Improving the quality of healthcare in Japan: A systematic review of procedural volume and outcome literature

Hiroaki Miyata[1,] *, Noboru Motomura[2], James Kondo[3], Shinichi Takamoto[2], Toshihiko Hasegawa[4]

[1] *Department of Healthcare Quality Assessment, Graduate School of Medicine, University of Tokyo, Tokyo, Japan;*

[2] *Department of Cardiothoracic Surgery, Graduate School of Medicine, University of Tokyo, Tokyo, Japan;*

[3] *Healthcare Policy Institute, Tokyo, Japan;*

[4] *Department of Health Policy and Management, Nippon Medical School, Tokyo, Japan.*

SUMMARY   **Though some policies have been implemented based on volume-outcome relationships in Japan, no studies systematically reviewed volume-outcome research conducted in Japan. Original data used in this study were obtained from MEDLINE searches using PubMed or from searches of the *Ichushi* database and complemented with manual searches. Two investigators reviewed and scored 13 articles, using a standard form to extract information regarding key study characteristics and results. Of the 13 studies we reviewed, 11 studies sought to detect the effects of hospital volume on outcomes while 2 examined the influence of individual physician volumes. Of the 13 studies, 9 studies (69.2%) indicated a statistically significant association between higher hospital volumes and better health outcomes. No study documented a statistically significant association between higher volumes and poorer outcomes. Higher review score is considered to be associated with significant association. The definition of low volume differed widely in each of the studies we reviewed. The 95%CI of healthcare outcomes is considerable even in studies that revealed a significant difference between volumes and outcomes. Higher hospital volumes are thought to be associated with better aggregate healthcare outcomes in Japan. For this reason, minimal-case-number standards might be effective to some extent. However, volume alone is not sufficient to predict the quality of healthcare. In addition, outcome-based evaluation might also be needed.**

Key Words: Volume-outcome, systematic review, healthcare, procedural volume, evaluation

Introduction

In 2002, the Japanese Ministry of Health, Labor, and Welfare set minimal standards by relating surgical fees to hospital procedure volumes (*1*). This policy might be based on the hypothesis that outcomes of complex healthcare procedures are better when done by providers or hospitals that perform them more frequently. For cardiac surgery specifically, those medical institutions that had an annual cardiac surgery procedural volume of fewer than 100 cases had their medical fees lowered by 30%. However, many stakeholders raised objections to these practices. One of the reasons for their objections stemmed from the fact that most medical institutions had their fees lowered; *i.e.* two thirds of Japanese medical institutes conducted fewer than 100 procedures per year (*2*). Though these standards were temporarily suspended starting in 2006, the Japanese Ministry of Health, Labor, and Welfare is still considering whether regionalization would be appropriate when considering hospital volumes.

Additionally, the Japanese Government updated medical practice laws in June of 2006. Each local

government was, starting in April 2007, given the power to require medical centers to submit and release "certain information" that would be considered useful to patients who are choosing a hospital (*3*). As of January 2007, this "certain information" included hospital procedural volumes but few outcome indicators such as operative mortality or morbidity rates. However, "certain information" could come to include outcome indicators similar to those used in public reporting in New York State (*4,5*). Examining whether hospital volume is information that should be revealed is crucial, as well as determining its accuracy.

Measuring and understanding the association between surgical volume and outcomes in the delivery of health services has been the focus of much research in the United States since the 1980s (*6,7*). Recently, two systematic reviews suggested that high volume is associated with better outcomes but that the degree of this association varies greatly (*8,9*). As the complications included in these findings are partly due to methodological shortcomings in many studies, a rigorous examination of the proposed volume-outcome association is extremely crucial. In addition, no studies have systematically reviewed volume-outcome research conducted in Japan. This study set out to conduct a systematic review of the research evidence linking volume and outcome in Japan, to summarize and describe the methodological rigor of the existing literature, and to examine the research and policy implications of these findings.

Materials and Methods

The original data for this review were identified by searches of MEDLINE using PubMed and by those of the Ichushi (Japana Centra Revuo Medicina) database. In addition, experts were contacted about missed studies. Articles identified were those investigating the association between hospital (or individual surgeon) procedural volume and outcomes from 1 January to 30 March 2007. The search terms used were 'volume (*syoureisuu*)', 'outcome (*tiryouseiseki*)', 'frequency', 'outcome assessment', 'regionalization', 'Japan' and 'Japanese'. Papers written in either English or Japanese were reviewed. Only studies on Japanese populations living in Japan were included. Instances of multiple publications from the same database were excluded, with only the most complete publication selected.

Two of the authors scored each article independently using an IOM scoring system regarding volume-outcome studies (*9*). Reviewers were not blinded to journal, authors, or findings. Any discrepancies were resolved by discussion. Quality scores were summed across all 10 criteria for each study. The maximum possible total score was 18. Higher scores reflect an increasing likelihood of the study's ability to discern a generalizable conclusion about the nature and extent

of the relationship between volume and outcome (Appendix).

A study was assigned one point if the sample was representative of the general population of all patients who might receive the treatments examined in the study. A study was assigned two points if it included 50 or more physicians and 20 or more hospitals. If only one of these criteria was met, the study was assigned one point. No points were assigned if neither criterion was met. In many studies authors reported the number of hospitals in their sample but not the number of treating physicians. In these instances, the number of physicians was estimated by assuming it would be at least equal to the number of hospitals. If the total sample size was 1,000 patients or more, the study was assigned one point. A study was assigned 2 points if the total number of adverse events was greater than 100, one point if it was 21-100, and no points if it was 20 or less.

A study was assigned no points if the study assessed the relationship between outcome and either hospital or physician volume. If both were assessed separately, the study was assigned one point. If the joint relationships of hospital and physician volume were assessed independently in a multivariate analysis, the study was assigned 2 points. Finally, if a study examined both of these, in addition to another important component of the care process, it was assigned 3 points. If the appropriateness of patient selection was not addressed, it was assigned no points. If appropriateness was measured, 1 point was assigned. If it was measured and taken into account in the analysis of the volume-outcome relationship, the study was assigned 2 points.

If the volume was analyzed in only 2 categories, the study was assigned no points. If more than 2 categories were assessed, or if volume was treated as a continuous variable, the study was assigned 1 point to credit a more sophisticated assessment of a possible dose-response relationship. In considering the various ways in which outcomes might be risk-adjusted, a study was assigned no points if no risk-adjustment was done at all. If data from insurance claims, hospital discharge abstract databases, or other sources of administrative data were used, the study was assigned 1 point. If data from clinical sources (*e.g.*, medical records or prospectively designed clinical registries) were used for risk-adjustment, the study was assigned 2 points. If clinical data were used in a logistic regression model that demonstrated good calibration by the Hosmer-Lemeshow test and good discrimination (by a C-statistic of 0.75 or greater), the study was assigned 3 points. If specific clinical processes of care were not measured, no points were assigned. If a single process was measured and its impact on risk-adjusted outcomes assessed, 1 point was assigned. If 2 or more such processes were measured and evaluated, 2 points were assigned. Finally, if death was the only outcome evaluated, no points were assigned. If other adverse

outcomes in addition to mortality were assessed, 2 points were assigned.

Results

This systematic review identified 13 articles (*10-22*). As a result of evaluating each article that studied more than one procedure as more than one study, these studies were found to cover 13 clinical topics. The methodological characteristics of the 13 articles are described in Tables 1-1 and 1-2. All studies identified were published after 2001.

With regard to the representative nature of the sample, 6 studies were considered using a representative database. Four studies were based on the Osaka Cancer Registry. The Osaka Cancer Registry has been operating since December 1962, covering Osaka Prefecture and its population of 8.8 million (*15*). Cancer incidence data in Osaka have been reported in 'Cancer incidence in five continents' volumes III to VIII (*23*). The Japanese coronary intervention study (*22*) consisted of a random sample (10%) of PCI procedures by a 2-step sampling process. First, 144 PCI facilities were randomly selected with stratification by hospital annual volume. Secondly, all PCI procedures were recorded at facilities performing 1-150 PCI per year. For the 2002 annual survey of the Japanese Society of Anesthesiologists (JSA) (*16*), 1,987,988 patients were registered from 704 training hospitals certified by the JSA. The 1996 National Patient Survey and 1996 National Hospital Survey (*19*) are 70% stratified random sampling surveys. The response rate in these studies was 100%.

With regard to the study sample size, 7 studies had sample sizes that exceeded 1,000, included 20 or more hospitals, 50 or more physicians, and more than 100 adverse events. With regard to the primary outcome, 11 studies reported mortality rates and 2 studies reported the length of hospital stays. Four studies measured outcomes besides death alone.

Among the 13 studies reviewed, 11 studies attempted to detect the effects of hospital volume on outcome whereas 2 examined the influence of individual physician volumes. No study examined both hospital and individual physician volumes or explored their joint effects. Additionally, no study measured the appropriateness of patient selection. Seven studies examined clinical processes of care, such as surgery type, surgical back up, ADL support, and additional treatment.

Nine studies used a multiple volume index and 2 studies used a two-category volume index. With regard to risk adjustment, 2 studies performed no adjustment while 3 studies used administrative data to adjust for some combination of age and sex. Though eight studies used clinical data in their risk-adjustment, no study reported a robustly discriminating and well-calibrated

risk model.

Of the 13 studies, 9 studies (69.2%) indicated a statistically significant association between higher hospital volumes and better health outcomes (Tables 2-1 and 2-2). Though the other 4 studies did not report a statistically significant association, their results indicated that higher hospital or physician volumes tended to be related to better health outcomes. No study documented a statistically significant association between higher volumes and poorer outcomes.

Higher review score is considered to be associated with significant association between procedural volume and healthcare outcomes. Regarding review scores, 3 of the 4 studies that did not indicate a statistically significant association between higher volume and better outcome received fewer than 3 points. Of those, 2 studies used results from a single hospital survey with patient populations of around 100. Another study was a retrospective survey regarding members of an academic association and did not state the patient sample size. Though the study regarding patients with AMI who had undergone PCI in 1997 (*22*) had earned a high score, with clinical risk-adjustment and sufficient sample size, results of the study did not indicate a statistically significant association. Another study involving AMI did not report a statistically significant association between the hospital volume and a shorter length of stay in 1998. However, the same study indicated a significant association between the two in 2002. Authors suggested that one of the reasons for their findings might have been that the use of clinical pathways as standardized protocols for management of patients with AMI had only been recently introduced to a high-volume hospital.

The definition of low volume in each study examined differed widely. Though definitions of low volume regarding ovarian (0.3 average per year; 84.5% of hospitals fall under the low volume category) and uterine cancer (0.6 average per year; 84.2% of hospitals fall under the low volume category) are very low, those concerning stomach cancer (16 average per year; 83% of hospitals fall under the low volume category) and AMI (7.3 average per year; 34.1% of hospitals fall under the low volume category) are relatively high. In terms of healthcare outcomes, the 95% confidence intervals were relatively high even in studies that indicated significant differences between hospital volumes and better outcomes.

Discussion

Results revealed that 9 of 13 Japanese studies claimed that all Japanese studies indicated a statistically significant association between higher hospital volumes and better health outcomes. No study showed a statistically significant association between higher volumes and worse outcomes. In Japan, higher hospital

Table 1-1. Methodological characteristics of volume-outcome studies 1

	1. Representativeness of sample		2. Number of hospitals or doctors		3. Total sample size (cases)		4. Number of adverse events		5. Unit of analysis	
	0 Not		0 H < 20 and MD < 50		0 < 1,000		0 ≤ 20		0 Hospital or MD	
	1 Representative		1 H < 20 or MD < 50		1 ≥ 1,000		1 21-100		1 Both separately	
			2 H ≥ 20 and MD ≥ 50				2 > 100		2 Both together	
									3 Both +	
Saika, 2007	1	The Osaka cancer registry	2	171 hospitals	1	2,819	2	>100	0	Hospital only
Tsuchihashi, 2004	1	Japanese coronary intervention study	2	129 hospitals	1	2,491	2	>100	0	Hospital only
Nabae, 2003	1	National patient survey and the national hospital survey	2	1,399 hospitals	1	4,576	2	>100	0	Hospital only
Ioka, 2004	1	The Osaka cancer registry	2	207 hospitals	1	3,523	2	>100	0	Hospital only
Ioka, 2005	1	The Osaka cancer registry	2	89 hospitals	1	1,937	2	>100	0	Hospital only
Nomura, 2003	1	The Osaka cancer registry	2	296 hospitals	1	15,413	2	>100	0	Hospital only
Irita, 2004	1	Intraoperative critical incidents independent of the surgical site	2	704 hospitals	1	1,987,988	2	804	0	Hospital only
Kinjo, 2004	0	Japanese coronary intervention study	1	25 hospitals	1	4,525	0	-	0	Hospital only
Mitsuyasu, 2006	0	10 domestic national hospitals, 9 private hospitals	0	19 hospitals	0	827	0	-	0	Hospital only
Haga, 2001	0	Six national hospitals in Japan that joined the E-pass study group	0	6 hospitals	0	902	0	18 in hospital death	0	Hospital only
Abe, 2005	0	Surgeon members of the Japan pancreatic surgery club	2	148 hospitals	0	-	0	two	0	MD only
Fujita, 2002	0	One University hospital	0	21 MDs	0	136	0	two	0	MD only
Fujino, 2002	0	One University hospital	0	-	0	107	0	nine	0	MD only

Table 1-2. Methodological characteristics of volume-outcome studies 2

(to be continued)

	6. Appropriateness of patient selection	7. Volume	8. Risk adjustment	9. Clinical processes of care	10. Outcomes	Total Score
	0 Not measured *1 Measured separately* *2 Measured and analysed separately*	*0 Two categories* *1 Multiple*	*0 None* *1 Admin only* *2 Clinical data* *3 Clinical +C > 0.75 and H/L test +*	*0 Not measured* *1 One* *2 2 +*	*0 Death only* *1 Death +*	
Saika, 2007	0 Not measured	1 Continuous	2 Clinical data	1 Additional treatment	1 30-day mortality, 5-year survival	11
Tsuchihashi, 2004	0 Not measured	1 Three categories at terciles of annual volume	2 Clinical data	1 Surgical backup	1 In hospital mortality or CABG	11
Nabae, 2003	0 Not measured	1 Continuous	1 Admin only	1 ADL support	1 In hospital mortality, length of stay	10
Ioka, 2004	0 Not measured	1 Four categories	2 Clinical data	1 Surgery type	0 5-year survival	10
Ioka, 2005	0 Not measured	1 Four categories	2 Clinical data	1 Surgery type	0 5-year survival	10
Nomura, 2003	0 Not measured	1 Divided into 4 categories of hospital volume with almost equal size	1 Admin only	0 Not measured	0 5-year survival	8
Irita, 2004	0 Not measured	1 Five categories	0 None	0 Not measured	0 7 day mortality	7
Kinjo, 2004	0 Not measured	0 Two categories	2 Clinical data	2 Coronary angiography before discharge, CABG before discharge	0 Length of hospital stay	6
Mitsuyasu, 2006	0 Not measured	0 Two categories	2 Clinical data	1 Transfer to another hospital length of hospital stay	0 Mean hospital charges,	3
Haga, 2001	0 Not measured	1 Three categories	2 Clinical data	0 Not measured	0 In hospital mortality	3
Abe, 2005	0 Not measured	1 Three categories	0 None	0 Not measured	0 Incidence of all arterial hemorrhages	3
Fujita, 2002	0 Not measured	0 Two categories	1 Admin	0 Not measured	1 Mortality and morbidity	2
Fujino, 2002	0 Not measured	0 Two categories	2 Clinical data	0 Not measured	0 Pancreatic leakage related mortality	2

Table 2-1. Summary table of the association between procedural volume and healthcare outcome in Japanese studies 1

Study	Field	Population	Time period	Patient #	MD #	Hospital #	Unit of Analysis	Primary outcome	Risk adjustment data source	Definition of low volume	Method	Volume-outcome results	Discussion regarding volume-outcome
Saika, 2007	Lung cancer, Stomach cancer	The Osaka Caner registry	1986-1995	2,819 (lung)	-	122 (lung)	Hospitals	30th day up to the 1830th day (5-year period mortality)	Clinical	Continuous	Logistic regression	In the logisticlogistic regression nalysis, the surgical volume index was positively associated with the survival of patients at every point during 5 years highest on the 90th day.	Data indicates that a surgical volume influence on stomach and lung cancer survival over 5 years and appears more prominently between 60th-120th days after surgery.
Tsuchihashi, 2004	Patients with AMI who had undergone PCI were identified	Japanese Coronary Intervention Study	1997	2,491	-	129	Hospitals	In hospital mortality need for CABG	Clinical	Low average 7.3 [1-16] (34.1%), middle average 24.4 [17-55] (32.5%), high average 26.6 [56-370] (33.3%)	Cochran-Armitage test	Mortality or CABG (low 9.9%, middle 7.8%, high 8.1%; *p*=0.66), adjusted mortality or CABG Odd ratio (Low, 1.00, middle 0.76 (0.44-1.31), high 0.70 (0.43-1.23): *p*=0.26)	There was no significant relationship between hospital volume and in-hospital outcome.
Nabae, 2003	Gastric, Colon and Rectal Cancer surgery	National patient survey and the National hospital survey	1998	4,576 (gastric)	-	1,399 (gastric)	Hospitals	In hospitals mortality rate, Length of stay	Admin	Gastric cancer 1-3 per month (68.6%), Colon cancer 1-2 per month (71.3%), Rectal cancer 1-2 per month (80.1%)	Logistic regression and multivariable regression model	In hospital mortality (Gastric: OR 0.88 *p*<0.01, Colon: OR 0.99 *p*=0.80, Rectal: OR 1.06 p<0.35), Length of Stay (Gastric β-019 *p*<0.001, Colon β -0.037 *p*<0.001, Rectal β -0.036 *p*<0.001)	In Gastric cancer surgery both in-hospital mortality and LOS were significantly associated. In Colon and Rectal cancer only LOS was significantly associated.
Ioka, 2004	Ovarian cancer	The Osaka cancer registry	1975-1995	3,523	-	207	Hospitals	5-year survival	Admin	High: average 8.8 (1.9%), medium: average 4.0 (4.8%), low: average 2.0 (6.7%), very low: average 0.3 (84.5%)	Cox regression model	High→very low 5-year survival (55.0%, 46.2%, 34.2%, 22.3%), Adjusted Hazard ratio (1.0, 1.1 [0.9-1.3], 1.4 [1.2-1.6], 1.6 [1.4-1.9])	After adjustment for age and other variables using the cox regression model, the hazard ratio correlated positively with hospital volume (*p*<0.01).
Ioka, 2005	Uterine cancer	The Osaka cancer registry	1990-1997	1,937	-	89	Hospitals	5-year survival	Clinical	High: average 28.8 (2.2%), medium: average 22.4 (2.2%), low: average 5.7 (10.1%), very low: average 0.6 (84.2%)	Cox regression model	High →very low 5-year survival (77.6%, 71.4%, 62.7%,45.7%), Adjusted Hazard ratio (1.0, 1.3 [1.0-1.5],1.3 [1.1-1.5], 2.0 [1.9-3.3])	Cox regression model, patient receiving care in very low, low, or medium-volume hospitals were found to have higher risk of death than patients receiving care in high volume hospitals.
Nomura, 2003	Stomach cancer	Osaka cancer registry	1990-1994	15,413	-	296	Hospitals	5-year survival	Admin	Very low: average 16 [1-84] 83%, low: average 148 [96-223], medium average: 298 [231-421], High: average 549 [487-644]	Cox's Proportional hazards model	5-year survival high→very low Localized cancer (84% [82-86], 86% [83-88], 82% [79-84], 76% [72-79]), Regional cancer (43% [39-47], 47% [43-51], 41% [37-45], 24% [21-28]), Adjacent cancer (12% [8-16], 13% [9-17], 12% [8-17], 5% [3-8]), Distant cancer (4% [2-7], 4% [2-7], 2% [1-4], 2% [1-4])	Positive relationship in localized, regional, adjacent cancer. Not clear in the case of the distant group.
Irita, 2004	Intraoperative critial incidents independent of the surgical site	2002 annual survey conducted by the subcommittee on surveillance of anesthesia-related critical incidents.	2002	1,987,988	-	704	Hospitals	7-day mortality	None	Fewer than 1,000: 62 (9.1%), 1,000-1,999: 204 (29.0%), 2,000 3,999: 288 (40.1%), 4,000-5,999: 110 (15.6%), more than 000: 40 (5.7%)	Ch-square test and fisher test	Mortality rate: fewer than 1,000: 14.89% [8.48-21.3], 1,000-1,999: 5.88%[3.05-4.67], 2,000-3,999: 5.97% [3.19-4.57], 4,000-5,999: 4.48% [3.20-4.88], more than 6,000: 2.99% [2.19-4.05]	Surgical volume was shown to affect mortality independent of the surgical site

Table 2-2. Summary table of the association between procedural volume and healthcare outcome in Japanese studies 2

(to be continued)

Study	Field	Population	Time period	Patient #	MD #	Hospital #	Unit of Analysis	Primary outcome	Risk adjusment data source	Definition of low volume	Method	Volume-outcome results	Discussion regarding volume-outcome
Kinjo, 2004	Acute myocardial infarction	Osaka Acute Coronary Insufficiency Study	1998-2003	4,113	-	25	Hospitals	Length of hospital stay	Clinical	AMI case load >50 patients/ year, Performance of PCI> 200 procedures/year	Multiply regression	AMI case load >50 patients/ year -0.123 p=0.021, Performance of PCI >200 procedures/year -0.114 p=0.034	With regard to time trends, admission to a high-Volume hospital was not a predictor of a shorter hospital stay but was significantly associated in 2002.
Mitsuyasu, 2006	Total hip arthroplasty (THA), Total arthroplasty (TKA)	10 domestic national hospitals, 9 private hospitals	2001-2003	827 (THA)	-	19	Hospitals	Mean hospital charge, Length of hospital stay	Clinical	HA: High 45-151 (69.5%), Low <45 (30.5%), TKA: High 40-160 (62.3%), Low <40 (37.7%)	Multiply regression	Mean total charge: THA < 0.001, TKA =0.045. Mean LOS: THA <0.001, TKA < 0.001. Preoperative mean LOS: THA <0.001, TKA <0.001	Hospital surgical case volume has significant effects on the total length ofstay for both THA and TKA and on the total cost for THA
Haga, 2001	Consecutive patients who underwent elective gastrointestinal operations	Six national hospitals in Japan	1998-1999	902	-	6	Hospitals	In hospitals mortality rate	Clinical	Low <100 n=1, Medium 100 - <200 n=3, High ≥200 n=2	Linear regression	Mortality rate: High vs. Low Medium (5.7% vs. 18.4%, p = 0.0350)	Stepwise decrease in mortality was observed in accordance with the volume of operations
Abe, 2005	Pancreatic reconstruction	Surgeon members of the Japan pancreatic surgery club	2002	-	-	148	Hospitals	Incidence of all arterial hemorrhages	None	High volume hospital: PD was performed at least 60 times (2.7%), Low volume hospital: PD was performed fewer than 20 times (55%).	Student's t-test	Incidence of all arteria hemorrhage (low 3.2%±6.4, medium 2.6%±3.8, high 2.9%±2.3) incidence of delayed arterial hemorrhage (low 2.3%±6.1, medium 2.0%±2.9, high 1.9% ±1.9)	The incidences of all adverse events did not differ significantly
Fujita, 2002	Total Gastrectomy	One University hospital	1995-1998	136	21	1	MD	Mortality and Morbidity	Admin	Two surgeons who had done 30 or more operations were defined as high volume, the remaining 19 surgeons who had done fewer than 15 operations were defined as low volume surgeons	Multivariate analysis	high: low: mortality(0, 2: p=0.17), complications (7, 24: p=0.04)	Multivariate analysis identified surgeon's volume as a significant factor for development of postoperative complications
Fujino, 2002	Pancreatic leakage	One University hospital	1984-2000	107	-	1	MD	Leakage-related mortality	Clinical	High (>20 cases/study period), medium (>10-20 cases/study period)	Logistic regression	Leakage related mortality-univariate logistic regression analysis (Medium 13.3%, High 6.5% : p=0.27)	Surgeon volume did not have any significant influence

volume is believed to be associated with better health care outcomes in aggregate. Many other foreign systematic reviews have also suggested similar results (*8,24-28*). Since hospital procedural volumes attribute to physicians' skills, experienced interdisciplinary teams, well-organized care processes, and hospital facilities, they are a necessary factor when outcomes are considered. With regard to healthcare quality improvement, regionalization of medical centers based on hospital procedural volumes might be acceptable to some extent. The definition of low volume in the studies was very heterogeneous, so minimal volume standards need to be set carefully for each specialty. Moreover, 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 healthcare expenditures.

Volume alone is not sufficient for prediction of outcome because there was a large variance in the results observed among individual centers, even in the studies that indicated a significant difference between volume and outcome. Not all high-volume providers have better outcomes, and not all low-volume providers have worse outcomes. In addition, hospital volume as well as a number of other parameters (namely, outcome monitoring, compliance with process measures, and appropriateness of patient selection for surgery) might be associated with better outcomes (*4,29*). Quality improvement in the healthcare field might not be achieved fully by only using the minimal volume standards. Evaluating and encouraging quality improvement based on healthcare outcomes might be another way of improving the quality of healthcare. Birkmeyer suggested three strategies for improving surgical quality based on performance: centers of excellence (selective contracting, financial incentives for patients, and public reporting to direct patients to the best hospitals or surgeons), pay for performance (improving quality at all hospitals by rewarding good performance with financial bonuses), and pay for participation (improving quality at all hospitals by underwriting clinical outcomes registries and quality-improvement activities) (*30*). These outcome-based evaluations need to satisfy two requirements: 1) detailed clinical data for risk adjustment (*30*) and 2) a large enough sample size for each hospital's outcome indicator (*31*). In Japan, however, clinical databases have not been established in most healthcare fields and discussion regarding risk-adjustment has not taken place. Ensuring a large enough sample size for each procedure may also be difficult because most medical centers belong to the very-low or low volume categories. Both minimal care standards and outcome-based evaluation might be effective to some extent as means of improving healthcare quality in Japan.

Several limitations should be noted. A negative publication bias may have existed to diminish the number of studies failing to report expected associations. In addition to the heterogeneous methods used in the studies, the number of procedures included in this review is limited. With regard to specific health policy recommendations, further detailed analysis is needed in each healthcare field.

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