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RESEARCH CORRESPONDENCE

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Clinical and Economic Burden of Acute Ischemic Stroke Following Transcatheter Aortic Valve Replacement

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Acute ischemic stroke is a devastating complication of transcatheter aortic valve replacement (TAVR). Therefore, several studies have sought to investigate predictors of post-TAVR stroke,[1,2] and to assess the potential role of cerebral embolic protection devices (EPDs) in reducing its incidence.[3–5] However, the impact of post-TAVR stroke on clinical outcomes, cost, and resource utilization has not been thoroughly studied. We utilized a nationwide database to assess the impact of post-TAVR acute ischemic stroke on in-hospital and 30-day morbidity and mortality, readmission rates and cost.

We identified patients who underwent TAVR between January 1, 2013 and December 31, 2014, using the National Readmission Database (NRD); a publicly available database of all-payer inpatient stays that includes data from 21 geographically dispersed states that account for 49.1% of all hospitalizations in the US. The NRD also contains verified patient linkage numbers that can be used to track readmissions across hospitals for individual patients. Patients were divided into two groups, based on the occurrence of an ischemic stroke during the same hospitalization. Acute ischemic stroke diagnoses were identified using the International Classification of Diseases-Ninth Revision-Clinical Modification ICD-9-CM codes (433–437.1). The primary end point was in-hospital mortality. Secondary endpoint included rates of severe disability (measured by the need for mechanical ventilation, gastrostomy, tracheostomy, and non-home discharges), length of stay, cost of the index hospitalization, 30-day readmission rate, and readmission-related mortality, length of stay and cost. To account for potential confounding factors, patients were entered into a nearest neighbor 1:1 variable ratio, parallel, balanced propensity-matching model using a caliper of 0.01 to ensure perfect matching. The following covariates were entered into the model: age, gender, race, hypertension, diabetes, anemia, prior sternotomy, chronic renal disease, obstructive lung disease, liver disease, coagulopathy, atrial fibrillation, conduction abnormalities, coronary artery disease, vascular disease, TAVR access, hospital teaching status, hospital bed size, hospital location (rural vs. urban), primary payer, and admission status (elective vs. non-elective). The primary and secondary end points were compared between the two groups before and after propensity-score matching.

A total of 30,054 TAVR patients (national estimate) were included in the study, of whom 776 (2.5%) suffered an acute ischemic stroke. Patients who suffered an ischemic stroke had significantly higher rates of crude and risk-adjusted in-hospital death (11.2% vs. 4% and 11.3% vs. 4.1%, respectively, $p < 0.001$). They also had longer hospitalizations, higher total cost, and higher incidences of mechanical ventilation, gastrostomy, tracheostomy, and non-home discharges (Table 1). At 30-day post-discharge, patients who suffered an acute ischemic stroke after TAVR were more likely to be readmitted, and their readmissions were associated with significantly higher mortality, longer length of stay and higher cost (Table 1).

The main findings of this study are:[1] acute ischemic stroke post-TAVR is associated with a substantial morbidity and a ~ 3-fold increase in in-hospital mortality,[2] post-TAVR ischemic stroke are also associated with a 32% increase in cost of index hospitalization, a 121% increase in nursing home and intermediate care facility utilization, and a 132% increase in cost of rehospitalization. These data are of potential economic importance in light of the expanding use of EPDs during TAVR. A recent meta-analysis of the randomized clinical trials and observational studies on the utility of EPDs in patients undergoing TAVR suggested that the number needed to treat to prevent one stroke with EPDs is 33 patients.[5] Hence, with the currently available data, the cost of preventing one stroke with EPDs is ~ 100,000$, which might be acceptable to the society in light of the substantial negative impact of post-TAVR stroke on the morbidity, mortality, resource utilization and cost. The Sentinel device (Claret Medical, Santa Rosa, CA, USA) is currently the only EPD that is approved by the drug and food administration for routine use during TAVR to reduce the risk of procedural stroke. Although the use of this device is associated with a significant incremental cost (~ 3,000$), the Centers for Medicare & Medicaid Services have recently approved its reimbursement via the new technology add-on payment program (NTAP; effective October 1, 2018).

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Table 1. Outcomes of patients with and without acute ischemic stroke following transcatheter aortic valve replacement.

	Unmatched cohorts			Matched cohorts		
	TAVR non-stroke (N = 30,054)	TAVR-stroke (N = 776)	*p*-value	TAVR non-stroke (N = 763)	TAVR-stroke (N = 763)	*p*-value
Age, mean (SD), y	81 (8)	83 (7)	<0.001	82 (8)	83 (7)	0.11
Female	47.5%	54.4%	<0.001	51.7%	53.1%	0.51
Hypertension	79.3%	74.4%	<0.001	74.9%	75.1%	0.99
Diabetes	34.5%	30.8%	0.031	28.9%	31.3%	0.55
Previous stroke/TIA	10.7%	10.9%	0.886	14.5%	10.6%	0.29
Atrial fibrillation	46.3%	51.1%	0.008	51.6%	50.7%	0.94
Vascular disease	29.7%	35.4%	0.001	37.8%	34.7%	0.99
Chronic renal disease	36.2%	33.3%	<0.001	32.9%	33.7%	0.75
Transfemoral access	76.9%	71.2%	0.001	74.4%	71.5%	0.35
In-hospital outcomes						
Death	4%	11.2%	<0.001	4.1%	11.3%	<0.001
Non-home discharge	28.6%	66.8%	<0.001	29.8%	66.1%	<0.001
Gastrostomy	1%	11%	<0.001	0.7%	10.8%	<0.001
Mechanical ventilation	1.2%	5.8%	<0.001	2.4%	13.3%	<0.001
Tracheostomy	2.7%	13.9%	<0.001	1.7%	5.1%	0.043
LOS, mean (SD), d	8 (8)	15 (12)	<0.001	9 (9)	15 (12)	<0.001
Admission cost*, US$	58,995 (32,723)	80,724 (45,926)	<0.001	59,584 (32,647)	79,242 (43,751)	<0.001
30-day outcomes						
Readmission	18.3%	23.2%	0.026	15.6%	20.5%	0.020
Death	0.9%	2.1 %	<0.001	1.3%	3.1%	0.034
LOS of readmission	6 (7)	10 (24)	<0.001	7 (7)	10 (22)	<0.001
Readmission cost*, US$	15,532 (39,442)	33,258 (132,317)	<0.001	14,471 (15,264)	33,578 (120,085)	<0.001

Notes. *Mean (SD).
NE, national estimate; TAVR, transcatheter aortic valve replacement; SD, standard deviation; Y, year; N, number; TIA, transient ischemic attack; LOS, length of stay; US, United States.

The cost data provided by our analysis can provide a benchmark for future cost-effectiveness analyses on embolic protection during TAVR. However, our study has two important limitations; (a) we utilized a national registry enrolling patients in 2013 and 2014, a period during which older generation valves were used and stroke rates were higher. (b) the cost of stroke measured in our study is limited to the additional cost of index hospitalizations and readmissions within 30 days. Costs related to intermediate care facility utilization, and long-term disability resulting from the stroke are not captured. Therefore, additional studies are needed to assess long-term impact of procedural strokes in contemporary TAVR practice, and to perform comprehensive cost-effectiveness analyses of the emerging EPDs.

Disclosure statement

The authors report no conflicts of interest.

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