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## Prevalence of In-Hospital Stroke Comparing MitraClip and Transcatheter Aortic Valve Implantation



Transcatheter aortic valve implantation (TAVI) and mitraclip (MC) are increasingly utilized for the treatment of aortic stenosis and mitral regurgitation, respectively. Perioperative stroke is one of the most serious complications following TAVI given the valve calcification and possible embolization during valve implantation, and thus ongoing trials are assessing the use of embolic protection device following TAVI. On the other hand, no such trials are being

conducted on MC as the evidence of stroke following MC is lacking and MC does not share the same etiology with TAVI.<sup>1</sup>

We studied the risk of stroke after TAVI and MC procedures from the Nationwide Readmission Database between January 2014 and December 2017.<sup>2</sup> Patients who underwent either TAVI or MC were selected using the appropriate ICD-9 or ICD-10 procedure codes. Among included patients, the occurrence of in-hospital stroke and the occurrence of in-hospital stroke within any readmission within 30 days were assessed. We performed chi-square and multivariable logistic regression to compare baseline characteristics and the rate of stroke after TAVI and MC procedures. Odds ratios and the 95% confidence intervals were used to report the risk of in-hospital stroke. All statistical analyses were performed by using the weighted values, hospital clusters, and strata of observations as provided by the Nationwide Readmission Database to measure national estimates. All statistical analyses were conducted using SPSS version 23. A 2-sided value of p < 0.05 was set for statistical significance.

A total of 148,645 and 15,570 patients underwent TAVI and MC, respectively. Most procedures were performed in high volume hospitals and teaching hospitals. Compared with MC patients, those who underwent TAVI were more likely to have hypertension, diabetes mellitus, dyslipidemia, and a history of a stroke/TIA. However, patients who underwent MC were significantly more likely to have congestive heart failure, and atrial fibrillation. During the study period, 2,974 (2%) TAVI patients and 169 (1.1%) MC patients developed in-hospital stroke (p < 0.001). Rates of in-hospital stroke following TAVI and MC did not differ based on the hospital procedural volume. A total of 843 (0.6%) TAVI patients and 92 (0.7%) MC patients developed stroke within 30-days following discharge (p = 0.658). Table 1 summarizes the baseline characteristics and outcomes. After adjusting for age and the presence of atrial fibrillation, congestive heart failure, hypertension, CHA2DS2-VASc score, and a history of stroke and/or TIA, TAVI was still associated with a higher risk of in-hospital stroke when compared with MC (OR = 1.866, 95% CI [1.595 to 2.184], p < 0.001).

This study demonstrates that inhospital stroke rates are significantly higher among patients undergoing TAVI than those undergoing MC. Previous studies using the American College of Cardiology and/or Society of Thoracic Surgery Transcatheter Valve Therapies registry have reported similar rates of after-procedural stroke rates for TAVI (2.3%) and MC (0.7%) as our analysis.<sup>3,4</sup> We cannot accurately specify the cause of relatively lower stroke rates in MC but we hypothesize that this may be because of the different underlying etiologies and thus mechanism of stroke. MC patients, specifically those with atrial fibrillation where strokes are more likely to be related to thrombus formation, may benefit more from anticoagulation than protection devices, decreasing the incentive to experiment these devices with MC procedures.

Another significant result of our analysis is that the penetration of MC was similar to TAVI in different hospital settings such as low vs. high procedural volume hospitals with no difference in stroke rates among hospitals based on their procedural volume. It is essential to recognize that procedural volume was not associated with any differences in stroke rate for TAVI or MC, a finding noted by other investigators.<sup>5</sup>

Limitations of this study include its retrospective nature as well as the limitations of the database itself that does not include the physical examination, imaging, procedural details, antithrombotic treatment, or long term follow up data.

Our study demonstrates that the MC procedure has a low but not negligible stroke rate.

## Disclosure

The authors declare no conflict of interest.

## **Declaration of Interests**

The authors declare that they have no known competing financial interests or personal relationships that could Readers' Comments 163

Table 1
Baseline characteristics and the rate of developing strokes among patients who underwent TAVI or Mitraclip (2014 to 2017)

Baseline characteristic	TAVI (n=148,645)		MITRA-Clip (n=15,570)		p Value*
Age (years), Median (IQR)	82 (76-87)		80 (72-86)		<.001
Gender					<.001
Men	80,036 (53.8%)		8,141 (52.3%)		
Women	68,609 (46.2%)		7,430 (47.7%)		
Comorbidities					
Hypertension	127,239 (85.6%)		12,205 (78.4%)		<.001
Diabetes Mellitus	52,157 (35.1%)		3,854 (24.8%)		<.001
Atrial Fibrillation	50,497 (34%)		7,740 (49.7%)		<.001
Congestive Heart failure	108,791 (73.2%)		12,304 (79%)		<.001
Dyslipidemia	99,440 (66.9%)		8,718 (56%)		<.001
Peripheral vascular disease	33,502 (22.5%)		1,968 (12.6%)		<.001
Aortic atherosclerosis	6,150 (4.1%)		328 (2.1%)		<.001
Smoking	52,395 (35.2%)		5,370 (34.5%)		.059
History of myocardial infarction	18,105 (12.2%)		2,378 (15.3%)		<.001
History of stroke/TIA	18,094 (12.2%)		1,789 (11.5%)		.013
CHA2DS2- VASc score <sup>†</sup> , mean (SD)	4.7 (1.4%)		4.4 (1.5%)		<.001
In-hospital stroke rates					
Overall In-hospital Stroke rate	2,974 (2%)		169 (1.1%)		<.001
Overall 30-day post-discharge stroke rate	843 (0.6%)		92 (0.7%)		.658
Based on hospital characteristics	Total TAVI cases	In-hospital stroke	<b>Total MITRA-Clip cases</b>	In-hospital stroke	
Procedural volume <sup>‡</sup>					
Low volume hospitals	26,928 (18.1%)	578 (2.1%)	4,368 (28.1%)	53 (1.2%)	
Medium volume hospitals	43,074 (39%)	873 (2%)			
High volume hospitals	78,643 (52.9%)	1,524 (1.9%)	11,202 (71.9%)	115 (1%)	
Bed-size <sup>§</sup>					
Small hospitals	6,498 (4.4%)	109 (1.7%)	657 (4.2%)	0	
Medium hospitals	27,468 (18.5%)	543 (2%)	3,364 (21.6%)	47 (1.4%)	
Large hospitals	114,680 (77.1%)	2,323 (2%)	11,549 (74.2%)	122 (1.1%)	
Hospital status					
Teaching	132,130 (88.9%)	2,678 (2%)	141,453 (90.9%)	156 (1.1%)	
Non-teaching	15,044 (10.1%)	275 (1.8%)	1,402 (9%)	13 (0.9%)	
Non-metropolitan	1,471 (1%)	21 (1.4%)	16 (0.1%)	0	

<sup>\*</sup> p value less than 0.05 was considered statistically significant. All statistical tests were 2-sided

have appeared to influence the work reported in this study.

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<sup>†</sup>CHA2DS2-VASc score was calculated based on: age (0: <65, 1: 65 to 74, 2: >74), gender (0: man, 1: woman), hypertension (1), diabetes mellitus (1), congestive heart failure (1), peripheral vascular disease/prior myocardial infarction/aortic atherosclerosis (1), and history of stroke/TIA (2).

<sup>&</sup>lt;sup>‡</sup> Procedural volume according to the following: for TAVI, a hospital was considered low-, medium-, or high-volume if it performed less than 50, 50 to 99, or more than 99 TAVR procedures a year, respectively; for MC a hospital was considered low- or high-volume if it performed less than 30 or more than 30 MC procedures a year, respectively.

<sup>§</sup> the definition of hospital bed size can be found on this link: https://www.hcup-us.ahrq.gov/db/vars/hosp\_bedsize/nrdnote.jsp

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