Procedural and Clinical Outcomes in TAVR for Bicuspid Versus Tricuspid AS

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On behalf of the Bicuspid AS TAVR Registry Investigators

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Disclosure Statement of Financial Interest

Sung-Han Yoon, MD

Within the past 12 months, I or my spouse/partner have had no financial interest/arrangement or affiliation with any organization(s).

Background

- TAVR indication is expanding into a lower-risk population
- The prevalence of bicuspid aortic valve is higher in a younger population
- Bicuspid AS has been excluded from randomized trials
- There is limited data comparing outcomes of TAVR for bicuspid versus tricuspid AS

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Methods

- The Bicuspid AS TAVR multicenter registry was used to compare the procedural and clinical outcomes between bicuspid and tricuspid AS
- Propensity-score matching was applied
- Procedural and clinical outcomes were assessed according to VARC-2 criteria

Participating Institutions (N = 33)

Nation	Institution	Investigator
Canada	St. Paul's Hospital	Danny Dvir, Philipp Blanke, Jonathon Leipsic, John G.Webb
Denmark	Rigshospitalet University Hospital	Ole de Backer, Lars Sondergaard
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France	Hospital Cardiologique Lille	Thomas Modine
France	Centre Hospitalier Unicersitaire Henri Modor	Masao Takahashi, Emmanuel Teiger
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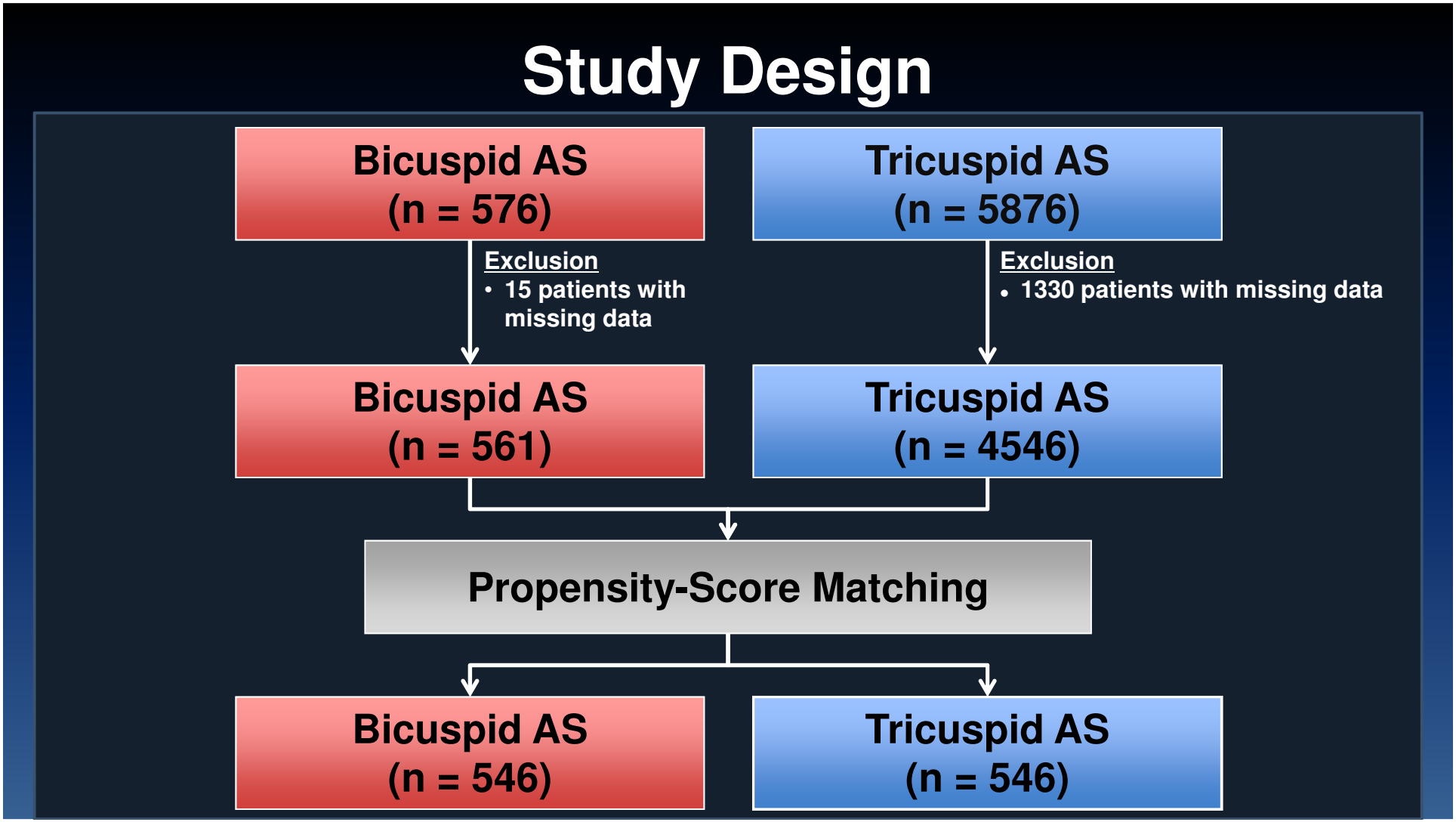
Germany	Hamburg University Heart Center	Florian Deuschl, Niklas Schofer, Ulrich Schaefer
Germany	Heart Center Brandenburg	Hidehiro Kaneko, Christian Butter
Germany	University Freiburg	Philipp Ruile, Gregor Pache, Franz-Josef
Germany	Rahr-University Bochum	Buntaro Fujita, Stephan M. Ensminger
Germany	Asklepios Klink St. Georg	Tobias Schmidt
Germany	Heart Center, Segeberger Klinken	Erik W. Holy, Mohamed Abdel-Wahab
Italy	San Raffaele Scientific Institute	Azeem Latib, Antonio Columbo
Italy	Ferrarotto Hospital	Marco Barbanti, Corrado Tamburino
Italy	IRCCS Pol SanDonato	Francesco Bedgoni, Luca Testa
Korea	Asan Medical Center	Seung-Jung Park
Netherland	Leiden University Medical Center	William K.F. Kong, Victoria Delgado, Jeroen J. Bax
Switzerland	University Hospital Zurich	Shingo Kuwata, Fabian Nietlispach
U.K.	Sussex Cardiac Center	Smriti Saraf, David Hildick-Smith
U.S.	Intermountain Heart Institute	Brian K. Whisenant
U.S.	New York-Presbyterian Hospital	S. Chiu Wong
U.S.	Columbia University Medical Center	Omar Khalique, Susheel Kodali, Martin Leon
U.S.	Cedars-Sinai Heart Institute	Raj Makkar

Study Design



Baseline Characteristics

Demographics

	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	P value
Age, years	77 ± 8	77 ± 8	0.91
Male	63%	61%	0.48
NYHA class III / IV	80%	82%	0.48
STS score, %	4.6±4.6	4.3±3.0	0.29
Logistic EuroSCORE, %	16.1±12.0	16.9±13.9	0.58

Baseline Characteristics
Comorbidities

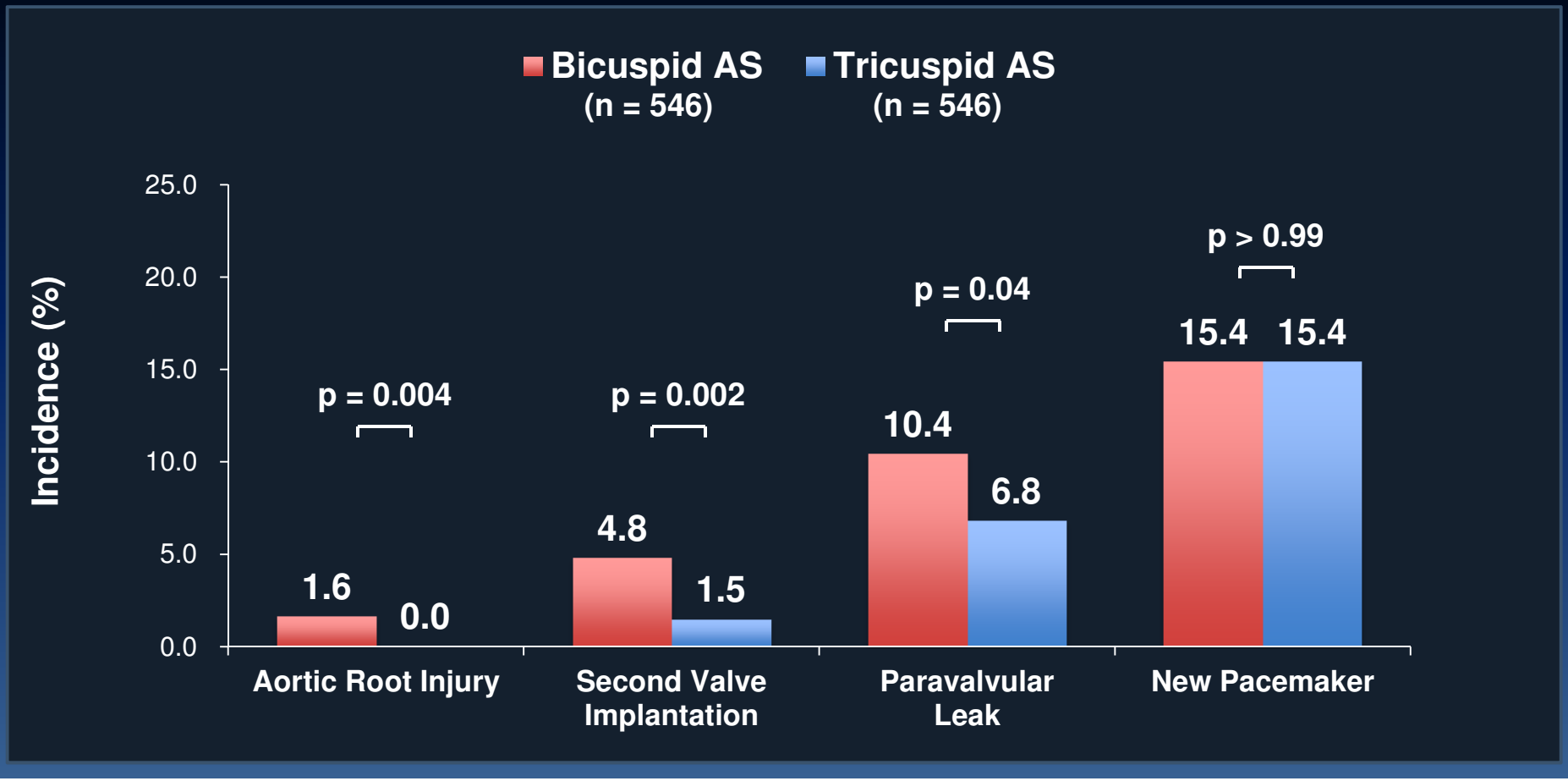
	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	P value
Diabetes mellitus	23%	23%	> 0.99
Creatinine, mg/dl	1.2±0.9	1.2±0.7	0.81
Peripheral vascular disease	15%	16%	0.93
Prior CVA	14%	13%	0.53
Chronic lung disease	18%	15%	0.23
Prior CABG	11%	12%	0.70
LVEF, %	52 ±15	52 ±15	0.99

Baseline Characteristics

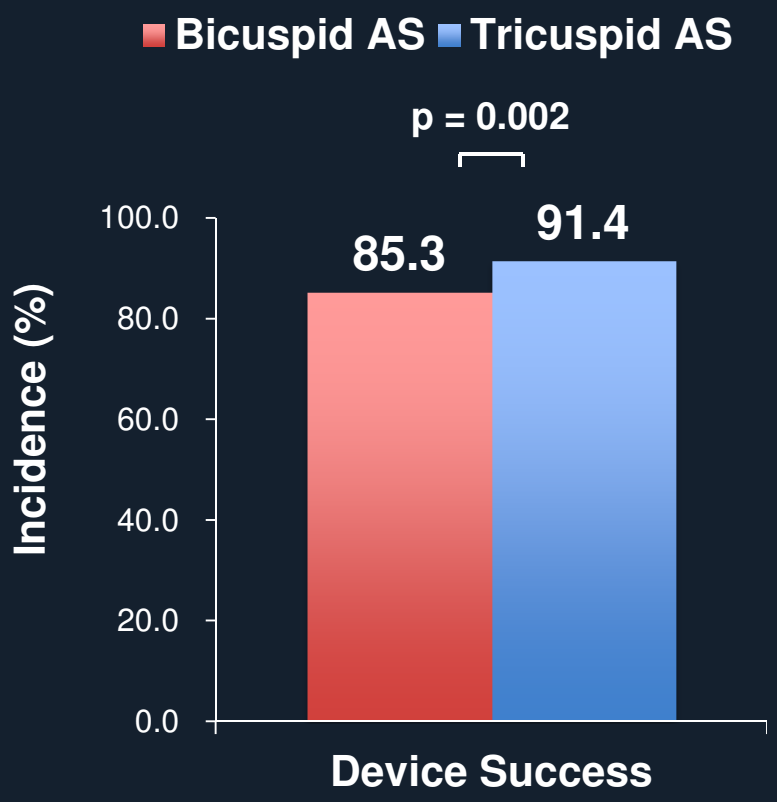
Procedure

	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	P value
Transfemoral access	86%	86%	0.93
Device			
Early generation devices	59%	59%	> 0.99
Sapien XT	28%	28%	0.77
CoreValve	30%	31%	0.73
New generation devices	41%	41%	> 0.99
Sapien 3	29%	30%	0.94
Lotus	8%	9%	0.73
Evolut R	4%	3%	0.32

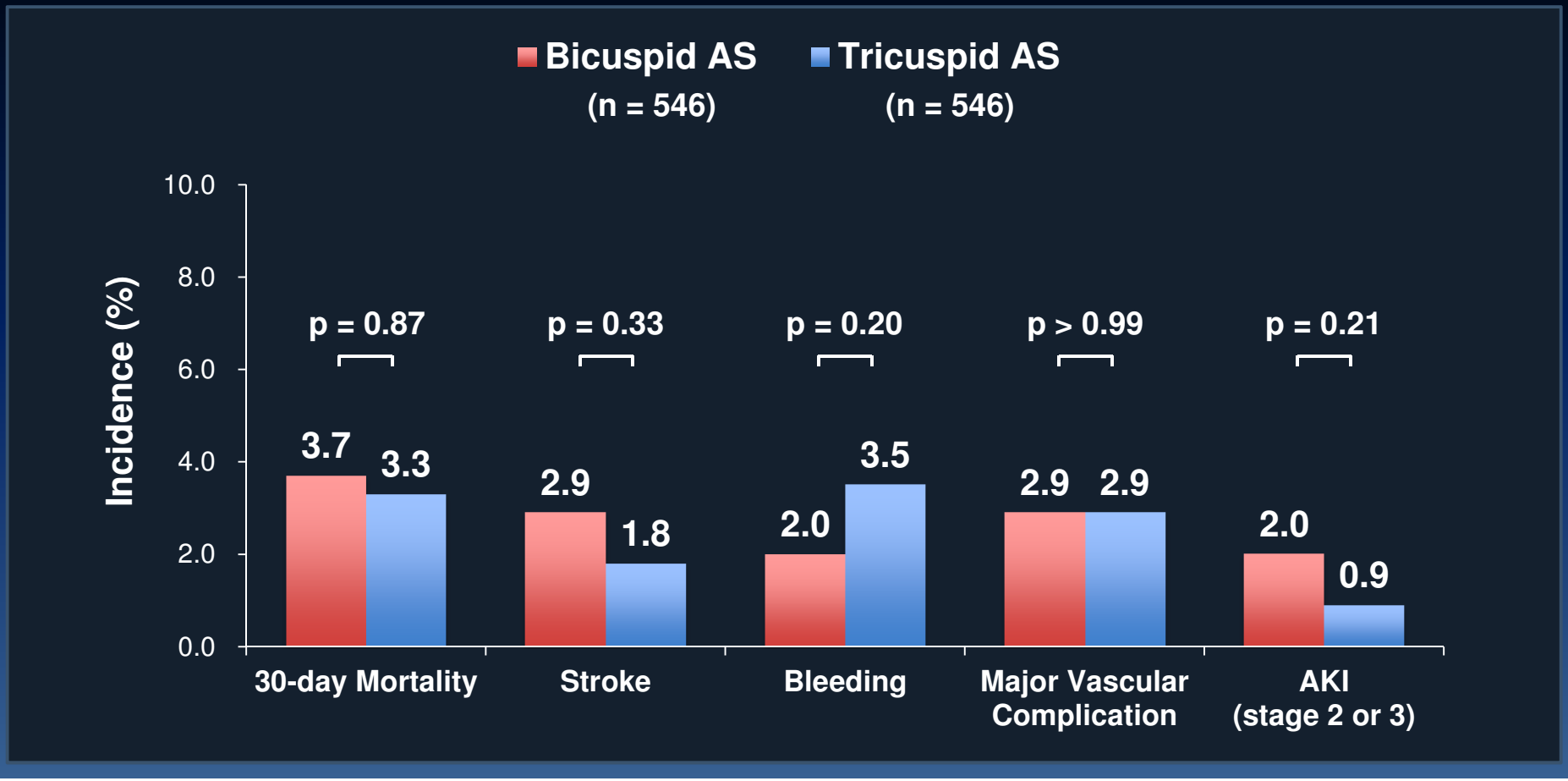
Procedural Outcomes



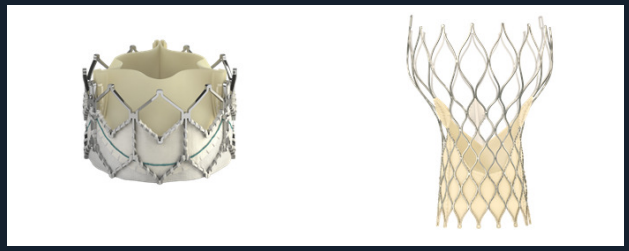
Procedural Outcomes



30-day Clinical Outcomes



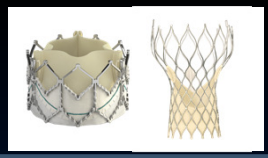
Device Evolution

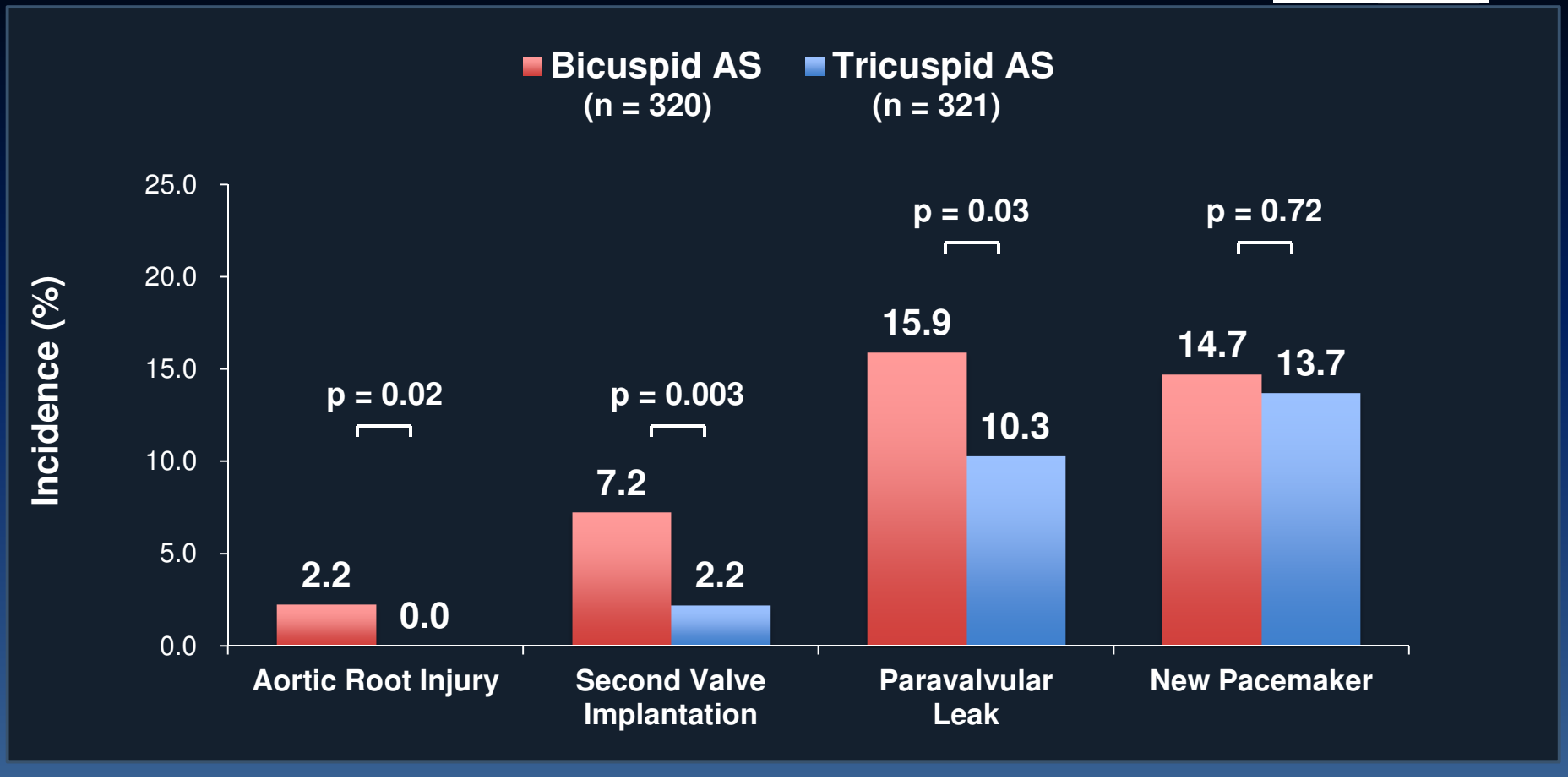
	Early Generation Devices		New Generation Devices		
Device	**Sapien XT**	**CoreValve**	**Sapien 3**	**Lotus**	**Evolut R**
					
Bicuspid vs Tricuspid AS	155 vs 150 (28% vs 28%)	165 vs 171 (30% vs 31%)	160 vs 162 (29% vs 30%)	43 vs 47 (8% vs 9%)	23 vs 16 (4% vs 3%)

Early Generation devices

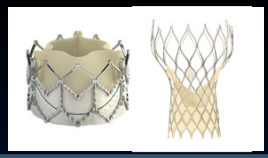
Procedural Outcomes

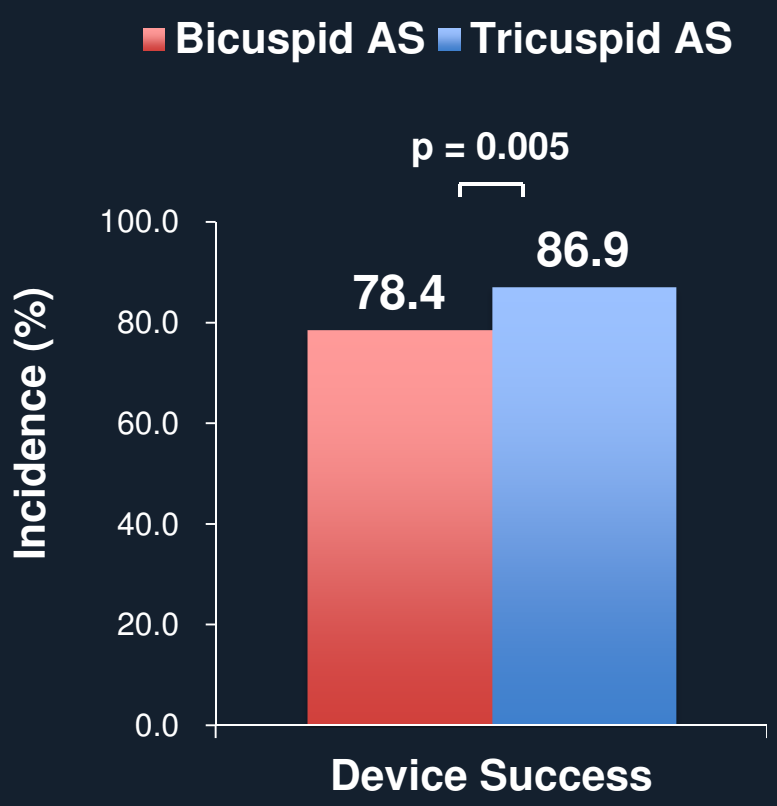
Early Generation Devices





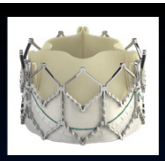
Procedural Outcomes
Early Generation Devices

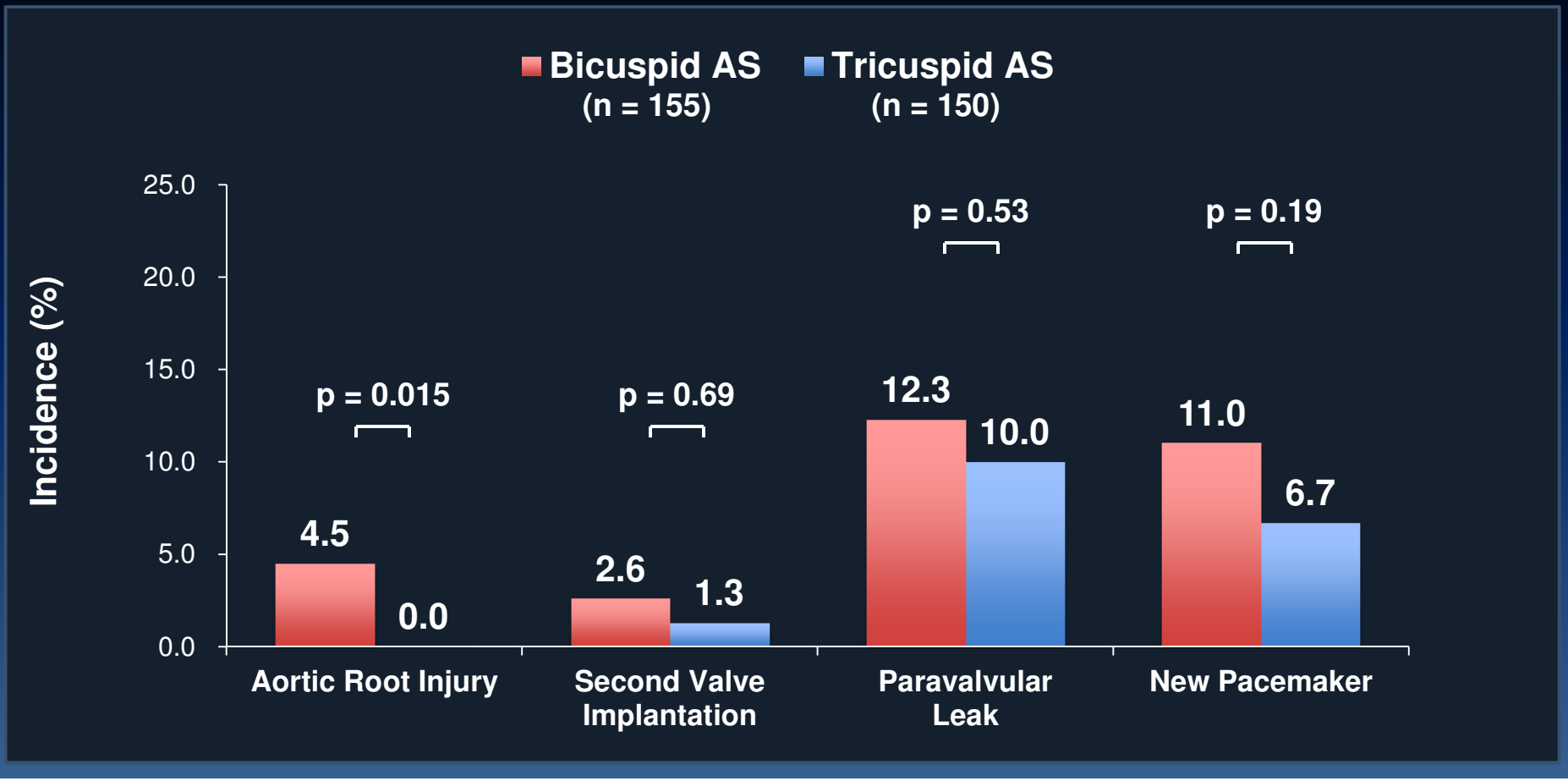




Procedural Outcomes

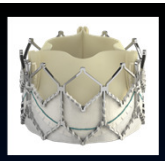
Sapien XT

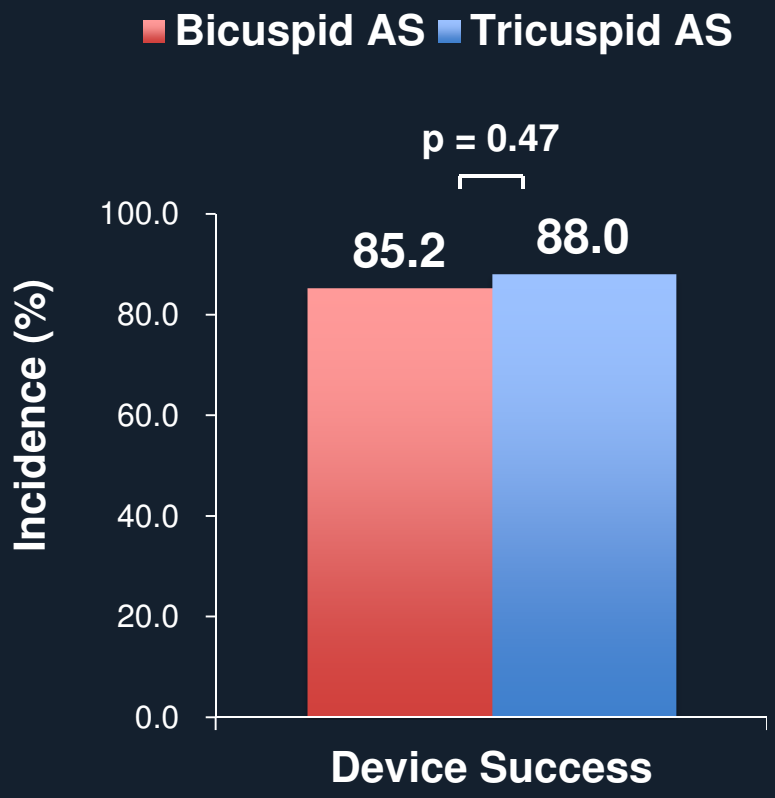




Procedural Outcomes

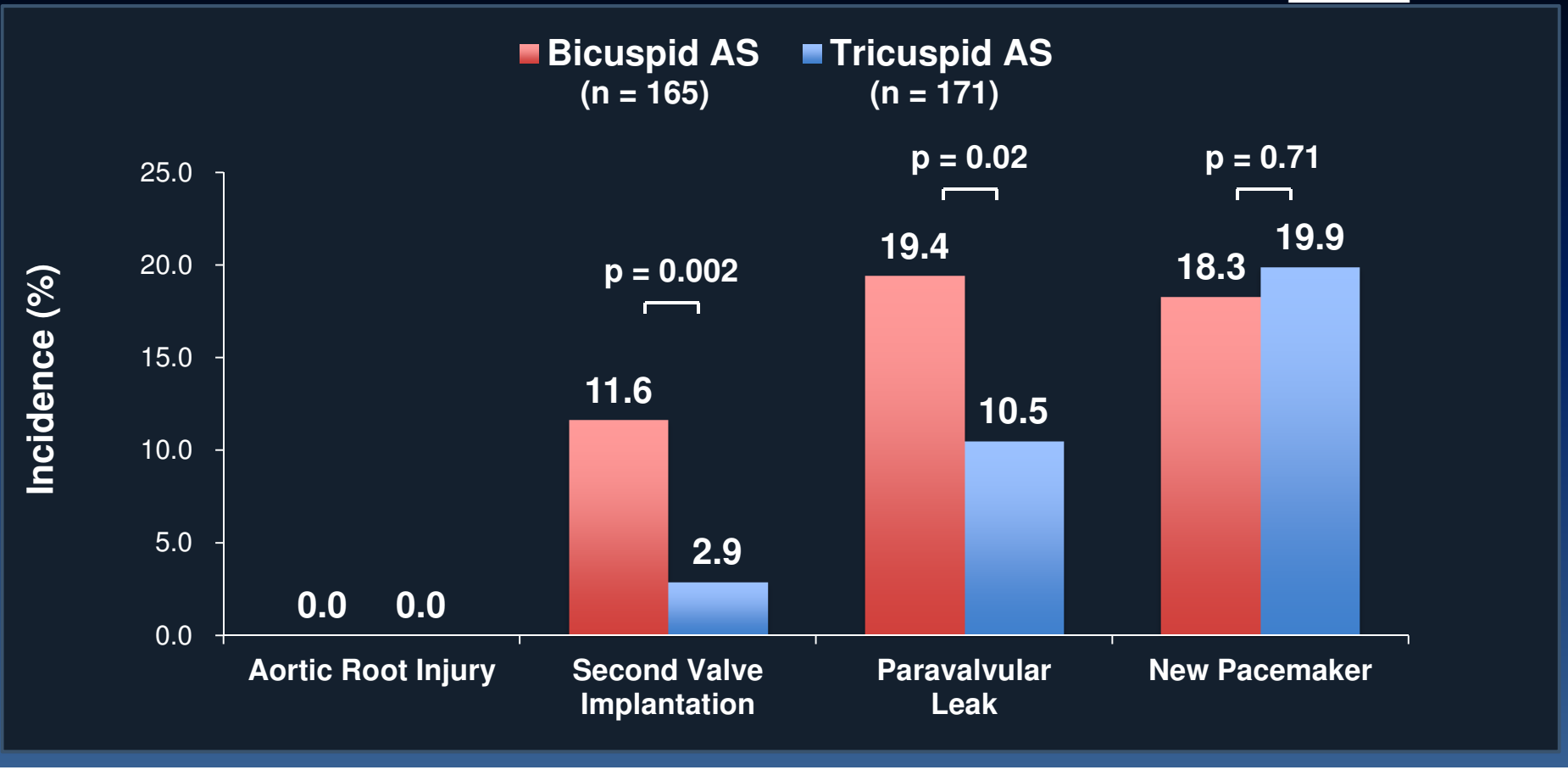
Sapien XT





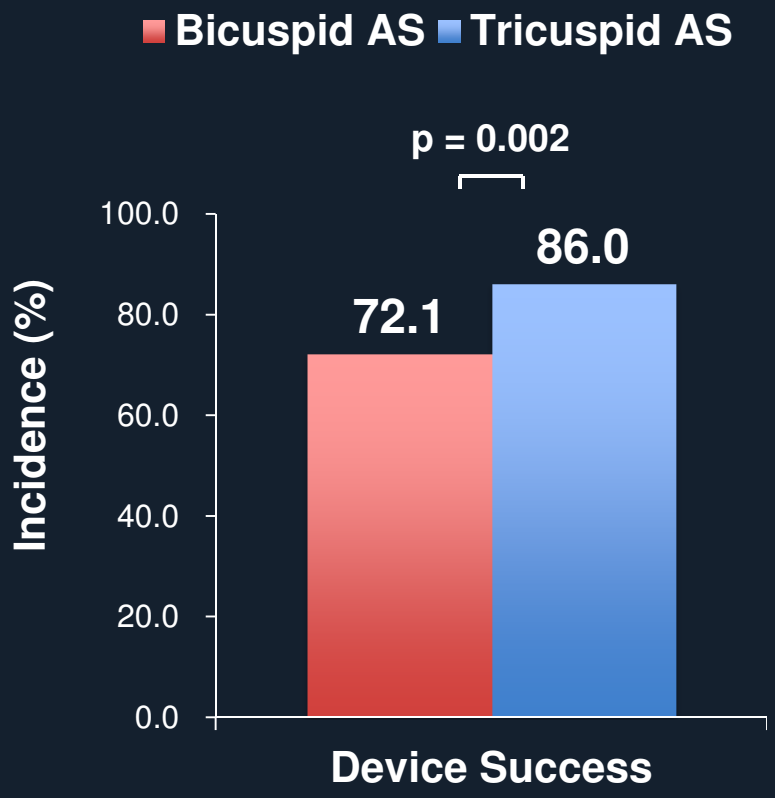
Procedural Outcomes

CoreValve



Procedural Outcomes

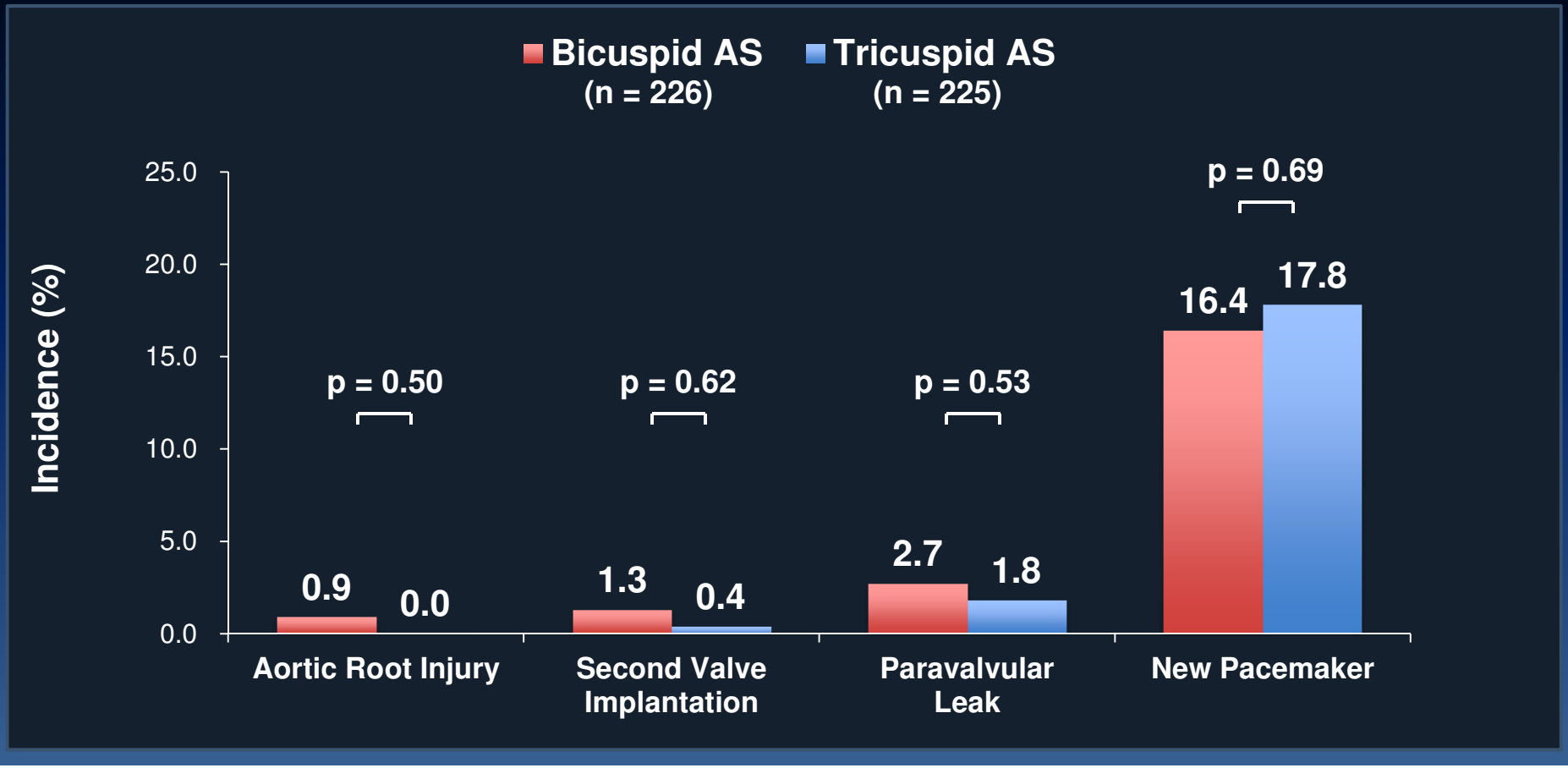
CoreValve



New Generation devices

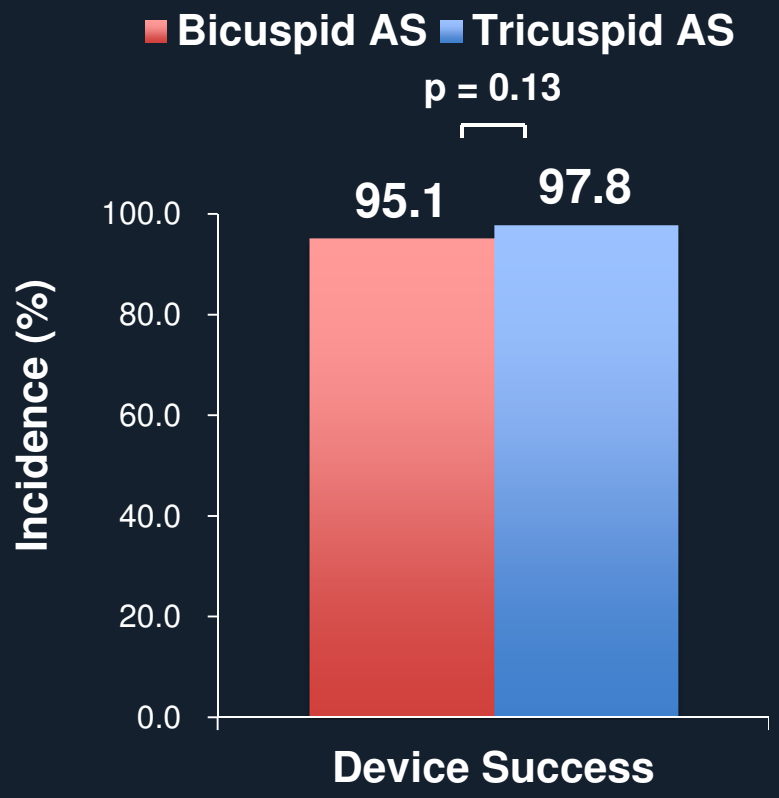
Procedural Outcomes

New Generation Devices



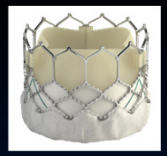
Procedural Outcomes

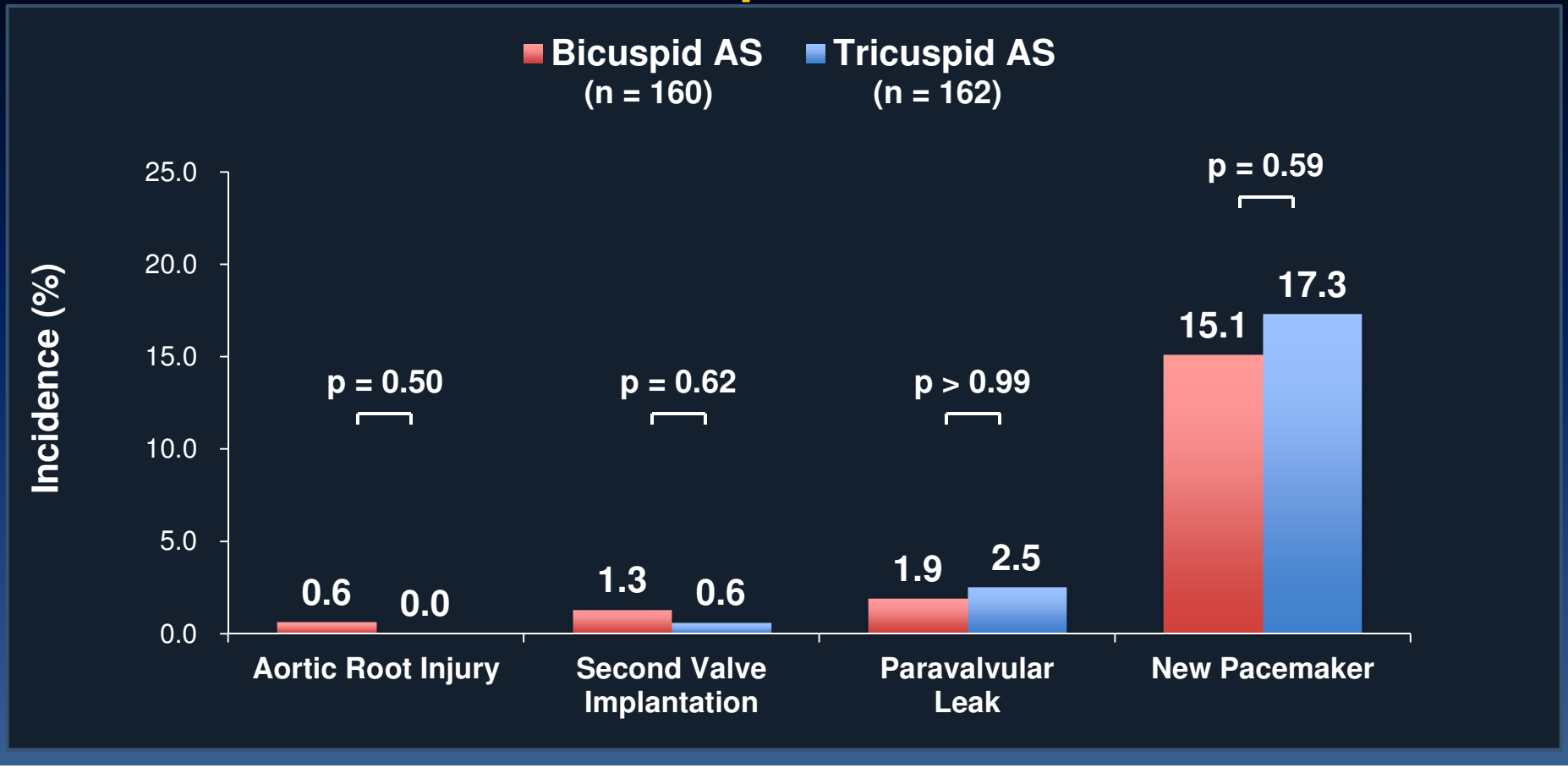
New Generation Devices



Procedural Outcomes

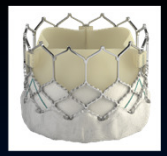
Sapien 3

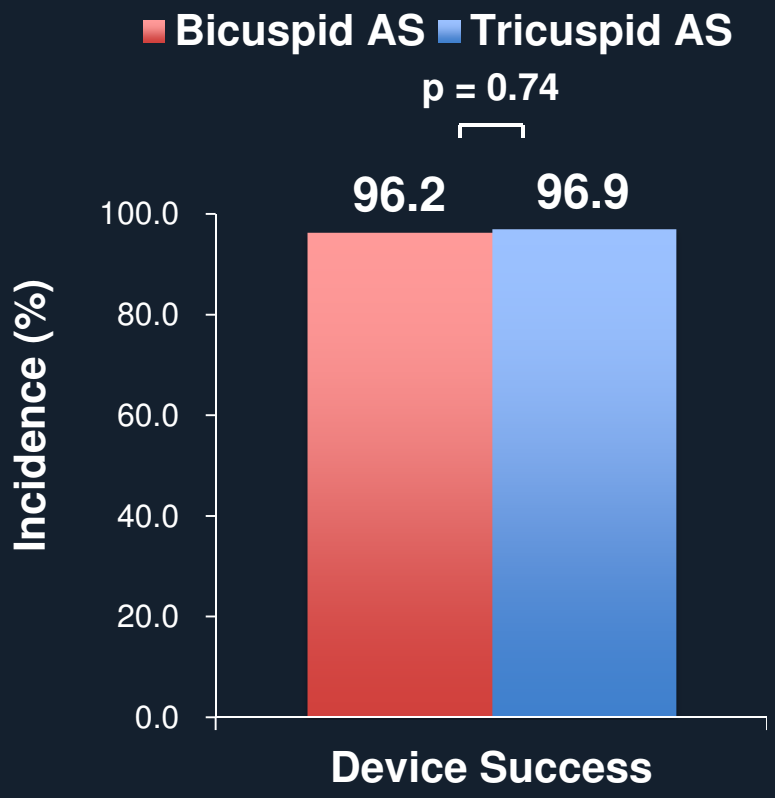




Procedural Outcomes

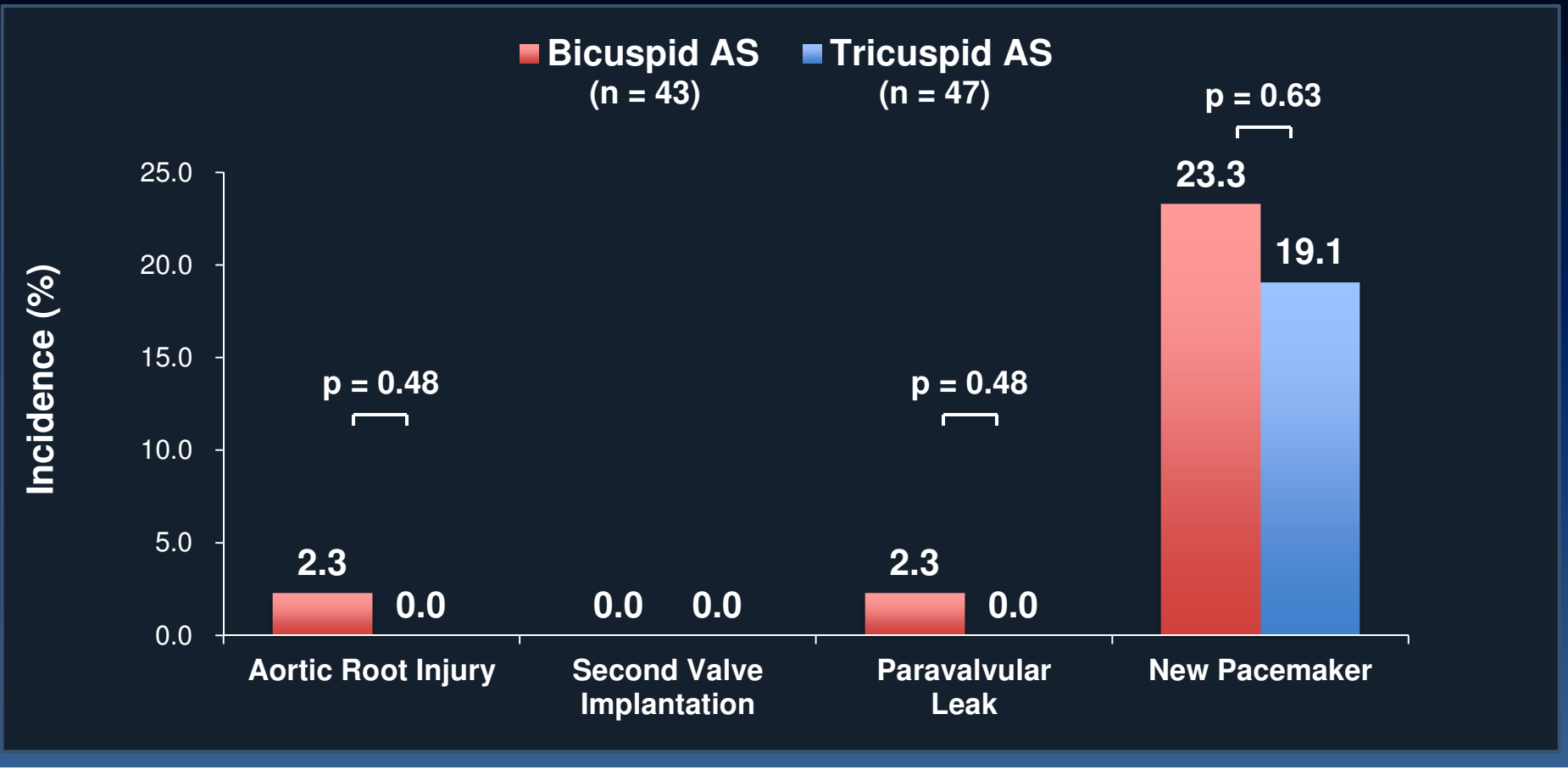
Sapien 3





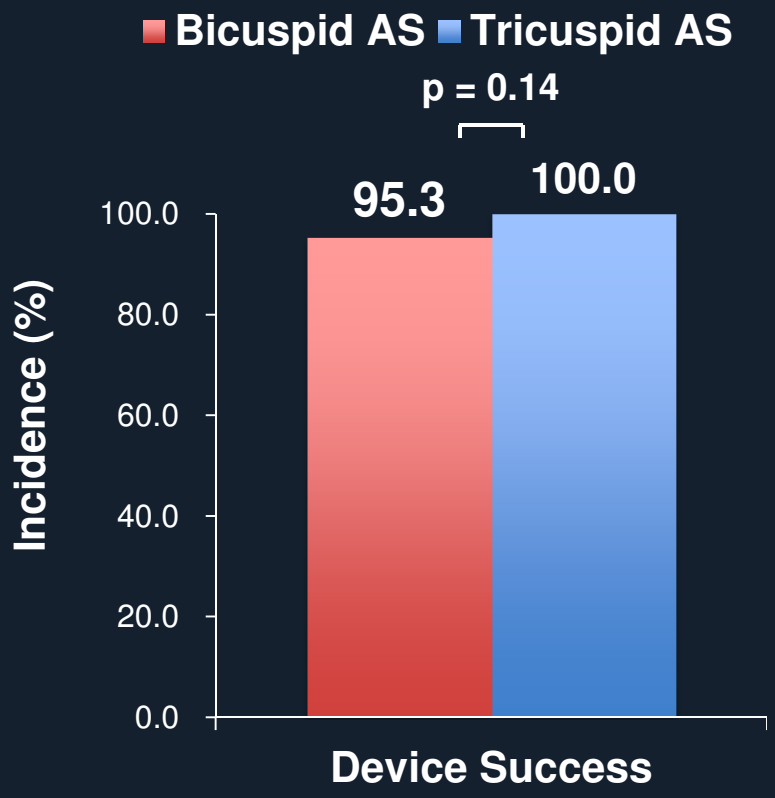
Procedural Outcomes

Lotus



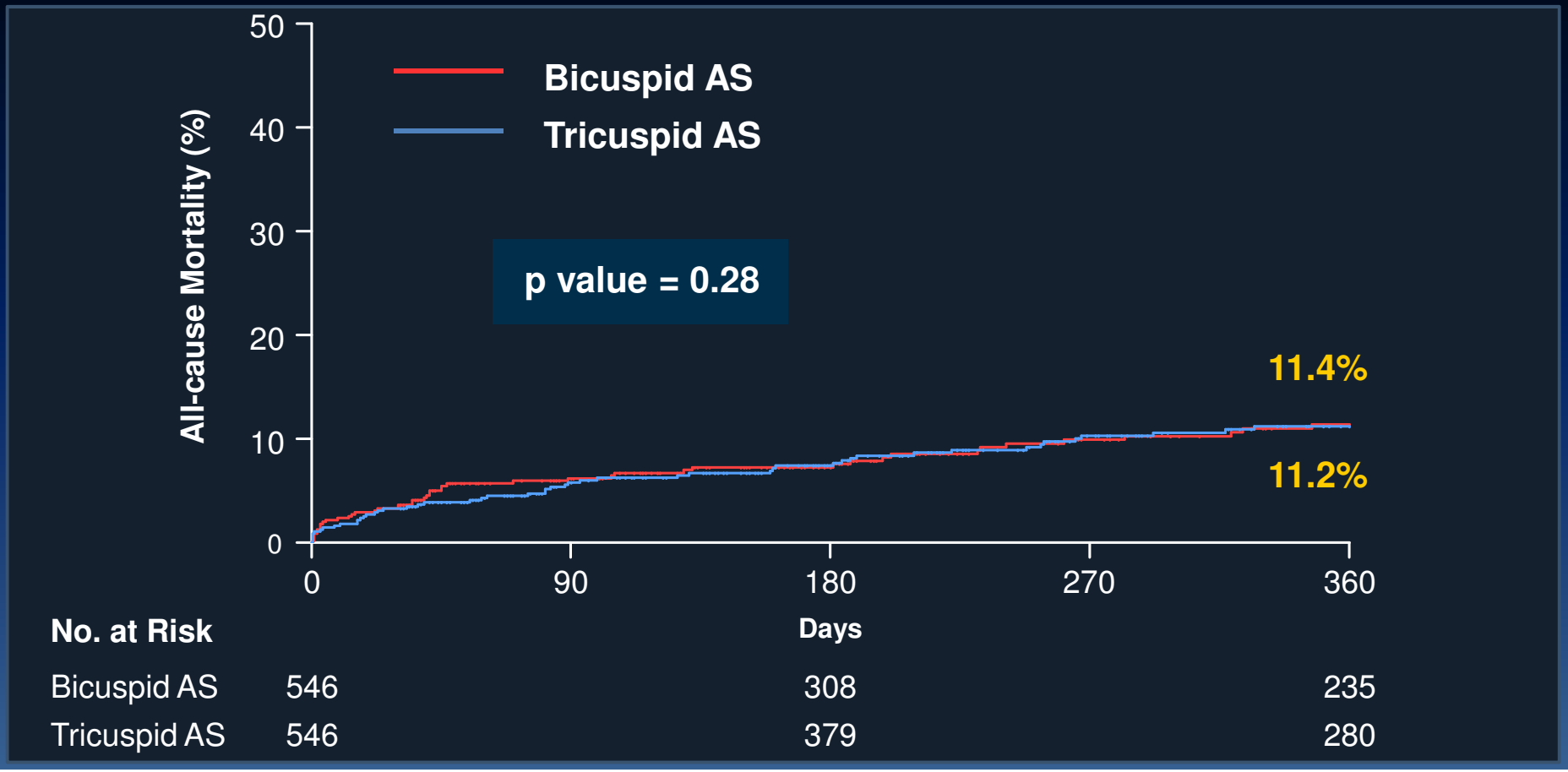
Procedural Outcomes

Lotus



Mid-term Mortality

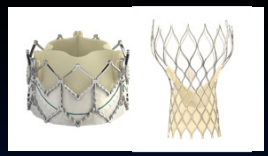
1-year All-cause Mortality

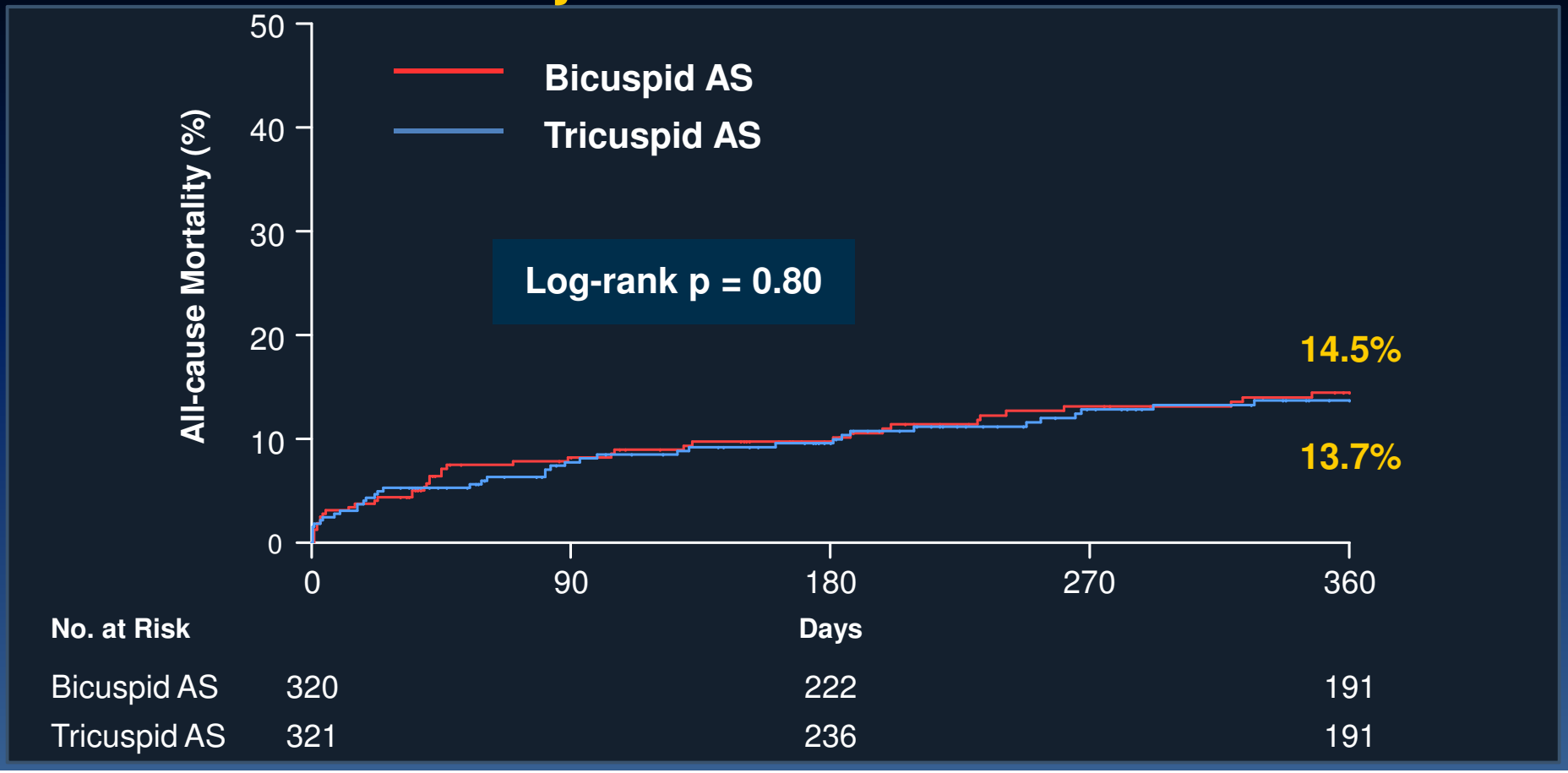


No. at Risk			
Bicuspid AS	546	308	235
Tricuspid AS	546	379	280

1-year All-cause Mortality

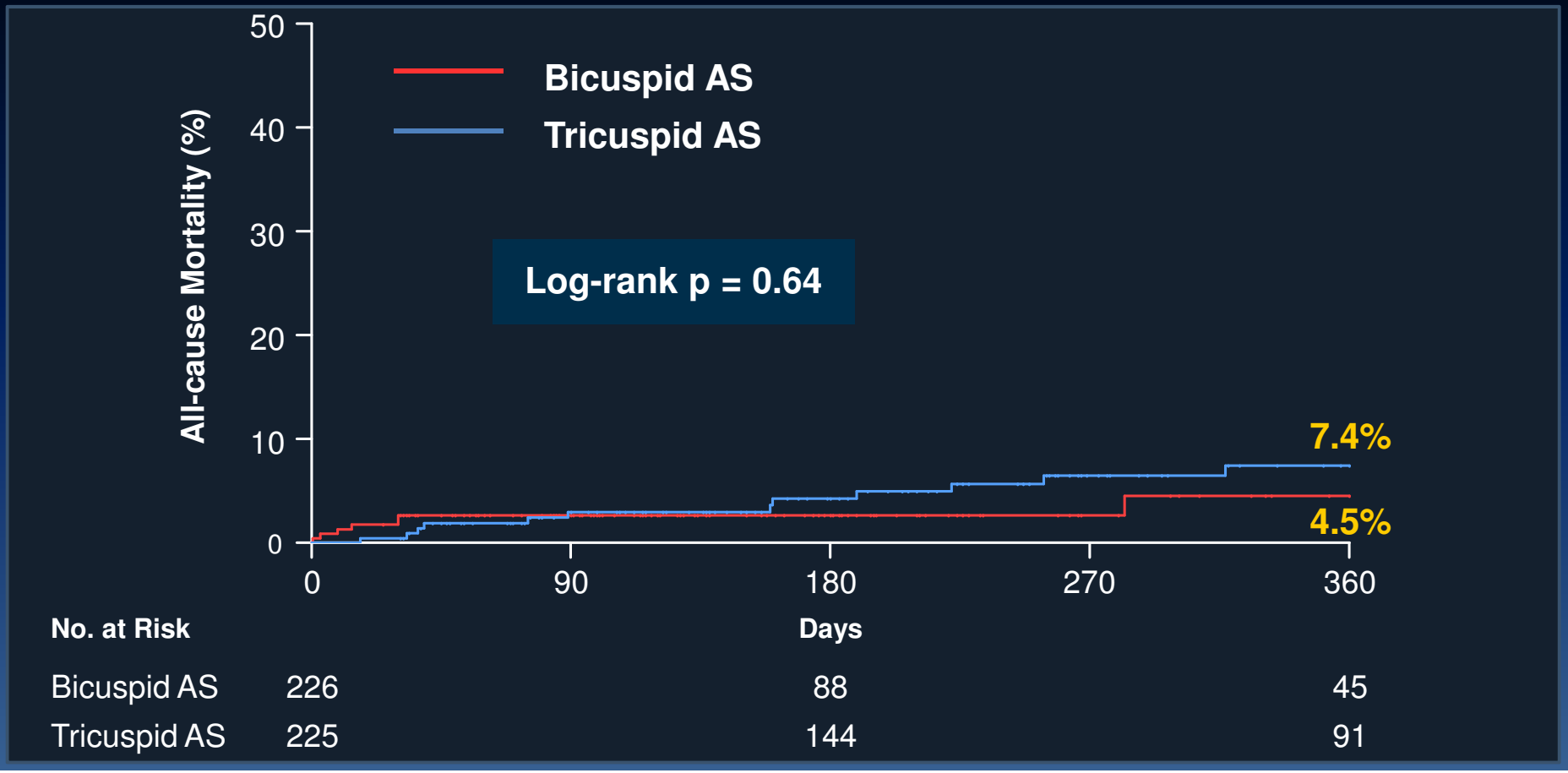
Early Generation Devices





1-year All-cause Mortality

New Generation Devices



Conclusions - 1

- TAVR for bicuspid AS was associated with *lower device success rate*
- Among patients receiving early generation devices, bicuspid AS had more frequent *aortic root injury* with Sapien XT, and moderate-severe *paravalvular leak* with CoreValve when compared to tricuspid AS
- Among patients receiving new generation devices, procedural outcomes were similar between bicuspid and tricuspid AS

Conclusions - 2

- 30-day clinical outcomes were similar between bicuspid and tricuspid AS
- All-cause mortality rates at 1-year were similar between bicuspid and tricuspid AS, across early and new generation devices

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