The First 100 Cases of Two Innovations Combined: Video-Assisted Minimally Invasive Aortic Valve Replacement Through Right Anterior Mini-Thoracotomy Using a Novel Aortic Prosthesis

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ABSTRACT

Introduction: Aortic valve replacement (AVR) via right anterior mini-thoracotomy (RAMT) is less traumatic than via other surgical routes; using a novel aortic valve may confer long-term resistance against valve deterioration, and thus be useful in younger, more active patients. Here we aim to validate using the INSPIRIS RESILIA valve with minimally invasive RAMT.

Methods: Between April 2017 and June 2019, 100 patients underwent video-assisted minimally invasive AVR by RAMT, using the INSPIRIS RESILIA aortic valve. Cannulation for cardiopulmonary bypass (CPB) was through femoral vessels. Clinical data were prospectively entered into our institutional database.

Results: Cardiopulmonary bypass (CPB) and cross-clamping times were 79 ± 38 and 41 ± 17 min. Surgical access was successful in 100% of cases. There were no cases of intraoperative mortality, 30-day mortality, cerebrovascular events, rethoracotomy for bleeding, valve-related reoperation, right internal mammary artery injury, or conversion to sternotomy. Intensive care and hospital stays were 2 ± 1 and 6 ± 3 days, respectively. One patient had a pacemaker fitted. Postoperative dialysis was necessary in one patient. Trace to mild aortic valve regurgitation occurred in two patients. No structural valve deterioration (SVD) and paravalvular leak were seen. At 1-year follow-up mean effective orifice area (EOA) was 1.8 ± 0.1 cm^2, peak gradient was 22.1 ± 3.1 mmHg, and mean gradient was 11.5 ± 2.3 mmHg.

Conclusion: Our preliminary experience suggests that RAMT for AVR using the INSPIRIS RESILIA aortic valve is safe, effective, and reproducible. Larger studies are needed to evaluate the long-term efficacy and durability of this new valve.

Keywords: Minimally invasive valve surgery; Aortic valve replacement; INSPIRIS RESILIA aortic valve

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Key Summary Points

Over the last two decades, minimally invasive aortic valve replacement (MIVAR) has demonstrated good safety and efficacy compared with both conventional and transcatheter aortic valve implantation (TAVI).

The use of video-assistance technology in minimally invasive surgery through right anterior mini-thoracotomy (RAMT) reduces operative times and improves outcomes.

To improve the durability of bioprostheses by reducing structural valve deterioration (SVD), Edwards Lifesciences has launched the INSPIRIS RESILIA bioprosthetic valve, incorporating novel RESILIA tissue preservation technology.

To optimize the short- and long-term outcomes of surgical aortic valve replacement, the INSPIRIS RESILIA valve was implanted via minimally invasive, video-assisted RAMT.

Primary safety and efficacy data at 1 year for the first 100 patients show that this procedure demonstrated 100% operative success with low rates of postoperative complications. Valve hemodynamic performance at 1 year was excellent with no paravalvular leak and no observed SVD.

These preliminary data suggest that the use of the INSPIRIS RESILIA valve with RAMT is safe, effective, and reproducible.

DIGITAL FEATURES

This article is published with digital features, including a summary slide, to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.14185076.

INTRODUCTION

During the last two decades, minimally invasive aortic valve replacement (MIAVR) has demonstrated increasing success in terms of safety and efficacy compared with both conventional sternotomy (CS) [1] and transcatheter aortic valve implantation (TAVI) [2].

Although right anterior mini-thoracotomy (RAMT) outcomes depend on mastering MIAVR techniques, they benefit both from advancements in cardiopulmonary bypass (CPB) techniques and from the utilization of video-thoracoscopic assistance; the latter adds considerable benefit to performance and procedural safety, bringing a reduction in cross-clamp times, CPB times, and ventilator support, and shorter intensive care and total hospital time [3–5].

To improve the durability of current bioprosthetic valves by potentially reducing structural valve deterioration (SVD), in 2016 Edwards Lifesciences launched a new generation of bioprosthetic valve—the INSPIRIS RESILIA (Edwards Lifesciences, Irvine, CA 92614, USA), which has been approved for use in Europe and the USA since 2017. The valve (model 11500A) is a stented, trileaflet valve composed of bovine pericardial tissue mounted underneath a flexible frame. It shares a similar design to the Carpentier-Edwards PERIMOUNT valve in terms of core stent construction and leaflet design [6]. The bovine tissue within the valve incorporates a novel preservation technology called RESILIA, which blocks residual aldehyde groups known to bind to calcium, and preserves the tissue with glycerol prior to surgical implantation, enabling dry storage of the valve [6]. A randomized controlled trial (RCT) animal study of mitral valve implants demonstrated a significantly reduced calcium build-up ($-$ 72%) compared with traditional valve tissue after 8 months in juvenile sheep [7], raising the prospect that this reduced calcification could potentially improve the longevity of the valve. RESILIA tissue has since been evaluated in two large clinical studies with

a combined total of over 800 patients across Europe and the USA. Both intermediate-term and final outcomes of these studies demonstrated safety and sustained hemodynamic performance up to 5 years of follow-up, with no SVD [8–11]. Furthermore, INSPIRIS RESILIA valve design promises increased tissue longevity, thus reducing the need for repeat surgery, along with the potential for effective future valve-in-valve (VIV) procedures thanks to specific valve design modifications [8].

In an attempt to further optimize the short- and long-term outcomes of surgical aortic valve replacement (SAVR), our institution combined these two surgical innovations: performing MIAVR with video-assisted RAMT and replacing the damaged valve with this novel prosthesis.

The aim of the current study was to analyze and present our 1-year outcomes for the first 100 such cases.

METHODS

Study Design and Data Source

This is a retrospective study of prospectively collected data from 100 patients with aortic valve disease (AVD) who underwent isolated aortic valve replacement with INSPIRIS RESILIA valve prosthesis via video-assisted RAMT in the Division of Cardiac Surgery, Heart Centre Siegburg-Wuppertal, University Witten-Herdecke (Germany) between April 2017 and June 2019. The data was collected from the electronic medical records and patient registry at our institution and include medical history, physical assessments, perioperative parameters, and discharge parameters (including electrocardiogram (ECG), laboratory results, and transthoracic/transesophageal echocardiography (TTE/TEE)).

All patients with AVD were included in this study except for pregnant women. The decision of valve type was made between patient and surgeon on the basis of many criteria such as lifestyle choice, desire for pregnancy, and/or contraindication for anticoagulation therapy.

The study was approved by the ethics committee of the Medical Association of North

Rhine, Germany (Ifd. Nr. 2019201/2019), and individual patient consent for the study was waived. The study was performed in accordance with the declaration of Helsinki 1964 and its later amendments.

The primary endpoint was 30-day mortality. Secondary endpoints were incidence of valve-related complications, hemodynamic performance of the valve, operative times, and duration of hospitalization.

The Valve

The INSPIRIS RESILIA aortic valve is a stented trileaflet valve comprised of RESILIA bovine pericardial tissue that is mounted on a flexible frame. The RESILIA bovine tissue within the valve incorporates a novel preservation technology, which blocks residual aldehyde groups known to bind to calcium, and preserves the tissue with glycerol prior to surgical implantation, enabling dry storage of the valve. The frame is designed to be compliant at the orifice as well as at the commissures. The wireform is made from cobalt–chromium alloy to improve spring efficiency and fatigue-resistance. Additionally, the valve is equipped with VFit technology, which includes fluoroscopically visible size markers and an expansion zone, to facilitate future VIV procedures [6].

Patients

The mean age of patients was 56 ± 9 years; 61 patients (61%) were male, and 61 (61%) were in New York Heart Association (NYHA) class I/II. Degenerative aortic valve stenosis was diagnosed in 93 patients (93%), aortic valve regurgitation in five patients (5%), and aortic valve endocarditis in two patients (2%). Elective, redo, and emergency surgery were performed in 97 patients (97%), six patients (6%), and three patients (3%), respectively. The size of the valves implanted ranged from 19 to 29 mm, as shown in Table 1. Relevant clinical characteristics of our patients are summarized in Table 2. Clinical data were prospectively entered into our institutional database.

Table 1 Valve size distribution

Valve size	N (%)
19 mm	2 (2)
21 mm	15 (15)
23 mm	42 (42)
25 mm	26 (26)
27 mm	14 (14)
29 mm	1 (1)

Table 2 Patient characteristics

Characteristic	N (%)
Mean age (years $\pm$ SD)	56 $\pm$ 9
Male	61 (61)
Mean BMI (kg/m^2)	24.2 $\pm$ 4.4
Diabetes	36 (36)
Peripheral vascular disease	9 (9)
Dyslipidemia	29 (29)
Hypertension	73 (73)
Coronary artery disease	12 (12)
Stroke	2 (2)
Chronic obstructive pulmonary disease	19 (19)
Chronic kidney disease	11 (11)
Mean Logistic EuroSCORE (%)	5.8 $\pm$ 6.4
NYHA class I/II	61 (61)
Pacemaker	1 (1)
Degenerative aortic valve stenosis	93 (93)
Aortic valve regurgitation	5 (5)
Aortic valve endocarditis	2 (2)
Atrial fibrillation	15 (15

BMI body mass index, *EuroSCORE* European system for cardiac operative risk evaluation, *NYHA* New York Heart Association

Operative techniques

All procedures were performed under conventional general anesthesia. The patient was placed in a supine position, and two defibrillator pads were placed across the chest wall. After heparin administration, cannulation for CPB was achieved through the common femoral vessels. Ultrasound sonography was peri- and postoperatively used to assess the femoral vessels. Surgical femoral access was performed in 63 patients (63%); the remaining 37 patients (37%) underwent percutaneous femoral artery access, and closure with the MANTA^{TM} vascular closure device (VCD) (Essential Medical Inc., Malvern, Pennsylvania, USA).

RAMT was performed 2 cm lateral to the sternal border to the level of second or third intercostal space (ICS) through a 3 to 5 cm skin incision (Fig. 1a). After dividing the intercostal tissue without resection or dislocation of the rib or cartilage transection, and preserving the right internal thoracic artery and vein, the pleural space was accessed laterally and a soft tissue retractor (Valve Gate^{TM} Soft Tissue Protector, Geister, Germany) was placed to optimize the exposure.

The pericardium was opened 5 cm above the phrenic nerve and stay sutures placed to obtain an optimal position and view of the aorta and aortic root. Two small incisions of 5 mm were made in the ICS above the mini-thoracotomy for placement of the 3D camera (Aesculap EinsteinVision, Tuttlingen, Germany) and Chitwood® aortic clamp (Scanlan International, Inc, St Paul, MN, USA). CO_2 was infused at a rate

of 3 l/min through the camera port. A long cardioplegia catheter (Medtronic DLP 9F, Ref 10012) secured by a 3.0 polypropylene purse-string was inserted into the ascending aorta. The left ventricular vent was placed through the right upper pulmonary vein and secured by a 3.0 polypropylene purse-string.

The ascending aorta was occluded with a Chitwood clamp, and crystalloid cardioplegia (Custodiol; Koehler Chemi, Alsbach-Haenlien, Germany) was administered antegrade into the aortic root. In cases of aortic regurgitation, cardioplegia was administered directly into the coronary ostia after opening the ascending aorta. A normothermic CPB was performed in all patients. Once the heart was arrested and
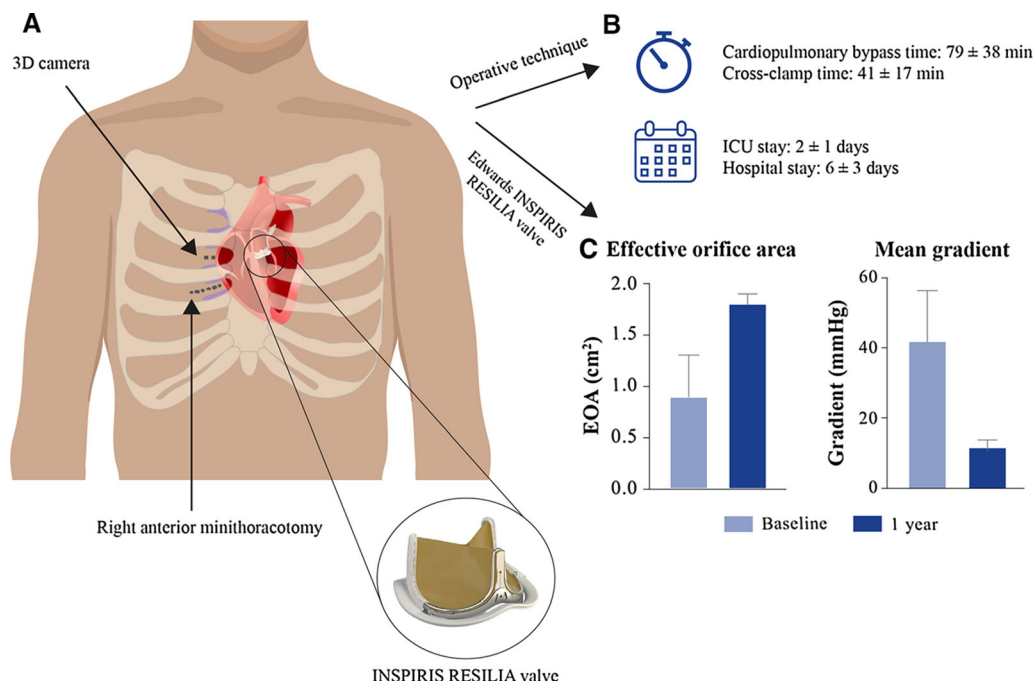
Fig. 1 Outcomes following implantation of INSPIRIS RESILIA aortic valve via video-assisted right anterior minithoracotomy. **a** Access for RAMT and 3D camera; **b** operative times achieved using video-assisted RAMT; **c** hemodynamic outcomes for the INSPIRIS RESILIA aortic valve. EOA effective orifice area, ICU intensive care unit

emptied, a transverse incision of the ascending aorta was performed. Thereafter, the native aortic valve was totally excised, and residual calcium debrided from the annulus. The annulus was sized, and annular sutures placed. The INSPIRIS RESILIA aortic valve was inserted and secured in the aortic annulus using automated suturing with Cor-Knot® (Cor-Knot®, LSI Solutions, USA). The aortotomy was closed in two layers with 4.0 Prolene and the heart deaired thorough the aortic and left ventricular vents. Ventricular pacing wires were placed before removing the cross-clamp. After declamping of the aorta and CPB weaning, protamine was administered at a 1:1 ratio to heparin. Intraoperative TEE was performed to assess the implanted prosthesis. A drain was placed through the cross-clamp incision site, the ribs were secured with two FiberWires (Arthrex; Naples, FL, USA), and intercostal nerve blocks were performed with bupivacaine (0.25%). The wound was then closed in layers.

Arterial and venous decannulation was performed. For cases of surgical access, soft tissue and skin closure was performed with a resorbable intracutaneous suture; for percutaneous access, the MANTA™ system was used for femoral artery closure followed by a resorbable intracutaneous suture to close the skin incision.

Statistical Analysis and Follow-up

All perioperative data were collected prospectively. Data are presented as mean ± SD. Categorical variables are expressed as percentages. All statistical analyses were performed with StatView (version 5.0) for Windows software (SAS Institute, Inc, Cary, NC). Follow-up for discharged patients took place in our outpatient clinic or by contacting the cardiologist by mail or telephone during a 2-month closing interval ending in February 2020 and was 100% complete.

Table 3 Operative data

Variable	N (%)
Surgical access via RAMT	100 (100)
Conversion to sternotomy	0 (0)
Surgical femoral access	63 (63)
Percutaneous femoral access	37 (37)
Elective surgery	97 (97)
Redo surgery	6 (6)
Emergent surgery	3 (3)
CPB time	79 ± 38 min
Cross-clamp time	41 ± 17 min

CPB cardiopulmonary bypass, *RAMT* right anterior mini-thoracotomy

RESULTS

Operative Outcomes

Operative data are shown in Table 3. The technical success rate was 100%, with no patients requiring conversion to full sternotomy. The surgery was performed electively in 97 patients (97%). CPB and cross-clamping times were 79 ± 38 min and 41 ± 17 min, respectively (Fig. 1b).

Intraoperative mortality, 30-day mortality, cerebrovascular events, rethoracotomy for bleeding, valve-related reoperation, right internal mammary artery (RIMA) injury, and conversion to sternotomy were all zero. No injury of phrenic nerve was noted.

Surgical femoral access was performed in 63 patients (63%). Of these patients, two (2.0%) developed wound infections in the groin and one (1.0%) developed a femoral lymphatic fistula. In the remaining 37 patients (37%) who received percutaneous femoral access, no cases of infection, vascular injury, malperfusion, compartment syndrome, lymphatic fistula, or conversion to surgical closure were noted (Table 4).

Table 4 Periprocedural outcomes

Variable	N (%)
Technical success	100 (100)
Intraoperative mortality	0 (0)
30-day mortality	0 (0)
Intensive care stay	2 ± 1 days
Hospital stay	6 ± 3 days
Cerebrovascular event	0 (0)
New postoperative dialysis	1 (1)
Postoperative onset of AF	24 (24)
Vascular dissection, perforation, or obstruction	0 (0)
Life-threatening/disabling bleeding	0 (0)
Rethoracotomy for bleeding	0 (0)
RIMA injury	0 (0)
Wound healing disorders	1 (1)
SVD	0 (0)
Paravalvular leak	0 (0)
Valve-related reoperation	0 (0)
Conversion to surgical closure	0 (0)
Wound infection in the groin	2 (2)
Hematoma in the groin	0 (0)
Femoral AV fistula	0 (0)
Femoral pseudo-aneurysm	0 (0)
Femoral lymphatic fistula	1 (1)
Femoral nerve injury	0 (0)
Occlusion or flow limiting of low extremity peripheral artery	0 (0)

AF atrial fibrillation *AV* atrioventricular, *RIMA* right internal mammary artery, *SVD* structural valve deterioration

Early and Late Morbidity and Mortality

Intensive care unit (ICU) stay and hospital stay were 2 ± 1 days and 6 ± 3 days, respectively (Fig. 1b). New postoperative dialysis was

necessary in one patient (1.0%). New onset of atrial fibrillation (AF) was observed in 24 patients (24%). A pacemaker was implanted in one patient (1.0%) because of an irreversible third-degree atrioventricular block (AVB). One patient (1.0%) developed a superficial thoracic wound infection and was treated conservatively.

No SVD, paravalvular leak, valve endocarditis, or valve-related thrombosis were seen in early and late postoperative follow-up. Trace to mild transvalvular aortic regurgitation was observed in two patients at discharge and at 1-year follow-up.

Hemodynamic Outcomes

At discharge, 6 months, and 1 year, mean effective orifice area (EOA) was 2.0 ± 0.2 cm^2, 1.9 ± 0.2 cm^2, and 1.8 ± 0.1 cm^2, respectively; peak gradients were 20.8 ± 4.3 mmHg, 21.1 ± 4.0 mmHg, and 22.1 ± 3.1 mmHg, respectively; and mean gradients were 10.6 ± 2.6 mmHg, 10.9 ± 2.5 mmHg, and 11.5 ± 2.3 mmHg, respectively (Fig. 1c).

Follow-up data for TTE, according to the valve size, at discharge, 6 months, and 1 year are shown in Table 5.

DISCUSSION

Since the first description in 1993, MIAVR via RAMT has drawn increasing confidence from surgeons—showing superiority over CS, with a lower transfusion rate, reduced duration of mechanical ventilation, and shorter ICU and hospital length of stay [3–5]. Importantly, and compared with other MIAVR accesses, RAMT has demonstrated lower morbidity and mortality, lower risk of postoperative impaired respiratory function and blood loss, less postoperative pain, and a quicker return to the normal productive lives of the patients [2, 12–14]. The superiority of RAMT over other MIAVR accesses and CS also suggests superiority of RAMT over TAVI. In contrast to TAVI, RAMT enables surgeons to remove the underlying pathology, i.e., the calcified aortic valve, and to exactly size and implant a suitable valve

Table 5 Transthoracic echocardiographic data

Variable	Follow-up	All valve sizes	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
EOA (cm^2)	Baseline	0.9 ± 0.4	0.7 ± 0.1	0.7 ± 0.3	0.8 ± 0.3	1.4 ± 1.3	1.2 ± 0.5	1.1 ± 0.0
	Discharge	2.0 ± 0.2	1.5 ± 0.1	1.8 ± 0.2	2.0 ± 0.2	2.2 ± 0.4	2.3 ± 0.2	2.4 ± 0.0
	6 months	1.9 ± 0.2	1.4 ± 0.0	1.8 ± 0.4	1.9 ± 0.5	2.1 ± 0.2	2.2 ± 0.4	2.4 ± 0.0
	1 year	1.8 ± 0.1	1.4 ± 0.0	1.7 ± 0.2	1.8 ± 0.1	2.0 ± 0.3	2.1 ± 0.2	2.3 ± 0.0
Peak gradient (mmHg)	Baseline	71.3 ± 22.1	79.4 ± 2.1	78.2 ± 31.5	75.3 ± 32.1	69.3 ± 5.8	63.7 ± 29.9	65.3 ± 0.0
	Discharge	20.8 ± 4.3	26.4 ± 1.1	24.5 ± 8.3	20.1 ± 4.1	18.8 ± 6.3	16.6 ± 5.7	18.8 ± 0.0
	6 months	21.1 ± 4.0	27.0 ± 0.9	24.8 ± 9.2	20.1 ± 3.8	18.5 ± 5.7	17.1 ± 4.9	19.1 ± 0.0
	1 year	22.1 ± 3.1	28.3 ± 1.0	25.7 ± 3.2	22.1 ± 5.6	19.2 ± 5.1	17.3 ± 4.1	20.2 ± 0.0
Mean gradient (mmHg)	Baseline	42.1 ± 14.0	45.4 ± 2.1	51.4 ± 23.2	50.4 ± 18.3	41.3 ± 15.9	32.9 ± 24.8	31.2 ± 0.0
	Discharge	10.6 ± 2.6	12.1 ± 1.7	12.9 ± 4.9	10.2 ± 2.3	10.1 ± 3.2	8.4 ± 3.4	10.3 ± 0.0
	6 months	10.9 ± 2.5	12.1 ± 1.5	13.2 ± 3.6	10.7 ± 3.8	11.2 ± 4.3	8.3 ± 2.1	10.4 ± 0.0
	1 year	11.5 ± 2.3	12.6 ± 1.5	14.1 ± 5.7	11.3 ± 1.2	11.4 ± 2.8	8.9 ± 2.7	11.2 ± 0.0

EOA effective orifice area

prostheses under direct vision. This results in better outcomes regarding postoperative paravalvular leak, permanent pacemaker implantation, vascular complications, and cerebrovascular events [2, 15–17]. Another recent innovation—RESILIA tissue—has shown in an RCT significantly reduced tissue calcification (− 72%) at 8 months after implantation in a juvenile sheep model in the mitral position. In two multicenter clinical studies, the European Feasibility Study and COMMENCE, safety and hemodynamic performance were demonstrated up to 5 years after implantation in a relatively young group of around 800 patients with no SVD [6, 7]. The RESILIENCE multicenter trial [18] is currently enrolling up to 250 patients younger than 65 years of age and with a minimum of 5 years since SAVR. It aims to provide a thorough description of SVD stages, and establish the long-term durability of RESILIA tissue valves up to 11 years of follow-up. Finally, two large real-world multicenter registries, INDURE (NCT03666741) [19] and IMPACT (NCT04053088) enrolling 400 and 600 patients, respectively, will assess the performance of the INSPIRIS RESILIA prosthesis in young patients less than 60 years of age and in patients with comorbidities.

Combining RAMT, an elegant minimally invasive technique, using this novel prosthesis has the potential to elevate SAVR patient outcomes to a next promising level, with the aim to (1) reduce mortality and morbidity while improving cosmetic and rehabilitation results, (2) to extend valve performance further especially in younger patients, allowing for potentially simpler decision-making when it comes to reintervention strategy owing to valve stent design characteristics. If these goals can be achieved, this would represent a significant evolution in SAVR, with maximum benefit for patients—the outcome that both cardiac surgeons and patients have been looking for. Our early outcome data were very satisfactory and encouraging, showing an absence of intraoperative and 30-day mortality, cerebrovascular events, rethoracotomy for bleeding, SVD, paravalvular leak, and valve-related thrombosis, with short ICU and hospital stay and satisfactory hemodynamic performance of the valve

prosthesis, comparable to that of other bioprosthetic valves. Apart from the development of transient AF in 24 patients (24%), there were no relevant postoperative complications.

Although the current American College of Cardiology/American Heart Association (AHA/ ACC) and European Society of Cardiology/ European Association for Cardio-Thoracic Surgery (ESC/ EACTS) guidelines recommend which type of aortic valve prosthesis should be used according to age and pre-existing conditions, the choice of prosthesis type remains a widely debated topic in aortic valve surgery [20–22]. It is widely known that mechanical prostheses are associated with a risk of thrombosis, or bleeding due to lifelong anticoagulation, while biological valves are associated with risks of SVD and subsequent reoperation especially in younger patients [23, 24]. Therefore, in order to improve outcomes, surgeons are embracing minimally invasive techniques and industries are improving valve technologies to become suitable for all patients.

Still today durability of bioprostheses is a debated theme, especially in young patients and in patients with predisposing factors for SVD. In fact, in recently published studies a significant difference in SVD was reported across various valve models even at short-term follow-up [25–27]; thus, the concept of durability should be tailored to patients' profiles and to the type of prostheses.

However, long-term data from several studies based on the widely used Carpentier-Edwards PERIMOUNT aortic valve demonstrate low rates of valve-related events and SVD up to 20 years, especially in patients aged over 60 years [28]. In younger age groups, although the expected valve durability was still 17.6 years, longevity is influenced by age and some patients might require reintervention [29]. Thus, it is hoped that the INSPIRIS RESILIA valve could potentially extend the long-term results of its predecessor as well as allow for an easier valve reintervention strategy owing to its design modifications.

In our cohort, in which 83% patients were aged 65 years or younger, and 62% were below 60 years, no SVD or valve-related complications were noted during the 1-year follow-up, and

hemodynamic data were similar to those observed in the previous studies. Despite the increased risk of SVD in patients under 65 years of age with a biological valve [30, 31], we believe that younger patients can significantly benefit from biological valves owing to the various reasons cited below. This has led to an increase in the use of biological valves, especially the novel INSPIRIS RESILIA aortic valve, in our institution.

1. The 2020 AHA/ACC guidelines lowered the age recommendations below which a mechanical valve is indicated, from 60 to 50 years; the guidelines also now state that patient preference should be taken into account when deciding on prosthesis type [21].
2. The choice of biological valve enables patients to avoid lifelong anticoagulation and its related severe bleeding complications [23].
3. Several studies demonstrate that the associated low mortality risk of redo surgery versus the increased risk of hemorrhage secondary to anticoagulation makes the option to use the bioprosthetic valve acceptable for younger patients [32–34]. Moreover, Milewski et al. reported that the choice of mechanical versus biologic/bioprosthetic valve does not affect the freedom from reoperation or survival rates in young patients under 30 years of age during mid- to long-term follow-up [35].
4. Data at 20 years, with a low rate of valve-related events and SVD associated with the Carpentier-Edwards PERIMOUNT bioprosthetic valve [28, 29], as well as the reduction in tissue calcification and significant improvement in hemodynamic performance shown by the preliminary results of RESILIA tissue studies [6–10], indicate that this new-generation RESILIA prosthesis will deliver much better results regarding hemodynamic performance and durability.
5. The new generation of bioprosthetic aortic valves enables a catheter-based VIV redo option when a previous prosthesis fails.

All previous cited reasons motivate us to implant more the new aortic valve prosthesis even in young patients. There is no doubt that larger size studies with long-term follow-up (over 20 years) are needed to evaluate the long-term efficacy and durability of the new INSPIRIS RESILIA aortic valve. In our opinion, shifting the indication age from 65 to 55 year and lower for biological valve lead to a great step in the evolution of aortic valve surgery and enables us to track and evaluate primarily data for very long time.

To our knowledge this is the first report to provide insights on MIAVR via RAMT with the INSPIRIS RESILIA valve. Patients should benefit from less traumatic MIAVR via RAMT at first intervention and the novel INSPIRIS RESILIA aortic valve looks an appealing concept. Particularly, we report very satisfactory early-term results, and longer-term follow-up data (over 20 years) are needed to confirm our early results. Nevertheless, reducing the age for recommendation of biological valves represents a great step in the evolution of valve surgery, and enables us to track and evaluate longer-term primary data.

Limitations

This study is limited by its retrospective single-arm design and small sample size without a comparable group. It presents a performance bias as all patients were not operated on by the same surgeon, and the enrollments were not consecutive, though due only to specific inclusion/exclusion criteria. The mode of patient follow-up by email and telephone contact also introduces a risk of ascertainment bias. Therefore, the results may reflect institutional practices and not be generalizable.

Moreover, the limited number of patients in this cohort and the lack of complete size-by-size analysis of hemodynamic performance for other bioprosthesis valves are one of the main limitations of this study. Furthermore, the study focused on early postoperative hemodynamic performance, and the impact of the previously demonstrated late improvement in hemodynamic performance of bioprosthesis valves has therefore not been evaluated. For the same reason, we could not analyze the effect of the

improved hemodynamic performance on left ventricular mass regression. The period from the diagnosis of AVD to operation for the evaluation of patients' disease severity could not be collected and analyzed because of the lack of first diagnosis date in the medical records in the majority of patients.

Finally, analysis of late outcomes was limited to 1 year of follow-up. It is limited to primary safety and efficacy at 1 year. Longer follow-up multicenter research would be required to confirm the findings of this study.

CONCLUSION

Our preliminary experience suggests that minimally RAMT for aortic valve replacement with the INSPIRIS RESILIA aortic valve can safely, effectively, and reproducibly be performed, and that the valve gives excellent hemodynamic performance. Further larger size studies are needed to evaluate the long-term efficacy and durability of the new valve.

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