Prosthetic valve replacement remains the most viable alternative for the treatment of severely diseased heart valves. The cumulative experience of mechanical prostheses and bioprostheses was evaluated for a 10-year performance comparison: Carpentier-Edwards standard porcine bioprosthesis (CE-S), 1,214 operations; Carpentier-Edwards supraannular porcine bioprosthesis (CE-SAV), 2,489; and mechanical prostheses, 1,364 operations (St. Jude Medical, Carbomedics, Duromedics, and Björk-Shiley Monostrut). The freedom from thromboembolism and hemorrhage at 10 years was 82% for CE-S, 78% for CE-SAV, and 65% for mechanical prostheses (p < 0.05). The relationship existed for major thromboembolism and hemorrhage, 91% (CE-S), 87% (CE-SAV), and 88% (mechanical) (p < 0.05), without clinical relevance. The freedom from structural valve deterioration and valve-related reoperation favored mechanical prostheses (p < 0.05) at 10 years (structural failure: 78% for CE-S, 81% for CE-SAV, and 99% for the mechanical group; reoperation: 74% for CE-S, 76% for CE-SAV, and 88% for mechanical prostheses). The freedom from fatal reoperation was not clinically different: 96% for CE-S, 99% for CE-SAV, and 99% for mechanical prostheses (p < 0.05) at 10 years. The freedom from valve-related mortality was not different (p = not significant) at 10 years: 87% for CE-S; 92% for CE-SAV; and 91% for mechanical. The freedom from permanent impairment or residual morbidity, primarily from thromboembolism, was 95% for CE-S, 92% for CE-SAV, and 95% for mechanical group (p < 0.05) but not clinically relevant. The freedom from overall valve-related complications favored both the bioprostheses groups over the mechanical group; 5-year rates were 86% for CE-S, 84% for CE-SAV, and 73% for mechanical (p < 0.05), the relationship extended to 9 years. There remains differentiating features between bioprostheses and mechanical prostheses at 10 years, but the serious complications of major thromboembolism and hemorrhage, fatal reoperation and valve-related mortality do not differentiate the prostheses types.

The past 10 years have seen an increased tendency toward valvular reconstruction and preservation techniques. However, prosthetic valve replacement still remains the most viable, if not the only alternative treatment of severely diseased heart valves. Although there has also been an increased use of homografts and autografts in the aortic and pulmonary positions, overall replacement with mechanical prostheses or bioprostheses represents the two most commonly used options for heart valve replacement [1-5].

Because of inherent differences between the types of prostheses, such as need for anticoagulation of mechanical valve implants with associated incidence of hemorrhagic complications and thromboembolic episodes, and the limited durability of bioprostheses, indications for implantation of either type of prostheses have had to be individualized considering patient age, sex, activity status, ability to self medicate, geographic area, and opportunity for follow-up, social situation, life expectancy, and possible contraindication to anticoagulation. Although, because of limiting factors such as mentioned, it may be relatively straightforward to choose a type of prosthesis for a specific individual, for the majority of patients the search for the ideal valve substitute continues, as demonstrated by the ongoing introduction of new mechanical valve designs and new generation/designs of bioprostheses. However, often we are left to choose a prosthesis where only life expectancy, quality of life, and prosthesis durability remains the only significant determinates.

Because of the low incidence of thromboembolism, almost nonexistent incidence of valve thrombosis, and the relative freedom from the risk of anticoagulant-related hemorrhage, bioprostheses do provide patients with a superior quality of life. On the other hand, mechanical valves offer patients extended durability, thus limiting the mortality and morbidity risks that would be associated with reoperation for replacement of a degenerated bioprosthesis.

This study presents a cumulative experience with mechanical prostheses and bioprostheses, evaluating specifically the 10-year performance of three groups of
Table 1. Patient Population

<table>
<thead>
<tr>
<th>Prosthesis Type</th>
<th>Mean Age (y)</th>
<th>Follow-up</th>
<th>Concomitant Procedures (%)</th>
<th>Mortality Early (%)</th>
<th>Mortality Late (%/pt-y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE-S</td>
<td>57.3</td>
<td>96.2</td>
<td>9968.1</td>
<td>325 (26.8)</td>
<td>92 (7.6)</td>
</tr>
<tr>
<td>Mechanical</td>
<td>56.1</td>
<td>98.4</td>
<td>3267.1</td>
<td>385 (28.2)</td>
<td>84 (6.2)</td>
</tr>
<tr>
<td>CE-SAV</td>
<td>64.1</td>
<td>96.1</td>
<td>12784.7</td>
<td>1017 (40.9)</td>
<td>185 (7.4)</td>
</tr>
</tbody>
</table>

Table 1 denotes the patient population of the three groups, mean age, follow-up, concomitant procedures, and early and late mortality.

The follow-up in all three patient groups was greater than 96% (CE-S 96.2%, CE-SAV 96.1%, and mechanical group 98.4%). The patients were followed through a combination of interviews by research coordinators, information from hospital records on readmission or reoperation, attending physician reports and written questionnaire to family physicians, as well as the Canadian Bureau of Vital Statistics for deceased patients. The valve-related complications, composites of complications, and deaths were classified and reported according to guidelines of the Society of Thoracic Surgeons and the American Association for Thoracic Surgery [6].

The anticoagulant regimen was essentially standard for the overall patient population. Heparin was not administered routinely in the postoperative period. Warfarin sodium was started on postoperative day 2 or 3 for mechanical prostheses and enteric-coated aspirin on the day of operation for bioprostheses. Warfarin was only administered to bioprosthetic patients where there was presence of associated risk factors of thrombosis such as atrial fibrillation. The level of anticoagulation has changed over time with lower levels (INR, 1.5 to 2.5) for aortic patients and intermediate levels (INR, 2.5 to 3.5) for mitral patients.

Statistical Analysis

Categorical parameters such as the incidence of early and late mortality was tested by $\chi^2$ test applying Yates's correction for contingency tables or Fisher’s exact test for smaller sample sizes. Actuarial survival analysis (Cutler-Eder method) was used to describe survival and freedom from valve-related complications and composites of valve-related complications. The comparisons among the groups were performed by the Lee-Desu comparison statistic. All statistical models were calculated with the BMDP version 4.2 and SPSS version 4.0 statistical packages.

Results

Early mortality includes all deaths within 30 days of operation and is reported as a crude value. The incidence
(percentage) of early mortality in each group is similar (p = not significant [NS]). Late mortality includes all deaths occurring beyond 30 days after operation and is reported as a linearized occurrence rate (percent per patient-year). There is a significant difference between the groups with the mechanical group (3.6% per patient-year) having the lowest late mortality rate (CE-S, 5.3% per patient-year; CE-SAV, 4.9% per patient-year) (p < 0.05 CE-S > CE-SAV > mechanical). Although there is a significant difference in late survival between the CE-SAV and mechanical groups, we believe that the higher late mortality observed in the CE-SAV group can be explained partially by its older population (mean age, 64 years).

The overall patient survival favors the biological populations at 10 years: 57.8% ± 1.5% for CE-S, 53.8% ± 1.5% for CE-SAV, and 47.1% ± 8.4% for the mechanical group (p < 0.05 mechanical > CE-SAV) (Fig 1). The patient survival by valve position is shown in Figures 2 to 4, p = NS between the groups for the aortic and multiple positions. In the mitral position the survival was different (p < 0.05 mechanical > CE-SAV) at 10 years, 43.1% ± 11.5% for the mechanical group, whereas it was 52.3% ± 2.4% and 49.9% ± 2.3% for the CE-S and CE-SAV groups, respectively. There was no difference with concomitant (p = not significant) but differences without concomitant (p < 0.05 mechanical > CE-SAV) procedures (Figs 5 and 6).

The freedom from valve-related complications and composites is presented in Figures 7 to 15. Figure 7 shows the freedom from overall complications, which was similar at 10 years: 75.7% ± 1.7% for CE-S, 77.5% ± 1.8% for CE-SAV, and 76.3% ± 4.3% for the mechanical group but different over time (p < 0.05 CE-S, CE-SAV > mechanical).

The freedom from valve-related reoperation (Fig 8) parallels structural valve deterioration for biological prostheses, 73.8% ± 1.5% for CE-S and 76.3% ± 1.8% for CE-SAV, whereas 88.0% ± 2.5% for the mechanical prostheses, at 10 years (p < 0.05 CE-SAV > CE-S, mechanical). The freedom from fatal reoperation was similar but different (p < 0.05 CE-SAV > mechanical, CE-S) (Fig 9).

The freedom from thromboembolism and antithrombotic hemorrhage at 10 years was 82.1% ± 1.4% for CE-S, 78.4% ± 1.4% for CE-SAV, and 64.8% ± 4.6% for the mechanical group (p < 0.05 CE-S > CE-SAV > mechanical) (Fig 10). The freedom from major thromboembolism and hemorrhage provides a different relationship (CE-S > CE-SAV, mechanical) (Fig 11).

Figure 12 shows the freedom from nonstructural dysfunction greater for the biological groups (p < 0.05 CE-S, CE-SAV > mechanical).

The freedom from structural valve deterioration at 10
years is 77.6% ± 1.5% for CE-S and 80.5% ± 1.7% for CE-SAV, whereas 99.6% ± 0.5% for the mechanical group, with one Duromedics failure (p < 0.05 mechanical > CE-SAV > CE-S) (Fig 13).

The freedom from valve-related residual morbidity or permanent impairment (neurologic deficit from thromboembolism, hemorrhage, or endocarditis) is also similar but different (p < 0.05 CE-S > mechanical, CE-SAV) (Fig 14).

The freedom from valve-related mortality is not different between groups (p = NS): 88.6% ± 1.1% for CE-S, 91.7% ± 1.0% for CE-SAV, and 91.3% ± 2.9% for mechanical group (Fig 15).

Comment

The study addresses the overall clinical performance of bioprostheses and mechanical prostheses. The experience at the University of British Columbia has demonstrated that the likelihood of prosthetic dysfunction and reoperation for porcine bioprostheses is a continuous function of age [7]. However, considering the distribution of the study groups, it is obvious from our recent experience that younger age has favored implantation of a mechanical prosthesis rather than a bioprosthesis, the mean age of the new generation CE-SAV population being 64 years as opposed to the previous generation CE-S of 57 years, compared with the mean age of the mechanical population of 56 years.

The overall experience with mechanical prostheses parallels the documentation from several current reports on these prostheses [1, 5, 8-11]. Kratz and colleagues [5] reporting in 1993 on the St. Jude Medical prosthesis that at 10 years the freedom from thromboembolism was 67%. This correlates closely with our overall mechanical prosthesis freedom from thromboembolism and hemorrhage of 65% at 10 years. The majority of the publications on the current generation of mechanical prostheses deal with patient survival, on the St. Jude Medical by Kratz [5], Czer [1], and Smith [12], and their colleagues, Björk-Shiley Monostrut from the Spanish co-operative study [8], and Duromedics by Moritz and co-workers [9, 10]. The early clinical experience with the new Carbomedics mechanical prosthesis reported in 1993 by de Luca and co-workers [11] demonstrated very acceptable clinical performance without untoward complications. The Duromedics mechanical prosthesis included in our patient population has a documented failure mode of disc and housing fracture attributable to cavitation. The only structural failure in our population is a disc fracture with embolization of a mitral Duromedics prosthesis. Moritz and colleagues [10] had two causes of leaflet escape in 507 Duromedics patients with a rate of 0.09% per patient-year. We recognize, however, the potential pitfalls of analyzing a heterogeneous group of mechanical prosthe-
ses, especially with the known incidence of structural failure of the Duromedics prosthesis.

The demonstration of patient survival with concomitant procedures did not reveal benefits for implantation of a mechanical prosthesis over a bioprosthesis, but without, benefits extended to mechanical prostheses. The significant influence of concomitant procedures, primarily coronary artery bypass grafting, on patient survival, in general, was distributed across the prostheses types. Overall, the patient survival at 10 years with concomitant procedures was in the 42% to 46% range, whereas without concomitant procedures it was 53% to 63%.

The mechanical experience is compared to the bioprosthetic results from our university, which have been extensively published [2, 3, 13].

There has been minimal documentation on comparison of the clinical performance of mechanical and bioprosthetic populations. The randomized trials have provided the majority of the comparison information. The randomized trials have been the Veterans Administration Study on Valvular Heart Disease [14, 15] and the Edinburgh Heart Valve Trial [16]. The Veterans Administration Study compared the previous generation Björk-Shiley spherical disc mechanical prosthesis and the Hancock standard porcine bioprosthesis, and the Edinburgh Heart Valve Study compared the Björk-Shiley spherical disc to the standard Hancock and Carpentier-Edwards prostheses. The overall performance of aortic and mitral replacements at 10 years were similar in patients randomized to a bioprosthesis versus a mechanical prosthesis. These results were essentially confirmed in our nonrandomized evaluation. The randomized trials confirmed that bleeding complication from anticoagulation were predominant in the mechanical valve populations. The incidences of thromboembolism, thrombosis, and prosthetic valve endocarditis were the same at 12 years between mechanical and bioprostheses. Reoperations were performed for structural failure of bioprostheses and paravalvular leak for mechanical prostheses. Our study confirmed the same with the reoperative freedom at 10 years of 88% for mechanical prostheses and 74% to 76% for porcine bioprostheses. The trials also showed that the failure of porcine bioprostheses occurred more frequently in the mitral position than the aortic position 5 or more years after implantation, an observation previously reported from nonrandomized studies [2-4]. The freedom from death, reoperation, major bleeding, major embolism, and endocarditis was less with porcine bioprostheses, especially in the mitral position. The trial investigators are of the opinion that the increased risk of reoperation with bioprostheses appeared to be a high price to pay for the reduced risk of bleeding due to the avoidance of anticoagulation.

From our experience, bioprostheses have a lower incidence of valve-related complications, including thromboembolism, anticoagulant hemorrhage, and nonstructural dysfunction than mechanical prostheses but an
increased rate of structural valve deterioration. The increased rate of structural valve deterioration results in an increased incidence of reoperation, but mechanical prostheses have a reoperative rate of 50% of bioprostheses at 10 years. This increased rate of structural failure and reoperation does not translate to an increased rate of valve-related mortality, which was similar with bioprostheses and mechanical prostheses in this review. We conclude that in our 10-year experience the implantation of bioprostheses does indeed provide an improved quality of life, as demonstrated by reduced thromboembolic and hemorrhagic morbidity, without any increase in valve-related mortality and with reduced overall rate of valve-related complications.

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