

Twenty-Year Results of the Hancock II Bioprosthesis

Michael A. Borger, Joan Ivanov, Susan Armstrong, Debbie Christie-Hrybinsky,
Christopher M. Feindel, Tirone E. David

*Division of Cardiovascular Surgery, Toronto General Hospital, University Health Network, and Department of Surgery,
University of Toronto, Toronto, Ontario, Canada*

Background and aim of the study: The Hancock II bioprosthesis (HII) has several design features designed to increase its durability. The study aim was to determine very long-term outcomes for the HII valve in a large patient population.

Methods: Long-term follow up was obtained by mail and/or telephone questionnaire of patients undergoing HII valve replacement surgery between 1982 and 2001 (n = 1,569). Follow up was complete on 1,568 patients (99.9%), and ranged from 0 to 250 months.

Results: Isolated aortic valve replacement (AVR) was performed in 1,010 patients and mitral valve replacement (MVR) in 559. The average (\pm SD) age of patients was 67 ± 11 years, and 65% were males. Long-term death occurred in 445 AVR patients and 275 MVR patients, of which 11% and 17%, respectively, were valve-related. Twenty-year freedom from thromboembolism (all results actuarial) was $79 \pm 3\%$ after AVR and $83 \pm 3\%$ after MVR; freedom from

endocarditis was $91 \pm 5\%$ and $85 \pm 5\%$, respectively. Twenty-year freedom from structural valve deterioration (SVD) was $73 \pm 16\%$ and $39 \pm 9\%$ in AVR patients aged ≥ 65 years and < 65 years, respectively. Similarly, 20-year freedom from SVD was $59 \pm 11\%$ and $27 \pm 9\%$ in MVR patients aged ≥ 65 years and < 65 years, respectively. When actual statistical techniques were applied (cumulative incidence), 20-year actual risk of SVD was $18 \pm 3\%$ in all AVR patients and $23 \pm 3\%$ in all MVR patients. Reoperation was required in 72 AVR patients, and was valve-related in 60. A total of 49 MVR patients underwent reoperation; 48 of these were valve-related.

Conclusion: The Hancock II bioprosthesis continues to show very good long-term results and durability, particularly in patients aged over 65 years.

The Journal of Heart Valve Disease 2006;15:49-56

An increasing number of cardiac surgeons have recommended a lower threshold age for tissue valve replacement (1), and this has resulted in an increasing prevalence of bioprosthetic implantations. The Hancock II porcine valve (Medtronic Inc., Minneapolis, MN, USA) was first implanted in 1982 at the authors' institution, and incorporated several design modifications of the standard Hancock valve that were intended to improve durability (2). The study aim was to examine very long-term results of the Hancock II valve in a large group of consecutive patients.

Presented in part at the Third Biennial Meeting of the Society for Heart Valve Disease, 17th-20th June 2005, Vancouver Convention and Exhibition Centre, Vancouver, Canada

Address for correspondence:

Dr. Michael A. Borger, Division of Cardiovascular Surgery, Toronto General Hospital, Room 4N-451, 200 Elizabeth Street, Toronto, Ontario, Canada M5G 2C4
e-mail: michael.borger@uhn.on.ca

Clinical material and methods

Patients

All patients undergoing valve replacement surgery with a Hancock II bioprosthesis at the present authors' institution between 1982 and 2003 were identified through a computerized database. Patients were included who underwent single Hancock II valve replacement (aortic or mitral) with or without concomitant cardiac procedures, but those patients who underwent double valve replacement or extra-cardiac procedures were excluded. Thus, a total of 1,569 patients was identified.

Operative technique

Standard operative techniques were employed as described previously (3-5).

Follow up

Follow up was obtained by telephone and/or mail questionnaire, followed by contact with the patient's

cardiologist or family physician. Long-term follow up was obtained for 1,568 patients (99.9%). The mean duration of follow up was 7.4 ± 4.9 years (range: 0 to 21 years).

Standard definitions were employed for clinical outcomes, including death, thromboembolism, endocarditis, bleeding event and paravalvular leak (6). Structural valve deterioration (SVD) was defined as clinically relevant valvular stenosis or insufficiency as determined by Doppler echocardiography, reoperation or autopsy (2).

Statistical analysis

Categorical variables were expressed as percentages, while continuous variables were expressed as mean \pm SD. All statistical analyses were performed using the SAS system (Version 8.1, Cary, NC, USA). Comparison of categorical variables was performed with chi-square or Fisher's exact tests, and continuous variables were analyzed with unpaired *t*-tests. Long-term survival was analyzed univariately using the method of Kaplan-Meier and multivariately with Cox regression.

A p-value <0.05 was considered to be statistically significant.

Results

A total of 1,010 patients underwent AVR and 559 MVR with a Hancock II bioprosthesis. The preoperative patient characteristics for the two groups of patients are listed in Table I. Typically, MVR patients had a smaller body surface area, were more likely to be female, had more symptoms, were more likely to be undergoing repeat surgery, and had a higher prevalence of preoperative atrial fibrillation and renal failure than AVR patients. Patients undergoing AVR were more likely to have a history of hypertension.

Intraoperative information is listed in Table II. Almost half of all patients underwent concomitant coronary bypass surgery. Tricuspid valve repair was performed more frequently in MVR patients, whereas replacement of the ascending aorta was more common in AVR patients. Operative times were similar for the two groups. The median size of implanted aortic bio-

Table I: Preoperative characteristics of aortic (AVR) and mitral valve replacement (MVR) patients.

Parameter	AVR (n = 1,010)	MVR (n = 559)	p-value
Age (years)*	67 \pm 11	67 \pm 11	0.8
Body surface area (m ²)*	1.85 \pm 0.21	1.77 \pm 0.23	<0.001
Male gender	76%	46%	<0.001
LVEF			
>60%	27%	31%	0.2
40-59%	42%	42%	-
20-39%	19%	19%	-
<20%	4%	4%	-
Unknown	8%	3%	-
NYHA class III or IV	77%	90%	<0.001
Congestive heart failure	44%	62%	<0.001
Urgent timing	12%	15%	0.19
Reoperation	10%	24%	<0.001
Endocarditis	6%	9%	0.12
Atrial fibrillation	10%	38%	<0.001
Diabetes	13%	16%	0.18
Hypertension	41%	35%	0.03
Renal failure	2%	4%	0.05
Aortic valve pathology			
Stenosis	56%	-	
Insufficiency	23%	-	
Mixed	21%	-	
Mitral valve pathology			
Stenosis	-	16%	
Insufficiency	-	72%	
Mixed	-	12%	

*Values are mean \pm SD.

LVEF: Left ventricular ejection fraction.

prostheses was 25 mm, while the median implanted mitral valve size was 29 mm.

The perioperative outcomes for the two patient groups is shown in Table III. MVR patients had a higher incidence of low output syndrome and in-hospital death, and had longer hospital lengths of stay.

Long-term survival is illustrated graphically in Figure 1. Ten- and 20-year survival was $61 \pm 2\%$ and $19 \pm 4\%$, respectively, in AVR patients, and $50 \pm 3\%$ and $6 \pm 3\%$ in MVR patients. A total of 445 AVR patients (44%) and 275 MVR patients (49%) died during the follow up period; causes of death are listed in Table IV.

Cox regression revealed the following independent predictors of long-term mortality (hazard ratios and 95% CI in parentheses) in AVR patients: increasing age (HR 1.19 per five-year interval; 1.12-1.25); left ventricular ejection fraction (LVEF) <40% (HR 1.30; 1.04-1.62); coronary artery disease (HR 1.23; 1.02-1.49); and atrial fibrillation (HR 1.72; 1.30-2.28). The independent predictors of long-term mortality in MVR patients were: increasing age (HR 1.29 per five-year interval; 1.20-1.38); LVEF <40% (HR 1.93; 1.46-2.54); mitral regurgitation (HR 0.76; 0.58-0.99); and endocarditis (HR 2.09; 1.29-3.37).

Freedom from thromboembolism (thrombosis, stroke or transient ischemic attack) in AVR and MVR patients is illustrated in Figure 2. Thromboembolism

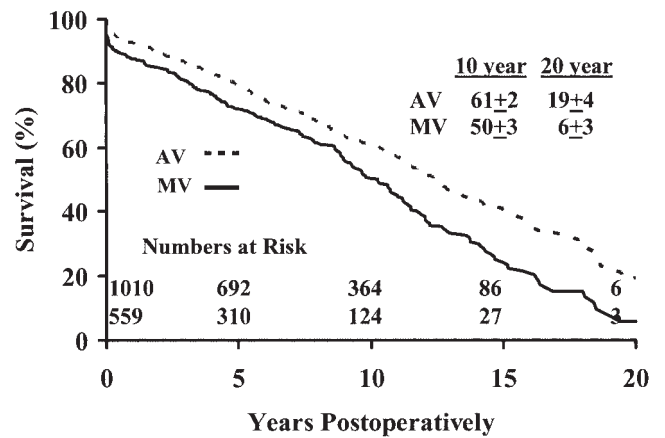


Figure 1: Long-term survival for patients undergoing aortic (AVR) and mitral valve replacement (MVR).

occurred in 95 AVR patients (9%) and 45 MVR patients (8%). There were four cases of valve thrombosis in MVR patients, and none in AVR patients. Twenty-year actuarial freedom from thromboembolism was $79 \pm 3\%$ and $83 \pm 3\%$ in AVR and MVR patients, respectively.

Long-term freedom from prosthetic valve endocarditis is shown in Figure 3. Endocarditis occurred in 27 AVR patients (3%) and 23 MVR patients (4%). Twenty-

Table II: Intraoperative characteristics of aortic (AVR) and mitral valve replacement (MVR) patients.

Parameter	AVR (n = 1,010)	MVR (n = 559)	p-value
AV repair	0%	2%	0.09
MV repair	6%	0%	0.01
TV repair	1%	11%	<0.001
Coronary artery bypass surgery	46%	45%	0.5
Replacement ascending aorta	12%	1%	<0.001
Aortic annular enlargement	20%	0%	<0.001
Mitral annular reconstruction	0%	3%	0.004
Aortic cross-clamp time (min)*	77 ± 29	77 ± 33	0.7
CPB time (min)*	103 ± 38	105 ± 43	0.5
Aortic valve size (mm)			
21	7%	-	
23	28%	-	
25	34%	-	
27	25%	-	
29	6%	-	
Mitral valve size (mm)			
25	-	5%	
27	-	27%	
29	-	31%	
31	-	30%	
33	-	7%	

*Values are mean ± SD.

CPB: Cardiopulmonary bypass; TV: Tricuspid valve.

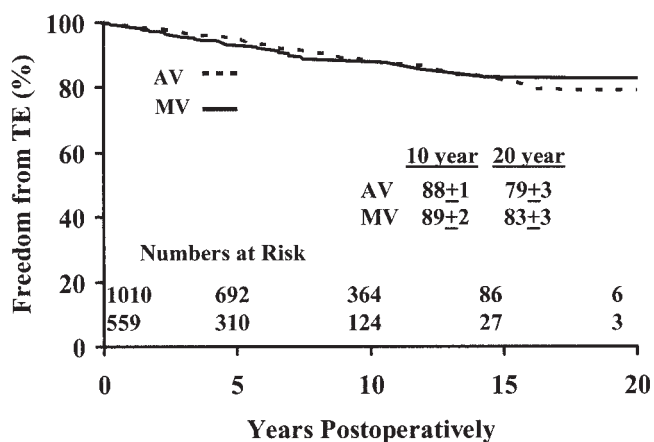


Figure 2: Actuarial freedom from thromboembolism (TE) in aortic (AVR) and mitral valve replacement (MVR) patients.

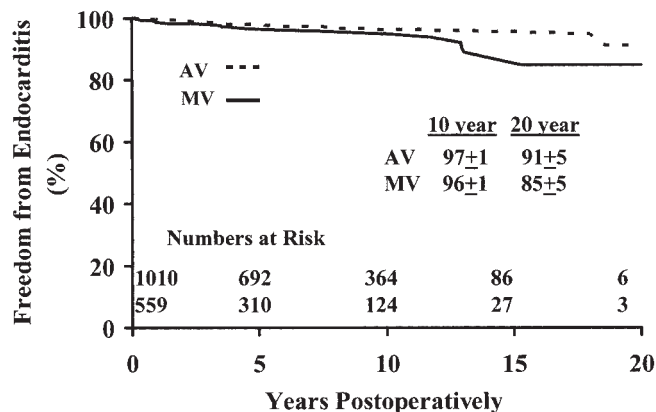


Figure 3: Actuarial freedom from prosthetic valve endocarditis in aortic (AVR) and mitral valve replacement (MVR) patients.

year actuarial freedom from endocarditis was $91 \pm 5\%$ in AVR patients and $85 \pm 5\%$ in MVR patients.

A major bleeding event occurred in 26 AVR patients (3%) and in 17 MVR patients (3%). Fatal hemorrhages occurred in five AVR patients (0.5%), two of whom were taking warfarin, and in five MVR patients (1%), four of whom were taking warfarin.

Structural valve deterioration occurred in 53 AVR patients (5%) and in 52 MVR patients (9%). Actuarial freedom from SVD in AVR patients aged ≥ 65 years and < 65 years is shown in Figure 4. The 20-year actuarial freedom from SVD was $39 \pm 9\%$ and $73 \pm 16\%$ in AVR patients aged < 65 years and ≥ 65 years. Freedom from SVD in MVR patients is shown in Figure 5. The 20-year actuarial freedom from SVD was $27 \pm 9\%$ and $59 \pm 11\%$ in MVR patients aged < 65 years and ≥ 65 years, respectively.

The occurrence of SVD in our patient population was also investigated using actual statistical techniques (cumulative incidence). The 10-, 15- and 20-year actual risk of SVD was $2 \pm 1\%$, $7 \pm 1\%$ and $18 \pm 3\%$, respectively, in all AVR patients. Similarly, 10-, 15- and 20-

year actual risk of SVD was $7 \pm 1\%$, $18 \pm 2\%$ and $23 \pm 3\%$, respectively, in all MVR patients.

Significant paravalvular leak occurred in three AVR patients and five MVR patients. All three AVR patients underwent reoperation, whereas only two MVR patients underwent repeat surgery. The remaining three MVR patients were at too-high risk for redo surgery. One MVR patient and none of the AVR patients required reoperation for hemolysis secondary to the paravalvular leak. The 20-year actuarial freedom from paravalvular leak was $99 \pm 1\%$ in AVR patients and $97 \pm 1\%$ in MVR patients.

A total of 72 AVR patients underwent reoperation during the follow up period, and 60 of these operations were valve-related. Likewise, 49 MVR patients underwent reoperation, and 48 of the operations were valve-related. Indications for reoperation are listed in Table IV. The 10- and 20-year actuarial freedom from reoperation for any cause was $94 \pm 1\%$ and $53 \pm 8\%$ in all AVR patients, and $88 \pm 2\%$ and $44 \pm 10\%$ in all MVR patients.

Table III: Early postoperative outcomes for aortic (AVR) and mitral valve replacement (MVR) patients.

Outcome	AVR (n = 1,010)	MVR (n = 559)	p-value
Myocardial infarction	1%	2%	0.09
Low-output syndrome	11%	21%	<0.001
Stroke	3%	3%	0.9
Hospital stay (days)*	9.9 ± 10.2	13.3 ± 18.6	<0.001
Death	4%	8%	<0.001

*Values are mean \pm SD.

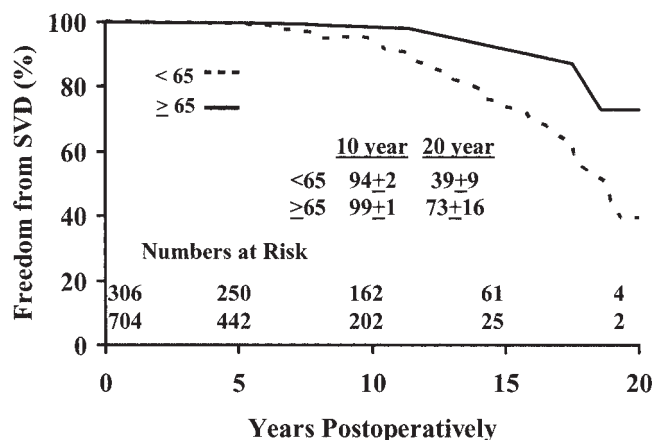


Figure 4: Actuarial freedom from reoperation for structural valve deterioration (SVD) in aortic valve replacement patients aged <65 years and >65 years.

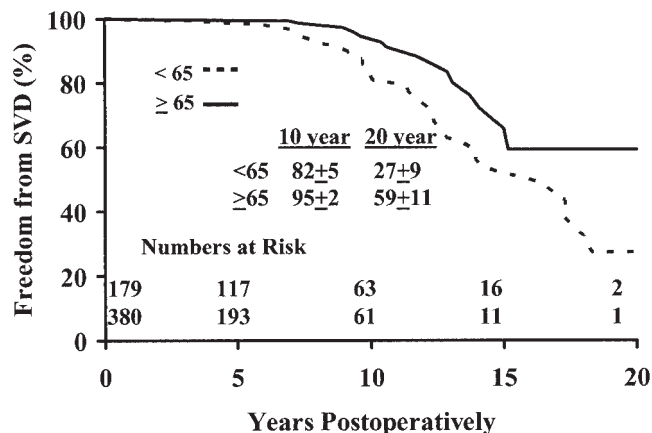


Figure 5: Actuarial freedom from reoperation for structural valve deterioration (SVD) in mitral valve replacement patients aged <65 years and >65 years.

Discussion

Today, bioprosthetic valves are recommended by an increasing proportion of cardiac surgeons (1). Several factors have contributed to this pattern, including an improved durability of second- and third-generation bioprostheses, the increasing age of valve surgery patients, a lower risk of anticoagulant-related hemorrhage, and a decreasing risk of mortality during reoperation. Although young patients who receive a tissue valve have a higher incidence of reoperation, their long-term survival is the same as that for patients who receive a mechanical valve. In addition, young patients who receive bioprosthetic valves may have increased

physical capacity and freedom from disability over time (7). It has been the observation of the present authors that an increasing proportion of young patients is now choosing bioprosthetic valves because of the limitations associated with lifelong anticoagulation.

Despite the increasing use of bioprosthetic valves, their principal limitation remains the development of SVD and failure over time. SVD is known to occur more frequently in the mitral position, and in younger patients. The original Hancock standard bioprosthesis was the first commercially available glutaraldehyde-fixed tissue valve, although its long-term durability was suboptimal (8). The Hancock II incorporated several features designed to improve durability compared to the Hancock standard. These design modifications included low-pressure fixation of the valve cusps, T6 anticalcification treatment, and a flexible acetyl homopolymer stent designed to minimize tissue creep (2).

The Hancock II valve was first implanted at the authors' institution in September 1982, and the current study was designed to examine the long-term durability of the Hancock II valve in the aortic and mitral valve positions. A large number of patients (n = 1,569) operated on at a single institution over a 21-year period were examined. To the best of the authors' knowledge, this represents the largest single-center experience with the Hancock II valve and the longest period of follow up published to date.

The results reveal that the Hancock II continues to show very good long-term outcome, particularly in patients aged over 65 years. Valve durability seems to be as good as for any other currently available bioprosthesis. In the present study, the 20-year actuarial freedom from SVD in patients aged ≥65 years was 73%

Table IV: Causes of death and reoperation in aortic (AVR) and mitral valve replacement (MVR) patients.

Cause of death/reoperation	AVR (n = 1,010)	MVR (n = 559)
No. of deaths	445	275
Valve-related	51 (11)	47 (17)
Cardiac, non-valve-related	152 (34)	90 (33)
Non-cardiac	195 (44)	92 (33)
Perioperative	47 (11)	46 (17)
No. of reoperations	72	49
Structural valve deterioration	45 (64)	39 (78)
Endocarditis	11 (15)	6 (12)
Aortic aneurysm/dissection	8 (11)	0 (0)
Paravalvular leak	3 (4)	2 (4)
Other valve	3 (4)	1 (2)
Coronary artery disease	1 (1)	0 (0)
Thromboembolism	0 (0)	1 (2)
Transplant	1 (1)	0 (0)

Values in parentheses are percentages.

in the aortic position and 59% in the mitral position. Actual analysis revealed even more optimistic results, with 15- and 20-year freedom from SVD of 93% and 82% in all AVR patients, and 82% and 77% in all MVR patients. These results were very similar to those reported by Rizzoli et al., who found the 15-year actual freedom from SVD for the Hancock II to be 92% in AVR patients and 85% in MVR patients (9).

Rates of freedom from SVD for the Hancock II compared favorably with those for other bioprosthetic valves with established long-term results (10-13). Comparison of different bioprosthetic series is difficult, however, because of the varying duration of follow up, different patient population ages, and disparate definitions of SVD. The 15-year actuarial freedom from SVD in AVR patients aged ≥ 65 years has been reported as 92% for the Carpentier-Edwards SAV valve (Edwards Lifesciences, Irvine, CA, USA) (10). Freedom from reoperation for SVD for the Biocor valve (St. Jude Medical, St. Paul, MN, USA) was 76% for AVR patients (mean age 69 years) and 92% for MVR patients (mean age 63 years) (11). Freedom from explant for SVD for the Perimount valve (Edwards Lifesciences) at 20 years was 82% in AVR patients aged ≥ 65 years (12). Similarly, freedom from explant for SVD in MVR patients aged ≥ 65 years was 86% for the Perimount valve (13). It should be noted, however, that the reported rates for these latter three studies were for freedom from explant for SVD, which results in more optimistic values than freedom from any SVD, as reported in the present study.

Structural failure in porcine valves is characterized by tissue degeneration, calcification, increased cusp stiffness and cusp tears. Previously, calcification was reported in 55% of explanted Hancock II valves, with severe calcification being present in 18% (14). Fibrous tissue overgrowth was also found in a large proportion of valves, particularly for those implanted in the mitral position. However, other investigators did not find any significant amount of pannus overgrowth in explanted Hancock II valves (15). Although calcification remains an important cause of failure of Hancock II valves, it does not appear to be as prevalent as in earlier generation porcine valves (15). Previously, long-term results were compared in standard Hancock and Hancock II valves and a greater freedom from SVD was observed in Hancock II prostheses (8).

The 20-year actuarial freedom from thromboembolism was approximately 80% in both the AVR and MVR groups in the present study. This compared favorably to the 20-year value of approximately 70% for the Perimount valve (12), and very favorably to the 15-year reported rate of 70% for mechanical valves (16). Valve thrombosis, in particular, was a rare event among the present patients, being observed in only

four MVR patients and in none of the AVR patients. The present authors ceased to use anticoagulation following tissue aortic valve replacement surgery in 1990, substituting daily aspirin (or ticlodipine for those patients unable to tolerate aspirin), and firmly recommend this management protocol. However, at present they continue to prescribe three months of postoperative anticoagulation (target INR 2.5-3.5) in Hancock II MVR patients. Some centers have stopped using postoperative warfarin altogether in tissue MVR patients in sinus rhythm, though the present authors have not yet adopted this practice. In MVR patients with persistent atrial fibrillation, warfarin therapy is continued indefinitely with a target INR of 2.0-3.0. It is the belief of the present authors that patients with permanent or persistent atrial fibrillation can benefit from a tissue mitral prosthesis since the target INR is lower than it is for a mechanical MVR, with a subsequently lower risk of anticoagulant-related hemorrhage.

In the present study the actuarial freedom from endocarditis at 20 years was 91% in AVR patients and 85% for MVR patients, and similar to values reported for other bioprosthetic and mechanical valves (10-13,16,17). Although prosthetic valve endocarditis is an uncommon occurrence with the Hancock II valve, it remains a dreaded complication for any prosthetic valve, with high rates of perioperative mortality (17).

Long-term survival was limited in both patient groups of the present study, with only 19% of AVR patients and 6% of MVR patients still alive 20 years after surgery. However, poor long-term survival following valvular surgery is in keeping with data reported for other series (16,18). The present low reported survival may be partly explained by the fact that the average patient age at implant was 67 years. A recent meta-analysis by Puvimanasinghe et al. revealed that the average life expectancy for a 65-year-old after tissue AVR surgery is 10.7 years (19). Interestingly, these authors found the cumulative life-time risk of a valve-related event to be lower with a tissue valve than a mechanical valve (44% versus 48%), and concluded that the current recommended age threshold for implanting a bioprosthesis should be lowered.

Survival was worse for MVR surgery than for AVR surgery in the current study and this, again, was in keeping with previous reports (16,18). The poor survival after MVR may be due to its deleterious effects on left ventricular function, particularly if the subvalvular apparatus is excised. It has been reported previously that subvalvular preservation lowers the risk of early mortality after MVR (4), but it remains to be seen whether this technique has a long-term impact on survival.

Study limitations

The main limitation of the present study was the small number of patients available for analysis at 20 years after surgery, and this resulted in an increased variability in estimates of outcome event rates. Nonetheless, it was felt important to report 20-year results in order to facilitate comparisons with other prosthetic valves that have been available commercially for a long period of time and to serve as a benchmark for the evaluation of future bioprostheses.

In conclusion, the Hancock II bioprosthesis was developed with several modifications intended to increase valve durability. The present study represents the largest series to date for this valve with the longest period of follow up. Very good results were observed 20 years postoperatively, notably among those patients aged >65 years. Hence, the Hancock II valve is an excellent choice for valve replacement surgery, with low rates of long-term SVD and very low rates of other valve-related complications.

References

1. Potter DD, Sundt TM, Zehr KJ, et al. Operative risk of reoperative aortic valve replacement. *J Thorac Cardiovasc Surg* 2005;129:94-103
2. David TE, Ivanov J, Armstrong S, Feindel CM, Cohen G. Late results of heart valve replacement with Hancock II bioprostheses. *J Thorac Cardiovasc Surg* 2001;121:268-277
3. David TE. Surgery of the aortic valve. *Curr Probl Surg* 1999;36:426-501
4. Borger MA, Yau TM, Rao V, Scully HE, David TE. Reoperative mitral valve replacement: Importance of preservation of the subvalvular apparatus. *Ann Thorac Surg* 2002;74:1482-1487
5. Borger MA, Preston M, Ivanov J, et al. Should the ascending aorta be replaced more frequently in patients with bicuspid aortic valve disease? *J Thorac Cardiovasc Surg* 2004;128:677-683
6. Edmunds LH, Jr., Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. *J Thorac Cardiovasc Surg* 1996;112:708-711
7. Ruel M, Kulik A, Lam BK, et al. Long-term outcomes of valve replacement with modern prostheses in young adults. *Eur J Cardiothorac Surg* 2005;27:425-433
8. Ikonmidis JS, Ivanov J, Miller DC, Armstrong S, David TE. Improved durability with the new Hancock II bioprosthesis (abstract). *Circulation* 1999;100(suppl.):I-525
9. Rizzoli G, Bottio T, Thiene G, Toscano G, Casarotto D. Long-term durability of the Hancock II porcine bioprosthesis. *J Thorac Cardiovasc Surg* 2003;126:66-74
10. Jamieson WRE, David TE, Feindel CM, Miyagishima RT, Germann E. Performance of the Carpentier-Edwards SAV and Hancock II porcine bioprostheses in aortic valve replacement. *J Heart Valve Dis* 2002;11:424-430
11. Myken P, Bech-Hanssen O, Phipps B, Caidahl K. Fifteen years follow up with the St. Jude Medical Biocor porcine bioprosthesis. *J Heart Valve Dis* 2000;9:415-422
12. Clinical Communique: Twenty year results of Carpentier-Edwards Perimount aortic pericardial bioprosthesis. <http://www.edwards.com/Products/HeartValves>
13. Marchand MA, Aupart MR, Norton R, et al. Fifteen-year experience with the mitral Carpentier-Edwards Perimount pericardial bioprosthesis. *Ann Thorac Surg* 2001;71:S236-S239
14. Butany J, Yu W, Silver MD, David TE. Morphologic findings in explanted Hancock II porcine bioprostheses. *J Heart Valve Dis* 1999;8:4-15
15. Bottio T, Thiene G, Pettenazzo E, et al. Hancock II bioprosthesis: A glance at the microscope in mid-long-term explants. *J Thorac Cardiovasc Surg* 2003;126:99-105
16. Khan SS, Trento A, DeRobertis M, et al. Twenty-year comparison of tissue and mechanical valve replacement. *J Thorac Cardiovasc Surg* 2001;122:257-269
17. Akowuah EF, Davies W, Oliver S, et al. Prosthetic valve endocarditis: Early and late outcome following medical or surgical treatment. *Heart* 2003;89:269-272
18. Oxenham H, Bloomfield P, Wheatley DJ, et al. Twenty year comparison of a Björk-Shiley mechanical heart valve with porcine bioprostheses. *Heart* 2003;89:715-721
19. Puvimanasinghe JP, Takkenberg JJ, Edwards MB, et al. Comparison of outcomes after aortic valve replacement with a mechanical valve or a bioprosthesis using microsimulation. *Heart* 2004;90:1172-1178

Meeting discussion

DR. FREDERICK J. SCHOEN (Boston, Massachusetts, USA): Can you tell us anything about the failures? Has this treatment delayed the same type of morphology and mechanism of failure, or has it switched the mechanism of failure - perhaps by completely inhibiting calcification - so that tearing becomes the predominant mode of failure?

DR. MICHAEL A. BORGER (Toronto, Canada): The mode of failure for this porcine valve is probably sim-

ilar to that for other porcine valves - it is just delayed. Previously, when we examined explanted Hancock II valves we found about 50% of them to be calcified, and severely so in about 20%. There was also a lot of pannus tissue overgrowth. When these patients re-present for reoperation, the occasional one has a sudden catastrophic leaflet tear. Many of the patients present with progressive stenosis or insufficiency.

DR. CHARLES YANKAH (Berlin, Germany): May I ask about the patients with atrial fibrillation? For how long did they receive anticoagulation, and how many of them developed stroke during that time?

DR. BORGER: Atrial fibrillation is one of the independent predictors of long-term death in our patient population. We believe that in such patients a bioprosthesis is best, particularly in the mitral position, because the target INR is about 2.0-2.5 compared to 3.0-3.5 for a mechanical mitral valve. The long-term risk of stroke is also higher in patients with atrial fibrillation. However, the higher the warfarin requirements, the higher the risk of bleeding events. We have not anticoagulated our tissue AVR patients since 1990. I can't stress strongly enough that warfarin is not required in tissue AVR surgery, but for MVR we continue warfarin for three months when the patient is in sinus rhythm.

DR. DENIS MODRY (Edmonton, Canada): Did I understand correctly that you have a 5% surgical mortality for isolated AVR?

DR. BORGER: For the entire 21-year period, yes, but most recently it has been about 2%

DR. MODRY: About 2%? We all understand the explanations, but the aim here is to achieve an absence of morbidity and mortality. Can you explain why it is even 2%? For isolated AVR, shouldn't it be under 1%?

DR. BORGER: But 50% of these patients had coronary bypass surgery, and 5-10% also had mitral or tricuspid valve repairs. This was not isolated AVR. At our institution, mortality after isolated AVR is now less than 1%.

DR. SUNDAR RAMANATHAN (Coimbatore, India): What was the indication for aortic root replacement? Did you do root widening, and did you use a predetermined minimal effective orifice area when you wanted to fit a valve of any particular size, depending upon the patient's body size? Also, which aortic root widening procedure did you use - the Manouagian, or another?

DR. BORGER: I always try to place the largest valve, based on patient body surface area. Using the manufacturer's nomogram is helpful, but if the patient has a body surface area of 1.8 m² and I can only place a 21-mm valve then I do Nicks root enlargement. But if I can only place a 19-mm valve, I would do the Manouagian, knowing that it will add about 10-15 minutes to the procedure. We try to place the largest valve possible in the aortic position, based on Dr. David's teachings.