


Article

The Development and Validation of a Nomogram for Predicting Poor Recovery in Cardiac Surgery Patients Using the Quality of Recovery-15 (QoR-15) Score

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Abstract

Background: Multiple risk factors may contribute to adverse postoperative outcomes in cardiac surgery. This study sought to develop a nomogram for predicting poor recovery in cardiac surgery patients based on the patient-reported global score of the 15-item Quality of Recovery (QoR-15) scale. **Methods:** A retrospective study was conducted involving adult patients who underwent cardiac surgery from July 2023 to July 2024. Data collected included demographics, clinical variables, and surgical details. Poor recovery was defined as a QoR-15 score less than 118 at 24 hours post-operation. Significant predictors of poor recovery were identified through multivariate logistic regression analysis and were used to develop a nomogram. The model's performance was evaluated using the area under the curve (AUC) and calibration plots. **Results:** Of the 1768 patients included, the incidence of poor recovery was 27.6%. Key predictors of poor recovery included age, gender, hypertension, diabetes, operation duration, cardiopulmonary bypass duration, intraoperative blood loss, ejection fraction, and the use of dexmedetomidine administration ($p < 0.05$). The nomogram showed a strong discriminative capability, with an AUC of 0.795 in the training dataset and 0.734 in the testing dataset. Calibration plots indicated a high level of consistency between predicted and actual probabilities. **Conclusion:** The nomogram effectively predicts a QoR-15 score < 118 in patients 24 hours after cardiac surgery and can be useful in forecasting poor recovery.

Keywords

cardiac surgery; nomogram; enhanced recovery after surgery

Introduction

Postoperative recovery in cardiac surgery patients is a critical phase that significantly impacts patient outcomes, healthcare resource utilization, and quality of life. The im-

portance of postoperative recovery is paramount, as it enables patients to resume daily activities without significant limitations [1,2].

Substantial consequences arise from poor postoperative outcomes following cardiac surgery, including increased morbidity, mortality, and prolonged hospital stays. These outcomes lead to higher healthcare costs due to extended care needs, additional procedures, and readmissions [1–3]. Furthermore, complications post-surgery can prolong and complicate the recovery process, adversely affecting patients' mental health and wellbeing.

Numerous risk factors contribute to poor postoperative outcomes in cardiac surgery patients. These include advanced age, pre-existing comorbidities such as diabetes, renal insufficiency, and chronic obstructive pulmonary disease (COPD), the complexity of the surgical procedure, and postoperative complications like infections, arrhythmias, and respiratory failure [4,5]. Factors such as the patient's nutritional status, adherence to medication regimens, and social support also influence recovery [4,5].

Current research on postoperative outcomes after cardiac surgery is extensive. Evidence supports the use of enhanced recovery after surgery (ERAS) protocols—multimodal care pathways designed to mitigate the surgical stress response and expedite recovery [1,2]. Additionally, patient-reported outcome measures are increasingly used to capture patients' perspectives on their recovery, offering insights that enhance traditional clinical outcomes [6].

The postoperative period for cardiac surgery patients necessitates a comprehensive, proactive management approach. By understanding risk factors and applying the latest research and technologies, improvements in patient outcomes and reductions in healthcare system burdens can be achieved [4,5].

The 15-item Quality of Recovery (QoR-15) scale assesses postoperative recovery quality based on patient evaluations [6]. Previous studies have demonstrated its effectiveness in reflecting recovery across physical, psychological, and social functions [7]. Patients benefiting from advanced surgical techniques or optimized anesthesia and pain management generally report higher QoR-15 scores [8].



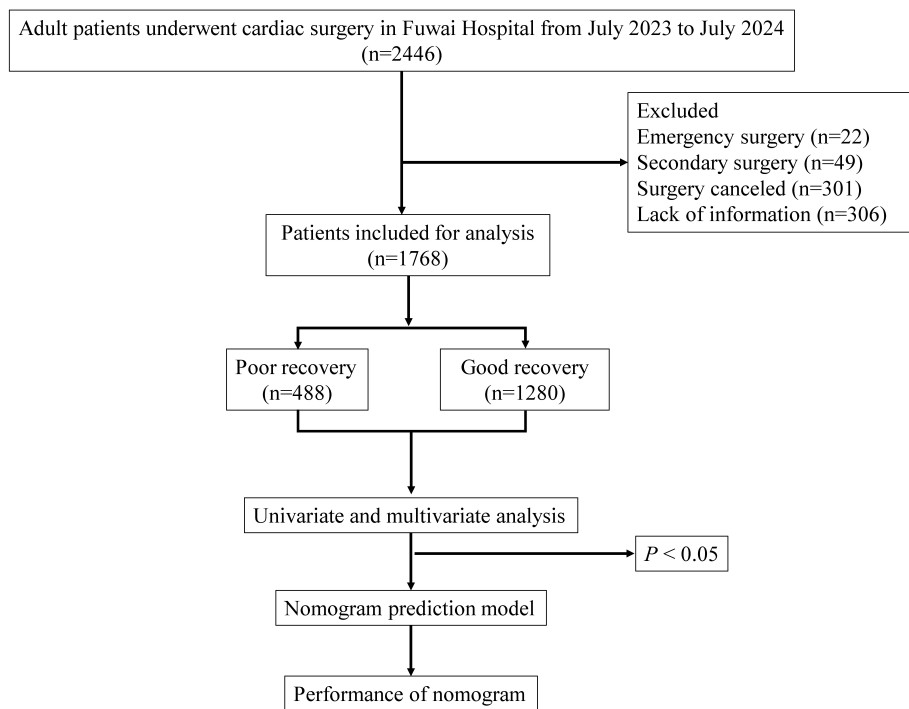


Fig. 1. Flowchart of the study.

A nomogram is a graphical model that integrates various factors for precise predictions. Prior studies have identified age, gender, ejection fraction, oxygen status, renal function, medical history, type of surgery, anesthetics, and cardiopulmonary bypass time as key predictors of postoperative outcomes. Despite these advances, nomograms are seldom used as predictive tools for poor recovery based on patient-reported QoR-15 scores in cardiac surgery. Thus, our aim was to develop a nomogram to predict early extubation in cardiac surgery.

Material and Methods

Study Design and Patients

Data were retrospectively collected from patients who underwent cardiac surgery at Fuwai Hospital between July 2023 to July 2024. Inclusion criteria for patients were: (1) adult patients, male or female, aged 18 to 80 years; and (2) patients scheduled for cardiac surgery. Exclusion criteria included: (1) emergency surgery; (2) secondary surgery; (3) surgery changed; (4) lack of essential information.

Data from Fuwai Hospital (Beijing) were randomly allocated, with 80% assigned to the training dataset and 20% to the testing dataset.

Outcome Measures

The primary outcome was the patient-reported global QoR-15 score at 24 hours post-surgery. The QoR-15 com-

prises 15 questions, each rated on an 11-point numerical scale reflecting frequency of occurrence. Scores range from 0 to 150, indicating poor to excellent recovery, respectively. Poor recovery was defined as a QoR-15 score below 118 at 24 hours post-operation. QoR-15 assessments were independently conducted by at least two nurses and/or anesthesiologists [6].

Data Collection and Model Development

Perioperative clinical data were retrospectively extracted from institutional electronic medical records by two members and verified by another. Demographics, laboratory tests, and surgical-associated information, which could influence postoperative recovery, were collected. All risk factors were included in a multivariate analysis. Multivariate logistic regression analysis was conducted to identify independent risk factors, using a stepwise method to precisely predict anastomotic leakage. Factors with $p < 0.05$ were included in the nomogram development.

The calculation is accessible online (<https://mvansmeden.shinyapps.io/BeyondEPV/>). Here, ‘n’ represents the sample size, ‘ φ ’ the anticipated outcome proportion, and ‘P’ the number of candidate predictor parameters; ‘MAPE’ denotes the average error of the estimated outcome probability permitted in the model. MAPE was set at 0.05, P at 5, and φ at 0.3, requiring a minimum of 450 participants.

The nomogram’s performance was assessed using the area under the receiver operating characteristic curve (AUROC) and calibration plots with bootstrap samples. Statistical analysis was performed using the SPSS 22.0 (IBM

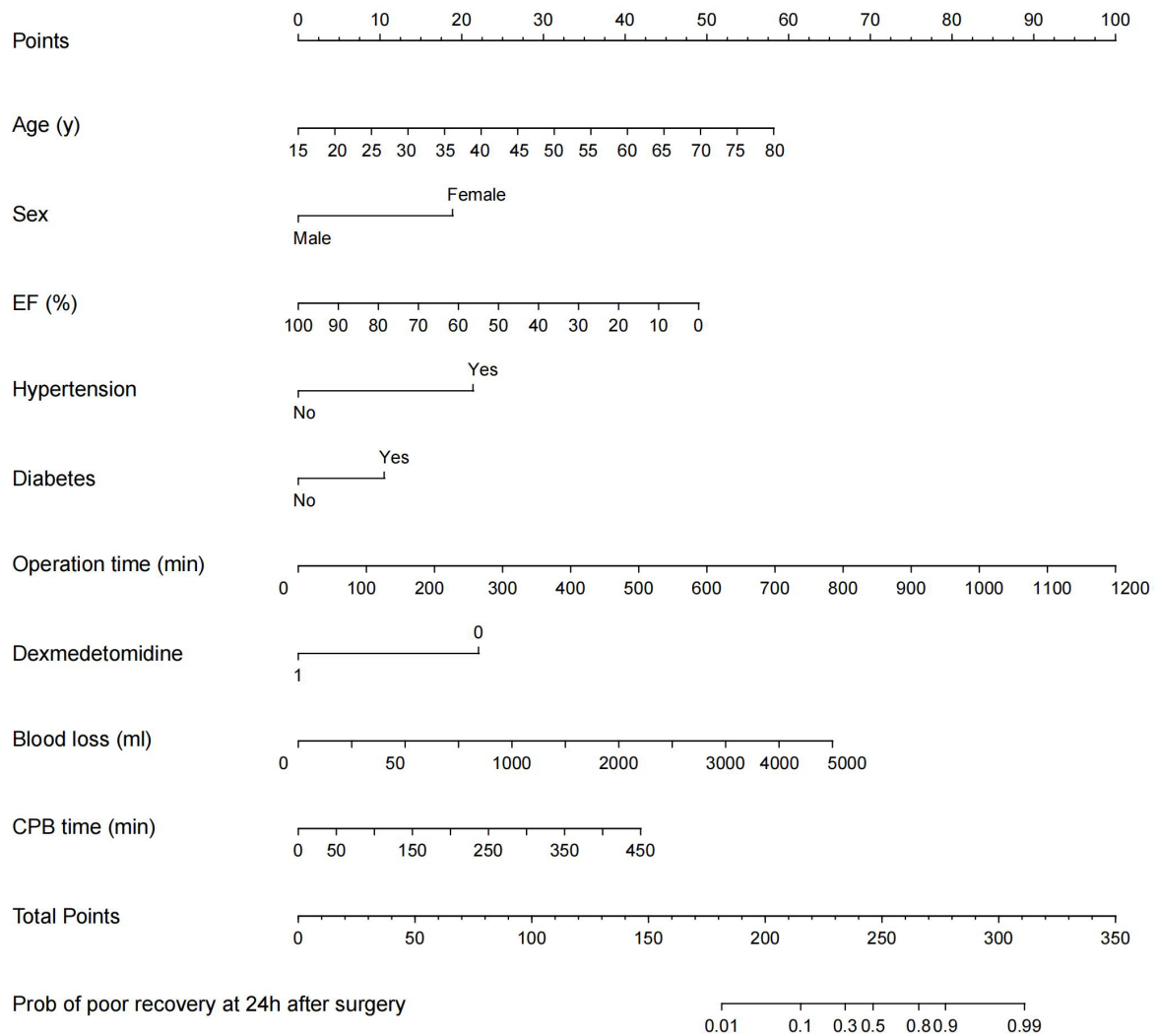


Fig. 2. Nomogram to predict poor recovery at 24 h after surgery. EF, ejection fraction; CPB, cardiopulmonary bypass.

Corp., Armonk, NY, USA) and R version 4.3.2 (The R Foundation for Statistical Computing, Vienna, Austria) with the car, rms, and pROC packages. For continuous variables conforming to a normal distribution, Student's *t*-test was employed, with results expressed as mean \pm standard deviation (SD). In contrast, the Mann–Whitney U test was applied to variables that did not meet the normality criteria, reporting outcomes as the median values (interquartile range). Categorical data were analyzed using chi-squared tests or the Fisher's exact test, where appropriate. A two-sided *p*-value below 0.05 was considered statistically significant.

Results

Demographic and Clinical Characteristics

Medical records of 2446 consecutive adult patients who underwent cardiac surgery from July 2023 to July 2024

at Fuwai Hospital were reviewed. A total of 22 patients were excluded due to it being emergency surgery, 49 patients were excluded due to it being secondary surgery, 301 patients were excluded due to their surgery being canceled and 306 were excluded due to lack of essential information. Ultimately, 1768 patients were included for univariate and multivariate analysis. Fig. 1 illustrates the study flowchart.

The median age at surgery for the entire cohort was 61.64 ± 9.72 years, and 71.27% (1260/1768) of the patients were male. The incidence of poor recovery (QoR-15 <118) stood at 27.60% (488/1768). The average body mass index (BMI) was 25.12 kg/m^2 , with prevalent comorbidities, including coronary artery disease (68.10%), hypertension (52.95%), and hyperlipidemia (57.92%). The mean ejection fraction (EF) was $56.73 \pm 7.87\%$, and the average serum albumin level was $40.56 \pm 3.72 \text{ g/L}$.

The results of the univariate analysis showed that the average age of patients in the poor postoperative recovery group was significantly higher than that of patients in the good postoperative recovery group. The propor-

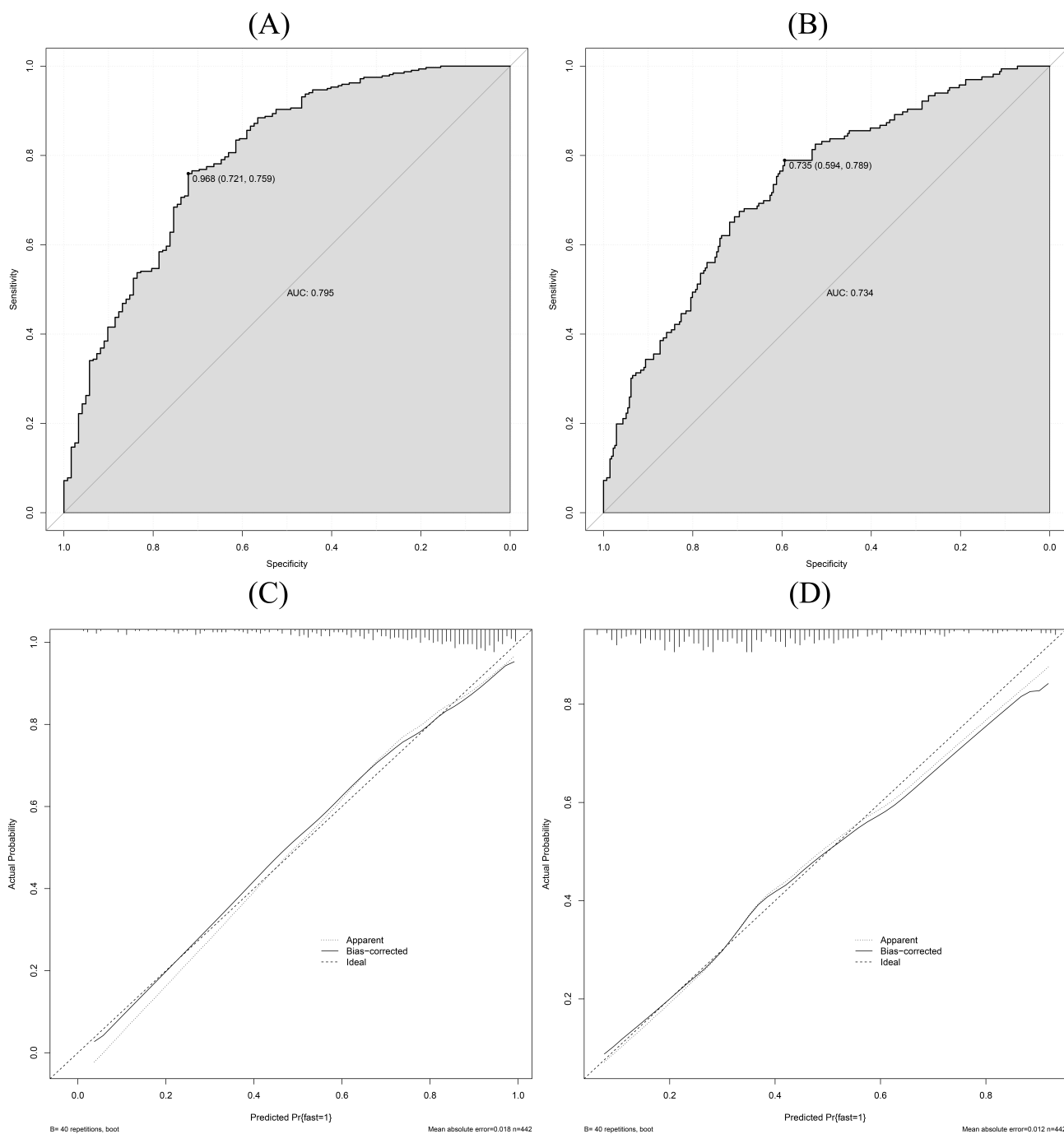


Fig. 3. The ROC curve and internal calibration curve. ROC curve analysis in training dataset (A) and testing dataset (B). Internal calibration curves of training set (C) and testing set (D). AUC, area under the curve; ROC, receiver operating characteristic.

tion of female patients in the poor postoperative recovery group (35.3% vs. 26.3%, $p < 0.001$), the proportion of patients with coronary heart disease before surgery (73.0% vs. 66.3%, $p = 0.007$), the proportion of patients with hypertension before surgery (59.0% vs. 50.6%, $p = 0.002$), the proportion of patients with diabetes (36.1% vs. 30.6%, $p = 0.029$), and the proportion of patients with pulmonary hypertension before surgery (11.5% vs. 8.0%, $p < 0.001$) were all significantly higher than those in the good post-

operative recovery group. The proportion of patients with high-risk anesthesia before surgery in the poor postoperative recovery group was significantly higher than that in the good postoperative recovery group ($p < 0.001$). In addition, the operation time of patients in the poor postoperative recovery group was significantly longer than that of patients in the good postoperative recovery group (358.11 ± 68.59 min vs. 301.58 ± 67.45 min, $p = 0.011$). Other baseline data, biochemical examination results, and intraoperative

Table 1. The demographic and perioperative information.

	Total (n = 1768)	QoR-15 \geq 118 (n = 1280)	QoR-15 <118 (n = 488)	<i>p</i>
Age (y)	61.64 \pm 9.72	56.94 \pm 12.11	62.64 \pm 9.21	0.02
Gender				<0.001
Male	1260 (71.3%)	944 (73.8%)	316 (64.8%)	
Female	508 (28.7%)	336 (26.3%)	172 (35.3%)	
Body mass index (kg/m ²)	25.32 \pm 3.52	25.27 \pm 3.26	25.49 \pm 3.97	0.56
Coronary heart disease	1204 (68.1%)	848 (66.3%)	356 (73.0%)	0.01
Valvular disease	645 (36.5%)	453 (35.4%)	192 (39.3%)	0.12
Aortic disease	163 (9.2%)	115 (9.0%)	48 (9.8%)	0.58
Hypertension	936 (52.9%)	648 (50.6%)	288 (59.0%)	0.002
Diabetes mellitus	568 (32.1%)	392 (30.6%)	176 (36.1%)	0.03
Stroke	183 (10.4%)	126 (9.8%)	57 (11.7%)	0.26
Hyperlipidemia	1024 (57.9%)	724 (56.6%)	300 (61.5%)	0.06
Pulmonary hypertension	158 (8.9%)	102 (8.0%)	56 (11.5%)	0.02
Ejection fraction (%)	56.73 \pm 7.87	58.42 \pm 7.14	55.84 \pm 8.72	0.01
HbA1c (%)	6.67 \pm 1.29	6.65 \pm 1.21	6.68 \pm 1.34	0.88
Creatinine (μ mol/L)	81.0 (67, 95)	80.0 (66, 94)	82.0 (68, 96)	0.61
TnI (ng/mL)	0.03 (0.01, 0.18)	0.01 (0.01, 0.15)	0.04 (0.01, 0.19)	0.37
ALT (IU/L)	26.0 (15, 34)	24.0 (17, 31)	27.0 (9, 37)	0.19
AST (IU/L)	23.0 (12, 34)	22.0 (14, 28)	25.0 (11, 36)	0.05
NT-proBNP (pg/pL)	425.0 (101, 745)	397.0 (84, 698)	567.0 (117, 754)	0.06
Serum albumin (g/L)	40.56 \pm 3.72	41.33 \pm 3.51	40.23 \pm 3.84	0.07
ASA classification				<0.001
I	4 (0.2%)	4 (0.3%)	0 (0.0%)	
II	100 (5.7%)	72 (5.6%)	28 (5.7%)	
III	1448 (81.9%)	1096 (85.6%)	352 (72.1%)	
IV	212 (12.0%)	104 (8.1%)	108 (22.1%)	
V	4 (0.2%)	4 (0.3%)	0 (0.0%)	
Surgery type				0.44
CABG	673 (38.1%)	477 (37.3%)	196 (40.2%)	
Valve	540 (30.5%)	394 (30.8%)	146 (29.9%)	
CABG + Valve	409 (23.1%)	296 (23.1%)	113 (23.2%)	
Others	146 (8.3%)	113 (8.8%)	33 (6.8%)	
Sufentanil (μ g)	330.70 \pm 55.52	326.75 \pm 57.48	330.98 \pm 50.60	0.71
Dexmedetomidine	1584 (89.6%)	1164 (90.9%)	420 (86.1%)	0.003
Intraoperative infusion (mL)	965.60 \pm 44.17	903.63 \pm 22.18	985.78 \pm 65.36	0.15
Intraoperative blood loss (mL)	592.82 \pm 101.59	587.24 \pm 88.38	598.24 \pm 103.12	0.05
Intraoperative blood transfusion	276 (15.6%)	196 (15.3%)	80 (16.4%)	0.58
Intraoperative albumin transfusion	144 (8.1%)	96 (7.5%)	48 (9.8%)	0.11
Operative time (min)	325.64 \pm 69.05	301.58 \pm 67.45	358.11 \pm 68.59	0.01
CPB time (min)	91.55 \pm 22.75	91.18 \pm 23.28	95.55 \pm 22.33	0.04
Intraoperative lowest temperature ($^{\circ}$ C)	24.90 \pm 3.45	25.80 \pm 3.03	24.72 \pm 3.58	0.52

The demographic and perioperative information in the study.

QoR-15, 15-item quality of recovery; HbA1c, glycosylated hemoglobin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; TnI, troponin I; ASA, american society of anesthesiologists; NT-proBNP, N-terminal pro-B type natriuretic peptide; CABG, coronary artery bypass grafting.

data showed no statistically significant differences. Table 1 shows the basic characteristics and intraoperative information.

Nomogram for Poor Recovery

Multivariate analysis indicated significant associations between poor postoperative recovery and age, gender, hypertension, and diabetes ($p < 0.05$). Prolonged operation

Table 2. Multivariate analysis of poor recovery.

	OR	95% CI	<i>p</i>
Age (y)	1.59	1.01 1.97	0.01
Gender	1.15	1.08 3.24	0.02
BMI (kg/m ²)	1.00	0.96 1.02	0.52
Coronary heart disease	1.71	0.74 1.90	0.54
Valvular disease	1.35	0.63 1.59	0.72
Aortic disease	1.18	0.35 4.00	0.79
Hypertension	1.23	1.09 1.58	0.02
Diabetes	1.09	1.03 2.49	0.03
Stroke	1.05	0.46 2.39	0.92
Hyperlipidemia	1.47	0.36 1.52	0.41
Pulmonary hypertension	1.20	0.86 1.65	0.71
Ejection fraction (%)	0.77	0.63 0.91	0.04
HbA1c (%)	1.04	0.85 1.27	0.73
Creatinine (μmol/L)	1.09	0.75 1.23	0.29
TnI (ng/mL)	1.13	0.59 2.19	0.72
ALT (IU/L)	1.14	0.98 1.25	0.97
AST (IU/L)	1.02	0.98 1.06	0.33
NT-proBNP (pg/pL)	1.31	0.13 1.74	0.48
Serum albumin (g/L)	1.00	0.92 1.61	0.32
ASA classification	1.28	0.31 1.62	0.18
Surgery type	1.00	0.27 1.24	0.13
Sufentanil (μg)	1.01	0.62 1.03	0.89
Dexmedetomidine	0.59	0.38 0.76	0.04
Intraoperative infusion (mL)	1.70	0.12 2.03	0.92
Intraoperative blood loss (mL)	1.33	1.03 1.87	0.02
Intraoperative blood transfusion	1.44	0.51 3.08	0.11
Intraoperative albumin transfusion	1.59	0.21 1.66	0.33
Operative time (min)	1.99	1.09 2.09	0.01
CPB time (min)	1.06	1.01 1.92	0.03
Intraoperative lowest temperature (°C)	0.98	0.95 1.02	0.29

BMI, body mass index.

times (OR = 1.99, 95% CI 1.09–2.00, *p* = 0.013), cardiopulmonary bypass (CPB) time (OR = 1.06, 95% CI 1.01–1.92, *p* = 0.027), and intraoperative blood loss (OR = 1.33, 95% CI 1.03–1.87, *p* = 0.019). Improved recovery was linked to higher ejection fractions (OR = 0.77, 95% CI 0.63–0.91, *p* = 0.044) and the intraoperative use of dexmedetomidine (OR = 0.59, 95% CI 0.38–0.76, *p* = 0.042) were factors for improving postoperative recovery.

Multivariate analysis identified that age, gender, hypertension, diabetes, operation time, CPB time, intraoperative blood loss, ejection fraction, and the intraoperative use of dexmedetomidine were significantly associated with poor recovery (Table 2). These variables were used to develop a nomogram to predict the probability of poor recovery after cardiac surgery (Fig. 2). The predictive model exhibited excellent discrimination, with a value of 0.795 for the training dataset and 0.734 for the testing dataset. The calibration curve closely approximated the ideal line, indicating that the observed probability was consistent with the predicted probability in the development cohort (Fig. 3).

Follow-up

The global QoR-15 score at 72 hours post-surgery was 121.46 ± 5.99 in the intervention group and 114.20 ± 5.90 in the control group (*p* < 0.001). Patients with a QoR-15 score ≥ 118 within the first 24 hours post-surgery reported higher scores in breathing easily, enjoying food, managing personal hygiene, returning to work or usual home activities, and feeling comfortable and in control (*p* < 0.05). No significant differences were observed in feeling rested, having a good sleep, communicating with family or friends, receiving support from hospital staff, and experiencing moderate or severe pain, worry, anxiety, sadness, or depression (*p* > 0.05). The results of the follow-up were shown in (Table 3).

Discussion

This retrospective study developed a predictive nomogram using the QoR-15 score to evaluate recovery quality after cardiac surgery. The critical factors found to influence postoperative recovery included age, gender, hypertension, diabetes, operation time, CPB time, intraoperative blood loss, ejection fraction, and intraoperative dexmedetomidine use. These were integrated into a multivariate model to devise a robust tool for identifying patients at higher risk for poor recovery, which is a key step in facilitating personalized interventions.

Our analysis underscored key demographic and clinical characteristics significantly impacting postoperative recovery. Age was a significant risk factor; older patients exhibited poorer recovery, consistent with previous findings that aging diminishes physiological reserves and increases susceptibility to postoperative complications [9,10]. Hypertension and diabetes also adversely affected recovery, in line with studies suggesting these conditions exacerbate cardiovascular complications post-surgery [9–11].

Intraoperative factors like extended operation and CPB times were linked to poorer recovery due to increased physiological stress and complication risks such as coagulopathy and myocardial dysfunction [4,5]. This highlights the necessity of optimizing surgical duration and minimizing CPB time in high-risk patients.

A significant finding was the positive impact of intraoperative dexmedetomidine use on recovery outcomes. Dexmedetomidine, an α_2 -adrenergic receptor agonist, has become popular in cardiac surgery for its analgesic, sedative, and cardioprotective properties [12]. Our results support its use in improving postoperative recovery, particularly by decreasing the need for opioids and enhancing hemodynamic stability. This finding aligns with previous research demonstrating the advantages of dexmedetomidine for reducing cases of delirium, facilitating earlier extubation, and improving overall patient satisfaction [12,13].

Table 3. QoR-15 score at 72 h after surgery.

	QoR-15 \geq 118 (n = 1280)	QoR-15 <118 (n = 488)	<i>p</i>
QoR-15 global score	121.46 \pm 5.99	114.20 \pm 5.90	<0.001
QoR-15 item scores			
1. Able to breathe easily	8.91 \pm 0.29	8.54 \pm 0.62	0.002
2. Been able to enjoy food	6.12 \pm 0.88	5.12 \pm 1.39	<0.001
3. Feeling rested	8.04 \pm 0.58	8.01 \pm 0.49	0.55
4. Have had a good sleep	8.17 \pm 0.87	8.04 \pm 0.61	0.11
5. Able to look after personal toilet and hygiene	7.52 \pm 0.88	6.27 \pm 1.09	<0.001
6. Able to communicate with family or friends	8.31 \pm 0.58	7.89 \pm 0.78	0.10
7. Getting support from hospital doctors and nurses	8.26 \pm 0.56	8.03 \pm 0.42	0.18
8. Able to return to work or usual home activities	6.67 \pm 0.67	6.15 \pm 1.07	0.01
9. Feeling comfortable and in control	8.15 \pm 0.69	7.49 \pm 0.82	0.01
10. Having a feeling of general well being	7.52 \pm 0.73	7.06 \pm 0.84	0.04
11. Moderate pain	8.52 \pm 1.23	8.82 \pm 2.11	0.07
12. Severe pain	9.67 \pm 0.35	9.82 \pm 0.56	0.65
13. Nausea or vomiting	8.11 \pm 1.03	8.32 \pm 1.28	0.33
14. Feeling worried or anxious	7.84 \pm 0.91	7.52 \pm 0.78	0.06
15. Feeling sad or depressed	8.07 \pm 0.72	8.09 \pm 0.71	0.85

In this study, a nomogram was constructed exhibiting exceptional discriminatory capabilities, as evidenced by AUROC values of 0.795 in the training set and 0.734 in the validation set, indicative of robust predictive efficacy. The calibration plot confirmed that the predicted probabilities of poor recovery were well aligned with observed outcomes, suggesting that the nomogram is a dependable tool for clinical application.

This tool offers several potential advantages in the clinical setting [4,14]. By using easily accessible preoperative and intraoperative data, clinicians can identify patients at high risk for poor recovery and customize perioperative management strategies accordingly [15]. For example, patients identified as high-risk may derive benefit from protocols emphasizing enhanced recovery post-surgery (ERAS), intensive surveillance following surgery, or proactive rehabilitation measures [16]. Moreover, the ability to predict recovery outcomes allows healthcare providers to engage in more meaningful discussions with patients and their families regarding prognosis and expected recovery status.

The outcomes of this research carry profound implications for clinical operations. Primarily, recognizing adjustable risk factors like hypertension and diabetes, along with intraoperative parameters, presents avenues to amplify recovery results through precise interventions. For instance, optimizing glycemic control in diabetic patients and maintaining strict blood pressure management in hypertensive individuals may enhance their postoperative recovery [17]. Additionally, the broader use of dexmedetomidine during surgery could improve recovery quality and decrease dependence on opioid analgesia [12,13]. Second, the nomogram could serve as a valuable tool for personalized medicine, enabling the stratification of patients based on their risk of poor recovery. This allows clinicians to allocate

resources more effectively, ensuring that high-risk patients receive the necessary support to optimize their postoperative outcomes [18]. Furthermore, using patient-reported outcomes such as the QoR-15 score provides a more comprehensive assessment of recovery, incorporating not only clinical metrics but also patient experiences and satisfaction [19,20].

However, this study's limitations must be recognized. Being retrospective, it is susceptible to biases such as selection bias and potential inaccuracies in data recording. Although a large, well-characterized cohort and meticulous statistical methodologies were employed to minimize these limitations, prospective research is imperative to corroborate these findings and enhance the nomogram's precision. The absence of multiple QoR-15 assessments throughout the study points is an area for improvement in subsequent investigations. Moreover, the focus on cardiac surgery patients from a single institution might impede the broader applicability of the results. Future research should endeavor to validate the nomogram across varied patient demographics and medical facilities to affirm its widespread applicability. Additionally, while the QoR-15 score is an established metric for gauging recovery based on patient input, it may not capture all objective clinical outcomes like morbidity or long-term functionality. Future research should thus integrate both subjective and objective indicators to yield a more exhaustive evaluation of recovery quality.

Additionally, future studies could investigate the use of the nomogram in guiding perioperative decision-making. Patients identified as high risk for poor recovery could be enrolled in ERAS protocols or other targeted interventions to enhance outcomes.

Conclusion

In conclusion, this study presents a novel nomogram tailored to forecast poor postoperative recovery, emphasizing the significance of demographic and surgical variables in recovery predictions. The nomogram has shown promising predictive accuracy and holds potential as a significant asset for customized perioperative care. Future research should aim to validate the nomogram in diverse patient groups and integrate it into routine clinical practices to enhance postoperative recovery and patient outcomes.

Availability of Data and Materials

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

Author Contributions

DD and QL helped in the design of the work and drafting the manuscript. SY, YJ, and FY helped with critical suggestions for the trial design and statistical analyses. All authors have participated sufficiently in the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

The study was carried out in accordance with the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of the Chinese Academy of Medical Fuwai Hospital (No. 2024-2272), and patients had previously signed a consent form for the use of their medical records for research.

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Conflict of Interest

The authors declare no conflict of interest. The study sponsors and funding agencies did not participate in the study design and will not be involved in the collection, management, analysis, or interpretation of the data, or in the preparation and submission of the manuscript.

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