

Evaluation of Extra Corporeal Membrane Oxygenation Support in Adult Cardio Respiratory Failure-An Observational Study

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1. Abstract

Extracorporeal life support is a rescue therapy when mechanical ventilation is unable to maintain adequate tissue oxygenation in the setting of acute cardiac or respiratory failure. Outcome is influenced not only by factors independent of ECMO but also by the potential complications related to ECMO. The study is designed to understand the outcomes of Extracorporeal membrane oxygenation in the management of Acute Cardio Respiratory failure in adult population.

The study is analytical and the data is prospectively collected from a local registry of ECMO patients and ICU clinical database. Further, clinical details were obtained from prospective review of patient medical records. The study period is from November 2013 and November 2015.

A total of 30 patients were included in the study 36.7% were weaned off ECLS and 33.3% survived to hospital discharge.

Incidence of Heparin Induced Thrombocytopenia was observed in 3 patients. 27 patients went into renal dysfunction. Both ICU duration (p=0.945) and duration of ECMO (0.736) support did not prove to be significant in predicting mortality. No cannula related vascular complications leading to limb ischemia or need for vascular repair were encountered in any patient.

Mean number of blood transfusions required during ECMO support were 15.17 units.

Infections acquired on ECMO support, p=0.052; 95% CI=0.007-1.707.

Our results endorse the use of ECMO as a rescue therapy in adults, although there are some risks associated with a learning curve as well as an important increase in the days of patient stay.

However, ECMO is still marred by frequent and significant complications such as renal derangement, bleeding and nosocomial infections.

2. Keywords: Acute respiratory distress; Extracorporeal membrane oxygenation; Swine flu; Prolonged mechanical ventilation

3. Abbreviations: ARDS: Acute Respiratory Distress Syndrome; CTVS: Cardio Thoracic Vascular Surgery; ECMO: Extra Corporeal Membrane Oxygenation; ECLS: Extra Corporeal Life Support; HIT: Heparin Induced Thrombocytopenia; ICU: Intensive Care Unit; MV: Mechanical Ventilation; RRT: Renal Replacement Therapy

4. Introduction

Extracorporeal membrane oxygenation (ECMO) is a rescue therapy to support severe respiratory and /or cardiac failure. Both veno-venous (VV) and veno-arterial (VA) ECMO are increasingly being used [1-6].

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VV ECMO support for severe influenza A (H1N1) pneumonitis was reported during the 2009 pandemic [3,7-10]. Despite increasing experience with ECMO and recent technical improvements, the mortality of patients receiving ECMO remains high, but varies between centres, patient subgroups and by indication [2,4,11-13]. While more randomized controlled trials are needed to define the place of ECMO in critically ill patient management, observational series may provide some useful data on factors associated with mortality and complications.

Outcome of patients on ECMO is influenced not only by factors independent of ECMO (patient illness severity, type of illness, other organ support) but also by the potential complications related to ECMO. Clarification of the impact of key ECMO complications on outcome could inform safer care and improve outcomes. ECMO complications may be mechanical (relating to the ECMO circuit components) or medical [14]. The latter are the most frequent and include bleeding, infection, embolism causing vascular and neurological complications and limb ischemia.

Haemorrhage and infections are the most frequent adverse events [2,14,15-22]. Nonetheless, neurologic complications are probably underestimated and can have devastating consequences on the prognosis [3,23]. Vascular complications such as amputation may be delayed and also perhaps under-reported. Bloodstream infections during ECMO have been associated with a poor outcome in paediatric patients [19,24] but the association remains uncertain in adults [17,21,25]. Bleeding is another frequent adverse event in these patients who are critical ill, exposed to anticoagulation and susceptible to coagulopathy and platelet dysfunction. The impact of bleeding on prognosis depends in part on how bleeding events are defined and recorded in the studies [2,14,26]. Mechanical complications and haemolysis have decreased with the introduction of centrifugal pumps, low-resistance polymethyl-pentene membranes and modern heparin-coated surfaces.

Extracorporeal membrane oxygenation (ECMO) is a valuable therapeutic option for patients with acute lung failure [27]. During the 2009 H1N1 influenza A pandemic, the use of veno-venous (VV) ECMO represented a successful rescue treatment for acute respiratory distress syndrome (ARDS) in patients failing conventional ventilation techniques [28]. Due to its additional costs and the need for trained expertise, however, a rational allocation of this limited resource is of fundamental importance.

Referral and transfer of patients with H1N1-related ARDS to specialized ECMO centres have been shown to be associated with a lower risk of death compared to non-ECMO-referred centres [27].

Currently, the decision to start ECMO is based on commonly used pulmonary scores assessing the severity of respiratory failure, such as Murray's acute lung injury score and the oxygenation index. "Conventional ventilation versus ECMO for Severe Adult Respiratory failure" (CESAR) Trial [6,28], identifies severely hypoxemic patients failing protective mechanical ventilation with an estimated mortality risk higher than 50% in comparison to conventional treatment.

Oxygenation failure, however, is rarely the direct cause of death in ECMO patients. On the contrary, a poor outcome is more likely to be determined by the presence of complications [2]. Besides bleeding complications, most directly linked to the procedure itself, the most common causes of death are related to non-protective mechanical ventilation or to infectious or non-infectious inflammation [27], leading to various degrees of organ dysfunction.

This study describes the experience of a single ECMO referral centre during a stable period of practice. The aim of this study was also to identify factors that were associated with outcome for ECMO.

5. Materials and Methods

5.1. Study area: Max Super Speciality Hospital is located in Saket, New Delhi, India which provides tertiary level medical care services and is one of the leading centres in

Northern India running the ECMO program successfully governed by the department of CTVS. The Max Super specialty hospital CTVS-ICU operates an ECMO program and retrieves patients on ECMO.

5.2. Study population: Data were prospectively collected from a local registry of ECMO patients and CTVS-ICU clinical database. Further clinical details were obtained from prospective review of patient medical records. The data is then entered in a preset form of variables which are allocated a score depending upon their value. The net values of all the variables are used further to determine the outcome of patients of Cardio Respiratory failure on ECMO from other hospitals. Our centre is registered in international ECMO registry (ELSO organization) and our database is updated in international registry of ELSO on a regular basis.

5.3. Inclusion criteria: All patients undergoing ECMO support in the Cardiothoracic and Vascular Surgery Department of Max Super Speciality Hospital will be included in the study. Prior approval from the Hospital Ethics committee and Scientific committee were obtained for the study.

5.4. Exclusion criteria

- Paediatric group of patients (<18 years of age) on ECMO support.
- Patients with FiO_2 of <80% for less than 6 hours.
- Patients with history of active cerebral bleeding.
- HIV positive patients.
- Patients with irreversible comorbidities.

5.5. Sample size: In this study we will recruit 30 subjects as sample size and the study would be considered complete as soon as the sample size is fulfilled. We have examined world literature and could not find any study of the type that we proposed to do. However, similar studies were done by Aumassetti et al. [29] studied ECMO for prolonged cardiac arrest, which included 22 patients and another study conducted by

Pagani et al. [30] for use of ECMO as bridge to transplant which included 33 patients.

Thus, we propose to take 30 cases as sample size for this single centre study which also could be feasible considering that not many cases get ECMO support in most Indian set-ups in view of high treatment cost along with high mortality.

5.6. Study design: The study is analytical and the data is prospectively collected from a local registry of ECMO patients and ICU clinical database. Further, clinical details were obtained from prospective review of patient medical records.

5.7. Study duration: The study period is from November 2013 and November 2015.

Primary end point of study will be-

Successful weaning from ECMO support.

Death of the patient on ECMO support.

Secondary end points of the study will be-

Patient going into HIT (Heparin Induced Thrombocytopenia) on ECMO.

Patients acquiring nosocomial infections on ECMO.

Patients requiring average number of blood transfusions during ECMO.

Patients encountering cannula related complications on ECMO.

Patients going into Renal dysfunction during ECMO support.

6. Statistical Methods

All data accrued during the study period would be prospectively analyzed by a bio statistician not associated with the study group.

As the primary objective under study is to analyses the overall efficacy of ECMO support in Cardio-Respiratory failure in Indian scenario. All data will be analyzed using t-test and Chi-square test as found suitable.

Multiple logistic regression was used to analyses the risk of predictor variables.

All data collected during the study was included in data listing.

The predictors exhibiting a statistically significant relationship with the outcome in the univariate analyses

were taken for a multivariate logistic regression analysis to investigate their independence.

For all statistical tests, a P value less than 0.05 was taken to indicate a significant difference.

7. Data Collection Methods

Patients over the age of 18 years who received ECMO support between November 2013 and November 2015 are included. Demographics, co-morbidities, hospital and ICU lengths of stay, acute physiology and chronic health evaluation and main diagnosis at admission were recorded.

The following parameters were collected at ECMO initiation: presence of cardiac arrest, sequential organ failure assessment (SOFA) score [31], plasma lactate level and arterial partial pressure of oxygen to inspired oxygen fraction ($\text{PaO}_2/\text{FiO}_2$) ratio. Days in ICU and days on mechanical ventilation (MV) before ECMO, days on ECMO and the requirement for catecholamines and renal replacement therapy (RRT) were recorded.

8. Results and Discussion

A total of 30 patients were included in the study out of which 28 received VV-ECMO therapy and 2 received VA-ECMO therapy.

Survival was 36.7% (11/30). 36.7% (11/30) were weaned off ECLS and 33.3% (10/30) survived to hospital discharge.

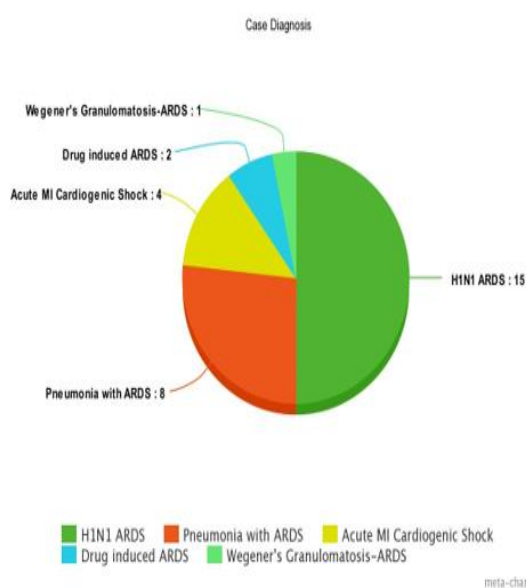


Figure 1: Pie Chart showing distribution of diseases requiring ECMO support in the study.

Study consisted of 11(36.7%) females and 19(63.3%) males. Successfully weaned off from ECMO were 6(54.5%) females and 4(21.1%) males within gender.

Incidence of Heparin Induced Thrombocytopenia on ECMO support was observed in a total of 3(10%) patients with gender distribution as 1(3.3%) female and 2(6.7%) males.

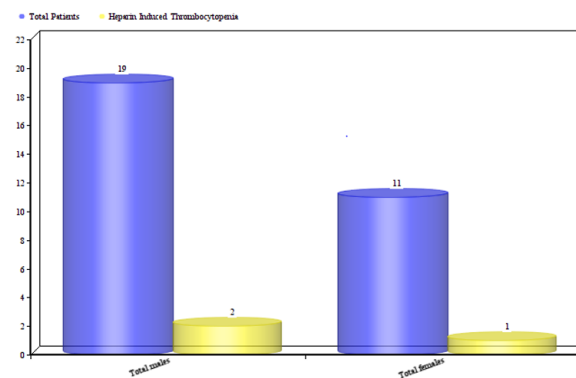


Figure 2: Gender distribution of incidence of HIT [Heparin Induced Thrombocytopenia] on ECMO Support.

A total of 27(90%) patients went into renal dysfunction during ECMO support out of which 10(37%) were females and 17(63%) were males.

All these patients received CRRT during ECMO support and renal parameters returned to baseline values in patients who survived.

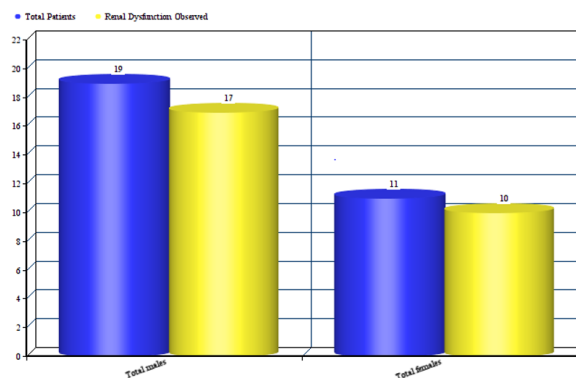


Figure 3: Incidence of Renal Dysfunction observed on ECMO support. Both ICU duration (p=0.945) and duration of ECMO (p=0.736) support did not prove to be significant in predicting mortality.

No cannula related vascular complications leading to limb ischemia or need for vascular repair were encountered in any patient.

Mean number of blood transfusions required during ECMO support were 15.17 units, with 13.36 units and 16.21 units, in females and males respectively.

Infections acquired on ECMO support, $p=0.052$;
95%CI=0.007-1.707).

Table 1: Sex cross tabulation of Incidence of HIT while on ECMO support.

HITT (Hepari Induced Thrombocytopenia) on ECMO *Sex Crosstabulation					
			Sex		Total
			Female	Male	
HITT (Hepari Induced Thrombocytopenia) on ECMO	No	Count	10	17	27
		% within HITT (Hepari Induced Thrombocytopenia) on ECMO	37.00%	63.00%	100.00%
		% within Sex	90.90%	89.50%	90.00%
		% of Total	33.30%	56.70%	90.00%
	Yes	Count	1	2	3
		% within HITT (Hepari Induced Thrombocytopenia) on ECMO	33.30%	66.70%	100.00%
		% within Sex	9.10%	10.50%	10.00%
		% of Total	3.30%	6.70%	10.00%

Table 2: Sex cross tabulation of Incidence of Renal Dysfunction observed on ECMO support.

Going into Renal Dysfunction *SEX Crosstabulation					
			Sex		Total
			Female	Male	
Going into Renal Dysfunction	No	Count	1	2	3
		% within Going into Renal Dysfunction	33.30%	66.70%	100.00%
		% within Sex	9.10%	10.50%	10.00%
		% of Total	3.30%	6.70%	10.00%
	Yes	Count	10	17	27
		% within Going into Renal Dysfunction	37.00%	63.00%	100.00%
		% within Sex	90.90%	89.50%	90.00%
		% of Total	33.30%	56.70%	90.00%

Table 3: Multivariate logistic regression analyzing ICU stay and number of days on ECMO support as independent factors of mortality.

Variables in the Equation							
		B	S.E.	Wald	df	P- value	Odds Ratio
Step 1 ^a	No. of ICU Days	-0.008	0.114	0.005	1	0.945	0.992

	Number of Days on ECMO	0.043	0.127	0.114	1	0.736	1.044
a. Variable(s) entered on step 1: No. of ICU Days, Number of Days on ECMO.							

Table 4: Incidence of infections acquired on ECMO support.

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	P-value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
No. of ICU Days	Equal variances assumed	3.266	0.081	-.926	28	0.362	-4.950	5.343	-15.895	5.995
	Equal variances not assumed			-1.112	27.511	0.276	-4.950	4.453	-14.080	4.180
Number of Days on Ventilator	Equal variances assumed	2.538	0.122	-.992	28	0.329	-5.100	5.139	-15.626	5.426
	Equal variances not assumed			-1.197	27.642	0.242	-5.100	4.262	-13.835	3.635
Number of Days on ECMO	Equal variances assumed	2.236	0.146	-.967	28	0.342	-4.800	4.966	-14.972	5.372

	Equal variance s not assumed			- 1.15 2	27.29 2	0.25 9	-4.800	4.168	- 13.34 8	3.748
Number of Infections Acquired on ECMO	Equal variance s assumed	.947	.339	2.03 2	28	.052	.850	.418	-.007	1.707
	Equal variance s not assumed			2.29 1	24.69 1	.031	.850	.371	.085	1.615

9. Discussion

Extracorporeal membrane oxygenation (ECMO) is increasingly being applied as life support for acute respiratory distress syndrome (ARDS) patients. However, the outcomes of this procedure have not yet been characterized in severe ARDS patients. The aim of this study was to evaluate the outcomes of severe ARDS patients supported with ECMO and to identify potential predictors of mortality in these patients.

A total of 30 severe ARDS patients (aged 23-66 years) who were treated with ECMO in the specialized medical intensive care unit of our tertiary care centre between November 2013 to November 2015 were prospectively reviewed. The clinical data of the patients on the day before ECMO initiation, on the first day of ECMO treatment, day-5 on ECMO and on the day of ECMO removal were collected and analyzed. All patients were treated with veno-venous ECMO except for 2 patients who were managed on VA-ECMO after a mean mechanical ventilation duration of 20.5 days.

One patient of VV-ECMO support suffered ECMO-pump thrombosis, for which hand-crank was used momentarily until whole circuit was changed. Patient, however, survived the treatment and managed to get in the successfully discharged category group.

Among the 11 patients (36.67%) who were successfully weaned from ECMO, 10 patients (33.33%) survived to

hospital discharge. Of the identified pre-ECMO factors, advanced age, a long duration of ventilation before ECMO, underlying lung disease and pulmonary barotrauma prior to ECMO were associated with unsuccessful weaning from ECMO. Furthermore, multiple logistic regression analysis indicated that both duration of ICU stays and stay on ECMO support were not independent predictors of hospital mortality.

10. Conclusion

Our results endorse the use of ECMO as a rescue therapy in adults with ARDS, although there are some risks associated with a learning curve as well as an important increase in the days of patient stay. The justification for the maintenance of an ECMO program in adults should be based on future studies of efficacy and cost effectiveness.

However, ECMO is still marred by frequent and significant complications such as renal derangement, bleeding and nosocomial infections. In addition, physiological and psychological symptoms are commonly described in long-term follow-up of ECMO-treated ARDS survivors.

Currently, there are no data to support ECMO as anything other than a rescue therapy in experienced centres at this time. Emergency physicians should consider early transfer to a specialized centre in the select patients in which ECMO has shown benefit. Continuing research

will likely spur further expansion of ECMO with increased utilization occurring in the emergency department and possibly even the prehospital setting. However, we encourage a cautious and evidence-based approach to future applications of ECMO prior to widespread adoption given the logistical and ethical challenges of this technology that has the potential to outpace the supporting data.

There is need to conduct further studies on ECMO support using a higher number of subjects to clarify the matter.

11. Limitations of the Study

Long-term follow-up was not done. A control arm with similar subset of patients managed on Mechanical ventilation was not taken in view of medical ethics.

This being a non-randomized study, it is difficult to make conclusive statement about the true value of ECMO support.

Sample size involved in the study was smaller due to lesser establishment of ECMO in India as well as cost management.

This is being single centre study done in national capital, drawing any final conclusion on the basis of its data would have limitations.

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