Prospective randomized comparison of CarboMedics and St. Jude Medical bileaflet mechanical heart valve prostheses: Ten-year follow-up

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Objective: This is the final report of a randomized controlled trial comparing the performance of CarboMedics (CarboMedics Inc., Austin, Tex) and St. Jude Medical (St. Jude Medical Inc, St Paul, Minn) bileaflet mechanical heart valve prostheses 10 years after surgery.

Methods: Between 1992 and 1996, 485 patients undergoing mechanical heart valve replacement were randomized to receive CarboMedics (n = 234) or St. Jude Medical (n = 251) prostheses for aortic (n = 288), mitral (n = 160), or double (n = 37) valve replacements. Patients were followed annually to the end of 2004.

Results: Demographic, preoperative, and operative characteristics were similar between the 2 groups. The median follow-up was 10 years in both groups (CarboMedics 99% complete, St. Jude Medical 98% complete; 3879 patient-years of follow-up). Overall, 165 patients died, 25 of valve-related causes. Ten-year survivals were 66.4% (95% confidence interval: 59.6%-72.3%) and 64.7% (95% confidence interval: 58.0%-70.6%) in the CarboMedics and St. Jude Medical groups, respectively ($P = .94$). Freedom at 10 years from valve-related mortality was 95.0% (95% confidence interval: 90.8%-97.3%) in the CarboMedics group and 93.0% (95% confidence interval: 88.3%-95.9%) in the St. Jude Medical group. During follow-up, 34 patients had a thromboembolic event, 79 patients had at least 1 bleeding event, and 14 patients required reoperation. There were no significant differences between the groups with respect to freedom from complications ($P \geq .12$); freedom from thromboembolism at 10 years (CarboMedics: 91.5%, 95% confidence interval: 86.5%-94.7%; St. Jude Medical: 92.2%, 95% confidence interval: 87.5%-95.2%); freedom from bleeding events (CarboMedics: 83.0%, 95% confidence interval: 76.6%-87.8%; St. Jude Medical: 77.5%, 95% confidence interval: 71.1%-82.7%); and freedom from death or valve-related complication (CarboMedics: 51.6%, 95% confidence interval: 44.7%-58.0%; St. Jude Medical: 46.2%, 95% confidence interval: 39.7%-52.4%). Linearized rates per patient-year were 1.1% in the CarboMedics group and 0.8% in the St. Jude Medical group for thromboembolism; 2.3% in the CarboMedics group and 3.2% in the St. Jude Medical group for bleeding events; and 0.72% in the CarboMedics group and 0.47% in the St. Jude Medical group for nonstructural valve dysfunction. International normalized ratio values were similar between the 2 groups throughout the study period.

Conclusion: At 10 years, the clinical outcome was similar with respect to these 2 mechanical bileaflet prostheses.

Introduced in 1977, the St. Jude Medical (SJM) (St. Jude Medical Inc, St. Paul, Minn) mechanical bileaflet prosthesis was the first bileaflet pyrolytic carbon prosthesis. The CarboMedics (CM) (CarboMedics Inc., Austin, Tex) mechanical bileaflet prosthesis was introduced as an investigational prosthesis in 1986 and received Food and Drug Administration approval in 1993. Both prostheses have been widely used, and there are extensive observational studies describing their clinical performance.[1-4] There are differences in the design of the 2 prostheses,[5] which could conceivably confer differences in thromboembolic risk and other aspects of clinical performance. However, Akins[6] concluded that rates for valve-related complications were essentially comparable between CM and SJM valves, although data for the CM valve from a smaller study population did show a slightly higher rate of thromboembolic complications in the mitral position, despite adequate anticoagulation. This finding has been supported by others.[7,8] In contrast, Jamieson and colleagues[7,9] found no significant differences in thromboembolic tendency between the CM and SJM prostheses in isolated mitral valve replacement (MVR) or double valve replacement (DVR). A recent meta-analysis of these 2 prostheses found comparable thromboembolism and bleeding rates, but differing thrombosis rates (lower with the CM aortic valve and higher with the CM mitral valve compared with the corresponding SJM valves). However, whether the differences observed were of any clinical importance was doubtful.[10] Long-term randomized studies to evaluate experiences with these prostheses have been lacking to date, although an interim analysis of this study at 5 years has been presented.[11]

Although some argue that randomized controlled trials are not essential in evaluating prostheses, the conflicting and occasionally worrisome outcomes reported in observational studies make randomized controlled studies an important contribution to the assessment of the clinical performance of particular valve prostheses.

This is the second and final report of a randomized controlled trial comparing the clinical outcome of patients who received either CM or SJM standard mechanical heart valves implanted at a single institution with a median follow-up of 10 years.

Abbreviations and Acronyms

AVR = aortic valve replacement
CM = CarboMedics
DVR = double valve replacement
INR = international normalized ratio
MVR = mitral valve replacement
NYHA = New York Heart Association
SJM = St. Jude Medical
SMR = standardized mortality ratio

Materials and Methods

Patient Recruitment

From July 1992 to June 1996, patients scheduled to undergo mechanical heart valve replacement surgery at the Bristol Heart Institute under the care of a team of 5 consultant cardiac surgeons were recruited by individual consent into the study, which was approved by the local hospital research ethics committee. Exclusion criteria included inability to obtain informed consent, known follow-up difficulties, surgery to the ascending aorta, history of bleeding diathesis, blood dyscrasias, major neurologic disorders (eg, epilepsy), and long-term hemodialysis. Random assignment was by card allocation at time of surgery.

Surgery and Postoperative Management

All operations were performed through a median sternotomy with cardiopulmonary bypass and mild systemic hypothermia (28°C-32°C). Myocardial protection consisted of intermittent antegrade ± retrograde cold (6°C) St. Thomas crystalloid or blood cardioplegia. The prostheses used in both the CM and SJM groups were of standard design. Interrupted or continuous suturing technique was used at the discretion of the operating surgeon. All patients received postoperative subcutaneous heparin until the international normalized ratio (INR) was greater than 2 with warfarin administration. On discharge, anticoagulation was managed in the community by general medical practitioners or at local hospitals according to the British Society of Haematology guidelines.[12] For the initial part of the study, these guidelines recommended a target INR of 3.0 to 4.5 for all patients with mechanical heart valves. Subsequent revisions of this advice have acknowledged that modern bileaflet prostheses may be anticoagulated at a lower level.[13]

Clinical and Study Follow-up

Patients were seen at 6 weeks for a clinical review and thereafter referred to their cardiologist for annual review. Study follow-up was primarily by postal questionnaire sent to each patient on the anniversary of his or her operation. Patients were contacted directly only when clarification of details was necessary. The family practitioner and/or hospital cardiologist was contacted, and hospital health records were used where appropriate to clarify clinical events.

When a death occurred, the postmortem report was requested. The death registry of the UK Office of National Statistics was used to provide details of deaths that were otherwise unobtainable.

Adverse events, when reported, were categorized by a clinician blinded to valve type. Anticoagulation data (last 10 INR values) and drug dosages were obtained from the anticoagulant history booklet carried by the patient and filled out by the physician responsible for the patient's care. Data collection was terminated at the end of December 2004, the planned end of the study.

Statistical Analysis and Data Reporting

The original "Guidelines for Reporting Morbidity and Mortality after a Cardiac Valvular Operation"[14] and its subsequent revi-