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

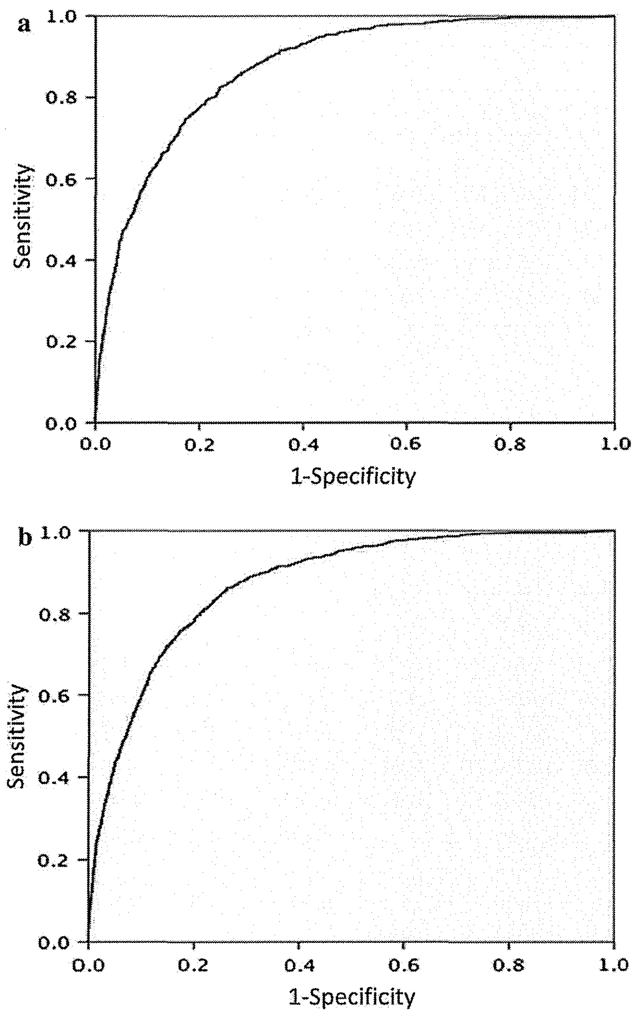

Fig. 1 The receiver operating characteristics (ROC) curves for the 30-day mortality (**a**) and surgical mortality (**b**) in the validation set

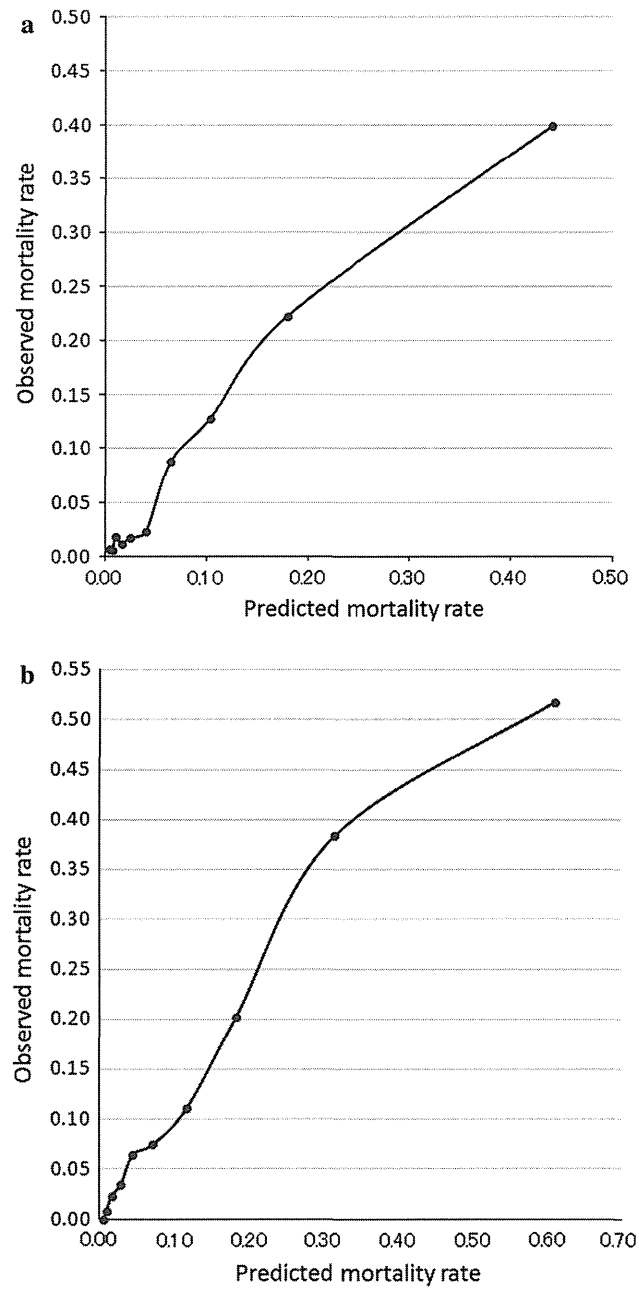

Fig. 2 The model calibration for the 30-day (**a**) and surgical (**b**) mortality models

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.

Acknowledgments We wish to thank all of the data managers and hospitals that participated in the NCD Project for their efforts in data entry. In addition, we wish to thank Prof. Hideki Hashimoto and Dr. Noboru Motomura for providing direction for the foundation of the NCD, and the working members of the JSGS database committee (Masayuki Watanabe, MD; Satoru Imura, MD; Fumihiko Miura, MD; Hiroya Takeuchi, MD; Ichiro Hirai, MD; Yoshio Takesue, MD; Hiroyuki Suzuki, MD; Megumi Ishiguro, MD; Hiroyuki Konno, MD; Makoto Gega, MD; and Akihiko Horiguch, MD). This study was partially supported by a research Grant from the Ministry of Health, Labour and Welfare of Japan.

Conflict of interest The authors report no conflicting financial interests.

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Korean J Thorac Cardiovasc Surg 2014;47:437-443 □ Review □
ISSN: 2233-601X (Print) ISSN: 2093-6516 (Online) http://dx.doi.org/10.5090/kjtcs.2014.47.5.437

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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Received: July 22, 2014, Revised: August 21, 2014, Accepted: August 22, 2014, Published online: October 5, 2014
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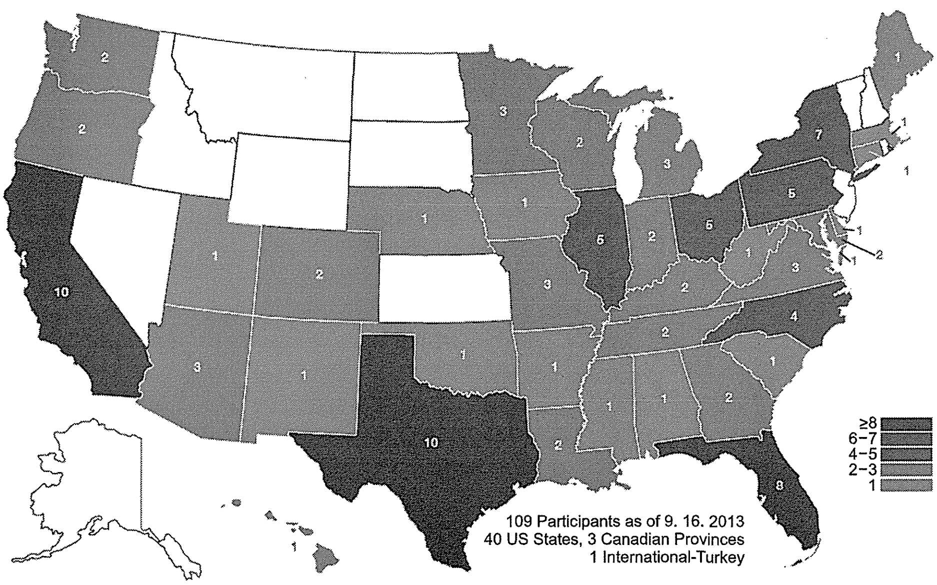

Fig. 1. The Society for Thoracic Surgeons National Database: the Congenital Heart Surgery Database participants (http://www.sts.org/sites/default/files/documents/congenitalMap.pdf).

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,

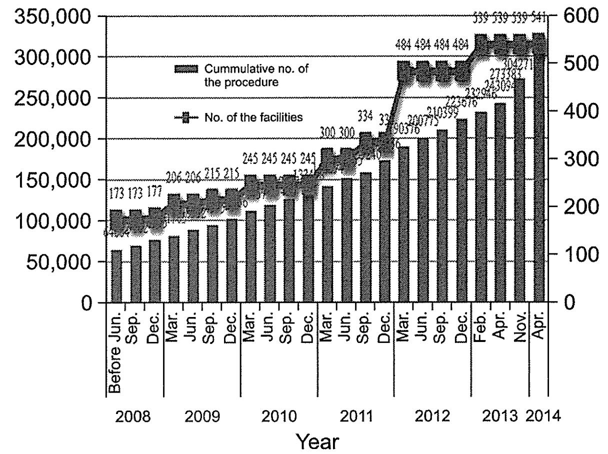

Fig. 3. The growth in the Japan Adult Cardiovascular Surgery Database, As of April 2014, the number of facilities were 541 and the cumulative number of procedures were 304,271.

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.

ACKNOWLEDGMENTS

This paper was presented at the 45th Fall Meeting of the Korean Society for Thoracic and Cardiovascular Surgery on November 8, 2013, in Seoul. I appreciate the hospitality of the members of the society and Prof. Woong-Han Kim of Seoul National University, who invited me to this outstanding meeting.

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European Journal of Cardio-Thoracic Surgery Advance Access published March 12, 2014

European Journal of Cardio-Thoracic Surgery (2014) 1–10
doi:10.1093/ejcts/ezu081

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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Received 6 October 2013; received in revised form 8 January 2014; accepted 4 February 2014

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

[†]Presented at the 27th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Vienna, Austria, 5–9 October 2013.

in redo CABG, and to retrospectively compare isolated redo CABG with or without cardiopulmonary bypass (CPB) using data from the JCVSD through propensity score (PS) matching.

MATERIALS AND METHODS

Study population

The JCVSD was established in 2000 with the goal of evaluating surgical outcomes after cardiovascular procedures in many centres throughout Japan [15, 16]. As of January 2013, JCVSD has recorded clinical information from over 500 hospitals, which comprises almost all hospitals with cardiovascular surgery units in Japan. The data collection form has 255 variables that are almost identical to those in the Society of Thoracic Surgeons (STS) National Database [available at: http://www.sts.org (25 February 2014, date last accessed)]. The definitions of JCVSD variables [available at: http://www.jacvsd.umin.jp (25 February 2014, date last accessed)] are also based on those of The STS National Database (Tables 1 and 2). Through the JCVSD web-based system, each participating hospital enters data and uses a feedback report in real time that includes risk-adjusted outcomes compared with all participating hospitals. Although participation in the JCVSD is voluntary, submissions tend to be thorough, with overall preoperative risk factors used in risk models missing in fewer than 3% of the entries. The accuracy of the submitted data is verified through monthly visits to each hospital by The Site Visit Working Group. The Site Visit Working Group members verify that the number of procedures from the original operative record list in the hospital matches that reported in the JCVSD. These members also examine each clinical chart of procedures and compare it with the JCVSD data.

Table 1: Unadjusted patient characteristics

Variables	Total redo CABG	On-pump redo CABG	Redo OPCAB	*P*-value
Patients	617	253	364	
Sex (male)	78.8	79.8	78.0	0.62
Age (years), mean (SD)	69.35 ± 9.2	68.87 ± 9.74	69.68 ± 8.81	0.28
Body surface area, mean (SD)	1.64 ± 0.18	1.64 ± 0.18	1.64 ± 0.18	0.54
Smoking	52.4	49.8	54.1	0.33
Body mass index >30 kg/m^2	5.2	5.1	5.2	1.00
Diabetes	46.2	45.5	46.7	0.81
Preoperative creatinine value	1.73 ± 2.29	1.68 ± 2.29	1.76 ± 2.29	0.70
Renal failure	18.5	18.2	18.7	0.92
Dialysis	9.1	9.6	9.4	0.89
Hyperlipidaemia	60.8	59.3	61.8	0.56
Hypertension	77.6	80.2	75.8	0.20
Cerebrovascular disease	11.0	12.6	9.9	0.30
Carotid stenosis	7.9	7.9	8.0	1.00
COPD (moderate and severe)	11.3	10.3	12.1	0.52
Extracardiac disease	20.9	23.7	19.0	0.16
Peripheral	18.0	19.8	16.8	0.34
Myocardial infarction	44.9	46.6	43.7	0.51
Previous coronary artery intervention	45.4	44.7	45.9	0.81
Unstable angina	32.9	38.3	29.1	0.019
Shock	4.9	7.9	2.7	0.0040
Congestive heart failure	14.7	17.0	13.2	0.21
Arrhythmia	11.7	13.8	10.2	0.16
NYHA class III or IV	28.4	31.2	26.4	0.20
Diseased vessels, %				
Left main disease	37.0	42.7	33.0	0.017
1	13.9	9.9	16.8	0.018
2	25.0	20.2	28.3	0.023
Triple-vessel disease	55.3	62.1	50.5	0.0050
LV impairment, %				
Good >EF:60%	34.5	35.2	34.1	0.80
≤EF:60%	65.2	64.0	65.9	0.67
Bad <EF:30%	8.1	9.9	6.9	0.18
Mitral valve insufficiency II–IV	21.1	20.9	21.2	1.00
Tricuspid valve insufficiency II–IV	14.6	17.4	12.6	0.11
Status, %				
Urgent	8.3	9.9	7.1	0.24
Emergency/salvage	8.1	10.7	6.3	0.071
Japan SCORE				
Expected 30 days operative mortality		7.66 ± 0.14	5.51 ± 0.1	0.023
Expected composite 30-day mortality or major morbidity		25.1 ± 0.18	21.9 ± 0.15	0.019

Values are percentage or mean ± SD values.
COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association; LV: left ventricular; EF: ejection fraction.

Table 2: Unadjusted outcomes

	Total redo CABG	On-pump redo CABG	Redo OPCAB	*P*-value
Intraoperative variables				
Operation time (min)	375.21 ± 147.0	427.61 ± 151.23	339.06 ± 132.61	<0.00010
Distal anastomoses mean (SD)	2.12 ± 1.10	2.30 ± 1.04	2.00 ± 1.12	0.0010
Number of distal anastomoses				
1, 2	66.9	60.1	71.7	0.0030
3	21.9	26.9	18.4	0.013
4, 5	10.7	13.0	9.1	0.15
6	0.5	0.0	0.8	0.27
Early outcomes				
30-day mortality	5.2	8.3	3.1	0.0050
Operative mortality	7.0	10.7	4.4	0.0040
Blood transfusion	74.2	88.9	64.0	<0.00010
Initial ventilator time (h)	45.21 ± 147.79	65.49 ± 160.32	31.17 ± 136.92	0.0050
Intensive care unit stay ≥8 days	10.2	15.4	6.6	0.0010
Postoperative morbidity				
Stroke	2.1	2.8	1.6	0.40
Transient	1.8	2.8	1.1	0.14
Continuous coma ≥24 h	1.8	3.2	0.8	0.058
Renal failure requiring dialysis	3.9	5.9	2.5	0.034
Renal failure	9.9	14.6	6.6	0.0010
Deep sternal wound infection	1.3	1.6	1.1	0.72
Prolonged ventilation	10.0	16.6	5.5	<0.00010
Reoperation for bleeding	2.4	3.6	1.6	0.18
Perioperative myocardial infarction	2.8	5.1	1.1	0.0040
Atrial fibrillation	12.3	13.8	11.3	0.38
Heart block	0.3	0.8	0.0	0.17
Gastrointestinal complication	3.1	2.8	3.3	0.82
Pneumonia	3.9	4.0	3.8	1.00
Readmission within 30 days	2.9	4.0	2.2	0.23
Composite 30-day mortality or major morbidity	14.9	22.9	9.3	<0.00010

Values are percentage or mean ± SD values.

Study end points

The study outcomes measured from the JCVSD were as follows: operation time and the number of distal anastomoses as the intraoperative variable, 30-day mortality, operative mortality, initial ventilation time, the number of patients who stayed in the intensive care unit ([ICU] stay) ≥8 days and blood transfusion as early outcomes. The 30-day mortality was defined as death within 30 days of the operation, regardless of the patient's geographic location, even if the patient had been discharged from the hospital. Operative mortality included any patient who died within the index hospitalization, regardless of the length of hospital stay, and including any patient who died after being discharged from hospital up to 30 days from the date of the operation. Hospital-to-hospital transfer was not considered discharge [17].

Major morbidity was defined as any of the five following postoperative in-hospital complications: stroke, reoperation for any reason, need for mechanical ventilation for more than 24 h postoperatively, renal failure with newly required dialysis or deep sternal wound infection [18]. In addition to the above complications, the following complications were defined as postoperative morbidities (Table 2): (i) renal failure (defined as an increase in serum creatinine value to twice preoperative levels or to >2.0 mg/dl, or new requirement for dialysis or haemofiltration); (ii) continuous coma for >24 h; (iii) perioperative myocardial infarction (defined as at least two of the following: continuous angina for >20 min regardless of nitrite treatment or rest, elevation of cardiac enzyme levels [creatine kinase (CK)-MB level >1/20 of the total CK level or twice preoperative levels and/or lactate dehydrogenase isozyme subtype 1 > subtype 2 and/or positive troponin]; new cardiac wall motion abnormalities; Q waves or ST-T elevation on more than 2 serial leads in the electrocardiogram); (iv) atrial fibrillation (new onset); (v) heart block requiring permanent pacemaker; (v) gastrointestinal complications; (vi) pneumonia and (vii) readmission within 30 days of discharge. In this analysis, composite 30-day mortality or major morbidity was considered a postoperative morbidity (Table 2).

Statistical analyses

We compared the baseline demographics of patients who underwent off-pump surgery with those of patients who underwent on-pump surgery. The PS matching [19] method was used for adjusting differences in baseline characteristics because the patients were not randomly assigned to receive redo OPCAB.

PS were calculated for each patient to adjust for confounders of group assignment using the following 13 preoperative variables, which include the circumstances under which surgeons generally tend to avoid or prefer to use CPB: age; presence of unstable angina; extracardiac disease; cerebrovascular disease (the presence of stroke or a history of transient ischaemic attack); a history of non-invasive carotid stenosis >75%; diabetes; renal failure; chronic lung disease (mild, moderate or severe); cardiogenic shock; a history of myocardial infarction; ejection fraction <30%; triple-vessel disease and left main disease (variables at the basis of the model are given in Table 3).

We performed a one-to-one matched analysis on the basis of estimated PS of each patient. The log odds of the probability that a patient underwent redo OPCAB was modelled as a function of the confounders, which we identified and included in our data set. C-statistics were calculated for evaluating the goodness of fit. The area under the curve of this PS model was 0.62. The estimated PS were compared between the redo OPCAB and on-pump redo CABG groups, and a 'match' occurred when 1 patient in the redo OPCAB had an estimated score within 0.6 standard deviation (SD) of another patient in the on-pump redo CABG. If two or more patients in the redo OPCAB group met this criterion, we randomly selected 1 patient for matching.

We performed univariate comparisons of patient characteristics and outcome variables between the PS-matched groups of redo OPCAB and on-pump redo CABG, using Fisher's exact tests or Pearson's χ^2 test and *t*-tests, as appropriate. A *P*-value of <0.05 was considered statistically significant. All statistical analyses were conducted using PASW version 18.0 (SPSS, Inc.; Chicago, IL, USA).

Table 3: Variables included in the propensity score model

Variables	B Value	*P*-value
Age	1.013	0.16
Carotid stenosis	0.978	0.94
Renal failure	1.067	0.77
Diabetes (insulin)	1.212	0.45
Cerebrovascular disease	0.853	0.56
COPD (mild, moderate or severe)	1.340	0.29
Extracardiac disease	0.740	0.44
Myocardial infarction	1.005	0.98
Unstable angina	0.807	0.25
Shock	0.401	0.035
Left main disease	0.749	0.36
Triple-vessel disease	0.627	0.0090
<EF:30%	0.720	0.067

COPD: chronic obstructive pulmonary disease; EF: ejection fraction.

RESULTS

We analysed the data of 34 980 patients who underwent isolated CABG and were included in the JCVSD between 2008 and 2011. Of these, 1.8% of patients [n = 617/34980] had undergone redo CABG.

Of these, 253 (41%) underwent an on-pump procedure, whereas the other 364 (69%) underwent an off-pump procedure (Fig. 1). Of note, 7.7% of patients (n = 28/364) who required intraoperative conversion from redo OPCAB to on-pump redo CABG were included in the redo OPCAB group for final analysis.

Unadjusted outcomes

The demographic and preoperative characteristics of patients undergoing redo OPCAB versus on-pump redo CABG before propensity matching are listed in Table 1. The on-pump redo CABG group had a significantly higher preoperative incidence of unstable angina and shock than the redo OPCAB group (38.3 vs 29.1%, P = 0.019; 7.9 vs 2.7%, P = 0.0040). The other preoperative data were similar between the two groups.

As for diseased vessels, the rates of triple-vessel and left main disease were significantly higher in the on-pump redo CABG group than in the redo OPCAB group (62.1 vs 50.5%, P = 0.0050; 42.7 vs 33.0%, P = 0.017). On the other hand, the redo OPCAB

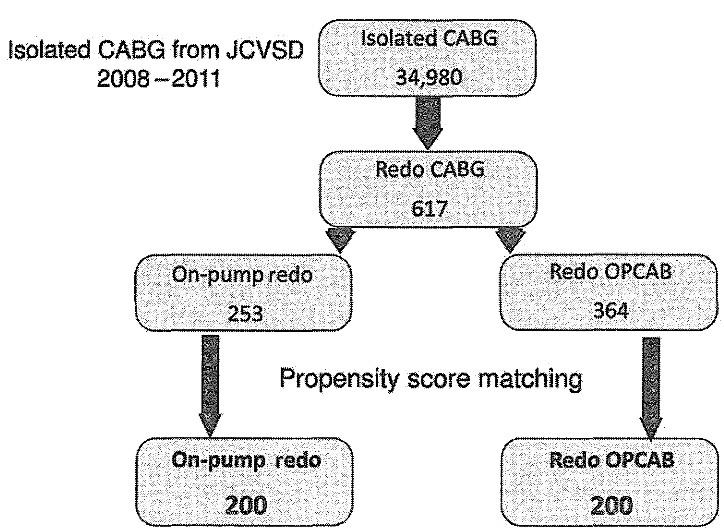

Figure 1: Patient selection. JCVSD: Japan Cardiovascular Surgery Database.

group had a lower number of diseased vessels compared with the on-pump redo CABG group (single-vessel disease: 9.9% in the on-pump redo CABG group versus 16.8% in the redo OPCAB group; double-vessel disease: 20.2% in the on-pump redo CABG group versus 28.3% in the redo OPCAB group). The Japan SCORE, (The Japan SCORE is a risk model based on the JCVSD. Expected mortality and expected composite 30-day mortality or major morbidity are calculated from this risk model.) [15, 16] were significantly higher in the on-pump redo CABG group than in the redo OPCAB group (7.66 ± 0.14% vs 5.51 ± 0.1, $P = 0.023$; 25.1 ± 0.18% vs 21.9 ± 0.15%, $P = 0.019$, respectively).

There were significant differences in intraoperative variables between the two groups (Table 2). The redo OPCAB group underwent a fewer mean number of distal anastomoses compared with the on-pump redo CABG group (2.00 ± 1.12 vs 2.30 ± 1.04, $P = 0.0010$). Operation times were significantly longer in the on-pump redo CABG group than in the redo OPCAB group, at 427.61 ± 151.23 vs 339.06 ± 132.61 min ($P < 0.00010$).

Significant differences between the groups were observed in early outcomes (Table 2). All of the outcomes were significantly worse in the on-pump redo CABG group than in the redo OPCAB group. The 30-day mortality was 8.3% in the on-pump redo CABG group and 3.1% in the redo OPCAB group ($P = 0.0050$).

Postoperative morbidities are given in Table 2. The incidences of renal failure, renal failure requiring dialysis, prolonged ventilation, perioperative myocardial infarction and composite 30-day mortality or major morbidity were higher in the on-pump redo CABG group than in the redo OPCAB group.

Table 4: Patient characteristics after propensity score matching

Variables	Total redo CABG	On-pump redo CABG	Redo OPCAB	*P*-value
Patients	400	200	200	
Sex (male)	80.5	83.0	78.0	0.26
Age (years), *mean (SD)*	*68.4 ± 9.4*	*68.7 ± 9.4*	*68.1 ± 9.3*	0.52
Body surface area, mean (SD)	1.65 ± 0.17	1.66 ± 0.2	1.63 ± 0.2	0.19
Smoking	53.3	52.5	54.0	0.84
Body mass index >30 kg/m^2	6.5	6.0	7.0	0.84
Diabetes	46.8	46.5	47.0	1.00
Preoperative creatinine value	1.7 ± 2.24	1.7 ± 2.3	1.7 ± 2.2	0.91
Renal failure	17.8	17.5	18.0	1.00
Dialysis	8.3	8.0	8.5	1.00
Hyperlipidaemia	60.8	61.0	60.5	1.00
Hypertension	76.0	80.0	72.0	0.079
Cerebrovascular disease	12.0	10.5	13.5	0.44
Carotid stenosis	8.5	8.0	9.0	0.86
COPD (moderate and severe)	2.3	2.5	2.0	1.00
Extracardiac disease	21.8	21.0	22.5	0.81
Peripheral	18.8	18.5	19.0	1.00
Myocardial infarction	47.5	47.0	48.0	0.92
Previous coronary artery intervention	46.3	45.0	47.5	0.69
Unstable angina	41.8	40.5	43.0	0.69
Shock	5.5	6.0	5.0	0.83
Congestive heart failure	16.5	16.5	16.5	1.00
Arrhythmia	12.8	13.5	12.0	0.77
NYHA class III or IV	34.5	32.0	37.0	0.34
Diseased vessels, %				
Left main disease	47.5	45.0	50.0	0.37
1	5.8	6.0	5.5	1.00
2	16.3	18.0	14.5	0.42
Triple-vessel disease	74.3	70.0	78.5	0.067
LV impairment, %				
Good >EF:60%	30.8	35.5	26.0	0.051
≤EF:60%	69.0	64.0	74.0	0.040
Bad <EF:30%	9.0	8.0	10.0	0.60
Mitral valve insufficiency II–IV	22.5	20.0	25.0	0.28
Tricuspid valve insufficiency II–IV	15.5	18.0	13.0	0.21
Status, %				
Urgent	10.0	10.0	10.0	1.00
Emergency/salvage	8.5	8.5	8.5	1.00
Japan SCORE				
Expected 30 days operative mortality		6.62 ± 0.12	6.37 ± 0.11	0.85
Expected composite 30-day mortality or major morbidity		24.95 ± 0.17	24.01 ± 0.17	0.58

Values are percentage or mean ± SD values.
COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association; LV: left ventricular; EF: ejection fraction.

Propensity-matched pairs

We selected 13 preoperative risk factors to eliminate the differences between the two groups (Table 3) and used PS matching with these preoperative risk factors to adjust for differences in baseline characteristics between the two groups. Using one-to-one matching, we selected 200 pairs from each group (Fig. 1).

Table 5: Results after propensity score matching 1

	Total redo CABG	On-pump redo CABG	Redo OPCAB	*P*-value
Intraoperative variables				
Operation time (min)	397.5 ± 148.16	441.3 ± 146.3	353.7 ± 136.9	<0.00010
Distal anastomoses mean (SD)	2.31 ± 1.12	2.41 ± 1.0	2.21 ± 1.2	0.074
Number of distal anastomoses				
1,2	60.0	56.5	63.5	0.18
3	26.3	28.5	24.0	0.36
4,5	13.0	15.0	11.0	0.30
6	0.8	0.0	1.5	0.25
The distribution of grafts				
Left ITA	36.3	36.5	36.0	1.00
Right ITA	32.3	27.5	37.0	0.054
Bilateral ITA	11.5	9.0	14.0	0.16
No ITA use	43.0	45.0	41.0	0.48

Values are percentage or mean ± SD values.
ITA: internal thoracic artery.

Table 6: Results after propensity score matching 2

	Total redo CABG	On-pump redo CABG	Redo OPCAB	*P*-value
Early outcomes				
30-day mortality	5.3	7.0	3.5	0.18
Operative mortality	7.5	9.5	5.5	0.18
Blood transfusion	82.8	94.0	71.5	<0.00010
Initial ventilator time (h)	47.8 ± 146.08	58.9 ± 137.5	36.8 ± 153.7	0.13
Intensive care unit stay ≥8 days	10.8	14.5	7.0	0.023
Cause of all death				0.59
Arrhythmia	1.0	1.0	1.0	
Bleeding	0.3	0.5	0.0	
Infection	0.8	0.5	1.0	
Low output syndrome	4.0	5.0	3.0	
Pulmonary	0.5	0.5	0.5	
Renal	0.3	0.5	0.0	
Others	2.0	3.0	1.0	
Postoperative morbidity				
Stroke	1.5	2.5	0.5	0.22
Transient	1.5	2.0	1.0	0.69
Continuous coma ≥24 h	1.5	2.0	1.0	0.69
Renal failure requiring dialysis	3.8	5.0	2.5	0.29
Renal failure	9.5	12.0	7.0	0.12
Deep sternal wound infection	1.0	1.0	1.0	1.00
Prolonged ventilation	11.0	15.0	7.0	0.016
Reoperation for bleeding	3.5	4.0	3.0	0.79
Perioperative myocardial infarction	3.0	4.5	1.5	0.14
Atrial fibrillation	12.5	14.0	11.0	0.45
Heart block	0.3	0.5	0.0	1.00
Gastrointestinal complication	2.0	2.0	2.0	1.00
Pneumonia	3.3	4.0	2.5	0.58
Readmission within 30 days	3.5	4.5	2.5	0.42
Composite 30-day mortality or major morbidity	16.3	21.5	11.0	0.0060

Values are percentage or mean ± SD values.

There were no significant differences among all preoperative factors, including shock, unstable angina, number of diseased vessels (94.3%: multivessel disease), left ventricular impairment and preoperative status between the two groups. Moreover, there were no significant differences in the Japan SCORE (expected mortality: 6.62 ± 0.12% vs 6.37 ± 0.11%, $P = 0.85$; expected 30-day mortality or composite major morbidity: 24.95 ± 0.17% vs 24.01 ± 0.17%, $P = 0.58$) (Table 4).

As for intraoperative variables (Table 5), there was no significant difference in the mean number of distal anastomoses after matching (2.41 ± 1.00 vs 2.21 ± 1.04, $P = 0.074$). The data of our study show that, in the on-pump redo CABG group, 35.0% of patients were given blood cardioplegia and 10.0% were given the crystalloid cardioplegia solution for myocardial protection. No cardioplegia was provided in 45.5% patients in the on-pump redo CABG group. In almost all patients in whom no cardioplegia was provided, the on-pump beating procedure was performed. Half of the on-pump redo CABG procedures are performed using the beating heart technique in Japan [20]. The JCVSD does not capture whether adequate myocardial protection was provided during CABG, particularly in the setting of patent mammary graft, for example, whether retrograde cardioplegia or systemic hyperkalaemia is used for achieving diastolic arrest and myocardial protection. The distribution of arterial versus vein grafts in the two groups is given in Table 5. There were no significant differences in the distribution of internal thoracic artery graft and the absence of ITA graft use in the two groups. The causes of all deaths in the two groups registered in the JCVSD are given in Table 6.

Operation time was significantly longer in the on-pump redo CABG group than in the redo OPCAB group (441.3 ± 146.3 vs 353.7 ± 136.9 min, $P < 0.00010$) (Table 5).

Regarding early outcomes (Table 6), the patients in the redo OPCAB group had a lower 30-day mortality rate (3.5 vs 7.0%, $P = 0.18$), a lower initial ventilator time (36.8 ± 153.7 vs 58.9 ± 137.5 h, $P = 0.13$), significantly shorter ICU duration (7.0 vs 14.5%, $P = 0.023$) and significantly decreased need for blood transfusions (71.5 vs 94.0%, $P < 0.00010$).

As for postoperative morbidities (Table 6), the redo OPCAB group had a significantly lower rate of prolonged ventilation (>24 h) (7.0 vs 15.0%, $P = 0.016$) and lower rates of composite mortality or major morbidities (11.0 vs 21.5%, $P = 0.0060$) than the on-pump redo CABG group. Although there were no significant differences in other morbidities, the redo OPCAB group had a lower rate in many postoperative morbidities.

DISCUSSION

In the present study, we present the contemporary Japanese results for redo CABG obtained from the JCVSD, which currently contains the clinical data from almost all Japanese institutions performing cardiovascular surgery.

Off-pump coronary artery grafting

OPCAB emerged in the mid-1980s and has since become increasingly popular worldwide. In Japan, OPCAB has become the standard management strategy for surgical coronary revascularization. The ratio of OPCAB in CABG has been increasing, especially since the year 2000; the annual rate of performing OPCAB is >60% [20, 21]. Several studies, including those conducted in Japan, have reported the effects of OPCAB and have compared OPCAB with conventional CABG [1–3], especially in patients with high comorbidity [4, 5].

Redo coronary artery bypass grafting

As described in several previous reports, the prevalence of redo CABG has recently reached a plateau [22, 23]. The Japanese Association for Thoracic Surgery (JATS) has been maintaining a registry of cardiovascular procedures in Japan since 1986; the number of isolated redo CABG in Japan has been basically decreasing, and its prevalence reached a plateau over a 10-year period. The latest version of the JATS Annual Report in 2011 showed that 223 patients underwent redo isolated CABG, and the prevalence of reoperation cases was 1.56% of total isolated CABG cases (14 256 patients) in 2011 [20]. This trend is apparently caused by improved medication for post-CABG patients, more frequent use of the internal mammary artery, more complete revascularization, older patient age at the time of primary surgery and increased use of percutaneous coronary intervention (PCI) for recurrent coronary disease after CABG in patients. Compared with Western countries, in Japan, PCI is used for patients with more severe coronary artery disease, and indications for PCI have expanded to include more indications than those included in its early stages.

Redo CABG can be performed safely in certain patients because of growing surgical experience, new technical strategies and better management of patient comorbidities. However, even in recent reports, the morbidity and mortality of such procedures remain higher (in the range of 4.2–6.8%) than those of primary procedures [20, 22–24].

Our data showed that the 30-day mortality in the redo CABG was significantly higher than in the primary CABG group (5.63 vs 1.46%, $P < 0.00010$). We hypothesize that the different characteristics inherent in the redo CABG patients may explain the higher mortality or morbidity rate in this group of patients compared with the primary CABG group. Redo patients are generally older, with a lower ejection fraction, and have multiple risk factors. In addition, their general physical condition is usually worse. Additionally, redo CABG tends to be more technically demanding, e.g. successful re-entry into the chest, management of patent bypass grafts or diseased patent grafts with adhesions, ischaemia caused by embolization of atheromatous debris from venous conduits, location of suitable conduits, aortic atherosclerotic disease that may prevent cross-clamping or aortic cannulation and/or inadequate myocardial protection caused by difficulties in delivering cardioplegia in the face of native and conduit stenoses [23]. The last two factors are directly associated with disadvantages of the on-pump procedure.

Concordantly, many reports have mentioned the benefits of OPCAB, especially in patients with several comorbidities, such as those undergoing redo CABG [4, 5]. Several recent reports of off-pump redo CABG have stated the advantage of morbidity and mortality [6–11]. Conversely, some reports have stated that these benefits may be limited to a selected group of patients because of the higher rate of incomplete revascularization in off-pump CABG. However, the mean number of distal anastomoses in these reports was 2 (Czerny *et al.* [12]: 1.3 ± 0.5; Tugtekin *et al.* [13]: 1.6 ± 0.60 and Kara *et al.* [14]: 1.15 ± 0.41). The present study data indicated that single-vessel disease had a frequency of only 13.9% (Table 1), which was reduced to only 5.8% after matching data were included. Most data (94.2%) were for multivessel disease (Table 4), and the mean number of distal anastomoses was no less than 2 in the redo OPCAB group (Tables 2 and 5). These reports were from many countries that have various circumstances concerning the management of CABG procedures (OPCAB is used only in 30% of cases in Western countries and in other Asian countries). Further, most of these results were reported single-institution studies [6, 7, 10–12, 14]. Therefore, these data might not clarify the specific benefits of off-pump surgery in redo CABG.

The present study was a comparative clinical study utilizing a large nationwide database (JCVSD) to achieve a higher evidence level and to obtain up-to-date clinical outcomes. To the best of our knowledge, thus far, similar comparative clinical studies aiming to clarify the superiority of each variable of the off-pump technique in redo CABG have not been conducted. In addition, Japan is the only country in which >60% of isolated CABGs are performed without a CPB, and our results may be very informative.

Data from the JCVSD in redo CABG

The present retrospective comparison before matching data is presented in Tables 1 and 2.

These data suggest that surgeons in Japan tend to perform off-pump procedures for patients requiring fewer grafts in stable condition and perform on-pump procedures for patients requiring a greater number of grafts in unstable conditions for redo CABG. Thus, longer operative times are observed in the on-pump redo CABG group than in the redo OPCAB group (427.61 ± 151.23 vs 339.06 ± 132.61 min, $P < 0.00010$). Early outcomes and most morbidities in the on-pump redo CABG group were worse than in the redo OPCAB. Thus, off-pump surgery seems to offer certain advantages in cases of redo CABG surgery. However, the indications for off-pump or on-pump reoperations are based on individual surgeon and institutional preferences. In addition, the two groups had unequal patient characteristics and significantly different severities in patient preoperative backgrounds, according to the Japan SCORE. Based on the unadjusted results, we selected 13 preoperative risk factors to eliminate the differences between the two groups; these included the number of diseased vessels, preoperative status and the circumstances under which surgeons in Japan generally tend to avoid or prefer to use CPB (Table 3). After matching the data of these patients with the data of those in the JCVSD, no significant differences were observed in expected mortality and expected 30-day mortality or major composite morbidities between the two groups. Therefore, the severity of patient preoperative backgrounds and the overall picture of the entire patient group profile were adequately adjusted between the two groups (Table 4).

In addition, there were no significant differences in the distribution of grafts (Table 5). Therefore, these factors, including severity of patient preoperative backgrounds, did not influence the results of our study when comparing the two groups after matching. In the present retrospective comparison, the results after propensity matching data from the JCVSD demonstrated that redo OPCAB was safe and effective when each variable was considered.

The most important result of the adjusted portion of the study was the absence of significant differences in the mean number of distal anastomoses after matching. In addition, there were no significant differences in the distribution of grafts. Nevertheless, the mean operation time was significantly shorter in the redo OPCAB group than in the on-pump redo CABG group (353.7 vs 441.3 min, $P < 0.00010$) (Table 5). These results suggests that redo OPCAB reduced the operation time in the equivalent number of distal anastomoses performed by the on-pump procedure, even for over 90% of multivessel disease cases (Table 4). We considered that the operation time increased in the on-pump redo CABG group because of the difficulty in achieving haemostasis during adhesion dissection in patients who developed coagulation abnormalities, a potential side-effect of CPB [25]. This may have led to higher intraoperative and postoperative blood loss and need for blood transfusions. Moreover, patients who developed pulmonary dysfunction secondary to CPB may have also presented longer operation times, contributing to worsening of respiratory insufficiency, prolonged mechanical ventilation and ICU stay (Table 6). These increased operation times emphasize several adverse occurrences associated with potential side-effects of CPB, such as a coagulopathy or pulmonary dysfunction [25], redo CABG procedure such as cardioplegia, arterial cannulation or aortic cross-clamping and the multiple risk factors usually present in redo CABG patients. In other words, by avoiding CPB, the operation time could be decreased, and the complications associated with on-pump redo CABG were reduced. As a result, the incidence of composite mortality or major complication in redo OPCAB was significantly lower than in the on-pump redo CABG. Most morbidities tend to be lower in redo OPCAB (Table 6).

Our findings from the JCVSD indicate that the off-pump surgical technique for redo CABG offers certain advantages, that is, it prevents potential side-effects of CPB and prevents complications of surgical procedures.

Despite these important findings, there were several limitations in the present study regarding data interpretation. It was a retrospective clinical study based on a large-scale database, and it provides weaker clinical evidence than a randomized prospective study and we did not have medium-term or long-term outcomes. In this study, a 30-day mortality rate of 7.00% and an operative mortality rate of 9.5% were observed (Table 6); our observation interval was 30 days, but early risk extends beyond this period. The JCVSD does not have data to account for this.

Nonetheless, our data suggest that the off-pump technique for redo CABG reduces operation time for an equivalent number of distal anastomoses performed using the on-pump procedure for multivessel diseases. As a result, the off-pump procedures had significantly lower rates of prolonged ventilation, blood transfusion and shorter duration of ICU stay and lower rates of composite mortality and major morbidities compared with the on-pump procedure.

In conclusion, the off-pump technique reduced operative mortality and reduced the incidence of major complications in redo CABG.

ACKNOWLEDGMENTS

We thank all members of the Japanese Cardiovascular Surgery Database for their tireless efforts to improve the quality of cardiovascular surgery.

Funding

This work was supported by The Japanese Society for Cardiovascular Surgery, The Japanese Association for Thoracic Surgery and Japan Heart Foundation.

Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

***Dr E. Wolner** (Vienna, Austria)*: This is a very interesting, very good paper and, for me, an unexpectedly greater difference in the mortality of the off-pump versus the on-pump group, in favour of the OPCAB group. This difference results from a matched group of patients. However, if you look at the unadjusted data in your slide No. 2, you see that you have more hypertension and more cardiovascular disease in the on-pump group. It is not statistically significant, but there are differences. And if you perhaps count all this data together (you have higher New York Heart Association class, you have more heart failure, you have, as you said, more unstable angina and more stroke), my conclusion is that the on-pump group is sicker than the OPCAB group.

So my first question is: Are you sure that your statistical analysis, this propensity score matching, reflects the real data between these two groups? Secondly, for me it is very surprising that in your country you have such a high number, I mean 60% or so, of off-pump versus on-pump coronary surgery. Usually in Germany it's 20%. In the STS database, it is also I believe a little bit more than 20%. What is the explanation that you have for such a high percentage of off-pump surgery in your country?

Dr Dohi: Thank you, a good question about an important point. In fact, before matching data were available, Japanese surgeons performed off-pump procedures for patients requiring fewer grafts and, on other hand, they performed on-pump procedures for patients requiring a greater number of grafts and who were in an unstable condition. Thus, the results are significantly worse in the on-pump group compared to those in the off-pump group. Could you repeat the other question?

Dr Wolner: Percentage of off- versus on-pump as a difference between your country and others.

Dr Dohi: In Japan almost 60% of isolated CABGs are performed as off-pump procedures. Our data indicate that approximately 70% off-pump procedures are performed, and OPCAB has become the standard CABG procedure in Japan. PCI is used for patients with more severe coronary artery disease in Japan compared with Western countries, in some cases in patients with LM lesions, 3-vessel disease or chronic total occlusion. This increased utilization of