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Validation of a Newly Proposed Risk-Predictive Model of Coronary Artery Bypass Graft Surgery in the Chinese Population

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ABSTRACT

Background: This research was aimed at validating a new risk model for in-hospital mortality in Chinese patients undergoing coronary artery bypass graft (CABG) surgery. This model (NYS), which was developed for isolated CABG surgery from data of New York's cardiac surgery reporting system in 2002, was proved effective, but its validation in Chinese patients has yet to be carried out.

Methods: The original model was recalibrated, and the fitness of the recalibrated model was tested in the Chinese Coronary Artery Bypass Graft Registry. From January 2004 to December 2005, 9248 patients undergoing CABG were enrolled in the Chinese CABG Registry, and 8120 patients who underwent isolated CABG were selected for the current study.

Results: The C statistic value for the original model was 0.74 (95% confidence interval [CI], 0.70-0.78), and the χ^2 statistic was >26.13 ($P < .001$), indicating a necessity for recalibration. The fit of the recalibrated model was satisfactory (C statistic, 0.74 [95% CI, 0.70-0.78]; $\chi^2 = 5.98$; $P = .65$). Furthermore, translation of risk profiles into NYS scores revealed strong correlations between risk-score levels and different end points, including in-hospital mortality, major adverse cardiac events, and length of intensive care unit stay. Independent predictors were identified in the Chinese CABG Registry. Many predictors for the Chinese CABG Registry were the same as those in the NYS model.

Conclusions: The original NYS system overestimates in-hospital mortalities in Chinese patients undergoing CABG, whereas the recalibrated model corrects such overestimations. This model can be a useful risk-predictive tool for Chinese patients undergoing isolated CABG.

The authors had full access to the data and take responsibility for its integrity. All authors have read and agreed to the manuscript as written.

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INTRODUCTION

Coronary artery bypass graft (CABG) surgery has been evolving into one of the major options for the treatment of coronary heart disease (CHD). Technological advances, which enable high-risk patients such as the elderly and those with severe comorbidities to benefit from this procedure, have widened the spectrum of patients eligible for CABG. Because of its role in CHD treatment, CABG merits a full evaluation of its appropriateness for individuals with a different baseline status. Furthermore, the quality of care and comparisons of adjusted surgical outcomes have always been of interest to providers, patients, and insurance companies. These purposes could be partly, if not fully, fulfilled via the development of a risk-predictive model. Unfortunately, although models such as EuroSCORE have been demonstrated effective for CABG patients [Toumpoulis 2004, 2005; Biancari 2006], only a few were specifically for patients undergoing isolated CABG surgery. Risk-predictive models specific for CABG patients might be more effective because the impacts of risk factors on CABG and non-CABG patients are different [Hannan 2006]. Moreover, new techniques for CABG have proliferated during the past decade. The previously identified risk factors could be out of date, and their influences on surgical outcomes might have changed with the surge in the state of the art.

Hannan and colleagues [2006] developed a risk-predictive model specific for CABG surgery from data of New York's cardiac surgery reporting system in 2002 and carried out temporal validation (in the current study, we call this model NYS, for New York score); however, the wider issue in terms of the model's generalizability has yet to be addressed. Therefore, we undertook an external validation of the NYS with data drawn from the Chinese Coronary Artery Bypass Graft Registry, which is a study involving multiple centers across China.

MATERIALS AND METHODS

Project Setup and Data Collection

The Chinese CABG Registry study, the steering group of which includes cardiac surgeons and researchers from Fuwai Hospital (affiliated with the Peking Union Medical College, Chinese Academy of Medical Sciences, Beijing, China), is a multicenter study with the primary purposes of the identification of risk factors and the evaluation of surgical outcomes in Chinese patients undergoing CABG surgery. The steering committee was in charge of supervision and coordination of institution recruitment and data collection. All 32 participating institutions, which were recruited on a voluntary basis, received detailed information at the beginning of the project on data-collection requirements and definitions of variables. A questionnaire containing items related to patient demographics, preoperative risk factors, operative information, postoperative treatment courses, and surgical outcomes was then designed. Data were collected from January 2004 to December 2005. All patients provided signed informed consent. Patients who underwent either isolated conventional on-pump CABG (cCABG) or isolated off-pump CABG (OPCAB) were selected for validation. Patients who underwent CABG concomitantly with other surgeries (valve surgery, aortic surgery, ventricular aneurysm repair, and so forth) were excluded from the study. Mortality was in-hospital mortality. Major adverse cardiac events (MACEs) included cardiac deaths, myocardial infarction, and stroke. Length of stay in the intensive care unit (ICU) was also reviewed.

Statistical Analysis

In our data (ie, the validation set), the fitness of the original NYS logistic model was evaluated via *C* statistics (area under the receiver operating characteristic curve) and the Hosmer-Lemeshow test. The former helps evaluate the discriminatory power of the model: a *C* statistic value of 1.0 is excellent, whereas a value ≤0.5 indicates a poor discriminatory ability. The discriminatory ability of a model is considered good if the *C* statistic value is >0.70 [Swets 1988]. The Hosmer-Lemeshow goodness-of-fit test, measures a model's fitness in terms of its calibration. In brief, the Hosmer-Lemeshow test calculates variation in the χ^2 statistic by comparing the observed and predicted mortalities for 10 equal-sized groups according to their predicted risks [Hosmer 1989].

For the recalibrated model in this study, we assumed the relative effects of the regression coefficients of the original model and therefore carried out the following recalibration method, as previously described [Steyerberg 2004]. First, the original model was expressed as:

$$M = \alpha_{\text{origin}} + \sum_{i=1}^{N} (\beta_{\text{origin},i})(X_i),$$

where α_{origin} is the intercept and $\beta_{\text{origin},i}$ is the coefficient of the *i*th covariate (X_i) in the original model. We then constituted a new logistic model in the validation set, namely the recalibrated model in which *M*, the linear predictor based on the training set, is the only covariate:

$$\log(p_{\text{recal}}) - \log(1 - p_{\text{recal}}) = \alpha_{\text{recal}} + (\beta_{\text{recal}} \times M),$$

where p_{recal} is the predicted risk by the recalibrated model, *M* represents the original logistic model, and α_{recal} and β_{recal} are the intercept and coefficient, respectively, of the new model.

The mortalities predicted by the original model and by the recalibrated model were calculated and compared with observed mortalities at each risk-score level. The algorithm of predicted mortality at each risk-score level was previously proposed [Sullivan 2004]. Then, after the predicted risks were translated into the NYS score system, the correspondence between the NYS risk-score levels and end points such as in-hospital mortality, MACE rate, and length of ICU stay was investigated by means of a nonparametric test of the trend across ordered groups [Cuzick 1985].

Finally, we identified risk predictors of in-hospital mortality in the Chinese CABG Registry with methods that are almost the same as those used for establishing the original NYS model [Hannan 2006]. In brief, preoperative risk factors were chosen as potential risk predictors of in-hospital mortality. Five continuous variables (ie, age, ejection fraction, left ventricular end-diastolic diameter, body mass index, and preoperative serum creatinine concentration) were subdivided into categories according to the similarity in mortalities within categories. The χ^2 test or the Fisher exact test was used in univariate analyses. Variables with a *P* value of <.05 were placed in the stepwise logistic regression model. After the data were split into 2 identical halves with almost the same mortalities and prevalences of important risk factors, cross-validation was carried out by fitting the identified variables with *P* values <.10 in the stepwise model of one of the halves to a stepwise model in the other half. The remaining variables with *P* values <.05 were left in the final logistic regression model for the entire set. The definitions of the 10 variables in the original NYS model remained unchanged during this procedure. Results were expressed as the odds ratio and the 95% confidence interval (CI).

A *P* value <.05 was considered statistically significant. All analyses were carried out with SAS statistical software (version 9.1; SAS Institute, Cary, NC, USA).

RESULTS

Baseline Status

From January 2004 to December 2005, 9248 CABG patients were enrolled in the Chinese CABG Registry, and 8120 patients who underwent isolated CABG were selected for the present trial. The isolated-CABG subgroup comprised 1695 female patients (20.87%) and 6425 male patients (79.13%). The mean age (±SD) was 62.72 ± 9.19 years; Table 1 lists baseline values. The prevalences of the 10 NYS variables in the original data and our data were compared (Table 2). The 2 data sets were similar in prevalence only for shock; significant differences in prevalence existed for all of the other variables. A comparison of ages was impossible because

Table 1. Baseline Values for Risk Factors in the Chinese Coronary Artery Bypass Graft Registry Study*

Age, y	62.72 ± 9.19
Female sex, % (n)	20.87% (1695)
Unstable hemodynamic state, % (n)	28.51% (2315)
Ejection fraction, % (n)	
≥40%	95.48% (7753)
30%-39%	3.93% (319)
20%-29%	0.58% (47)
<20%	<0.01% (1)
Preprocedural myocardial infarction, % (n)	10.26% (833)
Chronic obstructive pulmonary diseases, % (n)	1.27% (103)
Extensively calcified ascending aorta, % (n)	1.66% (135)
Peripheral arterial diseases, % (n)	2.76% (224)
Preoperative serum creatinine, % (n)	
<130.0 μmol/L	94.95% (7710)
130.0-199.9 μmol/L	4.04% (328)
≥200 μmol/L but not requiring dialysis	0.41% (33)
Requiring dialysis	0.60% (49)
Previous open heart operations, % (n)	1.98% (161)
Hypertension, % (n)	65.28% (5301)
Diabetes, % (n)	27.30% (2217)
Hyperlipemia, % (n)	55.81% (4532)
Family history of CHD, % (n)	8.21% (667)
Smoking, % (n)	46.93% (3811)
Unstable angina, % (n)	26.51% (2153)
Left main disease, % (n)	27.32% (2218)
Single-vessel disease, % (n)	3.90% (317)
Double-vessel disease, % (n)	15.41% (1251)
Triple-vessel disease, % (n)	80.69% (6552)
Stroke, % (n)	8.36% (679)
Pulmonary hypertension, % (n)	6.05% (491)
Congestive heart failure, % (n)	4.66% (378)
Previous PCI, % (n)	11.40% (926)
Pacemaker, % (n)	0.43% (35)
Atrial fibrillation, % (n)	2.54% (206)
Continuous ventricular tachycardia or ventricular fibrillation, % (n)	0.43% (35)
Emergency/urgency, % (n)	7.22% (586)
Left ventricular end-diastolic diameter, % (n)	
<60 mm	91.07% (7395)
≥60 mm	8.93% (725)
Body mass index, % (n)	
<18.6 kg/m^2	1.63% (132)
18.6-24.9 kg/m^2	46.51% (3777)
25.0-29.9 kg/m^2	44.96% (3651)
≥30.0 kg/m^2	6.90% (560)

*Age data are presented as the mean ± SD. All other data are prevalences. CHD indicates coronary heart disease; PCI, percutaneous coronary intervention.

of the lack of the source data. Table 3 lists the distribution of NYS risk scores in the Chinese CABG Registry. Patients with risk scores ≤10 constituted 98.95% of the patients. The lowest score recorded in our data was 0, and the highest score was 21. In general, patients with lower scores were younger and had fewer preoperative comorbidities.

Table 2. Comparison of the Prevalence of NYS Predictors for the Original Data and Our Data*

Predictors	Original Data	Our Data	*P*
Patients, n	16,120	8120	
Age ≥60 y	Unavailable	63.39%	
Female sex	28.67%	20.87%	<.001
Hemodynamic state			
Hemodynamically stable	98.57%	81.49%	<.001
Unstable	0.95%	27.89%	<.001
Shock	0.48%	0.62%	NS
Ejection fraction			
<20%	1.93%	<0.01%	<.001
20%-29%	6.87%	0.59%	<.001
30%-39%	13.29%	3.93%	<.001
≥40%	77.91%	95.48%	<.001
Preprocedural MI			
No preoperative MI within 20 d	76.04%	89.72%	<.001
<6 h	0.69%	1.12%	<.001
6-23 h	0.94%	2.46%	<.001
1-20 d	22.33%	6.67%	<.001
COPD	16.50%	1.27%	<.001
Extensively calcified ascending aorta	4.84%	1.66%	<.001
Peripheral arterial diseases	11.22%	2.76%	<.001
Renal failure requiring dialysis	1.63%	0.60%	<.001
Previous open heart operations	4.93%	1.98%	<.001

*NS indicates not statistically significant; MI, myocardial infarction; COPD, chronic obstructive pulmonary disease.

OPCAB procedures were undertaken in 75.26% (6111) of the patients, and cCABG procedures accounted for the remaining 24.74% (2009 patients). The mean numbers of distal arterial and distal venous anastomoses were 1.06 ± 0.66 and 2.15 ± 1.07, respectively. The mean number of anastomoses per diseased vessel was 1.17 ± 0.35. The in-hospital mortality rate was 2.19% (178 patients), and the cardiac mortality rate was 1.32% (107 patients). Postoperative myocardial infarction occurred in 0.54% (44) of the patients, and stroke was observed in 0.46% (37) of the patients. The overall MACE rate was 2.17% (176 patients). The median length of ICU stay was 2 days (interquartile range, 1.5-4 days).

The Fitness of the Original Model and the Recalibrated Model

In the recalibrated model, α_{recal} and β_{recal} were –3.69 and 0.76, respectively. The *C* statistic values of the original and recalibrated models were both 0.74 (95% CI, 0.70-0.78), indicating the good discriminatory abilities of both models. The Hosmer-Lemeshow test, however, revealed that the original model had a poor calibration ($\chi^2 > 26.13$; $P < .001$), in contrast to the recalibrated model ($\chi^2 = 5.98$; $P = .65$). Figure 1 shows the degrees to which predicted mortality matched observed mortality before and after recalibration. Patients with scores ≥11 constituted only 1.05% of the

Table 3. Distribution of NYS Scores in the Chinese Coronary Artery Bypass Graft Registry

Total Risk Score	Patients at Each Score	Cumulative Percentage of This Score or Less	Total Risk Score	Patients at Each Score	Cumulative Percentage of This Score or Less
0	21.65%	21.65%	6	2.55%	92.88%
1	17.52%	39.17%	7	3.37%	96.25%
2	12.60%	51.77%	8	0.99%	97.24%
3	22.20%	73.97%	9	1.16%	98.40%
4	4.85%	78.82%	10	0.55%	98.95%
5	11.51%	90.33%	≥11	1.05%	100%

patients; therefore, scores ≥11 were combined. The original model overestimated mortalities at each score level; however, mortalities predicted by the recalibrated model were quite close to observed mortalities. At the score level of 8 to 10, the predicted mortality tended to underestimate the observed mortality but was still slightly above the lower limit of the observed mortality (Figure 1).

Fitness of NYS Score System

When the NYS model was translated into the NYS score system, the *C* statistic value was 0.74 (95% CI, 0.70-0.78). A linear relationship between observed mortalities and risk-score levels was evident (test for trend, $P < .001$). There was also a strong correlation between corresponding score level and both MACE rate and length of ICU stay (Figures 2 and 3).

Predictors of In-Hospital Mortality in the Chinese CABG Registry

Age, preoperative serum creatinine concentration, ejection fraction (patients with ejection fractions <30% were merged into a single category because only 1 patient had an ejection fraction <20%), chronic obstructive pulmonary diseases, emergent/urgent surgery, and previous open heart operations were identified as risk predictors for in-hospital mortality in the Chinese CABG Registry (see Table 4 for all the independent risk factors and their odds ratios, CIs, and *P* values in the new model). The new model was found to be adequate (*C* statistic, 0.80; 95% CI, 0.76-0.84; $\chi^2 = 3.16$; $P = .37$). Although there were some differences, the new logistic model shared many variables with the NYS model.

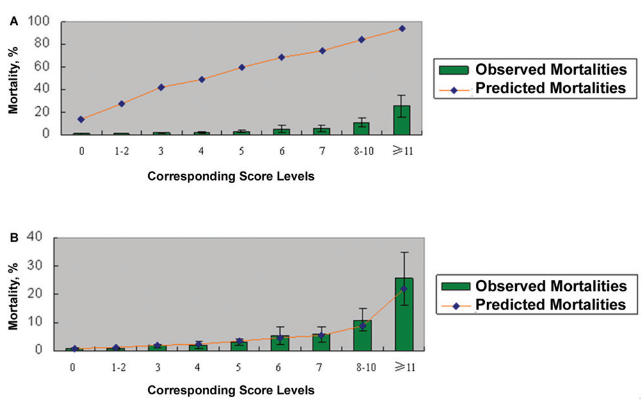

Figure 1. Observed mortalities and predicted mortalities at different risk-score levels. A, Predicted mortalities by the original logistic model. B, Predicted mortalities by the recalibrated NYS model. Observed mortalities are presented with 95% confidential intervals.

DISCUSSION

In the current study, the NYS model was validated in the Chinese CABG Registry. Although the original NYS system overestimates in-hospital mortalities, the recalibrated NYS system corrected such overestimations and performed well in the entire group. Moreover, strong correlations between risk-score strata and end points such as in-hospital mortality, MACE rate, and length of ICU stay also revealed the generalizability of the NYS model in Chinese CABG patients.

Why Is a Risk-Predictive Tool Needed for Chinese CABG Patients?

During the past several decades, the spectrum of diseases has been changing gradually in China. Ischemic heart disease, which ranked fifth in terms of prevalence in China between 1948 and 1958, climbed to rank first between 1972 and 1979 [Cheng 1998]. He and colleagues [2005] demonstrated CHD to be the third-leading cause of death from cardiovascular disease in China, after cerebrovascular disease and chronic pulmonary heart disease. Consequently, CABG and other treatments are increasing to meet the demand of the growing volume of patients with CHD. Under such circumstances, a risk-predictive tool is needed to facilitate decision making and quality control, which are vitally important for standardizing surgical procedures and improving the quality of care for Chinese CHD patients in the long run. Unfortunately, a risk-predictive model for Chinese CABG requires the

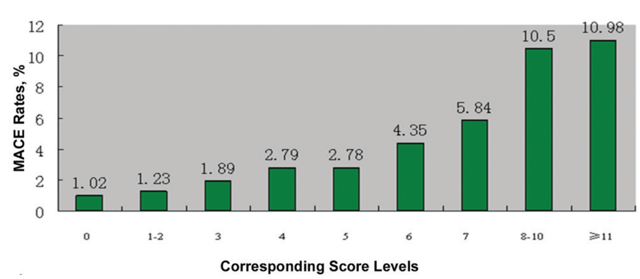

Figure 2. Major adverse cardiac event (MACE) rates at different score levels. $P < .001$, test for trend.

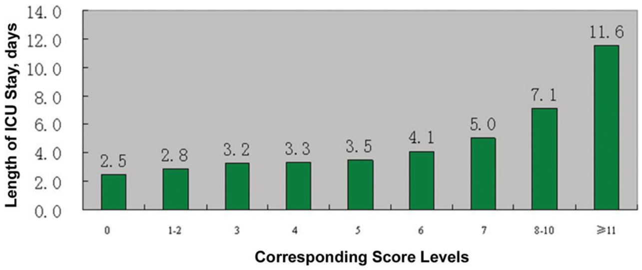

Figure 3. Mean lengths of intensive care unit (ICU) stay at different score levels. *P* < .001, test for trend.

establishment of a large population-based database across China; this effort is still in progress.

Moreover, in this era of globalizing medical resources, the gaps between different countries in such resources are actually getting smaller. The exchange of experience among different parts of the world has accelerated, and local experience has increasingly been transformed into worldwide benefit. Such exchanges of experience have to be based on comparable baselines, however. This goal can be fulfilled in part by applying generally accepted risk-predictive systems that can serve as a platform for unifying baseline assessments from different populations. Therefore, the introduction of an external risk-predictive model is needed for Chinese CABG.

What Are the Advantages of the NYS?

Compared with other scoring systems, most of which were published in the last century and were derived from patients who underwent various cardiac surgeries [Parsonnet 1989; Higgins 1992; Tu 1995; Nashef 1999], the NYS has several advantages. First, the NYS system was developed in patients undergoing isolated CABG. A better performance might be expected with the NYS system in this cohort, because our experience and that of others [Hannan 2006] indicated that the impacts of risk factors on CABG and non-CABG patients are different. Second, the NYS system was established during a period when new techniques were proliferating. Owing to innovations and refinements in surgical techniques, the risk-adjusted mortality of CABG has decreased by 23% while the preoperative risks have increased by 30% [Ferguson 2002]. The changing profile of preoperative risk factors and the interaction between risk factors and improvements in technique are more likely to have been embodied in a risk-predictive model that came forth during this period. Third, NYS is easy to manipulate because it incorporates only 10 variables that are easy to measure in clinical scenarios.

Table 4. Predictors of In-Hospital Mortality in the Chinese Coronary Artery Bypass Graft Registry*

	Odds Ratio	95% CI	*P*
Age			
<61 y	1.00	Reference	
61-69 y	1.54	1.02-2.32	.039
70-79 y	2.26	1.49-3.43	<.001
≥80 y	7.50	3.13-17.95	<.001
Preoperative serum creatinine			
<130.0 µmol/L	1.00	Reference	
130.0-199.9 µmol/L	2.72	1.68-4.41	<.001
≥200 µmol/L but not requiring dialysis	5.64	2.39-13.33	<.001
Requiring dialysis	5.80	2.01-16.69	.001
Ejection fraction			
≥40%	1.00	Reference	
30%-39%	2.03	1.23-3.37	.006
<30%	2.66	1.12-6.32	.027
COPD	2.68	1.28-5.61	.009
Previous open heart operations	2.47	1.18-5.14	.016
Emergency/urgency	4.51	3.18-6.40	<.001

*CI indicates confidence interval; COPD, chronic obstructive pulmonary disease.

To What Degree Does NYS Fit in the Chinese CABG Registry?

The original NYS overestimated in-hospital mortalities in the Chinese CABG Registry, but the overestimation was corrected by recalibration. Analogously, Liu et al [2004] noted similar observations when the Framingham CHD-assessment tool was applied in a Chinese multiprovincial cohort study. These results indicate that the overestimation of risks in the Chinese population by a Western risk-predictive system is not due to chance observation; however, such mismatches can be effectively adjusted by recalibration.

After recalibration, the NYS model was applied satisfactorily in the Chinese CABG Registry. There were no departures in terms of calibration, and the discriminatory ability was good for the entire data set. In addition, the translation of NYS-predicted risks into scores revealed strong correlation between risk-score strata and important end points, including in-hospital mortality, MACE, and length of ICU stay. This correlation might be explained by the fact that the selected end points in the current study shared risk predictors [Huijskes 2003; Thielmann 2007] and that such predictors have already been included in the NYS system.

What Has Been Hinted at in the New Logistic Model from the Chinese CABG Registry?

Many variables included in NYS system were also incorporated in the new model developed from the Chinese CABG Registry, but some differences still exist between the NYS model and the new logistic model (Tables 2 and 4). There is no doubt that the reasons for the differences are multifactorial. Ethnicity- or region-based differences, which have been demonstrated in numerous studies [Woo 1997; Wu 2001; Critchley 2004], might play an important role.

Other factors, such as differences in surgical strategies, might have an influence on the final models. For example, the variable of female sex, although recognized as a risk factor for in-hospital mortality in CABG patients [Tu 1995; Myers 1999], was excluded from the new model. Such a result was rationalized because Puskas and colleagues [Edwards 1998] had demonstrated that women patients undergoing OPCAB had a narrow sex-specific advantage in immediate outcomes.

Therefore, it is likely that the nonparsimonious adoption of OPCAB techniques in the Chinese CABG Registry benefited women patients and that the high proportion of OPCAB patients weakened the influence of female sex on outcomes after CABG.

Limitations of the Current Study

Despite the voluntary basis of the Chinese CABG Registry, the participating institutions are mainly referral or large-volume centers. Thus, the results may not be representative of the overall surgical level of CABG in China. Large population-based studies are required to further address this issue. In addition, with the exception of in-hospital mortality, the other end points in the current study (MACE and length of ICU stay) are different from those of the original report (cardiac surgery–reporting system complications and length of stay). We did not use the original end points because we could not acquire complete data for these variables; however, we suppose that the end points in the current study are relevant to those in the original report and that an analogy could be made to some extent.

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