Durability of internally stented pericardial aortic valves: Prosthesis size matters

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Mitroflow aortic bioprosthesis explanted 5 years after insertion.

Central Message

Valve choice and decision to enlarge aortic root should be informed by patient age and the likelihood of prosthesis-patient mismatch.

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Patient preference to avoid anticoagulation and the availability of transcatheter valve-in-valve techniques have spawned efforts to reexamine bioprosthetic aortic valve durability in nonelderly patients undergoing aortic valve replacement (AVR). Although it is well understood that younger age is the main risk factor for early structural valve deterioration (SVD), lipid-lowering drugs, prosthesis-patient mismatch, and higher postoperative transprosthetic gradients are probably also influential.¹

In their work reported in this issue of the *Journal*, Piccardo and colleagues² studied durability and clinical outcomes of the Mitroflow aortic bioprosthesis (12A or LX model; SORIN SpA, Milan, Italy) in 728 patients (mean age of 76 years) who underwent AVR between 1994 and 2011. They report an overall 30-day mortality of 10.3% (75 of 728 patients), with 5.5% (20 of 359 patients) having early death in the setting of nonemergency isolated AVR, which is significantly higher than in the most recent Mitroflow series (2.7% early deaths).³ Furthermore, Piccardo and colleagues² determined that the mean transvalvular gradient at discharge, bioprosthetic valve size 19, and severe prosthesis-patient mismatch were associated with SVD development. Curiously, however, no association was established between age and early SVD. Finally, Piccardo and colleagues² concluded, that the risk of early SVD seems higher for the Mitroflow size 19 and this size should be reserved when the annulus enlargement is risky or there is an anatomical contraindication to sutureless or stentless valve.

Although the findings reaffirm the previously proven acceptable midterm hemodynamic performance of the Mitroflow biologic aortic valve prosthesis³⁻⁶; several important questions remain. First, what are the reasons for the higher early mortality in the present series, and how might this have affected the reported results? Second,

what does this study tell us about bioprosthetic AVR durability in a rapidly growing population of nonelderly patients who are increasingly more likely to select bioprosthetic devices in the current era? Third, are the unadjusted comparisons between the SVD versus non-SVD groups and bioprosthesis size #19 versus greater than #19 robust enough to support the intended conclusions?

In a contemporary study of 1003 patients (mean age of 74.8 years) who underwent AVR with the Mitroflow bioprosthesis between 2004 and 2011, Narayanan and colleagues³ reported 27 early deaths (2.7%; 12 [1.2%] after isolated AVR). This study of Piccardo and colleagues² demonstrated a significantly higher early mortality, with cardiogenic shock and multiorgan failure as the most common reasons for early death. The reasons for this elevated mortality are unclear, because patients in this population actually had fewer symptoms (44% in New York Heart Association class III or IV vs 63.6%), and the number of patients aged 80 years or older was lower (26% vs 33%) than in the most recent Mitroflow series.³ The differences in early outcomes are noteworthy, and thus durability results during midterm follow-up must be interpreted accordingly.

Recent longitudinal studies on biologic aortic valve durability have indeed identified a probable effect of prosthesis-patient mismatch and transvalvular gradient on early SVD.¹ We agree with the assertion of Piccardo

and colleagues² in their article that placing the most hemodynamically efficient biologic device possible is essential when selecting valve type and size or considering the performance of aortic annular enlargement. Also peculiar is the fact that patient age at implantation did not appear to influence SVD in the report of Piccardo and colleagues,² whereas in previous studies this factor has been found to be a very important determinant of biologic valve longevity.^{1,3,7} Unfortunately, the current analysis,² comparing 2 different populations (SVD [n = 30] vs non-SVD [n = 482]) and also bioprosthesis valve size #19 (n = 73) versus size greater than #19 (n = 655), falls short of proving definitively that either are influential without the use of risk factor adjustment to control for confounding factors.⁸

Despite these challenges, we propose the following take-away messages from this report and the recently published literature. First, despite the absence of anti-calcification treatment of second-generation Mitroflow bovine pericardial bioprostheses, the current results reaffirm acceptable hemodynamic performance, survival, and freedom from valve-related reoperation, supporting its use in selected patients aged 60 years and older. Second, consideration should be given to recent literature noting an association between elevated postoperative transvalvular gradient and the risk of SVD in bioprosthetic valves. On the basis of this study of Piccardo and colleagues² and other work, the risk of accelerated degeneration in those with patient-prosthesis mismatch, particularly when size #19 or #21 valves are implanted, warrants consideration. Finally

the median duration of follow-up in this and other existing Mitroflow studies is approximately 5.5 years,^{5,7,9,10} and therefore continued clinical and hemodynamic assessments are essential to further our understanding of factors influencing long-term performance of this device.

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