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Original Research Article

EVALUATION OF THE PROGNOSIS OF PATIENT WITH CARDIOGENIC SHOCK UNDERGOING ECMO VS CONSERVATIVE MANAGEMENT: A PROSPECTIVE AND RETROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Cardiogenic shock (CS) is characterised by end-organ hypoperfusion resulting in abnormal organ homeostasis, leading to high patient morbidity and mortality. Veno-arterial ECMO (VA-ECMO) therapy in cardiogenic shock offers rapid improvement of circulatory status and a significant increase in tissue perfusion. Therefore, this study aims to compare and evaluate the prognosis of the two recognised therapeutic approaches in managing cardiogenic shock: early conservative therapy and early implantation of VA-ECMO on the background of standard care. **Materials and Methods:** This prospective and observational study was conducted over a year by the Emergency Department of a tertiary-care hospital, Kovai Medical Center and Hospital, Coimbatore, India. The study population comprises 60 patients with signs of cardiogenic shock, further divided into two groups. Thirty cardiogenic shocks undergo ECMO treatment complications (Group I), and 30 undergo Conservative treatment (Group II). **Results:** Most patients in both groups range from 40 to 60 years, with mean ages of 41.7 and 46.06. The male gender was high in both groups. In both groups, HTN comorbidity was observed predominantly (23.3% and 40%), followed by DM, COPD, CAD and CKD. Cardiac arrest was high in the ECMO group with 16.7%, whereas Neurological sequel was high in the conservative group with 53.3% cases. 50% of the mortality rate occurred in both groups. **Conclusion:** We concluded that ECMO support could prolong the therapeutic space and potentially allow the heart to recover from cardiogenic shock.

INTRODUCTION

Cardiogenic shock (CS) describes a physiological state of end-organ hypoperfusion characterised by reduced cardiac output in the presence of adequate intravascular volume.[1] The clinical criteria to diagnose cardiogenic shock are systolic blood pressure (SBP) measurements of <90 mm Hg for ≥30 minutes or the use of pharmacological or mechanical support to maintain an SBP ≥90 mm Hg.[2] Acute myocardial infarction (AMI) with subsequent ventricular dysfunction is the most frequent cause of CS, accounting for ~80% of cases. Mechanical complications such as ventricular septal (4%) or free wall rupture (2%) and acute severe mitral regurgitation (7%) are less frequent causes of CS after AMI.[3]

Cardiogenic shock has a high mortality rate despite numerous efforts in diagnosis and therapy. Oxygen supply and perfusion are critically reduced during shock and arrest, and both are physical processes that are, in principle, amenable to (temporary) extracorporeal mechanical support.[4] While, Refractory cardiogenic shock carries a poor prognosis, with an in-hospital mortality of ~50% despite pharmacological and mechanical circulatory support.[5] Options for acute percutaneous M Cardiogenic Shock include the intra-aortic balloon pump (IABP), axial flow pumps (Impella LP 2.5, Impella CP), left atrial to femoral arterial ventricular

assist devices (Tandem Heart) and venous-arterial extracorporeal membrane oxygenation (ECMO).[6]
Current clinical Guidelines of the European Society of Cardiology recommend consideration of ECMO use in patients with cardiogenic shock, remaining unstable despite administration of inotropes, vasopressors, ventilator support, reperfusion and revascularisation or as a "bridge to a decision" to stabilise hemodynamic Cardiogenic Shock. Veno-arterial ECMO (VA-ECMO) therapy in cardiogenic shock offers rapid improvement of circulatory status and a significant increase in tissue perfusion. On the other hand, ECMO is an invasive method that requires anticoagulation, and therefore the use of ECMO is probably associated with some complications, i.e., bleeding or leg ischemia. VA ECMO may also negatively influence left ventricular functions. Furthermore, implantation of ECMO also represents considerable financial costs, and mortality remains high despite the improvement of circulatory status.7 Therefore, this study aims to compare and evaluate the prognosis of the two recognised therapeutic approaches in the management of cardiogenic shock: early conservative therapy and early implantation of VA-ECMO on the background of standard care.

MATERIALS AND METHODS

This prospective and observational study was conducted in the Emergency Department of a tertiary-care hospital, Kovai Medical Center and Hospital, Coimbatore, India, for one year.
Sixty patients with signs of cardiogenic shock in our hospital are recruited and divided into two groups. Thirty cardiogenic shocks undergo ECMO treatment complications (Group I), and 30 undergo Conservative treatment (Group II).

Inclusion Criteria

Both male and female patients above 18 years of age, patients with acute myocardial infarction, fulminant myocarditis, cardiomyopathy, cardiac arrest (assisted CPR), medication overdose and sepsis are included.

Exclusion Criteria

Patients < 18 years with congenital heart disease and known cases of severe LVD are excluded.
Written approval from the Institutional Ethics Committee was obtained beforehand. After obtaining informed verbal consent from all cases with confirmed symptoms of cardiogenic shock were included in the study. Recruited patients were subjected to clinical and physical examination, and all the records were collected.
Detailed history regarding the demographic status of the patient and onset, duration, aggravation & relieving factors, positional & nocturnal variation, and occupational relation of the patient were collected. The patient's vital parameters were measured when presenting to the ED. The decision regarding hospitalisation of the patient in ICU care. The clinicians treated the patient according to their clinical judgement, not the set protocol.
Statistical analysis:
Data were analysed using SPSS version 24. Categorical data were analysed using percentages, while continuous data were analysed using standard deviation and mean. A chi-square test for association was conducted to determine the association between patient characteristics and outcomes. A chi-square test for association was conducted to determine the association between two variables.

RESULTS

In this study, most patients were in the age group of 40 to 60 years in both ECMO and Conservative groups (56.6% and 70%), with a mean age of 41.7 and 46.06 years, respectively. Compared to females, the male gender was high in both ECMO and Conservative groups (70% and 60%). In both ECMO and Conservative groups, HTN comorbidity was observed predominantly (23.3% and 40%), followed by DM, COPD, CAD and CKD (Table 1).

Table 1: Distribution of baseline characteristics in two groups

Variable		ECMO Group (n=30)		Conservative Group (n=30)	
		Frequency	Percentage	Frequency	Percentage
Age (Years)	< 20	3	10	0	0
	20 - 39	10	33.3	9	30
	40 - 59	13	43.3	15	50
	> 60	4	13.3	6	20
Gender	Male	21	70	18	60
	Female	9	30	12	40
Comorbidities	DM	7	23.3	12	40
	HTN	8	26.7	13	43.3
	CVA	1	3.3	0	0
	CAD	2	6.7	3	10
	COPD	2	6.7	3	10
	CKD	1	3.3	0	0

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Based on New York Heart Association (NYHA) classification and Killip classification, the maximum of the cases in both ECMO and Conservative groups fall under the class-4 (70-73% and 100%) category (Table 2).

Table 2: Frequency of Disease severity classification systems in both groups

Classification score		ECMO Group (n=30)		Conservative Group (n=30)	
		Frequency	Percentage	Frequency	Percentage
NYHA	Class 1	5	16.7	0	0
	Class 3	4	13.3	0	0
	Class 4	21	70	30	100
Killip score	Class 1	6	20	0	0
	Class 2	0	0	0	0
	Class 3	2	6.7	0	0
	Class 4	22	73.3	30	100

According to the EMR department, most patients recruited in both groups were intubated at 56.7% and 63.3%. Likewise, Inotropes were used among 83.3% of the cases in the ECMO group and 100% in the conservative group. About 16.7% of the patients in the ECMO group and 30% in the conservative group underwent IABP therapy. Cardiac arrest was observed among 16.7%% of the cases in the ECMO group and 13.3% in the conservative group. However, a neurological sequel in 50% of the cases in the ECMO group and 53.3% of the cases in the conservative group were adequate. We observed that 50% of mortality rate in both groups. In the ECMO group, 70% of the patients were in ECMO for 3 to 4 days (Table 3).

Table 3: Distribution of medical complications and outcomes in both group

		ECMO Group (n=30)		Conservative Group (n=30)	
		Frequency	Percentage	Frequency	Percentage
Intubation	Before EMR	7	23.3	3	10
	At EMR	17	56.7	19	63.3
Inotropes	No	5	16.7	0	0
	Yes	25	83.3	30	100
IABP Therapy	No	25	83.4	21	70
	Yes	5	16.7	9	30
Number of Days in ECMO	2	6	20	-	-
	3	13	43.3	-	-
	4	8	26.7	-	-
	5	2	6.7	-	-
	7	1	3.3	-	-
Cardiac arrest	Yes	5	16.7	4	13.3
	No	25	83.3	26	86.7
Neurological sequel	Yes	15	50	16	53.3
	No	15	50	14	46.7
Discharge outcome	Alive	15	50	15	50
	Dead	15	50	15	50

The actual mean hospital stay of these patients was observed to be lesser in the conservative group (6.3 days) and 12.33 days in the ECMO group, which was significantly higher (p=0.009) (Table 4).

Table 4: Distribution of mean hospital stay between study groups

	Groups	Mean	SD	P value
Mean hospital stays in days	ECMO	12.23	11.088	0.009
	Conservative	6.23	5.049	

DISCUSSION

Cardiogenic shock has a high mortality despite recent advances in diagnostic tools and therapeutic interventions. Cardiogenic shock is a clinical syndrome with various etiologies, phenotypes, and presentations. Consequently, this study compared immediate VA-ECMO with early conservative therapy in patients with rapidly deteriorating or severe cardiogenic shock. Age has been identified as a major risk factor for short- and long-term mortality in patients with CS. Recently two studies reported consistent findings of the graded relationship between older age and lower survival in CS that was additive to shock severity. Similar age cut-offs have been suggested for using ECMO as therapy for CS, although its use in older patients remains controversial.[5,8] Although these studies have highlighted the impact of age on outcomes in CS, they have not accounted for the severity of CS.

In our study, the most frequent comorbidities were HTN and diabetes mellitus and stroke. Several studies reported a history of previous heart disease and hypertension in 45%-55.8% of the population.9-11 However, Studies have reported that 56.2% of the patients had diabetes. Also, stroke rates vary from 10.9% to 14.2%.[9,12] Akin to our result, a meta-analysis from 2015 reported an in-hospital

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survival of 40.2% of 841 patients receiving VA-ECMO in cardiogenic shock and cardiac arrest. The complication rates were particularly high for renal impairment (47.4%), infection (25.1%) and neurologic deficits (13.3%).[13] More recently, another meta-analysis on outcomes of VA-ECMO for 5292 patients with refractory cardiogenic shock reported a 43.0% in-hospital, a 36.7% 1-year, and a 29.9% 5-year survival.6A retrospective trial from the US revealed a low mortality rate of 49% in about 800 ECMO runs in patients experiencing a cardiogenic shock. Surprisingly, in a matched cohort, the mortality rate of patients without ECMO was as low as 4%.[12] Regardless of decades of research, the efficacy of ECMO support in cardiogenic shock remains to be proven.

In our study, extracorporeal cardiopulmonary resuscitation (ECPR) was done in a few cases. VA-ECMO is increasingly utilised as a support strategy in out-of-hospital and in-hospital cardiac arrest settings. In addition, ECPR provides reversible causes of cardiac arrest and allows time for patients to recover from multi-organ failure.[14] Survival rates for out-of-hospital cardiac arrest with ECPR use have varied widely from 7% to 45%. Additionally, VA-ECMO has evolved to the point where it can be initiated within minutes by experienced clinicians and provides full cardiorespiratory support for several days. Therefore, this strategy enables the transfer of the sickest patients to experienced centres where additional diagnostic/therapeutic procedures may be performed while the VA-ECMO device maintains stable cardiorespiratory status.

Ultimately, the combination of better risk stratification of CS and the emergence of novel MCS strategies may improve outcomes and survival in the most severe cases of CS (SCAI Stages C-E). Accordingly, European and US guidelines on using VA-ECMO in patients with CS are evolving, and we anticipate updates shortly as more data becomes available. In the meantime, further prospective, randomised clinical trials are needed to expand the ARREST trial results and evaluate the effects of VA-ECMO support on the survival of patients with CS of various etiologies.

CONCLUSION

The study concluded an early implementation of VA-ECMO in patients with rapidly deteriorating or severe cardiogenic shock was comparable with the clinical outcomes compared with a conservative strategy in case of worsening hemodynamic status. Compared to conservative management, the number of days in hospital stay was higher in the ECMO group. Thus, ECMO support can prolong the therapeutic space, potentially allowing the heart to recover. With rising costs and resource utilisation, future research should focus on the impact of ECMO use on the survival and outcomes of patients with critical illnesses, including but not limited to cardiogenic shock. This warrants further study with large sample size and a multi-centre trial.

Conflict of interest: No conflicts of interest

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