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Article

The Establishment of a Transaxillary Minimally Invasive Aortic Valve Replacement Program: Considerations and First Patient Outcomes

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Abstract

Background: As minimally invasive and alternative approaches for aortic valve repair gain increased popularity, this trial reports on outcomes of an established program using the underreported novel right transaxillary (rTX) access for aortic valve surgery. **Methods**: Between June 2023 and May 2025, a total of 22 patients underwent aortic valve surgery using the rTx approach (female: n = 14 (63.6%); age: 64.5 (60.0–70.0) years; EuroSCORE II: 0.9 (0.6–1.1)), mainly for aortic valve stenosis (n = 17 (77.3%)) and primarily with cannulation of the right groin (n = 21 (95.5%)) for cardiopulmonary bypass (CPB). **Results**: The median aortic clamp time was 78.5 (74.8–90.3) minutes, and the median extracorporeal circulation time was 143.0 (134.8–178.3) minutes. One (4.5%) patient underwent acute surgical revision via sternotomy due to bleeding from the aortotomy, while aortic root replacement was successfully performed. One (4.5%) patient experienced a stroke, and one (4.5%) received a pacemaker for high-grade atrioventricular block. Regarding CPB and surgical access site complications, one (4.5%) patient had a postoperative hematoma at the right groin, and one (4.5%) had a surgically revised thoracic hematoma. The median intensive care unit stay was 1.0 (1.0–2.3) days. No patient died during the median follow-up period of 6.0 (3.0–16.5) months. **Conclusion**: Minimally invasive aortic valve surgery by rTX is feasible for a variety of valve pathologies, revealing good clinical outcomes even at the start of such a program. The low learning curve at experienced centers for minimally invasive cardiac surgery encourages other centers to adopt this approach as the potential future standard for aortic valve surgery.

Keywords: minimally invasive aortic valve surgery; right transaxillary aortic valve surgery; aortic valve surgery; minimally invasive cardiac surgery; cardiac surgery

1. Introduction

In an effort to minimize surgical trauma and invasiveness with consecutive benefit on patient outcome by minimally invasive aortic valve surgery (MIAVS) [1–4], the right transaxillary (rTX) access has emerged as a relatively novel approach in this regard. The experience with this approach and outcomes of the given technique are yet underreported in current literature.

With minimally invasive approaches tailored according to the patients' comorbidities and anatomical properties, transcatheter aortic valve implantation (TAVI) established the current benchmark of a truly minimally invasive approach for aortic valve stenosis. However, treatment assignment of a relative target population for TAVI with intended mitigation of associated surgical complications potentially deprives patients of an ideal treatment concept [5]. Interestingly, the patients' willingness of favoring a minimally invasive approach at the cost of increased procedural risk according to recent benefit-risk analysis [6] is matched by the surgeons preference for adopting minimally invasiveness in clinical practice, even by opposing recommendations of current guidelines [7,8], as TAVI represents currently the most common treatment option for aortic valve stenosis regardless of age [9].

Recent nation-wide registries report that still the majority of single aortic and mitral valve operations are being carried out by median sternotomy [10]. Hesitation of adapting given minimally-invasive approaches into clinical practice might considerably be based on a restricted surgical view, higher surgical complexity and approach specific drawbacks such as complications arising from peripheral cannulation [11].

In this regard, the novel rTX approach unfolds itself as a viable alternative by excellent exposure of the anatomical site, especially the aortic annulus, by entering a wider and more lateral intercostal space while offering very pleasing cosmetic results. Furthermore and in contrast to the right anterior thoracotomy (RAT) approach, this access is preserving the internal thoracic artery and there is no need of a non-tissue-friendly retractor. Another very important advantage is that this access perfectly allows to address the left atrial appendage and facilitate atrioventricular valve repair [12].

The current scarce literature on rTX reports on excellent clinical outcomes, with less postoperative atrial fibrillation, reduced transfusion requirements and shorter intensive care unit (ICU) stay compared to median sternotomy [13], as well as improved wound healing compared to RAT

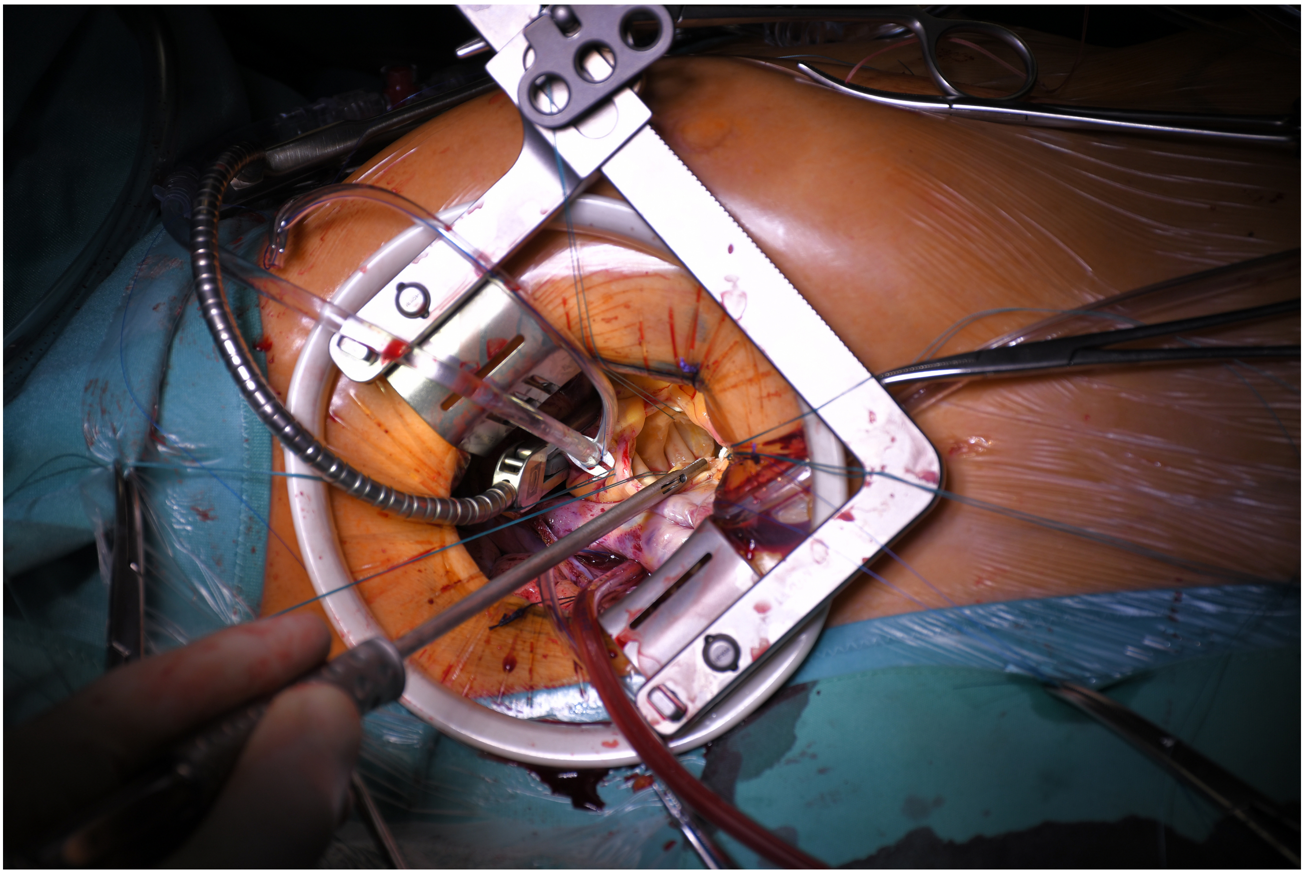

Fig. 1. Exposure of the aortic root with stay sutures during aortic valve replacement by the right transaxillary approach.

[14] and lower 30 day mortality in obese patients in this regard [15]. Reported longer cardiac ischemia times during the rTX approach and minimally invasive cardiac surgery in general [3,13,15], notably a potent mortality risk factor [16–18], might be reduced by application of sutureless deployment aortic valves (SUV) [19]. Application of SUV prosthesis might be appealing particularly in the given patient collective and those with increased operative risk [16,17]. However, potential clinical implications and surgical considerations of the respective prosthesis' choice during the rTX approach are not addressed in current literature.

Therefore, with the rTX approach currently emerging as a promising concept for aortic valve surgery, yet to be popularized as a standard of care concept during an ongoing demand for minimally invasive practices, we would like to share our first experience with the rTX access for aortic valve replacement and give insights on how to start a safe program at your center.

2. Methods

2.1 Study Design

The given study is a retrospective single center analysis of all patients undergoing aortic valve surgery by rTX approach from 06/2023-05/2025 at the Department of Cardio-Vascular and Thoracic Surgery of the Kepler University Hospital: Kepler University Hospital Ltd, Linz, Austria. The study approval was granted by the local ethics committee (No.: 1176/2023-20.10.2023).

Brachial plexus complications were evaluated by electromyography in case of sensomotoric deficit of the upper limbs, while stroke was assessed by cerebral computer tomography or magnetic resonance tomography. Evaluation of each was conducted by neurologists and radiologists. Electrocardiography was conducted continuously during intensive care unit stay, as well as once daily afterwards up to the seventh postoperative day and then at the physician's request during hospital stay.

2.2 Surgical Technique

Patient positioning is carried out according to the Javelin thrower's position and special care must be taken in regards to brachial plexus injury. At first, CPB is established with peripheral percutaneous cannulation via the femoral vessels, with application of two ProStyle™ systems (Abbott Vascular, CA, USA) for the femoral artery closure at the end of CPB. Percutaneous cannulation is proceeded according to the Seldinger technique at the right femoral artery (17 or 19 Fr, Maquet GmbH, Getinge Group, Rastatt, Germany) and at the right femoral vein (25 Fr, Maquet GmbH, Getinge Group, Rastatt, Germany). In case of contraindication for femoral cannulation, the left sub-

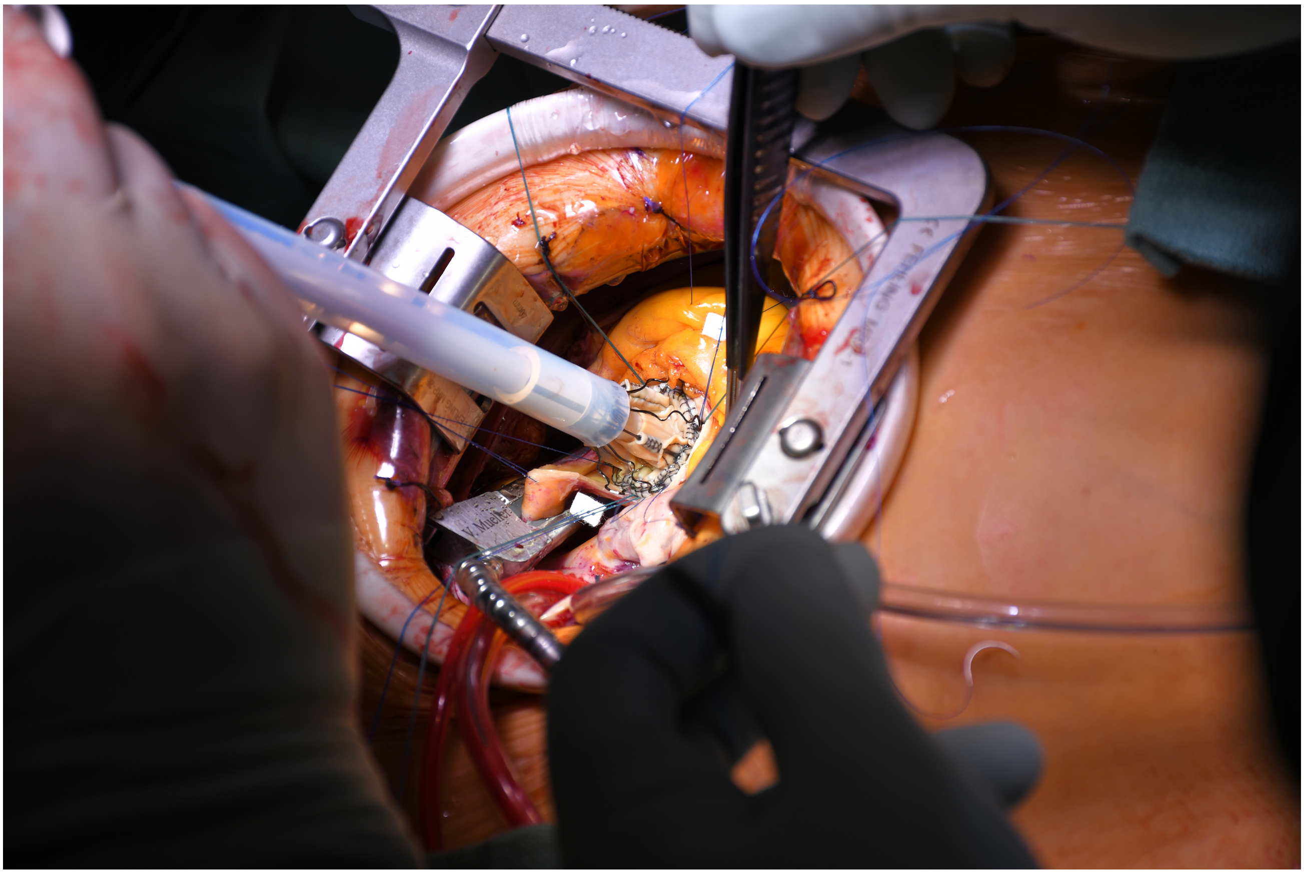

Fig. 2. Aortic valve replacement by the right transaxillary approach with the Perceval PLUS Sutureless Heart Valve® prosthesis.

clavian artery is surgically exposed and directly cannulated (cannulas from Maquet GmbH, Getinge Group, Rastatt, Germany). When CPB is started, lung insufflation is stopped and right axillary skin incision of 6 cm is made at the right anterior axillary line. The tissue between the right major pectoralis muscle and the latissimus dorsi muscle is dissected into the third intercostal space. Alexis® wound protector/retractor (Applied Medical Resources Corporation, Rancho Santa Margarita, CA, USA) and occasionally the MICS MRP-1F intercostal retractor® (Fehling Instruments GmbH, Karlstein, Germany) were inserted. Long shafted instruments are used for the procedure. After pericardial incision, six to eight pericardial stay sutures are applied for optimal exposure. A cardiac vent is placed into the right upper pulmonary vein and an antegrade cardioplegia cannula into the aorta. The aorta is carefully dissected next to the right pulmonary artery and cross-clamped with a COSGROVE Quick Bend™ Flex Clamp (V. Mueller®, Allegiance Healthcare Corp., IL, USA). Approximately 1-1,2 liters of St. Thomas cardioplegia is applied either antegrade through an antegrade cardioplegia cannula and additionally, or solely ostial through coronary ostium cannulae. Hockey stick aortotomy is performed, extending into the non-coronary sinus, and two to three stay sutures for exposure of the aortic valve are placed. After excision of the native aortic valve, the respective prosthesis is implanted with sutures tied by the COR-KNOT® (LSI Solutions, Victor, NY, USA) device in case of conventional biologic aortic valve prosthesis (Fig. 1). Regarding the implantation technique of the Perceval PLUS Sutureless Heart Valve® (Corcym UK Limited, London, UK) (Fig. 2), we refer to our previous publication in this regard [20]. Commissural stay sutures (3-0 Prolene RB) might add additional advantage of better exposure and are helpful as countertraction when sliding down the valve into the annulus. The aortotomy is closed by a pledged 4.0 Prolene SH double running suture. Only a single right-sided pleural drain was placed.

2.3 Patient Selection

All patients with isolated aortic valve disease including stenosis, regurgitation, endocarditis and fibroelastoma are screened by our structural heart disease team for whether they are eligible for rTX access, with patients included in the given series being ruled into the respective program non-consecutively within the given time interval. Emergency surgery, redo aortic valve surgery, and expected severe lung or pericardial adhesions are relative contraindications, as given circumstances might increase intricacy of aortic valve surgery by the rTX approach. Noteworthy, while preoperative morbidities such as chronic lung disease, renal failure and frailty impair feasibility of on-pump cardiac surgery in general, given attributes partially constitute the target patient collective intended to benefit from the rTX approach. Preoperative imaging for feasibility evaluation of the rTX approach during aortic valve surgery include transthoracic echocardiography, coronary angiography and extracranial vessel duplex sonography according to the institutions standard protocol of preoperative imaging for aortic valve surgery. Computed tomography angiography of the complete aorta is crucial for evaluation of aortic and peripheral vessel anatomic properties. While in case of severe peripheral vessel calcification, left subclavian artery cannulation is a viable alternative at our institution, severe ascending aortic calcification is considered a contraindication for the rTX approach. Although, commissural stay suture expose the aortic annulus closer to the access site, measured annulus to chest wall distance exceeding 13 cm and chest wall deformities might impede the feasibility of the procedure. Additional aortopathies like aortic atheroma, relevant aortic aneurysm and aortic dissection need to be ruled out. Additional procedures such as left atrial appendage closure (LAAc) or reduction ascending aortoplasty are easily feasible.

2.4 Statistical Analysis

SPSS statistical software Version 26 (IBM Corp, Armonk, NY, USA) and GraphPad Prism 9 (GraphPad Software, LLC., San Diego, CA, USA) was used for statistical analysis. Categorical data are presented as numbers and percentages, continuous variables as median and interquartile range (IQR).

3. Results

3.1 Preoperative Patient Characteristics

Within the given time interval, overall 22 patients underwent aortic valve surgery by the rTX approach. The median age was 64.5 (60.0–70.0) years, with 14 (63.6%) patients being female. The mean EuroSCORE II was 0.9% (0.6–1.1). No patient underwent prior cardiac surgery. Six (27.3%) patients presented with non-severe coronary heart disease at intended aortic valve surgery, without prior history of coronary revascularization. Further patient baseline data are revealed in Table 1.

Table 1. Patient baseline data.

n = (all)	22 (100)
Female	14 (63.6)
Age in years, median (IQR)	64.5 (60.0–70.0)
BMI, median (IQR)	25.8 (21.6–28.4)
EuroSCORE II in %, median (IQR)	0.9 (0.6–1.1)
Hypertension	10 (45.5)
Hyperlipidemia	14 (63.6)
Creatinine in mg/dL, median (IQR)	0.9 (0.8–1.0)
Diabetes mellitus	1 (4.5)
Chronic obstructive pulmonary disease	1 (4.5)
Atrial fibrillation	2 (9.1)
Endocarditis	1 (4.5)
Prior stroke	1 (4.5)
Coronary heart disease	6 (27.3)
Prior myocardial infarction	1 (4.5)

BMI, body mass index; EuroSCORE II, updated European system for cardiac operative risk evaluation; IQR, interquartile range.

3.2 Procedural and Echocardiography Data

All patients underwent elective aortic valve surgery. The majority of patients had severe aortic valve stenosis (n = 17; [77.3%]), with five (22.7%) patients having severe aortic valve regurgitation as primary surgical indication and seven (31.8%) patients having underlying bicuspid aortic valve morphology. In all but one patient (n = 21; [95.5%]), CPB was established via the right groin by percutaneous cannulation of the right femoral artery, while one (4.5%) patient underwent left subclavian artery cannulation due to severe calcifications and plaques of the abdominal aorta and femoral arteries. There was no conversion to median sternotomy or change of cannulation site. All patients underwent one CPB run and weaning from CPB was successful in all patients. Median aortic clamp time was 78.5 (74.8–90.3) minutes, while median extracorporeal circulation time being 143.0 (134.8–178.3) minutes. The majority of patients underwent antegrade cardioplegia application through an antegrade cardioplegia cannula (n = 20; [90.9%]), with cardioplegia applied through direct coronary cardioplegia cannulae in three (13.6%) patients with aortic insufficiency. During aortic valve surgery, one (4.5%) patient received concomitant left atrial appendage closure. Regarding the implanted aortic valve prosthesis, the majority of patients (n = 19; [86.4%]) received INSPIRIS RESILIA aortic valves® (Edwards Lifesciences, Irvine, CA, USA), with one (4.5%) patient receiving an Epic™ Max Aortic Stented Tissue Valve (Abbott Cardiovascular Inc, St Paul, MN, USA) and two (9.2%) patients receiving the Perceval PLUS Sutureless Heart Valve®. Noteworthy, one (4.5%) patient underwent aortic valve surgery with initially intended aortic valve repair for severe regurgitation by underlying left coronary sinus leaflet prolaps, which was intraoperatively converted to an aortic valve replacement due to unfavorable valve hemodynamics after attempted valve repair. After surgery, all patients had excellent valve hemodynamics without paravalvular regurgitation. Intraoperative characteristics and echocardiography data are depicted in Tables 2,3, respectively.

3.3 Postoperative Course

Median intensive care unit stay was 1.0 (1.0–2.3) days. No patient underwent conversion to sternotomy during the initial procedure. One (4.5%) patient underwent redo cardiac procedure for postoperative bleeding due to laceration of the non- and left coronary aortic sinus with consecutive aortic root replacement by median sternotomy and appli-

Table 2. Procedural data.

n = (all)	22 (100)
Arterial access site	
Left subclavian artery	1 (4.5)
Right femoral artery	21 (95.5)
Access site change	0
Aortic clamp time in minutes, median (IQR)	78.5 (74.8–90.3)
Extracorporeal circulation time in minutes, median (IQR)	143.0 (134.8–178.3)
Additional cardiac procedure	1 (4.5)
Aortic valve prosthesis	
Perceval PLUS sutureless heart valve	2 (9.1)
INSPIRIS RESILIA aortic valve	19 (86.4)
Epic Max aortic stented tissue valve	1 (4.5)
Prosthesis size in mm, median (IQR)	23 (21.0–25.0)

IQR, interquartile range.

Table 3. Echocardiography data prior and after surgery.

n = (all)	22 (100)
Preoperative values	
Aortic valve morphology	
Tricuspid aortic valve	15 (68.2)
Bicuspid aortic valve	7 (31.8)
Severe aortic valve stenosis	17 (77.3)
Severe aortic valve regurgitation	5 (22.7)
LVEF normal	21 (95.5)
Postoperative values	
V max in m/s, median (IQR)	2.1 (1.9–2.3)
Peak gradient in mmHg, median (IQR)	17.0 (15.0–22.0)
Mean gradient in mmHg, median (IQR)	10 (8.0–12.5)
Moderate – severe paravalvular leakage	0

LVEF, left ventricular ejection fraction; V max, maximum velocity of blood flow through the aortic valve.

cation of postoperative extracorporeal membrane oxygenation (ECMO). Weaning from ECMO was successful and the patient recovered completely during the hospital stay. One (4.5%) patient received pacemaker implantation (PMI) early after surgery for intermitting high-grade atrioventricular block. One (4.5%) patient experienced ischemic stroke one week after hospital discharge due to cardioembolic genesis with postoperative new onset of atrial fibrillation, despite adequate anticoagulation. Given patient recovered completely without residual neurologic deficit during the follow up. Overall postoperative new onset of atrial fibrillation, defined according to current guidelines [21], occurred in 11 (50%) patients during hospital stay. Among those patients sinus rhythm was documented at hospital discharge in all but 2 (9.1%) patients with underlying paroxysmal atrial fibrillation. One (4.5%) patient had a postoperative hematoma at the peripheral CPB access site, which resorbed during the ambulant follow up. One (4.5%) patient needed surgical revision due to a subcutaneous hematoma at the thoracic access site due to postoperative traumatic injury. No patient displayed brachial plexus complications. No patient died during the median follow-up of 6.0 (3.0–16.5) months (Fig. 3). Given adverse events are listed in Table 4.

Table 4. Postoperative adverse events.

n = (all)	22 (100)
Redo cardiac surgery	1 (4.5)
Conversion to sternotomy	0 (0)
New onset of atrial fibrillation	11 (50.0)
Permanent pacemaker implantation	1 (4.5)
Intermittent dialysis	1 (4.5)
Stroke	1 (4.5)
Brachial plexus complications	0 (0)
CPB access site complication	
Hematoma	1 (4.5)
Thoracic access site complication	
Hematoma	1 (4.5)
Overall mortality	0 (0)
ICU stay in days, median (IQR)	1.0 (1.0–2.3)
Hospital stay in days, median (IQR)	12.0 (10.0–16.0)

CPB, cardiopulmonary bypass; ICU, intensive care unit.

4. Discussion

In an effort to provide our best surgical therapy for aortic valve disease without compromising sight and safety, transaxillary access for aortic valve surgery is a very feasible option. Compared to the more medial access in RAT, this surgical access offers several advantages: the internal thoracic artery is preserved. There is no need for a retractor other than a soft-tissue retractor as a wider intercostal space is entered due to the more lateral access. The axillary skin incision has excellent cosmetic results. Furthermore, this surgical approach combined with enhanced recovery after cardiac surgery (ERACS) [22] is safe and feasible.

Our analysis on aortic valve replacement by the rTX approach reveals good postoperative outcomes and hemodynamic results at an early stage of our given program, which are comparable to studies with larger patient populations of the Dresden working group regarding low stroke and mortality rates [14,23]. Noteworthy, while mortality appears indifferent between groups of various access approaches in given trials comparing the rTX with the RAT and median sternotomy approach each in an all-comer population [14,23], in obese patients the rTX approach revealed a significant mortality benefit compared to the median sternotomy approach [15].

While in our analysis the procedures were carried out by four surgeons with high experience in MIAVS, only one surgeon had high experience in endoscopic minimally invasive cardiac surgery (>100 operations). Therefore, the

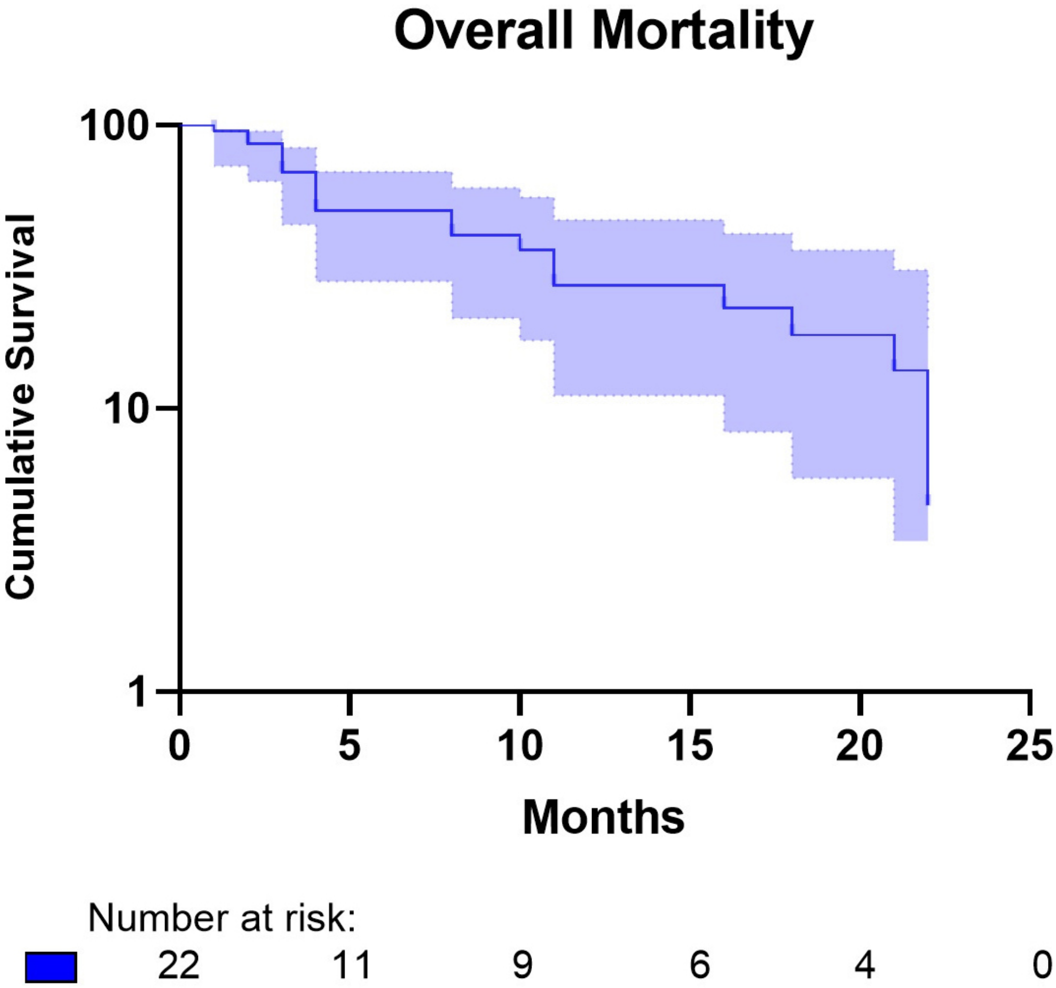

Fig. 3. Kaplan-Meier curve depicting the patients' survival rates during the respective follow up time.

feasibility and relatively flat learning curve of the given technique stimulate debates regarding the rTX approach being considered the primary access approach for the given patient collective in general. The shift towards the initiation of the rTX approach in clinical practice should be a gradual transition from median sternotomy towards thoracotomy due to the high safety of aortic valve repair by sternotomy. Therefore, from a surgeon's perspective, gaining experience on aortic valve repair by sternotomy and partial sternotomy cases is crucial and the principles of aortic valve surgery need to be well internalized before moving towards application of thoracotomy.

Moreover, preceding expertise within minimally invasive cardiac surgery in general is crucial, as the procedure is conducted by long-shafted instruments through a lateral view. Our center has an established minimally invasive cardiac surgery program, with surgeons additionally familiar with minimally invasive mitral valve surgery, as well as alternative aortic valve procedures such as the upper hemisternotomy approach and TAVI procedures. Given factors promoted preceding expertise in alternative cannulation strategies, handling long shafted instruments and being familiar with anatomical properties from a lateral access, all potentially contributing to the overall good early outcome presented in this patient series.

With high demand for MIAVS [6], a sufficient case volume is provided by the majority of patients requiring single aortic valve operation being considered viable candidates for the rTX approach, with exclusion criteria being primarily related to unfavorable anatomic properties.

Therefore, as establishing a given program requires interdisciplinary collaboration by a dedicated team for minimally invasive aortic valve procedures, explicit attention for evaluation of candidacy should be raised during interdisciplinary heart-team meetings, expanding surgical considerations for high-risk young patients and borderline TAVI candidates explicitly.

Although, as learning curves contribute to hesitation in adopting alternative approaches in clinical practice, with significantly higher complication rates at the start of each introduced program as in minimally invasive mitral valve surgery [24,25] respectively, data on learning curves for conducting MIAVS by long shafted instruments are scarce.

However, current literature indicates aortic valve surgery by alternative approaches being reliably reproduceable, as those are rather device-dependent as most patients require aortic valve replacement due the nature of the aortic valve pathology. In this regard, trials on the RAT approach revealed no significantly increased complication rates at the beginning of its implementation in clinical practice [26].

Therefore, despite the low rate of applied SUV prosthesis in our analysis, we expect their further application in our rTX program might additionally facilitate learning curves [27] and increase adaptation of MIAVS by decreasing CPB times [19,28] in clinical practice as well according to current literature, as we report relatively long CPB and aortic cross clamp times considering the limited experience at an early stage of our rTX program. Although, increased CPB times in MIAVS did not translate into associated adverse outcome in recent analysis [1–4], our longer perfusion times might conclude the relatively high rate of postoperative atrial fibrillation in our analysis. Accordingly, aortic cross clamp times of >75 minutes [29] and CPB times of >100 minutes [30] in cardiac surgery are considered relevant risk factors.

On the other side, consecutive oxidative and inflammatory stress promoting postoperative atrial fibrillation rates [31] by insufficient pericardial drainage might be exponentiated in our cohort as we did only place a single right-sided pleural drain perioperatively. Hence, novel research reported on a preventive benefit in this regard by retrocardial drain placement [32] and posterior left pericardiotomy [33] during cardiac surgery. As postoperative atrial fibrillation rates are usually reported lower at 11.7% after MIAVS in general [34] and after lateral access approaches in particular [35], Tokoro *et al.* [13] presented lower postoperative atrial fibrillation rates after rTX approach compared to the median sternotomy approach despite longer CPB times as well. However, Tokoro *et al.* [13] reported noteworthy on a specific drainage protocol implemented for pleural effusion reduction by a single pleural drain in patients undergoing the rTX approach. Although, exact quantification of postoperative pericardial effusion was impossible in this analysis considering its retrospective nature, no hemodynamically relevant pericardial effusion or tamponade was documented.

As multifactorial impact such as atrial anatomical properties [36] cannot be completely ruled out in our analysis, further research is required whether drainage strategies for pericardial effusion by placement of an additional retrocardial drain or adapting the pericardiotomy incision, as well as potentially reduced perfusion times by SUV application might exponentiate clinical benefits at an early stage of the rTX program. However, given potential benefit of SUV will have to be contrasted against considerable anatomical properties for proper valve deployment [20] and relatively increased PMI rates compared to conventional aortic valve prosthesis [19]. While the Dresden working group presented almost half of our CPB and aortic cross clamp times, a relatively high rate of SUV prosthesis was applied in their population, being indicative of the consecutively high PMI rates of 7.7–8.6% [14,23] as well.

Given the reported pitfalls, we consider the learning curve of the rTX approach primarily limited to the acquired expertise in peripheral CPB cannulation and in handling long shafted instruments with relatively limited exposure, with the technique considered a reliable approach, as reflected by the good clinical outcome at the start of our program. While our early experience suggests feasibility of the rTX approach, larger series are needed for confirmation, particularly in a high-risk patient collective.

Nevertheless, accustoming with the given circumstances contributes to additional facilitation of the learning curve by proper patient selection particularly at the start of the respective program, with application of the rTX approach regardless of valve prosthesis in relatively low risk patients, as well as expertise beyond surgical dexterity by monitoring results for reflection on and analysis of the individual surgical performance [37], enabling adaptation of surgical techniques within the respective field of profession.

The given study includes several limitations, with the analysis being a retrospective single-center study containing a small sample size and short follow-up. Moreover, precise quantification of postoperative pericardial effusion was not possible considering the retrospective nature of this study, all constraining the generalizability and statistical analysis of the given research.

5. Conclusion

Aortic valve surgery by the rTX approach is feasible and reproducable, with low complication rates at the start of the implementation of its program at experienced centers.

Availability of Data and Materials

The data underpinning this article will be shared upon a reasonable, justified request sent to the corresponding author.

Author Contributions

JG, AZ, PB: conceptualization, investigation, methodology, project administration, supervision, validation, and writing—review and editing. PS: conceptualization, data curation, formal analysis, investigation, methodology, project administration, supervision, validation, visualization, writing—original draft, and writing—review and editing. FH, MP and ID: conceptualization and writing—review and editing. All authors contributed to the article and approved the submitted version. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Ethics Committee of the Johannes Kepler University Linz, Austria (Ek. Number: 1176/2023; date of approval: Oct. 2023). Based on the retrospective study design and anonymized nature of the data, written informed consent was waived.

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Conflict of Interest

The authors declare no conflict of interest. All Authors are employees of Kepler University Hospital Ltd. However, the company had no role in the handling or conduct of the study. The authors had full access to all data in the study and take full responsibility for the integrity of the data and the accuracy of the data analysis.

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