

## Original Research Article

# Factors influencing the outcome of double valve replacement surgery

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### ABSTRACT

**Background:** Data on the influence of surgical variables in mortality and morbidity of patients undergoing double valve replacement (DVR) surgery are scarce. Objective of this study was to identify preoperative, intra operative and post-operative factors associated with mortality and morbidity of patients undergoing DVR surgery.

**Methods:** Between 2010 and 2016, patients who underwent double (Mitral and Aortic) valve replacement at our institution were analyzed. These patients were studied retrospectively for preoperative data and postoperative outcome including causes of deaths and the data was analyzed statistically.

**Results:** There were 150 patients, 107 were male (71.3%) and 43 were female (28.6%) Present study revealed a high mortality rate among female patient undergoing DVR surgery than males, which is statically significant at  $p < 0.05$ . Pre-operatively 100 patients (66.6%) were class IV NYHA symptoms. This study finds a significant correlation between preoperative NYHA and hospital mortality with higher mortality rate in NYHA class IV patients with  $p$ -value  $< 0.00001$  which is significant at  $p < 0.05$ . Long-term survival was also seen to be significantly dependent on the preoperative LVEF. Among intra operative parameter average total surgical time was 197.70 minutes (3.29 hours); average total cardio pulmonary bypass time was 82.67 minutes (1.37 hours) and average cross clamp time was 67.28 minutes (1.12 hours). Outcome groups (in-hospital death vs. hospital discharge) had a significant statistical difference in relation to variables, respectively: aortic cross clamp time (in minutes) of 77.66 and 67.40 ( $p = 0.001$ ); CPB 95.66 and 84.63 ( $p = 0.006$ ); and total surgical time 208.75 and 186.04 ( $p = 0.002$ ). Among the post-operative complications, immediate complications occurring within 7 days of surgery were; low cardiac output syndrome in 9.3% ( $n = 14$ ), bleeding leading to exploration was 8% ( $n = 12$ ), refractory arrhythmias in 3% ( $n = 5$ ), sepsis in 4% ( $n = 6$ ) and acute renal failure in 2% ( $n = 3$ ). Inter mediate post-operative complications (7 to 30 days of surgery) were wound infection in 26 patients (17.3%). There was no incidence of stuck valve or pulmonary thrombo embolism Overall mortality was 8% (12 patients) all within 30 days of operation. There was no statistical difference between the outcome and the types of prostheses used, either biological or metallic ( $p = 0.219$ ).

**Conclusions:** The study results have demonstrated a favourable survival outcome after DVR surgery. An advance age, female sex, a higher NYHA class, poor left ventricular function is associated with poor outcome. The operative mortality in patients undergoing DVR also depends on intra operative factors like total surgical time, CPB 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 surgery, Hospital mortality

## INTRODUCTION

Surgery for combined aortic and mitral valve disease or Double valve replacement surgery (DVR) was introduced in the early 1960s; until the mid-1970s, it was associated with a high operative mortality rate and unsatisfactory late results as the standard surgical techniques were yet to be established.<sup>1-3</sup> As surgical techniques got refined with time, improvement in CPB (cardio pulmonary bypass) techniques and good suture material was introduced, there was a marked decrease in operative mortality rates and a considerable increase in late postoperative survival rates in the 1980s and 1990s.<sup>4,5</sup> At present the perioperative risk of combined mitral and aortic valve surgery lies between 5% and 14%.<sup>6</sup>

Despite advances in perioperative evaluation, operative techniques, and post-operative care, few studies have focused on early postoperative morbidity and mortality of double valve surgery.<sup>7,8</sup> Determination of preoperative risk factors for adverse events should allow cardiac surgeons to better stratify high risk patients and develop strategies to improve the surgical outcome. This retrospective study of our institutional experience is designed to analyze the short-term results of double valve replacement (DVR) surgery and to identify the variables that contribute to the perioperative mortality and morbidity.

## METHODS

The study was conducted in the Department of Cardiovascular and Thoracic Surgery (CTVS), V.M.M.C and Safdarjung Hospital, New Delhi, India. All the valvular heart disease patients who have undergone DVR surgery from January 2010 to December 2016 were included in the study. Data was collected from patients' medical records in the hospital. This was a retrospective study and no informed consent form was signed.

### Inclusion criteria

All patients who underwent both aortic and mitral valve replacement.

### Exclusion criteria

- Patients who underwent valve surgery along with CABG.
- Patients with redo surgery.

Patient and procedure information was collected. Data included age, sex, associated comorbid conditions like; diabetes mellitus with and without sequelae, chronic renal failure, congestive heart failure, preoperative atrial fibrillation, type of valve lesion, functional class (NYHA) was analyzed. The variables investigated for intraoperative factors influencing the outcome were: cardio pulmonary bypass time, cross clamped time and total surgical time.

## Operative technique

In the surgical procedure, patients were placed in the supine position; a catheter was installed to measure the mean arterial pressure, and CVP catheter for central access route. Median sternotomy and systemic heparinization were followed by cannulation of the ascending aorta and BiCaval cannulation. All patients were operated by establishment of cardiopulmonary bypass with moderate hypothermia and with the use of membrane oxygenator. Myocardial protection was offered by instillation of cold crystalloid cardioplegia given through the coronary ostia that was repeated every 20 to 25 minutes. Retrograde cardioplegia was not used in any case. Improved protection of the ventricles was provided by use of topical ice slush. In all patients either Mechanical valve (ATS or St Jude Mechanical valve) or Bioprosthetic valve was used. The mitral valve was replaced first, but the aortic valve was excised as the first step through the aortotomy. The method invariably employed for both mitral and aortic valve implants used interrupted horizontal mattress sutures with Teflon pledgets.

## Postoperative management

All patients were managed in the intensive care unit with monitoring of vitals, urine output and serial arterial blood gas analysis. Judicious use of inotropic agents provided further therapeutic support. Ventilatory support was provided for 24 to 48 hours for patients with pulmonary hypertension. Oral anticoagulation was initiated with acenecumarol (Acitrom) from the day after surgery. A target INR of 2 to 3 was maintained. All patients underwent post-operative echo to check valve function before discharged.

## Follow-up

Our patients were followed up monthly so as to review the INR status, which needed a close watch to be maintained in a therapeutic range and 2D echo was repeated after 3 to 6 months.

## RESULTS

There were 150 patients, 107 were male (71.3%) and 43 were female (28.6%). Pre-operatively 100 patients (66.6%) were Class IV NYHA symptoms and 40 patients (26.6%) had Class III NYHA symptoms and 10 patient (6%) were class II NYHA symptoms (Table 1).

Pre operative co morbid disease were as follows: 24.6% had diabetes mellitus, 51.3% had pre existing atrial fibrillation, 41.3% had hypertension and 33.3% were in CHF. 16% of the patients had history of cerebro vascular accident (CVA). 10 patients had deranged renal parameter with creatinine level more than 2mg%. 76% patient had left ventricular hypertrophy in ECG.

10% (n=15) of patients had left ventricular ejection fraction (LVEF) between 20 to 40%, 40% (n=60) had LVEF between 40 to 60% and 50% (n=75) had LVEF more than 60% (Table 2).

**Table 1: Preoperative characteristic of patients.**

Parameter	Number of patients	Percentage (%)
Male	107	71.3
Female	43	28.6
Diabetes mellitus	37	24.6
Hypertension	62	41.3
Atrial fibrillation	77	51.3
CHF	50	33.3
<b>NYHA functional class</b>		
I	0	0
II	10	6
III	40	26.6
IV	100	66.6
History of CVA	24	16
Serum creatinine >2	10	6
ECG (LVH)	115	76.6

**Table 2: Left ventricular ejection fraction.**

Left ventricular ejection fraction	Number of patients	Percent
20-40 %	15	10
40-60%	60	40
>60%	75	50

The valve lesion among these patients was as follows. The mitral valve lesions were as follows 25.3% had severe mitral stenosis, 45.3% had severe mitral regurgitation and 29.3% had mixed lesion. The aortic valve lesions were; 50% had severe aortic regurgitation and 20% had severe aortic stenosis and 30% had mixed lesion.

**Table 3: Pathophysiological characteristic of valve lesion.**

Valve lesion type	Number of valves	% of patients
<b>Aortic valve</b>		
Stenosis	30	20
Regurgitation	75	50
Mixed	45	30
<b>Mitral valve</b>		
Stenosis	38	25.3
Regurgitation	68	45.3
Mixed	44	29.3

Patients who underwent DVR surgery, 92.77% received mechanical valve; of which 67.77% received ATS and 25% received SJM while 7.2% receive bio prosthetic valve.

**Table 4: Surgical time.**

Time in minutes	Average
Cross clamp	67.28
CPB	82.67
Total surgical time	197.70

Among intra operative parameter average total surgical time was 197.70 minutes (3.29 hours); average total cardio pulmonary bypass time was 82.67 minutes (1.37 hours) and average cross clamp time was 67.28 minutes (1.12 hours).

**Table 5: Postoperative complication and death.**

Complication	Number of patients (%)	Number of death (%)
Low cardiac output syndrome	14 (9.3%)	12 (85.7%)
Exploration for bleeding	12 (8%)	1 (8.3%)
Acute renal failure	12 (8%)	8 (66.6%)
Sepsis	6 (4%)	4 (66.6%)
Refractory arrhythmias	5 (3.3%)	1 (20%)
Wound infection	26 (17.3)	0 (0%)

Among the post operative complications, immediate complications occurring within 7 days of surgery were; low cardiac output syndrome in 9.3% (n=14), bleeding leading to exploration was 8% (n=12), refractory arrhythmias in 3% (n=5), sepsis in 4% (n=6) and acute renal failure in 2% (n=3). Inter mediate post-operative complications (7 to 30 days of surgery) were wound infection in 26 patients (17.3%). There was no incidence of stuck valve or pulmonary thromboembolism.

Overall mortality was 8% (12 patients) all within 30 days of operation. In all the twelve-patient death resulted from low cardiac output syndrome. Eight patient developed acute renal failure along with low cardiac output syndrome, four patient developed sepsis and one patient expired due to post-operative bleeding and development of low cardiac output syndrome.

## DISCUSSION

This study reviews our experience of combine aortic and mitral valve operation (DVR) performed over a 6-year period. At present the risk of perioperative mortality had declined considerably to between 5% and 12%.<sup>8</sup> The hospital mortality of 8% in the present study compared favourably with rates reported elsewhere. For example Bortolotti and associates cited hospital mortality of 19% in 221 patients having a dual mechanical prosthesis.<sup>11</sup> Bernal et al from Spain reported a mortality of 10.7% after double valve replacement using the Carbomedics valve.<sup>15</sup> Brown and co-workers cited an in-hospital mortality of 14%.<sup>9</sup> The long-term survival depends strongly on the preoperative New York Heart Association functional class (NYHA), advanced age, body surface

area, pulmonary artery hypertension, left ventricular enlargement, accompanying ischemic heart disease and ejection fraction. Surgical outcome also depends on aortic cross clamped time, total surgical time, experience of operating surgeon, technique and selection of prosthetic valve in addition to other systemic illnesses like diabetes mellitus and chronic renal failure.<sup>4</sup>

In resemblance to present observation, (107 males: 43 females) multi valvular disease has been reported more in male patients as reported in previous studies.<sup>9</sup> Present study revealed a high mortality rate among female patient undergoing DVR surgery than males, (Male:Female 5:7) which is statically significant at  $p<0.05$ .

The major predictor of increased risk continues to be the advanced preoperative functional disability. Majority of the patients in this study were in NYHA functional class III to IV (140 patients) is in similarity to other studies.<sup>8,10</sup> This study finds a significant correlation between preoperative NYHA and hospital mortality with higher mortality rate in NYHA class IV patients with  $p\text{-value}<0.00001$  which is significant at  $p<0.05$ .

Long-term survival was also seen to be significantly dependent on the preoperative LVEF, as shown also by Mueller et al.<sup>15</sup> Prolonged ventilation, inotropic support and long ICU stay was observed more in patients with ejection fraction of less than 45%. Mortality and morbidity being more in patients with less ejection fraction is well documented and present observations are comparable to others.<sup>8-9,12,14</sup>

This study show similar results as other previous studies, with regard to the greater involvement of the mitral valve, followed by the aortic valve. Literature indicates a predominance of mitral regurgitation, followed by aortic regurgitation.<sup>3,20</sup> This study shows a higher prevalence of aortic regurgitation, followed by mitral regurgitations, and only then mitral and aortic stenosis lesions.

Majority of our patients were under 40 years of age hence mechanical prosthesis was preferred, whereas in older patients bioprosthetic valves was preferred.<sup>15</sup> Bioprosthetic valve is indicated for patients with contraindication to anticoagulation therapy, with reduced life expectancy, in addition to the social indicator difficult access to anticoagulant therapy.<sup>3,9-12</sup> In majority of our patients mechanical prosthesis was preferred (St Judes valves in 55 patients, ATS valve in 75 patients), whereas in older patients bioprosthetic valves are preferred (bioprosthetic in 20 patients). According to Bortolotti et al mechanical prostheses perform better in the long term owing to their superior durability.<sup>11</sup> There was no statistical difference between the outcome and the types of prostheses used, either biological or metallic ( $p=0.219$ ). Hence choice of replacement device does not affect long term survival. Aortic cross clamp time, CPB time and total surgical time were variables that have influenced the occurrence of death in this study. Outcome

groups (in-hospital death vs. hospital discharge) had a significant statistical difference in relation to variables, respectively: aortic cross clamp time (in minutes) of 77.66 and 67.40 ( $p=0.001$ ); CPB 95.66 and 84.63 ( $p=0.006$ ); and total surgical time 208.75 and 186.04 ( $p=0.002$ ). The literature indicates a CPB time of  $>120$  minutes as a risk factor for mortality in heart surgeries.<sup>12-14</sup> In this study we observed more morbidity and mortality in patients with more than 95 minutes of CPB. Likewise, the prolong cross clamp time was associated with an increase of deaths, reported by the literature, which is 75 minutes.<sup>12</sup>

In the present study, an anticoagulant regimen with oral anticoagulant was adhered to with a target INR of between 2.0 and 3.0. The regimen was optimized to offer sufficient protection against thromboembolism and stuck valve on the one hand, and bleeding on the other hand. In the present study, there were 8 cases of major bleeding that required re exploration, and 15 cases of minor bleeding that did not require hospitalization. This compared favourably with a rate of 2.6% per pt-yr for bleeding events reported by Mueller et al.<sup>15</sup>

There was not a single case of paravalvular leak in present study. It is believed that the use of interrupted horizontal mattress sutures with Teflon pledgets play an important role in the prevention of paravalvular leak. Bortolotti et al reported an incidence of paravalvular leak of  $0.67\pm0.2\%$  in a study of DVR using mechanical prostheses.<sup>11</sup> Sethia and coworkers reported on a 14-year experience noting a high incidence of paravalvar leak (2% per year) and suggesting along with other experts that horizontal mattress sutures provide better valve stability and may eliminate this adverse valve-related complication and reduces the risk of ventricular rupture.<sup>19</sup>

In present study, we have routinely preserved the posterior mitral leaflet. As in a review by Talwar et al there was better long-term systolic function and LV performance both at rest and during exercise.<sup>16</sup> They also demonstrated increased LV end-diastolic pressures after chordal transection and conventional MVR where as these decreased after MVR with chordal preservation. It preserves LV geometry and function, reduces the operative mortality, improves early and long term results.

## CONCLUSION

In conclusion, the study results have demonstrated a favorable survival outcome after DVR, and have established the continued role for this procedure in patients with advanced double valve disease. An advanced age, female sex, a higher NYHA class, poor left ventricular function are associated with poor outcome. Surgical intervention should be done before irreversible left ventricular dysfunction. The operative mortality in patients undergoing DVR also depends on intra operative factors like total surgical time, CPB 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. Good surgical technique has virtually eliminated the risk of paravalvular leak and adherence to strict anticoagulation regime with regular follow up minimizes the chances of anticoagulation related complications.

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