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.

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

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.

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

Introduction

For many surgical procedures, operative mortality rates are substantially lower at hospitals that perform the surgeries more frequently.[1-3] As a result, recommendations have been made in many countries to concentrate, or regionalize, selected procedures in higher-volume hospitals.[4-6] In Japan, however, cardiovascular surgery programs proliferate without regulatory oversight due to a lack of existing standards for such programs. In the United States, the volume of Coronary Artery Bypass Graft (CABG) surgeries in similarly sized hospitals is categorized as less than 150, from 150 to 300, from 300 to 450, and greater than 450 surgeries per year.[7] According to these cut-offs, over 90% of Japanese hospitals are low-volume because they perform fewer than 150 CABG procedures annually.[8] Although the low-volume cardiovascular surgery programs have been loss-making,[24] many hospitals want such programs because they serve as backups for percutaneous coronary interventions (PCI) and because of the prestige associated with being a general hospital.

In 2002, the Japanese Ministry of Health, Labor, and Welfare established minimum standards for regionalization by connecting surgical fees to hospital procedure volumes.[9] For instance, medical institutions were subjected to a 30% reduction in their medical fees if they performed cardiovascular surgeries but had fewer than 100 such procedures each year. This policy is in accordance with the hypothesis that surgeons and hospitals performing complex healthcare procedures frequently have improved patient outcomes. Yet, many stakeholders objected to the policy. Since two-thirds of Japanese medical institutions perform fewer than 100 procedures per year, some complained that the majority of medical institutions suffered from lowered fees.[10] Though these standards were temporarily suspended in 2006, the Japanese Ministry of Health, Labor, and Welfare is still contemplating the use of regionalization based on hospital volume.

A systematic review of the relationship between procedure volume and patient

outcome in Japan,[11] as well as earlier systematic reviews,[12,13] suggests that high volume is associated with better outcomes. Volume-outcome effects have been found in both administrative data[14] of all cardiovascular surgery types and clinical data with full risk-adjustment.[8] These studies indicated that regionalization of hospitals based on procedural volume may help improve patient outcomes in Japan. However, regionalization may also introduce challenges such as increased travel time for patients, medical professional staffing, cooperation with other departments in the hospital, and healthcare expenditures. This study examines some of the effects of regionalization, including both its advantages and disadvantages.

Methods

Study Population

The Japanese Association for Thoracic Surgery (JATS) has conducted an annual survey of thoracic surgery since 1986. Each year, survey questionnaires are sent by JATS to all institutions performing cardiovascular surgery in Japan. The survey has high response rates, including 95.9% in 2001, 97.4% in 2002, 94.3% in 2003, and 90.3% in 2004.[15-18] The terminology definitions are based on published guidelines from the Society of Thoracic Surgeons and the American Association for Thoracic Surgery.[19] All cardiovascular surgeries, including CABG, valve, thoracic aortic, and congenital, performed between January 1, 2001 and December 31, 2004 were examined. The study included 209,221 procedures from 572 centers reporting at least one cardiovascular surgery during this period. Because of the high JATS survey response rates, these 572 centers represented nearly all Japanese institutions conducting coronary procedures. The primary study outcome in the JATS survey was 30-day mortality, defined as death within 30 days of the operation regardless of the patients' geographic location. While the survey included patients who were discharged from the hospital and died within 3 days of the operation, those who died in the hospital after 30 days were not included.

Analysis

In this study, data on hospital procedural volume was divided into categories for regionalization of cardiovascular surgery because several studies have suggested that higher volume is associated with better outcomes in Japan. The volume cut-offs were based on the number of hospitals such that each category contained approximately

twice as many hospitals as the preceding category. Using this criterion, the hospital volume, or regionalization, limits were fewer than 10, 10-24, 25-49, and 50-74 cardiovascular surgeries per year.

First, the distributions of cardiovascular surgeons and hospitals performing such surgeries were assessed for each regionalization category. Not all cardiovascular surgeons who worked in hospitals targeted by the regionalization cut-offs were forced to leave their employment immediately. As the remaining hospitals expanded their surgical volume, some of these surgeons were able to relocate to these hospitals. Based on estimates from cardiovascular surgery program directors, the remaining hospitals are expected to employ one new surgeon for each increase of 25-35 procedures.

Next, the change in the 30-day mortality rate after regionalization was assessed through two different approaches. First, the results were summarized after eliminating only low-volume hospitals whose overall quality was poor. Second, the remaining hospitals had their procedural volumes increased by evenly distributing the hospital volumes among them. Simple linear regression analysis was used to estimate the improvement in the 30-day mortality rate resulting from a one-case increase in procedural volume (Figure 1). The hospital procedural volumes were divided into ten categories so that adjustments could be made to allow for mortality rates of both 1/10 and 10/100. Since the variance of the mortality rate in a low-volume hospital is greater than in a high-volume hospital, the regression analysis was conducted for the total, rather than average, mortality rate in each category. For example, the total mortality rate for hospitals with a volume of 1-25 annual surgeries is equal to the total number of 30-day deaths in this category over the total number of surgeries in the category.

Finally, some studies suggest that the increase in patients' travel time should be considered as a disadvantage of regionalization.[20,21] In this study, this additional travel time was examined by each regionalization category. The extra travel distance was calculated using the linear distance from the hospital where each patient actually underwent surgery to the closest hospital that would survive in each regionalization category. Weighted averaging by the number of patients on each travel pathway was used to estimate the average travel distance. The number of patients was tabulated by extra travel distance for both emergency surgery and total cardiovascular surgeries.

Both CABG emergency surgery and acute-type thoracic aorta surgery were included in the analysis.

Results

This study included a total of 209,221 cardiovascular surgeries conducted in 572 Japanese hospitals from 2001 to 2004. An average of 91.4 cardiovascular surgeries were performed annually per hospital, with a median of 61.0 surgeries (IQR: 29.8-122.8). Each hospital had an average of 4.8 of the 2,670 total cardiovascular surgeons, with a median of 3.0 (IQR: 2.0-5.0). Similarly, an average of 2.4 specialist cardiovascular surgeons of the 1,341 total were at each hospital, with a median of 2.0 (IQR: 1.0-3.0). The effects of regionalization on hospitals and surgeons are shown in Table 1. According to the analysis, 238 hospitals (41.6%) will be likely targets for regionalization of those with an annual cardiovascular surgery volume between 25-49 cases. Over half (325 centers, 56.8%) of hospitals with an annual volume between 50-74 cases will also be likely targets. Up to 15.5% of cardiovascular surgeons may be affected by the regionalization.

Estimated changes in the 30-day mortality rate for cardiovascular surgery after regionalization are shown in Table 2. Based on the crude linear regression estimates, the 30-day mortality rate improved 0.12% for an annual volume increase of 10 cases (Figure 1). The estimated 30-day mortality rate for cardiovascular surgery in Japan was 4.62% without regionalization. After regionalization, the estimated rate was 4.40% for annual case volumes under 10, 4.28% for volumes between 10 and 24, 3.78% for volumes between 25 and 49, and 3.12% for volumes between 50 and 74.

The average additional distance traveled by each patient because of regionalization, based on data from all hospitals conducting cardiovascular surgery between 2001 and 2004, is shown in Table 3. For hospitals with an annual volume of 25-49 cardiovascular surgeries, 5,899 patients (11.3%) were affected with an average additional travel distance of 11.5 kilometers. For hospitals with a volume of 50-74 annual cardiovascular surgeries, 11,213 patients (21.4%) were affected with an average additional travel distance of 12.4 kilometers.

Table 4 demonstrates the effect of regionalization on patients' travel distance by distance and volume categories. While 693 of 5,899 patients (11.7%) in the

regionalization category of 25-49 annual surgeries traveled more than 30 extra kilometers after regionalization, 1,140 of 11,213 patients (10.2%) did the same for the regionalization category of 50-74 annual surgeries. The extra travel distance was also calculated based on the emergency status of the surgery. 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 between 10 and 24 (0.02% of total), 88.3 patients for volumes between 25 and 49 (0.2% of total), and 179.3 patients for volumes between 50 and 74 (0.3% of total).

Discussion

In this study, the impact of regionalization on the Japanese cardiovascular surgery program was estimated based on the annual surgical procedure volume in hospitals. The results indicate no significant improvement in the 30-day mortality rate after regionalization for hospitals with fewer than 10 and between 10 and 24 annual cardiovascular surgeries. However, the mortality rate does improve for volumes between 25-49 and 50-74 (Table 2). Currently, cardiovascular surgery programs proliferate without regulatory oversight in Japan due to a lack of existing standards for establishing such programs. A previous study from the United States indicated that mortality rates for Medicare patients undergoing CABG surgery were higher in states without certificate-of-need regulation. Thus, minimum volume standards may be somewhat effective in reducing the mortality rate. The current study indicates that a minimum annual volume standard of 50 cardiovascular surgeries would be effective in Japan.

Though the minimum procedural volume limits in this Japanese study were fewer than 10, 10-24, 25-49, and 50-74 cardiovascular surgeries per year, such cutoffs vary across countries. In the United States, the volume of Coronary Artery Bypass Graft (CABG) surgeries in similarly sized hospitals is categorized as less than 150, from 150 to 300, from 300 to 450, and greater than 450 surgeries per year[7]. Thus, appropriate standards in the United States may be higher than those in Japan. While 98.3% of Japanese hospitals are low-volume according this US definition, the 30-day mortality rate for categories with more than 41-50 procedures per year was stable (less than 2.0%)[8]. This is comparable to rates in most state and national CABG registries in the United States[22]. A number of reasons may explain the difference between the volume-outcome effects in Japan compared to other countries. Since many surgeons

in Japan belong to a single hospital, information and experiences regarding each patient are shared with many cardiovascular surgeons and other medical staffs in the hospital. Usually, cardiovascular surgery is performed by two or more consultant surgeons with trainees instead of by a single surgeon. On the other hand, the greatest advantage of a minimum volume standard is to increase sample sizes, thus enabling more precise assessment of risk-adjusted outcomes[23]. For risk-adjusted outcome evaluation, setting the volume standard to more than 75 procedures per year in Japan is preferred.

After regionalization, a patient must travel an extra 5.8 to 12.4 kilometers on average (Table 3). The results indicate that aggregates of the average patient travel distances were not very large. This may be because hospitals performing cardiovascular surgeries in urban areas, where most of the affected hospitals were located, are already geographically close together. On the other hand, some patients must travel over 30 additional kilometers after regionalization (Table 4). Such increases in travel time may have critical consequences if the patient needs emergency surgery. However, the results indicated that low-volume hospitals had relatively few emergency cases. Thus, improving the transportation system for emergency surgeries may be more effective in many regions than establishing or maintaining low-volume cardiovascular surgery programs.

In Japan, hospitals and cardiovascular surgeons may be strongly affected by the changes resulting from regionalization of cardiovascular surgery (Table 1). Although the low-volume cardiovascular surgery programs have been loss-making,[24] many hospitals want such programs because they serve as backups for PCI[30] and because of the prestige associated with being a general hospital. However, some studies have suggested that off-site PCI is feasible and safe for selected patients under specific conditions.[25,26] This problem can be attenuated by transferring physician to local hospitals to perform primary PCI,[27] or by establishing inter-hospital and interdisciplinary collaboration in each region.[28] The local government should be involved in each region, alongside the cardiologists and hospitals, with plans to improve the mortality rate of cardiovascular surgery. The medical staff needs to consider the effects of age-limit retirement and resident training with regionalization. Finally, a preparation period will be needed after the announcement of suitable minimum volume standards for regional medical planning and medical staff management.

This study has several limitations. First, while many factors related to regionalization of cardiovascular surgery were considered in this study, others such as healthcare expenditure were not addressed. Second, the estimated effects of regionalization, including changes in the 30-day mortality rate for cardiovascular surgery and inconvenience from additional travel, were based on crude predictions. As the voluntary survey data lacked adequate risk adjustment, in former study we also examined a data from Japan Adult Cardiovascular Surgery Database, a clinical registry modeled after the STS National Adult Cardiac Database[8]. In those analyses, distributions of patients' risk factors were not so different among each volume category. Thus, non-risk adjustment may not be a crucial limitation in this study.

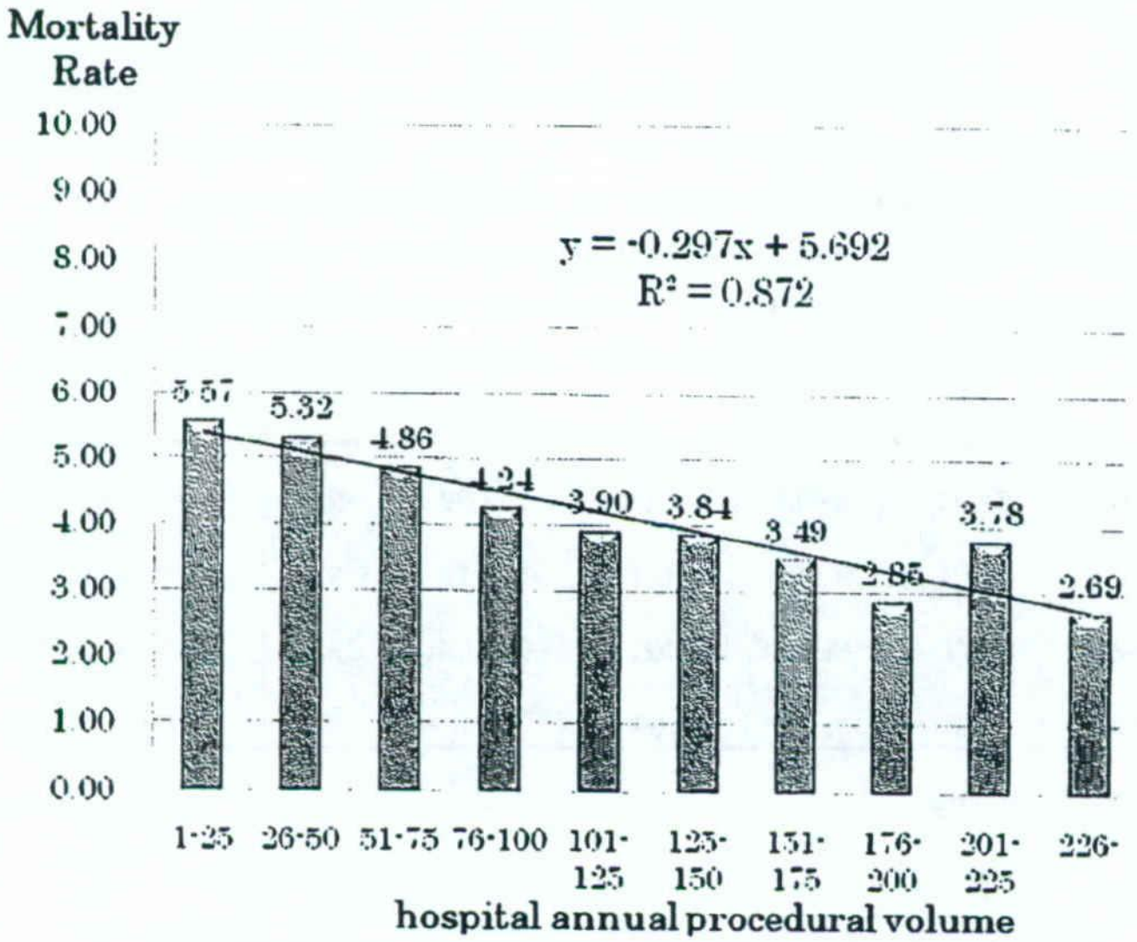
References

1. Birkmeyer JD, Siewers AE, Finlayson EVA, et al. Hospital volume and surgical mortality in the United States. N Engl J Med. 2002; 346: 1128-1137.
2. Begg CB, Cramer LD, Hoskins WJ, Brennan MF. Impact of hospital volume on operative mortality for major cancer surgery. JAMA 1998; 280: 1747-1751.
3. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. N Engl J Med 1979; 301: 1364-1369.
4. Epstein AM. Volume and outcome. It is time to move ahead. N Engl J Med 2002; 346: 1161-1164.
5. Birkmeyer JD. Raising the bar for pancreaticoduodenectomy. Ann Surg Oncol 2002; 9: 826-827.
6. The Leapfrog Group Web Site. Available at http://www.leapfroggroup.org. Accessed Nov 3, 2007.
7. Peterson ED, Coombs LP, DeLong ER, Haan CK, Ferguson TB. Procedural volume as a marker of quality for CABG surgery. Jama. Jan 14 2004;291(2):195-201.
8. Miyata H, Motomura N, Ueda Y, Matsuda H, Takamoto S. Effect of Procedural Volume on Outcome of CABG Surgery in Japan : Implication toward public reporting and minimal volume standards. Journal of Thoracic and Cardiovascular Surgery 2008; 135, 1306-1312
9. Miyata H, Motomura N, Takamoto S. Regionalization of cardiac surgery in Japan I-Effect of procedural volume on outcome of CABG surgery. Kyobu-Geka 2007;60:334-343. Japanese
10. Miyata H, Kondo JM, Motomura N, Fushimi K, Takamoto S. Regionalization of cardiac surgery in Japan II. Estimating the multiple effect of regionalization in cardiac surgery. Kyobu Geka 2007; 60:5. Japanese.
11. Miyata H, Motomura N, Kondo J, Takamoto S, Hasegawa T. Improving quality of healthcare in Japan: A systematic review of procedural volume and outcome literature, Bioscience Trend, BioScience Trends 2007; 1, 2: 81-89
12. Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Ann Intern Med 2002; 137: 511-520.
13. Institute of Medicine, Hewitt M. Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality: Workshop Summary. National Academy Press, Washington DC, USA, 2000.

14. Committee for Scientific Affairs, Kazui T, Osada H, Fujita H An attempt to analyze the relation between hospital surgical volume and clinical outcome. Gen Thorac Cardiovasc Surg. 2007 Dec; 55(12):483-92.
15. Yada I, Wada H, Fujita H. Thoracic and Cardiovascular Surgery in Japan during 2002: annual report by the Japanese Association for Thoracic Surgery. Jpn J Thorac Cardiovasc Surg. 2004; 52(10):491-508.
16. Yada I, Wada H, Shinoda M, Yasuda K. Thoracic and cardiovascular surgery in Japan during 2001: annual report by the Japanese Association for Thoracic Surgery. Jpn J Thorac Cardiovasc Surg. Dec 2003; 51(12):699-716.
17. Kazui T, Osada H, Fujita H. Thoracic and cardiovascular surgery in Japan during 2004. Jpn J Thorac Cardiovasc Surg. Aug 2006; 54(8):363-385.
18. Kazui T, Wada H, Fujita H. Thoracic and cardiovascular surgery in Japan during 2003: annual report by The Japanese Association for Thoracic Surgery. Jpn J Thorac Cardiovasc Surg. Sep 2005; 53(9):517-536.
19. Edmunds LHJ, Clark RE, Cohn LH, Grunkemeler GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations; the American Association for Thoracic Surgery, Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity. Annals of Thoracic Surgery. 1996;62: 932-935.
20. Birkmeyer JD, Siewers AE, Marth NJ, Goodman DC. Regionalization of high-risk surgery and implications for patient travel times. JAMA 2003; 290: 2703-08.
21. Kansagra SM, Curtis LH, Schulman KA. Regionalization of percutaneous transluminal coronary angioplasty and implications for patient travel distance. JAMA 2004; 292: 1717-23.
22. Shahian DM, Normand ST. Low-volume coronary artery bypass surgery: Measuring and optimizing performance. Journal of Thoracic and Cardiovascular Surgery 2008; 135: 1202-9.
23. Luft HS. Better for whom? Policy implications of acting on the relation between volume and outcome in coronary artery bypass grafting. J Am Coll Cardiol. 2001; 38: 1931-3.
24. Sese A. Economics of thoracic surgery in Japan. The Japanese Journal of Thoracic and Cardiovascular Surgery 2002; 50 Suppl: 139.(in Japanese)
25. Peels JO, Hautvast RW, de Swart JB, Huybregts MA, Umans VA, Arnold AE, Jessurun GA, Zijlstra F. Percutaneous coronary intervention without on site surgical back-up; two-years registry of a large dutch community hospital. Int J Cardiol. 2008, in press.

26. Paraschos A, Callwood D, Wightman MB, Tcheng JE, Phillips HR, Stiles GL, Daniel JM, Sketch MH Jr. Outcomes following elective percutaneous coronary intervention without on-site surgical backup in a community hospital. Am J Cardiol. 2005;95, 9: 1091-3.
27. Zhang Q, Zhang RY, Qiu JP, Zhang JF, Wang XL, Jiang L, Liao ML, Zhang JS, Hu J, Yang ZK, Shen WF. Prospective multicenter randomized trial comparing physician versus patient transfer for primary percutaneous coronary intervention in acute ST-segment elevation myocardial infarction. Chin Med J 2008; 121: 485-91
28. Le May MR, So DY, Dionne R, Glover CA, Froeschl MP, Wells GA, Davies RF, Sherrard HL, Maloney J, Marquis JF, O'Brien ER, Trickett J, Poirier P, Ryan SC, Ha A, Joseph PG, Labinaz M. A citywide protocol for primary PCI in ST-segment elevation myocardial infarction. N Engl J Med 2008; 358: 231-40.
29. Vaughan-Sarrazin MS, Hannan EL, Gormley CJ, Rosenthal GE. Mortality in Medicare beneficiaries following coronary artery bypass graft surgery in states with and without certificate of need regulation. JAMA. 2002; 288: 1859-66.
30. David E. Wennberg, MD, MPH; F. Lee Lucas, PhD; Andrea E. Siewers, MPH; Merle A. Kellett, MD; David J. Malenka, MD. Outcomes of Percutaneous Coronary Interventions Performed at Centers Without and With Onsite Coronary Artery Bypass Graft Surgery. JAMA. 2004;292:1961-1968.

Figure 1. The change in the 30-day mortality per an additional 25 annual cases



* The hospital procedural volumes were divided into ten categories so that adjustments could be made to allow for mortality rates of both 1/10 and 10/100.

** Since the variance of the mortality rate in a low-volume hospital is greater than in a high-volume hospital, the regression analysis was conducted for the total, rather than average, mortality rate in each category. For example, the total mortality rate for hospitals with a volume of 1-25 annual surgeries is equal to the total number of 30-day deaths in this category over the total number of surgeries in the category.

Table 1. The effects of regionalization on cardiovascular surgeons and surgery programs.

	Number of hospitals		Number of Surgeons		Annual volume	procedural	Estimated number of surgeons affected by regionalization*	
	N	%	N	%	N	%	N	%
Total	572	-	2,670	-	53,305	-	-	-
Annual volume under 10	53	9.3%	56	2.1%	221	0.4%	47-50	1.8-1.9 %
Annual volume 10-24	118	20.6 %	174	6.5%	1,378	2.6%	119-135	4.5-5.1 %
Annual volume 25-49	238	41.6 %	449	16.8%	5,899	11.3%	213-280	8.0-10.5 %
Annual volume 50-74	325	56.8 %	735	27.5%	11,213	21.4%	286-415	10.7-15.5 %

* First, the distributions of hospitals for cardiovascular surgery (column 1) and cardiovascular surgeons (column 2) were assessed by each regionalization category. Not all cardiovascular surgeons who worked in centers targeted by the regionalization cut-offs were forced to leave their employment immediately. As the remaining hospitals expanded their surgical volume (column 3), some of these surgeons were able to relocate to these hospitals. Based on estimates from cardiovascular surgery program directors, the remaining centers are expected to employ one new surgeon for each increase of 25-35 procedures. The final estimated number of surgeons affected by regionalization (who have to change their specialty) is displayed in column 4.

Table 2. Effects of regionalization on the 30-day mortality rate.

	I. Average 30-day mortality rate excluding hospitals under X	II. Average extra annual procedural volume gained by remaining centers	III. Estimated improvement of 30-day mortality rate by extra volume gain	IV. Estimated average 30-day mortality rate
No regionalization	—	—	—	4.62%
Annual volume under 10	4.41%	0.41	0.005%	4.40%
Annual volume 10-24	4.32%	3.04	0.04%	4.28%
Annual volume 25-49	3.99%	17.70	0.21%	3.78%
Annual volume 50-74	3.66%	45.40	0.54%	3.12%

* The change in the 30-day mortality rate after regionalization was assessed through two different approaches. First, the results were summarized after eliminating only low-volume hospitals whose overall quality was poor (column 1). Second, the remaining hospitals had their procedural volumes increased by evenly distributing the hospital volumes among them (column 2). Simple linear regression analysis was used to estimate the improvement in the 30-day mortality rate resulting from a one-case increase in procedural volume (the coefficient was determined in Figure 1). The estimated improvement in the 30-day mortality rate through volume redistribution is displayed in column 3. After combining the effects from these two approaches, the final estimated average 30-day mortality rate is shown in column 4.

Table 3. The effects of regionalization on the patients' average extra travel distance.

	Number of patients		Number of hospitals		Average extra travel distance* (km)
	N	%	N	%	
Annual volume under 10	211	0.4%	53	9.3%	5.8
Annual volume 10-24	1,378	2.6%	118	20.6 %	9.8
Annual volume 25-49	5,899	11.3%	238	41.6 %	11.5
Annual volume 50-74	11,213	21.4%	325	56.8 %	12.4
	Annual total of patient 52,305		Total no. of hospitals 649		—

* Weighted averaging by the number of patients on each travel pathway was used to estimate the average travel distance.

Table 4. The effects of regionalization on the patients' extra travel distance by categories of distance.

	<5 km		5-10 km		10-20 km		20-30 km		30-50 km		>50 km		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Annual volume under 10	158	74.9%	27	12.7%	2	1.1%	19	9.1%	4	2.0%	1	0.2%	211
Annual volume 10-24	794	57.7%	235	17.1%	119	8.6%	67	4.9%	96	7.0%	66	4.8%	1378
Annual volume 25-49	2,788	47.3%	1,359	23.0%	711	12.0%	349	5.9%	404	6.8%	289	4.9%	5899

週刊 Japan Medical Journal
1921年（大正10年）2月5日第三種郵便物認可（毎週土曜日発行）

日本医事新報

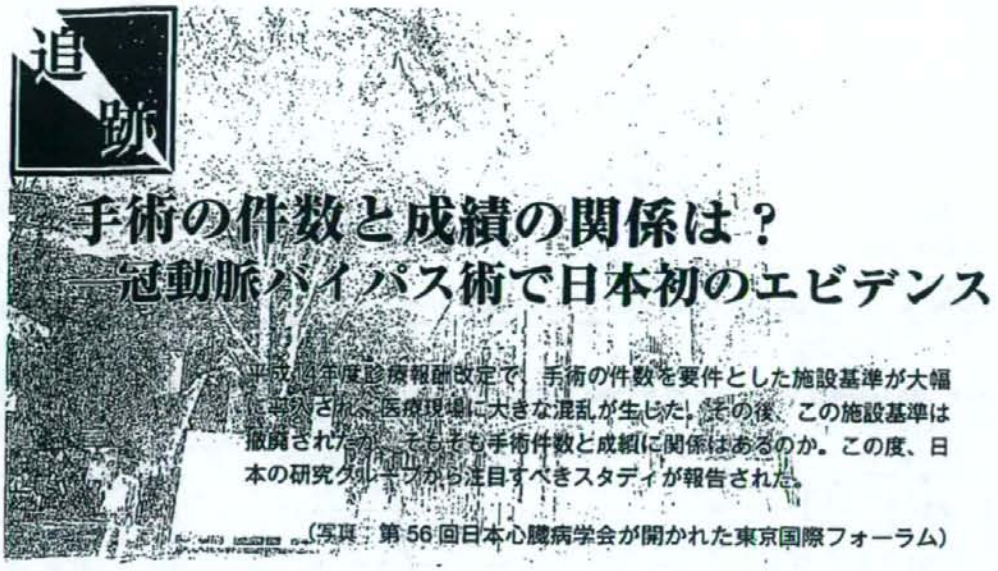
No.4404 | 2008年（平成20年）9月20日

http://www.jmedj.co.jp/

追跡

手術の件数と成績の関係は？
―冠動脈バイパス術で日本初のエビデンス

平成14年度診療報酬改定で、手術の件数を要件とした施設基準が大幅に導入され、医療現場に大きな混乱が生じた。その後、この施設基準は撤廃されたが、そもそも手術件数と成績に関係はあるのか。この度、日本の研究グループから注目すべきスタディが報告された。



（写真：第56回日本心臓病学会が開かれた東京国際フォーラム）

術者よりも施設の実績が影響

米国胸部外科学会の「胸部・心臓血管外科誌」（JTCS）の今年6月号に、日本人グループの論文が掲載された。

論文のタイトルは「日本における冠動脈バイパス術の成績に関する症例数の影響」。著者は高本眞一（東大院教授）、松田　暉（兵庫医大学長）、上田裕一（名大院教授）の各氏ら。

この論文は、日本胸部外科学会などのデータベースを基に、冠動脈バイパス術（CABG）における手術件数と成績（アウトカム）の関係を報告したもの。

日本でも近年、手術の件数とその成績の関係を検討した論文がいくつか発表されている。しかし、施設と術者（外科医）双方の手術件数を調べ、リスク調整をした上で成績との関係を明らかにしたのは今回が初めて。CABGの件数と成績の関係が日本から報告されたのも初めてのことだ。

年間手術件数が40件を超えると成績は安定

早速その結果を見てみよう。表1は、日本胸部外科学会が収集しているデータを基に、2001年から04年に国内540施設で行われたCABG計8万2611件を分析したもの。各施設の年間手術件数別に術後30日以内の平均死亡率を見た。

それによると平均死亡率は、年間手術件数が15件以下の施設では3・79％だったのに対し、51件以上の施設では1・61％にとどまった。年間手術件数が多いほど平均死亡率は明らかに低下した。

それでは、年間手術件数は何件以上あれば成績はよくなるのか。

図1は、表1の結果をより詳しく、各施設の年間手術件数10件区分別に見たもの。年間手術件数が40件を超えると平均死亡率は2％を下回り、それ以上は低い水準でほぼ一定になることが示された。

新たなデータベースJACVSDを活用

平均死亡率に影響を与えるのは、「施設」全体の手術件数か、それとも実際に手術をする「術者」の手術件数か。

その分析に当たり、日本胸部外科学会と日本血管外科学会が01年8月から合同でスタートさせた「日本成人心臓血管外科手術データベース」（JACVSD）が活用された。

検討の対象となったのは、データの安定性が保たれるようになった03年から05年の36施設4581例（リスク調整済み）。手術後30日

以内、あるいは手術後入院中の死亡率を調査した。

表2はその結果を見たもの。例えば、術者の手術件数が年間15件以下の水準であっても、施設の手術件数が51件以上と高い水準の場合は、死亡率は1・70％と低い値を記録した。

一方、術者が年間16件以上の手術を行っていても、施設の件数が16～30件と少ない場合では、死亡率は2・05％と高いことが分かった。

また、ロジスティック回帰分析に施設と術者の手術件数を同時に投入した場合（r＝0・30）に有意となったのは、施設の手術件数のみだった。

これにより、手術の成績は術者よりも施設全体の実績によって大きく左右されることが示された。

リスクの高い症例で病院の「実力」に差

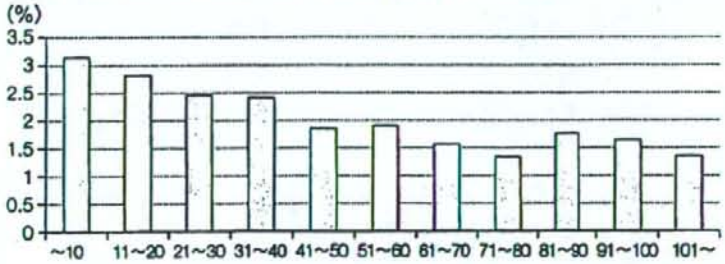
この結果を患者の年齢別に見たのが表3。65歳未満

（表1～表4、図1はJ Thorac Cardio Surg. 2008 Jun；135（6）：1308-1312から引用）

表1　日本の心臓外科施設の年間手術件数と30日死亡（2001～2004）

	日本の施設のCABG単独手術の年間症例数				
	≤15	16-30	31-50	≥51	合計
患者数	4,140	13,589	19,337	45,545	82,611
施設数	133	153	123	131	540
30日死亡数	124	349	412	700	1,585
緊急手術割合（%）	7.1	12.7	16.2	14.0	14.0
平均死亡率（%）（95% CI）	3.79（2.11-5.48）	2.60（2.17-3.01）	2.17（1.85-2.49）	1.61（1.80-1.43）	

図1　年間手術件数10件区分による死亡率の推移（2001～2004）



患者数	1,780	6,530	9,419	9,479	9,858	6,227	7,494	6,267	3,411	4,931	17,215
病院数	87	105	94	68	55	28	29	21	10	13	30

表2　施設と術者の手術件数区分ごとのリスク調整済み死亡率（2003～2005、n＝4,581）

術者年間手術件数	施設年間手術件数 16-30 %	n	31-50 %	n	≥51 %	n	全体 %	n
＜15	3.47	425	2.52	576	1.70	329	2.68	1,330
≥16	2.05	469	1.90	1,069	1.46	1,713	1.73	3,251
全体	2.67	894	2.14	1,645	1.50	2,042		

表3　施設における手術件数区分と年齢区分別死亡率の関係（2003～2005、n＝4,581）

	65歳未満 16-30	31-50	≥51	65歳以上 16-30	31-50	≥51
患者数	287	559	725	607	1,086	1,317
調整前死亡率	2.79	1.61	1.24	4.78	3.50	1.82
リスク調整後死亡率	1.53	1.23	1.03	3.28	2.62	1.73
P値		＜.05			＜.01	