9-5-2021

Safety, feasibility, and outcomes of transcaval access for the delivery of Impella microaxial-flow pump 5.0 in patients with acute heart failure

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Recommended Citation

Kazem A, Al-Darzi W, Mohammed M, Lemor A, Lee J, Wang D, Basir M, Alaswad K, O'Neill B, Frisoli T, Eng M, O'Neill W, and Villablanca P. Safety, feasibility, and outcomes of transcaval access for the delivery of Impella microaxial-flow pump 5.0 in patients with acute heart failure. Eur J Heart Fail 2021; 23(SUPPL 2):206.

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Acute Heart Failure–Nonpharmacological Treatment

VA-ECMO in patients that develop cardiogenic shock after cardiovascular surgery. clinically relevant outcomes.

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Funding Acknowledgements: Type of funding sources: None.

Background: Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is a temporary mechanical circulatory support device capable of providing robust cardiopulmonary support in the setting of refractory cardiogenic shock (CS). However, there is limited data regarding the outcomes in patients that develop cardiogenic shock after cardiovascular surgery and undergo VA-ECMO implantation.
Methods: This retrospective cohort study involved patients with profound CS that underwent VA-ECMO implantation between 02/2015-06/2020 in a tertiary cardiovascular centre. Patients were divided based on their indications for VA-ECMO into post-cardiovascular surgery-CS vs. non-cardiovascular surgery-CS (myocardial infarction-CS and heart failure-CS). Outcomes included in-hospital mortality, hemolysis, bleeding, acute kidney injury requiring continuous veno-venous hemo dialysis (CVVHD), and intensive care unit length of stay (ICU- LOS).
Results: A total of 59 patients with a mean age of 53 ± 17 were included in the analysis. Out of these, 34% (20) were female. VA-ECMO was implanted in 19 (32%) post-cardiovascular surgery patients, while the remaining 40 (68%) comprised the non-cardiovascular surgery group.
Outcomes: A total of 37/59 (63%) patients died. In-hospital mortality for post cardiovascular surgery-CS group was 47% (9/19) vs. 70% (28/40) for the non-cardiovascular surgery-CS group, $p = 0.0930$. Major bleeding events occurred more commonly in the post-cardiovascular surgery group 58% (11/19) vs 19% (7/37) in the non-cardiovascular surgery group, $p = 0.003$. The incidence of AKI requiring CVVHD was higher in the non-cardiovascular surgery group (60% vs. 42%), $p = 0.1973$. There were no differences in the risk of hemolysis, 47% (9/19) in the post-cardiovascular surgery group vs. 28% (11/39) in the non-cardiovascular surgery group, $p = 0.1496$. ICU LOS was 16 ± 10 vs. 11 ± 9 days between the post-cardiovascular surgery group and non-cardiovascular surgery group, respectively, $p = 0.0717$.
Conclusion: VA-ECMO in post-cardiovascular surgery patients that develop cardiogenic shock demonstrated similar mortality compared to that of non-cardiovascular surgery patients. However, it was associated with higher bleeding events.

Safety, feasibility, and outcomes of transcaval access for the delivery of Impella microaxial-flow pump 5.0 in patients with acute heart failure

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Funding Acknowledgements: Type of funding sources: None.

Background: Transcaval access (TCA) may enable fully percutaneous mechanical circulatory support (MCS) without the hazards of vascular complication in patients with heart failure that require left ventricular unloading.
Purpose: To review the safety, feasibility, and outcomes of using TCA to deliver Impella 5.0 MCS in patients with ischemic and non-ischemic systolic acute heart failure.
Methods: This single center retrospective study included all patients that underwent TCA placement of a 5.0 Impella from June 2015 to January 2021. Demographic, clinical and procedural variables, and in-hospital outcomes were collected. The procedure was performed by electrifying a caval guidewire and advancing it into a pre-positioned aortic snare. After exchanging for a rigid guidewire, a 22 or 24Fr sheath was delivered into the aorta and then the Impella 5.0 was placed in the left ventricle through TCA sheaths.
Results: A total of 43 patients were included in the analysis. The average age was 56.9 years (interquartile range [IQR], 52-65.5), of which, 70%(n=30) were males. Fifteen patients had non-ischemic cardiomyopathy and 28 had ischemic cardiomyopathy. Baseline average left ventricular ejection fraction prior to implantation was 23.6% (IQR, 13.75-29.75). 86% of the patients were in category C-D of the SCAI classification schema for cardiogenic shock (CS), 39.5% required inotropes and 48.8% required pressors prior to the procedure; 54% had a prior MCS in place. Only 18.6% of the cases had prior CT imaging reviewed for planning. TCA was successful in all attempted patients and the MCS delivery was achieved in 100% of the cohort. The available hemodynamic parameters prior and after Impella 5.0 implantation via TCA are summarized in table 1. From the total cohort, only 29 patients survived to explant device and TCA sheath. The explant was successful in all patients using nitinol occluders; two patients required a covered stent at the arteriotomy site due to right sided heart failure from residual fistula; no surgical repair was necessary. All residual fistulous tracks were graded as < or =2. In-hospital survival was 46.5% for the entire cohort; 53.3%(n=8) for the non-ischemic group and 42.8%(n=12) in the ischemic group. BARC bleeding >1 from Impella insertion/removal site was observed in 9.3%, which didn't require further intervention. No vascular complication of the access site was observed with TCA. During hospitalization, 20.9% had VT/VF and 4.7% a PEA after implantation (all CS patients). 13.9% of the patients had AKI requiring hemodialysis and no stroke was observed in the entire group. The average length of stay for entire cohort was 16.3 days (IQR, 3.25-18.75).
Conclusions: Transcaval access of 5.0 Impella is safe and feasible under expert hands for patients where more conventional MCS devices do not provide enough support or have inadequate peripheral arterial access

Table 1: Summary of Hemodynamics Prior to and Post Impella 5.0 Placement via Transcaval Access.

n=33	Prior to Implantation Mean (IQR)	Post-Implantation Mean (IQR)
Right Atrial Pressure (mmHg)	15.4 (10-20)	13.2 (9-16)
Pulmonary Artery Pulsatility Index (PAPi)	1.6 (0.9-1.9)	1.8 (0.9-2.3)
Mean Arterial Pressure (mmHg)	72 (64-83)	82 (75-88)
Cardiac Index (L/min/m2)	2.0 (1.5-2)	2.5 (1.9-3.1)
Cardiac Power Output (W)	0.6 (0.5-0.7)	0.8 (0.6-1)

Table 1

High doses of CD34+ cells delivered to patients in the CardiAMP Heart Failure (HF) trial

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Funding Acknowledgements: Type of funding sources: Private company. Main funding source(s): BioCardia, Inc.

Background: Intramyocardial injection of CD34+ cells is linked to improved heart disease outcomes in several studies. The CardiAMP HF trial is a multi-center, randomized, controlled, double-blind, pivotal trial that is evaluating treatment efficacy of autologous bone marrow cells (BMC),enriched with CD34+ cells, in patients with ischemic NYHA class II-III heart failure (HF). This study includes a cell potency assay to identify patients most likely to benefit from the autologous cell therapy, a point of care cell processing platform designed to preserve cell viability and process high BMC doses from a small volume, and a helical needle delivery system with 3-fold higher retention than straight needle delivery and 18-fold higher retention than intravascular delivery. CD34+ cells have previously been shown to harness tissue reparative features; however, little is known about the retained dosage of CD34+ cells from HF patients in comparison to prior trials.
Methods: Independent samples obtained from the concentrated BMC delivered to subjects enrolled (n=54) were evaluated for total nucleated cells (TNC) and CD34+ cells using analytically validated flow cytometry. Predicted in- situ dosages were compared to those achieved in other trials supporting efficacy with no patient selection approach and delivery approaches with less efficient myocardial retention.
Results: Mean dosage was $627M \pm 313$ TNC inclusive of mean number of $4.5M \pm 3.4$ CD34+ cells, with no significant inter-group or cohort variation. Based on retention data, the predicted dose retained acutely in the myocardium was 112M TNC with 810K CD34+ cells.
Discussion: These results compare favorably to the ~480K cells retained in the RENEW trial using GCSF mobilized CD34+ products delivered through a straight needle, and the ~35K CD34+ retained in the REPAIR AMI trial delivered through intravascular infusion.
Conclusion: Despite symptomatic HF, patient selection and point of care cell processing produces a high TNC and CD34+ cell dose. When paired with improved intramyocardial cell retention, the retained CD34+ dose exceeds those used in prior trials of enriched CD34+ cell therapy, the results of which supported clinical efficacy.