

Ten-year experience with the Perceval S sutureless prosthesis: lessons learned and future perspectives

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Contributions: (I) Conception and design: V Chauvette; (II) Administrative support: D Bouchard; (III) Provision of study materials or patients: D Bouchard; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

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Abstract: Aortic stenosis has traditionally been addressed with surgical aortic valve replacement (AVR). In recent years, several technologies have emerged as alternative treatment methods for aortic valve disease. Among them, the Perceval (LivaNova, London, UK) is a sutureless valve that has been used in clinical practice for over 10 years. It has been implanted in over 20,000 patients worldwide. With nearly 600 Perceval implants since 2011, the Montreal Heart Institute has developed a worldwide expertise with this technology. In this article, we provide an overview of the clinical data currently available in the literature and discuss the lessons we have learned from our experience with the Perceval prosthesis.

Keywords: Sutureless valves; Perceval S prosthesis; aortic valve replacement (AVR)

Received: 25 January 2018; Accepted: 03 February 2018; Published: 03 May 2018.

doi: 10.21037/jovs.2018.03.10

View this article at: <http://dx.doi.org/10.21037/jovs.2018.03.10>

Introduction

Aortic valve replacement (AVR) for aortic stenosis is one of the most commonly performed cardiac operations (1). For many years, AVR using a surgically implanted prosthesis has been the gold-standard in terms of treatment (2). However, as many as 32% of patients referred for surgical AVR were deemed too high risk for surgery (1). In recent years, transcatheter aortic valve implantation (TAVI) has emerged as a minimally invasive approach to treat these patients. The PARTNER 1 and 2 studies have demonstrated the superiority of TAVI over medical therapy in patients deemed to be inoperable, and the non-inferiority of TAVI in high and intermediate risk patients when compared with surgical AVR (3,4). However, TAVI has been associated with greater rates of paravalvular leaks (PVL), vascular complications and concerns about leaflet thrombosis when compared with conventional AVR (4-8). Moreover, the inability to excise the native valve during TAVI procedures has raised some concerns about the durability of this approach.

Sutureless valves represent a development in the management of patients undergoing surgical AVR. Their mechanism alleviates the need for suturing and allows for quick deployment of the valve, and thus has the potential to reduce the morbidity associated with long operative time, while still allowing for valve implantation under direct vision. Moreover, the absence of a sewing ring might result in improved hemodynamics when compared with other valves. The Perceval valve is made of bovine pericardium leaflets. It has a self-anchoring, self-expanding nitinol alloy stent that is covered by a thin carbo film coating (*Figure 1*).

The purpose of this article is to review our 10-year experience with the Perceval prosthesis, focusing on the situations in which we believe it is most useful, some pitfalls, as well as areas of future research.

Clinical data

Multiple non-randomized studies have described the

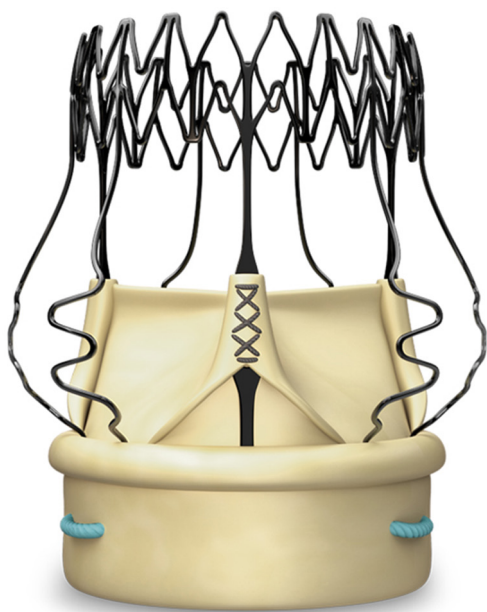


Figure 1 The Perceval S prosthesis.

characteristics of the Perceval valve, its strengths and its possible flaws. Short- and mid-term data appear favorable. Published series have reported survival ranging from 86% to 92% at 1 year, 82% to 87% at 2 years and 71% to 85% at 5 years (9). Postoperative hemodynamic characteristics of the Perceval also appear favorable. Mean effective orifice area (EOA) ranges from 1.4 ± 0.4 to 1.6 ± 0.4 cm², mean gradients range from 10 ± 5 to 14 ± 6 mmHg and mean peak gradients range from 19 ± 8 to 27 ± 11 mmHg in published series (9). In the seminal CAVALIER trial, mean and peak pressure gradients decreased from 45 and 73 mmHg preoperatively to 10 and 19 mmHg at discharge, respectively (10).

Sutureless versus standard AVR

The design of the Perceval allows for quick deployment, thus reducing overall operative time. This is potentially favorable for patients as it might reduce the morbidity associated with prolonged cardiopulmonary bypass (CPB) and cross-clamp time. Multiple studies have demonstrated the adverse effects of prolonged CPB and cross-clamp time (11-13). Ranucci *et al.* demonstrated a 1.4% increase in severe cardiovascular morbidity for each additional minute of cross-clamp time (11). Various studies have compared CPB and cross-clamp time between isolated surgical AVR with standard stented valves and with the Perceval

prosthesis. In a meta-analysis by Powell *et al.*, use of the Perceval prosthesis was associated with a significantly shorter duration of CPB and cross-clamp when compared to standard stented bioprostheses (CPB: 61.4 vs. 84.9 minutes, 95% CI: -27.4 to -18.3, $P < 0.00001$; cross-clamp: 38.6 vs. 63.3 minutes, 95% CI: -24.8 to -16.6, $P < 0.001$) (9). Multiple studies have also reported shorter intensive care unit (ICU) stay for the Perceval valve in isolated AVR and lower incidence of blood transfusion (14-16). However, some publications did show significantly higher rates of permanent pacemaker implantation with the Perceval valve (16-18). Recent studies have identified the presence of a preoperative RBBB, age, chronic renal dysfunction, and QRS duration as predictors of permanent pacemaker implantation following sutureless valve insertion (19,20). To date, no study has shown any statistical differences in terms of mortality when using the Perceval valve versus standard prostheses.

As one would expect, cross-clamp and CPB times are longer in combined cases (i.e., AVR with other concomitant procedure). To date, no trial has specifically addressed the difference in CPB and cross-clamp time between conventional AVR and sutureless AVR with the Perceval prosthesis in a cohort of patients undergoing concomitant procedures. Shrestha *et al.* performed a cohort study of patients undergoing sutureless with a concomitant procedure. They reported an average CPB and cross-clamp duration of 79 ± 32 and 51 ± 23 minutes, respectively.

Sutureless AVR versus TAVI

In recent years, TAVI has also emerged as a minimally invasive alternative to surgical AVR. Initial studies of TAVI have shown encouraging results in terms of mortality and valve performance for inoperable and high-risk patients (3). However, there remains concern over the rates of stroke, permanent pacemaker implantation, vascular injury and PVL (21,22). Because it is implanted under direct vision, the Perceval valve has the potential to alleviate many of these pitfalls.

Current data on stroke rates does not seem to favor one technology over the other. Rates of perioperative stroke range from 0% to 5% for the Perceval and from 2.5% to 5% for TAVI (14,23-25). A number of studies have shown significantly higher rates of permanent pacemaker implantation with TAVI compared to sutureless AVR with the Perceval (14,26). However, these findings have not been reproduced consistently, and recently published

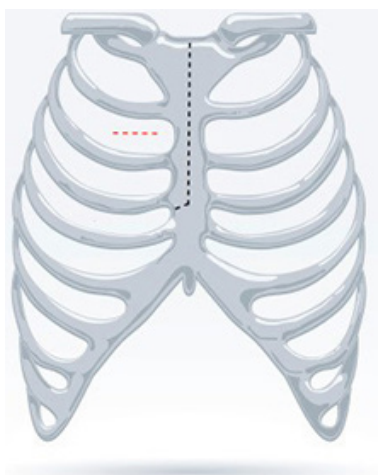


Figure 2 Surgical approaches to minimally invasive aortic valve replacement. Red dashed line represents right anterior thoracotomy. Black dashed line represents hemi-sternotomy.

systematic reviews and meta-analyses suggest that there is no significant difference in the rate of permanent pacemaker implantation between these technologies (9,27). These findings should be interpreted in light of the fact that self-expanding TAVI devices are associated with higher rates of conduction disorders than balloon-expandable devices (28).

Few studies have compared rates of vascular complications between TAVI and sutureless AVR. Because sutureless AVR is usually carried out through central cannulation—whereas TAVI relies on peripheral access—it follows that rates of vascular complications will invariably be higher with the use of TAVI. In a study by Biancari *et al.*, no vascular complication was reported in the Perceval group, whereas 11% of patients in the TAVI group had vascular complications ($P < 0.001$) (26). A majority of comparative studies have also shown lower rates of PVL with the use of the Perceval compared to TAVI (14,18,23). The importance of this finding lies in the fact that numerous studies have demonstrated a significant association between any degree of PVL and mortality following TAVI (29). A meta-analysis by Powell *et al.* showed significantly higher rates of PVL and early mortality in TAVI when compared with Perceval (9). Compared with TAVI, the Perceval has the advantage of allowing complete removal of the diseased valve and decalcification of the aortic annulus, thus reducing the risk of PVL. However, peak and mean transvalvular gradients seem to be lower with TAVI (14,30).

Specific uses

Sutureless valves in minimally invasive approaches

Minimally invasive approaches have various advantages over median sternotomy, including reduced blood loss and shorter ICU length of stay (31). However, minimally invasive AVR can be technically more challenging and is associated with longer CPB and cross-clamp times. Sutureless valves have the potential to overcome these shortcomings. Currently, there are two main techniques that have been described for minimally invasive AVR; the hemi-sternotomy and the right anterior minithoracotomy (Figure 2). The comparative benefits of these approaches—and the potential superiority of one technique over the other—remains a matter of controversy. Miceli *et al.* reported the largest series of minimally invasive sutureless AVR (164 right anterior thoracotomy and 117 hemi-sternotomy) published to date. They reported a survival of 90% at 1 year in a high-risk cohort of 281 patients. The average CPB and cross-clamp times were 81 and 48 minutes, respectively (32). In a separate study, Miceli *et al.* reported better results using the right anterior thoracotomy (lower incidence of postoperative atrial fibrillation, shorter ventilation time, shorter ICU stay, and shorter hospital stay) (33). On the other hand, Semsroth *et al.* found that the right anterior thoracotomy approach was associated with more perioperative complications (higher rates of conversion to sternotomy, longer cross-clamp time, more groin complications) when compared with the hemi-sternotomy approach (34). In a meta-analysis by Powell *et al.*, the rate of conversion from minimally invasive (defined as either hemi-sternotomy or right anterior thoracotomy) to full sternotomy ranged from 0% to 1.4% in published observational studies (9). The authors reported excellent results in terms of mean CPB time (68 ± 18 to 92 ± 27 minutes) and cross-clamp time (34 ± 10 to 59 ± 19 minutes).

Small calcified aortic annulus

Patients with small calcified aortic annuli are good candidates for sutureless AVR with the Perceval for multiple reasons. First, the sutureless design of the Perceval allows easier and faster implantation into the calcified root by alleviating the need for suture passing through a calcified annulus. Second, patients with small aortic roots are at high risk for prosthesis-patient mismatch, especially those with a high body mass index. This is particularly important as prosthesis-patient mismatch has been associated with worse

clinical outcomes and decreased survival (35,36). Aortic root enlargement can reduce the risk of prosthesis-patient mismatch. However, this approach is often technically challenging and can result in increased morbidity, especially in heavily calcified roots. Thus, patients with small and calcified aortic annuli may benefit from a sutureless valve since it has been shown to decrease the risk of prosthesis-patient mismatch in this population (37). Moreover, the design of the Perceval valve allows quick and reproducible deployment, even in heavily calcified roots (*Figure 1*).

Combined procedures

Combined and complex procedures can be associated with prolonged CPB and cross-clamp times, which may result in increased morbidity, especially in elderly and higher risk patients. The use of the Perceval prosthesis for combined cases can decrease overall surgical time. Concomitant mitral valve replacement was initially felt to be a contraindication to the use of the Perceval device, due to concerns over its potential interaction with the mitral prosthesis at the level of the aorto-mitral curtain. However, a number of case series have demonstrated the feasibility and safety of sutureless AVR in this setting (38). In the largest series on combined procedures (i.e., AVR with CABG and/or tricuspid annuloplasty and/or ascending aorta replacement and/or septal myomectomy) published thus far, Shrestha *et al.* reported mean CPB and cross-clamp times of 79 ± 32 and 51 ± 23 minutes. During a median follow-up of 444 days, 5 valve explanations were performed (4 PVL and 1 aortic root bleeding). The 30-day mortality was 2.1% (39).

Data on early structural deterioration

There have been very few reports of structural deterioration of the Perceval prosthesis. Bouhout *et al.* (40) reported the first case of early deterioration in a 56-year-old man who presented with symptoms of dyspnea and a transvalvular gradient of 84 mmHg. On intraoperative examination, the prosthesis leaflets were found to be stiffened due to severe calcification. The patient underwent redo-AVR with a mechanical valve and had an uneventful post-operative course. In 2015, Durand *et al.* (41) described an emergency TAVI in a 78-year-old female patient who presented in cardiogenic shock 3 years after having undergone sutureless AVR with a Perceval valve. The patient had severe aortic insufficiency on transthoracic echocardiography. Unfortunately, a computed tomography scan et transesophageal echocardiography

could not be performed due to hemodynamic instability. The suspected mechanism of aortic insufficiency was leaflet tearing. An emergency valve-in-valve procedure using a SAPIEN 3 transcatheter valve was performed and the patient had a quick recovery from her condition. These isolated cases notwithstanding, the Perceval prosthesis seems to have good short and mid-term durability. However, long-term data are lacking.

Special uses and off-label applications

Perceval in the setting of a failing homograft

Dohmen *et al.* reported the case of a 61-year-old patient who presented with homograft failure after a first redo procedure for prosthetic valve endocarditis and root abscess (42). The patient was initially treated for a type A dissection with aortic root and arch replacement using an elephant trunk. She developed infective endocarditis in the year following her initial surgery and was treated with an aortic homograft. Subsequently, she developed symptoms of dyspnea. Transthoracic echocardiography showed severe aortic stenosis with an orifice area of 0.4 cm^2 . A 21 mm Perceval valve was positioned in the homograft annulus after careful excision of the homograft leaflets. The patient had an uneventful post-operative course and was discharged on day 6.

Perceval in bicuspid aortic valves

There are currently few data on the use of the Perceval prosthesis in bicuspid valves. Initially, congenital bicuspid valve was considered a contraindication for the use of sutureless AVR, due to concerns over the fact that the aortic annulus in these patients is round rather elliptical. However, Nguyen *et al.* reported the implantation of the Perceval prosthesis in 25 consecutive patients with bicuspid valves (43). No PVL were observed on pre-discharge transesophageal echocardiography and there was no post-operative valve migration or embolization reported.

Triple-valve surgery

Mazine *et al.* reported the successful use of the Perceval in 6 patients who underwent triple-valve surgery. For each of these patients, the tricuspid valve was first addressed and annuloplasty was performed. A high transverse aortotomy was subsequently performed to remove the native valve,

decalcify and size the annulus. The mitral valve repair or replacement is done through the Sondergaard groove. Finally, the aortic annulus is resized to ensure accuracy of the measurements and the Perceval is deployed. All the patients in the series had a satisfactory postoperative course (44).

Aortic insufficiency

Sutureless valves were initially designed to treat patients with aortic stenosis. Very little literature addresses their use in patients with aortic insufficiency. Gilmanov *et al.* (45) published a series of 11 patients who underwent AVR for aortic regurgitation. Mean CPB and cross-clamp times were 130 ± 54 and 82 ± 32 minutes, respectively. One patient died in the early post-operative period; the others were successfully discharged. Seven patients were followed up to 1 year. During this period, there was no death, no residual para- or intravalvular leakage and no prosthesis migration/dislocation occurred.

Things we have learned

Since 2011, 577 Perceval devices have been implanted at the Montreal Heart Institute, making it one of the most experienced centers with the use of this technology. Over the years, we have learned to recognize situations in which sutureless AVR with the Perceval prosthesis is most useful, and to recognize and avoid some pitfalls.

Most useful use

Our experience with the Perceval has allowed us to appreciate the rapidity of its deployment and its usefulness in narrow spaces. Thus, we believe that the Perceval is best used in small calcified aortic roots, since it facilitates implantation while still allowing for annular decalcification. Moreover, it alleviates the excess operative risk associated with an annulus enlargement procedure. Furthermore, we find sutureless AVR to be especially useful in minimally invasive procedures, where it facilitates deployment through relatively small incisions. In our experience, favorable results were achieved with both a mini-sternotomy or right anterior thoracotomy approach. Both approaches have been used with low rates of conversion to full sternotomy. Finally, our group has a large experience with the use of the Perceval prosthesis in the setting of double or triple valve surgery, where the use of sutureless technology allows for significant reductions in CPB and cross-clamp times,

favorable clinical outcomes, and excellent hemodynamic parameters.

Pitfalls

The rate of permanent pacemaker implantation has been somewhat of a concern with the Perceval. The majority of the literature reports rates of permanent pacemaker implantation between 6% and 9%. However, some studies have reported rates as high as 23% (46). This is a concern, considering the significant morbidity associated with permanent pacemakers (47). Reports have found old age, presence of preoperative rhythm disturbances, height of the membranous septum, presence of a bicuspid aortic valve, and the requirement for concomitant mitral or tricuspid valve procedures to be predictors of post-operative permanent pacemaker implantation (20). Some studies have also suggested oversizing as an additional risk factor (48). During surgery, the risk of post-operative permanent pacemaker implantation can be alleviated by placing the guiding sutures precisely at the nadir of each cusp instead of a few millimeters below, as recommended by the manufacturer. This technical adjustment was first reported by the Toronto group and later confirmed by the Nuremberg group (20,49).

PVL have not been a major concern with the Perceval. The vast majority of published reports show very low rates of moderate or severe PVL (9). Thorough decalcification and sizing are important factors to keep the risk of PVL low.

Adequate sizing is critically important since undersizing can lead to prosthesis migration and oversizing is associated with bleeding complications, arrhythmias and stent invagination. A report by Margaryan *et al.* indicates that multidetector-row computed tomography might be helpful to determine adequate valve size preoperatively (50).

Areas of future research

The Perceval Sutureless Implant Versus Standard-Aortic Valve Replacement (PERSIST-AVR) study is one of the largest contemporary trials in the field of cardiac surgery (www.ClinicalTrials.gov, Identifier: NCT02673697). This prospective randomized controlled trial, for which enrollment started in 2016, will compare the Perceval prosthesis to other stented biological valves. Its primary endpoint is freedom from major adverse cerebrovascular and cardiac events (i.e., composite of all-cause mortality, myocardial infarction,

stroke, and valve re-intervention) at 1 year. The secondary endpoints include operative duration, length of hospital stay, quality of life at 1 month and 1 year, rate of pacemaker implantation and echocardiographic endpoints at various time points (up to 5 years). The study is designed on a non-inferiority model and has a target enrollment of 1,234 patients.

Future research efforts should also attempt to provide high-quality, prospective, randomized data to compare TAVI and sutureless valves in minimally invasive surgery.

Conclusions

Aortic stenosis is a highly prevalent disease, and its incidence is expected to increase further due to an aging population. The development of minimally invasive techniques has allowed surgeons to treat patients with multiple co-morbidities. Among these new technologies, the Perceval sutureless prosthesis offers interesting features. It allows quick and reproducible valve implantation, while still permitting decalcification of the aortic annulus. In our experience, the Perceval valve is most useful in patients with small calcified aortic annuli, concomitant procedure, and during operations carried out through a minimally invasive approach. A higher rate of permanent pacemaker implantation remains the Achilles' heel of this technology, but recent reports suggest that this risk can be mitigated with careful patient selection and attention to minute technical details. Finally, the Perceval prosthesis has shown good mid-term durability, with very few reports of valve deterioration. In the coming years, prospective, randomized, long-term data comparing the Perceval prosthesis with well-established stented aortic bioprostheses will determine the role of sutureless AVR in the surgical armamentarium. Comparison of minimally invasive sutureless AVR versus TAVI might shed some light on the relative merit of one technology over the other, especially in intermediate-risk patients.

Acknowledgements

None.

Footnote

Conflicts of Interest: D Bouchard is a proctor for LivaNova, London, UK. The other authors have no conflicts of interest to declare.

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doi: 10.21037/jovs.2018.03.10

Cite this article as: Chauvette V, Mazine A, Bouchard D. Ten-year experience with the Perceval S sutureless prosthesis: lessons learned and future perspectives. *J Vis Surg* 2018;4:87.