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# Risk Predictors for Long-Term Outcomes in Patients Undergoing REDO Isolated Aortic Valve Replacement with Sutureless Versus Sutured Bioprosthesis

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### Abstract

**Objective:** Long-term clinical outcomes in patients undergoing redo aortic valve replacement with sutured (SAVR) and sutureless aortic bioprosthesis remain hindered. We sought to evaluate risk predictors that influence survival after redo-SAVR versus redo-sutureless Aortic Valve Replacement (AVR).

**Methods:** All consecutive 82 patients undergoing isolated redo-AVR with either SAVR or sutureless bioprosthesis between 08/2010-03/2020 at our institution were included. Patients with concomitant procedures were excluded from the analysis. Primary outcome was analyses of long-term all-cause mortality. A propensity-adjusted analysis was used to compare groups. Kaplan-Meier were constructed to evaluate long-term survival.

### **OPEN ACCESS**

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Copyright © 2023 Dokollari A. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. **Results:** Preoperatively, redo-SAVR (n=57) and redo-sutureless (n=25) patients baseline characteristics were compared. Mean age was 67.2 *vs.* 68.5-year-old and mean Euroscore II 11% *vs.* 7.5%, in redo-SAVR *vs.* redo-sutureless, respectively. Intraoperatively, redo-SAVR experienced a higher cardiopulmonary (p=0.23) and aortic cross-clamp time (p=0.002) compared to redo-sutureless group. Postoperatively, only new incidence of Atrial Fibrillation (POAF) was higher in redo-SAVR group. Primary outcome of all-cause death at 5-years follow-up was redo-SAVR 7/57 (12.2%) *vs.* redo-sutureless 2/25 (8%), p=0.82; (HR 1.3 [0.2, 7.5]). New risk predictors for mortality in patients undergoing redo-SAVR included body mass index  $\geq$  30 kg/m<sup>2</sup> HR (1.21 [1.04, 1.5]), and tobacco use HR (11.1 [1.1, 112.3]).

**Conclusion:** Patients undergoing redo-SAVR experienced a higher incidence of POAF compared to patients undergoing redo sutureless valves. There were no differences on long-term all-cause death among groups.

Keywords: Sutureless; Aortic valve replacement; Reoperation; Sutured bioprosthesis; Longterm outcomes

### **Key-Points**

1) Understanding risk factors impacting in long-term prognosis in patients undergoing redo-AVR with SAVR or sutureless bioprosthesis may improve clinical outcomes.

2) Management of POAF after redo-AVR may improve in-hospital prognosis.

### Introduction

Landmark clinical trials describing the utilization of sutureless aortic bioprosthesis [1] for Aortic Valve Replacement (AVR) evidenced that this prosthesis provide a short aortic cross-clamp and cardiopulmonary bypass time. In this context, meta-analysis and review studies have shown both

benefits and [2,3] drawbacks of sutured and sutureless bioprosthesis including valve degeneration, pacemaker implantation and repeat intervention.

With technical advancement the sutureless bioprosthesis have been proven to be adaptable in redo-interventions by decreasing the operating time and overall, in-hospital complications rate [3]. While this is true to some extent, there is an ongoing debate on which bioprosthesis better fits an individual patients' profile in redo interventions.

The Pivot, Pivotal and CAVALIER clinical trials showed that sutureless valves outcomes had a lower incidence of periprocedural complications and suitable for elderly patients [1,4,5].

The goal of this study is to analyze risk predictors that impact long-term prognosis in patients undergoing repeat isolated repeat intervention for isolated AVR with bioprosthesis.

### **Methods**

### **Study population**

We identified all patients who underwent redo-AVR with either Sutured AVR (SAVR) and sutureless bioprosthesis between September 2005 and December 2020 at University of Florence, Italy. The study protocol was approved by the Institutional Review Board (IRB 2348IT). Patient individual consent was waived due to the retrospective nature of the study. Consecutive patients that underwent isolated AVR were included in the study. Patients with a concomitant procedure were excluded from the study. Patients were identified *via* operation codes in a digital operation registry, as well as from a centralized cardiac surgery database for all operations. In this database, the underlying in-hospital outcomes were recorded from the charts and death certificate made out by the responsible doctor.

### In-hospital and patients follow-up

During the entire hospital stay, patients were monitored by continuous five-lead telemetry, and atrial rhythm changes were detected from the computer and from the ward nurses and doctors. A standard 12-lead Electrocardiogram (ECG) was routinely performed on postoperative days 1, 2 and 5, and more often if an arrhythmia was detected. Episodes of arrhythmia were noted on patient surveillance charts and assessed twice daily and at discharge by the heart surgeon responsible for the case. All patients had at least one follow-up time point available. Follow-up was done at our outpatient's clinic and from the hospital registry. In case the patient did not present in the follow-up appointment we contacted the referring cardiologist to obtain follow-up clinical data.

### Primary and secondary goals and definitions

The main goal of this study is to identify risk predictors for mortality and analyze their impact on long-term prognosis in patients undergoing redo-AVR with SAVR and sutureless bioprosthesis. Primary outcome was analyses of long-term outcomes all-cause mortality. Clinical definitions are included in supplemental document 1. Covariates, exposures are included in a supplemental document 2. Patients were selected according to VARC 3 criteria [6]. Postoperative Atrial Fibrillation (POAF) was defined as an ECGverified episode lasting more than 1-min during the entire hospital Length of Stay (LOS).

### Statistical analysis for propensity-adjusted analysis

Groups were compared by one way ANOVA for continuous

variables and chi-square test of independence for categorical variables. Propensity-adjusted scores were calculated via a multiple logistic regression model with redo-SAVR vs. redo-sutureless, as the outcome in the model and preoperative variables as independent variables. Because of the small sample size, not all preoperative variables could be included in the propensity score model. Variables included were age, gender, Body Mass Index (BMI), Euroscore II, NYHA, hypertension, dyslipidemia, Chronic Obstructive Pulmonary Disease (COPD), prior stroke, Peripheral Vascular Disease (PVD), aortic stenosis, smoke, Ejection Fraction (EF), chronic dialysis, Coronary Artery Disease (CAD), and STEMI within the last 90 days. The purpose of propensity-adjusting method is to reduce bias, including residual confounding, and has been shown to reduce allocation biases. Propensity-adjustment was used for postoperative and long-term outcomes via linear and logistic regression models with redo-sutureless as the reference and propensity scores as covariates. To illustrate the effect of prosthesis choice on longterm survival, Kaplan-Meier cumulative curves were constructed and compared by log-rank test. All-cause mortality was compared between surgical groups with a Cox proportional hazard ratio and the propensity score plus age as covariates. A sensitivity analysis was done using redo-sutureless status as a time-dependent variable in a series of covariate-adjusted Cox proportional hazards regression models for all-cause mortality and the falsification end points using variables from the propensity model as covariates. This analysis allowed inclusion of patients who died within the first 30-days of surgery and was performed to account for possible immortal time bias. Finally, preoperative risk factors for each surgical group were determined by building Cox proportional hazard ratios via backward selection and compared by AIC. All analyses were performed in Stata 17.0 (Statacorp, LLC. College Station, TX). 95% confidence intervals and p-values are reported with a p-value <0.05 considered significant.

### Propensity-adjustment significance compared to propensity-score matching

Propensity-matching provides excellent matching before the analysis, while the propensity-adjustment accounts for biases during the analysis. Therefore, while seeing significant differences between preoperative variables, these differences are adjusted during the modeling process. Propensity-matching reduces the size of the groups while propensity-adjustment maintains the sample size of the groups. As shown by multiple studies [7], propensity-adjustments provides similar or better adjustment for biases when compared to propensity-matching because of the retainment of the sample size which increases the statistical power of the analysis and is particularly suitable for smaller sample sizes. In addition, the propensitymatched analysis bears allocation biases which are not present in the propensity-adjusted analysis.

### Valve design

The sutureless valve system consists of a tissue component made from bovine pericardium 163 and a self-expandable Nitinol stent, which has the dual role of supporting the valve and fixing it 164 in place. Prior to implantation the prosthesis diameter is reduced to a suitable size for loading it 165 on the holder. The valve is then positioned and released in the aortic root, where the stent design 166 and its ability to apply a radial force to the annulus allow stable anchoring of the device. The 167 handled delivery system includes the balloon catheter for expansion of the frame in the left 168 ventricular outflow tract, securing the valve in a supra-annular position.

### Surgical procedure for redo AVR using sutureless bioprosthesis

We perform full sternotomy using the sutureless bioprosthesis replacement. In addition, we perform standard central aortic and right atrial venous cannulation. After the institution of on-pump we cross-clamp the aorta and deliver antegrade and retrograde cardioplegia. We than open the aorta and remove the prosthetic valve with an adequate removal of annular calcification and debridement. We than implant the valve at the annulus level and balloon it with 2.5 ATM (as demonstrated by Yanagawa et al. [8]. After correct valve deployment and testing we close the aorta in standard fashion.

### **Results**

### **Preoperative characteristics**

Preoperative characteristics were similar among groups (Table 1). Mean age was 67.2-years old in the redo-SAVR *vs.* 68.5-years old in the redo-sutureless group, respectively. In addition, male population included 50.9% *vs.* 68% in the redo-SAVR *vs.* redo-sutureless bioprosthesis groups while mean EuroScore II values were 11% *vs.* 7.5% in the redo-SAVR *vs.* redo-sutureless, groups.

Table	1:	Preoperative	characteristics.

Variables	SAVR n=57	Redo- Sutureless n=25	p-value
Age years (mean/SD)	67.2 (14.1)	68.5 (8.3)	<0.001
Gender n(%)			0.353
Female n(%)	28 (49.1%)	8 (32.0%)	
Male n(%)	29 (50.9%)	17 (68.0%)	
Classification of Intervention			0.001
Elective n(%)	39 (68.4%)	15 (60.0%)	
Urgent n(%)	18 (31.6%)	10 (40.0%)	
Euroscore II (Mean/SD)	11.0 (9.3)	7.5 (6.0)	0.088
Euroscore >7 (Yes) n(%)	33 (57.9%)	10 (40.0%)	0.305
NYHA Functional Classification n(%)			0.015
Class I n(%)	0 (0.0%)	0 (0.0%)	
Class II (Mild) n(%)	5 (8.8%)	6 (24.0%)	
Class III (Moderate) n(%)	47 (82.5%)	17 (68%)	
Class IV (Severe) n(%)	5 (8.8%)	2 (8.0%)	
BMI kg/m <sup>2</sup> (Mean/SD)	27.8 (6.3)	28.0 (5.6%)	0.28
Obese ≥ 30 kg/m² n (%)	16 (28.1%)	8 (32.0%)	0.766
Creatine level (Median/IQR)	92 (79-109)	82 (73-107.5)	<0.001
Dialysis n(%)	13 (22.8%)	6 (24.0%)	0.006
Tobacco Use n(%)	23 (40.3%)	12 (48.0%)	0.115
COPD n(%)	10 (17.5%)	5 (20.0%)	0.93
HTN n(%)	47 (82.5%)	18 (72.0%)	0.203
Dyslipidemia n(%)	42 (73.7%)	19 (76.0%)	0.339
CAD n(%)	23 (40.3%)	17 (68.0%)	0.001
PVD n(%)	22 (38.6%)	10 (40.0%)	0.479
Diabetes n(%)	16 (28.1%)	8 (32.0%)	0.726
Stroke n(%)	18 (31.6%)	8 (32.0%)	0.254
Permanent Pacemaker n(%)	5 (8.8%)	1 (4.0%)	0.024
Aortic Stenosis n(%)	31 (54.4%)	17 (68.0%)	0.232
Atrial Fibrillation n(%)	17 (29.8%)	2 (8.0%)	0.032

Primary AVR operation combined (Yes) n(%)	25 (43.9%)	9 (36.0%)	0.801
Bicuspid Valve (Yes) n(%)	22 (39.3%)	5 (20.0%)	0.029
Associated CABG (Yes) n(%)	10 (17.5%)	8 (32.0%)	0.199
Associated Mitral Valve (Yes) n(%)	6 (10.5%)	0 (0.0%)	0.138
Associated Tricuspid Valve (Yes) n(%)	1 (1.7%)	0 (0.0%)	0.609
Associated Ascending/Hemi/ Total Arch (Yes) n(%)	7 (12.3%)	2 (8.0%)	0.829
Bentall (Yes) n(%)	2 (3.5%)	1 (4.0%)	0.988
EF% (mean/SD)	50.5 (12.8)	54.2 (10.6)	0.302
EF<50% n(%)	15 (26.3%)	4 (16.0%)	0.046
Platelet count (Mean/SD)	193.0 (60.5)	201.3 (65.7)	0.318
Warfarin Therapy (Yes) n(%)	10 (17.5%)	0 (0.0%)	0.084
Antiplatelet Therapy (Yes) n(%)	47 (82.5%)	19 (76.0%)	0.182
Aortic Valve Peak Gradient			0.058
Mild (<=50 mmHg)	19 (33.3%)	8 (32.0%)	
Moderate (<=75 mmHg)	17 (29.8%)	7 (28.0%)	
Severe (>75 mmHg)	21 (36.8%)	10 (40.0%)	
Aortic Valve Max Gradient mmHg (Mean/SD)	65.6 (32.1)	67.9 (26.1)	0.014
Aortic Valve Mean Gradient mmHg (Mean/SD)	39.5 (20.3)	39.0 (17.4)	0.061
Vmax m/s (Mean/SD)	3.8 (0.99)	3.8 (0.90)	0.041

NYHA class: New York Heart Association class; BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease; HTN: Hypertension; CAD: Coronary Artery Disease; PVD: Peripheral Vascular Disease; CABG: Coronary Artery Bypass Grafting; EF: Ejection Fraction; Vmax: Maximal Velocity

Table 2: Intraoperative	characteristics.
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Intra-operative Variables	SAVR n=57	Redo- Sutureless n=25	p-value
Trace/Mild Paravalvular Leak n(%)	0 (0.0%)	1 (4.2%)	<0.001
Cardiopulmonary Bypass Time (min) (Mean/SD)	109 (40.9)	87.4 (38.9)	0.023
Aortic Cross-Clamp Time (min) (Mean/ SD)	88.3 (34.4)	62.5 (29.4)	0.002
Intra-aortic Balloon Pump n(%)	1 (1.7%)	1 (4.0%)	0.529

### Intraoperative outcomes

Intraoperatively, aortic cross-clamp time 88.3 ( $\pm$  34.4) vs. 62.5 ( $\pm$  29.4) minutes and cardiopulmonary bypass time 109 ( $\pm$  40.9) vs. 87.4 ( $\pm$  38.9) minutes was higher in the redo-SAVR group compared to the redo sutureless group, respectively (Table 2).

### Postoperative and long-term clinical outcomes

Postoperatively, the redo-SAVR group had a higher incidence of Postoperative Atrial Fibrillation (POAF) compared to the redo sutureless group (Table 3). Long-term outcomes and a double robust sensitivity analysis did not show differences among groups at 1-, 2-, 3- and 5- years follow-up (Tables 4-7 and Figure 1). Table 5 is a Cox proportional hazard regression with two models, the first is univariable and the second is propensity-adjusted. We are comparing redo-SAVR group with redo-sutureless AVR as the reference group.

### Risk predictors impacting long-term prognosis analysis

New risk predictors for mortality in patients undergoing redo SAVR included Body Mass Index (BMI)  $\geq$  30 kg/m<sup>2</sup> HR (1.21 [1.0, 1.5]), and tobacco use HR (11.1 [1.1, 112.8]) (Table 8).

 Table 3: Postoperative outcomes.

Prosthesis				Propensity Score Adjusted		
Prostnesis	Redo SAVR n=57	Redo Sutureless n=25	p-value	Redo SAVR n=57	p-value	
Post-operative Characteristics				Adj. Mean Difference (95% CI)*		
Intubation Time (hrs) (Mean/SD)	34.3 (72.1)	12.2 (14.6)	0.014	20.0 (-7.4, 47.4)	0.151	
ICU Time (hrs) (Mean/SD)	79.3 (113.6)	43.8 (54.7)	0.005	21.2 (-23.5, 65.9)	0.35	
Peak Creatinine (Median/IQR)	96 (74-114)	108 (75-141)	0.567	-20.2 (-66.1, 25.8)	0.385	
EF % (mean/SD)	47.3 (15.0)	51.8 (7.6)	0.169	-2.8 (-10.0, 4.32)	0.436	
Chest Tube Loss (ml) Median/IQR)	410 (250-790)	310 (235-525)	0.269	206.8 (-64.4, 478.0)	0.134	
Vmax m/s (Mean/SD)	2.6 (0.6)	2.6 (0.9)	0.725	-0.1 (-0.5, 0.3)	0.749	
Gmed mmHg (Mean/SD)	16.2 (7.3)	15.5 (5.1)	0.798	1.3 (-2.8, 5.4)	0.531	
Hospital Length of Stay (Days) (Mean/SD)	10.2 (8.2)	11.2 (8.2)	<0.001	-1.9 (-5.7, 1.95)	0.336	
				Adj. Odds Ratio (95% CI)*		
Repeat intubation n(%)	5 (8.8%)	2 (8.0%)	0.242	1.0 (0.1, 6.9)	0.997	
Readmission to ICU n (%)	3 (5.3%)	4 (16.0%)	0.044	0.1 (0.02, 1.0)	0.053	
Inotrope use n (%)	54 (94.7%)	24 (96.0%)	<0.001	0.8 (0.07, 9.3)	0.877	
Norepinephrine use n (%)	56 (98.2%)	23 (92.0%)	<0.001	8.2 (0.6, 106.8)	0.107	
Epinephrine use n (%)	11 (19.3%)	2 (8.0%)	0.021	1.8 (0.3, 10.7)	0.512	
Dobutamine use n (%)	29 (50.9%)	8 (32.0%)	0.005	2.0 (0.7, 6.2)	0.207	
MI n (%)	6 (10.5%)	1 (4.0%)	0.129	0.99 (0.08. 11.78)	0.995	
Renal Failure n (%)	9 (15.8%)	2 (8.0%)	0.532	1.5 (0.3, 9.0)	0.623	
Other Arrythmia n (%)	13 (22.8%)	0 (0.0%)	0.017	N/A		
Atrial fibrillation n (%)	27 (47.4%)	2 (8.0%)	<0.001	5.7 (1.0, 30.5)	0.043	
Respiratory Failure n (%)	11 (19.3%)	2 (8.0%)	0.021	3.5 (0.6, 21.3)	0.175	
Stroke/TIA n (%)	4 (7.0%)	1 (4.0%)	0.71	1.8 (0.1, 20.8)	0.648	
Permanent Pacemaker n (%)	5 (8.8%)	1 (4.0%)	0.515	4.0 (0.3, 47.2)	0.265	
Reoperation for Bleeding n (%)	9 (15.8%)	4 (16.0%)	0.062	1.6 (0.03, 7.8)	0.553	
Infection n (%)	5 (8.8%)	1 (4.0%)	0.204	3.9 (0.3, 47.9)	0.287	
Hospital Mortality n (%)	4 (7.0%)	1 (4.0%)	0.309	1.6 (0.1, 25.5)	0.729	
ntra-operative Mortality n (%)	1 (1.7%)	0 (0.0%)	0.609	N/A		
EF < 50% n (%)	25 (43.9%)	7 (28.0%)	0.079	1.5 (0.5, 4.6)	0.481	
Paravalvular Regurgitation n (%)	0 (0.0%)	1 (4.0%)	<0.001	N/A		
RBC Units n (%)	38 (66.7%)	12 (48.0%)	<0.001	1.7 (0.5, 5.1)	0.369	
Platelet Units n (%)	23 (40.3%)	9 (36.0%)	<0.001	1.4 (0.4, 4.8)	0.539	
Plasma Units n (%)	21 (36.8%)	6 (24.0%)	0.001	1.1 (0.3, 3.9)	0.843	
Intra-aortic Balloon Pump n (%)	1 (1.7%)	0 (0.0%)	0.609	N/A	_	
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ICU: Intensive Care Unit; MI: Myocardial Infarction; TIA: Transitory Ischemic Attack; EF: Ejection Fraction; RBC: Red Blood Cells; Vmax: Maximal Velocity; Gmed: Mean Gradient

### Discussion

### Summary

1. Redo SAVR group had a high incidence of POAF compared to redo-sutureless AVR group.

2. We found new risk predictors for long-term mortality including BMI and tobacco use.

### Comments

This analysis provided several novel insights in the fragile population of patients undergoing repat AVR. Firstly, POAF incidence was higher in the redo-SAVR group compared to redosutureless bioprosthesis implantation in patients undergoing isolated redo-AVR. Secondly, new predictors that impact long-term prognosis appear associated with each group including BMI and tobacco smoke. Based on the findings from this study we speculate that preoperative evaluation based on patient's individual risk factors profile can help in prosthesis and interventional choice. In addition, optimization of modifiable risk predictors may improve clinical outcomes including rhythm control for patients with preoperative atrial fibrillation is mandatory.

The sutureless bioprosthesis have made a significant advancement in the last decade and its design has been increasingly preferred as a treatment for qualified patients with aortic valve disease with aortic valve replacement [5,6,8,9]. In addition, they have proven its noninferiority when compared to other sutured prosthesis [10-13]. The strongest points of these valves include a) the favorable Table 4: Univariate cox proportional hazard of long-term outcomes.

Risk Factors	Redo SAVR	Redo sutureless
RISK FACIOIS	HR (95% CI)	HR (95% CI)
Age (Years)	1.02 (0.96, 1.08)	1.09 (0.88, 1.34)
Gender (Female)	0.84 (0.19, 3.77)	2.38 (0.15, 38.22)
Euroscore II	1.03 (0.96, 1.11)	1.08 (0.92, 1.26)
NYHA	0.39 (0.07, 2.29)	0.48 (0.04, 6.14)
Dialysis	1.23 (0.24, 6.33)	N/A
Tobacco use	4.18 (0.81, 21.60)	0.95 (0.06, 15.28)
COPD	9.74 (2.14, 44.32)*	4.24 (0.26, 67.91)
Hypertension	1.36 (0.16, 11.35)	0.38 (0.02, 6.11)
Dyslipidemia	0.91 (0.18, 4.70)	N/A
Coronary Artery Disease	1.91 (0.43, 8.55)	0.63 (0.04, 10.3)
PVD	0.60 (0.12, 3.10)	1.12 (0.07, 18.42)
Diabetes	1.01 (0.19, 5.21)	1.60 (0.1, 26.26)
Stroke	0.38 (0.04, 3.16)	N/A
Ejection Fraction (EF)	0.96 (0.91, 1.01)	0.93 (0.84, 1.03)
EF<50%	2.50 (0.56, 11.22)	4.86 (0.30, 77.87)
STEMI w/in 90 days	N/A	3.77 (0.23, 61.0)
History of Atrial Fibrillation	3.34 (0.75, 14.9)	N/A
Aortic Stenosis	0.66 (0.15, 2.94)	0.52 (0.03, 8.32)
Prior Primary AVR	N/A	N/A
BMI kg/m <sup>2</sup>	1.14 (1.05, 1.24)*	0.88 (0.66, 1.17)
BMI >30 kg/m <sup>2</sup>	2.15 (0.48, 9.62)	N/A
Creatinine Level	0.999 (0.990, 1.01)	0.94 (0.85, 1.04)
Max Aortic Gradient mmHg	1.03 (0.97, 1.09)	1.02 (0.97, 1.09)
Mean Aortic Gradient mmHg	1.07 (0.96, 1.18)	1.07 (0.96, 1.18)

Table 5: Multivariate Cox proportional hazard of long-term outcomes.

Mortality		
Redo-SAVR* HR (95% CI)		
1.2 (0.2, 5.9)		
1.3 (0.2, 7.5)		
-		

°p<0.05, <sup>⊷</sup>p<0.001

\*reference group is SAVR

hemodynamics outcomes, b) a friendly implant in hostile annulus environment such as endocarditis and reoperations, c) facilitating future ViV-TAVR as sinus struts protect coronary ostia from obstruction and Nitinol cage expandable [14-16]. In this context, our study found that patients undergoing redo AVR with sutureless bioprosthesis had favorable postoperative in-hospital and long-term outcomes.

The Cavalier clinical trial evidenced the critical benefits of using sutureless bioprosthesis [1]. However, future clinical trial comparing sutured and redo-sutureless outcomes with redo SAVR bioprosthesis will give more insight to the right choice of patient. In this context, it is crucial to have a strong and successful heart-team collaboration, capable of selecting the right patient for different types of bioprosthesis

#### Table 6: Cumulative incidence of long-term outcomes.

All Cause Mortality	SAVR n=57	Redo-Sutureless n=25	p-value
1-year	4 (7.0%)	1 (4.0%)	0.71
2-years	5 (8.8%)	1 (4.0%)	0.731
5-years	7 (12.3%)	2 (8.0%)	0.821
7-years	7 (12.3%)	2 (8.0%)	0.821

#### Table 7: Unadjusted and adjusted models.

Propensity -adjusted	Unadjus	ted	Adjusted		
n (%)	Redo SAVR <sup>*</sup> HR (95% CI)	p-value	Redo SAVR <sup>*</sup> HR (95% CI)	p-value	
All-Cause Mortality					
1-year	1.8 (0.2, 15.8)	0.609	1.7 (0.2, 19.0)	0.67	
2-years	2.2 (0.3, 18.7)	0.48	1.7 (0.2, 18.3)	0.643	
5-years	1.3 (0.3, 6.5)	0.71	1.3 (0.2, 7.5)	0.74	
7-years	1.3 (0.3, 6.5)	0.71	1.3 (0.2, 7.5)	0.74	

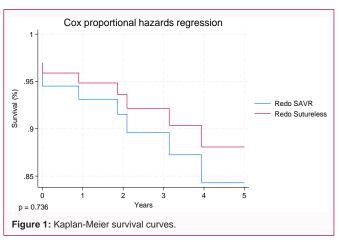
<sup>\*</sup>p<0.05; <sup>\*\*</sup>p<0.001

\*reference group is redo sutureless, adjusted for p-score and age

Ē	Biel: Festers for Martelity
т	Fable 8: Risk factor analysis. Double robust cumulative hazard function analysis.

	Risk Factors for Mortality				
SAVR	HR (95% CI)	Redo-Sutureless	HR (95% CI)		
Ejection Fraction	0.95 (0.89, 1.01)	Ejection Fraction	0.92 (0.8, 1.0)		
COPD	1.58 (0.2, 10.5)	COPD	4.9 (0.2, 96.4)		
BMI	1.21 (1.0, 1.4)				
Atrial fibrillation	1.43 (0.2, 9.2)				
Tobacco Use	10.22 (1.1, 94.8)				

COPD: Chronic Obstructive Pulmonary Disease; BMI: Body Mass Index



based on up-to-date clinical outcome from international literature. It is important that clinical cardiologist, interventional cardiologist, and cardiothoracic surgeons sees all the valves as complementary treatment options based on the patient-risk profile and cardiac anatomy rather than as competing procedures [17-20].

Given the apparent adequacy of our propensity-score weighting (with minimal standardized mean differences) based on elements available in claims data, it is likely that patients undergoing isolated redo AVR may benefit from these outcomes.

### Limitations

This retrospective study was subject to all limitations inherent to a non-randomized study, including potential selection bias regarding which patients underwent redo-AVR with either of the aforementioned bioprosthesis. However, the rigorous propensitymatched and propensity-adjusted analysis limited these biases. In addition, the study includes a large timeframe (2005-2020) and many advanced techniques and changes in medical treatments have occurred in this period. Another limitation is the single-center data; therefore, our analysis needs further validation from multicenter studies.

### Conclusion

There was no difference in term of long-term all-cause death among the two groups. Patients undergoing redo SAVR experienced a higher incidence of POAF compared to patients undergoing redo sutureless bioprosthesis implantation. New risk predictors for patients undergoing redo AVR included BMI and smoke. We hypothesize that patient's individual risk factors profile can help in prosthesis and interventional choice. In addition, optimization of modifiable risk predictors may improve clinical outcomes.

### References

- Laborde F, Fischlein T, Hakim-Meibodi K, Misfeld M, Carrel T, Zembala M, et al; Cavalier Trial Investigators. Clinical and haemodynamic outcomes in patients receiving the Perceval sutureless aortic valve: early results from a prospective European multicentre study (the Cavalier Trial)<sup>†</sup>. Eur J Cardiothorac Surg. 2016;49(3):978-86.
- Dokollari A, Ramlawi B, Torregrossa G, Sá MP, Sicouri S, Prifti E, et al. Benefits and Pitfalls of the Perceval sutureless bioprosthesis. Front Cardiovasc Med. 2021;8:789392.
- 3. Dokollari A, Torregrossa G, Sicouri S, Veshti A, Margaryan R, Cameli M, et al. Pearls, pitfalls, and surgical indications of the Intuity TM heart valve: A rapid deployment bioprosthesis. A systematic review of the literature. J Card Surg. 2022;37(12):5411-7.
- Shrestha M, Folliguet T, Meuris B, Dibie A, Bara C, Herregods MC, et al. Sutureless Perceval S aortic valve replacement: A multicenter, prospective pilot trial. J Heart Valve Dis. 2009;18(6):698-702.
- Fischlein T, Meuris B, Hakim-Meibodi K, Misfeld M, Carrel T, Zembala M, et al; CAVALIER Trial Investigators. The sutureless aortic valve at 1 year: A large multicenter cohort study. J Thorac Cardiovasc Surg. 2016;151(6):1617-26.e4.
- 6. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, et al; Valve Academic Research Consortium (VARC)-2. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document (VARC-2). Eur Heart J. 2012;33(19):2403-18.
- Elze MC, Gregson J, Baber U, Williamson E, Sartori S, Mehran R, et al. Comparison of propensity score methods and covariate adjustment: Evaluation in 4 cardiovascular studies. J Am Coll Cardiol. 2017;69(3):345-57.
- Yanagawa B, Cruz J, Boisvert L, Bonneau D. A simple modification to lower incidence of heart block with sutureless valve implantation. J Thorac Cardiovasc Surg. 2016;152(2):630-2.

- Sá MP, Jabagi H, Dokollari A, Awad AK, Van den Eynde J, Malin JH, et al. Early and late outcomes of surgical aortic valve replacement with sutureless and rapid-deployment valves versus transcatheter aortic valve implantation: Meta-analysis with reconstructed time-to-event data of matched studies. Catheter Cardiovasc Interv. 2022;99(6):1886-96.
- 10. Dokollari A, Cameli M, Mandoli GE, Kalra DKS, Poston R, Coku L, et al. Early and midterm clinical outcomes of transcatheter valve-invalve implantation versus redo surgical aortic valve replacement for aortic bioprosthetic valve degeneration: Two faces of the same medal. J Cardiothorac Vasc Anesthesia. 2021;35(11):3223-31.
- 11. Dokollari A, Coku L. Risk scores predicting patient-prosthesis mismatch after aortic valve replacement. Where do we stand? J Card Surg. 2021;36(8):2816-7.
- Dokollari A, Cameli M, Kalra DK, Gelsomino S, Bisleri G, Bonacchi M. Success in long-term outcome after cardiac surgery: Rise from an uncomplicated immediate postoperative course. J Card Surg. 2021;36(6):2053-4.
- Mazine A, Teoh K, Bouhout I, Bhatnagar H, Pelletier M, Voisine P, et al. Sutureless aortic valve replacement: A Canadian multicentre study. Can J Cardiol. 2015;31(1):63-8.
- 14. Casha AR, Manche A, Camilleri L, Yamagata K, Santucci S, Gauci M, et al. Sutureless Perceval aortic valve implantation compared with conventional Mitroflow valve replacement. Indian J Thorac Cardiovasc Surg. 2018;34:109-15.
- 15. Lorusso R, Jiritano F, Roselli E, Shrestha M, Folliguet T, Meuris B, et al. Perioperative platelet reduction after sutureless or stented valve implantation: results from the PERSIST-AVR controlled randomized trial. Eur J Cardiothorac Surg. 2021;60(6):1359-65.
- 16. Meco M, Montisci A, Miceli A, Panisi P, Donatelli F, Cirri S, et al. Sutureless perceval aortic valve versus conventional stented bioprostheses: Meta-analysis of postoperative and midterm results in isolated aortic valve replacement. J Am Heart Assoc. 2018;7(4):e006091.
- Nguyen A, Fortin W, Mazine A, Bouchard D, Carrier M, El Hamamsy I, et al. Sutureless aortic valve replacement in patients who have bicuspid aortic valve. J Thorac Cardiovasc Surg. 2015;150:851-7.
- 18. Miceli A, Berretta P, Fiore A, Andreas M, Solinas M. Sutureless and rapid deployment implantation in bicuspid aortic valve: results from the sutureless and rapid-deployment aortic valve replacement international registry. Ann Cardiothorac Surg. 2020;9(4):298-304.
- Gersak B, Glauber M, Bouchard D, Jug J, Solinas M. Oversizing increases pacemaker implantation rate after sutureless minimally invasive aortic valve replacement. Innovations (Phila). 2020;15(5):449-55.
- 20. Dokollari A, Margaryan R, Torregrossa G, Sicouri S, Cameli M, Mandoli GE, et al. Risk predictors that impact long-term prognosis in patients undergoing aortic valve replacement with the Perceval sutureless bioprosthesis. Cardiovasc Revasc Med. 2023;55:10-19.