Interventional procedure overview of percutaneous insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock

Contents

Table 1 Abbreviations

Abbreviation	Definition
AMI	Acute myocardial infarction
AMICS	Acute myocardial infarction related cardiogenic shock
BTB	Bridge to bridge
BTR	Bridge to recovery
BTT	Bridge to transplantation
CABG	Coronary artery bypass graft
CI	Confidence interval
HR	Hazard ratio
IABP	Intra-aortic balloon pump
LVAD	Left ventricular assist device
LVEF	Left ventricular ejection fraction
MCS	Mechanical circulatory support
MD	Mean difference
PCI	Percutaneous coronary intervention
RR	Relative risk
SCAI	Society for Cardiovascular Angiography and Interventions
SCAI-CSWG	Society for Cardiovascular Angiography and Interventions-Cardiogenic Shock Working Group
STEMI	ST-segment elevation myocardial infarction
VAD	Ventricular assist device
VA-ECMO	Venoarterial extracorporeal membrane oxygenation

The procedure, condition, current practice and unmet need

Information about the procedure, condition, current practice and unmet need is available in section 2 and 3 of NICE's interventional procedures consultation

document on percutaneous insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock.

Clinical assessment tools

SCAI SHOCK classification

The SCAI SHOCK classification uses 5 categories (A to E) to indicate the severity of cardiogenic shock:

- A (at risk) - haemodynamically stable patient not experiencing symptoms of cardiogenic shock, but at risk for its development
- B (beginning cardiogenic shock) - clinical evidence of haemodynamic instability without evidence of hypoperfusion
- C (classic cardiogenic shock) - clinical evidence of hypoperfusion that requires pharmacological or mechanical support
- D (deteriorating) - clinical evidence of shock that worsens or fails to improve despite therapy escalation
- E (extremis) - refractory shock or actual or impending circulatory collapse.

Since this classification was devised the SCAI-CSWG has proposed a modified classification with formal criteria for each stage, which was used by Møller (2024). In this version, stage B is defined as having either hypoperfusion or hypotension without the need for drug or device therapy. Stage C is defined as having hypoperfusion and hypotension using the same criteria as for SCAI stage B or having treatment for cardiogenic shock with 1 drug (vasopressor or inotrope) or 1 circulatory support device.

Outcome measures

The main efficacy outcomes included in-hospital, 30-day and 6-month mortality and longer-term survival. Safety outcomes included complications such as bleeding, limb ischaemia, stroke and acute kidney failure.

Evidence summary

Population and studies description

This interventional procedures overview is based on over 950,000 people from multiple studies including 1 randomised controlled trial (Møller 2024), 1 individual patient data meta-analysis (Thiele 2024), 5 systematic reviews and meta-analyses (Sassani 2025, Ardito 2023, Panuccio 2022, Bogerd 2025 and Stub 2025), and 3 registry studies (Movahed 2024, Padberg 2024 and Higuchi 2024). Of these, over 100,000 people had the procedure. There was some overlap in studies included in the systematic reviews, and the studies by Møller 2024 and Padberg 2024 were both included in at least 1 of the reviews. This interventional procedures overview is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This overview presents 10 studies as the key evidence in table 2 and table 3, and lists 138 other relevant studies in appendix B, table 5, including 20 case reports of adverse events (table 5a).

The evidence included studies that used Impella CP, 2.5 and 5.0 models. Impella 2.5 has lower maximum flow rate than Impella CP and they are both typically used for shorter durations than Impella 5.5.

Evidence was excluded on catheter-based intravascular microaxial flow pumps that were described as being inserted surgically or when Impella 5.5 was used, which is inserted surgically. Evidence was excluded from studies that primarily

used microaxial flow pumps as support during high-risk PCI, or for left ventricular unloading during VA-ECMO support.

The evidence included people with cardiogenic shock from various aetiologies, the most common being AMICS. People often had PCI as part of their treatment, either before or after percutaneous insertion of a catheter-based intravascular microaxial flow pump. In most studies, the mean or median age was above 60 years and there was a higher proportion of males than females. Studies included evidence from Europe, North and South America, Asia and Africa.

The randomised controlled trial by Møller (2024) included 355 people with STEMI related cardiogenic shock, mostly from Denmark and Germany, who had a microaxial flow pump (Impella CP) plus standard care or standard care alone. The median age was 67 years and 79% of the study population was male. The median LVEF at baseline was 25%, median arterial lactate level was 4.5 mmol per litre and 56% of people were SCAI-CSWG stage C, 28% were stage D and 16% were stage E. Randomisation to treatment groups was done before or after PCI. The study had strict inclusion and exclusion criteria. Notably, people who had been resuscitated from out-of-hospital cardiac arrest and remained comatose on arrival to the cardiac catheterisation laboratory and people with overt right ventricular failure were excluded. The primary end point was death from any cause at 180 days. A composite safety end point was severe bleeding, limb ischaemia, haemolysis, device failure, or worsening aortic regurgitation.

The individual patient data meta-analysis by Thiele (2024) included data from 1,059 people in 9 randomised controlled trials, 1 of which was Møller (2024). The study compared early routine use of active MCS with best medical therapy in people with AMICS having revascularisation. The evidence included several types of MCS, including VA-ECMO, and about 40% used a microaxial flow pump. People with non-myocardial infarction causes of cardiogenic shock were

excluded. The median age was 65 years and 80% of the study population was male. The median lactate at baseline was 5.6 mmol per litre. About half the study population had successful resuscitation before inclusion. The primary outcome was 6-month all-cause mortality.

The systematic review by Sassani (2025) included 2,617 people from 18 studies on cardiogenic shock related to acute coronary syndrome, 4 of which were prospective. The mean age was 64.7 years. In most of the studies, lactate levels at baseline varied from 4.7 to 8.6 mmol per litre. Where reported, the proportion of people with previous resuscitation ranged from 23% to 74%. The evidence included 2 types of microaxial flow pump (Impella 2.5 and Impella CP). The primary outcome was 30-day mortality.

The systematic reviews by Ardito (2023), Bogerd (2025) and Stub (2025) all compare microaxial flow pumps and VA-ECMO. Ardito (2023) included 44,951 people with cardiogenic shock from any cause, 13,848 of whom had a microaxial flow pump. The review included 102 studies, most of which were retrospective and observational. The mean age of the study populations ranged from 31 to 78 years. Most of the papers on microaxial flow pumps used Impella CP (41 papers), followed by Impella 2.5 (25 papers) and Impella 5.0 (20 papers). One paper used Impella 5.5, which is inserted surgically and so not within the remit of this assessment.

Bogerd (2025) included 108,736 people with AMICS, 92,262 of whom had a microaxial flow pump or percutaneous ventricular assist device. The review included 13 studies, describing 12 retrospective cohorts. The mean or median age ranged from 55 to 80.6 years and 73% of the study population was male. Outcomes were reported to hospital discharge. The type of microaxial flow pump used in each study was not specified in the review.

The systematic review by Stub (2025) included 5 propensity score-matched or adjusted studies with 9,871 people who had a microaxial flow pump or VA-ECMO. The matched sample included 984 people who had a microaxial flow pump. The most common aetiology of shock in the included studies was AMICS. The mean age was consistent across studies, ranging from 60.0 to 67.7 years and the proportion of males ranged from 70% to 86%. Of the 5 studies, 3 specified that the microaxial flow pump used was Impella CP or 2.5. Follow-up was in-hospital or 30 days.

The systematic review by Panuccio (2022) compared microaxial flow pump and IABP, and included 7,290 people with cardiogenic shock, most of whom had an acute coronary syndrome as the underlying cause. The review included 33 observational studies, describing 5,203 people who had a microaxial flow pump and 2,087 who had IABP. The main types of microaxial flow pump used were Impella CP (50%) and 2.5 (37%). The primary endpoint was 30-day or in-hospital mortality.

The studies by Movahed (2024), Padberg (2024) and Higuchi (2024) are all multicentre registries. Movahed (2024) used the US Nationwide Inpatient Sample database from 2016 to 2020 and included cardiogenic shock from any cause. A total of 844,020 people were included, 39,645 of whom had a microaxial flow pump alone and 6,790 people had a microaxial flow pump with IABP. The mean age was 66.4 years and 62% of the study population was male. The primary outcome was in-hospital mortality. The type of microaxial flow pumps was not specified but the paper describes the devices as being inserted percutaneously through the femoral artery.

Padberg (2024), which was also included in the review by Bogerd (2025), assessed data from a German registry from 2010 to 2017. It included 39,864 people with AMICS, 776 of whom had a microaxial flow pump. The

proportion of males was 61% overall and 69% in those who had temporary MCS. Outcomes for people who had a microaxial flow pump were compared to those who had VA-ECMO, IABP or no temporary MCS. People with out-of-hospital cardiac arrest before admission were not included in the data. The primary endpoint was in-hospital survival, and longer term estimates up to 8 years were reported. The type of microaxial flow pumps was not specified and it was not specified if they were all inserted percutaneously.

Higuchi (2024) included data from a Japanese nationwide registry from 2020 to 2022. It included 5,718 people with drug refractory heart failure who had a microaxial flow pump, most of which were Impella CP. The median age overall was 69 years and the cohort was divided into a younger group (less than 75 years) and an older group (75 years or above). There was a higher proportion of males in the younger group (81% versus 69%, $p<0.0001$). Most of the devices (93%) were inserted using transfemoral access. Impella combined with ECMO was used in 40% of people and 64% of the cohort had PCI. The primary outcome was 30-day mortality.

In addition to the key evidence summarised in table 2 and table 3, individual case reports describing adverse events associated with the procedure have been listed in table 5a in appendix B.

Table 2 presents study details.

Figure 1 Flow chart of study selection

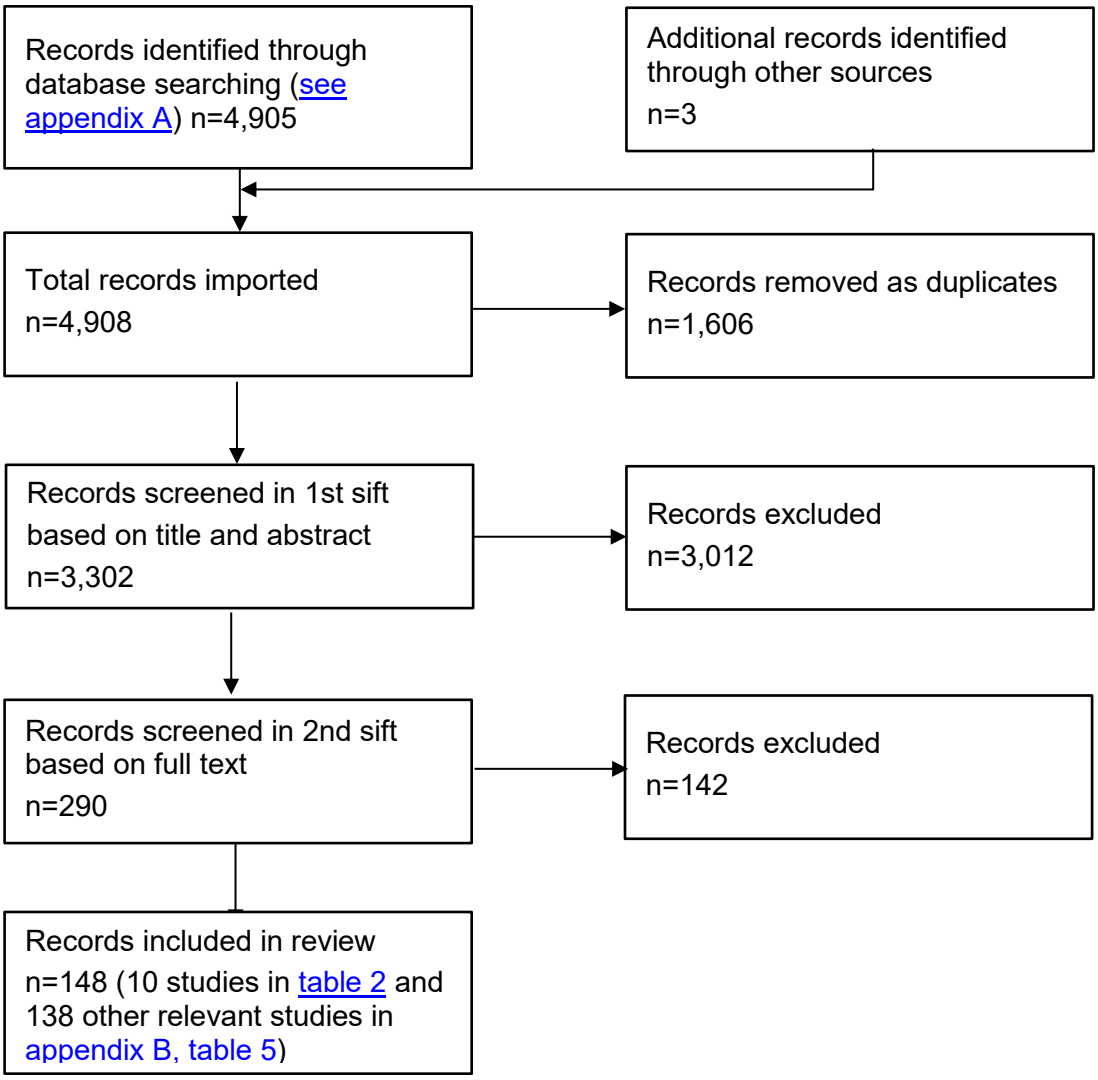

Table 2 Study details

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Møller J, 2024 Denmark, Germany, UK	**n=355 (179 microaxial flow pump)** Indication: STEMI and cardiogenic shock Median age=67 years Male sex=79% SCAI-CSWG stage at admission: • C=56% • D=28% • E=16% Median LVEF=25% (in both groups) Median arterial lactate level (mmol/litre)	International, multicentre, randomised controlled trial (DanGer Shock) Randomisation was done before PCI in 201 people (57%), in the cardiac catheterisation laboratory but after PCI in 96 people (27%), and after leaving the catheterisation laboratory in 58 people (16%). The primary end point was death from any cause at 180 days. January 2013 to July 2023	People aged 18 years or older with STEMI and cardiogenic shock were eligible for enrolment. Cardiogenic shock was defined as hypotension (systolic blood pressure below 100 mmHg or an ongoing need for vasopressor support), end-organ hypoperfusion with an arterial lactate level of 2.5 mmol per litre or greater, and a left ventricular ejection fraction of less than 45%.	• Microaxial flow pump (Impella CP, Abiomed) and standard care=179 • Standard care alone=176 97% of people had PCI. The microaxial flow pump was placed immediately after randomisation. In the event of haemodynamic instability, treatment could be escalated to additional MCS after randomisation in either trial group. In the microaxial-flow-device group, treatment could be	180 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Microaxial flow pump=4.6 • Standard care=4.5 Baseline characteristics were well balanced between the groups.		People who had been resuscitated from out-of-hospital cardiac arrest and remained comatose on arrival to the cardiac catheterisation laboratory and those with overt right ventricular failure were excluded.	escalated to the placement of an Impella 5.0, Impella RP device or extracorporeal life support. In the standard-care group, extracorporeal life support was recommended, although placement of an Impella 5.0 device was allowed. In the standard care group, 3 (2%) people had an Impella CP device inserted and 5 (3%) people had escalation to Impella 5.0. In the microaxial flow pump group, 170 (95%) had an Impella CP and 7 (4%) had escalation to Impella 5.0.	
2	Thiele H, 2024	**n=1,059 (533 MCS)** Indication: AMICS	Individual patient data meta-analysis	All randomised controlled trials comparing early	• MCS (53% VA-ECMO, 6% TandemHeart, 2%	6 months

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	Country of individual studies not reported Includes Møller J (2024)	19% of 1,008 people with available data presented with non-ST-elevation myocardial infarction and 52% of 1,037 people with available data had successful resuscitation before inclusion. Median age=65 years Male sex=80% Median lactate before PCI=5.6 mmol/litre (n=1,020). Lactate 5 mmol/litre or above at baseline=56% Median creatinine at baseline=1.3 mg/dl (n=650)	9 randomised controlled trials were included (4 compared VA-ECMO with control treatment and 5 compared left ventricular unloading devices, including microaxial flow pumps, with control treatment). The primary outcome was 6-month all-cause mortality in the intention-to-treat population for all active MCS devices. Search date: January 2024	(directly in the catheterisation laboratory after randomisation) routine use of active MCS including left ventricular loading (VA-ECMO) and unloading devices (including microaxial flow pumps) versus best medical therapy (including use of an IABP) in people with AMICS having revascularisation without ongoing cardiopulmonary resuscitation were included. In trials permitting various cardiogenic shock causes, people with non-	Impella 2.5, 38% Impella CP) • Standard care, including use of IABP 809 (83%) of 978 people with data had PCI with successful restoration of perfusion.	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
				myocardial infarction causes were excluded.		
3	Sassani K, 2025 Countries of individual studies were reported as: Denmark, Germany, Italy, the Netherlands, Norway, US, 'Europe' Includes Møller J (2024)	**n=2,617** Indication: cardiogenic shock related to acute coronary syndrome Mean age=64.7 years The percentage of people with prior resuscitation varied from 23% to 74% (in those studies that reported it). In most studies, the lactate levels varied from 4.7 to 8.6 mmol/litre. In the studies that reported it, LVEF ranged from 25 to 34%.	Systematic review and meta-analysis 18 studies were included (4 prospective and 14 retrospective). The primary endpoint was defined as 30-day mortality. Search date: September 2024	Studies were suitable for inclusion if reporting on a randomised controlled trial or observational study in which any kind of Impella device was used and cardiogenic shock was the indication. Studies were excluded if they included fewer than 50 people who had Impella, the indication was high-risk PCI without cardiogenic shock, or paediatric	Impella 2.5 and Impella CP	Up to 1 year Of the 18 studies, 10 only reported 30-day outcomes.

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
				populations or congenital heart disease were involved. Evidence on Impella 5.5 was excluded. In cases of studies in which different types of MCS were used, only data related to Impella were considered.		
4	Ardito V, 2023 Studies were primarily set in Europe, North and South America, Asia, the Middle East and Africa Most studies	**n=44,951 (13,848 microaxial flow pump)** Indication: cardiogenic shock The paper states that the mean sample size was 304 (median 62; range 7 to 9,774)	Systematic review and meta-analysis 102 studies were included, most of which were observational studies with a retrospective design. Seven used prospectively collected data and 4 used other designs	Studies on adults with cardiogenic shock (except for pregnant women) were included. Randomised controlled trials, observational and economic evaluations were included. Other designs, including case reports,	• Microaxial flow pump=58 papers • VA-ECMO=44 papers • Both microaxial flow pump and VA-ECMO=9 papers Type of microaxial flow pump used:	Up to 1 year

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	were done in the US, followed by Germany, Japan, France and South Korea.	Mean age ranged from 31 to 78 years.	(such as randomised controlled trials). 66 studies were single-centred and 36 were multicentred. The primary outcome was overall mortality. Search date: February 2022	single-patient case studies, guidelines, protocols, position papers, consensus statements, editorials, and letters were excluded. Only studies written in English or Italian were included for data synthesis. Only studies individually focused on Impella or VA-ECMO were eligible. Articles on the treatment of cardiogenic shock with devices other than Impella or VA-ECMO or with a combination of	• Impella CP=41 papers • Impella RP=5 papers • Impella 2.5=25 papers • Impella 5.0=20 papers • Impella 5.5=1 paper	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
				devices were excluded.		
5	Bogerd M, 2025 Germany, The Netherlands, US Includes Padberg (2024)	**n=108,736 (92,262 microaxial flow pump)** Indication: AMICS Male sex=73% Mean or median age ranged from 55 to 70.6 years. Microaxial flow pump-supported patients were considerably older in all age-reporting studies. The incidence of out-of-hospital cardiac arrest was reported in 5 studies and varied between 0 and 50%. Of the 5 studies, 3 reported a higher incidence of out-of-	Systematic review and meta-analysis 13 studies were included, describing 12 retrospective cohorts. Primary outcomes were intensive care unit length of stay, hospital length of stay, in-hospital costs and discharge destination. Search date: November 2024	Eligible studies were included if they described adults (18 years old or above) with AMICS (in at least 50% of the study population) and compared the use of a microaxial flow pump or percutaneous VAD with VA-ECMO. Studies had to report at least 1 of the primary outcomes. Studies comparing the use of VA-ECMO with the use of VA-ECMO plus unloading were excluded. Animal studies, abstracts	• Microaxial flow pump (not specified) • VA-ECMO 4 studies reported data for people who were treated with 2 or more devices (including IABP). A small proportion of the microaxial flow pump cohort were treated by TandemHeart instead, which is a percutaneous centrifugal LVAD. In 4 studies, all people had PCI. In another 4 studies, the proportion of people who had PCI was significantly	Hospital discharge

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		hospital cardiac arrest in the VA-ECMO cohort.		only, case reports or case series (defined as cohort of fewer than 10 people per treatment arm), systematic reviews and meta-analyses were excluded.	lower among the VA-ECMO cohort compared with the microaxial flow pump cohort. The proportion of people who had a CABG was higher in the VA-ECMO cohort in 3 studies. The type of Impella pumps used was not specified.	
6	Stub D, 2025 Germany, US, 'Europe'	**n=9,871 (8,718 microaxial flow pump, 984 matched)** Indication: cardiogenic shock The proportion of males ranged from 70% to 86% in the studies. The mean age was consistent across	Systematic review and meta-analysis 5 propensity score-matched or adjusted studies were included. The primary outcome of interest was short-term mortality, defined as either 30-day or in-hospital mortality. Search date: July 2023	To be included, the study had to be a comparative study of Impella versus VA-ECMO, include people with cardiogenic shock and must have reported survival data. Studies were excluded if: outcomes data were not stratified by intervention	• Microaxial flow pump (Impella) • VA-ECMO 2 of the included studies did not report the type of Impella device used while the remaining 3 studies used the Impella CP or Impella 2.5.	In-hospital or 30 days

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		studies, ranging from 60.0 to 67.7 years old. The most common aetiology of shock in the included studies was AMICS.		type, the study was incomplete with no available data, or the study was not available in full-text form. Studies that did not propensity score match patients or did not conduct adjusted analyses to account for variation in baseline demographic or disease characteristics were also excluded.		
7	Panuccio G, 2022 Country of individual studies not reported	**n=7,290 (5,203 microaxial flow pump)** Indication: all were admitted for cardiogenic shock and most had an acute	Systematic review and meta-analysis 33 observational studies (1 was prospective) were included, 7 of which provided a	Criteria for study inclusion: any clinical study in which an Impella device was used; the clinical setting in which Impella was used was cardiogenic	• Microaxial flow pump, n=5,203 • IABP, n=2,087 Type of microaxial flow pump (proportion of people; actual	Up to 1 year

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		coronary syndrome as the underlying cause of cardiogenic shock. Mean age=62.7 years	retrospective comparison between Impella and IABP use. The primary endpoint was 30-day or in-hospital mortality. Search date: December 2021	shock; (short-term mortality was reported. Exclusion criteria: case reports; editorials or systematic review or meta-analysis; mean age of study population less than18 years; case series of fewer than 10 patients; short term mortality was not reported; use of Impella device in clinical settings different from cardiogenic shock (for example high risk PCI).	numbers not specified) • Impella 2.5 (37%) • Impella CP (50%) • Impella 5.0 (13%)	
8	Movahed M, 2024 US	**n=844,020 (39,645 microaxial flow pump alone, 6,790 microaxial flow pump and IABP)**	Retrospective registry (Nationwide Inpatient Sample database)	People over 18 years old discharged from a Nationwide Inpatient Sample	• Microaxial flow pump without IABP=39,645	Not reported

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Indication: cardiogenic shock Mean age (years, p<0.001): • Overall=66.4 • Microaxial flow pump=64.4 • IABP=65.3 • Microaxial flow pump and IABP=64.0 • No microaxial flow pump or IABP=66.8 Male sex (p<0.001): • Overall=62% • Microaxial flow pump=72% • IABP=69% • Microaxial flow pump and IABP=71% • No microaxial flow pump or IABP=61%	The main outcome was in-hospital mortality 2016 to 2020	hospital in 2016 to 2020 with the following International Classification of Diseases, Tenth Revision, and Clinical Modification codes: Cardiogenic Shock (R57.0), Balloon Pump (5A02210), and Impella Pump (5A0221D). People who had ECMO were excluded.	• Microaxial flow pump with IABP=6,790 • IABP without microaxial flow pump=101,870 • No microaxial flow pump or IABP=694,715 The type of Impella pumps used was not specified but the text describes percutaneous insertion through the femoral artery.	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Ethnicity (p<0.001): • White: overall=68%, Microaxial flow pump=72%, IABP=70% Microaxial flow pump and IABP=69% No microaxial flow pump or IABP=67% • Black: overall=16%, Microaxial flow pump=10%, IABP=12% Microaxial flow pump and IABP=11% No microaxial flow pump or IABP=17% • Hispanic: overall=9%, Microaxial flow				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		pump=9%, IABP=10% Microaxial flow pump and IABP=10% No microaxial flow pump or IABP=9% • Asian or pacific islander: overall=3% Microaxial flow pump=3%, IABP=4% Microaxial flow pump and IABP=4% No microaxial flow pump or IABP=3% STEMI (p<0.001): • Overall=22% • Microaxial flow pump=48% • IABP=44%				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Microaxial flow pump and IABP=45% • No microaxial flow pump or IABP=17% Heart failure (p<0.001): • Overall=71% • Microaxial flow pump=73% • IABP=69% • Microaxial flow pump and IABP=80% • No microaxial flow pump or IABP=71% Systolic heart failure (p<0.001): • Overall=53% • Microaxial flow pump=60% • IABP=56%				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Microaxial flow pump and IABP=68% • No microaxial flow pump or IABP=52% Cardiomyopathy (p<0.001): • Overall=42% • Microaxial flow pump=50% • IABP=47% • Microaxial flow pump and IABP=52% • No microaxial flow pump or IABP=41% Cardiac arrest (p<0.001): • Overall=10% • Microaxial flow pump=12% • IABP=9%				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• Microaxial flow pump and IABP=10% • No microaxial flow pump or IABP=10%				
9	Padberg J-S, 2024 Germany	**n=39,864 (776 microaxial flow pump)** Indication: AMICS Male sex=61% (69% in the temporary MCS group versus 60% in the no temporary MCS group, p<0.001). Median age (p<0.001): • Microaxial flow pump=70.6 • VA-ECMO=63.7 • IABP=71.6 • No MCS=75.6	Retrospective multicentre registry (AOK-Die Gesundheitskasse) The primary endpoint was overall survival. January 2010 to December 2017	All patients aged 18 years and above, who were hospitalised with a primary diagnosis of acute myocardial infarction or cardiogenic shock and use of VA-ECMO or Impella between 2010 and 2017 (index hospitalisation). People with out-of-hospital cardiac arrest before admission were not included in the data.	• Microaxial flow pump, n=776 • VA-ECMO, n=833 • IABP, n=5,451 • No temporary MCS=32,804 People who had a microaxial flow pump were more likely to have PCI (95% versus 79% for VA-ECMO and 75% for IABP, p<0.001). People who had VA-ECMO or IABP were more likely to have coronary artery bypass graft surgery (IABP 32% versus VA-ECMO 26%	8-year survival estimates were reported.

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
					versus microaxial flow pump 2%, p<0.001). The type of Impella microaxial flow pumps used was not specified and it was not specified they were all inserted percutaneously.	
10	Higuchi R, 2024 Japan	**n=5,718** Indication: drug-refractory heart failure, particularly cardiogenic shock. Median age=69 years (IQR 58 to 77) 1,807 (32%) people were in the older group (age 75 or over) group and 3,911 (68%) were in the younger group (age below 75).	Japanese nationwide registry (J-PVAD) The primary outcome was the Kaplan-Meier estimated 30-day mortality. February 2020 to December 2022	Consecutive people using the Impella device in Japan.	• Impella 2.5 (4%, n=231) ○ Younger=4% ○ Older=5% • Impella CP (90%, n=5,149) ○ Younger=90% ○ Older=91% • Impella 5.0 or 5.5 (6%, n=338) ○ Younger=7% ○ Older=4% p<0.0001	Median follow up was 32 days (IQR 14 to 38) in the younger group and 30 days (IQR 10 to 36) in the older group, p<0.0001.

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up

		Male sex:
		• Younger group=81%
		• Older group=69%
		p<0.0001
		
		Cause of admission:
		• Cardiogenic shock (8%, n=472)
		  ○ Younger=8%
		  ○ Older=8%
		• Cardiac arrest (9%, n=529)
		  ○ Younger=12%
		  ○ Older=4%
		• Acute coronary syndrome (48%, n=2,717)
		  ○ Younger=43%
		  ○ Older=58%
		• Myocarditis (7%, n=402)
		  ○ Younger=9%
		  ○ Older=2%
					Transfemoral access site (93%, n=5,307):
					• Younger=92%
					• Older=94%
					p=0.023
					
					Median duration (hours):
					• Younger=113 (IQR 49 to 192)
					• Older=84 (IQR 28 to 163)
					p<0.0001
					
					Additional MCS (51%, n=2,907):
					• Younger=54%
					• Older=44%
					p<0.0001
					
					Microaxial flow pump combined with ECMO (40%, n=2,309):
					• Younger=44%	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up

		• Heart failure (14%, n=791)
		  ○ Younger=14%
		  ○ Older=13%
		• Chronic coronary syndrome (4%, n=258)
		  ○ Younger=4%
		  ○ Older=6%
		• Arrhythmia (3%, n=159)
		  ○ Younger=4%
		  ○ Older=1%
		• Other (7%, n=390)
		  ○ Younger=7%
		  ○ Older=7%
		p<0.0001
		
		Out of hospital cardiac arrest:
		• Younger group=24%
		• Older group=10%
		p<0.0001
					• Older=32%
					p<0.0001
					
					PCI (64%, n=3,638):
					• Younger=59%
					• Older=74%
					p<0.0001	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Median lactate levels, mmol/litre: • Younger group=4.3 (IQR 2.1 to 9.5) • Older group=4.1 (IQR 2.1 to 7.8) p=0.005 Median ejection fraction: • Younger group=25% (IQR 18 to 34) • Older group=30% (IQR 23 to 43) p<0.0001 The older group presented with a smaller body mass index, frequent acute coronary syndrome, and infrequent myocarditis. The younger group had				

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		more unstable haemodynamics, characterised by lower systolic blood pressure, a higher lactate level, and more frequent use of a vasopressor or inotrope and combined microaxial flow pump with ECMO.				

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Møller J, 2024	Among 179 people assigned to the microaxial-flow-pump group, the device was placed successfully in 170 (95.0%), and 3 people (1.7%) crossed over to receive standard care only. In 6 people (3.3%), device placement was attempted but was unsuccessful. In the standard-care group, 3 people (1.7%) had a microaxial flow pump. **Escalation to another mechanical circulatory support system**	**Composite safety end-point event** (severe bleeding, limb ischaemia, haemolysis, device failure, and worsening of aortic regurgitation) • Microaxial flow pump group=24.0% (43/179) • Standard care group=6.2% (11/176) RR 4.74, 95% CI 2.36 to 9.55, p value not reported In the microaxial flow pump group, the number needed to harm was 6.

First author, date	Efficacy outcomes	Safety outcomes
	• Microaxial flow pump group=15.6% (28/179) • Standard care group=21.0% (37/176) p value not reported **Death from any cause at 180 days (primary endpoint); intention-to-treat population** • Microaxial flow pump group=45.8% (82/179) • Standard care group=58.5% (103/176) HR=0.74, 95% CI 0.55 to 0.99, p=0.04 The number needed to treat to avoid 1 death was 8. Death from any cause at 180 days in the as-treated groups where statistical power was retained (n=170 for the microaxial flow pump group and n=173 for the standard care group), HR=0.77, 95% CI 0.57 to 1.03. **Composite cardiac endpoint (escalation of treatment to additional MCS (short- or long-term), heart transplantation, or death from any cause, whichever came first); intention-to-treat population** • Microaxial flow pump group=52.5% (94/179) • Standard care group=63.6% (112/176) HR=0.72, 95% CI 0.55 to 0.95, p=0.04	**Moderate or severe bleeding** • Microaxial flow pump group=21.8% (39/179) • Standard care group=11.9% (21/176) RR 2.06, 95% CI 1.15 to 3.66, p value not reported **Limb ischaemia** • Microaxial flow pump group=5.6% (10/179) • Standard care group=1.1% (2/176) RR 5.15, 95% CI 1.11 to 23.84, p value not reported **Renal replacement therapy** • Microaxial flow pump group=41.9% (75/179) • Standard care group=26.7% (47/176) RR 1.98, 95% CI 1.27 to 3.09, p value not reported **Stroke** • Microaxial flow pump group=3.9% (7/179) • Standard care group=2.3% (4/176) RR 1.75, 95% CI 0.50 to 6.01, p value not reported **Cardioversion after ventricular tachycardia or fibrillation**

First author, date	Efficacy outcomes	Safety outcomes
	Mean number of days alive and out of the hospital (range); intention-to-treat population • Microaxial flow pump group=82 (0 to 177) • Standard care group=73 (0 to 179) Mean between-group difference=8, 95% CI -8 to 25 p value not reported	• Microaxial flow pump group=33.0% (59/179) • Standard care group=29.5% (52/176) RR 1.17, 95% CI 0.75 to 1.83, p value not reported **Sepsis with positive blood culture** • Microaxial flow pump group=11.7% (21/179) • Standard care group=4.5% (8/176) RR 2.79, 95% CI 1.20 to 6.48, p value not reported
Thiele H, 2024	**6-month all-cause mortality (intention-to-treat); primary endpoint (MCS group includes VA-ECMO [53%], Impella CP [38%], Impella 2.5 [2%] and TandemHeart [6%])** • MCS group=50.7% (95% CI 46.5 to 55.0) • Standard care group=55.9% (95% CI 51.7 to 60.2) HR=0.87 (95% CI 0.74 to 1.03, p=0.10) There was no statistical evidence of heterogeneity of effects across trials. **6-month mortality (as treated)** • MCS group=54.6% (95% CI 50.7 to 58.6) • Standard care group=51.7% (95% CI 47.2 to 56.4) HR=1.04 (95% CI 0.87 to 1.23, p=0.10)	**Moderate or severe bleeding at 30 days (Bleeding Academic Research Consortium score 3 or above)** • MCS group=28.3% (143/506) • Standard care group=13.3% (67/503) OR=2.64 (95% CI 1.91 to 3.65), p value not reported **Stroke at 30 days** • MCS group=3.8% (19/498) • Standard care group=2.6% (13/496) OR=1.48 (95% CI 0.72 to 3.04), p value not reported **Peripheral ischaemic vascular complication at 30 days**

First author, date	Efficacy outcomes	Safety outcomes
	People from the control group who had active MCS had a mortality of 72.7% (95% CI 64.2 to 80.7) versus 51.4% (46.7 to 56.3) those without MCS. **6-month mortality in trials using left ventricular unloading MCS** • Left ventricular unloading group=47.3% (95% CI 41.3 to 53.7) • Standard care group=56.9% (95% CI 50.8 to 63.3) HR=0.80 (95% CI 0.62 to 1.02, p=0.075) **6-month mortality for people with STEMI without resuscitation or with only short resuscitation (low risk of hypoxic brain injury)** • MCS group=44.5% (95% CI 39.0 to 50.3) • Standard care group=55.4% (95% CI 49.7 to 61.1) HR=0.77 (95% CI 0.61 to 0.97, p=0.024) **30-day mortality** • MCS group=43.6% (95% CI 39.5 to 48.0) • Standard care group=47.1% (95% CI 43.0 to 51.5) HR=0.89 (95% CI 0.74 to 1.06, p=0.10) **HRs for 6-month all-cause mortality according to intention-to-treat in prespecified subgroups**	• MCS group=9.7% (50/518) • Standard care group=2.3% (12/516) OR=4.43 (95% CI 2.37 to 8.26), p value not reported **Sepsis at 30 days** • MCS group=16.7% (80/480) • Standard care group=13.9% (66/474) OR=1.28 (95% CI 0.87 to 1.88), p value not reported **Renal replacement therapy at 30 days** • MCS group=24.0% (116/484) • Standard care group=20.3% (98/482) OR=1.29 (95% CI 0.94 to 1.77), p value not reported

First author, date	Efficacy outcomes	Safety outcomes
	• Age 70 years or above=0.81 (95% CI 0.63 to 1.05) • Lactate 5 mmol/litre or above=0.80 (95% CI 0.65 to 0.98) • Cardiac arrest=0.91 (95% CI 0.71 to 1.15) • STEMI=0.84 (95% CI 0.69 to 1.01) • Non-STEMI=1.00 (95% CI 0.69 to 1.46) • Thrombolysis in Myocardial Infarction after PCI 0 to 2=0.57 (95% CI 0.38 to 0.85) • Thrombolysis in Myocardial Infarction after PCI 3=0.93 (95% CI 0.76 to 1.13) • Systolic blood pressure below 80 mmHg=0.63 (95% CI 0.46 to 0.87) • Systolic blood pressure 80 mmHg or above=0.93 (95% CI 0.74 to 1.16)	
Sassani K, 2025	**30-day mortality** • Mean=45% (range 28 to 67%) • Meta-analysis results=45% (95% CI 43 to 47; I^2=89.8%, 18 studies) Heterogeneity remained high after sensitivity or leave-out analyses.	**Ischaemia** • Mean=8% (range 3 to 13.6%) • Meta-analysis results=8% (95% CI 7 to 9; I^2=75.5%; 17 studies) **Bleeding** • Mean=14% (range 3 to 24%) • Meta-analysis results=13% (95% CI 12 to 14; I^2=73.3%, 17 studies)

First author, date	Efficacy outcomes	Safety outcomes
		Heterogeneity remained high after sensitivity or leave-out analyses.
Ardito V, 2023	**Overall mortality (reported at 30 days, 6 months and 1 year)** • Microaxial flow pump group=44% (95% CI 39 to 50; 42 papers, I^2=90.6%) • VA-ECMO group=50% (95% CI 43 to 58, 30 papers, I^2=94.3%) **Qualitatively labelled mortality outcomes (at discharge, in hospital, to the next therapy, to explant, and on device)** • Microaxial flow pump group=45% (95% CI 40 to 49; 39 papers, I^2=95.6%) • VA-ECMO group=49% (95% CI 45 to 53; 40 papers, I^2=95.2%) **Successful weaning** • Microaxial flow pump group=58% (95% CI 49 to 66, 9 papers, I^2=54.5%) • VA-ECMO group=53% (95% CI 47 to 60, 19 papers, I^2=74.4%) **Bridge to VAD** The proportion of people bridged to long-term LVAD was the same for microaxial flow pump and VA-ECMO	**Access site bleeding** • Microaxial flow pump group=16% (95% CI 8 to 27, 8 studies I^2=91.6%) • VA-ECMO group=19% (95% CI 14 to 23, 5 studies, I^2=25.6%) **Major bleeding** • Microaxial flow pump group=20% (95% CI 12 to 30, 15 studies; I^2=95.4%) • VA-ECMO group=25% (95% CI 16 to 34, 11 studies, I^2=88.0%) **Limb ischaemia** • Microaxial flow pump group=6% (95% CI 4 to 8, 19 studies; I^2=61.1%) • VA-ECMO group=10% (95% CI 7 to 15, 23 studies, I^2=90.2%) **Ischaemic stroke** • Microaxial flow pump group=0% (95% CI 0 to 0, 26 studies; I^2=66.8%) • VA-ECMO group=7% (95% CI 5 to 10, 24 studies, I^2=79.1%)

First author, date	Efficacy outcomes	Safety outcomes
	groups (10%), without statistically significant differences. **Bridge to transplant** • Microaxial flow pump group=4% (95% CI 0 to 12, 11 papers, I^2=91.8%) • VA-ECMO group=6% (95% CI 3 to 9, 14 papers, I^2=69.9%)	**Renal failure** • Microaxial flow pump group=34% (95% CI 26 to 43, 25 studies; I^2=96.1%) • VA-ECMO group=36% (95% CI 31 to 42, 23 studies, I^2=89.6%)
Bogerd M, 2025	**In-hospital mortality** • Microaxial flow pump group=44% • VA-ECMO group=57% RR=0.84, 95% CI 78 to 86, p<0.001, 11 studies, I^2=86% **Intensive care unit length of stay** 1 study (n=128) showed a MD of 10 days in favour of the microaxial flow pump. **Hospital length of stay** The averaged hospital length of stay was statistically significantly shorter in the microaxial flow pump group compared with the VA-ECMO group: MD=-5.31 (95% CI -6.55 to -4.06, p<0.001, 9 studies, I^2=89%)	No safety outcomes were reported

First author, date	Efficacy outcomes	Safety outcomes
	Proportion of survivors discharged home • Microaxial flow pump group=51% • VA-ECMO group=36% RR=1.45, 95% CI 1.28 to 1.64, p<0.001, 4 studies, I^2=73%	
Stub D, 2025	**In-hospital or 30-day mortality** The meta-analysis of the ORs from the included studies demonstrated that microaxial flow pumps statistically significantly reduced the odds of in-hospital or 30-day mortality compared to VA ECMO (OR 0.57, 95% CI 0.44 to 0.74; p<0.0001, I^2=27%). In absolute terms, the proportion of people who had a microaxial flow pump and died in-hospital or within 30 days (pooled 39.6%) was lower than the proportion of those who had VA-ECMO (pooled: 53.8%; p value not reported)	**Bleeding events needing transfusion** The meta-analysis showed statistically significantly lower odds of bleeding events needing transfusion in people who had a microaxial flow pump compared to VA-ECMO (OR 0.61, 95% CI 0.46 to 0.80; p=0.0004, I^2=0%). All studies reported a lower proportion of bleeding events needing transfusion in the microaxial flow pump cohort (pooled: 19.9%) compared to the VA-ECMO cohort (pooled: 28.8%; p value not reported).
Panuccio G, 2022	**Short-term mortality (30-day or in-hospital)** for microaxial flow pump=47.0% (95% CI 43.6 to 50.4, 33 studies, I^2=80.2%) Meta-regression analysis showed that older age was associated with a negative impact on the outcome (p=0.01).	**Vascular complications=6.4% (95% CI 4.8 to 8.1, 27 studies, I^2=77.1%)** At meta-regression analysis, older age (p=0.005), diabetes (p=0.007) and use of Impella 5.0 (p=0.04) were significant predictors of vascular access complications. No interaction was found between the percentage of higher MCS and the rate of vascular access complications (p=0.951).

First author, date	Efficacy outcomes	Safety outcomes
	There was a significant interaction between the percentage of people having higher MCS (Impella CP or Impella 5.0) and short-term mortality (p=0.004), suggesting a larger benefit with higher MCS. Positioning of microaxial flow pump before starting the PCI was associated with lower mortality, as the percentage of people put on microaxial flow pump support before PCI was a statistically significant moderator at meta-regression analysis (p<0.001). **Comparison of microaxial flow pump with IABP (n=4,166)** **Short-term mortality** • Microaxial flow pump group=45.8% • IABP group=36.8% RR=1.08; 95% CI 0.89 to 1.31; p=0.45, 7 studies, I^2=67% Sensitivity analysis showed that most heterogeneity was related to the different percentage of use of higher MCS (using Impella 5.0 or Impella CP). In the subgroup of studies with a higher percentage of adoption of higher MCS, RR=0.94; 95% CI 0.77 to 1.15; p=0.529. In the subgroup of studies with lower adoption of a high MCS, short-term mortality was higher with microaxial flow pumps (RR=1.26; 95% CI 1.08 to 1.48; p=0.005).	**Major bleeding=16.4% (95% CI 12.4 to 20.5, 29 studies, I^2=93.6%)** **Comparison of microaxial flow pump with IABP (n=4,166)** **Vascular access complications** • Microaxial flow pump group=10.7% • IABP group=3.1% RR=3.32; 95% CI 2.54 to 4.33; p<0.001, 7 studies, I^2=0% **Major bleeding** • Microaxial flow pump group=27.8% • IABP group=13.9% RR=1.99; 95% CI 1.75 to 2.25; p<0.001, 6 studies, I^2=0%

First author, date	Efficacy outcomes	Safety outcomes
	At meta-regression analysis including multiple moderators, the rate of microaxial flow pump related vascular complications (p=0.014) but not the proportion of adoption of higher MCS (p=0.058), nor age (p=0.067) was significantly associated with short-term mortality.	
Movahed M, 2024	**Inpatient mortality** • Overall=33.5% • No MCS=34.2% • Microaxial flow pump group=40.8% (OR 1.32, 95% CI 1.26 to 1.39, p<0.001) • IABP group=25.2% (OR 0.65, 95% CI 0.62 to 0.67, p<0.001) • Microaxial flow pump and IABP group=46.8% (OR 2.12, 95% CI 1.89 to 2.37, p<0.001) Using multivariate analysis adjusting for multiple demographics and patient-specific factors, microaxial flow pump remained associated with the highest mortality (OR 1.33, 95% CI 1.25 to 1.41, p<0.001), whereas IABP remained associated with the lowest mortality (OR 0.69, 95% CI 0.66 to 0.72, p<0.001). In a subgroup analysis, there was a statistically significant higher mortality in people who had	**Complications** **Pericardial effusion** • Microaxial flow pump group=4.1% • IABP group=4.0% OR=1.04 (95% CI 0.91 to 1.19, p=0.54) **Cardiac tamponade** • Microaxial flow pump group=2.6% • IABP group=2.1% OR=1.27 (95% CI 1.07 to 1.51, p=0.007) **Post procedural acute kidney failure** • Microaxial flow pump group=0.2% • IABP group=0.4% OR=0.44 (95% CI 0.25 to 0.77, p=0.004) **Acquired haemolytic anaemia** • Microaxial flow pump group=0.7%

First author, date	Efficacy outcomes	Safety outcomes
	microaxial flow pumps in all subgroups, whereas IABP reduced mortality in all subgroups studied.	• IABP group=0.1% OR=8.36 (95% CI 4.89 to 14.3, p<0.001) **Post procedural haemorrhage** • Microaxial flow pump group=2.3% • IABP group=1.2% OR=1.99 (95% CI 1.06 to 2.42, p<0.001) (Note: paper reported CIs as 10.64 to 2.42) **Acute post procedural respiratory failure** • Microaxial flow pump group=1.9% • IABP group=4.6% OR=0.41 (95% CI 0.34 to 0.49, p<0.001) **Disseminated intravascular coagulation** • Microaxial flow pump group=3.0% • IABP group=1.7% OR=1.76 (95% CI 1.48 to 2.08, p<0.001) **Cardiac perforation** • Microaxial flow pump group=1.3% • IABP group=0.9% OR=1.48 (95% CI 1.17 to 1.88, p=0.001)

First author, date	Efficacy outcomes	Safety outcomes
		Procedural bleeding • Microaxial flow pump group=0.3% • IABP group=0.1% OR=2.37 (95% CI 1.33 to 4.23, p=0.004) **Intraoperative cardiac functional disturbances** • Microaxial flow pump group=0.5% • IABP group=0.4% OR=1.41 (95% CI 0.97 to 2.05, p=0.08) **Post-procedural cerebrovascular infarction** • Microaxial flow pump group=0.05% • IABP group=0.07% OR=0.73 (95% CI 0.24 to 2.23, p=0.59) **Limb amputation** • Microaxial flow pump group=0.09% • IABP group=0.05% OR=1.64 (95% CI 0.63 to 4.22, p=0.31)
Padberg J-S, 2024	**Mortality during index hospitalisation** • Microaxial flow pump group=62.1% (482/776) • VA-ECMO group=58.6% (488/833) • IABP group=47.1% (2,569/5,451)	**In-hospital complications** **Acute kidney injury** • Microaxial flow pump group=43.9% (341/776) • VA-ECMO group=52.8% (440/833)

First author, date	Efficacy outcomes	Safety outcomes
	• No temporary MCS group=59.0% (19,367/32,804) p<0.001 Compared with no temporary MCS, there was no statistically significant difference in mortality in either the microaxial flow pump (p=0.09) or the VA-ECMO subgroups (p=0.79). There was also no statistically significant difference in the comparison of VA-ECMO and microaxial flow pumps (p=0.15). **Mortality during the case chain (for example, in continuing care hospitals or rehabilitation clinic)** • Microaxial flow pump group=11.9% (35/776) • VA-ECMO group=38.5% (132/833) • IABP group=11.8% (339/5,451) • No temporary MCS group=7.2% (20,336/32,804) p<0.001 **1-year Kaplan Meier survival estimates (95% CI)** • Microaxial flow pump group=29.3% (26.1 to 32.5) • VA-ECMO group=22.4% (19.5 to 25.2) • IABP group=40.6% (39.3 to 41.9) • No temporary MCS group=31.3% (30.8 to 31.8) **2-year Kaplan Meier survival estimates (95% CI)**	• IABP group=31.8% (1,732/5,451) • No temporary MCS group=26.9% (8,835/32,804) p<0.001 **Renal replacement therapy** • Microaxial flow pump group=30.5% (237/776) • VA-ECMO group=50.3% (419/833) • IABP group=25.2% (1,590/5,451) • No temporary MCS group=12.1% (3,975/32,804) p<0.001 **Bleeding** • Microaxial flow pump group=20.9% (162/776) • VA-ECMO group=38.1% (317/833) • IABP group=18.0% (980/5,451) • No temporary MCS group=9.3% (3,058/32,804) p<0.001 **Red blood cell transfusion** • Microaxial flow pump group=51.7% (401/776) • VA-ECMO group=88.4% (736/833)

First author, date	Efficacy outcomes	Safety outcomes
	• Microaxial flow pump group=27.5% (24.3 to 30.6) • VA-ECMO group=21.3% (18.5 to 24.0) • IABP group=37.7% (36.4 to 39.0) • No temporary MCS group=28.4% (28.0 to 28.9) **5-year Kaplan Meier survival estimates (95% CI)** • Microaxial flow pump group=22.4% (18.9 to 25.8) • VA-ECMO group=18.1% (15.3 to 21.0) • IABP group=30.7% (29.5 to 32.0) • No temporary MCS group=22.9% (22.4 to 23.4) **8-year Kaplan Meier survival estimates (95% CI)** • Microaxial flow pump group=11.2% (0 to 26.8) • VA-ECMO group=14.0% (7.4 to 20.6) • IABP group=25.3% (24.1 to 26.6) • No temporary MCS group=18.9% (18.4 to 19.4) A Cox proportional hazards model was used to adjust for confounders. Classical cardiovascular risk factors were associated with improved survival: arterial hypertension (HR 0.83, 95% CI 0.80 to 0.86, p<0.001), dyslipidaemia (HR 0.73, 95% CI 0.71 to 0.75, p<0.001), smoking (HR 0.92, 95% CI 0.89 to 0.95, p<0.001), history of previous myocardial infarction (HR 0.73, 95%	• IABP group=54.2% (2,954/5,451) • No temporary MCS group=21.7% (7,131/32,804) p<0.001 **Haemorrhagic stroke** • Microaxial flow pump group=1.6% (12/776) • VA-ECMO group=3.1% (26/833) • IABP group=1.0%% (53/5,451) • No temporary MCS group=0.8% (249/32,804) p<0.001 **Ischaemic stroke** • Microaxial flow pump group=4.0% (31/776) • VA-ECMO group=9.6% (80/833) • IABP group=5.3% (289/5,451) • No temporary MCS group=4.1% (1,347/32,804) p<0.001 **Sepsis** • Microaxial flow pump group=15.9% (123/776) • VA-ECMO group=22.5% (187/833) • IABP group=13.9% (757/5,451)

First author, date	Efficacy outcomes	Safety outcomes
	CI 0.71 to 0.75, p<0.001) or chronic heart failure (HR 0.71, 95% CI 0.69 to 0.73, p<0.001). Microaxial flow pumps (HR 1.25, 95% CI 1.15 to 1.35, p<0.001), and VA-ECMO (HR 1.57, 95% CI 1.45 to 1.69, p<0.001), were shown to be independent risk factors for mortality. IABP was associated with improved survival (HR 0.89, 95% CI 0.86 to 0.92, p<0.001).	• No temporary MCS group=9.2% (3,034/32,804) p<0.001

Higuchi, 2024	**30-day mortality**
	• Overall=34.6%
	• Younger group=32.5%
	• Older group=38.9%
	p<0.0001
	
	30-day mortality by type of support
	• Microaxial flow pump alone=24.4%
	• Microaxial flow pump combined with ECMO=49.5%
	p<0.0001
	
	Statistically significant predictors of 30-day mortality identified from multivariate analysis
	• Age 75 years or above: HR=1.83, 95% CI 1.56 to 2.16, p<0.001
	• Body mass index per 1kg/m^2 increase: HR=1.05, 95% CI 1.03 to 1.06, p<0.0001
		Procedural complications in people who had microaxial flow pump alone (n=3,409)
		• Bleeding=15.8% (538/3,409)
		• Cardiac tamponade=1.4% (47/3,409)
		• Cerebrovascular accident=4.5% (152/3,409)
		• Haemolysis=13.1% (446/3,409)
		• Limb ischaemia=3.7% (125/3,409)
		• Acute kidney injury=6.7% (227/3,409)
		• Sepsis=4.0% (136/3,409)
		• Vascular injury=0.9% (30/3,409)
		
		Incidence of microaxial flow pump related complications by age group
		• Bleeding
		  ○ Younger=20.9%
		  ○ Older=22.0%, p=0.33
		• Cardiac tamponade

First author, date	Efficacy outcomes	Safety outcomes
	• Myocarditis: HR=0.43, 95% CI 0.30 to 0.63, p<0.0001 • Arrhythmia: HR=1.29, 95% CI 1.07 to 1.55, p=0.007 • Lactate per 1 mmol/litre increase: HR=1.02, 95% CI 1.01 to 1.03, p=0.0005 • Creatinine per 1 mg/dl increase: HR=1.08, 95% CI 1.04 to 1.11, p=0.0003 • Total bilirubin per 1 mg/dl increase: HR=1.06, 95% CI 1.03 to 1.09, p=0.0004 • Albumin per 1 g/dl increase: HR=0.82, 95% CI 0.73 to 0.93, p=0.002 • Combined microaxial flow pump and ECMO: HR=1.80, 95% CI 1.39 to 2.34, p<0.0001 • Limb ischaemia: HR=1.49, 95% CI 1.13 to 1.97, 95% CI, p=0.007	○ Younger=1.8% ○ Older=3.5%, p<0.0001 • Cerebrovascular accident ○ Younger=6.1% ○ Older=4.9%, p=0.068 • Haemolysis ○ Younger=13.1% ○ Older=12.1%, p=0.32 • Limb ischaemia ○ Younger=3.5% ○ Older=5.6%, p=0.0001 • Acute kidney injury ○ Younger=8.3% ○ Older=8.8%, p=0.52 • Sepsis ○ Younger=5.1% ○ Older=5.7%, p=0.34 • Vascular injury ○ Younger=1.2% ○ Older=1.4%, p=0.24

Procedure technique

All catheter-based intravascular microaxial flow pumps were Impella devices (Abiomed). Of the 10 key studies, 7 specified the type of Impella devices used. In the randomised controlled trial by Møller (2024), Impella CP was the main intervention. A small proportion of people in the treatment and control groups had escalation to Impella 5.0, which has a higher flow rate. The other studies that reported the type of Impella mainly used Impella CP or Impella 2.5. In the systematic review by Ardito (2023), 41 papers used Impella CP, 25 used Impella 2.5 and 20 used Impella 5.0. The studies did not describe the technique of inserting the microaxial flow pump in detail, but none of them described surgical implantation as the main technique.

Efficacy

In-hospital or 30-day mortality

In-hospital or 30-day mortality was reported in 9 studies.

In the individual patient data meta-analysis of 9 randomised controlled trials by Thiele (2024), 30-day mortality was 44% (95% CI 40 to 48) for the MCS group, which included VA-ECMO as well as microaxial flow pumps, and 47% (95% 43 to 52%) for the standard care group (HR 0.89, 95% CI 0.74 to 1.06, p=0.10).

In the systematic review of 18 studies on cardiogenic shock related to acute coronary syndrome, the mean 30-day mortality was 45% (range 28 to 67%). The meta-analysis result was 45% (95% CI 43 to 47) but heterogeneity was high (I^2=90%) and remained high after sensitivity or leave-out analyses (Sassani 2025). In the systematic review of 13 studies on AMICS, in-hospital mortality was 44% for the microaxial flow pump group and 57% for the VA-ECMO group (RR=0.84, 95% CI 78 to 86, p<0.001, 11 studies, I^2=86%; Bogerd 2025). In the systematic review of 5 propensity score matched or adjusted studies on

cardiogenic shock from any aetiology, the odds of in-hospital or 30-day mortality was statistically significantly reduced in the microaxial flow pump group compared to VA-ECMO (OR 0.57, 95% CI 0.44 to 0.74, p<0.0001, I^2=27%). In absolute terms, the proportion of people who had a microaxial flow pump and died in-hospital or within 30 days (40%) was lower than the proportion of those who had VA-ECMO (54%; Stub 2025). In the systematic review of 33 studies on cardiogenic shock, 30-day or in-hospital mortality for the microaxial flow pump group was 47% (95% CI 44 to 50, I^2=80%. Meta-regression analysis showed that older age was associated with a negative impact on the outcome (p=0.01). There was a significant interaction between the percentage of people having higher MCS (Impella CP or Impella 5.0) and short-term mortality (p=0.004), suggesting a larger benefit with higher MCS. Positioning of a microaxial flow pump before starting PCI was associated with lower mortality. In the comparative analysis of 7 studies, short-term mortality was 46% for the microaxial flow pump group and 37% for the IABP group (RR 1.08, 95% CI 0.89 to 1.31, p=0.45, I^2=67%; Panuccio 2022).

In the retrospective registry study by Movahed (2024), in-hospital mortality was 34% overall, 34% in people who had no MCS, 41% in people who had Impella support (OR 1.32, 95% CI 1.26 to 1.39, p<0.001), 25% for people who had IABP (OR 0.65, 95% CI 0.62 to 0.67, p<0.001) and 47% for people who had both Impella and IABP (OR 2.12, 95% CI 1.89 to 2.37, p<0.001). Using multivariate analysis adjusting for multiple demographics and patient-specific factors, Impella remained associated with the highest mortality (OR 1.33, 95% CI 1.25 to 1.41, p<0.001), whereas IABP remained associated with the lowest mortality (OR 0.69, 95% CI 0.66 to 0.72, p<0.001). In the retrospective registry study by Padberg (2024), in-hospital mortality was 62% for people who had Impella, 59% for those who had VA-ECMO, 47% for those who had IABP and 59% for those who had no MCS (p<0.001). Compared with no temporary MCS, there was no statistically

significant difference in mortality in either the Impella (p=0.09) or the VA-ECMO subgroups (p=0.79). In the registry study by Higuchi (2024), 30-day mortality was 35% overall, 32% in the younger group and 39% in the older group (p<0.0001). When Impella alone was used, 30-day mortality was 24% compared to 50% when Impella combined with ECMO was used (p<0.0001). Age was a statistically significant predictor of mortality (HR for age 75 years or above was 1.83, 95% CI 1.56 to 2.16, p<0.001).

In the systematic review by Ardito (2023) of 102 studies on people with cardiogenic shock, an analysis of qualitatively labelled mortality outcomes was reported (at discharge, in hospital, to the next therapy, to explant, and on device). Mortality was 45% for microaxial flow pumps (95% CI 40 to 49, 39 papers, I^2=96%) and 49% for VA-ECMO (95% CI 45 to 53; 40 papers, I^2=95%) although there was a high degree of heterogeneity and 95% CIs overlapped.

6-month mortality

Mortality at 6 months was reported in 2 studies.

In the randomised controlled trial of 355 people, death from any cause at 180 days was statistically significantly lower in those who had a microaxial flow pump and standard care (46% [82 out of 179]) compared with those who had standard care alone (58% [103 out of 176]), in the intention to treat population (HR=0.74, 95% CI 0.55 to 0.99, p=0.04). The number needed to treat to avoid 1 death was 8 (Møller 2024). In the as-treated groups, the HR was 0.77, 95% CI 0.57 to 1.03.

In the individual patient data meta-analysis of 9 randomised controlled trials by Thiele (2024), there was no statistically significant difference in 6-month all-cause mortality between the MCS, which included VA-ECMO and Impella, and standard care groups in the intention to treat population (51% for the MCS group [95% CI

46 to 55] and 56% for the standard care group [95% CI 52 to 60]; HR 0.87 [95% CI 0.74 to 1.03], p=0.10). In the trials that used left ventricular unloading MCS, there was also no statistically significant difference in 6-month mortality (47% in the MCS group [95% CI 41 to 54] and 57% [95% CI 51 to 63] in the standard care group (HR 0.80, 95% CI 0.62 to 1.02, p=0.075). For people with STEMI without resuscitation or with only short resuscitation, the 6-month mortality was statistically significantly lower in the MCS group (44% [95% CI 39 to 50]) compared to the standard care group (55% [95% CI 50 to 61]; HR=0.77 [95% CI 0.61 to 0.97], p=0.024).

Longer term survival

Mortality or survival beyond 6 months was reported in 2 studies.

In the systematic review by Ardito (2023) of 102 studies on people with cardiogenic shock, overall mortality at 30 days, 6 months and 1 year combined was reported, although there was a high degree of heterogeneity. Mortality was 44% for microaxial flow pumps (95% CI 39 to 50, 42 papers, I^2=91%) and 50% for VA-ECMO (95% CI 43 to 58; 30 papers, I^2=94%).

In the retrospective registry study by Padberg (2024), Kaplan-Meier survival estimates for people who had a microaxial flow pump were 29% at 1 year, 28% at 2 years, 22% at 5 years and 11% at 8 years.

Bridge to recovery, durable LVAD or transplantation

In the systematic review by Ardito (2023) of 102 studies on people with cardiogenic shock, the rate of successful weaning was 58% (95% CI 49 to 66, 9 papers, I^2=54%) for microaxial flow pumps and 53% (95% CI 47 to 60, 19 papers, I^2=74%) for VA-ECMO. The proportion of people bridged to long-term LVAD was the same for the microaxial flow pump and VA-ECMO groups (10%), without statistically significant differences. Bridge to transplant was reported for

4% of people who had microaxial flow pump (95% CI 0 to 12%, 11 papers, I^2=92%) and 6% for people who had VA-ECMO (95% CI 3 to 9%, 14 papers, I^2=70%).

Composite outcomes

The randomised controlled trial of 355 people who had a microaxial flow pump and standard care or standard care alone reported a composite cardiac endpoint of escalation of treatment to additional MCS, heart transplantation, or death from any cause, whichever came first. This was 52% for the microaxial flow pump group and 64% for the standard care group (HR=0.72, 95% CI 0.55 to 0.95, p=0.04; Møller 2024).

Safety

Bleeding or vascular complications

Bleeding or vascular complications were reported as an outcome in 9 studies.

Moderate or severe bleeding was reported in a higher proportion of people in the microaxial flow pump group (22% [39 out of 179]) compared to the standard care alone group (12% [21 out of 176], RR 2.06, 95% CI 1.15 to 3.66) in the randomised controlled trial of 355 people (Møller 2024).

Moderate or severe bleeding at 30 days was reported in 28% (143 out of 506) of people who had MCS and 13% (67 out of 503) of people who had standard care (OR 2.64, 95% CI 1.91 to 3.65) in the individual patient data meta-analysis of 9 randomised controlled trials by Thiele (2024), which included the study by Møller (2024). The rate of access site bleeding was 16% in the microaxial flow pump group (95% CI 8 to 27, 8 studies, I^2=92%) and 19% in the VA-ECMO group (95% CI 14 to 23, 5 studies, I^2=26%) and major bleeding was 20% in the microaxial flow pump group (95% CI 12 to 30, 15 studies, I^2=95%) and 25% in

the VA-ECMO group (95% CI 16 to 34, 11 studies, I^2=88%) in the systematic review of 102 studies (Ardito 2023). The odds of bleeding events needing transfusion were statistically significantly lower in the microaxial flow pump group compared to VA-ECMO (OR 0.61, 95% CI 0.46 to 0.80, p=0.0004, I^2=0%) in the systematic review of 5 propensity score matched or adjusted studies (Stub 2025). The rate of major bleeding and vascular complications were both 16% in the systematic review of 33 studies, with high heterogeneity between studies. In the comparative analysis, the rate of vascular complications and major bleeding were statistically significantly higher in the microaxial pump group compared to the IABP group. The rate of vascular complications was 11% in the microaxial flow pump group and 3% in the IABP group (RR 3.32, 95% CI 2.54 to 4.33, p<0.001, 7 studies, I^2=0%) and the rate of major bleeding was 28% in the microaxial flow pump group and 14% in the IABP group (RR 1.99, 95% CI 1.75 to 2.25, p<0.001, 6 studies, I^2=0%; Panuccio 2022). The mean rate of bleeding was 14% (range 3 to 24%) in the systematic review of 18 studies (Sassani 2025).

Post procedural haemorrhage was reported in 2% of people who had a microaxial flow pump and 1% of people who had IABP (OR 1.99, p<0.001) and procedural bleeding was reported in 0.3% and 0.1%, respectively (OR 2.37, 95% CI 1.33 to 4.23, p=0.004) in the retrospective registry study by Movahed (2024). Bleeding was reported in 21% (162 out of 776) of people who had a microaxial flow pump, 38% (317 out of 833) of people who had VA-ECMO, 18% (980 out of 5,451) of people who had IABP and 9% (3,058 out of 32,804) of people who had no temporary MCS (p<0.001) in the retrospective registry study by Padberg (2024). Bleeding was reported in 16% (538 out of 3,409) of people and vascular injury was reported in 1% (30 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Limb ischaemia

Limb ischaemia was reported as an outcome in 5 studies.

Limb ischaemia was reported in a higher proportion of people in the microaxial flow pump group (6% [10 out of 179]) compared to the standard care alone group (1% [2 out of 176], RR 5.15, 95% CI 1.11 to 23.8) in the randomised controlled trial of 355 people (Møller 2024).

Peripheral ischaemic vascular complication at 30 days was reported in 10% (50 out of 518) of people who had MCS and 2% (12 out of 516) of people who had standard care (OR 4.43, 95% CI 2.37 to 8.26) in the individual patient data meta-analysis of 9 randomised controlled trials (Thiele 2024). The rate of limb ischaemia was 6% in the microaxial flow pump group (95% CI 4 to 8, 19 studies, I^2=61%) and 10% in the VA-ECMO group (95% CI 7 to 15, 23 studies, I^2=90%) in the systematic review of 102 studies (Ardito 2023). The mean rate of ischaemia was 8% (range 3 to 14) in the systematic review of 18 studies (Sassani 2025). Limb ischaemia was reported in 4% (125 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Stroke

Stroke was reported as an outcome in 5 studies.

Stroke was reported in 4% (7 out of 179) of people in the microaxial flow pump group and 2% (4 out of 176) of people in the standard care group (RR 1.75, 95% CI 0.50 to 6.01) in the randomised controlled trial of 355 people (Møller 2024).

Stroke at 30 days was reported in 4% (19 out of 498) of people who had MCS and 3% (13 out of 496) of people who had standard care (OR 1.48, 95% CI 0.72 to 3.04) in the individual patient data meta-analysis of 9 randomised controlled trials (Thiele 2024). The rate of ischaemic stroke was 0% in the Impella group (95% CI 0 to 0, 26 studies, I^2=67%) and 7% in the VA-ECMO group (95% CI 5 to 10, 24 studies, I^2=79%) in the systematic review of 102 studies (Ardito 2023). Haemorrhagic stroke was reported in 2% (12 out of 776) of people who had

microaxial flow pump, 3% (26 out of 833) of people who had VA-ECMO, 1% (53 out of 5,451) of people who had IABP and 1% (249 out of 32,804) of people who had no temporary MCS (p<0.001) in the retrospective registry study by Padberg (2024). In the same study, ischaemic stroke was reported in 4% (31 out of 776) of people who had microaxial flow pumps, 10% (80 out of 833) of people who had VA-ECMO, 5% (289 out of 5,451) of people who had IABP and 4% (1,347 out of 32,804) of people who had no temporary MCS (p<0.001). Cerebrovascular accident was reported in 4% (152 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Acute kidney injury, renal failure or renal replacement therapy

Acute kidney injury, renal failure or renal replacement therapy was reported as an outcome in 6 studies.

Renal replacement therapy was reported in a higher proportion of people in the microaxial flow pump group (42% [75 out of 179]) compared to the standard care alone group (27% [47 out of 176]; RR 1.98, 95% CI 1.27 to 3.09) in the randomised controlled trial of 355 people (Møller 2024).

Renal replacement therapy at 30 days was reported in 24% (116 out of 484) of people who had MCS and 20% (98 out of 482) of people who had standard care (OR 1.29, 95% CI 0.94 to 1.77) in the individual patient data meta-analysis of 9 randomised controlled trials by Thiele (2024). The rate of renal failure was 34% in the microaxial flow pump group (95% CI 26 to 43, 25 studies, I^2=96%) and 36% in the VA-ECMO group (95% CI 31 to 42, 23 studies, I^2=90%) in the systematic review of 102 studies (Ardito 2023). Post procedural acute kidney failure was reported in 0.2% of people who had a microaxial flow pump and 0.4% of people who had IABP (OR 0.44, 95% CI 0.25 to 0.77, p=0.004) in the retrospective registry study by Movahed (2024). Acute kidney injury was reported in 44% (341 out of 776) of people who had a microaxial flow pump, 53% (440 out

of 833) of people who had VA-ECMO, 32% (1,732 out of 5,451) of people who had IABP and 27% (8,835 out of 32,804) of people who had no temporary MCS ($p<0.001$) in the retrospective registry study by Padberg (2024). In the same study, renal replacement therapy was reported in 30% (237 out of 776) of people who had a microaxial flow pump, 50% (419 out of 833) of people who had VA-ECMO, 25% (1,590 out of 5,451) of people who had IABP and 12% (3,975 out of 32,804) of people who had no temporary MCS ($p<0.001$). Acute kidney injury was reported in 7% (227 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Sepsis

Sepsis was reported as an outcome in 4 studies.

Sepsis with positive blood culture was reported in a higher proportion of people in the microaxial flow pump group (12% [21 out of 179]) compared to the standard care alone group (4% [8 out of 176], RR 2.79, 95% CI 1.20 to 6.48) in the randomised controlled trial of 355 people (Møller 2024).

Sepsis at 30 days was reported in 17% (80 out of 480) of people who had MCS and 14% (66 out of 474) of people who had standard care (OR 1.28, 95% CI 0.87 to 1.88) in the individual patient data meta-analysis of 9 randomised controlled trials by Thiele (2024). Sepsis was reported in 16% (123 out of 776) of people who had a microaxial flow pump, 22% (187 out of 833) of people who had VA-ECMO, 14% (757 out of 5,451) of people who had IABP and 9% (3,034 out of 32,804) of people who had no temporary MCS ($p<0.001$) in the retrospective registry study by Padberg (2024). Sepsis was reported in 4% (136 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Pericardial effusion, cardiac tamponade or cardiac perforation

Pericardial effusion was reported in 4% of people in both the microaxial flow pump and IABP groups (OR 1.04, 95% CI 0.91 to 1.19, p=0.54) in the retrospective registry study by Movahed (2024). In the same study, cardiac tamponade was reported in 3% of people who had a microaxial flow pump and 2% of people who had an IABP (OR 1.27, 95% CI 1.07 to 1.51, p=0.007) and cardiac perforation was reported in 1.3% of people who had a microaxial flow pump and 0.9% of people who had an IABP (OR 1.48, 95% CI 1.17 to 1.88, p=0.001). Cardiac tamponade was reported in 1% (47 out of 3,409) of people who had support with Impella alone in the registry study by Higuchi (2024).

Cardiac function

Cardioversion after ventricular tachycardia or fibrillation was reported in 33% (59 out of 179) of people in the microaxial flow pump group and 30% (52 out of 176) of people in the standard care group (RR 1.17, 95% CI 0.75 to 1.83) in the randomised controlled trial of 355 people (Møller 2024).

Intraoperative cardiac functional disturbance was reported in 0.5% of people in the microaxial flow pump group and 0.4% of people in the IABP group (OR 1.41, 95% CI 0.97 to 2.05, p=0.08) in the retrospective registry study by Movahed (2024).

Haemolytic anaemia

Acquired haemolytic anaemia was reported in 0.7% of people in the microaxial flow pump group and 0.1% of people in the IABP group (OR 8.36, 95% CI 4.89 to 14.3, p<0.001) in the retrospective registry study by Movahed (2024).

Disseminated intravascular coagulation

Disseminated intravascular coagulation was reported in 3% of people in the microaxial flow pump group and 2% of people in the IABP group (OR 1.76, 95% CI 1.48 to 2.08, p<0.001) in the retrospective registry study by Movahed (2024).

Composite outcomes

A composite safety end-point event of severe bleeding, limb ischaemia, haemolysis, device failure and worsening of aortic regurgitation was reported in a higher proportion of people in the microaxial flow pump group (24% [43 out of 179]) compared to the standard care alone group (6% [11 out of 176)], RR 4.74, 95% CI 2.36 to 9.55) in the randomised controlled trial of 355 people (Møller 2024). In the microaxial flow pump group, the number needed to harm was 6.

Other adverse events

Case reports describing adverse events associated with the procedure have been listed in table 5a in appendix B. These include left ventricular perforation, aortic valve insufficiency, mitral regurgitation, mitral chordal rupture, functional mitral stenosis, right-to-left arterial shunt through an iatrogenic atrial septal defect, pseudoaneurysm, infected pseudoaneurysm, arteriovenous fistula, intracerebral haemorrhage, aortic saddle embolism, Impella inlet entrapment in the mitral subvalvular apparatus, intra-arterial fibrinous sheath development, coiled Impella drive line in the left ventricle, intravascular device tip fracture and haemolysis.

MHRA Field Safety Notice

An MHRA field safety notice was issued for all Impella heart pumps in April 2024. In summary, information on safe use of Impella pumps had been issued with 2 technical bulletins, but the instructions for use were not updated to include the same level of detail covered in the bulletins and 1 of the bulletins was not distributed to European customers. These included a technical bulletin for

operator mishandling of the Impella left-sided devices resulting in iatrogenic ventricular wall perforation and an Impella Product Update for an issue with fibres entrapped in the impeller. The action to mitigate the risk was for users to take note of amendment and reinforcement of instructions for use.

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following anecdotal or theoretical adverse events:

- Thrombosis around the device
- Thrombocytopenia
- Access site haematoma
- Aortic dissection or rupture
- Heart valve injury
- Compartment syndrome
- Irreversible neurological impairment
- Distal embolisation
- Device migration
- Closure device failure.

Six professional expert questionnaires for insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock were submitted. Find full details of what the professional experts said about the procedure in the https://www.nice.org.uk/guidance/indevelopment/gid-ipg10404/documents.

Validity and generalisability

- Although the evidence includes a relatively large randomised controlled trial based in Europe that included 1 UK centre (Møller 2024), most studies are non-UK based and might not be generalisable to practice within the UK. Most studies were observational and retrospective, which have more potential for bias than randomised controlled trials.
- The randomised controlled trial by Møller (2024) had very strict inclusion and exclusion criteria. People who had been resuscitated from out-of-hospital cardiac arrest and remained comatose on arrival to the cardiac catheterisation laboratory and people with overt right ventricular failure were excluded. The registry study by Padberg (2024) also specified that people with out-of-hospital cardiac arrest before admission were not included in the data. The 2 studies had conflicting results regarding the effect of microaxial flow pumps on mortality, but the outcomes were reported at different timepoints, the registry study lacked baseline data on patient characteristics and treatments were not randomly allocated. Also, the study by Møller (2024) used Impella CP but the study by Padberg (2024) did not specify what type of Impella microaxial flow pump was used.
- In the randomised controlled trial by Møller (2024), the finding of excess need for renal-replacement therapy in the microaxial-flow-pump group may be attributable to the fact that more patients died early in the standard-care group, which may have introduced a survival bias owing to a competing risk.
- In the randomised controlled trial by Møller (2024), allocation to treatment group was not masked and there may have been differential intensive care treatment between the 2 groups.
- Some studies included people who had the procedure more than 10 years ago. There may have been changes in the approach to treating cardiogenic shock over time.

- The individual patient data meta-analysis by Thiele (2024) includes different MCS devices analysed together as a group and results are not presented separately for microaxial flow pumps. Earlier trials included in the meta-analysis used IABP as the comparator, whereas in more recent trials the comparator was best medical therapy with MCS escalation in selected patients.
- The overall results reported by Thiele (2024) are dominated by the weight of 2 large studies, one of which was the trial on microaxial flow pumps by Møller (2024).
- Most of the systematic reviews reported high heterogeneity between studies.
- Studies included in the systematic reviews had different patient selection criteria and definition of outcomes, such as bleeding, may have differed.
- Safety and efficacy outcomes, such as vascular complication rates, are likely to be affected by the expertise of the study centre.
- Registry studies use data that has been collected for other purposes and may not include baseline characteristics such as the degree of cardiogenic shock. Also, they may not distinguish between different models of Impella.
- In the registry report by Movahed (2024), the authors note that the complication rate was lower than other publications, which they attributed to under-reporting.
- There was a lack of data on quality of life.
- The evidence included different devices, with different flow rates. Some of the devices used are no longer available or have been superseded.
- The study by Sassani (2025) had some discrepancies between the text and the tables; the results presented in this overview were extracted from the tables.
- The randomised controlled trial by Møller (2024) was supported by the Danish Heart Foundation and Abiomed.

Ongoing trials

- IMPELLA, Complications and Tolerance (IMPACT; NCT06644963); Observational study; France; n=800; estimated study completion: January 2025
- Evaluation of the Efficacy of Early Implantation of a Percutaneous Left Ventricular Assist Devices in Acute Coronary Syndrome Complicated by Cardiogenic Shock Compared to Conventional Therapy: a Prospective, Multicenter, Randomized, Controlled and Open-label Clinical Trial (ULYSS; NCT05366452); randomised controlled trial; France; n=204; estimated study completion: December 2026
- Observational Assessment of Support With Impella® Best Practices in Acute Myocardial Infarction Complicated by Cardiogenic Shock (NCT06964685); prospective cohort study; US; n=250; estimated study completion: October 2028
- Clinical Outcomes of Contemporary IMPELLA Devices in Cardiogenic Shock and High-risk Percutaneous Coronary Intervention (IMMERGE; NCT06690567); cohort study; Italy; n=700; estimated study completion: December 2024
- Cardiogenic Shock Working Group Registry (CSWG; NCT04682483); cohort study; US; n=5,000; estimated study completion: June 2026

Existing assessments of this procedure

The European Society of Cardiology 2021 guidelines for the diagnosis and treatment of acute and chronic heart failure recommends ‘Short-term MCS should be considered in patients with cardiogenic shock as a BTR, BTD, BTB. Further indications include treatment of the cause of cardiogenic shock or long-term MCS or transplantation.’ The class of recommendation is 2a (Conflicting evidence or divergence of opinion; weight of evidence or opinion is in favour of

usefulness or efficacy) and the level of evidence is C (Consensus of opinion of the experts or small studies, retrospective studies, registries).

The Australian Government's Medical Services Advisory Committee (MSAC) assessed transluminal insertion, management and removal of an intravascular microaxial blood pump (Impella), for patients requiring mechanical circulatory support in April 2024. The consumer summary states:

'MSAC noted that the clinical evidence for IMPELLA and ECPELLA was of high risk of bias, which created uncertainty in the conclusions made on this evidence. However, MSAC acknowledged cardiogenic shock is an emergency condition, which makes it difficult to conduct a low risk of bias trial where the safety and effectiveness of intervention is directly compared to the comparator by randomly assigning patients to either the intervention or comparator arm (i.e. a randomised controlled trial). Overall, MSAC considered that in this small population of high-risk patients, the low certainty evidence indicated that IMPELLA and ECPELLA provided a small but important reduction in mortality in the short-term (i.e. 30 days) and likely resulted in reduced mortality in the longer-term (i.e. at 6 and 12 months). MSAC noted uncertainty when considering whether IMPELLA and ECPELLA represented good value for money. However, MSAC considered that there is a clinical need for the intervention for the proposed small number of high-risk patients who are acutely unwell, and funding the intervention may provide a small cost saving to the MBS and a low financial impact to private health insurers.'

The American College of Cardiology Foundation and the American Heart Association, Inc. have published a 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint

Committee on Clinical Practice Guidelines. Regarding MCS and cardiogenic shock, the recommendations state:

- 'In selected patients with STEMI and severe or refractory cardiogenic shock, insertion of a microaxial intravascular flow pump is reasonable to avoid death.'

Class of recommendation: moderate; level of evidence: moderate quality of evidence from 1 or more RCTs, meta-analysis of moderate quality RCTs.

- 'In patients with mechanical complication of ACS, short-term MCS devices are reasonable for hemodynamic stabilization as a bridge to surgery.'

Class of recommendation: moderate; level of evidence: moderate quality of evidence from 1 or more well designed, well executed nonrandomized studies, observational studies or registry studies, or meta-analyses of such studies.

- 'In patients with AMI and cardiogenic shock, the routine use of IABP or VA-ECMO is not recommended due to a lack of survival benefit.'

Class of recommendation: No benefit (moderate); level of evidence: moderate quality of evidence from 1 or more RCTs, meta-analysis of moderate quality RCTs.

Related NICE guidance

Interventional procedures

Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults (2014) NICE interventional procedures guidance 482 (Recommendation: special arrangements); guidance update is in progress

Percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions (2018) NICE interventional procedures guidance 633 (Recommendation: special arrangements)

NICE guidelines

Acute heart failure: diagnosis and management (2014) NICE clinical guideline CG187 Last updated 17 November 2021 (Recommendation 1.7)

Professional societies

- British Cardiovascular Intervention Society
- British Cardiovascular Society
- The Intensive Care Society
- Society for Cardiothoracic Surgery in Great Britain & Ireland
- Royal College of Anaesthetists
- Faculty of Intensive Care Medicine
- British Society for Heart Failure
- NHS Blood and Transplant.

Evidence from people who have had the procedure and patient organisations

NICE received 3 questionnaires from people (or their carers) who have had insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock.

The views of people who have had the procedure were consistent with the published evidence and the opinions of the professional experts. Find full details

of what the professional experts said about the procedure in the https://www.nice.org.uk/guidance/ipg10404/documents.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 1 completed submission. This was considered by the interventional procedures technical team and any relevant points have been taken into consideration when preparing this overview.

References

1. Møller JE, Engstrom T, Jensen LO et al. (2024) Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock. The New England Journal of Medicine 390: 1382–93
2. Thiele H, Møller JE, Henriques JP et al. (2024) Temporary mechanical circulatory support in infarct-related cardiogenic shock: an individual patient data meta-analysis of randomised trials with 6-month follow-up. Lancet 404: 1019–28
3. Sassani K, Waechter C, Syntila S et al. (2025) The Role of Impella in Cardiogenic Shock Complicated by an Acute Myocardial Infarction: A Meta-Analysis. Journal of Clinical Medicine 14: 611
4. Ardito V, Sarucanian L, Rognoni C et al. (2023) Impella Versus VA-ECMO for Patients with Cardiogenic Shock: Comprehensive Systematic Literature Review and Meta-Analyses. Journal of Cardiovascular Development and Disease 10: 158
5. Bogerd M, Ten Hoorn L, Ten Berg S et al. (2025) Resource utilization associated with extracorporeal membrane oxygenation vs. microaxial flow pump for infarct-related cardiogenic shock. European Heart Journal: Acute Cardiovascular Care 14: 279–87
6. Stub D, Chan W, Ball J et al. (2025) IMPELLA COMPARED TO VENOARTERIAL EXTRACORPOREAL MEMBRANE OXYGENATION IN CARDIOGENIC SHOCK: A SYSTEMATIC REVIEW AND META-ANALYSIS OF PROPENSITY SCORE-MATCHED STUDIES. Shock 63: 512–19
7. Panuccio G, Neri G, Macri LM et al. (2022) Use of Impella device in cardiogenic shock and its clinical outcomes: A systematic review and meta-

analysis. International Journal of Cardiology. Heart & Vasculature 40: 101007

8. Movahed MR, Talle A, Hashemzadeh M (2024) Intra-aortic balloon pump is associated with the lowest whereas Impella with the highest inpatient mortality and complications regardless of severity or hospital types. Cardiovascular Intervention and Therapeutics 39: 252–61

9. Padberg J-S, Feld J, Padberg L et al. (2024) Complications and Outcomes in 39,864 Patients Receiving Standard Care Plus Mechanical Circulatory Support or Standard Care Alone for Infarct-Associated Cardiogenic Shock. Journal of Clinical Medicine 13: 1167

10. Higuchi R, Nanasato M, Hosoya Y et al. (2024) Outcomes of Older Patients With Cardiogenic Shock Using the Impella Device - Insights From the Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD). Circulation Reports 6: 505-513

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to catheter-based intravascular microaxial flow pump for cardiogenic shock from the medical literature.

Search strategy design and peer review

This search report is informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension (PRISMA-S).

A NICE information specialist ran the literature searches on 29/05/25. See the search strategy history for the full search strategy for each database. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in table 4a, taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the Peer Review of Electronic Search Strategies (PRESS) 2015 evidence-based checklist.

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low-probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

Limits and restrictions

The search was not limited by date or language.

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material.

The limit to remove animal studies in the searches is standard NICE practice, which has been adapted from Dickersin K, Scherer R, Lefebvre C (1994) Systematic Reviews: Identifying relevant studies for systematic reviews. BMJ 309(6964): 1286.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	29/05/2025	Wiley	Issue 4 of 12, April 2025	86
Cochrane Database of Systematic Reviews (CDSR)	29/05/2025	Wiley	Issue 5 of 12, May 2025	2
Embase	29/05/2025	Ovid	1974 to 2025 May 28	2827
INAHTA International HTA Database	29/05/2025	https://database.inahta.org/	-	10
MEDLINE ALL	29/05/2025	Ovid	1946 to May 28, 2025	1984

Search strategy history

MEDLINE ALL search strategy

1 Shock, Cardiogenic/ 11823

2 (Cardiogenic* adj4 shock*).tw. 17471

3 Heart Failure/ 156362

4 (heart adj4 failure).tw. 237316

5 Myocardial Infarction/ 185430

6 (((myocardial or heart) adj4 infarc*) or (heart adj4 attack*) or (cardiovascular* adj4 stroke*)).tw. 255205

7 Myocarditis/ 18213

8 (myocard* or carditis).tw. 466398

9 Cardiomyopathies/ 35439

10 Cardiomyopath*.tw. 95521

11 or/1-10 801927

12 (left adj4 ventric*).tw. 246176

13 Ventricular Function, Left/ 51337

14 12 or 13 255698

15 (Microaxial or micro-axial or axillary).tw. 43215

16 (((tube* or catheter*) and pump* and (valve* or intravascular)) or (flow adj4 pump*)).tw. 5352

17 mAFP.tw. 215

18 or/15-17 48602

19 14 and 18 1408

20 Heart-Assist Devices/ 19310

21 (heart adj4 assist* adj4 device*).tw. 1472

22 (Mechanical adj4 circulatory adj4 support*).tw. 6564

23 (intravascular adj4 support*).tw. 162

24 or/20-23 23544

25 11 and 19 and 24 686

26 Impella.tw. 1990

27 11 and 26 1569

28 SmartAssist*.tw. 10

29 25 or 27 or 28 2085

30 Animals/ not Humans/ 5307000

31 29 not 30 1984

Embase search strategy

1 cardiogenic shock/ 44785

2 (Cardiogenic* adj4 shock*).tw. 33787

3 heart failure/ 364889

4 (heart adj4 failure).tw. 406514

5 heart infarction/ 344388

6 (((myocardial or heart) adj4 infarc*) or (heart adj4 attack*) or (cardiovascular* adj4 stroke*)).tw.379166

7 myocarditis/ 41095

8 (myocard* or carditis).tw. 670916

9 cardiomyopathy/ 79320

10 Cardiomyopath*.tw. 157940

11 or/1-10 1306176

12 (left adj4 ventric*).tw. 395559

13 heart left ventricle function/52902

14 12 or 13 406495

15 (Microaxial or micro-axial or axillary).tw. 66088

16 (((tube* or catheter*) and pump* and (valve* or intravascular)) or (flow adj4 pump*)).tw. 8471

17 mAFP.tw. 291

18 or/15-17 74487

19 14 and 18 2845

20 heart assist device/ 8266

21 (heart adj4 assist* adj4 device*).tw. 2636

22 (Mechanical adj4 circulatory adj4 support*).tw. 12235

23 (intravascular adj4 support*).tw. 239

24 or/20-23 21809

25 11 and 19 and 24 583

26 Impella.tw,dv,dm. 6488

27 11 and 26 5248

28 SmartAssist*.tw,dv,dm. 36

29 25 or 27 or 28 5602

30 Nonhuman/ not Human/ 5700800

31 29 not 30 5423

32 clinical trial.pt. 273748

33 31 not 32 5398

34 (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. 6270848

35 33 not 34 2827

Cochrane Library (CDSR and CENTRAL) search strategy

#1 MeSH descriptor: [Shock, Cardiogenic] this term only 506

#2 (Cardiogenic* NEAR/4 shock*) 1828

#3 MeSH descriptor: [Heart Failure] this term only 14442

#4 (heart NEAR/4 failure) 41487

#5 MeSH descriptor: [Myocardial Infarction] this term only 14471

#6 (((myocardial or heart) NEAR/4 infarc*) or (heart NEAR/4 attack*) or (cardiovascular* NEAR/4 stroke*)) 44651

#7 MeSH descriptor: [Myocarditis] this term only 143

#8 (myocard* or carditis) 56343

#9 MeSH descriptor: [Cardiomyopathies] this term only 994

#10 Cardiomyopath* 6201

#11 {OR #1-#10} 93892

#12 (left NEAR/4 ventric*) 27129

#13 MeSH descriptor: [Ventricular Function, Left] this term only 3966

#14 #12 or #13 27129

#15 (Microaxial or micro-axial or axillary) 6854

#16 (((tube* or catheter*) and pump* and (valve* or intravascular)) or (flow NEAR/4 pump*)) 503

#17 mAFP 9

#18 {OR #15-#17} 7336

#19 #14 AND #18 159

#20 MeSH descriptor: [Heart-Assist Devices] this term only 396

#21 (heart NEAR/4 assist* NEAR/4 device*) 525

#22 (Mechanical NEAR/4 circulatory NEAR/4 support*) 352

#23 (intravascular NEAR/4 support*) 12

#24 {OR #20-#23} 812

#25 #11 and #19 and #24 47

#26 Impella 181

#27 #11 and #26 158

#28 SmartAssist* 2

#29 #25 or #27 or #28 196

#30 "conference":pt or (clinicaltrials or trialsearch):so 824537

#31 #29 NOT #30 in Cochrane Reviews, Cochrane Protocols 2

#32 #29 NOT #30 in Trials 82

INAHTA HTA Database search strategy

1 (cardiogenic shock)[mh] 11

2 Cardiogenic* AND shock* 19

3 (heart failure)[mh] 271

4 heart AND failure 408

5 (Myocardial Infarction)[mh] 122

6 (((myocardial or heart) AND infarc*) or (heart AND attack*) or (cardiovascular* AND stroke*)) 304

7 (myocarditis)[mh] 2

8 myocard* or carditis 292

9 (Cardiomyopathies)[mh] 25

10 Cardiomyopath* 54

11 #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 823

12 left AND ventric* 110

13 (Ventricular Function, Left)[mh] 5

14 #13 OR #12 111

15 (Microaxial or micro-axial or axillary) 41

16 (((tube* or catheter*) and pump* and (valve* or intravascular)) or (flow AND pump*))11

17 mAFP 0

18 #17 OR #16 OR #15 51

19 #18 AND #14 5

20 (Heart-Assist Devices)[mh]49

21 (heart AND assist* AND device*) 46

22 (Mechanical AND circulatory AND support*) 4

23 (intravascular AND support*) 9

24	#23 OR #22 OR #21 OR #20	77
25	#24 AND #19 AND #11	1
26	Impella	14
27	#26 AND #11	9
28	SmartAssist*	0
29	#28 OR #27 OR #25	10

Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.
- People with cardiogenic shock.
- Intervention or test: percutaneous insertion of a catheter-based intravascular microaxial flow pump.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in Appendix B: Other relevant studies.

Find out more about how NICE selects the evidence for the committee.

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary (tables 2 and 3) are listed in tables below. Case reports of safety outcomes that are not included in the main evidence are listed first in table 5a, followed by other studies that were not prioritised in table 5b. Non-randomised studies with fewer than 100 people, other than case reports of adverse events, and systematic reviews published before 2021 were excluded.

Table 5a additional studies identified – case reports of adverse events

Study	Number of people and follow up	Adverse event	Reason study was not included in main evidence summary
Asemota D, Kassam Z, Voto C et al. (2022) Pseudoaneurysm Formation After "Preclose"-Assisted Impella Insertion in a Patient With Cardiogenic Shock. Journal of Medical Cases 13: 202-206	Case report n=1 STEMI Impella CP	An Impella CP was inserted through the femoral artery, using a single Perclose device. After the Impella was removed, the patient had groin discomfort and a pseudoaneurysm was diagnosed by CT. This was successfully managed with thrombin injection.	Case report
Baldi T, Wolff T, Aschwanden M et al. (2009) Giant arteriovenous fistula after implantation of a percutaneous left ventricular assist device. Vasa - Journal of Vascular Diseases 38: 190	Case report n=1 Severe myocardial infarction Impella 2.5	Giant arteriovenous fistula Impella was in place for 6 days. During the following days after it was removed, a large pulsatile mass developed at the puncture site.	Case report

		Surgical revision was done.	
Elhussein TA, Hutchison SJ (2014) Acute mitral regurgitation: unforeseen new complication of the Impella LP 5.0 ventricular assist device and review of literature. Heart, Lung & Circulation 23: e100-4	Case report n=1 Impella 5.0 implanted using right axillary approach	Acute mitral regurgitation caused by chordal rupture and flail mitral valve leaflet as a result of Impella device displacement.	Case report
Fung NL, Tam DY, Nedadur R et al. (2024) Infected Pseudoaneurysm of an Outflow Graft After Left Ventricular Assist Device Insertion. Canadian Journal of Cardiology 40: 1352	Case report n=1 cardiogenic shock associated with non-ischaemic cardiomyopathy Transaxillary Impella	Recurrent fevers after LVAD implantation were caused by infected pseudoaneurysm of the outflow graft at the graft-aortic anastomosis. A durable LVAD was inserted after the Impella. Surgical treatment involved complete resection of the infected anastomosis and reconstruction of the aorta with a pericardial patch. The remainder of the outflow graft, the LVAD housing, and the driveline were left in situ.	Case report
Horio M, Kashiwazaki D, Tomita Tet al. (2023) Intracerebral Hematoma in Patients With Impella Ventricular Assist Device Placement for Cardiogenic Shock: Report of Three Cases. Cureus 15: e48863	Case reports n=3 2 people had AMI and 1 had dilated cardiomyopathy	Intracerebral haemorrhage in 3 people with Impella implantation for cardiogenic shock, which were treated by haematoma evacuation. This was successful in 2 of the 3 people. The other person died 14 days after admission.	Case reports

Ito F, Kimura M, Hyogo M et al. (2023) Aortic saddle embolism just after Impella CP removal in a patient with alcoholic cardiomyopathy. Cardiovascular Intervention and Therapeutics 38: 139-140	Case report n=1 Alcoholic cardiomyopathy Impella CP	The person recovered from cardiogenic shock and the Impella CP catheter was surgically removed on day 7. Forward flow of the arteriotomy site in the right common femoral artery was completely absent. Angiography revealed aortic saddle embolisation and occlusion of both common iliac arteries. Thromboembolectomy and Fogarty embolectomy catheters were selected, and a clot was removed. The final angiogram showed optimal blood flow without complications.	Case report
Khalid N, Shlofmitz E, Case BC et al. (2021) Entrapment of the Impella heart pump in the mitral subvalvular apparatus. EuroIntervention 16: 1262	Case report n=1 AMICS Impella 5.0	Impella inlet entrapment in the mitral subvalvular apparatus. The Impella device was explanted after 96 hours but the degree of mitral regurgitation remained unchanged. Extensive damage (ruptured chordae tendineae) precluded mitral valve repair, and a mitral valve replacement was needed.	Case report
Kishimoto S, Hiraoka A, Chikazawa G et al. (2025) A case of fatal acute saddle embolism of the terminal aorta after long-term support using Impella CP.	Case report n=1 Impella CP was used to support ventricular	Fatal acute saddle embolism of the terminal aorta. The Impella device was removed after surgery and arterial cannula reinsertion was done at	Case report.

Journal of Artificial Organs	septal rupture repair	the ipsilateral site. There was no pulsatile bleeding from the arterial cannulation site and CT showed complete occlusion of the bilateral common iliac arteries, extending to the abdominal aorta. The uncontrollable, rapid progression of acidaemia resulted in sudden cardiac arrest.	
Mutallimov M, Er F, Gassanov N (2022) Device fracture as a potential complication of a left ventricular microaxial pump catheter: a case report. European Heart Journal. Case Reports 6: ytac335	Case report n=1 cardiogenic shock caused by non-STEMI Impella CP	Intravascular device tip fracture An Impella CP pump was inserted without any complication before PCI. When the device was removed, a persistent mechanical resistance hindered the further catheter retraction. Fluoroscopy revealed a broken distal part of the pump at the level of the ascending aorta. The retained catheter tip was eventually snared with a snare catheter and removed without any complication.	Case report
Nakao Y, Aono J, Tasaka T (2019) Impella 5.0 Mechanical Assist Device Catheter-Induced Severe Hemolysis Due to Giant Swinging Motion - New Concern in Impella Usage. Circulation Journal 83: 2080	Case report n=1 Dilated cardiomyopathy Impella 5.0	Haemolysis was seen the day after Impella implantation. Fluoroscopy showed a large-amplitude swinging motion of the Impella device, which was striking the left ventricular septal wall. The device was repositioned to prevent this pendulum motion.	Case report

Olsthoorn JR, Goossens EAC, Lam K et al. (2022) Aortic Valve Insufficiency as a Late Complication After Impella Device Implantation. JACC: Cardiovascular Interventions 15: e91	Case report n=1 AMICS	Perforation of the noncoronary cusp leading to aortic valve insufficiency. An Impella device was implanted after PCI and used for 1 day. Severe aortic valve regurgitation was diagnosed 1 year later. Perforation of the noncoronary cusp was identified during surgery for aortic valve replacement.	Case report
Pantin EJ, Chyu D, Mungekar SS et al. (2015) Coiled Impella Drive Line in the Left Ventricle: A Rare Complication of a Left Ventricular Assist Device. Journal of Cardiothoracic and Vascular Anesthesia 29: 1308-10	Case report n=1 Congestive heart failure secondary to cardiac amyloidosis Impella 5.0	An Impella 5.0 device was inserted surgically inserted through the left axillary artery using transesophageal echocardiography guidance. In the intensive care unit, it was noted on a chest x-ray that a large portion of the Impella drive line coiled inside the left ventricle. The catheter was repositioned successfully in the operating room under fluoroscopy and transoesophageal guidance.	Case report
Pantin E, Kahan A, Chiricolo A et al. (2019) Intra-Arterial Fibrinous Sheath Development as a Potential Complication of the Impella Ventricular Assist Device. Journal of Cardiothoracic and Vascular Anesthesia 33: 501-505	Case reports n=3 Impella CP and 5.0	3 cases of intra-arterial fibrinous sheath development were described after explantation of Impella device. 1 person had Impella CP followed by Impella 5.0 and coronary artery bypass grafting. The Impella had to be surgically repositioned and then a redo sternotomy was used to	Case reports

		explant it 3 days later. The person died hours after surgery.	
Peritz DC, Linstroth L, Selzman CH et al. (2018) Left ventricular perforation after Impella R placement in a patient with cardiogenic shock. Catheterization and Cardiovascular Interventions 91: 894-896	Case report n=1 Myocarditis and decompensated heart failure Impella 2.5	Left ventricular perforation During transport to the facility, it was discovered that the Impella device had migrated through the left ventricle. The Impella was surgically removed, and biventricular support devices were placed. The person died after weeks in the intensive care unit.	Case report
Tamura S, Shimeno K, Abe Y et al. (2022) A right-to-left atrial shunt via an iatrogenic atrial septal defect after atrial fibrillation ablation induced by a percutaneous left ventricular assist device. European Heart Journal 43: 839	Case report n=1 Decompensated heart failure Impella was used to support cardiac ablation procedure	After the ablation, the person lapsed into severe hypoxaemia and pulseless electrical activity. Hypoxaemia improved after urgent use of VA-ECMO and a change in the Impella support level. The authors hypothesised that the right-to-left shunt through an atrial septal hole after puncture led to the hypoxaemia. They concluded that powerful unloading by Impella decreased the left atrial pressure to a lower level than the right atrial pressure, leading to the right-to-left atrial shunt and the following hypoxaemia and cardiac arrest.	Case report
Toggweiler S, Jamshidi P, Erne P (2008) Functional mitral stenosis: a rare complication of	Case report n=1	On follow-up, the Impella device was dislocated with the shaft of the device lying on the anterior mitral leaflet	Case report

the Impella assist device. European Journal of Echocardiography 9: 412-3	AMICS Impella 2.5	causing a functional mitral stenosis evident by an increased transmitral diastolic flow gradient. After removing the device, the patients' haemodynamics improved within minutes.	
Ueda K, Yoshitani K, Hosotani S et al. (2021) Aortic valve insufficiency after Impella device insertion that required aortic valve replacement after Heart Mate III left ventricular assist device implantation: a case report. Journal of Surgical Case Reports 2021: rjab420	Case report n=1 Dilated cardiomyopathy and acute decompensation of heart failure. Impella 5.0	Aortic insufficiency happened after Impella insertion, needing extra surgical intervention twice. 15 days after Impella insertion, a HeartMate 3 (Abbott, USA) device was implanted. Mild aortic insufficiency was detected before the Impella device was removed, which worsened because of prolapse of the noncoronary cusps. On postoperative day 1, the coaptation stitch on the right and noncoronary cusps had failed, causing severe aortic insufficiency. Emergency aortic valve replacement was done.	Case report
Vila P, de Vere F, Simon A et al. (2021) Severe aortic valve regurgitation requiring mechanical aortic valve replacement following Impella device implantation. Perfusion 36: 311-314	Case report n=1 cardiogenic shock Impella CP and VA-ECMO	Severe aortic regurgitation VA-ECMO was successfully explanted after 8 days of support, but transoesophageal echocardiogram showed severe aortic regurgitation. The aetiology was likely to be trauma to the right coronary cusp from the Impella pump. Aortic	Case report

		regurgitation persisted after the Impella pump was removed, so a median sternotomy and mechanical aortic valve replacement was done.	
Wang AY, Al Jabri A, Jewell ER et al. (2022) Iatrogenic Femoral Arteriovenous Fistula with Pseudoaneurysm Associated with Worsening Heart Failure Years after Percutaneous Impella Placement. Case Reports in Vascular Medicine 2022: 7005236	Case report n=1 Percutaneous Impella placement	Femoral arteriovenous fistula with pseudoaneurysm A 51-year-old man presented with volume overload symptoms secondary to heart failure and was found to have a femoral arteriovenous fistula and pseudoaneurysm likely caused by percutaneous insertion of an Impella VAD through the right common femoral artery, 3 years previously.	Case report
Yamamoto M, Yoneyama F, Kato H et al. (2020) Mitral chordal rupture by Impella 5.0 in a patient with fulminant myocarditis and inflammation of mitral chordae. European Heart Journal 41: 1943	Case report n=1 Lymphocytic fulminant myocarditis Impella 2.5 and 5.0 and VA-ECMO	Impella 2.5 was exchanged for Impella 5.0 after 7 days, for long-term mechanical support. Echocardiography showed trivial mitral regurgitation after 8 days from the exchange. The next day, there was massive regurgitation caused by chordal rupture of the posterior leaflet. A mitral valve replacement was done.	Case report

Table 5b additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Abdallah N, Mohamoud A, Almasri T et al. (2025) Relationships between sex and in-hospital outcomes of patients with acute cardiogenic shock receiving mechanical circulatory support. Cardiovascular Revascularization Medicine 73: 76-80	Retrospective registry (US National Inpatient Sample database) n=2,622,939 hospitalised for acute myocardial infarction.	Females admitted for AMICS were less likely to have temporary MCS despite a higher mortality rate and a slightly longer length of stay compared to males.	Retrospective study focusing on the relationship between sex and outcomes of MCS. Another study using data from the same source is included (Movahed 2024).
Abdullah KQA, Roedler JV, Vom Dahl J et al. (2021) Impella use in real-world cardiogenic shock patients: Sobering outcomes. PloS one 16: e0247667	Retrospective single centre cohort study n=125 cardiac arrest or cardiogenic shock Impella 2.5, 3.5 or CP	Hospital mortality was high (81%). Baseline lactate was 4.7 mmol/litre. In multivariable logistic regression, only age (adjusted OR 1.13 95% CI 1.06 to 1.20; p<0.001) and lactate (adjusted OR 1.23 95% CI 1.00 to 1.52; p=0.046) were associated with hospital mortality, and the respective optimal cut-offs were more than 3.3mmol/litre and age over 66 years.	Larger or more recent studies were prioritised.
Abusnina W, Ismayl M, Al-Abdouh A et al. (2022) Impella versus extracorporeal membrane oxygenation in cardiogenic shock: a	Systematic review and meta-analysis n=1,827 (10 studies)	In-hospital mortality was statistically significantly lower with Impella compared with ECMO (RR 0.80; 95% CI 0.65 to 1.00, p=0.05). There was no statistically significant difference in 30-day (RR	More recent systematic reviews are included.

systematic review and meta-analysis. Shock 58: 349-357		0.97, 95% CI 0.82 to 1.16, p=0.77) and 12-month mortality (RR 0.90, 95% CI 0.74 to 1.11, p=0.32). There was less risk of bleeding and stroke in the Impella group compared with the ECMO group.	
Ahmad S, Ahsan MJ, Ikram S et al. (2023) Impella Versus Extracorporeal Membranous Oxygenation (ECMO) for Cardiogenic Shock: A Systematic Review and Meta-analysis. Current Problems in Cardiology 48: 101427	Systematic review and meta-analysis n=7,884 (6,652 Impella; 13 studies)	Impella use was associated with lower in-hospital mortality (RR 0.88, 95% CI 0.80 to 0.94, p=0.0004), stroke (RR 0.30, 95% CI 0.21 to 0.42, p<0.00001), access-site bleeding (RR 0.50, 95% CI 0.37 to 0.69, p<0.0001), major bleeding (RR 0.56, 95% CI 0.39 to 0.80, p=0.002), and limb ischaemia (RR 0.42, 95% CI 0.27 to 0.65, p=0.0001). Baseline lactate levels were lower in the Impella group (SMD -0.52, 95% CI -0.73 to -0.31, p<0.00001). There was no statistically significant difference in mortality at 6 to 12 months, MCS duration, need for MCS escalation, bridge-to-LVAD or heart transplant, and renal replacement therapy use between Impella and ECMO groups.	More comprehensive and more recent systematic reviews are included.
Albulushi A, Tawfek A, Al Lawatia H (2024) Evaluating the efficacy and safety of temporary mechanical	Systematic review and meta-analysis n=3,450 (15 studies)	Mortality was 35% for Impella compared to 38% for other MCS modalities (p=0.07).	More comprehensive systematic reviews are included.

circulatory support devices in acute cardiogenic shock: A subgroup-specific systematic review. Current Problems in Cardiology 49: 102619		The incidence of limb ischaemia was 5%, and haemolysis was 7%. People with AMICS had a 15% reduction in mortality with Impella compared to a 25% reduction with other devices (p=0.04). Age-based subgroup analysis showed that people younger than 65 years benefited more from MCS devices, showing a 20% improvement in survival, compared to 10% in the older cohort (p=0.01).	
Ali S, Kumar M, Khlidj Y et al. (2025) Trends and outcomes of different mechanical circulatory support modalities for refractory cardiogenic shock in Takotsubo cardiomyopathy. American Heart Journal Plus: Cardiology Research and Practice 54: 100545	Retrospective registry (US Nationwide Readmission Database) n=2,025 (1,790 Impella)	In Takotsubo cardiomyopathy-associated cardiogenic shock, Impella and ECMO use has increased, while IABP use has declined from 2016 to 2020. In the absence of LV unloading, ECMO utilisation showed higher mortality, major bleeding, and adverse events than Impella.	Retrospective study, focusing on Takotsubo cardiomyopathy.
Ali S, Kumar M, Badu I et al. (2024) Trends and outcomes of different mechanical circulatory support modalities for acute myocardial infarction associated cardiogenic shock in patients undergoing early	Retrospective registry (US Nationwide Readmission Database) n=20,950 (19,628 Impella)	On propensity-matched cohorts (n=742), the ECMO cohort had higher adverse events, including mortality (52% versus 42%), sudden cardiac arrest (41% versus 32%), acute stroke (9% versus 5%) and major bleeding (16% versus 12%), p<0.05.	A larger study from a US registry is included. Study is included in systematic review by Bogerd (2025).

revascularization. American Heart Journal Plus: Cardiology Research and Practice 46: 100468			
Alushi B, Douedari A, Froehlig G et al. (2019) Impella versus IABP in acute myocardial infarction complicated by cardiogenic shock. Open Heart 6: e000987	Retrospective single-centre cohort study n=116 (62 Impella) AMICS	In people with AMICS, haemodynamic support with the Impella device had no statistically significant effect on 30-day mortality as compared with IABP.	Larger and more recent studies were prioritised.
Ancona MB, Montorfano M, Masiero G et al. (2021) Device-related complications after Impella mechanical circulatory support implantation: an IMP-IT observational multicentre registry substudy. European Heart Journal. Acute Cardiovascular Care 10: 999-1006	Multicentre registry (IMPella Mechanical Circulatory Support Device in Italy) n=406 (cardiogenic shock and high-risk PCI)	The most frequent complication was haemolysis (12%), which occurred almost exclusively in cardiogenic shock population. Access-site bleeding was observed in 10% of the overall population. Limb ischaemia was observed in 8% of the overall population, with a higher rate in the cardiogenic shock group compared to the PCI group. cardiogenic shock and right ventricular dysfunction appear as the strongest independent predictors of device-related complications.	Larger and more recent studies were prioritised.
Ando T, Nakamaru R, Kohsaka S et al. (2023) Access Site-Stratified Analysis of the Incidence, Predictors, and Outcomes of Impella-Supported	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry)	167 (6%) procedures used the transaxillary or trans-subclavian access approach rather than transfemoral. Predictors of the transaxillary or trans-subclavian approach included acute	Retrospective study focusing on the effect of different access approaches on outcomes.

Patients With Cardiogenic Shock. The American Journal of Cardiology 205: 198-203	n=2,564	coronary syndrome, cardiogenic shock, and inotropic use. 30-day mortality was comparable between approaches.	
Attachaipanich T, Attachaipanich S, Kaewboot K (2025) Timing of mechanical circulatory support in acute myocardial infarction complicated by cardiogenic shock: A systematic review and meta-analysis. American Heart Journal Plus: Cardiology Research and Practice 50: 100506	Systematic review and meta-analysis n=6,218 (36 studies)	Early MCS insertion (before PCI) was associated with a lower risk of in-hospital mortality compared to late insertion (after PCI), with an OR of 0.46 (95% CI 0.36 to 0.57), p<0.01. Subgroup analysis by MCS type (IABP, Impella, and ECMO) showed that early insertion significantly reduced in-hospital mortality, regardless of the MCS type. Early MCS insertion was also associated with lower 30-day mortality (OR 0.62, 95% CI 0.43 to 0.89, p=0.01) and 6-month mortality (OR 0.53, 95% CI 0.34 to 0.83, p=0.01) compared to late insertion. There was no difference in 1-year mortality or in MCS-related complications.	There is considerable overlap with other systematic reviews included in the key evidence.
Badiye AP, Hernandez GA, Novoa I et al. (2016) Incidence of Hemolysis in Patients with Cardiogenic Shock Treated with Impella Percutaneous Left Ventricular Assist Device. ASAIO Journal 62: 11-4	Retrospective cohort study n=118 devices cardiogenic shock	The average time of support was 86.6 hours, and the 30 and 90 days of survival were 65% and 60%, respectively. The cumulative incidence of haemolysis was 62%.	Larger and more recent studies were prioritised.

Baldetti L, Romagnolo D, Festi M et al. (2025) Impella malrotation affects left ventricle unloading in cardiogenic shock patients. ESC Heart Failure 12: 542-553	Retrospective single-centre cohort study n=100 cardiogenic shock Impella CP, 5.0, 2.5 and 5.5	Impella malrotation was identified in 36% of people with available echocardiography during Impella support and pulmonary artery catheter assessment before and during Impella support. Impella malrotation was associated with suboptimal unloading of the left ventricle, worse pulmonary haemodynamics and worse indexes of right ventricular afterload.	Small retrospective study.
Basir MB, Lemor A, Gorgis Sarah et al. (2023) Early Utilization of Mechanical Circulatory Support in Acute Myocardial Infarction Complicated by Cardiogenic Shock: The National Cardiogenic Shock Initiative. Journal of the American Heart Association 12: e031401	Retrospective multicentre single arm trial (National Cardiogenic Shock Initiative) n=406	Procedural survival, survival to discharge, survival to 30 days, and survival to 1 year were 99%, 71%, 68%, and 53%, respectively. Early use of MCS in AMICS was feasible across varying health care settings and resulted in improvements to early haemodynamics and perfusion.	Larger studies were prioritised.
Batchelor RJ, Wheelahan A, Zheng WC et al. (2022) Impella versus Venoarterial Extracorporeal Membrane Oxygenation for Acute Myocardial Infarction Cardiogenic Shock: A Systematic Review and Meta-	Systematic review and meta-analysis n=7,093 (6 studies)	Pooled in-hospital mortality was 42% in the Impella group versus 50% in the VA-ECMO group. Impella support for AMICS was associated with an 11% relative risk reduction in in-hospital mortality compared to VA-ECMO (RR 0.89; 95% CI 0.83 to 0.96, I^2=0%). Of the 6 studies, 3 adjusted	More recent systematic reviews were prioritised.

Analysis. Journal of Clinical Medicine 11		outcome measures via propensity-score matching with reported reductions in in-hospital mortality with Impella compared to VA-ECMO (RR 0.72; 95% CI 0.59 to 0.86, I^2=35%). Pooled analysis of 6- or 12-month mortality data reported a 14% risk reduction with Impella over the medium-to-long-term (RR 0.86; 95% CI 0.76 to 0.97, I^2=0%).	
Benenati S, Toma M, Canale C et al. (2022) Mechanical circulatory support in patients with cardiogenic shock not secondary to cardiotomy: a network meta-analysis. Heart Failure Reviews 27: 927-934	Network meta-analysis n=11,117 (346 Impella) Most were Impella 2.5	Data indicate that, in cardiogenic shock with various aetiologies, ECMO statistically significantly decreases short-term mortality as compared with other types of MCS or no support, especially when used in association with Impella or IABP. This finding should be considered hypothesis-generating and inform larger and adequately powered randomised controlled trials. The risk of bleeding is enhanced by MCS.	More recent systematic reviews were prioritised.
Bhuiyan R, Bimal T, Fishbein J et al. (2023) Percutaneous coronary intervention with Impella support with and without intra-aortic balloon in cardiogenic shock patients. Cardiovascular	Retrospective multicentre cohort study n=101 (61 Impella only, 40 Impella and IABP) Most people had acute	In people with cardiogenic shock who have PCI with either the Impella device alone or with Impella and IABP, major bleeding complications and major adverse cardiac and cerebrovascular events rates were high but not significantly different between the 2 groups. In	Larger studies were prioritised.

Revascularization Medicine 55: 68-73	myocardial infarction.	hospital mortality was relatively low in both groups despite the high-risk characteristics of this cohort.	
Bochaton T, Huot L, Elbaz M et al. (2020) Mechanical circulatory support with the Impella R LP5.0 pump and an intra-aortic balloon pump for cardiogenic shock in acute myocardial infarction: The IMPELLA-STIC randomized study. Archives of Cardiovascular Diseases 113: 237-243	Randomised controlled trial n=12 (6 Impella 5.0, 6 IABP)	In people with AMICS stabilised by initial treatment with inotropes and an IABP, the Impella 5.0 did not provide additional haemodynamic support or improvement in LVEF at 1 month.	Small sample size.
Bogerd M, Ten Berg S, Peters EJ et al. (2023) Impella and venoarterial extracorporeal membrane oxygenation in cardiogenic shock complicating acute myocardial infarction. European Journal of Heart Failure 25: 2021-2031	Multicentre retrospective cohort (Institut für das Entgeltsystem im Krankenhaus GmbH, InEK). n=4,088 (2,700 Impella)	In-hospital mortality was lower in the Impella versus VA-ECMO cohort (61% versus 67%, p=0.001). Adverse events occurred less frequently in Impella-supported patients: acute haemorrhagic anaemia (36% versus 68%, p<0.001), cerebrovascular accidents (4% versus 11%, p<0.001), thromboembolism of the extremities (5% versus 8%, p<0.001), systemic inflammatory response syndrome (21% versus 25%, p=0.004), acute kidney injury (44% versus 53%, p<0.001), and acute liver failure (7% versus 12%,	Retrospective study, which is included in the systematic review by Bogerd (2025).

		p<0.001). Impella patients were discharged home directly more often (20% versus 11%, p<0.001) whereas VA-ECMO patients were more often discharged to another care facility (22% versus 19%, p=0.031). Impella patients had shorter hospital stays and lower hospital costs.	
Bossi E, Marini C, Gaetti G et al. (2022) Efficacy and safety of Impella 5.0 in cardiogenic shock: an updated systematic review. Future Cardiology 18: 253-264	Systematic review and meta-analysis 17 studies Impella 5.0	Thirty-day survival rates ranged from 40 to 94%, myocardial recovery from 18 to 93%. Impella 5.0 is associated with a lower rate of vascular complications than other MCS such as VA-ECMO and is characterised by greater stability of the device position because of the surgical insertion and fixation. The main limitations of the work were linked to the quality and availability of included studies.	More recent systematic reviews were prioritised.
Bravo-Jaimes K, Mejia MO, Abelhad NI et al. (2022) Gender Differences in the Outcomes of Cardiogenic Shock Requiring Percutaneous Mechanical Circulatory Support. The American Journal of Cardiology 174: 20-26	Retrospective registry (US National Inpatient Sample database) n=113,305 percutaneous MCS for AMICS	Women needing percutaneous MCS had a higher comorbidity load, in-hospital mortality, acute respiratory failure, blood transfusions, and lower pulmonary artery catheter use.	A more recent study that uses the same database is included (Movahed 2024)

Briasoulis A, Kampaktsis P, Emfietzoglou M et al. (2023) Temporary Mechanical Circulatory Support in Cardiogenic Shock due to ST-Elevation Myocardial Infarction: Analysis of the National Readmissions Database. Angiology 74: 31-38	Retrospective registry (US Nationwide Readmission Database) n=80,997 people with cardiogenic shock because of STEMI (9,055 Impella) Type of Impella device not reported	30-day readmission rates did not differ among groups, whereas 90-day readmissions were higher among those with combined ECMO and IABP or Impella support (p=0.027). In-hospital mortality and complications including haemodialysis, transfusion, and stroke were the highest in the Impella and combined ECMO and IABP with Impella groups. Heart failure was the most common cause of readmission. Multivariable logistic regression showed female gender, diabetes, prior myocardial infarction, heart failure, chronic kidney, and peripheral artery disease as risk factors for 90-day readmissions.	Another US registry study is included. This study was included in review by Bogerd (2025) but it was identified as a distorting outlier and was therefore excluded from the primary meta-analysis.
Brush JE Jr, Harper AM, Kohan LC et al. (2025) Real-world interventional outcomes for cardiogenic shock complicating acute myocardial infarction. American Heart Journal Plus: Cardiology Research and Practice 53: 100540	Retrospective registry (American College of Cardiology's National Cardiovascular Data Registry) n=505 people with AMICS (73 MCS)	In MCS-inclined hospitals as compared with IABP-inclined hospitals, people had higher 180-day mortality (45% versus 34%, p=0.017), and bleeding rates (15% versus 1%, p<0.001), with trends toward higher 30-day mortality (41% versus 33%, p=0.064) and access site injury (5% versus 1%, p=0.063).	Larger studies were prioritised.
Buda KG, Hryniewicz K, Eckman PM et al. (2024) Early vs.	Retrospective registry (US Nationwide	There was no survival benefit of temporary MCS in all-comers with AMICS. The need for	Retrospective study, focusing on the effect of

delayed mechanical circulatory support in patients with acute myocardial infarction and cardiogenic shock. European Heart Journal: Acute Cardiovascular Care 13: 390-397	Readmission Database) n=294,839 people with AMICS (33,577 Impella)	Impella and VA-ECMO was independently associated with higher mortality, likely because of the acuity of people in this group. Among people having temporary MCS for AMICS, early intervention was associated with fewer complications, shorter lengths of stay, lower hospital costs, and fewer deaths and readmissions at 30 days.	timing of MCS on outcomes.
Chieffo A, Ancona MB, Burzotta F et al. (2020) Observational multicentre registry of patients treated with IMPella mechanical circulatory support device in ITaly: the IMP-IT registry. EuroIntervention 15: e1343-e1350	Multicentre registry (IMPella Mechanical Circulatory Support Device in Italy) n=406 (cardiogenic shock and high-risk PCI) Impella 2.5, Impella CP, Impella 5.0 and Impella RP	Rates of in-hospital and 1-year mortality in people with cardiogenic shock were 47% and 57%, respectively; 19% had LVAD implantation or heart transplant at 1 year. Rates of device-related complications were 37% in the setting of cardiogenic shock.	Larger and more recent studies were prioritised. Study is included in systematic review by Sassani (2025).
Chung JS, Emerson D, Ramzy D et al. (2020) A New Paradigm in Mechanical Circulatory Support: 100-Patient Experience. The Annals of Thoracic Surgery 109: 1370-1377	Retrospective single-centre cohort study n=100 acutely decompensated heart failure Impella 5.0	People had the device as a bridge to recovery (n=30), bridge to durable device (n=23), or bridge to transplantation (n=47). All devices were placed using an axillary artery approach. Overall survival was 64%. Survival was 50% for bridge to recovery, 48% for bridge to durable device and 81% for	Larger and more recent studies were prioritised.

		bridge to transplantation (p=0.007). Survival improved during the study period and was 90% overall in the most recent 30 people.	
De Ferrari T, Pistelli L, Franzino M et al. (2024) MI2AMI-CS: A meta-analysis comparing Impella and IABP outcomes in Acute Myocardial Infarction-related Cardiogenic Shock. International Journal of Cardiology 414: 132411	Systematic review and meta-analysis n=10,628 (8 studies) After excluding overlapping data, 4 studies (n=2,795) were used for mortality data.	In unselected people with AMICS, Impella use showed higher mortality than IABP (57% versus 46%; OR 1.44, 95% CI 1.29 to 1.60; p<0.001) and higher rates of major bleeding (30% versus 15%; OR 2.93, 95% CI 1.67 to 5.13; p<0.001).	There is a lot of overlap with the systematic review by Panuccio (2022), which includes more studies.
Del Rio-Pertuz G, Benjanuwattra J, Juarez M et al. (2022) Efficacy of Mechanical Circulatory Support Used Before Versus After Primary Percutaneous Coronary Intervention in Patients with Cardiogenic Shock From ST-Elevation Myocardial Infarction: A Systematic Review and Meta-Analysis. Cardiovascular Revascularization Medicine 42: 74-83	Systematic review and meta-analysis n=1,352 (203 Impella; 10 studies) STEMI complicated by cardiogenic shock	In people with STEMI complicated by cardiogenic shock who have primary PCI, the use of Impella or VA-ECMO before PCI statistically significantly decreased mortality, in contrast to IABP, in which no difference in mortality was found between using it before or after PCI.	More recent systematic reviews were prioritised.
Desai R, Hanna B, Singh S et al. (2021) Percutaneous Ventricular Assist	Propensity score matched analysis using retrospective	There was no difference in the in-hospital mortality (40% versus 37%, p=0.25); however,	Study focuses on outcomes in people with

Device vs. Intra-Aortic Balloon Pump for Hemodynamic Support in Acute Myocardial Infarction-Related Cardiogenic Shock and Coexistent Atrial Fibrillation: A Nationwide Propensity-Matched Analysis'. American Journal of the Medical Sciences 361: 55	registry data (US National Inpatient Sample database) n=886 in the matched group (443 Impella) AMICS and atrial fibrillation	the percutaneous VAD group had a lower incidence of post-procedural myocardial infarction and higher incidences of stroke (8% versus 4%, p=0.03), haemorrhage (6% versus 2%, p=0.01), discharges to home health care (14% versus 10%, p<0.001) and to other facilities (29% versus 25%, p<0.001) as compared to IABP group. There was no difference between the groups in terms of mean length of stay or hospital charges.	coexistent atrial fibrillation.
Dodoo SN, Kwapong YA, Agyemang-Sarpong A et al. (2024) Comparative Healthcare Resource Utilization of Percutaneous Mechanical Circulatory Support Using Impella Versus Intra-aortic Balloon Pump Use for Patients With Acute Coronary Syndrome and Cardiogenic Shock Undergoing Percutaneous Coronary Interventions: Insights From National Inpatient Sample. Current Problems in Cardiology 49: 102053	Retrospective registry (US National Inpatient Sample database) n=439,610 people admitted with acute coronary syndrome complicated by cardiogenic shock, supported by Impella or IABP	1:1 propensity score matching identified 2,620 people who had Impella with comparable severity index with people who had IABP. Impella was associated with higher in-hospital mortality compared with IABP (55% versus 46%, p<0.0001). People who had Impella developed more periprocedural complications, including vascular injury (5% versus 1%, p<0.0001), acute kidney injury (58% versus 42%, p<0.0001), end-stage renal disease needing dialysis (9% versus 1%, p=0.002) than those who had IABP.	Another study with more recent data from the same source is included (Movahed 2024).

Duan J, Shi Y, Luo G et al. (2021) Short-term efficacy and safety of different mechanical hemodynamic support devices for cardiogenic shock or high-risk PCI: A network meta-analysis of thirty-seven trials. Shock 55: 5	Network meta-analysis n=11,270 (38 studies)	The analysis suggested that ECMO with IABP might be a more suitable intervention measure in improving short-term mortality for people with cardiogenic shock and who had high-risk PCI. However, the result was limited by the lack of sufficient direct comparisons and evidence from randomised controlled trials. Moreover, bleeding and other device-related complications should be considered in clinical applications.	More recent systematic reviews were prioritised.
Feistritzer H-J, Desch S, Freund A et al. (2020) Prognostic Impact of Active Mechanical Circulatory Support in Cardiogenic Shock Complicating Acute Myocardial Infarction, Results from the Culprit-Shock Trial. Journal of Clinical Medicine 9	Subanalysis of randomised controlled trial (CULPRIT-SHOCK) and prospective registry n=1,055 people with AMICS (112 Impella)	The primary endpoint was a composite of all-cause death or renal replacement therapy at 30 days. It occurred more often in people who had active MCS devices compared with those without active MCS devices (72% versus 45%; p<0.001). All-cause mortality and bleeding rates were higher in the active MCS group (all p<0.001). After multivariable adjustment, the use of active MCS was associated with the primary endpoint (OR 4.0, 95% CI 2.7 to 5.9; p<0.001).	Larger and more recent studies were prioritised.
Haberkorn S, Uwarow A, Haurand J et al. (2020) Percutaneous left ventricular assist support is	Retrospective cohort study n=100 (50 Impella)	Pulmonary congestion decreased in people who had Impella at each time point post-implantation. No change in congestion status was observed in	Larger studies were prioritised.

associated with less pulmonary congestion and lower rate of pneumonia in patients with cardiogenic shock. Open Heart 7: no. 2	cardiogenic shock	people supported with IABP. Multivariate analysis indicated Impella support as an independent predictor for pulmonary decongestion (OR 4.06, 95% CI 1.15 to 14.35, p=0.030). The rate of early pneumonia was lower in the Impella group compared with the IABP group (54% vs 74%, p=0.037). Failure of pulmonary decongestion during mechanical circulatory support independently predicted early pneumonia (OR 0.28, 95% CI 0.12 to 0.70, p=0.006)	
Hill MA, Kwon JH, Shorbaji K et al. (2022) Waitlist and transplant outcomes for patients bridged to heart transplantation with Impella 5.0 and 5.5 devices. Journal of Cardiac Surgery 37: 5081-5089	Retrospective registry (United Network for Organ Sharing registry) n=738 Impella 5.0 and 5.5	There were 344 people waitlisted and 394 people transplanted with an Impella 5.0 (n=212 and 251) or 5.5 (n=132 and 143) device. In the transplanted cohort, unadjusted 1-year post-transplant survival was comparable at 91% versus 95% (p=0.661) for people supported by Impella 5.0 or 5.5 device, respectively, a finding that persisted after risk-adjustment (HR 1.22, p=0.699). Post-transplant complication rates were also comparable between 5.0 and 5.5.	More recent studies were prioritised.
Iannaccone M, Franchin L, Burzotta F et al. (2023) Impact of in-Hospital Left Ventricular Ejection Fraction	Multicentre registry, Italy (IMP-IT) n=279	Significant LVEF recovery was associated with improved outcomes in people with cardiogenic shock who had PCI during	Larger studies were prioritised.

Recovery on Long-Term Outcomes in Patients Who Underwent Impella Support for HR PCI or Cardiogenic Shock: A Sub-Analysis from the IMP-IT Registry. Journal of Personalized Medicine 13: no. 5	cardiogenic shock (n=116) and high-risk PCI (n=163) Impella 2.5 or CP	mechanical circulatory support with Impella, whereas complete revascularisation showed a significant clinical relevance in high-risk PCI.	
Iannaccone M, Franchin L, Hanson ID et al. (2022) Timing of impella placement in PCI for acute myocardial infarction complicated by cardiogenic shock: An updated meta-analysis. International Journal of Cardiology 362: 47-54	Systematic review and meta-analysis n=6,810 (13 studies) AMICS	Short-term mortality was reduced in those who had Impella support before PCI rather than during or after (37% versus 54%, RR 0.7; CI 0.56 to 0.88). Midterm mortality was also lower in the pre-PCI Impella group (48% versus 73%, RR 0.81; CI 0.68 to 0.97). The rate of device-related bleeding (RR 1.05; CI 0.47 to 2.33) and limb ischaemia (RR 1.6; CI 0.63 to 2.15) were similar between the 2 groups.	More recent systematic reviews were prioritised.
Iannaccone M, Albani S, Giannini F et al. (2021) Short term outcomes of Impella in cardiogenic shock: A review and meta-analysis of observational studies. International Journal of Cardiology 324: 44-51	Systematic review and meta-analysis n=3,933 (17 studies)	30-day mortality=48% (CI 44 to 52%). Based on metaregression analysis, the Impella 5.0 and the Impella CP devices were related to a higher survival rate, whereas the Impella 2.5 was not. Furthermore, a correlation with reduced mortality was found when Impella was initiated in cardiogenic shock not complicated by cardiac arrest, and before revascularisation.	More recent systematic reviews were prioritised.

		The vascular complication and major bleeding rate were 7% (95% CI 6 to 10%) and 15% (95% CI 11 to 21%) respectively, and were associated with older age and comorbidities, while the implantation of an Impella CP or 2.5 was associated with fewer complications.	
Ikeda Y, Ishii S, Nakahara S et al. (2025) Device-related adverse events and flow capacity of percutaneous ventricular assist devices. European Heart Journal. Acute Cardiovascular Care 14: 93-103	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=5,717 Drug-refractory acute heart failure, including cardiogenic shock	The overall incidence of major device-related problems, including haemolysis, major bleeding, kidney injury, sepsis, and pump stop, was 13%, 21%, 7%, 3%, and 1%, respectively. The all-cause mortality rate was 34%. The incident risks of haemolysis (HR 0.38, 95% CI 0.24 to 0.58), kidney injury (HR 0.32, 95% CI 0.18 to 0.57), and pump stop (HR 0.38, 95% CI 0.16 to 0.91) were lower in patients with high-flow PVAD compared with those with low-flow PVAD. The risks of major bleeding or sepsis did not differ significantly between groups. The risk of all-cause mortality was lower in people with high-flow PVAD compared with those with low-flow PVAD (HR 0.79, 95% CI 0.65 to 0.96).	A high proportion (45%) of people had concomitant VA-ECMO.
Ikeda Y, Ako J, Toda K et al. (2023) Short-	Multicentre registry	Overall 30-day survival was 63%. The 30-day	Larger studies were prioritised.

Term Outcomes of Impella Support in Japanese Patients With Cardiogenic Shock Due to Acute Myocardial Infarction - Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD). Circulation Journal 87: 588-597	(Japanese Percutaneous Ventricular Assist Device registry) n=593 AMICS	survival of the Impella alone and Impella plus VA-ECMO (ECPELLA) groups was 81% and 46%, respectively. Cox regression analysis revealed that older age and comorbid renal disturbance were common risk factors affecting 30-day mortality in both groups. Major adverse events were haemolysis (11%), haemorrhage or haematoma (8%), peripheral ischaemia (4%), stroke (1%), and thrombosis (1%). LVEF improved in both groups during support.	
Jang S-J, Malaguez W, Fabricio A et al. (2023) Early Clinical Outcomes of Patients With Stress-Induced Cardiomyopathy Receiving Acute Mechanical Support in the US. Journal of the Society for Cardiovascular Angiography & Interventions 2: 101185	Retrospective registry (US Nationwide Readmission Database) n=902 Stress-induced cardiomyopathy complicated by cardiogenic shock	People with ECMO or Impella had higher in-hospital mortality rates than those with IABP (37% versus 29% versus 18%, respectively). There was an increased adjusted risk of in-hospital death with Impella (adjusted OR 1.98; 95% CI 1.12 to 3.49) and ECMO (adjusted OR 4.15; 95% CI 1.85 to 9.32) versus IABP. Impella was associated with an increased risk of 30-day readmission compared to IABP (adjusted OR 2.53; 95% CI 1.16 to 5.51). People with ECMO or Impella had a higher incidence of renal replacement therapy and vascular or bleeding	Larger studies were prioritised.

		complications compared to those who had IABP.	
Javaid AI, Michalek JE, Gruslova AB et al. (2024) Mechanical circulatory support versus vasopressors alone in patients with acute myocardial infarction and cardiogenic shock undergoing percutaneous coronary intervention. Catheterization and Cardiovascular Interventions 103: 30-41	Propensity score matched analysis using retrospective registry data (US National Inpatient Sample database) n=17,762 AMICS and PCI	Impella use was associated with higher in-hospital major bleeding (31% versus 14%; p<0.001) and hospital charges (p<0.001) compared to IABP use, with no benefit in mortality (34% versus 27%; p=0.06). Impella use was associated with higher mortality (42% versus 36%; p=0.02), major bleeding (34% versus 23%; p=0.001), and hospital charges (p<0.001), when compared to the use of vasopressors without MCS. There were no statistically significant differences in clinical outcomes between IABP use and the use of vasopressor without MCS.	Another study reporting outcomes from the same database is included (Movahed 2024).
Jensen PB, Kann SH, Veien KT et al. (2018) Single-centre experience with the Impella CP, 5.0 and RP in 109 consecutive patients with profound cardiogenic shock. European Heart Journal. Acute Cardiovascular Care 7: 53-61	Retrospective single-centre cohort study n=109 cardiogenic shock after myocardial infarction, acute heart failure, or cardiac surgery Impella CP, 5.0, RP	During Impella therapy, 26 people (28%) died among those with myocardial infarction or acute heart failure. Of data available before placement lactate (HR 1.14, 95% CI 1.04 to 1.25, p=0.004) was the only predictor of death on support. During support, 5 people (5%) developed leg ischaemia needing intervention. Bleeding from the Impella insertion site was seen in 14 people (13%).	Larger and more recent studies were prioritised.

Jin C, Yandrapalli S, Yang Y et al. (2022) A Comparison of In-Hospital Outcomes Between the Use of Impella and IABP in Acute Myocardial Infarction Cardiogenic Shock Undergoing Percutaneous Coronary Intervention. The Journal of Invasive Cardiology 34: e98-e103	Propensity score matched analysis of retrospective registry data (US National Inpatient Sample database) n=51,150 (6,885 Impella) AMICS and PCI	After propensity matching, compared with the Impella group (n=1,592), the IABP group (n=8,638) had lower rates of sepsis (6% versus 13%; p=0.01), blood transfusion (9% versus 14%; p=0.01), and mortality (29% versus 50%; p<0.01). The IABP group had similar rates of cardiac arrest (20% versus 22%; p=0.32), in-hospital stroke (1.5% versus 1.6%; p=0.37), and length-of-stay (8.6 days versus 8.6 days; p=0.26) compared with the Impella group.	More recent studies were prioritised.
Joseph SM, Brisco MA, Colvin M et al. (2016) Women With Cardiogenic Shock Derive Greater Benefit From Early Mechanical Circulatory Support: An Update From the cVAD Registry. Journal of Interventional Cardiology 29: 248-56	International registry (cVAD) n=180 cardiogenic shock and PCI Impella 2.5	Early initiation of haemodynamic support before PCI with Impella 2.5, in the setting of AMI complicated by cardiogenic shock, was associated with a greater survival benefit to hospital discharge in women compared to men, despite a higher predicted risk of mortality and a greater revascularisation failure rate for women.	Larger and more recent studies were prioritised.
Karami M, Eriksen E, Ouweneel DM et al. (2021) Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: percutaneous mechanical circulatory support	Multicentre randomised controlled trial n=48 (24 Impella) AMICS	5-year mortality was 50% for percutaneous MCS and 63% for IABP (RR 0.87, 95% CI 0.47 to 1.59, p=0.65). MACCE rate was 50% in the percutaneous MCS group and 79% in the IABP group (p=0.07). There were no	Small randomised controlled trial, which is included in Ardito V (2023) and Bogerd (2025).

vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction. European Heart Journal. Acute Cardiovascular Care 10: 1009-1015		differences in left ventricular ejection fraction between the groups.	
Karami M, den Uil CA, Ouweneel DM et al. (2020) Mechanical circulatory support in cardiogenic shock from acute myocardial infarction: Impella CP/5.0 versus ECMO. European Heart Journal. Acute Cardiovascular Care 9: 164-172	Retrospective 2-centre cohort study n=128 (90 Impella) AMICS Impella CP or 5.0	People who had Impella CP or 5.0, or ECMO for cardiogenic shock after myocardial infarction did not differ in 30-day mortality. More device-related complications happened with ECMO compared to Impella support.	Larger studies were prioritised.
Karatolios K, Chatzis G, Markus BL et al. (2021) Comparison of mechanical circulatory support with venoarterial extracorporeal membrane oxygenation or Impella for patients with cardiogenic shock: a propensity-matched analysis. Clinical Research in Cardiology 110: 1404-1411	Retrospective single-centre propensity score matched analysis n=423 (300 Impella 2.5 or CP)	Survival rates were similar in both groups (hospital survival: Impella 48% and VA-ECMO 37%, p=0.07; 6-month survival Impella 46% and VA-ECMO 36%, p=0.07). There was no significant difference in survival rates, even after adjustment for baseline differences (hospital survival: Impella 51% and VA-ECMO 39%, p=0.16; 6-month survival Impella 46% and VA-ECMO 39%, p=0.43). Access-site bleeding and leg ischaemia was more common in people who had VA-ECMO (17% versus 7%, p=0.004;	Larger studies were prioritised. Study is included in Panuccio (2022) and Stub (2025).

		17% versus 8%, p=0.008).	
Katagiri Y, Kasai Y, Miyazaki M et al. (2025) Effect of Body Mass Index in Patients With Cardiogenic Shock Requiring Microaxial Flow Pump. JACC.	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=3,636	Crude 30-day mortality increased incrementally with higher BMI categories. Adjusted HRs for 30-day mortality (BMI 18.5 to 22.9 kg/m^2 as reference) were 0.71 (95% CI 0.56 to 0.90; p=0.005) for underweight, 1.03 (95% CI 0.88 to 1.21; p=0.681) for overweight, 1.37 (95% CI 1.19 to 1.57; p<0.001) for obesity, and 2.00 (95% CI 1.66 to 2.41; p<0.001) for severe obesity. People in the underweight and severe obesity groups had a higher incidence of bleeding after percutaneous coronary intervention under microaxial flow pumps, whereas haemolysis increased with higher BMI categories. Bleeding and haemolysis were associated with mortality only in people who were underweight.	Study focuses on effect of body mass index on outcomes.
Khalid N, Rogers T, Shlofmitz E et al. (2019) Adverse events and modes of failure related to the Impella percutaneous left ventricular assist devices: A retrospective analysis of the maude database.	US FDA MAUDE database n=407 reports	54% of reports were for Impella CP, 20% Impella 2.5, and 12% Impella 5.0. Most people had the Impella device for high-risk PCI. The most reported complication was bleeding (38% of reports), of which 70% needed blood transfusion. Significant vascular complications, including dissection and	More recent studies are included with complication rates. The FDA MAUDE data does not include a denominator so incidence rates could not be determined.

EuroIntervention; 15: 44		perforation, were documented in 67 reports (16%). Device malfunction and device separation were reported in 70 (17%) and 39 (10%) reports, respectively.	
Kim Y, Shapero K, Ahn SS et al. (2022) Outcomes of mechanical circulatory support for acute myocardial infarction complicated by cardiogenic shock. Catheterization and Cardiovascular Interventions 99: 658-663	Retrospective registry (US National Inpatient Sample database) n=54,480 (5,750 Impella)	After propensity score matching, Impella was associated with higher in-hospital mortality (OR 1.74, 95% CI 1.41 to 2.13) and transfusions (OR 1.97, 95% CI 1.40 to 2.78) than IABP, without association with acute kidney injury or stroke.	More recent studies were prioritised.
Klein A, Beske RP, Hassager C et al. (2025) Treating Older Patients in Cardiogenic Shock With a Microaxial Flow Pump: Is it DANGERous? Journal of the American College of Cardiology 85: 595-603	Multicentre randomised controlled trial (DanGer Shock) n=355 STEMI-related cardiogenic shock Impella CP	The predicted risk of mortality was higher in the standard-care group until about 77 years, after which the predicted risk became higher in the microaxial flow pump group (p=0.20). In people younger than 77 years, a reduced 180-day mortality was seen in people randomised to the microaxial flow pump (OR 0.45; 95% CI 0.28 to 0.73; p=0.001), compared to people aged 77 or above (OR 1.52; 95% CI 0.57 to 4.08; p=0.40).	Secondary analysis of trial that is included in the key evidence.
Kuchtaruk AA, Sparrow RT, Azzalini L et al. (2023) Unplanned readmissions after Impella mechanical	Retrospective registry (US Nationwide Readmission Database)	30-day readmissions after Impella MCS are relatively common and relate to sex, baseline comorbidities, presentation, expected	Registry studies with more comprehensive outcomes are included.

circulatory support. International Journal of Cardiology 379: 48-59	n=22,055	primary payer, discharge destination and initial length of hospital stay. Heart failure was the leading cause of cardiac readmissions, whereas infections were the most common cause among non-cardiac readmissions.	
Kuno T, Takagi H, Ando T et al. (2021) Safety and efficacy of mechanical circulatory support with Impella or intra-aortic balloon pump for high-risk percutaneous coronary intervention and/or cardiogenic shock: Insights from a network meta-analysis of randomized trials. Catheterization and Cardiovascular Interventions 97: e636-e645	Network meta-analysis n=1,996 (9 randomised controlled trials) cardiogenic shock or high-risk PCI	There was no statistically significant difference with Impella or IABP on all-cause mortality when compared with no MCS. Impella increased major bleeding compared with no MCS.	More recent systematic reviews were prioritised.
Lauten A, Engstrom AE, Jung C et al. (2013) Percutaneous left-ventricular support with the Impella-2.5-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circulation. Heart Failure 6: 23-30	Retrospective multicentre registry (EUROSHOCK) n=120 AMICS Impella 2.5	30-day mortality=64% After Impella 2.5 implantation, lactate levels decreased from 5.8 mmol/litre to 4.7 mmol/litre (p=0.28) and 2.5 mmol/litre (p=0.023) at 24 and 48 hours, respectively. Early major adverse cardiac and cerebrovascular events were reported in 18 (15%) people. Major bleeding at the vascular access site, haemolysis, and pericardial	Larger and more recent studies were prioritised.

		tamponade occurred in 34 (29%), 9 (8%), and 2 (2%) people, respectively. The parameters of age over 65 and lactate level above 3.8 mmol/litre at admission were identified as predictors of 30-day mortality. After 317 days of follow-up, survival was 28%.	
Lazkani M, Murarka S, Kobayashi A et al. (2017) A retrospective analysis of Impella use in all-comers: 1-year outcomes. Journal of Interventional Cardiology 30: 577-583	Retrospective single-centre registry n=262	For people with need for an Impella device, regardless of the indication, early implantation is associated with better in-hospital and 1-year outcomes as compared to when the device is implanted late as a bailout.	Larger and more recent studies were prioritised.
Lemor A, Dabbagh MF, Cohen D et al. (2022) Rates and impact of vascular complications in mechanical circulatory support. Catheterization and Cardiovascular Interventions 99: 1702-1711	Retrospective registry (US National Inpatient Sample database) n=221,700 (IABP, Impella or ECMO)	The rates of vascular complications were greatest with ECMO (16%) when compared with IABP (3%) and Impella (6%). Among people with vascular complications, in-hospital mortality was higher with ECMO (56%) when compared with IABP (26%) and Impella (34%). Peripheral arterial disease was the strongest predictor of vascular complications (adjusted OR 10.96, $p<0.001$). In risk-adjusted models, when compared with IABP, the use of Impella (adjusted OR 1.73, $p<0.001$), ECMO (adjusted OR	More recent studies were prioritised.

		5.35, p<0.001), or a combination of MCS devices (adjusted OR 3.47, p<0.001) was associated with higher odds of vascular complications.	
Lemor A, Hosseini D, Seyed H et al. (2020) Impella Versus Extracorporeal Membrane Oxygenation for Acute Myocardial Infarction Cardiogenic Shock. Cardiovascular revascularization medicine 21: 1465-1471	Retrospective registry (US National Inpatient Sample database) n=6,290 (5,730 Impella) AMICS and PCI	After propensity-match analysis, the ECMO cohort had significantly higher in-hospital mortality than Impella (43% versus 27%, OR 2.10, p=0.021). The incidence of acute respiratory failure and vascular complications were lower in the Impella cohort. Hospital stay was shorter, and hospital costs were lower in the Impella cohort compared to those who had ECMO.	More recent studies were prioritised.
Leon SA, Rosen JL, Ahmad D et al. (2023) Microaxial circulatory support for percutaneous coronary intervention: A systematic review and meta-analysis. Artificial Organs 47: 934-942	Systematic review and meta-analysis n=543 (5 articles) cardiogenic shock and PCI	People presenting with AMICS were similar at baseline in both pre-PCI and post-PCI groups. The pre-PCI group showed better early survival compared to post-PCI group.	More comprehensive reviews are included.
Leung C, Fong YH, Chiang MCS et al. (2025) Protocol-Driven Best Practices and Cardiogenic Shock Survival in Asian Patients. Journal of the American Heart Association 14: e037742	Prospective multicentre registry, Hong Kong (Queen Elizabeth Hospital PVAD Registry) n=109 The primary cause of	A suggestive trend of improving 30-day survival was observed (57%, 64%, and 7%) in successive one thirds of the cohort paralleling a similar trend in achievement of best practices. Achievement of protocol-advocated best practices, especially	Larger studies were prioritised.

	cardiogenic shock was AMI (67%)	early shock recognition and prompt percutaneous VAD support in appropriate patients, was associated with improved outcomes.	
Levine D, Volk L, Vagaonescu T et al. (2022) Risk of Stroke with Impella Placement Is Not Associated with Access Vessel. Innovations 17: 25-29	Retrospective single-centre cohort study n=349	Most devices were inserted through a minimally invasive approach (61%), while the remainder used central access (39%). The risk of stroke for the entire cohort was 10% (n=36), with no difference observed in any group. Overall mortality was 44% (n=155). Of the people who initially had a minimally invasive Impella, those who were upgraded had higher rates of mortality (57% versus 39%, p=0.03), postoperative dialysis (50% versus 27%, p<0.01), and sepsis (43% versus 20%, p<0.01).	Larger and more recent studies were prioritised.
Lewin D, Rojas SV, Billion M et al. (2024) Durable left ventricular assist devices following temporary circulatory support on a microaxial flow pump with and without extracorporeal life support. JTCVS Open 21: 168-179	Retrospective multicentre registry n=332 people bridged to durable LVAD Impella 5.5, 5.0 and CP	125 people (39%) also needed extracorporeal life support before or during microaxial flow pump therapy. The 30-day and 1-year survival were 88% and 71%, respectively. The following risk factors for 1-year mortality were identified: age (OR 1.02), specifically age over 55 years (OR 1.09), body mass index above 30 kg/m^2 (OR 2.2), female sex (OR for male sex,	Retrospective registry data, focusing on outcomes of durable LVAD after microaxial flow pump support.

		0.43), elevated total bilirubin (OR 1.12), and low platelet count (OR 0.996).	
Luiz L, Mesadri GD, Picado-Loaiza S et al. (2025) Sex-related outcomes during short-term mechanical circulatory support: A systematic review and meta-analysis of propensity-score matched studies. Perfusion 2676591251324643	Systematic review and meta-analysis n=18,720 (6 propensity score matched studies) Type of Impella device not reported	Subgroup analysis showed higher 30-day mortality during ECMO (OR 1.11; 95% CI 1.01 to 1.22; p=.038; I^2=0%) in males, but lower 30-day mortality during Impella therapy than females (OR 0.87; 95% CI 0.80 to 0.94; p=0.001; I^2=0%). Males had a higher need of myocardial revascularisation (OR 3.09; 95% CI 1.56 to 5.99; p=0.001; I^2=0%), but a higher risk of acute kidney injury (OR 1.20; 95% CI 1.09 to 1.31; p<0.001; I^2=18%).	Study focuses on sex-related outcomes.
Mangner N, Mierke J, Baron D et al. (2025) DanGer Shock-like profile predicts the outcome in ST-elevation myocardial infarction-related cardiogenic shock. ESC Heart Failure	Prospective single-centre registry n=478 STEMI-CS	Out of 225 people with STEMI-CS, 64 (28%) were considered DGS-like (met the criteria used in DanGerShock trial). All-cause mortality at 180 days was lower in the DGS-like compared to the DGS-unlike cohort (62% versus 72%, p=0.014) as was 30-day all-cause mortality (48% versus 70%, p<0.001). DGS-like remained an independent predictor of both 180-day (HR 0.57, 95% CI 0.39 to 0.83) and 30-day mortality (HR 0.48, 95% CI 0.32 to 0.72) in a multivariable analysis.	Small registry study comparing outcomes in a cohort similar to the DanGer Shock trial.

Medina ML, Lewin D, Treede H et al. (2025) Multicentre comparison of various microaxial pump devices as a bridge to durable assist device implantation. ESC Heart Failure	Retrospective multicentre cohort n=339 (247 Impella high flow [5+], 92 low flow [CP]) Acute de-compensated advanced heart failure	High-flow microaxial flow pump devices (+5) provided superior haemodynamic support, enhanced left ventricular unloading, and reduced dependence on catecholamines compared to lower-flow CP devices. These improvements were associated with lower rates of right ventricular failure, renal dysfunction, and liver injury. However, there was no statistically significant difference between groups regarding 30-day mortality rates.	Small, retrospective study comparing different microaxial flow pump devices.
Mierke J, Nowack T, Poege F et al. (2024) Sex-Related Differences in Outcome of Patients Treated With Microaxial Percutaneous Left Ventricular Assist Device for Cardiogenic Shock. Heart, Lung & Circulation 33: 1670-1679	Retrospective analysis of prospective single-centre registry (Dresden Impella Registry) n=432 Impella CP	The study showed no differences in all-cause mortality at 30 days between males and females who had microaxial percutaneous LVAD in cardiogenic shock.	Small study focusing on sex-related outcomes.
Mierke J, Nowack T, Loehn T et al. (2022) Predictive value of the APACHE II score in cardiogenic shock patients treated with a percutaneous left ventricular assist device. International Journal of Cardiology. Heart &	Analysis of data from prospective single-centre registry (Dresden Impella Registry) n=180 Impella CP	The predicted mortality calculated by the APACHE 2 score is overestimated in modern guideline-based treated cardiogenic shock with microaxial heart pumps. Nevertheless, the APACHE II score has an acceptable accuracy for prediction of intrahospital mortality, which can be	The study focuses on the predictive value of APACHE 2 score.

Vasculature 40: 101013		more precisely estimated by using an adjusted diagnostic category weight.	
Miller PE, Bromfield SG, Ma Q et al. (2022) Clinical Outcomes and Cost Associated With an Intravascular Microaxial Left Ventricular Assist Device vs Intra-aortic Balloon Pump in Patients Presenting With Acute Myocardial Infarction Complicated by Cardiogenic Shock. JAMA Internal Medicine 182: 926-933	Retrospective propensity-matched cohort study n=3,077 people who had PCI for AMICS	In this propensity-matched analysis of people having PCI for AMI complicated by cardiogenic shock, intravascular LVAD use was associated with increased short-term and 1-year risk of mortality, bleeding and kidney replacement therapy compared with IABP.	More recent studies were prioritised.
Miyashita S, Banlengchit R, Marbach JA et al. (2022) Left Ventricular Unloading Before Percutaneous Coronary Intervention is Associated With Improved Survival in Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock: A Systematic Review and Meta-Analysis. Cardiovascular Revascularization Medicine 39: 28-35	Systematic review and meta-analysis n=432 (5 studies) AMICS and PCI Impella 2.5, CP and 5.0	In the pooled analysis, people who had Impella before PCI had statistically significantly lower in-hospital mortality compared to those who had Impella after PCI (RR 0.62, 95% CI 0.50 to 0.76, I^2=0%). The lower mortality rate in the pre-PCI group remained evident at 30 days (HR 0.60, 95% CI 0.47 to 0.78, I^2=0%) and at 6 months (HR 0.66, 95% CI 0.44 to 0.97, I^2=0%).	More recent systematic reviews were prioritised.

Moustafa A, Khan MS, Saad M et al. (2022) Impella Support Versus Intra-Aortic Balloon Pump in Acute Myocardial Infarction Complicated by Cardiogenic Shock: A Meta-Analysis. Cardiovascular Revascularization Medicine 34: 25-31	Systematic review and meta-analysis n=3,921 (7 studies) AMICS	There was no difference in short-term mortality between Impella and IABP (RR 1.08, 95% CI 0.87 to 1.33, p=0.49). For safety endpoints, Impella was associated with higher incidence of major bleeding (RR 2.03, 95% CI 1.56 to 2.64, p<0.0001), limb complications (RR 3.67, 95% CI 1.56 to 8.65, p=0.003) as well as haemolysis (RR 9.46, 95% CI 1.75 to 51.22, p=0.009) compared with IABP. No statistically significant difference was observed for the incidence of stroke (RR 1.07 95% CI 0.34 to 3.31 p=0.91).	More recent systematic reviews were prioritised.
Movahed MR, Bradshaw S, Hashemzadeh M (2025) Mortality With Impella Is Lowest in Overweight and Obese but Is Highest in Morbid Obesity. Artificial Organs	Retrospective registry (US National Inpatient Sample database) n=86,810	Overall mortality=30% Using multivariate analysis adjusting for comorbid conditions, overweight and obesity remained statistically significantly associated with the lowest mortality (overweight: OR 0.3, CI 0.16 to 0.68, p=0.003, Obese: OR 0.8, CI 0.71 to 0.91, p<0.001) whereas morbid obesity was associated with the highest mortality (OR 1.17, CI 1.02 to 1.34, p=0.02).	Studies with more comprehensive outcomes were prioritised.
Munoz Tello C, Jamil D, Tran HH-V et al. (2022) The Therapeutic Use of Impella Device in Cardiogenic Shock:	Systematic review 30 articles	Most people with cardiogenic shock have an improvement using the Impella device. This evaluation was founded on the LVEF,	More recent systematic reviews with meta-analyses were prioritised.

A Systematic Review. Cureus 14: e30045		improvement in the cardiogenic shock criteria signs and symptoms, and favourable response in the follow-ups.	
Murthi M, Baskaran N, Memdani A et al. (2024) Comparison of in-hospital outcomes of ST-elevation myocardial infarction patients with cardiogenic shock receiving left ventricular mechanical circulatory support devices based on transfer status. Catheterization and Cardiovascular Interventions 104: 437-443	Retrospective registry (US National Inpatient Sample database) n=21,189 STEMI and cardiogenic shock	75% of people had in-house left ventricular support and (25%) were transferred. Primary outcome mortality did not significantly differ (45% versus 44%, p=0.66). After multivariate analysis, the transferred group had higher rates of ECMO, acute kidney injury, renal replacement therapy, major bleeding, and ischaemic stroke. Length of stay (8 versus 15 days, p<0.001) was higher in the transferred group.	Retrospective study, focusing on in-hospital outcomes according to transfer status.
Nair RM, Kumar S, Saleem T et al. (2024) Impact of Age, Gender, and Body Mass Index on Short-Term Outcomes of Patients With Cardiogenic Shock on Mechanical Circulatory Support. The American Journal of Cardiology 217: 119-126	Retrospective single-centre cohort study n=393 Type of Impella device not reported	People over 80 years had higher 30-day mortality (82% versus 49%, p=0.006). Patients with BMI 30 or above had higher 30-day mortality than those with BMI less than 30 (60% versus 45%, p=0.007). There was no difference in 30-day mortality between men and women. On multivariable logistic regression, both age and BMI had a positive linear relation with adjusted 30-day mortality whereas gender did not have a major effect.	Larger studies were prioritised.
Nakamura M, Imamura T, Ueno H	Multicentre registry	Among the people with AMICS who had Impella	Larger studies were prioritised.

et al. (2023) Sex-Related Differences in Short-Term Prognosis in Patients with Acute Myocardial Infarction-Related Cardiogenic Shock Receiving Impella Support in Japan: From the J-PVAD Registry. Medicina 59 (no. 7)	(Japanese Percutaneous Ventricular Assist Device registry) n=924 AMICS	support and revascularisation, female sex was independently associated with a lower 30-day survival. For females, early initiation of Impella support before revascularisation may improve their clinical outcomes.	
Nasu T, Ninomiya R, Koeda Y et al. (2024) Impella device in fulminant myocarditis: Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) registry analysis on outcomes and adverse events. European Heart Journal. Acute Cardiovascular Care 13: 275-283	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=269 (107 Impella alone, 162 Impella combined with ECMO) Fulminant myocarditis	30-day survival=74%. The success rate was 68% for the ECPELLA group and 83% for the Impella standalone group. Cox regression highlighted that lower estimated glomerular filtration rate and pre-Impella systolic blood pressure increased adverse event risk, while Swan-Ganz catheterisation use reduced it. Adverse events were noted in 49% of patients, such as bleeding (32%) and deteriorating renal function (9%).	Larger studies were prioritised.
Nersesian G, Potapov EV, Nelki V et al. (2021) Propensity score-based analysis of 30-day survival in cardiogenic shock patients supported with different microaxial left ventricular assist devices. Journal of	Retrospective propensity score-adjusted analysis from 2 centres n=126 cardiogenic shock	The unadjusted 30-day survival was higher in the Impella 5.0 or 5.5 group (58% versus 36%, p=0.021, OR 3.68, 95% CI 1.46 to 9.90, p=0.0072). After adjustment, the 30-day survival was similar for both devices (OR 1.23, 95% CI 0.34 to 4.18, p=0.744). Lactate levels above 8 mmol/litre and	Larger and more recent studies were prioritised.

Cardiac Surgery 36: 4141-4152	Impella CP, 5.0 and 5.5	preoperative cardiopulmonary resuscitation were associated with a statistically significant mortality increase in both cohorts (OR 10.7, 95% CI 3.45 to 47.34, p<0.001; OR 13.2, 95% CI 4.28 to 57.89, p<0.001, respectively).	
Nishimoto Y, Inohara T, Kohsaka S et al. (2023) 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. Journal of the American Heart Association 12: e031838	Retrospective nationwide Japanese Percutaneous Coronary Intervention (J-PCI) registry n=12,171 (622 Impella) Acute coronary syndrome complicated with cardiogenic shock	In-hospital mortality in people needing MCS=36%. In-hospital mortality was highest in the VA-ECMO alone group (58%) and lowest in the Impella group (25%), with the IABP-alone group at 26%, VA-ECMO plus IABP group at 56%, and ECPella group at 47%. Bleeding needing a blood transfusion was most prevalent in the ECPella group (8% and 6% for access and nonaccess sites, respectively), and least prevalent in the IABP-alone group (1%).	Study focuses on trends in MCS use.
Nishimura T, Toda K, Ako J et al. (2024) Prevalence of bleeding events in real-world Japanese registry for Percutaneous Ventricular Assist Device. Journal of Artificial Organs 27: 375-384	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=1,344 (653 Impella alone, 685 Impella with ECMO)	Overall 30-day survival was 67%, with Impella alone at 82% and ECPELLA at 53%. Overall bleeding or haematoma adverse events with a relation or not-excluded relation to Impella was 7%. Among them, the rates of haematoma and bleeding from medical device access sites were	Studies with more comprehensive outcomes are included.

		1% and 4%, respectively. There was no difference between aetiologies for these events.	
Nouri SN, Malick W, Masoumi A et al. (2022) Impella percutaneous left ventricular assist device as mechanical circulatory support for cardiogenic shock: A retrospective analysis from a tertiary academic medical center. Catheterization and Cardiovascular Interventions 99: 37-47	Retrospective single-centre cohort study n=115 cardiogenic shock (67% AMICS)	In-hospital mortality= 57%, numerically greater survival was noted with earlier device implantation. There was a statistically significant cardiac output improvement and pharmacological support reduction. 48 (42%) people needed ECMO. Complications were predominantly access site related (bleeding [10%], vascular injury [5%], and limb ischaemia [3%]).	Larger studies were prioritised.
O'Neill BP, Cohen MG, Basir MB et al. (2019) Outcomes Among Patients Transferred for Revascularization With Impella for Acute Myocardial Infarction With Cardiogenic Shock from the cVAD Registry. The American Journal of Cardiology 123: 1214-1219	Multicentre US registry n=475 cardiogenic shock and PCI Impella 2.5 or CP	Despite baseline differences, the mortality was similar in the transfer versus direct groups (47% versus 54% p=0.19). In a multivariate model, the factors independently associated with 30-day mortality in AMICS treated with revascularisation and Impella support were cardiopulmonary resuscitation (p<0.01), age (p<0.01), and STEMI (p=0.02). Whether the person was transferred or directly admittedly with AMICS was not an independent predictor of death.	More recent studies were prioritised.

O'Neill WW, Grines C, Schreiber T et al. (2018) Analysis of outcomes for 15,259 US patients with acute myocardial infarction cardiogenic shock (AMICS) supported with the Impella device. American Heart Journal 202: 33-38	Multicentre US registry n=15,259 people with AMICS	51% survived to explantation of Impella. Survival was higher when Impella was used as first support strategy, when invasive haemodynamic monitoring was used, and at centres with higher Impella implantation volume.	More recent studies were prioritised.
O'Neill WW, Schreiber T, Wohns DHW et al. (2014) The current use of Impella 2.5 in acute myocardial infarction complicated by cardiogenic shock: results from the USpella Registry. Journal of Interventional Cardiology 27: 1-11	Multicentre US registry (USpella) n=154 cardiogenic shock and PCI Impella 2.5	People who had Impella before PCI had better survival to discharge compared to those in the post-PCI group (65% versus 41%, p=0.003). Survival remained favourable for the pre-PCI group after adjusting for potential confounding variables. Initiation of support before PCI with Impella 2.5 was an independent predictor of in-hospital survival (OR 0.37, 95% CI 0.17 to 0.79, p=0.01) in multivariate analysis.	Larger and more recent studies were prioritised.
Ouazani Chahdi H, Berbach L, Boivin-Proulx L-A et al. (2022) Percutaneous Mechanical Circulatory Support in Post-Myocardial Infarction Cardiogenic Shock: A Systematic Review and Meta-analysis. The Canadian Journal of	Systematic review and meta-analysis 54 studies (including all types of percutaneous MCS)	There was a lack of adequately powered randomised data. The 2 meta-analyses of Impella compared with both conventional therapy and IABP support failed to show a clinical advantage. However, the high degree of interstudy heterogeneity among Impella studies suggests the possibility that either the studies may have	More recent systematic reviews are included and there is considerable overlap between this and other included systematic reviews.

Cardiology 38: 1525-1538		targeted 2 different post-AMI cardiogenic shock populations or there was differential application of Impella support between studies, such as differences in the timing of support either in relation to PCI or in the course of cardiogenic shock.	
Ouweneel DM, de Brabander J, Karami M et al. (2019) Real-life use of left ventricular circulatory support with Impella in cardiogenic shock after acute myocardial infarction: 12 years AMC experience. European Heart Journal. Acute cardiovascular care 8: 338-349	Single-centre registry n=172 cardiogenic shock Impella 2.5, 5.0 and CP	Overall 30-day mortality was 56% and 6-month mortality was 61%. Complications consisted of device-related vascular complications (17%), non-device-related bleeding (12%), haemolysis (7%) and stroke (4%). In a multivariate analysis, pH before Impella placement was a predictor of 6-month mortality.	Larger and more recent studies were prioritised.
Ouweneel DM, Eriksen E, Sjauw KD et al. (2017) Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction. Journal of the American College of Cardiology 69: 278-287	Randomised controlled trial (IMPRESS) n=48 (24 Impella CP)	At 30 days, mortality in people treated with either IABP or Impella was similar (50% and 46%, respectively; HR with Impella: 0.96; 95% CI 0.42 to 2.18; p=0.92). At 6 months, mortality for both groups was 50% (HR 1.04; 95% CI 0.47 to 2.32; p=0.923).	Larger and more recent studies were prioritised. Study is included in reviews by Ardito (2023), Panuccio (2022) and Sassani (2025).
Patel N, Sharma A, Dalia T et al. (2020) Vascular	Retrospective registry (US National	Overall incidence of vascular complications was 14%, out of which	More recent studies were prioritised.

complications associated with percutaneous left ventricular assist device placement: A 10-year US perspective. Catheterization and Cardiovascular Interventions 95: 309	Inpatient Sample database) n=31,263 percutaneous LVAD placements	56% needed surgical treatment. Acute limb thromboembolism and bleeding needing transfusion accounted for 28% and 22% of all vascular complications. Occurrence of a vascular complication was associated with higher in-hospital mortality (38% versus 30%, p<0.001) and length of stay (23 versus 12 days, p<0.001)	
Philipson DJ, Cohen DJ, Fonarow GC et al. (2021) Analysis of Adverse Events Related to Impella Usage (from the Manufacturer and User Facility Device Experience and National Inpatient Sample Databases). The American Journal of Cardiology 140: 91-94	US FDA MAUDE database n=885 reports related to Impella (1,206 complications)	Among people with adverse events reported, bleeding (33%), device deployment or retrieval issues (18%), vascular complications (16%), and death (12%) were the most common, and 8% of all complications were attributable to operator decision-making or technique.	More recent studies with large populations are included, which report complications. The FDA MAUDE data does not include a denominator so incidence rates could not be determined.
Pieri M, Iannaccone M, Burzotta F et al. (2024) Can a mechanical circulatory support comprehensive approach to cardiogenic shock at referral centers reduce 30-day mortality? Frontiers in Cardiovascular Medicine 11: 1509162	2-centre cohort study n=170 Acute myocardial infarction was the prevalent cause of cardiogenic shock (71%). Impella 2.5, 5.0, CP and RP	25% of people had out-of-hospital cardiac arrest. 34% of people had VA-ECMO, 39% had IABP before Impella support, and 59% had more than 1 inotrope. Expected mortality was higher than observed (52% versus 42%, p<0.001).	Larger studies were prioritised.

Rohm CL, Gadidov B, Ray HE et al. (2021) Vasopressors and Inotropes as Predictors of Mortality in Acute Severe Cardiogenic Shock Treated With the Impella Device. Cardiovascular Revascularization Medicine 31: 71-75	Retrospective single-centre cohort study n=276 Impella 2.5, CP and 5.0	All-cause in-hospital mortality=45%. Mortality increased with escalating use of vasopressors and inotropes, with the most significant increase in mortality from use of 2 agents to the use of 3 agents (8% versus 40%, p<0.001). There was no difference in mortality whether dobutamine or milrinone was used (44% versus 36%, p=0.41); there was increased mortality with use of multiple inotropes. People who had only vasopressors had increased mortality compared to those who had a combination of agents that included 1 inotrope.	Larger studies were prioritised.
Rohm CL, Gadidov B, Leitson M et al. (2019) Predictors of Mortality and Outcomes of Acute Severe Cardiogenic Shock Treated with the Impella Device. The American Journal of Cardiology 124: 499-504	Retrospective single-centre study n=204 Acute severe cardiogenic shock Impella 2.5, CP and 5.0	All-cause in-hospital mortality=45%. Non-survivors had a lower initial pH (7.24 versus 7.32, HR 1.03, p<0.0001), lower serum CO_2 (19.1 versus 21.3 mmol/litre, HR 1.08, p=0.002), higher lactate (6.8 versus 3.3 mmol/litre, HR 1.17, p<0.0001), and used a greater number of vasopressors and inotropes (4.3 versus 2.6, HR 1.44, p<0.0001). People who had Impella more than 4 days (n=45) had a longer intensive care unit stay (12.6 versus 6.9 days, p<0.001), longer total hospital stay (16.4	Larger and more recent studies were prioritised.

		versus 11.6 days, p=0.03), longer mechanical ventilation use (7.8 versus 4.4 days, p=0.002), and trend toward increased mortality (58 versus 42%, p=0.051).	
Saito Y, Shiko Y, Tateishi K et al. (2025) Combined Risk Stratification With Patient Characteristics and Biomarkers in Patients Treated With the Impella for Cardiogenic Shock. Journal of the American Heart Association 14: e040487	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=4,122	Of the 4,122 people with cardiogenic shock, the Impella was indicated for acute myocardial infarction in 2,575 (62%). Multivariable analysis identified 4 patient characteristics (age, body mass index, out-of-hospital cardiac arrest, and blood pressure) and 6 biomarkers (lactate, lactate dehydrogenase, creatinine, total bilirubin, albumin, and creatinine kinase) with cutoff values as factors significantly associated with in-hospital mortality.	Study focuses on development of a risk-stratifying model for in-hospital mortality.
Saito Y, Tateishi K, Toda K et al. (2023) Complications and Outcomes of Impella Treatment in Cardiogenic Shock Patients With and Without Acute Myocardial Infarction. Journal of the American Heart Association 12: e030819	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=2,047 AMICS (65%) versus non-AMICS	In the group without AMI, myocarditis was the leading cause of cardiogenic shock. Patients with AMICS were older and more likely to have cardiovascular risk factors than those with non-AMICS. The rates of in-hospital mortality (46% versus 44%, p=0.38) and major complications (35% versus 35%, p=0.85) were similar between the 2 groups. Overall, multivariable analysis identified older age, higher body mass	Larger registry studies were prioritised.

		index, previous transient ischaemic attack or stroke, out-of-hospital cardiac arrest, and the Impella 5.0 as factors significantly associated with the primary end point.	
Schafer A, Westenfeld R, Sieweke J-T et al. (2021) Complete Revascularisation in Impella-Supported Infarct-Related Cardiogenic Shock Patients Is Associated With Improved Mortality. Frontiers in Cardiovascular Medicine 8: 678748	Retrospective multicentre cohort study n=202 AMICS Impella CP	Overall 30-day mortality was 47%. Mortality was higher when Impella was implanted after PCI (Impella-post-PCI: 57%, Impella-pre-PCI: 38%, p=0.0053) and if revascularisation was incomplete. People with both pre-PCI Impella implantation and complete revascularisation had statistically significantly lower mortality (33%) than those with incomplete revascularisation and implantation after PCI (72%, p<0.001).	Larger studies were prioritised.
Schafer A, Werner N, Burkhoff D et al. (2020) Influence of Timing and Predicted Risk on Mortality in Impella-Treated Infarct-Related Cardiogenic Shock Patients. Frontiers in Cardiovascular Medicine 7: 74	Retrospective multicentre cohort study n=166 AMICS Impella 2.5 and CP	Impella use was associated with lower mortality than predicted in people deemed at high risk based predominantly on assessment using a validated risk score, the CardShock score. Overall 30-day mortality was higher when Impella was implanted after PCI (51%) compared to when Impella was implanted before PCI (28%), p=0.0039. Survivors were younger, had lower admission lactate levels, lower	Larger studies were prioritised.

		shock score values, and trended to be less often resuscitated. There was no difference regarding type of Impella or renal function between survivors and non-survivors.	
Scherer C, Lusebrink E, Kupka D et al. (2020) Long-Term Clinical Outcome of Cardiogenic Shock Patients Undergoing Impella CP Treatment vs. Standard of Care. Journal of Clinical Medicine 9: no. 12	Retrospective data from 2 centres n=140 (70 Impella) cardiogenic shock Impella CP	41% of people without cardiocirculatory support and 54% of people with Impella support died during the first month (p=0.17). After 1 year, mortality rates were similar in both groups (55% in conventional versus 59% in Impella CP group, p=0.30) as was mortality rate at long-term 5-years follow-up (64% in conventional versus 73% in Impella CP group, p=0.33). The rate of any bleeding event (37% versus 74%, p<0.001) as well as the rate of clinically significant bleeding was lower in the conventional group than in Impella CP group (15% versus 43%, p=0.002). There were no vascular complications in the control group whereas 7% of people in the Impella group (p=0.07) had vascular complications.	Larger studies were prioritised.
Schrage B, Sundermeyer J, Beer BN et al. (2023) Use of mechanical circulatory support in patients with non-	Propensity score-matched cohort n=534 (267 MCS)	In the matched cohort, MCS use was associated with a lower 30-day mortality (HR 0.76, 95% CI 0.59 to 0.97). However, complications were more frequent in	The study assessed a combination of MCS, including both percutaneous left ventricular

ischaemic cardiogenic shock. European Journal of Heart Failure 25: 562-572	132 people had pLVAD only (13 Impella 2.5, 118 Impella CP and 7 Impella 5.0 or 5.5)	people who had MCS, including severe bleeding (16.5% versus 6.4%) and access-site related ischaemia (6.7% versus 0%).	assist devices and ECMO.
Schrage B, Ibrahim K, Loehn T et al. (2019) Impella support for acute myocardial infarction complicated by cardiogenic shock: Matched-pair iabp-shock II trial 30-day mortality analysis. Circulation 139: 1249	Retrospective multicentre cohort study n=574 (237 Impella) AMICS Impella 2.5 and CP	In this retrospective analysis of people with AMICS, the use of an Impella device was not associated with lower 30-day mortality compared with matched people from the IABP-SHOCK II trial treated with an IABP or medical therapy.	More recent studies were prioritised.
Schultz J, Duval S, Shaffer A et al. (2022) Axillary or Subclavian Impella 5.0 Support in Cardiogenic Shock: A Systematic Review and Meta-analysis. ASAIO Journal 68: 233-238	Systematic review and meta-analysis n=256 (13 studies) Impella 5.0	30-day survival=66% (95% CI 59 to 73). Survival to the next therapy=68% (95% CI 60 to 76). The occurrence of adverse events over an average of 13 (95% CI 12 to 14) days of support was the following: stroke 6%, haemolysis 27%, pump thrombosis 4%, limb ischaemia 0.1%, major bleeding 5%, device malfunction 11%, exchange 7%, and infection 14%.	More comprehensive reviews are included.
Schurtz G, Rousse N, Saura O et al. (2021) IMPELLA R or Extracorporeal Membrane Oxygenation for Left Ventricular Dominant Refractory Cardiogenic Shock.	Retrospective single-centre cohort study n=128 (31 Impella) Refractory left ventricle	In unadjusted analysis, there was no statistically significant difference in 30-day mortality: 43% versus 58% in the VA-ECMO and Impella groups, respectively (p=0.152). After adjustment, VA-ECMO was associated with a	Larger studies were prioritised.

Journal of Clinical Medicine 10: no. 4	dominant cardiogenic shock Impella CP (n=26) and 5.0 (n=5)	statistically significant reduction in 30-day mortality (HR 0.25, p=0.004). A higher rate of MCS escalation was observed in the Impella group: 32% versus 10% (p=0.003).	
Seyfarth M, Sibbing D, Bauer I et al. (2008) A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. Journal of the American College of Cardiology 52: 1584-8	Randomised controlled trial n=25 (12 Impella) AMICS Impella 2.5	The cardiac index after 30 minutes of support was statistically significantly increased in people who had Impella compared with those who had IABP. 30-day mortality was 46% in both groups.	More recent and larger studies were prioritised. Study is included in review by Panuccio (2022).
Shah T, Lansky AJ, Grines CL et al. (2022) Mechanical Circulatory Support in Myocardial Infarction Complicated by Cardiogenic Shock: Impact of Sex and Timing. Journal of the Society for Cardiovascular Angiography & Interventions 1: 100002	Prospective multicentre postmarket registry (RECOVER 3) n=358 AMICS Impella 2.5, CP and 5.0	Overall survival to hospital discharge was 52%, with no difference in survival between women and men (46% versus 54%; p=0.25) Women had a survival benefit from early percutaneous LVAD use before PCI compared to after PCI (58% versus 34%; p=0.03), whereas post-PCI was not associated with worse survival in men (56% versus 50%, p=0.39). Outcomes in women and men who had	Larger studies were prioritised.

		percutaneous LVAD support before PCI were similar, whereas women who had it after PCI tended to have a higher mortality compared with men (p=0.08).	
Shirakabe A, Matsushita M, Shigihara S et al. (2025) Age-specific differences of Impella support in Japanese patients: The Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) registry analysis on outcomes and adverse events. Journal of Cardiology 85: 343-351	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=5,282	Increasing age was identified as a significant factor associated with higher 30-day mortality. While the incidence of major adverse events did not differ significantly across age categories, the occurrence of 2 or more additional adverse events was linked to increased 30-day mortality among older individuals.	Study focuses on age-related outcomes.
Singh H, Mehta RH, O'Neill W et al. (2021) Clinical features and outcomes in patients with cardiogenic shock complicating acute myocardial infarction: early vs recent experience with impella. American Heart Journal 238: 66-74	Retrospective cohort study n=649 AMICS	Use of Impella for AMICS during recent years is associated with lower unadjusted in-hospital mortality, which may reflect better patient selection, earlier device implantation, and improved management algorithms.	Larger and more recent studies were prioritised.
Suzuki S, Teraoka N, Ito K et al. (2025) A Novel Predictive Score Model for Successful Weaning From Mechanical Circulatory Support in Patients With	Retrospective single centre cohort study n=114	55 (48%) people were weaned from MCS successfully. The following variables were selected as the components of the simple version of the weaning score model:	Larger studies were prioritised.

Cardiogenic Shock. Journal of Cardiac Failure 31: 791-799	cardiogenic shock Impella 2.5, CP, 5.0 and 5.5	AMI, mean blood pressure 80 mmHg or above, lactate less than 10 mg/dL, QRS duration 95 milliseconds or less, and LVEF more than 35%.	
Syntila S, Chatzis G, Markus B et al. (2021) Comparison of Mechanical Support with Impella or Extracorporeal Life Support in Post-Cardiac Arrest Cardiogenic Shock: A Propensity Scoring Matching Analysis. Journal of Clinical Medicine 10: no. 16	Retrospective single centre cohort study n=159 (105 Impella) Out of hospital cardiac arrest with post-cardiac arrest cardiogenic shock following AMI Impella 2.5 and CP	The use of Impella 2.5 or CP, or extracorporeal life support in post-cardiac arrest cardiogenic shock after AMI was associated with comparable adjusted hospital and 12-month survival. People who had Impella had a greater LVEF improvement. Device-related access-site complications occurred more frequently with extracorporeal life support.	Larger studies were prioritised.
Takahashi K, Kubo S, Ikuta A et al. (2022) Incidence, predictors, and clinical outcomes of mechanical circulatory support-related complications in patients with cardiogenic shock. Journal of Cardiology 79: 163-169	Retrospective cohort study n=403	Haemolysis, major bleeding, thromboembolic events, and ischaemic stroke were observed in 42 (10%), 150 (37%), 52 (13%), and 30 people (7%), respectively. People with major bleeding had a higher in-hospital mortality than those without major bleeding (31% versus 56%, $p<0.001$). In multivariate analysis, both Impella and VA-ECMO were independent predictors of major bleeding and thromboembolic events. However, in-hospital	Larger studies were prioritised.

		mortality was similar between the Impella and IABP groups irrespective of the VA-ECMO insertion.	
Tarantini G, Masiero G, Burzotta F et al. (2021) Timing of Impella implantation and outcomes in cardiogenic shock or high-risk percutaneous coronary revascularization. Catheterization and Cardiovascular Interventions 98: e222-e234	Multicentre propensity score weighting analysis (IMP-IT Registry) n=365 High-risk PCI and cardiogenic shock Impella 2.5 and CP	Pre-procedural insertion was associated with an improvement in 1-year survival in people with AMICS treated with PCI. Among people having high risk-PCI, early Impella support was also associated with a lower rate of the composite of mortality, re-hospitalisation for heart failure, and need for LVAD or heart transplantation at 1-year. Impella use during or after PCI was associated with an increased in-hospital life-threatening and severe bleeding among patients with AMI-CS having PCI (7 versus 16%, p=0.1) and high risk-PCI (1 versus 9%, p=0.02).	Larger studies were prioritised.
Tariq MD, Jain H, Khan AM et al. (2024) Efficacy and safety of percutaneous mechanical circulatory support in patients with cardiogenic shock following acute myocardial infarction: A meta-analysis of randomized controlled trials.	Systematic review and meta-analysis n=442 (4 randomised controlled trials) AMICS	The pooled analysis showed that the odds of 6-month all-cause mortality were significantly lower with Impella compared to standard of care (OR 0.64, 95% CI 0.43 to 0.95; p=0.03). However, 30-day mortality reported no statistically significant difference between the 2 groups (OR 1.03; 95% CI 0.43 to 2.48; p=0.95). Impella was associated with a statistically	The review only includes 4 trials, the largest of which is included in the key evidence.

Medicine 103: e40595		significant increase in the odds of major bleeding (OR 3.61; 95% CI 1.14 to 11.40; p=0.03), limb ischaemia (OR 4.91; 95% CI 1.37 to 17.6; p=0.01), and sepsis (OR 2.75; 95% CI 1.25 to 6.08; p=0.01). No statistical significance was found in LVEF at follow-up between the 2 groups.	
Thakkar S, Patel HP, Kumar A et al. (2021) Outcomes of Impella compared with intra-aortic balloon pump in ST-elevation myocardial infarction complicated by cardiogenic shock. American Heart Journal Plus: Cardiology Research and Practice 12: 100067	Propensity score-matched analysis n=14,690 (7,345 Impella) STEMI complicated with cardiogenic shock	All-cause in-hospital mortality was higher in the hospitalisations needing Impella support as compared to IABP (42% versus 32%, adjusted OR 1.71; 95% CI 1.60 to 1.84, p<0.0001). Impella was associated with a higher risk of in-hospital complications and hospitalisation cost compared with IABP.	More recent studies were prioritised.
Toda K, Ako J, Hirayama A et al. (2023) Three-year experience of catheter-based micro-axial left ventricular assist device, Impella, in Japanese patients: the first interim analysis of Japan registry for percutaneous ventricular assist device (J-PVAD). Journal of Artificial Organs 26: 17-23	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=823 Drug refractory acute heart failure (45% AMICS)	Combination use of Impella and VA-ECMO=47% Pump stop=3% Major adverse events included haemolysis (11%), haemorrhage or haematoma (6%), peripheral ischaemia (2%), and stroke (2%). The overall 30-day survival was 62%. Survival of people with single Impella support was statistically significantly higher than people with Impella combined with VA-	Larger studies were prioritised.

	Impella 2.5 (72%), CP (6%) or 5.0 (17%)	ECMO support (81% versus 50%; p<0.01), who had lower blood pressure, lower LVEF, and higher degree of inotropic support.	
Udesen NLJ, Beske RP, Hassager C et al. (2025) Microaxial Flow Pump Hemodynamic and Metabolic Effects in Infarct-Related Cardiogenic Shock: A Substudy of the DanGer Shock Randomized Clinical Trial. JAMA Cardiology 10: 9-16	Substudy of randomised controlled trial (DanGer Shock) n=324 STEMI-CS	Use of a microaxial flow pump reduces the use of vasopressors and inotropic medication while maintaining haemodynamic stability and achieving faster normalisation of lactate level in patients with STEMI-CS.	The primary trial publication is included in the key evidence.
Virk HUH, Tripathi B, Gupta S et al. (2018) Trends, etiologies, and predictors of 90-day readmission after percutaneous ventricular assist device implantation: A national population-based cohort study. Clinical Cardiology 41 561-568	Retrospective registry (US Nationwide Readmission Database) n=7,074	1,562 (22%) people were readmitted within 90 days. Acute decompensated heart failure (23%) and acute coronary syndromes (11%) were the most common aetiologies and heart failure (OR 1.39, 95% CI 1.17 to 1.67), chronic obstructive pulmonary disease (OR 1.26, 95% CI 1.07 to 1.49), peripheral vascular disease (OR 1.30, 95% CI 1.09 to 1.56), and discharge into short- or long-term facility (OR 1.28, 95% CI 1.08 to 1.51) were independently associated with an increased risk of 90-day readmission following percutaneous VAD use.	More recent studies were prioritised.
Wernly B, Karami M, Engstrom AE et al.	Retrospective cohort study	The rates of vascular injuries (adjusted OR	Larger studies were prioritised.

(2021) Impella versus extracorporal life support in cardiogenic shock: a propensity score adjusted analysis. ESC Heart Failure 8: 953-961	n=149 (73 Impella) Impella 2.5	0.95; 95% CI 0.10 to 3.50; p=0.56) and bleeding needing transfusion (adjusted OR 0.44; 95% CI 0.09 to 2.10; p=0.29) were similar in the 2 groups (Impella and extracorporeal life support). The use of Impella or extracorporeal life support was not associated with increased odds of mortality (adjusted OR 4.19; 95% CI 0.53 to 33.25; p=0.17), after correction for propensity score and baseline lactate level. Baseline lactate level was independently associated with increased odds of 30-day mortality (per mmol/litre increase; OR 1.29; 95% CI 1.14 to 1.45; p<0.001).	
Whitehead EH, Thayer KL, Burkhoff D et al. (2020) Central Venous Pressure and Clinical Outcomes During Left-Sided Mechanical Support for Acute Myocardial Infarction and Cardiogenic Shock. Frontiers in Cardiovascular Medicine: 155	Retrospective multicentre cohort study n=132 cardiogenic shock (72% STEMI) Impella 2.5, CP, 5.0 and 5.5	59 people (45%) died in the hospital and 73 survived to discharge. Statistically significant differences between those who died in hospital and those who survived to discharge were noted in the rates of CPR (54 versus 36%, p=0.032) and mechanical ventilation (63 versus 40%, p=0.009). Central venous pressure was higher among those who died in the hospital (14.0 versus 11.7 mmHg, p=0.014), and a central venous pressure above	Larger studies were prioritised.

		12 identified people at higher risk for in-hospital mortality (65 versus 45%, p=0.02). Central venous pressure remained statistically significantly associated with in-hospital mortality even after adjustment in a multivariable model (adjusted OR 1.10, 95% CI 1.02 to 1.19 per 1 mmHg increase).	
Yahagi K, Gonda Y, Yoshiura D et al. (2025) Impact of lactate levels on admission in STEMI patients with cardiogenic shock treated with IMPELLA. Heart and Vessels	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=852 STEMI-CS	In-hospital mortality=42%. The rate of VA-ECMO combined with Impella use was 38%. The in-hospital mortality of Impella alone and ECPELLA group were 30% and 61%, respectively. The median lactate level was higher in non-survivors than in survivors (5.7 mmol/litre versus 3.5 mmol/litre, p<0.0001). A lactate cut-off value of 6.9 mmol/litre showed the best discrimination for in-hospital mortality. Patients classified as the SCAI SHOCK stage E have a higher mortality rate with Impella support alone.	Larger studies were prioritised.
Yokoi M, Ito T, Shintani Y et al. (2025) Clinical characteristics and short-term outcomes in patients with cardiogenic shock undergoing mechanical circulatory support	Multicentre registry (Japanese Percutaneous Ventricular Assist Device registry) n=2,578	Compared to people with primary Impella support, those who had IABP-Impella escalation showed similar 30-day mortality and major complications despite poorer clinical conditions before Impella support and a more complicated	Study focuses on short-term outcomes after IABP-Impella escalation.

escalation from intra-aortic balloon pump to impella: From the J-PVAD registry. Journal of Cardiology 85: 337-342		clinical course after Impella insertion.	
Zaiser AS, Fahrni G, Hollinger A et al. (2021) Adverse Events of Percutaneous Microaxial Left Ventricular Assist Devices-A Retrospective, Single-Centre Cohort Study. Journal of Clinical Medicine 10	Retrospective single-centre cohort study n=281	93% of people had at least 1 adverse event. Rates of in-hospital, 90-day, and 1-year mortality were 48%, 47%, and 50%, respectively. Complication rates: bleeding (62%), haemolysis (42%), acute kidney injury (50%), renal replacement therapy (35%) and limb ischaemia (13%).	Larger studies were prioritised.
Zhang Q, Han Y, Sun S et al. (2022) Mortality in cardiogenic shock patients receiving mechanical circulatory support: a network meta-analysis. BMC Cardiovascular Disorders 22: 48	Network meta-analysis n=10,985 (39 studies) cardiogenic shock aetiology: unstable angina, AMI, in-hospital cardiac arrest, out-of-hospital cardiac arrest, ischaemic cardiomyopathy and dilative cardiomyopathy	Regarding in-hospital mortality, the results showed no statistically significant differences between IABP and Impella, VA-ECMO plus IABP, Tandem Heart and medical therapy. IABP more effectively reduced the incidence of 30-day mortality compared with VA-ECMO and Impella for the treatment of cardiogenic shock.	More recent reviews are included.
Zweck E, Hassager C, Beske RP et al. (2024) Microaxial Flow Pump Use and Renal Outcomes in Infarct-Related Cardiogenic Shock: A Secondary	Substudy of randomised controlled trial (DanGer Shock)	Shock severity, allocation to microaxial flow pump, and device-related complications were associated with an increased risk of acute kidney injury. Acute kidney injury was	The primary trial publication is included in the key evidence.

Analysis of the DanGer Shock Trial. Circulation 150: 1990-2003	n=355 (179 microaxial flow pump) STEMI-CS	generally associated with higher mortality, but the allocation to microaxial flow pump consistently led to lower mortality at 180 days irrespective of the occurrence of acute kidney injury with or without renal replacement therapy initiation.	