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The Effect of a Transcatheter Mitral Valve Repair Program on the Outcomes of Mitral Valve Surgery: A Retrospective Multicenter Study

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Abstract

Background: After approval by CMS, the use of Transcatheter Mitral Valve Repair (TMVR) is being adopted by many centers. The present study was conducted to compare the outcomes of surgical mitral valve repair and/or replacement among centers with and without the TMVR program.

Methods: The subjects were derived from the Nationwide Inpatient Sample (NIS) using the ICD-9-CM procedure code of 35.12, 35.23 and 35.24 in the year 2011. If any center had performed at least one TMVR procedure in the year 2011 identified by ICD-9 code 35.97 (introduced in Oct 2010), the center was considered as TMVR capable. Propensity score was used to compare outcomes of mortality, complications, complications plus mortality, length of stay (LOS), cost of hospitalization and disposition.

Results: A total of 1,598 surgical mitral valve repair/replacements were performed in 2011 with 59.82% (956) in TMVR non-capable and 40.18% (642) in TMVR capable centers. After propensity matching, TMVR capable centers had significantly lower mortality compared to TMVR non-capable centers (1.7% *vs.* 3.2%, p=0.0034). TMVR capable centers were also noted to have lower incidence of post-procedural complications (34.7% *vs.* 38.3%, p=0.019) along with higher direct disposition to home and home health care facilities (86.1% *vs.* 79.9%, p<0.001) but a higher hospitalization costs ($48603 *vs.* $42883, p<0.0001).

Conclusion: Surgical mitral valve operations have better outcomes in terms of lower in-hospital mortality, lower post-procedural complications and better discharge disposition in centers with TMVR programs.

Keywords: Mitral valve surgery; TMVR; Mortality

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Introduction

Surgical mitral valve repair and replacement are the two major treatment options for patients with mitral regurgitation [1]. It is estimated, that 69% of patients undergoing a procedure for mitral regurgitation, undergo mitral valve repair. The operative mortality of mitral valve repair and replacement are thought to be about 1.4% and 3.7% respectively [2]. However, in selected patients who are at high operative risk with favorable anatomical characteristics, Transcatheter Mitral Valve Repair (TMVR) is a viable option. Following the Endovascular Valve Edge-to-Edge Repair Study (EVEREST) Trials, TMVR was approved by the Food and Drug Administration in October 2013 and subsequently the Centers for Medicare and Medicaid coverage in May 2014. This has led to gradual increase in its utilization by many centers across the nation. However, there is no data on the effect of TMVR, a relatively novel procedure on mitral valve surgical outcomes being performed

Table 1: Baseline table with outcomes in unmatched dataset.

Mitral valve surgeries in TMVR capable *vs.* non-capable centers in 2011	Unmatched Group			
Demographic Variables	**TMVR non-capable centers**	**TMVR capable centers**	**Overall**	**P-value**
Total No. of Observations (un weighted) (%)	956 (59.82%)	642 (40.18%)	1598	
Total No. of Hospitals (%)	160 (82%)	35 (18%)	195	
No. Mitral valve surgeries per hospital (Hospital Volume)				
Median (q1, q3)	10 (5, 19)	41 (20, 63)	15 (7, 41)	<0.001
Age (%)				
mean (standard err)	60.03 (0.45)	59.27 (0.58)	59.72 (0.36)	0.41
Sex (%)				
Male	49.04	55.03	51.46	<0.001
Female	50.96	44.97	48.54	
Race (%)				
Whites	74.41	62.66	69.66	<0.001
Blacks	10.28	6.8	8.88	
Hispanics	3.91	7.98	5.55	
Others	4.79	8.68	6.36	
Missing	6.62	13.88	9.55	
Charlson Score (%)				
0	40.67	40.31	40.52	0.01
1	30.11	32.93	31.25	
More than or equal to 2	29.22	26.76	28.23	
Co-morbidities (%)				
Obesity	9.48	7.81	8.81	0.01
Hypertension	56.69	51.71	54.68	<0.001
Diabetes Mellitus	14.91	13.02	14.15	0.02
Congestive Heart Failure	36.34	39.45	37.6	0.01
History of Chronic Pulmonary Disease	19.4	16.36	18.17	0.001
Peripheral Vascular Disease	6.59	9.1	7.6	<0.001
Fluid-electrolyte abnormalities & Renal Failure	38.71	35.3	37.33	0.002
Neurological disorder or paralysis	6.53	5.88	6.27	0.25
Anemia or coagulopathy	43.09	41.14	42.3	0.08
Solid Tumors or Metastatic Cancers or Lymphoma	0.68	0.8	0.73	0.53
Depression, Psychosis, or Substance Abuse	12.8	12.15	12.54	0.39
Liver disorders	1.97	2.99	2.38	0.01
Rheumatoid Arthritis/ Collagen Vascular diseases	2.18	3.02	2.52	0.02
Chronic blood loss anemia	1.73	1.65	1.7	0.77
Pulmonary circulation disorders	0.62	1.02	0.78	0.05
Hypothyroidism	11.24	9.65	10.6	0.03
Acute myocardial infarction	0.91	0.59	0.78	0.11
Median Household Income Category for patient's Zip code (%)				
0-25th percentile	24.3	15.07	20.58	<0.001
26-50th percentile	21.44	18.5	20.25	
51-75th percentile	27.51	26.29	27.02	
76-100th percentile	25.32	38.66	30.7	
Primary Payer (%)				
Medicare	40.36	41.42	40.79	<0.001
Medicaid	9.21	4.87	7.46	
Private including HMOs & PPOs	45.7	50.38	47.59	
Other/Self-pay/No charge	4.51	3.19	3.97	

Hospital Characteristics				
Bed size of Hospital depending on Location & Teaching Status (%)				
Small	7.5	3.78	6	<0.001
Medium	29.24	5.17	19.53	
Large	62.96	91.05	74.3	
Hospital Location & Teaching Status¥ (%)				
Rural	1.76	0.65	1.31	<0.001
Urban Non-teaching	38.15	6.36	25.32	
Urban Teaching	59.79	92.99	73.19	
Hospital Region (%)				
Northeast	24.06	20.99	22.82	<0.001
Midwest	15.3	27.87	20.37	
South	32.37	25.18	29.46	
West	25.32	24.97	25.18	
Missing	2.95	0.99	2.16	
Type of Admission (%)				
Non-elective	18.91	15.28	17.44	<0.001
Elective	80.68	84.72	82.31	
Admission Day (%)				
Weekdays	95.84	96.86	96.25	0.02
Weekends	4.16	3.14	3.75	
Disposition (%)				
Home	45.17	40.59	43.32	<0.001
Home Health Care	36.21	44.99	39.75	
Transfer to Short-term Hospital/other facilities	16.26	12.87	14.89	
In-hospital Mortality (%)	2.16	1.55	1.91	0.05
Length of hospital-stay-Median (Quartile 1 , 3), days	6 (5, 9)	6 (5, 9)	6 (5, 9)	
Cost (Mean, SE) ($)	44056 (1157)	46006 (1338)	44854 (876)	0.01

HMO: Health Maintenance Organization; PPO: Preferred Provider Organization
*= This represents a quartile classification of the estimated median household income of residents in the patient's ZIP Code. These values are 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. http://www.hcupus.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp.
¥=The inclusion criteria for the hospitals as teaching hospitals includes presence of an American Medical Association approved residency program, membership of the Council of Teaching Hospitals, or having a fulltime equivalent interns and residents to patient's ratio of 0.25 or higher.

in the same institutions. The present study was conducted to compare the post-procedural outcomes of surgical mitral valve repair and/or replacement between centers, which have adopted TMVR and those that did not.

Methods

The study subjects were obtained from the National Inpatient Sample (NIS) database, a subset of the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is the largest publicly available all-payer inpatient care database in the United States, and contains data on approximately 7 to 8 million discharges per year. The database is composed of stratified 20% sample of discharges from US community hospitals, excluding rehabilitation and long-term acute care hospitals [3]. National estimates are produced using sampling weights provided by the sponsor. Details regarding the NIS data have been previously published [4]. As a quality control measure and to maintain internal validity of the database, annual data quality assessments of the NIS are performed and the results of which have shown good correlation with other hospitalization discharge database in the United state [5]. The NIS data is also used to study trends in other acute medical and surgical conditions [6].

From NIS database of year 2011, we identified mitral surgery procedures by using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes, 35.12 (Open heart valvuloplasty of mitral valve without replacement), 35.23 (Open and other replacement of mitral valve with tissue graft) and 35.24 (Open and other replacement of mitral valve). We excluded observations with missing information for age, sex and mortality, excluded newborn and trauma admissions (7,652 observations), excluded patients undergoing CABG (5,570 observations), operations on other heart vessels (5,526 observations), pericardium (2,413 observations) and septum (2,080 observations), operations involving valves other than mitral valve (1,689 observations) and operations of mitral valves other than replacement (1,598 observations). Final study sample concluded 1,598 mitral valve procedures.

The primary outcome was in-hospital mortality, incidence of complications and any complications plus mortality in TMVR capable and non-capable centers. We also analyzed the LOS, cost

Table 2: Mitral valve surgery outcomes in propensity matched group^.

Mitral valve surgeries in TMVR non-capable versus TMVR capable centers in 2011	Propensity matched group^			
Demographic Variables	**TMVR non-capable centers**	**TMVR capable centers**	**Overall**	**P-value**
Total No. of Observations (Unweighted) (%)	397 (50%)	397 (50%)	794	
Total No. of Hospitals (%)	87 (71.90%)	34 (28.10%)	121	
No. Mitral valve surgeries per hospital (Hospital Volume)				
Median (q1, q3)	13 (6, 17)	31 (17, 67)	17 (9, 33)	<0.0001
Age (%)				
mean (standard err)	59.60 (0.72)	59.69 (0.73)	59.64 (0.52)	0.92
Sex (%)				
Male	50.01	49.93	49.97	0.96
Female	49.99	50.07	50.03	
Co-morbidities (%)				
Charlson Score (%)				
Mean (standard err)	1.12 (0.06)	1.07 (0.06)	1.09 (0.04)	0.38
0	38.34	42.71	40.59	0.0187
1	31.84	28.91	30.33	
More than or equal to 2	29.82	28.38	29.08	
Hospital Characteristics				
Bed size of Hospital depending on Location & Teaching Status (%)				
Small	4.2	5.94	5.09	0.05
Medium	8.08	8.11	8.1	
Large	87.72	85.95	86.81	
Hospital Location & Teaching Status (%)				
Rural	0.76	1.02	0.89	0.5
Urban Non-teaching	10.82	9.99	10.39	
Urban Teaching	88.42	88.99	88.71	
Type of Admission (%)				
Non-elective	17.68	14.33	15.96	0.0045
Elective	82.32	85.67	84.04	
Admission Day (%)				
Weekdays	96.43	95.54	95.97	0.15
Weekends	3.57	4.46	4.03	
Disposition (%)				
Home	48.56	41.76	45.07	<0.0001
Home Health Care	31.37	44.37	38.05	
Transfer to Short-term Hospital/other facilities	16.87	12.13	14.43	
In-hospital Mortality (%)	3.2	1.74	2.45	0.0034
Length of Hospital Stay (Mean, SE)	9.17 (0.49)	8.33 (0.35)	8.73 (0.30)	0.35
Cost (Mean, SE) ($)	42883 (2081)	48603 (2083)	45739 (1475)	<0.0001

of hospitalization, disposition and effect of hospital volume on the mortality. Preventable procedural complications were identified by Patient Safety Indicators (PSIs), which have been established by the AHRQ to monitor preventable adverse events during hospitalization. These indicators are based on ICD-9-CM codes and Medicare severity Diagnosis-Related Groups and each PSI has specific inclusion and exclusion criteria [7]. PSI individual measure technical specifications version 4.4, March 2012 was used to identify and define preventable complications [8]. Other procedure related complications were identified using ICD-9-CM codes listed in Supplementary Table 1 in any secondary diagnosis field. Similar methodology has been utilized before [9]. The ICD-9-CM codes used to identify each of these diagnoses and procedures. To calculate the actual cost per hospital visit, the data from NIS, i.e., total charges the hospitals billed for providing services was merged with Cost to-Charge Ratio files and latest cost file was used.

Demographic characteristics including age, gender, and race were identified using NIS variables (Table 1). The presence and severity of confounding and co-morbid conditions were defined by Deyo's

Table 3: Frequency of death and/or any complications in unmatched and propensity matched group^.

Mitral valve surgeries in TMVR capable *vs.* non-capable centers	Unmatched dataset				Propensity Matched Group^			
Complications (%)	TMVR non-capable	TMVR capable	Overall	P-value	TMVR non-capable	TMVR capable	Overall	P-value
Death	2.16	1.55	1.91	0.056	3.2	1.74	2.45	0.003
Any complications	37.23	37.7	37.42	0.67	38.32	34.69	36.46	0.02
Death+Any complications	37.53	37.88	37.67	0.75	38.57	34.98	36.72	0.02
Neurological Complications	1.11	0.89	1.02	0.35	1.58	0.93	1.25	0.07
Transmural MI	0.81	0.59	0.72	0.27	0.99	0.69	0.84	0.31
Deep sternal wound infection	1.09	0.48	0.84	0.01	0.97	0.75	0.86	0.46
Hemorrhage requiring transfusion	14.28	17	15.38	0.01	15.73	15.25	15.48	0.68
Cardiac Complications	12.8	14.95	13.67	0.01	11.55	13.49	12.55	0.07
Pericardial complications	0.61	0.15	0.42	0.01	1.23	0.23	0.72	0.01
Pacemaker Insertions	0.56	0.17	0.4	0.01	0.49	0.26	0.37	0.24
Respiratory failure	6.33	3.93	5.36	<0.001	6.68	3.86	5.23	<0.001
Infectious complications	4.37	3.79	4.13	0.21	6.46	3.87	5.13	0.01
PE and DVT *	0.63	1.18	0.85	0.01	0.74	0.93	0.84	0.51
Acute kidney injury	10.37	9.16	9.88	0.08	13.48	8.73	11.04	<0.001

modification of Charlson Co-Morbidity Index (CCI) or Charlson Score [10]. The inclusion criteria for the hospitals as teaching hospitals includes presence of an American Medical Association approved residency program, membership of the Council of Teaching Hospitals, or having a fulltime equivalent interns and residents to patient's ratio of 0.25 or higher. Hospitals were divided into TMVR capable centers using the ICD-9-CM with procedure code of 35.97 (introduced in Oct 2010) for TMVR procedure performed at least once during the year of 2011. Hospitals with no such procedure (ICD-9-CM of 35.97) performed in 2011 were considered as TMVR non-capable center. TMVR capability was used as a surrogate for Transcatheter mitral valve repair as that is the only technology available in the United States. Propensity match was done for the patient variables (age, gender, Charlson score) and the hospital variables (bed-size, location and teaching status of the hospital, day and type of admission). It was 1-1 matching with 8-digit greedy matching which allows matching till 8 digits after decimal points (Table 2). The Charlson score has 17 co-morbid conditions with differential weights. The score ranges from 0 to 33, with higher scores corresponding to a greater burden of co-morbid diseases (Supplementary Table 2).

The statistical analysis was done using Stata IC 11.0 (Stata-Corp, College Station, TX) and SAS 9.4 (SAS Institute Inc, Cary, North Carolina). Differences between categorical variables were tested using the chi-square test and differences between continuous variables were tested using student's t test for normally distributed variables and Wilcoxon signed rank test for non- Gaussian distribution.

Multivariate logistic regression model was used for categorical dependent variables. In multivariate model, we determined predictors of mortality of mitral valve outcomes, after adjusted for capability of TMVR, age, gender, hospital volume, Charlson score and type of hospital admission.

Results

Our analysis included 1,598 mitral valve repairs and replacement procedures performed in the United States during the study period in 2011. This included 827 mitral valve repairs and 771 mitral valve replacement procedures. Of all the mitral valve repair and replacement procedures performed, 59.82% (n=956) were performed in TMVR non-capable centers while 40.18% (n=642) were performed in centers capable of TMVR. Those procedures were performed in 195 different hospitals, which included 160 TMVR non-capable and 35 TMVR capable centers. The propensity matching for patient and hospital variables included the data from total 121 hospitals (87 TMVR non-capable and 34 TMVR capable centers with 397 procedures in each group). Table 1 shows baseline characteristics of the study population. The mean age of the overall cohort was 59.72 years and 48.54% of the subjects were female. Significant baseline burden of co-morbidities with a CCI score of ≥ 2 was observed in 28.23% of the study subjects. Hypertension, Anemia/coagulopathy, congestive heart failure, fluid and electrolyte abnormalities and renal failure were the most common co-morbidities and Supplementary Table 2 shows Deyo's modification of Charleston Co-Morbidity Index (CCI). Most the procedures were performed at large (74.3%), teaching hospitals (73.19%) and the primary insurance payer was Medicare/Medicaid (48%). Table 2 shows outcomes of mitral valve surgery in propensity matched dataset for patient and hospital related variables.

The overall mortality rate of mitral valve repair or replacement was 1.91%. Centers with TMVR capability had lower mortality rates (1.55%) for mitral valve repair or replacement compared to those without TMVR capability (2.16%). Propensity matching also revealed lower mortality rates in TMVR capable (1.74% *vs.* 3.2%, p-value of 0.0034) compared to TMVR non-capable centers. The length of stay was lower but statistically non-significant in centers with TMVR capability (Mean ± SE, 8.33 ± 0.35 days) compared to those with no TMVR capability (Mean ± SE, 9.17 ± 0.49 days), with p-value 0.35 in the propensity analysis. The disposition of subjects after procedure in TMVR capable centers was more frequent to home and home health care facilities (86.13% in TMVR capable *vs.* 79.93% in TMVR non-capable with p-value <0.001). However, the cost of hospitalization was higher in centers with TMVR capabilities (Mean ± SE, $48603 ± 2083) compared to centers without TMVR capabilities (Mean ± SE, $42883 ± 2081), p-value <0.0001. Table 3 shows the incidence of death and/or any other complications during and/or after the procedure. After propensity matching, the incidence of complications was less in

Table 4: Multivariate Simple Logistic Regression for Mortality.

	Unmatched Dataset		Propensity matched Dataset	
Variable	**Odds Ratio (95% Confidence Interval)**	**p-value**	**Odds Ratio (95% Confidence Interval)**	**p-value**
Status of TMVR capability				
Non-TMVR capable Hospital	1	Ref	1	Ref
TMVR Capable Hospital	1.27 (0.69,1.61)	0.81	0.45 (0.25, 0.78)	0.01
Age (in 5 year increment)	1.27 (1.18, 1.36)	<0.001	1.24 (1.14, 1.35)	<0.001
Hospital volume (in 5 procedures increment)	0.94 (0.89, 0.99)	0.03	1.045 (0.98, 1.11)	0.17
Sex				
Male	1		1	
Female	1.02 (0.73, 1.44)	0.89	1.33 (0.86, 2.06)	0.2
Charlson Score				
0	1	Ref	1	Ref
1	1.79 (1.02, 3.12)	0.04	0.92 (0.48, 1.76)	0.79
More than or equal to 2	3.79 (2.29, 6.26)	<0.001	2.22 (1.29, 3.80)	0.003
Type of Admission				
Non-elective	1	Ref	1	Ref
Elective	0.20 (0.14, 0.28)	<0.001	0.13 (0.08, 0.12)	<0.001

Table 1 (Supplementary): Procedural complications by ICD 9 code.

Any procedural complications	ICD-9 CODE
Neurological complications	
Postop-stroke	997.0, 997.00, 997.01, 997.02
Transmural MI	410.0, 410.6, 417.8, 417.9
Deep sternal wound infection	998.5, 857.1
Vascular complications	
Hemorrhage requiring Transfusion	99.0, 998.11, 998.12, 285.1
Cardiac complications	
Iatrogenic cardiac complications	997.1
	423.0-Hemopericardium
	423.3-Cardiac tamponade
	37.0-Pericardiocentesis
Permanent pacemaker implantation	37.80-83, 00.50, 00.51
Pericardial Complications	37
Post-op respiratory failure	PSI#
Pulmonary Embolism and DVT	PSI#
Post-op infectious complications	PSI#
Renal complications	
Acute Kidney Injury	PSI#

Post-procedural complications were identified by Patient Safety Indicators (PSIs) which have been established by the Agency for Healthcare Research and Quality to monitor preventable adverse events during hospitalization. These indicators are based on ICD-9-CM codes and Medicare severity Diagnosis-Related Groups and each PSI has specific inclusion and exclusion criteria. PSI individual measure technical specification version 4.4, March 2012 was used to identify & define preventable complications.

TMVR capable centers (34.69% *vs.* 38.32%, p-value 0.0194) compared with TMVR non-capable centers. The incidence of death and/or any complications was also lower in TMVR capable centers (34.98% *vs.* 38.57%, p-value 0.0209) compared to centers with no TMVR availability. Significantly lower rates of complications were observed in TMVR capable centers compared to TMVR non-capable centers for any renal complications including Acute Kidney Injury (8.73% *vs.* 13.48% and p-value <0.001), infectious complications (3.87% *vs.* 6.46%, p-value 0.0003), respiratory failure (3.86% *vs.* 6.68%, p-value <0.0001) and pericardial complications (0.23% *vs.* 1.23%, p-value 0.0002). Table 4 shows multivariate simple logistic regression analysis for mortality. TMVR capable centers have lower mortality rates (OR 0.45 and 95% CI of 0.25 to 0.78, p-value of 0.005) compared to TMVR non-capable centers. Propensity matching showed that increase in age was an independent risk factor for increase in mortality whereas gender has no significant impact on the outcome. Hospital volume is not statistically significant from mortality perspective in TMVR capable centers. From the survival perspective, elective admissions were associated with significantly decreased mortality (OR 0.13 and 95% CI of 0.08 to 0.12, p-value <0.0001).

Discussion

In this large retrospective study, we looked at the association of the availability of TMVR program with outcomes of surgical mitral valve repair or replacement. Majority of the centers were large, urban, teaching hospitals. We found lower in-hospital mortality rates with lower LOS and higher cost of hospitalization following surgical mitral valve replacement/repair in centers with TMVR capabilities. Furthermore, we observed significantly lower incidence of procedure-related complications and higher rates of disposition to home and home care facility after the surgical procedure in TMVR capable centers.

Mitral valve repair and replacement were the only major therapeutic strategies for mitral valve diseases until the advent of TMVR. The current AHA/ACC guidelines mention that TMVR may be considered in severely symptomatic NYHA Class III/IV patients with Stage D chronic primary mitral regurgitation who have a favorable anatomy, reasonable life expectancy and a prohibitive surgical risk (Class II b recommendation). TMVR thus offers a viable therapeutic option for patients who would otherwise succumb to the disease due to their high risk. TMVR is a complex procedure mandating the presence of a comprehensive heart valve team and requiring extensive resource utilization. It is speculated that the presence of transcatheter technologies could lead to increased referral

Table 2 (Supplementary): Deyo's modification of Charlson co-morbidity Index (CCI).

Reported ICD-9 CM Codes	Condition	Charlson Score
410-410.9	Myocardial Infarction	1
428-428.9	Congestive Heart Failure	1
433.9, 441-441.9, 785.4, V43.4	Peripheral Vascular Disease	1
430-438	Cerebrovascular Disease	1
290-290.9	Dementia	1
490-496, 500-505, 506.4	Chronic Pulmonary Disease	1
710.0, 710.1, 710.4, 714.0-714.2, 714.81, 725	Rheumatologic Disease	1
531-534.9	Peptic Ulcer Disease	1
571.2, 571.5, 571.6, 571.4-571.49	Mild Liver Disease	1
250-250.3, 250.7	Diabetes	1
250.4-250.6	Diabetes with Chronic Complications	2
344.1, 342-342.9	Hemiplegia or Paraplegia	2
582-582.9, 583-583.7, 585, 586, 588-588.9	Renal Disease	2
140-172.9, 174-195.8, 200-208.9	Any malignancy including leukemia and lymphoma	2
572.2-572.8	Moderate or Severe Liver Disease	3
196-199.1	Metastatic solid tumor	6
042-044.9	AIDS	6

of overall patients, better diagnosis due to the presence of a valve team, increased experience and expertise as a result and a lower risk patient pool going for surgery and the higher risk pool going for these transcatheter options.

Previously published aortic valve literature has noted a lower mortality for surgical aortic valve replacement in centers with transcatheter aortic valve replacement capabilities [10]. According to our study, the benefits of a transcatheter program and associated development of comprehensive heart valve teams could extend to improved clinical outcomes even in the case of mitral valve procedures. Additionally, our study covered a time prior to Food and Drug Administration and Centers for Medicare and Medicaid approval of TMVR. Thus, TMVR capable centers in our study were the ones where this was used as an investigational or pre-label device. These centers are usually expected to be higher volume and experienced centers with known better clinical outcomes. Even though higher procedure volumes leading to decrease in mortality for mitral valve procedures is demonstrated by earlier studies the hospital volume has not reached significance in our study from mortality perspective [11-13].

In our study, the overall in-hospital mortality for mitral valve repair or replacement was 1.91%. This was lower than the operative mortality of 2.45% reported by Gammie et al. [14] from the Society of Thoracic Surgeons Adult Cardiac Surgery Database from 2000 to 2007 likely representing an improvement in surgical technique and operator experience. There was a further reduction in post-procedural mortality in TMVR capable centers even in propensity matched cohorts with TMVR capable centers being predictive of lower in-hospital mortality even on multivariate analysis. In one of recent the studies by Swaans et al. [15] demonstrated that patients with high surgical risk treated with transcatheter approach for severe MR had similar survival rates compared to surgery and improved survival compared to conservative treatment. Outcomes similar to our study are also shown in the transcatheter aortic valve implantation program availability by Singh et al. [16]. Likewise, the overall rates of complications as well as several individual complication rates like pericardial and infectious complications, respiratory failure and acute kidney injury were significantly lower in TMVR capable centers. Lower rates of complications can further explain significantly higher disposition to home and home care facilities with lower transfers to short-term hospital facilities noted in our study. There was also a non-significant decrease in the LOS in TMVR capable centers. However, the cost of hospitalization was noted to be higher in TMVR capable centers and significant even in propensity-matched cohorts. This may be due to increased resource utilization at TMVR capable centers. Nonetheless, the benefits of reduced mortality and post-procedural complications might translate into reduced repeat hospitalizations, procedures and long term complications that need to be studied in additional long term follow up studies.

Some of the limitations of our study are inherent to analysis of a large administrative database including potential coding errors and misrepresentation of procedure volume. Furthermore, administrative databases could suffer from under-reporting of secondary or co-morbid diagnosis. Besides, we lacked long-term follow-up data as well as surgical procedural details. The data also lack the details on type of mitral valve disease, functional versus degenerative, echocardiographic data including left ventricular ejection fraction of the study subjects. The observational design of our study limits any inferences regarding temporal or causal association regarding outcomes. Nonetheless, it does not take away from the primary conclusion of the study that the TMVR capable surgical centers had significantly lower in-hospital mortality and procedural complications following mitral valve repair or replacement. Additionally, the sound NIS sampling design has been widely used for research previously and represents a large nationally representative sample for a detailed outcome analysis [17,18].

TMVR is an increasing popular therapeutic option for mitral valve disorders in selective patient populations that is being widely adopted across the nation. Our study demonstrated that the addition of TMVR programs in hospitals could improve clinical outcomes following surgical mitral valve repair or replacement including lower in-hospital mortality and post-procedural complications thus proving to be an important addition to their armamentarium.

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