Durability of pericardial versus porcine bioprosthetic heart valves

Gary L. Grunkemeier, PhD,[a] Anthony P. Furnary, MD,[b] YingXing Wu, MD, MS,[a] Lian Wang, MS,[a] and Albert Starr, MD[c]

Objectives: To compare the probability, and modes, of explantation for Carpentier-Edwards pericardial versus porcine valves.

Methods: Our porcine series began in 1974 and our pericardial series in 1991, with annual prospective follow-up. We used the Kaplan-Meier method and Cox regression for estimation and analysis of patient mortality, and the cumulative incidence function and competing risks regression for estimation and analysis of valve durability.

Results: Through the end of 2010, we had implanted 506 porcine and 2449 pericardial aortic valves and 181 porcine and 163 pericardial mitral valves. The corresponding total and maximum follow-up years were 3471 and 24, 11,517 and 18, 864 and 22, and 645 and 9. The corresponding probabilities (cumulative incidence function) of any valve explant were 7%, 8%, 22%, and 8%, and of explant for structural valve deterioration were 4%, 5%, 16%, and 5% at 15 years for the first 3 series and at 8 years for the fourth (pericardial mitral valve) series. Using competing risks regression for structural valve deterioration explant, with age, gender, valve size, and concomitant coronary bypass surgery as covariates, a slight (subhazard ratio, 0.79), but nonsignificant, protective effect was found for the pericardial valve in the aortic position and a greater (subhazard ratio, 0.31) and almost significant ($P = .08$) protective effect of the pericardial valve in the mitral position. Leaflet tear was responsible for 61% of the structural valve deterioration explants in the porcine series and 46% in the pericardial series.

Conclusions: Using competing risks regression, the pericardial valve had a subhazard ratio for structural valve deterioration explant of less than 1 in both positions, approaching statistical significance in the mitral position. The mode of structural valve deterioration was predominantly leaflet tear for porcine valves and fibrosis/calcification for pericardial valves. (J Thorac Cardiovasc Surg 2012;144:1381-6)

We began using Carpentier-Edwards (CE) porcine valves in 1974 and then migrated to the CE pericardial valves when they became available (aortic in 1991 and mitral in 2000). Surgeon preference for the pericardial valves was determined from tests performed by Edwards Laboratories and Professor Carpentier, revealing greater in vitro durability of pericardium. In 2003, we compared our experience with CE aortic valve replacement (AVR) in 518 porcine valves implanted from 1974 to 1996 and 1021 pericardial valves implanted from 1991 to 2002, with a maximum follow-up of 18 and 10 years, respectively.[1]

We found that the 10-year Kaplan-Meier freedom from explantation was lower for porcine than for pericardial valves (90% vs 97%, $P = .04$), and concluded that, "The current CE pericardial valve offers better midterm durability than the traditional CE porcine valve. Its freedom from SVD [structural valve deterioration] and reoperation makes it our current bioprosthesis of choice for AVR in appropriately selected patients."[1]

Dr Stuart Jamieson commented on our study, "Perhaps the most valuable conclusion from this study, and others similar to it, is that the durability of a tissue valve, in particular the durability of pericardial valves in the aortic position, is better than 90% at 10 years. However, the 10-year test is relatively easy to pass. Relative freedom from structural deterioration at 20 years will be the important milestone."[2]

We now have 8 years' additional follow-up. Although we have not yet achieved a 20-year estimate, we now have a fairly precise durability comparison for AVR at 15 years. In addition, we now also report on mitral valve replacement (MVR). Although we have far fewer MVRs, the mitral position is known to have a greater risk of structural valve deterioration (SVD) and, thus, similar to an accelerated fatigue tester, might provide a magnified comparison of any differences in durability.

MATERIALS AND METHODS

Clinical Material

Through the end of 2010, we had performed 506 CE porcine and 2449 CE pericardial isolated AVRs and 181 CE porcine and 163 CE pericardial

From the Medical Data Research Center,[a] Providence Health & Services, Portland, Ore; Starr-Wood Cardiac Surgery Group,[b] St Vincent Hospital and Medical Center, Portland, Ore; and [c]Division of Cardiovascular Medicine, Oregon Health & Science University, Portland, Ore.

This study was partially supported by a grant from Edwards Lifesciences.

Disclosures: Drs Starr and Furnary are consultants for Edwards Lifesciences. The other authors have nothing to disclose with regard to commercial support.

Read at the 38th Annual Meeting of The Western Thoracic Surgical Association, Maui, Hawaii, June 27-30, 2012.

Received for publication June 28, 2012; revisions received July 30, 2012; accepted for publication Aug 23, 2012; available ahead of print Sept 24, 2012.

Address for reprints: Lian Wang, MS, Medical Data Research Center, Providence Health & Services, 9205 SW Barnes Rd, Suite 33, Portland, OR 97225 (E-mail: Lian.Wang@providence.org).

0022-5223/$36.00

Copyright © 2012 by The American Association for Thoracic Surgery

http://dx.doi.org/10.1016/j.jtcvs.2012.08.060

Abbreviations and Acronyms

AVR	= aortic valve replacement
CABG	= coronary artery bypass grafting
CE	= Carpentier-Edwards
CIF	= cumulative incidence function
CRR	= competing risks regression
KM	= Kaplan-Meier
MVR	= mitral valve replacement
SHR	= subhazard ratio
SVD	= structural valve deterioration

isolated MVRs. By ''isolated,'' we mean no concomitant or previous valve replacement or repair procedures performed in another position. Concomitant coronary artery bypass grafting (CABG) was not an exclusion criterion. The implant techniques were standardized for the entire series, with the same aortic incision, myocardial protection, and the same surgical group. There was an informative pattern to the distribution of patient age over time (Figure 1). A gradual increase occurred in the mean age with the porcine valve, as late SVD became known to be related to a younger age. Then, a gradual revisiting of younger patient ages occurred as additional experience with the pericardial valve was gained—and with it, the perception of improved durability.

Because our primary interest was in the long-term durability, we restricted the subsequent analysis to operative survivors only, with 469 CE porcine and 2356 CE pericardial isolated AVRs and 158 CE porcine and 154 CE pericardial isolated MVRs (Table 1). Since 1960, we have prospectively interviewed all heart valve replacement patients at least annually for their entire life. At the end of 2010, the maximum follow-up for these 4 patient series ranged from 9 to 24 years (Table 1). We considered valve patients lost to follow-up if they were not known to be dead or to have had the valve explanted and had not responded to interview attempts for 2 years.

Because the present project involved only the study of existing records and used only de-identified data, it qualified for exemption from institutional review board approval, according to Exemption 45 CFR 46.101(b)(4).

Statistical Analysis

For the analysis of mortality, we use the Kaplan-Meier (KM) method[3] and Cox regression analysis.[4] For the analysis of valve explantation, we used the cumulative incidence function (CIF), the appropriate method to describe events with competing risks (death was considered a competing risk, because it precludes the possibility of a future explant). The CIF estimates the probability of a valve actually requiring explantation—before the patient dies. Analogous to the use of Cox regression for multivariate analysis of risk factors for death, competing risks regression (CRR) was used for the analysis of explantation. Instead of computing hazard ratios, such as would occur with Cox regression analysis, CRR computes subhazard ratios (SHRs), because the CIF is a subdistribution and not a complete distribution. This is because the probability of valve explant will not achieve 100%, as will the probability of patient death. The statistical packages used in this analysis included R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (StataCorp, College Station, Tex): all figures were produced using R, including the local regression (LOESS) nonparametric regression curves. See the Appendix for a discussion of the competing risks and software options for computing CIF and CRR.

RESULTS

Patient Mortality

Unadjusted late mortality was lower for pericardial than for porcine valves, in both AVR and MVR, although the numeric differences were not great: 81% versus 88% at 15 years for AVR ($P = .02$) and 50% versus 57% at 8 years for MVR ($P = .04$). Separate Cox regression analyses of late survival for AVR and MVR—using valve type, patient age at implantation, gender, CABG, and valve size (Table 2)—showed the pericardial valve to be protective (hazard ratio < 1) for mortality, significantly for MVR ($P = .003$) but not quite for AVR ($P = .054$).

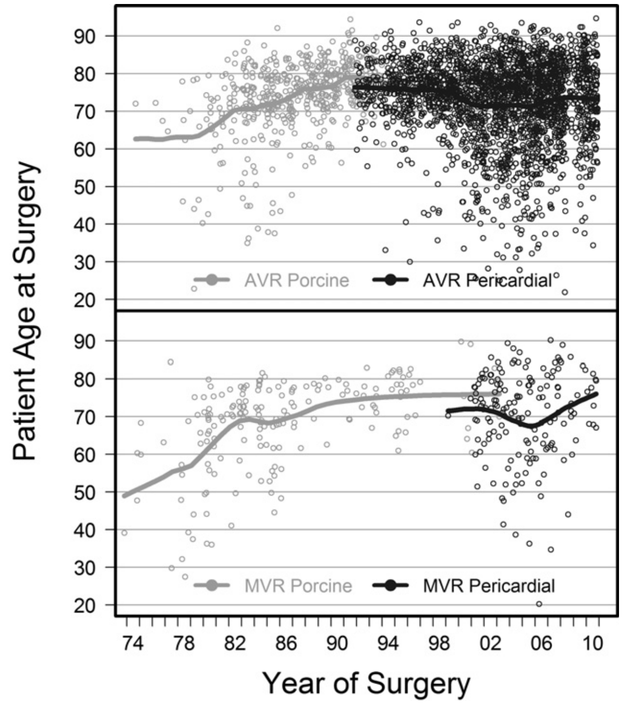

FIGURE 1. Scatter plot of patient age during implant year, with local regression (LOESS; locally weighted scatterplot smoothing) nonparametric regression curves fit to the individual points. *AVR*, Aortic valve replacement; *MVR*, mitral valve replacement.

Valve Explantation

Our main interests in the present study were the endpoints of overall explantation and explantation for SVD.

All explants. For each position, the porcine valve had a greater probability (CIF) of overall explantation than the pericardial valve at 10 years (Figure 2). However, the probabilities of valve explantation by 15 years were similar in the aortic position. The CIF probability of explantation by 15 years after porcine and pericardial AVR was 7% ± 1.3% (standard error [SE]) and 8% ± 1.2% (Figure 2), respectively ($P = .12$, using univariate CRR). The probabilities of explantation were 22% ± 3.7% by 15 years for porcine MVR and 8% ± 3.8% by 8 years for pericardial MVR ($P = .03$, using univariate CRR).

Explants for SVD. The CIF probability of explantation for SVD by 15 years after porcine and pericardial AVR was 4% ± 1.0% (SE) and 5% ± 0.9% (Figure 3), respectively

Download English Version:

https://daneshyari.com/en/article/5990274

Download Persian Version:

https://daneshyari.com/article/5990274

Daneshyari.com