Acute Cardiac Unloading and Recovery

Abstracts from the 4th Annual Acute Cardiac Unloading and REcovery (A-CURE) symposium held on 30 August 2019 in Paris, France

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A1  
Percutaneous Axillary Access for Mechanical Circulatory Support in Complex Higher-risk Indicated Procedures (CHIP)  
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A1.  
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Background: Patients with complex coronary disease, suboptimal haemodynamics and severe peripheral arterial disease (PAD) represent a uniquely challenging subset, as the often-required mechanical circulatory support (MCS) cannot be delivered via femoral access. Percutaneous axillary access provides an alternative access site for MCS in high-risk patients with severe PAD.  

Clinical Case: An elderly man with heart and liver failure presented with chest pain and a non-ST-elevation MI, coronary angiography showed severe left main (LM), left anterior descending (LAD), ramus and right coronary artery (RCA) disease, as well as a chronic total occlusion of the left circumflex coronary artery. Aortography showed an occluded distal aorta. After a heart team discussion, it was decided to pursue percutaneous axillary access for MCS using Impella CP to deliver complete revascularisation. Left radial artery access was used to manage the axillary access site and right radial access was the primary access for coronary intervention. Successful intravascular ultrasound-guided percutaneous coronary intervention of the LM, LAD, ramus and RCA arteries was performed, and the Impella was explanted at the end of the procedure after a successful weaning trial.  

Discussion: The axillary artery is a safe and feasible alternative percutaneous access site for large-bore devices in patients with prohibitive peripheral arterial disease. Explanation of axillary Impella is feasible and access site complications can be managed with appropriate planning.  

A2  
Admission Glucose Level is an Independent Predictor of Coronary No-reflow Phenomenon in Patients with STEMI  
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A2.  
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Background: Coronary no-reflow phenomenon is a well-known complication that is associated with poor prognosis in patients with ST-elevation MI (STEMI). However, the pathophysiology of no-reflow is complicated and it is challenging to develop effective treatment strategies. In this study, we aimed to reveal the association between admission glucose level and coronary no-reflow in patients with STEMI treated by primary percutaneous coronary intervention (PCI).  

Methods: We chose patients with STEMI who were treated by primary PCI. No-reflow was defined by angiographic TIMI flow grade ≤2. Univariable and multivariable logic regression analysis was used to reveal the association between predictors and no-reflow phenomenon.  

Results: A total of 542 patients were selected (mean age 60 ± 14 years, men 84%). After primary PCI, coronary no-reflow developed in 48 patients (8.9%). Univariable logic regression revealed the possible predictors of coronary no-reflow phenomenon as age (OR 1.04, 95% CI [1.02–1.06], p<0.001), systolic blood pressure (OR 0.99, 95% CI [0.98–0.99], p<0.01), diastolic blood pressure (OR 0.99, 95% CI [0.98–0.99], p<0.05), current smoker (OR 0.56, 95% CI [0.30–1.05], p=0.07), admission glucose level (OR 1.07, 95% CI [1.03–1.11], p<0.001), total occlusion (OR 1.92, 95% CI [0.93–3.95], p=0.08) and culprit artery initial TIMI flow grade (OR 0.67, 95% CI [0.46–0.97], p<0.05). After adjustment for these variables, age (OR 1.05, 95% CI [1.03–1.11], p<0.001), systolic blood pressure (OR 0.98, 95% CI [0.96–0.99], p=0.05) and admission glucose level (OR 1.07, 95% CI [1.02–1.12], p<0.01) were independent predictors of coronary no-reflow phenomenon.  

Conclusion: Pathophysiology of coronary no-reflow phenomenon after primary PCI is multifactorial. Admission glucose level is an independent and strong predictor of coronary no-reflow in patients with STEMI.  

A3  
Veno-arterial ECMO Versus Impella™ Bleeding Complications in Cardiogenic Shock Patients on Dual Antiplatelet Therapy  
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Background: A selective group of patients, presenting with INTERMACS-1 cardiogenic shock due to acute ischaemic heart failure, can be considered for mechanical circulatory support (MCS). Patients with biventricular failure, severe septic shock or oxygenation problems should be selected for veno-arterial extracorporeal membrane
We report single-centre data for 51 VA-ECMO and eight Impella patients between 2011 and 2019. Indication for MCS was acute ischaemic cardiogenic shock. Patient demographics, blood product transfusions and reported or radiographically diagnosed bleeding (BARC classification) complications were analysed. All patients received UFH and low-dose aspirin plus clopidogrel or ticagrelor. Impella CP flow was at least 2.5 l/min. Targets were haemoglobin 7 g/dl, fibrinogen 100 mg/dl (or 150 mg/dl when active bleeding) and platelet counts >50/µl.

Results: Patients supported by Impella were significantly older compared to the VA-ECMO group (VA-ECMO 52.8 years versus Impella 62.4 years; p=0.02). UFH levels and length of the MCS run were comparable in both groups. Total haemorrhage was comparable between both groups (mainly oozing from the insertion site in the Impella group; 63% versus VA-ECMO 72%; not significant), but major bleeds with BARC score ≥3 were significantly lower in the triple anticoagulated Impella group (DAPT 13% versus VA-ECMO 65%; p=0.005). Platelet and red blood cell transfusions were significantly lower in the Impella group (0.1 unit per day versus VA-ECMO 1.1, p=0.002, and 0.8 units per day versus VA-ECMO 2.6, p=0.02, respectively). Fresh frozen plasma transfusion rate was comparable.

Conclusion: Haemorrhage is frequent during extracorporeal support. However, in our cohort, triple anticoagulation in acute cardiogenic shock due to left ventricle failure resulted in a lower major bleeding rate when support was given by the left Impella device compared with VA-ECMO therapy. As a result, platelet and red blood cell transfusions were lower in the Impella group. These findings are probably partly explained by increased bleeding risk due to the cannula sizes and increased risk of consumptive coagulopathy due to the complexity and extensive foreign body surface of the ECMO circuit. We conclude that Impella support should be considered first choice in patients with indication for triple anticoagulant therapy and necessitating MCS towards recovery or other destination therapy.

A5 Completeness of Culprit Artery Flow Restoration is an Independent Long-term Prognostic Marker of Patients with Cardiogenic Shock Complicating STEMI

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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A5.

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Background: Regardless of the remarkable success rates of primary percutaneous coronary intervention (PCI) for patients with ST-elevation MI (STEMI) in recent decades, there remains a substantial number of patients who do not reach complete coronary flow restoration after primary PCI. In this study, we attempted to examine impact coronary flow restoration on long-term prognosis of patients with cardiogenic shock (CS) complicating STEMI.

Methods: We prospectively included patients with CS complicating STEMI who were treated by primary PCI. Degree of coronary flow restoration was evaluated by angiographic TIMI flow grade. All the patients were followed-up until occurrence of death or end of follow-up period. Kaplan–Meier estimation was used to reveal impact of coronary flow restoration after primary PCI and long-term prognosis.

Results: A total of 59 patients with CS complicating STEMI were selected. The mean age was 60 ± 13 years and the majority were...
men (n=49, 83%). The median follow-up duration was 19.6 months (interquartile range 5.3; 39.6). After primary PCI, complete coronary flow restoration (TIMI 3) was achieved in 46 patients (78%), and 13 patients (22%) had incomplete coronary flow restoration (TIMI ≤2). All-cause mortality during the follow-up period was more likely to be higher in patients who had incomplete coronary flow restoration compared with complete coronary flow restoration (61.5% versus 19.6%, p=0.003). After adjustment for age, culprit vessel, culprit vessel stenosis severity and multivessel disease, only completeness of coronary flow restoration was an independent predictor of long-term prognosis in patients with CS complicating STEMI (HR 0.41, 95% CI [0.22–0.79], p=0.007). Kaplan–Meier analysis showed that patients who had complete coronary flow restoration (TIMI 3) had a significant survival advantage compared with incomplete coronary flow restoration groups (log-rank p<0.001).

Conclusion: Culprit artery flow restoration after primary PCI is an independent long-term marker in patients with CS complicating STEMI, and those patients have a survival advantage compared with incomplete coronary flow restoration.

A6 Mechanical Thrombectomy in Combination with Glycoprotein IIb/IIIa Inhibitors with or without Stent Implantation in Patients Presenting with STEMI and High Thrombus Burden

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Background: High thrombus burden is an independent risk factor for death and complications, including no reflow, during primary percutaneous coronary intervention (PCI) for ST-elevation MI (STEMI).

Hypothesis: The aim was to investigate whether a strategy of mechanical thrombectomy in combination with glycoprotein IIb/IIIa inhibitors without stent implantation is associated with a reduced incidence of no-reflow phenomenon and other thrombotic complications compared with stenting in patients with high thrombus burden.

Methods: A total of 210 patients with STEMI and high thrombus burden treated with mechanical thrombectomy in combination with glycoprotein IIb/IIIa inhibitors with or without stent implantation. Patients were divided into two groups: non-stent PCI group (n=105) and stent PCI group (n=105). We assessed angiographic and electrocardiographic signs of myocardial reperfusion, as well as clinical outcomes. The endpoints were a myocardial blush grade of 0 or 1 (defined as absent or minimal myocardial reperfusion, respectively) and the postprocedural frequencies of a TIMI flow grade of 3, 48 hours after primary PCI, complete resolution of ST-segment elevation immediately after primary PCI, target vessel revascularisation, reinfarction, death and the combination of major adverse cardiac events by 30 days after randomisation. A myocardial blush grade of 0 or 1 occurred in 26.3% of the patients in the stent PCI group and in 17.1% of those in the non-stent PCI group (p<0.05). Complete resolution of ST-segment elevation occurred in 86.6% and 78.2% of patients, respectively (p=0.35). At 30 days, the rate of death of the stent PCI group and non-stent PCI group was 1.7% and 1.0%, respectively (p=0.33), and the rate of adverse events was 12.1% and 2.2%, respectively (p<0.01). The rate of adverse events was 12.1% and 2.2%, respectively (p<0.01).

Conclusion: Mechanical thrombectomy in combination with glycoprotein IIb/IIIa inhibitors without stenting is applicable and effective method in a large majority of patients with MI with ST-segment elevation and high thrombus burden. It results in better reperfusion outcomes than conventional PCI with stent, irrespective of clinical and angiographic characteristics at baseline.

A7 Concept and Design of the Novel, Pulsatile, Pulsatile Left Ventricular Assist Device PERKAT-LV

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Background: Despite developments in cardiology, cardiogenic shock due to left ventricular failure still has a very high morbidity and mortality. Patients suffering from cardiogenic shock often are in need of a temporary mechanical assist device. In addition, we deal with an increasing number of patients who cannot undergo surgical myocardial revascularisation. Those patients could benefit from a protected percutaneous coronary intervention. The available left ventricular assist device systems have specific advantages and disadvantages.

Hypothesis: Our aim is to develop a novel percutaneous, pulsatile assist device that minimises system-specific disadvantages.

Methods: The PERKAT-LV (PERKutane Katheterpumptechnologie) device consists of a self-expanding nitinol pump chamber that is covered by foils. Those foils carry multiple outflow valves at the proximal part of the pump chamber. A flexible suction tube with a pigtail-shaped tip and inflow valves is attached to its distal part. The system is designed for 16 Fr percutaneous implantation via the femoral artery. Pulling back the sheath unfolds the nitinol chamber in the descending aorta while the flexible suction tube bypasses the aortic arch and ascending aorta with the pigtail tip in the left ventricle. A standard intra-aortic balloon pump (IABP) is placed into the pumping chamber and is connected to an external IABP console. Balloon deflation generates a blood flow from the left ventricle into PERKAT-LV. During balloon inflation, blood leaves the system through the outflow valve foils in the descending aorta.

Results: Preliminary in vitro studies have demonstrated the feasibility of PERKAT-LV. Depending on the size of the ball on the IABP, flow rates of more than 2.5 l/min are possible.

Conclusion: The novel percutaneously implantable and pulsatile working PERKAT-LV device offers a circulatory support of more than 2.5 l/min in a first feasibility study. At the moment, the system is being studied in an in vitro series. After this, a first in vivo evaluation will follow. Based on the current results, we believe that the system is a promising new approach and could be used in clinical settings for patients in need of temporary left ventricular mechanical support.
A8
Reversal of MI-induced Changes in Gene Expression by Ventricular Unloading in Rats
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Background: Mechanical unloading of the left ventricle may support the recovery of the myocardium after an ischaemic insult, but the mechanisms underlying this reverse remodelling are largely unclear. Here, we used an unbiased transcriptomic approach to identify potentially relevant genetic pathways involved in reverse remodelling.

Hypothesis: We investigated the hypothesis that reverse cardiac remodelling by ventricular unloading normalises expression of genes deregulated by MI.

Methods: MI was induced by coronary artery ligation in syngenic male Lewis rats (12 weeks of age, n=12). In half of the animals, 6 weeks after coronary artery ligation, the infarcted hearts were mechanically unloaded by heterotropic heart transplantation for a period of 2 weeks. Sham-operated animals served as non-infarcted controls (n=6). Myocardial gene expression was investigated by Affymetrix microarray analysis. Coronary artery ligation led to a reduction of ejection fraction (60 ± 3%, n=12, versus 75 ± 2%, n=12, p<0.01) and left ventricular dilatation (7.9 ± 0.1 mm, n=12, versus 7.0 ± 0.1 mm, n=12, p<0.0001) 6 weeks after the intervention. Out of 10,230 genes investigated ~10% were significantly upregulated (n=182) or downregulated (n=874) after MI. Mechanical unloading normalised the expression of 133 of these genes. Out of those, five genes (Ctnna3, LATS1, Cyr61, Nfat5 and ACE2) are associated with the cardiac Hippo pathway, which has recently been shown to regulate adult cardiomyocyte proliferation and regeneration in human ischaemic heart failure.

Conclusion: Mechanical unloading normalises the expression of ~10% of cardiac genes specifically affected by MI. Modulation of the Hippo pathway may contribute to the beneficial effects of left ventricular unloading of ischaemic hearts.

A9
High-resolution Respirometry Reveals Enhanced Myocardial Mitochondrial Ketone Oxidation after Ventricular Unloading
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Background: Myocardial mitochondrial function is impaired in heart failure. Both ventricular unloading and enhanced ketone body oxidation potentially exert protective effects on myocardial function and mitochondria but have not been linked to each other yet. The gold standard high-resolution respirometry (HRR) has not been used to determine myocardial mitochondrial ketone oxidation as yet.

Hypothesis: We hypothesised that quantification of myocardial ketone-supported oxidative capacity (OC) utilising ex vivo HRR is feasible; and that ketone-associated OC is elevated under conditions of chronic mechanical ventricular unloading.

Methods: We developed new HRR (Oxygraph-2k) protocols, measuring oxygen flux generated by oxidation of the ketone substrates beta-hydroxybutyrate (HBA) and acetacetate (ACA). Ketone protocols were then applied to the left ventricular tissue of 10 C57BL/6 mice and 21 terminal heart failure patients, harvested at heart transplantation. Heart transplant recipients were subdivided into patients with left ventricular assist device prior to transplantation (UNLOAD group, n=9) or no unloading prior to transplantation (CON group, n=12).

Results: In rodent hearts, HBA alone yielded an OC of 25 ± 4 pmol/(s*mg wet tissue) above basal respiration (p<0.0001). When titrated after succinate, ACA increased OC by 93 ± 25 pmol/(s*mg) (p=0.0003). Study participants in UNLOAD and CON had comparable age and sex, while UNLOAD patients tended to have higher BMI (p=0.30, 0.34 and 0.10, respectively). There was no significant group difference in complex I-related or ACA-supported OC (p=0.09 and p=0.53), HBA-supported OC was 41% higher in UNLOAD compared to CON (34 ± 10 versus 48 ± 15 pmol/(s*mg), p=0.03). Overall, mitochondrial coupling efficiency was higher in UNLOAD (1.8 ± 0.6 versus 2.4 ± 0.5, p=0.02).

Conclusion: Quantification of ketone body OC with our novel method revealed increased HBA-supported myocardial mitochondrial respiration in chronically unloaded hearts. Our findings support a concept of cardioprotective effects of ventricular unloading via enhanced ketone oxidation in myocardial mitochondria, thus providing the failing heart an additional substrate as a fuel.

A10
Interleukin-1 Blockade in ST-segment Elevation in MI
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A10.
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Background: ST-segment elevation MI (STEMI) is associated with an intense acute inflammatory response. We tested whether interleukin-1 blockade with anakinra significantly reduced the area under the curve for high-sensitivity C-reactive protein levels (CRP-AUC) at 14 days in patients with STEMI.

Methods: We enrolled patients with STEMI within 12 hours of presentation. They were randomly assigned to anakinra 100 mg once daily (standard dose), anakinra 100 mg twice daily (high dose) or placebo for 14 days in a 1:1:1 ratio. Doppler echocardiography studies were obtained at enrolment and 12 months and appraised by a core laboratory blinded to allocation. A dedicated independent committee adjudicated clinical events, including death (D), new-onset heart
Mir Babar Basir,
During HR-PCI, good-quality PVL acquisition and analysis
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The framework of circulatory equilibrium is capable of
and Daniel Burkhoff
Khaldoon Alaswad,
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guide appropriate MCS device selection for patients who require a
procedure. PVLs were analysed to detect changes in LV contractility
pressures and volumes were measured with a conductance catheter
tertiary centres. Six patients had Impella CP device support. LV
Methods:
Hypothesis:
Background:
Assessment of High-risk Percutaneous Coronary
Intervention Haemodynamics with Pressure–volume Loop Analysis
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Dimitrios Karmpalioitis,2 William O’Neill2 and Daniel Burkhoff1,3
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A11.
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Background: Pressure-volume loops (PVLs) can provide valuable
information about left ventricular (LV) contractility and loading
conditions. Acquiring PVLs in real time during high-risk percutaneous
coronary intervention (HR-PCI) may improve our understanding of
procedural haemodynamic changes and the impact of haemodynamic
support devices.
Hypothesis: We sought to examine the feasibility and utility of PVL
analysis in assessing changes in LV contractility and loading conditions
during HR-PCI performed with and without Impella mechanical
circulatory support (MCS).
Methods: We enrolled nine patients who underwent HR-PCI at two
tertiary centres. Six patients had Impella CP device support. LV
pressures and volumes were measured with a conductance catheter
at different device flow levels and at key timepoints during the
procedure. PVLs were analysed to detect changes in LV contractility
and loading conditions.
Conclusion: During HR-PCI, good-quality PVL acquisition and analysis
was feasible, even in patients with Impella support. PVLs can
detect real-time changes in LV contractility and loading conditions,
including changes related to different procedural manoeuvres (e.g.
balloon inflations). PVL analysis can improve our understanding of the
haemodynamic changes during HR-PCI and potentially guide appropriate MCS device selection for patients who require a
supported HR-PCI.

A12
Upward Shift of Cardiac Output Curve Determined by the Synergistic Effect of Support Flow and Left Ventricular Ejection Fraction is the Fundamental Mechanism to Improve Haemodynamics by Left Ventricular Assist Device
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A12.
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Background: Left ventricular assist device (LVAD), including Impella, has saved the lives of many patients with severe left ventricular (LV) failure. However, it remains poorly understood how LVAD cooperates with LV and determines haemodynamics. The aim of this study is to develop a framework to quantitatively predict the haemodynamic impact of LVAD.
Hypothesis: We developed a circulatory equilibrium framework where we represented both the cardiac output (CO) curve and venous return (VR) surface as a function of the right (PRA) and left atrial pressure (PLA). The intersection between the CO curve and VR surface gives the circulatory equilibrium. LVAD flow (COLVAD) increases arterial pressure independent of CO of LV (COLV), and shifts the COLV curve downward. Adding the shifted COLV curve to COLVAD yields the total CO (COTotal) curve. Theoretical analysis using the framework of ventricular arterial coupling yields COTotal = COLV + COLVAD × LVEF (EF: ejection fraction). In contrast, LVAD does not change the VR surface or right ventricular CO curve. As a result, LVAD increases COTotal and decreases PLA, but does not change PRA.
Methods: We isolated the carotid sinuses to abolish baroreflex in five anaesthetised dogs. After a median sternotomy, we ligated the coronary artery to create LV failure. We inserted LVAD, and measured COTotal, PLA and PRA under various support levels of COLVAD (0–100 ml/kg/min). We determined the parameters of CO curve in each dog and evaluated EF (echocardiogram). Predicted COTotal, PLA and PRA matched well with those measured (SEE 7.98 ml/kg/min, 1.09 mmHg and 0.31 mmHg, respectively; r2 0.93, 0.94 and 0.99, respectively).
Conclusion: The framework of circulatory equilibrium is capable of quantitatively predicting LVAD haemodynamics. The upward shift of the LV CO curve resulting from the synergistic effect of LVAD flow and LVEF is the fundamental mechanism to improve haemodynamics. The proposed framework is useful for the safety and optimal management of Impella.

A13
A Matched-pair Analysis of the Association Between Early Use of Impella CP or IABP and 30-day Mortality in Patients with Acute MI and Cardiogenic Shock
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failure (HF) and hospitalisation for HF (HHF). Log-rank test was used to
compare Kaplan–Meier curves.

Results: We randomly assigned 99 subjects to anakinra once daily
(n=33), anakinra twice daily (n=31) or placebo (n=35). The CRP-AUC was significantly lower in the anakinra group than in the placebo group (67 [39–120] versus 214 [131–394] mg/day/I, p<0.001), without significant differences between the two anakinra arms, p=0.41. No significant differences were found between anakinra and placebo groups in the internal changes in left ventricular end-systolic volume (+1.4 [−9.8/+9.8] versus −3.9 [−15.4/+1.4] ml, p=0.21) or left ventricular ejection fraction between (+3.9% [−1.6/+10.2]) versus +2.7% [−1.8/+9.3], p=0.61). The incidence of D + HF and of D + HHF were significantly lower with anakinra versus placebo (9.4% versus 25.7%, p=0.046, and 0% versus 11.4%, p=0.011, respectively), with no difference between the anakinra arms (p=1.0).

Conclusion: In patients presenting with STEMI, interleukin-1 blockade with anakinra significantly reduces the systemic inflammatory response compared with placebo.

A11
Assessment of High-risk Percutaneous Coronary Intervention Haemodynamics with Pressure–volume Loop Analysis
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A11.
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Background: Pressure–volume loops (PVLs) can provide valuable information about left ventricular (LV) contractility and loading conditions. Acquiring PVLs in real time during high-risk percutaneous coronary intervention (HR-PCI) may improve our understanding of procedural haemodynamic changes and the impact of haemodynamic support devices.
Hypothesis: We sought to examine the feasibility and utility of PVL analysis in assessing changes in LV contractility and loading conditions during HR-PCI performed with and without Impella mechanical circulatory support (MCS).
Methods: We enrolled nine patients who underwent HR-PCI at two tertiary centres. Six patients had Impella CP device support. LV pressures and volumes were measured with a conductance catheter at different device flow levels and at key timepoints during the procedure. PVLs were analysed to detect changes in LV contractility and loading conditions.
Conclusion: During HR-PCI, good-quality PVL acquisition and analysis was feasible, even in patients with Impella support. PVLs can detect real-time changes in LV contractility and loading conditions, including changes related to different procedural manoeuvres (e.g. balloon inflations). PVL analysis can improve our understanding of the haemodynamic changes during HR-PCI and potentially guide appropriate MCS device selection for patients who require a supported HR-PCI.
Background: Following the Intraaortic Balloon Pump in Cardiogenic Shock II (IABP-SHOCK II) trial, intra-aortic balloon pump (IABP) was largely abandoned in southeastern Denmark and the use of Impella CP increased in patients with acute MI and cardiogenic shock (AMICS), creating two distinct time eras.

Hypothesis: Early use of Impella CP is associated with improved 30-day mortality in patients with AMICS, and early use of IABP is not.

Methods: We identified all patients with AMICS in southeastern Denmark in 2010–2017 by individual review of medical records. We included patients diagnosed with shock in the cardiac catheterisation laboratory receiving percutaneous coronary intervention (PCI) ≤24 hours of symptom onset and intensive care treatment. Early use of Impella CP/IABP was defined as device deployed before PCI, or as device deployed immediately after PCI if shock developed during PCI. Patients receiving early Impella CP/IABP were matched 1:1 to their nearest neighbour control from the same time era, according to a propensity score based on age, left ventricular ejection fraction (LVEF), lactate, estimated glomerular filtration rate and cardiac arrest before arrival to the cardiac catheterisation laboratory.

Results: We identified 40 patients receiving early Impella CP and 40 patients receiving early IABP. Patients receiving early Impella CP had median LVEF 15% (interquartile range [IQR] 10; 25) and median lactate 8.5 mmol/l (IQR 4.5; 11.7). Patients receiving early IABP had median LVEF 30% (IQR 20; 40) and median lactate 3.5 mmol/l (IQR 1.8; 5.7). Early Impella CP was associated with improved 30-day mortality versus the control group, corresponding to a number needed to treat of three (30-day mortality 40.0% versus 77.5%, p<0.001). Although numerically fewer patients died in the early IABP versus control group, the difference was not statistically significant (30-day mortality 27.5% versus 37.5%, p=0.35).

Conclusion: In patients with AMICS, early use of Impella CP was associated with improved 30-day mortality compared to a matched control group. Early use of IABP was not associated with improved outcome.

A14 Haemodynamic and Metabolic Changes Due to Left Ventricular Unloading by Impella Heart Pump in Patients Suffering from Cardiogenic Shock Within 24 Hours: Results from the Jenamacs Impella Registry
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Background: According to current guidelines, the use of active mechanical support devices for haemodynamic stabilisation of patients in cardiogenic shock (CS) should be considered. Active ventricular unloading by the axial flow pump Impella is a common approach that mechanically unloads the left ventricle and increases cardiac output. Until now, there are no published data showing the acute haemodynamic effect of left ventricular unloading by the Impella support in patients suffering from CS. The aim of the current registry trial was to observe the influence of the Impella heart pump on acute haemodynamic and metabolic parameters, as well as outcome data of patients in CS.

Results: We included 132 consecutive patients with CS and implantation of an Impella axial flow pump in clinical routine (mostly Impella CP). Before and after 24 hours of Impella support, invasive haemodynamic and metabolic parameters were assessed. There was an increase in pulmonary artery oxygen saturation from 52.60 ± 14.24 initially to 62.59 ± 9.45% after 10–30 min of Impella support (p=0.01), and an increase in cardiac output from 4.09 ± 1.65 l/min to 5.13 ± 1.63 (p=0.001) within the first 24 hours. There was a non-significant reduction in mean pulmonary artery pressure within 24 hours, from 29.25 ± 8.94 to 20.73 ± 8.48 mmHg (p=0.17). Despite no change in the mean arterial blood pressure within 24 hours (from 74.29 mmHg to 70.96 mmHg after 24 hours, p=not significant), a reduction of serum lactate from 5.54 ± 6.17 to 4.27 ± 6.21 mmol/l after support was started (p<0.03) was achieved. The overall mortality after 30 days was 78 out of 132 patients (59.09%). The mortality of patients >75 years (n=33) was 75%, and for patients ≤75 years (n=99) mortality was 25%.

Conclusion: The implantation of an Impella axial flow pump in patients suffering from cardiogenic shock leads to early left ventricular mechanical unloading and improvement of haemodynamic and metabolic parameters even after 24 hours. There is much higher mortality in patients >75 years of age.

A15 Impella Mechanical Circulatory Support for Takotsubo Syndrome with Shock
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Background: Takotsubo syndrome (TS) is an acute heart failure syndrome with considerable risk of shock, resuscitation and death. Left ventricular (LV) ejection fraction is strongly reduced and LV end-diastolic pressure is increased in almost all cases. Catecholamines are considered to play a causal role for the disease and aggravate outflow tract obstruction. Therefore, management of TS with shock is often a therapeutic dilemma. Mechanical circulatory support with veno-arterial extracorporeal membrane oxygenation increases afterload, while intra-aortic balloon pump induces or aggravates LV outflow tract obstruction in TS. In contrast, the Impella microaxial heart pump unloads the left ventricle and improves coronary and end-organ perfusion. Impella appears favourable for support in TS; however, data on the use of Impella in TS are lacking.

Hypothesis: Impella mechanical circulatory support in TS patients with shock is associated with favourable outcomes.

Methods: We retrospectively reviewed Impella patients at our institutions as well as in the cVAD registry to identify Impella-supported patients with TS. Patient characteristics and in-hospital outcomes were analysed.
Results: A total of 20 TS patients supported with an Impella pump (eight impella 2.5, 11 Impella CP and one impella 5.0) from six centres in Europe and five in the US were identified (age 61.5 ± 17.1 years, 80% women). The majority of patients had an apical TS type, and seven patients had a physical trigger. Seven patients had confirmed shock on admission. Patients were on catecholamines (1.9 ± 0.9) prior to Impella and had a mean systolic blood pressure of 100 ± 25 mmHg. Almost all patients (85%) were mechanically ventilated, and 37.5% sustained cardiac arrest requiring cardiopulmonary resuscitation prior to Impella. Lactate and pH before Impella were 4.1 ± 3.4 mmol/l and 7.30 ± 0.23, respectively. The median (interquartile range) support time was 2 (1–3.25) days. Of the 20 patients, 16 (80%) survived to discharge. Of those, 100% experienced myocardial recovery with a significant improvement of the LVEF at discharge compared to baseline (19.8% ± 8.5% on admission versus 54.3% ± 9.7% before discharge, p<0.001).

Conclusion: This is the first series of mechanical support with the Impella ventricular assist device in patients with TS and shock. In a cohort of patients with mainly refractory cardiogenic shock, Impella support was associated with remarkable survival and excellent myocardial recovery in survivors. Our data set the stage for prospective studies on Impella support in TS with shock.

A16
Yamanaka Factors as Drivers of Recovery in a Mouse Model of Heart Failure
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A16.
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Background: Cardiac recovery in the setting of acute and chronic unloading has been described. We have created a non-ischaemic mouse model of heart failure (HF) recovery to study the natural mechanisms of recovery. Yamanaka factors (OCT3/4, SOX2, KLF4 and C-MYC-OSKM) are a group of genes recently identified by Yamanaka et al. as important for the creation of induced pluripotent stem cells. OSKM genes have shown effects on mesenchymal to endothelial transition, a process that leads to the transition of a fibroblast to an endothelial cell and possibly a role in the resolution of fibrosis (seen in our recovery model).

Hypothesis: Expression of OSKM genes is elevated in the early phase of recovery in a non-ischaemic mouse model of HF recovery.

Methods: We used our non-ischaemic mouse model of recovery from HF, which consists of implantation of an osmotic pump that delivers angiotensin II (angII), combined with the addition of L-NAME and NaCl in the drinking water, to induce HF. At the end of 5 weeks (HF), the pump runs out of angII and the water is returned to normal water to begin the recovery phase following HF. Mice were euthanized at different time points to observe gene expression from tissues collected from control mice, as well as weeks 3 and 5 (HF) and weeks 7 and 9 (recovery). Expression was represented as the increase in fold change compared to control. We assessed fibrosis and heart weight as surrogate markers of the degree of HF or recovery. Polymerase chain reaction was used to quantitate OSKM gene expression.

Results: There is a trend of overall elevated expression in OSKM genes in the weeks after the injury was removed, which are considered the recovery weeks. SOX2, OCT4 and KLF4 are expressed in a progressive way from low to high, peaking by the end of recovery. Fibrosis percentage showed a statistically significant decrease in recovery compared to HF (p <0.05).

Conclusion: The increased expression of OSKM in the recovery period versus HF suggest that Yamanaka factors might play an important role in recovery from HF. This could reflect the contribution of these factors through stem cells or cell transitions (mesenchymal to endothelial) that could be used as targets for adjuvant therapy with unloading.

A17
Vascular Complications in Patients with STEMI and Cardiogenic Shock with Percutaneous Mechanical Circulatory Support Devices: Prevalence and Clinical Outcomes from a Large Nationwide Database
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A17.
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Background: Percutaneous mechanical circulatory support devices (pMCS), such as intra-aortic balloon pump (IABP), percutaneous ventricular assist device (PVAD; Impella or Tandem Heart) and extracorporeal membrane oxygenation (ECMO) are increasingly utilised in patients with ST-elevation MI (STEMI) and cardiogenic shock (STEMI-CS). Large-bore vascular access associated with pMCS may increase bleeding risk and vascular complications. Limited data examining vascular complications with pMCS devices exist.

Hypothesis: We hypothesise an increase in vascular complications with an increase in size of vascular bore access.

Methods: Using the National Inpatient Sample Database, we analysed the prevalence of vascular complications among 35,884 patients with STEMI-CS from 2005 to 2014. We quantified the impact of vascular complications on in-hospital mortality, length of stay (LOS) and healthcare costs.

Results: Among STEMI-CS patients, 338 out of 35,884 (0.9%) had critical limb ischaemia and 6,505 (18.1%) had bleeding complications, including haematomas (4.6%), that required blood transfusions (16.9%) and surgical or endovascular interventions (1.9%). No change in the incidence of vascular complications was noted from 2005 to 2014. The incidence of bleeding complications or acute limb ischaemia was higher among patients with larger-bore pMCS access in the following order: ECMO>PVAD>IABP=no MCS. Mortality rate among patients with bleeding complications and critical limb ischaemia was 27.5% and 35.8%, respectively. Mortality was highest among patients on ECMO who had a bleeding complication (51.0%) or critical limb ischaemia (57.1%). Bleeding complications or critical limb ischaemia were associated with increased LOS and cost of hospitalisation with or without pMCS use. However, inpatient mortality was lower among patients with bleeding complications (27.5% versus 30.8%, p<0.0001).

Conclusion: Vascular complications are common in STEMI-CS requiring pMCS, and are associated with increased LOS and healthcare cost. An
increase in the incidence of vascular complications was noted to be highest in patients with ECMO and was also associated with higher inpatient mortality among all devices. New approaches to reduce vascular complications with pMCS in STEMI and CS are required.

A18
Prevalence of Stroke and its Clinical Implication in Patients with Percutaneous Mechanical Circulatory Support Devices: A National Perspective
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A18.
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Background: Percutaneous mechanical circulatory support (pMCS), such as intra-aortic balloon pump (IABP), percutaneous ventricular assist device (PVAD; Impella or Tandem Heart) or extracorporeal membrane oxygenation (ECMO), have emerged as an important tool in recent years for stabilising patients with STEMI and cardiogenic shock (STEMI-CS). Stroke is a devastating complication and there is a lack of data on its incidence in patients with pMCS.

Hypothesis: We hypothesise that the incidence of stroke will be higher among patients on pMCS.

Methods: All patients with STEMI-CS were selected from a large National Inpatient Sample database between 2005 and 2014. They were then divided into four groups: no MCS, IABP, PVAD or ECMO. The incidence and outcomes of both ischaemic and haemorrhagic stroke among these patients was determined. In-hospital mortality, length of stay and healthcare cost was compared among them.

Results: In total, 35,884 patients were included in the study, of whom 1,523 (4.2%) developed acute strokes of ischaemic (2.8%) and haemorrhagic (0.5%) aetiology. The incidence of stroke was higher among patients with pMCS: ECMO (9.9%), PVAD (6.4%), no MCS (4.3%) and IABP (4.0%). Stroke was associated with higher inpatient mortality (38.6% versus 29.8%, p<0.0001), length of stay (15 versus 9 days, p<0.0001) and healthcare cost ($215,989 versus $141,779, p<0.0001) in patients with STEMI-CS. The incidence of mortality secondary to a haemorrhagic stroke was higher compared to an ischaemic stroke (60.9% versus 37.2%). We also noted that patients with pMCS had more events than those without pMCS (54.9% versus 41.3%).

Conclusion: In patients on pMCS, the incidence of stroke was highest in patients on ECMO. Mortality was higher in patients with haemorrhagic stroke relative to ischaemic stroke, irrespective of pMCS. Considering the increasing cost and poor outcomes with pMCS, there is a need for further research to help determine the best strategies to prevent stroke in this patient population.

A19
Perioperative Mechanical Circulatory Support for Improved Outcomes in High-risk Coronary Artery Bypass Grafting
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Background: Coronary artery bypass grafting (CABG) is the ideal revascularisation strategy for patients with complex coronary artery disease. While beneficial in patients with severe left ventricular dysfunction (LVD), ejection fraction (EF) <35%, this patient group presents a disproportionately high risk for postoperative mortality.

Hypothesis: Perioperative mechanical circulatory support (MCS) instituted for patients with severe LVD undergoing CABG will mitigate the occurrence of a low output state (LOS) and improve postoperative outcomes.

Methods: Seven patients with ischaemic cardiomyopathy and severe LVD presented with various stages of heart failure. Each underwent uncomplicated CABG with a preoperative microaxial (n=4) or durable (n=3) LVAD. Four patients met Medicare criteria for durable LVAD; three received a device during CABG. The remaining patients received a microaxial device prior to or at the time of CABG. An historical cohort of 61 patients who underwent conventional CABG was used for comparison.

Results: All microaxial patients survived to device explant. One died on day 12 postoperation due to aspiration. All durable LVAD patients were alive at latest follow-up, with one patient undergoing successful device explant after 302 days, with a recovered EF of 50%. Both microaxial (3.12 l/min, p=0.02) and durable LVAD (3.20 l/min, p=0.02) recipients demonstrated a significantly higher cardiac index 24 hours post-CABG compared to control patients (2.58 l/min).

Microaxial patients demonstrated equivalent time to vasopressor independence (1,877 versus 2,942 minutes, p=0.63), lactate normalisation (5 versus 373 minutes, p=0.30) and 24-hour vasoactive-inotropic score (VIS; 6.1 versus 3.9, p=0.52) compared to control patients. Durable LVAD, patients required vasopressors longer (7,336 versus 2,942 minutes, p<0.001), but had comparable lactate normalisation time and VIS. Length of stay was significantly longer for both microaxial and durable LVAD groups compared to controls. Primary device-related complications were gastrointestinal bleeding and reoperation for bleeding.

Conclusion: Perioperative MCS allows for improved haemodynamic support and mitigates the occurrence of LOS in patients with severe LVD undergoing CABG.

A20
Impella 5.0 Therapy Decreases Bleeding and Thromboembolic Complications in Patients after Change from Extracorporeal Life Support
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Background: Various options for temporary mechanical circulatory support (TMCS) have shown to improve survival, but little data exist on bleeding complications during the duration TMCS using different devices. All forms of TMCS require anticoagulation and carry a risk of bleeding, which has shown to be associated with a poor outcome.
Hyposthesis: The aim of this study was to compare bleeding complications under extracorporeal life support (ECLS) and Impella 5.0 therapy.

Methods: We retrospectively analysed all 26 patients who underwent veno-arterial ECLS and subsequent change to Impella 5.0 therapy in our institution between March 2016 and August 2018. Eleven patients were excluded from the study because both devices were explanted at the same time or the patient died while on tMCS. Anticoagulation protocol was comparable in both groups. We reviewed and compared the number of transfused packed red blood cells (PRBC) during the time of extracorporeal membrane oxygenation and Impella 5.0 support.

Results: We included 15 patients who were successfully weaned from ECLS and underwent subsequent Impella 5.0 implantation via the axillary artery without any periprocedural complications. The mean patient age was 57 ± 8.4 years and 12 (80%) patients were men. Acute cardiogenic shock due to ischaemic or dilative cardiomyopathy was the main indication for tMCS in 80%. Three other patients (20%) needed ECLS for postcardiotomy failure. The mean duration of ECLS and Impella 5.0 therapy (10.3 ± 5.7 days versus 12.3 ± 5.3 days) did not differ significantly (p=0.231). The average number of PRBC transfused under ECLS was significantly higher than during Impella 5.0 support (30.5 ± 19 versus 13.6 ± 16, p=0.005). Additionally, the PRBC rate per day was significantly reduced with Impella 5.0 support alone, from 3.3 to 1.2 PRBC (p=0.0007).

Conclusion: The need for blood transfusions is significantly lower in patients on Impella 5.0 therapy compared to patients on extracorporeal life support. To improve outcome and to increase survival rates in these patients, we recommend that extracorporeal membrane oxygenation be replaced by Impella 5.0 as soon as possible.

A21 Impact of Concomitant Vasactive Osmotic Treatment in Active Left Ventricular Unloading in Cardiogenic Shock

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Background: In patients with acute MI and cardiogenic shock (CS) treated with Impella CP, concomitant vasoactive drugs are often required. Studies investigating vasoactive drugs in combination with Impella CP and their impact on end-organ perfusion and left ventricular (LV) workload are lacking.

Hypothesis: The aim of this study was to investigate and compare the effect of adrenaline (AD), dopamine (DA), noradrenaline (NA) or phenylephrine (PE) in combination with Impella CP on end-organ perfusion and LV workload in a porcine model of CS.

Methods: CS was induced in nine pigs by stepwise injection of microspheres into the left main coronary artery. After 30 minutes with Impella CP support, pigs were randomised in a blinded crossover design to an infusion with either NA (0.10 µg/kg/min), AD (0.10 µg/kg/min) or DA (10 µg/kg/min) for 30 minutes each. PE (10 µg/kg/min) was given last for 20 minutes.

Additional NA infusion was allowed to maintain mean arterial pressure >50 mmHg. LV workload was evaluated by pressure–volume area (PVA) × HR measured by conductance catheter technique. End-organ perfusion was evaluated by venous oxygen saturations, from jugular bulb and renal vein catheters. Lactate level was measured in arterial blood at the end of each stage. Multilevel mixed-effects linear regression was used to assess differences from the Impella support only.

Results: All drugs, except NA, increased PVA × HR significantly. Arterial lactate increased during PE by 2.48 mmol/l (95% CI [0.87–4.08]), while no significant change was observed during DA, NA and AD. Renal oxygen saturation declined during PE infusion by −13 percentage points (95% CI [−24, −2]), while other drugs caused a non-significant increase. A similar trend was seen in cerebral oxygen saturation.

Conclusion: In a porcine model with profound CS treated with the Impella CP, vasoactive treatments, with the exception of NA, significantly increased LV workload. Venous saturations increased, although non-significantly, with all infusions, except PE, causing a reduction in venous saturations and increased arterial lactate level, indicating reduced organ perfusion.

A22 Cardiac Surgery Assisted by Impella Left Ventricular Support

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Background: The Impella left ventricular assist device is an effective tool for the treatment of cardiogenic shock. Supporting surgical patients with low left ventricular ejection fraction (LVEF) with Impella in the pre- and postoperative periods can improve the results and prevent the shock.

Hypothesis: Recent studies report the benefits of unloading the left ventricle before coronary reperfusion in the acute setting. We believe that the benefits can be extended to chronic ischaemic patients.

Methods: Between 2018 and 2019, 10 patients underwent cardiac surgery assisted by Impella 5.0. Five underwent off-pump coronary artery bypass grafting (OPCABG), two had OPCABG and mitral valve (MV) repair, one had aortic valve replacement (AVR) and MV repair, one had OPCABG and AVR, and one had left ventricular aneurysmectomy and MV replacement. The Impella 5.0 was surgically positioned, via side conduit, through to either the left femoral artery (n=8) or right axillary artery (n=2), 24 hours before the operation. The mean age was 63 ± 7 years. The mean baseline LVEF was 27.5% (20–32%) and the duration of Impella support was 8 days (4–12 days).
Results: Haemodynamics improved immediately after the positioning of mechanical support. The operations were conducted in the usual manner. A low dose of inotropes was used in all patients in the postoperative time. Mortality occurred in three patients (33%). In one case, this was due to multi-organ failure (MOF; an OPCABG patient), and in the other two cases the cause was intracranial bleeding (both in extracorporeal circulation patients). The device was weaned in all except the MOF patient, with optimal haemodynamics and no inotropes. The remaining seven patients had no major complications and were discharged into medical therapy at a mean of 21 days.

Conclusion: Impella preconditioning before surgery and as support in the postoperative period is feasible and effective, allows us to operate on low EF patients using low-dose inotropes and helps to avoid postcardiotomy cardiogenic shock. In OPCABG, it allows easier positioning and emptying of the heart. However, the two cases of intracranial bleeding remain to be explained, despite being successfully weaned from the support.

A23
Systemic Inflammatory Burden Correlates with Severity and Predicts Outcomes in Patients with Cardiogenic Shock Supported by a Percutaneous Mechanical Support Device
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Background: In-hospital mortality associated with cardiogenic shock (CS) remains as high as 50%. Inflammation plays a central role in the pathogenesis of heart failure; however, little is known about the role of inflammation as a prognostic marker or therapeutic target in CS.

Hypothesis: We sought to investigate whether systemic inflammation is associated with clinical outcomes in CS.

Methods: We retrospectively analysed clinical data, including the neutrophil-to-lymphocyte ratio (NLR), a marker of low-grade inflammation, among 111 consecutive patients with CS supported by veno-arterial extracorporeal membrane oxygenation (VA-ECMO) or Impella. Patients with sepsis were excluded from our analysis.

Results: Of the 111 patients, 55% (n=61) survived CS and either underwent device explantation (36%, n=40) or were bridged to left ventricular assist device or cardiac transplant (19%, n=21). Compared to non-survivors, survivors were younger (56 ± 2 years, p<0.001), had better renal function (creatinine 1.8 ± 0.1 versus 2.6 ± 0.2 mg/dl, p=0.0017), higher haemoglobin (12 ± 0.4 versus 10 ± 0.4 g/dl, p=0.006) and lower right atrial pressure (15 ± 1 versus 19 ± 1 mmHg, p=0.02) at the time of device implantation.

NLR was significantly lower in patients with earlier stages of cardiogenic shock (SCAI class C 6.5 ± 1 versus SCAI class D 10.8 ± 1, p=0.008). Compared to non-survivors, survivors had a lower NLR (7.4 ± 0.9 versus 14.4 ± 11, p<0.001). NLR was independently predictive of survival after adjusting for other covariates (OR 0.9, CI [0.83–0.98]). The discriminative power of NLR alone was similar to the MELD Xi score (AUC 0.73, p=0.0005 and AUC 0.73, p=0.018 respectively). The percentage elevation in NLR levels was higher among CS patients supported with VA-ECMO versus Impella (627.5 ± 319% versus 99.9 ± 28%, VA-ECMO versus Impella, p=0.02).

Conclusion: NLR is a simple, widely available marker of inflammatory burden and correlates with in-hospital mortality among patients with cardiogenic shock requiring percutaneous mechanical circulatory support.

A24
A Novel Post-Closure Method for Haemostatic Removal of the Impella CP Pump
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Objective: The aim of this study was to evaluate the safety and rates of adverse vascular events, including occurrence of access-site haematoma, pseudoaneurysm, ipsilateral limb ischaemia, ipsilateral vascular surgical intervention or access-site infection, of a novel post-closure methodology to achieve haemostasis at the femoral arteriotomy, as compared to the gold standard of continuous manual pressure.

Background: The use of percutaneous mechanical circulatory support has grown exponentially. Vascular complications remain a growing concern for large-bore endovascular devices and best practices for device removal do not exist. The latest generation Impella CP now has a stylet for wire re-access. We describe a novel technique of Impella CP removal using a rapid exchange, double-wire approach to deploy two suture-mediated closure devices for immediate haemostasis with the Impella CP.

Methods: Eight consecutive patients requiring Impella CP support between 2017 and 2019 were included in the analysis. Demographic, adverse vascular event and bleeding data among patients who underwent manual compression or post-closure Impella CP removal were collected from individual patient electronic medical records. Descriptive statistics were applied to evaluate numerical and categorical data between the manual compression and post-closure groups; p<0.05 was believed to be significant.

Results: No patients undergoing post-closure suffered an adverse vascular event: haematoma, pseudoaneurysm, ipsilateral limb ischaemia, ipsilateral vascular surgery or access-site infection. The incidence of access-site haematoma formation post device removal in patients receiving manual compression was significantly higher than among patients undergoing post-closure (7/20, 35% versus 0/8, 0%, p=0.05). There was a trend towards reduced access-site bleeding post-Impella CP removal in post-closure patients. Post-impella CP removal access-site bleeding occurred in 5/20 (25%) patients in the manual compression group, compared to 0/8 (0%) in the post-closure group (p=0.12).

Conclusion: The post-closure technique, when compared to manual compression for access-site haemostasis after impella CP removal, significantly reduces the rate of access-site haematoma formation. No patient who underwent the post-closure technique developed other access-site adverse events. Additionally, no patient who underwent
We report for the first time that LV unloading limits A-CURE Abstracts
INTERVENTIONAL CARDIOLOGY REVIEW
Correspondence:
Citation:
Tufts Medical Center, Boston, MA, US
Lija Swain, Xiaoying Qiao, Lara Reyelt, Aditya Chennojwala, Shreyas
Models of Ischaemia with and without Reperfusion
Integrity of Mitochondrial Complex I in Pre-clinical Substrate Utilisation and Protects the Functional Left Ventricular Unloading Preserves Energy with HF.
will test the safety and feasibility of the preCARDIA device in patients maintaining cardiac output in the setting of HF. The SVC Occlusion in a novel approach to mechanically reduce biventricular pressures while
pulmonary emboli or cardiac damage and no evidence of SVC damage showed no evidence of increased cerebral or ocular oedema, no output remained unchanged. The mean arterial pressure remained above 60 mmHg during SVC therapy. Gross and histologic pathology showed no evidence of increased cerebral or ocular oedema, no pulmonary emboli or cardiac damage and no evidence of SVC damage or thrombosis due to the preCARDIA device.
Results: Device insertion and activation was successful in all three pigs. At 6, 12 and 18 hours after initiation of SVC therapy, right internal jugular venous pressure increased; right atrial, pulmonary capillary wedge and mean pulmonary artery pressures decreased, while cardiac output remained unchanged. The mean arterial pressure remained above 60 mmHg during SVC therapy. Gross and histologic pathology
showed no evidence of increased cerebral or ocular oedema, no pulmonary emboli or cardiac damage and no evidence of SVC damage or thrombosis due to the preCARDIA device.
Conclusion: Intermittent SVC occlusion with the preCARDIA system is a novel approach to mechanically reduce biventricular pressures while maintaining cardiac output in the setting of HF. The SVC Occlusion in Subjects With Acute Decompensated Heart Failure (VENUS-HF) trial will test the safety and feasibility of the preCARDIA device in patients with HF.
A25
A Novel Superior Vena Caval Occlusion Catheter System Reduces Biventricular Filling Pressures While Maintaining Cardiac Output in a Model of Acute Congestive Heart Failure
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A25.
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Background: Congestion is a major determinant of clinical outcomes in heart failure (HF). Diuretics, ultrafiltration, inotropes or vasodilators have not improved clinical outcomes. We recently reported that short-term superior vena cava (SVC) occlusion rapidly reduces cardiac filling pressures and maintains cardiac output and systemic pressure in patients with HF. The preCARDIA system is a catheter-mounted SVC occlusion balloon and controller capable of intermittently occluding the SVC over prolonged periods of time. We tested the haemodynamic effects of the preCARDIA system in a swine model of congestive HF.
Methods: We employed a model of post-acute MI HF. The preCARDIA device was introduced and activated to occlude the SVC for 5 minutes, followed by 30 seconds of balloon collapse for 18 hours total.
Results: Device insertion and activation was successful in all three pigs. At 6, 12 and 18 hours after initiation of SVC therapy, right internal jugular venous pressure increased; right atrial, pulmonary capillary wedge and mean pulmonary artery pressures decreased, while cardiac output remained unchanged. The mean arterial pressure remained above 60 mmHg during SVC therapy. Gross and histologic pathology showed no evidence of increased cerebral or ocular oedema, no pulmonary emboli or cardiac damage and no evidence of SVC damage or thrombosis due to the preCARDIA device.
Conclusion: Intermittent SVC occlusion with the preCARDIA system is a novel approach to mechanically reduce biventricular pressures while maintaining cardiac output in the setting of HF. The SVC Occlusion in Subjects With Acute Decompensated Heart Failure (VENUS-HF) trial will test the safety and feasibility of the preCARDIA device in patients with HF.
A26
Left Ventricular Unloading Preserves Energy Substrate Utilisation and Protects the Functional Integrity of Mitochondrial Complex I in Pre-clinical Models of Ischaemia with and without Reperfusion
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Background: Mechanical unloading before reperfusion limits infarct size in pre-clinical models and is currently under clinical investigation in acute MI (AMI). The impact of left ventricular (LV) unloading on energetics or mitochondrial function in AMI is unknown. We hypothesised that LV unloading preserves myocardial metabolism and mitochondrial function in AMI.

Methods: AMI was induced by balloon occlusion of the left anterior descending (LAD) artery for 120 minutes in adult male pigs (n=5 per group), followed by reperfusion for 180 minutes. After 90 minutes of occlusion, animals were assigned to 30 minutes of continued occlusion, then immediate reperfusion (IR) or 30 minutes of LV unloading with persistent occlusion before reperfusion. Compared to IR, unloading reduced infarct size normalised to the area at risk by 41 ± 6% (p<0.01). Untargeted metabolomics were performed using tissue from the infarct zone (Metabolon). Compared to IR, unloading preserved glycolytic activity, fatty acid oxidation and amino acid utilisation, and increased tricarboxylic acid cycle metabolites, suggesting preserved mitochondrial function.

To further explore the impact of unloading on mitochondrial function, we performed Seahorse analysis on mitochondria isolated from the infarct zone. Compared to sham controls, IR reduced the function of mitochondrial complex I (CI), increased reactive oxygen species (ROS) levels, decreased adenosine triphosphate (ATP) levels and reduced mitochondrial membrane potential. In contrast, unloading preserved CI function and ATP levels while reducing ROS levels and maintaining membrane potential.

Since ischaemia alone converts CI from an activated to de-activated state, we next studied whether unloading limits ischaemic injury without reperfusion. Adult pigs (n=5–6 per group) were subjected to 120 minutes of LAD occlusion, followed by 120 minutes of occlusion, with or without LV unloading. No reperfusion was performed. Compared to sham controls, ischaemia increased deactivated CI levels and reduced CI activity. In contrast, unloading during ischaemia reduced infarct size, reduced deactivated CI levels and increased CI activity.

Conclusion: We report for the first time that LV unloading limits myocardial injury, preserves energy substrate utilisation and protects mitochondrial function after ischaemia injury, with or without reperfusion.

A27
Impact of Gender and Ischaemic Time in Anterior STEMI with Left Ventricular Unloading and Delayed Reperfusion: A Sub-study from the STEMI-DTU Safety and Feasibility Trial
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A2. Correspondence: William O’Neill, wonneill1@hfhs.org
Background: Prolonged ischaemic time increases myocardial infarct size (IS), which increases the risk of heart failure and mortality. However, pre-clinical work has demonstrated that mechanically unloading the left ventricle (LV) and delaying reperfusion reduces IS. The STEMI Door-To-Unload Pilot Trial (STEMI-DTU) demonstrated the feasibility and safety of LV unloading with delayed reperfusion in non-shock ST-elevation MI (STEMI) patients.
Methods: This multicentre, phase I randomised trial enrolled 50 patients with anterior STEMI referred for primary percutaneous coronary intervention within 1–6 hours of symptom onset. Patients were randomised to primary unloading with an Impella CP, followed by either 30 minutes of unloading prior to reperfusion (U-DR) or immediate reperfusion (U-IR). Here, we investigate two populations that may show additional benefit with LV unloading: patients with high ST-elevation (STE) and women.

Results: Of the 50 patients enrolled, 30 had STE >6 mm and cardiac magnetic resonance (CMR) at the defined timepoints (U-IR, U-DR-16). Baseline characteristics were similar between groups. The symptom onset to reperfusion (SOR) time for patients’ CMR data with STE >6 was 174 minutes in the U-IR group versus 227 minutes in the U-DR group (p=0.05). IS was as a percentage of the area at risk (AAR) at 3–5 days in this population was 59.9% versus 44.1% in the U-IR versus U-DR groups (p=0.04).

Of the 50 patients, 12 were women and 38 were men; of these, 10 women and 30 men had CMR evaluations at 3–5 days and 30 days. Women tended to be older than men, 65 versus 57 years (p=0.09) and have lower BMI. SOR time was 206 minutes versus 216 minutes for women versus men (p=NS). IS/AAR was 34.8% in women versus 51.7% in men (p=0.05), and 22.7% in U-DR women versus 48.0% in U-DR men respectively (p=0.001). Infarct size as a percentage of LV mass at 30 days was 10.5% versus 15.3% (p=0.24). This trend was preserved when matched by BMI. However, when matched by LV mass, women and men had similar infarct sizes.

Conclusion: Infarct size was reduced using LV unloading with delayed reperfusion in patients with large anterior STEMI despite an increase in SOR time. Strong trends were seen in infarct size reduction with unloading in women versus men and may be related to the degree of unloading relative to LV mass.

A28
A Novel Imaging Probe for the Detection of Autophagy in Pre-clinical Swine Models of Myocardial Ischaemia–reperfusion Injury
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A28.
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Background: Mechanical unloading before reperfusion limits infarct size in pre-clinical models and is currently under clinical investigation. Autophagy, an evolutionarily conserved catabolic cellular process, plays an important role in many diseases. However, in acute MI (AMI), the pathophysiological impact of autophagy remains controversial; it has been shown to promote either cardiomyocyte death or recovery. A major limitation is the inability to accurately detect and quantify autophagy within the area at risk (AAR) during AMI. We hypothesise that a recently developed autophagy-detecting nanoparticle (ADN), based on the FDA-approved drug ferumoxytol, to target lysosomal compartments during autophagy in vivo, could provide a robust fluorescent readout of autophagy levels in a swine model of AMI.

Methods: To validate the autophagy levels, we first quantified the autophagy gold standard, microtubule-associated light chain 3 (LC3) protein, in a swine model of myocardial ischaemia–reperfusion (IR) injury, with or without impella or extracorporeal membrane oxygenation (ECMO) interventions. Compared to sham controls, IR injury with or without interventions did not alter cytosolic LC3-I levels. Lipidated LC3-II, a marker of autophagosome formation, was significantly upregulated in IR pigs (by 48.7%, p=0.014), consistent with literature reports. Impella restored the increased LC3-II to levels comparable to sham (27.0% reduction, p=0.36 versus sham). ECMO further increased LC3-II levels twofold compared to sham (p<0.0001). The autophagy perturbations and restoration were further confirmed by p62 and Beclin-1 levels.

Results: To directly image autophagy levels with ADN, AMI was induced by balloon occlusion of the left anterior descending artery (LAD) for 120 minutes in an adult male pig. After 90 minutes of occlusion, we delivered 0.7 mg of ADN probe via intracoronary injection into the LAD, followed by reperfusion 30 minutes later. After 180 minutes of reperfusion, infarct size was quantified by triphenyltetrazolium chloride staining, and Evans blue counterstaining delineated the non-ischaemic septum from the AAR. Imaging of the ADN probe was performed by fluorescence reflectance imaging. In the representative mid-LV slice, ADN fluorescence was highly activated in the AAR, which was not seen in the contralateral septum. ADN intensity was quantified by signal-to-noise ratio, which increased significantly to 166.4 ± 22.5 in the AAR, compared to the septum (109.9 ± 6.4, p=0.013).

Conclusion: We report for the first time that cardiac-protective LV unloading restores basal autophagy levels, and further demonstrates the feasibility of quantitative autophagy imaging in the heart during AMI.

A29
Use of Echocardiography in Patients with Heart Failure Readmissions
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A29.
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Background: Overutilisation of transthoracic echocardiography (TTE) and increase in other cardiovascular testing have led the American College of Cardiology Foundation and the American Society of Echocardiography to develop indications for the appropriate use of cardiovascular imaging known as the Appropriate Use Criteria (AUC). It is estimated that approximately 10–15% of TTEs are not indicated and up to 30% of these tests ordered by primary care practitioners could have been avoided. This approach is important to limit unnecessary and costly echocardiograms.

Methods: We performed a chart review and data analysis of all patients who had primary discharge ICD10 code of heart failure (HF) between 1 June 2016 and 30 June 2017. The data were obtained from the Phoenix Veterans Administration (VA) Hospital corporate database. Observational status was excluded. These patients were subdivided into HF and readmissions for HF defined as hospitalisation within 1 year of the initial discharge.

The clinical indications for requesting TTE were obtained from the echo orders and the electronic medical record. The patient’s signs
and symptoms on admission were evaluated, as well as the stated reasons that led to the echo study. The indications for these tests were designated as appropriate, inappropriate or uncertain, based on the AUC guidelines. The clinical scenarios that were deemed inappropriate for repeat echocardiogram orders included patients with HF exacerbation that had a clear precipitant (i.e. medication non-compliance), no change in clinical presentation or routine surveillance.

Results: There were 51 patients with HF readmissions. Of these, 16 had repeat echocardiograms within 1 year. Of these 16 patients, nine met the criteria for inappropriate use. This is 56% of repeat TTEs in patients with HF readmissions. The majority of inappropriate use, accounting for 66%, was due to the patient having no change in symptomatology, while 33% had clear precipitating aetiologies. Half of the patients had reduced ejection fraction (<55%), while the other half had preserved ejection fraction (>55%). The average repeat echo was 3 months.

Conclusion: HF is one of the most common causes for hospitalisation in older patients. Rehospitalisation for HF is associated with increased mortality and contributes to rising healthcare costs. TTE represents the first-line cardiovascular imaging modality for the assessment of patients with HF. Other imaging modalities are an alternative, particularly if the patient has suboptimal windows on echocardiogram. There are no long-term studies or clear guidelines to determine correct utilisation of TTE in HF readmissions. This quality-improvement study sheds light on TTE overutilisation and provides an opportunity to reduce cost and avoid unnecessary procedures.

Over the years, initiatives, such as AUC and the Choosing Wisely campaign, have focused attention on the overreliance on procedures and tests. It is evident from the literature that education can decrease the rate of inappropriate ordering of tests. The interventional strategies range from passive to active, but certain measures have had encouraging results. One instrument is use of a point-of-care-decision support tool in the electronic medical record that can improve ordering when indicated and limit frequency by prompting the physician. Another approach is to study patient outcome and mortality related to the number of imaging procedures. Further studies and research are needed to determine whether applying the AUC guidelines achieves these goals.

In future, data can be extrapolated to correlate physical examination findings with imaging results, such as change in the jugular venous pulse amplitude. Additionally, AUC validity can be further evaluated in patients with reduced versus preserved left ventricular function, or those with specific complications, such as those with valvular heart disease. TTE is an important cardiovascular imaging tool and is cost-effective when it is clinically goal-directed with the history and physical examination.

The AUC was designed to guide clinicians to appropriately order imaging tests that affect the management of the patient. Therefore, routine testing with TTE when there is no change in the clinical status is not indicated. The quality-improvement project focuses on HF readmissions and the use of echocardiography at the Phoenix VA. Limitations of the study include one resident physician observation when it would be preferable to have multiple physicians evaluate the indications separately to see if there is disagreement.

A30 Risk Stratification-based Left Ventricular Global Longitudinal Strain is a Better Predictor of Early Outcome in Patients with Cardiogenic Shock Complicating Acute MI
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Background: Cardiogenic shock (CS) remains the leading cause of death in acute MI (AMI), and precise risk stratification is crucial for the subsequent immediate management of CS. However, effective early risk-stratification tools for patients with CS are lacking.

Hypothesis: In this study, we hypothesised that risk stratification based on left ventricular (LV) global longitudinal strain (GLS) is a better predictor of early outcome in patients with CS complicating AMI.

Methods: The LV GLS was estimated by a speckle-tracking-derived algorithm. The 30-day mortality was chosen for the indicator of early outcome after primary percutaneous coronary intervention in patients with CS complicating AMI. The possible predictors of outcome were chosen from demographic, clinical, cardiac enzyme, angiographic and echocardiographic measurements by univariable hazard regression. Independent relationships of possible predictors were confirmed by multivariable hazard regression.

Results: A total of 51 patients with CS complicating AMI were selected (mean age 64 ± 14 years, 76% men). The 30-day mortality was 27.5% (n=14). LV GLS was significantly impaired in patients who died compared with survivors (−8.4 ± 3.9% versus −13.1 ± 4.4%, p<0.001). The QRS time (HR 1.02, 95% CI [1.00–1.04], p<0.05), peak troponin level (HR 1.01, 95% CI [1.00–1.01], p<0.01), estimated glomerular filtration rate (HR 0.97, 95% CI [0.95–0.99], p<0.01), E/’ ratio (HR 1.06, 95% CI [1.02–1.09], p<0.001) and LV GLS (HR 1.19, 95% CI [1.07–1.33], p<0.001) were possible predictors of early outcome by univariable hazard regression. After adjustment for the above-mentioned variables, LV GLS was the only variable which was found to be an independent predictor of early outcome (HR 1.22, 95% CI [1.07–1.40], p=0.004). Furthermore, LV GLS showed good predictive capacity in receiver-operating characteristic curve analysis (area under the curve 0.79, cut-off value −10.8%, 95% CI [0.66–0.92], p<0.01). Kaplan–Meier estimation showed that patients with good LV recovery (LV GLS <−10.8%) had improved survival (log-rank p=0.006).

Conclusion: The risk stratification based on LV GLS is a better predictor of early outcome in patients with CS complicating AMI.

A31 Institutional Experience with Impella 5.0 and its Effect on Renal Function
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Citation: Interventional Cardiology Review 2019;14(3 Suppl 1):A31.
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Background: In recent years the use of the Impella 5.0 for patients in cardiogenic shock and decompensated heart failure (HF) has increased. However, the impact of the Impella 5.0 on renal function and recovery...
remains unclear. We report our institutional experience with the Impella 5.0 and its effect on renal function in this critically ill population.

**Hypothesis:** The Impella 5.0 will help preserve kidney function in patients in cardiogenic shock and decompensated HF.

**Methods:** A retrospective review was performed on all consecutive patients supported with Impella 5.0 from August 2017 to April 2019 at Froedtert and the Medical College of Wisconsin.

**Results:** Out of 44 Impella 5.0 devices implanted, 34 were evaluated as a ‘bridge to decision’ regarding the potential for recovery versus evaluation for long-term ventricular assist device (VAD). Twenty-three patients presented in cardiogenic shock and 11 in severely decompensated HF. The majority of the implantations were performed via axillary approach, and four via carotid. The average length of Impella duration was 11.7 days (range 0–48 days). Five patients (15%) died and 29 (85%) survived to next therapy. Of those who survived, 15 (44%) were weaned off Impella, eight (24%) had a left VAD placed, four (12%) required escalation to veno-arterial extracorporeal membrane oxygenation and two (6%) had cardiac transplant. Major adverse complications included one case of flail mitral leaflet requiring urgent mitral valve replacement and one case of ischaemic stroke. No devices malfunctioned. Twelve (35%) patients had chronic kidney disease (CKD) prior to admission, 10 of whom (29%) had end-stage renal disease and were on haemodialysis (HD). Average serum creatinine before Impella implantation was 2.10 and on discharge was 2.07. Three (9%) patients required new HD on discharge. Of the three patients requiring new HD on discharge, one (33%) had stage 3 CKD before admission, one (33%) had normal renal function before admission and one (33%) had unknown baseline renal function.

**Conclusion:** For patients in cardiogenic shock and decompensated HF, prolonged haemodynamic support with the Impella 5.0 is feasible and improves mortality compared to historical values. Less than 10% of patients in cardiogenic shock and decompensated HF required new HD on discharge, while the majority of patients preserved their baseline kidney function.

**A32**

**Impella can Increase Flow to the False Lumen and Impair Distal Coronary Flow in a Pig Model of Coronary Dissection**

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**Background:** Coronary dissection (CD) sometimes compromises haemodynamics and requires circulatory support. Impella compromises coronary flow in a certain form of CD.

**Hypothesis:** The Impella 5.0 will help preserve kidney function in patients in cardiogenic shock and decompensated heart failure.

**Methods:** Left anterior descending (LAD) artery dissection was created in Yorkshire pigs (n=6) by guidewire-induced intimal scratch and deep engagement of a blunt-cut-tip guiding catheter. The impact of Impella on CD was evaluated with a coronary pressure wire and LV pressure–volume catheter. Impella CP was set to P0 (no support) or P8 (maximal support). LAD flow delay time (DT) was calculated as the difference of LAD and LCX filling times in the angiogram.

**Results:** CD was successfully induced in the proximal LAD of all pigs, with four of them displaying large initial flaps. One pig exhibited TIMI-1 grade flow (DT 1.07 seconds), while other pigs had TIMI-2 to 3 (0.20 ± 0.08 seconds). With Impella support, LV unloading was successful, as evidenced by decreased LV end-diastolic pressure (23.2 ± 1.8 to 11.2 ± 2.8 mmHg, P<0.012), LV end-diastolic volume (136 ± 34 versus 102 ± 30 ml, P<0.029) and stroke work (6,452 ± 1,924 versus 4,989 ± 1,756 mmHg/ml, P<0.028). Maximal Impella support resulted in further delay of LAD flow in the pig with TIMI-1 (DT 2.53 seconds), whereas it remained similar in other pigs (DT 0.20 ± 0.14 seconds, P=1.00). LAD pressures distal to CD decreased in the pig with TIMI-1 (P<0.05) 36.7 to 29.6, P<0.18 to 10.8, P<0.22.9 to 17.1 mmHg), while they increased in other pigs (P<0.127.6 ± 25.1 to 140.8 ± 29.7, P<0.022; P<0.175.4 ± 27.6 to 100.7 ± 30.1, P<0.0006; P<0.1101.4 ± 23.1 to 117.0 ± 29.8 mmHg, P<0.013). The pressure of the false lumen increased after Impella support in the pig with further delay (P<0.742–99.0 mmHg), suggesting increased flow into the false lumen during Impella support.

**Conclusion:** We successfully created a pig model of CD. Impella effectively unloaded LV in pigs with CD, but worsened coronary pressure and flow in one pig with a large flap and low TIMI flow grading.

**A33**

**Improving the Gene Transduction Efficacy of Intracoronary Delivery Using the Impella**

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**Background:** Gene therapy is a promising option for heart failure patients, but there remains a lack of effective delivery mechanisms. The impella device is a heart pump that can increase coronary flow and pressure, an important factor in gene transduction efficiency when using intracoronary delivery. Because it also lends haemodynamic support, the impella can be coupled with balloon coronary occlusion to increase exposure time and allow for higher vector concentrations.

**Hypothesis:** We hypothesised that use of the Impella offers stable haemodynamics during coronary occlusion delivery of adeno-associated viral vector (AAV)-6 encoding luciferase and results in higher gene transduction efficiency than delivery without the Impella.

**Methods:** Two weeks after MI induction in Yorkshire pigs, intracoronary delivery of AAV-6-luciferase was performed: delivery with Impella + coronary artery block enhanced luciferase expression and results in higher gene transduction efficiency than delivery without the Impella.

**Results:** Impella support offered safe vector delivery during 1–2 minutes of CA and CS. Impella + coronary artery block enhanced luciferase expression globally in the heart, but not in non-heart tissue, such as the liver, compared to injection without coronary artery
we included 95 patients with a median age of 64.7 ± 1.56, p<0.001). RV ejection fraction (RVEF) (40 ± 6% versus 43 ± 8%, p<0.001) and RV fractional area change (FAC; 34 ± 9% versus 37 ± 9, p=0.037) were lower in patients with AR than those with MR. The RV eccentricity index was significantly higher in the AR group (2.5 ± 0.6 versus 2.1 ± 0.5, p=0.003). In both groups, LV EDVi showed a positive correlation with RV shape (RV eccentricity: r=0.693 for AR and r=0.525 for MR, p<0.001) and negative correlation with RV function (RVEF: r=−0.0545 for AR and r=−0.383 for MR, p<0.001; RV FAC: r=−0.816 for AR and r=−0.647 for MR, p=0.001).

Conclusion: Beyond the classical, but weak, effect of elevated PASP, RV remodelling in chronic LV volume overload owing to AR and MR can result from a complex interaction with the remodelling and enlarged LV.

A35
High Serum Phosphate Concentrations after ROSC in OHCA patients with MCS Indicates Favourable Outcome
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Background: Recent data suggest that one-third of patients meeting conventional ECG criteria for left bundle branch block (LBBB) may be misdiagnosed, and new, stricter ECG criteria for LBBB have been proposed (Strauss’ criteria). Accordingly, we used 2D speckle-tracking echocardiography to compare left ventricular mechanics in patients with LBBB according to conventional versus Strauss’ ECG criteria for LBBB.

Methods: We included consecutive adult patients reaching return of spontaneous circulation (ROSC) following out-of-hospital cardiac arrest (OHCA) in 2016 and 2017 who were transferred to University Hospital Düsseldorf for non-traumatic reasons. As a primary outcome, we compared survival to discharge grouped by high or low first serum phosphate levels after arrival (cutoffs: 2.5 and 3 mmol/l) with and without implantation of mechanical circulatory support (MCS; extracorporeal membrane oxygenation or Impella). Additionally, phosphate clearance after MCS implantation was calculated in survivors and non-survivors. Statistical analysis was performed by using Fisher’s exact test (case controls) and unpaired t-tests for detecting differences between the groups. Significance was assumed if p<0.05.

Results: We included 95 patients with a medium age of 64.7 ± 1.56 years; 66% were men and 41% had an acute MI (ST-elevation MI/non ST-elevation MI) as the assumed reason for OHCA. Baseline serum creatinine was 1.7 ± 0.12 mg/dl and baseline lactate was 8.3 ± 0.62 mg/dl. Shockable rhythm was present in 53.7% and medium time to ROSC was 22.9 ± 2.87 minutes in survivors and 40.1 ± 4.21 minutes in non-survivors (p=0.001). In 45 patients the average serum phosphate was 2.5 mmol/l, and 22 received MCS.

As expected, in patients without MCS, initial serum phosphate concentrations were higher in non-survivors compared to survivors (3.0 ± 0.17 versus 1.8 ± 0.16 mmol/l, p<0.0001). However, in patients with MCS, elevated initial phosphate levels above 2.5 mmol/l were associated with a greater chance of survival to discharge (cutoff 2.5 mmol/l: 39% versus 9%, p=0.03; cutoff 3 mmol/l: 50% versus 9.1%, p=0.02). In the time course following MCS implantation, phosphate clearance was higher in survivors than in non-survivors when initial serum phosphate was >2.5 mmol/l (2.9 versus 1.7 mmol/l, p=0.02). Survivors and non-survivors with MCS did not differ in initial serum lactate (6.99 versus 7.53), whereas patients without MCS did (4.6 versus 10.99, p<0.001). Initial serum phosphate showed close correlation to initial serum lactate over all groups (r=0.6, p<0.0001). Survivors in both groups were younger than non-survivors.

Conclusion: In patients with ROSC following OHCA, elevated initial serum phosphate (>2.5 mmol/l) is associated with improved survival in patients with MCS. Prospective analyses will help to clarify potential mechanisms.

A36
Impact of Left Ventricular Unloading on Coronary Flow in the Normal Myocardium
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Background: In a pig model of subacute MI, left ventricular (LV) unloading using Impella increased myocardial perfusion in the infarcted tissue, but not in the border and non-ischaemic remote myocardium.
Hypothesis: Impella-mediated LV unloading results in reduced coronary flow in the normal myocardium due to coronary auto-regulation.

Methods: Naïve pigs (n=5) underwent LV unloading with Impella during simultaneous monitoring of the LV pressure-volume relationship and coronary flow and pressure.

Results: Impella full support increased mean arterial pressure (median: 92.94 mmHg versus 105.6 mmHg, p=0.0024) together with minimum coronary pressure (median: 77.25 mmHg versus 97.65 mmHg, p<0.001). End-systolic volume (median 50.00 ml versus 17.00 ml, p=0.0042), end-diastolic pressure (median 17.00 mmHg versus 8.00 mmHg, p<0.001) and heart rate (72 BPM versus 68 BPM, p<0.001) were decreased, suggesting efficient unloading of the LV in normal heart. Interestingly, both peak and minimum coronary flow were decreased by Impella. Calculated microvascular resistance was increased as a result of increased coronary pressure and reduced flow, but with no large change in right atrial pressure. Detailed analysis of coronary flow and pressure waves by wave intensity analysis revealed no significant change in coronary suction wave.

Conclusion: LV unloading using Impella reduced coronary flow in normal myocardium. Increased coronary pressure, reduced LV wall stress, and lack of significant changes in right atrial pressure and coronary suction wave strongly suggest the role of auto-regulation as a mechanism.

A37
Peri-procedural Ventricular Unloading with Impella Optimises Outcomes in High-risk Patients at a Community Hospital
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Background: The role of myocardial unloading with Impella prior to elective cardiac operations in patients with diminished left ventricular (LV) function is yet to be established, particularly in the community hospital setting.

Hypothesis: Pre-operative selection of high-risk patients for placement of Impella devices to medically optimise them before surgery and assist with recovery in the immediate postoperative period should allow faster recovery, reduced intensive care and hospitalisation days, improved end-organ function and reduced inotropic needs immediately postoperatively.

Methods: Impella has been used at our hospital since 2014 for high-risk cath lab procedures and treatment of acute chronic heart failure (CHF) exacerbations. For many years, prophylactic intra-aortic balloon pump (IABP) had been used peri-operatively to support higher-risk patients, but starting in May 2017, we implemented a programme of peri-procedural unloading with Impella in select higher-risk patients in order to improve postoperative outcomes and avoid the need for urgent or emergent device implantation postoperatively. Data were collected retrospectively on these patients to identify outcomes in this high-risk cohort and to validate our site-specific algorithm for prophylactic placement of these devices.

Results: Since the initiation of this strategy, we have placed 149 Impella devices, with 36 devices placed in patients ultimately undergoing surgical intervention. The mean age in the surgical cohort was 63 ± 11 years (median 64 years) and 26 were men (72%). Of these, 25 patients were selected for elective Impella placement prior to surgery, with another 11 patients requiring Impella placement in the cath lab for unstable angina or acute CHF decompensation who ultimately underwent surgery following medical optimisation.

Surgical procedures included coronary artery bypass grafting (CABG; n=29), CABG/valve (n=5) and valve (n=2). In the CHF/shock cohort, the mean pre-op ejection fraction was 22 ± 10% (median 20%). There were three deaths in the 36 patients: two of 25 in the elective group and one of 11 in the unstable group. In the surviving patients, the mean total Impella duration was 5 ± 4 days (median 5 days), with a mean postoperative Impella duration of 4 ± 2 days (median 3 days).

Of patients with serious end-organ dysfunction, two of five patients with acute renal insufficiency requiring dialysis and two of four patients with hepatic insufficiency survived to discharge. Total inotrope duration was 2 ± 2 days (median 1 day), with only five patients requiring high-dose inotropes. The mean postoperative intensive care length of stay (LOS) was 7 ± 5 days (median 6 days) and the mean postoperative hospital LOS was 11 ± 5 days (median 10 days). Postoperative mortality was 8% (three of 36, 30 days or in-hospital).

Conclusion: Preoperative identification of high-risk patients who may benefit from LV unloading with Impella is possible in the community setting. More data might permit development of a selection algorithm that would be broadly applicable to optimise outcomes in high-risk cardiac surgery patients.

A38
Impella 5.0 Treatment as a Bridge-to-decision Option after Extracorporeal Life Support in Patients with an Unclear Neurological Outcome
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Background: Peripheral veno-arterial extracorporeal life support (ECLS) for cardiogenic shock has been shown to improve survival in patients in need of biventricular and lung failure, but is associated with complications. The Impella 5.0 seems to be a less invasive, but equivalent, haemodynamic alternative if right ventricular function allows switching from extracorporeal membrane oxygenation to Impella 5.0 and allows left ventricular (LV) unloading.

In patients with unclear neurological situations, ECLS should be discontinued promptly if there is no hope for healthy survival, according to Extracorporeal Life Support Organization guidelines. However, durable left ventricular assist device (LVAD) implantation is contraindicated in patients with unclear neurological outcomes, according to the International Society for Heart and Lung Transplantation recommendations. Impella 5.0 therapy might reduce ECLS-related complications and allow further evaluation of the neurological situation and further treatment options.
We retrospectively reviewed 30 patients (mean age 56.5 ± 10.7 years) who were in need of ECLS and underwent Impella 5.0 implantation after recovery of the right ventricular and pulmonary function with unclear neurological outcome between January 2016 and July 2018 in our institution. Neurological function was measured by cerebral performance category and modified Rankin scale.

Results: Twenty-six patients had prior cardiopulmonary resuscitation before ECLS implantation. The mean duration of cardiopulmonary resuscitation was 67.4 ± 32.3 minutes. Twenty-two patients had acute MI. The mean time on ECLS before Impella 5.0 implantation was 9.3 ± 1.7 days. Eighteen patients (60.0%) had concomitant Impella 2.5/CP treatment for LV unloading. All patients have been successfully weaned from ECLS and received Impella 5.0 implantation using the axillary artery. The mean time on Impella 5.0 alone was 16.3 ± 4.7 days. Seven patients had been bridged to a permanent LVAD. In 10 patients, myocardial function recovered and the Impella 5.0 has been explanted. The 30-day survival was 66.7%. Bleeding complications on ECLS improved in 75% after the switch to Impella 5.0, and 73.3% of patients were able to be extubated and mobilised after Impella 5.0 implantation. Both quantitative measures of cerebral performance improved after 30 days (p<0.01).

Conclusion: Impella 5.0 provides a good bridge-to-decision option for patients who, after ECLS implantation, have recovered RV and lung function and leads to LV unloading. It is an ideal solution to avoid ECLS-related complications, such as bleeding and limb ischaemia. Impella 5.0 therapy allows further evaluation of the neurological situation and further therapy after ECLS therapy. Almost two-thirds of patients survived with good neurological outcomes after Impella 5.0 therapy.

A39

Left Ventricular Assist Device Implantation after Extracorporeal Membrane Oxygenation Therapy and Subsequent Impella 5.0 Therapy: A Multicentre Analysis

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Background: Left ventricular assist device (LVAD) therapy in INTERMACS 1 and 2 patients is associated with a less favourable outcome compared to stable patients. Often, an arterial-venous extracorporeal membrane oxygenation therapy (ECMO) is implanted to stabilise patients first and improve end-organ function. However, ECMO therapy itself is associated with complications, such as thromboembolism and bleeding. Therefore, an Impella 5.0 is implanted to avoid these complications and unload the left ventricle. We report the multicentre experience in patients after change from ECMO to Impella 5.0 therapy with subsequent LVAD implantation.

Methods: We retrospectively evaluated nine patients in two European centres after ECMO, Impella 5.0 and subsequent LVAD implantation. The mean age was 53.0 ± 6.2 years and eight (88.9%) were men. ECMO was placed for acute MI in seven patients (77.8%) and eight patients (88.9%) were resuscitated. Median follow-up was 227 days (range 127–380 days).

Results: The median time on ECMO before Impella 5.0 implantation was 8 days (range 4–14 days). The ECMO was weaned successfully in all patients over a median of 22 hours (range 0–72 hours). Eight patients (88.9%) were mobilised while on Impella support. The total median time on Impella 5.0 was 17 days (range 12–21 days). Two patients underwent LVAD implantation as a re-do operation. Seven patients (77.8%) had a Medtronic HVAD and two patients (22.2%) had Abbott HeartMate 3 implantation. One patient (11.1%) experienced right ventricular (RV) failure requiring temporary RV assist device implantation. The 30-day survival was 100%. During follow-up, one patient was transplanted after 8 days. One patient died after 380 days. All other patients are still on the device.

Conclusion: The change from ECMO to Impella 5.0 therapy before LVAD implantation allowed LV unloading, end-organ recovery and assessment of RV function. Excellent survival was seen in this small patient cohort. This promising approach should be evaluated in a larger patient series.

A40

Unloading Left Ventricular Results in Right Ventricular Overloading in Large MI and Severe Left Ventricular Dysfunction

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Background: Right ventricular (RV) failure develops after left ventricular assist device therapy (LVAD) implantation in up to 30% of patients. The impact of acute left ventricular (LV) unloading using catheter-based LVAD on RV remains unclear.

Hypothesis: RV failure similarly develops after Impella support in severe heart failure.

Methods: Yorkshire pigs (n=6) received LV Impella support 1 week after percutaneous induction of MI. The impact of LV Impella support on RV was studied using monitoring pressure and volume using a Millar catheter in the RV. Additionally, the incidence of RV failure was studied by reviewing all the subacute MI pigs that received Impella in our lab.

Results: Heart rate showed significant decrease with LV Impella support (P0: 98 ± 8 to P8: 83 ± 9 BPM, p=0.001). RV dilated progressively as the LV Impella flow was increased (RV end-diastolic volume P0: 61 ± 23, P2: 63 ± 25, P5: 68 ± 25, P8: 73 ± 25 ml, and RV end-systolic volume P0: 27 ± 22, P2: 28 ± 21, P5: 29 ± 22, P8: 30 ± 22 ml). There were no significant differences in the RV contractility parameters, including maximum pressure, maximum dp/dt and RV end-systolic pressure–volume relationship. In contrast, minimum dp/dt deteriorated (P0: –333 ± 84 to P8: –242 ± 50, p=0.02) with higher LV support.

A review of 38 pigs identified 12 (32%) which showed signs of RV failure that required reduction of Impella flow or catecholamine.
administration. LV and RV functional analysis revealed that pigs with larger infarction and severe LV dysfunction are more prone to RV failure (large infarct size, larger LV volume and lower ejection fraction). The mean pulmonary artery before LV Impella was not different between the animals that developed RV failure and those that did not (22 ± 7 versus 19 ± 6 mmHg, p=0.12). Meanwhile, the mean right atrial pressure prior to LV Impella was higher in the pigs that developed RV failure (4.8 ± 3.0 mmHg versus 2.3 ± 1.4 mmHg, p=0.02).

Conclusion: Impella LV support results in flow-dependent chamber dilation of the RV. RV systolic function remains unaltered, but the diastolic function may deteriorate. Animals with larger infarction and severe LV dysfunction were prone to develop RV failure.

A41 Longitudinal Impact of Temporary Mechanical Circulatory Support on Durable Ventricular Assist Device Outcomes: An IMACS Registry Analysis

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Background: Patients with advanced heart failure and cardiogenic shock (CS) often require temporary circulatory support (TCS) as a bridge to durable ventricular assist devices (dVAD). We aim to characterise longitudinal outcomes of patients with and without CS.

Methods: Between 2013 and 2017, 13,813 adult patients classified as INTERMACS profiles 1–3 with continuous flow left ventricular assist devices or biventricular assist devices were registered into IMACS. Patients were subgrouped according to support type: extracorporeal membrane oxygenation (ECMO), intra-aortic balloon pump (IABP) or other TCS. Other TCS included all other surgical and percutaneous TCS devices. Estimated survival was compared based on the need for preoperative TCS and by profile.

Results: Preoperative TCS was used in 5,632 (41%). Of these, ECMO was used in 1,138 (20%), IABP in 3,901 (69%) and other TCS in 595 (11%). Patients requiring ECMO had a greater need for biventricular support after dVAD (22% ECMO, 5% IABP, 7% other TCS, p<0.001) with longer post-implant intensive care stays (ECMO 24 days, IABP 14 days, other TCS 12 days, p<0.001). INTERMACS profile 1–3 patients with pre-implant ECMO had the lowest longitudinal survival (82% at 1 month, 44% at 48 months) compared to IABP (93% at 1 month, 51% at 48 months), other TCS (92% at 1 month, 52% at 48 months) and non-TCS (95% at 1 months, 55% at 48 months, p<0.0001). Pre-implant ECMO (HR 2.03) conferred the highest comparative hazard impacting early phase survival (p<0.0001). Within the profile 1 TCS subgroup (overall 1 month survival 87%), ECMO was also associated with inferior survival (82%).

Conclusion: In patients with advanced heart failure and CS, the use of ECMO prior to dVAD was associated with lower longitudinal survival and increased utilisation of biventricular support compared to alternative TCS strategies. Further granular research focused on CS and pre-implant TCS is warranted to further understand these differences.
**A43**

**Percutaneous Impella RP Use for Refractory Right Heart Failure in Adolescents: Results from a Multicentre US Experience**

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**Background:** Percutaneous right ventricular assist device support with the Impella RP device (Abiomed) has been reported in adults, but a multicentre experience in children has yet to be reported.

**Hypothesis:** We hypothesised that the Impella RP can play an important role in the treatment of refractory right heart failure in children and young adults.

**Methods:** We included patients <21 years of age who underwent implantation of an Impella RP device for refractory right heart failure from June 2016 April 2018 at nine US (seven adult and two paediatric) centres. A total of 12 adolescents with a median age of 18 years (14–21 years), and median weight of 74.4 kg (49–112.4 kg) underwent Impella RP implantation.

**Results:** The underlying diagnosis was post-heart transplant rejection in five patients, primary myocarditis in three, cardiogenic shock in two, cardiomyopathy in one and arrhythmogenic right ventricular dysplasia in one (INTERMACS profile: cardiogenic shock in nine and slow progressive decline in three patients). The central venous pressure decreased significantly from a median of 20 mmHg (16–35 mmHg) to 12 mmHg (7–17 mmHg) post-Impella RP implantation (p=0.001). One patient was supported with an intra-aortic balloon pump (IABP) and the rest were concomitantly supported with a percutaneous or surgically placed left ventricular assist device. There were two procedural adverse events: one patient suffered a retroperitoneal haemorrhage from simultaneous Impella CP implantation and one patient underwent leg amputation due to arterial thrombosis from an IABP. There was one adverse event related to the Impella RP device (thrombosis resulting in explant). The average support duration was 6.5 days (4.8 hours to 18.4 days), and survival to hospital discharge was 83%. At a median follow-up of 11 months (5 days to 2.5 years), eight of 12 (67%) patients are alive with complete recovery.

**Conclusion:** In this multicentre experience, the use of the Impella RP device was found to be efficacious and safe when used in adolescents. The Impella RP device should be considered as a treatment modality in select adolescents with severe right heart failure refractory to medical therapy. Further studies are warranted to identify suitable candidates for Impella RP therapy for right heart failure.