Original research article

Consequences of Mechanical and Bioprosthetic Heart Valves Replacement in Tertiary Care Center of Bhopal.

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Abstract

Background: Heart valve replacements carry the pinnacle in surgical treatment for the patients with major cardiac illness though its ideas are not clear about their use due to many confounding factors like upsurge in incidences of stuck valve and anticoagulant related bleeding. The aim of our study was to compare outcomes after mitral, aortic or double valve replacements with mechanical versus bioprosthetic valves.

Methods: Data of 103 patients who underwent cardiac valve replacement [62 mitral, 25 aortic, and 16 double valve] with either mechanical [bileaflet valve, n=54] or biological [Hancock II, n=49] valve were retrospectively analyzed. Specific outcomes evaluatedwhich includefrequencies of valve thrombosis, systemic thromboembolism, anticoagulant related bleeding, structural valve dysfunction, prosthetic valve endocarditis, reoperation and death.

Results: Both the groups were comparable preoperatively except that patients receiving biological valve were more likely to be female and belonging to a rural setup. 30 day mortality was comparable in both groups. Incidences of valve related complications were significantly commoner in mechanical valve group. Two patients with mechanical valve required reoperation for stuck prosthetic valve at about 3 years after primary operation. Prosthetic valve endocarditis was not reported in either group. At 5 years there was no incidence of structural valve dysfunction was seen.

Conclusions: Mechanical valves are associated with a significantly higher complication rate compared with biological valves in Indian patients. Biological valves thus maybe specifically suited to the Indian scenario. However, in choosing a prosthetic valve, patients' involvement and informed consent should take the utmost importance.

Keywords: Thrombosis, Valve replacement, Endocarditis, biological valves.

Introduction

In case of Prosthetic wall replacements regardless ofour knowledge till date ideal valves are still missing. Considering the two major options for prosthetic valves mechanical and biological, resilience of the mechanicalvalve contests with the simplicity of maintenance biological valve. Alsowhile using bioprosthesesassociated side effects and use of anticoagulants are reduced to a greater extent[1]

As per present guidelines and directions use of mechanical valve in younger children and bioprostheses in older age group people are recommended and are used widely across the globe.[2]Nevertheless confusion still persists amongst surgeonsin middle aged adults who are running in their 3rd to5th decade of life specifically in Indian continent where use of anticoagulant therapy has to be implicated for over a life time of the patients.[3]Also these drugs have a very tapered therapeutic index which is influenced by many factors like decreased life expectancy, and limited amenities for testing and controlling of drug allied events[4.]Therefore in Indian continent prosthetic valve related issues are of concern where maintenance of adequate anticoagulation measures are involved.[5]

Considering all such facts present study targets to evaluate and identify the valve related morbidity in study population with prominence on the incidence and consequences of anticoagulant related event and structural valve weakening.

Materials and methods:
From Jan 2018 to December 2021, 103 consecutive cases that endured isolated valve replacement surgery at tertiary care hospital of the city were considered. Cases where replacement was done as part of a combined procedure, for example, coronary artery bypass surgery along with valve replacement surgery or atrial septal defect closure along with valve replacement were excluded from the study. The study group included 62 mitral valve replacements [MVR], 25 aortic valve replacements [AVR] and 16 cases of double valve replacement [DVR]. All cases were suffering from rheumatic heart disease and were subjected to surgery after cardiological consultation and echocardiographic evaluation.

Specifically measured outcomes included incidences of prosthetic valve thrombosis, systemic thromboembolism, infective endocarditis, reoperation and death.

Preoperative characteristics of the two groups are presented in Table 1 demonstrating relative comparability between groups. The biological valve group had a higher percentage of female and rural population, compared to the mechanical valve group. This was in keeping with our departmental policy of implanting biological valves infemales from a rural background.

In general, the choice of the valve was primarily determined by the patients after they had been presented with the relative merits and de-merits of the valves [mechanical versus biological] with emphasis on durability and anticoagulants related issues. Patients' socioeconomic background and thus ability to adequately comply with warfarin usage influenced our counselling.

The mechanical valve used was advancing the Standard – ATS [ATS Med.Inc. Minneapolis, USA]. The biological valve used was Hancock II [Medtronic Inc., Minneapolis, MN, USA]. This was in accordance with the valves approved at our hospital for clinical use.
Operative technique

All patients were operated on via a median sternotomy. Standard aorto-bicaval cannulation was used in all cases, except isolated aortic valve replacement where single 2 stage caval cannulation was used, along with moderate systemic (28°C) and local hypothermia using topical ice slush. Aorta was cross clamped and ante grade cardioplegia was infused via the aortic root. Total or near total chordal preservation was always attempted in mitral valve

replacements. Valves were seated using interrupted everting horizontal mattress sutures using 2-0 ethibond.

Post operatively the patients in either group received both aspirin and dicumarol to keep International Normal-ized Ratio in therapeutic range (2.0 to 3.0 in case of mitral or aortic valve replacement and 2.5 to 3.5 in case of double valve replacement) which was continued indefinitely in mechanical valve group whereas patients with bioprosthesis had their dicumarol stopped after 3 months.
Follow up

Patients were followed up in out-patient department for adequacy of anticoagulation and any valve related event.

Table 1: Preoperative character

Variables	Mechanical valve [n=54]	Biological valve [n= 49]	p value
Age (yrs) (mean±SD)	39±16	40±15	P > 0.05 NS
Male	155[60%]	96 [40%]	P > 0.05 NS
Female	102 [40%]	150 [60%]	P > 0.05 NS
Rural[vs. urban]	92[36%]	157[64%]	P > 0.05 NS
NYHA class III-IV	146[57%]	135[55%]	P > 0.05 NS
Congestive cardiac failure	33[13%]	27[11%]	P > 0.05 NS
Hypertension	7[3%]	9[4%]	P > 0.05 NS
Diabetes	10[4%]	12[5%]	P > 0.05 NS
Atrial fibrillation	77[30%]	73[30%]	P > 0.05 NS

NS= not significant
Regular 6 monthly echocardiography was performed in cases of bio-prosthetic valves to assess for any structural valve dysfunction.

Standard definitions were used for clinical outcomes[6]. Clinically suspected cases of prosthetic valve thrombosis were diagnosed by transthoracic and, when needed, trans-esophageal echocardiography and in most cases, unless directed otherwise by hemodynamic instability, by cine-fluoroscopy.

Statistical analysis
Differences in the baseline characteristics between groups were compared using the t test for continuous and chi-square test [or Fisher exact test where appropriate] for categorical variables. All p values were two tailed. Results were considered to be statistically significant if the p value was ≤0.05.

Results
Overall patients in two groups did not differ significantly. Age distributions were comparable and no statistically significant differences were noted in respect to functional status, co-morbidity, atrial fibrillation and incidence of congestive cardiac failure.
Patients in biological valve group were more likely to be from a rural setup and more of females had a biological valve.
Mortality and survival
Details of postoperative outcomes are listed in Table 2.

Table 2: Postoperative outcomescompared between the twoGroups

Variable	Mechanical valve	Biological valve	p value
TOTAL	54	49	>0.05
MVR	30	31	
AVR	14	12	
DVR	10	06	
30 day mortality	2 [3.7%]	2 [4.08%]	>0.05
5-year survival	51 [94.4%]	47 [95.9%]	>0.05
Valve thrombosis	3[5.5%]	0	0.04
Thromboembolism	4[7.4%]	1[2.04%]	0.02
Anticoagulant related bleeding	3[5.5%]	0	0.04
Prosthetic valve endocarditis	0	0	>0.05
Reoperation	3	0	0.03
Late mortality	3	0	0.03
Structural valve dysfunction	0	0	>0.05

The 30-days survival was comparable in two groups. At 3 yearsthere were two deaths in the mechanical valve group due to stuck prosthetic valve resulting in low cardiac output. Both patients presented to us in severe low cardiac output and acidosis. Attempts were made to open these valves using pharmacological means (using heparin and streptokinase or urokinase), but were unsuccessful. These patients were not considered surgical candidates because of the poor general status.

Valve related complications
Table 2 lists the occurrence of morbidity and mortality. There was a statistically significant trend toward higher complications in mechanical valve group with more cases of valve thrombosis, anticoagulant-related haemorrhage and systemic thromboembolism. Valve thrombosis and anticoagulant related bleeding were only seen in mechanical valve group.

Valve thrombosis was seen in 3 cases over these 5 years. Stuck prostheses included mitral prosthesis in nine and aortic in three. Presentation was with acute onset of dyspnoea. Primary thrombolysis was initially attempted in all these cases and was successful in 2 patients. One patients failed to respond and were subjected to reoperation following which they made uneventful recovery.

Anticoagulant related bleeding were seen in 3 cases as well. Presentation was with severe anaemia and melena in nine cases while three cases presented with severe epistaxis.Management involved fresh frozen plasma and packed red cell transfusion. INR was re-stabilized before discharge.
The occurrence of prosthetic valve endocarditis was not seen in either group.
Reoperation

At a mean follow up of 2.8 years (range 6 months to 5 years) there were 2 reoperations, both for prosthetic valve thrombosis in mechanical valve group.Structural valve degeneration was not detected at this follow up time.

Discussion

Soon after the heterotopic prosthetic valve grafting by Hufnagel in 1954, on September 21, 1960, Starr performed the first fruitfulorthotopic valve replacement in the mitral position, which was followed by Harken's implantation of prosthesis in aortic position[7-9].

As a result of these surgical achievements the prosthetic valve improvement has observedmany changes starting from tilting discs designs in late 60s and bileaflet designs in late 70s.Most of the part was occupied by fixations of flow characteristics and durability of the prosthesis[1]. However over since then flip side of mechanical valve replacement, in the form of anticoagulant need and its risks, has also raisedominously[10]. Such issues may not be conspicuous in developed countries with organized health care and homogenous literacy but in developing countries like India use and misuse of anticoagulant drug is a major cause of concern [3, 4].

Some risks were also evolved in young females desiring pregnancy where auxiliary risk of drug induced embryopathy also adds complexity to an already aggravatedconcern[11, 12]. Literature also confirms that in view of amplified bleeding secondary to accidental or incidental trauma inanticoagulated patients tied with risks inherent to valve and warfarin usage which is actually lower than expected survival rate [13, 14].

The scenario thus is gloomy at the least, calling for prudence and judgment beyond mere replacement of a diseased valve with perfunctory consideration of the replacement.Against this experience, and with few practical alternatives[3] more liberal usage of biological valve merits serious thinking, despite its limitations, as it offers definite advantages peculiar to developing countriessummed up as follows[15]. Liberty from acute prosthetic valve dysfunction and abrupt death as SVD of biological valve occurs gradually providing ample time for diagnosis and treatment. Usefulness in women of child-bearing age group. Indifferent in global actuarial survival and autonomy from major events. Affordable range of the products. A clear chance of reoperation may forewarn the surgeon to take necessary precautions during primary surgery, including the option of using pericardial membrane to facilitate later redo sternotomy. It is noteworthy that mechanical prostheses do not assure freedom from reoperation.

In view of illiteracy and poor follow up, coupled with ill-developed health care arrangement the current recommendation of ACC/AHA guidelines with reference to management of anticoagulation also has few practical implications in our set up [16].

As most of the population lack basic facility of prothrombin time estimation at their native place, patients have to travel for long distance to the hospital where they got operated, leading to non-compliance. If the patient's INR is off target it is desired to repeat INR within a week for optimizing the dose of dicoumarin, then the patient may have to stay near the hospital leading to loss of his livelihood. Most of the patients are illiterate and making them understand the need for regular blood test and dicoumarin intake is a difficult task and in all the above scenario a women has even more difficult situation, given the peculiar socioeconomic condition of developing countries, leading to loss of her compliance to treatment with time.

Based on such considerations and others, there are trends in the United States and Europe toward the increasing use of tissue rather than mechanical valves and toward the use of bioprostheses in progressively younger patients [17].

Al Halees from Saudi Arabia reported that only 25% of patients could be maintained in the therapeutic range of INR despite efforts to the contrary [5]. North et al have also noted that compliance is a major issue and biological valves imparted a survival advantage in their report [11].

Our study underscores the grave thrombotic and bleeding complications of mechanical valve though incidences of infective endocarditis and short term survival are similar with either type of valve.

Durability and thus risk of reoperation remains a nagging problem with biological valve though there are suggestions that the third-generation bioprostheses maybe even more durable and it has shown that 2nd generation Hancock II aortic valve are definitely superior to first[18].

The high risk of bleeding has been reported in a number of papers in the literature and it has been commented that Warfarin "is the second-most-likely drug, after insulin, to send Americans to the emergency room".[19, 20]

Two historic randomized clinical trials compared out-comes after valve replacement with a first-generation porcine heterograft and the Bjork-Shiley tilting-disc mechanical valve, namely, The Edinburgh Heart Valve Trial, conducted between 1975 and 1979 with an average follow-up of 12 years, and The Veteran Affairs (VA) Cooperative Study on Valvular Heart Disease, conducted between 1979 and 1982 with an average follow-up of 15 years; whereinThe Edinburgh trial showed a small survival advantage associated with a mechanical valve in the aortic but not in the mitral position and both trials showed increased bleedingassociated with mechanical valves though increased reoperation with tissue valves were also seen [19,20].

It can be safely stated that risk of reoperation is not necessarily a sufficient deterrent against using biological valve in young patient particularly when one considers the current risk of reoperation as well as the advantages it offers.

Conclusion:
In conclusion, making the right choice is not a simple balancing act between durability and improved hemodynamics of mechanical valve against the freedom from anticoagulant-related risks with biological valve and nor the waiting game for the utopian prosthesis; rather it is all about the realistic reappraisal of the patients' socioeconomic background and their ultimate survival and return to productive life.

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