表6．施設集約化による患者側への影響まとめ.

	平均死亡率の予測	施設を移動する患者数（年間平均）		30km 以上の移動人数		緊急手術に限定した 30km 以上患者数	
		人数	%	人数	%	人数	%
集約なし	4.62%	—	—	—	—	—	—
年間 10 件以下集約	4.40%	211 名	0.4%	4.8 人	0.01%	0.8 人	0.001%
年間 25 件以下集約	4.28%	1377 名	2.6%	162.5 人	0.3%	12.3 人	0.02%
年間 50 件以下集約	3.76%	5899 名	11.3%	692.8 人	1.3%	88.3 人	0.2%
年間 75 件以下集約	3.12%	11213 名	21.4%	1440 人	2.8%	179.3 人	0.3%

* 緊急手術については「CABG の手術状態緊急」.「急性大動脈瘤」の両方を数え上げた.

** 移動する患者の割合の母数には心臓外科手術の年間平均患者数 52305 を用いた

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Noboru Motomura, Hiroaki Miyata, Hiroyuki Tsukihara, Shinichi Takamoto and from the Japan Cardiovascular Surgery Database Organization

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Risk Model of Thoracic Aortic Surgery in 4707 Cases From a Nationwide Single-Race Population Through a Web-Based Data Entry System

The First Report of 30-Day and 30-Day Operative Outcome Risk Models for Thoracic Aortic Surgery

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Background—The objective of this study was to collect integrated data from nationwide hospitals using a web-based national database system to build up our own risk model for the outcome from thoracic aortic surgery.

Methods and Results—The Japan Adult Cardiovascular Surgery Database was used; this involved approximately 180 hospitals throughout Japan through a web-based data entry system. Variables and definitions are almost identical to the STS National Database. After data cleanup, 4707 records were analyzed from 97 hospitals (between January 1, 2000, and December 31, 2005). Mean age was 66.5 years. Preoperatively, the incidence of chronic lung disease was 11%, renal failure was 9%, and rupture or malperfusion was 10%. The incidence of the location along the aorta requiring replacement surgery (including overlapping areas) was: aortic root, 10%; ascending aorta, 47%; aortic arch, 44%; distal arch, 21%; descending aorta, 27%; and thoracoabdominal aorta, 8%. Raw 30-day and 30-day operative mortality rates were 6.7% and 8.6%, respectively. Postoperative incidence of permanent stroke was 6.1%, and renal failure requiring dialysis was 6.7%. OR for 30-day operative mortality was as follows: emergency or salvage, 3.7; creatinine >3.0 mg/dL, 3.0; and unexpected coronary artery bypass graft, 2.6. As a performance metric of the risk model, C-index of 30-day and 30-day operative mortality was 0.79 and 0.78, respectively.

Conclusion—This is the first report of risk stratification on thoracic aortic surgery using a nationwide surgical database. Although condition of these patients undergoing thoracic aortic surgery was much more serious than other procedures, the result of this series was excellent. (***Circulation*. 2008;118[suppl 1]:S153–S159.**)

Key Words: aneurysm ■ aorta ■ risk factor ■ risk model ■ surgery

Thoracic aortic surgery is one of the most challenging in the entire field of surgery. Because several aspects can combine to make aortic surgery difficult (eg, location of the lesion, patient's age, degree of atherosclerosis, and so on), it would be helpful for aortic surgeons to know the nature of parameters affecting the outcome of aortic surgery and the reasons why. Although many hospitals and surgeons have tried to clarify these parameters in their own units, to date, there has been no report of any nationwide study.[1–3] A risk stratification of surgical procedures would help to improve quality control. In the cardiovascular surgery field, 2 major sophisticated databases are available: the STS National Database in the United States and the EuroSCORE system in Europe. Nishida et al reported recently that the EuroSCORE system worked well in Japanese patients undergoing aortic surgery in a single hospital.[4] However, this does not mean that we should not endeavor to establish our own database on aortic surgery. To this end, in this article, we report for the first time on the risk stratification for thoracic aortic surgery based on data from a single nation. We used data from the Japan Adult Cardiovascular Surgery Database (JACVSD) to build up this stratification. Construction of this national database started in 2000 and a web-based data collection system had been introduced in 2002. The number of participating hospitals has gradually increased and currently approximately 180 hospitals are enrolled. After data cleaning, the risk model was developed using 4707 cases from 97 hospitals throughout Japan. In the future, we hope that this risk model will contribute to improved quality control of aortic surgery not only in Japan, but also throughout the world.

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Methods

Study Population

The JACVSD started in 2000 to estimate surgical outcomes after cardiovascular procedures in many centers throughout Japan. The database currently captures clinical information from approximately 180 hospitals (32.7% of all Japanese units performing cardiac surgery in 2005). The data collection form has a total of 255 variables (definitions are available online at www.jacvsd.umin.jp), and these are almost identical to those in the STS National Database (definitions are available online at http://wts.org). JACVSD constructed software for a web-based data collection system, and through this system, the data manager of each participating hospital was responsible for forwarding their data electronically to the central office. Although participation in the JACVSD is voluntary, data completeness is a high priority. The accuracy of submitted data was maintained by a data audit; this was achieved by random, monthly visits by administrative office members to a participating hospital when data were checked against clinical records. The validity of JACVSD data has been confirmed further by an independent comparison of the volume of cardiac surgery at a particular hospital entered in the JACVSD versus that reported to the Japanese Association for Thoracic Surgery (JATS) Registry.[5] Data were excluded from 14 centers that had entered less than 90% of the data entered into the JATS Registry. Exclusion of data from these 14 centers did not affect the outcome in terms of establishing preoperative risk.

We examined all cardiovascular surgery procedures relating to thoracic aortic surgery between January 1, 2000, and December 31, 2005. Initially, those JACVSD records that had been obtained without patients' informed consent were excluded from this analysis. Records with missing age (or out of range), sex, or 30-day status (see "End Points" for explanation) were also excluded. With the exception of body surface area, and preoperative creatinine value, all missing or out-of-range values were imputed using the variable-specific median value. After this data cleaning, the population for this risk model analyses resulted in 4707 aortic procedures from 97 participating sites throughout Japan.

End Points

The primary outcome measure of JACVSD was 30-day mortality, defined as death within 30 days of an operation regardless of the patient's geographic location. It included death within 30 days of an operation even if the patient has been discharged from the hospital. The secondary outcome measure was 30-day operative mortality, which was exactly the same as the 30-day operative mortality but as expressed in the STS National Database. This meant that any patient who died within the index hospitalization, regardless of the length of hospital stay, and including any patient who died after being discharged from hospital up to 30 days from the date of the operation. Major morbidity was as defined as any of the following 5 postoperative in-hospital complications: stroke, reoperation for whatever reason, need for mechanical ventilation for more than 24 hours after surgery, renal failure, or deep sternal wound infection.[6] In this analysis, composite operative mortality or major morbidity was used as the third end point.

Statistical Analysis

The statistical model was multiple logistic regression; the variables entered in the model were selected using bivariate tests, χ^2 tests for categorical covariates, and unpaired t tests or Wilcoxon rank sum tests for continuous covariates. All variables significant at the $P<0.2$ level were entered into the model provided they were present in at least 2% of the sample. A multivariate stepwise logistic regression analysis was then performed for each of the 3 outcomes. Stability of the model was checked every time the variable was eliminated. In the case of continuous variables, in which the relationship with outcome was not linear such as preoperative creatinine, we determined cutoff points. When all statistically nonsignificant variables had been eliminated from the model, "goodness-of-fit" testing was used to assess how well the model had discriminated and the area under the receiver operating characteristic curve was used to assess how well the model could discriminate between patients who lived from those who had died. Model calibration (the degree to which observed outcomes were similar to the predicted outcomes from the model across patients) was examined by comparing observed with predicted average within each of 10 equal-sized subgroups arranged in increasing order of patient risk. To evaluate the model calibration, the Hosmer-Lemeshow test for the lack of "goodness of fit" was applied.

Statement of Responsibility

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

Results

Risk Profile for Study Population

The JACVSD aortic patient population (total JACVSD aortic patient records=4707), had an average age of 66.5 years (SD 12.5); 67.5% were males. In this population, 25.5% required either an emergency (patient was taken to theater immediately after the diagnosis) or salvage (patient was transferred to the operating room under resuscitation) procedure; an additional 7.5% of this population required an urgent procedure (definition of emergency and urgent are same as the STS). Other preoperative comorbidities were chronic lung disease, 11.0% (of patients), renal failure, 9.2%; acute myocardial infarction; 3.2%; reoperation, 7.9%; and rupture or malperfusion, 9.7%. The replacement surgery involved aortic root in 10.1%; ascending aorta, 46.6%; aortic arch, 44.4%; distal aorta, 20.6%; descending aorta, 26.9%; and thoracoabdominal, 8.1%. Some patients had surgery involving more than one area. An abbreviated risk profile for the study population is shown in Table 1.

Outcome Rates

Outcomes of aortic surgery in the JACVSD study population were 30-day mortality (6.71%), 30-day operative mortality (8.58%), and composite 30-day mortality or major morbidity (30.13%). These rates and those for the specific major morbidities are presented in Table 2.

Model Results

Three different risk models were developed and the final logistic model with the ORs and 95% CIs for the ORs are presented in Table 3. Among the 3 models, there were 9 overlapping variables: status (elective, urgent, emergency, or salvage); renal failure or abnormal preoperative creatinine levels; reoperation; patient's age; lung disease (none, mild, moderate, or severe); acute myocardial infarction; neurological impairment, rupture, or malperfusion; unexpected coronary artery bypass graft (CABG); or CABG surgery.

Model Performance

To evaluate the models' performance, both a C-index (measure of model discrimination), which was the area under the receiver operating characteristic curve, and the Hosmer-Lemeshow test (measure of model calibration across risk groups to evaluate "goodness of fit") were evaluated. Figures 1 through 3 demonstrate the calibration of the models or how well the rates for the predicted event matched those of the

Table 1. Key Descriptive Data

Characteristics	Aorta Records for Entire Study Population (n=4707)	Aortic Surgery Outcome Groups: 30-Day Mortality (n=316)	30-Day Operative Mortality (n=404)	Major Morbidity/Operative Mortality Composite (n=1418)
Age, mean (SD), years	66.5 (12.8)	68.9 (11.6)	69.3 (11.7)	68.0 (12.1)
Males, %	67.5	74.4	74.3	67.4
Status, %				
Urgent	7.5	9.3	8.2	9.1
Emergency, salvage	25.5	56.3	54.2	42.4
Chronic lung disease, %	11	13.3	14.4	13.9
Renal failure, %	9.2	17.1	20.3	15
Acute myocardial infarction, %	3.2	10.1	8.9	5.4
Reoperation, %	7.9	11.7	12.6	12.1
Rupture or malperfusion, %	9.7	32.6	30.4	18.9
Location along the aorta of replacement surgery, %*				
Root	10.1	9.5	8.2	9.4
Ascending	46.6	45.9	45.5	50.5
Arch	44.4	48.4	49.5	51.6
Distal arch	20.6	22.8	22.5	22.8
Descending	26.9	27.8	27.7	25.5
Thoracoabdominal	8.1	11.4	11.1	9.4

*An individual patient could be reported in more than one category, ie, totals exceed 100%.

observed event among patient risk subgroups. The details of model performance metrics are shown in Table 4.

Discussion

Thoracic aortic surgery is one of the most challenging in the entire field of surgery. This is particularly the case for emergency surgical cases, which might be at greater risk of experiencing postoperative brain damage, or be in a worse preoperative condition due to systemic atherosclerosis than other categories of cardiac patients undergoing, for example, CABG or valve surgery. The basic concept of aortic surgery is simple, cut and sew. However, surgery involving the thoracic aorta is not so simple because in the operating room, the brain is susceptible to ischemia during aortic arch reconstruction, and severe atherosclerosis can lead to embolization of multiple organs, whereas any rupture of the thoracic aorta will require a quick procedure in response before it becomes too late. Acute dissection produces chemical substances, which can cause a violent reaction in vital organs. As a result, achieving good results from surgery of the thoracic aorta is quite challenging.

Table 2. Outcome of Aortic Surgery

Outcome	Percent (n=4707)
30-day mortality	6.71
30-day operative mortality	8.58
Based on the location along the aorta requiring surgery	
Root	7.00
Ascending	8.40
Arch	9.60
Distal arch	9.40
Descending	8.80
Thoracoabdominal	11.60
Composite operative mortality or major morbidity, including	30.13
Permanent stroke	6.14
Renal failure requiring dialysis	6.69
Prolonged ventilation	18.63
Deep sternal wound infection	1.40
Cardiac surgery reoperation	9.11

In this study, 4707 procedures were examined from 97 surgical units throughout Japan. The mean age was 66.5 (SD 12.8) years; two thirds of patients were male. Preoperatively, renal failure (serum creatinine >2.0 mg/dL) was seen in 9.2% of the patients and chronic lung disease in 11%, which was higher than in the isolated CABG population, which we had previously studied.[7] Reoperation cases were seen in 7.9%, which was also much higher than in this CABG population. The incidence of acute myocardial infarction was 3.2% among the population as a whole, which increased to 10.1% in the 30-day mortality group; prior rupture or malperfusion had occurred in 9.7% of cases. One third of our cases were for nonelective procedures, which was similar to that found in other countries.

In terms of the section along the aorta requiring replacement surgery, many cases included multiple areas, for example, the ascending aorta plus aortic arch or aortic arch

Table 3. ORs With 95% CIs for Aorta Risk Models

	30-Day Mortality		30-Day Operative Mortality		Major Morbidity/Operative Mortality Composite	
Variables	OR	95% CI	OR	95% CI	OR	95% CI
Status*						
Urgent	2.44	1.56–3.82	1.81	1.18–2.77	1.77	1.35–2.31
Emergency, salvage	3.90	2.89–5.26	3.67	2.80–4.81	2.62	2.12–3.23
Male sex	1.72	1.29–2.29	1.63	1.26–2.10		
Age, years	1.02	1.01–1.03	1.02	1.01–1.03	1.02	1.01–1.03
Reoperation	2.02	1.36–2.99	2.30	1.61–3.28	3.00	2.37–3.81
Acute myocardial infarction	2.56	1.55–4.24	2.18	1.36–3.50	1.75	1.21–2.55
Neurological impairment	2.29	1.56–3.35	1.82	1.25–2.63	1.78	1.36–2.35
CABG unexpected	2.74	1.29–5.84	2.58	1.25–5.34		
CABG					1.67	1.31–2.13
Rupture or malperfusion	2.24	1.63–3.08	2.10	1.57–2.81	1.95	1.52–2.50
Renal failure	1.51	1.07–2.12				
Creatinine value, preoperative						
Creatinine (1.5–3.0)			2.35	1.71–3.23	2.32	1.81–2.96
Creatinine (3.0–)			2.97	1.91–4.61	2.70	1.90–3.88
Chronic lung disease						
Moderate, severe	2.21	1.35–3.62	1.97	1.25–3.13		
Mild, moderate, severe					1.58	1.28–1.95
Left main coronary artery disease			2.38	1.24–4.57		
Congestive heart failure	1.55	1.03–2.35				
Left ventricular function (bad)	2.58	1.44–4.64	2.05	1.15–3.67		
Anticoagulants, use of			1.60	1.07–2.38		
Body mass index >26 kg/m^2					1.64	1.39–1.93
New York Heart Association Class IV					1.68	1.32–2.14
Aortic aneurysm type (dissection)					1.31	1.10–1.56
Smoker					1.27	1.10–1.46
History of resuscitation	3.03	1.56–5.87	1.81	1.03–3.18	2.27	1.34–3.85
Diabetes					1.28	1.03–1.61
Diabetes treatment			1.55	1.04–2.33		
Marfan syndrome					1.86	1.24–2.77

plus distal aortic arch; almost half of the cases involved ascending aorta or aortic arch replacement. In many hospitals in Japan, surgeons do not hesitate to operate on the aortic arch area. Although the 97 hospitals participating in this study were not always well-known specialist aortic centers, our results confirmed that surgeons in Japan were not hesitating to operate on the aortic arch area if needed.

Postoperatively, permanent stroke was reported in 6.14% of patients and 6.69% patients needed hemodialy-

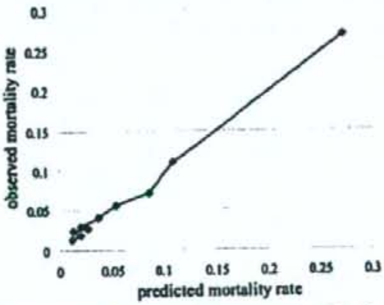

Figure 1. Thirty-day mortality risk model calibration.

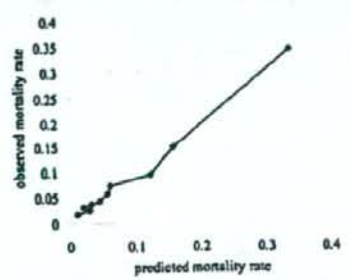

Figure 2. Thirty-day operative mortality risk model calibration.

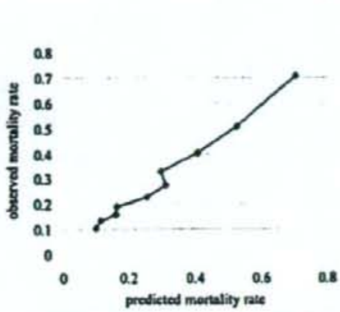

Figure 3. Major morbidity/30-day operative mortality composite risk model calibration.

sis. Although these numbers were slightly higher than reports from a few leading hospitals worldwide,[8,9] we feel they are acceptable. Prolonged ventilation was seen in 18.6% of patients, which was much higher than expected. This number was overestimated, however, because the definition of prolongation was more than 24 hours, which was the same as in the previously mentioned CABG series. Because of the high number of cases that involved acute dissection, on reflection, we feel this definition should have been extended to 74 hours.

The 30-day mortality rate of the whole population was 6.71%, which was better than we expected. The JATS publishes an Annual Report of all Registry data, and the most recent version had reported that the number of thoracic aortic procedures was 8907 with an overall hospital mortality rate of 8.96%.[10] The 30-day operative mortality associated with our overall procedure was 8.58%; this was similar to that of the JATS Registry report. Because of the huge variation between thoracic aorta procedures, depending on differences in the vulnerability of surgery at the various sites as well as the methods used for bypass machines and for protecting the integrity of the brain's function, it is difficult to discuss the overall outcome. Among our 4707 cases, the 30-day operative mortality rate of aortic arch replacement was 9.69% and that of the distal arch was 9.40%. Mortality rates from the world's leading hospitals for patients undergoing aortic arch replacement have been between 4% and 7%.[9,11–13] On the other hand, results from standard hospitals were not as good as from these leading hospitals. For example, the UK Cardiac Surgical Register in 2000 reported that the mortality rate for the aortic arch procedure was 28%.[14] The situation is the same for thoracoabdominal aortic surgery. Although a few leading hospitals are reporting excellent data such as an operative mortality rate of 5% to 14%, a multicenter discharge database in the United States covering 20% of that country's hospitals, including outcomes from many nonleading hospitals, reported 22.3% mortality from thoracoabdominal aorta procedure.[15] Although these data were old, and results are very likely to be much improved by now, nevertheless, these high mortality rates may be indicative of the real world of thoracic aortic surgery. In comparison with this information, the Japanese results for thoracic aortic procedure presented here were better than the US data. Our data were not just from the few top leading hospitals, but rather they represent 97 hospitals that cover more than 20% of hospitals performing thoracic aortic surgery in Japan. The reason for this better result in Japan is not easy to clarify and is multifactorial. Patients with thoracic aortic disease are more prevalent in Asia than in Western countries, and Japanese surgeons may be better experienced at handling such patients than their Western counterparts. Furthermore, the socioeconomic situation in Japan, including health insurance systems, is much different from the Western world. Japanese public health insurance covers the majority of medical expenses, and only a small payment is necessary from the individual patient after surgery. One benefit of this generous insurance system is that, in Japan, patients can stay in the hospital for several weeks without incurring excessive extra charges. Patients can also choose their surgeon and hospital regardless of their insurance policy or level of coverage. Surgeons are at liberty to perform surgical procedures and medical interventions of their own choice with less pressure and interference from the hospital's fund managers or the insurance companies than would be the case in many other countries. In Japan, a surgeon's salary is at a fixed, flat rate; therefore, it could be argued that they think more highly of retaining their reputation rather than their remuneration with the end result that they would make every effort to save a patient's life even if the costs were high in monetary terms. However, this generous situation may soon change because of recent increasing economic pressure from the government. Postoperative care in an intensive care unit or coronary care unit is mainly maintained by doctors who are either trainee surgeons or intensive care specialists, and not by the nursing staff, a system that may also be responsible for the better outcomes than seen elsewhere.

To evaluate the outcome of surgical procedure in this study, we mainly used 30-day mortality and 30-day operative mortality rates. It has been said that 30-day mortality or 30-day operative mortality rates represent a biased interval.[16] Some reports compare the outcome after a few days, whereas others recommend comparing after 60 days or longer.[17] The purpose of the database was to establish a means of quality control, and to accomplish this purpose, we needed a parameter, or parameters, that would allow us to compare our latest outcomes with old ones or with other parties' outcomes. When we started this project, the 2 major cardiac surgery databases were the STS National Database and the EuroSCORE, both of whom were using 30-day mortality and 30-day operative mortality as the main outcome parameters. Although we recognized the limitations of these parameters, nevertheless, we learned a lot from these 2 major databases and decided to use the same parameters.

Table 4. Aorta Risk Model Performance Metrics

	H-L test (*P* value)	C-index
30-day mortality	0.69	0.79
30-day operative mortality	0.36	0.78
Composite mortality	0.21	0.73

H-L indicates Hosmer-Lemeshow.

From our risk model, important variables affecting the 30-day operative mortality rates were status of emergency or salvage procedure (OR, 3.67; 95% CI, 2.80 to 4.81), preoperative high creatinine levels >3.0 mg/dL (OR, 2.97; 95% CI, 1.91 to 4.61), unexpected CABG (OR, 2.58; 95% CI,1.25 to 5.34), left main coronary artery disease (OR, 2.38; 95% CI, 1.24 to 4.57). Other factors, like rupture or malperfusion, chronic lung disease (moderate to severe), bad left ventricular function (ejection fraction <30%), and diabetes with treatment, were also significant risk factors for the 30-day or 30-day operative mortality in our series of patients. These parameters were almost the same as those reported in the previous studies from several major centers.[8,11] Through this risk model, we have constructed our own calculator for the expected mortality from thoracic aortic surgery, similar to the EuroSCORE or STS National Database Calculator. We feel certain that the employment of this calculator will contribute to improvement in the quality control of daily practice in the field of thoracic aortic surgery.

The C-indexes (the area under the receiver operating characteristic curve) of 30-day mortality and 30-day operative mortality in this study were 0.79 and 0.78, respectively. Several hospitals have tried to use the EuroSCORE for risk stratification of their results from thoracic aortic procedures, and the C-index from the original EuroSCORE varied between 0.58 and 0.68.[3,13] In comparison with these data, our risk model was shown to be a reliable model at this point with little fluctuation. Strictly speaking, we should have divided our data into 2 data sets, the analyzing data set and the validation data set, for the validation of our risk model. We fully acknowledge the importance of a validation data set to achieve a more accurate risk model. Unfortunately, the volume of our data (4707 cases) was not as large as that in the STS National Database, which contains over 500|000 pieces of data. When the EuroSCORE was developed in 1999, they used all 19|030 cases for the risk model construction and did not divide them into 2 data sets.[18] The validation of their risk model was done 3 years later by using the data of STS National Database.[19] Just as the Europeans did with their validation methodology, we also wanted to construct our new risk model by first using all of our data under initially limited conditions with a relatively small number of samples. When the volume of our data reaches an adequate size, hopefully in the near future, we fully intend to perform a validation by dividing our data into 2 data sets.

Study Limitation

Several limitations exist in this study. Although the data that we analyzed came from 97 hospitals from all over Japan, it cannot be assumed that the cases retrieved were representative of all Japanese cases. Furthermore, these 97 hospitals were relatively high-volume centers in comparison to many in Japanese hospitals, which might have affected our result even if the data were not particularly large. Third, we did not divide our data into analyzing and validation data sets because of the relatively small volume of our data. As covered in the preceding "Discussion," it is our intention to perform a validation of our risk model by dividing into the 2 data sets as soon as the volume of our data becomes large enough.

Conclusion

We have reported the first risk stratification study on thoracic aortic surgery that uses a nationwide cardiovascular surgery database. By analyzing 4707 procedures from 97 hospitals throughout Japan, 30-day and 30-day operative mortality rates were 6.71% and 8.58%, respectively. The results were quite satisfactory for a nationwide outcome of thoracic aortic surgery, and this system will contribute to improving the quality control of surgical practice in thoracic aortic procedures.

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Disclosures

None.

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First Report on 30-day and Operative Mortality in Risk Model of Isolated Coronary Artery Bypass Grafting in Japan

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Background. Risk models of coronary artery bypass grafting (CABG) using a large database are useful for improving surgical quality. To obtain accurate, high-quality assessments of the surgical outcomes, each country should maintain its own database. This study was conducted to collect Japanese data and prepare a risk stratification of isolated CABG procedures using the Japan Adult Cardiovascular Surgery Database (JACVSD).

Methods. We analyzed 7133 CABG-only records from 97 participating sites throughout Japan using a data entry form with 255 variables that was sent to the JACVSD office by our Web-based data collection system. The statistical model was constructed by multiple logistic regression. Model discrimination was tested using the area under the receiver operating characteristic curve (C index). Model calibration was tested by the Hosmer-Lemeshow test.

Results. Of 7133 operations, 47.2% had diabetes mellitus, 14.0% were urgent, and 15.6% involved peripheral vascular disease. The observed 30-day and operative mortality rates were 2.02% and 2.72%, respectively. Significant variables with high odds ratios included emergency or salvage status (3.71), preoperative creatinine value exceeding 3.0 mg/dL (3.59), aortic valve stenosis (3.01), and moderate to severe chronic lung disease (2.86). Hosmer-Lemeshow test and C-index values for 30-day mortality were satisfactory at 0.96 and 0.85, respectively.

Conclusions. The results obtained in Japan were at least as good as those reported elsewhere. The performance of our risk model also matched those of the Society of Thoracic Surgeons National Adult Cardiac Database and the European Society Database.

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Risk models of isolated coronary artery bypass grafting (CABG) have been reported from several series, especially in Western countries. The Society of Thoracic Surgeons (STS) National Adult Cardiac Database (NCD) and European System for Cardiac Operative Risk Evaluation (EuroSCORE) have contributed much to this field.

The number of CABG procedures has increased steadily in Japan, where cardiovascular disease was regarded as being less common than in Western countries. The Japanese lifestyle is now closer to those of Europe and the United States, especially the daily diet; however, a number of differences still remain. Genetics, the degree of mixing in racial backgrounds, education, workload, access to medical facilities, and social systems vary considerably. The purposes of this large-scale benchmark project with an integrated database are to evaluate the surgical procedures used and to improve the quality of cardiac surgery.

To assess daily practice in Japan, we need to build our own database system rather than borrow from other systems such as the STS NCD or the EuroSCORE system. We started a project to set up a nationwide integrated database in the cardiac surgery field, the Japan Adult Cardiovascular Surgery Database (JACVSD). The structure and content of the JACVSD are similar to those of the STS NCD. This is our first report of the risk model of isolated CABG in an East Asian population, which is comparable with such models used in Western countries and suggests new approaches for improving the quality of cardiac surgery.

Material and Methods

Because this study involves human subjects, 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.

The JACVSD Database

The JACVSD was inaugurated in 2000 to assess surgical outcomes after cardiovascular surgical procedures on a

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Table 1. Key Descriptive Data

Characteristic	All CABG Study (n = 7133)	30-day Mortality (n = 144)	Operative Mortality (n = 194)	Major Morbidity/30-day Mortality (n = 973)
Age, mean (SD), year	67.4 (9.5)	71.2 (8.4)	70.1 (9.2)	69.3 (8.8)
Men, %	76.7	74.3	73.7	74.1
Status, %				
Urgent, %	14.0	23.6	24.2	19.8
Emergency, salvage, %	7.8	37.5	34.5	18.4
Chronic lung disease, %	5.5	11.8	13.9	8.5
Cerebrovascular disease, %	14.5	22.9	20.6	18.7
Peripheral vascular disease, %	15.6	30.6	28.9	19.7
Diabetes mellitus, %	47.2	53.5	50.5	52.8
Diseased vessels, %				
1	5.1	5.6	4.6	3.9
2	26.1	20.1	19.1	23.7
3	67.2	71.5	73.7	70.9

CABG = coronary artery bypass grafting.

multicenter basis. The database currently captures clinical information from 151 hospitals as of July 2007 (28.5% of all units performing CABG in 2005), and we included in this study 111 hospitals that had enrolled by December 2005.

The data collection form has 255 variables that are almost identical to those of the STS NCD (available online at http://sts.org). The definitions of JACVSD variables (available online at http://www.jacvsd.umin.jp) are the same as those of the STS NCD. JACVSD created software for a Web-based data collection system, through which each data manager in each participating hospital sends data.

Although participation in the JACVSD is voluntary, data completeness is high. The overall preoperative risk factors were missing in fewer than 2% of the whole of the assembled data. The accuracy of submitted data was maintained by data auditing, which involves a number of administrative office members visiting a randomly chosen hospital on a monthly basis and checking the data against the clinical records. The ratio of JACVSD data registered to the true number of cases at the hospital has further been confirmed by comparing the data reported in advance to the Japanese Association for Thoracic Surgery (JATS) Registry [1]. We excluded 14 centers from 111 hospitals because they entered less than 90% of the amount of JATS Registry data. The data from 97 hospitals were analyzed. Exclusion of the 14 centers did not affect the preoperative risk for the outcome.

Study Population

We examined only isolated CABG operations between January 1, 2000, and December 31, 2005, excluding those in which valve or other major surgical procedures were involved. From the set of records with the CABG-only procedural designation, those in which the patient's age was outside the range selected and those in which sex was missing were excluded from this analysis. About 5% of records were missing 30-day mortality and were also excluded. Finally, after this data standardization process, the population for this risk model analysis comprised 7133 CABG-only patients from 97 participating sites throughout Japan, and their records were accessed.

Auditing

To perform the audit on a routine basis, we created the Site Visit Working Group (SV-WG). The WG members consist of one SV-WG chief (selected from the administrative office members) and 6 data managers from six areas in Japan. One hospital is randomly picked every month, and the SV-WG chief lists all the deceased patients and in advance makes printed tables that show all the entered variables of all the deceased patients. The chief also makes another table that includes the cases randomly picked up from the nondeceased patients.

The SV-WG (4 to 6 members) visits the selected hospital, and one member verifies the number of procedures from the original operative record list in the hospital and identifies it with the number of the JACVSD data. Other members look up the clinical charts of all the deceased patients and compare them with the printed table. The audit takes a day, from 9 A.M. to 5 P.M. If extra hours are

Table 2. Outcomes of Coronary Artery Bypass Grafting-Only Procedures

Outcome	Percentage for all CABG Records (n = 7133)
30-day mortality	2.02
Operative mortality	2.72
Major morbidity	11.62
Composite 30-day mortality or major morbidity	13.64
Permanent stroke	1.51
Renal failure requiring dialysis	3.18
Prolonged ventilation	5.76
Deep sternal wound infection	1.36
Cardiac reoperation	5.75

CABG = coronary artery bypass grafting.

Table 3. Risk Models of Coronary Artery Bypass Grafting Only

Variables	30-day Mortality OR (95% CI)	Operative Mortality OR (95% CI)	Composite OR (95% CI)
Status			
Urgent	1.98 (1.22–3.20)	2.03 (1.33–3.09)	1.43 (1.17–1.76)
Emergency, salvage	3.71 (2.24–6.12)	3.55 (2.34–5.73)	2.08 (1.60–2.68)
Shock	1.98 (1.15–3.39)	1.93 (1.19–3.11)	1.60 (1.18–2.17)
Creatinine value pre-op			
1.5–3.0, mg/dL	1.77 (1.04–3.03)	2.75 (1.75–4.31)	2.31 (1.81–2.96)
>3.0. mg/dL	3.59 (2.25–5.74)	4.95 (3.31–7.40)	3.19 (2.56–3.98)
Congestive heart failure	1.90 (1.23–2.92)	2.22 (1.19–2.43)	1.39 (1.14–1.68)
Chronic lung disease			
Moderate, severe	2.86 (1.24–6.58)	3.75 (1.81–7.74)	...
Mild, moderate, severe	...	...	1.50 (1.14–1.97)
LV function (bad)	1.94 (1.23–3.06)	...	1.59 (1.21–1.97)
Vascular disease	1.91 (1.28–2.85)	1.7 (1.18–2.43)	...
Age, years	1.04 (1.02–1.07)	1.03 (1.02–1.05)	1.03 (1.02–1.04)
Aortic stenosis	3.01 (1.38–6.55)	2.78 (1.39–5.56)	...
Reoperation	2.34 (1.13–4.87)	2.97 (1.61–5.47)	3.30 (2.38–4.56)
Current smoker	1.55 (1.03–2.34)	...	1.23 (1.03–1.46)
Arrhythmia	1.73 (1.12–2.67)	1.67 (1.06–2.36)	...
Inotropic agents	1.97 (1.22–3.18)	2.55 (1.68–3.88)	1.69 (1.28–2.23)
Digitalis	...	2.03 (1.18–3.50)	...
NYHA (classification)	...	...	1.43 (1.14–1.80)
BMI >26 kg/m²	...	...	1.53 (1.29–1.82)
Diabetes	...	...	1.19 (1.03–1.38)
CVA	...	...	1.32 (1.09–1.60)

BMI = body mass index; CI = confidence interval; CVA = cerebrovascular accident; LV = left ventricular; NYHA = New York Heart Association; OR = odds ratio.

available, members check the nondeceased patients using their clinical records and the tables that the SV-WG chief has prepared.

Since this audit system started as a routine practice from 2006, 21 hospitals have been audited so far. In the near future the SV-WG members will perform the audit in the area in their charge, and such audits can then be done in several hospitals at the same time every month all over Japan.

End Points

The primary outcome measure of JACVSD was 30-day mortality, defined as death within 30 days of an operation, regardless of the patient's geographic location, even if the patient had been discharged from the hospital. The second outcome measure of analysis was the operative mortality, defined as in-hospital or 30-day mortality (whichever was longer), which is equivalent to "the 30-day operative mortality" as defined in the STS NCD. Major morbidity was defined as any of five postoperative in-hospital complications: stroke, reoperation for any reason, need for mechanical ventilation for more than 24 hours postoperatively, renal failure with newly required dialysis, or deep sternal wound infection [2]. In this analysis we use composite 30-day mortality or major morbidity as the third end point.

Statistical Analysis

The statistical model was multiple logistic regression. The variables entered in the model were selected using bivariate tests, χ^2 tests for categoric covariates, and unpaired t tests or Wilcoxon rank sum tests for continuous

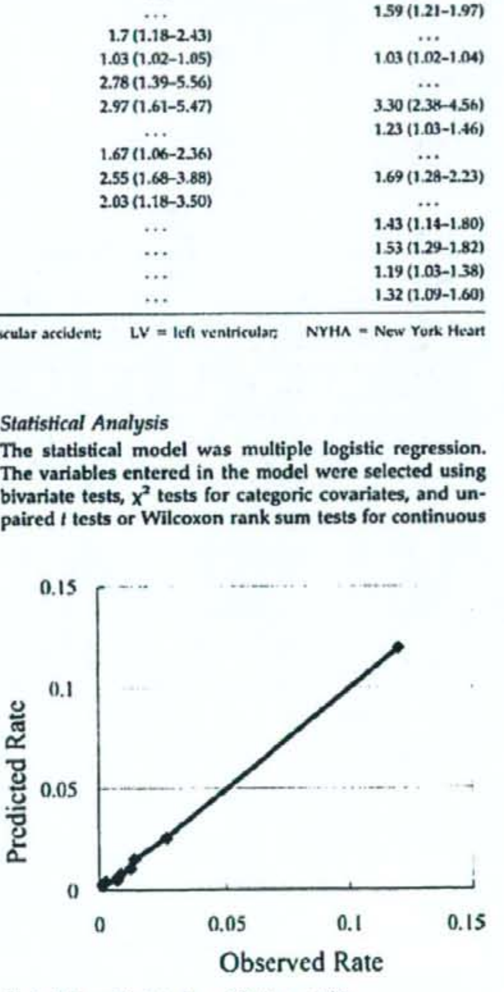

Fig 1. Risk model calibration of 30-day mortality.

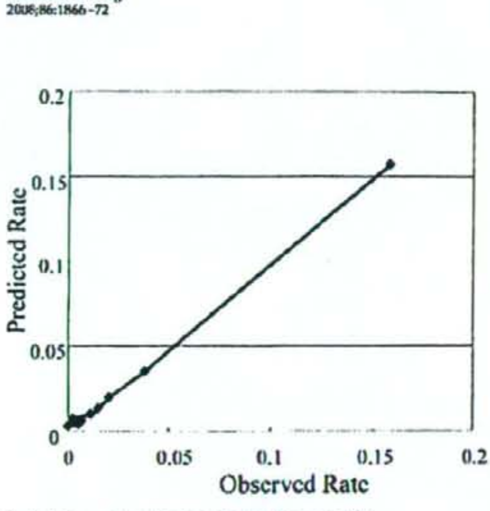

Fig 2. Risk model calibration of operative mortality.

covariates. All variables significant at the $p < 0.2$ level were entered into the model provided they were present in at least 2% of the sample. Nonsignificant variables were eliminated from the model one at a time, beginning with the variable having the highest *p* value. The stability of the model was checked every time a variable was eliminated. In the case of continuous variables where the relationship with outcome was not linear, such as preoperative creatinine levels, we determined cutoff points.

When all statistically nonsignificant variables had been eliminated from the model, goodness-of-fit testing was used to assess how good the discrimination was between survivors and nonsurvivors, and the area under the receiver operating characteristic (ROC) curve was used to assess how well the model could discriminate between patients who lived from patients who died. Model calibration (the degree to which observed outcomes are similar to the predicted outcomes from the model, compared across patient groups) was examined by comparing observed average with predicted average within each of 10 equally sized subgroups arranged in increasing order of patient risk. To evaluate model calibration, the Hosmer-Lemeshow test for the lack of goodness of fit was applied [3].

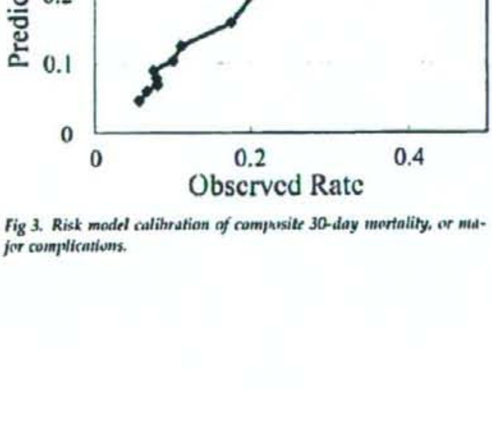

Fig 3. Risk model calibration of composite 30-day mortality, or major complications.

Table 4. Risk Model Performance Metrics for Coronary Artery Bypass Grafting Only

	H-L p-Value	C Index
30-day mortality	0.96	0.85
Operative mortality	0.65	0.86
Composite	0.46	0.71

H-L = Hosmer-Lemeshow test.

Results

Risk Profile for Study Population

The 7133 JACVSD CABG patients who were studied were an average (SD) age of 67.4 ± 9.5 years (median, 69.0 years). An emergency or salvage procedure was required in 7.8%, and 14.0% required an urgent procedure. Preoperative comorbidities were chronic lung disease, 5.5%; cerebrovascular disease, 14.5%; peripheral vascular disease, 15.6%; and diabetes mellitus (DM), 47.2%. An abbreviated risk profile for the CABG study population is summarized in Table 1.

Outcome Rates

Outcomes of isolated CABG in the JACVSD study population were 30-day mortality of 2.02%, operative mortality of 2.72%, major morbidity of 11.6%, composite 30-day mortality or major morbidity of 13.6%. The specific major morbidity rates are also presented in Table 2.

Model Results

Three different risk models were developed, and odds ratios (OR) and their 95% confidence intervals (CI) resulting from the final logistic model are identified in Table 3. In the three models had seven overlapping variables: status (elective, urgent, emergency, or salvage), preoperative creatinine value (<1.5, 1.5 to 3.0, >3.0 mg/dL), congestive heart failure, lung disease (none, mild, moderate, or severe), age, reoperation, and preoperative medication, such as inotropic agents.

Model Performance

To evaluate model performance, both a C-index test to measure model discrimination and an Hosmer-Lemeshow test to evaluate goodness of fit were performed. Figs 1, 2, and 3 demonstrates the calibration of models; that is, how well the predicted event rates match the observed event rates among patient subgroups of risk. The details of model performance metrics are compiled in Table 4.

Comment

This is our first report on the risk model derived from our database for isolated CABG in a Japanese population. The primary purpose of the surgical outcome database is to assess our own results and to enhance the quality of our surgical services. To achieve this purpose properly, the database has to be made using the patient population in Japan rather than borrowing from elsewhere. Two major risk models have been published in the cardiac surgery field, the STS NCD and the EuroSCORE. These two systems have a much longer history and a much larger patient volume than ours. However, the patient population and surgical services of these databases are different from ours. Race, daily diet, educational situation, public welfare state, medical insurance system, hospital availability, surgeon's situation, and hospital environment are among the factors that are quite different from each other, but all can affect the quality of surgery.

It is easy to calculate the expected mortality of our patients preoperatively by using the EuroSCORE or STS NCD calculator [4], but the results would not be based on actual data obtained from our own patient population, and it will not help to improve our quality control. In fact, Yap and colleagues [5] reported that the additive and logistic EuroSCORE did not accurately predict the outcomes of the Australian CABG population and that the use of the EuroSCORE models for risk prediction may not be appropriate in their patients.

It is for these reasons that we built our own database. Of course, it is very useful to examine these two large databases and compare them with our database. But it is more important to create our own database to understand our own situation and problems. Another reason was uncontrolled broadcasting by the mass media on surgical outcomes based on their questionnaire, which had no scientific background. Many newspapers and magazines have provided feature articles on hospital rankings of procedure volume. These data had no statistical background or validation, and such activities are futile [6]. Therefore, we realized that this is the time to create a scientific database ourselves and then to publish outcomes and findings specific to the population in Japan.

The characteristics of the studied patients in our database were similar to those reported by the STS NCD. The distribution of men, peripheral vascular disease, and the number of diseased vessels were almost identical to their counterparts in STS. In our Japanese study, there was less chronic lung disease (5.5% vs 15.0%, $p < 0.0001$ by χ^2 test), more elective cases (78.2% vs 61.7%, $p < 0.0001$), more cerebrovascular disease (14.5% vs 10.5%, $p < 0.0001$), and more DM patients (47.2% vs 31.6%) than those obtained in the STS.

The almost threefold difference in chronic lung disease was larger than the differences in the other variables. The smoking rate in Japan was much higher in the past, but has declined recently, so that the current rate of Japanese smokers in this study did not show as great a difference as the STS NCD rate (21.5% vs 18.1%). We do not know the exact reason for this great difference in chronic lung disease. Whether the population of isolated CABG patients was different from or similar to that in STS and other major databases, our own original database is needed because the outcome of medical services is affected by nonmedical environments.

The rate of DM in the patient population was 47.2%, which was a much higher rate than in Western countries and much higher than we expected. In the STS NCD, the ratio of DM was 31.6% and the OR of DM on operative mortality was 1.15. In contrast, DM was not included in a risk factor for 30-day mortality and operative mortality in this study. In our current version of database, a question about DM was not focused specifically on insulin treatment. Our next database version (version 4), which we are working on, will have a variable regarding the insulin treatment. Then, being a DM patient with insulin treatment would be a risk factor in the next version. In fact, DM was a risk factor of composite 30-day mortality and major morbidity even in this version (Table 3).

Table 3 presents the ORs of this risk model. These results were in general similar to those of the STS NCD. Reoperation was a more serious variable in the United States, and aortic stenosis was more serious in Japan. Also, the OR for renal dysfunction was higher in Japan than in the United States: a creatinine level of more than 3.0 mg/dL had an OR of 3.59 in our study, whereas that for renal failure and dialysis in the STS NCD was 1.88. The general condition of patients with renal failure and dialysis is worse in Japan than in the United States, because the health system in Japan is generous enough for such patients to survive longer. In addition, patients with better condition were to be treated by catheter interventions and only far more serious patients were referred to CABG. As a result, an older dialysis population with more severely complicated disease has been sent to cardiac surgeons in Japan.

The C indexes were 0.85 for 30-day mortality and 0.86 for operative mortality. These values were much higher than those in other databases [7, 8]. Generally, the smaller the number of entries that are found in the data set, the better the value of the C index. The Hosmer-Lemeshow test is also affected by the sample number. We used only 7133 records in this study—much fewer than the number used in the STS NCD—but the reliability of our database was still satisfactory. Because of the relatively small sample size, we did not divide these samples into two parts, one for analysis and the other for validation. We are accumulating sample data daily through our Web-based data entry system, and we will update our analysis using a much larger sample size in the near future to perform an updated analysis.

The operative mortality of this study in 2005 was 2.72%, which was a result similar to or better than other major nationwide database reports [9, 10]. Shroyer and colleagues [2] reported that the operative mortality of isolated CABG in 1997 to 1999 was 3.05% according to the STS NCD analysis. However, the latest report from the STS Database Web site showed a significant decrease in the operative mortality of unadjusted isolated CABG from 3.1% in 1997 to 2.1% in 2006 (http://www.sts.org/sections/stsnationaldatabase/publications/executive/article.html), which was better than our data of 2005. Composite major mortality or morbidity showed similar results: 13.64% vs 13.40%. However, Shroyer and colleagues' [2] data were collected several years before ours. The STS NCD Committee reported that mortality has improved over the last 10 years, even though surgeons had to face older, sicker, and higher-risk patients [11]. So their mortality rate might be better than ours if it were updated. In any event, these data indicate that the outcomes of cardiac interventions in Japan were as good as those of the United States.

The Japanese Association for Thoracic Surgery (JATS) has been maintaining a registry of cardiovascular procedures in Japan since 1986, and the latest version of the JATS Annual Report in 2004 showed that the number of cardiovascular units and isolated CABG in Japan was 539 and 19,930, respectively [1]. An average of 37.0 isolated CABG procedures were performed per year in all institutions. The total number of acquired operations (CABG + valve + thoracic aorta + arrhythmia) was 42,781, which was an average of 79.4 per year at each hospital. Some units are doing only pediatric congenital cardiac operations, and this average is greatly underestimated. But the number is definitely much smaller than in other countries.

The Japanese Board of Cardiovascular Surgery indicates that Japan had 1911 Board-certified cardiac surgeons as of March 2007 [12] who treated an average of 18.7 cases per year, including valve and arrhythmia procedures. Again, this number is much lower than it is in other countries. Nevertheless, the 30-day mortality in Japan is not worse than in those countries. The reason for the excellent results achieved by Japanese cardiac surgeons appears to be multifactorial [13]. The health insurance system in Japan covers most medical expenses, and a small individual payment is made at each operation [14]. Patients can remain in the hospital beyond the first week or two, if needed, without falling victim to the burden of excessive extra charges, and they can choose any surgeon and any hospital that they prefer, regardless of their insurance coverage. Surgeons can perform their surgical and medical duties at the maximum level with considerably less pressure from the hospital or the insurance company that would be felt in other countries.

Because of the small case volume, Japanese surgeons are able to hold both preoperative and postoperative conferences on each patient more intensively than is possible abroad. Moreover, usually, cardiac operations are not performed by a single consultant but rather by one or two consultant surgeons with trainees. Because a surgeon's salary is kept at a fixed, flat rate in Japan, each surgeon must take responsibility not only for himself but also for other surgeons. Surgeons usually do not have to operate twice a day in one operating theater, and they can spend ample time on both planning and accomplishing all surgical procedures with a high level of competence.

Postoperative care in an intensive care unit or cardiac care unit is mainly the task of doctors who are trainee surgeons or intensive care specialists, and not by the nursing staff, a system that may offer better care than the other systems [15]. Postoperative intensive treatment should prolong the patient's life beyond 30 days. Under these socioeconomic circumstances, surgical patients in Japan are able to receive the full benefit of the highest class of medical services [13].

As time periods are defined, 30-day mortality is usually shorter than operative mortality. In our series the difference between these two values was larger than STS NCD (2.02% and 2.72% in Japan vs 1.7% and 2.0% in STS NCD). The intensive postoperative treatment in Japan described above could explain the large discrepancy between 30-day mortality and operative mortality.

Theoretically, quality control can be influenced not only by surgical procedures but also by the nature of the processes used in surgical practice [16]. It is currently common practice to assess such processes during procedures. Our database also has such variables, for example, internal mammary artery usage, preoperative β-blocker usage, and so on. Although we could not include the process measurement in this article, we are planning in our next step to examine our data from the viewpoint of process measurement.

The final goal of a clinical database is to improve the quality of our daily practice. The STS NCD proved this effect in the early stage and published in 2002 [17]. But they estimated between 1990 and 1999, which took 10 years to prove the preferable effect even by their large database. Our database has just started, and another several years are needed to show the positive effect of the database on our daily practice.

In conclusion, this is our first report of the risk model of isolated CABG in the Japanese population using a newly developed database system. The patient profile was slightly different from those in the large databases in Western countries, but the risk-adjusted mortality and risk factors were similar. Although patient backgrounds and socioeconomic conditions differ, surgical outcomes in this field were achieved to the same level of excellence as in Western countries. Further analysis is needed, using our database, in the fields of valvular and aortic surgery. These analyses will contribute to maintaining a high level of quality in the Japanese heart surgeon's daily practice.

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INVITED COMMENTARY

The authors are to be commended for undertaking the development of a national database in cardiac surgery [1]. This is clearly a challenging task, but as pointed out by the authors, it is essential for improving the quality of care.

The purpose of a clinical database is to improve quality. It is surprising that there is little mention of demonstrated quality improvement in the JACVSD registry. Presumably there is a feedback mechanism in place to allow users to gauge their performance against national benchmarks. The feedback mechanism to database participants will likely be the major contributor to quality improvement, and therefore it should be presented both carefully and aggressively.

The authors have developed a cardiac surgery database that may serve as a prototype for contemporary clinical registries. It is particularly important that they have recognized the need for interoperability and interconnectivity, concepts that today are considered essential in the development of modern databases. Their decision to use a web-based system will exploit current technology to achieve maximum flexibility and nimbleness.

They also have chosen to use The Society of Thoracic Surgeons' data definitions, which avoids having to *reinvent the wheel* and allows direct comparisons between databases.

As more countries recognize the need for data collection and benchmarking, we can anticipate a proliferation of registries in the next few years. The Japanese group has done a lot that is right, and their model may serve as a guide for other countries choosing to develop clinical data registries.

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Effect of procedural volume on outcome of coronary artery bypass graft surgery in Japan: Implication toward public reporting and minimal volume standards

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See related editorial on page 1202.

Background: Since the Japanese government updated the medical practice laws, each hospital has to submit procedural volume from April 2007 and may sometime in the future have to submit some outcome indicators. It is very important to examine whether procedural volume is accurate and appropriate.

Methods: We analyzed 4581 procedures from 36 centers between 2003 and 2005 by clinical database. The effect of hospital volume on each outcome was tested by a hierarchical mixed-effects logistic regression model, covering clinical risk factors, procedural year, clinical processes, and hospital volume/surgeon volume as a fixed effect and random intercepts for sites.

Results: Logistic regression model revealed a significant association between hospital bypass graft volume and 30-day mortality ($P < .05$) and operative mortality ($P < .01$). Surgeon procedural volume, however, did not have a significant effect on those outcomes. The effect of hospital procedural volume was associated with better outcomes in most patient subgroups: age younger than 65 years ($P < .05$), age 65 years and older ($P < .01$), low risk ($P = .58$), and high risk ($P < .01$).

Conclusion: In Japan, high-volume compared with low-volume providers had better outcomes. As for public reporting in Japan, hospital-based evaluation might be more credible than surgeon-based evaluation. Although minimal volume standards might be effective to improve quality to some extent, volume has limitations as a marker of quality because of its wide range of variance.

Since the Japanese government updated the medical practice laws in June 2006, each local government has had the power to force medical centers to submit and bring forward "certain information" that is useful for patients choosing a hospital from April 2007 (http://www.mhlw.go.jp/topics/bukyoku/soumu/houritu/dl/164-4a.pdf).

As of January 2007, "certain information" includes procedural volume but few outcome indicators, such as operative mortality rate or morbidity rate. However, there is the possibility that "certain information" could include surgeon-specific outcome indicators similar to public reporting in New York State.[1,2] In Japan, it is very important to examine whether procedural volume is information that is appropriate to reveal and whether it is accurate.

Measuring and understanding the association between surgical volume and outcome in the delivery of health services has been the focus of much research since the 1980s in the United States.[3,4] Recently, two systematic reviews suggested that high volume is associated with better outcomes, but the degree of this association varies greatly.[5,6] As the complications included in these findings are partly due to methodologic shortcomings in many studies, it is very important to conduct a rigorous examination of volume-outcome association.

In Japan, whereas 9 studies suggest that a significant relationship between volume and outcomes does exist,[7-15] 4 studies suggest that no such relationship exists.[16-19]

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
JACVSD = Japanese Adult Cardiovascular Surgery Database
JATS = Japanese Association for Thoracic Surgery
STS = The Society of Thoracic Surgeons

Moreover, none of those Japanese studies examines the relationships of hospital and physician volume, appropriateness of patient selection, or risk adjustment by risk model with good calibration (Hosmer–Lemeshow test positive) and discrimination (C-index > 0.75). No association between hospitals' coronary artery bypass graft (CABG) surgery volume and outcome has been reported in Japan.

We undertook a contemporary examination of the association between hospital CABG procedural volume and outcome using clinical data available from the Japanese Adult Cardiovascular Surgery Database (JACVSD). The data collection form is almost identical with that of The Society of Thoracic Surgeons (STS) National Cardiac Database. We examined whether hospital volume and surgeon volume were associated with each outcome category (30-day mortality, 3-day operative mortality). We also examined how the association between hospital CABG volume and operative mortality varied as a function of patient age and predicted surgical risk.

As JACVSD participating hospitals did not cover all centers in Japan, we also examined the database of the Japanese Association for Thoracic Surgery (JATS). Although it was hard to adjust patient preoperative risk because of its aggregate data form, the JATS survey covered nearly all centers in Japan. We considered the nationwide trend and the potential health policy implications of using hospital volume in the context of health policy.

Methods

Survey 1 (JATS Database)

Study population. Since 1986, the JATS has conducted annual surveys of thoracic surgery. JATS sent out survey questionnaires to all institutions conducting cardiovascular surgery in Japan, and the response rates of the survey were very high (95.9% in 2001, 97.4% in 2002, 94.3% in 2003, and 90.3% in 2004).[20-23] The definitions of terms are based on the published guidelines of the STS and The American Association for Thoracic Surgery.[24] We examined isolated CABG surgery procedures, excluding those combined with valve or other major surgical interventions, performed between January 1, 2001, and December 31, 2004. We included 540 centers that reported at least one CABG procedure during 2001 through 2004. Because of the very high response rate of the JATS survey, 540 centers represent nearly all institutions in Japan doing coronary procedures.

Statistical analysis. The primary yardstick of outcome used by JATS was 30-day mortality, defined as death within 30 days of operation, regardless of the patient's geographic location. Although this criterion includes death within 30 days of operation even when the patient had been discharged from the hospital during those 30 days, patients who died in the hospital at greater than 30 days were ungraspable in the JATS survey. Hospital-isolated CABG annual case volume was averaged over a 4-year period (2001–2004) to increase its stability. Annual hospital procedural volume was divided into quarters (15≤, 16–30, 31–50, and >50). The break points were chosen to form 4 fairly equal-sized hospital samples, and similar volume differences were maintained among the groups. We simply showed average mortality rate (and 95% confidence interval) per hospital (Table 1).

Survey 2 (JACVSD)

Study population. The JACVSD was established in 2000 to report surgical outcomes after cardiothoracic procedures in detail. The database currently captures clinical information from 151 hospitals (28.5% of all centers performing CABG surgery). The data collection form has 255 variables in total, and these variables are almost identical to the STS National Database (available online at http://wts.org). The definitions of JACVSD variables (available online at http://www.jacvsd.umin.jp) are the same as those of the STS National Database. JACVSD constructed the software for the Web-based data collection system, and through this system each data manager in the participating hospitals submits data by computer. Although participation in the JACVSD is voluntary, data completeness is high, with overall preoperative risk factors used in risk models missing in fewer than 2%. The accuracy of the submitted data is checked through data auditing in monthly visits to each hospital by administrative office members. After checking the data using

TABLE 1. Hospital outcomes and characteristics in JATS database (2001–2004)

	Hospital CABG volume (procedures per year)				
	≥15	16–30	31–50	≤51	Overall
No. of patients	4,140	13,589	19,337	45,545	82,611
No. of hospitals	133	153	123	131	540
Status emergency	295	1,727	3,141	6,393	11,556
Thirty-day mortality	124	349	412	700	1,585
Emergency rate, %	7.1	12.7	16.2	14.0	14.0
Total mortality rate, %	3.00	2.57	2.13	1.54	1.92
Average mortality rate, % (95% CI)	3.79 (2.11–5.48)	2.60 (2.17–3.01)	2.17 (1.85–2.49)	1.61 (1.80–1.43)	

CI, Confidence interval.

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TABLE 2. Patient characteristics of JACVSD (2003–2005)

	Hospital CABG volume (procedures per year)			
	16–30	31–50	≥51	All
No. of patients	894	1645	2042	4581
No. of hospitals	13	14	9	36
Age, median (IQR)	69.0 (63–75)	69.0 (62–74)	69.0 (61–74)	69.0 (62–74)
Preop creatine, median (IQR)	0.9 (0.7–1.2)	0.9 (0.8–1.1)	0.9 (0.8–1.1)	0.9 (0.8–1.1)
Men, %	78.2	76.7	76.9	77.1
Chronic lung disease, %	7.4	5.0	5.5	5.7
Cerebrovascular disease, %	10.0	11.8	12.3	11.7
Hypertension, %	77.4	70.2	70.5	71.7
Diabetes, %	48.2	47.8	46.2	47.2
Left main artery disease, %	38.6	31.2	36.1	34.9
Three-vessel disease, %	69.7	68.8	66.3	67.8
NYHA class IV, %	12.9	12.3	8.4	10.7
Congestive heart failure, %	16.3	17.9	11.6	14.8
Shock, %	5.7	6.1	3.6	4.9
Reoperation, %	3.5	3.9	2.4	3.1
Emergency/salvage, %	7.8	7.4	7.3	7.5
Preoperative risk, %	2.4	2.0	1.7	2.0
Thirty-day mortality	2.68	1.95	1.47	1.88
Operative mortality	4.14	2.86	1.62	2.55

IQR, Interquartile range; *NHYA*, New York Heart Association. Preoperative risk was calculated on the basis on JACVSD 30-day mortality risk model. Number of patients is for 3-year periods (2003–2005).

the clinical records and operative notes, the audit members suggest that the hospital data manager complete and improve the data entry. The registration rate of JACVSD data has further been confirmed in independent comparisons of hospital CABG surgery volume submitted to the JACVSD against those reported to the JATS database. We excluded 11 centers that entered data for fewer than of the total number of cases compared with those in the JATS database. Inclusion of cases from these excluded centers strengthened the effect of procedural volume on outcome.

We examined isolated CABG surgery procedures, excluding those combined with valve surgery or other major surgical interventions, performed between January 1, 2003, and December 31, 2005. Fifty centers were members of JACVSD as of January 1, 2003. After excluding 11 centers for the aforementioned reason and excluding 3 centers because of extremely low CABG volume (reported < 15 CABG procedures per year), we ultimately included the data from 36 centers (Table 2).

TABLE 3. The effect of volume index on each outcome

Volume index (procedures per year)	Thirty-day mortality	Operative mortality
Hospital adult cardiac surgery volume	<.05	<.01
Hospital CABG-related surgery volume	<.05	<.01
Hospital CABG isolated volume	<.05	<.01
Surgeon adult cardiac surgery volume	NA	NA
Surgeon CABG-related surgery volume	NA	NA
Surgeon CABG isolated volume	NA	NA

CABG, Coronary artery bypass grafting; *NA*, not significant.

Statistical analysis. The primary outcome measure of JACVSD analysis was 30-day operative mortality, defined as in-hospital or 30-day mortality, whichever was longer.[25] The annual case volumes of hospitals and surgeons were averaged over a 3-year period (2003–2005) with a view to maintaining stability. Although volume was considered to be a continuous variable in this analysis, the patient and hospital characteristics and unadjusted outcomes were categorized by annual hospital procedural volume for display purposes. The break points were identical with those of JATS analysis (16–30, 31–50, and >50).

The effect of hospital volume on unadjusted outcomes was tested by a hierarchical mixed-effects logistic regression model. We examined the 6 types of volume index in this study: hospital adult cardiac surgery volume (CABG, valve, thoracic aorta, and other procedures), hospital CABG-related surgery volume (CABG plus valve or other procedures), CABG-only surgery volume per hospital, adult cardiac surgery volume per surgeon, CABG-related surgery volume per surgeon, and CABG-only surgery volume per surgeon (Table 3). In Japan, isolated CABG surgery accounts for 48% of all adult cardiac surgery, while 29% was valvular heart disease and 19% was thoracic aortic aneurysm.[22] These analyses included previously identified clinical risk factors,[1] procedure year, clinical process (off-pump CABG surgery, autologous blood transfusion), hospital procedural volume, surgeon volume as a fixed effect, and random intercepts for sites.[26] The C-indexes for this model in the study

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TABLE 4. Risk-adjusted mortality, by hospital and surgeon volume (n = 4581)

	Hospital CABG volume (procedures per year)							
	16-30		31-50		≥51		Overall	
Surgeon CABG volume (procedures per year)	%	n	%	n	%	n	%	n
>15	3.47	425	2.52	576	1.70	329	2.68	1330
≥16	2.05	469	1.90	1069	1.46	1713	1.73	3251
Overall	2.67	894	2.14	1645	1.50	2042		

Number of patients is for 3-year periods (2003–2005).

population were 0.83 for 30-day mortality and 0.84 for 30-day operative mortality.

As for 30-day operative mortality, we also presented volume interaction per hospital volume × surgeon volume (Table 4) and conducted subgroup analyses for patient age (<65 years and ≥65 years; Table 5) and patient preoperative risk (Table 6). Risk-adjusted mortality rates for each category were calculated by dividing the observed mortality rate by the expected mortality rate at the same hospital and multiplying by the overall CABG mortality rate of the JACVSD.

Results

Survey 1 (JATS Database)

Between January 1, 2001, and December 31, 2004, 82,611 isolated CABG procedures were performed at 540 hospitals in Japan. Average hospital procedural volumes ranged from 0.25 to 292.75 isolated CABG procedures (median, 28; interquartile range, 15–49). In Japan, 30 (5.6%) centers performed 100 or more procedures per year and 133 (24.6%) centers performed fewer than 15 procedures per year. Table 1 displays hospital outcomes and characteristics in the JATS database. High-volume hospitals (those performing > 50 procedures per year [n = 131]) had significantly lower mortality rates than those in the other 3 categories. Low-volume hospitals (those performing ≤ 15 procedures per year [n = 133]) were more likely to operate in elective cases. As for the JATS database, we also showed unadjusted 30-day mortality rates by procedural volume at 10 intervals (Figure 1). The mortality rate in hospitals performing 41 to 50 CABG procedures per year was 1.91%, and all mortality rates of the following categories (51–60, 61–70, 71–80, 81–90, 91–100, and ≥101 procedures/year) were lower than 2.0%.

Survey 2 (JACVSD)

Table 2 displays the patient characteristics and outcomes of the JACVSD as a function of hospital volume. Between 2003 and 2005, 4581 isolated CABG operations were performed at 36 participating hospitals. Thirteen of the JACVSD participating hospitals, involving 894 patients, were categorized as medium- to low-volume hospitals (16–30 procedures per year); 14 hospitals, with 1645 CABG patients, were categorized as medium- to high-volume hospitals (31–50 procedures per year); and 9 hospitals, with 2042 CABG patients, were categorized as high-volume (>50 procedures per year) hospitals. The medium- to low-volume hospitals were more likely than high-volume centers to operate on patients with chronic lung disease, on patients with hypertension or congestive heart failure, and in emergency or salvage cases. On the basis of preoperative risk factors, the average expected surgical mortality risk rates were 2.4% in medium- to low-volume hospitals, 2.0% in medium- to high-volume hospitals, and 1.7% in high-volume hospitals. Overall, there were 86 cases of 30-day mortality and 117 of 30-day operative mortality (31 patients died in the hospital at > 30 days). These outcome rates declined in high-volume hospitals in comparison with middle- to low-volume hospitals.

Table 3 displays the effect of volume index on each outcome. Only hospital procedural volume affected 30-day mortality and operative mortality significantly. Table 4 demonstrates the effect of hospital and surgeon procedural

TABLE 5. Unadjusted and risk-adjusted mortality by patient age group (n = 4581)

	Age < 65 years			Age ≥65 years		
	Hospital CABG volume			Hospital CABG volume		
	16–30	31–50	≥50	16–30	31–50	≥50
No. of patients	287	559	725	607	1086	1317
Unadjusted mortality	2.79	1.61	1.24	4.78	3.50	1.82
Risk-adjusted mortality	1.53	1.23	1.03	3.28	2.62	1.73
P value (hospital volume)		<.05			<.01	

Number of patients is for 3-year periods (2003–2005).

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