Less-Invasive Mitral Valve Operations: Trends and Outcomes From The Society of Thoracic Surgeons Adult Cardiac Surgery Database

James S. Gammie, MD, Yue Zhao, PhD, Eric D. Peterson, MD, MPH, Sean M. O'Brien, PhD, J. Scott Rankin, MD, and Bartley P. Griffith, MD

Division of Cardiac Surgery, University of Maryland Medical Center, Baltimore, Maryland; Duke Clinical Research Institute, Durham, North Carolina; and Centennial Medical Center, Vanderbilt University, Nashville, Tennessee

Background. **The purpose of this study was to examine utilization and outcomes of less-invasive mitral valve (LIMV) operations in North America.**

Methods. **Between 2004 and 2008, 28,143 patients undergoing isolated mitral valve (MV) operations were identified in The Society of Thoracic Surgeons Adult Cardiac Surgical Database (STS ACSD). The LIMV operations were defined as those performed with femoral arterial and venous cannulation.**

Results. **The LIMV operations increased from 11.9% of MV operations in 2004 to 20.1% in 2008 ($p < 0.0001$). In 2008, 26% of STS ACSD centers performed at least one LIMV operation, with a median of 3 per year. Patients in the LIMV group were younger and had fewer comorbidities. Median perfusion (135 versus 108 minutes) and cross-clamp times (100 versus 80 minutes, $p < 0.0001$) were longer in the LIMV group. Mitral valve repair rates were higher in the LIMV group (85% versus 67%, $p < 0.0001$). Adjusted operative mortality was similar (odds ratio 1.13, 95% confidence interval: 0.84 to 1.51, $p = 0.47$). Blood transfusion was less common (odds ratio 0.86, 95% confidence interval: 0.76 to 0.97, $p < 0.0001$) while stroke was more common (OR 1.96, 95% confidence interval: 1.46 to 2.63, $p < 0.0001$) in the LIMV group.**

Conclusions. **In selected patients, LIMV operations can be performed with equivalent operative mortality, shorter hospital stay, fewer blood transfusions, and higher rates of MV repair than conventional sternotomy. However, perfusion and cross-clamp times were longer, and the risk of stroke was significantly higher. Beating- or fibrillating-heart LIMV techniques are associated with particularly high risks for perioperative stroke.**

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Although the earliest open mitral valve operations were performed through a right thoracotomy, contemporary mitral valve surgery is dominated by a sternotomy approach [1]. Central cannulation and direct aortic cross-clamping enable mitral valve repair or replacement on a still heart with generous exposure and excellent results [2]. In an effort to decrease the invasiveness and perioperative disability associated with heart valve surgery, cardiac surgeons have introduced "less invasive" mitral valve operations. These operations are characterized by a nonsternotomy (usually a small thoracotomy) incision and some permutation of cannulation, tissue manipulation (direct or robotic), aortic occlusion, or visualization techniques. A less-invasive mitral valve (LIMV) operation has great appeal to patients, who often prefer a nonsternotomy approach, but outcomes have never been critically evaluated in a prospective randomized fashion. Several published meta-analyses have concluded that LIMV operations are associated with fewer blood transfusions, shorter lengths of hospital and intensive care unit stays, but with longer cardiopulmonary bypass and cross-clamp times [3, 4]. These studies are small, largely retrospective, and limited to centers with expertise in LIMV surgery. The purpose of this report is to evaluate trends in the operative approach to the mitral valve and to critically examine outcomes of LIMV operations compared with conventional sternotomy approaches using the power of The Society of Thoracic Surgeons Adult Cardiac Surgical Database (STS ACSD).

Material and Methods

Because the data used in analyses of the STS ACSD represent a limited data set (no direct patient identifiers) that was originally collected for nonresearch purposes, and the investigators do not know the identity of individual patients, the analysis of these data was declared by the Duke University Health System Institutional Review Board to be research not involving human subjects and is therefore considered exempt (Duke University Health System Protocol 00005876) [5–7].

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Address correspondence to Dr Gammie, Division of Cardiac Surgery, University of Maryland Medical Center, N4W94, 22 S Greene St, Baltimore, MD 21201; e-mail: jgammie@smail.umaryland.edu.

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Patient Population

The study population consisted of patients undergoing isolated primary mitral valve operations for mitral regurgitation with or without a concomitant atrial fibrillation (AF) correction procedure between January 1, 2004, and December 31, 2008. Patients with infective endocarditis, prior cardiac operation, cardiogenic shock, emergency operation, mitral stenosis, and concomitant coronary artery bypass graft, tricuspid, or aortic valve surgery were excluded.

Data Definitions

The STS ACSD includes four cannulation strategies: (1) aorta and atrial/caval, (2) aorta and femoral/jugular vein, (3) femoral artery and atrial/caval, and (4) femoral artery and femoral/jugular vein. For the purposes of this analysis, LIMV operations were defined as patients undergoing femoral arterial and femoral/jugular venous cannulation, whereas conventional mitral valve operations were defined as aorta and atrial/caval central cannulation. Aortic occlusion strategies included aortic cross-clamp, balloon occlusion, or no aortic occlusion. Robotic telemanipulation was identified from the field "robotic technology assisted yes/no." The primary outcome variable was operative mortality, defined as the greater of in-hospital or 30-day death from any cause. Secondary outcomes included rates of permanent stroke, deep sternal wound infection, renal failure, and reoperation for bleeding. A composite outcome consisting of operative mortality and major complications (including reoperation for valvular dysfunction or bleeding/tamponade, deep sternal wound infection, stroke, renal failure or prolonged ventilation or both) was also calculated.

Statistical Analysis

Patient characteristics and outcomes were summarized using the median and the 25th percentile to 75th percentile interquartile range (IQR) for continuous variables, and frequency and percentage for categorical variables. The Wilcoxon rank sum test was used to compare the distribution of continuous variables between groups, whereas the Mantel-Haenszel test was used for categorical variable comparisons.

To account for the correlation among patients within the same participant group, the risk-adjusted subgroup comparisons for binary outcomes were conducted using marginal logistic regression models fit using generalized estimating equations methodology, and the risk-adjusted comparisons for continuous outcomes were performed using linear mixed-effects models. Robust sandwich variance estimates were used to obtain 95% confidence intervals (CI) [8]. Preoperative patient factors included in the isolated valve surgery risk models have been recently published [9].

In addition, the outcome comparisons between less-invasive and conventional approaches were repeated using a propensity score matched pairs analysis. Covariates for the propensity model were the same as those described above. Each patient in the less-invasive group was matched to 1 patient with the most similar propensity score in the conventional group using a greedy matching algorithm [10, 11]. The differences in outcomes and baseline characteristics for the matched population were evaluated using the signed rank test for continuous variables and McNemar's test for binary variables.

The authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Patient Population

Between January 2004 and December 2008, 143,982 mitral valve operations were performed at 953 STS centers. From this total, 115,839 patients were excluded. The final population consisted of 28,143 patients undergoing isolated primary mitral valve operations for mitral regurgitation (Fig 1).

The distribution of cannulation, aortic occlusion, and robotic assistance strategies for patients undergoing isolated primary mitral valve operation for mitral regurgitation is outlined in Table 1.

Overall, 84.6% (23,821 of 28,143) of isolated primary mitral valve operations were performed using a conventional central cannulation (sternotomy) approach. The LIMV operations using femoral cannulation were performed in 15.4% of cases during the study period. The most common approach for LIMV operation was direct aortic occlusion without robotic assistance (1,654 of 4,322, 38.3%). Robotic assistance was used for 35.5% (1,533 of 4,322) of less-invasive operations. All patients in the conventional group had direct aortic cross-clamping; for the less-invasive group, aortic occlusion was with a clamp in 59.2% (2,557 of 4,322), with an endoaortic balloon in 28.9% (1,247 of 4,322), and no aortic occlusion in 12.0% (518 of 4,322). These patients underwent mitral valve surgery using either a beating- or fibrillating-heart

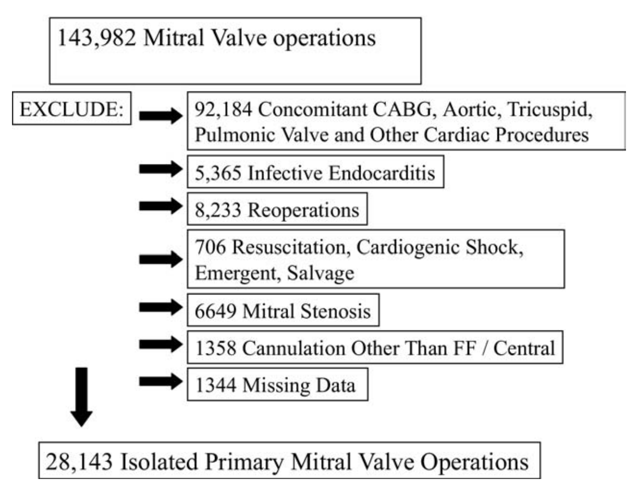

Fig 1. Patient population: exclusion criteria and final analysis population. (CABG = coronary artery bypass graft surgery; FF = femoral/femoral.)

Table 1. Distribution of Cannulation, Aortic Occlusion, and Robotic Assistance Strategies

Group	Cannulation	Aortic Occlusion	Robotic Assistance	n (%)
Conventional	Central	Direct	No	23,821 (84.6)
Less invasive 1	Femoral/femoral	Direct	No	1,654 (5.9)
Less invasive 2	Femoral/femoral	Direct	Yes	903 (3.2)
Less invasive 3	Femoral/femoral	Balloon	No	617 (2.2)
Less invasive 4	Femoral/femoral	Balloon	Yes	630 (2.2)
Less invasive 5	Femoral/femoral	None	No	518 (1.8)
Less invasive total	Femoral/femoral	—	—	4,322 (15.4)
Total				28,143 (100)

Twenty-four patients with femoral-femoral cannulation, robotic assistance, and no aortic occlusion were not included in this analysis.

approach, a conclusion supported by the observation that cardioplegia use was reported for 98.8% (23,536 of 23,821) of patients in the conventional group, but was not used for 96% (497 of 518) of patients in the no aortic occlusion LIMV operation group. Among patients who had robotic assistance, 58.9% (903 of 1,533) had direct aortic cross-clamping, and 41.1% (630 of 1,533) had endoaortic balloon occlusion.

The most recent versions of the STS ACSD data specifications do not include the type of incision used. A previous data specification (version 2.41) used between 2002 and 2004 included both incision type and cannulation strategy. To assure that the assumption that femoral cannulation was an appropriate surrogate for less invasive mitral valve operation, and that central cannulation represented a sternotomy approach, we examined version 2.41 data and identified 9,097 mitral valve operations with identical exclusion and inclusion criteria as the present analysis. Central cannulation was used for 92.2% (8,389 of 9,097) of these procedures, and full or partial sternotomy was the incision type for 98.6% (8,270 of 8,389) of patients identified as having central cannulation. Among the 708 patients (7.8%) identified as having femoral cannulation, more than 94% had a thoracotomy (91.7%) or small sternotomy (3.1%) approach. Thus, we concluded that the vast majority of patients identified as having femoral cannulation underwent mitral valve operation through an incision different from a conventional sternotomy.

Temporal Trends in Use of LIMV Operations

There has been a progressive adoption of LIMV operations over the period of this study, from 11.9% of isolated mitral operations in 2004 to 20.1% in 2008 ($p < 0.0001$; Fig 2). The percentage of these operations performed using balloon occlusion and robotic assistance has not changed over time ($p = 0.84$, $p = 0.17$, respectively).

Center-Specific Use of LIMV Surgery

To assess variation in the use of less-invasive techniques across institutions, we examined center-specific data during the latest year of the study. Among 709 centers reporting data to STS for each month during 2008, there were 6,598 primary mitral valve operations for isolated mitral regurgitation. Of these, 5,197 (78.8%) were conventional and 1,305 (19.8%) were less invasive. There were 186 centers (26.2%) that performed at least 1 LIMV operation in 2008 and 66 centers (9.3%) that performed 5 or more. The median number of primary isolated mitral valve operations for mitral regurgitation per center was 6 (IQR, 3 to 11). The median number of LIMV operations per center per year among centers reporting at least 1 LIMV operation was 3 (IQR, 1 to 7). The distribution of LIMV operations is outlined in Figure 3. Among centers performing LIMV operations, the percentage of isolated primary mitral valve operations done using less-invasive techniques (compared with conventional) ranged from 1.8% to 100% (median 33.3%, IQR, 15.4% to 57.1%). The number of centers reporting at least 1 LIMV operations using robotic assistance was 51 (7.2%, 51 of 709). The distribution of robotic mitral valve operations is outlined in Figure 4.

Patient Characteristics

Baseline characteristics of patients chosen to undergo less-invasive and conventional operations are outlined in Table 2. Patients selected for LIMV operations were younger, more likely to be male, and less likely to have comorbidities. A greater percentage of LIMV patients underwent elective operations and were asymptomatic before operation compared with those having conventional mitral operations.

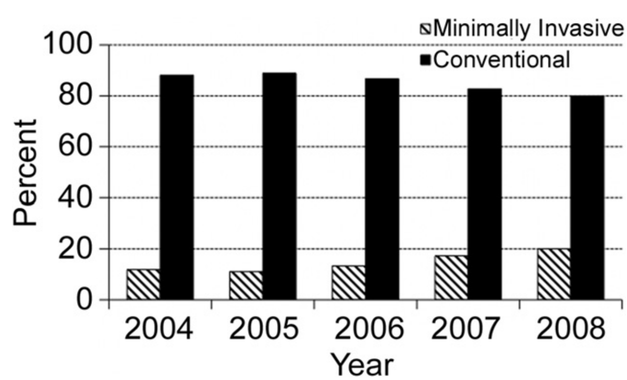

Fig 2. Adoption of less-invasive mitral valve operations (hatched bars) compared with conventional operations (black bars) over time.

Ann Thorac Surg
2010;90:1401–10

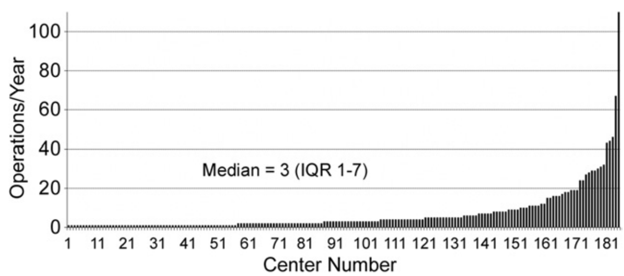

Fig 3. Distribution of less-invasive mitral valve operations among centers performing this operation. (IQR = interquartile range.)

Operative Data

Mitral valve repair rates were significantly higher in the less-invasive group compared with the conventional group (85% versus 67%, $p < 0.0001$). Median cardiopulmonary bypass and cross-clamp times were longer in the less-invasive group compared with the conventional group (cardiopulmonary bypass time 135 versus 108 minutes, respectively; $p < 0.0001$; and cross-clamp time 100 versus 80 minutes, respectively; $p < 0.0001$). The median operative time was longer (4.2 versus 3.4 hours, $p < 0.0001$) in the less-invasive group. Among patients with preoperative AF, fibrillation correction procedures were more commonly performed in the conventional group (5,646 of 6,989, 81%) than in the less-invasive group (656 of 911, 72%; $p < 0.0001$).

Unadjusted Perioperative Outcomes

Patients undergoing less-invasive mitral operations were in the intensive care unit and in the hospital 1 day less than patients having conventional mitral valve operations (Table 3). The likelihood of receiving any blood product transfusions was significantly lower in the less-invasive group, as was the incidence of new postoperative AF. The unadjusted mortality rate (1.84% versus 1.27%, $p = 0.0091$) and the composite outcome of morbidity or mortality (15.7% versus 12.9%, $p < 0.0001$) was higher among patients having conventional sternotomy mitral valve operations. As expected, the rate of mediastinitis was higher in this group. The unadjusted risk of permanent stroke was higher in the less-invasive group (1.87% versus 1.16%, $p < 0.0001$). Cause of death was more commonly neurologic (18.2% versus 7.1%, $p = 0.005$) in the less-invasive group.

Adjusted Outcomes

After adjusting for differences in preoperative characteristics, patients having LIMV operations had a similar risk of operative mortality (Table 4). Risk-adjusted rates of reoperation for bleeding were higher in the less-invasive group, whereas the risk-adjusted risk of blood transfusion and new postoperative AF was lower in the less-invasive group. The adjusted mean cross-clamp time was 26 minutes longer (118 versus 92 minutes, $p < 0.0001$) and the cardiopulmonary bypass time 40 minutes longer (163 versus 123 minutes, $p < 0.0001$) in the less-invasive group. There was an almost twofold higher risk of permanent stroke (adjusted odds ratio [OR] 1.96; 95% CI: 1.46 to 2.63, $p < 0.0001$) in the LIMV operation group, and this resulted in a significantly higher adjusted risk of the composite outcome of morbidity or mortality in the compared with the conventional group. The adjusted mean length of stay was shorter by 0.7 days (7.6 versus 6.9 days, $p < 0.0001$) in the less-invasive group.

Propensity Analysis

A propensity analysis was also performed to assess the relationship between operative approach and outcomes. Each patient in the LIMV operation group was matched to 1 patient with the most similar propensity score in the conventional group [12]. The LIMV operation and the matched conventional groups were well matched (Appendix Table 1*).

Outcomes in the matched groups were consistent with those obtained using the risk-adjusted multivariable analysis (Appendix Table 2*).

Association Between Specific Operative Strategy and Excess Stroke

To examine associations between operative strategy and the increased risk of stroke in the less-invasive group, we used the conventional method (central cannulation, direct cross-clamp, and no robotic assistance) as a reference and analyzed the risk of postoperative stroke using multivariate marginal logistic modeling.

Femoral cannulation was not independently related to increased risk for stroke in the LIMV operation patients (adjusted OR for femoral versus central cannulation 1.39, 95% CI: 0.90 to 2.15, $p = 0.14$). Use of beating- or fibrillating-heart techniques compared with aortic cross-clamping with cardioplegic cardiac arrest was associated with an adjusted threefold higher risk of stroke (adjusted OR 3.03, 95% CI: 1.66 to 5.51, $p = 0.0003$). We repeated the adjusted analyses excluding the less-invasive patients that had no aortic clamping (ie, beating- or fibrillating-heart techniques). The risk of stroke remained higher in the less-invasive group compared with the conventional

*See note at end of article regarding e-only Appendix.

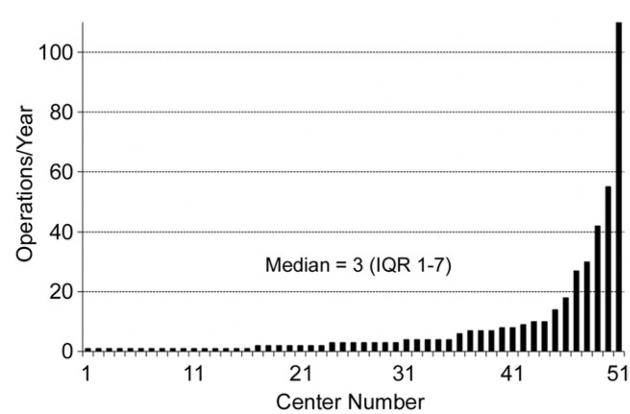

Fig 4. Distribution of robotic mitral valve operations. (IQR = interquartile range.)

Table 2. Characteristics of Patients Undergoing Less-Invasive Mitral Valve Surgery or Conventional Mitral Valve Surgery

Variable	Overall (n = 28,143)	Conventional (n = 23,821)	Less Invasive (n = 4,322)	*p* Value
Age, years, median	62.0	62.0	59.0	<0.0001
Sex, female,%	45.8	46.6	41.3	<0.0001
Body mass index, median	26.2	26.3	25.7	<0.0001
Diabetes mellitus,%	9.8	10.4	6.6	<0.0001
Renal failure,%	1.4	1.5	0.7	<0.0001
Chronic lung disease,%	16.7	17.7	11.2	<0.0001
Hypertension,%	57.7	58.7	52.6	<0.0001
Cerebrovascular accident	3.83	4.04	2.64	<0.0001
NYHA I, asymptomatic	14.7	14.3	16.7	<0.0001
Ejection fraction, median (interquartile range)	57.0 (50–61)	57.0 (50–60)	60.0 (50–62)	0.0021
Tricuspid regurgitation, moderate or severe,%	10.3	10.7	8.0	<0.0001
Procedure status, elective	82.5	80.6	92.8	<0.0001
Atrial fibrillation,%	28.1	29.3	21.1	<0.0001

NYHA = New York Heart Association.

group, but to a lesser extent (adjusted risk of stroke in less-invasive versus conventional = 1.52% versus 0.92%, $p = 0.0002$), suggesting that the high risk of stroke in this patient group contributed to, but did not completely explain, the elevated stroke risk in the less-invasive patients. Although we had hypothesized that use of the endoaortic balloon would have had an adverse impact on stroke compared with use of a direct cross-clamp, the results were more complex than we had expected. In the group of LIMV operations performed with the robot, the adjusted OR for stroke comparing use of the balloon versus direct cross clamping was 0.43 (95% CI: 0.15 to 1.18, $p = 0.10$). In contrast, use of the balloon (compared with direct aortic cross-clamping) was associated with a significantly higher rate of stroke in the nonrobotic group (adjusted OR 2.34, 95% CI: 1.04 to 3.96, $p = 0.036$). Overall, the use of the endoaortic balloon was not an independent predictor of a higher stroke rate.

Comment

One in five isolated primary mitral valve operations in North America is currently performed using less-invasive techniques. Younger patients with fewer comorbidities were preferentially selected for less-invasive approaches. Experience with LIMV operations is limited, with only one in four centers in the STS ACSD performing these operations in 2008, with a median case volume of three. Even fewer centers (less than 10%) perform robotic mitral valve operations. A previous report from the STS ACSD demonstrated a strong relationship between mitral valve operative volume and outcomes (re-

Table 3. Unadjusted Perioperative Outcomes

Variable	Overall (n = 28,143)	Conventional (n = 23,821)	Less Invasive (n = 4,322)	*p* Value
Operative mortality,%	1.75	1.84	1.27	0.0091
Reoperation for any reason,%	7.33	7.47	6.59	0.0424
Reoperation for bleeding,%	3.65	3.65	3.66	0.9794
Deep sternal wound infection,%	0.17	0.19	0.02	0.0118
Permanent stroke,%	1.27	1.16	1.87	0.0001
Postoperative atrial fibrillation,%	19.42	20.05	15.92	<0.0001
Renal failure,%	2.98	3.14	2.13	0.0003
Prolonged ventilation,%	9.1	9.5	7.0	<0.0001
Major morbidity or mortality,%	15.26	15.69	12.89	<0.0001
Acute limb ischemia,%	0.15	0.15	0.19	0.5567
Iliac/femoral dissection,%	0.02	0.02	0.05	0.2230
Aortic dissection,%	0.04	0.03	0.09	0.0842
Perioperative red blood cell transfusion,%	50.9	52.6	41.0	<0.0001
Perioperative platelet transfusion,%	23.9	25.3	15.8	<0.0001
Intensive care unit hours, median	42.0	44.8	26.4	<0.0001
Total ventilation hours, median	7.0	7.0	6.0	<0.0001
Postoperative length of stay, median days	6.0	6.0	5.0	<0.0001

Table 4. Odds Ratios (OR) for Outcomes of Less-Invasive Mitral Operations (Versus Conventional Sternotomy) Adjusting for Participant Correlations and Other Potential Variables)

Outcome	Adjusted OR	Lower 95% CI	Upper 95% CI	*p* Value
Mortality				
Operative mortality	1.13	0.84	1.51	0.419
Complications				
Any reoperation	1.12	0.95	1.32	0.177
Reoperation for bleeding/tamponade	1.22	1.01	1.48	0.040
Reoperation for valve dysfunction	0.89	0.48	1.64	0.702
Any infection	1.10	0.76	1.61	0.612
Permanent stroke	1.96	1.46	2.64	<0.001
Postoperative atrial fibrillation,%	0.79	0.70	0.89	<0.001
Renal failure	1.09	0.85	1.39	0.483
Prolonged ventilation	1.09	0.93	1.27	0.273
Major morbidity or mortality	1.14	1.01	1.29	0.029
Hospital stay				
Postprocedure length of stay >14 days	0.88	0.70	1.11	0.284
Blood product				
Perioperative red blood cell transfusion	0.86	0.76	0.97	0.014
Perioperative platelet transfusion	0.81	0.72	0.91	<0.001

CI = confidence interval.

pair rates and mortality) [13]. It is widely acknowledged that LIMV operations are technically more demanding than those approached through a sternotomy [14]. In one report, a learning curve as measured by operative efficiency did not reach a plateau until more than 135 LIMV operations were performed by a single surgeon [15]. Trento and colleagues [16] have presented an initial experience with 120 robotic LIMV operations and concluded that "... the learning curve is steep and long." Chitwood and colleagues [17] reported lower rates of reoperation for mitral valve repair failure in the latter two thirds of a series of 300 robotic mitral valve repairs. The present investigation documents progressive diffusion of LIMV operations to a growing number of mostly low-volume centers. Conclusions about the overall safety and efficacy of less-invasive mitral operations should be tempered by the knowledge that many surgeons are still gaining experience with this approach.

The operative mortality for patients having conventional and LIMV operations was similar when analyzed with both multivariable and propensity analyses. Operative mortality was less than 2% in all groups studied, the lowest mortality of any major cardiac operation reported to the STS ACSD [18]. Perfusion and cross-clamp times were consistently longer (by 40 and 15 minutes, respectively) in the less-invasive group, and this observation has been consistently reported in both single-center experiences and meta-analyses [4, 19]. Limited incision sizes, incomplete or inadequate exposure, and tissue manipulation using a robot or long-shafted instruments all increase time requirements to carry out key steps of a mitral valve operation. Prolonged cross-clamp and perfusion times have previously been reported as independent predictors of mortality, with a linear relationship among cardiopulmonary bypass time, ischemic time, and mortality rates [20, 21]. That relationship was not observed in this experience.

A consistent finding in this study was a lower transfusion rate in the less-invasive group, in addition to a higher rate of reexploration for bleeding. A small thoracotomy avoids marrow and sternal bleeding associated with median sternotomy, and decreases the amount of mediastinal dissection required to perform mitral valve surgery. Cannulation sites (another potential source of bleeding) are moved to the groin in a less-invasive approach. Despite the lower transfusion rate in the less-invasive group, the higher rate of reexploration for bleeding may be related to less complete visualization of chest wall bleeding sites. Others have reported chest wall bleeding as the dominant cause for reexploration [22]. It is also possible that less-invasive operations are associated with a lower threshold for return to the operating room.

The rate of mitral valve repair was not compromised by the use of less-invasive operative approaches, and in fact was significantly higher (85% versus 67%) in the less-invasive group. We cannot conclude that less-invasive techniques facilitate (or are detrimental to) mitral valve repair as there may be a strong bias toward use of less-invasive techniques for patients with mitral valve anatomy that is more likely to be repaired. Our finding that the average center performing LIMV surgery selected only one third of patients for this approach suggests that patient selection may explain, in whole or part, the higher repair rates for these patients. Global rates of mitral valve repair are affected by a variety of additional factors, including mitral valve pathoanatomy, surgeon experience, and institutional experience and volume [13, 23, 24]. Although some have criticized less-invasive approaches for technical limitations (exposure, video assistance, limited working space) and have suggested that this may compromise repair rates, the fact that the repair rate was substantially higher in the less invasive group argues against this conclusion.

Fewer patients with preoperative AF in the less-invasive group (72% versus 81%) were treated with an AF correction procedure [25]. Perhaps the prolonged bypass and cross-clamp times in the less-invasive group decreased the enthusiasm of the operating surgeon to spend additional time performing an AF correction procedure.

The most significant finding of this study was the markedly higher rate of permanent perioperative stroke in the less-invasive group compared with the conventional sternotomy group in unadjusted, adjusted, and propensity analyses. The adjusted OR for permanent stroke was 1.96 for less-invasive compared with conventional sternotomy operations in the multivariable analysis, and the likelihood of stroke was similarly increased in the propensity analysis. Among the 4,322 LIMV operations, there were 41 excess strokes compared with the propensity-matched group having conventional mitral valve operations. Additional analyses demonstrated a threefold higher risk of stroke for less-invasive operations performed without aortic occlusion (beating- or fibrillating-heart), which comprised 12% of the less-invasive group. Femoral cannulation was not an independent predictor of stroke.

One potential mechanism for increased stroke rates in patients having LIMV operations is cerebral air embolism. In all mitral operations, deairing the heart is challenging, and the limited exposure inherent in less-invasive approaches may be associated with more cerebral air embolism. Beating- or fibrillating-heart techniques without aortic occlusion have a further increased risk of air embolism due to lack of control of the aortic outflow. In all less-invasive cases, intracardiac air removal before removal of the aortic cross-clamp may be less effective, although this conclusion remains speculative. Other mechanisms predisposing to stroke in these less-invasive patients may include prolonged cross-clamp and cardiopulmonary bypass times, retrograde perfusion of the femoral/iliac vessels and the aorta, or aortic trauma from the endoaortic balloon. However, it should be reemphasized that this study strongly implicates nonaortic clamping (beating- or fibrillating-heart) approaches as an important contributor to the observed higher stroke rates. Others have shown that both cross-clamp and perfusion times are linearly related to stroke risk [26, 27]. Retroperfusion with femoral cannulation was not significant in this analysis, whereas the endoaortic balloon was associated with an increased stroke risk in the subset of patients having a nonrobotic approach.

By definition, deep-sternal wound infection cannot occur in patients having a small-thoracotomy incision. In this study, the rate of deep sternal wound infection was very low (0.08% overall), but in the propensity-matched comparison, a total of five sternal wound infections were avoided as a result of a nonsternotomy incision.

One key concern regarding less-invasive operations performed with femoral cannulation or endoaortic balloon occlusion is the risk of catastrophic aortic dissection. Others have reported rates of aortic dissection of between 0.2% and 1.4% [22]. The rates of aortic dissection reported in this series (0.03% for conventional sternotomy and 0.09% for less-invasive operations) were low, and the difference did not reach statistical significance. However, it is possible that patients converted to sternotomy and central cannulation for repair of an aortic dissection were missed in the present analysis, so firm conclusions cannot be reached on this issue.

The results of this study need to be interpreted within the context of an observational retrospective analysis. While attempts were made to adjust for patient characteristics in assessing outcomes, it is possible that unmeasured treatment selection biases or confounding variables played a part in assigning operative strategy. Patient exclusions included infective endocarditis, concomitant tricuspid valve operations, reoperations, mitral stenosis, and emergency operations, and thus we may not be assessing the impact of less-invasive surgical approaches on the full spectrum of mitral valve disease, although most published series to date have included few of these patients [14, 22, 28]. It is possible that the use of femoral-femoral cannulation is not an appropriate surrogate for less invasive mitral valve operation. However, analysis of data obtained from an earlier data specification suggests validity in that 95% of patients identified had operation using a nonsternotomy incision. We deliberately excluded patients having central/femoral or femoral/central cannulation strategies. Because the STS ACSD is limited to perioperative outcomes, the long-term outcomes of these two approaches cannot be defined.

Postoperative echocardiographic data are also not collected, so the quality of mitral valve repairs cannot be assessed. Others have reported higher reoperation rates, and it is possible that limited exposure and tissue manipulation limitations may compromise repair (or replacement) quality [14, 17]. Finally, the present series may not include patients converted to sternotomy (ie, it is an "as-treated" analysis, rather than an "intention to treat" analysis), which could bias the analysis toward limited procedures.

In conclusion, LIMV operations do not compromise the very low mortality rates that have been documented with conventional sternotomy mitral operations, nor is the likelihood of mitral valve repair decreased. Postoperative AF and transfusion rates were lower among patients having LIMV operations, as was the length of hospital and intensive care unit stay. Primary isolated mitral valve operations performed with less-invasive techniques required longer perfusion and aortic cross-clamp times, and were associated with a significantly higher rate of postoperative permanent stroke. As mitral valve operative techniques and strategies continue to evolve, the challenge will be to address the limitations and drawbacks of LIMV operations while capitalizing on its benefits. Further accrual of surgeon experience and improved technology may lead to more efficient operations and eliminate the increased risk of stroke identified in this study. Avoidance of noncardioplegia strategies is an important means of avoiding stroke and could be implemented immediately.

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The Appendix is available only online. To access it, please visit http://ats.ctsnetjournals.org and search for the article by Gammie, Vol. 90, pages 1401–1410.

DISCUSSION

DR W. RANDOLPH CHITWOOD (Greenville, NC): I rise to congratulate Dr Gammie and his coauthors for presenting this seminal J. Maxwell Chamberlain Memorial paper. Our STS members who have been responsible for the development and the maintenance of the STS Adult Cardiac Surgical Database also should be very proud of this paper. Our Society is at the top in providing accurate data to all cardiac surgeons in hopes of improving quality outcomes, and this Chamberlain paper will help us define the role of minimally invasive mitral valve surgery for the future.

Minimally invasive mitral valve surgery began in 1969 with the development of alternative methods of perfusion and instrumentation that allowed access through small to tiny incisions. That year, Alain Carpentier reported the first minimally invasive mitral repair done using a minithoracotomy and video assistance. Several months later, our group performed a video-assisted, minimally invasive mitral valve replacement. Doctors Cosgrove and Cohn initiated the hemisternotomy and parasternal incisions for mitral repairs using direct vision. Also, that year Dr Mohr in Germany began to replace and repair mitral valves through minithoracotomies using video assistance. At the 1997 meeting of the American Association of Thoracic Surgery, our group and that of Mohr presented inaugural feasibility studies of video-assisted, minimally invasive mitral surgery done using a minithoracotomy. Since that time, thousands of patients in the United States and Europe have undergone minimally invasive mitral valve operations, but very few studies have compared outcomes scientifically to the traditional sternotomy.

Dr Gammie has presented the most comprehensive scientific study to date comparing outcomes for patients undergoing either a minimally invasive or a traditional full sternotomy mitral operation. Patient cohorts compared were similar by both propensity-matching and risk-adjusted multivariate analysis. Despite a multiplicity of perfusion and arrest platforms in the 4,321 minimally invasive patients, several conclusions can be drawn.

In 4 years, the adoption of minimally invasive mitral surgery has increased from 12% to 20%, and of these, 35% are done using robotic techniques. Patients selected for minimally invasive surgery had less preexisting comorbidities, were younger and had fewer symptoms. Number three, despite longer perfusion and arrest times in the minimally invasive group, operative mortalities and major morbidities were significantly better with less postoperative atrial fibrillation, ventilation times, transfusions, and shorter lengths of stay. Minimally invasive operations had a higher propensity for repair, probably because the pathology may be more favorable. And, lastly, stroke rates were twofold higher in the minimally invasive surgery cohort but three times higher when fibrillating or beating heart techniques were used.

The data presented today parallel closely that of Modi and associates, as you can see on this slide, who last year reported a meta-analysis of 10 case-controlled studies comparing patients with either conventional or minimally invasive mitral valve surgery. These were approximately 1,400 patients in each cohort. Odds ratios showed that minimally invasive operations had less mortality and hospital length of stay and, in contradistinction to Dr Gammie's report, less reoperations for bleeding. In the meta-analysis, atrial fibrillation rates were similar for both minimally invasive and traditional operations, but at least one series showed less in the minimally invasive group. Stroke rates were similar. However, each of the centers used cardioplegic arrest on all minimally invasive surgery cases. Similarly, Suri compared recently 365 sternotomy-based mitral operations done between 1999 and 2006 at the Mayo Clinic with 350 contemporaneous operations done at the University of Pennsylvania. In propensity-matched patients, mortalities were similar, and there was no significant difference in transfusions, reexploration for bleeding, or length of stay. Our group at ECU found that in matched patient cohorts of 300 to 400 patients, the 5-year survival was statistically similar for sternotomy and minimally invasive operations. Stroke rates, however, were less with minimally invasive surgery.

The work presented by Dr Gammie presents a high-water mark in determining the value of minimally invasive surgery operations for several reasons. First, it represents a "nation of surgery," that is, many centers, different methods, different patient volumes, different levels of expertise. This is the best real world picture that we have to date. Nevertheless, there are glaring absences from the data sets that were available to the authors for this study. Assessment of echocardiographic quality of mitral valve repairs and durability remain absent from this data set. In the operating room, almost all of us know what our result is following a repair by transesophageal studies. Second, to compare effectively the sternotomy approach, we have to have long-term follow-up. Several studies suggest that minimally invasive patients have 95% to 97% durability, but these data are from large, focused centers. Real world data becomes a greater and more important challenge. Nevertheless, Dr Gammie's data show that minimally invasive mitral surgery is becoming one standard of care and can be safe and effective, in the short term at least.

I have two questions for you, Dr Gammie. First, how do we proceed to find out why minimally invasive patients had higher stroke rates? We know nothing about the deairing process or the completeness in any of these patients. Should we not collect specific transesophageal echocardiography data in our database? In studies from our 2,000 mitral valve repair series at our institution, we found fewer strokes in the minimally invasive and robotic patients, at 1.5% and 0.7% respectively.

The second question. Do you really believe that ventricular fibrillation is bad if patients are cooled appropriately and the heart vented? We found recently that this was not true in our studies at our institution and others, that we found no differences in stroke rates with ventricular fibrillation when we used it routinely in reoperations.

Maybe you want to answer these two questions.

DR GAMMIE: Thank you, Dr Chitwood. I am honored to have you as discussant for this paper and appreciate your insightful comments and analysis. Your name is synonymous with less invasive mitral surgery and your work anchors the literature on this subject. I fondly remember traveling to ECU to learn minimally invasive mitral valve surgery from you. I would address your questions as follows and I have one comment as well.

The absence of long-term follow-up is a clear weakness of the STS database, and, as you well know, several exciting initiatives are underway that will greatly enhance our ability to understand long term outcomes of heart valve operations. First, the data collected for heart valve surgery have been the poor stepchild in the database, and there is a comprehensive update in the data elements for heart valve surgery that will be implemented shortly and will give us a much better and clearer picture, and that will include some early echocardiographic analysis both in the operating room and on predismissal echocardiograms. In addition, thanks to the tireless efforts of Jeff Jacobs, the database committee, and DCRI, there is now the ability to link the STS Cardiac Database with CMS data and track long-term outcomes, including things such as mortality, readmissions for heart failure, and reoperations, and I think that that will give us a much clearer picture.

In terms of the stroke rate, there is no doubt that that is the most interesting finding, and if we simply call attention to the high stroke rate, I think that that will encourage further analysis and understanding of why there is a higher stroke rate. I don't know the answer as to why there is a higher stroke rate. Clearly, the bypass and cross-clamp times are longer and it has been shown in the literature that there is a linear relationship between those and the risk of stroke. I do believe that fibrillating or beating heart techniques, although they certainly have a role in some patients such as those having complex reoperations, are associated with a higher risk of stroke based on these data. Published series of these patients have generally been characterized by lower repair rates, and it is difficult to test a mitral valve repair in this situation. I am also concerned about particulate matter in the heart; perhaps there is less ability to see that through a small incision.

DR CHITWOOD: One last comment. I think we really need to have transesophageal echocardiography data. Many of us believe that minimally invasive mitral valve surgery techniques are improving continually, and we think that patients will cast their vote by their outcomes and the information that you have as well as the access. I thank the Society for the opportunity to present this fine paper.

DR DAVID H. ADAMS (New York, NY): Jim, I enjoyed your paper. There was a similar paper presented at the 42nd STS meeting in Chicago in 2006 by Cheema and colleagues with almost an identical finding from the New York State audited database. This particular study involved about 4,000 patients, and had an identical finding of an increase in stroke risk with a right minithoracotomy compared with sternotomy. So I would say we have to, as a group of surgeons, think this may be real; there are now two papers that have been presented at our Society in 4 years with the same conclusion. And my question to you is, how should we counsel patients today in terms of informed consent? In your own center where you have a successful practice in minimally invasive surgery, how are you going to talk to patients about this data, keeping in mind it takes several thousand patients to show a difference in stroke rate, which is not possible in single-center series?

DR GAMMIE: I think your own local institutional data bring to bear on that. For example, if you have done 200 of these and you have had no strokes, you can tell your patients that. Perhaps it is appropriate to counsel patients that some studies have shown that there is a higher risk of stroke.

I would point out that patients having mitral valve surgery generally are young: they are in their 50s or 60s. They tend not to have atherosclerotic disease if they are picked for this operation. So I think a real focus of our specialty should be to decrease stroke rates. One of our quality goals, in addition to providing mitral valve repair for these patients, is to really drive down the stroke risk, and I think this needs further aggressive study.

DR CLARK HARGROVE (Philadelphia, PA): Jim, that was a beautiful presentation, as usual. My questions relate to the EndoClamp (Ethicon, Somerville, NJ). Did you compare the stroke rate and also the rate of aortic dissections with the use of the EndoClamp versus the transthoracic clamp? And my second question is, why did you throw out the redos? We have found that the minimally invasive approach to the mitral valve in patients with previous cardiac surgery is actually the optimum approach.

DR GAMMIE: We recognize your previous publications on that, including your combined series with Dr Chitwood, and I know in that series that you saw a higher aortic dissection rate with the EndoClamp, and that was our a priori hypothesis. We did not see that. Now, as we point out in our paper, we may be missing those patients, because if they dissect, perhaps they are then changed to central cannulation after a graft is put in and we may not know the answer to that. We had assumed that we might see a higher stroke rate with the EndoClamp. We did not clearly see that effect.

DR ALAN SPOTNITZ (New Brunswick, NJ): Were you able to separate out robotic from nonrobotic cases?

DR GAMMIE: We did separate that out, that was not the primary focus of our paper, and we didn't see huge differences. We saw that repair rates were significantly higher in the robotic cases, 94% versus 80%, the perfusion time was about 13 minutes longer, and the total operation time was 30 minutes longer in the robotic less-invasive group compared with the nonrobotic less-invasive group. We didn't see any difference in stroke rates and there were some small differences in outcomes.

DR RICHARD J. SHEMIN (Los Angeles, CA): This was a timely study and a clearly presented paper. Obviously stroke is a major complication of cardiac surgery. Removal of air after less invasive mitral valve surgery requires skill and practice. Those of us who do high volume, minimally invasive cardiac surgery, have had to learn new techniques to conduct cardiopulmonary bypass and de-air the heart effectively and efficiently. I wonder whether or not the experience of the individual centers, measured by clinical volume of less invasive mitral valve operations, may have impacted the data. Obviously, it is not only the surgical exposure that the surgeon must deal with in these operations; it is really the conduct of the operation in regards to cardiopulmonary bypass and deairing. My question is whether you have any data in regard to volume and experience, and the impact on the incidence of stroke? Thank you.

DR GAMMIE: That is a very good question. The graph that showed the distribution of less invasive cases with a median number of three per year in 2008 speaks volumes to that issue. We did look at it with a center level cutoff of five minimally invasive operations per year, and we saw absolutely no difference. We still saw the higher stroke rate. We have not looked at it with higher volume outcomes. But I would suspect that we are seeing some degree of low volume effect here and perhaps we are early in a learning curve.

And speaking to the learning curve, Dr Chitwood, our paper, and others have shown that the learning curve for a less invasive mitral operation takes about 100 cases. There have been some data to support that.

DR STEVEN F. BOLLING (Ann Arbor, MI): Dr Gammie, a very nice paper. Do you think minimally invasive mitral valve surgery has now matured to the point where in a certain selected group of patients a large prospective trial between conventional surgery and minimally invasive surgery is warranted?

DR GAMMIE: That would be interesting. It would have to be a large trial.

DR FRIEDRICH WILHELM MOHR (Leipzig, Germany): I would like to know whether your study has a differentiation in terms of change of techniques during time, because I think all of us have learned how to avoid strokes by learning from bad experience, and this is reflected either by the individual surgeon's experience or institutional experience. Personally, we are looking at around 4,000 patients, and altogether stroke is not an issue in terms of being enhanced, but we have changed our techniques to control stroke in different steps. Is that reflected in your study?

DR GAMMIE: Thank you, Dr Mohr. We did look at the aortic occlusion strategy in terms of cross-clamping, balloon, and no cross-clamping, and we saw no statistical change over the years of our study, nor did we see a change in the application of robotic assistance.

Appendix Table 1. Characteristics of Patients Undergoing Less-Invasive Mitral Valve Operations Compared With Conventional Mitral Valve Operations After Propensity Matching

Variable	Overall (n = 8,644)	Conventional Matched (n = 4,322)	Less Invasive (n = 4,322)	*p* Value
Age, years, mean	58.6	58.7	58.5	0.4662
Sex, female,%	41.4	41.5	41.3	0.8575
Body surface area, m^2, mean	1.9	1.9	1.9	0.7717
Diabetes mellitus,%	7.4	7.4	7.4	0.7029
Creatinine, mg/dL, mean	1.0	1.0	1.0	0.4776
Chronic lung disease,%	11.5	11.7	11.2	0.9165
Hypertension,%	52.5	52.4	52.6	0.8956
Cerebrovascular accident,%	2.8	3.0	2.6	0.2893
Cerebrovascular disease,%	5.0	5.2	4.9	0.7343
NYHA I (asymptomatic)	16.6	16.5	16.8	0.7713
Congestive heart failure,%	32.6	33.0	32.1	0.2611
Ejection fraction, median (interquartile range)	60.0 (50–63)	60.0 (50–63)	60.0 (50–62)	0.2821
Tricuspid regurgitation, moderate or severe,%	8.0	8.0	8.0	0.9683
Procedure status, elective	92.7	92.5	92.8	0.561
Atrial fibrillation,%	21.3	21.5	21.1	0.5831
Mitral repair versus replacement,%	85.5	85.8	85.2	0.2801

NYHA = New York Heart Association.

Appendix Table 2. Outcomes of Patients Undergoing Less-Invasive Mitral Valve Operations Compared With Conventional Mitral Valve Operations After Propensity Matching

Variable	Overall (n = 8,644)	Conventional (n = 4,322)	Less Invasive (n = 4,322)	*p* Value
Perfusion time, minutes, median	120.0	105.0	135.0	<0.0001
Cross-clamp time, minutes, median[a]	100.0	79.0	100.0	<0.0001
Operation time, hours, median	3.72	3.37	4.15	<0.0001
Atrial fibrillation correction procedure,%	17.1	19.0	15.2	<0.0001
Intensive care unit hours, median	28.8	33.0	26.4	<0.0001
Total ventilation hours, median)	6.0	6.0	6.0	0.6058
Perioperative red blood cell transfusion,%	43.0	45.0	41.1	0.0001
Perioperative platelet transfusion,%	17.8	19.8	15.8	<0.0001
Reoperation for bleeding,%	3.16	2.66	3.66	0.0085
Reoperation for any reason,%	6.1	5.5	6.6	0.0389
Deep sternal wound infection,%	0.08	0.14	0.02	0.1250
Permanent stroke,%	1.40	0.93	1.87	0.0002
Prolonged ventilation,%	6.5	6.0	7.0	0.0372
Renal failure,%	2.0	1.9	2.1	0.4938
Acute limb ischemia,%	0.15	0.12	0.19	0.4054
Iliac/femoral dissection,%	0.03	0.02	0.05	1.0
Aortic dissection,%	0.05	0.00	0.09	0.1249
Postoperative atrial fibrillation,%	18.0	20.1	15.9	<0.0001
Operative mortality,%	1.18	1.09	1.27	0.4237
Neurologic cause of death,%	13.7	8.5	18.2	0.0455
Major morbidity or mortality,%	12.0	11.0	12.9	0.0072

[a] The matched pairs without aortic occlusion were excluded from this outcome comparison.