Sutureless valves: A future without sutures

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The ideal prosthetic valve is easy to implant, has excellent hemodynamic performance without intrinsic thrombogenicity, and has long-term durability associated with a low risk of endocarditis. Sutureless aortic valves have demonstrated many of these characteristics; however, no data regarding long-term durability are available.

Currently, aortic valve replacement (AVR) using sutured biological valves is the conventional treatment of choice in elderly patients with severe aortic disease. This surgical approach has shown excellent outcomes and hemodynamic performance, and a very high rate of freedom from structural valve degeneration for up to 15 years.^{1,2} Consequently, the introduction of a new generation of prostheses is a challenge, given the excellent results achieved with the “old” valves. Nevertheless, cardiac surgery is changing. Heart surgeons are moving toward less-invasive approaches, with the aim of reducing surgical trauma. In this setting, sutureless technology represents a natural evolution.

In this issue of the *Journal*, Fischlein and colleagues present the 1-year results of the Cavalier Trial, an international prospective multicenter study conducted in 658 high- to medium-risk patients undergoing AVR using the Perceval S prosthetic valve.³ Specifically, they report a 4.5% incidence rate of cardiac mortality and a 3% rate of stroke. Interestingly, no cases of valve thrombosis, migration, or structural deterioration occurred, and rates of major paravalvular leakage and endocarditis were very low (0.6% and 1.4%, respectively).

These results validate the positive outcomes achieved at 30 days post-AVR, confirming that the Perceval prosthetic valve is easy to implant, safe, and associated with excellent outcomes and hemodynamic performance.⁴

Sutureless valves have been designed as alternatives to conventional valves to simplify surgical implantation and reduce operative time, especially in the setting of minimally invasive procedures. Available evidence suggests that the use of sutureless valves is associated with decreased operative time, ventilation time, intensive care unit stay, and hospital stay, as well as fewer postoperative complications.⁵⁻⁹ In addition, compared with traditional valves, the costs are reduced by 25%.¹⁰

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Central Message

Sutureless aortic valves represent the emerging generation of prosthetic valves and show promising results in terms of postoperative outcomes and hemodynamic results.

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Despite these promising results, however, the Cavalier Trial did not address some important areas. First, no data were reported on the learning curve. In 5% of patients undergoing sutureless AVR, implantation failed due to dislodgement, malposition, paravalvular leakage, suspected aortic tear, or multiple unsuccessful attempts. These complications highlight the need for a learning curve, and the presence of a proctor is mandatory during the initial cases. We suggest conducting a specific study using CUSUM analysis to identify the number of proctored implantations required for each surgeon.

Second, the sutureless valve facilitates minimally invasive approaches; however, only 33% of cardiac procedures were performed through ministernotomy, and only 3 patients (0.4%) had a minithoracotomy approach. Since we introduced the sutureless technology, the number of minimally invasive procedures has more than doubled.¹¹ We previously demonstrated that sutureless AVR through either ministernotomy or minithoracotomy is safe and reproducible, and associated with excellent postoperative outcomes and 1-year survival.¹² Relative to our previous studies with stented valves, we found an overall 40% reduction in operative time. Subsequently, Dalèn and colleagues⁹ confirmed our results.

Third, sutureless technology speeds up the surgical procedure, reducing ischemia and cardiopulmonary machine times. In this setting, the Perceval S valve might improve surgical results, given the association between increased operative time and worse outcomes.¹³ These benefits should be

more evident in patients undergoing combined procedures. Nevertheless, only 30% of patients underwent combined procedures, most of which were concomitant myocardial revascularizations. No data on multiple valve surgery have been reported. Minh and colleagues¹⁴ suggested expanding the indications for sutureless AVR to patients with mitral disease, even though it is an off-label procedure.

Fourth, in the Cavalier Trial, a bicuspid aortic valve was considered a contraindication for Perceval S prosthetic valve implantation. However, a bicuspid aortic valve is the most common congenital cardiac disease, and an estimated 50% of all valve replacement surgeries for aortic valve stenosis can be attributed to it.¹⁵ Recently, Nguyen and colleagues¹⁶ demonstrated that the Perceval valve can be deployed in patients with a type 1 bicuspid aortic valve, and we have described the technique to deal with a type 0 bicuspid valve.

Finally, the strength of a biological valve is its long-term durability. This trial has been designed to evaluate the safety and effectiveness of the Perceval valve at 12 months after implantation. A longer follow-up is required to evaluate the long-term durability of the Perceval valve. However, a large cohort of patients undergoing sutureless AVR, which includes also patients enrolled in the Cavalier Trial, have shown satisfying results up to 5 years.¹⁷

An international expert consensus panel's recently published recommendations for the use of sutureless and rapid-deployment valves state that such valves should be considered the first-line treatment option for patients with several comorbidities, patients of advanced age, or patients with aortic wall abnormalities, such as a small calcified aortic root, porcelain aorta, or previously implanted aortic homograft or stentless valves.¹⁸ These valves in combination with a minimally invasive approach might be the appropriate treatment option for high-risk operable patients and a viable alternative to transcatheter aortic valve implantations.^{19,20} We need more data to confirm our hypothesis; however, the future will be without suture!

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