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APPENDIX. CONFERENCE DISCUSSION

Dr M. Antunes (Coimbra, Portugal): The Tokyo group reviewed the experience of tricuspid reoperation for severe tricuspid regurgitation from the national database. These were not necessarily reoperations on the tricuspid valve but just valve reoperations, the majority of the patients having had only left side valve surgery before. Two subgroups were analysed, patients who required tricuspid valve replacement (fortunately a minority from the results we saw), and those who were treated by valvuloplasty, which is not specified, and I suppose that that means annuloplasty, whether with a ring or with a suture.

Patients who had TVR were much sicker and had far more risk factors, hence, not surprisingly, they had much worse outcome. This is not the result of the type of procedure, and I don't think that the conclusion is correct. You needed to do further statistical analysis to see whether the type of operation itself really was a risk factor. I have doubts about that, except, of course, for AV block, but that requires just careful attention to the technique.

So this is a problem of the patients, not a problem of the type of operation, and for that reason I totally support your conclusion that these patients need to be improved before surgery and, in my experience, that can be done in the vast majority of cases with a significant improvement in the results.

So my question here, and again, it didn't become clear from the abstract or from your presentation, is what triggered reoperation for tricuspid regurgitation, the degree of regurgitation or the symptoms of the patients? And that's important, because not all the patients with severe tricuspid regurgitation get severely symptomatic, and if they are allowed to go too long, the reoperation becomes far more difficult.

And, with regard to all the previous presentations, I am not entirely convinced that the so-called remodelling of the right ventricle will happen necessarily and that it cannot be altered or greatly modified by persistence of intense anti-failure therapy, which means diuretics and vasodilators. We operate on these patients' left valves, they become totally asymptomatic and medical therapy is usually discontinued. In our practice, we keep these patients on vasodilators and diuretics, irrespective of the absence or presence of symptoms, and we do not have a high prevalence of patients requiring reoperation for tricuspid regurgitation.

My question is, what makes Japanese surgeons decide to go for a tricuspid valve procedure as a reoperation? Was it symptoms or was it the presence of tricuspid regurgitation, because that makes a difference?

Dr S. Saito (Tokyo, Japan): I am a co-author and will answer. The answer to the question is, basically it's the symptoms, rather than the presence of regurgitation. As you have pointed out, reoperative tricuspid surgery for symptomatic patients can be eventually too late. We Japanese surgeons and cardiologists frequently follow-up the patient who had left side surgery, and sometimes a very small amount of tricuspid regurgitation is found during the follow-up echocardiogram. The patients are looked at, together with liver enzyme elevation or symptoms. Basically, when the patient's symptoms become evident, such as oedema or right-sided failure, and are combined with a total bilirubin and liver enzyme elevation, that would be the perfect timing for the reoperation. Nevertheless, the cardiologists are following up the patients for too long, and when we are putting the patient on the operating table, sometimes it is quite difficult to repair. Would that be the answer to your question?

Dr Antunes: More or less. I understand that there are some language problems, but I think I left the message I wanted to give.

eComment. Right ventricular dysfunction in functional tricuspid regurgitation: a word of caution

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I have read the article by Umehara *et al.* [1] with great interest. The results shown in this paper are not unexpected. I think the decision of whether or not to operate on these patients depends on the state of right ventricular (RV) function. In severe RV dysfunction, functional tricuspid regurgitation (TR) provides the RV with an additional "escape". The choice facing the surgeon is clear. The greater the RV dysfunction, the greater the TR. This emphasis is fully understandable and focused on what occurs beyond the procedure. Mild or moderate functional TR left uncorrected at the time of left-sided valvular surgery can become severe in approximately 34% of cases, with a poor outcome and reduced survival [2]. Quality of life and survival are directly related to residual RV function rather than the type of procedure on the tricuspid valve. The presence of severe pulmonary hypertension and/or significant RV dysfunction can be a relative contraindication to reoperation [3]. Therefore, the risks and benefits of tricuspid valve reoperation should be carefully considered when severe RV systolic dysfunction and/or irreversible pulmonary hypertension are present, due to the possibility of RV failure following the procedure. I strongly recommend the assessment of RV systolic function by echocardiography (tricuspid annular plane systolic excursion >16 mm, tricuspid valve annular velocity >10 cm/s, and RV end-systolic area <20 cm^2) as a very important tool in the decision-making process. These observations address the option that these patients might be considered as inoperable [4].

Conflict of interest: none declared.

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Surgical risk model for acute diffuse peritonitis based on a Japanese nationwide database: an initial report on the surgical and 30-day mortality

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Abstract
Purpose Acute diffuse peritonitis (ADP) is an important surgical complication associated with high morbidity and mortality; however, the risk factors associated with a poor outcome have remained controversial. This study aimed in collecting integrated data using a web-based national database system to build a risk model for mortality after surgery for ADP.
Methods We included cases registered in the National Clinical Database in Japan. After data cleanup, 8,482 surgical cases of ADP from 1,285 hospitals treated between January 1 and December 31, 2011 were analyzed.
Results The raw 30-day and surgical mortality rates were 9.0 and 14.1 %, respectively. The odds ratios (>2.0) for 30-day mortality were as follows: American Society of Anesthesiologists (ASA) class 3, 2.69; ASA class 4, 4.28; ASA class 5, 8.65; previous percutaneous coronary intervention (PCI), 2.05; previous surgery for peripheral vascular disease (PVD), 2.45 and disseminated cancer, 2.16. The odds ratios (>2.0) for surgical mortality were as follows: ASA class 3, 2.27; ASA class 4, 4.67; ASA class 5, 6.54, and disseminated cancer, 2.09. The C-indices of 30-day and surgical mortality were 0.851 and 0.852, respectively.
Conclusion This is the first report of risk stratification after surgery for ADP using a nationwide surgical database. This system could be useful to predict the outcome of surgery for ADP and for evaluations and benchmark performance studies.

Keywords Acute diffuse peritonitis · Risk factor · Mortality · Risk model

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Introduction

Acute diffuse peritonitis (ADP) is an important surgical complication associated with a high incidence of morbidity and mortality [1–4], and is defined as the uncontained rapid spread of an intra-abdominal infection beyond the organ of origin to multiple (2–4) quadrants of the intra-abdominal cavity, regardless of the underlying disease processes, such as a ruptured appendix, ischemic colitis, gastrointestinal (GI) tract perforation, etc. [2–5]. Emergency surgery is defined as a surgery performed on a patient immediately after the diagnosis [6]. Although a definite preoperative diagnosis of a detailed etiology is difficult even using the recently developed imaging modalities [7, 8], the surgical management of ADP involves immediate evacuation of all purulent collections and source control [1–3].

Although the mortality rate from intra-abdominal infections was close to 90 % in the early 1900s, prior to the introduction of the basic principles of surgery, in the modern era, the reduction in mortality to below 20 % has resulted due to the better understanding of the role of damage control, prevention of intra-abdominal compartment

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syndrome, and improved antibiotic alternatives with newer, broad-spectrum medications [1]. However, most modern case series of secondary peritonitis with severe sepsis or septic shock have reported an average mortality rate of ~30 % [3].

Knowledge regarding the predictive factors and arrival at a consensus scoring system for the risk of mortality after surgery for ADP would be useful. Many hospitals and surgeons have tried to clarify these factors and develop scoring systems in their own units [1, 3, 9–13]. Although nationwide data regarding the quality of emergency surgical care using the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) have been reported in several studies [14–17], to date, there has been no report of a nationwide study focused on ADP.

The National Clinical Database (NCD) in Japan, which commenced patient registration in January 2011, is a nationwide project linked to the surgical board certification system. Submitting cases to the NCD is a prerequisite for all member institutions of both the Japan Surgical Society and the Japanese Society of Gastroenterological Surgery (JSGS), and only registered cases can be used for board certification. The NCD collaborates with the ACS-NSQIP [12], which shares a similar goal of developing a standardized surgery database for quality improvement. The NCD contains >1,200,000 surgical cases collected from >3,500 hospitals in 2011, and risk models of some of the procedures (total gastrectomy, right hemicolectomy, hepatectomy, pancreaticoduodenectomy, hepatectomy, etc.) have been created using these data [18–21]. In this study, a risk model was developed using 8,482 surgical cases of ADP from 1,285 hospitals throughout Japan. This risk model will hopefully contribute to the future improvement in the quality control of surgery for ADP.

Methods

Data acquisition

The NCD continuously recruits individuals to approve the inputted data from members of various departments in charge of annual cases, as well as data entry officers, through a web-based data management system to assure the traceability of the data. Furthermore, the project managers consecutively and consistently validate the data by inspection of randomly chosen institutions.

In this study, we focused on ADP cases in the GI surgery section of the NCD that were characterized by variables and definitions that were almost identical to those applied in the ACS-NSQIP [14–17, 22]. In the GI surgery section, all of the surgical cases are registered and require detailed input items for the eight procedures representing the performance of surgery in each specialty (low anterior resection, right hemicolectomy, hepatectomy, total gastrectomy, partial gastrectomy, pancreatoduodenectomy, esophagectomy, and ADP). All variables, definitions and inclusion criteria regarding the NCD are accessible from the website (http://www.ncd.or.jp/) to participate institutions, and are also intended to support an E-learning system in order for participants to input consistent data. The NCD provides answers to all queries regarding data entry (~80,000 inquiries in 2011) and regularly includes the responses to some of the queries as Frequently Asked Questions on the website.

Patient selection

A total of 8,482 patients who underwent surgery for ADP were identified from the NCD in 2011. Most of the patients who underwent surgery for ADP required emergency surgery within 24 h after admission, because the condition of the patients would otherwise have proven fatal or would have caused severe damage to the patients. This is differentiated from localized intra-abdominal abscess, which allows for a time-rich detailed exploration. Surgery for ADP (i.e., surgical debridement and/or drainage) is a procedure representing the performance of a surgery that has been allowed by the national Japanese insurance system. To reduce the bacterial load, the abdominal cavity is lavaged, with particular attention to areas prone to abscess formation (e.g., the paracolic gutters and subphrenic areas). When surgery is performed to address underlying diseases or resection of a perforated viscus with reanastomosis or the creation of a fistula, supplemental procedures, such as resection of the small intestine, colorectal resection and enterostomy, are also recorded. The NCD allows the inclusion of up to eight ICD-10 codes for the preoperative/postoperative diagnosis of each case. Possible causative diseases necessitating surgery in the NCD include peritonitis, intestinal perforation, appendicitis, gastroduodenal ulcer/perforation, intestinal obstruction and vascular insufficiency, etc.

Pre- and perioperative variables

The potential independent variables included the patient demographics, pre-existing comorbidities, preoperative laboratory values, and perioperative data. The demographic variables of age, gender, smoking status, and drinking status were considered. Patients were categorized on the basis of whether they were transferred directly by ambulance or not. General factors, such as the preoperative functional status [independent, partially dependent, and totally dependent with regard to a patient's ability to perform activities of daily living (ADL) 30 days and immediately before surgery] and the body mass index (BMI), were also considered. The ASA physical status classification was evaluated. We also considered preexisting comorbidities, including the cardiovascular status (congestive heart failure, coronary diseases, hypertension, previous cardiac surgery, and peripheral vascular disease), respiratory status (dyspnea, ventilator dependence, pneumonia, and chronic obstructive pulmonary disease), renal status (acute renal failure and dialysis), hematological status (bleeding disorders and preoperative blood transfusion), oncological status (disseminated cancer, chemotherapy and radiotherapy), preoperative blood transfusion, chronic steroid use, ascites, sepsis, diabetes, open wound, and pregnancy. The laboratory parameters included in the analysis were the white blood cell count, hemoglobin level, hematocrit, platelet count, prothrombin time and activated partial thromboplastin time, as well as the serum levels of albumin, total bilirubin, aspartate amino transferase, alanine aminotransferase, alkaline phosphatase, urea nitrogen, creatinine, sodium, hemoglobin A1c, and C-reactive protein (CRP). The length of the surgery, intraoperative blood loss and relaparotomy within 30 days after surgery for ADP were also considered. A total of 4,192 supplemental procedures for source control were also included.

Endpoints

The outcome measures of this study were the 30-day and surgical mortality rates. The former was defined as death within 30 days of surgery regardless of the patient's geographical location, even if the patient had been discharged from the hospital. The latter was defined as death within the index hospitalization period, regardless of the length of hospital stay (up to 90 days), as well as any patient who died after being discharged, up to 30 days from the date of surgery.

Statistical analysis

Data were randomly assigned into two subsets that were split 80/20, the first for model development, and the second for validation. The two sets of logistic models (30-day mortality and surgical mortality) were constructed for dataset development using stepwise selection of the predictors with a probability (P) value for inclusion of 0.05. A "goodness-of-fit" test was performed to assess how efficiently 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 with the predicted average within each of 10 equally sized subgroups arranged in increasing order of patient risk [6, 23].

Results

Outcomes

Among the data for the 8,482 patients stored in the NCD for 2011, the 30-day and postoperative mortality rates for ADP were 9.0 and 14.1 %, respectively. The causative diseases leading to the need for surgery are listed in Table 1. The development dataset (test set) included 6,759 records, and the validation dataset (validation set) included 1,723 records (Table 2). The rates of relaparotomy and readmission within 30 days in all records were 8.1 and 1.7 %, respectively, in these datasets.

Risk profile for the study population

The patient population that underwent surgery for ADP had an average age of 64.7 years (SD 18.6), 59.8 % of whom were males, and 38.7 % of patients were taken to the hospital by ambulance, 93.1 % of whom required emergency surgery. An abbreviated risk profile of the study population is shown in Table 3. The patients with partially/totally dependent and totally dependent evaluations of the ADL within 30 days before surgery comprised 20.7 and 7.7 % of the patients, respectively. Only 0.6 % of the patients had a BMI $\geq$35 kg/m^2. Of the included patients, 43.2 %

Table 1 The causative disease leading to the need for surgery

Diagnosis	Number	30-Day mortality		Surgical mortality	
		Number	Percent (%)	Number	Percent (%)
Acute peritonitis	4,378	429	9.8	652	14.9
Appendicitis	1,183	4	0.3	10	0.8
Intestinal perforation	1,576	148	12.9	222	19.3
Gastroduodenal ulcer/perforation	833	63	7.3	64	9.7
Intestinal obstruction	396	50	12.6	80	20.2
Cholecystitis/cholangitis	218	18	9.0	26	13.1
Vascular insufficiency	121	21	17.4	35	28.9
All cases	8,482	762	9.0	1,195	14.1

The listed diseases were not mutually exclusive

Causative diseases with fewer than 100 cases were not listed

Table 2 The outcomes of surgery for acute diffuse peritonitis

Outcomes	Test set ($n = 6{,}759$)		Validation set ($n = 1{,}723$)		Overall incidence ($n = 8{,}482$)	
	Number	Percent (%)	Number	Percent (%)	Number	Percent (%)
30-Day mortality	604	8.9	158	9.2	762	9.0
In-hospital mortality	938	13.9	241	14.0	1,179	13.9
Surgical mortality	950	14.1	245	14.2	1,195	14.1
Relaparotomy within 30 days	546	8.1	145	8.4	691	8.1
Readmission within 30 days	107	1.6	39	2.3	146	1.7

were ASA class 3–5. Regarding preexisting comorbidities, 20.5 % of patients had received preoperative blood transfusions, 22.7 % had ascites, 31.8 % had sepsis, and 13.5 % had diabetes.

The types of supplemental surgical procedures ($n = 4{,}192$) performed for source control are listed in Table 4. The primary surgical procedures were enterostomy (30.4 %), colorectal resection (19.9 %), closure of a perforated stomach/duodenum (13.0 %), appendectomy (12.4 %), resection of the small intestine (8.2 %), the Hartmann procedure (6.5 %), cholecystectomy/cholecystotomy (3.5 %), closure of a perforated small intestine (3.3 %), and surgery for intestinal obstruction (2.5 %).

Model results

Two different risk models were developed, and 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 as follows:

Predicted mortality = $e(\beta 0 + \Sigma \beta i\ Xi)/1 + e(\beta 0 + \Sigma \beta i\ Xi)$, where βi is the coefficient of the variable Xi in the logistic regression equation provided in Table 5 for the 30-day mortality and surgical mortality. $Xi = 1$ if a categorical risk factor is present and 0 if it is absent. For the age category, $Xi = 1$ if the patient age is <59 years old; 2 if the patient age is between 60 and 64; 3 if 65 and 69; four if 70 and 74; 5 if 75–79 and the $Xi = 6$ if the age was ≥80 years old. Between the two models, there were 16 overlapping variables: the age, ASA class 5, ASA class 4, ASA class 3, disseminated cancer, nontumor-bearing, preoperative transfusion, chronic steroid use, serum albumin <2.0 g/dL, serum total bilirubin ≥3.0 mg/dL, serum AST ≥35 U/L, serum ALP ≥600 U/L, serum urea nitrogen ≥20 or 25 mg/dL, serum Na <130 mEq/L and serum CRP ≥10.0 mg/dL.

The important variables (odds ratio >2.0) affecting the 30-day mortality were ASA class 3 (OR, 2.69; 95 % CI, 2.05–3.54), ASA class 4 (OR, 4.28; 95 % CI, 3.11–5.87), ASA class 5 (OR, 8.65; 95 % CI, 6.14–12.18), previous PCI (OR, 2.05; 95 % CI, 1.26–3.31), previous PVD surgery (OR, 2.45; 95 % CI, 1.16–5.17) and disseminated cancer (OR, 2.16; 95 % CI, 1.53–3.05), whereas those affecting the surgical mortality were ASA Class 3 (OR, 2.27; 95 % CI, 1.83–2.82), ASA Class 4 (OR, 4.67; 95 % CI, 3.61–6.05), ASA class 5 (OR, 6.54; 95 % CI, 4.83–8.84) and disseminated cancer (OR, 2.09; 95 % CI, 1.54–2.83).

Model performance

To evaluate the model performance, both a C-index (a measure of model discrimination) with a 95 % CI, which is the area under the receiver operating characteristic curve, and the model calibration across risk groups were evaluated. As a performance parameter of the risk model, the C-indices of the 30-day and surgical mortality were 0.851 (95 % CI, 0.822–0.880) and 0.852 (95 % CI, 0.828–0.875), respectively (Fig. 1). Figure 2 demonstrates the calibration of the models and how well the rates for the predicted events matched those of the observed events among the patient risk subgroups.

Discussion

Systemic sepsis is a life-threatening condition that may occur as a result of intra-abdominal infections of all types [1, 3]. In complicated intra-abdominal infections, the infection spreads beyond the organ of origin and causes either localized or diffuse peritonitis [2, 10]. Complicated intra-abdominal infections represent an important cause of morbidity, and are frequently associated with a poor prognosis [2, 10]. The mortality is reportedly reduced by 50 % following the introduction of the basic concepts of surgery for intra-abdominal infections by: (1) elimination of the septic foci, (2) removal of necrotic tissue and (3) drainage of purulent material. Advances that have provided a better understanding of the pathophysiology, the role of damage control, the prevention of intra-abdominal

Table 3 Key risk profiles and outcomes

	Records for the entire study population (*n* = 8,482)		Outcome groups			
			30-Day mortality (*n* = 762)		Surgical mortality (*n* = 1,195)	
	Number	Percent	Number	Percent	Number	Percent
Characteristics						
Demographics						
Age, mean (SD), years	64.7 (18.6)		74.8 (13.7)		74.5 (13.2)	
Males	5,072	59.8	416	8.2	667	13.2
Ambulance transportation	3,283	38.7	364	11.1	511	15.6
Preoperative risk assessment						
General						
ADL within 30 days before surgery						
Partially/totally dependent	1,756	20.7	342	19.5	535	30.5
Totally dependent	653	7.7	149	22.8	231	35.4
ADL immediately before surgery						
Partially/totally dependent	2,358	27.8	427	18.1	654	27.7
Totally dependent	1,162	13.7	258	22.2	375	32.3
Body mass index ≥35 kg/m^2	51	0.6	11	20.8	14	28.3
Weight loss over 10 %	442	5.2	77	17.4	134	30.3
ASA class 3, ASA class 4, or ASA class 5	3,664	43.2	641	17.5	976	26.6
Cardiovascular						
Congestive heart failure	237	2.8	71	30.0	103	43.4
Previous myocardial infarction	51	0.6	14	27.5	18	35.3
Angina pectoris	110	1.3	20	18.2	26	23.6
Hypertension without therapy	271	3.2	27	10.0	45	16.7
Previous PCI	170	2	37	22.0	44	26.2
Previous cardiac surgery	119	1.4	28	23.3	35	29.3
Previous surgery for PVD	51	0.6	14	28.3	24	47.2
Pulmonary						
Dyspnea	712	8.4	192	27.0	267	37.4
Ventilator-dependent	331	3.9	98	29.6	147	44.3
Pneumonia	305	3.6	84	27.6	125	40.9
COPD	288	3.4	46	15.8	71	24.6
Renal						
Acute renal failure	407	4.8	127	31.1	177	43.5
Dialysis	322	3.8	79	24.4	118	36.7
Oncological						
Non-tumor-bearing	7,490	88.3	618	8.3	947	12.6
Disseminated cancer	450	5.3	95	21.2	161	35.8
Chemotherapy	297	3.5	49	16.6	101	33.9
Radiotherapy	51	0.6	9	17.0	14	27.7
Hematological						
Bleeding disorder without therapy	560	6.6	159	28.5	214	38.2
Preoperative blood transfusion	1,739	20.5	351	20.2	535	30.8
Other						
Previous cerebrovascular disease	450	5.3	76	17.0	119	26.4
Chronic steroid use	365	4.3	71	19.4	109	29.9
Ascites without therapy	1,925	22.7	259	13.4	412	21.4
Sepsis	2,697	31.8	453	16.8	661	24.5

Table 3 continued

	Records for the entire study population (*n* = 8,482)		Outcome groups			
			30-Day mortality (*n* = 762)		Surgical mortality (*n* = 1,195)	
	Number	Percent	Number	Percent	Number	Percent
Diabetes	1,145	13.5	152	13.3	241	21.0
Preoperative laboratory value						
White blood cell count <4,500/μL	1,993	23.5	253	12.7	382	19.2
White blood cell count <4,000/μL	1,789	21.1	230	12.9	345	19.3
Hemoglobin <13.5 g/dL in males; <12.5 g/dL in females	4,419	52.1	541	12.3	886	20.1
Hemoglobin < 10.0 g/dL	1,734	20.4	268	15.5	442	25.5
Hematocrit <30 %	1,671	19.7	264	15.8	440	26.3
Platelet count <15,000/μL	1,484	17.5	297	20.0	406	27.4
Platelet count <12,000/μL	771	9.1	192	24.9	260	33.7
Platelet count <8,000/μL	288	3.4	104	36.1	137	47.6
Serum albumin <2.0 g/dL	619	7.3	141	22.8	225	36.4
Serum albumin <2.5 g/dL	1,612	19	291	18.1	491	30.5
Serum albumin <3.0 g/dL	2,943	34.7	450	15.3	746	25.3
Serum total bilirubin ≥3.0 mg/dL	365	4.3	76	20.9	113	31.0
Serum AST ≥35 U/L	2,036	24	331	16.2	483	23.8
Serum ALP ≥340 U/L	1,442	17	199	13.8	317	22.0
Serum ALP ≥600 U/L	407	4.8	76	18.8	113	27.8
Serum urea nitrogen ≥20 mg/dL	3,868	45.6	596	15.4	898	23.2
Serum urea nitrogen ≥25 mg/dL	2,748	32.4	503	18.3	736	26.8
Serum creatinine ≥1.2 mg/dL	2,171	25.6	401	18.5	591	27.2
Serum creatinine ≥2.0 mg/dL	984	11.6	216	22.0	320	32.5
Serum Na <130 mEq/L	475	5.6	78	16.5	135	28.3
Serum Na <13 5 mEq/L	1,976	23.3	245	12.4	398	20.1
Serum Na ≥145 mEq/L	314	3.7	71	22.5	95	30.2
Serum CRP ≥10.0 mg/dL	3,927	46.3	369	9.4	611	15.6
Operation						
Length of operation ≥6 h	51	0.6	12	24.0	16	32.0
Intraoperative blood loss ≥2,000 mL	161	1.9	40	24.5	62	38.2
Relaparotomy within 30 days	687	8.1	81	11.7	163	23.7

SD standard deviation, *ADL* activities of daily living, *ASA class* American Society of Anesthesiologists Physical Status Classification, *PCI* percutaneous coronary intervention, *PVD* peripheral vascular disease, *COPD* chronic obstructive pulmonary disease, *AST* aspartate amino transferase, *ALP* alkaline phosphatase, *Na* sodium, *CRP* C-reactive protein

compartment syndrome and antibiotic administration have collectively helped to reduce the mortality rate below 20 % [1].

In this study, the 30-day and surgical mortality rates after surgery for all acute types of primary, secondary and tertiary peritonitis [1–3] were 9.0 and 14.1 %, respectively. Recently, published studies reported that the 30-day mortality rate after surgery for ADP was 8–9 % [24, 25], whereas the surgical mortality rate was 12.8–33.3 % (12.8 % [26], 14 % [5], 19 % [24], 22 % [27], 21.8 % [12], 23.1 % [11] and 33.3 % [28]). For reference, the 30-day mortality rate of the patients in the ACS-NSQIP study of 5,083 patients who underwent emergency colorectal operations was 15.4 % [17]. Thus, although the 30-day mortality rate in this study was similar to that in previous studies, the surgical mortality rates in the previous studies from western countries was higher than that in the current study. We believe that our results were satisfactory for a nationwide outcome of surgery for ADP.

Early prognostic evaluation of complicated intra-abdominal infections is important to assess the severity and prognosis of disease [10]. A number of factors influencing the prognosis of patients with complicated intra-abdominal infections, as well as scoring systems to evaluate these

Table 4 Supplemental surgical procedures performed for source control and the outcomes

Surgical	Surgical procedures		Outcome groups			
			30-Day mortality		Surgical mortality	
	Number	Percent	Number	Percent	Number	Percent
Gastro-duodenum						
Closure of perforated stomach and/or duodenum	545	13.0	35	6.4	46	8.4
Gastrectomy	75	1.8	7	9.3	8	10.7
Postduodenal small intestine						
Resection of small intestine	345	8.2	35	10.1	67	19.4
Closure of perforated intestine	138	3.3	10	7.2	22	15.9
Surgery for intestinal obstruction	106	2.5	21	19.8	30	28.3
Enterostomy	1,276	30.4	185	14.5	280	21.9
Appendix						
Appendectomy	519	12.4	4	0.8	11	2.1
Colon and rectum						
Right-sided colon resection	177	4.2	19	10.7	32	18.1
Left-sided colon resection	326	7.8	47	14.4	68	20.9
Anterior resection	22	0.5	2	9.1	2	9.1
Hartmann procedure	273	6.5	32	11.7	44	16.1
Total colectomy	19	0.5	4	21.1	5	26.3
Hepato-biliary-pancreatic						
Hepatic resection/suturing the liver	8	0.2	1	12.5	2	25.0
Cholecystectomy/cholecystostomy	151	3.6	12	8.1	20	13.4
Choledocholithotomy/choledochoduodenostomy (-jejunostomy)/choledochostomy	29	0.7	7	25.0	7	25.0
Surgery for acute pancreatitis/resection of the pancreas/Drainage of pancreatic duct or cyst, %	8	0.2	2	22.2	4	44.4
Others						
Abdominoperineal resection/total pelvic exenteration	17	0.4	4	22.2	4	22.2
Splenectomy	13	0.3	3	21.4	4	28.6

A total of 4,192 supplemental surgical procedures were included. Surgical procedures performed fewer than eight times were not listed. Some patients underwent more than one surgical procedure

factors, have been reported [3, 10–13, 24]. From our risk model, the important variables identified to affect the 30-day mortality rate were ASA class 3, ASA class 4, ASA class 5, previous percutaneous coronary intervention (PCI), previous surgery for peripheral vascular disease (PVD) and disseminated cancer, whereas those affecting the surgical mortality rate were ASA class 3, ASA class 4, ASA class 5 and disseminated cancer. Although the ASA classification of fitness for surgery was not devised as a risk prediction score, several studies have reported the association between the ASA class and observed postoperative mortality in elderly patients following emergency GI surgery [13, 29]. In univariate and multivariate analyses of the mortality of emergency surgical patients, the ASA class has been consistently shown to be a good predictor of postoperative death, although this is despite its subjective nature and the inter-observer variations in measuring the ASA class [13].

Other significant factors identified by our risk assessment model, including age, ambulance transportation, the ADL, respiratory distress, preoperative pneumonia, bleeding disorders, preoperative blood transfusion and long-term steroid use, were also significant risk factors for the 30-day and/or surgical mortality. Several risk factors (age, dyspnea, previous PCI, disseminated cancer, long-term steroid use, bleeding disorder without therapy and preoperative blood transfusion) have been reported in previous studies [31, 32], although ambulance transportation and the ADL have not been previously reported. The rate of ambulance transport among the elderly is continually increasing along with the rapidly aging population in Japan [33]. In this study, 38.7 % of the 8,482 patients who underwent surgery for ADP were admitted to a hospital by direct ambulance transport. Among the critical components of health care systems, ambulance services play an important

Table 5 The odds ratios with 95 % confidence intervals for the risk models of surgery for acute diffuse peritonitis

Variables	30-Day mortality				Surgical mortality			
	β coefficient	OR	95 % CI	*P* value	β coefficient	OR	95 % CI	*P* value
Demographics								
Age category[a]	0.211	1.24	1.17–1.31	<0.001	0.234	1.26	1.20–1.33	<0.001
Ambulance transport	0.317	1.37	1.12–1.68	0.002				
Respiratory distress	0.462	1.59	1.22–2.06	<0.001				
ADL, totally dependent immediately before surgery	0.337	1.4	1.11–1.77	0.005				
ADL, totally dependent within 30 days before surgery					0.465	1.59	1.22–2.07	0.001
ADL, partially/totally dependent immediately before surgery,					0.303	1.35	1.12–1.64	0.002
Preoperative pneumonia					0.342	1.41	1.01–1.97	0.045
ASA class 5	2.157	8.65	6.14–12.18	<0.001	1.877	6.54	4.83–8.84	<0.001
ASA class 4	1.453	4.28	3.11–5.87	<0.001	1.542	4.67	3.61–6.05	<0.001
ASA class 3	0.99	2.69	2.05–3.54	<0.001	0.822	2.27	1.83–2.82	<0.001
Preexisting comorbidity								
Previous PCI	0.715	2.05	1.26–3.31	0.004				
Previous surgery for PVD	0.897	2.45	1.16–5.17	0.018				
Disseminated cancer	0.769	2.16	1.53–3.05	<0.001	0.735	2.09	1.54–2.83	<0.001
Non tumor-bearing	−0.436	0.65	0.48–0.87	0.003	−0.69	0.5	0.4–0.64	<0.001
Bleeding disorder without therapy	0.499	1.65	1.24–2.19	0.001	0.484	1.62	1.31–2.01	<0.001
Preoperative blood transfusion	0.472	1.6	1.13–2.28	0.009	0.595	1.81	1.32–2.49	<0.001
Chronic steroid use	0.552	1.74	1.21–2.50	0.003	0.651	1.92	1.39–2.65	<0.001
Weight loss over 10 %					0.331	1.39	1.02–1.90	0.036
Preoperative laboratory value								
White blood cell count <4,500/μL					0.404	1.5	1.25–1.8	<0.001
White blood cell count <4,000/μL	0.336	1.4	1.12–1.75	0.003				
Hemoglobin <13.5 g/dL in males; <12.5 g/dL in females					0.273	1.31	1.07–1.62	0.01
Hemoglobin <10.0 g/dL	0.254	1.29	1.03–1.61	0.024				
Hematocrit <30 %					0.209	1.23	1.01–1.51	0.044
Platelet count <15,000/μL	0.413	1.51	1.19–1.92	0.001				
Platelet count <12,000/μL					0.356	1.43	1.13–1.8	0.003
Platelet count <8,000/μL	0.424	1.53	1.03–2.26	0.033				
Serum albumin <2.0 g/dL	0.51	1.67	1.25–2.22	<0.001	0.394	1.48	1.14–1.93	0.003
Serum albumin <3.0 g/dL					0.316	1.37	1.13–1.67	0.002
Serum total bilirubin ≥3.0 mg/dL	0.532	1.7	1.16–2.49	0.006	0.676	1.97	1.40–2.76	<0.001
Serum AST ≥35 U/L	0.3	1.35	1.09–1.67	0.006	0.358	1.43	1.19–1.72	<0.001
Serum ALP ≥600 U/L	0.545	1.73	1.18–2.51	0.005	0.474	1.61	1.15–2.24	0.005
Serum urea nitrogen ≥20 mg/dL	0.569	1.77	1.28–2.43	0.001	0.563	1.76	1.35–2.29	<0.001
Serum urea nitrogen ≥25 mg/dL	0.343	1.41	1.06–1.88	0.02				
Serum creatinine ≥2.0 mg/dL					0.405	1.5	1.2–1.89	<0.001
Serum Na <130 mEq/L	0.521	1.68	1.21–2.35	0.002	0.56	1.75	1.31–2.33	<0.001
Serum Na ≥145 mEq/L	0.526	1.69	1.16–2.46	0.006				
Serum CRP ≥10.0 mg/dL	0.397	1.49	1.21–1.83	<0.001	0.423	1.53	1.27–1.83	<0.001
Intercept (β0)	−5.449			<0.001	−4.83			<0.001

ADL activities of daily living, *ASA class* American Society of Anesthesiologists Physical Status Classification, *PCI* percutaneous coronary intervention, *PVD* peripheral vascular disease, *COPD* chronic obstructive pulmonary disease, *AST* aspartate amino transferase, *ALP* alkaline phosphatase, *Na* sodium, *CRP* C-reactive protein, *OR* odds ratio, *CI* confidence interval

[a] Age, years, <59, 60–64, 65–69, 70–74, 75–79, ≥80

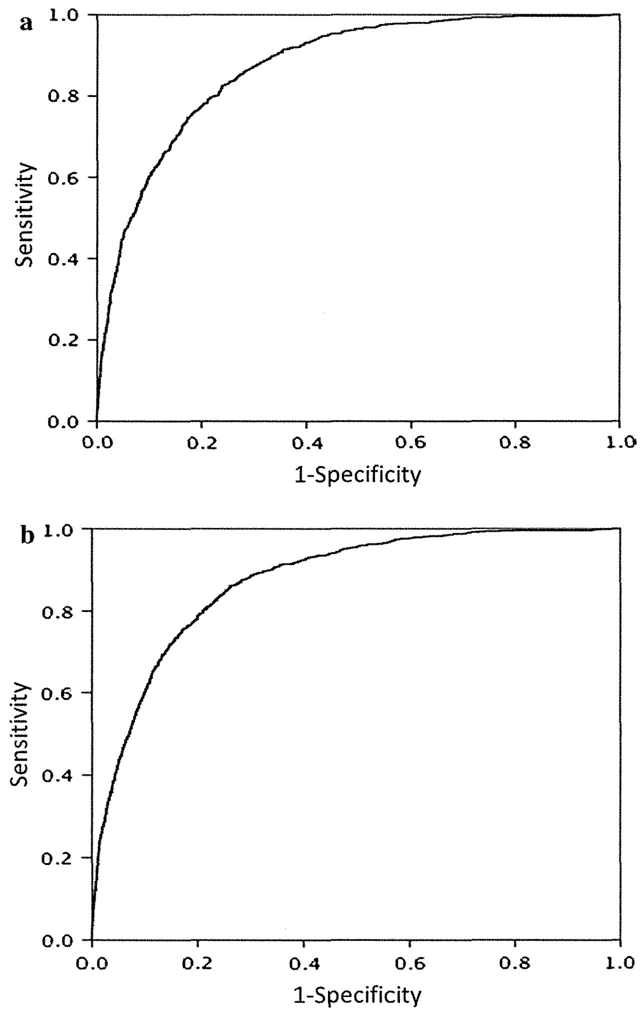

Fig. 1 The receiver operating characteristics (ROC) curves for the 30-day mortality (**a**) and surgical mortality (**b**) in the validation set

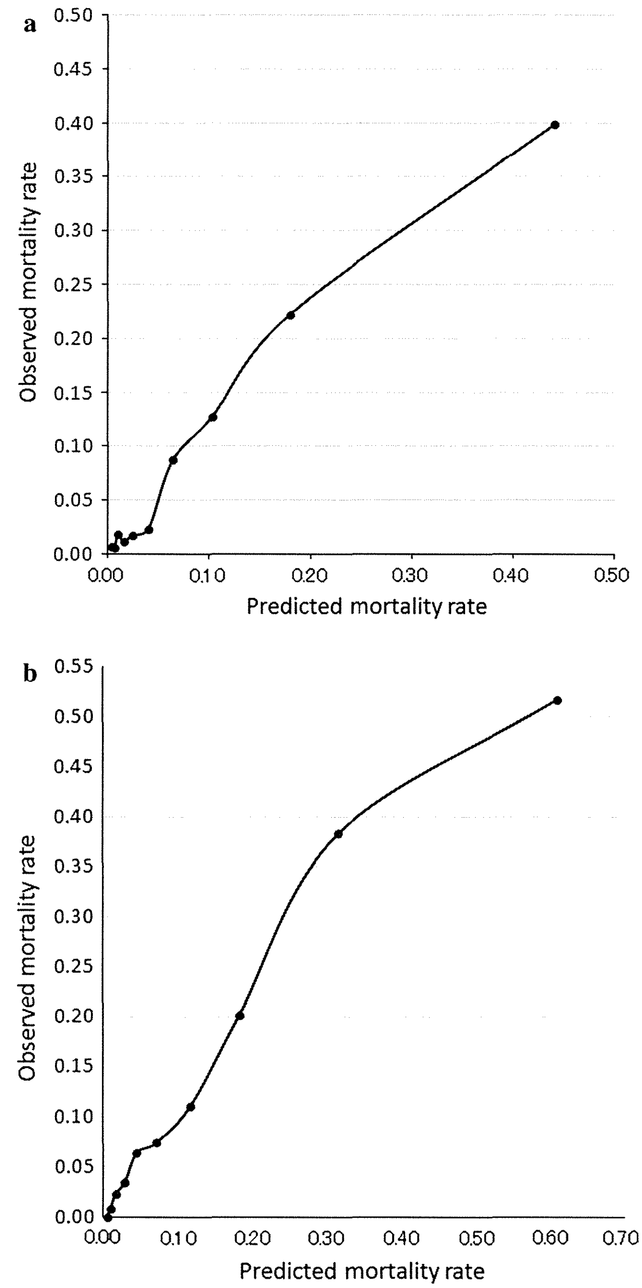

Fig. 2 The model calibration for the 30-day (**a**) and surgical (**b**) mortality models

part in the continuum of health care by providing prehospital care and transport in emergency situations [33]. The ADL describes the essential activities that a person needs to perform to be able to live independently. Particularly in the aging individual, the combination of acute and chronic diseases often results in disabilities and limitations in the ADL [34]. Functional limitations are particularly associated with mortality in patients with hip fractures and pulmonary infections, and in acute medical patients [34, 35]. In this risk model, not only the ADL (totally dependent) immediately before surgery, but also the ADL (totally/partially dependent) within 30 days before surgery was a significant risk factor for surgical mortality. These data suggest that assessment of the ADL within 30 days before surgery should be considered for the clinical management of ADP.

From our risk model, 12 laboratory factors (white blood cell count, hemoglobin, hematocrit, platelet count, and the serum levels of albumin, total bilirubin, aspartate amino transferase, alkaline phosphatase, urea nitrogen, creatinine, sodium and CRP) were significant risk factors for the 30-day and surgical mortality. These laboratory data may reflect the degree of physiological derangement due to the intra-abdominal infection and preexisting critical illness, and have been reported in previous studies.

The C-indices of the models for the 30-day and surgical mortality in this study were 0.851 and 0.852, respectively. These data indicate that our models were reliable. Although the usefulness of several scoring systems, such as the Acute Physiology and Chronic Health Evaluation (APACHE) score and the Mannheim Peritonitis Index, have been reported [13], they are not specific for Japanese patients who undergo surgery for ADP. The reliability of existing scores or indices for ADP surgery may be improved by including our risk model. The NCD collects data obtained before admission and during the hospitalization period. On the other hand, the APACHE database is a collection of data obtained only after the patient has been admitted to the intensive care unit [14]. Some NCD preoperative data were predictive of the patient outcomes, which may allow for the earlier identification of potential complications.

This study was associated with several potential limitations. First, except for the ASA class, the other scoring systems to potentially predict the mortality after surgery for ADP, such as the APACHE score and Mannheim Peritonitis Index [13], could not be determined from this database. Second, we could not distinguish between the two different types of intra-abdominal infections (community- and healthcare-acquired), from this database. Third, the risk of mortality differed between ADP due to upper gastrointestinal perforation and that caused by colon perforation, as shown in Table 1. The lack of information regarding the details of the causative diseases in some patients was another limitation of this study. Fourth, the effects of surgical procedures on certain causative disease should be analyzed in a future study.

In conclusion, this report is the first risk stratification study of surgery for ADP to use a nationwide NCD. By analyzing 8,482 patients from 1,285 surgical units throughout Japan, the 30-day and surgical mortality rates were determined to be 9.0 and 14.1 %, respectively. The results of this series are satisfactory regarding the nationwide outcome of surgery for ADP, and this system can be useful in predicting the outcome of surgery for ADP, and may be useful to evaluate and benchmark performance.

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Conflict of interest The authors report no conflicting financial interests.

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The National Clinical Database as an Initiative for Quality Improvement in Japan

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The JCVSD (Japan Cardiovascular Surgery Database) was organized in 2000 to improve the quality of cardiovascular surgery in Japan. Web-based data harvesting on adult cardiac surgery was started (Japan Adult Cardiovascular Surgery Database, JACVSD) in 2001, and on congenital heart surgery (Japan Congenital Cardiovascular Surgery Database, JCCVSD) in 2008. Both databases grew to become national databases by the end of 2013. This was influenced by the success of the Society for Thoracic Surgeons' National Database, which contains comparable input items. In 2011, the Japanese Board of Cardiovascular Surgery announced that the JACVSD and JCCVSD data are to be used for board certification, which improved the quality of the first paperless and web-based board certification review undertaken in 2013. These changes led to a further step. In 2011, the National Clinical Database (NCD) was organized to investigate the feasibility of clinical databases in other medical fields, especially surgery. In the NCD, the board certification system of the Japan Surgical Society, the basic association of surgery was set as the first level in the hierarchy of specialties, and nine associations and six board certification systems were set at the second level as subspecialties. The NCD grew rapidly, and now covers 95% of total surgical procedures. The participating associations will release or have released risk models, and studies that use 'big data' from these databases have been published. The national databases have contributed to evidence-based medicine, to the accountability of medical professionals, and to quality assessment and quality improvement of surgery in Japan.

Key words: 1. Clinical database
2. Quality improvement
3. Medical board
4. Patient safety
5. Medical expenditure

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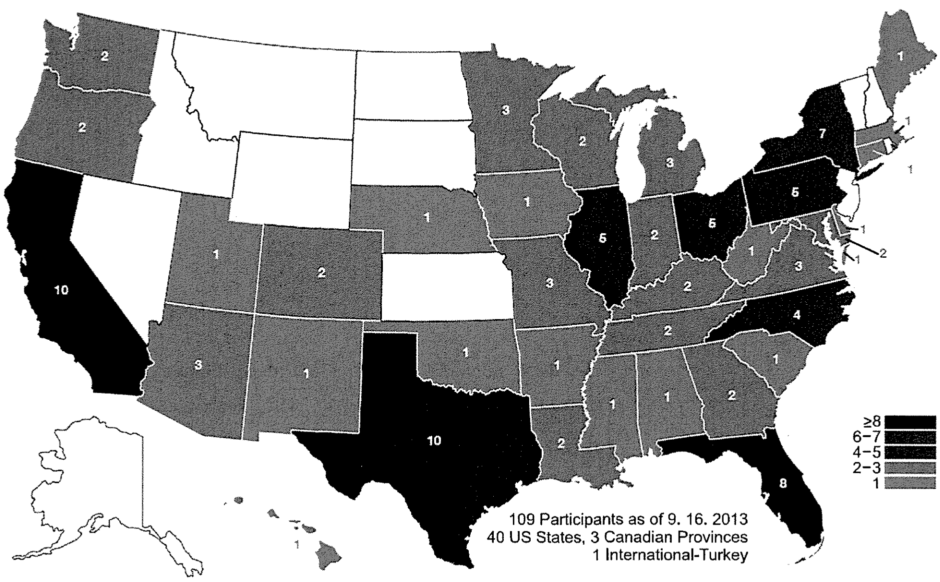

Fig. 1. The Society for Thoracic Surgeons National Database: the Congenital Heart Surgery Database participants (http://www.sts.org/sites/default/files/documents/congenitalMap.pdf).

INTRODUCTION: THE SOCIETY FOR THORACIC SURGEONS NATIONAL DATABASE

The first historical study of quality assessment in the medical field was reported by Ernest Amory Codman, MD, of Massachusetts General Hospital in 1920. To support his 'end results theory,' he made public the results of the review of his own hospital in a privately published book, "A study in hospital efficiency," in which he emphasized the importance of patient follow-up and quality assessment. He helped to found the Hospital Standardization Program, which eventually became the Joint Commission on Accreditation of Healthcare Organizations in 1987, and the Joint Commission in 2007, with the motto 'Helping Health Care Organizations Help Patients.'

From the 1970s through the 1980s, the rapid increase in medical lawsuits and the medical malpractice insurance crisis promoted risk management of medical practices in the United States. In 1989, the Society for Thoracic Surgeons (STS) started to establish national databases [1] as an initiative to improve quality and patient safety among cardiothoracic surgeons and to respond to strong public opinion about the importance of accountability. In 1997, an initiative was begun to improve data quality and auditing, and staff were hired to support these efforts. In the STS Congenital Heart Surgery Database data specification, (http://www.sts.org/sites/default/files/documents/CongenitalDataSpecsV3_22.pdf), the Patient National Identification (Social Security Number) is listed, but this field should be collected in compliance with state/local privacy laws. The STS National Database complies with the Health Insurance Portability and Accountability Act, and the federal government protects the STS National Database.

In 1998, the STS contracted with the Duke Clinical Research Institute (DCRI) for data warehousing and data analysis. In 1999, the Institute of Medicine published a report titled "To err is human: building a safe health system," which stated that 44,000 to 98,000 persons die in hospitals as a result of medical errors that could have been prevented. This report led worldwide health policy organizations to introduce initiatives for patient safety.

Today, the management of the National Database is one of the most important tasks of the STS. The database contains three components: adult cardiac surgery, general thoracic surgery and congenital heart surgery (Fig. 1).

The STS was the first professional organization to seek approval for its measures from the National Quality Forum (NQF), a multi-stakeholder health policy organization head-

Table 1. Progress in quality improvement in medical fields worldwide and the Japan Cardiovascular Surgery Database

Year	History
1920	Initial report of quality assessment by Codman, MD.
1989	Start of the Society for Thoracic Surgeons National Database
1998	Kick-off meeting for cardiovascular surgery database during the 7th annual meeting of the Asian Society of Thoracic and Cardiovascular Surgery in Singapore
1999	Report from the Institute of Medicine, 'To err is human'
2000	Database ad hoc committee started under the Japanese Society for Cardiovascular Surgery, and the Japanese Association for Thoracic Surgery
2000	Establishment of the Japan Cardiovascular Surgery Database
2001	The beginning of the data harvest on Japan adult cardiovascular surgery database, JACVSD, by 5 units
2008	The beginning of data harvest on Japan congenital cardiovascular surgery database, JCCVSD, by 7 units
2011	The JBCVS decided to adopt the reported data of the JACVSD and the JCCVSD for board certification
2011	Establishment of National Clinical Database
2013	The first "paper-less and web-based" board certification meeting of JBCVS
2014	A new organization for medical board certification in Japan

JACVSD, Japan Adult Cardiovascular Surgery Database; JCCVSD, Japan Congenital Cardiovascular Surgery Database; JBCVS, Japanese Board of Cardiovascular Surgery.

quartered in Washington, DC. In this manner, the STS has gained a positive reputation with the government and with health policy organizations. In addition, in 2010, the STS started to publicly report isolated coronary artery bypass grafting (CABG) composite star ratings not only on its own website but also on a consumer report website (www.consumerreportshealth.org) [2]. Later, public reporting of aortic valve surgery (AVR) and CABG+AVR began, and this year, will be extended to congenital heart surgery. The NQF has been releasing quality indicators in medical fields under the rubric of 'NQF-Endorsed Standards' (http://www.qualityforum.org/Home.aspx). For example, the standard measures of congenital heart surgery are 'participation in the STS National Database,' 'operative mortality stratified by the five STS-EACTS (European Association for Cardiothoracic Surgery) Mortality Categories,' and 'Risk Adjustment in Congenital Heart Surgery (RACHS-1) Pediatric Heart Surgery Mortality [3].' The STS states on its website that 'STS believes the public has a right to know the quality of the surgical outcomes, and considers public reporting an ethical responsibility of the specialty [4,5].'

THE JAPAN CARDIOVASCULAR SURGERY DATABASE

In turn, in 1998, at the 7th Annual Meeting of the Asian Society for Cardiovascular and Thoracic Surgery in Singapore, the need for an Asian Cardiovascular Surgery Database was discussed. First, a database ad hoc committee was formed by the Japanese Society for Cardiovascular Surgery (JSCVS) and the Japanese Association for Thoracic Surgery (JATS) (Table 1).

Moreover, quality improvement of cardiovascular surgery has been discussed by the members of the board of JSCVS and JATS since early 2000. In pursuit of this goal, three committees were organized by the JSCVS and JATS among its academic groups: 1) a board certification committee, 2) a center aggregation committee, and 3) a nurse practitioner and physician assistant committee.

In 2000, before this movement, the Japan Cardiovascular Surgery Database (JCVSD) was established with close ties to the JSCVS and JATS. The JCVSD and JSCVS invited the founder of the STS National Database to discuss starting the construction of the database. The JCVSD established input items comparable to those of the STS National Database. In the Congenital Heart Surgery Database, the common terminologies and the definitions of congenital heart diseases published in the "Annals of thoracic surgery [6]" were adopted, and 193 input items were established in the Japan Congenital Cardiovascular Surgery Database (JCCVSD).

Thus, the Congenital Heart Surgery Databases in the United States, Europe, and Japan were integrated by using common language in these databases. As a result, international comparisons became possible. Although the results were not reported, for example, the discharge mortality in the JCCVSD was 0.2%, 0.7%, 3.6%, 7%, and 17.6% for RACHS-1 categories 1, 2, 3, 4, and 5/6, respectively, during

Discharge mortality in RACHS-1 categories				
PACHS-1	RACHS-2	RACHS-3	RACHS-4	RACHS-5/6
0.20%	0.70%	3.60%	7%	17.60%

Fig. 2. Discharge mortality in the Japan Congenital Cardiovascular Surgery Database according to the RACHS-1 categories. RACH-1, Risk Adjustment in Congenital Heart Surgery.

2008 to 2010 (Fig. 2). This result is comparable to that reported from the STS Congenital Heart Surgery Database [7].

Unlike the STS National Database, the JCVSD employed web-based data collection. Data on adult cardiac surgery (Japan Adult Cardiovascular Surgery Database [JACVSD]) were collected beginning in 2001 by five participating units and data on congenital heart surgery (JCCVSD) were collected beginning in 2008 by seven units. JCVSD required informed consent from each patient according to the 'opt-in rule' to comply with the Private Information Protection Law. For Web-data transmission, high level secure socket layer was adopted for coding of the individual patient's information.

The JACVSD and JCCVSD grew to become national databases by the end of 2013 (Fig. 3). The most recent annual number of submitted procedures are 49,507 in JACVSD and 10,835 in JCCVSD. Twenty frequently cited papers dealing with topics such as risk models of isolated coronary bypass surgery [8], thoracic aortic surgery [9], and valve surgery [10] have been published in indexed international journals. The performance of the Congenital Heart Surgery risk model as measured by the C-index is over 0.8 [11].

On the basis of these risk models, a web-based risk calculator called JapanSCORE was released. With this tool, adult cardiac surgeons can estimate the 30-day mortality rate, in-hospital mortality rate, and major complication rate after inputting the patient's covariates before the surgical procedure. The estimated mortality rate is much lower than that derived by using EuroScore [12]. JapanSCORE contributes to obtaining adequate informed consent from the patients and the families, leading to increased satisfaction. In addition, benchmark reports have been released as support tools for quality improvement of participating institutions. In Japan,

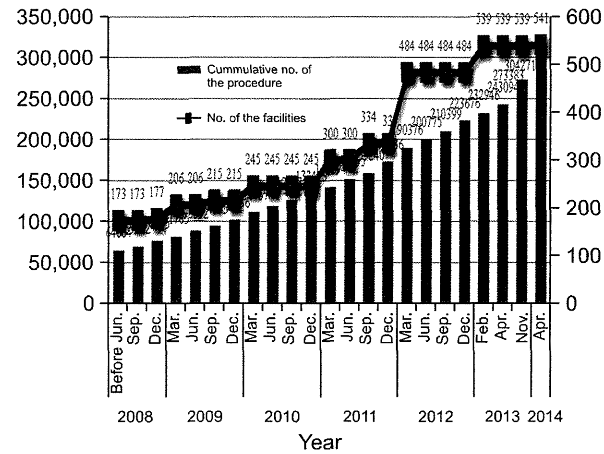

Fig. 3. The growth in the Japan Adult Cardiovascular Surgery Database, As of April 2014, the number of facilities were 541 and the cumulative number of procedures were 304,271.

many adult cardiac surgeons learn about the risks faced by their patients, as well as their own performance as a surgeon, through the risk-adjusted mortality and benchmark report.

To ensure fairness and transparency in evidence-based medicine (EBM), the JCVSD organized a data access and usage working group. This working group meets twice a year, and requests 100% of their data during at least for the immediate 2-years. After the working group accepts an application, the Department of Health Quality Assessment (HQA) of the University of Tokyo [13,14] analyzes the newly submitted data. The role of the HQA is similar to that of the DCRI for the STS National Database.

The JCVSD places importance on auditing the reported data. Site visits have been carried out since 2004. A site visit working group was established by the JACVSD. The members of the working group include two to three adult cardiac surgeons; visits to 70 sites have been carried out so far. Recently the HQA reported the details and outcomes of the site visits to the JCCVSD [15].

In 2011, the JCVSD started to collect a participation fee of 10,000 yen per year for each section in the JACVSD and the JCCVSD. The total number of sections was 658 (541 in the JACVSD, 117 in the JCCVSD) by the end of April 2014. This participation fee is much lower than that required by the STS National Database; however, it is an important financial resource, especially for site visits.

In 2011, the Japanese Board of Cardiovascular Surgery (JBCVS) decided to adopt the data of the JACVSD and the JCCVSD for board certification. In 2013, there were 162 new applicants and 1,003 renewals. The JBCVS held its first web-based and paperless review in September 2013. Compared with the previously employed review method that relied on the submission of operation records, the web-based and paperless review method had higher quality, lower cost, and required less time.

THE NATIONAL CLINICAL DATABASE

In 2010, the JCVSD served as the basis for the establishment of the National Clinical Database (NCD) in Japan, which includes clinician-initiated databases reflecting all surgical fields. The NCD adopted to "Web-based" data collection with the same security level of JCVSD as mentioned above to protect the individual patient's information. Through the central institutional review board in the University of Tokyo, an 'opt-out rule' was adopted, and informed consent became unnecessary. The NCD is governed by a committee whose members are representatives of medical associations related to surgery, such as the Japan Surgical Society (JSS), JSCVS, JATS, the Japanese Association for Chest Surgery, the Japanese Society of Gastroenterological Surgery, the Japanese Society of Pediatric Surgeons, the Japanese Society of Vascular Surgery, the Japanese Society of Endocrine Surgery, the Japanese Society for Mammary Cancer, and the Japanese Thyroid Association. The NCD establishes the surgical board certification system for the JSS, which requires 13 input items at the first level in the hierarchy of specialties. Six board certification systems, including the JBCVS and the databases of nine academic associations, are set at the second level as subspecialties. The main server was transferred from the HQA to the University Hospital Medical Information Network (UMIN) with a mirror-image backup. The HQA focused on data analysis and site visits, whereas the UMIN is responsible for data warehousing. The NCD uses cutting-edge statistical techniques to detect any trace of data inconsistency. The participating associations have supported the NCD financially and the database has grown rapidly; the total number of participating hospitals is 4105, and the number of cumulative procedures was 4,138,000 at the end of April 2014. The NCD covers 95% of total surgical procedures. The participating associations will release, or have released, their own risk models [16-18], and papers have been published based on data from the NCD [16].

NATIONAL CLINICAL DATABASES AND HEALTH SERVICES

The administrative database, diagnosis procedure combination (DPC)/par-diem payment system (PDPS) was introduced in Japan by the Japanese Ministry of Health, Labour and Welfare (MHLW, a government agency) in April 2003 to comprehensively assess fixed daily payments and to control medical expenditure in the acute setting based on the quality assessment. The number of participating hospitals by the end of April 2014 was 1,585, including all advanced-treatment hospitals, that is, university hospitals. In Japan, total health care expenditures have been increasing by 1 trillion yen annually, and health care expenditures make up 9.5% of the Gross Domestic Product, which puts Japan in the 16th position of the 34 member countries of the Organization for Economic Cooperation and Development. On the other hand, the population aging rate in Japan is over 24%, which is the highest rate in the world. Changes in population makeup and the growing proportion of elderly persons are the underlying issues relating to rising health care expenditures, and successive Cabinet office members and the MHLW have set policy directions to address this national issue. Quality improvement, quality assessment, and the pay-for-performance system provide methods to control medical expenditures. The Quality and Outcomes Framework (QOF), a system for the performance management and payment of genaral practitioners (GPs) in the National Health Service in England, Wales, Scotland and Northern Ireland was introduced as part of the new general medical services contract in April 2004. The QOF rewards GPs for implementing "good practice" in their medical practices. Participation in the QOF is voluntary for each partnership [19]. In contrast, in the United States, the Agency of Healthcare Research and Quality (AHRQ) has defined 'never events' or errors of medical care for which Medicare, the government healthcare insurance for aged and disabled persons, does not pay. In the C. Walton Lillehei Lecture of the 49th STS Annual Meeting, the director of the AHRQ emphasized that the federal government will pay for the quality, not for the volume.

In Japan, the NCD and DPC/PDPS could play complementary functions for quality assessment through adequate risk adjustment and the complete enumeration of procedures in various surgical fields. In the future, balancing professional autonomy and administrative leadership might be a recurrent issue for quality assessment and quality improvement in Japan.

PERSPECTIVES

Recently, the Japanese Association of Cardiovascular Intervention and Therapeutics proposed to the NCD a comparative study between percutaneous coronary intervention and CABG that would use well-tested statistical methods such as propensity score matching. Thus, the participation of units from nonsurgical fields, such as medical therapy, intervention, radiation therapy, and chemotherapy, will facilitate risk stratification of each treatment modality, and will contribute to the search for the best management of diseases and patients. A longitudinal follow-up database is needed for the design of such studies, and it is under construction.

Recently, the Pharmaceutical and Medical Device Agency (PMDA), a consultative organization of the MHLW, suggested to enroll in the JACVSD and perform follow-ups on the use of artificial valves for trans-aortic valve implantation. The PMDA recognized the completeness and reliability of the data of the JACVSD, and from a cost-performance point of view, the PMDA decided to outsource the post-market surveillance of newly covered medical devices in the cardiovascular surgical field. This demonstrates how the national database could contribute to the post-marketing surveillance of drugs and medical devices, and could help control randomized trials and multicenter studies.

The NCD will start to collect fees from participating hospitals according to the total number of enrolled surgical procedures. Clerical assistants have been widely employed throughout the country, which has gradually lightened the data input workload of young surgeons. Governmental support and some government funds are expected to be received for the continued maintenance of the national database.

CONCLUSION

Clinicians are responsible for patient safety and quality improvement, and the database will aid in achieving these goals.

As Reinertsen [20] stated, to truly improve quality, the system must, 1) eliminate unnecessary variation (standardize processes), and 2) achieve and document continuous improvement (in care processes and outcomes). In recent years, the importance of 'certainty, not excellence' of operations, and that of the concept of structure, process and outcome [21] have been emphasized, and multiple approaches, for instance, postgraduate education systems, reporting systems of malpractice to prevent recurrence, introduction of information technology, introduction of simulators, EBM, and other techniques, have been used for patient safety. The use of multiple strategies and teamwork are fundamental for patient safety.

Since it is methodologically based on the JCVSD, the NCD represents an interface between medical databases and board certification systems, which is its point of difference from the STS National Database. In 2014, a new organization for medical board certification was established in Japan that, beginning in 2017, will certify all medical boards in close collaboration with medical associations. This new organization will adopt the standards of the JCVSD and the NCD for evaluating the clinical practices of applicants. For the assessment of medical outcomes and quality, the JCVSD and the NCD will continue to be the sole reliable data source for surgical fields in Japan, where medical system reform will be implemented quickly and based on professional autonomy.

The national database is fundamental for quality improvement, patient safety, and the adequate control of medical expenditures in the country.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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論文 15

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ORIGINAL ARTICLE

ADULT CARDIAC

The off-pump technique in redo coronary artery bypass grafting reduces mortality and major morbidities: propensity score analysis of data from the Japan Cardiovascular Surgery Database[†]

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Abstract

OBJECTIVES: The benefits of off-pump coronary artery grafting (OPCAB) have been demonstrated. Especially in patients with a high number of comorbidities, redo coronary artery bypass grafting (CABG) remains a difficult entity of CABG, because patients are likely to have multiple risk factors and often have diseased patent grafts with adhesions. The aim of the present study was to evaluate the effects of the OPCAB technique in redo CABG on mortality and morbidity using data from the Japan Cardiovascular Surgery Database (JCVSD).

METHODS: We analysed 34 980 patients who underwent isolated CABG between 2008 and 2011, as reported in the JCVSD. Of these, 1.8% of patients (n = 617/34980) had undergone redo CABG, including those who underwent OPCAB (n = 364; 69%) and on-pump CABG (n = 253; 41%). We used propensity score (PS) matching with 13 preoperative risk factors to adjust for differences in baseline characteristics between the redo OPCAB and on-pump redo CABG groups. By one-to-one PS matching, we selected 200 pairs from each group.

RESULTS: There were no significant differences in patient background between the redo OPCAB and on-pump redo CABG groups after PS matching. There was no significant difference in the mean number of distal anastomoses after matching (2.41 ± 1.00 vs 2.21 ± 1.04, P = 0.074); nevertheless, the mean operation time was significantly shorter in the redo OPCAB than the on-pump redo CABG group (353.7 vs 441.3 min, P < 0.00010). Patients in the redo OPCAB group had a lower 30-day mortality rate (3.5 vs 7.0%, P = 0.18), a significantly lower rate of composite mortality or major morbidities (11.0 vs 21.5%, P = 0.0060), a significantly lower rate of prolonged ventilation (>24 h) (7.0 vs 15.0%, P = 0.016), a significantly shorter duration of intensive care unit (ICU) stay (ICU stay ≥8 days) (7.0 vs 14.5%, P = 0.023) and a significantly decreased need for blood transfusions (71.5 vs 94.0%, P < 0.00010) than patients in the on-pump redo CABG group.

CONCLUSION: The off-pump technique reduced early operative mortality and the incidences of major complications in redo CABG.

Keywords: Coronary artery disease • Off-pump • Coronary artery bypass grafting • Reoperation

INTRODUCTION

Although recent reoperative coronary artery bypass grafting (redo CABG) has been associated with improved outcomes, it remains a difficult procedure of CABG because patients are likely to have multiple risk factors. On the other hand, off-pump coronary artery grafting (OPCAB) has been reported to be beneficial [1–3], especially in patients with several comorbidities, such as those undergoing redo CABG [4, 5].

In fact, retrospective clinical studies comparing OPCAB and on-pump CABG in redo surgery suggest that OPCAB can reduce morbidity among redo CABG patients, while providing equivalent or superior operative results [6–14]. However, no comparative clinical studies utilizing data from a large nationwide database have validated the superiority of various variables of the off-pump technique in redo CABG.

In this study, we present the contemporary results of redo CABG registered in the Japan Cardiovascular Surgery Database (JCVSD), which currently contains clinical data from almost all Japanese hospitals where cardiovascular surgery is performed. Our aim was to evaluate the superiority of the off-pump technique

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