

Predictive Modeling of Early Mortality After Left Ventricular Assist Device Implantation: A Single-Center Exploratory Analysis

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Abstract

Background:

Early postoperative mortality remains a major clinical challenge in left ventricular assist device implantation. Accurate preoperative identification of high-risk patients could optimize candidate selection and improve perioperative management.

Methods:

From February 2021 to March 2025, 60 patients who underwent LVAD implantation at Zhongshan Hospital, Fudan University were included in the present study. Early mortality was defined as death within 2 months postoperatively, a threshold derived from survival analysis showing a distinct early hazard phase. Preoperative demographic, echocardiographic, hemodynamic, and laboratory variables were evaluated. Predictor selection used least absolute shrinkage and selection operator (LASSO) logistic regression with 10-fold cross-validation, followed by multivariable Firth logistic regression. Internal validation employed bootstrap resampling (1,000 iterations).

Results:

The mean age was 55 ± 10 years, and 50 (83%) patients had dilated cardiomyopathy. Kaplan–Meier analysis indicated an early hazard phase, with all deaths occurring by ~ 1.7 months after implantation. LASSO selected age, MELD-XI, passive cardiac index (PasCI), and mixed venous oxygen saturation (SvO_2) for multivariable modeling. In the final Firth model, lower SvO_2 (odds ratio [OR] 0.92; 95% CI 0.83–1.00; $p = 0.048$) and older age (OR 1.13; 95% CI 1.00–1.35; $p = 0.059$) were associated with higher early mortality. Internal validation yielded an optimism-adjusted AUC of 0.84.

Conclusions:

In this exploratory study, lower preoperative SvO_2 and older age were the principal predictors of early mortality after LVAD implantation. Our internally validated risk assessment model supports preoperative risk prediction and stratification; however, confirmation in larger, multicenter cohorts is warranted before broader adoption. (246/250)

Background

Left ventricular assist devices (LVADs) have become an established therapy for patients with end-stage heart failure (HF) in Western countries. In the early period, LVADs were primarily used as a bridge to transplantation (BTT) to stabilize terminal HF patients while waiting for donor hearts. However, with the persistent shortage of donor organs and the fact that many candidates do not meet transplantation criteria[1], LVAD therapy has gradually evolved from a BTT strategy into a destination therapy (DT) for selected non-transplant candidates, supported by decades of clinical experience demonstrating improved survival and quality of life[2–5].

In China, the prevalence of HF remains high, yet most patients rely predominantly on pharmacologic treatment[6, 7]. The shortage of donor hearts and the high cost of imported devices such as the HeartMate 3 have limited access to durable mechanical support. Over the past decade, several domestically developed LVADs have entered clinical trials, such as the CH-VAD, showing encouraging short-term outcomes[8].

Despite continuous advancements in LVAD technology, surgical techniques, and perioperative management, early mortality after implantation remains a major challenge. Data from the EUROMACS registry indicate that approximately one in five patients die within 90 days, most often from multiorgan failure or sepsis[9]. Subsequent studies have further identified right ventricular failure and postoperative infection as key contributors to early mortality[10]. This issue is particularly relevant in China, where patients often present with more advanced disease and multiple comorbidities, and national experience with durable LVADs is still accumulating.

Although established risk models, such as the HeartMate Risk Score and EUROMACS, provide valuable reference frameworks, these models were primarily derived from Western populations[9, 11]. Significant demographic and clinical differences exist between Western and Asian patients, and the current models focus mainly on long-term or overall mortality rather than early outcomes[12]. Evidences specific to Chinese LVAD recipients remain scarce. Therefore, we conducted an exploratory, data-driven study to identify preoperative predictors of early mortality after LVAD implantation and to develop an internally validated preliminary risk model tailored to this population.

Methods

Study Design and Population

This retrospective, single-center exploratory study aimed to develop and internally validate a predictive model for early mortality after durable LVAD implantation. Sixty consecutive adult patients who underwent LVAD implantation between February 2021 and March 2025 at Zhongshan Hospital, Fudan University, were included. Procedures were performed as destination therapy or BTT according to institutional criteria. Patients with reimplantation, concomitant transplantation, emergency ECMO support, or incomplete records were excluded. The overall workflow of variable selection and model validation is illustrated in Fig. 1. The study complied with the Declaration of Helsinki and was approved by the institutional review board (B2021-823); informed consent was waived owing to the retrospective design.

Outcome Definition

The primary outcome was early postoperative mortality, defined as all-cause death within two months after surgery, based on the early hazard phase observed on survival analysis. Patients alive beyond this period were classified as survivors. Survival status was verified through inpatient, outpatient, and follow-up records up to 12 months post-implantation.

Data Collection and Variables

Preoperative demographic, echocardiographic, catheter-derived hemodynamic, and laboratory variables were extracted from electronic medical records. Variables included patient characteristics, comorbidities, cardiac function indices, and right-heart catheterization measures. Composite indices such as the MELD-XI score and passive cardiac index (PasCI) were used to reflect hepatic–renal and hemodynamic function, respectively. Detailed variable definitions, formulas, and handling of missing data are provided in Supplementary Table S1.

Statistical Analysis

Continuous variables are presented as mean $\pm$ SD or median (IQR) and categorical variables as counts (%). Kaplan–Meier analysis was used to identify the early mortality cluster. Predictor screening was performed using least absolute shrinkage and selection operator (LASSO) logistic regression, followed by multivariable Firth penalized logistic regression for model construction. Multivariable modeling used a complete-case cohort; calibration and discrimination were assessed via calibration plots, the Brier score, and ROC analysis, and internal validation used 1,000 bootstrap resamples to obtain optimism-corrected performance. Detailed modeling steps, parameter tuning, and R implementation are described in the Supplementary Methods.

Results

Baseline Demographic, Echocardiographic and Hemodynamic Characteristics

The study included 60 LVAD recipients with a mean age of 55.2 ± 10.4 years; 86.7% were male. Most patients had dilated cardiomyopathy (83.3%), with ischemic etiology in 16.7%. The mean LVEF was $26.3 \pm 4.9\%$, indicating severe LV dysfunction. Moderate or greater mitral and tricuspid regurgitation were present in 50.0% and 20.0% of patients, respectively. Mean total bilirubin and creatinine were 17.8 ± 8.5 $\mu\text{mol/L}$ and 114.2 ± 39.2 $\mu\text{mol/L}$, corresponding to a MELD-XI score of 13.3 ± 3.2 . Invasive hemodynamic assessment showed elevated filling pressures (RAP 8.2 ± 5.8 mmHg; PCWP 19.6 ± 10.9 mmHg) and reduced perfusion (PasCI 0.54 ± 0.41 L/min/m²; SvO₂ $64 \pm 12\%$), consistent with advanced heart-failure physiology. Detailed baseline characteristics are summarized in Table 1. Of the 60 patients, 49 with complete preoperative data with 6 early deaths comprised the modeling cohort (see Table 3 and Table 4).

Table 1
Baseline Clinical and Hemodynamic Characteristics (n = 60)

Category	Variable	Value (Mean $\pm$ SD, n (%))
Demographics and Etiology	Age (years)	55.2 $\pm$ 10.4
	Gender (male)	52 (86.7%)
	BMI (kg/m ²)	24.5 $\pm$ 5.4
	Dilated cardiomyopathy	50 (83.3%)
	Ischemic cardiomyopathy	10 (16.7%)
	Diabetes mellitus	12 (20%)
	Hypertension	8 (13.3%)
	Renal failure	6 (10%)
Echocardiographic Findings	LVEF (%)	26.3 $\pm$ 4.9
	TAPSE (mm)	15.6 $\pm$ 2.7
	AR ($\geq$ moderate)	2 (3.3%)
	MR ($\geq$ moderate)	30 (50%)
	TR ($\geq$ moderate)	12 (20%)
Laboratory and Organ Function	Total bilirubin (μ mol/L)	17.8 $\pm$ 8.5
	Creatinine (μ mol/L)	114.2 $\pm$ 39.2
	ALT (U/L)	48.6 $\pm$ 57.8
	AST (U/L)	35.2 $\pm$ 34.2
	LDH (U/L)	241.2 $\pm$ 102.5
	MELD-XI score	13.3 $\pm$ 3.2
Pulmonary Artery Catheter–Derived Hemodynamics	RAP (mmHg)	8.22 $\pm$ 5.79
	mPAP (mmHg)	29.96 $\pm$ 14.4
	PCWP (mmHg)	19.63 $\pm$ 10.9
	PasCI (L/min/m ²)	0.54 $\pm$ 0.41
Continuous variables are presented as mean $\pm$ SD; categorical variables as n (%).		
Abbreviations: See list of abbreviations.		

Category	Variable	Value (Mean $\pm$ SD, n (%))
	SvO ₂ (%)	64.22 $\pm$ 12.37
	PVR (dyn·s·cm ⁻⁵)	271.04 $\pm$ 175.86
	PAPI	4.12 $\pm$ 2.57
Continuous variables are presented as mean $\pm$ SD; categorical variables as n (%).		
Abbreviations: See list of abbreviations.		

Table 3
Multivariable Firth Logistic Regression for Early Mortality ($\leq$ 2 Months)
After LVAD Implantation

Variable	OR (95% CI)	p value
Age (per year)	1.13 (1.00–1.35)	0.059
MELD-XI (per point)	0.93 (0.64–1.30)	0.680
Passive Cardiac Index (per L/min/m ²)	4.72 (0.24–60.50)	0.269
Mixed venous O ₂ saturation (per %)	0.92 (0.83–1.00)	0.048
Model sample: n = 49; events = 6.		
Abbreviations: See list of abbreviations.		

Table 4
Internal Validation of the Calibrated Risk Equation for Early Mortality After LVAD Implantation

Outcome	Sample size (n)	Mean predicted risk	SD	Min	Max
Survivor	43	0.101	0.102	0.003	0.551
Death	6	0.273	0.197	0.115	0.560
Internal validation was performed using bootstrap resampling (1,000 iterations). The mean predicted risk was higher among deaths (0.27 $\pm$ 0.20) compared with survivors (0.10 $\pm$ 0.10), indicating good model discrimination.					

Early Postoperative Survival Pattern

Kaplan–Meier analysis demonstrated that all deaths occurred within approximately 1.7 months after LVAD implantation, indicating a distinct early postoperative hazard phase (Fig. 2). Beyond this period, overall survival remained stable up to 12 months of follow-up. The estimated 1-month survival was 90.0%, and survival thereafter remained approximately unchanged once the early hazard phase had passed. Based on this temporal pattern, subsequent analyses focused on identifying preoperative predictors of early mortality.

Feature Selection and Model Development

Univariable Firth logistic regression was first performed to examine the relationship between preoperative variables and early mortality (Supplementary Table S2). None of the variables reached statistical significance, although mixed venous oxygen saturation (SvO_2) showed a near-significant association.

To account for potential multicollinearity and small sample size, all candidate variables were subsequently entered into a LASSO logistic regression with ten-fold cross-validation. The optimal penalty parameter ($\lambda_{\min} = 0.00407$) was selected at the minimum binomial deviance (Fig. 3A). Variables retained in the $\lambda_{\min}$ model included Age, MELD–XI, Passive Cardiac Index (PasCI), and mixed venous oxygen saturation (SvO_2), along with several hemodynamic and instability parameters (Table 2). At this feature-selection stage, cross-validated discrimination was high ($\text{AUC} = 0.992$; Fig. 3B); threshold-dependent metrics from this stage are reported with Fig. 3.

Table 2
LASSO Feature Selection and Cross-Validated Model Performance

Variable	Coefficient
Selected predictors at λ .min	
Intercept	4.4736
Age	0.2995
MELD-XI	-0.4142
Passive Cardiac Index	7.2252
Mixed venous O ₂ saturation	-0.2853
PVR	-0.0112
PAPI	0.2999
MAP	-0.0432
PAPI < 1.5	-7.7532
Pre-op instability	-1.6375
—	
CV folds	10
Lambda (min)	0.00407
Lambda (1se)	0.0198
AUC (λ .min)	0.992
Model n / events	49 / 6
Coefficients are shown for the model at λ min (0.00407) determined by 10-fold cross-validation. Model discrimination (AUC = 0.992) was internally validated.	
Abbreviations: See list of abbreviations.	

Guided by the LASSO selection, we fit the multivariable Firth logistic model in the complete-case cohort (n = 49; 6 deaths within ≤ 2 months). In the final model, lower SvO₂ (OR 0.92, 95% CI 0.83–1.00; p = 0.048) and older age (OR 1.13, 95% CI 1.00–1.35; p = 0.059) were associated with higher odds of early mortality, whereas MELD–XI and PasCI were not statistically significant (Table 3).

Model Calibration, Validation and Performance

The final Firth model included age, MELD–XI, PasCI, and SvO₂. The calibrated equation was:

$\text{logit}(p) = -3.890 + 0.122 \times \text{Age} - 0.073 \times \text{MELD--XI} + 1.552 \times \text{PasCI} - 0.083 \times \text{SvO}_2$.
The predicted probability was calculated as

$p = \frac{e^{\text{logit}(p)}}{1 + e^{\text{logit}(p)}}$. Internal validation using bootstrap resampling (1,000 iterations) demonstrated good model performance. The mean predicted risk was 0.27 ± 0.20 among patients who died ($n = 6$) and 0.10 ± 0.10 among survivors ($n = 43$), corresponding to an optimism-adjusted AUC of 0.84 (Table 4, Supplementary Figure S1). The ROC curve confirmed adequate discrimination between survivors and early deaths (≤ 2 months). Given the limited number of events, this internally validated model should be regarded as a hypothesis-generating tool, providing a simple and interpretable framework for estimating early mortality risk in LVAD candidates.

Discussion

In this exploratory single-center study, lower preoperative SvO_2 and older age emerged as the main predictors of early postoperative mortality after LVAD implantation. The internally validated model demonstrated good discrimination, suggesting that even within a relatively small cohort, key hemodynamic and clinical parameters may help identify high-risk patients.

SvO_2 as a global marker of oxygen balance plays a pivotal role in understanding early postoperative outcomes in LVAD recipients[13]. Physiologically, SvO_2 reflects the proportion of oxygenated hemoglobin in the blood returning to the right side of the heart after systemic circulation, thereby representing the balance between oxygen delivery and consumption[14]. A decrease in SvO_2 indicates insufficient oxygen supply or increased oxygen demand, whereas an elevated SvO_2 may occur when oxygen delivery is adequate, but tissues are unable to extract oxygen effectively. In patients supported with LVADs, SvO_2 must be interpreted in conjunction with other hemodynamic and clinical parameters, as mechanical support can mask underlying circulatory abnormalities. For example, SvO_2 can remain abnormally high in cases of impaired oxygen extraction due to mitochondrial dysfunction or systemic infection. Nevertheless, SvO_2 remains a valuable clinical marker of global tissue perfusion, and our findings are generally consistent with previous reports highlighting its prognostic significance in LVAD populations.

Age, another major determinant identified in our model, reflects the inherent vulnerability and reduced physiological reserve of the elderly population. Numerous studies have consistently identified older age as an independent predictor of mortality after LVAD implantation[15–18]. The inclusion of age in our model aligns with these prior findings, reinforcing its role as a robust and reproducible risk factor for adverse outcomes following mechanical circulatory support. These observations collectively suggest that even simple demographic factors can provide valuable prognostic information when combined with physiologic indicators such as SvO_2 .

In contrast, the predictive performance of the PasCI and MELD-XI score did not reach statistical significance in our analysis. Both parameters, however, remain physiologically relevant. PasCI provides a more stable hemodynamic assessment compared with conventional cardiac index and has been linked to postoperative right heart failure after LVAD implantation[19]. The MELD-XI score reflects combined

hepatic and renal dysfunction, both of which are well known to influence surgical and post-implant outcomes in LVAD patients[20, 21]. Prior studies in Western LVAD populations have shown a relationship between elevated MELD-XI (or related MELD scores) and increased morbidity and mortality[22], although some cohorts did not find a significant association (likely due to small sample sizes or low event rates) [23]. We postulate that the absence of significance in our cohort may similarly reflect a limited number of early mortality events rather than a true lack of predictive value. Given the paucity of data in Asian LVAD populations, larger multicenter studies are warranted to establish the predictive utility of MELD-XI in this demographic.

Despite the limited cohort size, this study offers several unique contributions. First, it represents one of the early analyses of Chinese patients implanted with domestically manufactured LVADs, a field that remains in its early stages of development. Data on Asian populations are sparse, and demographic as well as clinical characteristics differ markedly from those reported in Western registries such as INTERMACS[24] and EUROMACS[9]. Second, our study specifically focused on the early postoperative period, revealing that most deaths occurred within the first two months after implantation, whereas patients surviving beyond this phase achieved stable mid-term outcomes. This pattern underscores the critical importance of perioperative management in determining early survival. Third, despite a limited number of events, we applied a rigorous methodological approach using LASSO regularization followed by Firth logistic regression, improving model stability and interpretability[25]. This analytical framework provides meaningful preliminary evidence for risk assessment in an evolving field with limited clinical experience.

Nevertheless, several limitations should be acknowledged. The retrospective, single-center design and modest sample size restrict the generalizability of our findings. Although internal validation by bootstrap resampling demonstrated reasonable performance, external validation in larger, multicenter cohorts will be essential to confirm the robustness and clinical applicability of our model.

In conclusion, despite its exploratory nature, this study offers preliminary evidence on preoperative risk stratification in Chinese LVAD candidates and may guide perioperative strategies to lower early mortality, pending confirmation in larger multicenter studies.

Abbreviations

ALT	
alanine aminotransferase	
AR	
aortic regurgitation	
AST	
aspartate aminotransferase	
BTT	
bridge to transplantation	
CI	

confidence interval (in regression models); cardiac index (in hemodynamic formula)

CV

cross-validation

CVP

central venous pressure

LASSO

least absolute shrinkage and selection operator

LDH

lactate dehydrogenase

LVAD

left ventricular assist device

MAP

mean arterial pressure

MELD

Model for End-Stage Liver Disease

mPAP

mean pulmonary artery pressure

MR

mitral regurgitation

OR

odds ratio

PAPI

pulmonary artery pulsatility index

PasCI

passive cardiac index

PCWP

pulmonary capillary wedge pressure

PVR

pulmonary vascular resistance

RAP

right atrial pressure

SvO₂

mixed venous oxygen saturation

TR

tricuspid regurgitation

Declarations

These authors contributed equally to the work.

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Author contributions: Shuyang Lu drafted the manuscript; Junjiang Liu and Dingqian Liu collected the data; Guangwei Hao and Guowei Tu provided perioperative patient care; Kefang Guo and Lili Dong performed intraoperative catheterization and echocardiographic examinations; Ran Huo and Aurora Lee conducted statistical analysis and language editing; Xiaoning Sun and Chunsheng Wang performed the surgeries, conceived the study, and critically revised the manuscript.

Conflicts of interest: The authors declare no competing interests.

Ethics approval: The study design and a waiver of informed consent were approved by Zhongshan Hospital Fudan University Institutional Review Board (B2021-823, approved August 2021).

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Clinical Trial Number: Not applicable.

Human Ethics and Consent to Participate Declarations: Not applicable.

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Figures

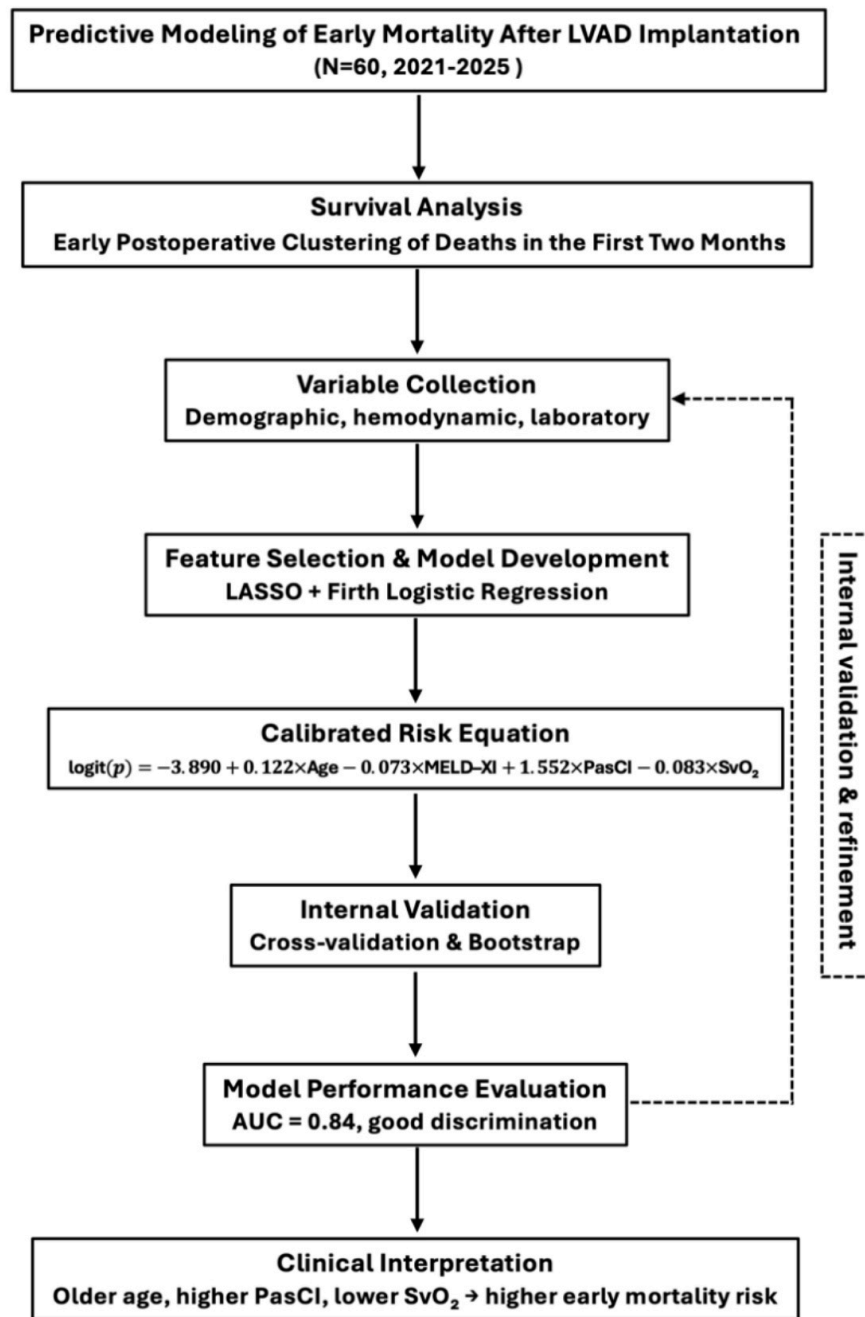


Figure 1

Flowchart of model development and internal validation for early mortality after LVAD implantation.

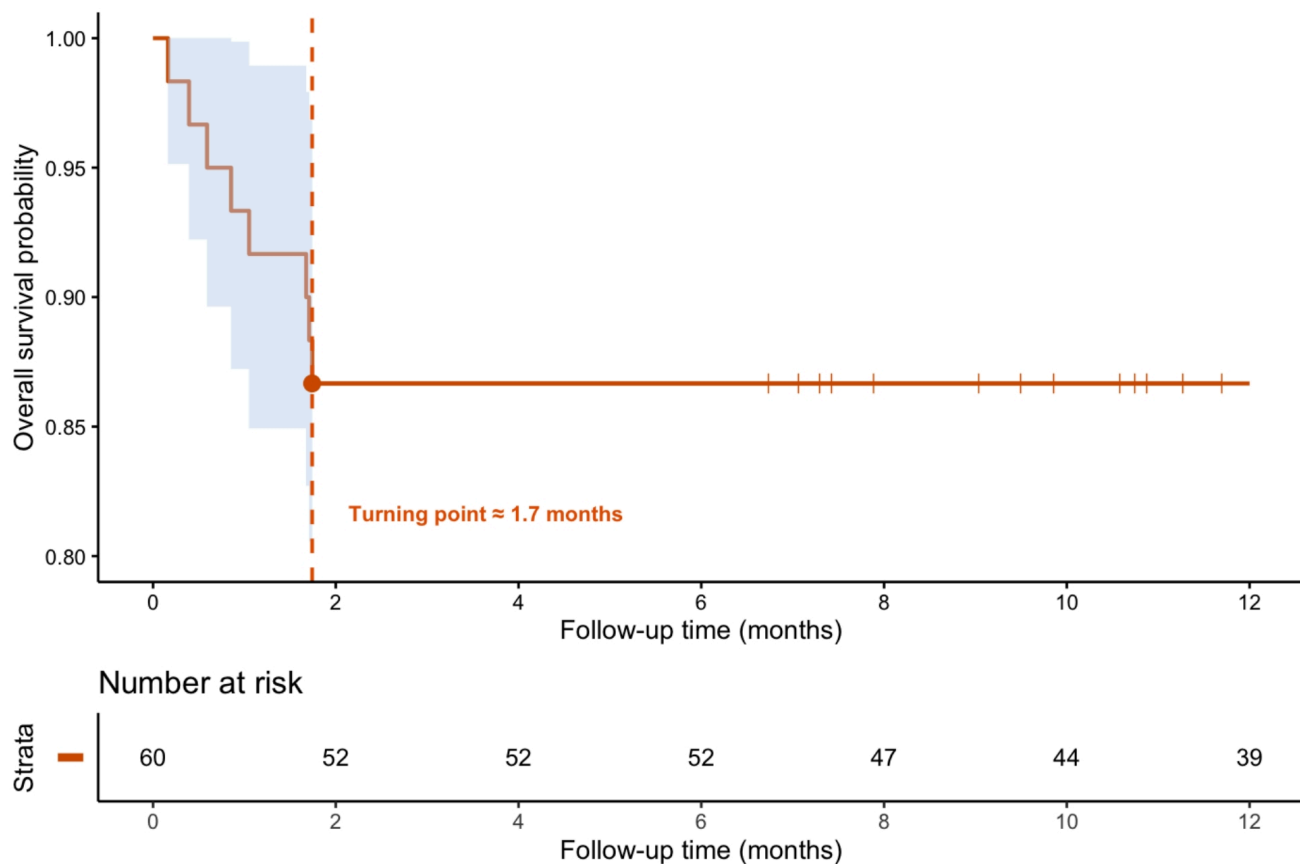


Figure 2

Kaplan–Meier survival curve of the study cohort after LVAD implantation. Survival analysis demonstrated clustering of deaths within the first two postoperative months (turning point ≈ 1.7 months), after which the survival curve plateaued.

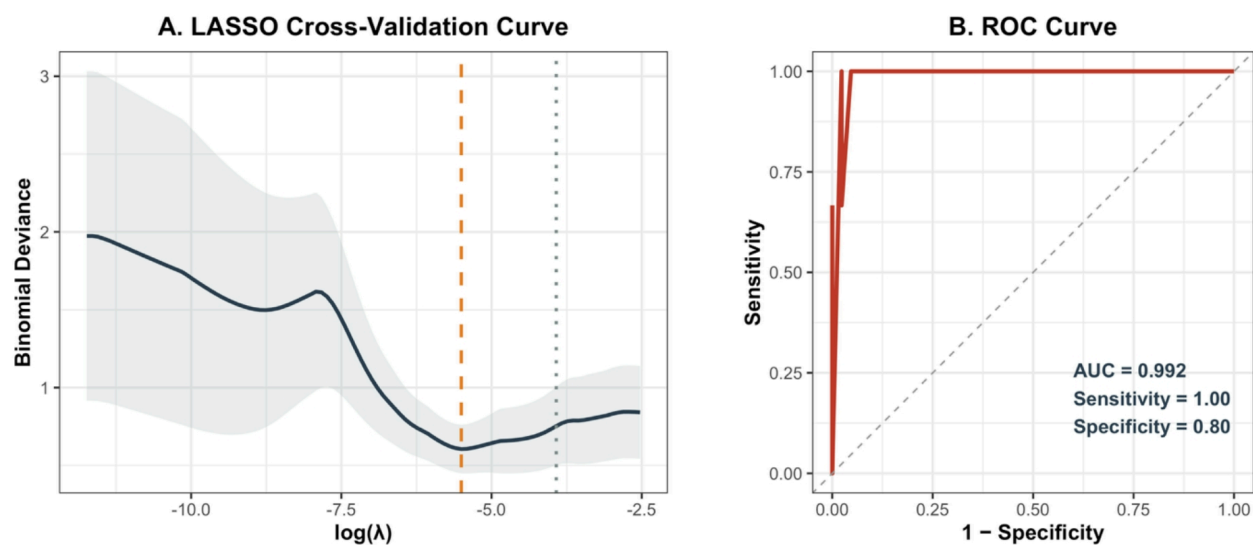


Figure 3

Feature selection and performance of the predictive model for early post-LVAD mortality. (A) Ten-fold cross-validation identifying the optimal penalty parameter ($\lambda_{\min} = 0.00407$). (B) Receiver operating characteristic (ROC) curve demonstrating excellent model discrimination (AUC = 0.99, sensitivity = 1.00, specificity = 0.80).

Supplementary Files

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

- [Supplementarydata.docx](#)