

Selection of Device Size Based on MDCT Assessment

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Size Selection for Balloon-expandable Valve

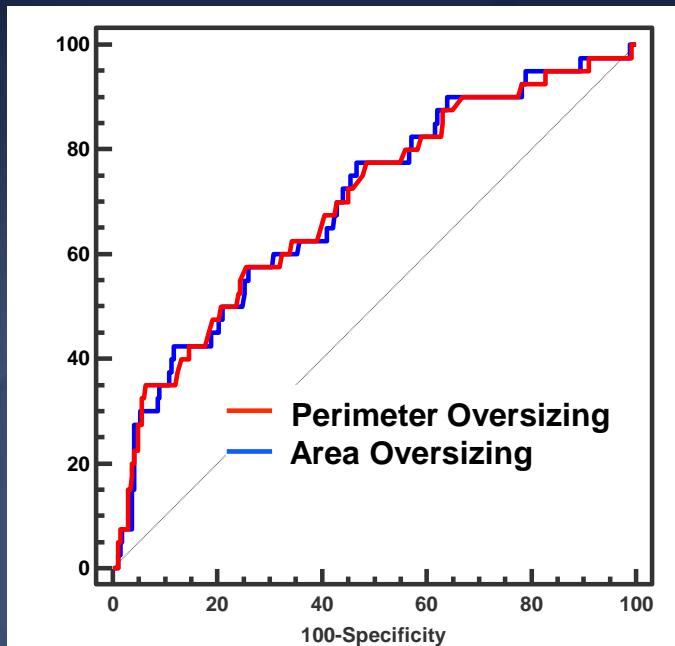
SAPIEN XT



SAPIEN 3

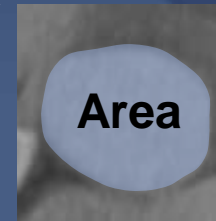


Area Oversizing Predicted Paravalvular Leakage for **SAPIEN XT**



	AUC	95% CI
Area oversizing	0.70	0.64–0.75
Perimeter oversizing	0.70	0.64–0.75

(N=306)



Cut-off point of **Area Oversizing** : **10%**

Oversizing is important but...

Predictors for Annulus Rupture

	OR (95% CI)	P value
Device Area / CT Area \geq 20%	8.38 (2.67-26.33)	< 0.001
Moderate/ Severe LVOT calcification	10.92 (3.23-36.91)	< 0.001

31 patients experienced annulus rupture during TAVI were matched control patients. Logistic regression analysis identified device area oversizing \geq 20% and moderate/severe LVOT calcification as predictor for annulus rupture.

Optimal Target for Area Oversizing : **SAPIEN XT**

10%

15%

20%

**Paravalvular
leakage**

Optimal

**Annulus
Rupture**

- Under-filling technique
- Post-dilatation

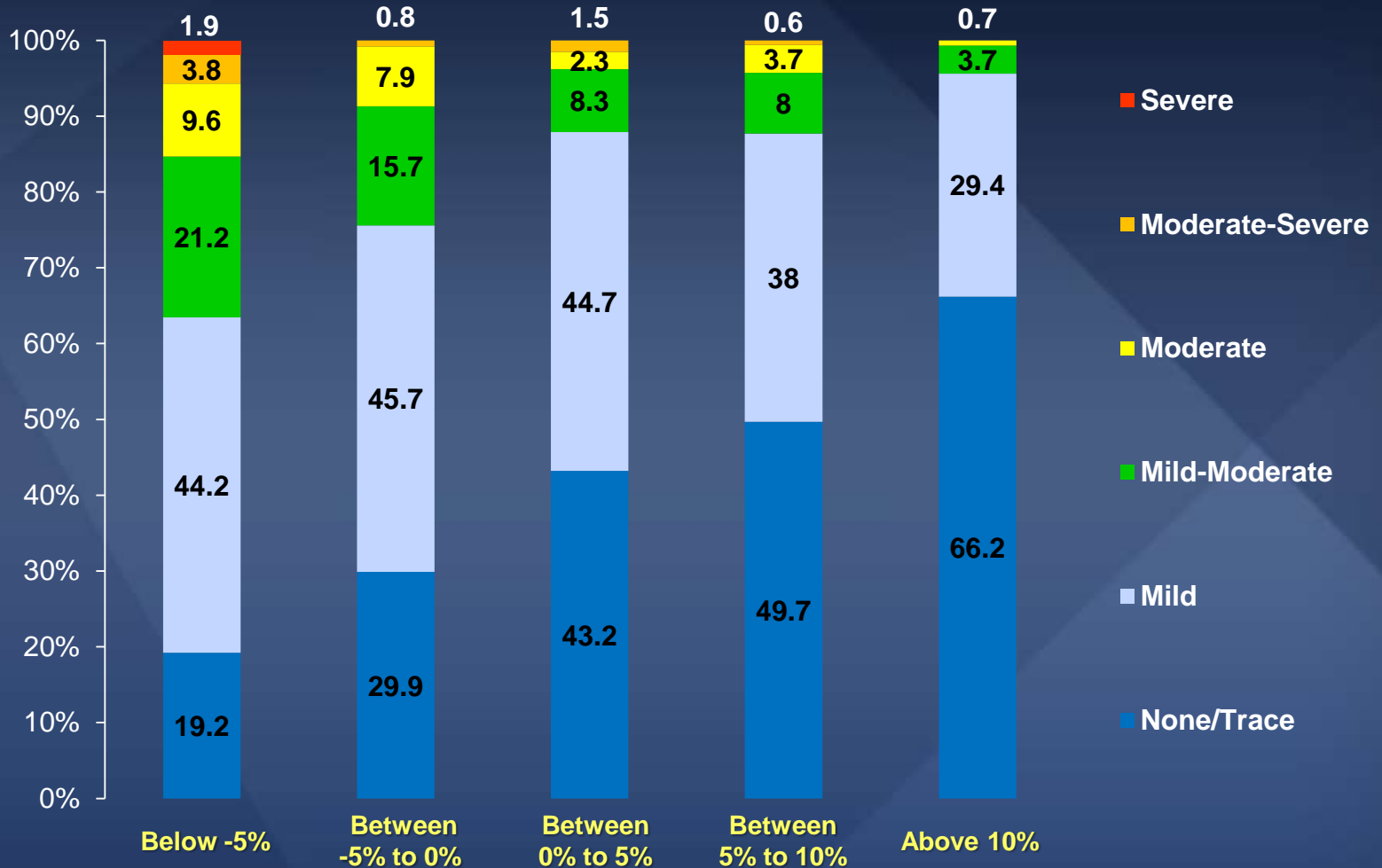
SAPIEN 3





Paravalvular Leak by Area Oversizing

Data from PARTNER trial

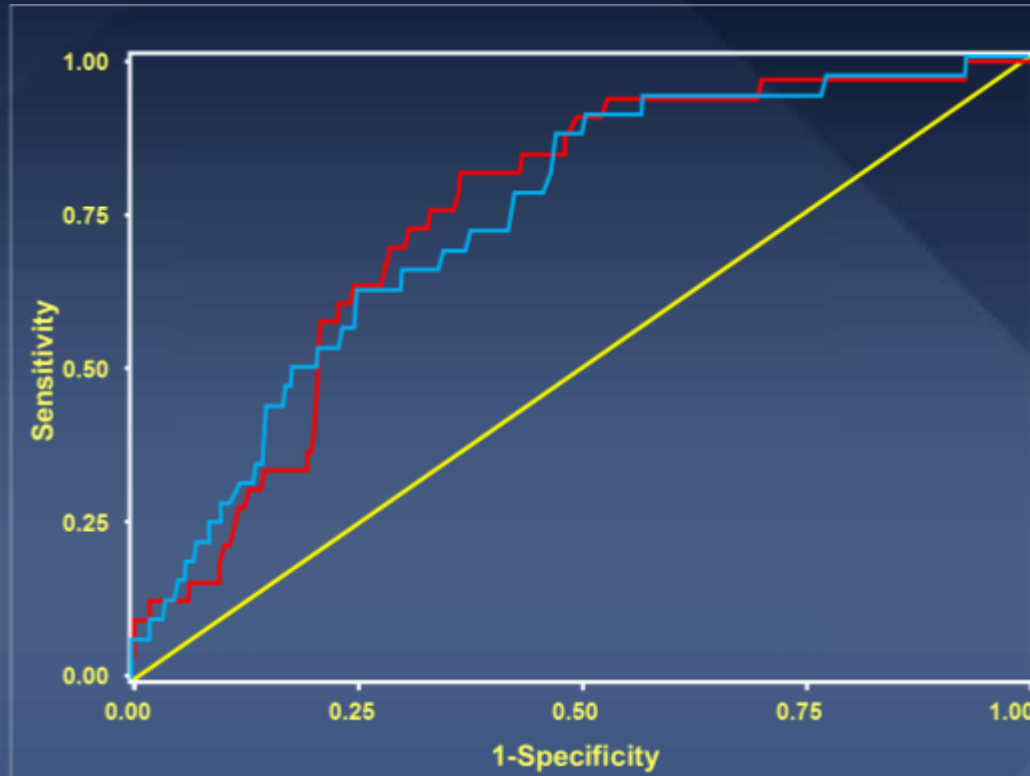


No annular rupture



New Concept for S3 Sizing

Data from PARTNER trial



Predictor for PAR	AUC [95% CI]	Optimal Cutoff	Sensitivity	Specificity	p-value
Area oversizing, %	0.74 [0.66,0.82]	0.05	.6364	.7495	<0.0001
Perimeter oversizing, %	0.75 [0.67,0.82]	-0.10	.8182	.8362	<0.0001

Oversizing and LBBB/PPM

Independent Predictors

	OR (95% CI)	P value
Low implantation, % of frame	1.06 (1.017-1.110)	0.006
Extreme Oversizing	3.489 (1.236-9.848)	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.

Optimal Target for Area Oversizing : **SAPIEN 3**

0%

5 - 15%

20%

**Paravalvular
leakage**

Optimal

**Annulus
Rupture**

PPM

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																						
23 mm																						
Area oversize, %	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			

• ~~Under-filling strategy~~

Choose the Smaller One for Borderline Case

Size Selection for Self-expandable Valve

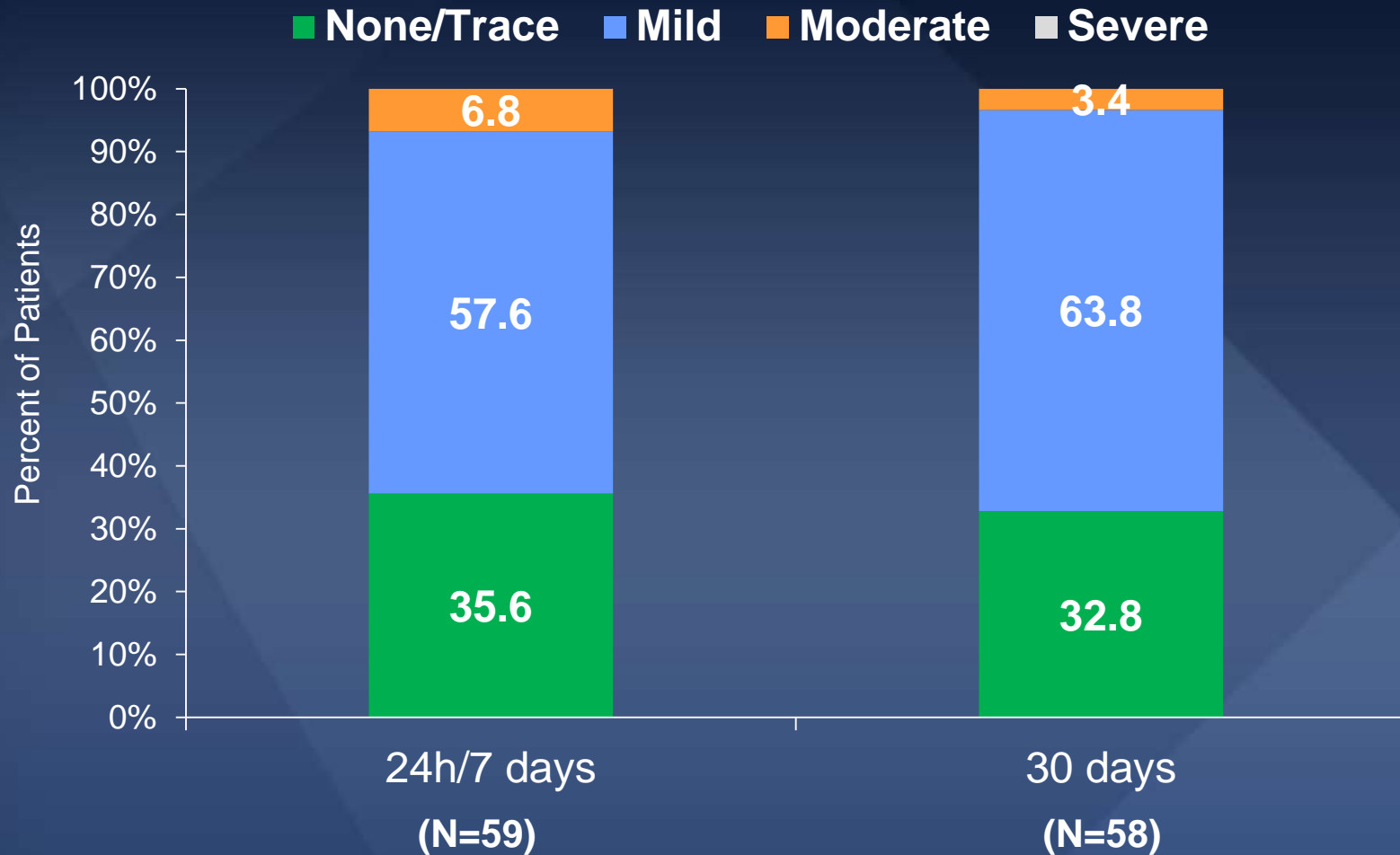
CoreValve



Evolut R



Less Paravalvular Leak with Evolut R



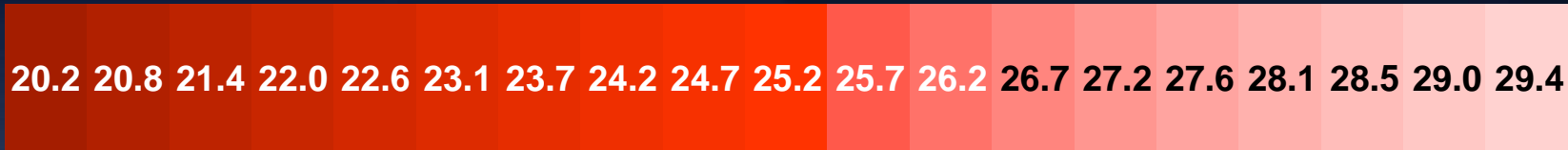
Manufacture's Recommendation

CoreValve

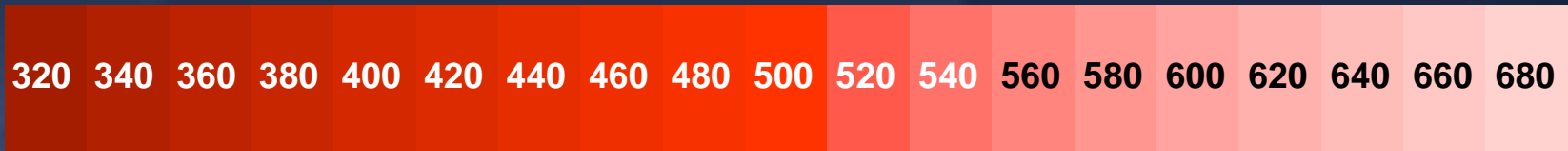
Device size (mm)	Annulus Diameter (mm)	Annulus Perimeter (mm)	Perimeter oversize
23	18-20	56.5-62.8	15.0 - 27.8
26	20-23	62.8-72.2	13.0 - 30.0
29	23-27	72.2-84.8	7.4 - 26.1
31	26-29	81.6-91.1	6.9 - 19.2

Device Type and Oversizing

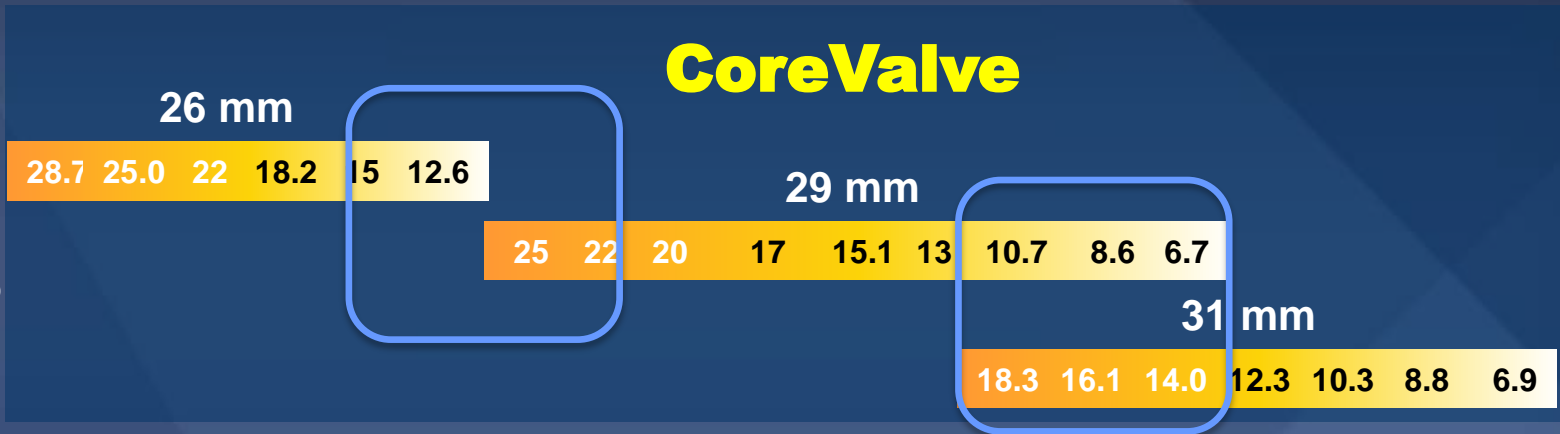
Diameter, mm



Area, mm²



Perimeter oversize, %

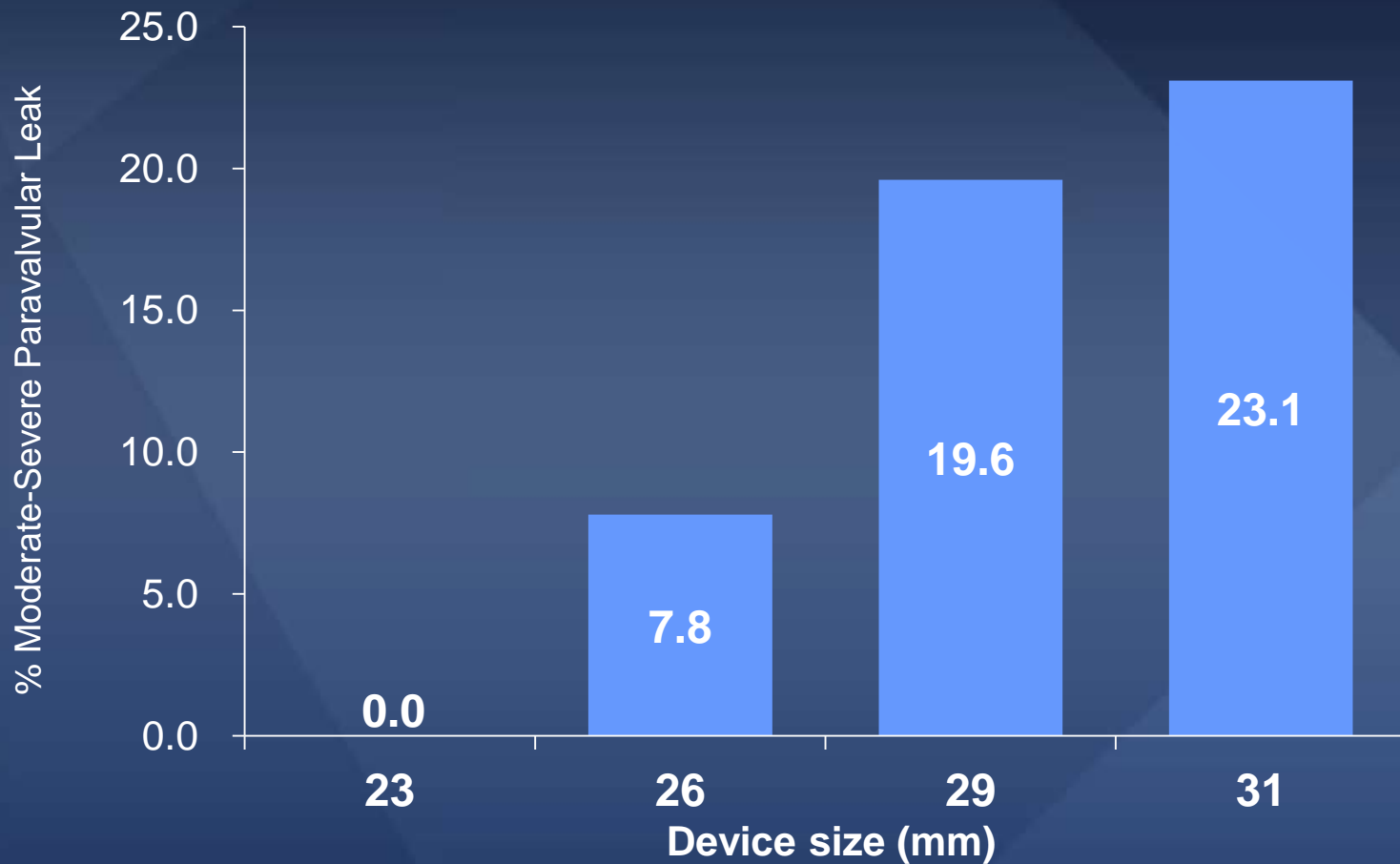


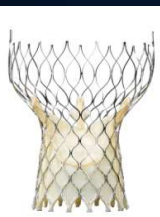


Device Size and Paravalvular Leak CoreValve

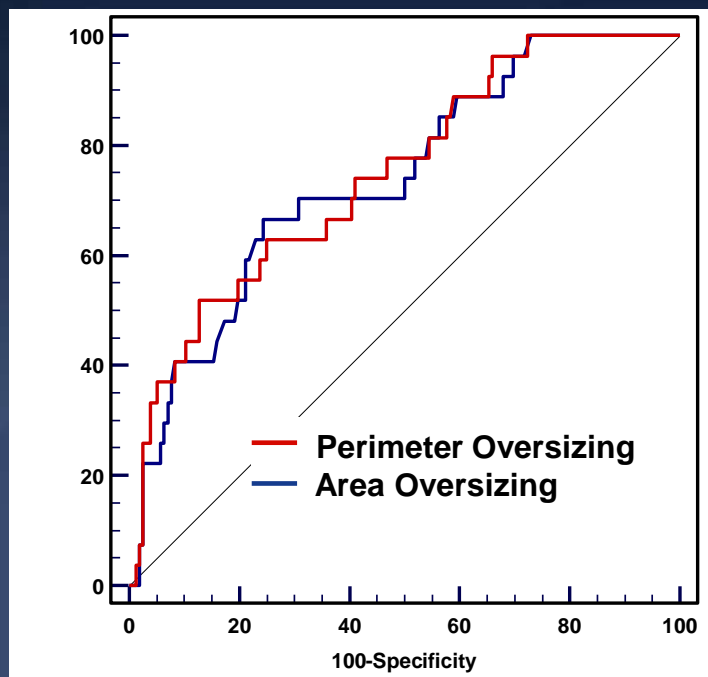
Moderate-Severe PVL

N=183



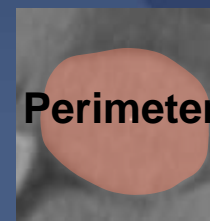


Perimeter Oversizing Predicted Paravalvular Leakage for CoreValve



	AUC	95% CI
Perimeter oversizing	0.74	0.64–0.86
Area oversizing	0.75	0.65–0.86

N=183



Cut-off point of Perimeter Oversizing : **13%**

Manufacture's Recommendation

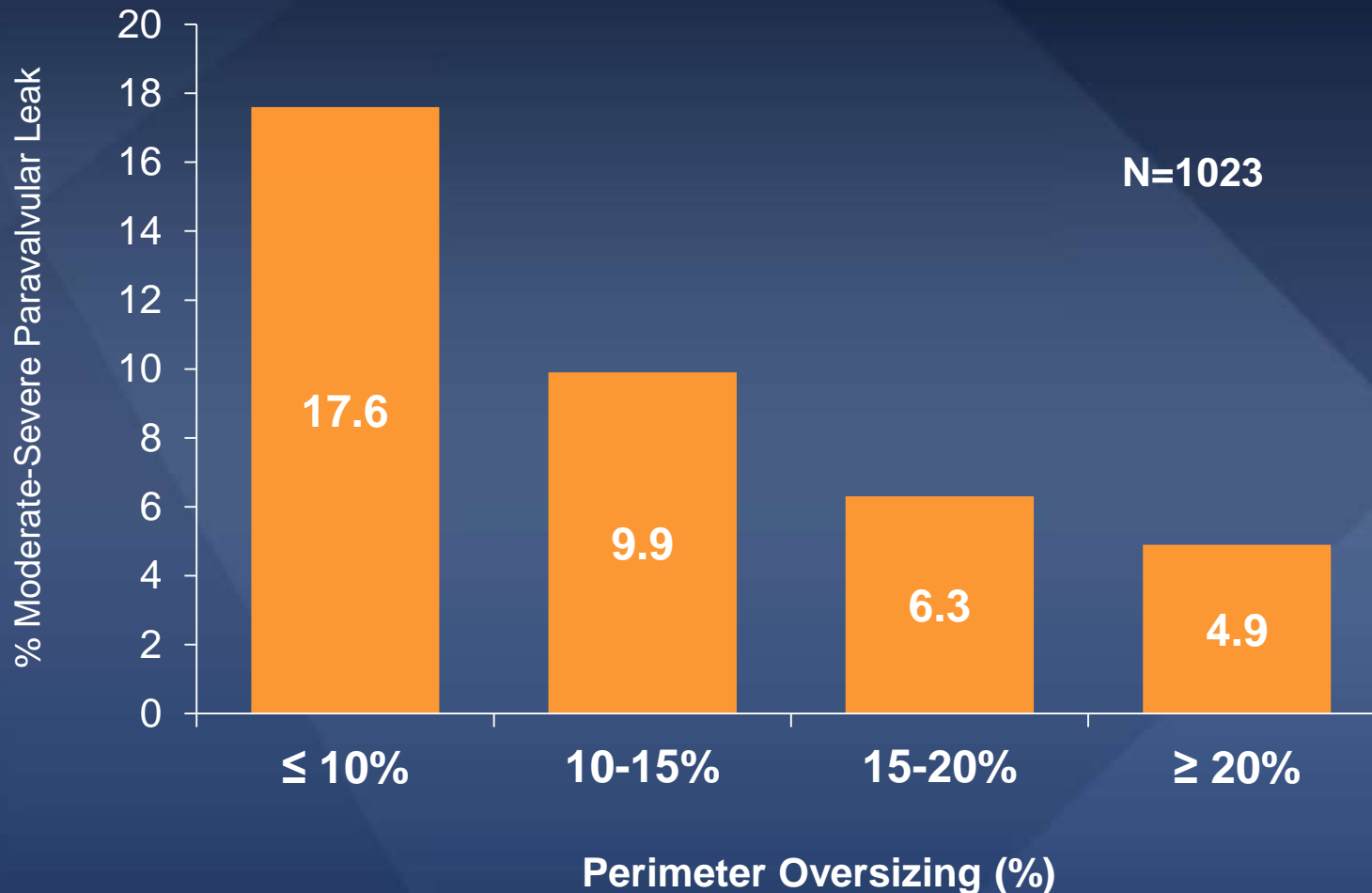
CoreValve

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	23-27	72.2-84.8	7.4 - 26.1
31	26-29	81.6-91.1	6.9 - 19.2

Perimeter Oversizing and Paravalvular Leak

Data from CoreValve US Clinical Trials

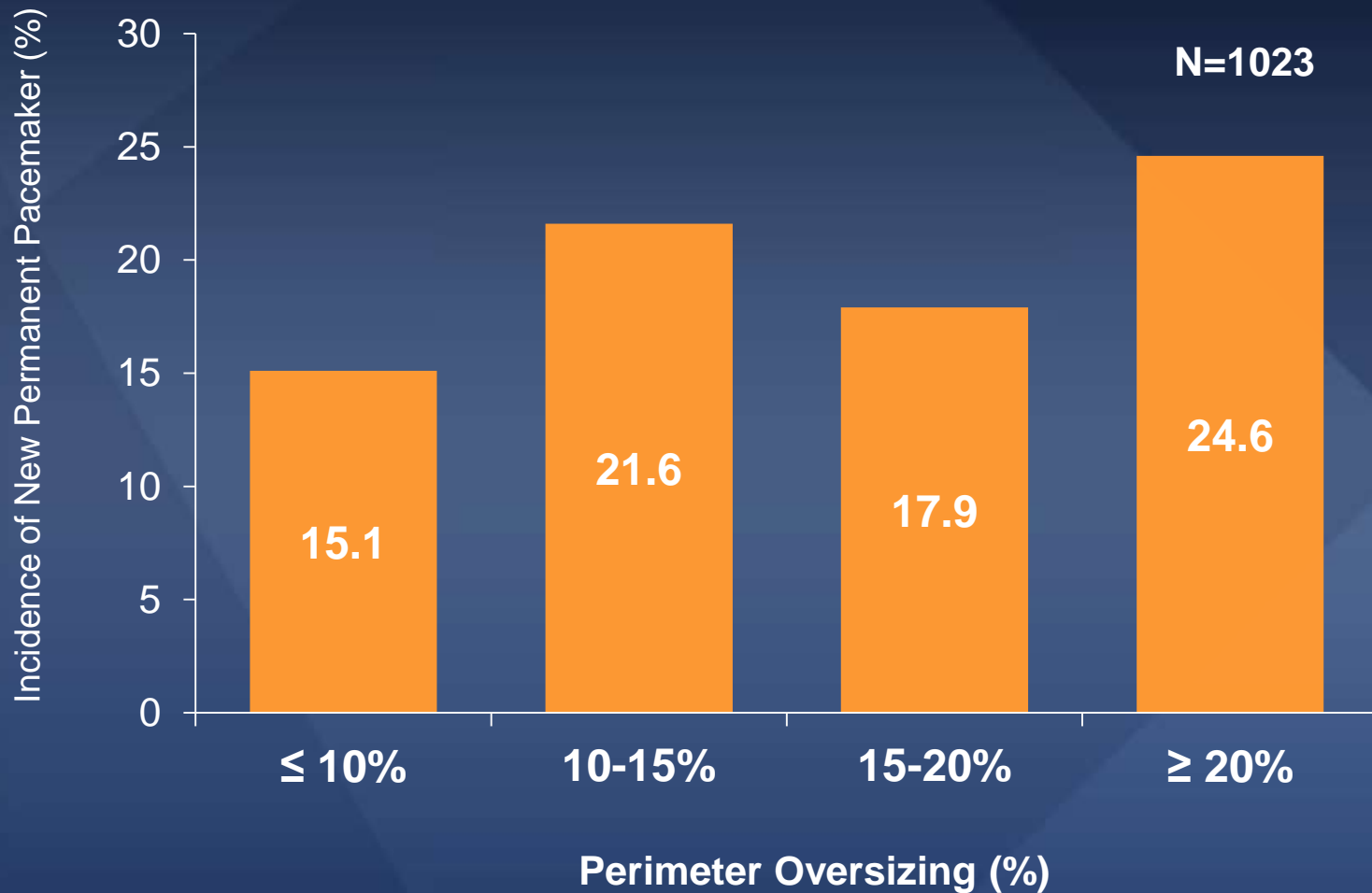
Moderate-Severe Paravalvular Leak



Perimeter Oversizing and Pacemaker

Data from CoreValve US Clinical Trials

New Permanent Pacemaker



Manufacture'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

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
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Area, mm ²	320	340	360	380	400	420	440	460	480	500	520	540	560	580	600	620	640	660	680
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SAPIEN 3

23 mm

26.9	20	12.8	7.0	1.5	-3.3	-7.7
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26 mm

23.6	18	14.8	8.0	3.8	-0.2	-3.9
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29 mm

20.2	16	11.9	8.2	4.7	1.4	-1.7	-4.6
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Area
oversize, %

Evolut R

26 mm

28.7	25.0	22	18.2	15	12.6
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29 mm

25.5	22.4	19.8	17.4	15.1	12.8	10.7
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Perimeter
oversize, %

Conclusion

1. *SAPIEN 3* has a wider range of target annulus size, requiring less degree oversizing compared to *SAPIEN/XT*
 - *Less Paravalvular Leak*
 - *Lower Risk of Annulus Rupture*
2. Redesigned *Evolut R* with retrievable system
 - *Less Paravalvular Leak*
3. For borderline cases
 - choose the *Smaller one for SAPIEN 3*
 - choose the *Larger one for Evolut R*
4. Both device covers almost all range of annulus size, and device selection will be operator's preference