	プロジェクト設計にあたって３．進捗状況の管理と参加手順				
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III. 研究成果の刊行物・別刷

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ORIGINAL ARTICLE—ALIMENTARY TRACT

Risk model for right hemicolectomy based on 19,070 Japanese patients in the National Clinical Database

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Abstract
Background Right hemicolectomy is a very common procedure throughout the world, although this procedure is known to carry substantial surgical risks. The present study aimed to develop a risk model for right hemicolectomy outcomes based on a nationwide internet-based database.
Methods The National Clinical Database (NCD) collected records on over 1,200,000 surgical cases from 3,500 Japanese hospitals in 2011. After data cleanup, we analyzed 19,070 records regarding right hemicolectomy performed between January 2011 and December 2011.
Results The 30-day and operative mortality rates were 1.1 and 2.3 %, respectively. The 30-day mortality rates of patients after elective and emergency surgery were 0.7 and 6.0 %, respectively ($P < 0.001$). The odds ratios of preoperative risk factors for 30-day mortality were: platelet <50,000/μl, 5.6; ASA grade 4 or 5, 4.0; acute renal failure, 3.2; total bilirubin over 3 mg/dl, 3.1; and AST over 35 U/l, 3.1. The odds ratios for operative mortality were: previous peripheral vascular disease, 3.1; cancer with multiple metastases, 3.1; and ASA grade 4 or 5, 2.9. Sixteen and 26 factors were selected for risk models of 30-day and operative mortality, respectively. The c-index of both models was 0.903 [95 % confidence interval (CI) 0.877–0.928; $P < 0.001$] and 0.891 (95 % CI 0.873–0.908; $P < 0.001$), respectively.
Conclusion We performed the first reported risk stratification study for right hemicolectomy based on a nationwide internet-based database. The outcomes of right hemicolectomy in the nationwide population were satisfactory. The risk models developed in this study will help to improve the quality of surgical practice.

Keywords Right hemicolectomy · Colorectal cancer · Mortality · Risk model · National Clinical Database

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Introduction

The rate of colorectal cancer in Japan is rapidly increasing [1, 2]. Although the extent of lymphadenectomy for colorectal cancer differs according to institutions, operative procedures such as bowel resection and anastomosis have been established. Right hemicolectomy is one of the standard approaches to treating colorectal diseases. Although an established procedure, some risks of postoperative mortality and morbidity are associated with hemicolectomy. The risk of intraoperative bleeding is higher after more aggressive lymphadenectomy such as D3 lymph node

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dissection or complete mesocolic excision with central ligation [3, 4].

Written informed consent is essential before patients undergo invasive medical procedures in light of medical ethics. In particular, operative mortality and morbidity risks should be explained. However, a nationwide prospective database has not yet been used to analyze post-surgical rates of mortality and morbidity in Japan, and data applied during the informed consent process have depended on each institution.

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) collects data from many institutions in the United States of America and uses them to prevent postoperative mortality and morbidity. The National Clinical Database (NCD) in Japan started to prospectively collect data about surgical procedures in January 2011. The quality of surgical procedures in Japan has previously been investigated within individual institutions or by study groups. However, these studies could not investigate the nationwide quality of surgery in Japan. The NCD has now enabled such an analysis. The distribution of diseases and the difference in mortality and morbidity rates by regions can be investigated using this database. It will also help to improve treatment outcomes by comparing those at individual institutions with others across the country. The NCD also collaborates with the certification system of each surgical society in Japan. Patients registered in the NCD will only be approved if each surgical society in Japan applies for certification. Detailed information is required for the following surgical procedures: oesophagectomy, distal gastrectomy, total gastrectomy, right hemicolectomy, low anterior resection, hepatectomy, pancreaticoduodenectomy, and surgery for acute diffuse peritonitis.

Here, we used NCD data to clarify and establish a risk model for 30-day and operative mortality after right hemicolectomy.

Methods

Data collection

The National Clinical Database (NCD) is a nationwide project in cooperation with the board certification system of surgery in Japan in which data from over 1,200,000 surgical patients at over 3,500 hospitals were collected in 2011. The NCD continuously identifies individuals who approve data, departmental personnel in charge of annual patients and data entry personnel via a web-based data management system and can thus assure data traceability. It also consecutively validates data consistency by randomly inspecting institutions.

Here, we focused on gastrointestinal surgery data in the NCD, the variables and definitions for which are almost identical to those of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). The program focuses on 30-day outcomes (whether a patient has been discharged from initial admission) via direct determination of the 30-day time point. Outcomes include morbidity (including respiratory, urinary tract, central nervous system and cardiac pathologies and other types), as well as mortality. The gastroenterological surgery section registers all surgical patients in a department and requires detailed input items for the eight procedures that represent surgical performance within each specialty. All variables and definitions of inclusion criteria regarding NCD are accessible to participating institutions on the website (http://www.ncd.or.jp/) and it supports E-learning so that participants can upload consistent data. It answers all inquiries regarding data entry (about 80,000 inquiries in 2011) and regularly opens some of them as Frequently Asked Questions on the website.

Endpoint

This study focuses on right hemicolectomies performed between January 1, 2011 and December 31, 2011 in Japan. Any NCD records that were denied entry by patients were excluded from this analysis. Records with missing information about age, sex or status at 30 days post-operation were also excluded. The primary outcome measure of this study was 30-day and operative mortality rates. Operative mortality includes all patients who died within the index hospitalization, regardless of the length of hospital stay (up to 90 days), as well as any patients who died after hospital discharge within 30 days from the date of the procedure.

Statistical analysis

Data were randomly assigned to two subsets that were split 80/20, one for model development (cohort 1) and the other for validation testing (cohort 2). Two sets of logistic models (30-day mortality and operative mortality) were constructed for a development dataset using step-wise selection of predictors with a P value for inclusion of 0.05. The 'goodness-of-fit' was tested to assess how well the model could discriminate between survivors and deceased patients. Model calibration (the degree to which observed and predicted outcomes were similar from the model across patients) was examined by comparing the observed with the predicted averages within each of 10 equally sized subgroups arranged in increasing order of patient risk.

Results

Right hemicolectomy

The number of registered patients who underwent right hemicolectomy was 19,507. Among these, 437 were

Table 1 Patient characteristics

	Cohort 1 $N = 15{,}275$ (25 percentile to 75 percentile)	Cohort 2 $N = 3{,}795$ (25 percentile to 75 percentile)	*P* value	Total Number (25 percentile to 75 percentile)
Age	73 (65–80)	73 (65–80)	0.628	73 (65–80)
Gender				
Male	7,684 (50.3 %)	1,901 (50.1 %)	0.828	9,585 (50.3 %)
Female	7,591 (49.7 %)	1,894 (49.9 %)		9,485 (49.7 %)
BMI	21.9 (19.6–24.1)	21.9 (19.6–24.2)	0.663	21.9 (19.6–24.2)
Length of hospital stay	19 (14–29)	20 (14–29)	0.602	19 (14–29)
Surgery				
Operation time (min)	180 (138–232)	178 (135–235)	0.548	180 (138–233)
Anesthesia time (min)	235 (190–294)	235 (186–295)	0.763	235 (189–295)
Bleeding (ml)	100 (36–245)	100 (38–258)	0.406	100 (37–250)
Preoperative blood test				
WBC (/μl)	6,000 (4,775–7,600)	5,990 (4,700–7,600)	0.653	6,000 (4,770–7,600)
Hemoglobin (g/dl)	11.2 (9.6–13.0)	11.2 (9.7–13.0)	0.328	11.2 (9.6–13)
Platelet (×10,000/μl)	25.8 (20.3–33.3)	25.6 (20.3–33.2)	0.656	25.7 (20.3–33.3)
Albumin (g/dl)	3.8 (3.3–4.2)	3.8 (3.3–4.1)	0.808	3.8 (3.3–4.2)
Total bilirubin (mg/dl)	0.5 (0.4–0.7)	0.5 (0.4–0.7)	0.13	0.5 (0.4–0.7)
AST (U/l)	20 (16–26)	20 (16–26)	0.943	20 (16–26)
ALT (U/l)	15 (11–21)	14 (10–21)	0.575	14 (11–21)
Creatinine (mg/dl)	0.73 (0.6–0.9)	0.73 (0.6–0.9)	0.852	0.73 (0.6–0.9)
Blood urea nitrogen (mg/dl)	14 (11–18)	14 (11–17.8)	0.663	14 (11–18)
Sodium (mEq/l)	140 (138–142)	140 (138–142)	0.281	140 (138–142)
PT-INR	1.03 (0.97–1.10)	1.03 (0.97–1.10)	0.306	1.03 (0.97–1.1)

BMI body mass index, *WBC* white blood cell, *PT* prothrombin time

excluded because of the lack of information and the simultaneous surgical procedure such as pancreaticoduodenectomy that were more complicated than right hemicolectomy. The development dataset (cohort 1) included 15,275 records and the validation dataset (cohort 2) included 3,795 records.

The median age at surgery was 73 years and 50.3 % were male. The median surgical duration was 180 min, the median blood loss was 100 ml (Table 1) and 7.4 % of the patients in this population underwent surgery because of diseases other than cancer. Table 1 shows the main results of preoperative blood tests. The findings did not significantly differ between the two cohorts.

Risk profile of study population

In this population, 8.4 % of patients underwent emergency surgery. Preoperative comorbidities included hypertension, diabetes mellitus, smoking (within 1 year), activities of daily living (ADL) with any type of assistance and other in 36, 17.1, 12.9, 10.2 and 24.8 %, respectively (Table 2). These preoperative risk factors did not significantly differ between the two cohorts.

Outcomes

The overall 30-day and operative mortality rates were 1.1 and 2.3 %, respectively (Table 3), and those of patients who underwent elective and emergency surgery were 0.7 and 6.0 %, respectively ($P < 0.001$). The rates of readmission and reoperation within 30 days were 2.4 and 3.2 %, respectively. The total complication rate after right hemicolectomy was 22.1 % and most of them were classified as grades I to III. The rates of grade IV and V complications were 0.7 and 0.9 %, respectively. The rates of major complications after right colectomy were surgical site infection (SSI), anastomotic leak, pulmonary embolism and cardiac events in 7.8, 1.7, 0.2 and 0.5 %, respectively (Table 3). Unfavorable perioperative events included blood loss of >1,000 ml in 2.9 % and a surgical duration that exceeded 6 h in 3.7 %.

Model results

Two risk models were developed and Tables 4 and 5 show the final logistic model with odds ratios (ORs) and 95 % confidence intervals (CIs) for logistic regression analyses. Sixteen and 26 factors were selected as risk models for 30-day and

Table 2 Preoperative risk and frequency

Preoperative risk	Cohort 1 ($N = 15{,}275$)		Cohort 2 ($N = 3{,}795$)		P value	Total ($N = 19{,}070$)		
	Number	Percent	Number	Percent		Number	Percent	30-day mortality rate (%)
Ambulance transport	771	5	191	5	0.997	962	5	6.4
Emergency operation	1,285	8.4	313	8.2	0.766	1,598	8.4	6
Diabetes mellitus	2,597	17	660	17.4	0.564	3,257	17.1	1.4
Smoking (within a year)	1,974	12.9	479	12.6	0.644	2,458	12.9	1.3
Alcohol	6,374	41.7	1,590	41.9	0.854	7,964	41.8	0.9
Respiratory distress	451	3	97	2.6	0.213	548	2.9	6.2
ADL with any assistance	1,580	10.3	370	9.7	0.295	1,950	10.2	5.3
COPD	427	2.8	116	3.1	0.384	543	2.8	2.6
Pneumonia	117	0.8	24	0.6	0.456	141	0.7	11.3
Ascites	560	3.7	135	3.6	0.769	695	3.6	7.3
Hypertension	5,507	36.1	1,365	36	0.939	6,872	36	1.4
Congestive heart failure	254	1.7	60	1.6	0.771	314	1.6	8.9
Myocardial infarction	108	0.7	28	0.7	0.838	136	0.7	4.4
Angina	257	1.7	61	1.6	0.827	318	1.7	2.8
Previous PCI	414	2.7	88	2.3	0.194	502	2.6	2.6
Previous cardiac surgery	215	1.4	44	1.2	0.273	259	1.4	2.7
Acute renal failure	54	0.4	10	0.3	0.53	64	0.3	29.7
Preoperative dialysis	157	1	40	1.1	0.865	197	1	8.6
Cerebrovascular disease	748	4.9	167	4.4	0.108	915	4.8	3.3
Cancer with multiple metastases	959	6.3	254	6.7	0.353	1,213	6.4	3.7
Chronic use of steroid	176	1.2	42	1.1	0.858	218	1.1	3.2
Weight loss over 10 %	881	5.8	212	5.6	0.694	1,093	5.7	3
Bleeding disorder	703	4.6	164	4.3	0.485	867	4.5	5.7
Preoperative blood transfusion	793	5.2	170	4.5	0.076	963	5	2.7
Preoperative chemotherapy	110	0.7	38	1	0.076	148	0.8	0.7
Preoperative radiotherapy	14	0.1	7	0.2	0.165	21	0.1	4.8
Sepsis	289	1.9	69	1.8	0.836	358	1.9	17
Previous PVD surgery	75	0.5	16	0.4	0.685	91	0.5	8.8
Pregnancy	1	0.007	1	0.03	0.358	2	0.01	0
Other than cancer surgery	1,154	7.6	263	6.9	0.201	1,417	7.4	5.2
ASA performance status								
Grade 3	1,944	12.7	461	12.1	0.336	2,405	12.6	3.2
Grade 4	155	1	34	0.9	0.511	189	1	14.8
Grade 5	59	0.4	16	0.4	0.783	75	0.4	30.7

ADL activity of daily living, *COPD* chronic obstructive pulmonary disease, *PCI* percutaneous coronary intervention, *PVD* peripheral vascular disease, *ASA* American Society of Anesthesiologists

operative mortality, respectively. Among the independent risk factors of 30-day mortality, those with odds ratios of >3 were <5 × 10^4 platelets/µl (OR 5.59), ASA grade 4 and 5 (OR 3.99), acute renal failure (OR 3.23), total bilirubin >3 mg/dl (OR 3.12) and AST >35 U/l (OR 3.08, Table 4). Among the independent risk factors for operative mortality, those with odds ratios of >2 were previous peripheral vascular disease (PVD), surgery (OR 3.13), cancer with multiple metastases (OR 3.08), American Society of Anesthesiologists (ASA) grades 4 or 5 (OR 2.91), AST >40 U/l (OR 2.66), <8 × 10^4 platelets/µl (OR 2.55), ADL with any type of assistance (OR 2.51), preoperative dialysis (OR 2.51), blood urea nitrogen over 60 mg/dl (OR 2.42), congestive heart failure (OR 2.16), and chronic steroid use (OR 2.01, Table 5). The Nagelkerke R^2 was 0.336 in the 30-day mortality model and 0.322 in the operative mortality model.

The scoring system for the mortality risk models according to the logistic regression equation was as follows:

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

Table 3 Outcome of right hemicolectomy

Outcome	Cohort 1 ($N = 15{,}275$)		Cohort 2 ($N = 3{,}795$)		P value	Total ($N = 19{,}070$)	
	Number	Percent	Number	Percent		Number	Percent
30-day mortality							
All	175	1.1	43	1.1	0.99	218	1.1
Elective	92	0.7	30	0.9	0.2	122	0.7
Emergency	83	6.5	13	4.2	0.14	96	6
30-day operative mortality							
All	342	2.2	88	2.3	0.76	430	2.3
Elective	209	1.5	61	1.8	0.27	270	1.5
Emergency	133	10.4	27	8.6	0.36	160	10
Readmission within 30 days	348	2.3	114	3	0.01	462	2.4
Postoperative complication (Clavian–Dindo)							
Grade I	1,344	8.8	349	9.2	0.44	1,693	8.9
Grade II	1,195	7.8	329	8.7	0.085	1,524	8
Grade III	552	3.6	130	3.4	0.58	682	3.6
Grade IV	113	0.7	30	0.8	0.75	143	0.7
Grade V	148	1	29	0.8	0.26	177	0.9
Total	3,352	21.9	867	22.8	0.24	4,219	22.1
Reoperation within 30 days	491	3.2	119	3.1	0.83	610	3.2
Postoperative complication							
SSI	1,168	7.6	310	8.2	0.28	1,478	7.8
Anastomotic leak	250	1.6	79	2.1	0.068	329	1.7
Pneumonia	293	1.8	77	2	0.65	370	1.9
Pulmonary embolism	24	0.2	9	0.2	0.28	33	0.2
Acute renal failure	97	0.6	22	0.6	0.81	119	0.6
Central nervous system event	122	0.8	27	0.7	0.67	149	0.8
Cardiac event	79	0.5	24	0.6	0.39	103	0.5
SIRS	107	0.7	36	0.9	0.11	143	0.7
Sepsis	112	0.7	41	1.1	0.038	153	0.8
Surgery							
Bleeding from 1,000 to 2,000 ml	328	2.1	87	2.3	0.58	415	2.2
Bleeding over 2,000 ml	110	0.7	31	0.8	0.53	141	0.7
Transfusion	445	2.9	117	3.1	0.59	562	2.9
Operation over 6 h	536	3.5	168	4.4	0.008	704	3.7

SIRS systemic inflammatory response syndrome

β_i is the coefficient of the variable X_i in the logistic regression equation provided in Table 4 for 30-day mortality, and Table 5 for operative mortality. $X_i = 1$ if a categorical risk factor is present and 0 if it is absent. For age category, $X_i = 1$ if patient age is <59; 60–64 $X_i = 2$; 65–69 $X_i = 3$; 70–74 $X_i = 4$; 75–79 $X_i = 5$; and ≥80 $X_i = 6$.

Model performance

To evaluate model performance, both the concordance c-index (a measure of model discrimination) with 95 % CIs, which is the area under the receiver operating characteristics (ROC) curve, and model calibration across the risk groups were evaluated. Table 6 shows details of model performance indicators. The c-indices were 0.903 and 0.891 for the 30-day and operative mortality risk models, respectively (Fig. 1a, b), and the c-indices in the validation datasets for these two models were 0.836 and 0.854, respectively (Fig. 1c, d). Figure 2 demonstrates the calibration of the models or how well the rates for the predicted event matched those of the observed event among patient risk subgroups.

Discussion

The present study investigated short-term outcomes after right hemicolectomy using data from the NCD. The 30-day

Table 4 Logistic regression model for 30-day mortality after right hemicolectomy in cohort 1

	β coefficient	*P* value	Odds ratio	95 % CI
Platelet under 5 × 10,000/μl	1.72	0.003	5.585	1.808–17.251
ASA grade 4 and 5	1.384	<0.001	3.99	2.209–7.208
Acute renal failure	1.173	0.005	3.232	1.415–7.383
Total bilirubin over 3 mg/dl	1.136	0.015	3.115	1.242–7.817
AST over 35 U/l	1.125	<0.001	3.082	2.151–4.415
ADL with any assistance	1.04	<0.001	2.83	1.959–4.087
ASA grade 3	0.84	<0.001	2.317	1.564–3.431
Congestive heart failure	0.831	0.004	2.296	1.308–4.028
Cancer with multiple metastases	0.777	0.001	2.174	1.379–3.427
Sodium under 138 mEq/l	0.724	<0.001	2.063	1.45–2.936
Sepsis	0.697	0.009	2.008	1.189–3.392
Albumin under 4 g/dl	0.683	0.008	1.979	1.199–3.266
Emergent surgery	0.662	0.003	1.938	1.255–2.991
Platelet under 12 × 10,000/μl	0.629	0.037	1.876	1.038–3.389
White blood cell over 9,000/μl	0.437	0.024	1.547	1.059–2.261
PT-INR over 1.1	0.409	0.025	1.505	1.052–2.152

ADL activity of daily living

Table 5 Logistic regression model for the operative mortality after right hemicolectomy in cohort 1

	β coefficient	*P* value	Odds ratio	95 % CI
Previous PVD surgery	1.14	0.009	3.126	1.336–7.312
Cancer with multiple metastases	1.126	<0.001	3.082	2.204–4.31
ASA grade 4 and 5	1.068	<0.001	2.91	1.792–4.727
AST over 40 U/l	0.978	<0.001	2.658	1.992–3.546
Platelet under 8 × 10,000/μl	0.936	0.02	2.55	1.16–5.604
Preoperative dialysis	0.921	0.027	2.507	1.084–3.902
ADL with any assistance	0.918	<0.001	2.505	1.886–3.326
Blood urea nitrogen over 60 mg/dl	0.882	0.009	2.415	1.243–4.689
Congestive heart failure	0.771	0.001	2.161	1.351–3.459
Chronic steroid use	0.698	0.041	2.009	1.028–3.927
Emergent surgery	0.656	<0.001	1.928	1.388–2.678
Sodium over 145 mEq/l	0.656	0.031	1.926	1.063–3.493
Sodium under 138 mEq/l	0.64	<0.001	1.896	1.45–2.48
Sepsis	0.508	0.021	1.662	1.08–2.559
Platelet under 12 × 10,000/μl	0.505	0.075	1.656	0.95–2.888
Weight loss over 10 percent	0.492	0.006	1.635	1.148–2.329
Blood urea nitrogen under 8 mg/dl	0.491	0.03	1.635	1.05–2.546
ASA grade 3	0.485	0.001	1.624	1.215–2.17
Cancer metastasis relapse	0.479	0.038	1.614	1.026–2.539
White blood cell over 9,000/μl	0.475	0.001	1.608	1.215–2.127
Total bilirubin over 1 mg/dl	0.469	0.004	1.598	1.159–2.203
Ascites	0.462	0.009	1.587	1.123–2.243
Albumin under 3 g/dl	0.372	0.009	1.45	1.098–1.914
Hematocrit under 37 % in male and 32 % in female	0.341	0.015	1.407	1.067–1.855
PT-INR over 1.1	0.31	0.02	1.364	1.05–1.771
Age	0.116	0.004	1.123	1.038–1.216

ADL activity of daily living, *PVD* peripheral vascular disease, *ASA* American Society of Anesthesiologist

Table 6 Model performance

	C-index	95 % CI	*P* value
Cohort 1			
30-day mortality	0.903	0.877–0.928	<0.001
30-day operative mortality	0.891	0.873–0.908	<0.001
Cohort 2			
30-day mortality	0.836	0.760–0.912	<0.001
30-day operative mortality	0.854	0.809–0.898	<0.001

CI confidence interval

and operative mortality rates of right hemicolectomy in 2011 were 1.1 and 2.3 %, respectively. The 30-day mortality rates after elective and emergency surgery were 0.7 and 6.0 %, respectively. These results were satisfactory compared with the findings of previous studies in which these rates varied between 1.4 and 8.4 % for elective surgery and were 22.5 % for emergency surgery [5–11]. One of the reasons for the more favorable outcomes in our study might be the elimination of cancer-care disparities among Japanese institutions. The first Japanese classification of colorectal cancer

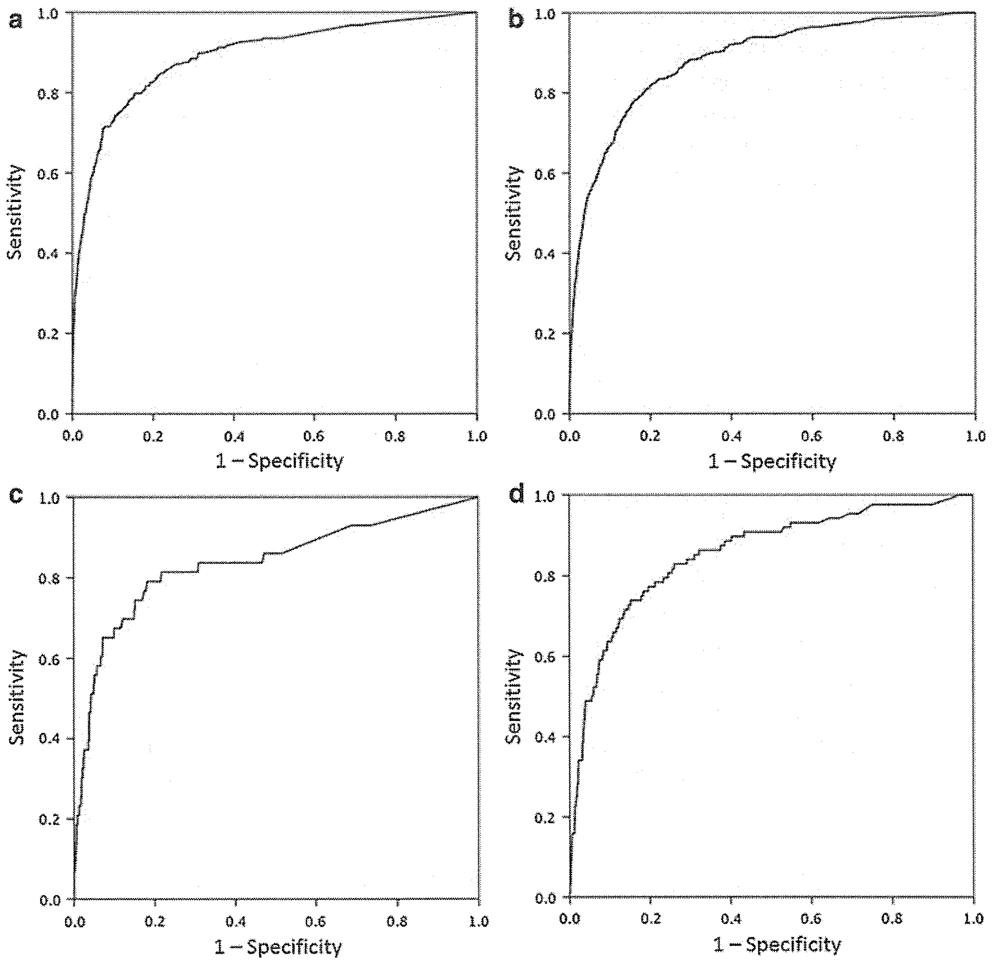

Fig. 1 Receiver operating characteristics (ROC) curves for 30-day mortality (**a**) and operative mortality (**b**) in cohort 1. ROC curves for 30-day mortality (**c**) and operative mortality (**d**) in cohort 2

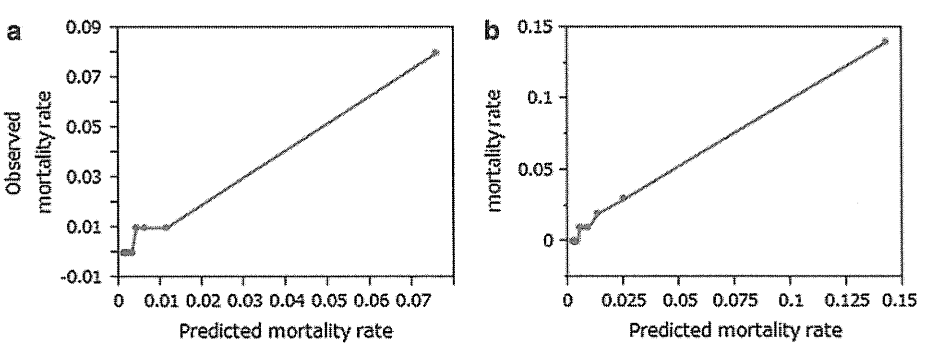

Fig. 2 Model calibration for 30-day mortality model (**a**) and operative mortality model (**b**)

published in 1977 defined various issues regarding how to record colorectal cancer surgery and pathological findings including the extent of regional lymph node dissection [12]. The Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines for the treatment of colorectal cancer were then published in 2005 [13]. These guidelines have helped to minimize differences in the care of patients with colorectal cancer in Japanese institutions. On the other hand, a German study group found 30-day mortality rates in low-, medium-, and high-volume centers of 2.6, 2.8, and 3.4 %, respectively [8]. Although outcomes could not be compared among institutions in the present study, some Japanese questionnaires uncovered a similar tendency, which should be clarified in the future (unpublished data; http://www.jsgs.or.jp/modules/en/index.php?content_id=10). The operative mortality rate up to 90 days in the present study was 2.3 %, which was twice the 30-day mortality rate. Visser et al. [5] noted that, "...death after colectomy is later than we think". Their study found that 30-day mortality rates after all, elective and emergency colectomies were 4.3, 1.4 and 15.8 %, respectively. On the other hand, mortality at 90 days increased to 9.1, 4.1 and 28.9 %, respectively [5]. These results indicate that the mortality rate is higher after than before 30 days. This should be a need-to-know item when obtaining written informed consent to undergo right hemicolectomy.

The rate of emergency surgery was 8.4 % in the present study, which is lower than the 18.5–22.5 % rates found in previous studies [5, 7, 9]. One of the reasons for the lower emergency rate might be the prevalence of colonoscopy in Japan. Colonoscopy is commonly applied to patients with positive fecal occult blood tests or with abdominal symptoms. Bowel obstruction caused by colon cancer can be an indication for a temporary stoma. In addition, the rate of emergency operations has decreased because of stents or transanal ileus tubes [14, 15]. The 30-day mortality rate of emergency surgery in this study was 6 % and lower than the 15.8–22.5 % rates identified in reports from other countries [5, 7, 9]. This might be due to a difference in comorbidity rates. A Dutch group reported that two-thirds of patients with gastrointestinal cancers had comorbidities [11]. Hypertension and diabetes mellitus were the major comorbidities in the present study, at rates of 36 and 17 %, respectively. However, considering the rapid increase in the elderly Japanese population, comorbidities in patients with colorectal cancer should be more carefully managed to maintain low mortality and morbidity rates after colectomy.

The morbidity rate was 22 % in the present study. Among these, the morbidity rates of Calvien–Dindo grades ≥III and ≥IV were 5.3 and 1.7 %, respectively. These rates of severe morbidities should be explained when written informed consent to undergo hemicolectomy is obtained. Among patients who underwent right hemicolectomy, 7.8 % developed SSI, which was similar to that in a recent study from Japan [16] and better than previous results [17]. One reason might be the low body mass index (BMI) of the Japanese. From this standpoint, risk models of the surgery should be developed by countries or by ethnic groups with similar lifestyles.

One of the main purposes of the present study was to establish a risk model of mortality after right hemicolectomy in Japan. The 16 and 26 risk factors for 30-day and operative mortality were selected by stepwise logistic regression analysis. The common risk factors for both were emergency surgery, ADL with any type of assistance, congestive heart failure, cancer with multiple metastasis, sepsis, ASA grade ≥3, platelet count, sodium <138 mEq/l, PT-INR over 1.1, and >9,000 white blood cells/μl. Patients with these risk factors should be prudently managed. The c-indices, which are the same as the area under the ROC curves (AUC), were 0.903 using the 16 factors and 0.891 using 26 factors in the 30-day and operative mortality risk models, respectively. The AUC results are considered excellent for AUC values between 0.9–1, good for AUC values between 0.8–0.9, fair for AUC values between 0.7–0.8, poor for AUC values between 0.6–0.7 and failed for AUC values between 0.5–0.6 [18]. Therefore, these risk models are reliable and useful in managing patients with right hemicolectomy. In addition, the c-indices of the 30-day and operative mortality risk models were 0.836 and 0.854, respectively, using the validation dataset. The accuracy of these risk models were validated statistically. This study has been performed as part of a project which aims to improve the quality of medical services. We will open a website through which physicians can get risk predictions (30-day and operative mortality rate) preoperatively, right after they enter a patient's information.

Some excellent risk models for the management of patients with colorectal cancer have been constructed, such as POSSUM, P-POSSUM, CR-POSSUM, and ACPGBI [19–22]. Ferjani et al. [23] reported that the ACPGBI was the most useful in predicting overall mortality among them. The ACPGBI uses the variables of age, ASA grade, cancer stage and operative urgency. The c-index in their study was 0.701. Fazio et al. [24] established the Cleveland Clinic Colorectal Cancer Model (CCCCM) based on patients who underwent surgery at the Cleveland Clinic. Their model included age, ASA grade, TNM stage, operative urgency, cancer resection and hematocrit. The c-index of operative mortality in the CCCCM was 0.801. Some risk factors with high odds ratio in our study were different from those in the previous studies. It might depend on differences of race or medical care system. We plan to establish a user-friendly scoring system that will be helpful for routine clinical use in Japan.

At the same time, the next step of this study will be to compare mortality and morbidity rates among institutions to improve the quality of care for Japanese patients after undergoing right hemicolectomy.

In conclusion, we have reported the first risk stratification study on right hemicolectomy in Japan using a nationwide internet-based database. The nationwide 30-day and operative mortality rates after right hemicolectomy were 1.1 and 2.3 %, respectively. These results were satisfactory. We have developed risk models for right hemicolectomy that will help to improve the management of this procedure.

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Conflict of interest All authors declare that there is no conflict of interest in this manuscript.

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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

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Objective: To create a mortality risk model after pancreaticoduodenectomy (PD) using a Web-based national database system.
Background: PD is a major gastroenterological surgery with relatively high mortality. Many studies have reported factors to analyze short-term outcomes.
Subjects and Methods: After initiation of National Clinical Database, approximately 1.2 million surgical cases from more than 3500 Japanese hospitals were collected through a Web-based data entry system. After data cleanup, 8575 PD patients (mean age, 68.2 years) recorded in 2011 from 1167 hospitals were analyzed using variables and definitions almost identical to those of American College of Surgeons–National Surgical Quality Improvement Program.
Results: The 30-day postoperative and in-hospital mortality rates were 1.2% and 2.8% (103 and 239 patients), respectively. Thirteen significant risk factors for in-hospital mortality were identified: age, respiratory distress, activities of daily living within 30 days before surgery, angina, weight loss of more than 10%, American Society of Anesthesiologists class of greater than 3, Brinkman index of more than 400, body mass index of more than 25 kg/m^2, white blood cell count of more than 11,000 cells per microliter, platelet count of less than 120,000 per microliter, prothrombin time/international normalized ratio of more than 1.1, activated partial thromboplastin time of more than 40 seconds, and serum creatinine levels of more than 3.0 mg/dL. Five variables, including male sex, emergency surgery, chronic obstructive pulmonary disease, bleeding disorders, and serum urea nitrogen levels of less than 8.0 mg/dL, were independent variables in the 30-day mortality group. The overall PD complication rate was 40.0%. Grade B and C pancreatic fistulas in the International Study Group on Pancreatic Fistula occurred in 13.2% cases. The 30-day and in-hospital mortality rates for pancreatic cancer were significantly lower than those for nonpancreatic cancer.
Conclusions: We conducted the reported risk stratification study for PD using a nationwide surgical database. PD outcomes in the national population were satisfactory, and the risk model could help improve surgical practice quality.

Keywords: in-hospital mortality, National Clinical Database (NCD), pancreaticoduodenectomy, risk factor, risk model

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The number of pancreatic surgical procedures has been increasing both in several Western countries and in Japan.[1,2] Pancreaticoduodenectomy (PD) is one of the most complex procedures in gastroenterological surgery and is often indicated for various diseases; thus, surgical techniques are continuously being improved.[3–6] Although the perioperative mortality rate of PD in high-volume centers is reportedly 1% to 2%,[7–9] population-based studies have reported a range of 4% to 8%.[10,11] However, the post-PD morbidity rate remains relatively high at 20% to 50%.[12–14] The curability of disease, whether malignant or nonmalignant, is typically anticipated after PD, although the long-term outcome differs depending on the original disease status.[2,6] Essentially, both surgeons and patients require precise risk information of the procedure before surgery; hence, many hospitals and surgeons have attempted to elucidate these factors and have consequently developed several scoring systems.[15–17] Are et al[18] reported that renal failure, hypothyroidism, liver disease, and hypertension were associated with post-PD mortality. Although several studies have contributed to a nationwide database regarding the quality of pancreatic resection using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) criteria, they have focused only on 30-day mortality.[18,19] However, mortality associated with pancreatic resection is reported more often after 30 days.[15,16,20] This report proposes a risk stratification system for post-PD mortality based on data from a single nation, including in-hospital postoperative outcomes, to complement the National Clinical Database (NCD) of Japan, thereby further defining its stratification criteria. We believe that this risk model will contribute to improvement in PD quality control not only in Japan but also worldwide.

METHODS

The NCD is a nationwide project in cooperation with the certification board of the Japan Surgical Society. In 2011, data from more than 1.2 million surgical cases were collected from more than 3500 hospitals. The NCD is continuously updated by data management departments from participating institutions and is evaluated annually using a Web-based data management system to ensure data traceability. Moreover, it validates data consistency through inspections of randomly selected institutions.

In this study, we focused on a data subset of gastroenterological surgery derived from the NCD using variables and definitions almost identical to those of the ACS-NSQIP. Indications for benign and malignant tumors were identified using the Union for International Cancer Control classification system. For this study, we selected cases with the exclusion criterion of simultaneous major hepatectomy. For subgroup analysis of PD procedures, lymph node dissection, vascular reconstruction, other organ excision, and gallbladder cancer surgery were included as variables. The present models focused on 30-day postoperative outcomes, regardless of whether the patient was discharged after initial hospital admission, through direct assessment of both the 30-day and in-hospital postoperative outcomes. In-hospital mortality was defined as death before postoperative day 30 and death among patients who were hospitalized for 30 days or more after surgery and died during that time. PD outcomes included mortality and rigorously defined morbidities categorized as wound, respiratory, urinary tract, central nervous system, cardiac, and others. All variables, definitions, and inclusion criteria are accessible on the NCD Web site (http://www.ncd.or.jp/), which is monitored to respond to inquiries regarding data entries (~80,000 inquiries in 2011), and responses are regularly posted under the heading "Frequently Asked Questions."

This research focused on PD surgical procedures performed from January 1, 2011, to December 31, 2011, in Japan. The NCD records of patients who refused access were excluded from this analysis. In addition, records with missing data regarding age, sex, or 30-day postoperative status were also excluded. Most Japanese hospitals performing surgery were included in this study, and a number of methods were used to verify the collected data. Because deterrents for input omissions are used in applications for specialist institutions, input was mandatory to apply for specialist status. To examine data reliability, randomly selected institutions were visited to confirm record consistency in the hospital registries. A well-known method was applied in which the input rate was calculated on the basis of recorded pre-2011 cases to ascertain that there were no omitted data from the records of each institution. Some of the surgical procedures were compared with the number of reported cases to verify the consistency in the number of submitted cases.

Data were randomly assigned into 2 subsets that were split 80/20, one for model development and the other for validation testing. The 2 sets of logistic models (30-day and in-hospital mortalities) were constructed to develop a data set using step-wise selection of predictors with a P value for inclusion of 0.05. A goodness-of-fit test was conducted to assess how well the model could discriminate between surviving and deceased patients. 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 averages with the predicted averages within each of the 10 equally sized subgroups arranged in increasing order of patient risk.

RESULTS

Preoperative Risk Profiles and Laboratory Data of the Study Population

The NCD patient population had a mean age of 68.2 ± 10.6 years, and 61.4% were men (Table 1). The following primary diagnoses were made: pancreatic carcinoma in 51.6% of the patients, extrahepatic bile duct carcinoma in 19.5%, carcinoma of the ampulla of Vater in 12.7%, perihilar bile duct carcinoma in 3.7%, metastatic tumors or recurrence in 1.9%, carcinoma of the gallbladder in 1.0%, and lesions other than cancer, including intraductal papillary mucinous neoplasm (IPMN), serous cystadenoma, solid pseudo-papillary neoplasm, and pancreatic neuroendocrine tumor in 8.6%.

The following significant preoperative risk factors related to both 30-day and in-hospital mortalities were observed: male sex, activities of daily living, body mass index of more than 25 kg/m^2, American Society of Anesthesiologists (ASA) class of greater than 3, angina, myocardial infarction, hypertension, chronic obstructive pulmonary disease, hemoglobin levels of less than 10.0 g/dL, serum albumin levels of less than 2.5 g/dL, total bilirubin levels of more than 2.0 mg/dL, creatinine levels of more than 3.0 mg/dL, and C-reactive protein levels of more than 1.0 mg/dL. On the contrary, significant risk factors for 30-day mortality alone included previous cardiac surgery and extrahepatic bile duct carcinoma. However, in subgroups of PD procedures, none of the following risk factors showed any significant difference in in-hospital mortality: lymph node dissection, vascular reconstruction, other organ excision, and gallbladder cancer surgery. Interestingly, lymph node dissection was associated with significantly lower 30-day mortality than the other variables.

Perioperative Risk Profile and Prevalence of Morbidity in the Study Population

The mean post-PD hospital length of stay was 29 days [interquartile range (IQR), 21–42 days] and post-PD length of stay in the 30-day and in-hospital mortality subgroups was 15 days (IQR, 7–23 days) and 31 days (IQR, 15–57 days), respectively (Table 2). The 30-day postoperative mortality rate was 1.2% (103 patients), whereas the in-hospital mortality rate was 2.8% (239/8575 patients).

Overall morbidities occurred in 40.0% of patients. Grade B or C pancreatic fistulas were reported in 13.2% of the patients. Furthermore, other significant operative risk factors associated with both 30-day and in-hospital mortalities included intraoperative estimated blood loss of more than 2000 mL and transfusion of more than 5 units. In addition, reoperations performed for any reason within 30 days were also significant risk factors; however, operation time of more than 6 hours was not a significant risk factor.

Postoperative complications were highly significant risk factors for 30-day and in-hospital mortalities and included surgical complications (bile leakage, anastomotic leakage, pancreatic fistula, and wound dehiscence), infection [surgical site infections (SSIs), urinary tract infection, standardized infection ratio, systemic sepsis, and septic shock], respiratory issues (pneumonia, unplanned intubation, pulmonary embolism, and prolonged ventilation >48 hours), renal failure, central nervous system complications, and cardiac issues.

Prevalence of Morbidity Associated With Vascular Reconstruction

The cases that underwent vascular reconstruction (n = 953; 11.1%) (Table 1) were characterized by higher blood loss and longer operation times than those in nonreconstruction cases (n = 7622; 88.9%); however, these cases had low complication rates for pancreatic fistulas (grade B or C; 6.8% vs 14.0%; $P < 0.001$) and SSIs (organ space with leakage, 4.5% vs 9.0%; $P < 0.001$). Pancreatic cancer was reported in 847 cases (88.9%) within the vascular reconstruction subgroup (n = 953).

Model Results and Performance

We developed 2 different risk models of preoperative factors for 30-day and operative mortalities. The final logistic model with the odds ratios and 95% confidence intervals is presented in Table 3. All risk model data were derived from multivariate analysis. There were 4 overlapping variables between the 2 groups: preoperative comorbidities (age, ASA class >3, and body mass index >25 kg/m^2) and

TABLE 1. Key Preoperative Risk Profiles and Outcomes

Characteristics	Entire Study Population (N = 8575), Positive Rate %	Outcome Groups: 30-d Mortality (n = 103; 1.2%)		Outcome Groups: In-hospital Mortality (n = 239; 2.8%)	
		%	*P*	%	*P*
Demographics					
Age, mean (SD), yr	68.2 (10.6)	72.2 (8.1)		72.8 (7.9)	
Male sex, %	61.4	1.4	0.01	3.1	0.022
Emergency surgery	0.9	6.4	0.002	12.8	<0.001
ADL within 30 d before surgery: Partially/totally dependent	3.2	3.3	0.005	11.8	<0.001
BMI >25 kg/m^2, %	14.8	2.1	0.005	3.8	0.026
ASA class >3	9.1	3.1	<0.001	8.6	<0.001
Habitual alcohol consumption	22.9	1.4	0.410	2.7	0.876
Smoking within a year	19.1	1.3	0.707	2.9	0.678
Brinkman index >400	25.6	1.5	0.140	3.3	0.115
Weight loss >10%	7.3	1.9	0.087	5.8	<0.001
Preexisting comorbidity					
Cardiovascular					
Congestive heart failure	0.4	2.8	0.353	19.4	<0.001
Angina	1.1	4.2	0.028	9.4	0.001
Myocardial infarction	0.4	8.8	0.008	20.6	<0.001
Hypertension	34.0	1.6	0.016	3.6	0.001
Previous PCI	2.4	2.4	0.100	7.3	<0.001
Previous cardiac surgery	1.1	4.3	0.025	6.5	0.045
Pulmonary					
COPD	2.6	4.5	<0.001	7.7	<0.001
Respiratory distress	1.0	5.6	0.004	17.8	<0.001
Renal					
Acute renal failure	0.1	42.9	<0.001	71.4	<0.001
Preoperative dialysis	0.6.	5.8	0.024	13.5	<0.001
Bleeding disorder	3.2	3.3	0.006	6.2	0.002
Other					
Previous cerebrovascular disease	3.1	3.0	0.015	5.9	0.004
Chronic steroid use	1.0	4.7	0.020	7.0	0.033
Disease					
Ampulla of Vater carcinoma	12.7	1.5	0.371	3.2	0.374
Extrahepatic bile duct carcinoma	19.5	1.7	0.032	3.5	0.046
Perihilar bile duct carcinoma	3.7	2.2	0.110	4.4	0.084
Gallbladder cancer	1.0	0.0	0.629	1.1	0.521
Pancreatic cancer	51.6	0.9	0.017	2.4	0.018
Cancer metastasis/recurrence	1.9	1.2	1.000	3.7	0.467
Duodenal cancer	3.5	1.0	1.000	3.3	0.590
Other than cancer surgery	8.6	1.0	0.722	2.4	0.640
Preoperative laboratory results					
WBC count >11,000/μL	1.9	3.1	0.013	11.2	<0.001
Hemoglobin levels <10 g/dL	8.5	0.7	0.594	5.0	<0.001
Platelet count <120,000/μL	3.3	1.7	0.086	3.8	0.001
PT/INR >1.1	22.0	0.3	0.055	4.6	<0.001
APTT >40 s	4.6	1.3	<0.001	7.7	<0.001
Serum albumin levels <2.5 g/dL	2.1	2.7	<0.001	9.8	<0.001
Serum total bilirubin levels >2.0 mg/dL	23.4	0.2	0.014	3.9	<0.001
Serum AST ≥100 U/L	11.9	0.5	0.760	4.1	<0.001
Serum ALT ≥100 U/L	20.4	0.3	0.713	2.9	0.871
Serum urea nitrogen levels <8.0 mg/dL	7.1	0.8	0.079	3.0	0.797
Serum urea nitrogen levels ≥25 mg/dL	4.0	1.5	0.304	6.2	<0.001
Serum creatinine levels ≥3.0 mg/dL	0.9	3.9	0.054	13.0	<0.001
Serum CRP levels >1.0 mg/dL	18.5	0.3	0.095	4.5	<0.001

(continued)

TABLE 1. *(Continued)*

Characteristics	Entire Study Population (N = 8575), Positive Rate %	Outcome Groups: 30-d Mortality (n = 103; 1.2%)		In-hospital Mortality (n = 239; 2.8%)	
		%	P	%	P
Lymph node dissection	40.8	0.9	0.015	2.5	0.229
Vascular reconstruction	11.1	1.5	0.429	2.9	0.754
Excision with inclusion of other organs	4.1	1.7	0.321	2.5	1.000

The variables of the Japanese NCD were almost identical to those of the ACS-NSQIP, other than alcohol consumption, which was divided into 3 categories: no alcohol consumption, occasional alcohol consumption, and habitual alcohol consumption. Hemoglobin content was not included as a variable by the ACS-NSQIP but was included in the NCD. Descriptive statistics were compared using the Fisher exact test for categorical data of 30-day and in-hospital mortalities of patients in the mortality and nonmortality groups. All statistical tests were 2-sided, and statistical significance was set as $P < 0.05$.

ADL indicates activities of daily living; ALT, alanine transaminase; APTT, activated partial thromboplastin time; ASA class, American Society of Anesthesiologists Physical Status Classification; AST, aspartate aminotransferase; BMI, body mass index; COPD, chronic obstructive pulmonary disease; CRP, C-reactive protein; PCI, percutaneous coronary intervention; PT/INR, prothrombin time/international normalized ratio; WBC, white blood cell.

TABLE 2. Prevalence of Morbidity With PD Outcomes

Characteristics	Entire Study Population (N = 8575), Positive Rate %	Outcome Groups: 30-d Mortality (n = 103; 1.2%)		In-hospital Mortality (n = 239; 2.8%)	
		%	P	%	P
Operation time >6 h	78.6	1.2	0.629	2.9	0.471
Intraoperative estimated blood loss >2000 mL	11.0	3.4	<0.001	6.9	<0.001
Intraoperative blood transfusion >5 units	35.9	2.1	<0.001	4.7	<0.001
Reoperation for any reason	5.1	7.7	<0.001	16.9	<0.001
Perioperative accident	0.8	11.8	<0.001	16.2	<0.001
Complications	40.0	2.9	<0.001	6.0	<0.001
Transfusion	7.5	11.0	<0.001	22.1	<0.001
Infectious complications:					
SSI	18.7	2.1	<0.001	6.2	<0.001
Wound dehiscence	2.1	5.4	<0.001	15.8	<0.001
Anastomotic leakage	13.0	2.9	<0.001	8.3	<0.001
Pancreatic fistula, grade B or C	13.2	2.4	<0.001	7.4	<0.001
Bile leakage	3.0	4.2	<0.001	9.7	<0.001
Pneumonia	2.6	11.8	<0.001	27.7	<0.001
Unplanned intubation	2.3	30.8	<0.001	52.3	<0.001
Pulmonary embolism	0.2	10.0	0.024	20.0	0.002
Prolonged ventilation >48 h	2.7	24.1	<0.001	46.1	<0.001
Acute renal failure	1.0	27.1	<0.001	56.5	<0.001
Urinary tract infection	0.8	2.9	0.205	10.0	0.003
SIRS	2.6	3.6	0.005	8.9	<0.001
Systemic sepsis	5.7	8.8	<0.001	21.6	<0.001
Septic shock	1.4	23.3	<0.001	55.2	<0.001
CNS complications	1.0	26.2	<0.001	41.7	<0.001
Cardiac complications	0.9	74.7	<0.001	85.3	<0.001

Wound dehiscence, anastomosis leakage, and pancreatic fistula grade B or C were not included as variables in the ACS-NSQIP but have been added to the Japanese NCD. Descriptive statistics were compared using the Fisher exact test for categorical data of 30-day and operative mortalities of patients in the mortality and nonmortality groups. All statistical tests were 2-sided, and statistical significance was set as $P < 0.05$.

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

preoperative laboratory data (activated partial thromboplastin time >40 seconds).

Male sex, emergency surgery, bleeding disorders, chronic obstructive pulmonary disease, and serum urea nitrogen levels of less than 8.0 mg/dL were independent variables in the 30-day mortality group. There were 6 independent variables in the in-hospital mortality subgroup: respiratory distress, activities of daily living within 30 days before surgery, angina, weight loss of more than 10%, Brinkman index more than 400, white blood cell count of more than 11,000 cells per microliter, platelet count of less than 120,000 per microliter, prothrombin time/international normalized ratio of more than 1.1, and serum creatinine levels of more than 3.0 mg/dL.

To evaluate model performance, the C-index (a measure of model discrimination), which was the area under the receiver operating characteristic curve, was calculated for the validation sets. The C-indices of the 30-day and in-hospital mortalities were 0.675 ($P < 0.006$; range, 0.551–0.799) and 0.725 ($P < 0.001$; range, 0.657–0.793), respectively, thereby indicating good performance for in-hospital mortality in the low-risk group. Details of model performance metrics for in-hospital mortality are displayed in Figure 1.

DISCUSSION

PD patients (N = 8575) from 1167 hospitals were used to construct the models in this study. Of 239 deaths, 103 occurred within 30 days and 136 after 30 days. The 30-day and in-hospital mortality rates after PD were 1.2% and 2.8%, respectively. Moreover, the overall morbidity rate was 40.0% and the grade B or C pancreatic fistula rate was 13.2%. These results indicated that the morbidity rates were comparable with those of previous study

TABLE 3. Risk Models of Preoperative Factors for Mortality Rates (30-Day and In-hospital) After PD

	30-d Mortality			In-hospital Mortality		
Variables	Odds Ratio	95% Confidence Interval	P	Odds Ratio	95% Confidence Interval	P
Age*	**1.260**	1.109–1.486	0.001	**1.283**	1.159–1.420	<0.001
Male sex	**1.971**	1.171–3.319	0.011			
Emergency surgery	**4.309**	1.364–13.618	0.013			
COPD	**2.446**	1.078–5.549	0.032			
Respiratory distress				**2.438**	1.197–4.963	0.014
ADL within 30 d before surgery				**2.479**	1.510–4.070	<0.001
Angina				**2.583**	1.199–5.562	0.015
Bleeding disorder	**4.436**	1.363–14.434	0.013			
Weight loss >10%				**2.102**	1.367–3.232	0.001
ASA grade ≥3	**2.207**	1.290–3.777	0.004	**2.124**	1.461–3.087	<0.001
Brinkman index >400				**1.609**	1.163–2.226	0.004
BMI >25 kg/m^2	**2.401**	1.444–3.992	0.001	**1.866**	1.289–2.703	0.001
WBC count >11,000/μL				**3.101**	1.645–5.843	<0.001
Platelet count <120,000/μL				**2.122**	1.190–3.784	0.011
PT-INR >1.1				**1.507**	1.093–2.078	0.012
APTT >40 s	**3.220**	1.716–6.043	<0.001	**2.001**	1.232–3.251	0.005
Serum urea nitrogen levels <8.0 mg/dL	**2.268**	1.144–4.498	<0.001			
Serum creatinine levels >3.0 mg/dL				**3.462**	1.450–8.266	0.005

*Less than 60, 60 to 65, 65 to 70, 70 to 75, 75 to 80, and more than 80 years.
Odds ratios and 95% confidence intervals for the associations of variables with mortality were calculated using logistic regression models.
ADL indicates activities of daily living; APTT, activated partial thromboplastin time; BMI, body mass index; COPD, chronic obstructive pulmonary disease; PT-INR, prothrombin time/international normalized ratio; WBC, white blood cell.

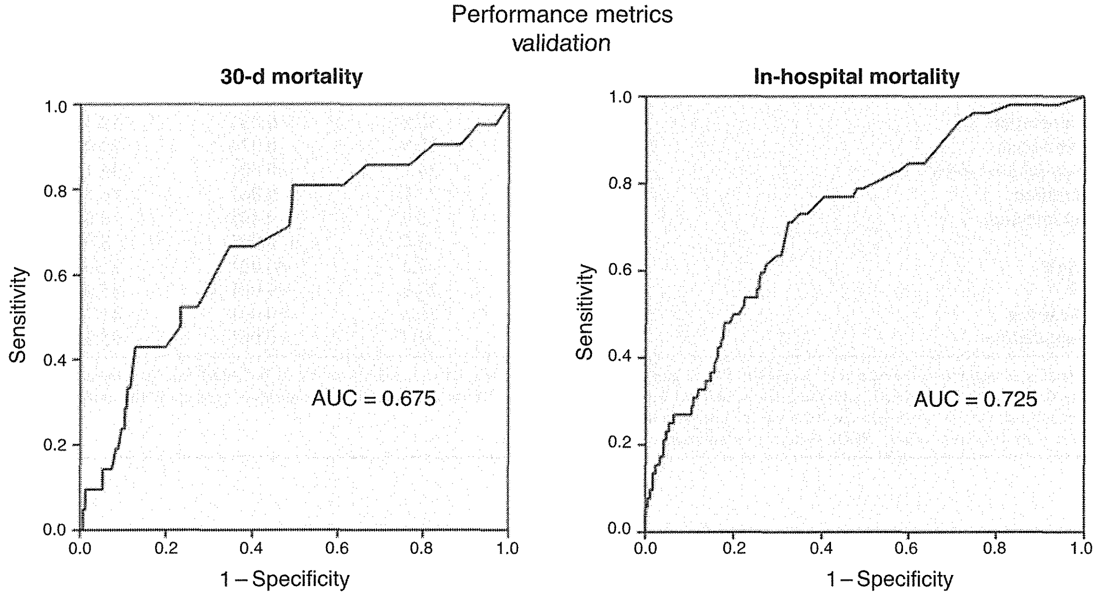

FIGURE 1. Calibration of the 30-day and in-hospital mortality risk models. The C-indices for 30-day and in-hospital mortalities are 0.675 (range, 0.551–0.799; $P < 0.006$) and 0.725 (range, 0.657–0.793; $P < 0.001$), respectively. AUC indicates area under the receiver operating characteristic curve.

results, regardless of whether they were from single-institution or nationwide studies.[12–14] The 30-day and in-hospital mortality rates in this analysis were considerably good compared with those in previous reports from single institutions.[7–9,15] Our risk models suggested that 13 variables were significant risk factors for in-hospital mortality.

The aforementioned parameters could prove useful to surgeons and patients in PD risk clarification as a potential therapeutic approach. In this report, we present our analysis of PD risk stratifications using a nationwide surgical database.

Risk stratification for PD was performed using the ACS-NSQIP database.[18,19] Parikh et al[19] reported that the 30-day mortality and complication rates after pancreatic resection using data of 7571 patients (2005–2008) after proximal (PD) (n = 4621), distal pancreatectomy (DP) (n = 2552), or total pancreatectomy (n = 177) and those who underwent enucleation (n = 221) were 2.5% and 32%, respectively; they also observed that the risk factors associated with 30-day mortality were age, sex, obesity, sepsis, functional status, ASA class, coronary heart disease, dyspnea, bleeding disorders, and extent of surgery. Furthermore, Kelly et al[20] reported overall 30-day complication and mortality rates of 28.1% and 1.2%, respectively, in 2322 DP patients. Moreover, preoperative variables associated with 30-day mortality were esophageal varices, neurological disease, dependent functional status, recent weight loss, elevated alkaline phosphatase levels, and elevated blood urea nitrogen levels. In the present study, in addition to these variables, preoperative laboratory data, including white blood cell count, hemoglobin, platelet count, prothrombin time, activated partial thromboplastin time, serum albumin, serum alanine transaminase, serum creatinine, and serum C-reactive protein, were found to be significant risk factors of in-hospital mortality. The major characteristics of this study were the relatively large number of PD patients and a relatively long postoperative hospitalization period of 29 days (IQR range, 21–42 days) compared with those among studies conducted in Western countries. Table 4 shows the differences in disease, 30-day mortality rates, in-hospital mortality rates, and complication rates between Japanese and Western cases retrieved from the literature.

Overall complications occurred in 40.0% of PD patients, and intraoperative variables and various complications were associated with 30-day and in-hospital mortalities, although the effects on mortality differed between the categories. Intraoperative variables, including blood loss of more than 2000 mL and intraoperative transfusion, were associated with mortality. Unplanned intubation, prolonged ventilation of more than 48 hours, renal failure, septic shock, and central nervous system and cardiac complications were very severe and contributed to the high mortality rates. In addition, SSIs and anastomotic leakage of pancreatic fistulas and bile were also associated with mortality. Because the cause of death was not identified in the NCD system, it was unclear whether these complications resulted in patient death. Regardless of either situation, prevention of surgical complications has been considered crucial for successful surgical treatment.[21–23]

PD is applicable to the treatment of pancreatic cancer and other conditions, such as carcinoma of the extrahepatic bile duct or the papilla of Vater.[24] However, carcinomas of the extrahepatic bile duct are often associated with a soft pancreas; thus, complication rates tend to be higher.

In the NCD system, indications for PD were included as variables (Table 1). In fact, the 30-day and in-hospital mortality rates for pancreatic cancer were 0.9% and 2.4%, respectively, which were significantly lower than those for nonpancreatic cancer. PD with combined portal vein resection has been reported as a treatment option for advanced pancreatic cancer. In this analysis, 953 vascular reconstruction cases (11.1%) were included. Despite the greater intraoperative blood loss and longer operation time, the 30-day and in-hospital mortality rates were 1.5% and 2.9%, respectively, which were not significantly different from those of nonreconstruction cases (1.2% and 2.8%, respectively) (Table 1). In contrast, complication rates for the incidence of pancreatic fistula and SSIs in organ spaces with leakage were significantly low. Most of the patients indicated for PD were recommended to undergo PD for the treatment of pancreatic cancer (847/953 cases; 88.9%). A similar report[25] documented that combined vascular resection for pancreatic adenocarcinoma had no adverse effects on postoperative mortality. The complication rate of vascular reconstruction cases was lower than those without reconstruction. Although the reason behind this is not very clear from the statistical analysis, it may be attributable to the fact that vascular resection cases are often typical pancreatic cancer cases associated with portal infiltration and a hard pancreas; however, cases that do not require portal vascular resection are those with a soft pancreas, such as cancer of the lower biliary duct (30-day and in-hospital mortality rates, 1.7% and 3.5%, respectively). Meanwhile, a report of 3582 PD patients added to the American College of Surgeons national database documented a 30-day postoperative mortality rate of 5.7% after vascular resection (n = 281; 7.8%), which was significantly higher than the corresponding 2.9% reported in cases without

TABLE 4. Differences Between This Study and Western Studies

Presenter	Year of Presentation	Study Period/	No. Cases	Surgical Procedure	Rate of (%) Malignancy	Mean Hospitalization Period, d	30-d (%) Mortality	In-hospital (%) Mortality	Rate of (%) Complication
Yeo et al[12]	1997	1990–1996	650	PD	82	—	1.4	1.4	41
Cameron et al[8]	2006	1969–2003	1,000	PD	85	9	1	1	41
Are et al[18]	2009	2000–2005	5,481	PD	—	>10 (61%)	—	5.2–6.3	—
Simons et al[14]	2009	1998–2006	102,417	PD and DP	—	16.5	—	6.3	22.7
Parikh et al[19]	2010	2005–2008	7,571	PD	66.5	—	2.5	—	31.8
Carroll et al[21]	2010	1991–2002	1,847	PD and DP	—	—	7.7	8.1	19.9
Venkat et al[15]	2011	1998–2009	1,976	PD	82	—	1.4	3.8	—
Castleberry et al[27]	2012	2005–2009	3,301	PD	100	—	2.9	—	33.3
	2012	2005–2009	281	PD with VR	100	—	5.7	—	39.9
Kim et al[5]	2012	2005–2008	4,975	PD	100	—	—	2.1	—
Assifi et al[29]	2012	2000–2010	553	PD	—	—	2	—	43.2
This study		2011	8,575	PD	91.7	29	1.2	2.8	40.0

VR indicates vascular resection.

vascular resection.[26] The difference between these 2 studies needs to be clarified and is currently being considered through a mutual collaboration of the ACS-NSQIP and the Japanese NCD. We believe our results present a useful reference for preoperative preparation in high-risk cases, such as recommendation of diets to obese individuals, notifying families and patients of higher risks and obtaining their informed consent, and not performing PD in prominently high-risk cases.

LIMITATIONS

Although this analysis included more than 8000 PD patients registered in 1 year, there were still several limitations. In Japan, PD is performed for cancers of the pancreatic head, lower bile duct, the ampulla of Vater, duodenum, gallbladder, and hilar bile duct, and pancreatic metastasis among others (eg, IPMN, serous cystic neoplasm, solid pseudopapillary neoplasm, pancreatic neuroendocrine tumor) Therefore, the following points should be considered when applying the results of this article to studies originating in other countries.

IPMNs may develop into invasive carcinoma or might be associated with pancreatic adenocarcinoma; therefore, accurate diagnosis and careful follow-up are recommended.[3,24,27,28] However, in the NCD system, detailed pathological information, such as IPMN classification, is not very clear and needs to be included as a variable in future. Moreover, the outcomes may have been influenced by hospital volume, hospital training status, hospital compliance, surgical specialization, resource utilization, and procedure-specific variables, including preoperative biliary drainage, pylorus preservation method, and ante/retrocolic reconstruction of the alimentary tract, among others.[11] These risk variables for mortality and morbidity will be evaluated in a future study using the present basic risk model.

CONCLUSIONS

The present risk stratification study of PD using a nationwide database included 8575 patients from 1167 surgical units throughout Japan, in which the 30-day and in-hospital mortality rates were 1.2% and 2.8%, respectively. The results of this series were sufficient to estimate the nationwide outcome of PD and thus this system will contribute to improvement in quality control of surgical practice in gastroenterological surgical procedures.

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Most of the authors of this study were members of the JSGS Database Committee or working members of the committee, who participated in creating gastroenterological surgery section of the NCD and analyzing data. All cases are input with items representing surgical performance in each specialty for 8 procedures: esophagectomy, partial/total gastrectomy, right hemicolectomy, low anterior resection, hepatectomy, pancreaticoduodenectomy, and operation for acute generalized peritonitis. Risk models for each procedure have been created by these authors under a unified vision. The authors' contribution is as follows:

Wataru Kimura: He made substantial contributions to conception and design, interpretation of data. He participated in drafting the article or revising it critically for important intellectual content. He wrote and submitted the manuscript, and revised and resubmitted the manuscript. He contributed to generally organize and manage the manuscript. He gave final approval of the version to be published.

Hiroaki Miyata: He made substantial contributions to acquisition of data and/or analysis. He contributed to almost all the statistics of the manuscript.

Mitsukazu Gotoh: He is one of the leaders of the NCD of Japan. He participated in creating gastroenterological surgery section of the NCD and analyzing data. With regard to the manuscript, he helped Dr Kimura on various problems and advised him. He participated in drafting the manuscript or revising it critically for important intellectual content.

Ichiro Hirai: He participated in drafting the manuscript or revising it critically for important intellectual content. He helped Dr Kimura in writing and managing the manuscript.

Akira Kenjo: He made substantial contributions to acquisition of data and/or analysis. He helped Drs Kimura and Hirai in writing and managing the manuscript, with special reference to the statistical aspects.

Yuko Kitagawa: He is a member of the JSGS Database Committee, who contributed in creating gastroenterological surgery section of the NCD and analyzing data. He made substantial contributions in acquisition of data.

Mitsuo Shimada: He is a member of the JSGS Database Committee, who contributed in creating gastroenterological surgery section of the NCD and analyzing data. He made substantial contributions in acquisition of data.

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Tohru Nakagoe: He is a member of the JSGS Database Committee, who contributed in creating gastroenterological surgery section of the NCD and analyzing data. He made substantial contributions in acquisition of data.

Kenichi Sugihara: He is a member of the JSGS, who contributed to creating gastroenterological surgery section of the NCD and analyzing data. He made substantial contributions in acquisition of data.

Masaki Mori: He is a member of the JSGS, who contributed in creating gastroenterological surgery section of the NCD and analyzing data. He made substantial contributions in acquisition of data.

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

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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.[1] Perioperative mortality rates in high volume cancer centers are reportedly 0% to 2%.[2-4] In contrast, population-based analyses using administrative data from Western countries have reported mortality rates of 5% to 10%,[4-7] indicating capacity for further improvement.

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

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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.

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