Choice of Prosthetic Heart Valves: 20-Year Results of the Edinburgh Heart Valve Trial

A recent edition of the Journal carried a robust debate between David S. Bach (1) and Shahbudin H. Rahimtoola (2) on the choice of prosthetic heart valves for individual patients requiring valve replacement surgery. Bach's (1) thesis was that prosthetic heart valves have evolved over the years to provide superior hemodynamics and durability compared to older valves, which had been included in randomized trials. Rahimtoola's (2) commentary, “The next generation of prosthetic heart valves needs a proven track record of patient outcomes at ≥15 to 20 years,” emphasized the importance of obtaining long-term data not available for the newer prostheses, and he stressed how important long-term data are from prospective randomized trials.

Bach (1) notes that in the Edinburgh Heart Valve Trial there was a trend favoring improved survival in association with the mechanical Bjork-Shiley prosthesis. We have recently published data from the 20-year follow-up of patients randomized in this trial. Interestingly, the trend toward improved survival at 12 years diminished as patients were followed for 20 years. Bach (1) also noted, “However, freedom from all valve-related complications for tissue and mechanical prostheses was indistinguishable at 12 years.” In fact, when we followed our patients for survival without a major event (i.e., freedom from death, re-operation, major hemorrhage, embolism, or endocarditis) there was a significantly better survival in favor of the Bjork-Shiley prosthesis for those undergoing mitral valve replacement (3). This benefit became apparent after 10 to 12 years of follow-up and as survival cures continued to separate thereafter.

This difference in survival without a major event was almost entirely accounted for by the increased need for re-operation in patients who had received a bioprosthesis with increasing years of follow-up. There was no significant difference in survival without a major event in the subgroup of patients who had undergone aortic valve replacement. These results would not support Bach's (1) statement, namely that “Bioprostheses were superior to mechanical valves prior to 12 years after surgery and were equivalent thereafter.” The risk of anticoagulant hemorrhage is of course not limited to those patients receiving a mechanical valve. We noted an increase in the use of anticoagulants in patients who had been randomized to receive a bioprosthesis during the course of the trial. At five years, 15% of patients with a porcine aortic prosthesis and 36% of those with a porcine mitral prosthesis were receiving warfarin; by 15 years this proportion had risen to 33% and 57%, respectively. The increasing use of warfarin with the passage of time reflected concomitant conditions such as atrial fibrillation and chamber dilation favoring the use of long-term anticoagulation.

These results emphasize the need for prolonged follow-up of patients in randomized trials of prosthetic heart valves as it is only with such prolonged follow-up that important differences between prostheses are seen to emerge. It is perhaps ironic that data from the Edinburgh Trial and the U.S. Department of Veterans Affairs trial have provoked such debate within the editorial pages of the Journal of the American College of Cardiology. We had submitted the manuscript of the 20-year follow-up to the Journal more than a year prior to Bach's (1) viewpoint and Rahimtoola's (2) commentary and previous editorial. The Journal declined our manuscript; acceptance may have cast more light than heat on the subsequent debate.

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REFERENCES


REPLY

I am glad Dr. Bloomfield concurs with and re-emphasizes the importance of obtaining long-term (≥15 to 20 years) follow-up data in patients with prosthetic heart valves (PHVs). The 20-year results of the Edinburgh Heart Valve trial (1) (Edinburgh trial) are reviewed in the Journal of the American College of Cardiology series entitled “The Year in Cardiology” (2). This trial showed that at 20 years the incidence of re-operation in patients receiving the porcine PHV was very much higher than in patients receiving the mechanical PHV; after mitral valve replacement it was 77.6% versus 13.4% ± p < 0.0001 (1), and after aortic valve replacement it was 56.2% versus 7.4%, p < 0.0001. In the Veterans Affairs (3) and Edinburgh trials (1), major differences between the mechanical and bioprostheses that were statistically significant appeared after about 10 to 12 years of follow-up.

I agree that the Edinburgh and Veterans Affairs trials are very important and provide useful data, but they should not be used as the sole source on which to choose a PHV (3–5). In the Edinburgh trial (1), at 20 years the survival with original prosthesis intact was better with mechanical valve, but the total mortality was not significantly different between a mechanical and porcine PHV. Noncardiac causes accounted for 23% to 28% of the deaths; data (PHV vs. non-PHV) on the cardiac causes of death in those with mechanical and porcine PHVs are not provided. This information might help to understand why all-cause mortality was not significantly different. It is of interest that the 30-day mortality of re-operation was 14.2% (18.3% before 1987 and 9.4% after 1987) (1).

Finally, the review (4) had not dealt with stentless PHVs in any detail because long-term follow-up data was not available. The Commentary (5) was able to show that Dr. Bach’s (6) unbridled
enthusiasm for the stentless porcine valve was not supported by the available data.

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REFERENCES


REPLY

In Dr. Bloomfield’s letter discussing the Viewpoint (1) and Commentary (2) recently published in the Journal, Dr. Bloomfield notes that, in long-term follow-up of the Edinburgh Heart Valve Trial (3), 1 mortality at 20 years did not differ between mechanical and tissue prostheses; 2) owing to differences in rates of re-operation, freedom from all valve-related complications was superior after mechanical mitral (but not aortic) valve replacement; and 3) over time, an increasing use of anticoagulant therapy was seen after tissue valve replacement. Dr. Bloomfield concludes that long-term follow-up of patients in randomized trials is the only means by which differences between prostheses can be elucidated.

Equivalence of mortality at 20 years supports that, using this end point, existing data (including those from the Edinburgh Heart Valve Trial) do not favor one prosthesis type over another. Freedom from all valve-related complications favors neither prosthesis type following aortic valve replacement, which comprises a preponderance of valve replacement surgeries in the United States; for both mitral and aortic valves, higher rates of re-operation after tissue compared with mechanical valve replacement exemplifies an inherent difference between prostheses. However, re-operation may be an end point more universally feared by cardiologists than by patients. Operative mortality for elective “re-do” valve replacement is not substantially different from that for initial surgery. Whereas some patients may wish to avoid re-operation at all costs, others are clearly willing, if given the option, to face the near-certainty of additional surgery in order to avoid daily anticoagulation. This argument is not obviated by an early experience showing increasing requirement over time for anticoagulation due to atrial fibrillation. Atrial fibrillation carries a lower thromboembolic risk (and therefore requires less aggressive anticoagulation) compared with mechanical mitral valve replacement. Moreover, earlier intervention as well as newer medical therapies and surgical and percutaneous procedures presently available for the treatment of atrial arrhythmias can be expected to lower the need for additional long-term anticoagulation compared with the cohort studied from the 1970s.

The tenet of the previously published Viewpoint (1) is not that long-term data are not desirable, but that for prosthetic valve choices that are made today, pertinent long-term, randomized data do not (and will never) exist. Although Dr. Bloomfield and his co-investigators (3) are to be commended for their study, the data as they relate to current decisions in prosthetic valve surgery are moot. In 2004, neither the Bjork-Shiley nor the original Hancock valve is available for implantation. Future randomized studies are unrealistic, and even if performed, valve technology would again have evolved by the time long-term data became available. Rather than attempting to extrapolate to current practice “tissue versus mechanical” data from valves that are obsolete and in some cases known to be poorly representative of currently available prostheses, this author asks the clinician to understand the limitations of these data, and to recognize that the gradual and continuing advances made in heart valve prostheses make a demand for only long-term, randomized data unrealistic and therefore unwise.

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REFERENCES


Increased Randomness of Heart Rate Could Explain Increased Heart Rate Variability Preceding Onset of Atrial Fibrillation

The recent study in JACC by Amar et al. (1) describes significant increases in heart rate variability (HRV) in the period preceding the onset of atrial fibrillation (AF) in postoperative patients. This increase in HRV is interpreted by the investigators as reflecting increased parasympathetic and sympathetic activity. Whereas this is a possible explanation, another equally plausible explanation requires testing. We propose that the increase in HRV is due to an increase in the randomness of the heart-period signal, associated with a marked increase in sympathetic activation. This would be