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Veterans Affairs Heart Team Experience with Transcatheter Aortic Valve Replacement and Minimally Invasive Surgical Aortic Valve Replacement

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STRUCTURED ABSTRACT

Objectives: Aortic valve disease is prevalent in the veteran population. Transcatheter aortic valve replacement (TAVR) and minimally invasive surgical aortic valve replacement (MIAVR) are minimally invasive approaches predominantly performed at higher-volume cardiac centers. The study aim was to evaluate our experience with minimally invasive techniques at a Veterans Affairs Medical Center (VAMC), since outcomes from lower-volume federal facilities are relatively unknown.

Methods: This study examines retrospective data from 228 consecutive patients who underwent treatment for isolated aortic valve disease with MIAVR or TAVR via intent-to-treat at a VAMC between January 2011 and July 2017. Perioperative outcomes were analyzed using Stata version 15.

Results: Operative mortality was 1.1% for MIAVR and 0.7% for TAVR (p=0.79, χ^2). Median length of hospital stay was 10 days (IQR:7–14) for MIAVR and 4 days for TAVR (3–6; p<0.001, Mann-Whitney). Post-operative new onset atrial fibrillation occurred in 52% of MIAVR patients and 5.2% of TAVR patients (p<0.001, χ^2). Stroke occurred in 2.2% of MIAVR patients and 3.0% of TAVR patients (p=0.71, χ^2). In patients who underwent MIAVR, 5.4% required placement of a permanent pacemaker post-operatively, compared to 14% of TAVR patients (p=0.04, χ^2). Mild paravalvular leak (PVL) affected 2.2% of MIAVR and 28% of TAVR patients, with moderate PVL reported in 2.2% of MIAVR and 3% of TAVR patients (p<0.001, χ^2).

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Conclusions: VAMC heart team offers MIAVR and TAVR to veterans with isolated aortic valve disease, and has achieved excellent outcomes despite relatively lower case volumes. Both offer excellent hemodynamic results, with low mortality in a complex population.

Introduction

Aortic valve replacement is the only effective treatment for patients with severe symptomatic aortic stenosis (AS) or aortic regurgitation (AR).[1–3] Aortic valve replacement remains one of the most commonly performed procedures in cardiac surgery, with ~67,500 surgical aortic valve replacements (SAVR) and 24,808 transcatheter aortic valve replacements (TAVR) performed annually in the U.S.[4,5] The Veterans Affairs (VA) Healthcare System services ~9 million patients at 144 hospitals nationwide.[6] In 2016, 53% of the veteran population was reported to be aged 65 years or older.[7] Since aortic stenosis predominantly affects the elderly, it is pivotal that VA medical centers (VAMC) not only offer excellent outcomes, but also offer the latest treatments for aortic valve disease. Most VA cardiac care centers are affiliated with academic centers of excellence, and are ideal for increasing access to innovative, advanced techniques and targeting a population in need.[8,9]

In recent years, TAVR and MIAVR have demonstrated significantly increased case volumes in the U.S., with patients demanding less invasive surgical options and TAVR expanding indications into intermediate-risk populations and ongoing trials in low-risk patients.[10,11] The smaller incisions of MIAVR confer the advantages of reduced pain, surgical trauma, and bleeding, in addition to shorter hospital stays and earlier functional recovery[11–15]. Despite the increasing popularity of MIAVR and TAVR, few studies have directly compared the outcomes of these techniques, and none have done so at low-volume federal institutions.[16] Due to technical complexity and multi-disciplinary nature of the heart team required for TAVR, and advanced surgical skills required for MIAVR, the majority of these procedures are performed at high-volume cardiac care facilities.[15,17] As a result, the current literature disproportionately reports outcomes from these high-volume cardiac centers, and outcomes at lower-volume federal facilities are unknown and excluded from the national Society of Thoracic Surgeons (STS) database[9].

Materials and Methods

This retrospective single-center intent to treat series evaluates consecutive aortic valve replacement via MIAVR or TAVR. Patients who received concomitant cardiac surgical procedures were excluded. The Institutional Review Board at San Francisco VAMC (SFVAMC) and Committee on Human Research at University of California San Francisco (UCSF) Medical Center approved this study. A total of 228 patients underwent treatment for isolated aortic valvular disease at our VAMC between January 25th, 2011 and July 31st, 2017; 93 patients underwent MIAVR and 135 patients underwent TAVR. Only 15% of isolated SAVR patients underwent full-sternotomy over this time period, but 100% of SAVR was performed via MIAVR by 2016. All patients received extensive pre-operative screening, including cardiac catheterization, echocardiography, and computed tomographic angiography (CTA). Medical records were used to assess patients' demographics, risk profiles, clinical presentations, operative characteristics, and post-operative morbidity and

mortality. Relevant preoperative data comparing MIAVR and TAVR cohorts were evaluated using variables from the STS risk score for predicted risk of mortality (PROM, or the risk of death at 30 days after the procedure).[18]

Operative Characteristics

MIAVR patients received mini-sternotomy (100%), planned using pre-operative CTA. Details on the MIAVR procedure have been previously described.[12,19,20] Patients undergoing MIAVR received Carpentier-Edwards Model 3300TFX Perimount bioprosthesis (n=64, 68.8%) or Edwards Intuity Model 8300AB Rapid Deployment sutureless bioprosthesis (Edwards Lifesciences, LLC) (n=23, 24.7%), with few receiving the St. Jude Medical mechanical aortic valves (St. Jude Medical Inc.) (n=6, 6.5%).

For TAVR patients, CTA was used to size aortic annulus, assess the burden of femoral arterial disease, and determine optimal vascular access. The majority of patients underwent transfemoral TAVR, with two undergoing transapical TAVR due to extensive peripheral arterial disease. TAVR patients included in this study received either SAPIEN (n=16, 11.9%), SAPIEN XT (n=31, 23.0%), SAPIEN 3 (S3) (n=45, 33.3%) (Edwards Lifesciences LLC), or Corevalve (n=16, 11.9%), Evolut R (n=27, 20.0%), (Medtronic, PLC) transcatheter heart valve (THV) using standard techniques previously described.[21]

Statistical Analysis

Statistical analyses were performed using Stata version 15 (StataCorp LLC). Data are presented as median with interquartile range (IQR) for continuous variables and percentages for categorical variables. Univariate analysis using Mann-Whitney-Wilcoxon test and Chi-squared (χ^2) test were performed for statistical analysis, with statistical significance defined as $p < 0.05$.

Results

Baseline Risk Profile

Patients' baseline characteristics are detailed in Table 1. Overall, TAVR patients were significantly older, and had a greater proportion of co-morbidities, including hypertension, prior stroke, lower ejection fraction, and higher New York Heart Association Class congestive heart failure. A majority of patients underwent treatment for AS: 90% MIAVR and 99% TAVR. AS severity was comparable between the two cohorts, with mean transvalvular gradient of 47mmHg (median) (IQR:40–55) in MIAVR and 44mmHg (38–50) in TAVR patients (p=0.06). Of MIAVR patients, 99% were low-risk with STS PROM <4% and 1.1% were intermediate-risk 4–8%.[22] TAVR cohort was considered intermediate, high, or prohibitive risk by 2 cardiac surgeons during multidisciplinary Heart Team pre-operative case conference. STS did not capture certain variables such as frailty, cirrhosis, pulmonary hypertension, porcelain aorta, among others.

Procedural Outcomes

Perioperative characteristics and outcomes are presented in Table 2. There was no significant difference in operative mortality between MIAVR (1.1%) and TAVR (0.7%), p=0.79). No

TAVR patients required conversion to SAVR. All outcomes are reported per VARC-2 (Valve academic research consortium-2) endpoint definitions.[23]

Median length of hospital stay was 10days (7–14) for MIAVR and 4days (3–6) for TAVR (p<0.001). Two MIAVR (2.2%) and 4 TAVR patients (3.0%) experienced stroke within 30days of procedure (p=0.71). One MIAVR patient (1.2%) experienced transient ischemic attack in postoperative period, while none were reported in TAVR cohort (p=0.23). There was a notably higher rate of new onset postoperative atrial fibrillation after MIAVR, occurring in 48 patients (52%), compared to 7 (5.2%) after TAVR (p<0.001). Post-operative complete heart block necessitating permanent pacemaker implantation (PPM) at index hospitalization occurred in 19 TAVR patients (14%), vs. 5 (5.4%) in MIAVR (p=0.04).

Hemodynamic Outcomes

Of 92 MIAVR patients, 69 received sutured valve, with median size of 23mm (21–25), and 23 received sutureless valve, with median size of 25mm (25–27). There was a significant difference in implanted valve size between patients who received sutured vs. sutureless valves, (p=0.003). Median valve size for 134 TAVR patients was 29mm (26–29). Similarly, there was a statistically significant difference in implanted valve size between sutureless valves and TAVR (p<0.001). Postoperative mean pressure gradient was 14mmHg (10–17) in sutured MIAVR, 6.1mmHg (3.9–10) in sutureless MIAVR, and 8.3mmHg (6–11) in TAVR cohort. The difference in postoperative mean pressure gradient was statistically significant between sutured and sutureless MIAVR (p<0.001); however, no significant difference was found between sutureless MIAVR and TAVR (p=0.07). Qualitative paravalvular leak (PVL) was noted to be worse in TAVR than MIAVR patients: 37 TAVR (28%) experiencing mild and 4(3%) experiencing moderate PVL, compared to 2 MIAVR (2.2%) experiencing mild and 2(2.2%) experiencing moderate PVL (p<0.001, χ^2).

Follow-up Data

Kaplan-Meier survival curves are illustrated in Figure 1a. Actuarial survival rates for TAVR were: 91.0%±2.5% at 1year, 79.6%±3.6% at 2years, and 58.6%±6.0% at 5years; for MIAVR were: 97.8%±1.5% at 1 and 2years postoperatively, and 88.8%±4.6% at 5years (p<0.01,). Actuarial freedom from late thromboembolism is shown (Figure 1b): for TAVR, 97.7% ±1.3% at 1 year, 94.8%±2.1% at 2 years, and 81.2%±12.7% at 5 years; for MIAVR, 98.9% ±1.1% at 1year, 95.0%±2.4% at 2years, and 89.3%±4.0% at 5years (p=0.73). Figure 1c demonstrates actuarial freedom from late structural valve deterioration defined as mean gradient ≥20mmHg-<40mmHg on echocardiography per recently defined guidelines[24]. For TAVR, rates were 99.2%±0.8% at 1year, 96.3%±1.8% at 2years, and 78.4%±12.6% at 5years; and for MIAVR, rates were 100%±0% at 1year, 100%±0% at 2years, and 96.5% ±3.4% at 5years (p=0.01). Actuarial freedom from late endocarditis is displayed in Figure 1d, with rates for TAVR 99.2%±0.8% at 1year, 99.2%±0.8% at 2years, and 95.9%±3.3% at 5years; for MIAVR, rates were 100.0%±0% at 1year, 100.0%±0% at 2years, and 96.6% ±3.4% at 5years (p=0.37). Actuarial freedom from late bleeding events is shown in Figure 1e: for TAVR, rates were 97.6%±1.4% at 1year and 96.7%±1.6% at 2 and 5years; for MIAVR, rates were 98.9%±1.1% at 1year, 97.6%±1.7% at 2years, and 95.3%±2.8% at 5years (p=0.91).

Discussion

Prevalence of aortic valve disease in veterans is on the rise, due to a high proportion of elderly individuals.[7,25] As a result, the number of isolated aortic valve replacements performed at VAMCs across the country has increased.[8] We report here a single center retrospective study of TAVR vs. MIAVR given the limited penetrance of both TAVR and MIAVR nationally across VAMCs. Our VAMC was the fourth TAVR center to be approved with the number of VA TAVR centers still limited nationally. Limited MIAVR numbers performed in VA centers nationally preclude multi-center analyses. While TAVR has been rapidly adopted, MIAVR still has limited adoption in the STS database, with an estimate of 12% MIAVR in the United States (US), 12% in United Kingdom, and ~25% in Germany.[26] At Cleveland Clinic, a high volume U.S. center, MIAVRs increased from 12.4% to 29.6% of total SAVRs over 18years in 2013.[15] These reflect estimates of MIAVR performance rates at higher volume cardiac surgery centers. Much of MIAVR literature is single institution or propensity matched cohorts, and do not capture regional or institutional practices of MAIVR versus conventional SAVR. Nevertheless, our VAMC has prioritized providing patients with the latest in AVR technology and converted our standard of care for isolated aortic valve disease exclusively to MIAVR or TAVR.[27]

TAVR demonstrated lower overall survival reflecting a higher risk elderly population, as evidenced by increased age, and greater presence of STS co-morbidities: hypertension, prior stroke, prior myocardial infarction (MI), end-stage renal disease (ESRD) on dialysis, and having a permanent pacemaker (PPM)/automatic implantable cardioverter-defibrillator (AICD) prior to procedure. We have demonstrated that minimally invasive AVR, MIAVR or TAVR, can be performed safely at our institution, with a low incidence of operative mortality that does not differ between the two approaches and compares similarly to results reported by high-volume facilities.[27] Terwelp et al. report outcomes from a propensity matched multi-institution retrospective review of 2,571 patients undergoing full sternotomy SAVR, MIAVR, and TAVR. Rates of postoperative complications observed in our patients mirrored theirs. They found higher incidence of stroke in TAVR and higher incidence of atrial fibrillation in MIAVR; we similarly found higher incidence of atrial fibrillation in MIAVR but no differences in stroke between the two cohorts.[27] Taken in conjunction with our results, these data support the notion that MIAVR and TAVR can be safely and effectively adopted into practice at both higher and lower-volume cardiac centers.

Outside the US, two studies directly compared MIAVR and TAVR postoperative outcomes, exclusively in high-risk patients.[28,29] Santarpino and colleagues specifically examined TAVR in comparison to MIAVR with sutureless valves.[28] They reported higher incidence of PPM requirement in MIAVR (10.8%) compared to TAVR (2.7%), whereas we found a higher rate of PPM with TAVR (14%) than MIAVR (5.4%).[28] This difference is likely due to their use of sutureless valves, because in our cohort, the majority of patients received sutured bioprostheses until sutureless valves were FDA approved and commercially available in 2016. They similarly report no difference in stroke rate between the two groups and significantly higher incidence of paravalvular leak in TAVR (13.5%) relative to MIAVR (0%).[28] A study by Miceli and colleagues similarly compared TAVR to MIAVR using sutureless valves through a right anterior mini-thoracotomy, while our MIAVRs were

performed via mini-sternotomy.[29] They demonstrated no significant difference in operative mortality or stroke rate, but significantly worse paravalvular leak in TAVR, with worse one- and two-year survival rates in this cohort.[29] We did not observe TAVR mortality related to paravalvular leak, likely due to recent TAVR devices having design modifications that reduced paravalvular leak.[30,31] In our study, TAVR patients were higher-risk than MIAVR patients. TAVR patients were categorized as intermediate-risk or greater during Heart Team discussions. Direct comparisons of similar intermediate- and high-risk patients between TAVR and MIAVR in our patients were not possible because the transitions to both technologies occurred during the same frame; thus, no retrospective cohort of MIAVR in those higher-risk categories existed for comparison. In addition, this time frame reflects TAVR expansion towards intermediate-risk patients nationally.

One notable finding of our study is the equivalent hemodynamics between sutureless MIAVR and TAVR. Studies have suggested improved hemodynamics with TAVR over SAVR given the smaller SAVR bioprosthetic sizes implanted vs. larger TAVR size with its stents' ability to widen left ventricular outflow tract (LVOT) and improve flow.[32–34] Our median MIAVR size implanted was indeed larger than our traditional SAVR bioprosthetic size, in part due to CTA sizing algorithm. Aortic annulus measurements obtained from preprocedural CTA helped to true-size MIAVR sutureless bioprosthesis, rather than under-sizing per manufacturer recommendations. An additional factor leading to excellent gradients with MIAVR sutureless bioprostheses was the design element of the cuffed stent anchoring the valve, which expanded the LVOT similar to TAVR. We found no significant differences in mean gradients between TAVR and MIAVR, where MIAVR had mean gradients <10mmHg. Since moderate structural valve deterioration has now been defined as gradient >20mmHg, achieving initial low gradients with TAVR or SAVR is important to achieving optimal valve performance and ensuring the best long-term outcomes.[24]

Conclusions

We report outcomes of minimally invasive techniques for AVR offered by a VAMC Heart Team, demonstrating these procedures can be performed safely and with excellent outcomes at low-volume federal facilities comparable to those published by high-volume cardiac centers. This study is important since 1) clinical outcomes from lower volume institutions are not often presented in the literature and as such it is crucial to demonstrate similar safety and feasibility of adopted techniques, 2) outcomes from federal facilities are not captured by national STS databases and such results should be evaluated and presented for clarity and transparency in this era, and 3) MIAVR is not widely adopted at federal facilities for a multi-center study and these results encourage adoption of TAVR and MIAVR techniques in veteran population. While MIAVR and TAVR differ in their associated postoperative complications relative to one another, both are safe and feasible at lower volume federal institutions with excellent clinical outcomes comparable to those reported for high-volume centers.

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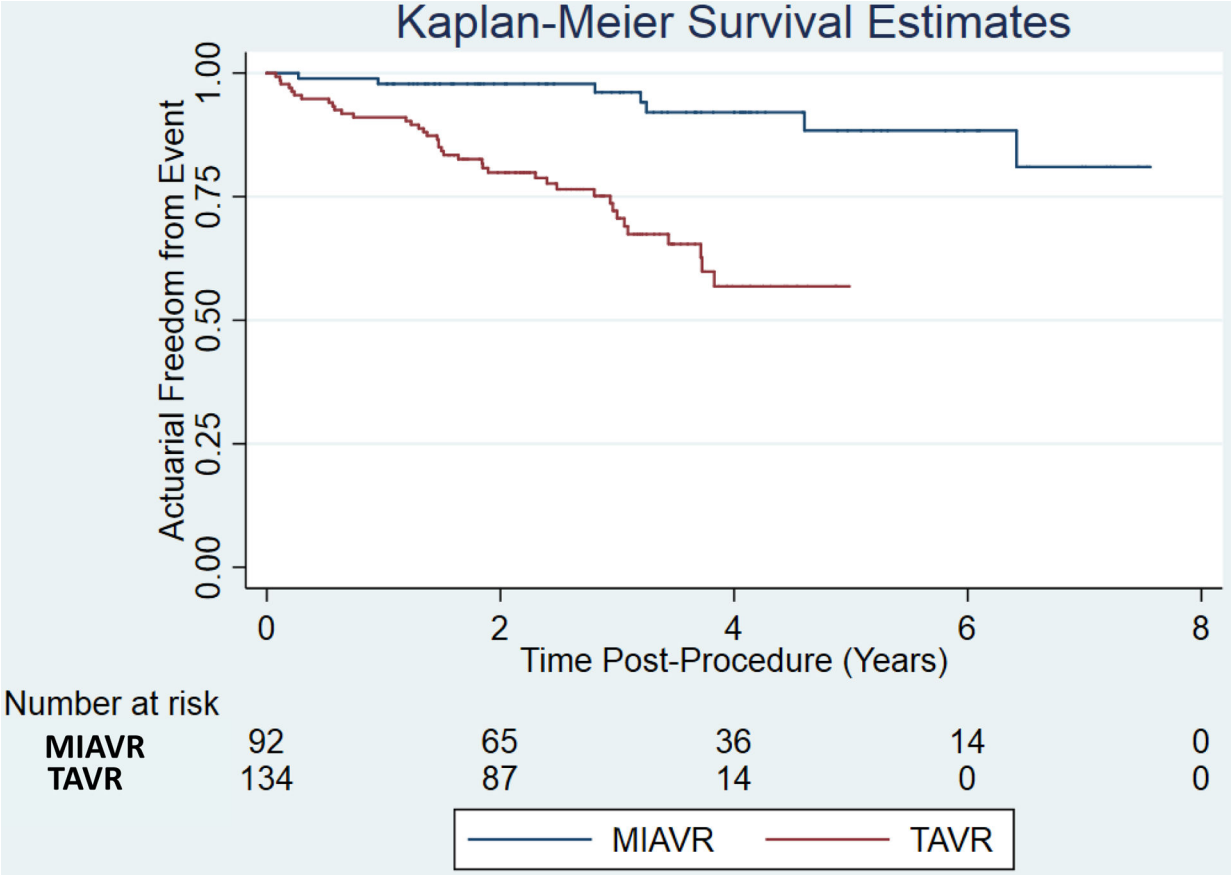

Figure 1a.
Kaplan-Meier Survival Estimates

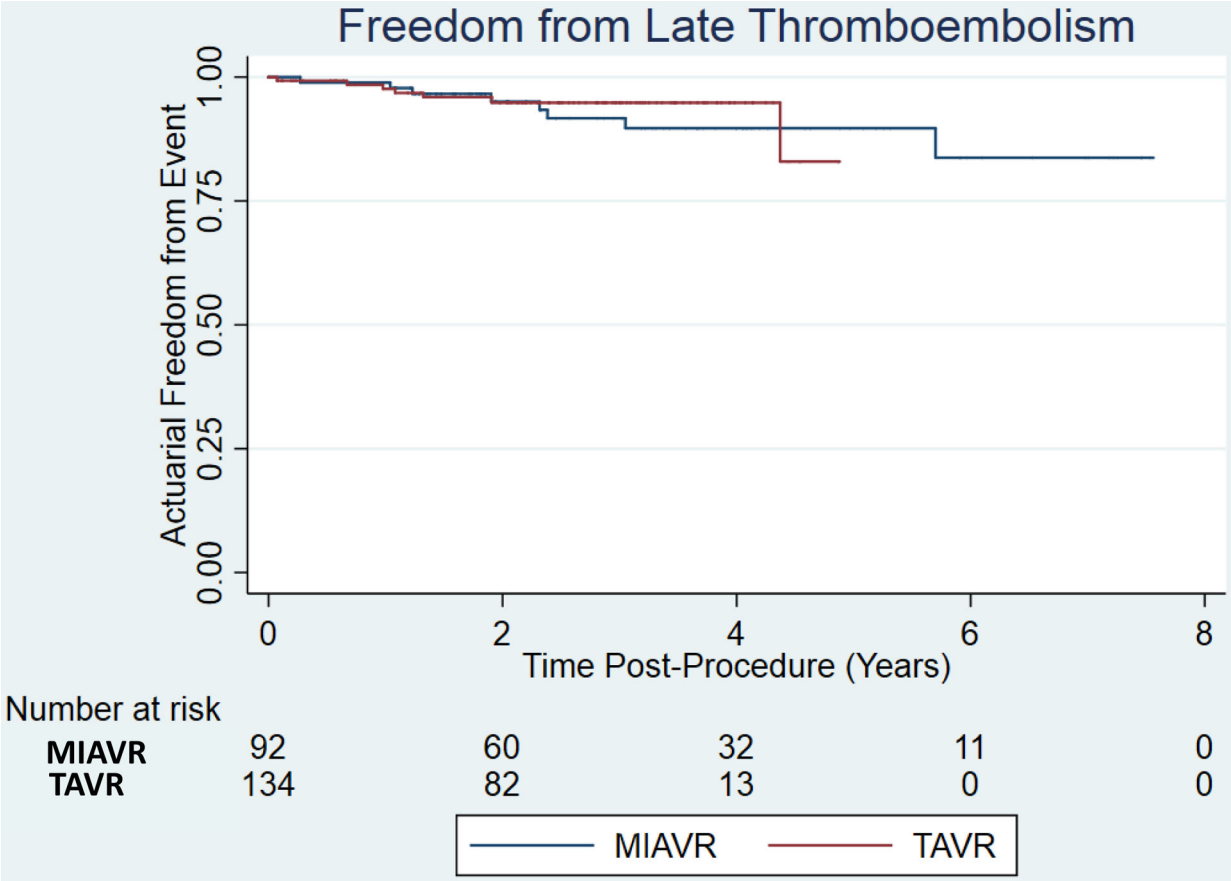

Figure 1b.
Freedom from Late Thromboembolism

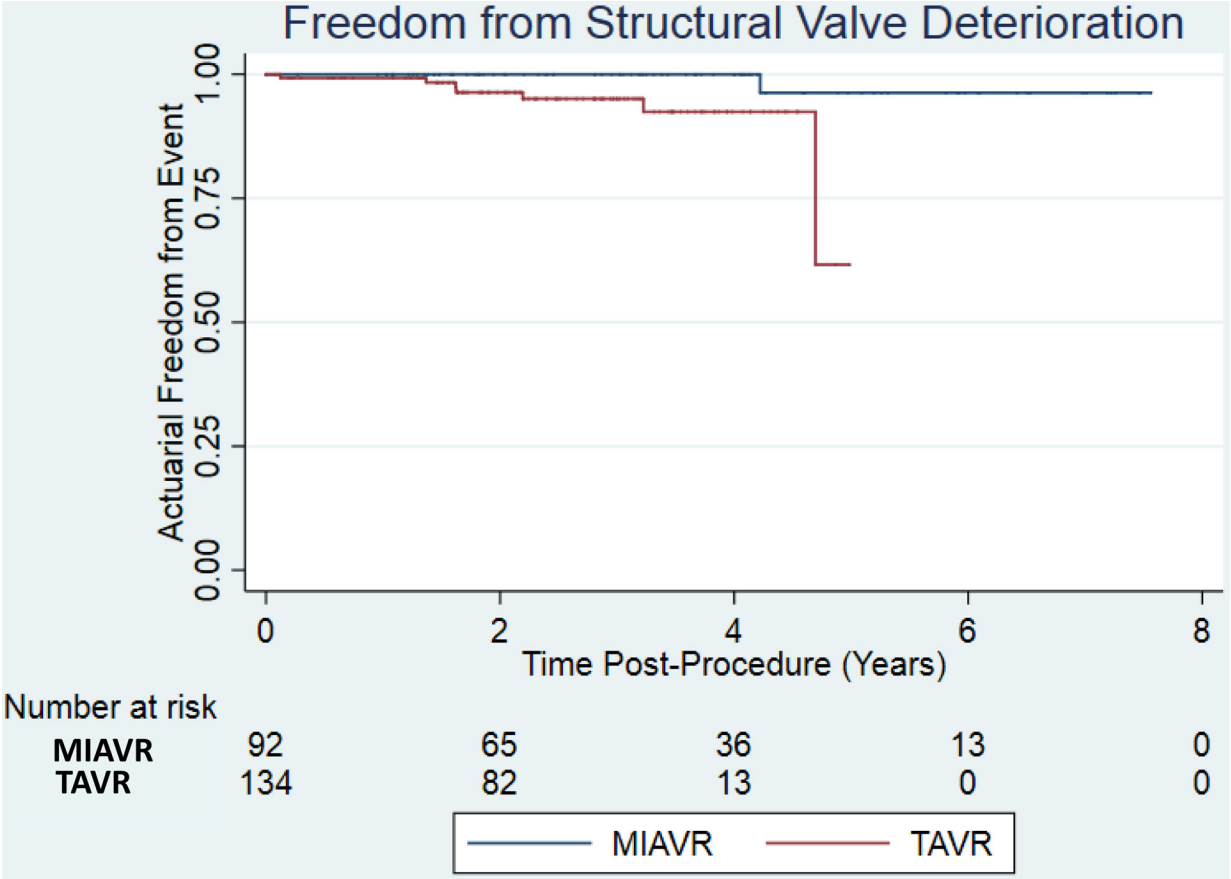

Figure 1c.
Freedom from Structural Valve Deterioration

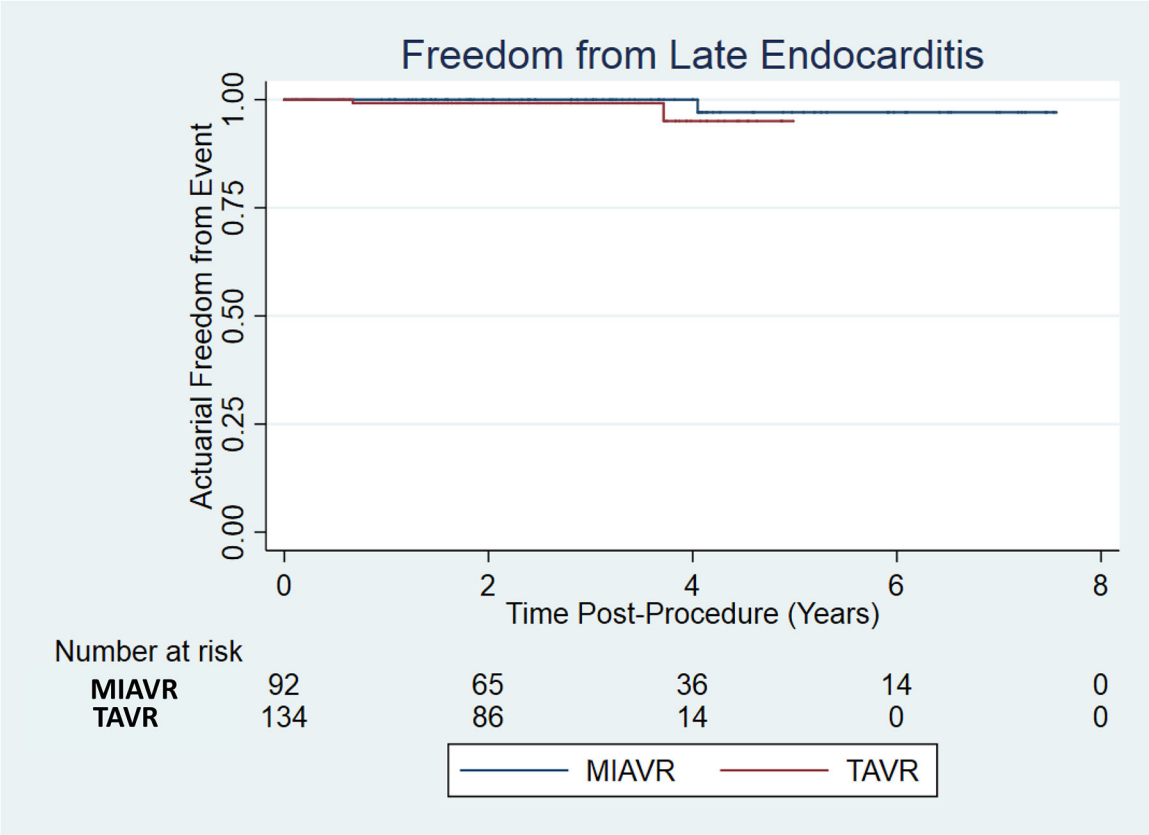

Figure 1d.
Freedom from Late Endocarditis

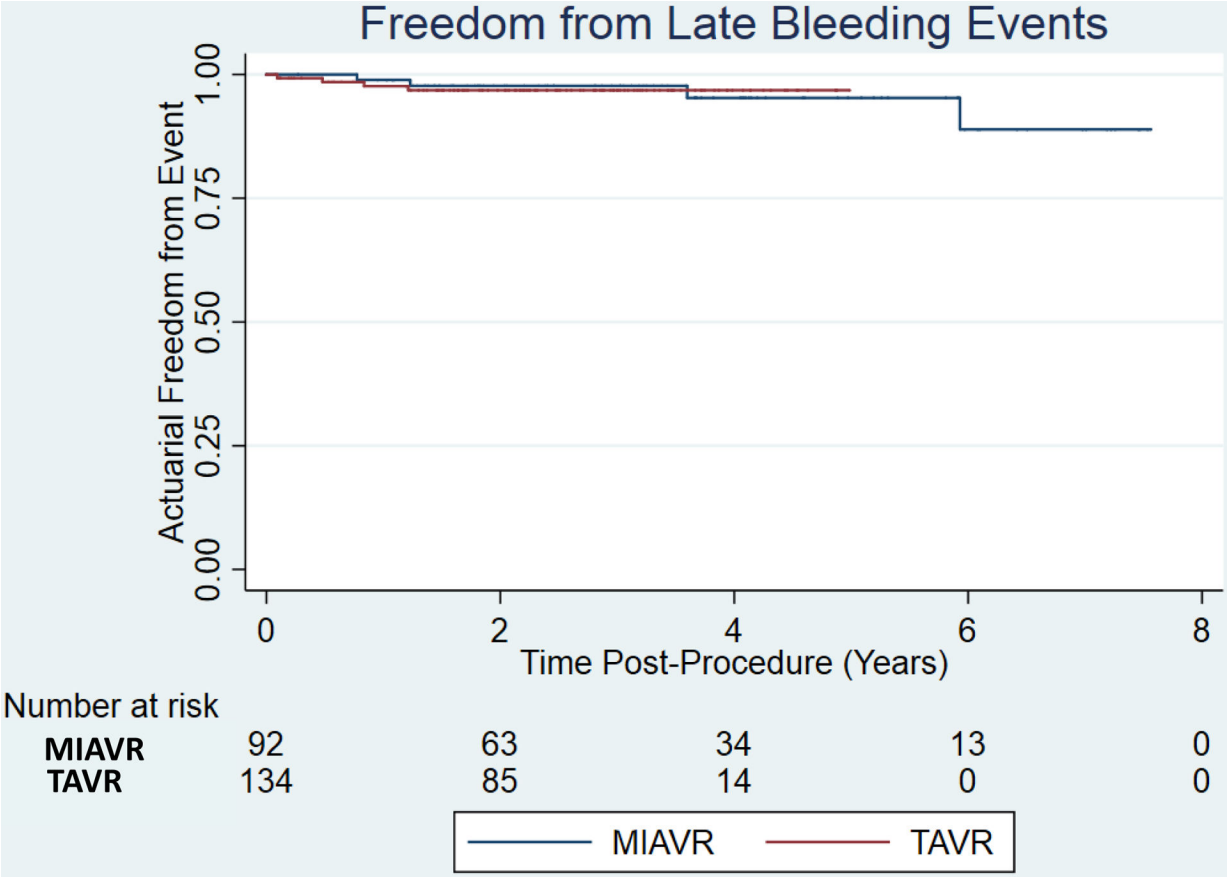

Figure 1e.
Freedom from Late Bleeding Events

Table 1.

Preoperative Characteristics

	MIAVR	TAVR	p-value
Patients, n	93	135	
Age (y), median (IQR)	68 (65–74)	79 (71–85)	< 0.001
Gender			
Male, n (%)	92 (99)	132 (98)	0.52
Female, n (%)	1 (1.0)	3 (2.0)	
STS Risk Score			
Predicted Risk of Mortality (%), mean (SD)	1.4 (0.69)	4.7 (4.7)	< 0.001
Smoking Status			
Current Smoker, n (%)	14 (15)	11 (8.1)	0.06
Prior Smoker, n (%)	58 (62)	76 (56)	
Diabetic, n (%)	31 (33)	60 (44)	0.08
Hypertension, n (%)	73 (78)	121 (90)	0.01
Prior Stroke, n (%)	1 (1.1)	10 (7.4)	0.03
Hyperlipidemia, n (%)	79 (84.9)	112 (82.9)	0.30
Prior Myocardial Infarction, n (%)	10 (10.8)	44 (11.4)	<0.001
Creatinine, mean (SD)	1.03 (0.22)	1.19 (0.38)	0.45
End Stage Renal Disease on Hemodialysis, n (%)	0 (0)	2 (1.5)	0.24
Prior Pacemaker or Automatic Implantable Cardioverter-Defibrillator (AICD), n (%)	0 (0)	14 (10.4)	0.001
New York Heart Association Class, n (%)			
Class I	15 (16)	1 (0.7)	< 0.001
Class II	46 (49)	9 (6.7)	
Class III	31 (33)	113 (84)	
Class IV	1 (1.1)	12 (8.9)	
Ejection Fraction (%), median (IQR)	63 (59–70)	60 (47–66)	< 0.001
Aortic Stenosis, n			
Aortic Valve Area (cm), median (IQR)	0.7 (0.6–0.9)	0.7 (0.6–0.8)	0.96
Mean Pressure Gradient (mmHg), median (IQR)	47 (40–55)	44 (38–50)	0.06
Aortic Insufficiency Grade, n (%)			0.01
None/Trivial	49 (52.7)	77 (57.0)	
Mild	21 (22.6)	43 (31.9)	
Moderate	13 (14.0)	12 (8.9)	
Severe	10 (10.7)	3 (2.2)	

Table 2.

Perioperative Characteristics & Outcomes

		MIAVR	TAVR	p-value
Valve Type				
Sutured	Bioprosthetic, n	65		
	Mechanical, n	5		
Sutureless	Edwards	23	92	
	Medtronic		43	
Valve Size (mm), median (IQR)				
	Total	23 (21–25)	29 (26–29)	
	Sutured Valve	23 (21–25)		*0.003
	Sutureless Valve	25 (25–27)	29 (26–29)	<0.001
Postoperative Length of Stay (days), median (IQR)		10 (7–14)	4 (3–6)	<0.001
Total pRBCs Used (units), mean (SD)		0 (0–2)	2 (1–2)	0.004
Operative Mortality, n (%)		1 (1.1)	1 (0.7)	0.79
Stroke, n (%)		2 (2.2)	4 (3.0)	0.71
Transient Ischemic Attack, n (%)		1 (1.2)	0 (0)	0.23
Atrial Fibrillation, n (%)				
	Total	48 (52)	7 (5.2)	<0.001
	Sutured Valve	36		
	Sutureless Valve	12		
Permanent Pacemaker, n (%)				
	Total	5 (5.4)	19 (14)	0.04
	Sutured Valve	4		
	Sutureless Valve	1		
Post-operative Renal Failure		2	1	0.35
New Hemodialysis		0	1	0.41
Paravalvular Leak				<0.001
	None, n (%)	78 (85)	62 (46)	
	Trace, n (%)	9 (9.8)	31 (23)	
	Mild, n (%)	2 (2.2)	37 (28)	
	Moderate, n (%)	2 (2.2)	4 (3.0)	
	Not reported, n (%)	1 (1.1)	0 (0)	
Post-operative Mean Pressure Gradient (mmHg), median (IQR)				
	Total	12 (7–16)	8.3 (6–11)	
	Sutured Valve	14 (10–17)		*<0.001
	Sutureless Valve	6.1 (3.9–10)	8.3 (6–11)	0.07

* = Comparison of sutured valve vs. sutureless valve