IS DECLOTTING A BETTER PROCEDURE THAN REDO MVR FOR STUCK MITRAL VALVE?

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ABSTRACT

Objective: To evaluate and compare the outcome of declotting versus Redo Mitral Valve replacement for stuck mitral valve in the early postoperative period.

Study Design: Retrospective interventional study.

Place and Duration of Study: Armed Forces Institute of Cardiology & National Institute of Heart Diseases (AFIC-NIHD) Rawalpindi from 1st Jan, 2010 to 31st Oct, 2013.

Patients and Methods: A total of 36 patients were selected. Group A (n = 28) underwent declotting & group B (n = 08) were treated by redo mitral valve replacement (MVR). Diagnosis of prosthetic valve obstruction was made on the basis of history, clinical examination, echocardiography and fluoroscopy. All patients were operated under general anesthesia & cardiopulmonary bypass (CBP). Total clamp and CPB time were recorded. Post operatively, patients were evaluated with daily progress parameter. The hemodynamic status, isotropic support, ventilation time, intensive care ward and total hospital stay were also recorded for comparison. Two-dimensional echocardiography was done before extubation and at discharge. Mortality rate was also compared in the two groups.

Result: No statistical difference was found on the basis of gender, age, interval between initial mitral valve replacement (MVR) and redo operation or decloting, anticoagulation status, New York Heart Association (NYHA) functional class, international normalized ratio (INR) level, trans thoracic echocardiography and fluoroscopy. The mean CBP time & cross clamp time was significantly less in group A than group B. Similarly mean ventilation time in group A was significantly less than in group B. The mean ITC stay was & mean hospital stay was not statistically significant. The mortality rate in group A & B was 7.14% & 50% respectively which was statistically significant.

Conclusion: Prosthetic valve thrombosis is a life threatening complication after mechanical mitral valve replacement with high mortality without timely and effective surgical intervention. Declotting, being a less aggressive surgical technique is recommended because of better outcome in terms of morbidity and mortality in the early post-operative period.

Keywords: Cardiopulmonary bypass, Cross clamp, Declotting, Stuck valve

INTRODUCTION

Mechanical heart valves have the advantage of longevity but carry a risk of thrombosis which is dependent on valve design, materials and host related interface. The four most dreadful complications following mechanical prosthetic valve replacement are dehiscence /disruption /dysfunction, infection, embolism and acute obstruction due to thrombosis / pannus formation. Endocarditis, dehiscence and pannus are common to both biological and mechanical valves; acute prosthetic thrombosis is mostly a complication of mechanical valves.

An acute obstruction of mechanical mitral valve is a life-threatening complication and is caused by the formation of fresh clot, fibrous tissue overgrowth (pannus) or both. It is often associated with embolism and / or life threatening deterioration in patient’s clinical status.

Prosthetic valve thrombosis is defined by any thrombus, in the absence of infection, attached to or near an operated valve, occluding part of the blood flow or interfering with valvular function. The most frequent underlying reason
for thrombosis is inadequate anticoagulant therapy with warfarin. The choice of treatment depends on the condition of the patient, echocardiographic & fluoroscopic findings and the expertise available. Different modalities include thrombolysis, surgical declotting of mitral prosthetic valve and redo mitral valve replacement (MVR).

In Pakistan, valvular disease is usually of rheumatic origin & is considered to be a disease of poor people who are less educated. After mitral valve replacement with prosthetic valve, in spite of detailed instruction about prompt anticoagulation and heralding signs of stuck valve, stuck mitral valve appears to be an emerging problem in our setup. Thrombolytic therapy should be reserved for patients with prosthetic valve thrombosis and New York Heart Association (NYHA) Class-IV, a low cardiac output state or in any patient in whom operation carries an unacceptable risk, or for small thrombi of less than 5 mm in size. However some do not agree with the policy of carrying out thrombolysis in patients who are hemodynamically unstable. Thrombolytic therapy also carries risk of bleeding, embolism and recurrent thrombosis. Keeping in view the limitation of thrombolytic therapy with additional complications of the procedure, a rationale is developed to adopt a suitable surgical technique with better results.

This study is designed to assess the outcome of the two surgical techniques in term of early recovery with less morbidity & mortality in the early post-operative period.

Table-1: Comparison of pre-operative variables between the groups.

<table>
<thead>
<tr>
<th>Preop Variable</th>
<th>Group A (n=28)</th>
<th>Group B (n=08)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>7 (25 %)</td>
<td>4 (50%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Female</td>
<td>21 (75%)</td>
<td>4 (50%)</td>
<td></td>
</tr>
<tr>
<td>Age (in years)</td>
<td>35.32 + 10.57</td>
<td>28.13 + 6.77</td>
<td>0.09</td>
</tr>
<tr>
<td>Interval (MVR/ Stuck valve in Months)</td>
<td>28.93 + 26.82</td>
<td>37.13 + 50.56</td>
<td>0.98</td>
</tr>
<tr>
<td>Anticoagulation status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor compliance</td>
<td>19 (67.9%)</td>
<td>7 (87.5%)</td>
<td>0.42</td>
</tr>
<tr>
<td>Inadequate anticoagulation</td>
<td>9 (32.1%)</td>
<td>1 (12.5%)</td>
<td></td>
</tr>
<tr>
<td>NYHA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td>13 (46.4%)</td>
<td>6 (75%)</td>
<td>0.23</td>
</tr>
<tr>
<td>Class IV</td>
<td>15 (53.6%)</td>
<td>2 (25%)</td>
<td></td>
</tr>
<tr>
<td>INR</td>
<td>2.26 + 1.45</td>
<td>1.57 + .48</td>
<td>0.22</td>
</tr>
<tr>
<td>Echocardiography (MPG mmHg)</td>
<td>20.39 + 5.62</td>
<td>19.44 + 7.11</td>
<td>0.33</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial</td>
<td>20 (71.4%)</td>
<td>6 (75%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Complete</td>
<td>8 (28.6%)</td>
<td>2 (25%)</td>
<td></td>
</tr>
</tbody>
</table>

PATIENTS AND METHODS

This retrospective interventional study was conducted in Cardiac Surgical Department of Armed Forces Institute of Cardiology & National Institute of Heart Diseases (AFIC-NIHD) Rawalpindi from 1st Jan, 2010 to 31st Oct, 2013. The Institutional Ethics Committee for Clinical Research approved the protocol.

All the patients who were diagnosed as stuck mitral valve and were operated during the study period were included in the study. All patients of both sexes, pregnant, partial and complete stuck valve & stuck mitral valve with other valve pathology were included in the study, while patients with multi-organ failure, chronic prosthetic mitral valve dysfunction & thrombus of less than 5 mm in size were excluded from the study.
A record of 36 patients was collected from Cardiac Surgery Database maintained in the department of Cardiac Surgery who underwent emergency surgery for stuck mitral valve during the period. These patients were divided in two groups based on the type of surgical intervention. Group A (n = 28) consisted of patients who underwent declotting of mitral prosthesis while group B (n: 08) consisted of patients having explantation of stuck prosthesis with Redo Mitral valve replacement (MVR).

In all patients, the diagnosis of prosthetic valve obstruction was made on the basis of history, clinical examination, echocardiography and fluoroscopy. Patients’ symptoms were recorded, including symptom duration, heart failure, expressed as New York Heart Association (NYHA) class, palpitations and syncope. Anticoagulation status was learned from admission international normalized ratio (INR) values. Inadequate anticoagulation was defined as interruption of anticoagulant therapy or INR level of less than 2.5 at the time of diagnosis of stuck valve. Two-dimensional echocardiography was performed with special emphasis on looking for opening excursion and completeness of closure of the prosthetic valve. Doppler echocardiography was performed to measure the pressure gradient across the valve. An increase in mean diastolic transvalvular gradient of more than 6 mm was considered suspicious. Fluoroscopy was the mainstay of the evaluation of leaflet mobility. The desired acquisition angle was side/pivot view, with the disks parallel to the X-ray beams. In case of bileaflet mechanical prosthesis, the stuck valve was classified into partial stuck valve if only one disk was moving and complete stuck valve if both the disks are immobilized. Once diagnosed, all patients were given infusion heparin 1000 international units (I.U) per hour, intravenous diuretics and inotropic support, if required, while preparing for emergency surgery.

Anesthesia was induced with 0.25-0.5 mg/kg morphine, 0.12 mg/kg pancuronium, and 2 mg/kg propofol. Before cardiopulmonary bypass (CPB), anesthesia was maintained with isoflurane inhalation, top up doses of morphine, and muscle relaxant (pancuronium). During CPB, anesthesia was maintained with 5-8 ug/kg/min of propofol and muscle relaxant. Femoral vessels were exposed and prepared for establishment of emergency CPB, if required. Chest was reopened through median sternotomy with redo oscillating saw. Once the adhesiolysis was carried out, aortic and bicaval cannulae were used to institute CPB, using a roller pump and membrane oxygenator, with identical priming solution. Systemic blood flow was maintained at 2.2 to 2.4 L/min/m² and mean arterial pressure at 60 to 70 mmHg. Systemic hypothermia (33.5°C) and hemodilution were applied. Intermittent antegrade warm blood cardioplegia was given through the aortic root after cross clamping. Mitral prosthesis was approached through left atrium or right atrium and septostomy depending on operator choice. In group A, all the thrombus was removed from the upper and surface of the valve, mobility of disks confirmed and the closure of the chamber was carried out. In group B, stuck prosthesis was explanted followed by redo MVR. Total clamp and CPB time were recorded. Post operatively, patients were evaluated with daily progress parameter. The hemodynamic status, inotropic support, post-operative, ventilation time,
intensive care ward and total hospital stay were also recorded for comparison. Two-dimensional echocardiography was done before extubation and at discharge.

Statistical analysis was performed with SPSS version 19.0. Data had been described through descriptive statistics. Differences between the groups were investigated with non-parametric test for quantitative variables & Chi-square test for qualitative variables. Differences were considered statistically significant at \( p \)-value < 0.05.

RESULTS

Pre-operative demographic and clinical characteristics are shown in table 1. None of the patients were in NYHA Class 1 or 11. In group A, 46.42% of patients had Atrial Fibrillation (AF) while in group B, 50% had AF at the time of presentation. All patients of both group showed absence or muffling of prosthetic valve sounds having partial stuck valve in 71.4% of cases in group A & 75% of cases in group B, both the groups were comparable with respect to gender, age, interval between initial mitral valve replacement (MVR) and redo operation or declotting, anticoagulation status, New York Heart Association (NYHA) functional class, international normalized ratio (INR) level, trans thoracic Echocardiography and fluoroscopy. One patient in group A had monoleaflet prosthesis (3.57%) while rest of the patients in both groups had bileaflet prosthesis. One patient (3.6%) in group A was ventilated before surgery while none of the patients of group B was ventilated preoperatively. Seventeen point eight five percent and twelve point five percent of patients received mild inotropic support in groups A & B respectively in the preoperative period.

In group A, three patients underwent devagus repair of tricuspid valve (10.7%) in addition to declotting. The mean cardiopulmonary bypass time was 97.36 ± 36.63 minutes in group A & 194.88 ± 60.34 minutes in group B (\( p < 0.001 \)). Similarly, the mean clamp time was 48 ± 17.65 minutes in group A & 125.75 ± 41.33 minutes in group B (\( p < 0.001 \)). The mean ventilation time in group A was 20.07 ± 31.58 hours in group A & 93.50 ± 179.36 hours in group B (\( p = 0.044 \)). In group A, 64.3% had mild inotropic support, 32.1% had moderate & 3.6% had heavy inotropic support in the post-operative period while none of the patients in group B were on mild inotropic support; with 50% of patients on moderate & 50% of patients were on heavy inotropic support (\( p < 0.001 \)). The mean ITC stay was 4.96 ± 3.3 days in group A & 6.50 ± 6.52 days in group B (\( p = 0.751 \)). Mean hospital stay was 9.61 ± 4.94 days in group A while it was 12.5 ± 7.31 days in group B (\( p = 0.251 \)) (Figure 1). The mortality rate in group A & B is shown in Figure 2. In group A, both the patients died of low cardiac output syndrome while in group B, two patients died of low cardiac output syndrome, one died of prolonged ventilation with septicemia & one death occurred because of massive intracranial bleed which was statistically significant (\( p = 0.005 \)).

DISCUSSION

Various prosthetic valves have been developed since Harken et al\(^9\). Now, the second generation bileaflet disk valves have been used clinically, like the St. Jude Medical Valve since 1977, Carbomedics valve since 1986 and ATS valve since 1992. Operation results and long-term results were generally satisfactory by improving of durability, anti-thrombosis and hemodynamics of the prosthetic valve\(^10\). But there are some reports of thrombotic valve dysfunction in the mitral position, occurs primarily in patients with suboptimal anticoagulant therapy, poor patient compliance and thrombotic condition\(^11\). The only other risk factor that has been identified is female sex\(^12\). These risk factors quoted in the literature were encountered in our study. A high percentage of our patients had atrial fibrillation (AF); however, AF has not so far been identified as risk factor for mechanical valve thrombosis\(^13\). Despite innovation in valve design and use of pyrolytic carbon, or other material to coat valve surfaces, the reported incidence of prosthetic
valve thrombosis still ranges from 0.03 to 4.3% per year\textsuperscript{14}.

Early diagnosis of prosthetic valve thrombosis is essential. The presentation of patients with valve obstruction ranges from asymptomatic thrombotic occlusion detected by routine echocardiography to cardiogenic shock. The most common presentation is dyspnea, orthopnea and paroxysmal nocturnal dyspnea. In the past, almost 50% of obstructed valves were diagnosed only at autopsy\textsuperscript{13}. Any new or worsening symptom or an embolic event in a patient with prosthetic valve should prompt thorough investigations to rule out valve obstruction\textsuperscript{15}. Auscultatory findings may be abnormal in up to 21.4% of patients with prosthetic valve thrombosis\textsuperscript{16}. This is in contrast to our study with 46.4% of patients presented in functional class 111 in group A & 75% of cases in NYHA Class 111 in group B with positive auscultatory findings in all patients of both groups. It is because of the fact that our patients report late in hospital when they are already in functional class 111 or 1V with partial or complete obstruction of prosthesis.

Echocardiography is currently the non-invasive method of choice for evaluation of prosthetic valve function. However, due to attenuation and acoustic shadowing by the mechanical prosthesis, the sensitivity of transthoracic echocardiography may be as low as 0% for detection of nonobstructive thrombi\textsuperscript{15}. Transesophageal echocardiography (TEE) is therefore often needed to confirm prosthetic valve thrombosis\textsuperscript{13}. Signs of thrombosis are on an increase in the transprosthetic pressure gradient to more than twice normal values, due to obstruction or an increase in transvalvular regurgitation\textsuperscript{17}. In our patients, valve obstruction without severe regurgitation was the leading haemodynamic finding in Doppler echocardiography and was confirmed on fluoroscopy which remains a useful procedure for diagnosing reduce disk/leaflet motion\textsuperscript{18}. We, however, did not perform TEE in any of our patients.

The recommended treatment options include thrombolysis and surgery. Thrombolysis harbors not only risk of embolism but also the probability of incomplete success. Moreover, it is indicated if the thrombus is 5 mm or smaller size or there is unacceptable high risk for surgical intervention\textsuperscript{7,8}. In this study, we came across with the patients who were in functional class 111 or 1V, thrombus involving both side of the prosthesis with partial or complete obstruction which ruled out the role of thrombolysis. Mortality rate after surgery depends on the clinical and functional class of the patient\textsuperscript{16, 19}. Patients in functional class 1 to 111 have operative mortality of 4.7%, a rate similar to that of primary valve replacement\textsuperscript{16}. On the other hand, patients who are in functional class 1V and critically ill, the mortality for emergency surgical intervention rises to 35-55\%\textsuperscript{16,19}. The two surgical modalities for management of stuck mitral valve include declotting/Thrombectomy and MVR. Declotting, being less aggressive approach than redo MVR with less cross-clamp and cardiopulmonary bypass time, was found to be superior in terms of less post-operative morbidity and mortality, as noted in our results (mortality: 7.14\% versus 50\%). Prolonged cross-clamp significantly correlates with major post-operative morbidity and mortality in both low and high risks patients\textsuperscript{20}. Prolonged CPB time has negative impact on splanchnic perfusion and hepatocellular integrity\textsuperscript{21}, which add further insult in already compromised patients of prosthetic valve thrombosis. While some authors have suggested that the rate of rethrombosis after declotting is higher than after valve replacement, a large series of 100 patients undergoing surgery for prosthetic valve thrombosis showed no difference in recurrent thrombosis between valve replacement and mechanical debridement (declotting)\textsuperscript{16}.

Stuck mitral valve prosthesis is a dreadful and lethal complication and accordingly, it is recommended that a more safe procedure be adopted to handle this complication. Declotting, being less aggressive, with less Cross Clamp &
CPB time as noted in our results, helps in preventing not only the jeopardized myocardium from further insult but also preventing deterioration of other vital organs that are affected by prolonged CPB time. Redo MVR should be considered in cases where there is structure failure of prosthesis, excessive pannus formation, prosthetic valve thrombosis associated with para valvular leak & prosthetic valve infective Endocarditis.

CONCLUSION

Prosthetic valve thrombosis is a lethal complication after mechanical mitral valve replacement with high mortality without timely and effective surgical intervention. Declotting, being a less aggressive surgical technique, is recommended because of better outcome in terms of morbidity and mortality in the early post-operative period.

REFERENCES
