J Plus Cardiol Res Pract* [Internet]. 2024 Oct 1 [cited 2025 Jul 1];46. Available from: <https://pubmed.ncbi.nlm.nih.gov/39431117/>
26. Wilkins C, Herrera T, Nagahiro M, Weathers L, Girotra S, Sandhu F. Outcomes of Hemodynamic Support With Impella for Acute Myocardial Infarction Complicated by Cardiogenic Shock at a Rural Community Hospital Without On-Site Surgical Back-up. *J Invasive Cardiol* [Internet]. 2019 Feb [cited 2025 Jul 1];31(2). Available from: <https://pubmed.ncbi.nlm.nih.gov/30700627/>
27. Vallabhajosyula S, Prasad A, Sandhu GS, Bell MR, Gulati R, Eleid MF, et al. Ten-year trends, predictors and outcomes of mechanical circulatory support in percutaneous coronary intervention for acute myocardial infarction with cardiogenic shock: MCS-assisted PCI in AMI-CS. *EuroIntervention* [Internet]. 2021 [cited 2025 Jul 1];16(15):e1254. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC9725008/>
28. Zeymer U, Bauer T, Hamm C, Zahn R, Weidinger F, Seabra-Gomes R, et al. Use and impact of intra-aortic balloon pump on mortality in patients with acute myocardial infarction complicated by cardiogenic shock: results of the Euro Heart Survey on PCI. *EuroIntervention*. 2011;7:437-41.
29. Nishimoto Y, Ohbe H, Nakata J, Takiguchi T, Nakajima M, Sasabuchi Y, et al. Effectiveness of an Impella Versus Intra-Aortic Balloon Pump in Patients Who Received Extracorporeal Membrane Oxygenation. *J Am Hear Assoc* . 2025 Feb 4;14(3).
30. Shi Y, Wang Y, Sun X, Tang Y, Jiang M, Bai Y, et al. Effects of mechanical circulatory support devices in patients with acute myocardial infarction undergoing stent implantation: a systematic review and meta-analysis of randomised controlled trials. *BMJ Open* [Internet]. 2021 Jun 29 [cited 2025 Jul 1];11(6):e044072. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC8245450/>
31. Lim Y, Kim MC, Oh S, Ahn JH, Lee SH, Hyun DY, et al. Strategies of Revascularization and Mechanical Circulatory Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock: A Systematic Review With Updated Evidence. *J Cardiovasc Interv* [Internet]. 2025 Jul 1 [cited 2025 Jul 1];4(3):212-22. Available from: <https://doi.org/10.54912/jci.2025.0004>
32. Saggu JS, Seelhammer TG, Esmaeilzadeh S, Roberts JA, Radosevich MA, Ripoll JG, et al. Mechanical Circulatory Support for Acute Myocardial Infarction Cardiogenic Shock: Review and Recent Updates. *J Cardiothorac Vasc Anesth* [Internet]. 2025 Apr 1 [cited 2025 Jul 1];39(4):1049-66. Available from: <https://www.sciencedirect.com/science/article/abs/pii/S1053077024009455>
33. Subramaniam A V., Barsness GW, Vallabhajosyula S, Vallabhajosyula S. Complications of Temporary Percutaneous Mechanical Circulatory Support for Cardiogenic Shock: An Appraisal of Contemporary Literature. *Cardiol Ther*. 2019 Dec 1;8(2):211-28.

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