

## Perceval Sutureless Valve – are Sutureless Valves Here?

Rahul Chandola<sup>1,\*</sup>, Kevin Teoh<sup>2</sup>, Abdelsalam Elhenawy<sup>3</sup> and George Christakis<sup>1</sup>

<sup>1</sup>Sunnybrook Health Sciences Centre, Toronto, Canada; <sup>2</sup>Southlake Regional Hospital, Newmarket, Ontario, Canada;

<sup>3</sup>University of Alberta hospital, Edmonton, Canada

**Abstract:** With the advent of transcatheter aortic valve implantation (TAVI) techniques, a renewed interest has developed in sutureless aortic valve concepts in the last decade. The main feature of sutureless aortic valve implantation is the speed of insertion, thus making implantation easier for the surgeon. As a result, cross clamp times and myocardial ischemia may be reduced. The combined procedures (CABG with AVR in particular) can be done with a short cross clamp time. Perceval valve also provides an increased effective orifice area as compared with a stented bioprosthesis. Sutureless implantation of the Perceval valve is not only associated with shorter cross-clamp and cardiopulmonary bypass times but improved clinical outcomes too. This review covers the sutureless aortic valves and their evolution, with elaborate details on Perceval S valve in particular (which is the most widely used sutureless valve around the globe).

**Keywords:** Aortic valve, bioprosthesis, Perceval valve, TAVI.

### INTRODUCTION

Owing to the increased life expectancy of the general population, there has been an increase in the prevalence of patients with valvular heart disease and a proportionate increase in the number of patients eligible for aortic valve replacement (AVR). More than 20% of conventional aortic valve surgery is performed on patients over 80 years in some countries. The proportion of patients between 61 and 70 years of age, undergoing isolated AVR with biological valves, has increased from 49.2% to 73.1% between 2003 and 2008 [1].

Because a considerable number of elderly patients with symptomatic severe aortic stenosis have significant comorbidities, AVR with cardiopulmonary bypass can be associated with a high perioperative mortality and morbidity. Studies have shown that increasing duration of cross-clamp significantly correlates with major post-operative morbidity and mortality in both low- and high-risk patients [2]. This led to the development of procedures that aimed at shortening the aortic crossclamp and operative time [3].

For surgical aortic valve replacements, the valve is fixed to the aortic annulus by placing sutures into the annulus and then through the sewing cuff of the prosthetic valve. Sutureless aortic valve is particularly advantageous as it obviates the need to put stitches to fix the valve, hence making the procedure faster [4].

In high-risk patients undergoing combined surgery with prolonged surgical time and in patients undergoing reintervention, sutureless bioprosthesis provides a useful

alternative, particularly reducing the implantation time considerably. As the annular stitches to anchor the valve are not required, the cross-clamp and CPB times are shortened. As there's no ring for valve anchorage, the effective orifice area of the valve is more for any given valve size. This would be potentially beneficial for patients with small aortic roots where risk of patient prosthesis mismatch is high [5]. Another significant advantage of sutureless valves is their utility in minimally invasive AVR. There's an increased technical difficulty in putting annular sutures in minimal invasive AVR because of the limitation of working space. Sutureless valves obviate this technical difficulty. The Perceval S valve may also be used as a first-line option during minimally-invasive procedures [6].

McGovern *et al.* came up with the concept of sutureless aortic valve in the early 1960s when they designed a ball-cage-type mechanical valve for sutureless implantation [7]. This valve continued to be used till 1980 but had some disadvantages especially high incidence of perivalvular leaks. Also its bulky size was not suitable for small annuli [8]. It also had a high incidence of thrombo-embolism (42%) and re-operation (16%) [8] and hence its use discontinued thereafter.

In the early years of last decade, the development of minimally invasive transcatheter valve implantation (TAVI) had been explored [9-12] and evolved quite significantly in last few years. Percutaneous technology has been developed with an aim to treat high-risk patients with reduced mortality and morbidity compared to surgical AVR (for high risk patients the in-hospital mortality rates of surgical AVR range from 3-8%) [13]. However, it is well known that transcatheter methods are not feasible in some patient groups, carry procedural risk and there is a significant concern about the durability and long term outcomes [13]. Percutaneous methods are not feasible in patients with small peripheral vessels,

\*Address correspondence to this author at the Sunnybrook Health Sciences Centre, 2075 Bayview Ave., Room H4 06, Toronto, ON, M4N 3M5, Canada; Tel: 416-480-6080; Fax: 416-480-6072; E-mail: [r\\_chandola@rediffmail.com](mailto:r_chandola@rediffmail.com)

heavily diseased aorta, bicuspid valves, Aortic annulus < 18 mm or > 25 mm for balloon expandable and < 20 or > 27 for self expandable devices, presence of asymmetric heavy valvular calcification (which may compress the coronary arteries during TAVI) and low-lying implantation of coronary arteries. During transcatheter implantation, the calcified aortic valve is pressed into the aortic wall without decalcification of the annulus. As a result, the prosthesis may be implanted in an inhomogeneous and irregular surface that may alter the geometry of the prosthesis leading to paravalvular leakage [14-16]. Also, there is a concern about the durability of transcatheter valve because damage to the pericardium may occur due to crimping of valve leaflets on the delivery catheter. Histological investigation of the pericardial cusp of Sapien-Edwards valves disclosed collagen bundle fragmentation and plasmatic insudation, which might interfere with mechanical properties and long-term durability. These findings are of concern, as structural deterioration at the time of implantation may be harmful and can possibly compromise the valve longevity [17]. Hence in TAVI, tissue structural degeneration deserves more attention and further investigation. In contrast, the Perceval valve is mounted on dedicated delivery device and its diameter is reduced to the desired size by collapsing it (not crimping). Long-term results of sutureless aortic valves are still limited, but no case of early degeneration has been reported so far. In the present form, Sutureless AVR cannot represent, obviously, an alternative to TAVI in inoperable patients, whereas space for a competitive role may be defined in high-risk patients, particularly in the case of combined coronary artery disease. There's an ongoing debate about careful selection of patients considered at a high risk for conventional AVR and candidates for TAVI and it has been shown that current surgical practice may have favourable results even in these difficult cases [18]. This indicates that expanding the TAVI indication may not be the only solution and that a shorter operative alternative like sutureless aortic valves may improve the surgical outcome.

The evolution of transcatheter aortic valve implantation has also evoked a parallel interest in surgical community and led to the revival of sutureless aortic valve concepts in the last decade [19]. Minimally invasive approaches for surgical AVR have evolved over a period of time. Of particular note is the development of sutureless valves which can be delivered using less invasive partial upper sternotomy. The implantation of sutureless aortic valves using minimally invasive methods have opened up a new field which is quite competitive with transcatheter procedures. Although the concept of sutureless valves came in sixties, there is a renewed interest after the evolution of transcatheter techniques. In high-risk patients undergoing combined surgery with expected prolonged surgical time and in patients undergoing reintervention, the use of sutureless bioprostheses is particularly valuable for the considerable reduction in the implantation time [4]. As mentioned before, during minimally invasive surgery, putting sutures along the aortic annulus can be technically challenging because of reduced working space. Sutureless Perceval S prosthesis is really helpful in such a situation and is technically simple. In addition, it may reduce the rate of paravalvular leakage, which is commonly related to suboptimal suturing of the bioprosthesis

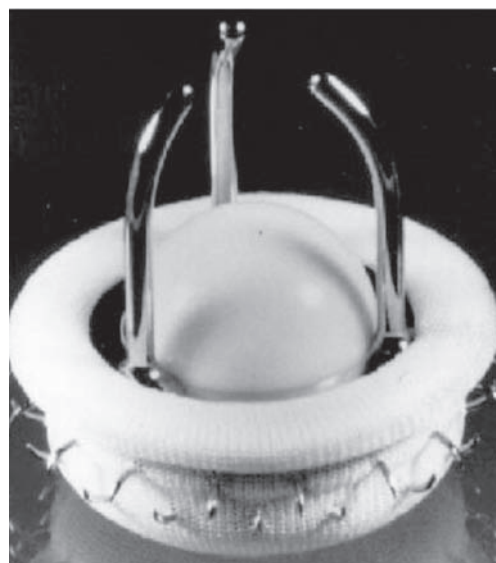
owing to reduced working space during minimal invasive procedures [6].

## EVOLUTION AND TYPES OF SUTURELESS AORTIC VALVES

Following Sutureless aortic valves have clinically been used so far:

### 1) Magovern-Cromie Sutureless Aortic Ball-cage Prosthesis

This valve has a barium-impregnated silicone ball in an open, three-strut titanium cage. It is inserted by rotating an implantation tool to engage multiple vertical pins into the aortic annulus. A central cylinder with an upper and a lower right hand and left-hand thread is engaged to two titanium rings containing titanium pins. As the central cylinder rotates, the rings are approximated, thereby ejecting the fixation metal pins into the adjacent tissue (Fig. 1). Dr George Magovern in 1962 developed this valve with Harry Cromie [20]. In a 25 year's review involving 728 implantation with this prosthesis, Magovern documented operative mortality of 11% for isolated aortic valve replacement and 15% for aortic valve replacement with concomitant cardiac procedures. Operative mortality declined to 4.9% after 1981. Incidence of paravalvular leak was 0.41%/patient-year while the incidence of valve endocarditis, valve thrombosis and embolic events was 0.43%/patient-year, 0.04%/patient-year; 3.95%/patient-year respectively. The incidence of aortic valve reoperation was 0.76%/patient-year. The 5-year, 10-year, and 20-year probability of survival corrected for normal mortality was 77%, 64%, and 52% for all discharged patients [21].



**Fig. (1).** Magovern chromie valve- This valve is inserted by rotating an implantation tool to engage multiple vertical pins into the aortic annulus.

The aim of introducing this sutureless valve was to shorten the operating time and avoid many of the complications of prolonged extracorporeal perfusion, but it had several disadvantages. Amongst the important disadvantages were a higher incidence of conduction defects [21] and fre-

quent perivalvular leak. The device was bulky and difficult to use in patients with small aortic annulus. Dehiscence occasionally occurred, especially in patients with large dilated aortic roots. Thrombosis and ball variance were also common as late complications [22]. Consequently, the implantation of this valve became very infrequent after late 80s.

## 2) 3F Enable Sutureless Aortic Valve Prosthesis

This valve is constructed from equine pericardial trileaflet valve sewn within a self-expandable Nitinol<sup>®</sup>-based stent. The self-expandable stent allows the device to remain in position due to radial recoil forces after re-warming (Fig. 2). Valves are available from 19 mm up to 29 mm. A new equine pericardial sutureless valve (3F-Enable) prosthesis based on a Nitinol<sup>®</sup> stent has been developed in 2005.



**Fig. (2).** 3f enable valve-It has a self-expanding Nitinol<sup>™</sup> frame to hold the valve in its position.

In 2006, 3FTherapeutics was taken over by ATS Medical Inc. and the 3F-Enable aortic valve prosthesis underwent some modifications and as claimed, will help prevent paravalvular leakage significantly. The early feasibility studies and trials of the 3f Enable device were conducted in 2005 [23] and 2006 [24]. A multicentre clinical trial was conducted between March 2007 and December 2009 comprising of 140 patients which concluded the device to be safe and of clinical utility [25]. Sadowski *et al.* [26] reported the device to be safe and effective at short- and mid-term followup with maximal and mean gradients of 11.6 and 6.8 mmHg, respectively on discharge. These echocardiographic parameters gradually came down to 10.1 and 5.2 mmHg at 4 years follow-up. 3F Enable received European conformity mark (CE) approval in 2010.

## 3) Intuity Valve System<sup>™</sup>

The Edwards Intuity Valve System Fig. (3) consists of a bioprosthesis, delivery system, and balloon catheter, which is used to deploy the valve after placement within the aortic annulus. The Intuity valve has a broad polyester sealing

cloth which covers the balloon expandable stainless steel frame. This sealing needs to be expanded at the level and slightly below the native aortic valve annulus. The Edwards Intuity Valve System (Edwards Lifesciences LLC, Irvine, Calif) is designed for rapid deployment AVR and is manufactured on the proven long-term safety and efficacy of the Carpentier-Edwards Perimount (Edwards Life sciences LLC) valve With inputs from design innovation from Edwards' transcatheter heart valves. After sternotomy and aortotomy, the native aortic valve leaflets are excised and meticulous debridement of the calcific annulus is performed. Three equidistant guiding sutures are placed through the lowest points in aortic annulus and then passed through the sewing ring of the the Intuity valve. The guiding sutures are used to lower the valve and delivery system into the annulus and secured into position. The stent frame is deployed gradually by inflating the balloon catheter to inflation pressures ranging from 3 to 5 atm, depending on the size of the prosthesis. When fully deployed, the prosthesis is fixed in a supra-annular position while the stent skirt frame is seated within the left ventricular outflow tract below the annulus in a flared configuration.

The Edwards life sciences started a Triton trial in 2010 (TRITON) and the valve received a CE mark in 2012 .The TRITON trial was designed to evaluate the safety and performance of the Edwards Intuity valve in Europe and the results of the trial demonstrated that for the isolated AVR procedures, mean aortic cross-clamp times were reduced by 43 %, and mean bypass times by 41 percent, compared to the STS National.



**Fig. (3).** Intuity valve-The polyester cuff of the valve provides adequate sealing at and just below the annular level.

## 4) Arbor Trilogy<sup>™</sup> Aortic Valve System

It is a modular sutureless valve manufactured by Arbor Surgical Technologies, Irvine, California. Its feasibility was reported in a study of 32 patients between 2006 and 2008 [27]. The study concluded that Sutureless aortic valve replacement is feasible and safe with the Trilogy System. After an initial learning curve, a more rapid and simple implantation could be achieved compared with conventional stented tissue valves.

### 5) Perceval® Sutureless Aortic Valve Bioprosthesis

The AVR with sutureless Perceval S aortic valve is feasible, safe and hemodynamically comparable to conventional xenografts. Due to the increased insertion speed, this valve allows short cross-clamp and operation times and is especially suitable for a mini-invasive approach. Multicenter Trials of the Sorin Perceval device have been ongoing in Europe to evaluate the safety, efficacy and feasibility of the valve since 2007 [28].

Having discussed the evolution of sutureless aortic valves, it'll be prudent to discuss the elaborate details on Perceval S valve in particular (which is the most widely used sutureless valve around the globe).

#### THE PERCEVAL VALVE

The Perceval S bioprosthesis is constructed from bovine pericardium fixed in a metal cage made up of an alloy of nickel and titanium, known as nitinol. Nitinol is unique in its malleability and excellent recoil, is able to withstand extreme deformation and return to its original shape after the removal of force. Because of this property, the cage can be compressed for the implantation and then released to reach its final diameter. The inflow ring of the valve has three loops corresponding to each sinus of the valve through which sutures are passed as a guide to aid prosthetic positioning in the native annulus (Fig. 4). Currently, four sizes of the Perceval S aortic valve prosthesis are available: small—S (19–21 mm); medium—M (22–23 mm), large—L (24–25 mm) and extra large XL version that recently received CE Mark Approval. Hence Perceval S can be used for annulus sizes ranging from 19 mm to 27 mm.

#### INDICATIONS FOR PERCEVAL VALVE

Following patients are considered suitable for a perceval valve:

- Elderly Patients requiring isolated AVR but at high surgical risk due to associated co-morbidities. Its important that the patient should be a candidate for standard surgical intervention.
- Patients needing AVR with concomitant bypass surgery in whom long pump times are expected to be detrimental in the presence of associated comorbidities.

- NYHA functional class III and/or IV.
- Preoperatively measured aortic annulus dimension between 19 to 27 mm.

#### Contraindications for Perceval valve

- Active endocarditis or other systemic infections.
- Dilatation of the ascending aorta exceeding 4cm in the sinotubular junction.
- Ratio between the sinotubular diameter and the aortic annulus more than 1.3.
- Bicuspid aortic valve with asymmetrical sinuses of Valsalva.
- Multivalve lesion.
- Annular size more than 27 mm (Perceval S can be used for annulus sizes ranging from 19 mm to 27 mm).

#### SURGICAL IMPLANTATION

After a median sternotomy, the patient is placed on cardiopulmonary bypass (CPB), cannulating the ascending aorta and right atrium. The heart is vented through the right upper pulmonary vein. Retrograde cardioplegia is the method of choice at our institution for myocardial protection though other groups report using selective or plain antegrade root cardioplegia with good results. Aortotomy should be transverse (and not oblique), around 2.5-3 cm above the annulus (Fig. 5). The diseased valve is completely removed and the annulus decalcified, if needed, and then sized. Correct sizing of the annulus is crucial for Perceval valve and determines the success of surgery in terms of appropriate positioning and functioning of the aortic valve prosthesis and absence of perivalvular leakage.

The valve sizers have an intraannular and a supraannular head. The intra-annular head of a particular sizer is similar in size to the supra-annular head of the smaller sizer (e.g. intra-annular head of L size corresponds to supra-annular head of M size). Ideally, the native annulus should allow the passage of the intra-annular head, but not the supra-annular head of the same sizer. No oversizing should be performed as it can result in unfolding of the device. 3/0 Prolene sutures are taken through the annulus at the nadir of each cusp (Fig. 6). The inflow ring has three loops through which these prolene sutures are passed (Fig. 7) and the prosthesis is guided to

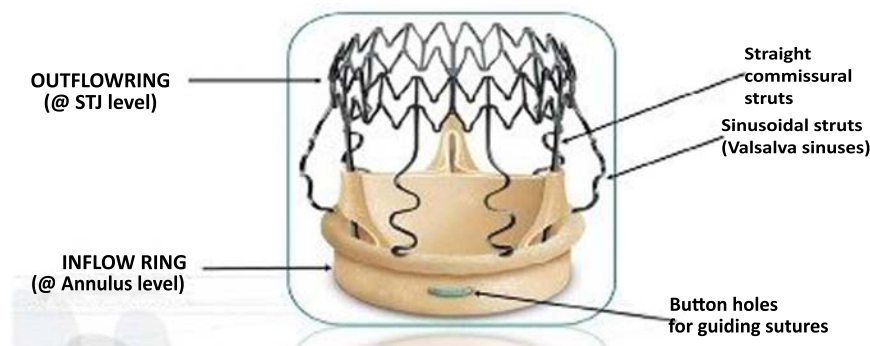
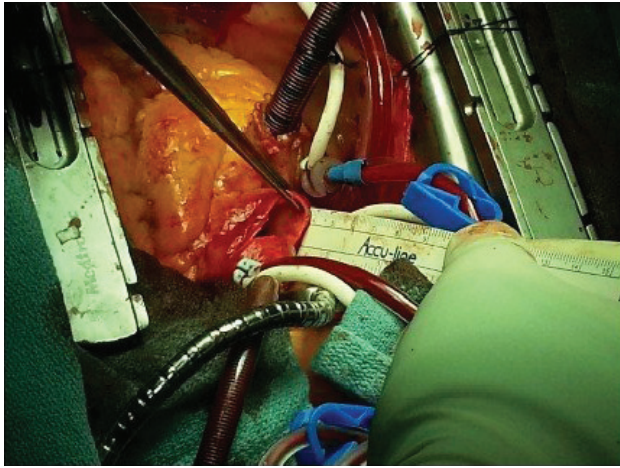
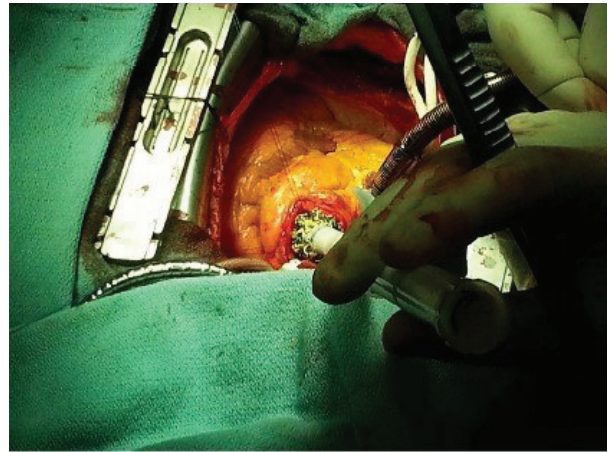


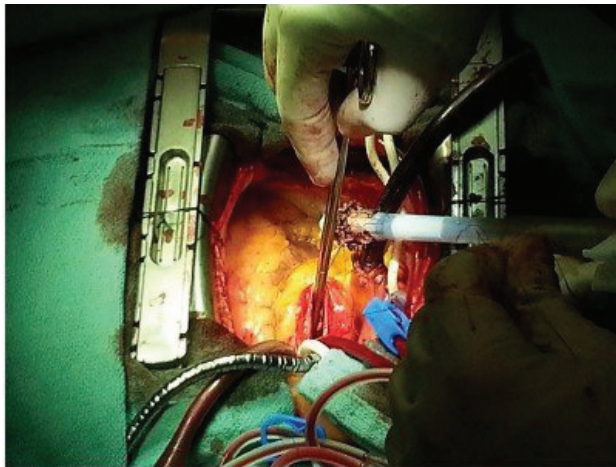
Fig. (4). Perceval S valve.



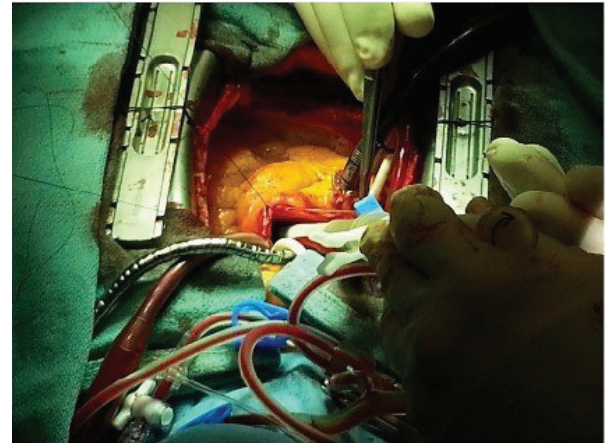
**Fig. (5).** Site of aortotomy.



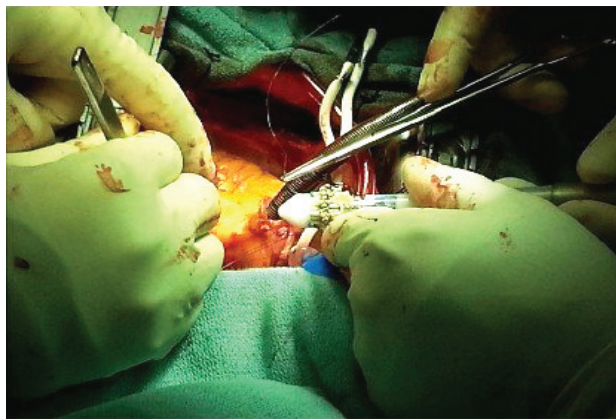
**Fig. (8).** Valve being guided into the annulus.



**Fig. (6).** Three sutures taken at the nadir of each cusp.



**Fig. (9).** Stent being deployed.



**Fig. (7).** Sutures passed through 3 loops on the valve.

correct position in annulus by sliding over these sutures (Fig. 8). Once the delivery system is in position, the stent is deployed by turning the release screw and leaving the valve in place (Fig. 9). The delivery system and the guiding sutures

are removed. A post dilatation balloon is inserted in the valve and dilated for 30 seconds at a pressure of approximately 4 atmospheres to optimize the area of contact between the prosthesis and the aortic annulus (Fig. 10). The aortotomy is closed, and the crossclamp is removed.

Following considerations are specifically useful for implantation (followed by our group, though the practice may vary amongst different groups).

1. Retrograde cardioplegia is helpful for myocardial protection as it can be given continuously throughout the procedure without interruption and doesn't need to be discontinued when the valve is lowered to its position. (though some centers report using selective or plain antegrade root cardioplegia routinely with good results).
2. Aortotomy is made 1 cm distal to the sinotubular junction, so as to leave a free edge for closure of the aortotomy after implantation of the device. In effect, the aortotomy is upto 2.5-3 cm above the annulus.
3. Due to the high aortotomy and the sutureless implantation with the valve collapsed on a holder, manipulation of the aortic root from outside and inside is abandoned.



Fig. (10). Balloon dilatation of the valve.

4. When coronary bypass surgery is needed, care is taken to implant the proximal grafts distal to the sinotubular junction to avoid interference with the valve stent. sometimes the proximal anastomosis of the second vein graft is done with another vein graft in a 'piggy-back fashion' so as to avoid doing 2nd proximal anastomosis in the ascending aorta.
5. Manipulation of the aorta as well as heart is avoided to avoid any accident. Hence CO<sub>2</sub> is used to minimize the air and a vent through RSPV is routinely applied.

#### CLINICAL TRIALS WITH PERCEVAL

**1) First in man trial:** A European, multicenter, prospective, non-randomized, clinical pilot trial was conducted from April 2007 to February 2008 where 30 patients (mean age: 81 +/- 4 years) underwent aortic valve replacement [29]. A clinical and echocardiographic follow up was performed at the time of hospital discharge and subsequently after one, three, six, and 12 months. There was one in-hospital death (3.3%), and three deaths occurred within 12 months of follow up (one death was valve-related, and two deaths were independent of the valve implantation). A total of 28 patients were assessed at one month post implantation, and 23 after 12 months. No migration or dislodgement of the valve had occurred, but there were two mild paravalvular leakages and two mild intravalvular insufficiencies. The preliminary results of the trial confirmed the safety and efficacy of the Perceval S sutureless aortic valve and it was concluded that shortening the aortic cross-clamp and cardiopulmonary bypass times may help to reduce the mortality and morbidity in a subset of high-risk patients.

**2) Perceval pivotal trial:** This clinical investigation is designed as a prospective and non-randomised study. From January 2007 to September 2011, a total of 208 high-risk patients received a Perceval bioprosthesis in 2 European centers. Valve implantation resulted in significant improvement of patients' symptoms. Mean preoperative and postoperative gradients were 48.6±18.6 mm Hg and 10.4±4.3 mm Hg, respectively, and preoperative and postoperative mean effective orifice areas were 0.7±0.2 and 1.4±0.4 cm<sup>2</sup>. Survival at 12 months was 87.1%, success of

implantation was 95%, and freedom from reoperation was 96%. In hospital mortality was 2.4%. During follow-up, 9 patients (4%) required reoperation for paravalvular regurgitation; 7 early and 2 late reoperations. Mean cross-clamp time (CCT) and extracorporeal circulation time (ECT) were, respectively, 33±14 minutes and 54±24 minutes, including 45 patients who underwent surgery through ministernotomy. Concomitant coronary bypass was done in 48 patients with mean CCT 43±13 and ECT 68±25 minutes.

**3) Cavalier trial:** This is a prospective non randomized trial with a primary objective to assess the safety and effectiveness of the Perceval S valve at 12 months after implantation. A total of 17 European centres are participating in this study. Estimated enrollment is 300 patients. Study was started in February 2010 and estimated completion date is September 2017.

#### DISCUSSION

Aortic stenosis (AS) is the most common valvular heart disease in the ageing population, with a prevalence of 4.6% in adults ≥ 75 years of age [30, 31]. It is known that prolonged cross-clamp time significantly correlates with major post-operative morbidity and mortality in both low- and high-risk patients. This effect increases with increasing cross clamp time [32]. Hence, there was a need to shorten the aortic crossclamp and consequently CPB time for aortic valve replacement specially in elderly patients with associated comorbidities and reduced cardiac reserve. The sutureless implantation of the Perceval S aortic valve aims at shortening aortic crossclamp time. Some investigators have reported the implantation times for a sutureless stent-mounted valve in the aortic position to be less than 20 minutes of aortic crossclamping. In a report by Flameng *et al.*, median duration of aortic crossclamping needed for the AVR was 17 minutes. Total aortic cross-clamp time, including the intermittent phases needed to perform the distal CABG anastomoses, was a median of 22 minutes and median CPB time was 46 minutes [33]. In a report by Santarpino *et al.* [34], Sutureless implantation of the Perceval valve was not only associated with shorter cross-clamp and cardiopulmonary bypass times but improved clinical outcomes too. Despite the higher surgical risk, patients receiving Perceval S valve less frequently required blood transfusion (1.1 ± 1.1 units versus 2.3 ± 2.8 units, p = 0.007), had a shorter intensive care unit stay (1.9 ± 0.7 versus 2.8 ± 1.9 days, p = 0.002) and a shorter intubation time (9.2 ± 3.6 hours versus 15 ± 13.8 hours, p = 0.01). The pooled estimates of a recent meta-analysis [35] reported mean gradients to be decreased significantly from 48.5 mmHg preoperatively to 9.4 mmHg at 1-year follow-up and 8 mmHg at 2-year follow-up. Pooled effective orifice area also increased from 0.7 cm<sup>2</sup> preoperatively to 1.9 cm<sup>2</sup> at 2-year follow-up, constituting over a 2-fold increase in area.

While long-term durability and hemodynamic data is currently lacking, sutureless valves appear to have excellent hemodynamic parameters at perioperative and short-term follow-up. Upto 37-41% of patients with severe symptomatic AS do not receive SAVR [36, 37]. In these patients with severe comorbidities and high surgical risk, transcatheter Aortic Valve Implantation (TAVI) has emerged

as a feasible and relatively safe option. In TAVI, there is a risk of dislodgement of calcium debris from the native valve or the root when the aortic root is dilated before placing the valve, resulting in stroke and peripheral embolism [38]. Calcium and debris may embolise to the coronary arteries causing myocardial infarction. Coronaries can also be obstructed by valve malpositioning [38]. Incidence of paravalvular leaks is significant with transcatheter techniques. In partner trial, paravalvular aortic regurgitation occurred in approximately 40% of patients and was associated with increased late mortality. A significant difference in the 2-year mortality was reported between patients with mild to severe paravalvular leak and patients without or with only trace paravalvular leak [39]. Sutureless valves on the other hand, have relatively low rates of paravalvular leaks. In a multicenter study including patients from 10 European referral centers, sutureless AVR with the Enable bioprosthesis (Medtronic, Inc, Minneapolis, Minn) was associated with a 2.1% rate of major paravalvular leaks. More recently, in the TRITON study [40] the 1-year clinical outcome of AVR with the sutureless Edwards Intuity prosthesis demonstrated a paravalvular leak rate of 2.3% (1.4% and 0.9% for early and late occurrences, respectively). The Perceval S sutureless bioprosthesis has a slightly worse performance relative to other models in terms of paravalvular leaks [41-43]. Though the first few sutureless AVR series have shown a high incidence of paravalvular leaks, in a latest propensity matching study [44], no patient in Perceval S group demonstrated paravalvular leak. In contrast to previous studies [41, 43] with reports of up to 12.5-15%, the pooled results from another systematic review also indicate lower paravalvular leak rates of 2-4% for Perceval valve [45]. The difference in rates of paravalvular leaks may be related to the way in which annular decalcification was carried out. In the 2 previously mentioned studies, it seems that the aortic annulus was only mildly decalcified. A moderate decalcification of the aortic annulus was performed in the later studies that could have accounted for the low rates of paravalvular leaks.

In a recent meta-analysis, the pooled estimates of 30-day and 1-year mortality rates for sutureless aortic valves were 2.1% and 5.1% respectively. These rates are equivalent to the mortality rates reported recently for surgical AVR [45]. In this same metaanalysis, safety of the valve was assessed. The incidence of neurological events at early follow-up was 1.9% and later follow-up was 1.5%. Weighted pooled estimates of renal failure, endocarditis and reoperation for bleeding were 1.2%, 2.2% and 1.4% respectively. Incidence of structural valve deterioration was 0.4%. These estimates are very much comparable to standard AVR. While there is not enough evidence for long term outcomes and randomized comparisons of sutureless AVR versus surgical AVR, there's ample evidence for low and acceptable mortality rates for in the short-term. Major limitation of the current evidence base is the absence of long-term data beyond 4 years for sutureless valves.

Pooled estimates of permanent pacemaker implantations for sutureless valves were slightly high (5.6%), comparable to pooled estimates of 3.0% for conventional AVR and lower

than that for TAVI (13.2%) reported in a recent study [46]. It is not clear presently whether this is related to the risk profile of these patients or the need for dilatation of the valve, that could potentially damage the conduction system.

With the advent of transcatheter aortic valve implantation techniques (TAVI), a renewed interest in sutureless aortic valve concepts have developed in the last decade. A concept originally put forward by Magovern in sixties, the sutureless valves have seen significant development in the past few years. The main feature of sutureless aortic valve implantation is the advantage of insertion speed, thus making implantation easier for the surgeon. As a result, cross clamp times and hence myocardial ischemia may be reduced. Another advantage of using percevals valve is that combined procedures (CABG with AVR in particular) can be employed with a short cross clamp time. This is especially helpful for the patients with nonstentable coronary artery lesions. Perceval valve also provides an increased effective orifice area as compared with a stented bioprosthesis. This quality makes it haemodynamically suitable for patients with small calcified aortic annulus [47]. Patients with small aortic annulus and normal aortic root morphology may benefit the most from aortic valve replacement with a Perceval valve, without increased risk of death or other major complications [48]. The incidence of paravalvular leaks is low in sutureless valves as compared to transcatheter procedures owing to the surgical excision of the native aortic valve and bulky calcifications of the aortic annulus. In the setting of minimally invasive AVR, sutureless Perceval S prosthesis is really helpful as it obviates the need to place the sutures and hence less working space is required. This makes the procedure technically simple. In addition, it may reduce the rate of paravalvular leakage, which is commonly related to suboptimal suturing of the bioprosthesis specifically during minimal invasive procedures [48].

Finally, in the era of valve-in-valve implantation, it has been suggested that sutureless aortic valve replacement may be considered in patients with previous aortic valve replacement. It has been implanted and found to be particularly useful in high-risk patients even when the diameter of the previously implanted valve is small [47].

## CONCLUSION

Sutureless aortic valves are new and promising tools in a surgeon's armamentarium for the treatment of aortic valve stenosis. It could increase applicability of surgical aortic valve replacement in the elderly with reduced cardiac reserve and severe comorbidities and would be specially helpful in minimal invasive surgeries because of the ease of implantation and insertion speed. Early and midterm results are encouraging. The evidence so far points to a similar mortality and complication rates with satisfactory hemodynamic performance in short term compared to conventional AVR. Results beyond 4 years with long-term follow-up data, adequately powered sample sizes and randomized trials are required to adequately assess the durability, hemodynamic performance and long-term complications of sutureless AVR.

## CONFLICT OF INTEREST

The authors confirm that this article content has no conflicts of interest.

## ACKNOWLEDGEMENTS

Declared none.

## REFERENCES

- [1] Bridgewater B, Gummert J, Kinsman R, Walton P. Towards global benchmarking: the Fourth EACTS Adult Cardiac Surgical Database Report. Oxfordshire: Dendrite Clinical Systems; 2010. Henley-on-Thames.
- [2] Al-Sarraf N, Thalib L, Hughes A, *et al.* Cross-clamp time is an independent predictor of mortality and morbidity in low and high-risk cardiac patients. *Int J Surg* 2011; 9(1): 104-9.
- [3] Berrekouw E, Vogel B, Fischer H, *et al.* Fast sutureless implantation of mechanical aortic valve prostheses using Nitinol attachment rings: Feasibility in acute pig experiments. *J Thorac Cardiovasc Surg* 2007; 134(6): 1508-12.
- [4] Santarpino G, Pfeiffer S, Concistré G, Grossmann I, Hinzmann M, Fischlein T. The perceval s aortic valve has the potential of shortening surgical time: does it also result in improved outcome? *Ann Thorac Surg* 2013; 96(1): 77-82.
- [5] Shrestha M, Maeding I, Höfler K, *et al.* Aortic valve replacement in geriatric patients with small aortic roots: are sutureless valves the future? *Interact Cardiovasc Thorac Surg* 2013; 17(5): 778-82.
- [6] Santarpino G, Pfeiffer S, Concistré G, Fischlein T. Perceval S aortic valve implantation in mini-invasive surgery: the simple sutureless solution. *Interact Cardiovasc Thorac Surg* 2012; 15(3): 357-60.
- [7] Magovern GJ, Cromie HW. Sutureless prosthetic heart valves. *J Thorac Cardiovasc Surg* 1963; 46: 726-36.
- [8] Scott SM, Sethi GK, Flye MW, Takaro T. The sutureless aortic valve prosthesis: experience with and technical considerations for replacement of the early model. *Ann Surg* 1976; 184: 174-8.
- [9] Cribier A, Eltchaninoff H, Bash A, *et al.* Trans-catheter implantation of balloon-expandable prosthetic heart valves. Early results in an animal model. *Circulation* 2001; 104 (suppl 2): 1552.
- [10] Boudjemline Y, Bonhoeffer P. Steps toward percutaneous aortic valve replacement. *Circulation* 2002; 105: 775-8.
- [11] Webb JG, Munt B, Makkar R, Naqvi T, Dang N. A percutaneous stent-mounted valve for treatment of aortic or pulmonary valve disease. *Catheter Cardiovasc Interv* 2004; 63: 89-93.
- [12] Grube E, Laborde JC, Zickmann B, *et al.* First report on a human percutaneous transluminal implantation of a self-expanding valve prosthesis for interventional treatment of aortic valve stenosis. *Catheter Cardiovasc Interv* 2005; 66: 465-9.
- [13] Zannis K, Folliguet T, Laborde F. New sutureless aortic valve prosthesis: another tool in less invasive aortic valve replacement. *Curr Opin Cardiol* 2012; 27(2): 125-9.
- [14] Joudinaud TM, Flecher EM, Curry JW, Kegel CL, Weber PA, Duran CM. Sutureless stented aortic valve implantation under direct vision: lessons from a negative experience in sheep. *J Card Surg* 2007; 22: 13-7.
- [15] Quaden R, Attmann T, Boening A, Cremer J, Lutter G. Percutaneous aortic valve replacement: resection before implantation. *Eur J Cardiothorac Surg* 2005; 27: 836-40.
- [16] Webb JG, Pasupati S, Humphries K, *et al.* Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation* 2007; 116(11): 755-63.
- [17] Thiene G, Basso C, Della Barbera M, Valente M. Pericardial leaflet injury in transcatheter aortic valve implantation: trick or treat. *Eur J Cardiothorac Surg* 2011; 40(1): 259-60.
- [18] Subramanian S, Rastan AJ, Holzhey D, *et al.* Conventional aortic valve replacement in transcatheter aortic valve implantation candidates: a 5-year experience. *Ann Thorac Surg* 2012; 94: 726-30.
- [19] Wendt D, Thielmann M, Pizanis N, Jánosi RA, Kamler M, Jakob H. Sutureless aortic valves over the last 45 years. *Minim Invasive Ther Allied Technol* 2009; 18(3): 122-30.
- [20] Gott VL, Alejo DE, Cameron DE. Mechanical heart valves: 2. 50 years of evolution. *Ann Thorac Surg* 2003; 76: S2230-39.
- [21] Magovern GJ, Liebler GA, Park SB, Burkholder JA, Sakert T, Simpson KA. Twenty-five-year review of the Magovern-Cromie sutureless aortic valve. *Ann Thorac Surg* 1989; 48(3 Suppl): S33-4-60.
- [22] Scott SM, Sethi GK, Flye MW, Takaro T. The sutureless aortic valve prosthesis: experience with and technical considerations for replacement of the early model. *Ann Surg* 1976; 184(2): 174-8.
- [23] Wendt D, Thielmann M, Buck T, *et al.* First clinical experience and 1-year follow-up with the sutureless 3F-Enable aortic valve prosthesis. *Eur J Cardiothorac Surg* 2008; 33(4): 542-7.
- [24] Leyh R, Yildirim C, Buck T, Sommer S, Herold U, Jakob H. Early single-center experience with the 3F-enable aortic valve bioprosthesis. *Herz* 2006; 31(5): 423-8.
- [25] Martens S, Sadowski J, Eckstein FS. Clinical experience with the ATS 3f Enable [REGISTERED] Sutureless Bioprosthesis. *Eur J Cardiothorac Surg* 2011; 40(3): 749-55.
- [26] Sadowski J, Kapelak B, Pfitzner R, *et al.* Sutureless aortic valve prosthesis '3F/ATS Enable'--4.5 years of a single-centre experience. *Kardiol Pol* 2009; 67: 956-63.
- [27] Breitenbach I, Wimmer-Greinecker G, Bockeria LA. Sutureless aortic valve replacement with the Trilogi Aortic Valve System: multicenter experience. *J Thorac Cardiovasc Surg* 2010; 140(4): 878-84.
- [28] Shrestha M, Folliguet T, Meuris B, *et al.* Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial. *J Heart Valve Dis* 2009; 18(6): 698-702.
- [29] Shrestha M, Folliguet T, Meuris B, *et al.* Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial. *J Heart Valve Dis* 2009; 18(6): 698-702.
- [30] Nkomo VT, Gardin JM, Skelton TN, *et al.* Burden of valvular heart diseases: a population-based study. *Lancet* 2006; 368: 1005-11.
- [31] Lindroos M, Kupari M, Heikkilä J, *et al.* Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. *J Am Coll Cardiol* 1993; 21: 1220-5.
- [32] Al-Sarraf N, Thalib L, Hughes A, *et al.* Cross-clamp time is an independent predictor of mortality and morbidity in low- and high-risk cardiac patients. *Int J Surg* 2011; 9(1): 104-9.
- [33] Flameng W, Herregods MC, Hermans H, *et al.* Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes. *J Thorac Cardiovasc Surg* 2011; 142: 1453-7.
- [34] Santarpino G, Pfeiffer S, Concistré G, Grossmann I, Hinzmann M, Fischlein T. The Perceval S aortic valve has the potential of shortening surgical time: does it also result in improved outcome? *Ann Thorac Surg* 2013; 96(1): 77-81.
- [35] Phan K, Tsai Y-C, Niranjan N, Yan TD, Di Eusanio M. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg* 2014. doi: 10.3978/j.issn.2225-319X.2014.06.01
- [36] Varadarajan P, Kapoor N, Bansal RC, *et al.* Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis. *Ann Thorac Surg* 2006; 82: 2111-15.
- [37] Bouma BJ, van Den Brink RB, van der Meulen JH, *et al.* To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart* 1999; 82: 143-8.
- [38] Laborde JC, Brecker SJ, Roy D, Jahangiri M. Complications at the Time of Transcatheter Aortic Valve Implantation. *Methodist Debaque Cardiovasc J* 2012; 8(2): 38-41.
- [39] Kodali SK, Williams MR, Smith CR, *et al.* Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med*; 2012; 366: 1686-95.
- [40] Kocher AA, Laufer G, Haverich A, *et al.* One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System. *J Thorac Cardiovasc Surg* 2013; 145: 110-5.
- [41] D'Onofrio A, Messina A, Lorusso R, *et al.* Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: a propensity-matched, multicenter analysis. *J Thorac Cardiovasc Surg* 2012; 144: 1010-6.
- [42] Folliguet TA, Laborde F, Zannis K, Ghorayeb G, Haverich A, Shrestha M, Shrestha. Sutureless Perceval aortic valve replacement: results of two European centers. *Ann Thorac Surg* 2012; 93: 1483-8.



- [43] Concistrè G1, Santarpino G, Pfeiffer S, *et al.* Two alternative sutureless strategies for aortic valve replacement: a two-center experience. *Innovations (Phila)* 2013; 8: 253-7.
- [44] Santarpino G, Pfeiffer S, Jessl J, *et al.* Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: a propensity-matched analysis of 2 strategies in high-risk patients. *J Thorac Cardiovasc Surg* 2014; 147(2): 561-7.
- [45] Phan K, Tsai Y-C, Niranjana N, Yan TD, Di Eusanio M. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg* 2014. doi: 10.3978/j.issn.2225-319X.2014.06.01.
- [46] Cao C, Ang SC, Indraratna P, *et al.* Systematic review and meta-analysis of transcatheter aortic valve implantation *versus* surgical aortic valve replacement for severe aortic stenosis. *Ann Cardiothorac Surg* 2013; 2: 10-23.
- [47] Santarpino G, Pfeiffer S, Fischlein T. Sutureless aortic valve replacement to prevent patient-prosthesis mismatch in the era of valve-in-valve implantation. *J Thorac Cardiovasc Surg* 2012; 144(1): 279-80.
- [48] Santarpino G, Pfeiffer S, Schmidt J, Fischlein T. Perceval sutureless aortic valve prosthesis: easy, fast, and safe. *Innovations(phila)* 2011; 6(6): 378-81.

---

Received: October 12, 2014

Revised: October 28, 2014

Accepted: November 03, 2014