EDITORIAL COMMENT

The Choice of Valve Protheses*

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The ideal prosthetic valve would have excellent hemodynamics (similar to a normal human valve in the same position), last a lifetime, be free of structural dysfunction or breakdown, and require no particular medical therapy such as anticoagulation. Needless to say, such a valve is yet to be available. However, valvular replacement is still relatively young—the first successful aortic valve replacement (a caged ball) was performed by Harken et al. in 1960 (1), and in the same year Starr and Edwards (2) successfully replaced the mitral valve using a caged ball valve of their own design. By 1967, approximately 2,000 Starr–Edwards valves had been implanted, and the caged ball valve prosthesis was the standard.

The first tissue valves used were homografts or xenografts, with the first homograft replacement being described by Heimbecker et al. in Toronto in 1962 (3), using an aortic homograft in the mitral position. Shumway and Lower (4) described experiments in dogs in which they replaced the mitral valve with a pulmonary autograft, and Ross (5) in 1967 described the clinical application of aortic replacement with a pulmonary autograft. The “Ross procedure” remains advocated by some for aortic valve replacement in certain situations (especially for younger patients) but turns a relatively straightforward operation (standard aortic valve replacement) into a double valve replacement of some complexity, because the pulmonary deficit now has to be replaced with a homograft, and the coronary arteries reimplanted in the autograft.

After 1960, other autogenous materials were used to manufacture biological prosthetic valves; these included pericardium, fascia lata, and dura mater. In 1964, Duran and Gunning (6,7) replaced an aortic valve in a patient using a xenograft porcine aortic valve. Carpentier and associates revived interest in xenograft valves by fixating porcine valves with glutaraldehyde. In addition, Carpentier also mounted the aortic pig valves on a stent to produce a bioprosthesis. From then on, Carpentier-Edwards (CE) porcine valves and Hancock and Angell-Shiley bioprostheses became more and more popular and were implanted in large numbers of patients (8,9).

Before 1980, pericardial valve prostheses had been abandoned because of a high rate of valve failure as the result of structural deterioration. In 1979, Carpentier and the presently called Edwards Lifesciences began the development of a pericardial valve in an attempt to improve upon the earlier pericardial valve designs. The aortic CE pericardial valve was introduced to clinical use in 1981 and approved for U.S. commercial distribution in September 1991 by the Food and Drug Administration. The pericardial valve is a biomechanically engineered valve—a stented valve with a biological component. In this way, it differs from a porcine (pig) stented valve, which incorporates the natural pig’s valve.

By 1995, the 10-year performance of this valve could be assessed (10–13). With intermediate follow-up showing satisfactory outcome and results, use of this valve became more popular, and in many centers across the country it became the biological valve of choice in the aortic position.

Debate on the choice between a mechanical versus tissue valve continues, and although some guidelines are in place for choosing one valve type over another, no definitive criteria yet exist. Just as advances have been made in tissue valves, newer generations of mechanical valves display distinct advantages over those used historically. Better hemodynamics and the possibility of lowering anticoagulation levels with the newer mechanical valves continue the competition and the debate of relative advantages of the mechanical or biological choice in various age groups.

Given the wide variety of tissue or mechanical valves available in the market today, the decision to place a particular valve may not be easy, and often is not based on solid scientific data. Many different types of biological prostheses remain available, such as porcine valves, pericardial valves, stentless valves, homografts, and autografts; with the porcine and pericardial stented valves being the most widely used.

In this issue of the Journal, Gao et al. (14) describe their experience with the durability of porcine and pericardial valves in the aortic position. Although in more recent years they have been using the pericardial valve exclusively, their overall experience includes 518 isolated aortic valve replacements with CE porcine valves and 1,021 replacements with CE pericardial valves. The porcine valves were placed between 1974 and 1996, and the pericardial valves between 1991 and 2002. Both groups have similar clinical profiles, and specifically the age groups and the age distribution are almost identical in both groups. Patients were followed at annual intervals, and the follow-up was 91% complete. Although all valve–related complications and deaths were defined and analyzed, the primary outcome of interest was bioprosthetic valve dysfunction.

When the results were analyzed for both groups, the authors were able to show that survival and valve complications were similar in both groups. However, there was a

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significant difference in valve-related structural deterioration and dysfunction, as measured by freedom from explantation. Overall, the CE pericardial valve had a significantly superior rate of freedom from explantation compared with the porcine valve, with only four pericardial valves being explanted during the study period as a result of structural valve deterioration (SVD).

Pericardial valves, as with xenografts valves, fail primarily because of leaflet calcification (15), and the rate of leaflet calcification with porcine valves has been shown to be related to the age of the patient. Jamieson et al. (16) in a 20-year follow-up of the porcine prosthesis showed that with the CE porcine valve the freedom from explant at 15 years was significantly greater for patients 70 years of age and older. In the study presented here, the authors demonstrate that age has a significant impact on the durability of the porcine valve in the aortic position, as have others; however, the same effect could not be shown in the pericardial group. This may be due to small number of patients with SVD in that group.

Relative freedom from structural deterioration that was independent of age would be a very important advance, and may confirm earlier studies with the pericardial valve. Cosgrove et al. (10) believed in 1995 that age was not a significant factor with 10-year follow-up of this valve, when patients 65 and older were compared with patients younger than 65. Similarly, Banbury et al. (17) showed excellent freedom from SVD and concluded that patients as young as 65 would have <10% chance of requiring explant before the age of 80.

One limitation of the current study is the fact that the authors have compared the second generation of pericardial valves with the older generation of porcine valves available in 1980s, and as the authors point out, they have exclusively used the pericardial valve in the last decade or so. This study would be more powerful if the patients had been randomized to either porcine or pericardial valves, with subsequent long-term follow-up. More importantly, because there are newer generations of tissue valves, including porcine valves both stented and stentless, the most effective study would be to compare their long-term durability to the other types of the newer valves available, in particular the pericardial valves as well as mechanical valves.

In the absence of randomized trials, this study from the Starr group is an important contribution to the literature. The authors believe that the pericardial valve has superior function and durability compared with the traditional porcine valve. Perhaps the most valuable conclusion from this study, and others similar to it, is that the durability of a tissue valve, in particular the durability of pericardial valves in the aortic position, is better than 90% at 10 years. However, the 10-year test is relatively easy to pass. Relative freedom from structural deterioration at 20 years will be the important milestone.

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