COMMENTARY: PROPHYLACTIC REPLACEMENT OF BJÖRK-SHILEY CONVEXO-CONCAVE VALVES

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Management of patients with the Björk-Shiley convexo-concave (BSCc) valve (Shiley, Inc., Irvine, Calif.) is of current interest because of the estimated 35,000 to 40,000 patients still alive with this valve. The article by Kallewaard and associates describes the results of valve replacement operations performed to preclude fracture of the welded outlet strut. To gain perspective on the role of such operations we should consider the risk of outlet strut fracture relative to the risk of replacement.

Physician deliberations

For more than a decade, teams of cardiac surgeons, cardiologists, and other physicians and scientists have met an average of three times a year to consider BSCc patient management guidelines. These were originally Shiley Medical Advisory Panels (60-degree, 70-degree, combined 60- and 70-degree) and recently have been convened as a result of a class action settlement (Bowling-Pfizer Supervisory Panel, Guidelines Committee). For 1 or 2 days each meeting, the attendees examined the latest information on outlet strut fracture and struggled to develop optimal recommendations. The consensus has always been on the conservative side (i.e., restricting the use of prophylactic replacement to very limited subgroups of patients), especially for the 60-degree valves.

Cause of outlet strut fracture

Unlike bioprosthetic heart valves, BSCc valves are not inevitably destined to failure given a long enough implant time. Outlet strut fracture requires a certain extreme alignment of the disk in relation to the outlet strut, a condition called tip loading,

present only in an unknown subset of valves. This condition was eliminated in April 1984, and outlet strut fracture has not been reported in the approximately 8000 valves manufactured since then. Also, none of the preceding models of Björk-Shiley valves, which also had welded outlet struts, had outlet strut fracture reported (approximately 250,000 implants). Tip loading is necessary but not sufficient; a minimum number of cycles with impact loads greater than a certain level are also required. These conditions are more likely to occur when certain combinations of valve and patient factors are present (e.g., age, size, and position).

Risk of outlet strut fracture

Over the past 20 years (through May 1997), outlet strut fracture was reported in 443 (0.5%) of the estimated 82,000 60-degree valves implanted. For the most recent year available (June 1996 through May 1997), eight of the twelve outlet strut fractures reported were in 60-degree valves, which is 0.02% of the estimated number of 60-degree valves still implanted. Only two outlet strut fractures were reported for small size (<29 mm) 60-degree valves, which have an even lower incidence of fracture, although 12 such valves were explanted in the present study. Multiplying these outlet strut fracture percentages by 2 or 3 to account for underreporting still yields relatively small percentages. The fracture rates for 70-degree valves are about seven times higher but, thankfully, they represent less than 5% of all BSCc valves, and in some countries many have already been replaced or have been rejected for replacement surgery. Evidence exists that the risk of outlet strut fracture is decreasing with increasing patient age.

Risk of replacement

It is important to have real data on prophylactic valve replacement to test and calibrate the risk models that have been generated for decision making in patients with BSCc valves. The Dutch investigators have been responsible for much innovative BSCc valve research. This article adds their experience to the relatively little published information

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about prophylactic replacement procedures. Operative mortality was 3% (95% CI 0% to 15%) or 6% (1% to 19%) if the death at 47 days is included; 9% had complications and the median hospital stay was 11 days (maximum 9 months).

Patient management

BSCc valves have served the patients living today for up to 20 years and for the overwhelming majority will continue to do so for their remaining lifetime. A small percentage of valves may fracture in the future, but it is impossible to determine which ones. It has only been possible to assign average risk values to groups of patients, and they are in general very low. Only about 3% of patients with 60-degree valves have an estimated risk greater than 1% per year, and about 0.03% have a risk greater than 2% per year. Even for this relatively high risk of 2% per year, the average time to fracture is 50 years, so only a minority of such patients will experience outlet strut fracture.

Psychologic burden

Prophylactic BSCc valve replacement is inevitably problematic because most explanted valves would not have ever fractured; yet an immediate penalty exists in terms of reoperative mortality, morbidity, and pain paid by all patients undergoing explantation to avert a relatively few future failures. This argument for conservatism is predicated on quantitative measures of mortality and morbidity and does not consider psychologic distress, which can be considerable when one owns a life-support device that is thought to be "defective." However, considering the statistical and epidemiologic realities, such undue alarm may be related more to the inappropriate risk communications to the patients than to the objective risk of the valve. These patients are best served by a conservative approach to explantation and physician-disseminated fact-based information about the risks of outlet strut fracture.