How Long Should Patients Be Treated With Postcardiotomy Venoarterial Extracorporeal Membrane Oxygenation? Individual Patient Data Pooled Analysis

OBJECTIVES: To investigate the optimal duration of venoarterial extracorporeal membrane oxygenation (ECMO) for cardiogenic shock refractory to medical therapies after cardiac surgery and whether its prolonged use is justified.

DATA SOURCES: Previously published articles on postcardiotomy venoarterial ECMO.

STUDY SELECTION: Articles reporting on the early outcome after postcardiotomy venoarterial ECMO in adult patients were identified through a systematic review of the literature.

DATA EXTRACTION: Data on prespecified patients' characteristics, operative variables, and outcomes were provided by the authors of previous studies on this topic.

DATA SYNTHESIS: Individual data of 1267 patients treated at 25 hospitals from ten studies were included in this meta-analysis. In-hospital mortality rates were lowest among patients treated 3–6 days with venoarterial ECMO. Multilevel mixed-effects logistic regression considering the cluster effect of the participating hospitals adjusted for individual patient's risk profile and operative variables showed that the risk in-hospital mortality did not significantly increase in patients treated more than 6 days up to 20 days.

CONCLUSIONS: The present study demonstrated that prolonged venoarterial ECMO support after adult cardiac surgery may be justified. However, the analysis was limited by the knowledge of only those circumstances known at the start of ECMO.

KEYWORDS: cardiac surgery; extracorporeal life support; extracorporeal membrane oxygenation; postcardiotomy; risk factors

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Venoarterial extracorporeal membrane oxygenation (ECMO) is an effective salvage therapy for improving early survival of patients with severe cardiogenic shock after cardiac surgery (1, 2). The optimal timing of weaning from venoarterial ECMO is not clearly established (3, 4) as it depends on the severity of physiological timeline of recovery from severe complications occurring before and after starting this salvage therapy. This issue is of clinical relevance because it may impact both the rate of failure of weaning from venoarterial ECMO and mortality after successful weaning (3). In a prior study, we observed that in-hospital mortality was lower in patients treated with postcardiotomy venoarterial ECMO for 4–7 days (5), but it remains unclear whether longer venoarterial ECMO support can be justified. Considering the significant resources associated with the use of venoarterial ECMO, data on the potential benefits of this therapy in patients requiring prolonged treatment are

KEY POINTS

Question: How long should patients be treated with postcardiotomy venoarterial extracorporeal membrane oxygenation (ECMO)?

Findings: Multilevel mixed-effects logistic regression showed lowest in-hospital mortality rates among patients treated 3–6 days with venoarterial ECMO. However, the differences in terms of in-hospital mortality were nonsignificant compared with patients treated up to 20 days.

Meaning: Provided a thoughtful assessment of patient's conditions and the coexistence of extracardiac postoperative complications, prolonged postcardiotomy venoarterial ECMO therapy can be considered a valuable option in patients without irreversible end-organ injury.

of crucial importance. We investigated this issue in an individual patient data (IPD) pooled dataset to gather a large sample of patients with prolonged postcardiotomy venoarterial ECMO.

METHODS

The present study was registered in the PROSPERO registry (CRD42022359392). A systematic review was performed to identify studies on postcardiotomy venoarterial ECMO for the present IPD meta-analysis. A literature search was performed in August 2022 through PubMed, Scopus, and Google Scholar. Population, intervention, comparison, and outcomes of the present study are summarized in **Supplementary table 1** (http://links.lww.com/CCM/H694). This study was accomplished following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (6) (**Supplementary table 2**, http://links.lww.com/CCM/H694). Institutional Review Board permission was not asked because of the meta-analytic nature of the study including anonymized data.

We included in the present analysis studies that fulfilled the following inclusion criteria: 1) studies providing data on patients who required venoarterial ECMO after any cardiac surgery procedure, including heart transplantation; 2) studies providing data on in-hospital mortality after postcardiotomy venoarterial ECMO; 3) studies including patients older than 18 years; 4) prospective or retrospective observational studies; 5) studies whose results were published in English language as a full article; 6) studies including at least ten patients; 7) studies reporting on arterial lactate levels at the time of venoarterial ECMO cannulation; and 8) articles published since 2015.

Studies were not eligible for this analysis if they: 1) did not provide information on the configuration of ECMO used; 2) did not provide information on the timing and site of cannulation of venoarterial ECMO; 3) did not provide data on arterial lactate levels at venoarterial ECMO cannulation; 4) included pediatric patients; and 5) reported on the use of other than venoarterial ECMO configuration (7).

The quality of the included studies was assessed using the National Heart, Lung, and Blood Institute Study Quality Assessment Tools (8).

Definition criteria of baseline risk factors, operative variables, data on venoarterial ECMO therapy, and outcomes are summarized in **Supplementary table 3** (http://links.lww.com/CCM/H694). The primary outcome measure of this study was in-hospital mortality, that is, death from any cause during the index hospitalization. The secondary outcome measure was mortality on venoarterial ECMO, that is, death without possibility of weaning from the venoarterial ECMO support.

Categorical variables were reported as counts and percentages. Continuous variables were reported as means and SDs as well as medians and interquartile ranges. Missing data were not replaced. Multilevel mixed-effects logistic regression was used to identify the independent predictors and to estimate the probabilities of in-hospital mortality and mortality on venoarterial ECMO considering the cluster effect of each participating hospital. Regression analysis first included all covariates listed in **Table 1**, but the duration of the venoarterial ECMO treatment. Further regression models included the duration of the venoarterial ECMO treatment as a covariate considering the mortality rate on the fourth day of venoarterial ECMO as the reference category. Likelihood ratio test was used to assess the difference of the results of the multilevel mixed-effect logistic regression and those of the conventional logistic regression. Calibration of the logistic regression models was assessed by estimating the area under the receiver operating characteristic curve

TABLE 1.
Patients' Characteristics, Operative Variables, and Venoarterial Extracorporeal Membrane Oxygenation Data and Their Prognostic Impact on In-Hospital Mortality

Clinical Variables	Overall Series, *n* = 1267	Alive, *n* = 421	In-Hospital Death, *n* = 846	Multivariable Analysis[a], OR (95% CI)
Baseline characteristics				
Mean age, yr	61.9 (13.9)	58.2 (14.6)	63.8 (13.1)	1.039 (1.027–1.051)
Median age, yr	64.7 (17.1)	60.8 (19.4)	66.1 (16.0)	
Female gender	399 (31.5)	108 (25.7)	291 (34.4)	1.424 (1.058–1.916)
Mean eGFR, mL/min/1.73 m^2	68 (33)	74 (34)	65 (33)	0.998 (0.993–1.002)
Median eGFR, mL/min/1.73 m^2	64 (37)	72 (36)	61 (37)	
Mean arterial lactate, mmol/L	8.5 (5.5)	6.7 (4.3)	9.3 (5.8)	1.116 (1.082–1.151)
Median arterial lactate, mmol/L	7.2 (7.4)	5.6 (5.3)	8.1 (7.6)	
Coronary artery disease	595 (47.0)	203 (48.2)	392 (46.3)	0.783 (0.508–1.209)
Type A aortic dissection	95 (7.5)	23 (5.5)	72 (8.5)	0.972 (0.442–2.139)
Preoperative acute neurologic event	74 (5.8)	14 (3.3)	60 (7.1)	1.913 (0.991–3.692)
Prior cardiac surgery	306 (24.2)	82 (19.5)	224 (26.5)	1.604 (1.143–2.252)
Procedural data				
Urgent/emergency surgery	635 (50.1)	206 (48.9)	429 (50.7)	1.028 (0.764–1.383)
Isolated CABG	286 (22.6)	98 (23.3)	188 (22.2)	1.107 (0.642–1.908)
Any CABG	597 (47.1)	200 (47.5)	397 (46.9)	1.102 (0.700–1.738)
Aortic valve procedure	459 (36.2)	163 (38.7)	296 (35.0)	0.822 (0.560–1.207)
Mitral valve procedure	448 (35.4)	150 (35.6)	298 (35.2)	1.094 (0.724–1.651)
Tricuspid valve procedure	179 (14.1)	53 (12.6)	126 (14.9)	1.154 (0.752–1.774)
Pulmonary valve procedure	6 (0.5)	2 (0.5)	4 (0.5)	0.161 (0.017–1.524)
Ventricular septal defect or ventricular wall repair	44 (3.5)	14 (3.3)	30 (3.5)	1.285 (0.577–2.865)
Septal myectomy	7 (0.6)	1 (0.2)	6 (0.7)	1.000 (1.000–1.000)
Aortic surgery	243 (19.2)	73 (17.3)	170 (20.1)	1.016 (0.473–2.183)
Aortic root replacement	127 (10.0)	44 (10.5)	83 (9.8)	1.276 (0.594–2.741)
Aortic arch surgery	63 (5.0)	9 (2.1)	54 (6.4)	2.800 (1.178–6.657)
Heart/heart and lung transplantation	31 (2.4)	8 (1.9)	23 (2.7)	0.677 (0.212–2.159)
Other procedures	68 (5.4)	15 (3.6)	53 (6.3)	3.632 (1.464–9.007)
Venoarterial ECMO at primary surgery	772 (61.1)	268 (63.8)	504 (59.8)	0.964 (0.723–1.284)
Intra-aortic balloon pump during venoarterial ECMO	517 (40.8)	172 (40.9)	345 (40.8)	0.873 (0.644–1.185)
Central venoarterial ECMO	555 (43.8)	163 (38.7)	392 (46.3)	1.304 (0.964–1.764)
Mean venoarterial ECMO duration, d	6.5 (6.4)	7.1 (5.7)	6.2 (6.8)	–
Median venoarterial ECMO duration, d	5.0 (6.5)	6.0 (6.0)	4.0 (6.0)	–
Heart transplant center	993 (78.4)	322 (76.5)	671 (79.3)	1.016 (0.640–1.611)
Heart transplantation/ventricular assist device after venoarterial ECMO	58 (4.6)	27 (6.4)	31 (3.7)	0.785 (0.410–1.504)

CABG = coronary artery bypass grafting, ECMO = venoarterial extracorporeal membrane oxygenation, eGFR = estimated glomerular filtration rate, OR = odds ratio.

[a]Multilevel mixed-effects logistic regression.

Categorical variables are counts and percentages. Continuous variables are means and SDs (in parentheses) as well as median and interquartile range (in parentheses). Dashes indicate these variables were not included in the regression model.

(AUC). Risk estimates of outcomes at each interval of venoarterial ECMO therapy were adjusted for the propensity score and were reported as odds ratios with their 95% CIs. Two-sided *p* value of less than 0.05 was considered statistically significant. Statistical analyses were performed using Stata (Version 15.1; StataCorp LLC, College Station, TX) statistical software.

RESULTS

Overall, a systematic review of the literature yielded 273 articles, and 31 were suitable for this analysis. The investigators of ten studies (Supplementary references, http://links.lww.com/CCM/H694) provided complete data on prespecified variables for the present IPD meta-analysis on 1267 patients treated at 25 hospitals (**Supplementary fig. 1**, http://links.lww.com/CCM/H694). The number of patients, type of studies, and quality of the included studies are summarized in **Supplementary table 4** (http://links.lww.com/CCM/H694). Baseline characteristics, operative data, and venoarterial ECMO related variables are reported in Table 1. The mean duration of venoarterial ECMO therapy was 6.5 ± 6.4 days (median, 5.0 d; interquartile range, 7.0 d; range, 1–55 d). In-hospital mortality and mortality on venoarterial ECMO of this pooled series were 66.8% and 44.4%, respectively. Crude mortality rates of in-hospital mortality and mortality on venoarterial ECMO were lowest in patients treated with venoarterial ECMO for 3–6 days (**Fig. 1**).

Multilevel mixed-effect logistic regression (likelihood ratio test; $p = 0.013$) yielded probabilities whose AUC was 0.741 (95% CI, 0.711–0.770) for predicting in-hospital mortality. Among all variables included in this analysis, a missing value was detected in 40 patients (3.2%), mostly due to missing information on preoperative level of serum creatinine. The probabilities considering the cluster effect of the participating hospitals had an AUC larger than the probabilities estimated by conventional logistic regression (AUC, 0.723; 95% CI, 0.693–0.753; $p < 0.001$). The independent predictors of in-hospital mortality were age, female sex, arterial lactate at venoarterial ECMO initiation, prior cardiac surgery, aortic arch surgery, and other mixed procedures (Table 1; and **Supplementary table 5**, http://links.lww.com/CCM/H694). The regression model for prediction of mortality on venoarterial ECMO (likelihood ratio test; $p < 0.001$) yielded probabilities with an AUC of 0.746 (95% CI, 0.719–0.773).

When compared with patients with the lowest crude in-hospital mortality, those treated with venoarterial ECMO for 4 days, in-hospital mortality was significantly increased only in patients treated 1 day, and those treated greater than 20 days with venoarterial ECMO (AUC,

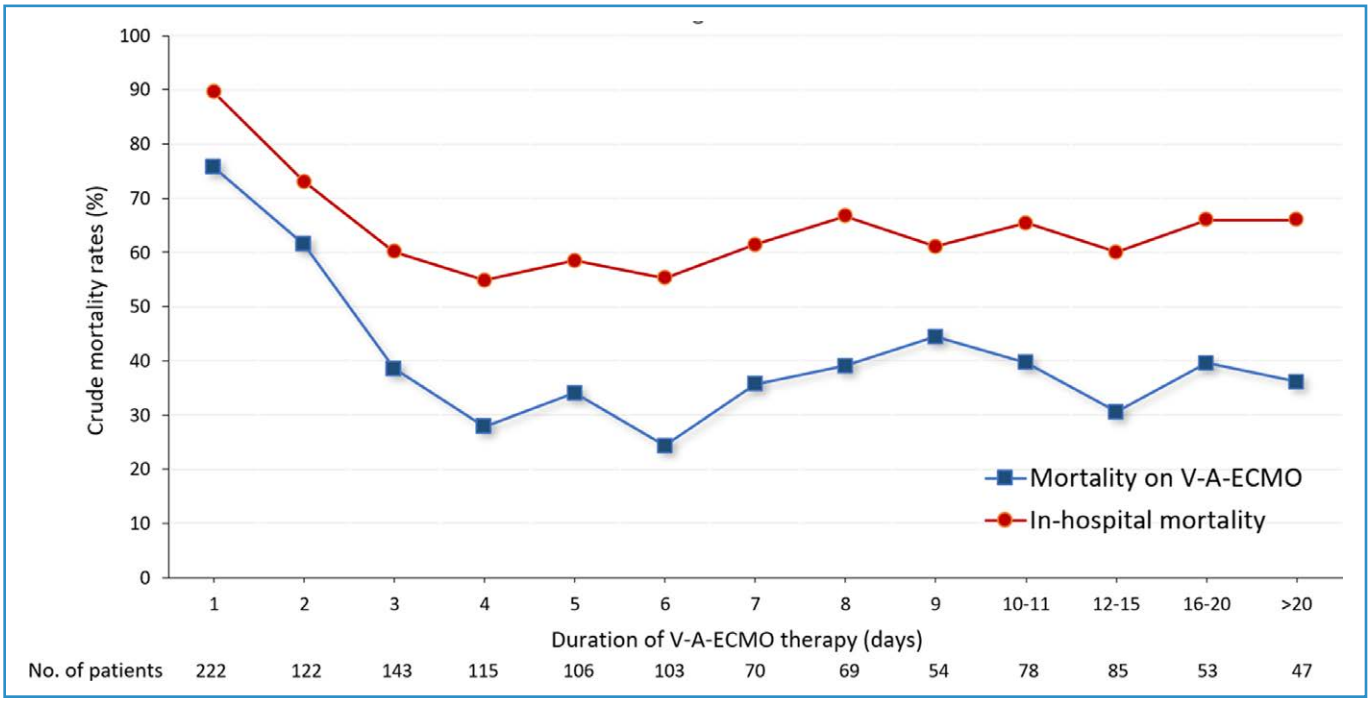

Figure 1. Crude rates of mortality on venoarterial extracorporeal membrane oxygenation (V-A ECMO) and during the index hospitalization.

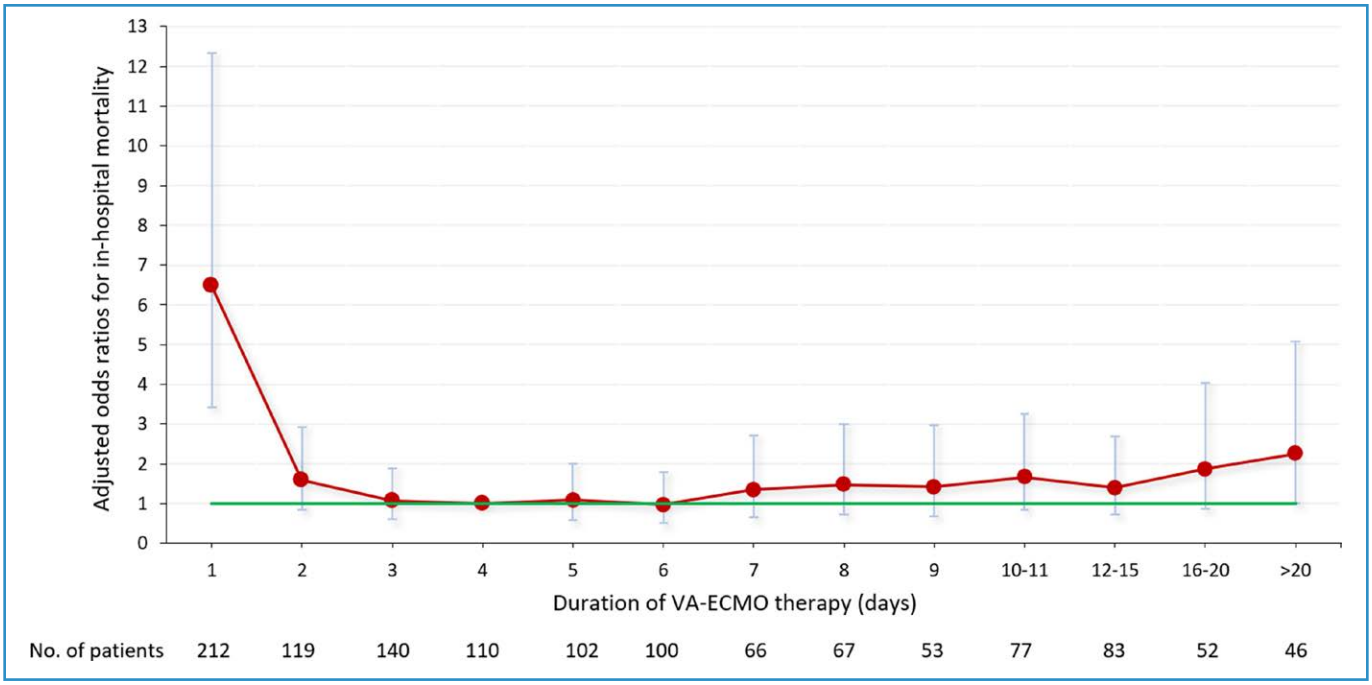

Figure 2. Adjusted odds ratios with their CIs for in-hospital mortality. The *green line* denotes an odds ratio of 1.0. V-A ECMO = venoarterial extracorporeal membrane oxygenation.

0.774; 95% CI, 0.747–0.801) (**Fig. 2**; and Supplementary table 5, http://links.lww.com/CCM/H694). Mortality on venoarterial ECMO was significantly increased in patients treated 1 or 2 days with venoarterial ECMO (**Fig. 3**). The risk estimates for in-hospital mortality were lowest among patients treated 3–6 days with venoarterial ECMO (Fig. 2).

DISCUSSION

The present analysis showed extremely high in-hospital and on venoarterial ECMO mortality rates in cardiac surgery patients when this mechanical circulatory support was employed only 1 day. Most patients in this group died on venoarterial ECMO, when it was obviously not planned to employ mechanical circulatory support for just 1 day. So, this is mostly about patients too sick to survive despite venoarterial ECMO support. This was likely related to the current difficulties in identifying patients who may not of postcardiotomy venoarterial ECMO. This analysis confirmed that advanced age, female sex, increased pre-venoarterial ECMO levels of arterial lactate, prior cardiac surgery, aortic arch surgery, and other procedures of mixed nature were predictive of in-hospital mortality as previously demonstrated (2). We observed lower mortality rates among patients treated 3–6 days with venoarterial ECMO, but such differences did not reach statistical significance. Indeed, this study demonstrated that, when appropriately selected, prolonged venoarterial ECMO therapy may save one third of these critically ill patients. Noteworthy, 39.1% of patients of this pooled series were treated with venoarterial ECMO for more than 6 days and their in-hospital mortality was 63.8%.

The present findings are not consonant to those of a recent multicenter study, which demonstrated a U-shape risk of in-hospital mortality, with the lowest crude rates of mortality in patients treated 4–7 with venoarterial ECMO treatment (9). However, this study can be considered only of descriptive nature because the results were not adjusted for baseline and operative covariates. Furthermore, the analysis did not consider any inter-institutional differences in terms of referral pathway, pre-venoarterial ECMO conditions, and institutional experience with this salvage therapy. Instead, the present study considered both the individual patient's risk profile and the possible cluster effect of treating hospitals on the outcomes. Indeed, the difference between the AUC of this multilevel logistic regression model was significantly larger than those of conventional logistic regression in predicting in-hospital mortality.

The results of the present analysis may be affected by several methodological limitations. First, the studies included in this analysis are of retrospective nature,

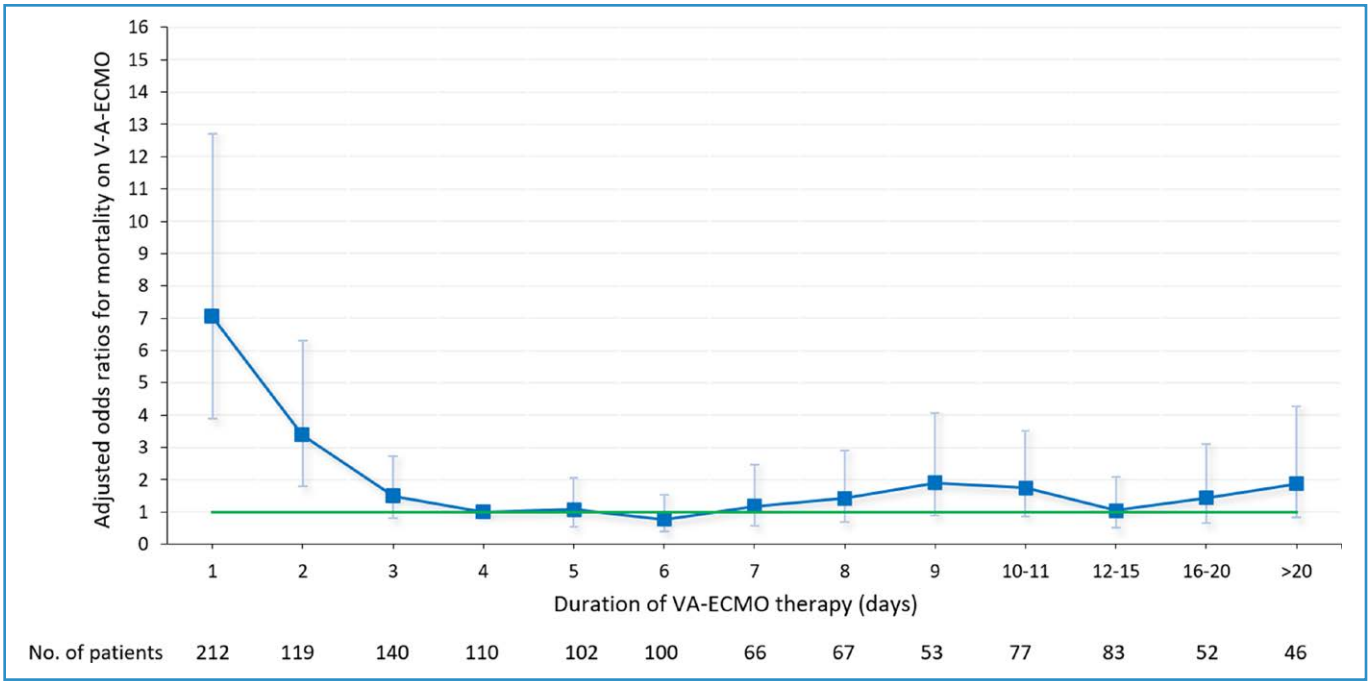

Figure 3. Adjusted odds ratios with their CIs for mortality on venoarterial extracorporeal membrane oxygenation (V-A ECMO) at different intervals of V-A ECMO therapy. The *green line* denotes an odds ratio of 1.0.

which is a major limitation of this analysis. Second, the investigators of ten of 31 studies accepted to participate to this IPD meta-analysis. This can be considered a methodological limitation that is common to meta-analyses evaluating patient level data. On the other hand, we believe that only investigators with high quality datasets are eager to participate in such pooled analyses. Despite the potential limitation of having failed to recruit data from all published articles suitable for the present analysis, IPD meta-analyses should be considered a gold standard of systematic review and may provide conclusive results to clinical questions, which may not be obtained from summary data. Third, the retrospective and multi-institutional nature of the study prevented us to know whether no individually specific duration of ECMO treatment was expected at the start of ECMO therapy. Fourth, the present IPD registry lacks data on biomarkers other than arterial lactate, which would have provided valuable information on pre-venoarterial ECMO systemic and end-organ injury. Indeed, biomarkers of liver failure and coagulopathy as well as data on cerebral oximetry and periods of intraoperative hypotension might have provided insights of crucial importance regarding the indication to and duration of postcardiotomy venoarterial ECMO. Finally, the results of clinical studies adjusted for baseline risk factors do not fully explain/justify a treatment and its prolonged duration without taking into consideration the adverse events occurring during the treatment. This can be recognized as a major limitation of the present analysis. On the other hand, the present findings suggest that postcardiotomy venoarterial ECMO therapy can be justified for more than 6 days in absence of severe extracardiac end-organ injury occurs or when replacement therapy is planned.

In conclusion, the present study demonstrated that prolonged venoarterial ECMO support after adult cardiac surgery may be justified. However, the analysis was limited by the knowledge of only those circumstances known at the start of ECMO.

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Drs. Biancari, Polvani, Mäkikallio, and Juvonen were involved in conceptualization. Drs. Biancari, Mäkikallio, and Juvonen were involved in methodology. Dr. Biancari was involved in software, validation, and visualization. Drs. Biancari, D'Errigo, and Rosato were involved in formal analysis. Drs. Biancari, Kaserer, Perrotti, Ruggieri, Cho, Dalén, Welp, Jónsson, Ragnarsson, Hernández Pérez, Gatti, Alkhamees, Loforte, Lechiancole, Spadaccio, Pettinari, Fiore, L'Acqua, Arafat, Albabtain, AlBarak, Laimoud, Djordjevic, Samalavicius, Alonso-Fernandez-Gatta, Wilhelm, Bonalumi, Mariscalco, and Polvani were involved in investigation and data curation. Drs. Biancari, Polvani, Mäkikallio, and Juvonen were involved in the original draft preparation of the writing. Drs. Biancari, Mäkikallio. and Juvonen were involved in supervision. All authors were involved in reviewing and editing the writing. All authors have read and agreed to the published version of the article.

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