

2021

## Preoperative Atrial Fibrillation/Flutter Impact on Risk-Adjusted Repeat Aortic Intervention Patients[PROTOCOL]

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### Recommended Citation

Novotny, Samantha; Dokko, Julia; Zhang, Xiaoyue; Agha, Sohaib; Yaligar, Ashutosh; Kolba, Natalie; Tummala, Vineet; Parikh, Puja; Pryor, Aurora; Tannous, Henry; Shroyer, A. Laurie; and Bilfinger, Thomas, "Preoperative Atrial Fibrillation/Flutter Impact on Risk-Adjusted Repeat Aortic Intervention Patients[PROTOCOL]" (2021). *Department of Surgery Faculty Publications*. 1.  
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**Title:** Preoperative Atrial Fibrillation/Flutter Impact on Risk-Adjusted Repeat Aortic Intervention Patients

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**Purpose and Specific Aims:**

Using publicly available de-identified Statewide Planning and Research Cooperative System (SPARCS) data reports, this study will identify the New York State (NYS)-based rates for hospital admissions with a diagnosis of aortic valve disease from 2005-2018:

- a. Patients who underwent first-time surgical AVR (SAVR) or transcatheter (TAVR) will be included.
  - i. Of these, patients who underwent repeat AVR (r-AVR; e.g., redo SAVR (r-SAVR) or valve-in-valve (ViV) TAVR) after first-time AVR will be identified.
  - ii. Patients with confounding conditions may be excluded, such as age <18, emergent admissions, endocarditis, aortic dissection, thoracic aortic aneurysm, solid cancer, metastatic cancer, and/or concurrent or 2-year prior CABG or PCI.
  - iii. Patients will be stratified by presence or absence of pre-operative atrial fibrillation (AF).
- b. Data on baseline demographics, prior comorbidities, procedural characteristics, and outcomes will be extracted.
- c. Across all of these categories, the hospital deaths and readmissions that occurred will be tracked. Risk-adjusted death and readmission rates will be coordinated after adjusting for age, ethnicity, and gender to compare outcomes in patients with and without pre-existing atrial fibrillation.

The following hypotheses will be tested:

H(0): There will be no difference in demographics and comorbidities in repeat AVR patients with and without pre-existing AF.

H(0): There will be no difference in risk-adjusted outcomes following repeat AVR between patients with and without pre-existing AF, after holding other factors constant.

As secondary hypotheses, the outcome-related sub-components may be evaluated. Additional tertiary analyses may be performed to explore opportunities to develop future research projects.

### **Background and Significance:**

Symptomatic severe aortic valve disease is managed via aortic valve replacement (AVR). Traditionally, surgical AVR (SAVR) was the standard of care. Since the relatively recent development of transcatheter AVR (TAVR) techniques, the volume of TAVR procedures has steadily increased and surpassed SAVR volume in 2019.<sup>1</sup> Notably, rates of bioprosthetic valve implantation compared to mechanical valve implantation have also increased.<sup>2,3</sup> Bioprosthetic valves pose higher risk of reoperation due to valve degeneration.<sup>4-7</sup> In cases of bioprosthetic valve degeneration, repeat AVR (r-AVR) is performed. Repeat procedures may be surgical, via redo SAVR (r-SAVR), or transcatheter, via valve-in-valve (viv) TAVR. Volumes of viv-TAVR have increased from 2011 to 2019.<sup>1</sup> In contrast, r-SAVR volumes significantly decreased in 2015-2016 compared to prior years, which may have been related to the FDA approval of viv-TAVR in 2015.<sup>8</sup>

With the increasing need for r-AVR, it is important to be able to risk-stratify patients who may be considered for intervention. In first-time AVR, predictors of adverse outcomes are well-known and include pre-operative atrial fibrillation (AF),<sup>9-13</sup> age,<sup>13</sup> congestive heart failure,<sup>13</sup> prior myocardial infarction,<sup>14</sup> mitral regurgitation,<sup>13</sup> tricuspid regurgitation,<sup>15</sup> renal disease,<sup>14,16</sup> and chronic lung disease.<sup>13,15</sup> However, predictors of r-AVR outcomes are poorly documented. This is of concern as patients undergoing r-AVR are already at elevated risk. Identifying risk factors for adverse events may allow clinicians to perform a more specific risk assessment when deciding to perform repeat procedures.

A particularly concerning pre-existing condition is AF, as it is a well-documented first-time AVR risk factor. Additionally, AF is a common comorbidity in patients with valvular heart disease.<sup>17-19</sup> AF and aortic stenosis become more prevalent with age and are progressive diseases.<sup>20</sup> However, there is a lack of evidence regarding outcomes of r-AVR in AF patients. Thus, this study aims to evaluate the impact of pre-operative AF on r-AVR outcomes including 30-day mortality, complications, and resource utilization.

### **Research Design and Methods:**

This retrospective observational cohort study will be done using the SPARCS publicly available dataset. With the help of the SBU SOM Bioinformatics Department and Biostatistics Core Lab, the SPARCS database will be matched/merged to the enclosed coding listings to generate study-specific de-identified aortic valve stenosis/disease reports. Furthermore, the Bioinformatics and Biostatistics team members will be responsible for providing descriptive statistics regarding patient demographics, comorbidities, and procedural outcomes. All analysis will use a p-value of  $\leq 0.05$  to indicate statistical significance. SAS version 9.4 will be used to complete all the necessary statistical tests.

**Please note, the SPARCS database will be de-identified. As noted on the SPARCS web site, “Public use data files contain de-identified data consisting of basic record-level detail. Public use files do not contain protected health information (PHI) under HIPAA.”**

**Sample Tables:**

Sample 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 (N=)	AF/AFL (N= , %)	No AF/AFL (N= , %)	P-value	Total (N=)	AF/AFL (N= , %)	No AF/AFL (N= , %)	P-value
<b>Patient Characteristics</b>								
Admission Type								
Elective								
Urgent								
Gender								
Female								
Male								
Age (years)								
Race								
Black								
Other								
Ethnicity								
Hispanic								
Other/Unknown								
Insurance								
Commercial								
Medicaid/Other								
Medicare								
<b>Risk Factors</b>								
Tobacco/smoking								
Obesity								
Hypertension								
CHF								
Cardiomyopathy								
Diabetes Mellitus								
CAD								
COPD								
Stroke								
Carotid Stenosis								
Cerebrovascular Disease								
Peripheral Vascular Disease								
MI								
PPM/ICD								
Depression								
Bipolar Disorder								
Schizophrenia								

Dementia  
Bicuspid Aortic  
Valve  
Syncope  
Dyspnea  
Chest Pain  
Hyperlipidemia  
Elevated Lipoprotein  
History of Mitral  
Valve Repair or  
Replacement  
AAA  
Non-Rheumatic  
Aortic Stenosis  
Rheumatic Heart  
Disease  
Obstructive Sleep  
Apnea  
Leukemia  
Lymphoma  
CKD with dialysis  
CKD without dialysis  
Iron Deficiency  
Anemia  
Rheumatoid  
Arthritis/Collagen  
Vascular Diseases  
Fluid and Electrolyte  
Disorders  
Pulmonary  
Hypertension  
Thrombocytopenia  
Hypothyroidism  
IABP  
Elixhauser Mortality  
Index  
Elixhauser  
Readmission Index

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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.

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

	r-SAVR				viv-TAVR			
	Total (N=)	AF/AFL (N= , %)	No AF/AFL (N= , %)	P-value	Total (N=)	AF/AFL (N= , %)	No AF/AFL (N= , %)	P-value
Permanent Stroke								
Renal Failure								
DSWI								
Prolonged Ventilation								
Repeat Procedure								
Major Complication								
30-day Operative Mortality								
Composite Endpoint								
In-Hospital Death								
LOS								
Post-Operative Days								
Conversion to SAVR								
30-Day Readmission								
AKI								
Cardiac Arrest								
Major Bleeding								
Prosthetic Valve Endocarditis								
TIA								
Vascular Complications								
MI								
Major Stroke								

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.

Sample Table 3: Univariate analysis for 30-day readmission among r-AVR patients

Variable	Level	Total (N=)	Row percentage		Column percentage		P-value*
			Yes (N=)	No (N=)	Yes (N=)	No (N=)	
Primary factors							
Pre-operative AF/AFL	No						
	Yes						
Surgery type	Redo SAVR						
	ViV TAVR						
Type of admission	Elective						
	Urgent						
Patients' characteristics							
Gender	Female						
	Male						
Age	Unit=year						
Race	Black						
	Other						
Ethnicity	Hispanic						
	Other\unknown						
Insurance	Commercial						
	Medicaid\Other						
	Medicare						
Risk factors							
Tobacco/Smoking	No						
	Yes						
Hypertension	No						
	Yes						
CHF	No						
	Yes						
Cardiomyopathy	No						
	Yes						
Diabetes mellitus	No						
	Yes						
CAD	No						
	Yes						
COPD	No						
	Yes						



Variable	Level	Row percentage			Column percentage		P-value*
		Total (N=)	Yes (N=)	No (N=)	Yes (N=)	No (N=)	
Stroke	No						
	Yes						
Carotid stenosis	No						
	Yes						
Cerebrovascular Disease	No						
	Yes						
Peripheral Vascular Disease	No						
	Yes						
MI	No						
	Yes						
PPM/ICD	No						
	Yes						
Depression	No						
	Yes						
Bipolar Disorder	No						
	Yes						
Schizophrenia	No						
	Yes						
Dementia	No						
	Yes						
Bicuspid Aortic Valve	No						
	Yes						
Syncope	No						
	Yes						
Dyspnea	No						
	Yes						
Chest Pain	No						
	Yes						
Dialysis	No						
	Yes						
Hyperlipidemia	No						
	Yes						
Elevated Lipoprotein	No						
	No						

Variable	Level	Row percentage		Column percentage		P-value*
		Total (N=)	Yes (N=)	No (N=)	Yes (N=)	
History of Mitral Valve Repair or Replacement	Yes					
AAA	No					
	Yes					
Non rheumatic aortic stenosis	No					
	Yes					
Rheumatic Heart Disease	No					
	Yes					
Obstructive Sleep Apnea	No					
	Yes					
Leukemia	No					
	Yes					
Lymphoma	No					
	Yes					
CKD, with dialysis	No					
	Yes					
CKD, without dialysis	No					
	Yes					
Obesity	No					
	Yes					
Iron Deficiency Anemia	No					
	Yes					
Rheumatoid arthritis/collagen vascular diseases	No					
	Yes					
Fluid and Electrolyte Disorders	No					
	Yes					
Pulmonary Hypertension	No					
	Yes					
Thrombocytopenia	No					
	Yes					
Hypothyroidism	No					
	Yes					
IABP	No					
	Yes					

Variable	Level	Total (N=)	Row percentage		Column percentage		P-value*
			Yes (N=)	No (N=)	Yes (N=)	No (N=)	
Elixhauser Readmission Index							

Note: For continuous variable, mean+/-std were reported.

\*: For categorical variables, p-values were based on Chi-squared test with exact p-value from Monte Carlo simulation; for continuous variables, p-value was based on Welch's t-test.

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

Sample Table 4: Univariate analysis for composite endpoint among r-AVR patients

Variable	Level	Total (N=)	Row percentage		Column percentage		P-value*
			Yes (N=)	No (N=)	Yes (N=)	No (N=)	
Primary factors							
Pre-operative AF/AFL	No						
	Yes						
Surgery type	Redo SAVR						
	ViV TAVR						
Type of admission	Elective						
	Urgent						
Patients' characteristics							
Gender	Female						
	Male						
Age	Unit=year						
Race	Black						
	Other						
Ethnicity	Hispanic						
	Other\unknown						
Insurance	Commercial						
	Medicaid\Other						
	Medicare						
Risk factors							
Tobacco/Smoking	No						
	Yes						

Variable	Level	Row percentage		Column percentage		P-value*
		Total (N=)	Yes (N=)	No (N=)	Yes (N=)	
Hypertension	No					
	Yes					
CHF	No					
	Yes					
Cardiomyopathy	No					
	Yes					
Diabetes mellitus	No					
	Yes					
CAD	No					
	Yes					
COPD	No					
	Yes					
Stroke	No					
	Yes					
Carotid stenosis	No					
	Yes					
Cerebrovascular Disease	No					
	Yes					
Peripheral Vascular Disease	No					
	Yes					
MI	No					
	Yes					
PPM/ICD	No					
	Yes					
Depression	No					
	Yes					
Bipolar Disorder	No					
	Yes					
Schizophrenia	No					
	Yes					
Dementia	No					
	Yes					
Bicuspid Aortic Valve	No					
	Yes					

Variable	Level	Row percentage		Column percentage		P-value*
		Total (N=)	Yes (N=)	No (N=)	Yes (N=)	
Syncope	No					
	Yes					
Dyspnea	No					
	Yes					
Chest Pain	No					
	Yes					
Dialysis	No					
	Yes					
Hyperlipidemia	No					
	Yes					
Elevated Lipoprotein	No					
	Yes					
History of Mitral Valve Repair or Replacement	No					
	Yes					
AAA	No					
	Yes					
Non rheumatic aortic stenosis	No					
	Yes					
Rheumatic Heart Disease	No					
	Yes					
Obstructive Sleep Apnea	No					
	Yes					
Leukemia	No					
	Yes					
Lymphoma	No					
	Yes					
CKD, with dialysis	No					
	Yes					
CKD, without dialysis	No					
	Yes					
Obesity	No					
	Yes					
Iron Deficiency Anemia	No					
	Yes					
	No					

Variable	Level	Row percentage		Column percentage		P-value*
		Total (N=)	Yes (N=)	No (N=)	Yes (N=)	
Rheumatoid arthritis/collagen vascular diseases	Yes					
Fluid and Electrolyte Disorders	No					
	Yes					
Pulmonary Hypertension	No					
	Yes					
Thrombocytopenia	No					
	Yes					
Hypothyroidism	No					
	Yes					
IABP	No					
	Yes					
Elixhauser Readmission Index						

Note: For continuous variable, mean+/-std were reported.

\*: For categorical variables, p-values were based on Chi-squared test with exact p-value from Monte Carlo simulation; for continuous variables, p-value was based on Welch's t-test.

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

Sample Table 5: Multivariable Model Findings for 30-Day Readmission

	Odds Ratio	95% Confidence Interval	P-value
Pre-operative AF/AFL			
Variable 1			
Variable 2			
Variable 3			
Model C-index =			

Sample Table 6: Multivariable Model Findings for STS MM Composite Endpoint

	Odds Ratio	95% Confidence Interval	P-value
Pre-operative AF/AFL			
Variable 1			
Variable 2			
Variable 3			
Model C-index =			

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