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Circulation. 2011;123:2602-2605

doi: 10.1161/CIRCULATIONAHA.110.979518

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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Prosthetic Heart Valve

Grace Huang, MD; Shahbudin H. Rahimtoola, MB, FRCP, DSc (Hon)

A 55-year-old invasive/clinical cardiologist worked full time, exercised regularly, and was asymptomatic. Two weeks previously, he had new onset of angina on exertion. Echocardiography/Doppler and cardiac catheterization confirmed the clinical assessment of severe aortic stenosis with a valve area of 0.5 cm²/m². The aortic valve was tricuspid; left ventricular ejection fraction was 0.60. Coronary arteriography showed no obstructive coronary artery disease. His body-mass index was 23 kg/m², body surface area 1.7 m², blood pressure 110/70 mm Hg, low-density lipoprotein 70 mg/dL, creatinine clearance 120 mL/min, and hemoglobin A1c 5.0. He had no comorbid conditions, and had never smoked.

Discussion

Several factors have to be taken into consideration in choosing a prosthetic heart valve (PHV; Table 1).¹ The choice is between mechanical and biological valves. An important determining factor is weighing the risks of anticoagulant therapy with mechanical valves or structural valve deterioration (SVD) with biological valves.

Table 1. Factors To Be Considered in the Decision for Choice of PHV

Age of the patient
Comorbid conditions, cardiac and noncardiac
Expected life span of patient
Use a PHV
that does not require root replacement for isolated aortic valve disease
with long-term follow-up outcomes that are at least as good as the best of the available PHV
with which individual physicians and medical centers have the necessary skill and experience
Probability of adherence and compliance with warfarin therapy
Patient's wishes and expectations
Other extenuating circumstances
PHV indicates prosthetic heart valve.
Adapted from Rahimtoola. ¹

Mechanical Valves

In 1960, the first clinically implanted PHVs by Harken and by Starr were mechanical valves. The modified Starr-Edwards valve introduced in 1965 did not have SVD, with up to 40 years of follow-up.² Other PHVs had similar results up to 20 to 30 years of follow-up.¹ In patients with aortic stenosis,² mechanical valves were proven to improve survival, functional class,

and left ventricular function, and to reverse clinical heart failure; there were reductions of left ventricular mass and of pulmonary hypertension. All patients with mechanical valves need life-long anticoagulation with warfarin, which is well tolerated by many patients.

Conclusion

For patients <60 years of age requiring aortic valve replacement (AVR), a mechanical valve is recommended. Any mechanical valve that has been approved by the appropriate governing body (Food and Drug Administration in the US)¹ and has documented excellent outcomes with 15 to 20 years of follow-up is appropriate.

This patient was adamant that he did not want to take life-long anticoagulant therapy. His clinical experiences had imprinted the difficulties and complications of anticoagulation, including frequency of blood draws, drug-drug interactions, dietary and activity restrictions, difficulty in maintaining a therapeutic international normalized ratio, genetic variations in warfarin metabolism, bleeding, stroke, and the need to discontinue anticoagulant therapy in certain conditions, which would

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(*Circulation*. 2011;123:2602-2605.)

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Circulation is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIRCULATIONAHA.110.979518

expose him to the risk of PHV thrombosis. He wanted to discuss the pros and cons of other options for PHV. The alternative is a biological valve.

Biological Valves for Aortic Valve Replacement

Biological Valves That Need Additional Aortic Root Replacement

Autograft (Ross principle), allograft (homograft), and stentless xenograft valves for AVR also need aortic root replacement, with reimplantation of the coronary arteries into the new root. These surgeries are complex, and the operative mortality is increased 2- to 3-fold compared with PHVs, which do not need aortic root replacement.^{1,3,4}

The rate of SVD is similar to a stented bioprosthesis, but reoperation for SVD is much more difficult and has a higher operative mortality because the previous replaced aortic root has to be rereplaced, and the coronary arteries have to be reimplanted into another new root.

Conclusion

These devices should not be used in patients who need only AVR.³ There are exceptions: for example, the use of

Table 2. Factors Other Than PHV That Determine Outcomes After PHV

Decade of age
Other valve disease
Complications of PHV
Comorbid conditions
Cardiac
Left ventricular dysfunction (systolic and diastolic), heart failure, New York Heart Association functional classes III and IV, coronary artery disease, myocardial infarction, coronary artery bypass graft, arrhythmias (eg, atrial fibrillation), pulmonary hypertension, and infective endocarditis
Noncardiac
Impaired renal function (creatinine clearance), renal dialysis, diabetes mellitus, hypertension, dyslipidemia, metabolic syndrome, smoking, liver disease, and lung disease

PHV indicates prosthetic heart valve. Adapted from Rahimtoola.¹

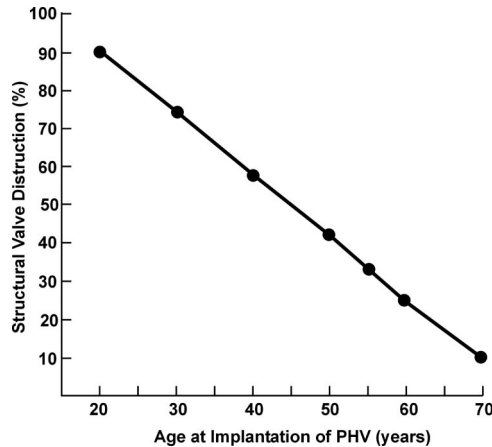


Figure 1. Cumulative mean incidence of SVD at 15 to 20 years in relation to age of patient at time of implantation with homografts and bioprosthesis. At 55 and 60 years of age, the incidences are 34% and 25%, respectively. PHV indicates prosthetic heart valve. Reproduced from Rahimtoola et al¹ with permission of the publisher. Copyright © 2008, Elsevier.

homograft in infective endocarditis with abscess or uncontrolled infection.

Biological Valves That Do Not Need Aortic Root Replacement for Aortic Valve Replacement: Bioprostheses

Stented xenografts/heterografts were introduced into clinical practice later in the 1960s. Carpentier coined the term bioprosthesis in 1971 for these PHVs, a term that currently applies to native porcine and bovine pericardial valves.

Mechanical Valves Versus Stented Bioprosthesis

Two large randomized trials (Edinburgh Heart Valve Trial [EHVT]⁵ and the Veterans Administration [VA] trial⁶) initiated in the late 1970s compared the results of mechanical valve (old Bjork-Shiley delron ring valve) to stented porcine valves. Their findings were similar: Structural valve deterioration of porcine valves began at 7 to 8 years after AVR, and there were no instances of SVD with the mechanical valves up to 20 and 18 years, respectively. The bleeding rate with mechanical valves was higher than with porcine valves, and there were no significant differences between the 2 valve types with regard to other valve-related complications, including

thromboembolism, endocarditis, and all complications.

The VA trial had several other important findings:⁶ (1) Structural valve deterioration occurred only in patients <65 years of age; (2) 60% of the deaths after AVR were not related to the prosthesis, but to associated comorbid conditions (Table 2); and (3) survival in the first 8 years after PHV was virtually identical between the mechanical and porcine valves. Thus, in the patient with no comorbid conditions, survival at 10 years will be similar whether mechanical or bioprosthesis valve is used.

Conclusion

In this patient, the choice for a PHV is a stented bioprosthesis.

Pros and Cons of a Bioprosthesis

Anticoagulant Therapy

There are no randomized trials of warfarin or aspirin versus placebo for prevention of thromboembolism, even in the first 3 months after bioprosthetic aortic or mitral valve replacement. Guidelines recommend low-dose aspirin; warfarin is recommended only in those with risk factors for thromboembolism. Risk factors include atrial fibrillation, prior thromboembolism, severe left ventricular dysfunction

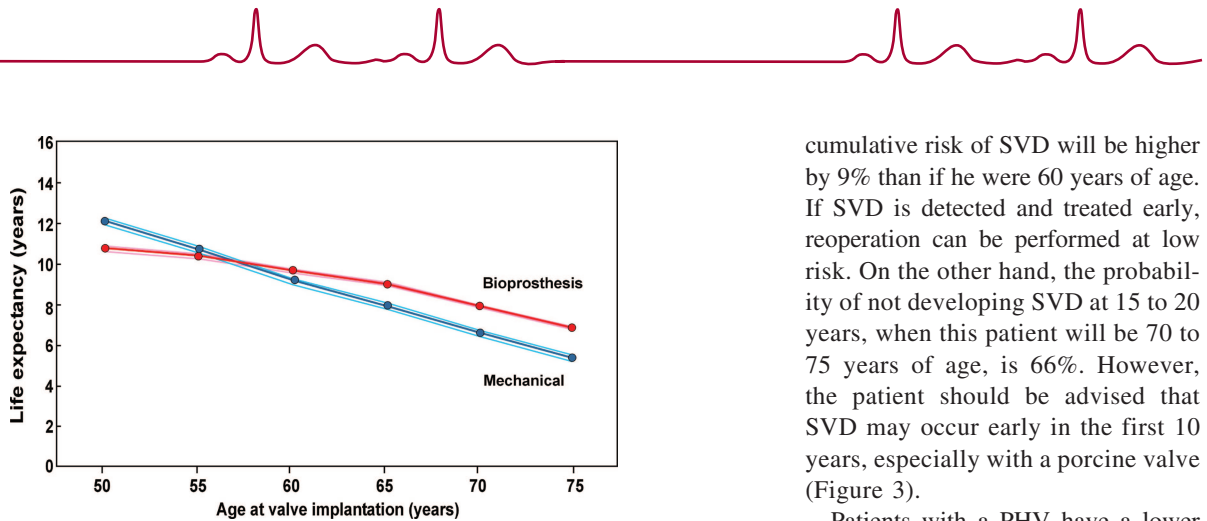


Figure 2. Event-free life expectancy after aortic valve replacement in the United States. Mean and 68% upper and lower confidence limits are shown. Adapted from van Geldorp et al⁸ with permission of the publisher. Copyright © 2009, Elsevier.

(ejection fraction <0.30), and hypercoagulable state. This patient is in the low-risk group and would need aspirin 81 mg/d.

Structural Valve Deterioration

The incidence of SVD is related to age of patient at time of implantation of bioprosthesis (Figure 1). Patients ≥65 years of age have a much lower rate of SVD than those <65 years of age.⁶ Because SVD does not stop occurring suddenly at 65 years of age, 60 years was a reasonable age for suggesting use of a bioprosthesis.⁷ The cumulative 15- to 20-year risk of SVD at implantation of 60 and 55 years of age averages 25% and 34%, respectively (Figure 1). At 55 years of age, the risk of subsequent reoperation with a biopro-

thesis is equal to that of bleeding with a mechanical valve.⁸

Survival

In the Medicare database, survival with a bioprosthesis was better than with a mechanical valve.⁹ The average event-free life expectancy was better with a bioprosthesis than with a mechanical valve,⁸ but event-free life expectancy is lower at 55 years of age at the time of PHV implantation by about 1 year, and is equal at 57 years of age (Figure 2).

Conclusion

This patient will enjoy the long-term benefit of not needing anticoagulation. Structural valve deterioration is the major problem. At 55 years of age, the

cumulative risk of SVD will be higher by 9% than if he were 60 years of age. If SVD is detected and treated early, reoperation can be performed at low risk. On the other hand, the probability of not developing SVD at 15 to 20 years, when this patient will be 70 to 75 years of age, is 66%. However, the patient should be advised that SVD may occur early in the first 10 years, especially with a porcine valve (Figure 3).

Patients with a PHV have a lower survival rate than age- and gender-matched people in the population,⁸ but 60% of deaths after aortic PHV are related to associated comorbid conditions.⁶ In this patient, the absence of comorbid conditions (Table 2) at a young age puts him at very low lifetime risk for cardiovascular disease, and gives him a markedly longer survival.¹⁰ At 10 years, his survival will be similar or very close to that of an aged-matched population, provided there are no serious complications of PHV, such as prosthetic endocarditis or SVD.

Porcine Versus Pericardial Valve

Structural valve deterioration begins at 7 to 8 years with a porcine valve and at 11 to 12 years with a Carpentier-Edwards (C-E) bovine pericardial (Perimount) valve. Ten years or longer after valve implantation, SVD is much lower with a C-E Perimount valve¹ (Figure 3).

Structural valve deterioration has been reported very early (at 3 to 44 months) in patients ≥68 years of age with use of a Medtronic Mosaic porcine valve.¹ Some porcine valves (Bicor) have a higher rate of SVD. Other pericardial valves, for example Mitroflow A12, are associated with early onset of SVD and a very high rate of SVD at 10 years.¹

Conclusion

Carpentier-Edwards Perimount valve has a more favorable rate of SVD than porcine valves.

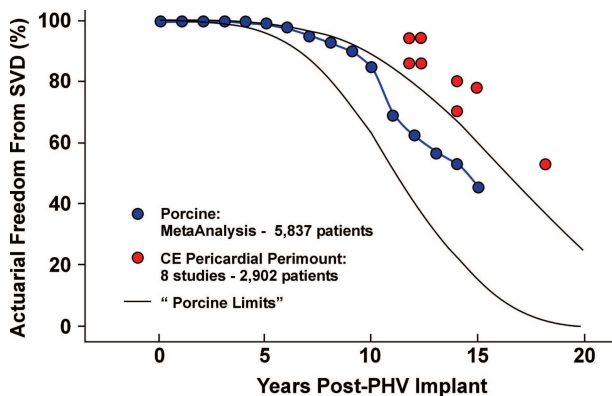


Figure 3. Porcine limits (black line) are the limits of SVD of earlier-model stented porcine bioprosthesis. Porcine (blue circles) is from a meta-analysis of later-model stented porcine bioprosthesis. Carpentier-Edwards is from studies of C-E pericardial Perimount valves (red circles). SVD indicates structural valve deterioration; CE, Carpentier-Edwards; and PHV, prosthetic heart valve. Reproduced from Rahimtoola et al¹ with permission of the publisher. Copyright © 2008, Elsevier.

Case Follow-Up

The patient received the C-E Pericardial (Perimount) valve. There were no postoperative complications. He returned to his cardiology practice on the 28th postoperative day. At 6 months, follow-up echocardiogram/Doppler showed PHV area was 1.2 cm²/m². He is leading a very active life, is exercising, is asymptomatic, and his medication is aspirin 81 mg/d.

Disclosures

Dr Rahimtoola has received honoraria for educational lectures that included PHVs from Edwards Lifesciences. Dr Huang reports no conflicts.

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