Journal of the American College of Cardiology
© 2010 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 55, No. 22, 2010
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2009.10.085

STATE-OF-THE-ART PAPER

Choice of Prosthetic Heart Valve in Adults

An Update

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In the last 7 years, more data have reconfirmed that patients' comorbid conditions are very important factors determining patient outcomes. Prosthetic heart valves (PHVs) that require aortic root replacement in the absence of aortic root disease are associated with poorer outcomes. For the vast majority of patients, the choice of PHV is between a mechanical valve and a stented bioprosthesis. The choice is largely dependent upon the age of the patient at the time of PHV implantation and on which complication the patient wants to avoid: specifically, anticoagulation therapy and its complications with the mechanical valve, and structural valve deterioration with a bioprosthesis. Data on the pros and cons of the choices and exceptions to the rules are discussed, and a new algorithm is developed. (J Am Coll Cardiol 2010;55:2413–26) © 2010 by the American College of Cardiology Foundation

"Not all innovations represent progress."

—Anonymous

"The feasibility of an operation is not the best indication for its performance."

—Lord Cohen of Birkenhead,
at 1950 Moynihan Lecture,
Royal College of Surgeons, England (1)

Determining the choice of a prosthetic heart valve (PHV) was published 7 years ago (2). In this update, a few issues are re-emphasized; however, the major thrust is on newer findings that have had an impact on the choice of PHV. Patients' survival after PHV has increased markedly; it is essential to consider the patient's point of view regarding the ideal PHV (Table 1), which should be the goal.

Factors Determining Outcomes After PHV Replacement

The Department of Veterans Affairs (VA) randomized trial, the only randomized trial that determined adjudicated causes of death (3), showed that 43% to 63% of the deaths were not related to the PHV (Table 2). It was previously emphasized that "patient-related factors," now called comorbid conditions, were very important in determining patient outcomes (4). Comprehensive lists of these are available (3–13); those useful in everyday practice are listed in Table 3.

Conclusions. When comparing outcomes with different PHVs, it is important to: 1) ensure that the baseline characteristics of the patients and their comorbid conditions are the same, or are at least very similar, which can be best determined by a good prospective randomized trial (14); and 2) determine cause of death when comparing survival after PHV replacement.

Mechanical PHV

Randomized trials. The Starr-Edwards valve (Edwards Lifesciences, Irvine, California), a model in use since 1965, was compared with the St. Jude Medical valve (St. Jude Medical, St. Paul, Minnesota), first used in 1977. For aortic valve replacement (AVR) and mitral valve replacement (MVR), there were no significant differences in survival, event-free survival, and all outcomes (15) (Fig. 1). The Carbomedics valve (Carbomedics, Austin, Texas) was compared with the St. Jude Medical valve. Up to 10 years, there were no significant differences in survival and freedom from complications after AVR and MVR (16) (Fig. 2).

Nonrandomized studies. Very long-term studies have shown good outcomes with virtually no structural valve deterioration (SVD) with the Starr-Edwards valve up to 40 years (17), with the Medtronic-Hall valve (Medtronic, Minneapolis, Minnesota) up to 20 and 25 years (18,19), with the old Bjork-Shiley valve (Shiley, Irvine, California) which incorporated a Delrin ring (DuPont, Wilmington, Delaware), and with St. Jude Medical valves (2).

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Manuscript received May 31, 2009; revised manuscript received October 23, 2009, accepted October 27, 2009.

JACC Vol. 55, No. 22, 2010
June 1, 2010:2413–26

Abbreviations and Acronyms

AVR = aortic valve replacement

C-E = Carpentier Edwards

$CHADS_2$ = congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischemic attack

CI = confidence interval

HR = hazard ratio

MVR = mitral valve replacement

PHV = prosthetic heart valve

SVD = structural valve deterioration

TSPV = Toronto stentless porcine valve

VA = Veterans Administration

VP-PM = valve prosthesis–patient mismatch

Conclusions. Mechanical PHVs that are approved by the Food and Drug Administration (FDA) and have good and comparable outcomes at ≥15 to 20 years of follow-up will likely have good outcomes on very long-term follow-up.

Biological PHVs That Require Aortic Root Replacement

Biological PHVs that require aortic root replacement include stentless and homograft PHV (both of which can sometimes be used without replacing the root), and the Ross principle (autograft).

Operative mortality. For isolated aortic valve disease without specific root pathology, using these 3 types of PHV that require aortic root replacement is associated with a higher operative mortality (9,20,21). Yacoub et al. (22), using selected low-risk patients (age >16 years) from Harefield Hospital in the United Kingdom and Rotterdam, the Netherlands, reported a low operative mortality with the Ross principle. These 2 groups and others analyzed 268 studies of the Ross principle between 2000 and 2008. Of 39 that met entry criteria, 17 involved adult patients and comprised 1,749 adult patients >18 years of age; their operative mortality was low (3.12%) (Table 4) (23). In comparison, David (24) has described 466 patients ≤50 years of age who had isolated AVR over a period of 20 years with 1 operative death (0.2%) (Table 4).

SVD. The younger the patient at the time of PHV implantation, the higher the risk of SVD, and SVD of biological valves should be evaluated with >10 years of follow-up (3). At 12 years, the rate of SVD for stentless porcine valve was 31 ± 4% (25); for patients <65 years of age, it was 48 ± 8%; and for patients ≥65 years of age, it was 15 ± 4%. The incidence of grade 2 or higher aortic regurgitation was 52 ± 5%. David (25), arguably the father of the stentless valve, stated that the Toronto stentless porcine valve (TSPV) has provided "... suboptimal durability particularly in patients less than 65 years of age. We now use this valve mostly in older patients who have a small aortic annulus." The hemodynamics of the TSPV are also not better than those of the stented Carpentier-Edwards (C-E) pericardial Perimount valve (Edwards Lifesciences) (see the following text). The rate of SVD for homografts is similar to that for bioprostheses (26); at 10 and 15 years, it was 30 ± 3.8% and 59.7 ± 5.1% (27), and at 13 years in another study, it was 31.2 ± 6.3% (28).

An updated report of the Ross principle in the earlier Rotterdam data on 146 patients with a mean follow-up of 8.7 years showed the reoperation rate of the autograft at 13 years was 30.8 ± 6.6%, but for patients ≥16 years of age, it was 43.3 ± 9.5% (29); the reoperation rate of the homograft in the pulmonary position was 12.9 ± 5.5% at 13 years (29). In another study of 91 younger patients (age 27 ± 10 years; range 6 to 49 years), the incidence of autograft dysfunction at 7 years was 25 ± 8% (30). In a meta-analysis of 39 studies, 17 studies in adults, the follow-up ranged from only 1.8 to 8.7 years and was <5 years in 59% (23). The authors concluded, "The Ross procedure provides satisfactory results for ... young adults," which is questionable. They also appropriately concluded, "Durability limitations become apparent by the end of the post-operative decade, in particular in younger patients" (23); reality sets in. For autografts (Ross principle), the rate of SVD at 13 years was 31.2 ± 6.3% (28). Ross's own data, which have the longest follow-up, had reported operative mortality of 7% to 13% and reoperation rates of 15% to 52% up to 20 years (31–33). Yacoub et al. (22) have warned that reoperation of an autograft root "is not simply a reoperation. [It is] a risk-carrying and demanding procedure" because aneurysmatic ascending aorta may be attached to the sternum, the pulmonary homograft may be compressed by and attached to the dilated autograft root, and the coronary buttons may also pose problems when they are removed from the autograft and reimplanted in a new root. These procedures usually require removal of the coronary arteries and reimplanting them in the new root. One study reported a 6% incidence of perioperative myocardial infarction in patients who did not have associated coronary artery disease (34).

Conclusions. In 2000, Ross advised the terminology "Ross procedure" should not be used because what surgeons are doing is not what he described; instead, it should be called the "Ross principle" (35). These procedures are associated with a 2- to 3-fold increase of operative mortality (Table 4).

Table 1 Patient's Point of View of the Ideal Prosthetic Heart Valve

The valve should:
Provide a cure
Have normal function
Provide normalization, or at least marked improvement of lifestyles and outcomes
Last a lifetime
PHV implantation should be:
Possible with very low mortality and morbidity
Nondestructive, that is, does not damage other parts of the cardiovascular system
Duration of hospitalization is short
Can be implanted at a cost that is affordable
Minimal needs for further:
Test(s) and procedure(s)
Therapy
Can be inserted percutaneously