Impella CP vs. IABP in AMI with Cardiogenic Shock

On behalf of the IMPRESS in Severe Shock Trial investigators

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Grant/Research Support

Company

- Abiomed Inc
- Abbott Vascular
- Biotronik
- BBraun



Background

- Cardiogenic shock
 - 10% of STEMI patients
- Treatment
 - Vasopressors or inotropic agents
 - Mechanical assist device





Background

• Impella:

- Increase cardiac output
- Unloading left ventricle
 - Increase coronary blood flow

Percutaneous LV Impella family

- Impella 2.5 (2.5 L/min)
- Impella CP (3.7 L/min)
- Impella 5.0 (5.0 L/min, surgical)





Background

• AIM:

 Compare IABP with Impella CP in mechanically ventilated cardiogenic shock patients after acute myocardial infarction







Design

Patients

STEMI with cardiogenic shock on Mechanical Ventilation

Design

International, 2 center, randomized, open label trial

• Funding

Academic Medical Center (Amsterdam, Netherlands) and

Haukeland University Hospital (Bergen, Norway)







- Inclusion criteria:
 - STEMI with primary PCI
 - Cardiogenic shock (BP < 90 mmHg OR the need for inotropes to remain BP > 90 mmHg)
 - Mechanical ventilation
- Exclusion criteria:
 - Severe aorta-iliac arterial disease
 - Known severe aortic valve disease
 - Known concomitant disease with life expectance < 1 year
 - CABG in past week





- Randomization before of directly after pPCI
- Informed consent after randomization
 - according to local protocol
 - Legal representative
 - Patient (after recovery)
- DSMB after each 10 patients



- Cross-over
 - Not allowed
- Revascularization
 - Immediate or staged PCI of non-culprit lesions left to operators discretion
- Duration of support:
 - Discretion of treating physician



- Primary outcome
 - 30 day mortality
- Secondary outcome
 - 6 month mortality
- Sample size
 - Estimated 35% absolute difference in survival rates
 - Superiority design, 80% power, $\alpha = 5\%$ (2-sided)
 - Interim analysis n=32, allowing increase sample size





Trial Flow Chart





Patient characteristics

	Impella CP n = 24	IABP n = 24
Age (years), n/n (%)	58 ± 9	59 ± 11
Male sex, n/n (%)	18/24 (75)	20/24 (83)
Hemodynamic variables before randomization		
Heart rate (beats/min)	81 ± 21	83 ± 28
Systolic blood pressure	81 ± 17	84 ± 19
Diastolic blood pressure	58 ± 22	57 ± 13
Prior myocardial infarction, n/n (%)	1/22 (5)	1/23 (4)
Catecholamines or inotropes, n/n (%)	24/24 (100)	22/24 (92)
Mechanical ventilation, n/n (%)	24/24 (100)	24/24 (100)
Cardiac arrest before randomization, n/n (%)	24/24 (100)	20/24 (83)
Witnessed arrest, n/n (%)	22/24 (92)	17/20 (85)
First rhythm VT/VF, n/n (%)	22/24 (92)	17/20 (85)
Time till return of spontaneous circulation (min)	21 [15-46]	27 [15-52]
Traumatic injuries at admission, n/n (%)	5/24 (21)	2/24 (8)
Blood values on admission		
Lactate (mmol/L)	7.5 ± 3.2	8.9 ± 6.6
Glucose (mmol/L)	16.2 ± 4.7	14.1 ± 5.3
Arterial pH	7.14 ± 0.14	7.17 ± 0.17



Procedural characteristics

	Impella CP n = 24	IABP n = 24
Moment of device placement		
Device placement before revascularization, n/n (%)	5/24 (21)	3/24 (13)
Device placement after revascularization, n/n (%)	19/24 (80)	21/24 (88)
Infarct-related artery, n/n (%)		
Left main	1/24 (4)	2/24 (8)
Left anterior descending	16/24 (67)	15/24 (63)
Left circumflex	6/24 (25)	3/24 (13)
Right coronary artery	1/24 (4)	4/24 (17)
Multi-vessel disease	15/24 (63)	21/24 (88)
Stent placement	23/24 (96)	24/24 (100)
Drug-eluting stent, n/n (%)	22/23(96)	22/24 (98)
Bare Metal Stent, n/n (%)	1/23 (4)	2/24 (8)
TIMI flow pre-PCI, n/n (%)		
0 or 1	20/24 (83)	20/24 (83)
TIMI flow post-PCI, n/n (%)		. ,
2 or 3	23/24 (96)	24/24 (100)
Syntax score pre-PCI	23.2 ± 8.7	28.2 ± 10.6

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Clinical course

	Impella CP n = 24	IABP n = 24
Mechanical circulatory support		
Duration of support (hours)	49 [28-76]	48 [24-77]
Crossover or upgrading to device with more support, n/n (%)	1/24 (4.2)	3/24 (12.5)
Mechanical ventilation		
Patients treated, n/n (%)	24/24 (100)	24/24 (100)
Duration (days since device placement)	4 [3-9]	4 [3-10]
Catecholamines		
Patients treated, n/n (%)	24/24 (100)	24/24 (100)
Number of days (days)	3 [2-6]	3 [2-5]
Inotropic therapy (dobutamine)		
Patients treated, n/n (%)	6/24 (25)	9/24 (38)
Number of days (days)	0 [0-1]	0 [0-2]
Renal replacement therapy, n/n (%)	8/24 (33)	7/24 (29)
Therapeutic hypothermia, n/n (%)	19/24 (79)	17/24 (71)
Blood products during admission, n/n (%)	11/24 (46)	8/24 (33)
Placement of ICD, n/n (%)	2/24 (8)	1/24 (4)
Days on Intensive care unit	7 [3-16]	7 [4-10]
Days of hospital admission	16 [3-26]	10 [6-24]

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Primary Endpoint







Clinical outcomes

	Impella CP n = 24	IABP n = 24
Cause of death		
Refractory cardiogenic shock	4 (17)	3 (13)
Post-anoxic neurological death	5 (21)	6 (25)
Other reason	3 (13)	3 (13)
Ischemic stroke	1 (4)	1 (4)
Major vascular complication	1 (4)	0 (0)
Major bleeding	8 (33)	2 (8)
Device related bleeding	3 (13)	1 (4)
Retroperitoneal	1 (4)	0 (0)
IABP/Impella puncture site	2 (8)	1 (4)
Non-device related bleeding	5 (21)	1 (4)
Gastro-intestinal bleeding	0 (0)	1 (4)
Bleeding at other puncture site	1 (4)	0 (0)
Other location	4 (17)	0 (0)
Hemolysis requiring extraction of the device	2 (8)	0 (0)
Surgical LVAD placement	0 (0)	1 (4)
Heart transplantation	0 (0)	0 (0)
Re-hospitalization	5 (21)	1 (4)
Cardiac	2 (8)	0 (0)
Non-cardiac	3 (13)	1 (4)



Discussion

- No difference in 30-day and 6-month mortality between Impella CP and IABP treated patients
- Major limitation:
 - underpowered trial
 - Interim analysis @32 pt: adaptation not meaningfull
 - Complete study as an exploratory study





Discussion

Unselected patient population:

- Cardiac arrest (92%)
- ROSC > 20 minutes (48%)
- Traumatic injuries (15%)

• Trend toward:

- more upgrading/crossover in the IABP group (1 versus 3)
- More bleeding in Impella patients (8 versus 2)





Meta-analysis

- Cardiogenic shock after STEMI
- 3 RCTs (n=95)
- Impella (n=49) versus IABP (n=46)





Seyfarth et al. J Am Coll Cardiol 2008;52:1584-1588 Ouweneel et al. Int J Cardiol 2016a;202:894-6 Ouweneel et al. J Am Coll Cardiol 2016b.



Conclusion

In this explorative study Impella CP was not associated with lower 30day mortality in AMI patients with cardiogenic shock



