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Long-term outcome with sutureless valves: 12 years of Perceval experience

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Introduction

The conventional treatment for aortic valve stenosis has always been surgical aortic valve replacement (AVR) using standard surgical valve prostheses. However, the use of transcatheter aortic valve implantation (TAVI) is expanding rapidly and currently TAVI paves its own way from intermediate- and high-risk patients to low-risk patients. This evolution has stimulated innovations within the field of surgical valves. Sutureless or rapid-deployment valves have been developed to make valve implantation faster, safer and less invasive. This design change continues to demonstrate that it has been an important and innovative strategy.

When looking at short-term outcomes, there are many studies and meta-analyses that have tried to compare standard valves, sutureless valves and TAVI among patients with a range of surgical risk levels. Recently, a network meta-analysis of 16,432 patients from seven randomized controlled trials and twenty-five propensity score-matched studies have compared all three options (1). While mortality and stroke outcomes were comparable for all three options, the sutureless AVR demonstrated less regurgitation than TAVI and less major bleeding and acute kidney injury than conventional AVR (1). Another meta-analysis reported less moderate to severe paravalvular leakage (PVL) and improved survival with sutureless AVR versus TAVI (2). Sutureless valves offer a faster implantation, with significantly reduced aortic cross-clamp and cardiopulmonary bypass times (2). The absence of a sewing ring may also result in improved hemodynamics (3). Unfortunately, prospective randomized data is still lacking.

The Perceval sutureless valve

The Perceval (LivaNova, London, UK) is a bioprosthetic heart valve made of bovine pericardium, built into a self-expandable nitinol stent (3), which supports the valve and fixes it in place. It is suitable for implantation using standard surgical techniques or minimally invasive methods (3).

Long-term follow-up with Perceval

Clinical experience with the Perceval valve has reached more than 12 years since the first-in-man implants were performed in 2007 (4). The valve has now been implanted in more than 50,000 patients worldwide. Results from the (first-in-man, n=30) pilot trial of Perceval showed—at the five year follow-up interval—one mild PVL, but no cases of dislodgement, structural valve deterioration, hemolysis or valve thrombosis (5). Hemodynamic performance results were good, with yearly single-digit mean gradients ranging from 7.6 ± 3.6 to 9.9 ± 4.6 mmHg (mean gradient) over five years (5). One of the centers from the pilot study (Leuven) used the Perceval valve on a daily basis and have, up to 2017, treated a further 438 patients with Perceval. Their long-term follow-up results were made available at the 2019 American Association for Thoracic Surgery (AATS) meeting (6). These 468 patients (mean age 79 years) have now been followed for up to eleven years (mean follow-up of 3.5 years). Overall, two-year mortality was 14.8% (6), which compares favorably to outcomes from other studies in similar elderly patients. The mean gradient was 13 ± 6 mmHg at the latest available echo follow-up in all patients. During extended follow-up, four valves were explanted

due to endocarditis and there was one case of structural valve degeneration (at 7 years) (6). Full results are due to be published soon (under review). The slightly elevated pacemaker implantation rate of 7.9% (6) has decreased to 4.7% in a consequent cohort of 190 patients from the same center after implementation of a new sizing strategy. These data were recently reported at the 2019 American Heart Association (AHA) meeting (7).

Combined results from three prospective, multicenter trials where Perceval valves were implanted in 731 patients (mean \pm SD age 79 ± 5 years) reported 25.9% using a minimally invasive approach (8). There were no cases of valve migration, structural valve degeneration, or valve thrombosis at the five-year follow-up (8). Mean gradient decreased from 42.9 ± 16.4 mmHg preoperatively to 10.3 ± 4.4 mmHg at discharge and again these remained relatively stable to five years (8). In a large single-center study, 617 patients (mean age 76 ± 7 years) were implanted with the Perceval valve (9). Only 1% of patients required reoperation. After a mean follow-up of 1.4 years (range, 0–4.3 years), the survival rate was 91.3%. Endocarditis occurred in two patients (at 6 and 10 months), one patient had valve degeneration, and one had pseudoaneurysm of the aortic root (9). Trivial or moderate PVL was present in thirty-three and three patients, respectively, at follow-up. In the ongoing CAVALIER trial (NCT01368666), 658 patients (mean age 78 ± 6 years) were implanted with the Perceval valve (10). At one-year follow-up, event rates were 8.1% for mortality, 3.0% for stroke, 1.9% for valve-related reoperation, 1.4% for endocarditis, and 0.6% for major PVL (10). There were no cases of valve thrombosis, migration, or structural valve deterioration, but the average follow-up was still limited (10). The full five-year follow-up results, including echo-core lab-reviewed data in all patients, are accepted for presentation at the next AATS meeting in 2020.

Despite use of the Perceval valve in more than 50,000 patients, there have been only rare case reports of late valve migration ($n=1$; 5 months after implantation) and early structural valve degeneration ($n=1$; 2 years after implantation).

Conclusions

Long-term follow-up data among patients implanted with the Perceval valve are promising, with low rates of PVL, the absence of dislodgement after proper valve seating, and low rates of structural valve deterioration or valve

thrombosis. Several patients have now been implanted with this prosthesis for over twelve years, with good clinical and echocardiographic follow-up. Additional long-term follow-up data, including echo-core lab-reviewed hemodynamics are expected soon.

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Footnote

Conflicts of Interest: BM is a consultant to LivaNova. DS has no conflicts of interest to declare.

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