



## Original Article

# Sutureless Perceval versus Bioprosthetic Aortic Valve, Single Center Experience

Mohamed Abdel Hafez Fouly

Cardiothoracic Surgery Department, Faculty of Medicine, Cairo University, Giza, Egypt

### Abstract

**Background:** High-risk patients are currently presenting for aortic valve replacement (AVR). Sutureless valves may decrease the operative risk in those patients. The objective of this study was to compare the short-term and one-year follow-up results of the sutureless Perceval valve versus bioprosthetic aortic valve.

**Methods:** The data of patients who underwent elective AVR with bioprosthesis were collected From March 2012 to March 2017. The patients were divided into two groups; group 1 included the patients who had a sutureless aortic valve (Perceval) (n= 25; 3.57% of total AVR patients), and group 2 included patients who had conventional bioprosthesis (n= 50; 7.1% of total AVR patients).

**Results:** The median age of patients in group 1 was 67 years (25th- 75th percentiles; 64-71), and in group 2 was 66 years (25th- 75th percentiles: 63 to 69). There is no significant difference in the patients' comorbidities between the two groups. The median duration of the ischemic time was significantly lower in group 1 (33 (25th-75th percentiles: 32- 35) vs. 60.5 (58- 66), respectively;  $p < 0.001$ ). Perceval valve was used more commonly in patients who had minimally invasive AVR (n= 21 (84%) in group 1 vs. 11 (22%) in group 2;  $p < 0.001$ ). Postoperative complications were comparable between both groups. The early paravalvular leak was non-significantly higher in group 1 (12% vs. 2%;  $p = 0.105$ ). The mean postoperative gradient was lower in group 1 (7 (7-9) vs. 10 (8-12) mmHg;  $p < 0.001$ ). The changes in valvular gradient were not significantly different between both groups ( $p = 0.5$ ). The hospital stay was lower in patients received Perceval valve (Coefficient: -1.3; 95% CI: -2.3- -0.29;  $p = 0.012$ )

**Conclusion:** Sutureless aortic valve (Perceval) is a new surgical technique for AVR, with potential advantages of reducing cross-clamp time and a subsequent reduction in myocardial ischemia, duration of cardiopulmonary bypass, and maintaining satisfactory hemodynamic outcomes through reducing patient prosthesis mismatch. All these advantages could help in decreasing postoperative hospital stay.

### Introduction

Patients presented for surgery for the degenerative aortic valve are older and have multiple co-morbidities with intermediate or high surgical risk profile. Minimally invasive approaches

and sutureless valves have been developed to decrease the operative time and surgical risk in those patients [1 – 3]. Sutureless valves offer satisfactory hemodynamics and reduce patients' prosthesis mismatch (PPM), in addition to shorter

### KEYWORDS

Sutureless aortic valve;  
Aortic bioprosthesis;  
Calcific aortic stenosis

### Article History

Submitted: 30 Dec 2019  
Revised: 20 Jan 2019  
Accepted: 21 Jan 2020  
Published: 1 Apr 2020



cardiopulmonary bypass and ischemic time [4 – 6]. For aortic valve prostheses, PPM is considered to be severe when the indexed effective orifice area (EOA) is less than 0.65 cm<sup>2</sup>/m<sup>2</sup> [7, 8].

The majority of evidence regarding sutureless aortic valve replacement was observed from limited randomized trials [3]. The International Valvular Surgery Study Group (IVSSG), which is the largest international collaborative group to investigate this technology, has formulated sutureless projects in the year 2014 to study the cost-effectiveness of this valve [9].

There are three commercially available types of sutureless aortic prostheses, including 3F Enable (Medtronic, Minneapolis, USA), Perceval S (Sorin, Saluggia, Italy), and Intuity Elite (Edward Lifesciences, Irvine, USA) [4]. The 3F Enable, together with Perceval S sutureless prosthesis, have nitinol metal frame, which positions the valve with no sutures required in the case of Perceval S valves or one stitch for Enable 3F valves [5]. The Intuity valve prosthesis works by a different mechanism that is based on a balloon-expandable stainless steel frame, which is implanted with the aid of a balloon-based catheter delivery system that expands the frame within the aortic annular position [10].

The superiority of the Perceval valve over the stented bioprosthetic valves is the subject of ongoing researches. The objective of this study was to compare the sutureless Perceval aortic valve to the conventional stented bioprosthetic aortic valve.

## Patients and Methods:

### Study design and patients

This research is a retrospective cohort study that was conducted in King Faisal Specialized Hospital over five years, starting from March 2012 till March 2017. The data of patients who underwent elective aortic valve replacement (AVR) with bioprosthetic valves were collected. The patients were divided into two groups; group 1 included the patients who had a sutureless aortic valve (Perceval) (n= 25; 3.57% of total AVR patients), and group 2 included patients who had conventional tissue bioprosthesis (n= 50; 7.1% of

total AVR patients). Patients were assigned to receive the Perceval valve according to the presence of associated comorbidities, which increase the operative risk such as renal failure or small aortic annulus.

The data collected included age, sex, and comorbidities, such as hypertension, diabetes, renal failure, and previous stroke. Operative data included the surgical approach, the ischemic, and total bypass times. Postoperative data included postoperative stroke, patient prosthesis mismatch, heart block, early and late paravalvular leak, structural valve deterioration (SVD), hospital stay, and follow-up echocardiography at an interval of 6 months and 1 year postoperatively.

Data collection was approved by the Institutional Review Board at King Faisal Specialized and Research Center, and the patient's consent to participate in research was obtained during procedure consent.

### Inclusion criteria

We included patients who had severe symptomatic aortic stenosis and aged from 60-80 years old with preserved contractility (ejection fraction  $\geq$ 50). All operations were performed either through a full or mini sternotomy.

### Exclusion criteria

We excluded patients who had a preoperative peripheral vascular disease or end-organ failure and patients who had an emergency AVR or concomitant procedures. Additionally, we excluded patients who had aortic root dilatation or AVR through anterolateral thoracotomy.

### Surgical procedures

The patients were cannulated either through the aorta and right atrium or femoro-femoral cannulation. After cross-clamping and arresting the heart with antegrade cold blood cardioplegia, the aortotomy was done in transverse fashion 1 cm above the sinotubular junction or 3.5 cm measured from the outside of the aorta from the aortic annulus. The level of the preaortic fat pad can be used as a landmark for the aortotomy. Three pledged stay sutures were used for better exposure. The leaflets were removed, while

Table 1: Preoperative and operative patients' data: (Continuous data are presented as median and (25th and 75th percentiles) and categorical variable as number and percentage)

|                      | Group 1 (n= 25) | Group 2 (n=50) | p-value |
|----------------------|-----------------|----------------|---------|
| Age (years)          | 67 (64- 71)     | 66(63-69)      | 0.604   |
| Male                 | 20 (80%)        | 30(60%)        | 0.083   |
| Diabetes mellitus    | 18 (72%)        | 40(80%)        | 0.435   |
| Hypertension         | 17 (68%)        | 37(74%)        | 0.585   |
| Stroke               | 2 (8%)          | 3(6%)          | >0.99   |
| Renal failure        | 1 (4%)          | 4(8%)          | 0.659   |
| Ischemic time (min)  | 33 (32- 35)     | 60.5(58-66)    | < 0.001 |
| CPB time (min)       | 61(59-62)       | 92 (88- 97)    | < 0.001 |
| Minimal invasive AVR | 21 (84%)        | 11(22%)        | < 0.001 |

AVR: aortic valve replacement; CPB: cardiopulmonary bypass

complete decalcification was not required. The annulus was sized with a provided valve sizer then three double-needle polypropylene sutures were passed through the aortic annulus at the midpoint between every 2 commissures [11, 12]. Each suture was passed through one of the eyelets of the prosthesis inflow ring. The valve was placed into the aortic annulus with the correct positioning of the valve with respect to rotational and axial axes [13]. The inflow section was released by rotating the knob in a clockwise direction. The outflow section was released by pulling the safety clip and then withdrawing the sheath [13]. Complete contact between the inflow ring and the annulus must be assured visually. Patency of coronary ostia and leaflet coaptation were confirmed. Finally, the guiding sutures are removed, and the aortotomy was closed, taking care that the sutures were not entrapped within the struts [14].

### Minimal invasive AVR

The minimal invasive AVR was done through a partial J sternotomy at the third to fifth intercostal space or a V-shaped approach at the level of the second or third intercostal space using the sternotomy saw [15, 16].

### Statistical Analysis

Continuous variables were presented as the 50th (median), 25th and 75th percentiles and were compared using the Wilcoxon rank-sum test. Binary variables were presented as number and percent and were compared using Chi-square or

Fisher exact test when the expected frequency is less than 5. Univariable regression analysis was used to test the relation between preoperative and operative variables and the length of hospital stay. The random-effect model was used to test the effect on valve type on the changes of the postoperative mean pressure gradient. A p-value of less than 0.05 was considered statistically significant. All analyses were performed using Stata 14.2 (Stata Corp- College Station- Texas-USA).

### Results

The median age of patients in group 1 was 67 years (25th- 75th percentiles; 64-71), and in group 2 was 66 years (25th- 75th percentiles: 63 to 69). There was no significant difference in the patients' comorbidities between the two groups (Table 1). The duration of the ischemic time was significantly lower in group 1 ( $P < 0.001$ ). (Table 1)

Minimal invasive access was used more in patients who received Perceval valves (n= 21 (84%) in group 1 vs. 11 (22%) in group 2;  $p < 0.001$ ) (Table 2). There was no significant difference between both groups as regards the early paravalvular leak (Table 2). Valve-related re-exploration was higher in group 1 (4% vs. 2%), but did not reach a significant level ( $p > 0.99$ ). Postoperative complications are presented in Table 2.

The median postoperative gradient on the replaced valve was statistically significantly lower

Table 2: Postoperative outcomes: (Continuous data are presented as median and (25th and 75th percentiles) and categorical variable as number and percentage)

|                              | Group 1 (n=25) | Group 2 (n=50) | p-value |
|------------------------------|----------------|----------------|---------|
| Early PVL                    | 3 (12%)        | 1(2%)          | 0.105   |
| Patients prosthesis mismatch | 0              | 4 (8%)         | 0.294   |
| HB requiring PM              | 0              | 4 (8%)         | 0.294   |
| Stroke                       | 0              | 3 (6%)         | 0.546   |
| Valve related re-exploration | 1 (4%)         | 1(4%)          | >0.99   |
| Re-exploration for bleeding  | 2(8%)          | 4 (8%)         | >0.99   |
| Late PVL                     | 2 (8%)         | 0              | 0.108   |
| SVD                          | 0              | 2 (4%)         | 0.550   |
| Mean postoperative PG (mmHg) | 7 (7-9)        | 10 (8- 12)     | < 0.001 |
| Hospital stay (days)         | 7 (6-8)        | 8 (7-9)        | < 0.001 |

HB: heart block; PG: pressure gradient; PM: pacemaker; PVL: paravalvular leak; SVD: structural valve deterioration

in group 1 compared to group 2 (7 (7-9) vs. 10 (8-12) mmHg;  $p < 0.001$ ). (Table 2) There was no statistically significant difference in the gradient between groups at follow-up. (Figure 1)

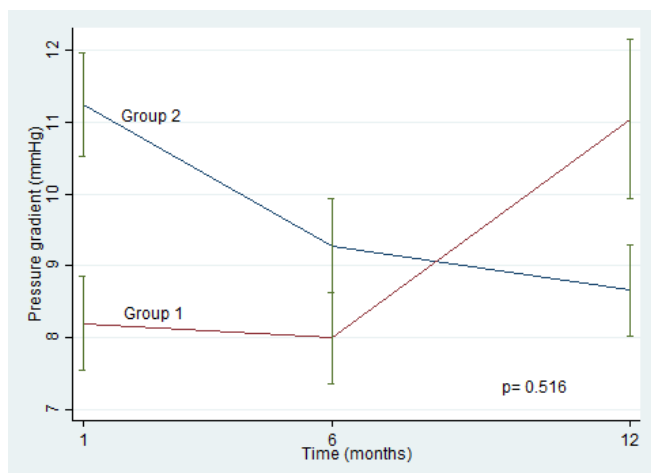


Figure 1: The mean transvalvular pressure gradient of both groups' early post-operative and at 6 months and one-year follow-up.

The hospital stay period was lower in group 1 (7 vs. 8 days,  $P < 0.001$ ) (Table 2). Factors affecting hospital stay are presented in Table 3, which include the bypass and ischemic time, the surgical approach, and the type of valve used.

## Discussion

We found that minimally invasive aortic valve procedures using the Perceval sutureless valve either through a full or mini-sternotomy approach were safe procedures and associated with a comparable complication rate to the bioprosthetic

valves despite the increased risk profile and advanced age of our patients. Moreover, the short cross-clamp and bypass times have confirmed the safety and feasibility of this valve type. As an alternative to bioprosthetic valve, the Perceval sutureless valve avoids passing the stitches through the annulus and knotting of the sutures to minimize the surgical trauma of the aortic annulus and, consequently, reducing both the ischemic time and bypass time, and this encouraged the surgeons in our center to do more minimally invasive cases with Perceval valve.

Several trials have demonstrated excellent clinical and hemodynamic outcomes for patients undergoing AVR with the Perceval valves [17 – 19]. In a study of 32 high-risk patients, Flameng and colleagues implanted Perceval valves within 20 minutes of aortic cross-clamping and reported no operative mortality and excellent clinical and hemodynamic outcomes [20]. In a study done by Folliguet and colleagues presenting the outcomes of 208 patients undergoing AVR, the mean cross-clamp time for isolated AVR was 33 minutes [17]. Santarpino and colleagues confirmed these results in 51 patients who had undergone a J-shaped mini sternotomy [18]. In contrast, Shrestha and colleagues described the outcomes of 35 patients who had undergone mini sternotomy and concluded that the Perceval valve is a technically more comfortable alternative, especially in small and calcified aortic roots [19].

Table 3: Univariable regression analysis for preoperative and operative factors affecting the length of hospital stay:

| Variables                  | Coefficient and 95% CI   | p-value |
|----------------------------|--------------------------|---------|
| Age                        | -0.00074 (-0.063- 0.062) | 0.981   |
| Gender                     | -0.5 (-1.55- 0.55)       | 0.344   |
| Diabetes mellitus          | -0.39 (-1.58- 0.79)      | 0.508   |
| Hypertension               | 0.81 (-0.28- 1.9)        | 0.143   |
| Preoperative stroke        | 0.74 (-1.24- 2.72)       | 0.457   |
| Preoperative renal failure | 1.17 (-0.8- 3.14)        | 0.240   |
| mAVR                       | -1.49 (-2.4- -0.55)      | 0.002   |
| Ischemic time              | 0.056 (0.025- 0.086)     | 0.001   |
| CPB time                   | 0.046 (0.019- 0.073)     | 0.001   |
| Valve type                 | -1.3 (-2.3- -0.29)       | 0.012   |

CI: confidence interval; CPB: cardiopulmonary bypass; mAVR: minimal invasive aortic valve replacement

We did not report heart block in the Perceval group compared to 8% in the bioprosthesis group; this is related to the fact of avoiding extensive decalcification of the annulus for implanting the Perceval valve [21]. The above-mentioned factor of avoiding heavily annular decalcification help in the reduction of the rate of post-operative stroke in the Perceval group, and this goes with what was mentioned in the literature by Phan and colleagues who found that pooled stroke incidences postoperatively appeared to be comparable to conventional AVR [22]. The current evidence demonstrates acceptable rates of neurological events for sutureless valves [3].

Excellent hemodynamic performance detected by the statistically significant low mean pressure gradient on the Perceval valve was the same demonstrated by François Laborde and colleagues where a reduction in the mean gradient and peak pressure gradients after using Perceval valve was observed to be an average of 10.2 and 19.3 mmHg postoperatively [23]. Additionally, this was confirmed by Sadowski and coworkers who reported maximal and mean gradients of 11.6 and 6.8 mmHg over Perceval valve, respectively [24]. All of these advantages of Perceval valve lead to a significant reduction in hospital stay period in the Perceval group with its economic effect on the decline of the medical service cost, and it was confirmed in another study [25].

Despite these excellent results, postoperative leak was high in the Perceval group with subsequent increase in the rate of valve-related re-exploration especially in the early years of the study as it was a new technique for us with difficult positioning of Perceval valve resulting in paravalvular leak and it disappeared in the late years of the study after attaining a good training level for the surgeons. This was proved by Phan and colleagues in their research where the incidence of valve dislocation with the paravalvular leak was 2.3%, and this complication might be a function of the learning curve involved in this innovative new surgical technique, and it is possible that paravalvular leak could be reduced with experience [22]. A rare complication was observed one year later in the Perceval group after surgery, which was a paravalvular leak in association with a high mean gradient in 2 cases (8%). This may be caused by stent fatigue later on, and this was reported in the literature [26]. Heart block and patients' prosthesis mismatch were more common with the bioprosthetic valves [19, 27].

D'Onofrio and associates performed a multicenter analysis of 38 sutureless surgery and 566 transcatheter aortic valve implantation (TAVI) procedures and showed that there was non-significant lower aortic regurgitation, pacemaker implantations and renal replacement therapy in the Perceval group [28]. Another study was done

by Santarpino, and colleagues expressed higher paravalvular leak in the TAVI group compared with the Perceval group [13]. Muneretto and colleagues compared 53 patients with a sutureless valve to 55 patients who underwent TAVI procedure and concluded that TAVI was associated with a higher rate of pacemaker implantations (25.5% vs. 2%) and local peripheral vascular complications in the femoral artery (14.5% vs. 0%) [14].

### Study limitations

The study is limited by the small number of patients; however, this is a report of our initial experience of using the sutureless aortic valve. The small patient's number limited the multivariable analysis to identify independent predictors of the outcome. The study is observational retrospective research and several risk factors may have affected the outcome and were unequally distributed between both groups. Longer follow-up is required to compare the mean gradient across the valve and structural valve dysfunction in both groups.

### Conclusion

Sutureless aortic valve (Perceval) is a new surgical technique for AVR, with potential advantages of reducing cross-clamp time and a subsequent reduction in myocardial ischemia and duration of cardiopulmonary bypass, and maintaining satisfactory hemodynamic outcomes through reducing patient prosthesis mismatch. All these advantages could help in decreasing postoperative hospital stay. A learning curve involved in this innovative new surgical technique is required to be attained by surgeons with gaining good experience to reduce its adverse events.

**Conflict of interest:** Authors declare no conflict of interest.

### References

1. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. [Burden of valvular heart diseases: a population-based study](#). *Lancet*. 2006; 368: 1005-11.
2. Vahanian A, Otto CM. [Risk stratification of patients with aortic stenosis](#). *Eur Heart J* 2010; 31: 416-23.
3. Brown JM, O'Brien SM, Wu C, Sikora JAH, Griffith BP, Gammie JS. [Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database](#). *J Thorac Cardiovasc Surg* 2009; 137: 82-90.
4. Phan K, Xie A, Di Eusanio M, Yan TD. [A meta-analysis of minimally invasive versus conventional sternotomy for aortic valve replacement](#). *Ann Thorac Surg* 2014; 98: 1499-511.
5. 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.
6. Rubino AS, Santarpino G, De Praetere H, et al. [Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: Results of a multicenter study](#). *J Thorac Cardiovasc Surg*. 2014; 148: 865-71.
7. Pibarot P, Dumesnil JG. [The Relevance of Prosthesis-patient Mismatch After Aortic Valve Replacement](#). *Nat Clin Pract Cardiovasc Med*. 2008; 5(12): 764-765.
8. Kapadia SR, Tuzcu EM, Makkar RR, et al. [Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy](#). *Circulation*. 2014; 130: 1483-92.
9. Shrestha M, Folliguet TA, Pfeiffer S, et al. [Aortic valve replacement and concomitant procedures with the Perceval valve: results of European trials](#). *Ann Thorac Surg* 2014; 98: 1294-300.
10. Phan K, Tsai YC, Niranjan N, et al. [Sutureless aortic valve replacement: a systematic review and meta-analysis](#). *Ann Cardiothorac Surg* 2015; 4: 100-11.
11. Pollari F, Santarpino G, Pfeiffer S, Fischlein T. [Double mitro-aortic valve replacement in a high-risk patient: the sutureless way](#). *G Ital Cardiol*. 2014; 15: 128-9.
12. 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* 2015.
13. 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.
  14. Muneretto C, Bisleri G, Moggi A, et al. Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement. *Interact Cardiovasc Thorac Surg* 2015; 20: 90-5.
  15. Lim JY, Deo SV, Altarabsheh SE, et al. Conventional versus minimally invasive aortic valve replacement: pooled analysis of propensity-matched data. *J Card Surg* 2015; 30:125-34.
  16. Phan K, Zhou JJ, Niranjana N, Di Eusanio M, Yan TD. Minimally invasive reoperative aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg* 2015; 4: 15-25.
  17. Folliguet TA, Laborde F, Zannis K, Ghorayeb G, Haverich A, Shrestha M. Sutureless Perceval aortic valve replacement: results of two European centers. *Ann Thorac Surg*. 2012; 93 (5): 1483-1488.
  18. Santarpino G, Pfeiffer S, Schmidt J, Concistrè G, Fischlein T. Sutureless aortic valve replacement: first-year single center experience. *Ann Thorac Surg*. 2012; 94 (2) 504-509.
  19. Shrestha M, Timm R, Höffeler K, et al. Minimally invasive aortic valve replacement with self-anchoring Perceval valve *J Heart Valve Dis*. 2013; 22 (2): 230-235.
  20. 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 (6): 1453-1457.
  21. Matthews IG, Fazal IA, Bates MGD, Turley A. In patients undergoing aortic valve replacement, what factors predict the requirement for permanent pacemaker implantation? *Interact CardioVasc Thorac Surg*. 2011; 12: 475 –9.
  22. Phan K, Tsai YC, Niranjana N, et al. Sutureless aortic valve replacement: a systematic review and meta-analysis. *Ann Cardiothorac Surg*. 2015; 4(2): 100-111.
  23. Laborde F, Fischlein T, Hakim-Meibodi K, et al. Clinical and haemodynamic outcomes in 658 patients receiving the Perceval sutureless aortic valve: early results from a prospective European multicentre study (the Cavalier Trial). *European Journal of Cardio-Thoracic Surgery*. 2016; 49 (3): 978–986.
  24. Sadowski J, Kapelak B, Pfitzner R, Bartuś K. Original article Sutureless aortic valve bioprosthesis '3F/ATS Enable'—4.5 years of a single-centre experience. *Kardiologia Pol* 2009; 67: 956-63.
  25. Pradelli L, Zaniolo O. Perceval Sutureless valves in isolated and concomitant AVR procedures: an economic model shows overall decrease of costs for isolated or combined operations. *Farmeconomia. Health Economics and Therapeutic Pathways*. 2012; 13 (4): 159-174.
  26. Fleissner F, Molitoris U, Shrestha M, Martens A. Stent distortion after sutureless aortic valve implantation: a new complication seen with a novel surgical Technique. *Interact Cardiovasc Thorac Surg* 2015; 20: 436- 8.
  27. Sénage T, Gillaizeau F, Le Tourneau T, Marie B, Roussel JC, Foucher Y. Structural valve deterioration of bioprosthetic aortic valves: An underestimated complication. *J Thorac Cardiovasc Surg*. 2019 Apr; 157(4): 1383-1390.
  28. 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.