Commentary: Two-year outcomes after surgical aortic valve replacement with a new bioprostheses—The data are still good!

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Central Message

A 2-year analysis of a new stented bovine, supra-annular pericardial aortic valve demonstrates low all-cause mortality, low valve-related adverse events, and stable hemodynamics in 604 patients.

See Article page 371.

The overwhelming success story of transcatheter aortic valve replacement (TAVR) in the past decade has led to a dramatic change in the indication of surgical aortic valve replacement (SAVR) for aortic valve stenosis. On the basis of the recently published evidence for TAVR in younger, low-risk patients with aortic stenosis, the indications for SAVR are expected to be further restricted in future guidelines.[1,2] Consequently, in addition to a further shift from SAVR to TAVR, cardiac surgeons are expected to change their strategy in the remaining SAVR population in favor of a more deliberate use of bioprosthetic valves in younger patients. In fact, reluctance to commit to a long-term oral anticoagulant treatment and the possibility of a future valve-in-valve intervention will most certainly have further effect on this decision, as is already reflected in the 2017 updated American Heart Association and American College of Cardiology guidelines for patients with valvular heart disease, which lowered the age limit for mechanical valves in the aortic position to 50 years and recommends an individualized valve choice (mechanical vs biologic) in patients scheduled for SAVR between 50 and 70 years of age.[3] This trend is also reflected in the current choice of aortic valve prostheses with over 85% of surgically implanted valves being biological[4,5]; a rate that is likely to increase further. Valve companies, in concert with cardiac surgeons, are refocusing their product lines to develop the optimal aortic bioprostheses in terms of hemodynamic performance, long-term durability (ie, tissue treatment), and suitable design for future TAVR interventions (flexible stent, low valve profile).[6]

In this issue of the *Journal*, Dagenais and colleagues[7] introduce the 2-year results of the PERIcardial SurGical AOrtic Valve ReplacemeNt (PERIGON) pivotal trial (sponsored by Medtronic Inc, Minneapolis, MN), which evaluated in a prospective, single-arm multicenter study (1110 implantations in 38 centers in the European Union, United States, and Canada) the results of SAVR with a novel stented, supra-annular, bovine pericardial tissue valve (Avalus; Medtronic). A total of 604 low-risk patients (mean age 70 years) who underwent SAVR with the new Avalus valve between 2014 to 2017 had a complete 2-year follow-up for the key efficacy and safety end points, including hemodynamic valve performance. Briefly, freedoms from all-cause death (94.3%), valve-related death (99.1%), thromboembolism (95.7%), and reintervention or explantation (>98%) were low, and no structural valve deterioration or thrombosis occurred at 2 years of follow-up. Importantly, echocardiographic follow-up showed satisfactory indexed effective orifice area (0.74 ± 0.19 cm^2/m^2) and mean pressure gradients (13 ± 5 mm Hg) that remained stable relative to those at discharge and 1-year follow-up,[8] respectively. Of note, the rates of moderate (44%) and severe (35%) patient-prosthesis mismatch at 2 years remain much higher relative to other biologic valves, a fact that has been addressed in a previous editorial comment after the 1-year analysis of this valve and did not negatively influence improvement in New York Heart Association functional class or left ventricular mass regression according to the authors.[9,10]

There are 2 important aspects that need to be emphasized for a valid interpretation of the current trial. The PERIGON pivotal trial is an industry-sponsored trial with a rigorous study protocol that was designed to fulfill the strict regulatory criteria of Food and Drug Administration regulatory trials. There is little doubt that the study protocol, the definition and adjudication of clinical end points and safety measures, and the routine assessment of valve performance (core echocardiography laboratory) meet the highest scientific standards. The validity of the data is therefore robust and informs the cardiovascular community regarding the satisfactory short-term efficacy and safety of SAVR with the Avalus bioprostheses. So far, so good.

The downside, however, is the obvious conflict of interest and involvement of the trial sponsor in the article preparation, which is clearly indicated throughout the article (authors affiliations, conflict of interest statement, statistical section, and acknowledgments). This bias unnecessarily calls into question to a certain extent the independent scientific position of the scientists involved on this study, which is mandatory even for industry-sponsored trials, with regard to the final data processing, analysis and preparation of the article. We all certainly accept the fact that large, prospective, multicenter trials of investigational medical products, such as the PERIGON pivotal trial, that aim to meet the highest standards are almost impossible nowadays without the logistic and financial support of the industry. The reader of this article, however, needs to cautiously judge for himself or herself whether this uncertain bias limits the scientific value of these otherwise robust data.

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