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The use of extracorporeal membrane oxygenation in the setting of postinfarction mechanical complications: outcome analysis of the Extracorporeal Life Support Organization Registry

Matteo Matteucci [a,b,*], Dario Fina[a,c], Federica Jiritano [a,d], Paolo Meani[e], Giuseppe Maria Raffa [a,f], Mariusz Kowalewski[a,g], Ibrahim Aldobayyan[a], Mohammad Turkistani[a], Cesare Beghi [b] and Roberto Lorusso [a,h]

[a] Department of Cardiothoracic Surgery, Heart and Vascular Centre, Maastricht University Medical Centre, Maastricht, Netherlands
[b] Department of Cardiac Surgery, Circolo Hospital, University of Insubria, Varese, Italy
[c] Department of Intensive Care Unit, IRCCS Policlinico San Donato, University of Milan, Milan, Italy
[d] Department of Cardiac Surgery, University Magna Graecia of Catanzaro, Catanzaro, Italy
[e] Department of Cardiology, Heart and Vascular Centre, Maastricht University Medical Centre, Maastricht, Netherlands
[f] Department for the Treatment and Study of Cardiothoracic Diseases and Cardiothoracic Transplantation, IRCCS-ISMETT (Instituto Mediterraneo per i Trapianti e Terapie ad alta specializzazione), Palermo, Italy
[g] Clinical Department of Cardiac Surgery, Central Clinical Hospital of the Ministry of Interior in Warsaw, Warsaw, Poland
[h] Department of Intensive Care Unit, Cardiovascular Research Institute Maastricht (CARIM), Maastricht University, Maastricht, Netherlands

* Corresponding author. Department of Cardiothoracic Surgery, Heart and Vascular Centre, Maastricht University Medical Centre, P. Debyelaan 12, 6221 AZ Maastricht, Netherlands. Tel: +31-43-3876032; fax: +31-43-3875075; e-mail: matteomatteucci87@gmail.com (M. Matteucci).

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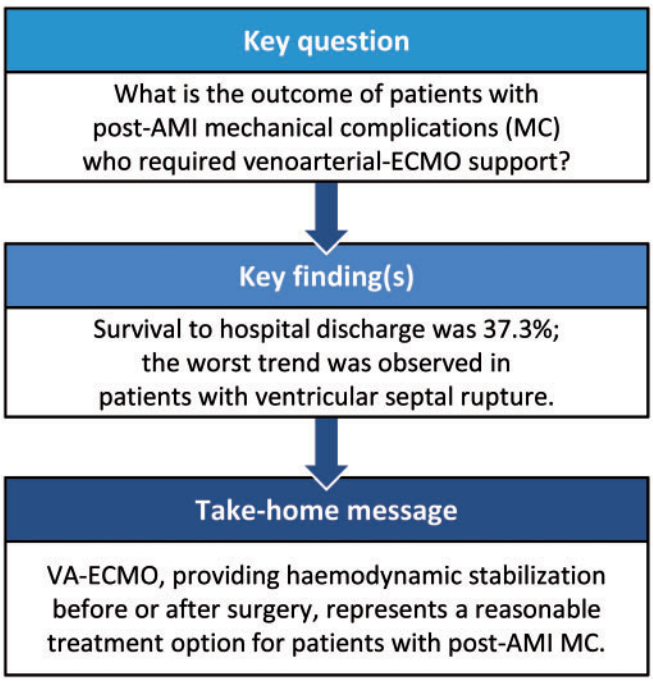

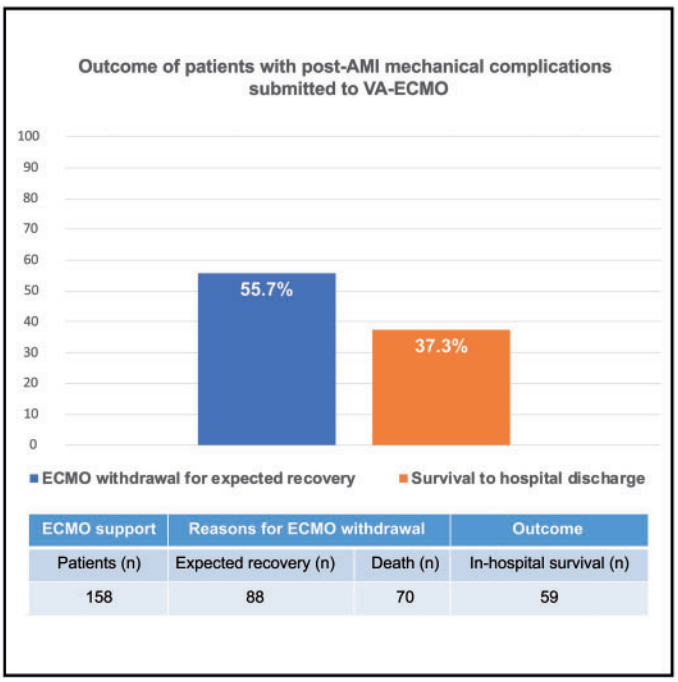

ECMO support	Reasons for ECMO withdrawal		Outcome
Patients (n)	Expected recovery (n)	Death (n)	In-hospital survival (n)
158	88	70	59

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Abstract

OBJECTIVES: Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) has been recently considered and used for patients with post-acute myocardial infarction mechanical complications (post-AMI MC); however, information in this respect is scarce. The purpose of this study was to evaluate the in-hospital outcomes of patients with post-AMI MC submitted to VA-ECMO, and enrolled in the Extracorporeal Life Support Organizations (ELSO)'s data Registry.

METHODS: This was a retrospective review of the ELSO Registry to identify adult (>18 years old) patients with post-AMI MC who underwent VA-ECMO support between 2007 and 2018. The primary end point of this study was in-hospital survival. ECMO complications were also evaluated.

RESULTS: The patient cohort available for this study included 158 patients. The median age was 62.4 years (range 20–80). The most common post-AMI MC was ventricular septal rupture ($n = 102$; 64.5%), followed by papillary muscle rupture ($n = 42$; 26.6%) and ventricular free-wall rupture ($n = 14$; 8.9%). Approximately a quarter of patients ($n = 41$; 25.9%) had cardiac arrest before VA-ECMO institution. The median duration of VA-ECMO was 5.9 days (range 1 h–40.3 days). ECMO complications occurred in 119 patients (75.3%). Overall, survival to hospital discharge for the entire patient cohort was 37.3%. Patients who had ventricular septal rupture as primary diagnosis had higher in-hospital mortality ($n = 66$; 64.7%).

CONCLUSIONS: In patients with post-AMI MC, VA-ECMO provides haemodynamic stabilizations and carries a potential to reverse otherwise lethal course. ECMO complications, however, remain an important limitation. Further investigations are required to better evaluate the efficacy and safety of ECMO in this context.

Keywords: Extracorporeal membrane oxygenation • Cardiogenic shock • Cardiac arrest • Mechanical complications • Acute myocardial infarction

ABBREVIATIONS

AMI	Acute myocardial infarction
ELSO	Extracorporeal life support organization
MC	Mechanical complications
VA-ECMO	Veno-arterial extracorporeal membrane oxygenation
VSR	Ventricular septal rupture

INTRODUCTION

Mechanical complications (MC) are rare but potentially lethal sequelae of acute myocardial infarction (AMI). These catastrophic complications include ventricular free-wall rupture, ventricular septal rupture (VSR) and papillary muscle rupture. Although with the advent of percutaneous coronary intervention there has been a significant drop in the incidence of post-AMI MC, mortality in patients who developed these complications remains high despite surgical repair [1–3]. The most common causes of death are cardiac arrest and cardiogenic shock [3, 4], encountered either preoperatively or postoperatively. In this context, veno-arterial extracorporeal membrane oxygenation (VA-ECMO) providing emergency haemodynamic and metabolic stabilization might potentially improve patient preoperative and postoperative conditions and enhance the chances of a favourable outcome. However, the severity of patient's illness, aggressiveness of the mechanical assistance and prolonged extracorporeal support invariably predispose to complications, which may further increase the risk of death. Although some investigators have reported the use of ECMO for post-AMI MC, its actual impact and related results have not been well documented. The most recent ESC/EACTS Guidelines on myocardial revascularization allocate ECMO support, in the presence of post-AMI MC, in class of recommendation IIb, level of evidence C (based on the consensus of opinion of the experts and/or small studies) [5]. The objective of the current study was to describe the in-hospital outcomes ofpatients with post-AMI MC who required VA-ECMO, and were enrolled in the Extracorporeal Life Support Organization (ELSO)'s data Registry.

MATERIALS AND METHODS

The Extracorporeal Life Support Organization Registry

Despite the expansion in the use of ECMO, the clinical management of ECMO remains mainly based on local protocols, and guidelines are lacking on many aspects of this practice. The ELSO Registry and the so-called Red Book, represent the most authoritative resource, and the ELSO website (https://www.elso.org) provides information and protocols to support clinical investigations. The ELSO Registry is a voluntary registry that collects information on use, complications and outcomes following ECMO support from ∼400 centres worldwide [6]. Data reported to the ELSO Registry from 1992 to 2016 include >110 000 paediatric and adult patients [6]. ELSO member centres report information to the Registry using a standardized collection sheet. Patient diagnosis is allocated using the International Classification of Disease, 9th or 10th edition codes. Data user agreement between ELSO and member centres allows the use of deidentified datasets for research without need for further regulatory approval.

Study population

We examined the ELSO database for all patients, from 1 January 2007 to 31 December 2018, who had International Classification of Diseases, 9th or 10th edition codes, which referred to post-AMI MC (ICD-9 codes 429.71 and 429.6, and ICD-10 codes I23.2-5). For this study, only data from adult patients (>18 years old) with post-AMI MC supported with VA-ECMO for cardiac indications were extracted. Subjects supported with veno-venous ECMO and those with multiple ECMO runs were excluded.

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Patient demographics (age, gender, race and weight), pre-ECMO condition and indication, process variables (duration of ECMO, location of cannulas, haemodynamic and laboratory information and procedures) and patient outcome information (complications, survival to hospital discharge) were analysed. Variables with >20% missing values were not included in the analysis.

Definitions and main goals

Cardiogenic shock was defined by systolic blood pressure <90 mmHg, mean arterial pressure <65 mmHg or requiring 2 or more vasopressor infusion for haemodynamic support. Central cannulation was defined as cannulation of the ascending aorta for patients' arterial blood inflow and the right atrium for drainage of venous blood; cannulation of the femoral or axillary artery for patients' arterial blood inflow and the femoral vein for drainage of venous blood was considered peripheral cannulation. Primary end points of the study were in-hospital survival and prevalence as well as type of ECMO complications. In-hospital survival was defined as survival to hospital discharge or another facility from the ECMO centre. According to the definition given by ELSO, ECMO complications were considered those complications associated with the ECMO run, or occurred as a consequence of ECMO. ECMO complications were categorized using the ELSO Registry complication code and included the following variables: mechanical (oxygenator failure, raceway rupture, pump failure, cannula problems, circuit change, heat exchanger malfunction, air in circuit, clots haemofilter, clots or thrombosis of circuit component), haemorrhagic (gastrointestinal haemorrhage and cannulation or surgical site bleeding), neurological (brain death, seizures, central nervous system diffuse ischaemia or infarction, intra- or extra-parenchymal central nervous system haemorrhage), renal (creatinine 1.5–3.0 mg/dl, creatinine > 3.0 mg/dl, renal replacement therapy required), cardiovascular (cardiopulmonary resuscitation, cardiac arrhythmia, tamponade), pulmonary (pneumothorax and pulmonary haemorrhage), metabolic (hyperbilirubinaemia, moderate and severe haemolysis), infective and peripheral complications (fasciotomy, limb amputation and ischaemia requiring limb reperfusion cannula). Regarding the reasons of ECMO discontinuation, the ELSO Registry form includes expected recovery, died or poor prognosis (irrecoverable disease), resource limitation (lack of equipment or personnel), ECMO complication and reason not specified.

Statistical analysis

Considering the quality of available data, only a descriptive analysis with pooled prevalence rates was carried out. Proportions were computed to summarize categorical data, while means and medians were calculated for continuous measures.

RESULTS

This study included 158 adult patients who developed post-AMI MC and were supported with VA-ECMO for cardiogenic shock or cardiac arrest. Median age was 62.4 years (range 20–80), and 124 subjects (78.5%) were male. The most frequent type of post-AMI MC was VSR (64.5%), followed by papillary muscle rupture (26.6%) and ventricular free-wall rupture (8.9%). In 146 patients (92.4%), the indication for VA-ECMO institution was cardiogenic shock; the remaining 12 subjects (7.6%) received VA-ECMO during extracorporeal cardiopulmonary resuscitation for cardiac arrest. Sixty-six (41.8%) subjects required intra-aortic balloon pump before ECMO. Baseline characteristics and pre-ECMO support information are reported in Table 1.

The median duration of VA-ECMO run was 5.9 days (range 1 h–40.3 days). The peripheral approach was more commonly used (88.6%) than the central one. Main ECMO support details are summarized in Table 2. Overall, 67 patients (42.4%) underwent cardiac surgery; in 42 subjects, the operation was performed before VA-ECMO implantation, in the remaining patients after, or during, ECMO support. Timing and type of cardiac operations performed are shown in Table 3. VA-ECMO for postcardiotomy syndrome was applied in 47 patients (29.7%) with cardiopulmonary failure after surgery. The median duration of ECMO support following cardiac surgery was 6.1 days (range 17 h–18.6 days). VA-ECMO weaning was possible in almost half of the patients (48.7%). ECMO support was discontinued in 44.3% of the subjects for death or in anticipation of death (diagnosis incompatible with life, irreversible organ failure, family request); in the remaining patients, the circulatory mechanical support was withdrawal for the following reasons: resources limitation ($n = 2$), ECMO complications ($n = 4$) or reasons not specified ($n = 5$). One patient (VSR group) was transitioned from VA-ECMO to left ventricular assist device, but he died during the hospital stay.

Table 1: Demographics, clinical characteristics and pre-ECMO information

Variables	Patients ($N = 158$)
Mean age (years)	62.4 ± 9.7[a]
Gender	
Male	78.5 (124/158)
Female	21.5 (34/158)
Mean weight (kg)	86.9 ± 19.6[a]
Main cardiovascular risk factors	
Hypertension	7 (11/158)
Diabetes mellitus	6.3 (10/158)
Dyslipidaemia	7.6 (12/158)
Chronic obstructive pulmonary disease	3.8 (6/158)
Chronic renal failure	5.1 (8/158)
Type of mechanical complication	
Ventricular free-wall rupture	8.9 (14/158)
Ventricular septal rupture	64.5 (102/158)
Papillary muscle rupture	26.6 (42/158)
Pre-ECMO clinical state	
Cardiogenic shock	92.4 (146/158)
Cardiac arrest (eCPR)	7.6 (12/158)
Pre-ECMO support	
Vasopressor-inotropic drugs	75.3 (119/158)
IABP	41.8 (66/158)
Cardiopulmonary bypass	13.3 (21/158)
Pre-ECMO blood gases	
pH	7.3 ± 0.15[b]
SaO_2 (%)	92.4 ± 12.5[c]

Data are shown as mean ± SD or % (n/N) as appropriate.

[a]Missing values: <1%.

[b]Missing values: 17%.

[c]Missing values: 19%.

ECMO: extracorporeal membrane oxygenation; eCPR: extracorporeal cardiopulmonary resuscitation; IABP: intra-aortic balloon pump; *N*: number; SaO_2: arterial oxygen saturation; SD: standard deviation.

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Overall, in-hospital survival rate was 37.3%. The worst trend was observed in the VSR group, in which only the 35.3% of the patients were discharged alive. Main clinical characteristics of this subgroup of patients are shown in Table 4. Outcomes, according to the type of post-AMI MC, are outlined in Fig. 1. In-hospital survival was higher in patients who underwent cardiac surgery (before, during or after VA-ECMO support), compared to patients who had ECMO placed in the absence of surgery (47.8% vs 29.7%). Conversely, worse survival rates were found in extracorporeal cardiopulmonary resuscitation and non-postcardiotomy VA-ECMO patients, when compared to their counterpart (25% vs 38.4% and 34.2% vs 44.7%, respectively). Peripheral and central VA-ECMO configurations showed comparable in-hospital survival (38.9% and 37.1%, respectively).

ECMO complications occurred in 75.3% of the subjects. Eighty-two patients (51.9%) experienced renal failure during ECMO support, with 63 adults requiring renal replacement therapy. Surgical or cannulation site bleeding occurred in 32.3% of the patients, whereas ischaemic stroke in nearly 9% of cases. Table 5 reported the remaining VA-ECMO complications. Median duration of ECMO was greater in survivors [6 (range 2 h–22 days) vs 5.8 days (range 1 h–40.3 days)] and in patients who developed complications during extracorporeal support [6.6 (range 1 h–78.8 days) vs 2.5 days (range 1 h–21.4 days)].

DISCUSSION

The use of ECMO has markedly progressed over the last 30 years because of technological improvement and increased experience [6]. Thus, the ECMO indications have been extended to patients with a variety of conditions, including not only cardiogenic shock and acute respiratory distress syndrome, but also cardiac arrest and septic shock [7, 8]. VA-ECMO has been recently considered as a method of resuscitation and circulatory support for cardiovascular collapse associated with post-AMI MC [3, 9]; however, its actual effectiveness in this context have not been well documented. Dedicated studies on the use of ECMO for post-AMI MC are, indeed, limited to case reports and few observational studies [10–12]. Therefore, we reviewed the ELSO Registry to provide information regarding this challenging group of patients.

Post-AMI MC are uncommon but are associated with significantly impaired cardiocirculatory and high early mortality without appropriate intervention [13]. These acute life-threatening complications include VSR, ventricular free-wall rupture and papillary muscle rupture, and are more common with ST-segment

Table 2: Main ECMO details

Variables	Patients (*N* = 158)
ECMO duration (h)	178.1 ± 168.4[a]
Cannulation strategy	
Central	11.4 (18/158)
Peripheral	88.6 (140/158)
Femoro-femoral	85.4 (135/158)
Axillo-femoral	3.2 (5/158)
Haemodynamics (mmHg)[b]	
Systolic blood pressure	84.6 ± 20.1[c]
Diastolic blood pressure	51.8 ± 14.4[c]
Blood gases[b]	
pH	7.4 ± 0.1[d]
SaO_2 (%)	97.9 ± 2.4[e]
Cardiac surgery under ECMO	15.8 (25/158)
Postcardiotomy ECMO	29.7 (47/158)

Data are shown as mean ± SD or % (*n*/*N*) as appropriate.
[a]Missing values: <1%.
[b]At 24 h on ECMO.
[c]Missing values: 16%.
[d]Missing values: 17%.
[e]Missing values: 19%.
ECMO: extracorporeal membrane oxygenation; *N*: number; SaO_2: arterial oxygen saturation; SD: standard deviation.

Table 3: Timing and details of surgical procedures performed

Surgical procedure (*n*)	Prior to ECMO support	During or after ECMO support
VSRr (*n* = 20)	12	8
VFWRr (*n* = 2)	1	1
MV surgery (*n* = 9)	5	4
CABG + VSRr (*n* =11)	9	2
CABG + MV surgery (*n*= 6)	4	2
CABG (*n* = 13)	6	7
Unknown (*n* = 6)	5	1
Total (*n* = 67)	42[a]	25[b]

Data are shown as number.
[a]In-hospital survival: 52.4% (22/42).
[b]In-hospital survival 40% (10/25).
CABG: coronary artery bypass grafting; ECMO: extracorporeal membrane oxygenation; MV: mitral valve; *n*: number; VFWRr: ventricular free-wall rupture repair; VSRr: ventricular septal rupture repair.

Table 4: VSR group of patients: main characteristics and outcome

Variables	Patients (*N* = 102)
Mean age (years)	62.9 ± 9.6[a]
Gender	
Male	79.4 (81/102)
Female	20.6 (21/102)
Mean weight (kg)	87.4 ± 18.5[a]
Pre-ECMO clinical state	
Cardiogenic shock	95.1 (97/102)
Cardiac arrest (eCPR)	4.9 (5/102)
Pre-ECMO support	
Vasopressor-inotropic drugs	74.5 (76/102)
IABP	43.1 (44/102)
Cardiopulmonary bypass	8.8 (9/102)
ECMO duration (h)	208.2 ± 242.5[a]
Cardiac surgery under ECMO	18.6 (19/102)
Postcardiotomy ECMO	21.6 (22/102)
In-hospital survival	35.3 (36/102)

Data are shown as mean ± SD or % (*n*/*N*) as appropriate.
[a]Missing values: <1%.
ECMO: extracorporeal membrane oxygenation; eCPR: extracorporeal cardiopulmonary resuscitation; IABP: intra-aortic balloon pump; *N*: number; SD: standard deviation; VSR: ventricular septal rupture.

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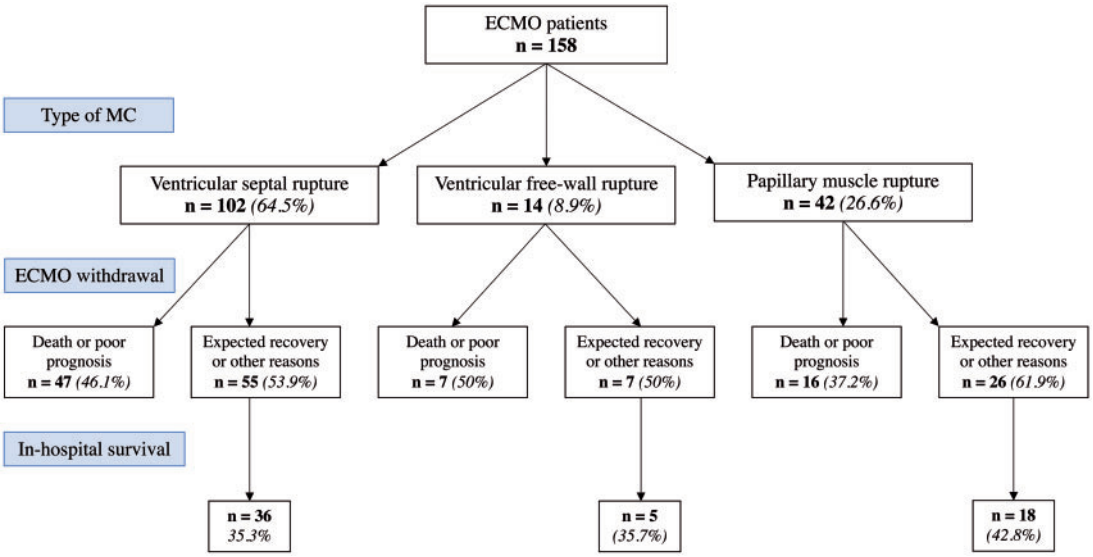

Figure 1: In-hospital survival of patients with postinfarction MC submitted to veno-arterial ECMO. ECMO: extracorporeal membrane oxygenation; MC: mechanical complications.

Table 5: Complications occurring during ECMO support

Complications	Patients (*N* = 158)
Mechanical	17.7 (28/158)
Haemorrhagic	32.3 (51/158)
Neurological	13.3 (21/158)
Renal	51.9 (82/158)
Cardiovascular	25.9 (41/158)
Pulmonary	4.4 (7/158)
Metabolic	13.9 (22/158)
Infective	23.4 (37/158)
Peripheral	3.2 (5/158)

Data are shown as % (*n*/*N*).
ECMO: extracorporeal membrane oxygenation; *N*: number.

elevation myocardial infarction [3, 13]. The most important factors for patient survival, beside the extent and time-to-onset of the post-AMI MC, are early diagnosis and timely treatment. Cardiogenic shock, with subsequent multiorgan failure, is the leading cause of death in these patients, and surgery is almost always required [14, 15]. In such a scenario, VA-ECMO may play an important role, not only giving the clinicians time to postpone the definitive treatment (bridge-to-surgical repair), but also contributing to improve preoperative patient conditions, if extremely poor [16], or to favour myocardial or general recovery after surgery (postoperative bridge-to-recovery). One clinical entity that appears to be well suited for bridging is VSR [12]. Disadvantage of an emergent surgery approach is the high probability of repair failure, and recurrent shunt, because of the fragility of the infarcted septum. A delay in operative intervention will allow time for necrotic myocardium to become more suitable for surgical correction [17], with improved chance of successful repair. On the other hand, the timing of definitive treatment must be customized in each case, as prolonged duration of mechanical circulatory support increases the potential for complications, which may ultimately jeopardize planned surgery.

Although being highly effective and allowing organ and patient recovery in otherwise lethal situations, ECMO itself represents a potential source of adverse events. Thus, complications occurring during ECMO may be a consequence of the pre-existing condition, or be directly related to this intervention. We found different rates of ECMO complications in our analysis when compared with meta-analyses that similarly investigated complication rates in ECMO [18, 19]. These studies used different criteria for identification of specific diagnoses, thereby this can explain the variation of complication rate reported. Interestingly, our findings are substantially similar to the published general data from the ELSO Registry [20]. We only observed a slightly higher rate of renal replacement therapy, ischaemic stroke and tamponade/surgical site bleeding. However, these findings are not surprising because patients with post-AMI MC had more frequent cardiac arrest prior to VA-ECMO implant, and nearly 45% of the subjects received a cardiac surgery procedure, a well-known risk factor for bleeding during ECMO run.

Regarding survival, nearly one-half of patients were successfully weaned from ECMO, and almost 40% were discharged from hospital. These findings are in accordance with the previously cited study from the ELSO Registry that showed an overall survival to hospital discharge of 41.4% [20], despite the expected more complex conditions of these patient subset. As mentioned above, literature on the use of VA-ECMO in patients with post-AMI MC is limited, making any meaningful analysis, or comparison, difficult. Nonetheless, if we consider the VSR subgroup of patients, our results are substantially similar with previous publications on this topic [12, 21], suggesting VA-ECMO to be considered as a reasonable approach in patients with postinfarction VSR complicated by cardiogenic shock. However, further and dedicated trials are necessary before a definitive evidence-based conclusion can be reached.

Limitations

This study has several important limitations. Data in the ELSO Registry are submitted voluntarily; thus, the accuracy of reporting

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is unknown. Furthermore, retrospectively collected information is subject to incomplete or missing reporting of events. This can explain the surprising low rates of cardiovascular comorbidities among the patient population. Policy, strategy and protocols for the use of mechanical circulatory support are individualized; this variability among ECMO centres constitutes further limitations. ECMO complications are defined and categorized according to the Organ definition. However, adjudication of complication type is also arbitrary and therefore misdiagnosis or inappropriate assignment is possible. Based on the definition of 'ECMO complication' given by ELSO, differentiation between complications intrinsically related to ECMO support and those occurring as a consequence of the pre-existing disease is not possible. As patient survival is limited to in-hospital course, events occurring in subjects transferred to other hospital-related facilities are not available, making the overall early outcome not completely described and final results likely underestimated. Finally, as is inherent in many databases, the general issue of selection bias is another major limitation, and for the ELSO Registry, there is a selection bias, in that it contains only patients for whom ECMO has been selected as therapy. Thus, the group of patients is uncontrolled and, thereby, the efficacy of VA-ECMO in subjects with post-AMI MC is not proven.

CONCLUSION

VA-ECMO can be utilized to support adults with cardiogenic shock due to post-AMI MC. Overall in-hospital mortality remains high, but the use of such a temporary support proved to allow delay in surgical repair in otherwise emergency patients and to support the cardiocirculatory functions up to the patient recovery and discharge. ECMO complications are, however, common. Further clinical research and investigations are required to provide additional insight in such a challenging setting, but timely VA-ECMO implant, either preoperatively, intraoperatively or postoperatively, is expected to provide additional benefit and, hence, improved early survival.

Conflict of interest: Roberto Lorusso is a consultant for Medtronic and LivaNova, and a member of the Advisory Board of Eurosets and PulseCath. All other authors declared no conflict of interest.

Author contributions

Matteo Matteucci: Conceptualization; Data curation; Formal analysis; Investigation; Writing—original draft. **Dario Fina:** Validation; Visualization. **Federica Jiritano:** Validation; Visualization. **Paolo Meani:** Validation; Visualization. **Giuseppe Maria Raffa:** Validation; Visualization. **Mariusz Kowalewski:** Validation; Visualization. **Ibrahim Aldobayyan:** Validation; Visualization. **Mohammad Turkistani:** Data curation; Validation; Visualization. **Cesare Beghi:** Validation; Visualization. **Roberto Lorusso:** Conceptualization; Investigation; Methodology; Supervision; Validation; Visualization.

Reviewer information

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