

## Outcomes of less invasive J-incision approach to aortic valve surgery

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**Objective:** Less invasive approaches to aortic valve surgery are increasingly used; however, few studies have investigated their impact on outcome. We sought to compare clinical outcomes after these approaches with full sternotomy using propensity-matching methods.

**Methods:** From January 1995 to January 2004, a total of 2689 patients underwent isolated aortic valve surgery, 1193 via upper J-hemisternotomy and 1496 via full sternotomy. Because of important differences in patient characteristics between these groups, a propensity score based on 42 variables was used to obtain 832 well-matched patient pairs (70% of possible cases).

**Results:** In-hospital mortality was identical for propensity-matched patients, 0.96% (8 in each). Occurrences of stroke ( $P > .9$ ), renal failure ( $P = .8$ ), and myocardial infarction ( $P = .7$ ) were similar. However, 24-hour mediastinal drainage was a third less after less invasive surgery (median, 250 vs 350 mL;  $P < .0001$ ), and fewer patients received transfusions (24% vs 34%;  $P < .0001$ ). More patients undergoing less invasive surgery were extubated in the operating room (12% vs 1.6%;  $P < .0001$ ), postoperative forced 1-second expiratory volume was higher ( $P = .009$ ), and fewer had respiratory failure ( $P = .01$ ). Early after operation, pain scores were lower ( $P < .0001$ ) after less-invasive surgery and postoperative length of stay shorter ( $P < .0001$ ).

**Conclusions:** Within that portion of the spectrum of isolated aortic valve surgery where propensity matching was possible, minimally invasive aortic valve surgery had not only cosmetic advantages, but blood product use, respiratory, pain, and resource utilization advantages over full sternotomy, and no apparent detriments. Less invasive aortic valve surgery should be considered for most aortic valve operations. (J Thorac Cardiovasc Surg 2012;144:852-8)

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In the mid-1990s, less invasive “keyhole” approaches for valve operations were pioneered with the intent of reducing morbidity, postoperative pain, and blood loss, improving cosmesis, shortening hospital stay, and reducing cost compared with the 50-year-old full sternotomy approach.<sup>1-10</sup> Furthermore, it was believed that less spreading of the incision, not interfering with the diaphragm, and less tissue dissection might improve outcomes, particularly respiratory function.<sup>7,8</sup> Although clinical studies suggest that some of these benefits have been realized, there has been no confirmatory large study or randomized trial.<sup>1-10</sup> Because patients undergoing aortic valve surgery are in general older and sicker than those undergoing isolated mitral valve surgery, cosmetic benefits of less invasive aortic valve surgery may not be as important. Yet potential improvement in postoperative pain and respiratory function, particularly in patients with advanced respiratory disease, and reduced blood loss, transfusion requirement, and intensive care unit (ICU) and hospital lengths of stay are of even greater possible benefit in this older population with more severe comorbidities. Despite these perceived advantages of less invasive surgery, full sternotomy remains the most widely used approach in isolated aortic valve surgery. Therefore, to evaluate the potential benefits of a minimally invasive approach, we performed a propensity-matched comparison of short- and long-term outcomes in

### Abbreviations and Acronyms

CL	= confidence limits
FEV <sub>1</sub>	= forced expiratory volume in 1 second
ICU	= intensive care unit

patients who underwent less invasive aortic valve surgery compared with patients who had full sternotomy.

## PATIENTS AND METHODS

### Patients

From January 1995 to January 2004, a total of 2689 patients underwent primary isolated aortic valve repair (n = 438) or replacement (n = 2251) surgery with (n = 25) or without (n = 2664) tricuspid valve repair; patients undergoing concomitant mitral valve surgery or coronary artery bypass grafting were excluded, as were those with active endocarditis. A minimally invasive approach was intended in 1193 (44%) patients and full sternotomy in 1496 (56%). In more recent years, the proportion of aortic valve operations performed through a less invasive incision has risen to 60% to 65% (Figure E1). Mean age was 60 ± 6 years (range, 18-97 years), and 66% were men.

Data were in part retrieved from the prospective Cardiovascular Information Registry and in part from each patient's medical record. These data were approved for use in research by the institutional review board, with patient consent waived.

### Surgical Technique

Conventional general anesthesia was used in all patients regardless of surgical approach, with identical protocols. Patients who underwent less invasive surgery had an 8- to 10-cm skin incision.<sup>1,3,7</sup> The upper sternum was divided in the midline, and this sternotomy was extended into the right fourth intercostal space, forming a J.<sup>7-9</sup> Approach to the aortic valve was via either an oblique aortotomy carried into the noncoronary cusp or a transverse aortotomy above the sinotubular junction, at the discretion of the surgeon. Aortic valve repair or replacement was then carried out according to the surgeon's standard technique.

Vacuum-assisted cardiopulmonary bypass with central cannulation was used in all patients.<sup>11</sup> Intraoperative transfusions, anesthetic technique, and timing of extubation were at the anesthesiologists' discretion. Intraoperative and postoperative transfusion and extubation were not driven by rigorous protocols, except that the philosophy of the teams was to minimize use of homologous blood products.

### Study Design

A number of differences in patient characteristics between less invasive and full sternotomy groups precluded interpretation of direct comparisons of outcomes (Table 1). Therefore, to reduce influence of selection, we used propensity matching to approximate a randomized trial.<sup>12-14</sup> In the spirit of such a trial, we followed the "intent-to-treat" principle, such that the 34 (2.8%) patients with an intended less invasive approach who were converted to full sternotomy were retained in the less invasive group. Initially, a parsimonious model based on variables in Appendix 1 was formulated by logistic regression analysis using bagging<sup>15</sup> (Table E1) to understand the drivers of patient selection. To this model were added nonsignificant variables to form a semisaturated propensity model. From this logistic regression model (C = .77) based on 42 preoperative and procedure variables predictable preoperatively (Appendix 1), a propensity score was generated for each patient. Greedy matching based on the propensity score was used to identify 832 patient pairs for comparison, 70%

of all possible pairs (Table E2).<sup>16</sup> Figure E2 indicates the portion of the spectrum of propensity from which matched pairs were obtained, and Table E2 documents characteristics of patients for whom either less invasive or full sternotomies were more heterogeneously applied during the study period. Figure E3 shows standardized differences<sup>17</sup> for a number of variables before and after matching, illustrating success in formulating comparable groups. This strategy was repeated for the 2000-2004 cohort (n = 648, less invasive patients; n = 712, full sternotomy patients) for whom incentive spirometry and pain scores were available, yielding 440 propensity-matched patient pairs, 68% of all possible pairs.

### Outcomes

Outcomes assessed included intraoperative support (myocardial ischemic time, cardiopulmonary bypass time), postoperative in-hospital mortality and morbidity (defined in accordance with the Society of Thoracic Surgeons National Database: [http://www.ctsnet.org/file/rptDataSpecifications252\\_1\\_ForVendorsPGS.pdf](http://www.ctsnet.org/file/rptDataSpecifications252_1_ForVendorsPGS.pdf)), blood product use, mediastinal drainage at 6 and 24 hours, hematocrit at hospital discharge, time to extubation (which was at the discretion of attending anesthesiologists in either the operating room or ICU), all incentive spirometry values after extubation, all pain scores, length of ICU and hospital stay, and long-term survival.

Incentive spirometry and pain scoring were performed and recorded prospectively and consecutively from January 2000 to January 2004. During that time 880 matched and 480 unmatched patients (n = 1260; 47% of study group) underwent operation. Both spirometry and pain scores were obtained routinely as part of clinical care after surgery. Spirometry was performed periodically by respiratory therapists using a Renaissance II bedside spirometer (Puritan Bennett, Carlsbad, Calif) until hospital discharge; a total of 3030 values were available for 621 matched patients (71%). Forced expiratory volume in 1 second (FEV<sub>1</sub>) values measured by this equipment were normalized to percent of predicted by the NHANES algorithm and used for analysis.<sup>18</sup> From patients' arrival in the ICU to hospital discharge, nursing staff recorded pain intensity—ranging from 0 (none) to 10 (severe)—approximately every 4 hours using the extensively validated Wong-Baker FACES (Facial Expression Scale) pain assessment.<sup>19,20</sup> A total of 21,154 valid pain scores were available for 718 matched patients (82%).

Survival was assessed by follow-up every 2 years using a questionnaire approved by the institutional review board, supplemented by data from the Social Security Death Master File.<sup>21,22</sup> A total of 10,893 patient-years of information was available for analyses among matched patients, with mean follow-up of 6.5 ± 3.0 years; 25% of survivors were followed up more than 9.1 years and 10% more than 10 years. For matched patients undergoing less invasive surgery, 5641 patient-years of follow-up were available for analyses, mean follow-up was 6.8 ± 2.9 years, and 10% were followed up more than 10 years. For matched patients undergoing full sternotomy, 5252 patient-years of follow-up were available for analyses, mean follow-up was 6.3 ± 3.0 years, and 10% were followed up more than 10 years.

### Comparisons

Categorical outcomes were compared using either the  $\chi^2$  or Fisher's exact test and continuous outcomes by the Wilcoxon rank sum nonparametric test. To compare temporal pattern of postoperative FEV<sub>1</sub> across time, we analyzed all 3030 repeated continuous values longitudinally using mixed-model regression,<sup>16</sup> with autoregressive order 1 correlation structure to accommodate the correlated nature of the observations within each patient.

To compare temporal pattern of postoperative pain across time, we combined pain scores into 5 categories because of low frequency of higher pain scores: 0 (pain score 0), 1 (pain scores 1-3), 2 (pain scores 4-6), 3 (pain scores 7 and 8), and 4 (pain scores 9 and 10). All 21,154 pain score categories were then analyzed longitudinally using a nonlinear cumulative logit mixed model for repeated measures that resolved a number of temporal

TABLE 1. Patient characteristics and operative details by surgical approach: Overall unmatched

Variable	Less invasive (n = 1193)		Full sternotomy (n = 1496)		P
	No.	%	No.	%	
<i>Demography</i>					
Women	390	33	532	36	.12
Age (y), mean ± SD	59 ± 16		61 ± 16		.01
BMI (kg · m <sup>-2</sup> ), mean ± SD	28 ± 5.6		28 ± 5.8		.005
<i>NYHA functional class</i>					
I	282	24	360	24	<.0001
II	719	60	775	52	
III	154	13	268	18	
IV	38	3.2	93	6.2	
<i>Indication for operation</i>					
Degenerative	927	78	818	55	<.0001
Rheumatic	105	8.8	112	7.5	.2
Congenital	69	5.8	115	7.7	.05
Other	92	7.7	451	30	<.0001
<i>Cardiac comorbidity</i>					
LV dysfunction	198/1156*	17	327/1375*	24	<.0001
Tricuspid regurgitation > moderate	14/1113*	1.3	57/1211*	47	<.0001
Atrial fibrillation/flutter	36	3	74	4.9	.01
<i>Noncardiac comorbidity</i>					
Hypertension	601/1172*	51	869/1459*	60	<.0001
Treated diabetes	68/1170*	5.8	133/1436	9.3	.001
COPD	177/1101*	16	282/1185	24	<.0001
<i>Procedure</i>					
Aortic valve repair	194	16	244	16	>.9
Aortic valve replacement	999	84	1252	84	>.9
Label size (mm)†					
≤19	97	9.7	131	11	
20/21	314	31	331	27	
22/23	366	37	399	33	
24/25	170	17	228	19	
26/27	49	4.9	105	8.6	
≥28	3	0.3	32	2.6	
Tricuspid valve repair	3	0.25	23	1.5	.0007

SD, Standard deviation; BMI, body mass index; NYHA, New York Heart Association; LV, left ventricular; COPD, chronic obstructive pulmonary disease. \*Number of patients with data available. †1226 (out of 1252) patients in the full sternotomy group have label size data.

components and their shaping parameters.<sup>23</sup> Each component was independently modulated by a time function with common random intercept.

Survival was compared nonparametrically by the Kaplan-Meier method and parametrically by a temporal decomposition model.<sup>23</sup>

## Presentation

Categorical variables are summarized as frequencies and percentages and continuous variables as means ± standard deviations, or as equivalent 15th, 50th (median), and 85th percentiles (for consistency with ± 1 standard deviation) when data were skewed. Asymmetric 68% confidence limits (CL) are consistent with ± 1 standard error. All analyses were performed using SAS (SAS Institute, Inc, Cary, NC) statistical software version 9.1.

## RESULTS

### Success of Intended Approach

Of the 34 conversions from a less invasive approach to full sternotomy, 18 (53%) occurred before the aortic clamp was applied, mostly because heart position precluded

adequate exposure; 3 (8.8%) occurred while the clamp was in place, primarily because of unusual anatomy; 12 (35%) occurred after clamp removal, primarily for repair of coronary sinus injury from the retrograde cardioplegia catheter, but also for left heart distention and ventricular fibrillation; 1 had insufficient documentation to classify (Table E3).

Among propensity-matched patients, ischemic time was shorter after a less invasive approach than after full sternotomy (58 ± 24 vs 71 ± 28 minutes;  $P < .0001$ ) as was cardiopulmonary bypass time (73 ± 32 vs 95 ± 37 minutes;  $P < .0001$ ).

### In-Hospital Mortality and Morbidity

In-hospital mortality was identical, 0.96% (CL, 0.63%-1.3%), among matched patients ( $P > .9$ , Table 2). Postoperative respiratory insufficiency (prolonged ventilatory support

TABLE 2. In-hospital outcomes by surgical approach, overall and in propensity-matched patients\*

Outcome	Overall					Propensity matched				
	Less invasive (n = 1193)		Full sternotomy (n = 1496)		P	Less invasive (n = 832)		Full sternotomy (n = 832)		P
	n	%	n	%		n	%	n	%	
Death	10	0.84	30	2.0	.01	8	0.96	8	0.96	>.9
Stroke	15	1.3	32	2.1	.08	11	1.3	11	1.3	>.9
Renal failure	7	0.59	25	1.7	.01	6	0.72	7	0.84	.8
Myocardial infarction	5	0.42	4	0.27	.5	4	0.48	3	0.36	.7
Deep sternal wound infection	9	0.75	12	0.8	.9	5	0.601	7	0.84	.6
Sepsis/septicemia	14	1.2	37	2.5	.01	11	1.3	18	2.2	.2
Return to OR for bleeding	60	5.0	77	5.1	.9	46	5.5	36	4.3	.3
RBC transfusion	267	22	614	41	<.0001	202	24	286	34	<.0001
Respiratory insufficiency	31	2.6	107	7.2	<.0001	24	2.9	45	5.4	.01

OR, Operating room; RBC, red blood cell. \*Morbidity as defined by, and submitted to, the Society of Thoracic Surgeons Adult Cardiac National Database.

beyond 24 hours) occurred less frequently after less invasive surgery than after full sternotomy; all other in-hospital complications occurred with similar frequency (Table 2).

### Bleeding and Transfusion

Prevalence of return to the operating room for bleeding was similar in matched groups (Table 2); however, mediastinal drainage was a third less at 6 and 24 hours after a less invasive approach (15th/50th/85th percentiles, 50/100/250 mL and 150/250/400 mL, respectively) than after full sternotomy (100/150/300 mL and 250/350/700 mL, respectively);  $P < .0001$ . Transfusion was less frequent after less invasive surgery than after full sternotomy (24% vs 34%;  $P < .0001$ ; Table 2), and despite this, hematocrit value at discharge was similar between groups ( $32\% \pm 4.2\%$  for less invasive surgery vs  $32\% \pm 3.7\%$  for full sternotomy;  $P = .6$ ).

### Respiratory Function

A substantially higher proportion of matched patients were extubated in the operating room after less invasive surgery than after full sternotomy (12% vs 1.6%;  $P < .0001$ ). Median time to extubation was also shorter (5.2 hours [CL, 2.5-12 hours] vs 6.9 hours [CL, 3.6-21 hours];  $P < .0001$ ). FEV<sub>1</sub> was higher immediately after extubation in the less invasive group, with the difference narrowing during the first 36 hours after surgery (Figure 1).

### Postoperative Pain

The general temporal pattern of pain score categories is illustrated in Figure 2, A. During the first 24 postoperative hours, only about a third of patients were pain free, and this proportion rose to about 60% by day 3 and stabilized. Matched patients undergoing less invasive surgery had less pain throughout their postoperative course than those undergoing full sternotomy ( $P < .0001$ ; Figure 2, B).

### Length of Stay

Among matched patients, median ICU and postoperative lengths of stay were shorter in the less invasive group than in the full sternotomy group. ICU stay (15th percentile/median/85th percentile) was 1/1/2 versus 1/1/3 days ( $P < .0001$ ). Total postoperative length of stay was 4/6/9.2 versus 5/6/12 days ( $P < .0001$ ).

### Survival

Survival at 1, 5, and 10 years was 96%, 90%, and 77% after less invasive surgery and 95%, 86%, and 73% after full sternotomy among matched patients ( $P = .2$ , Figure 3).

### DISCUSSION

Patients are increasingly self-educated and aware of minimally invasive options for cardiac surgery. In some cases,

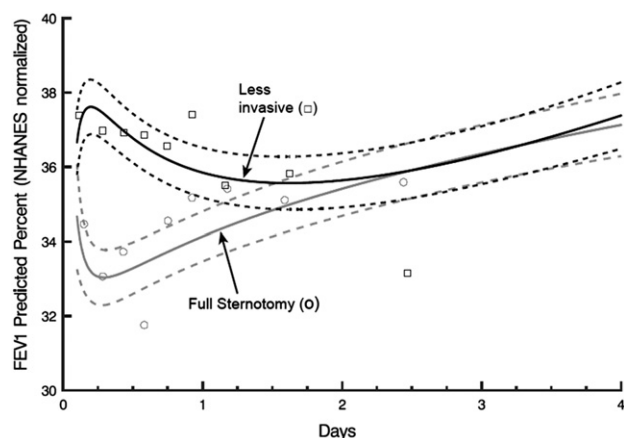
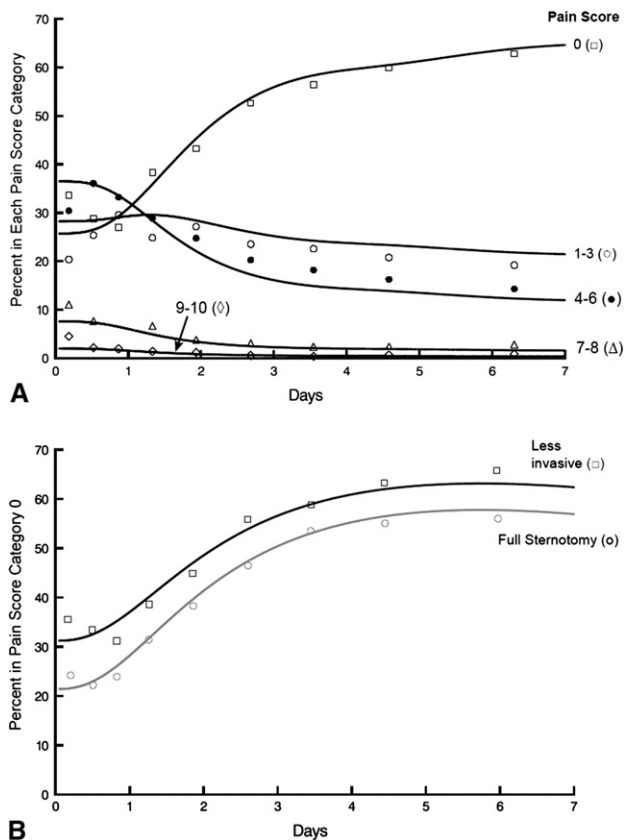


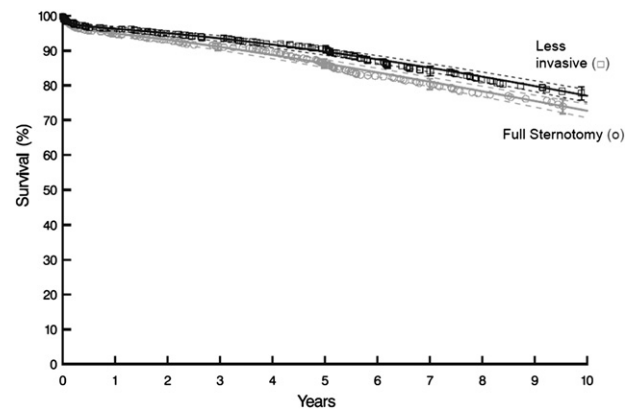
FIGURE 1. Temporal pattern of postextubation forced 1-second expiratory volume (FEV<sub>1</sub>) as percent of predicted after less invasive and full sternotomy aortic valve surgery among propensity-matched patients. Solid lines are parametric estimates of temporal trend enclosed within dashed lines 68% confidence limits (equivalent to  $\pm 1$  standard error). Symbols represent data grouped within time frames without regard for repeated assessment, simply to provide crude verification of model fit.



**FIGURE 2.** Temporal pattern of pain score categories after less invasive versus full sternotomy aortic valve surgery among propensity-matched patients. *Symbols* represent data grouped within time frames without regard for repeated assessment, simply to provide crude verification of model fit. *Solid lines* are parametric estimates of percentage of patients in each category. **A**, All pain score categories. **B**, Proportion of patients without pain (category 0).

they are being referred or self-refer for surgery only if a less invasive procedure can be performed. Concerns have been raised that less invasive procedures may result in longer operative, bypass, and aortic clamp times, increasing risk of complications. Were this the case, the perceived benefits of improved cosmesis and less pain and bleeding might not be worth the increased risk. Some patients with aortic valve disease also have not been offered less invasive approaches because of perceived fragility or advanced age. Indeed, on the basis of our experience, we find it particularly advantageous to use a less invasive approach for elderly frail patients and those with advanced respiratory disease. Of note, risk of respiratory insufficiency was lower in this study with the J-incision, and FEV<sub>1</sub> was higher early post-operatively. Risk of wound infection and sepsis may also be lower and easier to deal with.

As innovative transcatheter approaches to aortic valve insertion are being developed and tested in clinical trials<sup>24</sup> and used in practice, the results of full sternotomy versus less invasive surgery deserve close attention by cardiac surgeons,



**FIGURE 3.** Survival after less invasive and full sternotomy aortic valve surgery among propensity-matched patients. Each *symbol* represents a death, positioned actuarially, *vertical bars* 68% confidence limits, and *numbers in parentheses* patients remaining at risk. *Solid lines* are parametric estimates enclosed within dashed 68% confidence limits (equivalent to  $\pm 1$  standard error).

who may be able to offer a safer and less traumatic alternative. Specifically, the “gold standard” of aortic valve surgery via a full sternotomy may not be as tenable, as operative technique, anesthesia, perfusion, and postoperative care have improved, particularly for high-risk patients. Outcomes and potential advantages of currently available techniques for aortic valve surgery must be well understood to accurately evaluate transcatheter approaches for any given patient.

**Principal Findings**

In less than 3% of cases, a less invasive incision had to be converted to full sternotomy. That the majority of conversions to full sternotomy occurred before aortic clamping suggests that a careful evaluation of adequacy of exposure of the aorta and right atrium is necessary to achieve optimal results. Computed tomography scanning before surgery in borderline cases, particularly if an ascending aortic replacement is contemplated, may be of value.

A smaller number of cases were converted when a change in planned procedure occurred based on new information obtained in the operating room. Examples included detecting systolic anterior motion of the mitral valve requiring concomitant myectomy. Coronary sinus perforation and right atrial bleeding accounted for several conversions, suggesting that particular care is required in placing the retrograde cardioplegia catheter and venous cannulas because palpation cannot be used to check positioning. Indeed, some of us have abandoned using retrograde cardioplegia for minimally invasive J-incisions. In addition, access for deairing is limited. A maneuver that facilitates deairing is to slide a malleable retractor down to the left ventricle and compress it. Carbon dioxide field flooding is used routinely because of the 25-times quicker rate of absorption of



carbon dioxide compared with air. Venting the left ventricle is also limited with this approach, resulting in 4 conversions to place a vent or to adequately defibrillate. We routinely apply adhesive transcutaneous defibrillator pads before the operation to facilitate rapid defibrillation.

This study shows no disadvantages of less invasive surgery and several advantages: (1) postoperative pain is less, (2) blood loss and blood use are lower, (3) time to extubation is shorter and early respiratory capacity improved, and (4) length of stay is shorter. Although there was no major difference in survival, it should be noted that hospital and 30-day survivals were above 99% in both groups, and thus to show a difference would be statistically difficult. Of note, early and late survivals were not compromised.

Less perioperative bleeding and fewer blood transfusions are likely due to the smaller mediastinal dissection required for the less invasive approach. Less pain is likely related to less surgical dissection, less spreading of the sternum, and no escalation of tension on the posterior rib head and costovertebral ligaments because the chest wall is not opened like a trap door. The better pulmonary function can be explained by no interference with the diaphragm or dissection along it. Also, with less chest wall pain, patients may have less splinting of the chest and thus can breathe more deeply. All of these factors likely combine to influence length of stay. In an era in which health care costs are increasingly scrutinized and efficiency has become a paramount concern, the difference in length of stay has significant implications in terms of bed occupancy and hospital cost.

### Implications for Transcatheter Aortic Valve Replacement

Transcatheter aortic valve technology has progressed from an area of intense engineering interest to a clinical reality. One device is currently in clinical trials in the United States, and several are used extensively in Europe.<sup>24</sup> Although there is considerable excitement regarding the potential of transcatheter aortic valve replacement, the appropriate patient in whom to apply this technology remains uncertain. A number of recent reports have questioned the use of available risk-scoring tools to evaluate patients for transcatheter aortic valve replacement<sup>25</sup> because observed mortality is often much lower than would be expected based on the score. In a large real-world patient cohort, we show that less than 1% 30-day mortality and 1.3% risk of stroke can be achieved. These results should serve as a benchmark for comparison with results of transcatheter aortic valve replacement in patients who are also considered for surgical aortic valve replacement. Furthermore, when examining patients by age at operation at our institution,<sup>26</sup> for the 720 undergoing primary aortic valve replacement who were less than 70 years old, risk of death from January 2001 to January 2008 was 0.28%. It was only for patients older than 80 years undergoing reoperation that the risk increased above

that of reoperation in patients less than 70 years of age (2.3%), to 5.6%.<sup>26</sup>

### Limitations

Although heterogeneity in use of less invasive aortic valve surgery provided the opportunity for comparisons with full sternotomy, clearly, as a group, patients undergoing full sternotomy were sicker, with a less favorable prognosis than those undergoing less invasive surgery. When a propensity score was used to match patients, the comparison groups were intermediate in risk (Figure E2), and differences in most outcomes appeared to be explained by differences in patient characteristics rather than surgical approach (Table E2). Indeed, like randomized trials that address only that portion of the spectrum of disease for which equipoise is present, propensity methods address only that portion of the spectrum for which heterogeneity in practice is discovered (virtual equipoise). In both cases, it is tempting to extrapolate beyond the confines of the overlapping portions of the spectrum; we caution the reader to understand that at both extremes of the spectrum, surgeons at Cleveland Clinic during the period of this study systematically performed either less invasive or full sternotomy operations, and the factors driving this decision are those identified in Table 1: obesity, left ventricular function, acuity, disease etiology, tricuspid valve regurgitation, era of surgery, and intent to repair rather than replace the valve. We acknowledge that selection bias cannot be completely reversed by propensity-based methods and, in this study, cannot completely overcome distinct surgeon preferences. Because treatment was not masked, patients' self-reporting of pain scores may have been biased as well. This is also a single-institution study, which limits its generalizability. Nevertheless, time to extubation, spirometry values, and pain scores would largely have been uninfluenced by potential surgeon biases because these were determined or routinely collected by respiratory therapists, anesthesiologists, or nurses.

### CONCLUSIONS

Less invasive aortic valve surgery has cosmetic, blood product use, respiratory, and pain advantages and is equal in safety to full sternotomy. In addition, it appears to result in shorter length of stay, with potential cost savings. We routinely use the approach for most aortic valve and ascending aortic procedures, excluding those requiring additional procedures such as coronary artery or mitral valve surgery.

### References

1. Cosgrove DM III, Sabik JF, Navia JL. Minimally invasive valve operations. *Ann Thorac Surg.* 1998;65:1535-8; discussion 1538-9.
2. Gundry SR, Shattuck OH, Razzouk AJ, del Rio MJ, Sardari FF, Bailey LL. Facile minimally invasive cardiac surgery via ministernotomy. *Ann Thorac Surg.* 1998; 65:1100-4.

3. Cohn LH, Adams DH, Couper GS, Bichell DP, Rosborough DM, Sears SP, et al. Minimally invasive cardiac valve surgery improves patient satisfaction while reducing costs of cardiac valve replacement and repair. *Ann Surg.* 1997;226:421-6; discussion 427-8.
4. Chitwood WR Jr, Wixon CL, Elbeery JR, Moran JF, Chapman WH, Lust RM. Video-assisted minimally invasive mitral valve surgery. *J Thorac Cardiovasc Surg.* 1997;114:773-80; discussion 780-2.
5. Schroyers P, Wellens F, De Geest R, Degrieck I, Van Praet F, Vermeulen Y, et al. Minimally invasive video-assisted mitral valve surgery: our lessons after a 4-year experience. *Ann Thorac Surg.* 2001;72:S1050-4.
6. Grossi EA, Galloway AC, LaPietra A, Ribakove GH, Ursomanno P, Delianides J, et al. Minimally invasive mitral valve surgery: a 6-year experience with 714 patients. *Ann Thorac Surg.* 2002;74:660-3; discussion 3-4.
7. Svensson LG. Minimal-access "J" or "j" sternotomy for valvular, aortic, and coronary operations or reoperations. *Ann Thorac Surg.* 1997;64:1501-3.
8. Svensson LG, D'Agostino RS. Minimal-access aortic and valvular operations, including the "J/j" incision. *Ann Thorac Surg.* 1998;66:431-5.
9. Svensson LG, D'Agostino RS. "J" incision minimal-access valve operations. *Ann Thorac Surg.* 1998;66:1110-2.
10. Svensson LG, Nadolny EM, Kimmel WA. Minimal access aortic surgery including re-operations. *Eur J Cardiothorac Surg.* 2001;19:30-3.
11. Banbury MK, White JA, Blackstone EH, Cosgrove DM 3rd. Vacuum-assisted venous return reduces blood usage. *J Thorac Cardiovasc Surg.* 2003;126:680-7.
12. Rosenbaum PR, Rubin DB. The central role of the propensity score in observational studies for causal effects. *Biometrika.* 1983;70:41-55.
13. Rubin DB. The design versus the analysis of observational studies for causal effects: parallels with the design of randomized trials. *Stat Med.* 2007;26:20-36.
14. Blackstone EH. Comparing apples and oranges. *J Thorac Cardiovasc Surg.* 2002;123:8-15.
15. Breiman L. Bagging predictors. *Machine Learning.* 1996;24:123-40.
16. Bergstralh EJ, Konsanke JL. Computerized matching of cases to controls. Technical report No. 56. Department of Health Science Research. Rochester (MN): Mayo Clinic; 1995.
17. D'Agostino RB Jr. Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. *Stat Med.* 1998;17:2265-81.
18. Mannino DM, Buist AS, Petty TL, Enright PL, Redd SC. Lung function and mortality in the United States: data from the First National Health and Nutrition Examination Survey follow up study. *Thorax.* 2003;58:388-93.
19. Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs.* 1988;14:9-17.
20. Bieri D, Reeve RA, Champion GD, Addicoat L, Ziegler JB. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: development, initial validation, and preliminary investigation for ratio scale properties. *Pain.* 1990;41:139-50.
21. Boyle CA, Decoufle P. National sources of vital status information: extent of coverage and possible selectivity in reporting. *Am J Epidemiol.* 1990;131:160-8.
22. Newman TB, Brown AN. Use of commercial record linkage software and vital statistics to identify patient deaths. *J Am Med Inform Assoc.* 1997;4:233-7.
23. Blackstone EH, Naftel DC, Turner ME Jr. The decomposition of time-varying hazard into phases, each incorporating a separate stream of concomitant information. *J Am Stat Assoc.* 1986;81:615-24.
24. Svensson LG, Dewey T, Kapadia S, Roselli EE, Stewart A, Williams M, et al. United States feasibility study of transcatheter insertion of a stented aortic valve by the left ventricular apex. *Ann Thorac Surg.* 2008;86:46-54; discussion 54-5.
25. Osswald BR, Gegouskov V, Badowski-Zyla D, Tochtermann U, Thomas G, Hagl S, et al. Overestimation of aortic valve replacement risk by EuroSCORE: implications for percutaneous valve replacement. *Eur Heart J.* 2009;30:74-80.
26. Svensson LG. Evolution and results of aortic valve surgery, and a "disruptive" technology. *Cleve Clin J Med.* 2008;75:802-4.

## APPENDIX 1. Variables used in analyses

### Preoperative

Demographic	Age (y),* gender,* race,* weight (kg), height (cm), body surface area (m <sup>2</sup> ), body mass index (kg · m <sup>-2</sup> )*
Symptoms	NYHA functional class (I-IV)*
Ventricular dysfunction	Previous myocardial infarction,* degree of left ventricular dysfunction*
Aortic valve pathology	Aortic valve regurgitation,* aortic valve stenosis*
Aortic valve disease	Rheumatic,* degenerative,* congenital*
Other valve pathology	Tricuspid valve regurgitation*
Coronary anatomy	Left main trunk disease (% stenosis),* left anterior descending coronary artery system disease (maximum % stenosis),* right coronary artery system disease (maximum % stenosis),* left circumflex coronary artery system disease (maximum % stenosis)*
Other cardiac comorbidity	Atrial fibrillation,* complete heart block,* ventricular arrhythmia*
Noncardiac comorbidity	Hypertension,* treated diabetes,* peripheral arterial disease,* stroke,* carotid disease,* popliteal disease,* endocarditis,* smoking,* renal disease,* creatinine (mg · dL <sup>-1</sup> ),* blood urea nitrogen (mg · dL <sup>-1</sup> ),* bilirubin (mg · dL <sup>-1</sup> ),* hematocrit (%)*
Experience	Date of operation (years since January 1, 1995)*

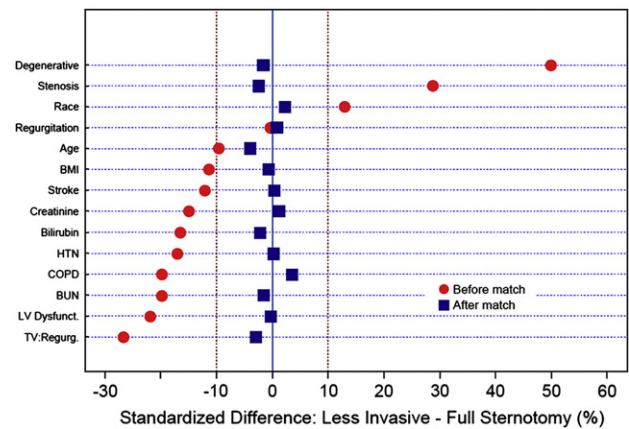
### Intraoperative

Aortic valve procedure	Repair,* replacement, prosthesis manufacturer*
Other procedure	Tricuspid valve repair*
Surgeon	A, B,* C, D,* E, F,* G,* H, I, J*

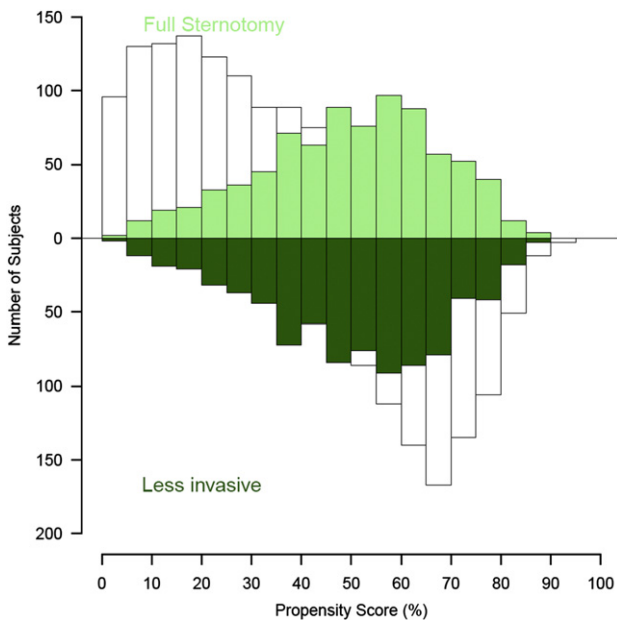
NYHA, New York Heart Association. \*Variables included in propensity score.



**FIGURE E1.** Percent of aortic valve surgery performed through a less-invasive incision. This graph incorporates cases performed after the study period.



**FIGURE E3.** Covariable balance plot before and after propensity-score matching on selected covariables. Symbols depict percent standardized differences<sup>17</sup> for covariables between patients in less invasive and full sternotomy groups. *BMI*, Body mass index; *BUN*, blood urea nitrogen; *COPD*, chronic obstructive pulmonary disease; *Dysfunct.*, dysfunction; *HTN*, hypertension; *LV*, left ventricular; *Regurg.*, regurgitation; *TV*, tricuspid valve.



**FIGURE E2.** Mirrored histogram of distribution of propensity scores for full sternotomy (bars above zero line) and less invasive (bars below zero line) approaches. Darkened area represents matched patient pairs, showing that they cover the complete spectrum of cases.

**TABLE E1.** Parsimonious model of factors associated with less invasive versus full sternotomy for aortic valve surgery\*

Factor	Coefficient ± SD	P	Reliability (%)†
<i>Higher likelihood of full sternotomy</i>			
Heavier‡	0.38 ± 0.86	<.0001	78
Severe LV dysfunction§	0.043 ± 0.012	.0004	85
Severe TV regurgitation	0.31 ± 0.061	<.0001	60
Higher BUN	0.026 ± 0.006	<.0001	74
Surgeon D	0.79 ± 0.17	<.0001	99
Surgeon G	0.805 ± 0.17	<.0001	99
<i>Higher likelihood of less invasive approach</i>			
<i>AV etiology</i>			
Degenerative	1.3 ± 0.11	<.0001	100
Rheumatic	1.2 ± 0.17	<.0001	100
Surgeon B	0.54 ± 0.16	.0008	99
More recent operation	0.51 ± 0.059	<.0001	100

*SD*, Standard deviation; *LV*, left ventricular; *TV*, tricuspid valve; *BUN*, blood urea nitrogen; *AV*, aortic valve. \*Obtained by logistic regression with variable selection by bagging. (Breiman L. Bagging predictors. *Machine Learning*. 1996;24:123-40.) †Frequency of occurrence in 1000 bootstrap models. ‡(Weight/80)<sup>2</sup>, squared transformation. §(LV dysfunction grade)<sup>2</sup>, squared transformation. ||Log(interval from 1/1/1995) to date of operation, logarithmic transformation.

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TABLE E2. Patient characteristics and operative details by surgical approach: Propensity-matched pairs

Variable	Propensity matched					Unmatched				
	Less invasive (n = 832)		Full sternotomy (n = 832)		P	Less invasive (n = 361)		Full sternotomy (n = 664)		P
	No.	%	No.	%		No.	%	No.	%	
<i>Demography</i>										
Women	298	36	293	36	.8	92	25	239	36	.0006
Age (y), mean ± SD	60 ± 16		61 ± 17		.5	56 ± 16		60 ± 16		<.0001
BMI (kg · m <sup>-2</sup> ), mean ± SD	28 ± 6.1		28 ± 5.5		.6	27 ± 4.1		29 ± 6.2		<.0001
<i>NYHA functional class</i>										
					>.9					<.0001
I	194	23	190	23		88	24	170	26	
II	482	58	486	58		237	66	289	44	
III	127	15	126	15		27	7.5	142	21	
IV	29	3.5	30	3.6		9	2.5	63	9.5	
<i>Indication for operation</i>										
Degenerative	615	74	618	74	.9	312	86	200	30	<.0001
Rheumatic	73	8.8	71	8.5	.9	32	8.9	41	6.2	.1
Congenital	52	6.3	48	5.8	.7	17	4.7	67	10	.003
Other	92	11	95	11	.8	0	0	356	54	<.0001
<i>Cardiac comorbidity</i>										
LV dysfunction	155/804*	19	144/794*	18	.5	43/352*	12	183/581*	31	<.0001
Tricuspid regurgitation > moderate	14/762*	18	22/752*	29	.2	0/351*	0	35/459*	7.4	<.0001
Atrial fibrillation/flutter	30	3.6	29	3.5	.9	6	1.7	45	6.8	.0003
<i>Noncardiac comorbidity</i>										
Hypertension	460/816*	56	452/816*	55	.7	141/356*	40	417/643*	65	<.0001
Treated diabetes	60/814*	7.4	55/811*	6.8	.6	8/356*	2.2	78/625*	12	<.0001
COPD	136/749*	18	124/740*	17	.5	41/352*	12	158/445*	36	<.0001
<i>Procedure</i>										
Aortic valve repair	126	15	118	14	.6	68	19	126	19	>.9
Aortic valve replacement	706	85	714	86	.6	293	81	538	81	>.9
Label size (mm)†										
≤19	71	10	82	12		26	8.9	49	9.5	
20/21	224	32	198	28		90	31	133	26	
22/23	259	37	235	33		107	37	164	32	
24/25	111	16	115	16		59	20	113	22	
26/27	39	5.5	61	8.6		10	3.4	44	8.5	
≥28	2	0.28	18	2.5		1	.34	14	2.7	
Tricuspid valve repair	3	0.36	10	1.2	.05	0	0	13	1.9	.008

SD, Standard deviation; BMI, body mass index; NYHA, New York Heart Association; LV, left ventricular; COPD, chronic obstructive pulmonary disease. \*Number of patients with data available. †In the full sternotomy group, 709 (of 714) propensity-matched and 517 (of 538) unmatched patients have label size data.

TABLE E3. Timing and reasons for conversion from less invasive to full sternotomy approach

Timing of conversion	Patient	General reason	Additional details
<i>Before clamping</i>			
	1	Poor exposure	Inadequate cardioplegia (misplaced retrograde catheter)
	2	Poor exposure	Aorta calcified
	3	Poor exposure	Heart low, adhesions
	4	Poor exposure	Heart low
	5	Poor exposure	Heart low
	6	Poor exposure	Heart low
	7	Poor exposure	Heart low
	8	Poor exposure	Heart low, leftward
	9	Poor exposure	Leftward heart
	10	Poor exposure	Left ventricular hypertrophy
	11	Poor exposure	Frozen right chest
	12	Poor exposure	Radiation heart disease
	13	Poor exposure	
	14	Adhesions	
	15	IVC injury during cannulation	Ascending aortic repair
	16	Coronary sinus perforation	
	17	Change in procedure plan	SAM and septal hypertrophy on ECHO, myectomy
	18	Ascending aorta repair	
<i>During clamping</i>			
	19	Poor exposure	Anterior annulus calcification
	20	Patent ductus	Intraoperative discovery of large patent ductus requiring repair
	21	LM injury	Repair of LM injury during coronary button mobilization
	22	Uncertain	Uncertain
<i>After clamping</i>			
	23	RV dysfunction	Planned for grafting, improved over time
	24	Fibrillation	To allow paddles
	25	Distention	VF unable to defibrillate, opened to place LV vent
	26	Distention	VF opened for manual compression
	27	Distention	VF and AI for adequate defibrillation
	28	Right atrial bleeding	
	29	Right atrial bleeding	
	30	Coronary sinus perforation	
	31	Coronary sinus perforation	
	32	Bleeding from root	Case converted to root replacement, calcification
	33	Cardiac arrest, tamponade	
	34	Reopen in OR for arrest	

IVC, Inferior vena cava; SAM, systolic anterior motion of mitral valve; ECHO, echocardiography; LM, left main coronary artery; RV, right ventricle; VF, ventricular fibrillation; LV, left ventricle; AI, aortic insufficiency; OR, operating room.