



Boston
Scientific

DEJEUNER DEBAT

Judi 6 juin Salon Diane 12h30 – 13h55

« UNE NOUVELLE VALVE AORTIQUE : PARLONS-EN ! »

Modérateurs : P. Commeau L. Leroux

Introduction

P. Commeau

ACURATE *neo*™ en pratique

M. Nejari

Les Challenges

- Quelles valves pour quelles anatomies ?
- Pourquoi une protection cérébrale ?
- ACURATE *neo* et coronaires

E. Maupas

L. Leroux

N. Combaret

Points à retenir – Conclusion

L. Leroux

Conflits d'intérêts

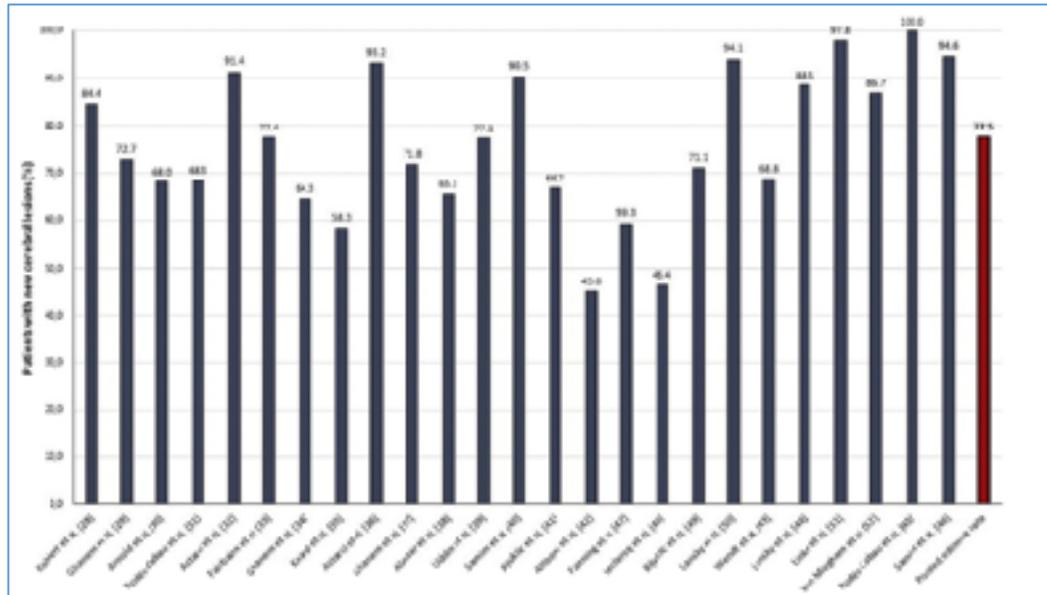
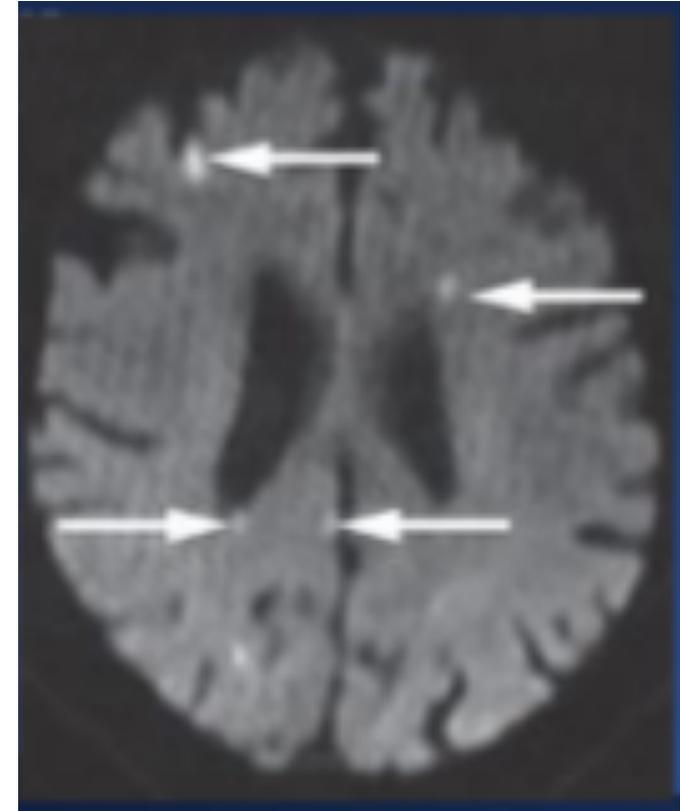
- Boston: proctor Acurate
- Corevalve: proctor Corevalve
- Abbott: Proctor MitraClip

Cas clinique

- Mme C, 82 ans, 50Kg/1m50
- HTA, dyslipidémie
- BPCO et coronaropathie stentée
- Traitement: Kardégic / plavix
- Bilan: Creat à 51
- Scanner OK
- ETT: Bon VG
- Euroscore 1 à 13.9%
- Décision Heart Team: TAVI (fragilité)

Est-ce la bonne décision?

- L'évènement cérébral est-il encore le tendon d'Achille du TAVI?
 - Evènement ischémique silencieux
 - Accident ischémique transitoire
 - AVC avec séquelles



Contents lists available at ScienceDirect
International Journal of Cardiology
journal homepage: www.elsevier.com/locate/ijcard

Elsevier

Silent cerebral injury after transcatheter aortic valve implantation and the preventive role of embolic protection devices: A systematic review and meta-analysis

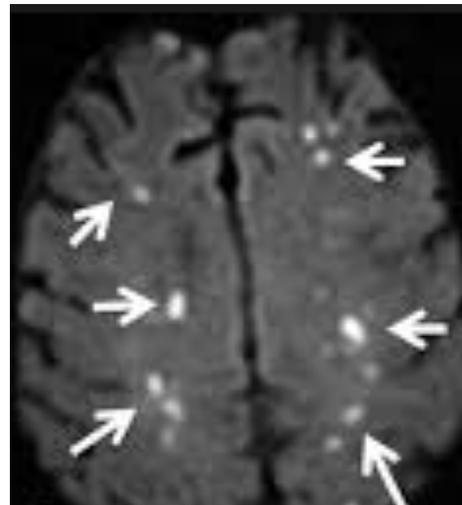
Mattio Fagnesi^a, Ezio A. Martini^b, Mauro Chiarito^c, Antonio Mangeri^d, Schaad J. Jobson^{*,e,f}, Nicola M. Van Mieghem^g, Sanjeev K. Kodali^h, Cosimo Godino^g, Giovanni Landoni^{*,e}, Antonio Colombo^{*,i,j}, Azreen Latif^{*,k}

La procédure...

- Simplified TAVI
 - Edwards 23
 - Anesthésie locale avec sédation propofol
 - Ponction AFD sous Echo
 - ACT >250
 - Pigtail par voie radiale droite
 - Stimulation sur guide
 - Fermeture par 2 proglides et un angioseal
 - Pas de difficultés au franchissement du RA
 - Pas de pré ou de post-dilatation
 - Pas de fuite significative ni d'élargissement du QRS
 - Transfert en module de surveillance post-interventionnelle

Mais:

- Appel pour monoparésie MSD au réveil
- IRM en urgence: multiples embolisations distales
- Avis Neuro-vasculaire: pas de geste
- Traitement: Aspirine / plavix



ACCIDENT VASCULAIRE CÉRÉBRAL
CHAQUE MINUTE COMPTE

Si vous ressentez
brutalement
une **faiblesse**
d'un côté du corps,
une **paralysie**
du visage, du bras
et/ou de la jambe
une **difficulté**
à parler...

c'est peut-être
un AVC
Accident
Vasculaire
Cérébral

COMPOSEZ VITE LE **15**

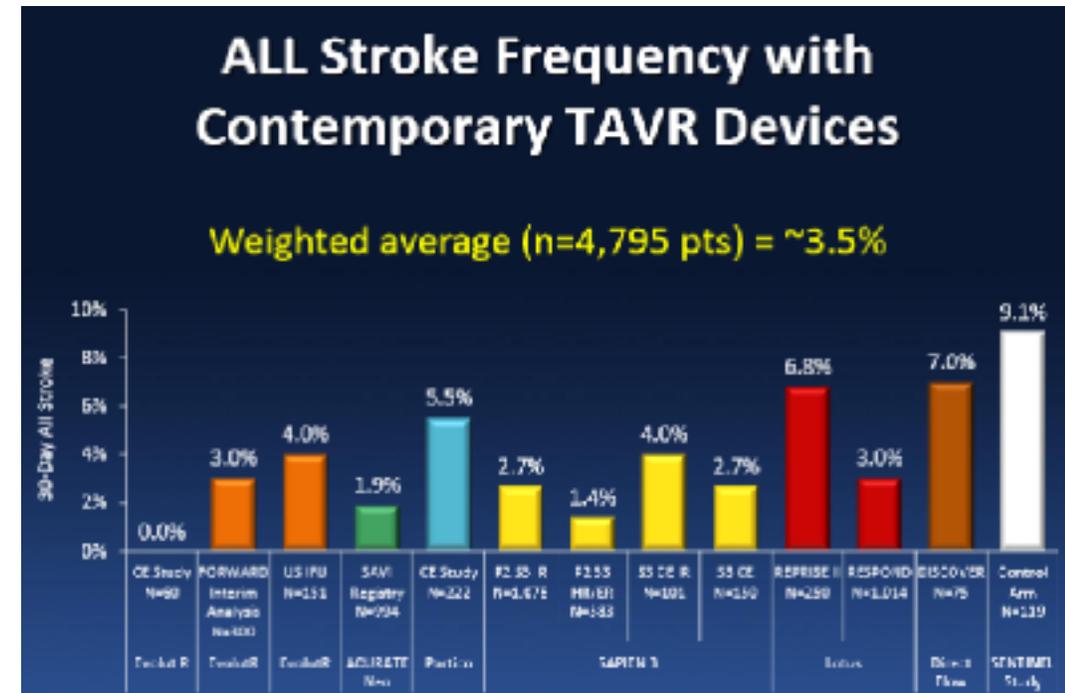
www.franceavc.com

Mon infirmier:
« C'est pas de ta faute!
Et c'est peut-être pas grave..»



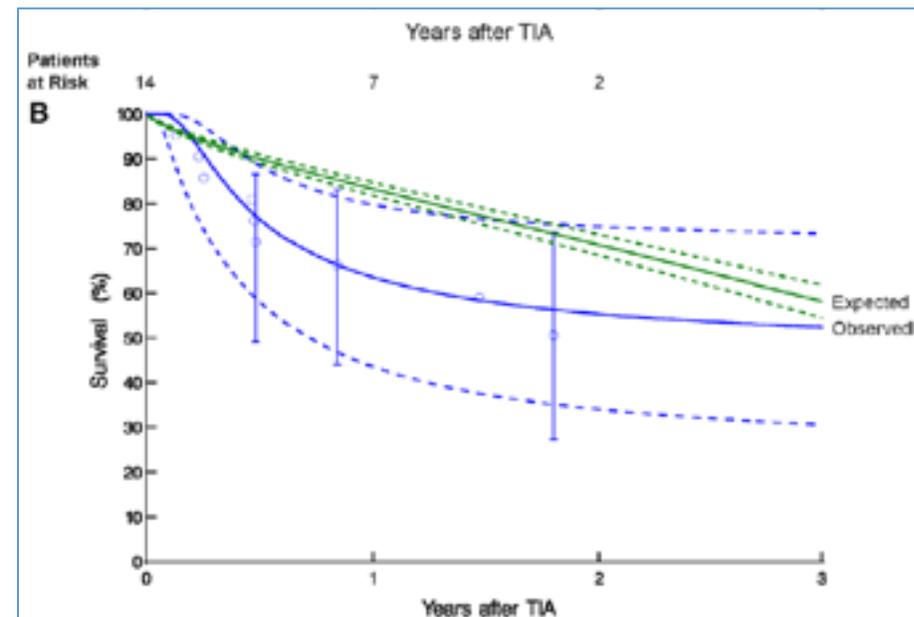
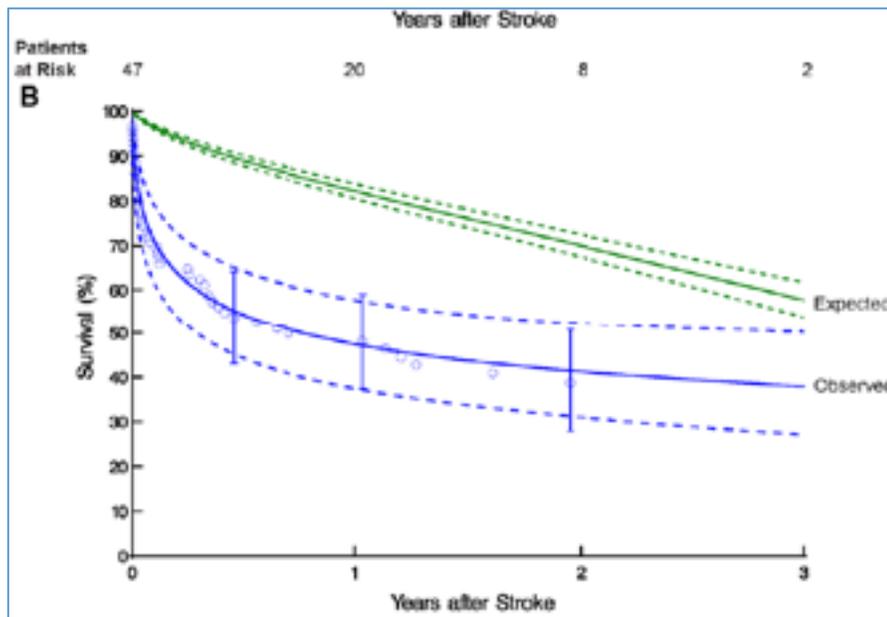
- A-t-on fait un TAVI le jour de son AVC???

Survenue d'un AVC clinique	30 jours	1 an
RA traitement médical	1,7%	4,5%
RA traité par TAVI	6,7%	10,6%



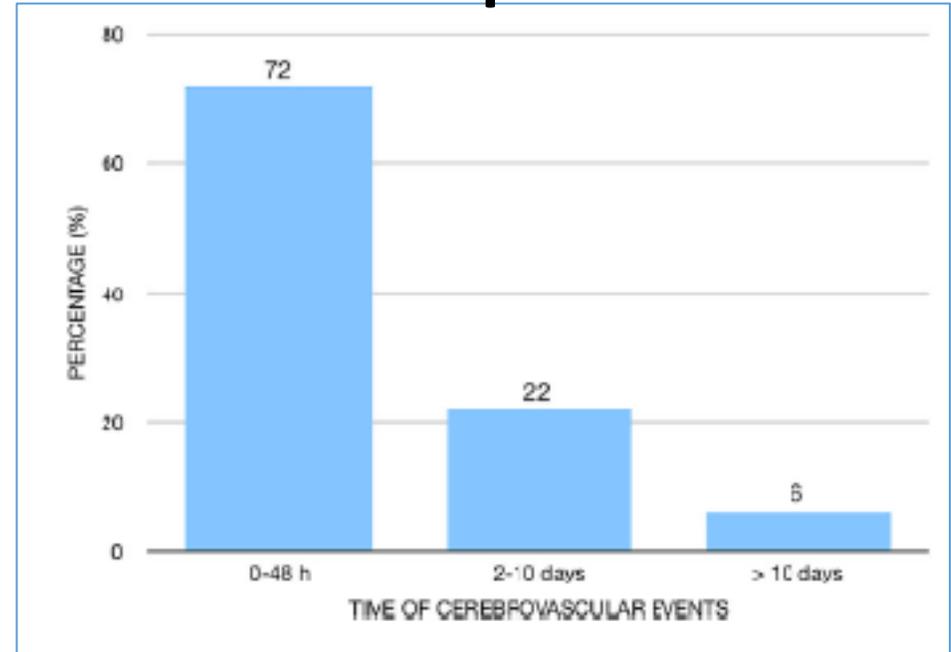
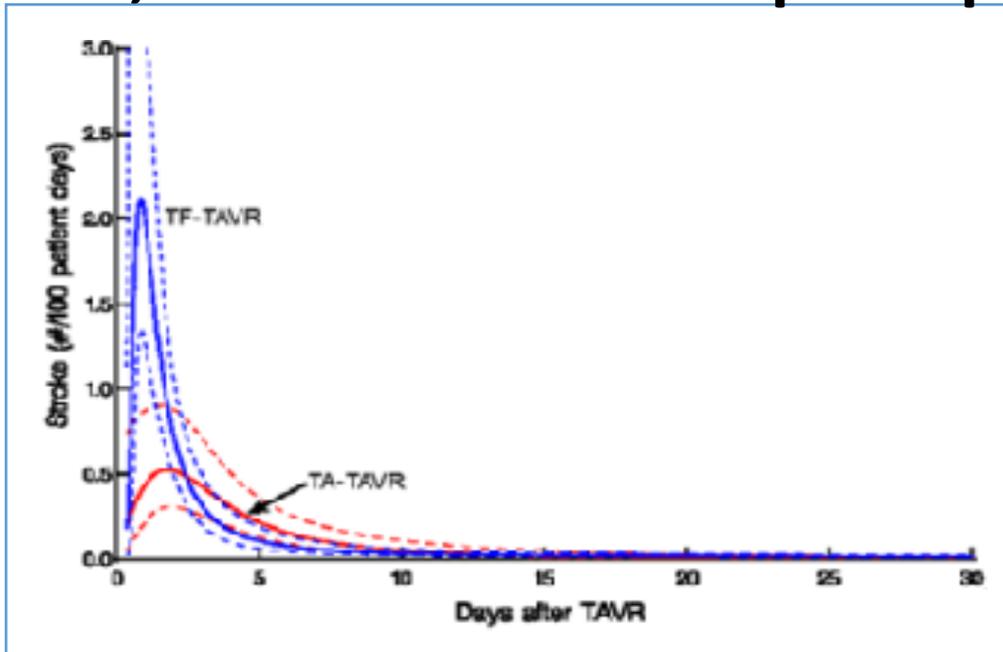
Quel est le pronostic?

Mortalité post-TAVI à 1 an	Eggebrecht et al.	Muralidharan et al.
Sans AVC Clinique (dans les 30J)	6,9%	6,4%
Avec AVC clinique (dans les 30J)	25,5%	12,3%





Mon réanimateur: « Pfff, elle n'aurait pas pu attendre un peu »



Insights Into Timing, Risk Factors, and Outcomes of Stroke and Transient Ischemic Attack After Transcatheter Aortic Valve Replacement in the PARTNER Trial (Placement of Aortic Transcatheter Valves)

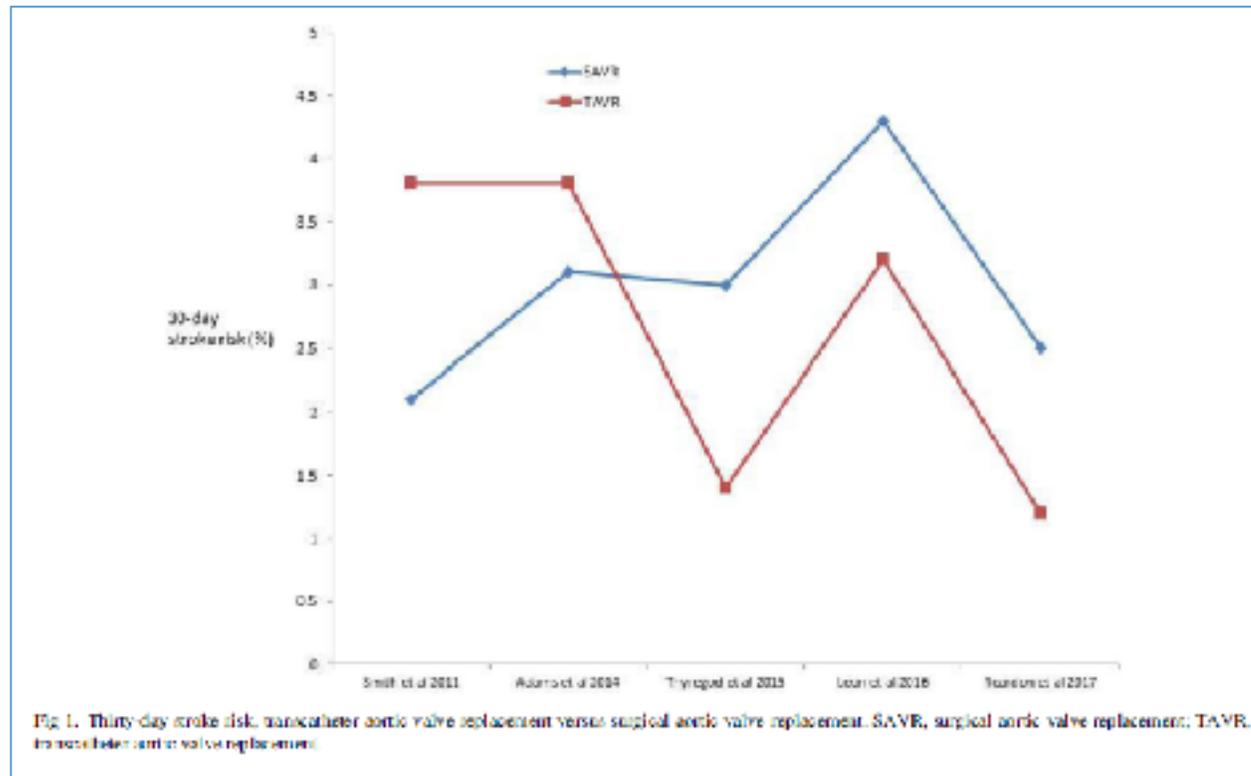
Sanku Kapadia, MD; Shikhar Agarwal, MD; D. Craig Miller, MD; John G. Webb, MD; Michael Mack, MD; Stephen Ellis, MD; Howard C. Herrmann, MD; Augusto D. Pochard, MD; E. Murat Tuzcu, MD; Lars G. Svensson, MD, PhD; Craig R. Smith, MD; Jeevantham Rajeswaran, PhD; John DeBorja, PhD; Michael Kodali, MD; Raj Mukherjee, MD; Vinod H. Thourani, MD; Eugene H. Blackstone, MD; Martin H. Leon, MD

Cerebral embolic protection systems for transcatheter aortic valve replacement

Tomasz Gasior MD¹ | Norman Mangner MD² | Julia Bijoch MD³ | Wojciech Wojakowski MD, PhD³

Mon chirurgien: « Tu aurais du la faire opérer! »

- La chirurgie fait-elle toujours mieux que le TAVI en termes d'AVC?



Mon chirurgien:
« Tu aurais du la faire opérer! »



THE PARTNER 3 TRIAL

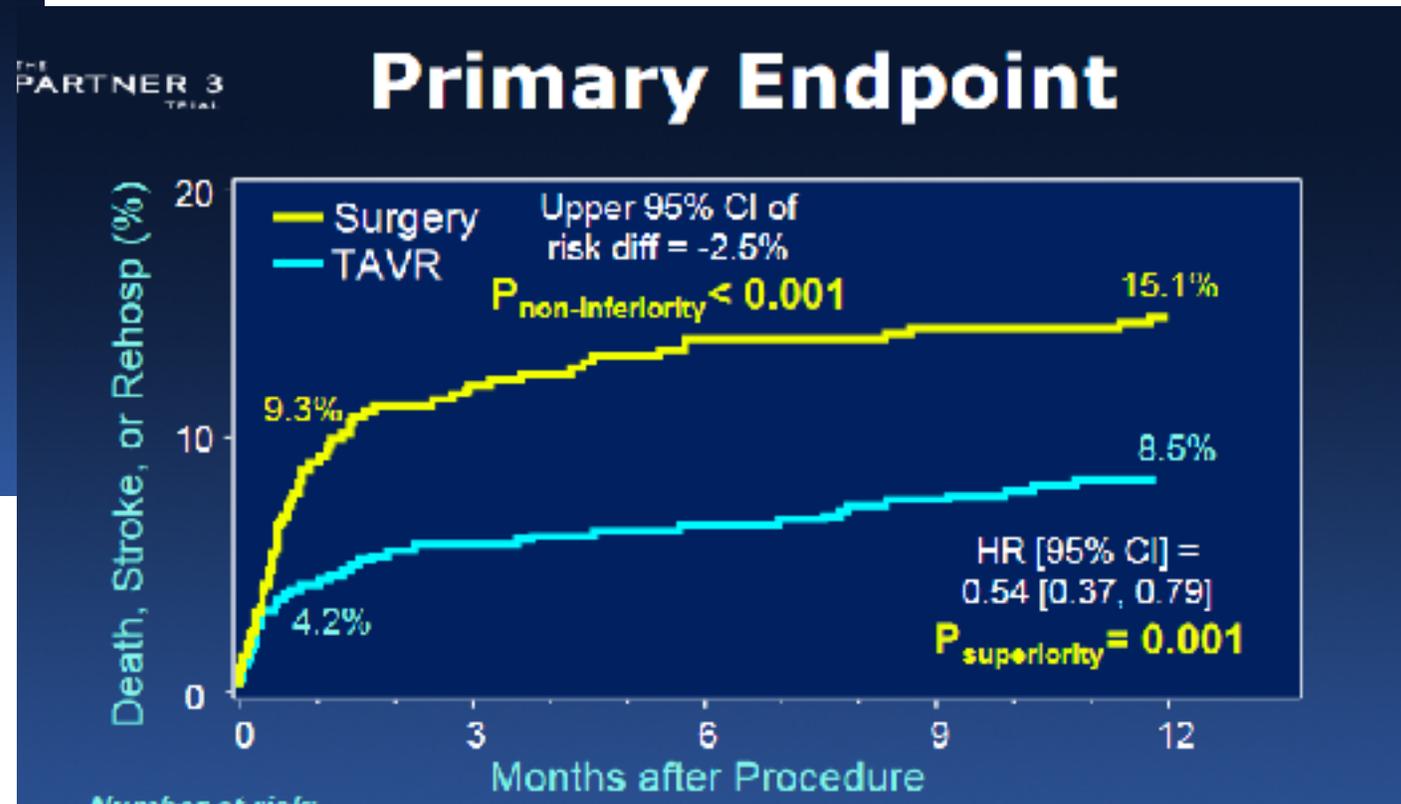
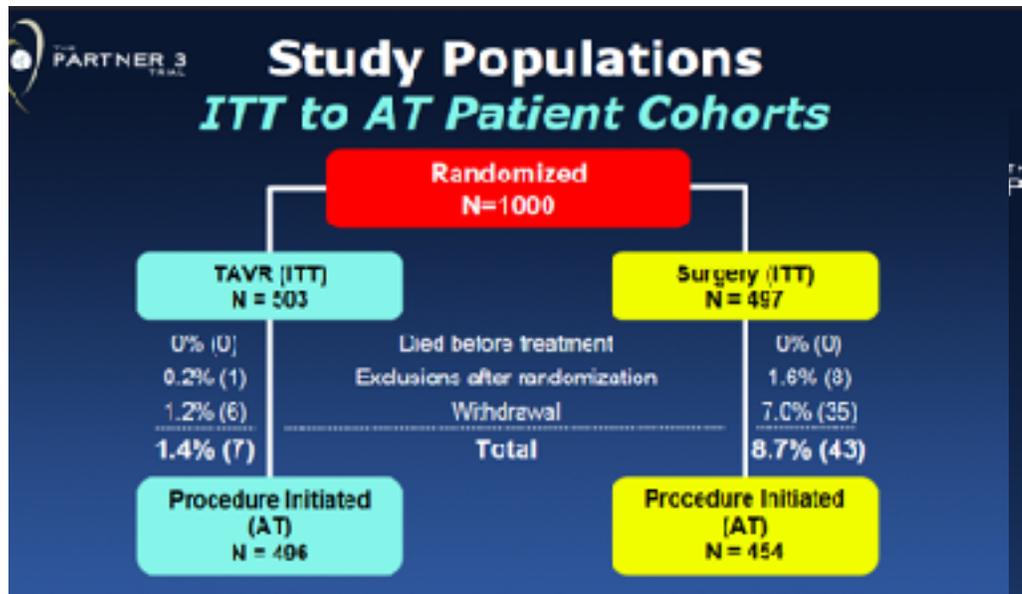
PARTNER 3

Transcatheter or Surgical Aortic Valve Replacement in Low Risk Patients with Aortic Stenosis

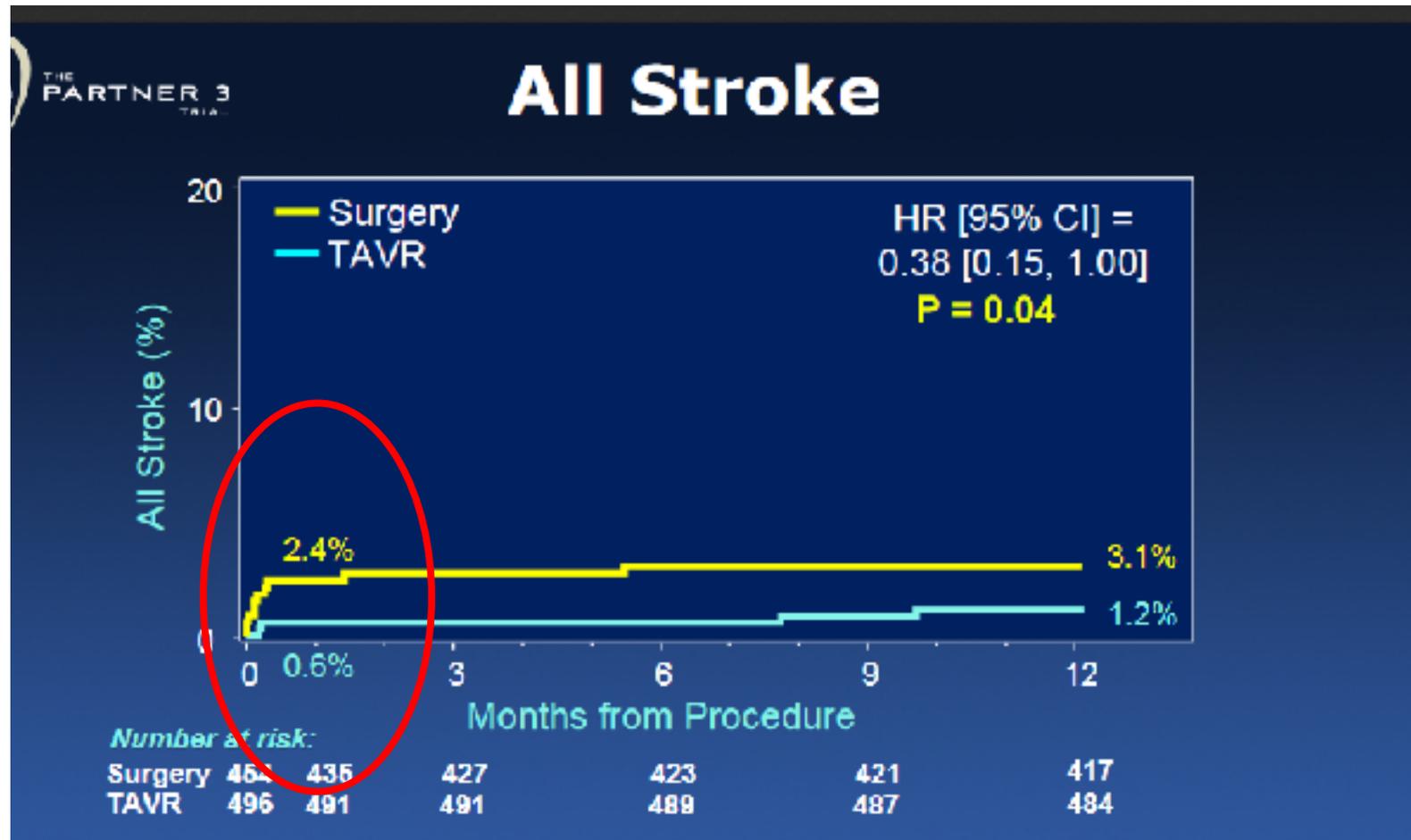


Martin B. Leon, MD & Michael J. Mack, MD
on behalf of the PARTNER 3 Trial Investigators

Mon chirurgien:
 « Tu aurais du la faire opérer! »



Mon chirurgien:
« Tu aurais du la faire opérer! »



Mon radiologue: « Tu pouvais pas le prévoir non? »

- Aorte? Peu de choses mais évident
- Massif valvulaire?



- Plus de 1000 femmes
- Analyse fine des calcifications au scanner:
 - les feuillets, les commissures, la LVOT

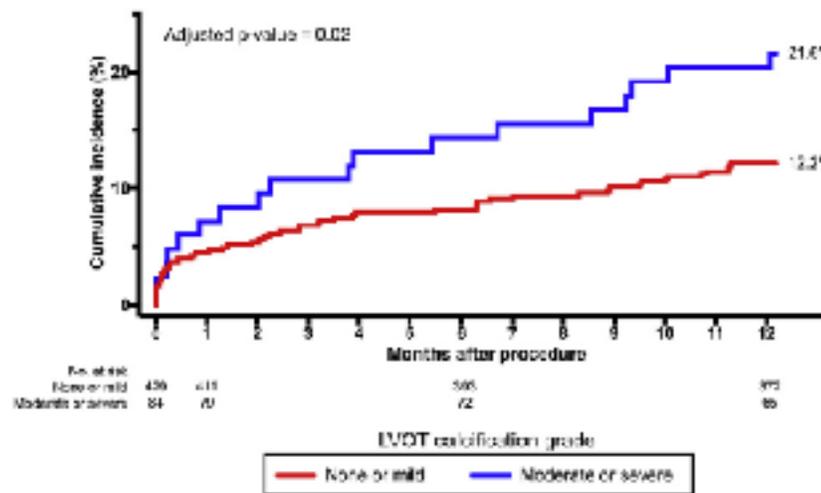
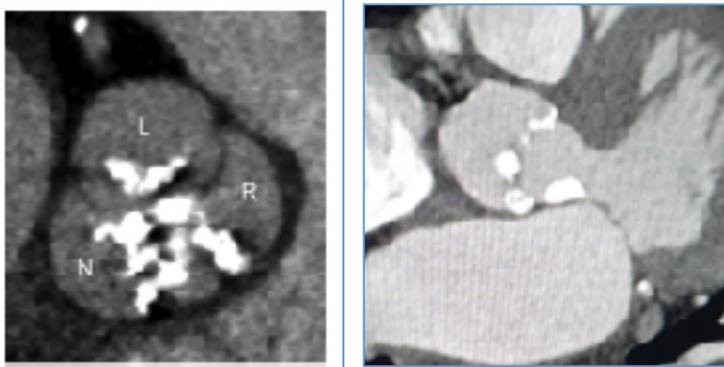


Fig. 2. Cumulative incidence of all-cause mortality or stroke stratified by LVOT calcification grade. Kaplan-Meier estimates (%). Mortality or stroke at one year was significantly higher in the subgroup with moderate or severe LVOT calcification (blue line).

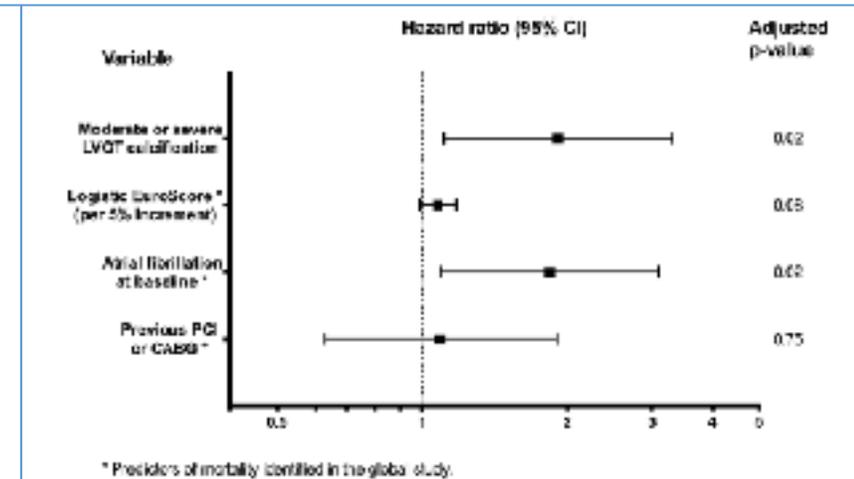


Fig. 3. Independent predictors of 1-year mortality or stroke. Cox proportional hazards model including significant univariate MDCT predictor (LVOT calcification grade) and pre-identified predictors for the primary endpoint (*). After adjustment, LVOT calcification remains an independent predictor of mortality or stroke at one year (n = 1029, CI = confidence interval).

Journal of Cardiovascular Computed Tomography 12 (2018) 338-344

Contents lists available at ScienceDirect

Journal of Cardiovascular Computed Tomography

Research paper

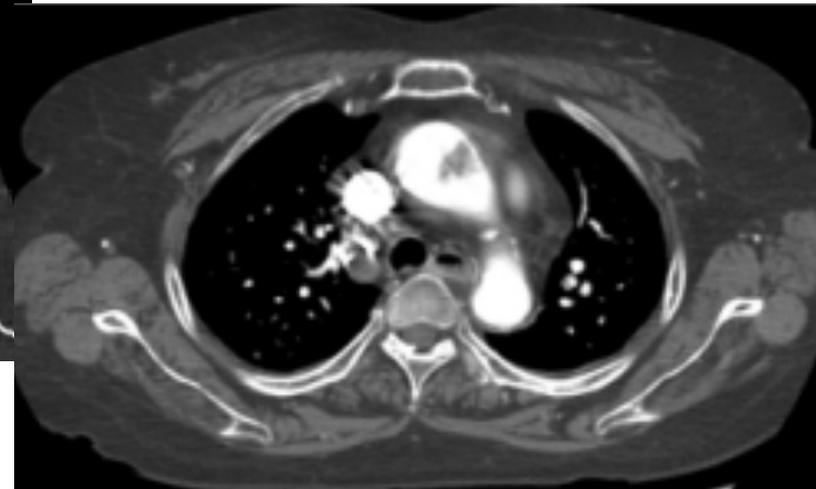
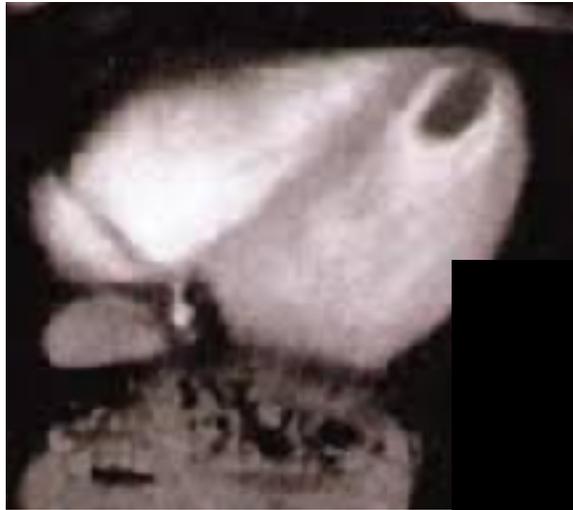
Computed tomography predictors of mortality, stroke and conduction disturbance in women undergoing TAVR: A sub-analysis of the WIN-TAVI registry

Marco Spaziano^{a,b,c}, Alaid Chieffo^a, Yusuke Watanabe^a, Jaya Chandrasekhar^a, Samantha Sartori^a, Thierry LeGif^a, Ansu Sonia Petronio^a, Pasquale Proditto^a, Didier Tchetche^a, Alessandro Iannuzzi^a, Nicholas M. Van Mieghem^a, Julinda Mehilli^a, Roxana Mehran^a, Matej Gleason Moric^a, on behalf of the WIN-TAVI Investigators



Mon échographiste:

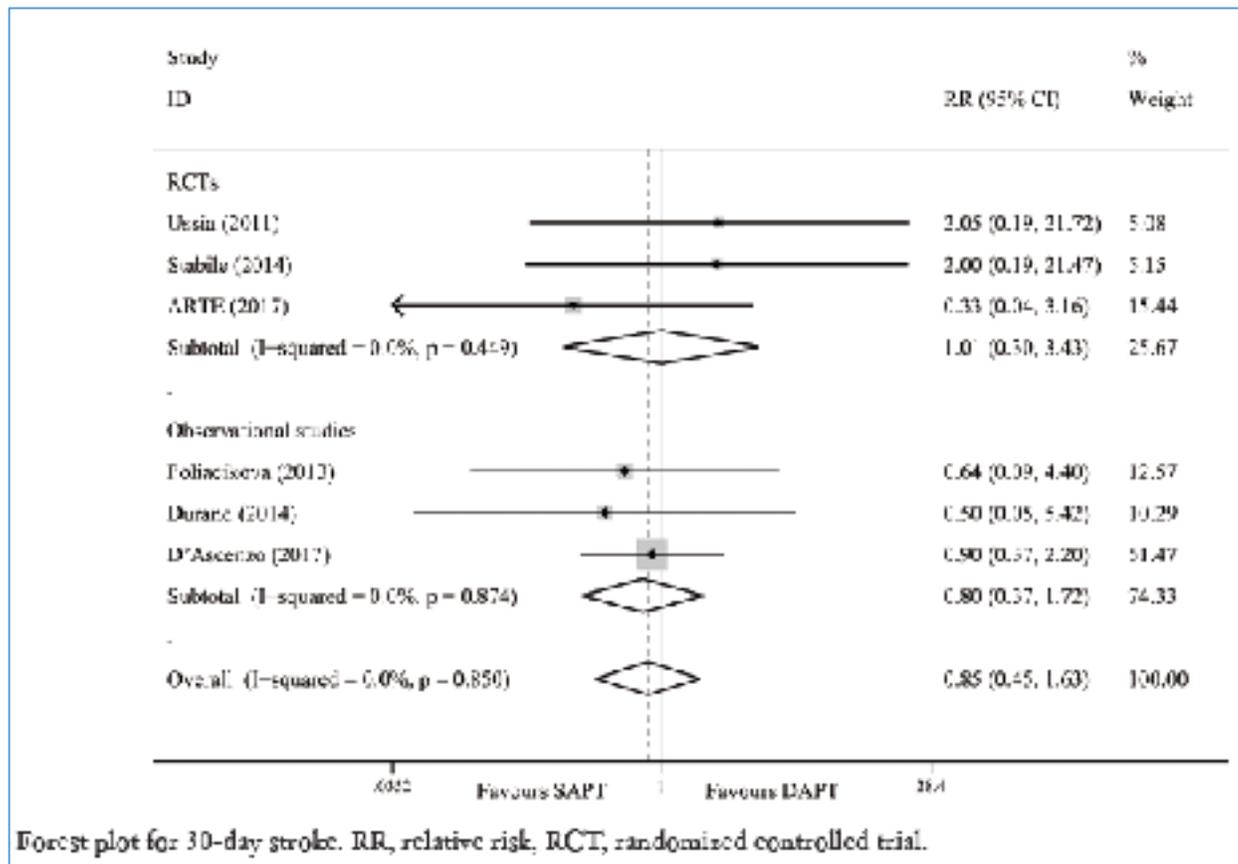
« Est-ce qu'au moins tu regardes mon écho avant? »



- Thrombus IntraVG ?
- Element mobile sur la valve?
- Débris aortiques ?



Mon rythmologue:
« Tu as du passer à côté de la FA !!
Peut-être qu'il faut plus les anticoaguler? »



BRAVO: Bivalirudine
GALILEO: Rivaroxaban

ATLANTIS: Apixaban
ENVISAGE: Edoxaban
AUREA: AVK

TICTAVI: Brilique
....

Original Article
Single or dual antiplatelet therapy after transcatheter aortic valve replacement: an updated systemic review and meta-analysis
Wenjie Zuo, Mingming Yang, Yanru He, Chunshu Hao, Lijuan Chen, Genshan Ma



Mon anesthésiste « Tu perds trop de temps dans le malade... »

- Plus de Débris lors du franchissement, de la prédilatation, du déploiement...
- D'où simplified TAVI
- Durée procédure 25 minutes!

Table 1. Early and late stroke predictors.

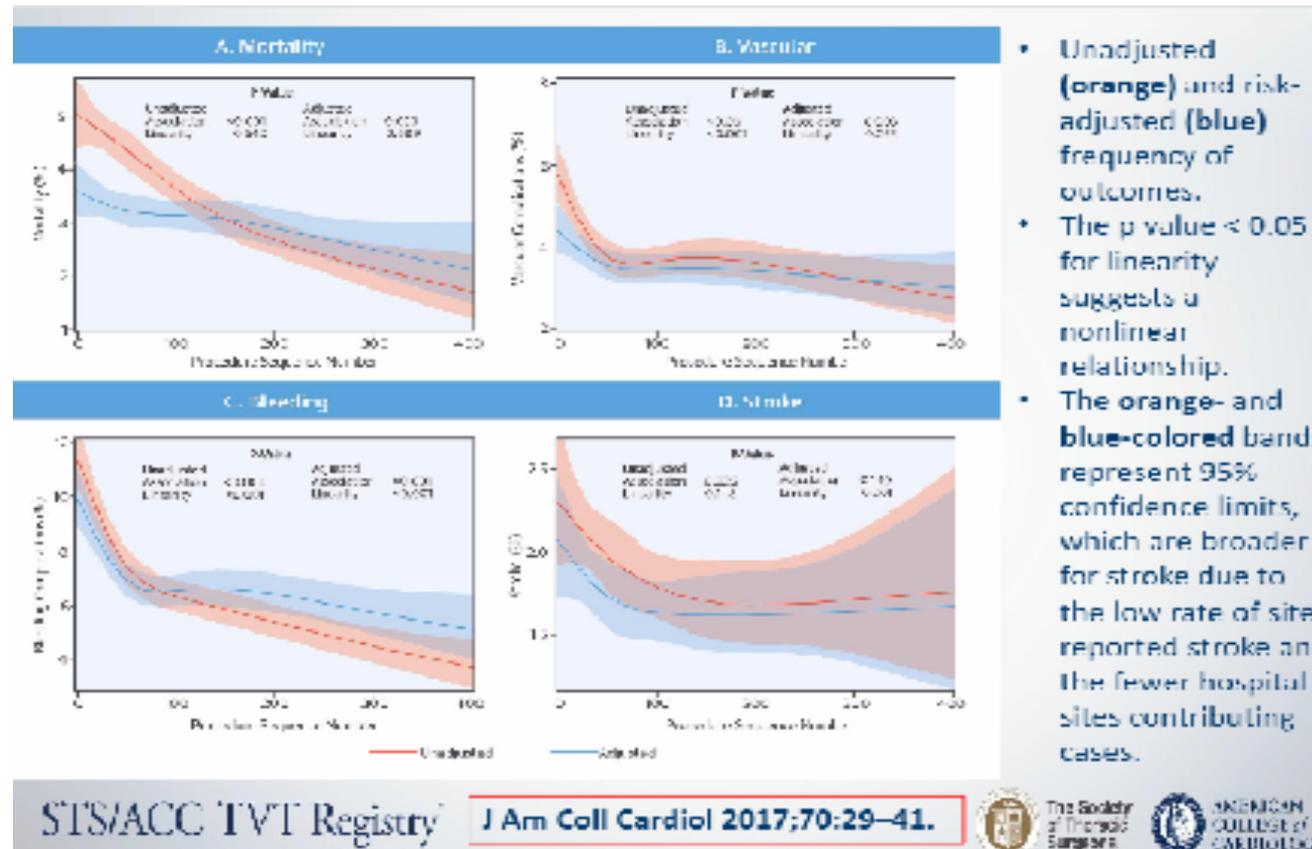
	Procedure related
Early phase (0–10 days)	AV annulus size
	Pure AS
	Total time in the Cathlab
	Time of delivery catheter in patient's body
	Rapid pacing
	Balloon predilatation
	Valve repositioning
	Balloon postdilatation (debatable)



Ma cadre de santé:

« Peut-être qu'avec le temps et l'expérience, vous serez meilleur... un jour! »

- Pas sûr....



La famille:

« Et bien sûr, vous allez nous dire que c'est de la faute de la malade! »

Table 1. Early and late stroke

	Patient related
Early phase (0–10 days)	Female gender
	CKD
	History of stroke
	PVD
	Low BMI
	History of falls
	NOAF
	Angina
	Absence of CABG

Portrait Robot

- Femme de petit gabarit
- Insuffisante rénale
- Avec AOMI mais sans coronaropathie
- Traquer la FA

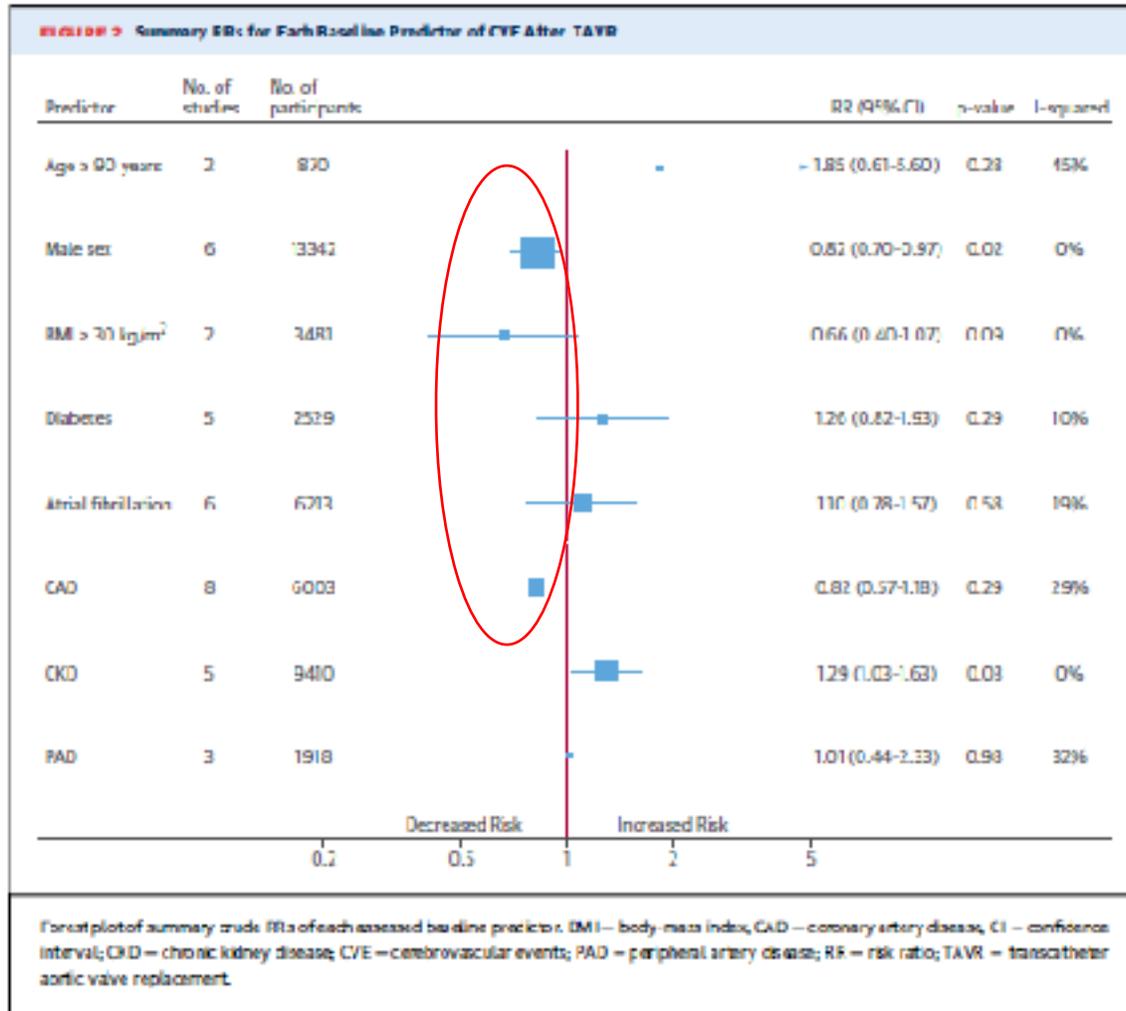
Journal of Geriatric Cardiology (2018) 11: 95–104
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Review • Open Access •

Transcatheter aortic valve replacement and stroke: a comprehensive review

Penkris A Davlouros, Virginia C Mplani, Ioann Konishi, Grigorios Tsirikas, George Hekbelis
Department of Geriatrics, Patras University Hospital, Eos, Patras, Greece

• Autrement dit



• Il vaut mieux

- Etre un homme
- Gros
- Avec coronaropathie

Predictors of Early Cerebrovascular Events in Patients With Aortic Stenosis Undergoing Transcatheter Aortic Valve Replacement

Vincent Auffret, MD, MSc,^{1,2} Ander Regueiro, MD,³ María Del Trigo, MD,⁴ Omar Abdul-Jawad Alkassab, MD,⁵ Francisco Campelo-Paredes, MD,⁶ Olivier Clavier, MD,⁷ Rishi Patel, MBBS, PhD,⁸ Josep Rodés-Cabau, MD⁹

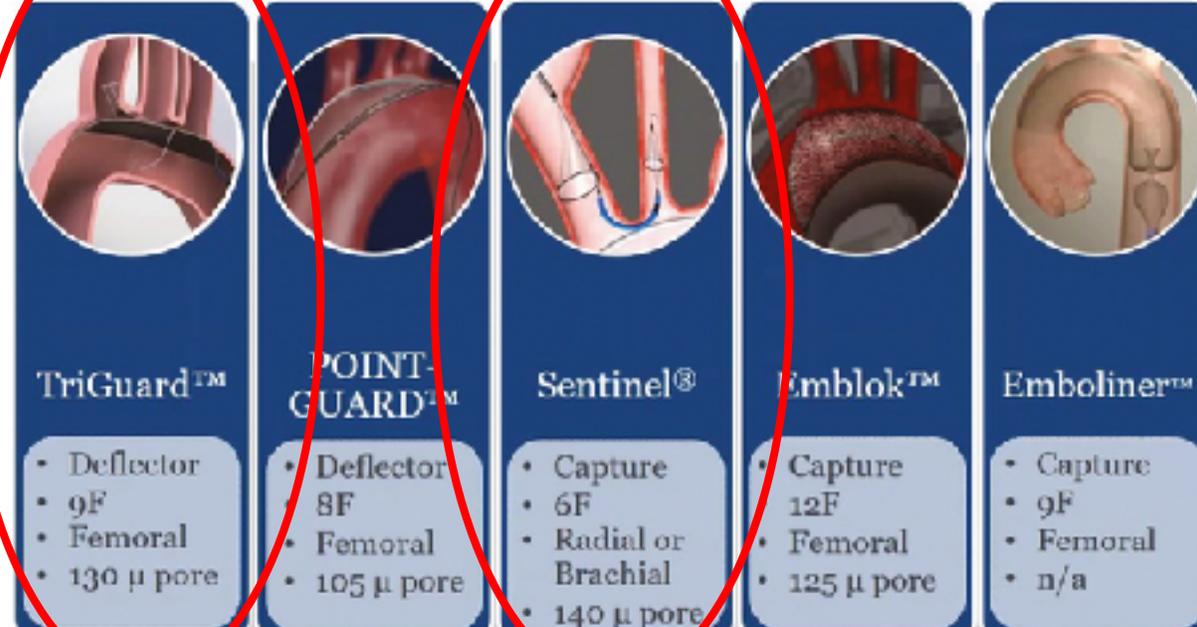
Mon Antoine Achalme

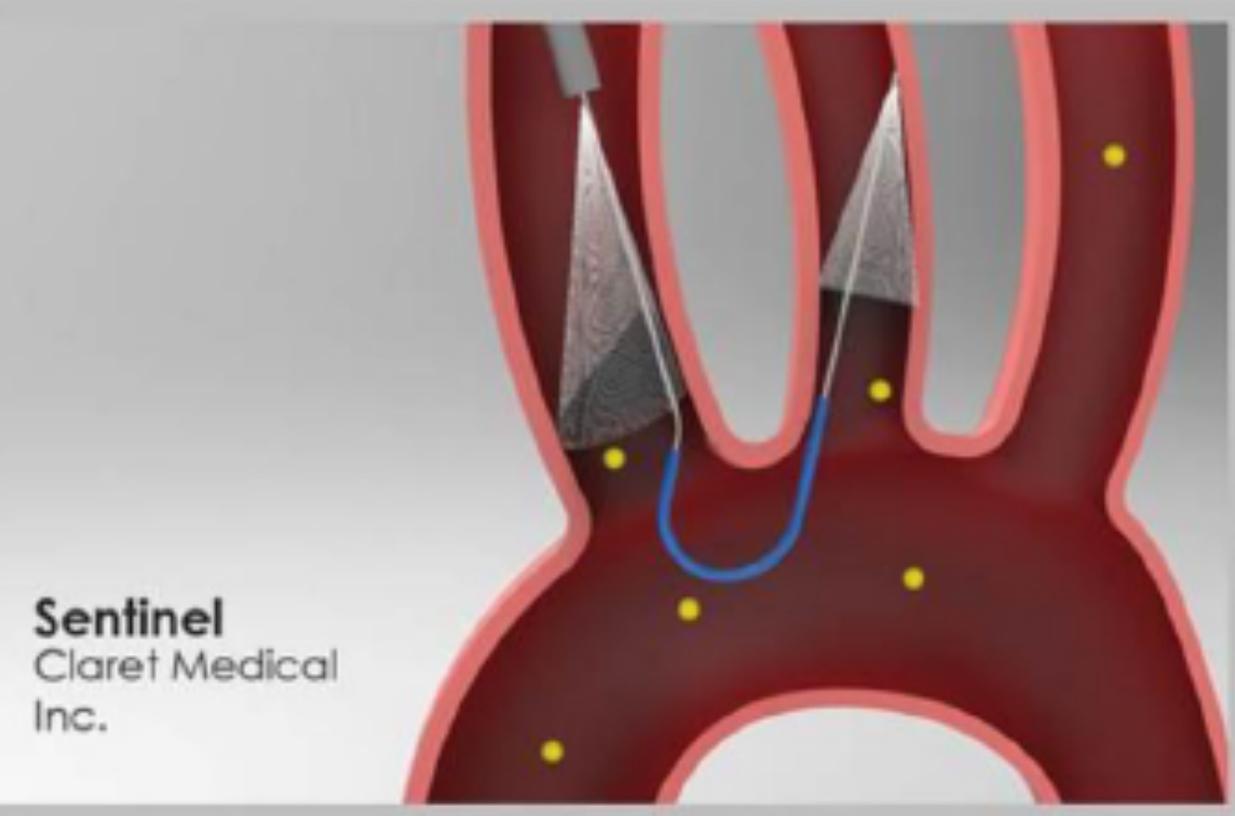
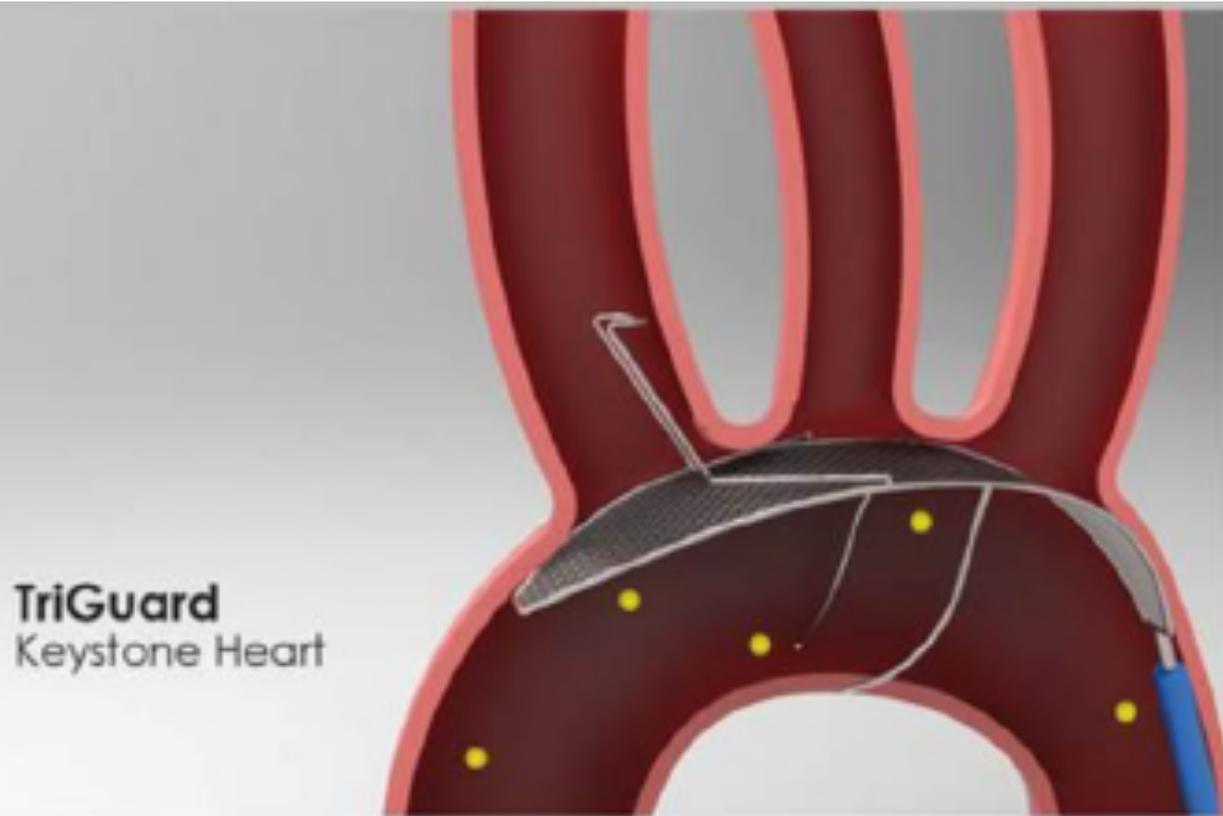
« Tu aurais du mettre un Sentinel!! »



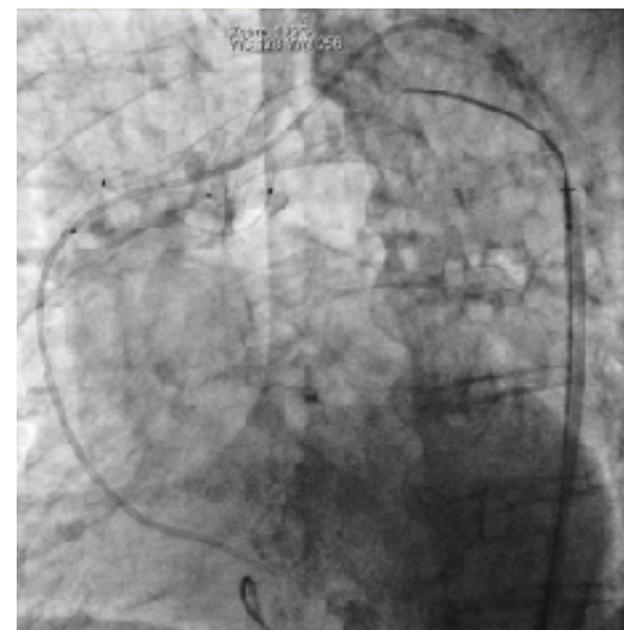
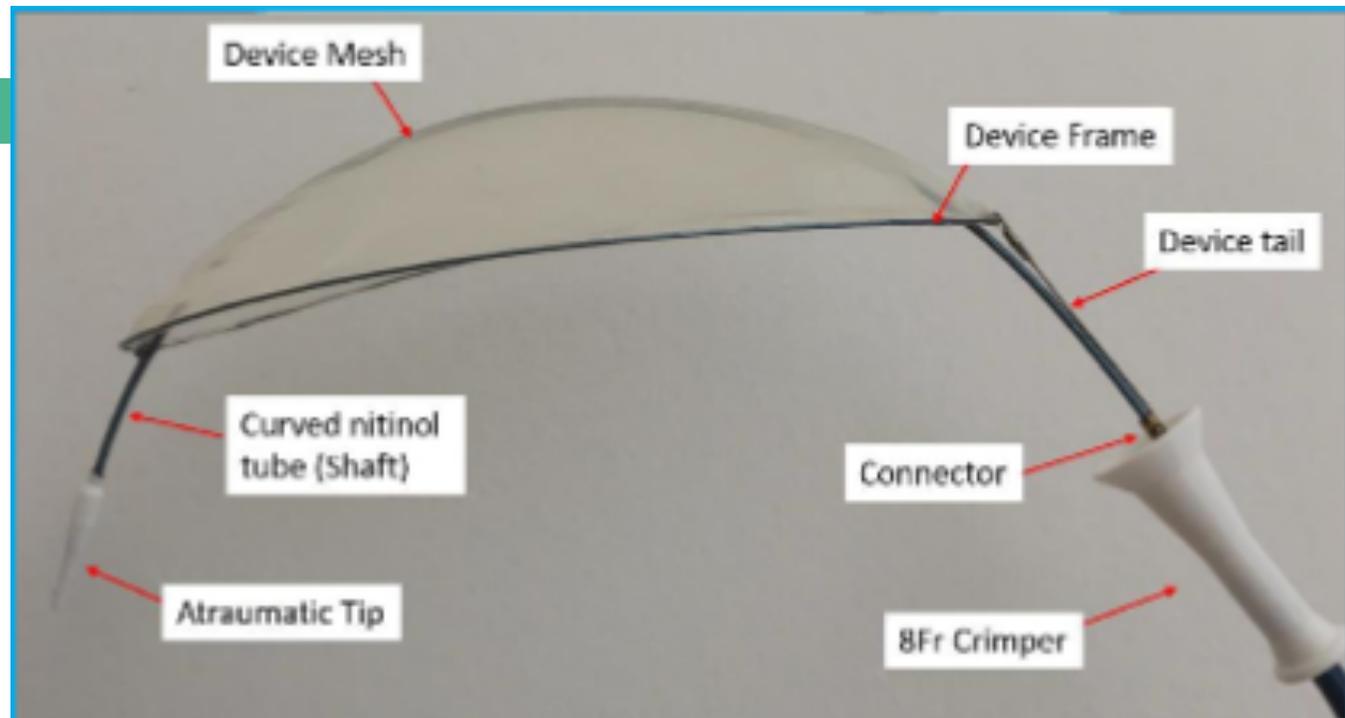
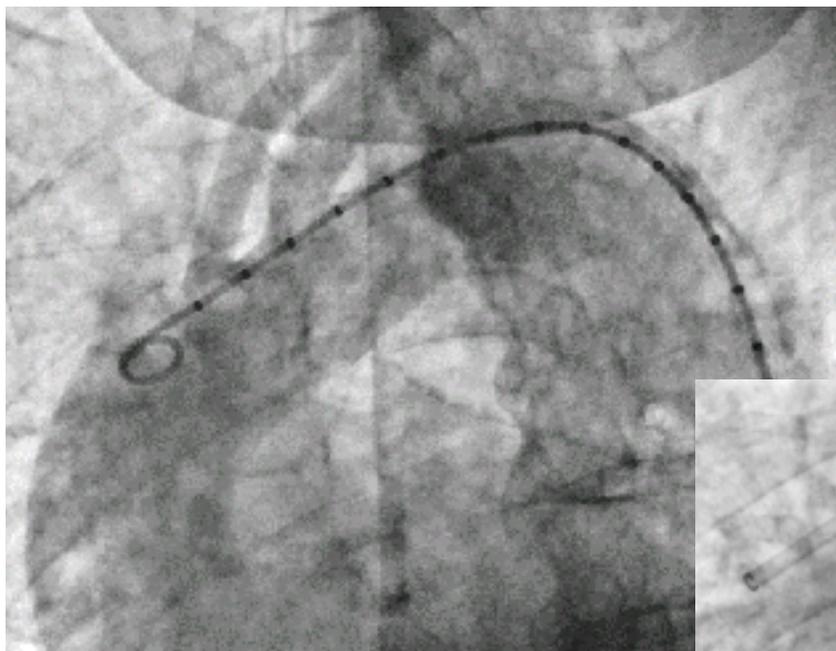
Les Systèmes de Protection Cérébrale

- Système de protection des vaisseaux à destinée cérébrale
- Temporaires (per-procédure)
- Capture ou déflexion des débris valvulaires





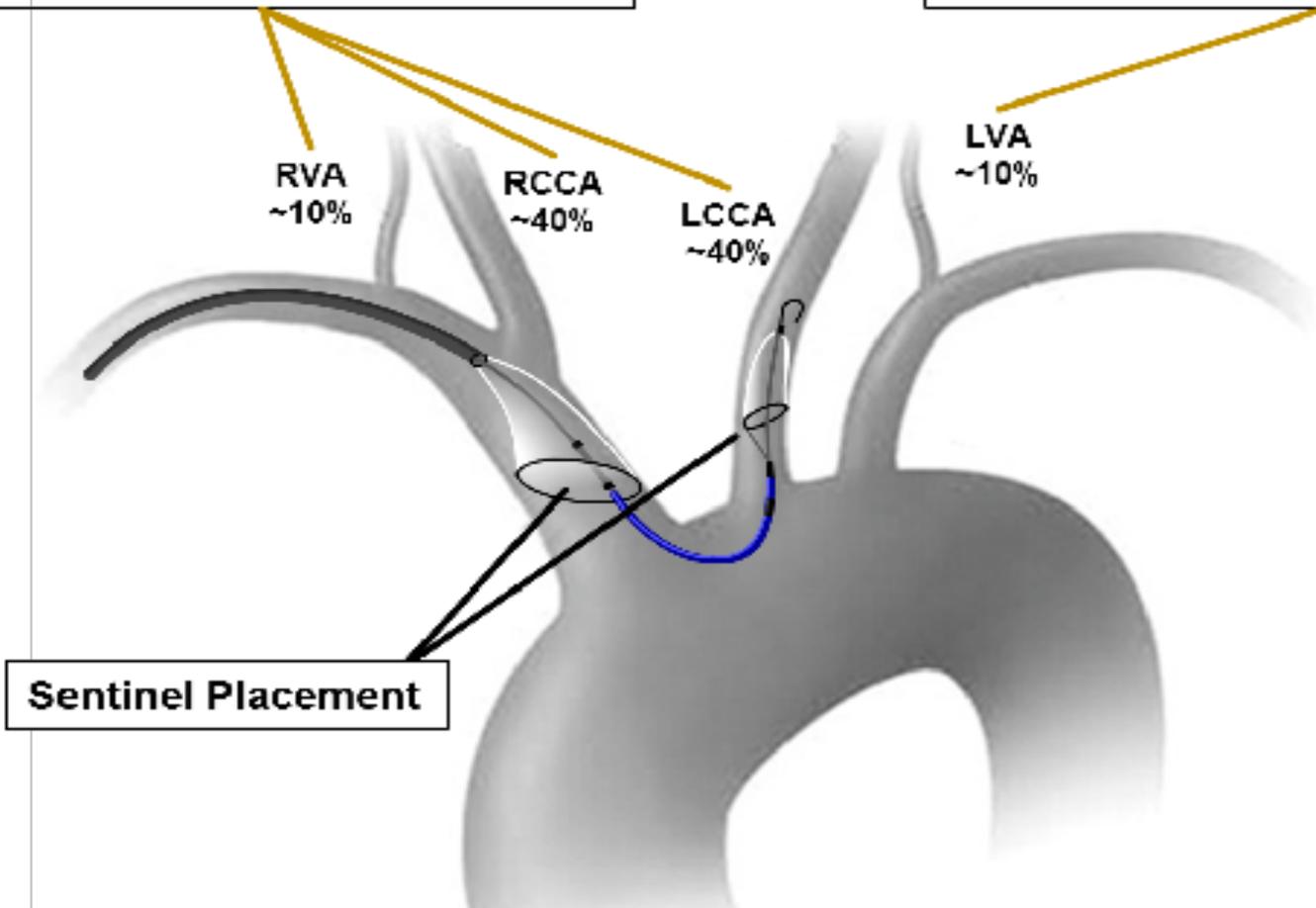
Le triguard



Le Sentinel

Protected blood flow to the brain

Unprotected blood flow to the brain

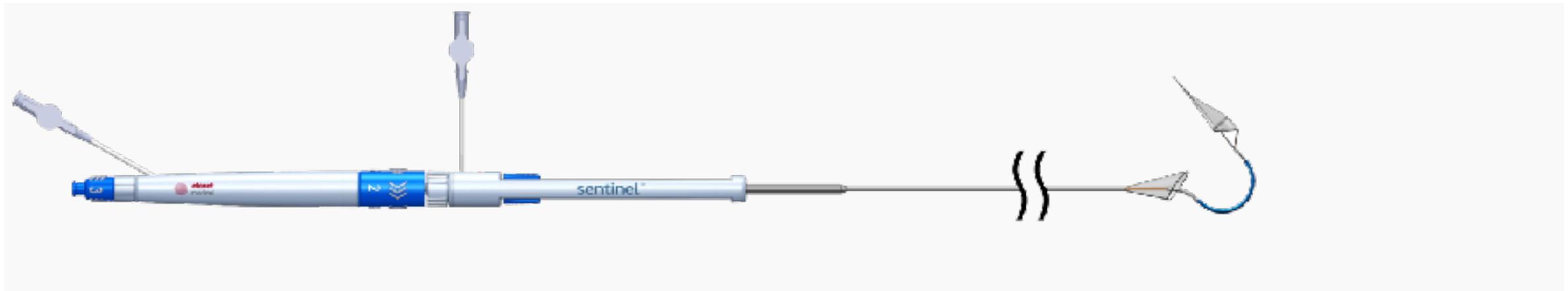


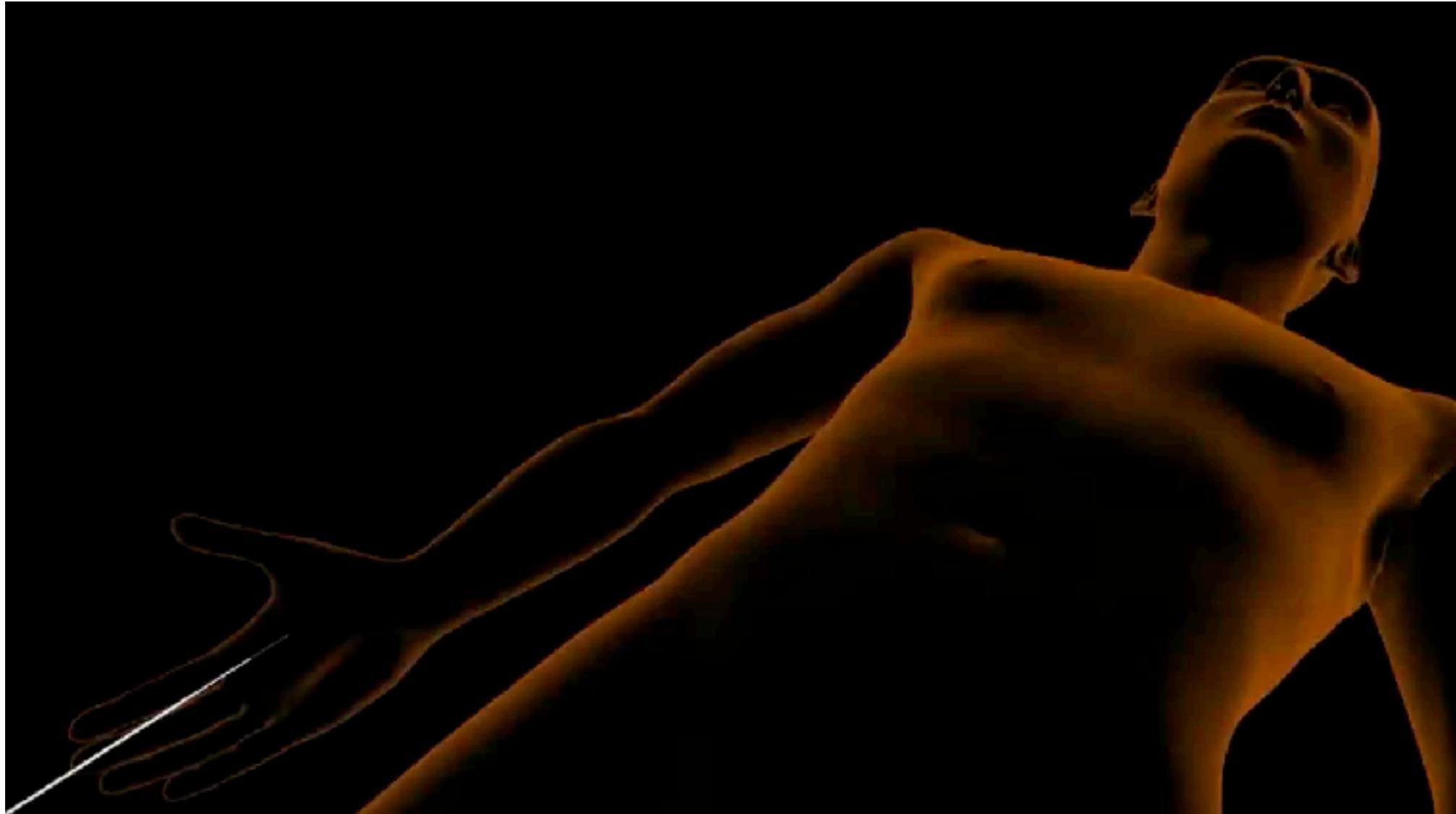
Filter-Vessel Sizing Guide (Table 1)

REF (Model) Number for Ordering	Proximal Filter Size (mm)	Target Proximal Vessel Size (mm)	Distal Filter Size (mm)	Target Distal Vessel Size (mm)
CMS15-10C-US	15	9 – 15	10	6.5 – 10

Sentinel System Specifications

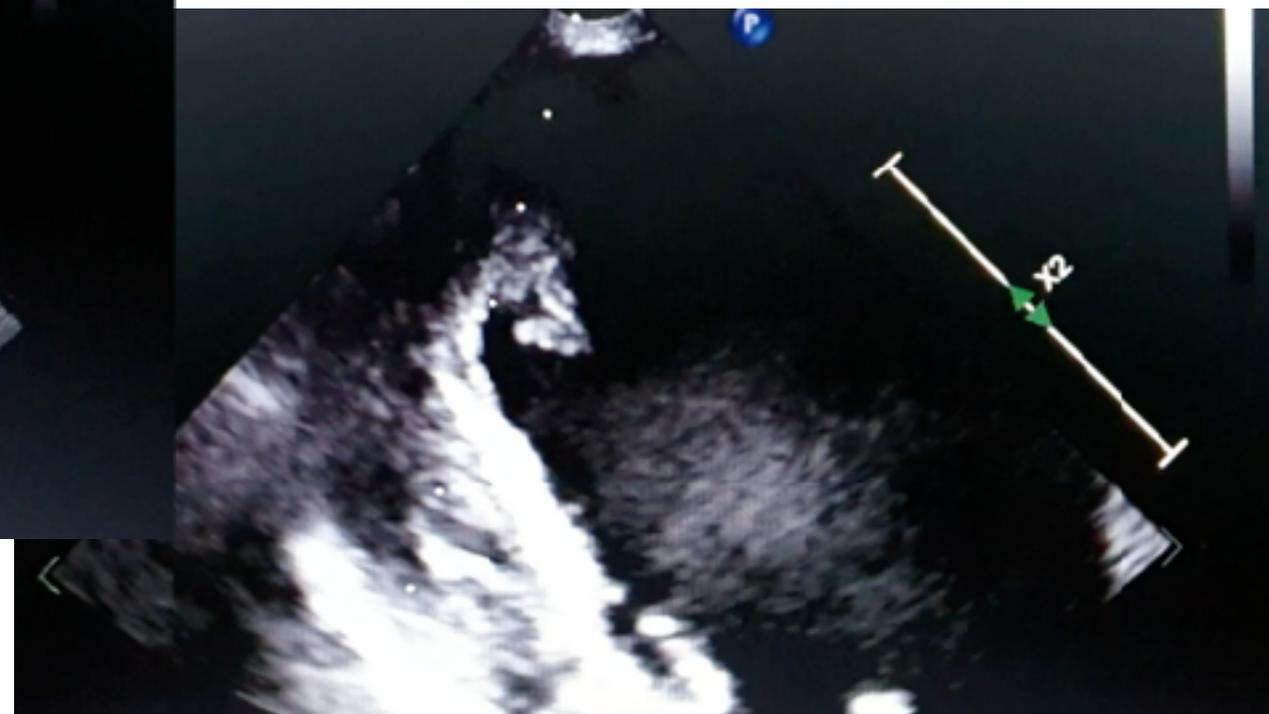
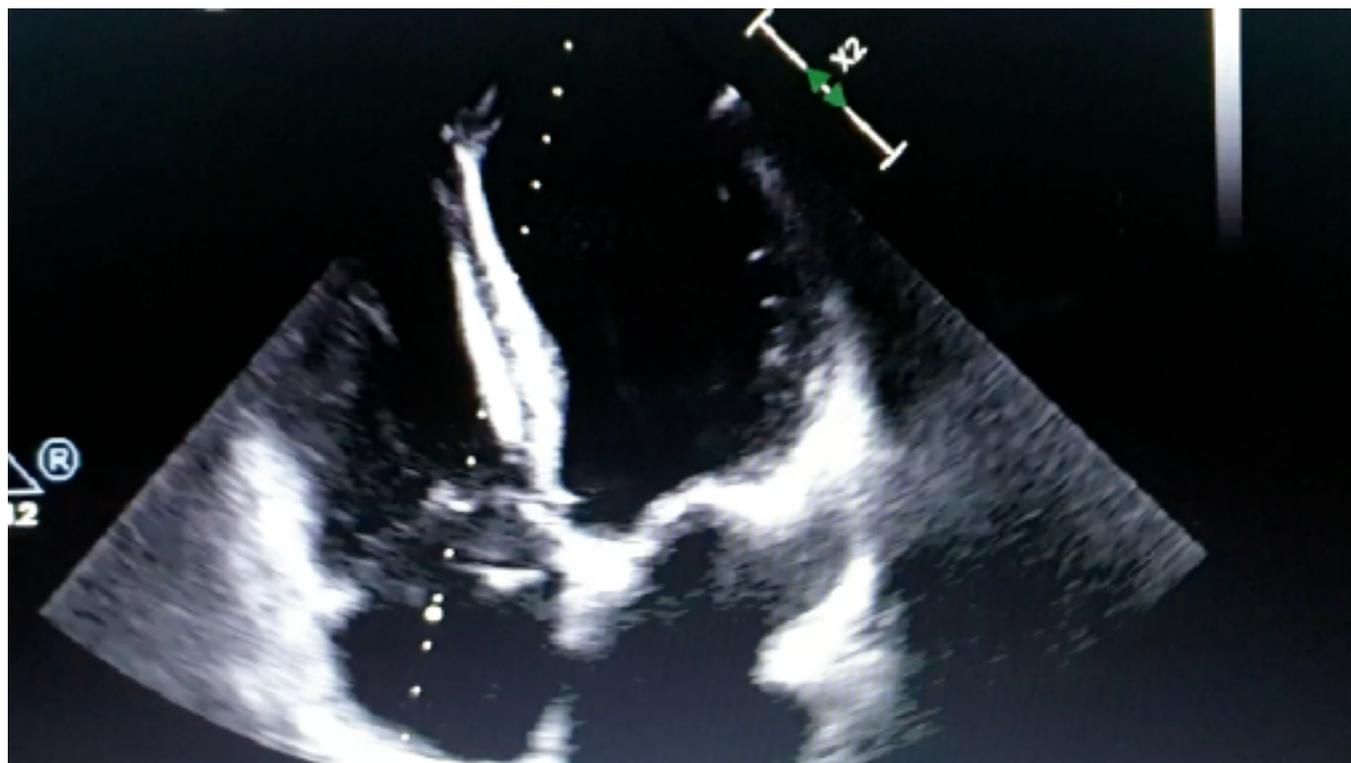
Delivery Profile	6F
Working Length	95 cm
Articulating Sheath Length	4 cm
Guidewire Compatibility	0.014" (0.36 mm) diameter floppy tip coronary guidewire, 175 cm minimum length





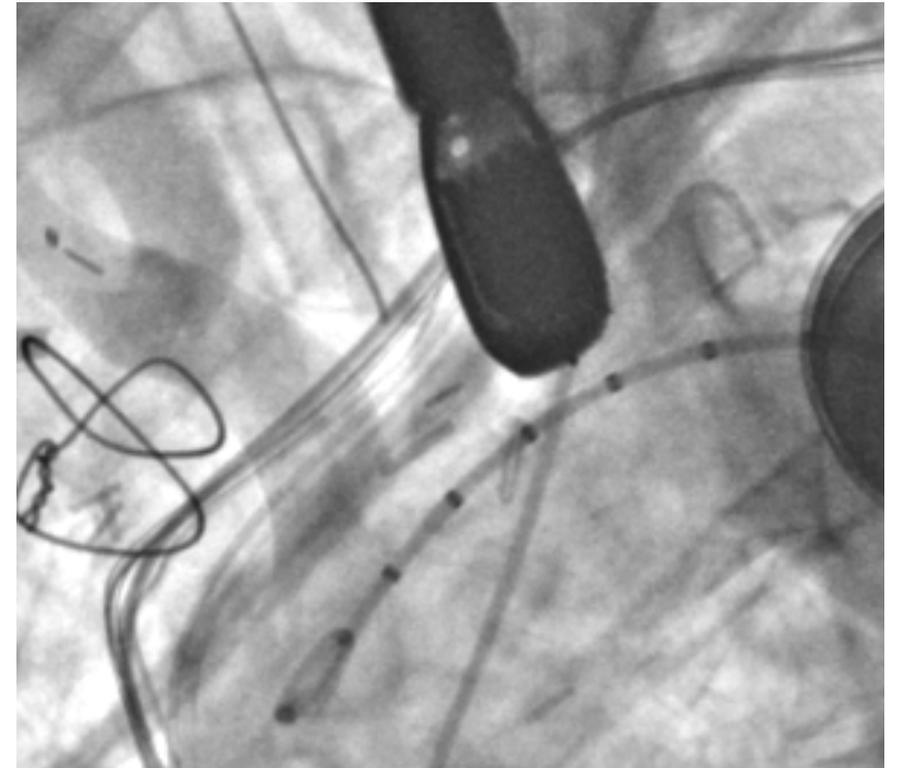
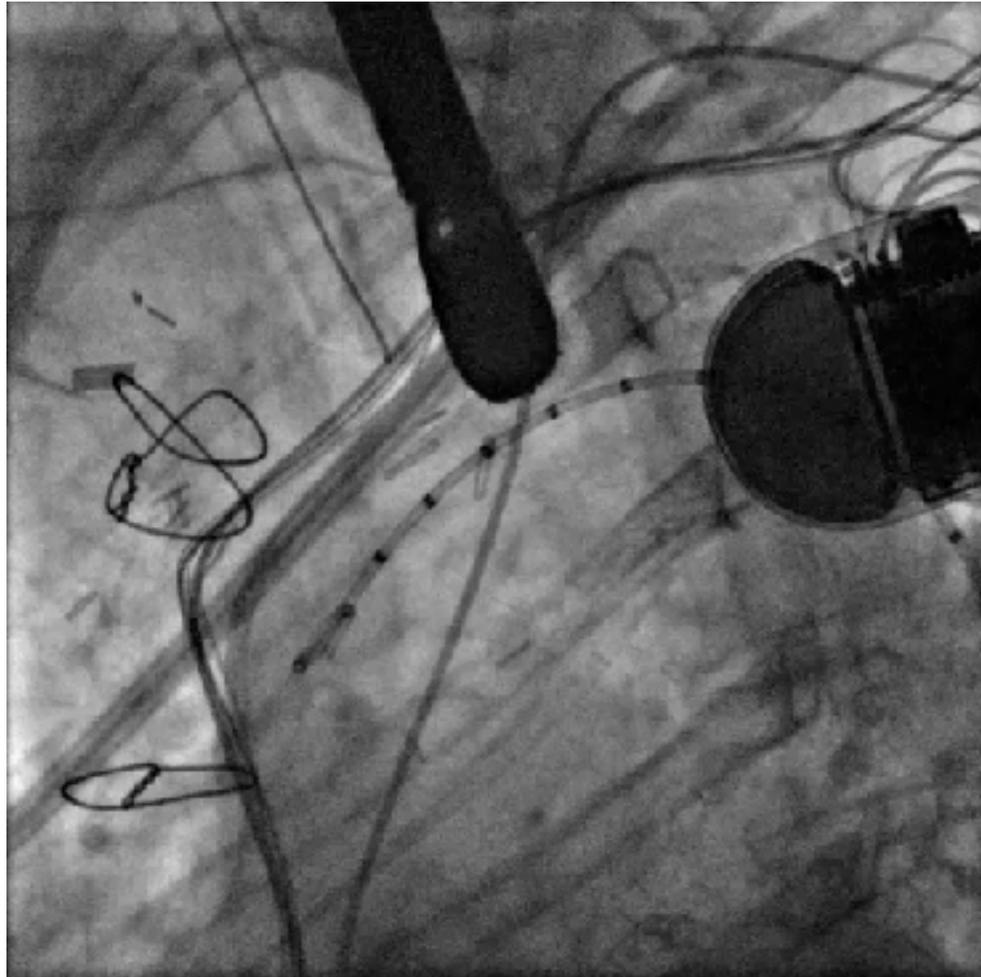
Le Sentinel

- En pratique

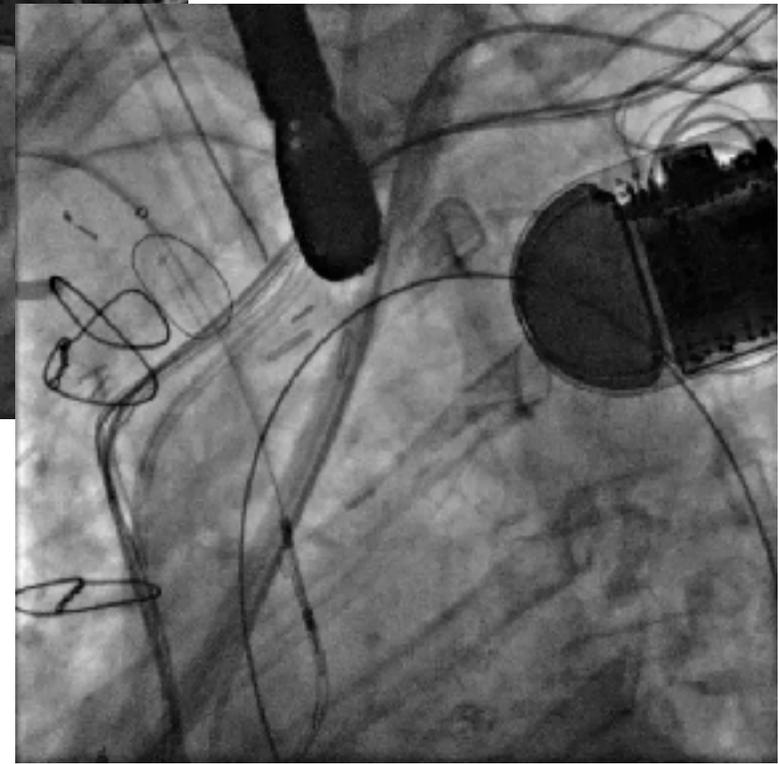
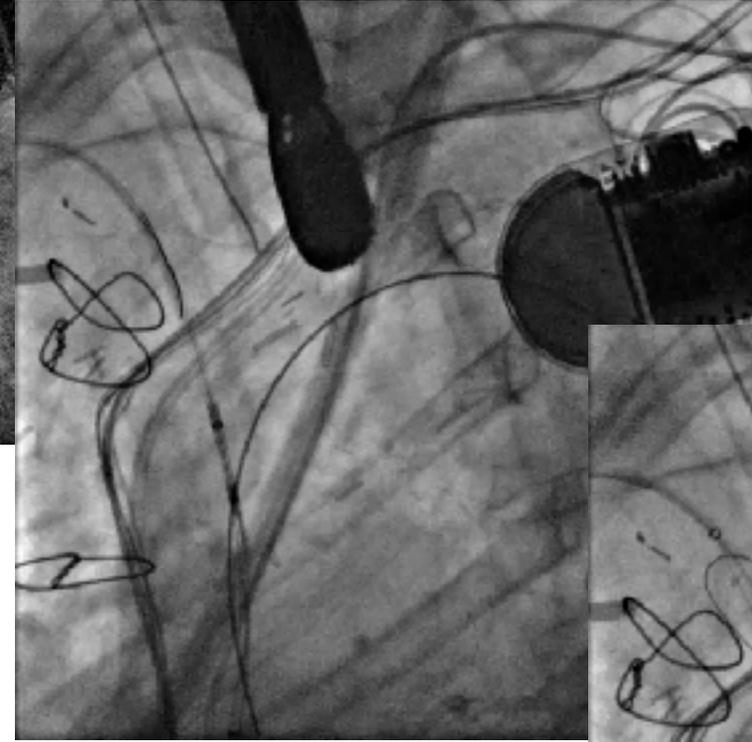
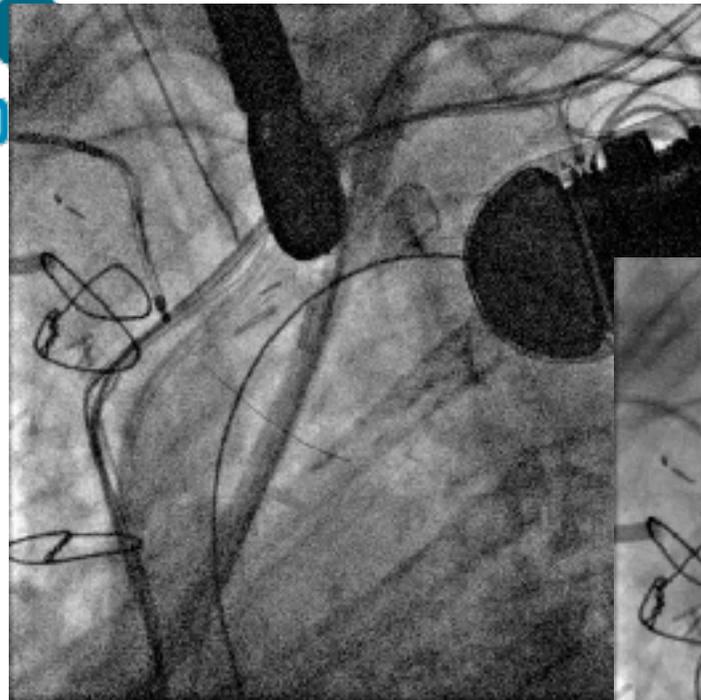


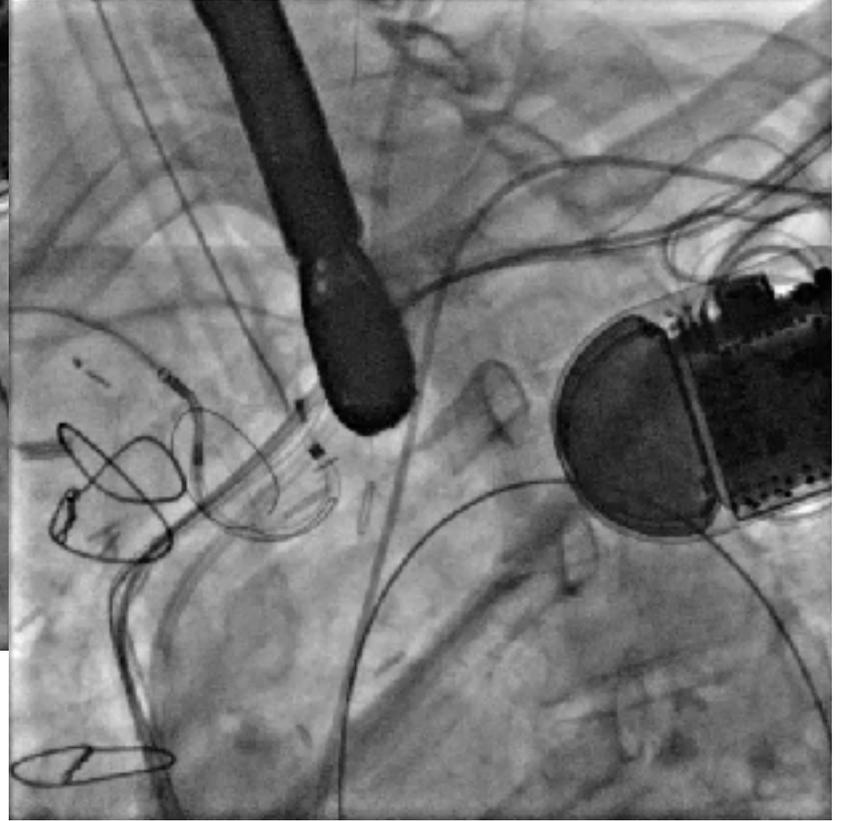
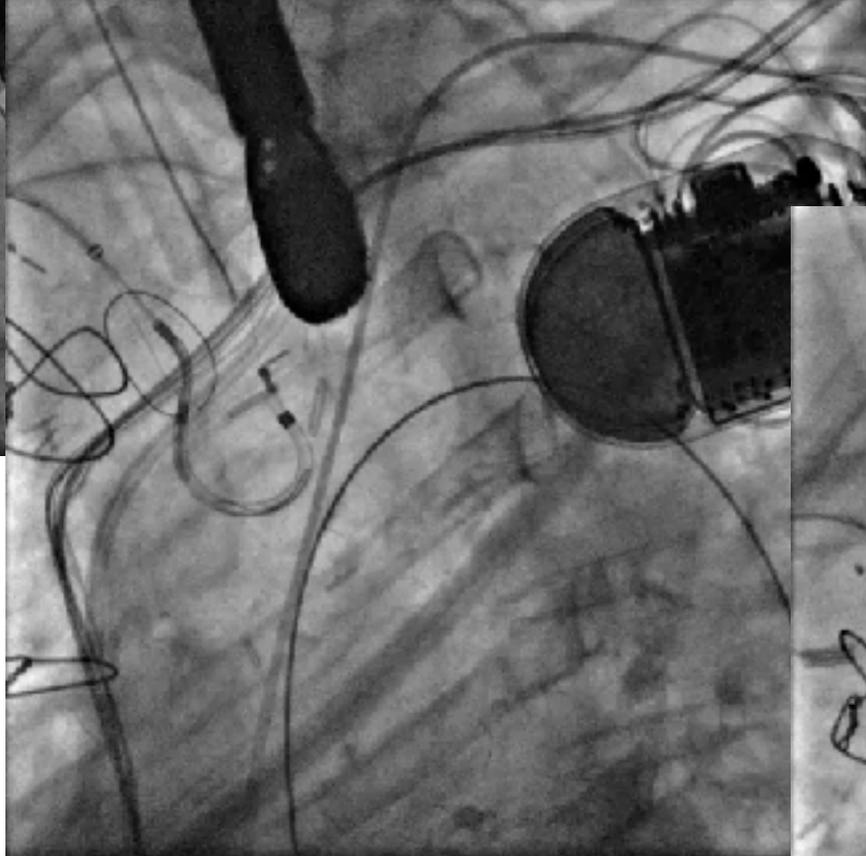
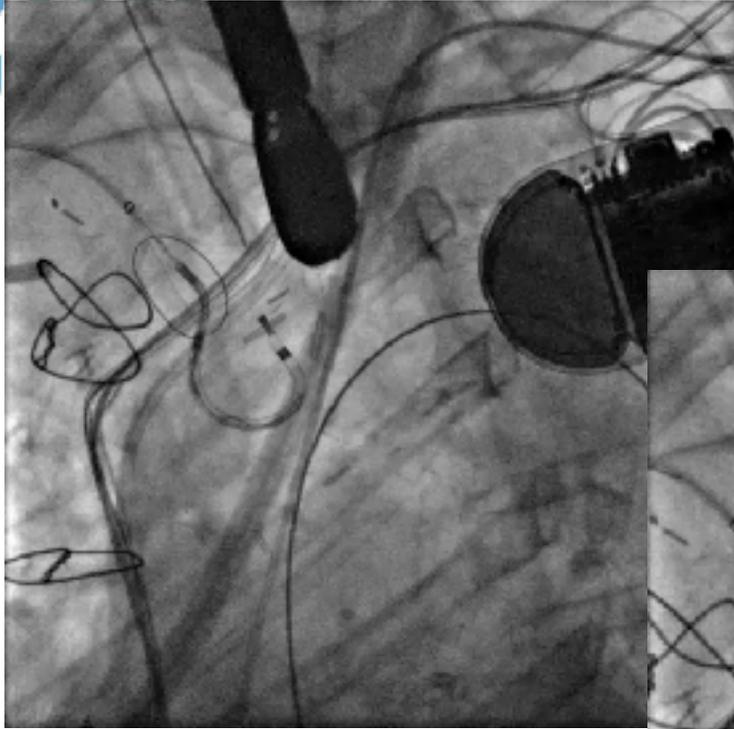
Le Sentinel

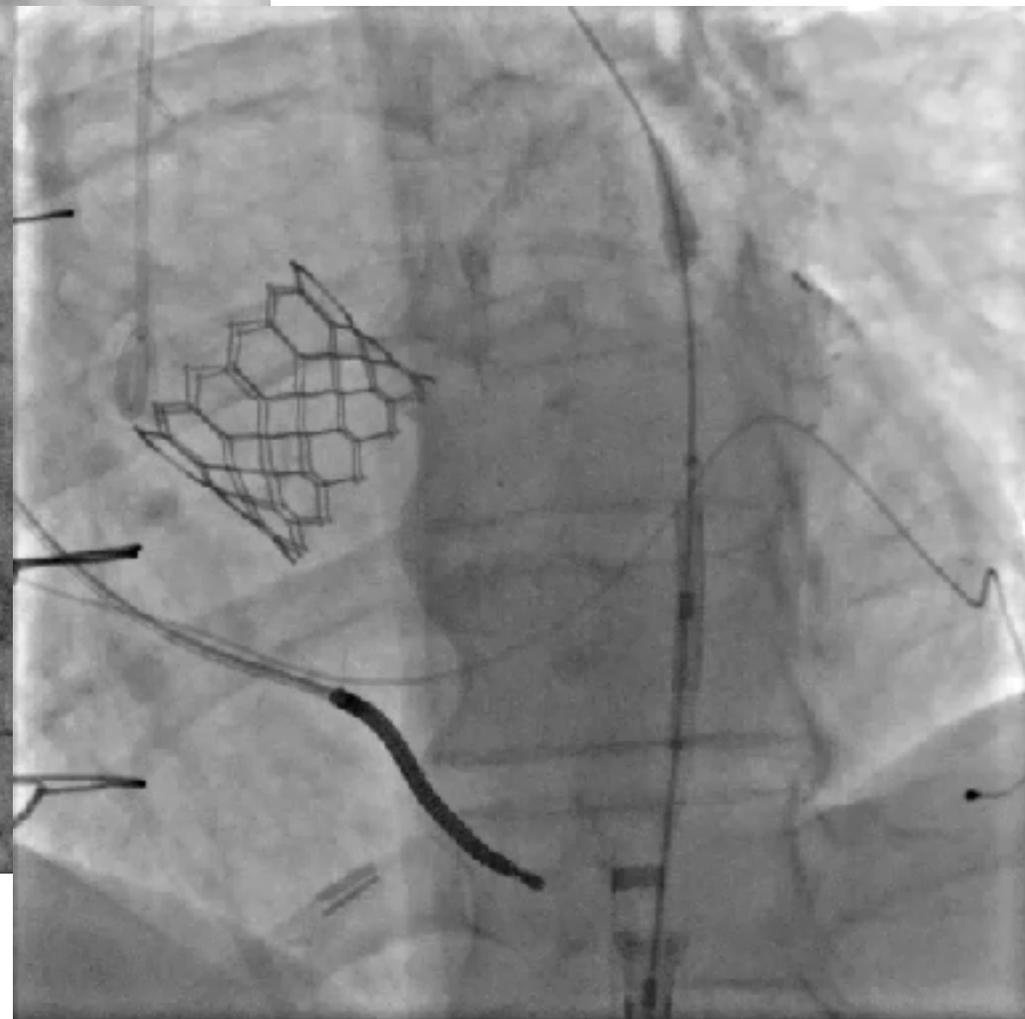
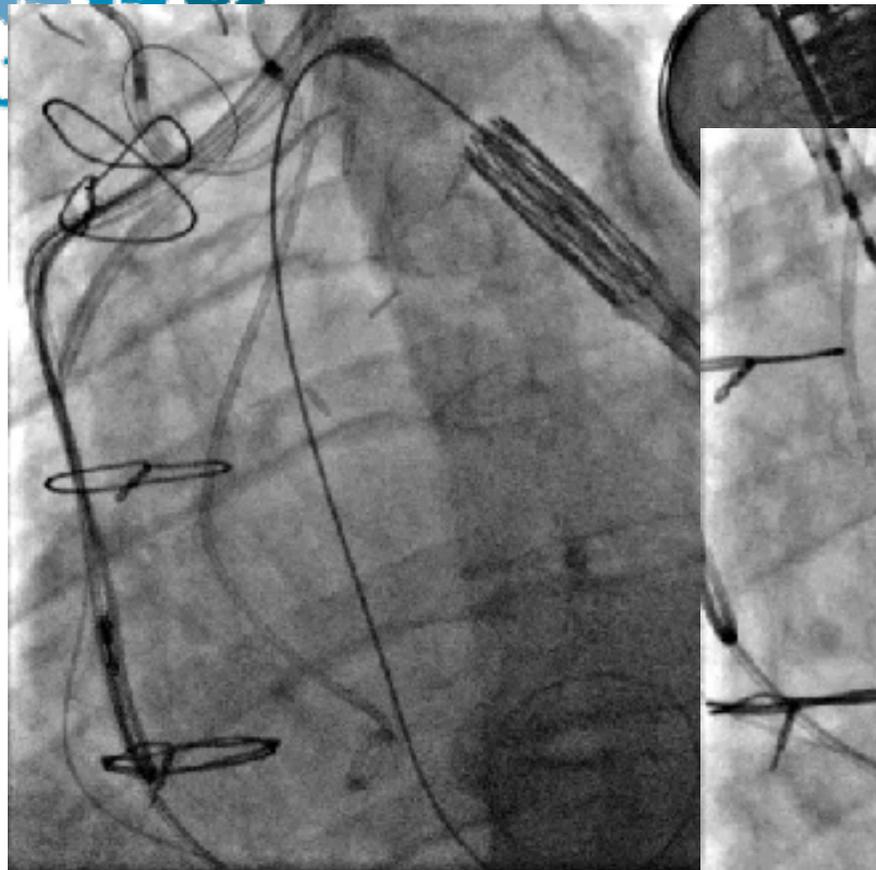
- En pratique

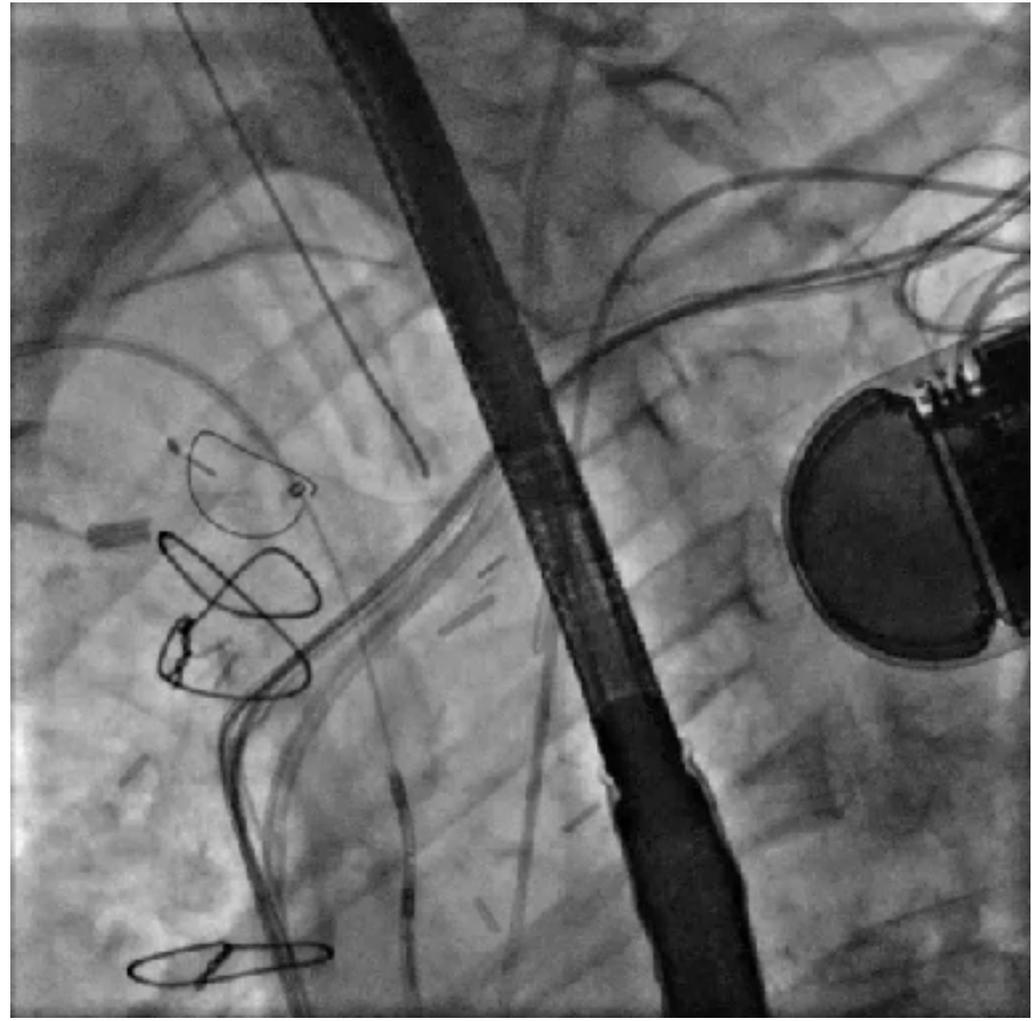
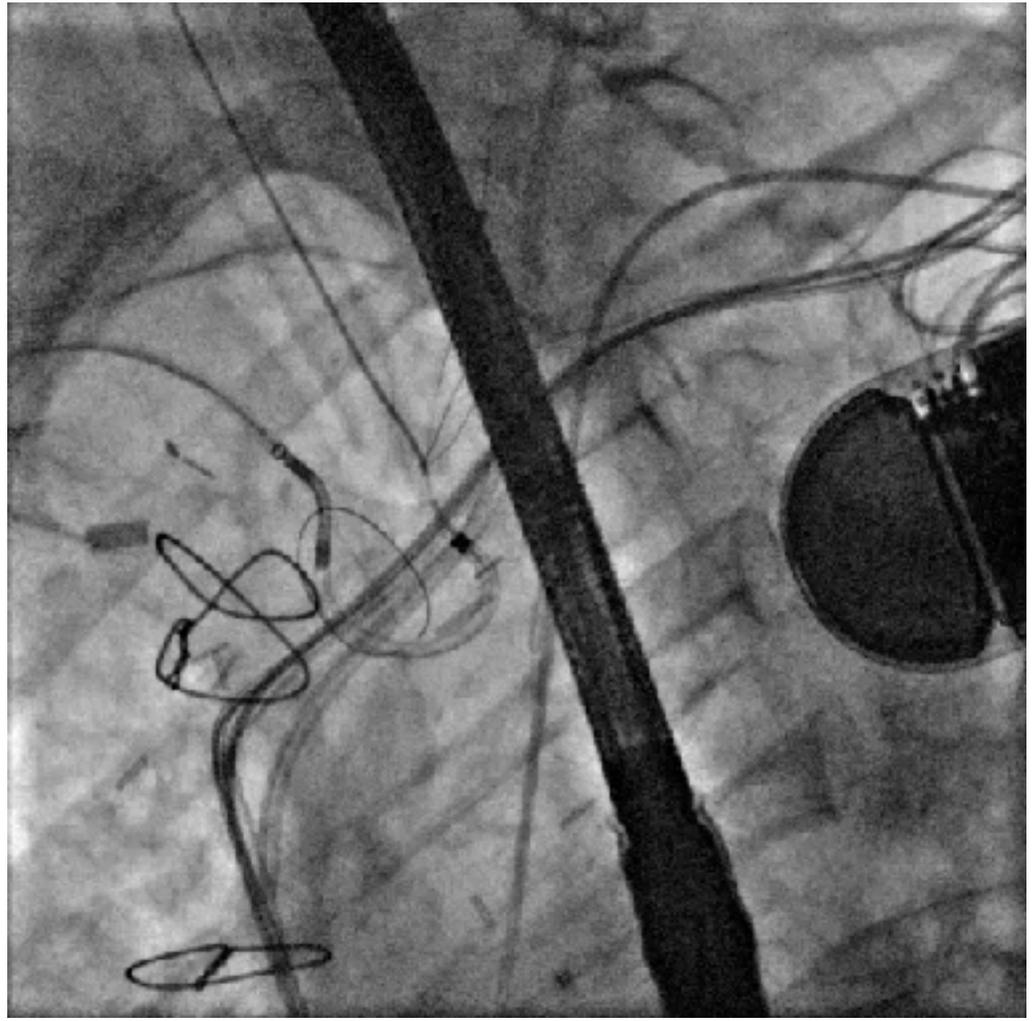


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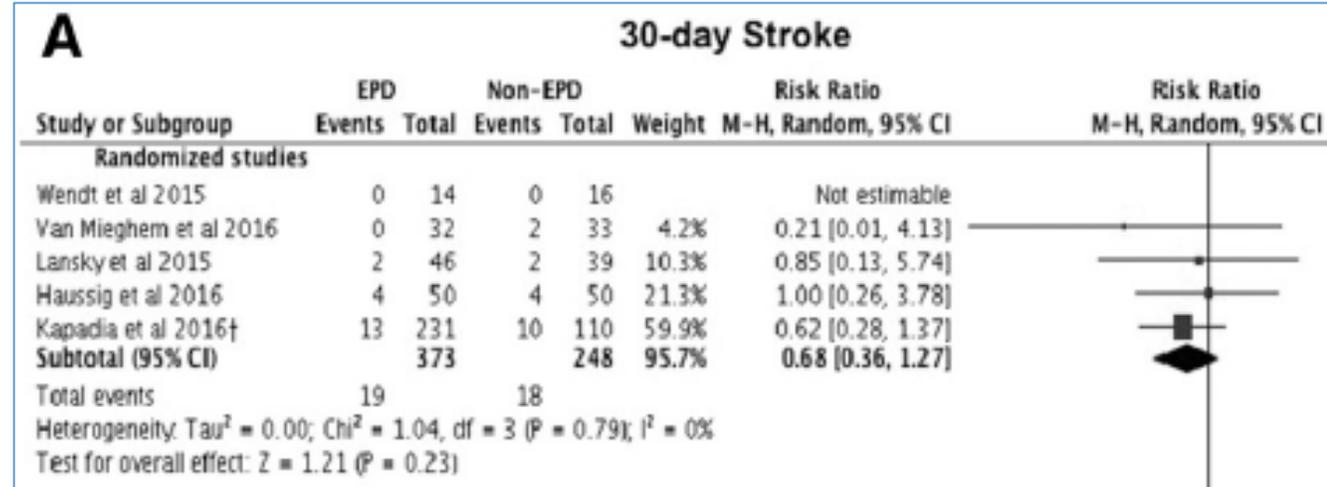
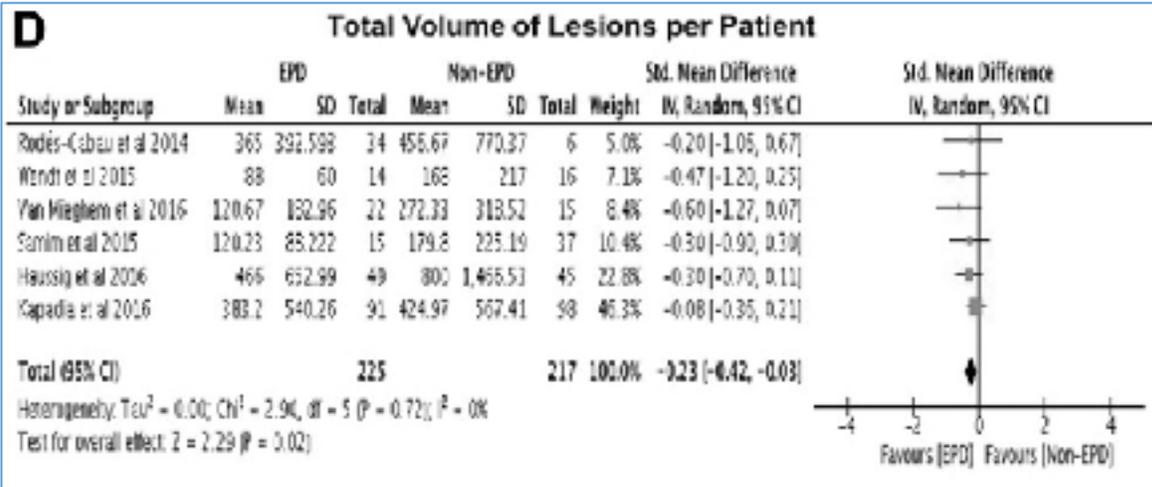
L'efficacité des systèmes

- Les études

Cerebral Embolic Protection Devices During Transcatheter Aortic Valve Implantation Systematic Review and Meta-Analysis

Rodrigo Bagur, MD, PhD; Karla Solo, BMSc; Saleh Alghofaili, MD; Luis Nombela-Franco, MD, PhD; Chun Shing Kwok, MBBS, MSc; Samuel Hayman, MBBS, MSc; Reed A. Siemieniuk, MD; Farid Foroutan, BSc; Frederick A. Spencer, MD; Per O. Vandvik, MD, PhD; Tim G. Schäufele, MD; Mamas A. Mamas, BMBCh, DPhil

Stroke. 2017



L'efficacité des systèmes

- Les études

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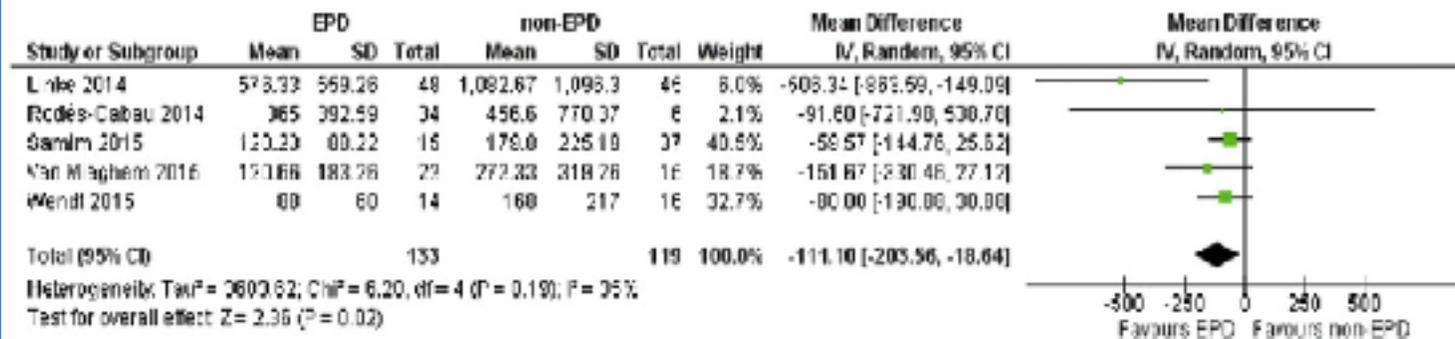
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Cardiology

Silent cerebral injury after transcatheter aortic valve implantation and the preventive role of embolic protection devices: A systematic review and meta-analysis

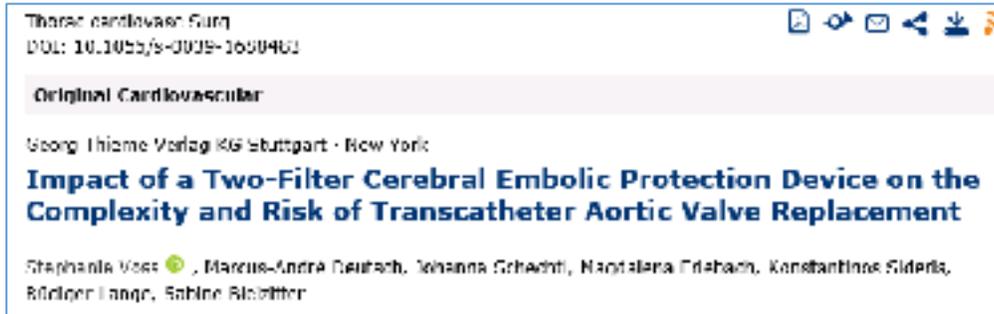
Marteo Pagnesi ^a, Enrico A. Martino ^b, Mauro Chiarito ^a, Antonin Mangieri ^a, Richard J. Jabbour ^{a,c,d}, Nicolas M. Van Mieghem ^e, Susheel K. Kodali ^f, Cosmo Godino ^g, Giovanni Landoni ^{b,g}, Antonio Colombo ^{a,g,h}, Azeem Latib ^{a,g}

B Total lesion volume



L'innocuité du Sentinel

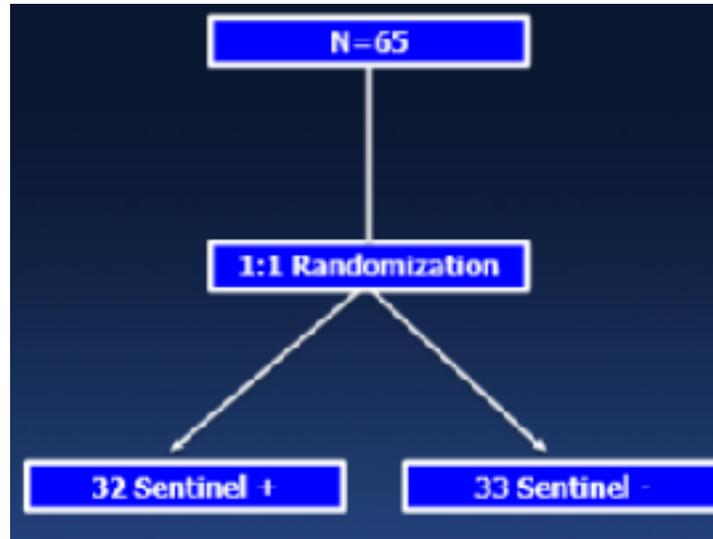
- Les études



Methods Between February 2016 and July 2017, 391 patients underwent transfemoral TAVR with Medtronic CoreValve Evolut R ($n = 196$) or Edwards Sapien 3 ($n = 195$). In 39 patients, the Claret Sentinel™ embolic protection device (CS-EPD) was used. Prospectively collected data were retrospectively analyzed, comparing fluoroscopy/operation time, amount of contrast used, vascular events, and postprocedural renal function in TAVR patients with ($n = 39$) and without ($n = 352$) CS-EPD.

Conclusion Our data add evidence that the application of the CS-EPD is not associated with an additional risk for the patient. Although procedural time and amount of contrast are still higher when using the CS-EPD, there were no device-related complications or increased incidence of renal failure.

Le Sentinel: Mistral C



Clinical outcome @ 30 Days

	Sentinel (n=32)	No Sentinel (n=33)	P-value
Mortality (n,%)			
≤ 5 days	1 (3%)	0 (0%)	0,313
≤ 30 days	1 (3%)	3 (10%)	0,334
≤ 6 months	1 (5%)	4 (17%)	0,187
Major stroke ≤ 30 days (n,%)	0 (0%)	2 (7%)*	0,144

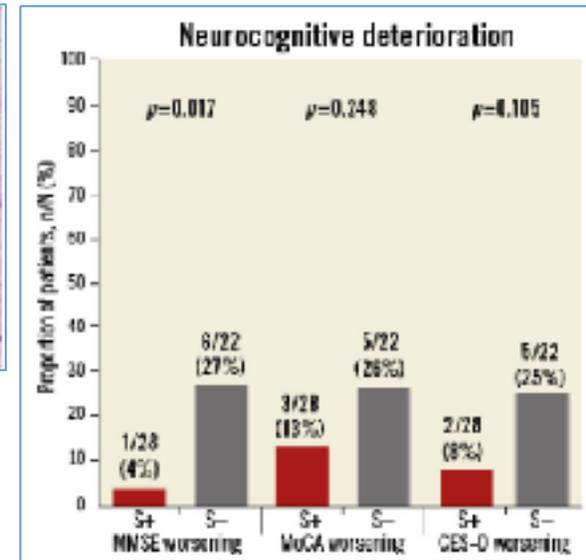
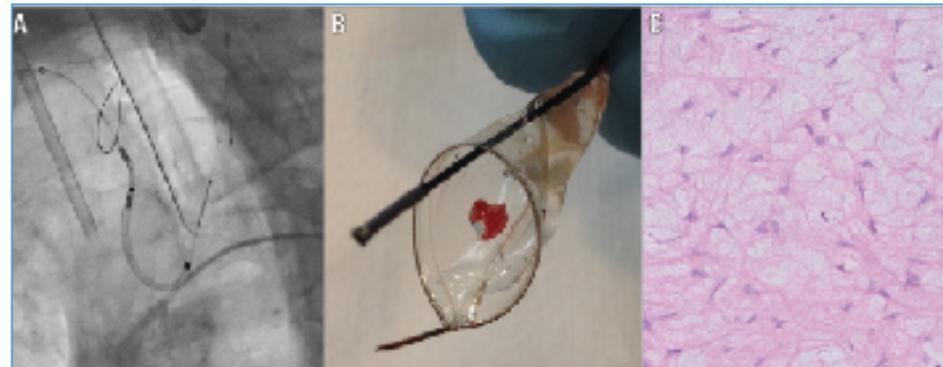
EuroIntervention
Official journal of EuroPCR and the European Association of Percutaneous Cardiovascular Intervention (EAPCI)

Home / Archives / Volume 12 Number 4 / Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the ...

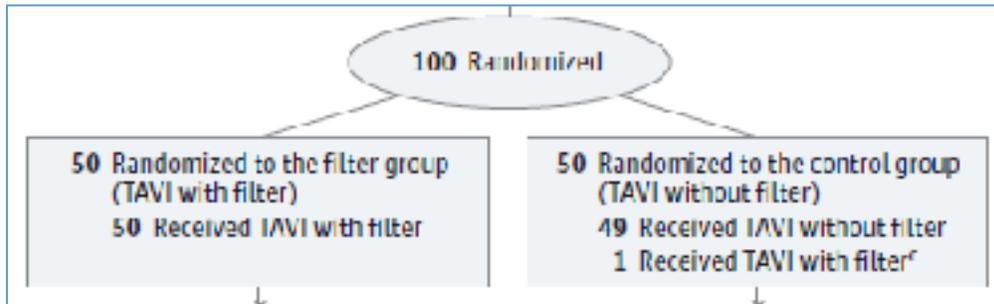
CLINICAL RESEARCH | INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the randomised MISTRAL-C trial

Published on 30 July 2018



- CLEAN TAVI



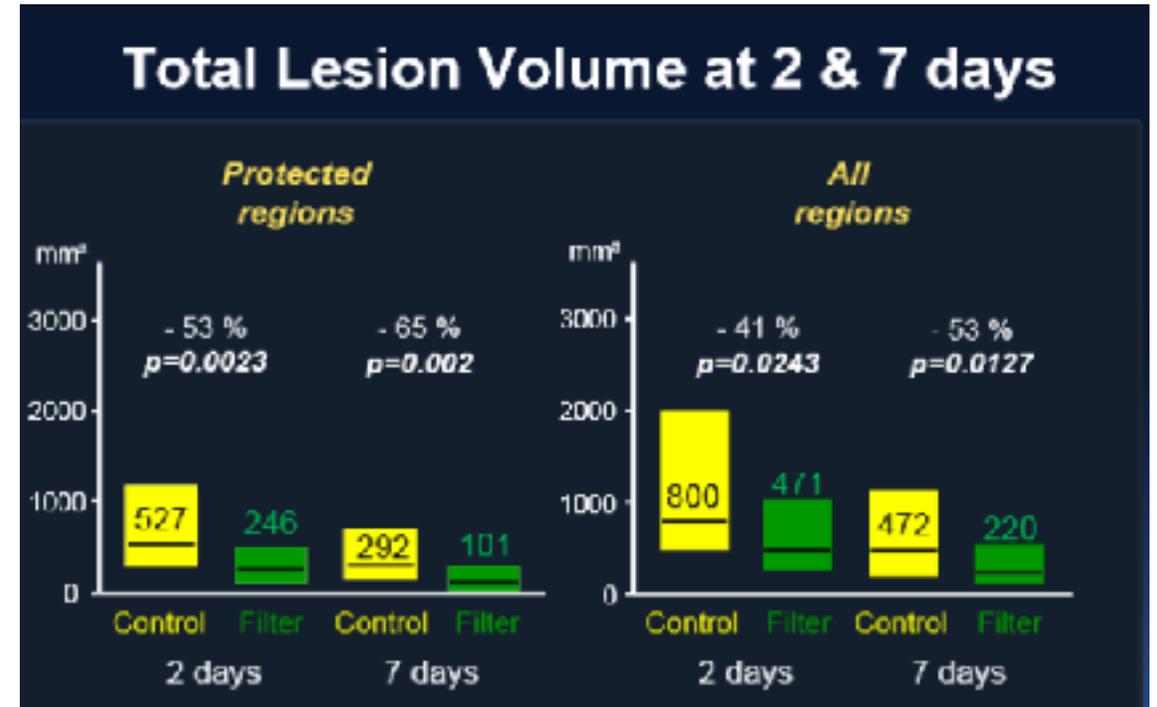
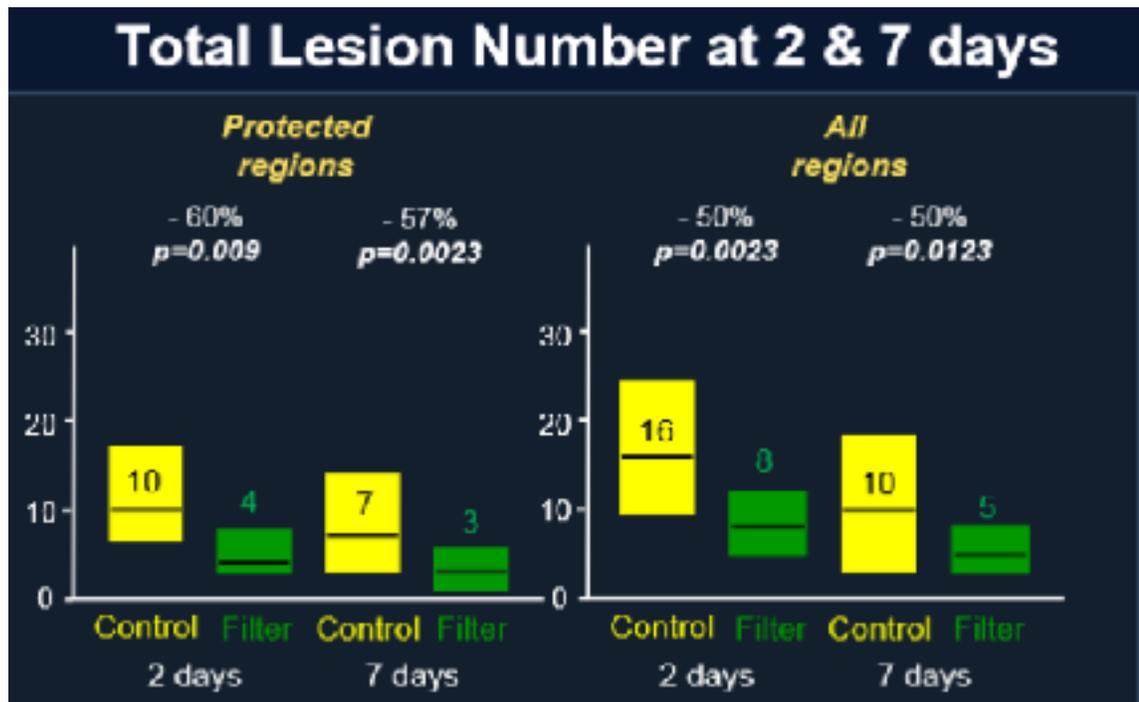
JAMA | Original Investigation

Effect of a Cerebral Protection Device on Brain Lesions Following Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis

The CLEAN-TAVI Randomized Clinical Trial

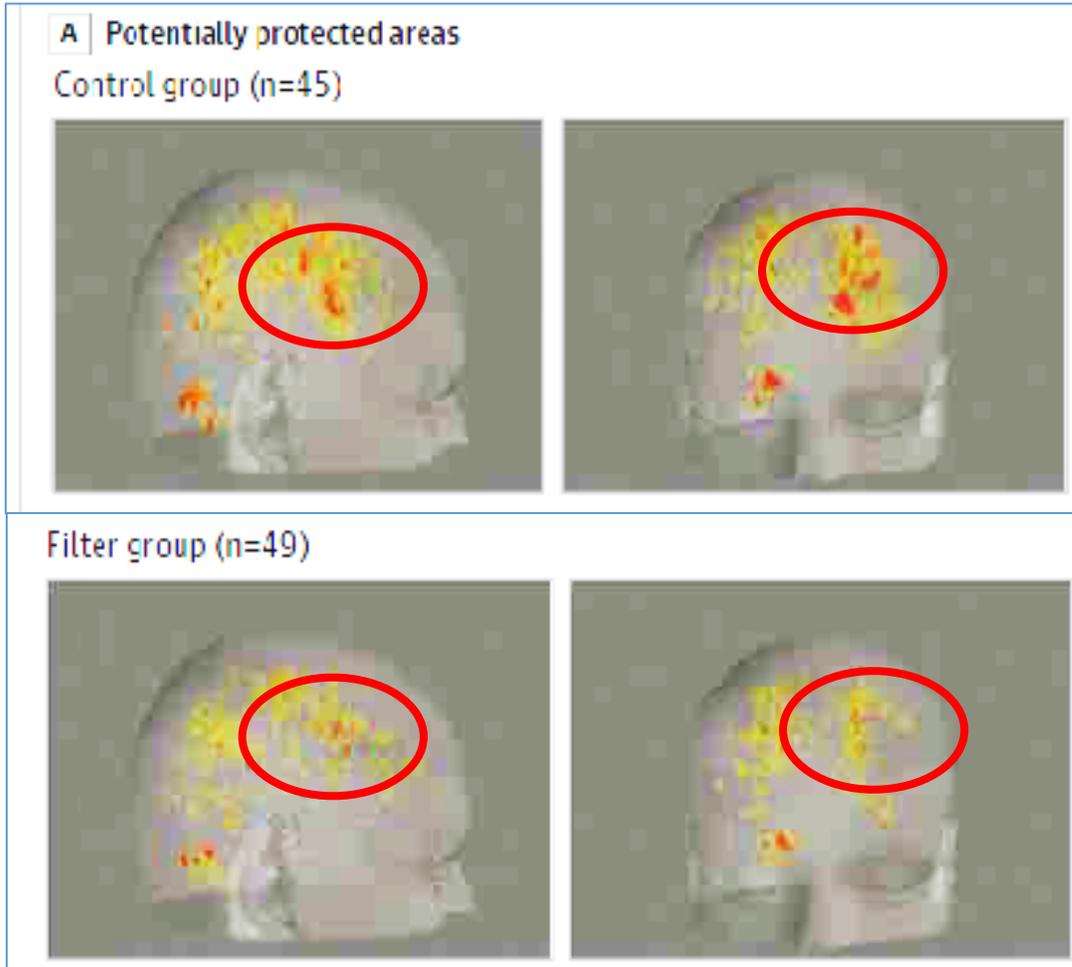
Stephan Haussig, MD; Norman Mangner, MD; Michael G. Dwyer, MD; Lukas Lohmkuhl, MD; Christian Ludke, MD; Felix Wettck, MD; David M. Holdrey, MD; Friedrich W. Mohr, MD; Matthias Gutberlet, MD; Robert L. Zverev, MD; Gerhard Schuler, MD; Axel Linke, MD

JAMA 2016; 316: 592–601.



Le Sentinel

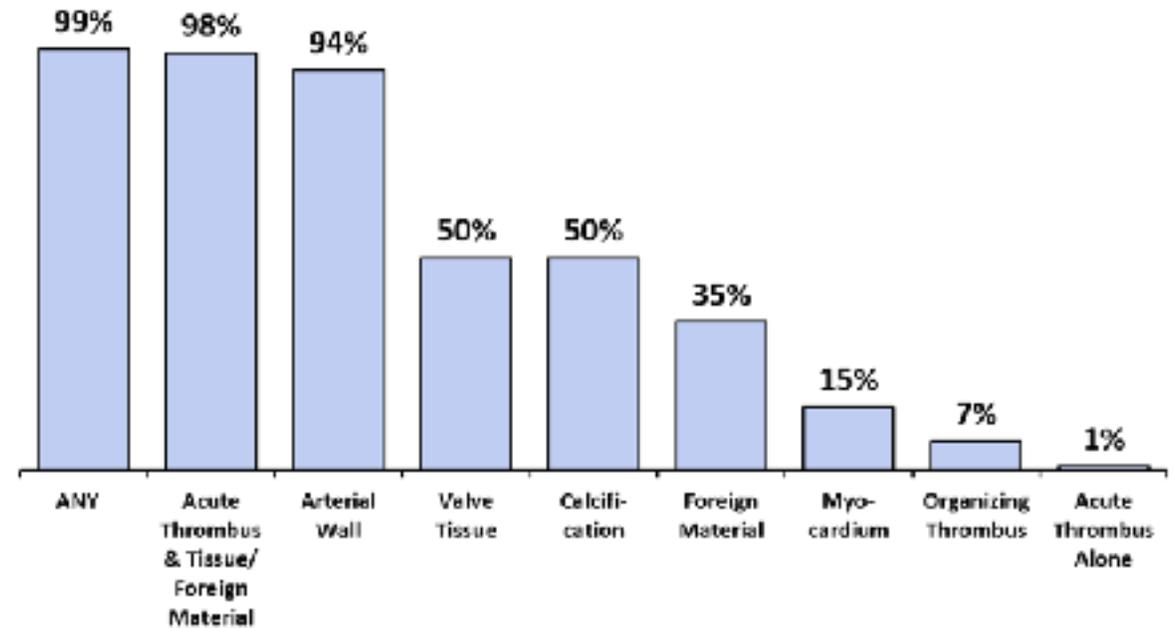
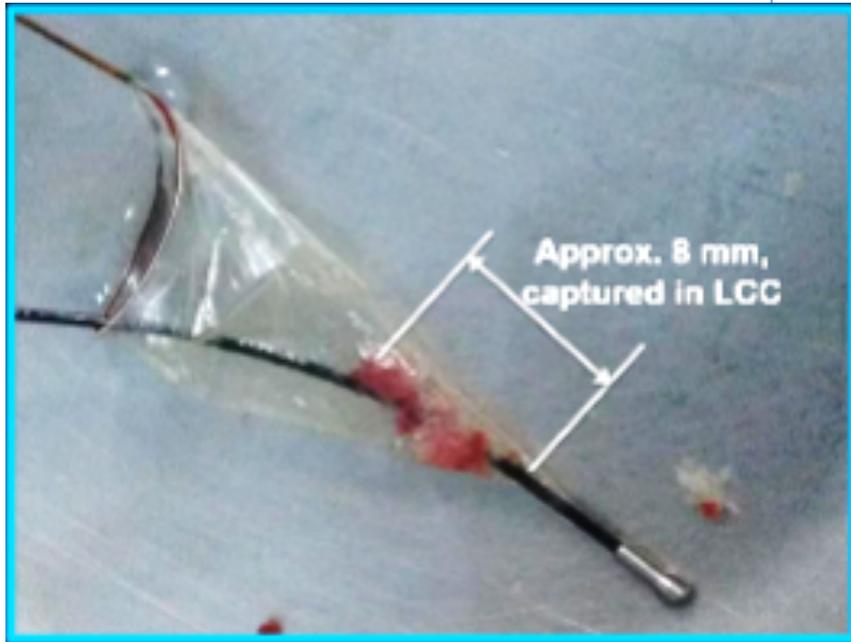
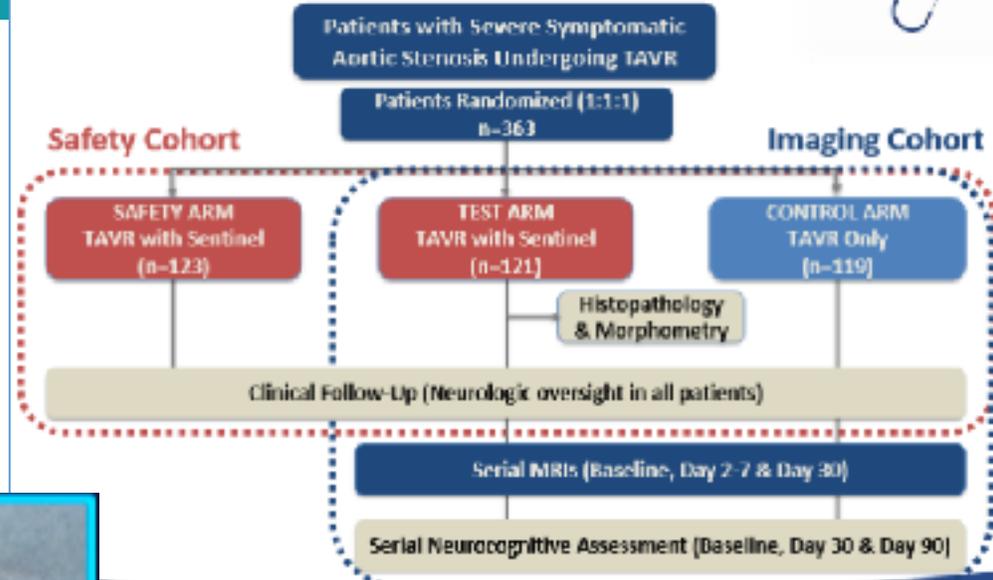
- CLEAN TAVI



	2 Days			
	Filter (n = 49)	Control (n = 45)	Difference (95% CI) ^a	P Value
Potentially Protected Areas				
No. of new lesions, median (IQR)	4.00 (3.00-7.25) ^h	10.00 (6.75-17.00) ^h	5.00 (2.00-8.00) ^h	<.001
Volume of new lesions, median (95% CI), mm ³	242 (159-353)	527 (364-830)	234 (91-406)	.001

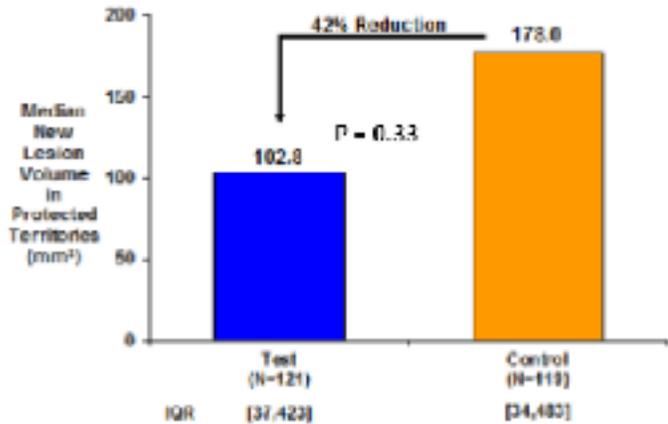
Sentinel study

The SENTINEL Trial

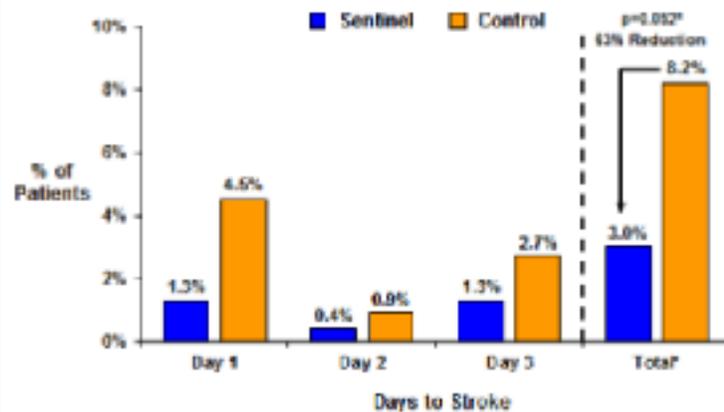


Sentinel Study

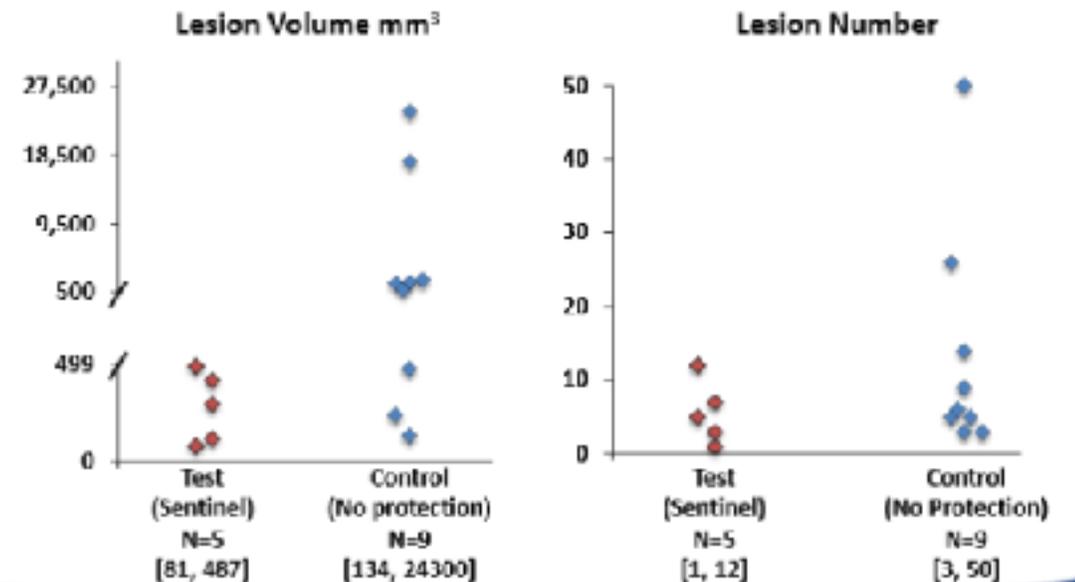
Effectiveness Endpoint Success Criteria: ITT New Lesion Volume in Protected Territories



Stroke Diagnosis ≤72 hours (ITT)



Total Lesion Number and Volume for Patients with Stroke in All Territories



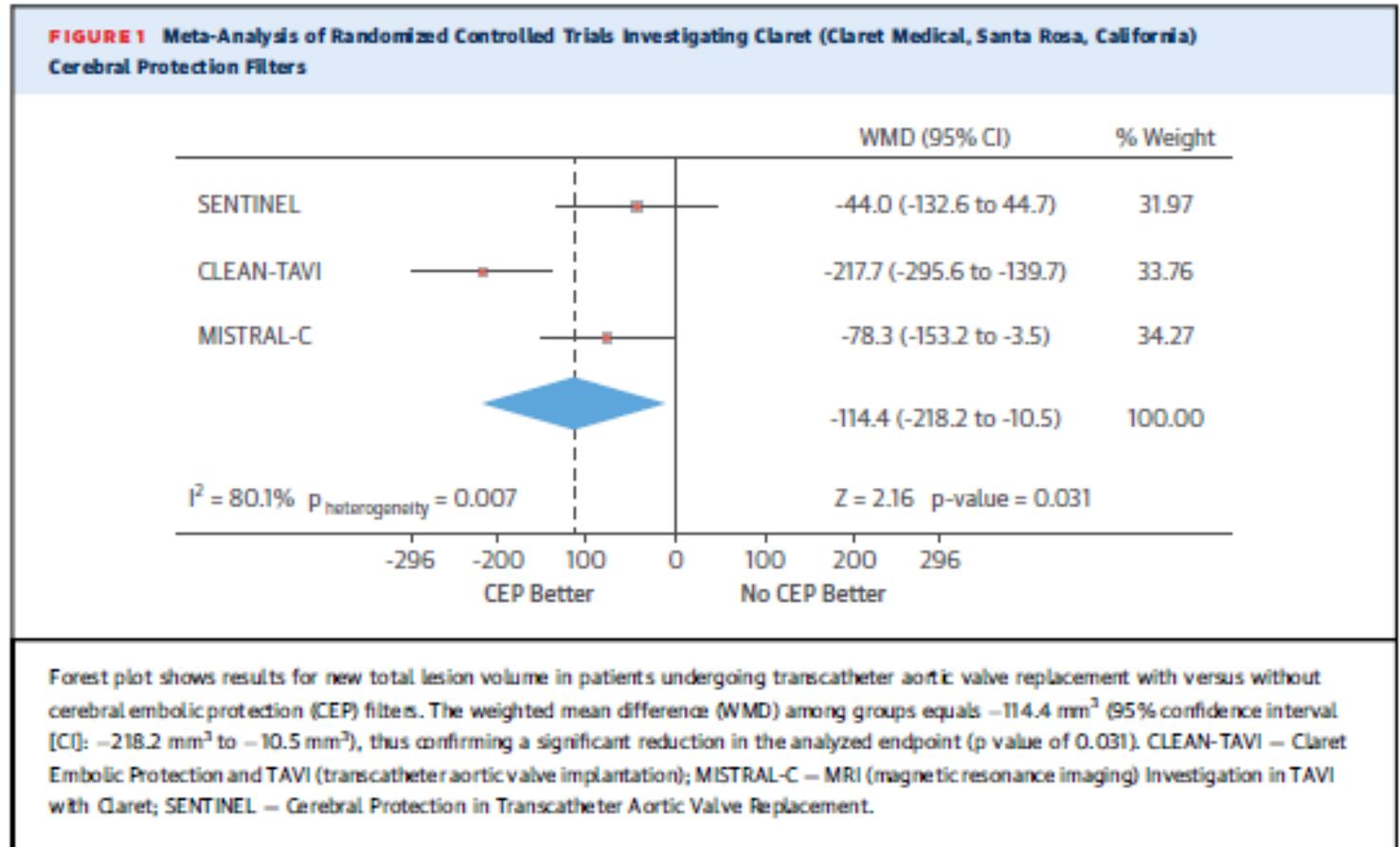
Sentinel Study

Summary of Results



- Excellent safety profile
 - No increase in MAACE - test vs control (7.3% vs 9.9%)
 - Low major vascular complications (0.4%)
- Captured embolic debris in almost all patients (99%), consisting of diverse material
- A reduction in 30-day strokes from 9.1% to 5.6%, which was not statistically significant (study was not powered for clinical endpoints)
- Although there was a reduction in DW-MRI new lesion volume with embolic protection (by 42%), the primary efficacy endpoint was not met ($p = 0.33$)

Meta-analyse Sentinel + Clean TAVI + Mistral C



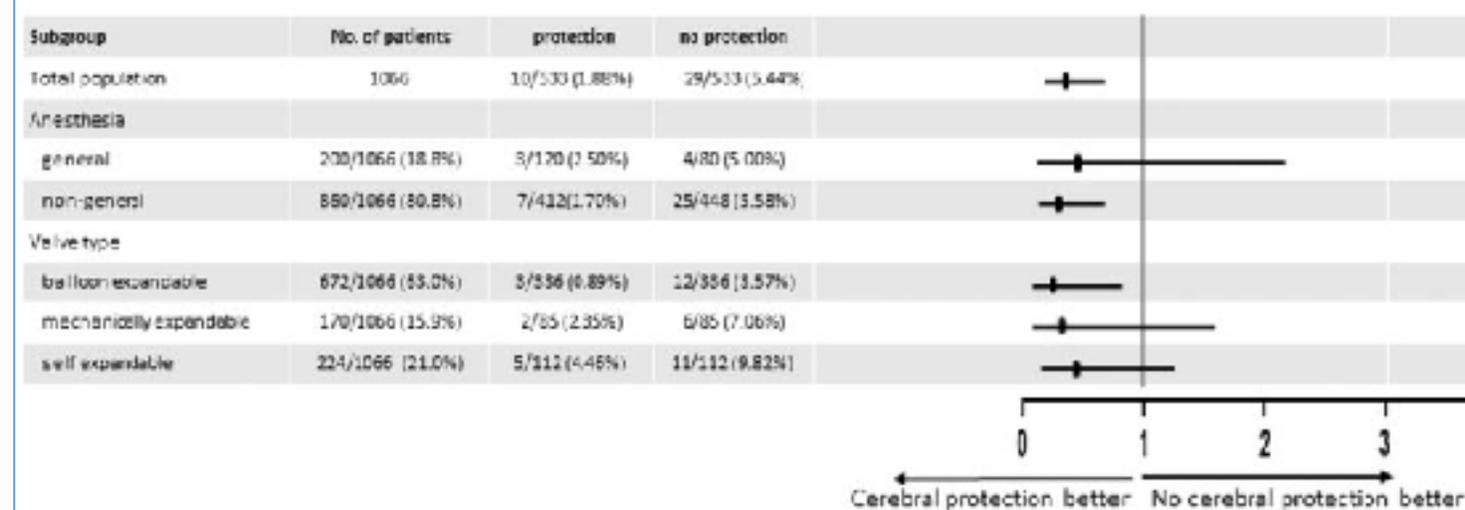
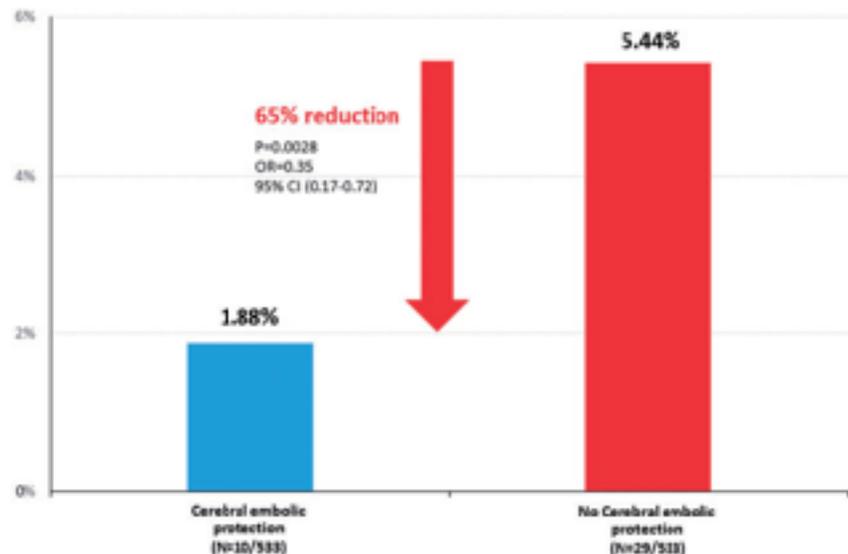
Efficacité clinique du Sentinel

Rate of peri-procedural stroke observed with cerebral embolic protection during transcatheter aortic valve replacement: a patient-level propensity-matched analysis

Julia Seeger¹, Samir R. Kapadia², Susheel Kodali³, Axel Linke⁴, Jochen Wöhrle^{1*}, Stephan Haussig⁶, Raj Makkar⁵, Roxana Mehran⁶, Wolfgang Rottbauer¹, and Martin Leon³

Methods and results

Patients from the SENTINEL US IDE trial were combined with the CLEAN-TAVI and SENTINEL-Ulm study in a patient level pooled analysis (N=1306). Propensity score matching was performed to adjust for possible confounders. The primary endpoint was procedural stroke within 72h post-TAVR according to Valve Academic Research Consortium-2 criteria. The secondary endpoint was the combination of all-cause mortality or all-stroke within 72 h after TAVR. In the propensity-matched population, 533 patients underwent TAVR without CEP and 533 patients underwent TAVR with CEP. TAVR patients without vs. with CEP were similar with respect to baseline characteris-



Conclusion

- D'ores et déjà:
 - On sait que le système SENTINEL est sûr et efficace
 - Indication formelle pour cas particuliers
 - Repérer la patiente à risque et la protéger
 - Optimiser la procédure et la médication
 - Réagir vite en cas d'AVC
- Demain: Paradoxe du Haut-Risque:
 - Le faible risque est-il plus précieux???
- D'autres indications?

Et dans le futur?

- Une obligations?



- D'autres devices ?

	Emblock	Point-Guard	Emboliner	ProtEmbo	Embolisher	Filterlex
Device Illustration						
Company	Innovative Cardiovascular Solutions	Transverse Medical	Cardiological Solutions	Protebix	Cardioplumes	Filterlex

- D'autres indications?



Merci pour votre attention !