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Venoarterial extracorporeal membrane oxygenation: A systematic review of selection criteria, outcome measures and definitions of complications

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ABSTRACT

Purpose: The purpose of this study was to systematically investigate the reporting of selection criteria and outcome measures, and to examine definitions of complications used in venoarterial extracorporeal membrane oxygenation studies (V-A ECMO).
Materials and methods: Medline, EMBASE and the Cochrane central register were searched for V-A ECMO studies from January 2005 to July 2017. Studies with ≤99 patients or without patient centered outcomes were excluded. Two reviewers independently assessed search results and undertook data extraction.
Results: Forty-six studies met the inclusion criteria, and all were retrospective, observational studies. Inconsistent reporting of selection criteria, ECMO management and outcome measures was common. In-hospital mortality was the most common primary outcome (41% of studies), followed by 30-day mortality (11%). Bleeding was the most frequent complication reported, most commonly defined as "bleeding requiring transfusion" (median ≥ 2 Units/day). Significant variation in reporting and definitions was also evident for vascular, neurological renal and infectious complications.
Conclusion: This systematic review provides clinicians with the most commonly reported selection criteria, outcome measures and complications used in ECMO practice. However non-standardized definitions and inconsistent reporting limits their ability to inform practice. New consensus driven definitions of complications and patient centred outcomes are urgently needed.

1. Introduction

As venoarterial extracorporeal membrane oxygenation (V-A ECMO) for cardiac failure becomes more widespread, high quality robust evidence is crucial to inform its appropriate use [1,2]. However, performing V-A ECMO research is challenging. It is a complex intervention with substantial inter-center variation in technique. Complications result from both the ECMO support and the patients' underlying illness. Furthermore, V-A ECMO for cardiac failure is uncommon, making it challenging to perform prospective trials with adequate power.

For clinicians, rigorous appraisal and understanding of the available data is essential to assist their clinical decision-making and delivery of care. High quality research methodology, standardized outcome

Abbreviations: V-A, Venoarterial; ECMO, Extracorporeal membrane oxygenation; V-V, Venovenous; E-CPR, Extracorporeal cardiopulmonary resuscitation; CI, Cardiac Index L/min/m^2; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; CT, Computerised topography; MRI, Magnetic resonance imaging; RIFLE, Risk, Injury, Failure, Loss, and End-stage Kidney Classification; RRT, Renal replacement therapy; NICE, National Institute for Health and Care Excellence; ELSO, Extracorporeal Life Support Organization; RBCs, Red Blood Cells.

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measures, and consensus driven definitions of complications are essential to facilitate ECMO research, which will in turn lead to better outcomes [3,4].

There has been little appraisal of the methodology and reporting used in current ECMO studies. Although several international guidelines exist, which include various definitions of ECMO and its complications, it is not clear to what degree these have been adopted into practice [5-7]. The aims of this study were to systematically investigate the reporting of selection criteria and outcome measures, and to examine the common definitions of complications used in current V-A ECMO studies.

2. Methods

The protocol for this review was prospectively registered with PROSPERO (International prospective register of systematic reviews; (CRD42015030031). We adopted the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for reporting this review [8].

2.1. Search strategy

MEDLINE, EMBASE, and Cochrane central register of controlled trials (CENTRAL) were searched for relevant studies from January 2005 to June 2017. We manually searched systematic reviews and searched references of relevant studies.

2.2. Inclusion and exclusion criteria

We included interventional and observational studies of ECMO for cardiac and respiratory failure in English language (see search strategy in Supplemental Digital Content). Studies were excluded if they were pathophysiological studies without patient-centred outcomes, if they had ≤99 patients, if there were co-interventions where the focus was not ECMO, all nonhuman studies, and paediatric studies (age <18 years). Studies earlier than 2005 were excluded to account for the rapidly changing nature of the ECMO field. Studies that had a mixture of modes were excluded if the predominant type (>50%) of ECMO was venovenous (V-V) or extracorporeal cardiopulmonary resuscitation (E-CPR).

2.3. Study selection and data extraction

All screening and data extraction was completed using Covidence software [10]. Titles and abstracts of all identified studies were screened by two of three authors (AB, AS, VB), with discrepancies resolved by consensus. Full text review of eligibility was conducted by three authors independently (AB, VB, AS) and relevant data was extracted in duplicate from included studies. Discrepancies were resolved by discussion and adjudication by a fourth author (CH).

2.4. Outcomes

The primary focus was the reporting of patient selection (inclusion, exclusion, and diagnostic groups), ECMO management, primary and secondary outcomes, and definitions of complications.

2.5. Analysis

The comparison between the number of patients in single centre versus multicentre studies was performed using chi square test (SPSS (Version 24 SPSS Inc., Chicago, IL, USA). No formal meta-analysis was performed on this descriptive systematic review.

3. Results

3.1. Selected studies

The initial search yielded 2885 articles, of which 2309 were excluded through title and abstract review, leaving 575 potentially meeting our inclusion criteria. After a complete text analysis, 529 were excluded, leaving 46 studies, encompassing 20,375 patients (Fig. 1 and Supplemental Digital Content - Tables 1 and 2).

3.2. Description of studies

Of the 46 studies evaluated, all were observational and retrospective in design, with no randomized controlled trials. Thirty-seven (80%) were single centre studies, while nine (20%) were multicentre. There were no single centre cohort studies, and only 3 multicentre cohort studies. The ECMO modality was mixed in 13/46 (28%) – 11 studies with V-A plus V-V patients, and 2 studies with V-A plus E-CPR patients. Multicentre studies had larger median numbers of patients compared to single centre studies (322 vs 154, $P \leq .01$). However there were no differences in the number of prospective studies, interventional studies or in the use of multivariate analyses (See Supplemental Digital Content - Table 2).

3.3. Patient selection (Table 1)

An indication for ECMO was reported in forty-three (94%) studies, with the most common indication being “cardiogenic shock” and “refractory heart failure”. Several terms, such as “heart failure refractory to treatment” were also used interchangeably. Thirty-three (72%) studies had specific physiological criteria (e.g., cardiac index [CI]) for initiating ECMO. The threshold for initiating ECMO for the 10 studies which reported a cardiac index was variable, with a median CI ≤2.0 L/min/m^2 (range ≤ 1.5–2.4 L/min/m^2) and a median for systolic blood pressure ≤ 80 mmHg (range 60–90 mmHg). Forty-three (94%) studies reported diagnostic groups, with the commonest being post-cardiac surgery (57%), followed by ECMO post-cardiac or respiratory transplantation (28%) and ECMO post-acute myocardial infarction (26%). Only 16 (37%) studies reported any exclusion criteria. A median age cut off of ≤80 years old was reported in 3 studies (range 65–80).

3.4. ECMO management (Table 2)

The details of the ECMO pump were specified in 27 (59%) studies. Ten (22%) studies reported routinely using 2 or more brands of pumps, and Rotaflow® (Maquet), Capiox® (Terumo) and Cardiohelp® (Marquet) were the most commonly reported. The type of oxygenator was reported in 23 (50%) studies, with Quadrox® and Affinity® (Medtronic) being the most common. A heparin anticoagulation strategy was reported in 24 (52%). The ECMO cannulation site was the most commonly reported information on cannulation 32 (69%) studies. Sixteen (35%) studies reported the use of anterograde leg perfusion cannulas with 9 (20%) performing these routinely, and 5 (11%) performing these on a selective basis.

3.5. Complications (Table 3)

Bleeding was the most commonly reported complication in 28 (61%) of studies. Twenty four (52%) of these studies defined bleeding more specifically. The most common definition was “bleeding requiring RBCs/transfusion”. Two or more units was the most common threshold (4 studies), with studies ranging from ≥1 units to five units [11]. The time period used to define the amount of bleeding was only reported in 4 studies – and ranged from <6 h [12] to 30 days [13]. “Bleeding requiring surgery” (eg surgical revision of a cannula or gastroenterological endoscopy) or “bleeding from cannulation or surgery” were the next

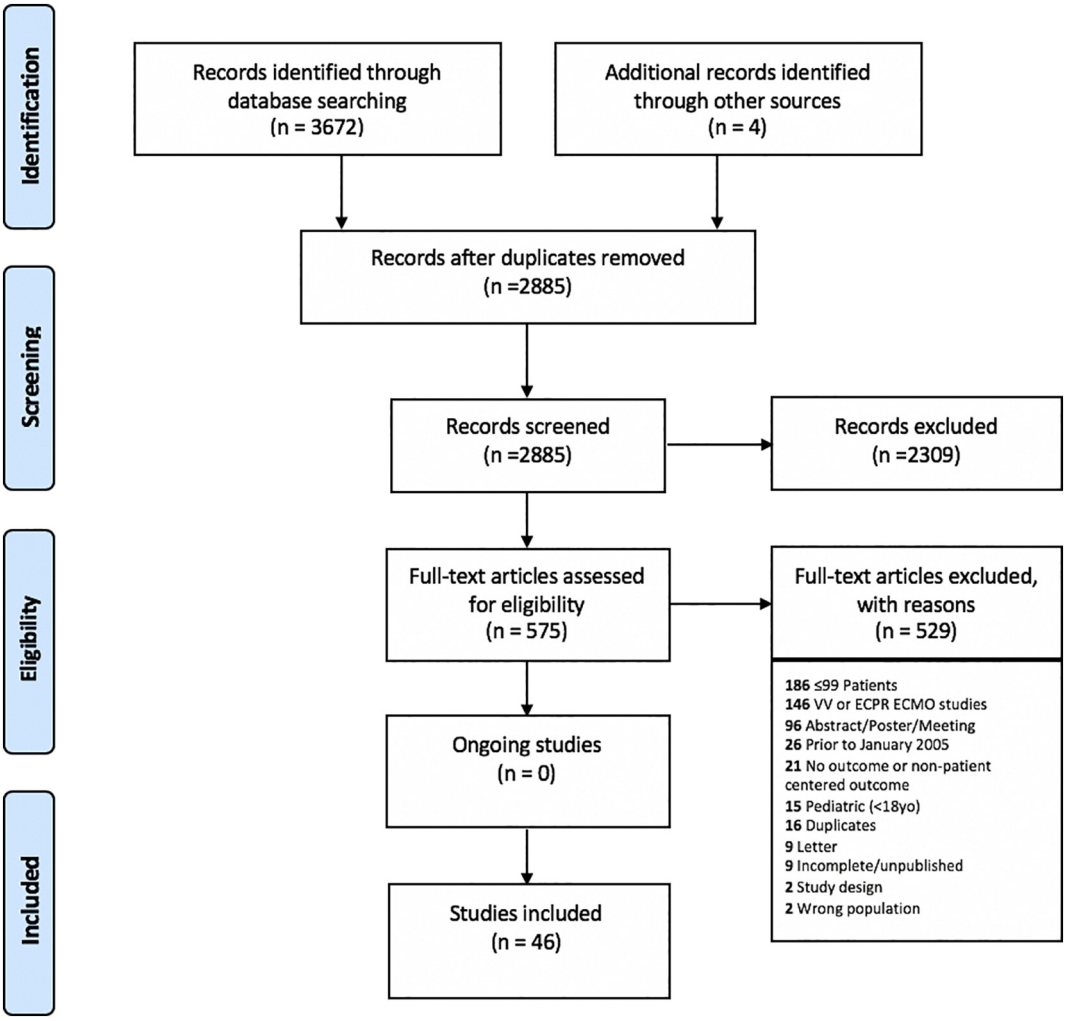

Fig. 1. Venoarterial ECMO flow diagram.

most common definitions. Several studies used definitions from Extracorporeal Life Support Organization (ELSO), European coronary artery bypass graft (ECABG) bleeding definition, or the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) bleeding definitions (Supplemental Digital Content: Definitions Used in Studies).

Vascular complications were reported in 26 (57%) studies and 23 (38%) studies defined this in more detail. Ischaemia was reported in 21 (45%) studies. This was defined in several studies as "pallor, pulselessness, gangrene" [14] or diagnosed "clinically and corroborated by 2D ultrasound" [12]. No studies defined thromboembolism. In one study, compartment syndrome was defined as compartment pressure > 30 mmHg [12], fasciotomy was defined as "fasciotomy for compartment syndrome", and amputation rates were also reported. Vascular injury was most commonly defined as "vascular injury requiring surgical repair" in 17 (37%) studies In a further study, vascular injury was defined as "vascular injury requiring surgery, but not repair on removal" [15]. Neurological injury was reported in 25 (54%) studies, with many studies reporting the incidence of stroke or intracranial haemorrhage (ICH). However a definition was only reported in 5 (11%) studies, most commonly as "evidence of ischaemia or blood on computerised topography (CT) or magnetic resonance imaging (MRI) scans" [15-19]. Others studies included ICD 9 or INTERMACS definitions of CVA and ICH (See supplemental file).

Renal failure was reported in 24 (52%) studies. "Acute kidney injury requiring renal replacement therapy (RRT)" was the most common definition, followed by the Risk, Injury, Failure, Loss, and End-stage Kidney (RIFLE) classification (Supplemental Digital Content). Whether the RRT was initiated before or during the ECMO was not specified in any studies. Infection or sepsis was reported in 19 (40%) studies, but only 15 (33%) studies had stated criteria or definitions. Other less commonly reported complications included: cannula infection in 8 (17%) studies and equipment failure in 9 (20%) studies. Equipment failure was most commonly described as a circuit change in 5 (11%) studies, but also included oxygenator change (4 studies) and circuit thrombosis (2 studies).

3.6. Outcomes measures (Fig. 2)

A single primary outcome was reported in 21 (46%) of studies. The most common was in-hospital mortality in 19 (41%), followed by 30-day mortality in 5 (11%). In 23 (50%) studies there were multiple primary outcomes, and these were most commonly assessing mortality across multiple time points. A non-mortality primary outcome was the focus of 9 other studies, including vascular complications in 4 (9%) [12,20-22], bleeding events in 2 (4%) [23,24], central nervous system (CNS) complications in 2 (4%) [17,18] and infection in one (2%) [25] study.

4. Discussion

This systematic review describes the most commonly reported patient selection criteria, ECMO management strategies, and outcome measures used in V-A ECMO studies and clinical practice. We found

Table 1
All Studies Reporting Patient Selection Criteria for VA-ECMO.

Selection criteria	Specific or defined criteria	Total studies no, (%)
Indications	Cardiogenic shock/refractory cardiac failure	29/46 (63%)
	Post cardiotomy cardiogenic shock	18/46 (39%)
	Cardiac arrest	12/46 (26%)
	Failure to wean from bypass	6/46 (13%)
	Any indication reported	43/46 (94%)
Specific physiological criteria	Presence of or refractory to inotropes	19/46 (41%)
	Cardiac index (median ≤ 2.0 L/min/m^2, range 1.5–2.2)	10/46 (22%)
	SBP (median ≤ 80 mmHg, range 60–90)	10/46 (22%)
	Presence of IABP[#]	19/46 (41%)
	Lactate (median ≥ 4 mmol, range 3–4)	3/46 (7%)
	Any specific physiological criteria	33/46 (72%)
Diagnostic category	Post cardiac surgery	26/46 (57%)
	Post transplantation surgery (cardiac and/or respiratory)	13/46 (28%)
	Post acute myocardial infarction	12/46 (26%)
	Cardiomyopathy	12/46 (26%)
	Myocarditis	6/46 (13%)
	Acute decompensated heart failure	4/46 (9%)
	Any diagnostic category reported	43/46 (94%)
Exclusions	Malignancy	4/46 (9%)
	Age (Median ≥ 80, Range 65–80)	3/46 (7%)
	Irreversible organ damage	3/46 (7%)
	Death expected within 24 h	3/46 (7%)
	Multiple runs of ECMO	2/46 (4%)
	Irreversible neurological damage	2/46 (4%)
	Mechanical ventilation ≥7 days	1/46 (2%)
	Not for resuscitation order	1/46 (2%)
	Any exclusions reported	17/46 (37%)

ECMO - Extracorporeal membrane oxygenation; *SBP - Systolic blood pressure; [#] IABP – Intra-aortic Balloon Pump.

Table 2
Studies reporting ECMO management.

Management	Details reported	Total studies n, (%)
Equipment	Type of ECMO pump	27/46 (59%)
	Type of oxygenator	23/46 (50%)
	IABP use	19/46 (41%)
Methodology	Anticoagulation use	24/46 (52%)
	Routine heparin administration	16/46 (35%)
	Bolus plus routine heparin administration	8/46 (17%)
	ECMO weaning protocol	20/46 (43%)
	Left ventricular venting	5/46 (11%)
Cannulation	Any Site	32/46 (69%)
	Femoral-femoral	31/46 (67%)
	Femoral-axillary	9/46 (20%)
	Central	18/46 (39%)
	Method of cannulation	25/46 (54%)
	Percutaneous	22/46 (48%)
	Open/Surgical	11/46 (24%)
	Anterograde leg perfusion cannula use	16/46 (35%)
	Routine	11/46 (24%)
	Selective	5/46 (11%)

ECMO - Extracorporeal membrane oxygenation; IABP – Intra-aortic Balloon Pump.

Table 3
Reporting and Definitions of ECMO Complications.

Complication	Reported	Common definitions used	Total studies n, (%)
Bleeding	28/46 (61%)	Bleeding requiring RBC's/transfusion (median ≥ 2 units, range 1-5U)	7/46 (15%)
		≥1Unit	4/46 (9%)
		≥2Units	1/46 (2%)
		≥3Units	1/46 (2%)
		≥4Units	1/46 (2%)
		≥5Units	1/46 (2%)
		Bleeding requiring surgical intervention	4/46 (9%)
		Bleeding from cannulation or surgery	3/46 (7%)
		ELSO[1] or ECABG[2] or INTERMACS[3] definitions	3/46 (7%)
		Any bleeding definition	24/46 (52%)
Vascular complications	26/46 (57%)	Ischaemia or thromboembolism	21/46 (46%)
		Vascular injury requiring surgical repair	17/46 (37%)
		Compartment syndrome	3/46 (7%)
		Fasciotomy	3/46 (7%)
		Amputation	3/46 (7%)
		Any vascular complications defined	23/46 (50%)
CNS injury	25/46 (54%)	CVA or ICH (not further defined)	8/46 (17%)
		Blood or ischaemia on CT/MRI	5/46 (11%)
		INTERMACS or ICD-9 or CPC scale definitions	3/46 (7%)
		Any CNS injury definition	23/46 (50%)
Renal failure	24/46 (52%)	AKI requiring renal replacement therapy #	10/46 (22%)
		RIFLE classification	3/46 (7%)
		KDIGO[6], AKIN or ICD9 codes each	3/46 (7%)
		Any renal failure definition	21/46 (46%)
Infection/sepsis	19/46 (41%)	Sepsis (not defined)	4/46 (9%)
		CDC[6] or INTERMACS[7] definitions each	4/46 (9%)
		Positive sputum or blood cultures	2/46 (4%)
		Any Infection/sepsis definition	17/46 (37%)
Cannula infection	9/46 (20%)	Local cannula site infection	4/46 (9%)
		Positive cultures	2/46 (4%)
		CLABSI or CRI criteria	2/46 (4%)
		Any cannula infection definition	8/46 (17%)
Equipment failure	9/46 (20%)	Circuit change	5/46 (11%)
		Oxygenator change	4/46 (9%)
		Circuit thrombosis	2/46 (4%)
		Equipment failure defined	9/46 (20%)

ECMO - Extracorporeal membrane oxygenation; ELSO – Extracorporeal life support organization; CNS – central nervous system; ICH – Intracranial haemorrhage; CVA – Cerebrovascular accident; RIFLE - Risk, Injury, Failure, Loss, and End-stage Kidney definition; RRT – Renal replacement therapy; RBCs – Red blood cells; CT – Computerised Tomography; MRI – Magnetic resonance imaging; INTERMACS - Interagency Registry for Mechanically Assisted Circulatory Support; CDC – Centers for Disease Control; CLABSI - Central Line Associated Blood Stream Infection ICD-9 – International classification of diseases. ECABG – European coronary artery bypass graft bleeding definition; CPC – Cerebral performance category; KDIGO – Kidney disease: improving global outcomes definition;

the reporting of these domains was highly variable and inconsistent across the studies. We found substantial variability in the definitions used for complications. These findings have significant implications for the interpretation of current V-A ECMO research.

Similar to previous systematic reviews of V-A ECMO [26,27], the vast majority of ECMO studies were single centre, retrospective, observational studies with a high potential for bias, and there were no

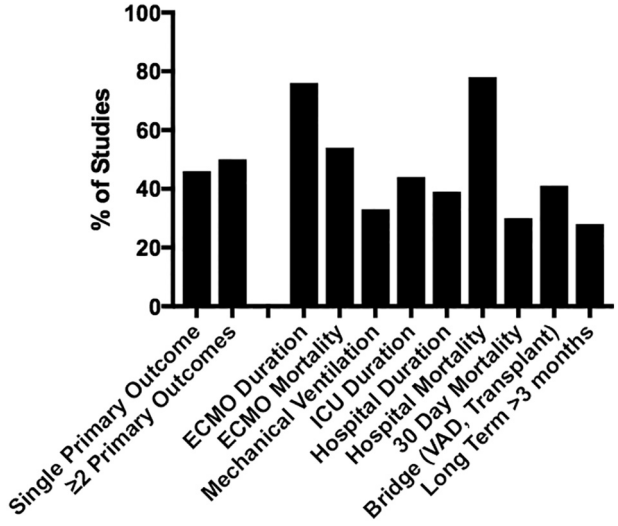

Fig. 2. Studies reporting outcome measures.

randomized controlled trials. This reflects an overall low quality of evidence to guide practice [28].

In our study, we found the selection criteria for commencing ECMO was inconsistent and poorly reported. For example, reporting of upper limits for age, number of organ failures, the disease process and the duration of mechanical ventilation differed greatly between studies. In one study, the threshold to commence ECMO was a cardiac index of <1.5 L/min/m^2 for entry [29], while another only required an index of <2.2 L/min/m^2 [25]. These factors have been demonstrated in published predictive models to have an important impact on overall outcomes [30]. Many studies also combined V-V and E-CPR populations with V-A ECMO patients, which leads to heterogeneous patient populations, with different indications and diseases processes, entering into each study. This in turn significantly limits the ability to compare studies [31].

We found the daily management of ECMO was poorly reported, with 50% or less of studies including information on the equipment or technique used in the study. ECMO is a complex intervention, and many individual aspects can impact outcomes. Poor description of the technique can limit the ability to reproduce and generalise to other systems, as well as limits the ability to compare across studies, as was recently observed in a meta-analysis of anterograde leg perfusion cannulas [32]. Reporting was highest for cannulation sites, type of ECMO pump, anticoagulation use, and weaning protocols, but poor for the type of anticoagulation used, the indications and methods used for LV decompression, and the use of anterograde leg perfusion cannulas. Reporting of the harlequin syndrome was not routine in any of the studies.

The primary outcome reported in the studies was also highly variable, and most had a short-term focus. Short term outcomes can be insensitive to the effect of interventions [33] and may not be as important to the patient or their family. As survival rates continue to improve in intensive care, functional outcomes, morbidity and long term survival are becoming more important measures of an intervention. This is reflected in the recent NICE guidelines for heart failure which recommend a combination of mortality and functional outcomes [34]. Furthermore, in our study 50% of studies also had multiple primary outcomes, which can lead to reporting bias, as multiple outcomes increase the chance of false positive results, especially when not defined a priori.

The reporting of complications in the studies was also inconsistent, and few utilized standardized definitions, such as the Extracorporeal Life Support Organization (ELSO) or the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) definitions. A bleeding event was defined in some studies as "bleeding requiring (any) RBC's/transfusion", while in others a specific threshold was chosen, such as the number of units of RBC transfused per day. The time period used to define the event was also variable – from 6 h up to 30 days significantly impairing the ability to compare bleeding rates across two different studies. Descriptors such as "bleeding requiring surgery" were common but are subjective, hospital specific, and are difficult to interpret between studies. Poor descriptions and subjectivity were also common in descriptions of ischaemia, thrombosis, acute kidney injury, stroke or intracranial haemorrhage, infection and cannula related infections. Low rates of reporting compilations can lead to the selective reporting of results, leading to bias[16]. For example, only reporting bleeding rates from femoral V-A cannulation may neglect other consequences such as lower limb ischaemia or amputation.

This review demonstrates the inconsistent reporting and definitions in current V-A ECMO research, and highlights the problems aggregating and interpreting current V-A studies, particularly in metanalyses. In order to meet this challenge, ECMO research needs to move from smaller, single center studies to well-designed prospective trials with consensus driven definitions of outcomes and complications. An important next step of this research will be to develop a core outcome set, consisting of consensus-derived and patient centered outcomes which should be consistently reported in clinical trials for a topic. These outcomes and definitions will improve the quality of data in future trials and registries, and will facilitate comparisons between separate studies in metaanalyses. Such a project is currently underway, using an international Delphi study, under the auspices of the International ECMO Network (ECMONet).

This review has a number of strengths. It focusses on an important gap in the literature, and was conducted using high quality systematic review methodology. A highly sensitive search strategy was developed which was independently reviewed by an information specialist in order to comprehensively cover the literature.

There are several limitations of this study. Studies with ≤99 patients were excluded (as per this previous systematic review [9]), but smaller volume studies may not have been represented. We also focused on studies with patient related clinical outcomes, which meant excluding pathophysiological only studies. The exclusion of studies with predominantly V-V ECMO or E-CPR patients also limited the number of eligible studies. However, we believe that these forms of ECMO are applied in distinctly different populations and require separate definitions.

5. Conclusion

This systematic review provides clinicians with the most commonly reported selection criteria, complications and outcome measures used in V-A ECMO studies and clinical practice. Clinicians need to be aware of the risks of comparing low quality of V-A ECMO studies, which include inconsistent reporting of selection criteria and outcomes, and the lack of standardized definitions of complications. Consensus-based definitions and core outcomes are urgently needed to address this issue.

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Ethics approval and consent to participate

All data presented has been previously published and referenced, and no patient or participants were contacted as part of the study.

Consent for publication

All authors have given final approval of the manuscript.

Availability of data and material

All data presented has been previously published and referenced.

Authors contributions

Authors contributed in the following way: Conception or design of the work (AB, VB, AS, EF, DB, JF, CH), Data collection (AB, VB, AS, CH), Data analysis and interpretation (AB, VB, AS, EF, DB, VP, JF, DK, JC, CH), Drafting the article (AB, VP, JF, JC, DK, CH), and critical revision of the article and final approval of the version to be published (AB, VB, AS, VP, LR, EF, DB, JC, DK, JF, CH).

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Conflict of interests

The authors declare that they have no conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcrc.2019.05.011.

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