Factors Influencing Mortality after Bioprosthetic Valve Replacement; A Midterm Outcome

Hassan Javadzadegan[1*], Amir Javadzadegan[2], Jafar Mehdizadeh Baghbani[2]

[1]*Cardiovascular Research Center, Tabriz University of Medical Sciences, Tabriz, Iran*
[2]*Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran*

ARTICLE INFO

ABSTRACT

Introduction: Although valve repair is applied routinely nowadays, particularly for mitral regurgitation (MR) or tricuspid regurgitation (TR), valve replacement using prosthetic valves is also common especially in adults. Unfortunately the valve with ideal hemodynamic performance and long-term durability without increasing the risk of bleeding due to long-term anticoagulant therapy has not been introduced. Therefore, patients and physicians must choose either bioprosthetic or mechanical valves. Currently, there is an increasing clinical trend of using bioprosthetic valves instead of mechanical valves even in young patients apparently because of their advantages.

Methods: Seventy patients undergone valvular replacement using bioprosthetic valves were evaluated by ECG and Echocardiography to assess the rhythm and ejection fracture. Mean follow-up time was 33 months (min 9, max 92).

Results: Mortality rate was 25.9% (n=18) within 8 years of follow-up. Statistical analysis showed a significant relation between atrial fibrillation rhythm and mortality (P=0.02). Morbidities occurred in 30 patients (42.8%). Significant statistical relation was found between the morbidities and age over 65 years old (P=0.005). In follow-up period, 4 cases (5.7%) underwent re-operation due to global valve dysfunction.

Conclusion: Our study shows that using biprosthetic valve could reduce the risk of morbidity occurrence in patient who needs valve replacement. However, if medical treatments fail, patients should be referred for surgery. This would reduce the risk of mortality because of lower incident of complications such as atrial fibrillation and morbidities due to younger patients' population.

Introduction

Valvular heart disease is one of the common conditions cardiologists and surgeons encounter during assessment process of patients. In the situation of serious regurgitation or stenosis an intervention on the valve such as repair, valvuloplasty or valve replacement should be performed. Although valve repair applied usually nowadays, particularly for mitral regurgitation (MR) or tricuspid regurgitation (TR), valve replacement using prosthetic valves is common especially in adults.[1] Unfortunately, the valve with ideal hemodynamic performance and long-term durability without increasing risk of bleeding due to long-term anticoagulant therapy has not been introduced yet. Therefore, patients and physicians must choose either bioprosthetic or mechanical valve each of which has cons and pros making decision difficult. Mechanical valves are more durable but need lifelong anticoagulation and increase the risk of thromboembolism. In contrast, tissue valves do not need long-term anticoagulation but carry the risk of structural failure and reoperation.[2,3] Currently, the use of bioprosthetic valves instead of mechanical valves is increasing even in young patients apparently because of its advantages.[4] In this study, we report a case series of patients undergone valve replacement using bioprosthetic valve and followed for a few years.

Materials and Methods

From July 2000 to Sep. 2008, seventy patients (with the mean age of 54.8 years, 24 males and 46 females) undergone valvular replacement using bioprosthetic valves were studied. Isolated aortic valve replacement (AVR), isolated mitral valve replacement (MVR), isolated tricuspid valve replacement, AVR with MVR and MVR with TVR were performed in 21, 23, one, 10 and 5 patients, respectively. Mean follow-up time was 33 months (min 9, max 92 months). All survived patients were assessed echocardiographicly.

Results

Atrial fibrillation was found in 34 patients (48.6%).

*Corresponding author: Hassan Javadzadegan, E-mail: djavadzad@yahoo.com

EKG findings are shown in Table 1. A mortality rate of 25.7% (n=18) was observed within 8 years of follow-up. Statistical analysis revealed a significant relation between atrial fibrillation rhythm and mortality (*P*=0.02). There were no statistical relation between mortality and other factors such as age more that 65 years old (P=0.931), sex (*P*=0.633), EF<30% (*P*=0.063), functional class (*P*=0.103), history of endocarditis (0.512), history of coronary heart disease (*P*=0.292), history of CABG (*P*=0.609), and combined CABG and valvular operation (0.262). Furthermore, there was no significant relation between operation type and mortality (*P*=0.325).

Cause of mortality due to valve function found in one patient (1.4%), other cardiac related causes were found in 6 patients (8.6%), non cardiac cause in 3 patients (4.3%). Mortality in 8 patients (11.4%) occurred due to cardiopulmonary arrest rather than distinguishable factors (cardiac or non-cardiac). Mortality occurred during first month after operation in 9 patients (12.8%), between the second month and first year in 4 patients (5.7%), in no one during second year and in 5 cases within the 3rd and 4th year. Mean time for morbidities which occurred in 30 patients (42.8%) was 8 months (min 1 max 60). Significant statistical relation was found between the morbidities and age over 65 years old (*P*=0.005) but not between morbidities and other above-mentioned factors listed above. Rate of morbidities is listed in Table 2. Symptom-free period was 20.3 months for all patients, 12 months for over 65 years old and 23.5 months for the rest. In the period of follow-up, 4 cases (5.7%) underwent re-operation. Mean free of operation time was 22 months (min 1, max 60) in these patients. These cases were evaluated

Table 1. Patients' characteristics before operation

	n	%
Age (y)	mean: 54.8	
F/M	46/24	
Rhythm		
AF	34	48.6
CHB	2	2.8
NSR	34	48.6
EF		
≥ 60	7	10
40-59	48	68.6
20-39	15	21.4
< 20	N/A	0
Functional class		
I	N/A	0
II	23	32.9
III	42	60
IV	5	7.1
History of endocarditis	6	8.6
Ischemic heart disease	24	34.3
History of CABG	3	4.3
History of valve surgery	10	14.3

AF: Atrial Fibrillation, CHB: Complete Heart Block, NSR: Normal Sinus Rhythm, EF: Ejection Fraction

Table 2. Post operative complications

Complication	n	%
Thromboembolism	7	10
CVA	2	2.9
PTE	2	2.9
DVT	1	1.4
Arterial embolism	2	2.9
Infective endocarditis	3	4.3
Hemorrhage	3	4.3
Cardiac tamponade	4	5.7
CHB	2	2.9
Re-operation	4	5.7
Early mortality	9	12.9
Late mortality	9	12.9

CVA: Cerebrovascular Accident, PTE: Pulmonary Thromboembolism, DVT: Deep Venous Thrombosis, CHB: Complete Heart Block.

echocardiographically and valve global dysfunction was distinguished. There was no significant relation between valve dysfunction and the above-mentioned factors.

Discussion

In 1961, Starr and Edwards described successful prosthetic valve replacement. Some patients who underwent valve replacement with the original Starr-Edwards prosthesis in the 1960s are alive to this day. In the last 40 years, more than 80 models of prostheses have been developed for patients requiring valve replacement; however, no ideal valve has been discovered yet.[5,6] Although there is wide consensus on the type of valve to be placed in younger and older patients, valve choice in the ages between 55 and 70 years is very difficult, because in this age span patients are no longer truly young and not yet truly old. This is the threshold age where it is difficult to balance the risk of the anticoagulation therapy with the need for a reoperation.[7] Furthermore, patients in this age span comprise a large group of patients in need of valve replacement.[4,5]

In recent decades two randomized trials have been compared survival and valve related morbidities associated to use of mechanical and bioprosthetic valves helping physicians in the choice of type of valve suitable for their patients. However, these studies have many limitations that potentially biasing the choice of one valve versus the other. High perioperative mortality rate, old style valves that are not available now and large number of redo sternotomy occurred in these studies which could be considered as some of the limitations of these studies.[5,8-11] Although some studies proved that no difference exists in mortality rate after mechanical or tissue valve replacement[11-13], these studies provoked that reoperation was higher after tissue valve replacement than mechanical and valve related morbidities were more common after mechanical valve implantation. It would be postulate that life style alterations after a mechanical valve replacement in a patient needing valve surgery are more likely. Oakley et al. mathematically proved that risk of mortality for 1st operation has no correlation with type of the valve and

overall risk of morbidities and mortality is approximately 2 fold when using mechanical valve.[4] These data might be an explanation to trend toward using bioprosthetic valve by surgeons; however, the need of long term result of randomized studies is obvious.

In our study, survival rate was not in an acceptable range after a mid-term follow-up possibly as a result of patients' co-morbidities; however, causes of death in almost half of patients who expired were not clarified limiting the conclusion. Also, the fact of postponing the surgery derived from cardiologists' or patients' late decision should be considered. The poor quality of life index and cardiac status of patients' are endorsing this theory. Valve related cause of death was reported just for one case that seems favorable. More than half of patients had no episode of any kind of morbidities during follow-up and morbidities significantly related to age more than 65 years old.

Conclusion

It could be concluded that tissue valves could be used for young patients (under 65 y/o) with no concern about the rate of consequences. Of course, a low rate of valve dysfunction happening in our cases would assist this thesis. However, large scale long-term studies should be performed to prove this idea.

Our data discuss that no hesitation about performing other procedures is acceptable because neither CABG nor other valve procedures which performed during the valve replacement had influence on patients' outcome.

Since atrial fibrillation had a significant effect on mortality rate, we discuss that therapeutic rout such as surgical, interventional and medical, would be preferable before or during valve replacement to control the atrial fibrillation.

Ethical issues: All patients gave written informed consents and the study was approved by our local Ethics Committee.

Conflict of interests: The authors declare no conflicts of interest.

References

1. Zoghbi WA, Chambers JB, Dumesnil JG, Foster E, Gottdiener JS, Grayburn PA, *et al.* Recommendations for evaluation of prosthetic valves with echocardiography and doppler ultrasound. **J Am Soc Echocardiogr** 2009;22:975-1014.
2. Rahimtoola SH. Lessons learned about the determinants of the results of valve surgery. **Circulation** 1988;78:1503-7.
3. Rahimtoola SH. Choice of prosthetic heart valve for adult patients. **J Am Coll Cardiol** 2003;41:893-904.
4. Oakley R, Kleine P, Bach DS. Choice of prosthetic heart valve in today's practice. **Circulation** 2008;117:253-6.
5. Bonow RO, Carabello B, de Leon AC, Edmunds LH Jr, Fedderly BJ, Freed MD, *et al.* ACC/AHA Guidelines for the Management of Patients With Valvular Heart Disease. Executive Summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease). **J Heart Valve Dis** 1998;7:672-707.
6. Vongpatanasin W, Hillis LD, Lange RA. Prosthetic heart valves. **N Engl J Med** 1996;335:407-16.
7. Wheatley DJ. The 'threshold age' in choosing biological versus mechanical prostheses in western countries. **J Heart Valve Dis** 2004;13:S91-4.
8. Bloomfield P, Wheatley DJ, Prescott RJ, Miller HC. Twelve-year comparison of a Bjork-Shiley mechanical heart valve with porcine bioprostheses. **N Engl J Med** 1991;324:573-9.
9. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH. Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. **J Am Coll Cardiol** 2000;36:1152-8.
10. Hammermeister KE, Sethi GK, Henderson WG, Oprian C, Kim T, Rahimtoola S. A comparison of outcomes in men 11 years after heart-valve replacement with a mechanical valve or bioprosthesis. Veterans Affairs Cooperative Study on Valvular Heart Disease. **N Engl J Med** 1993;328:1289-96.
11. Oxenham H, Bloomfield P, Wheatley DJ, Lee RJ, Cunningham J, Prescott RJ, *et al.* Twenty year comparison of a Bjork-Shiley mechanical heart valve with porcine bioprostheses. **Heart** 2003;89:715-21.
12. Chan V, Jamieson WR, Germann E, Chan F, Miyagishima RT, Burr LH, *et al.* Performance of bioprostheses and mechanical prostheses assessed by composites of valve-related complications to 15 years after aortic valve replacement. **J Thorac Cardiovasc Surg** 2006;131:1267-73.
13. Lund O, Bland M. Risk-corrected impact of mechanical versus bioprosthetic valves on long-term mortality after aortic valve replacement. **J Thorac Cardiovasc Surg** 2006;132:20-6.