Midterm Outcome of Bioprosthetic Valve Replacement in North West of Iran

Abstract:

Background: Although valve repair is applied usually nowadays, particularly for mitral regurgitation (MR) or tricuspid regurgitation (TR), valve replacement using prosthetic valves is 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 does not exist. Therefore patients and physicians must choose between bioprosthetic and mechanical valve. Currently clinical trends towards the increasing use of bioprosthetic valves instead of mechanical valves even in young patients apparently because of its advantages.

Materials and Methods: Seventy patients have undergone valvular replacement using bioprosthetic valves. Mean age was 54.8 years, 24 were male and 46 were female. Atrial fibrillation has been found in 34(48.6%). The patients have been evaluated by ECG and Echocardiography to assess the rhythm and ejection fracture. Mean follow-up time was 33 month (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 has been 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 dysfunction of valve.

Conclusion: our study shows that using bioprosthetic valve could reduce the risk of morbidity occurrence in a patient who needs valve replacement. However if medical treatments fail, in result of any reason, patients should be refered to surgical unit. This would reduce the risk of mortality because of lower incident of complications such as atrial fibrillation and morbidities due to younger patients' population.

Background:

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).(!!! INVALID CITATION !!!) Unfortunately the valve with ideal hemodynamic performance and long-term durability without increasing risk of bleeding due to long-term anticoagulant therapy does not exist. Therefore patients and physicians must choose between bioprosthetic and mechanical valve. Each of them has cons and pros that often make election difficult. Mechanical valves are more durable but needing lifelong anticoagulation drug usage and increasing the risk of thromboembolism, and in contrast, tissue valves do not need long-term anticoalgulant therapy but carry the risk of structural failure and reoperation (2, 3). Currently the clinical trends towards the increasing use of bioprosthetic valves instead of mechanical valves even in young

patients is apparently because of its advantages (4).
In this study we report a case series of patients who had undergone valve replacement using bioprosthetic valve that has been followed for a few years in our referral center of North West of Iran.

Materials and method:

From July 2000 To Sep. 2008, seventy patients have undergone valvular replacement using bioprosthetic valves. Isolated aortic valve replacement (AVR) in 21 patients, isolated mitral valve replacement(MVR) in 23 patients, isolated tricuspid valve replacement in one patient, AVR with MVR in 10 patients and MVR with TVR in 5 patients have been done. Mean age was 54.8 years, 24 were male and 46 were female. Atrial fibrillation has been found in 34 (48.6%). The patients have been evaluated by ECG and Echocardiography to assess the rhythm and ejection fracture. These data has been shown in table 1.
Follow-up:
Mean follow-up time was 33 months (min 9 max 92). All the survived patients assessed echocardiographicly and the medical records for any other operation.

Results:

Mortality:

This group of patients had a mortality rate of 25.7% (n=18) within 8 years of follow-up. Statistical analysis showed 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-year-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), combined CABG and valvular operation (0.262). Also there was no significant relation between the 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%) has occurred due to cardiopulmonary arrest but no distinguishable factor (cardiac or non cardiac) has been reported.
Mortality has been occurred during the first month after operation in 9 patients (12.8%), between the second month and the first year in 4 patients (5.7%), in no one during second year and in 5 cases within the 3rd and 4th year.

Morbidities:

Mean time for morbidities which occurred in 30 patients (42.8%) was 8 month (min 1 max 60). Significant statistical relation has been found between the morbidities and age over 65 years old (p=0.005) but there was no relation has been realized statistically between morbidities and other factors listed above. Rate of morbidities is listed in table2.
Symptom free period which were calculated was 20.3 month for all patients, 12 month for over 65-year-old and 23.5 month for the rest.

Re-operation:

In the period of follow-up 4 cases (5.7%) underwent re-operation. Mean free of operation time was 22 months (min 1, max60) in these patients. These cases were evaluated echocardiographicly and valve global dysfunctions have been distinguished. There was no significant relation between valve dysfunctions and the factors listed above.

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 actually in result of no ideal valve has been discovered yet (5, 6). Meanwhile; although there is a wide consensus on the type of valve to be put in younger and in 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 are comprises a large group of patients in need of valve replacement (4, 5).
In recent decades tow randomize have been compared survival and valve related morbidities associated to the 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 prioperative mortality rate, old style valves that are not available now and large number of redo sternotomy occurred in these studies are some of the limitations that make the election

difficult nowadays (5, 8-11).

Although some studies proved that no difference exists in mortality rate after mechanical and after tissue valve replacement (11-13) these studies provoked that reoperation was higher after tissue valve replacement than mechanical and valve related morbidities are more common after mechanical valve implantation.

It would be postulate that life style alterations after a mechanical valve replacement, in a patient who needs 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 randomize studies is obvious.

In our study survival rate is not in an acceptable range after a mid-term follow-up possibly in result of patients' comorbidities; however causes of death in almost half of patients who expired were not clarified and it would limit the conclusion. Also the fact of postpone 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 has been reported just for one case that seems favorable, but it perhaps reported in result of lack of data.

More than half of the patients had no episode of any kind of morbidities during follow-up and morbidities significantly related to age more than 65 years old. This could conclude that tissue valves would apply for young patients (under 65 y/o) with no concern about the rate of consequences. Of course a low rate of valve dysfunctions happened 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.

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

Table 2: Post operative complications
CVA: Cerebrovascular accident, PTE: Pulmonary thromboembolism, DVT: Deep venous thrombosis, CHB: complete heart block.

	n	%
Mean age	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

Table 1: Patients' characteristics before operation
AF: Atrial fibrillation, CHB: Complete heart block, NSR: Normal sinus rhythm, EF: Ejection fraction.

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