Comparison of Mechanical and Bioprosthetic Valves in terms of Perioperative Complications in Redo-Valve Surgeries

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ABSTRACT: Mechanical and Bioprosthetic valves were compared in terms of longer ICU stay, mortality, sternal wound infection, incidence / need for blood transfusions and perioperative haemorrhage in redo-surgeries. It was retrospective analysis of prospectively conducted study from March 2001-Feb 2010. Total Patients (N=25) were reoperated for valvular thrombosis(35%) and dehiscence(30%), endocarditis(25.7%) and structural degeneration(19.4%) during this period with previously replaced mechanical(n1=8) and tissue valves(n2=17). Statistical analysis was conducted with SPSS 16.0. CICU(Cardiac Intensive Care Unit) prolonged stay for both (7-30 days) and (>1 Month) was evidenced to be clearly greater in Tissue (n2) valve-group than Mechanical (n1) group (p<0.05). Risk analysis of confounding variables for prolonged ICU stay was carried out as well. Perioperative mortality was 8% in tissue valves and 4% in mechanical valves (p<0.05). Statistically significant SSSI (superficial surgical site infection) and perioperative bleeding was noted in bioprosthetic group as compared to mechanical valve-group. But no significant difference was found amongst two in terms of occurrence of mediastinitis(p=0.09). Ambivalent data was collected as regards the transfusion-requirements for two groups, as (>5 pint-requirement) was significantly greater in Tissue valves than Mechanical ones, whereas (<5 pint-requirement was comparatively more in mechanical vs. tissue valves. Overall study was conclusive to be favouring mechanical valves for better outcomes related to redo-valve surgeries.

Keywords: Bioprosthetic, Mechanical valves, ICU stay, Mediastinitis, Mechanical, Transfusion requirements.

1. INTRODUCTION

Over past 40 years, variety of mechanical as well as tissue valves have had been talked about with none of them being superior in hemodynamics and durability 1-3. Enlisted, various classes of prosthesis used till today, include Cryolife stentless, Edwards bileaflet, Hancock stented porcine, Ionescu shiley bovine pericardial, Medtronic stentless, Medtronic bileaflet, Stented Labor bovine & porcine, St.Judes Mechanical and Bioprosthetic, Biocore Stented, Bioflo stentless, Bjork shiley tilting disc, Carbomedics bileaflet, Carpenter Edwards stented, Duromedics bileaflet and Starr Edwards Caged ball prosthetic valves and Homografts. (Fig1.1---1.3)

Redo-operations for previously replaced valvular prosthesis has had been common and worldwide data suggests it to be 5-15% incident. Historically Redo-surgery has been associated with increased mortality and morbidity & it is of course technically difficult because of adhesions. Marian Ion Lunesco was the first cardiac surgeon to put a bioprosthetic (Tissue) valve for valve replacement surgery (Figure1.5, 1.6)

As for as need for redo-valve surgeries is concerned, various indications 4 have been established so far, most important and compulsive ones are structural degeneration, endocarditis, paravalvular leak, dehiscence, pannus formation (both type of valves) and acute prosthetic thrombosis (common in mechanical valves only).
Fig. 1.1
Ball & Cage Starr Edwards

Fig. 1.2
Björk-Shiley Tilting Disc Valve
Mechanical valve

Fig. 1.3
Carpentier Bioprosthesis
HANCOCK PORCINE MITRAL VALVES
1968

Fig 1.4 Hancock Porcine Tissue valves

Fig 1.5 Marian Ion Lunesco

Fig 1.6 Porcine Pericardial Tissue Valve (Bioprosthesis)

Fig 1.7 St. Jude’s mechanical prosthesis
As per literature review, mechanical valves last longer than average human life (mean span >100 yrs) whereas Tissue valves last only for 10-12 yrs at the most. Thromboembolic phenomenon, need for anti-coagulation and the incidence of endocarditic complications like bacteremia, annular abscess and vegetations are much more common in mechanical prosthesis (Fig1.7) as compared to ‘Tissue one’ depicting minimal to no evidence of all three. Pannus formation, dehiscence and paravalvular leaks however are equally incident among the two prosthetic species. Overall bleeding is 7-9% higher in mechanical as compared to biprosthetic valves whereas postoperative haemorrhage (8%) and operative haemorrhage (2%) has had been equally incident among two groups.

Acute prosthetic thrombosis has exclusively been noticed in mechanical group and infection remained equally distributed in both Tissue & mechanical prosthesis. Not much work has been done internationally to determine complications related to these valves in Redo- surgeries. This study has focussed on the same issue, comparing two types of prosthesis in a unique manner in terms of perioperative complications restricted to only Redo surgery.

2. Materials & Methods

It was a ten year long prospective study analysed retrospectively, between Mar, 2001---Feb, 2010. Total No. of 25 patients in all were followed retrospectively at Aga khan university hospital Karachi, Pakistan. Preoperative characteristics of patients belonging to both the groups is mentioned below in tabular form. Refer to (Table 2.1)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mechanical Valves</th>
<th>Tissue Valves</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;50 &lt;50</td>
<td>5 (70%)</td>
<td>9 (55%)</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>3 (30%)</td>
<td>8 (45%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Male</td>
<td>45%</td>
<td>50%</td>
<td>0.08</td>
</tr>
<tr>
<td>Female</td>
<td>55%</td>
<td>50%</td>
<td>0.07</td>
</tr>
<tr>
<td>NYHA class III-IV</td>
<td>80%</td>
<td>75%</td>
<td>0.06</td>
</tr>
<tr>
<td>Emergency Surgery</td>
<td>35%</td>
<td>5%</td>
<td>0.03</td>
</tr>
<tr>
<td>Afib</td>
<td>2 (24%)</td>
<td>6 (30%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Pulm HTN</td>
<td>1 (12%)</td>
<td>3 (17%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Preop renal dysfunction</td>
<td>3 (36%)</td>
<td>1(5.5%)</td>
<td>0.02</td>
</tr>
<tr>
<td>DM</td>
<td>5 (60%)</td>
<td>4(25%)</td>
<td>0.04</td>
</tr>
<tr>
<td>HTN</td>
<td>4 (50%)</td>
<td>5(27%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Mitral Valve</td>
<td>7(88%)</td>
<td>12 (72%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Aortic Valve</td>
<td>1 (12%)</td>
<td>5 (28%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>1 (12%)</td>
<td>1 (6%)</td>
<td>0.06</td>
</tr>
<tr>
<td>Previous neurological dysfunction</td>
<td>-</td>
<td>2 (12%)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

All patients undergoing redo surgeries were initially assessed clinically preoperatively and a set of labs( CBC, LFTs, viral serology, chemistry, coagulation profile & urine R/E) were carried out including lateral chest imaging studies as a set code-rourine for redo surgeries. Both groups (n₁ = 8, previously replaced mechanical prosthesis undergoing redo surgery) and ( n₂ = 17, previously replaced tissue valvular prosthesis undergoing redo surgery) were compared for the perioperative complications of redo- valve surgery in terms of longer ICU stay, mortality, sternal wound infection, perioprative haemorrhage and the transfusion requirements perioperatively.

Prolonged ICU stay was defined as cardiac ICU (CICU) stay > 7 days. It was further stratified into 7-30 days & > 1 month stay in CICU. Any In-hospital death (perioperative / postoperative ) was
taken as mortality. Redo-perioperative haemorrhage was considered into three categories, as mild (300-500ml or less), moderate (500ml-1L) and severe (as >1L). Transfusion requirements were calibrated as either none, 3-5 pints or >5 pints of either as Pack cells (RBCs) or whole blood postoperatively / perioperatively overall. Sternal wound infection was also considered as mediastinitis, superficial surgical site infection (SSSI) or no infection at all. Mediastinitis was taken as sternal dehiscence with positive cultures with / without (fever, chest wound drainage, chest pain , chills etc.)

All the collected data related to complications and their comparison between two groups was computed and analyzed with SPSS 16.0 & the results were tabulated and depicted graphically.

3. Results

Total Patients (N=25) were reoperated for valvular thrombosis(35%) and dehiscence(30%), endocarditis(25.7%) and structural degeneration(19.4%) during this period with previously replaced mechanical(n1=8) and tissue valves(n2=17). As per preoperative data, 60% of these (N=25) were tissue valves as compared to mechanical valves which were around 40% (Fig 3.1).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mechanical Valve(n1)</th>
<th>Bioprosthetic Valve(n2)</th>
<th>Total affected (N25)</th>
<th>$\beta$ Coefficient (Significance level)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resternotomy</td>
<td>8</td>
<td>17</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>6</td>
<td>3</td>
<td>24%</td>
<td>12%</td>
</tr>
<tr>
<td>Transfusion</td>
<td>1</td>
<td>7</td>
<td>4%</td>
<td>32%</td>
</tr>
<tr>
<td>requirements</td>
<td>2</td>
<td>8</td>
<td>24%</td>
<td>32%</td>
</tr>
<tr>
<td>Mediastinitis</td>
<td>1</td>
<td>4%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>SSSI</td>
<td>3</td>
<td>12%</td>
<td>8</td>
<td>32%</td>
</tr>
<tr>
<td>CICU prolonged</td>
<td>6</td>
<td>24%</td>
<td>10</td>
<td>40%</td>
</tr>
<tr>
<td>stay</td>
<td></td>
<td></td>
<td>16</td>
<td>64%</td>
</tr>
<tr>
<td>Peri/op Mortality</td>
<td>2</td>
<td>8%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>12%</td>
</tr>
</tbody>
</table>

Table 3.1

No significant difference was found amongst the two groups as per preoperative population characteristics (Table 2.1) as regards gender distribution and NYHA class, albeit significantly higher incidence of emergent surgery was noticed in mechanical group (35%) as compared to just (5%) in tissue valves ($p=0.03$). Similarly comorbid like Diabetes Mellitus (DM), HTN ($p<0.05$), preop renal dysfunction ($p=0.02$) were found to be more amongst mechanical valve population in significant range. (Table 2.1)

Among the total mechanical valves (n=8), only 12% were aortic in position and 88% were mitral prosthesis. Amongst the Tissue valves 72% were mitral and 28% were aortic in position.
Fig. 3.1 Sample Distribution

Fig 3.2 Over all Postop CICU stay both groups
CICU Prolonged stay: Comparison of 2 valvular types

Fig. 3.3: CICU Longer stay compared in both gps

Fig 3.4

CICU PROLONGED STAY: COMPARISON OF 2 VALVULAR TYPES

Mechanical
Tissue

<7 days
7-30 days
>1 Month

Fig 3.4
Fig 3.5

Fig 3.6- Risk stratification for prolonged CICU stay
------- Tissue vs. Mechanical valves
Risk Distribution Amongst Prolonged Stay: Mechanical vs Tissue Valves

- arrhythmias
- prexisting medical disorders
- bypass time
- postop renal derangement
- preop renal dysfunction
- PA systolic>60
- age>50

![Graph showing risk distribution](Image)

REDO-STERNOTOMY BLEEDING: MECHANICAL VS TISSUE VALVES

- > 1 L
- > 500 ml
- < 500 ml

![Graph showing bleeding comparison](Image)
**Redosternotomy Bleeding: Mechanical vs Tissue valves**

Fig 3.8

**TRANSFUSION REQUIREMENTS**

Fig 3.9
Fig 3.10

Transfusion Requirements For two Valvular Gps

Fig3.11 Prevalence of sternal wound infection overall

WOUND INFECTION

Fig 3.11 Prevalence of sternal wound infection overall
4. Discussion:

Since the advent of valvular surgery and the mastery in technical capability attained in this regard in the last century \(^7\) has really kliedoscopically enchanted the ostensible outcome of valvular disease and the related health - status of patients world wide. Despite recent advances in the transcutaneous device closures and valve replacement techniques, surgical valve replacements remains the treatment of choice for the most of patient population presentations for aortic and mitral valve disease in this part of the world.
Valve replacements and their comparison in terms of Tissue and Mechanical valves has been done ubiquitously all over the world especially in the last decade or so but not much data is available in this regard for redo valve surgeries at both aortic and mitral positions. The current study would add to this novice dimension in terms of prolonged stay, mortality, perioperative bleeding, transfusion requirements and sternal wound infection comparison between two classes of prosthetic valves.

Population demographics were clearly indicative of 2 groups having least confounding variables. Risk stratification score alluded to emergency surgery, preoperative renal dysfunction, diabetes and hypertension as statistically significant risk factors / confounding variables amongst the two classes of prosthesis undergoing redo - valve replacements, with possible effect on outcomes under study. Emergency surgery was done in 35% of mechanical valves (n=3) as compared to just 5% (n=1) in tissue valves (p=0.03). Preop renal dysfunction was 36% (n=3) in mechanical valve group versus 5.5% (n=1) in tissue valve group (p=0.02). Diabetes and Hypertension were also statistically significantly more in mechanical group vs tissue group preoperatively (Table 2.1).

No statistically significant difference was found amongst the two groups in terms of valvular distribution at mitral or aortic positions.

No significant difference was found among the two groups as regards preoperative data entailing age, sex distribution, pulmonary hypertension, preoperative atrial fibrillation and preoperative neurological dysfunction / Cerebrovascular accident (CVA).

CICU overall prolonged stay (n=16) in total population (N=25) was noticed as in three categories, ie; 35% had ICU stay for < 7 days, 40% had prolonged ICU stay ranging between 7-30 days and 20% had stay beyond 30 days. So 65% had prolonged ICU stay overall (Fig 3.2). Comparing two groups, mechanical valves fared considerably better as compared to tissue valves in terms of less CICU prolonged stay as 16% vs 20% respectively for < 1 month stay & 8% vs 12% respectively for > 1 month CICU stay with overall comparison of prolonged stay clearly indicating statistically significant difference (p < 0.05) between 2 groups discrediting Tissue valves as less better option in redo – surgeries as regards postoperative ICU stay (Table 3.2, Figs.3.3,3.4). It can clearly be construed that mechanical valves make only < 25% of the total patients having longer ICU stay whereas Tissue valves are around 40% of the toto (p = 0.02).

Well known co-morbidities which can affect longer ICU stay independently were also included into this discourse, so as to independently determine the effect of prosthetic class on CICU stay postoperatively in redo surgeries. Co-morbidities studied were preoperative / postoperative renal dysfunction, arrhythmias, postoperative pulmonary hypertension, increased cardiopulmonary byass (CPB) time, and pre-existing medical disorders (like DM & HTN). Although these risk factors were equally distributed among two groups, higher age group and pulmonary HTN were significantly higher in tissue-valve group and could possibly confound the longer ICU stay results of this study, though statistically significant difference was not appreciated between two prosthetic classes for both of them (Table 2.1 & Fig-3.5, 3.6), pulmonary HTN being 25% greater in Tissue group - patients vs mechanical group - patients, both of which had longer ICU stay. Although pulmonary HTN was noted in only 12 % of mechanical valves and 17% of tissue valves preoperatively (p >0.05) but mechanical valves accounted for none of post-operative pulmonary HTN observed in patients with longer ICU stay; which was almost 100% witnessed in Tissue group (p <0.05). The higher age (>50 yrs) was depicted by 70% vs 55% of mechanical and tissue valves respectively with no statistically significant difference between two groups postoperatively but the same was represented in overall aged population proportion as 43% (mechanical) and 67% (Tissue) of total %age of patients >50 yrs of age amongst the total patients who had longer (n=16) ICU stay postoperatively (Fig 3.7, 3.6, Table 2.1). Similarly prolonged CPB time (>110-120 min) , were equally distributed between two classes of prosthesis in prolonged ICU stay sub-population (n=16), but arrhythmias were about 3-4 times higher amongst the same population in mechanical group postoperatively (86%) vs 36% in tissue – group. About 30% of them were new onset post-operative arrhythmias with no previous preoperative dysrhythmias. Endocrinological disorders like DM and Hypertension were not in statistically significant range in this sub-population with longer ICU stay in contradistinction to preoperative data of whole population.

Table 3.1, Fig-3.8,3.9 are clearly alluding to perioperative / redosternotomy bleeding being considerably higher in both groups in 500-1500 mL range with only 1 patient in each group accounting for bleeding < 500ml / insignificant bleeding. Statistically significant (p <0.05) bleeding was only seen in > 1L range, with tissue valves having 2-3 times higher haemorrhage as compared to mechanical ones. Similarly significantly higher transfusion requirements

Perioperative mortality and superficial surgical site infection were both statistically significant with former being higher in mechanical cases and latter depicting greater numbers in tissue group. Mediastinitis was though equally distributed among the two classes of prosthesis, it never translated itself statistically in any of significant ranges. Mortality being quite significant (13%) overall was
about twice as high in mechanical – group as compared to tissue valve – group. The study overall was in favour of mechanical prosthesis for all upcoming future / current redo – surgeries, except for data regarding perioperative and postoperative in – hospital mortality.

Limitation of study were its retrospective nature and some of the confounding variables like preoperative renal dysfunction, DM, HTN and emergent surgery could not be excluded preoperatively from 2 groups, entailing bias in terms of both prolonged CICU stay and mortality. Similarly variables /risk factors for longer ICU stay could not be matched exquisitely amongst two groups.

5. References