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Original Article

An intensivist-led ECMO accreditation pathway and safety data over the first 4 years

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ABSTRACT

Objective: To describe the training and accreditation process behind an intensivist-led extracorporeal membrane oxygenation (ECMO) cannulation program, and identify the rate of complications associated with the ECMO cannulation procedure.
Design: A narrative review of the accreditation process, and a retrospective review of complications related to cannulation during the first four years of the intensivist program.
Setting: Royal Prince Alfred Hospital, a quaternary referral hospital in Sydney.
Participants: All patients initiated onto ECMO during the first four years of the intensivist cannulation program (August 2018 to August 2022).
Main outcome measures: All cases were reviewed for identification of 14 pre-defined adverse events which were classified as low, medium or high clinical significance complications.
Results: A total of 402 cannulations were attempted by the intensivist group in 194 separate cannulation episodes involving 179 patients. This included 93 V–V initiations, 69 V-A initiations (36 of these ECMO-CPR), 3 V-AV (veno-arteriovenous) initiations, 25 ECMO reconfigurations and four patients cannulated for peripheral cardiopulmonary bypass in cardiothoracic theatre. One of the 402 cannulations was halted as resuscitation was ceased, and one was halted and the patient transferred to theatre for central arterial cannulation. 394 out of the remaining 400 cannulations were successful (98.5%). Of 402 total cannulations, 32 complication events occurred (7.96% event rate), of which 15 (3.7% event rate) were low significance complications, 10 medium significance (2.5% event rate), and seven high clinical significance (1.7% event rate).
Conclusions: Our experience of the first four years of an intensivist-led ECMO service demonstrates that our training process and cannulation technique result in the provision of a complex therapy with low levels of complications, on par with those in the published literature.

1. Introduction

Initiation of Extracorporeal Membrane Oxygenation (ECMO) therapy is a technically complex, invasive procedure involving cannulation of the major vessels, connection of the ECMO circuit, and commencement and titration of ECMO flows, whilst concurrently managing resuscitation and organ support for the patient.

ECMO cannulation carries significant potential risks including vessel injury, major haemorrhage, limb ischaemia, thromboembolism, misconnection, air embolism and bloodstream infection.[1]

Percutaneous cannulation, as opposed to an open surgical technique, is associated with a lower in-hospital mortality and fewer complications,[2] with lower risks of infection, cannula site bleeding, vessel thrombosis and need for surgical vascular repair.[3–5] In addition to this, percutaneous cannulation can be performed in locations outside of the operating theatre, such as the Emergency Department or Intensive Care Unit, and by medical specialists other than surgeons.

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The joint SCCM-ELSO task force consensus statement recognises that many specialists, including intensivists, can perform cannulation for ECMO commencement.[6] Formal training and accreditation processes are required to ensure proceduralists are sufficiently trained and credentialled. There are numerous publications describing techniques for vessel cannulation,[5,7] configuration,[7,8] training methods for cannulation[9] and cannula configuration.[10,11] Medical intensivist-led cannulation of both V-A and V-V ECMO is described in the literature[12–14] and has been shown to be safe with a low rate of cannulation failure or complications.

In this article, we present our institution's training accreditation policy and describe our experience over the first four years of an intensivist-led cannulation program. Our cannulation technique in detail is included as an appendix (Appendix A).

2. History of our institution's ECMO service

Our institution is one of two state-wide ECMO referral centres, offering both in-house and retrieval services, with 64 ECMO runs in 2021. Our ECMO service was established in 2009 and initially, all ECMO cannulation was performed by cardiothoracic surgeons. In 2018 this transitioned to a primarily intensivist-led service in order to improve the availability of cannulators and to reduce disruption to the cardiac surgical theatre lists.

At our institution, ECMO may be initiated in the ICU, Emergency Department, Cardiac Catheterisation suite or Operating Theatre. All cannulations are performed using ultrasound guidance for vascular access and transoesophageal echocardiography (TOE) for wire placement and cannula positioning. On rare occasions TOE is unavailable or in the case of awake cannulation, transthoracic echocardiography (TTE) and/or fluoroscopy is used. Echocardiography is performed by accredited operators and fluoroscopy, when used, is performed by radiographers.

Intensivists are the principle cannulators for all V-V, V-A and ECMO-CPR cases aside from ECMO initiated for post-cardiac surgical cases within the operating theatre.

3. Initial transition phase

A total of ten intensivists have entered the ECMO cannulation training program. An initial group of six intensivists began in-vivo cannulations in mid-2018 and were supervised by cardiothoracic surgeons. Four of the initial six were senior intensivists with over 10 years of experience in our tertiary ICU; the remaining two were within 5 years of fellowship. All were experienced in ultrasound-guided central venous and arterial line placement, and standard management of the ECMO patient. Between 2019 and 2022 an additional four intensivists entered the training pathway, three were intensivists within 3 years of fellowship and one was a senior intensivist. All had the skill set mentioned above.

In 2019, three intensivists from the initial group reached the required competency and were able to perform ECMO cannulation independently. Intensivist cannulators subsequently entering the training pathway were trained primarily by these three intensivists. Of the ten in total, seven achieved full accreditation with three electing not to complete the program. At the time of writing, these seven intensivists are fully accredited and active for cannulation. Other specialists entering the program from the beginning would follow this same pathway. However, cannulation for peripheral cardiopulmonary bypass is a core skill of a specialist cardiothoracic surgeon and therefore ECMO cannulation is considered part of their usual scope of practice.

The average time to complete the minimum of 10 venous cannulae required for venous cannulation accreditation is 9 months.

3.1. Accreditation process

3.1.1. Entering the training pathway

Specialists or postgraduate fellows from Intensive Care, Cardiothoracic Surgery or Cardiac Anaesthesia may enter the training pathway via written application to the multidisciplinary accreditation panel. To date, only fellows or specialists from the Intensive Care stream have participated in the current ECMO cannulation training program.

In our centre, the panel consists of the head of the Cardiac Anaesthetic and Perfusion Service, a delegate of the director of Cardiothoracic Surgery, the director of the Intensive Care Service and an ECMO Intensivist accredited for V-A ECMO retrieval (the highest level of accreditation).

3.1.2. Progression

The training period takes up to 2 years, as opportunities for supervised cannulation are unpredictable and are shared in an equitable manner. Once an individual is formally accepted onto the training pathway, they are provided with orientation and then simulation-based training for cannulation and circuit connection. A face-to-face viva exam follows, then supervised porcine lab cannulation and circuit connection, and finally supervised in-vivo cannulation.

All simulated, porcine, and in-vivo cannulations are recorded in the central departmental logbook, providing comprehensive documentation of cannulations, circuit changes, decannulations, transports and additional procedures. At every stage of the training process, formative, summative and logbook reviews are conducted with the cannulator by the ECMO Head of Service (or representative).

3.1.3. Tiers of accreditation

There are discrete tiers of accreditation reflecting the increasing complexity of the different types of ECMO cannulation required (see Appendix B). Progression through the levels of accreditation is sequential and bidirectional.

3.1.4. Exiting the training pathway

An individual exits the training pathway by receiving accreditation for ECMO cannulation – this may be for all tiers, or to a specific tier only. An individual may also exit the training pathway without attaining accreditation.

3.1.5. Ongoing competency

To maintain accreditation, cannulators must perform a minimum of three vessel cannulations and 1 ECMO retrieval per year.

3.1.6. Accelerated accreditation

Candidates who can present a logbook of prior cannulation experience are eligible for the accelerated pathway. Following observed porcine V-A-ECMO cannulation and circuit connection, they are required to perform at least one successful in-vivo V-A cannulation without the intervention of a fully accredited supervisor. Following this, an application for and approval of accreditation by the panel proceeds as above.

3.1.7. Quality assurance

In keeping with ELSO guidelines, our unit has a strong emphasis on quality assurance and improvement processes.[6,15] We run a biannual ECMO Morbidity & Mortality meeting, and record ECMO outcomes through the EXCEL registry. We have developed a full-day in-house ECMO education course that is delivered to new medical and nursing staff regularly to ensure staff are trained in the management of these complex patients.

Table 1
Breakdown of ECMO cases by type.

Total cannulation episodes	194
V-V initiations	93
V-A initiations	69 (36 of these ECMO-CPR)
V-AV initiations	3
Circuit reconfigurations	25
Cardiopulmonary bypass	4

Table 2
Breakdown of cannulations by type.

Total successful cannulations	394
Venous cannulas	263
Arterial cannulas	72
Distal perfusion cannulas	50
Avalon cannulas	9

3.1.8. Outcomes of the intensivist-led cannulation program

We reviewed the complications of our ECMO cannulation procedure post transition to intensivist cannulation. Data was obtained from a review of the following resources:

- A centrally maintained departmental ECMO procedural logbook
- Mortality and morbidity data from departmental M&M meetings
- The electronic medical record

Retrospective collection and review of patient data were approved by the Sydney Local Health District Ethics Review Committee (RPAH zone), which waived the need for patient consent.

Over the first four years of the intensivist cannulation program, from August 2018 to August 2022, 402 cannulations were attempted by the intensivist group, in 194 separate cannulation episodes on 179 patients. A cannulation is defined as insertion of a single cannula, whilst a cannulation episode is defined as an attempt at ECMO initiation, or reconfiguration of an existing circuit requiring insertion of at least one additional cannula. One of the 402 cannulations was halted with the venous sheath successfully placed as the patient was taken to theatre for central arterial cannulation, and one was halted with venous access achieved and the tract dilated but prior to cannula insertion, as peripheral arterial access proved impossible and the ECMO-CPR attempt was abandoned. 394 out of the remaining 400 (98.5%) cannulation attempts were successful. The abandoned ECMO-CPR attempt was the only episode of complete failure to initiate out of the 194 cannulation episodes reviewed (0.5% ECMO initiation/reconfiguration failure rate).

The 194 cannulation episodes were divided into types of ECMO as listed in Table 1. Table 2 describes the breakdown of the 394 cannulations.

Of the eight unsuccessful cannulae, three were distal perfusion cannulae, three were venous cannulae (of which two had venous access achieved but no cannula inserted, as above) and two were arterial. These unsuccessful attempts are detailed later in the tables

Table 3
Classification of complications.

Low significance
>2 attempts at vascular access (where successful cannulation has occurred without haemorrhage or vascular injury)
Medium significance
Air entrainment to circuit without air embolism to patient
Connection issue (not leading to patient sequalae)
Failure to successfully place distal perfusion cannula, requiring specialist surgical assistance
High significance
Haemorrhage (as defined by need for >2U PRBC transfusion related to cannulation within the 24 h following cannulation, or surgical haemostasis other than simple suture)
Need for vascular surgical repair other than standard vascular surgical decannulation
Limb ischaemia
Cannulation of incorrect vessel(s)
Failure to cannulate leading to abandonment of cannulation, surgical cutdown or conversion to central ECMO
Air embolism to patient
New pericardial effusion
Wire complication (vessel perforation or fracture of wire)
Connection issue (leading to patient sequaelae)
Need for early (<24 h) reconfiguration due to inadequate cannula positioning/size

Table 4
Low clinical significance complications.

Low clinical significance = 15 complications/402 cannulations (3.7% complication rate per cannulation)
15 complications/194 cannulation episodes (7.7% complication rate per cannulation episode)
These complications involved 14 cannulation episodes and 14 patients

Complication	Number of events	Type of ECMO	Additional details
>2 attempts at vascular access for successful cannulation without haemorrhage, vascular injury or sequalae (n = 13)	1	V-V	
	1	V-A	
	1	V-AV	
	10	ECMO-CPR	8 cases required >2 attempts at 1 cannula, 1 case required >2 attempts for 2 cannulae
Technical difficulty with wire/dilation without sequalae or patient related complication (n = 2)	1	V–V	Access cannula kinked requiring exchange over wire
	1	V–V	Wire dislodgement during dilation, new vessel puncture required

Table 5
Moderate clinical significance complications.

Moderate clinical significance = 10 complications/402 cannulations (2.5% complication rate per cannulation) 10 complications/194 cannulation episodes (5.2% complication rate per cannulation episode) These complications involved 9 cannulation episodes and 9 patients			
Complication	Number of events	Type of ECMO	Additional details
Failure to cannulate, surgical assistance needed (n = 3)	2	ECMO-CPR	Failure to insert distal perfusion cannula, requiring vascular surgeon assistance, nil limb related sequalae (one patient also required >2 attempts for both venous and arterial cannulae)
	1	V-A	As above
Air entrainment without air embolism to patient (n = 2)	1	V-V	Air in oxygenator after run-on due to inadequate priming, deaired, nil embolism
	1	Reconfiguration V-A to V-AV	Air entrainment during cannulation for reconfiguration, deaired, nil embolism
Vascular complication, conservatively managed (n = 1)	1	V-A	Dissection of EIA/SFA, conservatively managed
Late cannulation site infection (n = 3)	1	V-A	Post-decannulation insertion site infection due to proximity to discharging LSCS wound, requiring vac dressing (the same patient had dissection of EIA/SFA above)
	1	V-V	Femoral cannulation site infection requiring reconfiguration
	1	V-V	RIJ cannulation site infection noted at the time of decannulation
Haemorrhage/haematoma, conservatively managed (n = 1)	1	V-A	Femoral haematoma, DSA performed, resolved with pressure and correction of coagulopathy

Table 6
High clinical significance complications.

High clinical significance = 7 complications/402 cannulations (1.7% complication rate per cannulation) 7 complications/194 cannulation episodes (3.6% complication rate per cannulation episode) Involving 7 cannulation episodes and 7 patients			
Complication	Number of events	Type of ECMO	Additional details
Failure to cannulate (n = 2)	1	V-A	Converted to central cannulation
	1	ECMO-CPR	Failure to cannulate artery, resuscitation ceased
Incorrect vessels cannulated (n = 4)	1	ECMO-CPR	Incorrect vessels cannulated, existing angio sheaths misidentified. Vascular surgical repair
	1	ECMO-CPR	Incorrect vessel cannulated (post-thrombolysis), surgical cannulation and ECMO initiation achieved, however patient later became unsupportable and died
	1	ECMO-CPR	Return cannula in SFA, required vascular repair and fasciotomy (this patient also had a 'low clinical significance' complication of >2 attempts at access)
	1	ECMO-CPR	Backflow cannula in vein leading to ischaemic leg requiring fasciotomy (this patient also had a 'low clinical significance' complication of >2 attempts at access)
Ischaemic limb (n = 1)	1	ECMO-CPR	Ischaemic leg (fulminant COVID myocarditis)

below and required either additional surgical support or cessation of resuscitation.

The medical records of all 402 cannulations were reviewed independently by two authors (SD, JA) looking for the occurrence of predefined complications, which were classified into low, medium and high clinical significance, as per Table 3.

Of 402 total cannulations, 32 complication events occurred (7.96% event rate per cannula insertion), of which 15 (3.7% event rate) were low significance complications (Table 4) and 10 medium significance (2.5% event rate) (Table 5). Only seven complications (1.7% event rate) had high clinical significance (Table 6). Six of these occurred as part of ECMO-CPR and the other during V-A cannulation in a critically ill patient. No high-significance complications were recorded in 93 V-V cannulations.

When expressed per cannulation episode, 32 complication events across 194 separate cannulation episodes give an overall complication rate of 16.5%, of which 7.7% were low clinical significance, 5.2% medium and 3.6% high clinical significance (Table 7).

Table 7
Complication events stratified by type of ECMO.

ECMO episodes by type (total = 194)	Complication events (total = 32)			
	Low clinical significance (n = 15)	Moderate clinical significance (n = 10)	High clinical significance (n = 7)	Total complications by type of ECMO
V–V (N = 93)	3	3	–	6/93 (6.5%)
V-AV (N = 3)	1	–	–	1/3 (33.3%)
V-A (non ECMO-CPR) (N = 33)	1	4	1	6/33 (18.2%)
V-A (ECMO-CPR) (N = 36)	10	2	6	18/36 (50%)
Circuit reconfiguration (N = 25)	–	1	–	1/25 (4%)
Bypass (N = 4)	–	–	–	–

4. Discussion

Our experience adds to the increasing body of evidence demonstrating that a cannulation program performed primarily by intensivists is achievable and safe with a low level of clinically significant complications.[13,16,17]

Our data demonstrated a 98.5% cannulation success rate with a low rate (4.2%) of medium and high clinical significance complications per cannula inserted, or 8.8% per cannulation episode, in keeping with data described in other reports of intensivist-led ECLS programs.[12,13,16] A paper describing an intensivist-led VV ECMO program quoted a major complication rate of 6.9% per patient, or 3.5% per cannulation attempt.[13] Their definition of major complications were similar to those we have included in 'high clinical significance' events. Our VV ECMO data showed no high clinical significance events, with 3.2% rate of moderate significance events per cannulation episode. Kraii et al. describe the development of their intensivist-led ECLS program and mention a complication rate of 4.6% – again the complications they describe would be in keeping with our 'high clinical significance' events.[16]

The Alfred group mention a complication rate of 8% in V-A ECMO (including ECMO CPR) patients cannulated in their intensivist-led program.[14] The complications they describe (vessel injuries requiring theatre, embolectomy, lower limb ischaemia) again seem on par with what we have labelled 'high clinical significance' complications, which had an incidence of 10.1% in our V-A (including ECMO-CPR) patient dataset.

We ascribe our low complication rate to a thorough and well-defined accreditation and training program, as well as strict quality assurance processes. The practice of TOE ± fluoroscopic guided cannulation is in keeping with ELSO guidelines[6] and results in a very low number of wire-related adverse events, with no reported medium or high-significance wire complications in our data set. There was a relatively high number of low clinical significance events related to multiple attempts for vessel access despite the use of real-time vascular ultrasound; the majority of these occurred in ECMO-CPR cases and most likely reflect the difficulty in gaining vascular access in a critically ill patient in a low cardiac output state and concurrent CPR. Challenging body habitus can also pose difficulties with initial vessel access. The lower frequency of observed complications in the VV cannulations supports our decision to apply a tiered approach to accreditation with VA ECMO accreditation requiring more extensive experience and training than VV accreditation.

Our centre has successfully trained a subset of intensivist cannulators, with a mean time of 9 months required to achieve the minimum venous in-vivo cannulations. Opportunities for cannulation are unpredictable, and staff frequently made themselves available when not on duty to attend cannulations as they occurred. All of the cannulators were involved in other aspects of ECMO management during and after their training time, including daily dedicated ECMO rounds, circuit changes, decannulations, education, supervision, and intrahospital transports.

ECMO programs are multidisciplinary endeavours. Although the focus of this paper is that the primary cannulators in our institution are intensivists, ECMO is provided by a team including cardiac anaesthetists, cardiac surgeons, cardiologists, respiratory physicians, emergency physicians and vascular surgeons. Highly trained specialist nursing staff are also essential, as are strict quality assurance processes and clear models for ongoing training, education and maintenance of skills.

5. Conclusion

Our experience of the first four years of an intensivist-led ECMO cannulation program has demonstrated that our training process and cannulation technique result in the provision of a complex therapy with low levels of complications on par with those in the published literature. To our knowledge, this is the first time an ECMO centre has published its formal accreditation pathway. Our multidisciplinary accreditation process ensures that all practitioners at our institution who perform ECMO vessel cannulation and initiation are appropriately trained and credentialled. This provides a transparent, safe and well-supervised process that allows effective clinical governance and results in good patient outcomes.

CRediT author statement

Stuart C. Duffin conceptualisation, methodology, investigation, writing – original draft **Judith H. Askew** conceptualisation, methodology, investigation, writing – original draft **Timothy J. Southwood** conceptualisation, writing – review and editing, supervision **Paul Forrest** writing - review and editing **Brian Plunkett** writing – review and editing **Richard J. Totaro** conceptualisation, writing – review and editing, supervision.

Conflict of interest

The authors declare that there is no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ccrj.2023.11.006.

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