Transcatheter Aortic Valve Implantation Readmissions in the Current Era (from the National Readmission Database)

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Transcatheter aortic valve implantation (TAVI) has become the mainstream treatment for severe aortic stenosis. Despite improvement in device iteration and operator experience rigorous outcome data outside the scope of clinical trials is lacking. Nationwide readmission database 2016 and 2017 was utilized to identify the study population. International Classification of Disease,10th edition codes were used to identify TAVI admissions. Outcomes of interest were the 90-day readmission pattern and in hospital complications of the TAVI procedure. A total of 73,784 TAVI related index admissions were identified in the Nationwide Readmission Database in 2016 to 2017. Forty four percent of patients undergoing TAVI in that timeframe were discharged within 48 hours of their procedure. 16,343 patients (22.2%) were readmitted within 90 days after discharge. Major cardiac co-morbidities like heart failure were prevalent more often in the group of patients that were readmitted within 90 days. Noncardiac causes however accounted for two thirds of these readmissions. The median time to 90-day readmission was 31 days. Multivariate analysis showed that nonagenarians, patients undergoing transapical TAVI, and patients with a higher comorbidity burden were more likely to be readmitted within 90 days. In conclusion, almost half of TAVI patients in the US are discharged within 48 hours after their procedure and 20% of all TAVI patients are readmitted within 90 days. Most readmissions are due to noncardiac causes. **(Am J Cardiol 2020;130:115−122)**

Degenerative aortic valve stenosis affects nearly 2.5 million people in the United States.[1,2] Transcatheter aortic valve implantation (TAVI) uptake has increased exponentially. Twenty-five thousand TAVIs are performed annually across >400 centers in the United States.[3,4] This number will increase further with FDA approval for TAVI in low surgical risk patients.[5,6] Although outcomes with TAVI were non inferior to surgical aortic valve replacement (SAVR) in these randomized control trials, it is still hotly debated whether these outcomes can be duplicated in the real world. Apart from the data in the STS/ACC registry, qualitative data in real world clinical practice is limited.[7−11] Readmission rate is an important metric used to gauge hospital performance. One in 5 Medicare beneficiaries are readmitted within 30 days of hospital discharge. This readmission rate is an annual financial burden of nearly $26 billion on the U.S. economy.[12] The hospital readmission reduction program (HRRP) has led to a significant decline in 30-day readmission rates over the last few years.[13−15] Penalizing hospitals with higher than expected rates of readmission after TAVI may occur in the not too distant future. A real-world patient population was used by the authors to determine the 90-day readmission rate after TAVI and identify patient characteristics associated with higher readmission risk after TAVI.

Methods

The study was derived from the Healthcare Cost and Utilization Project's National Readmission Database (NRD) of 2016 to 2017, sponsored by the Agency for Healthcare Research and Quality. The NRD is one of the largest publicly available all-payer inpatient care databases in the United States, which includes data on approximately 36 million discharges in year. NRD represented 58.2% of total US hospitalizations in 2017. Patients were tracked during same year using variable "NRD_visitlink," and time between 2 admissions was calculated by subtracting variable "NRD_DaysToEvent." Time to readmission was calculated by subtracting length of stay (LOS) of index admissions to time between 2 admissions. Sampling weights provided by the sponsor was used to produce National estimates. The details regarding the NRD data are available online.[16]

We queried NRD database using the International Classification of Diseases, Tenth Revision, procedure codes (ICD-10-PCS) for TAVI (02RF37Z, 02RF38Z, 02RF3KZ and X2RF332 for endovascular TAVI and 02RF37H, 02RF38H, 02RF3JH, 02RF3KH for transapical TAVI) in primary and secondary procedure fields to extract study

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population. Patients with age <18 years, with missing data for age, gender, or mortality were excluded. We also excluded index admissions done after month of September as we did not have 90-day follow-up data for the same. We identified in total 73,784 index admissions. Similar methods for data extraction were used and validated previously.[17−19] Patients who were readmitted to any hospital within 90 days (n = 16,343) within the same calendar year were further evaluated.

The primary endpoint of this study was readmission at 90-days and secondary endpoints were predictors of readmission, etiology of readmission and in-hospital outcomes. Causes of readmission were identified by using ICD-10 CM codes in primary diagnosis filed during readmission observation. We identified 1487 different ICD-10 CM diagnosis codes and combined the ones with similar diagnoses to make clinically important groups (Supplementary Table 1).

NRD variables were used to identify patients' demographic characteristics including age, gender, hospital characteristics (bed size and teaching status), patient-specific characteristics including median household income category for patient's zip code, primary payer, admission type, admission day and discharge disposition as per previously validated methodology.[20] Co-morbidities were identified by appropriate ICD-10 CM diagnosis codes in secondary diagnosis fields. Cost of hospitalization was calculated by merging cost to charge ratio provided by HCUP to main dataset and after adjusting for inflation.[21]

SAS 9.4 (SAS Institute Inc., Cary, North Carolina) was utilized for analyses. Wilcoxon rank sum test was used for differences between continuous variables as data was nonparametric, while chi-square test was used for the differences between categorical variables. Multivariate predictors of 30-day readmission was calculated using hierarchical logistic regression model. In multivariable logistic analysis for 90-day readmission, the authors only included variables that were statistically significant for readmission in the univariate model.

Results

Among 73,784 patients who underwent TAVI during index hospitalization in 2016 and 2017, 16,343 patients (22.2%) were readmitted within 90 days after discharge. Majority of the population were octogenarians (60.7%) and males (54.5%). Most were covered through Medicare/Medicaid (92.5%). Congestive heart failure was the most common cardiac etiology for readmission accounting for 77% of total cardiac causes. Compared with the group of TAVI patients that were nonreadmitted, the group of TAVI patients that were readmitted had a higher prevalence of medical comorbidities. The utilization of coronary angiography was higher among the group of TAVI patients that were readmitted compared with the group of TAVI patients that were non-readmitted (13.2% vs 10.2%, p <0.001). Detailed information about patient and hospital characteristics is provided in Table 1.

Compared with the group of TAVI patients that were nonreadmitted, the readmitted group had a higher incidence of complete heart block, transient ischemic attack/stroke, cardiogenic shock, acute kidney injury (AKI), major bleeding, and vascular complications during index hospitalization. The group of TAVI patients that were readmitted were more likely to be discharged to skilled nursing facilities during the index hospitalization than the group of TAVI patients that were nonreadmitted. (Table 2).

Non- cardiac admissions accounted for 63.75% of all readmissions within 90 days. Among the cardiac conditions responsible for readmissions- decompensated heart failure, hypertension, arrhythmias were most common. The most common noncardiac causes for readmission were infections (13.46%) followed by gastro intestinal causes/complications (6.76%), neurological complications (6.44%) and pulmonary causes/complications (6.27%) (Figure 1). The median time to 30-day readmission was 11 days and 90-day readmission was 31 days (Figure 2). Approximately 73% of patients were readmitted once and only 7% of patients had 3 or more readmissions within 30 days of discharge from index hospitalization (Supplementary Figure 1).

The results of univariate and multivariable hierarchical logistic regression analysis for predictors of 90-day readmission in Table 3. On univariate analysis, transapical approach compared with transfemoral or subclavian approach, nonagenarians compared with age< 80 years, comorbidities such as diabetes mellitus, atrial fibrillation, prior stroke, prior pacemaker/ICD, anemia, coagulopathy, prior PE/deep vein thrombosis (DVT), chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), liver disease, AKI and major bleeding were predictive of higher 90-day readmission. Other factors that were predictive of higher 90-day readmission included discharge to skilled nursing facility and LOS> 2 days. On multivariable analysis, transapical approach, nonagenarians, comorbidities such as diabetes mellitus, congestive heart failure, atrial fibrillation, prior stroke, prior pacemaker/ICD, anemia, COPD, CKD, liver disease, AKI and major bleeding were predictive of higher 90-day readmission. Discharge to skilled nursing facility and LOS >2 days were also predictive of higher 90-day readmission.

Approximately 44% of the patients were discharged within 48 hours of admission and only 31% patients required a stay of 5 days or more (Figure 3). The group of TAVI patients that were non-readmitted were discharged more often in less than 48 hours when compared to the group of TAVI patients that were readmitted (46.7% vs 33.2%, p <0.001). The mean) cost of index hospitalization for the group of TAVI patients that were readmitted was 57,066 USD compared with 52,204 USD for those without readmission (p <0.001) (Table 2).

Discussion

The principal findings of this study are: (1) One in 5 patients are readmitted within 90 days of discharge, (2) The median time to readmission is 31 days, (3) Noncardiac conditions accounted for nearly two-thirds of these readmissions,

Short term readmissions after cardiovascular procedures have gained significant attention since the role out of the HRRP. Previous studies have reported a significant decline in 30-day readmission rates across the diagnoses targeted in the HRRP.[15,22] Although, 30-day readmission rate has been

Table 1
Baseline characteristics of patients with index hospitalization for TAVI

	90 days follow up			
Variable	No Readmission	Readmission	Overall	p value
Index admission	n=57441	n=16343	n=73784	
Age (Years)				<0.001
<80 years	39.4%	39.4%	39.4%	
80-89 years	49.2%	48.6%	49.1%	
≥90 years	11.1%	13.1%	11.6%	
Men	54.7%	53.8%	54.5%	0.061
Women	45.4%	46.2%	45.5%	0.061
Primary payer				<0.001
Medicare/Medicaid	92.2%	93.6%	92.5%	
Private including HMO*	5.6%	4.8%	5.5%	
Other	2.2%	1.6%	2.1%	
Median household income category for patient's zip code†				0.276
1. 0-25th percentile	20.8%	20.8%	20.8%	
2. 26-50th percentile	27.3%	27.8%	27.5%	
3. 51-75th percentile	27.4%	27.6%	27.4%	
4. 76-100th percentile	24.5%	23.8%	24.3%	
Comorbidities				
Hypertension	13.5%	14.5%	13.7%	0.001
Diabetes mellitus	36.1%	40.8%	37.2%	<0.001
Smoker	0.4%	0.4%	0.4%	0.259
Obesity	18.3%	18.2%	18.3%	0.700
Congestive heart failure	71.4%	77.0%	72.6%	<0.001
Atrial Fibrillation/Flutter	38.5%	49.1%	40.8%	<0.001
Peripheral vascular disease	12.9%	14.2%	13.2%	<0.001
Coronary artery disease	69.0%	69.9%	69.2%	0.041
Carotid artery stenosis	6.7%	6.6%	6.6%	0.831
Prior myocardial infarction	12.7%	13.0%	12.7%	0.274
Prior percutaneous coronary intervention	2.6%	2.5%	2.5%	0.741
Prior coronary bypass	19.4%	18.1%	19.1%	<0.001
Prior stroke	11.7%	13.6%	12.2%	<0.001
Prior pacemaker or implantable cardioverter defibrillator	12.6%	14.2%	12.9%	<0.001
Anemia	12.7%	15.7%	13.4%	<0.001
Coagulopathy	1.4%	1.7%	1.4%	0.002
Prior pulmonary embolism/deep venous thrombosis	5.3%	6.0%	5.4%	<0.001
Chronic obstructive pulmonary disease	24.1%	30.2%	25.5%	<0.001
Pulmonary hypertension	18.9%	23.4%	19.9%	<0.001
Chronic kidney disease	34.1%	43.6%	36.2%	<0.001
Liver diseases	1.1%	1.5%	1.2%	<0.001
In-hospital procedures				
TAVR access				<0.001
Endovascular	97.6%	96.8%	97.4%	
Transapical	2.4%	3.2%	2.6%	
Coronary angiography	10.2%	13.2%	10.9%	<0.001
Percutaneous coronary intervention	1.2%	1.4%	1.2%	0.053
Mechanical circulatory support	1.0%	0.9%	0.9%	0.258
Hospital bed size‡				0.196
Small	4.5%	4.3%	4.4%	
Medium	20.0%	20.6%	20.2%	
Large	75.5%	75.1%	75.4%	
Teaching Status§				0.119
Nonteaching	12.2%	12.6%	12.3%	
Teaching	87.8%	87.4%	87.7%	
Admission type				<0.001
Non elective	18.5%	25.6%	20.1%	
Elective	81.5%	74.4%	79.9%	
Admission day				<0.001
Weekdays	96.1%	94.3%	95.7%	
Weekend	3.9%	5.7%	4.3%	

* HMO = Health Maintenance Organization.

† Represents a quartile classification of the estimated median household income of residents in the patients ZIP Code, derived from ZIP Code-demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. https://www.hcup-us.ahrq.gov/db/vars/zipinc_qrtl/nrdnote.jsp

‡ The bed size cutoff points divided into small, medium, and large have been done so that approximately one-third of the hospitals in a given region, location, and teaching status combination would fall within each bed size category. https://www.hcup-us.ahrq.gov/db/vars/hosp_bedsize/nrdnote.jsp

§ A hospital is considered to be a teaching hospital if it has an AMA-approved residency program, is a member of the Council of Teaching Hospitals (COTH) or has a ratio of full-time equivalent interns and residents to beds of 0.25 or higher. https://www.hcup-us.ahrq.gov/db/vars/hosp_ur_teach/nrdnote.jsp

Table 2
In-hospital outcomes after Transcatheter aortic valve implantation

	In-hospital outcomes			
Variable	No readmission	Readmission	Overall	p value
Surgical aortic valve replacement	0.2%	0.1%	0.1%	0.017
Complete heart block	9.0%	10.6%	9.3%	<0.001
Permanent pacemaker placement	*	*	*	0.141
Transient ischemic attack/Stroke	0.3%	0.5%	0.4%	0.027
Acute myocardial infarction	0.2%	0.2%	0.2%	0.619
Cardiogenic shock	1.8%	2.2%	1.9%	0.002
Cardiac arrest	0.8%	0.7%	0.8%	0.792
Acute kidney injury	10.0%	15.6%	11.3%	<0.001
Major bleeding	6.6%	8.8%	7.1%	<0.001
Vascular complications	3.6%	4.9%	3.9%	<0.001
Length of stay(days)				<0.001
≤2	46.7%	33.2%	44.0%	
>2	53.3%	66.8%	56.0%	
Discharge disposition				<0.001
Home	88.2%	78.1%	85.9%	
Skilled nursing facility	11.8%	21.9%	14.1%	
Cost of care in USD (mean± Std Error)	52204±160	57066±335	53278±145	<0.001

* Low numbers, not shown per HCUP policy.

extensively used to measure the in-hospital quality of care, its validity and reliability remains controversial.[23]

In an effort to consolidate the quality of care, CMS recently announced the creation of the bundled payment care initiative, wherein hospitals assume financial liability for the Medicare beneficiaries during a 90-day episode of care starting with index hospitalization.[24] Under these episode payment models (EPMs), hospitals are paid a fixed amount for all the services provided within the episode of care; eg.90 days. This represents a substantial divergence from the traditional fee for service model and penalizes hospitals with higher than the negotiated cost of care for that condition. Readmissions contribute significantly to this cost. This payment model incentivizes hospitals and providers to attempt delivery of high quality, efficient value-based care. Recent studies have reported 90-day readmission data following acute myocardial infarction and percutaneous coronary intervention, data related to TAVI are nonexistent.[25,26] The expansion of EPMs to include TAVI is likely not too far off and hence the results of this study are invaluable.

Approximately 22% of patients were readmitted within 90 days after the index procedure. The strongest predictor for readmission was being discharged to a skilled nursing facility after the procedure (OR 1.58, p <0.001). Length of stay was the second most important predictor in the multivariate model. Patients that had a longer length of stay after the TAVI had a 40% higher risk of readmission within 90 days. Patients undergoing TAVI with intrathoracic access and nonagenarians were also at higher risk for readmission. The higher the baseline co-morbidity burden and the occurrence of a

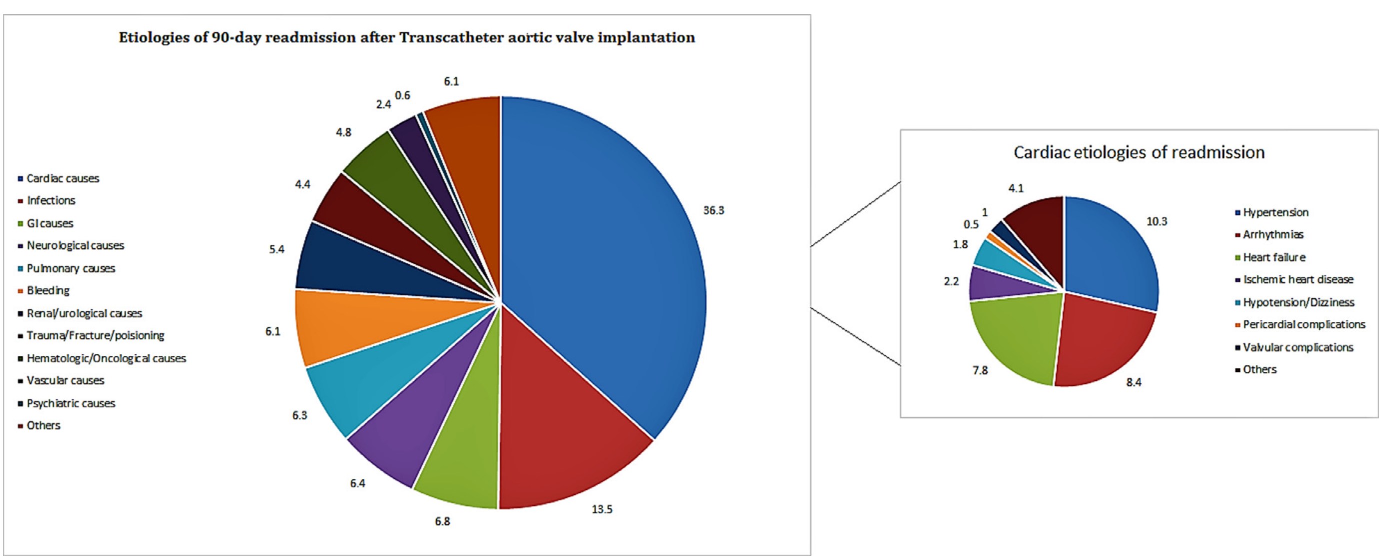

Figure 1. Etiologies of 90-day readmission after TAVI. TAVI, transcatheter aortic valve implantation.

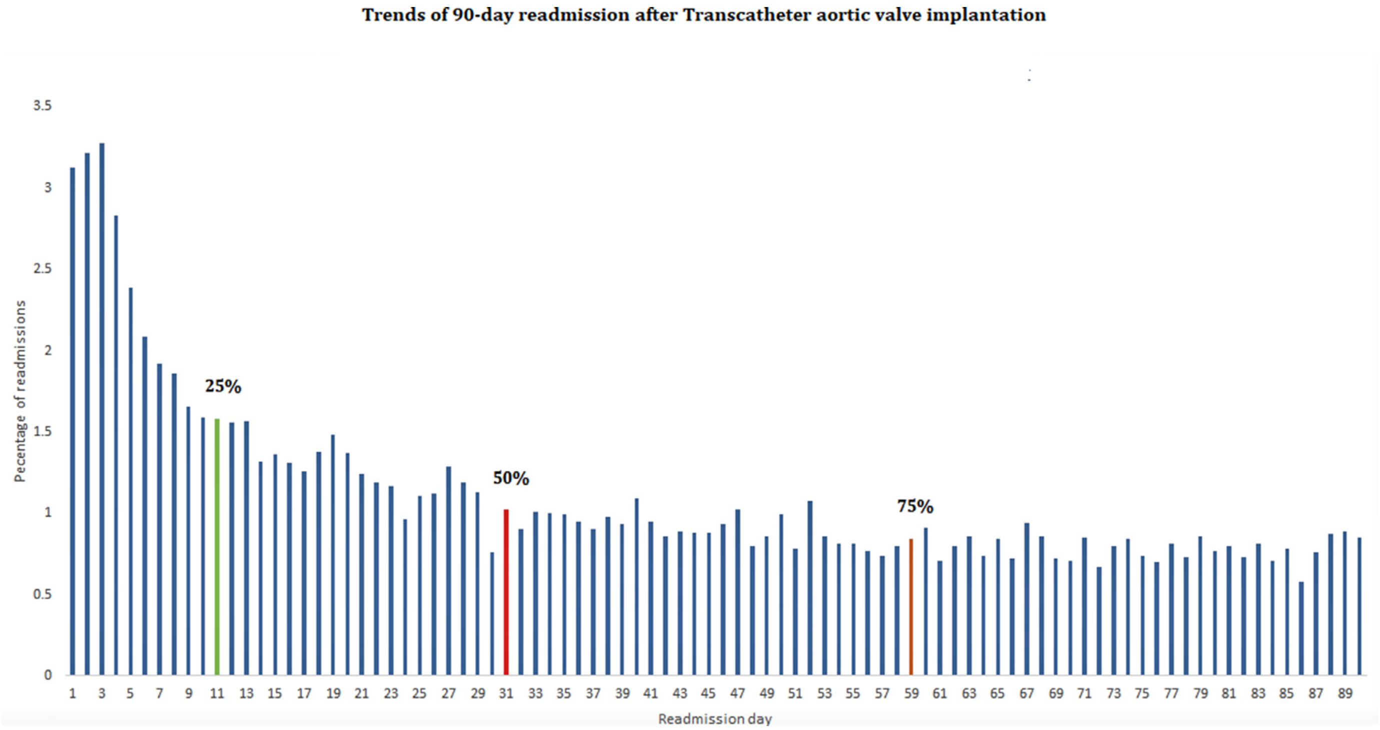

Figure 2. Trends in 90-day readmission after TAVI. TAVI, transcatheter aortic valve implantation.

procedural complication were also associated with a higher risk of readmission within 90 days. Murugiah et al and Kolte et al had reported 30-day readmission rates of 20.9 and 17.9%, respectively,[27] In the STS registry, the readmission rate at 1 year was approximately 25%.[28] In this study, the median time for readmission was a little over 1 month after the procedure. The 22.6% readmission rate at 90 days in this study, falls in-between that reported at 1 month and 1 year in multiple previous studies using different data sets and hence this number appears generalizable.

Since there is no perfect performance metric, payors and hospitals juggle between using outcomes, processes of care and structure as surrogates. The most commonly used utilization-based outcome is readmission. For both, TAVI and cardiac surgery, the 30-day readmission rate has been used as a surrogate for outcome. There is an ongoing hazard of mortality and readmission risk beyond 30 days for both TAVI and SAVR. This risk appears to plateau at 90 days and does not seem to change significantly over the next year. Hence, using 30-day data as a surrogate for outcome measurement has the potential to underestimate mortality by 40% and readmissions by 20% in the TAVI populaton.[27]

Voluntary hospital public reporting of TAVI outcomes will commence in August 2020. The publicly reported measures will be commercial transfemoral TAVI volume, in-hospital risk adjusted mortality and 30-day risk adjusted mortality. Hospitals will be benchmarked using a 3-star system like that used by the STS for surgical programs. Using a 30-day metric versus a 90-day metric would misclassify the rankings of 20% of hospitals participating in this report.[29,30]

Infections, gastro intestinal causes, neurological events, pulmonary issues, and bleeding rounded out the top 5 non-cardiac causes for readmissions in this study. Due to the diverse reasons for readmission, a comprehensive multidisciplinary strategy at discharge is vital. In addition to the cardiology team, home health nurses, physical therapists, nutritionists, and general internists play a vital role in minimizing the cascade of readmission in these vulnerable patients. Readmission reflects quality in different aspects of the health care delivery chain and should not be lumped with measures of processes that improve mortality and health status of patients undergoing TAVI. This is one of the limitations of using readmission be it at 30-days or 90-days as a surrogate for quality.

The economic impact of the TAVI explosion has not been felt by the health care system yet. Once TAVI is mainstream for low surgical risk patients, it has the potential to grow exponentially. The bundled payment care initiative model was initiated in October 2018 for TAVI and hospitals participating in this episode of care model of risk sharing will find the results of this study helpful. The cost of the index hospitalization was approximately $ 5000 more in the group that was readmitted within 90 days perhaps a reflection of the added cost for managing a procedural complication or baseline comorbidity.

The clinical implication of this study is that it provides institutions the roadmap on potential impact that bundled payments might have on contribution margins in the TAVI population they serve. By analyzing their individual readmission data, institutions can preemptively identify high risk patients with an increased likelihood for readmission and dedicate extra resources to minimize the likelihood of that occurring. This not only enhances patient care but also

Table 3
Univariate and Multivariate predictors of 90-day readmission after TAVI

Variable	Univariate predictors of 90-day readmission				Multivariable model for 90-day readmission			
	Odds ratio	LL	UL	p value	Odds ratio	LL	UL	p value
Approach								
Endovascular	Reference	Reference	Reference		Reference	Reference	Reference	
Transapical	1.48	1.34	1.64	<0.001	1.19	1.03	1.38	0.019
Age (Years)								
<80	Reference	Reference	Reference		Reference	Reference	Reference	
80-89	1.01	0.97	1.04	0.805	1.01	0.95	1.06	0.834
≥90	1.27	1.20	1.34	<0.001	1.22	1.12	1.32	<0.001
Men	Reference	Reference	Reference					N/A
Women	1.02	0.98	1.05	0.33				
Primary payer								
Medicare/Medicaid	Reference	Reference	Reference		Reference	Reference	Reference	
Private including HMO	0.85	0.78	0.92	<0.001	0.95	0.85	1.06	0.326
Other	0.76	0.66	0.86	<0.001	0.77	0.64	0.94	0.009
Comorbidities								
Hypertension	0.58	0.56	0.61	<0.001	0.96	0.86	1.06	0.053
Diabetes mellitus	1.20	1.16	1.25	<0.001	1.15	1.09	1.21	<0.001
Congestive heart failure	0.77	0.74	0.80	<0.001	1.17	1.10	1.24	<0.001
Atrial fibrillation/flutter	1.55	1.50	1.60	<0.001	1.39	1.32	1.46	<0.001
Peripheral vascular disease	0.89	0.84	0.94	<0.001	1.04	0.97	1.12	0.293
Coronary artery disease	0.86	0.83	0.89	<0.001	0.98	0.93	1.04	0.523
Prior CABG	0.88	0.84	0.92	<0.001	0.90	0.85	0.97	0.003
Prior stroke	1.15	1.09	1.21	<0.001	1.15	1.07	1.24	<0.001
Prior pacemaker or ICD	1.63	1.56	1.71	<0.001	1.09	1.01	1.17	0.022
Anemia	1.32	1.25	1.38	<0.001	1.13	1.06	1.22	<0.001
Coagulopathy	1.8	1.59	2.05	<0.001	1.17	0.96	1.43	0.115
Prior PE/DVT	1.15	1.07	1.24	<0.001	1.04	0.94	1.16	0.418
Chronic obstructive pulmonary disease	1.25	1.20	1.30	<0.001	1.26	1.19	1.33	<0.001
Pulmonary hypertension	0.98	0.94	1.03	0.452				N/A
Chronic kidney disease	1.54	1.48	1.59	<0.001	1.33	1.26	1.40	<0.001
Liver diseases	1.53	1.32	1.77	<0.001	1.24	1.01	1.53	0.038
Surgical AVR	0.83	0.52	1.35	0.457				N/A
Complete heart block	0.62	0.58	0.66	<0.001	1.03	0.94	1.11	0.550
TIA/Stroke	1.21	0.92	1.60	0.177				N/A
Cardiogenic shock	0.91	0.80	1.04	0.174				N/A
AKI	2.32	2.21	2.44	<0.001	1.20	1.11	1.29	<0.001
Major bleeding	1.45	1.36	1.55	<0.001	1.16	1.05	1.27	0.002
Admission type								
Nonelective	Reference	Reference	Reference		Reference	Reference	Reference	<0.001
Elective	0.13	0.13	0.14	<0.001	0.88	0.82	0.94	
Admission day								
Weekdays	Reference	Reference	Reference		Reference	Reference	Reference	0.812
Weekend	4.35	4.07	4.65	<0.001	1.01	0.90	1.14	
Disposition								
Home	Reference	Reference	Reference		Reference	Reference	Reference	<0.001
Facility/others	2.73	2.60	2.86	<0.001	1.58	1.47	1.69	
Length of stay								
≤2 days	Reference	Reference	Reference		Reference	Reference	Reference	<0.001
>2 days	2.05	1.97	2.12	<0.001	1.40	1.32	1.49	

HMO = Health Maintenance Organization; N/A = Not applicable.

financially incentivizes health systems to perform better because of their risk sharing. EPMs are likely to incentivize hospital networks to implement novel strategies to minimize post discharge readmissions. Additionally, results of this study will help in identification of vulnerable population in need of additional resources such as home health services, remote health monitoring, closer outpatient follow-up and individualized health care transition which can possibly improve readmission burden. Future research evaluating the real-world implementation of such models is needed.

The results of the current study need to be interpreted with few limitations. This is an administrative database using ICD-10 codes and therefore no patient level data is available for verification. Baseline characteristics known to be predictors of readmission like low socioeconomic class, level of education and race could not be ascertained. Relevant clinical data like NYHA heart failure class and

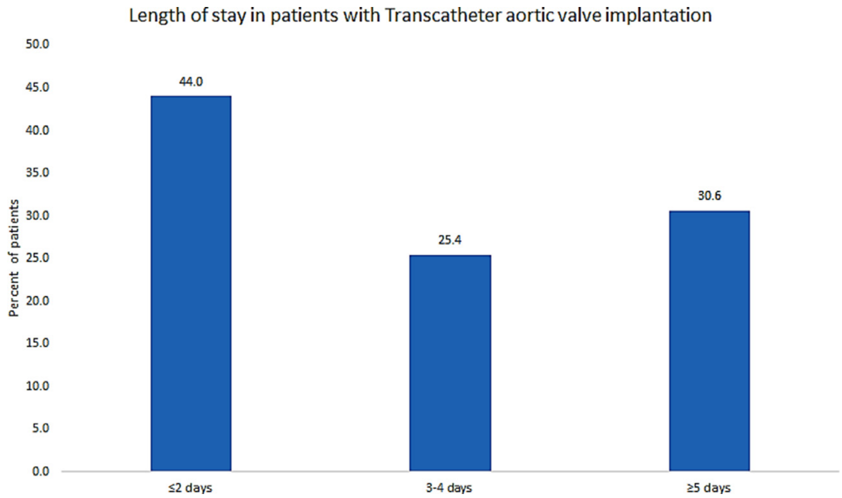

Figure 3. Length of stay in TAVI patients. TAVI, transcatheter aortic valve implantation.

STS-PROM also could not be determined. Death, which is a competing risk for readmission, when occurred outside the hospital could not be accounted for. NRD includes discharge level data from only 21 states across the U.S, and therefore generalizability of the current results might be limited. Despite these limitations, the large sample size and follow up to 90 days are unique assets of this dataset.

In conclusion, half of TAVI patients in the US are discharged within 48 hours after their procedure. Twenty percent of all TAVI patients are however readmitted within 90 days. Most readmissions are due to noncardiac causes. The elderly, frail patient with co-morbidities who then suffers a procedural complication is the highest risk for readmission. Future research should focus on development and implementation of institutional policies directed towards minimizing these readmissions by targeting these vulnerable patients.

Authors' Contribution

Byomesh Tripathi: Conceptualization, Writing-Original draft preparation; Lakshmi Akhila Nerusu: Data curation and visualization; Abhishek C. Sawant: Writing-Reviewing and Editing; Lalitsiri Atti: Validation and Software; Purnima Sharma: Conceptualization, Methodology; Ashish Pershad: Supervision, Writing-Reviewing and Editing.

Disclosures

None of the authors has any disclosures relevant to the content of the manuscript.

Supplementary materials

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