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Clinical outcomes of Mechanical circulatory support with Impella versus intra-aortic balloon pump in cardiogenic shock complicating acute myocardial infarction

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Abstract

Objective

The goal of this research was to compare the role of intra aortic balloon pump (IABP) vs. percutanous mechanical circulatory support (PMCS)Impella CP on the progression of cardiogenic shock following acute myocardial infarction.

Background

Acute myocardial infarction (AMI) is exacerbated with cardiogenic shock (CS) and had a high death rate despite advances in management. The use of short-term (PMCS) devices improves hemodynamics.

Patients

The study was prospective, conducted on (60 patient) admitted to coronary care unit (CCU), in chest diseases hospital in Kuwait with CS following AMI from January 2020 till January 2021.

Methods

60 cases with massive CS following AMI were randomly assigned to Impella-cp (n 30) or IABP (n 30) in a randomized, prospective, open-label trial (n 30). Massive CS was diagnosed as having a systolic blood pressure < 90 mm Hg or requiring inotropic or vasoactive therapy, as well as hypoperfusion. The1ry outcome was one month mortality.

Results

The 1ry outcome was death at one month, which was similar in cases treated with IABP and pMCS (43 percent and 46 percent, respectively). The 2ry end objective was the rate of device-related problems, which was minimal in this study group despite being greater than that demonstrated for non-emergent pLVAD-application. Transfusion-related hemorrhagic complications appeared in 13.3 percent of Impella patients vs. 3.3 percent of IABP patients (however surgical management of hemorrhagic complications was necessary in one person in the Impella group). Because of the larger sheath utilized in the Impella group, femoral artery thrombus was 26.7 percent compared to 3.3 percent in the IABP group. Cerebrovascular stroke

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was 30% in Impella versus 10% in IABP (reinfarction and revascularization were 6.6 percent in Impella vs. 10.9 percent in the IABP group, 2 cases needed CABG). Failure of the kidney was 43.3% in Impella vs. 33.3% at IABP group.

Conclusion

PCMS in the form of Impella is not related with increased short-term survival in cases with massive CS following AMI, but it is related to more thrombosis and bleeding risks when compared to IABP group. To elucidate any Impella advantages in future researches, better case selection, use of smaller sheaths, early implantation and should be avoided in futile patient.

Keywords: Impella· IABP · Mechanical Circulatory support· Cardiogenic shock ·Acute myocardial infarction.

Introduction

CS caused by AMI has been linked to in-hospital death rates. (1)Even in the era of rapid revascularization, incidence of death due to CS still elevated, and many subjects with massive CS die of multiple organ failure due to chronically end organ hypo perfusion.(2-7) Mechanical support IABP is (class IIa)with early revascularization and pharmaceutical treatment, but routine use is class III.(8,9) In subjects with severe myocardial dysfunction or cardiac arrest, IABP provides only limited hemodynamic support . As a result, multiple studies have failed to show that IABP treatment improves LV function or survival.(10–13)

For mechanical circulatory support, new percutaneous LV assist devices (pLVAD) were established, as the Impella-2.5 and CP. These devices decrease load on LVand promote recovery of cardiac activity, potentially improving myocardial healing. Impella is a catheter-mounted axial-flow pump that has a maximum flow of 4.0 L/min that can be placed percutaneously. In high-risk percutaneous coronary intervention (PCI) and in cases with hemodynamically stable massive anterior STEMI, short-term circulatory support with the device was safe and suitable. (14–17) A previous study reported that Impella-treated individuals had a lower cardiac index. (18)

PATIENTS

The study was prospective and included(60 patient) admitted to coronary care unit (CCU),in chest diseases hospital in Kuwait with CS following AMI from January 2020 till january2021.

An informed consent was obtained to use the data. Without delay, the legal representative's informed consent was gained. Alternatively, after recovery, informed consent was acquired.

METHODS

60 cases with massive CS following AMI were randomly assigned to Impella-cp (n 30) or IABP (n 30) in a randomized, prospective, open-label study (n 30). Massive CS was diagnosed by presence of a systolic blood pressure <90 mm Hg or requiring inotropic or vasoactive therapy, as well as impaired perfusion. The one month all-cause death rate was the 1ry outcome .Patients

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with Severe aorto-iliac arterial disease preventing IABP or pMCS placement, known severe cardiac aortic valvular disease, acute cerebrovascular insult, serious known concomitant disease with a life expectancy of less than one year, known participation in this study or any other trial within the previous 30 days, or coronary artery bypass grafting within the previous week were excluded.

TREATMENT. Eligible cases were managed with PMCS by Impella CP with IABP (control group). An internet-based tool was used to randomize the subjects in a 1:1 ratio. The treating physician decided when PMCS or IABP could be initiated (before, during, or shortly after the PCI).

PCI was performed on all of the patients, either as 1ry or a rescue procedure. The physician was free to choose the method of revascularization (immediate or staged PCI of non-causative lesions). The duration of mechanical support was left to the treating physician's discretion, and IABP or the PMCS device was removed according to standard clinical practice. Weaning was accomplished by lowering the trigger ratio (IABP) or the amount of assistance provided (PMCS).

Statistical analysis:

SPSS program version 23.0 was used to analyses the data (SPSS Inc., Chicago, Illinois, USA). When the distribution was parametric, the quantitative values were provided as mean, standard deviation, and ranges (normal). Quantitative variables were also given as numbers and percentages (P-value). P-values of less than 0.05 were considered significant.

RESULTS

Studied subjects Characteristics at Hospital Admission

In our study, 60 cases with AMI and CS were managed with the Impella-CP (n 30), IABP (n 30). Baseline characteristics revealed that age was 58.93±11.02 in the Impella group and 55.93±9.10 in the IABP group. According to the inclusion criteria, all patients had severe CS, with decreased systolic blood pressure (80.739mmhg in Impella, 81.233 in IABP), high plasma lactate (9.033 mmol/L in Impella, 6.673 for IABP), and a massive reduction of LV ejection fraction (24.90 for Impella, 30.008 for IABP; diagnosed by either echocardiography or ventriculography). Furthermore, 9 (30.0 percent) of the Impella cases and 5 (16.7 percent) of the IABP cases was resuscitated due to cardiac arrest.

Table (1): Comparison between IMPELLA and IABP Group regarding age, gender and BMI.

Demographic data	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Age (years) Mean±SD Range	 58.93±11.02 41–79	 55.93±9.10 38–70	 *t*=1.150	 0.255
Gender Female	4 (13.3%)	3 (10.0%)	FE	0.688

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Male	26 (86.7%)	27 (90.0%)		
BMI [wt/(ht)^2] Mean±SD Range	 27.87±2.27 24–35	 27.77±2.93 24–35	*t*=0.148	0.883

Using: t-Independent Sample t-test; FE: Fisher's Exact

P-value>0.05 NS

Table (2): Comparison between IMPELLA Group and IABP Group regarding risk factors.

Risk factors	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Obese Normal weight Overweight Obese	 1 (3.3%) 22 (73.3%) 7 (23.3%)	 3 (10.0%) 19 (63.3%) 8 (26.7%)	FE	0.526
Smoking	9 (30.0%)	16 (53.3%)	x^2=3.360	0.067
HTN	20 (66.7%)	20 (66.7%)	x^2=0.000	1.000
DM	22 (73.3%)	22 (73.3%)	x^2=0.000	1.000
Dyslipidemia	15 (50.0%)	19 (63.3%)	x^2=1.086	0.297
P.H of IHD	11 (36.7%)	11 (36.7%)	x^2=0.000	1.000
F.H of IHD	2 (6.7%)	1 (3.3%)	FE	0.554

Using: x^2: Chi-square test; FE: Fisher's Exact

P-value>0.05 NS

Table (3): Comparison between IMPELLA and IABP groups according to clinical examination.

Clinical examination	IMPELLA group (n=30)	IABP g roup (n=30)	Test value	p-value
FMC (hrs) Mean±SD Range	 9.00±7.77 2–48	 6.93±2.43 4–12	*U*=1.390	0.170
SBP (mmHg)				

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Mean±SD Range	80.73±9.64 60–110	81.23±3.72 70–90	*t*=-0.265	0.792
DBP (mmHg) Mean±SD Range	51.23±6.89 40–80	52.30±4.67 50–70	*t*=-0.702	0.486
RR Mean±SD Range	32.87±5.47 20–40	31.90±4.89 24–40	*t*=0.722	0.473
HR Mean±SD Range	100.83±16.67 76–150	97.13±20.81 20–130	*t*=0.760	0.450
SO2 Mean±SD Range	89.73±3.37 85–96	90.67±4.17 85–97	*t*=-0.953	0.345
PCWP Mean±SD Range	26.77±3.30 20–33	23.57±3.42 17–28	*t*=3.689	<0.001**
Cardiac index (CI) Mean±SD Range	2.65±0.61 2–4	3.28±0.54 2–4.2	*t*=-4.282	<0.001**
Klippe I II III IV	0 (0.0%) 5 (16.7%) 4 (13.3%) 21 (70.0%)	1 (3.3%) 7 (23.3%) 4 (13.3%) 18 (60.0%)	FE	0.668
MV	22 (73.3%)	18 (60.0%)	x^2=1.200	0.273
Arrest & CPR	9 (30.0%)	5 (16.7%)	x^2=1.491	0.222
Vasopressors Levophed Mean±SD Range	0.22±0.07 0.1–0.4	0.17±0.05 0.1–0.3	*U*=2.607	0.012*
Vasopressors Adrenaline Mean±SD Range	0.20±0.09 0.1–0.4	0.13±0.05 0.1–0.2	*U*=2.226	0.034*
Inotropes	2 (6.7%)	2 (6.7%)	FE	1.000

Using: t-Independent Sample t-test; U=Mann-Whitney test;

x^2: Chi-square test; FE: Fisher's Exact

*p-value>0.05 NS; *p-value <0.05 S; **p-value <0.001 HS*

Swan-ganz was inserted in almost both groups, pulmonary capillary wedge pressure (PCMP), cardiac output (COP), cardiac index (CI) was measured

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Table (4): Comparison between IMPELLA and IABP Groupsregardingtype of MI

ECG	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
STEMI	19 (63.3%)	27 (90.0%)	4.565	0.033*
NSTEMI	11 (36.7%)	3 (10.0%)		

*Using: Chi-square test; *p-value <0.05 S*

Table (5): Comparison between IMPELLA and IABP Groups regarding laboratory data.

Laboratory data	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Lytic therapy	N=19 14 (73.7%)	N=27 23 (85.2%)	x^2=0.349	0.555
HGB Mean±SD Range	 12.73±1.45 9–16	 12.62±1.56 9–16.8	*t*=0.274	0.785
TROP Mean±SD Range	 22600±7486 2000–27000	 24587±5580 8000–27000	*U*=-1.165	0.249
Lactate Mean±SD Range	 9.03±3.04 4.9–15	 6.67±3.50 3.5–15	*U*=2.790	0.007*
Creat Mean±SD Range	 231.87±174.08 79–820	 165.12±137.25 71–805	*U*=1.649	0.104
EF% Mean±SD Range	 24.90±10.19 15–55	 30.00±8.20 15–50	*U*=-2.136	0.037*

*Using: t-Independent Sample t-test; U=Mann-Whitney test; x^2: Chi-square test; P-value>0.05 NS; *p-value <0.05 S*

Table (6): Comparison between IMPELLA and IABP groupsregarding coronary anatomy andintervention.

Intervention	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Coronary Artery: *LM*	 18 (60.0%)	 8 (26.7%)	x^2=6.787	0.009*

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LAD	27 (90.0%)	26 (86.7%)	x^2=0.162	0.688
LCX	26 (86.7%)	19 (63.3%)	x^2=4.356	0.037*
RCA	26 (86.7%)	15 (50.0%)	x^2=9.320	0.002*
Vessels				
One vessel	2 (6.7%)	5 (16.7%)		
Three vessel	9 (30.0%)	7 (23.3%)	FE	<0.001**
Two vessel	4 (13.3%)	15 (50.0%)		
Multi-vessel	15 (50.0%)	3 (10.0%)		
PCI				
Culprit (LAD)	15(50%)	20(66.6%)		
Non culprite	15(50%)	10(33.4%)	1.097	0.295
Upgrade				
ECMO	7 (23.3%)	3 (10.0%)		
IABP	1 (3.3%)	0 (0.0%)	FE	0.071
IMPELLA	0 (0.0%)	5 (16.7%)		
No	22 (73.3%)	22 (73.3%)		
TIMI After				
I	2 (6.7%)	2 (6.7%)		
II	5 (16.7%)	5 (16.7%)	FE	1.000
III	23 (76.7%)	23 (76.7%)		

Using: x^2: Chi-square test; FE: Fisher's Exact

*P-value>0.05 NS; *p-value <0.05 S; **p-value <0.001 HS*

In most cases, the infarct-related artery was the left anterior descending (LAD) (66 percent in the IABP group, 50 percent in the Impella group). 3.57 days (IABP) and 4.47 (IABP) were the median durations of circulatory support (pMCS). During their stay in the CCU, all cases were administered catecholamine, and 33 percent of the IABP group received renal replacement therapy compared to 43 percent in Impella group. Upgrade with ECMO was introduced in 23% and 10% of the Impella and IABP groups respectively.

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Table (7): Comparison between IMPELLA and IABP groups regarding in hospital complications.

In hospital Complications	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Local Bleeding	8 (26.7%)	4 (13.3%)	FE	0.350
Retroperitoneal bleeding	4 (13.3%)	1 (3.3%)	FE	0.350
LV Thrombosis	2 (6.7%)	6 (20%)	FE	0.255
Femoral A thrombus	8 (26.7%)	1 (3.3%)	FE	0.030*
Renal failure	13(43.29%)	10(33.3)	0.282	0.595
Cerebral Haemorrhage	0 (0.0%)	2 (6.7%)	FE	0.150
Cerbral Strock	9 (30.0%)	3 (10.0%)	FE	0.053
Vent.Tachy	14 (46.7%)	13 (43.3%)	x^2=0.019	0.889
Atrial Tach	5 (16.7%)	1 (3.3%)	FE	0.085
Brady arrhythmia	4 (13.3%)	1 (3.3%)	FE	0.350
Reinfarction&revascularization	2 (6.6%)	3(10%)	FE	0.996
Sepsis	20 (66.7%)	13 (43.3%)	x^2=3.300	0.069
Duration of mechanical support Mean±SD Range	 4.47±2.03 0–9	 3.57±2.39 0–9	U=1.573	0.121
Hospital stay (days) Mean±SD Range	 13.47±11.50 0–42	 9.83±5.47 0–21	U=1.563	0.124

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Using: U=Mann-Whitney test; x^2: Chi-square test; FE: Fisher's Exact

*p-value>0.05 NS; *p-value <0.05 S; **p-value <0.001 HS*

Secondary end point:

Transfusion-related hemorrhagic complications appeared in 13.3 percent of Impella patients vs. 3.3 percent of IABP patients, while surgical management was mandatory in one patient (3.3 percent in impella group). Because of the larger sheath utilized in the Impella group, femoral artery thrombus was 26.7 percent compared to 3.3 percent in the IABP group. Cerebrovascular strock was 30% in Impella vs 10% in IABP, reinfarction and revascularization were 6.6 percent in Impella vs 10.9 percent in the IABP group, and two patients were sent for CABG. Impella had 43.3 percent renal failure compared to 33.3 percent in IABP.

Table (8): Comparison between IMPELLA Group and IABP Group according to mortality.

Mortality	IMPELLA Group (n=30)	IABP Group (n=30)	Test value	p-value
Alive	16 (53.38%)	17 (56.71%)	0.066	0.797
Death	14 (46.62%)	13 (43.29%)		

Using: FE: Fisher's Exact

The primary endpoint which was death at one month. It was 46% for Impella vs 43% for IABP .

DISCUSSION

CS occurs in 5% to 15% of subjects with AMI in current practice, and it's still linked with substantial in-hospital death rates ranging from 27% to 51 %.(1, 5,7,22) According to European Society of Cardiology protocols, IABP is helpful for management of cases who require mechanical assistance and is suggested with a class IIa recommendation. (8, 23) In cases with CS, current IABP utilization ranges from 11 percent to 86 percent. (1, 11, 19, 24, 25)

However, no data from randomized controlled studies has demonstrated that IABP improves survival. However, its efficacy still inconclusive. (10,26,27)

Ventricular assist devices (VADs) are a recent option for cases with CS because they cause hemodynamic support by replacing LV activity, potentially allowing stunned myocardium to recover. Surgical LVADs, on the other hand, usually necessitate lengthy and difficult insertion techniques. They are linked with a higher complications and death rate, and their invasiveness prevents them from being implanted right away in cases with acute CS. (28–30)

As a result, percutaneous devices have been created, such as the Impella-2.5 system in the EURO SHOCK registry, Impella CP in the IMPRESS severe shock trial, and Impella CP was used in our study. The Impella-2.5 and CP, in comparison to other percutaneous devices, is a low invasive system that allow introduction of transcatheter rapidly using normal catheterization methods and provide a maximum pump flow up to 4.0 L/min in CP. A larger version of the

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Impella system is also present enabling a highest flow rate of 5.0 L/min. This device, however, necessitates a surgical cut-down of the femoral artery. The Impella- CP is safe and effective in both elective and non-elective high-risk PCI procedures.

It has been shown that LV unloading enhances myocardial healing and reduces diastolic LV wall stress and pulmonary capillary wedge pressure immediately. (17, 18,31)

Moreover, in the experimental context, the device improved brain perfusion following cardiac arrest. (32)

However, studies on the Impella efficacy in cases with CS are currently few. Limited researches showed that the device increased cardiac index but did not affect survival. (18)

The data from the Impella–EUROSHOCK–registry, which is the largest study till now evaluating emergency support with the Impella-2.5–device for management of CS in 120 cases. Although survival rates in cases with CS differ in the present study, the 30-day survival rate for the EUROSHOCK registry was 35.8%, which looks quite low, and 54 percent for IMPRESS (for Impella and IABP) in our research was 54 percent for Impella and 57 percent for IABP. (6,18,34,35)

The death rate is 46% for Impella vs 43% for IABP in our study illustrated by selection bias that favors severely sick individuals with a bad hemodynamic status. Patients in our study had a worse hemodynamic profile during device implantation than those in the Impella–EUROSHOCK-registry, with lower SBP and DBP (91.21 and 57.17 mm Hg) vs. (SBP 80.7 in Impella group and 81.2 percent in IABP group, DBP 51,2 in Impella group and 52.3 in IABP group). (18)

In comparison to other studies, a higher percentage of patients had been resuscitated for cardiac arrest (30% in Impella vs 16.7% in IABP), PCWP was higher in Impella group (26.7 vs 23.5 in IABP), higher vasopressors dose in Impella group, cardiac index was lower in Impella group (2.6 vs 3.2 for IABP), plasma lactate levels were higher (9.03 vs 6.6) .

In our study, the EF was 24.9in the Impella group vs 30.0 in the IABP group, and it was 27 percent in the EURO SHOCK group, indicating that the complexity of coronary lesions was considerable. In the Impella group, 60 percent had LM and 50 percent had MVD, compared to 26.7 percent LM and 10% MVD in the other group.

The length of support was (107 hours for Impella, 85 hours for IABP, range 0-216 hours vs 43.5 hours in the EUROSHOCK trial.

The 2ry end point rate of device related problems was minimal, however, it is more than happened in non-emergent pLVAD indications. (14)

Bleeding needing blood transfusion was 13.3% of Impella cases vs. 3.3 percent of IABP cases (24.2 percent of EUROSHOCK patients), operative management of hemorrhagic complications was needed in one case (3.3%) vs. 5 (4.2%) EUROSHOCK patients. Because of the larger sheath utilized in the Impella group, femoral artery thrombus was 26.7 percent in the Impella group vs. 3.3 percent in the IABP group. Cerebrovascular stroke was 30% in Impella vs 10% in IABP (4%

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in IMPRESS registry), reinfarction and revascularization were 6.6 percent in Impella vs 10.9 percent in IABPgroup (6.7 percent infarct, re PCI 10.8% in IMPRESS), and 2 cases needed CABG in our research, which was the same as in IMPRESS. Impella had 43.3 percent renal failure compared to 33.3 percent in the IABP group (31.7 percent in EUROSHOCK vs 33 percent in IMPRESS).

When compared to the Tandem Heart pLVAD, the Impella-2.5 and CP therapy has a low complication rate. (35,37)

Clinical Implications

Outside of controlled trials, the study reflects worldwide usage of the Impella in modern practice. Depending on these findings, it is now only used in individuals with unresponsive CS who have not responded to 1stline treatment. This is due to a rare data indicating a clinical advantage from these devices, as well as existing protocols that prescribe IABP as the 1stline management for cases who require mechanical assistance.(38,39) Another difficulty is that pLVADs are more expensive and not available as IABP treatment.(25)

The current study shows that Impella-CP insertion is feasible and simple in cases who require immediate hemodynamic support. This sort of hemodynamic support, which is not based on randomized studies, should be used early in cases who do not respond to 1st line treatment. Moreover, lactic acid concentration at the moment of implantation has a predictive value and can be used to predict reduced perfusion, also PCWP, cardiac index and severely impaired LVEF which can help with treatment selection in our study we used to insert Impella in patients with severely poor hemodynamics. A considerable reduction in lactic acid concentration following the start of Impella therapy indicates partial recovery of perfusion and confirms the device's hemodynamic efficacy. These results are consistent with information found in the literature. (39)

Subjects with persistent elevated plasma lactate concentrations on Impella support may be considered using powerful assist devices (Impella 5.0), which was not available in our facility, therefore we used ECMO in 23.3 percent in the Impella group vs. 10% in the IABP group. (36)

The current study found no evidence of a survival benefit for cases who used other devices. This could be due to the limited number of cases and the presence of other factors like the time delay connected with the upgrading decision.

Our study is limited by the minimal number of cases. To determine the usefulness of PMCS in cases with CS following an AMI, adequately powered randomised clinical trials are required.

CONCLUSIONS

Routine therapy with PMCS was not linked with decreased one month death rate in cases with CS aggravating AMI in this exploratory research.

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