Interventional procedure assessment report of surgical insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock

Contents

Table 1 Abbreviations

Abbreviation	Definition
AMI	Acute myocardial infarction
AMICS	Acute myocardial infarction related cardiogenic shock
BTDD	Bridge to durable device
BTR	Bridge to recovery
BTT	Bridge to heart transplantation
CI	Confidence interval
CSWG	Cardiogenic Shock Working Group
ECMO	Extracorporeal membrane oxygenation
FDA MAUDE	Food and Drug Administration Manufacturer and User Facility Device Experience
HR	Hazard ratio
IABP	Intra-aortic balloon pump
INTERMACS	Interagency Registry for Mechanically Assisted Circulatory Support
IP	INTERMACS profile
LVAD	Left ventricular assist device
LVEF	Left ventricular ejection fraction
MCS	Mechanical circulatory support
NYHA	New York Heart Association
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
SD	Standard deviation
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 treatments and unmet need is available in NICE's HealthTech guidance on surgical insertion of a catheter-based left ventricular 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) – person is haemodynamically stable and not having 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. 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.

Karnofsky Performance Scale Index

The Karnofsky Performance Scale Index is an assessment tool for functional impairment. It can be used to compare effectiveness of different therapies and to

assess the prognosis in individuals. In most serious illnesses, the lower the Karnofsky score, the worse the likelihood of survival.

INTERMACS

INTERMACS profile (IP): this is a 7-profile categorisation for people with advanced heart failure, ranging from IP-1 as the most critical, to IP-7 as the least critical. IP-1 (critical cardiogenic shock), IP-2 (progressive decline on inotropes), IP-3 (stable but inotrope dependent), IP-4 (resting symptoms on oral therapy at home), IP-5 (exertion intolerant), IP-6 (exertion limited), IP-7 (placeholder – living comfortably with meaningful activity limited to mild physical exertion).

Outcome measures

The main efficacy outcomes included in-hospital, 30-day and 6-month mortality, and longer-term survival. NYHA class was also reported, which is described below. Safety outcomes included complications such as bleeding, limb ischaemia, stroke and acute kidney failure.

New York Heart Association (NYHA) functional class

The NYHA functional class is used to classify heart failure according to severity of symptoms and limitation of physical activity:

- Class 1 - no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, breathlessness, or palpitations.
- Class 2 - slight limitation of physical activity. Comfortable at rest but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
- Class 3 - marked limitation of physical activity. Comfortable at rest but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.

- Class 4 - unable to carry out any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken discomfort is increased.

Evidence summary

Population and studies description

This interventional procedures assessment report is based on about 7,600 people from 1 systematic review and meta-analysis (Kwon 2024), 1 prospective multicentre observational study (Abraham 2025) and 8 retrospective observational studies (Fried 2024, Ramzy 2023, Iyengar 2023, Gill 2023, Mahesh 2024, Schumer 2024, Feng 2025 and Kanwar 2025). The study by Gill (2023) was also included in the systematic review by Kwon (2024). Of the 6,400 people, about 4,200 had the procedure. In addition, there was a retrospective analysis of the US FDA MAUDE database describing 43 events associated with the procedure (Khalil 2025). This interventional procedures assessment report is a rapid review of the literature, and a flow chart of the complete selection process is shown in figure 1. This assessment report presents 11 studies as the key evidence in table 2 and table 3, and lists 89 other relevant studies in appendix B, table 5a.

Evidence was included if the indication was described as cardiogenic shock, from any aetiology, regardless of whether PCI was offered as part of the treatment pathway. 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. Evidence on right ventricular microaxial flow pumps was also excluded.

Studies were included if they described surgical insertion of a catheter-based intravascular microaxial flow pump or if they specified use of Impella 5.5, which is inserted surgically. In general, evidence on Impella 5.0 alone was not included in

this review unless it specifically stated it was inserted surgically. Most of the studies were based in the US and they all had a higher proportion of males than females. The mean or median age was typically above 55 years old.

The systematic review by Kwon (2024) included 707 people from 15 studies on Impella 5.5, 2 of which were prospective. Some of the studies included a proportion of people who had other Impella devices, so the number who had Impella 5.5 was 440, with a further 156 people having either 5.0 or 5.5. The main indication for the procedure across the studies was heart failure complicated by cardiogenic shock, followed by AMICS and postcardiotomy cardiogenic shock. The pooled mean age was 58.2 years and 86% of the study population was male. In 5 studies that reported it, the proportion of people who needed cardiopulmonary resuscitation before the procedure was 20%. Follow up was to hospital discharge or 30 days.

The prospective, multicentre study by Abraham (2025) included 444 people with heart-failure related cardiogenic shock. The mean age was 55.1 years and 86% were male. Most people (94%) were in NYHA class 3 or 4 at baseline and the median LVEF was 15%. Before having Impella 5.5, 48% of people were supported by other MCS devices, most commonly an IABP or Impella CP. Follow up was 12 months.

The study by Fried (2024) reported a retrospective analysis of data from a multicentre US registry. The most common aetiology was heart failure related cardiogenic shock, followed by AMICS. Of the 754 people included, 620 had Impella 5.5. The mean age was 58.6 years and 83% were male. Most people were SCAI stage D or E at baseline and the mean LVEF was 20%. Nearly half (46%) had at least 1 temporary MCS before surgical insertion of a microaxial flow pump. Follow up was to hospital discharge.

The retrospective study by Ramzy (2023) included multicentre registry data from 1,238 people who had either Impella 5.5 or Impella 5.0. The indications were AMICS, cardiomyopathy or postcardiotomy cardiogenic shock. People who had ECMO before or during Impella use were excluded. Follow up was to device explant only.

The retrospective study by Iyengar (2023) included 2,839 people who were on a waiting list for heart transplantation, with support from Impella 5.5 or IABP. The median age was younger in the Impella group (56 years) than the IABP group (58 years; p=0.002) and there was a statistically significantly higher proportion of males (87% versus 75%, p<0.001). At baseline, the functional status was described as severe in a higher proportion of people who had Impella compared with IABP (73% versus 64%, p<0.001). Follow up was 2 years.

Gill (2023), Mahesh (2024) and Kanwar (2025) all described retrospective analyses of prospectively collected registry data. In Gill (2023), 221 people had Impella 5.5 or 5.0 as a bridging strategy to transplant, durable LVAD or recovery. The aetiology of cardiogenic shock was non-ischaemic (51%) or ischaemic (23%) cardiomyopathy or AMICS (26%). The median age was 58 years and 86% were male. At baseline, the median LVEF was 15% and most people were IP-1 or IP-2. Half the study population were supported with another MCS device (Impella CP, IABP or ECMO) before implantation of the microaxial flow pump. A small proportion of people had concomitant ECMO or right VAD. The median follow-up period was 4 months. In Mahesh (2024), 107 people had Impella 5.5 as BTT, BTDD or BTR. A proportion of people had concomitant percutaneous right VAD support and 20 people were transitioned from ECMO support. The mean follow up was 23 months, with a maximum of 4.5 years. The main aim of Kanwar (2025) was to compare outcomes by duration of support with Impella 5.5 and by aetiology of cardiogenic shock. It included 927 people, 83% of whom were male, and the median age was 59 years. The most common aetiology was heart failure

related cardiogenic shock (68%) followed by AMICS (26%). A total of 81 (9%) people had an out of hospital cardiac arrest before admission. Outcomes were reported to 30 days.

Feng (2025) also compared outcomes by duration of support with Impella 5.5. It included 257 people, 85% of whom were male, with cardiogenic shock mostly related to heart failure (62%), followed by AMI (19%) and postcardiotomy (11%). Outcomes were reported to 60 days.

Schumer (2024) described a single-centre retrospective cohort study of 126 people who had the procedure for cardiogenic shock (including postcardiotomy cardiogenic shock), BTDD, BTT or planned support for high-risk cardiac surgery. The causes of cardiogenic shock were predominantly acute on chronic non-ischaemic cardiomyopathy, AMI and ischaemic cardiomyopathy. The median age was 62 years and 77% were male. At baseline, 32% of people had experienced cardiopulmonary resuscitation.

Khalil (2025) is a review of the FDA MAUDE database, describing 43 adverse events resulting in death, reported in association with use of Impella 5.5. The MAUDE database includes:

- mandatory reports from manufacturers and device importers when a device may have caused injury to a patient
- voluntary reports from other sources including healthcare professionals and patients.

Limitations of the database include under-reporting, duplicate reporting, incomplete reports and uncertainty if the device caused the complication being described. The true denominator for these events is not captured and the database is not designed to calculate or compare complication rates.

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

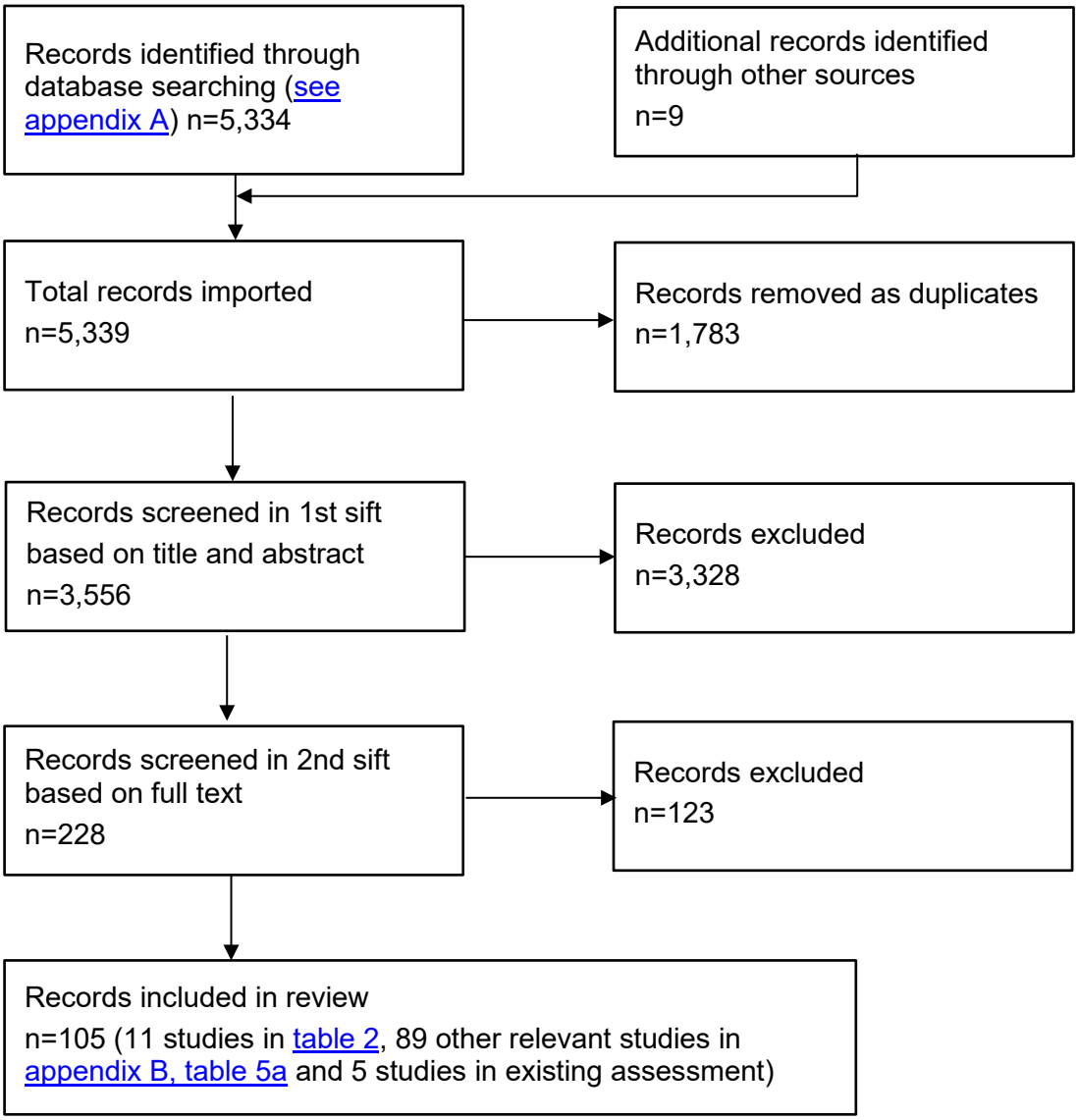

Table 2 Study details

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	Kwon J, 2024 Countries of individual studies: Germany, US	**n=707** Indication: across studies, 64% of people with Impella devices were supported for heart failure complicated by cardiogenic shock, 28% for AMICS, and 5% for postcardiotomy cardiogenic shock. Pooled mean age=58.2 years (SD 12.4) Male sex=86% 5 studies reported the proportion of people needing cardiopulmonary resuscitation before device implant, which had a pooled rate of	Systematic review and meta-analysis 15 studies were included (2 prospective and 13 retrospective). 13 studies (n=666) were included for quantitative meta-analysis of early survival after Impella implant. The main outcome was early survival (to discharge or 30 days). Search date: March 2023	For inclusion in the review, studies needed to report patient and treatment characteristics and outcomes with the Impella 5.5 device in 5 or more people. Database and registry analyses were excluded. Studies were included in the qualitative review regardless of indication of use for the device or therapeutic area under study.	• 62% Impella 5.5 (n=440) • 22% undifferentiated Impella 5.0 or 5.5 (n=156) • 15% Impella 5.0 (n=109) • 0.3% Impella CP (n=2) People often had prior support with other temporary MCS platforms, including ECMO, IABP and other Impella devices (mostly Impella 2.5 and CP). Vascular access was predominantly via the axillary artery, and only 1% used direct aortic access.	Hospital discharge 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
		20% among 356 people. Among 5 studies reporting preimplant dialysis, 24% of 219 people needed dialysis. Of 8 studies reporting serum creatinine at baseline, the pooled mean was 1.74 mg/dl (SD 1.16) among 473 people.			Rates of concomitant ECMO with Impella support were 25% of 661 people in studies reporting this characteristic, and concomitant right VADs were used in 20% of 328 people. Duration of Impella support had a pooled mean of 9.9 days (SD 8.2). among 630 people with available data.	
2	Abraham J, 2025 US	**n=444** Indication: cardiogenic shock caused by acute decompensated heart failure Mean age=55.1 years (SD 13.4) Male sex=86% Ethnicity:	Prospective multicentre, observational study (SURPASS, Surgical Unloading Renal Protection and Sustainable Support) Survival was assessed at hospital discharge	People with acute decompensated heart failure cardiogenic shock. Consecutive people having Impella 5.5 at each site were enrolled.	Microaxial flow pump (Impella 5.5, Abiomed) Before having Impella 5.5, 214 (48%) people were supported by other MCS devices, most commonly an intra-aortic balloon pump or Impella CP.	12 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
		• Asian=3% • Black or African American=26% • White=58% • Other or unknown=13% NYHA class 3 or 4=94% Median LVEF=15% (IQR 10 to 20) The most prevalent comorbidities at admission were hypertension (67%) coronary artery disease (47%) and diabetes (41%). 89% of people were taking inotropes, vasopressors or vasodilator medications, and 44% had right ventricular dysfunction.	and at 1 month, 3 months, 6 months, 9 months, and 12 months. August 2020 to October 2023		73 (16%) people had other MCS while on microaxial flow pump support, primarily VA-ECMO or right ventricular assist devices. The duration of Impella support in the full cohort was 21 days (median 15 days, IQR 8 to 26).	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
3	Fried J, 2024 US	**n=754** Indication: cardiogenic shock The most common aetiology was decompensated heart failure related cardiogenic shock (64%, [52% was described as acute on chronic heart failure]), followed by AMICS (28%). 60 people had other aetiologies including post-cardiotomy cardiogenic shock (n=8) or cardiogenic shock of unknown cause (n=34). Mean age=58.6 years (SD 12.9) Male sex=83%	Retrospective analysis of registry data (CSWG), including data from 34 US hospitals. The aim was to examine clinical profiles and outcomes in a contemporary, real-world cardiogenic shock registry of people who had an Impella 5.0 or 5.5 alone or in combination with other temporary MCS devices. Data was collected between 2020 and 2023.	Data was collected from consecutive people supported by Impella 5.0 or 5.5, regardless of the aetiology of cardiogenic shock.	• Impella 5.5, n=620 • Impella 5.0, n=134 317 (46%) people had at least 1 temporary MCS before Impella 5.0 or 5.5 implantation and 69 (10%) people had 2 temporary MCS devices placed before Impella 5.0 or 5.5. Impella was used as the first device in 374 (50%) people, and it remained their only device during hospitalisation in 240 (32%) people. Impella cannulation sites were available for 524 (69%)	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
		Ethnicity: • White=71% • Black=14% • Asian=3% • Other or unknown=12% 81 people (11%) had out of hospital cardiac arrest. SCAI stage at baseline (n=541): • B=12% • C=12% • D=54% • E=22% Mean LVEF at baseline=19.7% (SD 11.0)			people, with 94% axillary configuration. The median duration of pump support was 12.9 days (IQR 6.8 to 22.9) Impella 5.0 or 5.5 was used concomitantly with VA-ECMO in 119 people (17%) but whether Impella was placed after (as a de-escalation strategy) or simultaneously with VA-ECMO as venting strategy, was not recorded.	

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Mean lactate at baseline=3.4 mmol/litre (SD 3.4) Mean serum creatinine at baseline=1.9 mg/dl (SD 1.2) In the cohort of people who had 1 or more temporary MCS devices in addition to Impella 5.0 or 5.5, underlying aetiology of AMICS (34% versus 13%, p<0.001) and out of hospital cardiac arrest (14% versus 5.0%, p<0.001) were more common.				
4	Ramzy D, 2023 US	**n=1,238** Indication: AMICS, cardiomyopathy and postcardiotomy cardiogenic shock	Retrospective multicentre registry The main outcome was survival to device explant.	People with AMICS, cardiomyopathy or post-cardiotomy cardiogenic shock who had Impella 5.0 or Impella 5.5.	• Impella 5.5, n=582 • Impella 5.0, n=656	To device explant

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		Female sex=18% Within the subgroups, mean age ranged from 55.3 to 66.4 years. Mean age, years (SD): • AMICS Impella 5.5=59.5 (12.5) Impella 5.0=63.7 (10.8), p<0.001 • Cardiomyopathy Impella 5.5=55.3 (13.6) Impella 5.0=57.5 (12.4), p=0.059 • Postcardiotomy cardiogenic shock Impella 5.5=65.0 (10.6) Impella 5.0=66.4 (10.0), p=0.324	October 2019 to December 2020	People who had ECMO before or during Impella use were excluded.		

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		There was no statistically significant difference in gender distribution, baseline LVEF, or pulmonary artery catheterisation use.				
5	Iyengar A, 2023 US	**n=2,936 (452 microaxial flow pump)** Indication: waitlisted for heart transplantation Median age (years): • Microaxial flow pump group=56 (IQR 45 to 63) • IABP group=58 (IQR 48 to 64), p=0.002 Male sex: • Microaxial flow pump group=87%	Retrospective cohort study (United Network for Organ Sharing database) 628 people were included in a propensity score matched analysis. The aim was to compare waitlist and posttransplant outcomes of people bridged with IABPs to people who had Impella 5.5 therapy.	Age over 18 years, waiting for heart transplant, MCS while waiting for heart transplant, no previous transplants, Impella 5.5 or IABP support. People who had both therapies, were waiting for additional organs, or had previous transplants were excluded.	• Microaxial flow pump (Impella 5.5), n=452 • IABP, n=2,484	2 years

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		• IABP group=75%, p<0.001 Ethnicity: • Asian=4% • Black=29% • White=56% • Hispanic-Latino=10% Severe functional status (quantified by the Karnofsky Performance scale) • Microaxial flow pump group=73% • IABP group=64%, p<0.001 People with microaxial flow pump support had more functional impairment, higher wedge pressures, higher rates of preoperative diabetes	October 2018 to December 2021			

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		and dialysis, and more ventilator support (all p<0.05).				
6	Gill G, 2023 US	**n=221** Indication: non-ischaemic cardiomyopathy (51%), ischaemic cardiomyopathy (23%), or AMICS (26%) Median age=58 years (IQR 48 to 66 years) Male sex=86% Median LVEF=15% (IQR 11 to 20) Most people were INTERMACS score 1 (48%) or 2 (47%). Bridging strategy:	Retrospective analysis of prospective registry (single high-volume centre) The 75 most recent people with Impella 5.0 were compared with the 75 people who had Impella 5.5. The primary study endpoint was survival to device explantation for bridging destination: transplantation, durable device placement or recovery.	People with cardiogenic shock refractory to medical management who had Impella 5.0 or 5.5 as a bridging therapy.	• Impella 5.0, n=146 • Impella 5.5, n=75 Overall, 50% were supported with another MCS device before implantation: 26% had an Impella CP 22% had an IABP and 14% had ECMO. 93% of pre-existing devices were removed before implantation. 10% of people had concomitant ECMO and 9% had a concomitant right VAD.	Median 4 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
		• BTT=48% • BTDD=14% • BTR= 39%.	January 2014 to March 2022.		The median total duration of bridging support was 14 (IQR 7 to 26) days for BTT, 12 (IQR 6 to 22) days for BTDD and 8 (IQR 4 to 14) days for BTR. Total duration of support among all groups ranged from a minimum of 0 to a maximum of 137 days. A concomitant kidney transplant was done in 28% (n=26) of people who had heart transplantation.	
7	Mahesh B, 2024 US	**n=107** Indication: BTT (n=34), BTDD (n=25), BTR after postcardiotomy	Retrospective analysis of prospective registry	People who were bridged with larger microaxial LVADs placed surgically either to recovery or	Impella 5.5 Percutaneous right VAD support: • BTT=0%	Up to 4.5 years (mean 23 months, SD 17)

Study no.	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		cardiogenic shock (n=42), BTR or bridge to decision (n=6) Mean age (years): • BTT=53 (SD 12.4) • BTDD=57.5 (SD 13) • BTR=63.3 (SD 12.4) p=0.002 Female sex (%) • BTT=5.9 • BTDD=12.0 • BTR=9.5 p=0.69	The primary study end point was in-hospital mortality. January 2020 to May 2024	transplant or durable LVAD therapy. 6 people who were BTR or decision were excluded from the analysis: 4 were deemed to be ineligible for either transplantation or an LVAD because of social circumstances or metastatic cancer, 1 person was lost to follow up, and the sixth person had giant-cell myocarditis that improved with immunosuppressive therapy and the device was explanted on the 28th day.	• BTDD=20% • BTR=24% p=0.009 20 people were transitioned from ECMO to microaxial LVAD: 3 BTT, 6 BTDD, 11 BTR (p=0.043). Mean duration of microaxial flow pump support (days): • BTT=27 (SD 21) • BTDD=20 (SD 14) • BTR=14.5 (SD 11) p=0.003	
8	Schumer E, 2024 US	**n=126** Indication: planned support for high-risk cardiac surgery,	Single-centre retrospective cohort study	All people who had implantation of Impella 5.5 during the study period. There were no additional exclusion criteria.	Impella 5.5 PCI=36.5%	Median 318 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
		cardiogenic shock, BTDD, BTT, postcardiotomy cardiogenic shock. The causes of heart failure leading to cardiogenic shock were predominantly acute on chronic non-ischaemic cardiomyopathy, AMI and ischaemic cardiomyopathy. Median age=62.0 years (IQR 49 to 68) Male sex=77% Previous MI=60% Median lactate at baseline=1.5 (IQR 1.0 to 2.1; units not reported)	Outcomes included survival to device explant and hospital discharge, and longer-term survival. May 2020 to December 2022		Most implantations were done through a right axillary artery cutdown. Central aortic cannulation through a sternotomy was done at the time of high-risk cardiac surgery, whereas 1 person had placement through an upper sternotomy and 1 through right mini anterior thoracotomy. The median length of Impella 5.5 support was 9 days (IQR 7 to 15), with a maximum of 65 days. Most people outside of the high-risk surgery group needed some type of MCS in addition to the Impella 5.5, with	

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 creatinine at baseline=1.5 mg/dl (IQR 1.2 to 2.1) 32% of people had cardiopulmonary resuscitation			only 10 (11%) supported with the Impella 5.5 alone. In the BTT group, 3 people had VA-ECMO (before, after or at the time of Impella 5.5 insertion), and 2 had ECMO decannulated before transplant. In the BTDD group, 28% of people had Impella CP and 39% had VA-ECMO before Impella 5.5.	
9	Feng I, 2025 US	n=257 (114 had support for more than 14 days) Indication: cardiogenic shock The most common aetiology was decompensated heart	Retrospective cohort study comparing standard (14 days or less) and prolonged (more than 14 days) duration of support.	Consecutive adults (aged 18 years or older) implanted with Impella 5.5 for refractory cardiogenic shock at 2 centres between June 2020 and March 2024.	Impella 5.5 Duration of Impella 5.5 support ranged from 1 to 133 days. Median duration of device support in prolonged and standard cohorts was 25.0 days (IQR 19.0 to 36.0 days)	60 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
		failure (62%) followed by AMI (19%), and postcardiotomy (11%). Male sex=84.8% At baseline, the cohort with prolonged support was younger (56.5 versus 61.0 years; p=0.008), had a higher proportion of men (90.4% versus 80.4%; p=0.042), and was more likely to have history of congestive heart failure (93.9% versus 76.2%; p<0.001) or pulmonary hypertension (63.2% versus 42.7%; p=0.002) compared with the standard cohort. The indication for device insertion was more likely to be acute decompensated heart failure (74.6%	June 2020 and March 2024		and 7.0 days (IQR 5.0 to 11.0 days), respectively. Impella 5.5 was surgically implanted by anastomosis of a vascular graft to the right or left axillary artery, except in cases of postcardiotomy shock where the device could be placed via direct aortic puncture. Treatment of right ventricle failure while on device support was dictated by treating physicians and guided by centre-specific practices which included inotropic support, volume optimisation, and	

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 52.4%; p<0.001) and less likely to be postcardiotomy shock (4.4% versus 16.1%; p=0.005) in people who needed longer support.			escalation to other forms of support, including VA-ECMO.	
10	Kanwar M, 2025 US	n=927 (381 had support for more than 14 days) Indication: cardiogenic shock The most common aetiology was heart failure (67.6%) followed by AMI (26.5%). Male sex=82.7% Median age=59 years Common comorbidities included history of hypertension (63.8%), diabetes mellitus	Retrospective analysis of prospective, international, multicentre registry data (Cardiogenic Shock Working Group registry) People were categorised by duration of Impella 5.5 support (14 days or less compared with more than 14 days) and for aetiology of shock.	All people with cardiogenic shock who had an Impella 5.5 (with or without additional left sided temporary mechanical circulatory support during the hospitalisation) between 2022 and 2024 were included.	Impella 5.5 Median duration of support=13.1 days (7.1 days in the standard support group and 23.9 days in the prolonged support group, p<0.001). 379 (40.8%) people had Impella 5.5 as their initial device for cardiogenic shock management. Most people had another temporary mechanical circulatory support	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
		(40.7%), atrial fibrillation or flutter (36.8%) and chronic kidney disease (32.1%). Amongst the 531 people for whom CSWG-SCAI stage could be calculated at baseline, most (58%) were in CSWG-SCAI stage D. A total of 81 (8.7%) people had an out of hospital cardiac arrest before admission. Median LVEF=17.5%	2022 to 2024		device placed before being transitioned to Impella 5.5 - IABP in 316 (34.1%), Impella CP in 197 (21.3%) and VA-ECMO in 208 (22.4%) people.	
11	Khalil O, 2025 US	**n=43 event reports** The most common indication was haemodynamic instability after cardiac surgery, followed by cardiogenic shock or unknown origin, AMICS and end-stage heart failure awaiting	Retrospective analysis of FDA MAUDE database	The database was searched using the term “Impella 5.5” and results were filtered for cases with the outcome “death”.	Impella 5.5 The duration of device support ranged from 1 to 22 days, with a mean of 7 days (excluding an outlier with a duration of 144 days).	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
		LVAD or heart transplantation Mean age=63 years Male sex=79%				

Table 3 Study outcomes

First author, date	Efficacy outcomes	Safety outcomes
Kwon J, 2024	9.8% of people were bridged to transplant directly from microaxial flow pump support. Notably, rates of heart transplant ranged from 0% to 2% of people at German centres, compared with 33% of 297 people in US series. **Meta-Analysis of Survival Outcomes** • Survival to discharge=68% (95% CI 58 to 78, n=455, 11 studies, I^2=79.6%) • Survival to discharge for people who had Impella 5.5 only=78% (95% CI 72 to 82, n=294, 8 studies, I^2=0%)	**Complications** The most common complication was bleeding, which was reported with varying definitions in 9 to 41% of people across 11 studies. Access site bleeding needing re-exploration was reported in 9.9% of people (6 studies, n=422). Major vascular complications were reported in 4 studies, ranging from 0% to 15%, though definitions for these varied between studies. 11 out of 15 studies reported the incidence of stroke with rates ranging from 0% to 14%. Notably, the highest stroke rate was in the study reporting

First author, date	Efficacy outcomes	Safety outcomes
	30 day survival=65% (95% CI 56 to 74, n=597, 9 studies, I^2=77.4%)	support with a combination of ECMO and Impella, known as ECPELLA. Among 9 studies reporting rates of haemolysis, the incidence ranged from 0% to 23%. However, definitions for haemolysis varied between studies. The most common cause of device malfunction was device dislodgement, reported in 0% to 22% of people (5 studies). Pump thrombosis was reported in 0% to 15% of people, in 5 studies.
Abraham J, 2025	**Survival to discharge=75.0%** (24.6% had native heart survival, 46.6% had heart transplantation, and 24.3% had an LVAD) **Bridge to transplant**=35% (55/444; median duration of support=18 days) **Survival at 6 and 12 months** • Native heart survival=71.3% and 64.4% • Heart transplantation or durable LVAD=94.8% and 93.7% **Survival for people who had Impella 5.5 as the sole device**	**Adverse events while on Impella 5.5 support** • Stroke=3.6% (95% CI 2.1 to 5.8) • Clinically significant haemolysis=13.5% (95% CI 10.5 to 17.1) • Acute limb ischaemia=1.1% (95% CI 0.4 to 2.6) • Acute kidney injury with need for renal replacement therapy=10.4% (95% CI 7.7 to 13.6) • Bleeding events of any type=27.0% (95% CI 23.0 to 31.4) • Thrombocytopenia needing platelet transfusion=12.6% (95% CI 9.7 to 16.1) • Bacteraemia or sepsis=5.0% (95% CI 3.1 to 7.4)

First author, date	Efficacy outcomes	Safety outcomes
	• Discharge=86.5% (95% CI 81.8 to 91.1) • 6 months=78.3% (95% CI 72.6 to 84.0) • 12 months=76.8% (95% CI 70.9 to 82.8) 22.9% had native heart survival, 49.2% had heart transplantation, and 23.5% had an LVAD. People discharged after heart transplantation or durable LVAD had a conditional 6-month survival rate of 95.3% and a 12-month survival rate of 94.3%. People discharged alive with native heart survival had a conditional 6-month survival rate of 75.4%, and a 12-month survival rate of 71.4%. **Survival for people who had multiple temporary MCS devices** • Discharge=65.0% (95% CI 58.9 to 71.1) • 6 months=56.2% (95% CI 49.8 to 62.5) • 12 months=53.9% (95% CI 47.4 to 60.4) 26.6% had native heart survival, 43.5% had heart transplantation, and 25.3% had an LVAD. People discharged after heart transplantation or durable LVAD had conditional 6-month survival rates of 94.2% and 12-month survival rates of 93.0%, whereas people discharged alive with native heart survival had conditional 6-month survival rates of 67.4% and12-month survival rates of 58.0%.	• Infection=16.7% (95% CI 13.3 to 20.5) • Destabilising arrhythmia=33.1% (95% CI 28.7 to 37.7) • Right heart failure=5.4% (95% CI 3.5 to 7.9) **Adverse events for people who were supported with Impella 5.5 alone (n=207)** • Stroke=3.4% (95% CI 1.4 to 6.8) • Clinically significant haemolysis=13.0% (95% CI 8.8 to 18.4) • Acute limb ischaemia=0% (95% CI 0.0 to 1.8) • Acute kidney injury with need for renal replacement therapy=5.3% (95% CI 2.7 to 9.3) • Bleeding events of any type=23.7% (95% CI 18.1 to 30.1) • Thrombocytopenia needing platelet transfusion=4.8% (95% CI 2.3 to 8.7) • Bacteraemia or sepsis=3.4% (95% CI 1.4 to 6.8) • Infection=14.5% (95% CI 10.0 to 20.0) • Destabilising arrhythmia=28.0% (95% CI 22.0 to 34.7) • Right heart failure=3.4% (95% CI 1.4 to 6.8)

First author, date	Efficacy outcomes	Safety outcomes
Fried J, 2024	**In-hospital mortality=32.9% (248/754)** **Native heart survival=20.4% (154/754)** **Heart transplantation or durable LVAD=45.5% (341/754)** • LVAD=22.1% (167/754) • Heart transplantation=23.7% (179/754) The Kaplan-Meier survival curve showed worse survival in people who had an out-of-hospital cardiac arrest (p<0.0001) or whose baseline lactate was 4 mmol/litre or above (p<0.0003). Among people where both the device implant and explant date and time were available (n=337), the median duration of support was 12.9 (IQR 6.8 to 22.9) days. In 54 people with native heart recovery, the median support time was 12.7 (IQR 7.0 to 19.7) days and in 96 people who died, it was 10.5 (IQR 4.5 to 19.4) days. For those people bridged to heart transplantation or durable VAD, median support time was 14 (IQR 7.7 to 28.4) days. **Outcomes by cardiogenic shock aetiology** There was higher mortality for AMICS compared with heart failure related cardiogenic shock (45.2% versus	**Adverse event rates** • Stroke=6.8% (51/754) • Limb ischaemia=7.0% (53/754) • Major bleeding=46.3% (349/754) • Haemolysis=22.0% (166/754) • New renal replacement therapy for acute renal failure=35.1% (265/754) • In-hospital cardiac arrest=20.4% (154/754) **Adverse event rates when Impella 5.0 or 5.5 was used in isolation** • Stroke=5% • Limb ischaemia=3% • Major bleeding=34% • Haemolysis=17% • New renal replacement therapy for acute renal failure=24% • In-hospital cardiac arrest=9% **Outcomes by cardiogenic shock aetiology** • Limb ischaemia was 11.9% in the AMICS group versus 4.5% in heart failure related cardiogenic shock (p<0.001)

First author, date	Efficacy outcomes	Safety outcomes
	26.2%, p<0.001). Among the survivors, a higher proportion of people with AMICS had native heart recovery compared with people with heart failure related cardiogenic shock (29.5% versus 16.9%; p<0.001). Of the 341 people who had heart transplantation or durable VAD, most were from the heart failure related cardiogenic shock group (80% versus 14%, p<0.001). **Use of Impella 5.0 or 5.5 in isolation** When Impella 5.0 or 5.5 was used in isolation, in-hospital mortality was lower (20% vs 39%, p<0.001) and heart transplantation or durable VAD was higher (59% versus 43%, p<0.001).	• Major bleeding was 57.6% in the AMICS group versus 39.0% in heart failure related cardiogenic shock (p<0.001).

Ramzy D, 2023	**Aborted placement**
	• **AMICS**
	  ○ Impella 5.5=5.9% (10/169)
	  ○ Impella 5.0=4.9% (15/305), p=0.671
	• **Cardiomyopathy**
	  ○ Impella 5.5=3.8% (11/287)
	  ○ Impella 5.0=2.9% (7/245), p=0.634
	• **Postcardiotomy cardiogenic shock**
	  ○ Impella 5.5=4.8% (6/126)
	  ○ Impella 5.0=13.2% (14/106), p=0.033
		Haemolysis
		• **AMICS**
		  ○ Impella 5.5=3.2% (5/156)
		  ○ Impella 5.0=3.6% (10/278), p>0.99
		• **Cardiomyopathy**
		  ○ Impella 5.5=3.0% (8/270)
		  ○ Impella 5.0=9.3% (21/225), p=0.003
		• **Postcardiotomy cardiogenic shock**
		  ○ Impella 5.5=1.7% (2/117)
		  ○ Impella 5.0=1.1% (1/88), p>0.99

First author, date	Efficacy outcomes	Safety outcomes
	Successfully weaned or bridged to heart transplantation or durable LVAD • **AMICS** ○ Impella 5.5=70.5% (110/156) ○ Impella 5.0=56.8% (158/278), p=0.005 • **Cardiomyopathy** ○ Impella 5.5=88.1% (238/270) ○ Impella 5.0=76.9% (173/225), p=0.001 • **Postcardiotomy cardiogenic shock** ○ Impella 5.5=76.1% (89/117) ○ Impella 5.0=55.7% (49/88), p=0.003 **Expired on support or withdrawal of care** • **AMICS** ○ Impella 5.5=29.5% (46/156) ○ Impella 5.0=43.2% (120/278), p=0.005 • **Cardiomyopathy** ○ Impella 5.5=11.9% (32/270) ○ Impella 5.0=23.1% (52/225), p=0.001 • **Postcardiotomy cardiogenic shock** ○ Impella 5.5=23.9% (28/117) ○ Impella 5.0=44.3% (39/88), p=0.003 **Mean duration of support, days (SD)**	**Cerebrovascular accident** • **AMICS** ○ Impella 5.5=3.2% (5/156) ○ Impella 5.0=1.1% (3/278), p=0.143 • **Cardiomyopathy** ○ Impella 5.5=2.2% (6/270) ○ Impella 5.0=0.9% (2/225), p=0.301 • **Postcardiotomy cardiogenic shock** ○ Impella 5.5=1.7% (2/117) ○ Impella 5.0=1.1% (1/88), p>0.99 **Bleeding** • **AMICS** ○ Impella 5.5=0.6% (1/156) ○ Impella 5.0=1.8% (5/278), p=0.426 • **Cardiomyopathy** ○ Impella 5.5=1.1% (3/270) ○ Impella 5.0=2.2% (5/225), p=0.478 • **Postcardiotomy cardiogenic shock** ○ Impella 5.5=2.6% (3/117) ○ Impella 5.0=6.8% (6/88), p=0.177 **Vascular injury** • **AMICS**

First author, date	Efficacy outcomes	Safety outcomes

	• **AMICS**
	  ○ Impella 5.5=13.2 (20.2)
	  ○ Impella 5.0=8.7 (9.5), p=0.008
	• **Cardiomyopathy**
	  ○ Impella 5.5=15.1 (13.4)
	  ○ Impella 5.0=11.4 (10.6), p<0.001
	• **Postcardiotomy cardiogenic shock**
	  ○ Impella 5.5=10.2 (23.5)
	  ○ Impella 5.0=6.6 (8.3), p=0.127
		○ Impella 5.5=0.6% (1/156)
		○ Impella 5.0=0.0% (0/278), p=0.359
		• **Cardiomyopathy**
		○ Impella 5.5=0.0% (0/270)
		○ Impella 5.0=0.4% (1/225), p=0.455
		• **Postcardiotomy cardiogenic shock**
		○ Impella 5.5=0.0% (0/117)
		○ Impella 5.0=0.0% (0/88), p>0.99

Iyengar A, 2023	**Median time on MCS, days (IQR)** • Microaxial flow pump group=15 (8 to 27) • IABP group=9 (5 to 17), p<0.001 **Outcome (p<0.001)** • Death while on waitlist: microaxial flow pump group=9.3% (42/452), IABP group=2.4% (60/2,484) • Transplanted: microaxial flow pump group=84.7% (383/452), IABP group=91.7% (2,278/2,484) • Delisted (too sick): microaxial flow pump group=4.6% (21/452), IABP group=3.6% (89/2,484) • Delisted (recovered): microaxial flow pump group=0.2% (1/452), IABP group=0.7% (17/2,484) • Other: microaxial flow pump group=1.1% (5/452), IABP group=1.6% (39/2,484)	No safety outcomes were reported.

First author, date	Efficacy outcomes	Safety outcomes
	The main causes of death were cardiovascular and multiple organ failure. **Post-transplant outcomes (within 1 year)** • Dialysis: microaxial flow pump group=15.9%, IABP group=13.7%, p=0.268 • Death: microaxial flow pump group=5.4%, IABP group=6.1%, p=0.877 • Graft rejection: microaxial flow pump group=29.0%, IABP group=20.0%, p<0.001 • Pacemaker placement: microaxial flow pump group=0.9%, IABP group=1.6%, p=0.410 • Stroke: microaxial flow pump group=4.1%, IABP group=3.0%, p=0.361 **Post-transplant outcomes in propensity-matched cohort (n=628)** • Dialysis: microaxial flow pump group=16.2%, IABP group=12.5%, p=0.207 • Death: microaxial flow pump group=5.7%, IABP group=6.4%, p=0.574 • Graft rejection: microaxial flow pump group=30.2%, IABP group=22.7%, p=0.039 • Pacemaker placement: microaxial flow pump group=0.7%, IABP group=2.0%, p=0.226	

First author, date	Efficacy outcomes	Safety outcomes
	• Stroke: microaxial flow pump group=4.5%, IABP group=4.4%, p=0.611 **2-year survival after transplant (whole cohort)** • Microaxial flow pump group=90% • IABP group=90%, p=0.693 **2-year survival after transplant (propensity-matched cohort)** • Microaxial flow pump group=83% • IABP group=88%, p=0.874	
Gill G, 2023	**Survival to bridging destination=75.6% (n=167)**; 91.0% (n=152) of these survived to discharge. **Survival to discharge** • Overall=68.8% (152/221) • Impella 5.5=77.3% (58/75) • Impella 5.0=72.0% (54/75), p=0.45 Bridging outcomes improved over the study period: survival to device explant in the first, second and third tercile of people who had an implant was 65.8% (n=48), 82.4% (n=61) and 78.4% (n=58), respectively (p=0.05).	**Device exchange** • Overall=8.1% (18/221) • Impella 5.5=4.0% (3/75) • Impella 5.0=13.3% (10/75), p=0.04 **Haemolysis** • Overall=25.6% (46/180) • Impella 5.5=22.6% (14/62) • Impella 5.0=30.3% (20/66), p=0.18 **New renal failure needing dialysis** • Overall=22.2% (49/221) • Impella 5.5=24.0% (18/75)

First author, date	Efficacy outcomes	Safety outcomes
	Compared with people with an isolated microaxial flow pump, people with concomitant circulatory support were less likely to survive to device explant (41.5%, n=17 versus 83.3%, n=150; p<0.01). **30-day survival** • Overall=72.9% (95% CI 66.9 to 78.9) • Impella 5.5=77.6% (95% CI 68.0 to 87.3) • Impella 5.0=76.9% (95% CI 67.2 to 86.5) **Survival at 90 days after implantation** • BTT=80.9% (95% CI 73.4 to 88.4), • BTDD=52.2% (95% CI 34.0 to 70.3) • BTR=50.7% (95% CI 39.2 to 62.2) **Survival at 1 year** • BTT=72.9% (95% CI 64.0 to 81.8), • BTDD=46.7% (95% CI 28.8 to 64.5) • BTR=39.1% (95% CI 27.6 to 50.7) **Ambulatory within 24 hours of microaxial flow pump implantation** • Overall=23.5% (42/221) • Impella 5.5=17.3% (13/75)	• Impella 5.0=18.7% (14/75), p=0.43 **Bleeding needing return to theatre** • Overall=7.7% (17/221) • Impella 5.5=10.7% (8/75) • Impella 5.0=8.0% (6/75), p=0.57 **Ischaemic stroke** • Overall=2.7% (6/221) • Impella 5.5=2.7% (2/75) • Impella 5.0=2.7% (2/75), p=1.00 **Limb ischaemia** • Overall=1.8% (4/221) • Impella 5.5=1.3% (1/75) • Impella 5.0=0% (0/75), p=1.00 1 death was caused by lower limb ischaemia related to previous femoral Impella CP placement.

First author, date	Efficacy outcomes	Safety outcomes
	• Impella 5.0=26.7% (20/75), p=0.17	
Mahesh B, 2024	**In-hospital mortality** • BTT=5.9% (2/34) • BTDD=4.0% (1/25) • BTR=23.8% (10/42) p=0.021 In the logistic regression model, the category of cardiogenic shock was statistically significant for survival, with worse survival in the postcardiotomy support cardiogenic shock group compared with the group bridged to transplantation (OR 4.7, 95% CI 0.9 to 24, p=0.05). **Mortality during follow up (mean 23 months):** • BTT=8.8% (3/34) • BTDD=20.0% (5/25) • BTR=35.7% (15/42) p=0.019 **Actuarial survival at 4.5 years:** • BTT=90.7% (SD 5.1) • BTDD=79.2% (SD 8.3) • BTR=62.8% (SD 7.7)	**Postoperative complications** **Axillary haematoma** • BTT=14.7% (5/34) • BTDD=12.5% (3/25) • BTR=4.8% (2/42) p=0.32 **Device malfunction** • BTT=5.9% (2/34) • BTDD=8.0% (2/25) • BTR=4.8% (2/42) p=0.87 **Gastrointestinal bleed** • BTT=5.9% (2/34) • BTDD=4.0% (1/25) • BTR=14.3% (6/42) p=0.3 **Ischaemic stroke** • BTT=2.9% (1/34)

First author, date	Efficacy outcomes	Safety outcomes
	p=0.01 The category of cardiogenic shock (HR 3.63, 95% 1.03 to 12.9, p=0.04) and long-term postoperative dialysis (HR 3.9, 95% CI 1.6 to 9, p=0.002) were statistically significant predictors of long-term mortality.	• BTDD=8.0% (2/25) • BTR=19.0% (8/42) p=0.07 With an aggressive protocol for central nervous system strokes, 8 of the 11 people had complete resolution of neurological disabilities while 3 had residual deficits, isolated limb weakness (n=2) and dysphasia (n=1). **Dialysis** • BTT=11.8% (4/34) • BTDD=20.0% (5/25) • BTR=28.6% (12/42) p=0.195
Schumer E, 2024	1 person did not tolerate Impella 5.5 support because of acute, severe aortic insufficiency, and 1 person needed aortic valve repair at the time of durable LVAD implant for severe aortic insufficiency after Impella 5.5 removal. **Survival to Impella 5.5 explant** • Overall=76.2% (96/126) • High-risk cardiac surgery=91.2% (31/34) • Cardiogenic shock, BTR=63.1% (41/65) • BTDD=100% (5/5)	**Reoperation for bleeding** • Overall=13.5% (17/126) • High-risk cardiac surgery=11.8% (4/34) • Cardiogenic shock, BTR=10.8% (7/65) • BTDD=0% (0/5) • BTT=15.4% (2/13) • Postcardiotomy cardiogenic shock=44.4% (4/9) **Stroke** • Overall=10.3% (13/126)

First author, date	Efficacy outcomes	Safety outcomes
	• BTT=100% (13/13) • Postcardiotomy cardiogenic shock=66.7% (6/9) **Survival to discharge** • Overall=67.5% (85/126) • High-risk cardiac surgery=91.2% (31/34) • Cardiogenic shock, BTR=50.7% (35/65) • BTDD=40% (2/5) • BTT=100% (13/13) • Postcardiotomy cardiogenic shock=44.4% (4/9) **Survival at 6 months** • Overall=56.6% (60/106) • High-risk cardiac surgery=75.0% (15/20) • Cardiogenic shock, BTR=48.2% (30/62) • BTDD=20% (1/5) • BTT=100% (13/13) • Postcardiotomy cardiogenic shock=16.7% (1/6) **NYHA class at 90 days for whole cohort** • 1=27.0% (34/126) • 2=15.1% (19/126) • 3=6.3% (8/126)	• High-risk cardiac surgery=8.8% (3/34) • Cardiogenic shock, BTR=10.8% (7/65) • BTDD=0% (0/5) • BTT=0% (0/13) • Postcardiotomy cardiogenic shock=33.3% (3/9) **New dialysis** • Overall=27.8% (35/126) • High-risk cardiac surgery=17.6% (6/34) • Cardiogenic shock, BTR=26.2% (17/65) • BTDD=40.0% (2/5) • BTT=46.2% (6/13) • Postcardiotomy cardiogenic shock=44.4% (4/9) **Local infection** • Overall=3.2% (4/126) • High-risk cardiac surgery=6.3% (2/34) • Cardiogenic shock, BTR=1.5% (1/65) • BTDD=20.0% (1/5) • BTT=0% (0/13) • Postcardiotomy cardiogenic shock=0% (0/9)

First author, date	Efficacy outcomes	Safety outcomes
	• 4=3.2% (4/126) • Not reported=48% (61/126) **Location of removal** • Bedside=21.4% (21/98) • Operating room=78.6% (77/98)	
Feng I, 2025	**In-hospital mortality** • Standard duration of support=30.1% (43/143) • Prolonged support=23.0% (26/114) p=0.262 **60-day survival** Kaplan-Meier analysis of 60-day survival from time of Impella 5.5 implant showed increased survival in the prolonged cohort (83.0% versus 73.0%; log-rank test p=0.028). Kaplan-Meier analysis for survival from time of device explant among people who survived to explant showed similar 60-day survival in the 2 groups (91.8% for prolonged support versus 88.8% for standard; p=0.430). The prolonged support group were statistically significantly more likely to have been implanted as bridge to decision (42.1% versus 29.4%; p=0.046) and	**Stroke during device support or within 24 hours of explant** • Standard duration=8.4% (12/143) • Prolonged support=10.5% (12/114) p=0.712 **Other events during support** **Surgical site infection** • Standard duration=3.5% (5/143) • Prolonged support=11.4% (13/114) p=0.026 **Acute kidney injury needing continuous venovenous hemofiltration** • Standard duration=16.1% (23/143) • Prolonged support=17.5% (20/114) p=0.886

First author, date	Efficacy outcomes	Safety outcomes
	less likely to have been implanted to support a high-risk cardiac procedure (5.3% versus 13.3%; p=0.052). Ultimate destination was also more likely to be heart transplant (36.8% versus 16.1%; p<0.001) and less likely to be myocardial recovery (19.3% versus 32.2%; p=0.029) in the prolonged cohort.	**Reoperation for device migration** • Standard duration=1.4% (2/143) • Prolonged support=4.4% (5/114) p=0.282 **Reoperation for device malfunction** • Standard duration=1.4% (2/143) • Prolonged support=1.8% (2/114) p=1.00 **Reoperation for haemolysis** • Standard duration=0.7% (1/143) • Prolonged support=0% (0/114) p=1.00 **Left ventricle injury from insertion** • Standard duration=0.7% (1/143) • Prolonged support=0% (0/114) p=1.00 **Peripheral vascular injury** • Standard duration=10.5% (15/143) • Prolonged support=7.0% (8/114)

First author, date	Efficacy outcomes	Safety outcomes
		p=0.454 **Bleeding needing surgical exploration** • Standard duration=4.9% (7/143) • Prolonged support=7.0% (8/114) p=0.650 **Need for VA-ECMO initiation** • Standard duration=8.4% (12/143) • Prolonged support=14.0% (16/114) p=0.215 **Tracheostomy** • Standard duration=4.9% (7/143) • Prolonged support=9.6% (11/114) p=0.216
Kanwar M, 2025	**In-hospital mortality** • Overall=27.7% (257/927) • Standard duration of support=31.5% (130/413) • Prolonged support=20.2% (77/381) p<0.001 **Native heart survival** • Overall=27.4% (254/927)	**Adverse events while on Impella 5.5** **Stroke** • Overall=3.5% (32/927) • Standard duration of support=3.1% (13/413) • Prolonged support=5.0% (19/381) p=0.18 **Haemolysis**

First author, date	Efficacy outcomes	Safety outcomes
	• Standard duration of support=29.8% (123/413) • Prolonged support=21.8% (83/381) p=0.01 **Heart transplant** • Overall=27.2% (252/927) • Standard duration of support=22.0% (91/413) • Prolonged support=37.3% (142/381) p<0.001 **Durable LVAD** • Overall=17.4% (161/927) • Standard duration of support=16.5% (68/413) • Prolonged support=20.7% (79/381) p=0.13 People with AMICS had a lower in-hospital survival (59.3%) than people with heart failure related cardiogenic shock (76.7%). **Survival at 30 days after discharge (if discharged alive)** • Overall=98.9% (185/187) • Standard duration of support=100% (71/71) • Prolonged support=97.8% (88/90)	• Overall=8.1% (75/927) • Standard duration of support=8.0% (33/413) • Prolonged support=11.0% (42/381) p=0.21 **Limb ischaemia** • Overall=1.8% (17/927) • Standard duration of support=2.4% (10/413) • Prolonged support=1.8% (7/381) p=0.53 **Haematoma larger than 3 cm** • Overall=7.6% (70/927) • Standard duration of support=7.0% (29/413) • Prolonged support=10.8% (41/381) p=0.09 **Vascular event needing surgery** • Overall=1.4% (13/927) • Standard duration of support=1.7% (7/413) • Prolonged support=1.6% (6/381) p=0.89 **Any adverse event** • Overall=19.4% (180/927)

First author, date	Efficacy outcomes	Safety outcomes
	p=0.50 **Heart failure readmission within 30 days of discharge (if discharged alive)** • Overall=4.8% (9/187) • Standard duration of support=2.8% (2/71) • Prolonged support=5.6% (5/90) p=0.47	• Standard duration of support=20.1% (83/413) • Prolonged support=25.5% (97/381) p=0.07 People with AMICS were more likely to have at least 1 device related severe adverse event (26.2% versus 17.3%, p=0.04) and higher rates of limb ischaemia (4.6% versus 1.2%, p=0.03) compared with people with heart failure related cardiogenic shock in the standard duration cohort. For people supported for more than 14 days, rates of adverse event were similar with either aetiology.
Khalil O, 2025	No efficacy data was reported.	**Procedural complications, n=26** • Cardiac perforation, n=16 (often attributed to improper positioning or repositioning of the device within the left ventricle) • Graft or vessel-related issues, n=5 (including bleeding, graft detachment from the aorta, or vessel dissection) • Valvular damage of device mispositioning, n=5 **Device-related complications, n=14** • Device malfunction, with pump stoppage, n=8 (caused by issues such as electrical failure, biomaterial ingestion, or lumen damage) • Clot formation and embolic stroke, n=6

First author, date	Efficacy outcomes	Safety outcomes
		In 3 deaths, the cause remained uncertain, though sepsis was a shared complication.

Procedure technique

All the studies used the Impella 5.5 device (Abiomed) but some also used Impella 5.0 (n=1,045). In the studies that reported it, vascular access was predominantly through the axillary artery. A direct aortic access was only used in a small proportion of people. In the study by Ramzy (2023), which aimed to compare Impella 5.5 with Impella 5.0, insertion site was similar in people with AMICS and cardiomyopathy. People with postcardiotomy cardiogenic shock who had Impella 5.5 were more likely to have the device placed through the ascending aorta (40% versus 11%; p=0.001), whereas people with Impella 5.0 were more likely to have axillary access (76% versus 55%; p=0.031). In the registry study by Fried (2024), which included Impella 5.5 or 5.0, cannulation sites were available for 69% (524 out of 754) of people, with 94% axillary configuration. In the study by Feng (2025), axillary access was used except in people with postcardiotomy cardiogenic shock, when the device could be placed via direct aortic puncture.

Previous or concomitant support with other temporary MCS devices, including VA-ECMO, IABPs and right VADs, was commonly reported. The mean or median duration of Impella support varied from 7 to 27 days, in the studies that reported it.

Efficacy

Survival to device explant, hospital discharge or 30 days

Survival to hospital discharge or 30 days was reported in 7 studies. One study reported survival to device explant only.

In the systematic review of 15 studies (Kwon 2024), survival to discharge was 68% (95% CI 58 to 78, 11 studies, I^2=80%) and 30-day survival was 65% (95% CI 56 to 74, 9 studies, I^2=77%). For people who had support with Impella 5.5 only (n=294) rather than any Impella device, survival to discharge was 78% (95% CI 72 to 82, 8 studies, I^2=0%).

In the prospective, multicentre observational study of 444 people with cardiogenic shock caused by acute decompensated heart failure treated by Impella 5.5 alone or by multiple MCS devices (Abraham 2025), overall survival to discharge was 75%. For people who had support with Impella 5.5 only (n=207), survival to discharge was 86% (95% CI 82 to 91). For people who had multiple temporary MSC devices (n=237), survival to discharge was 65% (95% CI 59 to 71).

In the retrospective registry study of 754 people with cardiogenic shock that was mostly heart failure-related, including acute on chronic heart failure, or AMICS (Fried 2024), in-hospital mortality was 33% (248 out of 754). Native heart survival was 20% (154 out of 754) and 46% (341 out of 754) of people were bridged to heart transplantation or durable VAD. When Impella 5.0 or 5.5 was used in isolation, in-hospital mortality was lower than when another MCS device was used (20% versus 39%, $p<0.001$) and heart transplantation or durable VAD implantation was higher (59% versus 43%, $p<0.001$). The Kaplan-Meier survival curve showed worse survival in people who had an out-of-hospital cardiac arrest ($p<0.0001$) or whose baseline lactate was 4 mmol/litre or above ($p<0.0003$). There was higher mortality in the AMICS group compared with people who had cardiogenic shock associated with decompensated heart failure (45% versus 26%, $p<0.001$). Among the survivors, a higher proportion of people with AMICS had native heart recovery compared with people in the group with heart failure related cardiogenic shock (30% versus 17%; $p<0.001$). Of the 341 people who had heart transplantation or durable VAD, most were from the decompensated heart failure group rather than the AMICS group (80% versus 14%, $p<0.001$).

The retrospective registry study by Gill (2023) included 221 people with non-ischaemic cardiomyopathy, ischaemic cardiomyopathy or AMICS, who had Impella 5.5 or 5.0 as a bridging therapy. Overall survival to discharge was 69% (152 out of 221). Survival in the 2 groups were similar when the most recent 75 people who had Impella 5.0 were compared with people who had Impella 5.5

(72% versus 77%, p=0.45). Overall 30-day survival was 73% (95% CI 67 to 79) and there was no statistically significant difference between the 2 groups (p=0.94).

The retrospective registry study by Mahesh (2024) included 107 people who were bridged with Impella 5.5 to transplant, durable device implantation or recovery. In-hospital mortality was 6% (2 out of 34) in the BTT group, 4% (1 out of 25) in the BTDD group and 24% (10 out of 42) in the BTR group (p=0.021). In the logistic regression model, the category of cardiogenic shock was statistically significantly associated with mortality with worse survival in the postcardiotomy cardiogenic shock group compared with the BTT group (OR 4.7, 95% CI 0.9 to 24, p=0.05).

In the single-centre retrospective cohort study by Schumer (2024), 126 people had Impella 5.5 as planned support for high-risk cardiac surgery, cardiogenic shock, BTDD, BTT or postcardiotomy cardiogenic shock. The causes of heart failure leading to cardiogenic shock were predominantly acute on chronic non-ischaemic cardiomyopathy, AMI and ischaemic cardiomyopathy. Overall survival to device explant was 76% (96 out of 126) and survival to discharge was 68% (85 out of 126).

The retrospective multicentre registry study by Ramzy (2023) included 1,238 people with AMICS, cardiomyopathy or postcardiotomy cardiogenic shock who had implantation of Impella 5.5 or 5.0. Survival to device explant was stratified by cardiogenic shock aetiology and device. In all groups, Impella 5.5 was associated with a statistically significantly higher survival than Impella 5.0. In people with AMICS, 30% (46 out of 156) of people who had Impella 5.5 died on support or had care withdrawn compared with 43% (120 out of 278) of people who had Impella 5.0 (p=0.005). In the cardiomyopathy group, 12% (32 out of 270) of people who had Impella 5.5 and 23% (52 out of 225) of people who had Impella 5.0 died on support or had care withdrawn (p=0.001). In the

postcardiotomy group, 24% (28 out of 117) of people who had Impella 5.5 and 44% (39 out of 88) of people who had Impella 5.0 died on support or had care withdrawn (p=0.003).

In the study by Feng (2025), in-hospital mortality was 30% (43 out of 143) in people who had standard duration of support (less than 14 days) and 23% (26 out of 114) in people who had prolonged support (14 days or longer, p=0.262). In the study by Kanwar (2025), in-hospital mortality was 28% (257 out of 927) overall, 32% (130 out of 413) in people who had standard duration of support and 20% (77 out of 381) in people who had prolonged support (p<0.001). Native heart survival was 27% (254 out of 927) overall, 30% (123 out of 134) for standard duration support and 22% (88 out of 381) for prolonged duration support (p=0.01). People with AMICS had a lower in-hospital survival (59%) than people with heart failure related cardiogenic shock (77%). Survival at 30 days after discharge for people who were discharged alive was 99% (185 out of 187) overall and there was no statistically significant difference by duration of support.

Successful weaning or bridged to heart transplantation or durable LVAD

The rate of successful weaning or bridging to heart transplantation or durable LVAD was reported in 5 studies.

In the systematic review of 15 studies (Kwon 2024), 10% of people were bridged to transplant directly from Impella support.

In the prospective, multicentre observational study of 444 people, 35% (55 out of 444) of people were bridged to transplant (Abraham 2025).

In the retrospective multicentre registry study by Ramzy (2023), 70% (110 out of 156) of people with AMICS who had Impella 5.5 and 57% (158 out of 278) of people who had Impella 5.0 had successful weaning or bridge to heart transplantation or durable LVAD (p=0.005). In the cardiomyopathy group, the rates were 88% (238 out of 270) for people who had Impella 5.5 and 77% (173

out of 225) for people who had Impella 5.0 (p=0.001). In the postcardiotomy group, the rates were 76% (89 out of 117) and 56% (49 out of 88), respectively (p=0.003).

In the retrospective cohort study by Iyengar (2023), 2,839 people on a waiting list for heart transplantation were supported by Impella 5.5 (n=452) or IABP (n=2,484). At baseline people with Impella support had more functional impairment, higher wedge pressures, higher rates of preoperative diabetes and dialysis, and more ventilator support (all p<0.05). Mortality while on the waitlist was 9% (42 out of 452) in the Impella 5.5 group and 2% (60 out of 2,484) in the IABP group (p<0.001). Transplantation was done in 85% (383 out of 452) of people who had Impella and 92% (2,278 out of 2,484) of people who had IABP (p<0.001).

In the retrospective registry study by Gill (2023), survival to bridging destination was 76% (n=167).

Longer term survival

Survival beyond 30 days was reported in 6 studies.

In the prospective, multicentre observational study of 444 people with cardiogenic shock caused by acute decompensated heart failure (Abraham 2025), native heart survival was 71% at 6 months and 64% at 12 months. For people who had heart transplantation or durable LVAD, survival was 95% at 6 months and 94% at 12 months. For people who had support with Impella 5.5 only, survival at 6 months was 78% (95% CI 73 to 84%) and at 12 months it was 77% (95% CI 71 to 83%). For people who had multiple temporary MSC devices, survival was 56% (95% CI 50 to 62%) at 6 months and 54% (95% CI 47 to 60%) at 12 months.

In the retrospective cohort study by Iyengar (2023) of 2,839 people on a waiting list for heart transplantation supported by Impella 5.5 (n=452) or IABP (n=2,484), mortality within 1 year of transplant was 5% and 6%, respectively (p=0.877). In a

propensity-matched cohort of 628 people, rates were 6% in both groups. In the matched cohort, 2-year survival was 83% in the Impella group and 88% in the IABP group (p=0.874).

In the retrospective registry study by Gill (2023), survival at 90 days after implantation was 81% (95% CI 73 to 88) in the BTT group, 52% (95% CI 34 to 70) in the BTDD group and 51% (95% CI 39 to 62) in the BTR group. At 1 year, survival was 73% (95% 64 to 82) in the BTT group, 47% (95% CI 29 to 64) in the BTDD group and 39% (95% CI 28 to 51) in the BTR group.

In the retrospective registry study by Mahesh (2024), mortality during follow up (mean 23 months) was 9% in the BTT group (3 out of 34), 20% (5 out of 25) in the BTDD group and 36% (15 out of 42) in the BTR group (p=0.019). Actuarial survival at 4.5 years was 91% for BTT, 79% for BTDD and 63% for BTR (p=0.01). The category of cardiogenic shock (HR 3.63, 95% 1.03 to 12.9, p=0.04) and long-term postoperative dialysis (HR 3.9, 95% CI 1.6 to 9, p=0.002) were statistically significant predictors of long-term mortality.

In the single-centre retrospective cohort study by Schumer (2024), overall survival at 6 months was 57% (60 out of 106).

In the retrospective study by Feng (2025), Kaplan-Meier analysis for survival from time of device explant showed similar 60-day survival in people who had support for less than 14 days (89%) and people who had prolonged support (92%, p=0.430).

Unsuccessful device placement

In the retrospective multicentre registry study by Ramzy (2023), 6% (10 out of 169) of people with AMICS who had Impella 5.5 and 5% (15 out of 305) of people who had Impella 5.0 had aborted device placement (p=0.671). In the cardiomyopathy group, aborted device placement was reported in 4% (11 out of 287) of people who had Impella 5.5 and 3% (7 out of 245) of people who had

Impella 5.0 (p=0.634). In the postcardiotomy group, the rates were 5% (6 out of 126) and 13% (14 out of 106), respectively (p=0.033).

Ambulation

In the retrospective registry study by Gill (2023), 24% (42 out of 221) of people were ambulatory within 24 hours of Impella implantation. By device, the rate was 17% (13 out of 75) for Impella 5.5 and 27% (20 out of 75) for Impella 5.0 (p=0.17).

Duration of support

Mean or median duration of support was reported in 6 studies.

In the prospective, multicentre observational study of 444 people (Abraham 2025), the median duration of support for people bridged to transplant was 18 days.

In the retrospective registry study of 754 people (Fried 2024), the median duration of support was 12.9 days in the 337 people where both the device implant and explant date and time were available.

In the retrospective multicentre registry study by Ramzy (2023), the mean duration of support for people with AMICS was 13.2 days in the Impella 5.5 group and 8.7 days in the Impella 5.0 group (p=0.008). In the cardiomyopathy group, the mean duration of support was 15.1 days for people who had Impella 5.5 and 11.4 days for people who had Impella 5.0 (p<0.001). In the postcardiotomy group, the mean durations were 10.2 and 6.6 days, respectively (p=0.127).

In the retrospective cohort study by Iyengar (2023) of 2,839 people on a waiting list for heart transplantation, the median time on support was 15 days for Impella and 9 days for IABP (p<0.001).

Two studies (Feng 2025 and Kanwar 2025) compared outcomes for people who had support for less than 14 days with people who had prolonged support for 14 days or more.

Safety

Bleeding

Bleeding was reported as an outcome in all studies.

Bleeding was the most common complication reported across the studies in the systematic review by Kwon (2024). In 11 studies, the rate of bleeding with varying definitions ranged from 9% to 41% of people. Access site bleeding needing re-exploration was reported in 10% of people (6 studies, n=422). Bleeding events of any type were reported in 27% (95% CI 23 to 31) of people in the observational study of 444 people (Abraham 2025). The rate was 24% (95% CI 18 to 30) in the 207 people who were supported with Impella 5.5 alone. Major bleeding was reported in 46% (349 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the rate was 34%. Major bleeding was more common in people who had AMICS (58%) compared with heart failure related cardiogenic shock (39%, $p<0.001$).

In people who had AMICS, the rate of bleeding was 1% (1 out of 156) in the Impella 5.5 group and 2% (5 out of 278) in the Impella 5.0 group ($p=0.426$) in the retrospective study by Ramzy (2023). In people who had cardiomyopathy related cardiogenic shock, the rate was 1% (3 out of 270) in the Impella 5.5 group and 2% (5 out of 225) in the Impella 5.0 group ($p=0.478$). In people who had postcardiotomy cardiogenic shock, the rate was 3% (3 out of 117) in the Impella 5.5 group and 7% (6 out of 88) in the Impella 5.0 group ($p=0.177$).

Bleeding needing return to theatre was reported in 8% (17 out of 221) of people overall, 11% (8 out of 75) in the Impella 5.5 group and 8% (6 out of 75) in the Impella 5.0 group (p=0.57) in the retrospective registry study by Gill (2023).

Axillary haematoma was reported in 15% (5 out of 34) of people in the BTT group, 12% (3 out of 25) of people in the BTDD group and 5% (2 out of 42) of people in the BTR group (p=0.32) in the retrospective registry study by Mahesh (2024). Gastrointestinal bleed was reported in 6% (2 out of 34) of people in the BTT group, 4% (1 out of 25) of people in the BTDD group and 14% (6 out of 42) of people in the BTR group (p=0.3).

Reoperation for bleeding was reported in 14% (17 out of 126) of people in the single-centre retrospective cohort study by Schumer (2024).

Bleeding needing surgical exploration was reported in 5% (7 out of 143) of people who had support for less than 14 days and 7% (8 out of 114) of people who had prolonged support (p=0.650) in the retrospective study by Feng (2025).

Vascular complications

The rate of vascular complications was reported as an outcome in 4 studies.

Major complications, with varying definitions, were reported in 4 studies and ranged from 0% to 15% in the systematic review by Kwon (2024).

Vascular injury was reported in 1 person with AMICS in the Impella 5.5 group and 1 person with cardiomyopathy in the Impella 5.0 group in the retrospective study of 1,238 people by Ramzy (2023).

Peripheral vascular injury was reported in 10% (15 out of 143) of people who had support for less than 14 days and 7% (8 out of 114) of people who had prolonged support (p=0.454) in the retrospective study by Feng (2025). In the same study, 1 person had a left ventricle injury from device insertion. A vascular event needing

surgery was reported in 1% (13 out of 927) of people overall in the study by Kanwar (2025). There was no statistically significant difference by duration of support.

Stroke

Stroke was reported as an outcome in all studies.

The incidence of stroke ranged from 0% to 14% in 11 out of the 15 studies included in the systematic review by Kwon (2024). The highest incidence was in a study reporting support with Impella combined with ECMO (known as ECPELLA). Stroke was reported in 4% (95% CI 2 to 6) of people in the observational study of 444 people (Abraham 2025). The proportion was 3% (95% CI 1 to 7) in the 207 people who were supported with Impella 5.5 alone.

Stroke was reported in 7% (51 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the proportion was 5% (actual numbers not reported).

In people who had AMICS, cerebrovascular accident was reported in 3% (5 out of 156) of people in the Impella 5.5 group and 1% (3 out of 278) of people in the Impella 5.0 group (p=0.143) in the retrospective study by Ramzy (2023). In people who had cardiomyopathy, the proportion was 2% (6 out of 270) in the Impella 5.5 group and 1% (2 out of 225) in the Impella 5.0 group (p=0.301). In people who had postcardiotomy cardiogenic shock, the proportion was 2% (2 out of 117) in the Impella 5.5 group and 1% (1 out of 88) in the Impella 5.0 group (p>0.99).

Ischaemic stroke was reported in 3% (6 out of 221) of people overall, 3% (2 out of 75) in the Impella 5.5 group and 3% (2 out of 75) in the Impella 5.0 group (p=1.00) in the retrospective registry study by Gill (2023).

Ischaemic stroke was reported in 3% (1 out of 34) of people in the BTT group, 8% (2 out of 25) of people in the BTDD group and 19% (8 out of 42) of people in the BTR group (p=0.07) in the retrospective registry study by Mahesh (2024). Of the 11 people, 8 had complete resolution of neurological disabilities and 3 had residual isolated limb weakness or dysphasia.

Stroke was reported in 10% (13 out of 126) of people in the single-centre retrospective cohort study by Schumer (2024).

Stroke during device support or within 24 hours of explant was reported in 8% (12 out of 143) of people who had support for less than 14 days and 10% (12 out of 114) of people who had prolonged support (p=0.712) in the retrospective study by Feng (2025). Stroke was reported in 4% (32 out of 927) of people overall in the study by Kanwar (2025). There was no statistically significant difference by duration of support.

Haemolysis

Haemolysis was reported as an outcome in 7 studies.

In the systematic review by Kwon (2024), the incidence of haemolysis, with varying definitions, was reported in 9 studies and ranged from 0% to 23%. Clinically significant haemolysis was reported in 14% (95% CI 10 to 17) of people in the observational study of 444 people (Abraham 2025). The proportion was 13% (95% CI 9 to 18) in the 207 people who were supported with Impella 5.5 alone. Haemolysis was reported in 22% (166 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the proportion was 17%. Haemolysis was reported in 26% (46 out of 180) of people overall, 23% (14 out of 62) in the Impella 5.5 group and 30% (20 out of 66) in the Impella 5.0 group (p=0.18) in the retrospective registry study by Gill (2023).

In people who had AMICS, haemolysis was reported in 3% (5 out of 156) of people in the Impella 5.5 group and 4% (10 out of 278) in the Impella 5.0 group (p>0.99) in the retrospective study by Ramzy (2023). In people who had cardiomyopathy, the proportion was 3% (8 out of 270) in the Impella 5.5 group and 9% (21 out of 225) in the Impella 5.0 group (p=0.003). In people who had postcardiotomy cardiogenic shock, the proportion was 2% (2 out of 117) in the Impella 5.5 group and 1% (1 out of 88) in the Impella 5.0 group (p>0.99).

Reoperation for haemolysis was reported in 1 person who had support for less than 14 days and none of the people who had prolonged support (p=1.00) in the retrospective study by Feng (2025). Haemolysis was reported in 8% (75 out of 927) of people overall in the study by Kanwar (2025). There was no statistically significant difference by duration of support.

Limb ischaemia

Limb ischaemia was reported as an outcome in 4 studies.

Acute limb ischaemia was reported in 1% (95% CI 0.4 to 3) of people in the observational study of 444 people (Abraham 2025) and 0% (95% CI 0 to 2) in the 207 people who were supported with Impella 5.5 alone.

Limb ischaemia was reported in 7% (53 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the proportion was 3%. Limb ischaemia was more common in people who had AMICS (12%) compared with heart failure related cardiogenic shock (4%, p<0.001).

Limb ischaemia was reported in 2% (4 out of 221) of people overall, 1% (1 out of 75) in the Impella 5.5 group and 0% (0 out of 75) in the Impella 5.0 group (p=1.00) in the retrospective registry study by Gill (2023).

Limb ischaemia was reported in 2% (17 out of 927) of people overall in the study by Kanwar (2025). There was no statistically significant difference by duration of support. People with AMICS had higher rates of limb ischaemia (5% versus 1%, p=0.03) compared with people with heart failure related cardiogenic shock in the standard duration cohort. For people supported for more than 14 days, rates of adverse event were similar with either aetiology.

Acute kidney injury or renal failure needing renal replacement therapy

The need for renal replacement therapy was reported as an outcome in 6 studies.

Acute kidney injury with need for renal replacement therapy was reported in 10% (95% CI 8 to 14) of people in the observational study of 444 people (Abraham 2025). The rate was 5% (95% CI 3 to 9) in the 207 people who were supported with Impella 5.5 alone. New renal replacement therapy for acute renal failure was reported in 35% (265 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the proportion was 24%. New renal failure needing dialysis was reported in 22% (49 out of 221) of people overall, 24% (18 out of 75) in the Impella 5.5 group and 19% (14 out of 75) in the Impella 5.0 group (p=0.43) in the retrospective registry study by Gill (2023).

Dialysis was reported in 12% (4 out of 34) of people in the BTT group, 20% (5 out of 25) of people in the BTDD group and 29% (12 out of 42) of people in the BTR group (p=0.195) in the retrospective registry study by Mahesh (2024).

New dialysis was reported in 28% (35 out of 126) of people in the single-centre retrospective cohort study by Schumer (2024).

Acute kidney injury needing continuous venovenous hemofiltration was reported in 16% (23 out of 143) of people who had support for less than 14 days and 18%

(20 out of 114) of people who had prolonged support (p=0.886) in the retrospective study by Feng (2025).

Infection

Infection was reported as an outcome in 3 studies.

Bacteraemia or sepsis was reported in 5% (95% CI 3 to 7) of people in the observational study of 444 people (Abraham 2025). The proportion was 3% (95% CI 1 to 7) in the 207 people who were supported with Impella 5.5 alone. In the same study, infection was reported in 17% (95% CI 13 to 20) of people in the whole cohort and 14% (95% CI 10 to 20) of people who had Impella 5.5 alone.

Local infection was reported in 3% (4 out of 126) of people in the single-centre retrospective cohort study by Schumer (2024).

Surgical site infection was reported in 4% (5 out of 143) of people who had support for less than 14 days and 11% (13 out of 114) of people who had prolonged support (p=0.026) in the retrospective study by Feng (2025).

Arrhythmia or heart failure

Destabilising arrhythmia was reported in 33% (95% CI 29 to 38) of people in the observational study of 444 people (Abraham 2025). The proportion was 28% (95% CI 22 to 35) in the 207 people who were supported with Impella 5.5 alone. In the same study, right heart failure was reported in 5% (95% CI 4 to 8) of the whole cohort and 3% (95% CI 1 to 7) of people who had Impella 5.5 alone.

Cardiac arrest

In-hospital cardiac arrest was reported in 20% (154 out of 754) of people in the retrospective registry study of 754 people (Fried 2024). When Impella 5.0 or 5.5 was used in isolation, the proportion was 9% (actual numbers not reported).

Thrombocytopenia

Thrombocytopenia needing platelet transfusion was reported in 13% (95% CI 10 to 16) of people in the observational study of 444 people (Abraham 2025). The proportion was 5% (95% CI 2 to 9) in the 207 people who were supported with Impella 5.5 alone.

Device dislodgement

In the systematic review by Kwon (2024), the incidence of device dislodgement was reported in 5 studies and ranged from 0% to 22%.

Reoperation for device migration was reported in 1% (2 out of 143) of people who had support for less than 14 days and 4% (5 out of 114) of people who had prolonged support (p=0.282) in the retrospective study by Feng (2025).

Pump thrombosis

In the systematic review by Kwon (2024), the incidence of pump thrombosis was reported in 5 studies and ranged from 0% to 15%.

Device exchange

Device exchange (not otherwise described) was needed in 8% (18 out of 221) of people overall, 4% (3 out of 75) in the Impella 5.5 group and 13% (10 out of 75) in the Impella 5.0 group (p=0.04) in the retrospective registry study by Gill (2023).

Adverse events reported on the FDA MAUDE database

The review by Khalil (2025) searched the FDA MAUDE database for reports of events associated with Impella 5.5 that resulted in death. Of the 43 events identified, 26 were described as procedural, 14 were device-related and the cause was uncertain in 3. The most common procedural complication was cardiac perforation, which was often attributed to improper positioning or repositioning of the device within the left ventricle. Other procedural complications were graft or vessel-related issues, such as bleeding, and valvular

damage of device mispositioning. Device-related complications included device malfunction with pump stoppage and clot formation and embolic stroke.

Case reports

A number of case reports describing individual adverse events associated with Impella 5.0 or 5.5 are listed at the beginning of table 5a. These include infected pseudoaneurysm of an outflow graft, aortic valve leaflet injury, entrapment of the Impella pump in the mitral subvalvular apparatus, coiled Impella drive line in the left ventricle, and severe aortic regurgitation.

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).

The anecdotal and theoretical adverse events listed have all been reported in the literature and are described elsewhere in the assessment report.

Eight professional expert questionnaires were submitted for surgical insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock. Find full details of what the professional experts said about the procedure in the specialist advice questionnaires for this procedure.

Validity and generalisability

- There were no randomised controlled trials identified.
- Most of the evidence is from the US and it may 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 evidence is likely to include early experience with Impella 5.5 for most study centres. There is likely to be a learning curve for this procedure and outcomes may improve with experience.
- Most of the studies include cardiogenic shock from a variety of causes. Some of the evidence has reported separate outcomes by aetiology, which suggests there are differences in safety and efficacy.
- There was high study heterogeneity for outcomes reported in the systematic review (Kwon 2024), likely driven by highly selected patient populations and inclusion of other Impella devices (mostly Impella 5.0) in some studies.
- The systematic review included a high proportion of males (86%) and the aetiology was mainly heart failure complicated by cardiogenic shock, primarily due to cardiomyopathy. The authors note that outcomes may be better in this population compared with people who have AMICS or postcardiotomy cardiogenic shock.
- Registry studies may use data that has been collected for other purposes and may have missing data, such as baseline characteristics to define the stage of cardiogenic shock. Also, they may not distinguish between different models of Impella pumps. This is particularly important when they are used to compare different MCS devices. Also, there may not be sufficient data to establish a

temporal relationship between adverse events and the use of a microaxial flow pump or other temporary MCS devices.

- In the retrospective registry by Fried (2024), data from Impella 5.0 and Impella 5.5 were combined in most of the analyses because of their similarity as large-bore transvalvular micro-axial heart pumps. The authors note that there are improvements in the design of the Impella 5.5 and it may be superior to the Impella 5.0.
- The studies by Gill (2023) and Schumer (2024) were done at single high-volume centres and they might not be generalisable to all centres. Safety and efficacy outcomes, such as vascular complication rates, are likely to be affected by the expertise of the study centre.
- In the study by Schumer (2024), the authors noted that for people with cardiogenic shock, only people who survived long enough to reach the study centre were able to have Impella 5.5 implantation, which introduced selection bias.
- Definitions varied for outcomes such as bleeding and haemolysis.
- People commonly had other MCS devices either before, after or at the same time as the catheter-based intravascular microaxial flow pump.
- There was no quality-of-life data in the prioritised evidence.
- Several studies declared potential conflicts of interest. One of the authors of the systematic review by Kwon (2024) is a speaker and consultant for Abiomed, 3ive, LivaNova, and Abbott, another is employed by Abiomed and a third author is a consultant for Abiomed. The study by Fried (2024) was supported by institutional grants from Abiomed Inc, Boston Scientific Inc, Abbott Laboratories, Getinge Inc, and LivaNova Inc to Tufts Medical Center. Several of the authors have received consulting honoraria, institutional grant support, or have worked on the advisory board or acted as consultants for companies including Abiomed. For Ramzy (2023), several authors report honoraria, consulting fees or funding from companies including Abiomed, and

auxiliary medical writing services were provided by the device manufacturer. For Gill (2023), 1 author has received honoraria from Abiomed. For Schumer (2024), 1 author is a speaker for Abbott and Abiomed and receives honoraria from both and 1 author is a speaker for Abiomed and does not receive honoraria.

- Impella 5.0 is no longer available for use in the NHS.

Ongoing trials

- IMPELLA, Complications and Tolerance (IMPACT; NCT06644963); Observational study; France; n=800; estimated study completion: January 2025
- 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 Association for Cardio-Thoracic Surgery, the Society of Thoracic Surgeons, and the American Association for Thoracic Surgery have published guidelines on temporary mechanical circulatory support in adult cardiac surgery (Potapov 2025). These include the following recommendations:

- In patients with cardiogenic shock, it is recommended to initiate tMCS [temporary mechanical circulatory support] before the onset of severe organ dysfunction. (Class 1, level B)

- In patients with cardiogenic shock, escalating vasoactive and/or inotropic drugs should be considered as an indication for tMCS. (Class 2a, level B)

- In patients with cardiogenic shock, clinical signs of tissue hypoperfusion combined with rising lactate levels should be considered as an indication for tMCS. (Class 2a, level B)

- In patients in cardiogenic shock on high-dose vasoactive and/or inotropic drugs, early initiation of tMCS should be considered to reduce AKI. (Class 2a, level B)
- In patients in cardiogenic shock due to acute MI, tMCS may be considered prior to revascularisation. (Class 2b, level B)
- The initiation of tMCS is not recommended in patients with:
    - life expectancy less than 1 year,
    - severe, irreversible neurologic damage,
    - unwitnessed arrest,
    - known patient or family wishes against the use of tMCS. (Class 3, level C)
- In patients who are deteriorating while waiting for dMCS/HTx [durable mechanical circulatory support/heart transplant], tMCS is recommended. (Class 1, level B)
- In patients with post-procedural LCOS [low cardiac output syndrome], tMCS is recommended. (Class 1, level B)
- It is recommended that advanced age not be considered as an absolute contraindication for tMCS. (Class 1, level B)

An expert consensus statement on cardiogenic shock in women endorsed by the Heart Failure Society of America (Baron 2025) includes the following recommendations:

- tMCS is advised early for women in cardiogenic shock on inotropes/vasopressors, with persistent low cardiac output, rising lactate levels, or other signs of end-organ hypoperfusion, based on disease-specific and device-specific risk-benefit assessment.
- In patients presenting with SCAD-CS, tMCS support to recovery and selective revascularisation strategies in high-risk lesions may be appropriate.
- Selective early Impella use (either before or early in PCI) in women with AMI-CS without coma is reasonable; however, additional randomised evidence in women is needed.
- [For pregnant people with cardiogenic shock], early invasive haemodynamics assessment and consideration for early tMCS are critical to maternal survival.
- Clinical evidence is needed to inform optimal tMCS selection (Impella, VA-ECMO) and timing in women with heart failure related cardiogenic shock.
- Anticipated vascular complications should not deter use of potentially lifesaving tMCS; rather, risks should be mitigated with improved techniques for vascular access and follow best practices for indwelling devices.
- A standardised, team-based cardiogenic shock treatment protocol including mandatory hemodynamic assessment, timely diagnosis, and early, appropriate tMCS use may reduce sex disparities in cardiogenic shock outcomes.

Evidence gaps in the management of cardiogenic shock in women:

- Randomised evidence is needed to inform the benefit of tMCS, the optimal tMCS device selection, and timing for women with cardiogenic shock based on cardiogenic shock aetiology to determine device-specific complications and outcomes.

- RCT evidence in women to evaluate the risk benefit of Impella use in AMI-CS is an imperative.

- Evidence is needed to determine the optimal timing of tMCS in women with AMI-CS.

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

highrisk 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. 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 non-randomised 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

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 left ventricular 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.

Company engagement

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

References

1. Kwon JH, Bentley D, Cevasco M et al. (2024) Patient Characteristics and Early Clinical Outcomes With Impella 5.5: A Systematic Review and Meta-Analysis. ASAIO Journal 70: 557–64
2. Abraham J, Anderson M, Silvestry S et al. (2025) Outcomes of Surgically Implanted Impella Microaxial Flow Pumps in Heart Failure-Related Cardiogenic Shock. Journal of Cardiac Failure
3. Fried J, Farr M, Kanwar M et al. (2024) Clinical outcomes among cardiogenic shock patients supported with high-capacity Impella axial flow pumps: A report from the Cardiogenic Shock Working Group. The Journal of Heart and Lung Transplantation 43: 1478–88
4. Ramzy D, Soltesz EG, Silvestry S et al. (2023) Improved clinical outcomes associated with the Impella 5.5 compared to the Impella 5.0 in contemporary cardiogenic shock and heart failure patients. The Journal of Heart and Lung Transplantation 42: 553–57

5. Iyengar A, Rekhtman D, Weingarten N et al. (2023) Comparison of Intraaortic Balloon Pump and Impella 5.5 as Heart Transplant Bridging Strategies. The Annals of Thoracic Surgery 116: 811–17

6. Gill G, Rowe G, Chen Q et al. (2023) Bridging with surgically placed microaxial left ventricular assist devices: a high-volume centre experience. European Journal of Cardio-thoracic Surgery 63: https://doi.org/10.1093/ejcts/ezad116

7. Mahesh B, Peddaayyavarla P, Nguyen K et al. (2024) Use of Intravascular Micro-Axial Left Ventricular Assist Devices as a Bridging Strategy for Cardiogenic Shock: Mid-Term Outcomes. Journal of Clinical Medicine 13: 6804

8. Schumer EM, Bai YZ, Kotkar KD et al. (2024) Surgically implanted endovascular, microaxial left ventricular assist device: A single institution study. JTCVS techniques 23: 63–71

9. Feng I, Dardik G, Kaku Y et al. (2025) Outcomes of prolonged support on surgically implanted microaxial left ventricular assist devices for refractory cardiogenic shock. JTCVS open 25: 173–89

10. Kanwar MK, Uriel N, Carnicelli A et al. (2025) Outcomes of patients supported on Impella 5.5 for more than 14 days: A Cardiogenic Shock Working Group registry analysis. The Journal of Heart and Lung Transplantation 44: 1583–94

11. Khalil O, Krayem H, Kesari A et al. (2025) Complications Leading to Death in Patients Supported by the Impella 5.5: Analysis From the FDA MAUDE Database. Catheterization and Cardiovascular Interventions 106: 550–52

12. Potapov, Evgenij V. Bonaros, Nikolaos et al. (2025) EACTS/STS/AATS Guidelines on temporary mechanical circulatory support in adult cardiac surgery. The Annals of Thoracic Surgery doi: https://doi.org/10.1016/j.athoracsur.2025.09.005.

13. Baron SJ, Chou JC, Shah T et al. (2025) SCAI/EAPCI/ACVC Expert Consensus Statement on Cardiogenic Shock in Women. EuroIntervention 21: 894

Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to insertion of a 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 May 2025 and updated them on 17 November 2025. 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

Update search

For the updated searches there was no change to the strategy apart from the date limit from 29 May 2025 to 17 November 2025. So, the rerun strategies have not been included.

Table 4b Update search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	17/11/2025	Wiley	Issue 11 of 12, November 2025	0
Cochrane Database of Systematic Reviews (CDSR)	17/11/2025	Wiley	Issue 10 of 12, October 2025	9
Embase	17/11/2025	Ovid	1974 to 2025 November 13	244
INAHTA International HTA Database	17/11/2025	https://database.inahta.org/	-	0
MEDLINE ALL	17/11/2025	Ovid	1946 to November 14, 2025	176

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: surgical insertion of a catheter-based left ventricular 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 5a and 5b below. Case reports of safety outcomes that are not included in the main evidence are listed in table 5a and other studies that were not prioritised are listed in table 5b. Non-randomised studies with fewer than 20 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
Desai A, Sharma S, Ruiz J et al. (2025) Recognizing Post-Cardiac Injury Syndrome After Impella 5.5 Insertion in Cardiogenic Shock: A Case-Based Discussion. Biomedicines 13: 1737	Case report n=1 Impella 5.5	Impella 5.5 was used to augment left ventricular function while awaiting heart transplant. The person's post-Impella haemodynamics were stable, but he experienced sharp chest pain localised to the left precordium within the first few hours. Considering clinical progression, examination findings, imaging and laboratory results, the diagnosis of post-cardiac-injury pericarditis was made.	Case report
Fung NL, Tam DY, Nedadur R et al. (2024) Infected Pseudoaneurysm of an Outflow Graft After Left	Case report n=1	Infected pseudoaneurysm of the outflow graft at the graft-aortic anastomosis, treated by surgery.	Case report

Ventricular Assist Device Insertion. Canadian Journal of Cardiology 40: 1352	Non-ischaemic cardiomyopathy Transaxillary Impella insertion	The LVAD was successfully explanted and heart transplantation was done 12 days later.	
Ghannam AD, Takebe M, Harmon TS et al. (2021) Aortic Valve Leaflet Disruption: A Severe Complication of Impella 5.5. Cureus 13: e13235	Case report n=1 Impella 5.5 for support during high-risk redo coronary artery bypass graft	The device was removed on postoperative day 8, at which time cardiogenic shock happened because of aortic valve leaflet injury. The person was taken back to the operating room for a surgical aortic valve and IABP. His postoperative course was complicated by pneumonia, sepsis, and renal failure needing continuous renal replacement therapy.	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
Miyoshi T, Nishimura T, Hiasa Y et al. (2024) Mobile Thrombus Observed Around an Impella Device. Cureus 16: e70399	Case report n=1 Impella 5.5	Impella 5.5 was implanted after AMI. After device removal, CT scan showed thrombosis in the iliac artery.	Case report
Pantin EJ, Chyu D, Mungekar SS et al. (2015) Coiled Impella Drive Line	Case report n=1	An Impella 5.0 device was surgically inserted through the left axillary artery using	Case report

in the Left Ventricle: A Rare Complication of a Left Ventricular Assist Device. Journal of Cardiothoracic and Vascular Anesthesia 29: 1308-10	Congestive heart failure secondary to cardiac amyloidosis Impella 5.0	transoesophageal 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.	
Takagi K, Otsuka H, Saku K et al. (2024) Bailout Procedure Utilizing Balloon Dilatation for a Percutaneous Micro-axial Flow Pump Entrapped Within a Significantly Calcified Subclavian Artery. Cureus 16: e65804	Case report n=1 Cardiopulmonary arrest Impella 5.5	Implantation of Impella 5.5 from the right axillary artery was challenging because of calcification at the bifurcation with the common carotid artery. The device was successfully placed. Attempts to remove the device using standard techniques were unsuccessful because of its entrapment in the calcified area of the right subclavian artery. The right subclavian wound was reopened and a balloon dilation technique was used to remove the Impella device.	Case report
Wert L, Falk V, Potapov EV (2024) Severe aortic regurgitation after short-term treatment with microaxial left ventricular assist device in the transaxillary approach.	Case report n=1 cardiogenic shock, decades after being diagnosed with peripartum cardiomyopathy. Impella 5.5	Impella was used as a bridge to heart transplantation, but after 16 days, a durable LVAD was implanted by sternotomy on cardiopulmonary bypass. After Impella removal, transoesophageal echocardiography revealed severe aortic regurgitation. This was	Case report

European Heart Journal 45: 402		treated by aortic valve replacement.	

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 with males.	It is unclear if any surgically implanted devices were included.
Abiragi M, Singer-Englar T, Cole RM et al. (2023) Temporary Mechanical Circulatory Support in Patients with Cardiogenic Shock: Clinical Characteristics and Outcomes. Journal of Clinical Medicine 12 (no. 4)	Retrospective single-centre cohort study n=90 (31 Impella) Acute decompensated heart failure (98%), AMI (2%) Impella 5.5 (n=30), 5.0 (n=1)	Compared with people supported with IABP, people with Impella support had a longer median duration of support (15 versus 7 days, p<0.001). People with Impella support had a higher in-hospital mortality (19% versus 3%, p=0.018); however, there was no statistically significant difference in all-cause mortality over the course of follow up.	Larger studies were prioritised.
Abusnina W, Ismayl M, Al-Abdouh A et al. (2022) Impella versus extracorporeal	Systematic review and meta-analysis	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	It is unclear if any surgically implanted devices were included.

membrane oxygenation in cardiogenic shock: a systematic review and meta-analysis. Shock 58: 349-357	n=1,827 (10 studies)	no statistically significant difference in 30-day (RR 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.	It is unclear if any surgically implanted devices were included.
Albulushi A, Tawfek A, Al Lawatia H (2024) Evaluating the efficacy and safety of temporary	Systematic review and meta-analysis	Mortality was 35% for Impella compared with 38% for other MCS modalities (p=0.07).	It is unclear if any surgically implanted devices were included.

mechanical circulatory support devices in acute cardiogenic shock: A subgroup-specific systematic review. Current Problems in Cardiology 49: 102619	n=3,450 (15 studies)	The incidence of limb ischaemia was 5%, and haemolysis was 7%. People with AMICS had a 15% reduction in mortality with Impella compared with 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 with 10% in the older cohort (p=0.01).	
Alsoufi B, Kozik D, Oelkers B et al. (2025) Efficacy of Impella Microaxial left ventricular assist device as bridge to transplant in children with end stage heart disease. Interdisciplinary Ca rdiovascular and Thoracic Surg ery 40(10), ivaf249	Retrospective registry n=54 (Impella) 32 Impella 5.0 or 5.5, 20 Impella CP 2 Impella RP	42 children (71%) had a transplant while on Impella support (median 15 days, IQR 8 to 22). 3-year survival after transplant was not statistically significantly different for children who had Impella, another device, and no device before the transplant. Impella use in children as a bridge to heart transplantation has increased, with favourable early outcomes. The Impella 5.5 has contributed to this trend, likely due to its high-flow capacity and mobility potential. Further assessment of its advantages, efficacy, and safety is needed.	Larger studies have been prioritised.
Ali S, Kumar M, Khlidj Y et al. (2025) Trends and	Retrospective registry (US Nationwide	In Takotsubo cardiomyopathy-associated cardiogenic	It is unclear if any surgically implanted

outcomes of different mechanical circulatory support modalities for refractory cardiogenic shock in Takotsubo cardiomyopathy. American Heart Journal Plus: Cardiology Research and Practice 54: 100545	Readmission Database) n=2,025 (1,790 Impella)	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.	devices were included.
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: 4	Systematic review and meta-analysis n=44,951 (13,848 Impella)	Overall mortality (at 30 days, 6 months and 1 year) was 44% (95% CI 39 to 50%) in people who had Impella and 50% (95% CI 43 to 58%) in people who had VA-ECMO. The review highlighted the need to conduct more comparative studies in the field of MCS health technologies for treating cardiogenic shock.	Only 1 paper included Impella 5.5.
Asher M, Iyengar A, Rekhtman D et al. (2025) Acute Hemodynamic and Echocardiographic Consequences of Impella 5.5 Placement in Patients With Advanced Cardiogenic Shock. ASAIO Journal	Retrospective single-centre cohort study n=87 Advanced cardiogenic shock (51% non-ischaemic cardiomyopathy) Impella 5.5	1-year survival=67% At 30 days, 27 (31%) people were transplanted and 13 (15%) were bridged to a durable LVAD.	Larger studies were prioritised.

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 with 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 with late insertion. There was no difference in 1-year mortality or in MCS-related complications.	It is unclear if any surgically implanted devices were included.
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.

Bandini M, D'Ettore N, Iannotti W et al. (2024) Midterm outcomes of patients with native heart recovery after Impella 5+ for cardiogenic shock. European Journal of Heart Failure	Retrospective single-centre cohort study n=20 Impella 5.5	At 180 days, 19 (95%) people were alive. 40% of people had an implantable cardioverter-defibrillator and there were 2 admissions for heart failure. The mean LVEF was 34%, 5 (26%) people were NYHA class 1, 9 (47%) were NYHA class 2, and 5 (26%) were NYHA class 3. 1 person died from a non-cardiac cause.	Larger studies were prioritised.
Bashline M, DiBridge J, Klass WJ et al. (2023) Outcomes of systemic bivalirudin and sodium bicarbonate purge solution for Impella 5.5. Artificial Organs 47: 361-369	Retrospective single-centre cohort study n=34 Impella 5.5	Most people were bridged to heart transplantation (58%) followed by recovery (27%) and LVAD implantation (15%). One person had ischaemic stroke, and 26% developed clinically significant bleeding.	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).
Bernhardt A, Potapov E, Schibilsky D et al. (2021) First in man evaluation of a novel circulatory support device: Early experience with the Impella 5.5 after CE mark approval in Germany. Journal of Heart and Lung Transplantation 40: 850-855	Multicentre cohort study n=46 Impella 5.5 The main indication was ischaemic cardiomyopathy and AMI (48%).	The 30 days and 90 days survival rates were 74% (95% CI 63 to 89%) and 72% (95% CI 61 to 87%), respectively. Additionally, 16 people (35%) were weaned from the device for native heart recovery, and 19 (41%) were bridged to a durable device. 15 people (33%) were mobilised to a chair, and 15 (33%) were ambulatory. There was 1 stroke and no other thromboembolic complications. 7 people (15%) had pump thrombosis, and 9 (20%) had device exchange. 16 people (35%) had	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).

		bleeding needing transfusion during the whole treatment course. In 10 people (22%), the inflow cannula dislocated into the aortic root.	
Bochenek M, Sokolski M, Kedziora A et al. (2025) The Introduction of Impella 5.5 in Cardiogenic Shock: A Single-Center, Retrospective Propensity Score-Matched Analysis. Journal of Clinical Medicine 14: 7552	Retrospective propensity score matched cohort n=57 (17 Impella) Impella 5.5 Follow up: 6 months	The introduction of Impella 5.5 into the Shock Team algorithm was associated with improved short-term survival compared with a historical cohort having treatment with other mechanical circulatory support strategies. Survival at discharge, 30 days, and 3 months was statistically significantly higher in people who had Impella 5.5, whereas 6-month survival showed a favourable numerical trend, though not statistically significant in point analysis.	Larger studies have been prioritised.
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)	30-day readmission rates did not differ among groups, whereas 90-day readmissions were higher among people 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	It is unclear if any surgically implanted devices were included.

		regression showed female gender, diabetes, prior myocardial infarction, heart failure, chronic kidney, and peripheral artery disease as risk factors for 90-day readmissions.	
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).	It is unclear if any surgically implanted devices were included.
Buda KG, Hryniewicz K, Eckman PM et al. (2024) Early vs. delayed mechanical circulatory support in patients with acute myocardial infarction and cardiogenic shock. European Heart Journal: Acute Cardiovascular Care 13: 390-397	Retrospective registry (US Nationwide Readmission Database) n=294,839 people with AMICS (33,577 Impella)	There was no survival benefit of temporary MCS in all-comers with AMICS. The need for 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.	It is unclear if any surgically implanted devices were included.
Cevasco M, Shin M, Cohen W et al. (2023) Impella 5.5	Retrospective registry (United	402 (87%) people had transplantation, with 378 (81%) being directly	Another study using data from the same

as a bridge to heart transplantation: Waitlist outcomes in the United States. Clinical Transplantation 37: e15066	Network for Organ Sharing) n=464 Impella 5.5	bridged to transplant with the device. Waitlist death (7%) and clinical deterioration (5%) were the most common reasons for waitlist removal. Device complications and failure were uncommon (less than 5%). The most common post-transplant complication was acute kidney injury needing dialysis (16%). Survival at 1-year post-transplant was 90%.	source is included (Iyengar 2023).
Clothier JS, Kobsa S, Lester L et al. (2025) Evaluation of hemolysis in patients supported with Impella 5.5: a single center experience. Journal of Cardiothoracic Surgery 20: 143	Retrospective single-centre cohort study n=123 Impella 5.5	11 (44%) people with low haemolysis and 19 (73%) with high haemolysis died, with no statistically significant differences between postoperative complications. Haemolysis in this high-risk cohort had a poor prognosis. People with high haemolysis spent more days on Impella 5.5, needed more MCS, and required more blood product transfusions.	Small retrospective study, focusing on the effect of haemolysis on mortality.
Cohen WG, Rekhtman D, Iyengar A et al. (2023) Extended Support With the Impella 5.5: Transplant, ECMO, and Complications. ASAIO Journal (American Society for Artificial Internal Organs) 69: 642-648	Retrospective single-centre cohort study n=40 BTT, BTDD, BTR Impella 5.5	30-day mortality=22.5% 25 people (62%) were successfully bridged to transplant or durable LVAD, while 4 (10%) recovered without any further cardiac support. 5 of 11 people initially supported with VA-ECMO were either transitioned to durable LVAD, transplanted, or recovered. Lower pulmonary artery systolic pressure (p=0.029),	Larger studies were prioritised.

		among other factors, was associated with mortality.	
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.	Only 1 study included in the review described surgical insertion (Impella 5.0).
Dorken-Gallastegi A, Hong Y, Hess NR et al. (2025) Bridge to Heart Transplant With Temporary Mechanical Circulatory Support: Trends and Outcomes in the 2018 Allocation Policy Era. ASAIO journal (American Society for Artificial Internal Organs: 1992) 71: 571-578	National database (United Network for Organ Sharing) n=27,343 Impella 2.5, CP, 5.0, 5.5	The use of temporary MCS at the time of heart transplant waitlisting increased from 7% to 22% after the UNOS 2018 allocation policy change, making temporary MCS more prevalent than durable MCS. People who had temporary MCS have lower odds of 90 day waitlist mortality and higher incidence of transplant within 90 days with comparable 1 year mortality after transplant.	Studies with more outcomes reported have been prioritised. It is unclear how many people had surgical insertion of a microaxial flow pump rather than percutaneous insertion.
Dumitru I, DeWolf J, Sevillano M et al. (2025) Prolonged Impella 5.5 Support in Patients with	Retrospective cohort n=64	In this study, Impella 5.5 support for longer than the current FDA-approved 14-day duration was a safe and effective support	Larger studies have been prioritised.

Cardiogenic Shock: A Single-Center Retrospective Analysis. Journal of Clinical Medicine 14: 16	Impella 5.5 Follow up: 30 days	strategy. Impella 5.5 support lasted between 14 and 76 days, with an overall survival rate of 81% (52/64).	
Dumitru I, Rinde-Hoffman D, Sevillano M et al. (2024) Single Center Experience With Impella 5.5 for Escalation and De-Escalation of Cardiogenic Shock Patients. Journal of Interventional Cardiology 2024: 7044608	Retrospective single-centre cohort study n=36 Cardiomyopathy (72%), AMICS (28%) Impella 5.5	As a cohort, overall survival was 69%, 39% survived to discharge, 31% bridged-to-heart transplant or durable LVAD, and 31% did not survive.	Larger studies were prioritised.
Dwaah H, Jain N, Kapur NK et al. (2023) The impact of temporary mechanical circulatory support strategies on thrombocytopenia. Journal of Critical Care 73: 154216	Retrospective single-centre cohort study n=77 (11 Impella) Impella 5.5	VA-ECMO, venovenous ECMO, Impella 5.5, and IABP can all induce a drop in platelet count. The degree of platelet count drop, however, is higher in ECMO leading to an increased risk of thrombocytopenia compared with Impella 5.5, IABP, and Centrimag biventricular assist device. Platelet recovery occurred successfully in all MCS, suggesting reversibility of thrombocytopenia after MCS is explanted.	Small, retrospective study focusing on thrombo-cytopenia.
Edelson JB, Amdani S, Rosenthal DN et al. (2025) Multi-institutional outcomes of Impella use in pediatric patients: A brief	Retrospective cohort study n=150 paediatric patients Impella 5.5 (53%), Impella	The most common indication for implant was bridge to recovery (43%). 29% were supported with an Impella as a bridge to transplant and 27% as a bridge to transplant candidacy. Positive clinical outcomes were	Studies with more comprehensive reporting of outcomes have been prioritised.

communication from the ACTION Network. The Journal of Heart and Lung Transplantation 44: 1668–71	CP and Impella with ECMO	observed in nearly 90% and 32% of children supported with Impella were bridged to heart transplant.	
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 people 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).	It is unclear if any surgically implanted devices were included.
Freer R, Frost O, Sreenivas A et al. (2025) Mechanical circulatory support devices vs. standard medical therapy for treatment of myocardial infarction complicated by cardiogenic shock: a network meta-analysis. European Heart Journal. Quality of Care & Clinical Outcomes 11: 1184–95	Network meta-analysis n=1,907 (13% Impella) Impella 2.5, CP and 5.0	Impella reduced 6 to 12 month mortality versus standard medical therapy (RR 0.81, p<0.05) but increased need for renal replacement therapy, limb complications, and major bleeding (RR 1.6, p=0.02; RR 4.8, p=0.02 and RR 2.0, p=0.004, respectively).	It is unclear if any surgically implanted devices were included.

Funamoto M, Kunavarapu C, Kwan MD et al. (2023) Single center experience and early outcomes of Impella 5.5. Frontiers in Cardiovascular Medicine 10: 1018203	Single centre cohort study n=70 Acute decompensated heart failure and cardiogenic shock Impella 5.5	57 (81%) people survived to discharge, and 51 (76%) people survived at the time of the first 30 days post-discharge visit. 31 people (44%) had Impella support for a bridge to advanced surgical heart failure therapy (transplant or durable LVAD), 27 (39%) were a bridge to recovery or decision and 12 (17%) were used for planned perioperative support for high-risk cardiac surgery.	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).
George TJ, Sheasby J, DiMaio JM et al. (2023) Outcomes of surgical Impella placement in acute cardiogenic shock. Baylor University Medical Center Proceedings 36: 415-421	Retrospective single-centre cohort study n=90 Acute on chronic heart failure (56%), AMI (24%), and postcardiotomy (19%) Impella 5.0, 5.5	Overall, 77% of people survived to device removal, and 65% survived to hospital discharge. 1-year survival=54%. Neither aetiology of heart failure nor device strategy was associated with 30-day or 1-year survival. On multivariable modelling, the number of vasoactive medications before device implantation was associated with 30-day mortality (HR 1.94, 95% CI 1.27 to 2.96, p<0.01). Surgical Impella placement was associated with a decreased need for vasoactive infusions (p<0.01) and decreased acidosis (p=0.01).	Larger studies were prioritised.
George TJ, Schaffer JM, Harrington KB et al. (2022) Impact of preoperative Impella support on	Retrospective cohort study n=87 (27 Impella)	Preoperative Impella support was not associated with increased short or long-term mortality but was associated with improved	Larger studies were prioritised.

destination left ventricular assist device outcomes. Journal of Cardiac Surgery 37: 3576-3583	People with durable LVADs Impella 5.0, 5.5	renal and hepatic function as well as total body perfusion before LVAD implantation.	
Gramegna M, Stegmann A, Pieri M et al. (2025) Primary Anticoagulation With Bivalirudin Versus Heparin for Microaxial Flow Pump Supported Patients. ASAIO journal DOI: 10.1097/MAT.0000000000002595	Non-randomised comparative study n=180 Impella CP (47%), Impella 5.5 (36%), Impella 5.0 (16%), and Impella 2.5 (1%).	Comparison of systemic anticoagulation with heparin and bivalirudin. The bleeding rate was 27%, and the thrombosis rate was less than 10%. Direct thrombin inhibitor for anticoagulation was comparable to heparin with a possibly more stable effect on activated partial thromboplastin time.	Study focuses on anticoagulation strategies.
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.	Larger and more recent studies were prioritised.
Hong Y, Agrawal N, Hess NR et al. (2024) Outcomes of Impella 5.0 and 5.5 for cardiogenic shock: A single-center 137 patient experience.	Single centre cohort study n=137 cardiogenic shock caused by AMI,	The acute decompensated heart failure group had the highest survival rates at all time points. Acute kidney injury was the most common complication during	Larger studies were prioritised.

Artificial Organs 48: 771-780	acute decompensated heart failure and postcardiotomy Impella 5.0 or 5.5	Impella support in all 3 groups. Multivariable analysis demonstrated diabetes mellitus, elevated pre-insertion serum lactate, and elevated pre-insertion serum creatinine were independent predictors of in-hospital mortality, but the aetiology of cardiogenic shock did not impact mortality.	
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 people 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 with 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 complications compared with people who had IABP.	It is unclear if any surgically implanted devices were included.
Jonna S, Olaizola G, Raavi L et al. (2025) Impella 5.5 as Heart Transplant Bridge Facilitated Rehabilitation and	Retrospective cohort study n=65	The Impella 5.5 device facilitates rehabilitation and may enhance outcomes after heart transplantation.	Larger studies were prioritised.

Improves Post-Transplant Outcomes: Retrospective Cohort Study. ASAIO journal	People who had Impella support before heart transplantation Impella 5.5		
Kataria R, Khalil A, Coglianese E et al. (2022) Effect of Impella 5.5 on Preexisting Functional Mitral Regurgitation in Patients with Heart Failure-Related Cardiogenic Shock. Structural Heart 6:100072	Retrospective cohort study n=24 Heart failure-related cardiogenic shock Impella 5.5	Despite maximally tolerated Impella unloading, 6 people (25%) had persistent moderate to severe or severe functional mitral regurgitation, and 9 (38%) people had persistent moderate functional mitral regurgitation. There was a decrease in central venous pressure, pulmonary artery diastolic pressure, serum lactate, and vasoactive-inotrope score at 24 hours after Impella, and survival was 83%.	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).
Khan AW, Ahmad M, Gul U et al. (2025) Evaluating gender-based disparities in the outcomes of impella use in acute myocardial infarction patients with cardiogenic shock; insights from real-world global data. BMC Cardiovascular Disorders 25: 548	Retrospective cohort n=6,687 Follow up: mean 1 year	After adjusting for baseline sociodemographic and clinical characteristics, both males and females had similar mortality rates. However, males had a greater incidence of acute kidney injury and readmissions, whereas the incidence of critical limb ischaemia was markedly higher in the female cohort.	It is unclear if any surgically implanted devices were included.
Khan S, Isath A, Gregory V et al. (2025) Axillary artery access considerations in Impella 5.5 insertion: Insights	Retrospective single-centre cohort study n=75	10 people had a small axillary artery, with a mean diameter of 6.3 mm and 59 people (80%) had insertion via the right axillary artery. There was no difference	Small study, focusing on axillary artery access.

from exclusive axillary approach for successful support. Artificial Organs 49: 146-155	Impella 5.5	between the rates of stroke, ischaemia, bleeding, or infection when comparing by size or laterality. Survival to discharge was 60%, with 21% mortality on support, all in patients with a normal axillary artery diameter, but with no difference between right versus left.	
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.	It is unclear if any surgically implanted devices were included.
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, people who were upgraded had higher rates of mortality (57% versus 39%, p=0.03), postoperative dialysis (50% versus 27%, p<0.01), and	Small retrospective single centre study that focuses on the risk of stroke in association with access approach.

		sepsis (43% versus 20%, p<0.01).	
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, 0.43), elevated total bilirubin (OR 1.12), and low platelet count (OR 0.996).	Retrospective registry data, focusing on outcomes of durable LVAD after microaxial flow pump support.
Lewin D, Nersesian G, Lanmuller P et al. (2023) Complications related to the access site after transaxillary implantation of a microaxial left ventricular assist device. The Journal of Heart and Lung Transplantation 42: 679-687	Retrospective single-centre cohort study n=203 Impella 5.0 or 5.5	78 (38%) died while on temporary MCS. 55 (27%) were successfully weaned from Impella 5+ and 70 (34%) were bridged to a durable LVAD with a median follow-up time of 232 days after Impella 5+ explantation. In 119 people, the Impella was explanted, and the vascular graft was shortened, ligated, and pushed under the pectoralis muscle; in 6 people early graft infection prompted complete graft removal during explantation. In addition, 13 people (11%) developed a late-onset graft infection after a median of 86 days, needing complete (n=10) or partial (n=2)	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).

		explantation of the retained graft. 5 people (2%) developed a brachial plexus injury resulting in neurological dysfunction.	
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)	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. It is unclear if any surgically implanted devices were included.
Maffey MW, Kuchtaruk AA, Damluji AA et al. (2025) Association of Frailty With Readmissions and Outcomes After Impella Mechanical Circulatory Support. CJC Open 7: 972	Retrospective registry (US Nationwide Readmission Database) n=16,289 Follow up: 30 days	Frailty is common among people who have Impella support and is associated with higher rates of readmission and adverse outcomes during readmission.	It is unclear if any surgically implanted devices were included. Study focuses on impact of frailty on outcomes.
Maigrot J-LA, Starling RC, Soltesz EG et al. (2025) Trajectories following Impella 5.5 support are associated with initial presentation acuity. Artificial Organs 49: 137-145	Single-centre cohort study n=226 Impella 5.5 cardiogenic shock (decompensated heart failure, AMI	People in SCAI shock stage E had the highest mortality on Impella 5.5. Initial presentation acuity, as characterised by a clinically assessable stratification system (SCAI shock stages), was associated with immediate trajectories following Impella 5.5	Studies with more people or longer follow up were prioritised.

	and postcardiotomy) or assisted high-risk cardiac intervention	support. Earlier escalation to Impella 5.5 in some people with cardiogenic shock with less severe acuity may have contributed to hemodynamic stabilisation and salvage of end-organ function that facilitated more favourable outcomes.	
Maigrot J-LA, Thuita L, Tong MZY et al. (2024) Are there etiology-specific risk factors for adverse outcomes in patients on Impella 5.5 support? JTCVS Open 21: 123-137	Single-centre cohort study n=228 Impella 5.5 cardiogenic shock (AMI, decompensated heart failure, postcardiotomy, or other cause) or assisted high-risk cardiac intervention.	In people with ischaemic cardiomyopathy, the primary composite outcome of death, stroke, or new-onset dialysis while actively receiving Impella 5.5 support occurred in 42 (34%) people. Mortality occurred in 21 (17%), stroke occurred in 12 (10%), and new-onset dialysis was initiated in 23 (19%) people while actively receiving Impella 5.5 support. Among people who survived past Impella 5.5 support, 21 (17%) transitioned to durable LVAD or heart transplant, whereas the others were weaned without advanced therapies.	Studies with more people or longer follow up were prioritised.
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	High-flow microaxial flow pump devices (+5) provided superior haemodynamic support, enhanced left ventricular unloading, and reduced dependence on catecholamines compared with lower-flow CP devices. These improvements were associated with lower rates of right ventricular	Small, retrospective study comparing different microaxial flow pump devices.

	advanced heart failure	failure, renal dysfunction, and liver injury. However, there was no statistically significant difference between groups regarding 30-day mortality rates.	
Mehdizadeh-Shrifi A, Ahmed HF, Chappell G et al. (2025) The Increasing Utilization of the Impella Device as a Bridge-to-Transplantation in Pediatric Heart Centers Across the United States. World Journal for Pediatric & Congenital Heart Surgery: 21501351251330272	Retrospective multicentre registry (United Network for Organ Sharing database) n=50 Children with cardiogenic shock, refractory heart failure, arrhythmia Impella 5.5, CP, 5.0, RP	Of the 50 children, 42 (84%) had heart transplantation; 37 directly from an Impella and 5 from another device. The median age was 15 years, the youngest was 8 years old, 126 cm, and 27 kg. After transplant, 1-year survival was 94%.	Small retrospective study.
Miller P, Akcelik A, Murillo A et al. (2025) Bridging to orthotopic heart transplant: Reducing the risk of intra-operative blood loss. JHLT Open 8: 100220	Retrospective single-centre cohort study n=93 Impella 5.5	Use of temporary MCS did not lead to an increased risk of blood transfusion, which suggests that Impella 5.5 may be a safe bridging strategy to heart transplantation.	Small study, focusing on the risk of blood loss during heart transplantation.
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	It is unclear if any surgically implanted devices were included.

		was associated with the highest mortality (OR 1.17, CI 1.02 to 1.34, p=0.02).	
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: 252-261	Retrospective registry (US National Inpatient Sample database) n=844,020	Total inpatient mortality without any device was 34% versus 25% with IABP use (OR 0.65, 95% CI 0.62 to 0.67) but was highest at 41% with Impella use (OR 1.32, 95% CI 1.26 to 1.39). After adjusting for 47 variables, Impella use 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).	It is unclear if any surgically implanted devices were included.
Munoz Tello C, Jamil D, Tran HH-V et al. (2022) The Therapeutic Use of Impella Device in Cardiogenic Shock: A Systematic Review. Cureus 14: e30045	Systematic review 30 articles	Most people with cardiogenic shock have an improvement using the Impella device. This evaluation was founded on the LVEF, improvement in the cardiogenic shock criteria signs and symptoms, and favourable response in the follow ups.	No meta-analysis.
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	Retrospective single-centre cohort study n=393	People over 80 years had higher 30-day mortality (82% versus 49%, p=0.006). People with BMI 30 or above had higher 30-day mortality than people with BMI less than 30 (60% versus 45%, p=0.007). There was no difference in 30-day mortality between men	It is unclear if any surgically implanted devices were included.

American Journal of Cardiology 217: 119-126		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.	
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 Cardiac Surgery 36: 4141-4152	Retrospective propensity score-adjusted analysis from 2 centres n=126 cardiogenic shock Impella CP, 5.0 and 5.5	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 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).	Larger and more recent studies were prioritised.
Nersesian G, Tschope C, Spillmann F et al. (2020) Prediction of survival of patients in cardiogenic shock treated by surgically implanted Impella 5+ short-term left ventricular assist device. Interactive Cardiovascular and	Retrospective multicentre cohort study n=70 AMI (n=16), decompensated chronic heart failure (n=41), postcardiotomy (n=5) and acute myocarditis (n=8)	30-day survival=51%. Statistical analysis showed that an increase in lactate per mmol per litre (OR 1.22; p=0.015 and cardiopulmonary resuscitation before implantation (OR 16.74; p=0.009) were predictors of 30-day survival.	Larger studies were prioritised.

Thoracic Surgery 31: 475-482	Impella 5.0, 5.5		
Paghdar S, Desai S, Jang J-M et al. (2023) One-year survival in recipients older than 50 bridged to heart transplant with Impella 5.5 via axillary approach. Journal of Geriatric Cardiology 20: 319-329	Retrospective single-centre cohort study n=49 Ischaemic (63%) and non-ischaemic cardiomyopathy (37%) Impella 5.5	38 people aged 50 or older were supported with Impella 5.5 as BTT. 10 people had heart and kidney transplantation. For people that had reached the 1-year follow-up timeframe (22 of 38, 58%), the 1-year post-transplant survival was 95%.	Larger studies were prioritised.
Parker LE, Kang L, Milano CA et al. (2024) Microaxial Flow Pumps for Cardiogenic Shock: Effects on Hemodynamics, Hemolysis, and End-Organ Recovery. Journal of Cardiac Surgery 3584383	Retrospective cohort study n=95 Impella 5.5 Follow up: 30 days	Impella 5.5 support acutely improved markers of end-organ function and haemodynamics, including pulmonary vascular resistance.	Larger studies with more relevant outcomes have been prioritised.
Pieri M, Ortalda A, Altizio S et al. (2024) Prolonged Impella 5.0/5.5 support within different pathways of care for cardiogenic shock: the experience of a referral center. Frontiers in Cardiovascular Medicine 11: 1379199	Single-centre cohort study n=59 71% AMICS Impella 5.0, 5.5	Axillary cannulation was feasible in most people, and 36% were mobilised during support. 44 people (75%) survived to the next therapy or recovery: 21 people had recovery and 15 and 8 were bridged to long-term LVAD and heart transplantation, respectively. The global survival rate was 66%. The predictors of native heart recovery at multivariate analysis were the number of days on temporary MCS before upgrade to	Larger studies were prioritised.

		Impella 5.0 or 5.5 and improvement of LVEF within the first 7 to 10 days of support.	
Ramzy D, Anderson M, Batsides G et al. (2021) Early Outcomes of the First 200 US Patients Treated with Impella 5.5: A Novel Temporary Left Ventricular Assist Device. Innovations 16: 365-372	Retrospective multicentre cohort study n=200 Cardiomyopathy (45%), AMICS shock (29%), and post cardiotomy cardiogenic shock (16%) Impella 5.5	Overall survival to explant=74%. Survival outcomes were improved compared with historic rates observed with cardiogenic shock, particularly postcardiotomy cardiogenic shock.	More recent studies were prioritised.
Ramzy D, Soltesz E, Anderson M (2020) New Surgical Circulatory Support System Outcomes. ASAIO Journal 66: 746-752	Multicentre cohort study n=55 Cardiomyopathy (45%), AMICS (29%), postcardiotomy cardiogenic shock (13%) Impella 5.5	35 people (64%) were successfully weaned off device with recovery of native heart function. 11 people (20%) were bridged to another therapy, 2 people (4%) died while on support, and in care was withdrawn in 7 people (13%). Overall survival was 84%. There were no device-related strokes, haemolysis, or limb ischaemia. 4 people had purge sidearm damage, resulting in a pump stop in 2.	Larger studies were prioritised.
Rock JR, Kos CA, Lemaire A et al. (2022) Single center first year experience and outcomes with Impella 5.5 left ventricular assist device. Journal of	Retrospective single-centre cohort study n=24	Survival rate for Impella 5.5 use longer than 14 days was 67%. In the entire cohort and subgroup of device implantation more than 14 days, evidence of end organ damage improved with Impella 5.5 use. Complications were	Larger studies were prioritised. Study is included in systematic review by Kwon (2024).

Cardiothoracic Surgery 17: 124	Impella 5.5	similar to previously reported complication incidence of axillary inserted LVAD devices.	
Schmack L, Ali-Hasan-Al-Saegh S, Weymann A et al. (2024) Inflammatory and Hemolytic Responses of Microaxial Flow Pump Temporary Ventricular Assist Devices via Axillary Access in Cardiogenic Shock. Medicina 60 (no. 12)	Retrospective single-centre cohort study n=47 32% acute heart failure (n=15), 68% acute or chronic decompensated cardiomyopathy (n=32) Impella 5.5, 5.0, CP	30-day survival=78%. At 30 days, 47% of survivors no longer required mechanical support, while 26% were upgraded to a durable LVAD. Interleukin-6 levels were lower in people who had Impella 5.5 immediately after implantation (p=0.03) compared with people with smaller devices. Haptoglobin levels were higher in the Impella 5.5 group with overall lower rates of haemolysis.	Larger studies were prioritised.
Schurr JW, Pearson A, Delfiner MS et al. (2025) Hemodynamic Support With the Impella 5.5 Acute Mechanical Circulatory Support Device. ASAIO Journal 71: 300-307	Single-centre cohort study n=150 Impella 5.5	Primary outcome (recovery, durable LVAD, or heart transplant at 90 days)=59% Mortality=19%	Larger studies were prioritised.
Seese L, Hickey G, Keebler ME et al. (2020) Direct bridging to cardiac transplantation with the surgically implanted Impella 5.0 device. Clinical Transplantation 34: e13818	Retrospective registry (United Network for Organ Sharing registry) n=236 Bridge to transplantation	24% (n=57) had bridge to heart transplantation. Early and late post-transplant survival was 96% at 30 days, 94% at 90 days, and 90% at 1-year follow up. Post-transplant complications were infrequent, but the most common were renal failure needing dialysis (9%, n=5), cerebrovascular accidents (n=1), and	More recent studies were prioritised.

		pacemaker implant (n=1). The rate of waitlist removal for death or clinical deterioration was 20% (n=47). Bridge to durable continuous-flow LVAD=37% (n=87).	
Shapiro AB, Fritz AV, Kiley S et al. (2024) Comparison of Intraoperative Blood Product Use During Heart Transplantation in Patients Bridged with Impella 5.5 versus Durable Left Ventricular Assist Devices. Journal of Cardiothoracic and Vascular Anesthesia 38: 2567-2575	Retrospective single-centre cohort study n=43 BTT Impella 5.5	People who had BTT with Impella 5.5 had statistically significant lower median transfusions of cryoprecipitate, autologous blood salvage and platelets. Additionally, there was a trend toward lower transfusion of intraoperative packed red blood cells and fresh frozen plasma but these were not statistically significant.	Small retrospective study, focusing on blood product use during heart transplantation.
Sicke M, Modi S, Hong Y et al. (2024) Cardiogenic shock etiology and exit strategy impact survival in patients with Impella 5.5. The International Journal of Artificial Organs 47: 8-16	Retrospective single-centre cohort study n=67 34% AMICS, 66% acute decompensated heart failure Impella 5.5	People with cardiogenic shock associated with acute decompensated heart failure who had Impella 5.5 support had a higher rate of survival than people with AMICS. They were also successfully bridged to heart transplant more often than people with AMICS, contributing to increased survival.	Larger studies were prioritised.
Sommer W, Arif R, Kremer J et al. (2023) Temporary circulatory support with surgically implanted microaxial pumps in postcardiotomy cardiogenic shock following coronary	Retrospective cohort study n=42 People with ischaemic cardiomyopathy having coronary	Survival after 30 days (76% versus 48%, p=0.04) and 1 year (69% versus 30%, p=0.03) was better in the cohort who had Impella implantation during the initial surgery rather than delayed.	Larger studies were prioritised.

artery bypass surgery. JTCVS open 15: 252-260	artery bypass grafting Impella 5.0, 5.5		
Sugimura Y, Bauer S, Immohr MB et al. (2023) Clinical outcomes of hundred large Impella implantations in cardiogenic shock patients based on individual clinical scenarios. Artificial Organs 47: 1874-1884	Retrospective single-centre cohort study n=100 Acute cardiogenic shock Impella 5.5	In-hospital and 30-day mortality rates were 57% (n=51) and 49% (n=44), respectively. In-hospital mortality was lower in people with AMI compared with people with no AMI (p=0.07).	Larger studies were prioritised.
Sugimura Y, Bauer S, Immohr MB et al. (2022) Outcome of Patients Supported by Large Impella Systems After Re-implantation Due to Continued or Recurrent Need of Temporary Mechanical Circulatory Support. Frontiers in Cardiovascular Medicine 9: 926389	Retrospective single centre cohort study n=67 Acute coronary syndrome or ischaemic cardiomyopathy (82%), decompensation caused by dilated cardiomyopathy (13%). Impella 5.0, 5.5	In-hospital mortality=52% Explantation of Impella was done in 39 people (58%), 22 of whom (33%) recovered under Impella, and 10 further people (15%) survived after a successful transition to permanent MCS. In univariate analysis, femoral artery access was a significant risk factor for Impella dysfunction compared with subclavian artery access (43% versus 10%, p<0.05, OR 6.88).	Larger studies were prioritised.
Sugimura Y, Katahira S, Immohr MB et al. (2021) Initial experience covering 50 consecutive cases of large Impella implantation at a single heart centre. ESC Heart Failure 8: 5168-5177	Retrospective single centre cohort study n=49 Acute heart failure Impella 5.0, 5.5	30-day survival=56% In-hospital mortality was higher in people with biventricular failure (p<0.01, OR 5.63) or dilated cardiomyopathy (p=0.02, OR 15.8), whereas ischaemic cardiomyopathy was associated with lower	Larger studies were prioritised.

		mortality (p=0.03, OR 0.24).	
Sugimura Y, Bauer S, Immohr MB et al. (2021) Heparin-Induced Thrombocytopenia under Mechanical Circulatory Support by Large Impella for Acute Cardiogenic Shock. Journal of Cardiovascular Development and Disease 8 (no. 12)	Retrospective single centre cohort study n=56 Impella 5.0, 5.5	21 people were tested for heparin-induced thrombocytopenia and 6 were positive at 10.5 days after the first heparin administration during current admission. Associated thrombotic events were observed in 2 people resulting in Impella dysfunction (pump thrombosis and left ventricular thrombus formation).	Larger 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 Cardiogenic Shock. Journal of Cardiac Failure 31: 791-799	Retrospective single centre cohort study n=114 cardiogenic shock Impella 2.5, CP, 5.0 and 5.5	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: 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%.	Larger studies were prioritised.
Terauchi T, Yamamoto M, Hiraya D et al. (2025) Early door-to-unloading and in-hospital mortality in patients with non-acute coronary syndrome cardiogenic shock undergoing Impella introduction. Journal of Cardiology	Retrospective registry (J-PVAD) n=731 Impella CP (88%), 5.0 or 5.5 (8%), 2.5 (4%)	Early introduction of Impella for non-acute coronary syndrome cardiogenic shock was associated with lower in-hospital mortality, and the benefit was greater in people with myocarditis.	Only a small proportion of people had Impella 5.5.

Valdes CA, Bilgili A, Reddy A et al. (2024) Impella 5.5: A Systematic Review of the Current Literature. Innovations 19: 380-389	Systematic review n=573 (8 studies, all retrospective cohorts) Impella 5.5	Overall, Impella support appeared to be associated with favourable survival rates and manageable complications in various populations. Complications associated with Impella use included bleeding, stroke, and device malfunctions.	No meta-analysis. All relevant studies are included in the key evidence or appendix.
Valdes CA, Stinson G, Sharaf OM et al. (2024) Reconsidering FDA Guidelines: A Single-Center Experience of Prolonged Impella 5.5 Support. Innovations 19: 46-53	Retrospective single centre cohort study n=31 Impella 5.5	45% of people were supported for longer than 14 days and there were no statistically significant differences according to duration of support. The device-related complication rate was 10%. 30-day survival=71% In-hospital mortality=32% Among people surviving to explant, long-term strategy included bridge to durable ventricular assist device, cardiac transplant and cardiac recovery.	Larger studies were prioritised.
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 people who died in hospital and people 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 people who died in the hospital (14.0 versus 11.7 mmHg,	Larger studies were prioritised.

		p=0.014), and a central venous pressure above 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).	
Wu J, Li C, Xu Z et al. (2025) ECMO and impella increase stroke risk in acute myocardial infarction. Scientific Reports 15: 25402	Retrospective registry (US National Inpatient Sample) n=911,666 (8,312 Impella only, 41,560 after applying discharge weight) Follow up: to hospital discharge	Impella use alone demonstrated a modest but statistically significant increase in the risk of overall, ischaemic, and haemorrhagic stroke.	It is unclear if any surgically implanted devices were included.
Yokoyama H, Hosokawa S, Sata M et al. (2025) Impact of Baseline Cardiogenic Shock Severity on Outcomes in Patients Treated With Impella Device. Journal of the American Heart Association 14: e043266	Retrospective registry (J-PVAD) n=4,643 Impella CP (93%), 5.0 (2%), 5.5 (2%), 2.5 (2%)	The CSWG-refined SCAI staging system at baseline was associated with in-hospital death in the worse stage but not in the earlier stage of cardiogenic shock. Except for haemolysis, there were no statistically significant differences in complication rates after Impella insertion within each stage.	Only a small proportion of people had Impella 5.5.
Zubarevich A, Arjomandi Rad A, Szczechowicz M et al. (2022) Early	Retrospective single-centre cohort study	30-day mortality=38% 17 people (53%) were weaned off Impella support and 10 (31%)	Larger studies were prioritised.

experience with the Impella pump: Single-center registry. Artificial Organs 46:1689-1694	n=32 Acute cardiogenic shock Impella 5.0, 5.5 and CP	were successfully bridged to durable LVAD. Of the whole cohort, 26 people (81%) were able to be mobilised during the Impella support. 13 people (41%) had bleeding that needed blood transfusion.	Study is included in systematic review by Kwon (2024).