309. The patients were divided into 2 groups: the derivation and validation groups. The derivation group consisted of 209 patients who underwent surgery from January 2004 to June 2006, and the validation group consisted of 100 patients who underwent surgery from July 2006 to December 2007. The nomogram was constructed on the basis of derivation group data, and its predictive utility was validated in the validation group.

Statistical Analysis

The Kaplan-Meier method was used to estimate overall survival and recurrence-free survival, and the log-rank test was used to analyze differences in survival between groups. For the derivation group, the following potential prognostic variables were assessed: sex, age, and sex (general characteristics); tumor location, depth of invasion, regional lymph node metastasis, distant metastasis, lymphatic invasion, venous invasion, histologic differentiation, and the presence of concomitant CRCs and/or adenomas at the time of surgery (cancer-related variables); and smoking, body mass index greater than 25 kg/m^2, history of previous malignancies (CRC or extracolic malignancy), first-degree family history of CRC, hypertension, hyperlipidemia, and diabetes mellitus (patient background variables). A multivariate Cox proportional hazards analysis was performed using variables whose P value was less than 0.2 in univariate analysis. By following the method of Wang et al,[15] we built nomograms for predicting the probability of 3- and 5-year adenoma-free survival rates after surgery. The nomogram was subjected to 100 bootstrap resamples for calculating the estimated Harrell concordance index (c-index) as an index of model performance.[16] The c-index estimates the probability of concordance between predicted and observed outcomes in rank order and is equivalent to the area under the receiver operating characteristic curve, if there are no censored cases.[16] It represents the ability of the model to discriminate between patients who survived without adenoma development and those who did not. Higher values indicate better discrimination: a value of 0.5 indicates no predictive discrimination, whereas a value of 1.0 indicates perfect separation of patients with different outcomes.

We also performed calibration using a calibration curve, a graphic representation of the relationship between the observed outcome frequencies and the predicted probabilities, with both the derivation and validation groups. Using the constructed nomogram, the score of predicting the 5-year adenoma-free survival rate was calculated for both groups. All statistical analyses were performed using the statistical software program R 3.0.1 with rms and Hmisc packages (http://www.r-project.org/).

RESULTS

Of the 552 patients enrolled in the study, 243 were excluded for the following reasons: 227 patients did not undergo colonoscopic surveillance (CRC progression in 108 patients, other disease progression in 64 patients, and a move or change of hospital in 55 patients), 4 patients had colitic cancers, 3 patients had polyposis, and 3 patients died during the perioperative period. The differences between the included and excluded patients are presented in Table 1. Because a large proportion of the patients excluded from the analysis had residual cancer or recurrence, and most of the remaining excluded patients failed to receive surveillance because of the development of diseases other than CRC, the age and stage of initial CRC were higher in the excluded group than in the included group. General characteristics related to adenoma formation are also presented in Table 2. The characteristics of patients in the derivation and validation groups were comparable. The incidence of CRC formation per year was 0.0064 in both groups, and that of adenoma formation was approximately 0.084 in both groups. Although the 5-year adenoma-free rate was a little lower in the validation group, this difference was not statistically significant ($P = 0.077$).

TABLE 1. Differences Between Included and Excluded Patients

	Included	Excluded	*P*
Total, n	309	243	
Sex, n			
Male	199	149	
Female	110	94	0.4564
Age, mean ± SD, yr	63.2 ± 10.3	68.0 ± 11.7	<0.001
Location, n (%)			
Right hemicolon	68 (22.0)	78 (32.1)	
Left hemicolon	112 (36.2)	76 (31.3)	
Rectum	129 (41.7)	89 (36.6)	0.0288
Stage, n (%)			
0/I	99 (32.0)	45 (18.5)	
II	105 (34.0)	69 (28.4)	
III	84 (27.2)	70 (28.8)	
IV	21 (6.8)	59 (24.3)	<0.001

TABLE 2. Patient Characteristics

	Derivation Data Set	Validation Data Set
No. patients	209	100
Sex, n (%)		
Male	134 (64.1)	64 (64)
Female	75 (35.9)	36 (36)
Median follow-up time, yr	5.57	5.04
Total follow-up time, yr	1097.0	466.5
Total colorectal cancer cases developed during follow-up time, n	7	3
Incidence per year	0.00638	0.00643
Total colorectal adenoma cases developed during follow-up time, n	93	39
Incidence per year	0.08470	0.08359
Cumulative 5-yr adenoma-free rate	75.35%	71.71%
95% CI	68.31–81.25	61.30–80.22

CI indicates confidence interval.

Development of the Nomogram

The results of the univariate and multivariate analyses of the association between variables and the 5-year adenoma-free survival rate are shown in Table 3. In the univariate analysis, male patients and older patients had a significantly shorter adenoma-free survival time. The variables associated with progression of the primary cancer, such as T stage and presence of lymph node or distant metastasis, showed no correlation with postoperative adenoma development, consistent with our previous report. Although the presence of second or additional primary CRC showed no correlation, if both synchronous CRC and adenomas were included in the category sublesions, the presence of sublesions was strongly associated with postoperative adenoma development. We previously reported that the presence of diabetes mellitus correlated with postoperative development[11]; however, in this study, no variables concerning patient background, including diabetes mellitus, correlated with adenoma development.

Therefore, we performed multivariate analysis using the variables of sex, age, and the presence of concomitant colorectal

TABLE 3. Univariate and Multivariate Analyses of the Association Between Clinicopathological Factors and Postoperative Adenoma-free Intervals

	Univariate Analysis		Multivariate Analysis		
	5-yr Adenoma-free Survival	*P*	Hazard Ratio	95% CI	*P*
Sex					
Female	84.5%				
Male	68.2%	0.0404	1.75	0.89–3.71	0.1102
Age					
<70 yr	76.6%				
≥70 yr	62.4%	0.0188	1.95	1.04–3.54	0.0387
Cancer-related variables					
Tumor location					
Right-sided colon	74.9%				
Left-sided colon	74.6%				
Rectum	73.1%	0.7888			
Depth of invasion					
T1/2	72.7%				
T3/4	74.1%	0.9003			
Regional lymph node metastasis					
N0	72.2%				
≥N1	76.9%	0.3909			
Distant metastasis					
M0	73.3%				
M1	80.9%	0.503			
Lymphatic invasion					
Absent	74.5%				
Present	71.4%	0.8254			
Venous invasion					
Absent	73.9%				
Present	74.3%	0.957			
Histopathology					
Well or moderate	73.0%				
Other	90.9%	0.106	2.54	0.54–45.43	0.2874
Concomitant colorectal cancers at the time of surgery					
Absent	75.0%				
Present	64.0%	0.1367	1.45	0.66–2.93	0.3394
Concomitant colorectal cancers and adenomas at the time of surgery					
Absent	84.2%				
Present	61.0%	<0.0001	1.95	1.04–3.54	0.0387
Patient background variables					
Smoking					
Absent	77.6%				
Present	69.2%	0.1768	1.23	0.69–2.23	0.4825
Body mass index ≥25 kg/m^2					
Absent	72.2%				
Present	77.2%	0.5937			
History of malignancies					
Absent	74.8%				
Present	64.6%	0.1307	1.39	0.60–2.81	0.4158
Family history of colorectal cancer					
Absent	72.6%				
Present	83.8%	0.2803			
Hypertension					
Absent	77.2%				
Present	66.8%	0.0994	1.03	0.57–1.91	0.9314
Hyperlipidemia					
Absent	74.3%				
Present	69.6%	0.6153			
Diabetes mellitus					
Absent	75.4%				
Present	66.9%	0.399			

CI indicates confidence interval.

sublesions. Because the latter 2 variables were independent predictive factors in the prediction of adenoma development and sex also showed a trend toward correlation, we constructed the nomogram with point scales of these 3 variables (Fig. 1). The sum of the each variable point was plotted on the total point axis, and the estimated median 3- and 5-year adenoma-free survival rates were obtained by drawing a vertical line from the plotted total point axis straight down to the outcome axis. The c-index of this model was 0.709, indicating good discrimination. Figure 2A shows the calibration graph for the nomogram, in which the probability of 5-year adenoma-free survival as predicted by the nomogram is plotted against the corresponding observed survival rates obtained by the Kaplan-Meier method. This illustration demonstrates good calibration of the nomogram. Furthermore, the derivation group was further stratified into 3 groups according to the score calculated using the nomogram: the high-risk (>75th percentile of the group), low-risk (<25th percentile), and intermediate-risk (25th–75th percentile) groups. Figure 3A demonstrates that scoring with the nomogram effectively discriminated the risk of postoperative adenoma development.

Validation

To validate whether the nomogram would be applicable to other data sets, we conducted a validation study using data from the 100 CRC patients in the validation group. The c-index of the validation group was 0.712, demonstrating that the nomogram also showed good prediction in the validation patient group. Moreover, the calibration plot of the validation group demonstrated good calibration (Fig. 2B). Patients in the validation group were also stratified by percentile into 3

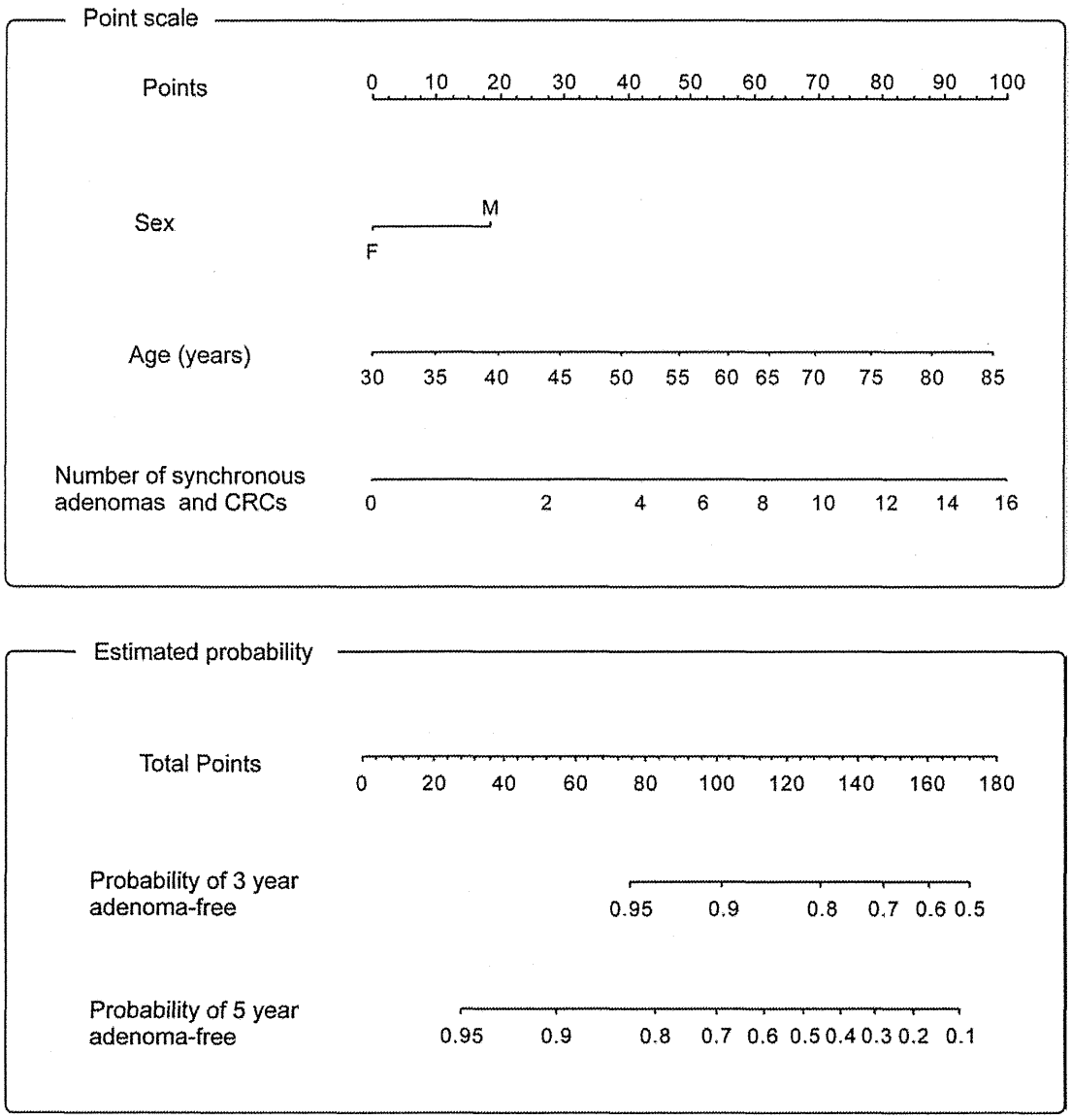

FIGURE 1. Nomogram for predicting postoperative adenoma-free survival after surgery for colorectal cancer. The 3- and 5-year probabilities of survival without adenoma or CRC development is estimated by summing the score of the 3 variables, that is, sex, age, and the number of synchronous adenomas and CRCs at the time of surgery.

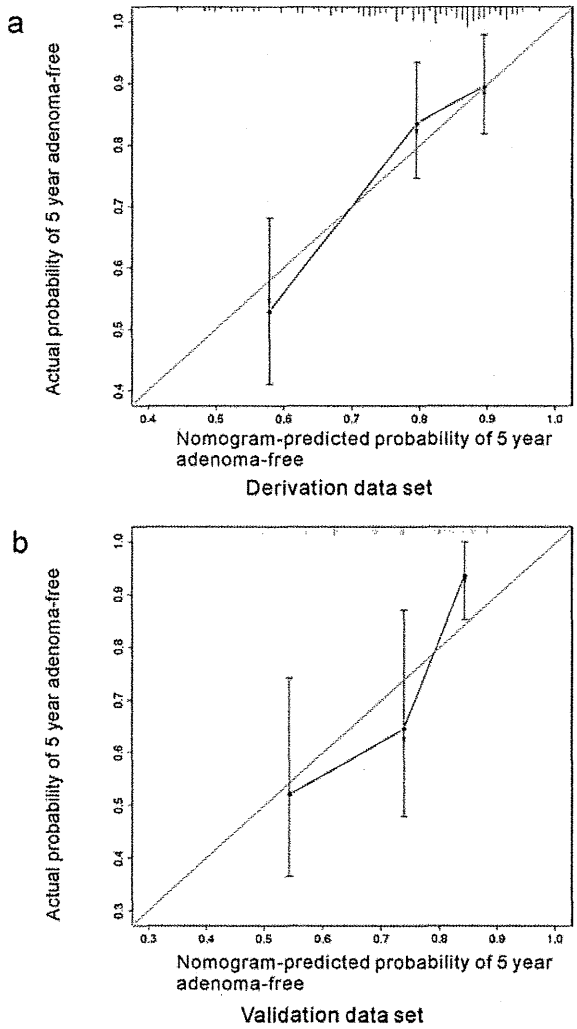

FIGURE 2. Calibration of the nomogram in the derivation (A) and validation (B) data sets. The horizontal axis is the nomogram-predicted probability of adenoma-free survival at 5 years, and the vertical axis is the actual adenoma-free survival rate estimated at 5 years using the Kaplan-Meier method. The line from the lower left to the upper right corner of the plot area is the reference line that indicates ideal prediction. Bars indicate 95% confidence intervals.

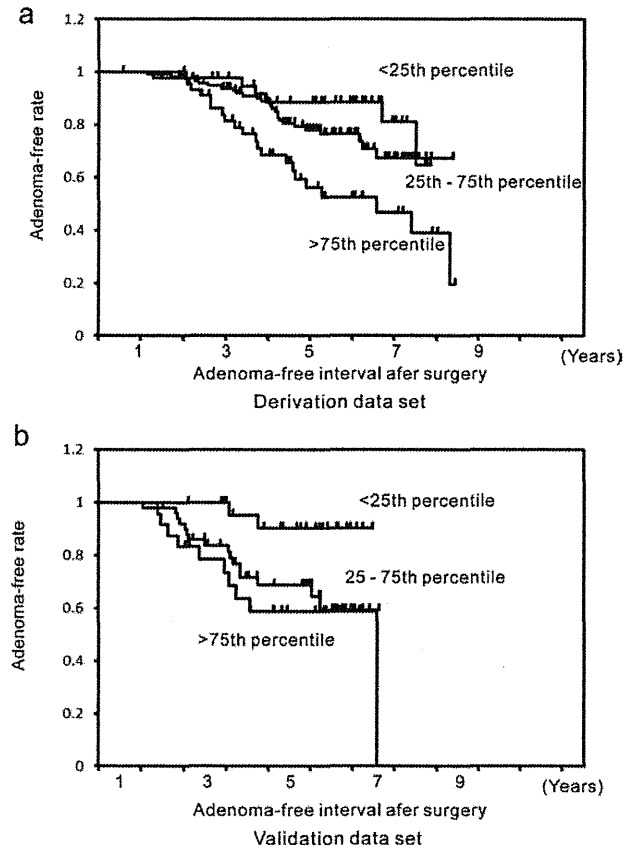

FIGURE 3. Actual adenoma-free survival curves of patients in the derivation (A) and validation (B) sets stratified by quartiles of the nomogram-predicted score. The patients were stratified into 3 groups according to their percentile of the nomogram-predicted score: <25th, 25th–75th, and >75th percentile.

groups (<25th, 25th–75th, and >75th percentile), and the adenoma-free survival in each group was found to increase in this order of patient groups, similar to the result of the derivation group (Fig. 3B).

DISCUSSION

Because CRC patients are at high risk for developing metachronous colorectal adenoma or carcinoma after resection of the primary tumor,[5,17] many studies have attempted to identify the risk factors predicting the development of postoperative neoplasms, but only a few factors have been reported. In the present study, we evaluated possible risk factors by dividing them into sex, age, cancer-related variables, and patient background variables. Initially, in our analysis, male sex was a higher risk factor for postoperative neoplasm development, but the correlation was not strong in the multivariate analysis. This may be explained by the fact that the male patients were on average older than the female patients and advanced age was a strong risk factor. Moon et al[18] also reported that male sex correlated with postoperative adenoma development in a univariate analysis; however, similar to our study, the correlation was not statistically significant by multivariate analysis. Furthermore, they found that age was a risk factor for adenoma development,[18–20] also corroborating our results.

The variables related to cancer progression or malignant potential, such as depth of invasion or presence of metastasis, showed no correlation with postoperative adenoma development. Although several studies have reported that the location of the primary CRC in the proximal colon is a risk factor for metachronous adenoma,[21,22] we failed to find any correlation between primary CRC location and the incidence of postoperative adenoma development. On the contrary, similar to the results of this study, the presence of synchronous colorectal adenomas has been reported to be a risk factor in many studies.[3,11,17,22,23] Chu et al[24] reported that 6.5% of patients with synchronous polyps had metachronous large bowel cancer whereas 3.4% of those without polyps developed metachronous large bowel cancer. Moreover, multiple polyps are associated with a higher risk of metachronous colorectal cancer than single polyps.[25] Correlations between other variables related to patient background and postoperative polyp development were also investigated. We evaluated a variety of

factors reported to be associated with adenoma formation, including previous cancer history, family history of CRC, hyperlipidemia, hypertension, diabetes mellitus, obesity, and smoking habits,[20,26–30] but no correlations were observed with any of these variables. In our previous study, we reported that diabetes was an independent predictive factor for adenoma development[11]; however, there was no correlation in the present study.

Because the nomogram is intended to be used for pragmatic postoperative surveillance in municipal hospitals, the variables included in the nomogram should be limited. Too many variables can make calculating the predictive score cumbersome, and variables with a lopsided risk group distribution will be less useful in clinical application, even if the variables are statistically significant. Although expression of MUC-5 in the initial CRC has been reported to have a protective effect,[22] and microsatellite instability has been reported to be a possible risk factor for the development of metachronous colorectal neoplastic lesions,[31] variables that require experimental techniques such as immunohistochemistry or gene analysis are inappropriate as parameters for a nomogram. Furthermore, a nomogram has an advantage over other statistic models because continuous variables can be directly converted to a prognosis-predicting score and therefore continuous variables are more desirable than categorized ones. From these perspectives, the variables we adopted for the nomogram in the present study are ideal (sex, age, and number of synchronous lesions).

Chung et al[32] evaluated the cumulative incidence of colorectal neoplasia development by stratifying patients according to risk factors. They recommended extending the surveillance interval beyond 5 years for the low-risk group, in which the 5-year incidence of adenoma development was 45.8%. A 3-year colonoscopic follow-up period was recommended for the high-risk group, in which the 5-year incidence of adenoma development as 57.8%. Similarly, a number of guidelines for polyp surveillance have been published and most of these recommend 3-year intervals for high-risk patients and intervals of 5 or more years for low-risk patients.[33–35] Further to these previous reports, we recommend extending the colonoscopic surveillance interval to 5 years for those whose probability of 5-year adenoma-free survival is more than 50%, that is, for those with fewer than 120 points according to the nomogram. Conversely, those with a probability of 5-year adenoma-free survival less than 50%, that is, with more than 120 points according to the nomogram, should undergo a colonoscopy at least every 3 years. However, there have been no published guidelines concerning the ideal colonoscopic interval after CRC resection. Therefore, the validity of the intervals recommended by our nomogram should be prospectively evaluated in the future.

The c-indexes of nomograms previously reported were approximately 0.7. For example, c-indexes were 0.68 to 0.73 for predicting the prognosis of rectal cancer,[36] 0.69 for predicting recurrence after surgery for breast cancer,[37] and 0.66 to 0.70 for predicting recurrence of desmoid fibromatosis.[38] The nomogram we constructed showed moderate prediction capability in the derivation set, comparable with these previous reports, as shown in both the calibration plot and the Kaplan-Meyer adenoma-free survival plot. The calibration plot showed a similar distribution to the ideal reference line, and the survival plot showed good stratification of metachronous lesion-free intervals by nomogram scoring. Because application of the nomogram to the validation set also showed moderate prediction capabilities in the calibration and survival plots, the nomogram may be applicable in other hospitals.

CONCLUSIONS

This nomogram is the first statistical model for predicting the development of metachronous colorectal lesions, and it may be of great assistance during postoperative surveillance after CRC surgery.

ACKNOWLEDGMENT

The authors thank Yukihide Kanemitsu from the National Cancer Center Hospital for providing statistical assistance.

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Predictors of 90-day mortality after congenital heart surgery: The first report of risk models from a Japanese database

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Objective: The purpose of this study was to develop risk models for congenital heart surgery short-term and midterm outcomes from a nationwide integrated database drawn from hospitals in Japan.

Methods: The Japan Congenital Cardiovascular Surgery Database collects clinical information from institutions throughout Japan specializing in congenital heart surgery. Variables and definitions used in the Japan Congenital Cardiovascular Surgery Database are almost identical to those of the Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery database for congenital heart surgery. We used logistic regression to develop risk models, which were then validated through spilt-sample validation. In addition to procedural complexity categories by Risk Adjustment in Congenital Heart Surgery (RACHS-1) score, we incorporated patient characteristics to predict surgical outcome.

Results: Among 8923 congenital heart operations performed at 69 sites with cardiac surgical programs, 30-day mortalities by RACHS-1 category were as follows: I, 0.1% (n = 1319); II, 0.5% (n = 3211); III, 2.2% (n = 3285); IV, 4.3% (n = 818); and V and VI, 8.6% (n = 290). From the test data set (n = 7223), we developed 3 risk models (30-day mortality, 90-day mortality, and 90-day and in-hospital mortality) with 11 variables, including age category, RACHS-1 category, preoperative risk factors, number of surgical procedures, unplanned reoperations, status of surgery, surgery type, asplenia, and prematurity (<35 weeks). For the performance metrics of the risk models, C statistic values of 30-day, 90-day, and 90-day and in-hospital mortalities for the test data set were 0.85, 0.85, and 0.84, respectively. When only the RACHS-1 score was used for discrimination, the C statistic values of 30-day, 90-day, and 90-day and in-hospital mortalities for the validation data set were 0.73, 0.73, and 0.77, respectively.

Conclusions: The proposed risk scores and categories have high discrimination power for predicting mortality, demonstrating improvement relative to existing consensus-based methods. Risk models incorporating these measures may be useful for comparing mortality outcomes cross institutions or countries with mixed cases. (J Thorac Cardiovasc Surg 2014;148:2201-6)

See related commentary on pages 2206-7.

Congenital heart surgery is one of the most challenging areas in the entire field of surgery. This may be particularly true for open palliative procedures with cardiopulmonary bypass in immature neonates with complex congenital heart disease. Open repair in adult patients with congenital heart disease also carries a high risk associated with multiorgan dysfunction because of long-standing cyanosis. The Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery database for congenital heart surgery lists 148 types of surgical procedures.[1] The need to establish clinical registries and quantitative tools for responsible outcome reporting has been recognized.

Previous risk classification of complex congenital heart surgery has been based on complexity scores, rather than surgical procedure-based classification. Satisfactory mortality prediction can be achieved with Society of Thoracic Surgeons–European Association for Cardiothoracic Surgery scores and categories (C statistics 0.784 and 0.733, respectively).[1] With respect to procedural complexity, the Risk Adjustment in Congenital Heart Surgery (RACHS-1)[2,3] and Aristotle[4,5] basic scores are used in the Society of Thoracic Surgeons and European Association for Cardiothoracic Surgery databases.[6] Each score is decided on by a committee composed of specialists, meaning that it is derived from subjective indicators that do not account

From the Japan Cardiovascular Surgery Database Organization, Tokyo, Japan.
Funded by a Grant-in-Aid for Scientific Research, the Ministry of Education, Culture, Sports, Science and Technology, Japan.
Disclosures: Authors have nothing to disclose with regard to commercial support.
Received for publication Sept 17, 2012; revisions received Dec 12, 2012; accepted for publication Jan 14, 2013.
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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2013.01.053

Abbreviations and Acronyms
JCCVSD = Japan Congenital Cardiovascular Surgery Database
RACHS-1 = Risk Adjustment in Congenital Heart Surgery

for patient factors.[2-5] In this study, we examined the validity of risk stratification according to procedural complexity by using data. The development of an objective model with high reproducibility is desired for benchmarking purposes.[7,8] In addition to incorporating the procedural complexity indicators mentioned previously, we also included patient-derived risk factors to develop an explanatory, objective model. Moreover, whereas previous studies have used in-hospital mortality for benchmarking,[9] we also incorporated 90-day mortality to assess longer-term outcomes than previously addressed.

CHD

MATERIALS AND METHODS

Study Population

In 2000, the Japanese Society for Cardiovascular Surgery established a nationwide database to assess surgical outcomes after cardiovascular surgery. In 2008, the Society launched the Japan Congenital Cardiovascular Surgery Database (JCCVSD) for congenital heart surgery.[10] The JCCVSD currently collects clinical information from 82 Japanese institutions specializing in congenital heart disease, covering almost all major congenital heart surgery programs in Japan. Each participating hospital has received the appropriate approval from the respective institutional review board.

Eight-two sites have participated in the JCCVSD, and 64 sites of these sites submitted the data of 2008 through 2010. Items in the database include demographic information, cardiac and noncardiac anomalies, comorbid conditions, and surgical type and outcomes. Definitions of these variables are essentially identical to those of the Society of Thoracic Surgeons database[11] (definitions are available online at http://sts.org). The JCCVSD has developed a web-based data-collection software system through which the data manager of each participating hospital can electronically submit data to the central office. Validity of the data sets has been confirmed by an independent comparison of the volume of cardiac surgery at a particular hospital entered in the JCCVSD versus that reported to the Japanese Association for Thoracic Surgery annual survey.[12]

We examined all congenital heart surgical procedures reported between August 1, 2008, and December 31, 2010. JCCVSD records obtained without patient consent were excluded from this analysis. We included 9401 records with age (or age range), sex, and 90-day status and excluded 2045 for which the RACHS-1 score was unavailable. On the basis of RACHS-1 scores,[2,3] we included only the operation with the highest RACHS-1 score for each hospital admission, excluding other surgical procedures (n = 478) within the same admission. In the end, the population for this analysis comprised 8923 congenital heart surgical procedures from 69 participating institutions throughout Japan.

With respect to risk factors, although the vast majority of JCCVSD patient are young, there are some adult congenital heart surgical cases. Although we added age category as a general risk factor, it is better to add acquired risk factors when assessing the adult population. Further research might better to consider this matter. Also, because of the limitation of low event rate, we used a large category of preoperative risk factor to examine risk in the JCCVSD at the initial phase.

End Points

The primary outcome measure of JCCVSD was 30-day mortality, which included any patient who died during the index hospitalization as of day 30 after the operation, regardless of the length of the hospital stay, and any patient who died after being discharged from the hospital within 30 days of the operation. The secondary outcomes of the JCCVSD were 90-day mortality and 90-day and in-hospital mortality. The 90-day mortality was defined as death within 90 days after the operation, regardless of in-hospital or out-of-hospital status. The 90-day and in-hospital mortality included any death during the index hospitalization, regardless of length of hospital stay, and any death occurring out of the hospital within 90 days after surgery.

Statistical Analysis

Data (n = 8923) were randomly divided into 2 subsets for model development, the test data set (7223 records; 80%) and the validation data set (1700 records; 20%). For the test data set, multivariate stepwise logistic regression analysis (forward inclusion method) was performed for each outcome. For the validation data set, the area under the receiver operating characteristic curve[13] was used to assess the discrimination power of the risk model for predicting patient mortality. Model calibration (the degree of similarity between observed outcomes and outcomes predicted by the model, compared across patient groups) was examined by comparing the observed and predicted averages within each of equally sized subgroups arranged in increasing order of patient risk.

RESULTS

Risk Profile of the Study Population

The patient population (total JCCVSD records, n = 8923) was classified according to RACHS-1 category[2,3] (category I, 1319; category II, 3211; category III, 3285; category IV, 818; category V, 4; and category VI, 286; Table 1). Of the patient population, 51.5% were male; 13.7% were neonates, 37.5% were infants, and 5.6% were adults; 26.8% were undergoing palliative operations and 73.2% were undergoing corrective operations; 6.2% had a birth weight lower than 2000 g; 2.2% were undergoing noninitial procedures; 68.4% were undergoing procedures with any preoperative risk factor; 2.1% had asplenia syndrome; and 0.5% were born at 32 to 35 weeks' gestation. The average hospital stays were 25.7 ± 37.3 days in the test data set and 26.0 ± 41.2 days in the validation data set.

Outcome Rates

Table 2 shows an abbreviated risk profile for the JCCVSD study population. Outcome rates associated with congenital heart surgery were 1.7% for 30-day mortality, 2.4% for 90-day mortality, and 2.8% for 90-day and in-hospital mortality. Outcome rates by RACHS-1 score (category I, II, III, IV, and V and VI combined) for 30-day mortality were 0.1%, 0.5%, 2.2%, 4.3%, and 8.6%, respectively; those for 90 day and in-hospital mortality were 0.2%, 0.7%, 3.0%, 5.5%, and 15.2%, respectively.

Model Results

Three different risk models (30-day mortality, 90-day mortality, and 90-day and in-hospital mortality) were

TABLE 1. Patient characteristics (n = 8923)

	Test data set (n = 7223)		Validation data set (n = 1700)		P
	n	%	n	%	value
RACHS-1 category					.989
I	1061	14.7	258	15.2	
II	2601	36.0	610	35.9	
III	2663	36.9	622	36.6	
IV	663	9.2	155	9.1	
V	3	0.04	1	0.1	
VI	232	3.2	54	3.2	
Age					
<28 d	980	13.6	241	14.2	.505
28 d-1 y	2695	37.3	654	38.5	.373
1-18 y	3144	43.5	704	41.4	.115
≥18 y	400	5.5	100	5.9	.598
Mortality					
30-d	123	1.7	28	1.6	1.000
90-d	168	2.3	210	2.4	.722
In-hospital	204	2.8	48	2.8	1.000
90-d and in-hospital	223	3.1	57	3.4	.588
Male sex	3694	51.1	904	53.2	.138
Preterm pregnancy	572	7.9	144	8.5	.457
Fetal diagnosis	1251	17.3	289	17.0	.775
Birth weight <2000 g	444	6.1	111	6.5	.577
Any preoperative risk factor	4922	68.1	1185	69.7	.223
≥2 surgical procedures	159	2.2	39	2.3	.794
Unplanned reoperations	489	6.8	130	7.6	.203
≥2 hospitalizations	633	8.8	134	7.9	.269
Status of surgery					
Urgent	567	7.8	126	7.4	.580
Emergency	148	2.0	48	2.8	.053
Surgery type					
Without CPB	1182	16.4	264	15.5	.421
Nonradical	1933	26.8	456	26.8	.976
Asplenia	145	2.0	43	2.5	.188
Down syndrome	282	3.9	67	3.9	.945
Polysplenia	58	0.8	11	0.6	.644
Prematurity					
<32 wk	14	0.2	5	0.3	.387
32-35 wk	33	0.5	8	0.5	1.000

RACHS-1, Risk Adjustment in Congenital Heart Surgery [score]; *CPB*, cardiopulmonary bypass.

developed. The final logistic models with odd ratios and 95% confidence intervals are presented in Table 2. We included 11 variables as adjustment factors for the final risk models, such as age (<28 days and <28 days), RACHS-1 category (I, II, III, IV, and V and VI combined), birth weight (<2000 g), the presence of preoperative risk factors, the number of procedure (>2), unplanned reoperation, status of surgery (urgent and emergency), surgery type (nonradical), asplenia, and prematurity (<35 weeks). We defined a *nonradical operation* as any palliative operation. For example, nonradical operations would include Blalock-Taussig shunt for cyanotic congenital heart disease.

Model Performance

C statistic values for 30-day, 90-day, and 90-day and in-hospital mortalities for the validation data set were 0.79, 0.81, and 0.84, respectively; for the test data set, they were 0.83, 0.85, and 0.84 respectively. When only the RACHS-1 score was used, C statistic values for 30-day, 90-day, and 90-day and in-hospital mortalities for the validation data set were 0.73, 0.73, and 0.77, respectively; for the test data set, they were 0.76, 0.78, and 0.77, respectively.

Observed Versus Predicted Mortality

The comparison of predicted and observed mortality by risk categories for 30-day mortality, 90-day mortality, and 90-day and in-hospital mortality are shown in Figures 1 through 3. For 30-day mortality, observed mortality and predicted mortality were 0.0072 and 0.0310 (risk >0.5%), 0.0050 and 0.0068 (0.5%-1.0%), 0.0063 and 0.0124 (1.9%-2.0%), 0.0318 and 0.0265 (2.0%-4.0%), 0.0710 and 0.0576 (4.0%-8.0%), and 0.1416 and 0.1792 (≥8.0%), respectively (Figure 1). For 90-day and in-hospital mortality, observed mortality and predicted mortality were 0.0036 and 0.0049 (>1.0%), 0.0095 and 0.0143 (1.0%-2.0%), 0.0234 and 0.0308 (2.0%-4.0%), 0.0753 and 0.0642 (4.0%-8.0%), 0.1765 and 0.1277 (8.0%-16.0%), and 0.2239 and 0.2964 (≥16.0%), respectively (Figure 3).

DISCUSSION

The risk model that incorporated patient characteristics in procedural complexity categories was more discriminating than a model that solely used procedural complexity categories. When only the RACHS-1 score was used, discriminating power was relatively satisfactory at 0.73 to 0.77. This discriminating power was similar to that seen with the population of the region in which RACHS-1 was designed,[3] suggesting that procedural complexity categories can also be applied to Japanese populations. Moreover, after incorporation of patient-derived factors such as age categories, preoperative weight, and preoperative risk factors, the C statistic values of models with 0.5 increased to more than 0.5, reflecting an increase in discriminating power. The mortality predicted by our risk model and the observed mortality were similar in both low-risk and high-risk groups, suggesting that our calibration was also valid to a certain degree. These findings suggest that a risk model that incorporates patient characteristics in procedural complexity categories according to RACHS-1 presents a useful framework for calculating predicted mortality.

In this study, a risk model was developed for 90-day mortality and in-hospital mortality in addition to 30-day mortality. A satisfactory 30-day mortality can be attributed

TABLE 2. Description of risk models (n = 7223)

	30-d mortality		90-d mortality		90-d and in-hospital mortality	
	OR	95% CI	OR	95% CI	OR	95% CI
Age <28 d	2.21	1.47-3.32	1.88	1.28-2.75	2.25	1.64-3.09
RACHS-1 category (I, II, III, IV, and V plus VI)	1.98	1.62-2.43	2.35	1.97-2.82	2.08	1.76-2.48
Birth weight <2000 g	—	—	2.23	1.32-3.78	1.99	1.21-3.26
Any preoperative risk factor	2.31	1.36-3.91	1.80	1.17-2.77	1.94	1.34-2.82
≥2 surgical procedures	—	—	—	—	1.96	1.19-3.22
Unplanned reoperations	1.96	1.10-3.57	2.00	1.18-3.38	2.12	1.34-3.36
Status of surgery						
Urgent	—	—	1.56	1.00-2.44	—	—
Emergency	4.13	2.34-7.28	4.52	2.62-7.77	3.46	2.12-5.65
Nonradical surgery	2.83	1.89-4.25	2.74	1.92-3.91	2.67	1.95-3.65
Asplenia	—	—	—	—	3.86	2.08-7.17
Prematurity	4.27	0.97-18.7	—	—	4.39	1.51-12.8

OR, Odds ratio; *CI*, confidence interval; *RACHS-1*, Risk Adjustment in Congenital Heart Surgery [score].

to the adequate provision of resources for hospital care, such as postoperative intensive care, and is reflected by long-term hospitalization that lasts on average 1 month, because mortality may be related to prolonged stay.[14] This exemplifies the characteristics of the Japanese health care system, and similar trends have been reported in the field of adult cardiac surgery.[15] Because long-term hospitalization is connected to the inefficient use of medical resources,[16] cost efficiency should also be considered in the future. Moreover, most deaths within 90 days occurred within the hospitalization period. This is connected to the fact that there were fewer missing values for variables that tend to be missing from foreign databases, such as 30-day mortality and 90-day mortality.[17] Although there is very little difference in included items and odds ratios for risk models of 30-day mortality and 90-day and in-hospital mortality, emergency surgery tends to have a relatively large effect on 30-day mortality, whereas birth weight and number of procedures tend to have a large effect on 90-day mortality. In light of the approximately 2-fold gap between 30-day and 90-day mortalities, it will be important to consider how to address patients who die within this period.[18]

Although our risk models showed good performance, there is still room for improvement. First, with respect to 90-day and in-hospital mortality, the model simultaneously overestimated the risk in the group with a predicted mortality greater than 16% and underestimated the risk in the group with a predicted mortality of 8% to 16%. Thus improving accuracy for high-risk groups will be important.

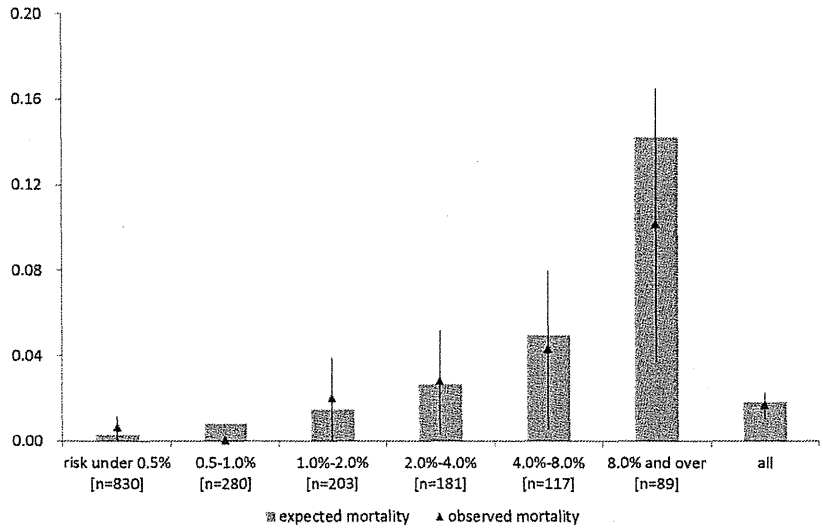

FIGURE 1. Predicted and observed 30-day mortality by risk categories.

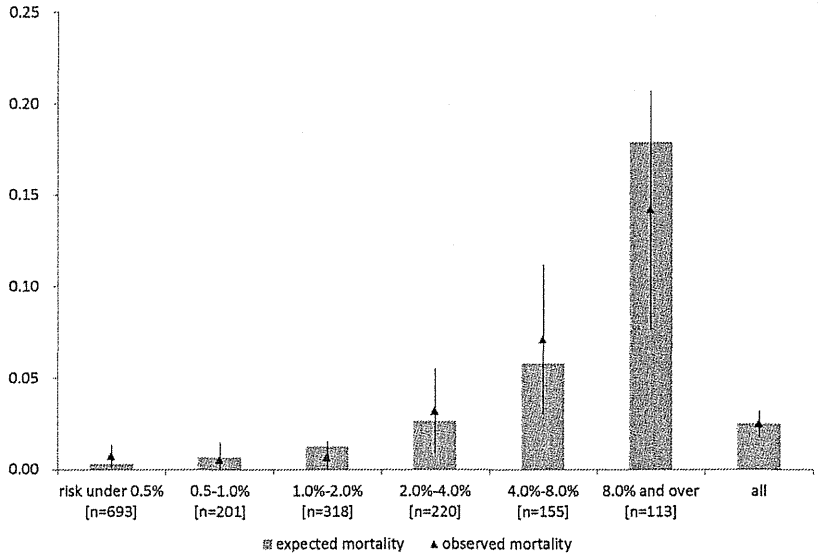

FIGURE 2. Predicted and observed 90-day mortality by risk categories.

Second, a better risk model might also be developed by not only restructuring highly complex procedural categories but also considering patient characteristics that contribute to high risk. Because of the limitation of low event rate, we used large category, preoperative risk factor, to examine risk in the JCCVSD in the initial phase. In addition, although the vast majority of the JCCVSD patient are youths, there are some adult congenital heart procedures. Although we added age category as general risk factor, it is better to add acquired risk factors when assessing the adult population. Further research might allow us to consider this matter more fully. For procedural complexity categories, calibration was increased, and discrimination did not differ when the categories were considered by increasing order of patient risk rather than by using the ordinal variables as each degree of complexity, which is why the former strategy was used. Third, death was the only outcome of this study. When considering the performance of pediatric cardiac surgical practice in its entirety, understanding complications is crucial.[19] In this context, focusing on complications and longer-term prognosis will likely be an effective strategy.

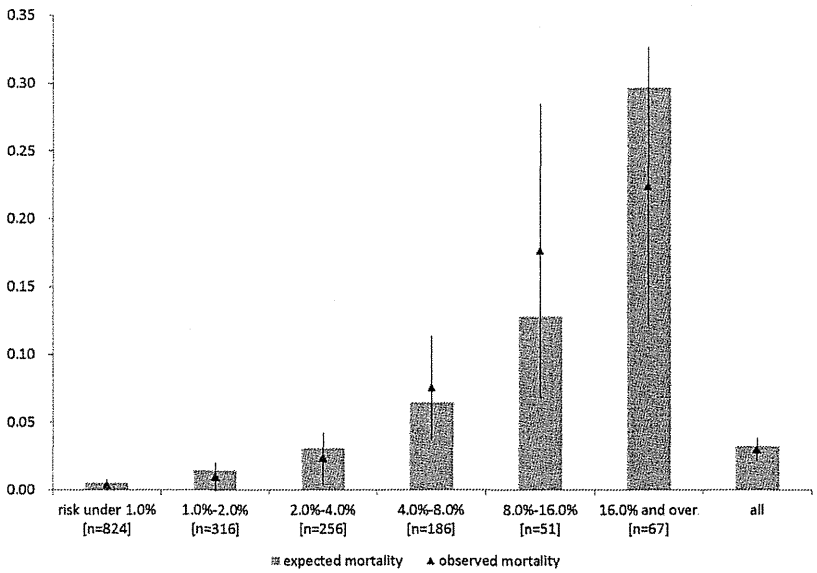

FIGURE 3. Predicted and observed 90-day and in-hospital mortality by risk categories.

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CHD

EDITORIAL COMMENTARY

Risk models for pediatric and congenital cardiac surgery

Jeffrey P. Jacobs, MD

See related article on pages 2201-6.

The Japan Congenital Cardiovascular Surgery Database (JCCVSD) is to be congratulated for their important contribution to congenital and pediatric cardiac care in the domains of outcomes analysis and quality improvement.[1] The authors have described the development of sophisticated congenital cardiac surgical risk models for short-term and mid-term outcomes based on integrated data from nationwide hospitals in Japan, using JCCVSD. This contribution is important because it describes the development of congenital cardiac surgical risk models that add to extant risk models by both the incorporation of several patient-specific variables and increased duration of follow-up.

JCCVSD uses the same nomenclature (International Pediatric and Congenital Cardiac Code) and data standards that are used in the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) and the European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Database (EACTS-CHSD).

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Disclosures: Author has nothing to disclose with regard to commercial support.
Received for publication Sept 29, 2014; accepted for publication Sept 29, 2014.

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J Thorac Cardiovasc Surg 2014;148:2206-7
0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2014.09.105

Operative Mortality and Complication Risk Model for All Major Cardiovascular Operations in Japan

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Background. The Japan Cardiovascular Surgery Database (JCVSD) is a nationwide benchmarking project to improve the quality of cardiovascular surgery in Japan. This study aimed to develop new JACVD risk models not only for operative mortality but also for each postoperative complication for coronary artery bypass grafting (CABG) operations, valve operations, and thoracic aortic operations.

Methods. We analyzed 24,704 isolated CABG operations, 26,137 valve operations, and 18,228 thoracic aortic operations. Risk models were developed for each operation for operative death, permanent stroke, renal failure, prolonged ventilation (>24 hours), deep sternal wound infection, and reoperation for bleeding. The population was divided into an 80% development sample and a 20% validation sample. The statistical model was constructed by multiple logistic regression analysis. Model discrimination was tested using the area under the receiver operating characteristic curve (C index).

Results. The 30-day mortality rates for isolated CABG, valve, and thoracic aortic operations were 1.5%, 2.5%, and 6.0%, respectively, and operative mortality rates were 2.4%, 3.8%, and 8.4%, respectively. The C indices for the end points of isolated CABG, valve, and aortic thoracic operations were 0.6358 for (deep sternal infection) to 0.8655 (operative mortality), 0.6114 (reoperation for bleeding) to 0.8319 (operative death), and 0.6311 (gastrointestinal complication) to 0.7591 (operative death), respectively.

Conclusions. These risk models increased the discriminatory power of former models. Thus, our models can be said to reflect the current state of Japan. With respect to major complications, useful feedback can now be provided through the Japan Cardiovascular Surgery Database Web-based system.

(Ann Thorac Surg 2015;99:130–9)

The evaluation of patient outcomes has become increasingly accepted as a first step in assessing and improving the quality of patient care. Because baseline patient variables influence outcomes of cardiovascular operations, risk adjustment based on clinical risk factors is required to understand quality improvement. Risk models of isolated coronary artery bypass grafting (CABG) have been reported from several series, especially in Western countries [1]. The Society of Thoracic Surgeons (STS) National Adult Cardiac Database (NCD) and the European System for Cardiac Operative Risk Evaluation (EuroSCORE) have contributed much to this field [2–6].

To assess daily clinical practice in the context of Japan, rather than relying on systems such as the STS NCD or the EuroSCORE, a Japan-specific database is needed. To this end, the Japan Cardiovascular Surgery Database (JCVSD) was established in 2000 as a benchmarking project to improve the quality of cardiovascular operations. As of 2013, the JCVSD has accumulated clinical information from more than 500 hospitals across Japan and is considered a national representative quality improvement initiative. The JCVSD data collection form has more than 300 variables, the definitions of which (available at: http://www.jacvsd.umin.jp) are based on those of the STS NCD (available at: http://www.sts.org).

Our previous reports using data from the JCVSD identified risk factors for isolated CABG [7], valve operations [8], and thoracic aortic operations [9]. However, these risk models only assessed mortality and composite morbidity. To improve the quality of cardiovascular operations, it is also important to identify risk factors for each postoperative complication. Thus, this study aimed to develop risk models not only for operative mortality but also for each postoperative complication.

Material and Methods

Study Population

We identified all cardiovascular procedures performed between January 1, 2005, and December 31, 2009. The

The Appendix can be viewed in the online version of this article [http://dx.doi.org/10.1016/j.athoracsur.2014.07.038] on http://www.annalsthoracicsurgery.org.

Accepted for publication July 21, 2014.

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Published by Elsevier

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2014.07.038

present study included 24,704 isolated CABG operations, 26,137 valve operations, and 18,228 thoracic aortic operations from 177 hospitals.

Data Collection

Through the JCVSD Web-based system, each participating hospital enters data and uses a real-time feedback report system that includes risk-adjusted outcomes, which are compared among all participating hospitals. Although participation in the JCVSD is voluntary, submissions tend to be thorough, with overall preoperative risk factors used in risk models missing in less than 3% of entries. The definitions of JCVSD variables are almost identical to those of the STS NCD (available online at http://sts.org).

The accuracy of submitted data is verified through monthly visits to each participating hospital by the site visit working group. Members of the group verify that the number of procedures from the original operative record listed for the hospital matches the number in the JACVSD. Members also examine each clinical record and compare it with that inputted into the JACVSD. In addition to source document verification, all hospital data are confirmed by independent comparisons of hospital adult cardiovascular surgical volume submitted to the JCVSD against that reported to the annual survey of the Japanese Association for Thoracic Surgery. This study was approved by the Institutional Review Board in each participating hospital. Informed consent was obtained from each patient to allow his or her data to be entered into this database.

End Points

The primary outcome measure of the JCVSD analysis was 30-day operative mortality, defined as death at 30 days or before hospital discharge. The other end points were operative death, and postoperative complications, including stroke, reoperation for bleeding, postoperative mechanical ventilation required for greater than 24 hours, renal failure, deep sternal wound infection, paraparesis, perioperative myocardial infarction, intensive care unit stay exceeding 7 days, and gastrointestinal complication. Also, using these outcomes, major morbidity was defined as any of the following postoperative complications: stroke, reoperation for bleeding, postoperative mechanical ventilation required for greater than 24 hours, renal failure, or deep sternal wound infection which occurred in hospital or within 30 days of an operation, regardless of the patient's geographic location after discharge.

Statistical Analysis

Data were randomly assigned into two subsets that were split 80/20, one for model development and the other for validation. The number of cases for isolated CABG, valve, and thoracic aortic operations were 19,762/4,942, 20,878/5,259, and 14,570/3,658, respectively. The Fisher exact test and two-sample t test were used to compare the validation and test data sets. To develop a risk model for each outcome, multiple logistic regression analysis using step-wise selection (backward method) of predictors with a p value for inclusion of less than 0.05 was conducted.

A goodness-of-fit test was performed to assess how well the model could discriminate between survivors vs nonsurvivors. When all statistically nonsignificant variables were eliminated from the model, goodness-of-fit testing was performed to assess the discrimination between survivors and nonsurvivors, and the area under the receiver operating characteristic curve was used to assess how well the model could discriminate between survivors and nonsurvivors. In our risk models, we did not consider intrainstitutional correlations and time trends with generalized estimating equations with empirical standard error estimates to account for patient clustering within institutions because these may be potential confounding factors when estimating regression coefficients for variables of primary interest [1–3]. We used SPSS 20.0 software (IBM Corp, Armonk, NY) for data analyses.

Results

Risk Profile of Study Population

The patient risk profile for each procedure is summarized in the Appendix. Patients in the isolated CABG group were a mean age of 68.3 years, 77.5% were men, and 18.5% required emergency operations. Preoperative comorbidities were chronic lung disease (mild, moderate, and severe; 7.1%) and renal failure (13.3%). Patients in the group with valve operations were a mean age of 66.4 years, 55.3% were men, and 6.0% required emergency operations. Preoperative comorbidities were chronic lung disease (mild, moderate, and severe; 9.6%) and renal failure (11.1%). Patients in the group with thoracic aortic operations were a mean age of 66.8 years. 65.6% were men, and 32.7% required emergency operations. Preoperative comorbidities were chronic lung disease (mild, moderate, and severe; 12.3%) and renal failure (8.8%).

Outcome Rates

Outcomes of each operation are summarized in Table 1. The 30-day mortality rates for isolated CABG, valve, and thoracic aortic operations were 1.5%, 2.5%, and 6.0%, respectively, and operative mortality rates were 2.4%, 3.8%, and 8.4%, respectively.

Model Results and Performance

Risk models were developed and final logistic models and model performance metrics are presented in Tables 2–4. Risk factors for isolated CABG were age, renal failure, prior CABG operation, cardiogenic shock, arrhythmia, and others. Risk factors for valve operations were age, renal failure, cerebrovascular disease, prior valve operation, and others. Risk factors for aortic thoracic operations were body mass index, noncardiac vascular lesion, acuity status, main reason for the indication of operation, location of the operation, and others.

Table 1. Outcomes for Patients Who Underwent Isolated Coronary Artery Bypass Grafting, Valve Operations, and Thoracic Aortic Operations

	Isolated CABG (n = 24,704)		Valve Operation (n = 26,137)		Thoracic Aortic Operation (n = 18,228)	
Outcome	No.	%	No.	%	No.	%
Death ≤30 days after operation	380	1.5	649	2.5	1,097	6.0
Operative death	582	2.4	1,000	3.8	1,523	8.4
Death or main complication[a]	2,893	11.7	3,776	14.4	5,397	29.6
Reoperation for bleeding	443	1.8	1,050	4.0	1,044	5.7
Stroke	373	1.5	471	1.8	1,233	6.8
Newly required dialysis	630	2.6	801	3.1	1,028	5.6
Deep sternal wound infection	456	1.8	404	1.5	371	2.0
Paraplegia/paraparesis	66	0.3	100	0.4	766	4.2
Prolonged ventilation	1,781	7.2	2,194	8.4	4,002	22.0
Perioperative MI	294	1.2	176	0.7	187	1.0
Gastrointestinal complication	403	1.6	494	1.9	688	3.8
Length of ICU stay ≥7 days	1,500	6.1	2,157	8.3	3,502	19.2

[a] Stroke, newly required dialysis, prolonged ventilation >24 hours, deep sternal wound infection, or reoperation for bleeding.

CABG = coronary artery bypass grafting; ICU = intensive care unit; MI = myocardial infarction.

The C indices for end points ranged from 0.6358 (deep sternal infection) to 0.8655 (operative mortality) for isolated CABG, from 0.6114 (reoperation for bleeding) to 0.8319 (operative mortality) for valve operations, and from 0.6311 (gastrointestinal complication) to 0.7591 (operative mortality) for aortic thoracic operations.

Comment

JCVSD is a database initiative that was started in 2000 with the aim of increasing the quality of cardiovascular operations in Japan. The first risk model was based on data up through 2005 [9] and was widely used for inter-institutional benchmarking with risk-adjusted outcomes, patient case conferences at each hospital, and informed consent before operations. The risk models developed in the present study include cases added to the database since 2005. As the number of participating facilities increased, so did the number of available cases in the database. This increased the discriminatory ability of the models and also allowed for more accurate assessments by the inclusion of a validation group. Thus, our models can be said to reflect the current state of Japan.

With respect to major complications, more useful feedback for use in the clinical context can now be provided with the development of individual risk models. In addition, we could assess characteristics and variations of clinical performance among institutions by use of risk models. In the future, we anticipate that identifying issues that differ among institutions, such as the rate of developing infectious diseases and bleeding, will work toward improving the quality of health care.

In addition to the presently developed models, other countries also have risk models for isolated CABG, valve operations, and thoracic aortic operations. Discussions on how to consider differences in countries and in race in the development and use of risk models are warranted. That patient background and disease incidence differ by country and race [10] highlights the importance of developing risk models that target Asian populations, such as Japanese people. Highlighting the usefulness of a Japan-specific risk model is that compared with other countries, the obese population is small in Japan, the rate of operations for thoracic aortic aneurysms is higher, and preoperative risk and the distribution of operative procedures greatly differ in Japan relative to other countries [11]. Moving forward, it will be useful to build a framework for sharing the significance of our findings in the international context through international collaborations and by considering racial, environmental, and institutional factors.

The rate of postoperative complications of isolated CABG, such as death and stroke, are not largely different from comparable data reported by the STS, although in Japan, renal and respiratory failure tend to be less frequent and infectious diseases are more frequent. On one hand, Japanese patients tend to be younger, have a lower body mass index, have a lower incidence of chronic respiratory failure, and have less history of myocardial infarction compared with patients of other countries [1]. On the other hand, when compared with data from the STS NCD, there are more patients with diabetes, a history of renal failure, angina, left main disease, and aortic valve stenosis in Japan. Although more patients have a history of diabetes in Japan compared with the United States, only a few models have identified diabetes history and therapy as risk factors. Despite the lower incidence of renal failure in Japan, the odds ratio for preoperative renal failure is markedly higher compared with that in the United States.

Table 2. Description of Risk Models for Isolated Coronary Artery Bypass Grafting

Variable	Category	Operative Death	Death or Main Complication	Reoperation for Bleeding	Stroke	Newly Required Dialysis	Deep Sternal Infection	Prolonged Ventilation >24 Hours	Gastrointestinal Complication	ICU Stay >7 Days
Age category, y	<60, 60–65, 65–70, 70–75, 75–80, ≥80	1.28	1.13	1.09	1.15	1.14		1.16	1.23	1.19
Body surface area, m2				0.93						
Gender	Male				1.44					0.88
Body mass index, kg/m^2	≥30		1.38					1.53		1.65
Past or present smoker	Yes							1.16	1.77	
Current smoker ≤1 month	Yes		1.23					1.20		1.17
Diabetes mellitus	Yes		1.18			1.78				
Diabetes treatment	Yes						1.27			
Renal failure	Yes	2.15	2.16	1.94		7.55	1.77	1.65	1.57	2.11
Chronic dialysis	Yes	1.98							1.55	
Hypertension	Yes		1.12		1.32		1.26			
Chronic lung disease	Moderate, severe									1.70
	Mild, moderate, severe	2.08	1.59			1.89	1.94	1.99	1.68	1.41
Noncardiac vascular lesion	Yes	1.72	1.31		1.37			1.26		
	Thoracic aorta					1.94				1.48
	Peripheral vessel (including abdominal aorta)						1.46			1.21
Cerebrovascular disease (TIA, RIND, CVA, coma)	Yes		1.28		1.98			1.23		1.29
Cerebrovascular disease if yes	Within 2 weeks before operation	2.89			2.59			1.61		
History of psychoneurotic disorder	Yes								1.91	
Prior CABG	Yes	2.46	2.26	5.17		1.70	2.06	1.81	1.85	2.37
Myocardial infarction	Yes		1.11					1.34		
Congestive heart failure	Yes	1.80	1.32			1.43	1.45	1.36		1.38
Angina	Unstable		1.15					1.25		
Cardiogenic shock	Yes	1.75	1.76	1.46		1.61	1.65	1.81	2.11	1.91
Arrhythmia	Yes	2.02	1.23			1.61		1.55	1.37	1.61
CCS Angina Grading Scale	≥II									1.23
NYHA Functional Classification	III		1.22					1.38	1.88	1.35
	IV	1.43	1.90		1.70	1.56		2.23	1.93	1.59
Medication ≤48 hours before operation	Yes	1.63				1.47				1.28
Aortic stenosis	Yes							1.42		
Mitral stenosis	Yes								3.44	
Diseased coronary vessels, No.	3		1.22	1.29			1.52	1.29	1.30	1.30

(*Continued*)

Table 2. Continued

Variable	Category	Operative Death	Death or Main Complication	Reoperation for Bleeding	Stroke	Newly Required Dialysis	Deep Sternal Infection	Prolonged Ventilation >24 Hours	Gastrointestinal Complication	ICU Stay >7 Days
Left ventricular function	Medium		1.12							1.26
	Bad	2.60	1.63	1.71		1.81		1.48		2.32
Mitral insufficiency	≥III	2.04								1.48
Acuity status	Urgent, emergency, salvage	2.05	1.68		1.40	2.05		2.12		2.11
	Emergency, salvage	3.38	2.33	1.75	2.13	2.33		2.76		3.17
Unplanned CABG	Yes	2.08	1.42		2.29	1.75		1.61		1.59
C statistics		0.8655	0.7294	0.6360	0.6744	0.8531	0.6358	0.7714	0.6756	0.7938

CABG = coronary artery bypass grafting; CCS = Canadian Cardiovascular Society; CVA = cerebrovascular accident; ICU = intensive care unit; NYHA = New York Heart Association; RIND = reversible ischemic neurologic deficit; TIA = transient ischemic attack.

It is important to note that Japan has a relatively high frequency of aortic diseases compared with other countries. In particular, Japan has a high incidence of aortic dissection, and this relates to patient characteristics such as high blood pressure and the presence of many elderly patients. One reason for this may be that computed tomography examinations are performed very often in Japan, thus presenting more opportunities to detect aortic diseases [12].

In the risk models of the present study, there were no exclusion criteria for the highly difficult thoracic aortic operations, and even if CABG or valve operations had been performed, if a thoracic aortic operation was also performed, and all of these were categorized as thoracic aortic operations. The characteristics of the operation were considered by including as risk factors whether rupturing was the reason the operation was indicated, type of valve operation (aortic valve, mitral valve, or multiple valve operations), type of aortic aneurysm, and the main reason that the operation was indicated. The International Registry of Acute Aortic Dissection has developed a risk model for thoracic aortic operations that targets only acute type A aortic dissection.

Although direct comparisons of the models are difficult, Japanese patients are evidently older and tend to have a higher incidence of diabetes. However, it should be noted that the risk factors used in the models are very different due to the characteristics of the database. Although our risk models have high discriminatory ability, improving the database's structure and methods for risk evaluation will be important to increase the quality of thoracic aortic operations throughout the world.

This study has some limitations. To improve the risk models, the risk factors to consider must be determined. Operative mortality tends to have high discriminatory ability, but some complications lack this ability. Although the STS has reported similar results regarding the limited discriminatory ability for the risk model of reoperation, we believe this should be improved. With respect to renal failure, there is much discussion in the field regarding which variables to use as indicators; for example, estimated glomerular filtration rate, creatinine clearance, and preoperative creatinine cutoff value. Although we simply used renal failure impairment and dialysis as risk factors related to renal dysfunction because they did not have a major effect, it will be necessary to continuously consider this aspect with usefulness for clinical interpretation about renal dysfunction.

In conclusion, the risk-adjustment models for isolated CABG, valve, and thoracic aortic operations in Japan were updated, and we developed additional risk models of not only operative mortality, 30-day morality, and composite morbidity but also of postoperative complications, including stroke, reoperation for bleeding, postoperative mechanical ventilation required for more than 24 hours, renal failure, deep sternal wound infection, paraparesis, perioperative myocardial infarction, intensive care unit stay exceeding 7 days, and gastrointestinal complications. Our new risk models will contribute to

Table 3. Description of Risk Models for Valve Operations

Variable	Category	Operative Death	Death or Main Complication	Reoperation for Bleeding	Stroke	Newly Required Dialysis	Deep Sternal Infection	Prolonged Ventilation >24 Hours	Gastrointestinal Complication	ICU Stay >7 Days
Age category, y	<60, 60–65, 65–70, 70–75, 75–80, ≥80	1.28	1.17	1.13	1.10	1.17	1.15	1.18	1.19	1.23
Body surface area, m^2				0.93						
Gender	Male		1.19	1.44	1.21					
Body mass index, kg/m^2	≥30		1.87			1.87	2.19	2.30		1.71
Current smoker ≤1 month	Yes			1.23						
Diabetes mellitus	Yes					1.70		1.12		
Diabetes treatment	Yes	1.21	1.18				1.28			1.28
Renal failure	Yes	2.27	2.16			4.82	1.53	1.69	1.79	2.05
Chronic dialysis	Yes	1.88			1.65		1.54	1.26	1.84	1.36
Hypertension	Yes		1.09			1.18		1.13		
Infective endocarditis	Yes		1.37		1.59	1.39		1.52		
	Active	1.70								1.59
Chronic lung disease	Moderate, severe								1.93	
	Mild, moderate, severe	1.48	1.48		1.44	1.35		1.74		1.44
Carotid artery lesion	Yes	1.44	1.30		2.12		1.69	1.55		
Noncardiac vascular lesion	Yes			1.37						
	Thoracic aorta	1.94	1.53			1.52		1.74		1.41
	Peripheral vessel (including abdominal aorta)	1.55	1.17						1.58	
Cerebrovascular disease	Yes		1.38		2.02			1.39		1.36
Cerebrovascular disease if yes	≤2 weeks									
History of psychoneurotic disorder	Yes	1.84	1.43	1.59		1.71	2.49		2.02	1.37
Prior valve operation	Yes	1.54	1.79	2.25		1.54	1.69	1.64	1.53	1.47
Prior PCI	Yes	1.39							1.43	
Myocardial infarction	Yes		1.19		1.37			1.37		1.29
Congestive heart failure	Yes	1.34	1.13	1.37	1.41					1.19
Angina	Yes									1.20
	Unstable	1.41								
Cardiogenic shock	Yes	1.74	1.67	1.66			1.80	1.64		1.33
Arrhythmia	Yes		1.15			1.24	1.28	1.15		1.14
NYHA Functional Class	II							1.23	1.52	1.27
	III	1.60	1.28			1.61		1.86	2.16	1.72
	IV	2.54	2.58			3.24		3.81	2.94	3.51
Medication ≤48 hours before operation	Yes	1.66			1.75	1.44	1.83			

(*Continued*)

Table 3. Continued

Variable	Category	Operative Death	Death or Main Complication	Reoperation for Bleeding	Stroke	Newly Required Dialysis	Deep Sternal Infection	Prolonged Ventilation >24 Hours	Gastrointestinal Complication	ICU Stay >7 Days
Mitral stenosis	Yes			1.28						
Aortic stenosis	Yes		1.26		1.40			1.24		
Diseased coronary vessels, No.	2		1.19			1.49		1.37		1.41
	3	1.49	1.48		1.91	1.67	1.59	1.50		1.62
Left ventricular function	Medium	1.21	1.13					1.22		1.23
	Bad	2.30	1.37					1.46		1.93
	Medium, bad					1.27				
Aortic insufficiency	≥II								1.26	
Mitral insufficiency	≥II				1.25		1.22			
Tricuspid insufficiency	≥II	1.27	1.23	1.29	1.26	1.30		1.13		1.34
	≥III	1.44				1.38		1.18	1.44	
Acuity status	Urgent	1.45	1.47					1.69		
	Emergency, salvage	1.65	1.70		2.05			1.90		
	Urgent, emergency, salvage					1.41			1.91	1.93
CABG	Yes		1.26	1.24			1.59	1.26		
Unplanned CABG	Yes	2.59	2.60		3.09	2.33		3.32		4.24
Aortic procedure	Yes	1.46		1.32		1.18			1.52	1.32
	Repair							1.48		
Mitral procedure	Yes									1.26
	Replacement	1.72	1.35		1.25	1.45		1.59		1.47
Multiple valve operation	Yes		1.20	1.21				1.19	1.55	
C-statistics		0.8319	0.7278	0.6144	0.6736	0.8083	0.6352	0.7882	0.7280	0.7837

CABG = coronary artery bypass graft surgery; ICU = intensive care unit; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

Table 4. Description of Risk Models for Thoracic Aortic Operations

Variable	Category	Operative Death	Death or Main Complication	Reoperation for Bleeding	Stroke	Newly Required Dialysis	Deep Sternal Infection	Paraparesis	Prolonged Ventilation >24 Hours	Perioperative MI	ICU Stay >7 Days	Gastrointestinal Complication
Age category, y	<60, 60–65, 65–70, 70–75, 75–80, ≥80	1.18	1.10	1.07	1.11	1.10		1.08	1.11		1.06	1.09
Body surface area, m^2						1.05			1.03			
Gender	Male	1.23	1.22	1.27	1.20	1.38		1.65			1.11	1.37
Body mass index, kg/m^2	≥30	2.00	2.01		1.34	1.80	2.66	1.44	1.96		1.81	1.41
Past or present smoker	Yes						1.51	1.34	1.16			1.26
Current smoker ≤1 month	Yes	1.20	1.17		1.22	1.34						
Diabetes mellitus	Yes							1.38			1.18	
Diabetes treatment	Yes						1.44					
Renal failure	Yes	1.79	1.63			4.17		1.36	1.44		1.79	1.82
Chronic dialysis	Yes	1.76										2.00
Hypertension	Yes		1.24		1.31	1.20		1.54	1.18		1.18	
Infective endocarditis	Yes		2.20			2.92	2.53		2.48		1.77	
	Active	2.59		1.93								
Chronic lung disease	Moderate, severe	1.45										
	Mild, moderate, severe	1.27	1.41			1.43	1.74		1.52		1.27	1.67
Carotid artery lesion	Yes		1.33		1.69				1.43			
Noncardiac vascular lesion	Peripheral vessel (including abdominal aorta)	1.48	1.51	1.28	1.28	1.60		1.46	1.61	1.57	1.35	1.32
Cerebrovascular disease	Yes	1.23	1.14		1.40				1.16		1.34	
Cerebrovascular disease if yes	≤2 weeks before operation		1.35		1.65			1.82				
History of psychoneurotic disorder	Yes	1.73	1.33		1.44	1.34		1.40	1.24		1.33	
Prior thoracic aortic operation	Yes	1.49	1.70	2.13		1.54	1.76		1.55		1.43	1.50
MI	Yes	1.44								2.46		
Congestive heart failure	Yes					1.50					1.46	1.42
Angina	Yes								1.20	1.90		
	Unstable											1.86
Cardiogenic shock	Yes	1.56	1.21	1.43					1.24		1.37	
Arrhythmia	Yes	1.29										1.40
CCS Angina Grading Scale	≥II							1.41				
	IV			1.79								
NYHA Functional Class	III		1.28						1.38			
	IV		1.22			1.52			1.28	1.81		

(*Continued*)