Perceval Sutureless Valve-A limbo concept or a future trial

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Abstract

Objective Aortic stenosis has traditionally been addressed with surgical aortic valve replacement with a stented prosthesis. Several technologies have emerged as an alternative treatment method for aortic valve disease. Among them, Perceval Sutureless valve has been used in clinical practice for more than a decade. The aim of this study was to evaluate the results of Perceval Sutureless valve from single centre in Indian population. Method Between April 2018 to December 2021, 30 elective patients underwent aortic valve replacement with the Perceval Sutureless valve. 19 patients had isolated AVR and 11 patients underwent AVR + Coronary artery bypass grafting (CABG) with average grafts 2.1 ± 0.8. Majority of isolated AVR, 12 of 19, were done by minimally invasive approach. Result Mean age was 67.3 ± 13.8 and mean STS score was 2.7 ± 1.5. Mean aortic cross clamp time for isolated AVR and combined procedure were 42 ± 11 and 74 ± 23 respectively. There was no in-hospital mortality. 3 patients required ventilation for > 24 hours. New onset left bundle branch block occurred in 4 patients which recovered before discharge in 2 patients. The peak and mean valve gradients were satisfactory. None of implanted valve showed para-valvular leak. Conclusion SAVR using Perceval Sutureless valve is associated with excellent results and represent a safe and effective treatment option for patients with severe AS. This valve also facilitates MI approach and reduces aortic x-clamp and cardiopulmonary bypass time.

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Abstract -

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Aortic stenosis has traditionally been addressed with surgical aortic valve replacement with a stented prosthesis. Several technologies have emerged as an alternative treatment method for aortic valve disease. Among them, Perceval Sutureless valve has been used in clinical practice for more than a decade. The aim of this study was to evaluate the results of Perceval Sutureless valve from single centre in Indian population.

Method

Between April 2018 to December 2021, 30 elective patients underwent aortic valve replacement with the Perceval Sutureless valve. 19 patients had isolated AVR and 11 patients underwent AVR + Coronary artery bypass grafting (CABG) with average grafts 2.1 ± 0.8. Majority of isolated AVR, 12 of 19, were done by minimally invasive approach.

Result

Mean age was 67.3 ± 13.8 and mean STS score was 2.7 ± 1.5. Mean aortic cross clamp time for isolated AVR and combined procedure were 42 ± 11 and 74 ± 23 respectively. There was no in-hospital mortality. 3 patients required ventilation for $>$ 24 hours. New onset left bundle branch block occurred in 4 patients which recovered before discharge in 2 patients. The peak and mean valve gradients were satisfactory. None of implanted valve showed para-valvular leak.

Conclusion

SAVR using Perceval Sutureless valve is associated with excellent results and represent a safe and effective treatment option for patients with severe AS. This valve also facilitates MI approach and reduces aortic x-clamp and cardiopulmonary bypass time.

Key Words: Aortic Stenosis, AVR, Minimally Invasive Surgery, Sutureless Valve

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1. Introduction

SAVR performed by median sternotomy has been the surgical standard of care for lesions of the aortic valve (1). Elective SAVR is associated with low morbidity, mortality and results in significant improved quality of life (2).

According to the society of thoracic surgeon (STS) database, the operative risk of SAVR has dramatically improved in the last decade, showing reduction in mortality from 4.3% to 2.6% (3).

In the past few years, the incidence of degenerative aortic valve disease has increased as a consequence of increased life expectancy (4). These patients of AS are elderly patients with severe co morbidities, leading to an increase operative risk and inherent higher morbidity and mortality risks (5).

In recent years, transcatheter aortic valve implantation (TAVI) has emerged as MI approach to treat these high risk patients. The PARTNER 1 and 2 studies have demonstrated the superiority of TAVI or medical therapy in patients deemed to be inoperable and non-inferiority of TAVI in high and intermediate risk patients when compared with SAVR (6, 7). Presently TAVI has moved to even in the low risk patients. (8) Despite improvement in design of Transcatheter valves, rate of pacemaker implantations, vascular complications and PVL are still higher with TAVI in comparison to SAVR (9).

Another inherent problem of transcatheter valve is crimping, which can lead to the damage of bio-prosthetic valve (10) and may effect long-term durability. Also, in Indian scenario, the cost of transcatheter valve is another important factor, limiting the use of TAVI in larger population (11).

This changing management for intervention on AV disease towards less invasive TAVI approach has led to the development of ways of reducing the physiological impact of SAVR. Sutureless implantation can reduce x-clamp and CPB time. It also facilitates minimally invasive aortic valve replacement (MIAVR), whereas the lack of stent and swing ring enables improved hemodynamics (12, 13). Current clinical experience demonstrates promising results for Sutureless valve technologies, such as reduced cardiac ischemia, CPB times and facilitated MI procedures. (14)

This study reports the largest single center experience of Sutureless Perceval valve along with its hemodynamic performance and the clinical outcome during early follow-up in Indian patients.

2. Material and Methods

(a) Patients

Between April 2018 to December 2021, 30 elective patients underwent AVR with the Perceval Sutureless Valve. Inclusion criteria were critical aortic valve stenosis, age > 60 years and patient opting for sutureless valve. The informed consent was in all patients. Exclusion criteria includes patient not opting for sutureless valve, ratio between Sino tubular junction to annulus > 1.3, bicuspid aortic valve, dilated ascending aorta and annulus < 18mm. Patients demographic profile and pre-operative echocardiography findings are mentioned in Table 1 and 2.

Out of 30 patients, 19 were isolated AVR and 11 patients underwent combined AVR + Coronary Artery Bypass Grafting (CABG) with average number of grafts were 2.1 ± 0.8. (Table 3)

The study was approved by the ethics committee of our hospital. Post operatively, all patients were prescribed oral anticoagulation drug for three months to maintain INR up to 2.0, later on it was replaced with either single or dual antiplatelet drugs depending upon CABG or no CABG.

(b) Surgical technique

Majority of isolated aortic valve replacements (12 of 19) were done by MI approach either right anterior thoracotomy or upper partial sternotomy.

Right anterior thoracotomy was used for right-ward aorta and α angle [?]45, whereas upper partial sternotomy was used for centric aorta. In both of these approaches, peripheral cannulation was done to establish CPB.

In combined operations like AVR+CABG, full median sternotomy was done and CPB was established by aortic and right atrial cannulation.

Aortic valve was approached through transverse aortotomy about 2cm above the conventional incision near the fat pad on ascending aorta. Diseased aortic valve was excised in toto and all calcium was removed. In

all patients myocardial protection was achieved by Del Nido Cardiopegia.

(C) Device and Implantation Technique

The Perceval bio-prosthetic sutureless valve has two components. The tissue valve which is made up of Bovine Pericardium, fixed with Glutaraldehyde and neutralized with homocystic acid. It is a double sheet design and has eyelets for guiding suture positioning. This tissue valve is mounted on self-expanding nickel – titanium alloy stent with anatomical strut design, double ring geometry and carbo film coating (Figure-1).

After the excision of diseased valve, its aortic annulus is meticulous decalcified. The appropriate size of the prosthesis is established when the valve sizer end marked with “” passes easily through the aortic annulus into the left ventricle, whereas the one marked with “” remains stable. Guiding sutures help to position the device at the exact level: 4-0 polypropylene suture (17mm needle) is placed 2 to 3 mm below the annulus, across the annulus, and exiting the aortic wall 2 to 3 mm above the annular line. This placement ensures that the bite is large enough to hold the traction applied during implantation of the device and the Perceval valve is not anchored too low in the left ventricular outflow tract (LVOT).

After the lower needle of the guiding suture has been passed through the eyelets of the device, the holder with the loaded valve is guided down to the annular level. Gentle traction is applied to the guiding sutures almost parallel to the holder, not tangled around the stent posts, while commissural stay sutures are released. Deployment is started with the screw on the tip of the implanting device, which unscrews the inflow portion of the valve. After that, the safety clip is removed, and the sheath is pulled back to deploy the outflow part of the stent. After deployment is complete, the holder is removed gently, avoiding entangling the device in the prosthesis. Accurate positioning of the valve is then reconfirmed. Post-ballooning is carried out with the size-dedicated balloon inserted into the prosthesis with the blue ring at the level of the upper edge of the leaflets. The balloon was inflated to 2-4 atm of pressure for the duration of 30 seconds depending upon valve size and annular calcification. After release the balloon is removed from the LVOT, as are the guiding and stay sutures.

Follow-up

All patients underwent transthoracic echocardiography at discharge, 6 months and 1 year post operatively. EKG was done on zero post op day and at discharge. It was repeated at 6 months and on completion of one year.

3. Results

In all 30 patients, the Perceval sutureless valve implantation was done uneventfully. The intraoperative characteristics and procedure details are mentioned in Table 3. X-clamp and CPB time for isolated aortic valve were 42 ± 11 and 54 ± 14 whereas 74 ± 23 and 101 ± 36 in combined procedures.

Intra operative valve hemodynamics were excellent with mean gradient of 13 ± 2.7 and peak gradient 21 ± 8.4 by post procedure intra operative TEE. No patient had PVL in immediate post-operative period. Pre discharge valve hemodynamics were also satisfactory and no patient had AR or PVL at discharge. 22 patients completed 1 year follow-up and 27 completed 6 months follow-up. All patient's echocardiography showed excellent valve hemodynamics and improved LV function. (Table 5).

Cardiac Rhythm and Pacemaker

Pre-operatively all patients were in normal sinus rhythm except one patient who had right bundle branch block (RBBB). In immediate post-operative period 22 patients came in NSR, 4 patients developed left bundle branch block (LBBB), in two patients it reverted to narrow QRS in ICU whereas in two patients LBBB persisted in follow-up. The patient having RBBB pre-operatively, developed complete heart block in immediate post-operative period which recovered on 6^{th}post-operative day, but RBBB persisted.

Post-operative course and follow-up

Average ICU stay was 2.4 ± 1.1 and hospital stay was 6.7 ± 1.2 in isolated AV replacement. In MI SAVR approach, shorter hospital and ICU stay was observed. Patient requiring combined procedure had longer hospital and ICU stay 10.9 ± 2.4 & 3.9 ± 1.6 respectively. Three patient required ventilation for > 24 hours and all of these were AVR + CABG patients. New onset atrial fibrillation was noticed in 4 patients and 3 patients had rising serum creatinine and they all responded to medical management. (Table 4)

There were no in-hospital mortality. All patients were in good clinical condition and maintained NYHA class I during entire follow-up period. There was no event observed related to implanted valve dysfunction.

4. Discussion

Multiple non-randomized studies, meta-analyses and registry have shown that Sutureless rapid deployment aortic tissue valve is safe and effective alternate to conventional SAVR and associated with improved clinical outcomes.

In majority of published studies on Perceval valve, the average age of patient was > 75 years, where as in our study the average age was 67.3 ± 13.8 years. Major advantage of Perceval sutureless valve was observed in intermediate and high risk group (15,16) whereas in our study all patients were in low or intermediate risk group with average STS score of 2.71 ± 1.54.

Various studies have demonstrated that duration of aortic x-clamp and CPB are independent predictors of survival after valve replacement and combined valve operation with CABG (17). In our study the average x-clamp time of 42 ± 11 minutes in isolated aortic valve and 74 ± 23 minutes in combined procedures. The CPB time was 54±14 minutes in isolated AVR and 101±36 in combined procedures. We observed 18% reduction in x-clamp time and 22% reduction in CPB time when we compared it with standard bio-prosthetic sutured valve by same surgeon. In CABG + AVR patient all distal anastomosis were done on pump beating heart which further reduced the x-clamp time.

Recently published Persist AVR trial has shown 30% reduction in x-clamp time and 20-25% reduction in CPB time by using Perceval in comparison of standard AVR in isolated AVR surgery (18).

In our experience we could perform MIAVR in 12 out of 19 isolated AVR patients. In SURD-IR registry it was observed that less invasive approach was used in two third of study patients and in 50% high risk patients, with good intermediate results in all risk categories (19).

In our study also we did not find any significant difference in x-clamp and CPB time between sternotomy AVR and MIAVR with use of Perceval, but the patient number are less to reach to a real conclusion.

There was no PVL in any of our patients. The vast majority of published reports shown very low rate of moderate to severe PVL (21) with proper decalcification, sizing and valve positioning, PVL is comparable with standard SAVR (14).

The rate of permanent pacemaker implantation has been a bit of concern with the Perceval. The majority of the literature reports of PPI between 6% and 9%. However some studies have reported rate as high as 23% (22). In order to avoid PPI, the key points are (i) proper decalcification of the annulus, (ii) correct sizing and certainly avoid over sizing, (iii) proper placement of guiding sutures, (iv) Adjusting balloon inflation between 2to 4mmHg (15), by using these modified guidelines we have noticed significant improved in rate of PPI.

4 patients developed new onset LBBB in immediate post-operative period. In two patients, it was recovered to normal EKG in ICU where as in 2 patients it was persisted in follow-up. One patient with preexisting RBBB had complete heart block in immediate post-operative period requiring temporary pacing but it was recovered on 6thpost-operative day. 2 patients developed new onset LBBB post implant which was persistent during follow-up. We had 2.4 ± 1.1 and 3.9 ± 1.6 days ICU stay and 6.7 ± 1.2 and 10.9 ± 2.4 days hospital stay in isolated AVR and combined procedure respectively. In these small number of patients we did not find much difference in ICU and hospital stay when compare to standard sutured aortic valve. Multiple studies have reported decrease in ICU stay and blood transfusions with use of Perceval sutureless valve in isolated

AVR (23). Marco Solinas et al reported reduction of ICU and hospital stay by adding Perceval valve and right anterior thoracotomy(20). In an international prospective registry statistically significant difference was noticed in ICU and hospital stay by using sutureless valve and MIAVR approach (24).

Rate of intraoperative stroke range from 0 to 5% for the Perceval and 2.5 to 5% for TAVI (26, 27). Data from Partner II trial and German registry indicates that the incidence of PVL after TAVI is significantly higher when compared with Sutureless aortic valve (28). SURD-IR registry has shown that in low risk patients, the mortality rate was lower in sutureless valve then that recorded in the NOTION trial 1.55 vs 2.1% (29). The most important piece of data concerns to patients deemed at very high risk, a patient population comparable to that included in the PARTNER trial cohort B (6). In this trial in hospital mortality was 2 fold higher than that observed in SURD-IR registry for sutureless valve (2.6% vs 5%) (19).

In two female patients with small aortic annulus, small size Perceval valve was implanted. Both patient showed excellent valve hemodynamics in post-operative period with no patient prosthesis mismatch.

In our limited experience, morbidity was low and we did not have any mortality even in follow-up. SURD-IR registry has compared the morbidity and mortality in patients undergoing sutureless rapid deployment valve and they found a extremely satisfactory results even in high risk (EURO score $>$ 10 - 20%) and very high risk (EURO score $>$ 20%) patients (19).

We noticed stable hemodynamics and satisfactory gradient in all our patients at 6 months and 1 year follow-up and none of our patient developed central or PVL.

The health economics of Perceval sutureless valve is highly dependent on the healthcare system, however the ability to facilitate MI surgery will enhance its cost effectiveness by reducing ICU stay, hospital stay and blood usage. Especially in high risk patients using sutureless valve instead of TAVI will further reduce the prosthesis cost (11).

5. Conclusion

AS is a highly prevalent disease and its incidence is expected to increase further, due to ageing population in India. The development of MI approach has allowed surgeons to treat patients with multiple co-morbidities. Perceval sutureless valve also enhances the feasibility of MIAVR by quick and reproducible valve implantation along with decalcification of the aortic annulus. In our limited experience, the Perceval sutureless valve is most useful in MIAVR, combined procedure and in high risk patient's sensitive to x-clamp and CPB time. Rate of Permanent Pacemaker implantation has been reduced significantly by technical changes and it will further reduces with introduction of new design Perceval sutureless valve. This valve also proves to be good alternate to TAVI in cost reduction. Satisfactory mid-term and long-term durability has been shown in various studies (18).

With increase in the number of Perceval sutureless valve implantation in India, the experience of other surgeons and center will also contribute to our findings and feasibility of its wide use.

Number of Patients Male Female	30 19 11
Age (Mean ± SD)	67.3 ± 13.8
STS Score (Mean ± SD)	2.70 ± 1.54
NYHA class II III	07 23
Risk Factors HT DM COPD Previous MI Unstable Angina	19 12 06 09 03
Pre-Operative EKG NSR RBBB	29 01

Table -1 Patient Demographics

Severe AS	27
AS + AR	03
Peak Gradient	74 ± 12

Mean Gradient	44.5 ± 19.2
Valve Orifice Area	0.51 ± 0.16
LVEF (%) > 50 35-50 < 35	07 20 03
Valve Annulus Diameter < 19 mm 19 – 21 22 – 23 24 – 25 26 – 27	02 05 12 07 04

Table -2 Preoperative 2D Echocardiography

Isolated AVR MIAVR Upper Sternotomy Right anterior thoracotomy Mid sternotomy AVR	19 05 07 07
Combined Procedure CABG (Average Graft)	11 (2.1 ± 0.8)
X- clamp Time Isolated AVR Combined	48 ± 11 81 ± 23
CPB Time Isolated AVR Combined	63 ± 14 106 ± 36
Perceval Valve Size S M L XL	07 13 06 04

Table - 3 Intra operative characteristics

1. Ventilation > 24 Hours	3
2. New onset AF	4
3. Rising serum creatinine > 2mg/dl	3
4. Post-operative EKG NSR New onset LBBB CHB	25 04 01
5. ICU stay (Days) Isolated AVR Combined Procedure	2.4 ± 1.1 3.9 ± 1.6
6. Hospital stay (Days) Isolated AVR Combined Procedure	6.7 ± 1.2 10.9 ± 2.4
7. In Hospital Mortality	Nil

Table − 4 Post-operative course

	At Discharge (n = 30)	At 6 months (n = 27)	After 1 year (n = 22)
Peak Gradient	22 ± 9.7	18 ± 4.8	19 ± 5.6
Mean Gradient	11 ± 2.9	10 ± 2.6	11 ± 1.8
EOA	1.5 ± 0.7	1.6 ± 0.4	1.5 ± 0.9
PVL	Nil	Nil	Nil
AR	Nil	Nil	Nil
EF (%) > 50 35 – 50 < 35	07 21 02	08 17 02	09 13 00

Table − 5 Post-operative and follow-up Echocardiography

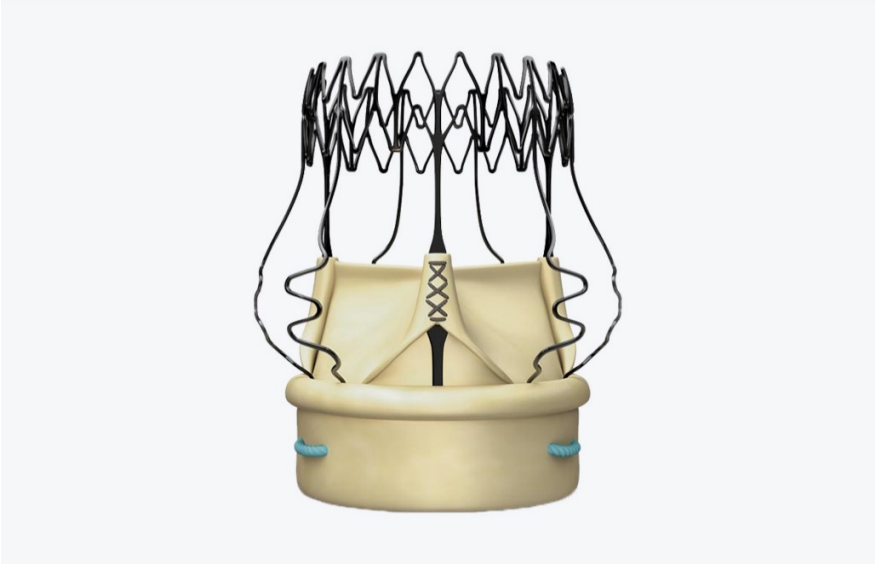

Figure - 1-Perceval Sutureless Aortic Valve Prosthesis

References:

1. Rosu, C., Soltesz, E.G. Selection of valve prostheses. Semin Thorac Cardiovasc Surg. 2015; 27: 152–158.

2. Carabello, B.A. Is it ever too late to operate on the patient with valvular heart disease? J Am Coll Cardiol. 2004; 44: 376–383.

3. Shrestha M, Folliguet T, Meuris B, et al. Sutureless Perceval S aortic valve replacement: A multicenter, prospective pilot trial. J Heart Valve Dis 2009; 18:698-702.

4. C.N. Manjunath, P. Srinivas, K.S. Ravindranath et al. Incidence and patterns of valvular heart disease in a tertiary care high-volume cardiac center: A single center experience, Indian Heart J. 2014 May; 66(3): 320–326.

5. Mohr FW., Holzhey D., Möllmann H et al. The German Aortic Valve Registry: 1-year results from 13,680 patients with aortic valve disease. Eur J Cardiothorac Surg 2014; 46: 808–816.

6. Leon MB, Smith CR, Mack M, et al. Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. N Engl J Med 2010; 363:1597-607.

7. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med 2016; 374:1609-20.

8. Gilbert H.L. Tang, Subodh Verma, Deepak L. Bhatt Transcatheter Aortic Valve Replacement in Low-Risk patients – A New Era in the Treatment of Aortic Stenosis, Circulation. 2019; 140: 801-803.

9. Kunal V. Patel, Wally Omar, Pedro Engel Gonzalez et al, Expansion of TAVR into Low-Risk Patients and Who Consider for SAVR, Cardiol Ther 2020; 9: 377 – 394.

10.S. Hamed Alavi, Elliott M. Groves, Arash Kheradvar, The Effects of Transcatheter Valve Crimping on Pericardial Leaflets Ann Thorac Surg 2014;97:1260–6.

11. Bana A; TAVR—present, future, and challenges in developing countries Indian Journal of Thoracic and Cardiovascular Surgery volume 2019; 35, 473–484.

12. Pollari, F., Santarpino, G., Dell'Aquila, A.M. Better short-term outcome by using sutureless valves: a propensity-matched score analysis. Ann Thorac Surg. 2014; 98: 611–616.

13. Santarpino, G., Pfeiffer, S., Concistré, G. et al. The Perceval S aortic valve has the potential of shortening surgical time: does it also result in improved outcome? Ann Thorac Surg. 2013; 96: 77–81.

14. Meco M., Montisci A., Miceli A. et al. Sutureless Perceval aortic valve versus conventional stented bioprostheses: meta-analysis of postoperative and midterm results in isolated aortic valve replacement. J Am Heart Assoc. 2018; 7: 1-9.

15. Ferdinand Vogt, Marco Moscarelli, Anna Nicoletti et al. Sutureless aortic valve and pacemaker rate : from surgical tricks to clinical outcomes Ann Thorac Surg. 2019 Jul;108 (1) :99-105.

16. Delphine Szecel, Roxanne Eurlings, Filip Rega et al. Perceval sutureless aortic valve implantation: mid-term outcomes. Ann Thorac Surg. 2021 Apr;111(4):1331-1337.

17. Ranucci M, Frigiola A, Menicanti L, Castelvecchio A et al. Aortic cross-clamp time, new prostheses, and outcome in aortic valve replacement. J. Heart Valve Dis 2012;21:732–9.

18.Theodor Fischlein, Thierry Folliguet, Bart Meuris et al. Sutureless versus conventional bioprostheses for aortic valve replacement in severe symptomatic aortic valve stenosis. J Thorac Cardiovasc Surg. 2021 Mar; 161(3):920-932.

19. Giuseppe Santarpino, Paolo Berretta, Theodor Fischlein et al. Operative outcome of patient at low, intermediate, high and 'very high' surgical risk undergoing isolated aortic valve replacement with sutureless and rapid deployment prostheses: results of the SURD-IR registry. Eur J Cardiothorac Surg 2019 Jul 1;56(1):38-43.

20. Marco Solinas, Giacomo Bianchi, Francesca Chiaramonti et al, Right anterior mini-thoracotomy and sutureless valves: the perfect marriage. Ann Cardiothorac Surg. 2020 Jul;9 (4):305-313.

21. Miceli A, Santarpino G, Pfeiffer S et al. Minimally invasive aortic valve replacement with Perceval S sutureless valve: Early outcomes and one-year survival from two European centers. J Thorac Cardiovasc Surg 2014;148: 2838-43.

22. Bouhout I, Mazine A, Rivard L et al. Conduction Disorders After Sutureless Aortic Valve Replacement. Ann Thorac Surg 2017;103:1254-60.

23. Dalén M, Biancari F, Rubino AS et al. Aortic valve replacement through full sternotomy with a stented bioprosthesis versus minimally invasive sternotomy with a sutureless bioprosthesis. Eur J Cardiothorac Surg 2016;49:220-7.

24. Paolo Berretta, Martin Andreas, Thierry P Carrel et al. Minimally invasive aortic valve replacement with sutureless and rapid deployment valve: a report from an international registry (Sutureless and Rapid Deployment International Registry). Eur J Cardiothorac Surg 2019 Oct 1;56(4):793-799.

25. Siontis GC, Praz F, Pilgrim T et al. Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of severe aortic stenosis: a meta-analysis of randomized trials. Eur Heart J 2016;37:3503-12. 10.1093.

26. D'Onofrio A, Salizzoni S, Rubino AS et al. The rise of new technologies for aortic valve stenosis: A comparison of sutureless and transcatheter aortic valve implantation. J Thorac Cardiovasc Surg 2016;152:99-109.

27. 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;147:561-7.

28. Mattia Glauber, MD, Lorenzo Di Bacco, MD, Jose Cuenca, MD et al. Minimally Invasive Aortic Valve Replacement with Sutureless Valve : Results From an International Registry. Innovations Volume: 15 issue: 2, page(s): 120-130.

29. Thyregod HG, Steinbru¨chel DA, Ihlemann N et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the allcomers NOTION randomized clinical trial. J Am Coll Cardiol 2015;65: 2184–94.