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Right Anterior Minithoracotomy for Aortic Valve Replacement with The Edwards Rapid Deployment Aortic Valve System

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Abstract

Background: Rapid deployment aortic valve systems may ease aortic replacement in challenging minimally invasive approaches. We report our results of a single-center observational study with the Edwards Rapid Deployment (RD) Valve System in Patients with a Right Anterior Mini-Thoracotomy Approach (RAT-AVR).

Methods: From 9/2013 to 3/2015, 30 consecutive patients received RAT-AVR with the RD valve system. Hemodynamic parameters and clinical outcome were assessed perioperatively, and at hospital discharge. To evaluate the learning curve patients were divided into three groups (Group 1; No.1-10 RD-AVR, group 2; No.11-20 RD-AVR, and group 3; No.21-30 RD-AVR) according to the chronological sequence.

Results: The median aortic clamp and cardiopulmonary bypass time for the entire patient cohort was 44.5 (35.0-54.3) min and 75.0 (63.8-102) min. Aortic clamp time (p=0.011) and cardiopulmonary bypass time (p=0.032) differed significantly between groups. Mortality rate was 6.7% and conversion rate was 6.7%, with no differences between groups. There was neither paravalvular leakage nor patient prosthesis mismatch.

Conclusions: RAT-AVR with the RD valve system is a feasible safe and reproducible procedure. Reproducible short cross-clamp-times can be achieved in a RAT-AVR setting within a short period of time, which might increase the acceptance of RAT-AVR among surgeons.

Keywords: Intuity Elite System; Minimally Invasive AVR; Right Anterior Thoracotomy

Glossary of Abbreviations

AVR	:	Aortic Valve Replacement
AV III°	:	Third Degree AV Block
BMI	:	Body Mass Index
BSA	:	Body Surface Area
CABG	:	Coronary Artery Bypass Grafting
COPD	:	Chronic Obstructive Pulmonary Disease
CPB	:	Cardiopulmonary Bypass
DM	:	Diabetes Mellitus
ECMO	:	Extracorporeal Membrane Oxygenation
EOA	:	Effective Orifice Area
ICU	:	Intensive Care Unit
LVEF	:	Left Ventricular Ejection Fraction
NYHA	:	New York Heart Association Classification
PAVD	:	Peripheral Arterial Vascular Disease
PPM	:	Patient Prosthesis Mismatch
RAT-AVR	:	Right Anterior Mini-thoracotomy Aortic Valve Replacement
RD	:	Rapid Deployment
RD-AVR	:	Rapid Deployment Aortic Valve Replacement

TND : Temporary Neurological Dysfunction

Introduction

Minimally invasive Aortic Valve Replacement through Right Anterior Mini-Thoracotomy (RAT-AVR) has been developed as an alternative to full sternotomy and hemi-sternotomy aortic valve replacement [1,2]. Although feasibility, reproducibility and favorable outcomes have been reported repeatedly over the last years [2-8] RAT-AVR has not yet become a widespread surgical technique. Frequently used arguments against hemi-sternotomy AVR are prolonged aortic cross-clamp and bypass time; these arguments may be even more pronounced for RAT-AVR, which can be a challenging procedure indeed. Albeit clinical outcomes for minimal invasive aortic valve surgery are promising, only 24.6 % of surgical AVR in Germany have been performed by minimally invasive access in 2013 [9]. The reluctance to adopt minimally invasive aortic valve surgery may have detrimental effects for the entire cardiac surgical field. Recent data comparing transcatheter AVR and surgical AVR in less than high risk patients showed no difference in mortality between patients during a 3 year follow up, with significantly higher incidences of fatal events and life-threatening bleeding complications in the surgical group [10]. These data clearly demonstrate that cardiac surgeons have to improve their surgical skills and have to adopt new surgical techniques to minimize surgical trauma, which will subsequently lead to better clinical outcomes [11]. Rapid deployment valve technologies or suture less valve technologies have been introduced recently to simplify full and hemi-sternotomy AVR, reducing cross-clamp and bypass time [12-14]. The data from recent publications clearly demonstrate the safety and effectiveness of this new technology [15, 16]. However, there are only few studies published regarding rapid deployment valves for RAT-AVR [17,18]. To the best of our knowledge, no study has been published evaluating the rapid deployment Edwards valve system for RAT-AVR and focusing on procedural surgical parameters. Thus, the aim of this study is to evaluate our experience with the rapid deployment Edwards valve system (RD-valve system) (Edwards Life science Corp; Irvine, Calif) for RAT-AVR.

Materials and Methods

The ethics committee of the University Hospital Wuerzburg approved the present study

This was a retrospective study of prospectively collected data from consecutive patients with aortic valve stenosis scheduled for elective RAT-AVR by means of the RD-valve system in the University Hospital Wuerzburg between 09/2013 and 03/2015. During this timeframe 54 patients received an RAT-AVR or isolated AVR. All patients scheduled for surgical aortic valve replacement underwent 64 slice computed tomography (Somatom Definition ATS, Siemens, Germany) without contrast enhancement to evaluate whether the patients are suitable for RAT-AVR. Criteria for suitability for RAT-AVR are described by Glauber et al. [1], his main criteria for RAT -AVR are 1. that >50% of the ascending aorta has to be on the right side of the right sternal edge and 2 the distance from the ascending aorta to the sternum should not exceed 10 cm with both measurements at the level of the pulmonary bifurcation. Since we believe that a distance of 10 cm between aorta could lead to a cumbersome implantation of biological aortic valve prosthesis we determine that the distance from the ascending aorta to the sternum should not exceed 8 cm. Thus, institutional contraindications for RAT-AVR were a distance > 8 cm between the sternum and the ascending aorta. Furthermore, an aortic annulus diameter greater than the diameter of the sinutubular junction was accepted as a contraindication for RAT-AVR. RD-valve system was primary choice for AVR in general, however, contraindication for RD-valve implantation were a bicuspid aortic valve, non-calcified aortic valve pathology and an aortic valve annulus >27mm in diameter. 24 patients met these exclusion criteria for the RD-valve system and subsequently received a normal stented bioprosthesis.

The RD-valve system consists of a stented bovine pericardial bio prosthesis. Basically, it is the Edwards Paramount platform (Edwards Life science Corp; Irvine, Calif) attached to a balloon expandable, cloth covered skirt frame at the inflow part of the valve. A balloon catheter is used to deploy the valve after proper placement within the native aortic annulus. During inflation of the balloon the skirt frame will be expanded, not the valve platform itself. According to the chronological sequence of RAT-AVR performed patients were divided into three groups (Group 1; No.1-10 RD-AVR, group 2; No.11-20 RD-AVR, and group 3; No.21-30 RD-AVR) in order to evaluate the effect of the learning curve with RD-valve system for RAT-AVR. In all patients' preoperative, perioperative and outcome data were recorded and compared. In particular aortic cross clamp time and cardiopulmonary bypass time. Furthermore, intubation time, incidence of stroke, Temporary Neurological Dysfunction (TND) and in- hospital mortality or 30-day mortality was recorded. In addition to clinical variables, postoperative transthoracic echocardiographic parameters (mean-maximum valvular gradients, aortic valve opening area and paravalvular leakage) were obtained before hospital discharge. PPM was calculated; severe PPM was defined as an effective orifice area < 0.65 cm^2/m^2 and moderate PPM was defined as <0.85 cm^2/m^2 [19, 20].

Surgical Procedure

All procedures were performed by one surgeon (R.L) with experience in RAT-AVR. After induction of general anesthesia RAT-AVR was performed through a 5-6cm skin incision placed above the third intercostal space, the fourth rib was separated from the sternum, and the right mammary artery was transected in all patients. Thorough dissection of mediastinal fat tissue

was performed, the pericardium was opened longitudinally, and numerous stay sutures were placed. A soft tissue retractor (Alexis Wound Protector, Applied Medical, USA), together with a small rib retractor (MRP-1, Fehling, Germany) was inserted to increase visualization of the surgical field. Direct ascending aortic cannulation with a flexible cannula (Easy flow Duo Cannula, Sorin Group, Italy) was performed in 24 patients; in the remaining 6 patients percutaneous arterial cannulation was performed. Percutaneous venous cannulation (RAP femoral venous cannula, Sorin Group Italy) was used in all patients. Surgery was performed at moderate hypothermia (32˚C) and the standard myocardial protection was used. Before clamping the aorta a left atrial vent was placed in the right upper pulmonary vein in a usual fashion. After administration of cardioplegia a standard hockey stick incision was performed to expose the native aortic valve and thorough decalcification of the aortic annulus was performed. Exact sizing is important to omit the risk of malposition of the valve, since oversizing will result in valve luxation and under sizing in paravalvular leakage. Three equidistant braided sutures were placed through the annulus at the nadir of each sinus as guiding sutures and were brought through the corresponding part of the sewing ring.

The valve system was lowered into the aortic annulus by use of the guiding sutures. The guiding sutures were snared and the balloon catheter was inflated for 10 seconds to deploy the stent frame. After deployment the delivery system and valve holder were removed, and the guiding sutures tied. The aortotomy was closed in a typical double layer fashion. After weaning the patient from cardiopulmonary bypass standard transoesophegal echocardiographic examination of the implanted valve was performed to rule out any paravalvular leakage. In all patients the separated rib was reattached to the sternum and standard closure of the thoracotomy was performed. Postoperative anticoagulation was in accordance with the Guidelines for Management of Patients with Valvular Disease [21]. According to that, all patients were put on vitamin K antagonists for three months, unless contraindications for oral anticoagulation were present.

Statistical Analysis

Statistical analysis was performed using SPSS, version 23. Patient demographics are presented as mean ± standard deviation, medians and interquartile ranges and number of observations with proportions (%), as appropriate. Differences across groups were assessed by Kruskal-Wallis-Test and χ^2-test/Fisher´s exact test; post hoc Mann-Whitney-U Test respectively. Two-sided p-values < 0.05 were considered statistically significant. Kruskal-Wallis Test (via simulation) was used for a retrospective power calculation. PASS 13 was used for power calculations.

Results

Patient's demographics are depicted in (Table 1).

Variable	All pts. (n=30)	Group-1 (n=10)	Group-2 (n=10)	Group-3 (n=10)	p-value
Age (y)	77(73.7-80.0)	75.6(71.4-78.8)	76.5(75.2-83.2)	78(73.5-80.0)	0.49
BSA (m^2)	1.88(1.71-2.01)	1.91(1.76-1.98)	1.9(1.7-2.05)	1.78(1.6-1.94)	0.36
BMI	26.5(24.1-28.4)	27.4(23.2-28.8)	25.9(22.8-28.1)	25.5(24.1-29.2)	>0.90
Female gender; % (n)	33 (10/30)	20 (2/10)	40 (4/10)	40 (4/10)	0.7
COPD; % (n)	47 (14/30)	50 (5/10)	40 (4/10)	50 (5/10)	1
DM; % (n)	50(15/30)	60 (6/10)	60 (6/10)	30 (3/10)	0.47
Creatinine (mg/dl)	1.2(1.0-1.43)	1.07(0.81-1.31)	1.20(1.05-1.3)	1.45(0.95-1.73)	0.35
Crea-clearance (ml/min)	59.0(48.8-71.8)	71.0(50.0-83.0)	57.0(50.0-68.5)	49.5(38.8-71.0)	0.12
Chron. Afib; % (n)	27 (8/30)	40 (4/10)	30 (3/10)	10(1/10)	0.45
PAVD; % (n)	20 (6/30)	0	40 (4/10)	20 (2/10)	0.12
Stroke; % (n)	6.7 (2/30)	0	10 (1/10)	10 (1/10)	>0.9
TND % (n)	6.7 (2/30)	0	10 (1/10)	10 (1/10)	>0.9
Art. hypertension; % (n)	97(29/30)	100 (10/10)	90 (9/10)	100 (10/10)	>0.9
Pul. hypertension; % (n)	47 (14/30)	50 (5/10)	40 (4/30)	50 (5/10)	>0.9
NYHA class III -IV; % (n)	66 (20/30)	70(7/10)	70(7/10)	60(6/10)	0.88
LVEF (%)	49.0(43.0-64.0)	63.5(44.5-70.5)	49.0(44.0-67.0)	47.0(41.3-58.3)	0.3
EuroScore II	6.9(5.0-11.7)	6.9(4.8-11.5)	6.9(4.9-13.3)	6.9(5.1-10.0)	0.82

Data presented as IQR and quartiles, or as % (n) unless otherwise indicated. BSA: body surface area; BMI: body mass index; TND: Temporary Neurological Dysfunction; COPD: Chronic Obstructive Pulmonary Disease; DM: Diabetes Mellitus; NYHA: New York Heart Association Classification; LVEF: Left Ventricular Ejection Fraction; PAVD: peripheral arterial vascular disease; pulmonary hypertension: mean pulmonary pressure > 30 mmHG. p-values were taken from Kruskal-Wallis Test, χ^2/Fisher's Exact Test.

Table 1: Patients characteristic

No difference was found in demographic data between the groups. Surgical data are shown in (Table 2).

Variable	All pts. (n=30)	Group-1 (n=10)	Group-2 (n=10)	Group-3 (n=10)	p-value	Post-hoc
CPB time (min)	75.0(63.8-102.0)	83.5(68-102.3)	87(62.5-113.0)	65(50-76.3)	0.032	Group 1 vs. 2; p=0.65 Group 1 vs. 3; p=0.025 Group 2 vs. 3; p=0.025
aortic clamp time (min)	44.5(35.0-54.3)	49(43.3-63.0)	45 (32.5-58)	35(29.5-41.3)	0.011	Group 1 vs. 2; p=0.33 Group 1 vs. 3; p=0.002 Group 2 vs. 3; p=0.10
Prosthesis Diameter (mm)	23(21-25)	23(21-25)	23(22-25)	23(22.5-25.5)	0.78	NA

Data presented as IQR and quartiles, CPB: Cardiopulmonary bypass. P-values were taken from Kruskal-Wallis-Test and post hoc Mann-Whitney testing.

Table 2: Intraoperative characteristics.

We observed significant difference in aortic cross-clamp time (p=0.011), and cardiopulmonary bypass time (p=0.032), post-hoc analysis for aortic cross clamp-time showed statistical significant difference between group 1 and group 3 (p=0.002), post-hoc analysis for cardiopulmonary bypass-time showed statistical significant difference between group 1 and group 3 (p=0.025) and group 2 and group 3 (p=0.025) respectively. The retrospective power analysis showed that the total sample of 30 subjects achieves a power of 0,857 at a significance level of 0.05 to detect a difference between the three groups concerning the aortic clamp time. This power allows assuming, that the probability of a type 1 error is low.

No differences for intra- and postoperative outcome were observed (Table 3).

Variable	All pts. (n=30)	Group-1 (n=10)	Group-2 (n=10)	Group-3 (n=10)	p-value	Post- hoc
Mortality; % (n)	6.7 (2/30)	0	10 (1/10)	10 (1/10)	>0.9	
Conversion rate; % (n)	6.7 (2/30)	0	20 (2/10)	0	0.31	
Stroke; % (n)	0	0	0	0	>0.9	
TND; % (n)	0	0	0	0	>0.9	
Re-exploration for bleeding; % (n)	0	0	0	0	>0.9	
New AV III°; % (n)	3.3 (1/30)	0	10 (1/10)	0	>0.9	
Ventilation time (h)	11(8-14)	11(10-13)	13(10-22)	8(7-12)	0.025	Group 1 vs. 2; p=0.34 Group 1 vs. 3; p=0.052 Group2 vs.3; p=0.012
ICU stay (h)	1(1-3)	2(1-3)	1 (1-5)	1(1-1)	0.18	

Data presented as median and interquartile ranges or as % (n), AV III°: third degree AV block, TND: temporary neurological dysfunction, ICU: intensive care unit. P-values were taken from Fisher's Exact test for binary variables and from ANOVA for continuous variables.

Table 3: Intra- and postoperative Outcome.

Conversion rate to full sternotomy was 6.7% (2/30), and hospital mortality was 6.7% (2/30). There was no valve explantation for paravalvular leakage or malposition. As aforementioned the only valve explantation was performed for aortic root replacement due to aortic root laceration. During the study neither herniation nor wound complications were detected. For patients with a valve diameter between 21mm to 27mm only single digit mean gradients were detected. Neither paravalvular leakage nor PPM was found in our patient cohort. The patient receiving an aortic root replacement was excluded from hemodynamic measurement, thus data from 29 patients are presented (Table 4).

Valve Size	Max. gradient (mmHG)	Mean gradient (mmHG)	EOA cm^2	Indexed EOA cm^2/m^2
19mm (n=1)	14	11	2	1.2
21mm (n=6)	12.0 (10.7 - 12.5	8.0 (7.0 - 9.0)	2.1 (2.0 - 2.2)	1.25 (1.16 - 1.35)
23mm (n=10)	12 (10.0 - 13.2)	7.5 (6.7 - 9.0)	2.3(2.2 - 2.4)	1.19 (1.14 - 1.26)
25mm (n=10)	11.0 (8.7 - 12.0)	7.0 (5.7 - 9.0)	2.5 (2.4 - 2.7)	1.34 (1.29 - 1.45)
27mm (n=2)	12	7	2.7	1.38
Data presented as IQR and quartiles or as single values for the 19 mm. EOA: effective orifice area.				

Table 4: Hemodynamics according to diameter: Edwards RD-valve system.

Discussion

We demonstrated a short and steep learning curve for implantation of Edwards's rapid deployment valve system for AVR through right anterior thoracotomy as evidenced by quickly decreasing aortic cross clamp time. Our data showed that only a small number of implantations are necessary to achieve aortic cross clamp time for RAT-AVR comparable to full sternotomy respectively upper hemi-sternotomy AVR using rapid deployment valve systems. After twenty implantation we were able to achieve a median aortic cross clamp time of 35.0(29.5-41.3) minutes, which is comparable to recently published data from other groups who demonstrated mean aortic cross clamp times between 26 and 41 minutes for the same valve type in upper hemi-sternotomy AVR [13,14]. Recently Bowdish and coworkers have conducted a comprehensive review of the literature comparing RAT-AVR to standard full sternotomy AVR. Consistent advantages were decreased ICU and hospital length of stay, decreased blood transfusion and ventilation time, while consistent were disadvantages like increased aortic cross-clamp and cardiopulmonary bypass time [5]. Rapid deployment aortic valve technologies have been introduced to simplify aortic valve replacement by reducing aortic cross-clamp and cardiopulmonary bypass time. It has been shown that these new valve technologies offer major advantages especially in minimally invasive surgical setups [12-16].

Basically, two different rapid deployment valve systems are commercially available these days, the Perceval S valve prosthesis (Sorin Biomedica Cardio Srl, Sallugia, Italy), and the Edwards RD-valve system. Data from Perceval S and 3f-Enable have been published in the context of AVR through right anterior thoracotomy. This is the first systematic evaluation of the Edwards rapid deployment valve system for RAT-AVR. The overall aortic cross clamp times (44.7 ± 13.2 minutes) in our patient cohort are favorably compared to published data with other aortic rapid deployment valve types. Vola and coworkers recently published their experience with *3f*-Enable sutureless valve implants for RAT-AVR in n=71 patients, they reported an aortic cross clamp time of 66 ± 19 minutes [18]. Gilmanov et al. reported comparable aortic cross clamp-times (59 ± 19 minutes) in 137 consecutive patients receiving the Perceval S valve for RAT-AVR [17]. When comparing aortic cross-clamp times it has to be acknowledged that rapid deployment valves are only auxiliary devices reducing cross clamp times. The same results can be achieved with conventional valves. Bowdish et al. reported on n=294 patients with RAT-AVR a mean cross clamp time of 58 minutes and Mikus et al. reported a mean cross clamp time of 52 minutes in n=206 patients [5,7]. However, these results are outstanding and may be difficult to be reproduced by others. The mean aortic cross-clamp time in our patient cohort was between 7- to 22 minutes shorter for the entire patient cohort and 16 to 31 minutes shorter for the last 10 patients in our cohort, compared with reports from other studies in RAT-AVR [5,7,17,18]. Although it is arguable whether this reduction in cross-clamp time is of clinical importance it has to be considered that firstly prolonged cross-clamp time is strongly correlated with postoperative morbidity and mortality [22,23], and secondly that potentially prolonged cross-clamp time is one of the main argument against any kind of minimal invasive AVR. Albeit the complexity of RAT-AVR may still be of concern for some surgeons' our data indicates that rapid deployment valve technology facilitates RAT-AVR with reasonable aortic cross clamp time. Sizing of the annulus was unsophisticated in all patients and did not influence prosthesis choice, with the exemption that the Edwards RD Intuity valve system is only available for an annulus size up to 27mm in diameter.

The longevity of rapid deployment valves has not been proven yet. The difference between the above mentioned valve systems are that except for the Edwards RD-valve system every valve has to be collapsed prior to implantation. Munnelly and coworkers demonstrated that crimping of bovine pericardium lead to tissue cracks and fiber damage detected by scanning electron microscopy [24], which could in time facilitate premature tissue failure. Speaking about long-term performance of the Edwards RD-valve system, it has to kept in mind that this valve system is basically a Paramount biological tissue valve attached to an expandable sub-annular skirt. Bourguignon et al showed long-term results for the Paramount valve with an age stratified freedom from reoperation due to structural valve deterioration at 15 years with 71% for patients < 60years, 83% for those between 60 to 70 years and 98% for patients >70 years [25], thus it can be speculated that the same longevity could be anticipated for the Edwards RD-valve system. However, whether balloon expansion of the sub-valvular skirt frame has any impact on leaflet tissue integrity that could alter the long-term performance has not been evaluated yet.

Valve hemodynamics at discharge showed excellent results. The mean pressure gradients at discharge showed single digit numbers for all valve size implanted, except the 19mm valve, these gradients are similar to those published for minimal hemi-sternotomy AVR [13,14,26]. Furthermore, neither PPM nor paravalvular leakage was detected in this series. Low incidences of PPM and paravalvular leakage have already been described for this rapid deployment valve system [13,14,26]. The complication rate was remarkably low: with an incidence of pacemaker implantation in the postoperative period of 3.3% (1/30). This compares favorably with previous reports for this valve type [13,14,26]. Two patients had to be converted to full sternotomy due to surgical complications. A 78-year-old female patient needed aortic root replacement in combination with CABG due to a lacerated aortic root after initial successful implantation of the RD valve. This lady presented with severe aortic root calcification. It has been described that especially in elderly females presenting with narrow atherosclerotic roots the aortic wall may susceptible to injury during aortic valve replacement, a finding present, in this patient [27]. The second patient was a 73-year-old male patient, who needed to be resuscitated while preparing for percutaneous venous femoral cannulation, external chest compression was performed, and the femoral venous cannula was rapidly introduced. After uneventful RAT-AVR the patient was weaned from cardiopulmonary bypass, however due to excessive blood loss the patient had to be put on bypass again. A full sternotomy was performed, a bleeding source was found in the right ventricle, due to laceration with the venous cannula.

Two patients died perioperatively; the aforementioned 78-year-old lady with a preoperative Euro Score II of 13.3% died postoperative day 5. The second patient, a 78-year-old male patient died on postoperative day 5 after an uneventful perioperative course. The postoperative routine echocardiography on the day of his death showed good hemodynamics of the implanted valve and a preserved left and right ventricular function. However, no autopsy was performed; although nothing indicates a valve related problem this death has to be considered as valve related mortality according guidelines for reporting mortality and morbidity after cardiac valve interventions [28]. A mortality rate of 6.7 % for single AVR appears high, however, Euro Score II for the entire patient cohort was 8.6±4.6%. During the same time frame a total of 54 RAT-AVR were performed with a cumulative mortality rate of 3.7% (2/54) (Euro Score II; 7.8±5%). Since completion of this study, 75 additional patients were treated with RAT-AVR (42 RD-valves; 33 standard valves) with no mortality. According to that 129 patients received RAT-AVR from 9/2013 to 6/2017, with n=72 patients receiving a RD-valve, the mortality rate for the entire patient cohort is 1.6% (2/129).

Limitation of the study

Several facts could have influenced our results.

The small number of patients evaluated. The aim of the study was to evaluate the learning curve for an RD-valve system for RAT-AVR. We demonstrated a rapid and steep learning curve after 30 patients only. Further improvement of aortic cross clamp time was not obvious anymore and reached a plateau, therefore we believe that the number of patient evaluated is sufficient large to demonstrate the learning curve. Furthermore, we performed a retrospective power analysis and calculated for the sample size n=30 subjects a power of 0.857 at a significance level of 0.05 for detecting differences in the aortic cross clamp time. This power analysis let us assume that a type 1 error can be excluded with a high probability.

- A selection bias cannot be ruled out definitively. However, this is a consecutive series of patients scheduled for RAT-AVR. The only contraindication for placing the Edwards RD-valve system was a true bicuspid aortic valve, and an annulus size larger 27mm. Furthermore, the groups were comparable concerning important confounder regarding a surgical approach, especially BMI.
- For the clearer understanding of the data presented it has to be pointed out that these data come from a single center and a single surgeon experience.

Conclusion

Our preliminary data indicate that the Edwards RD-valve system is a good match for RAT-AVR, with reproducible results and good hemodynamic performance. The valve has the potential to ease the surgical procedure, due to the trouble free fast implantation technique reflected by short aortic cross-clamp times,

which can be accomplished in a very short time frame. These factors might increase the acceptance of RAT-AVR within the surgical community. For final judgment of this valve system for RAT-AVR larger studies with multiple surgeons are mandatory to confirm our results. Furthermore, long-term follow up is necessary to evaluate the longevity of the valve and to prove the good hemodynamics in the long run.

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