Low volume ECMO results study

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The number of patients treated with extracorporeal membrane oxygenation (ECMO) is rising. The Extracorporeal Life Support Organization (ELSO) Registry records a more than four-fold increase in ECMO cases between 2008 and 2018.[1] Over this period, the number of centres registered with ELSO as providing ECMO increased from 150 to 435. Concerns have been raised regarding variability in outcome between centres. High volume ECMO centres seem to have lower mortality than low volume centres,[2,3] but this finding is not universal.[4,5] The minimal acceptable case volume for an ECMO service is controversial. Recommendations vary from six to 30 cases per annum.[6-8]

Princess Alexandra Hospital (PAH) and Gold Coast University Hospital (GCUH) are tertiary hospitals in Queensland, Australia. The intensive care unit (ICU) casemix in both hospitals encompasses adult critical care, including major trauma, cardiac surgery and neurosurgery, but not cardiac or lung transplantation. These two hospitals and Prince Charles Hospital (Queensland's lung and heart transplantation centre) participate equally in providing the Queensland adult ECMO retrieval service. The on-call hospital retrieves the ECMO patient to their ICU, unless it is clear a ventricular assist device or transplantation is required. The PAH ECMO service commenced in 2009 in response to the H1N1 influenza pandemic, while the GCUH ECMO service and cardiothoracic surgery program started in 2015.

GCUH and PAH have a high caseload of cardiac and respiratory failure. Evidence-based therapies such as prone positioning[9] and lung protective ventilation[10] are integrated into practice. ECMO is only used for significantly deranged physiology not responding to maximal conventional therapy. Both are low volume ECMO centres with less than 20 cases per year, although case volume is rising (Figure 1). Given concerns that low volume ECMO units may have poor outcomes, a retrospective observational study was performed.

ABSTRACT

Objectives: To report extracorporeal membrane oxygenation (ECMO) experience at Princess Alexandra and Gold Coast University hospitals and compare mortality with benchmarks.

Design: Case series of patients treated with ECMO.

Setting: Two adult tertiary Australian intensive care units with low ECMO case volumes.

Participants: Patients treated with ECMO, aged > 18 years.

Main outcome measures: Patients were categorised into respiratory, cardiac, and extracorporeal cardiopulmonary resuscitation (eCPR) groups. Observed mortality was compared with mortality predicted using individual risk of death predictions from the Survival after Veno-arterial ECMO (SAVE) and Respiratory ECMO Survival Prediction (RESP) scores; mortality predicted when mortality predictions of the SAVE score were modified to be consistent with the validation cohort in the SAVE study (Alfred Hospital); and with mortality predicted when eCPR patients were all assigned a risk of death equal to Extracorporeal Life Support Organization (ELSO) Registry eCPR mortality.

Results: Over 10 years, 86 patients were treated with ECMO. Eight deaths were observed in 49 patients with respiratory failure, below the 95% CI (13–24) for the deaths predicted by the RESP score ($P < 0.001$). Nine deaths were observed in 27 patients with cardiac failure, below the 95% CI (14–23) for the deaths predicted by the SAVE score ($P < 0.001$), but within the 95% CI (9–17) for the deaths predicted by the SAVE score modified to be consistent with the Alfred Hospital cohort ($P > 0.05$). Seven deaths were observed in the ten eCPR patients, within the 95% CI (4–10) predicted using the risk of death derived from the ELSO Registry.

Conclusions: Mortality in two low volume ECMO centres was not inferior to benchmarks.

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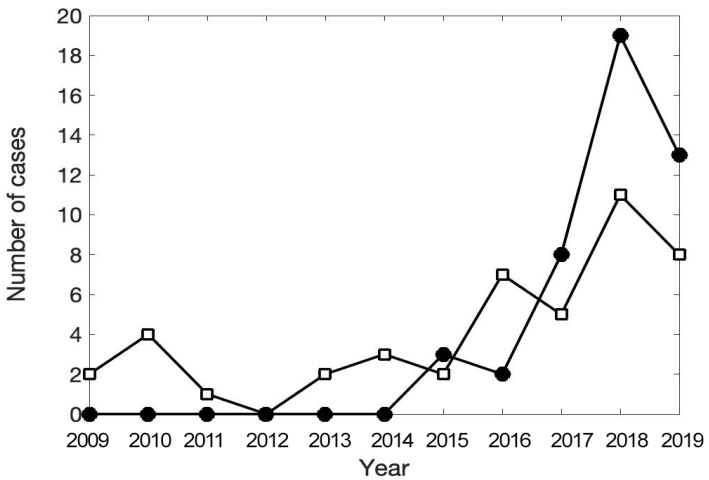
Figure 1. Extracorporeal membrane oxygenation (ECMO) case volume for the Princess Alexandra Hospital (PAH) and the Gold Coast University Hospital (GCUH)



Annual ECMO cases for GCUH (dots) and PAH (squares). Includes all patients regardless of age. While the number of cases is increasing in both hospitals, both are below the recommended case volume of 20–30 cases per year.[7]

Methods

The Human Research Ethics Committee of Metro South Hospital and Health Service granted approval for the study. All patients treated with ECMO at PAH and GCUH, discharged from acute care before 1 January 2020 were identified. Data were collected from individual medical records.

Data collected included baseline information from before ECMO was started, enabling individual risk of death (ROD) predictions with the Survival after Veno-arterial ECMO (SAVE)[11] and Respiratory ECMO Survival Prediction (RESP)[12] scores, information about ECMO runs, and information about patient outcomes. Data for SAVE and RESP scores were collected using the ELSO data collection rules in place when these scores were developed. The data elements collected and their definitions are described in the Online Appendix (appendix 1).

Patients were often admitted sequentially to several hospitals. A "continuous period of acute care" was defined as from first presentation to an acute care hospital until discharge to one of the following: home, a dedicated rehabilitation ward or hospital, a chronic care facility, or death. These end points were consistent with ELSO Registry end points, except that the ELSO Registry counts patients as survivors if they are transferred to another hospital, which underestimates mortality.[2] We only counted patients as survivors if they survived their continuous period of acute care.

A "continuous period of ICU care" was defined as from admission to any ICU until discharge from ICU, if ECMO was provided during this period. Any high dependency unit meeting the definition from the College of Intensive Care Medicine of Australia and New Zealand[13] was regarded as an ICU.

To benchmark the combined cohort (GCUH and PAH) mortality against ELSO Registry mortality, ROD predictions were made using RESP and SAVE scores, which were originally developed from the adult cohort of the ELSO Registry.[11,12] Risk predictions for cardiac ECMO patients were made in two ways. The first method used the SAVE score, assigning the patient to one of five risk classes, each class having a single predicted ROD. The second method used β-coefficients of a logistic regression model from the SAVE study to generate individual ROD predictions. Risk predictions from the RESP scores used the same methods, with β-coefficients provided by Professor David Pilcher (Intensive Care Specialist, Alfred Hospital; personal communication, October 2019). The β-coefficients and how to calculate individual ROD are described in the Online Appendix (appendix 2, pp 32-34). For extracorporeal cardiopulmonary resuscitation (eCPR), all patients were assigned a ROD of 0.71, the overall adult ELSO Registry mortality for eCPR.

We also benchmarked the combined cohort mortality against a well performing high volume ECMO centre. The Alfred Hospital (AH) in Melbourne has the highest ECMO caseload in Australia. Data on AH cardiac ECMO patients from July 2006 to December 2013 were used as the validation cohort in the SAVE study, but mortality in the AH cohort was lower than in the developmental cohort. The predicted mortality assigned to each of the five risk classes of the SAVE score was adjusted to the observed ROD in each of these classes in the AH cohort (Table 2) and then used to make individual ROD predictions.

Safer Care Victoria reported 30-day mortality over 5 years at AH as 37% for ECMO patients with respiratory disease as the primary diagnosis.[2] There were 310 ECMO separations at AH, with 23% in this respiratory disease group. This equates to 71 patients, with 26 deaths and 45 survivors. The CHEER study (Refractory cardiac arrest treated with mechanical CPR, hypothermia, ECMO and early reperfusion)[14] published data from AH on survival to discharge from hospital for 24 patients treated with eCPR, with 12 deaths and 12 survivors.

Fisher exact test (MATLAB) was used to compare our combined cohort respiratory and eCPR mortality with the mortality in the Safer Care Victoria and CHEER studies.

The SAVE and RESP scores predict ROD for individual patients. We used the Monte Carlo simulation[15] (Online Appendix, appendix 3, pp 35-36) to generate a probability distribution for the predicted number of deaths in the group as a whole.

The primary analysis in this audit was performed on the combined dataset for both hospitals. Secondary analysis was performed on data from each hospital individually. Patients under 18 years of age were excluded from the analysis, analogous to the adult cohort of the ELSO Registry.

Results

Results for the combined cohorts are reported in this article. The corresponding probability distribution functions are described in the Online Appendix (appendix 4, pp 37-46). Information for the PAH and GCUH cohorts is included in the Online Appendix (appendices 5 [pp 47-56] and 6 [pp 57-66] respectively). Two patients died during ECMO cannulation. In keeping with ELSO Registry data definitions, they were excluded because ECMO flow was never established. ECMO was provided to 90 patients. Data for the 86 patients aged 18 years or over are presented.

Descriptive statistics

We present here information about the combined (GCUH and PAH) cardiac and respiratory cohorts, baseline information (pre-ECMO) (Table 1 and Table 2), ECMO therapy (Table 3), and patient outcomes (Table 4). Information about the eCPR cohort is included in the Online Appendix (appendix 4, pp 37-46).

Table 1. Patient data before starting respiratory extracorporeal membrane oxygenation (ECMO), for the Princess Alexandra Hospital and the Gold Coast University Hospital combined

	Respiratory ECMO
Total number of cases	49
Median age (range), years	39 (18–75)
Sex, male	33 (67%)
Median weight (range), kg	90 (50–202)
Median body mass index (range)	28.7 (18.4–78.9)
Acute respiratory diagnosis group (one only per patient)	
Viral pneumonia	19 (39%)
Bacterial pneumonia	11 (22%)
Asthma	2 (4%)
Trauma and burn	3 (6%)
Aspiration pneumonitis	7 (14%)
Other acute respiratory diagnosis	7 (14%)
Non-respiratory and chronic respiratory diagnoses	0 (0%)
Immunocompromised	6 (12%)
Mechanical ventilation prior to ECMO	
< 48 hours	33 (67%)
48 hours to 7 days	11 (22%)
> 7days	5 (10%)
CNS dysfunction	11 (22%)
Acute associated non-pulmonary infection	6 (12%)
Neuromuscular blockade agents prior to ECMO	49 (100%)
NO use before ECMO	29 (59%)
HCO_3 infusion before ECMO	11 (22%)
Cardiac arrest before ECMO	7 (14%)
$PaCO_2 \geq 75$*	19 (39%)
Peak inspiratory pressure ≥ 42*	13 (27%)

RESP risk class	Predicted mortality (%)	Number of patients
I	8%	7 (14%)
II	24%	19 (39%)
III	43%	11 (22%)
IV	67%	9 (18%)
V	82%	3 (6%)

CNS = central nervous system; HCO_3 = bicarbonate; NO = nitric oxide; $PaCO_2$ = arterial partial pressure of carbon dioxide; RESP = Respiratory ECMO Survival Prediction. All patients aged > 18 years treated with ECMO for respiratory failure. * Worst value in 6 hours before ECMO start time. Data collected using Extracorporeal Life Support Organization (ELSO) rules in place when RESP scores were developed. Viral pneumonias with secondary bacterial infection were coded as viral pneumonia.

Table 2. Patient data before starting cardiac extracorporeal membrane oxygenation (ECMO), for the Princess Alexandra Hospital and the Gold Coast University Hospital combined

	Cardiac ECMO
Total number of cases	27
Median age (range), years	52 (18–69)
Sex, male	19 (70%)
Median weight (range), kg	80 (45–150)
Median body mass index (range)	25.4 (15.0–45.3)
Acute cardiogenic shock diagnosis group (one or more per patient)	
Myocarditis	2 (7%)
Refractory VT/VF	3 (11%)
Post-heart or lung transplantation	0 (0%)
Congenital heart disease	1 (4%)
Other diagnoses	24 (89%)
▸ Post-non-transplant cardiac surgery	10 (37%)
▸ STEMI	6 (22%)
▸ Pulmonary embolism	4 (15%)
▸ Septic cardiomyopathy	3 (11%)
▸ Thyrotoxic cardiomyopathy	3 (11%)
Acute pre-ECMO organ failures	
Liver failure	19 (70%)
CNS dysfunction	2 (7%)
Acute renal failure	14 (52%)
Chronic renal failure	1 (4%)
Duration of intubation prior to ECMO, hours	
< 10	19 (70%)
11–29	7 (26%)
≥ 30	1 (4%)
Peak inspiratory pressure ≤ 20*	4 (15%)
Pre-ECMO cardiac arrest	8 (30%)
Diastolic blood pressure ≥ 40*	15 (56%)
Pulse pressure ≤ 20*	14 (52%)
HCO_3 before ECMO ≤ 15*	18 (67%)

	Predicted mortality (%)		
SAVE risk class	**SAVE**	**AH cohort**	**Number of patients**
I	25%	0%	0 (0%)
II	42%	10%	1 (4%)
III	58%	28%	7 (26%)
IV	70%	37%	10 (37%)
V	82%	94%	9 (33%)

AH = Alfred Hospital; CNS = central nervous system; HCO_3 = bicarbonate; NO = nitric oxide; SAVE = Survival after Veno-arterial ECMO; STEMI = ST elevation myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia. All patients aged > 18 years treated with ECMO for cardiac failure. * Worst value in 6 hours before ECMO start time. Data collected using Extracorporeal Life Support Organization (ELSO) rules in place when SAVE scores were developed. Two of the patients with refractory VT/VF had myocarditis and one had STEMI; one patient had STEMI after non-transplant cardiac surgery; one patient had non-transplant cardiac surgery for ventricular septal defect complicating STEMI.

Table 3. Characteristics of extracorporeal membrane oxygenation (ECMO) for the Princess Alexandra Hospital (PAH) and the Gold Coast University Hospital (GCUH) combined

	Respiratory ECMO	Cardiac ECMO
Place ECMO first initiated		
ICU (PAH or GCUH)	27 (55%)	16 (59%)
Operating theatre (PAH or GCUH)	6 (12%)	7 (26%)
Cardiac catheterisation laboratory (PAH or GCUH)	0 (0%)	3 (11%)
Other hospital, then retrieved	16 (33%)	1 (4%)
Median days on ECMO (range)	13 (1–53)	6 (3–24)
Outcome of ECMO		
Died on ECMO or palliative withdrawal of ECMO	6 (12%)	5 (19%)
Survived ECMO	43 (88%)	22 (81%)
Median RBC units transfused during ECMO (range)	10 (0–84)	11 (0–113)
IABP while on ECMO	0 (0%)	7 (26%)
Circuit change-outs		
0	38 (78%)	25 (93%)
1	8 (16%)	1 (4%)
2	3 (6%)	1 (4%)
Second ECMO run	1 (2%)	0 (0%)

IABP = intra-aortic balloon pump; ICU = intensive care unit; RBC = red blood cells. All patients aged > 18 years treated with ECMO for cardiac or respiratory failure. If a patient was on ECMO for any part of a day, that day was counted as a day on ECMO; for the patient who had two ECMO runs, these have been combined to give the total days on ECMO.

Respiratory ECMO was provided to 49 patients and eight died (mortality rate, 16%). Cardiac ECMO was provided to 27 patients and nine died (mortality rate, 33%). eCPR was provided to ten patients and seven died (mortality rate, 70%). All patients who survived their continuous episode of ICU care were discharged home alive. Some had prolonged admission to rehabilitation facilities, mainly due to injuries from trauma.

Comparative statistics

Respiratory ECMO

Eight deaths were observed in 49 respiratory ECMO patients, below the 95% CI (13–24) for the deaths predicted by the RESP score class ($P < 0.001$). When the RESP logistic regression mortality predictions were used to generate the probability distribution, the eight observed deaths lay below the 95% CI (14–26) ($P < 0.001$).

Mortality was lower in our combined respiratory cohort (eight out of 49 patients died), than in the AH cohort (26 out of 71 patients died) from the Safer Care Victoria report ($P = 0.0226$; Fisher exact test).

Cardiac ECMO

Nine deaths were observed in the 27 cardiac ECMO patients, below the 95% CI (14–23) for the deaths predicted by the SAVE score class model ($P < 0.001$). When the SAVE logistic regression mortality predictions were used the 95% CIs were identical ($P < 0.001$).

With SAVE score class mortality predictions recalibrated to the AH cohort, the nine observed deaths lay within the 95% CI (9–17).

eCPR

The seven observed deaths in ten eCPR patients lay on the median value of the distribution generated using the ROD of 0.71 from the ELSO Registry, within the 95% CI (4–10). There was no difference between the mortality in our combined eCPR cohort (seven out of ten patients died), from the AH cohort in the CHEER study (12 out of 24 died) ($P = 0.4513$, Fisher exact test).

Discussion

Mortality for respiratory and cardiac ECMO in the combined cohort was lower than predicted by the SAVE and RESP scores. These scores are validated tools for predicting survival in ECMO patients developed from the ELSO Registry, adjusting for severity of illness and casemix differences. The ELSO Registry includes data from a range of health systems worldwide, with variations in resources and models of care. The mortality of patients admitted to ICU differs between

Table 4. Patient outcomes for extracorporeal membrane oxygenation (ECMO) for the Princess Alexandra Hospital and the Gold Coast University Hospital combined

	Respiratory ECMO	Cardiac ECMO
Continuous period of ICU care (days),* median (range)	27 (2–102)	18 (2–81)
Total invasive mechanical ventilation days,† median (range)	25 (2–100)	14 (2–77)
Total ICU days,† median (range)	27 (2–102)	18 (2–81)
Continuous period of acute care (days), median (range)	39 (7–142)	32 (3–133)
Total hospital admission including rehabilitation (days), median (range)	40 (7–280)	46 (3–429)
Renal replacement therapy while in ICU	28 (57%)	16 (59%)
Total number of patients	49	27
Discharge destination at end of continuous period of acute care		
Died	8 (16%)	9 (33%)
Dedicated rehabilitation ward or hospital	13 (27%)	10 (37%)
Chronic care facility	0 (0%)	0 (0%)
Home	28 (57%)	8 (30%)

All patients aged > 18 years treated with ECMO for cardiac or respiratory failure. Any part of a day was counted as a full day. * Continuous period of ICU care during which ECMO commenced. † Includes readmissions to the ICU. All patients who died did so in the ICU. All survivors were eventually discharged home. Six of the cardiac ECMO patients were transferred to another centre for consideration of ventricular assist device (VAD) or cardiac transplantation; none received cardiac transplantation; one received a VAD, but did not survive; of the five patients who did not receive transplantation or VAD, two survived.

low and high income countries.[16] Australian intensive care is well resourced, which may contribute to the lower mortality in our cohort. The nursing model of care in Australia has at least one nurse per ECMO patient, which is not the case in all countries.

The mortality for our combined cohorts for respiratory and cardiac ECMO, was no higher than in corresponding cohorts from the AH, despite differences in case volume. There were important differences in data collection methodology and outcome parameters between the Safer Care Victoria report and our study. By definition, low volume centres have low case numbers, reducing the power of statistical analysis. Despite these limitations, these comparisons were important to screen for potentially poor outcomes.

Neither PAH or GCUH have a formal eCPR program. eCPR is only undertaken in highly selected patients when appropriate staff are available. With only ten patients in our combined eCPR cohort, statistical power is limited, so no meaningful conclusions can be drawn about comparative mortality.

This study only included patients who received ECMO. Criteria for commencing ECMO differ between hospitals, which may introduce selection bias. The casemix at high volume, heart–lung transplantation centres such as AH will be different to low volume centres. More complex patients with high mortality may preferentially be transferred from low volume centre to high volume centres, although our study minimises the effect of this by attributing mortality to the centre in which ECMO was commenced. Differences in casemix may explain the variations in outcome, as methods for risk adjustment are imperfect. We did not compare complication rates, length of ICU and hospital stay, or cost with benchmarks. Long term morbidity was not directly assessed, but all patients were eventually discharged home.

A narrative has been built up in the literature that low volume ECMO centres cannot perform ECMO with acceptable mortality.[2,7,8] It is argued ECMO should be restricted to large volume ECMO centres. Our study demonstrates that good outcomes can be obtained in low volume centres. Our findings are supported by two recent studies from the United States which found mortality was higher in centres with high case volumes,[4,5] leading to the conclusion that "in properly selected patients, ECMO can be performed with acceptable results in U.S. centers that do not perform a high volume of ECMO".[5]

We have demonstrated that high ECMO volumes are not necessary to achieve good outcomes. Limiting ECMO to high volume centres has disadvantages. Firstly, a high volume centre may not offer the full range of services required. In Queensland, the cardiothoracic transplantation hospital does not manage major trauma or obstetrics. Secondly, when emergent ECMO is required, a retrieval team may not arrive in time. Emergent ECMO could be initiated by clinicians of a non-ECMO hospital, and then the patient could be transferred to an ECMO centre,[2] but ECMO initiation is a high risk procedure. Planning for an emergent high risk procedure to be performed by clinicians unfamiliar with the process is questionable. Thirdly, in non-ECMO hospitals, the threshold for initiating ECMO may be high due to logistics of retrieval and lack of familiarity. Delaying ECMO until multiple organ dysfunction is established may worsen outcomes. This factor may contribute to the observed case volume relationship in other studies. Finally, in Australia, the geography and distance make retrieval logistically challenging and difficult for the patient and their family. Patients living outside of capital cities, for whom ECMO is only a bridge

to recovery, may be better managed closer to home at a smaller volume centre.

Our study does not provide information about why PAH and GCUH have low ECMO mortality, despite relatively low case volumes, but several factors may contribute.

Firstly, team work. There is close liaison about ECMO cases between intensivists, cardiac surgeons and medical perfusionists. ECMO cannulation is an infrequent procedure in a low volume ECMO unit, while cardiac surgeons and perfusionists are familiar with cannulating large vessels and initiating cardiopulmonary bypass. During ECMO initiation, there is clear role assignment. Often a cardiac surgeon and an intensivist will perform cannulation together, assisting with skill acquisition.

Secondly, maximising exposure to ECMO of the clinicians involved. With surgical procedures, outcome depends on both hospital case volume and case volume of individual practitioners.[17,18] At PAH and GCUH, the ECMO service is consultant-driven, with minimal registrar involvement in decision making. The number of intensivists and nurses providing the service has been deliberately limited. There are usually two nurses per ECMO patient to maximise exposure, but this is reduced in the stable patient. While one intensivist is rostered to care for the ECMO patient, other intensivists assist as required. Daily group discussions by the bedside share knowledge and experience. During the development of our ECMO services, helpful advice was provided by the major Australian ICUs with ECMO training courses: AH and St Vincent's Hospital (Sydney). PAH provided clinical support to GCUH with their initial ECMO patients.

Thirdly, education and credentialing. We have in-house education programs for the nurses who provide ECMO, although many also attend recognised ECMO training courses. Before intensivists are credentialed in ECMO they must attend a recognised ECMO training course. Simulation is an important part of the process used to develop and maintain skills.[19]

Finally, while PAH and GCUH have low ECMO case volumes, they treat high volumes of patients with cardiac and respiratory failure. Nearly 1700 patients were ventilated in the PAH ICU in 2019, more than any other ICU in Australia (unpublished data accessed from the Australian and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation Adult Patient Database). The PAH cardiac catheterisation laboratory provided percutaneous coronary intervention for 412 ST elevation myocardial infarctions (STEMIs) in 2018,[20] more than any other hospital in Queensland. High volume ECMO services are likely to have a high volume of patients with cardiac and respiratory failure, which may explain some of the relationship between case volume and outcome in ECMO centres, rather than the number of ECMO runs per se. This may limit the generalisability of our results to other low volume ECMO services.

Conclusions

This study demonstrates that with appropriate processes in place, good outcomes can be achieved in low volume ECMO services. To maintain reasonable equity of access to ECMO, particularly in a large decentralised state such as Queensland, some low volume ECMO services will be required. Monitoring of outcomes is essential so poor outcomes can be identified early and corrected. Inclusion of ECMO patients into the Australian and New Zealand Intensive Care Society Adult Patient Database is an important step in this direction.

Competing interests

None declared.

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