TABLE 6. Association between hospital CABG volume and mortality by expected risk (n = 4581)

	Expected risk < 1.5% Hospital CABG volume			Expected risk > 1.5% Hospital CABG volume		
	16–30	31–50	≥50	16–30	31–50	≥50
No. of patients	432	921	1252	462	724	790
Unadjusted mortality	0.69	0.98	0.16	7.36	5.25	3.92
Risk-adjusted mortality	0.37	0.55	0.09	5.22	3.81	3.25
P value (hospital volume)		NA			<.01	

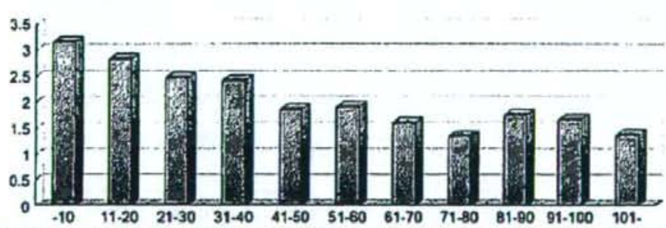
Preoperative risk was calculated based on JACVSD 30-day mortality risk model. Results were further adjusted with risk group to ensure constant risk profiles. Number of patients is for 3-year periods (2003–2005).

volume on risk-adjusted 30-day operative mortality rates. As there was colinearity between these factors ($r = 0.385$), only hospital procedural volume had a significant effect on 30-day operative mortality ($P < .001$). Overall, the highest mortality rates (3.47%) were observed when patients were treated by low-volume surgeons at middle- to low-volume hospitals, and the best results (1.46%) were obtained by high-volume surgeons at high-volume hospitals. We have shown the effect of volume on outcome in patient subgroups (Tables 5 and 6). Regarding the patient age group, the effect of hospital volume was apparent in both groups (age < 65 years, $P < .05$; age ≥ 65 years, $P < .01$). Patients at expected high operative risk (>1.5%, $P < .01$) demonstrated consistently lower mortality when treated at higher-volume centers. In contrast, among those with a risk of less than 1.5%, there was not a significant volume effect on 30-day operative mortality rates.

Discussion

Both JATS and JACVSD analyses demonstrated an association between hospital CABG procedural volume and CABG outcome. Although high-quality evaluations of CABG volume–outcome relationships using data from the STS National Cardiac Database[27] also found an association between volume and outcome, the effects of hospital volume were modest compared with our findings. This may be partly due to the straightforward case mix across volume category (Table 2) or the different distribution of hospital CABG procedural volume in each country. As 4 fairly equal-sized hospital volume break points were 150 or less, 150 to 300, 300 to 450, and greater than 450 in the United States, 98.3% of Japanese centers would be categorized as low-volume hospitals by the US definition. In Japan, there are no standards for opening a cardiac surgery program; they simply proliferate without any regulatory oversight. Although low-volume cardiac surgery programs are loss-making of themselves, many hospitals want a cardiac surgery program not only for the backup of percutaneous coronary intervention but also for prestige as a general hospital. Our results suggest that minimal volume standards of cardiac surgery would be an effective way to improve CABG outcomes.

The outcome improvement shown in Figure 1 also suggested that the effect of the hospital volume learning curve might be stronger in lower volume distribution in Japan. The reason for the difference regarding volume effect between Japan and other countries may be multifactorial. As many surgeons belong to a single hospital in Japan, information and experiences of conferences on each patient are shared with many cardiac surgeons and other medical staffs in the hospital. Usually, cardiac surgery is performed not by a single consultant but by two or more consultant surgeons with trainees. Characteristics of the Japanese health insurance system might be another reason, because insurance covers a large part of the medical expense with a small individual payment at each operation.[28] Patients can stay in the hospital



	-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90	91-100	101-
No. of patients	1780	6530	9419	9479	9858	6227	7494	6267	3411	4931	17215
No. of hospitals	87	105	94	68	55	28	29	21	10	13	30

Figure 1. Unadjusted 30-day mortality rates by CABG procedural volume in JATS database (2001–2004).

beyond 1 or 2 weeks if needed without extra huge expenses, and they can choose any surgeon and hospital they prefer, regardless of their insurance. Surgeons can conduct surgical and medical treatments at the maximum level with less pressure from the hospital and insurance company compared with surgeons in other countries. Moreover, postoperative care in the intensive or critical care unit is maintained mainly by physicians and not by nursing staffs in Japan, which may lead to better care than otherwise.[29] Because of these differences, minimal volume standards for CABG surgery in Japan might be preferable at lower levels than those in the United States.

As noted in previous studies by Peterson,[27] Hannan,[30] and their associates, Table 4 shows that even for very low numbers of cases, low-volume surgeons have substantially better results when they operate at higher-volume hospitals. High-volume hospitals might also be important as teaching institutes. Tables 5 and 6 show that the volume–outcome relationship may be most evident for higher risk patients (older, more comorbidities). In addition to regionalization of cardiac surgery, patient transfer system (eg, transferring high-risk patients to high-volume hospitals quickly) also needs to be developed for better quality of cardiac surgery in Japan.

As for public reporting, hospital-based evaluation might be more relevant than surgeon-based evaluation. Hospital volume index (total adult cardiac procedure volume, hospital CABG-related surgery procedural volume, and hospital CABG-only procedural volume) was significantly associated with 30-day mortality and operative mortality. On the other hand, the surgeon–volume index was not significantly associated with these outcomes. Inasmuch as there are few open-bed hospitals and most surgeons and their teams belong to a single hospital in Japan, a large proportion of surgeon volume might be accounted for by hospital volume. Other studies suggest that individual report cards might discourage surgeons from operating on high-risk patients, because it is surgeons, not hospitals, that choose whether or not to accept a patient for surgery.[1,2] As for the public reporting regarding outcomes of cardiac surgery in Japan, releasing a hospital-based outcome might be more preferable.

In 2002, the Japanese Ministry of Health, Labor and Welfare set minimal standards by references to hospital procedure volume for medical treatment fees on surgery.[31] As for cardiac surgery, medical institutes in which the annual cardiac surgery procedural volume was less than 100 had their medical treatment fees lowered by 30%. As many stakeholders objected, these standards were suspended in 2006. Minimal volume standards for CABG surgery in Japan may also be modest not only because most medical institutes (over 60%) had been lowered by those standards[32] but also because of the limitation of procedural volume as a marker of CABG quality. Even when a significant association exists, hospital volume is not a complete predictor of outcome for individual hospitals. Inasmuch as hospital procedural volume embraces physicians' skills, experienced interdisciplinary teams, well-organized care processes, and hospital facilities, it is a necessary factor when outcomes are considered. However, many other parameters (namely, outcome monitoring, compliance with process measures, appropriateness of patient selection for surgery) may also be associated with better outcomes.[1,33] Thus volume alone is not sufficient for predicting outcome in Japan. In addition, there was wide variance in the results observed among individual centers, particularly those in the low-volume category (Table 1), indicating that not all high-volume providers have better outcomes and not all low-volume providers have worse outcomes. Further studies should include an examination of those parameters to improve the outcomes of individual centers.

Outcome-based evaluation is also an important way to improve quality of CABG surgery. However, surgical mortality has several limitations as an indicator of hospital quality under the present circumstances in Japan because small sample size and low event rates combine to diminish statistical power.[34] Although volume is not a complete indicator of quality, high-volume providers have, on the whole, better outcomes than low-volume providers. In addition, the effect of hospital procedural volume was significantly associated with better outcomes in almost all patient subgroups (except for low-risk surgery). Regionalization of medical centers on the basis of hospital procedural volume might be effective to improve quality to some extent. However, regionalization has an impact not only on hospital quality, but also on patients' access, staffing of medical professionals, cooperation with other departments in the hospital, and health care expenditure. As for specific health policy recommendations, further analysis is needed to consider these factors. When case loads become large enough to support outcome measurement through regionalization, it is also feasible to base quality assessments on both outcome data and volume (or on one of these).

Several limitations should be noted. In the JACVSD analysis, we excluded centers that submitted fewer than JATS results, because the appropriateness of patient selection for procedural conditions seemed to be important for a volume–outcome study. A former study also found that high-volume surgeons performed a higher proportion of operations for which the indications were inappropriate than low-volume surgeons.[35] It is probably appropriate for fair comparison to exclude centers whose reporting is incomplete. Moreover, improving quality of the database is a continuing issue in JACVSD. As for data accuracy, not only data auditing but also to educate each site's input data in correct definition is important.

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EDITORIAL

Editorial

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In 2002, the Japanese Ministry of Health, Labor, and Welfare set minimum standards by relating surgical fees to hospital procedure volumes.[1] This policy may have been based on the hypothesis that outcomes of complex health care procedures are better when done by providers or hospitals that perform them more frequently. Specifically, for cardiac surgery, medical institutions that had an annual cardiac surgery procedure volume of fewer than 100 cases had their medical fees lowered by 30%. However, many of those closely involved raised objections to this practice. Although this standard has been suspended since 2006, the Japanese Ministry of Health, Labor, and Welfare is still considering whether regionalization based on hospital volumes would be appropriate.

Meanwhile, the Japanese government updated the medical practice laws in June 2006. Each local government was given the power to require medical centers to submit and release "certain information" that, it was thought, would be useful to patients who are choosing a hospital, starting in April 2007.[2] As of January 2007, this "certain information" includes hospital procedural volumes but few outcome indicators such as operative

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mortality or morbidity rates. However, there exists a possibility that the "certain information" could come to include outcome indicators similar to those used in public reporting in New York State.[3,4] We are facing calls for more accountability for quality improvement in thoracic surgery.

The report[5] from the Committee for Scientific Affairs of the Japanese Association for Thoracic Surgery (JATS) offered valuable insight into these issues. In addition to its representativeness, the Committee's report covered, on the one hand, many procedures in thoracic surgery; on the other hand, its limitations should also be noted: its failure to address risk adjustment, the appropriateness of patient selection, and the variety of outcomes. As for coronary artery bypass grafting (CABG) surgery, another report[2] from the Japanese Adult Cardiovascular Database (JACVSD) conducted risk-adjusted analysis, and its results suggested an inverse correlation between hospital volume and operative mortality. Many other systematic reviews from outside Japan have suggested similar results in the health care field.[6–11] Because a hospital's procedural volume in each field can be attributed to the skills of its physicians, experienced interdisciplinary teams, well-organized care processes, and hospital facilities, it is necessary that they be included when outcomes are considered. Although further detailed study may be needed, especially for lung cancer surgery and esophageal cancer surgery, the report of Kazui et al.[5] is important not only for health policy issues but also for quality improvement regarding Japanese thoracic surgery.

As for health care quality improvement, regionalization of medical centers based on hospital procedural volumes might be acceptable to some extent. However, we thought that the former minimum standard set by the

Japanese Ministry of Health was premature because approximately two-thirds of Japanese medical institutions still conduct fewer than 100 procedures each per year.[12] As the definitions of low volume within each field and from field to field vary widely,[5] minimum volume standards need to be set carefully for each specialty. Moreover, regionalization has an impact not only on hospital quality but on patient access, staffing with medical professionals, cooperation with other departments in the hospital, and health care expenditure. It is essential to examine carefully the effects of minimum volume standards.

Volume alone is not sufficient for predicting outcome, as indicated by the large variation in the results observed among the individual centers. Not all high-volume providers have better outcomes, and not all low-volume providers have worse outcomes. In addition, not only hospital volume but many other parameters (e.g., outcome monitoring, compliance with process measures, appropriateness of patient selection for surgery) may well be associated with better outcomes.[3,13] Quality improvement in the health care field can probably not be achieved satisfactorily using minimum volume standards alone. Evaluating and encouraging quality improvement based on health care outcomes is also important for improving the quality of thoracic surgery.

Birkmeyer and Birkmeyer[14] suggested three strategies for improving surgical quality based on performance: (1) centers of excellence (selective contracting, financial incentives for patients, public reporting to direct patients to the best hospitals or surgeons); (2) improvement of quality in all hospitals by offering greater financial reward for superior performance ("pay for improvement"); and (3) improvement of quality in all hospitals by underwriting clinical outcome registries and quality improvement activities ("pay for participation").[14] These outcome-based evaluations need to satisfy two requirements: (1) detailed clinical data for risk adjustment,[14] and (2) a large enough sample size for each hospital's outcome indicator.[15]

In Japan, however, no mature clinical database projects and no forums for discussion regarding risk adjustment have been established except cardiovascular fields. It may also be difficult in many medical centers to ensure a large enough sample size for each procedure. We believe it is too early to initiate public reporting or "pay for performance" procedures. Therefore, a "pay for participation" system appears to be the prime choice, at least for the time being, for improving the quality of surgery in Japan.

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Expert Commentary

Low-volume coronary artery bypass surgery: Measuring and optimizing performance

David M. Shahian, MD,[a] and Sharon-Lise T. Normand, PhD[b]

See related article on page 1306.

In the current issue of the *Journal*, Miyata and colleagues[1] describe the relationship between coronary artery bypass grafting (CABG) procedural volume and outcome in Japan. In reality, however, there are no high-volume programs in this study. What the authors have actually provided us is the most extensive study of low-volume and extremely low-volume CABG surgery in the literature. It complements previous studies from the United States that include some programs with low volumes, and it provides a striking counterpoint to New York studies that are weighted toward the high end of the volume spectrum.

This report illustrates the potential for good performance at low volumes, as well as the statistical challenge of accurately measuring performance when sample sizes are small. It raises a number of unresolved issues in the ongoing volume–outcome debate, at least as applied to CABG surgery. For example, some payers and other stakeholders continue to promote best-practice volume requirements that are increasingly beyond the grasp of many programs, particularly as overall CABG volumes decrease nationally. Is this appropriate policy given the available outcomes data? Because many lower-volume programs function at a high level, can the public be protected while at the same time not penalizing such excellent programs? Is there a rational lower volume limit for CABG surgery programs? Are there better ways to measure performance that are less compromised by small sample sizes? Are there specific process and structural approaches that might promote optimal functioning of small programs?

Is Low-volume CABG Surgery a Performance Problem or a Measurement Problem?

CABG is unique: it is a mature, standardized procedure that is performed more frequently than any other complex operation and that has also been scrutinized more thoroughly. Notwithstanding the general validity of the volume–outcome relationship for a number of medical conditions and surgical procedures, data from a variety of sources suggest that many low-volume CABG providers achieve excellent results.

We believe the fundamental issue with low-volume CABG surgery is not inherently poor performance but rather the difficulty in accurately measuring performance. These 2 perspectives have quite different implications. If it were clear that low-volume CABG providers were uniformly poor performers, immutably limited by their lack of sufficient "practice," then the only reasonable solution would be volume thresholds. For some highly complex but very infrequently performed procedures, such as esophagectomy or pancreatectomy, this might well be a justifiable approach.

In reality, however, excellent performance is achieved by many CABG providers whose volumes, although they might number in the hundreds annually, do not meet the thresholds of organizations like the Leapfrog Group (450 procedures per year). In this circumstance, volume standards would unfairly stigmatize or penalize such high-quality but low-volume providers. Furthermore, at a time when CABG volumes

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are decreasing, such thresholds could also have unintended negative consequences. Given the importance of cardiac surgery to most institutions, failure to meet guidelines for "center of excellence" status or premium reimbursement might have substantial adverse implications. This could result in a perverse incentive to relax appropriateness criteria to meet volume thresholds, which might have a net negative effect on the health system.

If one views low-volume CABG providers as a heterogeneous group, many of whom provide excellent results, then the main issue is how to accurately measure the performance of individual programs, a challenge with small sample sizes and limited mortality events. More comprehensive and robust approaches to performance measurement could be developed that are less limited by such concerns, and specific programmatic initiatives could also be implemented to facilitate high performance in smaller programs.

We will examine both the evidence for a CABG volume–outcome relationship as well as statistical problems with assessing performance in low-volume programs. Findings from the study of Miyata and colleagues[1] will be reviewed in the context of these two issues. Finally, recommendations will be presented to enhance both performance and its measurement in low-volume CABG programs.

Previous CABG Volume–outcome Studies

Although the strength of the CABG volume–outcome relationship is probably exaggerated in some studies by failure to account for sample size and clustering (eg, through the use of hierarchical models),[2] there is little question that some association exists. This was evident in the original work of Luft and associates[3] nearly 30 years ago, and it has been demonstrated in numerous subsequent studies, including those from the modern era.[4-11] The strongest data supporting a volume–outcome association come from New York, although these studies include very few programs that are truly low volume, and their findings might not be generalizable. In 2004, for example, there were 39 New York programs providing isolated CABG surgery, and 75% of these programs had volumes of greater than 214 procedures. It remains uncertain whether the CABG volume–outcome relationship applies to all patients[10] or primarily to those at higher risk.[12,13]

Notably, the volume strata and mortality ranges for CABG are quantitatively unique among complex procedures in which the volume–outcome association has been investigated. In studies by Birkmeyer and associates[4] using claims data on 901,667 Medicare patients, low and high volume hospital categories for CABG were < 230 procedures and > 849 procedures respectively, with an absolute mortality difference of only 1.1% (4.5% vs 5.6%) between these two extremes. In contrast, the low and high volume ranges were <1 and >16 procedures for pancreatecomy and <2 and >19 procedures for esophagectomy, with absolute differences in adjusted mortality that were orders of magnitude greater (16.3% vs 3.8% for pancreatectomy, 20.3% vs 8.4% for esophagectomy) than those for CABG.

Perhaps because it is a mature and frequently performed procedure, the volume–outcome association for CABG is weak. Studies by Peterson and coworkers[13] using 2000–2001 data from the Society of Thoracic Surgeons (STS) National Adult Cardiac Database, adjusted for risk factors and clustering, demonstrated only a 0.07% decrease in mortality for every additional 100 procedures ($P = .004$). Because there was substantial variability in mortality in all strata of volume, there was limited ability to discriminate among providers based solely on volume. Similar findings were noted in a study of 228,738 patients by Rathore and associates[7] using data from the 1998–2000 Nationwide Inpatient Sample. In both studies, the vast majority of low-volume providers are distributed widely and symmetrically about the mean, with variation increasing at progressively smaller program volumes. Scatterplots of observed mortality versus volume in these studies look strikingly similar to the funnel appearance of the 95% confidence intervals of a binomial event, with an average occurrence rate of about 2% to 3%, taken at various sample sizes.[14] This is illustrated in Figure 1, a scatterplot based on the 2004 isolated CABG results from Massachusetts, New York, Ontario, and California. Superimposed scatterplot smoothers are roughly horizontal, showing little volume–outcome association. Much of the variability in mortality at low volumes, regarded by many as an indicator of inconsistent performance, is quite likely explained by sampling error.

Outcomes Profiling in Low-volume Programs

An alternative approach to volume thresholds is outcomes profiling. Public reporting of CABG outcomes is favored by many policymakers and has been mandated by law in states like New York and Massachusetts. Properly performed (by no means a trivial caveat), such reports are reasonably objective, they provides transparency and accountability, and they address the most important interest of patients: operative survival. However, they are the most demanding in terms of the need for high-quality data, audit and validation, and appropriate analytic methodologies. Even with larger sample sizes, comparative assessment of provider performance can be challenging, especially when based on a single outcome such as mortality. This becomes increasingly problematic as sample sizes (program volumes) decrease, a feature illustrated previously with regard to volume–outcome studies.

Outcomes profiling generates estimates of provider performance derived from a snapshot in time, typically a year of clinical activity. Such observed results are used to estimate "true" underlying program quality, ideally with confidence intervals that indicate how certain we are about this point estimate. As noted previously, the statistical confidence intervals around point estimates of mortality, an infrequent binomial event, become quite wide with small sample sizes (annual program volumes).[5] Much of the variation of annual

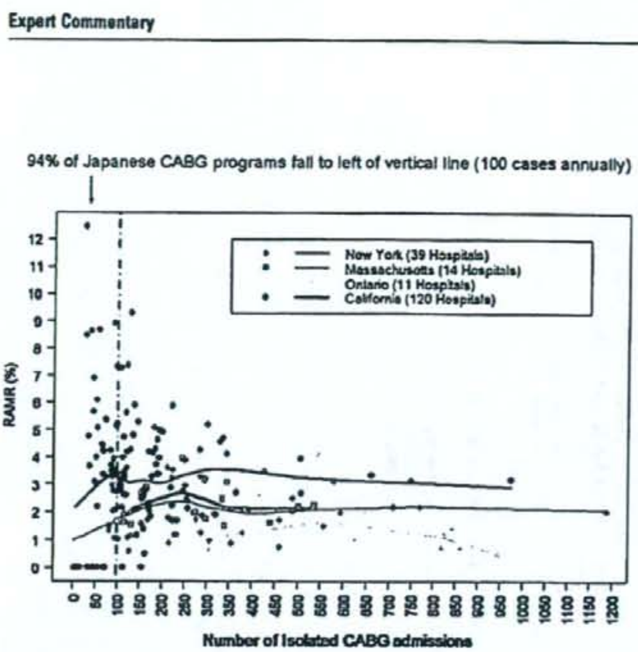

Figure 1. Scatterplot of 2004 coronary artery bypass grafting *(CABG)* volume *(x-axis)* and risk-adjusted mortality rates *(RAMR; y-axis)* from New York, Massachusetts, California, and Ontario. Superimposed scatterplot smoothers are relatively flat. There is wide variability in outcomes at low volume, which is predominately sampling error. In the 2001–2004 Japanese CABG experience reported by Miyata and colleagues,[1] approximately 94% of programs would lie to the left of the vertical line drawn at a volume of 100 procedures annually (estimated by averaging the results over these 4 years). Individual hospital data from Japan were not available.

mortality rates among low-volume programs (eg, fewer than 100–150 procedures per year), as shown in Figure 1, can be largely explained by random statistical fluctuation, and this in turn limits the ability to draw firm conclusions about program quality.[5,15] In studies by Dimick and colleagues,[15] CABG was the only complex procedure performed with sufficient frequency by most programs to detect a doubling of mortality rate based on 3-year aggregate data. However, as CABG mortality rates continue to decrease, the sample sizes necessary to detect meaningful differences increase correspondingly.

The Japanese Experience: Extremely Low-volume CABG Surgery

This brings us to the study by Miyata and colleagues[1] in the current issue of the *Journal*, an extreme and revealing illustration of both the "problems" of low-volume surgery, as well as some potential solutions. The authors describe the demographics of CABG programs in Japan, where annual volumes are so uniformly low that there is simply no US analog.[3,4,7] In Japan there has been limited regulatory oversight of cardiac surgery program proliferation or performance prior to the past few years. Relative to their population size, lower incidence of coronary disease, and number of isolated CABG procedures, the number of CABG providers in Japan far exceeds that of any publicly reported US states or the province of Ontario, as demonstrated in Table 1. Overall, 76% of Japanese programs perform fewer than 50 CABG procedures annually. Only 5.6% of 540 Japanese cardiac surgery programs (representing most of the programs in the country) performed at least 100 CABG procedures annually between January 2001 and December 2004, and 24.6% of programs performed fewer than 15 procedures annually. Median annual CABG volume was 28 procedures per year during this period (interquartile range, 15–49 procedures), and the average annual volumes ranged from 0.25 to 293 isolated CABG procedures. Using a threshold of 150 procedures annually, 98.3% of Japanese programs would be classified as low or very low volume by US standards. Based on the findings of Miyata and colleagues,[1] 94% of Japanese CABG programs would fall to the left of the vertical line (annual volume of 100 procedures) in Figure 1, which would be very low volume by US and Canadian standards.

By comparison, during 2000–2001, the median volume of CABG procedures among STS National Adult Cardiac Database participants was 253,[13] notably still less than the Leapfrog threshold of 450 procedures. At the high-volume extreme, New York has had a longstanding aggressive approach to monitoring and improving cardiac surgery quality.[16] Between 1997 and 1999, median CABG volume at New York hospitals was 527 procedures (mean, 577 procedures; interquartile range, 331–816 procedures). Only 2.14% of patients undergoing CABG were treated at hospitals performing fewer than 200 such procedures annually,[10,11] and only about one tenth of New York hospitals had annual CABG volumes of less than 200 procedures.

Given the consistently low volume of most Japanese CABG programs, their overall results will come as a surprise to many. The most complete data source for this study was a survey of 540 programs collected by the Japanese Association for Thoracic Surgery, including almost all programs in the country. The overall mortality rate was 1.9%, and mortality for all volume categories above 41 to 50 procedures per year was less than 2%, which is comparable with rates in most US state and national CABG registries. Mortality rates

TABLE 1. 2004 CABG volumes, numbers of programs, and outcomes for selected states and provinces compared with estimated annual Japanese experience

Region	Population aged ≥18 y*	2004 isolated CABG admissions	2004 CABG admissions per 100,000 adults	2004 CABG programs	2004 CABG programs per 1000 CABG admissions	2004 isolated CABG volume, median (min–max)	2004 crude operative† mortality (%)	2004 RAMR (%), median (min–max)‡
California§	26,924,935	19,101	70.9	120	6.3	120 (4–975)	3.29	3.30 (0–12.5)
New Jersey‖	6,635,222	6177	93.1	17	2.7	290 (102–755)	1.98	NA
Massachusetts¶	4,988,309	3986	79.9	14	3.5	287 (101–537)	2.01	2.09 (1.50–3.95)
New York#	14,791,841	12,988	87.8	39	3.0	288 (1–1188)	2.09	2.01 (0–3.6)
Ontario**	9,439,990	7196	76.2	11	1.5	647 (305–945)	1.24	1.11 (0.46–4.11)
Pennsylvania††	9,635,748	13,359	138.6	60	4.5	195 (56–888)	2.31	NA
Japan (current study)‡‡	105,943,707	20,000 (‡‡)	18.9	540+	27	28 (0.25–293) (‡‡)	1.92 (‡‡)	NA

CABG, Coronary artery bypass grafting; *RAMR*, risk-adjusted mortality rate; *NA*, not applicable.

* For the US States: US Census Bureau Population Estimates 2006 (http://www.census.gov/popest/states/asrh/SC-EST2006-01.html); for Ontario: Statistics Canada, Canada's National Statistics Agency, Age and Sex for the Population of Canada, Provinces, Territories, Census Metropolitan Areas and Census Agglomerations, 2001 and 2006 Censuses (http://www12.statcan.ca/english/census06/data/topics/RetrieveProductTable.cfm?ALEVEL=3&APATH=3&CATNO=&DETAIL=0&DIM=&DS=99&FL=0&FREE=0&GAL=0&GC=99&GK=NA&GRP=1&IPS=&METH=0&ORDER=1&PID=88984&PTYPE=88971&RL=0&S=1&ShowAll=No&StartRow=1&SUB=0&Temporal=2006&Theme=66&VID=0&VNAMEE=&VNAMEF=&GID=837983); for Japan: Statistics Bureau, 2005 Population Census, First Basic Complete Tabulation (http://www.stat.go.jp/English/data/kokusei/2005/kihon1/00/hyodai.htm).

† Operative mortality was defined as follows: for California, Massachusetts, Ontario, and Pennsylvania, all deaths occurring within 30 days of surgical intervention, regardless of where the patient died; for New Jersey, all deaths up to 30 days after surgical intervention or deaths occurring during the hospital stay in which the operation was performed, regardless of the number of days after the procedure; for New York, all deaths within the hospitalization, all discharges (alive or dead) to hospice care except those still alive at 30 days, and all other 30-day deaths.

‡ New Jersey and Pennsylvania present risk-adjusted mortality rates graphically and do not report specific numbers.

§ California CABG Outcomes Reporting Program (2007). Coronary Artery Bypass Graft Surgery in California: 2003–2004 Hospital and Surgeon Data. CA Office of Statewide Planning and Development; http://www.oshpd.ca.gov/HID/Products/Clinical_Data/CABG/03-04fullreport.pdf.

‖ New Jersey Department of Health and Senior Services (May 2007). Cardiac Surgery in New Jersey 2004. Office of the Commissioner; http://www.nj.gov/health/healthcarequality/documents/cardconsumer04.pdf.

¶ Massachusetts Data Analysis Center (October 2006). Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: January 1, 2004–December 31, 2004. Department of Health Care Policy, Harvard Medical School; http://www.massdac.org/reports/CABG%202004.pdf.

\# New York State Department of Public Health (June 2006). Adult Cardiac Surgery in New York State: 2002–2004; http://www.health.state.ny.us/diseases/cardiovascular/heart_disease/docs/cabg_2002-2004.pdf.

** Guru V, Wang J, Donovan L, Tu JV (June 2006). Report on Coronary Artery Bypass Surgery in Ontario: Fiscal Years 2002–2004; http://www.ccn.on.ca/memberpdfs/Report-CAB-Surg-Ontario-2002-2004.pdf.

†† Pennsylvania Health Care Cost Containment Council (February 2006). Pennsylvania's Guide to Coronary Artery Bypass Graft Surgery 2004; http://www.phc4.org/reports/cabg/04/docs/cabg2004report.pdf.

‡‡ Miyata and colleagues (current study).[1] 2004 volume estimated from 2001–2004 aggregate data. Number of programs (540) represents, per Miyata and colleagues, almost all CABG programs in Japan. Crude mortality rate is based on 2001–2004 aggregate data. Risk-adjusted results are not presented because they are based on only a small sample of overall programs.

for programs with annual volumes of less than 41 to 50 procedures ranged from 2.42% to 3.15%.

Because these voluntary survey data lacked both adequate risk adjustment and careful audit, the authors also studied a small subset of 36 highly selected Japanese programs that contributed data to the Japanese Adult Cardiovascular Surgery Database, a clinical registry modeled after the STS National Adult Cardiac Database. Table 2 of their article demonstrates that patients in these programs had a distribution of risk factors not dissimilar to what would be observed in many US CABG registries. Unadjusted 30-day mortality was 1.88%, and operative mortality (including in-hospital deaths occurring after 30 days) was 2.55%. Risk-adjusted 30-day mortality was 1.50% for programs with an annual volume of 51 or more procedures and 2.14% for hospital volumes of 31 to 50 procedures.

What Do the Japanese Results Tell Us?

These aggregate data illustrate the feasibility of achieving good overall performance at low volumes, but they do not address the problem of accurately measuring individual hospital performance based on small samples. Although individual hospital volumes and outcomes are not provided by the authors, one would presume that at median volumes of 28 procedures per year, random sampling variation alone could result in mortality rates from zero to greater than 10% for some programs, regardless of their underlying true performance. With volumes and sampling variability in this range, there is virtually no practical way to monitor quality in any meaningful time frame.

What are the implications of these generally favorable results for policymakers in Japan and the United States? In our view, despite the reasonable overall results, this study certainly should not be interpreted as justification for reduced vigilance of low-volume programs. Rather, it is just another example, albeit a dramatic one, of how low-volume programs can often function quite well. This study does not address the issue of identifying individual high- and low- performing, low-volume programs.

The Japanese study also leaves many other important questions unanswered. For example, there are few if any truly high-volume programs in this study with which to compare the performance of their otherwise low-volume centers. Overall Japanese CABG mortality rates seem reasonable, but are they optimal given their demographics and current resources? If Japan had a number of true high-volume programs, would their mortality rates for the same patient population be even lower than those currently being reported?

How Can Low-volume Programs Perform at High Levels?

These seemingly good results should also lead us to inquire more deeply into the structures and processes of care at these low-volume Japanese programs. Even with the obvious caveats regarding sample size and risk adjustment, there is no compelling evidence in these results or elsewhere in the literature of a CABG mortality crisis in Japan. Perhaps there are lessons from this extreme example that might be applicable to less extreme but smaller programs in other countries. To some extent there is truth in the axiom that practice makes perfect, and some level of repetition is essential for any complex task. But repetition is not the only or perhaps even the best path to high performance. Countless repetitions of suboptimal practices only reinforce those practices and leads to no improvement whatsoever. Identification of optimal practices affords the opportunity for substantial learning with every repetition, even if the overall number of repetitions is smaller.

Why have so many programs been able to perform at least reasonably well in this very low-volume environment? Are there unmeasured differences in case mix or selection criteria compared with the US experience? Is there a proportionately higher volume of other types of cardiac surgery, including CABG combined with other procedures, that maintains both technical proficiency for individual surgeons and also effective team functioning? Are there particular surgical techniques, perfusion methodologies, or standardized perioperative care routines that have enhanced the overall outcomes of their patients?

Team functioning can affect CABG outcomes to a greater extent than in other procedures. Cardiac surgery is a team effort, a complex interaction of surgeons, assistants, nurses, anesthesiologists, and perfusionists. Low-volume surgeons have better results when operating at high-volume hospitals,[8,11] presumably because they benefit from their standardized processes and team functioning. By the same token, even a higher-volume surgeon might not function optimally when working with an unfamiliar team. In a recently reported California experience, much of the salutary effect of being a higher-volume surgeon was negated if the surgeon did not perform these cases in the same institution (and presumably with the same team).[17]

In the Japanese experience most surgeons work with their own teams and function in only one hospital. Many cases are staffed by 2 attending surgeons, and the authors also note the importance of physician oversight of postoperative intensive care unit care. Finally, because of their insurance system, there is less pressure for early discharge, which might reduce the frequency and adverse effect of unrecognized late complications and readmissions.

Recommendations

In light of past research and current findings, we can envision a number of approaches to low-volume CABG surgery that might have applicability both in Japan and elsewhere.

Extreme Low-volume CABG Surgery: Consolidation or Regionalization

Is there a lower acceptable limit for CABG volume? Despite our strong support of direct outcomes measurement and general skepticism of volume thresholds, it is intuitively difficult to believe that optimal CABG results can be achieved in an institution performing a few procedures a month, the situation in many Japanese programs. Perhaps there are unique geographic, demographic, cultural, or political considerations that support the perpetuation of the most extreme low-volume Japanese programs, but these should be individually reviewed. Within this group, it is certainly possible that some programs perform well. However, at such extreme low volumes, there is no possibility of accruing sufficient data to reliably measure performance, at least in a reasonable time frame. Consolidation of the most extreme low-volume programs would be, in our opinion, a significant step toward a more rational CABG delivery system in Japan (and elsewhere). How to define this category of programs is challenging, but in many areas fewer than 100 to 125 isolated CABG procedures annually might be a reasonable starting point for discussion. The exception might be a center performing a large number of other cardiac procedures combined with CABG.

Low-volume CABG Surgery: Improving Performance Assessment

There are many smaller programs above the extreme low end of the volume spectrum, and for them it is essential to develop better, more comprehensive, and timely methods to monitor performance. This will necessitate uniform adoption of some currently available methods, as well as the implementation of some more innovative approaches.

Clinical data registry

Although participation in a clinical data registry is important for all cardiac surgery programs, it should be absolutely mandatory for lower-volume programs to maximize the available information regarding patient case mix, appropriateness of surgical indications, and risk-adjusted performance. In Japan, the Japanese Adult Cardiovascular Surgery Database would seem to be an appropriate instrument with which to implement such a program, particularly given its established mechanisms for audit and validation.

Statistical methodologies

For low-volume programs, performance estimates should be based on multiple years of aggregate data and can be reported as a rolling average. This provides larger sample sizes, albeit at the expense of using some data that are several years old and perhaps less relevant to current conditions. The use of hierarchical statistical models is also recommended to address sample size and clustering issues.[18-20]

Several graphical methods can also aid in monitoring program performance. Funnel plots have been advocated for performance measurement[14] because they explicitly depict the increasing random statistical uncertainty of a binomial event at small sample sizes. The results from low-volume programs look much less anomalous when viewed from this perspective.

Another graphical approach to monitoring performance, the CUSUM (Cumulative Sum) chart and its variants,[21] has also been used increasingly in recent years. These methods provide sensitive, real-time monitoring with the potential for earlier detection of deteriorating trends in performance, and they might be less dependent on the accrual of large sample sizes.

Composite measures

Composite measures of CABG quality have recently been developed and implemented by the STS,[22,23] and these might be particularly advantageous in following small programs that have a correspondingly low number of mortality end points. Because they contain more end points encompassing multiple domains of care (not just mortality), such composites are useful in assessing and comparing quality. Additional end points include both morbidity outcomes measures and process measures, the latter including use of internal thoracic artery grafts and medications proved to reduce long-term cardiovascular risk. The STS composite CABG measure has been shown to enhance the ability to differentiate performance among providers.

Appropriateness

Given the pressure to attain volume thresholds, it is particularly important to monitor procedures at lower-volume programs for appropriateness. This can be done by using standard criteria established by the American College of Cardiology/American Heart Association.

Patient satisfaction

Measures of patient satisfaction are becoming increasingly important, such as the Consumer Assessment of Healthcare Providers and Systems program. Such measures can be particularly useful in assessing the relative value to patients of having surgical intervention in their smaller local hospital versus traveling to a larger tertiary center.

Direct expert review

Finally, in some situations regulators might determine that a particular low-volume program must undergo case-by-case monitoring by an external expert panel as the quid pro quo for continued licensure. This expert committee could meet on a regular basis to review both appropriateness and outcomes for each case.

Low-volume CABG Surgery: Process and Structural Aids to High Performance

Adherence to best practice guidelines

In addition to using more reliable and comprehensive measures of performance, smaller programs must have strong incentives to use established best practices. Based on practices developed at larger institutions, these might help to offset their relatively smaller experience.

Case selection

Except for emergencies in which patient transfer is not feasible, smaller programs should be highly selective in the type of cases they perform. Although the individual surgeons might be skilled and experienced in more complex operations, the experience of the team will likely be limited, as will the other hospital resources necessary to care for such patients perioperatively.

Sponsorship and oversight by tertiary centers

Ideally, low-volume programs should not function in isolation. When feasible, they should be sponsored by larger tertiary centers that share the responsibility for ensuring and improving their quality. Standardized processes of care can be directly imported from the tertiary center, and there might be periodic exchange of staff to bring new ideas and techniques. Teaching conferences and lectures can be scheduled regularly, either live or by means of videoconferencing, and there might even be resident rotations from the tertiary center to the low-volume program. The low-volume center may enjoy some volume purchasing advantages because of its affiliation with the larger center. Sponsoring institutions share joint responsibility with the low-volume center for staff credentialing, scrutiny of outcomes, and remediation when appropriate. Finally, the low-volume center has an established referral pathway for more complex and severely ill patients. Because they are part of the larger program, there is no incentive to retain cases for which they are not equipped (patient-program mismatch). A prototype for such an arrangement has been in place in Massachusetts for a number of years and has functioned quite well.

Team functioning

Small programs should generally be restricted to one surgical practice group to minimize the potentially adverse effect of competition for a limited number of cases. This structure also maximizes the joint experience of the single surgical team, an extremely important consideration, particularly given the recent report from California.[17] It may be useful to have two attending surgeons scrub, particularly for more difficult cases, apparently a common practice in Japan. This maximizes the experience of both surgeons and provides additional peer assistance.

Team functioning and cohesiveness can also be fostered through crew resource management training, simulations, and regular team visits to tertiary centers.

Summary

Volume is only a proxy for outcomes, such as risk-adjusted mortality, and the volume–outcome relationship holds true only on average.[9] Because of the weak relationship of CABG outcomes to volume and the large sampling variation of observed mortality at low volume, attempts to improve CABG performance primarily through volume thresholds are problematic, except at the extreme. Direct outcomes measurement is a much more reliable approach for both accountability and consumer guidance, and it is more predictive of subsequent program performance.[24] From this perspective, the greatest advantage of volume thresholds is to increase sample sizes to enable more precise assessment of risk-adjusted outcomes,[25] the real metric on which we should focusing.

Many low-volume programs perform at a high level. Although it is appropriate to discourage extremely low-volume programs, many lower-volume centers not meeting Leapfrog or similar thresholds do provide high value to the public. Approaches should be considered that optimize the functioning of such units, and more comprehensive techniques should be used to facilitate performance monitoring in lower-volume settings.

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Toward quality improvement of thoracic aortic surgery: estimating volume-outcome effect from national clinical database☆

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Abstract

Background: Although understanding the association between surgical volume and outcome has been the focus of much research, no study has yet reported the volume-outcome effect for thoracic aortic surgery. **Methods:** From the clinical database, we identified and analyzed 2875 procedures that took place across 36 centers between 2003 and 2005. The effect of hospital procedural volume was assessed for each outcome measure using a hierarchical mixed-effects logistic regression model. Clinical risk factors, procedural year, clinical processes, range of replacement, hospital volume and surgeon volume were set as fixed effects and sites were used as random intercepts. **Results:** The logistic regression model revealed that hospital thoracic aortic surgery volume was linked to statistically significant decreases in both 30-day mortality ($p = 0.127$: OR 0.988–0.999) and operative mortality ($p = 0.022$: 0.989–0.999). In addition, subgroup analysis showed that increased hospital volume was associated with reduced mortality rates in patients under 65 years of age ($p = 0.038$: 0.982–0.999) and in high-risk surgical candidates ($p = 0.019$: 0.989–0.999). Thoracic aortic surgery volume of surgeons, hospital adult cardiovascular surgery volume and surgeons adult cardiovascular surgery volume did not significantly impact these outcomes. **Conclusions:** In this study higher annual hospital thoracic aortic surgery volume of hospitals is associated with reduced mortality rates for thoracic aortic surgery. In Japan it is not the hospital general adult cardiovascular surgery volume, but the hospital specific thoracic aortic surgery volume that might be preferable for quality indicator of thoracic aortic surgery.

Keywords: Thoracic aortic surgery; Volume-outcome effect; Quality improvement; Public reporting; Cardiovascular; Clinical database

1. Introduction

Since the 1980s, much research has focused on measuring and understanding the association between surgical volume and outcomes in the delivery of health services [1,2]. Though two systematic reviews have suggested that high volume is associated with better outcomes for many surgical procedures [3,4] no study has yet reported volume-outcome effects for thoracic aortic surgery. Aneurysm and dissection are the principal thoracic aortic diseases, and the surgical principles and techniques used to treat these conditions are similar [5]. Thoracic aortic surgery accounts for 19% of all adult cardiac surgery in Japan, while isolated CABG surgery accounts for 48%, and valve surgery accounts for 29% [6]. Because thoracic aortic surgery comprises a large proportion of the cardiac surgery in Japan, volume-outcome analyses of these procedures have important implications for Japanese health policy. Moreover, such an analysis may also be valuable for other countries considering the efficacy of their healthcare delivery systems.

In this study, we investigated the association between hospital thoracic aortic surgery volume and clinical outcomes, using data from the Japan Adult Cardiovascular Surgery Database (JACVSD). The data collection form for the JACVSD is almost identical to that of the Society of Thoracic Surgeons (STS) National Cardiac Database. Because previous systematic reviews [3,4] have suggested that the variability in reported volume-outcome associations can be partly attributed to methodological shortcomings, rigorous design and analysis was considered to be essential. In this study we examined the relationships of hospital and surgeon procedural volume, appropriateness of patient selection, risk

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adjustment by risk model [7] with good calibration (H–L test +) and discrimination (C-index >0.75). We also used a hierarchical mixed-effects logistic regression model [8].

2. Methods

2.1. Study population

The JACVSD was established in 2000 to report detailed surgical outcomes following cardiothoracic procedures. In 2009, the database captured clinical information from nearly half of the centers conducting cardiovascular surgery in Japan. The data collection form has a total of 255 variables, which are almost identical to those used in the STS National Database (available online at http://sts.org). Definitions of JACVSD variables (available online at http://www.jacvsd.umin.jp) are also based on those of the STS National Database. Through the JACVSD system, data managers at each participating hospital enter data into a web-based data collection system. While participation in the JACVSD is voluntary, submissions tend to be thorough, with overall preoperative risk factors used in risk models missing in fewer than 3% of entries. The accuracy of the submitted data is verified through monthly visits to each hospital by administrative office members. After checking the data against clinical records and operative notes, administrators request that hospitals clarify any incomplete or unclear submissions. The validity of JACVSD data has further been confirmed by independent comparisons of hospital adult cardiovascular surgery volume submitted to the JACVSD against that reported to the JATS (The Japanese Association for Thoracic Surgery) data registry. We excluded eight centers that entered fewer cases in JACVSD than in JATS.

We identified all thoracic aortic surgery procedures performed between January 1, 2003 and December 31, 2005, including those combined with CABG surgery, valve surgery or other major surgical interventions. Fifty centers were members of JACVSD as of January 1st, 2003. After excluding eight centers for incomplete submissions and two centers for low thoracic aortic surgery volume (<5 procedures per year), our analysis included data from 40 centers. Including data of these 10 centers did not affect results of analysis.

2.2. Statistical analysis

The primary outcome measure of JACVSD analysis was 30-day operative mortality, defined as either 30-day mortality or death prior to hospital discharge [9]. The annual case volume of hospitals and surgeons was averaged over three years (2003–2005) to stabilize volume fluctuations.

The impact of hospital volume on unadjusted outcomes was tested using a hierarchical mixed-effects logistic regression model. Two indices of volume were employed in this study: thoracic aortic surgery volume of hospitals and surgeons, and total adult cardiovascular surgery volume (CABG, valve, thoracic aorta, other) of hospitals and surgeons. Previously identified clinical risk factors [7], procedure year, clinical events (beta-blocker usage), range of replacement (root, ascending, arch, distal aorta, descending, thoracoabdominal, abdominal) hospital procedural volume, and surgeon volume were set as fixed effects, and sites were used as random intercepts [8].

For 30-day operative mortality, we also presented volume interaction per hospital volume × surgeon volume (Table 3) and conducted subgroup analysis by patient age (<65 years and >65 years, Table 4 and preoperative risk (Table 5). Risk-adjusted mortality rates for each category were calculated by dividing the observed mortality rate by the expected mortality rate at the same hospital and multiplying by the overall thoracic aortic mortality rate of the JACVSD.

3. Results

Table 1 displays the patient characteristics of the JACVSD as a function of hospital volume. Between 2003 and 2005, 2875 thoracic aortic surgeries were performed at 36 participating hospitals. Although volume was considered to be a continuous variable in this analysis, unadjusted outcomes were divided according to annual hospital procedural volume for display purposes. The break points were selected to create three similarly sized hospital samples (5–20, 20–40, >40) of JATS data registry. Thirteen of the JACVSD participating hospitals, involving 481 patients, were categorized as medium-low volume hospitals (5–20 procedures per year); 14 hospitals, with 996 thoracic aortic surgery procedures, were categorized as medium-high volume hospitals (21–40 procedures per year); and 9 hospitals, with 1398 thoracic aortic surgery procedures, were categorized as high-volume (>40 procedures per year) hospitals. Based on risk models presented in former research [7], we calculated patient preoperative risks. The C-index values for these models were 0.78 for 30-day mortality and 0.78 for 30-day operative mortality. The average expected surgical mortality risk rates were 4.7% in medium-low volume hospitals, 5.3% in medium-high volume hospitals, and 4.0% in high-volume hospitals.

Overall, there were 210 cases of operative mortality, including 168 cases of 30-day mortality (42 patients died in hospital at greater than 30 days). Rates of operative mortality were reduced in high-volume hospitals, as compared to middle-low volume hospitals (Table 1). Table 2 displays the effect of each volume index on mortality outcomes. Only thoracic aortic surgery volume of hospitals was associated with significantly reduced 30-day mortality and 30-day operative mortality. Table 3 demonstrates the effect of hospital and surgeon procedural volume on risk-adjusted operative mortality rates. The lowest risk-adjusted operative mortality results (6.9%) were found in both high-volume surgeons at high-volume hospitals and low-volume surgeons at high-volume hospitals. Subgroup analysis of the impact of volume indices on mortality outcomes is shown in Tables 4 and 5. These subgroup analyses revealed that both unadjusted and risk-adjusted mortality rates were lower in high-volume hospitals than in middle-low volume hospitals. Only patients with expected risk over 6% ($p < 0.05$) and patients under 65 years of age ($p < 0.05$), however, had consistently lower mortality when treated at high-volume centers. No statistically significant effect of volume was noted in patients with an expected risk of less than 6% or in patients 65 years of age and older.

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Table 1
Patients characteristics and outcomes.

	Hospital thoracic aortic surgery volume, procedures per year**			All	p value
	5–20	20–40	40–		
No. of patients	481	996	1398	2875	
No. of hospitals	13	14	9	36	
Age at operation, median (IQR)	69.0 (61–75)	69.0 (59–75)	69.0 (58–75)	69.0 (59–75)	0.500
Sex (male)	63.6	64.1	69.1	66.4	0.006
Body mass index >26	21.4	20.7	20.3	20.6	0.945
History of smoking	45.7	47.9	45.4	46.3	0.691
History of diabetes	10.0	8.5	9.4	9.2	0.859
Diabetes control	6.9	5.5	6.5	6.2	0.608
Preoperative creatinine 2.0–4.0	4.2	3.7	3.7	3.8	0.952
Preoperative creatinine 4.0–	1.7	1.7	2.6	2.1	0.220
COPD (moderate, severe)	4.0	2.6	3.6	3.3	0.135
Neurological impairment	7.1	5.0	5.4	5.5	0.294
Marfan syndrome	4.8	3.1	4.6	4.1	0.869
Previous aortic stent graft	1.9	1.1	2.1	1.7	0.312
Myocardial infarction	2.5	3.2	1.8	2.4	0.095
Congestive heart failure	6.0	8.1	5.4	6.4	0.002
History of resuscitation	2.3	1.9	1.1	1.6	0.082
NYHA class IV	10.6	8.6	4.7	7.1	<0.001
Left main disease >50%	2.1	1.5	1.6	1.7	0.639
LV function (bad)	2.1	1.7	1.4	1.6	0.533
Reoperation	7.3	7.8	9.2	8.4	0.271
Status (urgent)	11.4	6.5	7.2	7.7	0.002
Status (emergent, salvage)	28.9	33.0	19.1	25.6	<0.001
CABG	6.4	8.4	4.1	6.0	<0.001
Unexpected CABG	1.0	1.5	0.5	0.9	0.057
Aneurysm type (dissection)	45.3	47.1	38.4	42.7	<0.001
Ope indication (rupture***)	8.5	12.7	7.9	9.6	<0.001
Preoperative risk (operative mortality)*	4.7 (3.1–9.0)	5.3 (3.2–9.9)	4.0 (2.8–7.9)	4.4 (3.0–8.8)	<0.001
30-day mortality	9.6	6.1	4.4	5.9	<0.001
30-day operative mortality	10.8	7.7	5.8	7.3	0.002

* Preoperative risk was calculated on the basis on JACVSD risk model.
** Number of patients are for 3-year periods (2003–2005).
*** Extravasation of blood to the out side of aortic lumen.

Table 2
The effect of volume index on each outcome.

Volume index, procedures per year	30-day mortality		Operative mortality	
	p values	Odds ratio	p values	Odds ratio
Hospital thoracic aortic surgery volume	0.027	0.988–0.999	0.022	0.989–0.999
Surgeon thoracic aortic surgery volume	0.324	0.997–1.010	0.491	0.996–1.008
Hospital adult cardiovascular surgery volume	0.246	0.998–1.000	0.057	0.998–1.000
Surgeon adult cardiovascular surgery volume	0.847	0.997–1.002	0.619	0.998–1.003

Table 3
Risk-adjusted mortality, by hospital and surgeon volume ($n = 2875$).

Surgeon thoracic aorta volume, procedures per year	Hospital thoracic aorta volume, procedures per year*						Overall	
	5–20		20–40		40–			
	%	n	%	n	%	n	%	n
–15	11.0	481	7.2	640	6.9	595	8.2	1716
15–	–	0	7.9	356	6.9	803	7.2	1159
Overall	11.0	481	7.5	996	6.9	1398		

* Number of patients are for 3-year periods (2003–2005).

4. Discussion

In this study higher annual hospital thoracic aortic surgery volume of hospitals is associated with reduced mortality rates for thoracic aortic surgery. In Japan it is not the hospital general adult cardiovascular surgery volume, but the hospital specific thoracic aortic surgery volume that might be preferable for quality indicator of thoracic aortic surgery.

Hierarchical mixed-effects logistic regression models suggested that high-volume hospitals had better outcomes than low-volume hospitals. These results support the findings of previous systematic reviews, which have reported that

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Table 4
Unadjusted and risk-adjusted mortality by patient age group ($n = 2875$).

	Age younger than 65 years			Age 65 years and older		
	Hospital thoracic aorta volume*			Hospital thoracic aorta volume*		
	5–20	20–40	40–	5–20	20–40	40–
No. of patients	169	351	517	312	645	881
Unadjusted mortality	10.06	5.41	4.26	11.22	8.99	6.70
Risk-adjusted mortality	7.23	4.32	3.99	10.54	7.48	6.94
p value (hospital volume)	0.0375			Did not converge		
Odds ratio	0.982–0.999			–		

* Number of patients are for 3-year periods (2003–2005).

Table 5
Association between hospital thoracic aortic surgery volume and mortality, by expected risk ($n = 2875$).

	Expected risk <6.0%*			Expected risk ≥6.0%*		
	Hospital thoracic aorta volume			Hospital thoracic aorta volume		
	5–20	20–40	40–	5–20	20–40	40–
No. of patients	280	546	900	201	450	498
Unadjusted mortality	3.21	3.30	2.00	21.39	13.11	12.65
Risk-adjusted mortality**	2.49	2.63	1.60	19.78	11.94	12.58
p value (hospital volume)	0.263			0.019		
Odds ratio	0.990–0.1003			0.989–0.999		

* Preoperative risk was calculated based on JACVSD risk model.
** Results further adjusted with risk group to ensure constant risk profiles.

high volumes are associated with better outcomes across a wide range of procedures and conditions [3,4]. Table 3 shows that the mortality outcomes of high-volume surgeons at high-volume hospitals were similar to those of low-volume surgeons at high-volume hospitals. Though both hospital volume and surgeon volume might affect outcomes of thoracic aortic surgery, the effect of hospital volume made a stronger impact on outcomes than surgeon volume in Japan. Similarly, our previous volume-outcome analysis for isolated CABG surgery found similar tendency between surgeon volumes and CABG outcomes [10]. This finding counters a recent study in American hospitals, which found that surgeon volume was inversely related to operative mortality for many procedures [11]. The reason that surgeon volume appears to have less effect on mortality outcomes in Japan than in other countries is likely multi-factorial. Because multiple surgeons are affiliated with a single hospital in Japan, information from patient cases and conference experiences are shared with many cardiovascular surgeons and other medical staff in a given hospital. The requirement within the Japanese cardiovascular surgery system that at least two surgeons perform a given cardiac surgery procedure might also contribute to the reduced effect of surgeon volume on mortality outcomes. Even when a low-volume surgeon acts as the primary surgeon, high-volume surgeons often participate as assistant surgeons, particularly in complex procedures like thoracic aortic surgery. High-volume hospitals might also pass down techniques by serving as teaching institutes. For these reasons, the effect of surgeon volume on outcomes of thoracic aortic surgery in Japan might be different from those of other countries.

Though thoracic aortic surgery volume of hospitals significantly impacted mortality outcomes, total adult cardiovascular surgery volume of hospitals did not reach statistical significance. As thoracic aortic surgery is one of most difficult procedures in cardiovascular surgery, some centers never perform it and transfer their patients to other centers. Moreover expert surgeons of thoracic aortic surgery and expert surgeons of other cardiovascular procedure (CABG surgery or valvular surgery, congenital heart surgery) are different in many Japanese hospitals. Thus, a hospital that has high volume of total adult cardiovascular surgery does not always have high volume of thoracic aortic surgery. Our results suggest that procedural volume of total adult cardiovascular surgery may not be a relevant indicator for outcome of thoracic aortic surgery. As for the public reporting regarding high-risk procedures such as thoracic aortic surgery, hospital procedural volume of the appropriate procedures may be more useful than those of total procedures.

Even with a statistically significant association between overall hospital volume and bulk mortality trends, hospital volume does not completely predict outcome for individual hospitals. Although not all high-volume providers have better mortality outcomes and not all low-volume providers have worse outcomes, hospital procedural volume is an important parameter. Hospital procedural volume encompasses physician skill, the experience of interdisciplinary teams, the organization of care processes, and the quality of hospital facilities. Many other parameters, however, may be more closely associated with outcomes. Such parameters may include outcome monitoring, compliance with process measures, and appropriateness of patient selection for surgery [12,13]. Volume alone, therefore, is not sufficient to predict mortality outcomes in Japan. Further studies should include an examination of alternative parameters in

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order to improve the outcomes of individual centers. Outcome-based evaluation is also an important strategy to improve the quality of cardiovascular surgery. Use of surgical mortality as an indicator of hospital quality, however, is of limited value in the current Japanese system because small sample size and low event rates tend to diminish statistical power [14]. If caseloads become large enough to support outcome measurement through establishment of high-volume centers, quality assessments may be based on both outcome data and volume.

Several limitations of this study should be noted. In the JACVSD analysis, we excluded centers that had fewer submissions to JACVSD than to JATS, because we felt that surgical patient selection should be matched across databases in a volume-outcome study. In addition, a previous study revealed that high-volume surgeons performed a higher proportion of operations with inappropriate surgical indications than low-volume surgeons [15]. The quality of database information, particularly in JACVSD, is also a concern. We determined that excluding centers with incomplete reporting was appropriate. Regarding data accuracy, future efforts to carefully audit data submission and educate medical centers as to term definitions will be important.

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Title: Toward quality improvement of cardiovascular surgery in Japan: An estimation of regionalization effects from a nationwide survey.

Article Type: Full Length Article (FLA)

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Keywords: Quality Improvement; Regionalization; Cardiovascular Surgery; Mortality; Policy development; Patients' travel time

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Abstract: Introduction: In this study, we estimate the effects of regionalization for cardiovascular surgery in Japan, accounting for both its advantages and disadvantages.
Methods: This study includes 209,221 procedures from nearly 572 hospitals that conducted cardiovascular surgery in Japan between 2001 and 2004. For the regionalization parameter, hospital surgical volume was divided into four categories: under 10, 10-24, 25-49, and 50-74 average cardiovascular surgeries per year. The effects of regionalization on the 30-day patient mortality rate and an additional travel distance for patients were examined.

Results: The 30-day mortality rate for cardiovascular surgery was 4.62% without regionalization. After regionalization, the estimated rate was 4.40% for annual case volumes under 10, 4.28% for volumes 10-24, 3.78% for volumes 25-49, and 3.12% for volumes 50-74. The average annual number of patients who must travel at least an extra 30 kilometers after regionalization are: 0.8 patients for case volumes under 10 (0.001% of total patients), 12.3 patients for volumes 10-24 (0.02% of total), 88.3 patients for volumes 25-49 (0.2% of total), and 179.3 patients for volumes 50-74 (0.3% of total).

Conclusion: The results indicate that, after regionalization, the 30-day mortality rate did improve for hospitals with 25-49 and 50-74 annual surgeries. While increased travel times may be critical for patients requiring emergency surgery, the results suggest that low-volume hospitals get relatively few such cases. In many regions, improving the transportation system for emergency cases may be more effective than maintaining a low-volume.