



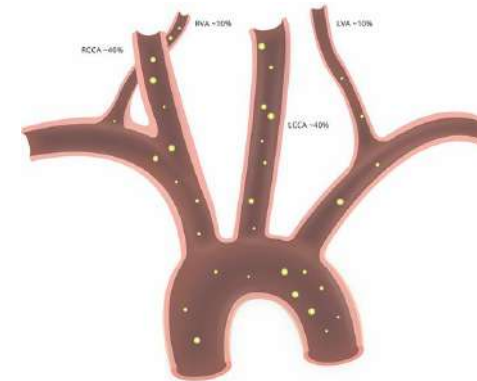
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Cerebral Embolic Protection Enough Evidence or A Matter of Faith



Alberto Rodrigues

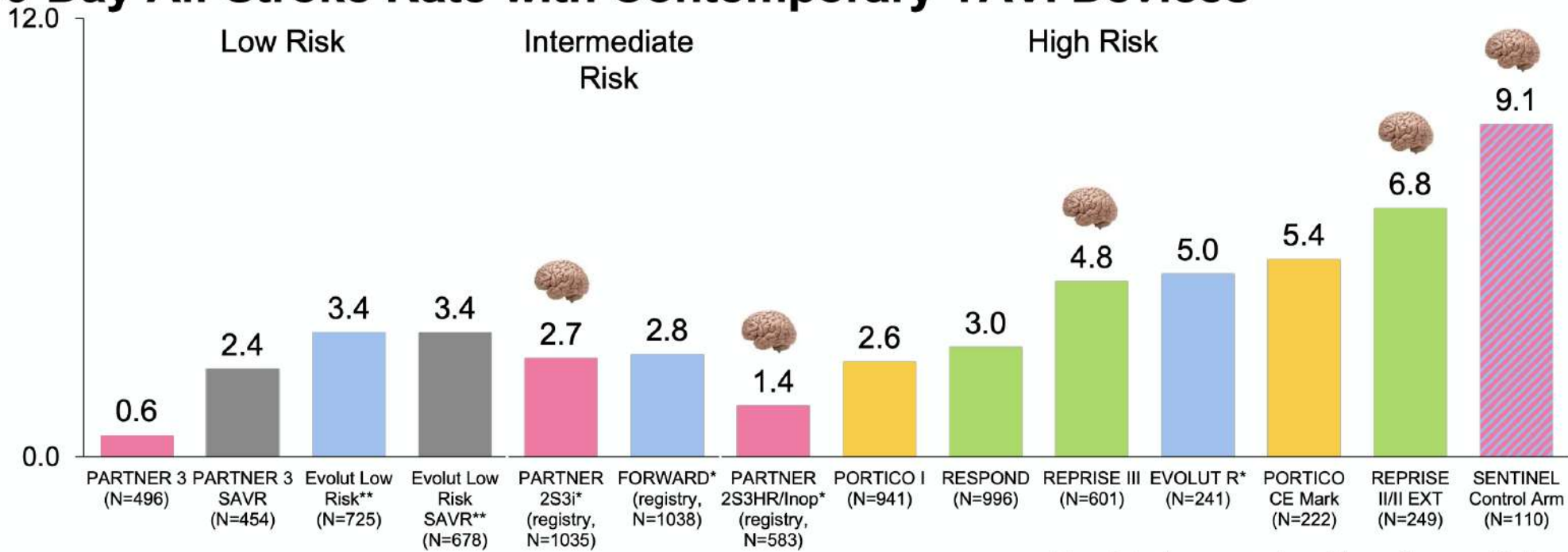


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Unidade de Diagnóstico e
Intervenção Cardiovascular

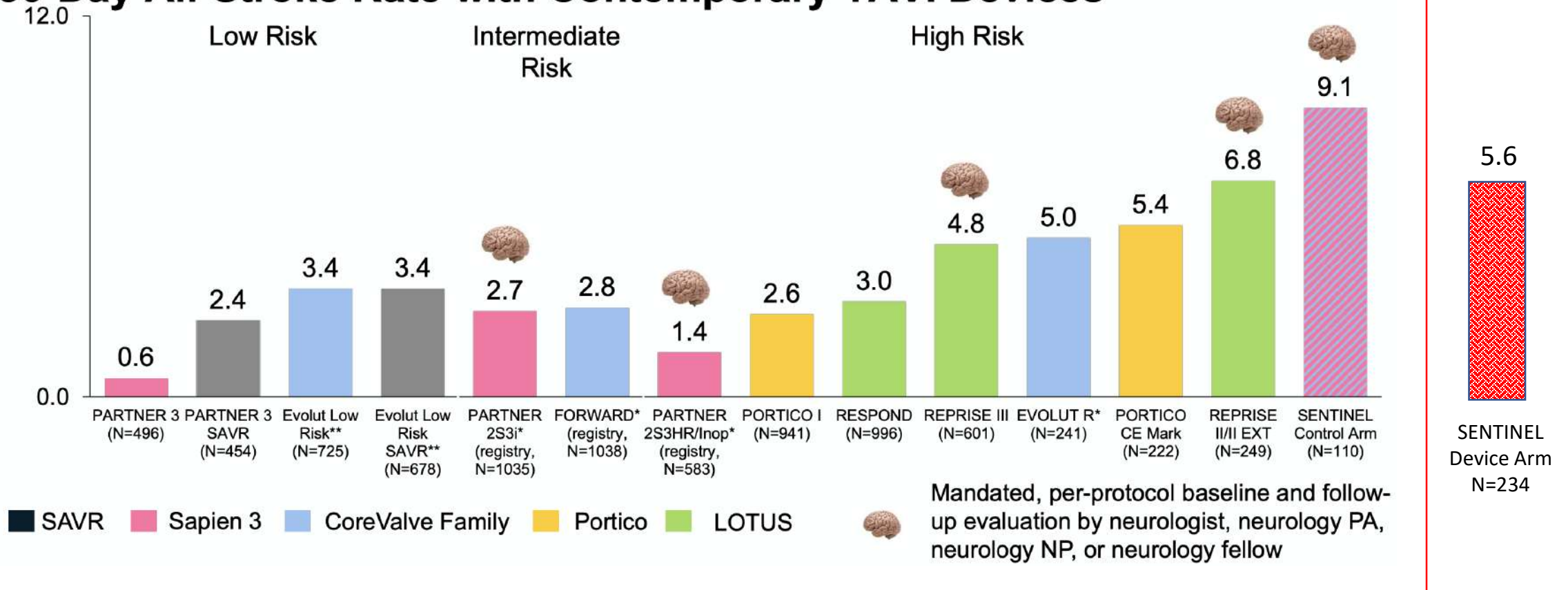
30-Day All-Stroke Rate with Contemporary TAVI Devices



SAVR
 Sapien 3
 CoreValve Family
 Portico
 LOTUS

Mandated, per-protocol baseline and follow-up evaluation by neurologist, neurology PA, neurology NP, or neurology fellow

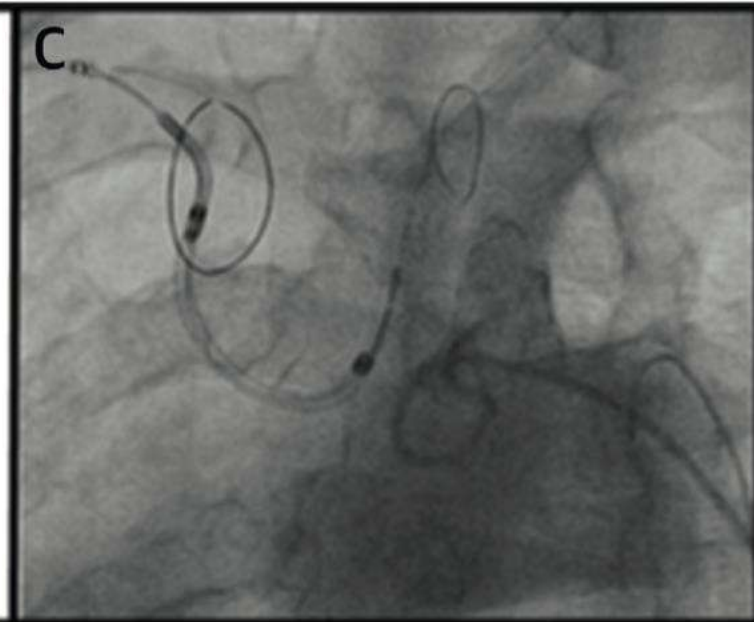
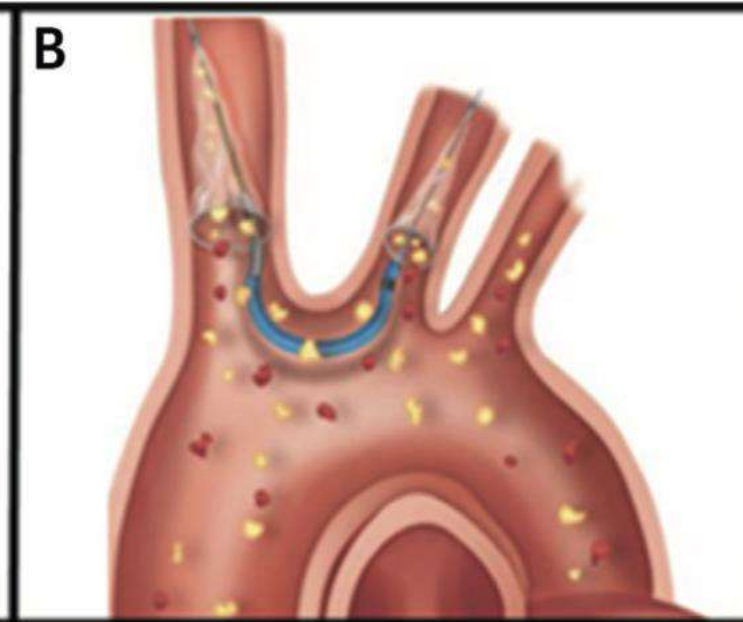
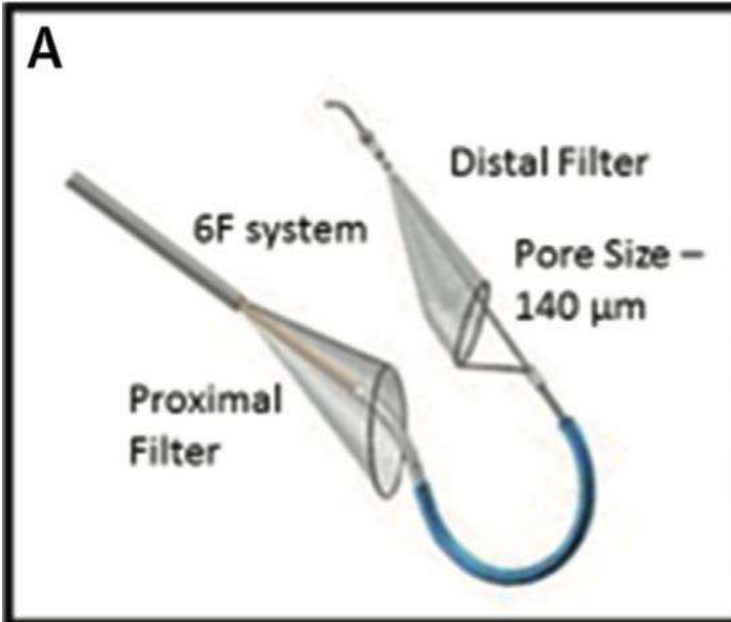
30-Day All-Stroke Rate with Contemporary TAVI Devices



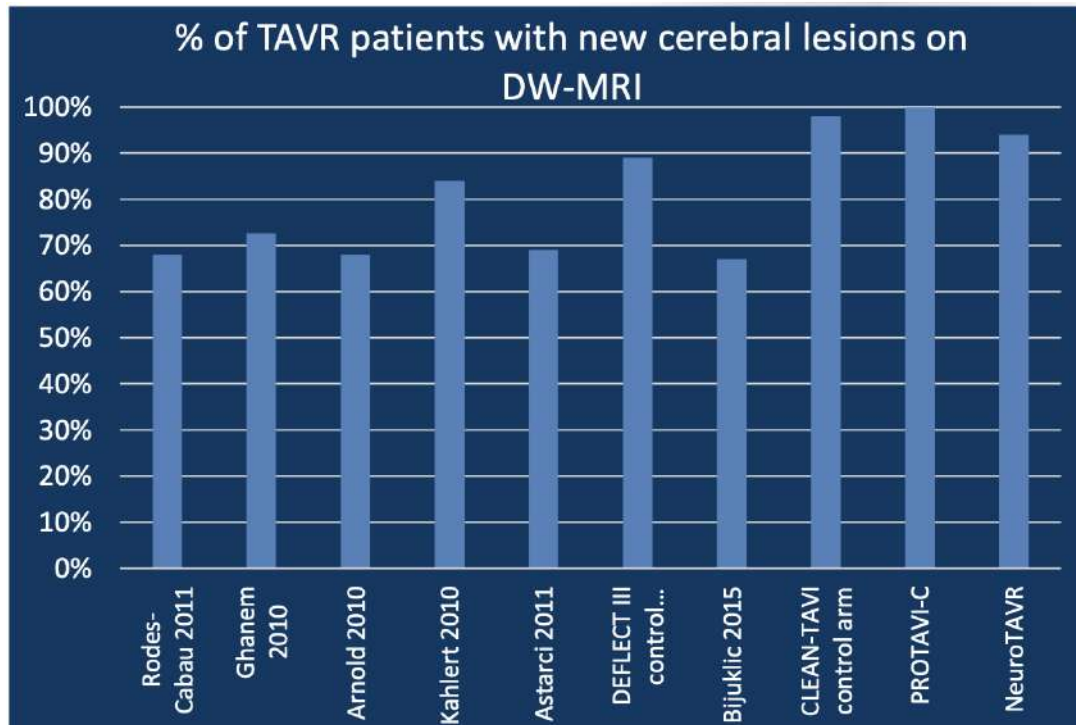
SENTINEL Trial

	Device Arm (n=234)	Control Arm (n=111)	p-value
30-day Clinical Outcomes			
Any MACCE[†]	7.3%	9.9%	0.40
Death (all-cause)	1.3%	1.8%	0.65
Stroke	5.6%	9.1%	0.25
Disabling	0.9%	0.9%	1.00
Non-disabling	4.8%	8.2%	0.22
AKI (Stage 3)	0.4%	0%	1.00
TIA	0.4%	0%	1.00
Sentinel Access Site Complications	0.4%	N/A	0.53

Kappadia et al. JACC 2017



The case for Cerebral Embolic Protection



- 80% new silent ischemic lesions
- Debris captured in 99% of patients (SENTINEL Trial)

1. Sacco et al., Stroke 2013
2. Vermeer et al., Stroke 2003
3. Vermeer et al., New Engl J Med 2009

SENTINEL Trial

TABLE 3 Median Total New Lesion Volume and Number of New Lesions (Unadjusted Analysis, Day 2 to 7)

	Control Arm (n = 98)	Device Arm (n = 91)	Hodges-Lehmann Estimate of Location Shift (95% CI)	p Value
Median total new lesion volume in protected territories, mm ³	178.0 (34.3-482.5)	102.8 (36.9-423.2)	-21.1 (-94.9 to 21.8)	0.3345*
Median total new lesion volume in all territories, mm ³	309.8 (105.5-859.6)	294.0 (69.2-786.4)	-8.6 (-110.7 to 68.6)	0.8076*
Median number of new lesions in protected territories	3 (1-6)	2 (1-6)	0 (-1 to 0)	0.8979†
Median number of new lesions in all territories	5 (2-10)	3 (2-10)	-1 (-2 to 1)	0.7667†

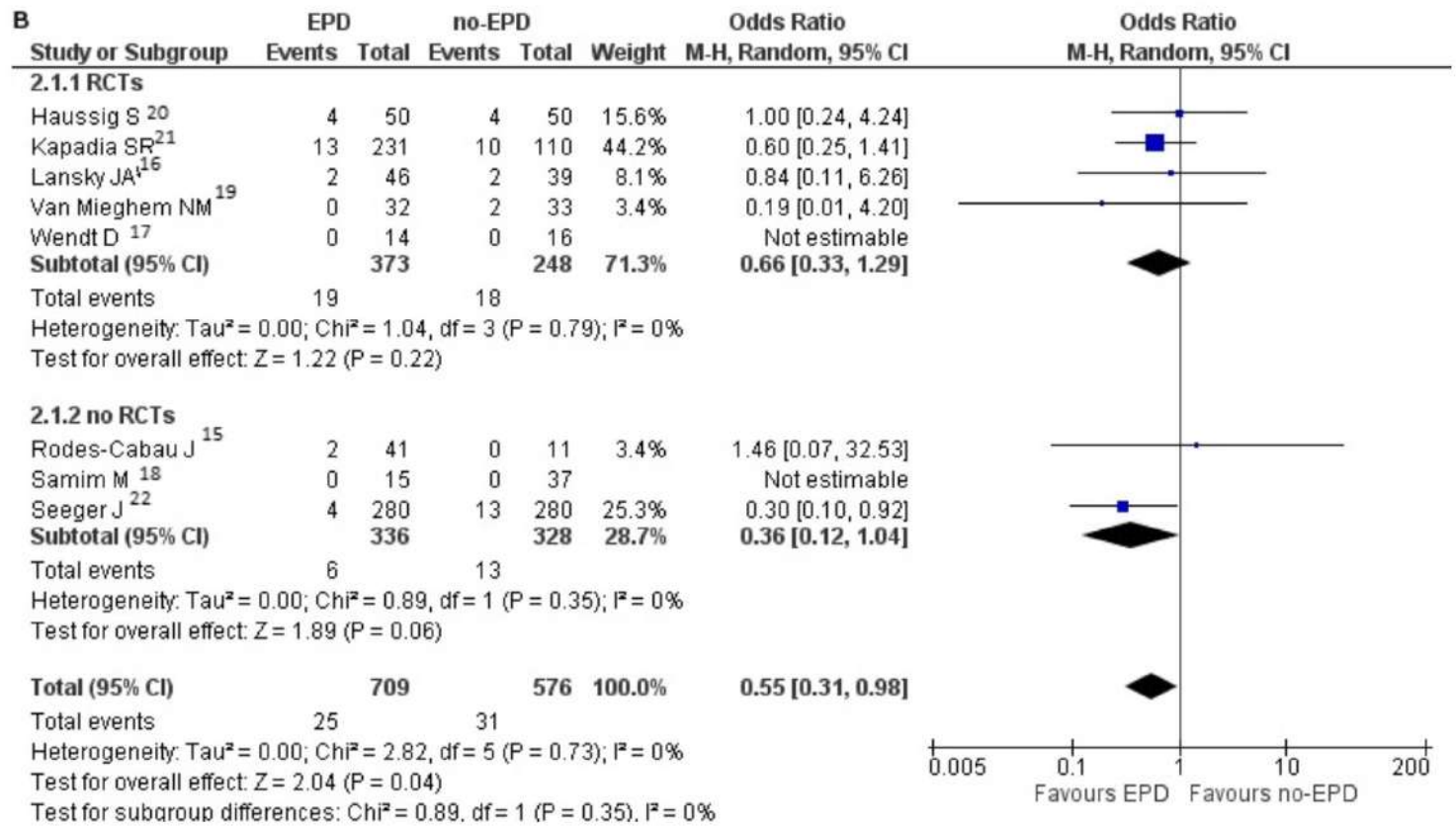
Values are median (interquartile range). *On the basis of the Wilcoxon test. †On the basis of the negative binomial regression model. CI = confidence interval.

CONCLUSIONS TCEP was safe, captured embolic debris in 99% of patients, and did not change neurocognitive function. Reduction in new lesion volume on magnetic resonance scans was not statistically significant. (Cerebral Protection in Transcatheter Aortic Valve Replacement [SENTINEL]; [NCT02214277](#)) (J Am Coll Cardiol 2017;69:367-77)
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Kappadia et al. JACC 2017

CEP Trials

30 day stroke meta-analysis

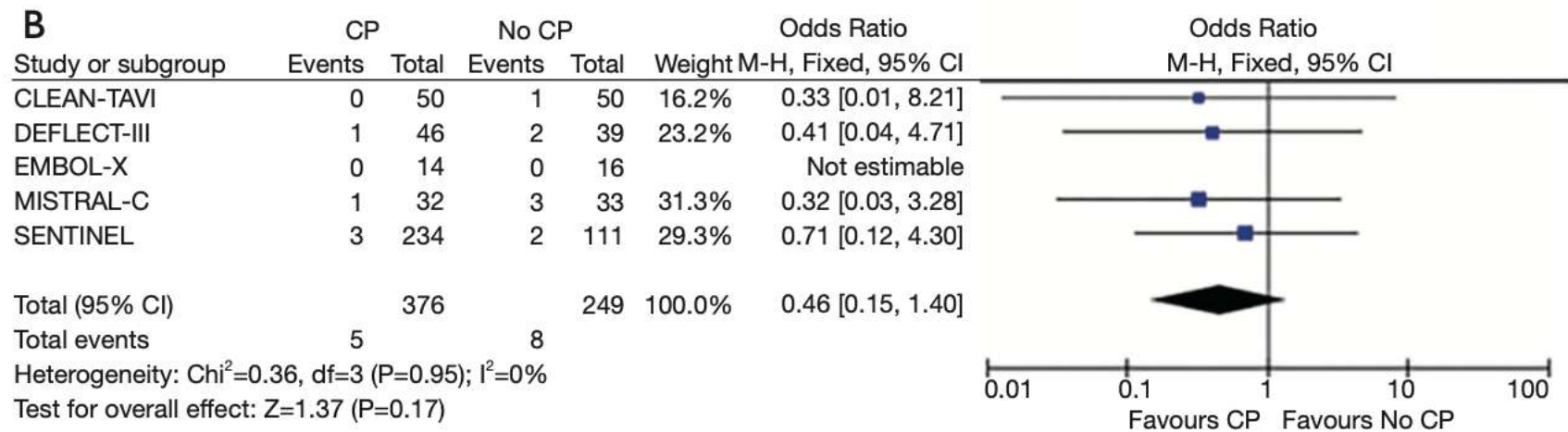


J Am Heart Assoc. 2018



CEP Trials

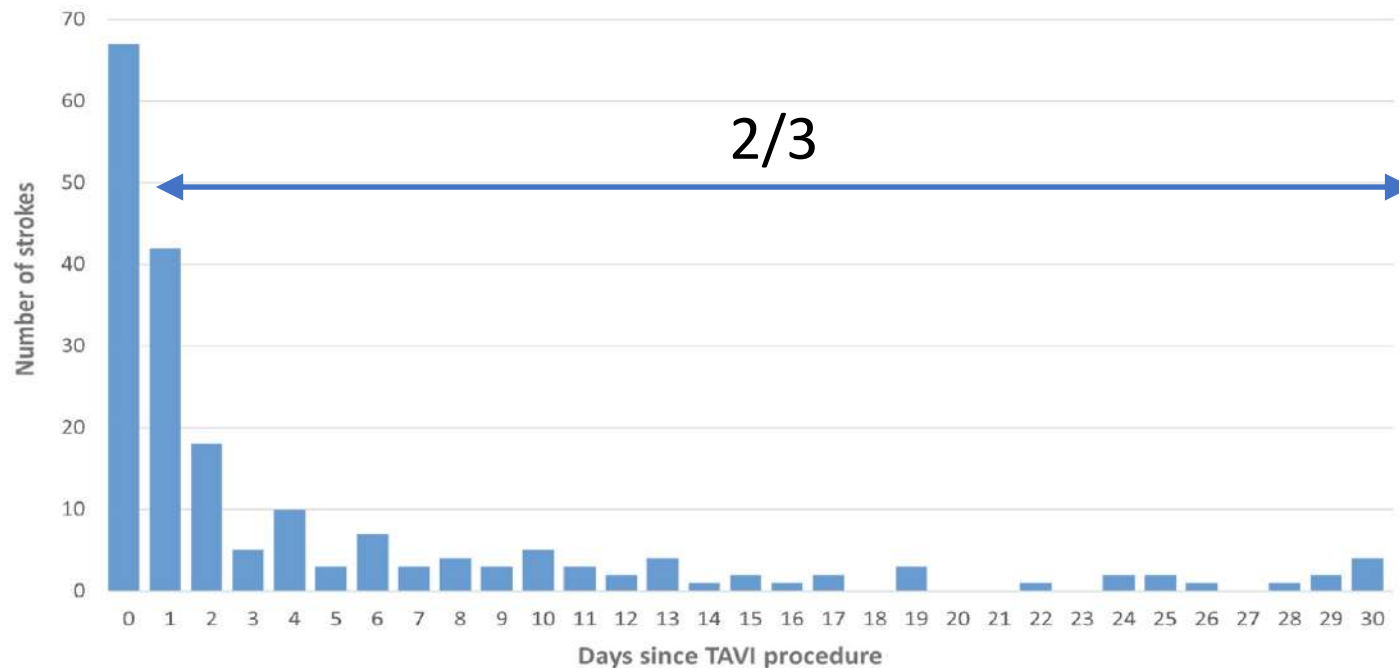
30 day stroke meta-analysis: RCT only



J Am Heart Assoc. 2018

TAVI: Timing of Stroke

Figure 1. Timing of stroke in the first month after TAVI



Stroke Incidence:

- 34% - TAVI Day
- 66% - After procedure

Vlastra, W et al. Circulation Cardiovasc Interv. 2019;

CEREBRAL EMBOLIC PROTECTION ENOUGH EVIDENCE?

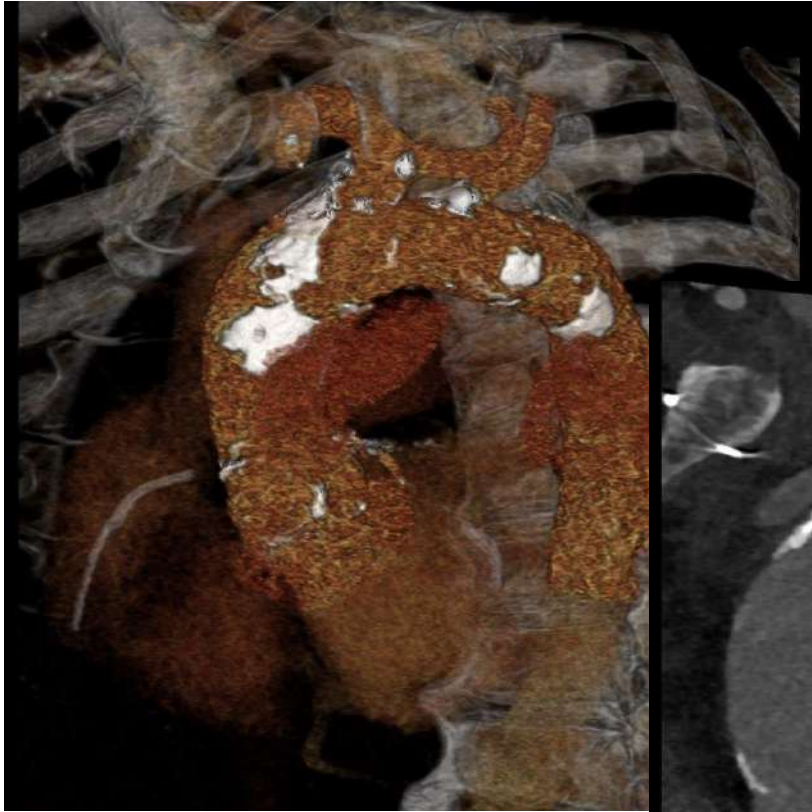
NO!

CEREBRAL EMBOLIC PROTECTION A MATTER OF FAITH?

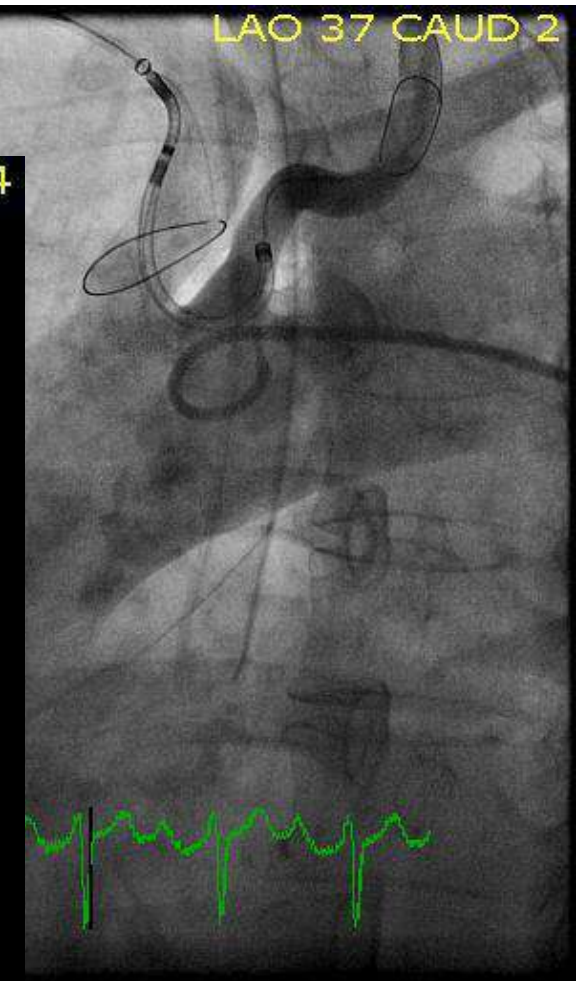
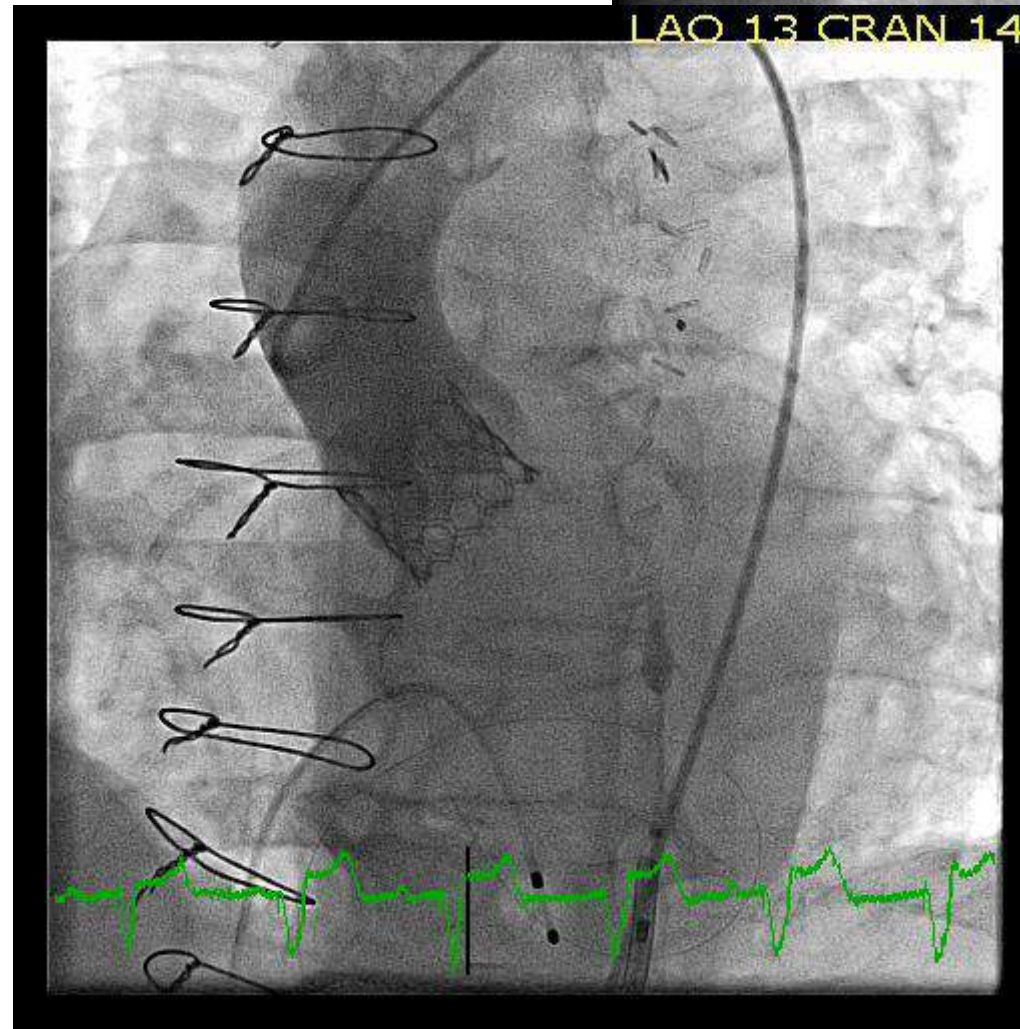


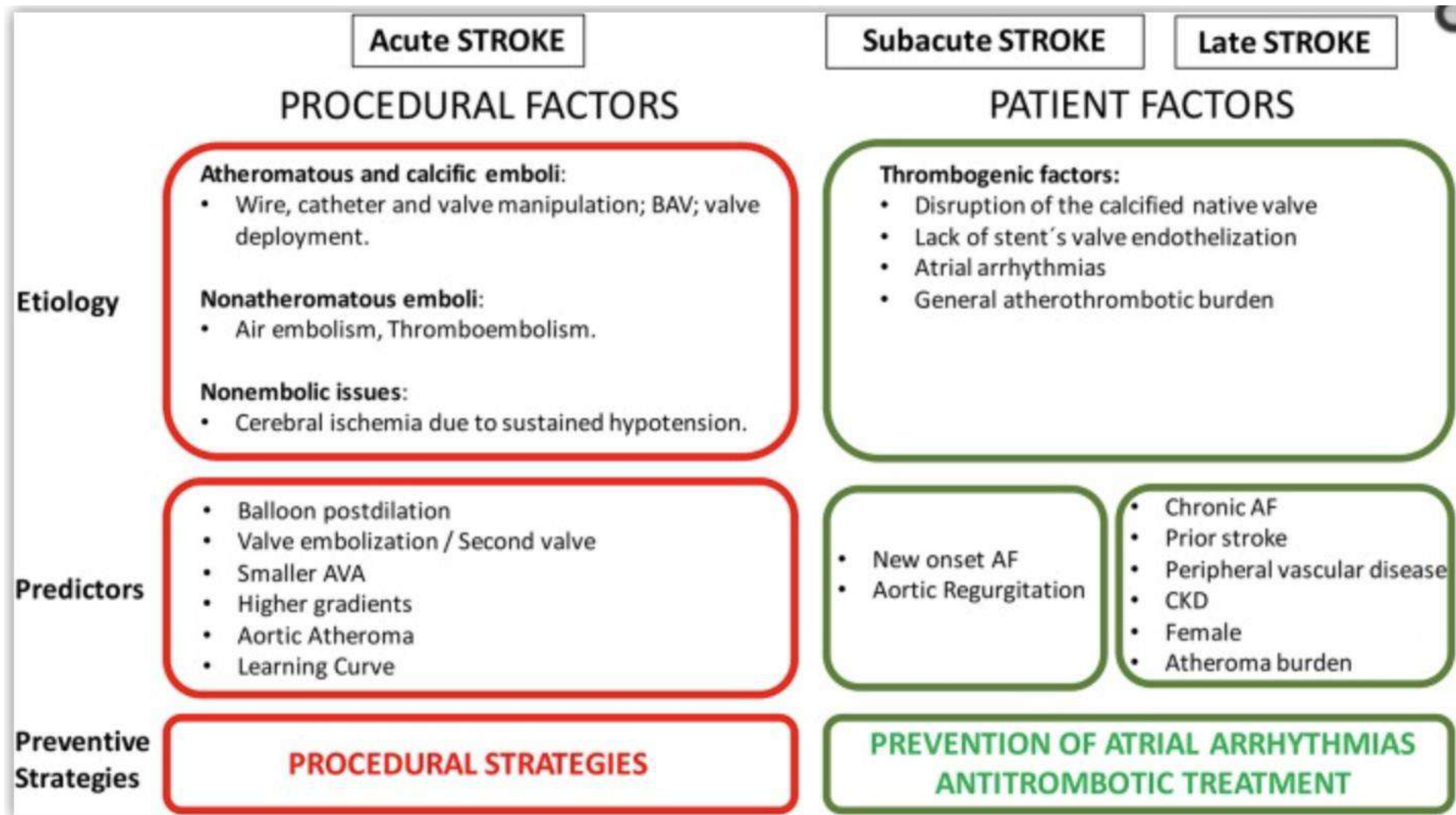
ANDREI RUBLEV, Andrei Tarkovsky, 1966

Complex atherothrombotic aortic plaques



- CEP with Sentinel
- Uneventful Sapien 3 transfemoral implantation

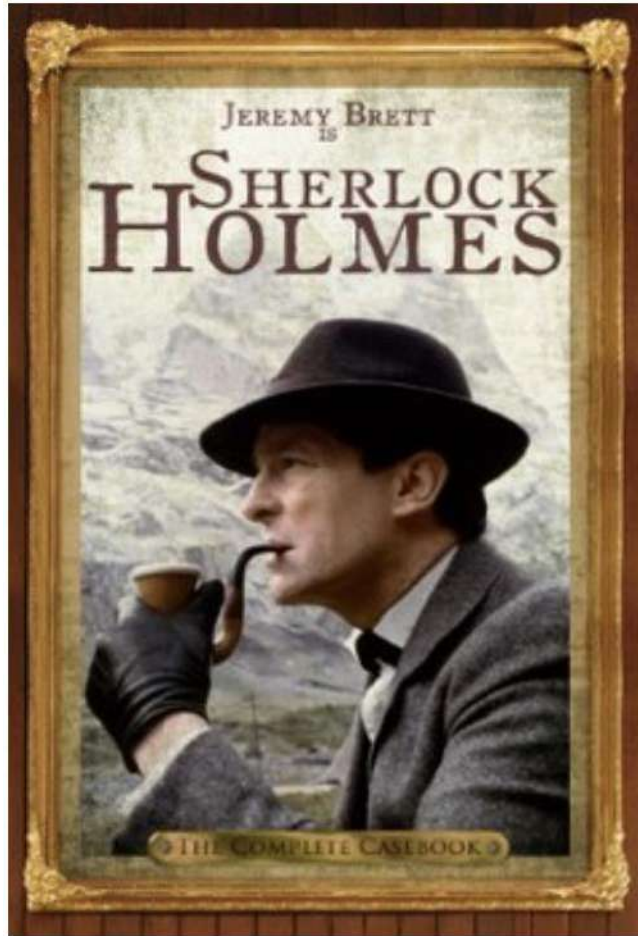




Front Cardiovasc Med. 2018

CEREBRAL EMBOLIC PROTECTION

A MATTER OF REASON



- There's a rationale for CEP use
- There is no perfect device
- Stroke after TAVI is multifactorial and the majority occurs after the procedure
- Currently CEP use should be selective, individualized:
 - Anatomic conditions (thrombus, atheroma, valve characteristics)
 - Procedural issues (balloon dilation, type of valve)

The End

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