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The impact of prior stroke on the outcome of patients with severe aortic stenosis undergoing transcatheter aortic valve replacement

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ABSTRACT

Aims: The present study aimed to evaluate the impact of prior cardiovascular events (CVE) on outcome in patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR).
Methods and results: Patients with severe AS undergoing TAVR between May 2007 and March 2015 were included and categorized to patients with and without prior stroke, defined as embolic, hemorrhagic stroke and transit ischemic attack. Baseline, procedural characteristics, in-hospital outcomes, and 1-month and 1-year mortality were compared in accordance with the Valve Academic Research Consortium-2 consensus. A cohort of 662 consecutive patients with severe AS undergoing TAVR were included in the analysis. Of these, 120 patients had prior stroke, and 542 without. Transfemoral access was used in 78% (571), and pre-TAVR balloon aortic valvuloplasty was performed in 87% (574). Patients with prior stroke had a higher mean Society of Thoracic score compared to those without (10.1% versus 8.8%, respectively; $p = 0.006$) and higher rates of atherosclerotic disease involving the coronary, peripheral, and carotid arteries. Patients with prior stroke also had more occurrence of in-hospital minor stroke (3.3% versus 0.7%; $p = 0.04$). Nevertheless, similar mortality rates were recorded at 1, 6, and 12 months, and there were no significant differences in major stroke, bleeding, or post-procedure hospital stay between both groups.
Conclusion: Prior history of stroke infers a higher risk for in-hospital minor stroke, yet no impact on other outcomes post TAVR. Therefore, history of prior stroke should not be considered an exclusion criterion for TAVR in patients with severe AS.

1. Introduction

Patients undergoing stroke are prone to a subsequent cerebrovascular event and considered at high risk for any further intervention. Usually patients who experienced stroke are suffering from other comorbidities and are at higher risk for a subsequent event. Stroke is a major complication of both transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR). In most TAVR trials, patients with a history of stroke were excluded [1]. In the PARTNER trial [2], although a recent neurologic event was an exclusion criterion, the rates of cerebrovascular events (CVE) were almost double in the TAVR group in comparison to patients who underwent SAVR (3.8 versus 2.1, respectively). However, subsequent trials and registries [3,4] indicate that the actual incidence of stroke has declined in the TAVR population due to the evolution and improvement of the TAVR technique and devices and patient selection. Patients with prior stroke may be at higher risk due to hemodynamic instability coagulation issues and impaired neurological reserve. A history of a prior stroke in patients undergoing SAVR has been identified as an independent risk factor for post-procedural stroke [5,6]. However, there are scarce data regarding incidence of post-procedural stroke and mortality in patients with prior stroke undergoing TAVR. The present study aimed to evaluate the impact of prior CVE in patients undergoing TAVR in regard to in-hospital and early and late mortality outcomes.

2. Methods

The present study is an observational, prospective single-center study. The study populations included patients with severe aortic stenosis undergoing TAVR with and without a prior history of stroke, defined as previous stroke embolic or hemorrhagic or transient ischemic attack. All patients were evaluated by our multidisciplinary heart team to be at a high or prohibitive risk for SAVR. All consecutive patients with severe symptomatic aortic stenosis confirmed by transthoracic echocardiography and invasive hemodynamic evaluation who were treated with TAVR between May 2007 and March 2015 were included and categorized according to their history of prior stroke. All data were

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prospectively collected and stored in the internal Aortic Valve System database of the MedSatar Cardiovascular Research Network.

All patients had conscious sedation or general anesthesia administered by our cardiac anesthesiologists in our hybrid catheterization laboratory. Transapical access was performed by a thoracic surgeon, and transfemoral access was achieved via a percutaneous route. All patients received either a self-expandable device (valve sizes: 23, 26, 29, 31 mm) or a balloon-expandable device (valve sizes: 23, 26, 29 mm). Intraprocedural, prevalve balloon aortic valvuloplasty (BAV) was preformed for the majority of our balloon-expandable valve cases for the aim of testing the expansion capacity of the native annulus and preparing the annulus for implantation of the transcatheter heart valve. As opposed to the self-expanding valves, pre-BAV was usually performed only if the baseline cardiac computed tomography demonstrated a significant burden of native annular or leaflet calcification and/or fibrosis of the native aortic leaflets. The TAVR was implanted under the instruction for use for each valve.

Table 1
Clinical characteristics according to no prior stroke and prior stroke.

	No prior stroke (N = 542)	Prior stroke (N = 120)	p
Age, years, SD	83 ± 7.9	83.2 ± 7	0.82
BMI, SD	27.89 ± 7.5	26.2 ± 5	0.005
LVEF, SD	49.3 ± 18.3	43 ± 19.8	0.24
NYHA class III or IV	90% (475)	85.7% (102)	0.18
Cardiovascular risk factor			
Hypertension	93.2% (506)	95% (114)	0.46
Diabetes	33.1% (179)	34.2% (41)	0.98
Insulin dependent diabetes	10.9% (59)	10.8% (13)	0.98
Hyperlipidemia	79.1% (427)	84.9% (101)	0.15
Current or prior smoking	33.6% (159)	31.4% (33)	0.66
Past medical history			
COPD	36.4% (197)	27.5% (33)	0.06
Renal insufficiency (GFR < 60/dialysis)	43.8% (235)	59% (69)	0.003
History of cancer	26.2% (121)	21.7% (20)	0.36
Carotid artery disease	12.3% (56)	67.8% (61)	<0.001
Peripheral vascular disease	32.5% (171)	42.9% (51)	0.03
History of CAD	72.4% (323)	83.8% (83)	0.02
Prior CABG	31.7% (171)	45% (54)	0.005
Prior PCI	31.5% (169)	26.9% (32)	0.32
Prior MI	18.4% (97)	20.2% (24)	0.65
Prior valve surgery	4.9% (23)	3.3% (3)	0.78
Prior BAV	27.5% (135)	37.8% (37)	0.04
Multiple prior BAV	2.9% (13)	12.8% (11)	<0.001
Baseline rhythm			
History of atrial fibrillation/flutter	43.2% (234)	35.8% (43)	0.14
Pacemaker	25.1% (94)	22% (20)	0.54
Baseline ECG sinus rhythm	61.7% (255)	66.3% (55)	0.44
Baseline ECG atrial fibrillation	19.7% (81)	13.6% (11)	0.2
Baseline antiplatelet and anticoagulation treatment			
Aspirin	83.3% (229)	94.5% (69)	0.02
Clopidogrel	46.9% (84)	58.2 (32)	0.14
Warfarin	37.6% (65)	32% (16)	0.47
Discharge antiplatelet and anticoagulation treatment			
Aspirin	95.1% (270)	95.8% (69)	1
Clopidogrel	91% (262)	85.7% (60)	0.19
Warfarin	34.2% (51)	43.5% (20)	0.25
Porcelain aorta	7.2% (39)	8.3% (10)	0.66
Frailty	43% (101)	47.2% (25)	0.57
STS Score			
STS Score > 8	52.2% (283)	64.7% (77)	0.013
STS Score, SD	8.8 ± 4.5	10.1 ± 4.9	0.006

BAV: balloon aortic valvuloplasty; BMI: body mass index; CAD: coronary artery disease; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; CVE: cerebral vascular events; ECG: electrocardiogram; GFR: glomerular filtration rate; LVEF: left ventricle ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard derivation; STS: Society of Thoracic Surgeons.

Table 2
Baseline cardiac computed tomography angiography, echocardiography, and catheterization according to prior stroke and no prior stroke.

	No prior stroke (N = 542)	Prior stroke (N = 120)	p
Cardiac CTA indices			
Moderate or severe ascending aorta calcification	25.1% (74)	41.5% (22)	0.01
Severe aortic valve calcification	39.1% (117)	48.2% (27)	0.2
AVA, mm^2,SD	45.3 ± 9.8	44.2 ± 7.7	0.68
MLD right side,* mm^2, SD	7.28 ± 1.25	6.89 ± 1.21	0.008
MLD left side,* mm^2, SD	7.24 ± 1.21	6.91 ± 1.18	0.02
Echocardiographic indices			
LVEF, %, SD	52.2 ± 14	54.2 ± 12	0.17
LVEDD, SD	4.47 ± 0.7	4.32 ± 0.6	0.04
LVESD, SD	3.09 ± 0.9	3 ± 0.7	0.4
Left atrial diameter, SD	4.53 ± 0.8	4.45 ± 0.7	0.3
AVA, cm^2, SD	0.67 ± 0.13	0.64 ± 0.12	0.04
AVA indexed, cm^2/m^2, SD	1.85 ± 0.26	1.77 ± 0.21	0.001
Aortic valve max velocity, m/s, SD	4.3 ± 0.5	4.4 ± 0.5	0.1
Mean gradient, mmHg, SD	47.3 ± 12.6	48.6 ± 12.6	0.4
Moderate and severe aortic regurgitation	5.5% (23)	4.4% (4)	0.8
Moderate and severe mitral regurgitation	11.4% (54)	10.6% (11)	0.8
Severe MAC	35.6% (160)	37.9% (36)	0.7
Severe right ventricle dysfunction	2.9% (14)	1.9% (2)	0.7
PASP, mmHg, SD	45.5 ± 15.3	45 ± 18.6	0.8
Catheterization indices			
Three vessel disease (>50%)	18.2% (62)	31.7% (20)	0.01
Left anterior descending coronary artery >50% stenosis	38.5% (134)	59.4% (38)	0.002

* Including common/external iliac and common/external femoral arteries. AVA: aortic valve area; CTA: cardiac tomography angiography; LVEF: left ventricle ejection fraction; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; MAC: mitral annular calcification; MLD: minimal lumen diameter; PASP: pulmonary artery systolic pressure; SD: standard derivation.

Prespecified clinical, procedural, and laboratory data were prospectively collected for all patients during screening, on admission, immediately post-procedure, and during follow-up. This included demographic information, medical history, clinical data (baseline treatment, baseline electrocardiogram, echocardiographic indices), and laboratory indices. The Society of Thoracic Surgeons (STS) score was calculated for every patient. Procedural data collected in the database included type of anesthesia, device access, pre and post TAVR balloon, number of valves deployed, pacing and hypotension during the procedure, and type and size of valve. Immediate post-procedural complications and post-procedural data, including major and minor stroke, occurring during the index procedure were collected and assessed in accordance with the Valve Academic Research Consortium (VARC)-2 guidelines [7]. The prior history of stroke was collected from the notes of the patient's cardiologist and the information provided by the patient. All patients presenting a stroke after the procedure had a clinical evaluation by an experimented neurologist and a neuroimaging documentation (brain computer tomography or brain magnetic resonance imaging) was performed. Long-term follow-up was based upon the clinical trial requirements. Clinical events were adjudicated by an independent cardiologist who determined the nature of the event. The local institutional review board approved the data collection.

The primary end-point was all-cause mortality at 1 year of follow-up. In addition, secondary outcomes included a comparison of complications during the index hospitalization, such as acute kidney injury, major vascular complication, bleeding, stroke, atrial fibrillation, new pacemaker implantation, and mortality.

Continuous variables were expressed as mean ± standard deviation for normally distributed variables and compared using student's t-test. Median and interquartile range for non-parametric variables were compared using the Mann–Whitney test. Categorical variables were expressed as numbers and percentages and compared using chi-square or Fisher's exact test as appropriate. Uni- and multivariate Cox