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SHORT COMMUNICATION

# Impella CP use in patients with non-ischaemic cardiogenic shock

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## Abstract

**Aims** From the various mechanical cardiac assist devices and indications available, the use of the percutaneous intraventricular Impella CP pump is usually restricted to acute ischaemic shock or prophylactic indications in high-risk interventions. In the present study, we investigated clinical usefulness of the Impella CP device in patients with non-ischaemic cardiogenic shock as compared with acute ischaemia.

**Methods and results** In this retrospective single-centre analysis, patients who received an Impella CP at the University Hospital Würzburg between 2013 and 2017 due to non-ischaemic cardiogenic shock were age-matched 2:1 with patients receiving the device due to ischaemic cardiogenic shock. Inclusion criteria were therapy refractory haemodynamic instability with severe left ventricular systolic dysfunction and serum lactate >2.0 mmol/L at implantation. Basic clinical data, indications for mechanical ventricular support, and outcome were obtained in all patients with non-ischaemic as well as ischaemic shock and compared between both groups. Continuous variables are expressed as mean ± standard deviation or median (quartiles). Categorical variables are presented as count and per cent. Twenty-five patients had cardiogenic shock due to non-ischaemic reasons and were compared with 50 patients with cardiogenic shock due to acute myocardial infarction. Resuscitation rates before implantation of Impella CP were high (32 vs. 42%; $P = 0.402$). At implantation, patients with non-ischaemic cardiogenic shock had lower levels of high-sensitive troponin T (110.65 [57.87–322.1] vs. 1610 [450.8–3861.5] pg/mL; $P = 0.001$) and lactate dehydrogenase (377 [279–608] vs. 616 [371.3–1109] U/L; $P = 0.007$), while age (59 ± 16 vs. 61.7 ± 11; $P = 0.401$), glomerular filtration rate (43.5 [33.2–59.7] vs. 48 [35.75–69] mL/min; $P = 0.290$), C-reactive protein (5.17 [3.27–10.26] vs. 10.97 [3.23–17.2] mg/dL; $P = 0.195$), catecholamine index (30.6 [10.6–116.9] vs. 47.6 [11.7–90] μg/kg/min; $P = 0.663$), and serum lactate (2.6 [2.2–5.8] vs. 2.9 [1.3–6.6] mmol/L; $P = 0.424$) were comparable between both groups. There was a trend for longer duration of Impella support in the non-ischaemic groups (5 [2–7.5] vs. 3 [2–5.25] days, $P = 0.211$). Rates of haemodialysis (52 vs. 47%; $P = 0.680$) and transition to extracorporeal membrane oxygenation (13.6 vs. 22.2%; $P = 0.521$) were comparable. No significant difference was found regarding both 30 day survival (48 vs. 30%; $P = 0.126$) and in-hospital mortality (66.7 vs. 74%; $P = 0.512$), although there was a trend for better survival in the non-ischaemic group.

**Conclusions** These data suggest that temporary use of the Impella CP device might be a useful therapeutic option for bridge to recovery not only in ischaemic but also in non-ischaemic cardiogenic shock.

**Keywords** Impella; Non-ischaemic cardiogenic shock

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## Introduction

The Impella CP device (Abiomed, Danvers, MA) is indicated for short-term left ventricular mechanical support (≤4 days) in cardiogenic shock due to acute myocardial infarction (AMI) or planned cardiac surgery.[1] Current guidelines indicate a class IIb recommendation in patients with therapy refractory cardiogenic shock in ST-segment elevation myocardial infarction, due to little knowledge on survival benefits.[2] Even less is known regarding use of the Impella CP in patients with

shock due to non-ischaemic origin. Limited time of operation and missing options for blood oxygenation might favour the use of alternative assist devices such as extracorporeal membrane oxygenation (ECMO) or tandem heart in these indications. However, the minimally invasive nature of Impella therapy and effective ventricular unloading, as compared with increased afterload in ECMO therapy, might in fact favour Impella CP use for bridge-to-recovery or destination therapy in such patients. The aim of this study was to investigate the role of Impella CP support in patients with non-ischaemic cardiogenic shock as compared with shock in AMI.

## Methods

This single-centre retrospective case–control study investigated patients who received an Impella CP device due to acute non-ischaemic cardiogenic shock. Inclusion criteria were therapy refractory haemodynamic instability with severe left ventricular systolic dysfunction and serum lactate >2.0 mmol/L at implantation, with excluded AMI. Twenty-five patients were included and compared with 50 patients who received an Impella CP due to AMI with shock during the same period. Outcome measures were haemodialysis, ECMO, or left ventricular assist device implantation, heart transplantation, 30 day survival, and overall in-hospital mortality. For the univariate analysis, just one variable was fitting at a time in the logistic regression model in order to find which variable is individually predictive. Univariate predictors were analysed in a multivariate analysis. The odds ratio and 95% confidence interval were determined. Statistical analyses were performed using SPSS Statistics 24 (IBM). Continuous variables are expressed as mean ± standard deviation or median (quartiles). Categorical variables are presented as count and per cent.

## Results

Mean age was 61 ± 13 (range 19–85) years, and 72% were male. Main underlying diseases for cardiogenic shock in the non-ischaemic group were dilated cardiomyopathy ($n$ = 9; 36%), chronic ischaemic cardiomyopathy ($n$ = 2; 7.7%), hypertrophic cardiomyopathy ($n$ = 2; 7.7%), myocarditis ($n$ = 2; 7.7%), catecholamine-induced cardiomyopathy due to pheochromocytoma ($n$ = 1; 3.8%), non-compaction cardiomyopathy ($n$ = 1; 3.8%), takotsubo cardiomyopathy ($n$ = 1; 3.8%), and sarcoidosis ($n$ = 1; 3.8%).

The need for resuscitation before Impella implantation was frequent in both groups (32 vs. 42%; $P$ = 0.402). Patients with non-ischaemic cardiogenic shock had lower serum levels of lactate dehydrogenase (377 [279–608] vs. 616 [371.3–1109] U/L; $P$ = 0.007) as well as high-sensitive troponin T (110.65 [57.87–322.1] vs. 1610 [450.8–3861.5] pg/mL; $P$ = 0.001). Glomerular filtration rate (43.5 [33.2–59.7] vs. 48 [35.75–69] mL/min; $P$ = 0.290), C-reactive protein (5.17 [3.27–10.26] vs. 10.97 [3.23–17.2] mg/dL; $P$ = 0.195),

**Table 1** Clinical characteristics and outcome

| Patient characteristics | Non-ischaemic shock ($n$ = 25) | Myocardial infarction ($n$ = 50) | $P$ |
|---|---|---|---|
| Mean age (years) | 59 ± 16 | 61.7 ± 11 | 0.401 |
| Mean BMI (kg/m$^2$) | 26.5 ± 5.9 | 28.3 ± 5 | 0.247 |
| Resuscitation (%) | 8 (32) | 21 (42) | 0.402 |
| Haemoglobin (g/dL) | 12.2 ± 2.8 | 13.3 ± 2.3 | 0.100 |
| Creatinine (mg/dL) | 1.6 (1.24–2.6) | 1.33 (1.06–1.96) | 0.372 |
| GFR (mL/min/m$^2$) | 43.5 (33.2–59.7) | 48 (35.75–69) | 0.290 |
| CRP (mg/dL) | 5.17 (3.27–10.26) | 10.97 (3.23–17.2) | 0.195 |
| LDH (U/L) | 377 (279–608) | 616 (371.3–1109) | **0.007** |
| HsTNT (pg/mL) | 110.65 (57.87–322.1) | 1610 (450.8–3861.5) | **0.001** |
| pH | 7.33 ± 0.17 | 7.29 ± 0.14 | 0.293 |
| Lactate (mmol/L) | 2.6 (2.2–5.8) | 2.9 (1.3–6.6) | 0.424 |
| Catecholamine index (μg/kg/min) | 30.6 (10.6–116.9) | 47.6 (11.7–90) | 0.663 |
| Catecholamine pressure index | 0.39 (0.13–1.4) | 0.6 (0.18–1.1) | 0.592 |
| Catecholamine index after implant | 30.66 (20.65–78.57) | 33.34 (19.9–69.8) | 0.981 |
| Mean duration of Impella (days) | 5 (2–7.5) | 3 (2–5.25) | 0.211 |
| Mean ventilation time (days) | 3 (1–12) | 3.5 (1–13) | 0.738 |
| Intermittent haemodialysis (%) | 13 (52) | 23 (47) | 0.680 |
| Systolic pressure explant (mmHg) | 85.1 ± 20.5 | 92 ± 24.7 | 0.328 |
| MAP explant (mmHg) | 63.5 ± 20.5 | 68.9 ± 14.1 | 0.243 |
| ECMO (%) | 3 (13.6) | 10 (22.2) | 0.521 |
| LVAD (%) | 1 (4.0) | 3 (6.0) | 1 |
| Heart transplantation (%) | 4 (16) | 0 (0) | **0.010** |
| 30 day survival (%) | 12 (48) | 15 (30) | 0.126 |
| Overall in-hospital mortality (%) | 16 (66.7) | 37 (74) | 0.512 |

BMI, body mass index; CRP, C-reactive protein; ECMO, extracorporeal membrane oxygenation; GFR, glomerular filtration rate; HsTNT, high-sensitive troponin T; LDH, lactate dehydrogenase; LVAD, left ventricular assist device; MAP, mean arterial pressure.


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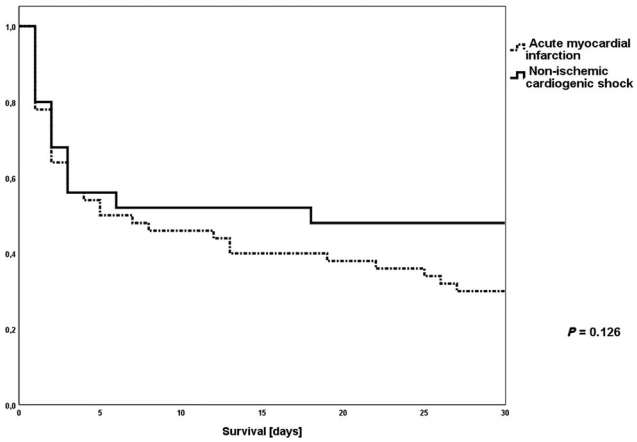
**Figure 1** Thirty day survival in ischaemic vs. non-ischaemic shock




catecholamine index (30.6 [10.6–116.9] vs. 47.6 [11.7–90] μg/kg/min; *P* = 0.663), and serum lactate (2.6 [2.2–5.8] vs. 2.9 [1.3–6.6] mmol/L; *P* = 0.424) were comparable. Almost half of the cohort individuals developed sepsis during hospital stay (52.6 vs. 38.5%; *P* = 0.379). Mean ventilation time (3 [1–12] vs. 3.5 [1–13] days; *P* = 0.738), rates of haemodialysis (52 vs. 47%; *P* = 0.680), and transition to ECMO (13.6 vs. 22.2%; *P* = 0.521) were also comparable, while the non-ischaemic group showed a trend for longer duration of Impella support (5 [2–7.5] vs. 3 [2–5.25] days, *P* = 0.211). No significant difference was found regarding in-hospital mortality (66.7 vs. 74%; *P* = 0.512), although there was a trend for better 30 day survival in the non-ischaemic group (48 vs. 30%; *P* = 0.126) (*Table 1* and *Figure 1*).

Several predictors for mortality were identified including serum lactate, ventilation time, haemoglobin, pH, $SaO_2$, base

**Table 2** Predictors of mortality

| Predictor | Coefficient | SE coefficient | *Z* | *P* | Odds ratio | 95% CI | |
|---|---|---|---|---|---|---|---|
| | | | | | | Lower | Upper |
| Acute myocardial infarction | | | | | | | |
| Lactate (mmol/L) | 0.100 | 0.040 | 6.270 | **0.012** | 1.106 | 1.022 | 1.196 |
| Ventilation (days) | 0.054 | 0.023 | 5.369 | **0.020** | 0.947 | 0.905 | 0.992 |
| Haemoglobin (g/dL) | 0.356 | 0.098 | 0.854 | **0.001** | 1.427 | 1.178 | 1.728 |
| pH | 4.469 | 1.468 | 9.265 | **0.002** | 0.011 | 0.001 | 0.204 |
| SaO2 (%) | 0.066 | 0.029 | 5.178 | **0.023** | 0.936 | 0.885 | 0.991 |
| BE (mmol/L) | 0.066 | 0.039 | 2.838 | 0.092 | 0.937 | 0.868 | 1.011 |
| Glucose (mg/dL) | 0.001 | 0.001 | 2.360 | 0.124 | 1.001 | 1.000 | 1.003 |
| Bleeding anaemia | 1.048 | 0.455 | 5.307 | **0.021** | 0.351 | 0.144 | 0.855 |
| Resuscitation | 0.939 | 0.363 | 6.674 | **0.010** | 2.557 | 1.254 | 5.212 |
| Sepsis | 0.386 | 0.533 | 0.524 | 0.469 | 1.471 | 0.517 | 4.183 |
| Impella time (days) | 0.308 | 0.110 | 7.903 | **0.005** | 0.735 | 0.592 | 0.911 |
| MAP | 0.058 | 0.016 | 13.152 | **0.001** | 0.944 | 0.915 | 0.974 |
| Non-ischaemic cardiogenic shock | | | | | | | |
| Lactate (mmol/L) | 0.114 | 0.088 | 1.692 | 0.193 | 1.121 | 0.944 | 1.332 |
| Ventilation (days) | 0.152 | 0.075 | 4.119 | **0.042** | 0.859 | 0.742 | 0.995 |
| Haemoglobin (g/dL) | 0.278 | 0.232 | 1.438 | 0.231 | 1.321 | 0.838 | 2.081 |
| pH | 1.940 | 1.899 | 1.044 | 0.307 | 0.144 | 0.003 | 5.936 |
| SaO2 (%) | 0.057 | 0.042 | 1.888 | 0.169 | 0.944 | 0.870 | 1.025 |
| BE (mmol/L) | 0.049 | 0.042 | 1.330 | 0.249 | 0.952 | 0.876 | 1.035 |
| Glucose (mg/dL) | 0.006 | 0.003 | 3.324 | 0.068 | 1.006 | 1.000 | 1.013 |
| Bleeding anaemia | 12.059 | 8.838 | 0.001 | 0.975 | 0.320 | 0.123 | 0.715 |
| Resuscitation | 0.365 | 0.579 | 0.399 | 0.528 | 1.441 | 0.464 | 4.480 |
| Sepsis | 1.090 | 0.734 | 2.205 | 0.138 | 2.975 | 0.705 | 12.545 |
| Impella time (days) | 0.962 | 0.333 | 8.357 | **0.004** | 0.382 | 0.199 | 0.734 |
| MAP | 0.040 | 0.019 | 4.575 | **0.032** | 0.961 | 0.926 | 0.997 |
| Total group | | | | | | | |
| Lactate (mmol/L) | 0.118 | 0.038 | 9.924 | **0.002** | 1.125 | 1.046 | 1.211 |
| Ventilation (days) | 0.057 | 0.022 | 6.951 | **0.008** | 0.944 | 0.905 | 0.985 |
| Haemoglobin (g/dL) | 0.131 | 0.067 | 0.854 | **0.050** | 1.140 | 1.000 | 1.299 |
| pH | 3.634 | 1.134 | 10.276 | **0.001** | 0.026 | 0.003 | 0.244 |
| SaO2 (%) | 0.063 | 0.0237 | 0.586 | **0.006** | 0.939 | 0.898 | 0.982 |
| BE (mmol/L) | 0.063 | 0.0285 | 0.233 | **0.022** | 0.939 | 0.889 | 0.991 |
| Glucose (mg/dL) | 0.002 | 0.001 | 5.136 | **0.023** | 1.002 | 1.000 | 1.003 |
| Bleeding anaemia | 1.078 | 0.445 | 5.860 | **0.015** | 0.340 | 0.142 | 0.815 |
| Resuscitation | 0.807 | 0.2967 | 0.447 | **0.006** | 2.241 | 1.255 | 4.002 |
| Sepsis | 0.847 | 0.421 | 4.047 | **0.044** | 2.334 | 1.022 | 5.329 |
| Impella time (days) | 0.431 | 0.099 | 18.905 | **0.000** | 0.650 | 0.535 | 0.789 |
| MAP | 0.120 | 0.069 | 6.665 | **0.002** | 0.941 | 0.916 | 0.987 |

BE, base excess; CI, confidence interval; MAP, mean arterial pressure.

excess, glucose, bleeding anaemia, resuscitation, sepsis, and Impella time (*Table 2*). From the patients with non-ischaemic cardiogenic shock and without mechanical device support (ECMO and left ventricular assist device) or transplantation, only 24% (six from 25) survived. In the resuscitation group, only 21% (six from 29) survived, compared with 36% in the total cohort (27 from 75).

## Conclusions

Thirty day mortality in our study generally was high, mainly driven by post-resuscitation mortality. However, overall survival rates were similar to those found in recent large shock trials.[3–5] Our current data suggest that benefit of Impella CP therapy might be similar in non-ischaemic compared with ischaemic shock. Moreover, a substantial percentage of patients without acute ischaemia recovered without further need for intensified haemodynamic mechanical support. Of note, a relatively large proportion of patients in the non-ischaemic cohort initially suffered from chronic cardiomyopathies. Here, several alternatives for bridge-to-recovery or destination therapy are available. Just recently, feasibility of the larger Impella 5.0 in bridge-to-heart transplantation was demonstrated.[6] The current results position short-time use of the Impella CP as an alternative in the treatment of patients with cardiogenic shock due to underlying non-ischaemic cardiomyopathy and/or complicating additional factors. However, additional studies are needed to test whether these findings can be confirmed in larger patient populations and which subgroups might benefit most from Impella therapy.

## Conflict of interest

None declared.

## References


1. Lemaire A, Anderson MB, Lee LY, Scholz P, Prendergast T, Goodman A, Lozano AM, Spotnitz A, Batsides G. The Impella device for acute mechanical circulatory support in patients in cardiogenic shock. *Ann Thorac Surg* 2014 Jan; **97**: 133–138.
2. O'Gara PT, Kushner FG, Ascheim DD, Casey DE Jr, Chung MK, de Lemos JA, Ettinger SM, Fang JC, Fesmire FM, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX, American College of Cardiology F, American Heart Association Task Force on Practice G, American College of Emergency P, Society for Cardiovascular A, Interventions. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the American College of Emergency Physicians and Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv* 2013; **82**: E1–E27.
3. Thiele H, Akin I, Sandri M, Fuernau G, de Waha S, Meyer-Saraei R, Nordbeck P, Geisler T, Landmesser U, Skurk C, Fach A, Lapp H, Piek JJ, Noc M, Goslar T, Felix SB, Maier LS, Stepinska J, Oldroyd K, Serpytis P, Montalescot G, Barthelemy O, Huber K, Windecker S, Savonitto S, Torremante P, Vrints C, Schneider S, Desch S, Zeymer U, Investigators C-S. PCI strategies in patients with acute myocardial infarction and cardiogenic shock. *N Engl J Med* 2017; **377**: 2419–2432.
4. Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J, de Waha A, Richardt G, Hennersdorf M, Empen K, Fuernau G, Desch S, Eitel I, Hambrecht R, Lauer B, Bohm M, Ebelt H, Schneider S, Werdan K, Schuler G. Intraaortic balloon pump in cardiogenic shock IIti. Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomised, open-label trial. *Lancet* 2013; **382**: 1638–1645.
5. Hochman JS, Sleeper LA, Webb JG, Sanborn TA, White HD, Talley JD, Buller CE, Jacobs AK, Slater JN, Col J, McKinlay SM, LeJemtel TH. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. SHOCK Investigators (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock). *N Engl J Med* 1999; **341**: 625–634.
6. Lima B, Kale P, Gonzalez-Stawinski GV, Kuiper JJ, Carey S, Hall SA. Effectiveness and safety of the Impella 5.0 as a bridge to cardiac transplantation or durable left ventricular assist device. *Am J Cardiol* 2016; **117**: 1622–1628.