The report by Svennevig and colleagues in this issue of Circulation will stand as an important contribution to our knowledge of the outcomes after heart valve replacement. This article, along with other extensive published series of patients followed up for as many as 4 decades after mechanical heart valve replacement, now help form the basis on which present and future decisions are made for patients with valvular heart disease.

Decades ago, the properties of an ideal valve replacement were described by the late Dr Dwight Harken, a pioneer in cardiac surgery; included in these properties are durability (at least as good as a native valve), no thrombogenicity (hence, warfarin anticoagulation not required), no inherent gradient, and easy to implant. How close a prosthetic heart valve approaches these ideals can only be determined after large numbers of implants, assiduous management of anticoagulation, complete patient follow-up, and the test of time. Because mechanical aortic valves are generally implanted in younger patients, the interaction of the prosthesis with the patient, the propensity (or lack thereof) of tissue ingrowth that can interfere with valve function, the long-term structural integrity, and the thrombogenicity and relative resistance to variability in anticoagulation can only be determined with the patient population size and duration of thorough follow-up reported in this issue of Circulation for the Hall-Medtronic prosthesis, as well as in previous publications for other mechanical heart valves.

To date, no mechanical or bioprosthetic valve prosthesis has achieved the ideal profile described by Harken. However, we now recognize that some available valve prostheses may approach these ideal properties, and this type of long-term outcome study should guide prosthesis selection as we go forward.

Valve replacement surgery has a long and important history, with initial efforts aimed to deal with aortic valve regurgitation by implantation of valves in the descending aorta. With the development of cardiopulmonary bypass in the 1950s, it became possible to replace diseased heart valves in their native location with prostheses. There followed what Dr L. Henry Edmunds described as “the great ‘valve rush’ of the late 1950s and early 1960s.” In 1960, the first successful mechanical aortic valve implantation in the orthotopic position was performed with short-term survival, a key advance at that time. There followed many efforts with varying prosthetic designs, types of prosthetic materials, and surgical methods of implantation. Three basic types of mechanical heart valves achieved notable clinical use: the ball-in-cage valve (eg, the Starr-Edwards valve prosthesis), the bileaflet valve (eg, the St. Jude valve prosthesis), and the single tilting-disc valve (eg, the Hall-Medtronic valve, the subject of the report by Svennevig et al). With this publication of the long-term results after implantation of the Hall-Medtronic valve, reliable long-term data are now available to assess the results with these 3 major types of mechanical aortic valves for up to 4 decades.

Early clinical studies of the outcomes after heart valve implantation were often impeded by lack of uniform definitions for valve-related morbidity and mortality, such as bleeding and thromboembolic complications. Meaningful comparisons of various types of prostheses became possible after the development of guidelines with standardized definitions. With these analytic tools and definitions in place, meaningful analyses and comparisons began to appear.

With the passage of time, with the accumulation of clinical experience, and with the acquisition of follow-up data, several important observations and principles have emerged that form the basis of decision-making and practice today. First, irrespective of theoretical design considerations and newly developed biomaterials, it is only the test of time that will reveal the long-term properties, durability, and outcomes associated with any valve prosthesis. Although contemporary engineering methods, such as finite element analysis and computational fluid dynamics, allow for optimized valve designs, on occasion these analyses have proved unreliable for the prediction of clinical performance, durability, and risk of thromboembolic complications after prostheses implantation in patients.

Second, in the case of aortic valve replacement, the size of the aortic prosthesis relative to the size of the patient is now known to be important, particularly for patients with left ventricular hypertrophy or left ventricular dysfunction, so that the prosthetic gradient will not be excessive and left ventricular afterload will be minimized. In fact, in the contemporary analysis of valve prostheses, it is the effective orifice area in vivo, indexed to the size of the patient (ie, body surface area), rather than the mechanical, geometric area that determines the gradient properties of a given prosthesis in a particular
patient. This issue becomes particularly important in the patient with a small aortic root where smaller size prosthetic valves must be implanted. The article by Svennevig et al documents outcomes that were less favorable in patients who received smaller aortic prostheses, although patient size (i.e., body surface area) was not included in the analysis.

Third, to the extent that mechanical design and construction material selection permit, a valve must be as thromboreistant as possible. Through experience it has been learned that not only is the choice of prosthetic material important, but also the design must result in a flow that is as laminar as possible to diminish turbulence and also incorporate sufficient diastolic washing of valve components to minimize microthrombi. However, even with the most assiduous management of warfarin anticoagulation, patients may sometimes be below the desired range of anticoagulation or other medical or surgical illness may require that anticoagulation be diminished or even stopped for a period of time. For these reasons, only when large populations of mechanical valve recipients are examined in long-term follow-up, with the unavoidable patient exposure to variability in anticoagulation and the exigencies of concomitant illness, is the relative thromboresistance of a given prosthesi truly evident.

Three types of mechanical heart valves have the longest implant history and the largest number of implants worldwide: the Starr-Edwards ball-in-cage prosthesi approved by the US Food and Drug Administration in 1965, the St. Jude bileaflet prosthesis, approved in 1977, and the Hall-Medtronic single tilting-disc prosthesis, developed by Karl-Victor Hall, Arne Woien, and Robert Kaster and subsequently purchased by Medtronic, Inc., also approved in 1977. The Starr-Edwards prosthesis, although it has an important place in the history of heart valve replacement and a 4-decade history of durability, has unsatisfactory hemodynamic properties, particularly in smaller sizes, and important thromboembolic risk, which thus make it rarely indicated in modern practice. With the St. Jude and Hall-Medtronic valves, for which long-term follow-up and outcomes are now available that extend up to nearly 3 decades, several common themes have emerged.

Although these 2 mechanical prostheses have major differences in design, when various aspects of their long-term performance are compared, they are striking in their similarity. Both valves have similar hemodynamic properties with respect to effective orifice area for a given valve size and hence, their ability to relieve left ventricular outflow tract gradient. Both valves have similar long-term mechanical durability within the time frame of follow-up. Both valves also have strikingly similar thromboembolic risk profiles and risk of endocarditis and bleeding complications. From the standpoint of implanting surgeons, both prostheses have similar implantability. (Some would argue that the Hall-Medtronic valve is less forgiving of poor implantation techniques, particularly suture entrapment.) Accordingly, with respect to valve selection for patients where a mechanical aortic prosthesis is indicated, these 2 types of prostheses can now be considered equivalent.

The report by Svennevig et al also contains some other important implications about choice of aortic valve prosthesis with respect to long-term prognosis of a patient related to age at the time of implantation and other comorbid illnesses, particularly coronary artery disease. Currently available bioprosthetic aortic valves, which do not require warfarin anticoagulation and have very low thrombosis and embolism risks, now have acceptable durability, particularly when implanted in patients >60 or 65 years old. The striking difference in survival shown in Figure 3 in the study by Svennevig et al related to age at the time of implant must enter carefully into the selection of valve prosthesis for a given patient. Although the long-term outcomes of patients who have received St. Jude and Hall-Medtronic valves are excellent, especially in young patients, these valves are likely not appropriate for use in patients in an older age group, in patients with significant comorbidities that influence survival, such as coronary artery disease, or because of the need for anticoagulation, which carries increased risk in older patients. Currently, modern bioprosthetic aortic valves are generally selected for patients over the age of 60 years. As these prostheses are subject to longer follow-up, and as newer technologies to prevent structural deterioration of bioprosthetic valves evolve, the age recommended for their implantation may continue to decline, and in accordance with current trends, fewer mechanical aortic valves will be implanted in the future, unless new forms of anticoagulation, such as direct thrombin inhibitors, diminish the anticoagulation drawbacks of mechanical valves.

Disclosures

None.

References

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