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References


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EDITORIAL COMMENTARY

Encouraging durability results for sutureless aortic valve: The new gold standard for aortic valve replacement?

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See related article on pages 84-8.

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Aortic valve replacement using stented valves is the conventional standard approach in the treatment of aortic valve disease. Despite the excellent long-term results with biological stented valves, sutureless technology recently has been developed as an alternative to stented valves in high-risk patients to simplify the surgical implantation and reduce the operative times.1-3

The Perceval S (Sorin Group, Milan, Italy) sutureless valve is new self-expanding prosthesis made of bovine pericardium mounted in a nitinol stent. Several studies
have reported excellent results in terms of postoperative outcomes, hemodynamic performances, and structural valve deterioration and freedom from reoperation at 1-year follow-up. However, there are no data on the long-term durability.

The pilot trial is the first clinical, prospective, nonrandomized study conducted in 3 cardiac centers on 30 elderly (mean age, 80 years) high-risk patients who underwent aortic valve replacement between April 2007 and February 2008. It was designed to assess the safety of the Perceval S in terms of mortality and morbidity at 30 days and 1 year and to evaluate its hemodynamic performance up to 1-year follow-up. In this issue of the Journal, Meuris and colleagues report the 5-year clinical and hemodynamic outcomes of these patients, adding evidence for the safety and durability of these bioprostheses at midterm follow-up. Specifically, overall 5-year survival was 72.3%, and freedom from endocarditis and aortic valve thrombosis was observed within the 5-year follow-up. Finally, only 1 patient had moderate perivalvular leak at 1 year, and 2 patients had mild perivalvular leak at 1 and 5 years. Despite these promising results, the low sample size and the low number of patients at risk at 5-year follow-up limit this study. Nevertheless, Shresta and colleagues recently confirmed these data, reporting the midterm clinical and hemodynamic results on 731 patients undergoing aortic valve replacement in 25 European centers. Most important, neither valve migration nor structural valve degeneration or thrombosis was observed at 5-year follow-up. In addition, the rate of major perivalvular leakage was 1.4% and 1% at early and late follow-ups, respectively, similar to data reported by the Placement of Aortic Transcatheter Valves (PARTNER) 1A trial for the stented valves (1.9 at 1 year and 0.9% at 2 years) and lower than for those undergoing transcatheter aortic valve implantation (7% at 1 year and 6.9% at 2 years). Paravalvular leak is now considered a negative outcome, because it has been demonstrated that even the presence of mild regurgitation is associated with lower survival at 5 years. Finally, 26% of patients underwent a minimally invasive procedure, demonstrating the feasibility and safety of this bioprosthesis using this approach. Recently, we reported our experience of aortic valve replacement with the Perceval S through a right minithoracotomy or ministernotomy and showed that this approach is a safe and reproducible procedure associated with excellent hemodynamic results, postoperative outcomes, and 1-year survival. To date, this is the largest study on minimally invasive aortic valve replacement using sutureless valves.

The learning curve is an important advantage of the sutureless technology. According to Meuris and colleagues, 2 proctored implants are advised for the Perceval S implantation through a standard sternotomy. Nevertheless, our CUSUM analysis has shown that a minimum of 10 procedures is required to implant the Perceval S through a right anterior minithoracotomy.

Finally, from an economic point of view, compared with stented valves, the use of the Perceval S might be associated with savings, mainly related to a reduction of surgery costs for fewer complications and shorter intensive care and hospital length of stay.

The Perceval S sutureless valve demonstrates excellent clinical outcomes and hemodynamic performance at 5-year follow-up, requires a short learning curve, and facilitates minimally invasive approaches. Although more data are required and a longer follow-up is mandatory, these encouraging results indicate that the sutureless technology is a promising alternative to the standard biological valves and in the future might be the new gold standard for aortic valve replacement, especially in minimally invasive settings.

References

