Sutureless Valve Replacement Through a Right Anterior Mini-thoracotomy in Elderly Patients With Stenotic Bicuspid Aortic Valve

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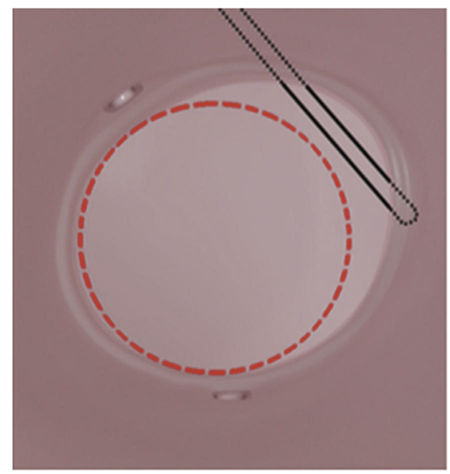
Several indications for sutureless aortic valve replacement (SU-AVR) have been a matter of debate. We evaluated our experience with Perceval-S (LivaNova group, Saluggia, Italy) SU-AVR in patients with severe aortic stenosis (AS) involving bicuspid aortic valve (BAV), even though presence of BAV is still considered to be a contraindication for sutureless valves. From January 2013 through March 2018, 13 patients with severe AS involving BAV underwent SU-AVR with the Perceval-S (LivaNova group, Saluggia, Italy) prosthesis in a single center. Preoperative evaluation included coronary catheterization and multi-sliced computerized tomography was performed in all patients. Three-dimensional transthoracic echocardiography was used to evaluate for obtaining the anatomy and phenotype of BAV. Minimally invasive approach through right anterior thoracotomy from third intercostal space was performed for all patients. The mean age was 72.8 ± 2.26 years ranging from 70 to 77, and 53.8% (n = 7) were male. The mean aortic valve gradient decreased from 46.4 ± 13.8 to 13.6 ± 4.4 mmHg postoperatively. The mean aortic valve area increased from 0.69 ± 0.22 to 1.81 ± 0.38 cm^2. There was no in-hospital mortality. One patient (7.6%) had third-degree atrioventricular block requiring permanent pacemaker implantation. Mean follow-up was 15.1 ± 6.3 months (maximum 2 years). No major paravalvular leakage or valve migration occurred postoperatively. This study shows that SU-AVR is a technically feasible and safe procedure in patients with severe AS and BAV with acceptable good



Elliptic remodeling with additional U-mattress inter-commissural suture.

Central Message

SU-AVR is a technically feasible and safe procedure in AS patients involving BAV anatomy with acceptable good surgical outcomes with additional moves of elliptic remodeling or annular reduction.

Perspective Statement

Our experience highlights that in patients with BAV and severe aortic valve stenosis undergoing SU-AVR, a critical technical aspect is optimal careful positioning of the prosthetic valves in order to avoid interference due to anatomical asymmetry of the BAV and maintaining the best circularity with additional intercommissural U-mattress sutures.

Abbreviations: AF, atrial fibrillation; AS, aortic stenosis; AV, atrioventricular; AVR, aortic valve replacement; BAV, bicuspid aortic valve; CPB, cardiopulmonary bypass; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PAP, pulmonary artery pressure; PASP, pulmonary artery systolic pressure; PVL, paravalvular leak; SU-AVR, sutureless aortic valve replacement

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Disclosures: The authors have no financial disclosures that would be a potential conflict of interest with the current manuscript.

Funding: This project was internally funded.

Meeting Presentation: Presented in EACTS Annual Meeting 2017, Vienne, Austria.

Key Question: Is presence of bicuspid aortic valve in severe aortic stenosis considered a contraindication for SU-AVR?

Key Findings: Elliptical remodeling and annular reduction with inter-commissural U mattress suture is the crucial step.

Take-home Message: SU-AVR is a technically feasible and safe procedure in severe AS patients involving bicuspid aortic valve anatomy with acceptable outcomes.

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https://doi.org/10.1053/j.semtcvs.2018.09.025

surgical outcomes. Presence of BAV in AS should not be considered a contraindication to Perceval-S prosthesis (LivaNova group, Saluggia, Italy).

Semin Thoracic Surg 31:458–464

Keywords: Sutureless aortic valve replacement, Bicuspid aortic valve, Congenital cardiac anomaly

INTRODUCTION

Bicuspid aortic valve (BAV) is the most common cardiac anomaly, which occurs in 1% of the population. In 75% of these cases, pure severe aortic stenosis (AS) accompanies with severe symptoms at the end of late adulthood.[1] Aortic valve replacement (AVR) remains the gold standard for severe symptomatic AS in adult patients. In recent years, substantial technological advances have been made for the treatment of aortic valve disease. Specifically, transcatheter aortic valve implantation (TAVI) and sutureless AVR (SU-AVR) have emerged as promising and useful alternatives to standard AVR in frail, elderly patients with high surgical risk.[2,3] Moreover, being able to perform SU-AVR in each type of aortic valve disease will provide performing AVR with shorter aortic cross clamp and myocardial ischemic times even in minimally invasive aortic surgery when compared to conventional AVR[4,5] and also maintain the valve in conforming to physiologic movements of the aortic root due to sutureless design of Perceval combined with its flexible stent. However, in contrast to TAVI, SU-AVR requires excision of the aortic valve and complete decalcification of the aortic root to avoid paravalvular leakage.[6]

Several studies suggest that the presence of BAV might limit the role of SU-AVR due to concerns related to the presumed risk of poor seating or paravalvular regurgitation due to severe distortion of native valve leaflets[7] so there is limited evidence in the literature regarding the validity of these concerns or how they might be managed technically.

In our institution, severe AS involving BAV are surgically treated during AVR surgery through a right anterior mini-thoracotomy in 13 patients. SU-AVR might provide important advantages in such cases by reducing operative times and facilitating AVR but the feasibility and safety of this approach has not been validated. Therefore, we reviewed our outcomes with SU-AVR in the setting of minimally invasive aortic valve surgery.

METHODS

Our institutional Ethical Committee obtained approval for the use of this data. Informed written consent was obtained from all patients. Between January 2013 and March 2018, 559 consecutive patients who underwent aortic valve surgery were identified. The cause of valvular disease was rheumatic in 79.8% (119/149) and degenerative in 20.1% (30/149) of patients. Disease of aortic valve was documented as bicuspid AS in 40 patients during this period. In this retrospective, observational cohort performed at a single center, we identified 13 patients with severe AS accompanied with BAV who underwent SU-AVR with a Perceval prosthesis (LivaNova group, Saluggia, Italy). During this period, 43 patients with various forms of aortic valve diseases underwent SU-AVR with a Perceval prosthesis in total at our institution (Fig. 1). For this study, inclusion criteria were severe aortic valve stenosis; age more than 70 years old; EuroScore greater than 5; documented BAV by TEE or transthoracic echocardiography (TTE); candidate for biological valve implantation; NYHA function class of III or greater, and calcified aortic annulus. Exclusion criteria were severe aortic valve stenosis without BAV, ascending aorta dilatation and history of previous cardiac surgery. Over the study period, diagnosis of BAV and following of the patients postoperatively by TEE or TTE were carried out by a team, which includes cardiologists and cardiovascular surgeons.

Preoperatively, all patients underwent thoracic computed tomography without contrast enhancement for evaluating the relationship among sternum, intercostal space, ascending aorta, and aortic annulus due to determine the availability of the patient to the aortic surgery with RAT. Open software in our university is also available to reconstruct three-dimensional (3D) images of the chest. This information is very important for operative planning. Because being available for RAT; patient should have (1) rightward located ascending aorta (at the right side in respect to right sternal border at the level of main pulmonary artery), (2) <10 cm the distance between ascending aorta and sternum, and (3) an angle >45° (angle between the midline and inclination of ascending aorta).

The Perceval sutureless valve is a next-generation aortic bioprosthesis made of bovine pericardium within an elastic nitinol stent produced from nickel and titanium. Atraumatic collapsing by a dedicated delivery system allows rapid deployment of the valve within the aortic root without crimping of the bioprosthesis. Social Security Agency in Turkey addressed the reimbursement issue for Perceval implantation with specific indications following CE approval of the device, in 2013.

Surgical Approach

Steps and details in the surgery were summarized in an intraoperative record and animation type of video as Video 1 and Video 2, respectively. All patients had intraoperative transesophageal echocardiographic (TEE) evaluation. Right anterior mini-thoracotomy through third intercostal space and moderate hypothermic (32°C) cardiac arrest were performed for all procedures. Cardiopulmonary bypass (CPB) was initiated with femoral artery and femoral vein cannulation, venous drainage

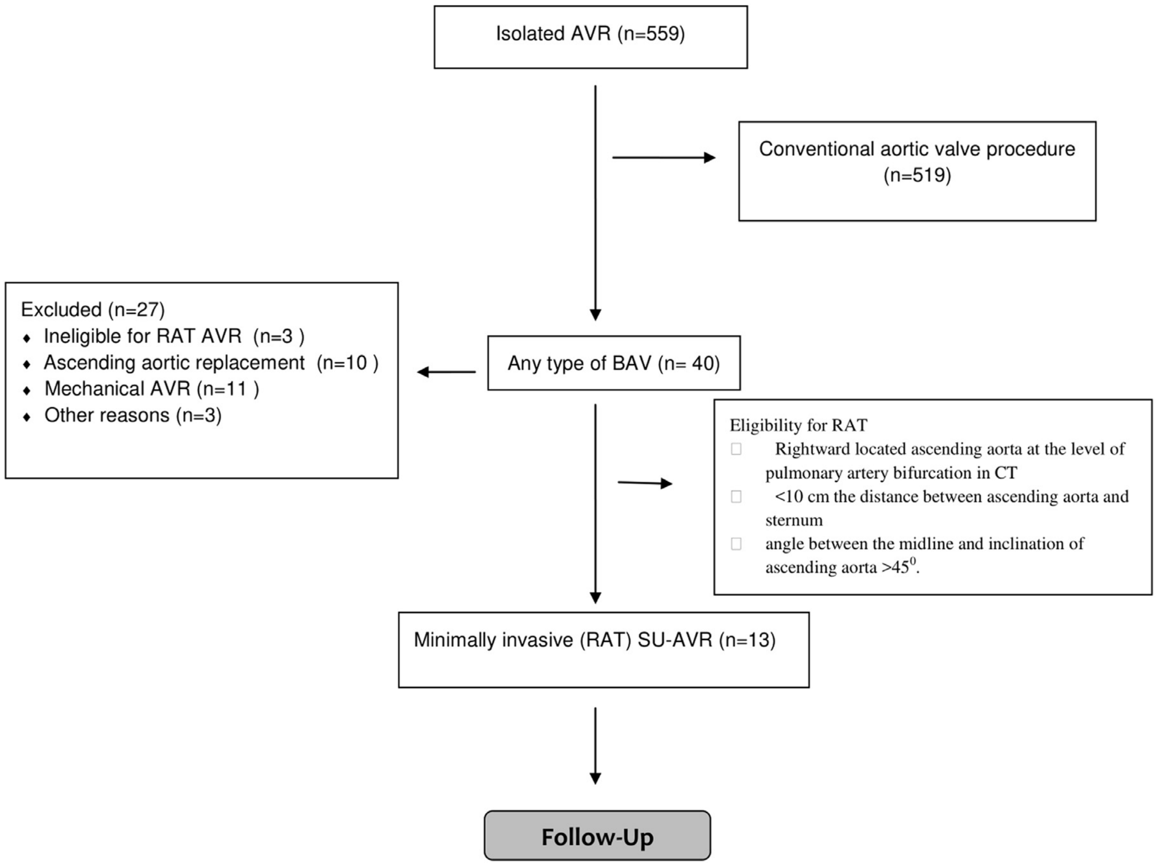


Figure 1. Flow diagram of the patients with undergoing isolated aortic valve surgery.

was supported with vacuum assist. Custodiol-HTK cardioplegia was administered for myocardial protection. The carbon dioxide (CO_2) diffuser was placed in the pericardial cavity, and CO_2 was delivered just before opening of the aorta until closure of aortotomy. As suggested by Perceval implantation guidelines, the aorta was opened transversely approximately 3.0−3.5 cm above the level of aortic annulus. The native aortic valve was removed and complete decalcification was performed. After having a clear annular surface, we evaluated right and left coronary ostiums. This step is the most important phase of surgery. In the regard of the type of BAV, annular shape, and commissural heights, distance between the coronary ostiums can be varied so that maintaining the circular annulus with the best anatomical aspects is critical depends on the different anatomical types. Sizing of the aortic valve was repeated using the appropriate Perceval-S sizers. After deciding the type of BAV and anatomical abnormalities, we created and marked 3 imaginary new commissures with the help of the projections of the corners of Perceval-S sizer adjusted according to position of coronary ostiums. The crucial point left after this point is to provide best circular surface as much as we can. The main determination of the annular shape and size was performed intraoperatively via inspection after stenotic valve excision and decalcification. In this regard, we put intercommissural U-mattress sutures with 4-0 polyprolene into annulus and tied to shrink annulus for changing elliptical shape into circular one. Then 4-0 polyprolene guiding sutures were passed through at the nadir of each imaginary new intercommissural level to avoid mispositioning of guiding sutures after the additional interventions into annulus. The collapsed Perceval valve was delivered using its dedicated holder using the 3 guiding sutures and deployed at the level of aortic annulus after maintaining circular annulus. The delivery system and the 3 guiding sutures were then removed. After deployment, a dedicated balloon was inserted into the prosthesis and inflated at a pressure of 3−4 atm. pressure for not more than 30 seconds to improve nitinol stent apposition with the aortic root and the annulus. Subsequently, Perceval-S was irrigated with warm saline. Once the correct positioning of the prosthesis was visually confirmed, the ascending aorta was closed in 2 layers.

Follow-Up

All patients underwent TTE at discharge and at 3, 6, and 12 months postoperatively and annually thereafter by cardiologist team member, together with a complete physical examination, electrocardiography registration, chest radiography, and blood sampling. Postoperatively, all patients were given aspirin lifelong and warfarin for 3 months. Target international normalized ratio was 2.5−3.5 for 3 months if sinus rhythm was restored in patients with exclusively biological valve replacement.

Statistical Analysis

Valve-related complications are reported according to the Guidelines of the Ad Hoc Liaison Committee for Standardizing Definitions of Prosthetic Heart Valve Morbidity.[5] Continuous data are expressed as mean ± standard deviation or median (range), and categorical data as percentages. Operative mortality in this study is defined to include all deaths occurring during the hospitalization following the operation.

RESULTS

Patients Preoperative Baseline Characteristics

Between January 2013 and March 2018, a total of 13 (30.2%) of 43 patients undergoing SU-AVR had documented BAV. In this study, phenotypically, 4 patients had a symmetrical type 0 BAV without raphe (true BAV), 4 patients had a type 1 BAV with incomplete raphe which is partially fused between left and right coronary cusps, 2 patients had type 1 BAV with complete raphe between right and noncoronary cups, and 1 patient had type 1 BAV with complete raphe between left and noncoronary cusps. Two patients had type 2 BAV with 2 separate raphes composition. Detailed patient preoperative characteristics are summarized in Table 1. Mean age of patients was 72.8 ± 2.26, and 53.8% (n = 7) were male. All patients were in NHYA III or greater. Median logistic EuroScore predicted that mortality was 9.3 ± 1.65. Atrial fibrillation was present in 2 (15.3%) and 10 patients were in sinus rhythm. Mean left atrial diameter was 4.5 ± 0.4 cm. The mean body mass index was 26.4 ± 2.69 kg/m^2.

Table 1. Baseline Patients Characteristics

Variables	Value (n = 13)
Age, years	72.8 ± 2.26
Male gender	7 (53.8%)
Body mass index (kg/m^2)	26.4 ± 2.69
Diabetes	4 (30.7)
Hypertension	5 (38.4)
Hyperlipidemia	3 (23)
Chronic pulmonary disease	4 (30.7)
Extracardiac arteriopathy	1 (7.6)
Smoking	7 (53.8)
Logistic EuroScore	9.3 ± 1.65
Previous cardiac surgery	0 (0.0%)
NYHA class	
III	8 (61.5)
IV	5 (38.4)
LVEF	53.07 ± 7.2
PASP (mmHg)	39.2 ± 9.75
Left atrial size (cm)	4.5 ± 0.4
Aortic valve mean gradient (mmHg)	46.4 ± 13.8
Aortic valve area (cm^2)	0.69 ± 0.22
Aortic annulus (mm)	20.8 ± 1.4
Type of BAV	
Type 0	4 (30.7)
Type 1	7 (53.8)
Raphe between L-R	4 (30.7)
Raphe between R-N	2 (15.3)
Raphe between N-L	1 (7.6)
Type 2	2 (15.3)
Rhythm	
Sinus	10 (76.9)
AF	2 (15.3)
Other	1 (7.6)

AF, atrial fibrillation; BAV, bicuspid aortic valve; BMI, body mass index; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure.
Values are M ± SD, or n (%).

Surgical Procedures

Detailed intraoperative data are listed in Table 2. All patients underwent Perceval-S (Sorin) successfully by RAT surgical approach. Only 1 patient had to require of conversion to full sternotomy due to continuous bleeding from unrecognizable area. The mean cardiopulmonary bypass time was 54.5 ± 4.4 minutes and the mean cross-clamp time was 40.3 ± 3.1 minutes. Ten patients received a large sized (24−25 mm) and 3 patients received an extra-large size Perceval prosthesis (26−27 mm). All implanted valves were evaluated by intraoperative TEE after discontinuation of CPB. Eight patients had severe aortic valve calcification. There was no perioperative mortality.

One patient who had type 2 BAV pathology required redeployment due to supra-annular malpositioning due to unable to maintain the circularity of annulus. Perceval was easily and safely removed, 1 more intercommissural U-mattress suture between the left and noncoronary commissure was placed and successfully reimplanted after providing more circular area. The valve function was checked using TEE intraoperatively.

Table 2. Intraoperative Data

Variables	Value (n = 13)
CPB time (min)	54.5 ± 4.4
Cross-clamp time (min)	40.3 ± 3.1
Perceval prosthesis size	
L (24−25 mm)	10 (76.9)
XL (26−27 mm)	3 (23.1)
Surgical approach	
Complete/partial sternotomy	0 (0)
Right anterior mini-thoracotomy	13 (100)
Aortic valve asymmetric calcification	8 (61.5)
Redeployment	1 (7.6)
Exploration for bleeding	2 (15.3)
Requirement of conversion to sternotomy	1 (7.6)

CPB, cardiopulmonary bypass.
Values are M ± SD, or n (%).

Table 3. Early Clinical Outcomes (n = 13)

Variables	Value (n = 13)
Stroke (%)	1 (7.6)
Valve migration/embolization	0 (0)
Endocarditis	0 (0)
Delirium	2 (15.3)
Re-exploration for bleeding (%)	1(7.6)
Myocardial infarction	0
Acute kidney injury	1 (7.6)
Renal replacement therapy	1 (7.6)
Postoperative AF	2 (15.3)
Aortic valve	
Absence of PVL (%)	12 (92.3)
PVL ≤1 (%)	1 (7.6)
PVL >1 (%)	0 (0)
Mean gradient (mmHg)	13.6 ± 4.4
Peak gradient (mmHg)	17.1 ± 4.9
EOA (cm^2)	1.81 ± 0.38
Temporary PM (%)	1 (7.6)
AV block requiring PM (%)	1 (7.6)
Sinus rhythm restoration (%)	11 (84.6)
ICU length of stay (d)	3.1 ± 1.4
Hospital stay (d)	8.2 ± 2.4

AF, atrial fibrillation; AV, atrioventricular; EOA, effective orifice area; ICU, intensive care unit; PM, pacemaker; PVL, paravalvular leakage. Values are M ± SD, or n (%).

No evidence of aortic regurgitation was found in any patient. The mean of mean aortic valve gradient decreased from 46.4 ± 13.8 to 13.6 ± 4.4 mmHg postoperatively. The mean aortic valve area increased from 0.69 ± 0.22 to 1.81 ± 0.38 cm^2. Only in 1 patient, we observed grade ≤1 aortic insufficiency at discharge, which required no further information (Table 3). Cerebrovascular accident occurred in 1 patient within 12 hours after the surgery. However, cranial tomography and magnetic resonance imaging revealed no ischemic or bleeding complication. The patient fully recovered after 2 months of physical rehabilitation. Only 1 patient (7.6%) required permanent pacemaker implantation due to third-degree atrioventricular block.

The mean hospital and intensive care unit stay from surgery to discharge were 8.2 ± 2.4 and 3.1 ± 1.4 days, respectively. Over this period, re-exploration due to bleeding which occurred only in 1 patient, thereafter they could easily be controlled.

Echocardiographic Evaluation and Early Follow-Up

Postdischarge data were obtained from all patients (100%). Patients were followed for 15.1 ± 6.3 months (maximum 2 years). They were examined before discharge, 1, 6, and 12 months after discharge with TTE, blood tests, and chest X-ray. One patient was evaluated by the cardiology pacemaker outpatient clinic for pacemaker testing and adjustment every 6 months. No mortality occurred in postdischarge period. Ten patients were in NYHA class I and showed significant symptomatic improvement symptoms after surgery.

TTE at follow-up days were obtained for all patients. No migration or structural damage occurred. The mean of mean transvalvular gradient was 13.6 ± 4.4 mmHg, and the mean aortic valve area was 1.81 ± 0.38 cm^2. Only 1 patient (7.6%) had mild paravalvular regurgitation.

DISCUSSION

BAV is still most common cardiac anomaly which seen in 1% of the population since its estimated first description >500 years ago by Leonardo da Vinci.[8] Most of patients with BAV admit to hospitals with underlying isolated severe AS requiring surgery, bacterial endocarditis, or aortic dissection.[9] In addition to that, half of the BAV patients have also severe aortic regurgitation, exhibit a significant loss of medial elastic aortic fibers, and they are recently been associated with a higher risk of aortic dissection compared to BAV patients with isolated severe AS.[10] But in our manuscript, we had not included BAV patients with aortic regurgitation.

Sutureless prosthetic heart valve implantation was first described by Magovern and Cromie in 1963 employing engagement of multiple vertical pins within the stent of a mechanical valve.[11] Twenty-five years of experience with the Magovern-Cromie Sutureless ball-cage mechanical valve was reported by Magovern et al with an 11% operative mortality for isolated AVR and 15% for AVR with concomitant cardiac procedures.[12] At follow-up, the incidence of paravalvular leak and thromboembolic event rate was unacceptably high. However, the concept of sutureless valve technology has evolved, while the search for ideal bioprosthesis for AVR still continues today. New-generation sutureless aortic valve bioprostheses may provide an alternative therapeutic option especially in elderly high-risk surgical patients with favorable clinical outcomes. On the other hand, implantation of SU-AVR is limited to some indications. It is especially considered as contraindicated in patients with BAV due to its different anatomical aspects of the aortic root in terms of annulus geometry (more elliptic not circular as tricuspid valve structure), sinus asymmetry and difference between the heights of each leaflets commissures, so that BAV stenosis requiring surgical correction especially in the elderly remains complex and challenging. However, as Wijesinghe et al[7] reported in 2010, the success of TAVI in bicuspid AS depends on the selection of appropriate patients. While the patients with type 1 BAV (symmetrical true raphe (complete or incomplete), 3 V-shaped sinus valsalva structure, semicircular annulus (not elliptical), similar height of leaflet commissures are good candidate for the surgery, patients with bulky leaflets, type 0 BAV, enlarged aortic root, dilated ascending aorta, and significant aortic regurgitation might be at a higher risk of failure to achieve satisfactory results. A recent manuscript also provides technical recommendations and usage of SU-AVR in patients with BAV stenosis and shows that Perceval (Sorin) is feasible and associated with encouraging results.[13]

Our experience represents the largest series employing Perceval through right mini-thoracotomy in patients with BAV stenosis. Our experience highlights that in patients with BAV and severe aortic valve stenosis undergoing SU-AVR, a critical technical aspect is optimal careful positioning of the prosthetic valves in order to avoid interference due to anatomical asymmetry of the BAV and maintaining the best circularity with additional intercommissural U-mattress sutures. As Nguyen et al emphasized, the most crucial point during surgery is to recreating 3 natural nadirs points positioned at 120° with the aim of recreating a circular annulus. It is easier in patients with type 1 because of the closing measured values of heights of each leaflet commissures, including 3 sinus valsalva and more importantly having a complete raphe helps the surgeon diverging the recreated cups in appropriate position.

According to our center experience with SU-AVR in patients with BAV stenosis, beside the recreating 3 natural nadirs, other 4 important surgical techniques have to be performed to have a successful result. First, after removal of the native valve leaflets, a thoroughly decalcification of the aortic annulus was performed to restore its elasticity and adaptability to the new implanted prosthetic valve for all patients. We initially removed eccentric or bulky protruding intraluminal calcifications, rather than performing extensive intra-annular decalcification prior to this study. However, with experience, we preferred thorough decalcification of the aortic annulus to optimize valve seating and prevent postoperative paravalvular leakage. Second, if the BAV is not in type 1 structure and the commissures heights are at different heights, a commissural plication may be required to restore the circularity of the aortic annulus. Third, maintaining the circularity of annulus by putting in intercommissural U-mattress polyprolene sutures in the elliptical corners. Fourth, the collapsed Perceval valve was delivered using its dedicated holder using the 3 guiding sutures and deployed at the level of circular aortic annulus, it has to be fixed correctly to the recreated natural nadirs and visually confirmed. We created a surgical intervention model for the different types of BAV in regards of their anatomical challenges (Fig. 2). According to our experience, maintaining the circularity is the most important step in this kind of valvular pathology. While 1 intercommissural U-mattress suture is mostly sufficient for elliptical remodeling in type 0 BAVs, additional mattress suture and commissural plication may be required in type 2 BAVs. Approach to type 1 BAVs is mostly exactly same as surgeons do in tricuspid aortic valve due to its semicircular annulus and symmetrical true raphe. Only in 1 patient, we had experienced not correctly fixed Perceval to aortic annulus because the underlying anatomy of aortic valve was type 2 and aortic annulus was so elliptical. This case required redeployment, at which time the guiding sutures were repositioned, one more intercommissural U-mattress suture and close commissural plication were placed into annulus between left and noncoronary

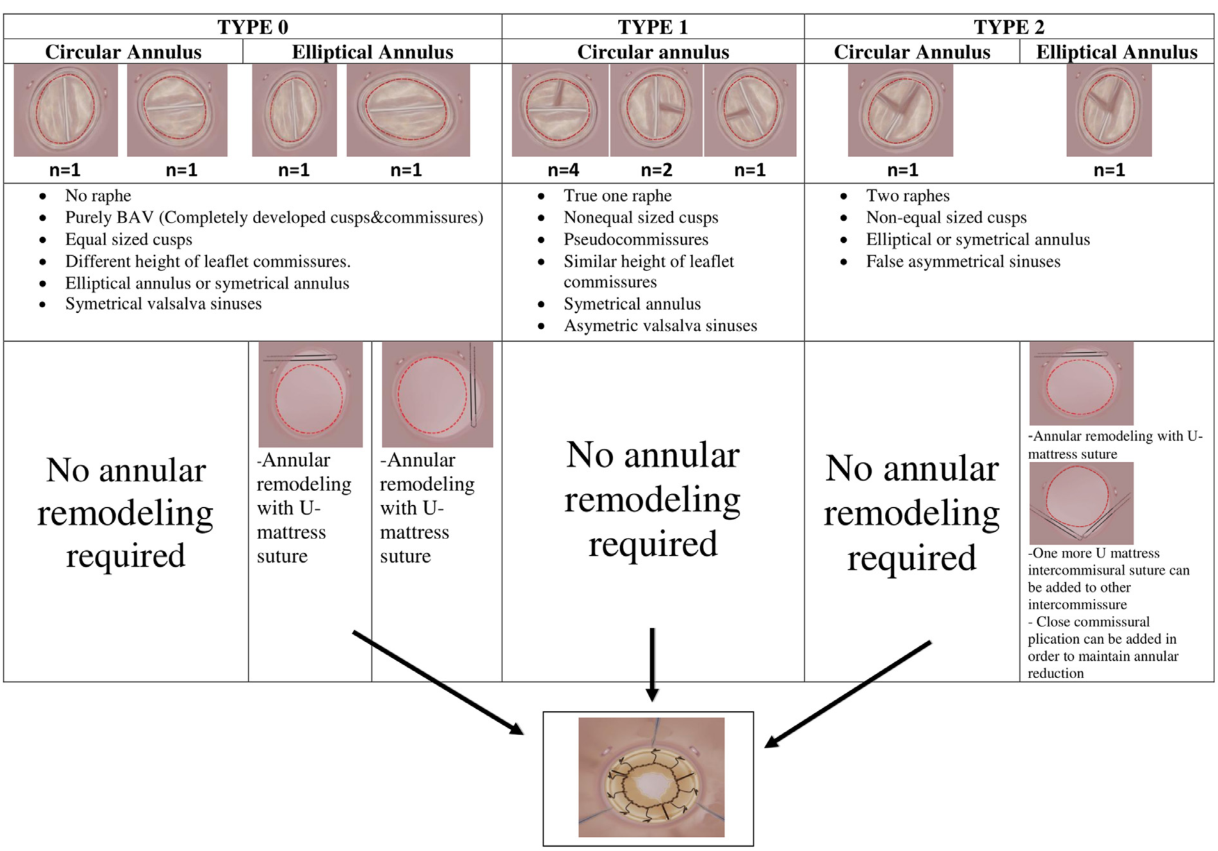


Figure 2. Technical considerations for different type of BAVs.

commissures and Perceval was successfully reimplanted. Easy recollapsing provided by the Perceval design is a great advantage for surgeons in this scenario. Using the "χ-movement" technique is practical and reproducible for the removal of Perceval prosthesis as reported by Santarpino et al.[14]

We have shown that implantation of RAT SU-AVR is feasible in patients with BAV severe AS at high surgical risk. Despite anatomical asymmetry and elliptic nature of the aortic annulus, the postoperative results were satisfactory, with at every patient, a degree of aortic regurgitation minimal or 1. Mean of the mean gradient of aortic valve was decreased from 46.4 ± 13.8 mmHg to 13.6 ± 4.4 mmHg, and effective orifice area was increased from 0.69 ± 0.22 to 1.81 ± 0.38 cm^2.

Study Limitations

Limitations of the present study are single center, and retrospective study design. Another limitation of this study is the lack of control group receiving conventional aortic valve substitutes. Therefore, we planned a large prospective, randomized, controlled trial comparing sutureless valves and other types of aortic valves implantation through RAT in patients with BAV stenosis.

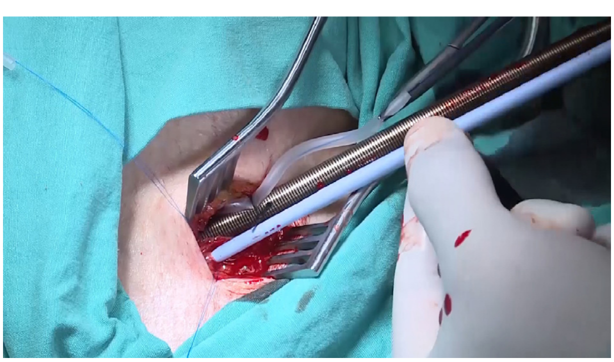
In conclusion, RAT SU-AVR in the setting of BAV stenosis in elderly patient population is a reliable surgical alternative to standard surgical AVR simplifying surgical procedure despite it is still an off-label procedure which means randomized, prospective control trials are required to see the role of SU-AVR in the patients with BAV. Long-term follow-up will determine the role of RAT SU-AVR in patients with BAV. Our main aim with this manuscript is to address that RAT BAV surgery including SU-AVR can be safely performed with acceptable outcomes in experienced centers.

Acknowledgment

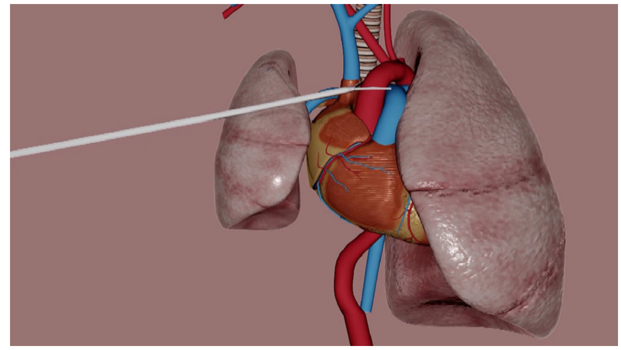
We sincerely thanks to Saadet Aslan for echocardiographic assessments, and all ICU nurses for their outstanding assistance.

SUPPLEMENTARY MATERIAL

The following is the supplementary data to this article:



Video 1. Intraoperative video record of a 78-year-old female patient with BAV stenosis who underwent sutureless aortic valve replacement.



Video 2. Animation video of the surgery of aortic valve replacement in patients with BAV.

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