With simplication and low risk patient TAVI is the first option to treat severe aortic stenosis ?

Dr Hakim Benamer for ICPS Team

ICPS Massy, France

Conflict of interest

Proctoring for Edwards

TAVI for all patient?

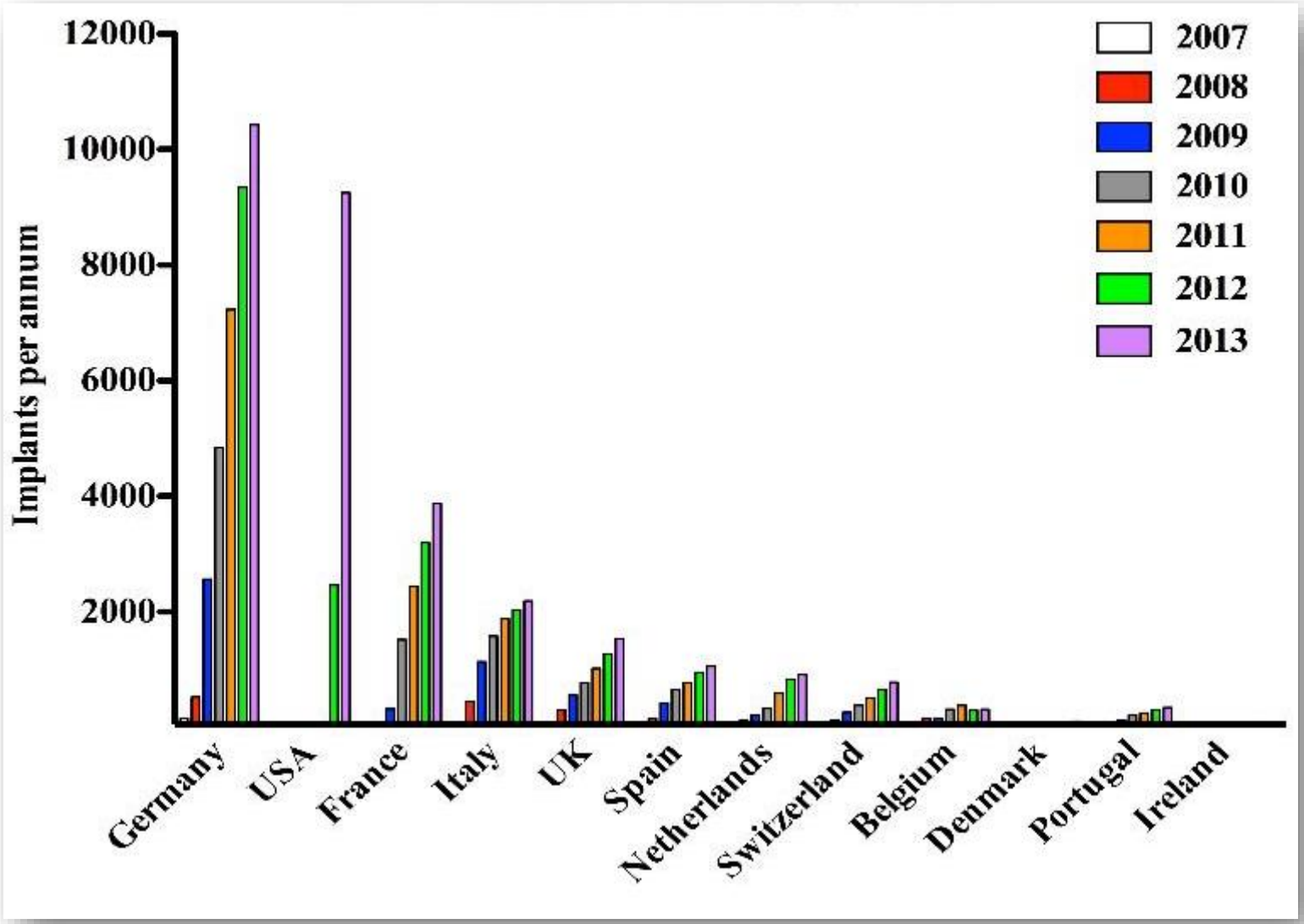
What is it clear today

17 years ago: First case at Rouen in FRANCE

Compassionate: 76 years old, cardiogenic shock, surgical recusal

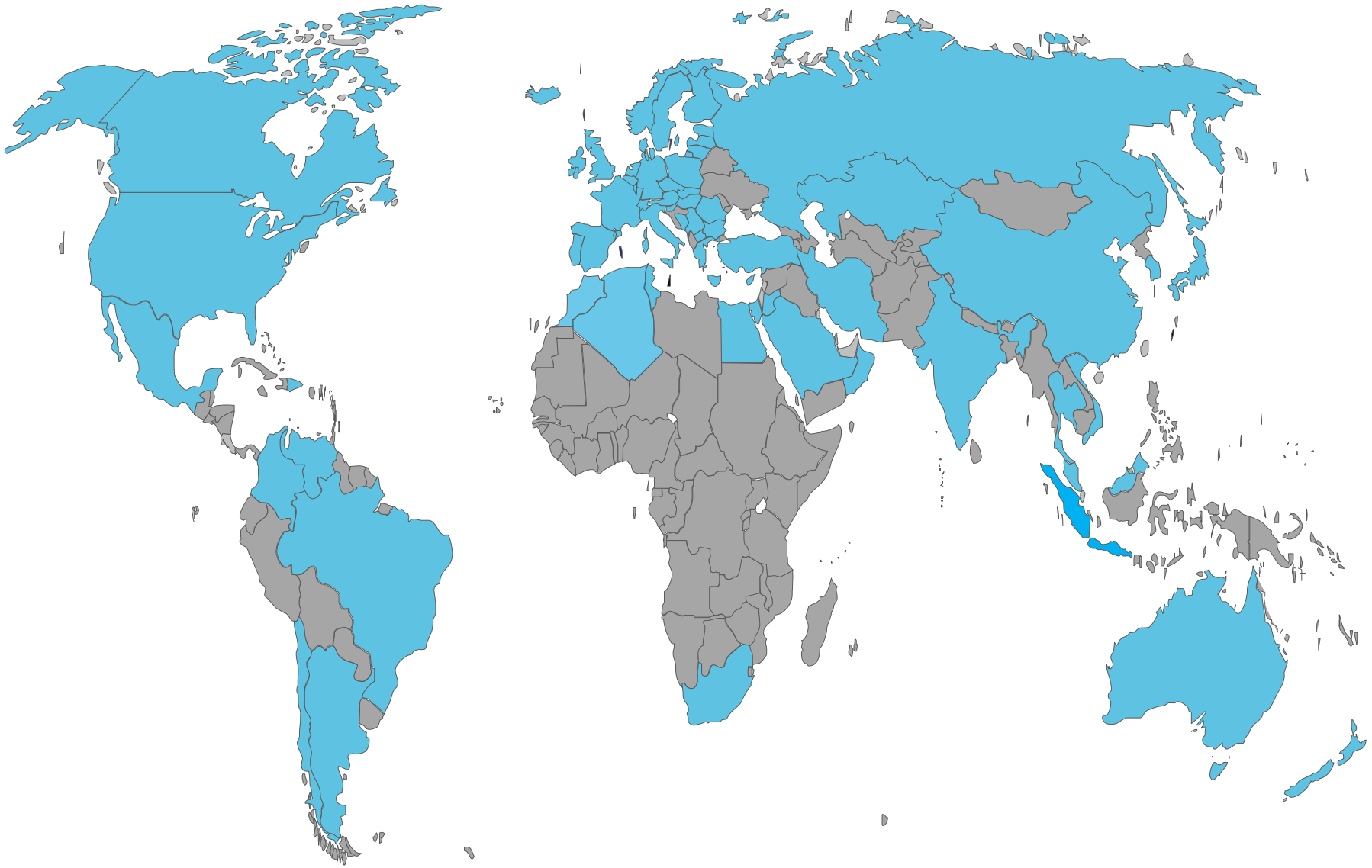
16 Avril 2002

Fast progression in the World



Courtesy of Darren Mylotte

> 500 000 case in > 80 countries

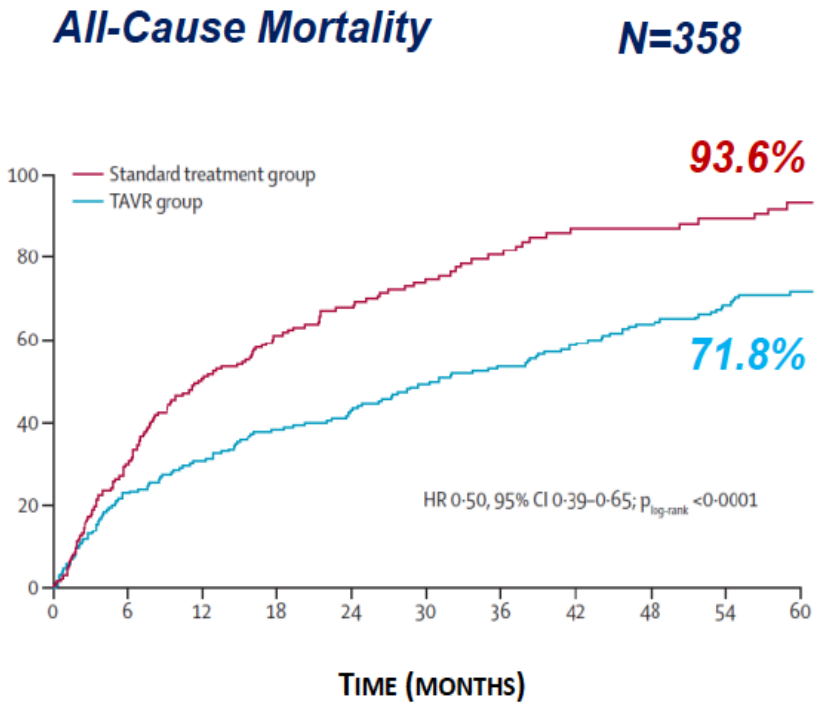


INOPERABLE patients:

TAVI vs médical TTT

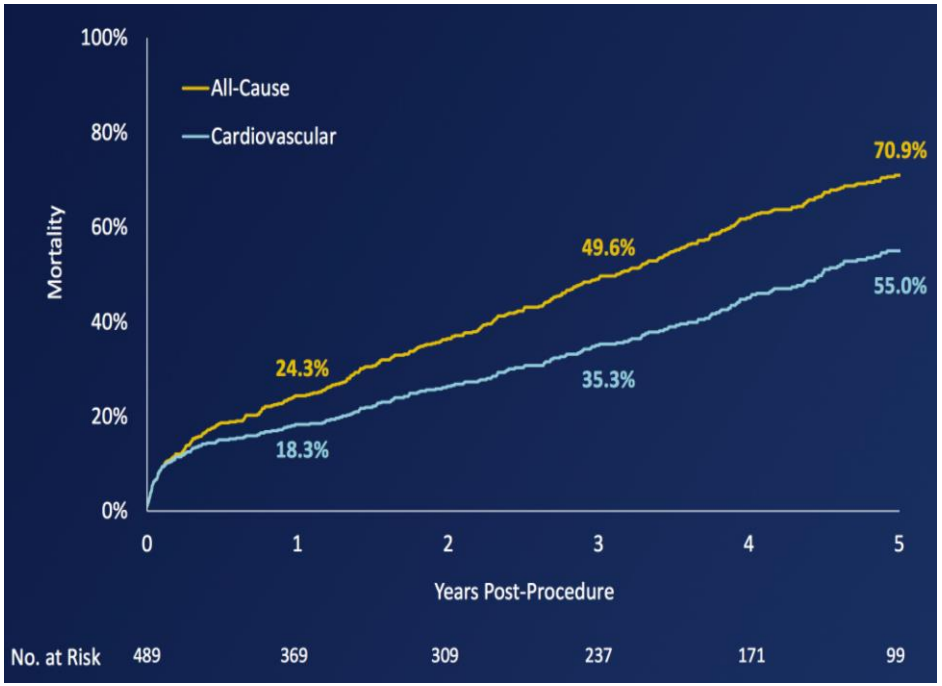
PARTNER 1B

Kapadia et al. Lancet 2015



Corevalve extreme risk

Petrossian et al ACC 2018



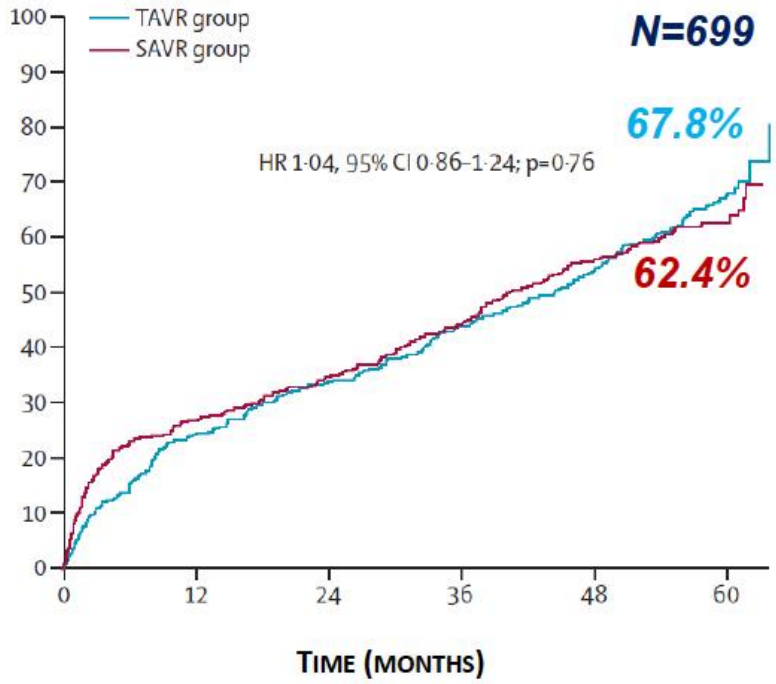
HIGH SURGICAL RISK patient:

TAVI vs Surgery

PARTNER 1A: 5-Year Follow-up

Mack MJ et al. *Lancet* 2015

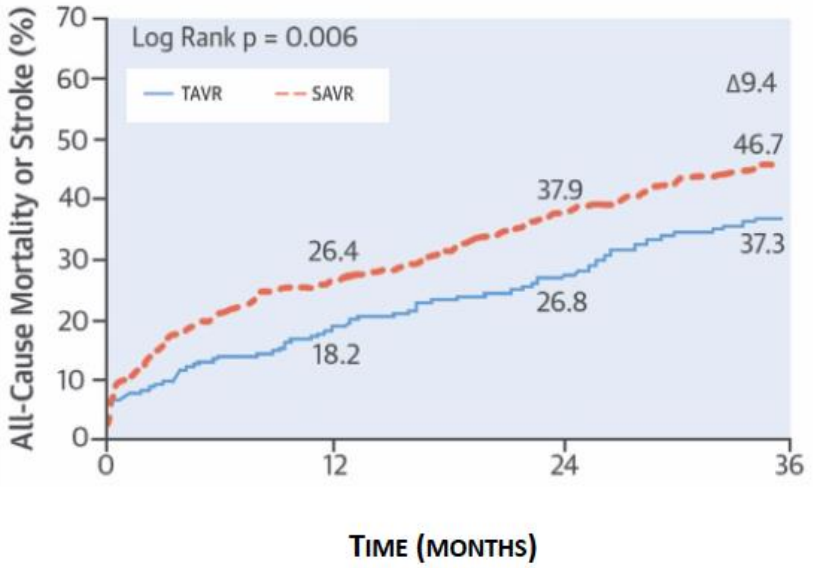
All-cause Mortality



CoreValve High-Risk: 3-Year Follow-up

Deeb M et al. *J Am Coll Cardiol* 2016

All-cause Mortality or Stroke



INTERMEDIATE surgical risk patient:

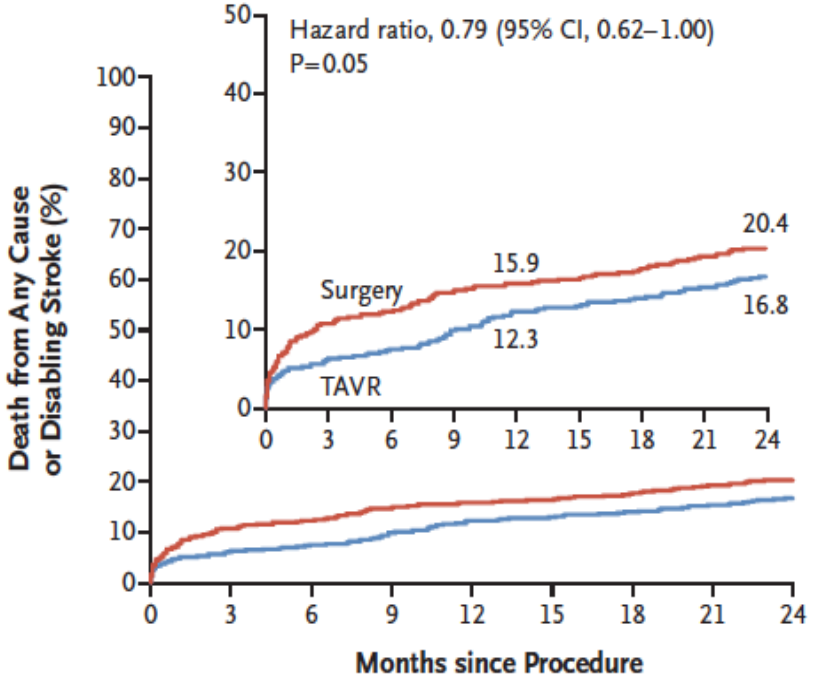
TAVI vs Surgery

PARTNER 2A: 2-Year Follow-Up

Leon MB et al. *N Engl J Med* 2016

All-cause Mortality or Stroke

N=2032

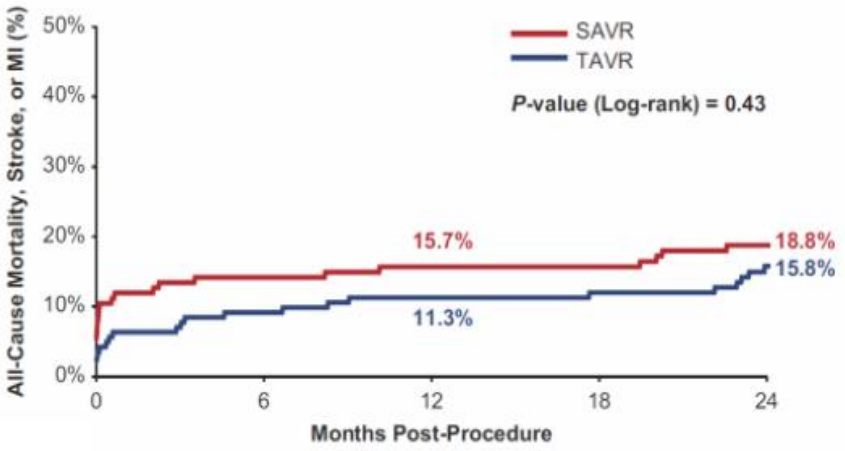


NOTION: 2-Year Follow-Up

Søndergaard L et al. *Circ Cardiovasc Interv 2016*

All-cause Mortality, Stroke, or MI

N=280



TAVI for all patient?

What is it new today?

LOW RISK PATIENT

PARTNER 3 *NCT02675114*	CoreValve *NCT02701283*	NOTION-2 *NCT02825134*
Low surgical risk as assessed by Heart Team		
STS < 4%	*STS < 3%*	*STS < 4%*
Sample Size		
N=1,228	*N=1,200*	*N=992*
1:1 Randomization TAVI Vs. SAVR		
SAPIEN 3	*Evolut R*	*Any CE-approved device*
Primary Endpoint		
All-cause mortality, Any strokes, or re-hospitalization at 1 year	*All-cause mortality, any stroke, life-threatening bleeding, major vascular complications, or AKI at 30-day*	*All-cause mortality, myocardial infarction, or any stroke at 1-year*

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*

NEJM 2019

Evolut™ Low Risk Trial

1468* Randomized Patients

TAVR ITT N=734

SAVR ITT N=734

12 Not attempted

3 SAVR patients underwent attempted TAVR

53 Not attempted

TAVR AT* N=725

SAVR AT* N=678

4 TAVR patients underwent SAVR and 1 SAVR patient underwent TAVR

1 Not implanted

TAVR implanted N=722

SAVR implanted N=680

Popma et al. NEJM 2019

Study Timeline and Valves Studied

2016	2017	2018

First Patient Randomized
Mar. 28, 2016

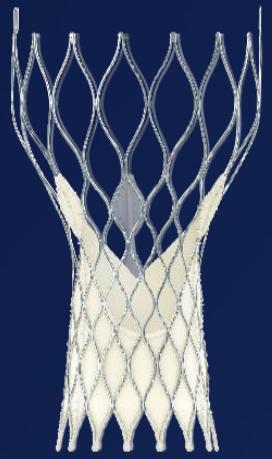
*Last Patient Randomized
Nov. 27, 2018

CoreValve 31 mm

Evolut R: 23, 26, 29 | Added Evolut R 34 mm

Evolut PRO: 23, 26, 29 mm

Primary Endpoint Assessment Dec. 27, 2018



Vascular access
- 99% transfemoral
- 0.6% subclavian
- 0.4% direct aortic

CoreValve = 3.6%	Evolut R = 74.1%	Evolut PRO = 22.3%

*For this analysis

Baseline Characteristics

Mean ± SD or %	TAVR (N=725)	SAVR (N=678)
Age, years	74.1 ± 5.8	73.6 ± 5.9
Female sex	36.0	33.8
Body surface area, m^2	2.0 ± 0.2	2.0 ± 0.2
STS PROM, %	1.9 ± 0.7	1.9 ± 0.7
NYHA Class III or IV	25.1	28.5
Hypertension	84.8	82.6
Chronic lung disease (COPD)	15.0	18.0
Cerebrovascular disease	10.2	11.8
Peripheral arterial disease	7.5	8.3

There are no significant differences between groups.

Baseline Cardiac Risk Factors

Mean ± SD or %	TAVR (N=725)	SAVR (N=678)
SYNTAX Score	1.9 ± 3.7	2.1 ± 3.9
Permanent pacemaker, CRT or ICD	3.2	3.8
Prior CABG	2.5	2.1
Previous PCI	14.2	12.8
Previous myocardial infarction	6.6	4.9
Atrial fibrillation/flutter	15.4	14.5
Aortic valve gradient, mm Hg	47.0 ± 12.1	46.6 ± 12.2
Aortic Valve area, cm^2	0.8 ± 0.2	0.8 ± 0.2
Left ventricular ejection fraction, %	61.7 ± 7.9	61.9 ± 7.7

There are no significant differences between groups.

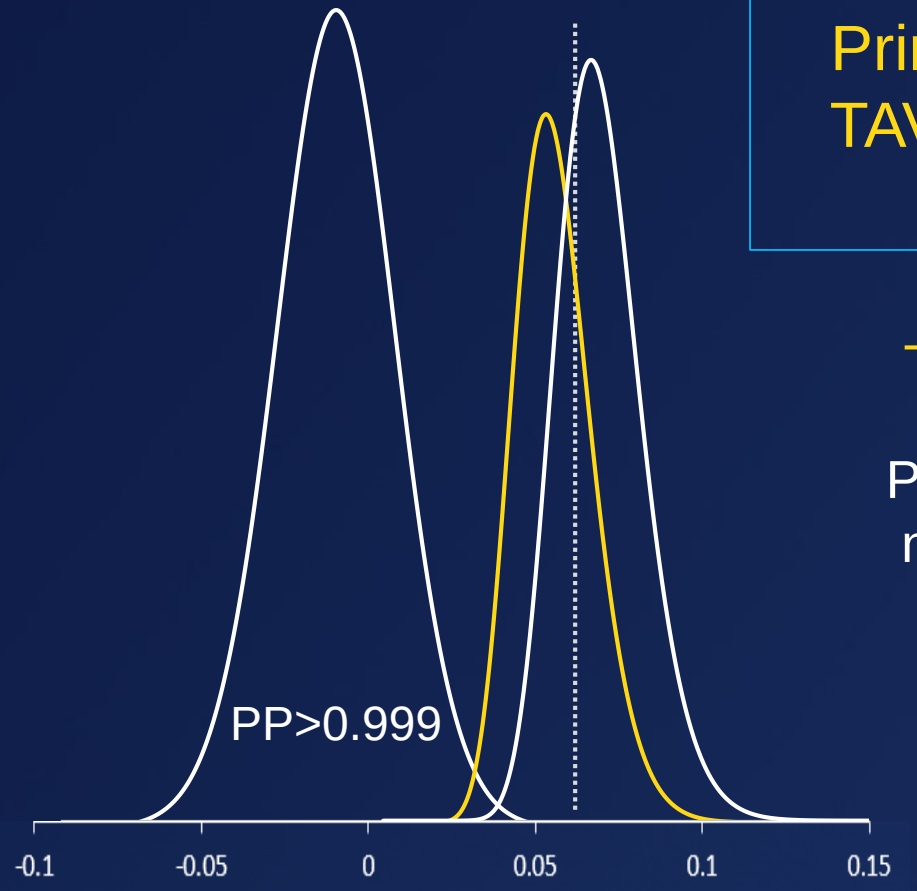
TAVR Procedural Data

%	TAVR (N=724)
General anesthesia	56.9
Iliofemoral access	99.0
Embolic protection device used	1.2
Pre-TAVR balloon dilation	34.9
Post-TAVR balloon dilation	31.3
More than 1 valve used	1.2
Partial or complete repositioning of the valve (Evolut/PRO only)	37.3
Staged or concomitant PCI performed	6.9

Primary Endpoint

All-Cause Mortality or Disabling Stroke at 2 Years

Evolut™ Low Risk Trial



Primary Endpoint Met
TAVR is noninferior to SAVR

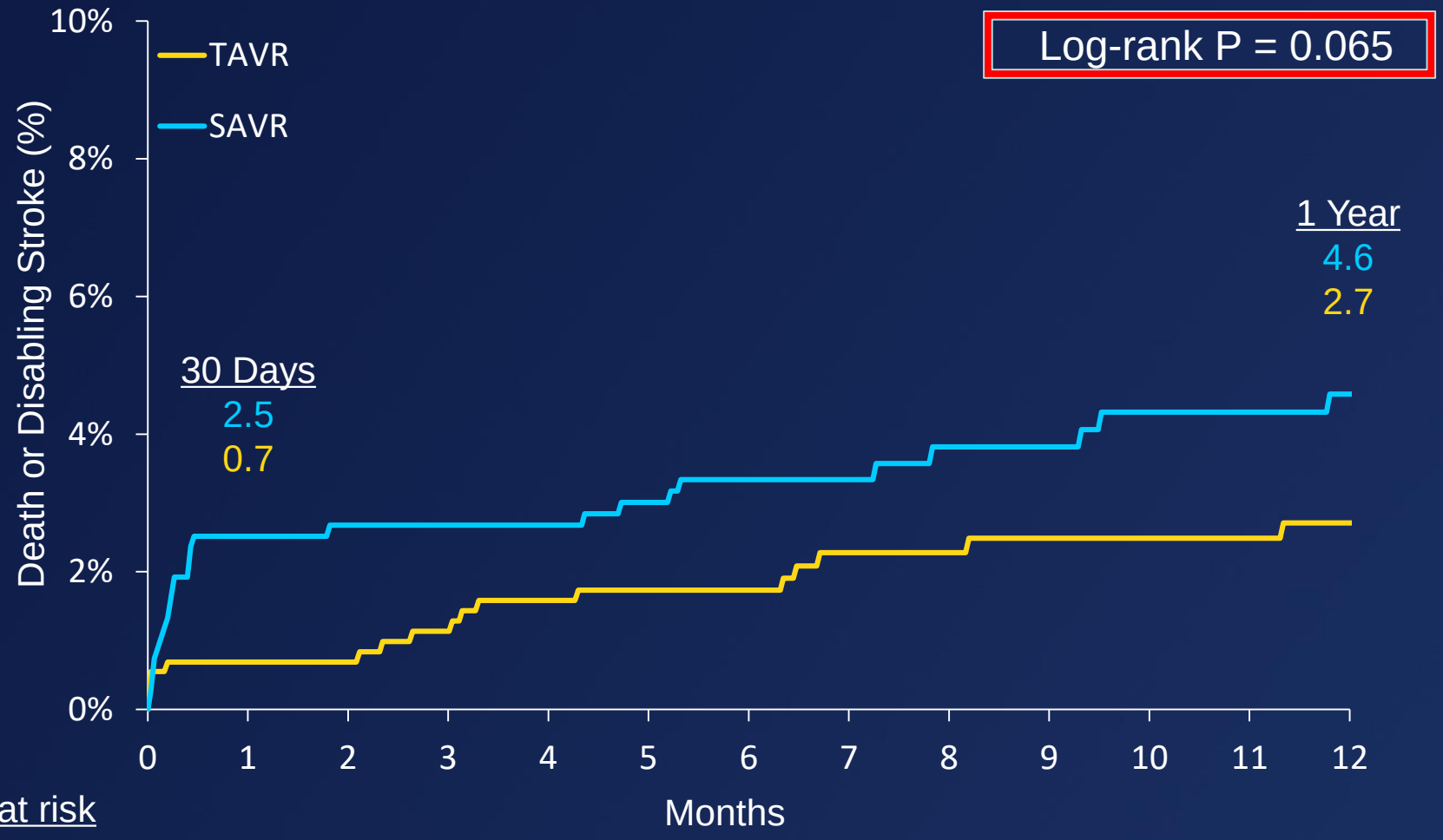
TAVR 5.3% SAVR 6.7%

Posterior probability of noninferiority > 0.999

TAVR –SAVR difference = -1.4% (95% BCI; -4.9, 2.1)

K-M All-Cause Mortality or Disabling Stroke at 1 Year

Evolut™ Low Risk Trial

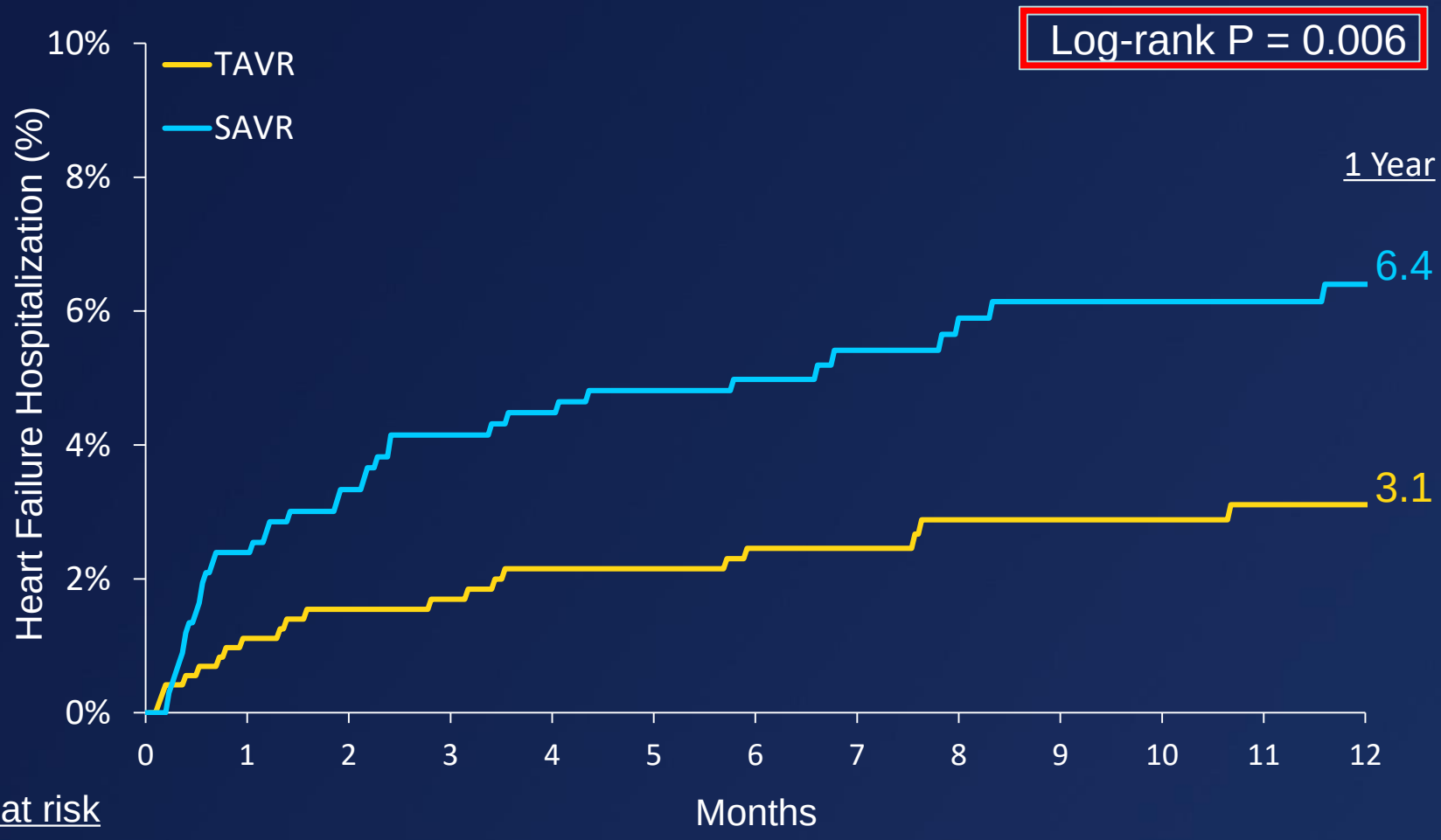


No. at risk

TAVR	725	718	648	435
SAVR	678	656	576	366

K-M Heart Failure Hospitalization at 1 Year

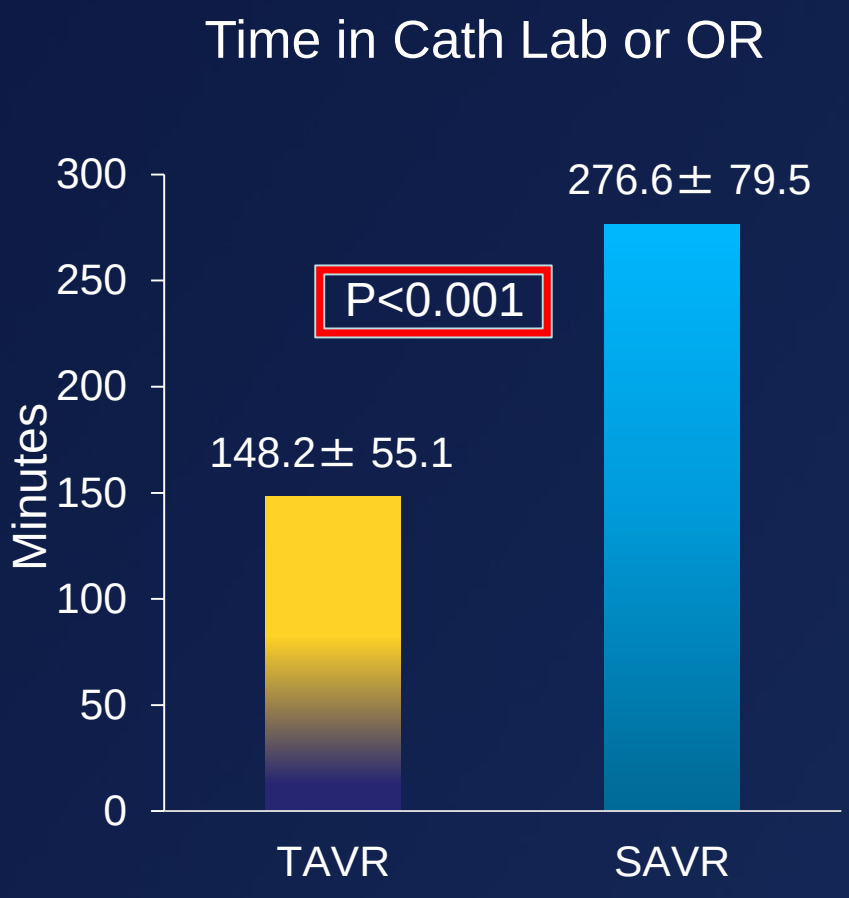
Evolut™ Low Risk Trial

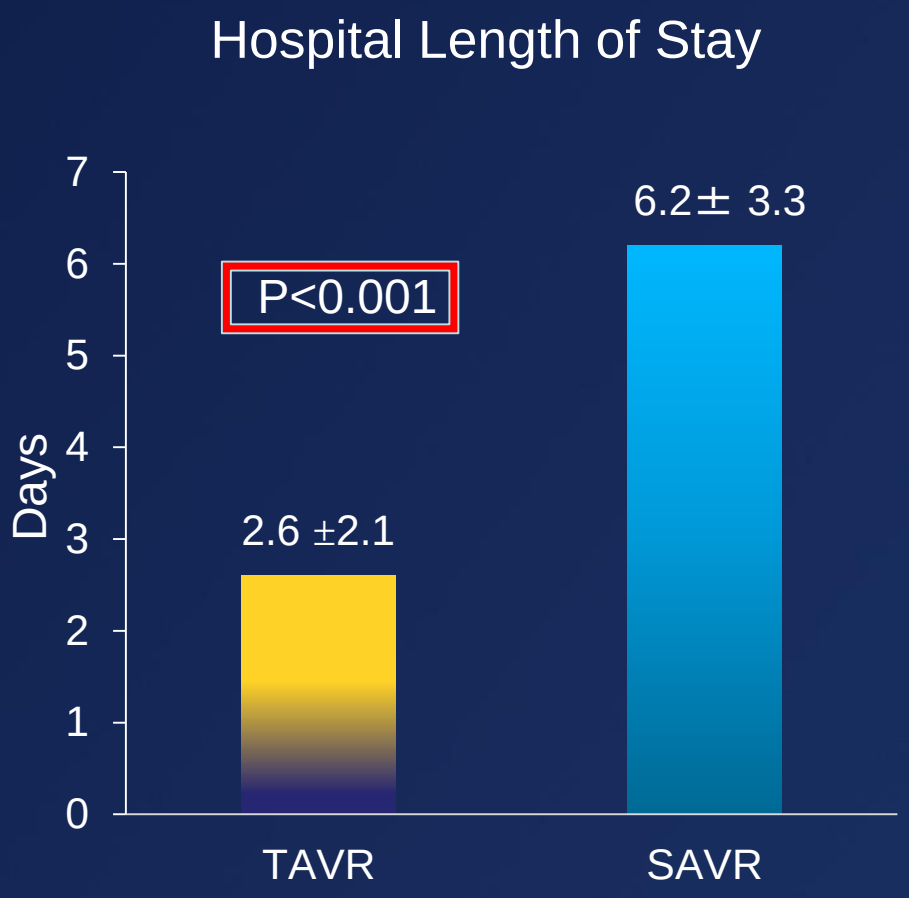


No. at risk

TAVR	725	712	636	420
SAVR	678	649	561	358

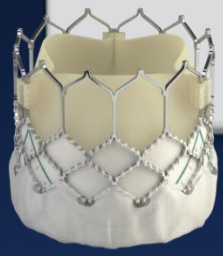
Procedural Time and Length of Stay





THE PARTNER 3 TRIAL

Study Flow and Follow-Up



1520 patients with severe symptomatic AS at low surgical risk consented between March 25, 2016 and October 26, 2017 at 71 sites in the US, Canada, Japan, ANZ

Excluded from Randomization N=520

- Anatomic exclusions (n=308)
- Clinical exclusions (n=89)
- Other exclusions (n=38)
- Incomplete screening (n=85)

Eligible for Enrollment and Randomized N=1000 at 71 sites

TAVR N=503

Surgery N=497

Leon et al. NEJM 2019

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	TAVR (N=496)	Surgery (N=454)
Age — yr	73.3±5.8	73.6±6.1
Male sex — no. (%)	335 (67.5)	323 (71.1)
Nonwhite race or ethnic group — no. (%)†	38 (7.7)	45 (9.9)
Body-mass index‡	30.7±5.5	30.3±5.1
STS score§	1.9±0.7	1.9±0.6
EuroSCORE II score¶	1.5±1.2	1.5±0.9

NEJM 2019

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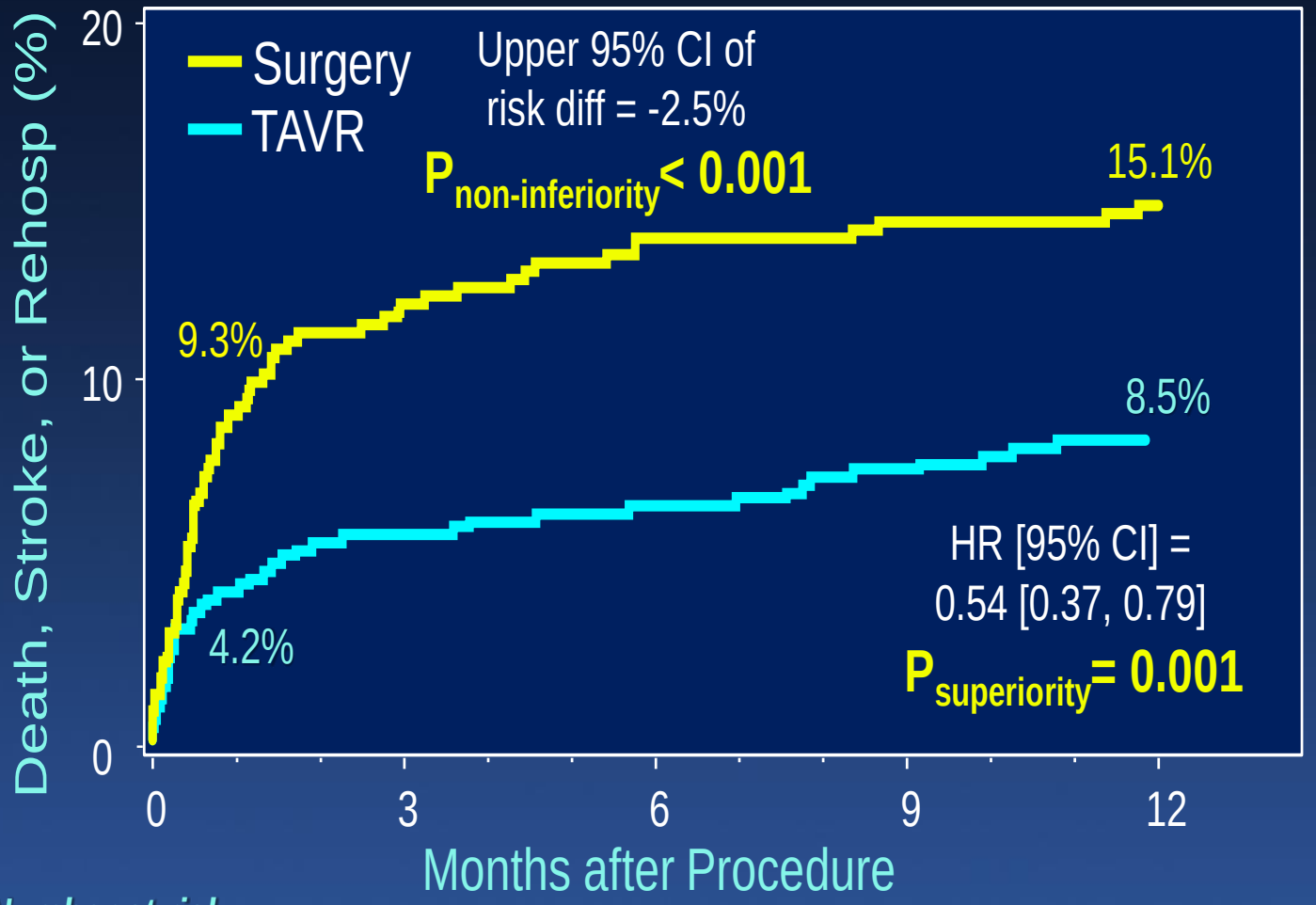
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	TAVR (N=496)	Surgery (N=454)
Pulmonary hypertension — no./total no. (%)	23/495 (4.6)	24/454 (5.3)
Aortic-valve area — cm^2	0.8±0.2	0.8±0.2
Aortic-valve gradient — mm Hg	49.4±12.8	48.3±11.8
Left ventricular ejection fraction — %	65.7±9.0	66.2±8.6
Moderate or severe regurgitation — no./total no. (%)		
Aortic	19/484 (3.9)	11/446 (2.5)
Mitral	6/477 (1.3)	14/437 (3.2)
Tricuspid	8/473 (1.7)	10/430 (2.3)
Systolic annular perimeter on CT — mm	78.1±6.9	78.6±7.2
Systolic annular area on CT — mm^2	473.5±83.3	479.6±87.6

NEJM 2019

THE PARTNER 3 TRIAL

Primary Endpoint

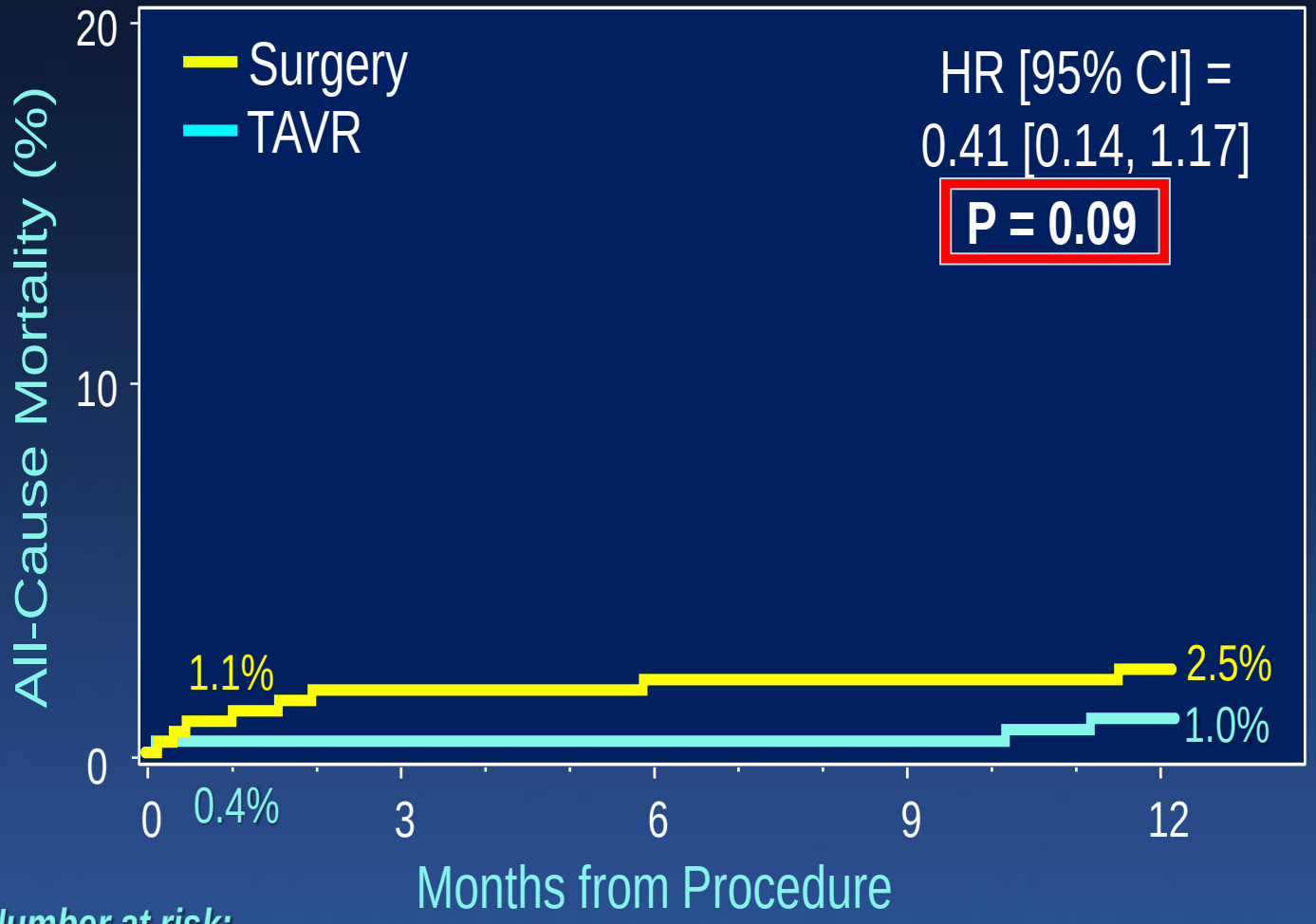


Number at risk:

Surgery	454	408	390	381	377	374
TAVR	496	475	467	462	456	451

THE PARTNER 3 TRIAL

All-Cause Mortality

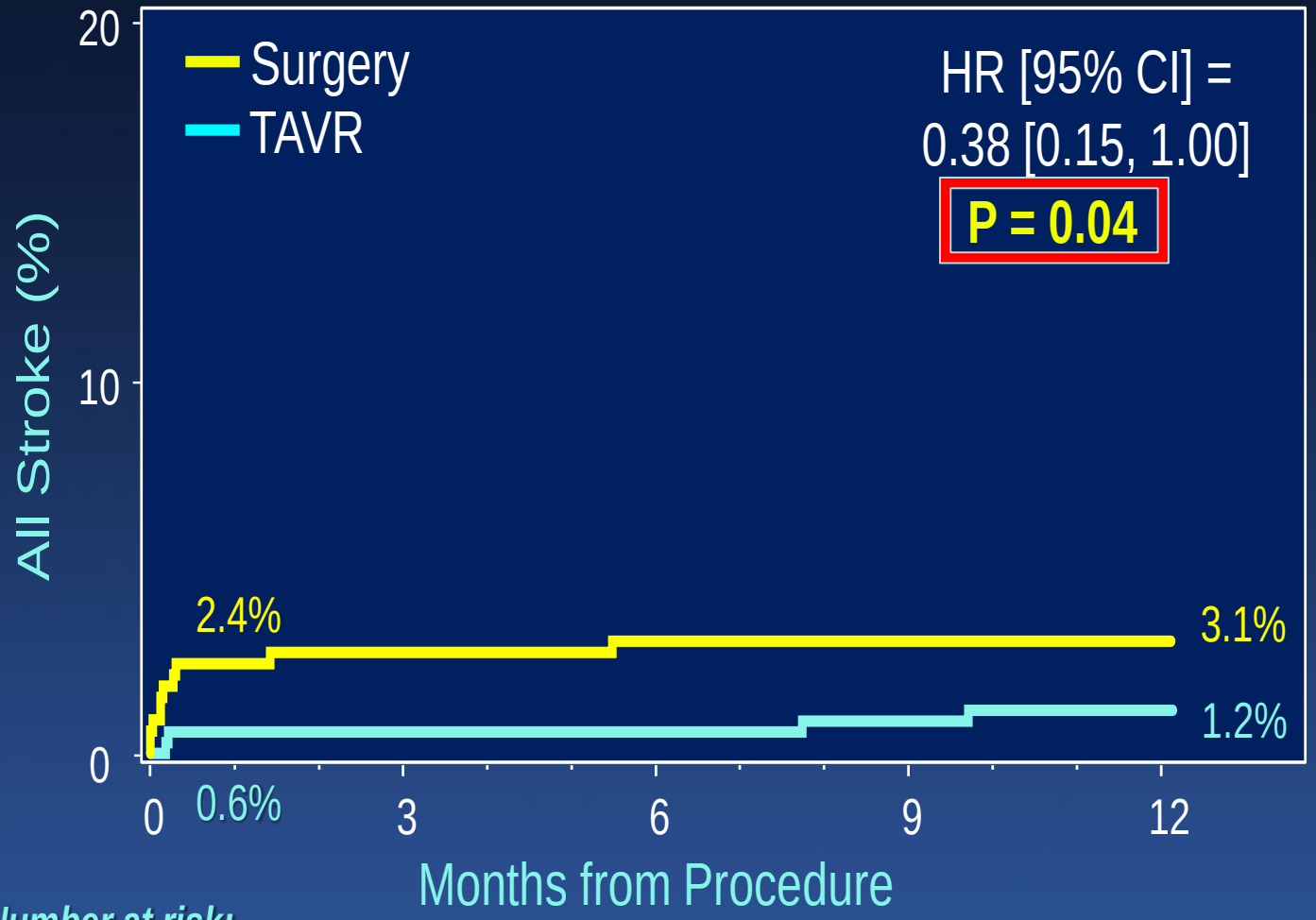


Number at risk:

Surgery	454	445	438	433	431	427
TAVR	496	494	494	493	492	488

THE PARTNER 3 TRIAL

All Stroke

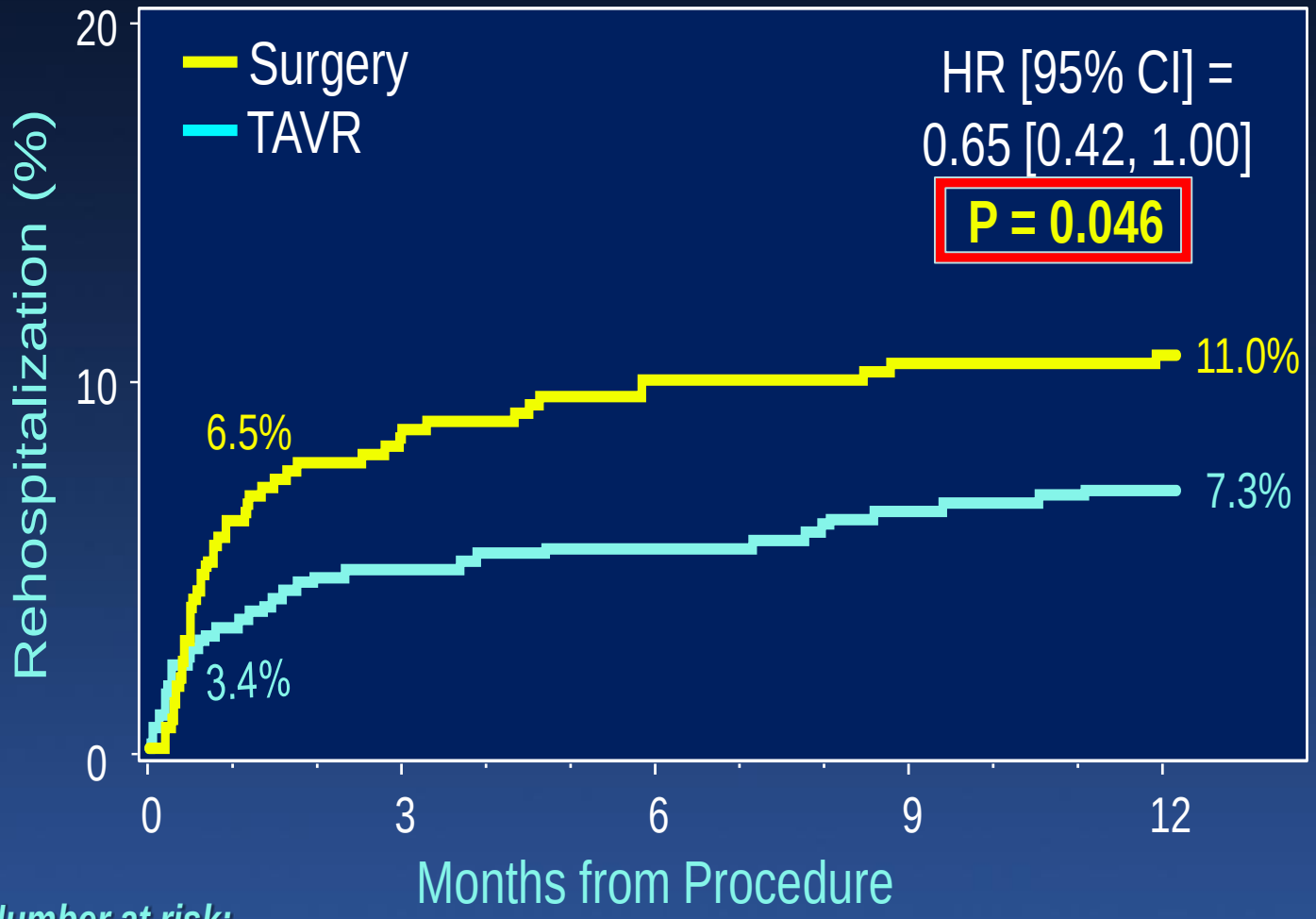


Number at risk:

Surgery	454	435	427	423	421	417
TAVR	496	491	491	489	487	484

THE PARTNER 3 TRIAL

Rehospitalization



Number at risk:

Surgery	454	416	399	389	385	382
TAVR	496	477	469	465	459	453

Transcatheter Aortic-Valve Replacement with a

Subgroup	No. of Patients	TAVR	Surgery	Difference (95% CI)	P Value for Interaction
		no. of events/total no. (%)		*percentage points*	
Overall	950	42/496 (8.5)	68/454 (15.1)	−6.6 (−10.8 to −2.5)	
Age					0.21
<74 yr	516	29/273 (10.6)	36/243 (14.9)	−4.3 (−10.1 to 1.5)	
>74 yr	434	13/223 (5.8)	32/211 (15.3)	−9.5 (−15.3 to −3.7)	
Sex					0.27
Female	292	13/161 (8.1)	24/131 (18.5)	−10.4 (−18.3 to −2.5)	
Male	658	29/335 (8.7)	44/323 (13.8)	−5.1 (−9.9 to −0.3)	
STS-PROM score					0.98
≤1.8	464	21/232 (9.1)	36/232 (15.7)	−6.7 (−12.6 to −0.7)	
>1.8	486	21/264 (8.0)	32/222 (14.5)	−6.5 (−12.2 to −0.8)	
Left ventricular ejection fraction					0.48
≤65	384	20/208 (9.6)	30/176 (17.2)	−7.6 (−14.5 to −0.7)	
>65	524	21/264 (8.0)	32/260 (12.4)	−4.4 (−9.6 to 0.7)	
NYHA class					0.54
I or II	687	23/341 (6.8)	50/346 (14.5)	−7.8 (−12.4 to −3.2)	
III or IV	263	19/155 (12.3)	18/108 (16.9)	−4.7 (−13.5 to 4.1)	
Atrial fibrillation					0.67
No	786	33/418 (7.9)	51/368 (14.0)	−6.1 (−10.5 to −1.7)	
Yes	163	9/78 (11.6)	17/85 (20.3)	−8.7 (−19.9 to 2.5)	
KCCQ overall summary score					0.27
≤70	407	23/219 (10.5)	37/188 (19.9)	−9.4 (−16.5 to −2.4)	
>70	536	18/275 (6.5)	29/261 (11.2)	−4.6 (−9.2 to 0.2)	

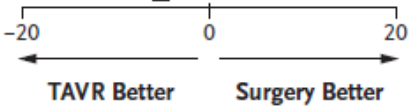


Figure 2. Subgroup Analyses of the Primary Composite End Point of Death from Any Cause, Stroke, or Rehospitalization.

All percentages are Kaplan–Meier estimates. Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) scores range from 0 to 100%, with higher scores indicating a greater risk of death within 30 days after the procedure. Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores range from 0 to 100, with higher scores indicating fewer physical limitations and a greater feeling of well-being. NYHA denotes New York Heart Association.

NEJM 2019

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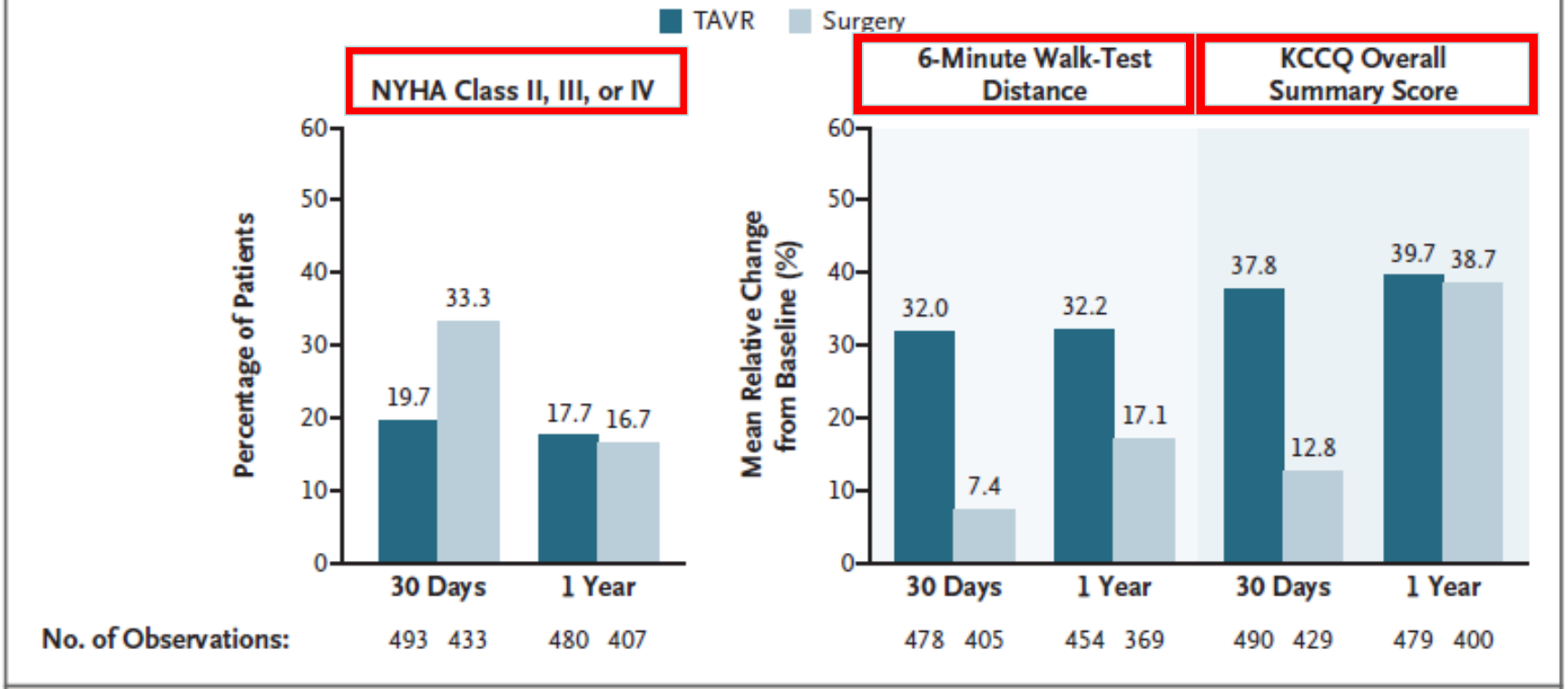


Figure 3. Functional Status and Quality of Life at 30 Days and 1 Year.

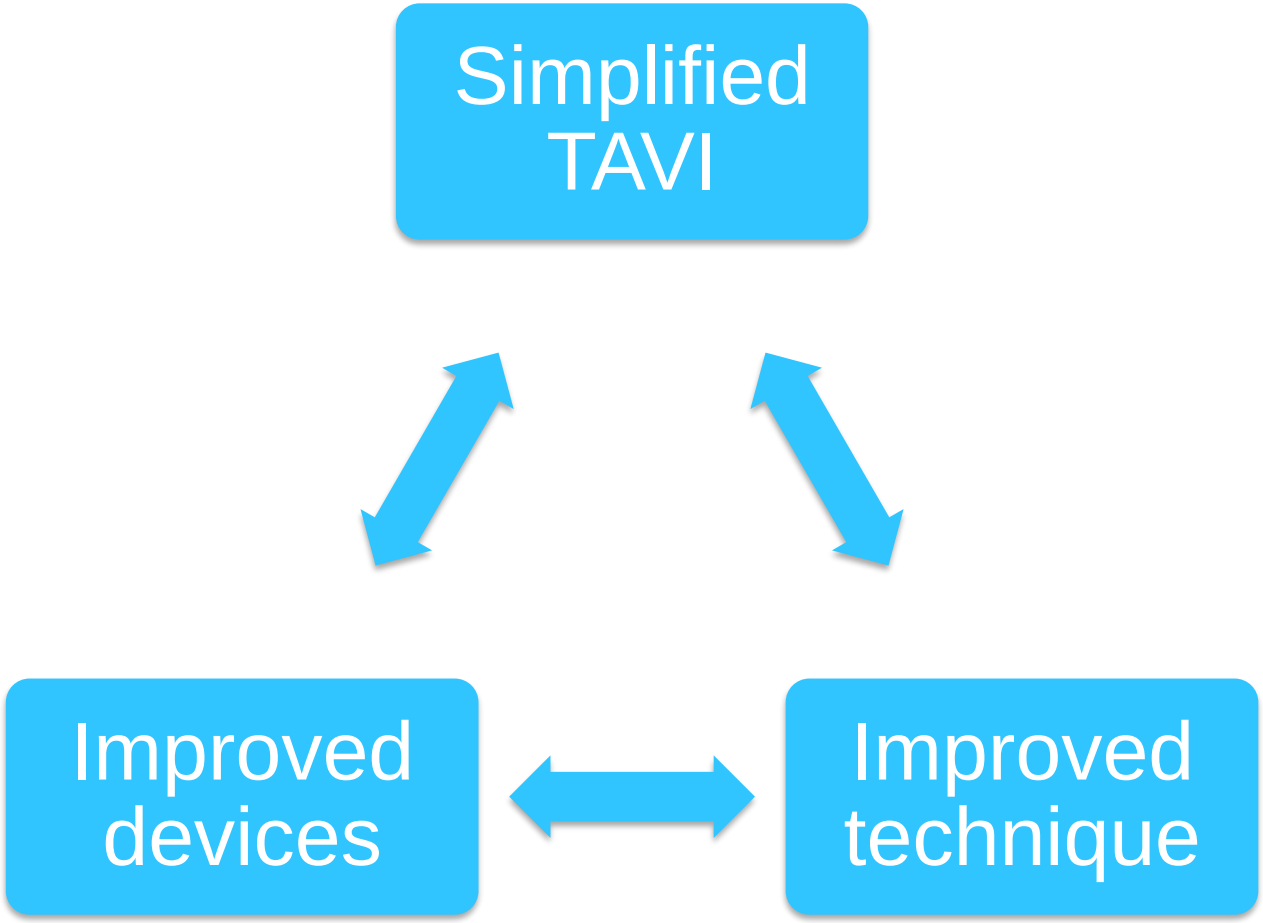
NYHA class and 6-minute walk-test distance are measures of functional status, and the KCCQ overall summary score is a measure of quality of life.

NEJM 2019

Improvement of our results

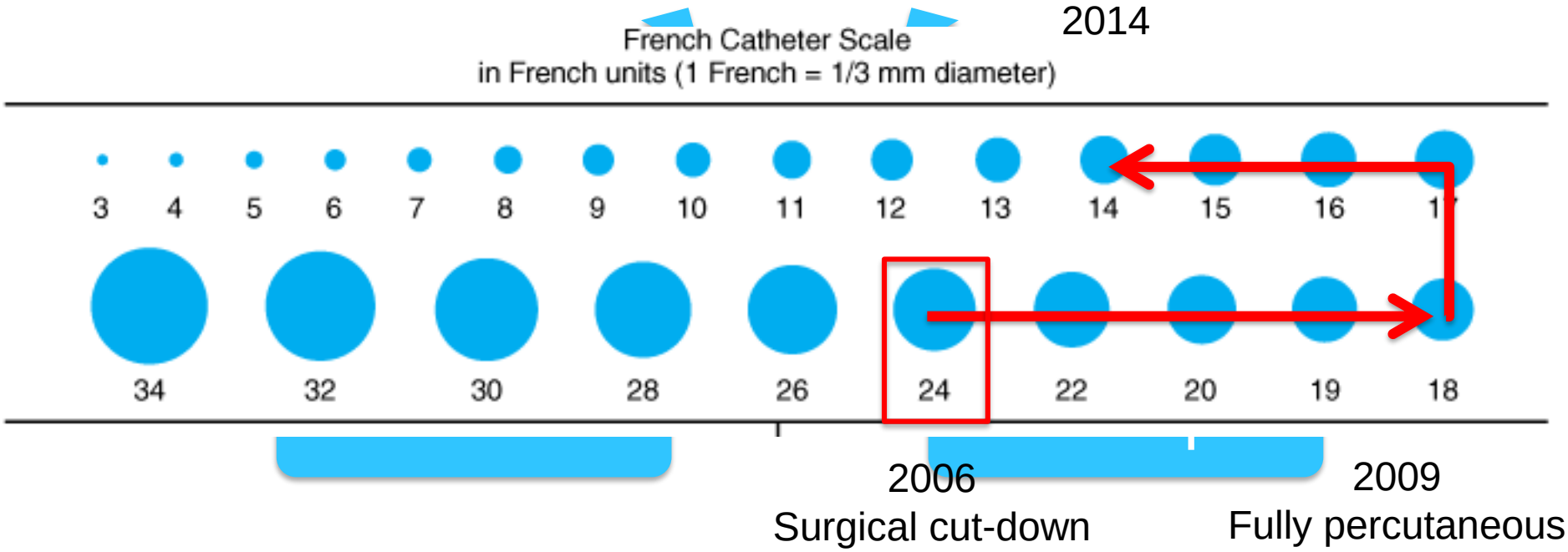
✓ Simplification

Simplified TAVI: History



Simplified TAVI: History

Simplified TAVI



Simplified TAVI: History

Improved devices

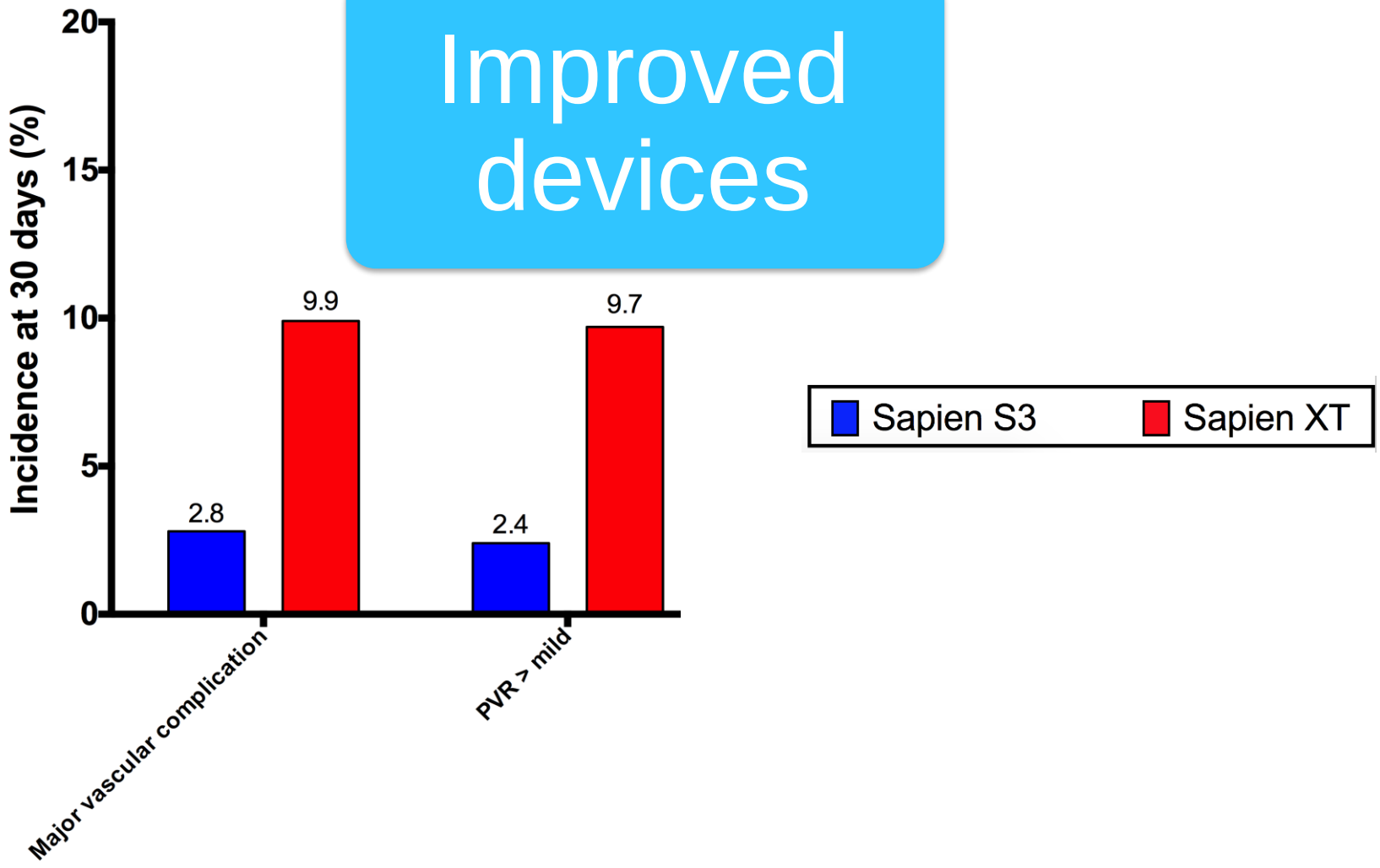
Sapien

Sapien XT

Sapien 3

Simplified TAVI: History

Improved devices



Sawaya, Spaziano, Lefèvre et al. WJC, 2016

Simplified TAVI: History

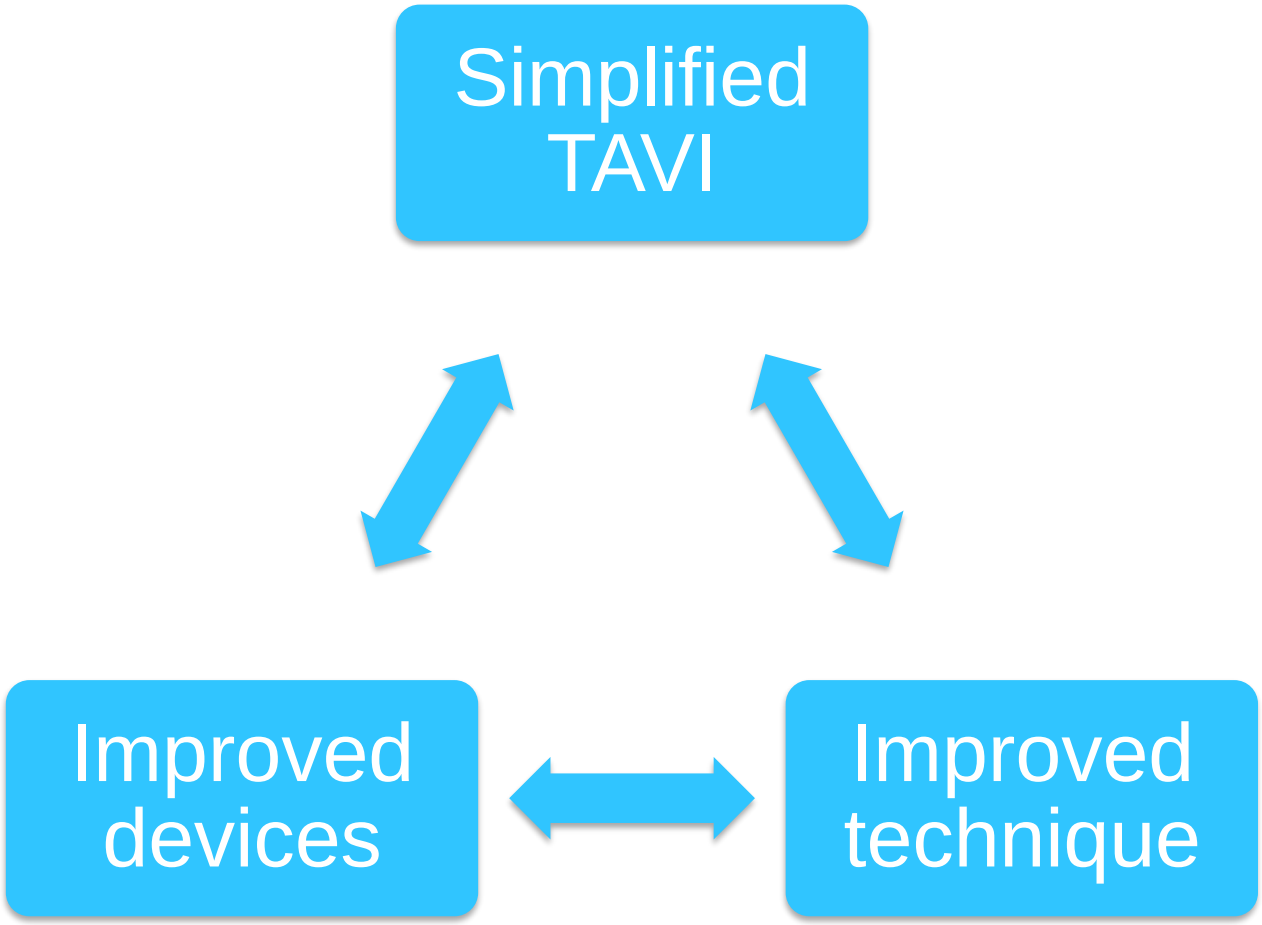
Improved devices

Corevalve

Evolute R

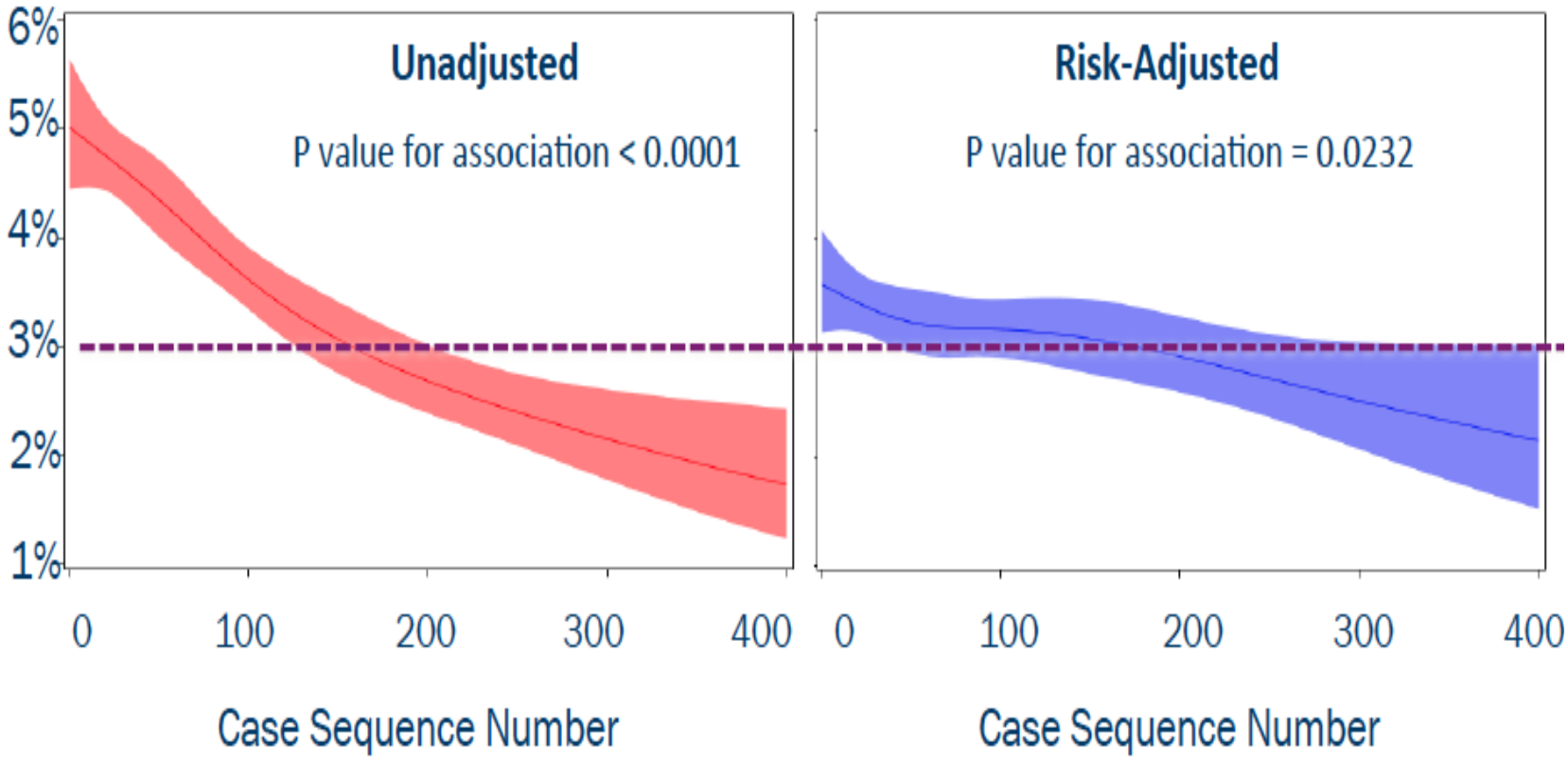
- ✓ Recapturable, repositionable
- ✓ More controlled deployment
- ✓ Less PVL
- ✓ Less AVB

Simplified TAVI: History



TVT registry (2012-2015, 42998 Pts)

30-day mortality and learning curve



Carroll et al. ACC 2016

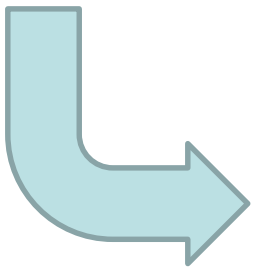
First transapical case in Massy in the hybrid room 2009


PCR
Live case EuroPCR 2016

Complications 2006-2009

General anesthesia

- Hemodynamic instability
- Late stroke identification
- Pulmonary infection
- Difficult extubation



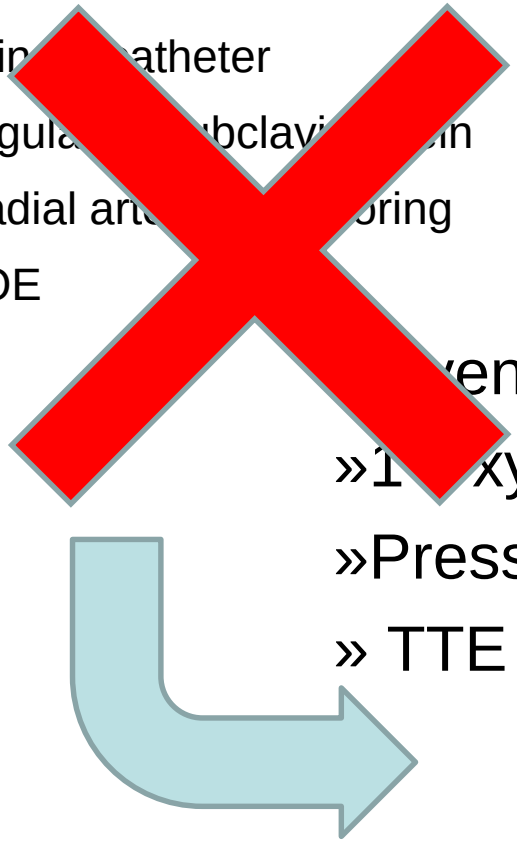
» Conscious sedation April 2009

» 0% General anesthesia.

Complications 2006-2009

Too much monitoring

- Urin atheter
- Jugula bclavi in
- Radial art ring
- TOE



enous lines

»1 xymeter

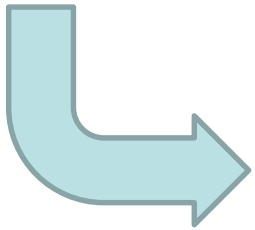
»Pressure monitoring through TRA

» TTE

Complications 2006-2015

Main access vascular complications

- Dissection/occlusion
- Perforation, rupture
- Hematoma
- Transfusion

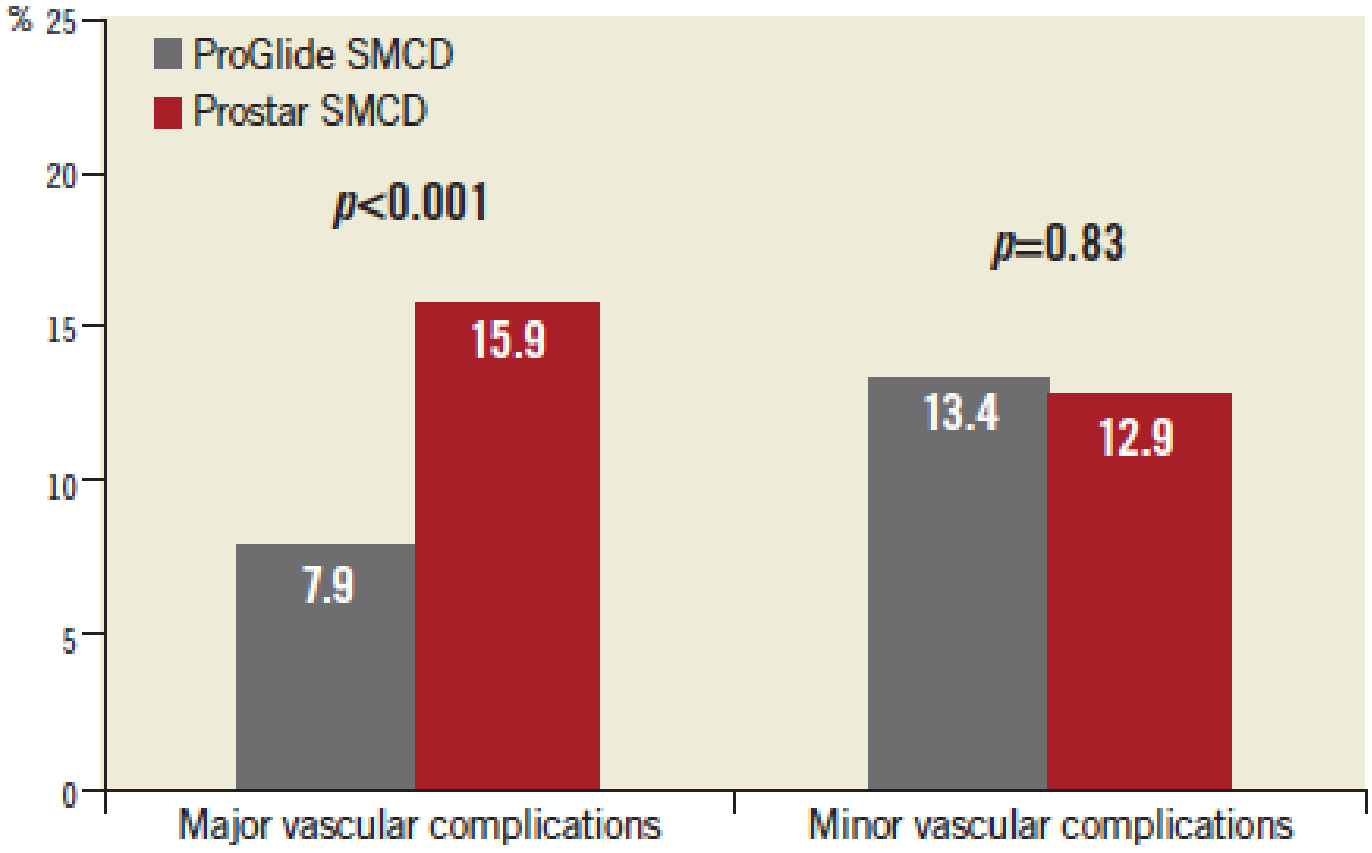


» Better pre-procedural screening

» Peripheral interventions toolbox

» 2 proglides 2015

Proglide vs Prostar

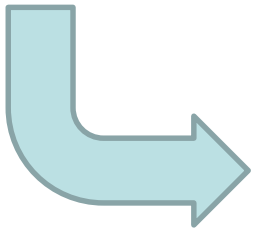


Mehilli et al. Eurointervention 2016;12:1298-1304

Complications 2006-2015

Secondary access vascular complications

- Dissection/Occlusion
- Perforation
- Hemorragie
- Transfusion

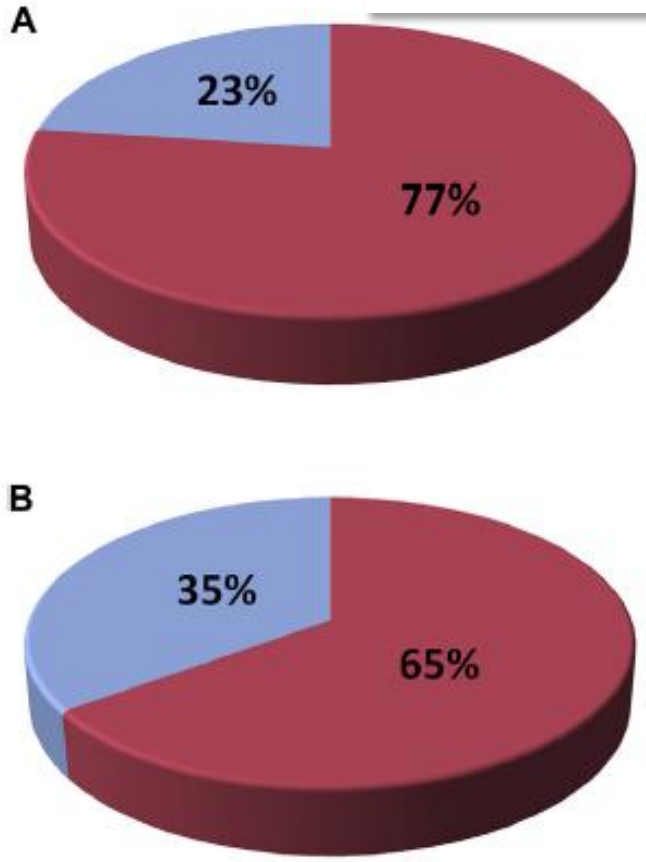


» Radial for second access

Complications 2006-2015

Impact of the Use of Transradial Versus Transfemoral Approach as Secondary Access in Transcatheter Aortic Valve Implantation Procedures

Vascular Complic.



Major Vascular Complic.

Minor Vascular Complic.

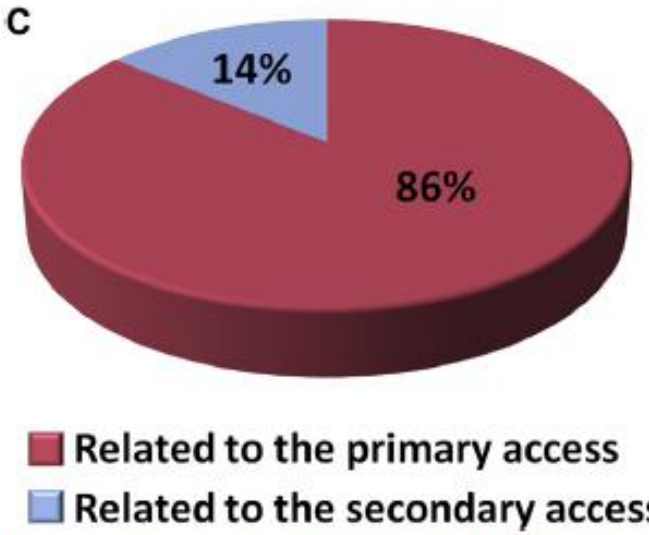


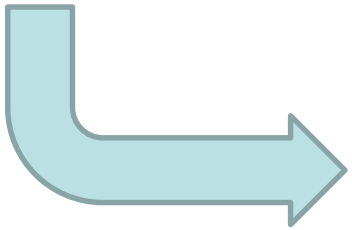
Figure 1. Vascular access site complications according to primary versus secondary access. *(A)* Proportion of vascular access site complications related to the primary versus secondary access. *(B)* Proportion of major vascular access site complications related to the primary versus secondary access. *(C)* Proportion of minor vascular access site complications related to the primary versus secondary access.

R Allende *et al*. Am J Cardiol 2014;114:1729-1734

Complications 2006-2014

Predilatation

- Ac[illegible]aortic [illegible]gurgitation
- Highe[illegible]l AV Block ?
- Higher [illegible]f stroke ?



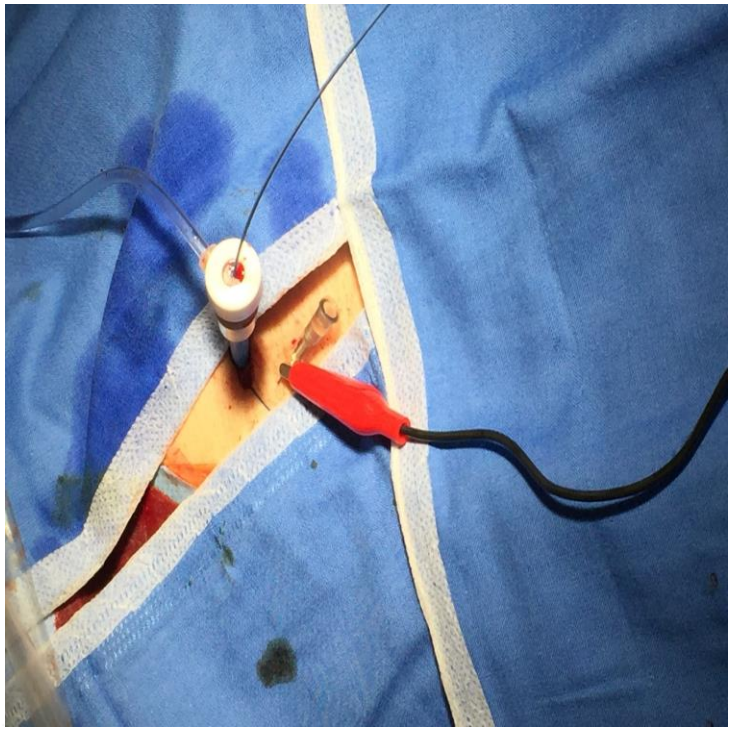
No predilatation

Complications 2006-2015

Temporary Pace-Maker

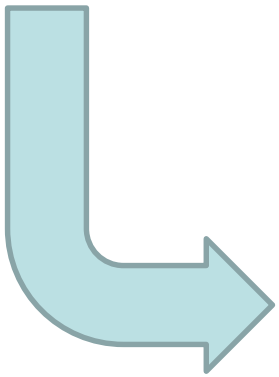
- Pe rdial e sion/ tamponade
- Infecti
- Hema
- Tra lusion

LV wi



Complications 2006-2015

Acute Kidney Injury



» Screening 1-2 weeks before

» Patient preparation

» Contrast media/saline (80/20%)

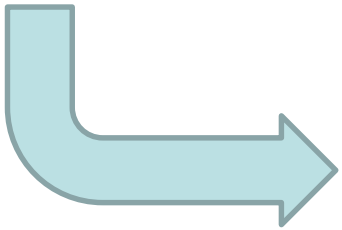
» Renal guard (clairance < 40)

» Optimal view defined by MSCT

Complications since 2006

Rare complications

- Ani[illegible]s rupt[illegible]e
- LV Per[illegible]on
- Coron[illegible]lusions
- PVI[illegible]1

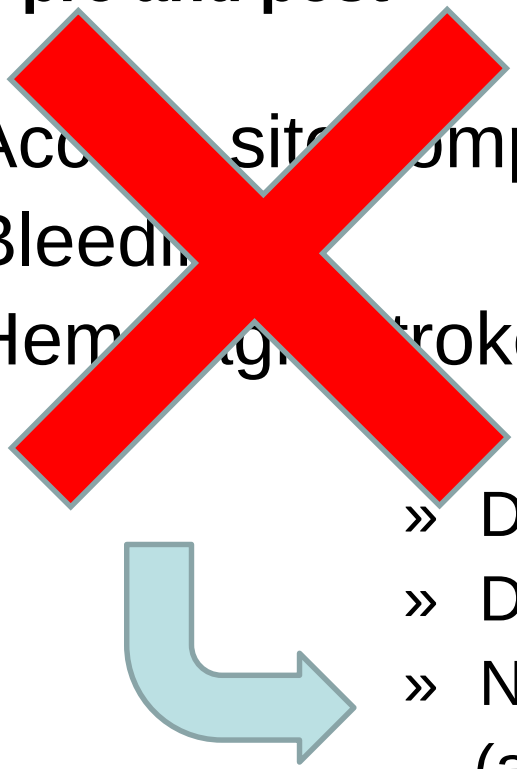


» MSCT, MSCT, MSCT
» S3, Evolute R
» Dedicated wire
» Coronary protection

Complications since 2006

DAPT pre and post

- Acc[illegible] sit[illegible]omplications
- Bleedi[illegible]
- Hem[illegible]g[illegible]troke



» DAPT post only 1 month
» DAPT 3-6 months in case of stent
» No DAPT in patient on anticoagulant (anticoag. and plavix 3-6 mths post stenting)

Improvement of our results

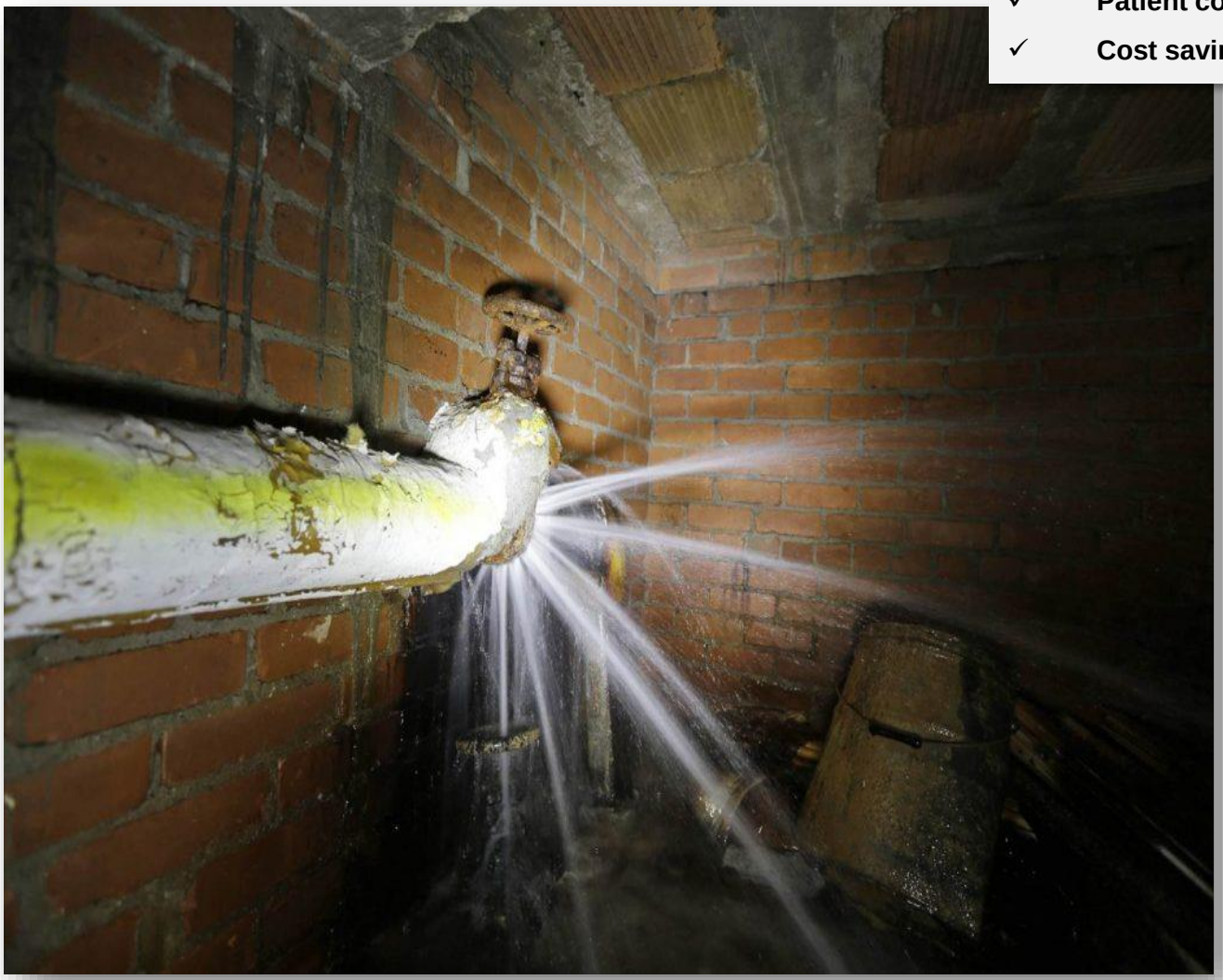
- ✓ Simplification
- ✓ Remaining questions

Remaining questions ?

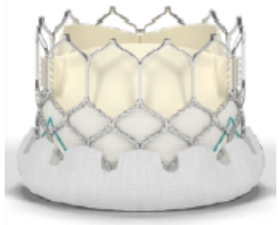
- ✓ Paravalvular leak
- ✓ Durability
- ✓ Bicuspid aortic stenosis
- ✓ Pace maker placement
- ✓ Patient confort
- ✓ Cost saving

Paravalvular leak >2/4

- ✓ **PARAVALVULAR LEAK**
- ✓ **Durability**
- ✓ **Bicuspid aortic stenosis**
- ✓ **Pacemaker placement**
- ✓ **Patient confort**
- ✓ **Cost saving**

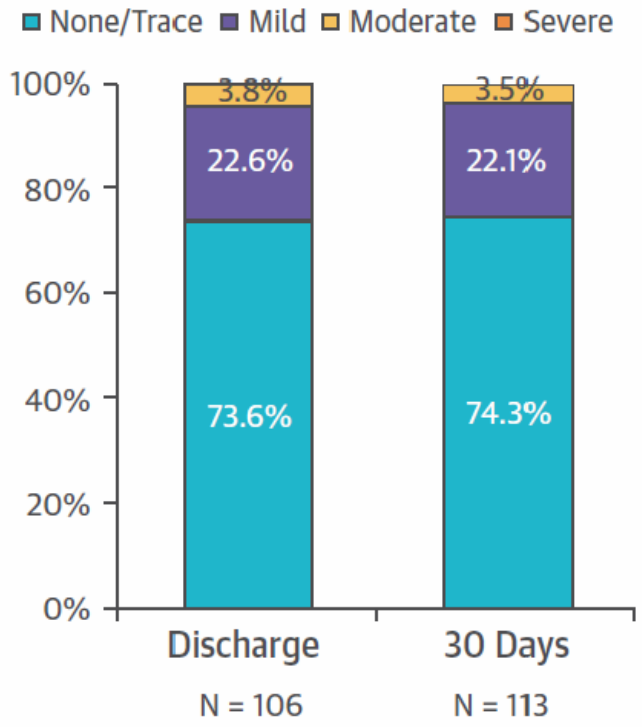


Paravalvular leak >2/4

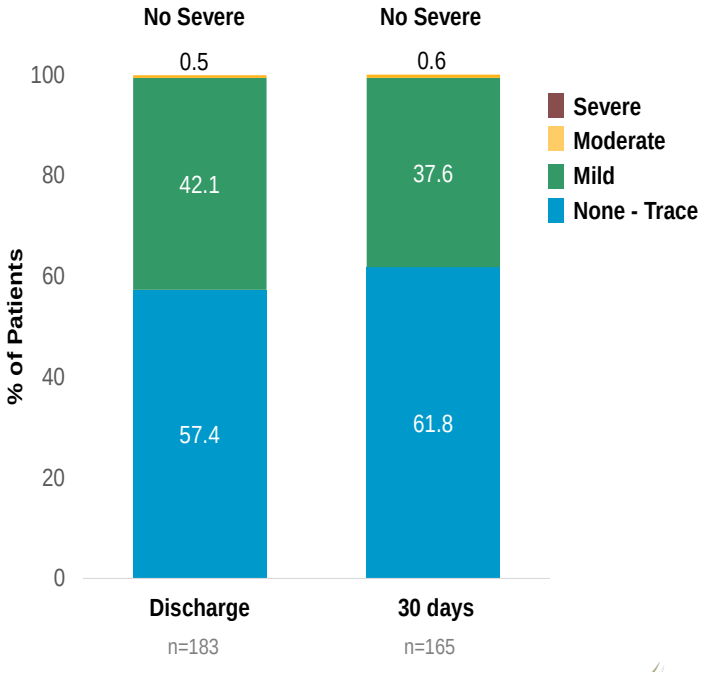


SAPIEN 3
n=160, age 83.6, STS 7.5

CENTERA
N=2003, age 83, STS 6.1

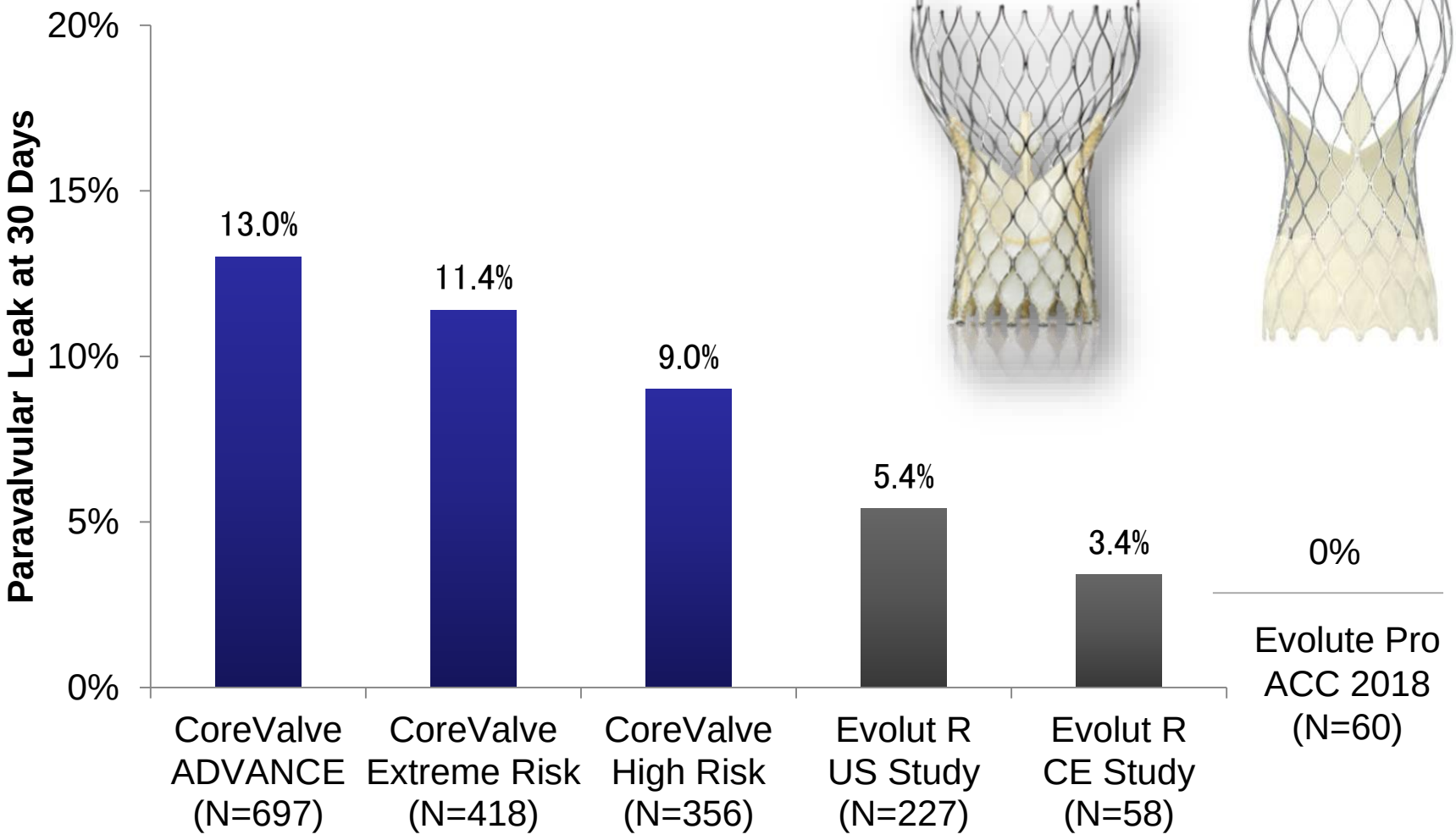


Webb et al. JACC 2014



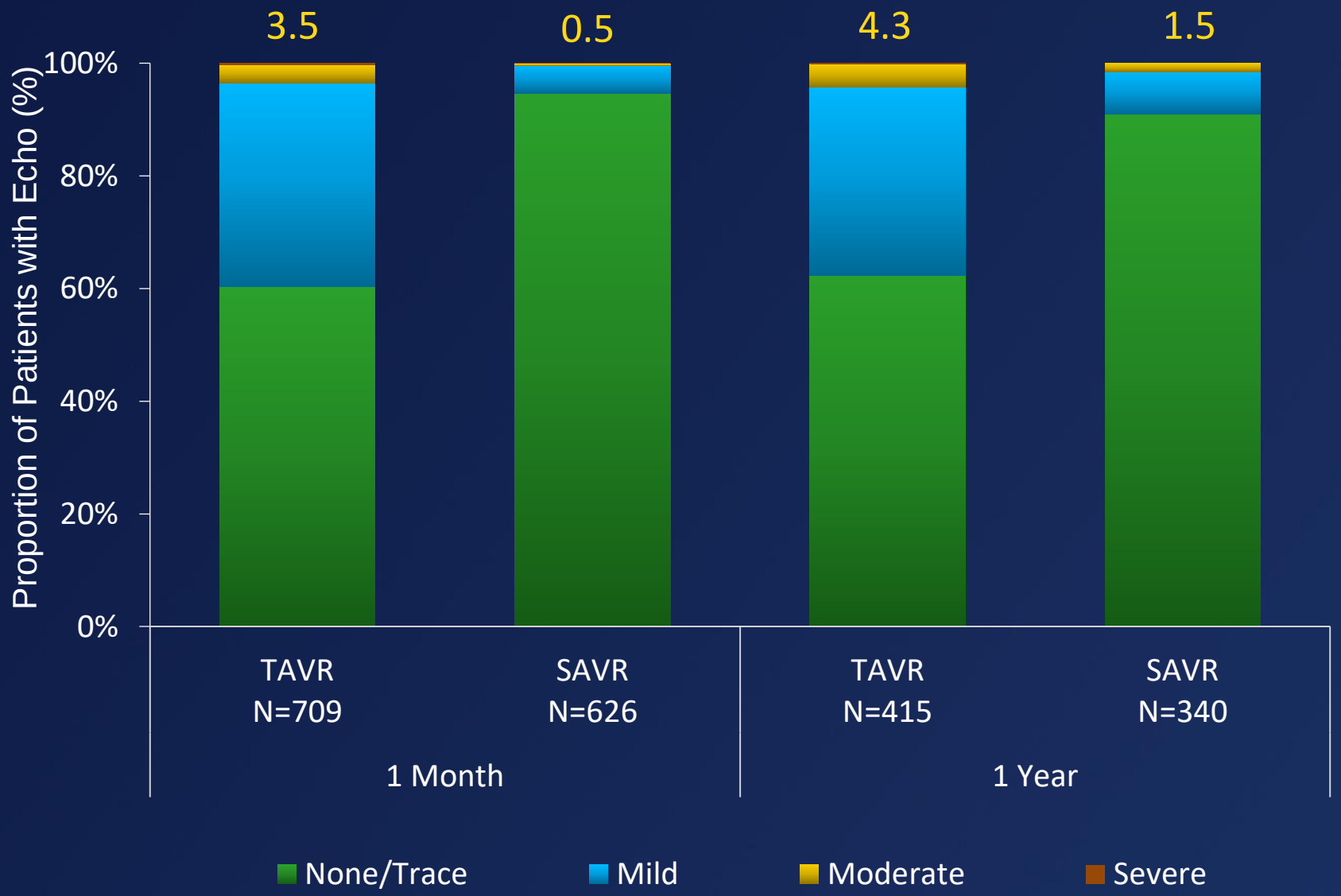
Tchetche et al. EuroPCR 2017

Paravalvular leak >2/4



Total Aortic Valve Regurgitation

LOW RISK

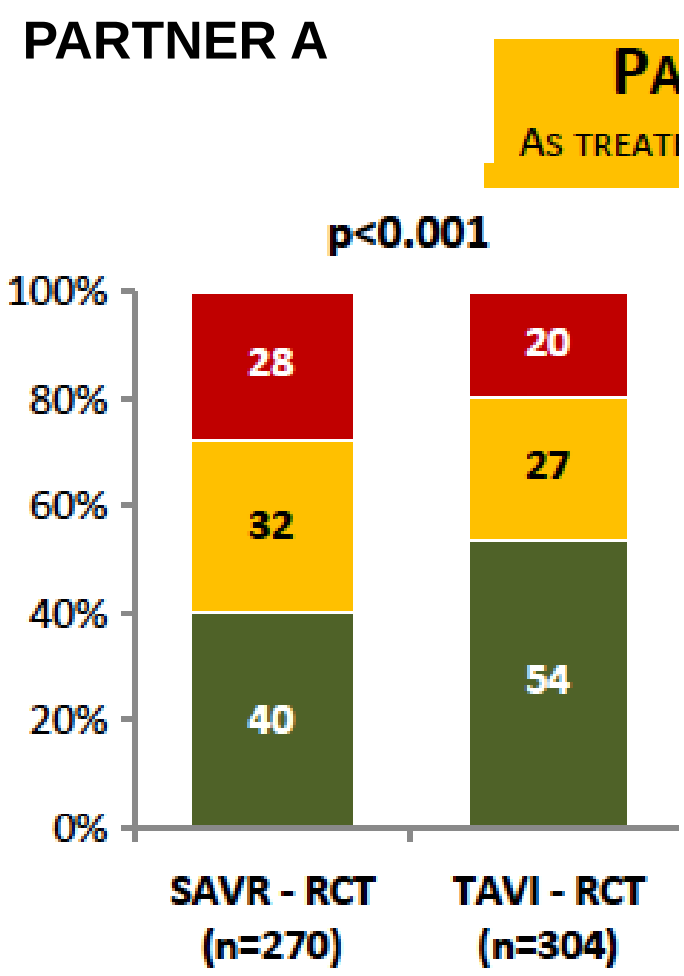


Implant population. Core lab assessments.

- ✓ Paravalvular leak
- ✓ DURABILITY
- ✓ Bicuspid aortic stenosis
- ✓ Pacemaker placement
- ✓ Patient confort
- ✓ Cost saving

Durability

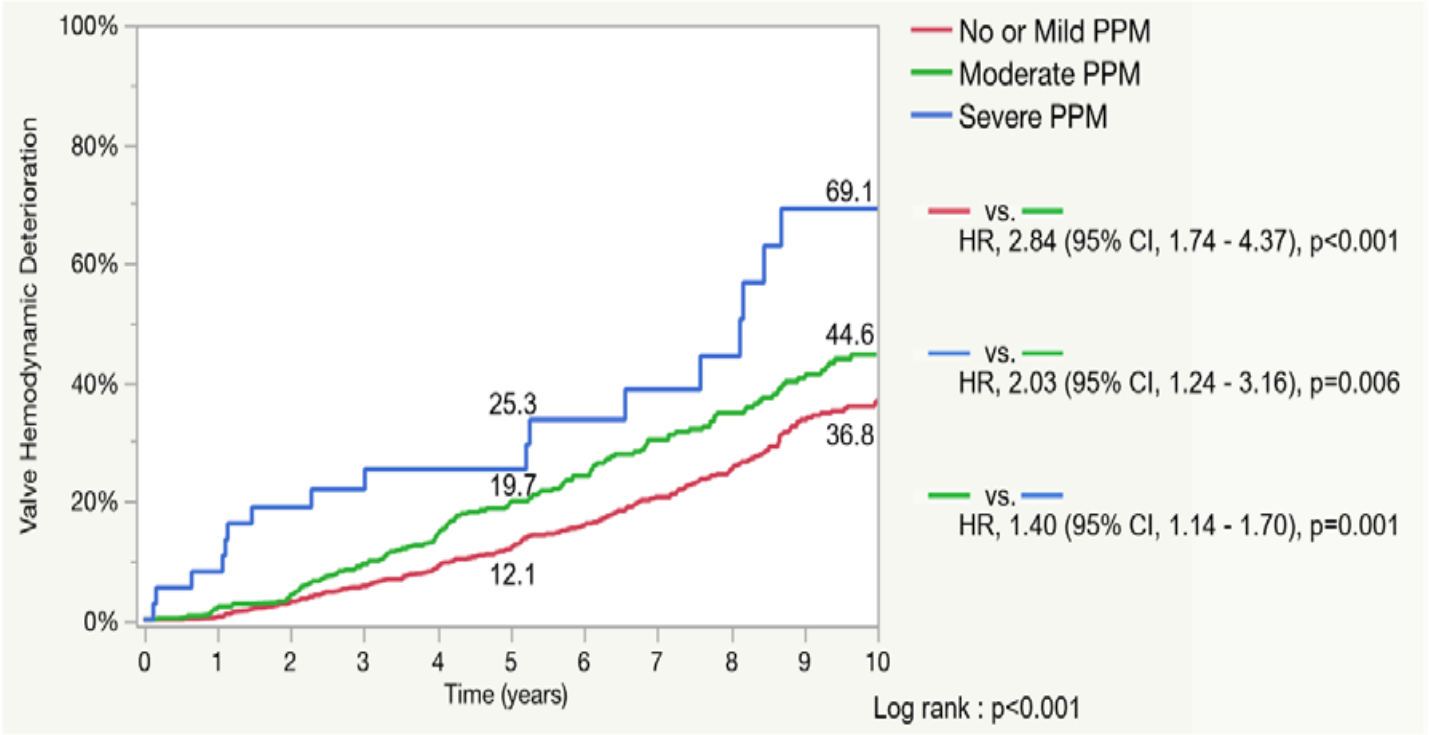
Mismatch


PARTNER A
PA
AS TREATI
p<0.001
100%
80%
60%
40%
20%
0%
28
32
40
20
27
54
SAVR - RCT
(n=270)
TAVI - RCT
(n=304)

Prosthesis-Patient Mismatch

Implant population. Core lab assessments.

Mismatch (Quebec registry) Hemodynamic deterioration



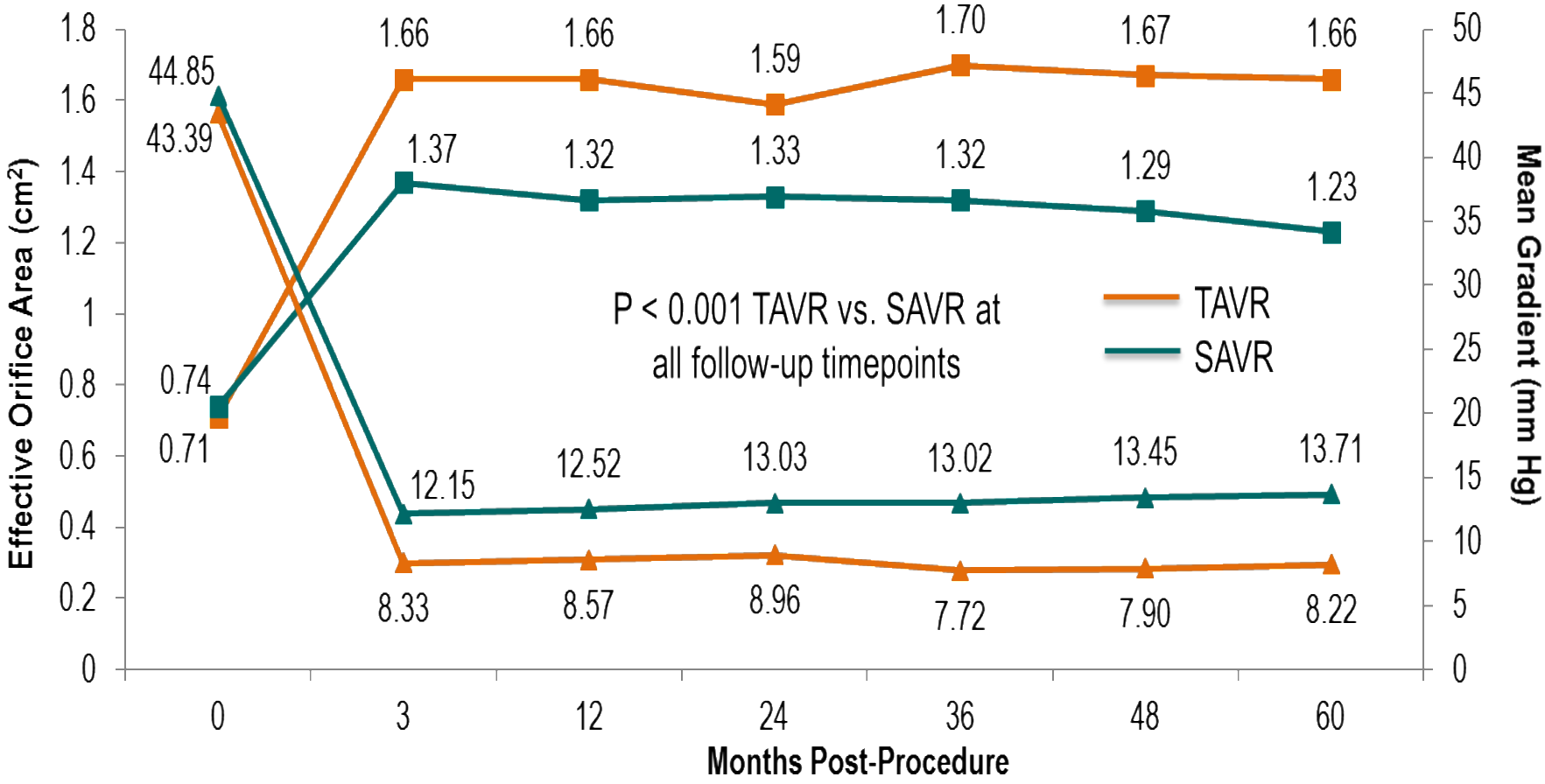
No. at Risk

No or Mild PPM.	901	875	636	420	263	152
Moderate PPM.	449	432	313	210	136	74
Severe PPM.	37	31	22	16	10	4

Salaun et al. Circulation 2018

Notion Trial

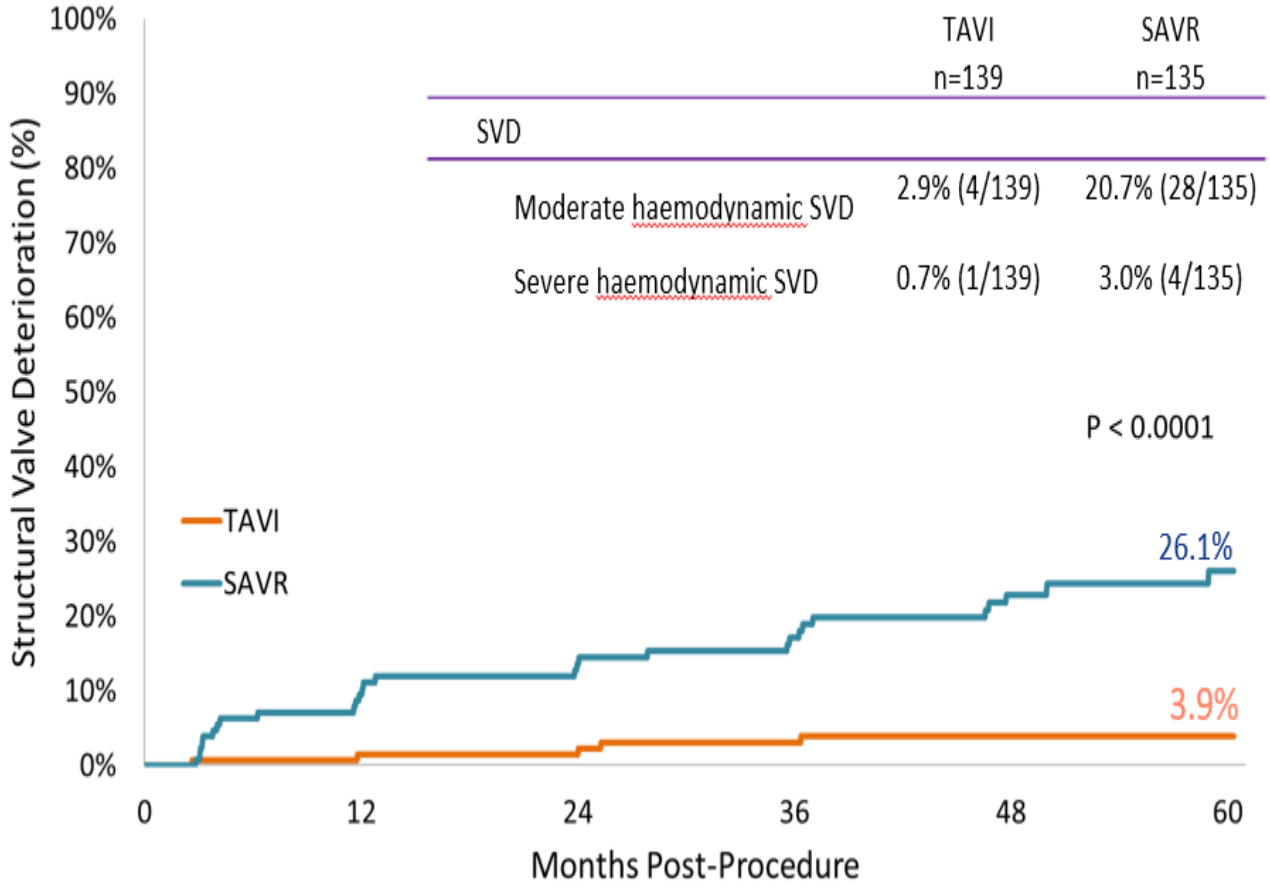
Aortic Valve Performance



Thyregod et al. ACC 2018

Notion Trial

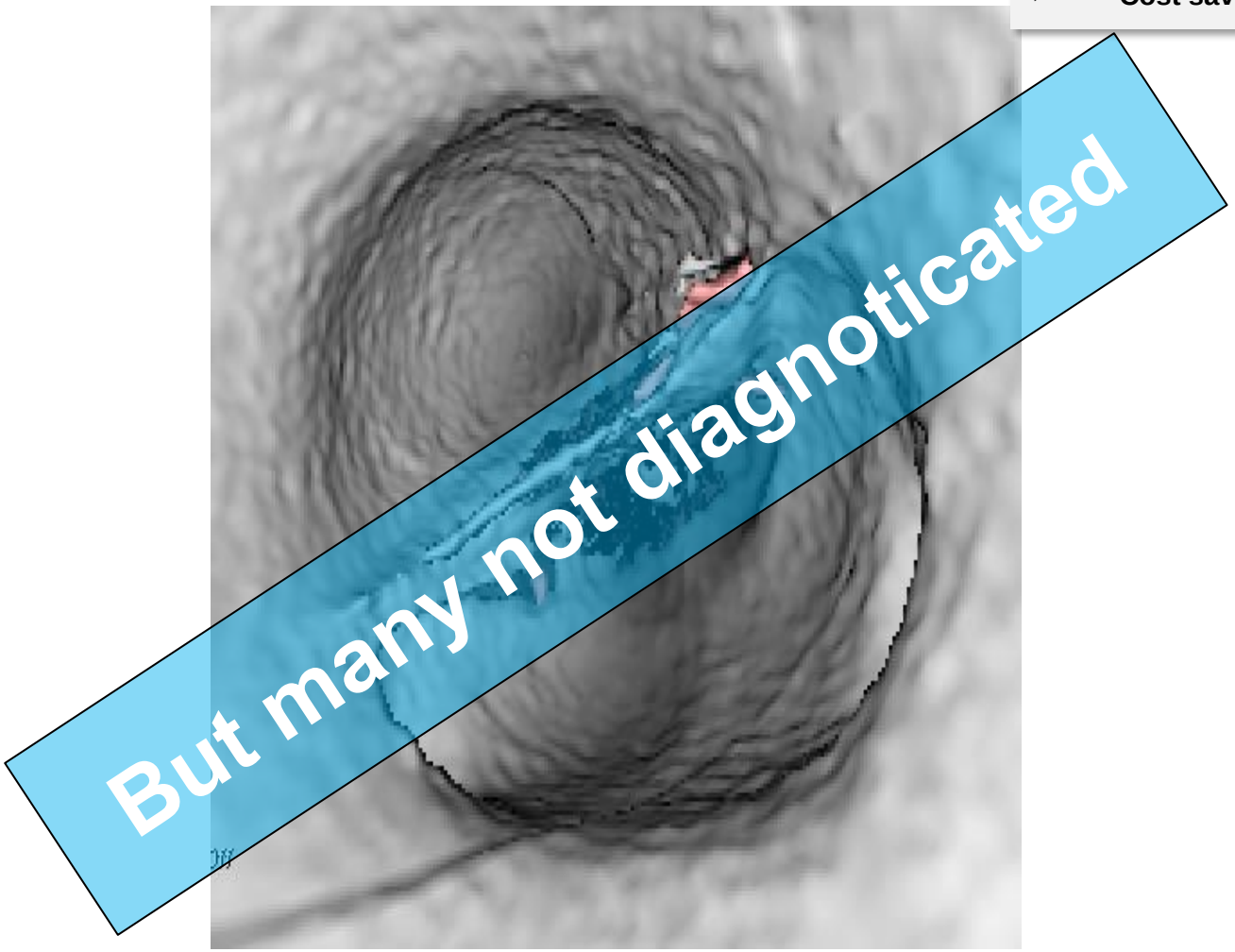
Durability



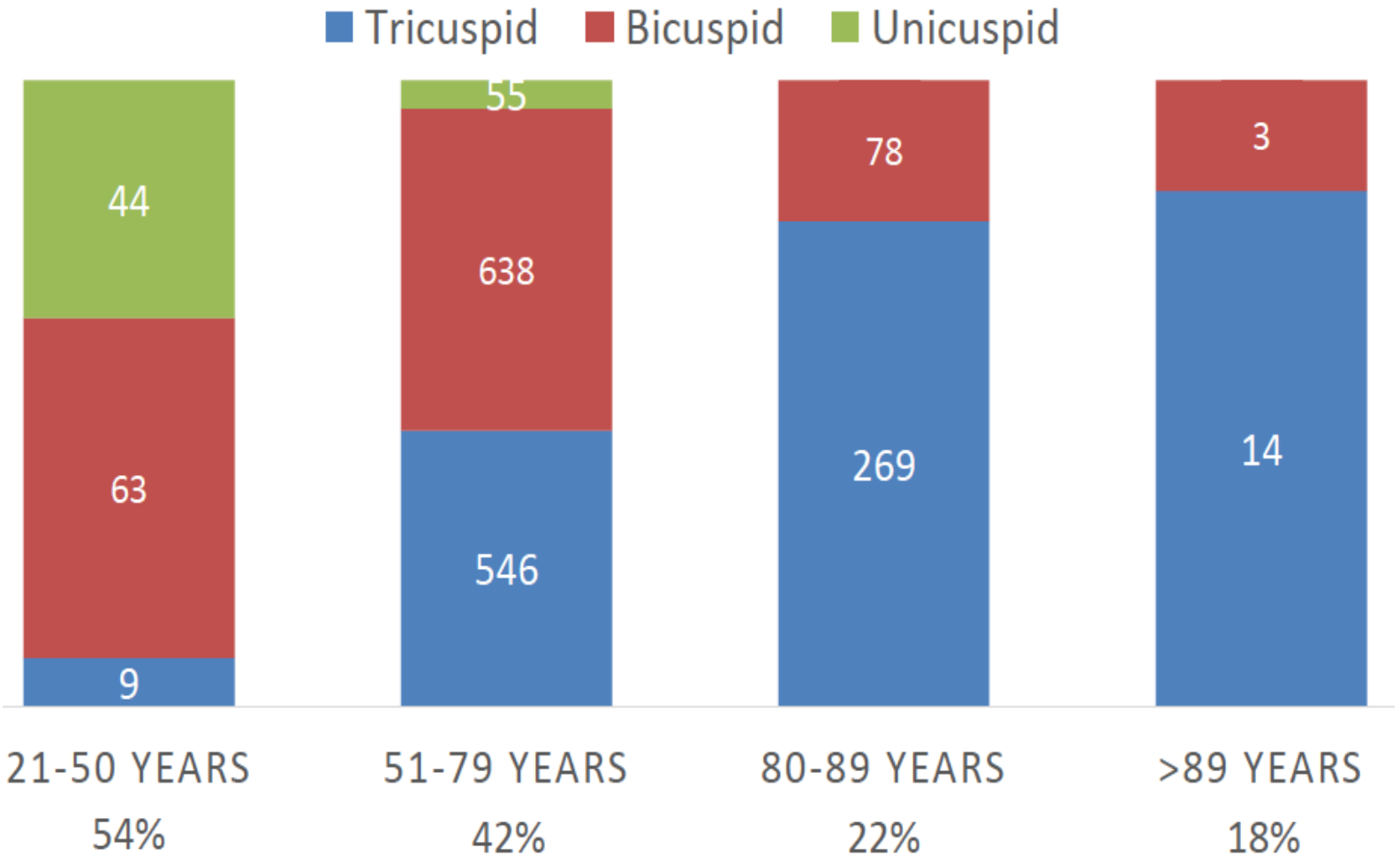
Sondergaard et al. EuroPCR 2017

No RCT for Bicuspid aortic stenosis

- ✓ Paravalvular leak
- ✓ Durability
- ✓ BICUSPID AORTIC STENOSIS
- ✓ Pacemaker placement
- ✓ Patient confort
- ✓ Cost saving



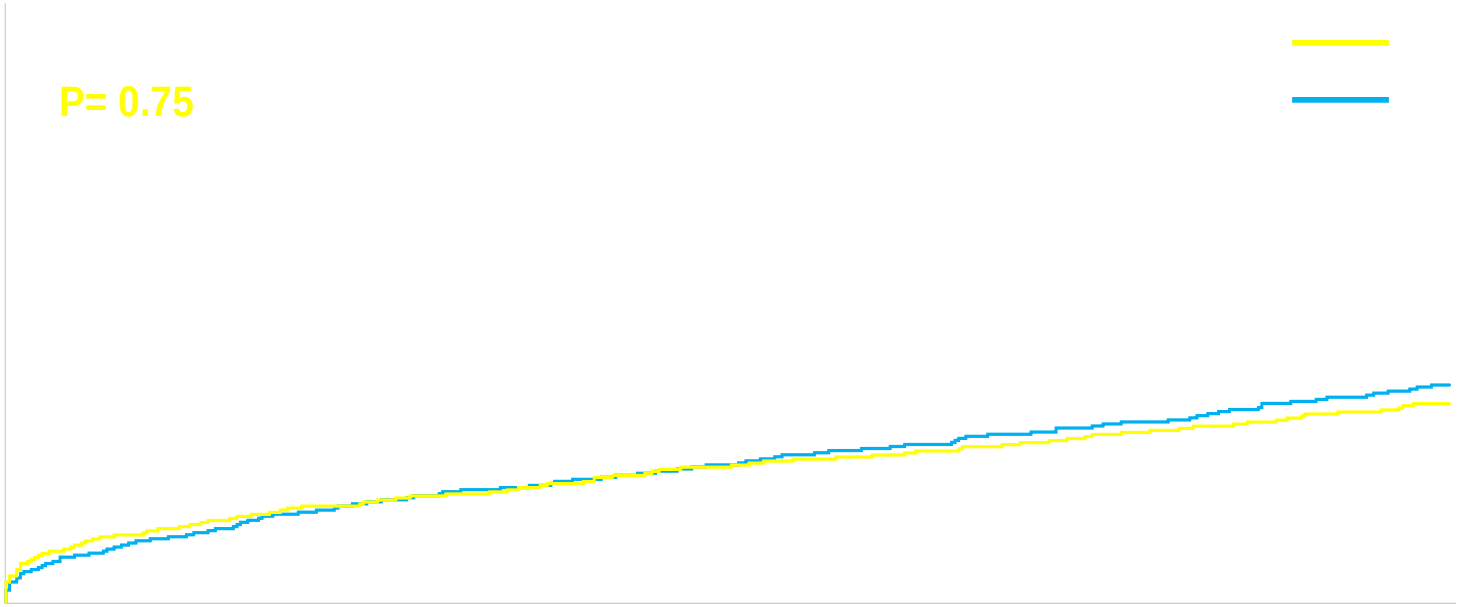
Bicuspid aortic stenosis



Roberts et al. Am J Cardiol 2012; 109:1632-6

Registre TVT (Sapien 3)

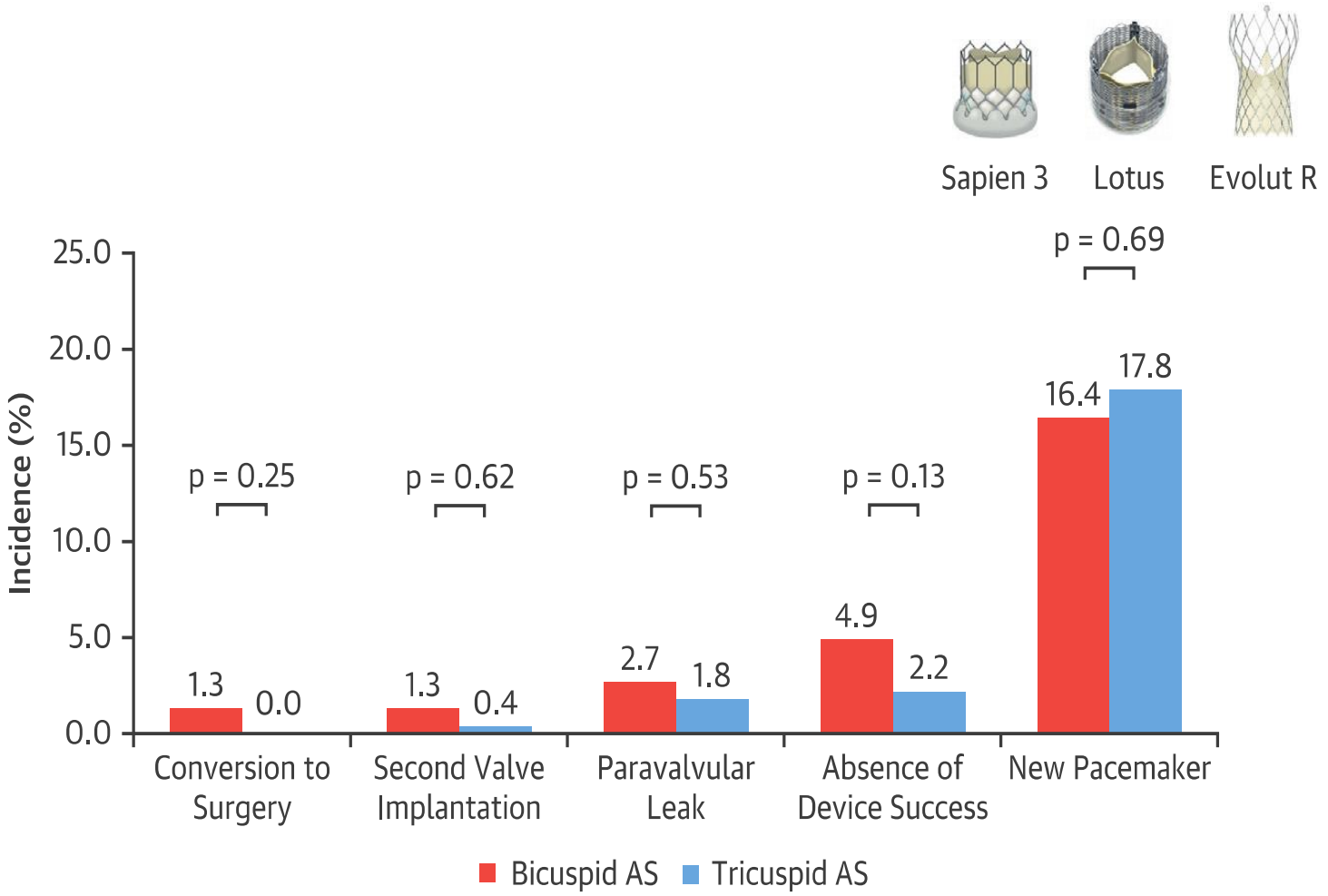
1-Year Mortality or Stroke – Matched



Bicuspid	2691	1234	1196	1135	910
Tricuspid	2691	1341	1296	1226	952

Makkar et al. ACC 2019

International registry of bicuspid AS



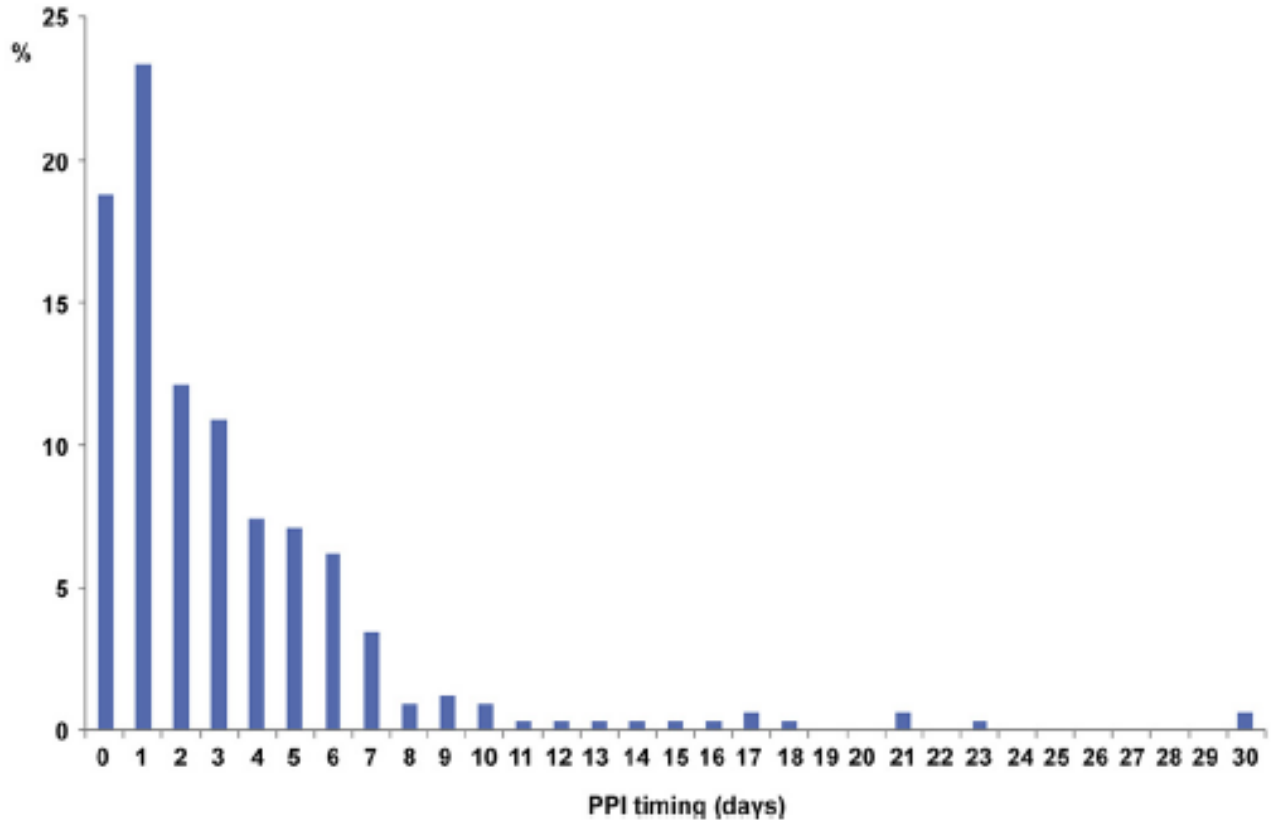
Yoon et al. JACC 2017; 69:2579-89

PACEMAKER PLACEMENT

	Mortalité		AVC		Pace Maker		FA		IA	
	TAVI	Chir	TAVI	Chir	TAVI	Chir	TAVI	Chir	TAVI	Chir
PARTNER3 1000 pts	1	2.5	1.2	3.1	**7.5**	**5.5**	11.6	20.3	0.6	0.5
EV LOW R 1468 pts	2.4	3	0.8	2.4	**19.4**	**7.5**	9.8	38.3	4.3	1.5

Mack MJ et al; Partner 3. New Engl J Med; March 2019
Popma J et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. New Engl J Med March 2019

TIMING of IMPLANTATION



The histogram displays frequency distribution of time to permanent pacemaker implantation (PPI).

Comparison of Incidence, Predictors, and Outcomes of Early Infective Endocarditis after Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in the United States

Dhaval Kolte, MD, PhD[a], Andrew Goldsweig, MD[b], Kevin F. Kennedy, MS[c], J. Dawn Abbott, MD[a], Paul C. Gordon, MD[b], Frank W. Sellke, MD[a], Afshin Ehsan, MD[a], Neel Sodha, MD[a],

- ✓ Paravalvular leak
- ✓ Durability
- ✓ Bicuspid aortic stenosis
- ✓ Pacemaker placement
- ✓ PATIENT CONFORT
- ✓ Cost saving

2013 to 2014 Nationwide Readmissions Databases to determine the incidence of early IE after TAVI and surgical aortic valve replacement (SAVR) in the US. In 29,306 TAVI and 66,077 SAVR patients

Baseline characteristics and in-hospital complications in patients undergoing TAVI versus SAVR

Variable	Propensity Matched		p value
	TAVI (n = 15,138)	SAVR (n = 15,030)	
Major bleeding	3,858 (25.5%)	6,247 (41.6%)	<0.001
Vascular complications	821 (5.4%)	673 (4.5%)	<0.001
Sepsis	251 (1.7%)	306 (2.0%)	0.013
*LOS, days**			
Mean ± SD	8.2 ± 12.6	11.0 ± 14.3	<0.001
Median (IQR)	6 (4–9)	8 (6–13)	
*Discharge disposition**			<0.001
Home (self-care)	5,541 (36.6%)	3,400 (22.6%)	
Short-term hospital	134 (0.9%)	168 (1.1%)	
Skilled nursing facility	3,940 (26.0%)	5327 (35.4%)	
Home health care	5,523 (36.5%)	6,136 (40.8%)	

Am J Cardiol 2018;122:2112−2119

Comparison of Incidence, Predictors, and Outcomes of Early Infective Endocarditis after Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in the United States

[b], Kevin F. Kennedy, MS[c], J. Dawn Abbott, MD[a],
[a], Afshin Ehsan, MD[a], Neel Sodha, MD[a],
ert D. Aronow, MD, MPH[a,*]

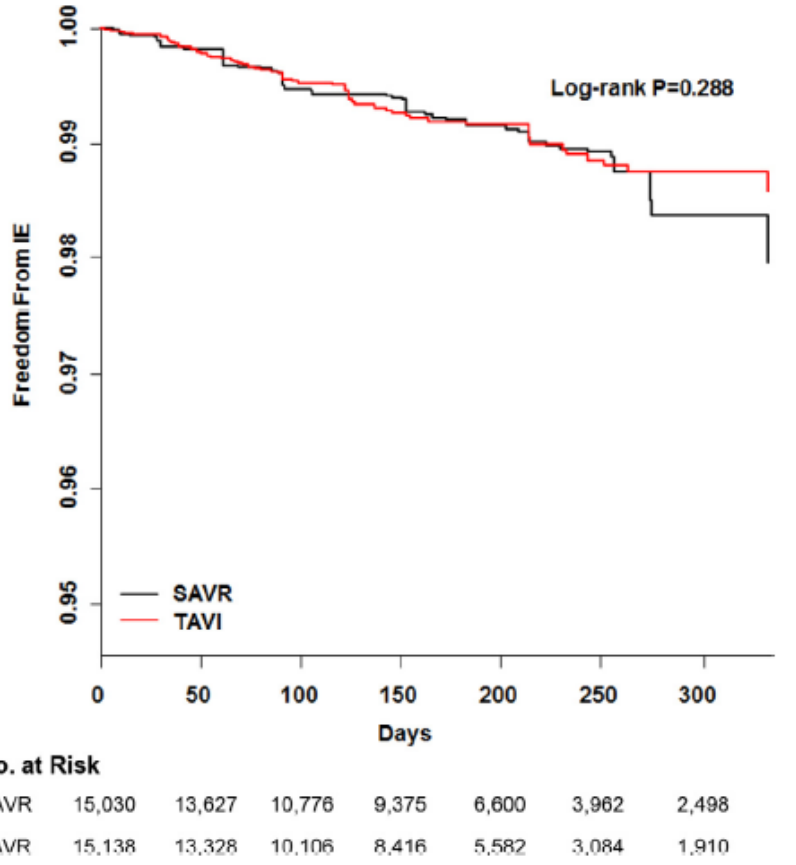


Figure 2. Kaplan-Meier curves for freedom from infective endocarditis following TAVI versus SAVR in the propensity-matched cohort. TAVI = transcatheter aortic valve implantation; SAVR = surgical aortic valve replacement.

In a propensity-matched cohort of 15,138 TAVI and 15,030 SAVR patients (weighted), there were no significant differences in the **incidence rates** of IE **1.7%** [95% CI 1.4% to 2.0%] vs **1.9%** [95% CI 1.6% to 2.2%] per person-year, log-rank p = 0.29) or in the median (interquartile range) **time to IE** (91 [48 to 146] vs 92 [61 to 214] days, p = 0.13).

Am J Cardiol 2018;122:2112−2119

Applied Nursing Research 26 (2013) 174–179

Contents lists available at ScienceDirect

Applied Nursing Research

journal homepage: www.elsevier.com/locate/apnr

Pain intensity, interference and patient pain management strategies the first 12 weeks after coronary artery bypass graft surgery

Kristen A. Sethares, PhD, RN, CNE [a,*], Elizabeth Chin, PhD, RN, APN [a], Inge Costa, BSN, RN, PCCN, CCRN [b]

[a] University of Massachusetts Dartmouth College of Nursing, North Dartmouth, MA 02747, USA
[b] Peace Harbor Hospital, Florence, OR, USA

Methods: Baseline data were collected by interview in the hospital after CABG surgery using the Modified Brief Pain Inventory. One to 12 weeks after discharge, weekly telephone interviews were conducted to collect data.
Results: Pain levels and interference with activities of daily living were greatest during hospitalization and decreased over 12 weeks. Pain interfered the most with coughing and sleep. Once opioid medications ran out, activity modification was primarily used to manage pain.

Sample included 80 adults

Applied Nursing Research 26 (2013) 174–179

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journal homepage: www.elsevier.com/locate/apnr

Pain intensity, interference and patient pain management strategies the first 12 weeks after coronary artery bypass graft surgery

Table 3
Predominant pain relieving strategies for post-surgical pain.

Week	1	2	3	4	5	6	7	8	9	10	11	12
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Patients reporting any level of post-surgical pain from 1 to 10	74 (93%)	54 (77%)	55 (76%)	58 (78%)	32 (42%)	32 (45%)	33 (46%)	20 (29%)	21 (30%)	20 (29%)	16 (24%)	14 (20%)
Pharmacologic pain intervention												
Opioids	67	35	21	20	10	6	7	6	2		3	
Acetaminophen	4	18	19	19	13	11	12	6	6	7	3	3
NSAIDS	2	4	4	2	6	5	4	3	5	6	3	2
Other	6	2	1						1			
Total number patients utilizing pain medication regardless of post-operative pain report	79	59	45	41	29	22	23	15	14	13	9	5
Non-pharmacologic pain intervention												
Activity modification	3	37	25	22	10	18	13	10	9	2	1	1
Pillow for coughing	All	All	5	5	5			1	1			
Heat/cold therapy		2	3	1		1	3	1			1	
Relaxation/distraction			1	1			3	3	1		2	
Topical cream				1		1	2					
Sleep/rest position (recliner	4	4	3	3	2	3	4			1		
Bear it							1	8				

Cost-effectiveness analysis of the SAPIEN 3 TAVI valve compared with surgery in intermediate-risk patients

Gordon Goodall[a], Mark Lamotte[b], Mafalda Ramos[b], Franck Maunoury[c], Barbora Pejchalova[a] and Gerard de Pouvourville[d]

[a]Edwards Lifesciences S.A., Nyon, Switzerland; [b]IQVIA, Corporate village, Zaventem, Belgium; [c]Statesia, Le Mans, France; [d]ESSEC Business School, Cergy Pontoise, France

- ✓ **Paravalvular leak**
- ✓ **Durability**
- ✓ **Bicuspid aortic stenosis**
- ✓ **Pacemaker placement**
- ✓ **Patient confort**
- ✓ **COST SAVING**

*The analysis was performed using a novel Markov model with data derived from the **PARTNER II** randomized controlled trial for survival, clinical event rates, and quality-of-life.*

Table 5. Cost, life expectancy, and quality-adjusted life expectancy in intermediate risk patients undergoing TAVI with SAPIEN 3.

	TAVI	sAVR	Difference
Total Lifetime Cost	€34,157	€34,596	−€439
Index Admission	€26661	€23303	+€3358
Rehabilitation	€892	€2574	−€1682
Post-discharge Complications	€3,393	€5,567	−€2174
Management	€3,211	€3,152	+€59
Life expectancy, years	5.87	5.44	0.42
Quality-adjusted life expectancy	4.06	3.65	0.41
€/life-year gained			Dominant
€/QALY gained			Dominant

Abbreviations. TAVI, transcatheter aortic valve implantation; sAVR, surgical aortic valve replacement; QALY, quality-adjusted life year.

JOURNAL OF MEDICAL ECONOMICS 2019, VOL. 22, NO. 4, 289–296

ESC European Society of Cardiology
European Heart Journal (2017) **38**, 2739–2791
doi:10.1093/eurheartj/ehx391

2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Helmut Baumgartner* (ESC Chairperson)

B) Choice of intervention in symptomatic aortic stenosis		
Aortic valve interventions should only be performed in centres with both departments of cardiology and cardiac surgery on site and with structured collaboration between the two, including a Heart Team (heart valve centres).	I	C
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in *Table 7*). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table 7*), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B

Conclusion

- ✓ 17 years after the case TAVI is a good alternative for patients with intermediate and low risk (very good results)
- ✓ The screening is very important (Angio, CT Scan),
- ✓ Heart team decision
- ✓ Procedure are simplified (« PCI like »).
- ✓ Results of durability of TAVI are good and must be confirmed
- ✓ Results in Bicuspid aortic stenosis are encouraging
- ✓ It is clearly more confortable for the patient
- ✓ It seems to be cost saving
- ✓ We have now to reduce the rate of pacemaker placement

GRACIAS