Minimalist TAVR in Asan Medical Center

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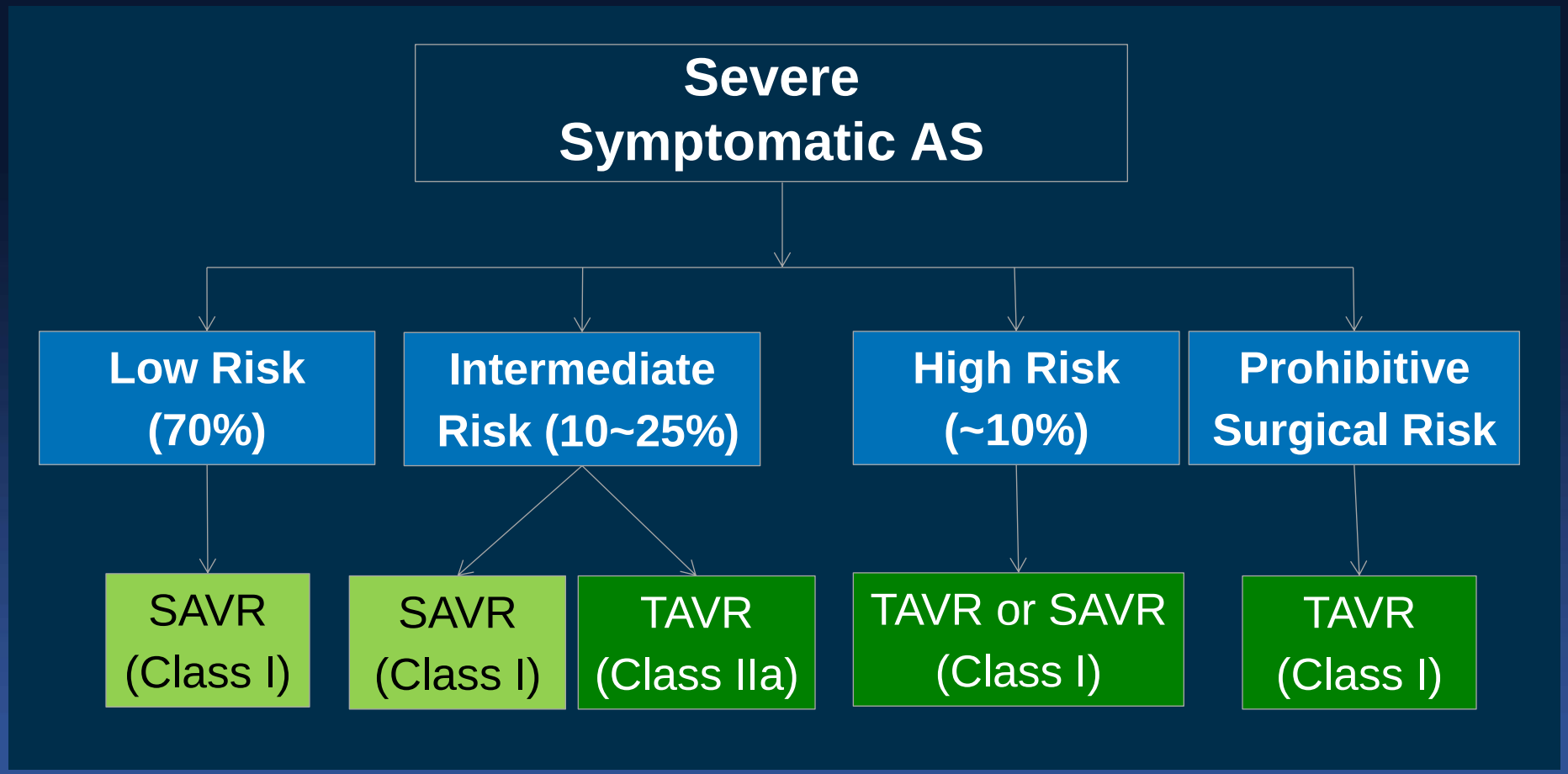
Heart Institute, Asan Medical Center, Seoul, Korea

Current Status of TAVR

2017 AHA/ACC Guideline
Focused Update



Adams DH et al, NEJM 2014; 370:19; Mack MJ et al, Lancet 2015, March; Kapadia SR et al, Lancet 2015, March; Reardon, MJ et al, N Engl J Med 2017; 376:1321-1331, SURTAVI study

TAVR in Low Risk, ACC 2019

Sapien 3

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

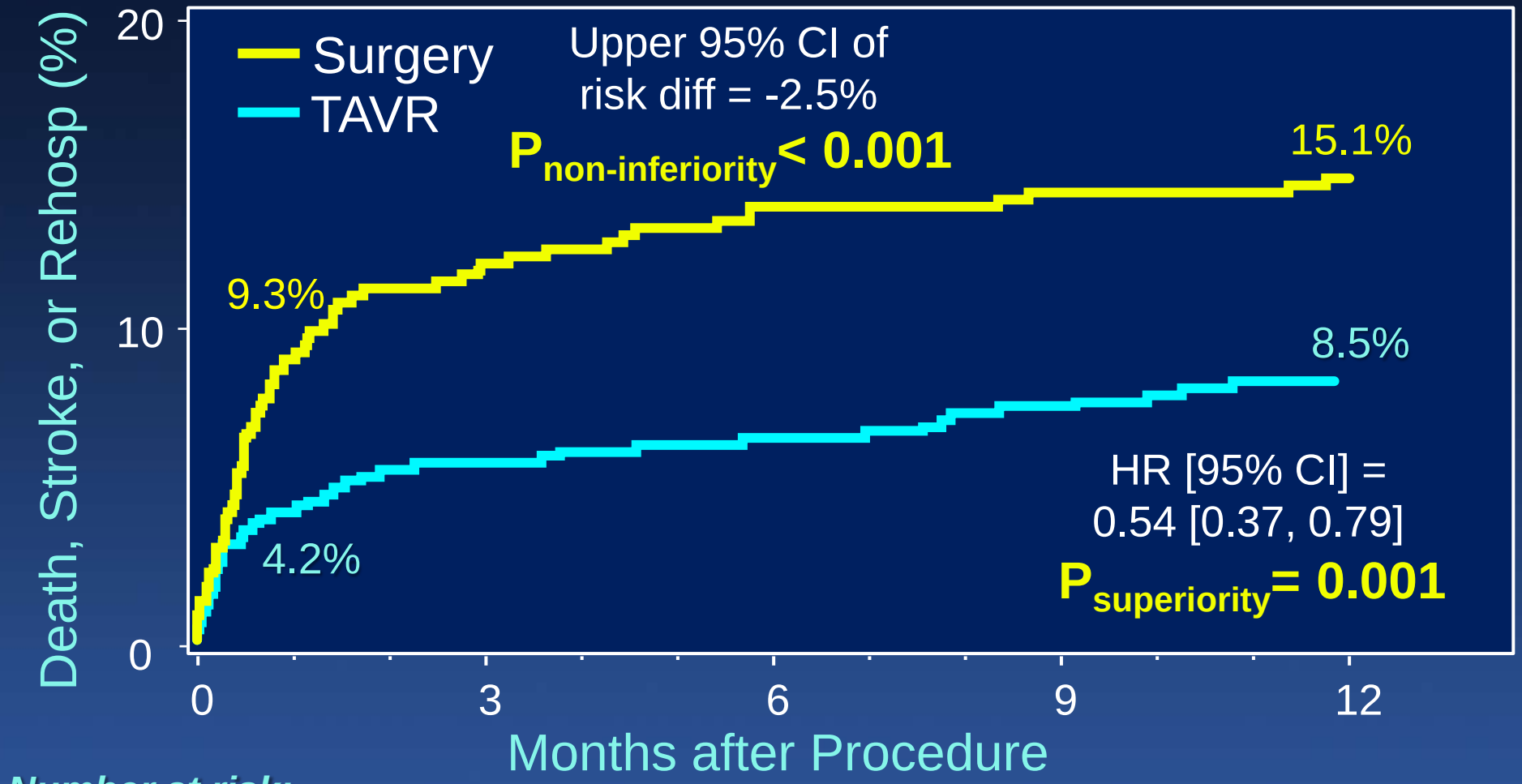
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

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*

THE PARTNER 3 TRIAL

Primary Endpoint

All-cause Mortality, Strokes, or Re-hospitalization at 1 year

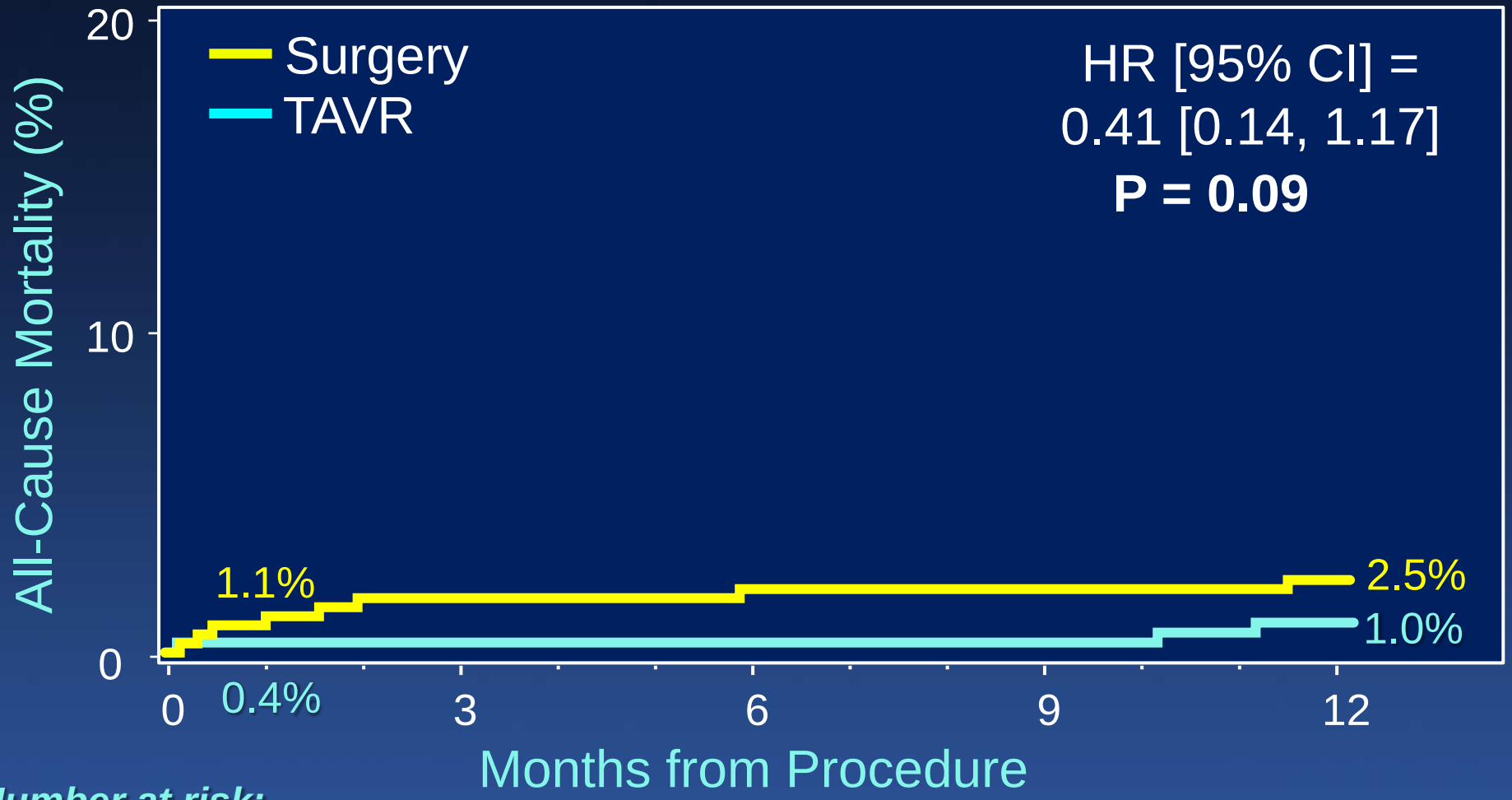


Number at risk:

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

THE PARTNER 3 TRIAL

All-Cause Mortality

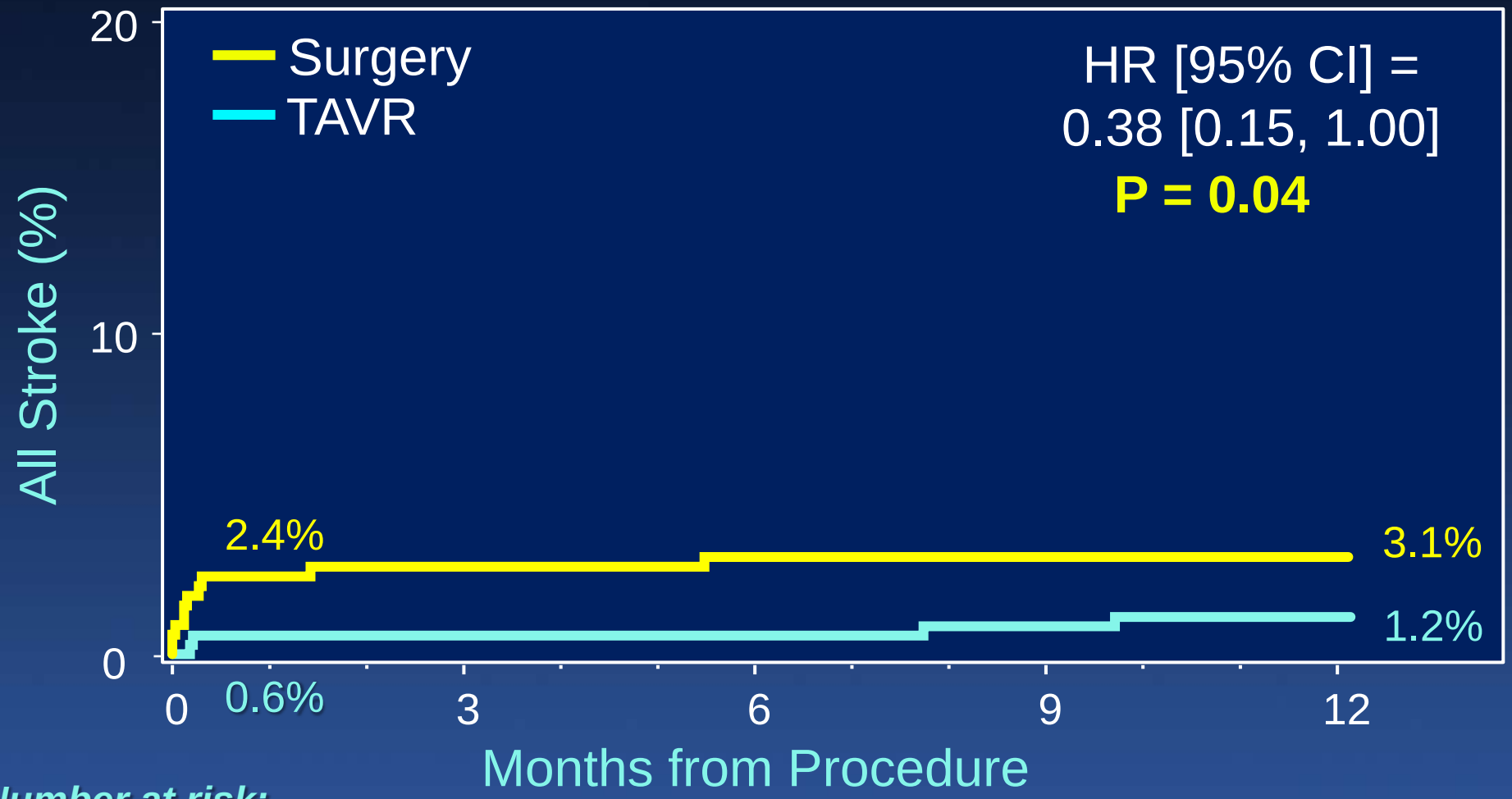


Number at risk:

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

THE PARTNER 3 TRIAL

All Stroke

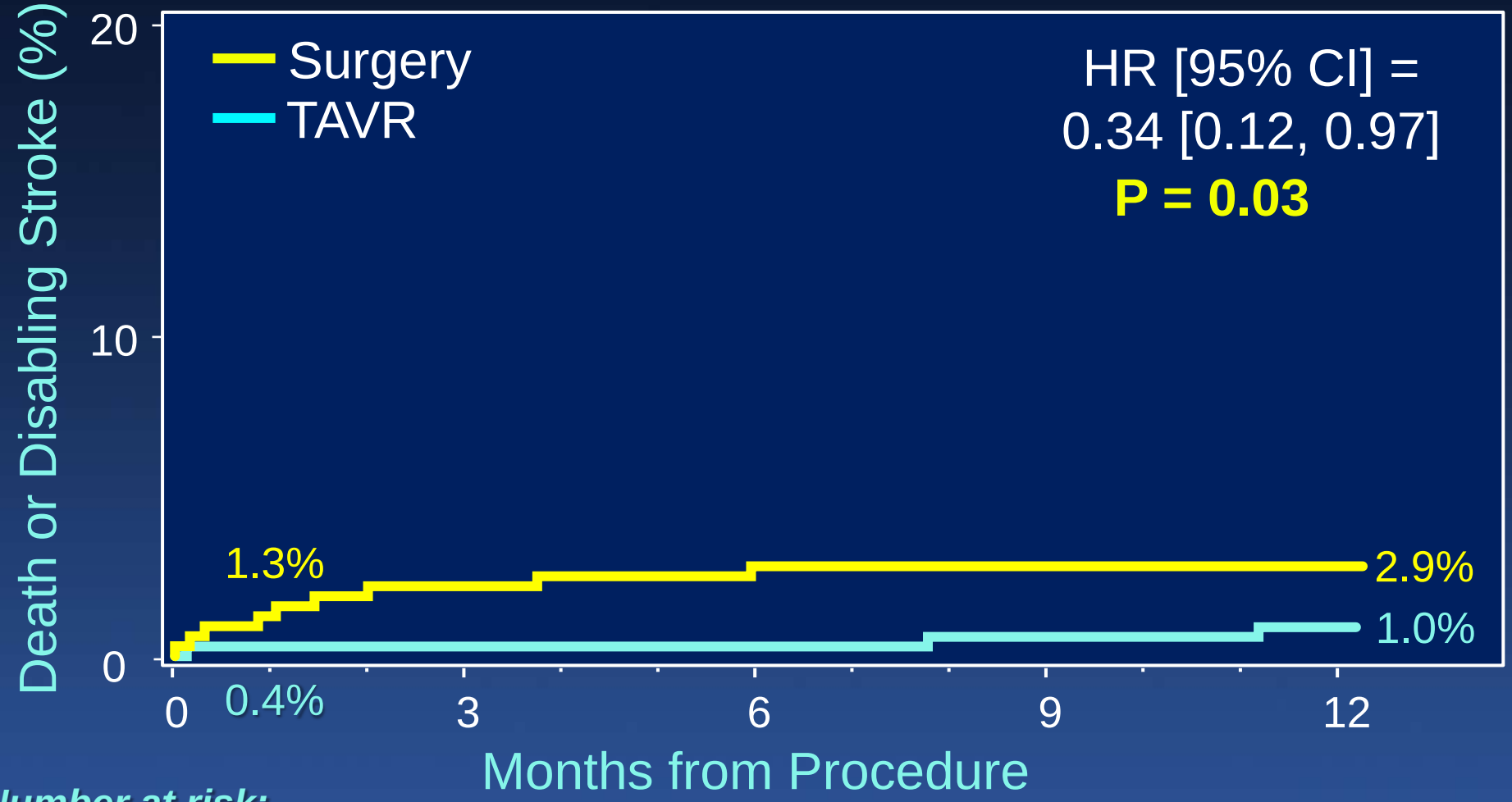


Number at risk:

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

THE PARTNER 3 TRIAL

Death or Disabling Stroke

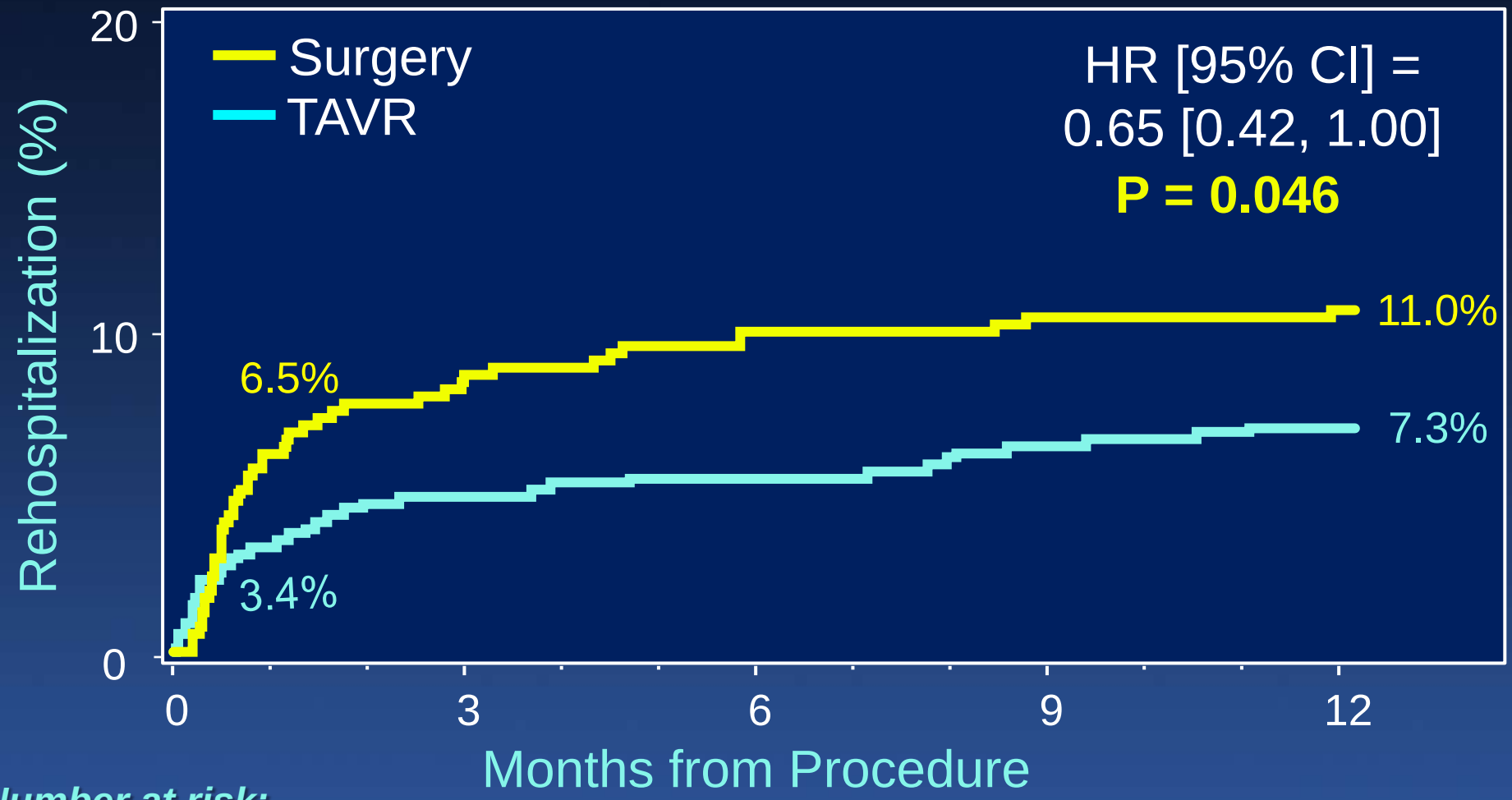


Number at risk:

Surgery	**454**	**444**	**436**	**432**	**430**	**426**
TAVR	**496**	**494**	**494**	**493**	**491**	**488**

THE PARTNER 3 TRIAL

Rehospitalization



Number at risk:

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

Evolut R

The NEW ENGLAND JOURNAL of MEDICINE

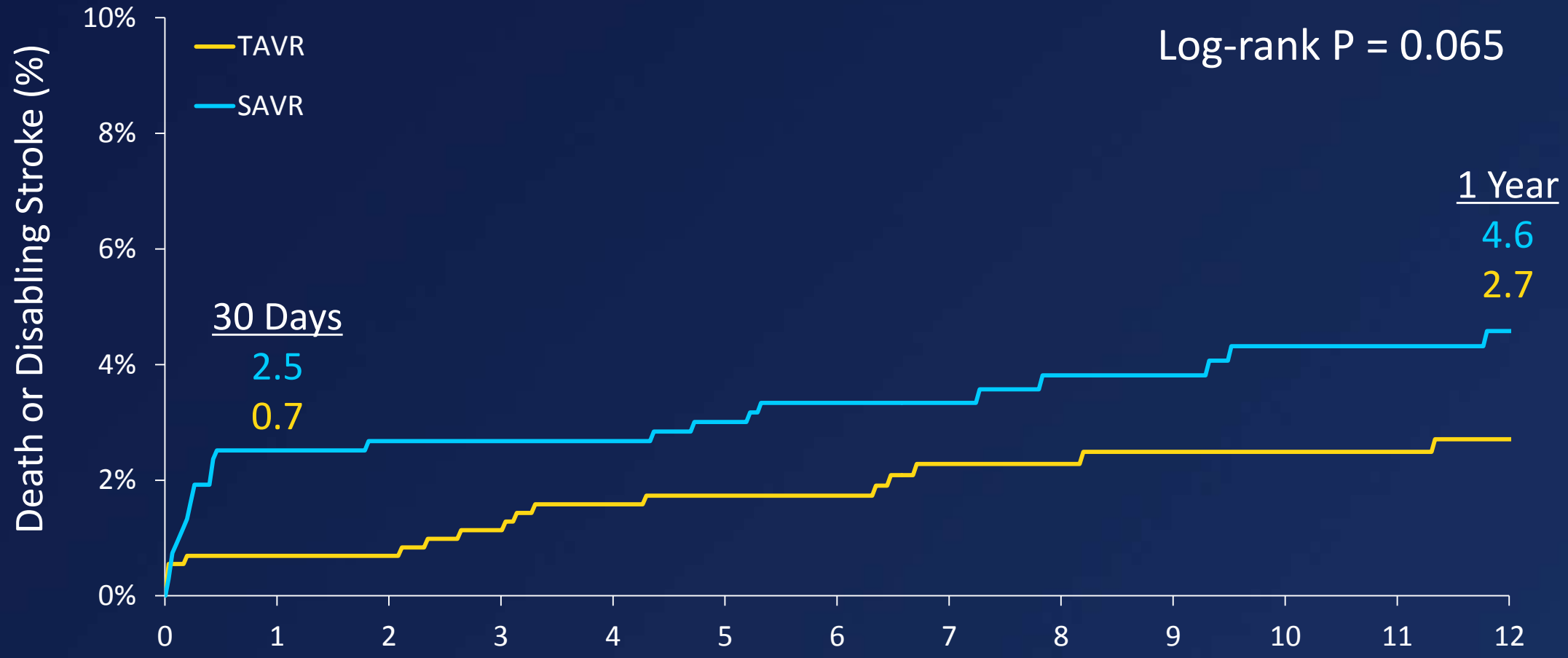
ORIGINAL ARTICLE

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*

All-Cause Mortality or Disabling Stroke at 1 Year

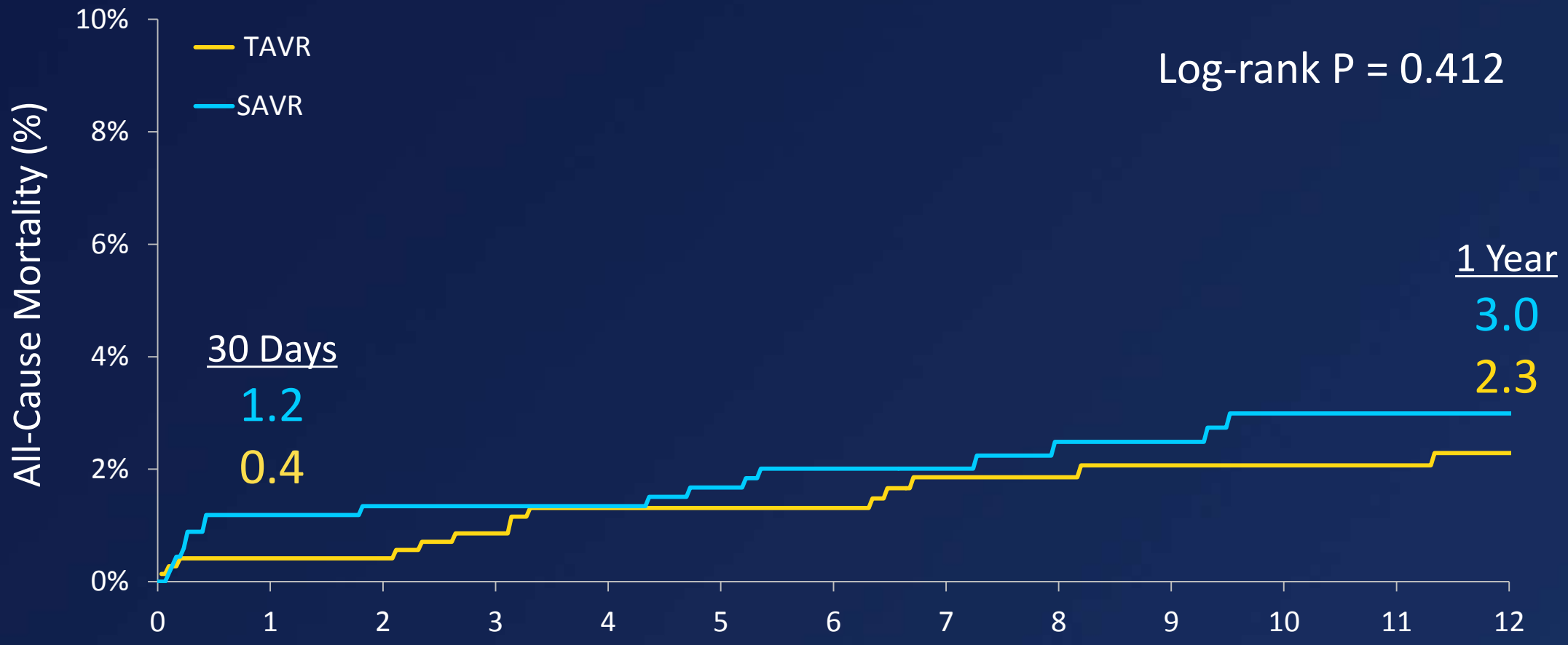
Evolut™ Low Risk Trial



No. at risk					
TAVR	725	718	648		435
SAVR	678	656	576		366

Rates of All-Cause Mortality at 1 Year

Evolut™ Low Risk Trial

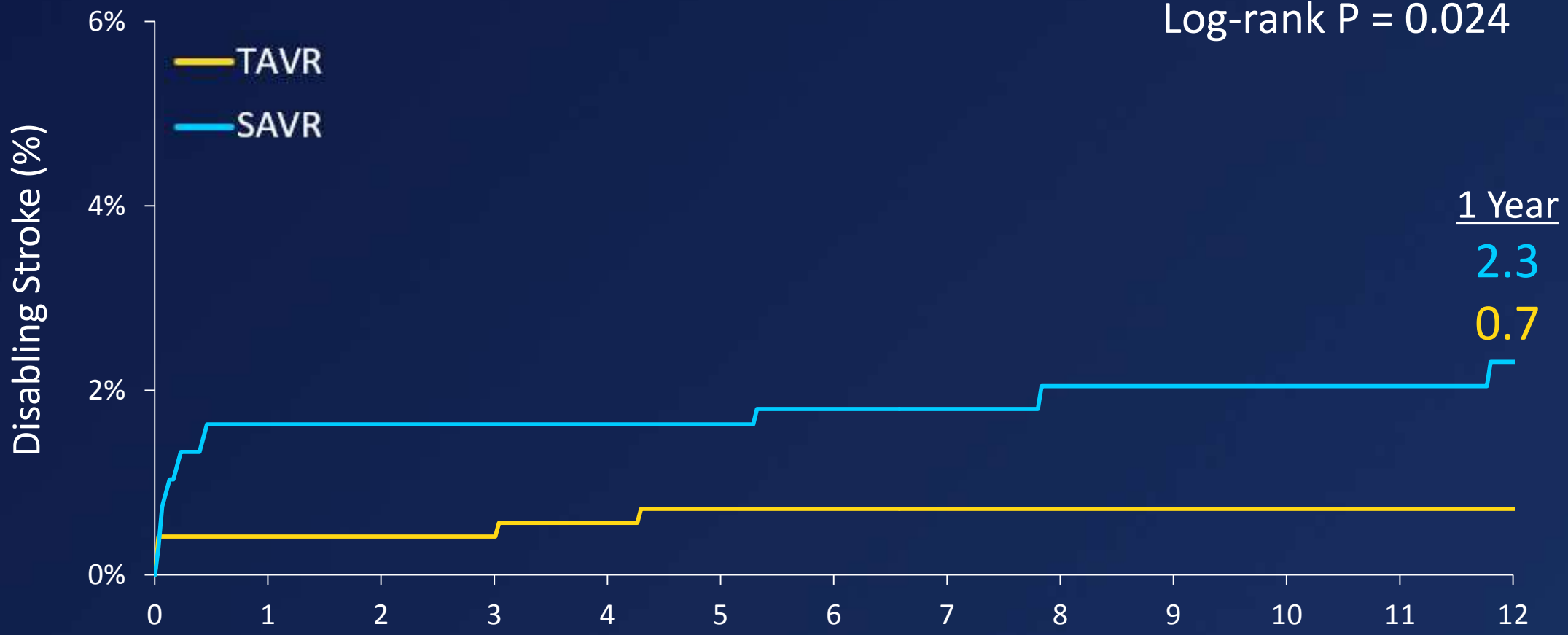


Log-rank P = 0.412

No. at risk					
TAVR	725	720	651	435
SAVR	678	665	583	373

Disabling Stroke at 1 Year

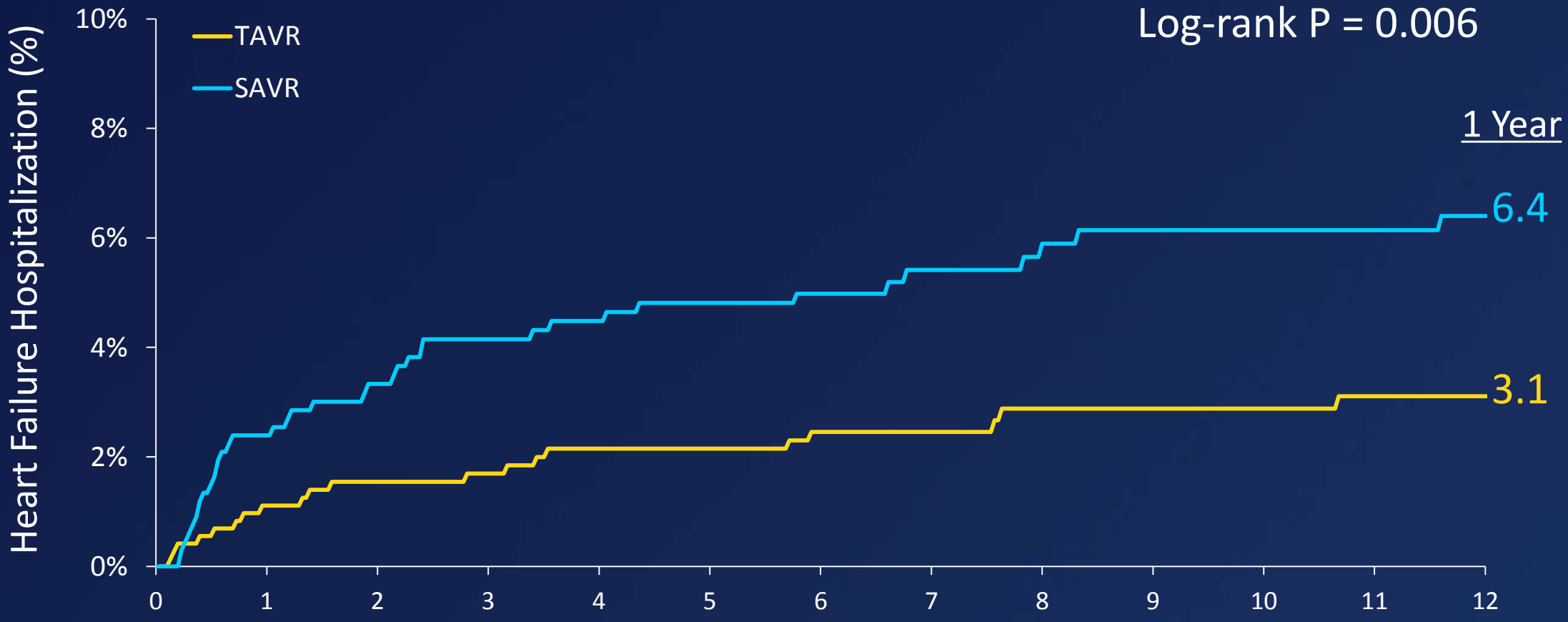
Evolut™ Low Risk Trial



No. at risk				
TAVR	725	720	648	435
SAVR	678	656	576	366

Heart Failure Hospitalization at 1 Year

Evolut™ Low Risk Trial

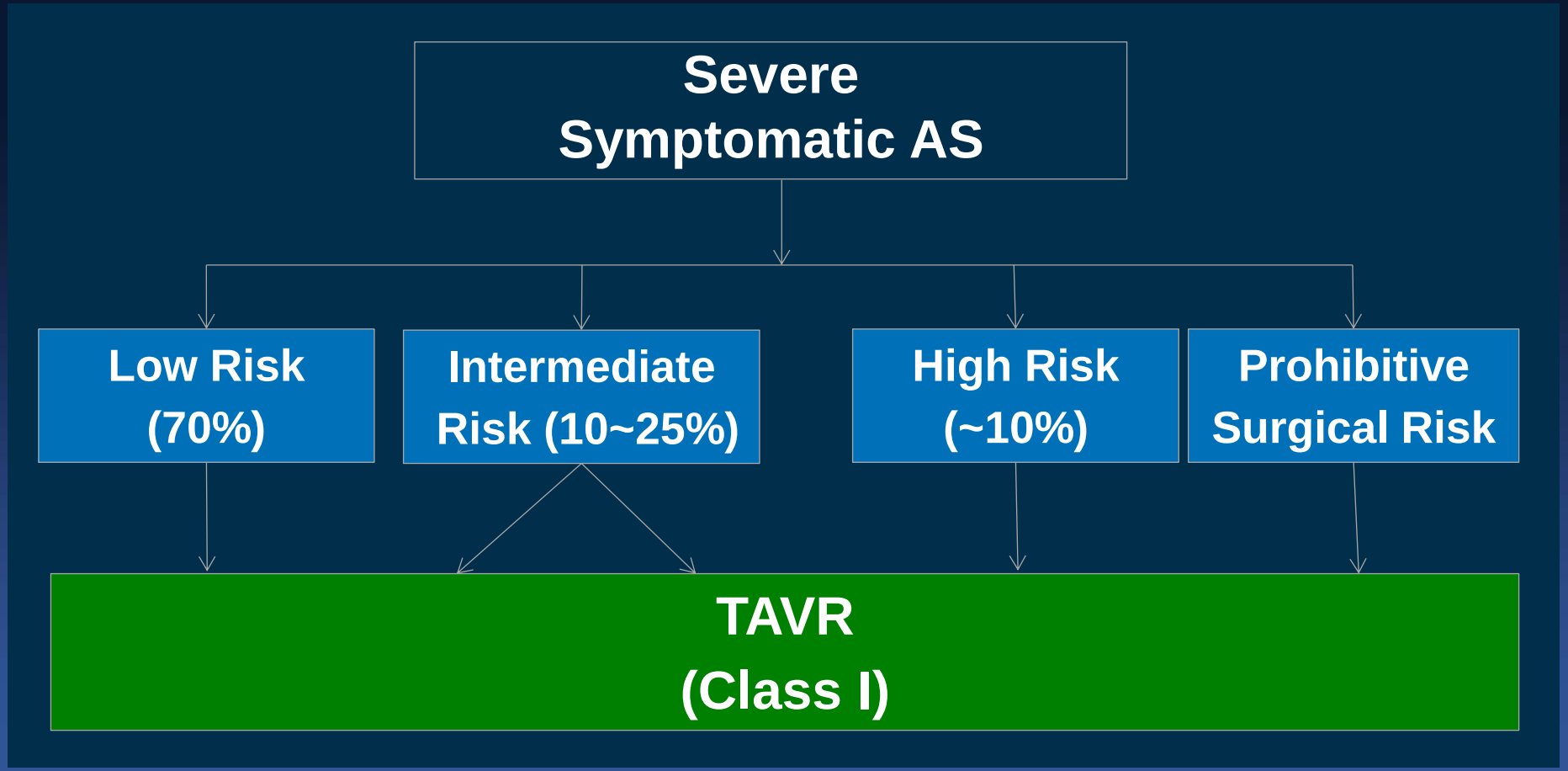


No. at risk				
TAVR	725	712	636	420
SAVR	678	649	561	358

TAVR Won !

ACC 2019

2025 AHA/ACC Guideline



TAVR
in Asan Medical Center

TAVR Complications

More Experienced,
Less Complicated

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

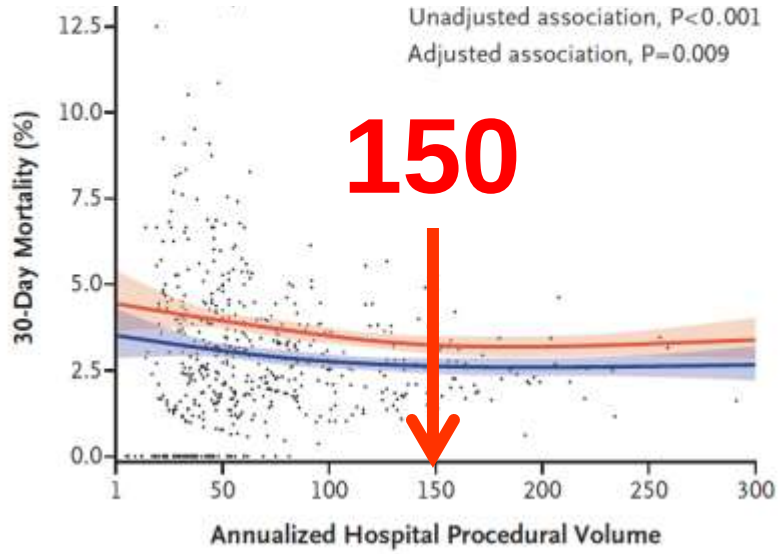
HOSPITAL AND OPERATOR PROCEDURAL VOLUMES

Between January 1, 2015, and December 31, 2017, a total of 113,662 TAVR procedures with commercially approved devices were performed at 555 hospitals by 2960 operators (Fig. S1 in the Supplementary Appendix). The main analysis population included 96,256 transfemoral TAVR procedures performed at 554 sites by 2935 operators.

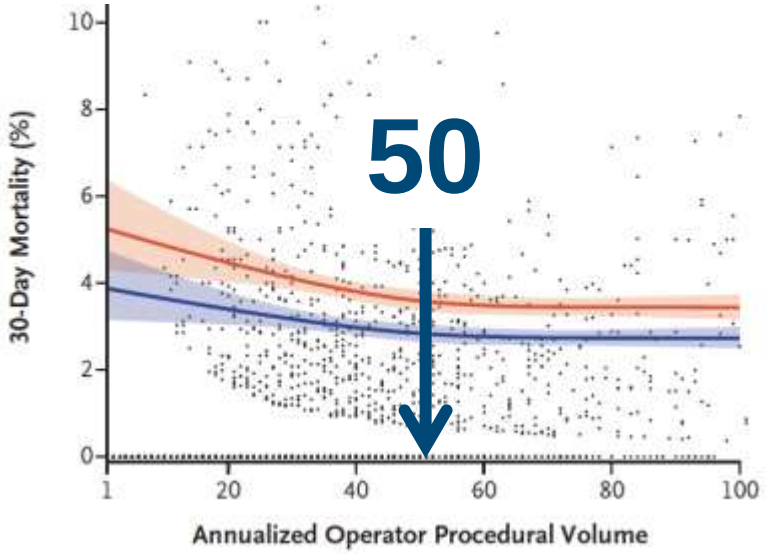
ABSTRACT

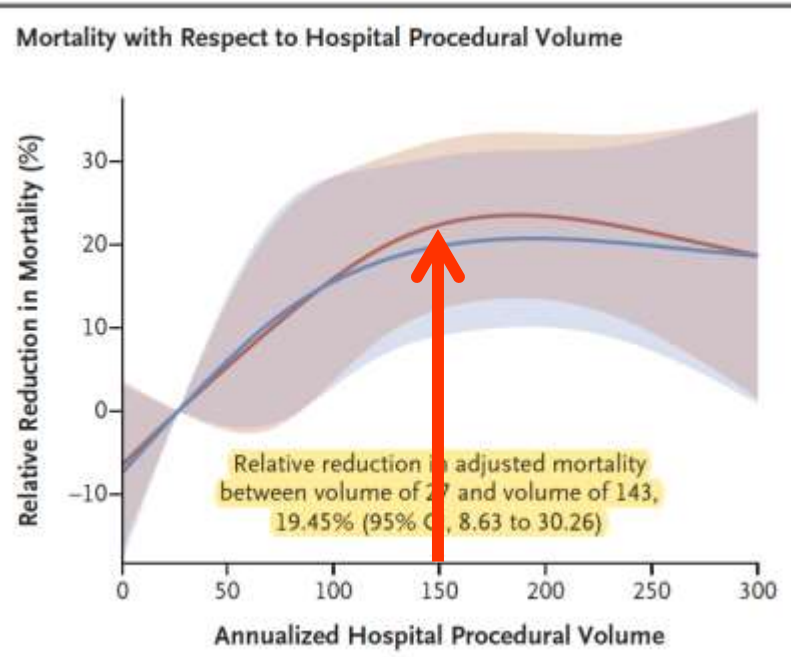
NEJM.org
2019 April 3

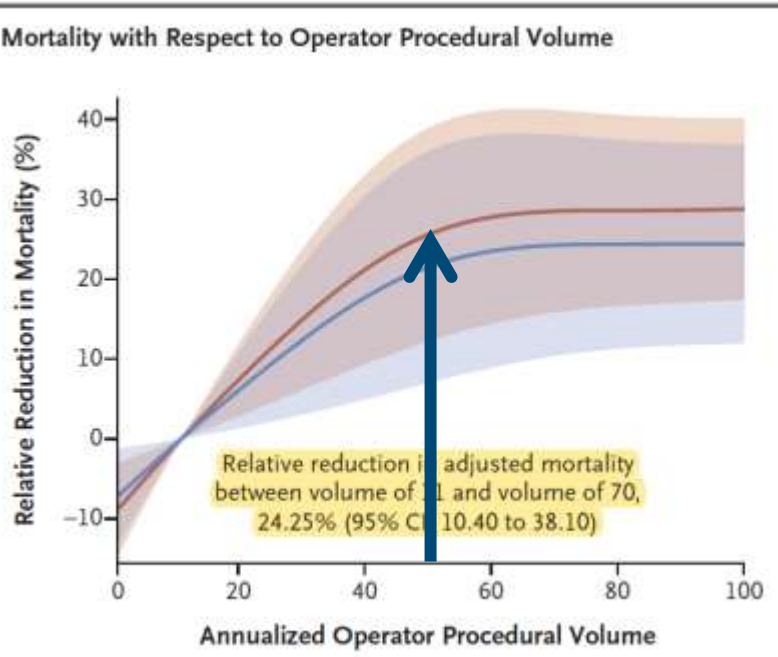
Hospital Procedural Volume and Mortality



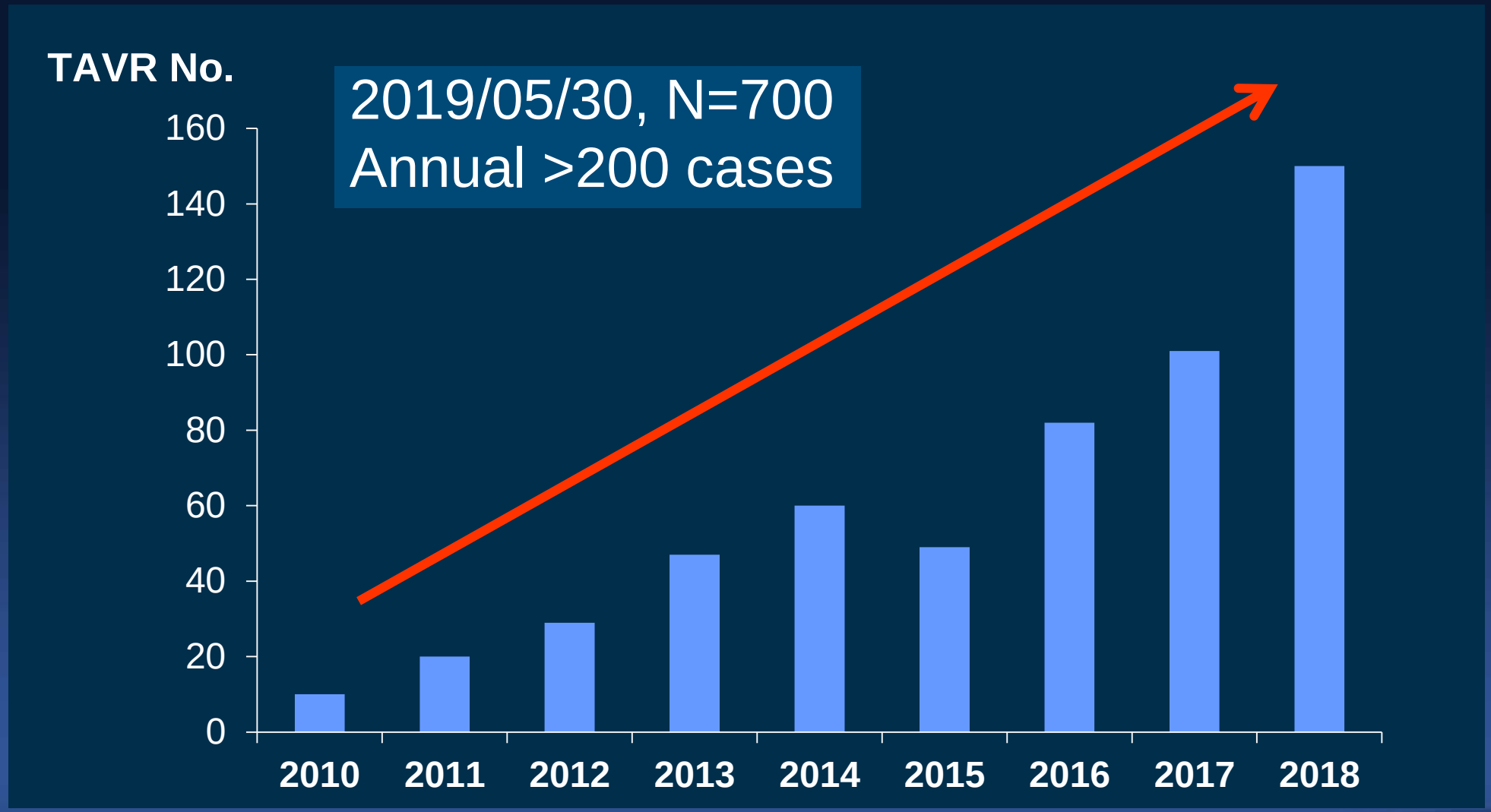
Operator Procedural Volume and Mortality







TAVR in Asan Medical Center



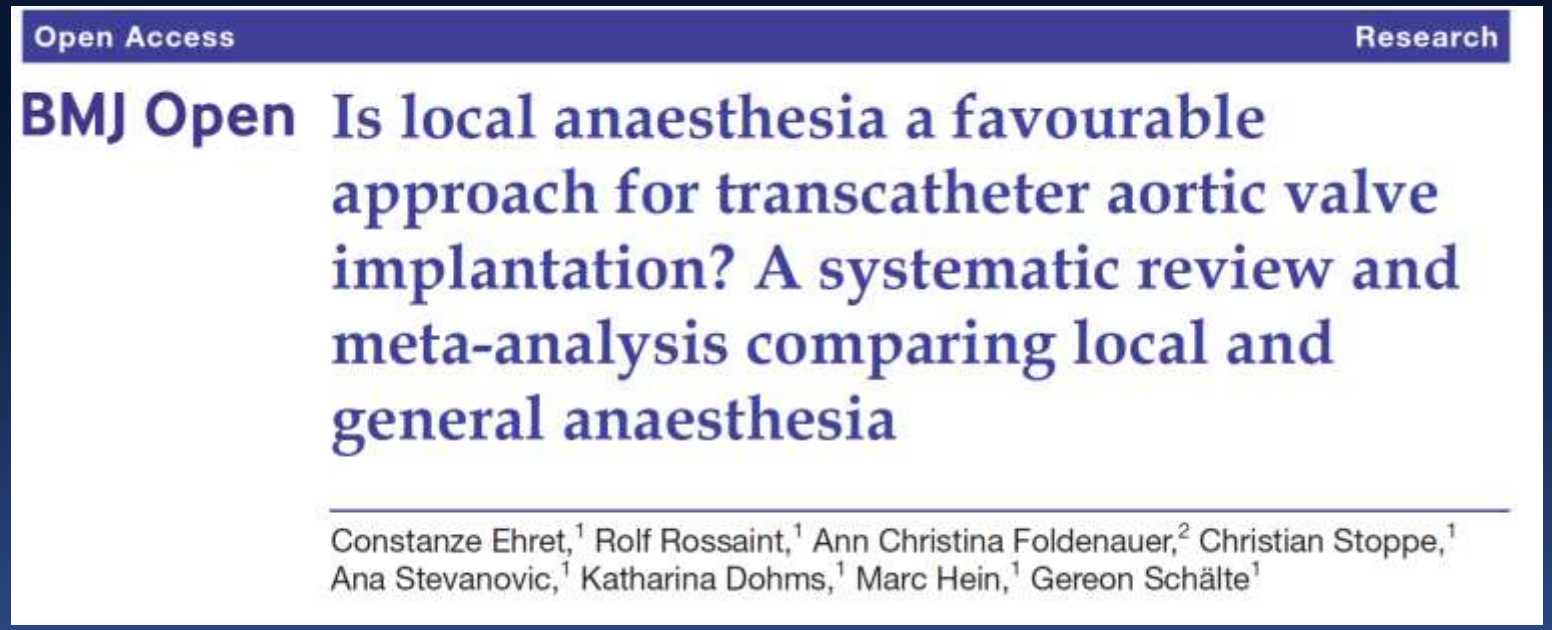
"Minimalist Approach"
TAVR in AMC

98%

No General Anesthesia,
No TEE
30 min. Procedure
One Day stay in CCU
Discharge on Day #3
Cardiac Rehabilitation Program

Minimalist TAVR
Why?

Systemic Review and Meta-Analysis
Local and General Anesthesia



Open Access Research

BMJ Open

Is local anaesthesia a favourable approach for transcatheter aortic valve implantation? A systematic review and meta-analysis comparing local and general anaesthesia

Constanze Ehret,[1] Rolf Rossaint,[1] Ann Christina Foldenauer,[2] Christian Stoppe,[1] Ana Stevanovic,[1] Katharina Dohms,[1] Marc Hein,[1] Gereon Schälte[1]

Ehret C et al. BMJ Open. 2017;7(9):e016321.

Systemic Review and Meta-Analysis
Local and General Anesthesia

30-Days Mortality	No Difference
In-Hospital Mortality	No Difference
Stroke	No Difference
New pacemaker insertion	GA Is Better
Pneumonia	MAC Is Better

Ehret C et al. BMJ Open. 2017;7(9):e016321.

Why Minimalist TAVR ?

Patient Side

Less invasive approach,
Least amount of morbidity,
Decreased pain,
Rapid return to normal activity,
Cognitive recovery,
Short hospitalization,

Hospital Side

Increased cost-effectiveness,
Less resource utilization,
Patient satisfaction,
Optimal hospital bed flow,

What Has Allowed Minimalist TAVR evolution?

- Newer-generation TAVR systems (lower profile, more predictable deployment)
- Improved screening and patient selection
- Improved technique with lower complications
- Experienced operator expertise

Outcomes of TAVR

Standard Performance (VARC-2*) for High-Risk AS patients (@ 30 days)

• All-cause mortality	< 3%
• Major (disabling) strokes	< 2%
• Major vascular complications	< 5%
• New permanent pacemakers	< 10%
• Mod-severe PVR	< 5%

Baseline Characteristics (n=848)

Asian TAVR Registry, 2017

	N=848
Age	81.8 ± 6.6
Female	53.3%
STS score	5.2 ± 3.8
BMI, kg/m^2	23.0 ± 3.8
Diabetes mellitus	30.1%
NYHA class III/IV	63.0%
CAD	44.7%
Previous stroke	10.5%
Peripheral vascular disease	15.4%
COPD	11.7%
Sapien	549(65%)
CoreValve	299(35%)

Outcomes of TAVR

Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*
• All-cause mortality	< 3%	2.5%
• Major (disabling) strokes	< 2%	2.2%
• Major vascular complications	< 5%	5.0%
• New permanent pacemakers	< 10%	9.5%
• Mod-severe PVR	< 5%	9.8%

Baseline Characteristics (n=623)

Korea -TAVI registry, 2018

	N=623
Age (Years)	78.6±6.3
Female	51.6 %
STS score	7.83± 8.86
DM	34.6 %
HTN	77.1 %
Stroke or TIA	15.3 %
PAOD	12.7 %
CKD on dialysis	6.4 %
Hospitalization period (Days)	12.1±7.5
TAVR to discharge (Days)	7.8±6.2

Outcomes of TAVR

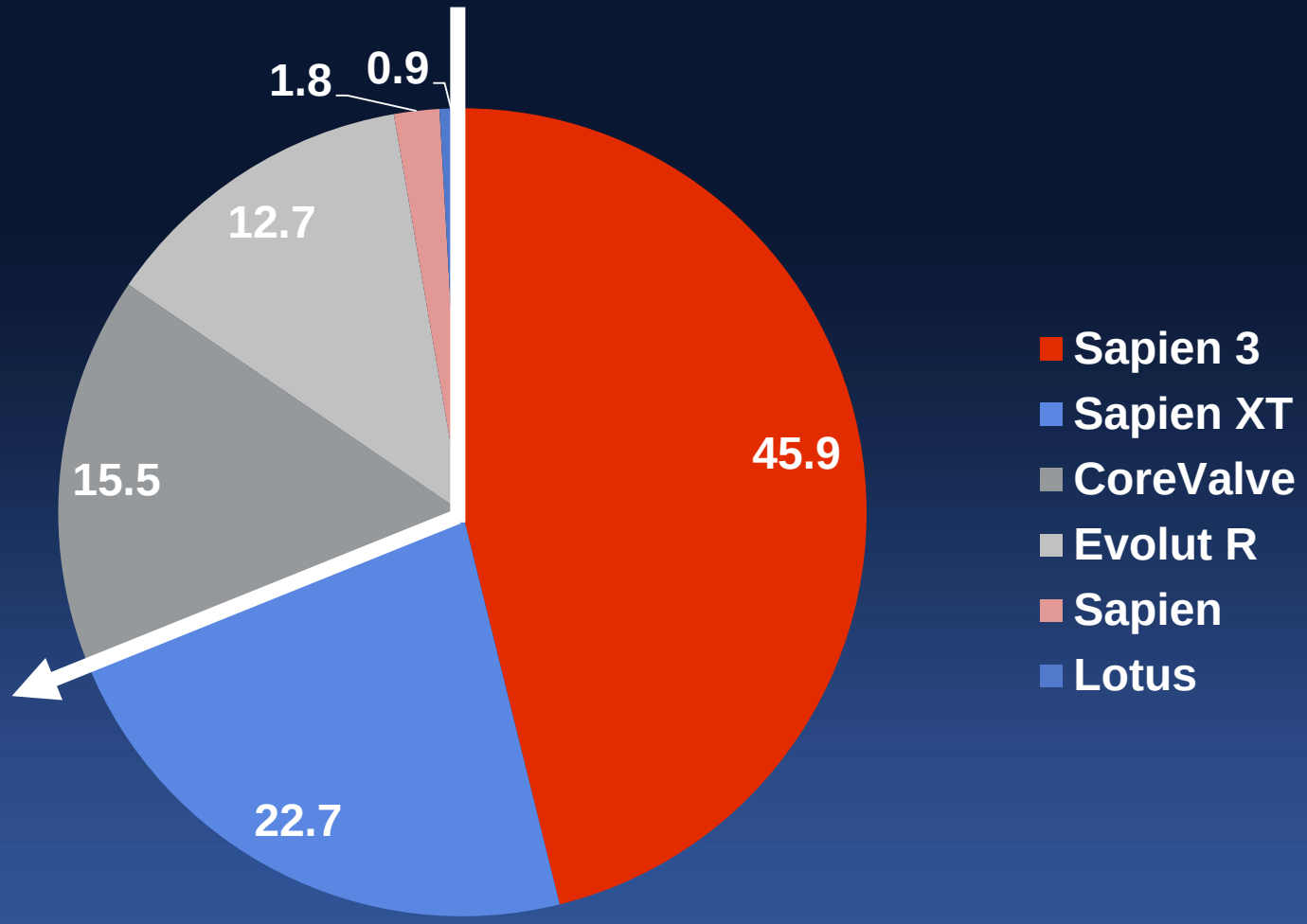
Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*	*Korea 2018*
• All-cause mortality	< 3%	2.5%	4.5%
• Major (disabling) strokes	< 2%	2.2%	1.4%
• Major vascular complications	< 5%	5.0%	6.8%
• New permanent pacemakers	< 10%	9.5%	5.3%
• Mod-severe PVR	< 5%	9.8%	5.4%

Baseline Characteristics (n=533)

AMC -TAVI registry, 2018

	N = 533
Age, years	78.9 ± 5.2
Male sex	261 (49.0%)
BMI, kg/m^2	23.9 ± 3.3
Logistic Euroscore (%)	14.9 ± 11.7
STS risk score (%)	4.1 ± 3.0
DM	175 (32.8%)
Hypertension	424 (79.5%)
Atrial fibrillation	75 (14.1%)
Coronary artery disease	201 (37.7%)
Previous MI	25 (4.7%)
Previous stroke	65 (12.2%)
Peripheral vascular disease	29 (5.4%)
Chronic Kidney Disease	157 (29.5%)
COPD	115 (21.6%)
LV Ejection fraction, %	58.5 ± 10.9

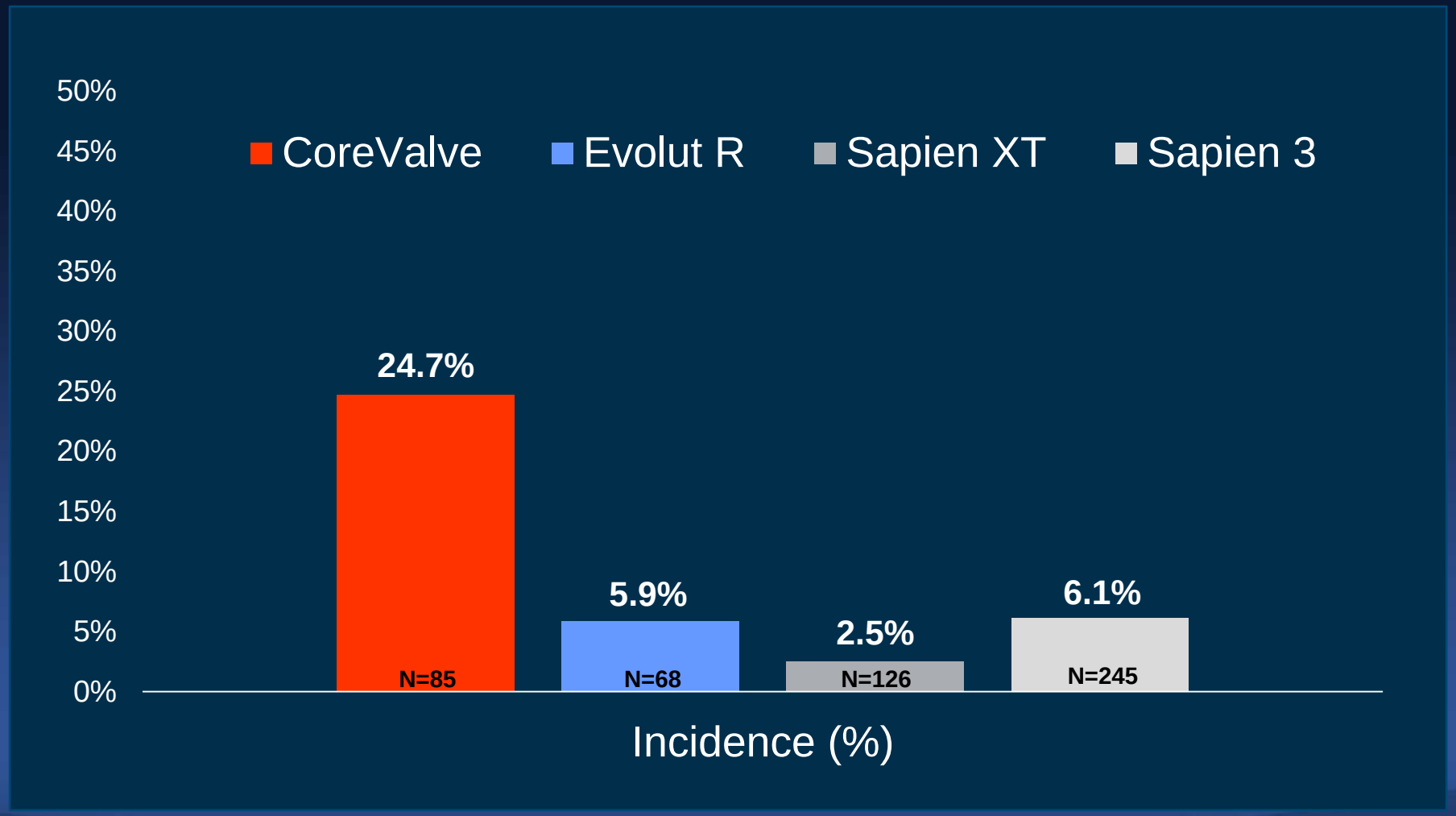
Device


1.8
0.9
12.7
15.5
45.9
22.7
Sapien 3
Sapien XT
CoreValve
Evolut R
Sapien
Lotus

Procedural Outcomes
TAVR in AMC

	Overall (N = 533)
Device success	520 (97.6%)
Conversion to surgery	8 (1.5%)
Coronary obstruction	4 (0.8%)
Implantation of two valves	13 (2.4%)
New permanent pacemaker	45 (8.4%)
PVL ≥ moderate	46 (8.6%)
Major vascular complication	37 (6.9%)
Length of hospital stay (days)	8.4±13.2

Incidence of PPM
TAVR in AMC



30 Days Outcomes
TAVR in AMC

	Overall (N = 533)
Death, all	14 (2.6%)
Cardiac death	9 (1.7%)
Non-cardiac death	5 (0.9%)
Stroke, all	16 (3.0%)
Disabling	8 (1.5%)
Non-disabling	8 (1.5%)
Death or disabling stroke	22 (4.1%)
Bleeding	168 (31.%)
Life-threatening	35 (6.6%)
Major	99 (18.6%)

Outcomes of TAVR

Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*	*AMC 2018*
• All-cause mortality	< 3%	2.5%	2.2%
• Major (disabling) strokes	< 2%	2.2%	0.7%
• Major vascular complications	< 5%	5.0%	3.6%
• New permanent pacemakers	< 10%	9.5%	8.7%
• Mod-severe PVR	< 5%	9.8%	2.9%

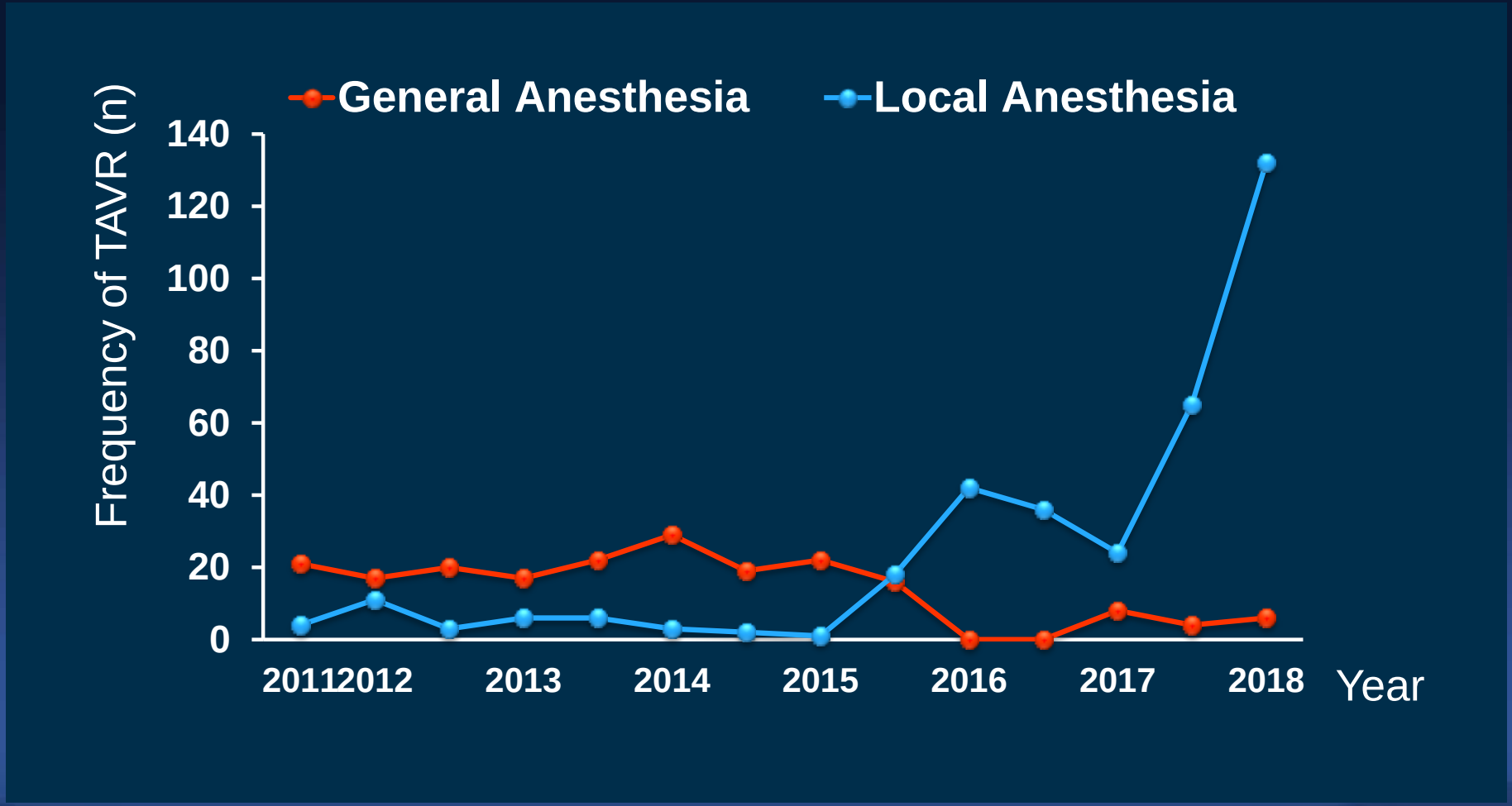
What is the Difference ?
TAVR in AMC

1. *"Heart Team" Perfect Collaboration*
2. *Contemporary "Minimalist Approach"*
   Simplify the Procedure
3. *"CT Algorithm for Device Selection"*
   Pre-TAVR Meticulous CT Measurement

"Minimalist Approach"
TAVR in AMC

- No General Anesthesia,
- No TEE
- No Complications
- 30 min. Procedure
- One Day stay in CCU
- Discharge on Day #3
- Cardiac Rehabilitation Program

"Minimalist Approach"
TAVR in AMC



TAVR in AMC
Baseline Characteristics

	Overall (N = 533)	General Anesthesia (N = 214)	Conscious Sedation (N = 319)	P value
Age	78.9 ± 5.2	77.7 ± 5.6	79.6 ± 4.8	<0.001
Male sex	261 (49.0%)	110 (51.4%)	151 (47.3%)	0.36
BMI, kg/m^2	23.9 ± 3.3	23.9 ± 3.4	23.8 ± 3.3	0.88
STS risk score, %	4.1 ± 3.0	4.4 ± 3.7	3.8 ± 2.5	0.66
DM	175 (32.8%)	73 (34.1%)	102 (32.0%)	0.61
HTN	424 (79.5%)	183 (85.5%)	241 (75.5%)	0.005
Atrial fibrillation	75 (14.1%)	29 (13.6%)	46 (14.4%)	0.78
CAD	201 (37.7%)	92 (43.0%)	109 (34.2%)	0.04
Previous MI	25 (4.7%)	10 (4.7%)	15 (4.7%)	0.99
Previous stroke	65 (12.2%)	20 (9.3%)	45 (14.1%)	0.10
PVD	29 (5.4%)	14 (6.5%)	15 (4.7%)	0.36
CKD	157 (29.5%)	68 (31.8%)	89 (27.9%)	0.34
COPD	115 (21.6%)	41 (19.2%)	74 (23.2%)	0.27

TAVR in AMC
Procedural Characteristics

	Overall (N = 533)	General Anesthesia (N = 214)	Conscious Sedation (N = 319)	P value
Aortic-valve area, cm²	0.61 ± 0.17	0.63 ± 0.20	0.61 ± 0.15	0.52
AV Vmax, m/s	4.9 ± 0.8	4.9 ± 0.8	4.9 ± 0.8	0.91
Mean gradient, mmHg	59.4 ± 21.9	59.0 ± 21.9	59.6 ± 21.9	0.93
Bicuspid AV	60 (11.3%)	21 (9.8%)	39 (12.2%)	0.38
LV EF, %	58.5 ± 10.9	57.9 ± 11.3	58.9 ± 10.6	0.29
Device type				<0.001
Balloon-expandable	376 (70.5%)	127 (59.3%)	249 (78.1%)	
Self-expandable	152 (28.5%)	85 (39.7%)	67 (21.0%)	

TAVR in AMC
Procedural Outcomes

	Overall (N = 533)	General Anesthesia (N = 214)	Conscious Sedation (N = 319)	P value
Device success	520 (97.6%)	206 (96.3%)	314 (98.4%)	0.11
Conversion to surgery	9 (1.7%)	6 (2.8%)	3 (0.9%)	0.10
Coronary obstruction	4 (0.8%)	2 (0.9%)	2 (0.6%)	0.69
Implantation of two valves	15 (2.8%)	11 (5.1%)	4 (1.3%)	0.01
New permanent pacemaker	45 (8.4%)	19 (8.9%)	26 (8.2%)	0.77
PVL ≥ moderate	46 (8.6%)	32 (15.0%)	14 (4.4%)	<0.001
Major vascular complication	24 (4.5%)	14 (6.5%)	10 (3.1%)	0.06
Length of hospital stay (days)	13.2±15.0	15.1±14.0	11.9±15.6	<0.001

TAVR in AMC
30 Days Outcomes

	Overall (N = 533)	General Anesthesia (N = 214)	Conscious Sedation (N = 319)	P value
Death, all	14 (2.6%)	10 (4.7%)	4 (1.3%)	0.02
Cardiac death	9 (1.7%)	7 (3.3%)	2 (0.6%)	0.02
Non-cardiac death	5 (0.9%)	3 (1.4%)	2 (0.6%)	0.36
Stroke, all	16 (3.0%)	11 (5.1%)	5 (1.6%)	0.02
Disabling	8 (1.5%)	5 (2.3%)	3 (0.9%)	0.19
Non-disabling	8 (1.5%)	6 (2.8%)	2 (0.6%)	0.043
Death or disabling stroke	22 (4.1%)	15 (7.0%)	7 (2.2%)	0.006
Bleeding	168 (31.%)	99 (46.3%)	69 (21.6%)	<0.001
Life-threatening	35 (6.6%)	25 (11.7%)	10 (3.1%)	<0.001
Major	99 (18.6%)	53 (24.8%)	46 (14.4%)	0.003

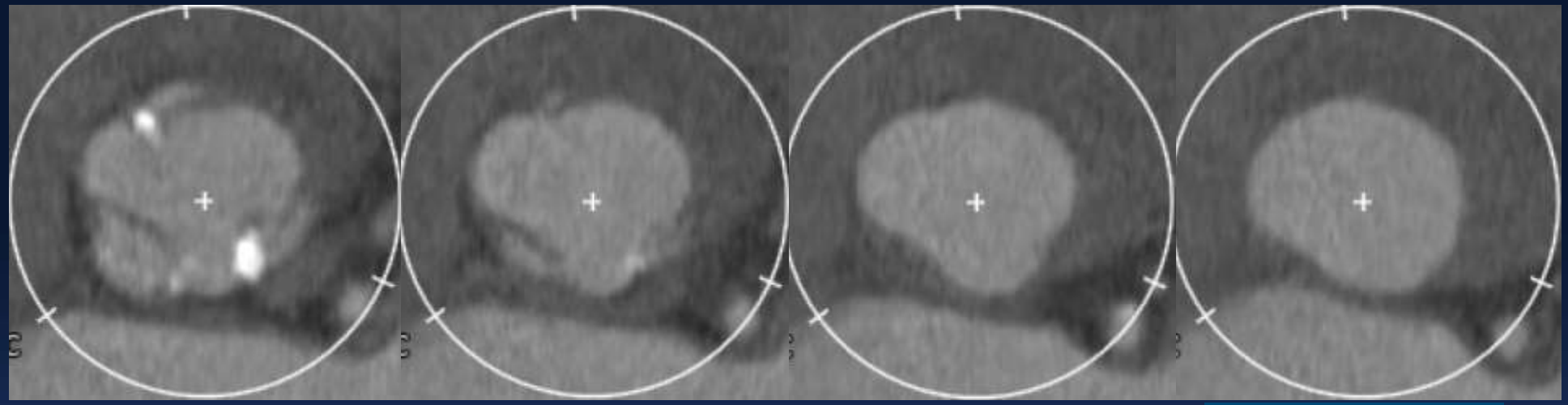
Outcomes of TAVR

Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*	*AMC 2018*	*AMC "MAC"*
• All-cause mortality	< 3%	2.5%	2.2%	1.3%
• Major (disabling) strokes	< 2%	2.2%	0.7%	0.9%
• Major vascular complications	< 5%	5.0%	3.6%	3.1%
• New permanent pacemakers	< 10%	9.5%	8.7%	8.2%
• Mod-severe PVR	< 5%	9.8%	2.9%	4.4%

A Case of Minimalist Approach

- CT screening, Device selection, Size Selection (fine tunning)
- No General Anesthesia,
- No TEE, TTE or ICE (intracardiac echo)

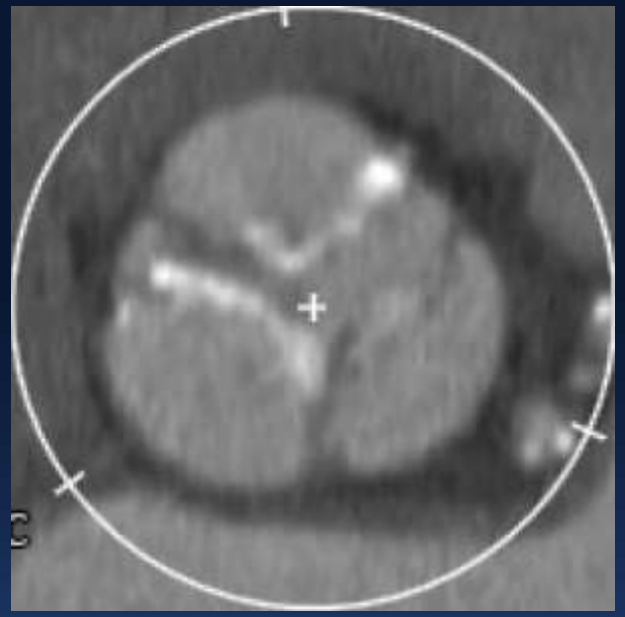
Case #1 – 75/M with severe AS



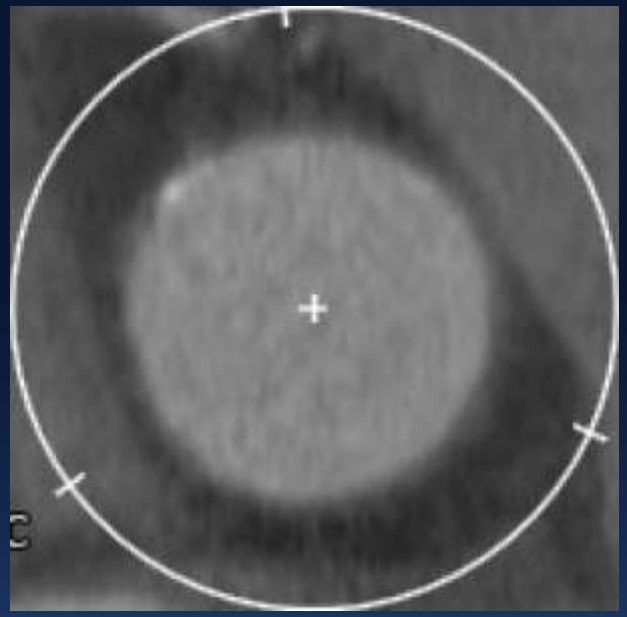
Annulus plane

Aortic Annulus parameters	
Annulus short diameter	22.4 mm
Annulus long diameter	28.1 mm
Annulus mean diameter	25.3 mm
Annulus area	507 mm^2
Annulus area-driven diameter	25.4 mm
Annulus perimeter	81.2 mm
Annulus perimeter-driven diameter	25.9 mm

CT findings – Aortic Valve Complex



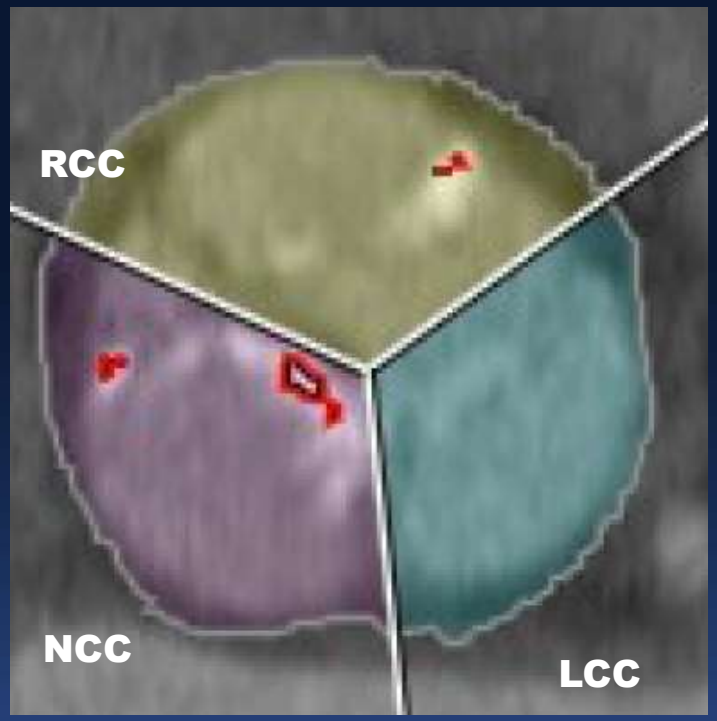
Sinus of Valsalva



STJ

Sinus of Valsalva		STJ	
Area	858 mm^2	Area	701 mm^2
Sinus / Annulus Area Ratio	1.69	STJ/ Annulus Area Ratio	1.38
NCC diameter	33.6 mm	Mean diameter	29.9 mm
LCC diameter	33.3 mm	Height of STJ	28.4 mm
RCC diameter	32.7 mm		
Mean Sinus / Annulus Area Ratio	**1.83 ± 0.27**	**Mean STJ / Annulus Area Ratio**	**1.49 ± 0.29**

CT findings – Aortic Valve Complex



Calcium volume	
NCC	13 mm^3
RCC	24 mm^3
LCC	24 mm^3
Total	61 mm^3

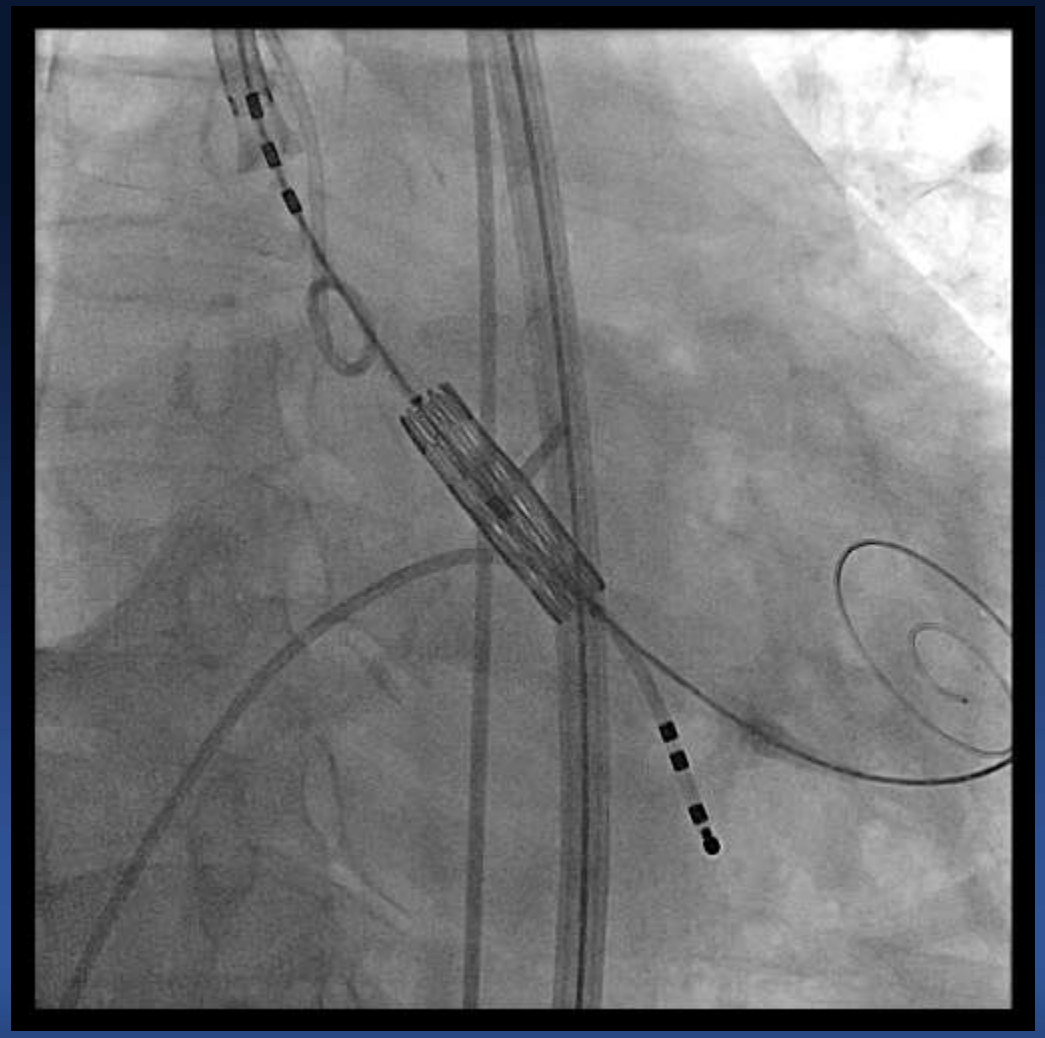
Mean Amount of total Calcium **355.4 ± 289.9**

Sapien 3, 29 mm with 3 cc underfill

Size	Area Oversize (%)	Perimeter Oversize (%)
23	80.6	88.0
24	87.8	91.8
25	95.2	95.7
26	102.3	99.4
27	110.3	103.2
28	118.6	107.0
29	127.9	111.2

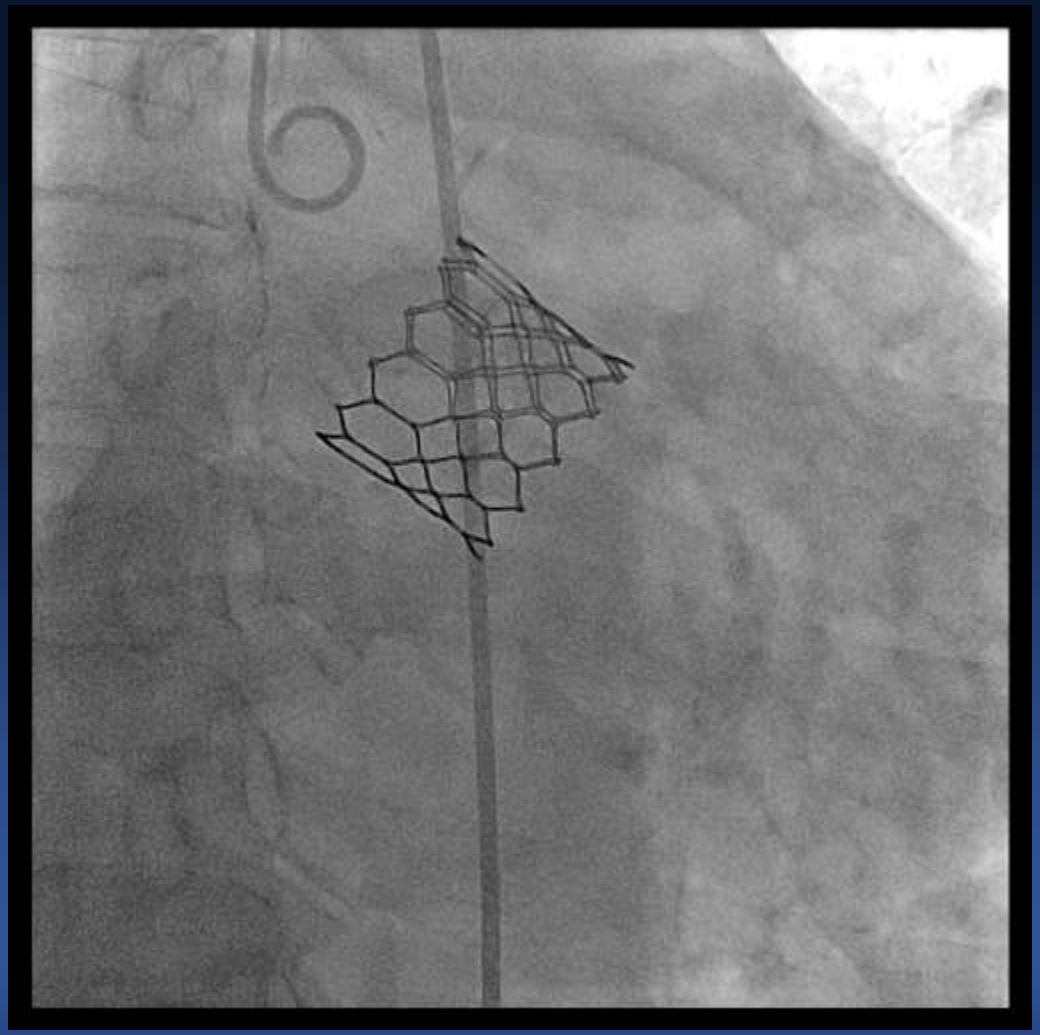
Sapien 29 mm with 3cc underfill

Sapien 29 mm with 3cc underfill



Sapien 29 mm with 3cc underfill

Trivial PVR



Sapien 29 mm with 3cc underfill

Post-procedural ICE

Summary: Minimalist TAVR

- An international trend toward minimalist TAVR appears as safe as conventional strategy.
- Careful patient selection, dedicated procedural technique and post-procedural care are keys to success.
- Minimalist TAVR if done appropriately can provide clinical and economic benefits.