Usefulness of Impella support in different clinical settings in cardiogenic shock

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ABSTRACT

BACKGROUND   The Impella pump has emerged as a promising tool in patients with cardiogenic shock (CS). Despite its attractive properties, there are scarce data on the specific clinical setting and the potential role of Impella devices in CS patients from routine clinical practice.

METHODS   This is an observational, retrospective, single center, cohort study. All consecutive patients with diagnosis of CS and undergoing support with Impella 2.5®, Impella CP® or Impella 5.0® from April 2015 to December 2020 were included. Baseline characteristics, management and outcomes were assessed according to CS severity, age and cause of CS. Main outcome measured was in-hospital mortality.

RESULTS   A total of 50 patients were included (median age: 59.3 ± 10 years). The most common cause of CS was acute coronary syndrome (ACS) (68%), followed by decompensation of previous cardiomyopathy (22%). A total of 13 patients (26%) had profound CS. Most patients (54%) improved pulmonary congestion at 48 h after Impella support. A total of 19 patients (38%) presented significant bleeding. In-hospital mortality was 42%. Among patients with profound CS (n = 13), five patients were previously supported with venoarterial extracorporeal membrane oxygenation. A total of eight patients (61.5%) died during the admission, and no patient achieved ventricular recovery. Older patients (≥ 67 years, n = 10) had more comorbidities and the highest mortality (70%). Among patients with ACS (n = 34), 35.3% of patients had profound CS; and in most cases (52.9%), Impella support was performed as a bridge to recovery. In contrast, only one patient from the decompensated cardiomyopathy group (n = 11) presented with profound CS. In 90.9% of these cases, Impella support was used as a bridge to cardiac transplantation. There were no cases of death.

CONCLUSIONS   In this cohort of real-life CS patients, Impella devices were used in different settings, with different clinical profiles and management. Despite a significant rate of complications, mortality was acceptable and lower than those observed in other series.

Cardiogenic shock (CS) is a severe clinical condition which includes systemic hypotension and tissue hypoperfusion secondary to cardiac dysfunction with adequate or elevated filling pressures, and is commonly associated to a poor prognosis.[1] Clinical practice guidelines[2] recommend the use of inotropic drugs and vasopressors in order to maintain organ perfusion, early revascularization in cases due to acute coronary syn- drome (ACS) and the use of mechanical circulatory support (MCS) in refractory cases.[1,2] However, despite all these measures, mortality remains high in most series.[3] The use of inotropic drugs and vasopressors increases myocardial oxygen consumption and proarrhythmic risk,[4] and the use of MCS is associated with a high rate of complications[5]. A better prognosis has been consistently observed in high volume centers with full availability of percu-

taneous coronary intervention (PCI), MCS, intensive cardiac care unit and especifically trained shock teams.[6-10] Given the complexity of these patients, current guidelines recommend to organize the care of CS in different center networks according to the severity of patients.[2]

As stated before, MCS has emerged during the last years as a promising tool in critically ill patients with refractory CS. The ideal device in patients with CS requires an easy and quick insertion, the ability to unload left ventricle (LV) and increase cardiac output in order to restore tissue hypoperfusion. In this sense, the Impella devices (Abiomed Inc., Massachusetts, USA), consists of a transvalvular axial pump with femoral or axillary insertion that collects blood from the LV and ejects it directly into the ascending aorta.[3] The Impella device provides MCS with an increase in mean arterial pressure, an increase in cardiac output and peak coronary blood flow while unloading LV, reducing end-diastolic volume, wall stress and oxygen consumption, thus favoring myocardial recovery.[1,3] However, despite these attractive properties, there are scarce data on the specific clinical setting to use Impella devices and the efficacy and complications in its use in real world. Most publications report experience in high risk PCI or after acute myocardial infarction complicated by CS.[11]

Therefore, the aim of this study was to collect the results and complications of the use of Impella devices in a real world high complexity CS referral center over a five-year period in non-selected patients with CS of any etiology.

METHODS

This is an observational, retrospective, single center, cohort study. Data collection was performed in a tertiary care CS referral hospital. All consecutive patients aged 18 years or older hospitalised with a diagnosis of CS and undergoing support with Impella 2.5®, Impella CP® or Impella 5.0® from April 2015 to December 2020 were included. Inclusion criteria were as follows: (1) systolic blood pressure < 90 mmHg (in the absence of hypovolemia and after adequate fluid challenge) for 30 min or need for vasopressor therapy to maintain systolic blood pressure > 90 mmHg; and (2) signs of hypoperfusion (altered mental status/confusion, cold periphery, oliguria < 0.5 mL/kg per h for the previous 6 h, blood lactate > 2 mmol/L).

Cases in which MCS was used in the context of high-risk PCI, without associated CS and with Impella device removal in < 24 h after the procedure were excluded. Severity of CS was assessed by the INTER-MACS (Interagency Registry for Mechanically Assisted Circulatory Support)[12] and SCAI (Society for Cardiovascular Angiography and Intervention)[13] classifications.

Clinical management of patients (including antithrombotic treatment, need for coronary angiography, selection of Impella device and timing of insertion and removal) was up to each medical team according to current recommendations. If coronary angiography was performed, vascular access, antithrombotic drugs and the choice of stents and other devices were left to operator's decision. The degree of Impella support was adjusted to the minimum sufficient to improve hemodynamic conditions in order to avoid hemolysis. Impella 2.5® was used from April 2015 to September 2016, Impella CP® was available from September 2016 and Impella 5.0® was available from December 2019.

Data Collection

Data were retrospectively collected by local investigators by review of medical records, using standardized case report forms. Demographics, baseline clinical features, electrocardiographic and echocardiographic data, laboratory and angiographic parameters were collected. In-hospital clinical outcomes were also collected, such as the need for invasive procedures and in-hospital complications (bleeding and its location, need for blood transfusion, need for surgery, infectious complications requiring antibiotics, and hospital mortality).

Definitions

Significant hemolysis was defined as the need for reduce or change the support or blood transfusion without bleeding from another origin. Significant ischemia was defined as an ischemic complication leading to device removal. Vascular complications were divided into major or minor according to the VARC (Valve Academic Research Consortium)-2 scale[14] and significant bleeding complications were

classified according to the BARC (Bleeding Academic Research Consortium) scale (BARC types 3 or 5 bleeding)[15]. Pneumopathy was defined as the presence of chronic obstructive pulmonary disease with need for chronic bronchodilator treatment or obstructive sleep apnea syndrome. Renal failure was quantified according to the KDIGO (Kidney Disease: Improving Global Outcomes) scale[16]. Profound CS was defined as stages D or E from the SCAI classification.[13] Elderly patients were defined as those aged 67 years or older for the purpose of this study.

Outcomes

Main outcome measure was in-hospital mortality. The assignment of the cause of death was based on clinical judgment of the physician taking care of the patient at the time of death. Death was deemed cardiac when it was due to myocardial infarction, heart failure or sudden death. Clinical follow-up after the admission was carried out by local investigators through medical visit or review of medical history.

Statistical Analysis

Baseline characteristics and clinical management were assessed according to the different subgroups (severity of CS, age and cause of CS). The analysis of normal distribution of variables was performed using the Shapiro-Wilk test. Categorical variables were reported as frequencies and percentages, and statistical differences were analyzed by using the Pearson's chi-squared test. Continuous variables were reported as mean ± SD or median (interquartile range), and statistical differences were analyzed using the independent Student's t-test or Wilcoxon-Mann-Whitney test, as appropriate. Two-sided P-value < 0.05 were considered statistically significant. Statistical analysis was performed using STATA 13.1 (Stata Corp, College Station, TX, USA).

Ethics Statement

All procedures performed in this study were in accordance with the ethical standards of the Institutional Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Reference Institutional Ethics Committee.

RESULTS

A total of 50 patients were included. The main characteristics of patients are shown in Table 1. Most patients (82%) were male and the median age was 59.3 ± 10 years. The prevalence of cardiovascular risk factors was low, and in more than half of the cases, there was no history of known heart disease. In cases with previous heart disease, non-ischemic dilated cardiomyopathy was the most common condition, followed by ischemic heart disease with previous PCI. Only 8% of patients had previous atrial fibrillation.

The burden of comorbidites was also low, with pneumopathy standing out in 18% of cases. There was a low proportion of chronic kidney disease, stroke, previous bleeding or peripheral artery disease.

The most common cause of CS was ACS (68%), followed by decompensation of previous cardiomyopathy (22%). A total of 11 patients (22%) had profound CS. Fourteen patients had a previous cardiorespiratory arrest (eight patients of out-of-hospital).

Prior to implantation, the median left ventricular ejection fraction (LVEF) was 34.78% ± 16.1% and, in cases with Swan-Ganz catheter data available, the median pulmonary wedge pressure was 24 mmHg.

Most patients (88%) received inotropic treatment before Impella insertion, with a median inotrope score of 8. Around two of each three required respiratory support, either non-invasive (non-invasive mechanical ventilation or high flow nasal cannula) or invasive mechanical ventilation. Almost half of patients underwent intra-aortic balloon counterpulsation before the Impella support.

Data about clinical course at 48 h after Impella support are summarized in Table 2. Most patients (54%) had improved pulmonary congestion. Impella support resulted in hemodynamic improvement as assessed by a trend to reduce inotrope score (interquartile range: 6−8, P = 0.169), and a significant reduction in pulmonary wedge pressure (interquartile range: 18−24 mmHg, P = 0.004), with a slight non-significant increase in mean arterial pressure (interquartile range: 68−71 mmHg, P = 0.138). The median time with Impella ventricular support was 6 days (interquartile range: 2.3−6 days).

A significant ventricular recovery allowing withdrawal of Impella support was observed in 11 pa-

Table 1   Baseline characteristics and clinical management for the whole cohort (n = 50).

Variables	n	Percentages
Male	41	82%
Age, yrs	59.3 ± 10	
Cardiovascular risk factors		
Hypertension	18	36%
Diabetes mellitus	20	40%
Active smoker	17	34%
Former smoker	15	30%
Previous heart disease		
No heart disease	31	62%
Ischemic heart disease	6	12%
Ischemic dilated cardiomyopsathy	4	8%
Non-ischemic dilated cardiomyopathy	7	14%
Other	2	4%
Comorbilities		
Chronic kidney disease	4	8%
Pneumopathy	9	18%
Stroke	5	10%
Peripheral artery disease	5	10%
Causes of cardiogenic shock		
Acute coronary syndromes	34	68%
Descompensated myocardiopathy	11	22%
Other	4	8%
Severity of shock		
INTERMACS status		
1	11	22%
2	14	28%
≥ 3	25	50%
Previous cardiac arrest		
Out-hospital	8	16%
In-hospital	6	12%
Clinical management		
Support before Impella		
None	21	42%
Intra-aortic balloon pump	22	44%
Extracorporeal membrane oxygenation	7	14%
Strategy		
Recovery	24	48%
Trasplant	21	42%
Bridge to other support	4	8%
Vascular acces		
Femoral	21	58%
Axillary	15	42%
Impella device		
2.5®	2	4%
CP®	39	78%
5.0®	9	18%

Table 2   Hemodynamic and blood test data at baseline and 48 h after support.

Variables	Baseline	48 h after support	P-value
Creatinin, mmol/L	111 (77–135)	146 (75–211)	0.001
Alanine aminotransferase	41 (18–82)	37 (17–111)	0.399
pH	7.41 (7.32–7.47)	7.41 (7.40–7.45)	0.325
Lactate, mmol/L	1.6 (1.02–3.26)	1.27 (0.99–2.19)	0.170
Hemoglobin, g/L	104 (92–135)	92 (85–108)	< 0.001
Platelet count, × 10^3	223 (146–323)	149 (91–239)	< 0.001
Inotrope score	8 (4–17.5)	6 (0.5–15)	0.169
Mean blood pressure, mmHg	68 (65–70)	71 (67–75)	0.138
Heart rate, beats/min	100 (90–111)	100 (87–110)	0.369
Pulmonary wedge pressure, mmHg	24 (22–29)	18 (14–23)	0.004

Data are presented as median (interquartile range).

tients (22%). In 22 patients (44%), escalation to another support (most frequently Levitronix-Centrimag®) or heart transplantation were needed. In eight patients (16%), withdrawal of the device was due to the occurrence of support-related complications.

During Impella support, 26 patients (52%) developed significant hemolysis (Table 3). Among patients with hemolysis, there was a high rate of need for renal replacement therapy (35%) as well as a significant worsening of pre- and post-implantation creatinine levels (interquartile range: 111−146 mmol/L, $P = 0.001$).

The incidence of suffering significant bleeding was 19 patients (38%). In contrast, the proportion of arterial ischemia or major vascular complications was low. The incidences of ischemic stroke with embolic mechanism, device thrombosis and displacement were five patients (10%), four patients (8%) and six patients (12%), respectively. Of note, both cardiopulmonary resuscitation and electrical cardioversion maneuvers ($n = 10$) were shown to be safe, because no patient required device repositioning after their application.

Median intensive cardiac care unit stay was 21 days (interquartile range: 8−35 days) and median hospital stay was 41 days (interquartile range: 14−61 days). Overall, in-hospital mortality was 42%. Most deaths were due to cardiovascular causes (52.4%), followed by post-anoxic brain injury (19%) and refractory multiorgan dysfunction (9.5%). During a mean follow-up of 393 days, only one death was observed among the group of patients surviving at hospital discharge ($n = 29$).

Subgroup Analysis

Profound CS

Among patients with the most severe CS ($n = 13$), five patients were supported with venoarterial extracorporeal membrane oxygenation (VA-ECMO) and five patients with intra-aortic balloon counterpulsation before the Impella implantation. Subsequently, five patients required escalation to other support (four patients with Centrimag-Levitronix® and one patient with VA-ECMO). Median inotrope score was reduced from 9 to 5 at 48 h after the Impella support ($P = 0.138$). A total of eight patients (61.5%) died during the admission. No patients achieved ventricular recovery, since all patients surviving underwent heart transplantation.

Older Patients

This subgroup included ten patients, of whom one patient was female. Among these patients, there was a greater burden of cardiovascular risk factors (60% of hypertension, 60% of diabetes mellitus and 70% of dyslipidemia). Most patients (60%) had previous heart disease, mainly in the form of ischemic heart disease. Only one patient had a history of atrial fibrillation. The prevalence of non-cardiac comorbidities was as follows: 20% of chronic kidney disease, 20% of lung disease, and three patients prior stroke.

The CS was due to ACS in most cases (80%), and three cases of them had been recovered from cardiorespiratory arrest. The severity of CS was slightly higher in this group. A total of three patients presented with profound CS. These patients had also a

Table 3   In-hospital clinical course.

Variables	*n*	Percentages
Congestion improvement	27	54%
Significant hemolysis	26	52%
Arterial ischemia	4	8%
Vascular complication		
None	43	86%
Minor	3	6%
Major	3	6%
Bleeding		
None	28	56%
1	1	2%
2	1	2%
3	19	38%
4	0	0%
5	0	0%
Renal impairment		
None	21	58%
1	3	8%
2	3	8%
3	9	25%
Continuous renal replacement therapy	12	24%
Cause of device withdrawal		
Recovery	11	22%
Trasplant	15	30%
Upgrade to other support	12	24%
Support-related complications	8	16%
Death	10	20%
In-hospital mortality		
Overall	21	42%
Cardiovascular	11	22%
Neurological	4	8%
Multiorgan dysfunction	2	4%
Other	4	8%

poorer LV systolic function (median LVEF: 26.4%), with up to 30% of cases with biventricular dysfunction.

Respiratory support was required in 80% of patients (half non-invasively and half invasively), and 40% of patients underwent intra-aortic balloon counterpulsation. At 48 h after Impella implantation, improvement in congestion was observed only in 20% of cases, although there was a non-significant reduction of inotrope score (from 14 to 5.5, $P = 0.075$). Hemolysis occurred in 40% of patients and bleeding in 30%

of patients. There were no cases of ischemia or vascular access complications. Mortality in this group was 70%, always of cardiovascular cause.

Causes of CS

The decompensated cardiomyopathy group ($n = 11$) comprised mostly (81.8%) dilated cardiomyopathy (45.5% of non-ischemic) with severe ventricular dysfunction (mean prior LVEF: 16.2% ± 9.7%). Mean age was 54.4 years. Only one patient from this group presen-

ted with profound CS. Only one patient required invasive mechanical ventilation, and one patient received assistance after recovery from in-hospital cardiorespiratory arrest. In 90.9% of patients, Impella support was used as a bridge to cardiac transplantation, with axillary access in 54.5% of patients.

At 48 h, the inotrope score was reduced (from 8 to 4, $P = 0.192$) and 54.5% of patients had improved congestion. A total of six patients presented hemolysis, with one case of vascular access complication and one case of embolic stroke. There were no cases of death and six patients (54.5%) achieved cardiac transplantation, although three patients required escalation to another device (Centrimag-Levitronix®).

Among patients with ACS-related CS ($n = 34$), mean age was 60.9 years, and 85.3% of patients were male. Around one of each three patients from this group (35.3%) had profound CS. Most patients (54%) required mechanical ventilation. A total of 11 patients had recovered from cardiorespiratory arrest (six patients of out-of-hospital and five patients of in-hospital). In most cases (52.9%), Impella support was performed as a bridge to recovery. Improvement of congestion at 48 h of Impella support was slightly higher among these patients (60.6%), and the median inotrope score was slightly reduced from 8 to 5 ($P = 0.224$). The rate of complications was hemolysis (50%), arterial limb ischemia (8.8%) and embolic stroke (8.8%), respectively. Mortality in this group was 47.1%, in most cases due to cardiovascular causes (56.2%). Recovery was achieved in 29.4% of patients, while three patients were transplanted and nine patients required escalation to other support.

DISCUSSION

Main findings from this study are: (1) in this real-life cohort of CS patients from a tertiary care referral center, Impella devices were used in different clinical settings of CS, with different clinical profiles and clinical management; (2) despite a significant rate of complications, mortality was acceptable and significantly lower than those observed in other series; and (3) the poorer prognosis was observed among patients at older ages, probably treated to their higher burden of comorbidities and the fact of not being candidates for other advanced therapies.

Mortality in CS patients is still unacceptably high

despite advances in the management of critically ill patients. In this sense, mechanical support devices have emerged during the past years as an attractive tool for patients with refractory CS. There are several devices available with different properties that can help to treat different profiles of patients with CS. Impella devices provide cardiac output ranging from 2.5 L/min to 5 L/min for supporting the failing heart, allow a minimally invasive insertion and contribute to unload LV, in contrast to other devices such as VA-ECMO.

The information about the potential benefit of Impella devices in patients with CS is scarce. Most data come from observational studies,[1,3,4] with its inherent selection bias and potential residual confounding. There are three small randomized clinical trials comparing Impella support with intra-aortic balloon counterpulsation in patients with CS. All of these studies consistently showed that, although Impella offers better hemodynamic support, this did not translate into improved mortality mostly due to the high rate of complications, especially bleeding, vascular and infectious events.[17] Patients from our series had a significant rate of complications, especially bleeding, hemolysis and stroke. This fact was probably related to the severity of patients and their underlying heart disease, as well as the need for antithrombotic drugs and performance of invasive procedures. The high rate of hemolysis was probably related to our definition, including all cases of hemolysis that required lowering the degree of Impella support. Other series only considered hemolysis requiring removal of the device or transfusion.[3,4] On the other hand, our higher rate of upgrade to other devices might be related to the availability of other types of MCS as well as cardiac transplantation.[3,4]

Due to its particular characteristics, both Impella 2.5® and Impella CP® may be especially indicated for treating mild or moderate CS (stages B or C) in patients with ACS undergoing PCI in the cathlab that do not have right heart failure. To our judgement, the cardiac output provided by Impella devices alone may not be enough for treating refractory CS in patients with severe multiorgan failure. In this sense, the IMPRESS trial[18] randomized 48 patients with severe CS complicating acute myocardial infarction to Impella CP® or intra-aortic balloon pump ($n = 24$). Both thirty-day and six-month mortality in patients

treated with either intra-aortic balloon pump or Impella CP® were similar. Importantly, most patients from the IMPRESS trial had cardiac arrest and all of them underwent invasive mechanical ventilation.[18] In our opinion, in this complex setting, a higher cardiac output is commonly needed, and probably a biventricular support with ability for oxygenating blood may allow a faster correction of systemic perfusion and recovery of multiorgan failure. In this sense, the proportion of patients recovered from cardiac arrest in our series was significantly lower than in other series[3,4,19]. However, it is important to remark that Impella devices may play an interesting role in patients with profound CS when added to VA-ECMO support by contributing to unload LV in order to avoid or treat pulmonary congestion.[20] These devices might also be useful in a second stage of CS, when multiorgan failure has been recovered in order to continue support and unload LV until complete recovery or the performance of other definite strategies.

Data from our study revealed that most CS cases undergoing Impella support were due to ACS, in most cases with mild or moderate CS. In this setting results were acceptable, with a high rate of recovery and successful weaning of Impella support. On the other hand, around one of each three cases of Impella support were used in patients with profound CS, in most cases along with VA-ECMO support in order to unload LV or after an ECMO run to complete support after multiorgan failure has been recovered. As described previously, mortality in patients with profound CS was higher than those observed in the whole cohort.[21] It is important to note that among profound CS patients no ventricular recovery was achieved. This fact may suggest the need for an early consideration for other advanced therapies such as heart transplantation or a switch to other circulatory support devices, probably with greater support and duration.

Another potential clinical setting where Impella devices may play an important role is in patients with non-ischemic CS potentially suitable for heart transplantation. This is a very interesting group, since most data available about the impact of Impella support in CS refer to patients with ACS. However, some authors have suggested that temporary use of Impella devices might be a useful therapeutic also in non-ischemic CS.[19] In this setting, both Impella CP® but especially Impella 5.0® can contribute to restore cardiac output and to unload LV, thus allowing the initial systemic hypoperfusion to recover and achieve a potential organ donation in emergent waiting list. Impella 5.0® requires surgical insertion, but in patients with mild or moderate CS that need several days or weeks to recover an axillary approach may allow an early mobilisation and rehabilitation in order to achieve heart transplantation in a good condition. Data from our series revealed good outcomes in this setting, with a lower percentage of mechanical ventilation or cardiorespiratory arrest and a high percentage of axillary implantation. The objective associated with implantation was mainly cardiac transplantation, and no death was observed among these patients.

The assessment of mechanical support in CS patients at older ages deserves special comment, since these patients are often excluded in clinical trials whereas they comprise a large proportion of the cardiovascular high risk patient population.[22,23] This group showed a higher comorbidity burden and a slightly more severe clinical presentation (higher percentage of cardiac arrest, mechanical ventilation, biventricular involvement or concomitant mitral regurgitation). A lower proportion of this group improved at 48 h after the onset of support (20%), probably due to a slower clinical response in this complex clinical setting. As described in other series, mortality was significantly higher among CS patients at older ages.[23,24] Several factors may probably contribute to this higher mortality in the elderly,[25] but their poorer profile of comorbidities and their usually more conservative management are probably the most important. It is important to note that the evidence about the impact of mechanical support is even lower in the elderly, so the indication of mechanical support in this setting should be carefully weighed against the risk of severe complications in order to avoid futility. In this sense, ACS was the most common cause of CS among older patients from this series, and the mechanical support was performed as a bridge to recovery in almost all of these cases.

LIMITATIONS

This study has some mentionable limitations.

Firstly, its observational and retrospective nature. Therefore, it is not possible to exclude some degree of selection bias and residual confounding. Secondly, all devices were not available across the entire period of study, so the selection of each device was related to logistic considerations and the experience of the team at each period. Last but not least, this was a single center study with a small sample size, so our findings should be validated in larger series with different clinical profile and management.

Despite these limitations, in our opinion, this study retrieves novel and interesting data about the promising role of Impella devices in the management of CS patients in different clinical settings. The CS is a critical condition in which engaging randomized studies is very complex due to the severity of the disease. In this sense, real-life registries like ours can provide important information about newer tools for managing CS. Improving their management and outcomes would lead to important clinical, social and economic consequences.

CONCLUSIONS

In these real-life registry of CS patients from a tertiary care referral center, Impella devices were used in different clinical settings of CS, with different clinical profiles and clinical management. Despite observing a significant rate of complications, mortality was acceptable and lower than those observed in other series. The attractive properties of the Impella devices (providing cardiac output for supporting the failing heart, with a minimally invasive insertion and the ability to unload LV) allow the management of patients with CS in different clinical conditions.

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