Choice of Prosthetic Heart Valve in Today’s Practice
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In this update, current guidelines addressing prosthesis selection published by the American College of Cardiology/American Heart Association (ACC/AHA) and the European Society of Cardiology (ESC) are discussed, along with additional data that affect choices in valve prostheses. The case of a 50-year-old man undergoing aortic valve replacement is used to address anticipated operative mortality, risk of reoperation, and valve-related morbidity and mortality. The apparent advantages associated with the use of a bioprosthesis even in a relatively young patient help to explain current clinical trends toward the increasing use of tissue valves. We also provide a simplified algorithm that may be used to facilitate the choice of valve procedure in patients with heart valve disease.

The outcomes after surgery for valvular heart disease in terms of survival, functional status, and quality of life are determined primarily by patient-related factors such as age, ventricular function, and other comorbidities. However, outcomes also are influenced by surgical factors; the best clinical outcomes often are associated with valve repair, although mitral repair in adults remains the exception rather than the rule. For patients who require valve replacement, the valve prosthesis can significantly influence outcome.

The ideal prosthetic valve that combines excellent hemodynamic performance and long-term durability without increased thromboembolic risk or the need for long-term anticoagulation does not exist. Hence, patients and their physicians need to choose between a mechanical and a tissue (bioprosthetic) valve. In general, the advantageous durability of mechanical valves is offset by the risk of thromboembolism and the need for long-term anticoagulation and its associated risk of bleeding. In contrast, bioprosthetic valves do not require long-term anticoagulation yet carry the risk of structural failure and reoperation.

Two historic randomized clinical trials compared outcomes after valve replacement with a first-generation porcine heterograft and the original Bjork-Shiley tilting-disc mechanical valve: the Edinburgh Heart Valve Trial, conducted between 1975 and 1979 with an average follow-up of 12 years, and the Veteran Affairs (VA) Cooperative Study on Valvular Heart Disease, conducted between 1979 and 1982 with an average follow-up of 15 years. The Edinburgh trial alone showed a small survival advantage associated with a mechanical valve in the aortic but not in the mitral position; both trials showed increased bleeding associated with mechanical valves and increased reoperation with tissue valves; and both showed that structural failure of tissue valves and overall thromboembolic complications were greater after mitral than after aortic valve replacement. Although these trials are notable for their prospective, randomized design, their major limitation is that comparisons were made between first-generation porcine heterografts and the Bjork-Shiley mechanical valve, all of which are now obsolete. Thus, the ability to extrapolate these data to decisions made in modern practice is limited.

To a large degree, based on these historical studies and in the interest of freedom from reoperation, previous guidelines from the ACC/AHA heavily weighted patient age in decisions between using a tissue and mechanical prosthesis. Without robust, large-scale, multicenter, randomized trials comparing current-generation tissue and mechanical valves, the revised 2006 ACC/AHA guidelines and
the 2007 ESC guidelines rely predominantly on level C evidence to support recommendations in prosthesis selection. In the current ACC/AHA guidelines, class I recommendations for prosthesis selection are limited to the use of a mechanical prosthesis in the setting of an existing well-functioning mechanical valve and the use of a bioprosthetic aortic or mitral valve in the setting of patient unwillingness to take warfarin or of a major contraindication to its use. In distinction to earlier guidelines, both the 2006 ACC/AHA guidelines and the 2007 ESC guidelines also make allowance (class IIa and class I, respectively) for preference of the informed patient in decisions involving prosthesis selection.

A meta-analysis of 32 articles evaluated mortality from 15 mechanical and 23 biological valve series including 17 439 patients and 101 819 patient-years of follow-up. This meta-analysis found no difference in risk-corrected mortality between mechanical and bioprosthetic aortic valves regardless of patient age and suggested that the choice between a tissue and mechanical valve should not be based on age alone. Another large retrospective study comparing mechanical and tissue aortic valve replacement in 3062 patients with combined follow-up of 22 182 patient-years reported that age but not valve type was predictive of valve-related mortality. In this study, reoperation was higher after tissue aortic valve replacement only for patients <60 years of age, but combined valve-related morbidity was higher after mechanical valve replacement for all patients >40 years of age.

There are trends in the United States and Europe toward the increasing use of tissue rather than mechanical valves and toward the use of bioprostheses in progressively younger patients. These trends are supported by data showing that advances in tissue fixation and anticalcification treatment have resulted in current-generation bioprostheses that have superior durability compared with the first-generation porcine valves used in the 2 randomized trials performed in the late 1970s. As an example, the second-generation Hancock II aortic valve has 81% ± 5% freedom from structural valve deterioration after 15 years in patients with a mean age of 65 years at the time of implantation, which is superior to the 57% ± 4% freedom from structural valve deterioration at 15 years in patients with a mean age of 69 years using the first-generation Hancock bioprosthesis. Similarly, the Carpentier-Edwards pericardial aortic valve has 94% freedom from structural valve deterioration at 10 years and 77% at 15 years in patients with a mean age of 65 years, with a <10% chance that a 65-year-old patient would require reoperation before 80 years of age. Ongoing studies suggest that third-generation bioprostheses may be even more durable, with 92±8% freedom from structural valve deterioration at 10 years and 90±8% freedom from structural valve deterioration at 15 years in patients with a mean age of 54 years at the time of surgery. In addition, advances in myocardial protection and cardiac surgical techniques have led to lower risks at reoperation, making the prospect of redo valve surgery less onerous.

Other measurable factors such as total energy loss, closing volumes, and coronary perfusion also may prove to be of importance. Ultimately, however, measurable and meaningful clinical outcomes, including freedom from structural valve deterioration, freedom from valve-related morbidity and mortality, and patient lifestyle and quality of life, should be the dominant factors guiding prosthesis choice. These decisions should be made after informed discussions among the patient, the cardiologist, and the cardiac surgeon. The main determinants of valve selection are individual patient life expectancy, the patient’s tolerance to the need for repeat valve replacement, and the use of oral anticoagulants with its associated changes in lifestyle (Figure).

One means to aid in the choice between a mechanical and a tissue prosthesis is to envision the anticipated outcomes for a specific patient. For the example of a 50-year-old man with no comorbidities undergoing aortic valve replacement, anticipated operative mortality, risk of reoperation, and future valve-related morbidity and mortality can be estimated using published and available data. With the logistic EuroSCORE, operative mortality is 1.5% regardless of the prosthesis implanted. After mechanical valve replacement, there is a 0.3%/y chance of reoperation, yielding a 9% risk of reoperation (30 years × 0.3%/y) if the man lives to be 80 years of age. However, the chance of death at reoperation is ~24%, assuming that reoperation is done on an emergency basis at 65 years of age, yielding a 2.1% chance of death at reoperation. Valve-related mortality is 0.5%/y for a patient 51 to 60 years of age and 1.1%/y in patients ≥61 years of age, yielding a cumulative risk of valve-related mortality of 27% over 30 years: (10 × 0.5%)+(20 × 1.1%). Valve-related morbidity is 2.2%/y for a patient 51 to 60 years of age, 2.7%/y for a patient 61 to 70 years of age, and 2.9%/y for a patient ≥71 years of age, yielding a cumulative risk of valve-related morbidity of 78% over 30 years, (10 × 2.2%)+(10 × 2.7%)+(10 × 2.9%), and a cumulative 108.6% risk of valve-related morbidity or mortality (30.6% mortality + 78% morbidity) over 30 years.

In contrast, initial valve replacement with a bioprosthesis would result in at least 1 anticipated reoperation before 80 years of age. If reoperation occurs at 65 years of age (15 years after initial surgery), operative risk is 5.8%, assuming that surgery is done electively. The anticipated risk of valve-related mortality after bioprosthetic valve replacement is 0.6%/y for a patient 51 to 60 years of age, 1.0%/y for a patient 61 to 70 years of age, and 1.3%/y for a patient ≥71 years of age, yielding a cumulative risk of valve-related mortality of 29% over 30 years.
similar to that after mechanical valve replacement. However, valve-related morbidity is only 0.3%/y for a patient 51 to 60 years of age, 0.4%/y for a patient 61 to 70 years of age, and 0.5%/y for a patient age ≥71 years of age, yielding a cumulative risk of valve-related morbidity of 12% over 30 years—(10×0.3%)+(10×0.4%)+(10×0.5%)—and a cumulative 48.3% risk of valve-related morbidity or mortality—36.3% mortality +12% morbidity—over 30 years. Even if the patient required a second reoperation, the cumulative risk increases by only 10.8% (calculated at 75 years of age).

Mortality risk is not different after mechanical and after tissue valve replacement.4,9,10 A 50-year-old patient should anticipate at least 1 reoperation after bioprosthetic valve replacement, but overall, valve-related morbidity is far higher after mechanical valve replacement. In addition, lifestyle alterations are more likely after mechanical valve replacement owing to long-term anticoagulation with warfarin. Presented with this projected scenario, some patients will opt to try to avoid reoperation, whereas others will opt to minimize lifestyle changes and limit the risks of valve-related morbidity while accepting the likelihood of at least 1 reoperation. It is this level of information that can help lead to a truly informed patient deciding between a mechanical and a tissue prosthesis.

Ideally, it would be desirable to have access to long-term outcome data for current-generation tissue and mechanical prostheses studied in large, multicenter, randomized clinical trials. However, large-scale randomized trials are unlikely to be performed, and if they were, pertinent clinical data would be available only after 15 to 20 years. By the time that long-term data became available, newer prostheses likely would have supplanted those in use today, and as is the case with the historic VA5 and Edinburgh4 heart valve trials, data would be obsolete before they were available. Because of this paradox, the practitioner is forced to make informed clinical recommendations based on incomplete data, including data extrapolated from the historic randomized controlled trials and data from more recent nonrandomized studies. The ACC/AHA guidelines7 and ESC guidelines8 provide a structure for decision making. However, without compelling data from pertinent large-scale, long-term trials, decisions will and should remain influenced by experience and expertise. This is not to say that data from randomized clinical trials would not be helpful but rather that, in the absence of long-term outcome data for current-generation prostheses studied in large, multicenter, randomized clinical trials, mortality risk is not different after mechanical and after tissue valve replacement.4,9,10 A 50-year-old patient should anticipate at least 1 reoperation after bioprosthetic valve replacement, but overall, valve-related morbidity is far higher after mechanical valve replacement. In addition, lifestyle alterations are more likely after mechanical valve replacement owing to long-term anticoagulation with warfarin. Presented with this projected scenario, some patients will opt to try to avoid reoperation, whereas others will opt to minimize lifestyle changes and limit the risks of valve-related morbidity while accepting the likelihood of at least 1 reoperation. It is this level of information that can help lead to a truly informed patient deciding between a mechanical and a tissue prosthesis.

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| Table. Projected Future Risks After Aortic Valve Replacement in a 50-Year-Old Man, Assuming 30-Year Survival |
|------------------------------------------|------------------|------------------|
|                                       | Mechanical Valve | Bioprosthetic Valve |
| Replacement, %  | Replacement, %   |                   |
| Operative mortality | 1.5              | 1.5              |
| Death at reoperation (risk of reoperation×risk of death at reoperation) | 2.1              | 5.8 (+ 10.8 for second reoperation) |
| Valve-related mortality (cumulative for 30 y) | 27               | 29               |
| Valve-related morbidity (cumulative for 30 y) | 78               | 12               |
| Total risk of morbidity and mortality over 30 y | 108.6 (59.1 if 2 reoperations) | 48.3 |

See text for detailed explanation.
of such trials, the clinician must guide patients in making an informed choice that relies on available data and is appropriate for the individual patient.

Disclosures
Dr Kleine has served as a consultant to Medtronic. Dr Bach has received research support and is a consultant to Edwards Lifesciences, Medtronic, and St Jude Medical. Dr El Oakley reports no conflicts.

References