

Sutureless aortic valve replacement in high-risk patients with active infective endocarditis

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Background: Surgical aortic valve replacement remains the gold standard of treatment in patients with active infective endocarditis. Such procedures tend to carry a significantly higher operative risk when compared to the conventional aortic valve replacement for a non-infective aortic valve disease. Sutureless aortic valve replacement (SU-AVR) has been introduced into cardiac surgery to allow for a simpler implementation of minimally invasive procedures. Although SU-AVR in several extended indications has proven to be successful, the data on the implementation of SU-AVR in patients with infective aortic valve endocarditis remain scarce. The aim of the study was to examine the feasibility of SU-AVR in high-risk patients with active infective aortic valve endocarditis.

Methods: Between December 2019 and March 2022, a total of 151 consecutive patients underwent a SU-AVR for various indications at our institution. Of those, in 13 consecutive high-risk patients SU-AVR was indicated because of infective aortic valve endocarditis. In all cases Perceval S aortic valve prosthesis (Corcym, Saluggia, Italy) was used and the implantation has been performed with Snugger-method.

Results: The mean age of the patients at operation was 74.05±11.6 years. Eight of the patients suffered from prosthesis endocarditis while the other five patients presented with the endocarditis of the native aortic valve. All patients suffered from multiple comorbidities, as reflected by a mean logistic EuroSCORE of 47.9%±23.1% and EuroSCORE II of 28.7%±22.0%. In 8 patients (61.5%) a concomitant procedure was necessary. Also 8 patients (61.5%) underwent a redo procedure. Bypass- and cross-clamp (CC) times were 89.8±33.6 and 59.1±27.8 minutes, respectively. We observed no paravalvular leakage and no cases of left-ventricular outflow tract obstruction. Postoperative mean gradients after SU-AVR implantation were 8.1±4.8 mmHg.

Conclusions: SU-AVR in patients presenting with active infective endocarditis is a safe and feasible surgical alternative to the conventional operation. Clearly, this operative approach should be considered particularly for high-risk patients in whom successful operative outcomes are determined by a reduction in bypass and CC time. SU-AVR provides excellent hemodynamic performance with a low risk of paravalvular leakage and low transvalvular gradients, whilst simplifying the surgical procedure.

Keywords: Infective endocarditis; sutureless aortic valve replacement (SU-AVR); Perceval

Submitted Apr 12, 2022. Accepted for publication Jun 11, 2022. doi: 10.21037/jtd-22-486 View this article at: https://dx.doi.org/10.21037/jtd-22-486

Introduction

Despite the rapid development of transcatheter approaches for aortic valve replacement, the treatment of choice in patients presenting with active infective endocarditis remains surgical aortic valve replacement. These procedures tend to carry a significantly higher operative risk, compared to the conventional aortic valve replacement for a non-infective aortic valve disease (1-3). Patients presenting with active infective endocarditis often already suffer from end-organ impairment due to sepsis, therefore presenting with severe comorbidities and higher risk scores. Moreover, in an elevated proportion of cases a redo procedure is required on a previously implanted infected valve prosthesis. Cardiopulmonary bypass (CPB) time and aortic CC time have been proven to be important independent predictors of mortality in patients undergoing cardiothoracic procedures (4). Thus, approaches enabling a reduction in ischemia-reperfusion injury during cardiothoracic surgical procedures are very desirable, especially in patients with complex infective valvular pathology and multiple comorbidities (5).

Rapid deployment aortic valve prostheses have been developed to allow for a broader implementation of minimally invasive access into aortic valve surgery (6). Thereafter, sutureless aortic valves have demonstrated promising results such as impeccable hemodynamic performance, ensuring low transvalvular gradients, which is of great importance in patients with small aortic annuli (7). Furthermore, sutureless valve prostheses have led to a drastic reduction in implantation time, mainly owing to the simplicity and reproducibility of their implantation technique (8,9). The Perceval S (LivaNova) sutureless aortic valve is a collapsible, stent-mounted, bovine-pericardium prosthesis with nitinol stent produced with nickel and titanium. Indeed, a major advantage of this prosthesis is the minimal amount of artificial tissue which mainly consists of the leaflets mounted onto the stent. The latter could hypothetically contribute to its' lower susceptibility to infectious processes.

Although, successful outcomes for numerous indications have been described after surgical sutureless aortic valve replacement (SU-AVR), including multivalve procedures, small annuli and bicuspid aortic valves (5,8,10-12), there remains a lack of data originating from large randomized multicenter trials. Therefore, the implementation of sutureless aortic valve prostheses in patients with active infective endocarditis is still considered an off-label procedure and is in fact listed as a contraindication in the product description. Although the implementation of Perceval valve in patients with infective endocarditis despite it being a contraindication is rarely performed offlabel, it has been already described in smaller patients' cohorts (13).

To explore the validity of this contraindication, we sought to analyze our clinical experience with SU-AVR in high-risk patients presenting with active infective endocarditis and evaluate the postoperative outcomes and technical challenges related to Perceval sutureless valve prosthesis. We present the following article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-486/rc).

Methods

Study design and population

Between December 2019 and March 2022, a total of 151 consecutive patients underwent a SU-AVR at our institution. Of those, SU-AVR was indicated in 13 consecutive highrisk patients due to infective aortic valve endocarditis. In all cases the Perceval S aortic valve prosthesis (LivaNova, Saluggia, Italy) was used. Eight of the patients suffered from previous valve prosthesis endocarditis while the other five patients presented with endocarditis of the native aortic valve [according to the modified Duke criteria to diagnose aortic infective endocarditis (14)].

All cases were evaluated preoperatively by our institutional interdisciplinary Heart Team and Endocarditis Team, consisting of a cardiac surgeon, cardiac anesthesiologist, interventional cardiologist and microbiologist. Postoperative echocardiographic evaluation of the hemodynamic performance of the implanted valve prosthesis was performed prior to hospital discharge. Prospective data collection was obtained from the institutional database, including patients' demographics; baseline clinical characteristics; laboratory, echocardiographic, and hemodynamic parameters; intraoperative variables; and postoperative outcomes. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The present study obtained Institutional Review Board approval of the University Duisburg-Essen (Ref# 21-10427-BO). All patients signed and gave informed consent to evaluate their data anonymously.

Surgical technique for SU-AVR

Implantation of Perceval sutureless aortic valve was performed in Snugger-technique as previously described (10,15). In brief, all cases were performed via median sternotomy in normothermic cardiac arrest. For the initiation of the CPB, the direct cannulation of the ascending aorta and the right atrium was performed. An exception was made in two cases which involved tricuspid valve repair, here bicaval cannulation was performed. Custodiol-HTK (Köhler Chemie GmbH, Bensheim, Germany) was administered directly via aortic route. A high transverse aortotomy was performed and the native or prosthetic aortic valve was decalcified and excised in toto seeking a radical debridement of the diseased tissue. Xenogenic pericardium was used in two cases to stabilize the infected area and aortic annulus.

Particular care was taken during the sizing of the Perceval prosthesis in cases of concomitant mitral valve procedures. As previously described, the following was done to avoid technical complications such as left ventricular outflow tract (LVOT) obstruction and mispositioning or migration of the sutureless prosthesis (5). Subsequently, three 3/0 prolene sutures were placed into the nadires of each aortic sinus for the correct positioning of the prepared Perceval prosthesis. The valve was released and the balloon was expanded for 30 seconds by 4 atm for all prosthesis sizes. Sterile 37 °C saline has been added into the aortic root to support the stabilization of the nitinol stent of the sutureless prosthesis. After macroscopically securing the correct positioning of the Perceval prosthesis, the aortotomy was closed in a regular manner with 4/0 prolene double layered suture.

Postoperative antibiotic therapy

All patients were treated with intravenous antibiotic therapy consisting of meropenem, rifampicin and vancomycin for 6 weeks according to our standard regiment. The administration of rifampicin was stopped after 10 days, whereas the intravenous therapy with two other substances has been carried out for another 6 weeks. In cases where the causative organism has been isolated, antibiotic therapy has been deescalated according to the resistogram and given intravenously also for six weeks.

Outcomes and definitions

The primary end-points of this study were 30-day mortality,

6-month mortality and device success, which was evaluated with transthoracic echocardiography. The secondary end-point was the development of any postoperative adverse events as defined by the Valve Academic Research Consortium (VARC-2) (16).

Statistical analysis

The data were analyzed using IBM SPSS Version 27 (IBM Corporation, Chicago, IL., USA). To assess normality of the data, Shapiro-Wilk test has been used. We expressed the quantitative data according to their distribution as the mean and standard deviation (SD) or median and interquartile range (IQR). Categorical data are expressed as frequency and percentage.

Results

Baseline characteristics

The mean age of the patients at operation was 74.05± 11.6 years (Table 1). All patients (n=13) presented with active infective aortic valve endocarditis, of whom 8 patients (61.5%) suffered from aortic valve prosthesis endocarditis (Table 2). All patients presented with elevated infectious parameters with mean white blood cells (WBC) of 10.7±5.4/nL, median C-reactive protein (CRP) of 6.2 (IQR, 0.6-16.9) mg/dL and median procalcitonin (PCT) of 0.21 (IQR, 0.02-2.7) ng/mL. In 7 patients the causative organism has been known prior to surgical procedure [staphylococcus aureus (n=4) and staphylococcus faecalis (n=3)]. In those patients, antibiotic therapy could be deescalated according to the resistogram. The remaining 6 patients have been treated with our standard antibiotic regiment for 6 weeks. All patients suffered from multiple comorbidities, as presented in the Table 1 and reflected by a mean logistic EuroSCORE of 47.9%±23.1% and EuroSCORE II of 28.7% ±22.0%.

Intraoperative characteristics

Intraoperative variables are listed in *Table 2*. All patients underwent SU-AVR using the Perceval S (LivaNova) sutureless aortic valve prosthesis due to active infective aortic valve endocarditis. During the echocardiographic evaluation of 6 patients (46.2%), a vegetation on the aortic valve was found. In 8 patients (61.5%), a concomitant procedure was necessary. Additionally, 8 patients (61.5%) underwent a redo procedure. Three patients (23.1%)

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Table 1 Baseline characteristics

Characteristics	Value		
Female	6 (46.2)		
Age, years	74.05±11.6		
BMI, kg/m ²	25.4±5.4		
Diabetes	2 (15.4)		
Pulmonary hypertension	1 (7.7)		
Peripheral arterial disease	3 (23.1)		
Arterial hypertension	8 (61.5)		
Chronic obstructive pulmonary disease	1 (7.7)		
CAD	6 (46.2)		
History of PCI	2 (15.4)		
Kidney failure	9 (69.2)		
Dialysis	1 (7.7)		
Creatinine, mg/dL	1.6±0.94		
GFR	51.2±23.9		
WBC, /nL	10.7±5.4		
CRP, mL/dL	6.2 (IQR, 0.6–16.9)		
PCT, ng/mL	0.21 (IQR, 0.02–2.7)		
Apoplex	2 (15.4)		
NYHA I–II	4 (30.8)		
NYHA III	9 (69.2)		
EF, %	53.6±5.6		
Logistic EuroSCORE	47.9±23.1		
EuroSCORE II	28.7±22.0		
Data are expressed as mean + standard deviation or modians			

Data are expressed as mean ± standard deviation or medians and interquartile ranges or numbers (percentages). BMI, body mass index; CAD, coronary arterial disease; PCI, percutaneous coronary intervention; GFR, glomerular filtration rate; WBC, white blood cells; CRP, C-reactive protein; PCT, procalcitonin; NYHA, New York Heart Association Class; EF, ejection fraction.

underwent a concomitant mitral valve repair with an annuloplasty ring and in another 5 patients (38.5%) a concomitant biological mitral valve replacement was performed. In addition, in 3 patients (23.1%) a tricuspid valve repair with a Duran Band (Medtronic) was performed. Operating- and CC times were 181.9 ± 42.0 and $59.1\pm$ 27.8 minutes, respectively. The mean CPB time was 89.8 ± 33.6 minutes. The mean number of units of blood transfusions was 4.2 ± 1.6 units per patient. Table 2 Intraoperative characteristics

Table 2 Intraoperative characteristics	
Characteristics	Value
Urgent procedure	5 (38.5)
Emergent procedure	8 (61.5)
Re-do procedure	8 (61.5)
Prothesis-endocarditis	8 (61.5)
Vegetation	6 (46.2)
Vegetation, cm	0.7±0.9
Aortic regurgitation	7 (53.8)
AR I–II°	1 (7.7)
AR >II°	6 (46.2)
AS I–II°	4 (30.8)
MR II–III°	7 (53.8)
MS >II°	1 (7.7)
TR II–III°	3 (23.1)
Sinus rhythmus	8 (61.5)
Atrial fibrillation	5 (38.5)
Permanent pacemaker	1 (7.7)
ICD	1 (7.7)
Operating time, min	181.9±42.0
CPB-time, min	89.8±33.6
CC-time, min	59.1±27.8
Perceval size	
S	3 (23.1)
Μ	6 (46.2)
L	0
XL	4 (30.8)
Concomitant procedure	8 (61.5)
MV-repair	3 (23.1)
MV-replacement	5 (38.5)
TV-repair	3 (23.1)
Myectomy	1 (7.7)
ICD-explantation	1 (7.7)
Transfusions	
EC, unit	4.2±1.6
TC, unit	0.8±0.9
Fibrinogen, g	1.9±1.5

Data are presented as mean ± standard deviation or numbers (percentages). AR, aortic regurgitation; AS, aortic stenosis; MR, mitral regurgitation; MS, mitral stenosis; TR, tricuspid regurgitation; ICD, implantable cardioverter-defibrillator; CPB, cardiopulmonary bypass; CC, cross clamp; MV, mitral valve; TV, tricuspid valve; EC, erythrocyte concentrate; TC, thrombocytes concentrate.

Table 3 Postoperative outcomes

Table 5 1 Ostoperative outcomes		
Characteristics	Value	
Re-thoracotomy	1 (7.7)	
Stroke	0	
AVB III	0	
Pacemaker implantation	0	
Paravalvular leakage	0	
Tachyarrhythmia	7 (53.8)	
Acute kidney failure	8 (61.5)	
New onset dialysis	4 (30.8)	
Septic shock	1 (7.7)	
Mean gradient, mmHg	8.1±4.8	
Time on respirator, days	1.0 (IQR, 0.5–1.0)	
ICU stay, days	9.2±6.5	
In hospital stay, days	12.2±7.9	
30-day mortality	3 (23.1)	
In-hospital mortality	3 (23.1)	
6-month mortality	6 (46.2)	
Follow-up time, days	356.0 (IQR, 24.5-695.5)	

Data are expressed as mean ± standard deviation or medians and interquartile ranges or numbers (percentages). AVB, atrioventricular block; ICU, intensive care unit; IQR, interquartile range.

Postoperative outcomes

Postoperative outcomes are displayed in *Table 3*. In all patients we observed an optimal device implantation success. One patient died intraoperatively following severe septic low output syndrome, another two patients died at the ICU due to spontaneous acute unmanageable lung bleeding. Therefore, we observed a 30-day mortality of 23.1%. The key characteristics of the patients responsible for the 30-day mortality are portrayed in the *Table 4*.

Postoperative mean gradient after SU-AVR implantation was 8.1±4.8 mmHg. We observed no PVL and no cases of LVOT obstruction. No cases of postoperative third-degree atrioventricular block and subsequent permanent pacemaker implantation were observed in our cohort. Additionally, we detected no postoperative stroke in our cohort.

Discussion

In the following study, a total of 13 high-risk patients

presenting with active infective endocarditis underwent a SU-AVR with Perceval prosthesis. This study provides a number of interesting findings:

- (I) SU-AVR is a technically feasible treatment option in high-risk patients presenting with active infective endocarditis, offering a high technical procedural success rate with a significant reduction of CC- and CPB-time.
- (II) In our cohort we did not observe any cases of device dislocation or PVL after SU-AVR with the Snugger-method.
- (III) No patients in our cohort developed a third-degree atrioventricular block and there were no cases of postoperative permanent pacemaker implantation.
- (IV) SU-AVR in patients with active infective endocarditis provides a great hemodynamic performance with low transvalvular gradients.
- (V) Although, in patients presenting with active infective endocarditis we observe a relatively high mortality predicted by the high risk-scores, it was most likely not associated with the type of the used valve prosthesis.

Following the great successes of transcatheter aortic valve replacement technologies in high-risk patient cohorts, TAVR procedures have also been recently implemented as an alternative to conventional surgical aortic valve replacement in intermediate and low-risk patients (17). Nonetheless, TAVR technologies are still not applicable to patients with active infective endocarditis, where the conventional SAVR remains the treatment of choice (18). Active infective endocarditis presents itself as a valvular heart disease with a significantly elevated mortality rate, majorly due to the septic state of patients also affecting the end-organs. Therefore, most of the patients demonstrate high risk scores predictive of a high operative risk. New generation sutureless valve prostheses may provide an alternative therapeutic option for such patients, thereby reducing the operative risk. Unfortunately, the presence of an active infective aortic valve endocarditis represents a contraindication for the implementation of sutureless valve prostheses, limiting their applicability only to bailout strategies and off label use. In our previous research we had already suggested extending the indication for SU-AVR to patients presenting with more complex aortic valve pathologies (5,8,10).

In the following study, we analyzed an extremely highrisk cohort portrayed by the mean logistic EuroSCORE of 47.9%±23.1% and EuroSCORE II of 28.7%±22.0%.

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Table 4 Patients	responsible for	30-day mortality
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Characteristic	Patient 1	Patient 2	Patient 3
Female sex	0	1	1
Age, years	82	75	78
Emergency	1	1	1
Prosthesis IE	1	1	1
ICU preoperative	1	1	1
Logistic ES	81.66	50.81	53
ES II	70.73	29.2	27,4
MR	IV	III	IV
Concomitant procedure	1	1	1
Surgical procedure	SAVR Perceval XL, MVR	SAVR Perceval S, MVRp 29 mm	SAVR Perceval S, MVRp 29 mm
Re-do	1	1	1
Previous procedure	Z.n. SAVR bio '!2	MVRp '84, MVRp + TVRp '97	SAVR + MVRp '14
Operating time, min	190	250	220
CC time, min	65	124	83
CPB time, min	124	142	108
MPG, mmHg	7	15	3
COD	Unmanageable septic vasoplegia	Unmanageable lung bleeding	Unmanageable lung bleeding

IE, infective endocarditis; ICU, intensive care unit; ES, EuroSCORE; MR, mitral regurgitation; SAVR, surgical aortic valve replacement; MVR, mitral valve replacement; TVRp, tricuspid valve replacement; CC, cross clamp; CPB, cardiopulmonary bypass; MPG, mean pressure gradient; COD, cause of death.

It could therefore be understood why in these patients we observed a relatively high 30-day and 6-month mortality, which is most probably unrelated to the type of the implanted valve prosthesis but could rather be attributed to the complexity of the procedure and the multimorbidity of the patients at the time of surgery (Table 4). Indeed, three patients in our cohort died during the first 30 days postoperative. All three of the patients presented with a logistic EuroSCORE over 50% and EuroSCORE II over 27%, which indicates an extremely high preoperative morbidity. The first patient presented with prosthesis endocarditis and underwent an emergent redo combined procedure. Although, the technical aspect of SU-AVR and concomitant mitral valve repair was flawless, after disconnecting from the CPB the patient suffered from a severe septic vasoplegia and due to the patient's 82 years of age the surgical team abstained from implanting an Extracorporeal Life Support Device. The second patient, a 75-year-old female, initially had an uneventful postoperative

course following an emergent combined redo procedure. However, two days after successfully weaning her from the respirator, a severe spontaneous lung bleeding occurred, which unfortunately was unmanageable even after input from the colleagues of the pulmonology department. The third patient was a 78-year-old female who had an uneventful postoperative course and was discharged on the eleventh postoperative day after the high-risk combined redo procedure. The patient was then readmitted with signs suggestive of pericardial tamponade for which an evacuation of pericardial effusion was carried out followed by her being directly weaned from the respirator. Unfortunately, the patient also developed spontaneous unmanageable lung bleeding, which was attempted to be controlled endoscopically but failed and subsequently led to the patients' death.

Besides the patients' age and comorbidities, having a relatively high proportion of patients with prosthesis endocarditis in our cohort (61.5%) also contributed to the high mortality, which in the current literature is estimated to range around 40–80% (19). Indeed, the high mortality rate reported in our cohort aligns with the data in the literature on high-risk patients presenting with active infective endocarditis. Moreover, no cause of death was related directly to the use of Perceval prosthesis. Taking into consideration the patients' desire to be treated after being thoroughly informed about the mortality and morbidity of infectious valve disease, supports the urgent need for developing surgical techniques and simplifying procedures for high-risk patients in whom radical debridement with a root replacement would take the already predicted high surgical risk to an unacceptable level.

A large portion of our cohort (61.5%) also underwent a concomitant procedure on the mitral- or tricuspid valve. Our team has already described our experience with SU-AVR in combined procedures, with this cohort showing no additional technical challenges for the implementation of sutureless prosthesis in patients undergoing concomitant mitral valve operation. Nonetheless, additional care should be taken while positioning and sizing both of the prostheses, as we have previously stated (5).

The current literature confirms that prolonged CPB and CC times remain significant factors determining ICU and hospital length of stay, mediastinal blood loss, and in-hospital mortality (20). Concistrè et al. in their single-center cohort study, report a CPB- and aortic CC time of 140±51.5 and 91.5±29.5 minutes, respectively in patients undergoing SU-AVR in combined procedures (21). Salsano et al. also emphasized the prognostic importance of CPB- and CC-time in patients undergoing surgery for infective endocarditis (22). Furthermore, CPB- and CC-time is also an independent predictor of mortality in elderly patients, as it correlates with a time-dependent inflammatory response (23). In our study, we observed a mean CPB- and aortic CC-time of 89.8±33.6 minutes and of 59.1±27.8 minutes, respectively. In our experience, SU-AVR performed specifically with the Snugger-method as described previously, allows a significant reduction of both CPB- and aortic CC-time (8,15). Moreover, the Snuggermethod provides a great technical success to the sutureless valve implantation in our cohort, which explains why in none of the patients a prosthesis dislocation or LVOT obstruction was observed.

The excellent hemodynamic performance of the Perceval valve was already previously discussed by our team (5,8). In this high-risk cohort, despite concomitant mitral valve procedures we observed a mean transvalvular gradient of 8.1 \pm 4.8 mmHg, being comparable to those previously mentioned in the study by Concistrè *et al.* (21). Remarkably, we also did not observe any cases of PVL following SU-AVR in our cohort, despite over a half of the cases having a concomitant mitral valve procedure performed (5,12). Indeed, postoperative PVL might be prevented by careful positioning of the prosthesis, proper decalcification and debridement followed by a patch reconstruction of the aortic annulus if necessary. Moreover, it is important to highlight that the experience of the surgical team plays a key role in the implantation success.

In our study none of the patients needed a permanent pacemaker implantation due to third degree atrioventricular block. The current literature on sutureless valve implantation shows comparable rates of pacemaker implantation in patients after either isolated SU-AVR or SU-AVR with concomitant mitral valve procedures (24). Furthermore, Robich *et al.* report significantly lower rates of permanent pacemaker implantation in concomitant mitral valve surgery with SU-AVR than when compared to conventional SAVR (25). Additionally, Clemence *et al.* show significantly higher rates of permanent pacemaker implantation in patients presenting with aortic valve endocarditis (26).

Disabling neurologic adverse events stroke are one of the most feared complications in cardiothoracic surgery. In the following cohort we observed no cases of disabling stroke, which agrees with our previous results after SU-AVR (5). Almost half of our cohort presented with vegetations on the aortic valve, which determined the urgency of the surgical procedure in most of the cases (27).

Study limitations

This study is limited by its retrospective, non-randomized singe-center nature and short follow-up time. Unfortunately, most of the data on this procedure is scarce and comes from a few analyses of small cohorts. Therefore, further prospective studies on larger cohorts should be conducted to validate the feasibility, safety and efficiency of this concept.

Conclusions

SU-AVR in patients with active infective endocarditis presents a safe and feasible alternative to conventional SAVR. This operative approach should be particularly considered for high-risk patients in whom successful

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operative outcomes are often determined by a reduction of CBP- and CC-time. As we have already presented in our previous studies, SU-AVR provides excellent hemodynamic performance with a low risk of PVL and low transvalvular gradients, whilst also drastically simplifying the surgical procedure. Extending the indications for SU-AVR towards infective endocarditis treatment could significantly benefit the patients presenting with a high operative risk. Precise sizing and positioning of the valve prostheses in multivalvular procedures is crucial for the postoperative outcome.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd. amegroups.com/article/view/10.21037/jtd-22-486/rc

Data Sharing Statement: Available at https://jtd.amegroups. com/article/view/10.21037/jtd-22-486/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups. com/article/view/10.21037/jtd-22-486/coif). AW is working as a proctor for LivaNova. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The present study obtained Institutional Review Board approval of the University Duisburg-Essen (Ref# 21-10427-BO). All Patients signed and gave informed consent to evaluate their data anonymously.

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Cite this article as: Zubarevich A, Rad AA, Szczechowicz M, Ruhparwar A, Weymann A. Sutureless aortic valve replacement in high-risk patients with active infective endocarditis. J Thorac Dis 2022;14(9):3178-3186. doi: 10.21037/jtd-22-486 speed? Bypass time and outcomes after isolated aortic valve replacement surgery. Interact Cardiovasc Thorac Surg 2014;19:21-6.

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