Impact of Valvular Prosthesis Type on Cardiovascular Outcomes in Patients on Chronic Dialysis

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The best valve substitute in patients on chronic dialysis undergoing valve replacement surgery is still a matter of ongoing debate. When choosing a mechanical valve, the preservation and durability of the biological components of a bioprosthesis should be weighed against the risk of life-threatening bleeding or major thrombo-embolism generally linked to the use of life-long anticoagulants.

Methods

The standards of valve selection have changed over time. It has long been believed that tissue valves undergo premature degeneration due to calcium metabolism derangements in patients with end-stage renal disease. Bleeding was the most common valve-related complication and represented a major drawback of mechanical valves. Two studies demonstrated a survival advantage in favour of mechanical prostheses. It can be concluded that surgeons should not hesitate to implant bioprostheses because singular valve decomposition would be uncommon in this patient population. Prosthesis selection should be based on the same criteria as those used for non-dialysis patients.

Keywords: Renal Dialysis; Heart Valve Prostheses; Bioprostheses; Prostheses and Implants, analysis.

ABSTRACT: There is conflicting evidence guiding valve prosthesis selection in patients with end-stage renal disease on dialysis. We sought to determine, after reviewing the relevant literature, the best valve substitute in patients on chronic dialysis. A total of 9 retrospective studies compared the outcomes of two valves, showing similar results and highlighting the safety of implanting bioprostheses in patients on chronic dialysis. Standards of valve selection have changed over time. It has long been believed that tissue valves undergo premature degeneration due to the derangements in calcium metabolism in patients with end-stage renal disease. This is based on a report by Lamberti who described two patients with accelerated degeneration of their bioprosthetic valves.1

In 1998, American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommended the use of mechanical valves in patients on dialysis. However, 7 retrospective studies from North America and two from Japan specifically compared the outcomes of the two valves and showed similar results,
highlighting the safety of implanting a bioprosthesis in patients on chronic dialysis.\(^2-10\) Recently, accumulating data supporting the very low incidence of rapid tissue valve degeneration in dialysis patients has been taken into consideration, and the 2006 ACC/AHA practice guidelines do not specify the best choice for valve replacement in dialysis patient.

To provide the best evidence to address this issue, a literature review of the most relevant studies was performed using PubMed. The most relevant papers treating this problem are listed and summarised in Table 1.

### Results

**Lucke et al.** reviewed 19 consecutive patients with end-stage renal disease from a single institution who had undergone aortic, mitral or aorto-mitral valve replacement.\(^2\) The mechanical valve patients (n = 10) had a significantly higher rate of postoperative cerebrovascular events or bleeding complications than the bioprosthetic patients (n = 9). No subsequent reoperations were required for biological valve failure. The overall estimated Kaplan-Meier survival was 42 ± 14% at 60 months.

**Kaplon et al.**, from the Cleveland Clinic Foundation, found comparable results for both types of valves when reviewing 42 patients on preoperative dialysis undergoing valve replacements;\(^3\) 17 received mechanical valves and 25 received a bioprosthesis. Of the 25 fitted with bioprosthetic valves, 4 required reoperation with one admitted for mitral bioprosthesis degeneration. Prosthetic valve-related complications and survival were similar for both mechanical and bioprosthetic valves.

**Herzog et al.** reviewed the US Renal Data System database. Dialysis patients (n = 5,858) hospitalised for heart valve replacement surgery were the subjects of the study.\(^4\) Tissue valves were used in 881 patients (15%). Aortic valve replacement was performed in 58%, mitral valve replacement in 32%, and combined aortic and mitral valve replacement in 10%. There was no significant difference in survival related to type of valve. The two-year survival rate was 39.7 ± 3.5% with tissue valves versus 39.7 ± 1.4% for non-tissue valves.

**Brinkman et al.** found that the choice of valve substitute used in dialysis patients did not influence early and late survival; however, with a mechanical valve there were a six-fold higher incidence of late bleeding or stroke in patients on dialysis.\(^5\)

**Chan et al.** investigated the results of 69 valve replacements in patients with end-stage renal disease.\(^6\) One case of structural valve deterioration (SVD) occurred in the bioprosthesis group, requiring reoperation at 95 months after surgery. A survival advantage was observed in favour of mechanical prostheses at 5 years. Nevertheless, composites of complications were similar between the two groups.

**Toole et al.** reviewed 50 dialysis patients undergoing left-sided valve replacement.\(^7\) The tissue valve group had significantly higher Kaplan-Meier freedom from valve-related morbidity and mortality at three years. Freedom from reoperation was not significantly different.

**Filsoofi et al.** analysed data from 155 patients with renal failure who underwent left-sided valve surgery, of whom 108 patients were on chronic dialysis.\(^8\) Regarding the type of prosthesis, hospital mortality and freedom from reoperation were similar in patients with mechanical and biological valves.

**Umezu et al.** analysed data from 63 consecutive dialysis patients who underwent valvular surgery.\(^9\) The mechanical group had a higher rate of bleeding events but there was no SVD up to the 5-year follow-up. However, both mechanical and bioprosthetic valve patients had similar survival and event-free rates.

**Tanaka et al.** performed a retrospective review on 73 aortic valve replacements for dialysis patients.\(^10\) No SVD of the bioprosthesis was seen in this series. Valve-related complications were documented in 12 of 44 patients in the mechanical valve group and in 2 of 21 patients in the bioprosthesis group. The all-cause survival rate of patients with bioprosthesis was significantly worse than that of patients with mechanical valves.

### Discussion

A major concern of cardiovascular surgical teams when implanting a bioprosthesis in a patient on dialysis is SVD, and many papers have been written on the subject. However, none of the studies have been randomised controlled trials. Only 4 cases of SVD requiring reoperation (at 10–96 months after
Table 1: Literature review comparing the outcomes of bioprosthesis versus mechanical valve replacement in patients with end-stage renal disease on chronic dialysis

<table>
<thead>
<tr>
<th>Author and study period</th>
<th>Aortic/ Mitral/ Aorto-mitral</th>
<th>Number or %; Mean age in years; Mean follow-up</th>
<th>B failure</th>
<th>Bleeding and thrombo-embolic events</th>
<th>Overall survival</th>
<th>Comments and conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herzog, et al. 1978–1998</td>
<td>3,398; 1,875/585</td>
<td>5,858; 32 ± 53 months</td>
<td>N/R</td>
<td>N/R</td>
<td>At 2-years: B = M</td>
<td>Little insight into the actual cause of adverse survival of dialysis patients after VR. Decision on VR type based on claims data. Current practice guidelines of use of B heart valves in haemodialysis patients should be rescinded.</td>
</tr>
<tr>
<td>Lucke, et al. 1979–1994</td>
<td>19</td>
<td>1,875/585; 881 ; N/R</td>
<td>25</td>
<td>N/R</td>
<td>At 12 months: B = M</td>
<td>Relative short follow-up period. Follow-up completed in 78%. Preference should be given to B valve instead of M valve prostheses.</td>
</tr>
<tr>
<td>Chan, et al. 1985–2000</td>
<td>40/22/0</td>
<td>69</td>
<td>15 months</td>
<td>1 mitral failure after 95 months</td>
<td>At 5 years: B = M</td>
<td>The study encompasses data from 4 hospitals over 27 years. Variability such as surgical technique can influence outcomes.</td>
</tr>
<tr>
<td>Kaplon, et al. 1986–1998</td>
<td>27/1/4</td>
<td>42</td>
<td>25</td>
<td>Stroke</td>
<td>At 3 years: B = M</td>
<td>Follow-up was 100%. Surgeons should not hesitate to implant B valves.</td>
</tr>
<tr>
<td>Umezu, et al. 1990–2007</td>
<td>44/33/7</td>
<td>61 (64 VR)</td>
<td>3 months</td>
<td>Survival rate at midterm</td>
<td>B = M</td>
<td>Follow-up was accomplished in 95.2%. Prosthesis selection should be based on patient's profile as well as criteria for non-dialysis patients.</td>
</tr>
<tr>
<td>Toole, et al. 1991–2004</td>
<td>31/2/0</td>
<td>50 (60 VR)</td>
<td>11 months</td>
<td>3-year F from V/R MBD and MRT</td>
<td>At 5 years: B = M</td>
<td>No standardised protocols used for prosthesis choice; data subject to individual surgeon biases. Also, number of M valve recipients was small. Unacceptably high rates of compl. and death with M valves.</td>
</tr>
<tr>
<td>Tanaka, et al. 1995–2007</td>
<td>73/0/0</td>
<td>73</td>
<td>3 months</td>
<td>5-year all-cause survival rate</td>
<td>B = M</td>
<td>Concomitant procedures performed in 49% of cases. The advantage in the all-cause survival in favour of the M valve group is difficult to interpret, because the patients who received B valves were significantly older. Regarding aortic VR, dialysis patients can be treated just like non-dialysis patients.</td>
</tr>
<tr>
<td>Fisovati, et al. 1996–2006</td>
<td>N/R</td>
<td>G1: 47 NDDRF</td>
<td>2.5 years</td>
<td>5-year F from reoperation</td>
<td>At 5 years: B = M</td>
<td>Clinical outcomes limited to major post-operative MBD and MRT. No information on late compl. QoL or causes of death during follow-up.</td>
</tr>
</tbody>
</table>

B = bioprosthesis; M = mechanical; VR = valve replacement; N/R = not recorded; patient-y = patient-year; F = freedom; V/R = valve-related; compl. = complications; hyper-PTH = hyperparathyroidism; MDD = morbidity; MRD = mortality; G = group; NDDRF = non-dialysis-dependent renal failure; QoL = quality of life.
the initial valve replacement surgery) were identified from the 9 retrospective studies. Of note, the mean follow-up of each study was relatively short; therefore, definite conclusions about the long-term performance of tissue valves in this patient population cannot be drawn.

Bleeding was the most common valve-related complication, representing a major drawback of mechanical valves. Thromboembolic events were reported in 35 patients, of whom 31 received mechanical prostheses. A total of 7 of the 9 studies did not demonstrate a survival difference according to prosthesis type. The remaining two studies demonstrated a survival advantage in favour of mechanical prostheses. However, patients who received bioprosthetic valves were older and more likely to have had a previous myocardial infarction or to have received concomitant coronary artery bypass grafting.

Recently, Chan et al. performed a systematic review and meta-analysis of valve replacement in patients on dialysis. In 9 studies published from 1997 to 2010, no difference in survival was observed between the valve types (bioprosthesis versus mechanical prosthesis; hazard ratio 1.3, 95% CI 1.0–1.9, \( P = 0.09 \)). However, bioprosthetic valves were associated with fewer valve-related complications compared with mechanical prostheses (odds ratio 0.4, 95% CI 0.2–0.7, \( P = 0.002 \)). They concluded that there was no survival difference following valve replacement with either bioprosthesis or mechanical prosthesis in patients on dialysis.

More recently, Pai et al. published their review on the same subject. They found 8 relevant retrospective studies and concluded that there was no significant difference in the results and survival between patients receiving a mechanical and those receiving a bioprosthetic valve. However, bleeding complications were more common with mechanical valves.

**Conclusion**

It can be concluded that dialysis patients after cardiac valve replacement suffer poor midterm and long-term survival rates. Therefore, due to the limited life expectancy of these patients, physicians should not hesitate to implant bioprosthetic valves because SVD will be uncommon in this patient population. Prosthesis selection should be based on the same criteria used for non-dialysis patients.

**References**