

# **TAVR for Bicuspid Aortic Valve Stenosis**

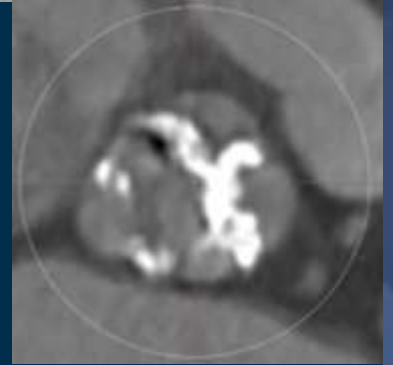
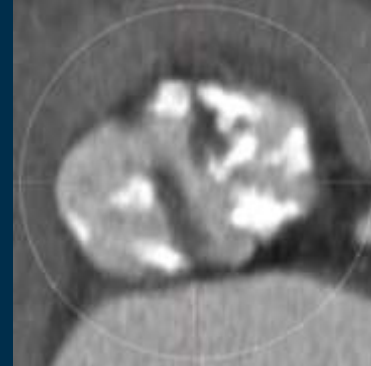
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# Challenges of TAVR in BAV

## 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 <sup>1</sup>		Yousef <sup>2</sup>
	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

<sup>1</sup>Mylotte, et al., *JACC* 2014; 64: 2330-39;

<sup>2</sup>Yousef, 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 Core Valve)*

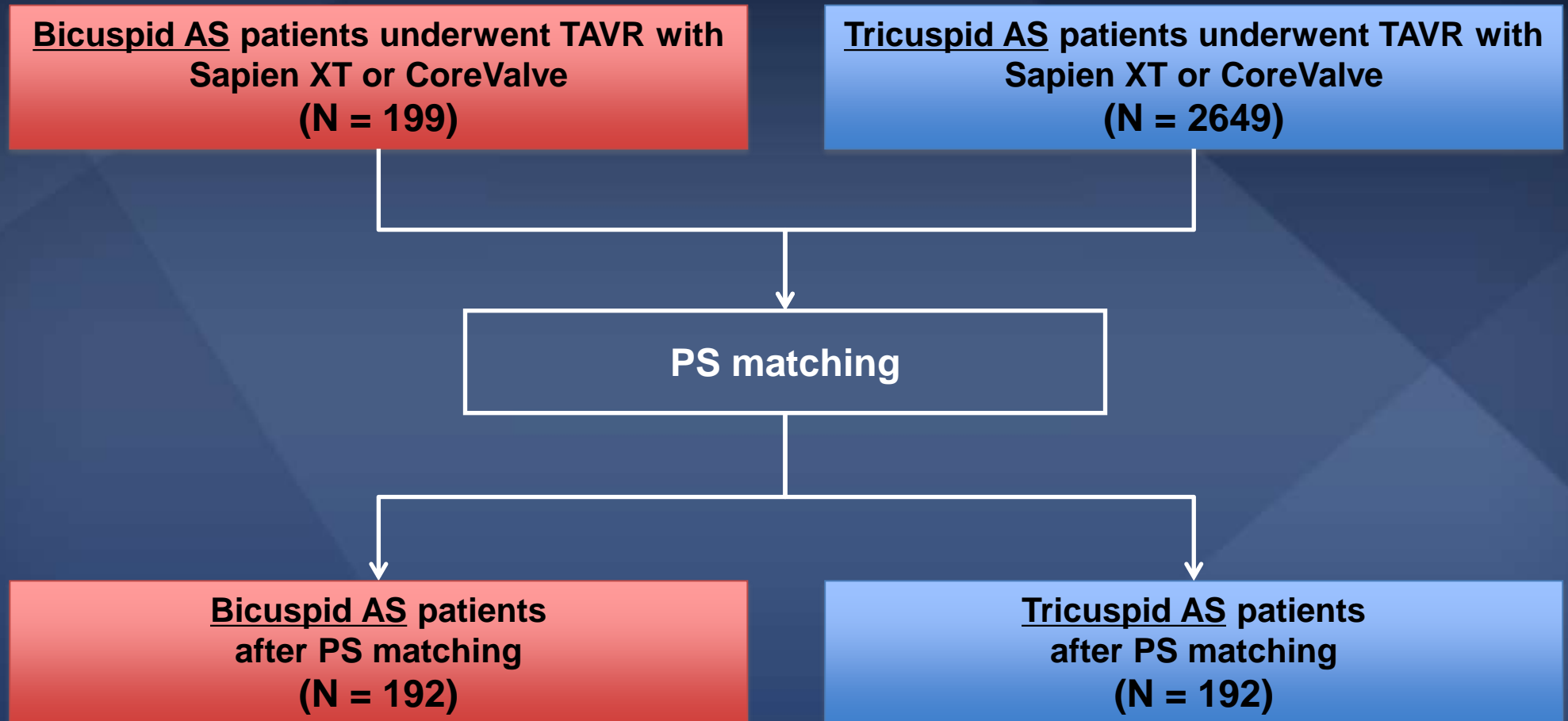
# Bicuspid TAVR Registry

*NCT 02394184*

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

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

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

# TAVR in Bicuspid vs. Tricuspid AS

## Procedural Outcomes

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



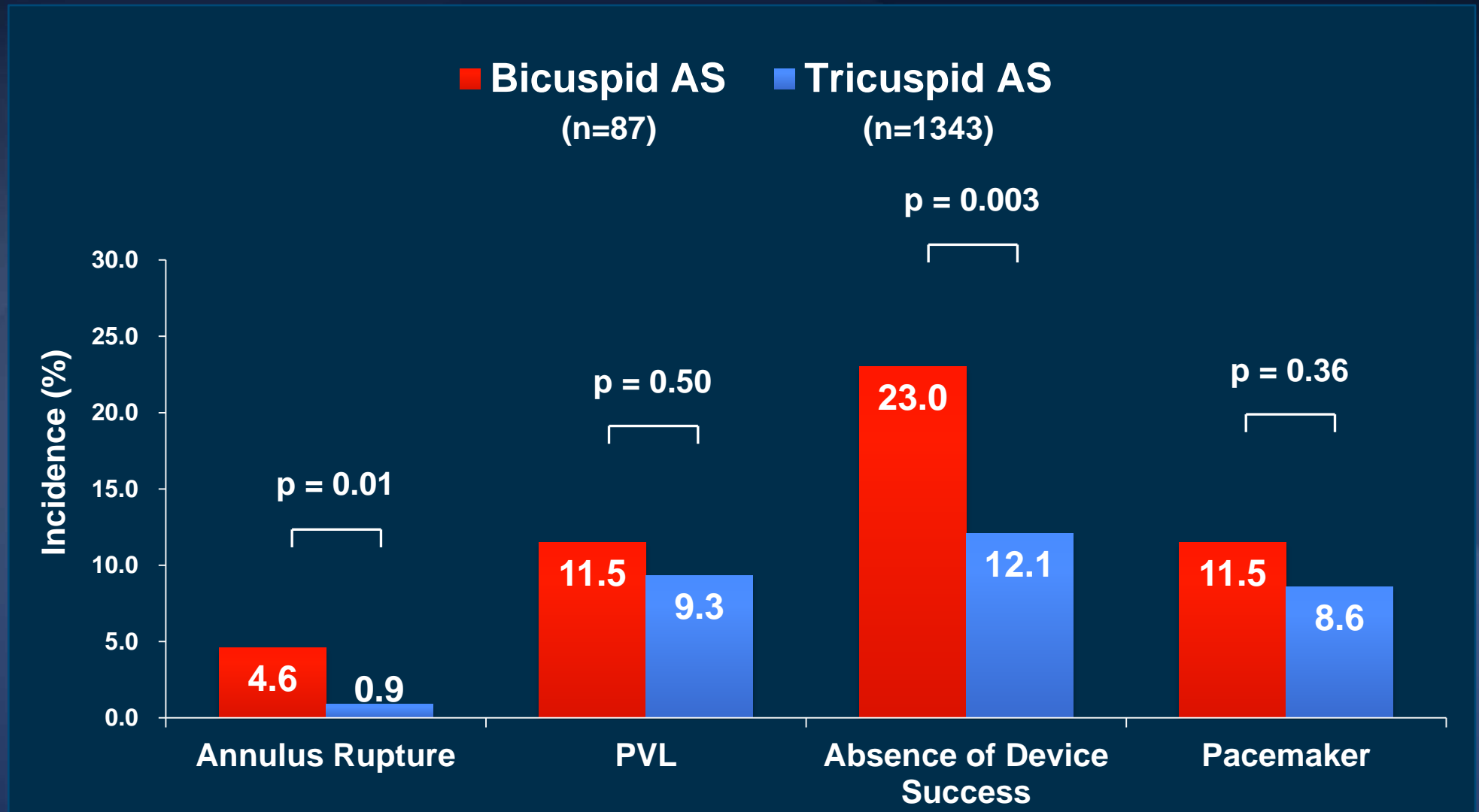
# TAVR in Bicuspid vs. Tricuspid AS

## 30-day Outcomes

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

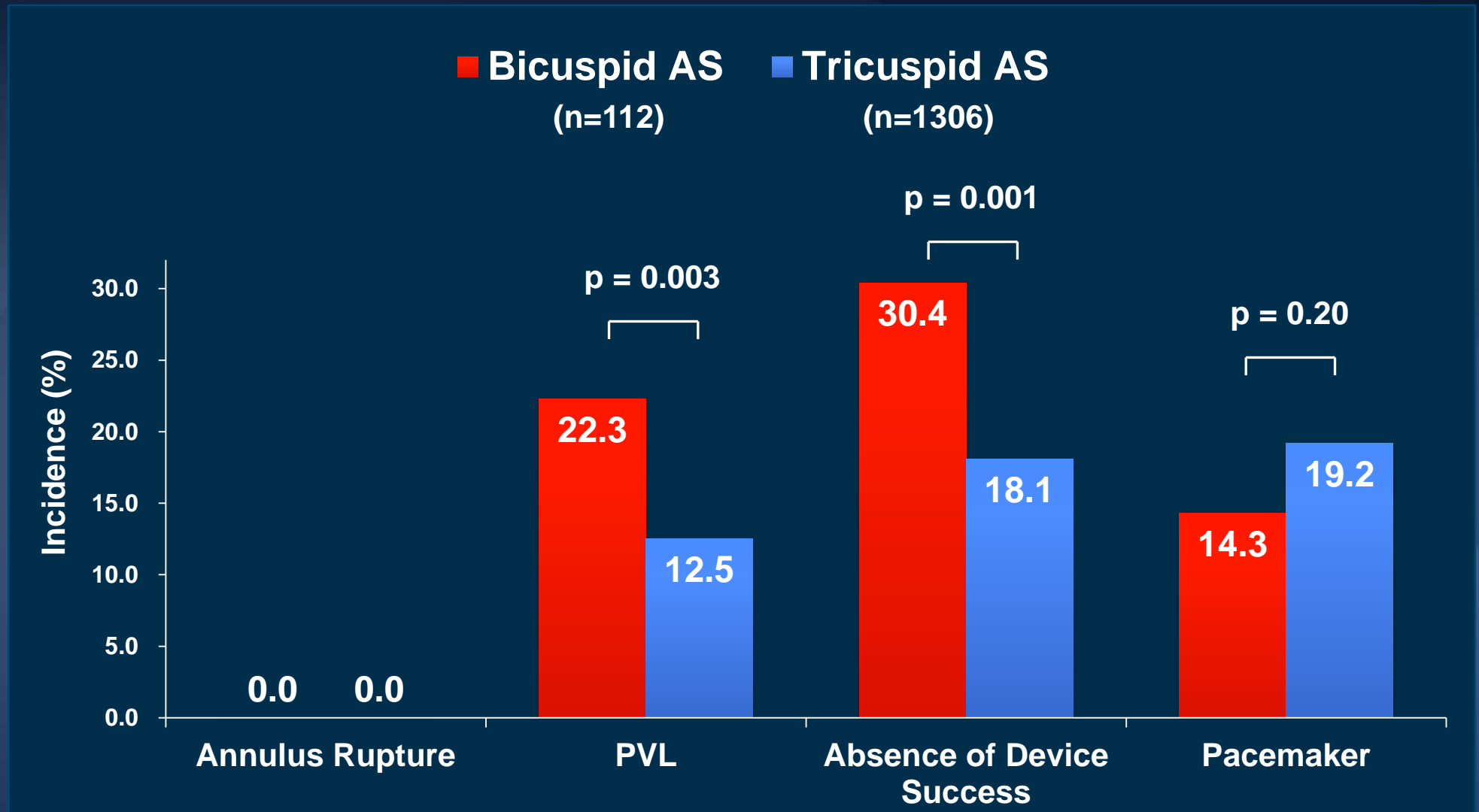
# TAVR in Bicuspid vs. Tricuspid AS

## SAPIEN XT



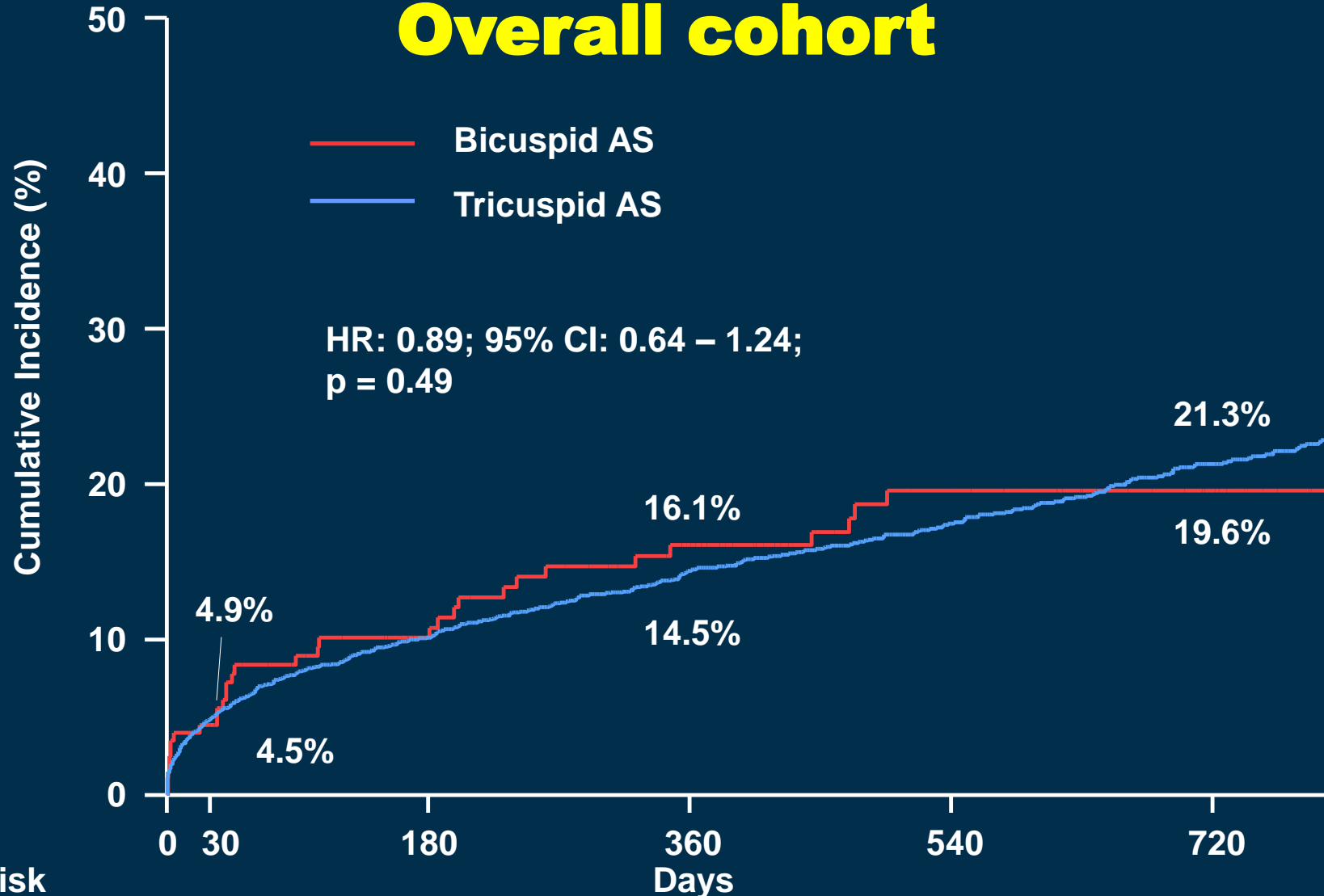
# TAVR in Bicuspid vs. Tricuspid AS

## CoreValve



# All-cause Mortality

## Overall cohort

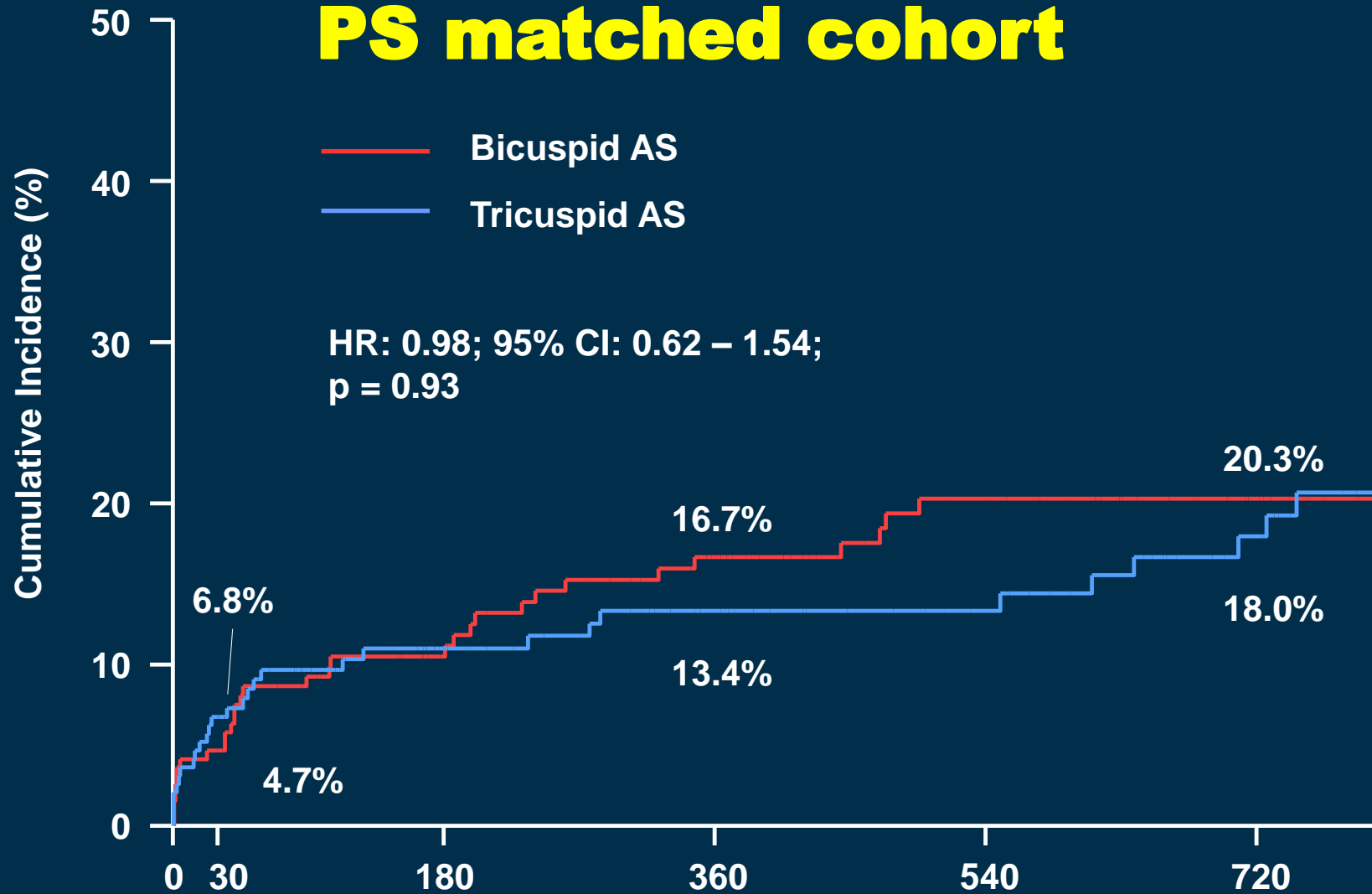


No. at Risk

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

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

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

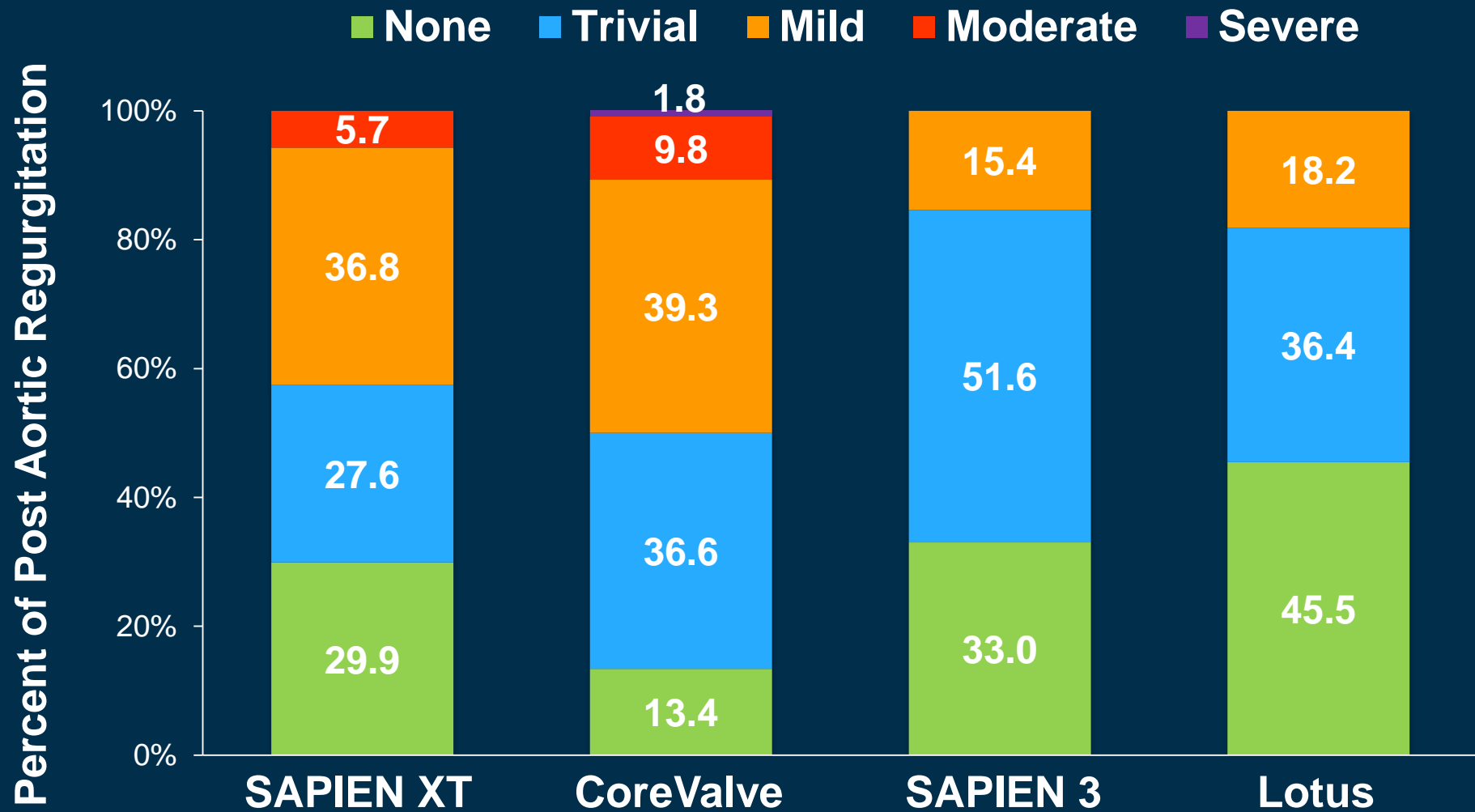


# The Bicuspid TAVR Registry

## Procedural Data

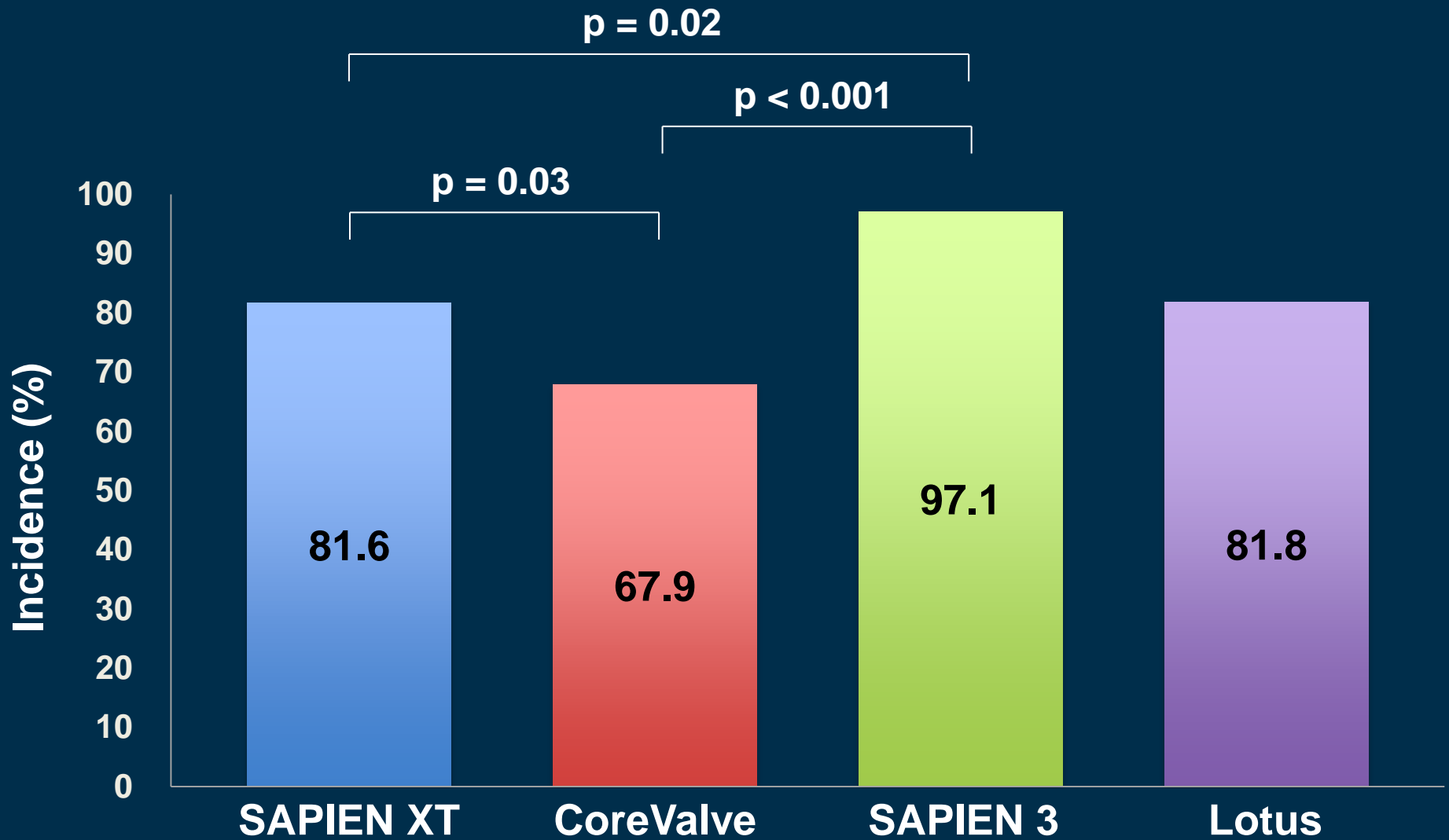
	<b>Overall ( N = 301)</b>	<b>Old devices (N = 199)</b>	<b>New devices (N = 102)</b>	<b>p value</b>
<b>Transfemoral access</b>	<b>84.1%</b>	<b>78.4%</b>	<b>95.1%</b>	<b>&lt; 0.001</b>
<b>Device type</b>				
<b>Sapien XT</b>	–	<b>87 (43.7%)</b>	–	<b>&lt; 0.001</b>
<b>CoreValve</b>	–	<b>112 (56.3%)</b>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

# New- vs. Old-generation Devices Post Aortic Regurgitation



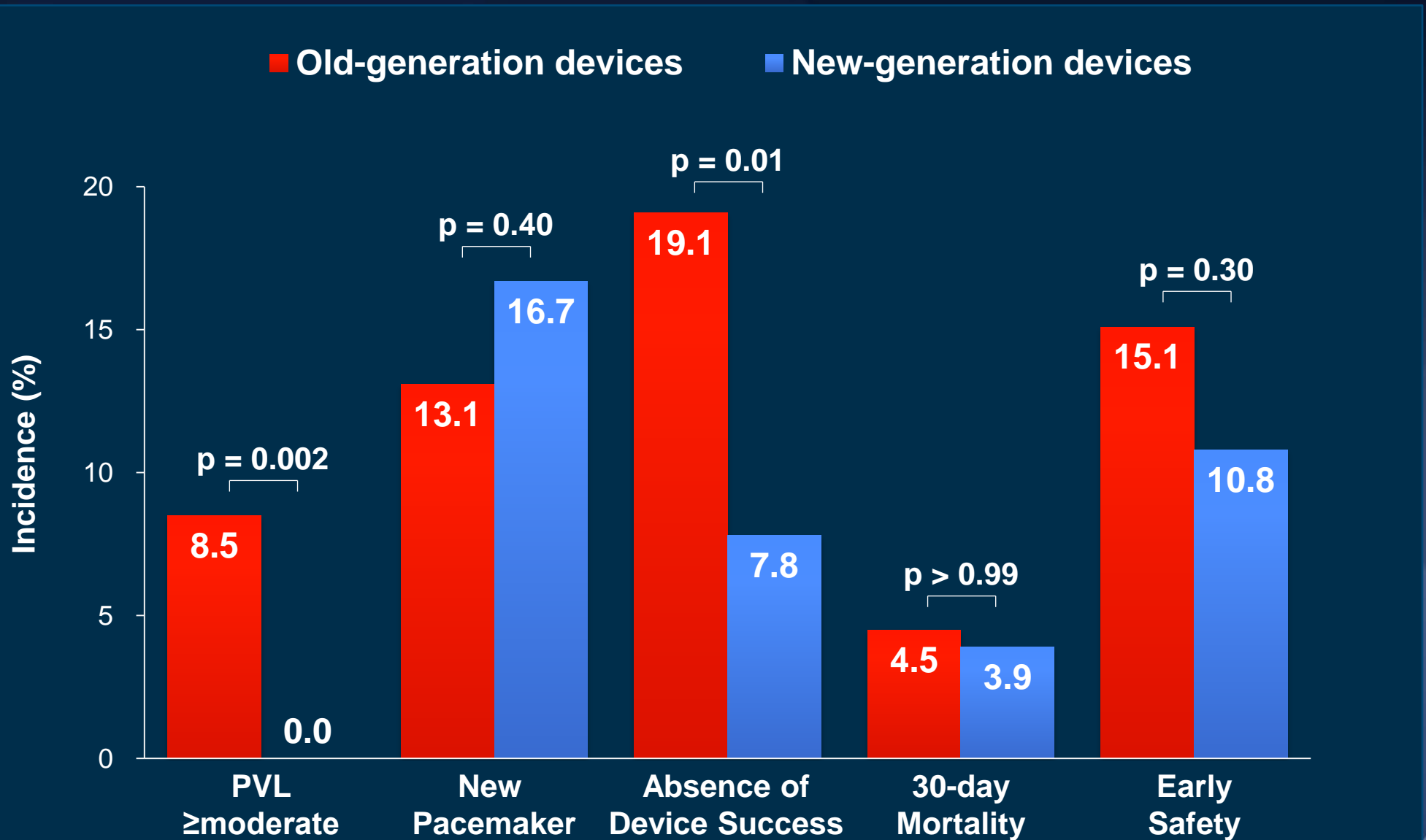
# New- vs. Old-generation Devices

## 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*