

# Single centre experience of double valve replacement using mechanical valves

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## Abstract

**Introduction:** Cardiac valvular disease in India is most commonly caused by Rheumatic aetiology, many of which end up getting operated for the same. There is still existing controversy about the selection of ideal valves that can be used for replacement.

**Objective:** Objective of this study was to retrospectively analyse the variable which can be easily assessed in the patients undergoing DVR (Double Valve replacement) using mechanical valves for its outcomes.

**Methods:** All the patients who underwent DVR + Tricuspid valve repair/annuloplasty between October 2017 to January 2019, were identified and retrospectively their data was analysed.

**Results:** 72 patients who underwent the procedure. Most common aetiology was Rheumatic. 69.4% were in NYHA (New York Heart Association) class II, 33.33% had chronic atrial fibrillation. 45.6% had associated tricuspid valve disease, and no chordae was preserved in 27.7%. Overall mortality was 5.5%

**Conclusion:** The study revealed a favourable survival outcome after DVR surgery. The operative mortality in patients undergoing DVR depends on intra operative factors like total surgical time, bypass time and aortic cross clamped time and has improved remarkably over time, with the improvisation of extracorporeal circulation methods, myocardial protection techniques and postoperative management.

**Keywords:** Double valve Replacement, Tricuspid valve repair, Patient Prosthesis mismatch

## INTRODUCTION

It was in the 1960s that first double valve replacement was carried out, using first generation mechanical prosthesis. Up to mid-1970s, it was related with a high operative death [1-3]. The high profile first generations of valves, old cardiopulmonary bypass methods and flawed myocardial protection were some of the major factors for dismal outcomes. With the introduction of second-generation mechanical low profile bi-leaflet mechanical valves, improvement in myocardial protection techniques enhanced the short, medium, and long-term survival and prognosis in the early 1980s. [4-6]

Rheumatic heart disease is one of the most common cause of cardiac valvular disease, and in particular in India the number is very significant. Most of the patients are in third decade of life, but no age is exempt, except the first decade. Symptomatology may be gradual, or sudden onset. The natural history of the disease is also not well known though varies from individual to individual. The patients may present with stenotic or regurgitant lesions, or a combination of both, the disease may affect single or multiple valves.

Many previous studies have compared the outcomes of double valve replacement (DVR) as per the implanted prosthesis, still there is existing controversy regarding selection of ideal heart valves in a patient undergoing DVR [7-9, 11-13]. Some studies on DVR, along with the type of valves, have also studied the effects of pre-operative and intra-operative variables on the outcomes [3-5, 10-14]. The operative risk of DVR is still between 5 and 13%, whereas an isolated aortic valve replacement (AVR) the risk is less than 4% [9, 10].

Pyrolytic carbon is used to manufacture St Jude Medical (ST Jude Medical Inc, St Paul, Minn) bi-leaflet valve, which was introduced in 1977 and got FDA approval in 1982. Its central flow design offers low transvalvular gradient, and pyrolytic carbon is used to make it durable and resistant to thrombus. These attributes have been verified in studies which have used this valve [5, 16-23].

## Material and methods:

Retrospectively we analysed the data of all the patients who underwent Double Valve Replacement + Tricuspid valve repair/annuloplasty. We take into account all the patients from October 2017 to January 2019, who underwent the above-mentioned procedure on an elective basis after complete pre-operative workup.

The patients who were excluded were –

1. Any patient undergoing concomitant Coronary artery bypass grafting – 04 cases
2. Any patient undergoing emergency valve surgery - 06 cases
3. Any patient who received Bioprosthetic Valve as replacement – 12 cases
4. Any patient who had mitral valve repair coupled with aortic valve replacement - 02 cases

5. Any patient who underwent concomitant aortic root enlargement- 07 cases

At our institute, the following mechanical prosthesis were used in the patients who are included in the study –

1. For mitral valve replacement –
  - a. St Jude Medical Masters Series Mechanical Heart Valve (sizes 25 mm to 33 mm)
2. For Aortic valve replacement –
  - a. St Jude Medical Regent Mechanical Heart Valve (sizes 17mm to 25 mm)
3. For Tricuspid Valve Annuloplasty –
  - a. Medtronic Contour 3D 690R Annuloplasty Ring – Tricuspid Operative Procedure –

All patients underwent DVR + TV repair(double valve replacement + tricuspid valve repair) under standard cardiopulmonary bypass. Myocardial protection was accomplished by the collective institution of moderate hypothermia, topical cooling of myocardium with ice slush and ostial perfusion of the coronaries after aortotomy with potassium cardioplegia. At our institute most commonly used cardioplegia solutions are Del Nido and Custodial, as per the surgeon's preference. The valve replacement was done as per the usual protocols using Teflon pledgeted sutures. All the mitral valves and aortic valves were put as per the minimum size as advocated by matching patient's body surface area to the charts having Effective Orifice Area (EOA) of the St Jude Mechanical prosthesis, to avoid any incidence of patient prosthesis mismatch (PPM). Intra-operative and post-operative operative blood transfusions, inotropic requirements, time on ventilatory support varied on per patient basis as per requirement.

Immediate post-operative complications occurring within 10 days of the surgery were taken into account and included re-exploration, low cardiac output syndrome, transfusion related acute lung injury, refractory arrhythmias, acute renal failure, evidence of cerebrovascular incident, stuck valve (prosthetic valve thrombosis), sepsis and death.

The anticoagulation regime consisted of giving patient warfarin loading dose followed by titration of the dose to maintain the international normalized ratio (INR) between 2.5-3.5.

Routine post-operative 2D echo was done in all the patients on Post-operative day 1 and then as and when required.

### Results :

There were total of 72 patients who were included in the study with 46 males (63.8%) and 26 females (36.2%). The average age amongst males was 33 years while amongst female it was 32 years. The other demographic details are evaluated in Table 1. Out of 72, aetiology of 70 cases was Rheumatic heart disease while there was one case of degenerative valvular disease while the other one was having Marfan's Syndrome. There were 3

cases who underwent Percutaneous trans-septal mitral commissurotomy before they had to undergo Double valve replacement, while there were 4 cases who had an operative history of Closed Mitral Valvotomy, with a scar mark on the left 5th intercostal space.

69.4% of the patients were NYHA class II, 27.7% patients were NYHA class III, and 2.70% patients were NYHA class IV. 33.33% patients were pre-operatively having Atrial fibrillation while 66.66% patients were in Normal sinus rhythm. LA clot was present in 8.33% of patients, while 2.77% of them had a history of Cerebrovascular accident and were on anti-epileptic drugs. 11.11% patients were admitted with congestive cardiac failure, and were first stabilised using diuretics and inotropic supports and then were posted for surgery. 8.3% patients were diabetic while 16.6% patients were hypertensive. There was one case having infective endocarditis (Table 2). Left ventricular ejection fraction of 20-40% was in 6.94% of patients, 87.5% patients had left ventricular ejection fraction of 40-60% while 5.55% patients had left ventricular ejection fraction of >60%.

The valve lesions consisted of stenotic, regurgitant and mixed type in both aortic and mitral valve, while tricuspid valve mainly had regurgitation as the lesions. 26.3% patients had mitral regurgitation, 31.9% had stenotic mitral valve while 41.8% had mixed type of lesion. Meanwhile 48.6% of patients had aortic regurgitation, only 5.5% had pure stenotic lesions while 45.8% had mixed type of lesions (Table 3). The severity of tricuspid valve regurgitation is summarised in Table 4. 61.1% had no evidence of pulmonary arterial hypertension (PAH), 5.5% had mild PAH, 23.6 % had moderate PAH while 9.7% had severe PAH. Those patients having severe pulmonary hypertension were started on Sildenafil (dose as per weight) post-operatively.

Among the intra-operative parameters, the average aortic cross clamp time was 169.04 minutes while average total cardiopulmonary bypass time was 213.84 minutes. 5.55% patients underwent left atrial reduction plasty along with double valve replacement. 37.50% patients had total chordal preservation using various techniques while 34.72 % patients had posterior chordal preservation. In 27.77% patients, chordae could not be preserved due to the severity of the disease. The different sizes of valves put in the patients are summarised in Table 5, 6 and 7. The most common size of mitral valve implanted was 29mm while 19mm was the most common aortic valve which was implanted. It is to be noted that tricuspid repair was done using annuloplasty rings while one patient each underwent De Vega annuloplasty and Commissurotomy respectively.

The overall mortality was 5.55% of total patients. 2.77% patients had transfusion related acute lung injury as cause of death while one patient each was lost due to acute kidney injury and sepsis respectively. We could successfully manage the cases of low cardiac output syndrome patients in the post-operative settings as per standard protocols and all of them

eventually recovered. 11 patients had refractory arrhythmias, and all of them had pre-operative atrial fibrillation. The rate was then controlled by the combination of beta blockers, calcium channel blockers and amiodarone, on per patient basis. There were no reported cases of prosthetic valve thrombosis while one patient had post-operative cerebrovascular accident which was managed conservatively (Table 8).

#### Demographic Details – (Table 1)

Parameter	Male	Female
Average Age	33 years	32 years
Average weight	49.57 kg	49.8 kg
Average Height	158.46 cm	155.34 cm
Average BSA (Body surface area)	1.48	1.46
Minimum Age	14 years	18 years

#### Other Parameters – (Table 2)

	Total	% OF TOTAL PATIENTS
LA/LAA Clear	66	91.6
LA/LAA Clot	06	8.33
History of CVA	02	2.77
CCF	08	11.11
Diabetes Mellitus	06	8.33
Hypertension	12	16.66
Infective endocarditis (active)	01	1.38

LA – left atrium, LAA- left atrial appendage, CVA- cerebrovascular accident

CCF- congestive cardiac failure

#### Characteristic of valve lesions: - (Table 3)

TYPE OF LESION IN MITRAL VALVE	Total	% OF TOTAL PATIENTS
Regurgitation	19	26.3
Stenosis	23	31.9
Mixed	30	41.8
TYPE OF LESION IN AORTIC VALVE	TOTAL	% OF TOTAL PATIENTS
Regurgitation	35	48.6
Stenosis	04	5.5
Mixed	33	45.8

#### Associated Tricuspid Valve Disease: - (Table 4)

	Total	% OF TOTAL PATIENTS
No Disease	32	44.4
Mild Tricuspid Regurgitation	13	18.05
Moderate Tricuspid Regurgitation	14	19.4
Severe Tricuspid Regurgitation	12	16.6

#### Mitral Valve Size – (Table 5)

Valve Size (in mm)	Total	% OF TOTAL PATIENTS
25mm	06	8.33
27mm	19	26.38
29mm	33	45.83
31mm	13	18.05
33mm	01	1.38

#### Aortic Valve Size – (Table 6)

Valve Size (in mm)	Total	% OF TOTAL PATIENTS
17	03	4.16
19	30	41.66
21	26	36.11
23	09	12.50
25	04	5.55

#### Tricuspid Valve Intervention-(Table 7)

	Total	% OF TOTAL PATIENTS
No Intervention	53	73.61
De Vegas Annuloplasty	01	1.38
Commissurotomy	01	1.38
26mm ring	01	1.38
28mm ring	06	8.33
30mm ring	06	8.33
32mm ring	04	5.55

**Post-Operative complications – (Table 8)**

Complications	Number of Patients	Number of Deaths	% of total patients
Re-Exploration	05	None	None
LCOS	13	None	None
TRALI	04	02	2.77
AKI	03	01	1.38
Refractory Arrhythmias	11	None	None
CVA	01	None	None
Prosthetic Valve Thrombosis	None	None	None
Sepsis	04	01	1.38

LCOS – Low cardiac output syndrome, TRALI – Transfusion related acute lung injury, AKI – Acute kidney injury, CVA- Cerebrovascular accident

**Discussion**

The morbidity and mortality associated with double valve replacement (DVR) is one of the many challenges for a cardiac surgeon. In a developing country like India, the patients often present late to the tertiary centre for their treatment. This delay in starting the treatment often puts the patient at higher risk of morbidity and mortality post-surgery. Medical and surgical management of the patient with multiple valvular disease is according to severity of each valvular lesion and myocardial factors are also taken in account.

Cartwright et al first reported concurrent aortic and mitral valve replacement.<sup>[24]</sup> Besides rheumatic heart disease, connective tissue disorders like Marfan's Syndrome may affect the annulus of more than one valve leading to varied lesions. Degenerative calcifications of aortic valve can be associated with mitral annular dilatation. Other pathological conditions like infective endocarditis and papillary muscle dysfunction due to ischaemia may be a cause of regurgitation in multiple valvular disease.<sup>[25]</sup>

Operative risk of DVR is about 50% higher than that for the single valve replacement, which due to advancement in modern technologies has shown a declining trend and it now ranges from 5 to 10%.<sup>[26]</sup> 63% survival rate for DVR equated to 80% for single valve has been stated as early as 1993.<sup>[27]</sup>

The long-term survival depends on many patient demographic factors as discussed earlier, the time of presentation, NYHA class at the time of presentation and the duration of the disease. Intraoperative and postoperative factors like myocardial protection, aortic cross clamp time and total cardiopulmonary bypass time are directly or indirectly related to the morbidity and mortality of the patients. Also, the comorbidities of the patient play a significant role.

We must stress that the severity of combined valvular lesions must be addressed before deciding a specific form of therapy. Co-existing lesions can adversely complicate the surgery or alter the expected post-operative recovery.<sup>[28,29]</sup>

Timing for surgical intervention in a patient having combined valvular disease is not defined yet.<sup>[30]</sup> Heart failure and sudden death are the foremost late causes of death. Heart failure can occur in a subtle way, many years after valve replacement. The advent of new treatment regimes, such as angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin II receptor blockers (ARB's), has led to long-term improvement of secondary left ventricular failure.

Pre-operative left ventricular ejection fraction (LVEF) is an important determinant of post-operative long-term survival after DVR. The post-operative recovery after successful DVR is also limited when pre-operative LVEF is severely depressed.<sup>[31,32]</sup>

Peri-operative mortality in our study was 5.5%. These results compare favourably with other long-term studies of this prosthesis.<sup>[21-23]</sup> Our data shows that preoperative patient characteristics such as age, previous valve replacement, cardiac function, and coronary disease may have a greater influence on operative mortality than the type of valve prosthesis implanted. Similar operative mortality is seen in other studies using various types of valves.<sup>[9, 33-35]</sup>

Diseased tricuspid valve may cause chronically overloaded right ventricle which can become dilated and in post-operative state, biventricular failure may occur. Tricuspid valve repair should be done when significant disease or regurgitation is present, because only correction of left sided disease will not eliminate the disease of right side. Though, this leads to increased duration of operation<sup>[37,38]</sup>. Many studies have shown that if LVEF is compromised in pre-operative state, potential for improvement after DVR is limited.<sup>[32,36,39]</sup>

Czer et al<sup>[18]</sup> described the actuarial survival rate at was 51% for AVR, 47% for DVR, and 41% for MVR after 9 years. Arom et al<sup>[5]</sup> reported, which comprised of operative deaths, 9-year survival rate of 75.5% for AVR, 73.8% for DVR, and 57.7% for MVR. Their series consisted of patients who also required concomitant coronary artery bypass grafting.

The occurrence of thromboembolic and anticoagulant related haemorrhage depends on the anticoagulant state. In most series, warfarin is used for anticoagulation. However, the method for testing the anticoagulant state, the adequate range of warfarin control, or both, differ from institution to institution. At our institute we use INR (international normalised ratio) as the standard method for checking the anticoagulant state of the patient.

A patient having a mechanical valve who has suffered intracranial bleed, the role of anticoagulant, whether to continue or to stop during the treatment, baffles the treating doctor. However, the anticoagulation on which the patient is,

can be withheld safely for 7-14 days if the patient has suffered intracranial bleed with low incidence of thromboembolic episode. Patient having prosthetic valves, anticoagulation in the form of heparin can be instituted as early as 3 days and can be switched back to oral anticoagulation on which the patient was, at 7 days, without any major concern for bleeding [40].

Long-term survival was significantly reliant on on the pre-operative LVEF, as also shown by Mueller et al [41]. Prolonged ventilation, inotropic support and long ICU stay was seen more in patients with LVEF of less than 45%. Mortality and morbidity being more in patients with low LVEF is well documented and observations in our study are comparable to others. [42-45]

Literature shows a prevalence of mitral regurgitation, trailed by aortic regurgitation. [7,24] This study shows a higher prevalence of aortic regurgitation, followed by mixed mitral lesions, and only then mitral and aortic stenosis lesions.

Bioprosthetic valve is implanted in patients with contraindication to anticoagulation therapy, with reduced life expectancy, a woman who wishes to complete a family, in addition to the social indicator which specifies tough access to anticoagulant therapy. [24,43,44,45]

As per Bortolotti et al mechanical valves are better in the long term due to their superior durability.[7]

There was not a single case of paravalvular leak in present study. It is said that the use of interrupted horizontal mattress sutures with Teflon pledgets play a major part in the prevention of paravalvular leak. Bortolotti et al stated an incidence of the same in  $0.67 \pm 0.2\%$  in a study of DVR using mechanical prostheses.[7] Sethia et al reported on a 14-year experience noting a high incidence of paravalvular leak (2% per year) and suggest that horizontal mattress sutures improve valve stability and may reduce this valve related complication, along with the fact that it also reduces the chance of ventricular rupture[46]

### Conclusion

In summary, operative mortality for patients undergoing combined aortic and mitral valve replacement has decreased significantly over the past 10 years because of improvements in myocardial protection and other advances in perioperative care. Patients who are classified in higher NYHA grades, with hemodynamically significant aortic and mitral valvular lesions can be offered DVR with low operative risk and a significant chance for improvement in the quality of their lives. The survival of patients labelled pre-operatively as higher NYHA grade is probably better than that of patients who do not undergo surgery, even though this point is un-documented.

For patients with symptomatic cardiac failure, DVR is sometimes performed as a life-saving effort. Most of these patients are improved after surgery. In our study, the peri-

operative risk factors and mortality is having comparable results with other studies. Good surgical technique and advancement in technology has significantly reduced the morbidity and mortality associated with DVR. Advancement in valve designs may further reduce the anti-coagulation related risk factors to the patients.

### Limitation of the study

A possible limitation of the study is its retrospective character. Additional follow-up may be able to show the current status of all survivors in the near future

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