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Research Article

Keywords: Shock, Cardiogenic, Cardiac Surgical Procedures, Extracorporeal Membrane Oxygenation, Lactic Acid, MELD score, Mortality, ECMELLA

Posted Date: November 14th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11515982/v1

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Additional Declarations: No competing interests reported.

Predictors of mortality in patients treated with ECMELLA after cardiac surgery – a single-center experience

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Abstract:

Background: Postcardiotomy cardiogenic shock (PCS) remains a serious complication after cardiac surgery associated with high perioperative mortality. Over the last years, the use of veno-arterial extracorporeal life support (VA-ECLS) combined with left ventricular unloading by a microaxial flow pump (ECMELLA) has increased. Data on mortality predictors in patients treated with ECMELLA for PCS remain limited. We aimed to identify factors associated with 30-day all-cause mortality after ECMELLA implantation.

Methods: We retrospectively analyzed consecutive patients who received concomitant VA-ECLS and a microaxial pump after cardiac surgery at our university center between 2019 and 2024. Clinically relevant surrogate parameters were assessed along with 30-day mortality. Discriminative ability was assessed by receiver operating characteristic (ROC) analysis. Survival was analyzed using Kaplan–Meier estimates with log-rank testing, and predictors of

30-day mortality were identified using univariable and multivariable Cox proportional hazards regression.

Results: Of the 34 patients, 26 (76.5%) died within 30 days. The Model for End-stage Liver Disease (MELD) score was significantly higher in non-survivors than in survivors (18.5 [IQR 10.7] vs. 14.9 [IQR 2.8], p = 0.010). The MELD excluding INR (MELD-XI) score was likewise higher in non-survivors (17.6 [IQR 9.7] vs. 10.2 [IQR 2.6], p = 0.001). Lactate levels were significantly lower in survivors at 12 hours (p = 0.03), 18 hours (p = 0.004) and 24 hours (p = 0.02) after ECMELLA initiation. Discrimination was best at 18 hours (AUC 0.824, p < 0.001). Aortic cross-clamp time was not associated with 30-day mortality when analyzed as a continuous variable; however, an exploratory cutoff of ≥63 minutes was associated with increased mortality (HR 3.20, 95% CI 1.34–7.65, p = 0.009). In univariable Cox regression, MELD-XI ≥12.5 (HR 2.87, 95% CI 1.13–7.32) and lactate ≥2 mmol/L at 18 hours (HR 4.47, 95% CI 1.48–13.52) were associated with 30-day mortality, but neither remained independently associated in multivariable analysis.

Conclusions: Biological markers, including MELD-XI and lactate, could provide complementary prognostic information before and after ECMELLA implantation, whereas the prognostic value of a prolonged aortic cross-clamp time, observed only in an exploratory threshold analysis, remains uncertain.

Keywords:

Shock, Cardiogenic; Cardiac Surgical Procedures; Extracorporeal Membrane Oxygenation; Lactic Acid; MELD score; Mortality; ECMELLA

Background

Cardiogenic shock (CS) is a state of critical end-organ hypoperfusion caused by severe myocardial contractile dysfunction, in which the heart cannot maintain adequate cardiac output despite normal or even elevated preload [1]. Acute myocardial infarction (AMI) with impaired myocardial contractility remains the most common cause of CS [2]. Other etiologies are increasingly encountered, such as postcardiotomy cardiogenic shock (PCS). PCS is a serious complication occurring in approximately 1% of patients after routine cardiac surgical operations [3]. Despite advances in diagnostics and management, CS remains associated with a high mortality [4].

Temporary mechanical circulatory support (tMCS) is now central to the management of CS. The EACTS/STS/AATS guidelines recommend initiating tMCS before severe organ dysfunction develops and identify escalating vasoactive and inotropic requirements, clinical signs of tissue hypoperfusion and rising lactate as indications. Its role also extends to refractory cardiac arrest [5]. The use of veno-arterial extracorporeal life support (VA-ECLS), also known as veno-arterial extracorporeal membrane oxygenation (VA-ECMO), has increased in recent years [6]. VA-ECLS restores systemic perfusion but increases left ventricular (LV) afterload, which may necessitate LV unloading; in current practice, this is increasingly achieved with a microaxial pump. This combination, known as ECMELLA or ECpella, has been associated with higher weaning rates, but with an increased risk of complications, including bleeding, limb ischemia, and stroke compared to the combination of VA-ECLS and IABP [7].

Routine laboratory parameters reflecting tissue perfusion and secondary organ dysfunction have been widely investigated as prognostic markers in CS. Higher absolute lactate concentrations and slower lactate clearance during tMCS have been associated with increased mortality, and serial measurement is recommended to assess prognosis and treatment response [5]. The Model for End-Stage Liver Disease (MELD) score was originally developed to predict

short-term mortality in patients with end-stage liver disease [8]. Elevated MELD and MELD-variant scores (MELD-Na and MELD-XI) have also been associated with poor outcomes in CS, advanced heart failure, heart transplantation, and VA-ECMO [9–13].

Data on ECMELLA in the postcardiotomy setting remain limited, and predictors of outcome in this specific population are poorly defined. Identifying predictive factors would help guide the indication for tMCS and the assessment of treatment response. This study aims to identify factors associated with 30-day all-cause mortality after ECMELLA implantation in patients after cardiac surgery.

Methods

This retrospective single-center study included all consecutive patients who received concomitant VA-ECLS and a microaxial pump (Impella 2.5, CP, 5.0, or 5.5) after cardiac surgery at our university center, between January 2019 and December 2024. All patients receiving mechanical circulatory support in our institution are systematically recorded in an internal institutional database, which was used to identify all eligible patients. Exclusion criteria were age <18 years, incomplete data for the analyzed variables, and the concomitant use of a temporary right ventricular assist device.

The study was conducted in accordance with the Declaration of Helsinki. As it was a retrospective analysis of fully anonymized data routinely collected at our institution, the need for formal ethics approval and informed consent was waived by the Ethics Committee of the Ärztekammer Westfalen-Lippe (ref no. 2026-710-f-N).

Thirty-day all-cause mortality after ECMELLA implantation was used to stratify the cohort into survivors and non-survivors. All patients either died in hospital or remained hospitalized beyond 30 days after ECMELLA implantation; therefore, 30-day follow-up was complete, and no patient was lost to follow-up. ECMELLA implantation time was defined as the time at which

both VA-ECLS and the microaxial pump were established simultaneously. Weaning was defined as the complete and permanent removal of both mechanical circulatory support devices (VA-ECLS and Impella) without subsequent reimplantation. Transition to long-term mechanical circulatory support, such as a left ventricular assist device (LVAD), was also considered as successful weaning. Assessed complications occurring during ECMELLA support comprised bleeding events (thoracic bleeding, gastrointestinal or abdominal bleeding, and groin bleeding), ischemic complications (bowel and limb ischemia), neurological events (ischemic stroke, hemorrhagic stroke, or mixed forms), and the need for renal replacement therapy. Detailed definitions of these complications are provided in Additional file 1.

Demographic, clinical, and laboratory data were collected from electronic medical records. Complete laboratory panels, including the parameters required to calculate the MELD and MELD-XI scores, were obtained immediately before ECMELLA implantation. Serum lactate was additionally recorded at 6-hour intervals during the first 48 hours of support. If no measurement was available at a given time point, the value was estimated as the mean of the closest preceding and following measurements. At our institution, lactate levels of 2 mmol/L or less are considered normal.

The MELD and MELD-XI scores were calculated using the following formulas [9, 14]:

$$MELD = 3.78\ln(Bilirubin) + 11.2\ln(INR) + 9.57\ln(Creatinine) + 6.43$$

$$MELD - XI = 5.11\ln(Bilirubin) + 11.76\ln(Creatinine) + 9.44$$

Values of bilirubin, creatinine, and INR below 1.0 were set to 1.0. Creatinine was limited to a maximum of 4.0 mg/dL and set to 4.0 mg/dL in patients receiving ≥2 dialysis sessions or 24 hours of continuous venovenous hemodialysis within the preceding 7 days.

Mechanical circulatory support

VA-ECLS characteristics: All patients were intubated during therapy. Venous drainage cannulas ranged from 21 to 23 French and were inserted via the femoral vein alone or in combination with the internal jugular vein. Arterial return cannulas (15–19 French) were placed in either the femoral artery or the right axillary artery. When feasible, a distal perfusion cannula was inserted into the superficial femoral artery or the brachial artery, respectively.

Microaxial pump characteristics: Impella 2.5 or CP devices were implanted percutaneously via the femoral artery. Impella 5.0 or 5.5 devices were surgically implanted via the right axillary artery using a 10-mm Dacron graft. In one case, the Impella device was implanted in the ascending aorta. The Impella purge fluid contained either glucose-unfractionated heparin or a glucose-bicarbonate-based solution.

Anticoagulation: All patients received anticoagulation during mechanical support with unfractionated heparin, targeting an activated partial thromboplastin time (aPTT) of 50–60 seconds.

Statistical methods

Categorical variables are presented as absolute numbers and percentages and were compared between groups using the χ^2 test or Fisher's exact test when expected cell counts were below five. No comparison was performed when one group contained no patients with the characteristic of interest; this is indicated by "—" in the tables. For continuous variables, normality was assessed using both the Shapiro–Wilk and Kolmogorov–Smirnov tests. Normally distributed variables are presented as means ± standard deviations and were compared using Student's t-test. Non-normally distributed variables are reported as medians with interquartile ranges (IQR) and were compared using the Mann–Whitney U test. A two-sided p-value < 0.05 was considered statistically significant.

Receiver operating characteristic (ROC) curves were generated. The area under the curve (AUC) was used to quantify the accuracy of the MELD score, MELD-XI score and lactate in predicting 30-day all-cause mortality after ECMELLA implantation. The optimal cutoffs for the MELD score, the MELD-XI score and the aortic cross-clamp time were determined using the Youden index.

A Kaplan–Meier plot was generated to estimate survival. The log-rank test was performed to compare survival curves. Cox proportional hazards models were used to estimate hazard ratios (HR) with 95% confidence intervals. Covariates associated with mortality in univariable analysis at $p \leq 0.05$ were entered simultaneously into a multivariable model; covariates that did not reach significance were then removed to obtain the final model.

Data collection was conducted using Microsoft Excel, and statistical analyses were performed using IBM SPSS Statistics (version 31.0.0; IBM Corp., Armonk, NY). This study is reported in accordance with the STROBE guidelines (Additional file 2).

Results

- **Baseline demographics**

A total of 34 patients were included in the study (Figure 1). Mean age was 62.5 ± 12.2 years, and twenty-six patients (76.5%) were male. All assessed baseline characteristics are summarized in Table 1.

Figure 1. Patient selection among all patients supported with VA-ECLS between January 2019 and December 2024

A total of 230 patients received VA-ECLS support during the study period. Of these, 119 had undergone cardiac surgery, and 34 received concomitant Impella support. As none of these patients met the exclusion criteria, the final study cohort comprised 34 patients.

- **Overall mortality**

Overall mortality was 76.5% (n = 26); four of these patients died within 24 hours of ECMELLA initiation. Baseline characteristics, comorbidities and preoperative status did not differ significantly between survivors and non-survivors (Table 1). Of the 8 survivors, 2 were bridged to a permanent LVAD; none of them underwent heart transplantation.

Table 1. Baseline demographic, clinical, and preoperative characteristics

Variable	Overall (n = 34)	Survivors (n = 8)	Non-survivors (n = 26)	p-value
Age (years)	62.5 ± 12.2	58.8 ± 11.4	63.6 ± 12.3	0.300
Male	26 (76%)	5 (63%)	21 (81%)	0.400
Comorbidities				
• Arterial hypertension	25 (74%)	6 (75%)	19 (73%)	0.900
• Atrial fibrillation	5 (15%)	0 (0%)	5 (19%)	0.300
• Diabetes mellitus	10 (29%)	3 (38%)	7 (27%)	0.700
• Obesity	8 (24%)	1 (13%)	7 (27%)	0.600
• Prior stroke	2 (6%)	0 (0%)	2 (8%)	—
• COPD	5 (15%)	1 (13%)	4 (15%)	1.000
• CKD	11 (32%)	1 (13%)	10 (38%)	0.200
• Permanent pacemaker	3 (9%)	0 (0%)	3 (12%)	—
• Prior cardiac surgery	2 (6%)	0 (0%)	2 (8%)	—
Indication for surgery				
• CAD	28 (82%)	8 (100%)	20 (77%)	—
• AVR	4 (12%)	0 (0%)	4 (15%)	—
• MVR	9 (26%)	0 (0%)	9 (35%)	—
• MVS	1 (3%)	0 (0%)	1 (4%)	—
• TVR	3 (9%)	0 (0%)	3 (12%)	—
• Aortic aneurysm	1 (3%)	0 (0%)	1 (4%)	—
• Endocarditis	3 (9%)	0 (0%)	3 (12%)	—
Preoperative status				
• Admission to ICU/IMC	20 (59%)	6 (75%)	14 (54%)	0.400
• EuroSCORE II (%)	23.2 (23.2)	24.9 (24.2)	22.7 (23.4)	0.800
• MI	18 (53%)	6 (75%)	12 (46%)	0.200
NYHA class				
• NYHA I–II	7 (21%)	0 (0%)	7 (27%)	
• NYHA III–IV	27 (79%)	8 (100%)	19 (73%)	0.800
LVEF				
• LVEF < 30%	15 (44.1%)	5 (62.5%)	10 (38.5%)	
• LVEF ≥ 30%	19 (55.9%)	3 (37.5%)	16 (61.5%)	0.410

COPD: chronic obstructive pulmonary disease; CKD: chronic kidney disease; CAD: Coronary Artery Disease; AVR: Aortic Valve Regurgitation; MVR: Mitral Valve Regurgitation; MVS: Mitral Valve Stenosis; TVR: Tricuspid Valve Regurgitation; ICU: Intensive Care Unit; IMC:

Intermediate Care; EuroSCORE II: European System for Cardiac Operative Risk Evaluation II; MI: Myocardial Infarction; NYHA: New York Heart Association; LVEF: Left Ventricular Ejection Fraction.

- **Postoperative complications**

Renal replacement therapy was required in most patients (79%), with no significant difference between survivors and non-survivors (75% vs. 81%, p = 1.000). The most frequent bleeding complications were thoracic bleeding (29%), followed by gastrointestinal or abdominal bleeding (18%). Stroke occurred in 35% of patients, without difference between survivors and non-survivors. Mesenteric and limb ischemia occurred in 9% and 15% of cases, respectively, with no difference between groups (Table 2).

Table 2. Postoperative complications and adverse events

Variable	Overall (n = 34)	Survivors (n = 8)	Non-survivors (n = 26)	p-value
Bleeding	15 (44%)	4 (50%)	11 (42%)	1.000
• Gastrointestinal or abdominal bleeding	6 (18%)	1 (13%)	5 (19%)	1.000
• Groin bleeding	2 (6%)	0 (0%)	2 (8%)	—
• Thoracic bleeding	10 (29%)	4 (50%)	6 (23%)	0.195
Mesenteric ischemia	3 (9%)	0 (0%)	3 (12%)	—
Limb ischemia	5 (15%)	1 (13%)	4 (15%)	1.000
Stroke (total)	12 (35%)	3 (38%)	9 (35%)	1.000
• Ischemic stroke	4 (12%)	1 (13%)	3 (12%)	1.000
• Hemorrhagic stroke	4 (12%)	0 (0%)	4 (15%)	—
• Mixed ischemic + hemorrhagic	4 (12%)	2 (25%)	2 (8%)	0.229
Renal replacement therapy	27 (79%)	6 (75%)	21 (81%)	1.000

- **Operative and mechanical circulatory support characteristics**

Survivors had a significantly shorter aortic cross-clamp time compared to non-survivors (36.5 [IQR 54.5] vs. 74.0 [IQR 126.0] minutes, p = 0.017). Cardiopulmonary bypass (CPB) duration was also shorter in survivors, without reaching significance (124 ± 80 vs. 195 ± 107 minutes, p = 0.100). The interval between VA-ECLS and Impella implantation did not differ significantly (survivors 5.33 [IQR 13.65] vs. non-survivors 3.58 [IQR 14.33] hours, p = 0.717). Surgically implanted devices (Impella 5.0 or 5.5) were more frequently used in survivors (75% vs. 31% p = 0.050) (Table 3). Fourteen patients were weaned from both VA-ECLS and the

191 microaxial pump. Of these, 8 survived beyond 30 days, whereas 6 died after weaning; in these
192 6 patients, the mean interval from weaning to death was 87.6 ± 42 hours.

193 **Table 3. Operative characteristics and mechanical circulatory support parameters**

Variable	Overall (n = 34)	Survivors (n = 8)	Non-survivors (n = 26)	p-value
Emergency surgery	17 (50%)	6 (75%)	11 (42%)	0.100
CPR	13 (38%)	3 (37%)	10 (38%)	1.000
Number of procedures	1.4 ± 0.8	1.0 ± 0.0	1.5 ± 0.8	0.100
Aortic cross-clamp time (min)	62.50 (IQR 121.50)	36.50 (IQR 54.50)	74.00 (IQR 126.00)	**0.017**
CPB time (min)	178.5 ± 104.6	124 ± 80	195 ± 107	0.100
CPB fluid balance (ml)	1306.00 (IQR 2665.25)	1130.00 (IQR 1363.00)	1456.00 (IQR 3121.75)	0.735
VA-ECLS duration (hours)	131.3 ± 96	216 ± 140	113 ± 84	—
Microaxial pump duration (hours)	181.2 ± 114	273 ± 120	151 ± 101	—
VA-ECLS and Impella time interval (hours)	4.14 (IQR 14.33)	5.33 (IQR 13.65)	3.58 (IQR 14.33)	0.717
Microaxial pump type				
• Impella 2.5 / CP	20 (59%)	2 (25%)	18 (69%)	
• Impella 5.0 / 5.5	14 (41%)	6 (75%)	8 (31%)	**0.050**

194 *CPR: Cardiopulmonary Resuscitation; CPB: Cardiopulmonary Bypass; VA-ECLS: Veno-*
195 *Arterial Extracorporeal Life Support.*
196 *VA-ECLS–Impella time interval: interval between implantation of VA-ECLS and implantation*
197 *of the Impella. When the Impella was implanted first, the interval was recorded as 0 hours.*

198 • **Laboratory findings**

199 Pre-ECMELLA-implantation laboratory values revealed significant differences in renal
200 function between survivors and non-survivors, as reflected by lower potassium levels (4.1 ±
201 1.2 vs. 5.1 ± 0.7 mmol/L, p = 0.004), higher eGFR (69.0 [IQR 24.0] vs. 39.5 [IQR 33.3]
202 mL/min/1.73 m², p = 0.006), and lower creatinine levels (1.1 ± 0.2 vs. 1.7 ± 0.7 mg/dL, p =
203 0.020) in survivors. Other laboratory parameters, including inflammatory markers, coagulation
204 profiles, and cardiac enzymes, did not differ significantly between groups (Table 4).

205 **Table 4. Laboratory parameters before ECMELLA implantation**

Variable	Overall (n = 34)	Survivors (n = 8)	Non-survivors (n = 26)	p-value
pH	7.31 ± 0.14	7.3 ± 0.1	7.3 ± 0.2	0.300
Potassium (mmol/L)	4.9 ± 1.0	4.1 ± 1.2	5.1 ± 0.7	**0.004**
Calcium, ionized (mmol/L)	1.13 (IQR 0.13)	1.14 (IQR 0.16)	1.13 (IQR 0.16)	0.236

Hemoglobin (g/dL)	9.50 (IQR 1.45)	8.85 (IQR 1.95)	9.60 (IQR 1.43)	0.220
CRP	4.05 (IQR 8.35)	2.85 (IQR 5.13)	4.85 (IQR 15.38)	0.177
Platelets (×10⁹/L)	132.5 ± 66.0	155.0 ± 58.8	126.5 ± 67.9	0.300
PTT (s)	63.00 (IQR 82.25)	131.50 (IQR 175.50)	58.50 (IQR 64.50)	0.152
INR	1.85 (IQR 0.85)	1.90 (IQR 0.70)	1.80 (IQR 1.20)	0.889
eGFR (mL/min/1.73 m²)	48.00 (IQR 35.75)	69.00 (IQR 24.00)	39.50 (IQR 33.25)	**0.006**
Creatinine (mg/dL)	1.6 ± 0.7	1.1 ± 0.2	1.7 ± 0.7	**0.020**
AST (U/L)	563.00 (IQR 1138.75)	410.50 (IQR 642.50)	675.00 (IQR 2078.50)	0.141
ALT (U/L)	165.50 (IQR 860.75)	104.00 (IQR 229.50)	349.00 (IQR 990.25)	0.120
Bilirubin (mg/dL)	1.30 (IQR 1.08)	0.90 (IQR 0.68)	1.35 (IQR 1.25)	0.084
CK (U/L)	1509.50 (IQR 4281.25)	1547.50 (IQR 4973.00)	1397.50 (IQR 4326.00)	1.000
CK-MB (U/L)	195.50 (IQR 442.50)	162.00 (IQR 776.50)	213.00 (IQR 439.25)	0.801

CRP: C-Reactive Protein; PTT: Partial Thromboplastin Time; INR: International Normalized Ratio; eGFR: Estimated Glomerular Filtration Rate; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase; CK: Creatine Kinase; CK-MB: Creatine Kinase Myocardial Band; ECMELLA: Veno-Arterial Extracorporeal Life Support combined with a microaxial flow pump.

- **MELD Score**

Both MELD and MELD-XI scores were significantly higher in non-survivors before ECMELLA implantation (Figure 2). The median MELD score was 14.9 (IQR 2.8) in survivors and 18.5 (IQR 10.7) in non-survivors (p = 0.010). Similarly, the MELD-XI score was lower in survivors [10.2 (IQR 2.6)] compared to non-survivors [17.6 (IQR 9.7)] (p = 0.001).

Figure 2. MELD and MELD-XI Scores Before ECMELLA

Before ECMELLA implantation, the MELD-XI score showed good discriminative performance, with an area under the curve (AUC) of 0.868 (p = 0.001), whereas the MELD score demonstrated slightly lower performance with an AUC of 0.796 (p = 0.001). The optimal cutoff value for the MELD-XI score was 12.46 (Figure 3).

Figure 3. ROC curves of MELD and MELD-XI scores for survival prediction before ECMELLA implantation

- **Lactate**

Lactate was elevated in both groups before implantation. After implantation, survivors showed a rapid decline in lactate levels within the first hours, whereas non-survivors had a slower and more gradual decrease over time, as illustrated in Figure 4.

Figure 4. Lactate kinetics over time after ECMELLA implantation

The median lactate before ECMELLA implantation was 8.15 (IQR: 6.85) mmol/L in the survivor group and 7.5 (IQR: 6.78) mmol/L in the non-survivor group; this difference was not significant ($p = 0.935$). Peak lactate was 9.75 (IQR: 4.85) vs. 11.35 (IQR: 7.4) mmol/L ($p = 0.291$). Lactate levels were significantly lower in survivors at 12 hours ($p = 0.030$), 18 hours ($p = 0.004$) and 24 hours ($p = 0.021$) after ECMELLA implantation, but did not differ at 6, 30, 36, 42 or 48 hours. Among these time points, lactate at 18 hours showed the best discriminative ability with an AUC of 0.824 ($p < 0.001$) (Figure 5).

Figure 5. ROC curves of lactate at 12, 18, and 24 hours after ECMELLA implantation

We analyzed the time to normalization of lactate levels (< 2 mmol/L), excluding the four patients who died within 24 hours. Durable lactate normalization was reached significantly more often by survivors than by non-survivors (6 [75%] vs. 6 [27.3%], $p = 0.034$).

- **Survival Analysis**

In univariable Cox regression, a MELD-XI score ≥12.5 before ECMELLA implantation (HR 2.87, 95% CI 1.13–7.32, $p = 0.027$) and a lactate level ≥2 mmol/L at 18 hours (HR 4.47, 95% CI 1.48–13.52, $p = 0.008$) were associated with higher mortality. When analyzed as a continuous variable, aortic cross-clamp time was not significantly associated with 30-day mortality in Cox regression. However, an exploratory cutoff of ≥ 63 minutes, identified using the Youden index, was associated with increased mortality (HR 3.20, 95% CI 1.34–7.65, p =

0.009). Impella 5.0 or 5.5, compared with Impella 2.5 or CP, showed a non-significant trend toward lower mortality (HR 0.47, 95% CI 0.20–1.10, p = 0.081).

The Kaplan–Meier analysis showed that a MELD-XI score ≥12.5, lactate ≥2 mmol/L at 18 hours and an aortic cross-clamp time ≥63 minutes were associated with higher mortality (log-rank p = 0.022, 0.010 and 0.006, respectively) (Figure 6).

Figure 6. Kaplan–Meier survival curves for pre- and post-implantation predictors

A: MELD-XI ≥12.5; B: lactate ≥2 mmol/L at 18 hours; C: cross-clamp time ≥63 minutes.

Multivariable Cox proportional hazards regression initially included the MELD-XI score, lactate at H18 and aortic cross-clamp time as binary covariates. Cross-clamp time was non-significant in the initial model and was removed, leaving lactate at H18 and the MELD-XI score in the final model. The overall model reached statistical significance (p = 0.014). Both lactate >2 mmol/L at H18 and MELD-XI ≥12.5 prior to ECMELLA implantation showed a trend toward increased 30-day mortality risk (HR 2.57, 95% CI 0.84–7.85, p = 0.097 and HR 2.01, 95% CI 0.65–6.19, p = 0.223, respectively), without reaching statistical significance.

Discussion

Our study mainly showed that mortality and morbidity in patients treated with ECMELLA after cardiac surgery remain high. We also identified potential mortality predictors, namely the MELD and MELD-XI scores and lactate, whereas the aortic cross-clamp time emerged only in an exploratory threshold analysis.

Published ECMELLA series report 30-day or in-hospital mortality between 43.2% and 61% [7, 15–23]. The 30-day mortality in our cohort was 76.5%, above the rates reported in these series. One explanation lies in how other series handled early deaths. Several of these studies excluded patients dying within 24 hours of ECMELLA initiation, which lowers reported

mortality. This explains the excess only partially: in our cohort, excluding the 4 patients who died within the first 24 hours still leaves a mortality of 73.3%. Another explanation is the composition of our cohort, which included only postcardiotomy patients, whereas most published ECMELLA series exclude such patients or report mixed populations. We identified no large ECMELLA series restricted to postcardiotomy patients for direct comparison. However, the meta-analysis by Kienlein et al. [24], which pooled studies of patients treated with VA-ECLS after cardiac surgery, reported an overall in-hospital mortality of 68.9% (range 42.6%–81.8%), which is broadly comparable to the mortality observed in our cohort.

Bleeding occurred in 44% of patients (thoracic 29%, abdominal or gastrointestinal 18%, groin 6%), comparable to the 48% reported by Ott et al. [25]. Stroke was two- to threefold more frequent than reported elsewhere (35% vs. 11.6% and 17.5%; Schrage et al. [21] and Radakovic et al. [22]). Renal replacement therapy was also more frequent (79% vs. 36–38%; Ott et al. [25] and Soh et al. [7]), a difference likely explained by our institutional practice of early initiation to achieve rapid negative fluid balance. Limb ischemia (15%) matched other ECMELLA cohorts (11–12.7%; Ott et al. [25], Radakovic et al. [22], Grandin et al. [19]), whereas mesenteric ischemia (9%) nearly tripled the 3.3% of Schrage et al. [21]. The higher rates of stroke and mesenteric ischemia may partly reflect the more critically ill, higher-risk (high EuroSCORE II) postcardiotomy profile of our population, together with variations in patient selection, postoperative anticoagulation, and surveillance practices across centers.

Hyperlactatemia in cardiogenic shock results from three mechanisms: (i) increased pyruvate generation due to acceleration of glycolysis, such as that induced by catecholamine excess with β-agonist stimulation or by metabolic stress, (ii) reduced pyruvate utilization secondary to tissue hypoxia, causing hypoxia-related hyperlactatemia; and (iii) impaired lactate clearance due to hepatic or renal dysfunction. In patients treated with tMCS, these mechanisms frequently coexist, substantially complicating clinical interpretation [26].

In our cohort, neither baseline nor peak lactate was associated with 30-day mortality, and median baseline lactate was paradoxically higher among survivors. However, lower lactate at 12, 18, and 24 hours after implantation was significantly associated with reduced mortality, with the strongest discrimination at 18 hours (AUC 0.824).

This finding contrasts with most reports, which showed elevated baseline lactate to be associated with higher mortality in cardiogenic shock, including tMCS populations [27–30], although smaller studies found no prognostic value for baseline lactate and emphasized follow-up values instead [31, 32]. This discrepancy likely reflects the multifactorial nature of baseline lactate, influenced not only by tissue hypoperfusion but also by catecholamine stimulation and impaired hepatic or renal clearance [26]. Indeed, an early lactate increase during epinephrine infusion has been linked with improved survival in shock, suggesting that hyperlactatemia does not necessarily indicate irreversible hypoxia but may reflect preserved metabolic responsiveness [33]. Similarly, patients with better-preserved circulation may exhibit higher measurable lactate concentrations because lactate accumulated within hypoperfused tissues is more effectively washed out into the systemic circulation, whereas severely impaired circulation may initially underestimate the true metabolic burden. Although this mechanism remains speculative, it may partly explain the lack of association between baseline lactate and mortality in our cohort.

In contrast, persistent hyperlactatemia after ECMELLA implantation more likely reflects ongoing hypoperfusion and failure of metabolic recovery despite mechanical support, which explains its stronger association with mortality [26, 34]. Consistent with this, several studies have shown that lactate clearance and serial values outperform peak and baseline measurements as survival predictors [34–36].

Evidence specific to ECMELLA-supported patients remains scarce: in a Japanese multicenter registry, Yahagi et al. [37] found no difference in in-hospital mortality according to admission

lactate in ECMELLA patients, whereas admission lactate was significantly associated with mortality in patients receiving Impella alone. Besides serial values and lactate clearance, metrics such as time to lactate normalization and the area under the lactate–time curve [38] deserve evaluation and could, combined into a composite score, refine risk stratification.

Several studies have investigated the MELD score and its surrogates (MELD-XI and MELD-Na) across acute and chronic cardiac conditions for the estimation of short- and long-term mortality. However, findings have not been unanimous. In heart transplantation, several studies reported that an elevated MELD-XI score was associated with increased short- and long-term post-transplant mortality [9, 12, 39]. The MELD score also showed excellent discriminatory performance for predicting operative mortality in patients undergoing emergency heart transplantation [40]. In contrast, Ortiz-Bautista et al. [41] found no association between pre-transplant MELD-XI and 30-day or 1-year mortality. In patients supported with an LVAD, a higher MELD-XI score was associated with higher mortality, early right heart failure, infection and lower weaning rates [10, 42]. Similarly, in a postcardiotomy population, elevated MELD and surrogate scores were independently associated with poor survival and adverse clinical events [43]. To our knowledge, no study has specifically examined the MELD score in patients treated with ECMELLA. In VA-ECLS, however, several reports have shown that a higher MELD-XI score is independently associated with increased mortality, with a discriminatory performance equivalent or superior to that of the SAVE score, the reference risk score in VA-ECLS, while being easier to obtain, which makes MELD a practical tool [44–46].

In our cohort, both the MELD and MELD-XI scores, assessed before ECMELLA implantation, showed good discriminatory performance for predicting mortality, the highest AUC being 0.868 for MELD-XI before ECMELLA implantation. Unlike lactate, MELD and MELD-XI were associated with mortality already before ECMELLA implantation, making them readily available parameters to inform the decision to initiate ECMELLA. Our multivariable analysis

was unable to demonstrate an independent association of the MELD-XI score and lactate at H18 with mortality. Two hypotheses can be considered, and they may well coexist: first, the hepatic and renal dysfunction reflected by a high MELD-XI score may delay lactate clearance, so that the two variables partly capture the same prognostic information; and second, this organ dysfunction may indicate a broader multiorgan failure that influences mortality independently of lactate. Given the small number of events, the model was underpowered to separate these hypotheses.

A prolonged aortic cross-clamp time was associated with higher mortality in exploratory threshold analyses, whereas no association was found when the variable was analyzed continuously. This is consistent with previous reports after cardiac surgery [47–49]. Data under MCS are scarce and inconsistent: cross-clamp time was significantly longer in non-survivors in one prospective study [50], whereas other retrospective series found no difference [31, 32, 51]. The cross-clamp time cutoff of 63 minutes was derived from our small cohort and may therefore be subject to overfitting. It is also influenced by the fact that some patients underwent beating-heart coronary bypass surgery, in which extracorporeal circulation was established without aortic cross-clamping, resulting in a cross-clamp time of 0 minutes. This cutoff should therefore be considered exploratory rather than an established clinical threshold.

Other studies identified predictors that we did not confirm, such as younger age [22] and the occurrence of complications [25]. This discrepancy may reflect differences in how complications were defined and assessed. Early unloading, with Impella implantation within 2 hours of VA-ECLS initiation, was associated with lower mortality [21]. In our cohort, this time interval exceeded 2 hours in both survivors and non-survivors (median 5.33 and 3.58 hours, respectively), and this was not statistically significant, most likely because Impella implantation was usually delayed in our practice, leaving no early-unloading group.

Limitations:

This study has several limitations. It was a single-center retrospective analysis of a small cohort. The resulting number of events limits statistical power and the number of covariates that could be entered into the multivariable model. The exploratory nature of the analyses and the limited sample size made adjustment for multiple testing unfeasible. The identified cutoff values carry a risk of overfitting and require external validation. Furthermore, post-implantation parameters, including serial lactate measurements, may be subject to survivor bias, as they were only available in patients surviving to the respective assessment time. Some variables required to calculate the SAVE score, such as diastolic blood pressure, pulse pressure and peak inspiratory pressure, were not available. Our findings are therefore hypothesis-generating and require confirmation in larger, ideally multicenter, cohorts.

Conclusions

In our experience, the use of ECMELLA in postcardiotomy patients could not prevent death in most patients. However, a higher MELD-XI score before ECMELLA implantation and persistent hyperlactatemia after initiation of support were both associated with adverse outcome. A prolonged aortic cross-clamp time was associated with increased mortality in exploratory threshold analyses, whereas no association was found when the variable was analyzed continuously. These findings suggest that biological markers, including MELD-XI and lactate, could provide complementary prognostic information before and after ECMELLA implantation, whereas the prognostic value of aortic cross-clamp time remains uncertain and should be regarded as exploratory. Given the small sample size and the exploratory nature of this study, these findings should be interpreted with caution and should not be used in isolation for clinical decision-making. Larger prospective multicenter studies are needed to validate these findings and to further define the role of these parameters in risk stratification and patient management.

List of abbreviations

ALT: Alanine aminotransferase

AMI: Acute myocardial infarction

aPTT: Activated partial thromboplastin time

AST: Aspartate aminotransferase

AUC: Area under the curve

AVR: Aortic valve regurgitation

CAD: Coronary artery disease

CI: Confidence interval

CK: Creatine kinase

CK-MB: Creatine kinase myocardial band

CKD: Chronic kidney disease

COPD: Chronic obstructive pulmonary disease

CPB: Cardiopulmonary bypass

CPR: Cardiopulmonary resuscitation

CRP: C-reactive protein

CS: Cardiogenic shock

ECMELLA: VA-ECLS combined with a microaxial pump (Impella), also known as ECpella

ECMO: Extracorporeal membrane oxygenation

eGFR: Estimated glomerular filtration rate

412 EuroSCORE II: European System for Cardiac Operative Risk Evaluation II

413 HR: Hazard ratio

414 ICU: Intensive care unit

415 IMC: Intermediate care

416 INR: International normalized ratio

417 IQR: Interquartile range

418 LV: Left ventricle / left ventricular

419 LVAD: Left ventricular assist device

420 LVEF: Left ventricular ejection fraction

421 MCS: Mechanical circulatory support

422 MELD: Model for End-stage Liver Disease

423 MELD-XI: Model for End-stage Liver Disease excluding INR

424 MELD-Na: Model for End-stage Liver Disease incorporating serum sodium

425 MI: Myocardial infarction

426 MVR: Mitral valve regurgitation

427 MVS: Mitral valve stenosis

428 NYHA: New York Heart Association

429 PCS: Postcardiotomy cardiogenic shock

430 PTT: Partial thromboplastin time

431 ROC: Receiver operating characteristic

SAVE: Survival After Veno-arterial ECMO (score)

tMCS: Temporary mechanical circulatory support

TVR: Tricuspid valve regurgitation

VA-ECLS: Veno-arterial extracorporeal life support

VA-ECMO: Veno-arterial extracorporeal membrane oxygenation

Declarations

Ethics approval and consent to participate

The need for formal ethics approval and informed consent was waived by the Ethics Committee of the Ärztekammer Westfalen-Lippe (ref. no. 2026-710-f-N), as this was a retrospective analysis of fully anonymized, routinely collected data.

Clinical trial number

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

No specific funding was received for this study; only institutional resources were used. Open Access funding was enabled and organized by Projekt DEAL.

Authors' contributions

NS and DMB jointly conceived the study. DMB helped provide data. NS and DMB designed and implemented the analysis with assistance from MB. NS and DMB wrote the manuscript. MB, VM, SL, PLH, SB, PKZ, DB and JTS edited the manuscript and provided conceptual advice. All authors read and approved the final manuscript.

Acknowledgements

We acknowledge the support provided by the Open Access Publication Funds of Ruhr-University Bochum

Additional files

Additional file 1 (.pdf) Complications definition. Detailed definitions of the bleeding, ischemic and neurological complications and of renal replacement therapy assessed during ECMELLA support.

Additional file 2 (.pdf) Strobe checklist. Completed STROBE checklist for cohort studies.

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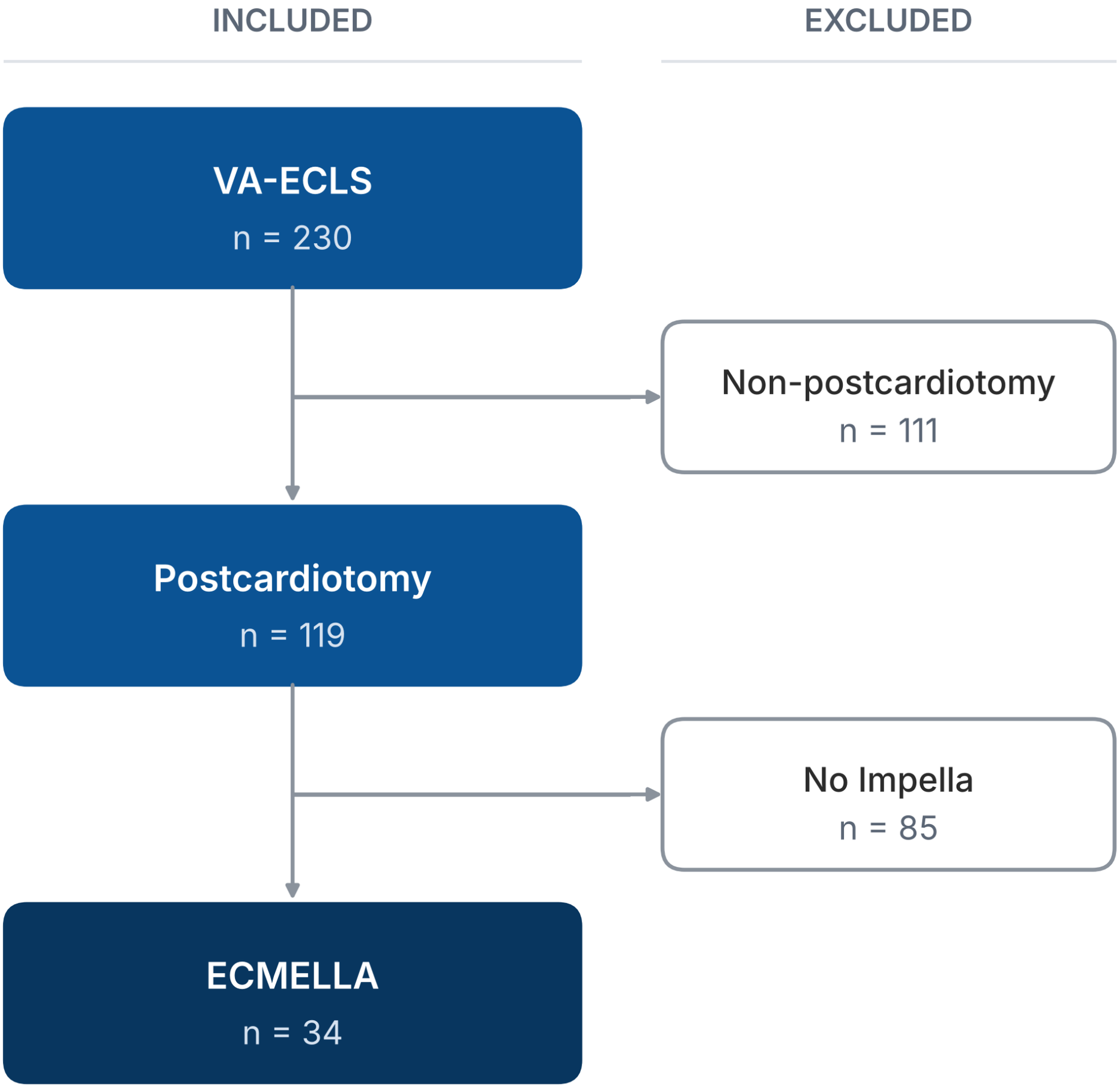
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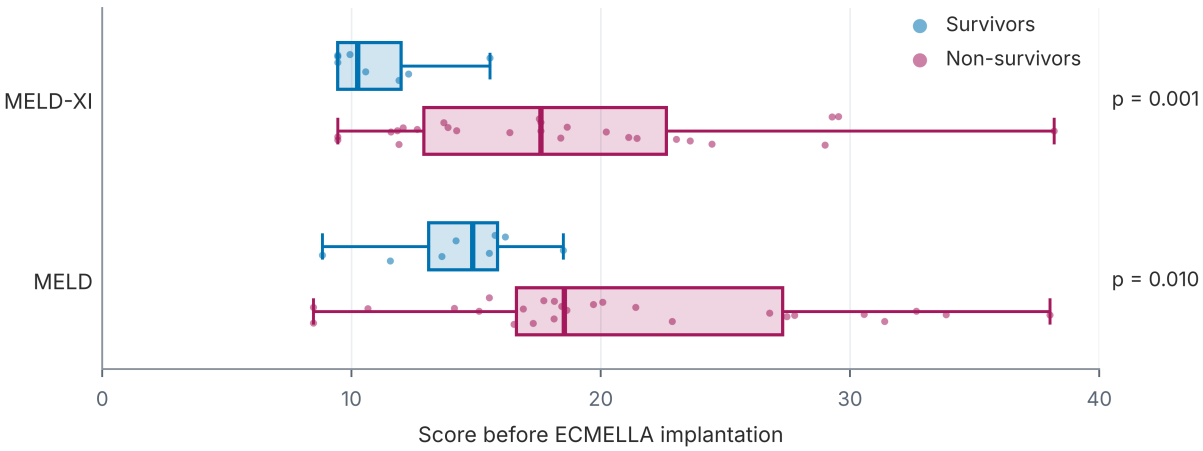
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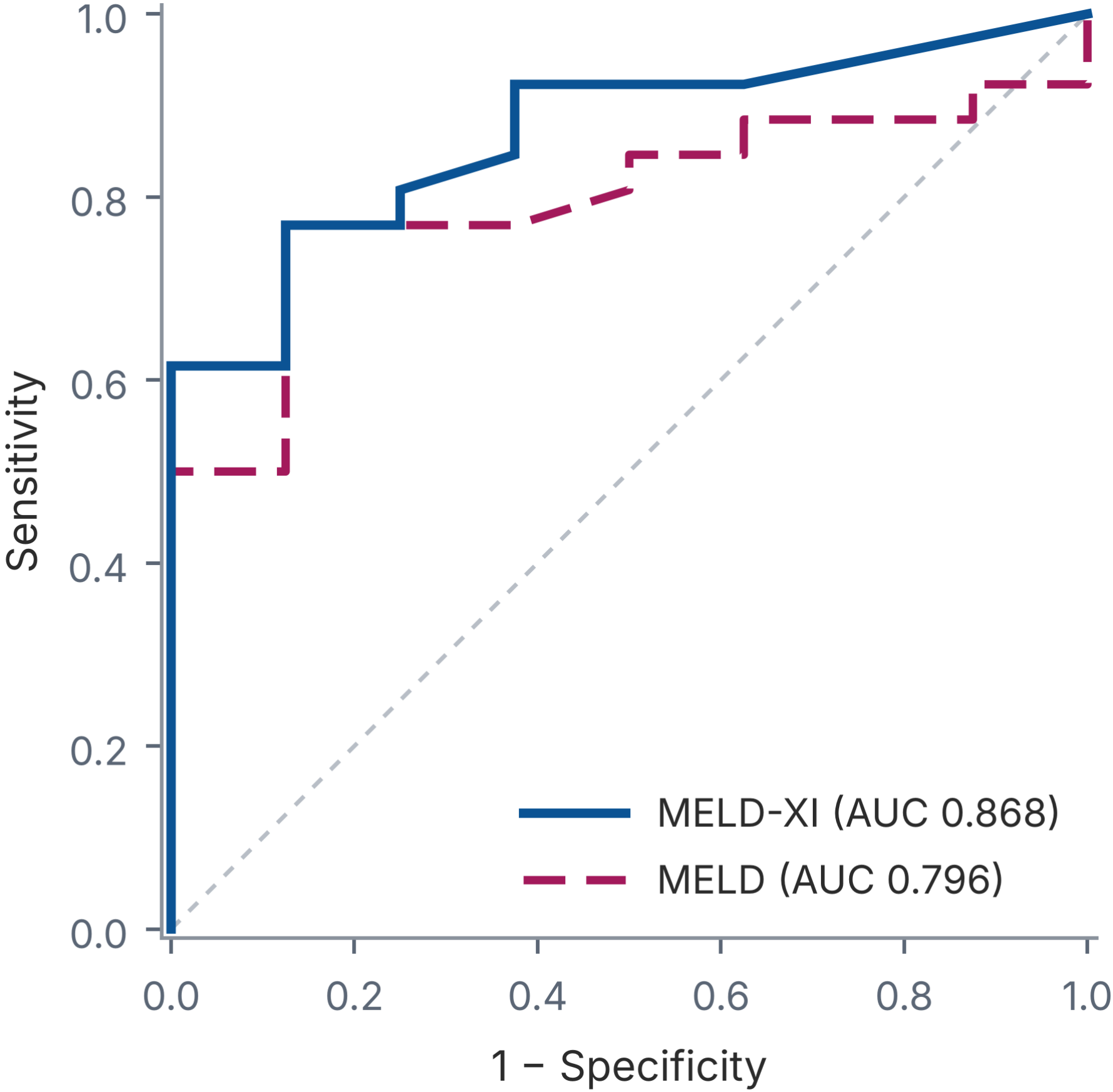
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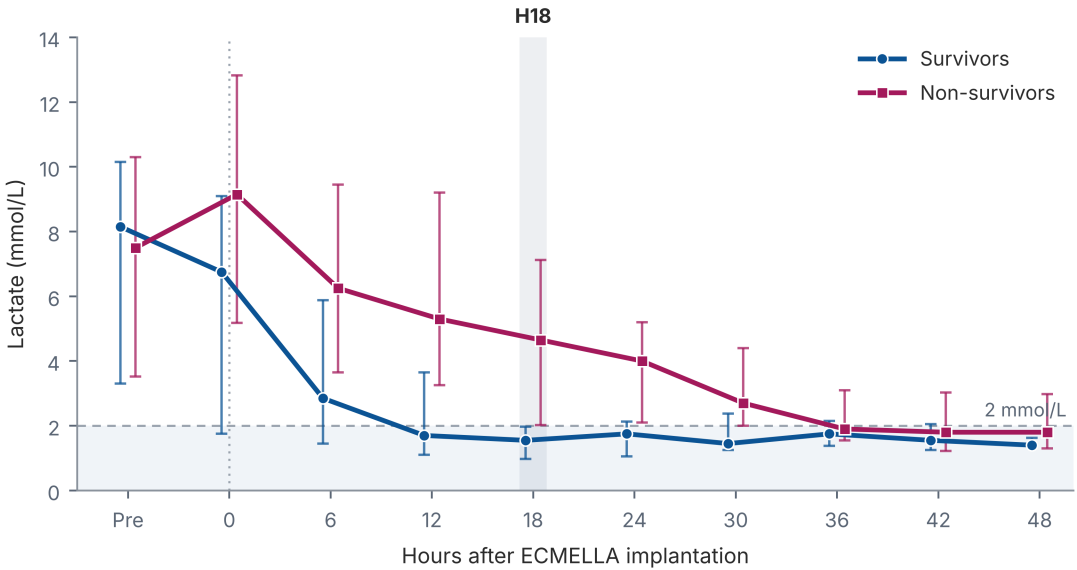
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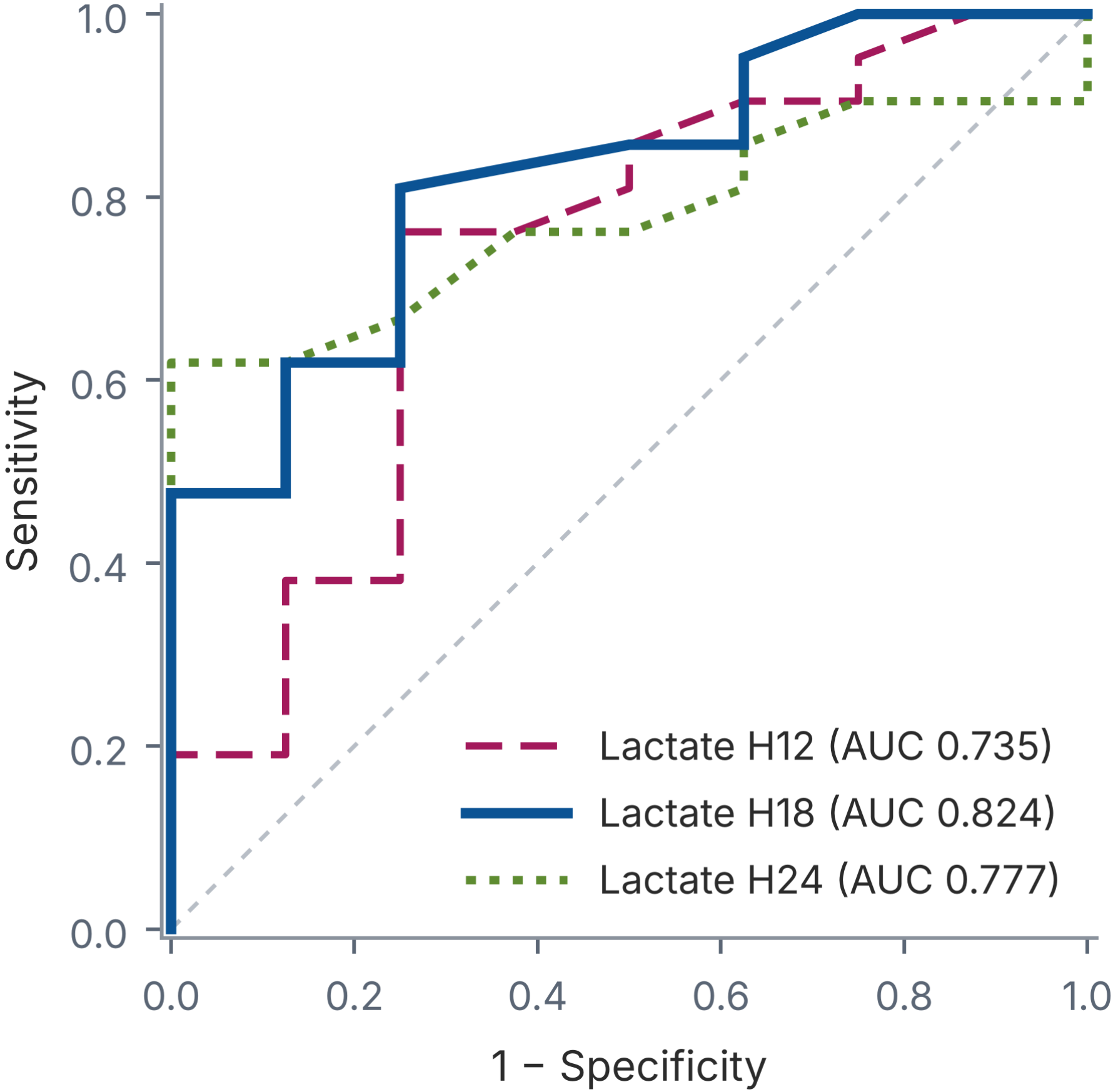

INCLUDED
EXCLUDED
VA-ECLS
n = 230
Non-postcardiotomy
n = 111
Postcardiotomy
n = 119
No Impella
n = 85
ECMELLA
n = 34

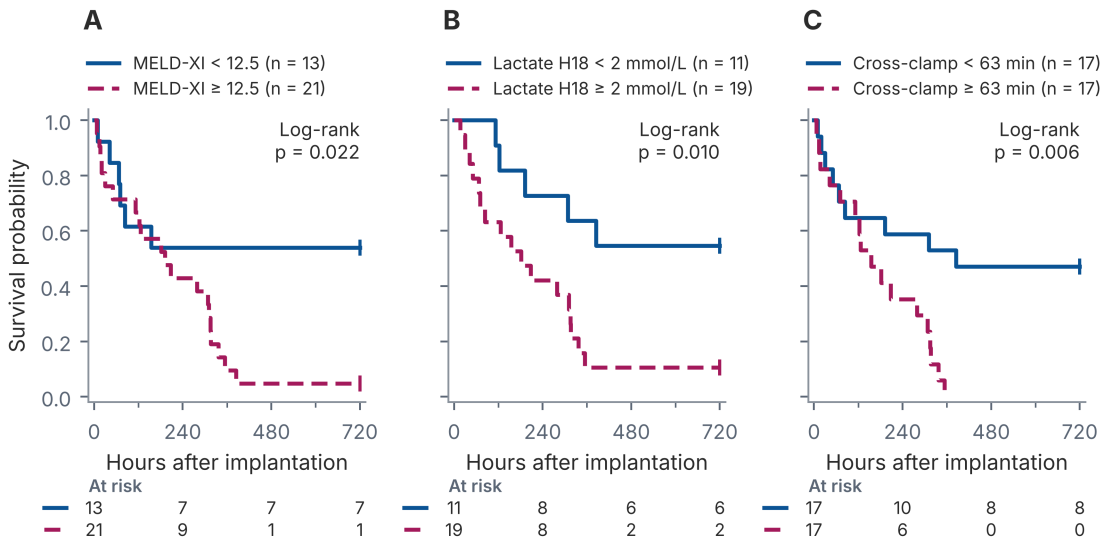

Survivors
Non-survivors
MELD-XI
MELD
p = 0.001
p = 0.010
0
10
20
30
40
Score before ECMELLA implantation


1.0
0.8
0.6
0.4
0.2
0.0
Sensitivity
0.0
0.2
0.4
0.6
0.8
1.0
1 – Specificity
MELD-XI (AUC 0.868)
MELD (AUC 0.796)



n survivors	8	8	8	8	8	8	8	8	8	8
n non-survivors	26	26	26	23	22	21	21	19	18	18


1.0
0.8
0.6
0.4
0.2
0.0
Sensitivity
0.0
0.2
0.4
0.6
0.8
1.0
1 – Specificity
Lactate H12 (AUC 0.735)
Lactate H18 (AUC 0.824)
Lactate H24 (AUC 0.777)


A
MELD-XI < 12.5 (n = 13)
MELD-XI ≥ 12.5 (n = 21)
Log-rank
p = 0.022
Survival probability
1.0
0.8
0.6
0.4
0.2
0.0
0
240
480
720
Hours after implantation
At risk
13 7 7 7
21 9 1 1
B
Lactate H18 < 2 mmol/L (n = 11)
Lactate H18 ≥ 2 mmol/L (n = 19)
Log-rank
p = 0.010
0
240
480
720
Hours after implantation
At risk
11 8 6 6
19 8 2 2
C
Cross-clamp < 63 min (n = 17)
Cross-clamp ≥ 63 min (n = 17)
Log-rank
p = 0.006
0
240
480
720
Hours after implantation
At risk
17 10 8 8
17 6 0 0

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- GraphicalAbstract.png
- Additionalfile1complicationsdefinition.pdf
- Additionalfile2StrobeChecklist.pdf