Relation of Hospital Volume With In-Hospital and 90-Day Outcomes After Transcatheter Mitral Valve Repair Using MitraClip

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MitraClip therapy has shown increasing use since it was commercially adopted among US hospitals in October 2013. However, the relation of institutional MitraClip volume with outcomes is unclear. This study sought to examine the association between hospital volume and outcomes after transcatheter mitral valve repair using the MitraClip device. Using the Nationwide Readmissions Database, we identified all patients who underwent a MitraClip procedure and categorized hospitals into tertiles based on their annual procedure volume: low (≤3 procedures/year), medium (4 to 13/year), and high (≥14/year) volume centers. Multivariable logistic and Cox regression analyses were performed to examine the impact of institutional MitraClip volume on in-hospital and 90-day outcomes, respectively. From 2014 to 2015, a total of 3,420 procedures were performed at 266 hospitals with a median annual procedural volume of 5 per hospital. Low (n = 81), medium (n = 86), and high (n = 99) volume hospitals performed 147 (4.3%), 403 (11.8%), and 2,870 (83.9%) MitraClip procedures, respectively. The low versus high hospital volume was independently associated with increased in-hospital mortality (7.8% vs 3.0%; adjusted odds ratio [aOR] 2.64; p = 0.04), acute myocardial infarction (10.2% vs 2.2%; aOR 2.93; p = 0.02), and acute respiratory failure (19.3% vs 7.7%; aOR 2.24; p = 0.02) during index admission as well as 90-day all-cause readmissions (37.8% vs 26.6%; adjusted hazard ratio 1.54; p = 0.03), and 90-day infective endocarditis (2.4% vs 0.3%; adjusted hazard ratio 10.06; p = 0.003). In conclusion, low hospital MitraClip volume is an independent determinant of worse outcomes including in-hospital mortality and 90-day readmissions. **(Am J Cardiol 2019;124:63−69)**

Mitral regurgitation (MR) is the most frequent valvular heart disease in the United States.[1,2] Surgical repair of the mitral valve (MV) is the standard of care for patients with chronic, severe primary MR.[3] However, a significant portion of patients with severe MR have multiple co-morbidities, which preclude them from receiving open MV surgery.[4] To address this unmet need for the high-risk population, transcatheter MV repair using the MitraClip device (Abbott Vascular, Santa Clara, California) was developed and then approved by the US Food and Drug Administration (FDA) in October 2013.[5] Hospital volume and clinical outcome relation has been well observed in numerous cardiovascular surgeries and percutaneous procedures.[6−8] However, there was no such relation found for MitraClip in a German registry.[9] Given the increasing MitraClip volume in the United States, we aimed to test our hypothesis of a positive association between institutional MitraClip volume and in-hospital as well as 90-day outcomes using a large contemporary US database.

Methods

This study used 2014 and 2015 data from the Nationwide Readmissions Database (NRD). The NRD is an annual database developed by the Agency for the Healthcare Research and Quality and designed for nationally representative analyses of readmissions using weights. In 2015, the NRD contained greater than 17 million discharge records from 2,367 hospitals in 27 states to represent more than 35 million hospitalizations.[10] Verified, de-identified patient linkage numbers were used to track each patient across hospitals within a state in a given year. Each encounter in the NRD contains the International Classification of Diseases-Ninth Revision-Clinical Modification (ICD-9-CM) codes to indicate diagnoses and procedures performed during hospitalization. Starting in October 2015, the NRD utilized ICD-10-CM codes. Additionally, the NRD provides Clinical Classification Software (CCS) codes that group multiple ICD codes into clinically meaningful categories to facilitate statistical analysis. We used the combination of ICD-9-CM, ICD-10-CM, and CCS codes to identify our study cohort, co-morbidities, causes of readmissions, and in-hospital and 90-day outcomes (Supplementary Table 1).

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See page 68 for disclosure information.

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All patients 18 years of age or older who underwent a MitraClip procedure (ICD-9-CM code 35.97 and ICD-10-CM code 02UG3JZ) during the study period were included. After identifying the annual institutional procedural volume, we excluded patients discharged from October 1 to December 31 each year to allow 90-day follow-up. The final cohort includes data from January 1, 2014 to September 30, 2014 and January 1, 2015 to September 30, 2015. Patients with missing length of hospital stay or missing discharge disposition data (n = 1) were excluded to properly capture the interval until readmission. After the initial analyses of baseline characteristics and in-hospital outcomes, those who died during index admissions were excluded from the readmission analyses.

The NRD variables used are patient age, gender, primary payer, hospital location, teaching status, and bed size. Comorbidities included in the analysis and their respective ICD-9-CM and CCS codes are shown in Supplementary Table 1. Unique hospital identification numbers were used to determine annual hospital volume by computing the total number of procedures performed at each institution in a given year. Hospitals were categorized into procedural volume tertiles based on annual institutional procedural volume cutoffs established at the thirty-third and sixty-seventh percentiles.[8] Hospitals in the first volume tertile were defined as the low volume centers.

Study outcomes were selected based on the recommendation from the Mitral Valve Academic Research Consortium.[11] In-hospital outcomes included all-cause mortality, bleeding requiring transfusion, acute kidney injury, stroke, acute myocardial infarction (AMI), permanent pacemaker insertion, acute respiratory failure (ARF), vascular injury, and open MV surgery. The 90-day outcomes included all-cause readmission, infective endocarditis, congestive heart failure exacerbation, and open MV surgery. All ICD-9-CM and ICD-10-CM codes used to capture outcomes are provided in Supplementary Table 1.[12,13] In the readmission analysis, only the first readmission within 90 days of discharge was included. Principal diagnoses of 90-day readmissions were identified and dichotomized into cardiac and noncardiac causes.

All analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina) and accounted for hospital-level clustering of patients and complex sampling design of NRD; according to the recommendations from the Agency for Healthcare Research and Quality for analyses of the NRD.[14] For descriptive analyses, we compared baseline characteristics by the hospital volume category. Rao-Scott chi-square test was used for categorical variables and either Kruskal-Wallis nonparametric test or survey-specific linear regression was used for continuous variables. A restricted cubic spline function was used to test the linearity of the association between the in-hospital outcomes and the institutional volume as a continuous variable using 3 knots at annual volume-tertile cutoffs: 3, 13, and 30 procedures. To examine the independent association of institutional MitraClip volume with each in-hospital and 90-day outcome, we created separate multivariable logistic regression and Cox proportional hazards regression models, respectively. Covariates that had univariate significance with the respective outcomes ($p < 0.1$) were included. A sensitivity analysis with different annual volume cutoffs (≤12, 13 to 24, and >24 procedures per year for low-, medium-, and high volume centers, respectively) was performed to examine the association between institutional volume and in-hospital outcomes. All tests were 2-sided with p values <0.05 indicating statistical significance.

Results

The median annual procedural volume of MitraClip was 5 per hospital in the United States during the study period. Of 266 hospitals, 81 (30.5%), 86 (32.3%), and 99 (37.2%) hospitals were categorized into the low (≤3 procedures/year), medium (4 to 13/year), and high (≥14/year) volume centers, respectively. Of 3,420 MitraClip procedures, 147 (4.3%) procedures were performed in low-, 403 (11.8%) in medium-, and 2,870 (83.9%) in high volume centers. The total number of annual MitraClip procedures increased from 1,071 in 2014 to 2,349 in 2015. The numbers of medium- and high volume hospitals significantly increased (p for trend <0.001) whereas the number of low volume centers remained stable (p for trend = 0.99) during the study period.

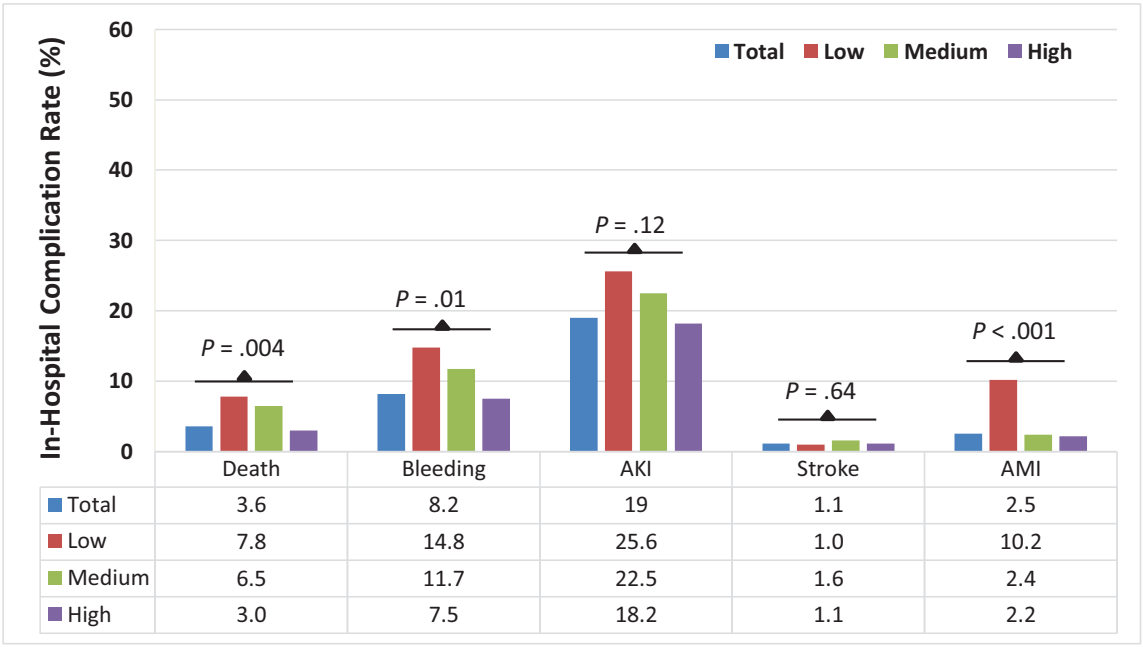
Table 1 shows the baseline characteristics of patients who underwent MV repair with a MitraClip procedure stratified by hospital volume. Patients receiving MitraClip at high volume centers were older and had a greater burden of co-morbidities including hypertension, coronary artery disease, previous percutaneous coronary intervention, previous coronary artery bypass graft, congestive heart failure, chronic kidney disease, and previous implantable cardioverter-defibrillator placement than those at low volume centers. High volume centers were more likely to be teaching and large institutions located in urban areas, whereas low volume centers more frequently performed MitraClip procedure as a nonelective procedure. Patients who underwent MitraClip therapy at high- versus low volume centers had a shorter length of hospital stay and were more likely to be discharged home.

Adverse events, including death, bleeding requiring transfusion, AMI, permanent pacemaker insertion, ARF, and vascular injury, were more common in those who underwent a MitraClip procedure at low volume centers (Figure 1). After adjustment for preprocedural risk factors, low hospital volume of MitraClip was independently associated with increased odds of in-hospital all-cause mortality, AMI, and ARF compared with high volume (Table 2). Restricted cubic spline analysis suggested a linear association between hospital volume and in-hospital outcomes (p for overall association with death = 0.02; p for nonlinear association with death = 0.10). Analysis of the annual hospital procedural volume as a continuous variable in the multivariable model demonstrated similar volume-outcome associations (e.g., odds of in-hospital all-cause mortality decreased by 10% for every 10-case increase in annual hospital procedural volume; Supplementary Table 2). A sensitivity analysis of in-hospital outcomes was performed by recategorizing hospitals into low (≤12 procedures/year), medium (13 to 24/year), and high (>24/year) volume centers. Association of low volume status (vs high volume) with mortality (6.9% vs 3.1%; unadjusted odds ratio [OR]

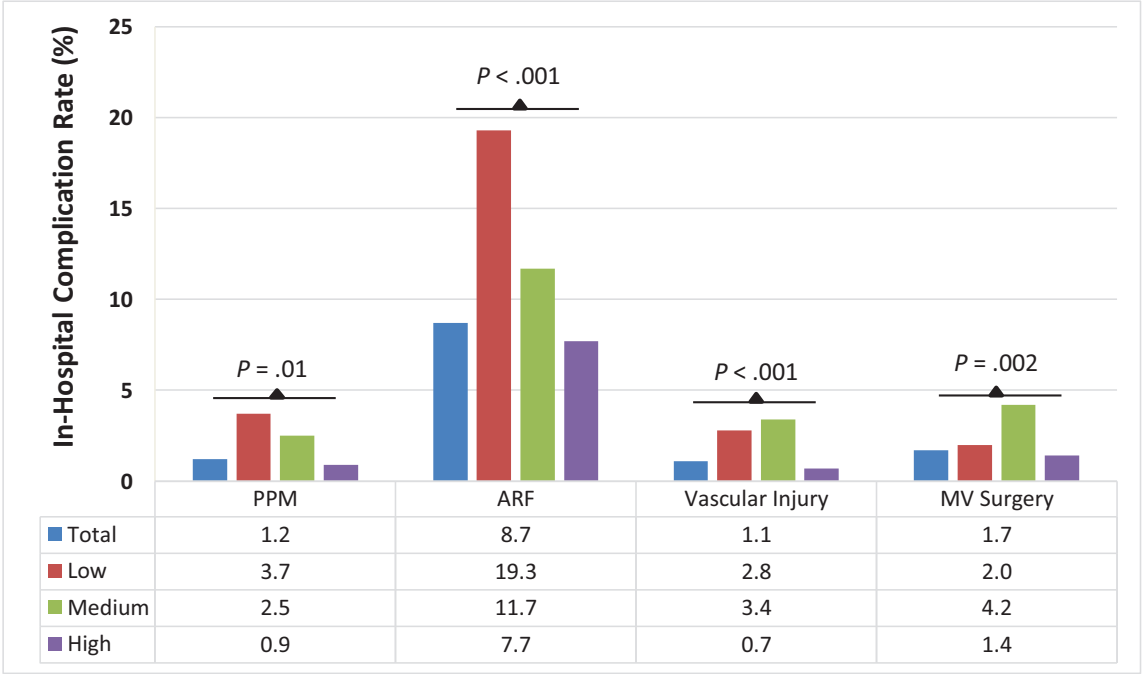
Table 1
Baseline characteristics and in-hospital outcomes of patients who underwent MitraClip at low-, medium-, and high volume hospitals in the united States, 2014 to 2015

Characteristics	Overall	Hospital volume*			p value
		Low (n = 81)	Medium (n = 86)	High (n = 99)	
Number of patients	n = 3420	147	403	2870	
Patient characteristics					
Age, mean ± SE (years)	75.9 ± 0.4	64.7 ± 1.2	70 ± 1.2	77.2 ± 0.4	<0.001
Women	1661 (48.6%)	69 (46.9%)	196 (48.6%)	1396 (48.6%)	0.95
Smoker	1194 (34.9%)	45 (30.8%)	122 (30.3%)	1027 (35.8%)	0.20
Hypertension	2498 (73.0%)	93 (63.7%)	260 (64.5%)	2145 (74.7%)	0.001
Diabetes mellitus	874 (25.6%)	43 (29.2%)	85 (21.1%)	746 (26.0%)	0.21
Dyslipidemia	1938 (56.7%)	69 (46.9%)	193 (47.9%)	1676 (58.4%)	0.001
Coronary artery disease	2006 (58.7%)	68 (46.2%)	187 (46.5%)	1751 (61.0%)	<0.001
Prior percutaneous coronary intervention	592 (17.3%)	12 (7.9%)	41 (10.3%)	539 (18.8%)	<0.001
Prior coronary bypass	781 (22.8%)	18 (12.1%)	73 (18.1%)	691 (24.1%)	0.003
Prior heart valve surgery	385 (11.3%)	22 (15.2%)	47 (11.7%)	316 (11.0%)	0.51
Congestive heart failure	2656 (77.7%)	94 (63.9%)	262 (65.1%)	2300 (80.1%)	<0.001
Peripheral vascular disease	417 (12.2%)	19 (13.3%)	51 (12.7%)	347 (12.1%)	0.93
Pulmonary hypertension	1200 (35.1%)	57 (38.8%)	149 (36.9%)	995 (34.7%)	0.67
Asthma	256 (7.5%)	14 (9.4%)	26 (6.3%)	216 (7.5%)	0.54
Chronic obstructive pulmonary disease	946 (27.6%)	42 (28.9%)	109 (27.0%)	794 (27.7%)	0.95
Chronic kidney disease	1149 (33.6%)	37 (25.0%)	98 (24.4%)	1015 (35.3%)	0.001
Renal dialysis	175 (5.1%)	12 (8.0%)	18 (4.4%)	146 (5.1%)	0.38
Anemia	823 (24.1%)	41 (28.2%)	104 (25.7%)	678 (23.6%)	0.48
Coagulopathy	530 (15.5%)	37 (25.6%)	101 (25.1%)	391 (13.6%)	<0.001
Atrial fibrillation/flutter	2087 (61.0%)	77 (52.8%)	237 (58.8%)	1773 (61.8%)	0.19
Prior stroke	376 (11.0%)	–†	34 (8.4%)	334 (11.6%)	0.06
Prior pacemaker	417 (12.2%)	19 (12.9%)	49 (12.3%)	349 (12.2%)	0.98
Prior implantable cardioverter-defibrillator	408 (11.9%)	–	18 (4.4%)	384 (13.4%)	<0.001
Depression	241 (7.0%)	15 (10.1%)	31 (7.6%)	195 (6.8%)	0.51
Hypothyroidism	592 (17.3%)	19 (12.9%)	48 (11.9%)	525 (18.3%)	0.01
Obesity	352 (10.3%)	17 (11.9%)	38 (9.5%)	297 (10.3%)	0.77
Elective procedure	1278 (69.6%)	43 (52.3%)	162 (68.1%)	1073 (70.7%)	0.01
Weekend admission	206 (6.0%)	18 (12.3%)	24 (5.9%)	165 (5.7%)	0.08
Elixhauser co-morbidity scores, median (IQR)	3 (2-5)	3 (2-5)	3 (2-4)	3 (2-5)	0.23
Hospitalization with Elixhauser co-morbidity scores >4	1836 (53.7%)	83 (56.6%)	206 (51.2%)	1547 (53.9%)	0.67
Primary payer					<0.001
Medicare	2830 (82.8%)	67 (46.2%)	286 (71.0%)	2477 (86.3%)	
Medicaid	117 (3.4%)	21 (14.2%)	18 (4.5%)	78 (2.7%)	
Private	386 (11.3%)	42 (28.4%)	77 (19.0%)	267 (9.3%)	
Self-pay/other	87 (2.5%)	17 (11.2%)	22 (5.5%)	48 (1.7%)	
Hospital characteristics					
Hospital teaching status					
Teaching	3158 (92.3%)	108 (74.0%)	366 (90.8%)	2684 (93.5%)	0.002
Hospital Location					
Urban	2652 (77.6%)	75.0 (51.3%)	305 (75.6%)	2273 (79.2%)	0.01
Hospital bed size					<0.001
Small	152 (4.4%)	22 (15.0%)	25 (6.2%)	105 (3.7%)	
Medium	634 (18.6%)	34 (23.3%)	47 (11.7%)	552 (19.2%)	
Large	2634 (77.0%)	90 (61.7%)	331 (82.1%)	2213 (77.1%)	
In-hospital outcomes					
Length of hospital stay (days), median (IQR)	3 (1-7)	8 (4-18)	5 (3-12)	3 (1-6)	<0.001
Prolonged hospital stay					
Length of stay ≥8 days	882 (25.8%)	81 (55.1%)	156 (38.6%)	646 (22.5%)	<0.001
Cost, median (IQR), US$‡	42,319 (30,314-55,930)	46,456 (28,042-64,550)	44,077 (25,741-61,191)	41,587 (30,366-54,578)	0.07
Disposition					<0.001
Death	124 (3.6%)	11 (7.8%)	26 (6.5%)	87 (3.0%)	
Home	2846 (83.3%)	101 (69.0%)	307 (76.2%)	2438 (85.0%)	
Facility§	447 (13.1%)	34 (23.2%)	70 (17.3%)	344 (12.0%)	

Anemia: ICD-9-CM codes: 280.1 to 281.9, 285.21 to 285.29, 285.9, 280.0, 648.20 to 648.24.
Obesity: ICD-9-CM codes: 278.0, 278.00, 278.01, 278.03, 649.10 to 649.14, 793.91, V85.30 to V85.39, V85.41 to V85.45, V85.54.
Dyslipidemia: Clinical Classifications Software code 53.
* Annual procedure volume: 1 to 3 (low volume center), 4 to 13 (medium volume center), 14 to 197 (high volume center).
† In accordance with the nationwide data use agreement, patient numbers ≤10 are not reported.
‡ Cost analysis is limited to 2014 data.
§ Facility includes skilled nursing facility, intermediate care facility, and inpatient rehabilitation facility.



	Death	Bleeding	AKI	Stroke	AMI
Total	3.6	8.2	19	1.1	2.5
Low	7.8	14.8	25.6	1.0	10.2
Medium	6.5	11.7	22.5	1.6	2.4
High	3.0	7.5	18.2	1.1	2.2



	PPM	ARF	Vascular Injury	MV Surgery
Total	1.2	8.7	1.1	1.7
Low	3.7	19.3	2.8	2.0
Medium	2.5	11.7	3.4	4.2
High	0.9	7.7	0.7	1.4

Figure 1. In-Hospital outcomes of patients who underwent MitraClip at low-, medium-, and high volume centers during index hospitalization.
AKI = acute kidney injury; AMI = acute myocardial infarction; ARF = acute respiratory failure; MV = mitral valve; PPM = permanent pacemaker insertion.

2.36; 95% confidence intervals [CI] 1.34 to 4.15; adjusted OR 2.66; 95% CI 1.42 to 4.99) and ARF (19.3% vs 7.7%; unadjusted OR 1.90; 95% CI 1.24 to 2.90; adjusted OR 1.77; 95% CI 1.12 to 2.80) remained significant after adjustment for covariates (Supplementary Table 3).

The overall incidence of 90-day all-cause readmission was 27.4% with a median time to readmission of 22 days (interquartile range: 7 to 46 days). Ninety-day readmission rates were 37.8% (95% CI 29.6 to 46.0), 29.8% (95% CI 25.2 to 34.4), and 26.6% (95% CI 24.9 to 28.2) for low-, medium-, and high volume centers, respectively. The low volume status was independently associated with increased risk of all-cause 90-day readmissions (Table 2). Of 903 readmissions, 405 (44.9%) resulted from cardiac causes and 498 (55.1%) were due to noncardiac causes (Figure 2). The proportions of cardiac versus noncardiac causes of readmission were similar regardless of volume status of hospitals ($p = 0.45$). However, readmission rate due to infectious cause was significantly higher in the low volume versus high volume centers (16.6% vs 7.1%; $p = 0.01$). None of the readmission rates of other causes were significantly different across hospital volume categories

Table 2
Unadjusted and adjusted association of hospital MitraClip volume with in-hospital and 90-day outcomes (high volume center is the reference)

Clinical outcomes In-hospital outcomes during index admission	Univariate regression		Multivariable regression	
	Unadjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value
Death				
Low	2.71 (1.27-5.78)	0.01	2.64 (1.04-6.69)	0.04
Medium	2.22 (1.15-4.31)	0.02	2.60 (1.27-5.31)	0.01
Bleeding				
Low	2.16 (1.26-3.71)	0.01	1.30 (0.69-2.46)	0.42
Medium	1.65 (0.99-2.74)	0.05	1.54 (0.91-2.59)	0.11
Acute kidney injury				
Low	1.54 (0.95-2.51)	0.08	1.12 (0.59-2.10)	0.73
Medium	1.30 (0.88-1.92)	0.18	1.72 (1.12-2.64)	0.01
Stroke				
Low	0.89 (0.43-1.84)	0.76	0.76 (0.38-1.51)	0.43
Medium	1.52 (0.45-5.10)	0.50	1.65 (0.56-4.88)	0.37
Acute myocardial infarction				
Low	5.14 (2.44-10.84)	<0.001	2.93 (1.23-6.97)	0.02
Medium	1.10 (0.46-2.65)	0.83	0.78 (0.27-2.29)	0.66
Permanent pacemaker insertion				
Low	4.41 (1.14-17.13)	0.03	3.61 (0.81-16.13)	0.09
Medium	3.00 (1.09-8.28)	0.03	2.95 (1.14-7.67)	0.03
Acute respiratory failure				
Low	2.87 (1.71-4.84)	<0.001	2.24 (1.17-4.30)	0.02
Medium	1.59 (0.96-2.64)	0.07	1.61 (0.95-2.74)	0.08
Vascular injury				
Low	4.00 (0.87-18.26)	0.07	3.53 (0.74-16.72)	0.11
Medium	4.96 (1.94-12.68)	0.001	3.68 (1.29-10.46)	0.01
Open mitral valve surgery				
Low	1.49 (0.89-2.50)	0.13	0.54 (0.25-1.14)	0.10
Medium	3.14 (1.26-7.81)	0.01	1.14 (0.38-3.43)	0.81
Ninety-day outcomes	Unadjusted hazard ratio (95% CI)	p value	Adjusted hazard ratio (95% CI)	p value
All-cause readmission				
Low	1.58 (1.10-2.25)	0.01	1.54 (1.05-2.25)	0.03
Medium	1.14 (0.86-1.53)	0.36	1.27 (0.94-1.71)	0.12
Infective endocarditis				
Low	9.42 (1.47-60.20)	0.02	10.06 (2.26-44.79)	0.003
Medium	4.75 (0.89-25.38)	0.07	9.16 (2.32-36.09)	0.002
Congestive heart failure exacerbation				
Low	1.40 (0.56-3.53)	0.47	1.03 (0.38-2.79)	0.96
Medium	1.20 (0.63-2.31)	0.58	1.41 (0.68-2.94)	0.36
Open mitral valve surgery				
Low	6.26 (1.52-25.70)	0.01	2.25 (0.50-10.19)	0.29
Medium	1.82 (0.48-6.86)	0.38	1.32 (0.35-5.08)	0.68

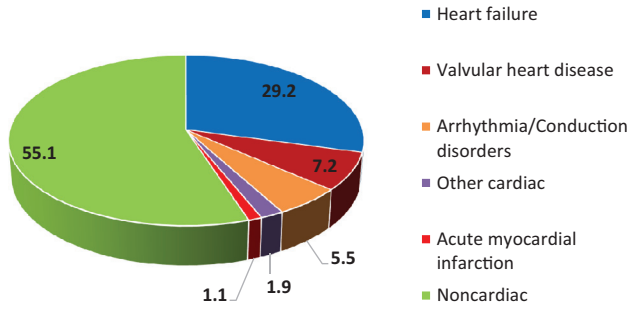


Figure 2. Causes of 90-day readmissions of patients who underwent MitraClip[a].
[a]Values are presented as percentage.

(Supplementary Figure 1A and B). Infectious endocarditis occurred more frequently in low- and medium volume centers than high volume centers (2.4%, 1.3%, and 0.3%, respectively; p = 0.01). The multivariable analysis, adjusting for baseline risk factors, demonstrated that low volume status was an independent predictor of infective endocarditis (Table 2). Patients from low volume centers had higher rates of in-hospital mortality during readmissions compared with medium- and high volume centers (13.3%, 5.3%, and 5.6%, respectively), but the difference was not statistically significant (p = 0.21).

Discussion

Given the high prevalence of MR and rising MitraClip volume in the United States, it is imperative to assess the impact of institutional MitraClip volume on clinical outcomes

to ensure the delivery of unbiased clinical benefits to patients in a real-world setting. In this study, we identified that during 2014 and 2015 the US annual hospital procedural volume of MitraClip was low (5/hospital), but the numbers of MitraClip procedures and high volume centers increased over time. Notably, low institutional volume was associated with worse outcomes including in-hospital mortality and 90-day all-cause readmissions.

An analysis of the German multicenter TRAMI (TRAnscatheter Mitral valve Interventions) registry from 2010 to 2013 did not demonstrate a significant difference in the in-hospital complications between low- and high volume centers.[9] This study was underpowered with a relatively small number of hospitals (828 patients from 21 hospitals) which may explain the lack of statistical difference in the rates of adverse outcomes between low- and high volume centers. Additionally, the volume cutoff used to dichotomize the hospitals into low- and high volume centers (annual procedure number of 1 to 37 and 32 to 78, respectively) appears relatively high in light of a median annual volume of 5 MitraClips per hospital in the United States. This may have diluted the difference between volume groups. Two other studies using NRD examined 30-day readmissions after a MitraClip procedure.[15,16] However, both NRD studies only included one full year of data limiting the study power and were not specifically designed to examine the independent impact of hospital MitraClip volume on clinical outcomes.

In the present study of 3,420 patients from 266 hospitals, we observed an inverse relation between the institutional annual MitraClip volume and in-hospital complications as well as 90-day readmissions. The impact of higher hospital MitraClip volume on the improved outcomes may be a function of accumulated experience with the procedure that enhanced multidisciplinary collaboration whereas mitigating adverse events. Importantly, we found that low volume hospitals were more likely to perform MitraClip as a nonelective procedure. Similar findings were previously demonstrated in several cardiovascular surgeries.[6] One plausible explanation is that a considerable number of elective cases might have been referred from low to high volume centers. Sicker patients who underwent urgent MitraClip procedures at less experienced centers would face double jeopardy leading to higher mortality which underlines the importance of proper patient selection by cohesive multidisciplinary heart valve team and selective referral of high-risk patients to high volume centers.[17] In addition to the appropriate patient selection, MitraClip procedure requires a dedicated postprocedural care along with close surveillance postdischarge given multiple co-morbidities of these patients. Experienced centers with established MitraClip programs likely would provide the necessary postprocedural care which may contribute to the lower rates of 90-day readmissions.

The Centers for Medicare and Medicaid Services recommend that hospitals performing MitraClip procedures have ≥10 mitral repair surgery in the previous year. However, the minimum number of MV surgeries required to achieve the desired MitraClip outcomes and whether or not MV surgery volume has an impact on the outcomes of MitraClip remain unanswered. The current threshold of 10 surgeries may not adequately exclude inexperienced heart valve centers, which can lead to worse outcomes at the low MitraClip volume centers. Further research is needed to examine the potential association of MV surgery volume with MitraClip outcomes and establish pertinent guidelines to enhance the outcomes of MitraClip.

Secondary MR accounts for two-thirds of the entire etiology of MR, and a significant portion of patients who receive MitraClip in Europe has secondary MR.[18−21] In the United States, based on the COAPT Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation trial that showed mortality benefit of MitraClip therapy among patients with severe secondary MR, the FDA approved MitraClip for secondary MR in March 2019.[22,23] Accordingly, it is anticipated that a larger group of patients will receive a MitraClip procedure and more hospitals will adopt MitraClip therapy. Therefore, further studies would be necessary to identify the appropriate MitraClip institutional volume threshold and experiences of the heart valve program to provide optimal outcomes to the patients.

This study is not without limitations. The detailed clinical information including the severity of MR and perioperative echocardiographic data were not available in the NRD. Potential referral bias between low- and high volume centers caused by related unmeasured confounders cannot be entirely excluded although our analysis adjusted for baseline risk factors and the elective nature of procedures. We were unable to incorporate effects of a learning curve, previous experience of MitraClip before FDA approval, and operator-level volume owing to the limitation of the NRD.[24] Lastly, out-of-hospital mortality is not available in the NRD, and unaccounted 90-day mortality could have biased our readmission analysis.

In conclusion, US hospitals performed a median of 5 commercial MitraClip procedures during 2014 and 2015. Low annual institutional MitraClip volume was associated with worse clinical outcomes including increased in-hospital mortality and 90-day readmission. Therefore, selective referral of patients to higher volume institutions with experienced heart valve teams should be encouraged. Further nationwide prospective study with granular clinical data is needed to determine the minimum institutional volume threshold, identify the centers of excellence for the referral, and establish consensus recommendations accordingly.

Disclosures

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.04.006.

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