Less invasive versus conventional double-valve surgery: A propensity-matched comparison

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Objective: Less invasive approaches to double-valve surgery are used for improved cosmesis; however, few studies have investigated their effect on outcome. We sought to compare these less invasive approaches with conventional full sternotomy.

Methods: From January 1995 to January 2004, 114 patients underwent primary double-valve surgery through a less invasive approach and 381 through conventional sternotomy. Because there were important differences in the patients' characteristics, a propensity score based on 42 factors was used to obtain 81 well-matched patient pairs (71% of possible matches) for comparison of in-hospital morbidity and mortality, mediastinal drainage, transfusion requirements, pulmonary function, pain, and long-term survival.

Results: In-hospital mortality was similar for propensity-matched patients: 6.2% (5/81) for those undergoing less invasive surgery and 2.5% (2/81) for those undergoing conventional sternotomy ($P > .4$). Occurrences of stroke ($P > .9$), renal failure ($P = .4$), myocardial infarction ($P > .9$), and infection ($P > .9$) were also similar. However, 24-hour mediastinal drainage was less after less invasive surgery (median, 250 vs 400 mL; $P < .0001$), but a similar proportion of patients received transfusions (28% vs 40%, $P = .2$). An equivalent proportion of patients were extubated in the operating room (7.7% vs 7.0%, $P > .9$), and median hours to extubation were similar (5.0 vs 6.5 hours). Pain scores were equivalent ($P > .3$). Long-term survival was also similar (82% and 76% at 10 years, $P = .07$).

Conclusions: Within that portion of the spectrum of double-valve surgery in which propensity matching was possible, less invasive surgery had cosmetic and blood product use advantages over conventional surgery and no apparent detriments. (J Thorac Cardiovasc Surg 2011;141:1461-68)

Supplemental material is available online.

Less invasive valve surgery can be performed through a variety of approaches, such as partial upper sternotomy,[1-7] partial lower sternotomy,[3] transverse sternotomy, right parasternal thoracotomy,[4] right minithoracotomy with video-assisted thoracoscopy,[8,9] and totally robotic surgery.[5,8] Large experience with these techniques in many centers[9-12] has proved their safety, efficacy, and potential benefits compared with conventional sternotomy in treating isolated mitral or aortic valve disease. Whether combined surgical intervention on both aortic and mitral valves through a less invasive approach has an advantage or even a disadvantage is unclear, and a randomized trial is unlikely. Therefore, we performed a propensity-matched comparison of in-hospital outcomes and long-term survival in patients who underwent less invasive combined mitral and aortic valve surgery with those who had conventional full sternotomy.

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Supported in part by the Kenneth Gee and Paula Shaw, PhD, Chair in Heart Research (to E.H.B.) and the Judith Dion Pyle Chair in Heart Valve Research (to A.M.G.).

Disclosures: Dr Gillinov is a consultant to Edwards Lifesciences, St Jude Medical, and Medtronic.

Received for publication Oct 29, 2008; revisions received Feb 5, 2010; accepted for publication May 5, 2010; available ahead of print Nov 1, 2010.

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0022-5223/$36.00

doi:10.1016/j.jtcvs.2010.05.053

MATERIALS AND METHODS

Patients

From January 1995 to January 2004, 495 patients underwent primary combined aortic and mitral valve surgery (Table 1) with or without tricuspid valve repair at Cleveland Clinic. Patients undergoing concomitant coronary artery bypass grafting, ablation surgery for atrial fibrillation, or reoperation were excluded, as were those with endocarditis. Less invasive surgery was performed in 114 (23%) patients, and conventional full sternotomy was performed in 381 (77%) patients. Unmatched mean age was 59 ± 14 years among patients undergoing less invasive surgery and 62 ± 15 years among patients undergoing conventional surgery, with nearly equal sex distribution (Table 2).

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.

Abbreviations and Acronyms
CL = confidence limit
FEV_1 = forced expiratory volume in 1 second

Surgical Technique

Two less invasive approaches were included in this study. From 1995 through 1996, a right paramedian incision was used that included division of the third and fourth costal cartilages (9 [7.9%] patients)[1]; from 1997 onward, this changed to a J incision beginning at the sternal notch and ending at the fourth intercostal space (105 [92%] patients).[6,7] With these less invasive chest-wall incisions, the mitral valve was accessed through a transseptal incision and the aortic valve through an aortic "hockey stick" incision.

Conventional general anesthesia was used in all patients regardless of surgical approach. In those undergoing full median sternotomy, the mitral valve was usually visualized by means of an incision in the left atrium anterior to the right pulmonary veins and the aortic valve through a "hockey stick" aortic incision. Patients who underwent less invasive surgery had a 3- to 4-inch (8- to 10-cm) skin incision.[1,6,10]

Vacuum-assisted cardiopulmonary bypass with central cannulation was used in all patients.[13] Intraoperative transfusions, anesthetic technique, and timing of extubation were at the anesthesiologist's discretion. Intraoperative and postoperative transfusion and extubation were not derived from strict protocols. In the early phase of this study, there was a learning curve involved in developing the technique, which was, however, technically similar to conventional sternotomy.

Study Design

A number of differences in patients' characteristics precluded direct comparison of outcomes (Table 2). Therefore, to reduce the influence of selection, we used propensity matching to approximate a randomized trial.[14-16] In the spirit of such a trial, we followed the intent-to-treat principle, such that the 11 (9.6%) patients with an intended less invasive approach who were converted to conventional sternotomy were retained for analysis in the less invasive group, as they would be in a randomized clinical trial. Initially, a parsimonious model based on variables in Appendix 1 was formulated by means of logistic regression analysis using bagging for variable selection (see Table E1) to understand the drivers of patient selection.[17] To this model were added nonsignificant variables to form a propensity model. From this, a propensity score was generated for each patient from a logistic regression model (C = 0.81) based on 42 preoperative variables and procedure variables predictable preoperatively (Appendix 1). Greedy matching based on the propensity score was used to identify 81 patient pairs for comparison (Table 2), 71% of all possible matches.[18] Figure 1 indicates that the propensity-matched patients are drawn from across the entire spectrum of propensity. However, unmatched patients (see Table E2) are predominantly those for whom conventional sternotomy was rather systematically applied. Clearly, as seen from the figure, there is good overlap between the procedures after propensity adjustment. This strategy was repeated for the 2000–2004 cohort with spirometry and pain scores, yielding 43 propensity-matched patient pairs.

Outcomes

Outcomes assessed included intraoperative support (myocardial ischemic time and 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), blood product use, mediastinal drainage at 6 and 24 hours, hematocrit value at hospital discharge, time to extubation (which was at the discretion of attending anesthesiologists in either the operating room or intensive care unit), all incentive spirometry values after extubation, all pain scores, length of hospital stay, and long-term survival.

Spirometry and pain scoring were performed and results recorded from January 2000 to January 2004. Both spirometric values and pain scores were obtained routinely, as part of clinical care, from all patients after surgical intervention. Spirometry, consisting of forced expiratory volume in 1 second (FEV_1; in milliliters), was performed periodically by respiratory therapists using a Renaissance II bedside spirometer (Puritan Bennett, Carlsbad, Calif) until hospital discharge; a total of 385 values were available for 31 of the 43 matched patients undergoing a less invasive procedure and 34 of the 43 patients undergoing conventional surgery. FEV_1 values were normalized to percent predicted values by the National Health and Nutrition Examination Survey algorithm.[19] Pain intensity, ranging from 0 (none) to 10 (severe), was recorded by nursing staff from the patients' arrival in the intensive care unit to hospital discharge by using the extensively validated Wong–Baker visual analog scale.[20,21] A total of 3337 pain scores were available for 33 (77%) of the 43 patients undergoing less invasive surgery and 36 (84%) of the 43 patients undergoing conventional surgery.

Survival was assessed based on follow-up every 2 years by using an institutional review board–approved questionnaire supplemented by the Social Security Death Index.[22,23] For matched patients undergoing less invasive surgery, 291 patient-years of follow-up were available for analyses, mean follow-up was 3.6 ± 2.4 years, and 10% were followed for more than 7.3 years. In the matched cohort undergoing conventional sternotomy, 297 patient-years of follow-up were available for analyses, mean follow-up was 3.7 ± 2.1 years, and 10% were followed for more than 6.5 years.

Comparisons

Categorical outcomes were compared by using either the χ^2 or Fisher's exact test and continuous outcomes by using the Wilcoxon rank-sum nonparametric test. To compare temporal patterns of postoperative FEV_1 across time, the repeated continuous values were analyzed longitudinally by using mixed-model regression,[18] with autoregressive order 1 correlation structure to accommodate the correlated nature of the observations within each patient.

To compare temporal patterns of postoperative pain across time, pain scores were combined into 5 categories because of the low frequency of higher 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). The pain-score category was analyzed longitudinally by using a nonlinear cumulative logit mixed model for repeated measures that resolved a number of temporal components and their shaping parameters[24] in the cumulative odds domain. Each component was independently modulated by a time function with common random intercept. Survival was compared nonparametrically by using the Kaplan–Meier method and parametrically by using a temporal decomposition model.[24]

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 when data were skewed. Asymmetric confidence limits (CLs) are equivalent to ± 1 standard deviation (68%). All analyses were performed with SAS statistical software version 9.1 (SAS Institute, Inc, Cary, NC).

RESULTS

Intraoperative Support

Among propensity-matched patients, intraoperative myocardial ischemic time was shorter with less invasive surgery (86 ± 23 vs 97 ± 33 minutes, $P = .02$) than with conventional sternotomy, as was cardiopulmonary bypass time (105 ± 32 vs 124 ± 47 minutes, $P = .004$).

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