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Results of Data Verification of the Japan Congenital Cardiovascular Database, 2008 to 2009

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Abstract

Background: Since 2008, data concerning pediatric cardiovascular surgeries performed in Japan have been collected in the Japan Congenital Cardiovascular Surgery Database (JCCVSD). We assessed the quality of the JCCVSD data through data verification activities conducted in 2010. **Methods:** During 2008 to 2009, 3345 patients with 4327 procedures at 25 hospitals were registered in the JCCVSD. Among them, six sites were selected for data verification. The completeness of case registration was assessed by comparison with original operational logs. Also, data accuracy of patient demographics, surgical outcomes, and processes were assessed with 10% of the registered cases by comparison with medical records. **Results:** Verification of case registration completeness involved 968 (28.9%) patients and 1279 (29.1%) procedures. As to completeness, we confirmed 1266 (99.0%) of the 1279 procedures. Data accuracy was verified for 129 (3.9%) patients. Accuracy of status of discharge and 30 and 90 days after surgery were very high (99.2%, 100%, and 100%, respectively). Data items with numeric information exhibited lower exact accuracy due to typing error and inconsistent use of rounding; however, the differences between the submitted and the original data were not statistically significant. **Conclusions:** High completeness and acceptable range of data accuracy were verified for the data submitted to the JCCVSD in 2008 to 2009. The high accuracy regarding follow-up outcomes was especially noteworthy. The initial success of the JCCVSD should be strengthened through further sophistication of registration protocol, continual training of data managers and auditors, and rigorous expansion of verification activities.

Keywords

congenital heart surgery, congenital heart disease, database (all types), statistics

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Introduction

Clinical registry database has been increasingly recognized as a powerful tool to promote health care quality improvement initiatives and to support decision making of various stakeholders including patients, clinical specialists and their staff, hospital administrators, and government agencies.[1-3] Recent projects to strengthen clinical databases through the linkage of the data with claim data and other existing databases[4] have sought to further extend the potential of clinical registries to enhance international collaborative research[5] and clinical trials.[6]

To achieve these purposes in a scientifically sound manner, it is imperative to assure the quality of clinical registry database.[7] However, false reports due to the underreporting of adverse events are often problematic and can seriously bias the validity of conclusions based on the clinical database of concern.[8,9] Data verification for quality assurance is highly recommended,[10-12] although the implementation of a verification regimen can often be an enormous challenge.

Data verification is often conducted by comparing the information in primary source documents in hospitals with the

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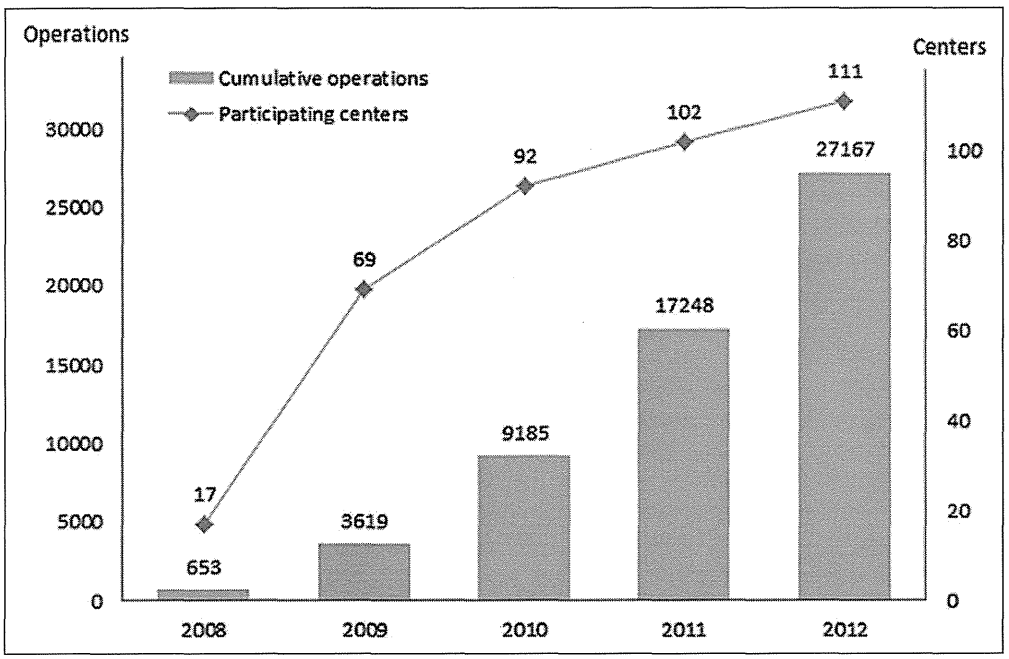

Figure 1. Total number of participating hospitals and operations in the Japan Congenital Cardiovascular Surgery Database (JCCVSD).

database information.[13] Data quality is assessed in terms of completeness of the registry (whether all eligible patients are registered)[14] and the accuracy of data entry (whether the collected data are consistent with the primary source documents).[15] Clinical databases including the Society of Thoracic Surgeons (STS) National Database, the European Congenital Heart Surgeons Association/European Association for Cardio-Thoracic Surgery Database, and National Cardiovascular Data Registry founded by the American College of Cardiology have already adopted this method.[16-19] Although data verification requires intensive resource, data verification through inspection of participating sites is one of the most effective methods to assure data quality.

There are few clinical registry systems in Japan. Among them, the Japan Congenital Cardiovascular Surgery Database (JCCVSD)[20] began the registration of pediatric cardiovascular surgeries nationwide in 2008. This is the first report on the JCCVSD data quality based on data verification activities conducted in 2010.

Materials and Methods

Data Source

The JCCVSD was established by the Japan Cardiovascular Surgery Database Organization as a part of a large project to establish a nationwide database to assess outcomes of cardiovascular surgeries with the goal of improving the quality of care. Hospitals that participated in the JCCVSD are required to register all congenital cardiovascular surgery cases. From August 2008 to December 2009, 25 hospitals submitted data of 3345 patients with 4327 procedures to the JCCVSD. Recently, participating hospitals in the JCCVSD have increased, and 25 hospitals of 2008 to 2009 are 22.5% in the participating hospitals of 2012 (Figure 1). The JCCVSD is the nationwide database that covers all congenital cardiovascular surgeries, in Japan now.

Data were collected using specialized data collection forms that contain approximately 300 variables, including demographics, preoperative risk, operative information, postoperative complication, and outcomes. These variables are almost identical to those of the STS registry; the JCCVSD and STS use the same definitions for variable items. Data are submitted through an Internet case form and are automatically checked for selected key items. Registration is closed annually, with the data fixed to allow no further entry. Each participating hospital is required to assign a data manager accountable for data traceability. Each hospital must also obtain ethical approval from its institutional review board for the entry of all patient information to the database.

Methods of Data Verification

Of the 25 participating hospitals, 6 were selected for data verification. Three of the sites were nominated by the JCCVSD steering committee, because this was the first trial for the JCCVSD. The remaining three were randomly selected with consideration given to the balance of hospital volume and types of hospital (eg, university hospital, highly specialized hospital, and public hospital). The selected hospitals registered 968 patients with 1279 procedures, which represented 28.9% and 29.1% of the total registry, respectively.

Verification was conducted between December 2010 and July 2011. For the completeness check, we compared an operation log with the data submitted to the JCCVSD. If patient

Table 1. List of Abstracted Data Elements.

ID
Gender
Blood type
Date of birth
Date of admission
Date of surgery
Date of death
Date of discharge
Readmission within 30 days after surgery (yes or no)
Status at discharge (alive or dead)
Status at 30 days after surgery (alive or dead)
Status at 90 days after surgery (alive or dead)
Height
Weight
Cardiopulmonary bypass time in minutes
Aortic cross-clamp time in minutes
Operation time in hours and minutes
Anesthesia time in hours and minutes
Intubation (yes or no)
Date and time of intubation
Date and time of extubation

identification (ID) and the date of operation matched the database record, the case was regarded as "confirmed." If not, the case was regarded as "unconfirmed," and medical records other than an operation log were referred to. Nonregistered cases or those found in an operation log without registration to the JCCSVD were systematically reviewed by the JCCVSD steering committee to decide whether they should be registered or not.

For the accuracy check, the cases were selected randomly to ensure representative of each hospital statistically. In the view of the feasibility of data verification, 10% of the cases registered for the first admission and first operation were randomly selected if the number of registered cases in a particular hospital was more than 100. Otherwise, ten cases were randomly selected to ensure a sufficient number of cases for comparison. In all, 129 cases were randomly selected, which corresponded to 10.2% of the total registry in the six hospitals or 3.9% of the total JCCVSD registration. Accuracy assessment involved 25 variables including patient demographics, intraoperative information, and outcomes as listed in Table 1. We chose these variables for verification due to several reasons. First, these variables are regarded as influential parameters to define the quality of surgery. Second, the definition of the terms must be unambiguous and standardized. Third, identification of the variables in the existing medical records is relatively easy. At each on-site visit, we referred to hospital records regarding surgery, anesthesia, intensive care unit and nurse care, and cardiopulmonary bypass as source documents and checked the consistency of variable values with those in the registered data. Continuous values were rounded off. If the data submitted to the JCCVSD were the same as those in the source documents, we judged the items as "consistent." If any value was inconsistent, we sought additional information to identify the cause of the discrepancy.

The time of the start and end of each verification procedure was recorded to assess the variability of the verification process. When data inconsistency was found, requiring additional information sources, the search was limited to within approximately 20 minutes. Since the first hospital was used as a pilot test for the verification procedures, the verification time was measured in the remaining five hospitals after the standardization of the procedure. We hypothesized that the time needed for verification should be shorter when the source of reference records was electronic rather than paper based, the number of auditors was larger, and the degree of record accuracy was higher.

A nonclinical department (Department of Healthcare Quality Assessment, Graduate School of Medicine, University of Tokyo), which was commissioned as a neutral and impartial institution by the Japan Cardiovascular Surgery Database Organization, was in charge of data verification in collaboration with the JCCVSD steering committee. Data verification was carried out by two staff members who were independent of the JCCVSD, free from any clinical practice, and who had general medical knowledge (one was a registered nurse and the other was a health information manager) after standardized audit training. The auditors had a written contract to strictly follow the confidentiality obligation for hospital information and were allowed access to the data only for verification.

Statistical Analysis

Completeness of case registrations was assessed with the following aspects: (1) proportion of confirmed cases in registered cases, (2) proportion of multiple cases in registered cases, and (3) proportion of unregistered cases in recorded cases of operating log in hospitals.

Accuracy of data entry was expressed as a proportion of consistent items among 21 items per verified case. We also calculated an item-wise proportion of data consistency between source data and the data submitted to the JCCVSD. For continuous variables, we calculated the mean and standard deviation and compared the difference between the source and the submitted data by paired t test. In some cases where we could not identify the original source in the unified method, it was considered missing and was excluded from the calculation.

The total time to verify the data for each case was compared using the medical records (paper and/or electronic), the number of auditors, and the degree of accuracy. The degree of record accuracy per case was categorized into four levels (100% [25 of 25 items], 90% to 99% [23-24 of 25 items], 80% to 90% [20-22 of 25 items], or $\leq$80% [20 of 25 items]) using nonparametric tests.

All analyses were performed with SAS version 9.2 (SAS Institute, Cary, North Carolina).

Results

Completeness of Registration

We confirmed 1266 of the 1279 cases, and the proportion of confirmed cases in registered cases was 99.0%. Nine cases

Table 2. Results of Item-Wise Accuracy of Registered Data Compared to Original Records (N = 129).

	n	Proportion of Consistent	95% CI	Range for Each Site	The Difference Between the Means of Collected Data and Data in Primary Source[a]		
					Mean[c]	SD	*P* Value[b]
ID	127	0.99	(0.98-1.01)	(0.90, 1.00)	–	–	–
Gender	127	0.99	(0.98-1.01)	(0.97, 1.00)	–	–	–
Blood type	127	0.99	(0.98-1.01)	(0.94, 1.00)	–	–	–
Date of birth	127	0.98	(0.96-1.01)	(0.90, 1.00)	0.26	2.39	.21
Date of admission	127	0.98	(0.95-1.00)	(0.90, 1.00)	0.24	2.39	.26
Date of surgery	127	0.98	(0.95-1.00)	(0.86, 1.00)	−0.04	0.26	.10
Date of death	127	1.00	–	(1.00, 1.00)	–	–	–
Date of discharge	127	0.99	(0.98-1.01)	(0.97, 1.00)	−0.12	1.50	.38
Readmission within 30 days after surgery (yes or no)	127	0.98	(0.95-1.00)	(0.80, 1.00)	–	–	–
Status at discharge (alive or dead)	127	0.99	(0.98-1.01)	(0.97, 1.00)	–	–	–
Status at 30 days after surgery (alive or dead)	124	1.00	–	(1.00, 1.00)	–	–	–
Status at 90 days after surgery (alive or dead)	120	1.00	–	(1.00, 1.00)	–	–	–
Height	124	0.87	(0.81-0.93)	(0.55, 1.00)	−0.19	1.49	.15
Weight	127	0.83	(0.77-0.90)	(0.36, 1.00)	−0.13	3.18	.64
Cardiopulmonary time in minutes	124	0.99	(0.98-1.01)	(0.97, 1.00)	−0.007	0.09	.32
Aortic cross-clamp time in minutes	124	1.00	–	(1.00, 1.00)	–	–	–
Operation time in hours and minutes	127	0.99	(0.98-1.01)	(0.93, 1.00)	−0.02	0.26	.32
Anesthesia time in hours and minutes	127	0.94	(0.89-0.98)	(0.64, 1.00)	−0.57	11	.56
Intubation (yes or no)	127	0.98	(0.96-1.01)	(0.86, 1.00)	–	–	–
Date and time of intubation	123	0.43	(0.34-0.52)	(0.12, 1.00)	−582	6526	.32
Date and time of extubation	115	0.79	(0.72-0.87)	(0.69, 1.00)	9.1	124	.41

Abbreviations: χ^2, chi-square; CI, confidence interval; SD, standard deviation.
[a] In this verification, we did not collect the data of nonregistered cases.
[b] Paired *t* test for numeric data and χ^2 test for categorical data.
[c] The measures of each numeric variable are as follows: day—date of birth, date of admission, date of surgery, date of death, and date of discharge; minute—cardiopulmonary time in minutes, aortic cross-clamp time in minutes, operation time in hours and minutes, anesthesia time in hours and minutes, date and time of intubation, and date and time of extubation; cm—height; and g—weight.

were falsely duplicated due to typing error or incomplete assignment of unique ID, and proportion of multiple cases in registered cases was 0.7% (9 of 1266). We could not confirm four cases in the operation log submitted by the hospitals. There were 13 cases that were not registered yet should have been eligible, and the proportion of unregistered cases in the recorded cases of operating log in hospitals was 1.0% (13 of [1266 + 13]).

Accuracy of Data Entry

Source documents for 2 of the 129 cases were not identified at the time of verification (one was in use by hospital staff for clinical purposes and the other was not prepared due to unknown reasons).

The following items displayed item-wise data accuracy higher than 95%: ID, gender, blood group, date of birth, date of admission, date of surgery, date of discharge, status at discharge, cardiopulmonary bypass time and aortic cross-clamp time, date of death, readmission within 30 days after surgery, and the status 30 and 90 days after surgery. Among them, status at 30 and 90 days after surgery exhibited a perfect match between registration and original records. The items with a proportion higher than 80% were height and weight, and those less than 80% were date and time of intubation and extubation. No statistically significant difference was found for postoperative hospital length of stay, age at operation, weight, height, and operation time (Table 2). Among the 129 cases, median case-wise accuracy was 91% with interquartile range of 86% to 95%.

Most of the data inconsistencies were due to typing errors. In addition, operation time, anesthetic time, and date and time of intubation and extubation were often inconsistently rounded up, out, or down by ten minutes the in registration records. The JCCVSD could not detect the date/time of height, weight, and other measurements that were repeated in a single hospitalization event, which hindered the identification of source records. Some data managers mistook the definition of date and time of intubation and incorrectly entered date and time at patient entry to the operation room.

Table 3. Time Spent for Data Verification.

	n	Mean (SD)	Median	Min – Max
All	110	7.1 (3.9)	6.0	2.0 – 20.0
Medium of source document				
Electric health record	64	7.7 (4.0)	6.0	2.0 – 20.0
Both electric health record and paper record	32	6.6 (3.7)	5.0	3.0 – 20.0
Paper record	14	5.4 (2.9)	5.0	2.0 – 11.0
Number of auditing staff to verify for each case				
One staff	71	8.0 (4.0)	6.0	3.0 – 20.0
Two staffs	39	5.5 (3.0)	5.0	2.0 – 15.0
Number and proportion of agreement items for each case				
25 items (100%)	29	6.9 (4.2)	6.0	2.0 – 20.0
23-24 items (90% < 99%)	36	5.9 (3.1)	5.0	2.0 – 15.0
20-22 items (80 < 90%)	33	8.3 (4.2)	8.0	3.0 – 20.0
<20 items (≤80%)	12	7.8 (3.5)	6.5	4.0 – 15.0

Abbreviation: SD, standard deviation.

Furthermore, in cases involving transfer to other facilities after surgery, completeness of the follow-up of survival information varied among the hospitals.

Time Spent for Data Verification

Median time for data verification per case was 6.0 minutes, ranging from 2.0 to 20.0 minutes (Table 3). Verification of paper-based records took a median of 5.0 minutes, while electronic and the combination of both types took 6.0 and 5.0 minutes, respectively ($P = .08$). Median time of verification was 6.0 minutes when one auditor conducted the verification, and 5.0 when both the auditors participated ($P < .05$). Concerning the degree of record accuracy per case, the median time in minutes was 6.0, 5.0, 8.0, and 6.5 for 100%, 90% to 99%, 80% to 90%, and ≤80%, respectively ($P < .05$).

Comment

Quality improvement initiatives need to be based on the scientific evidence generated from reliable and valid data. In this report, we demonstrated that the JCCVSD on pediatric cardiovascular surgeries achieved fairly complete registration of cases and accurate data collection of clinical information. Thus, this database could potentially be useful in improving the quality of care.

In regard to the completeness of registration, there were very few unregistered patients for the first operations in the same administration. Duplicated registration occurred mainly due to typing error and misassignment of unique patient ID. Such cases could have been avoided by fool-proof modification of data entry to display potential duplication if several essential variables (eg, ID, birth date, sex, and date of surgery) were identical. More fundamentally, however, a hospital's capacity to maintain operation logs and other clinical record documentation in an accountable and traceable fashion is essential. An interview with a data manager revealed that failed registration happened, because the site hospitals differently interpreted the registration criteria for subsequent operations during the same administration and arbitrarily decided whether such cases should be registered as independent operation or operative complication for any reason after surgery. This underscores the importance of keeping data managers informed about the criteria for clarification. As such, validation could involve interactive processes between daily practice at the site hospitals and refinements of the registration system.

As to the accuracy of data, categorical information such as demographics showed a high proportion of consistency. Continuous variables presented a lower level of accuracy due to inconsistent use of rounding up, mistyping, and other technical reasons; however, the difference between the submitted data and the source documents was relatively small. Some clinical databases have adopted "acceptable range" for the judgment of data consistency for continuous variables.[21] As such, the judgment rule of accuracy for continuous variables is a matter of debate in other databases.[19,21] Training of data managers in each site hospital was also essential for accurate data collection through enhanced compliance with the definition of data items. The display design of entry form was another influential factor in avoiding entry errors. In this regard, the JCCVSD has some important factors to maintain high-quality data, such as nomination of the data manager in charge of securing data traceability, a fool-proof entry system that does not allow missing values for essential information, and organizing a meeting of data managers twice each year for continuous training.

Another characteristic of the JCCVSD is high accuracy in follow-up outcomes, especially the 90-day mortality after surgery, compared to other congenital databases,[17] which warrants some discussion. Success of patient follow-up could be attributed to social environments specific to Japan, such as longer length of hospital stay, limited number of hospitals eligible for congenital heart surgery, and better accessibility to continuous treatment under universal coverage by public health insurance system.[22]

When the activities of data audit expand, we should take serious account of efficiency in terms of cost and time. As we evaluated the time required for data verification, paper-based source and the number of auditors were significant factors to reduce the time. However, we have not yet determined how many auditors are most efficient in what conditions. Additionally,

the time for data verification can be affected by whether hospitals have standardized formats of medical records or not. The methodology of data verification of clinical databases remains to be systematically studied, and we acknowledge the need of further surveys to establish standardized and efficient mode of data verification in comparison with examples from other recommendations.[23] Appropriate size and method of sampling for validation is another important factor to determine efficiency as well as validity of audit. In this regard, the current data verification chose six hospitals in an ad hoc manner, which should be recognized as a study limitation.

The present study demonstrates the initial success of the JCCVSD in high-quality data collection for improvement in the quality of pediatric cardiovascular surgery. However, we are still challenged by some limitations for further improvements. First, hospitals adopted a variety of record formats for operation logs that seriously hindered standardized data collection and threatened the results of our assessment of registry completeness. This should be resolved through standardization of clinical information on operation logs based on the subspecialty consensus. Second, we found that the registration of adult cases with congenital heart conditions could be problematic, given that such a case may be inconsistently registered to the adult cardiovascular surgery database rather than pediatric database. This should also be solved by consensus building among the subspecialty circle. Third, as already mentioned, half of the hospitals we surveyed were selected randomly, but the rest were selected by request from the JCCVSD committee. Thus, there might be selection bias of hospitals. Furthermore, we did not calculate sample size for statistical power, which might have led to overlooking significant inconsistency. Fourth, we should add other important variables for data verification of clinical databases. For example, diagnosis, procedure, and outcomes (eg, postoperative complications) are important information as fundamental statistics in clinical databases. Assessment of accuracy in coding these variables with systematic method of verification will be required to assure quality of clinical database.

In summary, we conducted data verification of the JCCVSD and found that data of the JCCVSD in 2008 to 2009 exhibited high completeness of registration and accuracy of data entry. The initial success in quality assurance of the JCCVSD should be strengthened through further sophistication of registration protocol, continual training of data managers and auditors, and rigorous expansion of verification activities.

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Declaration of Conflicting Interests

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ORIGINAL ARTICLE – ADULT CARDIAC

Surgical results of reoperative tricuspid surgery: analysis from the Japan Cardiovascular Surgery Database†

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Abstract

OBJECTIVES: Tricuspid valve insufficiency (TI) following cardiovascular surgery causes right-side heart failure and hepatic failure, which affect patient prognosis. Moreover, the benefits of reoperation for severe tricuspid insufficiency remain unclear. We investigated the surgical outcomes of reoperation in TI.

METHODS: From the Japan Cardiovascular Surgery Database (JACVSD), we extracted cases who underwent surgery for TI following cardiac surgery between January 2006 and December 2011. We analysed the surgical outcomes, specifically comparing tricuspid valve replacement (TVR) and tricuspid valve plasty (TVP).

RESULTS: Of the 167 722 surgical JACVSD registered cases, reoperative TI surgery occurred in 1771 cases, with 193 TVR cases and 1578 TVP cases. The age and sex distribution was 684 males and 1087 females, with an average age of 66.5 ± 10.8 years. The overall hospital mortality was 6.8% and was significantly higher in the TVR group than in the TVP group (14.5 vs 5.8%, respectively; $P < 0.001$). Incidences of dialysis, prolonged ventilation and heart block were also significantly higher in the TVR group than in the TVP group. Logistic regression analysis revealed that the risk factors of hospital mortality were older age, preoperative renal dysfunction, preoperative New York Heart Association Class 4, left ventricular dysfunction and TVR.

CONCLUSIONS: Surgical outcomes following reoperative tricuspid surgery were unsatisfactory. Although TVR is a last resort for non-repairable tricuspid lesions, it carries a significant risk of surgical mortality. Improving the patient's preoperative status and opting for TVP over TVR is necessary to improve the results of reoperative tricuspid surgery.

Keywords: Tricuspid valve • Reoperation • Database

INTRODUCTION

Tricuspid valve insufficiency (TI) following cardiovascular surgery causes right-sided heart failure and hepatic failure, which affect the prognosis [1, 2]. Tricuspid valve repair after cardiac surgery is less commonly performed than left-sided valve repair, and there are relatively few reports with small samples [3–5]. Thus, the outcomes of surgical intervention for severe tricuspid insufficiency remain unclear. The Japan Adult Cardiovascular Surgery Database (JACVSD) is a nationwide database established in 2000. The number of participating hospitals has gradually increased, and now, most hospitals performing cardiovascular surgeries have been enrolled. The Japan System for Cardiac Operative Risk Evaluation (Japan SCORE) is a risk model developed from JACVSD [6–8]. Therefore, we used JACVSD to examine the results of surgical treatment for TI following cardiac surgery. The objective of this study is to analyse the surgical outcomes, specifically comparing tricuspid valve replacement (TVR) and tricuspid valve plasty (TVP).

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MATERIALS AND METHODS

Study population

JACVSD was established to facilitate evaluation of surgical outcomes after cardiovascular procedures in centres throughout Japan. It currently captures clinical information from most Japanese hospitals. The data collection form has a total of 255 variables that are almost identical to those of the Society of Thoracic Surgeons' (STS) National Database [(definitions are available online at Websites: Japan Adult Cardiovascular Database. http://www.jacvsd.umin.jp) (The Society of Thoracic Surgeons. http://sts.org)]. JACVSD has developed a software for web-based data collection that enables the data manager at participating hospitals to electronically submit the data to the central office. Although participation in JACVSD is voluntary, data completeness is high, and the accuracy of submitted

data is maintained by regular data auditing in which monthly visits are made to participating hospitals to check the reported data against clinical records. Data validity is further confirmed by independent comparison of the cardiac surgery volume at specific hospitals entered in JACVSD with that reported in the annual survey of the Japanese Association for Thoracic Surgery.

Comparison of tricuspid valve replacement with tricuspid valve plasty cases

We examined all patients undergoing tricuspid valve repair after primary cardiac surgery between 1 January 2006 and 31 December 2011. In particular, we compared TVR with TVP cases. JACVSD records obtained without informed patient consent were excluded. Approximately 20% of patients were asymptomatic; however, they had some evidence of deterioration of end-organ function such as that of liver or kidney. Records with missing age (or age out of range), missing sex or missing 30-day status were also excluded.

Hospital death was defined as follows: death from any cause within 30 days after surgery if the patient was discharged from hospital or death at any time if the patient was not discharged. Using the definition from a previous study, major morbidity was defined as any of the following five postoperative in-hospital complications: stroke, reoperation for any reason, mechanical ventilation beyond 24 h after surgery, renal failure or deep sternal wound infection [9, 10].

Statistical analysis

Continuous variables were expressed as mean ± standard deviation. Categorical variables were compared using the χ^2 test or Fisher's exact test. Continuous variables were compared using Student's *t*-test. In case of non-normal distribution, the non-parametric Wilcoxon test was used. Logistic regression analysis was used to identify independent predictors of clinical outcomes. Predictors associated with a *P* value of <0.2 on univariate analysis were entered into multivariate analysis using stepwise selection. Results were expressed using hazard ratios. Preoperative patient risk factors in the JACVSD risk models were entered as independent variables. All *P* values were two sided, and $P < 0.05$ was considered statistically significant.

RESULTS

There were 167 722 surgical cases from 516 participating institutes throughout Japan registered with JACVSD. After applying the exclusion criteria, the available population for analysis was 1771 cases who underwent tricuspid insufficiency repair following primary cardiac surgery. These included 193 cases of TVR and 1578 cases of TVP.

Baseline characteristics

Comparisons of baseline characteristics between the TVR and TVP groups are presented in Table 1. There were 684 male and 1087 female patients, with an average age of 66.5 ± 10.9 years. Patients in the TVR group were significantly younger than those in the TVP group ($P = 0.002$). Furthermore, the patients undergoing TVR had a higher prevalence of hypertension and hyperlipidaemia. Among all the patients, 738 (41.7%) were New York Heart Association (NYHA) Class 3 or 4; the TVR group also had a higher incidence of NYHA Class 3 or 4 ($P < 0.001$) and preoperative congestive heart failure within 2 weeks of surgery ($P < 0.001$).

Of the total number of patients, 229 (12.9%) had cerebrovascular disease (CVD), and the prevalence of CVD in the TVP group was higher than that in the TVR group ($P = 0.013$). The prevalence rate of renal failure and infective endocarditis was 171 (9.7%) and 143 (8.1%) cases, respectively, and there was no difference between the groups. Urgent and emergency surgery was required in 61 (3.4%) and 21 patients (1.2%), respectively, and the rates were similar in both groups. The 30-day mortality and hospital mortality calculated by the Japan SCORE were 7.4 ± 9.1 and 10.3 ± 11.5%, respectively, and they were similar between the two groups.

Cardiac status and concomitant procedure

Comparison of cardiac status and concomitant procedures between the TVP and TVR groups are presented in Tables 2 and 3. The TVP group patients had a higher prevalence of aortic valve stenosis ($P = 0.008$), mitral valve stenosis and concomitant aortic valve replacement ($P < 0.001$), mitral valve replacement ($P < 0.001$) and multiple valve operations performed ($P < 0.001$). More than half of the patients in the TVR group underwent single valve operations. The patients in the TVR group also had a higher incidence of TI Grade 3 or 4 ($P < 0.001$) and tricuspid stenosis ($P < 0.001$).

Surgical results

Comparison of surgical results is presented in Table 4. Aortic clamp time was significantly longer in the TVP group (20 min). The overall intubation time was 58 ± 237 h; in the TVR group, it was 115 ± 396 h, which was significantly longer than that in the TVP group ($P < 0.001$). Intensive care unit stay was also significantly longer in the TVR group ($P < 0.001$). Actual mortality was lower than logistic mortality, except for hospital mortality in the TVR group.

Morbidities are shown in Table 5. More than 14% of all patients were ventilated for longer than 24 h, and this figure approached 20% in the TVR group. The total number of renal failure and hemodialysis cases was 181 (10.2%) and 100 (5.6%), respectively, with more cases in the TVR group ($P = 0.01$) than in the TVP group ($P = 0.044$). Heart block occurred in 7.8% of the TVR group patients. Gastrointestinal bleeding and multiorgan failure were also significantly higher in the TVR group, at *P* values of 0.008 and 0.001, respectively.

Risk factor analysis

Risk factors for operative death are displayed in Table 6. The following were determined to be risk factors for operative death: age, NYHA Class 4, renal dysfunction, active infective endocarditis, shock, inotropic agent use, aortic stenosis, left ventricular dysfunction and TVR. Preoperative status, including the use of inotropes and shock, also had a high hazard ratio. The hazard ratio for TVR was 3.188.

ORIGINAL ARTICLE

Table 1: Baseline characteristics

	Total (n = 1771)	TVR (n = 193)	TV repair (n = 1578)	P value
Age (years)	66.5 ± 10.9	63.4 ± 13.3	66.6 ± 10.5	0.002
Body surface area (m^2)	1.49 ± 0.17	1.49 ± 0.17	1.49 ± 0.19	0.617
Body mass index	20.9 ± 3.05	21.0 ± 3.5	20.9 ± 3.0	0.445
Male:female	684:1087	71:122	613:965	0.579
Smoking	417 (23.5%)	37 (19.2%)	380 (24.1%)	0.129
Diabetes mellitus	281 (15.9%)	26 (13.5%)	255 (16.2%)	0.335
Diabetes mellitus therapy	207 (11.7%)	22 (11.4%)	185 (11.7%)	0.895
Hyperlipidaemia	371 (17.6%)	18 (9.3%)	293 (18.6%)	*0.001
Hypertension	625 (35.3%)	50 (25.9%)	575 (36.4%)	*0.004
NYHA 3 or 4	738 (41.7%)	107 (55.4%)	631 (40.0%)	*< 0.001
Canadian Cardiovascular Society 3 or 4	77 (4.3%)	14 (7.3%)	63 (4.0%)	*0.036
Urgent	61 (3.4%)	7 (3.6%)	54 (3.4%)	0.883
Emergent	21 (1.2%)	2 (1.0%)	19 (1.2%)	0.839
Renal failure	171 (9.7%)	21 (10.9%)	150 (9.5%)	0.541
Hemodialysis	41 (2.3%)	3 (1.6%)	38 (2.4%)	0.457
Creatinin (mg/dl)	1.18 ± 5.2	1.06 ± 0.62	1.20 ± 5.5	0.497
Cerebrovascular disorder	229 (12.9%)	14 (7.3%)	215 (13.6%)	*0.013
Recent cerebrovascular disorder	12 (0.7%)	2 (1.0%)	10 (0.6%)	0.52
Infectious endocarditis	143 (8.1%)	14 (7.3%)	129 (8.2%)	0.658
Active infectious endocarditis	76 (4.3%)	5 (2.3%)	71 (4.5%)	0.217
Moderate-to-severe respiratory disorder	102 (5.8%)	14 (7.3%)	88 (5.6%)	0.345
Extracardiovascular disease	99 (5.6%)	11 (5.7%)	88 (5.6%)	0.944
Peripheral artery disease	68 (3.8%)	7 (3.6%)	61 (3.9%)	0.871
Thoracic vascular disease	48 (2.7%)	6 (3.1%)	42 (2.7%)	0.718
Neurological disorder	30 (1.7%)	2 (1.0%)	28 (1.8%)	0.453
Myocardial infarction	50 (2.8%)	5 (2.6%)	45 (2.9%)	0.836
Angina pectoris	71 (4.0%)	5 (2.6%)	66 (4.2%)	0.287
Unstable angina pectoris	11 (0.6%)	1 (0.5%)	10 (0.6%)	0.847
Congestive heart disease	795 (44.9%)	124 (64.2%)	671 (42.5%)	*<0.001
Shock	34 (1.9%)	4 (2.1%)	30 (1.9%)	0.87
Atrial fibrillation	1053 (59.5%)	106 (54.9%)	947 (60.0%)	0.174
Inotropic agents	30 (1.7%)	5 (2.6%)	25 (1.6%)	0.306
Percutaneous cardiac intervention	64 (3.6%)	6 (3.8%)	58 (3.7%)	0.69
Logistic 30-day mortality	7.4 ± 9.1%	6.7 ± 9.2%	7.5 ± 9.1%	0.257
Logistic operative mortality	10.3 ± 11.5%	10.8 ± 11.9%	10.2 ± 11.4%	0.532
Logistic 30-day mortality and morbidity	32.7 ± 14.9%	36.7 ± 15.6%	32.2 ± 14.7%	*<0.001

TV: tricuspid valve; TVR: tricuspid valve replacement.
*Means significant.

Table 2: Cardiac status

	Total (n = 1771)	TVR (n = 193)	TV repair (n = 1578)	P-value
Tricuspid stenosis	15 (0.8%)	12 (6.2%)	15 (0.2%)	*<0.001
Tricuspid valve insufficiency 3 or 4	1072 (60.5%)	149 (77.2%)	923 (58.5%)	*<0.001
Aortic stenosis	372 (21%)	25 (13.0%)	347 (21.0%)	*0.004
Mitral stenosis	719 (40.6%)	26 (13.5%)	693 (43.9%)	*<0.001
Pulmonary stenosis	4 (0.2%)	1 (0.5%)	3 (0.2%)	0.365
AV insufficiency 3 or 4	141 (8.0%)	6 (3.1%)	135 (8.6%)	*0.008
MV insufficiency 3 or 4	744 (42%)	45 (23.3%)	699 (44.3%)	*<0.001
Triple vessel disease	38 (2.1%)	1 (0.5%)	2.3 (4.8%)	*0.098
Left main trunk	31 (1.8%)	1 (0.5%)	30 (2.2%)	0.167
Left ventricle function medium or bad	818 (46.2%)	110 (57.0%)	708 (44.9%)	*0.008

AV: aortic valve; MV: mitral valve; TV: tricuspid valve; TVR: tricuspid valve replacement.
*Means significant.

DISCUSSION

Tricuspid valve regurgitation is harmful to long-term survival and can lead to biventricular heart failure. Tricuspid regurgitation, which is at least moderate, has been associated with increased mortality, regardless of the pulmonary artery systolic pressure of left ventricular ejection fraction [1]. Indeed, guidelines indicate the need for more aggressive treatment of tricuspid regurgitation [11].

Table 3: Concomitant procedures

	Total (n = 1771)	TVR (n = 193)	TV repair (n = 1578)	P-value
Aortic valve plasty	19 (1.1%)	1 (0.5%)	18 (1.1%)	0.428
Aortic valve replacement	467 (26.4%)	24 (12.4%)	443 (28.1%)	*<0.001
Mitral valve plasty	182 (10.2%)	11 (5.7%)	170 (10.8%)	*0.028
Mitral valve replacement	1268 (71.6%)	67 (34.3%)	1201 (76.1%)	*<0.001
Single valve operation	158 (8.9%)	99 (51.3%)	59 (3.7%)	*<0.001
Multivalve operation	1613 (91.1%)	94 (48.7%)	1519 (96.3%)	*<0.001
Triple valve operation	333 (18.8%)	11 (5.7%)	322 (20.4%)	*<0.001
Coronary artery bypass grafting	96 (5.4%)	4 (2.1%)	92 (5.8%)	*0.03

TV: tricuspid valve; TVR: tricuspid valve replacement.
*Means significant.

Table 4: Surgical outcomes

	Total (n = 1771)	TVR (n = 193)	TV repair (n = 1578)	P-value
Operation time (min)	432 ± 145	457 ± 176	429 ± 140	*0.031
Extracorporeal circulation time (min)	204 ± 80.2	201 ± 100	204 ± 77	0.586
Clamp time (min)	133 ± 54	110 ± 64	135 ± 53	*<0.001
Intubation time (h)	58 ± 237	115 ± 396	51 ± 208	*<0.001
ICU stay longer than 8 days	260 (14.7%)	48 (24.9%)	212 (13.4%)	*<0.001
30-day mortality (%)	69 (3.9%)	13 (6.7%)	56 (3.6%)	*0.031
Hospital mortality (%)	120 (6.8%)	28 (14.5%)	92 (5.8%)	*<0.001
30-day mortality and morbidity	405 (22.9%)	52 (26.9%)	353 (22.9%)	0.153

TV: tricuspid valve; TVR: tricuspid valve replacement; ICU: intensive care unit.
*Means significant.

Table 5: Morbidities

	Total (n = 1771)	TVR (n = 193)	TV repair (n = 1578)	P-value
Reoperation for bleeding	137 (7.7%)	15 (7.8%)	122 (7.7%)	0.984
Stroke	39 (2.2%)	2 (1.0%)	37 (2.3%)	0.242
Prolonged ventilation (over 72 h)	257 (14.5%)	38 (19.7%)	219 (13.9%)	*0.031
Pneumonia	115 (6.5%)	25 (13.0%)	90 (5.7%)	*<0.001
Renal failure	181 (10.2%)	30 (15.5%)	151 (9.6%)	*0.01
Dialysis required	100 (5.6%)	17 (8.8%)	83 (5.3%)	*0.044
Heart block	73 (4.1%)	15 (7.8%)	58 (3.7%)	*0.007
Gastrointestinal bleeding	55 (3.1%)	12 (6.2%)	43 (2.7%)	*0.008
Multiorgan failure	64 (3.6%)	15 (7.8%)	49 (3.1%)	*0.001

Prolonged ventilation: ventilation for more than 24 h; Renal failure: postoperative creatinine level twice the preoperative level; TV: tricuspid valve; TVR: tricuspid valve replacement.
*Means significant.

For recurrent cases of isolated tricuspid regurgitation, reoperation is associated with high mortality rates and is rarely recommended [3–5, 12–14]. In this study, many of the patients requiring tricuspid valve repair following cardiac surgery had severe preoperative statuses, with prior congestive heart failure, poor cardiac function, NYHA Class 3 or 4 and CVD. The patients in the TVR group had a higher prevalence of congestive heart failure, NYHA Class 3 or 4 and poor left ventricular function than those in the TVP group.

The TVP group patients had a higher prevalence of comorbid valve disease than the TVR group patients, requiring more concomitant valve procedures rather than a relatively simple, isolated tricuspid valve repair. The patients in the TVR group had higher grades of TI and stenosis requiring isolated TVR operations. Despite the complex multivalve procedures in the TVP group, extracorporeal circulation time was similar between the two groups and operation time was significantly longer in the TVR group. This

Table 6: Risk factors for operative death

Variables	Univariate *P*-value	Multivariate *P*-value	HR	95% CI
Age	<0.001	0.001	1.255	1.091–1.443
NYHA 4	<0.001	<0.001	2.739	1.569–4.782
Renal dysfunction	<0.001	0.001	2.575	1.554–4.268
Active infectious endocarditis	<0.001	0.014	2.494	1.204–5.164
Shock	<0.001	0.002	4.189	1.727–10.163
Inotropic agents	<0.001	0.007	3.519	1.403–8.824
Aortic stenosis	0.38	0.017	1.8	1.109–2.924
Left ventricle dysfunction	<0.001	0.001	2.031	1.332–3.097
Tricuspid valve replacement	<0.001	<0.001	3.188	1.93–5.266

HR: heart rate; 95% CI: 95% confident interval; NYHA: New York Heart Association.

suggests that TVR was performed after failed repair due to severe tricuspid regurgitation and stenosis, resulting in prolonged extracorporeal circulation and operative time. The poorer preoperative status of patients in the TVR group resulted in significantly worse surgical results despite similar surgical results in both groups.

TVR is the last resort for nonrepairable tricuspid pathology. The hospital mortality of TVR is unsurprisingly higher than that of TVP [1, 3, 15, 16]. There are few articles focusing on tricuspid valve reoperation or repair. Park *et al.* [3] and Jeong *et al.* [5] included small samples and reported hospital mortality rates at 0 and 2%, respectively. In an earlier nationwide study that included primary operation, Shabocky *et al.* reported an overall in-hospital mortality rate of 10.6%, with 13.6% in the TVR group and 9.5% in the TVP group [13]. We found an overall mortality rate of 6.8%, with the TVR and TVP groups at 14.5 and 5.8%, respectively. Therefore, our hospital mortality for reoperation was lower.

Various risk factors have been identified previously. Jeong *et al.* [5] reported age and low ejection fraction as risk factors for tricuspid reoperation. Jeganathan *et al.* [12] reported age, male gender, postoperative low cardiac output syndrome and stroke as risk factors for early death with neither pathology nor surgery type influencing early mortality. However, in this study, multivariate analysis revealed that, in addition to the preoperative status (i.e. age, NYHA class, renal function, infective endocarditis, shock, neck vessel stenosis and active infective endocarditis), TVR itself was a major risk factor for operative death, with a hazard ratio of 3.188. To minimize TI after cardiac surgery, it is important to improve a patient's preoperative status and avoid TVR where possible.

According to the ESC/EACTS guideline [17], isolated operation on the tricuspid valve should be considered for persistent or recurrent severe TR after left-sided valve surgery either for symptomatic or asymptomatic patients having progressive RV dilatation or dysfunction. Valve repair is preferable to valve replacement and surgery should be carried out early enough to avoid irreversible RV dysfunction and better management.

Limitations

Although this study is a relatively large-scale, multicentre study, it is retrospective in design. For patients with tricuspid valve disease, liver dysfunction resulting from right-sided heart failure is an important issue; however, data regarding liver function have only recently been included in JACVSD and have not been obtained in this study. There is a potential selection bias inherent to a database dataset. 'Because of the large number difference between the two groups, good matched pairs or propensity score matching analysis was not possible'.

Furthermore, information on the previous operation was lacking because the categorizations in the database were changed during the study period. The late outcome and quality-of-life data were also not available in the database.

CONCLUSION

In conclusion, we described reoperation for tricuspid valve repair following cardiac surgery. Many of the patients had complex comorbidities and poor cardiac function. Therefore, the operative risk was high, and the results were not entirely satisfactory. However, we were able to determine that TVR itself carries a significant risk of operative mortality. Improvement of a patient's preoperative status and choice of TVP over TVR are important factors that can improve the outcomes of reoperation for tricuspid valve repair following cardiac surgery.

Conflict of interest: none declared.

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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 $\geq$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