TAVR in Asia, Korea and Asan Medical Center

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Current Status of TAVR
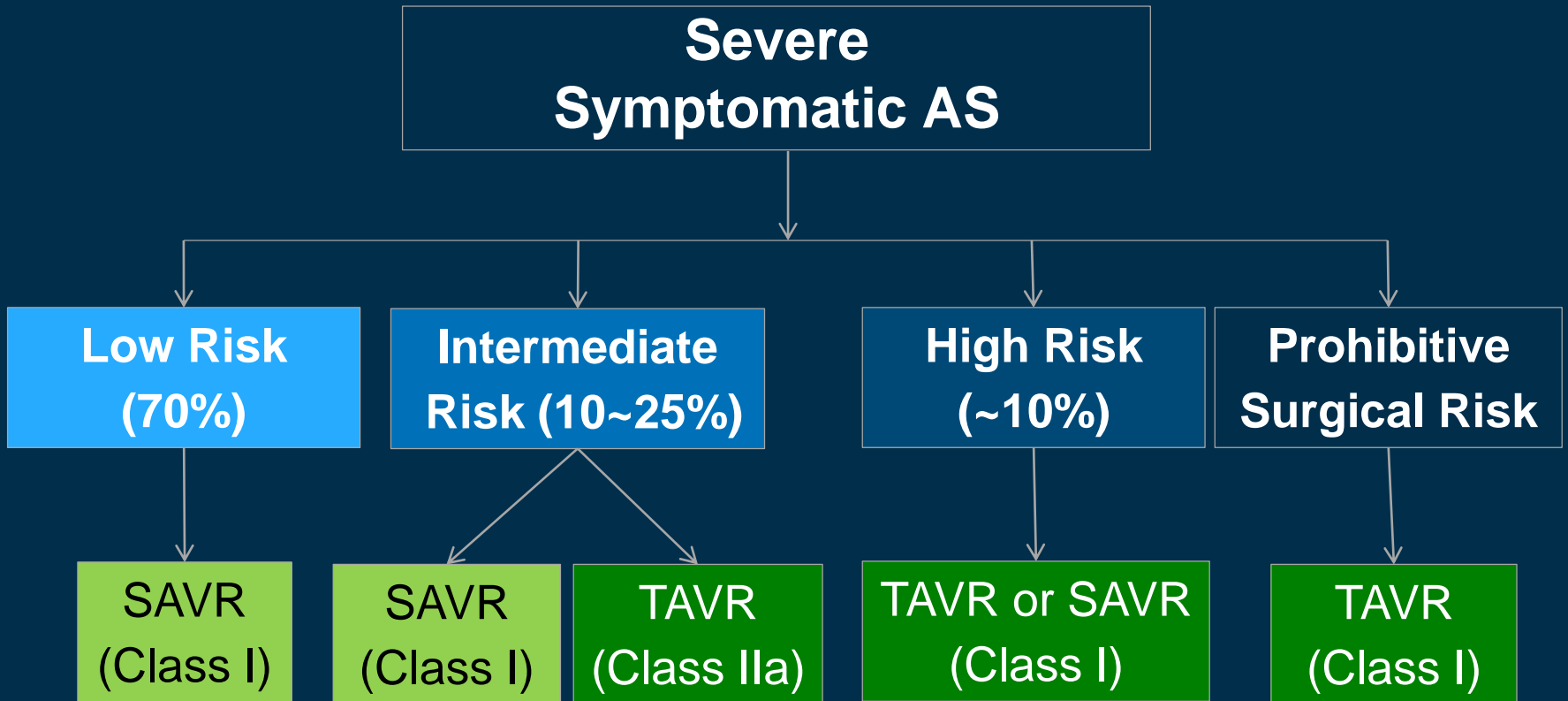
Functional Classification
of Severe AS Patients

**Inoperable,
Prohibitive Surgical Risk**

High Risk   **> 8%**

Intermediate Risk   **4-8 %**

Low Risk   **< 4%**

2017 AHA/ACC Guideline *Focused Update*

Severe Symptomatic AS

Low Risk (70%) → Intermediate Risk (10~25%) → High Risk (~10%) → Prohibitive Surgical Risk

SAVR (Class I)

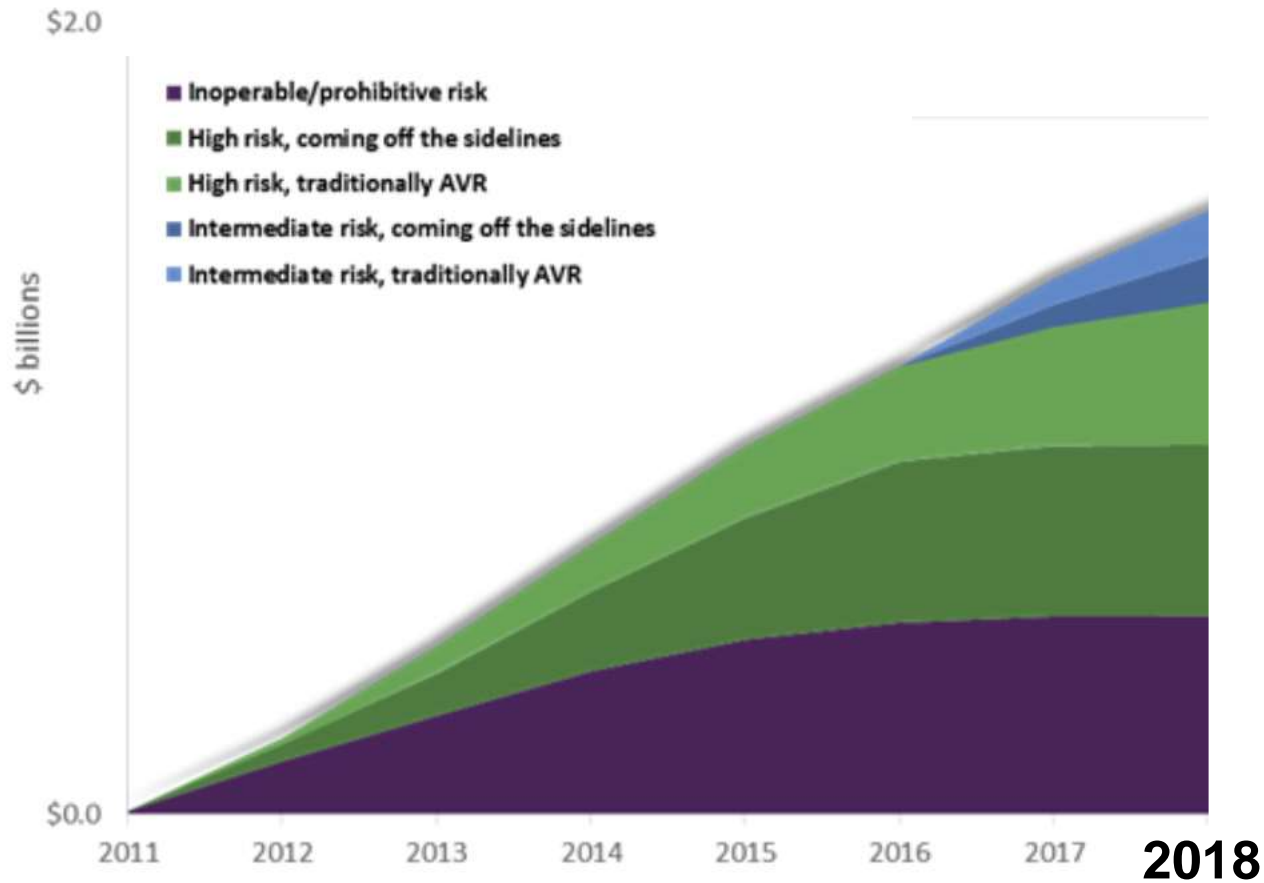SAVR (Class I) — TAVR (Class IIa)
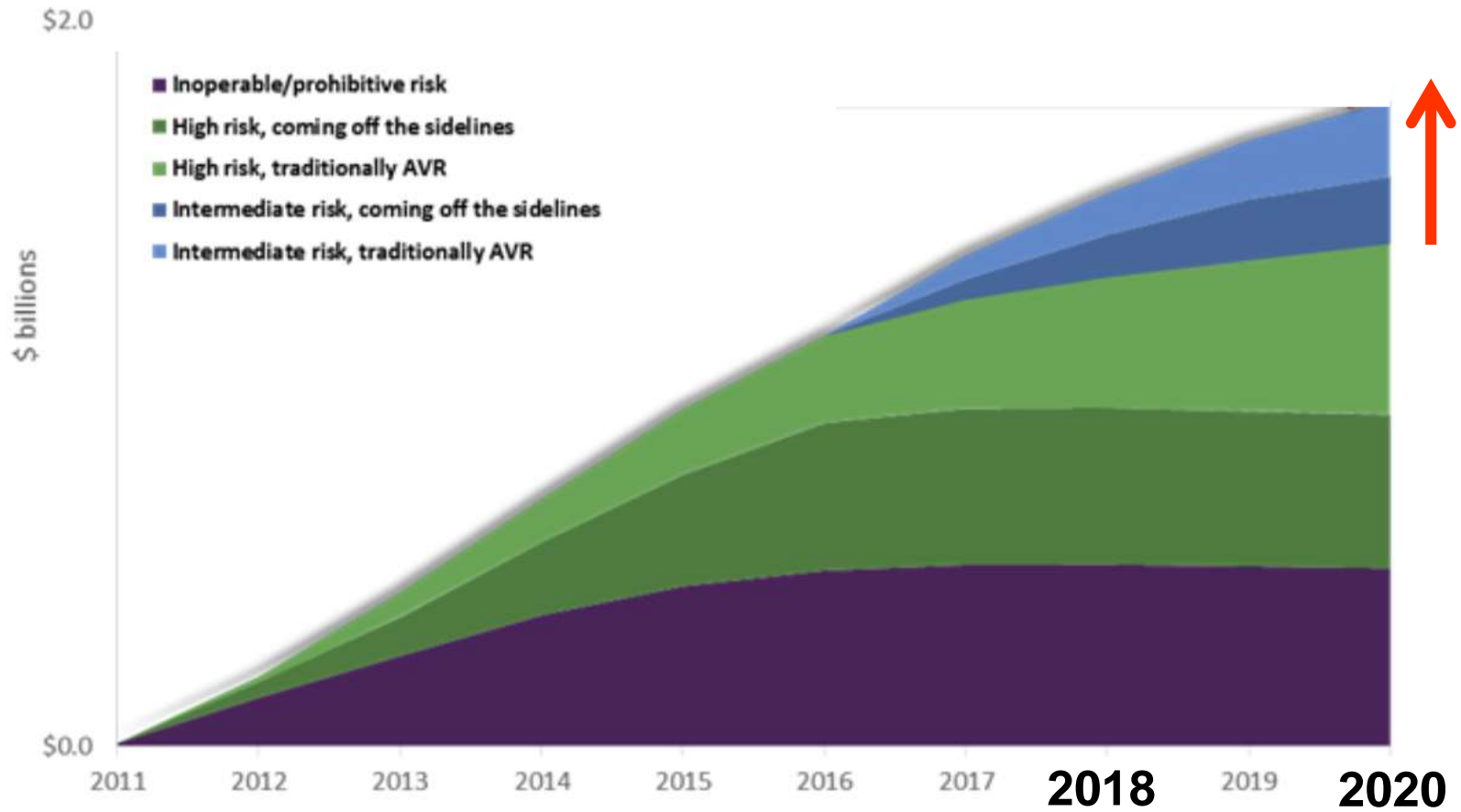
TAVR or SAVR (Class I)

TAVR (Class I)

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 US

TAVR in US

We Have A Choice !

Sapien 3
Evolut R
Symetis
Lotus
Portico
Direct Flow
Engager
Jena Valve
Centera
Venus A Valve
Shanghai Valve
Trinity

Colibri
Inovare
Thubrikar
Valve Medical
Syntheon Verso
Triskele
BioValve
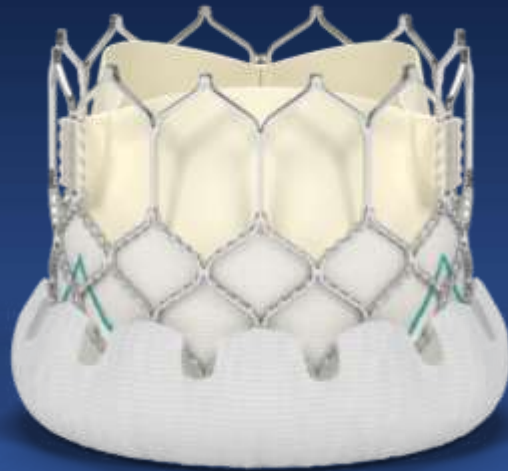*MyVal*
HLT
NVT (Nautilus)
J - Valve
Xeltis
Zurich TEHV

Current Active Evolving Device

Sapien 3

Evolut R

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%**

The Asian TAVR Registry

Sponsored Investigator; Park Seung-Jung,MD
Collaboration with CVRF, ClinicalTrials.gov: NCT02308150

5 Countries,   **11 centers**

HongKong	Queen Elizabeth Hospital
Singapore	National University Heart Centre
Taiwan	National Taiwan University
	Cheng-Hsin Hospital
Korea	Seoul National University Hospital
	Asan Medical Center
Japan	Shonan Kamakura General Hospital
	Keio University Hospital
	Teikyo University Hospital
	Saiseikai Yokohama Eastern Hospital
	Kokura Memorial Hospital

Asian vs Caucasian
Comparison of Aortic Annulus

	Asian	Caucasian	
	N=202	N=106	P value
Annulus Area, mm^2	406 ± 70	430 ± 77	0.007
Annulus Perimeter, mm	73 ± 6	75 ± 7	0.008
Mean Diameter, mm	23 ± 2	24 ± 2	0.009
LCA height, mm	12 ± 3	13 ± 3	< 0.001
RCA height, mm	17 ± 3	17 ± 4	0.82

Small aortic annulus, Small vascular access,
Higher Prevalence of Bicuspid Aortic Valve (?)

Baseline Characteristics (n=848)

	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%)

CardioVascular Research Foundation

UNIVERSITY OF ULSAN COLLEGE MEDICINE

ASAN Medical Center

Procedural Outcomes

	N=848
Access site	
Transfemoral	86.2%
Transapical	12.6%
Transsubclavian,Tranaortic	0.4%, 0.8%
Procedural success	97.5%
Conversion to surgery	1.8%
Coronary obstruction	1.3%
Implantation of two valves	4.5%
New permanent pacemaker	9.5%
Paravalvular leakage (PVL) ≥ moderate to severe	9.8%

Asian TAVR Registry, 2017

30 days Outcomes

Mortality	
Any cause	2.5%
Cardiovascular cause	1.7%
Stroke	
All	3.8%
Disabling	2.2%
Bleeding	10.9%
Life-threatening	6.4%
Major	4.5%
Vascular complications	9.7%
Major	5.0%
Minor	4.7%

Asian TAVR Registry, 2017

Outcomes of TAVR

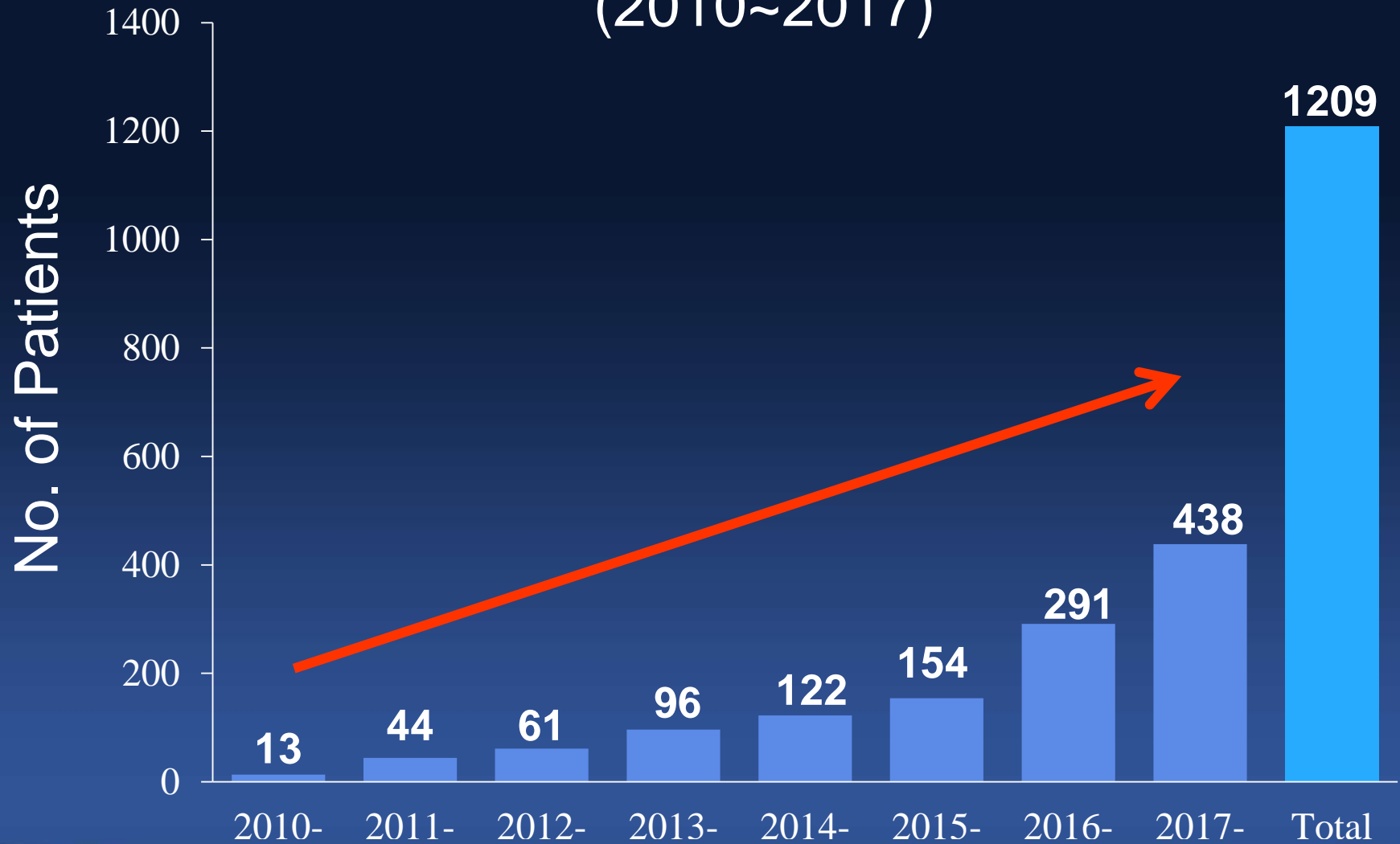| Standard Performance (VARC-2*) for High-Risk AS patients (@ 30 days)		Asian 2017
All-cause mortality	< 3%	2.5%
Major (disabling) strokes	< 2%	2.2%
Major vascular complications	< 5%	5.0%
New permanent pacemakers	< 10%	9.5%
Mod-severe PVR	< 5%	9.8%

VARC* Vascular Academic Research Consortium

TAVR in Korea
What is the Difference ?
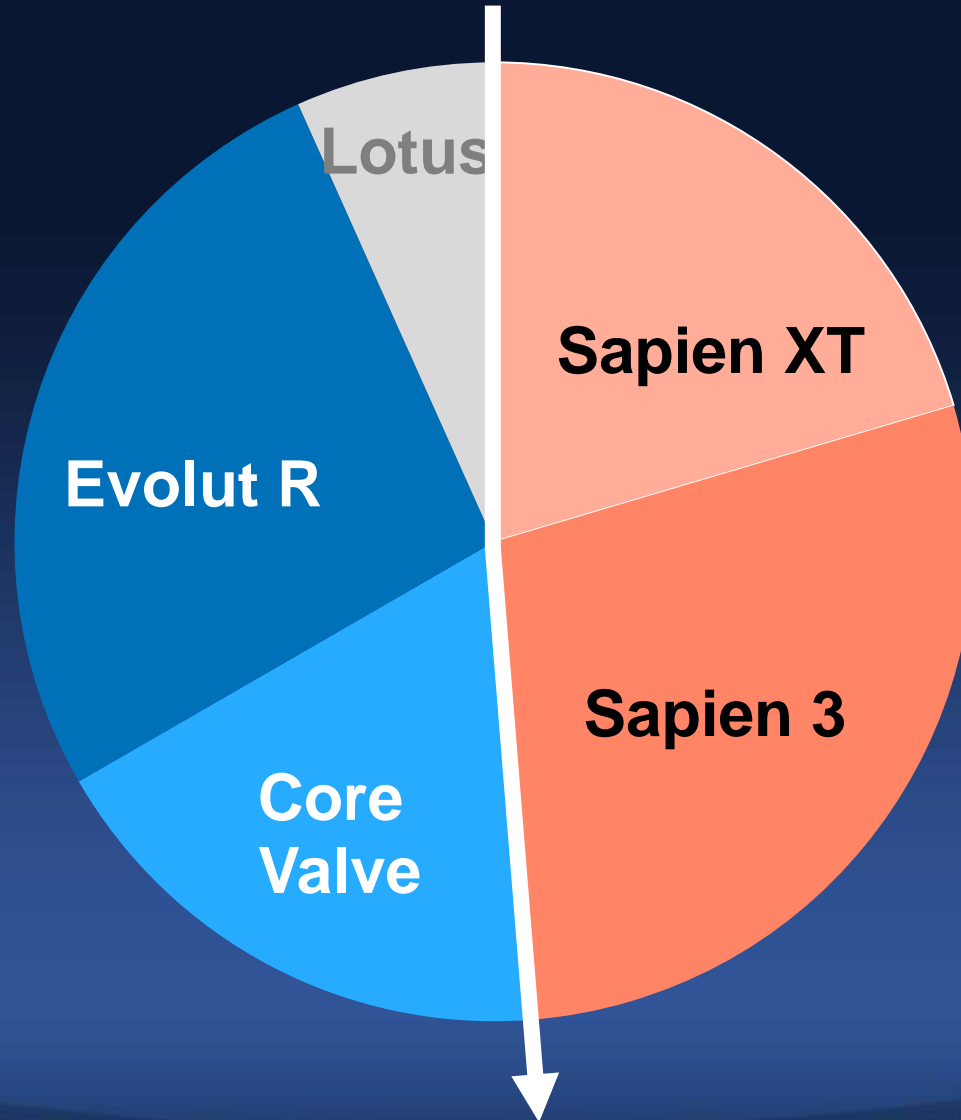
Baseline Characteristics (n=623)

	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

K-TAVI registry, 2018

Procedural Characteristics

	N=623
Approach	
Femoral	614 (97.8%)
Apical	11 (1.8%)
Subclavian	3 (0.5%)
Operation room	
Hybrid room	358 (57.0%)
Cath room	270 (43.0%)
Anesthesia duration (mins)	131.5±43.2
General anesthesia	533 (84.9%)
Conscious sedation	95 (15.1%)

30 days Outcomes

Device Success	625/627 (99.7%)
PVL, moderate to severe	5.4%
Permanent Pacemaker Rate	5.3%
Stroke, all	1.4%
Bleeding	11.5%
Aortic dissection	1.7%
Aortic rupture	0.2%
Death, all	4.5%
Stoke, all	1.4%

K-TAVI registry, 2018

Outcomes of TAVR

Standard Performance (VARC-2*) for High-Risk AS patients (@ 30 days)		Asian 2017	Korea 2017
• 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%

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What is the Difference ?
TAVR in AMC (n=485 pts)

TAVR in AMC

|	N = 421
Age, years	78.7 ± 5.2
Male sex	202 (48.0%)
BMI, kg/m^2	23.9 ± 3.4
Logistic Euroscore (%)	15.6 ± 12.2
STS risk score (%)	4.3 ± 4.4
DM	59 (14.0%)
Hypertension	358 (85.0%)
Atrial fibrillation	59 (14.0%)
Coronary artery disease	153 (36.3%)
Previous MI	22 (5.2%)
Previous stroke	42 (10.0%)
Peripheral vascular disease	22 (5.2%)
Chronic Kidney Disease	125 (29.7%)
COPD	64 (15.2%)
LV Ejection fraction, %	58.5 ± 10.9

Device

- SAPIEN
- SAPIEN XT — 120 (28.5%)
- SAPIEN 3 — 151 (35.9%)
- CoreValve — 83 (19.7%)
- EVOLUT R — 52 (12.4%)
- LOTUS
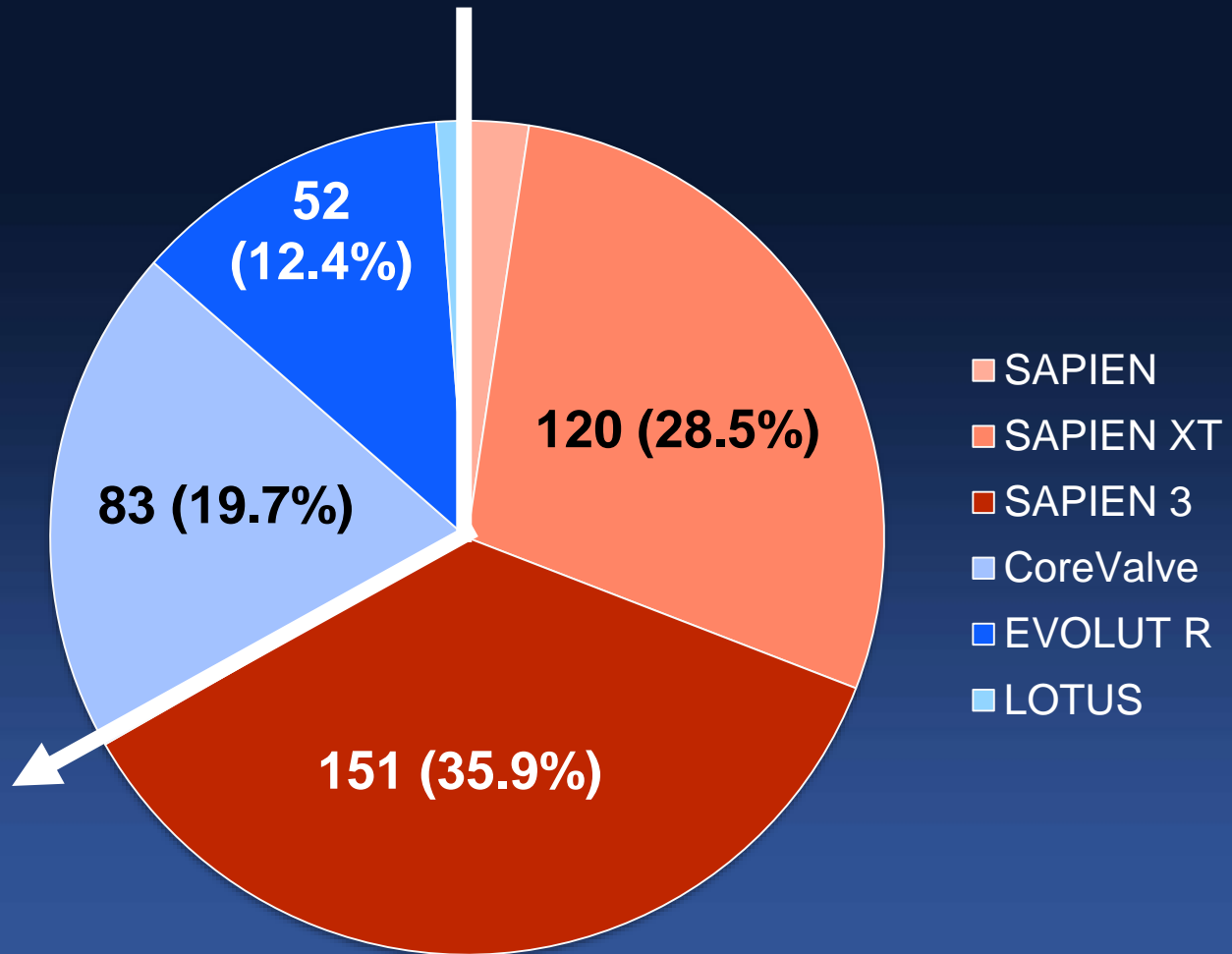
Procedural Outcomes
TAVR in AMC

	Overall (N = 403)
Device success	393 (97.5%)
Conversion to surgery	6 (1.5%)
Coronary obstruction	1 (0.2%)
Implantation of two valves	12 (3.0%)
New permanent pacemaker	34 (8.4%)
PVL ≥ moderate	25 (6.3%)
Major vascular complication	19 (4.7%)
Length of hospital stay (days)	8.6±13.5
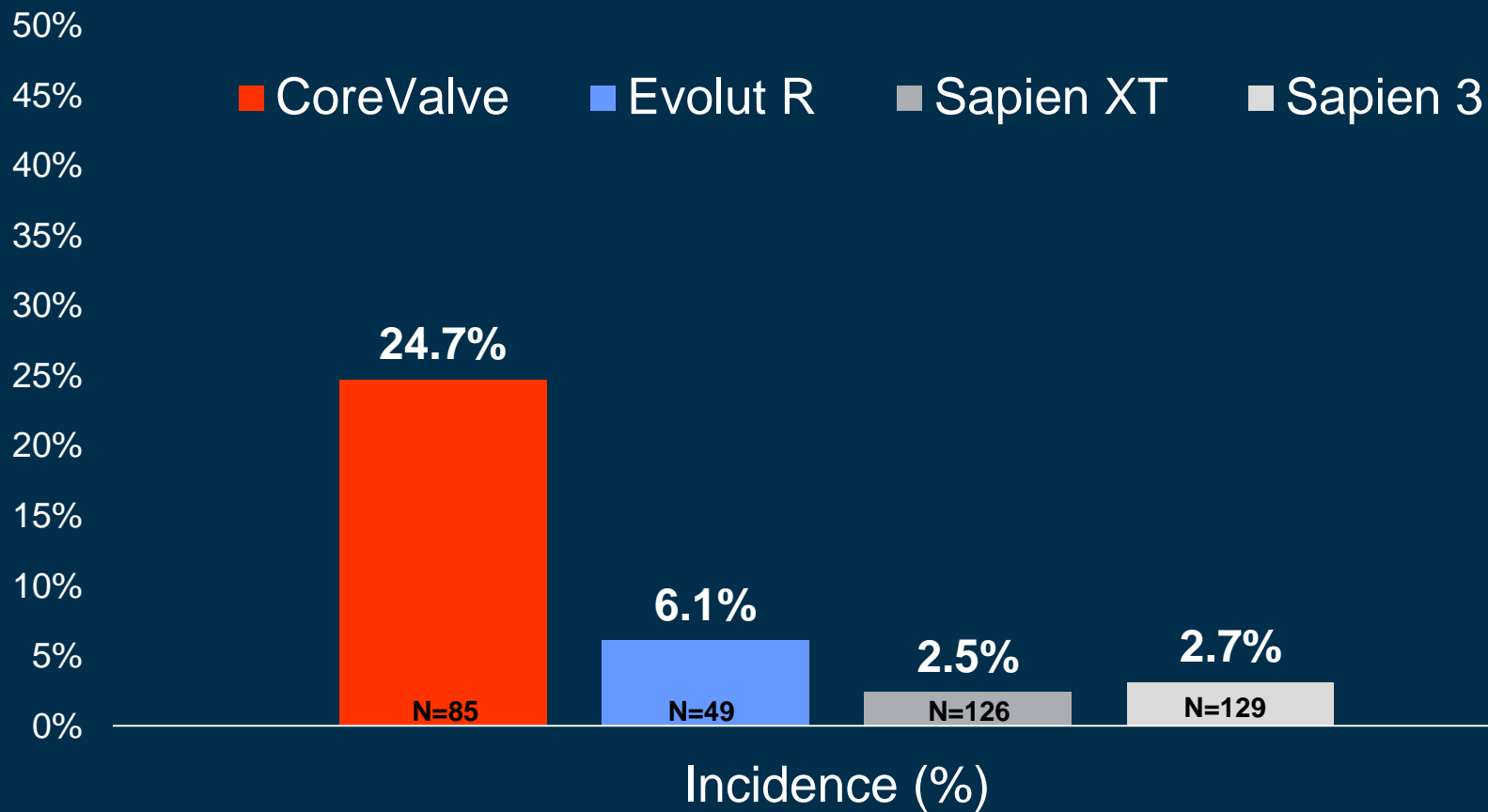
30 Days Outcomes
TAVR in AMC

	Overall (N = 403)
Death, all	10 (2.5%)
Cardiac death	6 (1.5%)
Non-cardiac death	4 (1.0%)
Stroke, all	13 (3.2%)
Disabling	6 (1.5%)
Non-disabling	7 (1.7%)
Death or disabling stroke	15 (3.7%)
Bleeding	130 (32.3%)
Life-threatening	30 (7.4%)
Major	117 (29.0%)

Outcomes of TAVR

Standard Performance (VARC-2*) for High-Risk AS patients (@ 30 days)		Asian 2017	AMC 2018
• All-cause mortality	< 3%	2.5%	2.5%
• Major (disabling) strokes	< 2%	2.2%	1.3%
• Major vascular complications	< 5%	5.0%	4.8%
• New permanent pacemakers	< 10%	9.5%	8.6%
• Mod-severe PVR	< 5%	9.8%	5.6%

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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
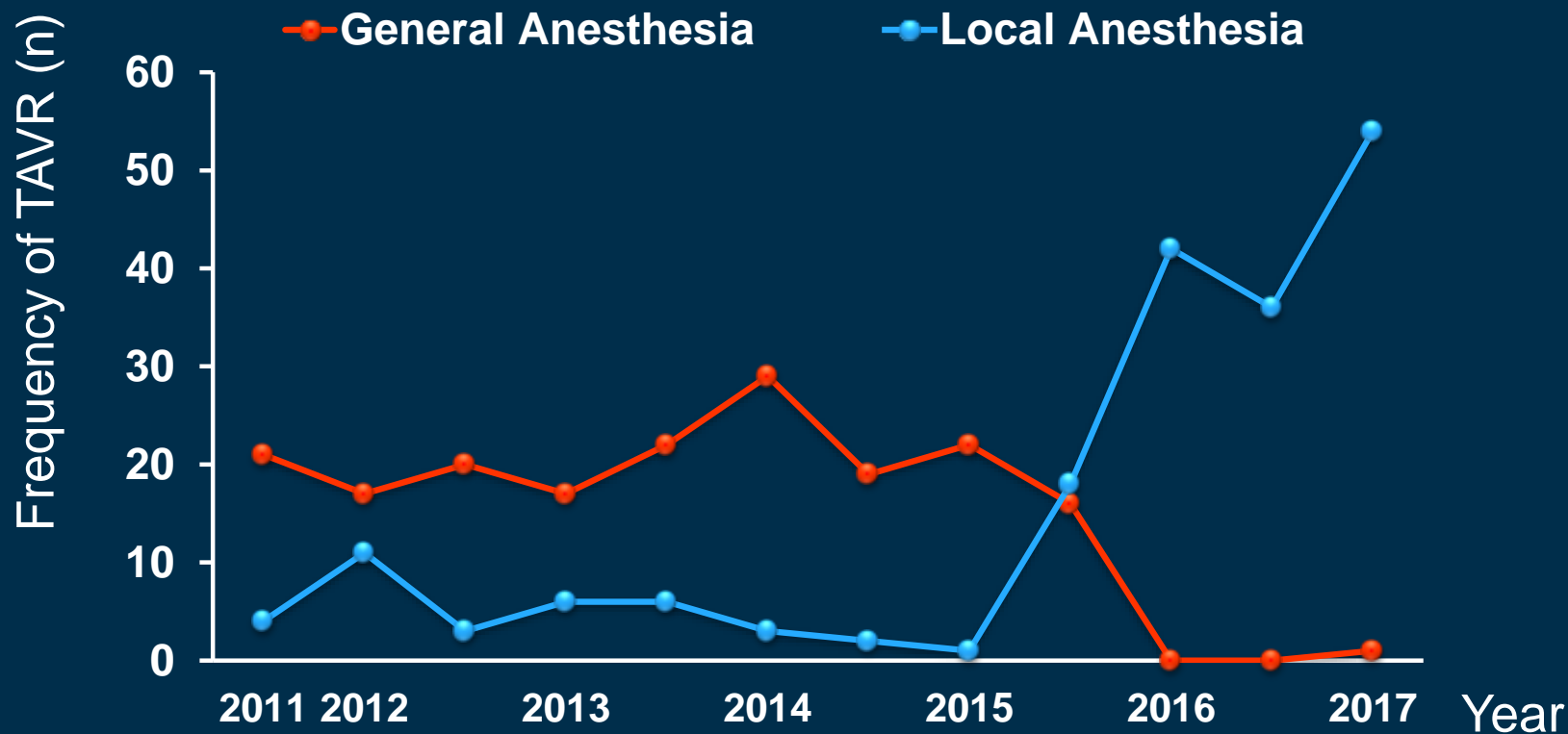
TAVR in AMC
Baseline Characteristics

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
Age	78.8 ± 5.0	77.9 ± 5.3	79.7 ± 4.6	0.001
Male sex	189 (46.9%)	99 (49.5%)	90 (44.3%)	0.30
BMI, kg/m^2	24.0 ± 3.3	24.1 ± 3.2	23.8 ± 3.4	0.41
STS risk score, %	4.1 ± 3.2	4.2 ± 3.8	4.0 ± 2.5	0.57
DM	128 (31.8%)	67 (33.5%)	61 (30.0%)	0.39
HTN	339 (84.1%)	168 (84.0%)	171 (84.2%)	0.94
Atrial fibrillation	57 (14.1%)	28 (14.0%)	29 (14.3%)	0.92
CAD	143 (35.5%)	78 (39.0%)	65 (32.0%)	0.11
Previous MI	19 (4.7%)	6 (3.0%)	13 (6.4%)	0.12
Previous stroke	39 (9.7%)	16(8.0%)	23 (11.3%)	0.22
PVD	21 (5.2%)	13 (6.5%)	8 (3.9%)	0.31
CKD	114 (28.3%)	61 (30.5%)	53 (26.1%)	0.29
COPD	62 (15.4%)	36 (18.0%)	26 (12.5%)	0.11

TAVR in AMC
Procedural Characteristics

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
Aortic-valve area, cm²	0.60 ± 0.17	0.60 ± 0.17	0.60 ± 0.16	0.92
AV Vmax, m/s	5.0 ± 0.8	4.9 ± 0.8	5.0 ± 0.9	0.33
Mean gradient, mmHg	60.8 ± 22.9	59.7 ± 22.6	62.4 ± 23.4	0.29
Bicuspid AV	35 (8.7%)	20 (10.0%)	15 (7.4%)	0.37
LV EF, %	58.3 ± 11.1	58.8 ± 10.8	57.8 ± 11.4	0.45
Device type				0.003
Balloon-expandable	261 (64.8%)	115 (57.5%)	146 (71.9%)	
Self-expandable	142 (35.2%)	85 (42.5%)	57 (28.1%)	

TAVR in AMC
Procedural Outcomes

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
Device success	393 (97.5%)	193 (96.5%)	200 (98.5%)	0.16
Conversion to surgery	6 (1.5%)	5 (2.5%)	1 (0.5%)	0.10
Coronary obstruction	1 (0.2%)	1 (0.5%)	0	0.50
Implantation of two valves	12 (3.0%)	10 (5.0%)	2 (1.0%)	0.02
New permanent pacemaker	34 (8.4%)	20 (10.0%)	14 (6.9%)	0.26
PVL ≥ moderate	25 (6.3%)	20 (10.2%)	5 (2.5%)	0.002
Major vascular complication	19 (4.7%)	17 (8.5%)	2 (1.0%)	<0.001
Length of hospital stay (days)	8.6±13.5	9.7±8.8	7.4±16.8	<0.001

TAVR in AMC
30 Days Outcomes

	Overall (N = 403)	General Anesthesia (N = 200)	MAC (N = 203)	P value
Death, all	10 (2.5%)	9 (4.5%)	1 (0.5%)	0.01
Cardiac death	6 (1.5%)	5 (2.5%)	1 (0.5%)	0.10
Non-cardiac death	4 (1.0%)	4 (2.0%)	0	0.043
Stroke, all	13 (3.2%)	11 (5.5%)	2 (1.0%)	0.01
Disabling	6 (1.5%)	4 (2.0%)	2 (1.0%)	0.40
Non-disabling	7 (1.7%)	7 (3.5%)	0	0.07
Death or disabling stroke	15 (3.7%)	12 (6.0%)	3 (1.5%)	0.015
Bleeding	130 (32.3%)	86 (43.0%)	44 (21.7%)	<0.001
Life-threatening	30 (7.4%)	21 (10.5%)	9 (4.4%)	0.02
Major	117 (29.0%)	79 (39.5%)	38 (18.7%)	<0.001

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%	2.5%	0.5%
• Major (disabling) strokes	< 2%	2.2%	1.3%	1.0%
• Major vascular complications	< 5%	5.0%	4.8%	1.0%
• New permanent pacemakers	< 10%	9.5%	8.6%	6.9%
• Mod-severe PVR	< 5%	9.8%	5.6%	2.5%

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Remaining Issues of TAVR

Durability

Bioprosthetic Surgical Valve Failure — Time to Failure - All (n = 1304). Histogram of Number of Cases vs Time to Failure (years), with 7-11 years highlighted. from VIVID Registry
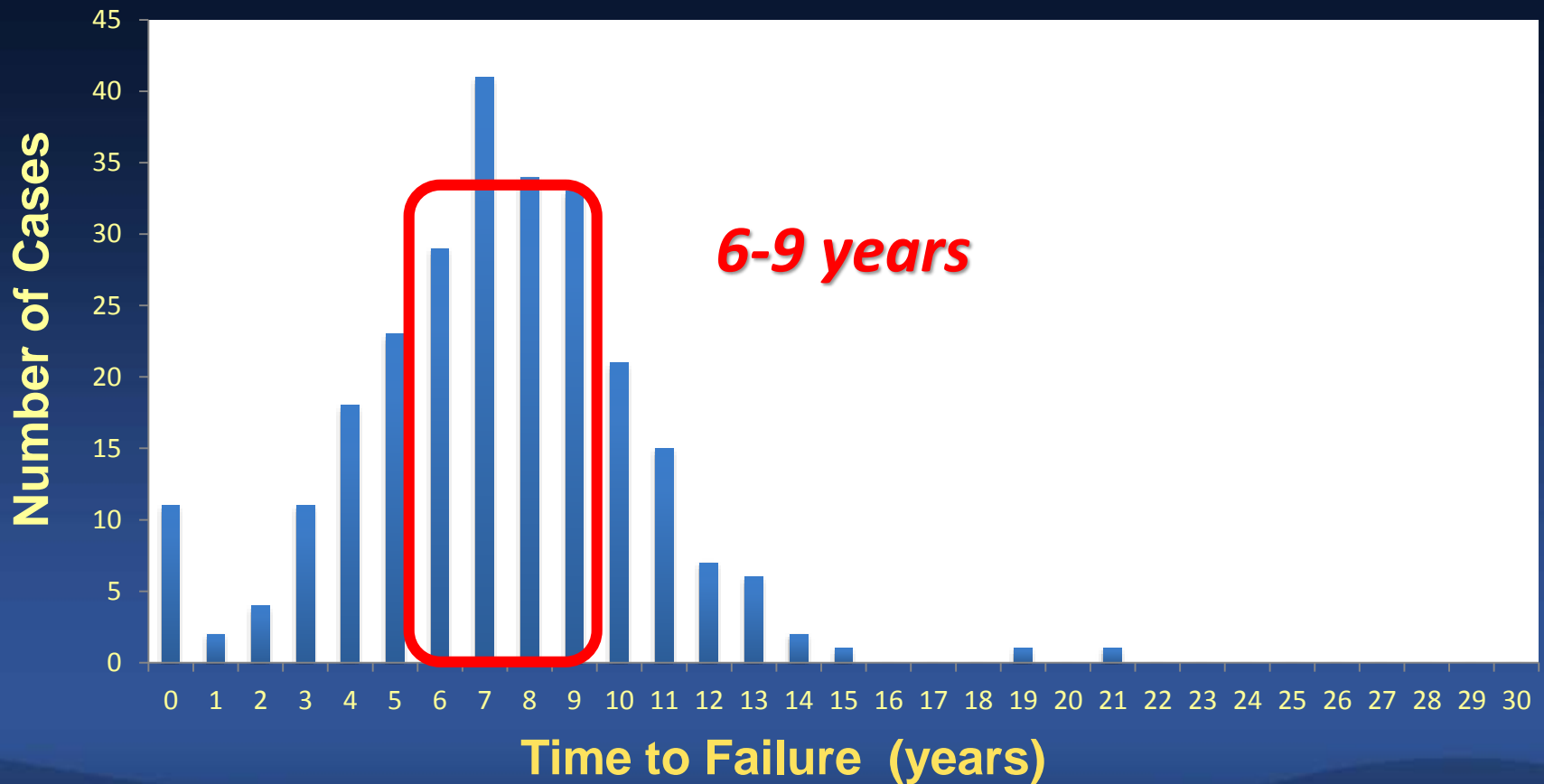
NOTION: TAVR in Low-Risk Patients Maintains Its Momentum Through 6 Years
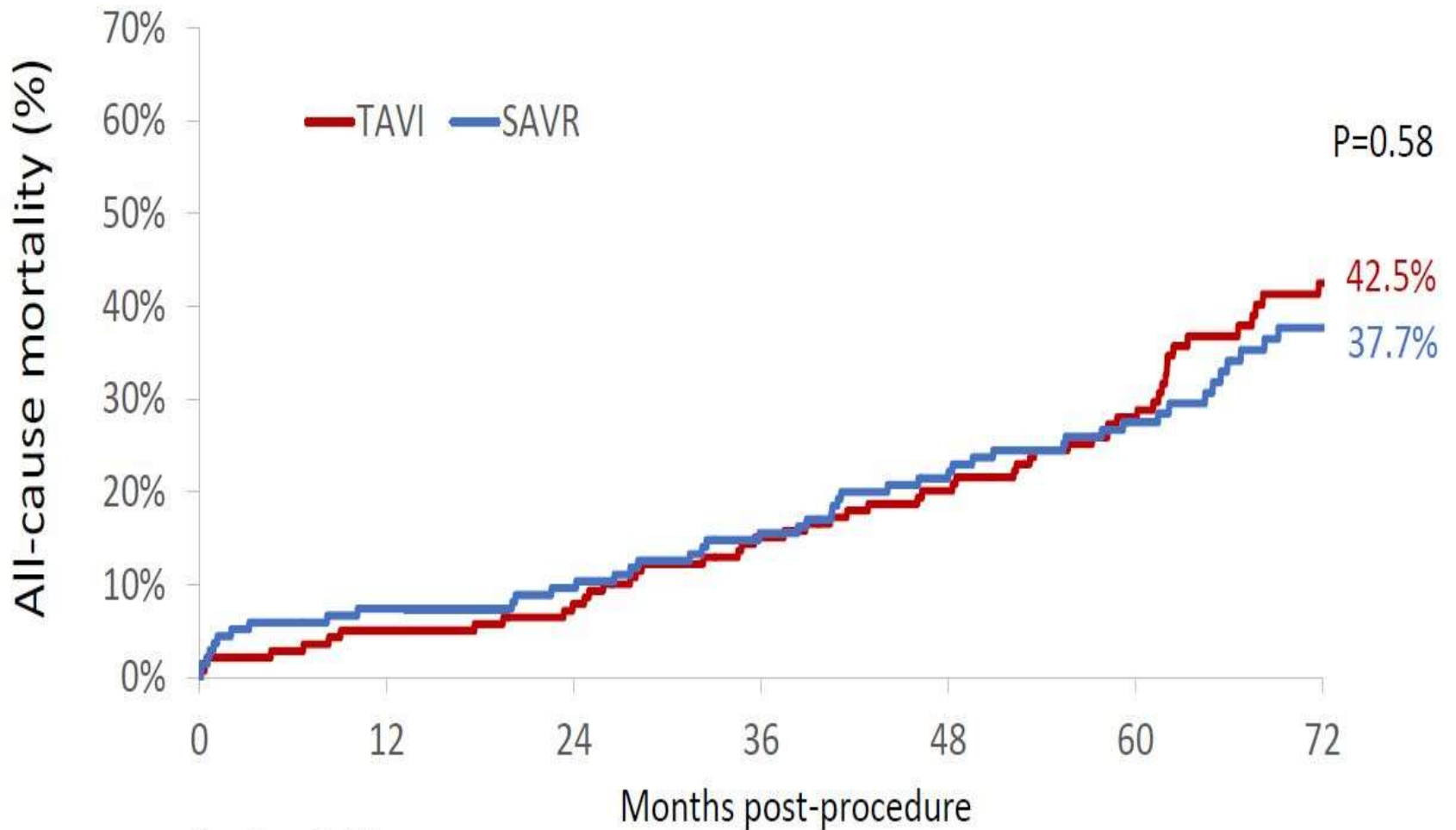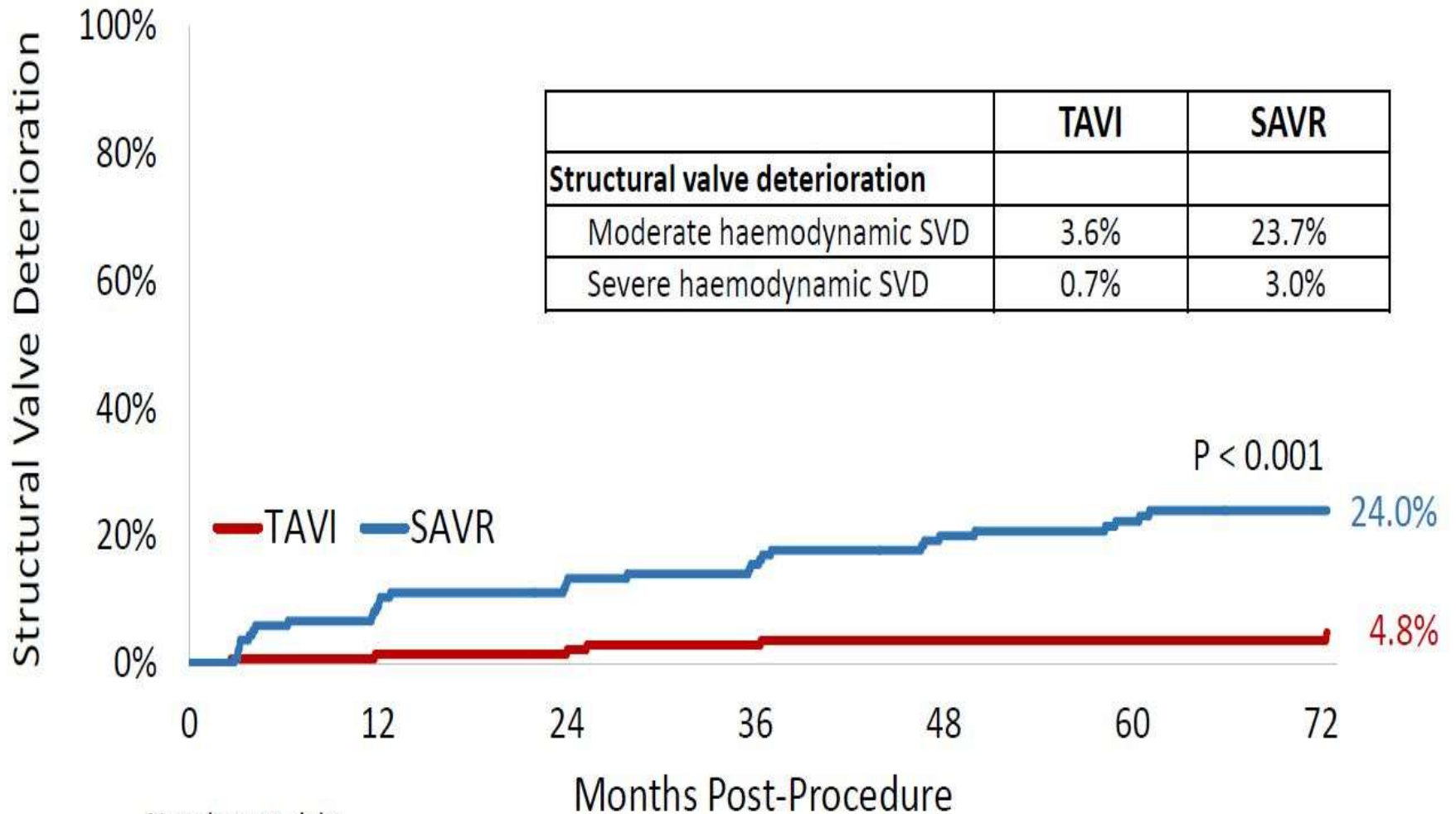
TAVR in CHU Rouen
239 pts from 2002-2011 (> 5 years FU)

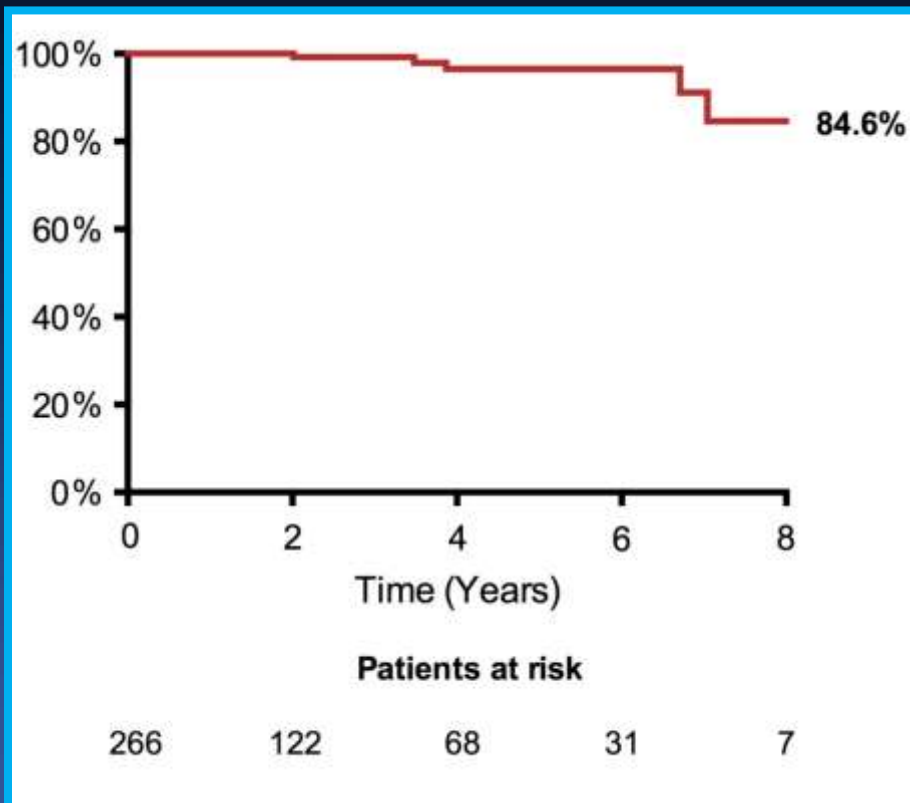*Freedom from either reoperation, or pressure gradient >40 mmHg or severe AR*
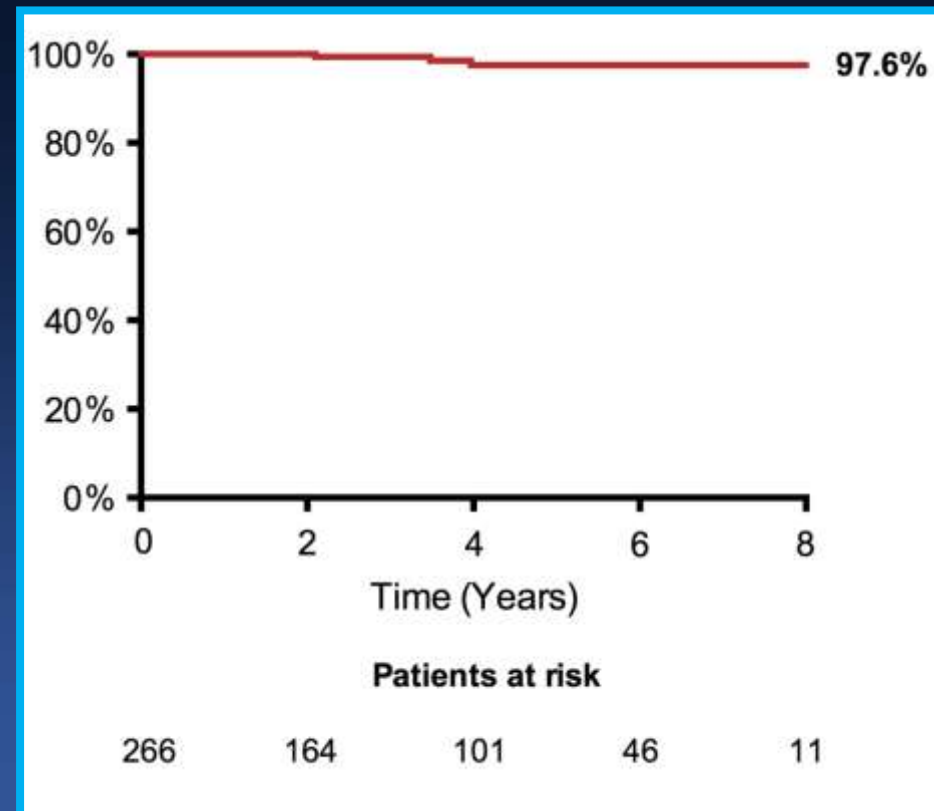

8 Years FU

TAVR in AMC
443 pts from 2010 (> 5 years FU)

Freedom from Re-operation or Re-intervention

Preliminary Data from AMC TAVR, 2018
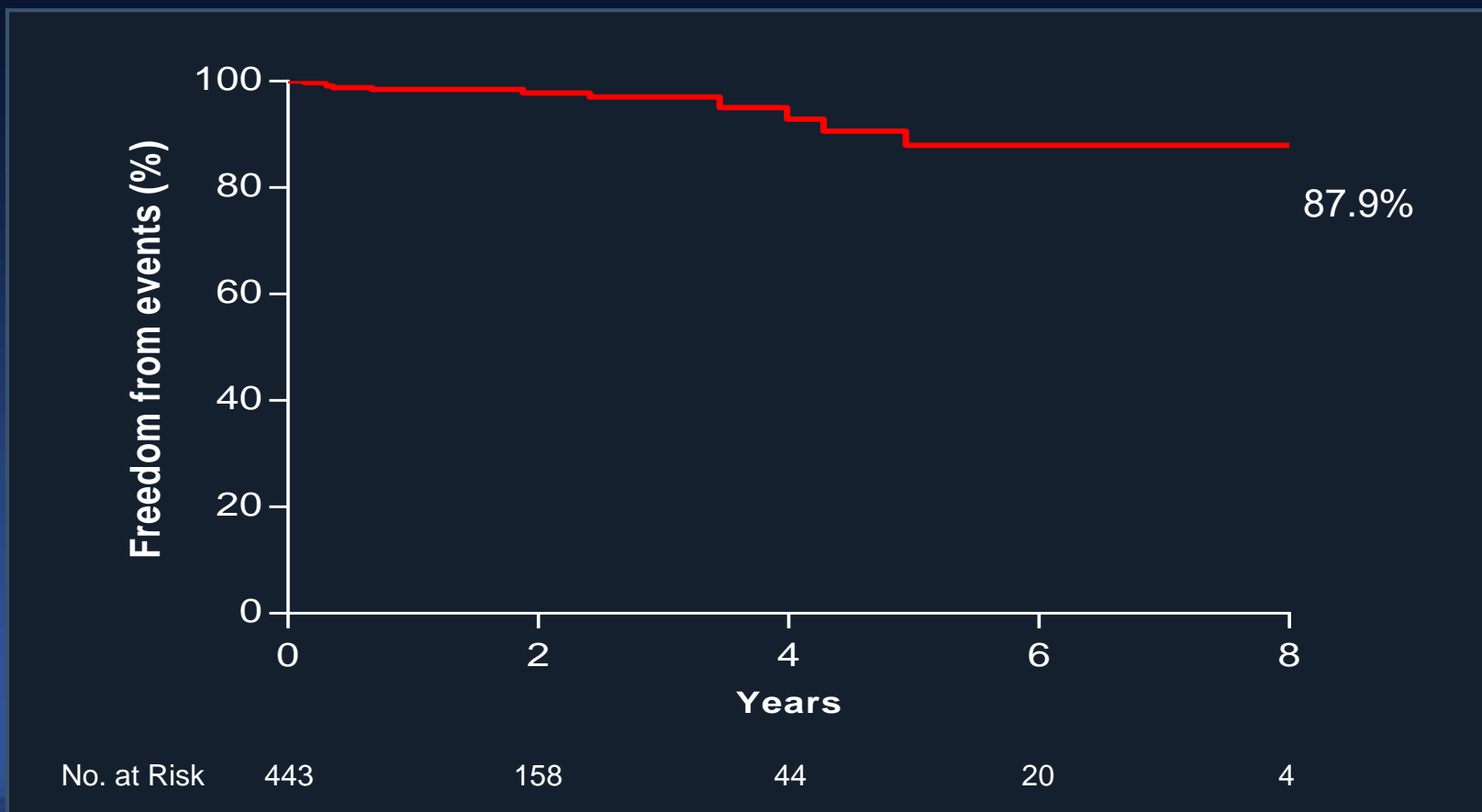
TAVR in AMC
443 pts from 2010 (> 5 years FU)

8 Year Survival

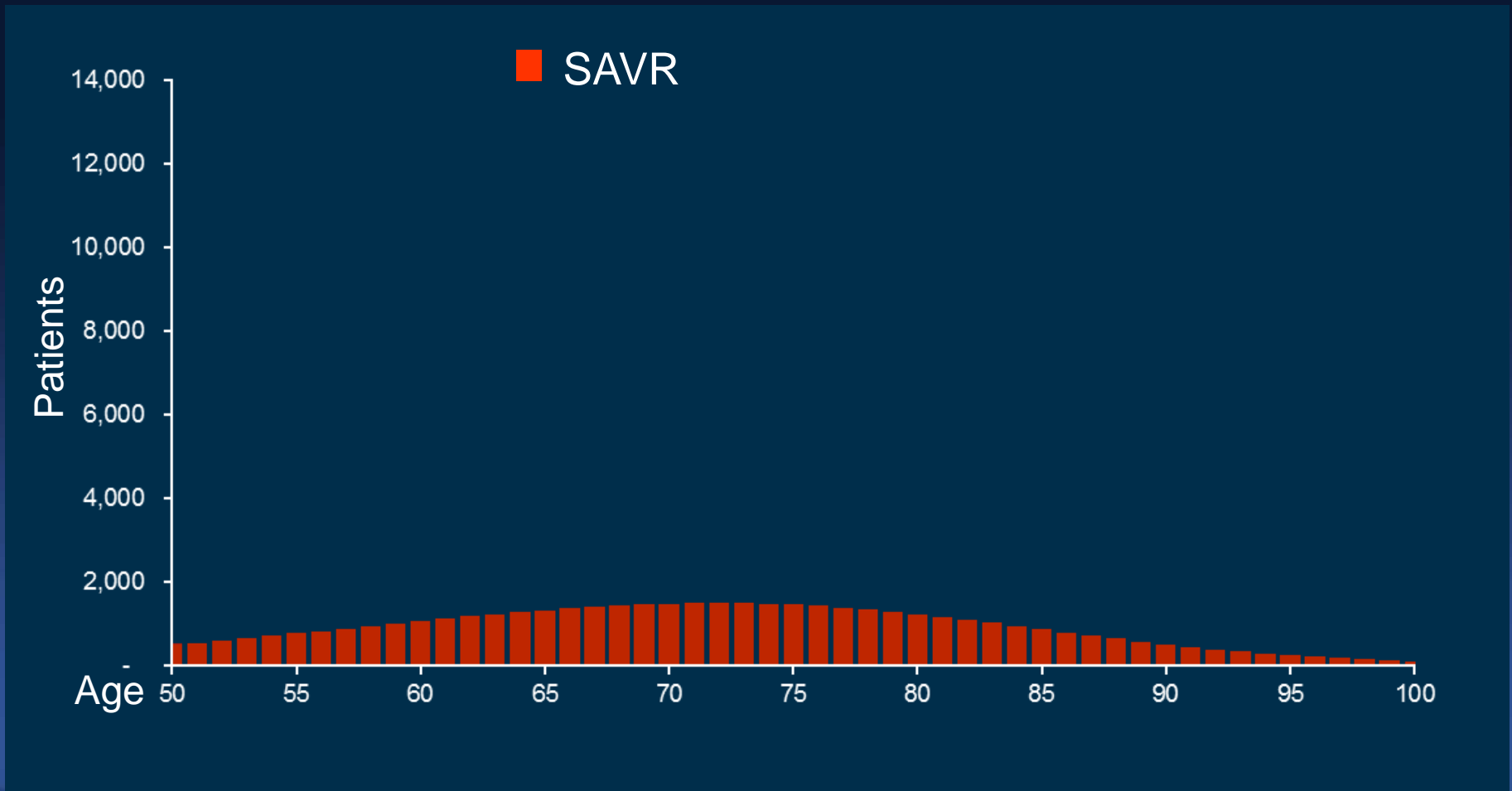*Preliminary Data from AMC TAVR, 2018*

Durability Issue
of TAVR

We Need more Data.
So far, So Good !

Future Perspective
of TAVR

Surgical AVR (SAVR)
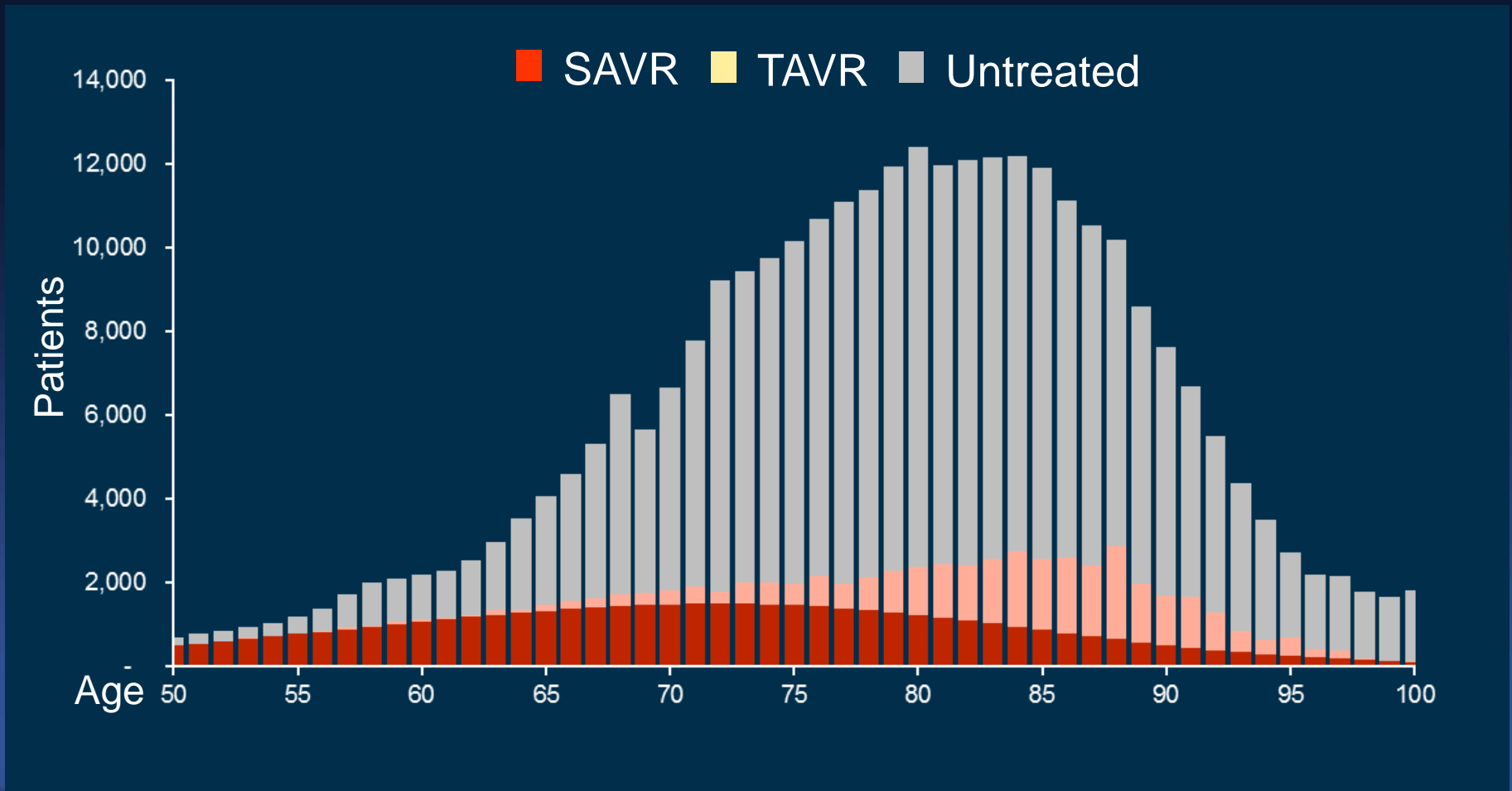## Severe Symptomatic AS Patients in the U.S.

Nkomo 2006, Iivanainen 1996, Aronow 1991, Bach 2007, Freed 2010, Iung 2007, Pellikka 2005, Brown 2008, Thourani 2015,

SAVR + TAVR
Severe Symptomatic AS Patients in the U.S.

Nkomo 2006, Iivanainen 1996, Aronow 1991, Bach 2007, Freed 2010, Iung 2007, Pellikka 2005, Brown 2008, Thourani 2015,
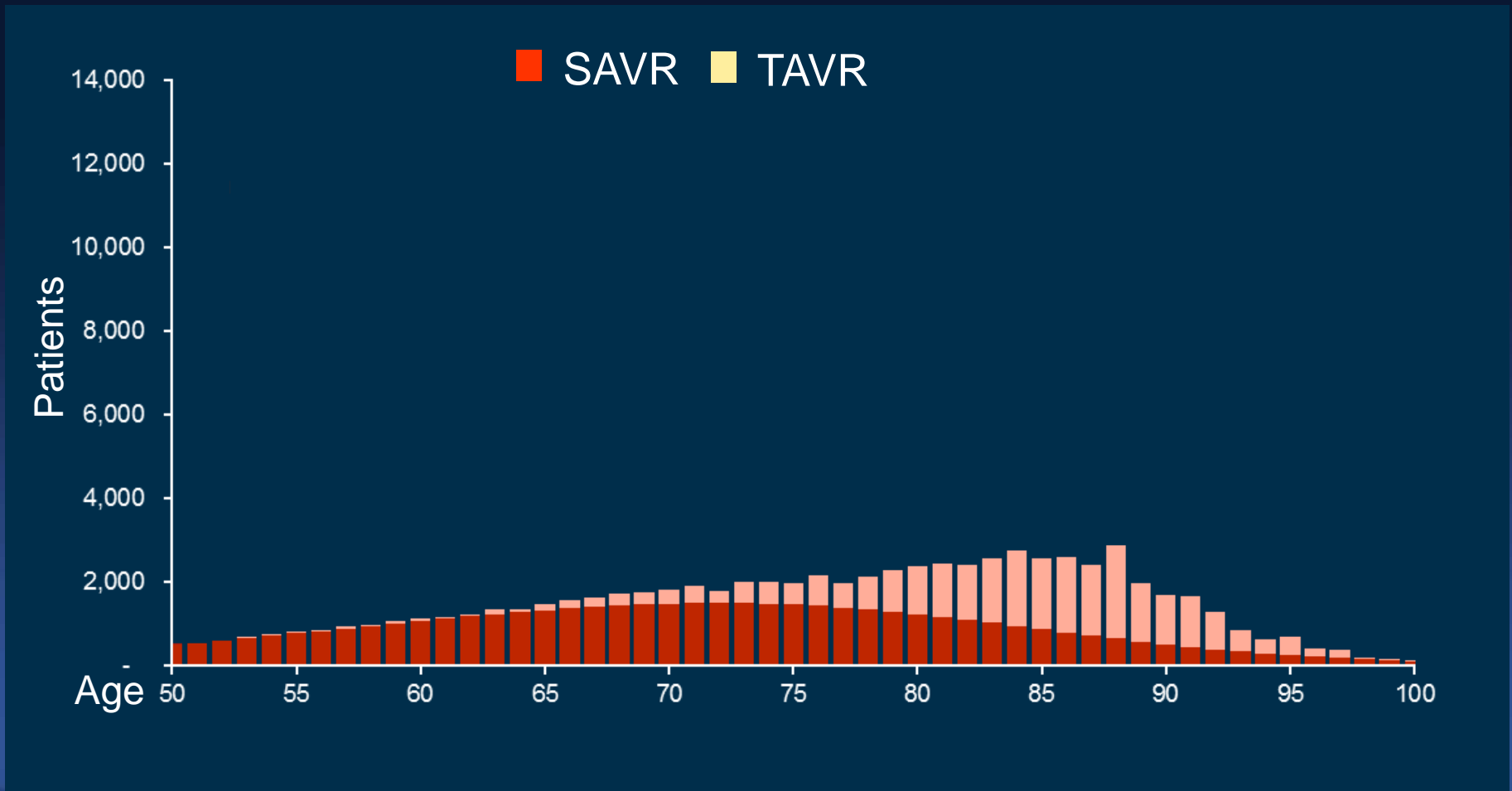
SAVR + TAVR + Untreated AS
Severe Symptomatic AS Patients in the U.S.

Nkomo 2006, Iivanainen 1996, Aronow 1991, Bach 2007, Freed 2010, Iung 2007, Pellikka 2005, Brown 2008, Thourani 2015,

Expanding Clinical Indications Of TAVR

- Bicuspid AV disease
- Bioprosthetic valve failure (aortic and mitral)
- Low-risk patients (all-comers)
- Severe asymptomatic AS
- Low-flow, low-gradient AS
- Moderate AS + CHF
- High-risk AR

TAVR in 2025

Evolving TAVI 2025 - TAVR Would be mainstream therapy for almost all aortic stenosis patients. SAVR should be considered only for patients who are not suitable for TAVR.