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Preoperative atrial fibrillation/flutter impact on risk-adjusted repeat aortic intervention patients

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Abstract

Aim: Impacts of pre-operative atrial fibrillation or flutter (AF/AFL) upon repeat aortic valve replacement (r-AVR) patients' risk-adjusted short-term outcomes is unknown.

Methods: From 2005-2018, New York State AF/AFL versus non-AF/AFL adults' risk-adjusted r-AVR outcomes were compared. Primary endpoints included the Society of Thoracic Surgeons' 30-day operative mortality or major morbidity (MM) composite and 30-day readmission (READMIT); the MM sub-components were secondary endpoints. Multivariable logistic regression models evaluated AF/AFL impact upon these endpoints while holding other factors constant.

Results: Of 36,783 adults initially undergoing aortic valve replacement, 334 subsequently underwent r-AVR. Within this r-AVR group, 42.4% of repeat surgical (r-SAVR) patients had AF/AFL; 50.4% of repeat transcatheter (viv-TAVR) patients had AF/AFL. R-SAVR AF/AFL patients were older and had more comorbidities than those without AF/AFL. Viv-TAVR AF/AFL patients were similar to those without AF/AFL except for lower rates of chronic obstructive pulmonary disease. Comparing risk-adjusted r-AVR outcomes, AF/AFL did not impact MM



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[odds ratio (OR), 95% confidence interval (CI): 1.23, 0.66-2.28, $P = 0.512$] or READMIT (OR, 95%CI: 1.15, 0.60-2.19, $P = 0.681$). Black race (OR, 95%CI: 2.89, 1.01-8.32, $P = 0.049$) and Elixhauser mortality score (OR, 95%CI: 1.07, 1.04-1.10, $P < 0.0001$) predicted MM risk. Cerebrovascular disease (OR, 95%CI: 2.54, 1.23-5.25, $P = 0.012$) predicted READMIT risk, while viv-TAVR was protective compared to r-SAVR (OR, 95%CI: 0.44, 0.21-0.91, $P = 0.027$).

Conclusion: AF/AFL was not associated with risk-adjusted short-term r-AVR outcomes. Black race, Elixhauser mortality score, and cerebrovascular disease predicted adverse outcomes.

Keywords: Atrial fibrillation, atrial flutter, aortic valve replacement

INTRODUCTION

Atrial fibrillation (AF) and atrial flutter (AFL) are common arrhythmias occurring in patients with valvular disease, with 25% to 40% of severe aortic valve disease patients having comorbid AF^[1-3]. Both aortic stenosis (AS) and AF are progressive diseases, and their prevalence increases with older age^[4]. Development of AF may produce symptoms that lead to intervention for previously asymptomatic aortic valve pathology. The definitive treatment for severe AS is aortic valve replacement (AVR); these procedures can be performed either by a transcatheter AVR (TAVR) intervention or via surgical AVR (SAVR).

Pre-operative AF has been associated with poor outcomes following cardiac surgery^[5-7] and has previously been studied in patients undergoing first-time AVR. The impact of AF on mortality following first-time AVR is not clear as several studies report AF to be an independent predictor of mortality, while others did not identify AF as a risk factor for mortality^[1,8-11]. However, AF has been associated with various major complications after first-time AVR. Following SAVR, there is an increased risk of adverse cerebrovascular and cardiac events in patients with pre-existing AF^[9]. Post-TAVR, patients with AF have higher rates of bleeding events, renal failure, and permanent pacemaker placement^[1]. AF patients also have increased healthcare utilization requirements following first-time AVR, such as length of hospital stay and adjusted healthcare costs^[11].

While the effects of pre-existing atrial fibrillation or flutter on first-time SAVR and TAVR outcomes have been well-studied, there is a paucity of data regarding the impact of these arrhythmias in repeat AVR (r-AVR) procedures. Specifically, prosthetic valve failure is a significant concern following AVR interventions; in these cases, r-AVR via redo SAVR (r-SAVR) or valve-in-valve (viv) TAVR (viv-TAVR) is the standard of care^[12]. As a synopsis, this study addressed the knowledge gap regarding the impact of pre-operative AF/AFL on risk-adjusted r-SAVR and viv-TAVR outcomes. Comparing r-AVR patients with and without AF/AFL, this study's primary outcomes of interest included 30-day readmission and a composite of major complications and/or 30-day operative mortality. Additional secondary outcomes included mortality, length of stay, and adverse cardiac, renal, neurologic, and vascular complications.

METHODS

Database description and ethical approval

This retrospective, observational cohort study was conducted to compare risk-adjusted r-SAVR and viv-TAVR outcomes in patients with preoperative AF/AFL (AF/AFL+) and without pre-operative AF/AFL (AF/AFL-). The New York State Statewide Planning and Research Cooperative System (SPARCS) database was used for data collection. Developed in 1979, SPARCS is an all-payer reporting database that compiles information from hospitals throughout New York State regarding demographics, diagnoses, therapeutic interventions, and outcomes. Coordinated via the Department of Surgery (Dr. Pryor-Principal Investigator),

r-AVR patients' records were extracted from the SPARCS database. For the 2005–2018 New York State SPARCS database records, de-identified reports were generated by the Biostatistical Consulting Core Lab; using only de-identified reports for this study, a “not human subjects research” written exemption for these analyses was received by the Stony Brook University Committee on Research in Human Subjects (IRB 2021-00563). The study's protocol is available online at: <https://commons.library.stonybrook.edu/dos-articles/1/>.

Patient population

This study's analyses relied upon a comprehensive list of billing codes (see [Supplementary Table 1](#); using coding manuals, these billing codes were identified by expert coders, the billing code details were extracted by the study data analytics team. All billing codes used were validated by the study's clinician team. Using these codes, the inpatient records for adults (age > 18) undergoing a non-emergent AVR procedure from January 2005 through November 2018 were extracted. Duplicate records ($N = 23$), records with unknown gender ($N = 1$), and records missing unique personal identifiers (UPID; $N = 193$) were excluded. Patients who had an r-AVR at least 30 days after the first AVR were identified. Due to the increased risk for an adverse post-AVR event, patients with concomitant or prior coronary artery bypass graft or percutaneous coronary intervention, prior thoracic aortic aneurysm, aortic dissection, active endocarditis, solid tumor without metastasis, or metastatic cancer were also excluded. Demographics, baseline health conditions, and Elixhauser comorbidity score (See [Supplementary Table 2](#)) at r-AVR were considered. The Elixhauser score described patients' risk of mortality and readmission based on pre-existing diagnoses^[13].

Study outcomes

Co-primary study endpoints included the Society of Thoracic Surgeons' (STS) composite endpoint [major morbidity (MM); a composite comprised of 5 major complications and/or 30-day operative mortality] and 30-day readmission (READMIT). As secondary study endpoints, the STS composite's individual 30-day operative mortality and 5 major morbidity sub-components were separately examined; these included STS major complications of a periprocedural permanent stroke, renal failure, prolonged ventilation, deep sternal wound infection, and/or repeat procedure within 30 days of the first r-AVR procedure^[14]. The STS 30-day operative mortality definition included both in-hospital death and all deaths within 30 days of the procedure. Additional secondary outcomes were evaluated, including length of hospital stay [length of stay (LOS); time from admission date to discharge date], post-procedure LOS (time from procedure date to discharge date), as well as non-STs post-procedural clinically relevant SAVR/TAVR complications including myocardial infarction, cardiac arrest, acute kidney injury, prosthetic valve endocarditis, major stroke, transient ischemic attack, major bleeding, and vascular complications. As comorbidities are commonly difficult to differentiate from post-procedural complications by exclusively using billing codes, major complications were identified only if there had been no prior evidence of that condition for the two years preceding the procedure. Following October 2015, new ICD-10 complication codes were also used to differentiate complications from comorbidities^[15,16].

Statistical analysis

Statistical analyses were performed by an institutional biostatistical consulting core lab team member with SPARCS data analytics expertise and SAS 9.4 (SAS Institute Inc., Cary, NC) biostatistics/database programming experience; data extraction, analysis and manuscript writing tasks occurred from January 2021 to February 2022. Demographics, baseline health conditions, and Elixhauser comorbidity score (See [Supplementary Table 2](#)) at r-AVR were considered. The Elixhauser score describes patients' risk of mortality and readmission based on pre-existing diagnoses. Chi-square tests with exact P -values based on Monte Carlo simulation were utilized to examine the marginal association between categorical variables (patients' characteristics, risk factors, specific Elixhauser comorbidities) and AF/AFL+, as well as between categorical variables and binary outcomes (e.g., MM and READMIT)^[17]. Welch's t -tests were used to

compare the unadjusted marginal differences in continuous variables (age, Elixhauser readmission score, Elixhauser mortality score) by AF/AFL+ or by binary outcomes (MM and READMIT).

As the first step, the cardiac literature was carefully reviewed to identify the patients' risk factors to be considered as model-eligible for the MM and READMIT multivariable logistic regression models. Based on these initial literature-based conceptual variable lists, endpoint-specific bivariate screenings (P -value < 0.10) were evaluated to identify potential associations; additionally, these variables' effect sizes were ordered to identify the optimal multivariable model-eligible variables. Importantly, variables were removed from model eligibility consideration for any coding completeness issues, clinical interpretability challenges, or collinearity with well-established AVR risk factors. Given inherent sample size ($n = 334$) limitations, the number of MM and READMIT endpoints was divided by 10 to identify the maximum number of multivariable risk model-eligible variables; thus, there were 6 MM model-eligible variables and 5 READMIT model-eligible variables pre-screened to be included in multivariable models^[18,19]. Similarly, a multivariable logistic regression model reported the other patient characteristics that were most commonly associated with pre-operative AF/AFL ($n = 152$ AF/AFL patients; 15 AF/AFL pre-screened variables were included as AF/AFL model-eligible).

Based on nested c-index comparisons, the multivariable models containing the Elixhauser score performed better than models utilizing Elixhauser-related comorbidities; thus, the Elixhauser score's weighted sub-components were not further considered as model-eligible variables^[20]. In each logistic regression analysis, an odds ratio (OR) > 1.00 indicated an adverse outcome impact, while an OR < 1.00 indicated a protective effect. Observed/expected (O/E) ratios were calculated using baseline regression models without the key variables of interest compared; however, final study regression models directly assessed the impact of these key variables of interest. For all analyses performed, the protocol-driven statistical significance threshold was set at $P < 0.05$; however, all unadjusted p-values are reported for independent review. Statistical analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Data extraction isolated 74,675 AVR records and identified 73,945 patients undergoing an initial AVR procedure, among which 36,783 were kept after performing exclusion criteria. Following these AVR patients subsequently, there were 334 patients with r-AVR records meeting all study inclusion and exclusion criteria [Figure 1]. Of these, 205 patients underwent r-SAVR; 42.4% of r-SAVR patients had pre-operative AF/AFL. In the viv-TAVR group of 129 patients, 50.4% had pre-operative AF/AFL. Comparing r-SAVR to viv-TAVR patients, there was no difference in the baseline AF/AFL rates ($P = 0.156$).

Baseline patient characteristics

As described in Table 1, r-SAVR AF/AFL+ patients were significantly older (mean \pm standard deviation: 69.92 ± 11.06 vs. 59.17 ± 14.00 , $P < 0.001$) and less often Hispanic (1.2% vs. 8.5%, $P = 0.029$) compared AF/AFL-patients. For r-SAVR patients with AF/AFL+ versus AF/AFL-, cerebrovascular disease (19.5% vs. 8.5%, $P = 0.021$), permanent pacemaker or implantable cardiac defibrillator (16.1% vs. 4.2%, $P = 0.004$), hyperlipidemia (63.2% vs. 46.6%, $P = 0.018$), rheumatic heart disease (11.5% vs. 3.4%, $P = 0.028$), fluid and electrolyte disorders (4.6% vs. 0.0%, $P = 0.032$), and pulmonary hypertension (26.4% vs. 11.9%, $P = 0.007$) were more frequently reported. Although viv-TAVR AF/AL+ versus AF/AFL- patients had similar distributions for demographics and comorbidities, there were no statistically significant risk factor differences other than AF/AFL+ viv-TAVR patients had lower rates of chronic obstructive pulmonary disease (15.4% vs. 31.3%, $P = 0.033$).

Table 1. Baseline characteristics and risk factors in patients with and without pre-operative AF/AFL undergoing r-SAVR and viv-TAVR

	r-SAVR				viv-TAVR			
	Total	AF/AFL (42.4%)	No AF/AFL (57.6%)	P-value	Total	AF/AFL (50.4%)	No AF/AFL (49.6%)	P-value
Patient characteristics								
Admission type (%)								
Elective	82.0	82.8	81.4	0.7963	78.3	78.5	78.1	0.9630
Urgent	18.1	17.2	18.6		21.7	21.5	21.9	
Gender (%)								
Female	36.6	42.5	32.2	0.1293	46.5	44.6	48.4	0.6634
Male	63.4	57.5	67.8		53.5	55.4	51.6	
Age (years) (mean ± std)	63.73 ± 13.87	69.92 ± 11.06	59.17 ± 14.00	< 0.0001	76.13 ± 10.00	76.23 ± 10.29	76.03 ± 9.79	0.9103
Race (%)								
Black	10.2	12.6	8.5	0.3306	3.1	4.6	1.6	0.6254
Other	89.8	87.4	91.5		96.9	95.4	98.4	
Ethnicity (%)								
Hispanic	5.4	1.2	8.5	0.0278	1.6	1.5	1.6	1.0000
Other/ Unknown	94.6	98.9	91.5		98.5	98.5	98.4	
Insurance (%)								
Commercial	39.0	19.5	53.4	< 0.0001	17.1	21.5	12.5	0.2012
Medicaid/ Other	4.9	3.5	5.9		0.8	1.5	0.0	
Medicare	56.1	77.0	40.7		82.2	76.9	87.5	
Risk factors								
Tobacco/Smoking (%)	38.1	37.9	38.1	0.9762	42.6	43.1	42.2	0.9187
Obesity (%)	19.5	16.1	22.0	0.2887	24.0	18.5	29.7	0.1357
Hypertension (%)	76.1	79.3	73.7	0.3544	88.4	84.6	92.2	0.1798
CHF (%)	15.6	18.4	13.6	0.3462	55.0	58.5	51.6	0.4310
Cardiomyopathy (%)	6.3	5.8	6.8	0.7643	14.7	16.9	12.5	0.4785
Diabetes mellitus (%)	2.9	1.2	4.2	0.2451	1.6	1.5	1.6	1.0000
CAD (%)	30.2	34.5	27.1	0.2566	76.0	81.5	70.3	0.1357
COPD (%)	4.4	3.5	5.1	0.7321	23.3	15.4	31.3	0.0330
Stroke (%)	8.8	11.5	6.8	0.2385	11.6	16.9	6.3	0.0935
Carotid stenosis (%)	2.4	2.3	2.5	1.0000	3.9	6.2	1.6	0.3645
Cerebrovascular disease (%)	13.2	19.5	8.5	0.0206	20.9	27.7	14.1	0.0571
Peripheral vascular disease (%)	3.9	5.8	2.5	0.2932	9.3	6.2	12.5	0.2412

MI (%)	5.9	4.6	6.8	0.5677	17.8	18.5	17.2	0.8501
PPM/ICD (%)	9.3	16.1	4.2	0.0038	20.2	26.2	14.1	0.0870
Depression (%)	7.3	5.8	8.5	0.4586	10.9	10.8	10.9	0.9755
Bipolar disorder (%)	1.0	2.3	0.0	0.1782	0.0	0.0	0.0	-
Schizophrenia (%)	0.0	0.0	0.0	-	1.6	0.0	3.1	0.2448
Dementia (%)	0.0	0.0	0.0	-	3.1	4.6	1.6	0.6260
Bicuspid aortic valve (%)	1.0	0.0	1.7	0.5103	0.0	0.0	0.0	-
Syncope (%)	0.5	0.0	0.9	1.0000	0.0	0.0	0.0	-
Dyspnea (%)	3.4	3.5	3.4	1.0000	3.9	4.6	3.1	1.0000
Chest pain (%)	2.4	3.5	1.7	0.6621	2.3	3.1	1.6	1.0000
Hyperlipidemia (%)	53.7	63.2	46.6	0.0184	67.4	69.2	65.6	0.6621
Elevated lipoprotein (%)	0.0	0.0	0.0	-	0.0	0.0	0.0	-
History of mitral valve repair or replacement (%)	19.0	16.1	21.2	0.3583	11.6	13.9	9.4	0.4283
AAA (%)	2.4	2.3	2.5	1.0000	1.5	0.0	3.1	0.2477
Non-rheumatic aortic stenosis (%)	55.6	49.4	60.2	0.1259	64.3	72.3	56.3	0.0569
Rheumatic heart disease (%)	6.8	11.5	3.4	0.0283	8.5	7.7	9.4	0.7322
Obstructive sleep apnea (%)	12.7	8.1	16.1	0.0867	10.9	9.2	12.5	0.5506
Leukemia (%)	0.5	1.2	0.0	0.4244	1.6	3.1	0.0	0.4911
Lymphoma (%)	1.0	1.2	0.9	1.0000	0.8	1.5	0.0	1.0000
CKD with dialysis (%)	1.0	2.3	0.0	0.1810	4.7	4.6	4.7	1.0000
CKD without dialysis (%)	19.0	23.0	16.1	0.2144	39.5	38.5	40.6	0.8016
Iron deficiency anemia (%)	13.7	9.2	17.0	0.1101	13.2	13.9	12.5	0.8212
Rheumatoid arthritis & collagen vascular diseases (%)	3.9	3.5	4.2	1.0000	5.4	3.1	7.8	0.2743
Fluid & electrolyte disorders (%)	2.0	4.6	0.0	0.0319	0.8	1.5	0.0	1.0000
Pulmonary hypertension (%)	18.1	26.4	11.9	0.0073	22.5	26.2	18.8	0.3139
Thrombocytopenia (%)	31.7	34.5	29.7	0.4634	16.3	16.9	15.6	0.8417
Hypothyroidism (%)	11.7	12.6	11.0	0.7203	19.4	15.4	23.4	0.2473
IABP (%)	3.4	5.8	1.7	0.1327	0.8	0.0	1.6	0.4945
Elixhauser mortality index score	13.60 ± 11.15	15.14 ± 11.02	12.47 ± 11.16	0.0896	14.45 ± 10.55	15.43 ± 10.61	13.45 ± 10.48	0.2888
Elixhauser readmission index score	22.20 ± 14.59	23.67 ± 14.68	21.13 ± 14.49	0.2198	30.52 ± 15.60	30.43 ± 15.45	30.61 ± 15.87	0.9485

r-SAVR: Redo surgical aortic valve replacement; viv-TAVR: valve-in-valve transcatheter aortic valve replacement; AF/AFL: atrial fibrillation/flutter; CHF: congestive heart failure; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; PPM: permanent pacemaker; ICD: implantable cardiac defibrillator; AAA: abdominal aortic aneurysm; CKD: chronic kidney disease; IABP: intra-aortic balloon pump.

As overall comorbidity complexity scores, the Elixhauser summary indices were not different for r-SAVR patients with and without pre-operative AF/AFL (Elixhauser Mortality Index: 15.14 ± 11.02 vs. 12.47 ± 11.16 , $P = 0.090$; Elixhauser Readmission Index: 23.67 ± 14.68 vs. 21.13 ± 14.49 , $P = 0.220$). Similarly, viv-TAVR patients with AF/AFL+ versus AF/AFL- had no difference in their Elixhauser summary indices (Elixhauser Mortality Index: 15.43 ± 10.61 vs. 13.45 ± 10.48 , $P = 0.289$; Elixhauser Readmission Index: 30.43 ± 15.45 vs. 30.61 ± 15.87 , $P = 0.949$).

Outcomes following repeat AVR

Repeat AVR outcomes are described in [Table 2](#). Study endpoints were evaluated in the r-SAVR and viv-TAVR cohorts [[Figure 2](#)]. Rates of the main study endpoints were similar for patients with AF/AFL compared to those without after r-SAVR (STS composite endpoint: 24.1% vs. 14.4%, $P = 0.076$; 30-day readmission: 19.5% vs. 14.4%, $P = 0.329$) and viv-TAVR (STS composite endpoint: 18.5% vs. 15.6%, $P = 0.668$; 30-day readmission: 15.4% vs. 9.4%, $P = 0.301$). Of all r-AVR procedures, the AF/AFL+ versus AF/AFL- patients had no differences identified for the MM composite (21.7% vs. 14.8%, $P = 0.103$) and for 30-day READMIT (17.8% vs. 12.6%, $P = 0.191$). Across all r-SAVR outcomes evaluated, the AF/AFL+ patients had increased rates of prolonged ventilation (10.3% vs. 2.5%, $P = 0.031$) and cardiac arrest (14.9% vs. 5.1%, $P = 0.016$). Additionally, r-SAVR patients with AF/AFL had significantly increased post-operative days (12.74 ± 11.23 vs. 9.31 ± 8.05 , $P = 0.017$). Viv-TAVR patients with and without AF/AFL had similar rates of clinical and resource utilization outcomes. Univariate analysis results for 30-day readmission and the composite endpoint are described in [Supplementary Tables 3 and 4](#).

Multivariable modeling for preoperative atrial fibrillation

To understand the nature of the r-AVR patient population presenting with AF/AFL, a multivariable model was built to identify the other patient characteristics associated with preoperative AF/AFL risk. The multivariable model's patient characteristics identified to be associated with presence of preoperative AF/AFL included older age (OR, 95%CI: 1.03, 1.01-1.05, $P = 0.017$), along with no documented history of cerebrovascular disease (OR, 95%CI: 0.44, 0.23-0.86, $P = 0.017$) or prior pacemaker or implantable cardiac defibrillator (OR, 95%CI: 0.45, 0.22-0.92, $P = 0.029$); this model's c-index was 0.729 and Hosmer-Lemeshow test statistic P -value = 0.0617 (indicating no lack of model fit).

Multivariable modeling for primary study outcomes

The impact of AF/AFL on the STS composite endpoint was evaluated while holding other variables constant [[Table 3](#)]. This final model had a C-index of 0.753. Presence of pre-operative AF/AFL did not significantly impact odds of the composite (OR, 95%CI: 1.23, 0.66-2.28, $P = 0.512$). Other predictors of the composite endpoint included black race (OR, 95%CI: 2.89, 1.01-8.32, $P = 0.049$) and Elixhauser mortality score (OR, 95%CI: 1.07, 1.04-1.10, $P < 0.0001$).

For 30-day readmission, the impact of AF/AFL was evaluated holding other model-eligible variables constant [[Table 4](#)]. For this 30-day readmission model, the model had a c-index of 0.682. Pre-operative AF/AFL did not affect odds of 30-day readmission (OR, 95%CI: 1.15, 0.60-2.19, $P = 0.681$). However, history of cerebrovascular disease predicted 30-day readmission (OR, 95%CI: 2.54, 1.23-5.25, $P = 0.012$); additionally, viv-TAVR compared to r-SAVR procedures were protective against 30-day readmission (OR, 95%CI: 0.44, 0.21-0.91, $P = 0.027$).

As sensitivity analyses, the multivariable model built predicting the likelihood of patients incurring preoperative AF/AFL was added to the co-primary endpoint models built for the composite endpoint and for 30-day readmission [[Supplementary Tables 5 and 6](#)]. As these propensity scores did not substantially alter this study's co-primary models' findings, the current study conclusions should be considered robust.

Table 2. Outcomes of r-SAVR and viv-TAVR in patients with and without pre-operative AF/AFL

	r-SAVR				viv-TAVR			
	Total	AF/AFL (42.4%)	No AF/AFL (57.6%)	P-value	Total	AF/AFL (50.4%)	No AF/AFL (49.6%)	P-value
Permanent stroke (%)	2.4	3.5	1.7	0.6406	0.8	1.5	0.0	1.0000
Renal failure (%)	12.7	13.8	11.9	0.6817	10.1	10.8	9.4	0.7925
DSWI (%)	1.0	1.2	0.9	1.0000	0.0	0.0	0.0	-
Prolonged ventilation (%)	5.9	10.3	2.5	0.0307	6.2	4.6	7.8	0.4949
Repeat procedure (%)	0.0	0.0	0.0	-	0.0	0.0	0.0	-
Major complication (%)	18.1	23.0	14.4	0.1143	14.7	16.9	12.5	0.4785
30-day operative mortality (%)	2.9	2.3	3.4	0.7034	4.7	4.6	4.7	1.0000
Composite endpoint (%)	18.5	24.1	14.4	0.0764	17.1	18.5	15.6	0.6684
In-hospital death (%)	2.9	2.3	3.4	0.7021	4.7	4.6	4.7	1.0000
LOS (%)	11.86 ± 10.16	13.47 ± 11.73	10.68 ± 8.69	0.0628	8.27 ± 9.94	9.54 ± 9.39	6.98 ± 10.38	0.1454
Post-operative days (%)	10.77 ± 9.65	12.74 ± 11.23	9.31 ± 8.05	0.0167	7.22 ± 9.49	8.49 ± 9.11	5.92 ± 9.75	0.1246
Conversion to SAVR (%)	-	-	-	-	0.0	0.0	0.0	-
30-day readmission (%)	16.6	19.5	14.4	0.3287	12.4	15.4	9.4	0.3005
AKI (%)	12.7	13.8	11.9	0.6817	9.3	9.2	9.4	0.9775
Cardiac arrest (%)	9.3	14.9	5.1	0.0161	3.9	4.6	3.1	1.0000
Major bleeding (%)	5.9	5.8	5.9	0.9555	2.3	1.5	3.1	0.6135
Prosthetic valve endocarditis (%)	2.0	0.0	3.4	0.1412	0.0	0.0	0.0	-
TIA (%)	0.0	0.0	0.0	-	0.8	1.5	0.0	1.0000
Vascular complications (%)	0.0	0.0	0.0	-	0.0	0.0	0.0	-
MI (%)	1.5	0.0	2.5	0.2728	4.7	4.6	4.7	1.0000
Major stroke (%)	2.9	2.3	3.4	0.7127	2.3	3.1	1.6	1.0000

r-SAVR: Redo surgical aortic valve replacement; viv-TAVR: valve-in-valve transcatheter aortic valve replacement; AF/AFL: atrial fibrillation/flutter; DSWI: deep sternal wound infection; LOS: length of stay; AKI: acute kidney injury; TIA: transient ischemic attack; MI: myocardial infarction.

Table 3. Multivariable model findings for STS MM composite endpoint

	Odds ratio	95% confidence interval	P-value
Pre-operative AF/AFL	1.23	0.66-2.28	0.512
Admission type: elective vs. urgent	0.55	0.27-1.10	0.093
Race: black vs. other	2.89	1.01-8.32	0.049
Insurance: commercial vs. medicare	0.66	0.27-1.59	0.632
Insurance: medicaid/other vs. medicare	0.66	0.11-4.09	0.632
Age	1.01	0.98-1.04	0.636
Elixhauser mortality score	1.07	1.04-1.10	< 0.0001

Model C-index = 0.753. STS: Society of thoracic surgeons; MM: major morbidity; AF/AFL: atrial fibrillation/flutter.

DISCUSSION

This novel retrospective, observational database analysis assessed the impact of preoperative AF/AFL on risk-adjusted clinical and resource outcomes for patients undergoing r-AVR procedures while holding other factors constant. While these arrhythmic conditions have previously been evaluated in first-time AVR, there was a paucity of data regarding AF/AFL in r-AVR candidates. Holding other risk factors constant, this r-

Table 4. Multivariable model findings for STS 30-day readmission endpoint

	Odds ratio	95% confidence interval	P-value
Pre-operative AF/AFL	1.15	0.60-2.19	0.681
Surgery type: viv-TAVR vs. r-SAVR	0.44	0.21-0.91	0.027
Cerebrovascular disease	2.54	1.23-5.25	0.012
Age	1.02	0.99-1.05	0.117
Elixhauser readmission score	1.02	0.997-1.04	0.102

Model C-index = 0.682. STS: Society of thoracic surgeons; AF/AFL: atrial fibrillation/flutter; r-SAVR: Redo surgical aortic valve replacement; viv-TAVR: valve-in-valve transcatheter aortic valve replacement.

AVR study did not find that pre-operative AF/AFL increased the risk of 30-day readmission or the risk of incurring the STS MM composite comprised of major complications and/or mortality.

These repeat AVR-related findings do not support the previously reported negative impacts of AF/AFL in first-time AVR^[8-10,21-24]. Several theories for worse outcomes with pre-operative AF/AFL have been proposed. AF may be a consequence of more chronic and severe aortic valve disease and may lead to reduced cardiac output, both of which could contribute to increased resource utilization and worsened outcomes^[8]. Additionally, AF is known to result in atrial fibrosis and structural remodeling that may contribute to longer-term cardiovascular mortality which may require additional post-procedural care^[10,25].

For r-SAVR patients, baseline demographics and medical conditions differed between AF/AFL versus non-AF/AFL patient sub-groups. Pre-operative AF/AFL patients in the r-SAVR cohort were significantly older and less commonly of Hispanic ethnicity, but had higher rates of cerebrovascular disease history, permanent pacemaker/implantable cardiac defibrillator, hyperlipidemia, rheumatic heart disease, fluid and electrolyte disorders, and pulmonary hypertension. Among viv-TAVR patients, those with and without pre-operative AF/AFL generally had similar demographics. AF/AFL viv-TAVR patients had lower rates of chronic obstructive pulmonary disease compared to non-AF/AFL patients. Notably, Elixhauser comorbidity scores were similar between patients with and without pre-operative AF/AFL for both r-SAVR and viv-TAVR, indicating relatively comparable comorbidity burdens.

There was no association between 30-day readmission or the MM composite endpoint with AF/AFL for either r-SAVR or viv-TAVR. However, r-SAVR AF/AFL patients had higher prolonged ventilation, cardiac arrest, and post-operative length of stay days than the non-AF/AFL group. Previous literature has found preoperative AF associated with a longer length of stay for both first-time SAVR and TAVR^[11]. In contrast to prior publications regarding SAVR and TAVR outcomes, the current study found no difference in postoperative stroke rates between AF/AFL versus non-AF/AFL patients^[26]. Use of perioperative and/or postoperative anticoagulation was unknown but may have contributed to this finding.

Multivariable analyses evaluating the impact of AF/AFL yielded several predictors of these study endpoints. Black race and Elixhauser mortality score predicted the composite endpoint; this is consistent with previous studies showing increased risk of prolonged ventilation, renal failure, and need for reoperation after first-time SAVR in patients of black race^[27]. However, the impact of black race on first-time TAVR outcomes is not clear. Patients of black race were shown to have increased post-TAVR intubation and hemodynamic instability^[28]. In contrast, other published reports did not find a similar racial association with major complications or mortality^[29,30]. Future research, therefore, now appears warranted to evaluate potential r-AVR racial disparities in clinical and resource outcomes.

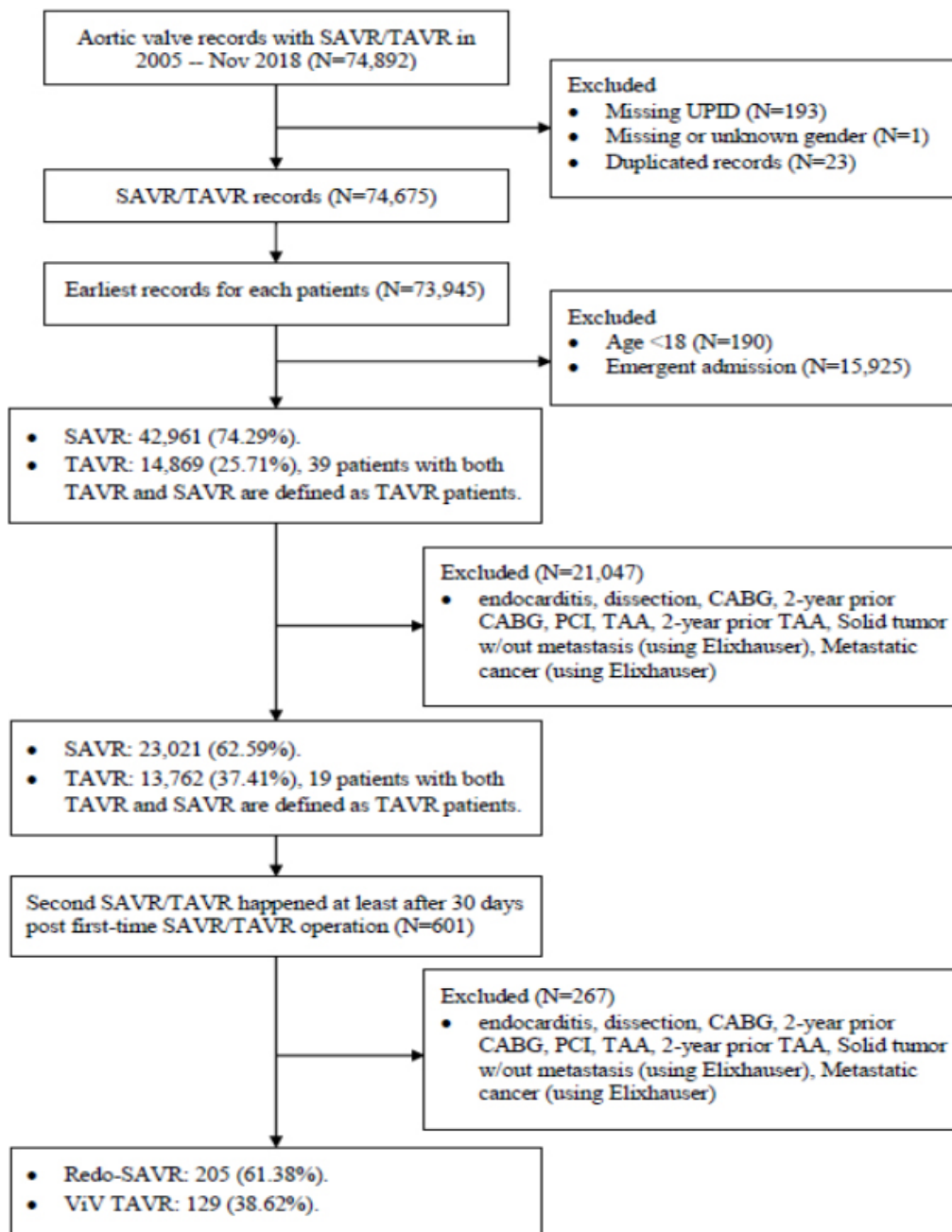


Figure 1. Data extraction flowchart. SAVR: Surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement; CABG: coronary artery bypass graft; PCI: percutaneous coronary intervention; TAA: thoracic aortic aneurysm.

Comparing the predictors for the 30-day composite endpoint, there were important differences between first-time and repeat AVR procedures. Although female sex, age, congestive heart failure (CHF), coronary artery disease, cerebrovascular disease, and renal function were previously documented to impact first-time SAVR patients' adverse clinical outcomes^[31,32], these were not identified in the present r-AVR study. Similarly, pulmonary hypertension, renal function, and diabetes had been found to be predictors of post-TAVR adverse clinical outcomes in a prior study^[33].

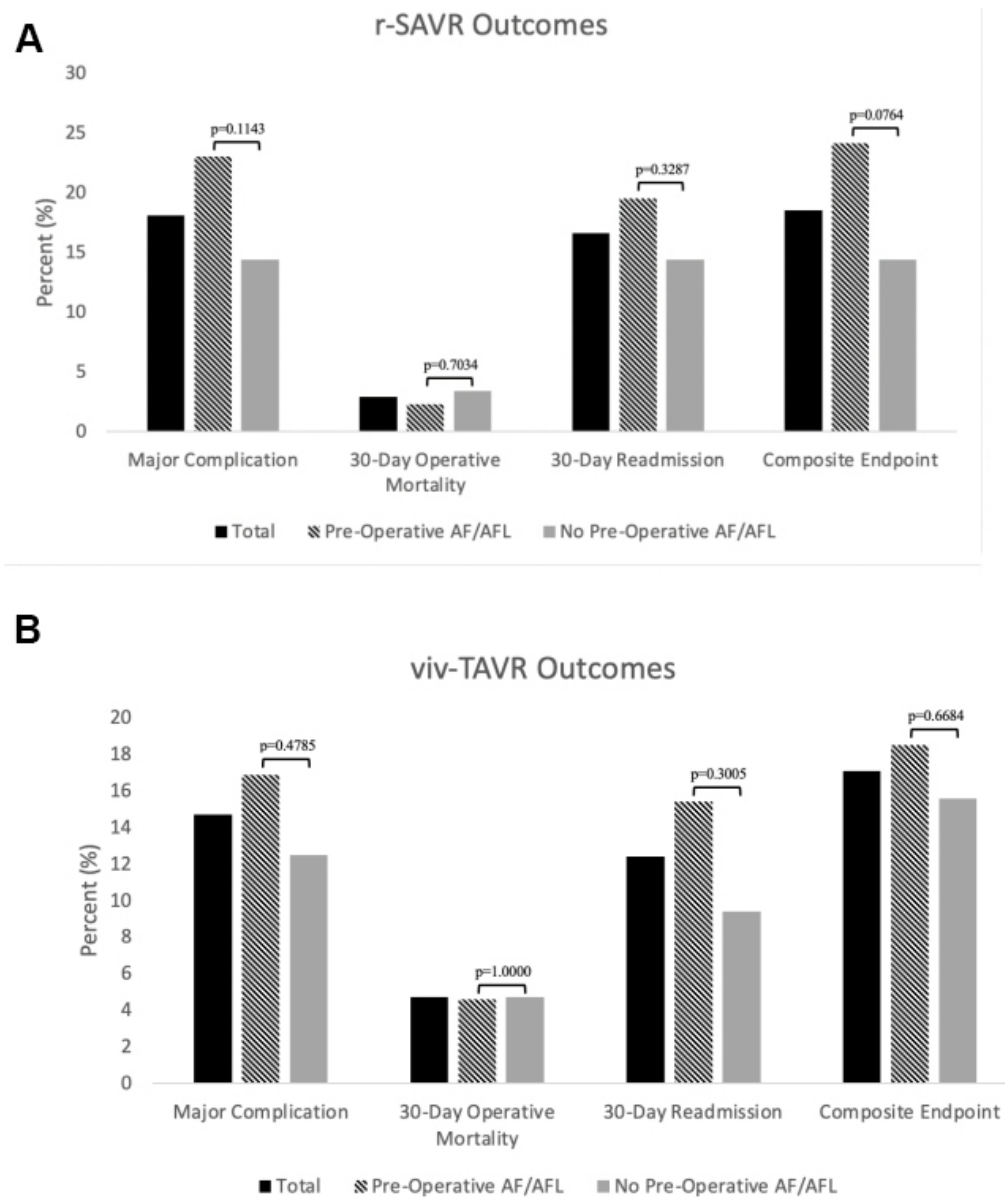


Figure 2. Endpoint outcomes in patients with and without pre-operative AF/AFL undergoing (A) r-SAVR and (B) viv-TAVR. r-SAVR: Redo surgical aortic valve replacement; AF/AFL: atrial fibrillation/flutter; viv-TAVR: valve-in-valve transcatheter aortic valve replacement.

For 30-day readmission, cerebrovascular disease was predictive while viv-TAVR was protective compared to r-SAVR. In contrast, first-time SAVR and TAVR were shown to have similar 30-day readmission rates in prior reports^[34-36]. Other risk factors associated with 30-day readmission have previously been described in the literature, such as female sex, age, and chronic kidney disease in first-time SAVR patients^[21], and CHF, chronic obstructive pulmonary disease, pacemaker, diabetes, renal failure, and anemia in first-time TAVR patients^[22,37-39].

Interestingly, not all historically reported first-time AVR comorbidities were found to be predictive of r-AVR patients' 30-day readmission; thus, this r-AVR study's small sample size may have limited ability to detect these well-documented risk factors for first-time AVR. Additionally, a first-time AVR survivor or

referral bias may have occurred, where higher-risk first-time AVR patients did not survive or were not referred as candidates for r-AVR procedures.

This study has identified several factors putting patients at high risk of adverse r-AVR outcomes, including black race, Elixhauser mortality score, and cerebrovascular disease. These high-risk groups may require additional attention from the clinical care team to consider options for mitigating these increased risks for adverse events following r-AVR procedures and facilitating closer post-discharge monitoring for “at-risk” patients. Furthermore, clinicians may wish to consider these findings during their pre-operative evaluations regarding patient referrals for r-AVR interventions as well as during patient-clinician discussions of informed consent. Importantly, additional research appears warranted to evaluate the impact of pre-operative AF/AFL patients’ long-term outcomes.

Limitations

As an observational database analysis, this study has several inherent limitations. As with any retrospective cohort study, there may have been unknown confounding factors impacting the MM composite and/or READMIT endpoints. To address this limitation, however, all literature-based risk factors that were previously identified with a potential association with the endpoints were evaluated in this r-AVR study.

Additionally, this study was limited by a small sample size ($n = 334$). As a follow-up to this study, future analyses of a much larger r-AVR database should be planned. Given these preliminary findings, future research should utilize a database containing at least 15,518 r-AVR records to detect a difference in the READMIT endpoint; for the MM endpoint, a future study should plan to utilize a database of at least 5857 r-AVR records. These future sample size projections were based on a power of 80% and a significance level of 0.05. Given these findings, however, national databases (e.g., the MEDPAR or Cerner national database) will be required to address this question more rigorously. Thus, these preliminary findings based on the New York State AF/AFL patients’ experience should be re-verified by testing these same hypotheses in a larger r-AVR population.

Across SPARCS hospitals’ r-AVR procedures reported, this study focused on the population of adult New York State residents; thus, the post-procedural follow-up endpoints (i.e., 30-day readmissions and 30-day operative death) might be most accurate. Given that children (under age 18) may have other complex congenital cardiac abnormalities requiring phased sets of cardiac procedures, these were removed. As New York residents may have differential risks, moreover, their findings may not be reliably generalized to other populations with a different risk profile.

As this SPARCS billing database was used to drive hospital reimbursement, the billing codes have been assumed to be reasonably accurate. However, SPARCS administrative billing errors in coding may exist, particularly for the subgroup of billing codes not directly tied to differential reimbursement. As hospital billing codes transitioned from ICD-9 to ICD-10 in October 2015, moreover, there may have been transition-related coding-related inconsistency challenges for patient risk factors, treatment, and outcome codes. As the transition of ICD-9 codes to the newer ICD-10 codes may have been imperfect, a historical “look back” period of 2-years was used to augment the new ICD-10 complication classification codes; this approach assured that comorbidities (i.e., important risk factor diagnoses existing pre-procedure, such as the patient having a prior stroke pre-procedure) could be differentiated from complications (i.e., new diagnoses arising post-procedure, such as a patient having a perioperative stroke). Given the SPARCS database does not contain current procedural terminology codes (i.e., cardiac interventionalist billing codes) regarding all of the cardiac procedure’s details (e.g., type and size of prosthetic valve implant) or

echocardiographic information (e.g., aortic valve area, gradient across the valve, velocity across the valve, and dimensionless index), this clinical information was not available for endpoint risk-adjustment. Based on billing codes alone, continuous arrhythmias could not be distinguished from intermittent arrhythmias to analyze for a differential effect on outcomes. Additionally, SPARCS does not include medication details (i.e., national drug codes); thus, the impact of different medical management approaches using specific drug therapies either pre-procedure or perioperatively could not be further investigated.

In conclusion, Pre-operative AF/AFL was not associated with 30-day readmission or the composite endpoint, consisting of major complications and/or operative mortality, following r-SAVR and viv-TAVR. However, this study identified other predictors of these adverse outcomes, including black race, Elixhauser mortality score, and cerebrovascular disease, which may allow clinicians to identify patients at elevated r-AVR risk.

DECLARATIONS

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Availability of data and materials

Data was obtained from the 2005-2018 New York State Statewide Planning and Research Cooperative System database.

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Conflicts of interest

The authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

This study (IRB2021-00563: Pre-AF r-AVR SPARCS Study) relies on deidentified data reports; thus, this study was determined to be "not human subjects research" by the institutional review board of the Stony Brook University Committee on Research in Human Subjects on November 2, 2021.

Consent for publication

Not applicable.

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