Protected TAVR

Didier Tchétché.

Clinique Pasteur, Toulouse, France

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Disclosure:

-Consultant for

Abbott/Boston Sci/Edwards/Medtronic/HighLife/
T-Heart/Caranx Medical

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What do we know

At least 50% of stroke after TAVI are periprocedural

Disabling stroke impacts hospital stay, quality of life and survival

Risk creep related to the decrease of stroke rates

75-99% of debris captured in filter-based CEP post TAVI

Inconclusive data about the clinical impact of CEP

SENTINEL Cerebral Embolic Protection Device

- Two independent filters capture & remove embolic material
- Polyurethane filter, pore size = 140 µm
- Standard right trans-radial sheath access (6F)
- One size accommodates most vessel sizes; fits ~90% of anatomies
- Deflectable compound-curve catheter facilitates cannulation of LCC
- Minimal profile in aortic arch (little interaction with other devices)

- 3 out of the 4 cerebral vessels are protected

(left vertebral artery circulation is unprotected)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cerebral Embolic Protection during Transcatheter Aortic-Valve Replacement

Samir R. Kapadia, M.D., Raj Makkar, M.D., Martin Leon, M.D., Mohamed Abdel-Wahab, M.D., Thomas Waggoner, D.O., Steffen Massberg, M.D., Wolfgang Rottbauer, M.D., Ph.D., Samuel Horr, M.D., Lars Sondergaard, M.D., Juhana Karha, M.D., Robert Gooley, M.B., B.S., Ph.D., Lowell Satler, M.D., Robert C. Stoler, M.D., Steven R. Messé, M.D., Suzanne J. Baron, M.D., Julia Seeger, M.D., Susheel Kodali, M.D., Amar Krishnaswamy, M.D., Vinod H. Thourani, M.D., Katherine Harrington, M.D., Stuart Pocock, Ph.D., Rodrigo Modolo, M.D., Ph.D., Dominic Allocco, M.D., Ian Meredith, M.D., Ph.D., and Axel Linke, M.D., for the PROTECTED TAVR Investigators*

PROTECTED TAVR Study

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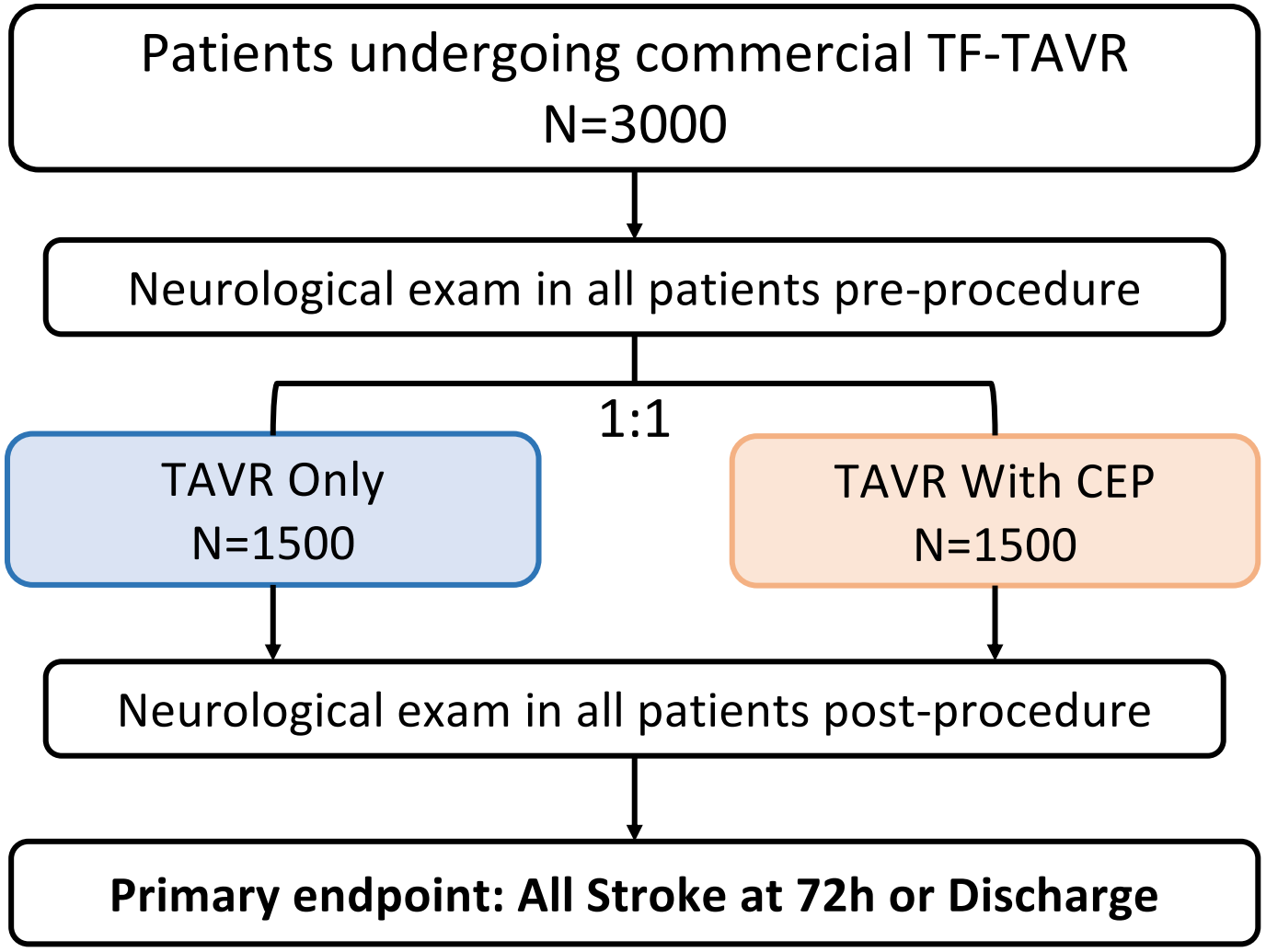
OBJECTIVE

To study whether clinical stroke in transfemoral TAVR is reduced with CEP, across all risk groups and all commercially available devices

DESIGN

Prospective, post-market, multicenter randomized controlled trial at 51 centers in North America, Europe, and Australia

PROTECTED TAVR Study Design



- Patients of all risk categories eligible
- Any commercially available TAVR device

Neurological examination

- At baseline
- Discharge or 72 hours after TAVR (whichever comes first)
- Performed by a neurology professional
- mRS, NIHSS, MoCA, CAM-ICU

- Adaptive study design with interim analysis at 70% enrollment

mRS, Modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; MoCA, Montreal Cognitive Assessment; CAM-ICU, Confusion Assessment Method for Intensive Care Unit Patients

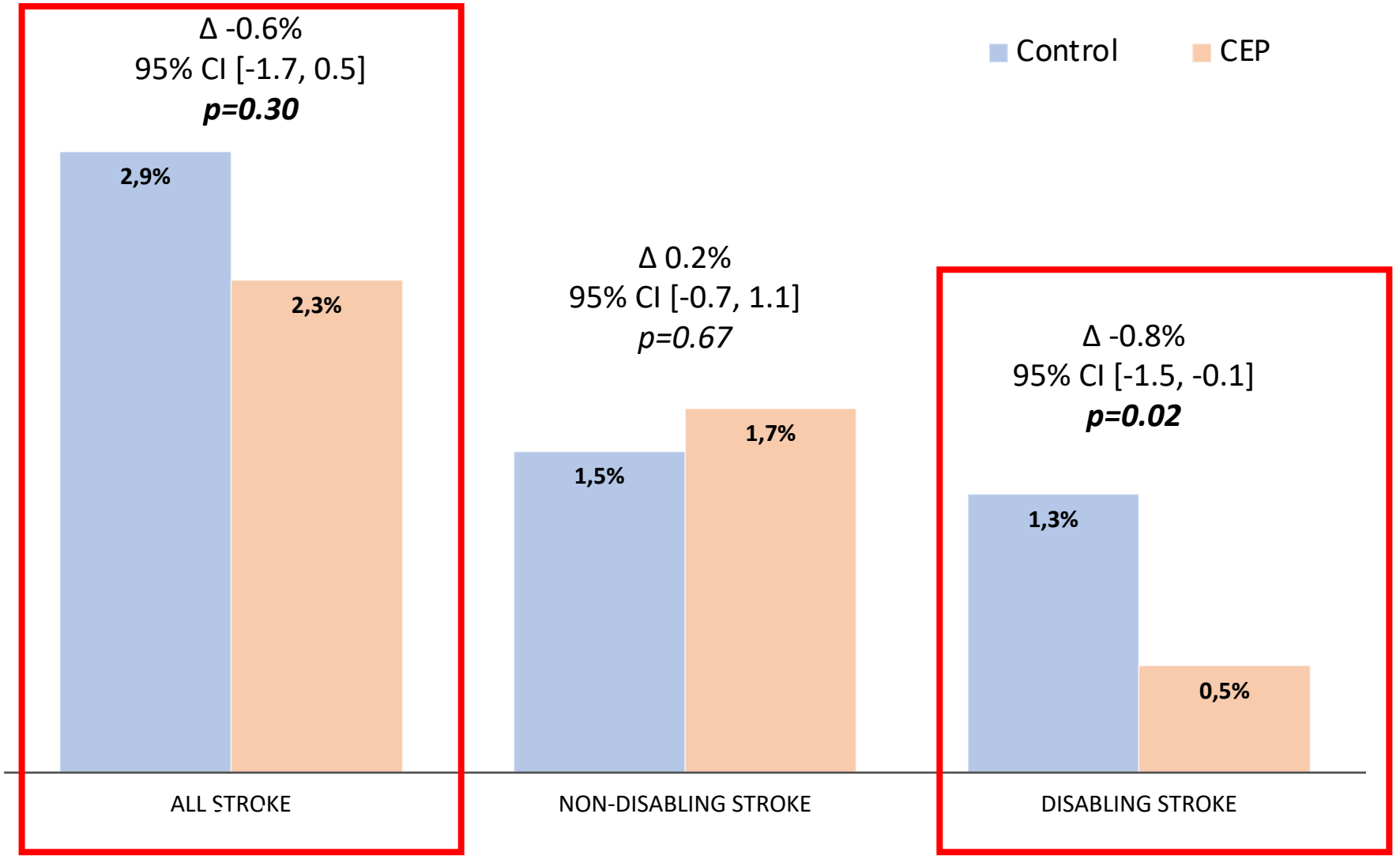
Baseline Demographics

	Control (N=1499)	CEP (N=1501)
Age (years)	78.9±7.8	78.9±8.0
Female Sex	37.8%	42.0%
Society of Thoracic Surgeons score, %	3.4±2.8	3.3±2.7
STS score <3%	58.2%	55.6%
Surgical Risk (per Heart Team)		
Extreme/High Risk	30.4%	30.4%
Intermediate Risk	34.2%	33.2%
Low risk	35.4%	36.3%
Native Valve Calcification Severity (site-reported)		
None/Mild	15.2%	16.2%
Moderate	29.5%	29.4%
Severe/Extreme	55.3%	54.4%
CHA_2DS_2-VASC score	4.2±1.3	4.2±1.3

Procedural Characteristics

	Control (N=1499)	CEP (N=1501)
Anesthesia		
General Anesthesia	26.4%	26.8%
Local or Conscious Sedation	73.6%	73.2%
Valve Anatomy		
Tricuspid Valve	89.5%	87.5%
Bicuspid Valve	8.1%	8.7%
Bio-prosthesis	2.5%	3.7%
Prosthetic Valve Type		
Balloon Expandable Valve	63.7%	64.3%
Non-Balloon Expandable Valve	36.3%	35.7%
Balloon Dilatation		
Pre-dilatation	41.9%	38.5%
Post-dilatation	25.7%	26.2%

Primary Endpoint: All Stroke at 72h / Discharge

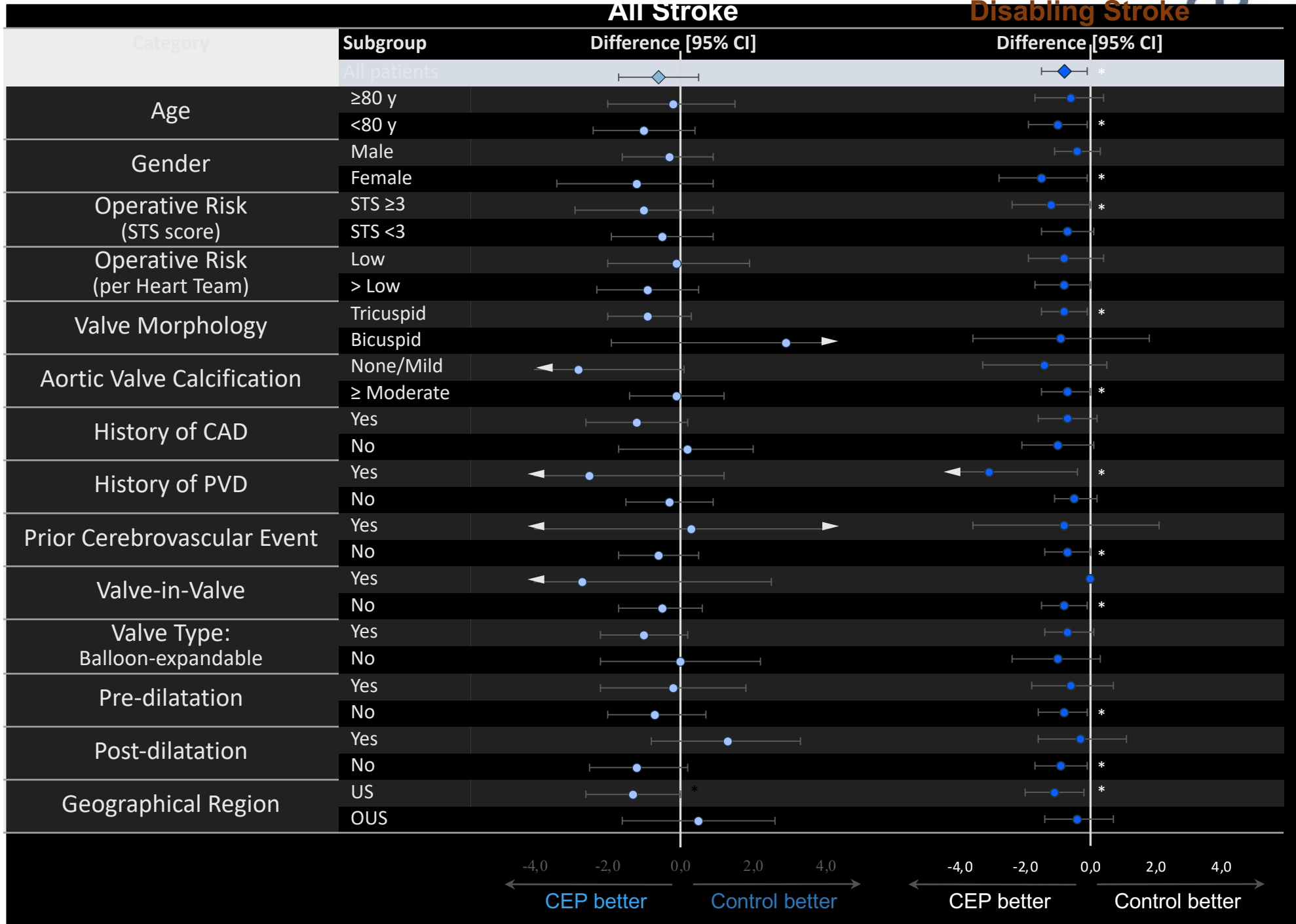


Clinical Outcomes at 72h / Discharge

Event at ≤72h / Discharge **ITT population**	**Control** (N=1499)	**CEP** (N=1501)
All-cause Mortality	0.3% (4)	0.5% (8)
Cardiovascular Mortality	0.3% (4)	0.5% (8)
Safety composite (all-cause mortality and stroke)	3.0% (45)	2.7% (41)
CEP Access Site-related Vascular Complication (Major or Minor)	N/A	0.1% (1)
Acute Kidney Injury (stage 2 or 3)	0.5% (7)	0.5% (8)

Note: A per-protocol analysis for the primary endpoint and other outcomes yielded similar results to those in the ITT population.

Subgroup Analyses



Conclusions

- Use of Sentinel CEP was feasible in 94.4% of attempted patients and was safe, with no major complications
- Use of CEP did not reduce overall periprocedural stroke
- Fewer disabling strokes were observed with CEP, but non-significant
- No specific subgroups were identified which strongly favored CEP use for overall stroke reduction

Limitations

- Trial design was practical in order to facilitate enrollment and data collection
  - As a consequence, the study was restricted to **a small number of endpoints with only short-term follow-up**
- The study was **not powered to detect a treatment difference for disabling stroke**

CEP Reduce Lesion Number And Volume (by MRI)

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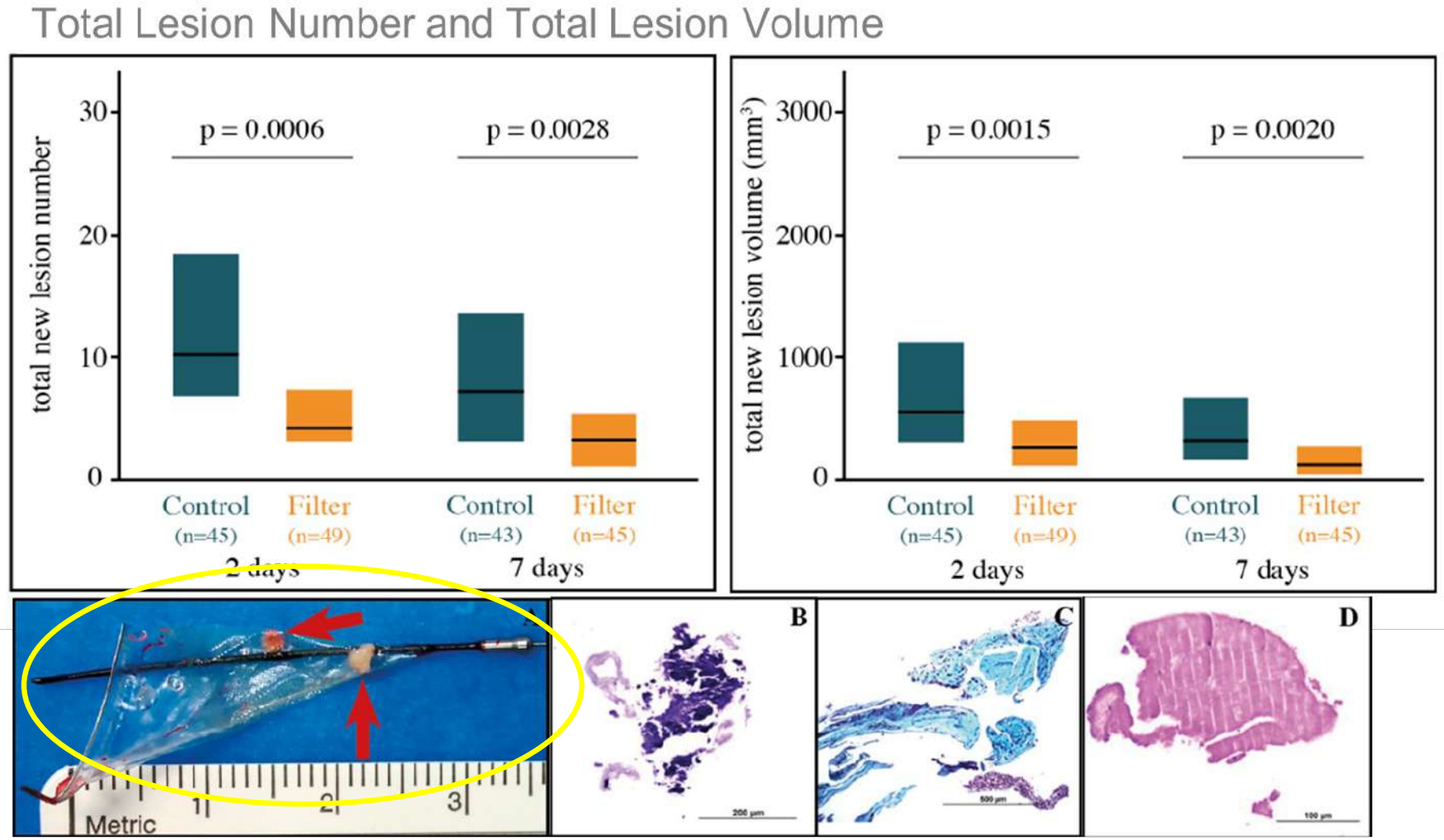

CLEAN-TAVI STUDY

Haussig S, … Linke A. JAMA. 2016(6):592-601.

Sentinel Cerebral Protection System

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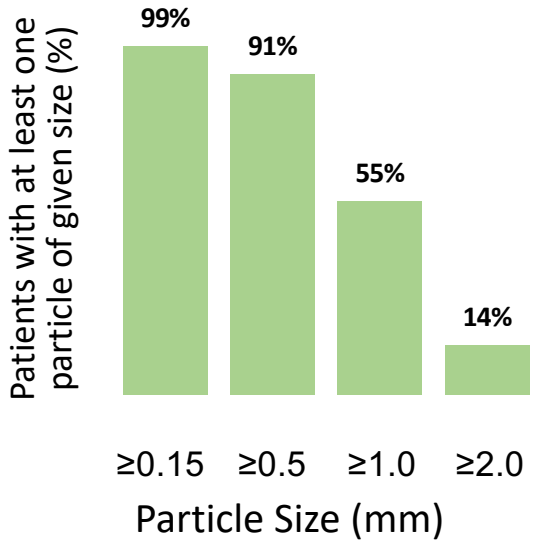
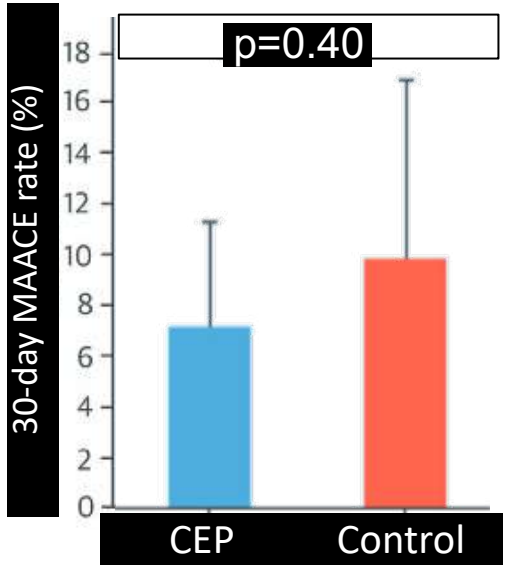
Sentinel IDE Trial : 363 patients randomized 2:1 to TAVR with or without CEP

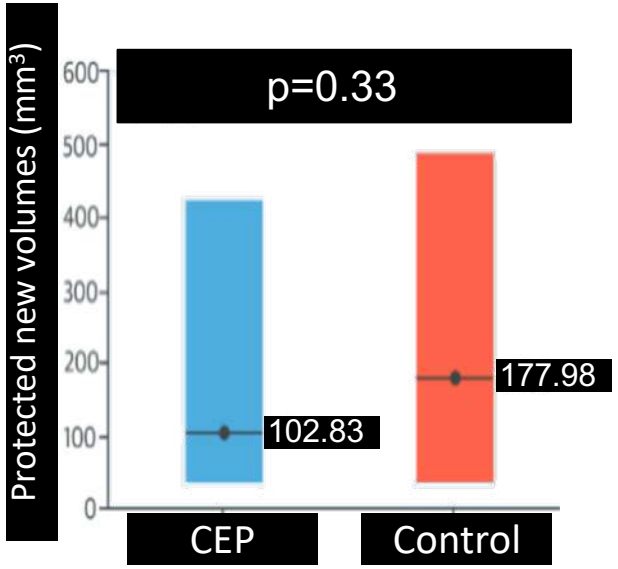
Captured debris in 99% of patients



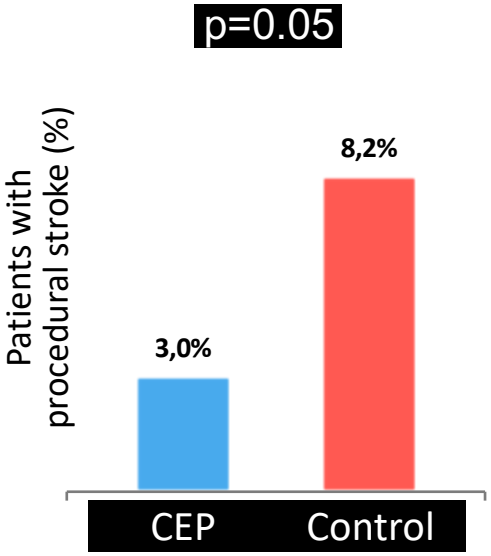
Device was safe
(No increase in 30-day MAACE)



New cerebral lesion volume reduction
(No statistical difference)



Reduced stroke 72 hours post-TAVR[2]
(Post-hoc analysis)



[1]Kapadia SK, et al. J Am Coll Cardiol 2017;69:367–77. [2]Seeger J, et al, Euro Heart J, 2019 May 1;40(17):1334-1340.

Is Protected-TAVR likely to change my practice?

- **No** systematic use
- CPDs are safe and might have the potential to reduce major strokes.
- Need for properly powered studies
- Use in highly selected patients
- Cost is an issue

MERCI

THANK YOU

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OBRIGADO

GRAZIE

BEDANKT

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Спасибо

EFHARISTO