Table 23 in 2006

	Cases	30-Day mortality	Hospital mortality
22. Pediatric surgery	479	3 (0.6)	4 (0.8)

( ), % mortality

Table 24 in 2006

	Cases		30-Day deaths	%	Hospital mortality	%
23. Combined resection of neighboring organ(s)	1,120		16	1.43	23	2.05
Organ resected	Primary lung cancer			Mediastinal tumor		
	Cases	30-Day mortality	Hospital mortality	Cases	30-Day mortality	Hospital mortality
Aorta	16	0 (0.0)	1 (6.3)	6	6 (100.0)	2 (33.3)
Superior vena cava	58	0 (0.0)	2 (3.4)	88	2 (2.3)	3 (3.4)
Pulmonary artery	149	1 (0.7)	1 (0.7)	2	1 (50.0)	0 (0.0)
Left atrium	54	2 (3.7)	2 (3.7)	1	0 (0.0)	0 (0.0)
Diaphragm	117	1 (0.9)	2 (1.7)	15	0 (0.0)	0 (0.0)
Chest wall (including ribs)	549	3 (0.5)	8 (1.5)	15	0 (0.0)	1 (6.7)
Vertebra	37	0 (0.0)	1 (2.7)	3	0 (0.0)	0 (0.0)
Esophagus	8	0 (0.0)	0 (0.0)	2	0 (0.0)	0 (0.0)

( ), % mortality

Table 25 in 2006

	Cases	30-Day mortality	Hospital mortality
24. Operation of lung cancer invading the chest wall of the apex	141	2 (1.4)	3 (2.1)

( ), % mortality
Includes tumors invading the anterior apical chest wall and posterior apical chest wall (superior sulcus tumor, so-called Pancoast type)

(C) Esophageal surgery

During 2006 alone, a total of 11,610 patients with esophageal disease were registered from 518 institutions (response rate 93.5%) affiliated with the Japanese Association for Thoracic Surgery and/or to the Japan Esophageal Society. Among these institutions were 95 (18.3%) in which 20 or more patients underwent esophageal surgery during the year of 2006, indicating a slight shift of esophageal operations to higher-volume institutions when compared to the data of 2005 (14.9%)[1] (Table 1). Of 2,231 patients with a benign esophageal disease, 755 (33.8%) underwent surgery, and 25 (1.1%) underwent endoscopic resection; the other 1,451 (65.0%) patients did not have any surgical treatment (Table 2). Of 9,379 patients with a malignant esophageal tumor, 6,548 (69.8%) underwent resection—esophagectomy in 5,236 (55.8%) and endoscopic mucosal resection (EMR) including endoscopic submucosal dissection (ESD) in 1,312 (14.0%)—and 2,831 (30.2%) patients did not undergo resection (Tables 3, 4). The decrease in patients with benign esophageal disease is obvious when looking at the figures for hiatal hernia, esophagitis, and esophageal varices.[1] This decrease in registered cases of benign esophageal diseases for these few years may indicate that more of these patients are being treated in medical departments (Fig. 1).

Among benign esophageal diseases (Table 2), esophageal varices, esophagitis (including reflux esophagitis), and hiatal hernia were the most common in Japan. Achalasia, benign esophageal tumors, spontaneous rupture of the esophagus, and congenital esophageal atresia are also common diseases that were treated surgically. Thoracoscopic and/or laparoscopic procedures have been widely adopted for benign esophageal diseases, in particular achalasia, hiatal hernia, and benign tumors. Open surgery was performed in 466 patients with a benign esophageal disease, with 30-day mortality in 7 (1.5%) and hospital mortality (including 30-day mortality) in 19 (4.1%). Thoracoscopic and/or laparoscopic surgery was performed in 289 patients, with 30-day mortality in 2 (0.7%) and hospital mortality in 4 (1.4%). The difference in these death rates between open and scopic surgery seems to be related to the conditions requiring open surgery. Most of the deaths were found in patients with spontaneous esophageal rupture, which required open surgery.

Most of the malignant diseases were carcinoma (Table 3). Among esophageal carcinomas, the incidence of squamous cell carcinoma was 92.2%, and that of adenocarcinoma (including Barrett's cancer) was 3.6%. The resection rate among patients with a squamous cell carcinoma was 69.0%, and that for patients with an adenocarcinoma was 86.5%.

According to location, cancer in the thoracic esophagus was the most common (Table 4). Of the 3,036 patients (32.4% of total esophageal malignancies) with superficial esophageal cancer (in the mucosal and submucosal layers), 1,398 (46.0%) underwent esophagectomy, and 1,312 (43.2%) underwent EMR. Advanced esophageal cancer (invading deeper than the submucosal layer) was observed in 6,307 (67.2%) patients. The 30-day mortality and hospital mortality rates after esophagectomy for patients with a superficial cancer were 0.6% and 1.3%, respectively. There were no EMR-related deaths. Of the 6307 patients with advanced esophageal cancer, 3,822 (60.6%) underwent esophagectomy, with 1.4% 30-day mortality rate and 3.7% hospital mortality rate.

Multiple primary cancers were observed in 1,310 (14.0%) of all the 9,379 patients with esophageal cancer. Synchronous cancer was found in 802 (8.6%) patients, and metachronous cancer (found before esophageal cancer) was observed in 508 (5.4%). The stomach is the commonest site for both synchronous and metachronous other malignancies followed by head and neck cancer (Table 4).

Among esophagectomy procedures, transthoracic esophagectomy through a right thoracotomy was the technique most commonly adopted for patients with a superficial cancer as well as for those with an advanced cancer (Table 5). Transhiatal esophagectomy, commonly performed in Western countries, was adopted in only 5.5% of Japanese patients with a superficial cancer who underwent esophagectomy and in 1.9% of those with an advanced cancer. Thoracoscopic and/or laparoscopic esophagectomy was adopted for 297 patients (21.2%) with superficial cancer and for 434 patients (11.4%) with advanced cancer. The number of cases of thoracoscopic and/or laparoscopic surgery for superficial or advanced cancer has been increasing for several years (Fig. 2).

Combined resection of neighboring organs with an esophageal cancer was performed in 201 patients (Tables 5, 6). Resection of the aorta together with the esophagectomy was not performed in 2006. Tracheal and/or bronchial resection combined with esophagectomy was performed in 17 patients, with no hospital mortality. Lung resection combined with esophagectomy was performed in 62 patients, with the 30-day mortality rate 3.2% and the hospital mortality rate 4.8%.

Salvage surgery after definitive (chemo-)radiotherapy was performed in 200 patients, with the 30-day mortality rate 3.0% and the hospital mortality rate 8.0% (Table 5).

Lastly, despite the efforts of the Committee to cover wider patient populations for this annual survey, for most of the institutions that responded to the questionnaire it was the departments of thoracic or esophageal surgery that provided the data. It should be noted that a larger number of patients with esophageal diseases have likely been treated medically and endoscopically. We will continue our efforts to achieve a more complete survey through active collaboration with the Japan Esophageal Society and other related societies.

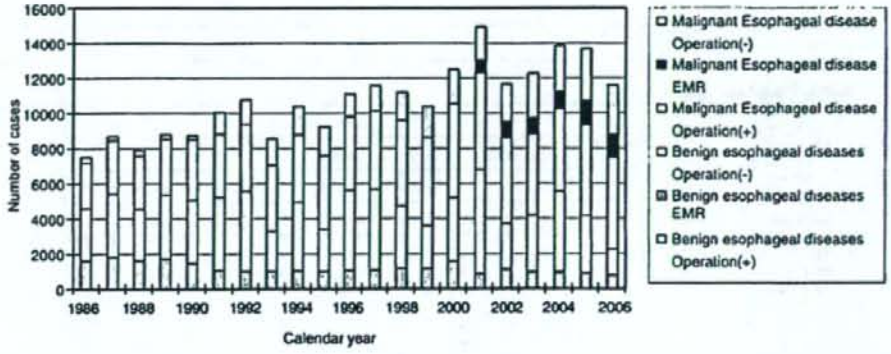

Fig. 1 Annual trend of inpatients with esophageal disease

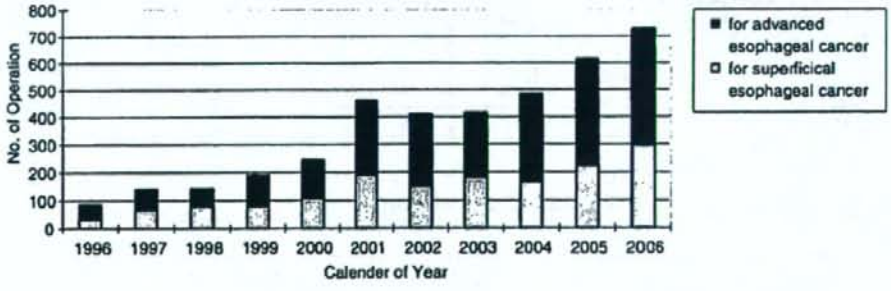

Fig. 2 Annual trend of video-assisted esophagectomy for esophageal malignancy

Table 1 Number of esophageal operations performed in 2006 in participating institutions in 2006

No. of esophageal operations			
during 2006 at the institution	Benign esophageal disease	Malignant esophageal disease	Benign + malignant disease
1–4	195	218	202
5–9	31	106	117
10–19	15	85	104
20–29	1	31	28
30–39	1	20	26
40–49	0	10	12
≥50	0	25	29
Total	243	495	518

Table 2 Benign esophageal disease in 2006

	Operation (+)									Endoscopic resection	Operation (−)	Total
	No. of patients			30-Day mortality			Hospital mortality					
	Total	Open	T/L	Total	Open surgery	T/L	Total	Open surgery	T/L			
1. Achalasia	128	21	107	0	0 (0.0)	0	0	0 (0.0)	0		44	172
2. Benign tumor	58	35	23	0	0 (0.0)	0	0	0 (0.0)	0	25	48	131
(1) Leiomyoma	39	19	20	0	0 (0.0)	0	0	0 (0.0)	0	12	31	82
(2) Cyst	5	3	2	0	0 (0.0)	0	0	0 (0.0)	0	2	5	12
(3) Others	13	12	1	0	0 (0.0)	0	0	0 (0.0)	0	11	12	36
(4) Not specified	1	1										1
3. Diverticulum	20	16	4	0	0 (0.0)	0	0	0 (0.0)	0		18	38
4. Hiatal hernia	204	98	106	1	1 (1.0)	0	2	1 (1.0)	1		186	390
5. Spontaneous rupture of the esophagus	76	70	6	4	4 (5.7)	0	9	9 (12.9)	0		8	84
6. Esophageal perforation	0	0	0	0	0 (0.0)	0	0	0 (0.0)	0		0	0
7. Esophago-tracheal fistula	23	23	0	0	0 (0.0)	0	2	2 (8.7)	0		9	32
8. Congenital esophageal atresia	47	47	0	1	1 (2.1)	0	2	2 (4.3)	0		4	51
9. Congenital esophageal stenosis	3	3	0	0	0 (0.0)	0	0	0 (0.0)	0		4	7
10. Corrosive stricture of the esophagus	6	6	0	0	0 (0.0)	0	0	0 (0.0)	0		16	22
11. Esophagitis, esophageal ulcer	50	27	23	1	0 (0.0)	1	2	1 (3.7)	1		417	467
12. Esophageal varices	83	67	16	1	0 (0.0)	1	1	0 (0.0)	1		639	722
(1) Laparotomy	28	26	2	0	0 (0.0)	0	0	0 (0.0)	0			28
(2) Others	0			0							0	0
(3) Sclerotherapy				0							639	639
13. Others	57	53	4	1	1 (1.9)	0	5	4 (7.5)	1		58	115
Total	755	466	289	9	7 (1.5)	2	23	19 (4.1)	4	25	1,451	2,231

( ), % mortality
T/L, thoracoscopic and/or laparoscopic

Table 3 Malignant esophageal disease (histological classification) in 2006

	Resection (+)	Resection (−)	Total
Carcinomas	6,445	2,780	9,225
1. Squamous cell carcinoma	5,966	2,679	8,645
2. Basaloid (-squamous) carcinoma	53	6	59
3. Carcinosarcoma	38	6	44
4. Adenocarcinoma in a Barrett's esophagus	187	22	209
5. Other adenocarcinoma	109	24	133
6. Adenosquamous carcinoma	34	3	37
7. Adenoid cystic carcinoma	7	1	8
8. Small-cell carcinoma	30	34	64
9. Undifferentiated carcinoma (non-small-cell type)	13	4	17
10. Others	8	1	9
Other malignancies	38	8	46
1. Malignant nonepithelial tumors	13	1	14
2. Malignant melanoma	23	5	28
3. Other malignant tumors	2	2	4
Not specified	65	43	108
Total	6,548	2,831	9,379

Resection, including endoscopic resection

Table 4 Malignant esophageal disease (clinical characteristics) in 2006

	Operation (+)			EMR	Operation (−)	Total
	Cases	30-Day mortality	Hospital mortality			
1. Esophageal cancer	5,236	63 (1.2)	162 (3.1)	1,312	2,831	9,379
A. Location						
(1) Cervical esophagus	192	2 (1.0)	7 (3.6)	41	221	454
(2) Thoracic esophagus	4,397	57 (1.3)	145 (3.3)	1,059	2,393	7,849
(3) Abdominal esophagus	393	2 (0.5)	5 (1.3)	81	92	566
(4) Multiple cancers	244	2 (0.8)	5 (2.0)	82	89	415
(5) Others/not described	10	0 (0.0)	0 (0.0)	49	36	95
B. Tumor depth						
(1) Superficial cancer	1,398	8 (0.6)	18 (1.3)	1,312	326	3,036
(2) Advanced cancer	3,822	55 (1.4)	141 (3.7)		2,485	6,307
(3) Not specified	16	0 (0.0)	3 (18.8)		20	36
2. Multiple primary cancers	938	6 (0.6)	15 (1.6)		372	1,310
A. Synchronous	594	3 (0.5)	7 (1.2)		208	802
(1) Head and neck	165	1 (0.6)	1 (0.6)		69	234
(2) Stomach	279	1 (0.4)	3 (1.1)		65	344
(3) Others	123	1 (0.8)	3 (2.4)		56	179
(4) Triple cancers	27	0 (0.0)	0 (0.0)		18	45
B. Metachronous	344	3 (0.9)	8 (2.3)		164	508
(1) Head and neck	83	1 (1.2)	2 (2.4)		47	130
(2) Stomach	137	1 (0.7)	3 (2.2)		47	184
(3) Others	105	1 (1.0)	2 (1.9)		57	162
(4) Triple cancers	19	0 (0.0)	1 (5.3)		13	32

( ), % mortality
EMR, endoscopic mucosal resection (including endoscopic submucosal dissection)

Table 5 Malignant esophageal disease (surgical procedures) in 2006

	Cases	30-Day mortality	Hospital mortality
Superficial cancer			
1. Endoscopic mucosal resection	1,312	0 (0.0)	0 (0.0)
2. Esophagectomy	1,398	8 (0.6)	18 (1.3)
(1) Transhiatal esophagectomy	77	0 (0.0)	1 (1.3)
(2) Thoracoscopic and/or laparoscopic procedure	297	3 (1.0)	5 (1.7)
(3) Transthoracic (rt.) esophagectomy and reconstruction	915	5 (0.5)	11 (1.2)
(4) Transthoracic (lt.) esophagectomy and reconstruction	46	0 (0.0)	1 (2.2)
(5) Cervical esophageal resection and reconstruction	18	0 (0.0)	0 (0.0)
(6) Two-stage operation	10	0 (0.0)	0 (0.0)
(7) Others/not specified	35	0 (0.0)	0 (0.0)
Advanced cancer			
1. Endoscopic mucosal resection	0	0	0
2. Esophagectomy	3,822	55 (1.4)	141 (3.7)
(1) Transhiatal esophagectomy	72	2 (2.8)	2 (2.8)
(2) Thoracoscopic and/or laparoscopic procedure	434	3 (0.7)	13 (3.0)
(3) Transthoracic (rt.) esophagectomy and reconstruction	2,891	46 (1.6)	110 (3.8)
(4) Transthoracic (lt.) esophagectomy and reconstruction	148	1 (0.7)	3 (2.0)
(5) Cervical esophageal resection and reconstruction	108	1 (0.9)	5 (4.6)
(6) Two-stage operation	62	0 (0.0)	3 (4.8)
(7) Others/not specified	107	2 (1.9)	5 (4.7)
Combined resection of other organs	201	5 (2.5)	9 (4.5)
(1) Aorta	0	0 (0.0)	0 (0.0)
(2) Trachea, bronchus	17	0 (0.0)	0 (0.0)
(3) Lung	62	2 (3.2)	3 (4.8)
(4) Others	122	3 (2.5)	6 (4.9)
Salvage surgery	200	6 (3.0)	16 (8.0)

Table 6 Mortality after combined resection of neighboring organs in 2006

	Esophagectomy			Combined resection											
				Aorta			Tracheobronchus			Lung			Others		
Year	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1996	4,194	120	2.86%	7	3	42.86%	24	0	0.00%	50	2	4.00%	78	4	5.13%
1997	4,441	127	2.86%	1	0	0.00%	34	5	14.71%	56	1	1.79%	94	3	3.19%
1998	4,878	136	2.79%	4	0	0.00%	29	0	0.00%	74	1	1.35%	128	2	1.56%
1999	5,015	116	2.31%	5	0	0.00%	23	2	8.70%	68	0	0.00%	122	1	0.82%
2000	5,350	81	1.51%	2	0	0.00%	23	2	8.70%	69	0	0.00%	96	1	1.04%
2001	5,521	110	1.99%	1	0	0.00%	26	1	3.85%	83	3	3.61%	99	2	2.02%
2002	4,904	66	1.35%	3	1	33.33%	20	2	10.00%	63	0	0.00%	63	1	1.59%
2003	4,639	45	0.97%	0	0	0.00%	24	2	8.33%	58	0	0.00%	88	1	1.14%
2004	4,739	64	1.35%	2	0	0.00%	17	0	0.00%	59	5	8.47%	119	2	1.68%
2005	5,163	52	1.01%	1	0	0.00%	11	1	9.09%	67	1	1.49%	73	1	1.37%
2006	5,263	63	1.20%	0	0	0.00%	17	0	0.00%	62	2	3.23%	122	3	2.46%
Total	54,107	980	1.81%	26	4	15.38%	248	15	6.05%	709	15	2.12%	1,082	21	1.94%

a, number of patients who underwent the operation
b, number of patients who died within 30 days after operation
c, direct operative mortality: b/a ratio (%)

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Performance of in-hospital mortality prediction models for acute hospitalization: Hospital Standardized Mortality Ratio in Japan

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Abstract

Objective: In-hospital mortality is an important performance measure for quality improvement, although it requires proper risk adjustment. We set out to develop in-hospital mortality prediction models for acute hospitalization using a nation-wide electronic administrative record system in Japan.

Methods: Administrative records of 224,207 patients (patients discharged from 82 hospitals in Japan between July 1, 2002 and October 31, 2002) were randomly split into preliminary (179,156 records) and test (45,051 records) groups. Study variables included Major Diagnostic Category, age, gender, ambulance use, admission status, length of hospital stay, comorbidity, and in-hospital mortality. ICD-10 codes were converted to calculate comorbidity scores based on Quan's methodology. Multivariate logistic regression analysis was then performed using in-hospital mortality as a dependent variable. C-indexes were calculated across risk groups in order to evaluate model performances.

Results: In-hospital mortality rates were 2.68% and 2.76% for the preliminary and test datasets, respectively. C-index values were 0.869 for the model that excluded length of stay and 0.841 for the model that included length of stay.

Conclusion: Risk models developed in this study included a set of variables easily accessible from administrative data, and still successfully exhibited a high degree of prediction accuracy. These models can be used to estimate in-hospital mortality rates of various diagnoses and procedures.

Background

Numerous studies have shown that the quality of healthcare is variable and often inadequate [1-3]. Initiatives to measure healthcare quality are an important focus for policymakers who believe that such measurements can drive quality-improvement programs [4]. The measurement of

healthcare quality includes process and outcome measurements [5]. Outcome evaluation, including in-hospital mortality, requires adequate risk-adjustment for different patient mixes to make appropriate evaluations of healthcare performance [6]. Because of the clear definition of outcome and influential patient conditions, disease-specific risk adjustment models have been developed to a certain extent in several specialties (e.g. cardiovascular diseases) and have been available for various quality improvement activities [7-10].

Although disease-specific risk adjustment may be useful for quality improvement of a specific type of care, more generic case-mix risk-standardized outcomes are required for generalized quality evaluation across specialties [11]. In the United States, several generic case-mix measures are available in commercial as well as non-commercial sources (e.g. APACHE, MedisGroup, Adjusted Clinical Group, Diagnostic Cost Groups, and the RxRisk model) [12-14], and have been applied to categorizing patients according to resource needs. However, many of these systems require detailed clinical and/or administrative data that involve extensive data collection. Furthermore, most of these case-mix measures target healthcare costs rather than clinical outcomes.

To alleviate the burden of data collection, risk prediction models for in-hospital mortality using administrative data have been proposed [15,27-29]. One study used a modified version of the Charlson Index [16] as a summary score of co-existing diagnoses. A recent international comparative study [17] demonstrated that the estimated comorbidity index could predict the chance of in-hospital death with relatively high precision (c-index of approximately 0.80), although the accuracy was suboptimal when Japanese data were analyzed. In this study, we developed a new prediction model for in-hospital mortality by using the same electronic dataset with national standardized format used in the aforementioned study. We successfully exceeded previously demonstrated predictive precision by including patient demographics and multiple administrative variables. Our study demonstrates a potential use of the developed prediction model for benchmarking the quality of healthcare across various performance units with the national database.

Methods

Data source

We used a dataset provided by the Ministry of Health, Labor, and Welfare that was originally used to evaluate a patient classification system newly introduced to 80 university affiliated hospitals and 2 national center hospitals for reimbursement since 2003. The new classification system, called Diagnosis Procedure Combination (DPC), includes information regarding up to two major diagnoses and up to six co-existing diagnoses. The 2003 version of the DPC patient classification system includes 16 major diagnosis categories (MDC) and 575 disease subcategories which are coded in ICD-10 format. The dataset also included additional information on patient demographics, use and types of surgical procedures, emergency/elective hospitalization, length of stay (LOS), and discharge status including in-hospital death [18-20]. The dataset originally included information derived from hospital administrative and clinical information provided by participating hospitals to the Ministry research group, then was made anonymous and fed back to the hospitals for benchmarking purposes. Records for 282,064 patients who were discharged from 82 hospitals between July 1, 2002 and October 31, 2002 were distributed and made available for public use as of June 2008. Following the inclusion criteria of previous studies on Hospital Standardized Mortality Ratio (HSMR) [21,22], we excluded MDC categories with mortality rates of less than 0.5% from our analysis. The data (n = 224,207) were then randomly assigned further into two subsets that were split 80/20, one for model development and the other for validation tests. The development dataset included 179,156 records and the validation dataset included 45,051 records. The datasets were made anonymous and prepared by the government sector for public use. Thus, data use was officially approved and protection of confidential information is ensured.

Model building

We started with a prediction model by referring to the Canadian model of HSMR as mentioned earlier [21,22]. The model includes age as the ordinal variable (under 60, 60–69, 70–79, 80–89, and 90 and over), gender, use of an ambulance at admission, admission status (emergency/elective), LOS, MDC, and comorbidities (model 1). We also tested another prediction model which omitted LOS (model 2). The rationale is that the model without LOS should be a "pure" prediction model since LOS can be regarded as an outcome affected by patient characteristics and hospital care quality. Several diagnosis-specific models also consider the duration of hospitalization as a part of outcome and do not include it as a predictor variable [23,24]. Based on Quan's methodology [15], the ICD-10 code of each co-existing diagnosis was converted into a score, and was summed up for each patient case to calculate a Charlson Comorbidity Index score. Scores were then classified into five categories: 0, 1–2, 3–6, 7–12, and 13 and over.

We did not include surgical treatment status as a risk parameter because the decision of whether or not to operate on a patient with a certain medical condition would vary and depend on the clinical judgment of each hospital

team. Also, surgery is not a treatment option in certain areas of medicine.

Analytical Methods

A multivariate logistic regression analysis was performed to predict in-hospital mortality by using the development dataset. Tests of model performance and model fitness were conducted using the test dataset. The prediction accuracy of the logistic models was determined using the c-index [25], and the c-index of the full (models 1 and 2) and partial models were compared. A c-index value of 0.5 indicates that the model is no better than random chance in predicting death, and a value of 1.0 suggests perfect discrimination. The models were calibrated by plotting observed versus predicted deaths based on risk. All analyses were conducted with SPSS version 15.0J (SPSS Japan, Inc).

Results

Patient Demographics in the Models

Table 1 shows in-hospital mortality by MDCs in the original full dataset. We excluded 6 out of 15 diagnostic categories due to low mortality rates (< 0.5%). The 9 remaining diagnostic categories (n = 224,207) accounted for almost 99% of in-hospital mortality in total acute hospitalization cases. We further grouped 4 MDCs with lowest mortality into one, resulting in 6 MDCs for the following analysis.

Of the 179,156 patients included in the development dataset, 53.2% were male, 35.9% had emergency status at admission, and 8.9% used an ambulance (Table 2). Nearly half (46.6%) of the patients were under 60 years of age at admission, and 9.2% were 80 years or over. The digestive system, hepatobiliary system, and pancreas

Table 1: Discharge mortality rate in each Major Diagnostic Categories (n = 282064)

	number of patients	discharge mortality	Discharge mortality rate (%)	Contributing proportion to all discharge mortality (n = 6117)	cumulative mortality rate	MDC code	category in prediction models
Digestive System, CHepatobiliary System And Pancreas	51514	1932	3.8	31.6	31.6	6	
Respiratory System	30283	1719	5.7	28.1	59.7	4	
Blood and Blood Forming Organs and Immunological Disorders	6070	592	9.8	9.7	69.4	13	
Kidney, Urinary Tract and Male Reproductive System	24415	417	1.7	6.8	76.2	11	others
Nervous System	16192	360	2.2	5.9	82.1	1	
Circulatory System	29408	282	1.0	4.6	86.7	5	
Female Reproductive System, Pregnancy, Childbirth And Puerperium	25659	246	1.0	4.0	90.7	12	others
Injuries, Burns and Others	19113	206	1.1	3.4	94.1	16	others
Breast	4752	151	3.2	2.5	96.6	9	others
Musculoskeletal System And Connective Tissue	16801	142	0.8	2.3	98.9	7	others
Endocrine, Nutritional And Metabolic System	10828	47	0.4	0.8	99.6	10	excluded
Skin, Subcutaneous Tissue	4458	9	0.2	0.1	99.8	8	excluded
Ear, Nose, Mouth And Throat	14086	5	0.04	0.1	99.9	3	excluded
Pediatric disease	3497	5	0.14	0.1	100.0	15	excluded
Eye	19768	3	0.02	0.0	100.0	2	excluded
Newborn And Other Neonates (Perinatal Period)	5220	1	0.02	0.0	100.0	14	excluded
Total	282064	6117	2.2				

Table 2: Characteristics of patients in learning dataset and test dataset (n = 224207)

		All patients (n = 224207)		Learning dataset (n = 179156)		Test dataset (n = 45051)	
		Patients	%	Patients	%	Patients	%
Major Diagnostic Category	Nervous System	16192	7.2	12996	7.3	3196	7.1
	Respiratory System	30284	13.5	24277	13.6	6007	13.3
	Circulatory System	29407	13.1	23570	13.2	5837	13.0
	Digestive System, CHepatobiliary System And Pancreas	51514	23.0	41125	23.0	10389	23.1
	Blood and Blood Forming Organs and Immunological Disorders	6070	2.7	4829	2.7	1241	2.8
	Others	90740	40.5	72359	40.4	18381	40.8
Sex	male	119216	53.2	95343	53.2	23873	53.0
Age (years)	under60	104341	46.5	83518	46.6	20823	46.2
	60–69	47703	21.3	38148	21.3	9555	21.2
	70–79	51481	23.0	41104	22.9	10377	23.0
	80–89	18033	8.0	14305	8.0	3728	8.3
	90-	2649	1.2	2081	1.2	568	1.3
Status emergency		80515	35.9	64282	35.9	16233	36.0
Use of an ambulance		20052	8.9	15996	8.9	4056	9.0
Total score of Charlson Index	score0	153710	68.6	122898	68.6	30812	68.4
	score1,2	50996	22.7	40812	22.8	10184	22.6
	score3–6	13742	6.1	10856	6.1	2886	6.4
	score7–12	4095	1.8	3234	1.8	861	1.9
	score13-	1664	0.7	1356	0.8	308	0.7
Length of stay (days)	under10	109769	49.0	87979	49.1	21790	48.4
	10–19	52871	23.6	42114	23.5	10757	23.9
	20–29	26190	11.7	20824	11.6	5366	11.9
	30-	35377	15.8	28239	15.8	7138	15.8
Hospital mortality		6047	2.7	4804	2.7	1243	2.8

made up the largest share (22%) of MDCs, followed by the respiratory system (13.5%), circulatory system (13.1%), and nervous system (7.2%). The majority of patients (68.6%) had a total score of 0 for the Charlson Comorbidity Index, and only 2.5% of patients had a score higher than 6.

Prediction Models (development dataset; n = 179,156)

Table 3 shows the in-hospital mortality prediction model with LOS as a predictor (Model 1). Using those with a LOS under 10 days as a reference, the odds ratio of in-hospital death for patients with longer LOS increased linearly; the odds ratio for patients with LOS ≥ 30 days reached 4.35 (4.01–4.72). Using the neurological MDC as a reference, MDCs for respiratory, digestive, hepatology, and hematology diseases showed a significantly higher odds ratio for in-hospital death, whereas the cardiology MDC showed a significantly lower odds ratio. Older age, gender, use of an ambulance at admission, and emergency admission status also showed significantly higher odds ratios. Finally, scores for Charlson Index categories exhibited an increasing linear trend in odds ratio as scores increased.

Table 4 shows the prediction model without LOS (model 2). The overall statistical significance of odds ratios was completely identical to that of model 1, although the magnitude was somewhat smaller for MDCs and larger for Charlson Index categories.

Model Performance (test dataset; n = 45,051)

Table 2 compares patient characteristics in the test dataset (n = 45,051 patients) to those of the development dataset. The two datasets were almost identical in the distribution of patient characteristics and case mix. In-hospital mortality rates were 2.68% and 2.76% for the development and test datasets, respectively.

Table 5 shows the c-indexes for models 1 and 2, and those using a partial set of predictors. C-index values were fairly high in both models (0.841 and 0.869 for models 1 and 2, respectively). A partial model which only included patient characteristics had a c-index of 0.727, and the addition of MDC increased the c-index to 0.786. Further including the comorbidity index resulted in only a marginal increase to 0.841. The model that included more

Table 3: MODEL1 Hospital mortality prediction model with length of stay (n = 179156)

		odds ratio	95% CI lower	95% CI upper	p
Sex	Male	1.20	1.13	1.28	0.00
Age	under60, 60–69, 70–79, 80–89, 90-	1.47	1.43	1.51	0.00
Major Diagnostic Category	Nervous System	*			0.00
	Respiratory System	3.97	3.47	4.55	0.00
	Circulatory System	0.69	0.58	0.83	0.00
	Digestive System, CHepatobiliary System And Pancreas	3.27	2.85	3.74	0.00
	Blood and Blood Forming Organs and Immunological Disorders	6.77	5.73	7.98	0.00
	Others	1.27	1.10	1.46	0.05
Status emergency		3.72	3.47	3.99	0.00
Use of an ambulance		1.82	1.68	1.98	0.00
Total score of Charlson Index	score0	*			0.00
	score1,2	1.44	1.33	1.57	0.00
	score3–6	4.07	3.72	4.45	0.00
	score7–12	8.25	7.32	9.29	0.00
	score13-	15.05	12.86	17.61	0.00
Length of Stay	under10	*			0.00
	10–19	1.39	1.26	1.52	0.00
	20–29	1.90	1.71	2.11	0.00
	30-	4.35	4.01	4.72	0.00

information on comorbidities showed a higher c-index. Figures 1 and 2 demonstrate the goodness of fit regarding the models (i.e., how well the predicted mortality rates match the observed mortality rates among patient subgroups of risk). Close agreement between the predicted and observed mortality rates with our models was seen across various patient risk subgroups analyzed.

Discussion

The prediction model of in-hospital mortality developed in this study is fairly consistent with observed mortality. Results also suggest that inclusion of both comorbidity and other demographic/clinical characteristics of patients account for the better performance of our model compared to a previously described model [17]. When administrative data are used in clinical outcomes research, algorithms to code comorbidities are essential for defining comorbidities. Charlson comorbidity measurement tools [16] are widely used with administrative data to determine the burden of the disease or case-mix. Past studies suggest that the original Charlson Index by chart review and its adaptations for use with administrative databases discriminate mortality similarly [15,17]. The database used in this study assigns to each patient one to six diagnostic codes. Counting multiple comorbidities markedly enhanced accuracy compared to counting

Table 4: MODEL2 Hospital mortality prediction model without length of stay (n = 179156)

		odds ratio	95% CI lower	95% CI upper	p
Sex	Male	1.19	1.12	1.26	0.00
Age	under60, 60–69, 70–79, 80–89, 90-	1.58	1.54	1.62	0.00
Major Diagnostic Category	Nervous System	*			0.00
	Respiratory System	3.40	2.98	3.89	0.00
	Circulatory System	0.56	0.47	0.67	0.00
	Digestive System, CHepatobiliary System And Pancreas	2.66	2.32	3.03	0.00
	Blood and Blood Forming Organs and Immunological Disorders	8.09	6.88	9.52	0.00
	Others	1.15	1.00	1.32	0.05
Status emergency		3.72	3.51	3.27	3.76
Use of an ambulance		1.82	1.87	1.72	2.03
Total score of harlson Index	score0	*			0.00
	score1,2	1.63	1.50	1.77	0.00
	score3–6	5.30	4.86	5.77	0.00
	score7–12	10.89	9.70	12.23	0.00
	score13-	19.65	16.87	22.90	0.00

Table 5: Hospital mortality prediction model performance metrics

	C-index (95%CI)
Model 1 (with length of hospital stay)	0.869 (0.860–0.879)
Model 2 (without length of hospital stay)	0.841 (0.830–0.852)
Patients characteristics only (age, sex, status emergency, use of an ambulance)	0.727 (0.713–0.742)
Patients characteristics with MDC	0.786 (0.773–0.799)
Charlson index only main diagnosis	0.585 (0.567–0.603)
Charlson index with up to 4 diagnosis	0.639 (0.621–0.692)
Charlson index with up to 6 diagnosis	0.675 (0.657–0.692)

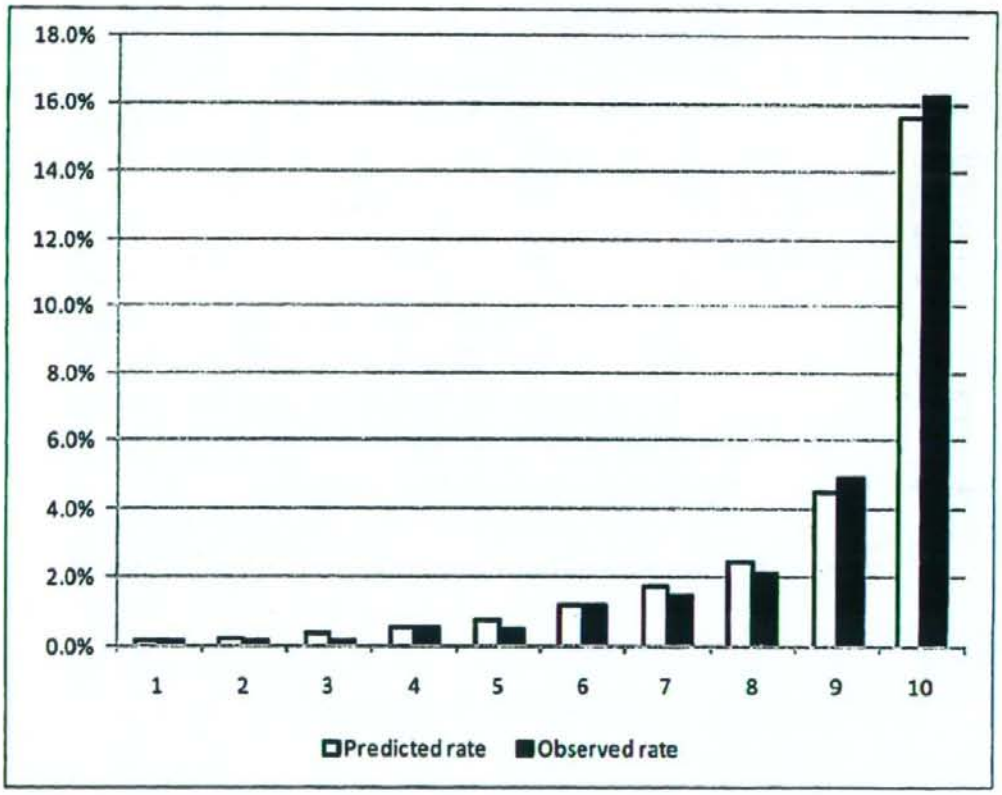

Figure 1
Model1 hospital mortality prediction model calibration (n = 45051). * Figure 1 shows the result of the goodness of fit test regarding the model 1 based on test dataset (n = 45051).

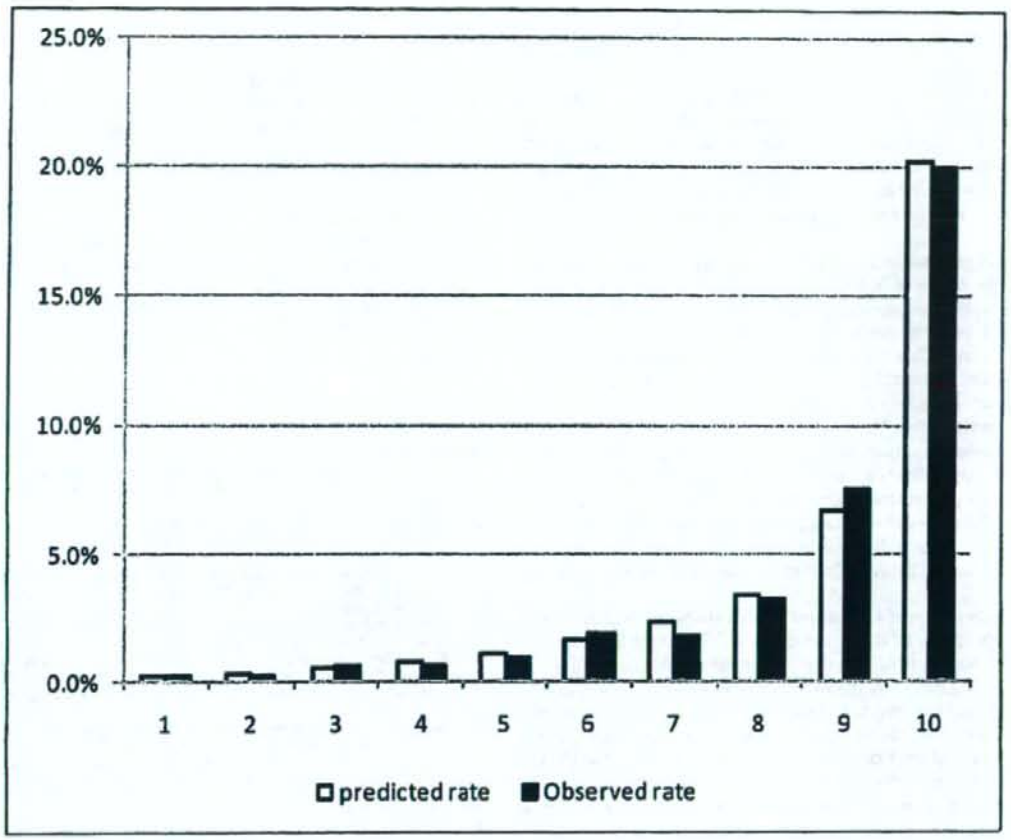

Figure 2
Model2 hospital mortality prediction model calibration(n = 45051). * Figure 2 shows the result of the goodness of fit test regarding the model 2 based on test dataset (n = 45051).

comorbidity based on a single ICD-10 code. In addition to comorbidities based on ICD-10 codes, MDCs were also incorporated into our models. By including MDCs, our model could better reflect the characteristics of major patient conditions among all co-existing diagnoses. This may also help to explain the improved performance of our model compared to former prediction models (c-index: 0.69–0.71) which incorporated only the Charlson Index in the analysis of Japanese data [17].

Recent studies in the U.S. introduced a new risk prediction model that includes extended administrative data with lab test results [30,31]. Although the inclusion of detailed clinical data may further improve prediction performance, it requires a sophisticated standardized information system on a nationwide scale. Our prediction model exhibited a comparable level of precision, using variables easily accessible in conventional administrative electronic record systems. As we demonstrated, inclusion of patient demographics, conditions at admission, and the category of major diagnosis with a summary score of comorbidities may be useful and efficient in improving model performance.

In the present study, we developed two models that include and exclude LOS. It is possible that a hospital may promote premature discharge in order to lower in-hospital mortality, thereby adjusting for LOS to allow for a fair

comparison of hospital performance. However, the duration of hospitalization is a parameter reflecting various factors other than in-hospital mortality risk, such as the quality of hospital management and socio-economic conditions that facilitate earlier discharge (e.g. availability of informal care at home). Since no major difference in accuracy was observed between the two models, we believe that the use of model 1, which excludes LOS, would be more suitable to adjust for the likelihood of in-hospital death purely due to patient conditions.

In contrast to the risk factor of age, gender did not have a pronounced impact on mortality in our study. Previous studies on cardiovascular surgery in Japan have also shown that the impact of gender on in-hospital mortality is negligible even in risk prediction models with detailed clinical variables [9]. The odds ratio of the circulatory system category was unexpectedly low and may require some explanation. The average risk of cardiovascular hospitalization may have been relatively low in this study because many patients are hospitalized for cardiac catheterization as a post-intervention evaluation in Japan. Thus, an alternative model that categorizes hospitalization for evaluation separately may increase performance in Japanese cases and deserves further consideration in future studies.

A number of limitations of this study are worth noting. Exclusion of 6 low mortality MDCs might bias the performance of our models. Given the c-index for model 2 (n = 282,064) was 0.854, we believe that our model can be useful for hospital mortality analysis in all types of disease. Nevertheless, it would be necessary to update the hospital prediction model periodically, given that the relative importance of factors contributing to mortality may change due to future medical innovations in diagnosis and therapy.

Conclusion

This study is one of the few Japanese studies that verifies and demonstrates the accuracy of in-hospital mortality prediction models that take into account all diseases. As standardized hospital mortality rates could be used as indicators of quality of care and in setting national standards, risk adjustment in relation to in-hospital mortality is thought to be useful in implementing hospital-based efforts aimed at improving the quality of medical treatment[26]. The risk model described in this study demonstrates a good degree of discrimination and calibration. In addition to its statistical evaluation, it is important that the model can be readily used for risk prediction by clinicians in the field. A major task for the future is to consider how to improve this model in order to make it more detailed, its analytical qualities even more convincing, and its use more compelling.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

HM conceived of the study and designed the protocol. HM and HH1 wrote the paper. HH2 managed data collection and data cleaning. All authors have read and approved the final manuscript.

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中外医学社

3. 心臓血管外科データベースの現状

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key words　database, quality control, cardiac surgery, risk stratification, risk adjusted mortality, risk calculator, EuroSCORE, JapanSCORE

動　向

循環器疾患に対する外科手術は外科学全体の中でも最重症患者を取り扱う領域であり，手術成績からみても最も困難な領域といえよう．drug eluting stentの出現以来それまで増加の一途を示していた冠動脈バイパス手術が減少する傾向がみられたが，全体で見れば本邦ではその手術総数は減少するどころか毎年増加の一途をたどっている(図1)[1]．その中には高齢者や以前であれば手術適応なしとされた重症例など，外科医にとってより厳しい症例が増えてきているものと思われる．さらに社会は心臓外科医だけでなく医療者に対してdaily practiceの透明性を求め，我々としてもaccountabilityを示す必要が増大しており，実際にrisk calculatorを始め，データベースを利用する外科医が増えてきているのが現状であろう．

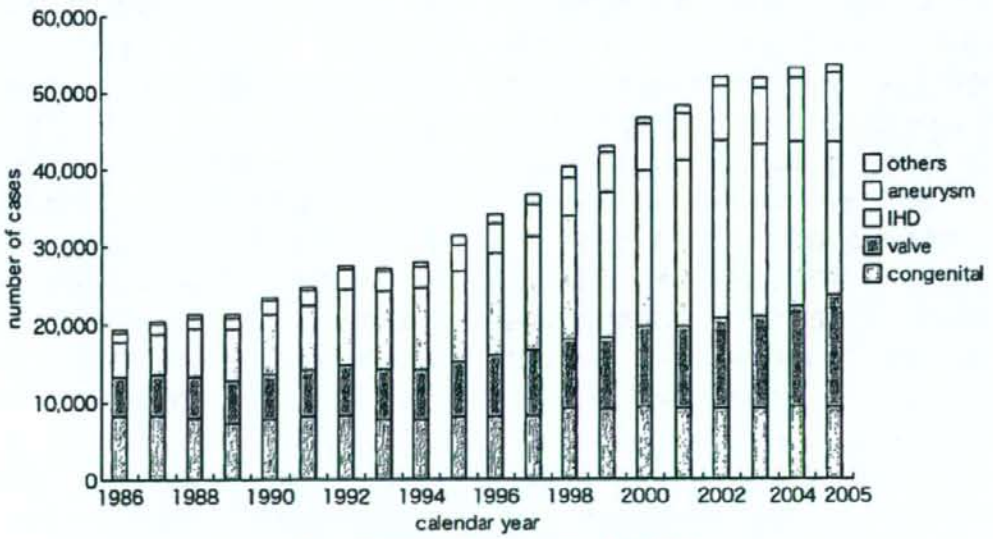

図1　日本胸部外科学会アンケート調査結果

A. 海外でのデータベースの動き

これまで心臓外科領域では欧米に信頼すべきデータベース（STS National Database）とcalculator（EuroSCORE）があり，我々もこの二つのシステムを愛用していた．

STSは膨大なデータをもとにリスクモデルを定期的に改訂し，成人だけでなく小児先天性疾患分野でも様々な解析を報告してきている．冠動脈バイパスの成績そのものは2006年までにSTSから多くの重要な仕事が発表され[2-4]，2007年以降はバイパス手術にまつわる周辺事項の解析が発表されてきている．Savageらは糖尿病患者での使用内胸動脈の本数と正中創深部感染との関連をSTS National Databaseを用いて検証した．その結果，120,793例の単独バイパス術中両側ITA群（1,732例，全体の1.4%）の正中創深部感染発生率は2.8%で，左ITA群（119,061例，全体の98.6%）での正中創深部感染発生率が1.7%であったのに比し優位に高かったことを報告している．ちなみに両者間で病院死亡率には有意差はなかったとしている（1.7%と2.3%）[5]．Puskasらはバイパス手術成績における男女差をSTS National Databaseを用いてオフポンプとオンポンプで解析した．その結果，オンポンプでは女性がリスクファクターになるが，オフポンプではリスクファクターにはならず，むしろ良好な成績が得られたと述べた[6]．バイパス以外の領域では，Hernandezが左室形成術の統計をSTSデータベースを用いて報告している[7]．それによると，2002年から2004年の間でSTSデータベース参加施設576施設のうち左室形成術を行ったのが141施設で，計731患者に施行されていた．病院死亡は9.3%で再手術14.1%，strokeが3.3%，腎不全が8.1%であったと報告している．141施設中，10例以上の症例数をもった施設は20施設に過ぎず，分散施設での死亡率の高さを指摘している．一方，Songらは僧帽弁手術の成績を男女差の観点から分析した[8]．STSデータベースを用いて2002年から2005年にかけての単独僧帽弁形成術あるいは弁置換術24,977例を分析した．バイパス術と違い女性が49%を占めていた．60歳以上の高年齢ではその成績に男女差はあまりなかったが，59歳以下では明らかに女性の方が病院死亡率が高値を示した．彼らは月経の存在が高リスクに関与しているのではと推察し，月経前でのホルモン療法の可能性を提唱している．

B. volume-outcomeに関する議論

症例数が多いほどその成績がよいというvolume-outcomeの話題は施設集約化という社会的な課題の中で現在ホットな議題とされている．科学的にはこの仮説は正しいとされているが心臓外科の分野でも，しかも日本の現状においてもそれが正しいのかどうかは重要なポイントとなろう．Petersonらは2004年にSTSデータベースを用いて単独CABGではvolume-outcomeによって病院死亡率に差はあるものの65歳以下の若年者や低リスク患者では大きな影響を与えないと報告した[9]．Careyらは，バイパス手術ではvolume-outcome効果がみられたがカテーテル治療ではみられなかったとした[10]．バイパス手術以外では，Gammieらが僧帽弁手術でのvolume-outcome効果を報告し[11]，Cowanらが胸腹部大動脈手術でのvolume-outcome効果を報告している[12]．先天性分野では，HirschらがNorwoodや大血管スイッチ手術といった難易度の高い手技でのvolume-outcomeを報告している[13]．日本からもいくつかの論文が報告されている．Kazuiらは日本胸部外科学会アンケート調査のデータから冠動脈バイパス術，弁膜症手術，急性大動脈解離手術，肺がん手術といった手技においてvolume-outcome効果があることを報告したが，少数施

設においてはその成績にはばらつきが多く，小規模施設が必ずしも悪いとはいえないと報告した[14]．オーストラリアのTanらも小規模施設でも平均的な成績は充分残せるが，ハイリスク患者に関してはやはり大規模施設に送るべきであろうと述べている[15]．一方で，Miyataらは施設の症例数だけでなく各外科医の症例数と成績を比較検討した．その結果，施設症例数にはvolume-outcome効果がみられたが，各外科医の症例数と成績にはvolume-outcome効果はみられなかったと報告した[16]．また，同論文の中で興味深い内容として，経験数の少ない外科医が大規模施設で行った場合の成績は経験数の多い外科医が小規模施設で行った場合よりも良好であった点である．このことはまだ若く経験数の少ない外科医であっても大規模施設であれば安全に手術を行うことができ，教育面においても大規模施設が有利であることが想像される．また，大規模施設という意味の中には，単なる症例数が多いという点だけでなく，充実した設備や麻酔科などの他科との連携といったprocessやconstructionといったvolume以外の要素が含まれているものと思われる．さらに注目すべき点は，Miyataらの論文に対し，editorサイドからexpert commentaryが加えられており，日本の施設が欧米と比べた場合extremely low-volumeであるにもかかわらずその成績が素晴らしいことを取り上げ，"What Do the Japanese Results Tell Us？"という項目をつけ日本から学ぶものがあると述べている点である[17]．ニューヨーク州などでは従来のvolume-outcome効果の論文から，政府や保険会社が最低症例数を徐々にあげていこうとする動きがあったが，小規模施設でも日本のように丁寧な手術を行えば良好な成績が出せることを科学的に証明し，米国での行き過ぎた施設集約化に歯止めをかけた報告といえよう．ちなみに，Miyataらは心臓以外も含む広い領域でのvolume-outcomeに関する日本初の論文をレビューしており，その中で良好な結果を得るためには最低症例数というのはある程度必要であろうが，volumeのみが医療の質を決定するものではないと結論づけており，今後の医療政策にも示唆に富んだ報告をしている[18]．

C. EuroSCOREの検証

EuroSCOREは長年にわたり心臓血管外科領域での誰でも使える簡便なrisk calculatorとして開発され[19]，世界中でまた日本においても幅広い支持を受けてきた[20,21]．重篤な疾患を扱う心臓外科医にとってきわめて有用なツールとして使用されてきたが[22,23]，数年前から予測死亡率が実際よりも高めに出るとの報告が出現し，特に重症例においてその傾向が著しいといわれている[24,25]．EuroSCOREは最近そのホームページにて新たなcalculator "EuroSCORE2008"の作成に取りかかることを公表しているが（http://www.euroscore.org/EuroSCORE2008.htm），完成にはまだ数年はかかりそうである．

D. 本邦での心臓血管外科手術データベース

これまでは心臓血管外科分野においてはデータベースに関する仕事は欧米に頼らざるを得ない状況であった．しかしながら，これらのデータベースは欧米人のデータであり，しかも主として冠動脈バイパス手術の成績が中心であるので，日本の実情には合わない．我々は2000年から全国データベース構築に取り組み，最近冠動脈バイパス手術[26]，弁膜症手術，大血管手術の三つのリスクモデルとcalculatorを開発した．この日本初のNational Databaseと世界初の大血管手術のcalculator（JapanSCORE）に関して詳細に論じてみたい．

E. 日本成人心臓血管外科手術データベース（JACVSD）

北米におけるSTS National Database，ヨーロッパにおけるEuroSCORE systemの成功を受けて，1999年の第7回アジア心臓血管外科学会（シンガポール）においてアジアでも大規模データベース構築の議題があがった．これを受けて2000年からJACVSDのプロジェクトが開始された．日本心臓血管外科学会と日本胸部外科学会の協力を得て5つの施設で開始された．そして東京大学内にある大学病院医療情報ネットワーク（UMIN）との共同研究でweb-basedのデータ入力システムが構築された[27]．現在の組織構成を図に示す（図2）．

その後徐々に実績を伸ばし2008年6月現在では180施設が参加し，累積登録症例数も63,000件を突破した（図3）．現在さらに参加施設が増大し200施設を突破している．

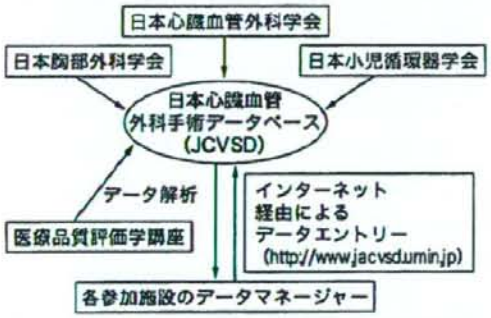

図2　日本心臓血管外科手術データベースの機構図

F. JACVSDからみた本邦の心臓大血管手術

これら6万件以上のデータのうち2005年までのデータから，欠損値や入力率の悪い施設を除き，データクリーニングを施した約2万件を用いて単独バイパス術，弁膜症手術，大血管手術の3つの分野でrisk modelを作成した．表1に3つの分野の内訳をJACVSD，EuroSCORE，STS National Databaseで比較したものを示した．JACVSDでは約2割が大血管手術であるが，ヨーロッパでは2%，米国ではわずかに1%にも満たない（表1）．このことからも海外のデータベースを用いていては大血管手術を含めた本邦心臓外科の詳細は分析できないことが示唆されよう．

約2万件のデータから単独冠動脈バイパス手術のみを抽出した大血管手術のみを抽出した4,707

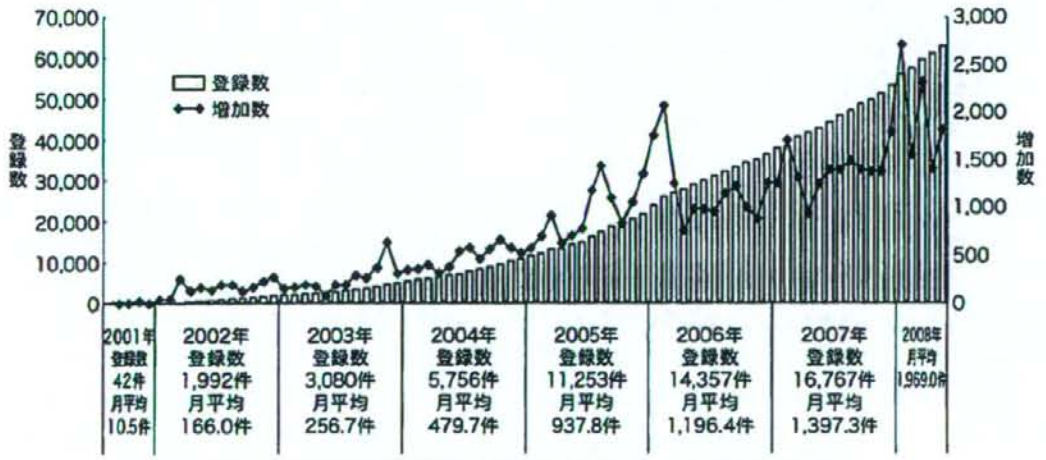

図3　JACVSD登録数推移（全登録数63,092件，2008年5月時点）