World Journal of Surgery and Surgical Research

Research Article
Published: 16 Mar, 2020

Urgent Peripheral ECLS as a Rescue in Refractory Cardiogenic Shock

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Abstract

Background: Despite vast development in the diagnosis and management of shock, cardiogenic shock, a condition with inadequate blood circulation due to primary heart failure, remains a clinical challenge with high mortality. Extracorporeal Life Support (ECLS), although considered a last resort in the management of cardiogenic shock, is being used increasingly.

Methods: A retrospective study of patients with refractory cardiogenic shock requiring ECLS was performed. All patients were evaluated by our multi-disciplinary team for suitability as candidates for ECLS. A peripheral veno-arterial ECMO was implanted using a CentriMag® (Thoratec) pump head and Medos hilite® 7000LT oxygenator as a standard set. Outcomes in patients were analyzed based on the aetiology of cardiogenic shock, *viz.* acute Decompensated Heart Failure (DHF), Post-Cardiotomy Cardiogenic Shock (PCCS), Post-Primary Coronary Intervention (PCI).

Results: 33 patients (7 females) with a mean age of 47 (range: 18 to 83) years, required the ECLS for the refractory cardiogenic shock of various aetiologies; DHF=14, PCCS=11, PCI=8. In DHF group 2 patients died on ECLS, 5 were weaned and 7 were bridged to ventricular assist device. 9 (62%) patients could be discharged home and survived for more than 1 year of ECLS explantation. In the PCCS group, 6 patients died on ECLS, 3 were weaned and 2 were bridged to ventricular assist device. 4 (36%) patients could be discharged home and survived for more than 1 year of ECLS explantation. In the PCI group, 4 patients died on ECLS and 4 were weaned; however, only 1 (13%) patient could be discharged home and survived for more than 1 year of ECLS explantation.

Conclusion: ECLS is a rescue in the management of patients with cardiogenic shock. Outcomes of the ECLS for refractory cardiogenic shock due to DHF and PCCS are encouraging; however, they remain poor in the PCI patients mainly due to the majority of patients in that group being eCPR and with high SOFA and APACHE II scores. The use of ECLS must be decided depending on individual risk factors.

Keywords: Extracorporeal life support; Extracorporeal membrane oxygenator; Refractory cardiogenic shock

Introduction

Despite the advances in medical management, refractory cardiogenic shock still carries a very high mortality [1]. In conventional management of cardiogenic shock, the utilization of short-term mechanical circulatory assist devices remains a last resort and often the outcomes are not favourable due to their delayed use. However, in recent years it is being used commonly as their availability and experience keep growing. They help not only in stabilizing the patient hemodynamically but also in reversing any end-organ damage by an immediate improvement in cardiac output [2-4]. Cardiogenic shock refractory to conventional management of diuretics, inotropes and IABP usually present as a rapid deterioration of the patient's condition requiring the urgent introduction of the mechanical circulatory support and given the uncertainty of the recovery of myocardial function, the short-term support as a bridge to a decision is most convenient and popular. ECLS, in this case, bears an advantage of being introduced percutaneously, bed-side in the intensive care units and by that instantaneously. Unlike short-term ventricular assist devices, ECLS avoids sternotomy and subsequent re-explorations of the chest for bleeding [3,4]. Thus, ECLS proves to be ideal mechanical circulatory support in the management of cardiogenic shock.

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Received Date: *06 Feb 2020*
Accepted Date: *11 Mar 2020*
Published Date: *16 Mar 2020*

Citation:
Mohite PN, Garda RF, Husain M, Farmidi A, Umakumar K, Dhar D, et al. Urgent Peripheral ECLS as a Rescue in Refractory Cardiogenic Shock. World J Surg Surgical Res. 2020; 3: 1207.

Table 1: Pre- ECLS characteristics. Baseline situation prior to MCS implantation.

	DHF	PCCS	PCI	P-value
Age (yrs) mean ± SD	38.2 ± 15.1	55.7 ± 17.7	52.3 ± 10.1	0.017
Female (%)	4 (28.6%)	2 (18.2%)	1 (12.5%)	0.645
eCPR n (%)	1 (7.1%)	3 (27.3%)	6 (75%)	0.004
Uncertain neurological status n (%)	5 (35.7%)	6 (54.5%)	7 (87.5%)	0.064
Number of inotropes	2.4 ± 1.0	2.8 ± 1.2	1.6 ± 1.3	0.093
IABP n (%)	5 (35.7%)	5 (62.5%)	4 (57.1%)	0.064
Mechanical Ventilation n (%)	11 (78.6%)	9 (100%)	6 (85.7)	0.157
Dialysis n (%)	7 (50%)	7 (63.6%)	5 (62.5%)	0.751
Multi-organ failure n (%)	10 (71.4%)	9 (81.8%)	6 (75%)	0.833
Glasgow coma scale	10.6 ± 6.2	5.4 ± 3.7	5.4 ± 4.7	0.026
SOFA score	9.4 ± 2.8	13.8 ± 3.0	16.3 ± 3.1	0.003
APACHE II score	23 ± 8.5	32 ± 6.6	33 ± 9.0	0.009

Aetiology of the cardiogenic shock is multi-factorial; however, post-cardiotomy cardiogenic shock, acute decompensation of advanced chronic heart failure and primary coronary intervention are the most commonly found reasons [2,4-7]. In the present study, we categorized our patients with refractory cardiogenic shock supported with urgent peripheral ECLS according to the aetiology of the cardiogenic shock to compare the outcomes according to the aetiology.

Methods

A retrospective study of the patients undergoing peripheral urgent peripheral VA ECMO for refractory cardiogenic shock was performed. The Ethical Committee of the Royal Brompton and Harefield NHS foundation trust approved this study and waived the patient consent. All patients were evaluated by our multi-disciplinary team for suitability as a candidate for ECMO. The standard ECMO set at our institution included a CentriMag® (Thoratec; CA, USA) centrifugal pump and Medos hilite® 7000LT (Medos®, Germany) oxygenator. Arterial cannulation was performed using a 17, 19 or 21 French BioMedicus® (Medtronic, USA) femoral cannula. For the venous drainage, a 25, 27 or 29 French BioMedicus® single-stage femoral cannula was used [6]. For distal arterial perfusion, either a 10 Fr to 12 Fr pediatric BioMedicus® Seldinger's cannula or a 5 Fr to 8 Fr introducer sheath was inserted into the femoral artery distal to the insertion site of the systemic arterial cannula. The cannulation was achieved by either percutaneous, open or hybrid technique. With the percutaneous technique, all the cannulas were inserted by Seldinger technique *via* long subcutaneous tunnels to enable non-surgical removal after weaning. In the open technique, the femoral vessels were surgically exposed and the cannulas were inserted under direct vision and the wound is closed primarily. In hybrid technique, the venous cannula was inserted percutaneously by Seldinger technique whereas the arterial (outflow and distal limb perfusion) cannulas are inserted by open technique. After access and system checks, ECMO was initiated with low flows, gradually increasing to a target of a minimum flow of 60 ml/kg/min.

A baseline Activated Clotting Time (ACT) was measured before the procedure. A bolus of 100 IU/kg body weight of un-fractionated of heparin was administered to achieve an ACT of ≥ 200 seconds at which time implantation commenced. On ECMO, an activated Partial Thromboplastin Time (aPTT) between 60 sec to 80 sec or Activated Clotting Time (ACT) between 160 sec to 180 sec was maintained *via* continuous intravenous infusion of unfractionated heparin. Both, systemic and leg perfusion cannula flows were continuously monitored with flow meters. All ECMO systems were surveyed twice daily by a perfusionist who performed the pre and post oxygenator blood gas analyses to ensure the proper functioning of oxygenator as well as the necessary cannula, connection and monitor checks.

Statistical Analysis

All data was recollected retrospectively Data collection was possible from patient medical records, using IntelliSpace Critical Care and Anesthesia (ICCA) and Electronic Patient Record (EPR), retrospectively. Statistical analysis was performed using the newest version of IBM SPSS available at the time of analysis. Continuous data will be represented as mean ± Standard Deviations (SD) or median and interquartile range, depending on data distribution. Categorical variables will be expressed as numbers and percentages. Inter-group comparisons were performed using either one-way anova or kruskal-Wallis test for normal and non-normal continuous variables, respectively. Pearson's χ^2 or Fisher exact tests were used for categorical data dependent on the minimum expected count in each cross tab. A p-value <0.05 was considered statistically significant.

Results

In this retrospective observational study, we have recollected all consecutive patients as a total number of 33 who underwent Mechanical Circulatory Support (MCS) devices for life-threatening refractory cardiogenic shock who remained in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scale 1 once optimized medico-pharmacological therapy. We categorized the study cohort according to the aetiology of the cardiogenic shock, that is, DHF, PCCS and PCI.

The baseline characteristics are listed in Table 1. The average age for the whole cohort was 47 years with a range between 18 to 83. Patients in the subgroups PCCS and PCI group were considerably older compared to DHF group. There is clear male gender predominance, as female accounts for less than 30% in all groups. Note that all patients were critically ill with a sustained Multiorgan Failure (MOF) in >70% in all studied categories, with more than an inotropic drug needed, requiring Mechanical Ventilation (MV) in >75% of the cases and Renal Replacement Therapy (RRT) in >50%.

Table 2: ECLS: Variables pre and post ECMO implementation for refractory cardiogenic shock.

Pre-ECLS, mean ± SD	**DHF**	**PCCS**	**PCI**	**P-value**
Heart rate	106 ± 28	83 ± 48	87 ± 20	0.337
Mean arterial pressure	60.4 ± 17.4	48.9 ± 25.8	55.9 ± 31.3	0.502
Central venous pressure	16 ± 3.8	20 ± 4.8	16 ± 5.2	0.089
Urine output (ml/Hr)	51 ± 39	19 ± 35	11 ± 17	0.02
p^H	7.28 ± 0.17	7.13 ± 0.14	6.66 ± 1.33	0.113
SvO_2 (%)	52.3 ± 16.4	44.4 ± 14.5	40.5 ± 19.1	0.386
Lactate	8.6 ± 6.6	8.9 ± 5.2	10.6 ± 5.2	0.745
pO_2/FiO_2	278 ± 161	125 ± 118	71 ± 36	0.002
Urea (mmol/L)	14.3 ± 5.7	10.4 ± 5.3	9.8 ± 4.2	0.092
Creatinine (mmol/L)	146 ± 50	122 ± 49	155 ± 72	0.403
Bilirubin (mmol/L)	37.2 ± 21.6	56.5 ± 41.0	36 ± 47.1	0.342
ALP	97.1 ± 47.6	82.7 ± 79.1	147 ± 285	0.627
ALT	676 ± 955	468 ± 956	584 ± 925	0.862
Post-ECLS, mean ± SD				
Heart rate	93 ± 20	98 ± 27	98 ± 22	0.826
Mean arterial pressure	74 ± 14	70 ± 12	72 ± 7	0.726
Central venous pressure	11.5 ± 2.9	12.1 ± 4.4	10.2 ± 3.9	0.606
Urine output (ml/Hr)	96 ± 68	25 ± 34	27 ± 33	0.004
p^H	7.44 ± 0.06	7.42 ± 0.03	7.43 ± 0.03	0.654
SvO_2 (%)	73.0 ± 7.9	75 ± 10.1	74 ± 6.8	0.893
Lactate	4.3 ± 5.0	6.7 ± 6.2	13.5 ± 24.8	0.308
pO_2/FiO_2	328 ± 270	275 ± 262	169 ± 74	0.478
Urea (mmol/L)	9.6 ± 4.6	9.3 ± 4.2	7.8 ± 3.7	0.68
Creatinine (mmol/L)	108 ± 58	132 ± 43	94 ± 38	0.374
Bilirubin (mmol/L)	36.2 ± 21.4	68 ± 45.3	41 ± 55	0.421
ALP	58 ± 36	75 ± 81	87 ± 136	0.741
ALT	622 ± 888	804 ± 823	518 ± 1033	0.811

IABP was used mostly in PCCS and PCI setting, maintained at the time of upgrading MCS, accounting for 62.5 and 57.1% respectively. This is reflected with calculated scores recorded pre-establishment of MCS with a mean SOFA score of 9.4,13.8 and 12.3 and APACHE II score of 23, 32 and 33; accounting for each subgroup DHF, PCCS and PCI independently.

At the time of implantation, PCI subgroup presented with the worst end-organ dysfunction parameters showing a mean worse pH 6.66 ± 1.33, mean maximum lactate of 10.6 ± 5.2 and mean SvO_2 40.5 ± 19.1. The aetiology of refractory cardiogenic shock was acute-on-chronic decompensated heart failure in 14 patients, followed by in post-cardiotomy setting in 11 patients and PCI in 8 patients, according to for 42.4%, 33.3% and 22.7% respectively. Six patients in the PCI group were placed into ECLS under eCPR, accounting for 75% in this group.

Once on ECLS, higher flows were achieved in PCCS group requiring 5.59 ± 0.51 L/min, whilst lower were used or achieved in PCI subgroup with 3.17 ± 0.57 L/min. In Table 2, changes in variables linked to signs of end-organ dysfunction are charted divided by categories. As expected, once on ECLS an increase in mean arterial pressure, reduction in CVP, improvement in urine output, better $PaFiO_2$ ratio, more normalized p^H and higher SvO_2 were achieved. We also observed a reduced use in the number of inotropic support required and levels of lactates in all groups, except in PCI subgroup. This could be because most of them were supported in extremis in an eCPR situation requiring more time for plateauing parameters once organ-damage reperfusion takes place and homeostasis is finally achieved.

The quickest weaning of the ECLS happened in the PCCS group with a mean of 5.8 ± 5.9 days, whilst the longest was observed in the DHF group with a mean of 11.1 ± 6.1 days (Table 3). Successful weaning was possible in a high percentage in all groups, most likely to happen in the DHF group with a rate of 78.6%, followed by PCI and PCCS with similar rates of success (50% and 45.5%).

Regarding complications, the oxygenator failure occurred in 10% to 21.4% cases of the whole cohort studied. The most common complication was bleeding in all groups, accounting for high percentages looking by subgroups (78.6%, 60% and 75%). Note that in the population studied, no strokes happened in any of the subgroups. Renal and liver failures as well as SIRS/sepsis were widespread factors in all subgroups.

Focusing on outcomes analyzed by categories, 2 patients died on ECLS, 5 were weaned and 7 were bridged to ventricular assist device in the DHF group. 9 (62%) patients could be discharged home

Table 3: Prognosis and Early Outcomes.

	DHF	PCCS	Post-PCI	P-value
Duration of support	11.1 ± 6.1	5.8 ± 5.9	7.6 ± 3.4	0.07
Follow-up	465 ± 408	266 ± 345	128 ± 346	0.125
ITU stay	21 ± 15	12 ± 12	15 ± 13	0.238
Hospital stay	40 ± 33	24 ± 30	18 ± 19	0.206
Successful weaning	11 (78.6%)	5 (45.5%)	4 (50%)	0.189
1 yr Mortality	7 (50%)	7 (63.6%)	7 (87.5%)	0.213
Blood and blood products				
Blood Transfusion (units)	21.1 ± 13.1	20.3 ± 23.1	16.3 ± 9.2	0.797
Platelets (units)	5.1 ± 3.7	10.2 ± 16.2	7.1 ± 6.6	0.478
FFP (units)	3.9 ± 4.8	4.7 ± 4.2	1.5 ± 2.3	0.245
Complications				
Infection	5 (35.7%)	1 (9.1%)	3 (37.5%)	0.252
Bleeding	11 (78.6%)	6 (60%)	6 (75%)	0.593
Limb Ischemia (LI)	4 (28.6%)	4 (40%)	1 (12.5%)	0.435
LI requiring intervention	2 (14.3%)	3 (30%)	0	0.216
Stroke	0	0	0	
Hepatic failure	3 (21.4%)	4 (40%)	4 (57.1%)	0.255
Renal failure	3 (21.4%)	7 (63.6%)	4 (50%)	0.093
SIRS	10 (71.4%)	2 (20%)	4 (50%)	0.046
Oxygenator failure	3 (21.4%)	1 (10%)	1 (12.4%)	0.72
Multi-organ failure	3 (21.4%)	7 (70%)	4 (50%)	0.056

and survived for more than 1 year of ECLS explantation. In PCCS group, 6 patients died on ECLS, 3 were weaned and 2 were bridged to ventricular assist device. 4 (36%) patients could be discharged home and survived for more than 1 year of ECLS explantation. In the PCI group, 4 patients died on ECLS and 4 were weaned; however, only 1 (13%) patient could be discharged home and survived for more than 1 year of ECLS explantation.

Discussion

Principal idea of this study was to compare the patients with refractory cardiogenic shock supported on peripheral ECLS depending upon the aetiology of the shock and we found out that the outcomes of the ECLS are inferior in the PCI patients. Aetiology of the refractory cardiogenic shock is diversified and can be broadly categorized into PCCS, acute decompensated chronic heart failure, and PCI.

PCCS is seen in patients after utilization of cardiopulmonary bypass in the cardiac surgeries mainly due to myocardial stunning or hibernation and its incidence range between 2% to 6% of all cardiac surgical procedures [8,9]. PCCS is more prevalent nowadays due to worsening risk profiles of patients undergoing cardiac surgery mainly due to increasing age; redo procedures and complexity of surgeries [10]. PCCS is traditionally managed with inotropes, diuretics, inhaled nitric oxide, IABP; however, patients refractory to these measures require intervention with short-term mechanical circulatory support. ECLS, in this scenario, offers biventricular as well as respiratory support [11]. ECLS introduced peripherally in the cases of PCCS allows closure of the chest, extubating and waking up of the patient while being supported on the ECLS. It obviates the need for chest reopening during its explantation, unlike short-term VADs [12]. ECLS support in PCCS has remained poor (15% to 41%) when compared to primary allograft failure (74% to 46%) [13,14]. With 36.4% of patients alive at one year, our study demonstrated comparable survival in the PCCS group.

In advanced chronic HF patients, especially in case of acute decompensation, poor response to medical therapy with failing end-organ function are the early signs of deterioration, often requiring inotropic and intra-aortic balloon pump support. Inotrope requirement to treat heart failure is certainly the limit of medical therapy and inotrope dependency has a poor prognosis [15]. Many patients, who are initially stabilized on inotropes, deteriorate and develop end-organ failure while waiting for the heart transplantation. ECLS introduced at this stage in such patients offers effective circulatory support, stabilizes them hemodynamically and also halts the ensuing or revert the established end-organ failure [16]. In chronic heart failure patients with a small chance of myocardial recovery, the ECLS mainly acts a bridge to heart transplant or a bridge to long-term ventricular assist devices. Patients with a high probability of receiving an organ offer can be maintained on ECLS for a longer time in the hope of getting the organ offer. On the contrary, patients with large body surface area, blood group 'O', high HLA antibody titer should be bridged to the long-term VAD. In the present study, 50% of patients in this decompensated heart failure group were bridged to the long-term VAD.

The patient population undergoing PCI is more complex and older [17]. Mortality risk for shock has remained unchanged at approximately 50%, despite effective revascularization and reduced door to balloon times [18]. The ECLS improves cardiac output and cardiac power, reduce intracardiac filling pressures, wall stress, and myocardial oxygen consumption and thus offers the interventionist a

layer of protection against hemodynamic distresses during the High-Risk Percutaneous Coronary Intervention (HR-PCI) [19]. Currently available short-term mechanical circulatory assist devices to support high-risk PCI include the IABP, Impella (Abiomed Inc., Danvers, Massachusetts), Tandem Heart (Cardiac Assist, Inc., Pittsburgh, Pennsylvania), or ECMO. IABP through diastolic augmentation decreases cardiac workload and increases cardiac output; however, only by 0.5 L/min [20]. The TandemHeart is technically difficult to implant as it requires transseptal access into the left atrium and could be time-consuming and unsuitable for impending or full-blown cardiogenic shock [21]. Impella, essentially a left ventricular assist device inserted percutaneously *via* femoral artery may improve the cardiac output by 2.5 L/min to 4 L/min depending upon the size [22]. The biggest advantage of Impella over the ECLA is its ability to unload the left ventricle; however, its duration is limited and it can support only failing left ventricle, unlike ECLS that can support both ventricles as well as compromised respiratory function.

In the present study, survival in the PCI patients was significantly inferior (12.5% at one year) compared to the PCCS and DHF patients. This can be explained by the pre-ECLS characteristics of patients that show high SOFA and APACHE II score, high lactate and low s VO_2 in the PCI group compared to other two groups. 75% of patients in this group were put on ECLS with ongoing CPR (eCPR). Besides, PCI patients that require ECLS are considered high risk for PCI complications due to the danger of hemodynamic collapse during balloon inflations or complex procedures, particularly if coronary dissection with vessel closure or no-reflow should occur [23-26]. Kagawa et al. [27] report 61 cases of intra-arrest PCI with a survival rate of 29% at 1-month. In another study, 14 patients who experienced intra-procedural cardiac arrest had in-hospital mortality of 50% [28]. In the present study, differences in the outcomes were observed in the study subgroups; however, significant risk factors were identified across the groups that determined outcomes of the ECLS in the refractory cardiogenic shock. In the clinical practice individual risk factors should be paid attention at the time of decision making for utilization of the ECLS.

Limitations of the Study

This study is an analysis of prospectively collected registry data. The study cohort was small and therefore most of the characteristics did not reach any statistical significance. The study was not randomized and although we grouped the patients in 3 categories, the possibility of bias cannot be ruled out. However, the main purpose of the study was to assess the feasibility and safety of ECLS technique in RCS patients and in that the study has fulfilled the criteria.

Conclusion

Urgent peripheral ECLS proves to a rescue in the management of patients with refractory cardiogenic shock being able to put bedside, percutaneously and most importantly instantaneously. In our cohort of patients, the outcomes of the ECLS in refractory cardiogenic shock due to DHF and PCCS are encouraging; although, remain poor in the PCI patients. However, the majority of the patients in the PCI group in our study were under cardio-pulmonary resuscitation and had a high SOFA and APACHE II score. Therefore, the utilization of ECLS should be decided depending on the individual risk factors.

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