Bicuspid TAVR Registry
Early- and New-Generation Devices

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Introduction

- TAVR has been an established therapy for high-risk patients with symptomatic severe AS.
- Bicuspid AS were not enrolled in initial pivotal randomized trials. Moreover, real-world experience of TAVR for bicuspid AS has been limited, mostly due to anatomical challenges.
- Newer transcatheter heart valves have shown favorable outcomes with less PVL and fewer vascular complications than earlier devices.

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Objectives

- Compare the procedural and clinical results of TAVR in bicuspid AS with the use of early- and new-generation devices.

- Examine long-term mortality

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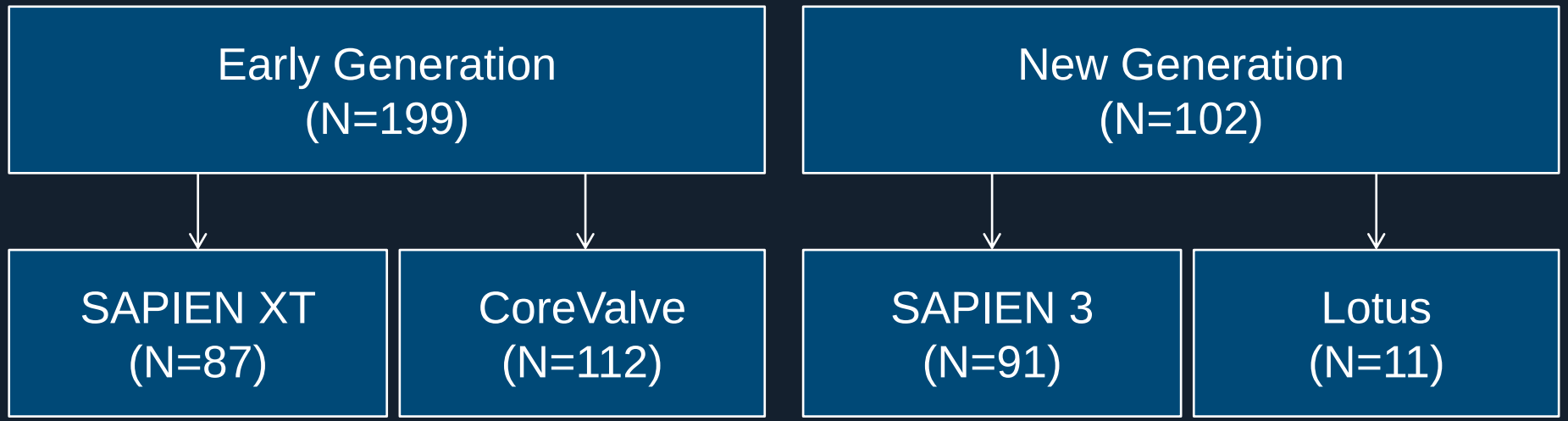
Methods

Between April 2005 and May 2015,
a total of **301** patients with bicuspid AS undergoing TAVR were enrolled from **20** heart centers in Europe, North America, and Asia-Pacific.



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Baseline Characteristics

	Overall (N = 301)	Early 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

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Type of Bicuspid AV*

	Type 0	Type 1	Type 2
Overall	12%	86%	2%
Early Device	13%	85%	3%
New Device	10%	89%	1%

*Sievers HH et al. J Thorac Cardiovasc Surg 2007;133:1226–33.

Procedural Characteristics

	Overall (N = 301)	Early devices (N = 199)	New devices (N = 102)	p value
TransFemoral Access	84.1%	78.4%	95.1%	< 0.001
Nontransfemoral Access	15.9%	21.6%	4.9%	< 0.001
Transapical	39.6%	9.0%	20.0%	
Transsubclavian	20.8%	4.0%	40.0%	
Transaortic	35.4%	8.5%	0	
Transcarotid	4.2%	0	40.0%	
Device Type				
Sapien XT	–	87 (43.7%)	–	< 0.001
CoreValve	–	112 (56.3%)	–	
Sapien 3	–	–	91 (89.2%)	
Lotus	–	–	11 (10.8)	

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Procedural and Clinical Outcomes

	Overall (N = 301)	Early devices (N = 199)	New devices (N = 102)	p value
Procedural Outcomes				
Conversion To Surgery	8 (2.9%)	7 (4.0%)	1 (1.0%)	0.27
Coronary Obstruction	3 (1.0%)	5 (1.5%)	0	0.55
Annular Rupture	5 (1.7%)	4 (2.0%)	1 (1.0%)	0.67
Second Valve Implantation	14 (4.7%)	13 (6.5%)	1 (1.0%)	0.04
New Permanent Pacemaker	43 (14.3%)	26 (13.1%)	17 (16.7%)	0.40
PVL ≥ Moderate	255 (84.7%)	161 (80.9%)	0	0.01
Clinical Outcomes				
Stroke, Disabling	3 (1.0%)	3 (1.5%)	0	0.55
Bleeding, Life Threatening	10 (3.3%)	7 (3.5%)	3 (2.9%)	>0.99
Vascular Complication, Major	12 (4.0%)	9 (4.5%)	3 (2.9%)	0.76
Acute Kidney Injury, Stage 2,3	8 (2.7%)	5 (2.5%)	3 (2.9%)	>0.99
Death at 30 days	13 (4.3%)	9 (4.5%)	4 (3.9%)	>0.99

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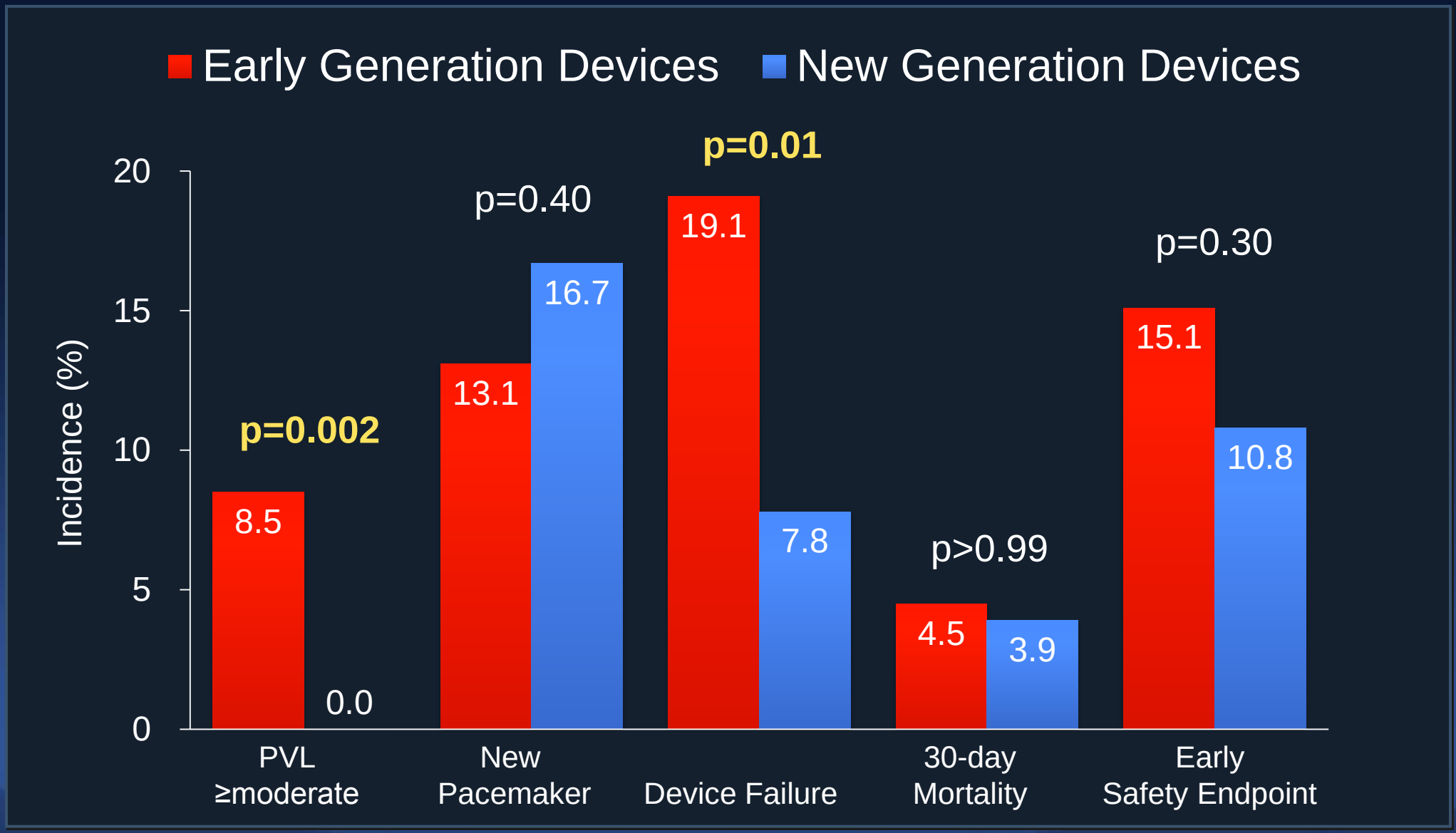
30-Day Outcomes



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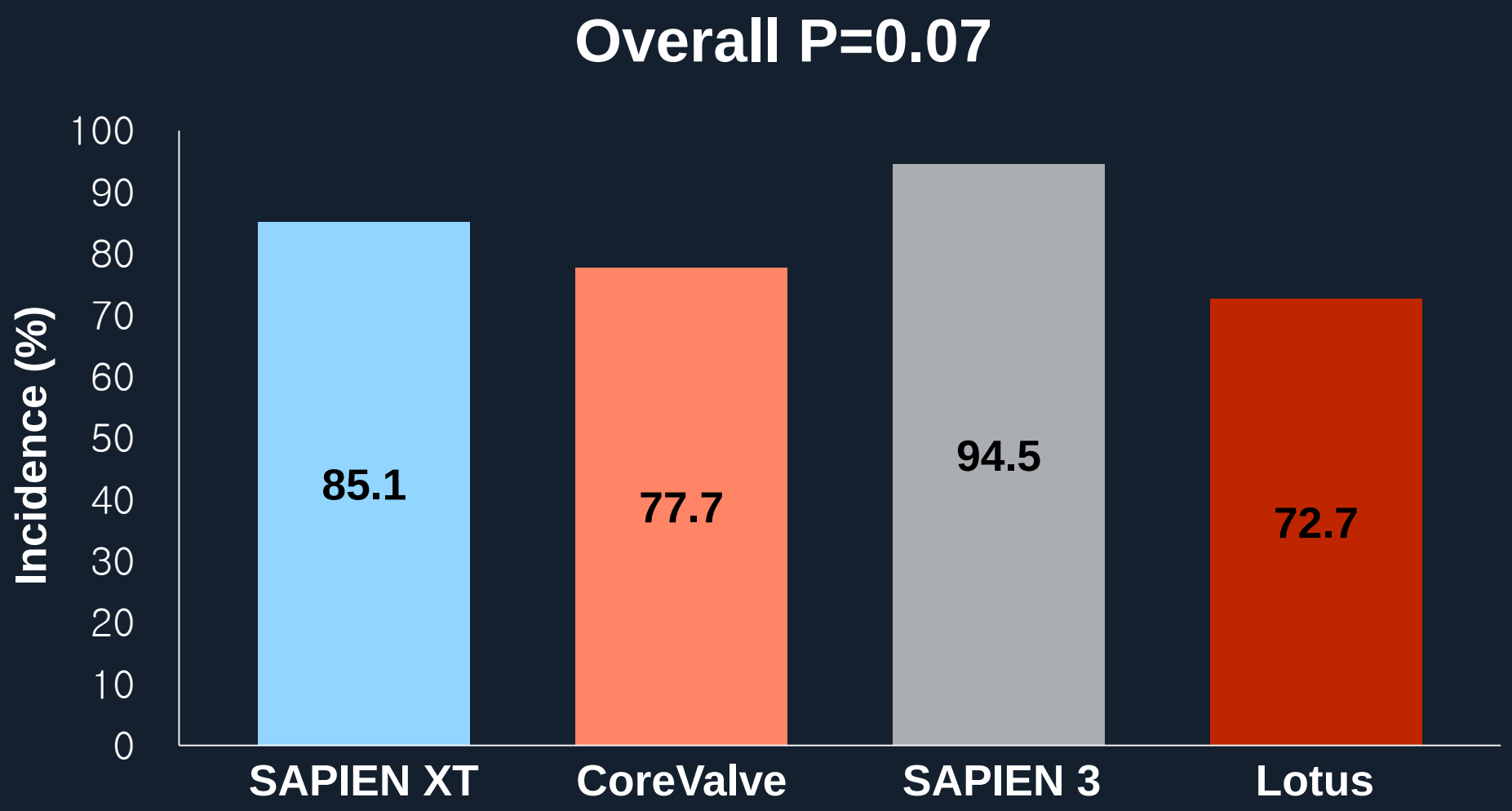
Device success



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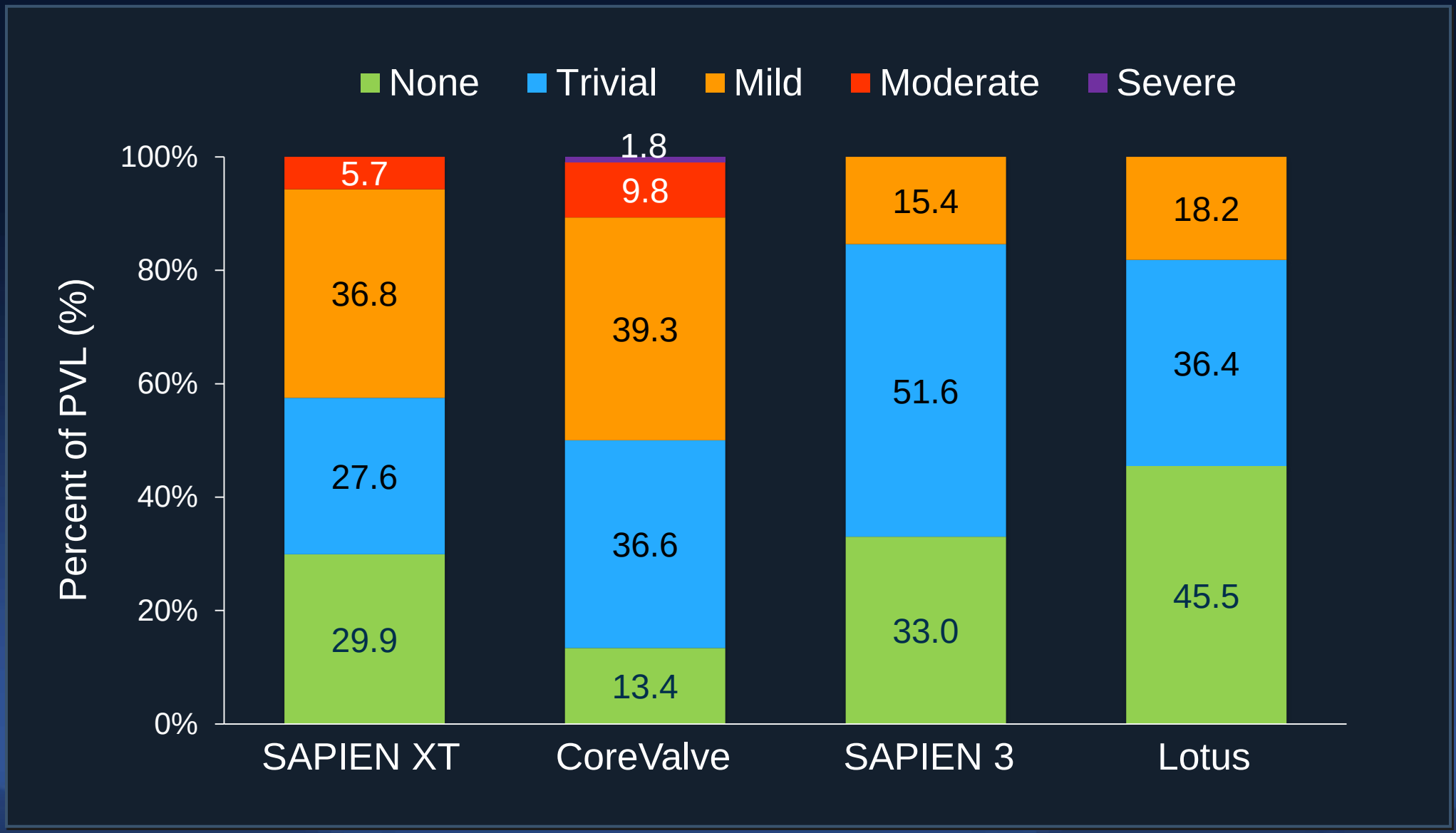
Paravalvular Leakage



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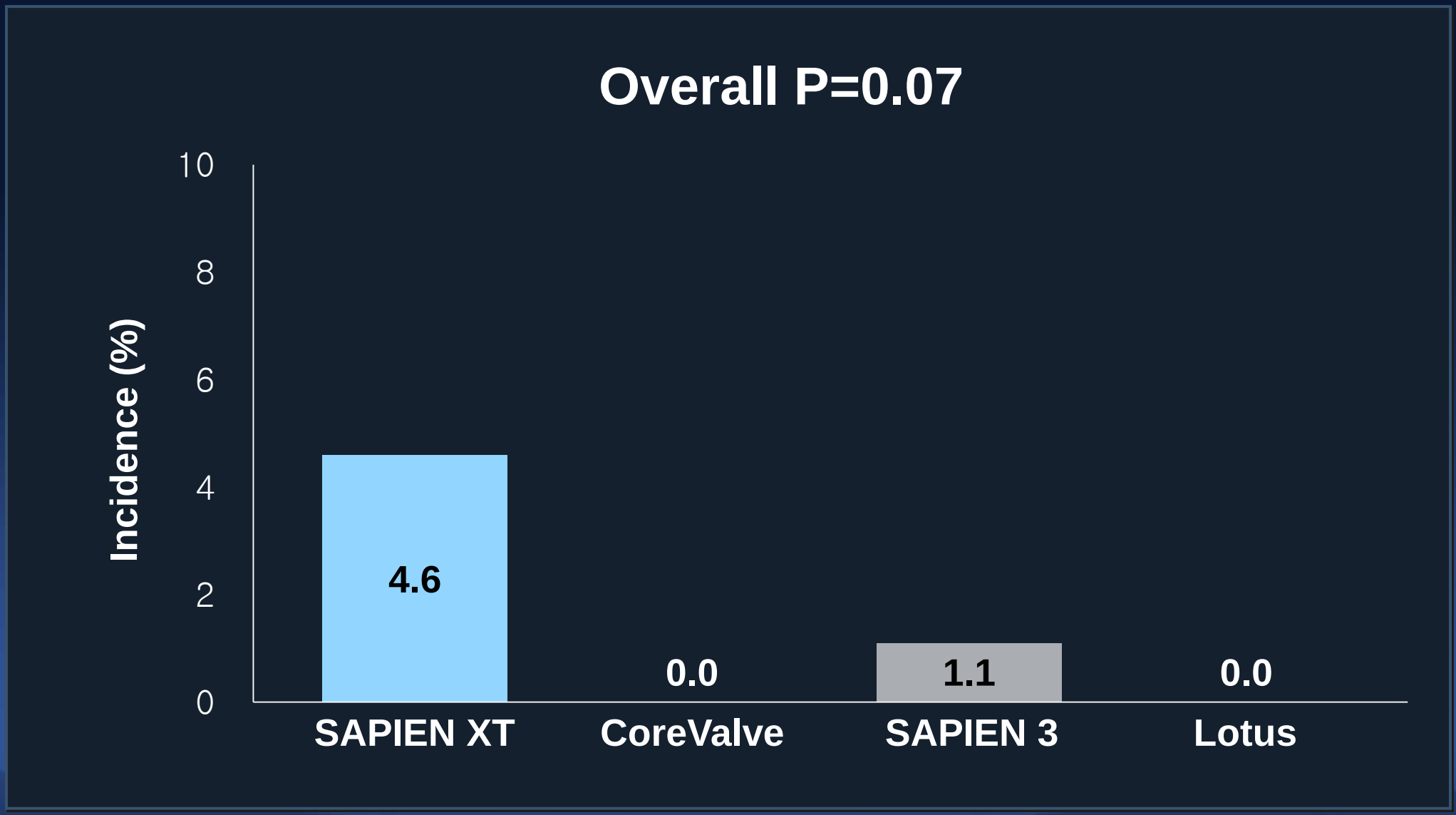
Annular Rupture



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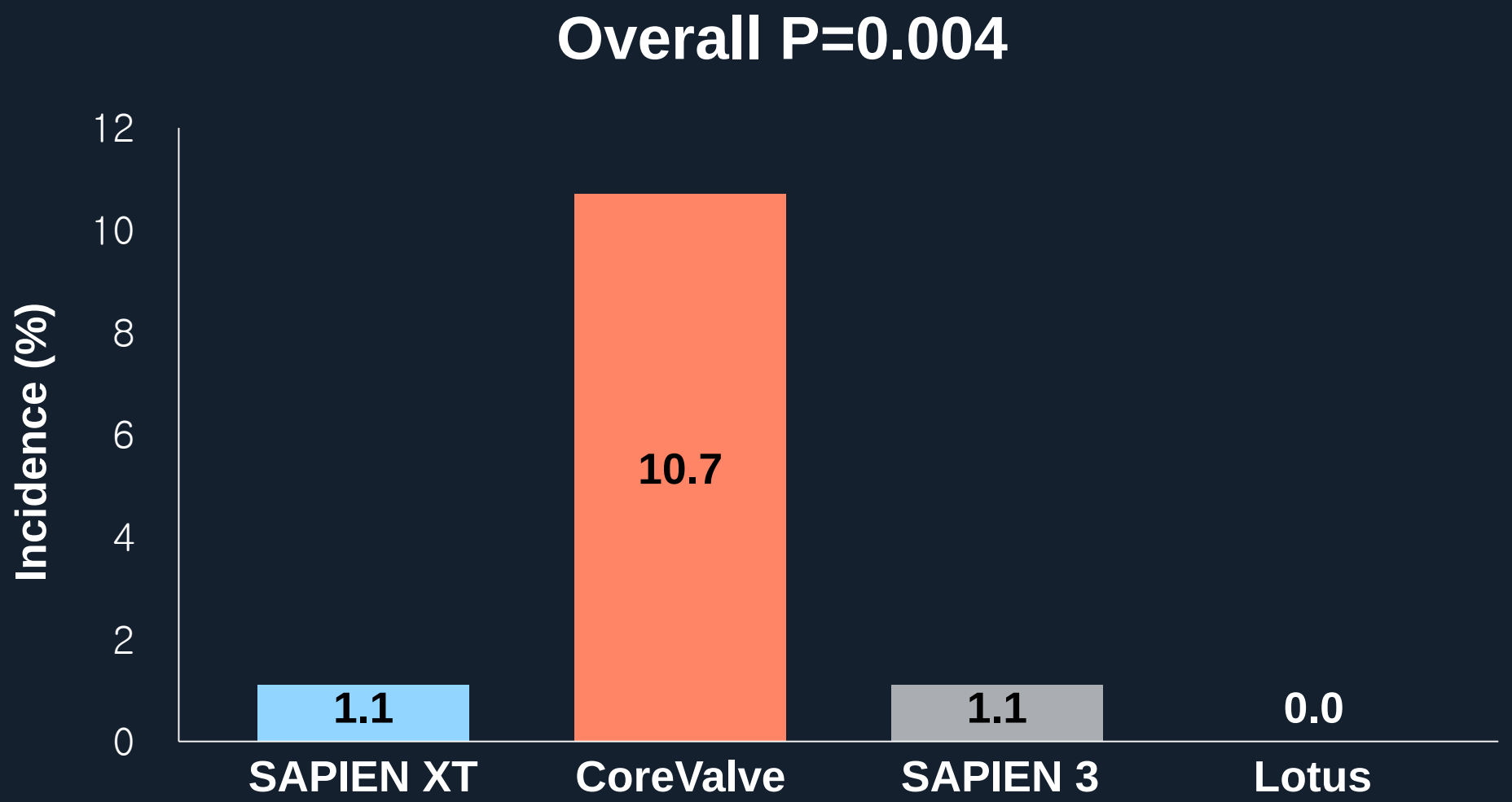
Second Valve Implantation



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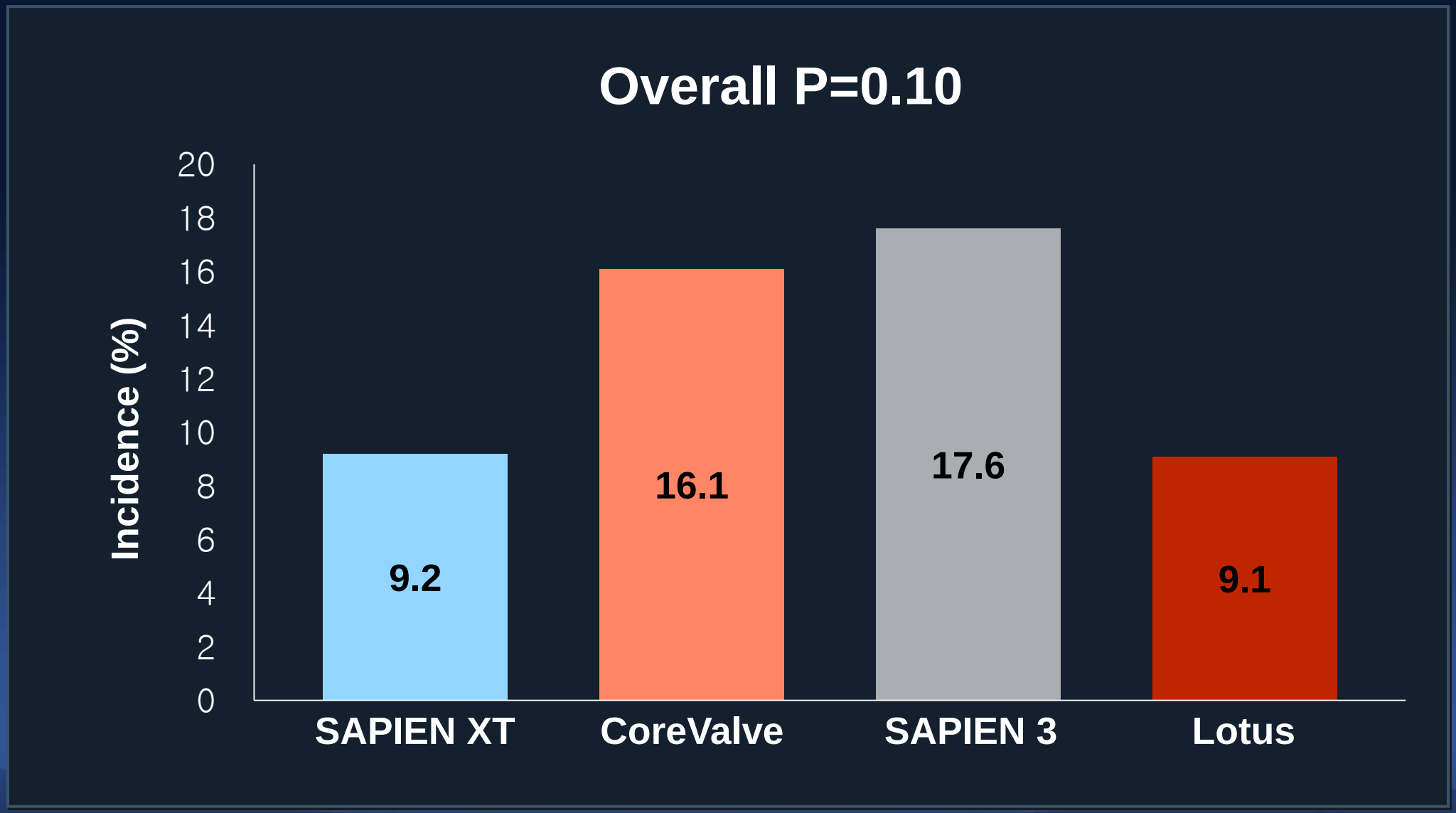
New Permanent Pacemaker



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Independent Predictors of Any Death In Patients with BAV Undergoing TAVR

	Hazard Ratio (95% CI)	p value
Logistic EuroScore	1.03 (1.01-1.05)	0.03
Life-Threatening or Major Bleeding	2.76 (1.24-6.11)	0.01
Acute Kidney Injury (Stage 2 or 3)	5.48 (1.66-18.12)	0.005

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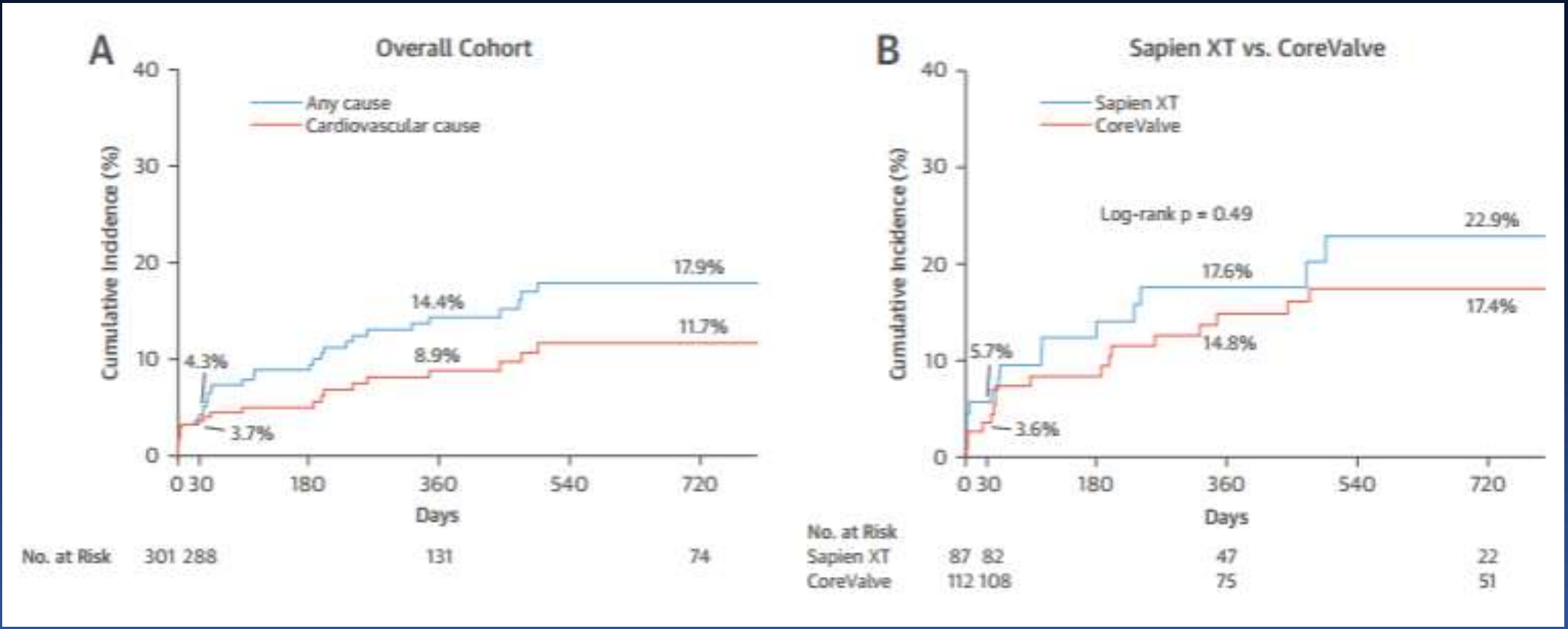
Long-term Mortality at 2 Year



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Conclusion

- Overall clinical outcomes of TAVR in bicuspid AS are comparable to those of reported studies
- New-generation devices are associated with less PVL, and consequently a higher device success rate than early-generation devices
- These improved procedural outcomes did not translate into a significant reduction in 30-day mortality or other major clinical endpoints

Conclusion

- Relatively high risk of PPM should be considered.
- This study suggested that selected patients with bicuspid AV stenosis would be a candidate of TAVR with better devices.