Less invasive versus conventional heart valve surgery in patients with severe heart failure

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Objective: Patients with severe heart failure might benefit from reduced operative trauma, but rarely undergo less-invasive valve surgery. The present study compared the outcomes of less-invasive heart valve surgery with those of complete sternotomy in such patients.

Methods: From January 1995 to July 2010, 871 patients in New York Heart Association class III or IV underwent valve surgery (aortic or mitral, or both). A less-invasive approach was used in 205. Propensity score matching yielded 185 matched pairs for outcomes comparison adjusted for patient characteristics and 139 pairs adjusted further for individual surgeon.

Results: Without considering surgeons, myocardial ischemic times (59 ± 27 vs 64 ± 26 minutes, $P = .04$), cardiopulmonary bypass times (75 ± 35 vs 86 ± 34 minutes, $P < .0001$), and intensive care unit stays (median, 24 vs 43 hours; $P = .007$) were shorter for less-invasive surgery. Hospital morbidity, mortality (1.6% [3 of 185] vs 2.7% [5 of 185]; $P = .5$), and long-term survival (53% and 48% at 12 years; $P = .3$) were similar. After considering the surgeon, these benefits were not apparent; rather, efficiency, safety, and effectiveness were equivalent to those of complete sternotomy. Thus, myocardial ischemic (63 ± 30 vs 62 ± 25 minutes, $P = .8$) and cardiopulmonary bypass (80 ± 40 vs 81 ± 31 minutes, $P = .5$) times were similar, as were intensive care unit stay (median, 28 vs 30 hours; $P = .09$), postoperative complications, in-hospital mortality (2.2% [3 of 139] vs 3.6% [5 of 139]; $P = .5$), and long-term survival (57% and 53% at 12 years; $P = .5$).

Conclusions: In selected patients with severe heart failure, less-invasive valve surgery is a viable option, yielding at least equivalent efficiency, safety, and effectiveness to complete sternotomy. However, achieving these outcomes requires surgeons experienced in less-invasive surgery. (J Thorac Cardiovasc Surg 2014;148:161-7)

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Less-invasive heart valve surgery has been associated with less operative trauma, fewer complications, and shorter postoperative hospitalization than operations performed through a complete sternotomy.[1-5] Nevertheless, patients with severe heart failure, who might be expected to benefit most from a reduction in operative trauma, rarely undergo less-invasive valve surgery.

The goals of the present study were to (1) compare the efficiency, safety, and effectiveness of less-invasive approaches to those of complete sternotomy in patients with severe heart failure undergoing primary isolated aortic valve or mitral valve surgery, or both; and (2) explore surgeon preference to identify circumstances in which 1 approach might be optimum.

METHODS

Study Population

From January 1995 to July 2010, 10,791 adults underwent primary isolated mitral valve repair or replacement, primary isolated aortic valve repair or replacement, or a combined primary procedure for rheumatic, degenerative, or functional valve disease with or without concomitant tricuspid valve surgery at Cleveland Clinic (Figure E1). Percutaneous aortic valve

Abbreviations and Acronyms	
CL	= confidence limits
CPB	= cardiopulmonary bypass

insertion, procedures that included mitral annular debridement, and emergency operations were excluded. Of the remaining 10,714 patients, 871 had symptomatic heart failure (New York Heart Association class III or IV) within 2 weeks before surgery. Less-invasive surgery was performed in 205 patients (23%) and complete sternotomy in 666 (77%). A total of 267 mitral valve replacements (43%), 342 mitral valve repairs (57%), 417 aortic valve replacements (96%), and 15 aortic valve repairs (4%) were performed. The characteristics of these 871 patients and operative details are presented in Table E1. These patients constituted, in part, a subgroup of previously reported investigations of less-invasive cardiac valve surgery, and the operations were classified on an as-treated basis.[1,2,6]

Data Sources

Clinical data were obtained from the Cardiovascular Information Registry, a prospective database updated concurrently with patient care. Preoperative transthoracic echocardiographic data were obtained from the echocardiography database. The institutional review board approved the use of these data for research, with the patient consent requirement waived.

Surgical Technique

General endotracheal anesthesia was used in all patients, regardless of the surgical approach. Double-lumen intubation with single-lung ventilation was used in operations performed by way of thoracotomy and a robotic approach.[7] The most common less-invasive approach was partial upper sternotomy (167 patients [85%]) beginning at the sternal notch and ending at the fourth intercostal space.[8,9] Other approaches included partial lower sternotomy (n = 5), left thoracotomy (n = 3), right thoracotomy (n = 4), right parasternal (n = 4), transsternal (n = 2), and robotic (n = 10) using previously described techniques.[7,9,10] The type of approach was reflective of individual surgeon preference.

Cardiopulmonary bypass (CPB) with vacuum-assisted venous drainage and central or peripheral cannulation was used in all patients with normothermic or mild hypothermia.[11] Combined antegrade and retrograde blood cardioplegia was used in all patients.

Endpoints

The primary efficiency endpoints were the CPB and myocardial ischemic times. The safety of the operative approach was assessed by comparing in-hospital mortality and morbidity, defined in accordance with the Society of Thoracic Surgeons National Database (available at: http://www.ctsnet.org/file/rptDataSpecifications252_1_ForVendorsPGS.pdf). *Effectiveness* was assessed by long-term survival.

Follow-up

The Social Security Death Master File, queried on December 22, 2010, was used to identify patients' vital status.[12,13] Only 7 patients (0.8%) were missing follow-up data after hospital discharge, because no Social Security number was available. A total of 4583 patient-years of passive follow-up data were available for analysis. Mean follow-up was 5.2 ± 4.1 years (median, 4.4), with 25% of survivors followed up >9.3 years and 10% >12 years.

Comparison Methods

Efficiency. CPB and myocardial ischemic times are summarized as the mean ± standard deviation, and comparisons were made using the Wilcoxon rank sum test.

Safety. In-hospital mortality and morbidity are expressed as frequencies and percentages, and comparisons were made using the chi-square test. When the frequency was <5, Fisher's exact test was used.

Effectiveness. Overall nonparametric survival estimates were obtained using the Kaplan-Meier method and compared using the log-rank test. A parametric model was used to resolve a number of phases of instantaneous risk of death (hazard function) and to estimate shaping parameters.[14] (For additional details, see http://www.clevelandclinic.org/heartcenter/hazard.)

All analyses were performed using SAS statistical software, version 9.1 (SAS Institute, Cary, NC). Percentages and parametric estimates are accompanied by asymmetric 68% confidence limits (CLs), comparable to ±1 standard error.

Missing Values

A Markov chain Monte Carlo technique was used to impute missing values as necessary,[15] with fivefold multiple imputation for all multivariable regression models performed using PROC MI and PROC MIAnalyze (SAS, version 9.1).

Study Design

Comparisons adjusted for patient characteristics. A meaningful direct comparison of outcomes was precluded by the differences in patient characteristics (Table E1). To reduce the influence of selection bias, we used propensity matching.[16] Initially, the factors associated with complete sternotomy were identified by "bagging" (automated forward stepwise logistic regression using 1000 bootstrap resamplings and a *P* value for variable retention of .05) using only patient characteristics (see the Appendix).[17] Variables identified in ≥50% of these models were retained as a parsimonious model (Table E2).

To this model, other patient characteristics and intended procedure variables that might be related to unrecorded selection factors (semisaturated model) were added (see the Appendix). A propensity score was calculated for each patient by solving this model (C-statistic, 0.81) for the probability of undergoing complete sternotomy. We used a "greedy" matching strategy to match the less-invasive and complete sternotomy cases.[18] Less-invasive cases with propensity scores deviating >0.10 from those of full sternotomy were considered unmatched. This yielded 185 (90% of possible matches) well-matched pairs (Figure E2). The effectiveness of this matching strategy was evaluated by standardized differences of the variables before and after matching (Figure E3). Characteristics of 185 matched patients and the procedures are listed in Table 1.

Comparison adjusted for surgeon preference. We further accounted for surgeon preference by developing a second model with the individual surgeons entered into the analysis (Table E3). The C-statistic of this propensity model was 0.879. Greedy matching using propensity scores yielded 139 (68% of patients undergoing less-invasive surgery) well-matched pairs (Figure E4). The performance of this matching strategy was evaluated by standardized differences of variables before and after matching (Figure E5). The characteristics of these 139 matched patient pairs and the procedures are listed in Table 1.

RESULTS

Outcomes Adjusted for Patient Characteristics

Efficiency. Myocardial ischemic time (59 ± 27 vs 64 ± 26 minutes, *P* = .04) was shorter with less-invasive surgery than with complete sternotomy, as was the CPB time (75 ± 35 vs 86 ± 33 minutes, *P* < .0001; Table 2, matched group; Table E4, unmatched group).

In-hospital mortality was 1.6% (3 patients; 68% CL, 0.7-3.2%) in the less-invasive group and 2.7%