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Outcome of Heart Valve Prosthesis in a Tertiary Care Hospital in Bangladesh: A Retrospective Study

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Abstract

Background: Prosthetic heart valve for middle aged patients requiring valve replacement remains controversialBecause of the co-morbidities and limited life expectancy, bioprosthesis is the likely choice for older aged patients.

Objective: The aim of the study was to quantify long term survival rate and major morbidity in patients undergoing heart valve replacement and to optimise selection criteria of biologic versus mechanical valve prostheses.

Methods: This retrospective cohort study evaluated among 565 patients of 45 to 65 years of age undergoing isolated, primary heart valve replacement in either aortic or mitral position using mechanical or bioprosthetic valve.

*Results:*Long time survival benefit was similar between aortic valve replacement (AVR) versus mitral valve replacement (MVR) patients regarding replacement with either mechanical and bioprosthetic valve. Postoperative incidence of morbidities like valve related complications, endocarditis, and bleeding were statistically not significant in this study. There was no significant difference in terms mortality after both AVR and MVR regarding use of bioprosthesis versus mechanical valve. Although, most common causes of mortality were prosthesis related and haemorrhage that was observed in both study group. Follow up at 10 years observed mean survival rate were 86.6%, 90.3% in mechanical AVR and MVR respectively, whereas patients with bioprosthesis demonstrate survival rate of 82.3% after AVR and 76.9% following MVR.

Conclusion: With a life expectancy of at least 15 years, mechanical prostheses should be considered in patients below 50 years in Bangladesh. However, patients more than 50 years of age or with multiple comorbidities like coronary artery disease, renal disease, lung disease, coronary disease, or a life expectancy less than 15 years, bio prostheses may be good options for better outcome.

Keywords: Mechanical valve, Bioprosthesis, Aortic valve replacement, Mitral valve replacement

Introduction

Choice of prosthetic heart valve for middle aged patients requiring valve replacement remains controversial than those of young and older aged patients.[1] Because of the co-morbidities and limited life expectancy, bioprosthesis is the likely choice for older aged patients according to most of the guidelines as it unburden them from the use of anticoagulation and related risks for their remainder life time.[1,2]In young patients who expect a longer life time, durability of the valve remains the principle concern as well as to avoid reoperation from valve degeneration seen in the use of bioprosthesis. Therefore, despite the risk of thromboembolism, haemorrhage and burden of lifelong use of anticoagulation and related risks, mechanical valve is the usual choice of prosthesis for this age group as it provides durability for longer periods, freedom from structural valve degeneration, less likelihood of re-operation and related risks and also provide better effective orifice area for a similar sized bioprosthetic valve.[3,4] This benefits of mechanical valve outweigh the risk of its use in younger aged patients, but being in the middle of the spectrum of life expectancy, middle aged patients may be benefited from use of either types of valve, mechanical or bioprosthesis.[5,6]

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The Edinburgh trial and the Veterans Affairs (VA) trial favored mechanical valve use where study suggested bioprosthesis use in middle aged population has better outcome.[7,8]Tissue valves have had multiple merits compare to mechanical valve like well tolerated, widely available, longevity in elderly patient is excellent, with concurrent subvalvular structure preservation that may maximize durability to leading up of 15 years.[7]Moreover, future implantation of transcatheter based valve innovations is also possible. In spite of these focal points, it is surely knowing that bioprosthetic valves have a high disappointment rate in those patients younger than 60, that regularly requires the requirement for reoperation. But in elderly patient, bioprosthesis carries a lower risk of reoperation due to valve structure degeneration and also avoid some major complications like hemorrhagic and thrombotic complications that associated with mechanical valve.[7,8] Considering above factors, some authors prefer bioprosthesis in an elderly patient more than 60 years. Though optimal prosthesis nature for young patients is still unclear.[5,7-9]

Contrarily, mechanical prosthesis offers multiple advantages over tissue valve. For instance, mechanical valves are easy to implant, free from structural degeneration, have more orifice area and more durable.[7,9] However, lifelong anticoagulation therapy is a high profile counterpoint that need to account during choosing of a mechanical valve. Most of the major guidelines have recommended mechanical prosthesis in young adult patient requiring valve replacement.[8,9]More essentially, few authors take note of that the hemorrhagic complications was comparative, though use of mechanical valves and their related anticoagulation therapy rises significant risk for bleeding.[10] Moreover, many published articles report that the flexibility from valve degeneration and reoperation in patients accepting a mechanical prosthesis contrasted to bioprosthesis is significantly higher because of the fundamental social difficulties of dealing with the patient's subsequent care or regular follow up to maintain proper coagulation profile in remote area.[9-11]

In this study, it was examined a multicenter database to measure contrasts in long term outcome including survival rate, stroke, bleeding complication, and reoperation rate following heart valve replacement. Because of the long ongoing controversy and fewer published data regarding optimal prosthesis for middle aged group, this study which is based on the 20 years experienced on valve surgery of a single surgeon's practice in patients aged 45 to 65 years, aims to provide supportive information for prosthesis selection in this age group as well as to evaluate the survival and long term outcome of the enrolled patients.

Materials and Methods

This retrospective cohort study evaluated total 565 patients undergoing isolated heart valve surgery between the year of 1998 and 2017 in a single surgeons practice. Patients experiencing single valve surgery either aortic valve replacement (AVR) or mitral valve replacement (MVR) were randomized to implant either bioprosthesis or mechanical prosthesis in operating room. Informed written consent was taken from every patient. A wide range of demographic variables and baseline characteristics were evaluated, including patient's characteristics, NYHA functional class, left ventricular function, haemodynamics, valve pathology and associated comorbidities like coronary artery disease, renal function impairment, diabetes etc. Exclusion criteria were redo surgery, concurrent other valve repair or replacement, coronary artery bypass graft, aortic surgery, renal failure, and also aortic surgery.

*Follow-up procedure:*From 1998 to 2017, follow-up for valve related complications, NYHA functional status, proper coagulation profile, and death was recorded at follow up clinic visits and also over phone in a structured data collection sheet. The follow-up was terminated in December 31, 2017.There were two primary study end points, firstly cause of death including operative mortality and secondly time to first occurrence of any complications like bleeding, systemic embolism, endocarditis, thrombosis, prosthetic valvular regurgitation either central or perivalvular regurgitation, non-thrombotic valve obstruction, and reoperation. Primary valve failure indicated by presence of either central valvular regurgitation or non-thrombotic valve obstruction. Hospital record was used to collect data regarding suspected valve-related complication or patient death and a subcommittee of three doctors blinded as to the type of prosthesis decided final decision about the cause of death whether it was a complication of the

randomised valve or not. If death was not due to valve-related complication, the subcommittee would have evaluated whether the occurrence was due to either cardiac, non-cardiac, or the cause could not be identified. Sudden death without obvious cause or post-mortem examination was classified as valve-related cause of mortality. Baseline characteristics were compared between two groups using chi-square test for categorical variables and *t* test for continuous variables. Kaplan-Meier estimator and the log-rank statistic used to evaluate survival rate (time to death) and first occurrence of valve-related complication were contrasted between two study group. Results were appraising to be statistically significant when *p* value was <0.05.

Results

Patient characteristics: Compared to patients who had mechanical prosthetic valve, bioprosthetic valve patients were older (age in Mean±SD is 54.43 ±1.5 years and 51.75 ±2.5 years at bioprosthetic AVR and bioprosthetic MVR patients respectively versus 47.5±2.5 years and 45.75±2.5 years at mechanical AVR and mechanical MVR respectively). The preoperative characteristics of the study population were also assessed(table-I). There is a higher preoperative cumulative incidence of comorbidities like atrial fibrillation, hypertension, heart failure, diabetes mellitus, smoking, and renal impairment in patients who received mechanical valve in comparison to bioprosthetic valve patients. Patients with preoperative lower ejection fraction (<30%) and NYHA class III-IV substantially received bioprosthetic valve replacement.

Morbidity: Incidence of valve related complications, endocarditis, and bleeding following AVR and MVR were statistically not significant ($p<0.05$) in study patients and only 5.04% patients had incidence of systemic embolism after mechanical MVR. However, prosthetic valve thrombosis incidence was none observed after bioprosthesis and perivalvular regurgitation rate was insignificant between study population. There was no incidence of primary valve failure was observed in this study (table II).

Mortality: Though, mortality rate was not significant after AVR and MVR regarding use of bioprosthesis versus mechanical valve, however incidence was slightly higher in bioprosthetic AVR and also in mechanical MVR (table III).

Table I: Baseline characteristics of study population (n=565).

Variables		Aortic valve prosthesis		Mitral valve prosthesis	
		Mechanical (n=187)	**Bioprosthetic (n=62)**	**Mechanical (n=238)**	**Bioprosthetic (n=78)**
Age in years (Mean±SD)		47.5±2.5	54.43±1.5	45.75±2.5	51.75±2.5
Smoking		44.92%	41.9%	39.9%	40.02%
Atrial fibrillation		4.23%	3.2%	52.9%	52.6%
Heart Failure		27.8%	29.03%	42.02%	38.5%
Hypertension		45.99%	46.8%	19.75%	15.4%
Diabetes		11.22%	9.8%	10.5%	7.7%
Renal impairment		2.13%	3.23%	3.4%	2.5%
LVEF	>50%	91.5%	91.94%	86.97%	88.5%
	30-50%	7.4%	4.81%	12.6%	11.5%
	<30%	1.1%	3.25%	0.43%	0.0%
Coronary artery disease	SVD	16.6%	11.3%	5.9%	2.6%
	DVD	7.5%	3.2%	2.9%	1.3%
	TVD	2.7%	0.0%	0.0%	0.0%
NYHA functional class	Class I - II	72.7%	74.2%	63.1%	65.7%
	Class III - IV	27.3%	25.8%	36.9%	34.3%

Note: LVEF=Left Ventricular Ejection Fraction; SVD=Single vessel disease; DVD= Double vessel disease; TVD= Triple vessel disease; NYHA =New York Heart Association.

Table II: Long term outcome at 20 years after heart valve replacement (n=565)

Variables	Aortic valve prosthesis			Mitral valve prosthesis		
	Mechanical (n=187)	Bioprosthetic (n=62)	*p* Value	Mechanical (n=238)	Bioprosthesis (n=78)	*p* value
Death rate	45.45%	48.38%	0.689	48.32%	47.43%	0.888
Valve-related complication	60.42%	61.29%	0.904	63.44%	65.38%	0.756
Systemic embolism	0.0%	0.0%	0.000	5.04%	0.0%	0.413
Bleeding	15%	12.90%	0.689	14.69%	14.10%	0.896
Endocarditis	2.67%	1.61%	0.638	4.62%	1.28%	0.180
Valve thrombosis	1.60 %	0.0%	0.317	1.26%	0.0%	0.317
Perivalvular regurgitation	1.07%	1.61%	0.727	1.68%	1.28%	0.810
Reoperation	1.07%	1.61%	0.727	0.0%	0.0%	0.000
Primary valve failure	0.0%	0.0%	0.000	0.0%	0.0%	0.000
Follow up Regular	50.80%	61.29%	0.152	56.72%	62.82%	0.342
Irregular	35.83%	20.97%	0.003	35.71%	21.80%	0.222
Drop out	13.37%	17.74%	0.395	7.57%	15.38%	0.040

n = Number of patients randomised
p = Difference between mechanical and bioprosthetic valve groups

Table III: Causes of death of study population (n=234)

Variables		Aortic valve prosthesis		Mitral valve prosthesis	
		Mechanical (n= 73)	Bioprosthetic (n=24)	Mechanical (n=106)	Bioprosthesis (n=31)
	Prosthesis related	19 (26.03%)	6 (25.0%)	58 (54.72%)	14 (45.16%)
Cardiac causes	Heart failure	6 (8.22%)	2 (8.33%)	8 (7.55%)	4 (12.90%)
	MI	1 (1.36%)	0 (0%)	2 (1.90%)	2 (6.45%)
	Endocarditis	3 (4.11%)	2 (8.33%)	3 (2.83%)	2 (6.45%)
	Subvalvular damage	1 (1.36%)	0 (0%)	1 (0.94%)	0 (0%)
	Others	2 (2.72%)	0 (0%)	2 (1.90%)	1 (3.23%)
Non cardiac disease	Haemorrhage	17 (23.29%)	3 (12.5%)	8 (7.55%)	2 (6.45%)
	Stroke	4 (5.48%)	2 (8.33%)	3 (2.83%)	0 (0%)
	Infection	2 (2.72%)	0 (0%)	3 (2.83%)	0 (0%)
	Sudden death	9 (12.33%)	4 (16.66%)	6 (5.66%)	1 (3.23%)
	Others	1 (1.36%)	0 (0%)	2 (1.90%)	0 (0%)
Undiagnosed		8 (11.02%)	5 (20.83%)	10 (9.43%)	5 (16.13%)

Note: MI- Myocardial Infarction

Death from cardiac causes include prosthesis related causes, heart failure, myocardial infarction, endocarditis, valve structure damage and other cardiac causes which are presented in Table- III. Incidence of death from prosthesis related causes was high after MVR in comparison to AVR and heart failure rate was slightly higher in bioprosthetic MVR group of patients. Although, myocardial infarction and endocarditis was more (6.55%) after bioprosthesis in contrast to mechanical valve replacement. Incidence of valve structure damage and other cardiac causes was also insignificant among study population. Incidence of death from haemorrhage was slightly higher (23.29%) after mechanical AVR, but the occurrence of stroke, infection, and non-cardiac cause was not significant between mechanical and bioprosthesis. Moreover, infection rate was zero after bioprosthetic AVR and bioprosthetic MVR andsudden death was more common among AVR patients. Undiagnosedcauses of mortality were high after tissue valve replacement in both aortic and mitral position.

Table IV: Predictors of patient survival

Variable	Beta (β)	Chi-square	P *value*	*Hazard ratio*	*95% CI*
Age ≥ 60 y	0.48 ± .13	9.47	0.002	2.0	(1.2, 2.1)
EF < 30%	0.46 ± .14	10.7	0.0004	2.1	(1.2, 2.0)
Coronary disease	0.29 ± .06	13.08	0.0005	1.4	(1.1, 1.6)
NYHA class IV	0.41 ± .15	7.26	0.0040	1.5	(1.1, 2.1)
Heart failure	0.39 ± .16	9.48	0.0200	1.5	(1.1, 2.0)
Endocarditis	0.34 ± .23	8.33	0.0004	2.2	(1.4, 3.5)
Stroke	0.48 ± .72	6.88	0.003	2.0	(1.1, 2.1)

Note: CI-Confidence interval

Late survival: Over 20 years of a single surgeons practice of mechanical valve replacement in both aortic and mitral position, survival rate at 5, 10 and 20 years follow up was insignificant (mean survival rate was 94.65%, 86.63% and 69.51% after mechanical AVR, and 96.66%, 90.33% and 73.94% after mechanical MVR).

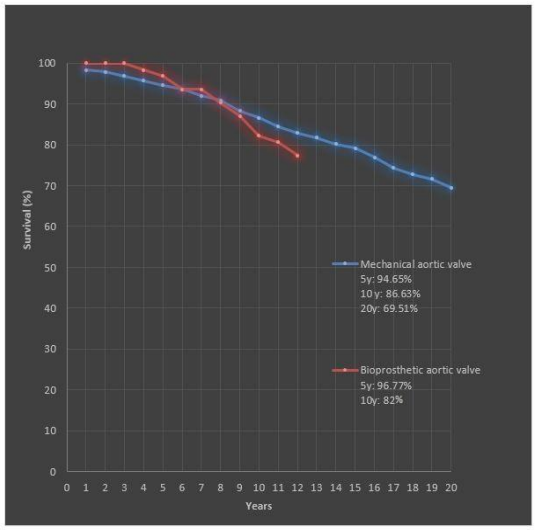

Figure 1: Survival curves according to overall survival rate after aortic valve replacement (AVR) In patients aged between 45 to 65 years.

However, follow up at 5 and 10 years after bioprosthesis observed no statistical difference (p<0.05) in both position (mean survival rate was 96.77% and 82.25% after AVR and 93.58% and 76.92% following MVR).

Independent risk factors for lower long term survival after AVR and MVR was associated with those age ≥60 years at surgery, low ejection fraction <30%, poor NYHA functional class, presence of heart failure, endocarditis and stroke also were assessed (table IV). Survival curve for overall survivor in patients aged 45 to 65 after AVR and MVR were also performed (figure 1 and figure 2) respectively.

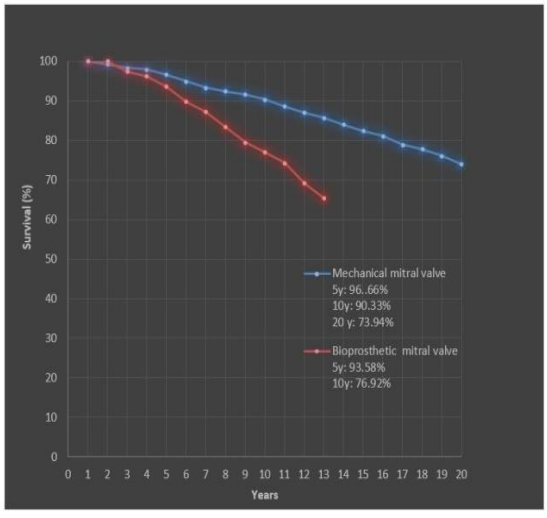

Figure 2: Survival curves according to overall survival rate after Mitral valve replacement (MVR) in patients aged between 45 to 65 years.

Discussion

Considering the risk in lifelong anticoagulation versus benefit of long durability in mechanical valves and risk of limited durability requiring reoperation versus benefit of relief from lifelong anticoagulation burden in case of tissue valve leads to difficulty in choosing appropriate valve for middle aged patients. This study observed following findings: Firstly, older patients with limited life expectancy likely to be benefited from bioprosthesis; Secondly, long term survival benefit was similar between AVR versus MVR patients as well as no statistical difference in survival curve between mechanical and bioprosthetic valve patients; and finally- patients with age more than 60 years, having coronary artery disease, LVEF<30%, poor NYHA functional class, heart failure, endocarditis and stroke were associated with lower long time survival rate. Nevertheless, the higher incidence of death rate remains undiagnosed after bioprosthesis because most of the patients were elderly aged and lack of routine autopsy practice in Bangladesh.

A very few large studies have compared outcomes between biologic and mechanical valve replacement. The rate of hemorrhage with mechanical prostheses in this study was higher than bioprosthesis; which was reported in most of the published articles.[1,5,8,9] This will result from the low-risk population and where anticoagulation was maintained at lower levels. Thromboembolic rate of this study can be compared with other reports for both mechanical and biologic prostheses also.[3,9,10] In past, it was accentuated that aftereffects of valve surgery with respect to bleeding complication, NYHA functional class, valve function, and LVEF are dependent on patient factors like nature of prosthesis, type of surgery, and postoperative follow up care.[5,7-10] Moreover, surgeons should be very cautious regarding comparing data from different studies to choose particular valve for a patient.[4,8,11]

The postoperative management of life long anticoagulation therapy and continuous monitoring for international normalized ratio (INR) is troublesome especially in patients from rural area.[1,5,8-11] In a study, Manji et al report comparative achievement in an anticoagulation center in provincial Kenya.[12] In this investigation, they built up a drug specialist to adopt anticoagulation facility and noticed that with regular follow up and education, the mean time in therapeutic range (TTR) was 64.6% on the whole comers, however in the gathering with mechanical

prosthesis, the mean TTR was 77%.[12] But Hodge et al. depict the advancement of a comprehensive INR administration program situated in community clinic and general practitioner centers in Australia.[13] Utilizing instruction, conventions and purpose of INR device, they report TTR of 69% utilizing the standard INR level of 2.0-3.0. They additionally observed that with the appropriation of testing in each 14 days, the TTR was as high as 78%, an outcome that opponents even the best-directed clinical trials of warfarin.[13]Once more, it might be contended that Australia is a developed country and a comparative result would be harder to accomplish in a developing country because of inadequate financial support.[8,10-13]

In a patient with less than 15 years expected survival rate; like more than 60 years of age, multiple comorbidities lung disease, renal disease, having ejection fraction of less than 40%, or with coronary artery disease would be reasonable candidates for bioprostheses.[3-7,10,12] In a study, Hammermeister et al observed that long term mortality rate was high in both groups and majority of the mortality (60%) are not related to the prosthesis.[14] In a review, Brown et al. reported that a 10-year survival benefit in patients between 50 to 70 years favoring mechanical prostheses over bioprosthesis.[15] This may be due to systematic bias arising from the inclination to implant mechanical valves in healthy patients with better life expectancy and in contrast patients received bioprosthesis were older, have multiple comorbidities, and more symptomatic with poor LV function, which is concordance with other findings also.[2,10,13-18] However, McClure et al observed in a single-center study of similar group of study population (less than 65 years of age) and demonstrate no significant long term survival difference after surgery.[19] This significant survival benefit associated with mechanical prosthesis probably due to focusing several points like lifestyle, maintenance of proper anticoagulation therapy, and relative low risks of major comorbidities, for instance bleeding complications, TIA or stroke, and reoperation which is also supported by other articles also.[11,18,20-22] In this study, risk factors for stroke did not identify to be affected by the types of prosthesis, which is also similar with the many authors findings.[8,11,21-25]

In this review, incidence of death from prosthesis related causes, valve structure damage and also heart failure was more after mechanical valve replacement than bioprosthesis. Only a limited incidence of systemic embolism has occurred after mitral valve replacement with mechanical prosthesis. Moreover, there was no incidence of primary valve failure observed after both MVR and AVR. However, patients must be informed regarding merits and demerits of different types of prosthesis for valve replacement. Finally, patient factors and preferences for prosthesis have great role in choosing of the prosthetic heart valve.

Conclusion

Bioprosthetic valve is most suitable for elderly patients with lower likelihood ratio of major bleeding complications; though reoperation risk is so high after 15 years of surgery due to degenerative changes. However, mechanical valve replacement is the choice of treatment in younger age population considering all adverse effect.

Conflict of interest: None

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