Toward quality improvement of thoracic aortic surgery: estimating volume-outcome effect from nationwide survey

Hiroaki Miyata, Noboru Motomura, Yuichi Ueda, Hiroyuki Tsukihara, Koichi Tabayashi, Shinichi Takamoto

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 procurement, 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 \( p = 0.127: \text{OR} 0.988—0.999 \) and operative mortality \( p = 0.022: \text{OR} 0.982—0.999 \). 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.

---

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...
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.
4. Discussion

In this study, higher annual hospital thoracic aortic surgery volume 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 specifically 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 high-after-patient.
Table 4
Unadjusted and risk-adjusted mortality by patient age group (n = 2875).

<table>
<thead>
<tr>
<th>Expected risk &lt;6.0%</th>
<th>Expected risk &gt;6.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital thoracic aorta volume</td>
</tr>
<tr>
<td></td>
<td>5—20</td>
</tr>
<tr>
<td>No. of patients</td>
<td></td>
</tr>
<tr>
<td>Unadjusted mortality</td>
<td>280</td>
</tr>
<tr>
<td>Risk-adjusted mortality</td>
<td>3.21</td>
</tr>
<tr>
<td>p value (hospital volume)</td>
<td>0.263</td>
</tr>
<tr>
<td>Odds ratio</td>
<td>0.990—0.999</td>
</tr>
</tbody>
</table>

* 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).

<table>
<thead>
<tr>
<th>Expected risk &lt;6.0%</th>
<th>Expected risk &gt;6.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital thoracic aorta volume</td>
</tr>
<tr>
<td></td>
<td>5—20</td>
</tr>
<tr>
<td>No. of patients</td>
<td></td>
</tr>
<tr>
<td>Unadjusted mortality</td>
<td>169</td>
</tr>
<tr>
<td>Risk-adjusted mortality</td>
<td>7.23</td>
</tr>
<tr>
<td>p value (hospital volume)</td>
<td>0.0375</td>
</tr>
<tr>
<td>Odds ratio</td>
<td>0.982—0.999</td>
</tr>
</tbody>
</table>

Odds ratio 0.990—0.1003 0.989—0.999
p value (hospital volume) 0.263 0.019

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

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 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.

Acknowledgment

The authors thank all members of Japanese Cardiovascular Surgery Database, Takahiro Kiuchi and Yasuki Kobayashi for their tireless efforts to ensure the timeliness, completeness and accuracy of the registry data.

References


Editorial comment

Toward quality improvement of thoracic aortic surgery: estimating volume—outcome effect from nationwide survey

Since the first report dealing with the surgical volume—outcome relationship published 3 decades ago by Luft and co-workers in the NEJM [1], a great number of articles have addressed this issue. Whatever the studied surgical specialty, they have generally concluded that this relationship exists and that it is in favour of the high volume structures.

In cardiovascular surgery, such studies have been most often focussed on coronary artery bypass grafting as, indeed, it has represented for decades the largest cohorts of patients and the most frequent procedures performed in most centres as well as by each individual surgeon.

In their article entitled 'Toward quality improvement of thoracic aortic surgery: Estimating volume outcome effect from nationwide survey’, Miyata and co-workers extend this issue to the results of thoracic aortic surgery and analyse the relationship between those results and the hospital surgical volume as well as the individual surgeon volume in Japan [2]. The same group had recently published a similar article on coronary surgery, in which they concluded that ‘In Japan, high-volume compared to low-volume providers had better outcomes...’ [3]. Using the same methodology and database in the present study, they demonstrate and conclude similarly that hospital thoracic aortic surgery volume is...