Service delivery model of extracorporeal membrane oxygenation in an Australian regional hospital

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Joe McCaffrey, Neil R Orford, Nicholas Simpson, Jill Lamb Jenkins, Christopher Morley and Vin Pellegrino

ABSTRACT

Background: The role of extracorporeal membrane oxygenation (ECMO) for adults in regional centres with low numbers of patients receiving ECMO is unclear. A robust service delivery model may assist in the quality provision of ECMO.

Objective: To describe a novel ECMO service delivery model in a regional Australian hospital, reporting on patient characteristics and outcomes before and after its implementation.

Methods: An observational cohort study of all patients receiving ECMO at the University Hospital Geelong intensive care unit before and after implementation of a new ECMO clinical service model. The program included intensivist training in cannulation and care for ECMO patients, nurse accreditation in ECMO maintenance, and establishing a relationship with an ECMO centre caring for a high number of patients. Data included ECMO caseload, circuit configuration, complications, durations of therapy, and survival to ECMO weaning and ICU and hospital discharge.

Results: During the 14-year period for which we collected data, 61 adults received ECMO: 21 (35%) before and 40 (65%) after implementation of the structured program. The median annual case rate increased significantly between periods from two (range, 0–5 cases) to 10 (range, 5–13 cases) ($P < 0.01$). Other changes from before to after implementation included more medical indications for ECMO (48% v 80%; $P < 0.01$), higher peripheral cannulation configuration (57% v 98%; $P < 0.01$) and greater intensivist involvement as cannulation proceduralists (29% v 80%; $P < 0.01$). There were no significant differences between cohorts in ECMO weaning or duration, complication rates or ICU or in-hospital mortality.

Conclusions: Provision of ECMO in a tertiary regional hospital within a multifaceted clinical service model is feasible and safe. Partnership with a centre providing ECMO for a high number of patients during service development and delivery is desirable.

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The use of extracorporeal membrane oxygenation (ECMO) to treat severe adult cardiac and respiratory failure has increased in the past decade. Advances in the technology relating to ECMO,[1] supportive evidence,[2-4] and greater clinical experience[5] have all contributed to increasing activity in the area of ECMO. Despite these factors, ECMO remains a complex therapy with use restricted to very few patients in the intensive care unit.

At present, ECMO is provided mostly in specialised metropolitan hospitals with annual caseloads of greater than 30 ECMO patients.[6-9] Survival rates for patients receiving ECMO appear to be higher in institutions that use this therapy more frequently,[9-11] but there are many factors confounding this observation (such as patient selection bias, timing bias and resource bias). The role of adult ECMO in centres managing lower numbers of patients receiving ECMO remains unclear.

A robust service delivery model is likely to make the provision of ECMO safer in centres managing lower numbers of patients.[12,13] Key factors include a clear clinical governance structure, ongoing training, accreditation, maintenance of standards, sustainable program delivery and consideration of the caseload required to maintain proficiency.[6-8,10,12-16]

Because of the expanding role of ECMO in critical care, we developed a service delivery model at our tertiary regional hospital, where we had previously managed a low volume of patients receiving ECMO. We describe the components of our program and report characteristics, annual caseload, circuit configuration, complications and survival of patients supported on ECMO, before and after implementation of the new service model.

Methods

Setting

The University Hospital Geelong (UHG) ICU is a regional, level 3 ICU with 24 adult beds. It is a mixed medical, surgical, cardiothoracic and level 2 paediatric unit with over 1700 admissions and 450 cardiac surgical cases annually. It services a population of about 500 000 people in the Barwon South-Western region of Victoria, Australia.

Patients

The first patient managed with ECMO at UHG was in 2002, and its use was sporadic over the ensuing 9 years. During this period, cardiac surgeons inserted most ECMO cannulae, and a perfusionist was required to continuously monitor for circuit complications. This model resulted in the frequent cancellation of cardiac surgical cases and early interhospital transfer of patients from UHG. Intensivists at UHG had variable experience with ECMO, and clinical advice was routinely sought from a high-volume ECMO centre, The Alfred Hospital ICU (Melbourne, Victoria).

ECMO service delivery model

We developed a new clinical service model for ECMO over 36 months in consultation with intensivists, ICU nursing staff, cardiothoracic surgeons, perfusionists, and The Alfred Hospital ICU staff. This new program was implemented in May 2011.

Our model involves a formal approach to education, accreditation, cannulation and the management of ECMO hardware and circuitry. Management protocols were established in alignment with both The Alfred Hospital[17] and international ECMO guidelines.[15]

The ECMO initiation procedure was changed to occur principally in the ICU, and required a minimum of three intensivists: two for cannulation and one to provide echocardiographic support. A perfusionist was required to initiate ECMO and thereafter reviewed the circuit twice daily and remained on call to provide emergency assistance until successful weaning from ECMO had occurred. Two ICU nurses were allocated to each patient: one accredited to manage the ECMO circuit, and a second for routine patient care. In the event of two patients supported on ECMO simultaneously, one accredited nurse would manage both circuits.

Videoconference facilities were introduced for case discussion between hospitals, cardiac surgical staffing was changed and ECMO equipment was upgraded to align with the pump and circuitry used at The Alfred Hospital (CardioHelp HLS set 7.0, Maquet).

Service monitoring

We developed an ECMO database to prospectively collect patient demographic data, indications for ECMO, treatment configuration, complications, lengths of stay and mortality. To monitor activity and outcomes after the introduction of the new service, data from all patients receiving ECMO before May 2011 were retrospectively added to the database.

We undertook a cohort study of all adult patients receiving ECMO at UHG before the introduction of the new clinical service model (January 2002 – April 2011) and after its introduction (May 2011 – December 2015). Our aim was to monitor the safety of the new program and identify any trends in ECMO use over time. We sought to determine the number of patients receiving ECMO, the circuit configurations, complications, durations of therapy, and survival to ECMO weaning and ICU and hospital discharge. We tested differences between cohorts with the Wilcoxon rank-sum test for continuous variables, and with the Fisher exact test for binary outcomes, using R software (R Core Team).

The Barwon Health Research Ethics Committee approved our data collection and waived the requirement for patient consent.

Results

Patient characteristics and caseload

During the 14-year period, a total of 61 patients received ECMO: 21 (35%) before and 40 (65%) after the introduction of the structured program. The median annual case rate increased significantly between periods, from two cases (range, 0–5 cases) to 10 cases (range, 5–13 cases) per year ($P < 0.01$) (Figure 1). There were no significant differences in age, sex, weight or severity of illness between the cohorts (Table 1).

Circuit configuration

Venoarterial (VA) ECMO represented 66% of cases overall, with 15 cases (71%) in the before group, and 25 cases (63%) in the after group. There were six cases (29%) of venovenous (VV) ECMO over the 9-year before period, which increased to 15 cases (37%) in the 4.5-year after period. ECMO configuration (VV or VA) did not differ significantly between groups (Table 1).

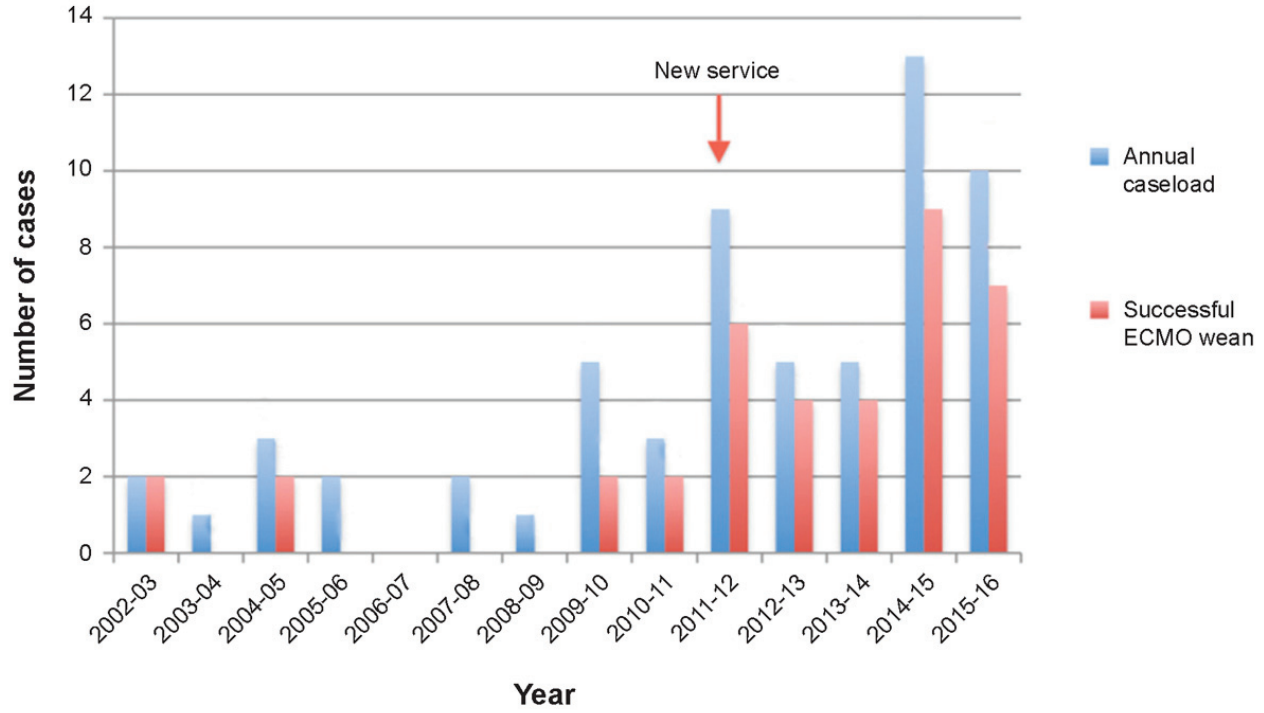
Indications for ECMO

After introduction of the new program, a significantly greater proportion of patients received VA ECMO after admission to ICU with a medical diagnosis (before program, 48% v after program, 80%), and a lower proportion received ECMO after cardiac surgery (before program, 52% v after program, 15%; $P < 0.01$). This was associated with a significant increase in patients with cardiogenic shock after myocardial infarction receiving ECMO (before program, 4.8% v after program, 30%; $P < 0.01$) (Table 2).

Cannulation

Intensivists performed significantly more cannulations in the ICU after introduction of the new service (before program, 29% v after program, 80%; $P < 0.01$). The number of central cannulations also declined significantly (before, 43% v after, 3%; $P < 0.01$) (Table 1).

Figure 1. Annual ECMO caseload and successful weaning, 2002 to 2016



ECMO = extracorporeal membrane oxygenation. UHG = University Hospital Geelong.

Duration of therapy

The duration of each ECMO treatment did not differ significantly between cohorts (3.6 v 5.1 days; $P = 0.50$), but a significantly longer hospital length of stay (16 v 28.6 days; $P = 0.04$), and trend towards a longer ICU length of stay (8.2 v 16.3 days; $P = 0.06$), was observed following implementation of the new service (Table 1).

The overall proportion of patients on ECMO transferred to another hospital was not significantly different between time periods (before, 33% v after, 18%; $P = 0.21$). However, subgroup analysis of VV ECMO cases revealed a significant reduction in transfer rates following introduction of the new program (before, 66% v after, 7%; $P = 0.01$) (Table 3).

Complications

The overall complication rates between groups were similar (Table 4). Mechanical complications involving ECMO circuitry were significantly less frequent after implementation of the new service (33% v 6%; $P < 0.02$). There were no differences in the rates of major bleeding (40% v 17%; $P = 0.08$) or technical complications, including difficult or failed cannulations, vascular damage requiring surgical intervention, or changes to circuit configuration after start of ECMO (27% v 34%; $P = 0.75$).

Outcomes

Survival to ECMO weaning did not differ between cohorts (before program, 52% v after program, 74%; $P = 0.10$), and nor did survival to ICU or hospital discharge (before program, 38% v after program, 56%; $P = 0.28$). No patient died in hospital after successful ECMO weaning and ICU discharge. The cumulative caseload and hospital survival is depicted in Figure 2.

Discussion

Major findings

We describe the key features, demographics and outcomes before and after the introduction of a structured ECMO program in a tertiary regional hospital. The program was associated with a fivefold increase in annual ECMO caseload, more medical indications for ECMO, greater intensivist involvement in cannulation, and fewer VV ECMO patients requiring interhospital transfer. There were no significant differences in survival or adverse events. These data are supportive of the conclusion that an ECMO service can be safely provided in a regional hospital.

Table 1. Patient, clinical and outcome characteristics before and after start of structured ECMO program

Characteristic	Before (*n* = 21)	After (*n* = 40)	*P*
Median cases per year,* (IQR)	2 (1.0–4.0)	10 (5.0–10.0)	< 0.01
Demographic variable			
Median age, years (IQR)	53.0 (35.0–64.0)	57.0 (38.0–63.0)	0.90
Women, *n* (%)	8 (38.1%)	8 (20.0%)	0.14
Median weight, kg (IQR)	87 (70.0–97.0)	88.5 (75.0–110.0)	0.41
Admission category, *n* (%)			< 0.001
Medical†	10 (47.6%)	32 (80.0%)	
Surgical	0	2 (5.0%)	
Cardiothoracic	11 (52.4%)	6 (15.0%)	
Critical illness-related			
Median APACHE II score‡ (IQR)	21.0 (18.0–24.0)	20.5 (16.0–29.3)	0.93
Median SOFA score§ (IQR)	16.0 (14.5–18.0)	14.0 (12.5–16.0)	0.09
CRRT used,¶ *n* (%)	8 (38.1%)	25 (62.5%)	0.10
Catecholamines used,¶ *n* (%)	20 (95.2%)	40 (100%)	0.34
ECMO configuration, *n* (%)			0.58
Venoarterial	15 (71.4%)	25 (62.5%)	
Venovenous	6 (28.5%)	15 (37.5%)	
Cannulation, *n* (%)			< 0.01
Peripheral	12 (57.1%)	39 (97.5%)	
Central	9 (42.9%)	1 (2.5%)	
Cannulator, *n* (%)			< 0.01
Intensivist	6 (28.6%)	32 (80.0%)	
Cardiac surgeon	15 (71.4%)	8 (20.0%)	
Outcome			
Median ECMO duration, days (IQR)	3.6 (1.9–9.2)	5.1 (3.0–9.0)	0.50
Median ICU LOS, days (IQR)	8.2 (2.8–17.6)	16.3 (6.5–26.2)	0.06
Median hospital LOS, days (IQR)	16 (6.3–21.7)	28.6 (6.6–41.3)	0.04
Transfer, *n* (%)	7 (33.3%)	7 (18.0%)	0.21
ECMO survival, *n* (%)	11 (52.4%)	29 (74.3%)	0.10
ICU survival, *n* (%)	8 (38.1%)	22 (56.4%)	0.28
Hospital survival, *n* (%)	8 (38.1%)	22 (56.4%)	0.28

ECMO = extracorporeal membrane oxygenation. IQR = interquartile range. APACHE = Acute Physiology and Chronic Health Evaluation. SO-FA = Sequential Organ Failure Score. CRRT = continuous renal replacement therapy. ICU = intensive care unit. LOS = length of stay. * Adjusted to account for the periods before and after introduction of new program in 2011: actual caseload before program introduction (Jan–Apr 2011) was 2; actual caseload after program introduction (May–Dec 2011) was 7. † Defined as any indication for ECMO not directly resulting from a surgical procedure. ‡ Based on diagnosis at admission. § Worst values calculated within 24 hours before cannulation. ¶ Treatment provided while patient receiving ECMO.

Table 2. Demographic, clinical, indication and outcome characteristics for patients receiving VA ECMO, before and after start of structured ECMO program

Characteristic	Before (*n* = 15)	After (*n* = 25)	*P*
Median cases per year,* (IQR)	1.5 (1.0–2.8)	6.0 (4.0–6.0)	< 0.01
Demographic variable			
Median age, years (IQR)	63.0 (48.0–68.5)	59 (52.0–67.0)	0.50
Women, *n* (%)	4 (26.7%)	2 (8.0%)	0.39
Median weight, kg (IQR)	90 (72.5–101.0)	81 (75.0–100.0)	0.86
Critical illness-related			
Median APACHE II score† (IQR)	22.0 (18.5–24.0)	26.0 (18.0–30.0)	0.52
Median SOFA score‡ (IQR)	16 (14.5–18.0)	14.0 (13.0–16.8)	0.30
CRRT used,§ *n* (%)	6 (40.0%)	17 (68.0%)	0.33
Catecholamines used,§ *n* (%)	15 (100%)	25 (100%)	1.0
Indication, *n* (%)			
Post-cardiotomy	10 (47.6%)	5 (12.5%)	< 0.01
Cardiogenic shock	1 (4.8%)	12 (30.0%)	0.01
Cardiomyopathy	4 (19.0%)	8 (20.0%)	0.72
Cannulation, *n* (%)			< 0.01
Peripheral	9 (60.0%)	24 (96.0%)	
Central	6 (40.0%)	1 (4.0%)	
Cannulator, *n* (%)			< 0.01
Intensivist	2 (13.3%)	17 (68.0%)	
Cardiac surgeon	13 (86.7%)	8 (32.0%)	
Outcome			
Median ECMO duration, days (IQR)	3.4 (1.3–5.9)	4.2 (2.3–5.7)	0.48
Median ICU LOS, days (IQR)	5.8 (2.5–13.5)	11.9 (4.8–26.4)	0.09
Median hospital LOS, days (IQR)	10.3 (5.1–18.8)	27.0 (4.9–44.7)	0.20
Transfer, *n* (%)	3 (20.0%)	6 (25.0%)	1
ECMO survival, *n* (%)	8 (53.3%)	19 (79.0%)	0.19
ICU survival, *n* (%)	5 (33.3%)	12 (50.0%)	0.52
Hospital survival, *n* (%)	5 (33.3%)	12 (50.0%)	0.52

VA = venoarterial. ECMO = extracorporeal membrane oxygenation. IQR = interquartile range. APACHE = Acute Physiology and Chronic Health Evaluation. SOFA = Sequential Organ Failure Score. CRRT = continuous renal replacement therapy. ICU = intensive care unit. LOS = length of stay. * Adjusted to account for the periods before and after introduction of new program in 2011: actual caseload before program introduction (Jan–Apr 2011) was 2; actual caseload after program introduction (May–Dec 2011) was 6. † Based on diagnosis at admission. ‡ Worst values calculated within 24 hours before cannulation. § Treatment provided while patient receiving ECMO.

Table 3. Demographic, clinical, indication and outcome characteristics for patients receiving VV ECMO, before and after start of structured program

Characteristic	Before (*n* = 6)	After (*n* = 15)	*P*
Median cases per year,* (IQR)	0 (0–1.0)	2.0 (1.5–4.0)	0.03
Demographic variable			
Median age, years (IQR)	31.5 (25.8–35.8)	52.0 (31.0–58.0)	0.08
Women, *n* (%)	4 (66.7%)	6 (40.0%)	0.36
Median weight, kg (IQR)	80 (72.5–92.8)	95 (76–128.5)	0.20
Critical illness-related			
Median APACHE II score† (IQR)	18.5 (16.5–20.5)	17.0 (12.5–25.0)	0.82
Median SOFA score‡ (IQR)	15.5 (13.5–16.5)	13 (12.0–14.5)	0.21
CRRT used,§ *n* (%)	2 (33.3%)	10 (66.7%)	0.33
Catecholamines used,§ *n* (%)	5 (83.3%)	15 (100%)	0.29
Indication			
Viral pneumonia	2 (9.5%)	4 (10.0%)	0.57
Bacterial pneumonia	1 (4.8%)	3 (7.5%)	0.77
Aspiration pneumonia	0	2 (5.0%)	
Other¶	3 (14.3%)	6 (15.0%)	
Cannulation, *n* (%)			1.0
Peripheral	6 (100%)	15 (100%)	
Central	0	0	
Cannulator, *n* (%)			0.07
Intensivist	4 (66.7%)	15 (100%)	
Cardiac surgeon	2 (33.3%)	0	
Outcome			
Median ECMO duration, days (IQR)	10.4 (4.4–12.0)	8.4 (4.9–10.3)	0.61
Median ICU LOS, days (IQR)	17.4 (14.9–19.1)	20.9 (11.5–25.4)	0.51
Median hospital LOS, days (IQR)	21.4 (16.5–24.1)	30 (21.0–38.5)	0.15
Transfer, *n* (%)	4 (66.7%)	1 (7.1%)	0.01
ECMO survival, *n* (%)	3 (50.0%)	11 (73.3%)	0.35
ICU survival, *n* (%)	3 (50.0%)	11 (73.3%)	0.35
Hospital survival, *n* (%)	3 (50.0%)	11 (73.3%)	0.35

VV = venovenous. ECMO = extracorporeal membrane oxygenation. IQR = interquartile range. APACHE = Acute Physiology and Chronic Health Evaluation. SOFA = Sequential Organ Failure Score. CRRT = continuous renal replacement therapy. LOS = length of stay. ICU = intensive care unit. * Adjusted to account for the periods before and after introduction of new program in 2011: actual caseload before program introduction (Jan–Apr 2011) was 0; actual caseload after program introduction (May–Dec 2011) was 1. † Based on diagnosis at admission. ‡ Worst values calculated within 24 hours before cannulation. § Treatment provided while patient receiving ECMO. ¶ Including acute respiratory distress syndrome; pulmonary embolism; and post-operative, post-traumatic, non-surgical and non-traumatic conditions.

Table 4. Complication rates* of ECMO before and after start of structured program,† *n* (%)

Complication	Before (*n* = 15)	After (*n* = 35)	*P*
Mechanical	5 (33.3%)	2 (6.0%)	0.02
Technical‡	4 (26.7%)	12 (34.3%)	0.75
Bleeding-related	6 (40.0%)	6 (16.7%)	0.08
CVS-related	3 (20.0%)	0	0.02
CNS-related	2 (13.3%)	1 (2.9%)	
Sepsis	1 (6.7%)	2 (5.7%)	
Metabolic	1 (6.7%)	3 (8.6%)	
Limb-related	1 (6.7%)	5 (14.3%)	0.65

CVS = cardiovascular system. CNS = central nervous system. * Calculated as rate per patient-ECMO run (based on guidelines[13]). † Transferred patients excluded unless complications arose before transfer. ‡ Including difficult cannulation (multiple attempts or unable to pass backflow cannula), failed cannulation, death on cannulation, vascular damage requiring intervention, and changes to configuration after commencement of ECMO (see guidelines[13]).

Comparison with previous studies

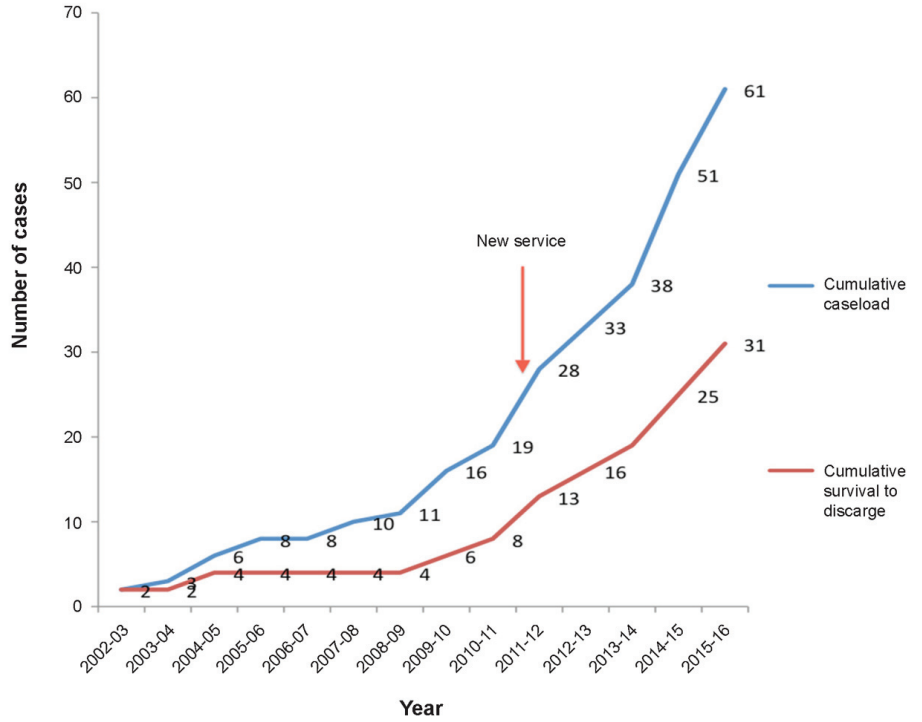
As far as we are aware, this is the first study to describe the establishment of a structured ECMO service and outcomes in a regional centre. The complication rates and outcomes of this service are in keeping with similar programs worldwide,[6,16,18] and compare favourably with results reported by the Extracorporeal Life Support Organization (ELSO) adult international summary.[5]

The role of ECMO in low-volume centres has been questioned.[9-12] A retrospective analysis of more than 10 000 adults on the ELSO registry categorised units according to their annual ECMO caseload.[9] Mortality was inversely proportional to volume, with the highest recorded mortality rates occurring in units with fewer than six cases per year. Since the introduction of our structured ECMO program, our median unit volume has increased from fewer than five cases per year to 10 cases per year (low-to-moderate volume category). Our mortality rate during this period was similar to that of high-volume centres managing more than 30 cases per year,[9] and our complication rates were comparable to those recorded in the ELSO registry.[18] Models describing ICU-led services, specifically the use of intensivists and nursing staff as cannulators and ECMO specialists in high-volume centres, report outcomes suggesting that they are safe, feasible and cost-effective.[6,16,19,20] Our results add to this literature by reporting similar outcomes with a model of ICU-led ECMO delivery in a low-to-moderate volume regional centre with formal support from a high-volume centre.

Implications for clinicians and policy makers

We believe several elements assisted in the transition, maintenance of standards and safe outcomes after the

Figure 2. Cumulative ECMO caseload and hospital survival, 2002–2016



ECMO = extracorporeal membrane oxygenation. UHG = University Hospital Geelong.

introduction of this new program. These include model type, governance structure and partnership with a high-volume ECMO centre. These observations are in keeping with previous reports,[6,8-15] and may inform the debate surrounding guidelines on minimum caseloads, organisational structure, and the processes of care required to maintain a safe service, as recommendations currently vary.[12-14]

The change in our model type has resulted in other advantages, including the ability to care for patients in their geographical region, the removal of barriers to the timely initiation of ECMO, providing a unit capacity to manage multiple ECMO patients concurrently, empowering ICU nursing staff in a new technical skill, and allowing perfusionists to continue to provide services for cardiac surgery while patients are receiving ECMO.

Future research

Telehealth technology has been described in the ICU setting,[21] and has been shown to be an independent predictor of survival when used in remote ICUs.[22] Its specific use in ECMO has not been widely reported until now, although it has been shown to enhance care in other specialised areas of ICU practice.[23] Initially, our program relied heavily on videoconferencing, which aided the establishment of working relationships and facilitated timely discussions on patient selection, appropriate mode and configuration of supports, retrieval, trouble-shooting and weaning strategies.

Strengths and limitations

Our study has various strengths, including that it was a prospective study examining robust outcome measures on all patients who received ECMO within our unit, with few reported missing data. It addresses a topical area of practice (concerns regarding ECMO service proficiency and safety in regional centres), which was unreported in the literature. It also shows the feasibility of a model relying heavily on telehealth technology in partnership with a high-volume centre.

It is important to note that we measured only key clinical variables directly related to ECMO. A limitation of our study is that many other clinical service changes may have influenced our observations. Patient selection, management protocols, changes in staff and improved outcomes over time may all have influenced our findings. Although we were able to demonstrate that an ICU nurse can be trained to manage an ECMO circuit, we cannot determine the cost-effectiveness of this model. A recent study suggests that there may be a 60% cost reduction when comparing similar models of service described in our study.[16] Our results are restricted by our small sample size but are the largest reported from a regional hospital.

Conclusion

The provision of ECMO in a tertiary regional hospital within the construct of a multifaceted clinical service model is feasible and safe. Partnership with a high-volume centre during service development and delivery is desirable.

Competing interests

None declared.

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