

TAVR for Bicuspid Aortic Valve Stenosis

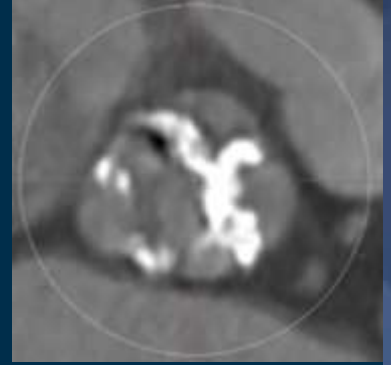
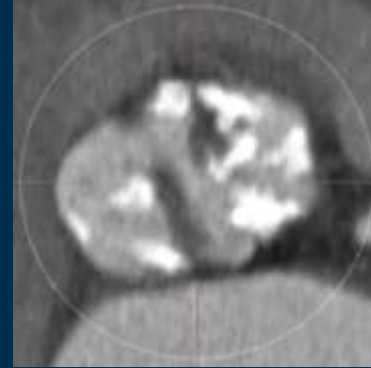
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Challenges of TAVR in BAV

Anatomical Features

- Heavily calcified leaflet
- Calcified raphe
- Elliptical and larger annulus
- Dilated and/or horizontal aorta
- Lack of standardized annulus measurements



Current Evidence of TAVR in BAV

	Mylotte ¹		Yousef ²
	Sapien (n=48)	CoreValve (n=91)	All* (n=108)
Age, years	78 ± 10	78 ± 8	76 ± 14
STS (%)	5.0 ± 3.9	4.8 ± 3.1	–
Log EuroSCORE (%)	15.3 ± 10.7	14.5 ± 10.7	17.2 ± 12.2
Post AR ≥ mild (%)	19.6	32.2	25.2
Post AR ≥ moderate (%)	6.5	5.5	9.6
PPM (%)	6.5	5.5	19.4
30-day mortality (%)	6.3	4.9	8.3
1-year mortality (%)	20.8	12.5	16.9

¹Mylotte, et al., *JACC* 2014; 64: 2330-39;

²Yousef, et al., *Int J Cardiol* 2015; 189: 282-8

*Sapien (n=61) and CoreValve (n=47)

Remaining Issues

1. Relatively younger and lower-risk group

*Direct Comparison of Outcomes After TAVR
in **Bicuspid vs. Tricuspid AS***

2. *Evolution of TAVR devices*

*New-generation devices (**SAPIEN 3 and Lotus**) vs.
Old-generation devices (SAPIEN XT and CoreValve)*

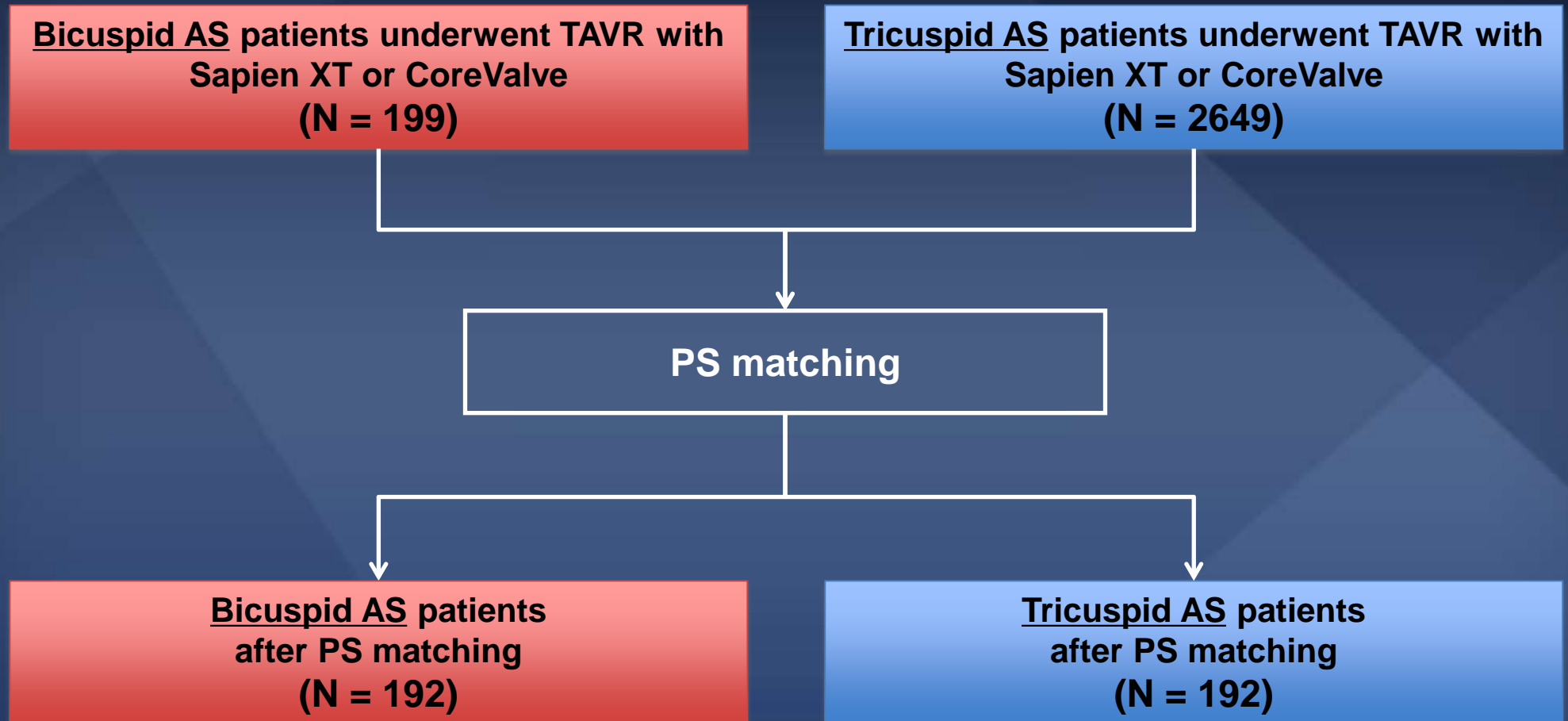
Bicuspid TAVR Registry

NCT 02394184

Total (n=301)	Old-generation devices (n=199)	
	Sapien XT (n=87)	CoreValve (n=112)

20 centers from 14 countries
in Europe, North America and Asia-Pacific

Outcomes of TAVR in Bicuspid vs. Tricuspid AS



TAVR in Bicuspid vs. Tricuspid AS

Baseline Characteristics

	Bicuspid AS (N = 199)	Tricuspid AS (N = 2649)	p value
Age	77.0±8.9	82.0±6.4	< 0.001
Male	64.8%	48.0%	< 0.001
NYHA class III/IV	74.4%	76.5%	0.49
Logistic EuroSCORE	15.0±11.2	16.8±11.8	0.03
STS score	4.6±5.1	5.7±5.2	0.02
Diabetes mellitus	20.6%	26.5%	0.07
Hypertension	60.3%	73.4%	< 0.001
Previous stroke	15.1%	10.9%	0.07
Peripheral vascular disease	11.1%	16.8%	0.03
Previous PCI	19.1%	27.6%	0.009
Previous CABG	7.5%	13.8%	0.01
LVEF, %	53±15	55±13	0.06

TAVR in Bicuspid vs. Tricuspid AS

Procedural Outcomes

	Bicuspid AS (N = 199)	Tricuspid AS (N = 2649)	p value
Procedural related death	1.5%	1.5%	> 0.99
Annulus rupture	2.0%	0.5%	0.02
Second valve implantation	6.5%	3.0%	0.006
New PPM	13.1%	13.9%	0.76
Post-AR > mild	17.6%	10.9%	0.004
Device success	72.9%	85.0%	< 0.001

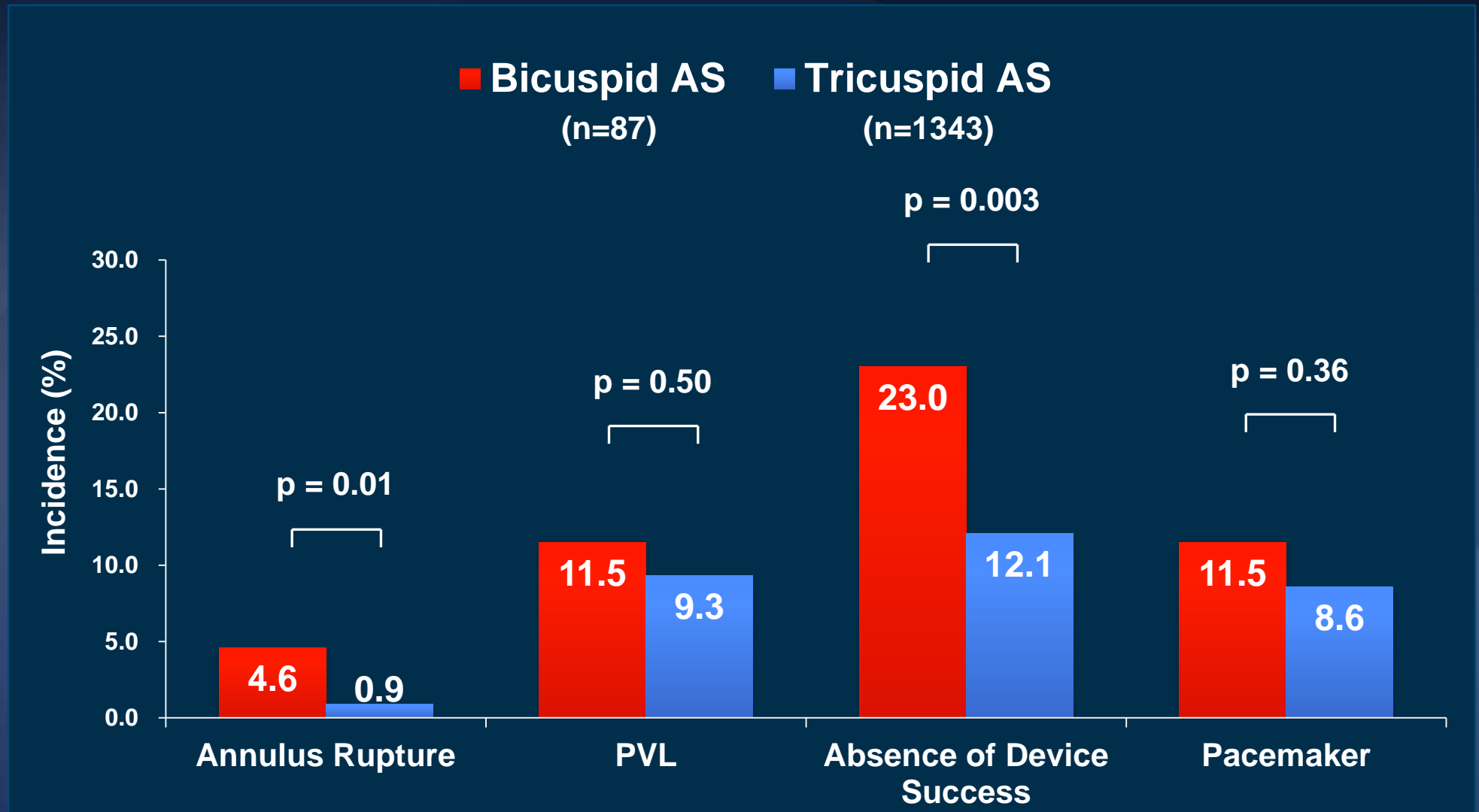
TAVR in Bicuspid vs. Tricuspid AS

30-day Outcomes

	Bicuspid AS (N = 199)	Tricuspid AS (N = 2649)	p value
All stroke	2.5%	2.0%	0.60
Life-threatening bleeding	3.5%	6.5%	0.10
Major vascular complications	4.5%	6.6%	0.24
AKI stage 2-3	2.5%	3.1%	0.63
Early safety endpoints	15.1%	17.4%	0.41
30-day mortality	4.5%	4.9%	0.79

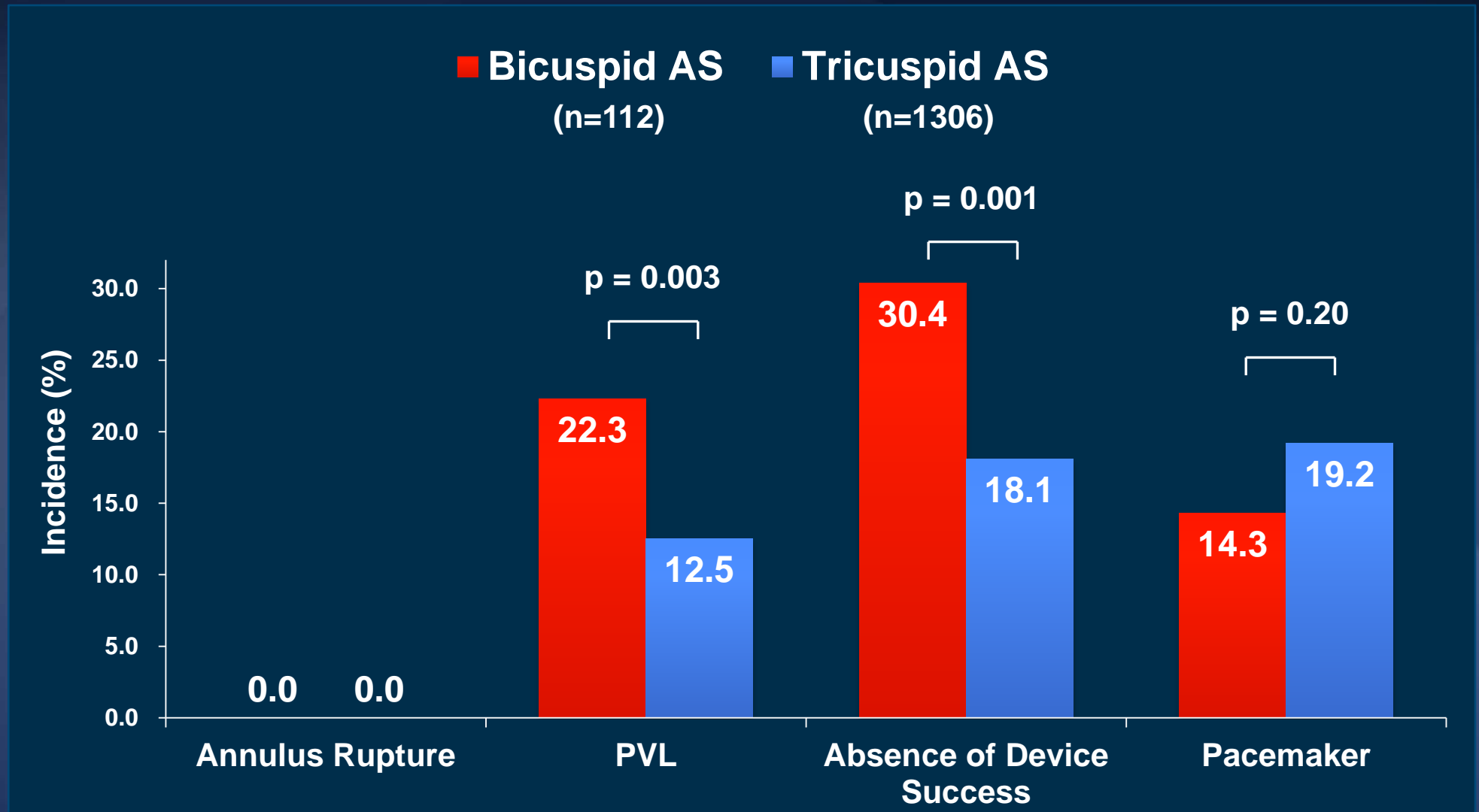
TAVR in Bicuspid vs. Tricuspid AS

SAPIEN XT



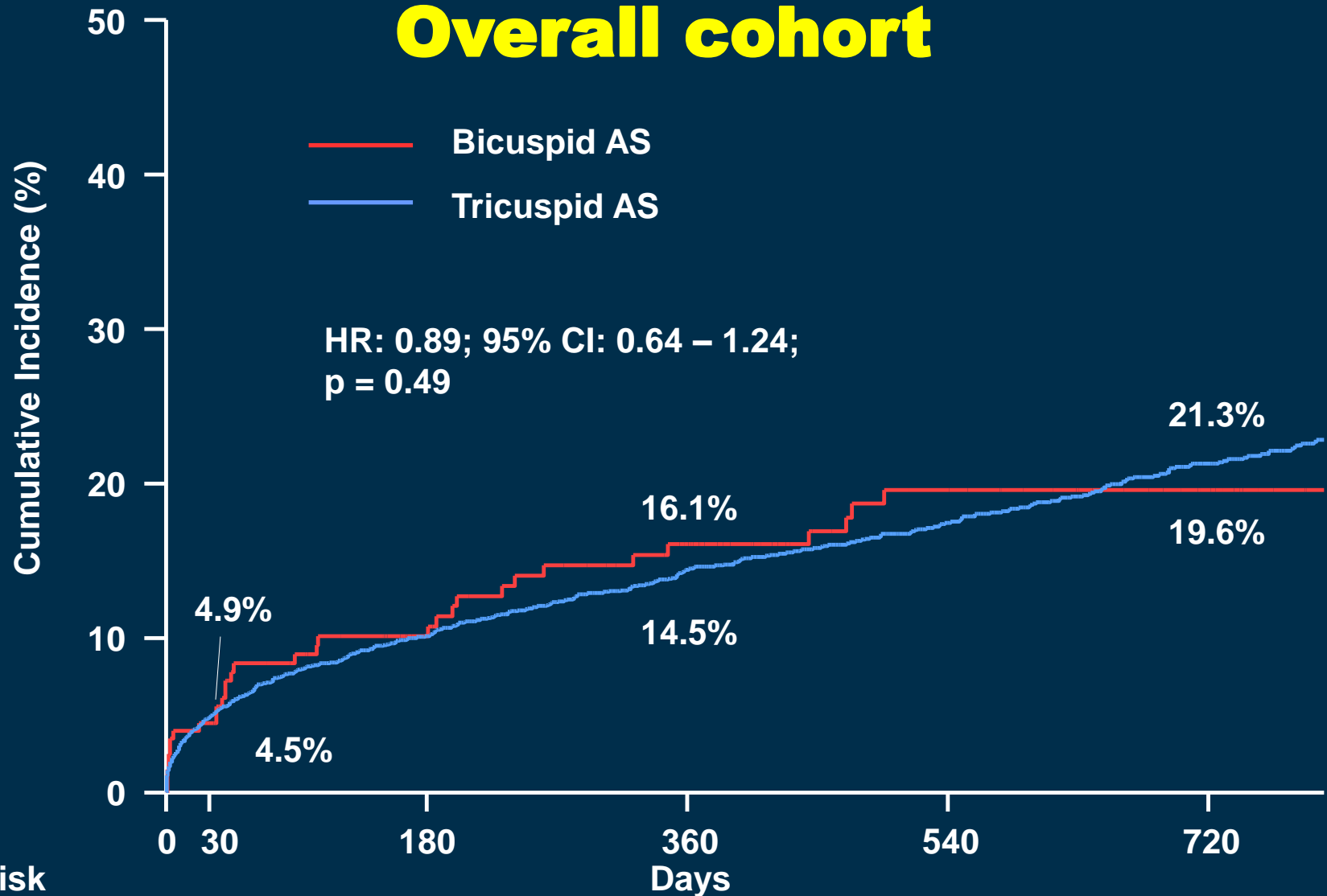
TAVR in Bicuspid vs. Tricuspid AS

CoreValve



All-cause Mortality

Overall cohort

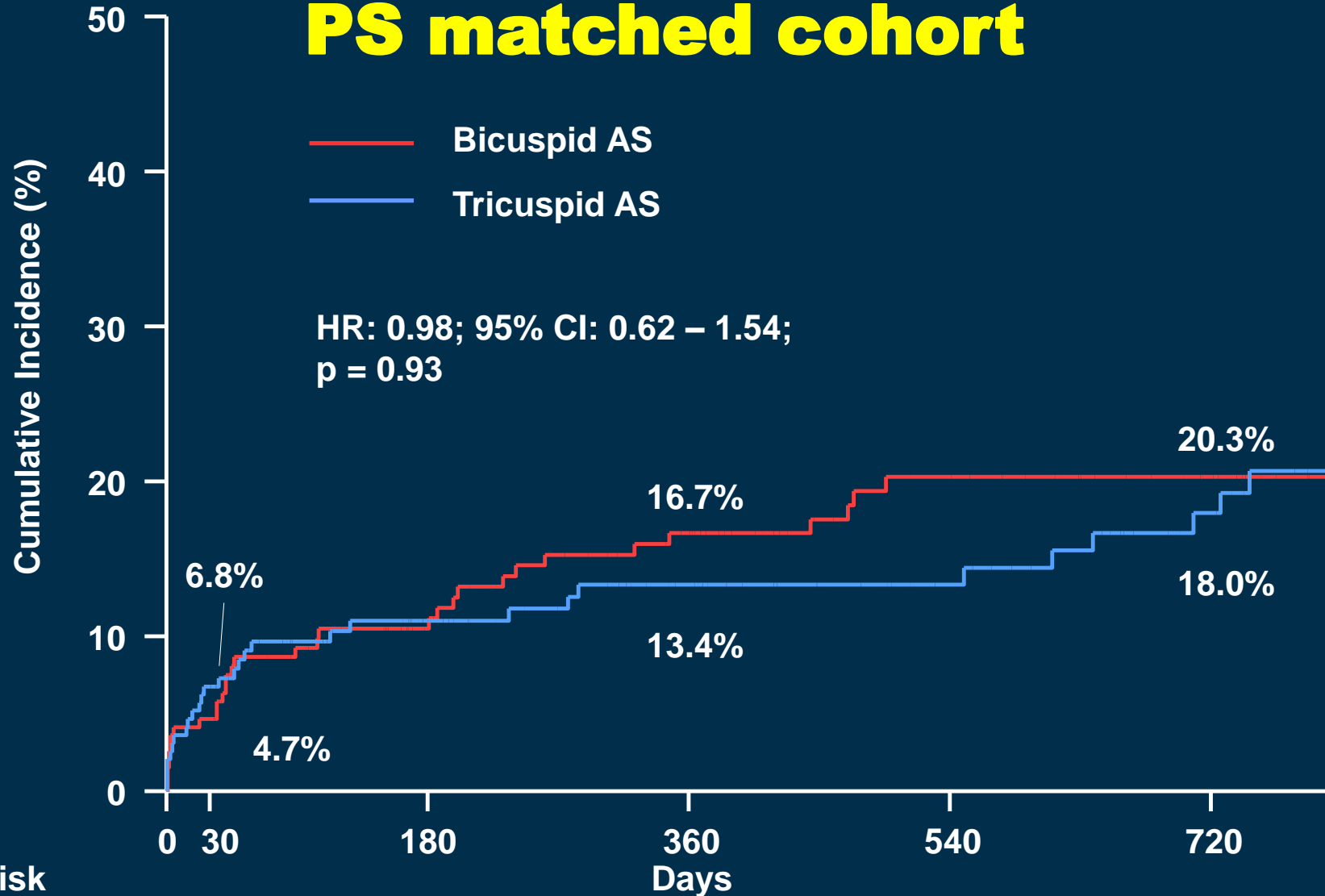


No. at Risk

Bicuspid AS	199	190	121	74
Tricuspid AS	2644	2513	1399	809

All-cause Mortality

PS matched cohort



No. at Risk

Bicuspid AS	192	183	115	71
Tricuspid AS	192	179	103	65

TAVR for Bicuspid AS with SAPIEN XT and CoreValve

Summary

1. Long-term Mortality was comparable to Tricuspid AS
2. Lower Device Success Rate
 - Annulus Rupture with SAPIEN XT
 - Paravalvular Leak with CoreValve

Advance with New-generation devices??

Bicuspid TAVR Registry

NCT 02394184

Total (n=301)	Early-generation devices (n=199)		New-generation devices (n=102)	
	SAPIEN XT (n=87)	CoreValve (n=112)	SAPIEN 3 (n=91)	Lotus (n=11)

20 centers from 14 countries
in Europe, North America and Asia-Pacific

The Bicuspid TAVR Registry

Baseline Characteristics

	Overall (N = 301)	Old devices (N = 199)	New devices (N = 102)	p value
Age	77.0 ± 9.2	77.0 ± 8.9	77.0 ± 9.8	0.97
Male	57.5%	64.8%	43.1%	< 0.001
NYHA class III/IV	74.1%	74.4%	73.5%	0.88
Logistic EuroSCORE	14.9 ± 11.7	15.0 ± 11.2	14.7 ± 12.8	0.88
STS score	4.7 ± 5.2	4.6 ± 5.1	4.9 ± 5.4	0.57
Previous stroke	16.3%	15.7%	18.6%	0.43
Peripheral vascular disease	12.6%	11.1%	15.7%	0.42
COPD	17.3%	18.1%	15.7%	0.60
LVEF, %	51 ± 15	53 ± 15	48 ± 16	0.004

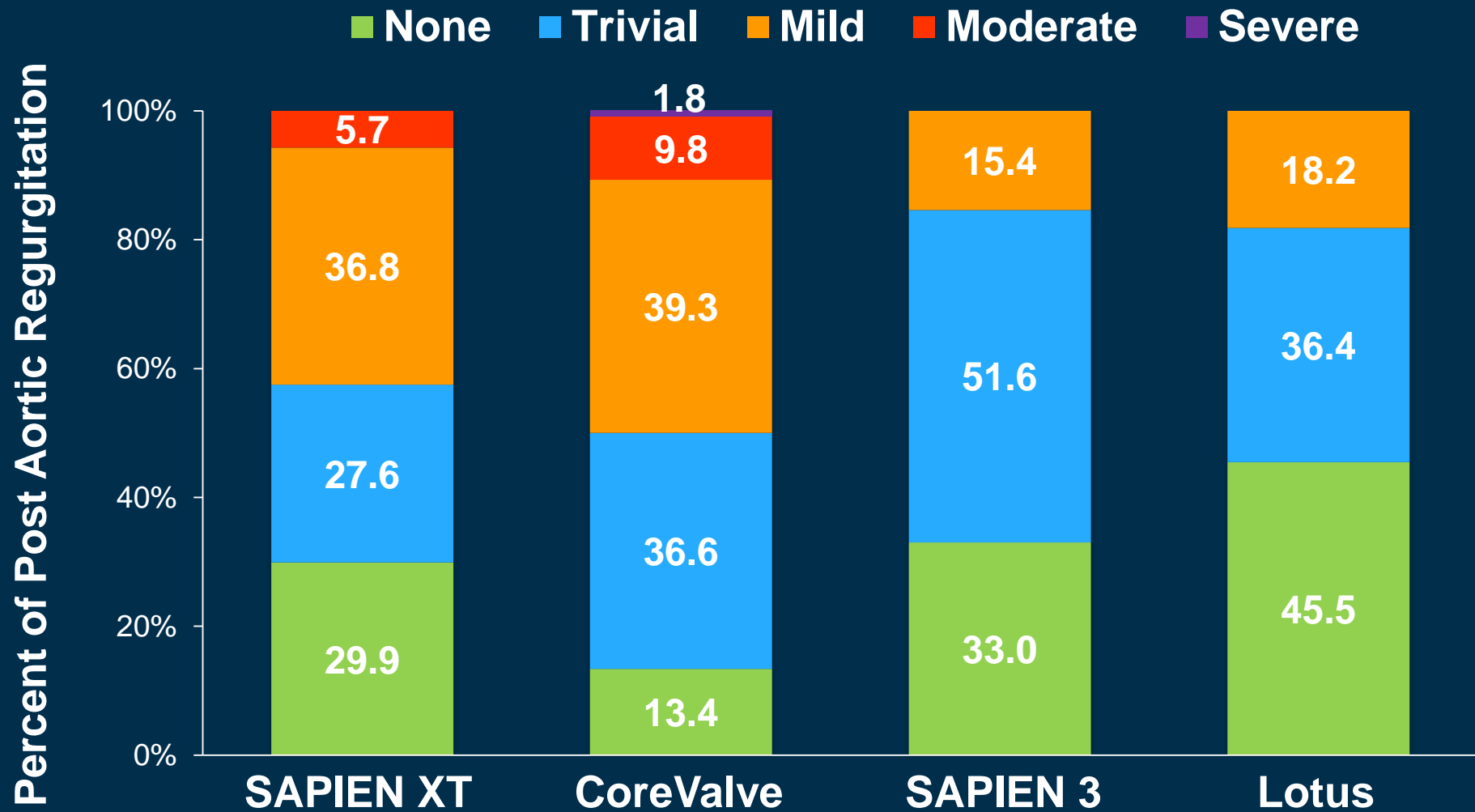
The Bicuspid TAVR Registry

Procedural Data

	Overall (N = 301)	Old devices (N = 199)	New devices (N = 102)	p value
Transfemoral access	84.1%	78.4%	95.1%	< 0.001
Device type				
Sapien XT	–	87 (43.7%)	–	< 0.001
CoreValve	–	112 (56.3%)	–	
Sapien 3	–	–	91 (89.2%)	
Lotus	–	–	11 (10.8)	
Type of bicuspid				
Type 0	11.9%	13.0%	10.1%	
Type 1	86.2%	84.5%	88.9%	
Type 2	1.9%	2.5%	1.0%	

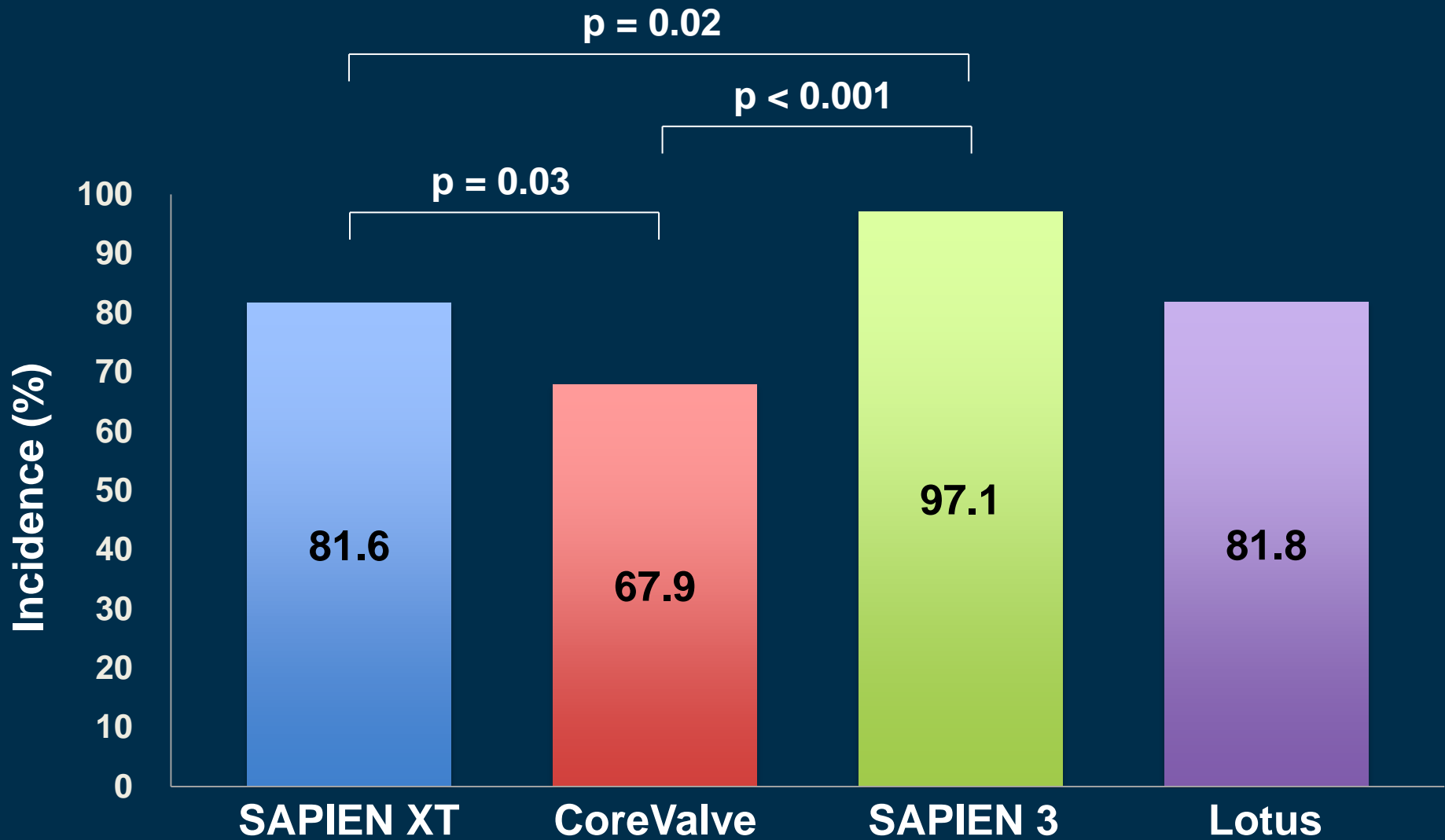
New- vs. Old-generation Devices

Post Aortic Regurgitation



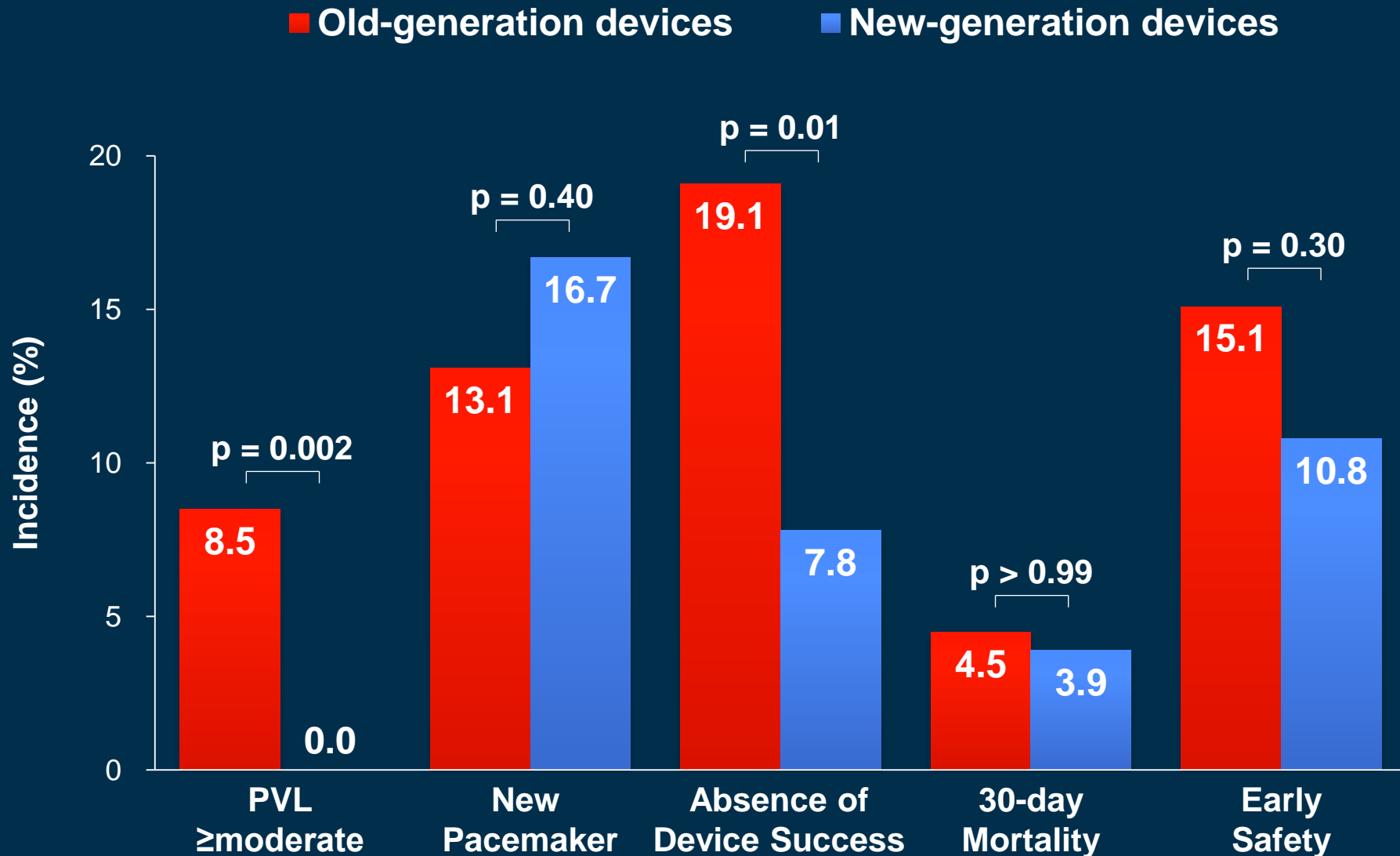
New- vs. Old-generation Devices

Device success



New- vs. Old-generation Devices

30-day Outcomes



Conclusions

1. *Comparable Short- and long-term Mortality*
2. *Lower Device Success Rate* with old-generation devices
 - *Annulus Rupture with SAPIEN XT (4.6%)*
 - *Paravalvular Leak with CoreValve*
3. *New-generation devices showed excellent outcomes*
 - *NO moderate or severe Paravalvular Leak*
 - *Improved Device Success*
4. *Long-term outcomes with new-generation devices need to be evaluated*