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REVIEW
Miscellaneous

The impact of extracorporeal membrane oxygenation on mortality in patients with cardiogenic shock post-acute myocardial infarction: a systematic review and meta-analysis

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Aims Cardiogenic shock remains the leading cause of death in patients hospitalized with acute myocardial infarction. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is increasingly used in the treatment of infarct-related cardiogenic shock. However, there is limited evidence regarding its beneficial impact on mortality. The aim of this study was to systematically review studies reporting the impact of VA-ECMO on mortality in patients with acute myocardial infarction complicated by cardiogenic shock.

Methods and results A comprehensive search of medical databases (Cochrane Register and PubMed) was conducted. Studies that reported mortality outcomes in patients treated with VA-ECMO for infarct-related cardiogenic shock were included. The database search yielded 1194 results, of which 11 studies were included in the systematic review. Four of these studies, with a total of 586 patients, were randomized controlled trials and were included in the meta-analysis. This demonstrated that there was no significant difference in 30-day all-cause mortality with the use of VA-ECMO compared with standard medical therapy [odds ratio (OR) 0.91; 95% confidence interval (CI) 0.65–1.27]. Meta-analysis of two studies showed that VA-ECMO was associated with a significant reduction in 12-month all-cause mortality (OR 0.31; 95% CI 0.11–0.86). Qualitative synthesis of the observational studies showed that age, serum creatinine, serum lactate, and successful revascularization are independent predictors of mortality.

Conclusion Veno-arterial extracorporeal membrane oxygenation does not improve 30-day all-cause mortality in patients with cardiogenic shock following acute myocardial infarction; however, there may be significant reduction in all-cause mortality at 12 months. Further studies are needed to delineate the potential benefit of VA-ECMO in long-term outcomes.

Registration The protocol was registered in the PROSPERO International Prospective Register of Systematic Reviews (ID: CRD42023461740).

Keywords Extracorporeal membrane oxygenation • Cardiogenic shock • Acute myocardial infarction

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Introduction

Cardiogenic shock is a well-recognized complication of acute coronary syndrome (ACS), affecting 5–10% of cases of acute myocardial infarction (MI).[1] Despite advances in early revascularization techniques, cardiogenic shock in the context of acute MI is associated with significantly high mortality with up to 35–50% of patients not surviving to hospital discharge or 30-day follow-up.[2,3]

Establishing coronary reperfusion is the most effective therapeutic intervention in patients with acute MI complicated by cardiogenic shock.[4] Whilst this rectifies coronary blockage, it may not be sufficient to support the threatened myocardium. Management should also focus on maintaining haemodynamic stability and adequate tissue perfusion. Volume expansion and pharmacological therapies in the form of inotropes and vasopressors can be used to maintain cardiac output, although doses and duration of treatment should be kept to a minimum due to the associated increase in myocardial oxygen demand and vasoconstriction.[5]

Mechanical circulatory support systems have been developed to aid with haemodynamic stabilization in patients with cardiogenic shock. The intra-aortic balloon pump (IABP) remains the most widely used mechanical assist device. According to the European Society of Cardiology guidelines, it has a class IIb recommendation for patients with ACS and severe/refractory cardiogenic shock, whilst its routine use is not recommended in patients with cardiogenic shock post-ACS without mechanical complications.[6] However, evidence from a large meta-analysis suggests that, although its use may have a positive effect on haemodynamic parameters, there is no survival benefit linked to its use.[7] In addition, the IABP-SHOCK II trial, one of the largest randomized studies on the subject, showed that the use of IABP did not have an impact on mortality in patients with cardiogenic shock post-MI.[8] Similarly, there is currently no high-level evidence supporting the use of left ventricular assist devices such as Impella in this patient population and their use remains a class IIb recommendation from the American College of Cardiology.[9,10]

Extracorporeal membrane oxygenation (ECMO) is an alternative system that can offer circulatory support and pulmonary gas exchange, restoring organ perfusion in left, right, or biventricular failure.[11] Its use has substantially increased over the last two decades, with studies suggesting an advantageous impact on patients' survival and outcomes.[12,13] Whilst veno-venous ECMO requires stable haemodynamics, veno-arterial ECMO (VA-ECMO) bypasses both the heart and the lungs, providing in this way respiratory and haemodynamic support in cardiogenic shock.[14]

Currently, the use of ECMO is recommended only for refractory cases of cardiogenic shock post-acute MI and is reliant on individual experience in dedicated treatment centres.[3] The goal of this systematic review and meta-analysis is to provide concise evidence and evaluate the impact of ECMO on mortality in patients with acute MI complicated by cardiogenic shock.

Methods

This systematic review and meta-analysis was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[15] and has been submitted and registered with PROSPERO (registration number: CRD42023461740). We performed a focused review and meta-analysis of all the studies in the literature reviewing the use of ECMO in the management of patients with cardiogenic shock secondary to acute MI. The co-primary endpoints of this meta-analysis were 30-day all-cause mortality and 12-month mortality.

Search strategy

PubMed and Cochrane databases were systematically searched from inception until 26 August 2023. The key terms used for the search were ((myocardial infarction) OR (acute coronary syndrome)) AND ((extracorporeal membrane oxygenation) OR (ECMO)) AND (mortality).

Data extraction

After the removal of duplicates, all the remaining studies were screened at the title/abstract level. All studies that investigated the impact of ECMO on mortality in adult patients (>18 years old) with acute MI complicated by cardiogenic shock were included. Studies that included other causes of cardiogenic shock or compared ECMO with other forms of mechanical circulatory support, such as IABP, were excluded. Studies that were published in any language other than English were also excluded. The selected studies then underwent full-text screening. This process was performed by four independent investigators (S.P., N.J., J.M., and V.T.).

Any conflicts were solved by discussion with the senior author (V.V.), after which consensus was achieved.

Data analysis

Odds ratios (ORs) and 95% confidence intervals (CIs) were generated using raw data provided by each study included in the meta-analysis. Odds ratios are shown for each study and for overall effect estimate of the meta-analysis. A random-effects model with inverse-variance weights was used to combine the effect measures from all studies on a logarithmic scale independent of the degree of heterogeneity. Statistical heterogeneity was assessed using I^2 statistics. Statistical analyses were conducted using the Review Manager (RevMan) software (V.5.4; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Funnel plots are provided where appropriate. Statistical significance was defined as $P < 0.05$.

Results

The systematic search yielded 1194 results. After removing the duplicates, 1042 studies were excluded at the title/abstract level and 135 studies underwent full-text evaluation. Out of these, 11 studies met the inclusion criteria and their data were extracted. The study selection process is shown in *Figure 1*.

Four of the 11 included studies were randomized controlled trials with a total of 568 patients.[16–20] Of these patients, 284 were randomized to VA-ECMO and 284 were randomized to optimal medical therapy. The four trials used similar inclusion criteria, though the EURO-SHOCK trial required successful or attempted percutaneous coronary intervention (PCI) for randomization. The main features of these studies are summarized in *Table 1* and the number of events provided by each trial for all-cause mortality is depicted in Supplementary material online, *Table S1*. The risk of bias assessment of these trials is demonstrated in Supplementary material online, *Table S2*.

From the total population in these four studies, 30-day all-cause mortality was 47%, with 265 patients not surviving. There was no significant difference between the VA-ECMO group and the control group, with 30-day all-cause mortality being 45% and 48%, respectively (OR 0.91; 95% CI 0.65–1.27, I^2 0%) (*Figure 2*). Sensitivity analysis for 30-day all-cause mortality, including only the EURO-SHOCK and ECLS-SHOCK I trials, also showed no significant impact of VA-ECMO on 30-day all-cause mortality (see Supplementary material online, *Figure S1*). The funnel plot for this meta-analysis showed no significant publication bias (see Supplementary material online, *Figure S2*). Two studies with a total of 77 patients had examined the impact of VA-ECMO on 12-month all-cause mortality.[16,18] Meta-analysis of these two trials showed that VA-ECMO was associated with a reduction in 12-month all-cause mortality compared with optimal medical therapy; overall OR 0.31; 95% CI 0.11–0.86, I^2 0% (*Figure 3*).

Additionally, seven observational studies, including 1036 patients, were analysed separately to review rates of all-cause mortality in

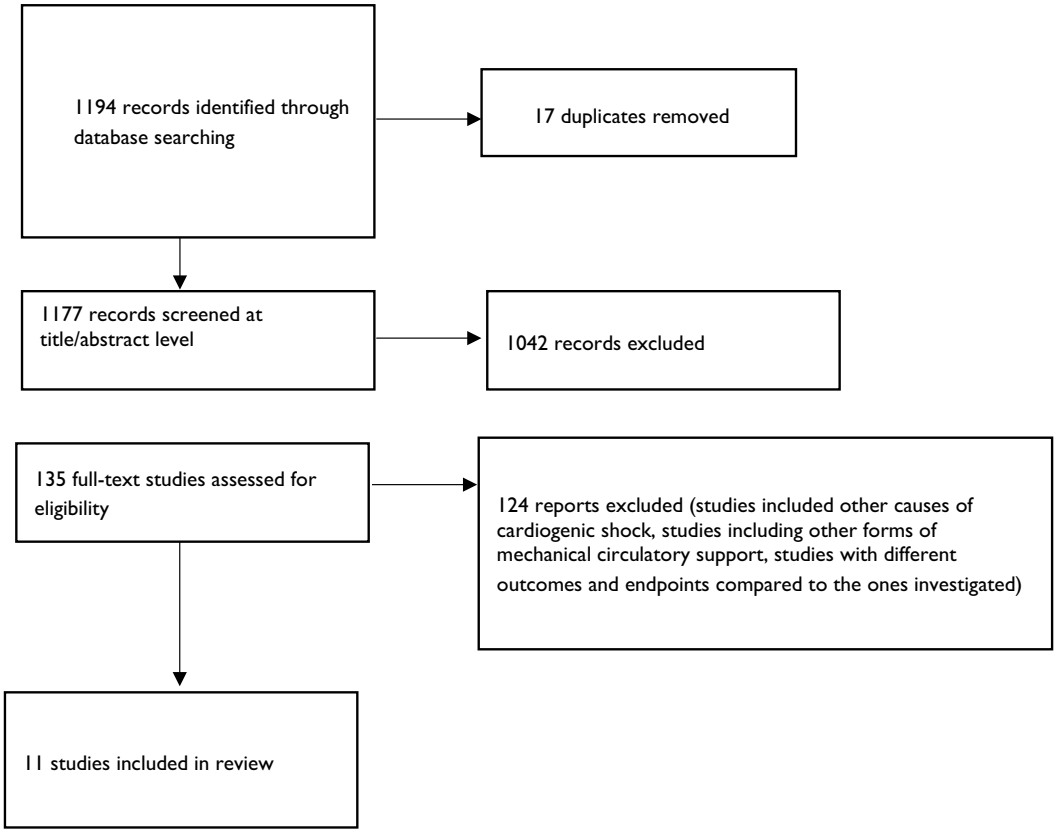

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the study selection process.

patients treated with VA-ECMO for cardiogenic shock post-acute MI. *Table 2* summarizes these studies along with their main characteristics and outcomes of interest.

All 1036 patients included in the observational studies were treated with VA-ECMO, and, therefore, no comparator data regarding mortality outcomes in standard medical therapy were available. Four studies commented on the timing of VA-ECMO initiation in relation to coronary revascularization.[21,23,25,27] Veno-arterial ECMO initiation occurred either during or after PCI and in-hospital mortality ranged from 33–67.3%. Pozzi *et al.*[24] specifically looked at the impact of timing of VA-ECMO initiation on survival in patients with refractory cardiogenic shock following acute MI and found no survival benefit in the early implantation (on the day of PPCI) of VA-ECMO (hazard ratio 1.18; 95% CI 0.94–1.48). Four studies performed multi-variate analysis looking at independent predictors of in-hospital mortality.[21–23,25] The success of coronary revascularization was commented on in five studies with a total of 273 patients described as undergoing successful PCI or bypass grafting. Both Fried *et al.*[22] and Sakamoto *et al.*[25] demonstrated that successful revascularization, defined as restoration of TIMI 3 flow, is an independent predictor of survival. Kim *et al.*[23] found that the method of coronary revascularization did not affect weaning from VA-ECMO or in-hospital mortality. Age, serum creatinine, serum lactate, successful revascularization, and VA-ECMO-related complications were all found to impact survival.

Four of the included observational studies commented on rates of VA-ECMO-associated complications.[21,23,25,26] Major haemorrhage requiring transfusion of blood products was seen in 42% of patients. Peripheral vascular complications including lower limb ischaemia were reported in 10% of patients, with one patient requiring amputation.

Discussion

This systematic review and meta-analysis evaluated the impact of VA-ECMO on both 30-day and 12-month mortality in patients with cardiogenic shock following acute MI. The results demonstrated that VA-ECMO is associated with significant reduction in 12-month all-cause mortality. However, this benefit was not demonstrated for 30-day all-cause mortality, as patients treated with VA-ECMO had similar mortality compared with those treated with standard optimal medical therapy. In addition, a systematic review of all the observational studies showed that timing of VA-ECMO initiation in relation to coronary revascularization did not effect survival and that age, serum creatinine, serum lactate, success of coronary revascularization, and VA-ECMO-related complications are all independent predictors of in-hospital mortality.

Cardiogenic shock is a complex disease process associated with critical cellular and metabolic impairment and multisystem organ dysfunction.[28] In the context of ACS, cardiogenic shock is associated with significantly high mortality and remains the leading cause of death in hospitalized patients, with observational studies quoting acute MI as an independent predictor of mortality.[1,29,30] Mechanical circulatory support systems such as VA-ECMO aim to achieve haemodynamic stability in patients with refractory cardiogenic shock either as a bridge to recovery or bridge to more permanent treatments such as ventricular assist devices or transplantation. As such, there has been a gradual increase in rates of

Table 1 Characteristics of randomized controlled trials

Study	Year	Population	Follow-up period	Outcomes	Adjustment methods
EURO-SHOCK trial[16] NCT03813134	2023	35 patients with persistent cardiogenic shock 30 min after PPCI	12 months	30-day and 12-month all-cause mortality was not statistically different between the two groups (HR 0.56; 95% CI 0.21–1.45, $P = 0.22$ and HR 0.52; 95% CI 0.21–1.26; $P = 0.14$, respectively). Vascular and bleeding complications occurred more often in the VA-ECMO arm (21.4% vs. 0% and 35.7% vs. 5.6%, respectively).	The primary analysis was performed according to the intention-to-treat principle. HR with a 95% CI obtained from a Cox proportional hazard model stratified for OHCA.
ECLS-SHOCK I[17,18] NCT02544594	2019 2021	42 patients with cardiogenic shock post-acute MI	30 days & 12 months	The primary study endpoint, left ventricular ejection fraction (LVEF) at 30 days, was similar among surviving patients in the ECLS group (50.0%) and in the control group (50.8%) 30-day all-cause mortality occurred in 19% in VA-ECMO group and 33% in control group; 12-month all-cause mortality occurred in 19% in ECLS group and 38% in control group.	Lachin's procedure using the Mann–Whitney *U* test was used for primary analysis
ECLS-SHOCK[19] NCT03637205	2023	417 patients with cardiogenic shock after acute MI and early planned revascularization	30 days	Early routine ECLS was not superior to usual medical therapy alone. 30-day all-cause mortality occurred in 47.8% in the ECMO group and 49% in the control group (RR 0.98, 95% CI 0.8–1.19, $P = 0.81$). ECLS was associated with more complications, in particular bleeding and peripheral vascular events.	The primary analysis was performed according to the intention-to-treat principle. Chi-square test was used to compare the incidence of a primary-outcome event and the relative risk was calculated with the corresponding 95% CI.
ECMO-CS[20] NCT02301819	2023	117 patients in total, 73 with cardiogenic shock following acute MI	30 days	The primary endpoint, a composite of all-cause 30-day mortality, resuscitated circulatory arrest or need for another MCS, was similar among patients in the ECMO group (59.5%) and those in the control group (67.6%); 30-day all-cause mortality occurred in 48.6% in VA-ECMO group and 43.2% in control group.	Analyses were performed according to the intention-to-treat principle. The time to occurrence of primary endpoint was analysed using the Kaplan–Meier method with hazard ratios calculated using Cox proportional hazards model.

ECMO use for cardiogenic shock over the last decade and its use is recommended in international guidelines (level IIb).[31,32]

Our findings regarding the effect of VA-ECMO on 30-day all-cause mortality are in keeping with another recent meta-analysis that showed no overall significant reduction in 30-day mortality with the early use of VA-ECMO (OR 0.93; 95% CI 0.66–1.29).[33] Additionally, our review is the first to evaluate the impact of VA-ECMO on 3- and 12-month mortality and include retrospective data.

However, the meta-analysis of the only two randomized controlled trials that had 12-month mortality data, consisting of 77 patients in

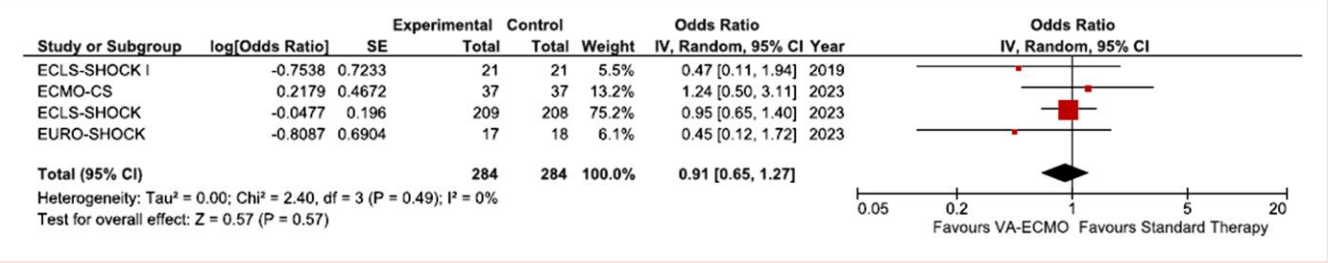

Figure 2 Meta-analysis of randomized controlled trials focusing on 30-day all-cause mortality.

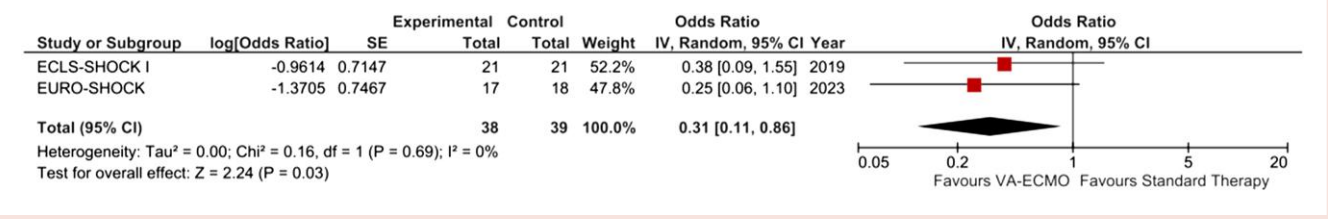

Figure 3 Meta-analysis of randomized controlled trials focusing on 12-month all-cause mortality.

total, showed that VA-ECMO results in a survival benefit in the long term, with a significant reduction in 12-month all-cause mortality compared with medical therapy alone.[16,18] One of the trials included in this meta-analysis, the EURO-SHOCK trial, mandated that patients underwent successful or attempted revascularization prior to the initiation of VA-ECMO and continued to have features of cardiogenic shock for more than 30 min after revascularization. For the second study of this meta-analysis, the ECLS-SHOCK I trial, all patients were commenced on VA-ECMO after completion of their PCI procedure. The optimal timing of VA-ECMO initiation in relation to coronary revascularization remains a contentious issue. A small non-randomized trial of 253 patients demonstrated that early initiation of VA-ECMO prior to revascularization was associated with an improvement in clinical outcomes including in-hospital mortality and the need for ventricular assist devices or transplantation.[34] Given that this may be an important factor that may have influenced the survival of patients initiated on ECMO, further studies are needed to understand the potential impact of the timing of the VA-ECMO initiation on short- and long-term mortality outcomes.

Initial clinical presentation and severity of coronary artery disease are likely to impact mortality outcomes. Overall, fewer patients presented with ST-segment elevation MI in the ECLS-SHOCK I and EURO-SHOCK trials. A significant difference was also seen in the number of diseased vessels between the control and ECLS groups in the ECLS-SHOCK I trial with 76% of patients in the control group having three-vessel disease, compared with 24% in the intervention group. Given that multi-vessel coronary artery disease is associated with an increased risk of cardiovascular mortality, this may have affected the 12-month mortality data, especially in the context of such a small sample size.

Additionally, the EURO-SHOCK trial permitted the use of IABP in both patient groups as a means of left ventricular unloading. A recent meta-analysis of retrospective data has demonstrated that combination therapy of VA-ECMO and IABP in patients with cardiogenic shock due to acute MI may result in a reduction in mortality.[35] It is important to note that both the EURO-SHOCK and ECLS-SHOCK I trials were based on small sample sizes, with a combined population of 77 patients, and, therefore, the results should be interpreted with caution.

Mortality rates of patients treated with VA-ECMO remained high in the observational studies with age, serum creatinine, serum lactate, and successful revascularization quoted as independent predictors of mortality.[22,23,25] Reasons for ECMO failure are multi-factorial and device-related complications may outweigh the potential benefit. Treatment with VA-ECMO was associated with an increased risk of bleeding events requiring transfusion of blood products as well as peripheral vascular complications including critical lower limb ischaemia. However, the studies included in this review identified no significant increase in the incidence of stroke between the treatment groups nor was there a significant difference in neurological outcome. In fact, the EURO-SHOCK trial noted a reduction in the incidence of stroke and recurrent MI in patients who had received VA-ECMO compared with those receiving optimal medical therapy alone.

It is possible that the benefit seen in VA-ECMO is derived from utilizing it in patients following coronary revascularization as well as in patients who have multiple co-morbidities. Finally, there may a possibility that the benefit of VA-ECMO is only realized after 30 days. Patients who have not been treated with VA-ECMO, whilst alive at 30 days following conventional therapy, may continue to deteriorate, unlike patients treated with VA-ECMO, leading to higher mortality at 12 months. As such, reporting of 12-month mortality outcomes for the remaining randomized controlled trials that have not reported this to date is essential.

Conclusion

In summary, whilst the use of VA-ECMO does not improve 30-day all-cause mortality in patients with refractory cardiogenic shock following acute MI, there is evidence to suggest that it may provide a long-term survival benefit. Further studies are needed to evaluate the potential survival benefit of VA-ECMO in the long term and weigh it against the complication risk it carries.

Table 2 Characteristics of observational studies

Study	Year	Population	Follow-up period	Outcomes	Adjustment methods
Esper et al.[21]	2015	18 patients with cardiogenic shock supported with VA-ECMO in the cardiac catheterization lab at the time of presentation.	6 months	12 out of 18 patients (67%) survived until discharge and 10 (55%) were alive at 6 months. Age, sex, diabetes, renal failure, and left ventricular impairment did not affect survival; 4 patients developed critical limb ischaemia and 17 required blood transfusion for bleeding.	Comparisons were made using the student's *t*-test or Wilcoxon non-parametric tests for continuous variables and the chi-square test or Fischer's exact test for categorical variables.
Fried et al.[22]	2022	126 patients with acute myocardial infarction who received VA-ECMO for refractory cardiogenic shock	30 days	The primary outcome of ventricular recovery (survival to discharge without left ventricular assist device or transplant) was seen in 39 (31%) patients. Patient survival was 54% at 30 days. Age, creatinine, serum lactate, and lack of restoration of TIMI 3 flow in culprit artery were significant predictors of in-hospital mortality.	The Student's *t*-test and the Wilcoxon rank sum test were used to compare groups for continuous variables, where appropriate. Logistic regression was used to determine significant predictors of the primary outcome. Variables with a *P*-value of ≤0.20 in univariable analysis were included in a multivariable model.
Kim et al.[23]	2012	27 patients with ECMO support for acute MI with CS	Mean follow-up duration of 16.5 ± 16.5 months	22 patients were successfully weaned from ECMO and 16 patients survived to discharge. The in-hospital mortality was 40.8%. Pre-ECMO serum lactate was independently associated with in-hospital mortality. The 30-day mortality was 37%.	The χ^2 test and the Student's *t*-test were used to compare categorical and continuous variables, respectively. Multi-variate stepwise logistic regression analysis was used to evaluate risk factors for mortality.
Pozzi et al.[24]	2023	649 patients with cardiogenic shock who were revascularized on admission and required VA-ECMO within 6 days of presentation	90 days	All-cause 90-day mortality rate was 64.3%. There was no statistical difference in mortality in early VA-ECMO implantation (on the day of PPCI) compared with delayed; HR 1.18; 95% CI 0.94–1.48, $P = 0.153$.	Propensity score-based analyses using the inverse probability of treatment weighting method was used to compare all-cause mortality in each VA-ECMO time group and hospital volume group. Hazard ratios with CIs were estimated from weighted Cox model.
Sakamoto et al.[25]	2012	98 patients with cardiogenic shock	Hospital stay (mean 53.4 ± 120 days)	All-cause in-hospital mortality was observed in 66 (67.3%) patients. Unsuccessful angioplasty and ECLS-related complications such as lower limb ischaemia were independent predictors of in-hospital mortality.	Continuous variables were assessed by the Student *t*-test or the Mann–Whitney *U* test and the χ^2 test was used for categorical variables. Multivariate logistic regression analysis was used to identify predictors of in-hospital mortality.
Van den Brink et al.[26]	2018	12 patients with cardiogenic shock who received VA-ECMO in addition to PPCI.	12 months	30-day mortality occurred in 33% of patients, which was also the mortality on VA-ECMO; 50% patients experienced complications including haemorrhage and limb ischaemia; 1-year survival was 42% (5/12).	Descriptive statistics with number and percentages.
Wagner et al.[27]	2019	106 patients with cardiogenic shock	5 years	30-day survival was 54.4%; survival after 1 year was 42.2% and 38% at 5 years. The severity of coronary artery disease had no significant effect on long-term survival.	Comparisons were performed using the Student *t*-test and the χ^2 test when appropriate. Multi-variable Cox regression analysis was performed to identify prognostic indicators for long-term survival. Corresponding hazard ratios with 95% CIs were calculated.

Lead author biography

Dr Sophie Paddock (MBBS, MClinEd, FHEA, MRCP) graduated from Norwich Medical School and is currently employed as a NIHR Academic Clinical Fellow in Cardiology at Norfolk and Norwich University Hospital.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

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