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Research Article

Transcatheter Aortic Valve Replacement Improves the Quality of Life for Patients with Chronic Obstructive Pulmonary Disease

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a common comorbidity in patients with aortic stenosis and when severe is a surgical aortic valve replacement contraindication. However, the impact of COPD in patients undergoing TAVR is unclear. This study defines TAVR risks/benefits including quality of life, morbidities, and mortality in COPD patients. All patients undergoing TAVR from August 2012 to June 2023 at a single institution were retrospectively reviewed (n = 1565). 1273 patients with preoperative pulmonary function testing were studied. FEV1/FVC and FEV1% predicted were used to separate patients into groups of COPD severity based on the GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria. Preoperative and postoperative quality of life (QoL) were measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ). Adverse outcomes and mortality at 30-days and 1-year were measured. Severe and very severe COPD patients had significantly higher rates of new onset atrial fibrillation and myocardial infarction compared to patients with no COPD or mild to moderate COPD. There were no statistically significant differences in rates of stroke, permanent pacemaker implantation, 30-day mortality, or 1-year mortality. TAVR improved QoL in all patients regardless of COPD severity or use of home oxygen. Severe COPD patients had the greatest improvement in KCCQ QoL at 30-days and 1-year post-TAVR, while very severe COPD patients had the smallest improvement in KCCQ QoL. Patients with COPD experienced an improvement in quality of life regardless of severity of COPD. Additionally, one year mortality was not significantly different between COPD severity groups. Therefore, TAVR benefits should not be withheld for COPD patients regardless of their severity.

Keywords

Structural Heart Disease, Transcatheter Aortic Valve Replacement (TAVR), Chronic Obstructive Pulmonary Disease (COPD)

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1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) has been reported to increase the risk of surgical and transcatheter aortic valve replacement (SAVR and TAVR) [1]. Among patients with aortic stenosis undergoing TAVR, the prevalence of COPD ranges from 14% to 43% [1-3]. In previous research comparing TAVR and SAVR in COPD patients, TAVR was found to be preferred over SAVR due to significantly fewer respiratory related and non-respiratory related complications [4], and shorter length of hospital stays [5]. However, current research still shows that mortality and rates of adverse outcomes are higher in COPD TAVR patients compared to non-COPD TAVR patients [1, 6-12], particularly in COPD patients with poor mobility or those who were oxygen dependent [13, 14]. With current evidence associating COPD with higher mortality and morbidity and less improvement in function post-TAVR [1, 3, 8, 13], the decision to proceed with TAVR for patients with COPD can be difficult. Many studies have shown poorer outcomes in COPD TAVR patients, but the severity of COPD at which TAVR is contraindicated for is unclear. This study intends to define the potential risks and benefits of TAVR regarding adverse outcomes, mortality, and quality of life in patients with various levels of COPD severity.

2. Materials and Methods

All patients undergoing TAVR at a Sanford hospital in Fargo, North Dakota from August 2012 to June 2023 were retrospectively reviewed (n = 1565). Patient demographics, preoperative workup, procedural details and complications, and post-procedural outcomes were retrospectively reviewed. 1273 patients with preoperative pulmonary function testing were studied. Chronic obstructive pulmonary disease severity was assessed using conventional pulmonary function testing and the GOLD criteria [15], (Table 1).

Table 1. *GOLD COPD Criteria.*

GOLD Class	Criteria
Mild	FEV1/FVC < 0.7 and FEV1% predicted ≥ 80%
Moderate	FEV1/FVC < 0.7 and 50% ≤ FEV1% predicted < 80%
Severe	FEV1/FVC < 0.7 and 30% ≤ FEV1% predicted < 50%
Very Severe	FEV1/FVC < 0.7 and FEV1% predicted < 30%

GOLD criteria for mild, moderate, severe, and very severe COPD based on FEV1/FVC ratio and FEV1%.

Patients on home oxygen therapy were also analyzed independently. Quality of life after TAVR was quantified using the Kansas City Cardiomyopathy Questionnaire (KCCQ) before TAVR and 30-days and one year after TAVR. Baseline adjusted values for KCCQ were calculated as KCCQ at 30-days/1-year minus preoperative KCCQ. Mortality rates at 30-days and 1-year and rates of adverse outcomes post-TAVR including stroke, permanent pacemaker implantation, new onset atrial fibrillation, and myocardial infarction were calculated. Adverse outcomes were defined according to the criteria established in the Valve Academic Research Consortium 3 (VARC) [16].

Statistical Methods

Mean (SD) and median (IQR) values were computed for all continuous variables, and frequency distributions were calculated for all categorical variables. Demographic and other variables using Wilcoxon signed-rank test was used for non-normally distributed or t-test for normally distributed continuous variables and Chi-square or Fisher's exact tests for categorical variables. 95% confidence intervals were estimated using multivariable logistic regression. Kaplan-Meier survival estimates were calculated for patients based on their GOLD classification group, and log-rank test was used to determine significant differences between the categories. Additionally, Kaplan-Meier survival estimates were calculated for patients on home oxygen and patients not on home oxygen, and log-rank test was used to determine significant differences between the categories. Statistics were performed using SAS (SAS Institute, Cary, NC; Version 9.4 Users Guide). All statistical tests were two-tailed with $p < 0.05$ considered significant.

3. Results

Patient demographics and co-morbidities are detailed in Table 2. Patient demographics and co-morbidities within each COPD severity level as defined by the GOLD criteria are shown in Table 3.

Table 2. *Patient Demographics.*

Demographic	All Patients
STS Score	18.45
Gender (% F)	42.30%
BMI	30.42
Age at Procedure	79
Tobacco Use History	58.66%
Smoking History	57.57%
Diabetes	35.14%

Demographic	All Patients	Demographic	All Patients
HTN	85.75%	Hypercholesterolemia	20.77%
CAD	67.92%	Stroke/TIA	12.52%
CHF	40.64%		
PVD	12.74%		
CKD	27.80%		
Hyperlipidemia	77.32%		

Demographics of all TAVR patients analyzed, including STS score, gender, BMI, age at procedure, tobacco and smoking history, and various comorbidities.

Table 3. *Patient Demographics based on GOLD COPD Severity.*

Demographic	None	Mild	Moderate	Severe	Very Severe	p-value
STS Score	17.73	27.43	26.43	5.00	4.72	<0.0001
Gender (% F)	45.93%	32.73%	33.67%	29.89%	29.41%	0.0003
BMI	31.40	28.34	30.28	29.35	27.09	<0.0001
Age at Procedure	78.44	81.78	78.60	74.90	73.13	<0.0001
Tobacco Use History	51.16%	65.45%	79.08%	83.91%	82.35%	<0.0001
Smoking History	50.12%	62.73%	78.57%	83.91%	82.35%	<0.0001
Diabetes	38.49%	20.91%	36.22%	29.89%	11.76%	0.0008
HTN	87.33%	80.91%	84.10%	83.91%	70.59%	0.1010
CAD	67.91%	66.36%	63.78%	67.82%	58.82%	0.7721
CHF	35.81%	33.64%	46.43%	58.62%	47.06%	<0.0001
PVD	10.81%	12.73%	13.78%	18.39%	5.88%	0.2158
CKD	28.37%	19.09%	26.53%	28.74%	11.76%	0.2836
Hyperlipidemia	81.63%	75.45%	76.53%	74.71%	64.71%	0.0886
Hypercholesterolemia	23.05%	16.36%	16.33%	20.69%	11.76%	0.1348

Patient demographics and comorbidities within each COPD severity level as defined by the GOLD criteria.

Clinical outcomes, including stroke, permanent pacemaker implantation, new onset atrial fibrillation, and myocardial infarction, and mortality rates at 30-days and 1-year for patients within varying COPD severity groups as classified by the GOLD criteria are demonstrated in Table 4. Rates of myocardial infarction were significantly increased in patients with increased severity of COPD ($p = 0.0342$). Additionally, rates of new-onset atrial fibrillation were significantly increased in patients with increased severity of COPD ($p = 0.0046$). However using the GOLD criteria, there was not a significant difference in mortality at 30-days ($p = 0.5281$) or 1-year after TAVR ($p = 0.1369$). Kaplan-Meier survival analysis was performed comparing GOLD COPD severity groups over a time period of approximately 7 years post-TAVR, and the Kaplan-Meier curves are shown in Figure 1. There is a significant difference in survival amongst these groups ($p < .0001$).

Table 4. *Outcome Rates and Mortalities based on GOLD criteria severity groups.*

Clinical Outcomes	All Patients (n = 1273)	None (n = 861)	Mild (n = 110)	Moderate (n = 198)	Severe (n = 87)	Very Severe (n = 17)	p-value
Stroke	68 (5.34%)	48 (5.57%)	4 (3.64%)	12 (6.06%)	4 (4.60%)	0 (0.00%)	0.6969
TIA or Delirium	38 (2.99%)	22 (2.56%)	5 (4.55%)	6 (3.03%)	5 (5.75%)	0 (0.00%)	
Pacemaker	150 (11.78%)	103 (11.96%)	12 (10.91%)	22 (11.11%)	11 (12.64%)	2 (11.76%)	0.9898
New Onset Atrial fibrillation	172 (13.51%)	106 (12.31%)	15 (13.64%)	24 (12.12%)	21 (24.14%)	6 (35.29%)	0.0046
MI	219 (17.20%)	138 (16.03%)	15 (13.64%)	37 (18.69%)	25 (28.74%)	4 (23.53%)	0.0342
30-Day Mortality Rate	41 (3.22%)	27 (3.14%)	6 (5.45%)	7 (3.54%)	1 (1.15%)	0 (0.00%)	0.5281
1-Year Mortality Rate	131 (10.29%)	78 (9.06%)	17 (15.45%)	24 (12.12%)	9 (10.34%)	3 (17.65%)	0.1369

Clinical outcomes following TAVR, including stroke/TIA, permanent pacemaker implantation, new onset atrial fibrillation, and myocardial infarction, and mortality rates at 30-days and 1-year for patients within varying COPD severity groups as classified by the GOLD criteria. The data presented here includes the raw number of patients who experienced the adverse outcome and the percentage of patients within each severity group that experienced the adverse outcome.

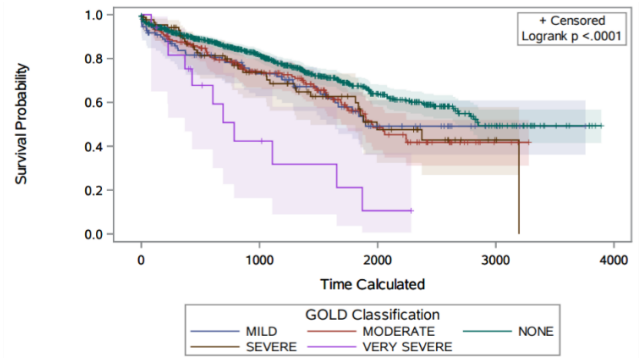

Figure 1. *Graph showing the survival probability of each GOLD COPD severity group as a function of time (days) following TAVR over about 7 years.*

Clinical outcomes, including stroke, permanent pacemaker implantation, new onset atrial fibrillation, and myocardial infarction, and mortality rates at 30-days and 1-year for patients on home oxygen compared to those not on home oxygen are demonstrated in Table 5. Rates of stroke were significantly increased in patients on home oxygen (p = 0.0156). Additionally, rates of myocardial infarction were significantly increased in patients on home oxygen (p = 0.0158). While 30-day mortality was not significantly different between patients on home oxygen and those not on home oxygen (p = 1.0), 1-year mortality was significantly increased in patients on home oxygen (p = 0.0163). Additionally, Kaplan-Meier survival analysis was performed comparing home oxygen patients and non-home oxygen patients over a time period of approximately 7 years post-TAVR, and the Kaplan-Meier curves are shown in Figure 2. There is a significant difference in survival between patients on home oxygen and those not on home oxygen (p <.0001).

Table 5. *Outcome Rates and Mortalities separated by use of home oxygen therapy.*

Clinical Outcome	All (n =1561)	No Home Oxygen (n = 1422)	Home Oxygen (n = 139)	p-value
Stroke	85 (5.45 %)	72 (5.06%)	13 (9.35%)	0.0156
TIA or Delirium	49 (3.14%)	41 (2.88%)	8 (5.76%)	
Pacemaker	177 (11.34%)	156 (10.97%)	21 (15.11%)	0.1420
New Onset Atrial fibrillation	198 (12.68%)	183 (12.87%)	15 (10.79%)	0.5929
MI	254 (16.27%)	221 (15.54%)	33 (23.74%)	0.0158
30-Day Mortality Rate	51 (3.27%)	47 (3.31%)	4 (2.88%)	1.0000

Clinical Outcome	All (n =1561)	No Home Oxygen (n = 1422)	Home Oxygen (n = 139)	p-value
1-Year Mortality Rate	165 (10.57%)	142 (9.99%)	23 (16.55%)	0.0163

Clinical outcomes following TAVR, including stroke/TIA, permanent pacemaker implantation, new onset atrial fibrillation, and myocardial infarction, and mortality rates at 30-days and 1-year for patients on home oxygen compared to those not on home oxygen. The data presented here includes the raw number of patients who experienced the adverse outcome and the percentage of patients within each home oxygen use group that experienced the adverse outcome.

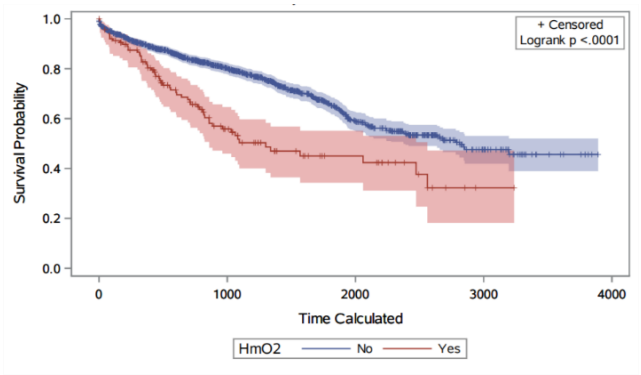

Figure 2. *Graph showing the survival probability of the home oxygen group compared to the non-home oxygen group as a function of time (days) following TAVR over about 7 years.*

Average preoperative KCCQ scores and 30-day and 1-year postoperative KCCQ scores for each GOLD COPD severity group are shown in Table 6. Additionally, the change in KCCQ score from preoperative to 30-days postoperative and preoperative to 1-year postoperative for each GOLD COPD severity group are shown in Table 6. Among the GOLD COPD severity groups, significant differences were observed in preoperative KCCQ, 30-day KCCQ, 1-year KCCQ, change in KCCQ at 30-days, and change in KCCQ at 1-year. The Severe COPD group experienced the greatest improvement in KCCQ at 30-days and 1-year, while the Very Severe COPD group experienced the least improvement in KCCQ at 30-days and 1-year.

Table 6. *Quality of Life by GOLD criteria severity group.*

KCCQ Time	None	Mild	Moderate	Severe	Very Severe	p-value
Preoperative	40.85 (32 – 49) (n = 833)	41.19 (34 – 48) (n = 109)	36.53 (29 – 44) (n = 190)	33.22 (24 – 40) (n = 85)	34.44 (28 – 41.5) (n = 16)	<.0001
30-Days	58.31 (55 – 64) (n = 761)	56.19 (51 – 64) (n = 95)	55.95 (51 – 64) (n = 171)	53.47 (49 – 62) (n = 77)	50.33 (41 – 60) (n = 15)	<.0001
1-Year	59.25 (58 – 64) (n = 587)	57.2 (53 – 64) (n = 65)	57.09 (54 – 64) (n = 137)	55.12 (48 – 64) (n = 58)	50.57 (42 – 61) (n = 7)	<.0001
Change at 30-Days	17.16 (9 – 26) (n = 752)	14.74 (6 – 23) (n = 95)	18.80 (11 – 28) (n = 171)	19.99 (11 – 29) (n = 77)	14.47 (5 – 25) (n = 15)	0.0097
Change at 1-Year	17.86 (9 – 27) (n = 573)	16.27 (8 – 24) (n = 64)	20.89 (11 – 31) (n = 133)	20.79 (12 – 29) (n = 56)	13 (4 – 16) (n = 7)	0.0166

Quality of life as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) within each GOLD COPD severity group assessed preoperatively, 30-days following TAVR, 1-year following TAVR, and the change in quality of life from preoperative to 30-days and 1-year following TAVR. The data presented here includes the average KCCQ values and the interquartile ranges.

Average preoperative KCCQ scores and 30-day and 1-year postoperative KCCQ scores for patients with and without home oxygen use are shown in Table 7. Additionally, the change in KCCQ score from preoperative to 30-days postoperative and preoperative to 1-year postoperative for patients with and without home oxygen use are shown in Table 7.

Between the home oxygen group and the non-home oxygen group, significant differences were observed in preoperative KCCQ, 30-day KCCQ, 1-year KCCQ, and change in KCCQ at 30-days. The home oxygen group had lower KCCQ values preoperatively and at 30-days and 1-year but experienced a greater improvement in KCCQ at 30-days and 1-year compared to the non-home oxygen group.

Table 7. *Quality of life grouped by Home Oxygen Use.*

KCCQ Time	No Home Oxygen	Home Oxygen	p-value
Preoperative	40.14 (31 – 48)	31.70 (25 – 38)	<.0001
	(n = 1380)	(n = 132)	
30-Days	57.97 (55 – 64)	52.28 (47 – 62)	<.0001
	(n = 1250)	(n = 113)	
1-Year	59.09 (57 – 64)	53.53 (47 – 62)	<.0001
	(n = 935)	(n = 83)	
Change at 30-Days	17.56 (9 – 26)	20.31 (12 – 29.5)	0.0223
	(n = 1238)	(n = 112)	
Change at 1-Year	18.59 (10 – 28)	21.28 (12 – 30)	0.0650
	(n = 910)	(n = 82)	

Quality of life as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) for patients on home oxygen compared to those not on home oxygen assessed preoperatively, 30-days following TAVR, 1-year following TAVR, and the change in quality of life from preoperative to 30-days and 1-year following TAVR. The data presented here includes the average KCCQ values and the interquartile ranges.

4. Discussion

Overall, the severity of COPD in patients undergoing TAVR, whether defined by the GOLD criteria or use of home oxygen, affects the rates of adverse outcomes following TAVR. More severe COPD patients tended to have higher rates of adverse outcomes post-TAVR. The risk of adverse outcomes in COPD patients undergoing TAVR is well documented [6, 7, 9, 13]. Our study additionally identifies an increasing risk of myocardial infarction, atrial fibrillation, and stroke associated with increasing severity of COPD (Table 4, Table 5). However, it may be difficult to differentiate whether this increase in adverse outcomes is directly caused by the TAVR procedure or due to the underlying comorbidities that tend to occur more frequently in more severe COPD patients. For example, the presence of congestive heart failure (CHF) and a history of smoking and tobacco use tended to be more common in patients with more severe COPD (Table 3). Previous research also suggests that the increased risk of long-term adverse outcomes may be attributed to coexisting comorbidities and frailty seen in COPD patients, rather than the TAVR procedure itself [9]. However, other comorbidities, such as hypertension, coronary artery disease (CAD), peripheral vascular disease (PVD), chronic kidney disease (CKD), and hyperlipidemia, were not significantly more frequent in more severe COPD patients (Table 3). These potential confounding variables further add to the complexity of determining a causal relationship between the TAVR procedure and increased adverse outcomes in patients with more severe COPD. Regardless of if there is a causal relationship between TAVR and adverse outcomes in patients with COPD, physicians should be aware that patients with severe or very severe COPD may be at an increased risk for new onset atrial fibrillation, myocardial infarction, and stroke, and they should monitor and treat these patients appropriately.

Despite the increased rates of adverse outcomes post-TAVR in patients with more severe COPD, severity of COPD does not significantly impact short-term survival following TAVR as demonstrated by a lack of significant difference in 30-day mortality. This was apparent when using both the GOLD criteria and home oxygen as indicators of COPD severity. Furthermore, COPD severity as defined by the GOLD criteria also did not significantly affect 1-year mortality rates post-TAVR. However, the home oxygen group did have a significantly higher 1-year mortality rate compared to the non-home oxygen group. These trends suggest that patients with COPD tolerate the TAVR procedure well and that their mortality in the short term is not directly impacted by the TAVR procedure. These trends could additionally suggest that the use of home oxygen, as opposed to the GOLD criteria, might more accurately highlight the more severe patients who could possibly see less survival benefit from the TAVR pro-

cedure.

While COPD severity does not significantly impact mortality in the short-term post-TAVR (30-days to 1-year), long-term mortality post-TAVR (> 1 year) is impacted by severity of COPD. This is evident in the Kaplan Meier survival analysis curves done for both the GOLD criteria (Figure 1) and home oxygen use (Figure 2), which compare survival rates over 7 years post-TAVR. For the GOLD COPD groups, the No COPD group, as expected, has the most positive survival curve, while the Mild, Moderate, and Severe curves follow a similar lower trajectory over 7 years. The Very Severe group, however, significantly deviates from the other curves and has a much poorer prognosis. Prior research consistently demonstrates a higher overall risk of mortality in COPD patients compared to those without COPD [1, 9-12]. While this study confirms an increased risk of long-term mortality, it diverges from earlier findings by showing no significant difference in short-term mortality (30-days to 1-year) between COPD and non-COPD patients. This suggests that the elevated risk of long-term mortality in patients with more severe COPD is likely attributable to the underlying disease and associated comorbidities rather than the TAVR procedure itself, as COPD severity does not appear to influence mortality rates within the first year post-TAVR. Overall, regarding mortality, this data suggests that patients with COPD tolerate the procedure well, but severity of COPD continues to affect survival rates past 1-year regardless of the valve replacement.

Regardless of severity of COPD, whether defined by the GOLD criteria or the use of home oxygen, on average KCCQ values improved following TAVR at 30-days and 1-year in all groups. Additionally, of the GOLD COPD groups, the Severe group saw the most improvement in KCCQ scores at 30-days and 1-year, suggesting that patients with increasing COPD severity experience more improvement in quality of life compared to less severe COPD patients. In other words, these more severe COPD patients have more to gain in quality of life from the TAVR procedure compared to their less severe counterparts. In contrast, previous studies have suggested that home oxygen use predicts less improvement in quality of life at 1-year [14, 17] and that greater COPD severity is associated with diminished symptomatic improvement following TAVR [8]. This study introduces a novel finding: patients with increasingly severe COPD showed greater improvements in quality of life, a critical consideration when evaluating the holistic benefits of TAVR for COPD patients. However, consistent with prior research [8], the patients with very severe COPD, while still showing an increase in KCCQ scores, experience the smallest overall improvement in these values post-TAVR compared to all other COPD severity groups. This suggests that there may be a COPD severity cut-off at which the most severe COPD patients begin to experience diminishing returns in quality-of-life following TAVR. Identifying this cut-off point and risk factors that predict less symptomatic improvement post-TAVR could be the topic of future research. Additionally, a more in-depth ethical discussion is required to assess how these benefits of improved quality of life compare to the risks of increased adverse outcomes in more severe COPD patients undergoing TAVR.

5. Conclusions

Our findings suggest that increased COPD severity is associated with higher rates of adverse outcomes, however, short-term mortality is not significantly different. Long-term mortality in patients with COPD who receive TAVR does not appear to be improved, however, regardless of severity, on average patients with COPD experienced an improvement in quality of life. Additionally, this data suggests that patients with increasing COPD severity experienced greater improvement in quality of life compared to their less severe counterparts. Therefore, the benefits of TAVR should not be withheld for COPD patients regardless of severity.

Abbreviations

COPD	Chronic Obstructive Pulmonary Disease
TAVR	Transcatheter Aortic Valve Replacement
QoL	Quality of Life
KCCQ	Kansas City Cardiomyopathy Questionnaire
SAVR	Surgical Aortic Valve Replacement
GOLD	Global Initiative for Chronic Obstructive Lung Disease
FEV1	Forced Expiratory Volume in 1 Second
FVC	Forced Vital Capacity
FEV1%	Forced Expiratory Volume in 1 Second Percentage of the Predicted Value
VARC	Valve Academic Research Consortium 3
STS	Society of Thoracic Surgery
BMI	Body Mass Index
HTN	Hypertension
CAD	Coronary Artery Disease
CHF	Congestive Heart Failure
PVD	Peripheral Vascular Disease
CKD	Chronic Kidney Disease
TIA	Transient Ischemic Attack
MI	Myocardial Infarction
HmO2	Home Oxygen

Author Contributions

Greta Schwartz: Data curation, Writing – original draft
Hunter Row: Writing – review & editing
Jacob Tupa: Data curation
Ashley Matter: Data curation
Abe Sahmoun: Formal Analysis
Thomas Haldis: Supervision
Cornelius Dyke: Conceptualization, Project administration, Supervision, Writing – review & editing

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Data Availability Statement

The data is available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

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Research Fields

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Hunter Row: Transcatheter Aortic Valve Replacement, Cardiovascular Surgery, Cardiac Surgical Outcomes, Hemostasis and Coagulation, Cardiovascular Health Disparities

Jacob Tupa: Transcatheter Aortic Valve Replacement, Cardiothoracic Surgery, Rural Health Disparities, ENT Conditions, Head & Neck surgery

Ashley Matter: Transcatheter Aortic Valve Replacement, Orthopedic Surgery, Cardiology, General Surgery, Cardiothoracic Surgery

Abe Sahmoun: Epidemiology, Biostatistics, Health Services Research, Oncology, Surgery, Quality of care

Thomas Haldis: Transcatheter Aortic Valve Replacement, Interventional Cardiology, Vascular Medicine, Endovascular Interventions, Cardiovascular Health Disparities

Cornelius Dyke: Cardiovascular Health Disparities, Cardiac Surgical Outcomes, Patient Blood Management, Hemostasis and Coagulation, Perioperative Blood Pressure Management