How Do We Choose Specific Valve Type in Our TAVR Practice

Duk-Woo Park, MD, PhD

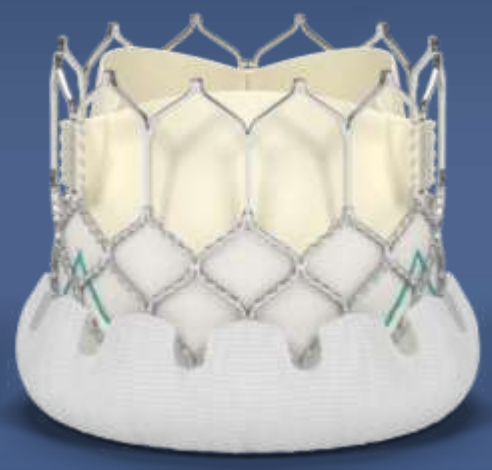
Heart Institute, University of Ulsan College of Medicine,
Asan Medical, Seoul, Korea

Conflict of Interest Statement

- I have nothing to disclose
- No financial relationships

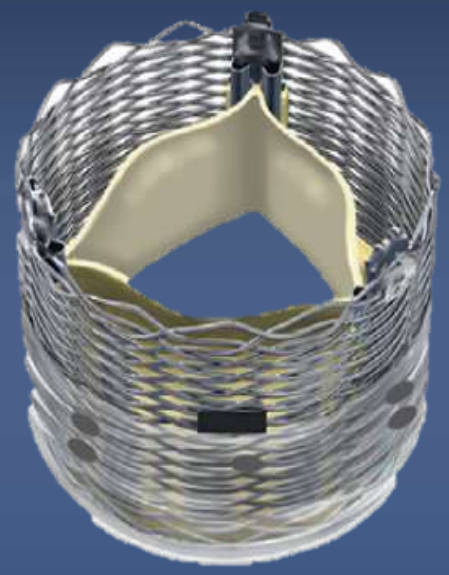
Current "Standards" for TAVR in Korea

Sapien 3



Evolut R

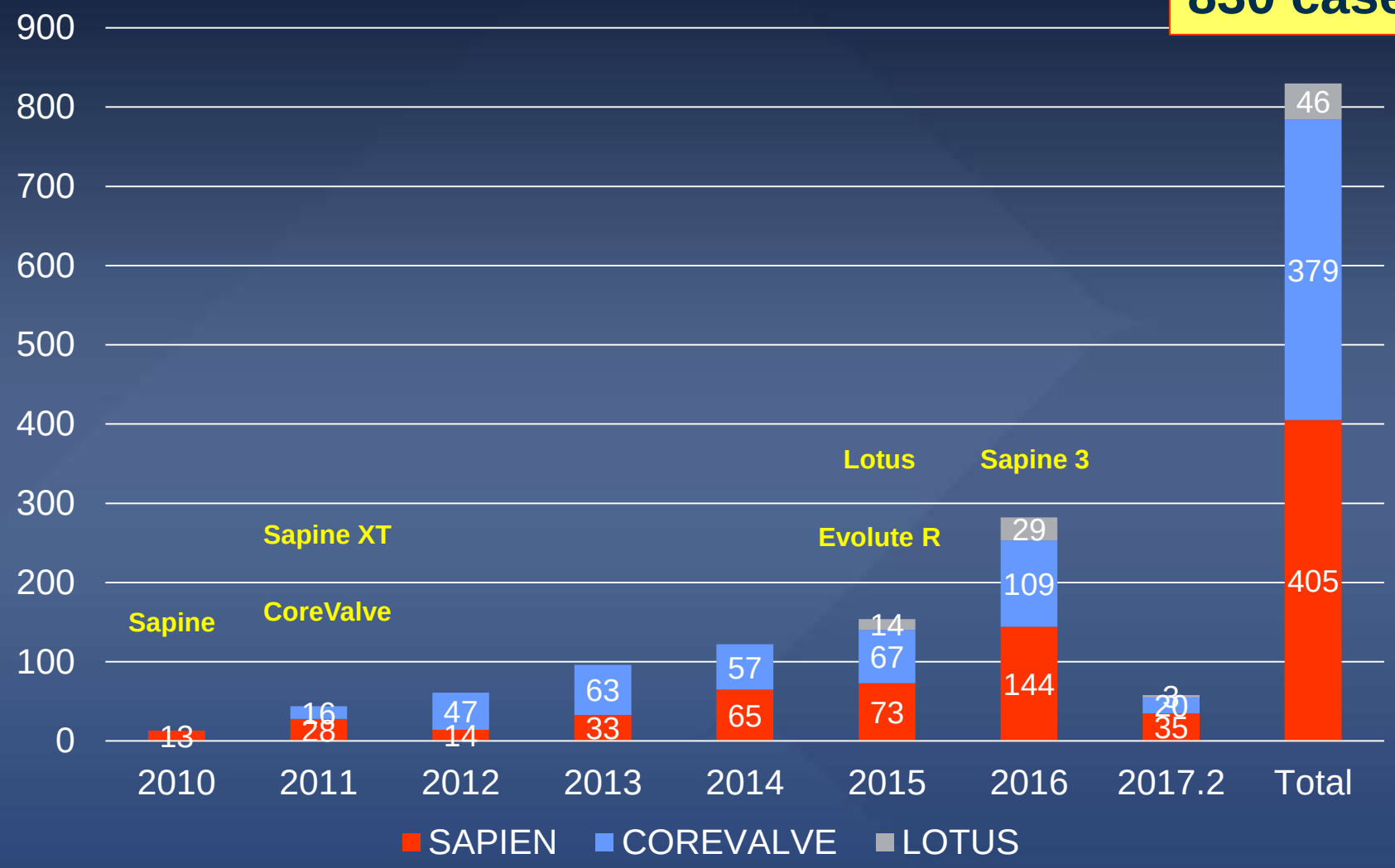
Lotus



TAVR Status in KOREA

All TAVR (2010~2017.2)

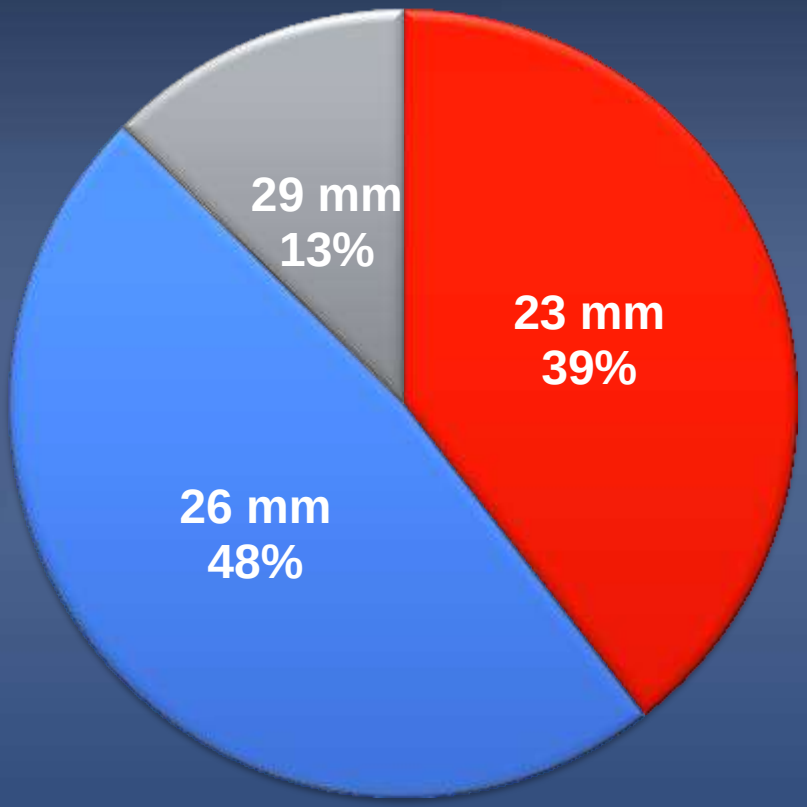
Total 830 cases



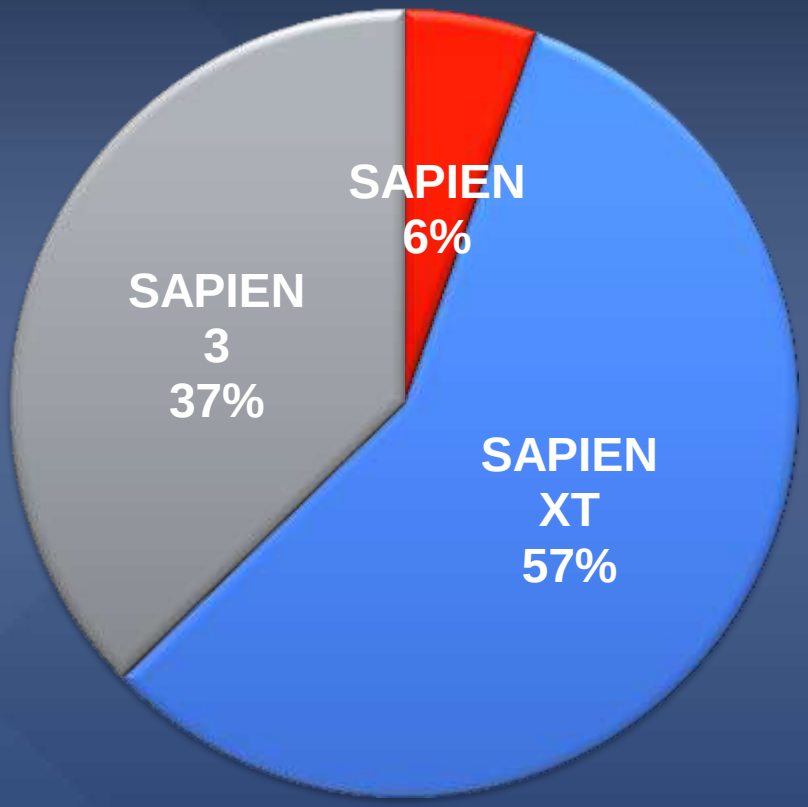
TAVR Status in KOREA

SAPIEN (N=405)

Valve Size



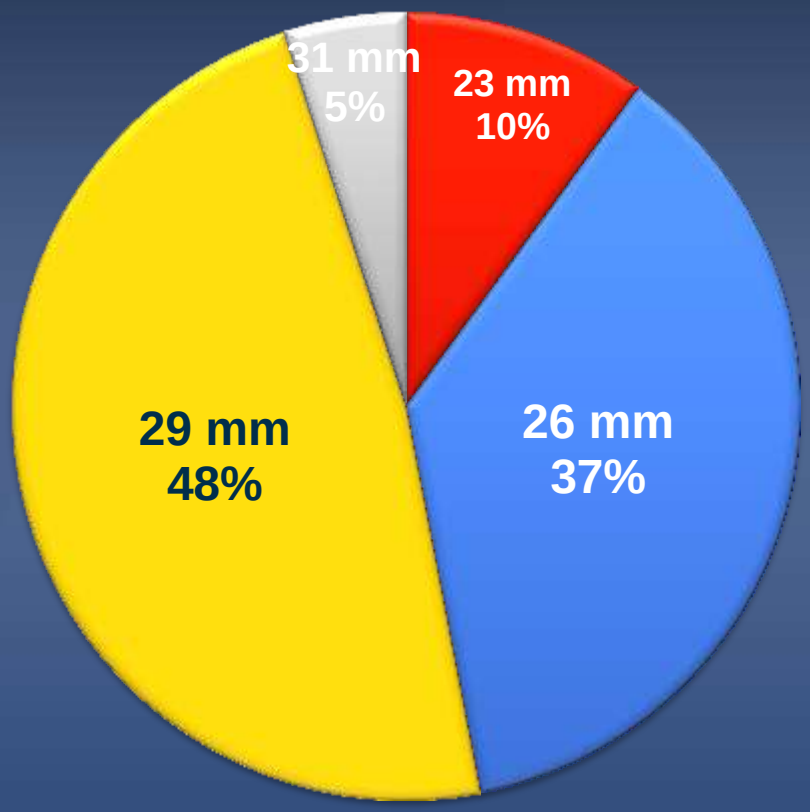
Valve Type



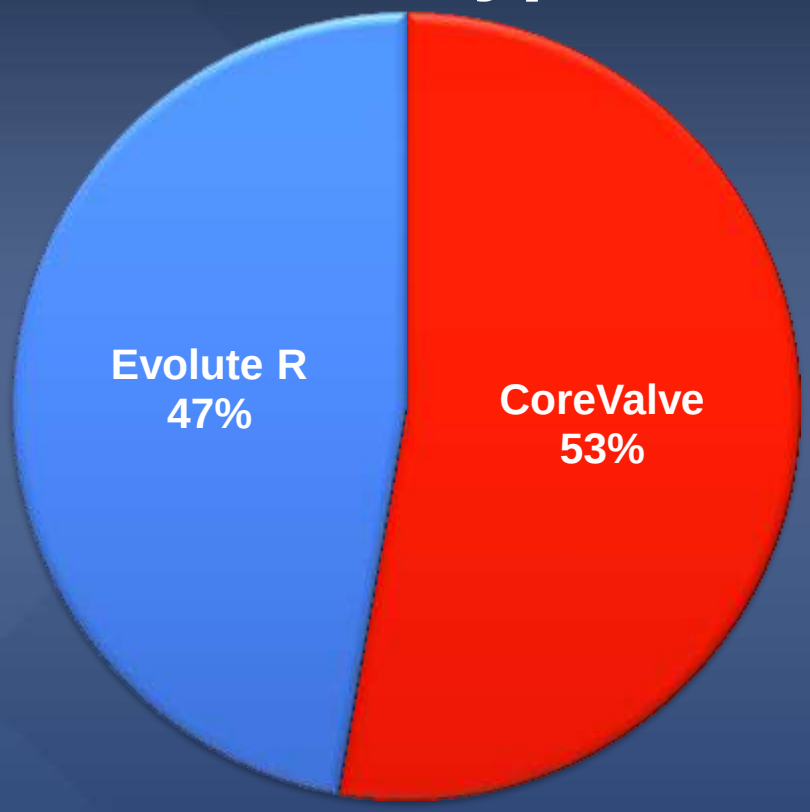
TAVR Status in KOREA

CORE-VALVE (N=379)

Valve Size



Valve Type



How Do We Do Optimal Valve Type Selection?

At first,
We should understand the features and limitations of Specific TAVR devices.

Circularization of the Annulus

Balloon-expandable prosthesis

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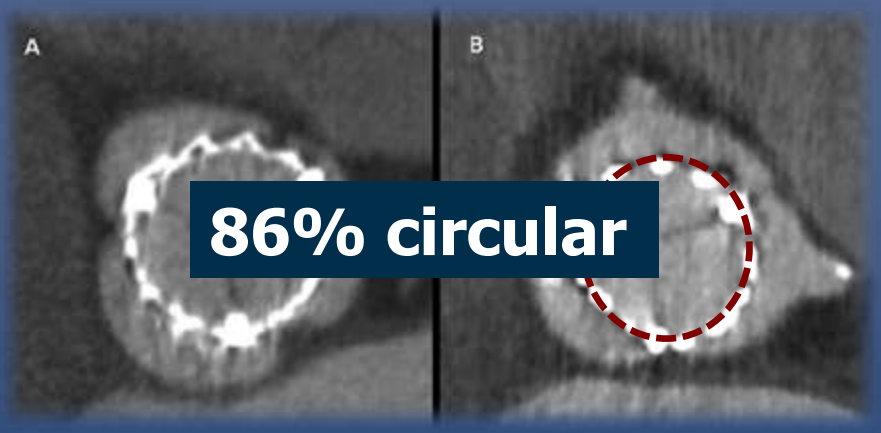
Prosthesis "remodels" the annulus

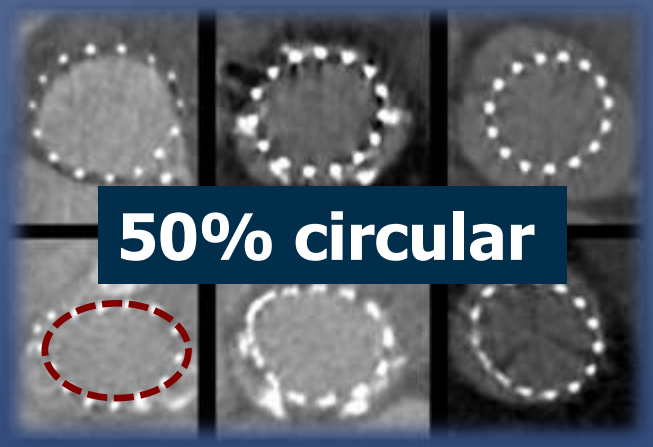


Delgado et al. Eur Heart J 2010;31:1114-1123

Self-expanding prosthesis

↓

The "annulus" remodels the prosthesis



Schultz C et al. JACC 2009; 54:911-8

Size Selection for Balloon-Expandable Valve

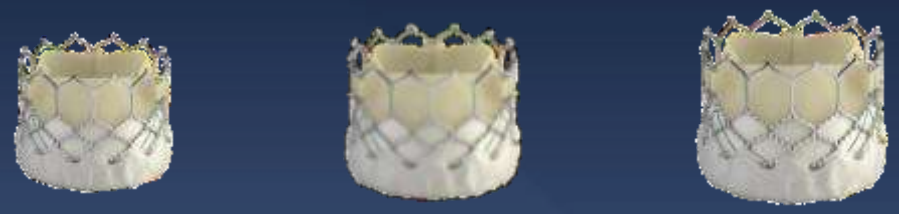
SAPIEN 3

SAPIEN XT

Skirt to Prevent Paravalvular Leakage

Area Oversizing

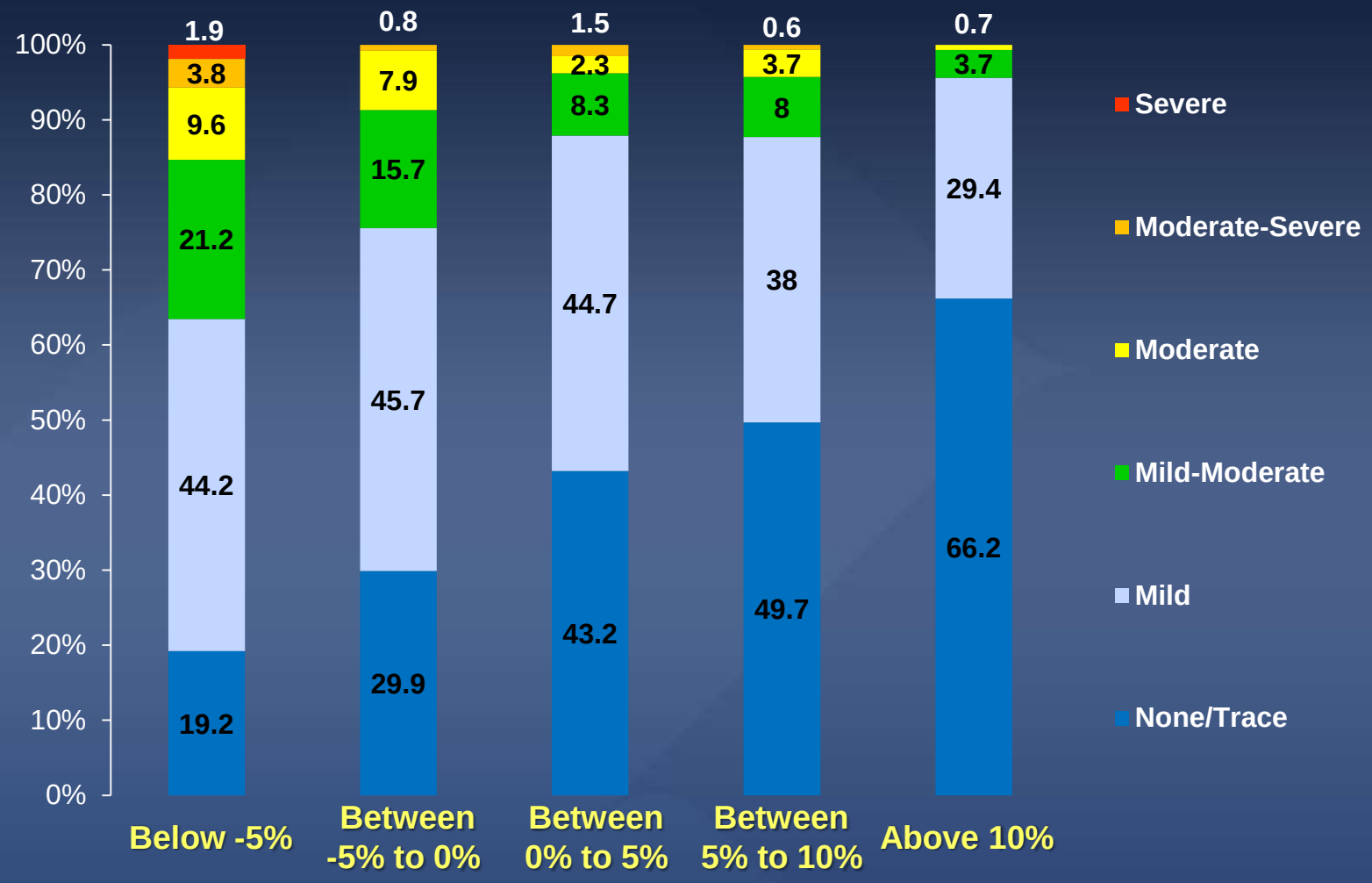
Complete Range of Valve Sizes Expands



SAPIEN 3 Valve Size	23mm	26mm	29mm
Native Annulus Size By TEE	18-22mm	21-25mm	24-28mm
Native Annulus Area (CT)	338-430mm²	430-546mm²	540-683mm²
Area-derived Diameter (CT)	20.7-23.4mm	23.4-26.4mm	26.2-29.5mm

Paravalvular Leak by Area Oversizing

Data from PARTNER trial



No annular rupture

Oversizing and LBBB/PPM

Independent Predictors

	OR (95% CI)	P value
Low implantation, % of frame	1.06 (1.02-1.11)	0.006
Extreme Oversizing	3.49 (1.24-9.85)	0.018

208 patients without previous PPM and baseline conduction abnormality were analyzed. New PPM, or new PPM/LBBB occurred in 34 (16%) and 57 (31%) patients.

Husser et al. JACC Cardiovasc Interv 2016

CVRF

Optimal Target for Area Oversizing : SAPIEN 3

0%

5 - 15%

20%

Paravalvular leakage

Optimal

Annulus Rupture

PPM

Size Selection for Self-Expandable Valve

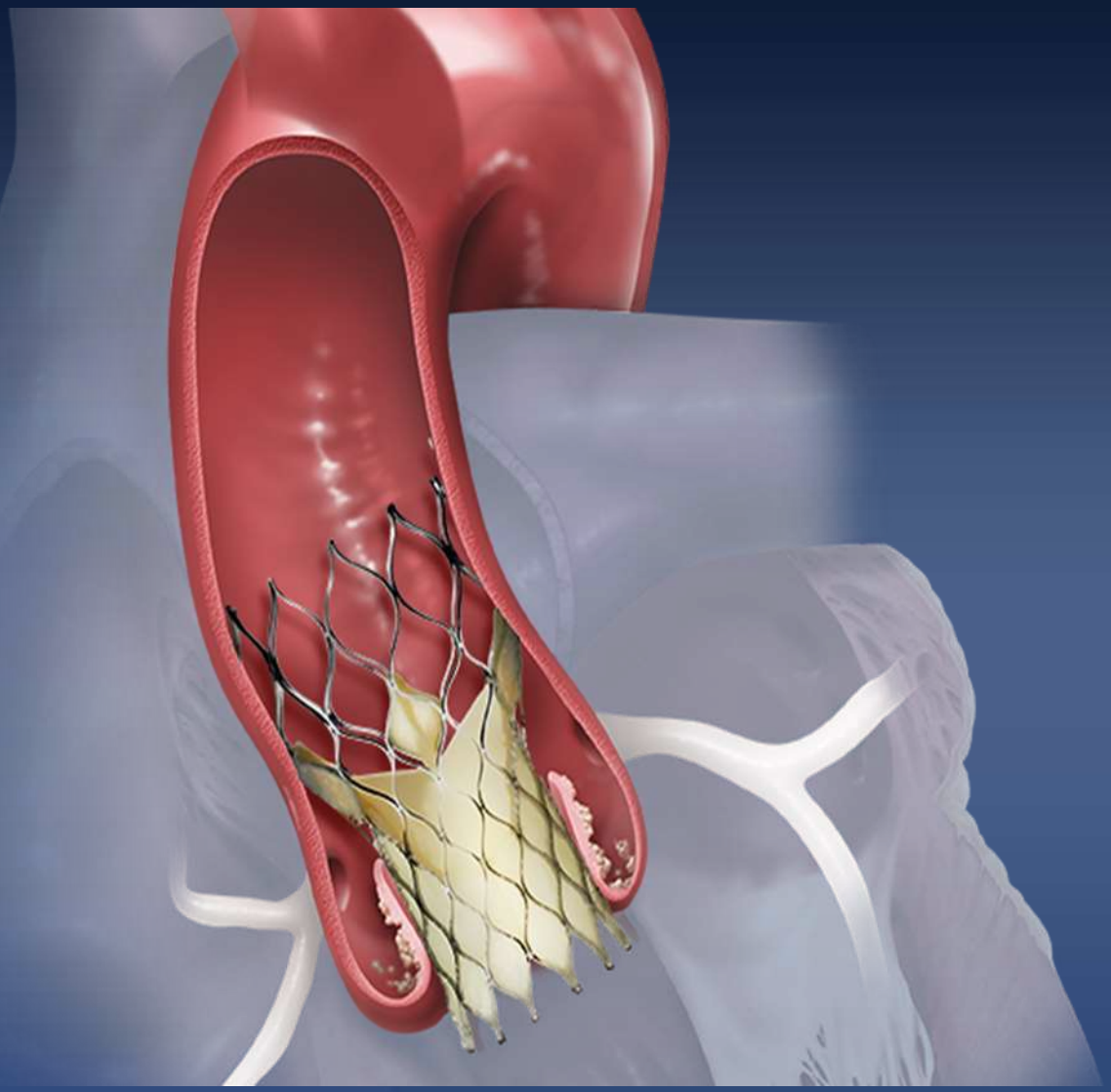
Evolut R

CoreValve

Perimeter Oversizing

Evolut R

- Tapered shape of the frame
- If needed, coronary access can be achieved through the struts of the frame
- Can be completely recaptured in an emergency situation

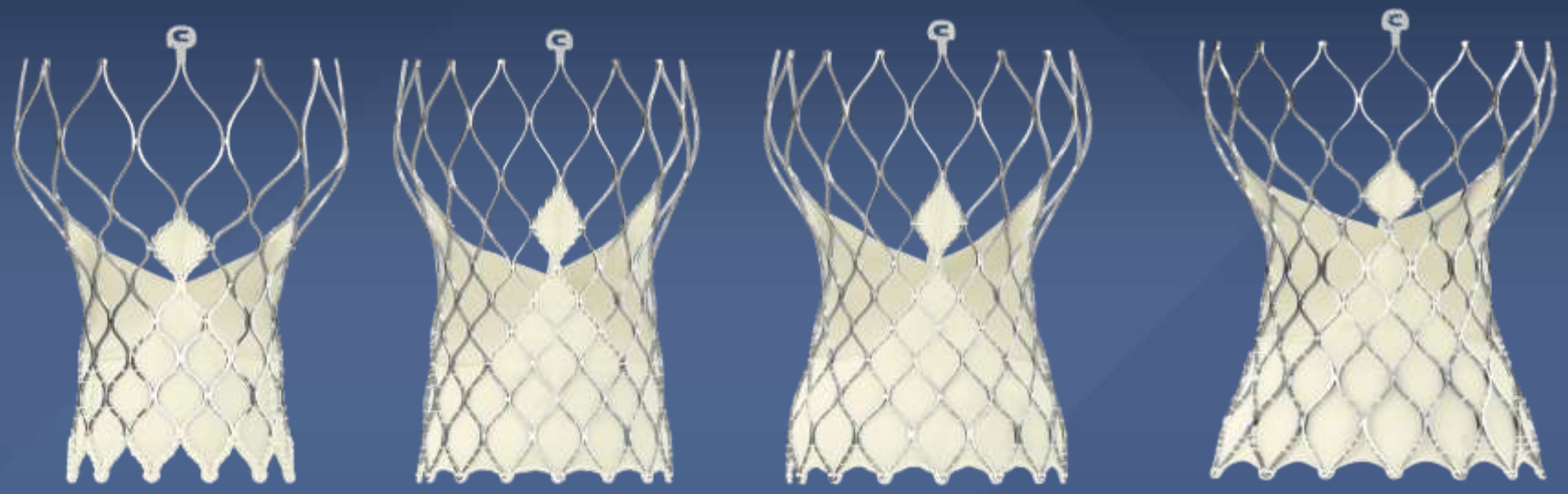


Evolut R : broader coverage of size

Indicated Size Range

Evolut R 23, 26, 29 mm
CE and FDA Approved

Evolut R 34 mm
Received IDA Approval

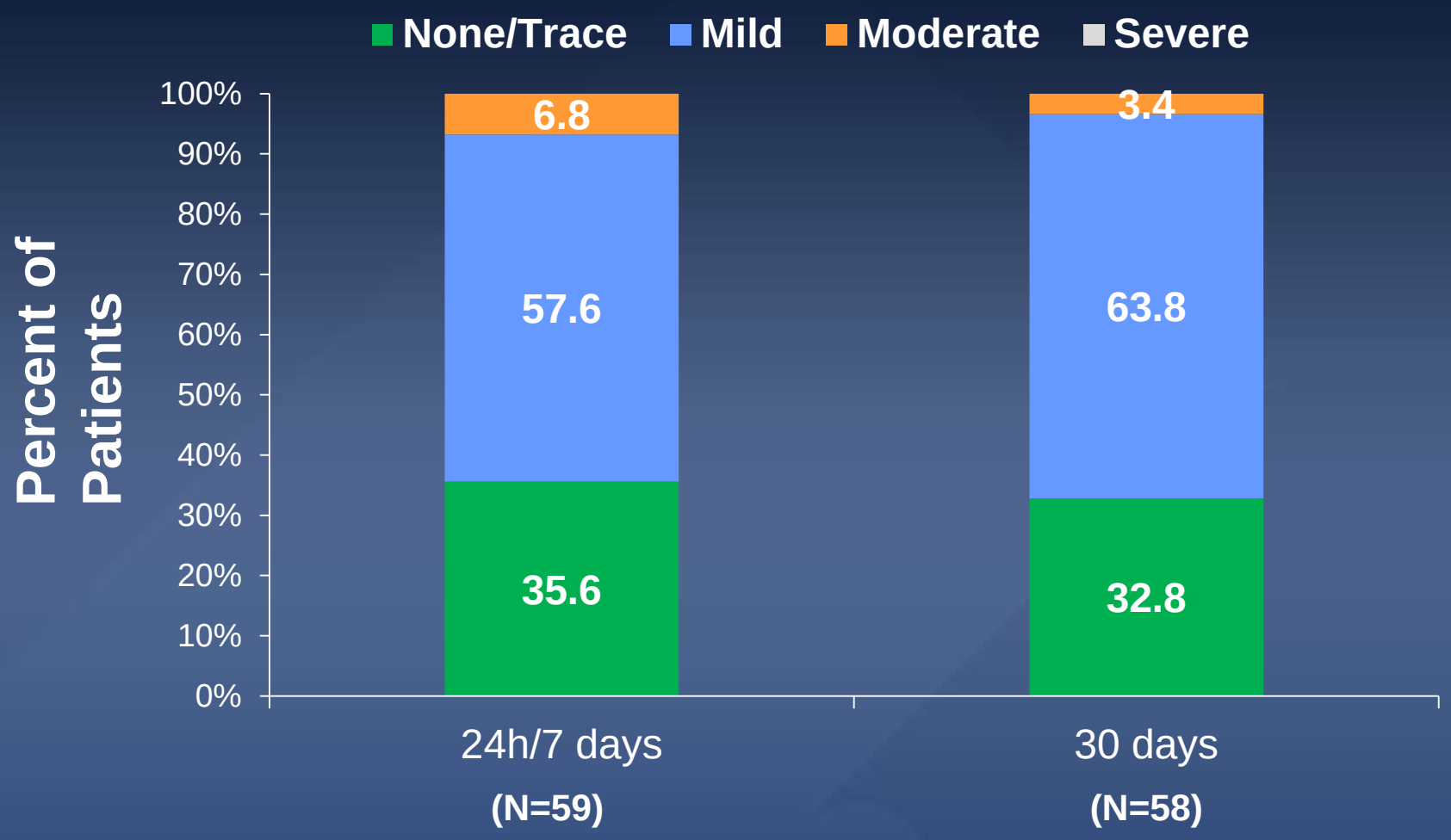


Evolut R 23 mm	Evolut R 26 mm	Evolut R 29 mm	Evolut R 34 mm

18 19 20 21 22 23 24 25 26 27 28 29 30

Patient Annulus Diameter Range (mm)

Less Paravalvular Leak with Evolut R

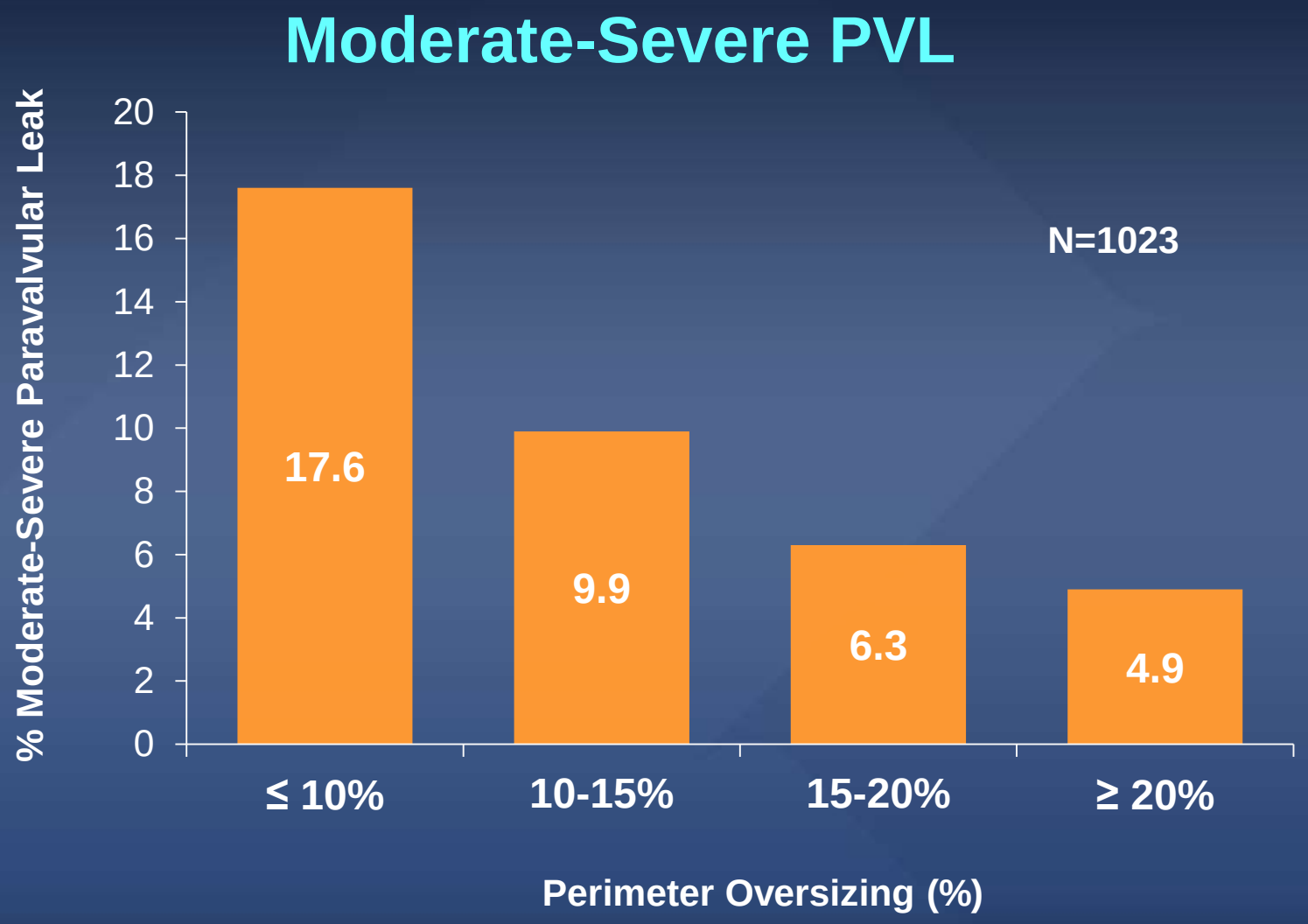


Manoharan et al. JACC Cardiovasc Interv. 2015

CVRF

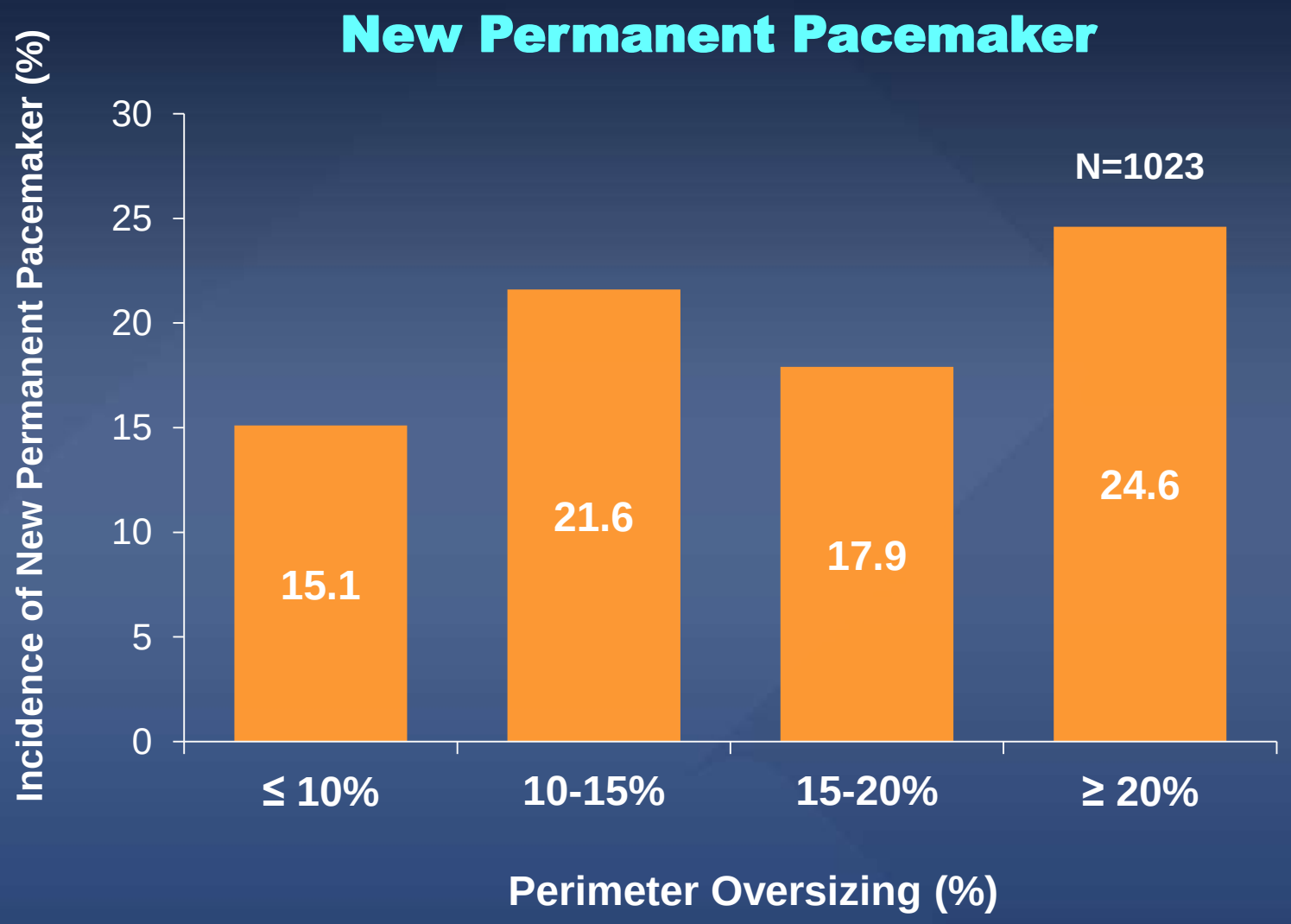
Perimeter Oversizing and Paravalvular Leak

Data from CoreValve US Clinical Trials



Perimeter Oversizing and Pacemaker

Data from CoreValve US Clinical Trials



Manufacuture's Recommendation
Evolut R

Device size (mm)	Annulus Diameter (mm)	Annulus Perimeter (mm)	Perimeter oversize (%)
23	18-20	56.5-62.8	**15.0 - 27.8**
26	20-23	62.8-72.2	**13.0 - 30.0**
29	23-**26**	72.2-**81.6**	**11.5 - 26.1**

Choose the Larger One for Borderline Case

Size Matters: Device Type and Oversizing

Diameter, mm	20.2	20.8	21.4	22.0	22.6	23.1	23.7	24.2	24.7	25.2	25.7	26.2	26.7	27.2	27.6	28.1	28.5	29.0	29.4
Area, mm^2	320	340	360	380	400	420	440	460	480	500	520	540	560	580	600	620	640	660	680

SAPIEN 3

Area oversize, %	23 mm	26.9	20	12.8	7.0	1.5	-3.3	-7.7											
	26 mm						23.6	18	14.8	8.0	3.8	-0.2	-3.9						
	29 mm													20.2	16	11.9	8.2	4.7	1.4	-1.7	-4.6

Evolut R

Perimeter oversize, %	26 mm	28.7	25.0	22	18.2	15	12.6												
	29 mm						25.5	22.4	19.8	17.4	15.1	12.8	10.7						

CVRF

How To Choose Valve Type (Balloon-Expandable vs Self-Expandable) in the TAVR Practice?

Mostly, depending on the physician's preference

1. Personal experience
2. Availability of device
3. Clinical and anatomical situations

Until recently, there is no clear-cut criteria favoring Specific type of device.

Valve Type Selection in AMC

- **Size Matters:** Select valve with size in the “Safety Zone”

- **Prefer SAPIEN 3**
  - Less annular/subannular calcification
  - Annulus eccentricity (less eccentric)

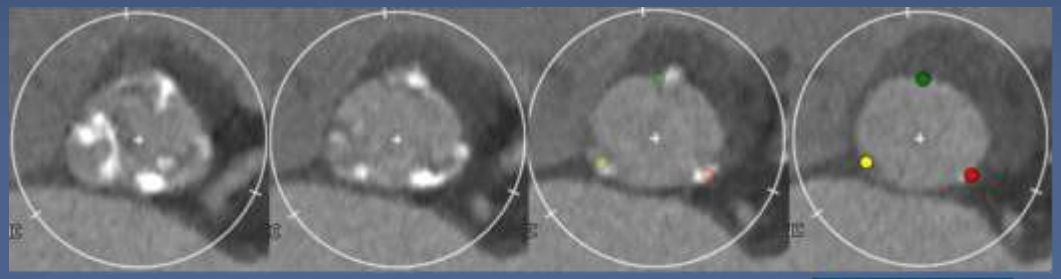
- **Prefer EVOLUTE R**
  - Severe heart failure (avoid rapid ventricular pacing)
  - Bicuspid valve with severe calcification
  - Low coronary height (<10 mm)
  - Larger annulus (>29 mm)
  - Smaller peripheral vessel diameter (<5.5 cm)

Lowest Delivery Profile

Valve Size	23mm	26mm	29mm
CoreValve Evolut R Device			
Minimum Vessel Diameter	5.0mm	5.0mm	5.0mm
Outer Diameter	with 14Fr-Equivalent InLine™ Sheath 18Fr True 18Fr (OD)		
Sapien 3 Device			
Minimum Vessel Diameter	5.5mm*	5.5mm*	6.0mm*
Inner Diameter Outer Diameter Expanded Outer Diameter	17.4Fr△ 14Fr 23Fr†	17.4Fr△ 14Fr 23Fr†	19.5Fr△ 16Fr 24.5Fr†

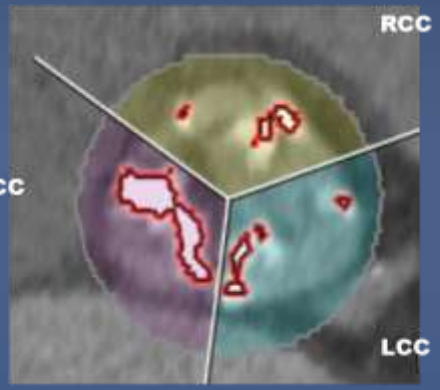
Case #1.

- 81/F, Severe AS
- LV EF 38%
- Aortic annular area = 455 mm2 / perimeter = 76.2 mm
- Moderate amount of calcium



Annulus plane

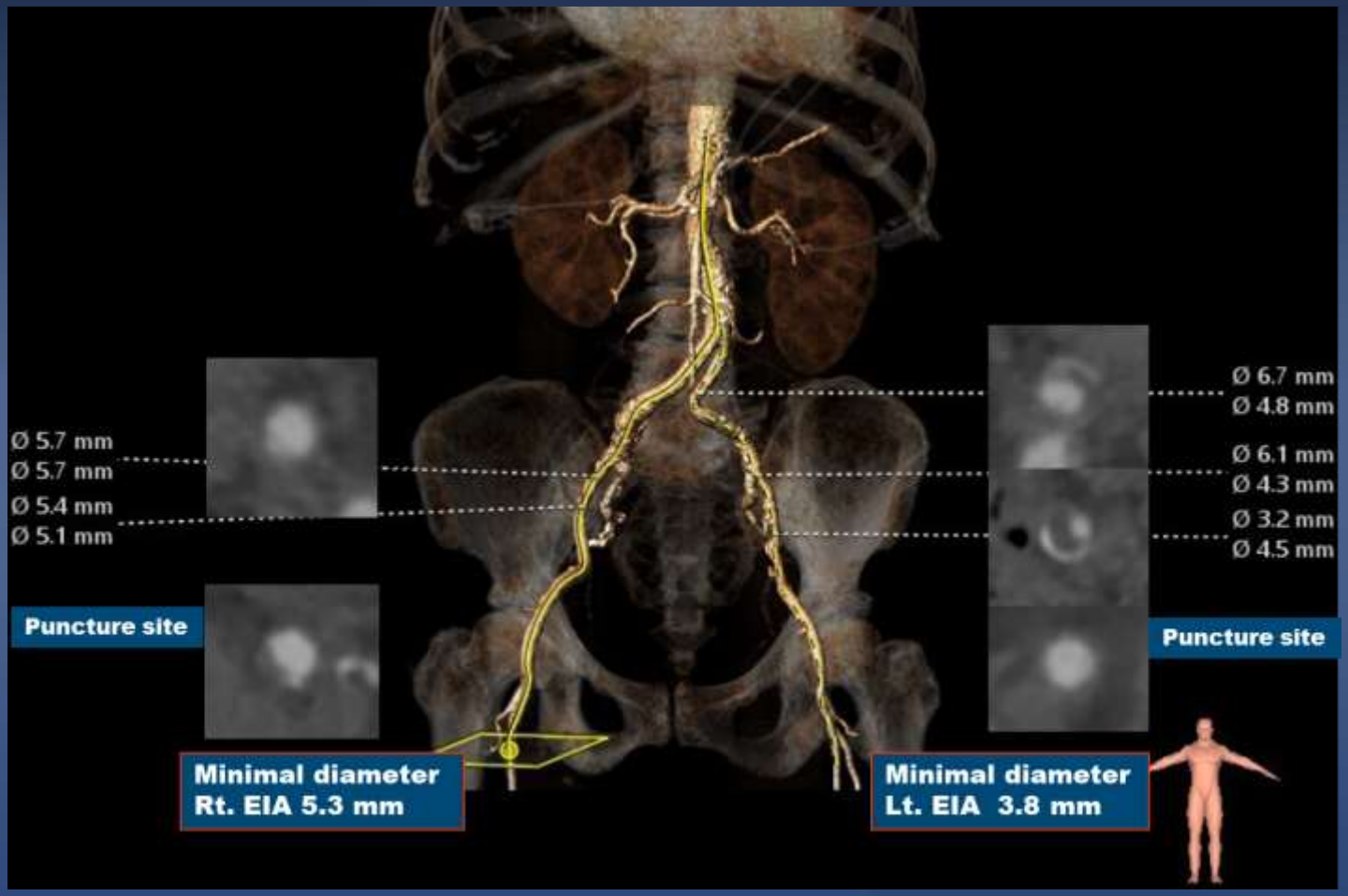
Aortic Annulus parameters	
Annulus short diameter	22.1 mm
Annulus long diameter	26.5 mm
Annululs mean diameter	24.3 mm
Annulus area	455 mm^2
Annulus area-driven diameter	24.1 mm
Annulus perimeter	76.2 mm
Annulus perimeter-driven diameter	24.3 mm



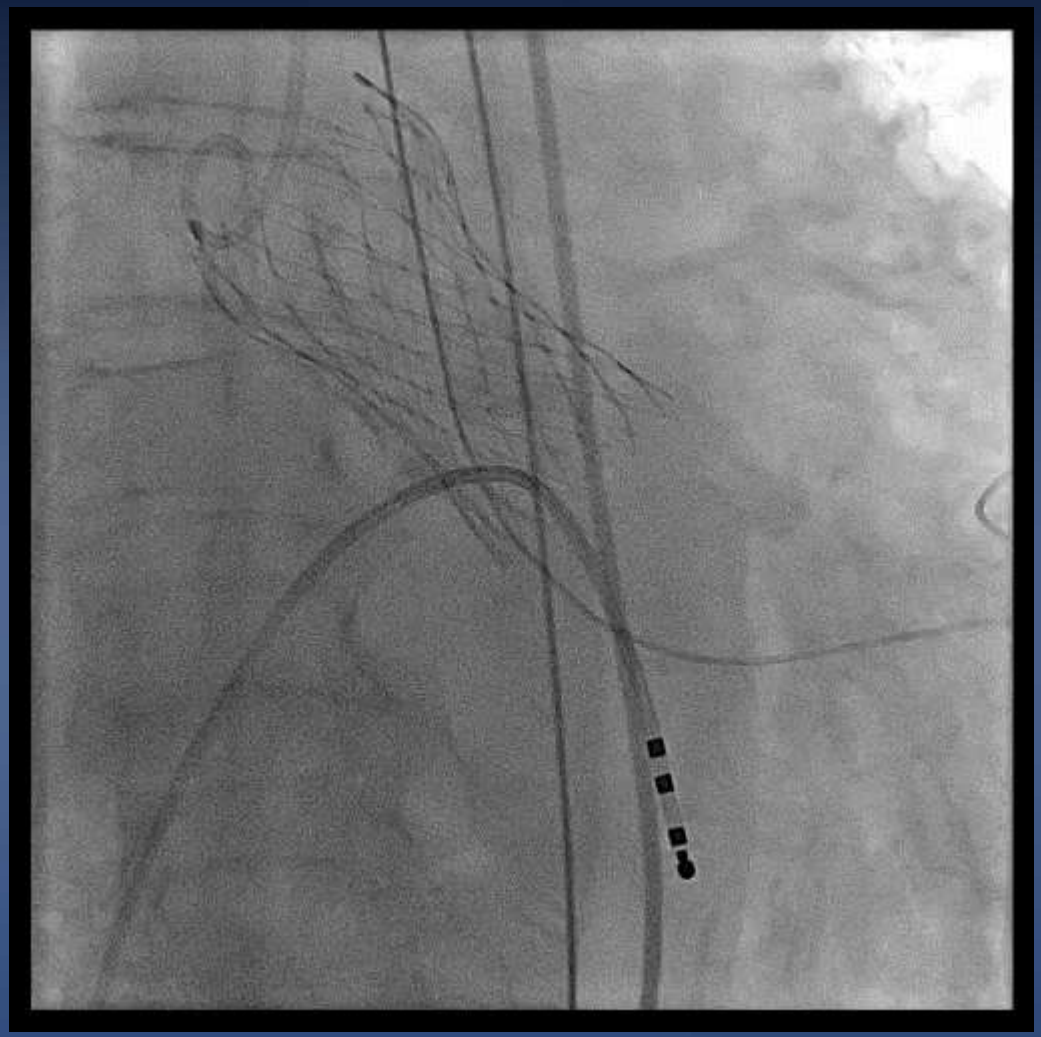
Calcium volume	
NCC	190 mm^3
RCC	58 mm^3
LCC	91 mm^3
Total	339 mm^3

Case #1.

Mimimal Rt.iliac artery diameter : 5.3mm



TAVR with Evolut R 29mm



Comparative Results

Balloon-Expandable vs. Self-Expandable

CHOICE Trial

CHOICE trial

Balloon-expandable SAPIEN XT (N=121)

Self-expandable CoreValve (N=120)

To assess the comparative performance of both technologies regarding overall device success in high-risk patients with severe aortic stenosis

Abdel-Wahab M, Mehilli J, Frerker C et al. JAMA 2014

CHOICE Trial : Procedural Details

Characteristic	Balloon-expandable Valve N=121	Self-expandable Valve N=120	P Value
Balloon predilatation, %	100	88.3	< 0.001
Percent oversizing, %			
TEE diameter, %	12.8	17.7	< 0.001
MDCT diameter, %	9.6	15.8	< 0.001
MDCT area, %	19.5	30.8	< 0.001
MDCT perimeter, %	7.2	14.8	< 0.001
Balloon postdilatation, %	19.8	49.2	< 0.001
Implant of ≥ 2 valves	0.8	5.8	0.03

Abdel-Wahab M, Mehilli J, Frerker C et al. JAMA 2014

CHOICE Trial : Procedural Outcome

	Balloon-expandable Valve N=121	Self-expandable Valve N=120	P Value
Immediate procedural mortality, %	0	0	
Final aortic regurgitation			
Angiography, %			
Moderate	**3.3**	**14.1**	**< 0.001**
Severe	**0.8**	**4.2**	
Echocardiography, %			
Moderate	**0.8**	**5.8**	**< 0.005**
Severe	**0.8**	**0**	

Abdel-Wahab M, Mehilli J, Frerker C et al. JAMA 2014

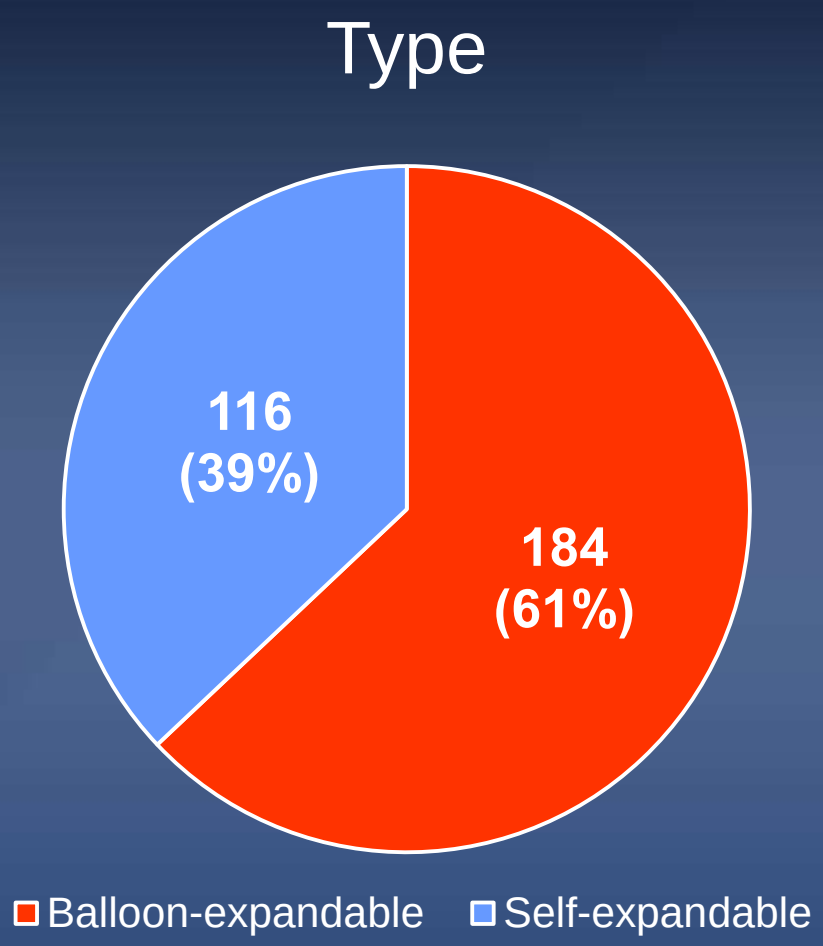
CHOICE Trial

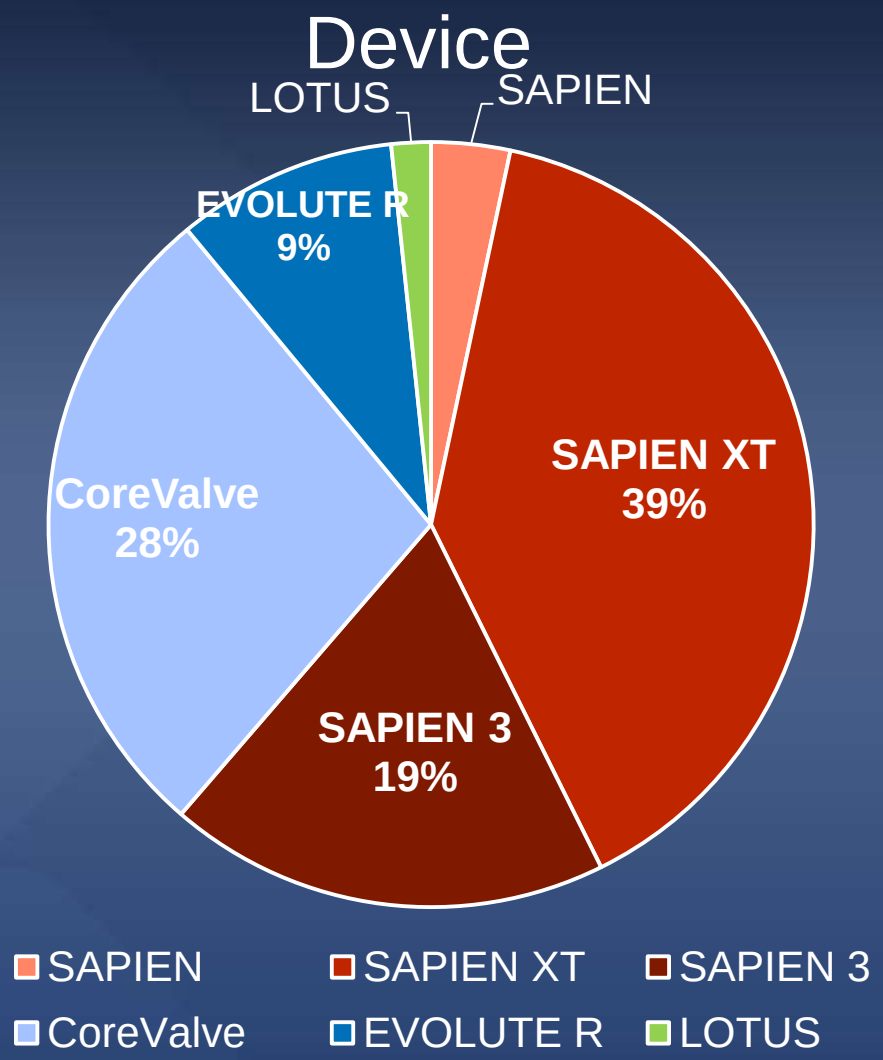
	Balloon-expandable Valve N=121	Self-expandable Valve N=120	P Value
Device success (primary endpoint)	**95.9**	**77.5**	**< 0.001**
30-day clinical outcomes			
Death, %			
Any cause	4.1	5.1	0.77
Cardiovascular causes	4.1	4.3	0.99
Stroke	5.8	2.6	0.33
Life threatening bleeding	8.3	12.0	0.35
Vascular complications	14.0	12.8	0.78
Rehospitalization for heart failure	0.0	4.3	0.02
NYHA class improvement	94.3	86.7	0.06
New permanent pacemaker	**17.3**	**37.6**	**0.001**

Abdel-Wahab M, Mehilli J, Frerker C et al. JAMA 2014

TAVR in Asan Medical Center (N=300)

TAVR Device Proportion





TAVR in AMC
Baseline Characteristics

	Overall (N = 300)	SAPIEN (N = 184)	CoreValve (N = 111)	p value
Age	78.6 ± 5.0	78.4 ± 5.0	78.5 ± 5.1	0.80
Male sex	147 (49.0)	89 (48.4)	55 (49.5)	0.84
BMI, kg/m^2	24.0 ± 3.3	24.1 ± 3.5	23.9 ± 3.1	0.65
STS risk score (%)	4.5 ± 5.0	4.8 ± 5.9	4.2 ± 2.8	0.36
NYHA class III or IV	66 (22.0)	39 (21.2)	28 (25.2)	0.42
CAD	123 (41.0)	69 (37.5)	53 (47.7)	0.08
Previous MI	16 (5.3)	11 (6.0)	5 (4.5)	0.59
Previous stroke	29 (9.7)	21 (11.4)	7 (6.3)	0.15
PVD	20 (6.7)	14 (7.6)	6 (5.4)	0.47

TAVR in AMC
Baseline Characteristics

	Overall (N = 300)	SAPIEN (N = 184)	CoreValve (N = 111)	p value
DM	99 (33.0)	63 (34.2)	34 (30.6)	0.52
HTN	263 (87.7)	163 (88.6)	95 (85.6)	0.45
COPD	53 (17.7)	25 (13.6)	28 (25.2)	0.01
CRF	100 (33.3)	64 (34.8)	35 (31.5)	0.57
Atrial fibrillation	26 (8.7)	13 (7.1)	12 (10.8)	0.26
Aortic-valve area — cm2	0.61 ± 0.16	0.62 ± 0.17	0.59 ± 0.15	0.14
Mean gradient — mm Hg	60.7 ± 21.6	59.6 ± 21.8	62.2 ± 21.3	0.33
LVEF, %	58.4 ± 10.8	58.9 ± 10.3	57.5 ± 11.8	0.30
Bicuspid AV	9(3.0)	4 (2.2)	5 (4.5)	0.26
MR, moderate to severe	36 (12.0)	23 (12.5)	13 (11.7)	0.84

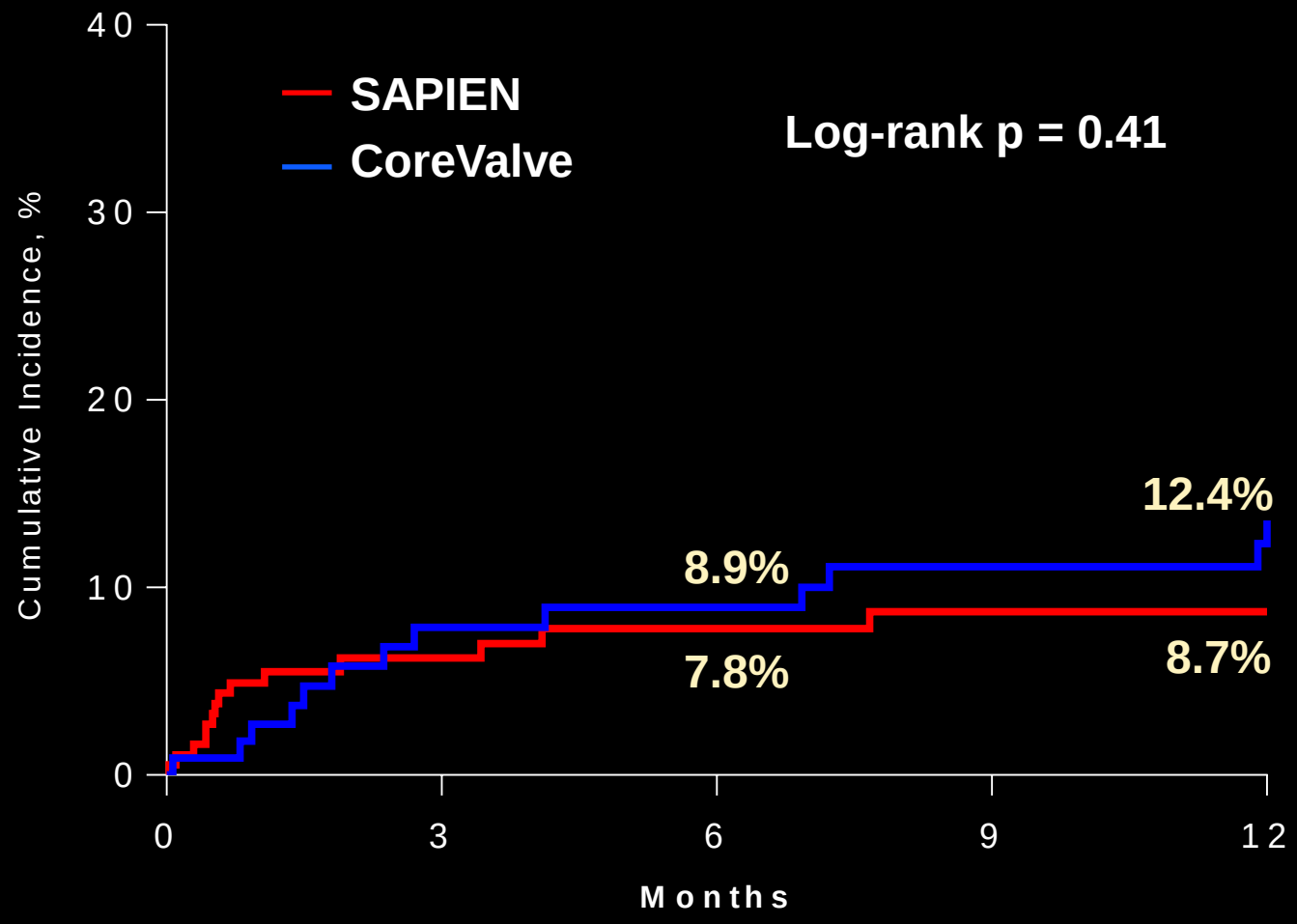
TAVR in AMC
CT Data

	Overall (N = 300)	SAPIEN (N = 184)	CoreValve (N = 111)	p value
Minimal annular diameter, mm	21.1 ± 2.2	21.2 ± 2.1	21.0 ± 2.4	0.53
Maximal annular diameter, mm	26.5 ± 2.6	26.6 ± 2.6	26.4 ± 2.7	0.73
Annulus area, mm^2	437.8 ± 80.3	438.2 ± 78.6	435.6 ± 84.7	0.80
Perimeter, mm	75.7 ± 6.6	75.8 ± 6.3	75.5 ± 7.2	0.75
Total calcium volume	367.8 ± 315.8	313.2 ± 240.6	492.7 ± 419.8	0.004
NCC cusp	173.5 ± 178.6	146.8 ± 136.7	232.6 ± 242.2	0.014
RCC cusp	107.5 ± 120.3	86.3 ± 81.2	157.5 ± 173.4	0.004
LCC cusp	91.8 ± 99.7	86.0 ± 95.2	102.6 ± 103.7	0.29

TAVR in AMC
Procedural Outcomes

	Overall (N = 300)	SAPIEN (N =182)	CoreValve (N =110)	p value
Procedural success	292 (97.3)	179 (97.3)	108 (97.3)	0.99
Conversion to surgery	5 (1.7)	3 (1.6)	2 (1.8)	0.91
Coronary obstruction	1 (0.3)	1 (0.6)	0	0.43
Implantation of two valves	11 (3.7)	2 (1.1)	9 (8.1)	0.002
New permanent pacemaker	30 (10.0)	5 (2.7)	23 (20.7)	<0.001
Paravalvular leakage ≥ moderate	39 (13.0)	15 (8.2)	24 (21.6)	0.001
Device success	288 (96.0)	177 (96.2)	106 (95.5)	0.64
Major vascular complication	17 (5.7)	9 (5.0)	7 (6.4)	0.63

1-Year Death or Disabling Stroke
SAPIEN vs CoreValve



In Summary, How We Choose?

- Selection of specific TAVR valve is based on several clinical and anatomical factors.
- Optimal image acquisition and imaging-based personalized approach is helpful for decision-making of specific valve type.
- Optimal valve selection between balloon-expandable and self-expandable may improve procedural and long-term clinical outcomes of TAVR.