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Research Article

A Risk Prediction Model for Adverse Events after Surgical Valve Replacement

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Background. Although several risk-predictive models for patients undergoing surgical valve replacement (SVR) have been published, reports on composite endpoints of adverse events in these patients are limited. This study aimed to establish a novel, easy-to-use prognostic prediction model of composite endpoints in patients following SVR. *Methods*. According to the inclusion criteria, patients with successful SVR were enrolled. Adverse events, including heart failure hospitalization, stroke, major bleeding, uncontrolled infection, secondary surgery, postoperative arrhythmia, and all-cause mortality during follow-up, were tracked. All datasets were randomly divided into the derivation and validation cohorts at a ratio of 7 to 3. Logistic regression analysis was used to screen for independent predictors and construct a nomogram for adverse events. We further presented a calibration curve and decision curve analysis for evaluating prediction models. *Results*. According to the multivariate logistic regression analyses, three variables were selected for the final predictive model, including platelet-to-lymphocyte ratio, diabetes mellitus, and albumin. A nomogram was then constructed to present the results. The C-index of the model was 0.73 (95% confidence interval: 0.65–0.81) for the derivation cohort and 0.75 (95% confidence interval: 0.64–0.86) for the validation cohort. The calibration curve demonstrated that the results of the nomogram agreed with actual observations (Brier score = 0.09). *Conclusions*. We developed an effective nomogram to predict the occurrence of composite adverse events in patients following SVR. This model could be used to evaluate the mid-term risks of adverse events as well as provide clinicians and patients with a basis for decision-making.

1. Introduction

Cardiovascular diseases have become one of the leading causes of death worldwide, resulting in an increased awareness of the importance of preventing cardiovascular risk factors. Although most cardiovascular diseases are caused by coronary pathology, the incidence of valvular heart disease (VHD) is increasing [1]. It is estimated that moderate or severe VHD occurs in 2.5% of the adult population in the United States [2], while in Sweden, there are approximately six new cases per 10,000 people [3]. In patients with irreversible cardiac dysfunction, despite optimal medical treatment, surgical valve replacement (SVR) is an efficient therapy that reduces mortality and improves outcomes [4, 5]. However, in clinical practice, outcomes in some patients undergoing surgery remain poor. Several related prognostic models of cardiac surgery have been established [6, 7]. According to a study including 4008 patients who underwent aortic valve replacement, 2.4% of them died in the hospital [8]. There is still a lack of predictive models for other adverse events that also have great impacts on the postoperative prognosis and long-term survival of patients. Therefore, we summarized these adverse events in a unified manner to establish a composite endpoint prediction model for clinical practice.

2. Methods

2.1. Study Cohort. In this single-center, retrospective analysis, patients who successfully underwent SVR surgery at the First Affiliated Hospital of Wenzhou Medical University between January 2020 and December 2021 were included.

To test the performance of the models, we randomly divided patients into two groups at a ratio of 7 to 3. The inclusion criteria were as follows: (1) patients with successful SVR in the surgical room, (2) patients with comprehensive follow-up data, and (3) patients aged ≥18 years.

2.2. Data Collection. Baseline characteristics including age, sex, smoking and drinking status, body mass index, concomitant disease, and blood pressure on admission, as well as laboratory blood indicators, including complete blood cell count and liver and kidney function, were collected. The red blood cell distribution width- (RDW-) to-albumin ratio (RAR), RDW-to-platelet ratio (RPR), hemoglobin-to-RDW ratio (HRR), and platelet-to-lymphocyte ratio (PLR) were calculated, and patients were divided into the high and low groups according to the cut-off value using the receiver operating characteristic (ROC) curve. Nutritional status was evaluated using the prognostic nutritional index (PNI), which is calculated as follows: PNI = serum albumin (g/L) + 0.005 × total lymphocyte count (10^9/L) [9]. Days of postoperative cardiac care unit (CCU) stays were also recorded. Moreover, echocardiographic parameters, such as left ventricular end-diastolic diameter, left atrial diameter (LAD), and LV ejection fraction, as well as the 12-lead electrocardiogram (ECG), were also documented.

2.3. Definition of Adverse Events. Adverse events, including unplanned heart failure hospitalization (HFH), stroke, major bleeding, uncontrolled infection, second cardiac surgery, postoperative arrhythmia, and all-cause mortality, were recorded. HFH was diagnosed as new onset or worsening HF that could not be controlled with medications and required intravenous diuretics. Stroke was a transient ischemic attack or cerebrovascular accident, in which the blood flow to the brain was blocked. Major bleeding included patients who required hospitalization, surgical intervention, and blood transfusion, as well as those experiencing hemoglobin reduction ≥2 g/dL, with bleeding involving critical areas, or recurrent bleeding that impaired the ability to participate in normal activities. Uncontrolled infections were those necessitating the use of antibiotics regardless of the infection site. Secondary heart surgery was defined as a second SVR following the initial procedure. Postoperative arrhythmia referred to the new onset of arrhythmia in a postoperative setting. If patients had more than one adverse event during the follow-up, only the first occurrence was recorded. We tracked patients for adverse events through hospital electronic medical record systems and telephone follow-up until June 2022.

2.4. Statistical Analysis. The normality of continuous variables was analyzed using the skewness-kurtosis normality test. All normally distributed continuous variables were presented as mean ± standard deviation, whereas non-normally distributed continuous variables were expressed as median with interquartile range. Categorical variables were expressed as numbers and percentages. The independent-samples *t*-test was used to compare the differences in continuous variables (if normal distribution); otherwise, the Mann–Whitney *U* test was performed (if non-normal distribution). We used the chi-square test or Fisher exact test to compare the differences between categorical variables, as appropriate. Univariate logistic regression was used to quantify the association between candidate predictors and adverse events in the training set. Variables with $P < 0.1$ were included in the multivariate logistic regression analysis for correction and construction of a predictive model. A likelihood ratio test with backward step-down selection was applied to the multivariate logistic regression model. Variance inflation factors with an alert threshold value of 2.5 were used to assess collinearity between candidate variables. In the backward stepwise selection of multivariate logistic regression analyses, the variables that were more frequently included in the final model were predictors. Model discrimination was quantified using Harrell's c-statistic and area under the ROC curve (AUC), and 1,000 bootstrap resamplings were used for unbiased evaluation of the nomogram. Calibration curves and decision curves analysis (DCA) curves were plotted to describe the consistency between the nomogram-predicted probability and actual adverse events in the training and validation sets, respectively. The overall performance of the prediction model was assessed using an integrated Brier score. Statistical analyses were performed using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, United States) and R version 4.1.3 (The R Project for Statistical Computing, Vienna, Austria). The "pROC" package was used to plot ROC curves. The "rms" package was used for nomogram construction and calibration. The "rmda" package was used to plot the DCA curve. Statistical tests were two-sided, and statistical significance was set at $P < 0.05$.

3. Results

3.1. Characteristics of the Study Cohort. A total of 458 patients (53% men) were enrolled in this study (Figure 1). Table 1 presents the basic clinical characteristics and biochemical and echocardiographic parameters on admission of the patients who were divided into two groups based on whether they had an adverse event. The average age of the final population was 60 ± 13 years and the median follow-up was 14.4 (8.2–20.9) months. The incidence of composite endpoints was 13% (death in 1%, stroke in 1%, heart failure in 2%, major bleeding in 2%, uncontrolled infection in 2%, second operation in 1%, and postoperative arrhythmia in 4%). The cut-off values of RAR, RPR, HRR, and PLR were 0.386, 0.066, 4.23, and 88.49, respectively. The occurrence of complications was tracked during the follow-up, as seen in Table 2.

3.2. Development and Validation of the Risk Prediction Model. Using random numbers generated by a computer, the majority (70%) of the patients was randomly assigned to the training cohort ($n = 320$) and the remaining 30% were assigned to the validation cohort. There were no significant

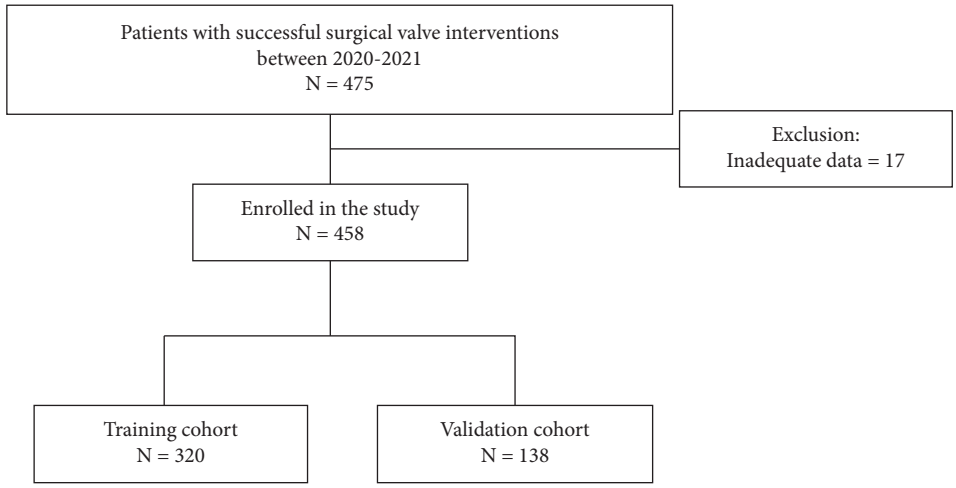

Figure 1: Study flowchart. SVR, surgical valve replacement.

differences in characteristics between the two cohorts (Supplemental Table 1). Nine variables (PNI, RAR, RPR, HRR, PLR, hemoglobin, RDW, albumin, and serum creatinine) were included in the univariate analysis, and three variables (PLR, hemoglobin, and albumin) were retained after multivariable analysis (odds ratio (OR) and 95% confidence interval (CI): 3.055 and 1.363–6.845, $P = 0.007$; 2.296 and 1.163–7.363, $P = 0.023$; 0.873 and 0.803–0.950, $P = 0.002$, respectively, seen in Table 3). The nomogram is shown in Figure 2. In addition, the variables in the multivariate analysis were not highly collinear in the collinearity diagnosis.

The AUC of the prediction model is shown in Figure 3. In the training and test cohorts, the calculated c-index values for model discrimination were 0.73 (95% CI: 0.65–0.81) for the derivation cohort and 0.75 (95% CI: 0.64–0.86), respectively. The discrimination ability of the model was moderate. The calibration chart showed that the occurrence of endpoint events was in good agreement with actual observations (Figure 4). On DCA, the included variables showed improvement of the clinical net-benefit of models (Figure 5).

4. Discussion

Herein, we used simple parameters based on clinical conditions and laboratory indicators to develop a new prediction model to assess the risk of adverse events in patients undergoing SVR. In our study, the c-index values of the derivation and validation cohorts were high, indicating moderate levels of predictive ability. The calibration curve exhibited excellent consistency.

Although SVR is an efficient procedure for patients with irreversible heart failure, a large number of patients may experience different complications [5]. There are many scoring systems for predicting adverse events in patients undergoing cardiac valvular surgery, which estimates disease severity, and guiding therapy decisions. The Acute Physiology and Chronic Health Evaluation (APACHE) [10], Simplified Acute Physiology Score [11], Sequential Organ Failure Assessment (SOFA) [12], and Cardiac Surgery Score (CASUS) [13] are widely used in cardiac surgery. However, the majority of scoring systems are not designed for patients undergoing cardiac surgery patients. Dynamic or periodic model refitting has been reported to be another efficient method for predicting clinical outcomes in these patients. Hickey et al. summarized dynamic models for predicting in-hospital mortality [14]. Although these dynamic models have better prediction accuracy, increased complexity and difficulty in model fitting and summarizing model performance limit their application in clinical practice. Recently, many studies have developed models for predicting post-operative atrial fibrillation models in patients after cardiac valvular surgery [15, 16]. The clinical use of the CHADS2 and CHA2DS2-VASc scoring systems for predicting AF following cardiac surgery has been reported in previous studies and has demonstrated a well-validated predictive value. However, there are limited data on the composite endpoints of the prediction model in this population, despite using simple clinical data [17].

A long-term observational study found that a history of DM was associated with dramatically increased risks of death from all causes [18], which may be explained by more severe abnormalities in the lipid and lipoprotein abnormalities, particularly elevated levels of triglycerides and reduced levels of high-density lipoprotein. PLR integrates two simple indicators that can be easily calculated from a complete blood count. Platelets can interact with a variety of cell types, including endothelial cells, dendritic cells, T lymphocytes, neutrophils, and mononuclear phagocytes. Numerous viral or bacterial infections have repeatedly been proven to raise the risk of thrombosis, which can take the form of arterial thrombosis or venous thromboembolism and may worsen atherosclerosis. Therefore, even though thrombosis by platelets may be a useful strategy for boosting the immune system, it may also considerably raise the risk of cardiovascular disease. PLR initially serves as a systemic inflammatory biomarker to predict the prognosis of malignant illnesses. Recently, PLR has been used as a prognostic marker for cardiovascular disease. Previous studies have

Table 1: Baseline characteristics of the population.

Variable	Total $N = 458$	No event $N = 397$	Event $N = 61$	P value
Follow-up period (months)	14.4 (8.2–20.9)	15.7 (10.1–21.5)	1.1 (1.0–6.5)	<0.001
Age (years)	61 ± 13	59 ± 12	61 ± 15	0.075
Sociodemographic factors				
Men (*n*, %)	245 (53%)	216 (54%)	29 (48%)	<0.001
Elderly (>65 y, *n*, %)	183 (39%)	151 (38%)	32 (52%)	0.317
Lifestyle risk factors				
Current smoking (*n*, %)	95 (21%)	83 (21%)	12 (20%)	0.825
Current drinking (*n*, %)	89 (19%)	76 (19%)	13 (21%)	0.690
Current health status				
Overall overweight/obesity (*n*, %)	193 (42%)	169 (43%)	24 (39%)	0.635
Diabetes (*n*, %)	47 (10%)	35 (9%)	12 (20%)	0.009
Hypertension (*n*, %)	145 (32%)	121 (30%)	24 (39%)	0.168
Dyslipidemia (*n*, %)	217 (47%)	193 (49%)	24 (39%)	0.177
Coronary heart disease (*n*, %)	74 (16%)	61 (15%)	13 (21%)	0.240
Atrial fibrillation (*n*, %)	138 (30%)	126 (32%)	12 (20%)	0.056
Chronic kidney disease (*n*, %)	157 (34%)	131 (33%)	26 (43%)	0.140
Hepatic insufficiency (*n*, %)	25 (5%)	19 (5%)	6 (10%)	0.106
Metabolic risk factor				
BMI (kg/m^2)	23.5 ± 3.5	23.5 ± 3.6	23.5 ± 3.2	0.764
SBP (mmHg)	128 (115–144)	128 (115–143)	131 (114–146)	0.391
DBP (mmHg)	76 (67–86)	76 (67–87)	74 (66–82)	0.161
Hemoglobin (g/L)	131 (119–141)	133 (121–143)	124 (106–134)	<0.001
WBC (10^9/L)	6.2 (5.1–7.7)	6.3 (5.0–7.7)	6.2 (5.2–7.5)	0.661
Total lymphocyte count (10^9)	1.5 (1.3–1.9)	1.6 (1.3–1.9)	1.4 (1.2–1.8)	0.047
RDW (%)	13.2 (12.7–14.1)	13.2 (12.7–14.0)	13.6 (12.7–14.9)	0.082
Platelet (10^9/L)	201 (166–244)	202 (167–247)	192 (166–214)	0.143
Albumin	38.9 (36.4–41.1)	39.1 (36.8–41.3)	37.2 (33.5–39.4)	<0.001
Aspartate aminotransferase (U/L)	23.5 (19.0–32.0)	24.05 (19.0–31.0)	22.5 (18.3–32.8)	0.874
Urea nitrogen (mmol/L)	6.3 (5.2–8.0)	6.4 (5.2–8.0)	6.1 (5.0–8.2)	0.450
Uric acid (umol/L)	380 (312–465)	380 (316–465)	372 (306–467)	0.869
TC (mmol/L)	4.6 (3.8–5.4)	4.6 (3.9–5.4)	4.2 (3.4–5.1)	0.043
TG (mmol/L)	1.3 (1.0–1.8)	1.3 (0.9–1.8)	1.3 (1.0–1.8)	0.690
HDL-c (mmol/L)	1.0 (0.8–1.3)	1.0 (0.9–1.3)	1.0 (0.7–1.2)	0.032
LDL-c (mmol/L)	2.5 (2.0–3.1)	2.5 (2.0–3.1)	2.4 (1.8–3.0)	0.120
PNI	46.8 (43.9–50.1)	47 (44.6–50.4)	44.3 (39.1–47.1)	<0.001
RAR	0.33 (0.31–0.38)	0.34 (0.31–0.38)	0.37 (0.33–0.43)	<0.001
RPR	0.07 (0.05–0.08)	0.07 (0.05–0.08)	0.07 (0.06–0.09)	<0.001
HRR	10.00 (8.67–10.91)	10.08 (8.87–10.98)	9.02 (7.44–10.28)	0.033
PLR	126.33 (99.30–169.01)	126.05 (98.04–169.08)	127.91 (105.43–168.52)	<0.001
Echocardiography				
LVEF (%)	63.1 (56.1–66.9)	63.1 (56.1–66.9)	62.7 (57.5–66.9)	0.908
LVEDD (mm)	56.0 (50.0–62.0)	56.0 (50.0–62.0)	55.0 (49.0–62.0)	0.528
LAD (mm)	49.0 (44.0–55.0)	49.0 (45.0–56.0)	47.0 (44.0–52.0)	0.032
Type of the surgery				0.509
Valve repair	226 (49.3%)	193 (48.6%)	33(54.1%)	
Valve replacement	232 (50.7%)	204 (51.4%)	28 (45.9%)	
Type of the valve				0.394
Mitral valve	225 (49.1%)	191 (48.1%)	34 (55.7%)	
Tricuspid valve	204 (44.5%)	179 (45.1%)	25 (41.0%)	
Aortic valve	29 (6.3%)	27 (6.8%)	2 (3.3%)	

BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; WBC, white blood cell; RDW, red cell distribution width; TC, total cholesterol; TG, triglycerides; HDL-c, high-density lipoprotein-cholesterol; LDL-c, low-density lipoprotein-cholesterol; RAR, RDW-to-albumin ratio; RPR, RDW-to-platelet ratio; HRR, hemoglobin-to-RDW ratio; PLR, platelet-to-lymphocyte ratio; LVEF, left ventricular ejection fraction; LVEDD, left ventricular end-diastolic diameter; LAD, left atrium diameter.

demonstrated that higher platelet and lower lymphocyte counts are associated with negative cardiovascular outcomes [19]. Low albumin levels are associated with increased short- and long-term mortalities. Serum albumin is a readily available peptide that has long been selected by protein chemists as a model for physical or chemical studies. The liver is where albumin is made. Reduced synthesis, increased catabolic rate, extravascular distribution, and exogenous loss cause decreased albumin concentration. Albumin synthesis is impacted by both inadequate dietary intake and systemic

Table 2: Adverse events during the follow-up.

Variable	Total
Death (*n*, %)	6 (1%)
Stroke (*n*, %)	4 (1%)
Heart failure (*n*, %)	11 (2%)
Major bleeding (*n*, %)	9 (2%)
Uncontrolled infection (*n*, %)	8 (2%)
Second operation (*n*, %)	5 (1%)
Postoperative arrhythmia (*n*, %)	18 (4%)

Table 3: Multivariate analysis for factors associated with adverse events.

Variables	OR (95% CI)	*P*
PLR	3.055 (1.363–6.845)	0.007
DM	2.926 (1.163–7.363)	0.023
Albumin	0.873 (0.803–0.950)	0.002

PLR, platelet-to-lymphocyte ratio; DM, diabetes mellitus.

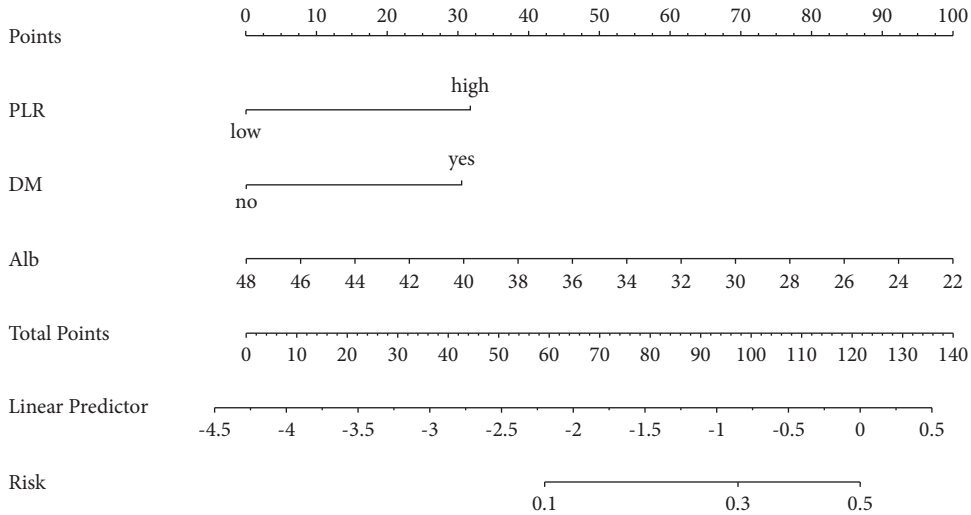

Figure 2: Nomogram for the prediction of composite endpoints prognostic model in patients following SVR. SVR, surgical valve replacement; PLR, platelet-to-lymphocyte ratio; DM, diabetes mellitus.

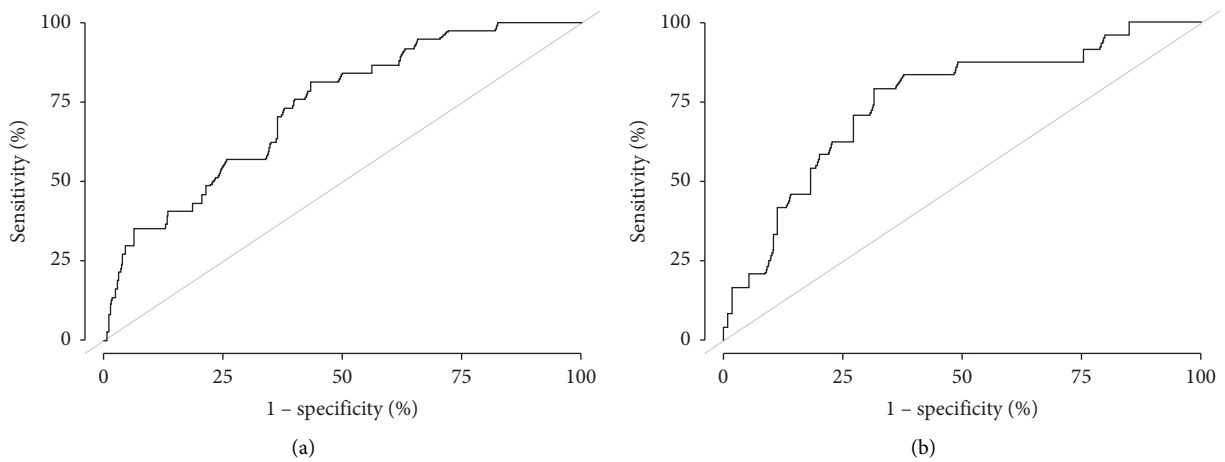

Figure 3: The ROC curve for the composite endpoints risk nomogram. The *x*-axis represents the specificity of composite endpoints by the nomogram and the *y*-axis represents the sensitivity of composite endpoints. (a) ROC of training set. AUC training = 0.73 (95% CI: 0.65–0.81); (b) ROC of validation set. AUC validation = 0.75 (95% CI: 0.64–0.86). ROC, receiver operating characteristic; AUC, area under the ROC curve.

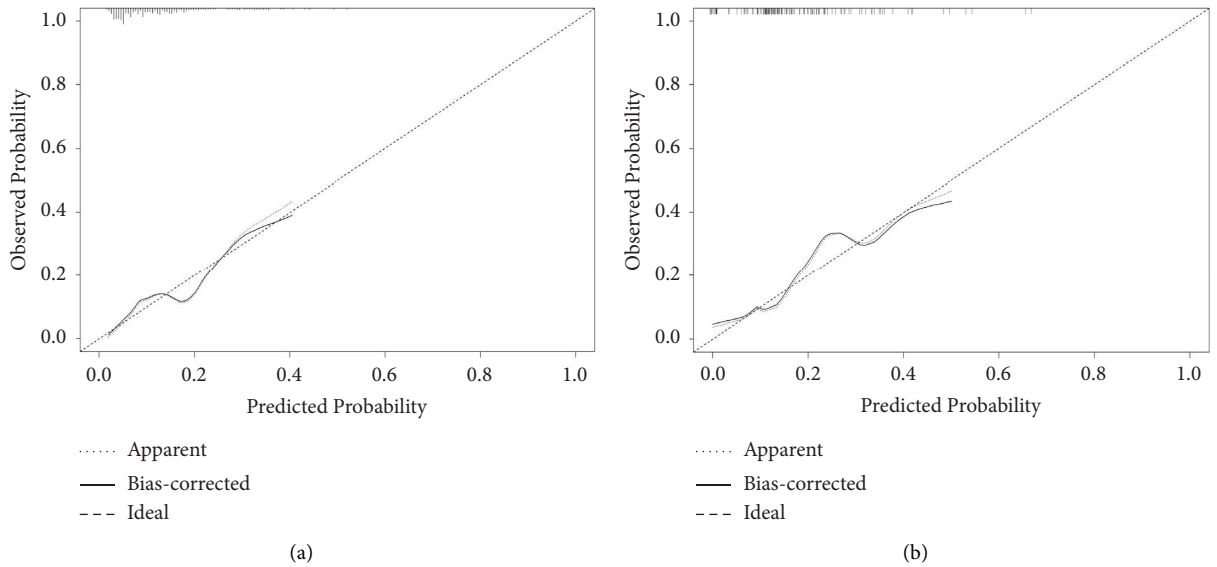

Figure 4: Calibration curve. The x-axis represents the predicted composite endpoints risk. (a) Calibration curve of training set (Brier score = 0.09); (b) calibration curve of validation set (Brier score = 0.12).

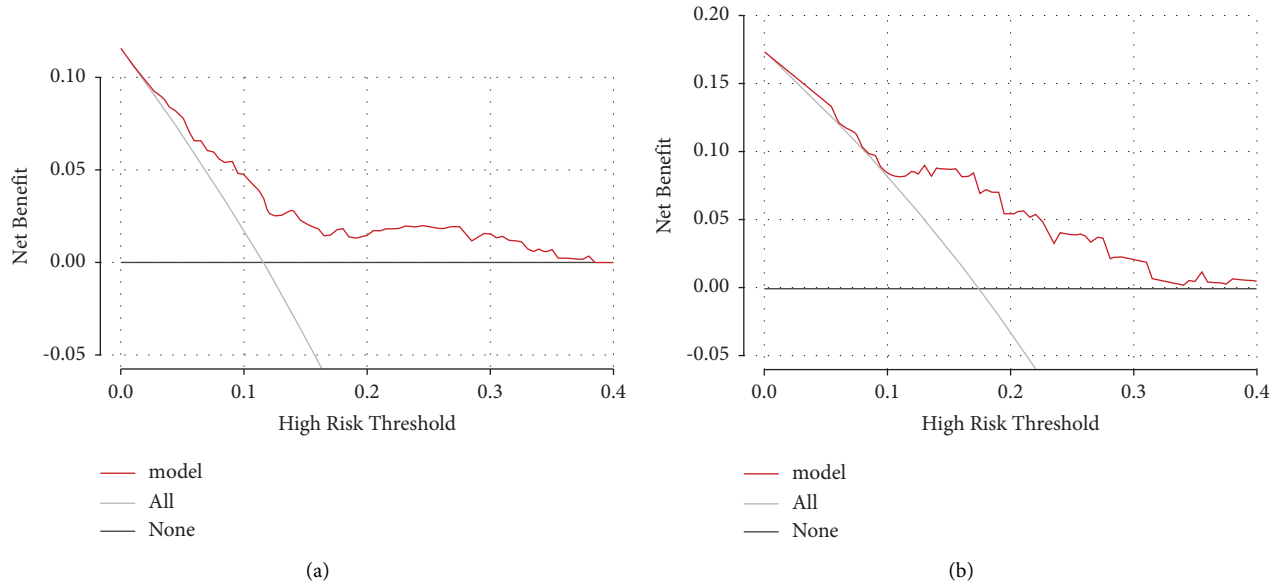

Figure 5: Decision curve analysis (DCA). (a) DCA for training set; (b) DCA for validation set.

inflammation [20]. Physiological circumstances, such as cancer, renal failure, and chronic lung disease, raise resting energy consumption and albumin catabolism [20]. In patients with chronic renal disease or heart failure, the light effect is a significant factor in the lowered serum albumin content [21]. Patients with nephritic syndrome typically have direct exogenous albumin loss [22]. A large cohort study showed that before discharge, a normalized albumin level was associated with a lower risk of mortality than hypoalbuminemia [23].

Although there are many risk prediction models for patients after cardiac surgery, a model based on simple data is required. Our present model emphasized the significance of a new indicator, PLR, in risk scoring as well as improved the risk assessment and treatment of patients following a heart valve surgery. The indicators included in our model are simple and easy to obtain, which facilitates their active promotion at basic hospitals.

5. Limitations

This was a single-center, observational, internal validation study with a small cohort of patients. This type of research relied on historical records, which might be missing or incorrectly recorded, making it susceptible to selection bias and information bias; records also frequently lack information on confounding factors that influence the relationship between exposure and outcome, making it

difficult to control confounding factors interference. Therefore, the integrity and authenticity of historical data would have a direct bearing on the viability of this form of research and the veracity of research results. External validation in more extensive, multicenter prospective studies is needed to further valid our results. Our study population was limited to patients undergoing SVR and could not be generalized to other populations. Since data were obtained from a small population data, we could not conduct a subgroup analysis regarding the type of valve replacement.

6. Conclusion

Our study developed an effective nomogram for predicting the occurrence of composite endpoints of adverse events in patients undergoing SVR. This model could evaluate the mid-term risk of adverse events and provide clinicians, patients, and their families with a decision-making basis.

Data Availability

The data presented in this study are available from the corresponding author upon request. Due to ethical reasons, the data are not publicly available.

Ethical Approval

The audit was agreed upon by the hospital clinical governance unit and was conducted with full regard to the confidentiality of individual patients and the principles of the Declaration of Helsinki (approval number: YS2022306). Individual patient data were anonymized. Patient data are held by the authors and are available from the corresponding author upon reasonable request.

Consent

Informed consent was not required for an audit of existing clinical practice.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Supplementary Materials

The supplement material was uploaded as attachment. (*Supplementary Materials*)

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