Long-term Survival after Aortic Valve Replacement Using Smeloff-Cutter Prosthesis

By Simon J. K. Lee, M.D., Carol Barr, R.N., John C. Callaghan, M.D., and Richard E. Rossall, M.D.

SUMMARY

The long-term prognosis of 187 consecutive patients who received single aortic valve replacement using Smeloff-Cutter prosthesis was studied. Of the 163 patients who survived the operation, a long-term follow-up (up to eight years) was obtained in 153 patients (95%). A total of 34 patients (22%) died during the follow-up period. Including the hospital mortality, the actuarial survival rate of our patients with Smeloff-Cutter prosthesis was 0.69 after the fifth year and 0.611 after the eighth year of follow-up. This is similar to the actuarial survival rate of patients with Starr-Edwards prosthesis but it appears significantly better than the expected survival rate of symptomatic patients with aortic stenosis treated without surgery. Thus, this result supports the contention that aortic valve surgery in properly selected patients can prolong life expectancy in addition to relieving symptoms in patients with aortic valve disease. The majority of surviving patients reported to have improved (88%) since the operation and to be symptom free (82%).

The Selection of Patients for aortic valve replacement and the choice of the type of artificial valve to be used should be based on figures of long-term survival and degree of symptomatic improvement for the valve in question. The long-term results of aortic valve replacement using the Starr-Edwards prosthesis have been reported but comparable data on the Smeloff-Cutter prosthesis have not been published. The purpose of this communication is to report the late results of replacement of the aortic valve using the Smeloff-Cutter prosthesis in 187 consecutive patients.

Patient Material and Methods

A total of 200 patients had single aortic valve replacement performed by three cardiac surgeons during the period 1966 to 1972, inclusive, at the University of Alberta Hospital. (Patients who had procedures on other valves or aortoconorony bypass surgery were excluded.) Ten patients were excluded from the analysis because they had resection of the ascending aorta necessitating its grafting as well. Two of these ten patients died in hospital and an additional three patients died during the follow-up period. In addition, three other patients were excluded from the analysis because, in each case, surgery was undertaken as an emergency procedure in a terminal state. Two of these patients died in the hospital and the third patient died eight months later from congestive heart failure.

Table 1 summarizes the patient population and their symptoms before operation. Ninety-nine patients had clinical and hemodynamic findings of pure or dominant aortic stenosis (age 51 ± 10 yr); 31 patients had combined aortic stenosis and regurgitation (age 49 ± 12 yr) and 57 patients had pure or dominant aortic regurgitation (age 44 ± 12 yr). One hundred fifty-six patients were male; 31 patients were female. All patients except eight experienced one or more of the following symptoms: dyspnea on exertion, left ventricular failure (paroxysmal nocturnal dyspnea or pulmonary edema), angina, or dizziness or syncope on exertion. In eight patients symptoms were nonspecific, such as palpitation and easy fatigueability. In these patients, surgery was undertaken because of abnormal electrocardiogram (ECG) and chest X-ray and hemodynamic abnormalities.

The findings of 12 lead ECGs are summarized in table 2 and heart size assessed by chest X-ray is summarized in table 3. On the whole, the cardiothoracic ratio was larger in patients with pure or dominant aortic regurgitation than in patients with aortic stenosis. The difference in distribution of the cardiothoracic ratio is significant (P < 0.01, x² = 25.63).

Left and right heart catheterization was carried out in all except three patients. In patients with dominant aortic stenosis, a systolic pressure gradient over 50 mm Hg was considered significant. In patients with pure or dominant aortic regurgitation, a significant degree of regurgitation was demonstrated by aortic root cineangiography. As a rule, the presence of an enlarged left ventricle on chest X-ray and an abnormal ECG were necessary conditions for operation in patients with aortic regurgitation.

None of the patients were denied surgery on the basis of severity of disease or the presence of high risk factors.

Detailed descriptions of the operative procedure have been published previously. Briefly, the operation was carried out using temporary cardiopulmonary support with a Travenol disposable bubble oxygenator primed with buffered Ringer's lactate solution. The minimum flow rate was maintained at 40 ml/kg/min and the temperature of the perfusate was maintained between 30 and 37°C. Arterial blood gases and pH were monitored frequently during the operation. In 143 cases the operation was carried out with cor-
The actuarial long-term survival rate was calculated by equation IV of Elveback\(^6\) as used by Duvoisin and McGoon.\(^1\) Chi-square test was carried out for a 2 X 2 contingency table with Yates correction or n \times m contingency table. \(P\) value was based on single tail Chi-square table.

### Results

Of the 187 patients studied, 24 died within the first month of surgery giving a hospital mortality of 12.8%. The causes of hospital death are listed in table 4. In 12 of the patients, death was related to technical problems. Of the 163 patients who survived the operation, a minimum period of twelve months follow-up was obtained in 153 of the cases (95%). The follow-up period ranged from one to eight years and a total of 34 patients (22%) died during this time. The actuarial survival data of our patients is listed in table 5 and it is compared in figure 1 with those of the Mayo Clinic. The causes of the late deaths are listed in table 6.

Thromboembolic complications occurred in 24 patients (15%). Seven of these patients were not receiving anticoagulants, while 15 were receiving anticoagulants at the time of the complication. In the other two patients, the anticoagulation status is unknown. Cerebrovascular accidents, probably from thromboembolism, occurred in a total of 19 patients (12%). In four of these, the symptoms were only transient. Nine patients survived the embolization with residual defects while the embolus proved fatal in the other six patients (3.9%). Of these six fatal cases, four patients did not receive anticoagulants, and in two patients anticoagulation status at the time of this complication is unknown. Peripheral embolization occurred in four patients and these included emboli to the femoral artery in one, to the retinal artery with partial loss of vision in one, to the renal artery in one, and to the coronary artery in the remaining case.

Abbreviations: AS = aortic stenosis; AS & AR = combined aortic stenosis and regurgitation; AR = aortic regurgitation; LVF = left ventricular failure.

### Congestive Heart Failure

Congestive heart failure, despite administration of medical treatment, caused death in four patients. In two of these, the murmur of aortic regurgitation was present on auscultation indicating some residual aortic regurgitation presumed to be due to a paravalvular leak. The remaining two patients had congestive heart failure prior to surgery.

At the time of the follow-up, a total of 20 patients (18%) had some symptoms: nine with residual effects of cerebrovascular accident, one with partial loss of vision of one eye secondary to a peripheral embolus, five with heart failure, four with hemolytic anemia and one patient with angina following unsuccessful aortic-coronary bypass surgery. In addition four patients had mild to moderate degrees of paravalvular regurgitation at the time of postoperative catheterization but were asymptomatic.

Prosthetic endocarditis was diagnosed in three patients during the follow-up period. Two of them died subsequent to re-operation. The remaining one patient died from widespread embolization and aortic regurgitation. One additional patient had mycotic aneurysm of the aorta and died during re-operation.

Re-operation was necessary in a total of 14 patients (9%). Residual paravalvular aortic regurgitation was the indication in eight (including two patients with prosthetic endocarditis). Three of these eight patients died during the second operation. Three additional patients died during the follow-up period and the

### Table 3

<table>
<thead>
<tr>
<th>Cardiothoracic Ratio</th>
<th>Number &lt; 51%</th>
<th>51 - 60%</th>
<th>&gt; 60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>96</td>
<td>52</td>
<td>37</td>
</tr>
<tr>
<td>AS &amp; AR</td>
<td>30</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>AR</td>
<td>54</td>
<td>7</td>
<td>38</td>
</tr>
<tr>
<td>Total</td>
<td>180*</td>
<td>70</td>
<td>92</td>
</tr>
</tbody>
</table>

\(X^2 = 25.63; P < 0.01\)

*Chest X-rays were not available for determination of CT ratio in seven patients.*

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remaining two patients are alive. Four months after the initial operation one patient underwent an aortocoronary bypass procedure for stenosis of the main left coronary artery which was apparently caused by the coronary perfusion cannula used during the first operation. (The coronary arteriogram had been normal prior to the initial operation.) One other patient underwent coronary bypass surgery for obstructive coronary artery disease. Both of these patients are living. One patient subsequently had mitral valve replacement and is living, and another underwent mitral and tricuspid valve replacement unsuccessfully. One patient had re-operation because of recurrent embolism due to thrombosis of the prosthetic valve and is alive. The remaining one patient died during re-operation for mycotic aneurysm of the ascending aorta. Thus, six of the 14 patients who had re-operation are living (42%).

Discussion

Obviously, late survival following aortic valve replacement depends on many factors including myocardial function prior to surgery, the presence or absence of associated cardiac disease, postoperative paravalvular regurgitation, infection and prosthesiscorrelation complications.

After discharge, systemic thromboembolic complications occurred in 15.7% of patients but fatal complications were rare, occurring in seven patients (4.6%). Only one of these patients was known to have received anticoagulants at the time of this complication.

Barnhost et al.7 recently reported approximately 20% incidence of thromboembolism in 5 years in patients with Starr-Edwards prosthesis models 1000 and 1200 but this complication was reduced using a later model (1260) — less than 5% in three years. However, they did not find a significant difference between model 1260 and cloth covered valve (2310) in three years of follow-up. Our incidence of thromboembolism using Smeloff-Cutter prosthesis is somewhat lower than in patients with Starr-Edwards prosthesis model 1000 and 1200, but a meaningful comparison cannot be made with model 1260 or 2310.

Thromboembolic complication depends not only on the type of prosthesis but also on the adequacy of anticoagulation. Among the living 120 patients at the time of follow-up, 99 patients were on anticoagulants and 19 patients were not. In our series, most of the serious thromboembolic complications occurred in patients who were not given anticoagulants. In a previous study from this institution, a significantly higher incidence of thromboembolic complication was encountered in the patients who did not receive or who received inadequate anticoagulation compared to those who received adequate anticoagulation.

There were five (3.6%) sudden deaths for which autopsy examination was not performed. As far as we could ascertain, however, none of the deaths or serious complications could be ascribed to ball variance.

Comparison of hospital and late mortality between the groups of pure aortic stenosis (AS) and combined

Table 5

Survival Following Surgery

<table>
<thead>
<tr>
<th>Interval following surgery (yr)</th>
<th>Total persons living and under observation at beginning of interval</th>
<th>Events during interval</th>
<th>Living withdrawals</th>
<th>Survival rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1</td>
<td>187</td>
<td>36</td>
<td>10*</td>
<td>1.000</td>
</tr>
<tr>
<td>1 - 2</td>
<td>141</td>
<td>3</td>
<td>12</td>
<td>.8071</td>
</tr>
<tr>
<td>2 - 3</td>
<td>120</td>
<td>4</td>
<td>13</td>
<td>.7890</td>
</tr>
<tr>
<td>3 - 4</td>
<td>103</td>
<td>1</td>
<td>12</td>
<td>.7616</td>
</tr>
<tr>
<td>4 - 5</td>
<td>76</td>
<td>4</td>
<td>13</td>
<td>.5969</td>
</tr>
<tr>
<td>5 - 6</td>
<td>55</td>
<td>4</td>
<td>10</td>
<td>.6865</td>
</tr>
<tr>
<td>6 - 7</td>
<td>41</td>
<td>1</td>
<td>20</td>
<td>.6319</td>
</tr>
<tr>
<td>7 - 8</td>
<td>20</td>
<td>1</td>
<td>19</td>
<td>.6116</td>
</tr>
</tbody>
</table>

*Includes ten patients lost to follow-up.
aortic stenosis and regurgitation (AS & AR) revealed no significant difference; hence these two groups were treated as one in the following analysis. No significant difference was found in either hospital mortality or late mortality between the two groups of AS and AS & AR and pure aortic regurgitation (AR) (table 4). The six year actuarial survival was 0.622 in AS and AS & AR group, and 0.674 in AR group.

Presence of angina before surgery appears to increase the hospital mortality (table 8). This is probably due to the fact that some patients with angina had significant coronary artery disease (which was not bypassed) and developed myocardial infarction during the perioperative period. The late mortality, however, did not differ between the two groups.

In table 9, the mortality was compared in the patients who did and did not experience left ventricular failure before the operation. The over-all hospital mortality was not different between the two groups. This is due to the fact that most hospital deaths were of a technical nature, and only three of 24 hospital deaths were directly due to poor left ventricular function (table 4). In the groups with AS and AS & AR, the late mortality was higher (31% vs 17%) in patients who had experienced left ventricular failure, although the difference is not statistically significant. The experience of the Mayo Clinic indicates that the long-term survival is influenced by the preoperative heart size. In our experience (table 10), the hospital mortality was lowest (8%) in patients with cardiothoracic

### Table 6

**Causes of Late Death**

<table>
<thead>
<tr>
<th>Causes</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolization</td>
<td>6</td>
<td>21%</td>
</tr>
<tr>
<td>Cerebral</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coronary</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Noncardiac</td>
<td>5</td>
<td>14.5%</td>
</tr>
<tr>
<td>Sudden unexpected death</td>
<td>5</td>
<td>14.5%</td>
</tr>
<tr>
<td>Heart failure</td>
<td>5</td>
<td>14.5%</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>4</td>
<td>11.5%</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td>Re-operation</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td></td>
</tr>
</tbody>
</table>

### Table 7

**Aortic Lesion and Survival**

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Hospital mortality</th>
<th>Late mortality*</th>
<th>Combined mortality*</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS and AS &amp; AR</td>
<td>130</td>
<td>18 (14%)</td>
<td>26 (20%)</td>
<td>44 (31%)</td>
</tr>
<tr>
<td>AR</td>
<td>57</td>
<td>6 (10%)</td>
<td>8 (14%)</td>
<td>14 (25%)</td>
</tr>
</tbody>
</table>

*Excluding ten patients without long-term follow-up.
NS = P > 0.05.

### Table 8

**Angina and Survival**

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Hospital mortality</th>
<th>Late mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS and AS &amp; AR</td>
<td>65</td>
<td>13 (20%)</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>AR</td>
<td>65</td>
<td>5 (8%)</td>
<td>17 (30%)</td>
</tr>
<tr>
<td>No angina</td>
<td>38</td>
<td>3 (8%)</td>
<td>6 (18%)</td>
</tr>
</tbody>
</table>

*X^2 = 4.303; P < 0.05 — Angina vs no angina patients in both groups.
NS = P > 0.05.
estimated that the average survival is 1½ to 2 years after the onset of congestive heart failure and 3 years after syncope or angina in patients with aortic stenosis. Using similar autopsy data, Duvoisin and McGoon estimated the survival rate of symptomatic patients with aortic stenosis to be only about 20% after 3 years and 5% after 6 years. However, such estimation based on autopsy studies may introduce bias as living patients are automatically excluded in the analysis. Recently, Frank et al. reported their prospective observation on 15 patients with hemodynamically significant aortic stenosis treated without surgery; 52% died within 5 years and 90% within 10 years of diagnosis. A similarly poor prognosis was also reported by Rappaport: 62% died within 5 years of diagnosis and 80% died within 10 years.

The prognosis of symptomatic patients with aortic regurgitation is less well documented but it should be similar to that of the patients with aortic stenosis. Therefore, our experience as well as that of the Mayo Clinic suggests that aortic valve replacement in patients with these symptoms (angina, syncope or pre-syncope, or heart failure) can prolong life expectancy.

However, the same conclusion cannot be drawn in asymptomatic patients or patients with dyspnea only on strenuous exertion, as the natural history of such patients is unknown and is expected to be better than in those with the triad of symptoms. Recently, Rappaport pointed out that the medically treated prognosis is better in aortic regurgitation (75% survival in 5 years) than in aortic stenosis (38% survival in 5 years). Segal et al. also pointed out that the average interval from the appearance of major aortic insufficiency to the development of symptoms is ten years. More recent evidence, however, suggests that asymptomatic patients with severe aortic regurgitation who have cardiomegaly on chest X-ray, ECG evidence of left ventricular hypertrophy and strain, and abnormal blood pressure, are in a high risk group. Although the five year mortality in this group was only 30%, an additional 50% of patients developed heart failure or angina during the same period.

Our data (Table 11) suggest that surgery before the appearance of angina, syncope or left ventricular failure does not necessarily improve the hospital or late mortality. Thus, prophylactic surgery appears unjustifiable. However, the surgery should be undertaken without delay once symptoms of angina, syncope or left ventricular failure appear and before the appearance of gross cardiac enlargement (cardiothoracic ratio over 60%), since the result of surgery is poor in such patients.

## References
LONG-TERM PROGNOSIS AFTER AV REPLACEMENT


Long-term survival after aortic valve replacement using Smeloff-Cutter prosthesis.
S J Lee, C Barr, J C Callaghan and R E Rossall

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