Background: There are only limited numbers of reports about long-term results of tricuspid valve replacement (TVR) with bioprosthetic and mechanical prostheses. We analyzed risk factors for tricuspid valve replacement and compared long-term clinical results of bioprosthetic and mechanical valves in tricuspid position. Material and Method: We reviewed 77 cases of TVR, which were performed between October 1978 and December 1996. Mean age was 38.8 ± 15.9 years. Bioprostheses were implanted in 26 cases and mechanical prostheses were implanted in 51 cases. Result: The operative mortality was 15.6% and late mortality was 12.3%. Survival for bioprosthetic and mechanical valve group at 5, 10 and 13 years was 81.3% vs. 100%, 66.1% vs. 100%, and 60.6% vs. 100% (p=0.0175). Free from valve related re-operation for bioprosthetic and mechanical valve group at 5, 10 and 13 years was 100% vs. 93.9%, 100% vs. 93.9% and 58.3% vs. 93.9% (p=0.3274). Linealized incidences of valve related re-operation for bioprosthetic and mechanical valve group was 2.27%patient-years and 1.10%patient-years. Risk factor analysis showed that presence of preoperative ascites, hepatomegaly larger than 2 finger breaths, poor preoperative NYHA functional class and number of tricuspid valve replacement were risk factors for early mortality, and the use of bioprosthetic valve and number of open heart surgery were risk factors for late mortality. Conclusion: Long-term survival of mechanical valve was superior to bioprosthetic valve in tricuspid position. We recommend mechanical valve in tricuspid position if the patient can be closely followed up.


Key words: 1. Tricuspid valve, replacement
2. Heart valve prosthesis
3. Bioprosthesis

INTRODUCTION

In most tricuspid valve disease, TVR is uncommon procedure and tricuspid valve annuloplasty is usually performed initially. But when tricuspid valve repair or annuloplasty is not possible or not successful, TVR should be considered[1]. There are only limited numbers of report about the long-term result of TVR and there are also controversies about the choice of valve in tricuspid position[2-7]. This study was undertaken to compare the long-term clinical results between bioprosthetic and mechanical prostheses in tricuspid position and to find risk factors for early and late death in TVR.
MATERIALS AND METHODS

From October 1978 to December 1996, total 77 cases of tricuspid valve replacement (TVR) were performed in 70 patients at Yonsei Cardiovascular Center. 26 cases of TVR were performed using bioprosthetic valve and 51 cases of TVR were performed using mechanical valve. Among 70 patients, 32 patients were male and 38 patients were female with a mean age of 38.8 ± 15.9 years (bioprostheses: 36.0 ± 19.8 years, mechanical: 40.2 ± 13.4 years). Sixty-nine patients received TVR for the first time and 8 patients have received TVR previously. One patient who received redo-TVV had received first TVR at other hospital. The causes of TVR were rheumatic in 48, congenital in 12, prosthetic valve failure in 8 and others in 9 patients. Detailed patients’ profiles are shown at Table 1. We used bioprosthetic valves in 26 cases (Carpentier-Edwards in 21 and Han Cock in 5) and mechanical valves in 51 cases (Carbo Medic in 19, Saint Jude in 23, Duro-Medic in 5, ATS in 3, Bjork Shiley in 1). We reviewed all preoperative medical records to evaluate risk factors for operation and late mortality. Preoperative NYHA functional class for all patients were as follows; II: 11, III: 44, IV: 22.

Among 77 cases, single valve replacement was 35 cases (bioprostheses: 17, mechanical: 18), double valve replacement was 29 cases (bioprostheses: 8, mechanical: 21) and triple valve replacement was 12 cases (bioprostheses: 1, mechanical: 11). The number of previous open heart surgery was as follows; 1 time: 35 cases (bioprostheses: 7, mechanical: 28), 2 times: 6 cases (bioprostheses: 2, mechanical: 4), 3 times: 1 case (mechanical). All operations were performed through median sternotomy with the use of standard cardiopulmonary bypass. Myocardial protection was provided by moderate hypothermia to 28–32°C, and cold crystalloid potassium rich cardioplegic solution or cold blood cardioplegic solution infusion. All valves were secured in position by an interrupted horizontal mattress suture technique or continuous suture technique. Anticoagulation was done with intravenous heparin at early postoperative period, and later changed to oral warfarin sodium. Target INR was 2.5–3.5. All surviving patients have been examined in the outpatient clinic at least once every 3 months by surgeon or by their referring physician. In 1993, we established ‘valve clinic’ to follow up patients who had been received valve operation (especially with mechanical prostheses) more closely, and all patients who had received valve surgery were registered and followed up by regular annual check ups. This program allowed us to monitor INR (international normalization ratio) range more closely in these patients. All statistical analyses was done by statistician using SAS ver. 8.1. Variables entered into risk factor analysis included types of valves (bioprostheses or mechanical) implanted, number of previous open heart surgery taken, number of previous TVR, preoperative NYHA functional class, preoperative total bilirubin, SGOT and SGPT levels, number of valve used, preoperative presence of ascites, pitting edema, neck vein engorgement, hepatomegaly.

Definitions of events and methods of analyzing the results followed the guidelines published in this journal[8].

RESULTS

1) Hospital Mortality

Twelve patients died during hospitalization (15.6%). Four patients were in bioprosthetic valve group (15.4%) and eight patients were in mechanical valve group (15.7%). Among 12 patients, 8 patients received redo or trido-open heart surgery (bioprostheses: 4, mechanical: 5) and 3 cases received redo-tricuspid valve replacement (mechanical: 3). Among 12 patients, 6 patients received single valve replacement and 5 patients received double valve replacement, and 1 patient

<table>
<thead>
<tr>
<th>Sex</th>
<th>Bioprosthetic</th>
<th>Mechanical</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
<td>31</td>
<td>44</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>35.9 ± 19.8</td>
<td>40.2 ± 13.4</td>
<td>38.8 ± 15.9</td>
</tr>
<tr>
<td>Causes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatic</td>
<td>13</td>
<td>35</td>
<td>48</td>
</tr>
<tr>
<td>Valve failure</td>
<td>1</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Congenital</td>
<td>10</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Isolated TR</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>SBE</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Chordae rupture</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

TR=Tricuspid regurgitation.
Table 2. Causes of mortality

<table>
<thead>
<tr>
<th></th>
<th>Bioprostheses</th>
<th>Mechanical</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early</td>
<td>Heart failure</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Low cardiac output</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Arrhythmia</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Sepsis</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Sudden death</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Late</td>
<td>CHF</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Cerebral hemorrhage</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Chronic renal failure</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

CHF = Congestive heart failure.

received triple valve replacement. Causes of hospital mortality are shown at Table 2.

2) Follow Up

Follow up was performed during two months from January to February 2001. All medical records were reviewed and all patients were interviewed via their hospital visit or phone or mail except one patient (Follow up rate: 98.5%). The total cumulative follow-up was 501.9 patient-years. Cumulative follow up for bioprosthetic valve group was 220.2 patient-years (6~238 month) and 281.8 patient-years for mechanical valve group (2~164 month). The maximum follow up for bioprosthetic valve group was 238 months, and 164 months for mechanical valve group. Postoperative NYHA functional class were as follows; I: 33, II: 22, III: 6, IV: 4.

3) Late Mortality

There were 8 cases of late death (12.3%). Seven cases were in bioprosthetic valve group (31.8%) and one case was in mechanical valve group (2.3%). Among 8 patients, 5 patients received redo or trido-open heart surgery. Five patients received single valve replacement (bioprostheses: 5) and 3 patients received double valve replacement (bioprostheses: 2, mechanical: 1). One late death in mechanical valve group occurred at 164 months after operation. Other causes of late mortality are shown at Table 2.

4) Survival

Overall survival rate for all patients at 60, 120, 180 months was 93.6±3.1%, 82.4±6.8% and 64.6±13.5%, respectively. Overall survival for bioprosthetic valve group at 60, 120, 180 months was 81.3±8.4%, 66.1±10.5% and 60.6±11.0%. Overall survival for mechanical valve group at 60, 120 and 163 months are all 100%. There was statistical difference between two groups in overall survival (p=0.0175).

5) Thromboembolism

There were 4 cases of valve thrombosis. All cases developed in mechanical valve group and developed within 12 months after valve replacement. All cases were treated with intravenous heparin and urokinase infusion without re-operation. Thromboembolism free survival for all patients at 60, 120, 180 months was all 93.8±3.0%. Thromboembolism free survival for mechanical valve group was 90.7±4.4% after 12 months and there was no statistical difference between two groups (p=0.1523). Linealized incidences of thromboembolism for all valve group was 0.83/patient-years and 1.54%/patient-years for mechanical valve group. There was no anti-coagulation related hemorrhage.

6) Valve failure and Re-operation

There were 5 cases of structural valve failure in bioprosthetic valve group and 3 cases of nonstructural valve failure in mechanical valve group. And these 8 cases comprised of valve related re-operation in this study. All structural valve failure was valve cusp tearing or severe valve leaflet calcification and all cases occurred from 143 months to 194 months after valve replacement. All cases received re-replacement of valve with mechanical valve. Among 3 cases of nonstructural valve failure, two cases were pannus formation and one case was paravalvular leakage. Paravalvular leakage occurred 26 months after operation and pannus formation occurred 27 and 29 months after operation. Paravalvular leakage was repaired and pannus formation was treated with valve re-replacement. Free from valve related re-operation for all patients at 60, 120 and 180 months was 100%, 100% and 62.8±13.7%. Free from valve related re-operation for bioprosthetic valve group at 60, 120 and 180 months was 100%, 100% and 58.3
Table 3. Linealized incidences of valve related complications (% per patient-years)

<table>
<thead>
<tr>
<th></th>
<th>Bioprostheses</th>
<th>Mechanical</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thromboembolism</td>
<td>0</td>
<td>1.54</td>
<td>0.83</td>
</tr>
<tr>
<td>Reoperation</td>
<td>2.27</td>
<td>1.10</td>
<td>1.62</td>
</tr>
<tr>
<td>Nonstructural failure</td>
<td>0</td>
<td>1.10</td>
<td>0.61</td>
</tr>
<tr>
<td>Structural failure</td>
<td>2.27</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Valve related mortality</td>
<td>2.27</td>
<td>0.35</td>
<td>1.19</td>
</tr>
<tr>
<td>Valve related event</td>
<td>3.63</td>
<td>3.16</td>
<td>3.38</td>
</tr>
</tbody>
</table>

-16.1%. Free from valve related re-operation was 93.9 ± 3.9% from 29 months to 164 months in mechanical valve group. There was no statistical difference between two groups (p=0.3274 by Wilcoxon, p=0.9507 by Log-Rank). Linealized incidences of valve related re-operation for both group is 1.62%/patient-years (Table 3).

7) Valve related Mortality

There were 6 cases of valve related mortality. Five cases developed in bioprosthetic valve group and one case in mechanical valve group. Two cases in bioprosthetic valve group died during redo valve replacement. Other 4 patients died of unknown etiology. Free from valve related mortality for all patients at 60, 120 and 180 months was 95.1 ± 2.8%, 90.1 ± 5.3% and 66.7 ± 16.3%. Free from valve related mortality for bioprosthetic valve group at 60, 120 and 180 months was 89.5 ± 7.0%, 83.1 ± 9.0% and 59.8 ± 16.1%. For mechanical valve group, free from valve related mortality at 50, 120 and 164 months was 97.7 ± 2.3%. There is no statistical difference between two groups (p=0.1222).

8) Valve related event

There were 16 cases of valve related event. 8 cases were in bioprosthetic valve group and the others were in mechanical valve group. Event-free survival for all patients at 50, 120 and 180 months was 84.6 ± 4.5%, 80.4 ± 6.0% and 53.0 ± 12.1%. Event-free survival for bioprosthetic valve group at 60, 120 and 180 months was 89.5 ± 7.0%, 83.1 ± 9.0% and 48.5 ± 14.4%. Event-free survival for mechanical valve group after 29 months was 82.2 ± 5.7% and there was no statistical difference between two groups (p=0.3771).

Linealized incidences of valve related event for both group was 3.38%/patient-years (Table 3).

9) Risk factor analysis

We analyzed risk factors for operative mortality and late mortality using univariate and multivariate analysis. Concerning for operative mortality, presence of preoperative ascites (p=0.0032) and hepatomegaly larger than 2 finger breaths (p=0.0056) and preoperative NYHA functional class (p=0.0359) were significant risk factors in univariate analysis. In multivariate analysis, presence of preoperative ascites (p=0.009) and number of tricuspid valve replacement (p=0.0031) were significant risk factors. Concerning for late mortality, use of bioprostheses valve was the only significant risk factor in univariate analysis (p=0.0423). In multivariate analysis, use of bioprostheses valve (p=0.0175) and number of open heart surgery (p=0.0091) were risk factors.

DISCUSSION

TVR carries high operative mortality than other position of valve. Our operative mortality rate of 15.6% (bioprostheses: 15.4% and mechanical: 15.7%) is comparable with those in literature reports which range from 7.7% to 27%[2-15]. In this study, there was no difference in operative mortality between two groups and this result is also comparable with others[6, 7, 12]. Among 8 early deaths in mechanical valve group, 7 of 8 patients had received two or three times of previous open heart surgery and 4 of 8 patients died of heart-unrelated causes. The late mortality rate of 12.3% (bioprostheses: 31.8%, mechanical: 2.3%) is comparable to or somewhat lower than those of other reports which range from 9.2% to 57%[2, 7, 12, 16]. Some authors reported that there was no late mortality in their follow-up period[5, 12]. Among 7 late death in bioprosthetic group, 6 patients died of valve related cause; 3 patients due to unknown cause, and 3 patients due to heart failure during redo-TV. One late death in mechanical prostheses died of end stage renal disease at 164 months after operation. Despite no statistical difference between two groups in valve related mortality (p=0.1222), there was tendency to develop valve related mortality more frequently in bioprosthetic valve group. And it may be related
to the use of porcine bioprosthetic valves in the study periods.

Valve thrombosis and pannus formation has been an important valve related complications in TVR with mechanical valve. The higher incidences of tricuspid valve thrombosis in older mechanical valves have been confirmed by several authors[17-21]. Recently, Kawano et al. reported 6 cases of valve thrombosis among 19 patients who had been received TVR with St. Jude Medical valve (linearized incidence; 2.9%/patient-years). But two of them did not take warfarin sodium regularly[5]. Dalrymple-Hay et al. also reported high prevalence of valve thrombosis in TVR with mechanical valve[6]. But Nakano et al. reported one valve thrombosis with 96.9% free from valve thrombosis at 14 years and Singh et al. reported no valve thrombosis[3,4]. In this study, 4 cases of valve thrombosis occurred within 12 months after operation and all cases were treated with intravenous thrombolytic therapy without re-operation. The linearized incidences of valve thrombosis in mechanical valve group was 1.54%/patient-years and this was higher than the results of other position of valve which we had already reported (MVR; 0.54%/patient-years, AVR; 0.33%/patient-years)[22]. But there was no statistical difference between two groups (p=0.2319) and the occurrence of valve thrombosis did not influence survival or re-operation of affected patients.

Valve related re-operation is also an important consideration in selection of valve. In this study, there was no statistical difference between two types of prostheses. But, valve-related re-operation occurred in different period after operation. All re-operation in mechanical valve occurred within 26 months after initial operation. But in bioprosthetic valve, all re-operations occurred beyond 145 months after initial operation. The causes of early phase re-operations were all non-structural valve failure and late phase re-operations were structural valve failure. Rizzoli et al. reported that the risk of re-operation in bioprostheses was 4.7%/patient-years for 300 years and 2.2%/patient-years for mechanical prosthesis during 137 years. They also reported that bioprosthetic valve degeneration showed a steeper rate after 7 years[9]. Dalrymple-Hay et al. insisted that the first 10 years after TVR is crucial in the decision making process for the optimal implant and the risk of re-operation due to structural degeneration of bio-

prosthetic valve is significantly lower than the risk of death in this period[6]. But in this study, there was no late death in mechanical valve within 10 years and all bioprosthetic valve degeneration occurred at least 10 years after initial operation. And survival rate of bioprosthetic valve group was poorer than the mechanical valve group at 10 years. And among 7 late deaths in bioprosthetic valve group, 3 died of structural valve failure and 3 died of unknown causes. Despite no statistical difference, linearized incidence of re-operation was somewhat higher in bioprosthetic valve group (2.27%/pt-yrs) than mechanical valve group (1.10%/pt-yrs). Our incidence for mechanical prostheses is somewhat lower than the reports of Kawano et al[5]. In this study, free from reoperation at 164 months was 93.0±3.9% and this result is also better than other reports[5-7].

Valve related event represents overall events about valve. In this study, the difference of linearized incidences of bioprosthetic and mechanical prostheses was small (3.63 vs. 3.16%/pt-yrs). Event free survival at 164 months for both groups was similar and there were no statistical differences (p=0.9216 in Log Rank, p=0.3771 in Wilcoxon test).

In patients with mechanical valve replacement, postoperative regular follow up and daily taking of warfarin sodium is very important. As Chang et al. pointed, intensive follow up of patients who had been received valve surgery could lessen the incidences of valve related complications[22]. We have checked up patients with TVR more closely and such a follow up resulted in good long-term survival.

Despite no statistical difference, the linearized incidence of reoperation was somewhat high in bioprosthetic prostheses than mechanical prostheses. Inevitably, most patients with bioprosthetic prostheses must receive redo surgery and this may be a serious risk to such patients. In risk factor analysis, the number of tricuspid valve replacement was risk factor for early mortality, and the use of bioprosthetic valve and the number of previous valve surgery were risk factors for late mortality. I think these facts are important for patients below 60 years, because structural bioprosthetic valve failure had occurred 10 years after initial operation. We must balance between the risk of valve-related complications and the risk of re-do operation. Nowadays, people live longer than previous days, so we must treat patients more aggressively.
expecting the patient lives longer. Daily taking a warfarin sodium and life long regular check up of PT may be a stress to patients. But if we take care of them more closely, they could live longer with little risk of valve-related complications.

As a conclusion, if the patients have no contraindication to anticoagulation therapy and are not old age, and postoperative regular, careful follow up is possible, we recommend using mechanical valve in tricuspid position.

REFERENCES

=국문 조목=

배경: 삼혈관마약대치술의 장기 결과에 대한 연구결과는 보고된 바가 많지 않다. 이에 저자들은 삼혈관마약대치술의 위험인자를 분석해보고, 삼혈관마약대치술의 장기 결과를 알고자 연구를 시행하였다. 대상 및 방법: 대상 환자는 1978년 10월부터 1996년 12월까지 삼혈관마약대치술을 시행 받은 환자 70명을 대상으로 후향적인 연구를 진행하였다. 7명의 환자들은 2차례의 삼혈관마약대치술을 시행받아 총 77예의 삼혈관마약대치술을 시행하였다. 환자의 평균 나이는 38.8±15.9세였으며, 26예에서는 조직관막, 51예에서는 기계판막을 이식하였다. 결과: 수술 사망률은 15.6%였고, 만기 사망률은 12.3%였다. 5년, 10년 그리고 13년에서의 생존율은 조직판막과 기계판막이 각각 81.3% vs. 100%, 66.1% vs. 100%, 60.6% vs. 100%였다(p=0.0175). 판막과 관련된 재수술이 없을 확률은 5년, 10년 그리고 13년에서 조직판막과 기계판막이 각각 100% vs. 93.9, 100% vs. 93.9% 그리고 58.3% vs. 93.9%였다(p=0.3274). 판막과 관련된 재수술을 시행할 확률은 조직판막이 2.27%/환자-년이었고, 기계판막이 1.10%/환자-년이었다. 수술 사망과 관련된 위험인자 분석상, 수술 전 복수, 간비대, NYHA class가 나쁜수록, 그리고 삼혈관마약대치술을 여러 번 받는 경우가 유의한 위험인자로 분석되었다. 조직판막과 관련된 유의한 위험인자로 분석되었다. 결론: 기계판막을 이용하여 삼혈관마약대치술을 시행한 환자들, 장기적 생존율에 조직판막의 이용률을 이용한 환자들보다 우수하였다. 따라서 수술 후에 적절한 추적관찰이 가능하다면, 기계판막을 이용하여 삼혈관마약대치술을 시행하는 것이 필요하다고 생각한다.

중심 단어: 1. 삼혈관마약대치술 2. 인공심장판막 3. 조직관막