Cerebral Embolism Following Transcatheter Aortic Valve Implantation : Comparison of Transfemoral and Transapical Approaches

Josep Rodés-Cabau[1], Eric Dumont[1], Robert H Boone[2], Eric Larose[1], Rodrigo Bagur[1], Ronen Gurvitch[2], Fernand Bédard[3], Daniel Doyle[1], Robert DeLarochellière[1], Cleonie Jayasuria[2], Jacques Villeneuve[1], Alier Marrero[4], Mélanie Côté[1], Philippe Pibarot[1], John Webb[2]

[1]Quebec Heart & Lung Institute, Laval University, Quebec city, Quebec, Canada; [2]St Paul's Hospital, University of British Columbia, Vancouver, British Columbia, Canada; [3]Department of Neuroradiology, Enfant-Jesus Hospital, Laval University, Quebec city, Quebec, Canada; [4]Montreal Neurological Institute, McGill University, Montreal, Quebec, Canada;

Potential conflicts of interest

Speaker's name: …Josep Rodés-Cabau……

x **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- x Consulting (Edwards Lifesciences Inc.)
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ **I do not have any potential conflict of interest**

Background

- Transfemoral (TF) transcatheter aortic valve implantation (TAVI) has been associated with a high rate of cerebral embolism as evaluated by diffusion-weighted magnetic resonance imaging (DW-MRI)

- The transapical (TA) TAVI approach avoids both the manipulation of large catheters in the aortic arch/ascending aorta and the retrograde crossing of the aortic valve, and this might led to a lower rate of cerebral embolism

- No data exist on the incidence of cerebral embolism following TA-TAVI as evaluated by DW-MRI

Objectives

1) To compare TA-TAVI versus TF-TAVI with respect to the incidence of cerebral embolism as evaluated by DW-MRI

2) To determine the predictive factors associated with cerebral embolism during the TAVI procedures

Methods

- Prospective multicenter study including patients with severe symptomatic aortic stenosis who underwent TAVI

- The patients were selected for TF or TA approach depending on the size, disease and degree of calcification of iliofemoral arteries

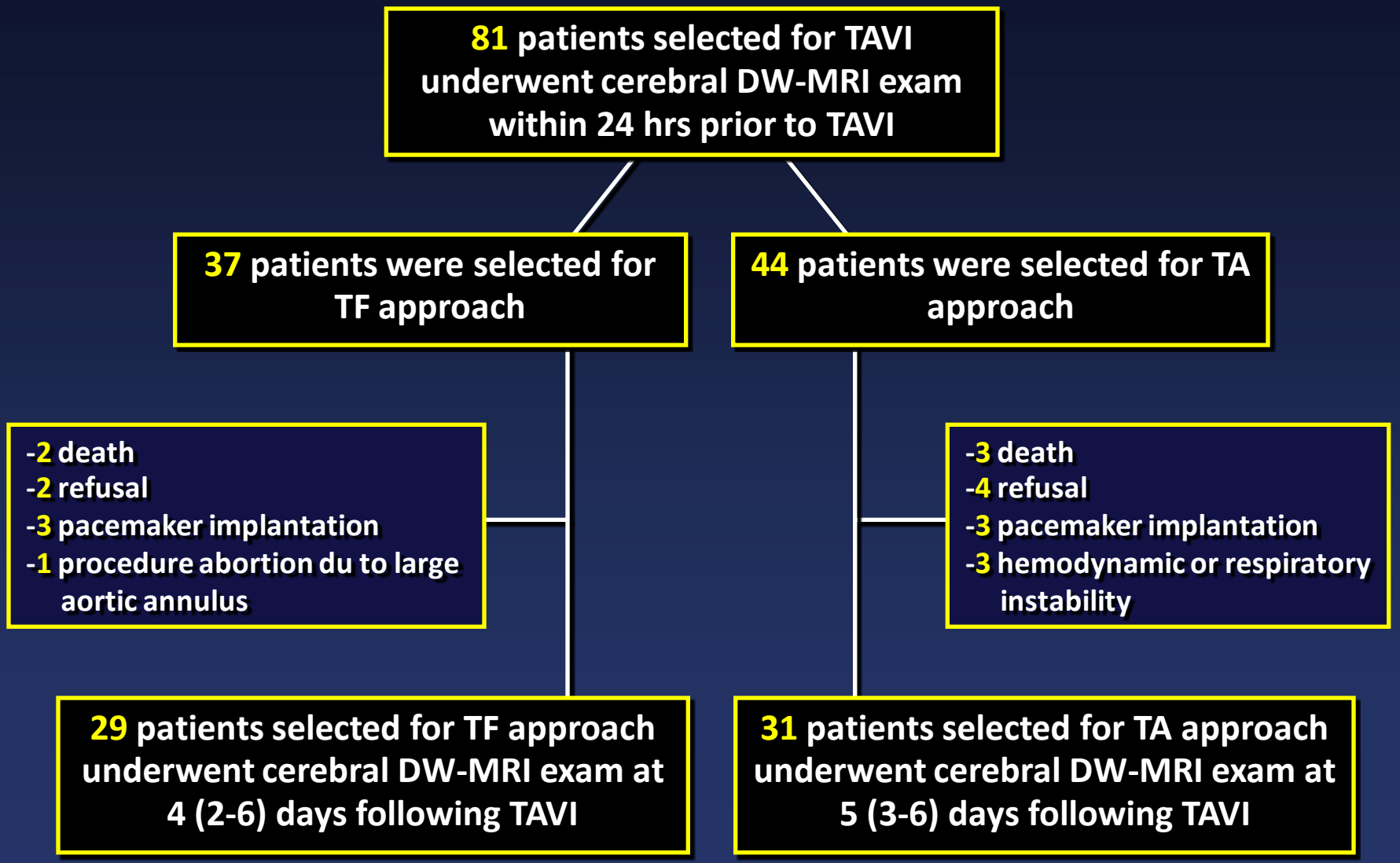
- All TAVI procedures were performed with the 23- or 26-mm Edwards valve (Edwards SAPIEN or SAPIEN XT, Edwards Lifesciences Inc., Irvine, CA)

Methods

- Cerebral DW-MRI exams were performed within the 24 hrs prior to TAVI and within the 6 days following TAVI

- All DW-MRI exams were analyzed by a neuroradiologist blinded to the clinical data. The presence, number, size and location of all new focal diffusion abnormalities were recorded

- Neurological and cognitive functions were assessed by the National Institutes of Health Stroke Scale (NIHSS) questionnaire and the Mini-Mental State Examination (MMSE) at DW-MRI timepoints


81 patients selected for TAVI underwent cerebral DW-MRI exam within 24 hrs prior to TAVI
37 patients were selected for TF approach
44 patients were selected for TA approach
-2 death
-2 refusal
-3 pacemaker implantation
-1 procedure abortion du to large aortic annulus
-3 death
-4 refusal
-3 pacemaker implantation
-3 hemodynamic or respiratory instability
29 patients selected for TF approach underwent cerebral DW-MRI exam at 4 (2-6) days following TAVI
31 patients selected for TA approach underwent cerebral DW-MRI exam at 5 (3-6) days following TAVI

Clinical Characteristics

Variables	All patients (n=60)	Transfemoral (n=29)	Transapical (n=31)	P value
Age (years)	83±7	84±7	81±7	0.17
Male sex (n,%)	30 (50)	16 (55)	14 (45)	0.61
Diabetes (n,%)	15 (25)	9 (31)	6 (19)	0.38
Dyslipidemia (%)	44 (73)	17 (59)	27 (87)	0.02
Hypertension (n,%)	45 (75)	19 (66)	26 (84)	0.14
Chronic atrial fibrillation (n,%)	14 (23)	7 (24)	7 (23)	1.00
Coronary artery disease (n,%)	44 (73)	17 (59)	27 (87)	0.02
Prior stroke (n,%)	9 (15)	4 (14)	5 (16)	1.00
Peripheral vascular disease	19 (32)	5 (17)	14 (45)	0.03
Carotid stenosis (n,%)	6 (10)	2 (7)	4 (13)	0.67
STS-PROM score (%)	7.7±4.6	8.1±5.5	7.3±3.6	0.55
Logistic EuroSCORE (%)	18.9±12.8	17.6±11.3	20.1±14.1	0.46

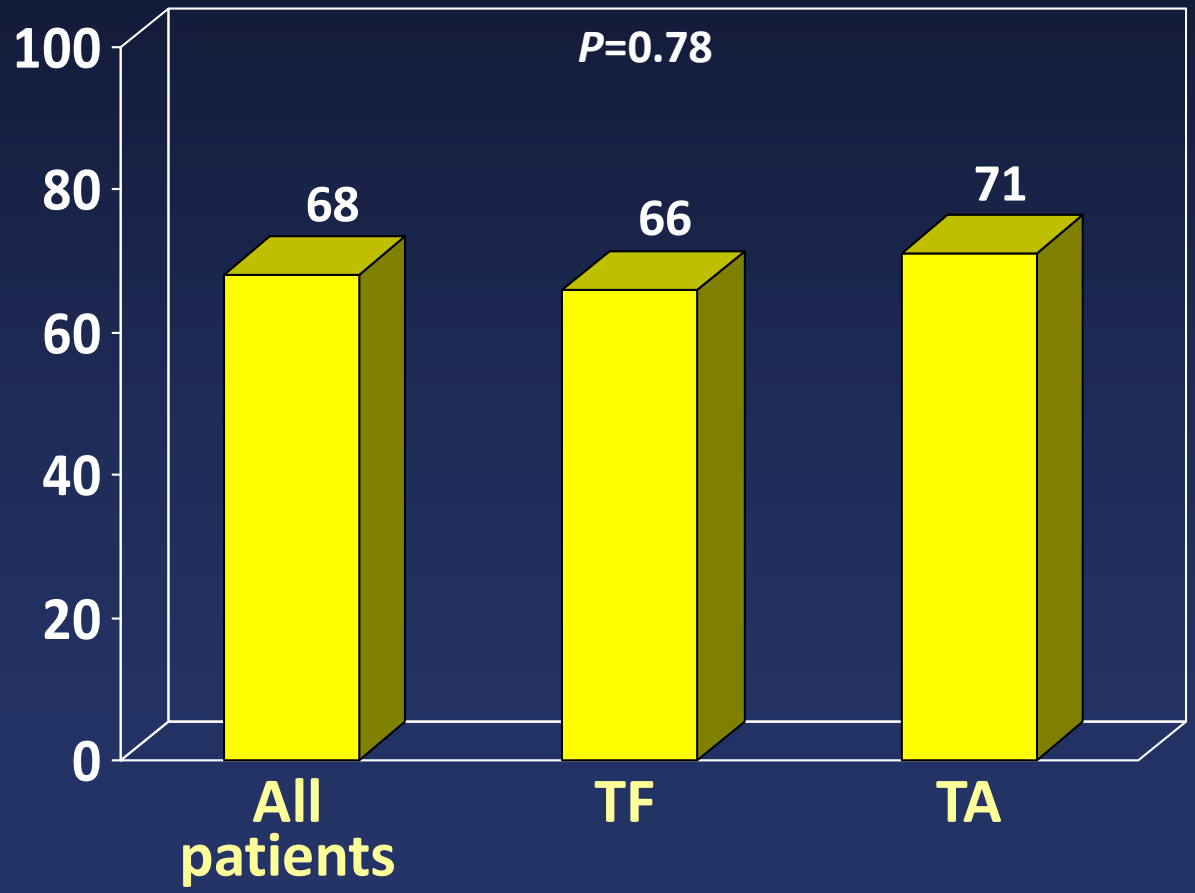
Variables	All patients (n=60)	Transfemoral (n=29)	Transapical (n=31)	P value
Echocardiographic variables				
Mean aortic gradient (mmHg)	43±17	42±15	44±19	0.76
Aortic valve area (cm^2)	0.63±0.18	0.67±0.18	0.61±0.17	0.22
LVEF (%)	55 ±13	52±16	57±11	0.15
LVEF <40%	10 (17)	7 (24)	3 (10)	0.17
Aortic annulus diameter (TEE, mm)	22±2	23±2	21±2	<0.0001
Aortic plaques ≥4mm (ascending aorta/arch,n,%)	17 (28)	8 (28)	9 (29)	0.57
Computed tomography				
Aortic valve leaflet calcium volume (38 pts, CT, ml, median [25^{th}-75^{th} IQR])	2020 (1350-4140)	2870 (1890-5300)	1650 (1300-2570)	0.04

Procedural Characteristics

Variables	All patients (n=60)	Transfemoral (n=29)	Transapical (n=31)	P value
Valve diameter (mm)				
23	28 (47)	10 (34)	18 (58)	0.12
26	31 (52)	18 (62)	13 (42)	
Catheter size (Fr)				
22	10 (17)	10 (34)	-	
24	18 (30)	18 (62)	-	
26	31 (52)	-	31 (100)	
Ratio aortic annulus/valve diameter	0.84±0.17	0.84±0.25	0.85±0.04	0.91
Rapid pacing runs	5±2	4±2	6±2	<0.0001
Procedure duration (min)	83 (70-140)	120 (96-180)	72 (65-81)	0.07
Successful procedure	59 (98)	28 (97)	31 (100)	0.48
Procedural complications				
Valve embolization	0	0	0	-
Valve malposition	1 (2)	0	1 (3)	1.00
Need for a second valve	2 (3)	0	2 (6)	0.49
Need hemodynamic support	2 (3)	0	2 (6)	0.49
Major access site complications	5 (8)	3 (10)	2 (6)	1.00
Life threatening arrythmias	2 (3)	1 (3)	1 (3)	1.00

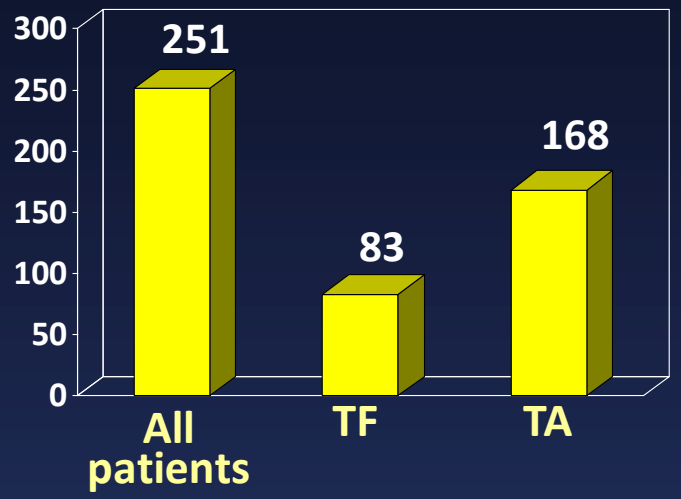
DW-MRI Results Post-TAVI

Patients with new lesions (%)

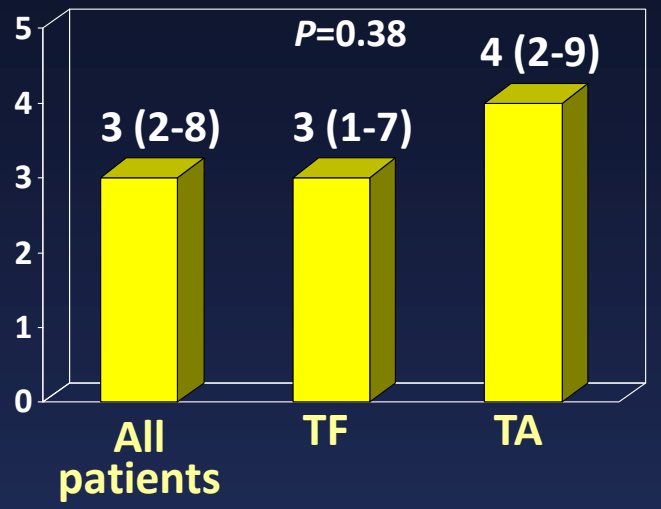


DW-MRI Results Post-TAVI

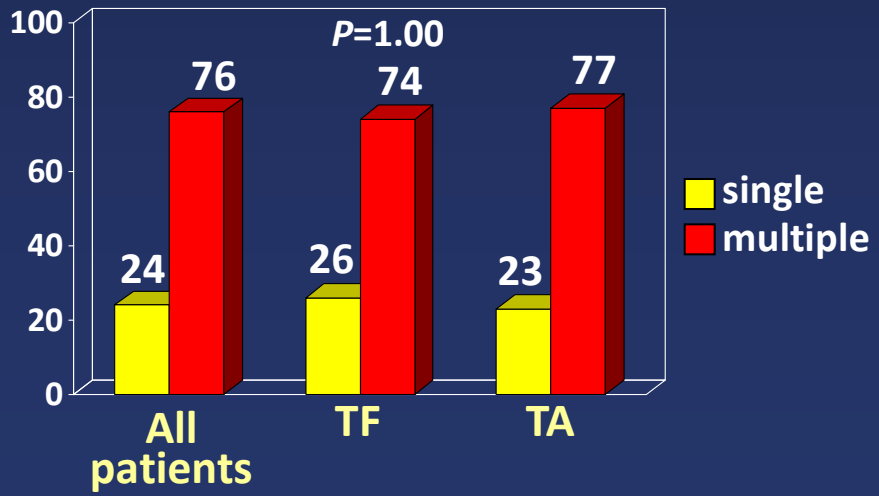
Total number of lesions



Lesions/patient (median, 25th-75th)

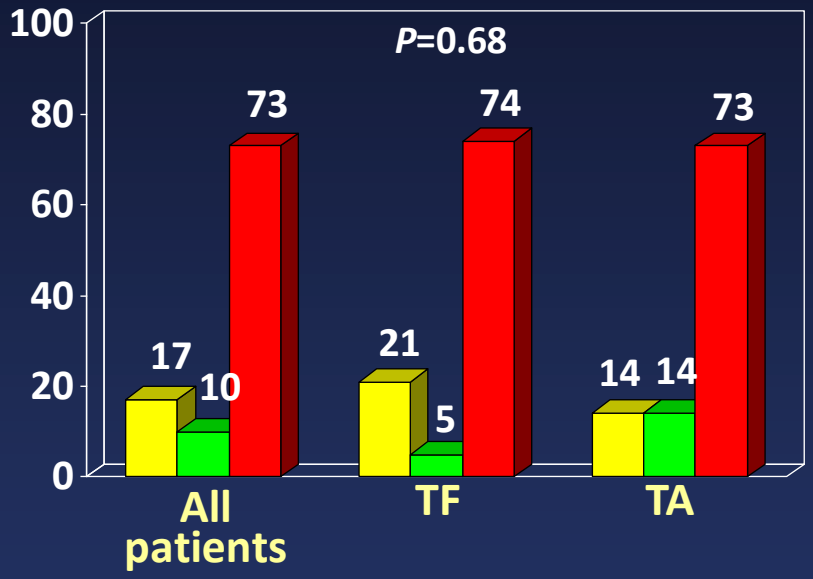


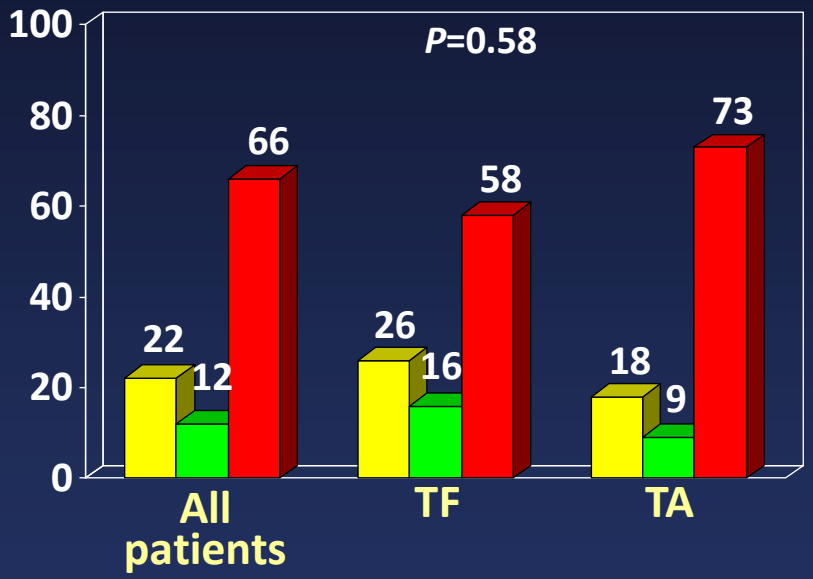
Patients with single/multiple lesions (%)



DW-MRI Results Post-TAVI

Lesion location, patients (%)



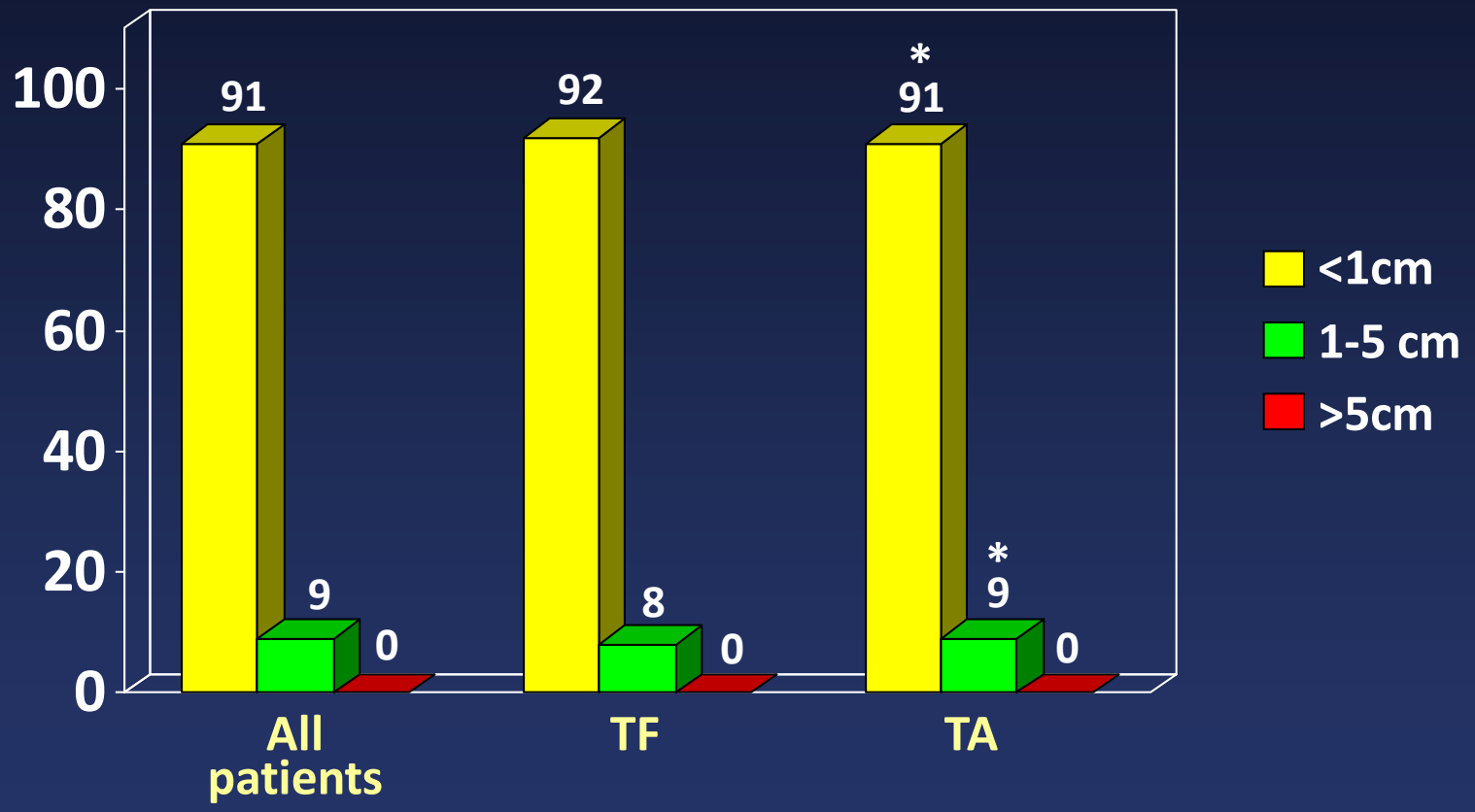


- Right hemisphere
- Left hemisphere
- Bilateral lesions

- Anterior circulation territory
- Posterior circulation territory
- Anterior and posterior circulation territories

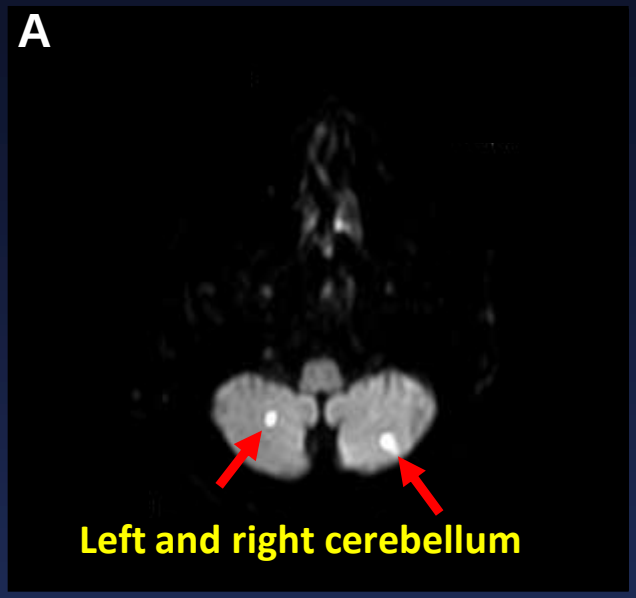
DW-MRI Results Post-TAVI

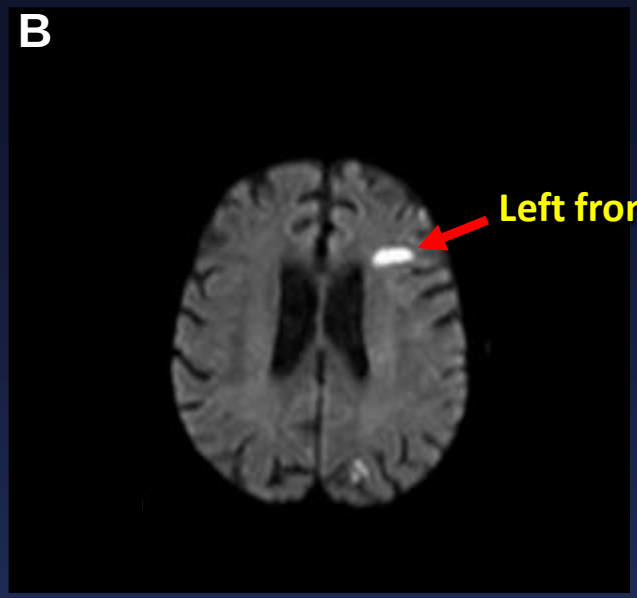
Lesion size

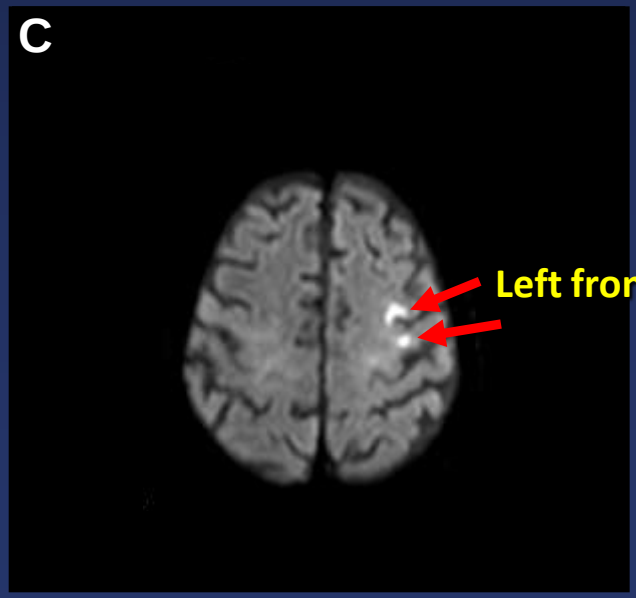


* *P*=1.00 vs. TF

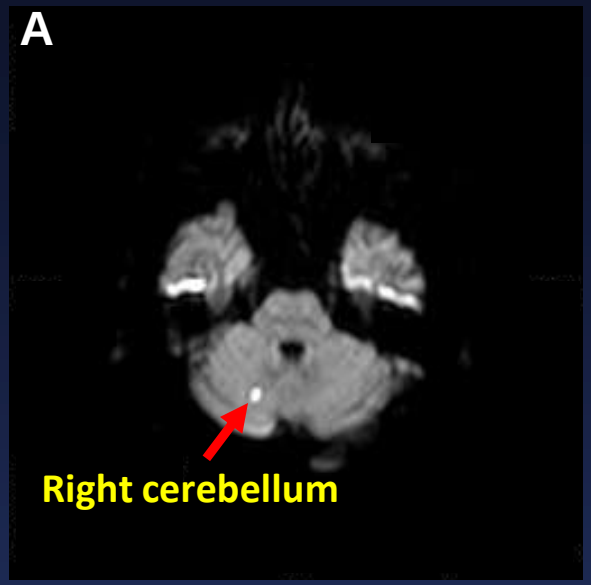
DW-MRI Images Following TA-TAVI

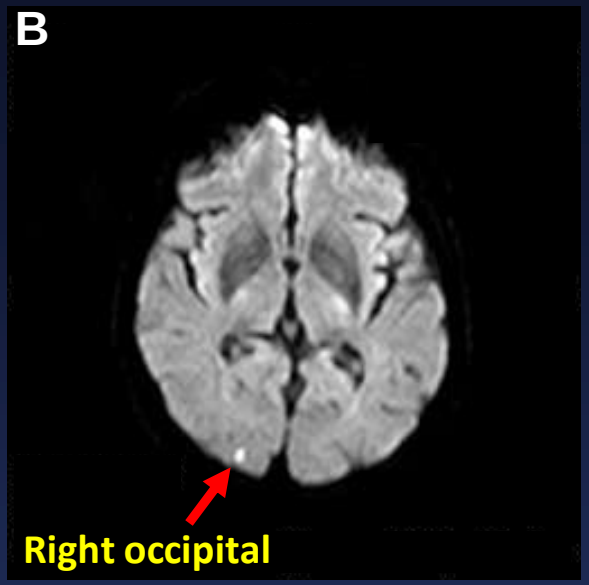


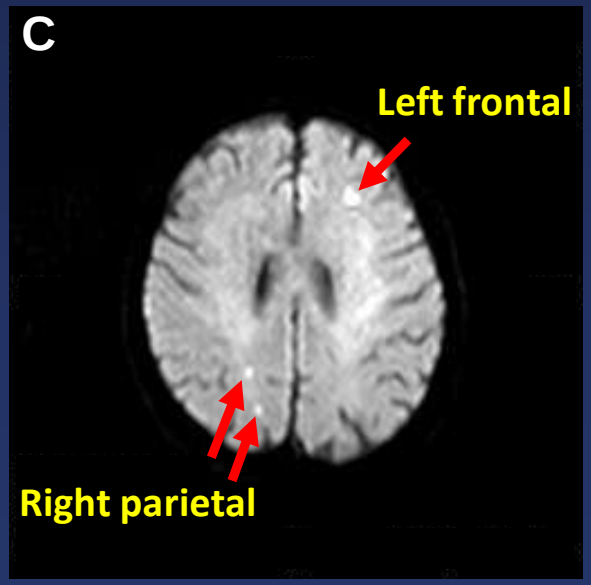


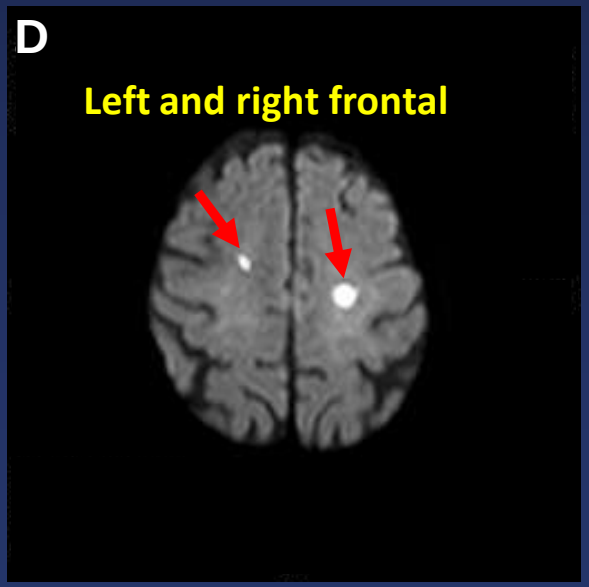


DW-MRI Images Following TF-TAVI









Baseline Characteristics According to the Presence or Absence of New Cerebral Lesions Following TAVI

	New cerebral lesions		
Variables	Yes (n=41)	No (n=19)	P value
Age (years)	83±8	82±6	0.79
Male sex (n,%)	24 (59)	6 (32)	0.09
Diabetes (n,%)	11 (27)	4 (21)	0.75
Dyslipidemia (n, %)	31 (76)	13 (68)	0.55
Hypertension (n,%)	32 (78)	13 (68)	0.55
Chronic atrial fibrillation (n,%)	10 (24)	4 (21)	1.00
Coronary artery disease (n,%)	33 (80)	11 (58)	0.11
Prior stroke (n,%)	7 (17)	2 (11)	0.71
Pheripheral vascular disease	14 (34)	5 (26)	0.77
Carotid stenosis (n,%)	3 (7)	3 (16)	0.37
STS-PROM score (%)	8.1±5.2	6.9±2.9	0.27
Logistic EuroSCORE	19.5±14.2	17.5±9.5	0.59

Baseline Characteristics According to the Presence or Absence of New Cerebral Lesions Following TAVI

Variables	New cerebral lesions		
	Yes (n=41)	No (n=19)	P value
Echocardiographic variables			
Mean aortic gradient (mmHg)	44.8±19.3	38.6±9.5	0.12
Aortic valve area (cm^2)	0.63±0.19	0.65±0.12	0.55
LVEF (%)	54.5±12.1	56.3±15.9	0.65
LVEF<40%)	8 (20)	2 (11)	0.48
Aortic annulus diameter (TEE, mm)	22±2	21±2	0.66
Aortic plaques≥4mm (ascending aorta/arch,(n,%)	10 (24)	7 (37)	0.53
Computed tomography			
Aortic valve leaflet calcium volume (computed tomography) (mm^3), median (25^{th}-75^{th})	2340 (1300-4140)	1830 (1460-3430)	0.88

Procedural Characteristics According to the Presence or Absence of New Cerebral Lesions Following TAVI

	New cerebral lesions		
Variables	**Yes (n=41)**	**No (n=19)**	**P value**
Valve diameter (mm)			
23	18 (44)	10 (53)	0.78
26	22 (53)	9 (47)	
Ratio aortic annulus/valve diameter	0.83±0.21	0.97±0.04	0.23
Rapid pacing runs	5±2	5±2	0.29
Approach			
Transfemoral (n,%)	19 (46)	10 (53)	0.78
Transapical (n,%)	22 (54)	9 (47)	
Successful procedure (n,%)	40 (98)	19 (100)	1.00
Procedure duration , median (25^{th}-75^{th})	82 (70-124)	96 (65-180)	0.27
Procedural complications (n,%)			
Valve embolization	0	0	-
Valve malposition	1 (2)	0	1.00
Need for a second valve	2 (5)	0	1.00
Need hemodynamic support	1 (2)	1 (5)	0.54
Major access site complications	2 (5)	3 (16)	0.31
Life threatening arrythmias	2 (5)	0	1.00

Neurological and Cognitive Test Results

Variables	Baseline	Post-TAVI	P value
NIHSS (median, min-max)			
All patients	0 (0-8)	0 (0-8)	1.00
Transfemoral*	0 (0-8)	0 (0-8)	1.00
Transapical*	0 (0-3)	0 (0-3)	1.00
MMSE (median, min-max)			
All patients	28 (17-30)	28 (16-30)	0.136
Transfemoral	25 (17-30)	24 (16-29)	0.774
Transapical	29 (26-30)	28 (22-30)	0.144

*2 patients (1 patient in each group) had a clinically apparent stroke within the 24 hours following TAVI

Conclusions

- TAVI was associated with a high rate (68%) of new silent cerebral ischemic lesions as evaluated by DW-MRI, with no differences between the TF (66%) and TA (71%) approaches

- Most patients had multiple cerebral lesions of small size, distributed in the 2 cerebral hemispheres and vascular territories

- No clinical, echocardiographic, computed tomography or procedural factors were found to be predictors of new cerebral ischemic lesions

Conclusions

- The occurrence of new cerebral ischemic lesions was not associated with an impairment of neurological or cognitive functions

- These results provide important insight into the mechanisms of cerebral embolism associated with TAVI and support the need for further research to both reduce the incidence of cerebral embolism during these procedures and better determine their clinical relevance