

# Risk Stratification of 7,732 Hepatectomy Cases in 2011 from the National Clinical Database for Japan

Akira Kenjo, MD, PhD, Hiroaki Miyata, PhD, Mitsukazu Gotoh, MD, PhD, Yukou Kitagawa, MD, PhD, FACS, Mitsuo Shimada, MD, PhD, FACS, Hideo Baba, MD, PhD, FACS, Naohiro Tomita, MD, PhD, Wataru Kimura, MD, PhD, Kenichi Sugihara, MD, PhD, Masaki Mori, MD, PhD, FACS

- BACKGROUND:** There has been no report on risk stratification for hepatectomy using a nationwide surgical database in Japan. The objective of this study was to evaluate mortality and variables associated with surgical outcomes of hepatectomy at a national level.
- STUDY DESIGN:** We analyzed records of 7,732 patients who underwent hepatectomy for more than 1 segment (MOS) during 2011 in 987 different hospitals, as identified in the National Clinical Database (NCD) of Japan. The NCD captured 30-day morbidity and mortality as well as 90-day in-hospital mortality outcomes, which were submitted through a web-based data entry system. Based on 80% of the population, independent predictors for 30-day mortality and 90-day in-hospital mortality were calculated using a logistic regression model. The risk factors were validated with the remaining 20% of the cohort.
- RESULTS:** The median postoperative length of hospitalization was 16.0 days. The overall patient morbidity rate was 32.1%. Thirty-day mortality and 90-day in-hospital mortality rates were 2.0% and 4.0%, respectively. Totals of 14 and 23 risk factors were respectively identified for 30-day mortality and 90-day in-hospital mortality. Factors associated with risk for 90-day in-hospital mortality were preoperative condition and comorbidity, operative indication (emergency surgery, intrahepatic/perihilar cholangiocarcinoma, or gallbladder cancer), preoperative laboratory data, and extent and location of resected segments (segment 1, 7, or 8). As a performance metric, c-indices of 30-day mortality and 90-day in-hospital mortality were 0.714 and 0.761, respectively.
- CONCLUSIONS:** Here we report the first risk stratification analysis of hepatectomy using a Japanese nationwide surgical database. This system would predict surgical outcomes of hepatectomy and be useful to evaluate and benchmark performance. (J Am Coll Surg 2014;218:412–422. © 2014 by the American College of Surgeons)

The safety and efficacy of liver resection have improved dramatically in recent years, allowing broader indications for the procedure in both benign and malignant diseases.<sup>1</sup> Perioperative mortality rates in high volume cancer centers are reportedly 0% to 2%.<sup>2–4</sup> In contrast, population-based

analyses using administrative data from Western countries have reported mortality rates of 5% to 10%,<sup>4–7</sup> indicating capacity for further improvement.

In 2006, the Japanese Society of Gastroenterological Surgery (JSGS) formed a committee to devise a database

**Disclosure Information:** Nothing to disclose.

Dr Gotoh received a research grant from the Ministry of Health, Labor and Welfare in Japan.

National Clinical Database (NCD) and the hospitals participating in NCD are the source of the data used herein and they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Received May 19, 2013; Revised November 5, 2013; Accepted November 11, 2013.

From the Japanese Society of Gastroenterological Surgery (JSGS) database committee (Kenjo, Miyata, Gotoh, Kitagawa, Shimada, Baba, Tomita, Kimura), the JSGS (Sugihara, Mori); the National Clinical Database (Miyata), Tokyo; the Department of Regenerative Surgery, Fukushima Medical University, Fukushima City, (Kenjo, Gotoh); Department of

Healthcare Quality Assessment, Graduate School of Medicine, The University of Tokyo, Tokyo (Miyata); Department of Surgery, Graduate School of Medicine, Keio University, Tokyo (Kitagawa); Department of Digestive and Pediatric Surgery, The University of Tokushima Graduate School, Tokushima (Shimada); Department of Gastroenterological Surgery, Graduate School of Medical Sciences, Kumamoto University, Kumamoto (Baba); Department of Lower Gastrointestinal Surgery, Hyogo College of Medicine, Hyogo (Tomita); First Department of Surgery, Yamagata University Faculty of Medicine, Yamagata (Kimura); Department Surgical Oncology, Tokyo Medical and Dental University, Tokyo, (Sugihara); Department of Gastroenterological Surgery, Osaka University, Graduate School of Medicine, Osaka, Japan (Mori).

Correspondence address: Mitsukazu Gotoh, MD, PhD, Department of Regenerative Surgery, Fukushima Medical University, 1-Hikarigaoka, Fukushima City 960-1295, Japan. email: mgotoh@fmu.ac.jp

#### Abbreviations and Acronyms

ADL	= activities of daily living
ASA	= American Society of Anesthesiologists
JSGS	= Japan Society of Gastroenterological Surgery
LOS	= length of stay
MOS	= more than 1 segment
NCD	= National Clinical Database
PT-INR	= prothrombin time-international normalized ratio
ROC	= receiver operating characteristic
SSI	= surgical site infection

to track surgical cases performed in Japan over 3 years (2006 to 2008), which reported relatively low mortality rates in major surgical procedures.<sup>8,9</sup> The JSGS, realizing the importance of risk-adjusted surgical outcomes for accurate comparisons and quality improvement, created the database as a subset of the National Clinical Database (NCD) of Japan, with significant support from the Japan Surgical Society. Submitting cases to the NCD is a prerequisite for all member institutions of both the Japan Surgical Society and JSGS, and only registered cases can be used for board certification.

The NCD collaborates with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP),<sup>10</sup> which shares a similar goal of developing a standardized surgery database for quality improvement. Traditionally, various governing bodies, including the ACS-NSQIP, have used 30-day patient mortality as a benchmark to assess the quality of both hospital and surgeon performance in virtually all major surgical procedures. However, Mayo and colleagues<sup>11</sup> recently reported that mortality based only on known data at 30 days is misleading and greatly underestimates the actual perioperative mortality by up to 50% compared with data at 90 days. The Japanese system of universal health care allows almost all patients who undergo surgery to be cared for in the hospitals performing the operation until the patients can function independently in activities of daily living (ADL).<sup>12,13</sup> Therefore, the risk for 30- and 90-day in-hospital mortality should be analyzed using parameters similar to those of the ACS-NSQIP for patients undergoing hepatectomy of more than 1 segment (MOS). We evaluated more than 7,000 cases to formulate risk models associated with hepatectomy. This is the first reported hepatectomy risk model of cases derived from a nationwide population recorded through a web-based data entry system.

## METHODS

### Data collection

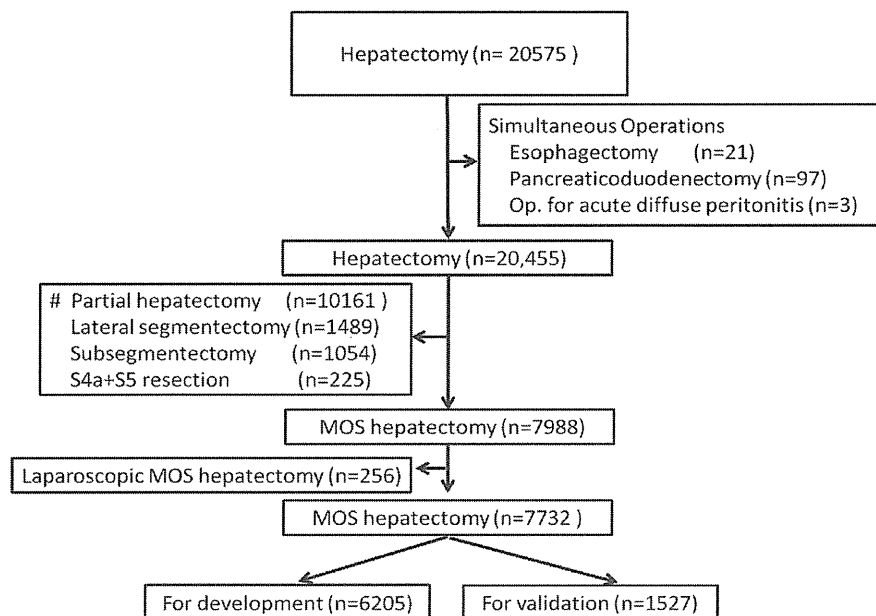
The NCD is a nationwide collaborative in association with the Japanese surgical board certification system, in which

more than 1.2 million surgical cases from over 3,500 hospitals were collected throughout 2011. The NCD is continuously in communication with hospital personnel who approve data and those in charge of tracking cases annually, as well as those responsible for data entry through the NCD web-based data management system, assuring data traceability. The NCD also consistently validates submitted data through random site visits. Hepatectomy outcomes include rigorously defined morbidities (categorized as wound, respiratory, urinary tract, central nervous system, and cardiac, among others) as well as mortality. Furthermore, the NCD supports an e-learning system for participants to continuously input data, responds to all inquiries regarding data entry (approximately 80,000 inquiries in 2011), and regularly posts some of the queries received via the website under the heading, "Frequently Asked Questions."

This analysis focused on hepatectomy procedures performed in Japan from January 1, 2011 to December 31, 2011. We collected data on 20,455 hepatectomy cases after excluding patients undergoing simultaneous operations including esophagectomy (n = 21), pancreaticoduodenectomy (n = 97), and operations for acute diffuse peritonitis (n = 3). The 30-day mortality and 90-day in-hospital mortality rates for the 20,455 cases were 1.2% and 2.3%, respectively.

The variables and definitions adopted by the NCD are almost identical to those established by ACS-NSQIP. The detailed input of these items for hepatectomy is limited only to procedures in which MOS were resected, excluding the lateral segment. All variables, definitions, and inclusion criteria maintained by the NCD are accessible to participating institutions on their website at <http://www.ncd.or.jp/>. The numbers of cases of partial hepatectomy, lateral segmentectomy, systemic subsegmentectomy, and S4a/S5 resection were 10,161; 1,489; 1,054; and 225, respectively. Thirty-day and 90-day in-hospital mortality rates for each procedure were 0.7/1.3%; 0.5/1.3%; 0.8/1.4%; and 0.9/1.3%, respectively. These cases were not applicable for this analysis. Although laparoscopic surgery has been widely applied for lateral segmentectomy and partial hepatectomy, laparoscopic surgery for MOS was performed only in a limited number of institutes as clinical trials. These cases were also excluded from this study. The exclusion criteria and the respective number of cases are shown in a flow chart in Figure 1. As a result, 7,732 patients, who underwent MOS hepatectomy in 987 hospitals from January 1 2011 to December 31, 2011, were eligible for inclusion.

Indications for benign and malignant tumors were identified using the Union for International Cancer Control (UICC) classification system. Specific hepatectomy procedures were identified by variables indicating resected



**Figure 1.** Study population and development and validation of risk stratification. MOS hepatectomy refers to hepatectomy of more than 1 segment, with the exception of lateral segmentectomy.

segments (S1–S8), which were included in the development of the risk model.

### Endpoints

The primary endpoints of this analysis were 30-day mortality and 90-day in-hospital mortality. Records with missing patient data regarding age, sex, or 30-day postoperative status were excluded. The 90-day in-hospital mortality included all patient deaths occurring within the hospitalization period regardless of the length of hospital stay (up to 90 days), and all deaths after hospital discharge (up to 30 days postoperatively).

### Statistical analysis

We used SPSS (version 20) for data analysis. Univariate analysis of the data was performed using the Fisher's exact test, the unpaired Student's *t*-test, and the Mann–Whitney U test. To develop the risk model, data were randomly assigned to 2 subsets: 80% (6,205 records) for model development and 20% (1,527 records) for validation. The 2 sets of logistic models (30-day mortality and 90-day in-hospital mortalities) were constructed for development dataset using stepwise selection of predictors with *p* value <0.05 for inclusion. A goodness-of-fit test was performed to assess how well the model could discriminate between patient survival and death. Model calibration (the degree to which the observed outcomes were similar to the predicted outcomes from the model across patients) was examined by

comparing the observed and predicted averages within each of 10 equally sized subgroups arranged in increasing order of patient risk.

## RESULTS

### Risk profiles and laboratory data of the study population

As shown in Table 1, the NCD patient population had a mean ( $\pm$ SD) age of  $66.9 \pm 11.8$  years (range 0 to 98 years) and 70.6% ( $n = 5,457$ ) were male. In this population, 1.2% arrived at the hospital by ambulance and 0.8% required emergency surgery. An abbreviated risk profile for the study population is shown in Table 1. In brief, 10.2% of the patient population had an American Society of Anesthesiologists (ASA) classification of III to V; partial/total dependency for ADL was 3.1%; 3% of patients had a body mass index  $>30$  kg/m<sup>2</sup>; and weight loss of  $>10\%$  occurred in 2.7% of patients. With regard to pre-existing comorbidities, 36.3% had hypertension, 24.8% had diabetes mellitus, 2.7% had COPD, 0.8% had preoperative dialysis, 3.6% had cerebrovascular disease, 1.7% had esophageal varices, 2.1% had ascites, and 1.1% required blood transfusion.

Primary diagnoses were hepatocellular carcinoma in 47.0% of the patients, metastatic liver disease in 29.0%, intrahepatic cholangiocarcinoma in 11.9%, perihilar cholangiocarcinoma in 4.4%, gallbladder cancer in

**Table 1.** Key Preoperative Risk Factors and Surgical Outcomes

Characteristics	Entire study population (n = 7,732)	30-d Mortality (n = 157, 2.0%)		90-d In-hospital mortality (n = 309, 4.0%)	
		Data	p Value	Data	p Value
Demographics					
Age, y, mean (SD)	66.9 (11.8)	70.6 (12.7)		71.1 (11.4)	
Males, %	70.6	2.2	0.11	4.3*	0.048
Ambulance transport, %	1.2	8.9*	<0.001	15.6*	<0.001
Preoperative risk assessment					
General					
ADL within 30 d before surgery	3.1	8.1*	<0.001	16.1*	<0.001
Body mass index >30 kg/m <sup>2</sup> , %	3.0	3.0	0.34	5.1	0.39
Alcoholism, %	25.0	1.7	0.46	3.6	0.35
Current smoker (within 1 y), %	19.5	2.1	0.76	4.2	0.71
Diabetes, %	24.8	2.5	0.09	4.9*	0.022
Pulmonary					
Ventilator dependent, %	0.2	14.3*	0.032	28.6*	0.002
Pneumonia, %	0.2	10.5	0.06	31.6*	<0.001
COPD, %	2.7	5.3*	0.003	9.7*	<0.001
Respiratory distress, %	1.7	7.6*	<0.001	16.7*	<0.001
Hepatobiliary					
Ascites, %	2.1	8.6*	<0.001	15.3*	<0.001
Gastrointestinal					
Esophageal varices, %	1.7	3.9	0.19	6.2	0.18
Cardiac					
Congestive heart failure, %	0.6	4.7	0.22	9.3	0.09
Previous PCI, %	2.2	2.3	0.78	3.5	>0.99
Previous cardiac surgery, %	1.4	4.0	0.15	6.0	0.30
Hypertension, %	36.3	2.5*	0.023	6.9*	0.002
Renal					
Acute renal failure, %	0.1	14.3	0.13	14.3	0.25
Dialysis, %	0.8	9.4*	0.002	10.9*	0.013
Central nervous system					
Previous cerebrovascular disease, %	3.6	4.3*	0.014	7.6*	0.004
Nutritional/immune/other					
Disseminated cancer, %	6.2	1.7	0.74	4.6	0.47
Chronic steroid use, %	0.9	2.9	0.40	8.8	0.05
Weight loss >10%	2.7	3.4	0.20	10.2*	<0.001
Bleeding disorder, %	1.1	5.2*	0.001	16.3*	0.002
Preoperative blood transfusion, %	1.1	10.3*	<0.001	18.4*	<0.001
Chemotherapy, %	5.7	1.4	0.39	2.9	0.32
Radiotherapy, %	0.6	3.4	0.45	3.4	>0.99
Sepsis, %	0.4	7.1	0.11	14.3*	0.024
Emergency case, %	0.8	17.5*	<0.001	23.8*	<0.001
ASA classification (III, IV, or V), %	10.2	6.0*	<0.001	10.4*	<0.001
Epidural anesthesia, %	66.7	1.6*	<0.001	3.4*	<0.001
Disease					
Hepatocellular carcinoma, %	47.0	2.3	0.15	4.0	0.95
Intrahepatic cholangiocarcinoma, %	11.9	2.2	0.71	5.2*	0.049
Metastatic liver tumor, %	29.0	0.9*	<0.001	2.0*	<0.001
Gallbladder cancer, %	2.1	7.5*	<0.001	13.8	<0.001

(Continued)

Table 1. Continued

Characteristics	Entire study population (n = 7,732)	30-d Mortality (n = 157, 2.0%)		90-d In-hospital mortality (n = 309, 4.0%)	
		Data	p Value	Data	p Value
Perihilar cholangiocarcinoma, %	4.4	5.0*	0.001	11.2*	<0.001
Other than cancer, %	5.5	1.7	0.72	3.6	0.80
Preoperative laboratory data					
Hemoglobin <10 g/dL, %	7.0	4.6*	<0.001	10.6*	<0.001
Platelet count <120,000 / $\mu$ L, %	12.4	3.5*	<0.001	5.7*	0.01
Platelet count <80,000/ $\mu$ L, %	2.4	5.9*	0.001	9.7*	<0.001
Serum albumin <3.5 g/dL, %	16.1	5.1*	<0.001	10.4*	<0.001
Serum albumin <3.0 g/dL, %	4.7	8.3*	<0.001	17.1*	<0.001
Serum AST $\geq$ 35 IU/L, %	38.8	3.2*	<0.001	6.0*	<0.001
Serum total bilirubin >2.0 mg/dL, %	2.8	6.0*	<0.001	13.0*	<0.001
Serum creatinine $\geq$ 2.0 mg/dL, %	1.4	8.2*	<0.001	9.1*	0.012
PT-INR >1.1, %	23.4	3.9*	<0.001	7.1*	<0.001

Descriptive statistics were compared using Fisher's exact test for respective variables between the mortality and nonmortality groups.

\*Statistical significance ( $p < 0.05$ ).

ADL, activities of daily living; ALP, alkaline phosphatase; ALT, alanine transaminase; ASA class, American Society of Anesthesiologists Physical Status Classification; AST, aspartate aminotransferase; CRP, C-reactive protein; PCI, percutaneous coronary intervention; PT-INR, prothrombin time—international normalized ratio.

2.1%, and noncancerous lesions in 5.5%. In this population, 0.8% ( $n = 63$ ) required emergency surgery.

### Procedure-related results

All performed hepatectomy procedures are listed in Table 2. As shown, medial segmentectomy and left lobectomy had lower mortality rates; however, hepatectomy with revascularization and for gallbladder cancer, perihilar cholangiocarcinoma, and right-side hepatectomy involving MOS were associated with increased 30-day mortality and 90-day in-hospital mortality. Combined caudate lobe resection and major hepatectomy with caudate lobe resection had poorer in-hospital mortality rates.

### Length of stay in hospital and outcome rates

The admission rate to the ICU and length of stay (LOS) in the hospital were examined (Table 3). Fifty-six percent of all patients were admitted to the ICU, with a median LOS of 1 day. The median LOS after surgery was 16.0 days for the entire study population, and the median LOS in the ICU for the mortality population was prolonged to 3.0 days. The outcomes of hepatectomy in the NCD 2011 study population included a 30-day mortality rate of 2.0% and a 90-day in-hospital mortality rate of 4.0%. A total of 203 patients (2.6%) underwent reoperation within 30 days. Overall, postoperative complications of all grades occurred in 30.4% of the patients. Incidence rates for specific major morbidities are presented in Table 4.

The following variables increased in the 30-day mortality and 90-day in-hospital mortality groups: reoperation within 30 days, surgical complications (anastomotic leakage, bile leakage, wound dehiscence, and postoperative transfusion), infectious complications (surgical site infection [SSI], pneumonia, systemic inflammatory response syndrome, and systemic sepsis), respiratory complications (unplanned intubation and prolonged ventilation of >48 hours), renal complications (renal failure and acute renal failure), central nervous system complications, and cardiac complications. In the 30-day mortality group, the incidences of pulmonary embolism and cardiac complications were elevated compared with those of overall in-hospital mortality. By contrast, the incidence of postoperative infectious complications (SSI, bile leakage, sepsis, and systemic inflammatory response syndrome) was elevated in the 90-day in-hospital mortality group.

### Model results and performance

Two different risk models were developed; the final logistic model with odds ratios and 95% confidence intervals are presented in Table 5. The scoring system for the mortality risk models according to the logistic regression equation was:

$$\text{Predicted mortality} = e^{(\beta_0 + \sum \beta_i X_i)} / 1 + e^{(\beta_0 + \sum \beta_i X_i)},$$

where  $\beta_i$  is the coefficient of the variable  $X_i$  in the logistic regression equation provided in Table 5 for 30-day mortality and 90-day in-hospital mortality.  $X_i = 1$  if a categorical risk factor is present and 0 if it is absent. For age category,

**Table 2.** Surgical Procedures for Hepatectomy

Hepatectomy	Involved segments	Cases, n	30-d Mortality			90-d In-hospital mortality		
			Deaths, n	%	p Value	Deaths, n	%	p Value
One segment		2,641	43	1.6	0.07	70	2.7	<0.001
Medial	S4	331	1	0.3	0.015	2	0.6	<0.001
Anterior	S5,8	454	10	2.2	0.73	19	4.2	0.81
Posterior	S6,7	681	12	1.8	0.78	19	2.8	0.10
Two segments		4007	74	1.8	0.26	157	3.9	0.73
Left	S2,3,4	797	8	1.0	0.033	11	1.4	<0.001
Right	S5,6,7,8	1359	37	2.7	0.06	75	5.5	0.14
Central	S4,5,8	209	1	0.5	0.13	6	2.9	0.59
More than 2 segments								
Right hepatectomy with S1	S1,5,6,7,8	137	4	2.9	0.36	13	9.5	0.003
Right trisegmentectomy	S4,5,6,7,8	646	16	2.5	0.38	33	5.1	0.14
Right trisegmentectomy with S1	S1,4,5,6,7,8	40	2	5.0	0.20	4	10.0	0.07
Left hepatectomy with S1	S1,2,3,4	356	6	1.7	0.85	15	4.2	0.78
Left trisegmentectomy with S1	S1,2,3,4,5,8	41	2	4.9	0.20	6	14.6	0.005
Procedure								
Isolated S1 resection	S1	53	3	5.7	0.09	3	5.7	0.47
Hepatectomy including S1	S1 or S1+other	1182	29	2.5	0.26	75	6.3	<0.001
Hepatectomy including S2	S2+other	2081	30	1.4	0.029	65	3.1	0.018
Hepatectomy including S3	S3+other	2202	31	1.4	0.016	73	3.3	0.05
Hepatectomy including S4	S4+other	3051	45	1.5	0.005	106	3.5	0.07
Hepatectomy including S5	S5+other	3711	96	2.6	0.001	201	5.4	<0.001
Hepatectomy including S6	S6+other	3729	93	2.5	0.006	182	4.9	<0.001
Hepatectomy including S7	S7+other	3593	95	2.6	<0.001	184	5.1	<0.001
Hepatectomy including S8	S8+other	3866	103	2.7	<0.001	209	5.4	<0.001
Hepatectomy with revascularization		203	12	5.9	0.001	25	12.3	<0.001
Hepatectomy for gall bladder cancer		107	7	6.5	0.006	14	13.1	<0.001
Hepatectomy for hilar bile duct cancer		172	6	3.5	0.006	12	7.0	0.071

Descriptive statistics were compared using the Fisher's exact test for categorical data of operative procedures between the mortality and nonmortality groups.

$X_i = 1$  if patient age is <59 years;  $X_i = 2$  if age is 60–64;  $X_i = 3$  if age is 65–69;  $X_i = 4$  if age is 70–74;  $X_i = 5$  if age is 75 to 79; and  $X_i = 6$  if age is  $\geq 80$ .

As shown, between the 2 groups there were 13 overlapping variables: age, male sex, status (emergency surgery),

preoperative comorbidities (ASA grade  $\geq 3$ , ADL before 30 days requiring any assistance, and ascites), primary diagnosis (gallbladder cancer), preoperative laboratory data (albumin  $\leq 3.5$  g/dL, aspartate transaminase  $\geq 35$  IU/L, creatinine  $\geq 2.0$  mg/dL, and prothrombin time international normalized

**Table 3.** Length of Stay in Hospital

Variable	Entire study population (n = 7,732)	Hepatectomy outcomes groups	
		30-d Mortality (n = 157)	90-d In-hospital mortality (n = 309)
LOS in hospital, d			
Mean (SD)	29.2 (23.0)	23.8 (19.0)	46.0 (36.1)
Median (IQR)	22.0 (16–34)	19.0 (11–32)	38.0 (18–66)
LOS after surgery, d			
Mean (SD)	23.7 (57.5)	13.2 (9.3)	35.1 (32.6)
Median (IQR)	16.0 (12–25)	12.0 (4.5–21)	27.0 (12–51)
ICU admission, n (%)	4,299 (55.6)	155 (98.7)	212 (68.6)
LOS in ICU, d			
Mean (SD)	2.5 (8.4)	8.3 (19.7)	9.2 (17.8)
Median (IQR)	1.0 (1–2)	3.0 (1–10)	3.0 (1–9)

IQR, interquartile range; LOS, length of stay.

**Table 4.** Prevalence of Morbidity with Hepatectomy Outcomes

Postoperative outcomes	Entire study population (n = 7,732)		Hepatectomy outcomes groups			
	n	%	30-d Mortality (n = 157)		90-d In-hospital mortality (n = 309)	
			n	%	n	%
30-day mortality	157	2.0				
Operative mortality	309	4.0				
Readmission within 30 d	138	1.8	2	1.3	5	1.6
Reoperation within 30 d	203	2.6	30	19.1	53	17.2
Surgical complication						
Anastomotic leak	137	1.8	6	3.8	32	10.4
Bile leak	620	8.0	19	12.1	69	22.3
Wound dehiscence	90	1.2	8	5.1	24	7.8
Transfusion >5 U	327	4.2	77	49.0	138	44.7
Infectious complication						
Surgical site infection						
Superficial incisional	357	4.6	10	6.4	41	13.3
Deep incisional	148	1.9	12	7.6	31	10.0
Organ space	428	5.5	18	11.5	55	17.8
Organ space with leakage	108	1.4	3	1.9	19	6.1
Pneumonia	183	2.4	34	21.7	82	26.5
Urinary tract infection	41	0.5	3	1.9	10	3.2
SIRS	115	1.5	7	4.5	22	7.1
Systemic sepsis	323	4.2	61	38.9	139	45.0
Respiratory						
Unplanned intubation	175	2.3	67	42.7	130	42.1
Pulmonary embolism	20	0.3	5	3.2	6	1.9
Prolonged ventilation over 48 h	197	2.5	63	40.1	128	41.4
Renal						
Renal failure	193	2.5	61	38.9	115	37.2
Acute renal failure	95	1.2	40	25.5	77	24.9
CNS	87	1.1	32	20.4	59	19.1
Cardiac complication	70	0.9	53	33.8	65	21.0

CNS, central nervous system; SIRS, systemic inflammatory response syndrome.

ratio [PT-INR]  $\geq 1.1$ ), resected segment (S8), and operative procedure (revascularization).

Serum creatinine level  $\geq 2.0$  mg/dL was an independent variable in the 30-day mortality group. There were 10 independent variables in the 90-day in-hospital mortality group: COPD, preoperative pneumonia, intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma, hemoglobin  $\leq 10$  mg/dL, platelet count  $\leq 80,000$  cells/ $\mu$ L, albumin  $\leq 3.0$  g/dL, tumor location (S1 or S7), and left trisegmentectomy with S1 resection.

The final models discriminated the development sets with areas under the receiver operating characteristic (ROC) curve of 0.828 and 0.826 for 30-day mortality and 90-day in-hospital mortality, respectively. To evaluate the models' performance, the C-index (a measure of model discrimination), which is the area under the ROC curve, was calculated for each validation set. The C-indices of 30-day mortality

and 90-day in-hospital mortalities were 0.714 and 0.761, respectively, indicating good performance for 90-day in-hospital mortality in the low-risk group. Details of models' performance metrics are given in Figure 2.

## DISCUSSION

In this study 7,732 cases were enrolled for MOS hepatectomy. Universal health care in Japan allows patients to remain hospitalized for several weeks after surgery if they require additional medical care. The NCD includes variables almost identical to those included in the ACS-NSQIP database and can capture the clinical course of in-hospital patients up to 90 days postoperatively.

This retrospective study evaluated 7,732 cases of MOS hepatectomy, in which the 30-day mortality and 90-day in-hospital mortality rates were 2.0% and 4.0%, respectively,

**Table 5.** Risk Models for 30-Day Mortality and 90-Day In-Hospital Mortality after Hepatectomy

Variables	30-d Mortality					90-d In-hospital mortality				
	$\beta$ coefficient	Odds ratio	95% CI		p Value	$\beta$ coefficient	Odds ratio	95% CI		p Value
Age category*	0.33	1.38	1.22	1.57	<0.001	0.31	1.36	1.24	1.49	<0.001
Sex, male	0.46	1.58	1.01	2.48	0.047	0.43	1.53	1.11	2.12	0.021
Emergent surgery	1.35	3.84	1.52	9.74	0.008	1.02	2.78	1.18	6.60	0.022
ADL before 30 d	0.73	2.07	1.09	3.93	0.026	1.03	2.79	1.72	4.52	<0.001
COPD						0.7	2.02	1.13	3.61	0.027
Ascites	0.74	2.10	1.03	4.28	0.042	0.62	1.85	1.02	3.36	0.043
Preoperative pneumonia						1.33	3.77	1.20	11.85	0.045
ASA $\geq$ grade 3	0.7	2.02	1.28	3.19	0.004	0.71	2.03	1.44	2.86	<0.001
Intrahepatic cholangiocarcinoma						0.58	1.78	1.19	2.66	0.011
Hilar bile duct carcinoma	0.92	2.52	0.98	6.46	0.05	0.7	2.00	1.25	3.23	0.008
Gallbladder cancer	1.4	4.07	1.64	10.11	0.007	1.18	3.24	1.76	5.99	<0.001
Hemoglobin <10 g/dL						0.59	1.80	1.20	2.72	0.024
Platelet count <120,000/ $\mu$ L	0.56	1.74	1.08	2.80	0.022	0.45	1.57	1.03	2.40	0.035
Platelet count <80,000/ $\mu$ L						0.76	2.15	1.06	4.33	0.001
Serum albumin <3.5 g/dL	0.7	2.01	1.34	3.02	0.007	0.5	1.64	1.16	2.34	0.027
Serum albumin <3.0 g/dL						0.52	1.67	1.04	2.69	0.045
Serum AST $\geq$ 35 U/L	0.84	2.31	1.55	3.44	<0.001	0.53	1.69	1.28	2.24	<0.001
Serum creatinine >2.0 mg/dL	1.37	3.94	1.77	8.79	<0.001					
PT-INR >1.1	0.55	1.73	1.17	2.57	0.003	0.35	1.41	1.05	1.90	0.015
Hepatectomy with s1						0.48	1.62	1.12	2.33	0.031
Hepatectomy with s7						0.45	1.56	1.14	2.14	0.009
Hepatectomy with s8	0.77	2.17	1.45	3.24	0.002	0.67	1.96	1.42	2.71	<0.001
Hepatectomy with revascularization	1.35	3.84	1.89	7.82	0.006	1.09	2.96	1.71	5.14	0.001
Left trisegmentectomy with S1 resection						1.36	3.89	1.40	10.82	0.018
Intercept ( $\beta$ 0)	-7.22				<0.001	-6.52				<0.001

\*Age, y, <59, 60–64, 65–69, 70–74, 75–79,  $\geq$ 80.

ADL, activities of daily living; ASA class, American Society of Anesthesiologists Physical Status Classification; AST, aspartate aminotransferase; PT-INR, prothrombin time–international normalized ratio.

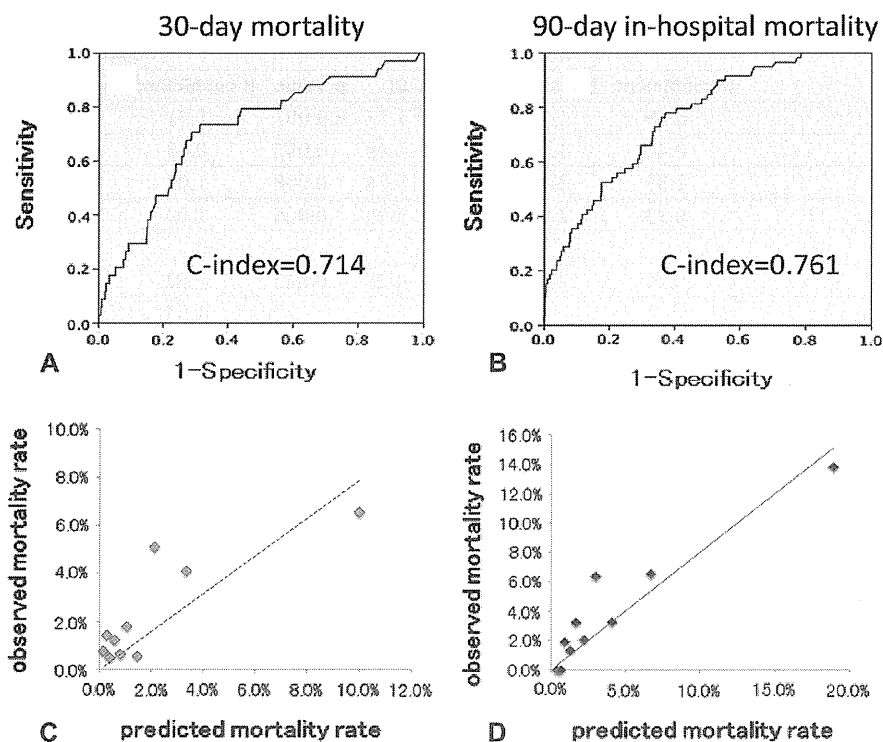
and complications occurred in 32.1%. Certain preoperative and operative indications, preoperative laboratory data, and the extent and location of resected segments, were stratified for risk of 30-day mortality and 90-day in-hospital mortality after MOS hepatectomy. To the best of our knowledge, this is the first report to convincingly demonstrate the incidence of preoperative comorbidities, postoperative complications, and mortality rates among patients who underwent hepatectomy using the Japanese NCD.

In the NCD, all types of hepatectomy cases ( $n = 20,455$ ) including MOS hepatectomy were registered as available patient data on mortality. The 30-day mortality and 90-day in-hospital mortality rates for all hepatectomy cases were 1.2% and 2.3%, respectively, which were comparable with the findings from a second nationwide Japanese database, the Diagnosis Procedure Combination (DPC) database,<sup>14</sup> in which the in-hospital patient mortality rate after hepatectomy between July 2007 and December 2008 ( $n = 5,207$ ) was 2.6%<sup>15</sup> and the in-hospital mortality

rate within 30 days of surgery in patients undergoing hepatectomy for various reasons between July 2007 and December 2009 ( $n = 18,046$ ) was 1.1%.<sup>14</sup> The DPC database is a discharge abstract and administrative claims database of inpatient admissions only from secondary and tertiary care hospitals in Japan, which represent approximately 40% of all inpatient admissions to these institutes. Importantly, the DPC database does not include some important clinical data that might more accurately reflect the risk of patient death, such as organ failure and a number of other preoperative comorbidities. In contrast, this NCD analysis included detailed data from 987 participating institutes, better representing a nationwide study of risk stratification.

Reporting deaths that occur within a maximum of 30 days of surgery likely underestimates the true mortality rate associated with hepatic resection. For example, Mayo and colleagues<sup>11</sup> showed that the number of patient deaths was underestimated by 36% and 52% after 30





**Figure 2.** Thirty-day mortality and 90-day in-hospital mortality risk models and calibrations. Receiver operating characteristic (ROC) curves for the prognostic model performance predicting (A) 30-day mortality, (B) 90-day in-hospital mortality, (C) observed vs predicted mortality rates for 30-day mortality, and (D) 90-day in-hospital mortality in the validation set are illustrated. For model calibration, the observed and predicted averages within each of 10 equally sized subgroups were plotted (C, D).

days of hepatectomy for hepatocellular carcinoma and colorectal liver metastasis, respectively, when compared with the number of deaths within 30 days. In this study, we found a similar number of patient deaths after 30 days. Several morbidities occurred more often in association with mortality after 30 days, including organ space SSI and anastomotic leakage. In fact, we identified several risk factors for 90-day in-hospital mortality that were not detected in the risk models of 30-day mortality.

As indicated by the risk models formulated for our analysis, several patient and perioperative factors were significant in both 30-day mortality and 90-day in-hospital mortality rates, including emergency surgery, patient status (age, sex, ADL, and ASA class), and comorbidity (COPD, ascites, and preoperative pneumonia). Our results were in accordance with those of previous analyses using large nationwide databases of Western countries.<sup>16,17</sup> We also found that indications for hepatectomy, including intrahepatic cholangiocarcinoma, perihilar cholangiocarcinoma, and gallbladder cancer (which is usually associated with biliary anastomosis) were significant risk factors of 90-day in-hospital mortality. These findings were also

compatible with those of 2 previous single-institution analyses,<sup>18,19</sup> but not with those from a nationwide study.

The NCD variables, which are similar to those established by ACS-NSQIP, were used for the first time to demonstrate that preoperative laboratory variables could be significant risk factors for mortality, which included platelet count ( $<120,000$  or  $<80,000$  cells/ $\mu\text{L}$ ), prolonged prothrombin time-international normalized ratio (PT-INR)  $>1.10$ , and serum levels of hemoglobin ( $<10$  g/dL), albumin ( $<3.5$  and  $\geq 3.0$  g/ $\mu\text{L}$ ), aspartate aminotransferase ( $\geq 35$  U/L), and creatinine ( $>2.0$  mg/dL). These data indicated that liver function parameters themselves, which deteriorated possibly in association with cirrhosis, could be significant risk factors for mortality. These findings were also comparable with those of Schroeder and associates,<sup>20</sup> who recommended using the Child-Turcotte-Pugh (CTP) score (to assess the prognosis of chronic liver disease) and ASA score to predict treatment outcomes. Notably, our risk score included 3 relevant variables (ascites, serum albumin, and PT-INR) among 5 included in the Child-Turcotte-Pugh criteria (encephalopathy, ascites, serum albumin, serum bilirubin, and PT-INR). The extent

of resection has been shown to be an important risk factor for mortality in many reports. Indeed, various criteria have been used to predict the success of hepatectomy procedures; for example, laparoscopic radiofrequency ablation or enucleation, wedge resection, and lobectomy in the Nationwide Inpatient Sample database<sup>16</sup>; minor, intermediate, and major resection ( $\geq 3$  segments) in a nationwide French database;<sup>17</sup> hepatectomy (partial lobe, extensive, left, and right) in the ACS-NSQIP database;<sup>21</sup> and limited resection, segmentectomy, lobectomy, and extended lobectomy with or without reconstruction in the Japanese DPC database.<sup>14</sup> Because a variety of operative procedures are currently performed,<sup>2,22-25</sup> it is difficult to categorize each according to the variables described herein. So, in this NCD analysis, we included variables that indicate the specific resected liver subsegments (S1 to S8), which makes it possible to identify which type of hepatectomy was performed. For the first time, we present a model that clearly demonstrated that resection, including S1, S7, or S8, is a risk factor for 90-day in-hospital mortality.

With these variables, our model performed very well in its discriminatory ability in both the development and validation datasets. The C-indices of the validation datasets for 30-day mortality and 90-day in-hospital mortalities were 0.714 and 0.761, respectively. Although the usefulness of the Portsmouth-Physiological and Operative Severity Score for enumeration of Mortality and Morbidity<sup>26</sup> and the Estimation of Physiologic Ability and Surgical Stress<sup>27</sup> has been established for predicting the risk of hepatectomy, they seem to be unsuitable to rate the prognoses of patients who undergo hepatectomy because these models frequently overestimate postoperative mortality.<sup>28</sup> To overcome this problem, we are currently creating a novel scoring system suitable for hepatectomy according to these risk models, which will be made available in each participating cancer center in the near future.

### Limitations

Although this analysis included more than 7,000 hepatectomy cases registered in a single year, there were still several limitations. First, the use of nationally collected data, derived from all types of patients and hospitals, would be expected to contribute to improving the quality control of the surgical procedures; however, outcomes obtained in this study may have been influenced by several factors characteristic of each hospital, such as case volume, training status, compliance, surgical specialization, resource use, and procedure-specific variables (ie, portal vein embolization, inflow occlusion to liver, and laparoscopic approach).<sup>29-34</sup> Second, our risk models to predict hepatectomy complications were not evaluated according to the Clavien–Dindo criteria in this analysis, although they

will be included in a future study. Third, this analysis used a nationwide database, but it was limited to a single race. Therefore, our results should be evaluated in comparison with those of other countries using the same variables and definitions. To this end, we are currently planning a mutual collaboration with ACS-NSQIP.

### CONCLUSIONS

In conclusion, the Japanese NCD, which is similar to the American ACS-NSQIP database, has collected data from virtually all hepatectomy cases covered by the universal health care system of Japan. Among this population, the 30-day mortality and 90-day in-hospital mortality rates were 2.0% and 4.0%, respectively, which were quite satisfactory. We also developed risk models for hepatectomy that will contribute to improved quality control of procedures and may be useful to evaluate and benchmark performance.

### Author Contributions

Study conception and design: Kenjo, Miyata, Gotoh, Kitagawa, Shimada, Baba, Tomita, Kimura, Sugihara, Mori  
Acquisition of data: Miyata

Analysis and interpretation of data: Kenjo, Miyata, Gotoh  
Drafting of manuscript: Kenjo, Miyata, Gotoh, Kitagawa, Shimada, Baba, Tomita, Kimura

Critical revision: Tomita, Sugihara, Mori

**Acknowledgment:** We wish to thank all of the data managers and hospitals participating in this National Clinical Database project for their continued efforts in entering the data. We also would like to thank Prof Hideki Hashimoto and Noboru Motomura, MD for providing direction for the foundation of NCD and the working members of the JSGS database committee (Masayuki Watanabe, MD; Satoru Imura, MD; Fumihiko Miura, MD; Hiroya Takeuchi, MD; Ichiro Hirai, MD; Yoshio Takesue, MD; Hiroyuki Suzuki, MD; Megumi Ishiguro, MD; Hiroyuki Konno, MD; Makoto Gega, MD; Nagahide Matsubara MD; and Akihiko Horiguchi, MD). We would also like to acknowledge Norihiro Kokudo, MD and Kenneth Nollet, MD for their important suggestions regarding this manuscript.

### REFERENCES

1. Poon RT, Fan ST, Lo CM, et al. Improving perioperative outcome expands the role of hepatectomy in management of benign and malignant hepatobiliary diseases: analysis of 1222 consecutive patients from a prospective database. *Ann Surg* 2004;240:698–708.
2. Makuuchi M, Imamura H, Sugawara Y, et al. Progress in surgical treatment of hepatocellular carcinoma. *Oncology* 2002; 62:74–81.

3. Nagino M, Nimura Y, Nishio H, et al. Hepatectomy with simultaneous resection of the portal vein and hepatic artery for advanced perihilar cholangiocarcinoma: an audit of 50 consecutive cases. *Ann Surg* 2010;252:115–123.
4. Asiyanbola B, Chang D, Gleisner AL, et al. Operative mortality after hepatic resection: are literature-based rates broadly applicable? *J Gastrointest Surg* 2008;12:842–851.
5. Dimick JB, Wainess RM, Cowan JA, et al. National trends in the use and outcomes of hepatic resection. *J Am Coll Surg* 2004;199:31–38.
6. Nathan H, Segev DL, Mayo SC, et al. National trends in surgical procedures for hepatocellular carcinoma: 1998–2008. *Cancer* 2012;118:1838–1844.
7. Kohn GP, Nikfarjam M. The effect of surgical volume and the provision of residency and fellowship training on complications of major hepatic resection. *J Gastrointest Surg* 2010;14:1981–1989.
8. Suzuki H, Gotoh M, Sugihara K, et al. Nationwide survey and establishment of a clinical database for gastrointestinal surgery in Japan: Targeting integration of a cancer registration system and improving the outcome of cancer treatment. *Cancer Sci* 2011;102:226–230.
9. Database Committee of the Japanese Society of Gastroenterological Surgery. Report on the fiscal 2009 survey by database committee of the Japanese Society of Gastroenterological Surgery. [Internet]. Tokyo: The Japanese Society of Gastroenterological Surgery; 2011 March. Available at: [http://www.jsgs.or.jp/modules/en/index.php?content\\_id=10](http://www.jsgs.or.jp/modules/en/index.php?content_id=10). Accessed November 16, 2012.
10. Hall BL, Hamilton BH, Richards K, et al. Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. *Ann Surg* 2009;250:363–376.
11. Mayo SC, Shore AD, Nathan H, et al. Refining the definition of perioperative mortality following hepatectomy using death within 90 days as the standard criterion. *HPB (Oxford)* 2011;13:473–482.
12. Ikegami N, Yoo BK, Hashimoto H, et al. Japanese universal health coverage: evolution, achievements, and challenges. *Lancet* 2011;378:1106–1115.
13. Hashimoto H, Ikegami N, Shibuya K, et al. Cost containment and quality of care in Japan: is there a trade-off? *Lancet* 2011;378:1174–1182.
14. Yasunaga H, Horiguchi H, Matsuda S, et al. Relationship between hospital volume and operative mortality for liver resection: Data from the Japanese Diagnosis Procedure Combination database. *Hepatol Res* 2012;42:1073–1080.
15. Sato M, Tateishi R, Yasunaga H, et al. Mortality and morbidity of hepatectomy, radiofrequency ablation, and embolization for hepatocellular carcinoma: a national survey of 54,145 patients. *J Gastroenterol* 2012;47:1125–1133.
16. Simons JP, Hill JS, Ng SC, et al. Perioperative mortality for management of hepatic neoplasm: a simple risk score. *Ann Surg* 2009;250:929–934.
17. Farges O, Goutte N, Bendersky N, et al. ACHBT-French Hepatectomy Study Group. Incidence and risks of liver resection: an all-inclusive French nationwide study. *Ann Surg* 2012;256:697–704.
18. Belghiti J, Hiramatsu K, Benoist S, et al. Seven hundred forty-seven hepatectomies in the 1990s: an update to evaluate the actual risk of liver resection. *J Am Coll Surg* 2000;191:38–46.
19. Breitenstein S, DeOliveira ML, Raptis DA, et al. Novel and simple preoperative score predicting complications after liver resection in noncirrhotic patients. *Ann Surg* 2010;252:726–734.
20. Schroeder RA, Marroquin CE, Bute BP, et al. Predictive indices of morbidity and mortality after liver resection. *Ann Surg* 2006;243:373–379.
21. Pitt HA, Kilbane M, Strasberg SM, et al. ACS-NSQIP has the potential to create an HPB-NSQIP option. *HPB (Oxford)* 2009;11:405–413.
22. Ogata S, Belghiti J, Varma D, et al. Two hundred liver hanging maneuvers for major hepatectomy: a single-center experience. *Ann Surg* 2007;245:31–35.
23. Makuuchi M, Thai BL, Takayasu K, et al. Preoperative portal embolization to increase safety of major hepatectomy for hilar bile duct carcinoma: a preliminary report. *Surgery* 1990;107:521–527.
24. Beck-Schimmer B, Breitenstein S, Bonvini JM, et al. Protection of pharmacological postconditioning in liver surgery: results of a prospective randomized controlled trial. *Ann Surg* 2012;256:837–845.
25. Harada N, Ishizawa T, Muraoka A, et al. Fluorescence navigation hepatectomy by visualization of localized cholestasis from bile duct tumor infiltration. *J Am Coll Surg* 2010;210:e2–e6.
26. Lam CM, Fan ST, Yuen AW, et al. Validation of POSSUM scoring systems for audit of major hepatectomy. *Br J Surg* 2004;91:450–454.
27. Banz VM, Studer P, Inderbitzin D, et al. Validation of the estimation of physiologic ability and surgical stress (E-PASS) score in liver surgery. *World J Surg* 2009;33:1259–1265.
28. Haga Y, Ikejiri K, Takeuchi H, et al. Value of general surgical risk models for predicting postoperative liver failure and mortality following liver surgery. *J Surg Oncol* 2012;106:898–904.
29. Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011;364:2128–2137.
30. Dimick JB, Cowan JA Jr, Colletti LM, et al. Hospital teaching status and outcomes of complex surgical procedures in the United States. *Arch Surg* 2004;139:137–141.
31. Brooke BS, Dominici F, Pronovost PJ, et al. Variations in surgical outcomes associated with hospital compliance with safety practices. *Surgery* 2012;151:651–659.
32. Csikesz NG, Simons JP, Tseng JF, et al. Surgical specialization and operative mortality in hepato-pancreatico-biliary (HPB) surgery. *J Gastrointest Surg* 2008;12:1534–1539.
33. Pearse RM, Moreno RP, Bauer P, et al. European Surgical Outcomes Study (EuSOS) group for the Trials groups of the European Society of Intensive Care Medicine and the European Society of Anaesthesiology. Mortality after surgery in Europe: a 7 day cohort study. *Lancet* 2012;380:1059–1065.
34. Gedaly R, McHugh PP, Johnston TD, et al. Obesity, diabetes, and smoking are important determinants of resource utilization in liver resection: a multicenter analysis of 1029 patients. *Ann Surg* 2009;249:414–419.

## Editorial

## 大規模臨床データベースの現況と課題

1) 東京大学大学院医学系研究科小児外科, 2) National Clinical Database 運営委員長

岩中 督<sup>1)2)</sup>

2011年1月から、日本外科学会系の外科手術については、National Clinical Database (以下、NCD) に登録することが義務化された。NCDの運営責任者の立場から、誌面をお借りして、このデータベースの現状とこれからの課題について会員諸氏にメッセージをお届けしたい。

おおよその日本外科学会会員は、このNCDの役割を理解してくださっていると信じている。従前の専門医制度では、外科専門医や領域の専門医を申請したい、あるいは更新したい外科医は、その都度自分で症例登録を行っていた。NCDを用いることにより、外科専門医制度の1階部分である外科専門医、2階部分である各領域の専門医、さらには3階に相当する一部の消化器外科領域の専門医制度まで、誰かの一度の入力で済むことになり、会員各位の個々の症例登録が不要になった。『ちょっと楽になったぞ!』と、お気づきの会員も増えているに違いない。事業開始当初の動きの遅いon-line環境も改善され、入力を担当する若手外科医やクラークの物理的ストレスはかなり軽減されてきていると信じている。

さて、このNCDはどのような役割を果たすことができるのであろうか。入力項目は、術式によって、また領域によって異なっている。我が国の外科診療の実態を把握するために設定した、すべての領域に共通の項目と、アカデミアの立場から医療水準を科学的に評価するための詳細な臨床情報項目とで、データベースは設計されている。この臨床情報部分に詳細な入力を義務づけた学会では、そのrisk-adjustされたデータを分析して、個々の医療機関の医療水準評価・その結果のフィードバックなどを行いつつ、医師主導の臨床研究も簡便に行いたいと計画中である。NCDではすべての手術で、担当した外科医の履歴が把握できてい

るので、共通項目と一部の領域別データを用いれば、専門医の適正な配置や専門医を育成する施設のあり方、施設の集約や棲み分けに向けた各施設の役割など、様々な視点からの政策提案が行えよう。日本外科学会をはじめとするすべての加盟学会では、このデータベースのさらなる利活用を検討中であり、日本外科学会内に「NCDデータ利活用ワーキンググループ」も立ち上げて、議論が始まっている。また先行した心臓血管外科領域ではすでに多くの学術雑誌にその利活用結果が収載されているが、消化器外科領域においても、英文誌への投稿が始まった。また、消化器外科領域の膨大な臨床情報を利用した臨床研究の公募も開始された。会員諸氏には、『苦労したが入力した甲斐があった!』とご理解いただける日が、もうすぐやってくることを保証したい。

さてその一方で、課題も山積している。他領域の外科学会から参加の意思表示も届きはじめ、今後どのようにこのNCDを発展的に育てていくかが、喫緊の課題である。NCDの基盤が大きくなれば、それだけ行政に対する影響力も大きくなるが、NCDの悉皆性や科学的な精神をどれだけ他領域にご理解いただけるか、今後NCD理事会などで検討する必要がある。また、NCDの成果をどのように発信していくか、個別の医療機関が同定されずに如何に外科診療の実態を市民に伝えられるかも、並行して検討していく必要がある。最終的には、市民にとって最適の外科医療を提供することを目的としたデータベースであり、いろいろな立場からの意見を拝聴する必要がある。加えてデータベースの維持には多額の経費を必要とする。この件についても、関連する学会に支援をお願いしつつ、自立に向けた活動を強化していきたい。

THE PRESENT AND FUTURE OF NATIONAL CLINICAL DATABASE

Tadashi Iwanaka<sup>1,2</sup>Professor, Department of Pediatric Surgery, The University of Tokyo Hospital, Tokyo, Japan<sup>1</sup>, Chairman of Steering Committee, National Clinical Database<sup>2</sup>© Japan Surgical Society Journal Web Site : <http://journal.jssoc.or.jp>

日本外科学会雑誌 第114巻 第4号

169

## 特 集

## National Clinical Database の現状とこれから

## 1. 特集によせて

1) 東京大学大学院医学系研究科小児外科, 2) National Clinical Database 運営委員長

岩中 督<sup>1)2)</sup>

National Clinical Database (NCD) を立ち上げる、いわゆる『産みの苦しみ』『黎明期』は終わった。2010年に法人化されたこのデータベースは、2011年1月の症例から登録が開始された。立ち上げ当初は様々な課題に対して多くのクレームが寄せられたが、2012年に開催された日本消化器外科学会総会の特別企画で、初めて2011年登録症例の集計・分析結果が報告され、この期を境にクレームより評価の意見、特にNCDのさらなる利活用に向けた前向きな意見が、寄せられるようになった。現在は、いわゆる『発展期』『成長期』というところであろうか。このNCDをさらに成熟させていくためには、すべての外科医がNCDの価値を体感し、自ら進んでNCDに参画する必要がある。NCDは、専門医制度とリンクさせ、手術症例登録をほぼ義務化することで始まった。しかしながら、

我が国の外科学の状況を学会員で共有しさらなる飛躍の一助とすること、各施設や各外科医の医療水準評価を行い、それを個々にフィードバックすること、さらにこのデータベースの上位に臨床研究などを容易に構築できるようにすること、というアカデミックな活動がもう一つの大きな目的である。そのアカデミックな興味をインセンティブとして本データベースの悉皆性を担保したい、と常々考えてきたが、ようやくアウトカムを出せるところに到達した。本特集では、各領域におけるNCDの利活用の状況、さらにはこれからの展望について、各領域の責任者クラスに寄稿をお願いした。データベースを根拠にした科学としての外科学を、すべての日本外科学会会員に楽しんでいただきたい。

2. 外科専門医制度で果たしたNCDの役割とこれから……………慶應義塾大学外科 北 郷 実
3. 消化器外科領域におけるNCDの利活用  
……………福島県立医科大学臓器再生外科, National Clinical Database (NCD),  
日本消化器外科学会データベース委員会 後 藤 満 一
4. 小児外科領域におけるNCDの利活用—NCDがもたらす小児外科医療の  
パラダイム・シフト—……………自治医科大学小児外科 前 田 貢 作
5. 乳腺領域におけるNCDの利活用  
……………日本乳癌学会登録委員会, 東海大学乳腺・内分泌外科 徳 田 裕
6. 心臓血管外科領域のさらなる発展……………東京大学心臓外科 本 村 昇
7. 呼吸器外科領域における今後の取り組み……………東京医科大学外科1講座 池 田 徳 彦

THE PRESENT AND FUTURE OF NATIONAL CLINICAL DATABASE

Tadashi Iwanaka<sup>1,2</sup>Department of Pediatric Surgery, The University of Tokyo Hospital, Tokyo, Japan<sup>1</sup>, Chairman of Steering Committee, National Clinical Database<sup>2</sup>© Japan Surgical Society Journal Web Site : <http://journal.jssoc.or.jp>

特集

National Clinical Database の現状とこれから

3. 消化器外科領域における NCD の利活用

- 1) 福島県立医科大学臓器再生外科学講座, 2) 東京大学大学院医学系研究科医療品質評価学講座,
- 3) 浜松医科大学外科学第二講座 (消化器・血管外科分野),
- 4) 大阪大学大学院医学系研究科外科学講座消化器外科学,
- 5) National Clinical Database (NCD), 6) 日本消化器外科学会データベース委員会

後藤 満<sup>1)5)6)</sup>, 宮田 裕章<sup>2)5)6)</sup>, 今野 弘之<sup>3)5)6)</sup>, 森 正樹<sup>4)5)</sup>

キーワード

National Clinical Database (NCD), 医療水準評価, リスクモデル, フィードバック, がん登録

I. 内容要旨

NCD 事業は、外科関連の専門医制度を共通基盤とし、医療水準の把握と改善に向けた取り組みの支援、政策提言、参加学会間の連携をめざし、日本外科学会とともに外科関連の専門医制度をもつ学会が合同で開始した。消化器外科領域では、医療水準評価対象術式の2011年登録症例約12万例を用い、8術式のリスクモデルを構築した。このモデルを用いることで、各症例の術前リスク評価が可能となるとともに、各診療科のベンチマークの設定が可能となる。さらに、施設カテゴリー（認定施設、関連施設、外科医数）、Hospital volume、専門医の関与、地域、救急搬送、外傷手術、内視鏡手術、肥満、高齢者、などの各因子のアウトカムに与える影響の解析が可能となる。消化器外科領域では、既に、日本消化器外科学会データベース委員会により、日本外科学会ならびに消化器外科関連学会を対象として、NCD データを利用した臨床研究の公募が行われた。複数の研究プロジェクトが採択され、これらの解析が始まろうとしている。

II. はじめに (設立, 運営, データ集積)

NCD 事業は、2010年4月、1) 外科関連の専門医

のあり方を考えるための共通基盤の構築、2) 医療水準の把握と改善に向けた取り組みの支援、3) 患者さんに最善の医療を提供するための政策提言、4) 領域の垣根を越えた学会間の連携をめざし、日本外科学会とともに外科関連の専門医制度をもつ学会が合同でスタートさせた<sup>1)2)</sup>。2011年1月より登録が開始され、2013年6月現在、全国3,900以上の参加施設、5,000以上の診療科のネットワークにより構成されている。登録症例数は年間120万例に及ぶ。2011年の登録症例のうち、消化器外科領域では、約2,200の診療科から約61万例の手術症例が登録され、そのうち悪性腫瘍を対象としたものは22万例、医療水準評価対象術式の登録症例は約12万例に及ぶ。そのNCD術式ごとの集計結果は日本外科学会のホームページで一般公開されている<sup>3)</sup>。本稿では、NCD 消化器外科領域において、今後、どのようなNCDの利活用が行われるかについて概説する。

III. NCD のデータ入力構造と RASO

NCD の入力項目は、1 症例ごとに、A. 統計的調査、B. 医療評価調査、C. 臨床研究までの入力が可能となるように、システムが構築されている。A は外科専門医申請に必要な項目、B は消化器外科専門医申請

EVOLUTION AND FUTURE OF THE NATIONAL CLINICAL DATABASE: FEEDBACK FOR SURGICAL QUALITY IMPROVEMENT

Mitsukazu Gotoh<sup>1,5,6)</sup>, Hiroaki Miyata<sup>2,5,6)</sup>, Hiroyuki Konno<sup>3,5,6)</sup> and Masaki Mori<sup>4,5)</sup>

Division of Surgery, Fukushima Medical University<sup>1)</sup>, Department of Healthcare Quality Assessment, University of Tokyo Postgraduate School of Medicine<sup>2)</sup>, Second Department of Surgery, Hamamatsu University School of Medicine<sup>3)</sup>, Department of Surgery, Osaka University Graduate School of Medicine<sup>4)</sup>, National Clinical Database<sup>5)</sup>, Member of the Japanese Society of Gastroenterological Surgery Database Committee<sup>6)</sup>

### 3. 消化器外科領域における NCD の利活用



図1 NCD Feedback 画面 (案)。Risk Calculator, 施設診療科の患者背景とパフォーマンスの全国比較, 手術件数などを確認できる。

に必要な項目である。さらにその上の専門性を求める学会、例えば日本肝胆膵外科学会では、より詳細な項目の入力を必要としている。Aの項目は外科専門医制度委員会で、Bの項目は日本消化器外科学会と関連する8学会・研究会(日本食道学会、日本胃癌学会、大腸癌研究会、日本肝癌研究会、日本肝胆膵外科学会、日本膵臓学会、日本内視鏡外科学会、日本腹部救急医学会)のデータベース関連委員で構成される消化器外科関連専門医制度委員会、消化器外科関連データベース委員会で検討されたものである。A項目は13項目、B項目はB1、B2項目に整理される。B1は、患者イニシャル、国籍、腹腔鏡使用の有無、主たる麻酔種別、米国麻酔科学会全身状態分類、手術情報として、手術時間、術中出血量、術中MAP輸血量、悪性腫瘍の場合はStage(UICC)、術後経過情報として術後診断(入院時と異なる場合)、術後30日以内の再手術、最重症ケアユニットからの退出日、退院日、退院時転記、術後30日以内の再入院、術後30日状態に関する項目を追加している。また、B2としてはACS-NSQIPのRASO評価可能な項目に、さらに関連学会から追

加が望ましいとされた項目を含む。内訳は、術前臨床所見、手術情報、検査値、消化器外科術後情報からなる。

このB2項目が入力される医療水準評価対象術式には、食道切除再建術、胃切除術、胃全摘術、結腸右半切除術、低位前方切除術、肝切除術、膵頭十二指腸切除術、急性汎発性腹膜炎に対する手術の8術式が含まれ、入力されたデータの質の検証後、各術式におけるリスクモデルが作成される。具体的には、患者術前状態を示す項目を独立変数に設定し、死亡あるいは合併症などのアウトカムを従属変数に設定した多重ロジスティック回帰分析を行いモデルを構築する。モデルに含まれる独立変数は変数増加法(尤度比)により選択しており、この構築モデルはACS-NSQIPで実施されているものと同様である。NCDへの入力過程は全て追跡可能であり、ランダムに行われるオーディットにより、原資料との齟齬がないか、定期的な検証を受けている。NCDの入力システムを含め作成された各リスクモデルに関する論文を、術式別に国際学術誌に投稿し、peer reviewを受けている。既に、複数の術式

### 3. 消化器外科領域における NCD の利活用



図2 Risk Calculator による当該症例の予測死亡率の表示例 (案)。

について論文が採択された<sup>4)~7)</sup>。今後、採択された術式から順次、臨床現場へフィードバックが開始される。

具体的なフィードバック内容について概説する。NCDのFeedback画面上では、①Risk Calculator、②施設診療科の患者背景とパフォーマンスの全国比較、③手術件数について情報が得られる(図1)。①Risk Calculatorでは、登録データに基づいて構築されたリスクモデルを用いて、手術を受ける患者の死亡率や合併症発症率等の予測値を計算することができる。操作は、Risk Calculatorのボタンをクリックし、消化器外科専門医領域を選択し、術式を選択し、リスクモデルの項目として抽出された項目のデータをWEB上で入力する。即座に、その症例の手術関連死亡や主な合併症の発生予測値が画面上に現れる(図2)。この結果は患者へのインフォームドコンセントを取得する際、あるいは医局でのカンファレンスなどで利用できる。また、②施設診療科の患者背景とパフォーマンスの全

国比較では、患者の術前リスクに関する項目の集計結果、および、登録データに基づいて推定された自施設診療科のパフォーマンス(死亡率や合併症発症率など)を確認することができる。また、このパフォーマンスは経時的に追跡できるので、質の向上あるいは低下につながったイベントを拾い上げることが可能となる。③手術件数については、術式ごとの手術件数を確認することができる。自分達の診療科の手術件数をみることで、当該術式の手術件数が全国のどのあたりに位置するのかを知ることができる。

今後、NCDの消化器外科領域では、これまでに入力されたデータをもとに、施設カテゴリー(認定施設、関連施設、外科医数)、Hospital volume、専門医の関与、地域、救急搬送、外傷手術、内視鏡手術、肥満、高齢者、などの各因子のアウトカムに与える影響を解析し、報告していくことが予定されている。一方、前向き研究としては、新しい入力項目を加えた介入研究も、限定された施設では実施可能である。ただし、前



### 3. 消化器外科領域における NCD の利活用

者は NCD の事業を周知することにより、オプトアウトの条件で実施することで倫理委員会での承認を得ているが、介入研究の場合は、個別に倫理委員会の承認を必要とする。

C. 臨床研究の部分には、既に日本肝胆膵外科学会の詳細項目や膀胱癌登録、乳癌登録が実装されている。平成 24・25 年度厚生労働科学研究費補助金（がん臨床研究事業）研究課題「精度の高い臓器がん登録による診療ガイドラインや専門医育成への活用に関する研究」<sup>10)</sup>を得て、5 大がんを含む他の消化器がん登録の実装も進んでいる。これらのシステムを利用し、地域・院内がん登録との連携もとりながら予後情報の流し込みについても検討が進んでおり、これらが稼働すれば、周術期のみならず長期の予後も踏まえた医療の質の評価が可能となる。

#### IV. データ利活用のルール

これらの研究の利活用には一定のルールがある。データ登録とその利用については関連学会がガバナンスをもって行う。また、B. 医療評価調査以上のデータを複数の学会が利用する場合、例えば、B. 医療評価調査、C. 臨床研究の両方のデータを利用した研究を行う場合は、関連学会が両者の合意のもとで行い、また、結果の公表にあたっては共同で行うことになる。

消化器外科領域では、既に、日本消化器外科学会データベース委員会により、日本外科学会ならびに消化器外科関連学会を対象として臨床研究の公募が行われ、複数の研究プロジェクトが採択され、解析が始まろうとしている。その中の一つは「NCD 消化器外科領域と ACS-NSQIP との国際連携による医療水準向上プログラムの作成」と題し、①NCD の消化器外科領域における医療水準評価対象術式と比較可能な ACS-NSQIP の術式において、死亡率、合併症の発生率を含むアウトカム評価を行い、その臨床的特徴を明らかにすること、②医療水準評価対象の 8 術式におけるリスクモデルが、わが国のみならず、米国の医療水準評価に応用可能なものかどうかを検証すること、さらに、③同一の手技や治療法に関する、日本と米国の実施状況や効果について、比較検討する分析を行うことなどが、予定されている。

研究には、これまでに入力されたデータを利用する後ろ向き研究と、今後の入力データを利用する前向き研究とがある。前向き研究では新たな入力項目を加え

ることも可能であるが、この場合は、合意した共同研究施設のみでのデータ入力となる。新たな項目を学会単位で認めることは入力者の過大な負担につながるため、会員にフィードバックできる十分な内容をもつかどうか、学会単位の十分な検討が必要である。また、解析経費、データベース構築のための費用も新たに発生するため、研究経費の入手法も勘案した申請が必要となる。

#### V. おわりに

2011 年から症例登録が始まった NCD では、年間 120 万を超える症例が集積されている。これは、参加されている診療科の先生方の多大なるご尽力によるものである。今後、各診療科のベンチマークの指標や、各患者の術前リスクが各端末から入手できるようになるとともに、大規模なデータベースを利用した臨床研究が可能となり、さらなる医療の質の向上が期待できる。なお、臨床研究を実施するうえでは、NCD データは日常診療のなかの貴重な時間を割いて入力された All Japan としての財産であり、関連学会の連携を基盤としていることに留意すべきことは言うまでもない。

#### 文 献

- 1) 岩中 督, 宮田裕章: 外科学会会員のための企画 National Clinical Database (NCD) 構築に向けて 全体構想. 日外会誌, 111 (5): 306-310, 2010.
- 2) 後藤満一, 宮田裕章, 杉原健一: 外科学会会員のための企画 National Clinical Database (NCD) 構築に向けて 実際の運営. 日外会誌, 111 (6): 373-378, 2010.
- 3) National Clinical Database (NCD) の集計結果の報告 (<https://www.jssoc.or.jp/other/info/info20130430.html>)
- 4) Watanabe M, Miyata H, Gotoh M, et al.: Total gastrectomy risk model: data from 20,011 Japanese patients in a nationwide internet-based database. Ann Surg, in press.
- 5) Kimura W, Miyata H, Gotoh M, et al.: A Pancreaticoduodenectomy Risk Model Derived from 8575 Cases from a National Single-Race Population (Japanese) Using a Web-Based Data Entry System: The 30-Day and In-hospital Mortality Rates For Pancreaticoduodenectomy. Ann Surg, 2013 (Epub ahead of print).
- 6) Kobayashi H, Miyata H, Gotoh M, et al.: Risk model for right hemicolectomy based on 19,070 Japanese patients in the National Clinical Database. J Gastroenterol, 2013 (Epub ahead of print).

### 3. 消化器外科領域における NCD の利活用

7) Kenjo A, Miyata H, Gotoh M, et al : Risk Stratification of 7,732 Hepatectomy Cases in 2011 from the National Clinical Database for Japan. *J Am Coll Surg*. 2013 (Epub ahead of print).

床研究事業 採択のお知らせ ([http://www.jsjgs.or.jp/modules/oshirase/index.php?content\\_id=226](http://www.jsjgs.or.jp/modules/oshirase/index.php?content_id=226))

8) 平成 24 年度厚生労働科学研究費補助金 がん臨

利益相反：なし

#### EVOLUTION AND FUTURE OF THE NATIONAL CLINICAL DATABASE : FEEDBACK FOR SURGICAL QUALITY IMPROVEMENT

Mitsukazu Gotoh<sup>1,5,6</sup>, Hiroaki Miyata<sup>2,5,6</sup>, Hiroyuki Konno<sup>3,5,6</sup> and Masaki Mori<sup>1,5</sup>

Division of Surgery, Fukushima Medical University<sup>1</sup>

Department of Healthcare Quality Assessment, University of Tokyo Postgraduate School of Medicine<sup>2</sup>

Second Department of Surgery, Hamamatsu University School of Medicine<sup>3</sup>

Department of Surgery, Osaka University Graduate School of Medicine<sup>4</sup>

National Clinical Database<sup>5</sup>

Member of the Japanese Society of Gastroenterological Surgery Database Committee<sup>6</sup>

The National Clinical Database (NCD) was founded in April 2010 as the parent body of a database linked to the surgical board certification system. Registration began in 2011, and to date more than 3,900 facilities have enrolled, with an accumulation of more than 1.02 million cases per year. Related activities will primarily focus on providing high-quality healthcare to patients and the general public, with the clinical setting serving as the driving force behind improvements. Clinical research using the database and evidence-based policy recommendations will impact businesses, the government, and insurers. In the gastroenterological surgery section, 120,000 cases have accumulated with items representing surgical performance in each specialty for eight procedures : esophagectomy ; partial and total gastrectomy ; right hemicolectomy ; low anterior resection ; hepatectomy ; pancreatoduodenectomy ; and surgery for acute diffuse peritonitis. Risk models have been created for the mortality and morbidity of each procedure. These models will be available for participating hospitals and may be useful for decision making by surgeons as well as patient counseling. Studies are in progress using the NCD database to contribute to improving the quality control of surgical procedures.

---

© Japan Surgical Society    Journal Web Site : <http://journal.jssoc.or.jp>

## 特 集

## National Clinical Database の現状とこれから

## 6. 心臓血管外科領域のさらなる発展

東京大学医学部心臓外科

本村 昇

**キーワード** データベース, NCD, リスクモデル, 心臓血管外科手術データベース, JapanSCORE

## I. 内容要旨

日本心臓血管外科手術データベース (Japan Cardiovascular Surgery Database ; JCVSD) は National Clinical Database (NCD) が発足するより 10 年前の 2000 年に発足した。目的は心臓血管外科手術の Quality Improvement を通じての国民の福祉向上である。Web-base の入力方式を採用し入力項目と定義は北米の巨大データベース, STS National Database にならった。発足当初は 5 施設であった参加施設は徐々に増加し, 現在では 500 以上の施設が参加している。2008 年にはリスクモデルが完成し, これによる手術死亡率計算式 (JapanSCORE) が公開となり, 重症度補正死亡率が使用可能となった。データベースの quality 向上のために 3 つの委員会を設けた。i) 入力データの正確性を担保するために, 毎月施設を訪問するサイトビジット検討委員会。ii) 入力項目や定義の明瞭化, 改定を司る入力項目検討委員会。iii) 膨大なデータを誰がどのように使用するのかを吟味するデータ利用検討委員会である。これら貴重なデータを用いて既に多くの結果が世界的な学会や論文に発表されている。さらに, 保険改訂事業, 心臓血管外科専門医業務, また, 企業とも連携し, デバイス申請に向けた治験業務, 市販後調査業務にも積極的に提携使用されている。全国から集められた正確で膨大なデータを有効活用し, 外科医のためだけでなく, 患者さん視点に立った医療に向けてさらなる努力を続けていきたい。

## II. はじめに

National Clinical Database (NCD) が 2010 年に開始され, 外科一般領域, 消化器外科領域など広範囲の外科系領域で膨大な数のデータが入力されている。この NCD の雛形となった基盤データベースが心臓血管外科領域での日本心臓血管外科手術データベース, Japan Cardiovascular Surgery Database (JCVSD) である。JCVSD は欧米の心臓外科関連データベースを見倣い 2000 年に発足し, 試行錯誤を繰り返しながら発展を遂げ, 現在ではほぼ全ての心臓血管外科施設 530 以上の施設が参加している。その目的は, 本データベースを用いて本邦の心臓血管外科手術の Quality Improvement を行い, ひいては国民の福祉向上に期することである。本稿では, 日本初の全数登録を目指した臨床データレジストリである JCVSD の現状を振り返り, 将来への展望につなげてみたい。

## III. JCVSD の沿革

JCVSD 発足のきっかけとなったのは, 1999 年のアジア心臓血管外科学会で, 北米と欧州での心臓外科データベース (STS National Database と EuroSCORE システム) 成功を受けアジアでもデータベース作成の機運が盛り上がり, そのパイロットスタディとしてまず日本で開始してもらいたいとの要請があった事による。2000 年から 5 施設 (東京大学, 北海道大学, 東北大学, 神戸大学, 九州医療センター) が集まり, UMIN (大学病院医療情報ネットワーク, University hospital Information Network) との共同研究で開始された。

JAPAN CARDIOVASCULAR SURGERY DATABASE: PAST AND FUTURE

Noboru Motomura

Department of Cardiac Surgery, University of Tokyo, Tokyo, Japan

## 6. 心臓血管外科領域のさらなる発展

表1 JCVSDの沿革

1999年5月	米国胸部外科学会のデータベース (STS National Database) の成功を受け、第7回アジア心臓血管外科学会でアジア地域における同様のデータベース作成が討論された
2000年2月	JACVSD 構築に向けて、データベース小委員会が日本心臓血管外科学会、日本胸部外科学会のもとで発足
2001年8月	JACVSD (成人) 5施設でインターネットを介して直接的かつリアルタイムなデータ入力を開始
2002年1月	JACVSD (成人) 21施設、登録数約2,000件
2003年1月	JACVSD (成人) 64施設、登録数約5,100件
2005年1月	JACVSD (成人) 112施設、登録数約22,000件
2006年7月	JACVSD (成人) ワーキンググループ発足
2007年10月	データ解析機能 (Japan SCORE) 設置
2007年12月	グラフ化によるデータ解析機能設置
2008年1月	JACVSD (成人) 176施設、登録数約76,000件 入力システム Ver. 4 運用開始
2008年2月	JCCVSD (先天性) 7施設でデータ入力開始
2008年10月	リスクモデル、Japan SCORE 構築
2009年1月	JACVSD (成人) 210施設、登録数約81,000件
2009年2月	Japan SCORE 医療関係者に公開
2009年4月	統計データの参加施設利用を開始
2010年1月	JACVSD (成人) 244施設、登録数約105,000件 JCCVSD (先天性) 71施設、登録数約3,600件
2011年1月	JACVSD (成人) 336施設、登録数約133,000件、外科系9学会がNCDに入力開始。
2011年6月	心臓血管外科専門医とのリンクが決定
2012年3月	参加施設が500を突破 (日本のほぼ10割に)

STS National Database 事務局にも見学に行き、日本のデータベース立ち上げへの協力が得られた。入力項目と定義はSTS National Database に倣いながら1年がかりで決定した。1症例当たり255項目となった。データ入力はweb-basedとし、手術のたびにリアルタイムにデータ入力される方式とした。データベースへの参加はvoluntaryであり、忙しい心臓血管外科の日常業務の中で積極的に参加する施設は限られており、参加施設増大には時間がかかった(表1)。2008年には、冠動脈バイパス術<sup>1)</sup>、弁膜症手術<sup>2)</sup>、胸部大血管手術<sup>3)</sup>の3領域でリスクモデルが構築され、同時にリスク予測式であるJapanSCOREが作成された。これをきっかけに参加施設が増大し始めた。2011年には日本心臓血管外科専門医制度とのリンクが公表され参加施設が急増し、2012年には500施設を突破し、2013年10月の時点では成人部門(JACVSD)が533施設(図1)、先天性部門(JCCVSD)が115施設と本邦のほぼ全ての施設が参加している(両者の数値は成人と先天性の重複も含んでいる)。

### IV. 業務内容

本データベースは、日本心臓血管外科手術データベース機構 (Japan Cardiovascular Surgery Database Organization; JCVSDO) が行っており、日本心臓血

管外科学会、日本胸部外科学会、日本小児循環器学会がサポートしている。各施設にデータマネージャーを置き、login ID と password を配り決められた web site からデータ入力が行われる。データマネージャーは複数でもよく、外科医以外にもパラメディカル、秘書などが担当してもよい。

入力項目は術前、術中、術後の詳細な情報を網羅しており、1症例当たり350程の項目を用意してある(図2)。が、例えばCABG症例では大血管の項目はスキップできるので平均すると1例当たり概ね150程度の入力項目数となる。入力方式はweb-based方式であり、半年ごとにまとめてデータ送信するというのではなく、一症例毎にリアルタイムに入力する。Web-basedにすることにより、入力項目に変更やプログラムの更新などがあった場合でも、そのたびに新しい入力プログラムを各施設に配布する必要が無く、Web上のプログラムを更新するのみでよく、経済的にも実務的にも望ましいと考えている。

### V. ワーキンググループ

業務内容面でデータベースの高い品質を確保するために3つのワーキンググループ(検討委員会)を設け、日常業務を分担推進している。

①データ項目検討委員会：入力項目の定義はSTS