Best evidence topic - Valves

Do bigger hospitals or busier surgeons do better adult aortic or mitral valve operations?

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Keywords: Volume; Outcome; Cardiac; Aortic; Mitral; Mortality

1. Introduction

A best evidence topic was constructed according to a structured protocol which is fully described in the ICVTS [1].

2. Clinical scenario

A 60-year-old male patient presented with symptomatic severe mitral regurgitation due to anterior and posterior leaflet prolapse confirmed by recent echocardiography. This case was referred by the local cardiologist to the joint Cardiology-Cardiothoracic meeting, emphasizing that an expert mitral valve surgeon should perform this operation. At this meeting another cardiologist suggested the case should be undertaken at a high volume hospital to achieve a better outcome based on the volume–outcome relationship (VOR) in cardiac surgery. It is important to consider whether it would be best for the surgery to be undertaken at a local hospital or to refer this patient to a high volume hospital or surgeon and you decide to evaluate the evidence by performing a literature search to clarify the effect of volume on outcome in adult aortic and mitral valve surgery.

3. Three-part question

In [adult patients undergoing aortic or mitral valve surgery], does [operation at a high volume hospital or by a high volume surgeon] result in better [outcome]?

4. Search strategy

Medline 1950 to November week 3 2009 using OVID interface: (aortic valve.mp. OR exp Aortic Valve/OR mitral
### Table 1

Summary of the best evidence papers

<table>
<thead>
<tr>
<th>Author, date and country, Study type, level of evidence</th>
<th>Patient group</th>
<th>Outcomes</th>
<th>Key results</th>
<th>Quality score</th>
<th>Weakness</th>
<th>Comments and conclusion</th>
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</thead>
<tbody>
<tr>
<td>Birkmeyer et al., (2002), N Engl J Med, USA, [2]</td>
<td>6-year period: 151,610 patients in 1069 hospitals undergoing AVR, Average Charlson score ≥ 3 = 9.06</td>
<td>In-hospital mortality or mortality 30 days after surgery</td>
<td>Adjusted mortalities for volume categories: Volume category (1): AVR 9.3%, MVR 15.1%. Volume category (2): AVR 8.6%, MVR 13.9%. Volume category (3): AVR 8.5%, MVR 13.3%. Volume category (4): AVR 7.9%, MVR 12.3%. Volume category (5): AVR 7.1%, MVR 11.6%.</td>
<td>7/18</td>
<td>Patients under the age of 65 years were excluded</td>
<td>Mortality rates adjusted for age, sex, race, year of procedure, social security income, urgency of admission and coexisting conditions which were compiled into a Charlson score</td>
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<tr>
<td>Retrospective cohort study (level 2b)</td>
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<td>Risk adjustment has negligible effect on the relationship</td>
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<tr>
<td>Birkmeyer et al., (2003), N Engl J Med, USA, [3]</td>
<td>2-year period: 42,541 patients under the care of 2440 surgeons undergoing AVR, Average Charlson score ≥ 3 = 9.43</td>
<td>In-hospital mortality or mortality 30 days after surgery</td>
<td>Adjusted mortality of SV categories: Category (1) 9.1%. Category (2) 7.8%. Category (3) 6.5%. Adjusted mortalities of HV (1) for SV categories: (1) 8.7%. (2) 7.7%. (3) 6.6%. Adjusted mortalities of HV (2) for SV categories: (1) 9.5%. (2) 7.9%. (3) 7.3%. Adjusted mortalities of HV (3) for SV categories: (1) 10.2%. (2) 7.7%. (3) 6.1%. SV accounted for 100% of the apparent effect of the HV in AVR.</td>
<td>9/18</td>
<td>Patients under the age of 65 years were excluded</td>
<td>Mortality rates adjusted for characteristics both the patients and the hospitals. For patients; age, sex, race, year of procedure, social security income, urgency of admission and coexisting conditions which were compiled into a Charlson score for hospitals; type of ownership (not-for-profit, for-profit, or government), location (urban or non-urban), and teaching status</td>
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<tr>
<td>Retrospective cohort study (level 2b)</td>
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<td>Authors conclude that ‘for many procedures, the observed associations between HV and operative mortality are largely mediated by SV. Patients can often improve their chances of survival substantially, even at high-volume hospitals, by selecting surgeons who perform the operations frequently’</td>
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<tr>
<td>Gammie et al., (2007), Circulation, North America, [4]</td>
<td>4-year period: 13,614 patients in 575 hospitals undergoing elective</td>
<td>In-hospital mortality or mortality 30 days after surgery</td>
<td>Volume category (1): Observed mortality 3.08%. Rate of mitral valve repair 47.7%</td>
<td>12/18</td>
<td>The study did not examine the effect of SV on outcome</td>
<td>Clinical data were used for risk adjustment including; age, gender, race, body mass index, smoking, renal failure</td>
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<tr>
<td>Retrospective cohort study (level 2b)</td>
<td>mitral valve surgery for mitral regurgitation 4 annual HV categories used to sort the volumes into quartiles: (1) 1–35 (2) 36–70 (3) 71–140 (4) &gt;140</td>
<td>In-hospital complications (stroke, re-operation, RF, and ventilation &gt; 24 h) Composite end-point of the above two outcomes Frequency of mitral valve repair Frequency of BPV use in older patients (&gt;65 years)</td>
<td>Rate of BPV use (in &gt;65 years) 59% Volume category (4): Observed mortality 1.11% Rate of mitral valve repair 77.4% Rate of BPV use (in &gt;65 years) 75% Adjusted odds ratio for mortality in the highest volume category compared with the lowest-volume category 0.48 Risk adjustment resulted in no significant differences in measures of morbidity across the volume categories, except for prolonged ventilation</td>
<td>7/18</td>
<td>were observational, therefore, difficult to conclude that these care processes had a causal relationship with better outcomes</td>
<td>(RF), hypertension, endocarditis, chronic lung disease, cerebrovascular accident, cerebrovascular disease, peripheral vascular disease, recent myocardial infarction, congestive heart failure, angina, arrhythmia, New York Heart Association class, and ejection fraction</td>
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<tr>
<td>Goodney et al., (2003), Ann Thorac Surg, USA, [5]</td>
<td>6-year period: 684 hospitals performed 817,606 isolated CABGs, 142,488 AVRs (54% with concomitant CABG), and 61,252 MVRs (45% with concomitant CABG) Patients aged 65–99 HV categorized into deciles (on the basis of operative mortality with isolated CABG) For the effect of volume a cut-off point of 100 valve replacements per year (~50th percentile) was chosen</td>
<td>In-hospital mortality or mortality 30 days after surgery Mortality rate of 1st and 10th deciles: (1) AVR = 6.0% MVR = 10.1% (10) AVR = 13% MVR = 20.5% Effect of volume on correlation coefficient between CABG mortality and (1) AVR &lt;100 valve a year 0.578 &gt;100 valve a year 0.585 (2) MVR &lt;100 valve a year 0.494 &gt;100 valve a year 0.546 P=0.001 for all correlations</td>
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<td>7/18</td>
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<td>Goodney et al., (2003), Ann Surg, USA, [6]</td>
<td>6-year period in &gt;1000 hospitals 151,610* patients undergoing AVR Average Charlson score% ≥ 3 = 9.06</td>
<td>Postoperative length of stay (days) 30-day readmission</td>
<td>Volume category (1): AVR Length of stay – 10.2 Re-admission – 18.9% MVR Length of stay – 12.3</td>
<td>8/18</td>
<td>Patients under the age of 65 years were excluded</td>
<td>Adjusted for age, sex, race, social security income, urgency of admission and coexisting conditions which were compiled</td>
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<td>64,935 patients undergoing MVR</td>
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<td>Re-admission – 21.9%</td>
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<td>Average Charlson score: ( \geq 3 = 10.12 )</td>
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<td>Volume category (5):</td>
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<tr>
<td>Patients aged 65–99</td>
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<td></td>
<td>AVR Length of stay – 11.5</td>
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<tr>
<td>5 annual HV categories used to sort the patients into quintiles:</td>
<td>(1) &lt; 43</td>
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<td>Re-admission – 19.2%</td>
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<td>(2) 43–74</td>
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<td>MVR Length of stay – 14.3</td>
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<td>(3) 75–119</td>
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<td>Re-admission – 21.9%</td>
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<td>(4) 120–199</td>
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<td>(5) &gt; 199</td>
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<td>Goodney et al., (2003), Circulation, USA, [7]</td>
<td>Patients aged 65–99</td>
<td></td>
<td>In-hospital mortality or mortality 30 days after surgery</td>
<td>Mortality:</td>
<td>6/18</td>
<td>Patients under the age of 65 years were excluded</td>
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<td>Retrospective cohort study (level 2b)</td>
<td>60% in patients aged 65–69</td>
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<td>AVR:</td>
<td></td>
<td>The use of administrative data rather than clinical data in risk adjustment</td>
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<td>59,389 patients undergoing AVR</td>
<td>2 patient risk categories:</td>
<td></td>
<td></td>
<td>Low-risk patients VHVH – 7.9%</td>
<td></td>
<td>The study did not examine the effect of SV on outcome</td>
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<tr>
<td>Patients aged 65–99</td>
<td>– High-risk (patients in the highest 25th percentile of predicted mortality)</td>
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<td>VHVH – 6.1%</td>
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<td>2,543 patients undergoing MVR</td>
<td>– Low-risk (patients in the lowest 75th percentile of predicted mortality)</td>
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<td>2 HV categories: VHVH, highest 20th percentile of procedure volume, &gt; 199</td>
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<td>VDHV, lowest 20th percentile of procedure volume, &lt; 43</td>
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<tr>
<td>Schelbert et al., (2005), Circulation, USA, [8]</td>
<td>The recommended use of BPV in older patients undergoing AVR</td>
<td></td>
<td>48% of patients received BPV</td>
<td>9/18</td>
<td></td>
<td>Risk adjustment model included, age; year of AVR surgery; female gender; angina pectoris; and several comorbid conditions (peripheral vascular disease, non-metastatic cancer, coagulopathy, peptic</td>
</tr>
<tr>
<td>Retrospective cohort study (level 2b)</td>
<td>Patients grouped</td>
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<td>36% in patients aged 65–69</td>
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<td>80,470 patients aged ( \geq 65 ) in 1045 hospitals undergoing isolated AVR</td>
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<td>60% in patients aged ( \geq 90 )</td>
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<td>48% of patients received BPV</td>
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<td>Similar use in men and women</td>
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<td>as receiving BPV or mechanical aortic valve</td>
<td>included hospital characteristics (teaching status and ownership) were conducted</td>
<td>(49% vs. 48%)</td>
<td>Rate of BPV use in the lowest and highest volume deciles: (1st) – 28% (10th) – 68%</td>
<td>and in risk adjustment</td>
<td>The study did not examine the effect of SV on outcome</td>
<td>ulcer disease, and primary diagnosis of acute myocardial infarction</td>
</tr>
<tr>
<td>HV categorized into deciles (on the basis of mean annual volume)</td>
<td>BPV use was significantly lower in major teaching hospitals than in other hospitals (44% vs. 55%) and in for-profit hospitals than in not-for-profit hospitals (40% vs. 49%), P &lt; 0.001 for both</td>
<td></td>
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<td></td>
<td>Authors conclude that HV was a strong predictor of BPV use in older patients undergoing AVR. The lower use of BPVs in low-volume hospitals is at odds with recent guidelines recommending BPVs in patients aged ≥65 years</td>
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<tr>
<td>Mean age 76</td>
<td>42% women</td>
<td>94% white</td>
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</table>

AVR, aortic valve replacement; MVR, mitral valve replacement; HV, hospital volume; SV, surgeon volume; BPV, bio-prosthetic valves; CABG, coronary artery bypass grafting; VH VH, very high-volume hospital; VL VH, very low-volume hospital.

*Figures are extracted from data used by the same group in earlier work [2].

valve.mp. OR exp Mitral Valve/OR exp Thoracic Surgery/OR exp Cardiac Surgical Procedures/) AND (hospital volume.mp or procedural volume.mp OR surgical volume.mp OR volume standardS.mp OR volume-outcome.mp). In addition, the reference lists of all the relevant papers were searched.

5. Search outcome

A total of 160 papers were found using the reported search. From these, seven papers [2–8] (Table 1) were identified as representing the best evidence to answer this clinical question.

6. Methodology scoring

The methodological quality, strength of study and the ability to generalise conclusions of each article was assessed using a predefined scoring system specifically designed to measure the degree to which the study design is likely to reveal increased accuracy regarding the magnitude and nature of the relationship between volume and outcome. This was initially developed by Halm et al. [9, 10] and modified by Mayer et al. [11]. The scoring system (Table 2) consists of 10 questions which consider the representativeness of the study sample, sample size, number of adverse events, unit of analysis, inclusion of clinical processes of care, appropriateness of patient selection, volume categories, quality of risk adjustment and outcome measurements; with a maximum possible score of 18.

7. Comment

The inverse relationship between procedural volume and adverse outcomes in different types of surgery has been supported by numerous studies [2, 9, 12, 13]. Considerable focus has been placed on coronary artery bypass grafting (CABG), leaving relatively modest reflection on the outcomes of adult cardiac valve surgery. Seven clinical studies, comprising over 500,000 patients were identified to answer the above question.

VOR is a concept concerning both health providers and cost payers to achieve better outcome in a cost–effective mode. VOR in adult cardiac valve surgery remains questionable, partly due to lack of clinical evidence. It is now >25 years since this concept was initiated and only seven studies were found attempting to investigate this relationship in adult aortic or mitral valve surgery. There are three key questions about VOR that need to be answered in regard to clinical practice: 1) Is the hospital volume (HV) or surgeon volume (SV) more significant? 2) What is the cut-off value for volume? 3) Which type of operation?

To answer these questions, extensive studies with robust methodology considering patient, hospital and surgeon factors that can affect VOR should be conducted. Bridgewater et al. [14] proposed 19 criteria of best practice standards for mitral valve repair. In these recommendations, volume thresholds were treated as equivalent and not superior to other standards and they confirmed the absence of supportive data for these volume thresholds. This paper supports the idea that VOR is not a simple equation and it represents a complex interaction between several variables. Perhaps only when these other factors are standardised then this relationship becomes valid.

These seven papers did not investigate particularly the effect of SV and the clinical processes of care. In addition, patient populations, risk adjustment systems, volume types and categories, type of surgery and outcomes were all heterogeneous. This made the process of identifying a robust conclusion quite difficult. For example, outcomes assessed by these studies were heterogeneous as follows:
four papers used mortality, one paper used morbidity, one paper used care processes and one paper examined all the above-mentioned outcomes. Only one paper assessed the effect of both HV and SV on outcome, while the rest assessed only HV. The type of valve operated on was also heterogeneous. It is important to notice that none of these papers were based on data from Europe. It is not clear whether this is due to a lack of awareness or due to concept disbelief. This makes the generalisation of the reported conclusions for the European population debatable. Another point is the presence of common authorship and repetitive or overlapped data in many of these studies; although we did not exclude any of them because they investigated different aspects of VOR. In addition, analysis of methodological quality, strength of study and the ability to generalise conclusions with the above-mentioned scoring system results with a median total quality score of eight which is not strong enough to defend the reported conclusions.

### 8. Clinical bottom line

VOR in adult aortic or mitral valve surgery is a result of complex interactions between numerous factors that were not deeply investigated in the above limited number of studies. The availability of high quality clinical processes of care, physician and other professional skills and organisational skills in high-volume hospitals may be the real reasons behind better outcomes rather than just the volume element. Therefore, we conclude that regionalisation of adult aortic or mitral valve surgery to high-volume hospitals or surgeons based on the presence of such a limited number of modest quality studies would be an unjustifiable policy.

### References


