Speaker's name: Thomas Cuisset, MD, PhD

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

x Consulting: Astra Zeneca, Daiichi Sankyo, Eli Lilly, Medicines Company

❒ Employment in industry

❒ Stockholder of a healthcare company

❒ Owner of a healthcare company

x Others: Lecture Fee

Abbott Vascular, Astra Zeneca, Biotronik, Boston Scientific, Cordis, Daichi Sankyo, Edwards, Eli Lilly, Hexacath, Iroko Cardio, Medtronic, Servier , Terumo

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

EUROPCR 2016

'Morceaux Choisis'

Atul PATHAK, *Clinique Pasteur, Toulouse (HTA)*
Antoine SAUGUET, *Clinique Pasteur, Toulouse (Périph.)*
Thomas CUISSET, *CHU Timone, Marseille (Coro / Structurel)*


11,588 participants
Including
Nurses and Allied Professionals
and Physicians

HTA

Case conclusion: how does this SPRINT study apply to my practice?

Professor Atul PATHAK

Head of Clinical Research

HTN and Heart Failure Unit

Autonomic Unit

apathak@clinique-pasteur.com

C2RC
Cardiovascular
Clinical Research Center

In practice: Doctor's view

- SPRINT trial is a plea for fighting agains therapeutic inertia

- When you see a patient above 140 mm Hg : intensify the treatment

  New findings from SPRINT, HOPE-3,VALUE and the meta-analysis of patients with type-2 diabetes provide solid evidence for treating people having hypertension (BP 140/90 mmHg)

- When you see a patient below 140 mm Hg

  There is a prize to pay to gain reduction in outcome (adverse drug reactions)

  Ideal candidate patient with Hypertension and Heart Failure

  Below 140 is what SPRINT is about ((with adjustment, e.g. 120+16 = 136 < 140 mm Hg)

  SPRINT support the need for alternative non pharmacological approach to reach target BP

S.R. Group, J.T. Wright Jr., J.D. Williamson,*et al.* **A Randomized Trial of Intensive versus Standard Blood-Pressure Control.** *N Engl J Med*

Consensus on Treatment Recommendations

Considerations for future RDN studies

Study population

To include patients with moderate rather than resistant hypertension
To exclude patients with stiff large arteries (e.g. isolated systolic hypertension)

Study design

To standardize concomitant antihypertensive therapy
To monitor drug adherence as potential confounder of BP response

Study outcomes

To use the change in ABPM as a primary efficacy parameter

Procedural aspects

Asymmetric and most probably distal renal artery targeting is required

C. Tsioufis

CCC for RDN, Mahfoud et al, European Heart Journal ,2015

Périphérique

RANDOMIZED TRIAL OF STENT VERSUS SURGERY FOR ASYMPTOMATIC CAROTID SURGERY

N=1453 patients < 79Yo, Asymptomatic ,not at high risk for surgical complications

	Stent group (n=1089)	Endarteriectomy (n= 364)	P Value
Death,Stoke,MI < 30 Days	3.8%	3.4%	Non inferior
Stroke,Death < 30 Days	2.9%	1.7%	NS
30 Days-5 Years Freedom from ipsilateral stroke	97.8%	97.3%	P=0.51
Overall survival	87.1%	89.4%	P=0.21
5 Years stoke free survival	93.1%	94.7%	P=0.44

Kenneth Rosenfield for ACT I investigators ,Randomized trial of stent versus surgery for asymptomatic carotid stenosis. N Engl J Med 2016;374:1011-20.

LONG TERM RESULTS OF STENTING VERSUS ENDARTERIECTOMY FOR CAROTID STENOSIS

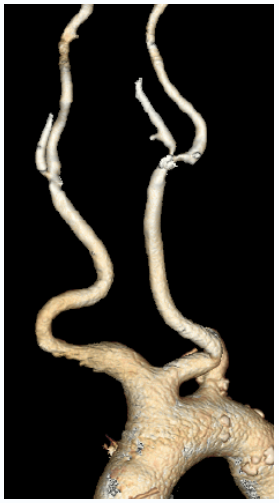
N=2502 patients Symptomatic and asymptomatic patients 10 years follow up

	Stent group (n=1089)	Endarteriectomy (n= 364)	P Value
Death,Stoke,MI < 30 Days	5.2%	4.5%	P=0.38
Periprocedural stroke< 30 Days	4.1%	2.3%	P=0.01
Periprocedural MI<30 Days	1.1%	2.3%	P=0.03
Death,Stroke ,MI at 10 Years	11.8%	9.9%	P=NS
Ipsilateral stroke 10 Years	6.9%	5.6%	P=NS

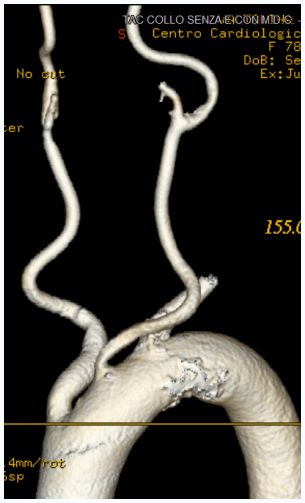
Driven by minor strokes
No difference regarding major stroke

Thomas G Brott for CREST investigators. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis . N Engl J Med 2016;374:1021-31.

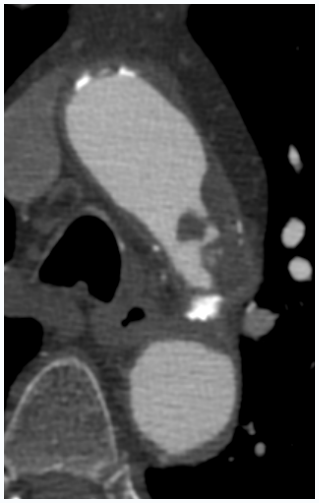
CAS through radial approach
TO DECREASE AORTIC ARCH MANEUVER



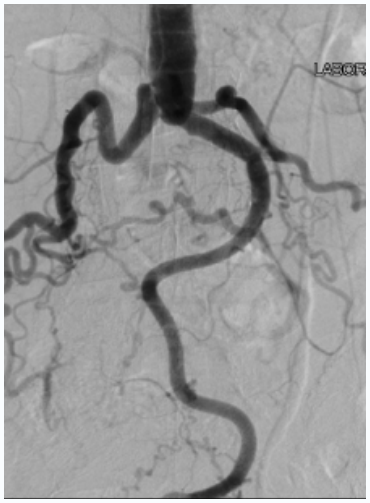
Bovine aortic arch +LICA



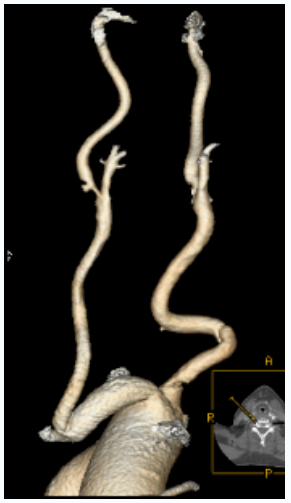
Type II-III aortic arch +RICA



Aortic arch disease +RICA/LICA



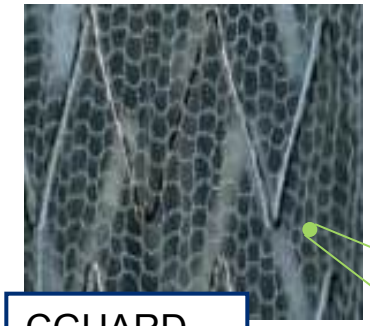
Peripheral arterial disease +RICA/LICA



'Pongeant' innominate artery +RICA

Frequency of indications for TR CAS

Double mesh stents cell size comparisons



CGUARD

TERUMO

GORE

*165µ

375

500

1050

1900

Closed cell stent

Open cell stent

* Average in lesion at expanded state

Clinical Outcome

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

	CARENET CGuard with only Distal EPD (N=26*)
Incidence of New Lesions	46%
Lesions (per patient)	1.62 ±2.68
Volume (per patient)	0.061 ±0.11 cm^3

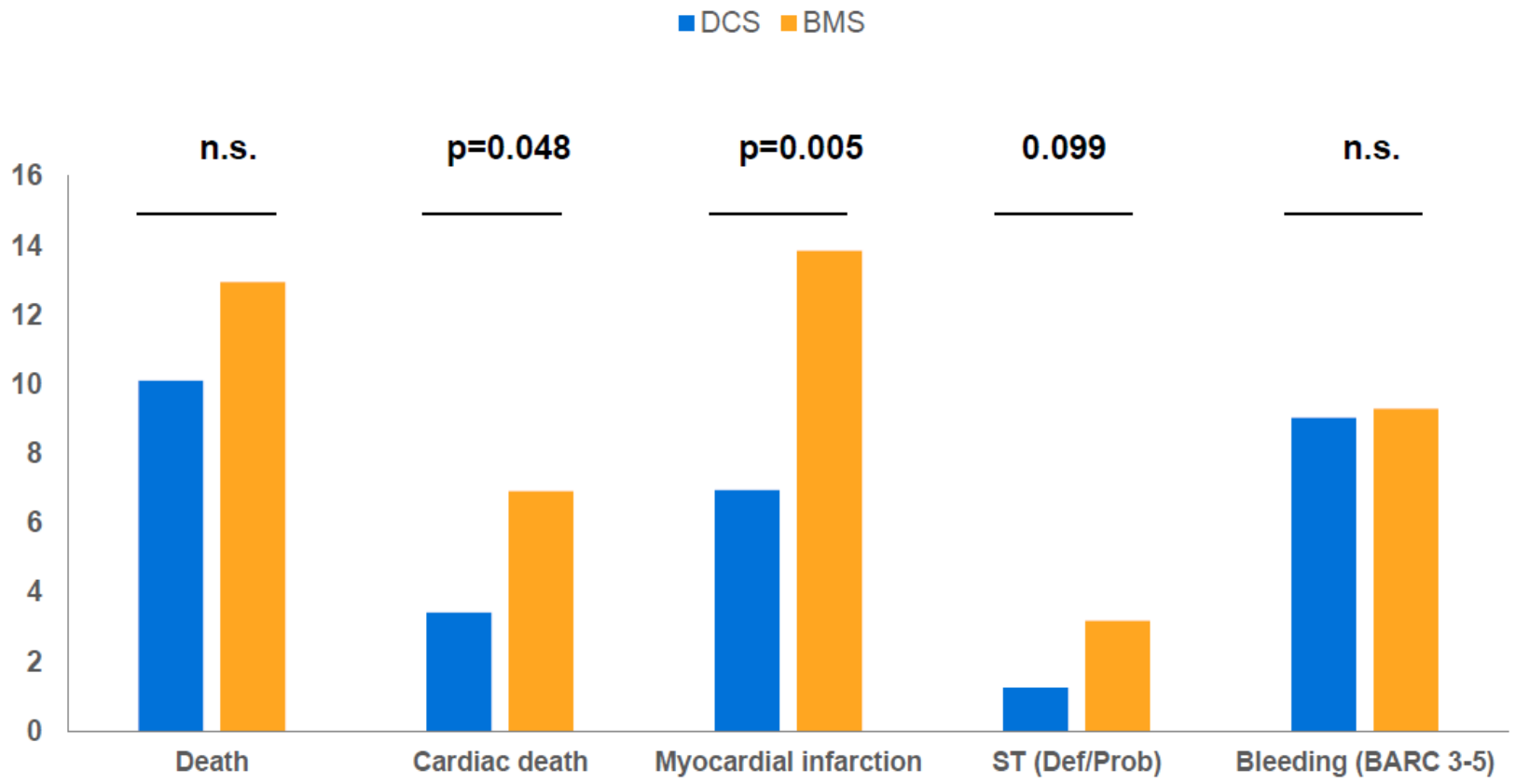
Coronaires

Coronaires

Etudes 'Head to Head'

LEADERS FREE ACS

12 Month Follow-up



Naber et al, EUROPCR 2016

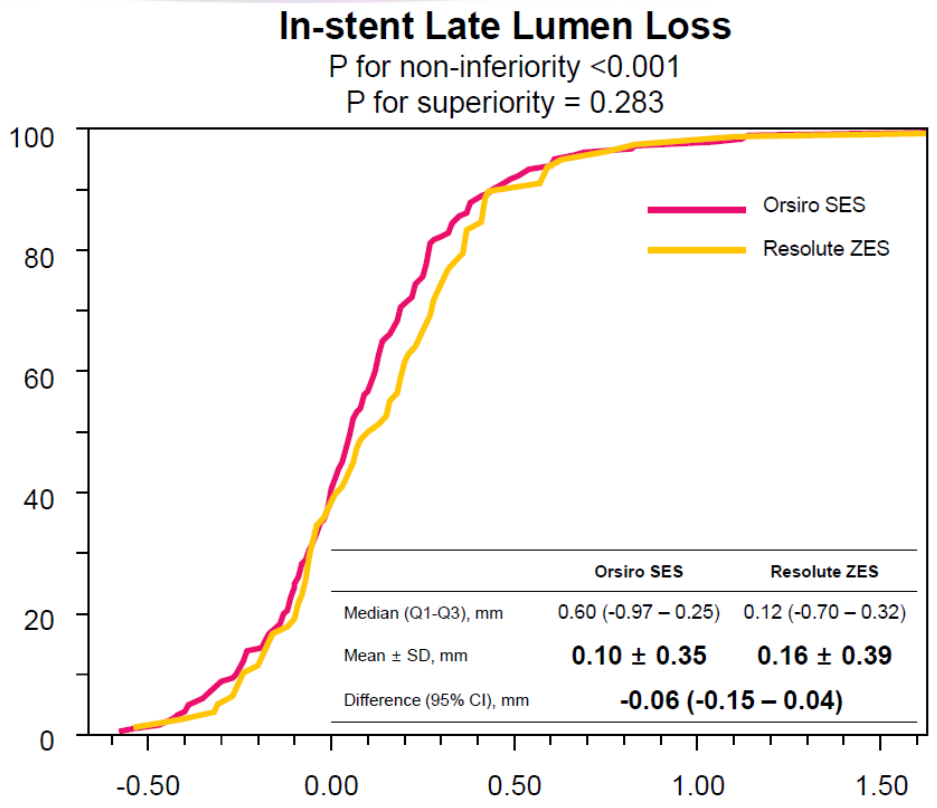
Leaders-FREE ‘ACS’ Questions

Probablement la fin des stents nus mais …

Durée DAPT optimale avec DCS ??

Comparaison DCS et nouveaux DES ??

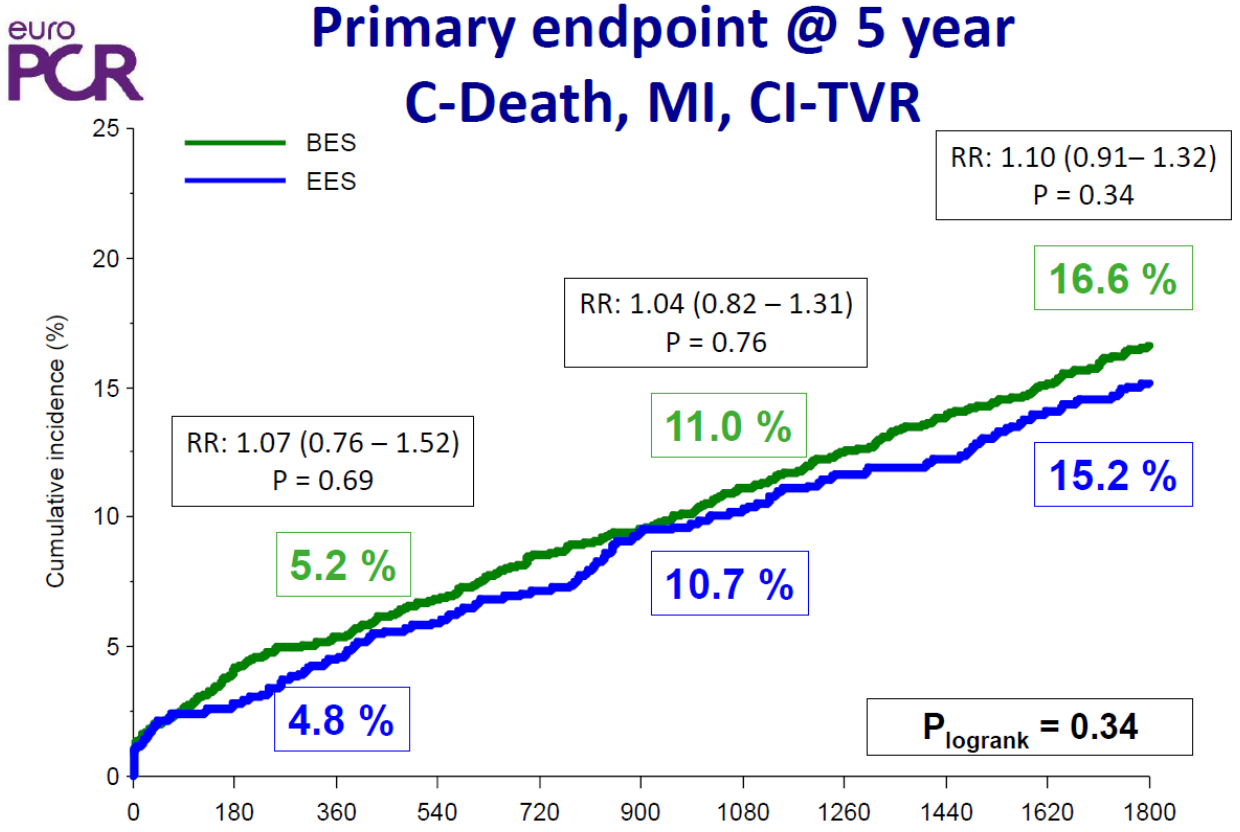
Angiographic outcomes of Orsiro biodegradable polymer sirolimus-eluting stents and Resolute Integrity durable polymer zotarolimus-eluting stents : Results of ORIENT trial



Kang et al, EUROPCR 2016

The Final 5 Year Results From The COMPARE II trial

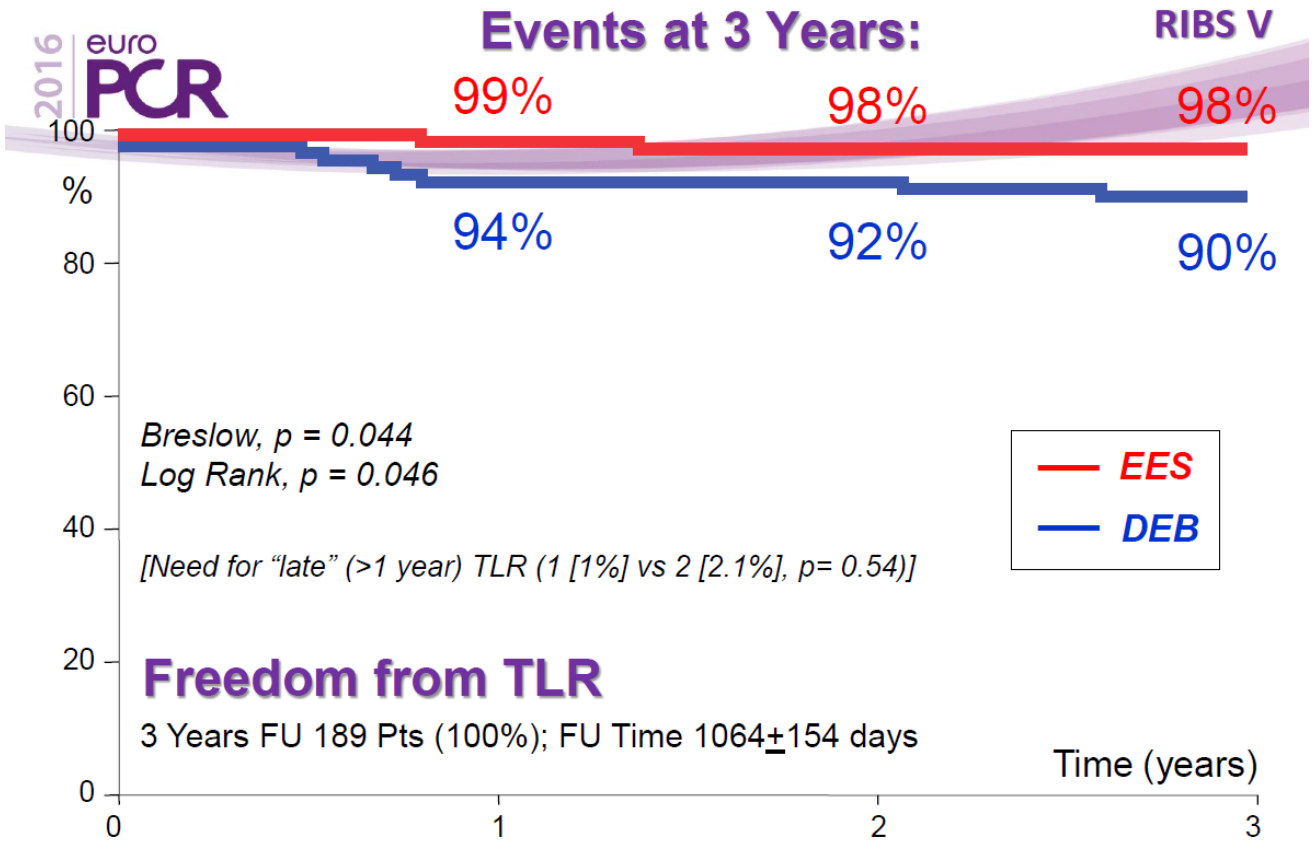
The first real long-term results between Biodegradable Polymer-BES and Durable Polymer-EES



Smits et al, EUROPCR 2016

RIBS V

The 3-Year Clinical Follow-up of the RIBS V Randomized Clinical Trial



Alfonso et al, EUROPCR 2016

Coronaires

BRS

France Absorb Registry

In-hospital and 30 days Results

Inclusion 2089 patients de 09.2014 à 04.2016

Patient: 55 ans (critère âge dans 70% cas), STEMI 17%

Procédure: Prédilatation 93%, postdilatation 72%, OCT 15%

Thrombose BVS à 30 jours: 1.05% (22/2089)

Koning et al, EUROPCR 2016

Effect of DAPT termination at 12 months on very late scaffold thrombosis in regular clinical practice: Data of a regional collaboration

At risk for late ST while on DAPT — N = 600

Late ST — N = 5 *(0.83%)*

No FU > 1 year — N = 48

At risk for *very* late ST while *off* DAPT — N = 547

ST > 1 year – 15 months — N = 3 *(0.55%)*

DAPT > 1 an avec BVS ?

Van Geuns et al, EUROPCR 2016

Safety and Clinical Performance of the Drug Eluting Absorbable Metal Scaffold in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries at 12-month Follow-up-BIOSOLVE-II

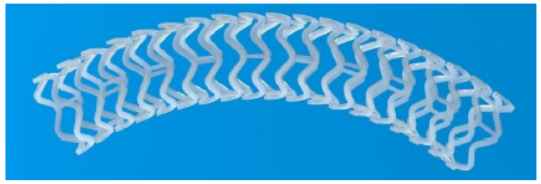
	6-month		12-month	
	N=120	%	N=118	%
TLF[1]	4	3.3	4	3.4
Cardiac Death	1[2]	0.8	1[2]	0.8
Target Vessel MI	1	0.8	1	0.8
Clinically driven TLR	2	1.7	2	1.7
CABG	0	0.0	0	0
Scaffold Thrombosis Definite or probable	0	0.0	0	0.0

Résultats cliniques encourageants et in Scaffold LLL 0.35 mm

* FU angio optionnel à M12 (45/123)

Haude et al, EUROPCR 2016

FANTOM II Trial



***Fantom*®** **(REVA Medical)**
Sirolimus-Eluting Bioresorbable Scaffold
Desaminotyrosine Polycarbonate

In-Scaffold Analysis	Baseline (n=115)	Post Procedure (n=112)	6 Months (n=100)
RVD (mm)	2.68 ± 0.37	2.75 ± 0.40	2.69 ± 0.35 (n=101)
MLD (mm)	0.79 ± 0.29	2.47 ± 0.37	2.20 ± 0.39
Diameter Stenosis (%)	70.3 ± 10.4	10.7 ± 7.6	16.8 ± 11.5 (n=99)
Acute Gain (mm)	1.67 ± 0.41		
Acute Recoil (%)	2.9 ± 8.8		
Mean LLL (mm)			0.29 ± 0.38
Median LLL (mm)			0.22 (-0.43, 1.77)
In-Segment Analysis			
Mean LLL (mm)			0.21 ± 0.32
Median LLL (mm)			0.16 (-0.43, 1.67)

FANTOM BRS

125 µ, Visibile au Rx
Inflation rapide
Postdilatation à 0.75-1 mm

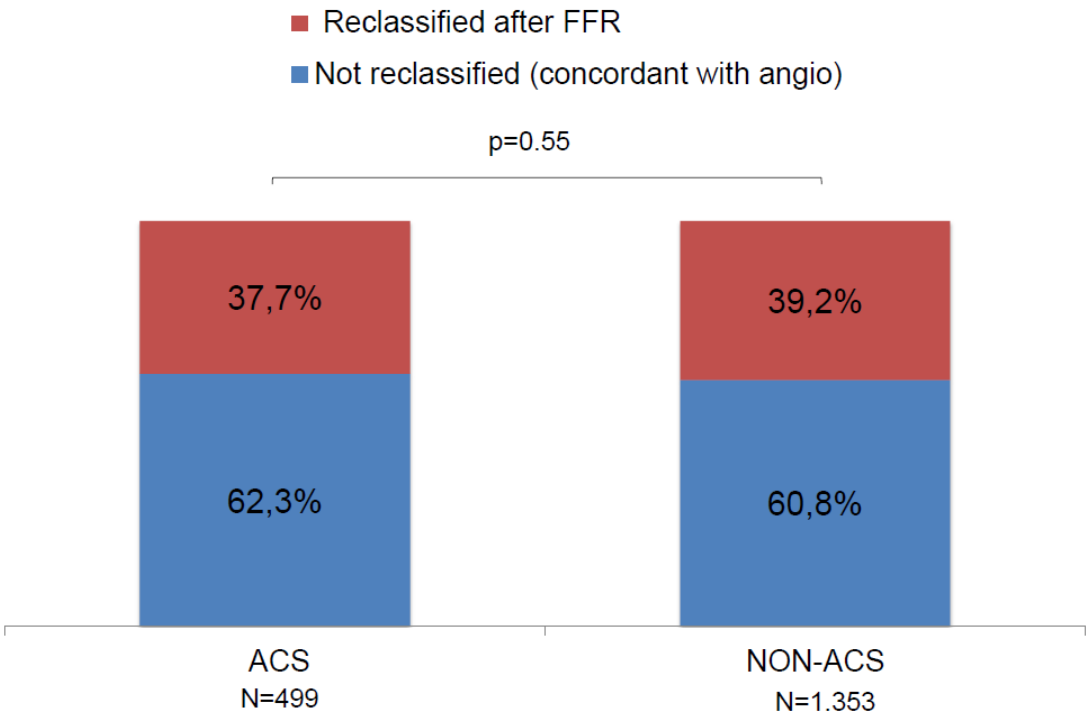
Abizaid et al, EUROPCR 2016

Coronaires

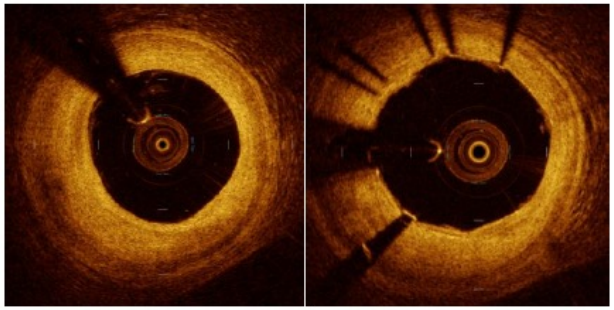
Imagerie et FFR

Impact of routine Fractional Flow Reserve on management decision and 1-year clinical outcome of ACS patients: Insights from the POST-IT and R3F Integrated Multicenter registriEs - Implementation of FFR in Routine Practice (**PRIME-FFR**)

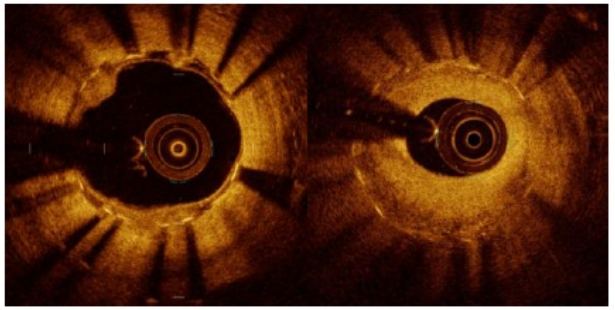
Overall management change in patients in whom FFR was used for decision



Van Belle et al, EUROPCR 2016



2016 euro PCR



In-Vivo Healing Response to Bioresorbable, Abluminal Polymer Everolimus-Eluting Stent versus Durable, Conformal Polymer Zotarolimus-Eluting Stent

The TRANSFORM OCT trial

*TRiple Assessment of Neointima Stent FOrmation to Reabsorbable polyMer with OCT

OCT demonstrates **similar in-vivo healing response** between BP-EES Synergy™ and DP-ZES Resolute Integrity™ at 3-month, with minimal neointima, high rate of mature tissue and no difference with regards to maximum length of consecutive uncovered struts

Guagliumi et al, EUROPCR 2016

Sessions Pratiques « Learning »
Fin de la « toute-puissance » de l'EBM ?

TASTE et TOTAL → Les gens aspirent encore

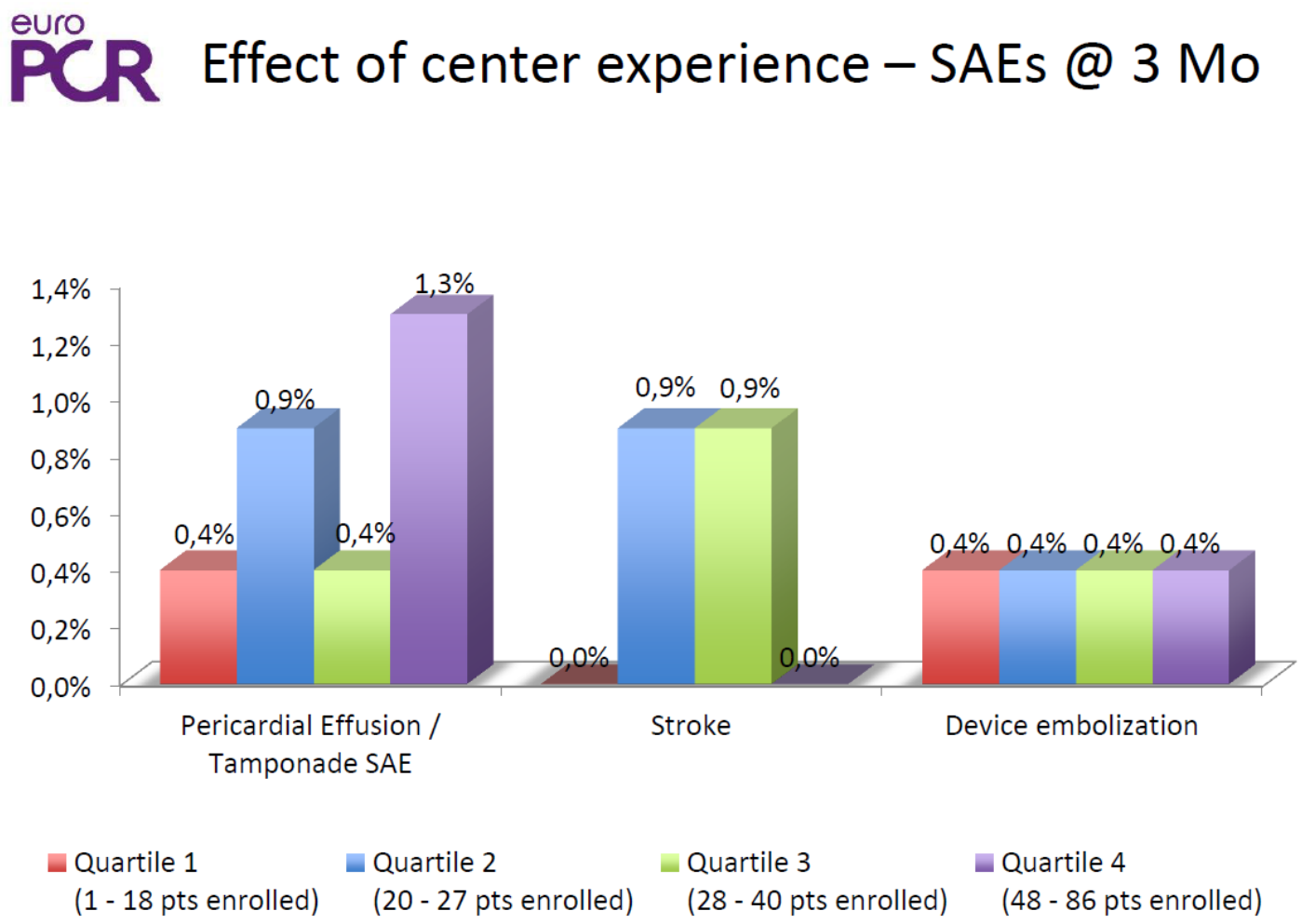
PRAMI → Les gens font souvent que la « coupable »

DAPT → Les gens font souvent DAPT courte

….

Structurel

Fermeture Auricule: Registre Ewolution

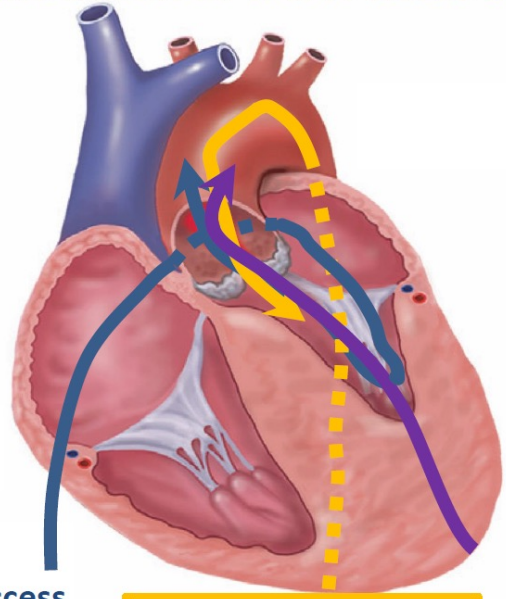


Bergmann et la, EUROPCR 2016

2016 Ethica Award

John Webb

John Webb – The Pioneer
Innovation in TAVI Access Sites



Antegrade TF Access
(Cribier. April, 2002)

Retrograde TF Access
(Webb. Jan, 2005)

Transapical Access
(Ye, …, Webb.
Oct, 2005)

Extending TAVI to low risk patients

Defining 'Low Risk'

Results Outcomes
& Complications

Durability

Patient Preference
& Extending TAVI

Extending TAVI to low risk patients

Defining 'Low Risk'

Results Outcomes
& Complications

Durability

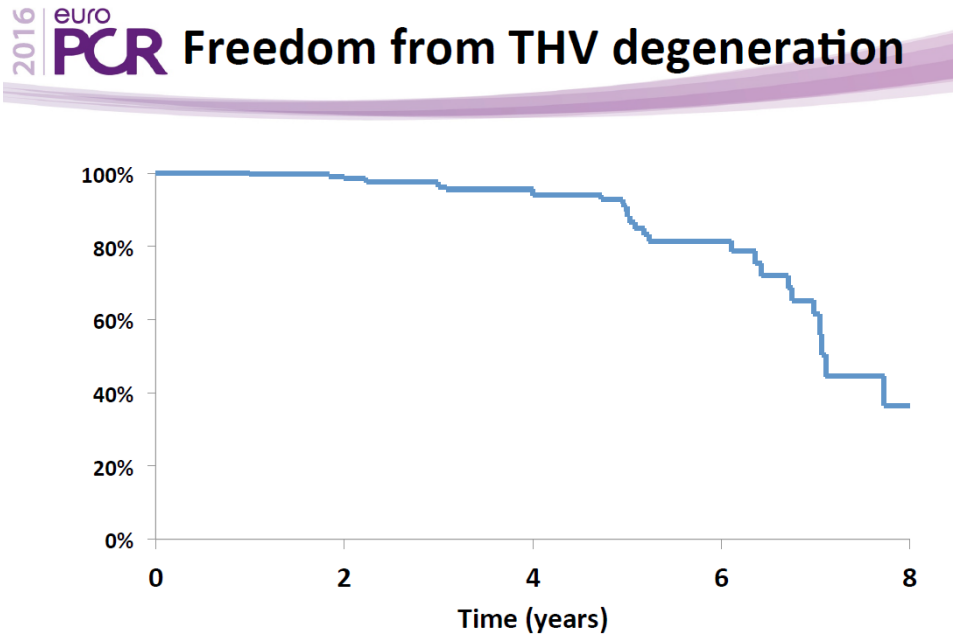
Patient Preference
& Extending TAVI

First look at long-term durability of transcatheter heart valves:
Assessment of valve function up to 10-years after implantation

378 patients (Vancouver et Rouen)
TAVI > 5 ans (5-14)

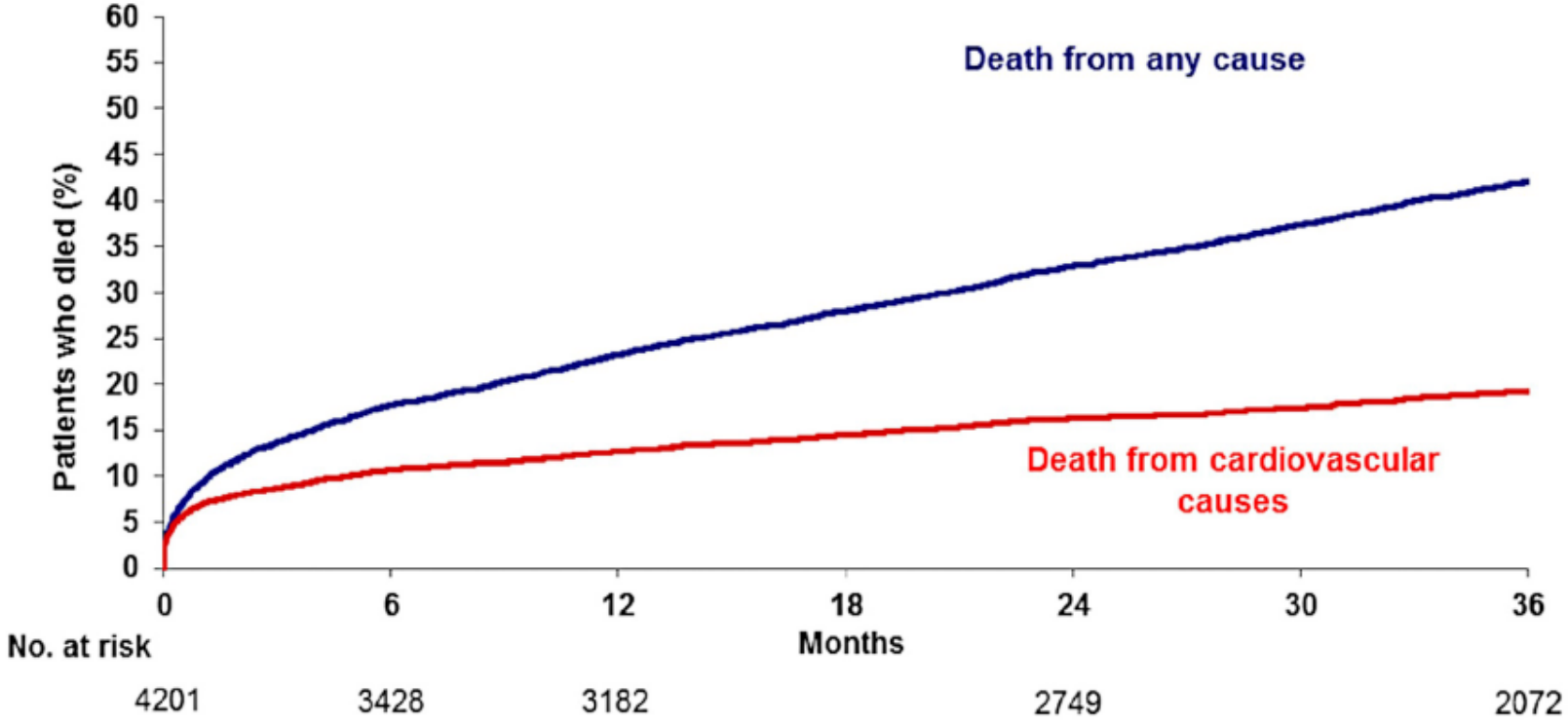
Dégénérescence si:
IA ≥modérée ou Gt≥ 20 mmHg
Absent à J30 et non lié à EI

50% à 8 ans



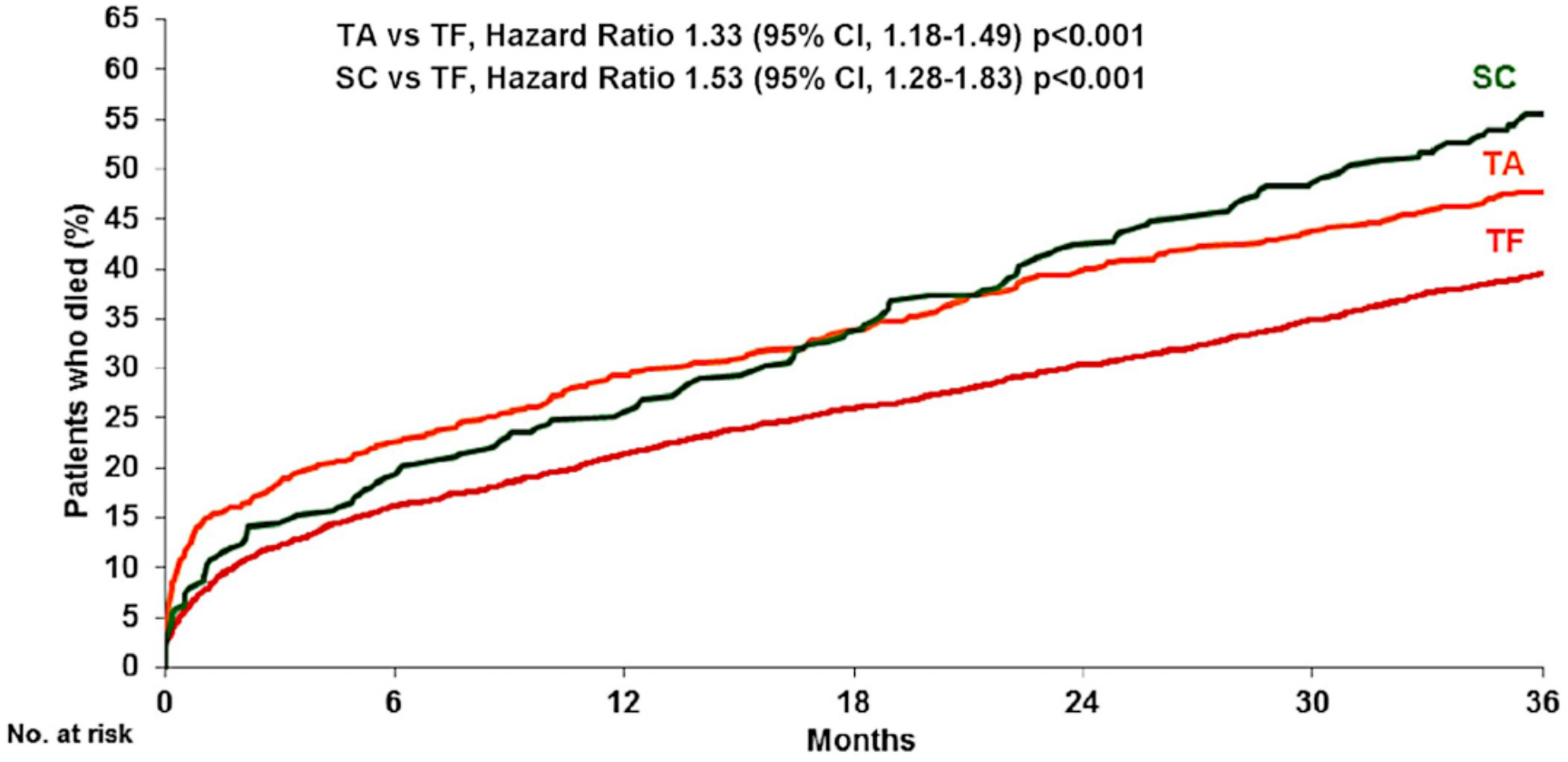
Dvir et la, EUROPCR 2016

Late outcomes of TAVI in high-risk patients: FRANCE 2 registry



Gilard et al, EUROPCR 2016

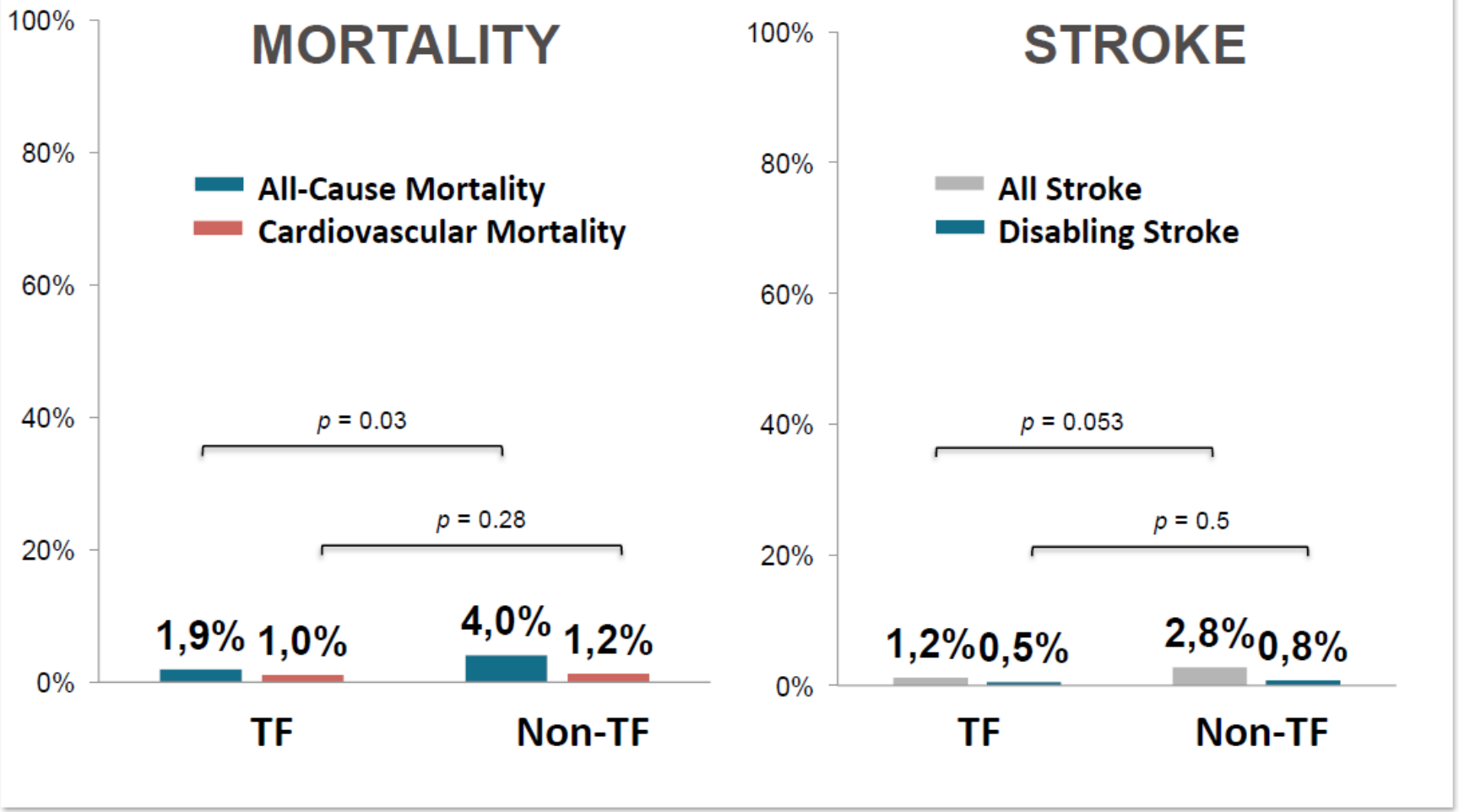
Late outcomes of TAVI in high-risk patients: FRANCE 2 registry



N=4201

Gilard et al, EUROPCR 2016

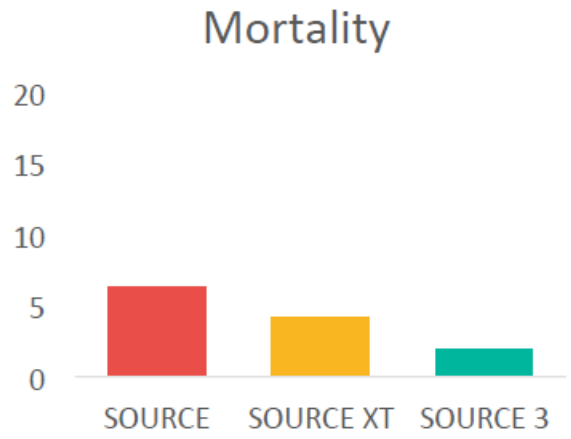
30-Day Mortality and Stroke
(AT n = 1947)

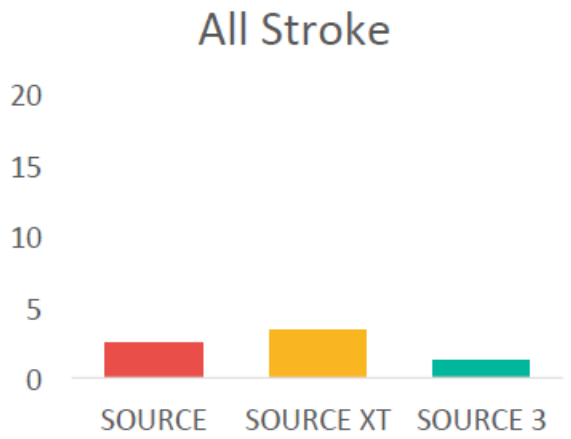


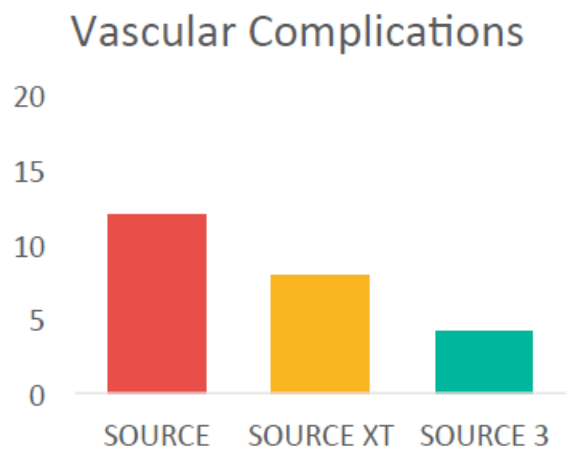
CEC Adjudicated

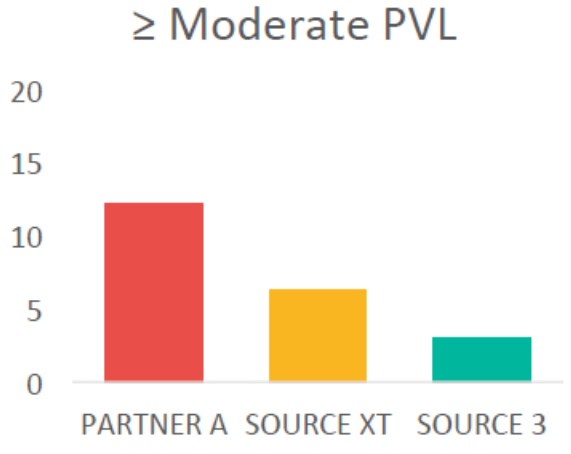
Wendler et al, EUROPCR 2016

SOURCE Registries
TF - Clinical Outcomes at 30 Days









Wendler et al, EUROPCR 2016

TAVI: Avec ou sans Chirurgie Cardiaque ?

Matched pairs*: Outcomes

	CS- (n=555)	CS+ (n=555)	p	OR	95% CI
Intraprocedural complications	**51 (9.2%)**	**57 (10.3%)**	**0.543**	**0.884**	**0.594-1.316**
- Device malpositioning	9 (1.6%)	8 (1.4%)	0.806	1.127	0.432-2.943
- Device embolisation	2 (0.4%)	2 (0.4%)	1.00	1.00	0.140-7.125
- Coronary occlusion	2 (0.4%)	4 (0.7%)	0.38	0.498	0.091-2.731
- Aortic dissection	1 (0.2%)	2 (0.4%)	0.563	0.499	0.045-5.520
- Annular rupture	4 (0.7%)	4 (0.7%)	1.00	1.00	0.249-4.019
- Pericardial tamponade	4 (0.7%)	7 (1.3%)	0.363	0.568	0.165-1.9525
- Acute cardiac decompensation	4 (0.7%)	2 (0.4%)	0.413	2.007	0.366-11.004
- Cerebral embolism	1 (0.2%)	1 (0.2%)	1.00	1.00	0.062-16.028
- Aortic regurgitation ≥ 2	15 (2.7%)	6 (1.1%)	0.047	2.542	0.979-6.600
- Rhythm disturbances	8 (1.4%)	12 (2.2%)	0.367	0.662	0.268-1.632
-Vascular injury	14 (2.5%)	22 (4.0%)	0.175	0.639	0.323-1.262
Conversion to open heart surgery	2 (0.4%)	5 (0.9%)	0.255	0.398	0.077-2.059
In-hospital death	**10 (1.8%)**	**16 (2.9%)**	**0.234**	**0.618**	**0.278-1.374**
Cerebrovascular event	**18 (3.2%)**	**18 (3.2%)**	**1.00**	**1.00**	**0.515-1.943**
New pacemaker/ICD implantation	114 (20.5%)	105 (18.9%)	0.497	1.108	0.824-1.489
Days in hospital after TF-TAVI	10.4 ± 7.1	9.8 ± 6.4	0.139	0.088	-0.029-0.207

- **Close cooperation in the Heart Team is key**
- **Lack of a CS department on-site should not be regarded as contraindication for TAVI**

Eggebrecht et al, EUROPCR 2016

Merci …