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20’

Cerebrovascular events in femoral TAVI

Flavio L. Ribichini
Universidad de Verona
Italia

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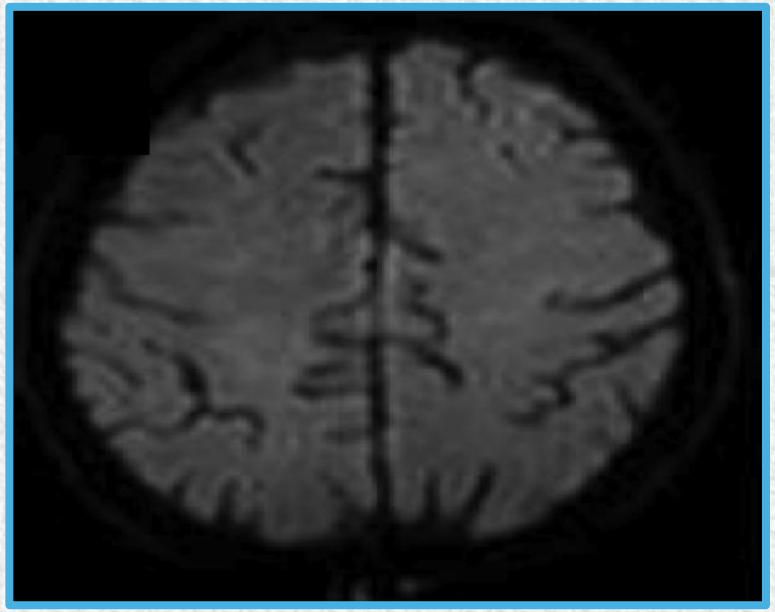
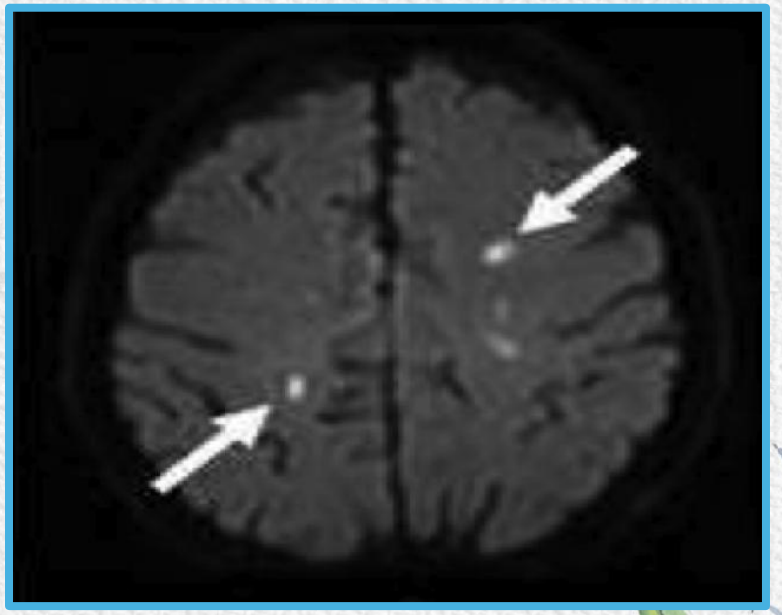
SILENT CEREBRAL EMBOLIC EVENTS ARE COMMON

New DW-MRI lesions post TAVI





DW-MRI: sensitivity 94%; specificity 97% for detecting stroke considered procedure of choice to detect acute neurologic deficits

NEUROCOGNITIVE DECLINE AND NEW LESIONS

- Pre-existing and new lesions on DW-MRI after catheterization is related to cognitive decline

- Patients with new ischemic lesions post CABG (20%) had a larger neurocognitive decline than the patients with stable MRI images

Lund et al, Ann Thorac Surgery 2005 - Restrepo et al, Stroke 2002

NEUROCOGNITIVE DECLINE AND NEW LESIONS

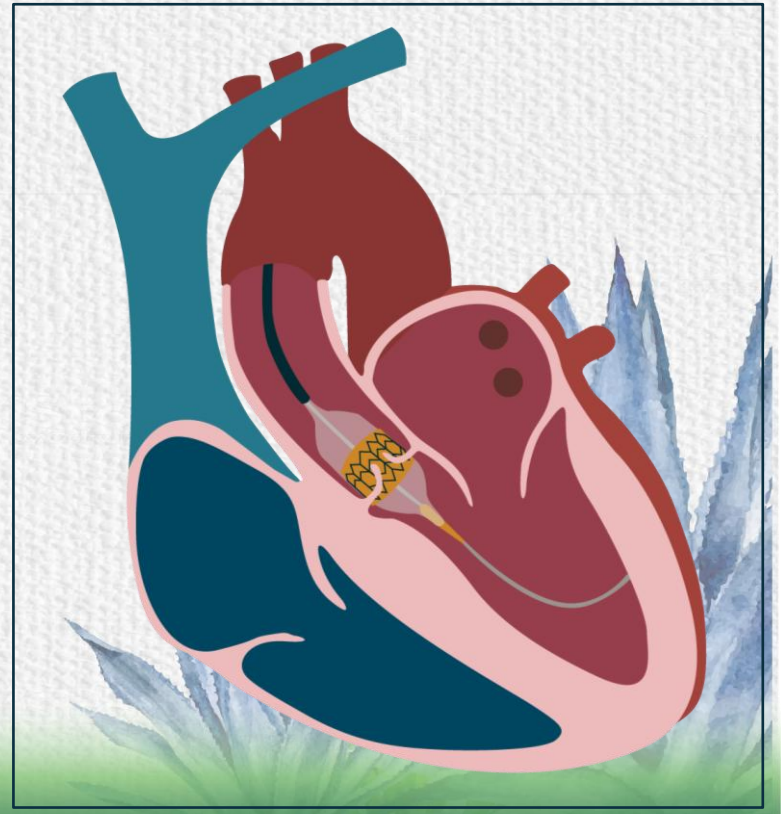
- Pre-e… …after cathe… …ine
- Patie… …ABG (20%)… …than the p…

The link between DWMRI lesions and decline in cognitive function has yet to be established in the TAVI cohort

Lund et al, Ann Thorac Surgery 2005 - Restrepo et al, Stroke 2002

BACKGROUND

Technological advancements, refinements in techniques and increased operator experience have reduce **periprocedural strokes** (within 30 days) to **approximately 2%** of patients undergoing TAVI.



- Carroll J.D., et al. STS-ACC TVT Registry (*Ann Thorac Surg. 2021*). 72.991 included in 2019. 30-days strokes: 1.090 patients **(2.3%).**

- Levi a., et al. The ASTRO-TAVI Study Group (*J Am Coll Cardiol Intv 2022*). 16.615 patients included between 2006 and 2021. 30-days stroke: 387 patients **(2.3%).**

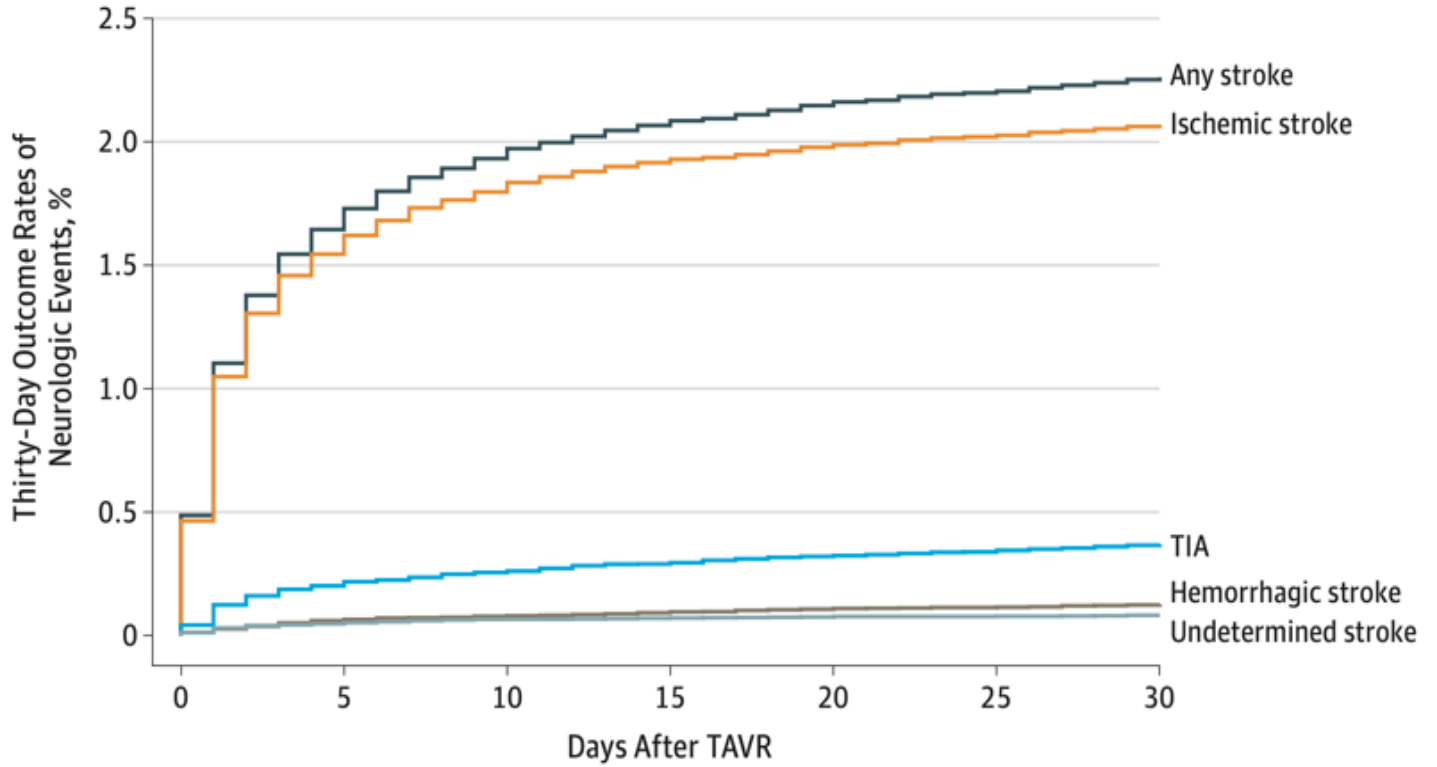
Huded C.P., et al. *JAMA.* 2019

STS-ACC TVT Registry.

101.430 patients included between 2011 and 2017.

30-days stroke of any kind: 2290 patients **(2.3%)**

Figure 1. Neurologic Events Within 30 Days of Transcatheter Aortic Valve Replacement



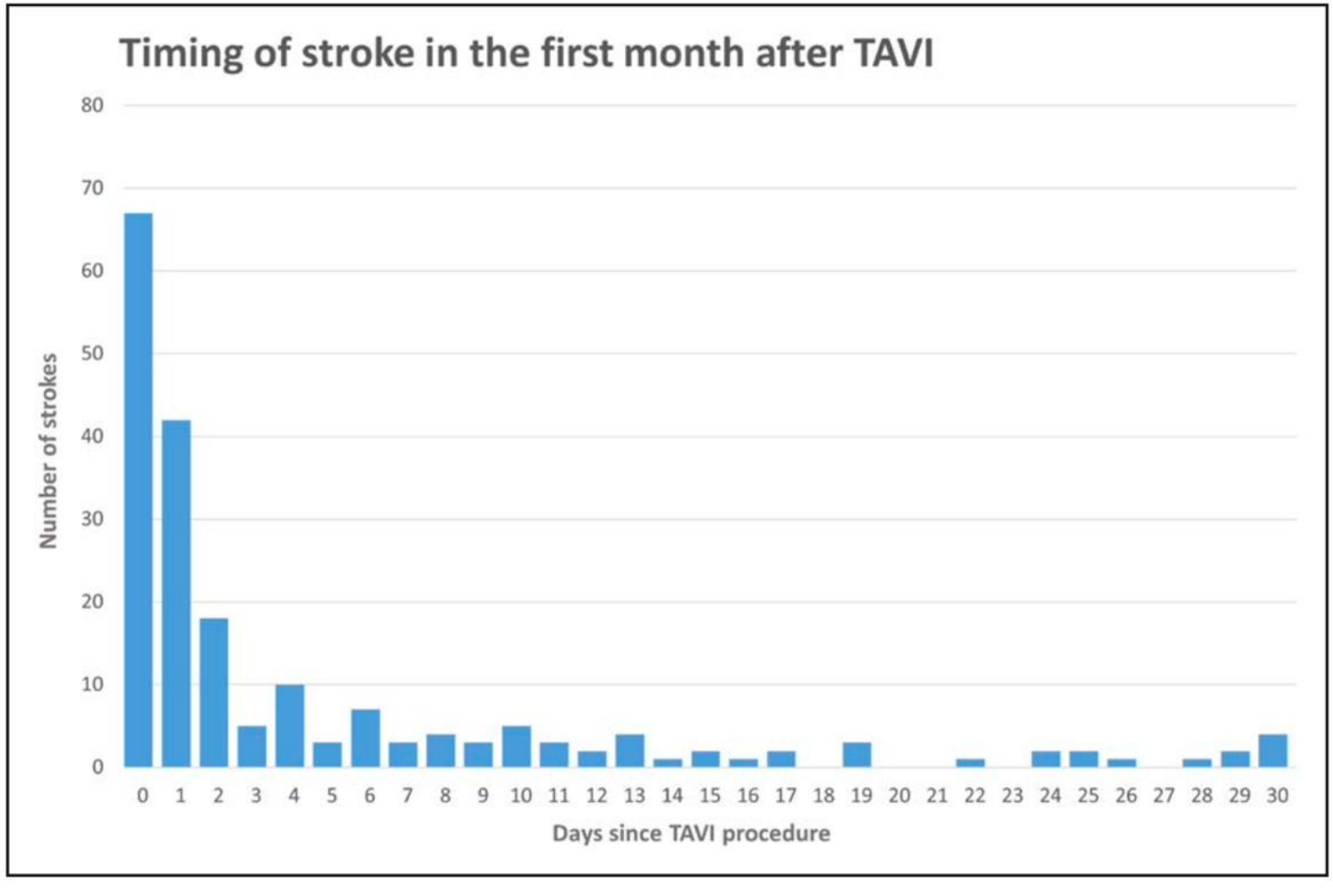
Vlastra W, et al.

Circ Cardiovasc Interv. 2019

The CENTER-Collaboration

10 982 patients included between 2007 and 2018

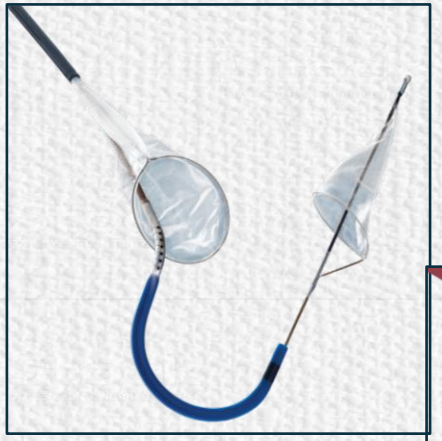
30-days stroke: 261 patients **(2.4%).**

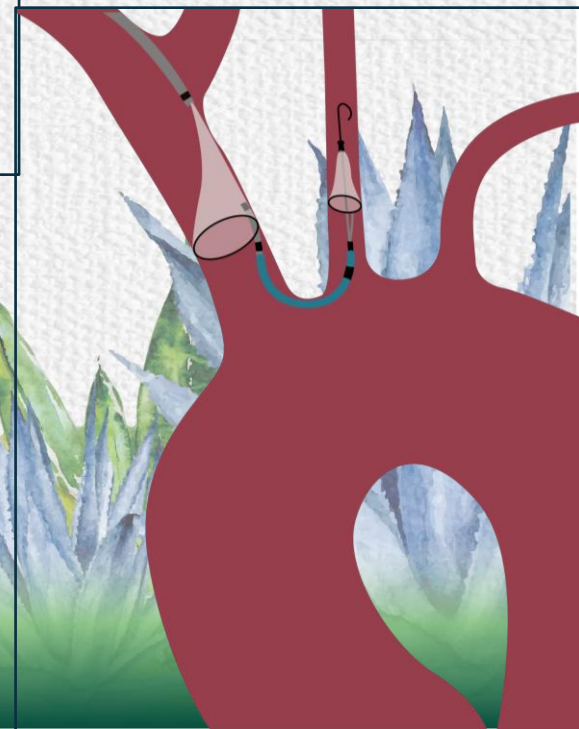


RATIONALE

The **SENTINEL™ Cerebral Protection System (CPS)** (Boston Scientific) is the most widespread cerebral embolic protection (CEP) device used to mitigate the risk of embolization of vascular or heart debris during TAVI.

- Dual filter-based intra-luminal CEP device 6-Fr sheath compatible.
- Right radial or brachial artery access over a 0.014-inch guidewire.
- Proximal filter positioned in the brachiocephalic trunk, the second filter in the left common carotid artery.
- It covers all brain areas supplied by 3 out of 4 arteries (excluding left vertebral artery).

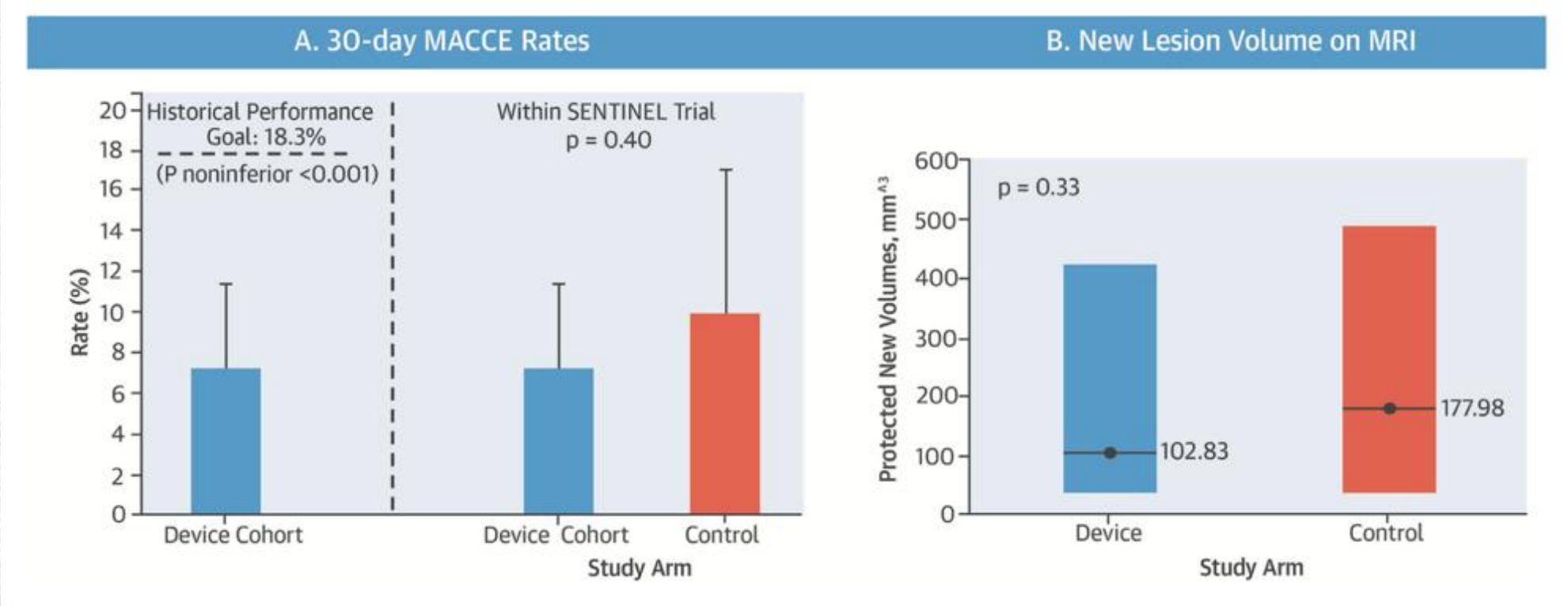




The SENTINEL trial

Kapadia S. R., et al. *J Am Coll Cardiol.* 2017

- 363 patients undergoing TAVR to a safety arm (n=123), device imaging (n=121), and control imaging (n=119).
- Primary safety endpoint: MACCE at 30 days.
- Primary efficacy endpoint: reduction in new lesion volume in protected brain territories on MRI at 2 to 7 days.



Strokes at 30 days were 9.1% in control subjects and 5.6% in patients with devices (p=0.25).

REGISTRIES

Megaly M., et al. Ischemic Stroke With Cerebral Protection System During Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol Intv.* 2020

- 36.220 patients included. After propensity score matching: **525 CEP group vs. 1.050 Control group.**
- Ischemic stroke during the index hospitalization: the risk was lower with CEP (1% vs. 3.8%, **p=0.003**).

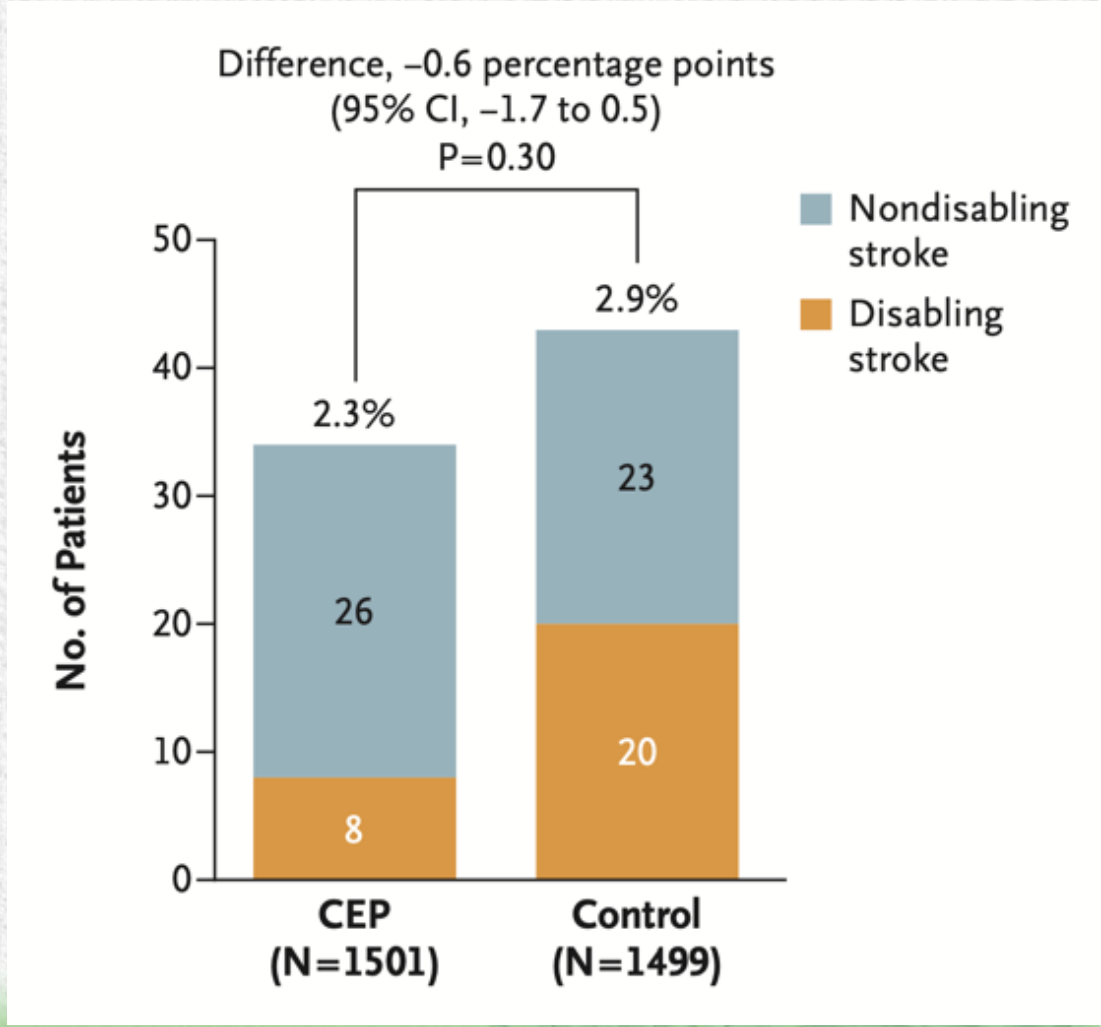
Butala N. M., et al. Cerebral Embolic Protection and Outcomes of Transcatheter Aortic Valve Replacement. Results from the TVT Registry. *Circulation.* 2021

- 123.186 patients included **(12.409 CEP group vs. 110.777 Control group)**
- Primary unadjusted analysis: no association between CEP use and in-hospital stroke (1.3% vs. 1.5%, p=0.083)
- Secondary analysis (propensity score–based model): CEP use was associated with lower in-hospital stroke (1.3% vs. 1.58%, **p=0.018**).

The PROTECTED TAVR trial

Kapadia S. R., et al. *N Engl J Med.* 2022

- 3.000 patients underwent TAVR: 1.501 in the CEP group vs. 1499 in the Control group.
- Primary endpoint (clinical stroke within 72 hours after TAVR): 2.3% vs. 2.9%, **p=0.30.**
- Additional prespecified endpoint (disabling stroke): 0.5% vs. 1.3%.
- **The number needed to treat (NNT) to prevent one additional disabling stroke would be 125**



The NEW ENGLAND JOURNAL of MEDICINE

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Routine Cerebral Embolic Protection during Transcatheter Aortic-Valve Implantation

Rajesh K. Kharbanda, Ph.D.,[1-3] James Kennedy, M.Sc.,[2] Zahra Jamal, M.Sc.,[4] Matthew Dodd, Ph.D.,[4] Richard Evans, B.A.,[4]

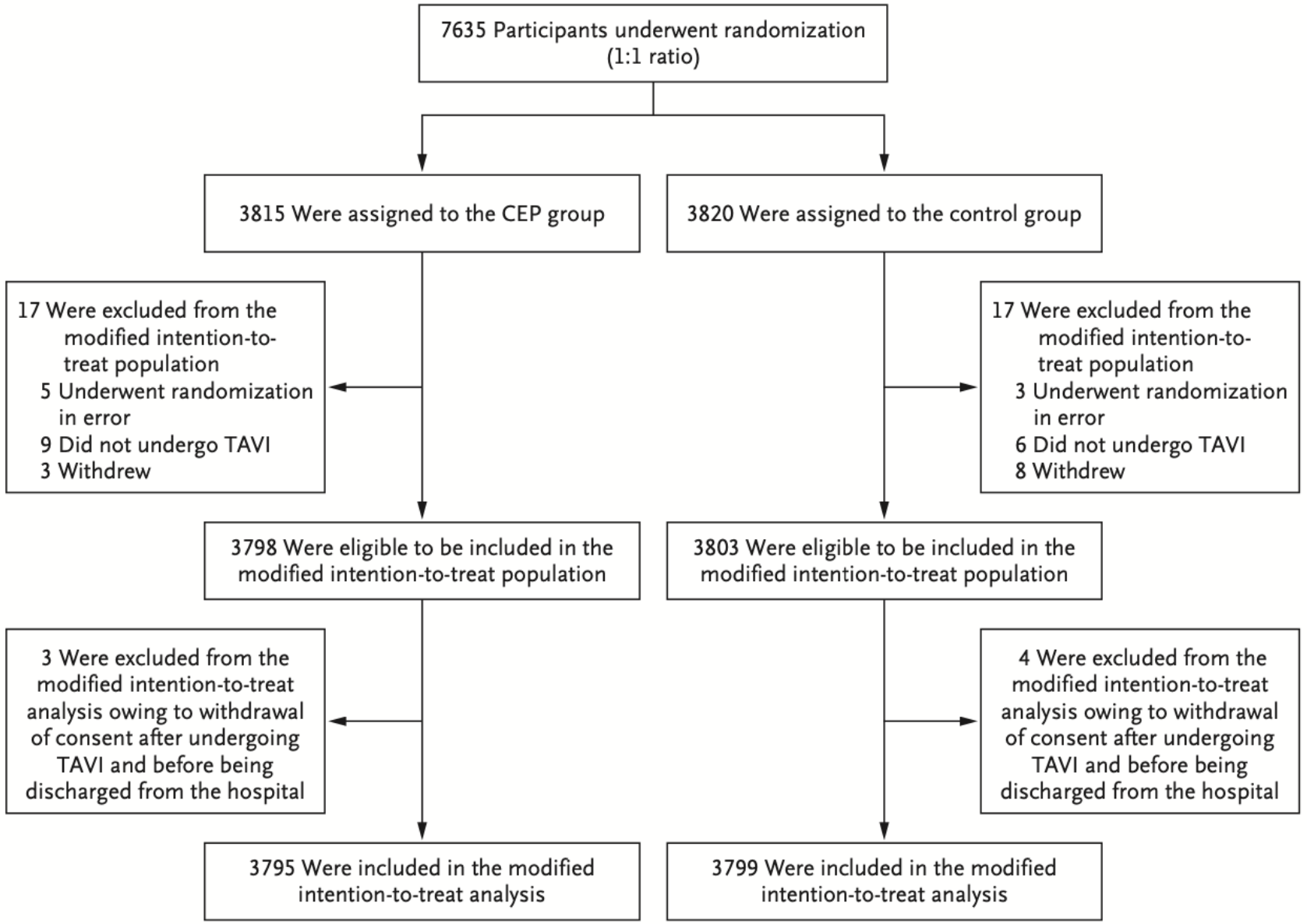
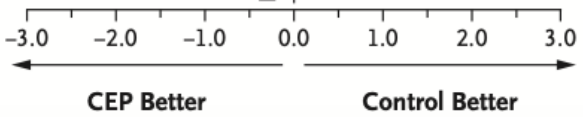


Figure 1. Randomization and Treatment.

Outcome	CEP Group (N=3798)	Control Group (N=3803)	Treatment Effect	
			Risk Difference (95% CI)†	Risk Ratio (95% CI)†
	no./total no. (%)		*percentage points*	
Primary outcome				
Stroke within 72 hr after TAVI or before discharge, if sooner	81/3795 (2.1)	82/3799 (2.2)	−0.02 (−0.68 to 0.63)‡	0.99 (0.73 to 1.34)‡
Ischemic stroke	80/3795 (2.1)	82/3799 (2.2)		
Hemorrhagic stroke	1/3795 (<0.1)	0/3799		
Secondary outcomes				
Disabling stroke within 6 to 8 wk after TAVI§¶	47/3795 (1.2)	53/3799 (1.4)	−0.2 (−0.7 to 0.4)	0.89 (0.60 to 1.31)
Ischemic stroke	47/3795 (1.2)	53/3799 (1.4)		
Hemorrhagic stroke	0/3795	0/3799		
Severe stroke within 72 hr after TAVI or before discharge, if sooner‖	18/3795 (0.5)	19/3799 (0.5)	0.0 (−0.3 to 0.3)	0.95 (0.50 to 1.80)
Ischemic stroke	18/3795 (0.5)	19/3799 (0.5)		
Hemorrhagic stroke	0/3795	0/3799		
Death within 72 hr after TAVI or before discharge, if sooner	29/3795 (0.8)	26/3799 (0.7)	0.1 (−0.3 to 0.5)	1.12 (0.66 to 1.89)
Death or stroke within 72 hr after TAVI or before discharge, if sooner	108/3795 (2.8)	104/3799 (2.7)	0.1 (−0.6 to 0.8)	1.04 (0.80 to 1.36)
Death	29/3795 (0.8)	26/3799 (0.7)		
Nonfatal stroke	79/3795 (2.1)	78/3799 (2.1)		
Death, stroke, or TIA within 72 hr after TAVI or before discharge, if sooner	126/3795 (3.3)	117/3799 (3.1)	0.2 (−0.6 to 1.0)	1.08 (0.84 to 1.38)
Death	29/3795 (0.8)	26/3799 (0.7)		
Nonfatal stroke	79/3795 (2.1)	78/3799 (2.1)		
TIA	18/3795 (0.5)	13/3799 (0.3)		

Subgroup	CEP	Control	Risk Difference (95% CI)
	no. of events/no. of participants (%)		*percentage points*
All participants	81/3795 (2.1)	82/3799 (2.2)	0.0 (–0.7 to 0.6)
Age			
<80 yr	28/1466 (1.9)	23/1452 (1.6)	0.3 (–0.6 to 1.3)
80 to <85 yr	26/1203 (2.2)	28/1238 (2.3)	–0.1 (–1.3 to 1.1)
≥85 yr	27/1126 (2.4)	31/1109 (2.8)	–0.4 (–1.7 to 0.9)
Sex			
Female	37/1484 (2.5)	45/1459 (3.1)	–0.6 (–1.8 to 0.6)
Male	44/2311 (1.9)	37/2340 (1.6)	0.3 (–0.4 to 1.1)
Race or ethnic group			
White	75/3545 (2.1)	75/3539 (2.1)	0.0 (–0.7 to 0.7)
Asian, Black, mixed, or other	3/60 (5.0)	2/61 (3.3)	1.7 (–5.4 to 8.8)
Native bicuspid valve			
Bicuspid	8/322 (2.5)	7/305 (2.3)	0.2 (–2.2 to 2.6)
Tricuspid	72/3388 (2.1)	74/3418 (2.2)	0.0 (–0.7 to 0.6)
EuroSCORE II			
Low: <4%	44/2124 (2.1)	39/2180 (1.8)	0.3 (–0.5 to 1.1)
Intermediate: 4 to 8%	15/554 (2.7)	18/529 (3.4)	–0.7 (–2.7 to 1.4)
High: >8%	3/215 (1.4)	8/210 (3.8)	–2.4 (–5.4 to 0.6)
Type of valve			
Self-expanding valve	42/1611 (2.6)	54/1614 (3.3)	–0.7 (–1.9 to 0.4)
Balloon-expanding valve	38/2166 (1.8)	28/2167 (1.3)	0.5 (–0.3 to 1.2)
Balloon dilation before valve implantation			
No	42/2074 (2.0)	33/2075 (1.6)	0.4 (–0.4 to 1.2)
Yes	39/1714 (2.3)	49/1718 (2.9)	–0.6 (–1.6 to 0.5)
Balloon dilation after valve implantation			
No	62/3123 (2.0)	62/3093 (2.0)	0.0 (–0.7 to 0.7)
Yes	19/662 (2.9)	19/693 (2.7)	0.1 (–1.6 to 1.9)
Aortic-valve calcification			
None, mild, or moderate	45/1945 (2.3)	40/1910 (2.1)	0.2 (–0.7 to 1.1)
Severe	36/1786 (2.0)	42/1806 (2.3)	–0.3 (–1.3 to 0.6)



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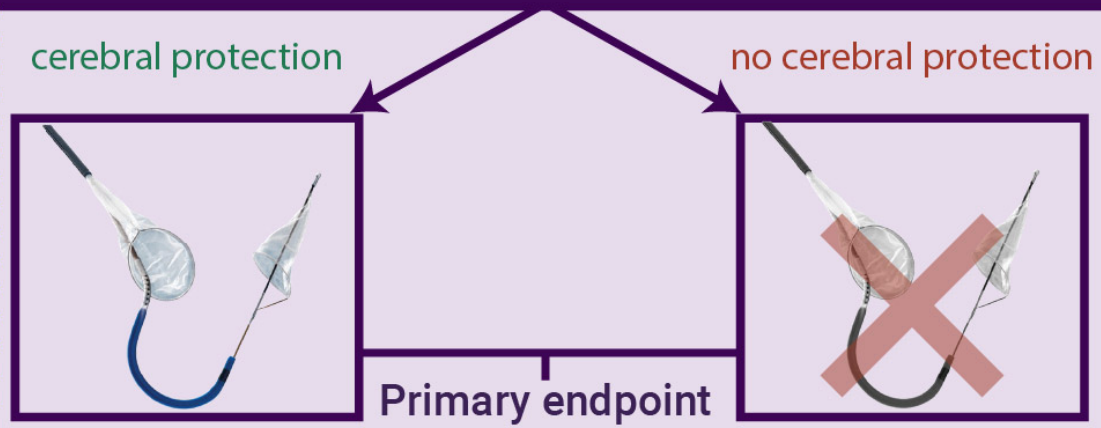
IPD meta-analysis of PROTECTED TAVR and BHF PROTECT-TAVI

R. Kharbanda et al.

10635 individual patients data from PROTECTED TAVR and BHF PROTECT-TAVI randomized to



Primary endpoint

Modified intention to treat analysis

Incidence of stroke 72h post TAVI or at hospital discharge

Cerebral protection during TAVI does not reduce the incidence of peri-procedural stroke

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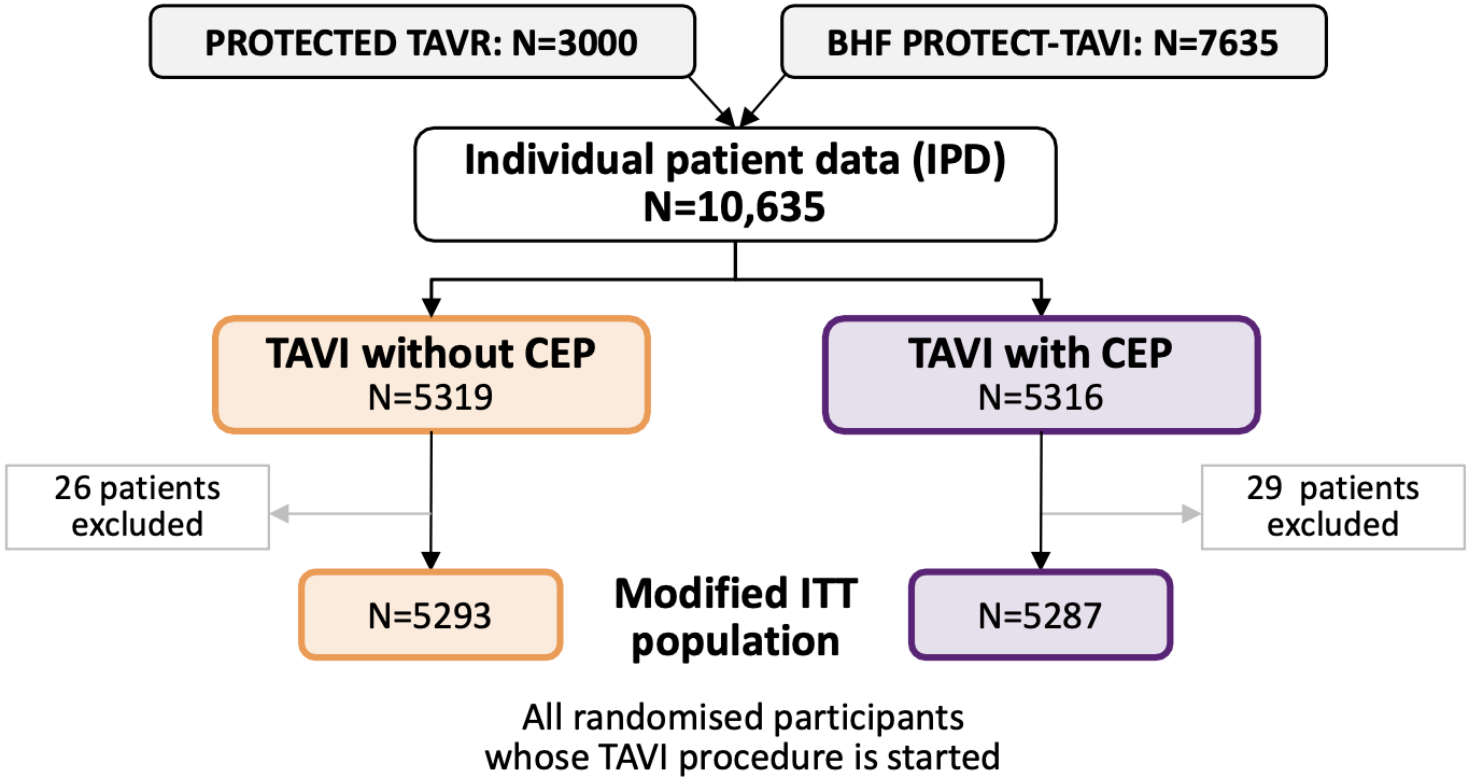
Prospective individual patient data (IDP) meta-analysis



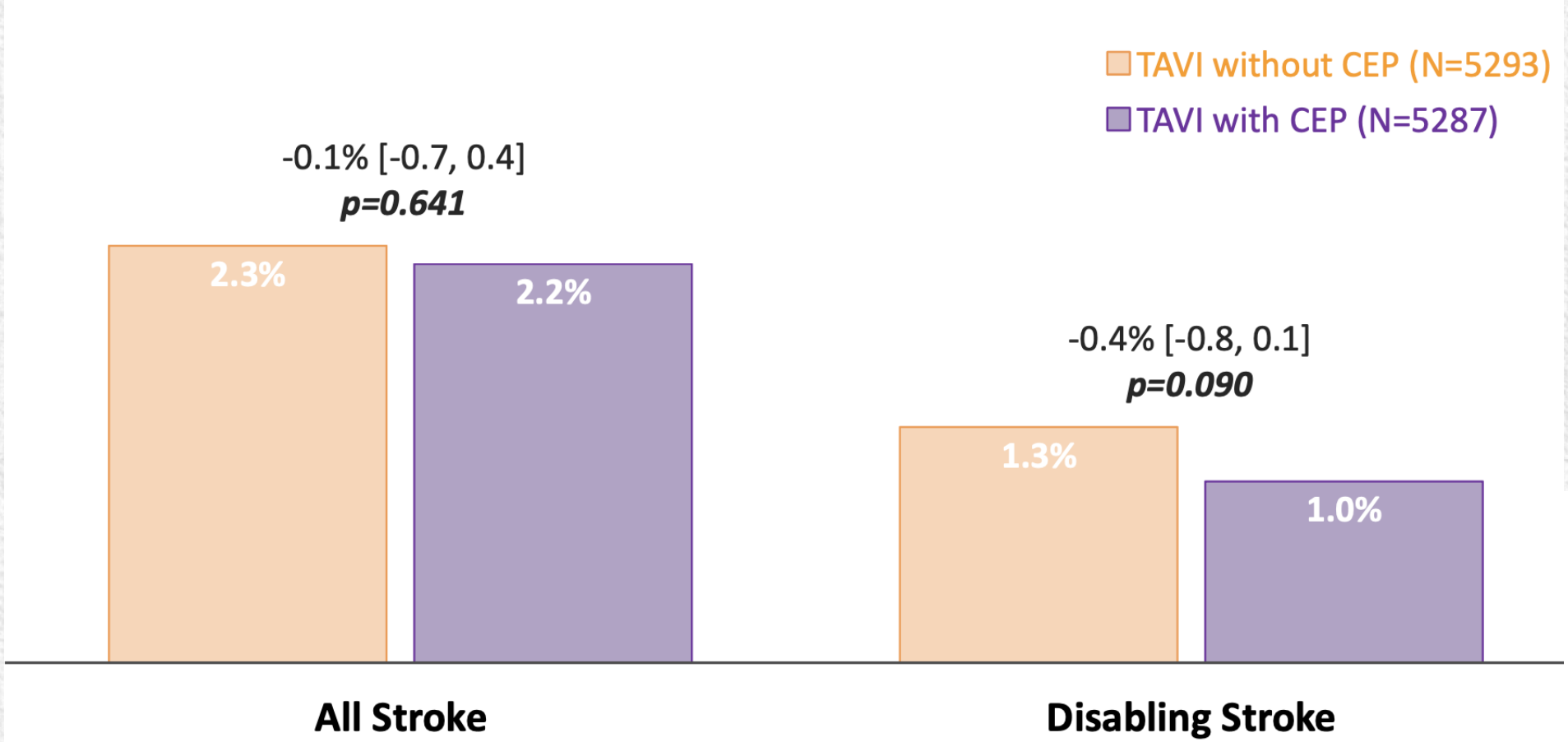
Primary analysis: Difference in incidence of stroke (72h post-TAVI or hospital discharge) between interventional (CEP) and control (no CEP) arms of the trials

Patients characteristics

Modified ITT population

	TAVI without CEP N=5293	TAVI with CEP N=5287
Mean Age	80.6±7.0	80.6±7.0
Sex	38.2% Female	39.9% Female
Surgical Risk	STS Score: 2.6% [1.7, 4.2] EuroScore II: 2.5% [1.6, 4.3]	STS Score: 2.7% [1.7, 4.1] EuroScore II: 2.6% [1.6, 4.4]
Native Valve Type	8.2% Bicuspid	8.8% Bicuspid
Medical History		
Coronary artery disease	40.6%	41.2%
Prior coronary revascularization	18.8%	17.8%
History of stroke	6.8%	6.3%
History of transient ischemic attacks	7.1%	7.6%
History of atrial fibrillation or flutter	33.5%	34.0%

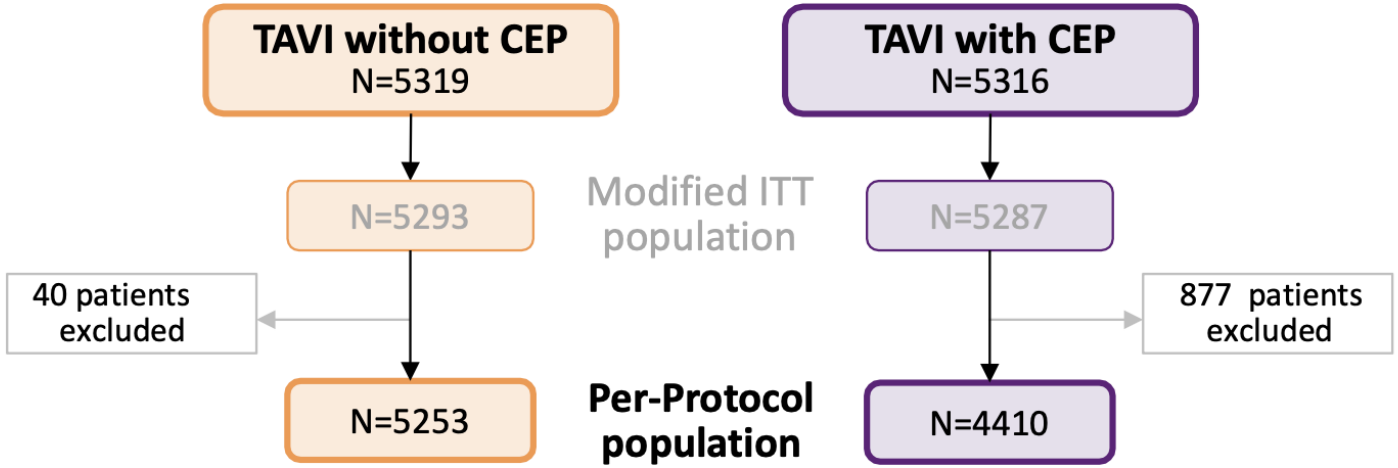
Stroke and disabling stroke at 72h post-TAVI or discharge



No evidence in modified ITT population that a routine strategy of CEP is effective in reducing overall stroke

Secondary anlyses

Is CEP effective when we account for non-adherence?



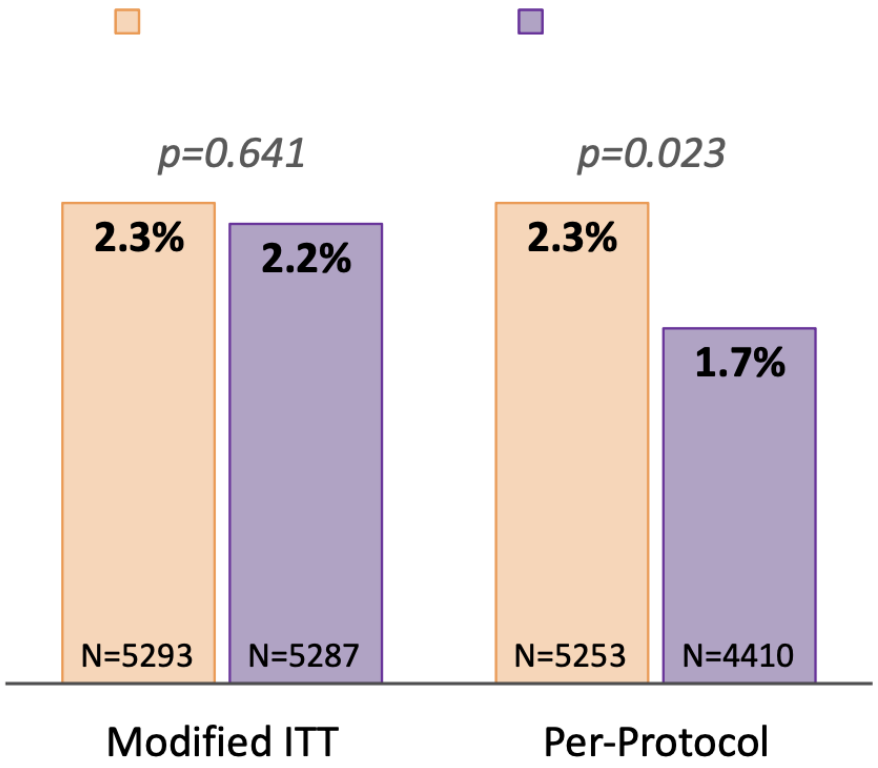
Secondary analyses: **Complier Average Causal Effect (CACE)**

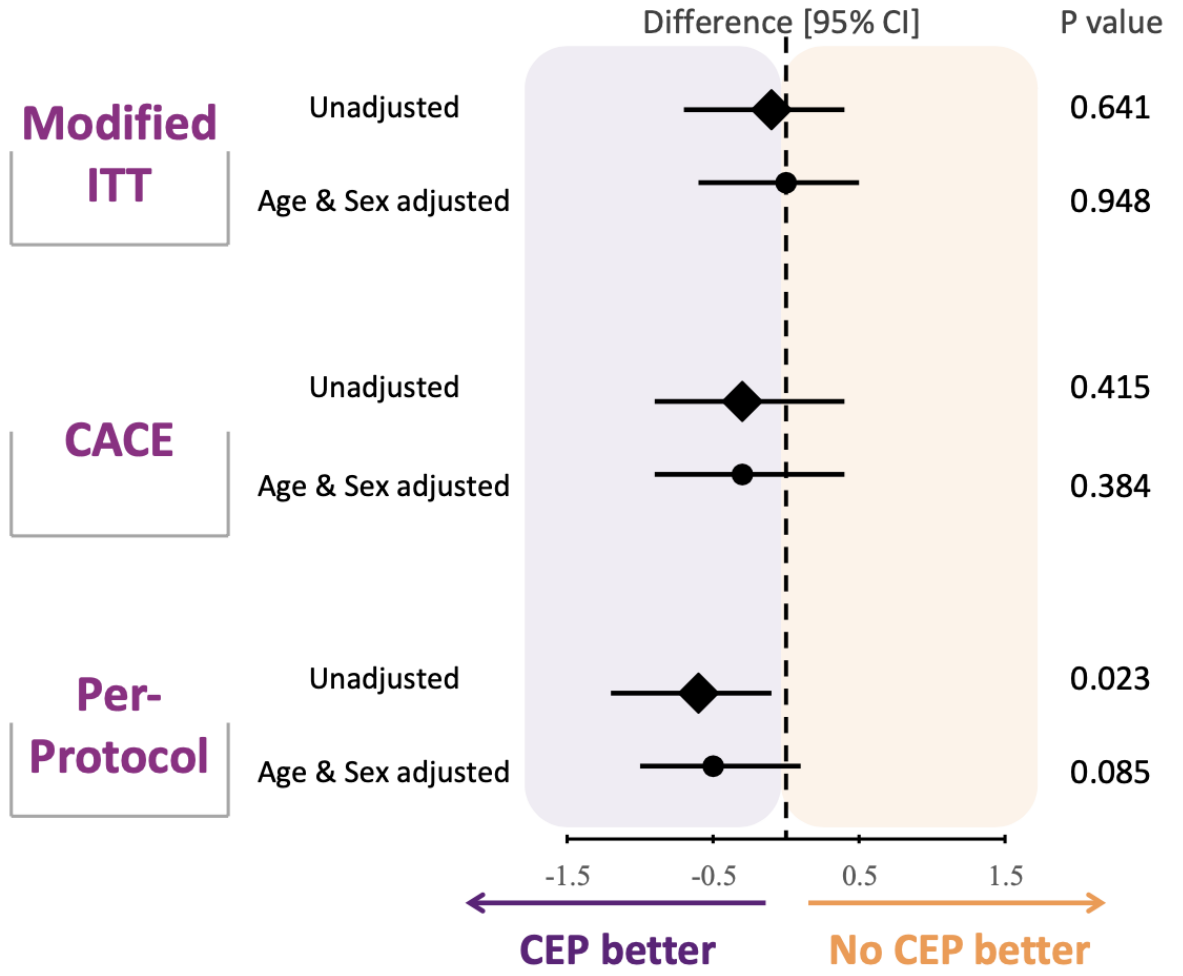
- Adjusts modified ITT estimate to account for dilution due to non-adherence

Per-Protocol

- Includes patients receiving randomized intervention as specified / intended
- 83.4% of patients had CEP with both filters successfully deployed

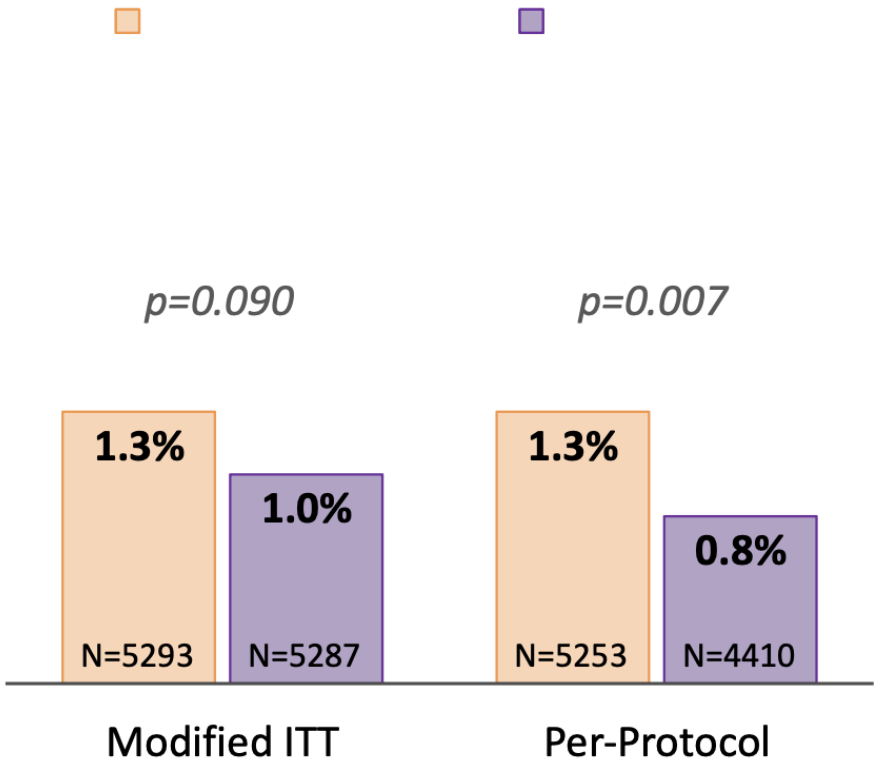
Secondary anlyses: all stroke

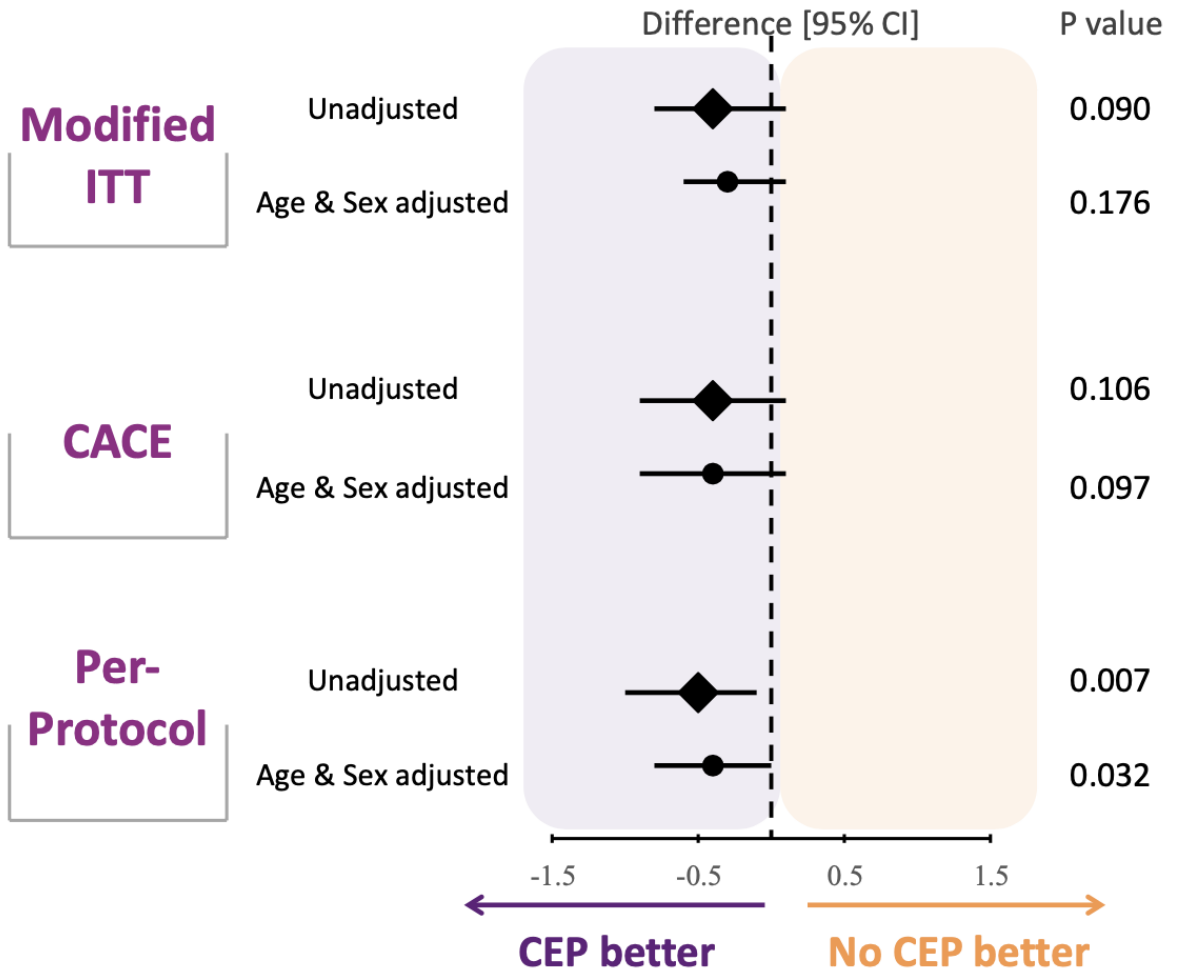




europcr.com

Secondary anlyses: disabling stroke





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Caveats of interpretation

- Complier Average Causal Effect (CACE) analysis
  - Preserves randomisation
  - Assumes no harm with unsuccessful filter deployment

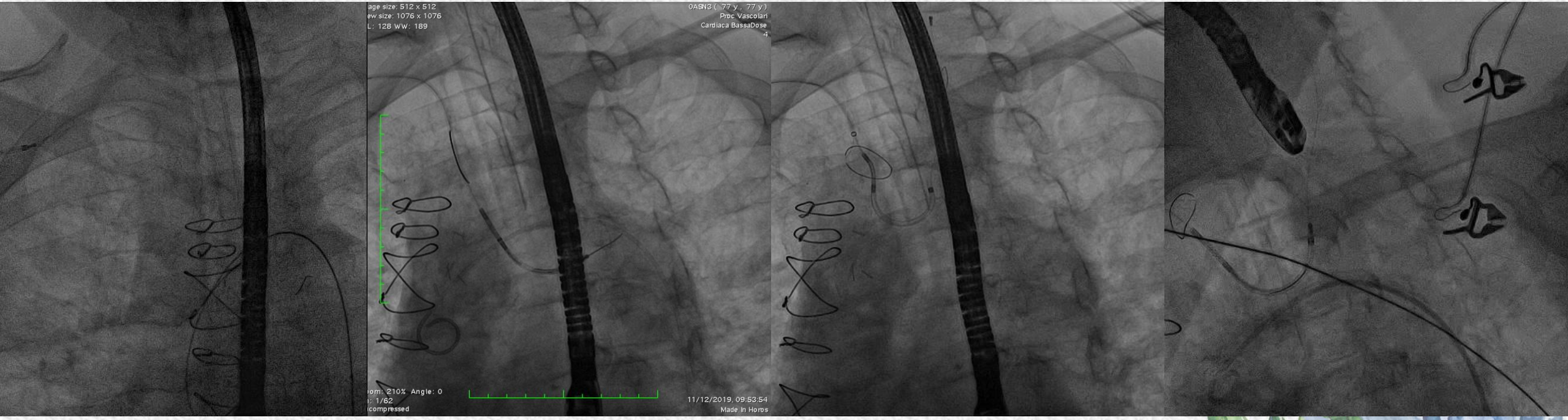
- Per-Protocol analysis
  - Limits population to patients with successful filter deployment
  - May introduce selection bias

Conclusions

- No reduction in periprocedural stroke with Sentinel CEP compared with control as a routine strategy

- In secondary analysis to account for non-adherence
  - No significant difference in stroke with CEP using CACE analysis
  - Per-Protocol analysis suggests that disabling stroke may be reduced in the CEP group

Cerebral protection system Sentinel™ positioned in both common carotid arteries from the right radial



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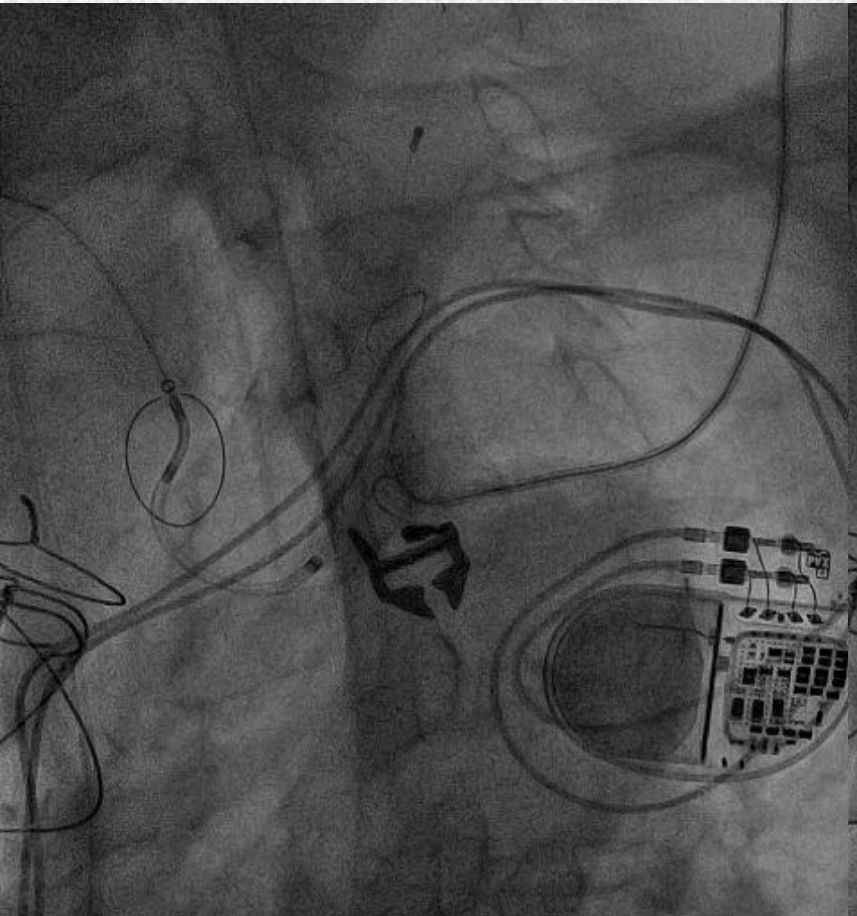
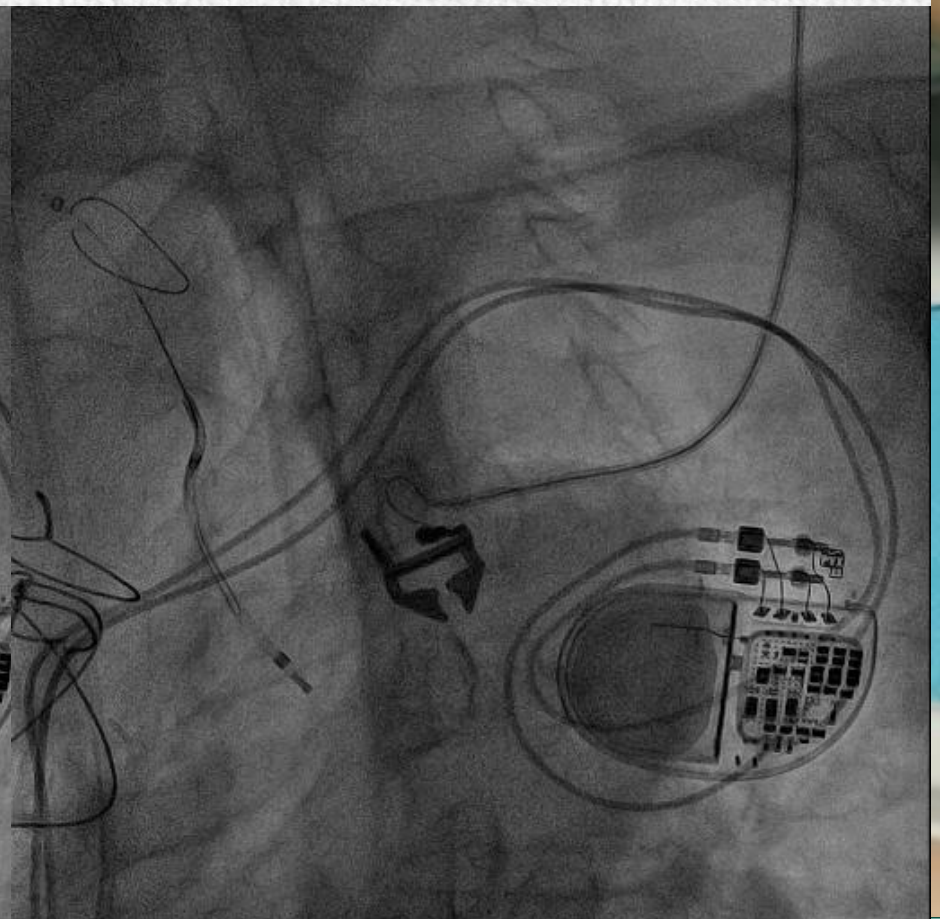
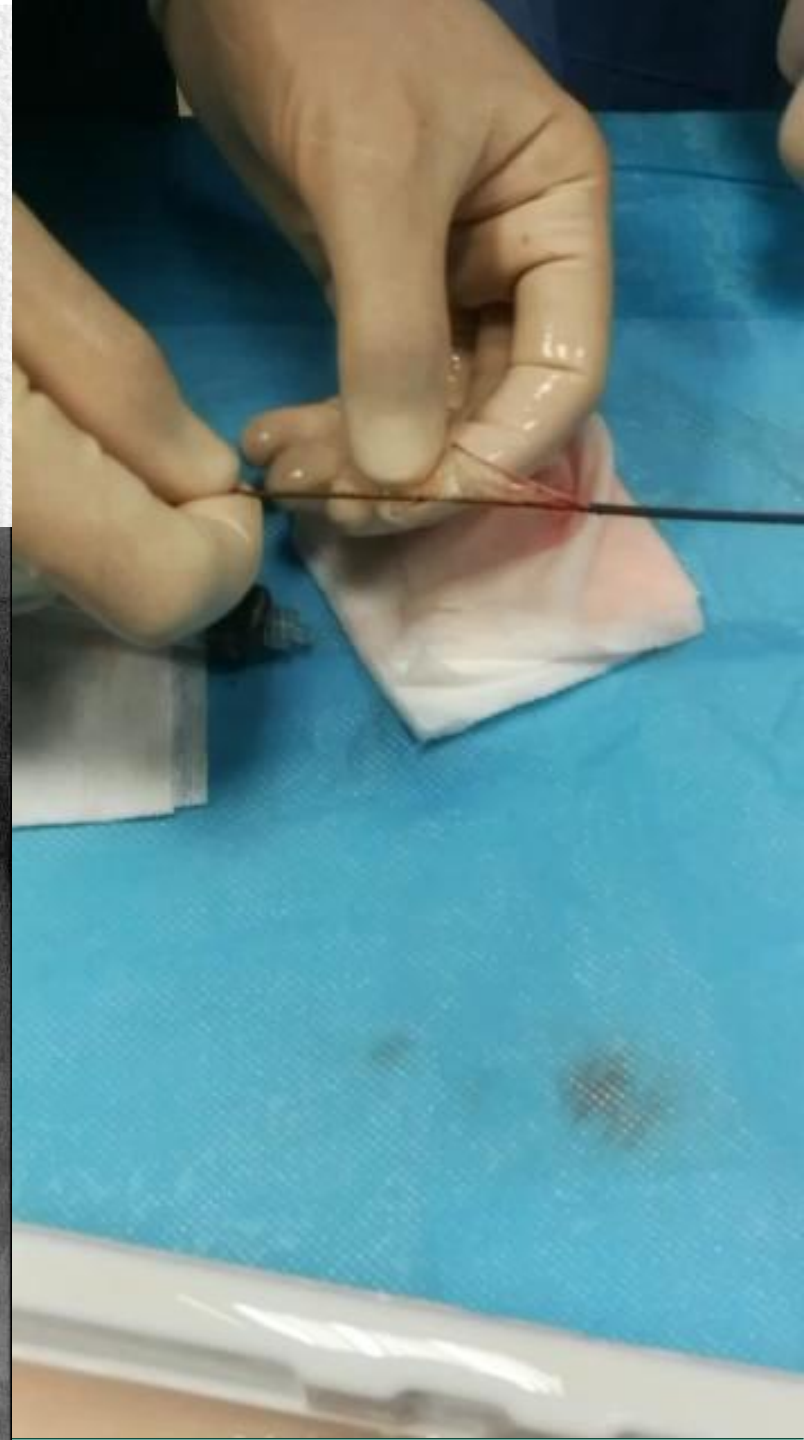
Removal of filter in LCCA

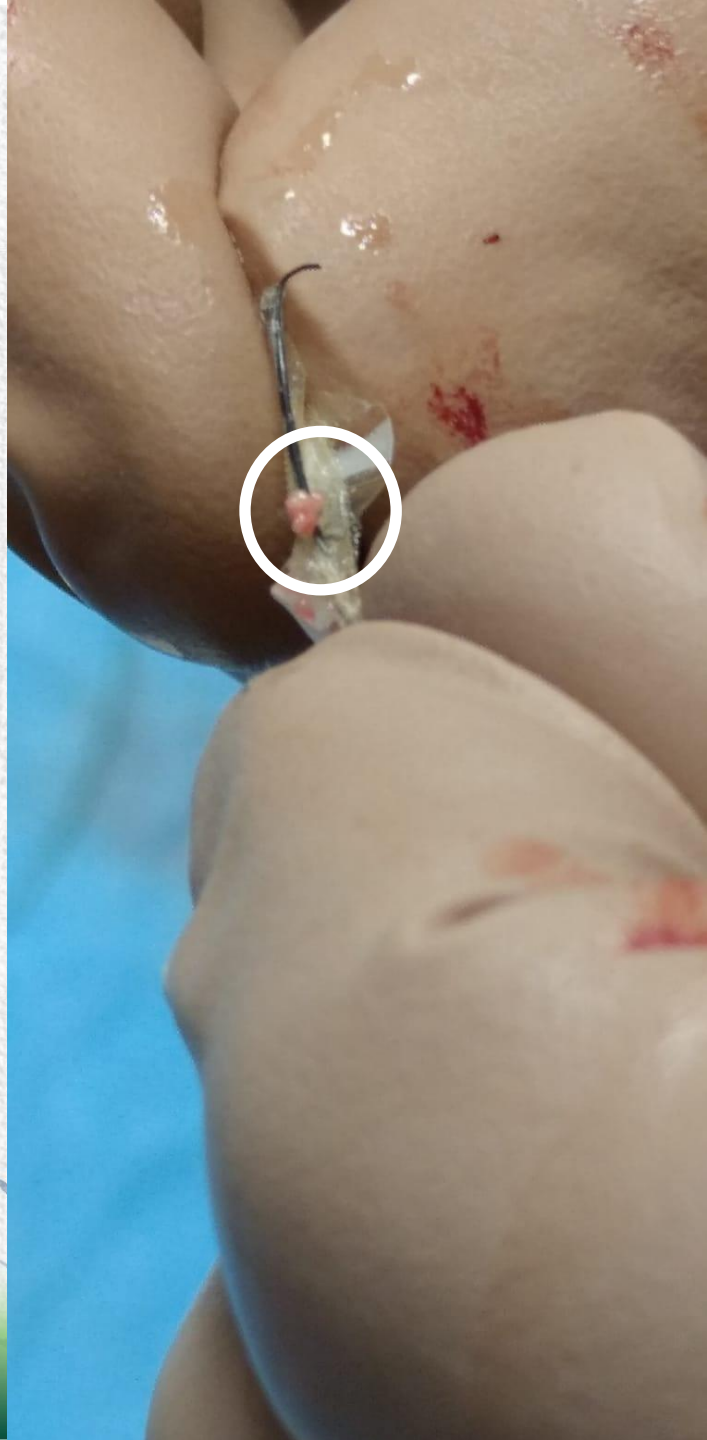


Removal of filter in RCCA



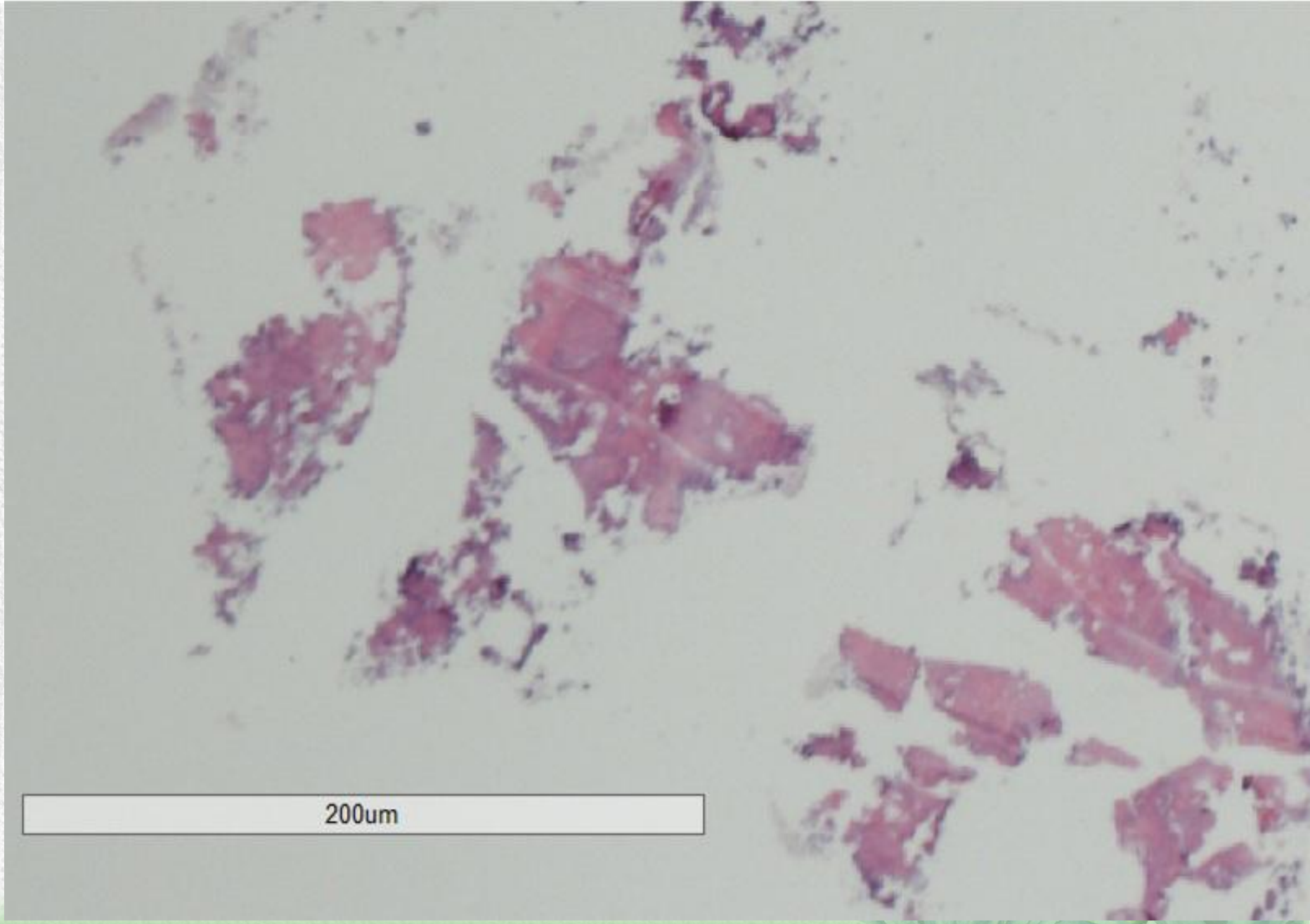


Embolization of lacerated bioprosthesis leaflet after BASILICA?



Histology:

acellular tissue confirms the origin from pericardial surgical valve

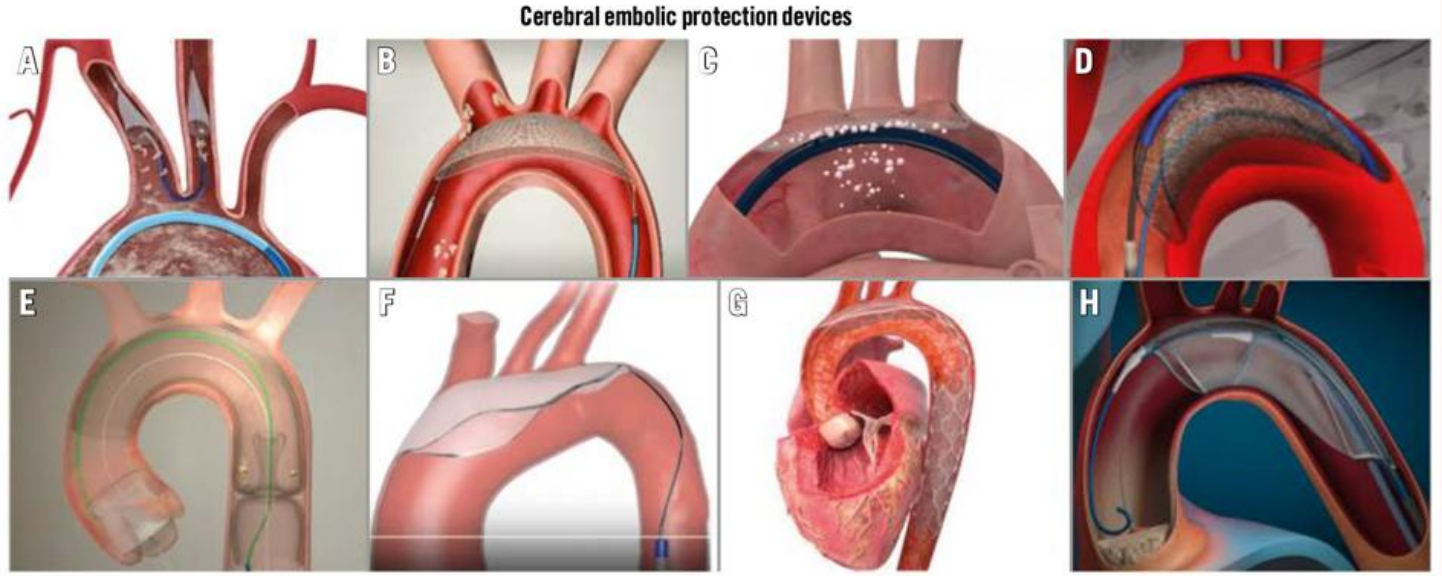


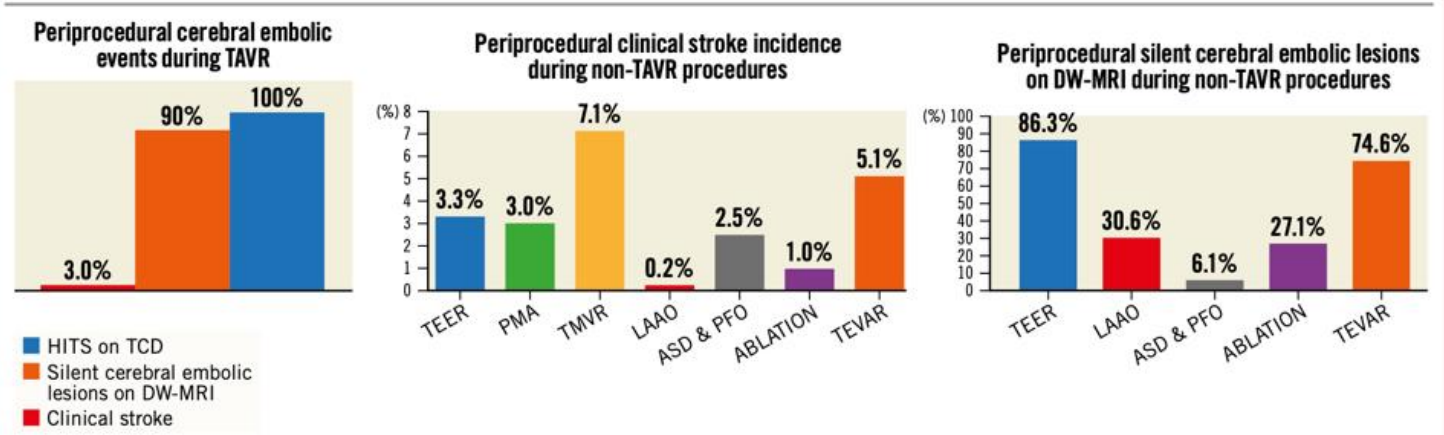
Other CEP devices are currently under development

Jimenez Diaz V. A., et al. Cerebral embolic protection during transcatheter heart interventions. State-of-the-Art. *EuroIntervention* 2023

EuroIntervention

CENTRAL **ILLUSTRATION** Cerebral embolic protection devices and data on TAVR and non-TAVR procedures.





A) SENTINEL; B) TriGUARD 3; C) ProtEmbo; D) Emblok; E) Emboliner; F) POINT-GUARD; G) CAPTIS; H) FLOWer
ASD: atrial septal defect; DW-MRI: diffusion-weighted magnetic resonance imaging; HITS: high-intensity transient signal; LAAO: left atrial appendage occlusion; PFO: patent foramen ovale; PMA: percutaneous mitral annuloplasty; TAVR: transcatheter aortic valve replacement; TCD: transcranial Doppler; TEER: transcatheter edge-to-edge repair; TEVAR: thoracic endovascular aortic repair; TMVR: transcatheter mitral valve replacement

- Identify TAVI stroke risk factors and develop a risk score

- Explore patient subgroups to identify those where CEP might be effective

Electro-surgery assisted procedures: BASILICA, Lampoon,

Mitral and Aortic VIV

Valve in MAC

Severe aortic arch atherosclerosis

BUT ROUTINE USE IS NOT INDICATED