RESUSCITATION 140 (2019) 178–184

Available online at www.sciencedirect.com

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Clinical paper

Impella use in acute myocardial infarction complicated by cardiogenic shock and cardiac arrest: Analysis of 10 years registry data

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Abstract

Aims: To assess characteristics and outcome of patients treated with Impella for acute myocardial infarction (AMI) complicated by severe cardiogenic shock (CS) or cardiac arrest (CA).

Methods and results: From 2008 through 2017, 92 patients with AMI complicated by CS were treated with Impella. Survival varied according to clinical presentation. Patients in cardiogenic shock without CA had a 75% 30-day survival. Patients with CA and return of spontaneous circulation (ROSC) had a 43% survival and those with CA and ongoing cardio-pulmonary resuscitation (CPR) had a 6% 30-day survival. Age, pre-existing hypertension, coronary disease, ventilatory support and use of adrenergic agents were associated with worse prognosis. Complications were predominantly access site related.

Conclusions: In this registry of patients with AMICS treated with Impella, hypertension and older age were found to be negatively predictive for survival. Patients without CA had the highest 30-day survival. In patients with ROSC, survival was strongly related to age and comorbidity. Patients with ongoing CPR had very high mortality.

Keywords: Cardiogenic shock, Mechanical circulatory support, Left ventricular assist device, Acute myocardial infarction

Introduction

Mortality in acute myocardial infarction (AMI) complicated by cardiogenic shock (AMICS) remains high[1–3] and reperfusion alone is often insufficient to restore cardiac function. Vasopressors and inotropic agents are widely used but have failed to show any survival benefit and have weak recommendations.[4–6] Mechanical circulatory support can increase cardiac output, unload the left ventricle and improve coronary perfusion pressure allowing the myocardium to rest and potentially recuperate.[7–9]

The Impella (Abiomed, Danvers, MA) is a small temporary percutaneous left ventricular assist device (LVAD). The range of Impella devices provides 2.5–5.0 l/min of support and delivers better ventricular unloading than veno-arterial extracorporeal membrane oxygenation (VA-ECMO).[10] The percutaneous Impella 2.5 provides an output of up to 2.5 l/min, whilst the Impella CP provides up to 3.5 l/min. The Impella 5.0 requires surgical cut-down and is less often used. Patient selection remains difficult as some patients are irreversibly ill and cannot be saved, whereas deployment in relatively too healthy patients exposes them to unnecessary complication risks.

Haukeland University Hospital serves as primary percutaneous coronary intervention (PCI) centre for a population of approximately 700 000, and as tertiary centre for an additional 350 000.[11] It was the first PCI centre in Norway to use the Impella in cardiogenic shock

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https://doi.org/10.1016/j.resuscitation.2019.04.022

(2004). Based on experimental animal studies,[12–14] indication for Impella was extended in 2011 to patients with cardiac arrest (CA).

The purpose of this study was to analyse Impella use in patients with AMICS, assess prognostic predictors, and investigate differences in subgroups depending on clinical presentation and pre-existing risk factors.

Methods

A retrospective, explorative, registry-based analysis of all patients with AMICS at Haukeland University Hospital in the period 2008–2017 treated with early revascularization in which an Impella device was deployed. Decision to deploy Impella was based on team clinical judgement. Absolute contraindications included critical non-cardiac illness, known terminal disease, dementia, presence of thrombus in the left ventricle, severe aortic stenosis or mechanical heart valve as well as severe peripheral vascular disease. Acid-base and lactate levels were used in the evaluation of patients but was not used as a formal inclusion or exclusion criteria. There was no upper age limit, but very old age (>80 years) was considered a relative contraindication.

Before 2011 patients with cardiac arrest were not considered for percutaneous mechanical circulatory support (pMCS). From 2011 indication was extended to patients with AMI and cardiac arrest. Both patients with ongoing cardiopulmonary resuscitation (CPR) and patients with return of spontaneous circulation (ROSC) before arrival in the cardiac catheterization laboratory (cath lab) were considered candidates.

For unconscious and sedated patients, contraindications included unwitnessed cardiac arrest, more than 5 min no-flow time and pulseless electrical activity as presenting rhythm. Both patients with and without ventilation during initial resuscitation were considered for pMCS. At least two treating physicians assessed Impella indication including medical history, consciousness, peripheral circulation, hemodynamics, respiration, acid-base, lactate and focused point of care echo. Impella was initiated upon agreement that survival was unlikely without and likely with successful pMCS. Depressed left ventricular (LV) function was required for Impella deployment. All patients were assessed with hand-held echocardiography prior to or during the procedure. Formal echo data were not routinely entered into patient records in the acute setting.

All patients with CPR upon arrival had CPR continued during and after Impella deployment and revascularization. CPR was terminated if deemed ineffective after post-procedure observation.

From 2004 till the end the end of 2017, a total of 158 Impella had been implanted at our centre in a real-life clinical setting. Starting in 2008, they were entered in a registry and a total of 120 patients were identified. Indication for Impella was AMICS in 92 patients, myocarditis, post-cardiotomy or cardiomyopathy in 23 patients and high-risk PCI in 5 patients. Indications, patient characteristics, and outcomes were assessed through the electronic health record. Permission to establish HIMPIT (Haukeland IMPella qualITy assurance project) from the local data protection official was obtained to extract and analyse the data as part of a quality improvement program.

Statistical analyses were performed in RStudio: Integrated Development for R version 1.1.456 (RStudio, Inc., Boston, MA). Between-group differences were evaluated using Student's T-test for continuous variables and chi square test/Fisher's exact test for categorical variables. Univariable and multivariable cox proportional-hazards model were used to assess predictors of survival. Survival differences between subgroups were assessed with Kaplan-Meier curves and log rank test. A two-sided alpha-level of 0.05 was used.

Results

Temporal trends and device type

92 patients (85% male, mean age 61.4 years — range 31–84 years) presented with AMICS from 2008 through 2017 and received left heart Impella support. Of these, 71% were treated with Impella CP, 28% with Impella 2.5 and 7% with Impella 5.0. 13% received additional support with VA-ECMO. Patients treated with 2.5 had a 62% survival, CP 39% survival, and 5.0 had 33% survival (p = NS).

Patients' baseline characteristics and clinical presentation

The baseline characteristics are listed in Table 1. 71% presented with ST-elevation myocardial infarction. 18.5% had ongoing CPR and 55.5% CA with ROSC at arrival in the cath lab. Median time from chest pain to pMCS was 4.7 h (mean 24.6, range 0.6–257). 82% received mechanical ventilatory support (VS) and 48% were treated with adrenergic agents prior to Impella deployment. Left ventricular ejection fraction (LVEF) evaluated by echocardiography at the time of initiation of Impella was 26% (documented in only half of patients). In the CPR group 70% were out-of-hospital cardiac arrest and all patients had ventricular fibrillation (VF) as presenting rhythm. Median time from CA to pMCS was 1.86 h (mean 1.78, range 0.17–3.7).

Subgroups and survival

CA with ROSC or ongoing CPR upon arrival in the cath lab significantly impacted 30-day survival. Survival curves according to CA status

Table 1 – Patients' baseline characteristic and clinical presentation.

Baseline and procedural characteristics	n/total (%)
Gender — Male (%)	78/92 (85%)
Smoker	38/76 (50%)
Hypercholesterolemia (statin usage)	24/90 (27%)
Hypertension	41/89 (46%)
Diabetes	17/91 (18%)
Prior coronary disease (PCI or CABG)	17/92 (20%)
Renal insufficiency (eGFR <60)	24/83 (29%)
Anaemia (Hb <12 g/dl)	19/88 (22%)
Mechanical Ventilatory support	75/92 (82%)
Cardiac arrest (all)	68/92 (74%)
Cardiac arrest with ROSC	51/92 (55%)
Cardiac arrest with ongoing CPR	17/92 (18%)
STEMI	65/92 (71%)
Adrenergic agents prior to Impella[a]	43/89 (48%)
EF at implantation time (mean)	26 %(N = 44)
Mean age, years, n = 92	61.4
Mean eGFR, ml/min, n = 83	74
Mean haemoglobin, g/dl, n = 88	13.7

[a] Adrenergic agents, excluding sedated and ventilated patients on low-dose noradrenaline.

(Fig. 1a) illustrates the trend towards increased mortality in the setting of CA with ROSC and with ongoing CPR (log rank p < 0.0001). Overall 30-day survival was 45%, but in CA with ongoing CPR upon arrival in the cath lab, this number dropped to 6%. In the absence of CA, 30-day survival was 75%.

Age also impacted survival. Fig. 1b demonstrate differences in survival according to age groups. Patients <50 years had a 30-day survival of 71%, whereas in the age group >70 years, 29% survived beyond 30 days.

The combined impact of CA status and age is shown in Fig. 2. The impact of age is particularly evident in patients with ROSC, where patients >70 years (N = 13) had a 15% 30-day survival, 50–70 years (n = 31) 45% survival and younger patients <50 years (n = 7) 86% survival.

Table 2 is a contingency table exploring the relationship between age and CA with sub-stratification regarding presence or absence of relevant clinical risk factors. In patients with ROSC, stratification for mechanical ventilatory support showed a worse 30-day survival (39%) with VS compared to those without (80%). Patients >70 years with ROSC and VS had a 0% survival. Pre-existing medically treated hypertension in patients with ROSC reduced 30-day survival from 65% (N = 26) to 21% (N = 24).

Analysis of prognostic factors

Hazard ratios (HR) for the risk of death were calculated using univariable cox regression for relevant clinical factors readily available upon admission (Fig. 3). CA with ongoing CPR upon arrival in the cath lab, the need for adrenergic agents, ventilatory support, medically treated hypertension, known coronary disease, and age were all associated with increased HR. CA with ongoing CPR upon arrival in the cath lab was the factor most strongly associated with the risk of death (HR 5.51, p < 0,01). Of the pre-existing classical cardiovascular risk factors, medically treated hypertension had the highest hazard ratio (HR 2.27, p < 0.01). Higher LVEF (HR 0.95, p=<0.01), as well as full revascularization at index procedure (HR 0.48, p = 0,01), were associated with better prognosis. Time from chest pain to Impella did not influence survival.

In cox multiple regression (Supplementary Table S2), persisting CA with ongoing CPR (HR 6.09, p = <0.001) and pre-existing hypertension (HR 2.91, p = 0,01) remained statistically significant. Full revascularization at index procedure, age, prior coronary disease, and the use of adrenergic agents lost it statistical significance although a numerical trend persisted.

Upgrade to V-A ECMO support

12 patients received VA-ECMO support in addition to Impella. Three had ongoing cardiac arrest and received VA-ECMO as extracorporeal cardiopulmonary resuscitation (ECPR) prior to Impella, nine presented after ROSC and had inadequate effect of Impella. In the nine that presented with ROSC, 30-day survival was 33%. No patients with ongoing CPR at admission survived to discharge.

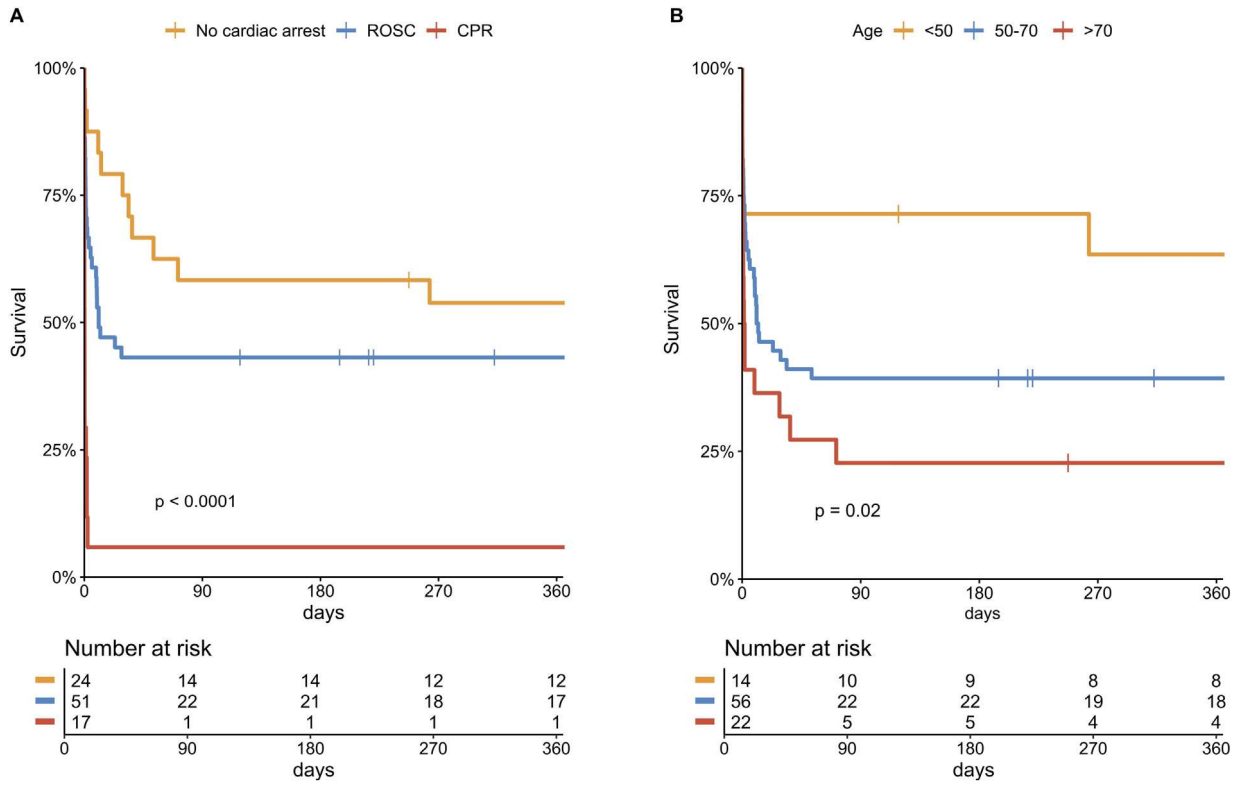

Fig. 1 – (A) One-year survival curves according to cardiac arrest status. Presence of cardiac arrest with ROSC or ongoing CPR was associated with lower survival (log rank p < 0.001). Patients with cardiac arrest with ongoing cardiopulmonary resuscitation (CPR) had an extremely high short-term mortality where 16/17 patients died within 72 h. (B) One-year survival curves according to age group (<50, 50–70, >70 years). Older age was associated with poorer short-term and long-term survival (Log rank p = 0.02).

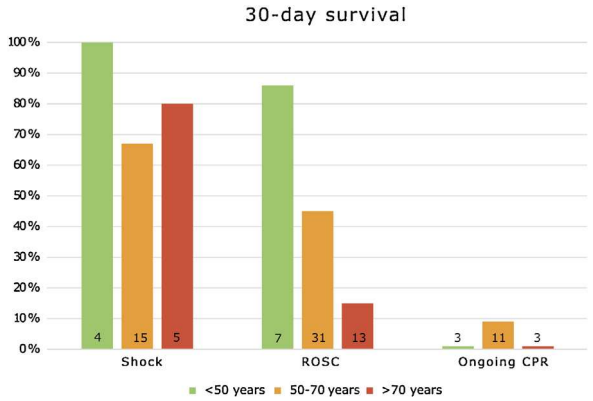

Fig. 2 – 30-day survival according to cardiac arrest status and age. Column height on the Y-axis represents 30-day survival. The number in each column represents the number of patients in each subgroup. Patients with cardiac arrest and ongoing CPR had extremely low 30-day survival, whereas in patients without cardiac arrest survival was excellent. In patients with cardiac arrest and ROSC survival was dependent on age. CA = cardiac arrest, CPR = cardiopulmonary resuscitation, ROSC = Return of spontaneous circulation.

Table 2 – Subgroups and 30-day survival.

	All		<50 years		50–70 years		>70 years	
	Survival	n	Survival	n	Survival	n	Survival	n
All	45%	92	71%	14	44%	57	29%	21
No cardiac arrest								
All	75%	24	100%	4	67%	15	80%	5
No VS	82%	11	100%	3	80%	5	67%	3
VS	69%	13	100%	1	60%	10	100%	2
No AA	79%	14	100%	1	78%	9	75%	4
AA	67%	9	100%	3	40%	5	100%	1
No HT	83%	12	100%	4	67%	6	100%	2
HT	73%	11		0	75%	8	67%	3
Cardiac arrest with ROSC								
All	43%	51	86%	7	45%	31	15%	13
No VS	80%	5	50%	2	100%	1	100%	2
VS	39%	46	100%	5	43%	30	0%	11
No AA	50%	30	100%	4	53%	19	14%	7
AA	26%	19	50%	2	33%	12	0%	5
No HT	65%	26	86%	7	61%	18	0%	1
HT	21%	24		0	25%	12	17%	12
Ongoing CPR								
All	6%	17	0%	3	9%	11	0%	3

AA = Adrenergic agents, excluding sedated and ventilated patients on low-dose noradrenaline, CPR = Cardiopulmonary resuscitation, HT = medically treated hypertension, ROSC = Return of spontaneous circulation, VS = ventilatory support.

Timing of impella implantation

Impella was implanted after PCI in most cases (81%, N = 74). There was no trend towards improved survival if pMCS was initiated before PCI (Fig. 3).

Impella support time, short and long-term survival

Median time of Impella support was 44.8 h (mean 69.5 h, range 0.3–307), and markedly longer in 30-days survivors (median 70.0 vs 18.8 h, p = 0.001). Overall survival at 30 days and one year was 45% and 39%, respectively. In the non-survivors, 45% died within 24 h after Impella initiation, 59% within 48 h and 67% within seven days. In patients with ongoing CPR, all deaths occurred within 72 h.

Complications

Clinically relevant access site bleeding occurred in 7% (N = 6). One patient suffered a retroperitoneal hematoma. Two patients with long Impella support time (115 and 220 h) experienced severe limb ischemia shortly after removal of the Impella. Two patients suffered cerebral stroke. One patient developed severe aortic regurgitation due to dislocation of the Impella 5.0 and underwent transcatheter aortic valve implantation.

Discussion and limitations

Our data shows that in AMICS survival is highly dependent on clinical presentation, most of all absence or presence of CA, but also on age and pre-existing risk factors.

Impella has shown promising results in animal studies in reducing left ventricular wall stress and infarct size[15–17] and deployment in humans leads to improved hemodynamic parameters and reduction in lactate[18,19] indicating possible clinical benefit. To date, the limited prospective randomized studies in AMICS have failed to show survival benefit.[19,20] Our data indicate adequate patient selection is likely crucial for optimal clinical efficacy.

Temporal trends and device type

Up to 2013, the Impella 2.5 was used as the primary device with 5.0 as upgrade when 2.5 was inadequate. The survival of 33% with 5.0 upgrade after failure on 2.5 likely reflect a benefit of upgrade to the more powerful device. Since 2013, only Impella CP was used. Before 2011 patients with ongoing CPR/refractory cardiac arrest were not considered as candidates for Impella and the difference in patient population on 2.5 may explain a trend towards better survival with 2.5

Patients' baseline characteristics and clinical presentation

Most patients had undergone CA, were sedated and on ventilatory support, and underlines that these are some of the most critically ill patients that are encountered in interventional cardiology.

The complex clinical and logistic presentation of such patients is reflected in relatively long median and mean times to treatment in the registry. Time to Impella is influenced by patient-related and logistic delays. 20% had >24 h from onset of chest pain to Impella deployment due to delayed transfer, diagnosis or patient delay. Three patients with CA and complicated transport and significant logistic delay were included despite very long time from first CA. These had intermittent episodes of VF and ROSC during transfer but ongoing CPR upon arrival.

Subgroups and survival

Patient selection is challenging in shock and circulatory collapse. Some patients cannot be saved regardless of revascularization and

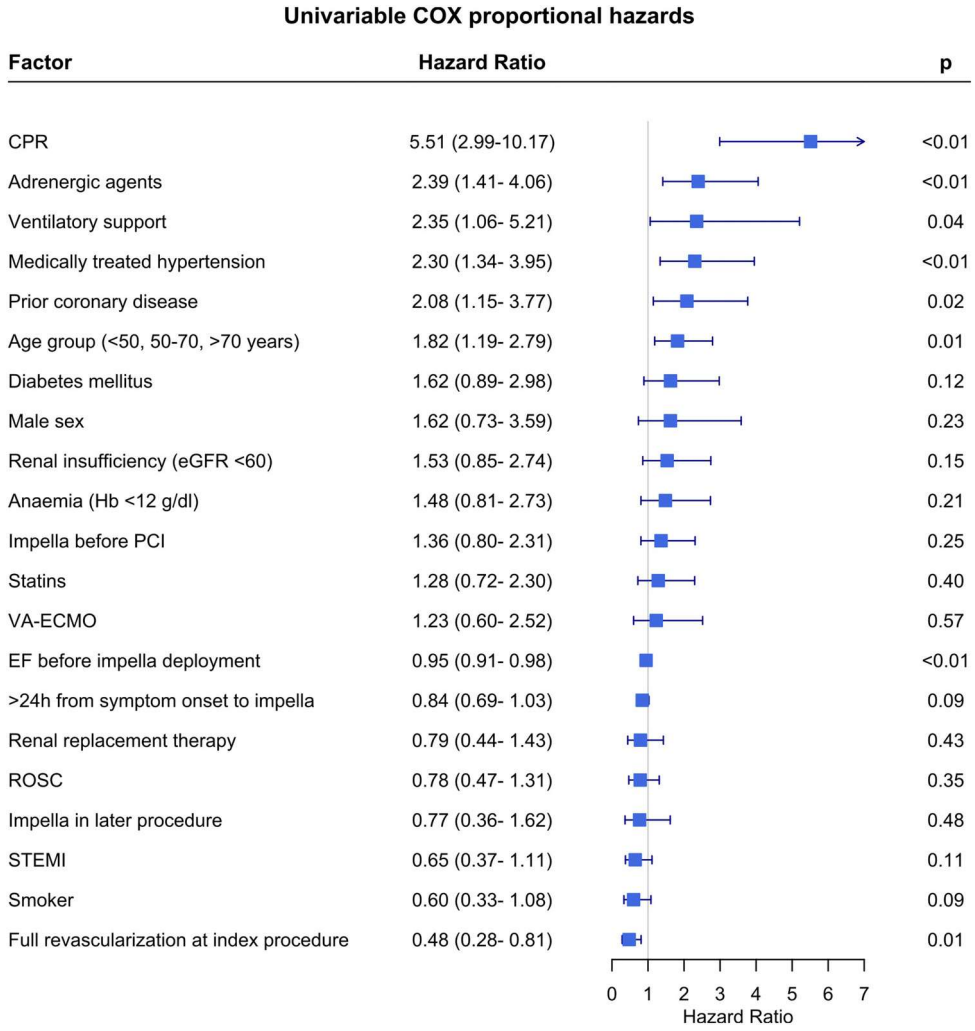

Fig. 3 – Hazard ratios for death in univariable cox regression for relevant clinical factors readily available upon admission. Cardiac arrest with ongoing CPR, the need for adrenergic agents and ventilatory support, medically treated hypertension and older age were associated with higher hazard ratios. CPR = cardiac arrest with ongoing cardiopulmonary resuscitation upon arrival in the cath lab. ROSC = cardiac arrest with return of spontaneous circulation, EF = left ventricular ejection fraction, eGFR = estimated glomerular filtration rate, Hb = haemoglobin, h = hours.

pMCS. Inappropriate use of circulatory support can represent significant ethical and economical challenges whereas in some patients lifesaving effect of pMCS can be clearly appreciated clinically. Thus, it is essential to identify the right patients.

Recently published ECPR data[21] indicate survival of 23% in hospitals with ECPR capabilities and 8.5% in hospitals without ECPR. In our data, patients with CA and ongoing CPR had a very high mortality irrespective of age with 6% survival. The comparatively lower survival in our patients may be related to challenging geographic and climatic condition in Western Norway. This is reflected in a median time from cardiac arrest to MCS of 1.86 h indicating the real-world challenges of implementing optimal ECPR protocols.

In the Impress trial that included almost exclusively patients with CA and ROSC[22] 30-day survival was approximately 50% when treated with IABP or Impella. In comparison, we found 43% survival in patients with ROSC. In this group, age had a major impact on survival. 30-day survival was poor in patients above 70 years that presented after ROSC, and if concomitant VS was needed, mortality was 100%. This in contrast to younger patients (<50 years) with cardiac arrest and ROSC who had excellent survival (86%).

There is little available data on survival after shock without CA as most publications include a significant post CA population. 7412 patients in Netherlands with STEMI[23] had 80% in-hospital survival if complicated by cardiogenic shock with relatively few CA cases(CA 6.5%, author communication) which compares to our 75% 30-day survival in patients without cardiac arrest.

Due to the retrospective nature of our study and limited number of patients in each subgroup, these findings are limited to hypothesis generating observations.

In our data, some patient subgroups, in particular cardiac arrest with ongoing CPR and older patients in cardiogenic shock after ROSC seem to have little benefit from pMCS with Impella.

Analysis of prognostic factors

In univariable cox regression, cardiac arrest, mechanical ventilation, lower LVEF and use of adrenergic drugs were associated with a higher

hazard ratio for death. This seems reasonable as they are markers of more profound cardiogenic shock. Assessing the impact of LVEF is limited by a high proportion of missing LVEF data as echocardiography during the procedure was not routinely documented. Patients with less reduced left ventricular (LV) function could represent a group with more reversible cardiac dysfunction where Impella has the strongest potential for advantage. Very poor LV function may be a marker of irreversible cardiac dysfunction with limited effect of Impella.

Hypertension was associated with increased mortality and may represent a marker of cardiovascular dysfunction with impaired cardiac and arterial elasticity, autoregulation and metabolism with diminished treatment effect. The impact of pre-existing hypertension and LVEF at admission may represent topics for further research.

In accordance with previous studies, full revascularization at index procedure was associated with better outcome and supports the importance of relieving reversible ischaemia as shown in previous studies.[24]

In cox multiple regression, cardiac arrest with ongoing CPR and pre-existing hypertension remained statistically significant. Possibly due to limited data, only a non-significant trend was found for the other factors in the multivariate analysis (Supplementary Table S2).

Upgrade to VA-ECMO support

In patients with inadequate clinical response to Impella support, VA-ECMO was added. VA-ECMO has been used in ECPR in our institution since 2012 and a formalized quick response team is established. VA-ECMO can provide improved systemic circulation, augmented blood flow and oxygenation compared to Impella. However, VA-ECMO may increase afterload and LV pressure in absence of unloading. Impella deployment is quick and minimally invasive, but hemodynamic efficacy of Impella alone may be inadequate due to limited output and further hampered by impaired left ventricular filling during CA. In case of biventricular failure, Impella only supports the left side. Combining VA-ECMO and Impella may better address hemodynamic requirements during CA than either alone. VA-ECMO as primary hemodynamic intervention with Impella for LV unloading represents an attractive approach. Patients with ROSC that were upgraded to a combination of VA-ECMO and Impella due to inadequate effect of Impella alone probably represent a subset with very poor prognosis. In this group a 30-day survival of 33% likely indicates a meaningful clinical effect of this approach.

Timing of impella implantation

In most of our patients pMCS was initiated after PCI in concordance with European and American Guidelines.[6,25] We found no differences in 30-day survival between patients who had the Impella implanted before or after PCI.

Impella support time, short and long-term survival in AMICS

Impella support time was longer in survivors compared to non-survivors reflecting many early deaths in the non-survivor group. Most non-survivors died shortly after admission, and there were few non-survivors that had prolonged ICU stays. With strained hospital budgets and an ever-increasing pressure on hospital beds, it is important to note that the clinical use of Impella does not seem to inappropriately prolong the time to death in irreversibly ill patients.

Complications

Access site complications (bleeding, hematoma, limb ischemia) were the most common complications, which underlines the importance of optimal femoral puncture technique. In this population of critically ill patients, complications are to be expected, and it can be hard to distinguish which are device-related, and which are secondary to the underlying illness or other concomitant treatment.

Limitations

This is a single-centre retrospective real-life explorative registry-based study with limited number of subjects and no control group. The small number of patients limits the statistical power of data analysis. Indications and follow up were not standardised.

Conclusions

In this registry of patients with AMICS treated with Impella, hypertension and older age were found to be negatively predictive for survival. Patients without CA had the highest 30-day survival. In patients with ROSC, survival was strongly related to age and comorbidity. Patients with ongoing CPR had very high mortality.

Impact on daily practice

Impella can be useful and may be considered for patients with AMI and severe shock in appropriately selected patients. Team clinical judgement can be useful in identifying patients with favourable prognosis. In selected patients that do not respond to initial Impella treatment, addition of VA-ECMO may be feasible. Caution should be exercised in patients with ongoing CPR and elderly with ROSC after cardiac arrest.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Funding

No funding.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.resuscitation.2019.04.022.

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