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POLICLINICO SAN DONATO

**Francesco Bedogni**  
**IRCCS**  
**Policlinico San Donato**



ECOCARDIOCHIRURGIA®  
ECO-RM-TC  
CHIRURGIA-INTERVENTISTICA

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# IX CONGRESSO NAZIONALE ECOCARDIOCHIRURGIA 2017

- 28 - 29 MARZO 2017 MILANO, 27 - 28 - 29 MARZO 2017 MILANO, 27 - 28 - 29 MARZO 2017 MILANO  
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17 MILANO, 27 - 28 - 29 MARZO 2017

**MILANO, 27 - 28 - 29 MARZO 2017**



**DIRETTORI**  
ANTONIO MANTERO  
GIUSEPPE TARELLI

**COORDINATORI  
ESECUATIVI**  
FRANCESCO ALAMANNI  
EMANUELE CATENA  
GIOVANNI CORRADO  
CORRADO LETTIERI

**PROGRAMMA  
FINALE**

**Centro Congressi**  
**Palazzo delle Stelline**  
Corso Magenta, 61  
20123 Milano

## **TAVI:**

**la tecnologia progredisce , l'esperienza degli operatori  
aumenta, le complicanze si riducono: quindi...**



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# 2007-2017





# Big Five

- **Access site complications**
- **Stroke**
- **Coronary occlusion**
- **Residual aortic regurgitation**
- **Cardiac rhythm disturbances**

# Vascular Complications

## Prevention and treatment

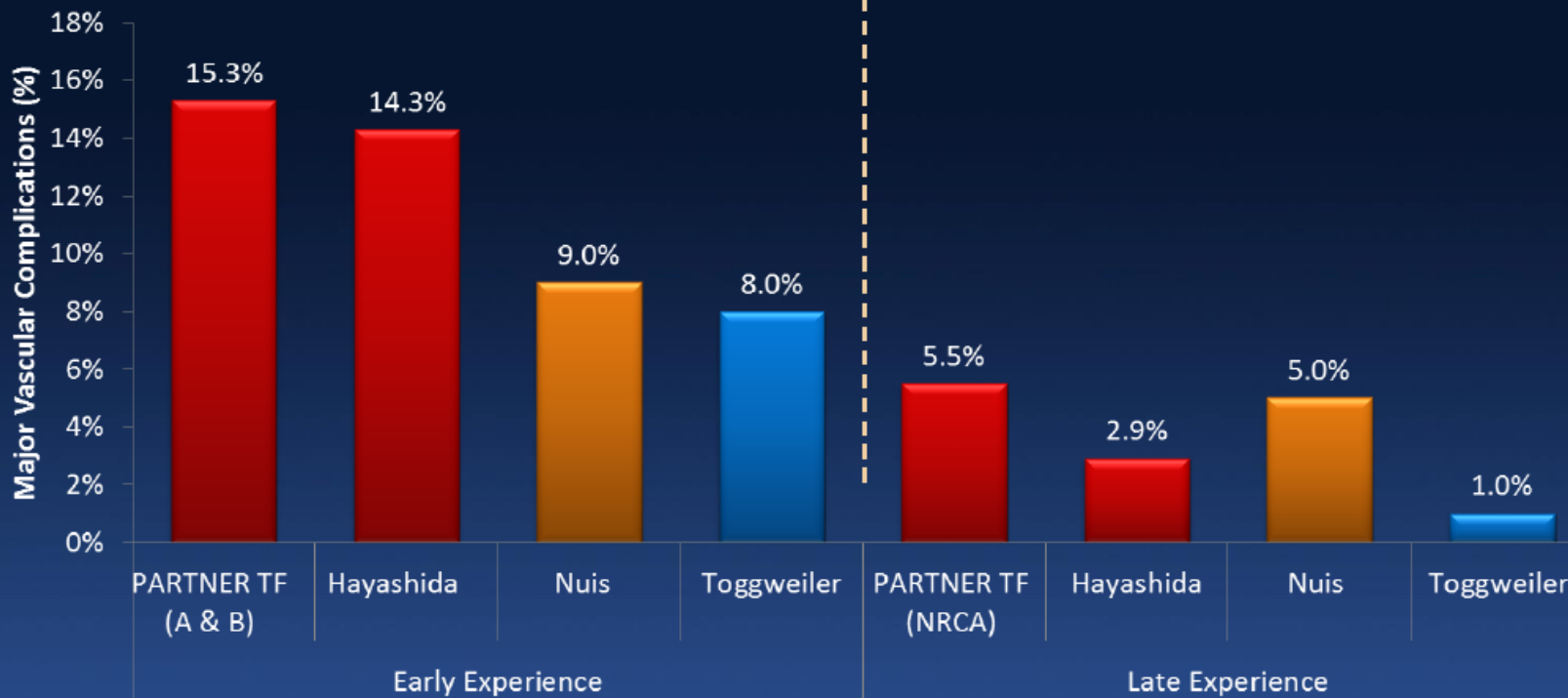
- **Vascular imaging and patient selection**
- **Lower profile of delivery systems**
- **Technique of puncture**
- **Management of access closure**
- **Endovascular management of complications**
- **Site and operator experience**





# Learning Course

## Major Vascular Complications



<sup>1</sup>Fearon, et al., presented at ACC 2013; <sup>2</sup>Hayashida, JACC Card Int 2011; 4(8): 851-8;

<sup>3</sup>Nuis, Am J Cardiol 2011; 107: 1824-1829; <sup>4</sup>Toggweiler, JACC 2012; 59(2): 113-8

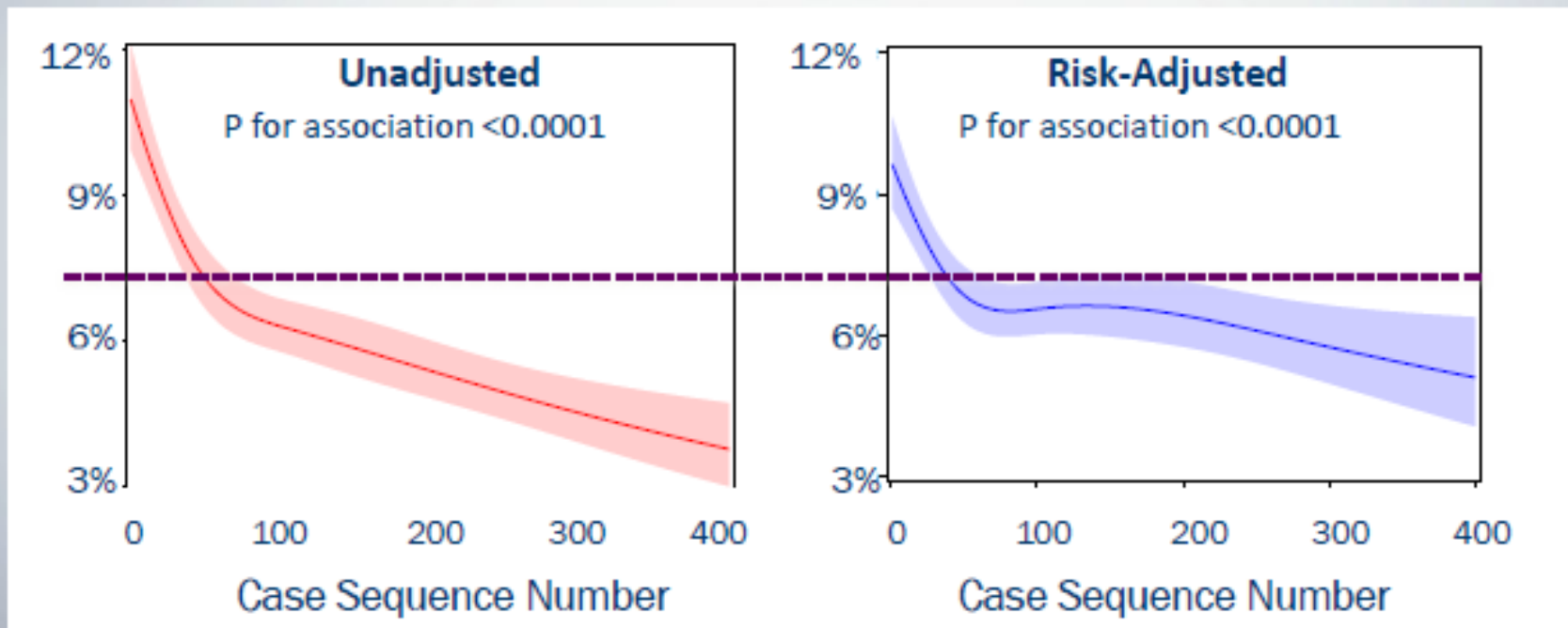


# Relationship between procedure Volume and outcome for TAVR in US

ACC 2016

## Bleeding Complications

VARC Major Bleeding or VARC Life-Threatening Bleeding



Risk-adjusted algorithm incorporates relevant TVT data elements.

STS/ACC TVT Registry





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# Stroke

The NEW ENGLAND JOURNAL of MEDICINE

## EDITORIALS



### Transcatheter Aortic-Valve Implantation — At What Price?

Hartzell V. Schaff, M.D.

In 2000, Bonhoeffer et al. described transvenous placement of a pulmonary-valve prosthesis and speculated that similar technology might be used in other cardiac valves, including the aortic position.<sup>1</sup> Two years later, the first transcatheter insertion of an aortic-valve prosthesis was performed by Cribier et al.<sup>2</sup> Transcatheter aortic-valve patients who are eligible for transfemoral insertion and may decrease vascular injury. **But the increased risk of stroke associated with transcatheter replacement, as compared with surgical replacement, is a special concern.** Smith and colleagues report a 5.5% risk of stroke or transient ischemic attack within 30 days after



Incidence = 2.8 %

**(adjusted HR 19.62)**

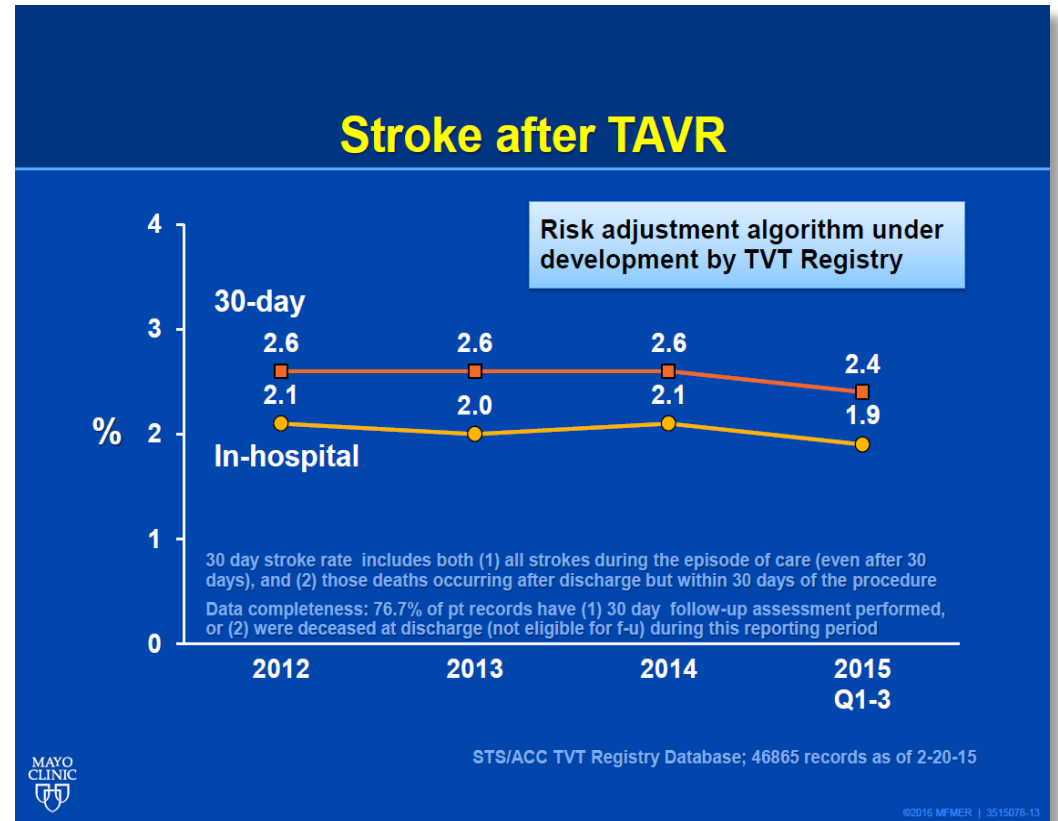
95% CI 1.81-212.13, p=0.014)

Italian Registry 2007-2008

Ussia et al EHJ 2012

# TVT Registry shows no significant decline in stroke rate over time

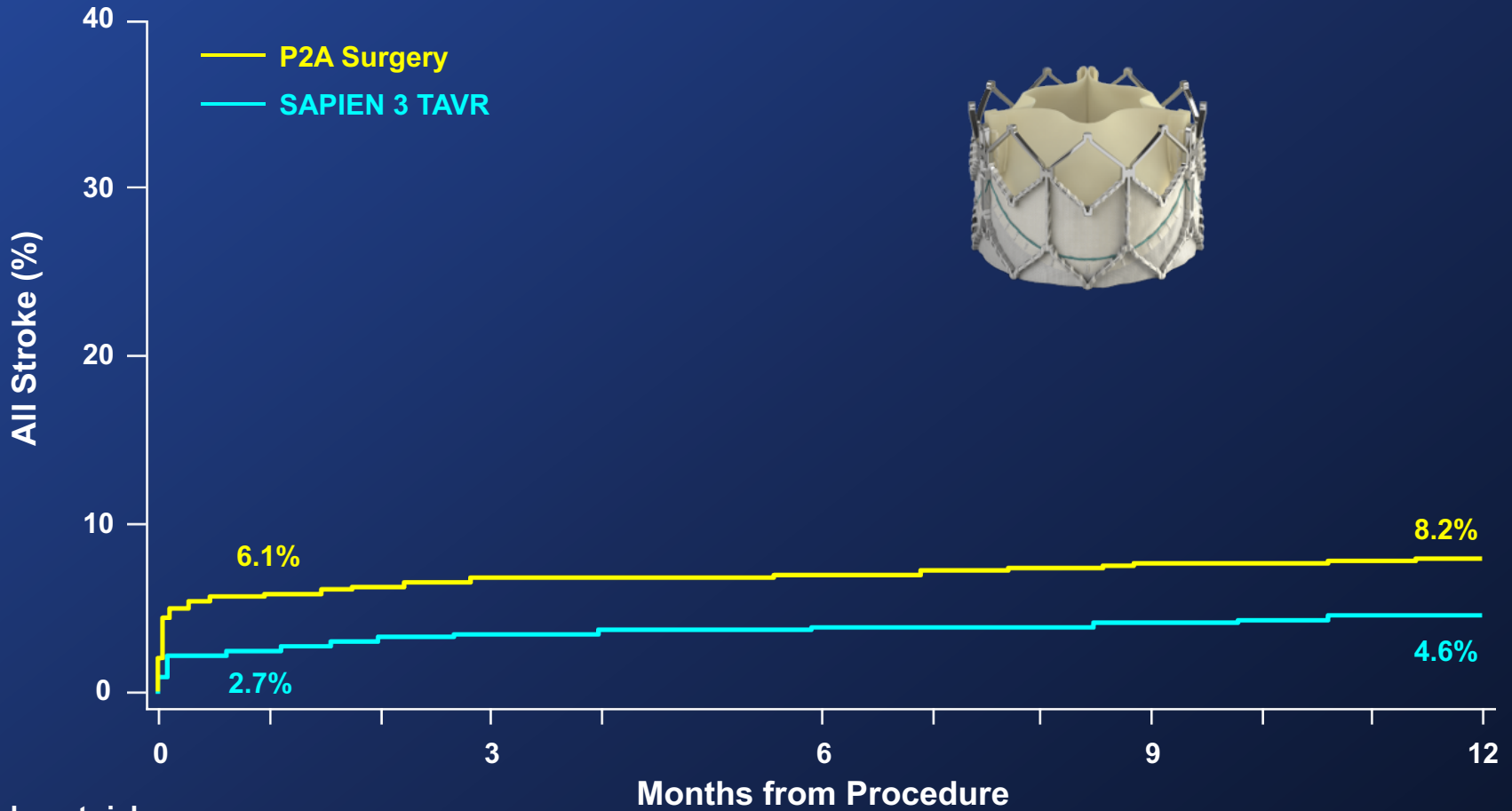
- Over 53,000 US TAVR patients
- No significant decline in stroke rate over time
- Self-reported rates without prospective neurologist exams pre and post-procedure likely underestimate true rates





# Unadjusted Time-to-Event Analysis

## All Stroke (AT)



Number at risk:

**P2A Surgery** 944  
**S3 TAVR** 1077

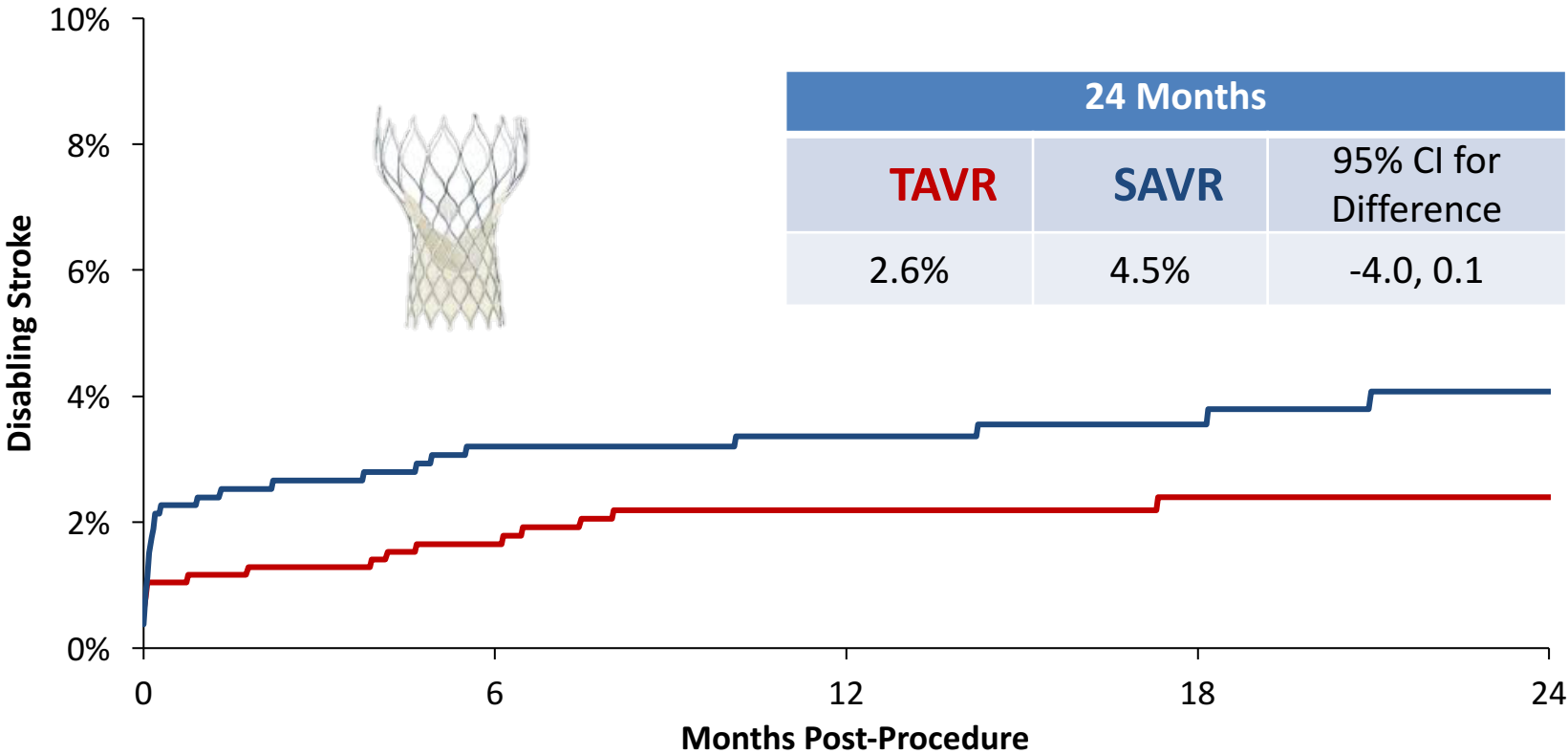
**805**  
**1012**

**786**  
**987**

**757**  
**962**

**743**  
**930**

# Disabling Stroke



No. at Risk	0	6	12	18	24
SAVR	796	674	555	407	241
TAVR	864	755	612	456	272

**SURTAVI TRIAL ACC 2017**

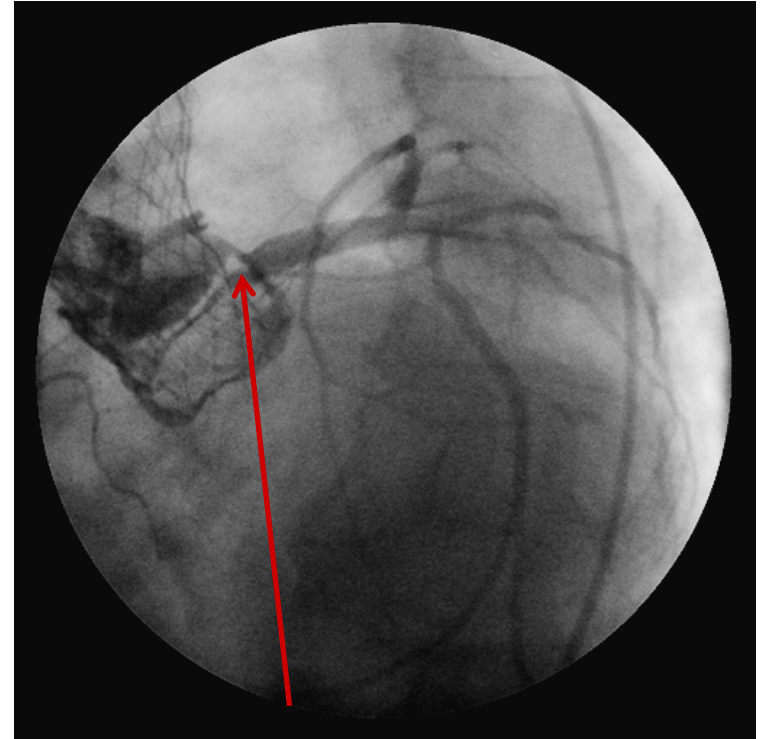
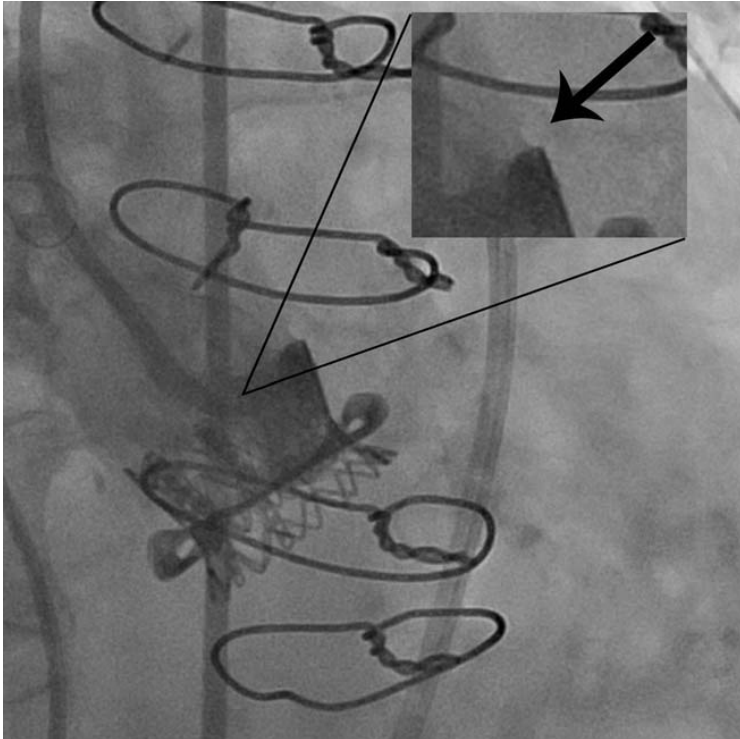


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# Coronary Obstruction Following Transcatheter Aortic Valve-in-Valve Implantation For Failed Surgical Bioprostheses


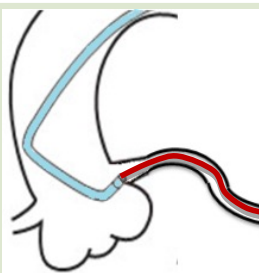
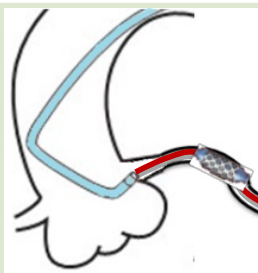
Ronen Gurvitch,<sup>1</sup> MBBS, Anson Cheung,<sup>1</sup> MD, Francesco Bedogni,<sup>2</sup> MD,  
and John G. Webb,<sup>1\*</sup> MD

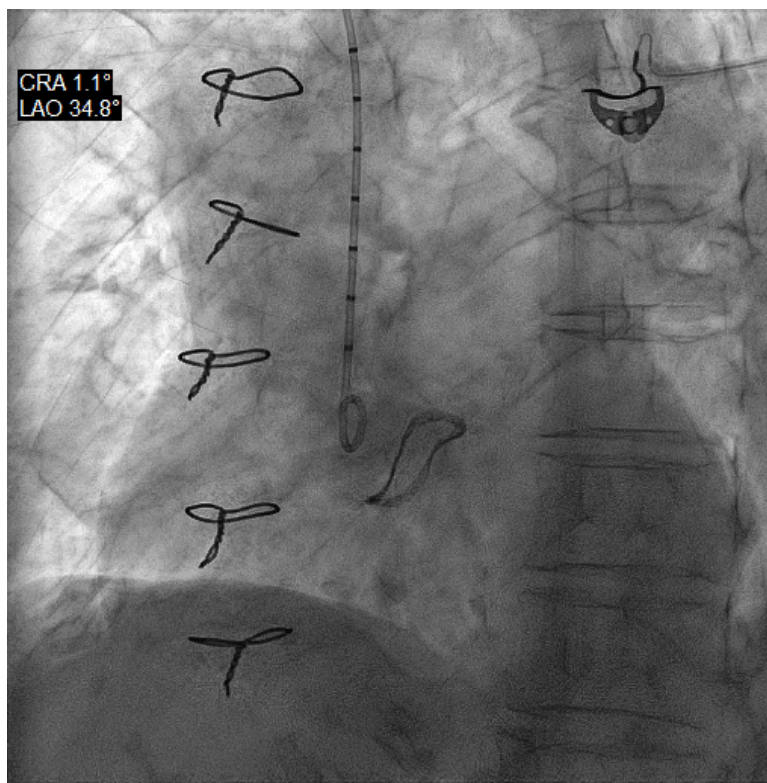
Catheterization and Cardiovascular Interventions 77:439–444 (2011)



## Left Main protection during very high risk Transcatheter Aortic Valve-in-Valve procedure. A Collaborative Registry

Luca Testa<sup>1</sup>, Tarun Chakravarty<sup>2</sup>, Azeem Latib<sup>3</sup>, Fausto Castriota<sup>4</sup>, Montone RA<sup>1</sup>, Alberto Cremonesi<sup>4</sup>, Antonio Colombo<sup>3</sup>, Raj Makkar<sup>2</sup>, Francesco Bedogni<sup>1</sup>

Access		+		++		++
Support		+/-		+		++
Ant deliverability		+/-		+		++



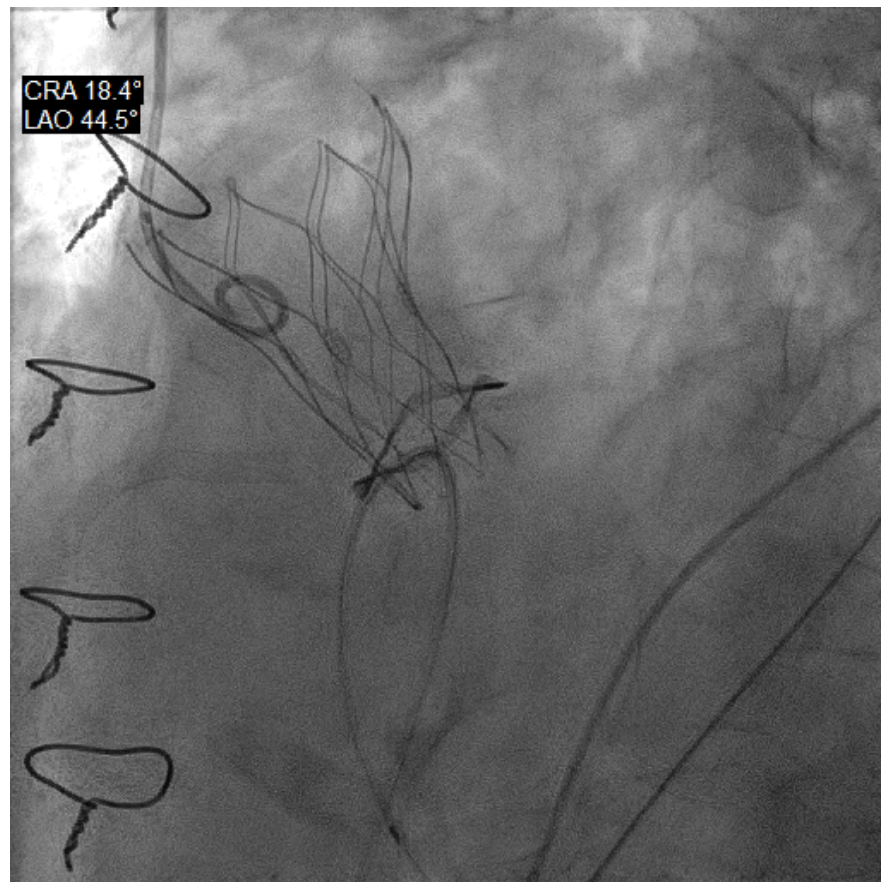
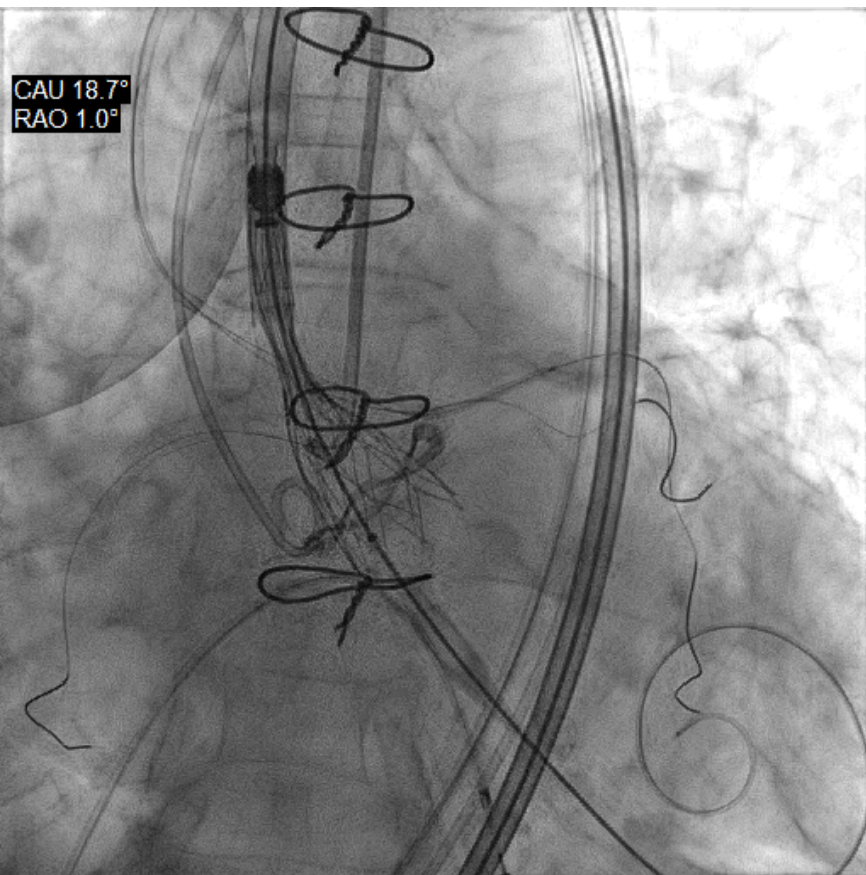




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# Mitraflow 21

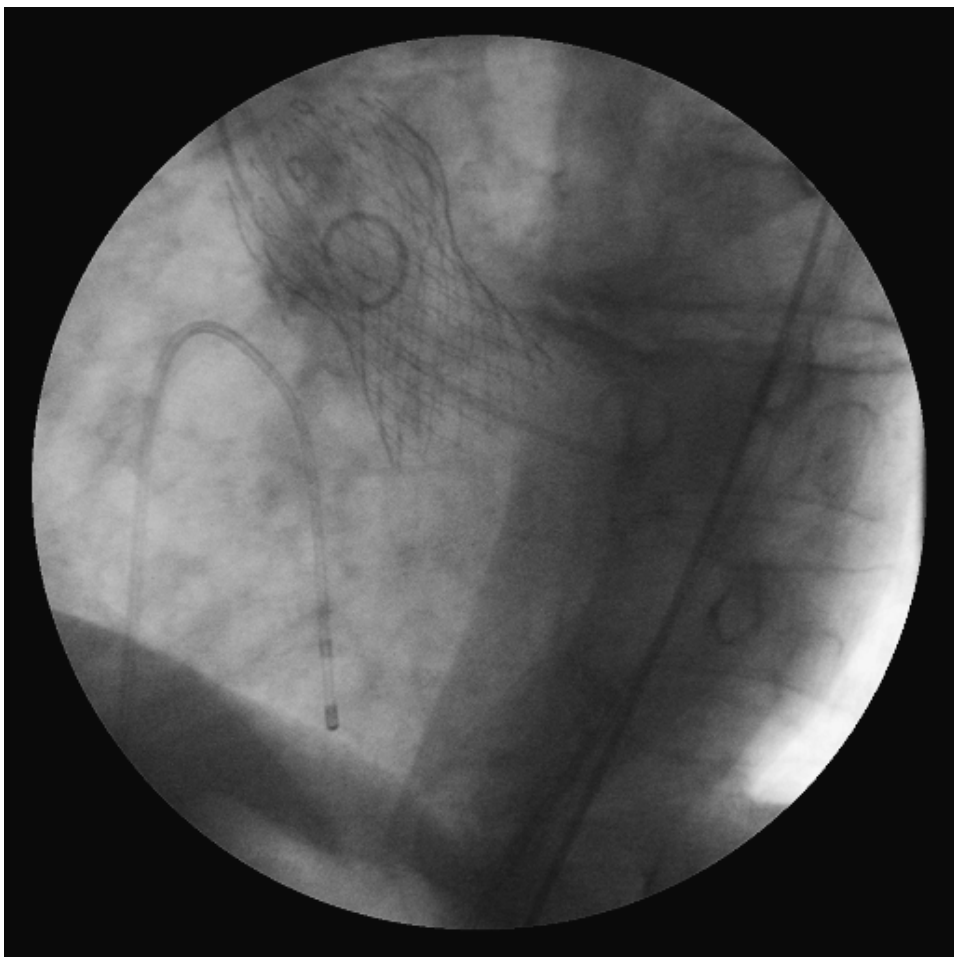
## Double protection and Double stent ostial implantation



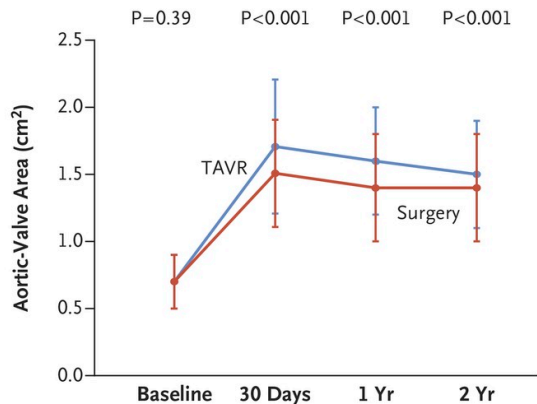


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# AR paravalvular leak



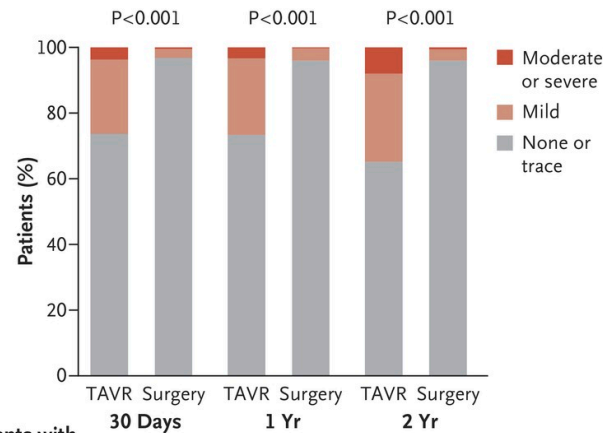
### A Aortic-Valve Area



#### No. of Patients with Echocardiographic Findings

	Baseline	30 Days	1 Yr	2 Yr
TAVR	899	829	695	567
Surgery	861	727	590	488

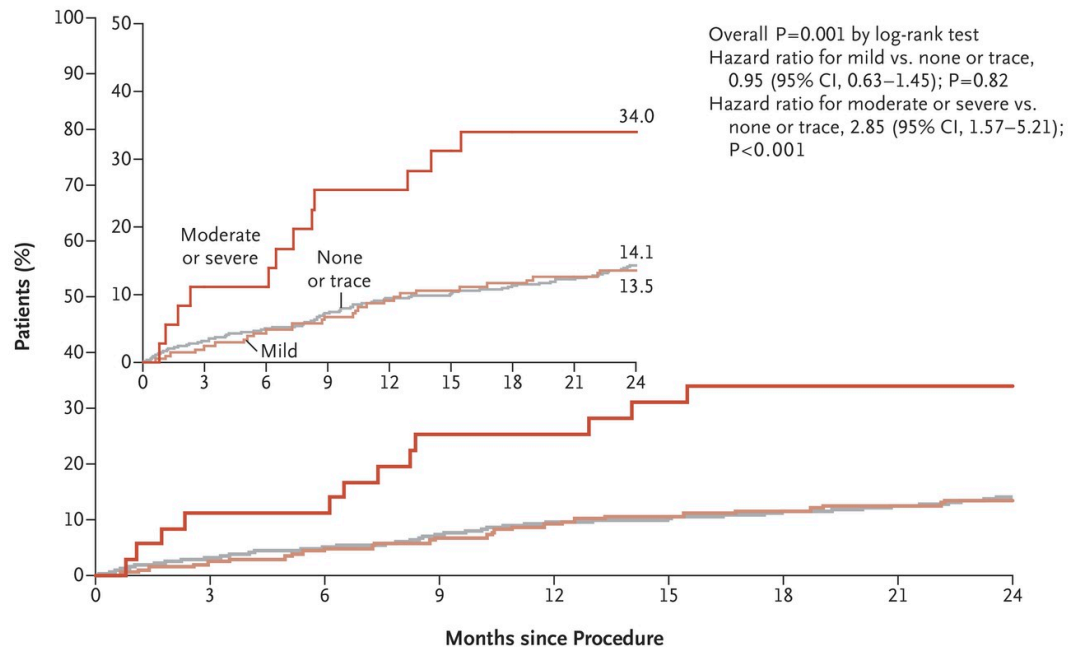
### B Paravalvular Aortic Regurgitation



#### No. of Patients with Echocardiographic Findings

	30 Days	1 Yr	2 Yr
TAVR	872	728	600
Surgery	757	611	514

### C Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation



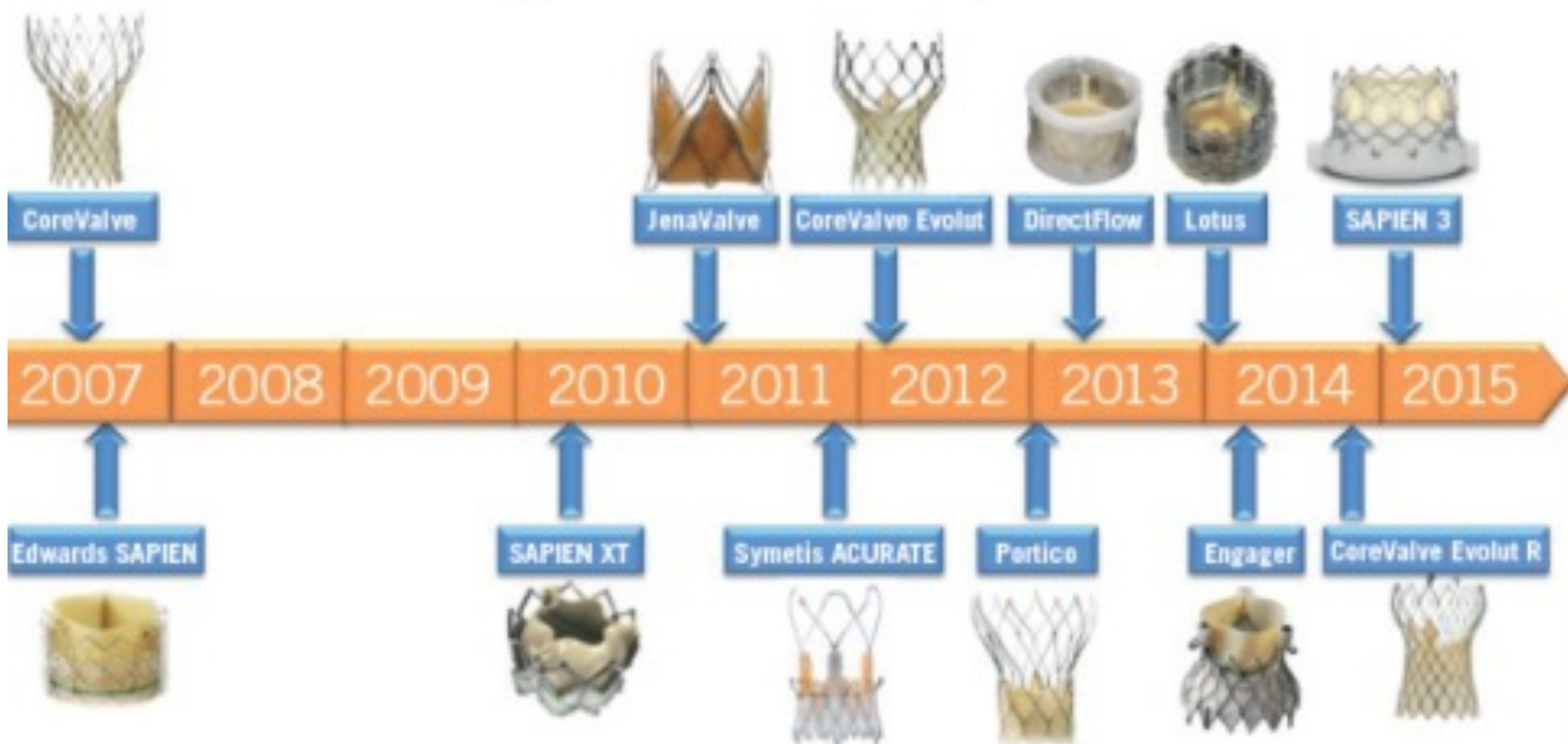
#### No. at Risk

	0	3	6	9	12	15	18	21	24
None or trace	701	678	664	647	628	621	612	605	585
Mild	210	204	199	194	188	184	182	180	175
Moderate or severe	36	32	32	26	26	24	22	22	21



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# Approved CE Mark TAVI Systems



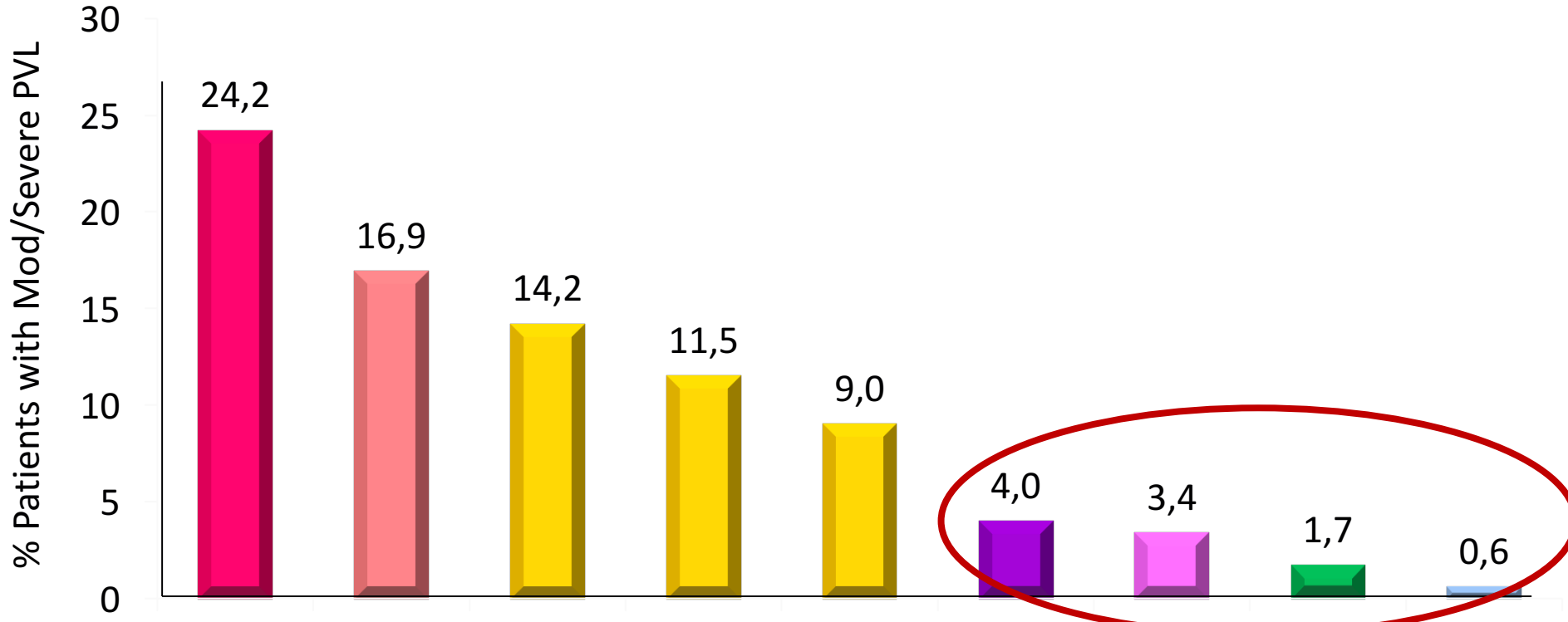




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# 1 Month Moderate & Severe PVL

## TAVI Clinical Trials

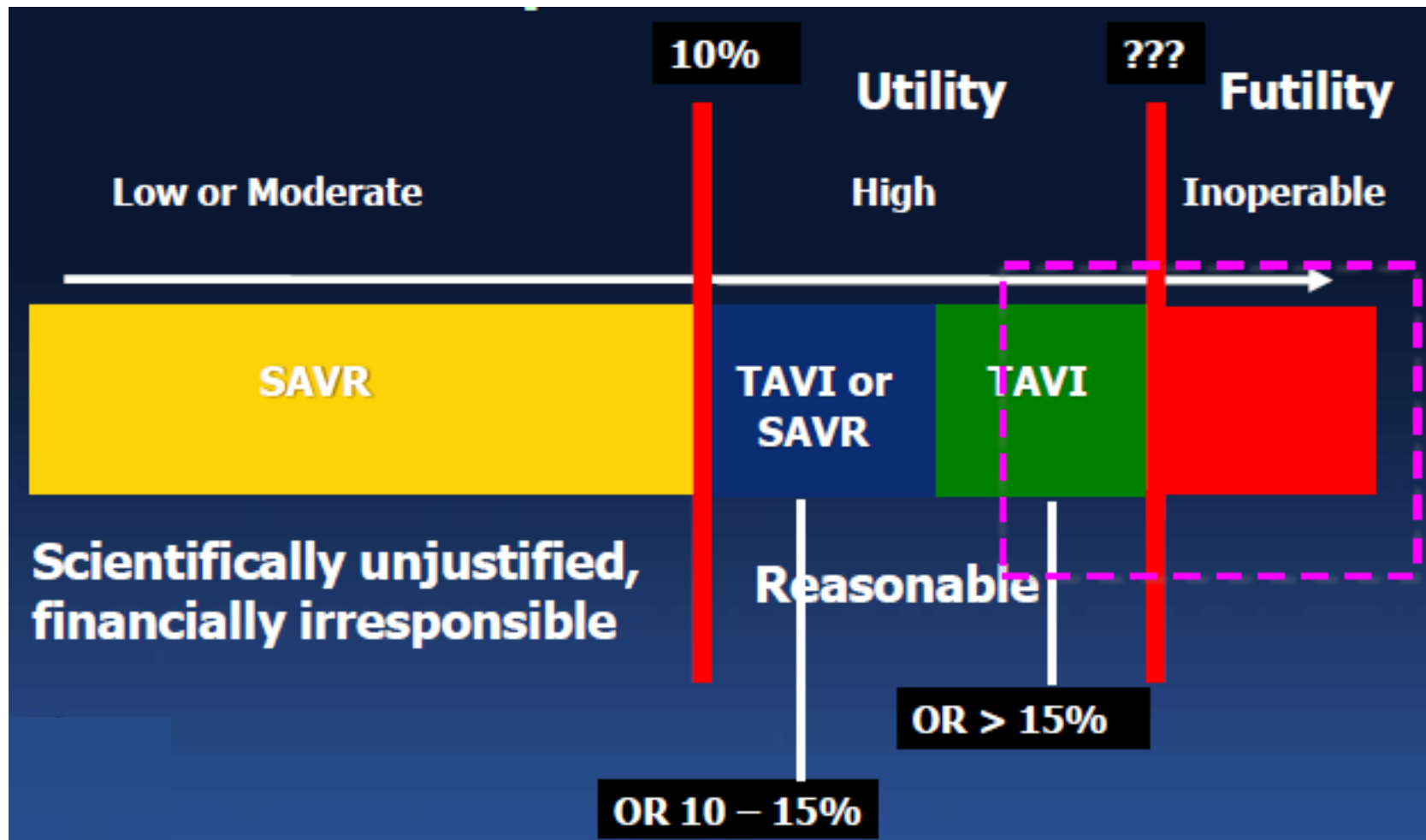


	SAPIEN XT PARTNER II, Inop <sup>1</sup>	SAPIEN PARTNER II Inop <sup>1</sup>	CoreValve ADVANCE <sup>2</sup>	CoreValve Extreme Risk <sup>3</sup>	CoreValve High Risk <sup>4</sup>	Portico CE Study <sup>5</sup>	SAPIEN 3 <sup>6</sup>	Direct Flow DISCOVER <sup>7</sup>	LOTUS REPRISE II & EXT <sup>8</sup>
	N=236	N=225	N=639	N=418	N=390	N=75	N=150	N=100	N=250

<sup>1</sup>Leon M, ACC 2013, <sup>2</sup>Linke A, PCR 2014. <sup>3</sup>Popma J, JACC 2014; 63(19): 1972-81, <sup>4</sup>Adams D, N Engl J Med 2014; 370: 1790-98. <sup>5</sup>Manoharan, et al. TCT 2014. <sup>6</sup>Webb J, EuroPCR 2014. <sup>7</sup>Schofer, JACC 2013. <sup>8</sup>Ian Meredith, London Valves 2014. Results from different studies not directly comparable. Information provided for educational purpose only



# Optimal TAVI eligibility according to operative risk





# 2014 – AHA/ACC TAVI Guidelines

*Nishimura et al. JACC*

## **Class I:**

- Heart Valve Team should collaborate on decisions
- Pts not suitable for AVR and survival > 12 mos

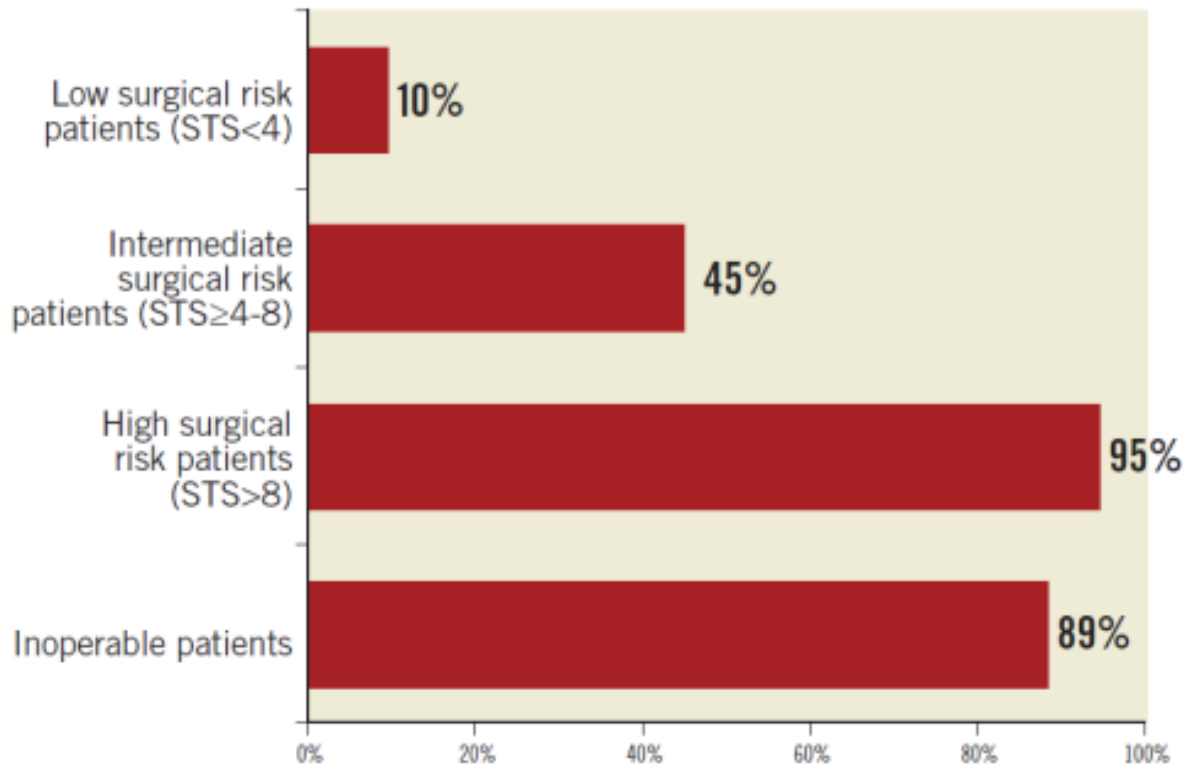
## **Class IIa:**

- Reasonable alternative to surgical AVR in high surgical risk pts

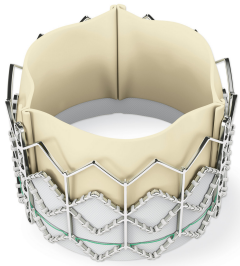
Recommendations	COR	LOE
Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.4) with low or intermediate surgical risk (Section 2.5 in the full-text guideline)	I	A
For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care	I	C
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo	I	B
TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.4) and who have high surgical risk (Section 2.5 in the full-text guideline)	IIa	B
Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS	IIb	C
TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS	III: No Benefit	B

# Patient risk distribution

Current status of transcatheter valve therapy in Europe:  
results from an EAPCI survey







# TAVI clinical data – RCT



Futile	Extreme Risk	High Risk	Intermediate Risk	Low Risk
	STS >15%	STS 10-15%	STS 4-10	STS <4%

PARTNER1B	PARTNER1B CoreValve	PARTNER IIA S3i	NOTION
-----------	------------------------	--------------------	--------

Standard  
vs TAVI

SAVR  
vs TAVI

SAVR  
vs TAVI

SAVR  
vs TAVI

# Inoperable patients with severe AS

## PARTER 1 B

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

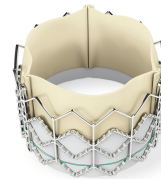
Prof Samir R Kapadia, MD<sup>✉</sup>, Prof Martin B Leon, MD, Raj R Makkar, MD, Prof E Murat Tuzcu, MD, Prof Lars G Svensson, MD, Susheel Kodali, MD, Prof John G Webb, MD, Prof Michael J Mack, MD, Prof Pamela S Douglas, MD, Prof Vinod H Thourani, MD, Vasilis C Babaliaros, MD, Prof Howard C Herrmann, MD, Wilson Y Szeto, MD, Augusto D Pichard, MD, Mathew R Williams, MD, Gregory P Fontana, MD, Prof D Craig Miller, MD, William N Anderson, PhD, Prof Craig R Smith, MD for the PARTNER trial investigators

Jodi J Akin<sup>\*</sup>, Michael J Davidson<sup>†</sup>

<sup>\*</sup> J J Akin MS has no affiliations

<sup>†</sup> M J Davidson MD died in January, 2015

Published Online: 15 March 2015



Journal of the American College of Cardiology  
© 2014 by the American College of Cardiology Foundation  
Published by Elsevier Inc.

Vol. 63, No. 19, 2014  
ISSN 0735-1097/\$36.00  
<http://dx.doi.org/10.1016/j.jacc.2014.02.556>

### Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

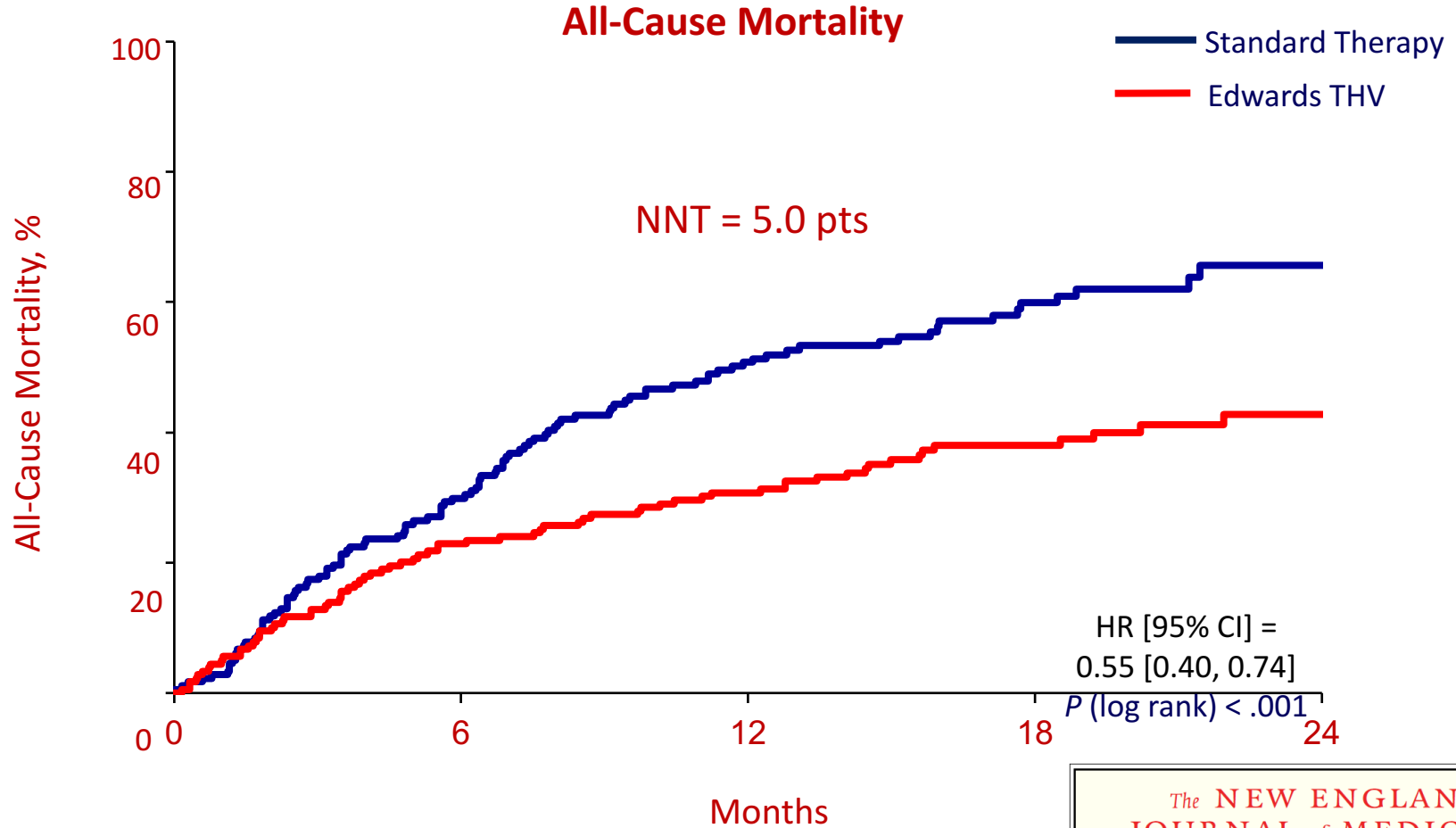


Jeffrey J. Popma, MD,<sup>\*</sup> David H. Adams, MD,<sup>†</sup> Michael J. Reardon, MD,<sup>‡</sup> Steven J. Yakubov, MD,<sup>§</sup> Neal S. Kleiman, MD,<sup>‡</sup> David Heimansohn, MD,<sup>||</sup> James Hermiller, Jr, MD,<sup>||</sup> G. Chad Hughes, MD,<sup>¶</sup> J. Kevin Harrison, MD,<sup>¶</sup> Joseph Coselli, MD,<sup>#</sup> Jose Diez, MD,<sup>#</sup> Ali Kafi, MD,<sup>\*\*</sup> Theodore Schreiber, MD,<sup>\*\*</sup> Thomas G. Gleason, MD,<sup>††</sup> John Conte, MD,<sup>‡‡</sup> Maurice Buchbinder, MD,<sup>§§</sup> G. Michael Deeb, MD,<sup>|||</sup> Blasé Carabello, MD,<sup>¶¶</sup> Patrick W. Serruys, MD, PhD,<sup>##</sup> Sharla Chenoweth, MS,<sup>\*\*\*</sup> Jae K. Oh, MD,<sup>†††</sup> for the CoreValve United States Clinical Investigators

*Boston, Massachusetts; New York, New York; Houston, Texas; Columbus, Ohio; Indianapolis, Indiana; Durham, North Carolina; Detroit and Ann Arbor, Michigan; Pittsburgh, Pennsylvania; Baltimore, Maryland; Palo Alto, California; Rotterdam, the Netherlands; and Minneapolis and Rochester, Minnesota*



# Partner Trial cohort B Inoperable patients



The NEW ENGLAND  
JOURNAL of MEDICINE

Numbers at Risk			
Edwards THV	179	138	122
Standard Therapy	179	121	83

Transcatheter Aortic-Valve Implantation  
for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*

# High surgical risk

## 2011 PARTNER 1 A (Mean STS 12)

### 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

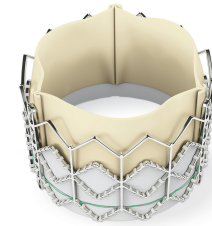
Prof Michael J Mack, MD<sup>✉</sup>, Prof Martin B Leon, MD, Prof Craig R Smith, MD, Prof D Craig Miller, MD, Prof Jeffrey W Moses, MD, Prof E Murat Tuzcu, MD, Prof John G Webb, MD, Prof Pamela S Douglas, MD, William N Anderson, PhD, Eugene H Blackstone, MD, Susheel K Kodali, MD, Raj R Makkar, MD, Gregory P Fontana, MD, Prof Samir Kapadia, MD, Prof Joseph Bavaria, MD, Rebecca T Hahn, MD, Prof Vinod H Thourani, MD, Vasilis Babaliaros, MD, Prof Augusto Pichard, MD, Prof Howard C Herrmann, MD, David L Brown, MD, Mathew Williams, MD, Michael J Davidson, MD<sup>†</sup>, Prof Lars G Svensson, MD for the PARTNER 1 trial investigators

<sup>†</sup> M J Davidson died in January, 2015

Jodi Akin<sup>\*</sup>

<sup>\*</sup> J Akin MS has no affiliations

Published Online: 15 March 2015



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

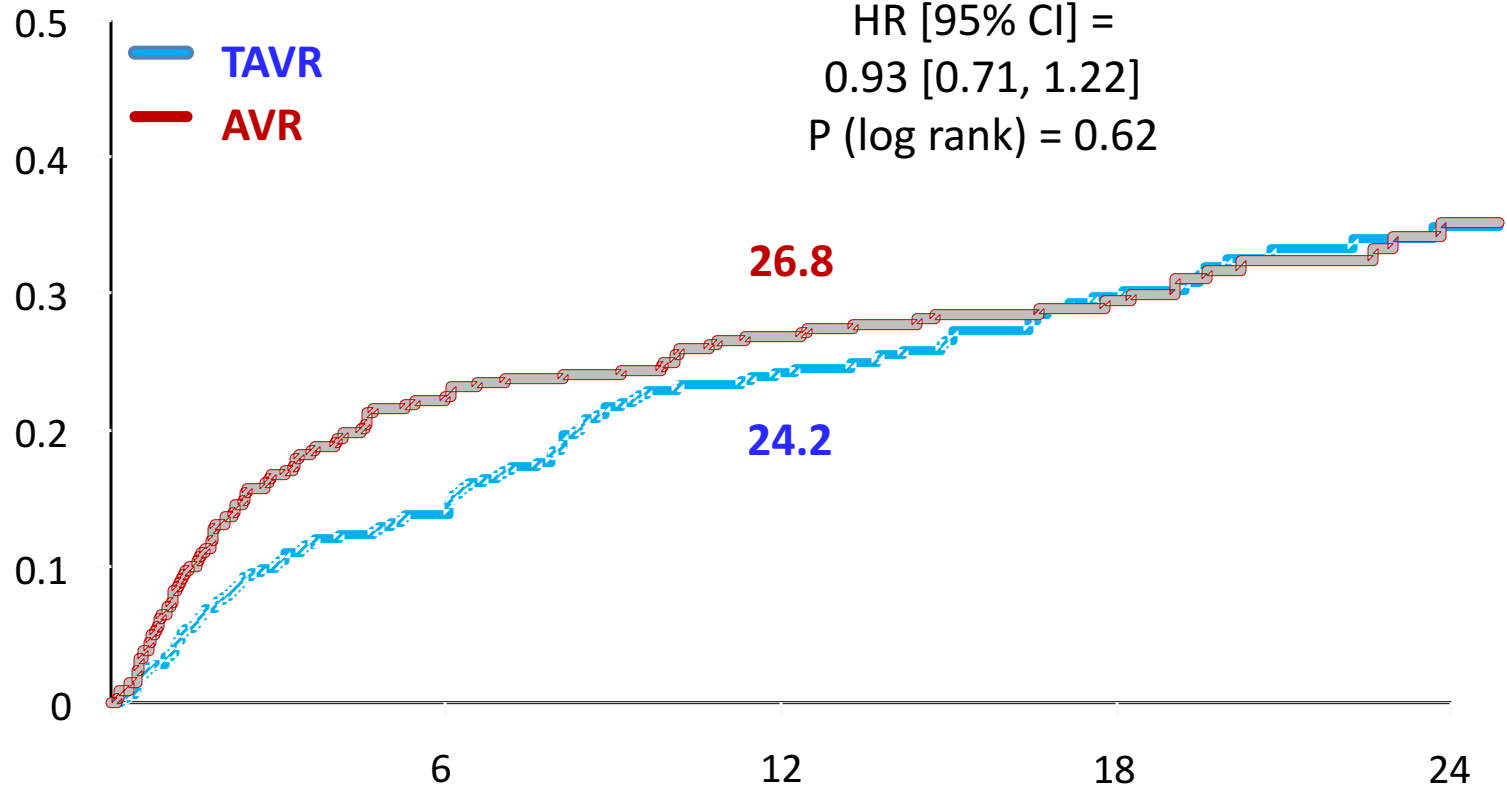
David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators\*



2014 COREVALVE US TRIAL Mean STS 7.4



# Primary Endpoint: All-Cause Mortality



No. at Risk

Months

TAVR	348	298	260	147	67
AVR	351	252	236	139	65



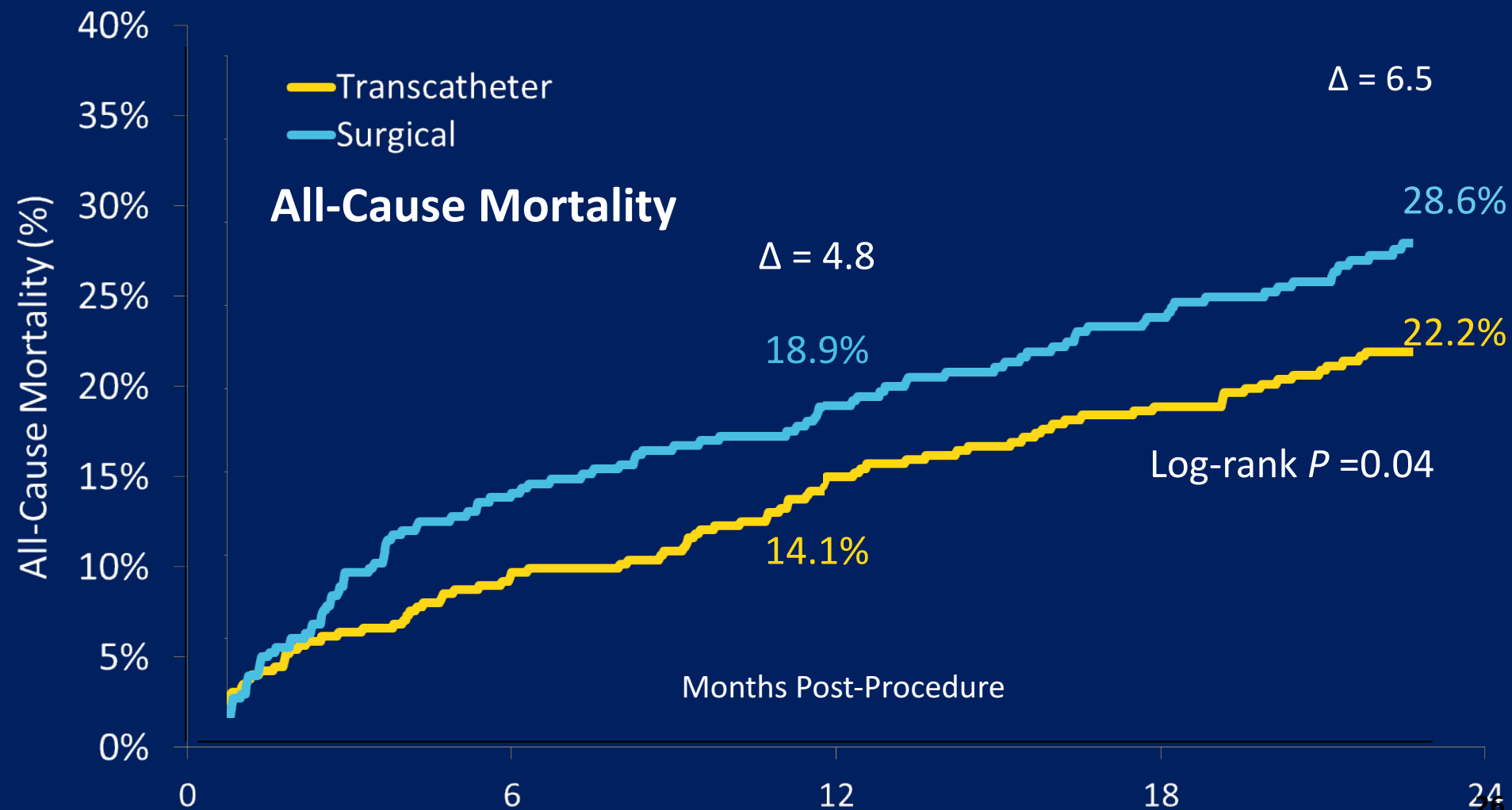
ORIGINAL ARTICLE

# Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

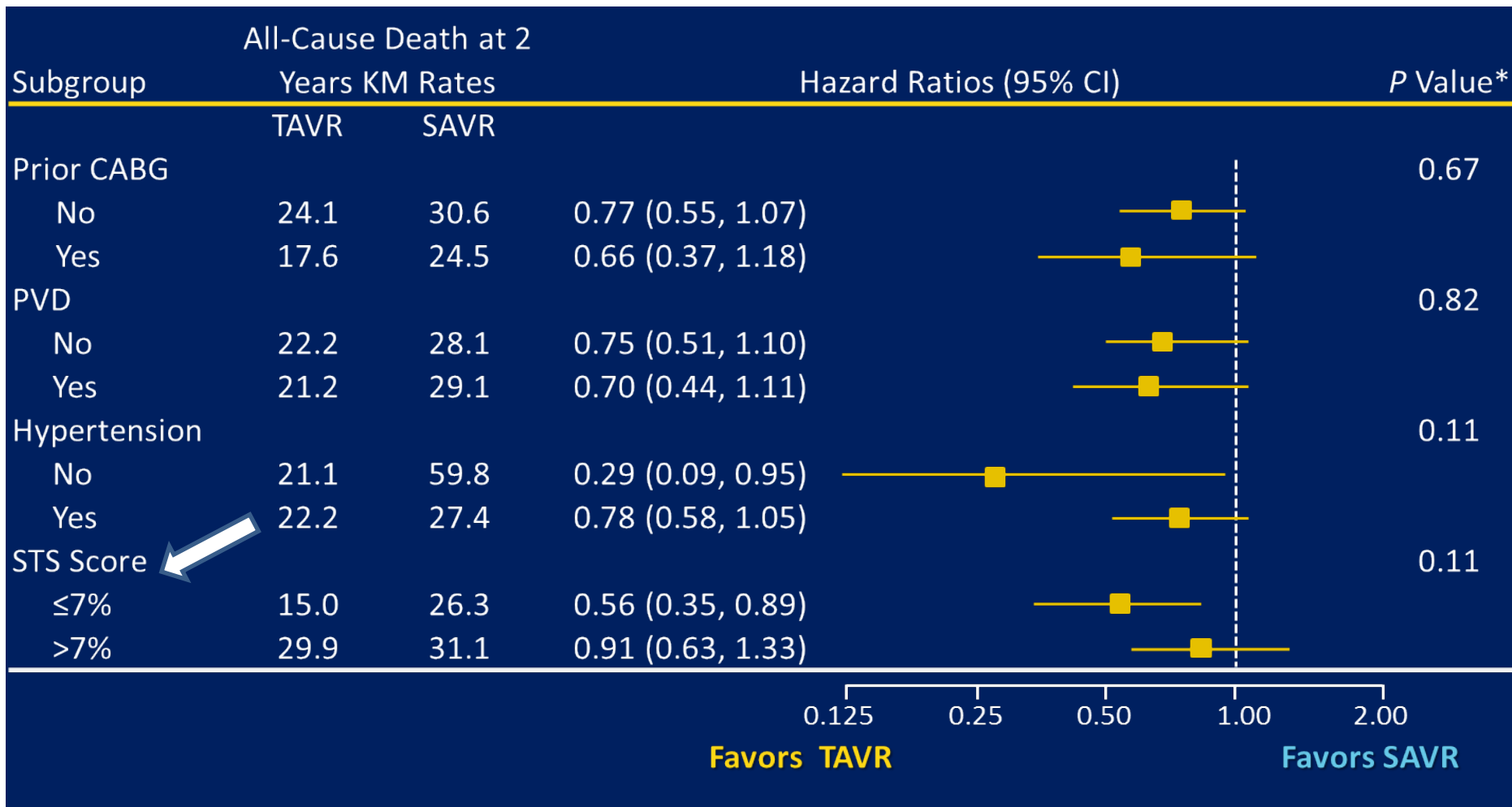
D.H. Adams et al. for the CoreValve Clinical Investigator

29 March 2014

## Corevalve US clinical trial ACC 2015



# Subgroup Analysis for 2-Year Mortality



# Intermediate Risk

2016 PARTNER 2 (STS 5.8)

*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

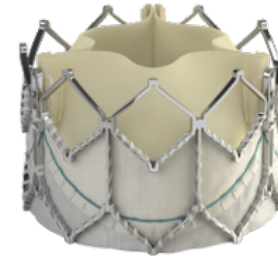
ESTABLISHED IN 1812

APRIL 28, 2016

VOL. 374 NO. 17

## Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,  
Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D.,  
D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D.,  
Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D.,  
Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D.,  
Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D.,  
Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D.,  
Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.D.,  
and John C. Webb, M.D., for the PARTNER 2 Investigators\*



2017 SURTAVI (STS 4.5)

*The* NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE



## Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard,  
M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason,  
J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams,  
S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang,  
H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein,  
for the SURTAVI Investigators\*

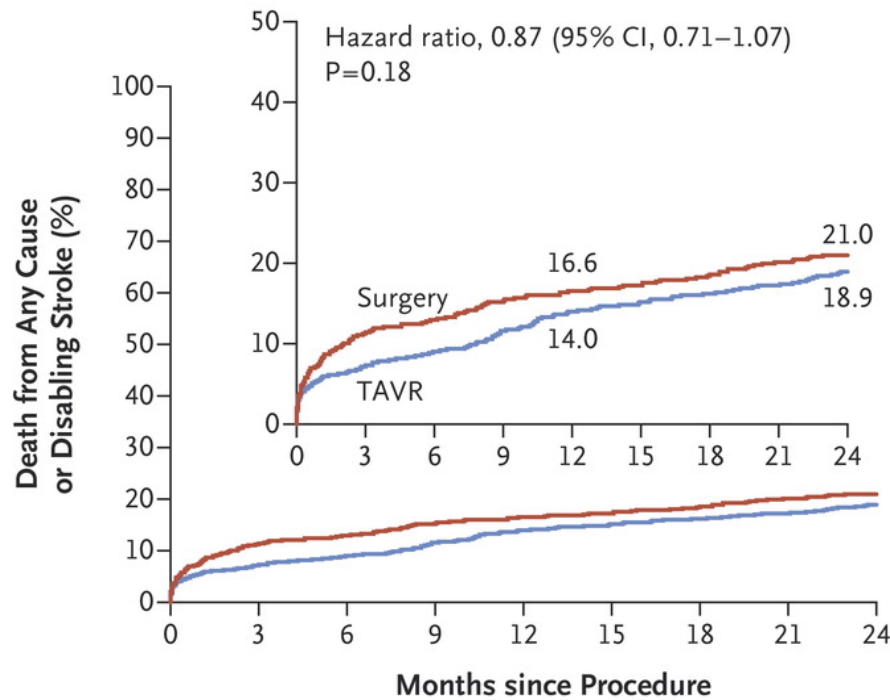


## Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators\*

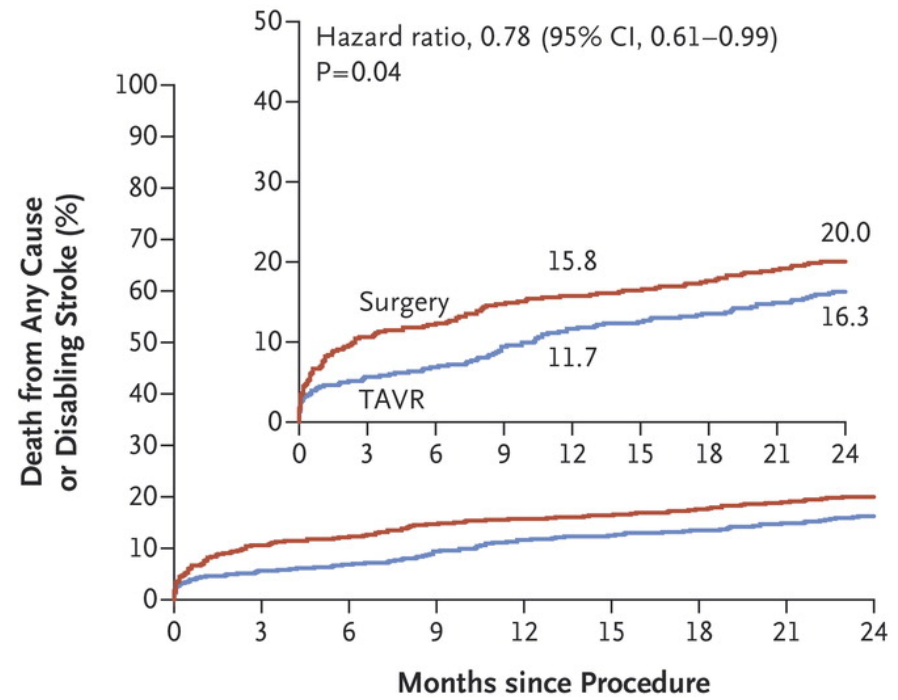
# Partner 2° ACC 2016

As-Treated Population



No. at Risk	0	3	6	9	12	15	18	21	24
TAVR	994	917	900	870	842	825	811	801	774
Surgery	944	826	807	779	766	743	731	715	694

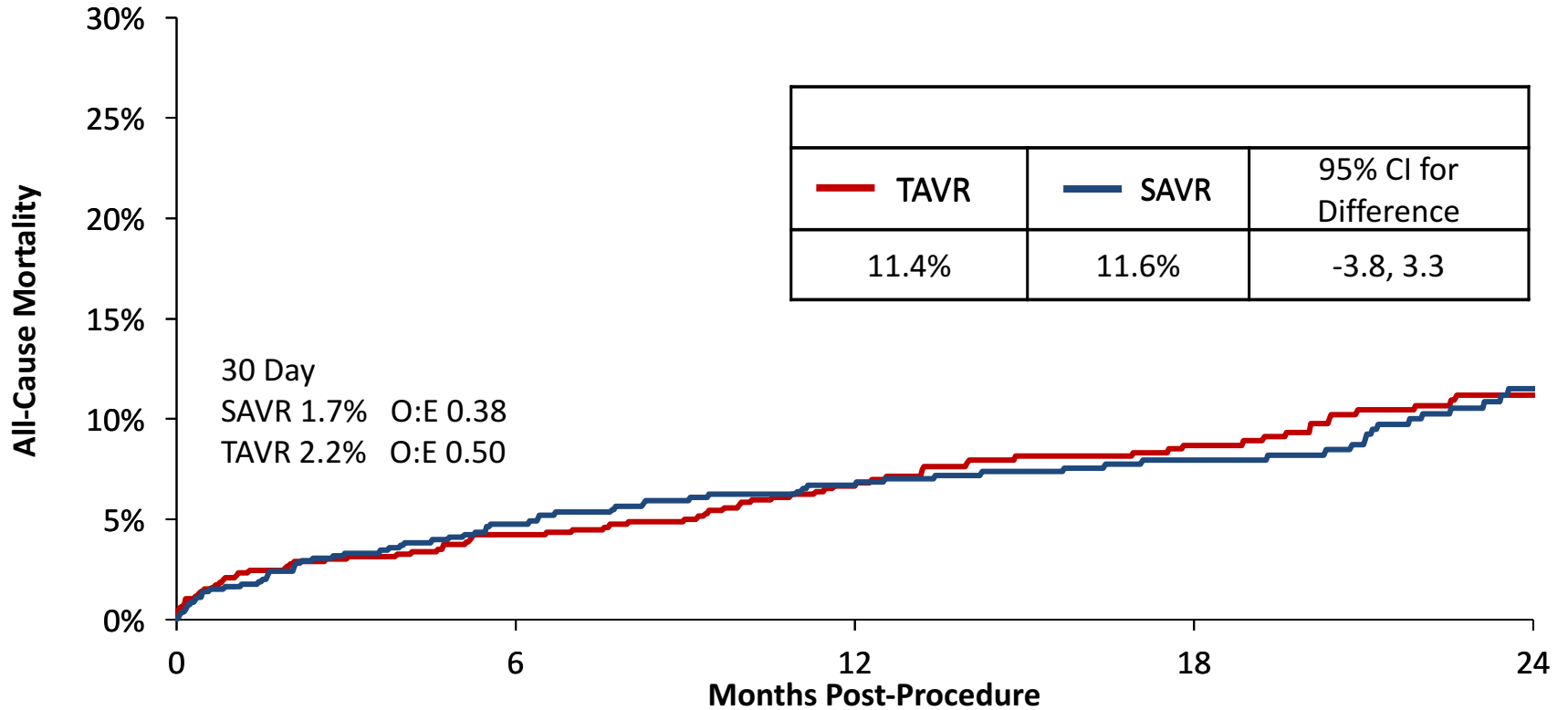
Transfemoral-Access Cohort, As-Treated Analysis



No. at Risk	0	3	6	9	12	15	18	21	24
TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537

# SURTAVI

## All-Cause Mortality



No. at Risk

SAVR	796	690	569	414	249
TAVR	864	762	621	465	280



# LOW RISK

## NOTION trial ( STS 3)

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY  
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PUBLISHED BY ELSEVIER INC.

VOL. 65, NO. 20, 2015  
ISSN 0735-1097/\$36.00  
<http://dx.doi.org/10.1016/j.jacc.2015.03.014>

# Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis

## 1-Year Results From the All-Comers NOTION Randomized Clinical Trial



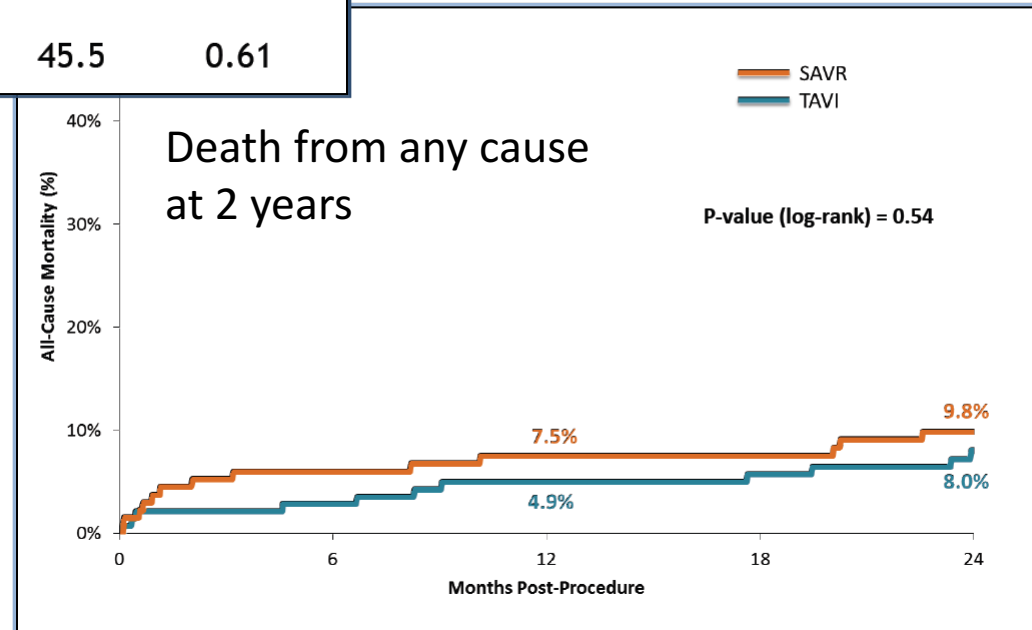
Hans Gustav Hørsted Thyregod, MD,\* Daniel Andreas Steinbrüchel, MD, DMSc,\* Nikolaj Ihlemann, MD, PhD,†  
Henrik Nissen, MD, PhD,‡ Bo Juel Kjeldsen, MD, PhD,§ Petur Petursson, MD,|| Yanping Chang, MS,¶  
Olaf Walter Franzen, MD,† Thomas Engstrøm, MD, DMSc,† Peter Clemmensen, MD, DMSc,† Peter Bo Hansen, MD,#  
Lars Willy Andersen, MD, DMSc,# Peter Skov Olsen, MD, DMSc,\* Lars Søndergaard, MD, DMSc†



# THE NOTION TRIAL

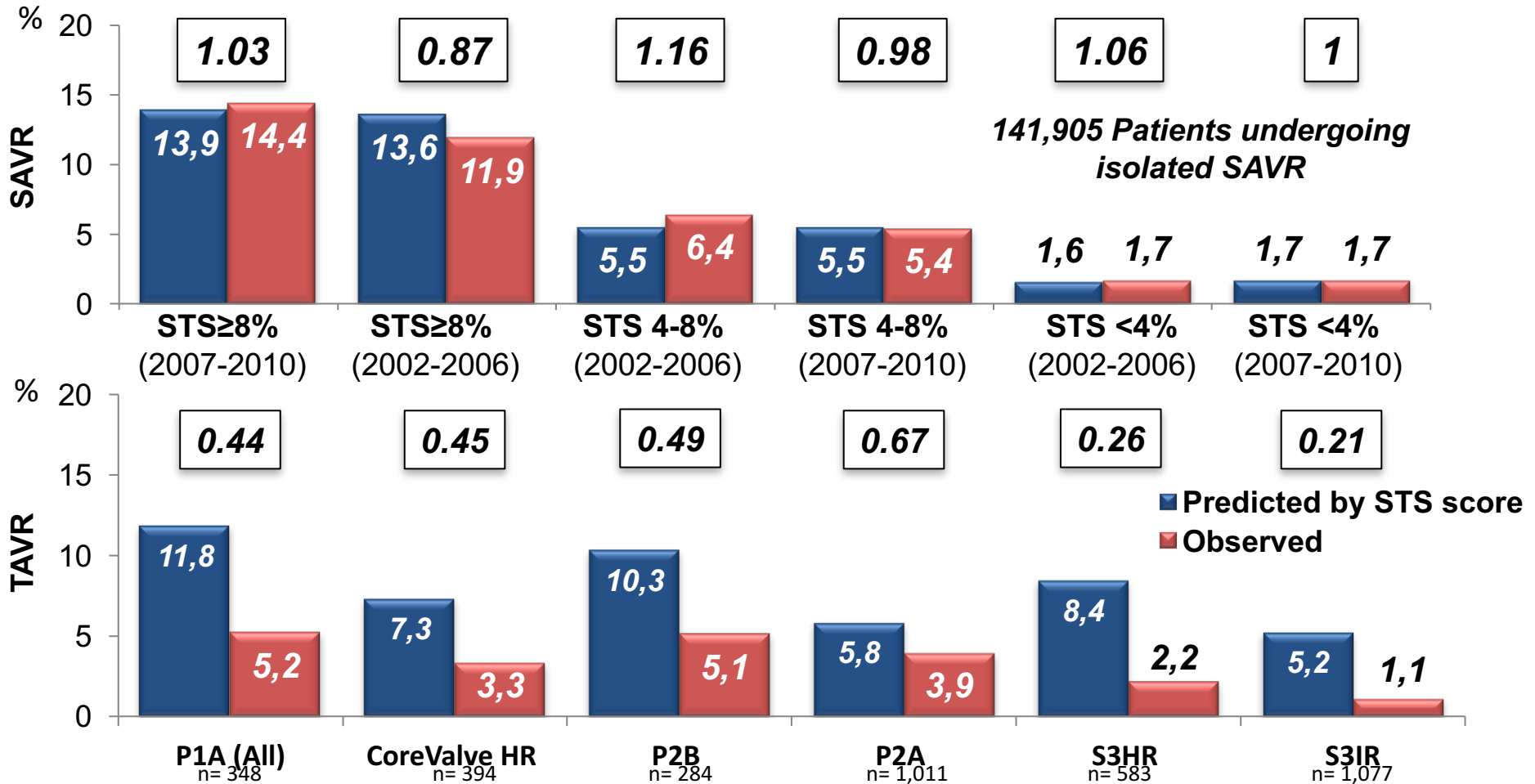
## An All-Comers Randomized Clinical Trial comparing Transcatheter with Surgical Aortic Valve Replacement in Pts with Aortic Valve Stenosis

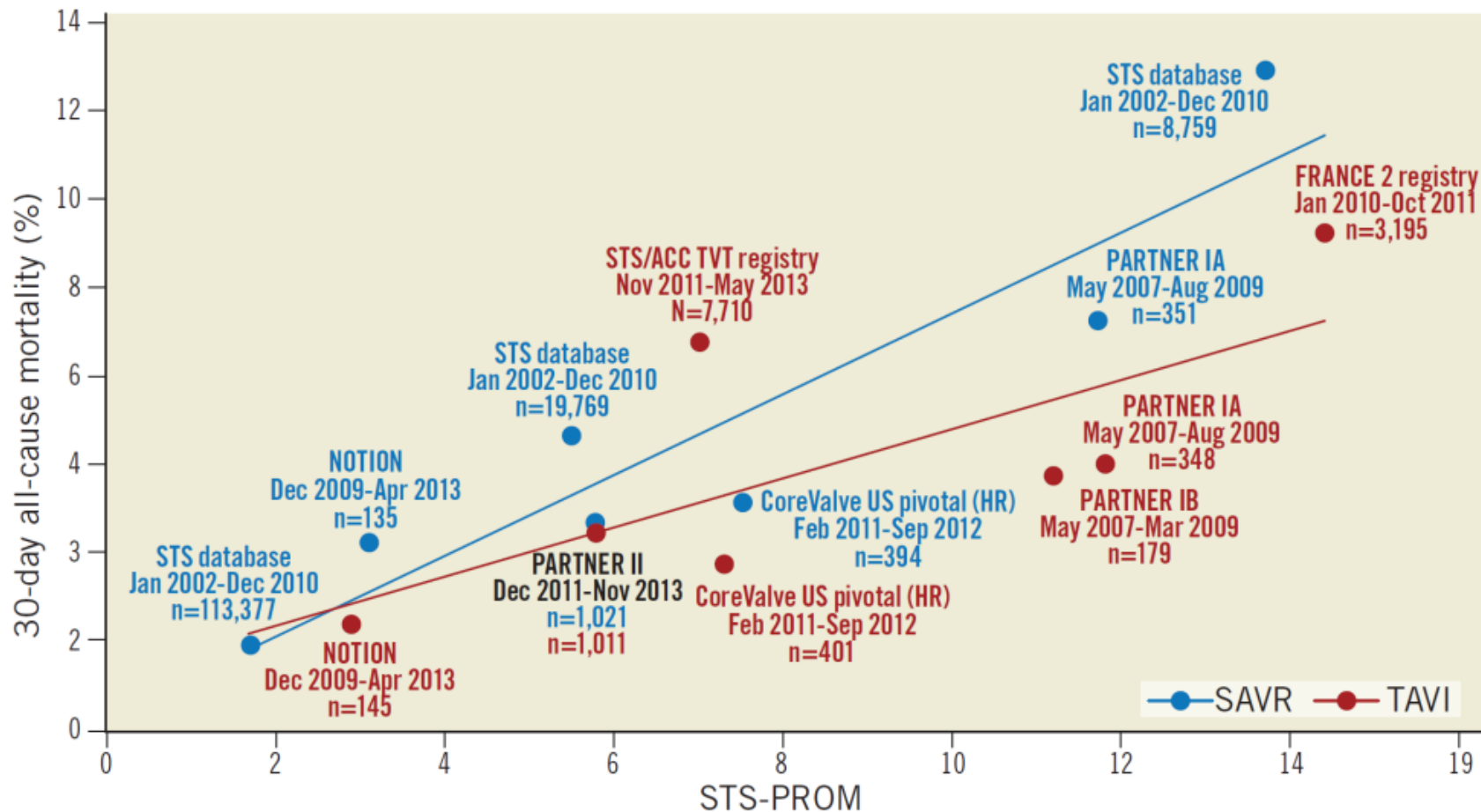
Characteristic, % or mean $\pm$ SD	TAVI n=145	SAVR n=135	p-value
Age (yrs)	79.2 $\pm$ 4.9	79.0 $\pm$ 4.7	0.71
Male	53.8	52.6	0.84
STS Score	2.9 $\pm$ 1.6	3.1 $\pm$ 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 $\pm$ 4.0	8.9 $\pm$ 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61



# OBSERVED VS. PREDICTED MORTALITY AT 30 DAYS AFTER SAVR or TAVI

Thourani et al, *Ann Thorac Surgery* 2015  
Pilgrim et al, *JACC* 2015





STS database: Thourani et al - *Ann Thorac Surg.* 2015;99:55-61; NOTION: Thyregod et al - *J Am Coll Cardiol.* 2015;65:2184-94; PARTNER II: Leon et al - *N Engl J Med.* 2016;374:1609-20; STS/ACC TVT registry: Mack et al - *JAMA.* 2013;310:2069-77; US pivotal (HR): Adams et al - *N Engl J Med.* 2014;370:1790-8; PARTNER IB: Leon et al - *N Engl J Med.* 2010;363:1597-607; PARTNER IA: Smith et al - *N Engl J Med.* 2011;364:2187-98



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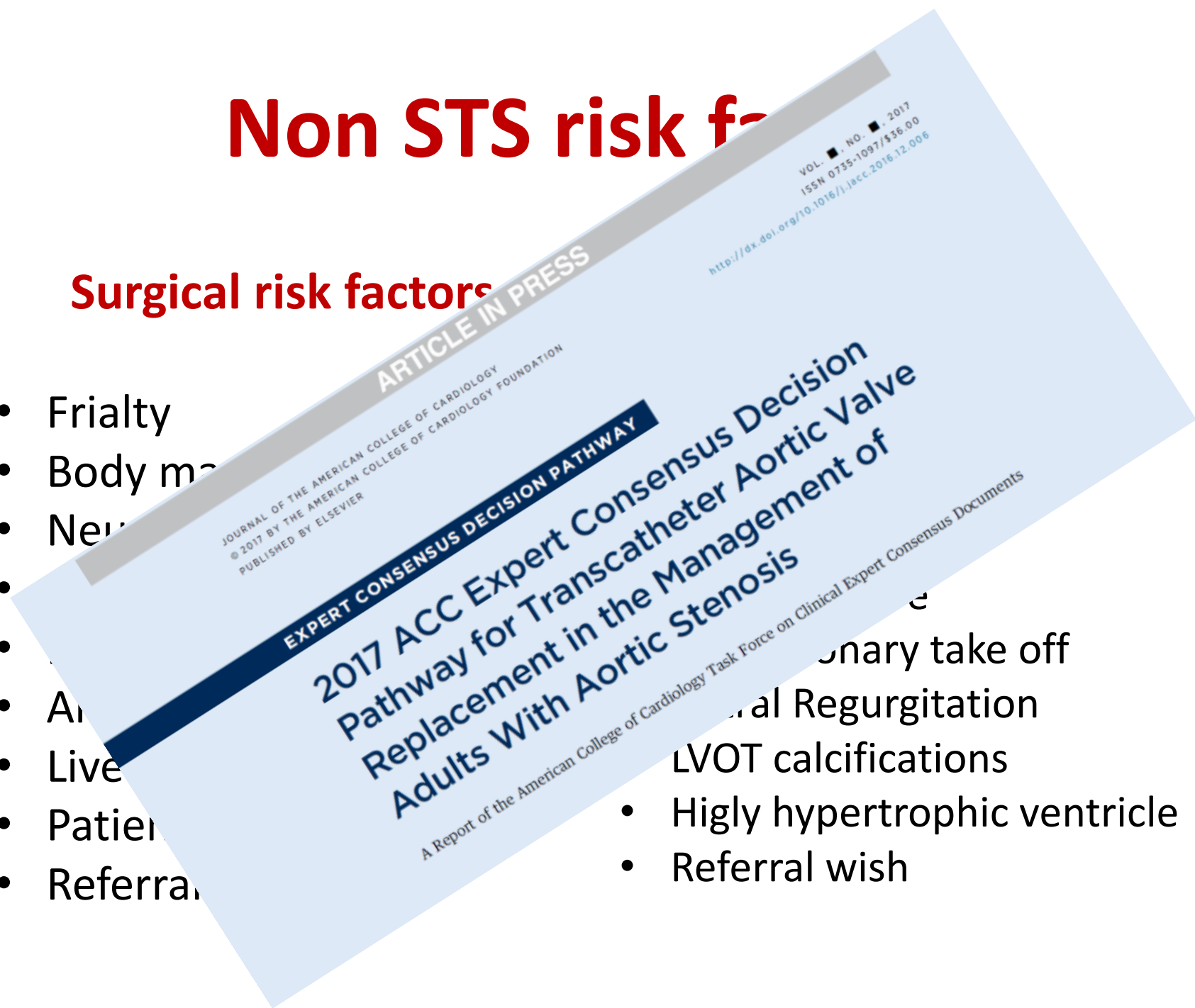


# Non STS risk factors

## Surgical risk factors

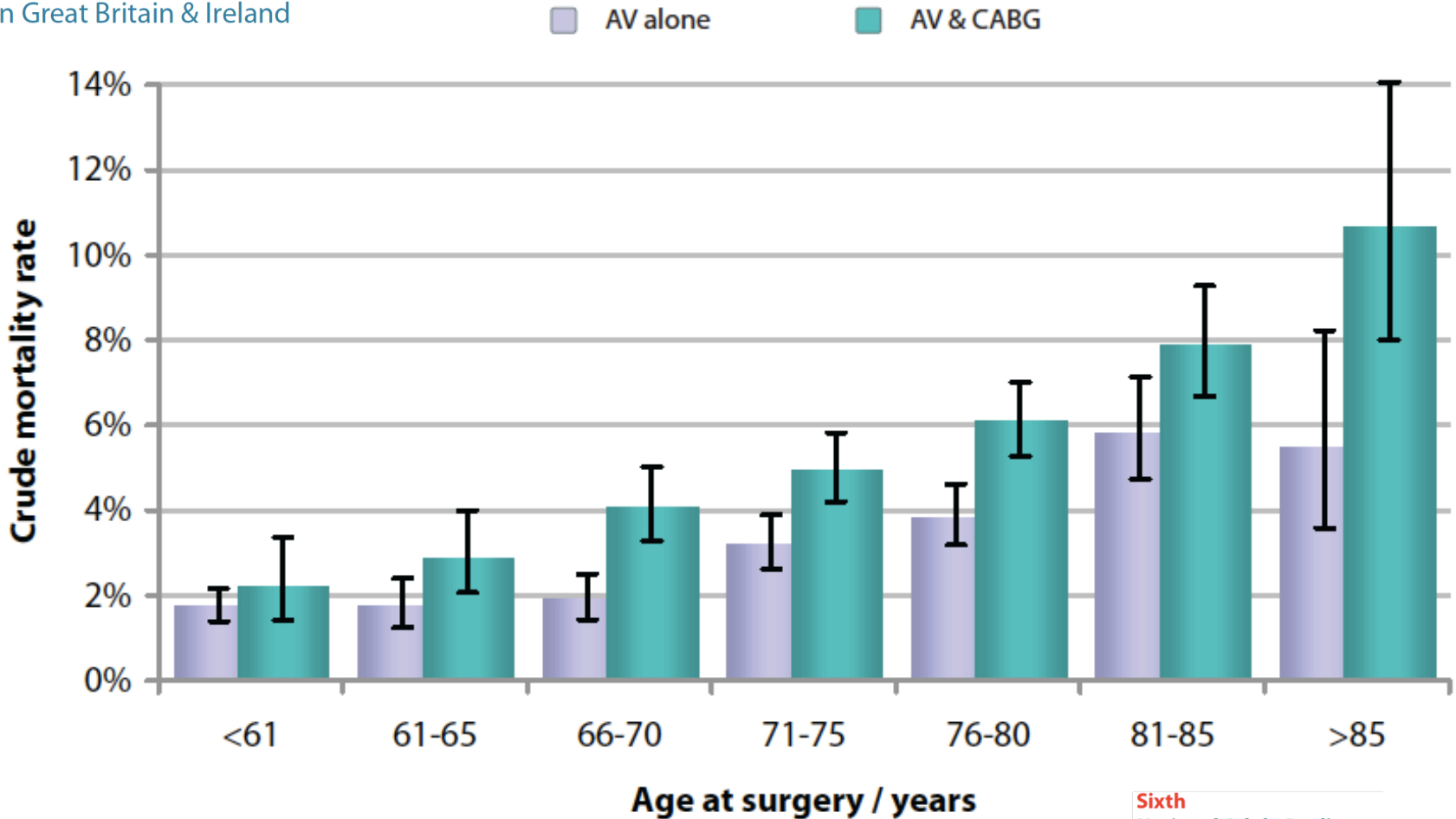
- Frailty
- Body mass index
- Neurocognitive
- Anemia
- Acute kidney injury
- Aortic regurgitation
- Live donor
- Patient frailty
- Referral

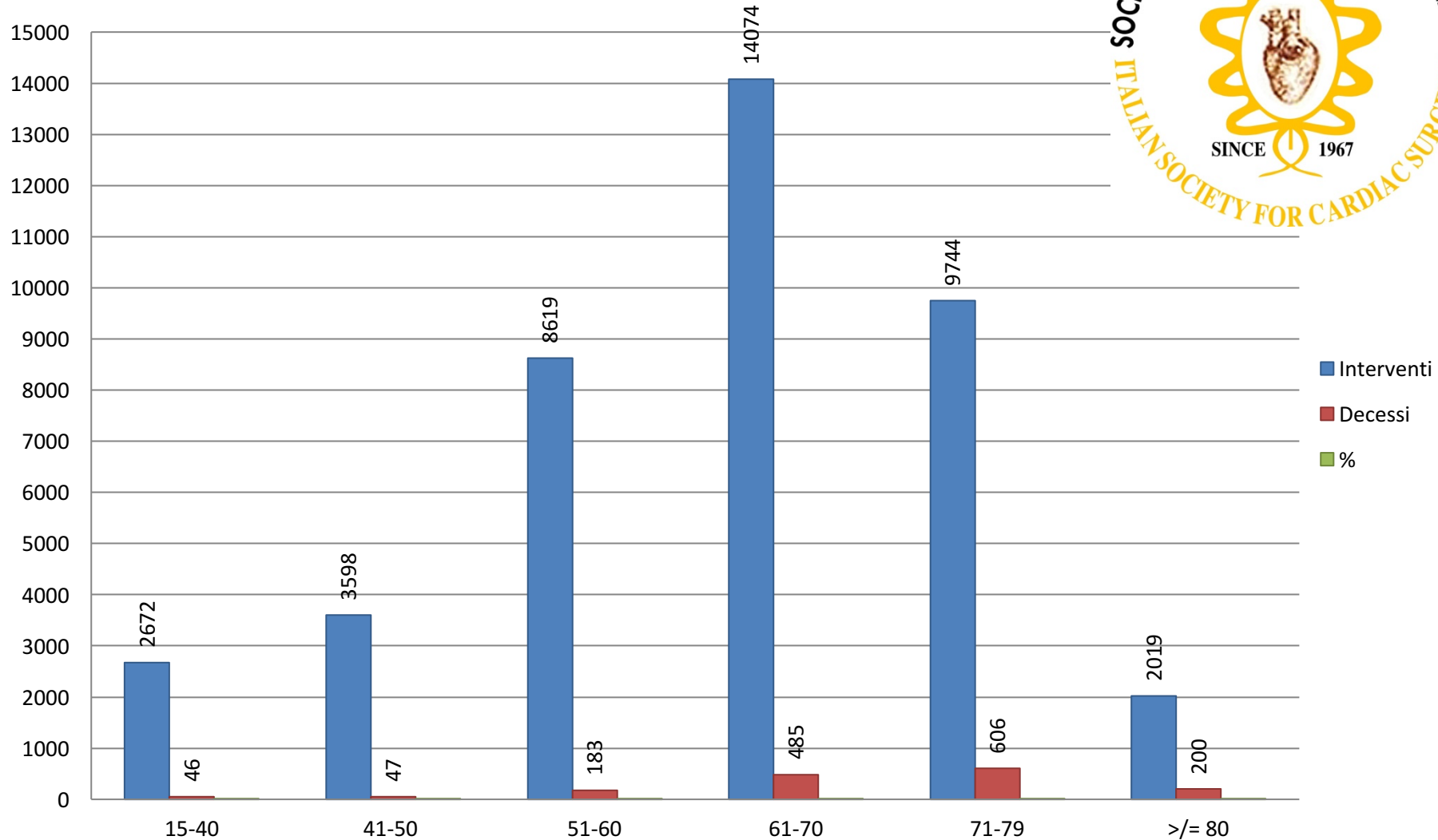
- Secondary take off
- Aortic Regurgitation
- LVOT calcifications
- Highly hypertrophic ventricle
- Referral wish



# Impact of Age Alone

All AV surgery: Crude mortality and age;  
financial years 2004-2008 (n=30,126)





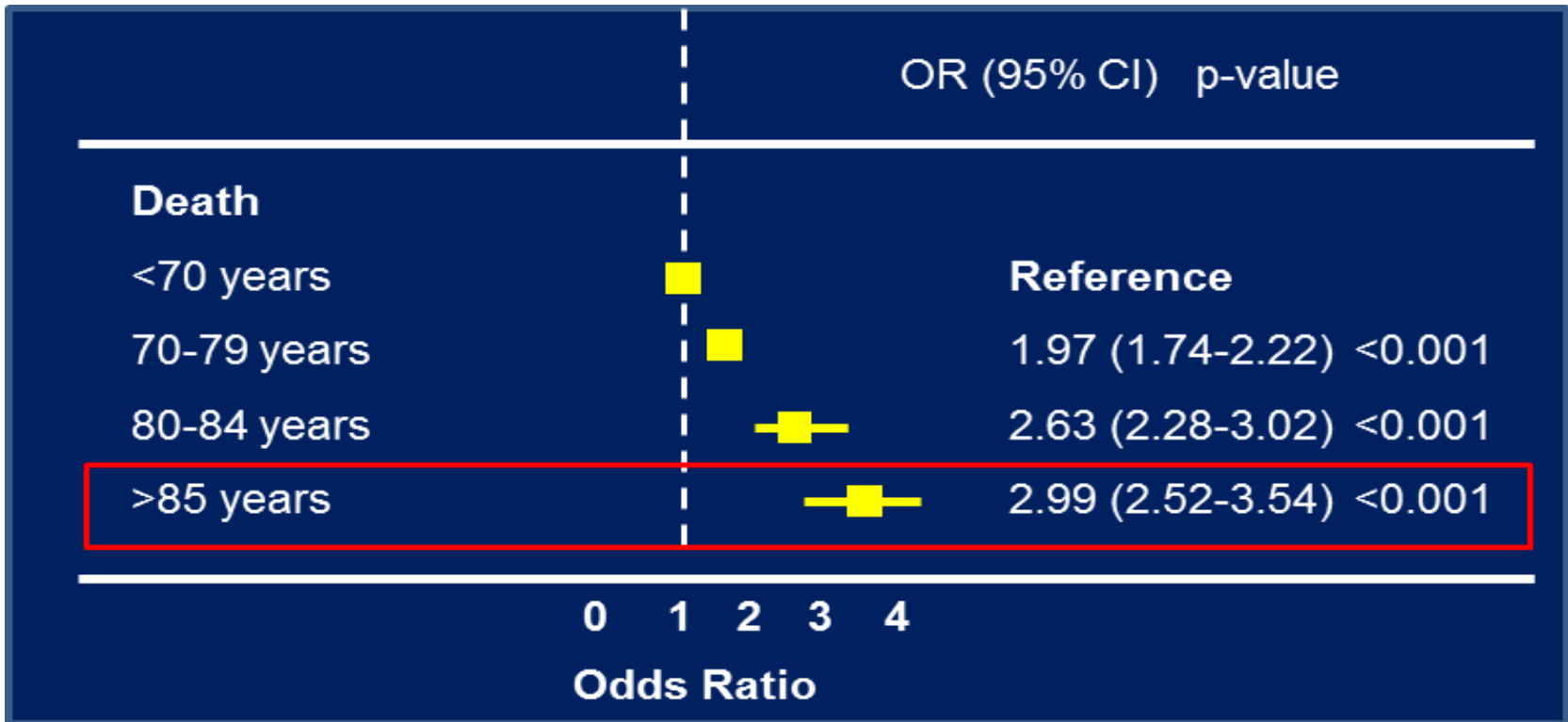
**Mort.**

1.7%      1.3%      2.1%      3.4%      6.2%      **10%**



# FACTORS FAVORING TAVR VS. SAVR

**SAVR – US Registry - 104,699 pts**





## **PARTNER 1 STS 11.6%**

Age						
≤85 yr	28/96 (29.2)	46/90 (51.1)		0.57 (0.39–0.83)	5	0.54
>85 yr	27/83 (32.5)	43/89 (48.3)		0.67 (0.46–0.96)	6	

**Leon MB et al. *NEJM*, 2010**

## **U.S. COREVALVE STS 10.3%**

Age						
≤85 yr	26/204 (12.9)	33/194 (17.2)		0.72 (0.43–1.20)		0.97
>85 yr	29/186 (15.7)	34/163 (21.4)		0.71 (0.43–1.16)		

**Adams D et al. *NEJM*, 2014**

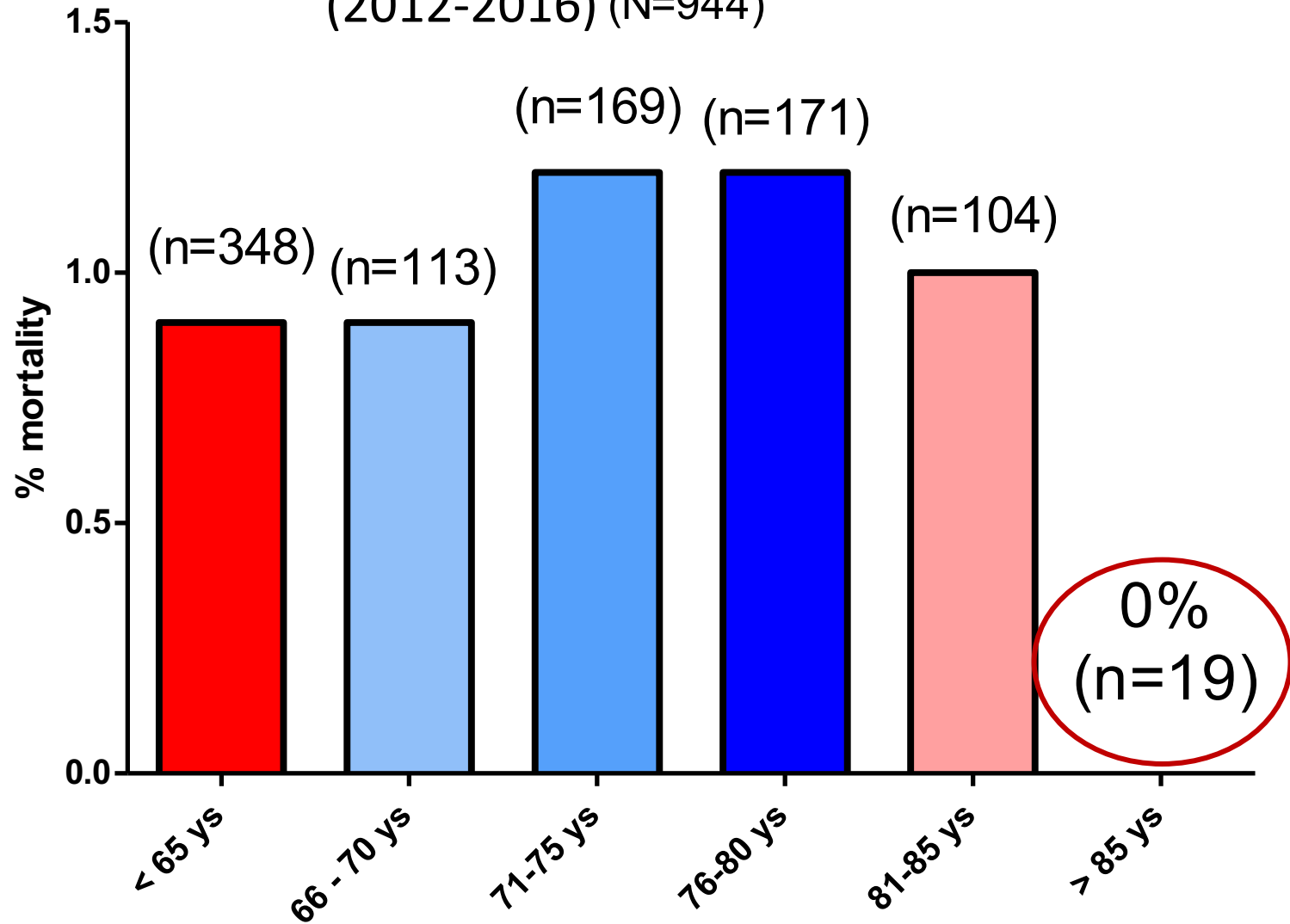
## **PARTNER 2 STS 5.8%**

Age						
<85 yr	1245	111/626 (18.0)	114/619 (19.5)		0.90 (0.69–1.17)	0.96
≥85 yr	787	81/385 (21.5)	88/402 (23.6)		0.89(0.65–1.20)	

**Leon MB et al. *NEJM*, 2016**



# ISOLATED AORTIC VALVE REPLACEMENT (2012-2016) (N=944)



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TAVI Settembre 2015 – Febbraio 2017  
≥ 85 anni

Numero procedure: 133

Percentuale sul numero totale di procedure: 45,9 %

STS score medio: 7,4

Risultati

Mortalità a 30 giorni dalla procedura: 2 ( 1,5 %)



# ***SURGICAL RISK AND AGE***

**Mean Age across studies:**

83

84

83

83

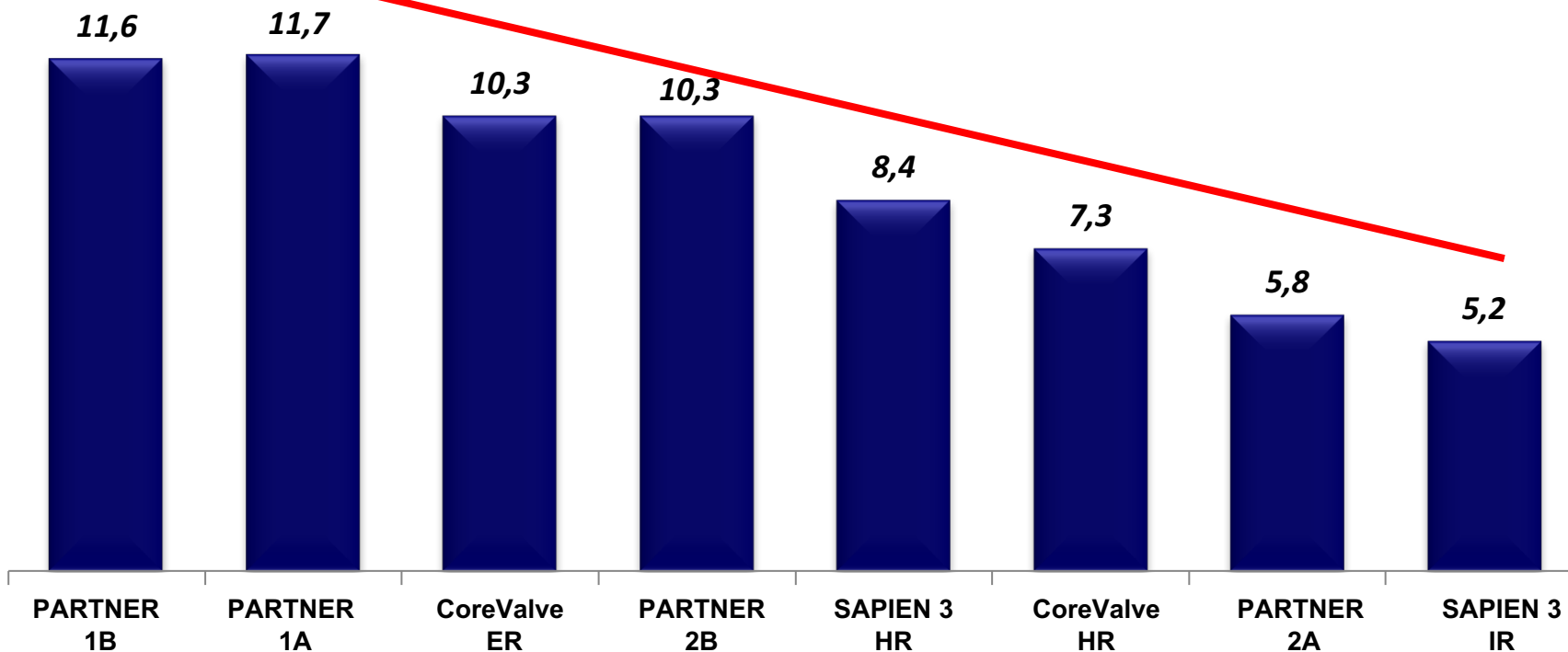
84

82

83

82

STS Score

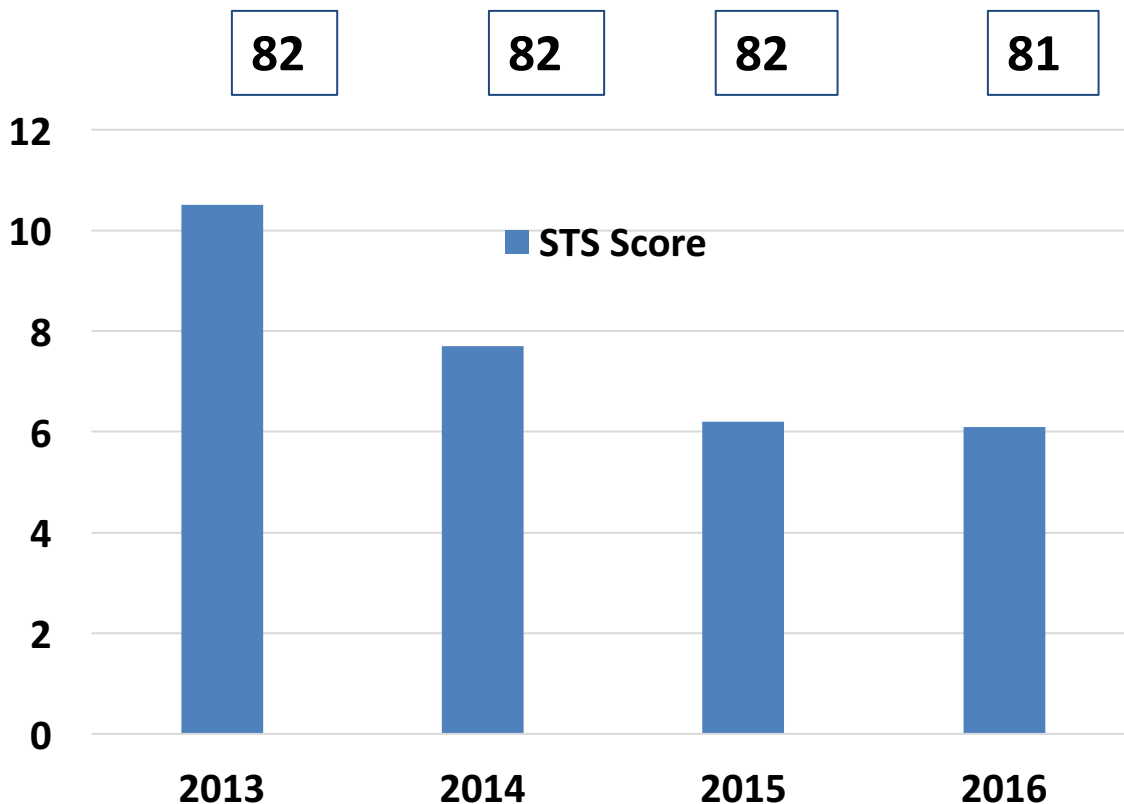




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# TAVI Age and STS 2013- 2016 in High volume Italian Centers

Age



IRCCS Policlinico San Donato  
Uni Padova  
IRCCS San Raffaele  
Catania Ferrarotto

AO Mauriziano Torino  
Uni Pisa  
Cotignola



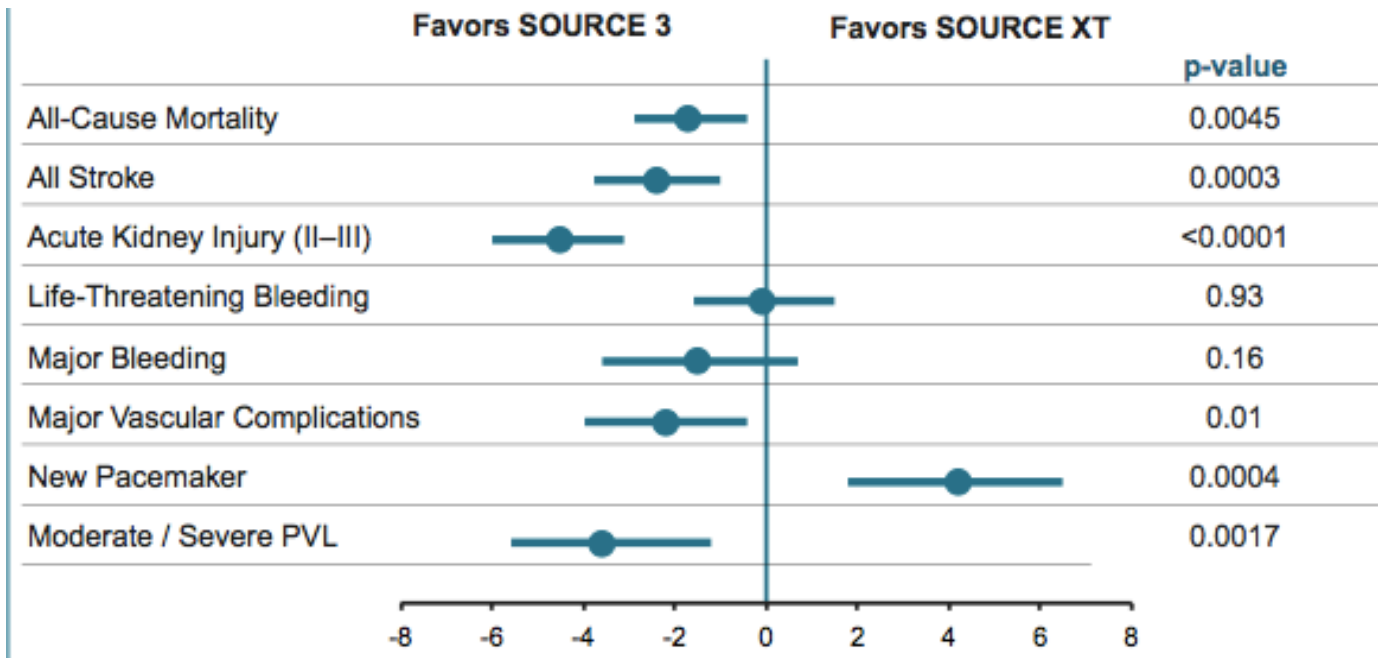
# Approved CE Mark TAVI Systems



# Real world experience with SAPIEN XT and SAPIEN 3 Results from the SOURCE XT and SOURCE 3 European Multi-Center Registries



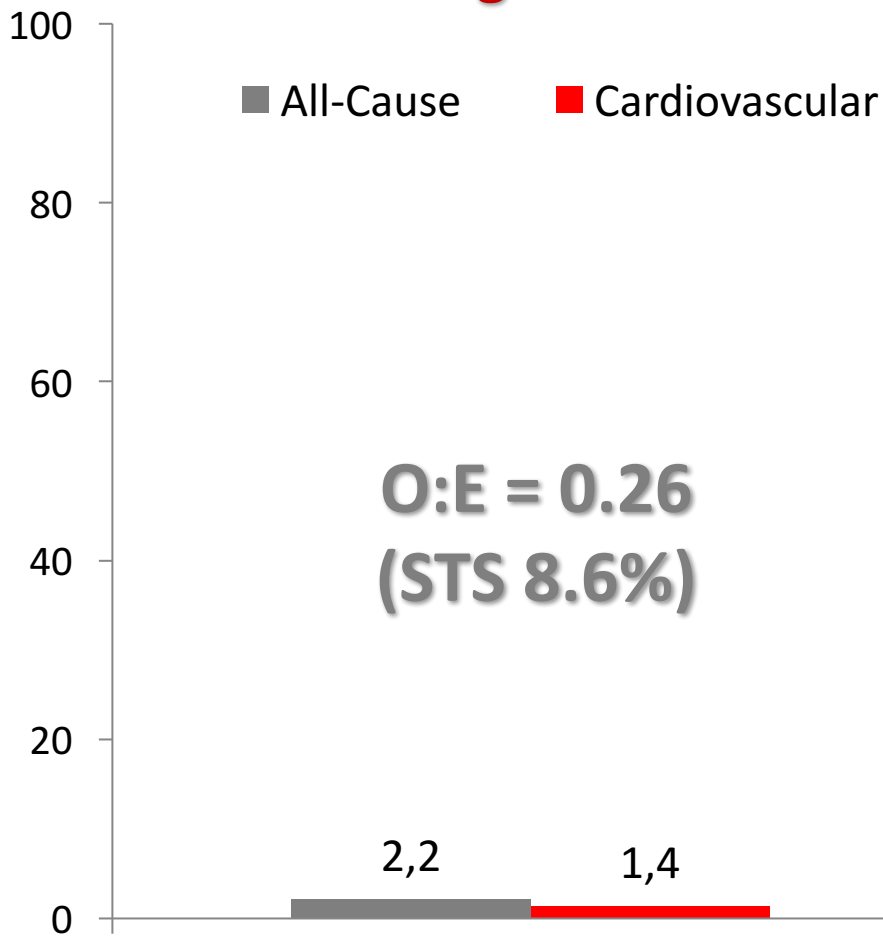
## Propensity Adjusted 30-day Outcomes 1947 pts S3 vs 2688 pts XT



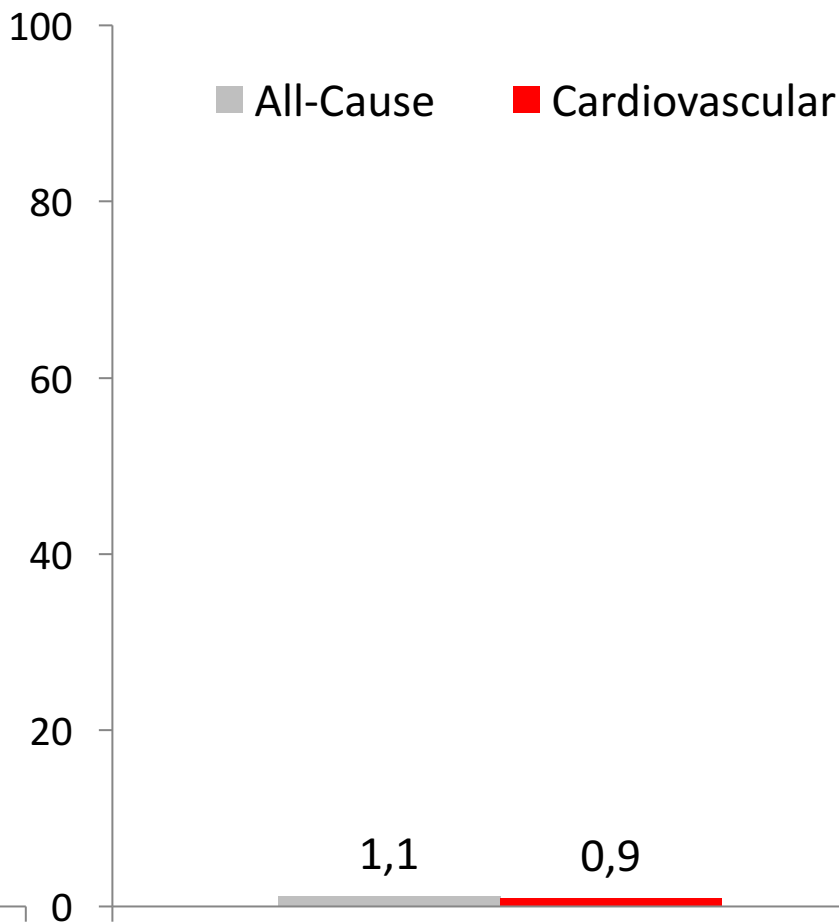
# Mortality SAPIEN 3

## At 30 Days (As Treated Patients)

### High Risk



### Intermediate Risk



S3i





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# Evolut R vs Corevalve

discharge and 30-days COMPLICATIONS propensity analysis)

ALL-CAUSE DEATH

Core-  
Valve

2,8%

4,3%

Evolut

0,5% 0,5%

IN-HOSPITAL DEATH

CARDIOVASCULAR  
DEATH

Core-...

1,4%

2,9%

Evolut

0,5% 0,5%



## Available Data of Second Generation Valves

Valve	30 Days					1 Year				
	Patients (n)	Mortality (%)	All Strokes (%)	PVL (%) (None, Mild, Moderate, Severe)	Post-Gradient PPM (%) Mean (mm Hg)	Mortality (%)	Stroke (%)	PVL (%) (None, Mild, Moderate, Severe)	PPM (%)	
S3 (12)	583	2.2	1.5	64/33/2.5/0	13 11.1	14.4	4.3	68/29/2.7/0	16.9	
DFM (6)	100	1.0	6.0	79/20/1.2/0	17 12.6	10.0	9.0	68/32/0/0	20.0	
Evolute R (13)	60	0	0	33/64/3/0	11.7 8.1	6.7	3.4	62/34/4/0	15.2	
Lotus (14)	120	4.4	5.9	83/16/1/0	28.6 11.5	10.9	9.5	89/11/0/0	32.2	
Portico (15)	102	2.9	3.9	15/73/3/0	9.8 8.7	7.8	5.9	7/87/0/0	10.8	

## Transcatheter aortic valve replacement—state of the art and a glimpse to the future: ‘the Tailored Approach’

Francesco Bedogni, Alessandro Frigiola, Marco Ranucci, Nedy Brambilla, Rocco Antonio Montone, Mauro Agnifili, Lorenzo Menicanti, and Luca Testa\*

*Coronary Revascularisation Unit, IRCCS Policlinico S. Donato, S. Donato Milanese, piazza E. Malan, Milan, Italy*



## Special indications

- **Small , tortuos diseased femoral artery**
- **Tortuous , calcified , porcelain aorta**
- **Horizontal aorta**
- **Bicuspid valve**
- **Extremely eccentric aortic valve annulus**
- **Heavy calcifications: diffuse, leaflets, LVOT**
- **Pure Aortic regurgitation**
- **Valve in Valve (Stented vs Stentless)**
- **Low Ejection fraction**
- **Severe hypertrophic left ventricle**



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# TAVI September 2015 – February 2017

## IRCCS Policlinico San Donato

Number procedures : 290

Mean age 83.5 y      STS score 6.3

### Results

30-day all cause mortality:	6 pts (2.0 %)
30-day cardiovascular mortality:	4 pts (1.2 %)
30-day stroke:	3 pts (1.0 %)

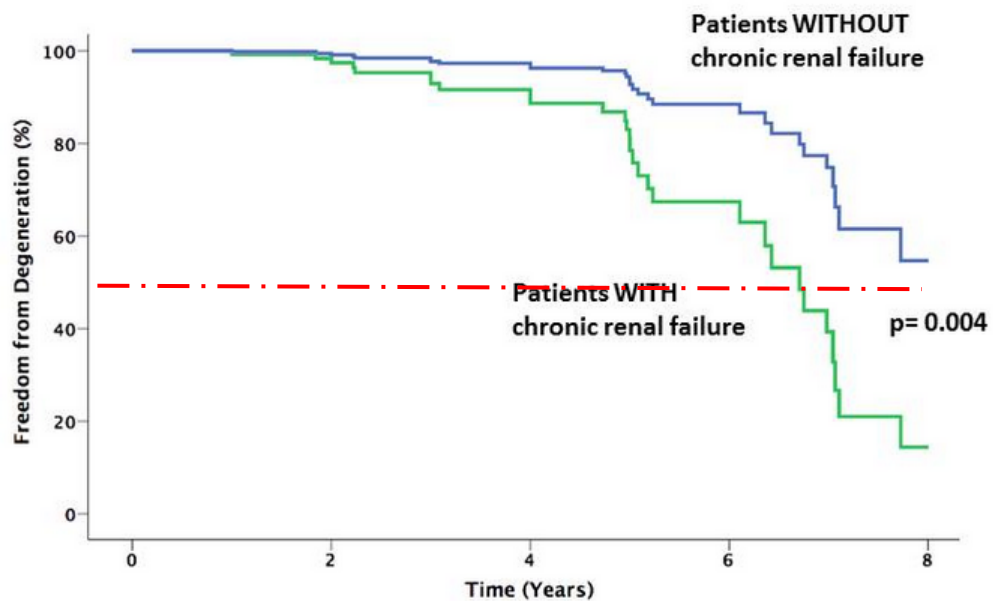
# Open Questions

- Durability
- Rate and impact of PM and LBBB
- Long term impact of Mild AR
- Impact of stroke prevention devices
- Operator's experience





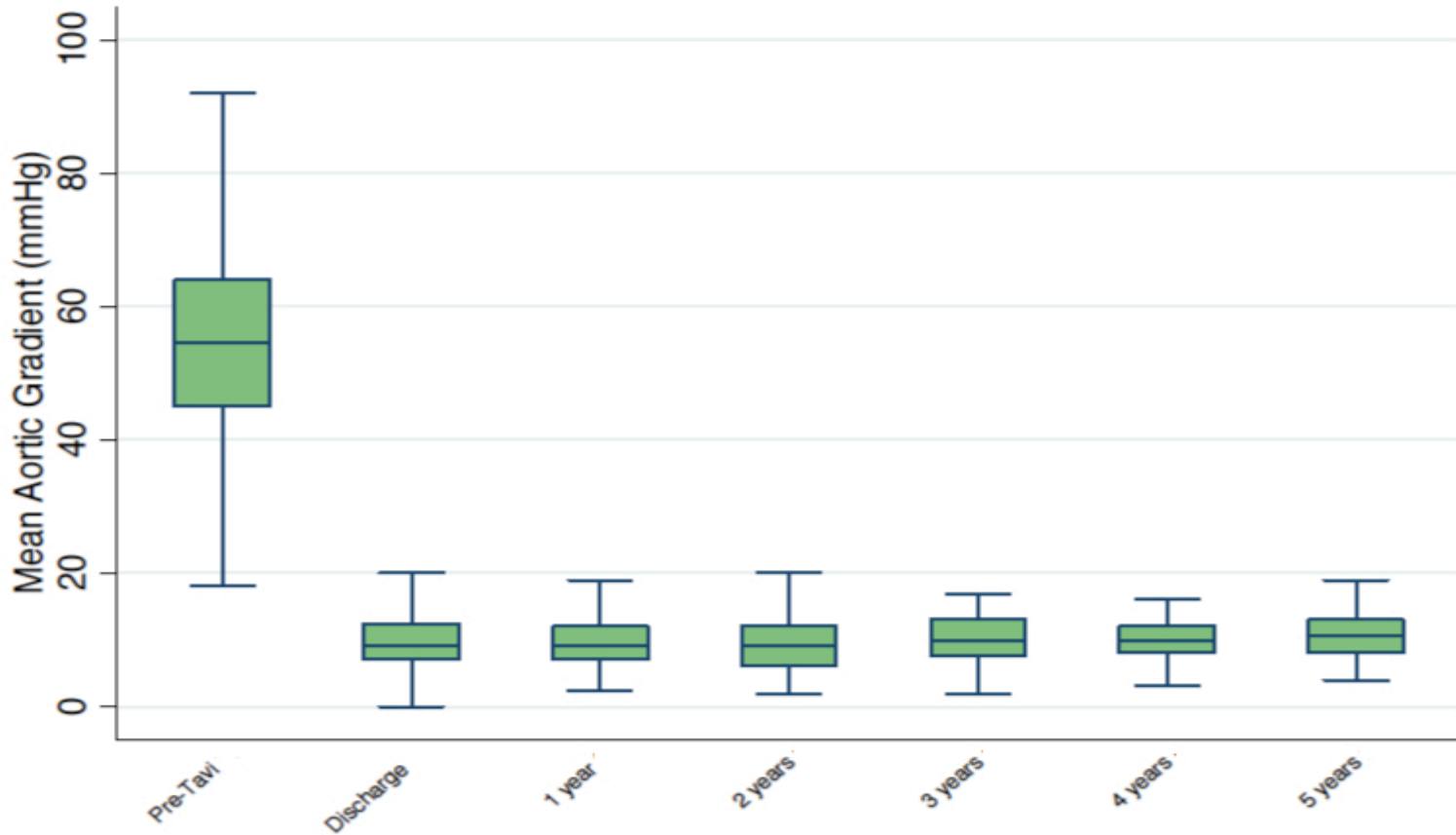
2016 | euro  
**PCR** Freedom from THV degeneration





# Durability

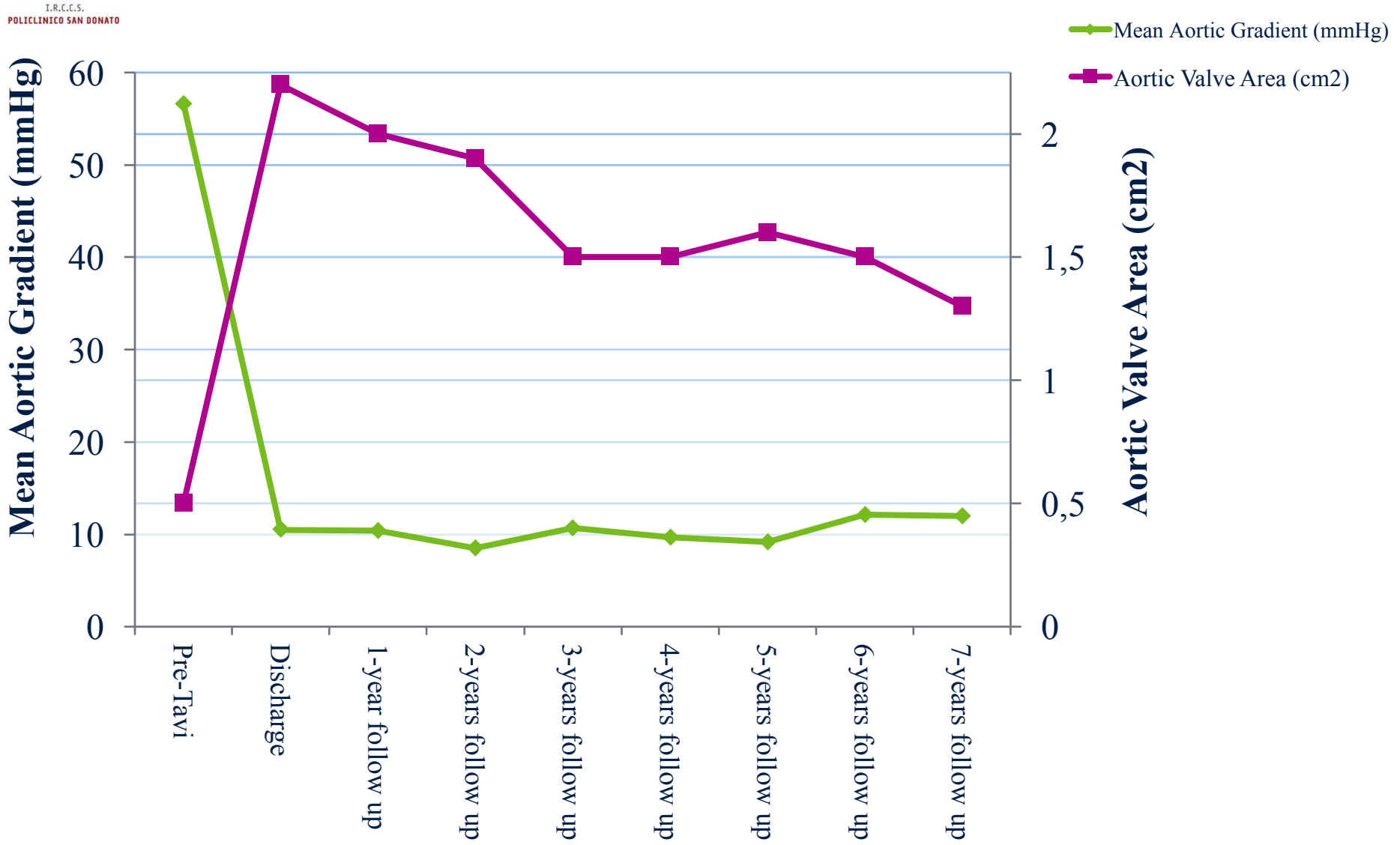
## Corevalve italian Registry 5 years Follow up



**. Time trends in transaortic mean gradient.**



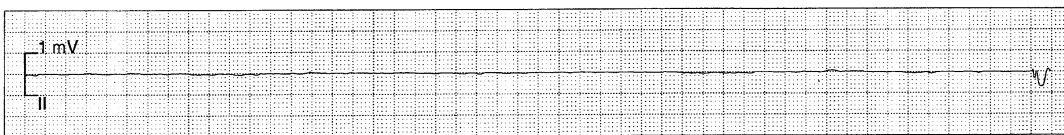
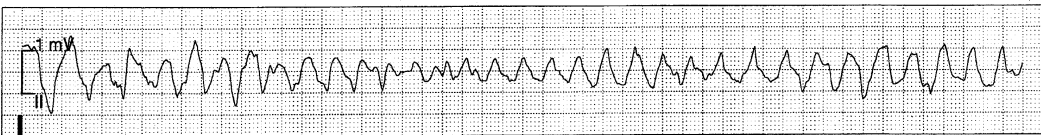
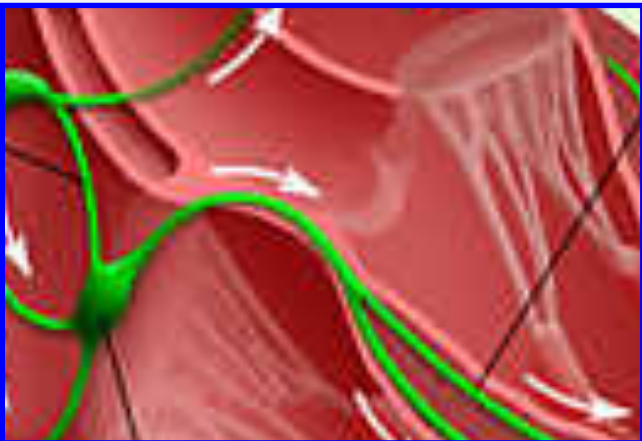
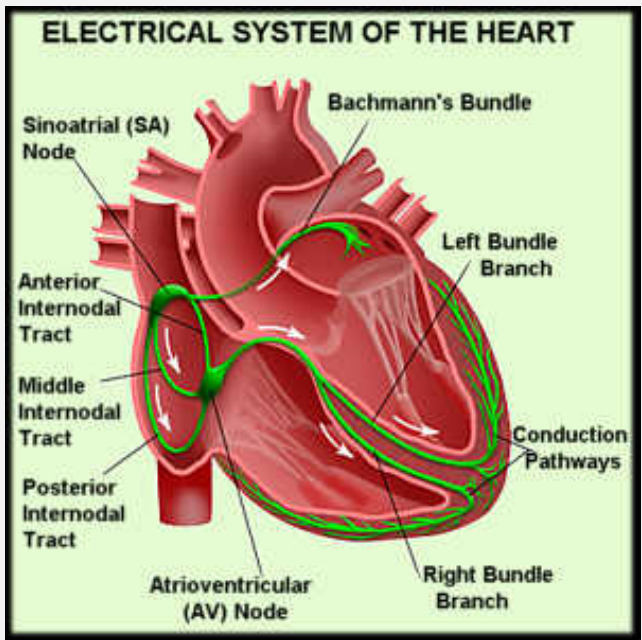
# ECHOCARDIOGRAPHIC OUTCOMES OVER 7-YEARS FOLLOW UP





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# Cardiac rhythm disturbances



Post-implant



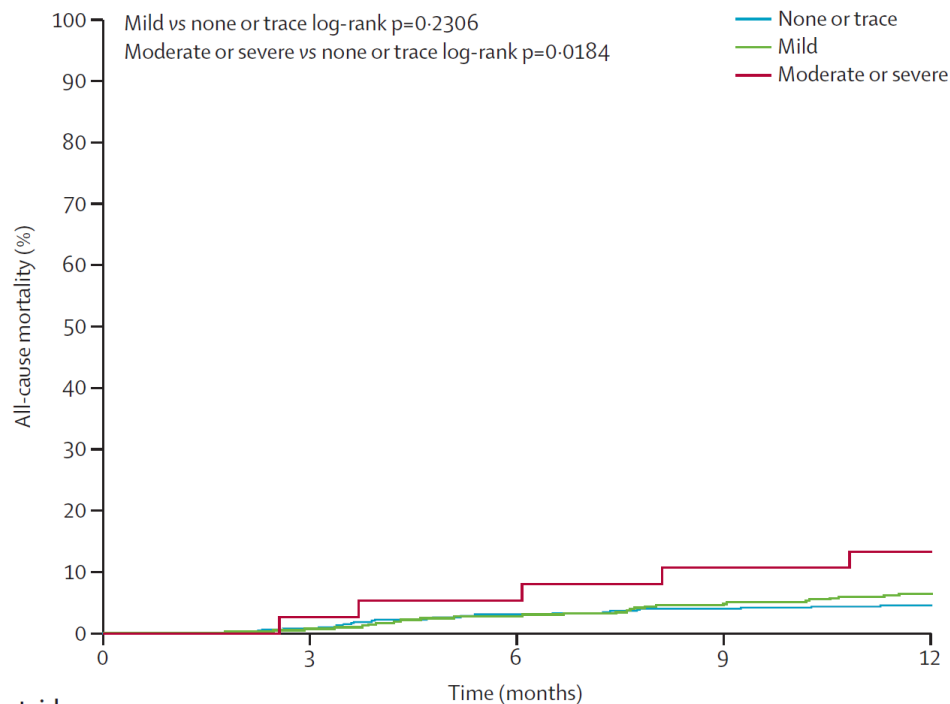
## New PM Rate

- Sapien 3 12%
- Evolut R 15%
- Direct Flow 17%
- Portico 10%
- Symetis 9%
- Boston 28%



# Aortic Valve Regurgitation

## All-Cause Mortality Stratified by PVR Severity



Only moderate or severe PVR was associated with increased late mortality

Number at risk		Time (months)				
	0	3	6	9	12	
None or trace	508	503	492	484	474	
Mild	446	440	430	419	406	
Moderate or severe	38	37	36	33	31	





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# Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION



## Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement

Nicolas M. Van Mieghem, Marguerite E.I. Schipper, Elena Ladich, Elham Faqiri, Robert van der Boon, Abas Randjgari, Carl Schultz, Adriaan Moelker, Robert-Jan van Geuns, Fumiyuki Otsuka, Patrick W. Serruys, Renu Virmani and Peter P. de Jaegere

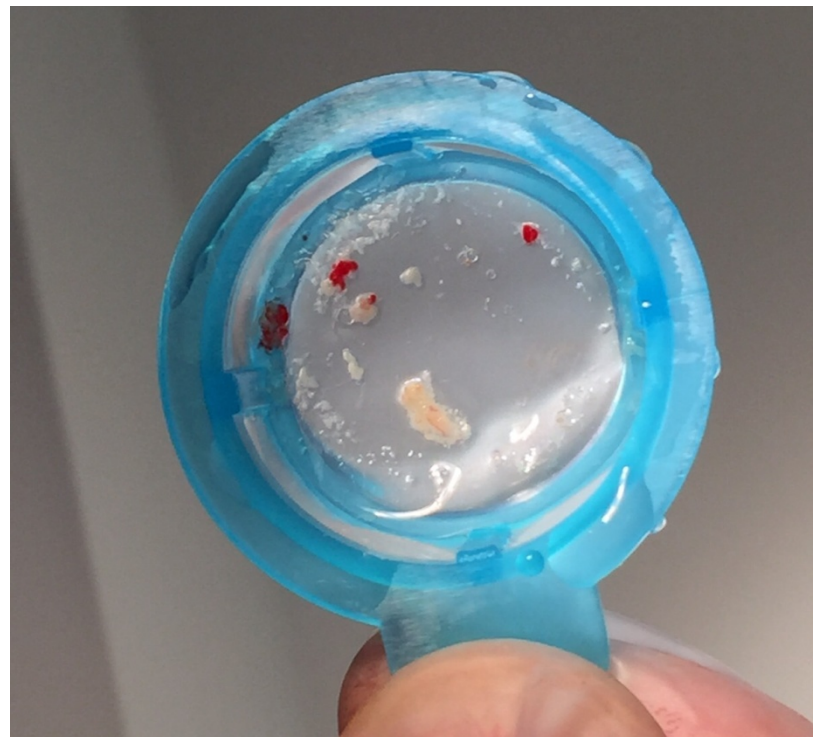
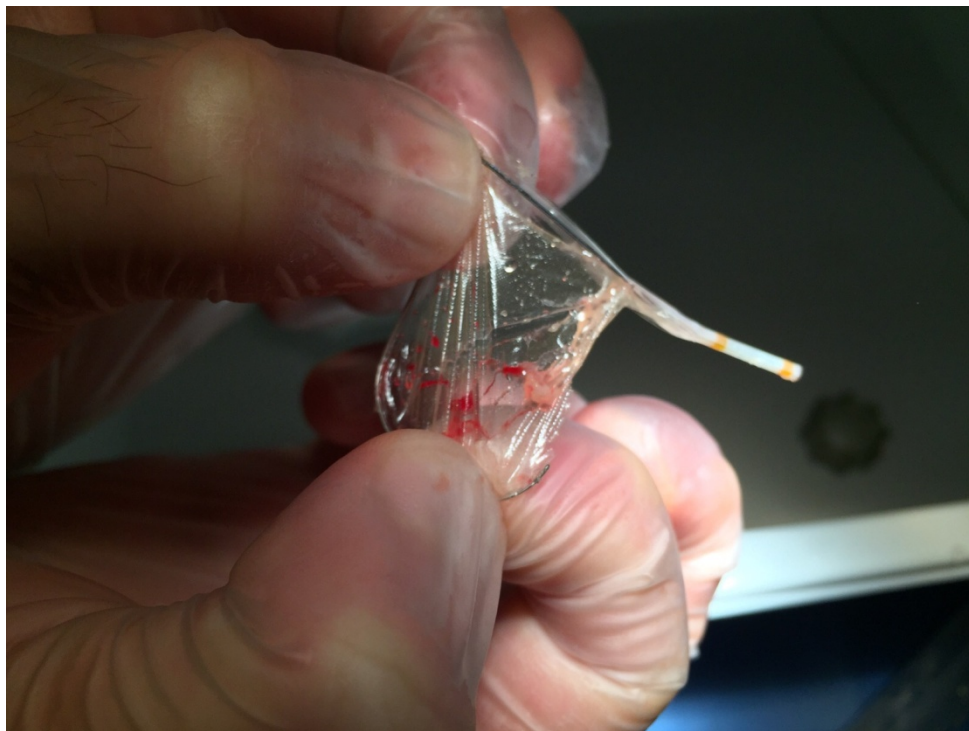
*Circulation*. 2013;127:2194-2201; originally published online May 7, 2013;

doi: 10.1161/CIRCULATIONAHA.112.001091

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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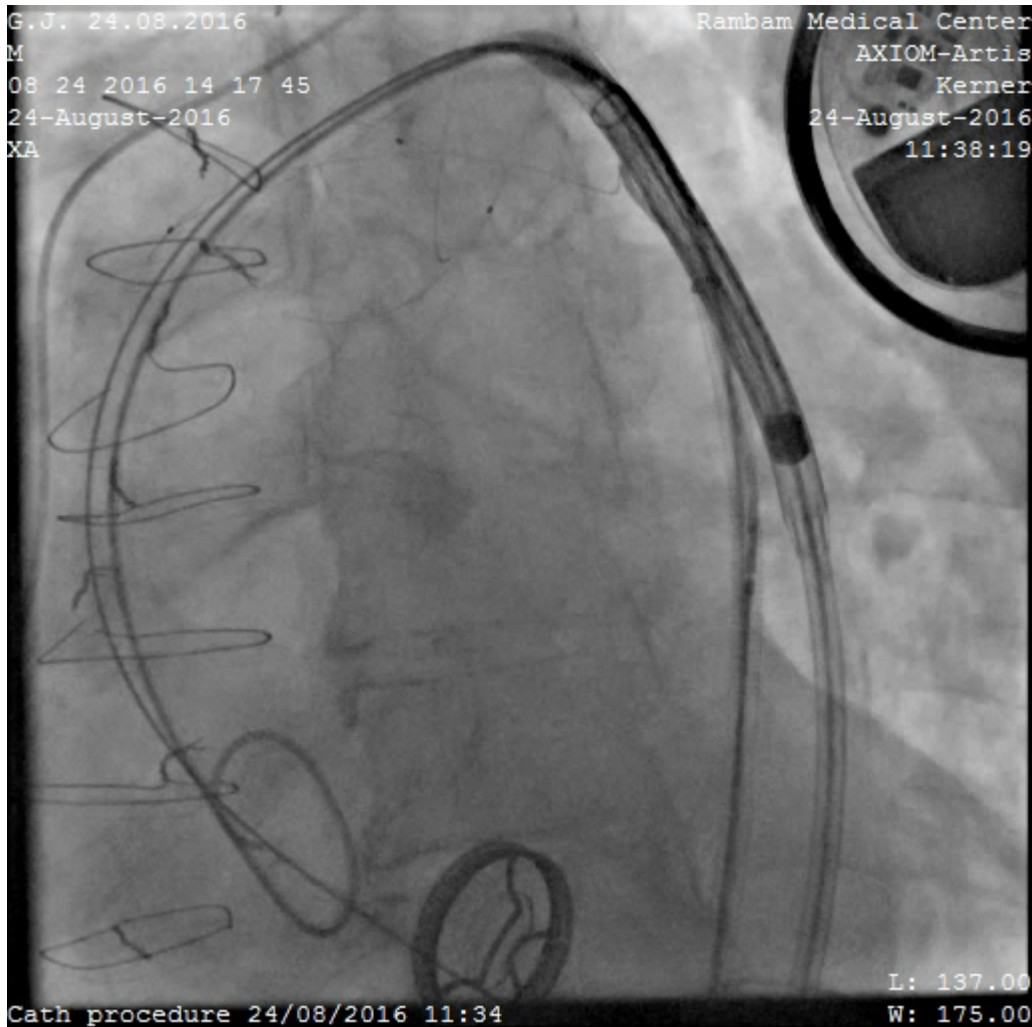
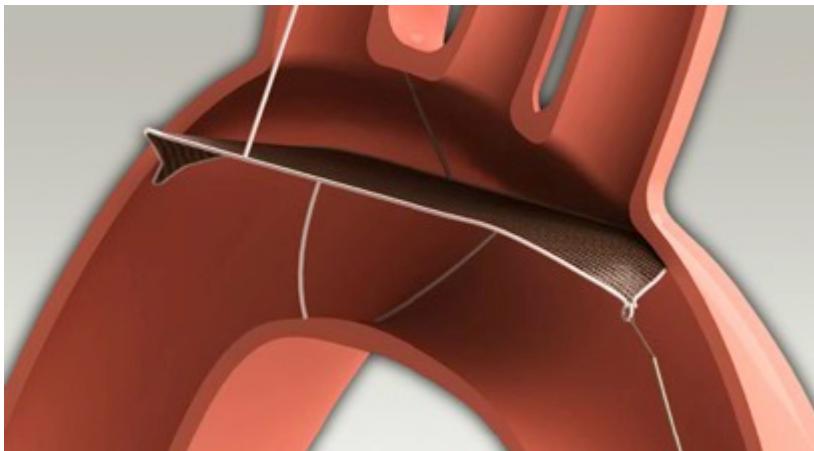
Print ISSN: 0009-7322. Online ISSN: 1524-4539





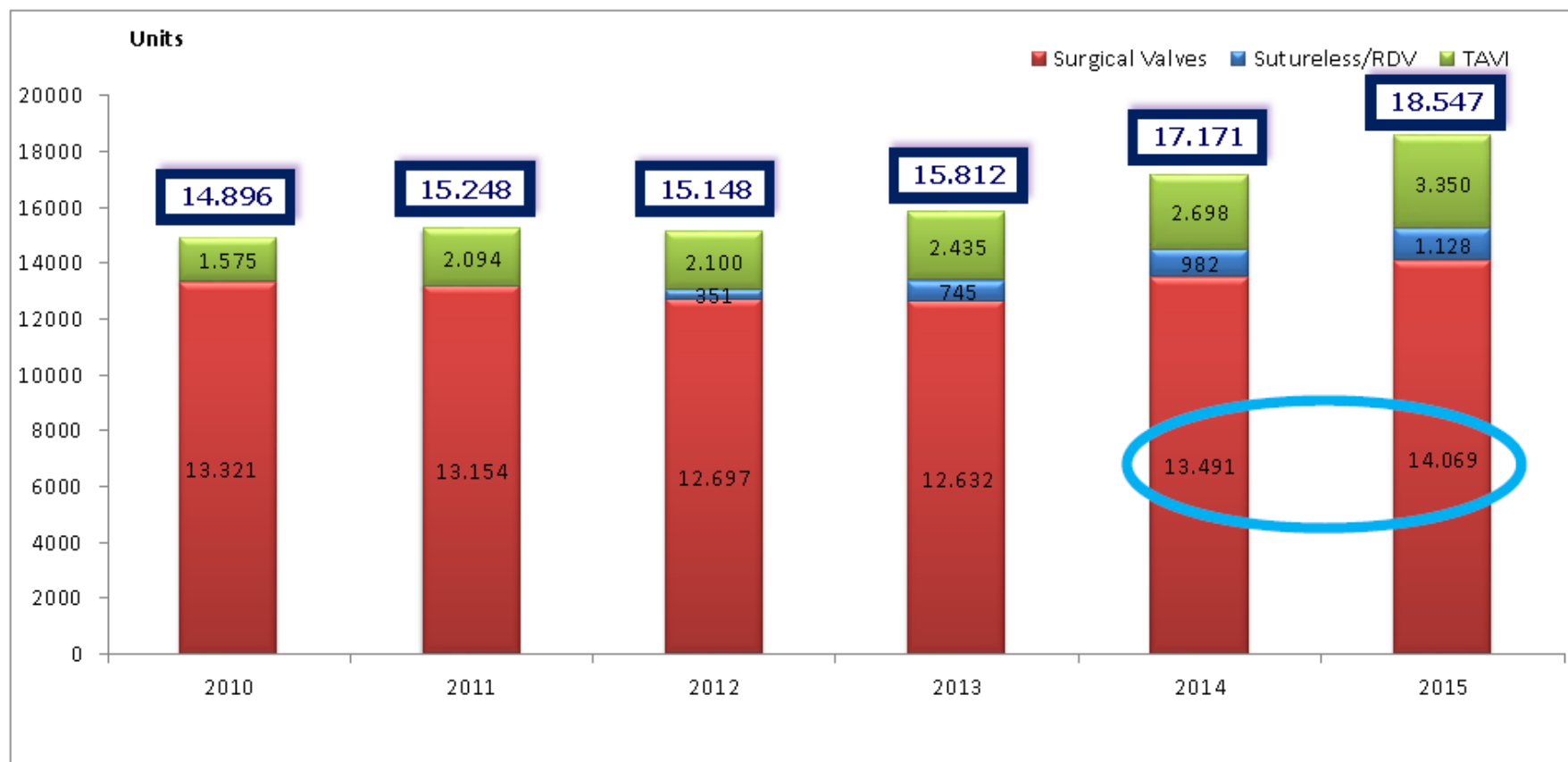
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# TriGuard™ HDH during TAVI Navigation





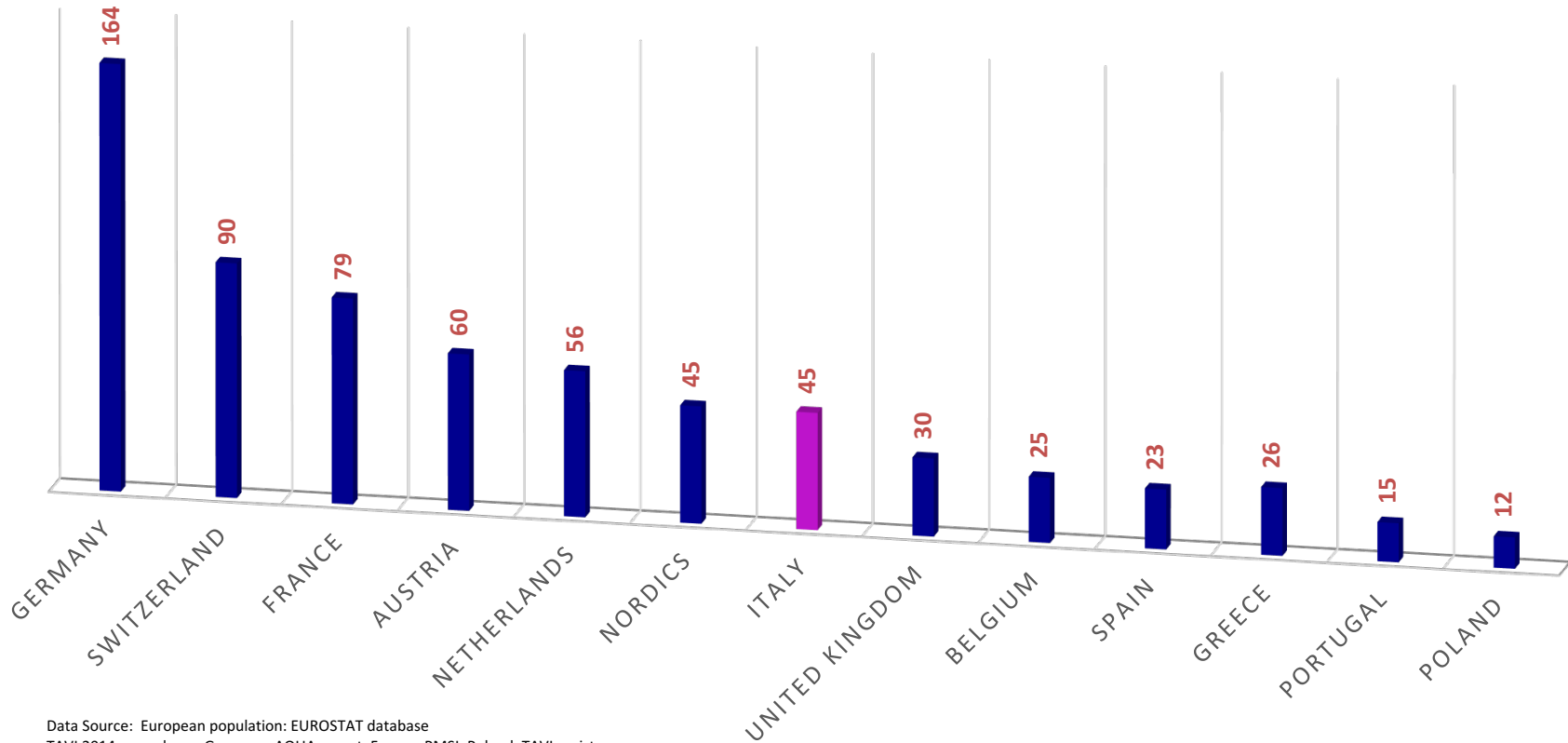
# Aortic Replacement Segment





# Diffusione TAVI in Europa: dati 2014

## PROCEDURES/MILLION INHABITANTS



Data Source: European population: EUROSTAT database

TAVI 2014 procedures: Germany: AQUA report, France: PMSI, Poland: TAVI registry

TAVI 2014 procedures: Switzerland, Austria, Netherlands, Nordics, Italy, UK, Belgium, Spain, Greece, Portugal, Spain: BIBA medical (Independent third party data)



# Popolazione eligibile a TAVI – Francia



Le modèle met en évidence que parmi les patients de plus de 75 ans avec sténose aortique sévère symptomatique :

- 28,7% des patients récusés à la chirurgie seraient éligibles au traitement par bioprothèse valvulaire aortique implantée par voie transcutanée, soit rapporté à la population française **7 809 patients**.
- 5,2% des patients opérables seraient à haut risque chirurgical (STS-PROM >10%) parmi lesquels 80% seraient éligibles à un traitement par bioprothèse valvulaire aortique implantée par voie transcutanée, soit rapporté à la population française **2 430 patients**.

Cette estimation est une estimation basse car les indications retenues par la Commission concernent un score STS > 8%.

- 7,809 pazienti inoperabili
- 2,430 pazienti ad alto rischio (STS > 10%)

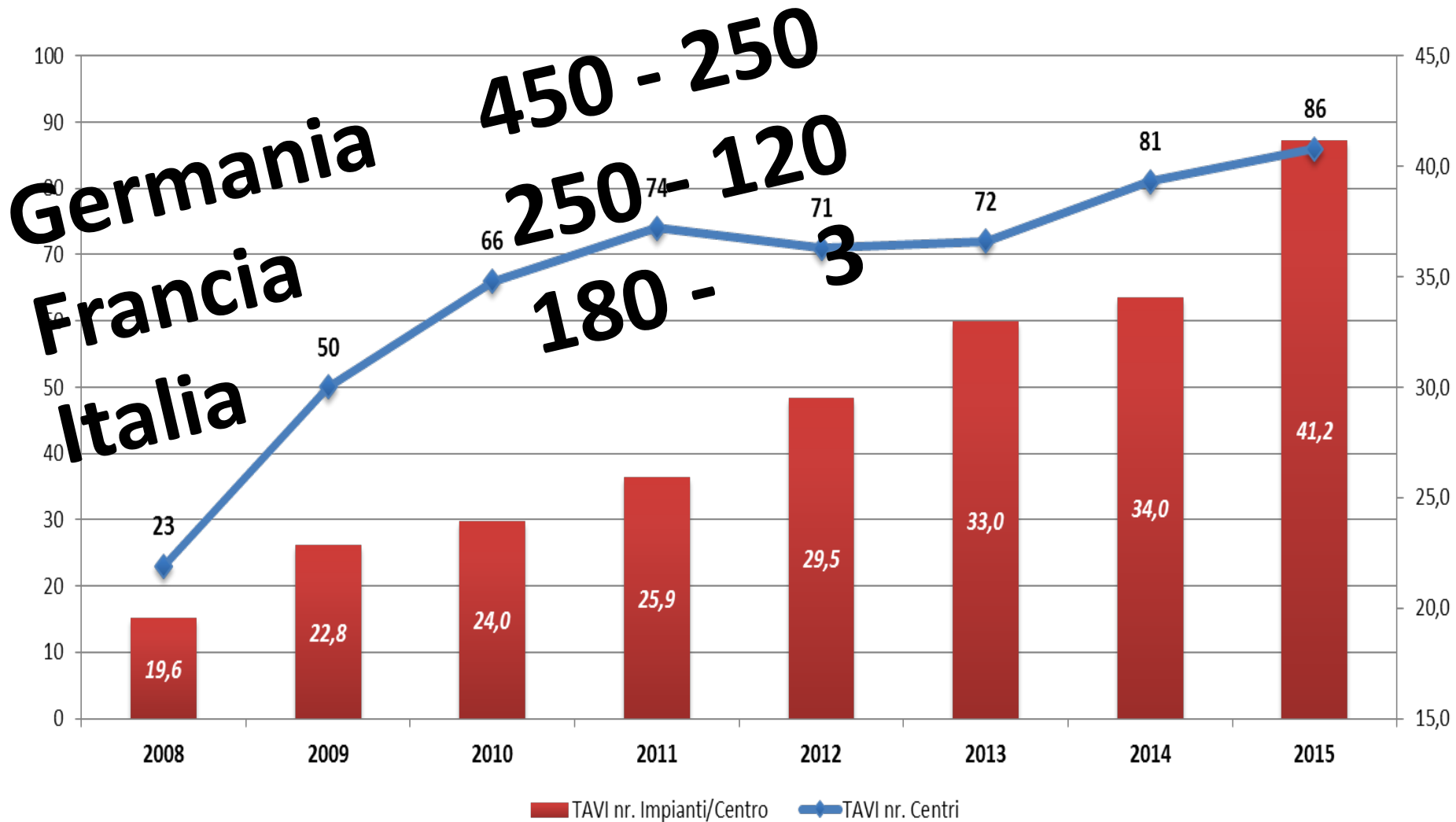


- 10,239 pazienti eligibili a TAVI
- 155 pazienti per milione di abitanti





# Evoluzione dei Centri TAVI in Italia

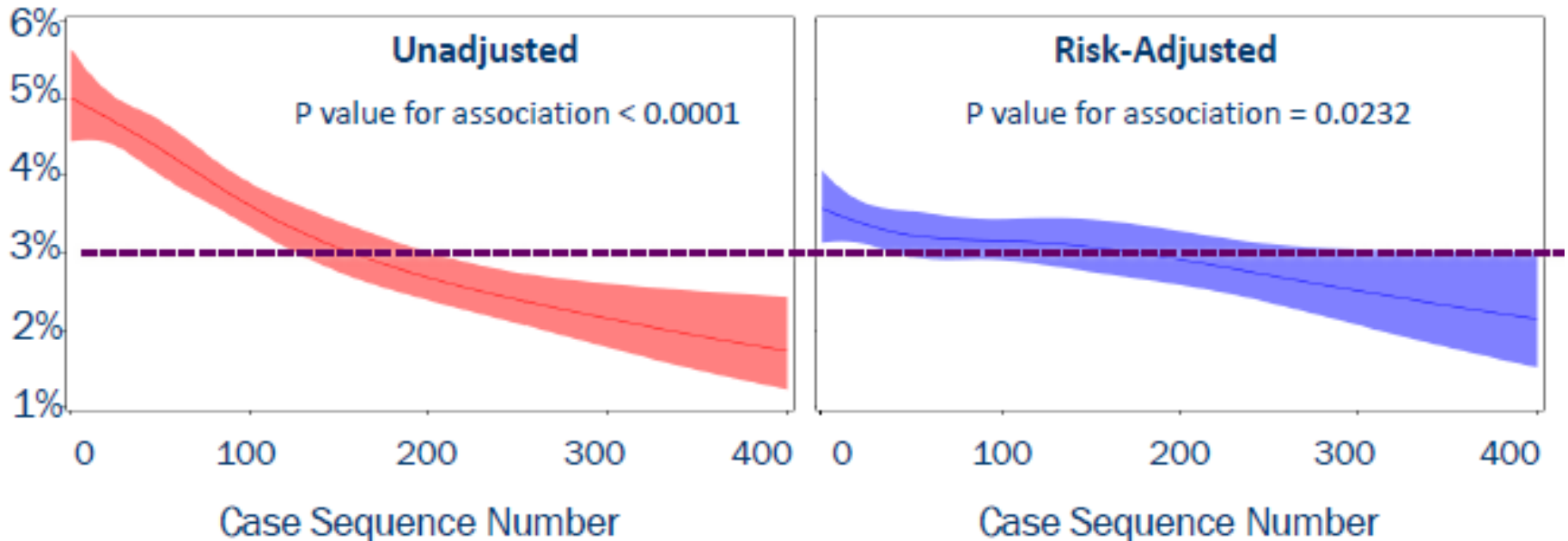




# Relationship between procedure Volume and outcome for TAVR in US

ACC 2016

## In-Hospital Mortality



95% Confidence limits represented by colored bands

# Transcatheter aortic valve implantation (TAVI) by centres with and without an on-site cardiac surgery programme: preliminary experience from the German TAVI registry

■ EuroIntervention 2014;10:602-608

Holger Eggebrecht<sup>1\*</sup>, MD; Rajendra H. Mehta<sup>1,2</sup>, MD, MS; Michael Haude<sup>3</sup>, MD; Stefan Sack<sup>4</sup>, MD; Harald Mudra<sup>5</sup>, MD; Ralph Hein<sup>5</sup>, MD; Johannes Brachmann<sup>6</sup>, MD; Ulrich Gerckens<sup>7</sup>, MD; Karl-Heinz Kuck<sup>8</sup>, MD; Ralf Zahn<sup>9</sup>, MD; Udo Sechtem<sup>10</sup>, MD; Gert Richardt<sup>11</sup>, MD; Steffen Schneider<sup>12</sup>, PhD; Jochen Senges<sup>12</sup>, MD

European Heart Journal Advance Access published May 17, 2016



European Heart Journal  
doi:10.1093/eurheartj/ehw190

**FASTTRACK CLINICAL RESEARCH**  
TAVI

SAVONA  
6 MAGGIO  
2016

## Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery departments: preliminary results from the prospective German aortic valve quality assurance registry (GAVI) in 1000 patients

**Holger Eggebrecht<sup>1\*</sup>, Maike Bestehorn<sup>2</sup>, Michael Bestehorn<sup>3</sup>, Kurt Bestehorn<sup>4</sup>, Thomas Voigtländer<sup>1</sup>, Karl-**

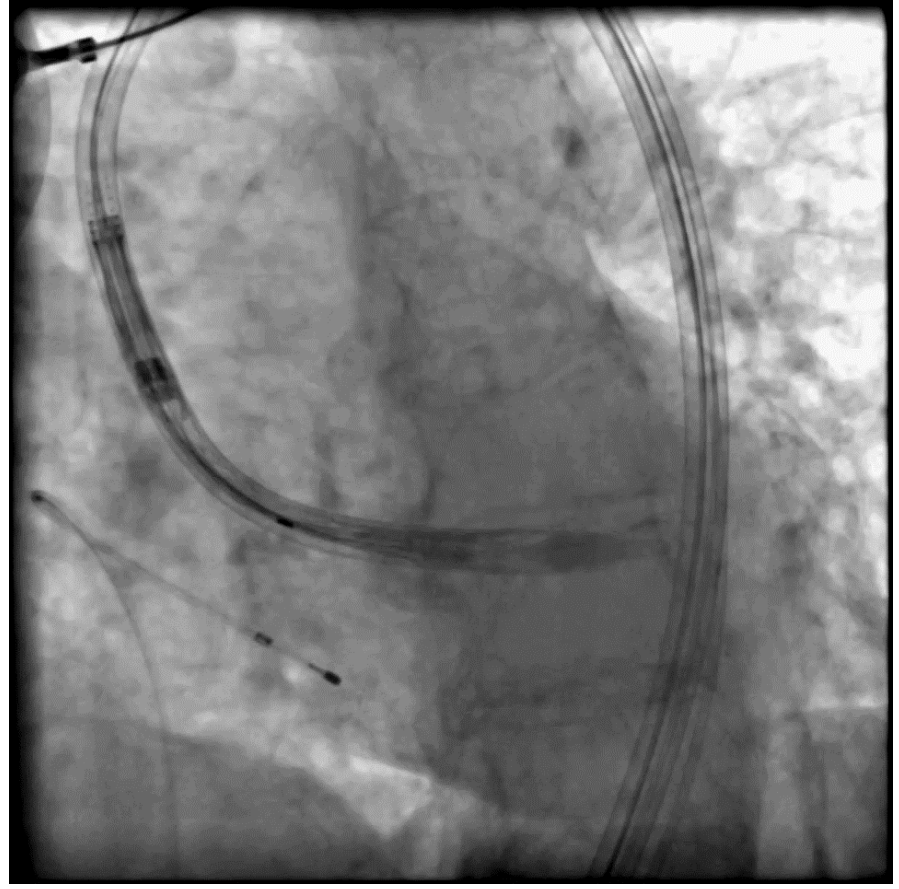
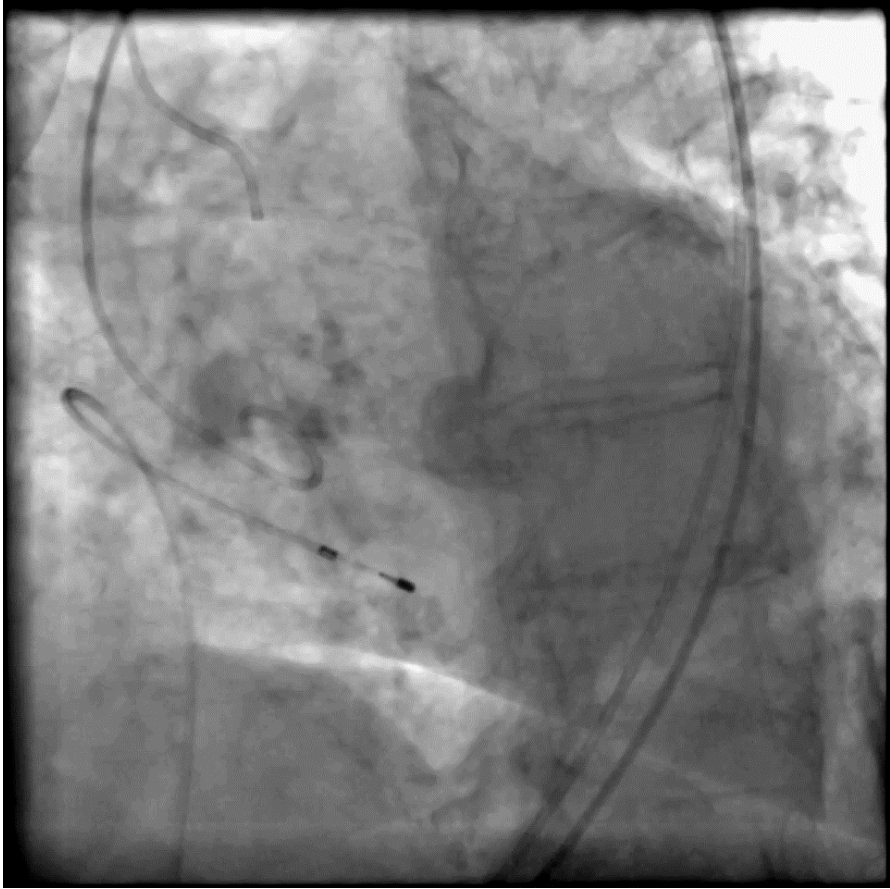
### 12.15 TAVOLA ROTONDA

Introduce: *B. Brunetto, G. Mazzotta*

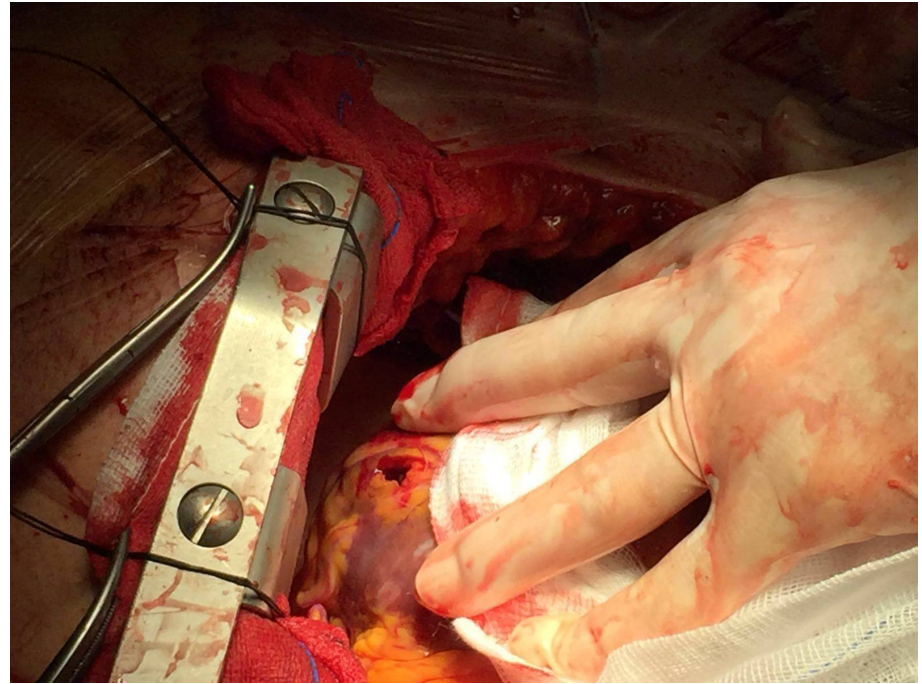
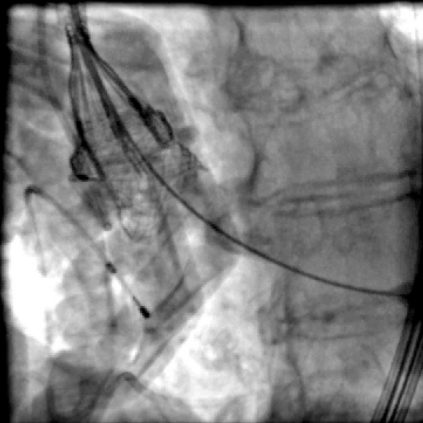
#### **Siamo pronti a decentrare le TAVI?**

- Il parere dell'Emodinamista - *P. Bellone*
- Il parere del Cardiochirurgo - *F. Santini*
- Il parere del Cardioanestesista - *G. Buscaglia*
- Il parere del clinico - *S. Domenicucci*
- Il parere dell'infermiere - *A. Falco*

<sup>1</sup>Cardioangiological Center Bethanien (CCB) and AGAPLESION Bethanien Hospital, Frankfurt, Germany; <sup>2</sup>Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; <sup>3</sup>Technical University of Dresden, Dresden, Germany; and <sup>4</sup>Duke Clinical Research Institute and Duke University Medical Center, Durham, NC, USA



# LV free wall Perforation







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Grazie per la pazienza ed attenzione



# Conclusioni

*“Il presente va  
giudicato guardando il  
passato ma va vissuto  
guardando il futuro”*

*Soren Kirkegaard*

