TAVR for Bicuspid Aortic Valve

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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 assessing the outcomes of TAVR in Bicuspid AS

Background

Recent Published study

ORIGINAL INVESTIGATIONS

Outcomes in Transcatheter Aortic Valve Replacement for Bicuspid Versus Tricuspid Aortic Valve Stenosis

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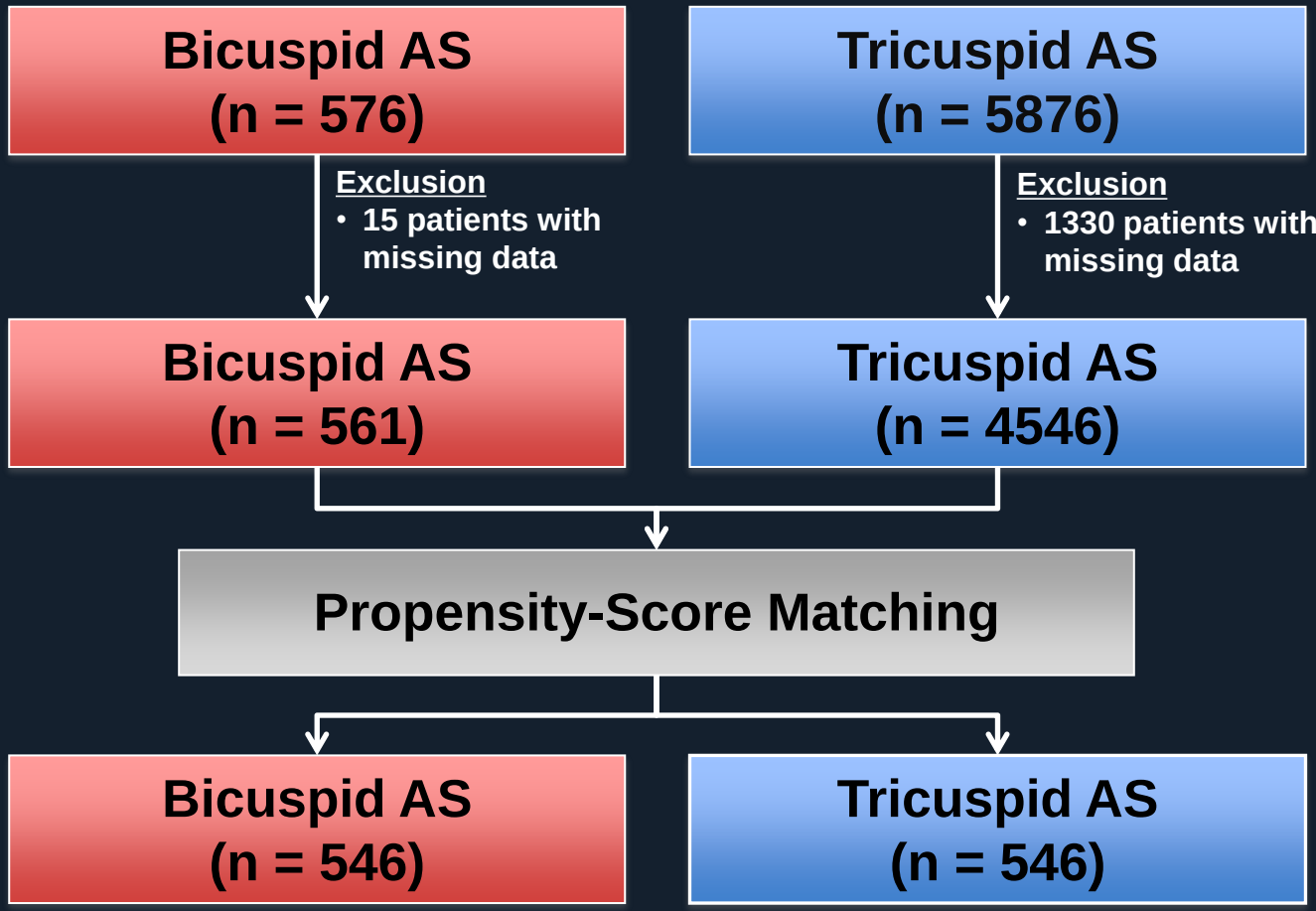
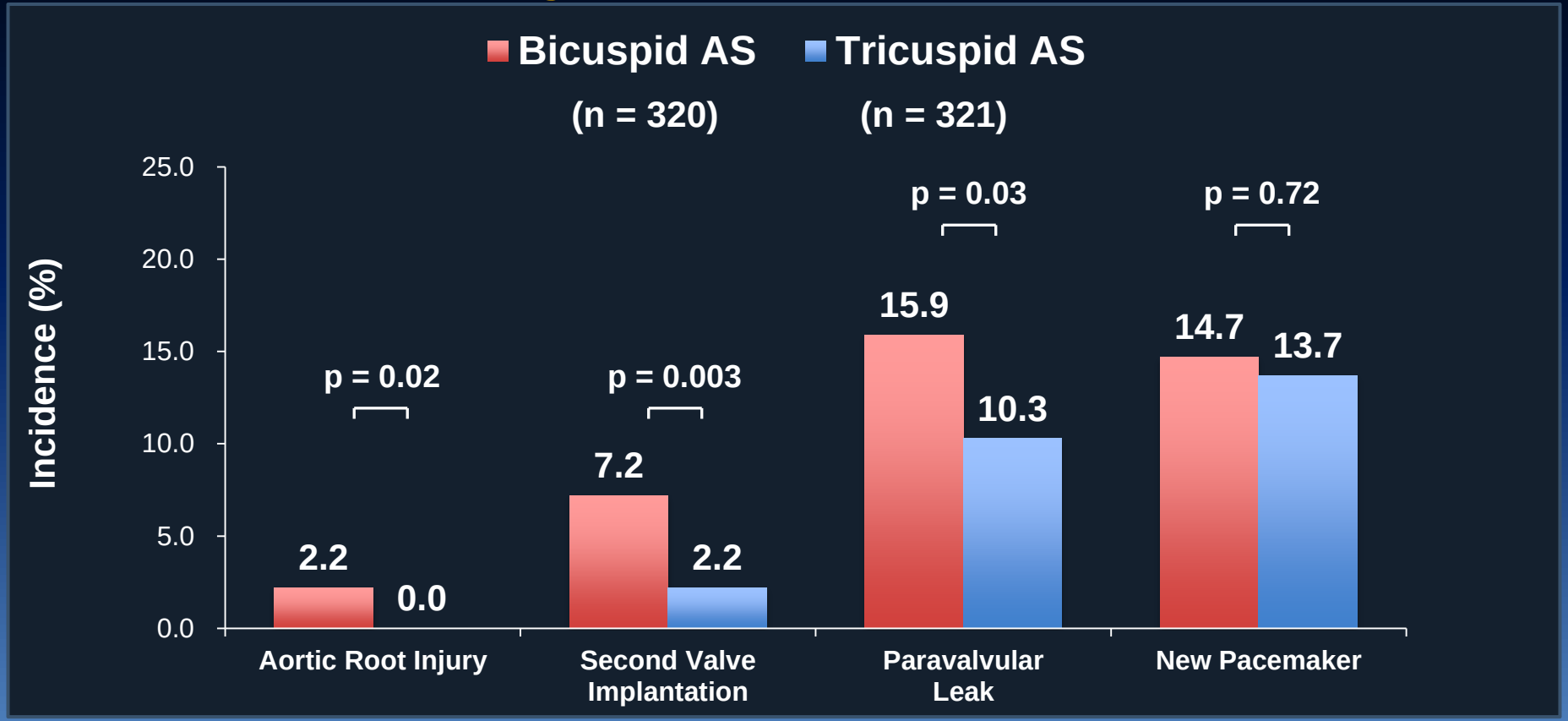
Study Design



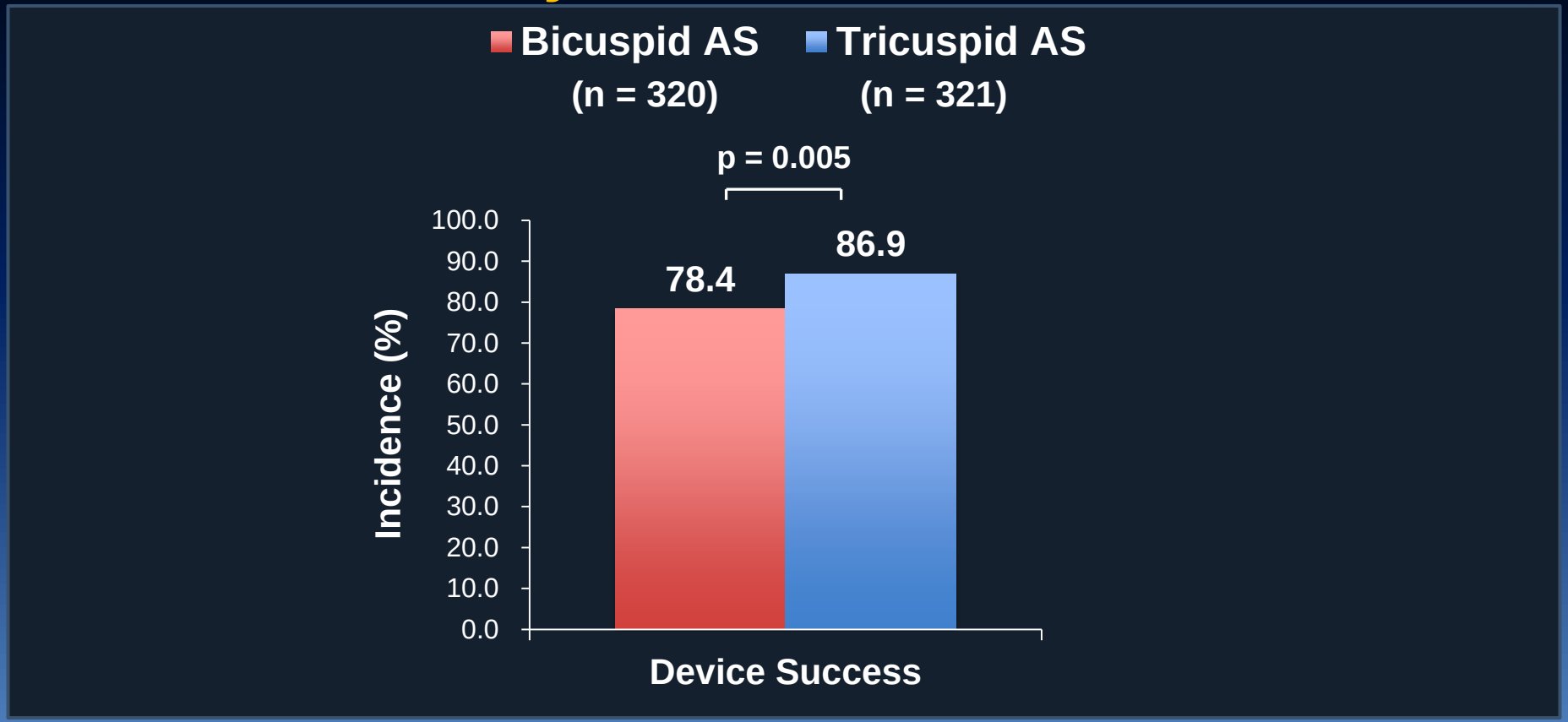
Procedural Outcomes

Early Generation Devices



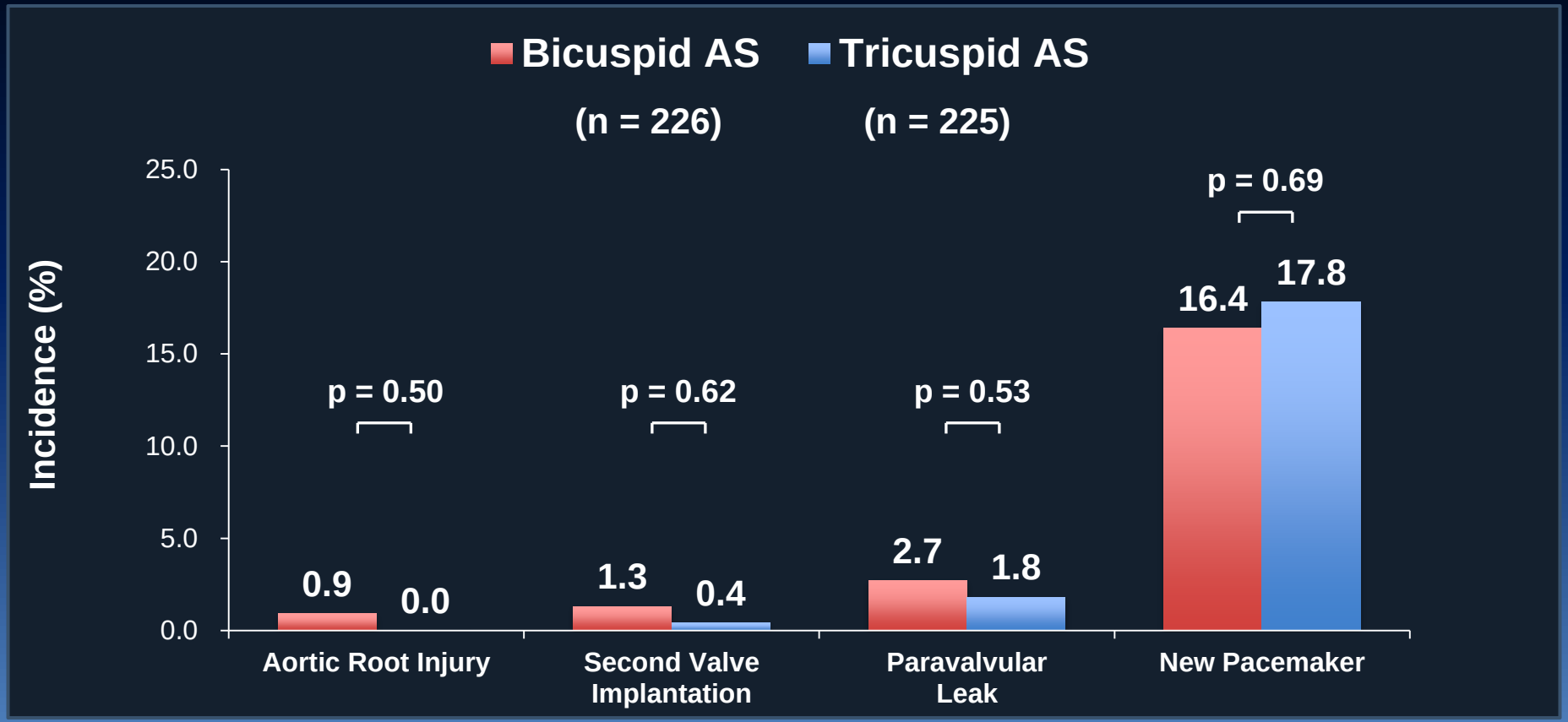
Procedural Outcomes

Early Generation Devices



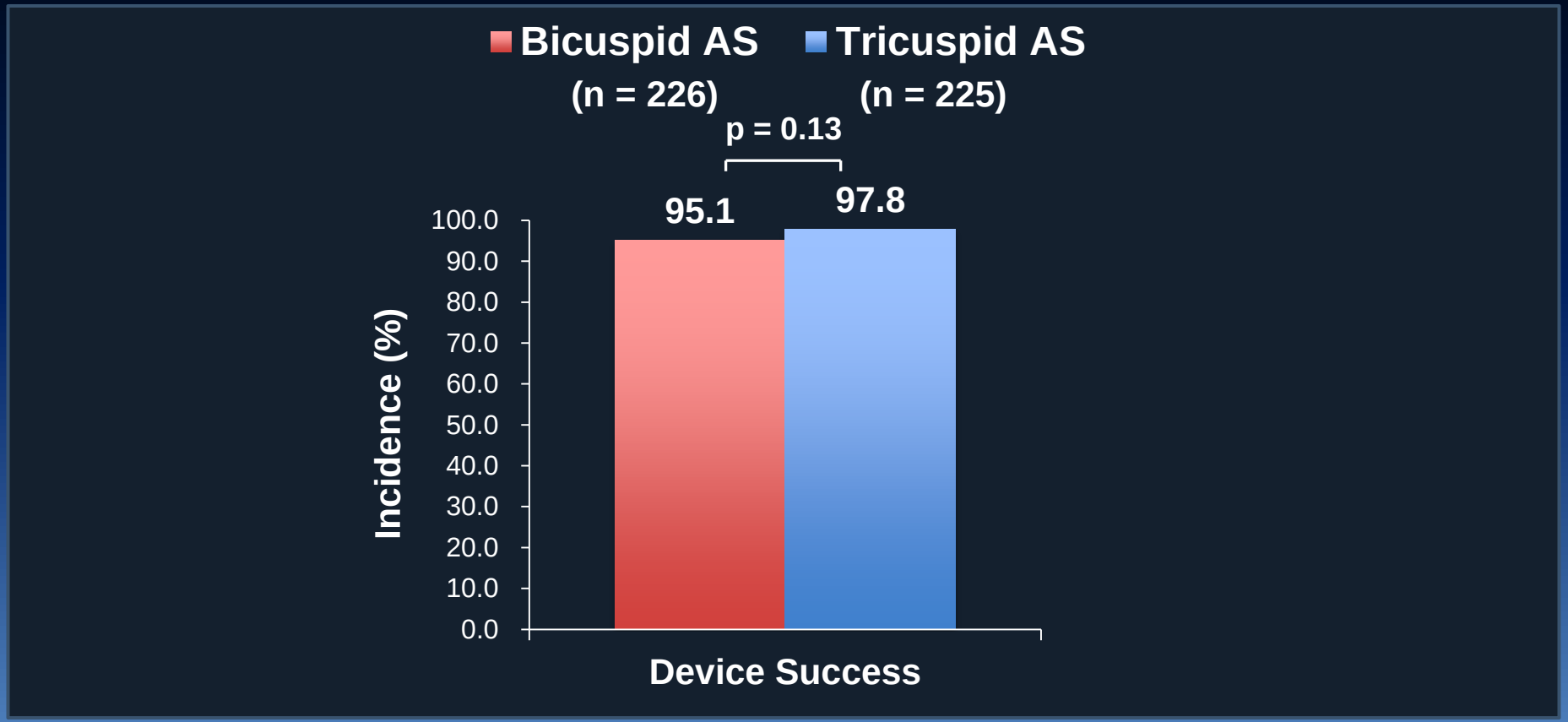
Procedural Outcomes

New Generation Devices



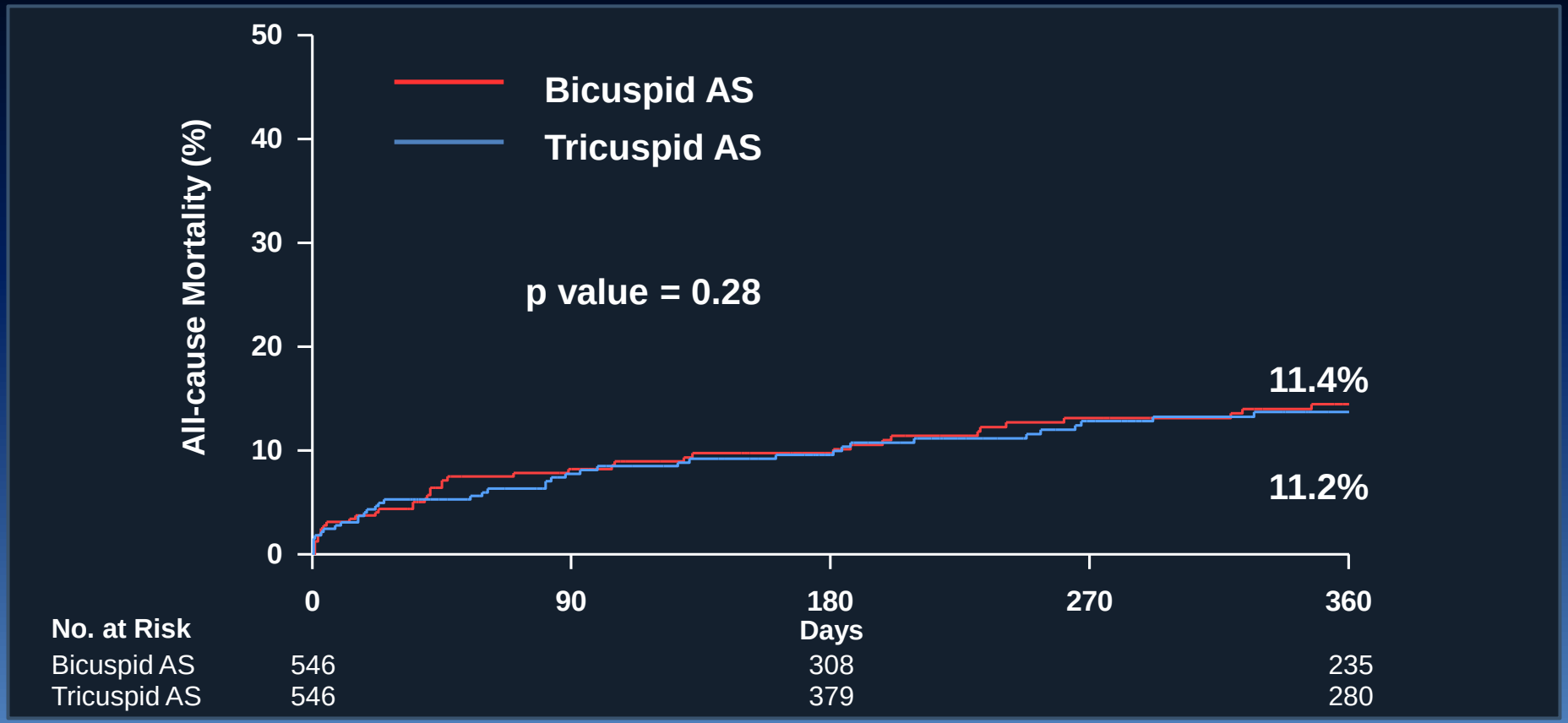
Procedural Outcomes

New Generation Devices



1-year All-cause Mortality

Overall Propensity Matched Cohort



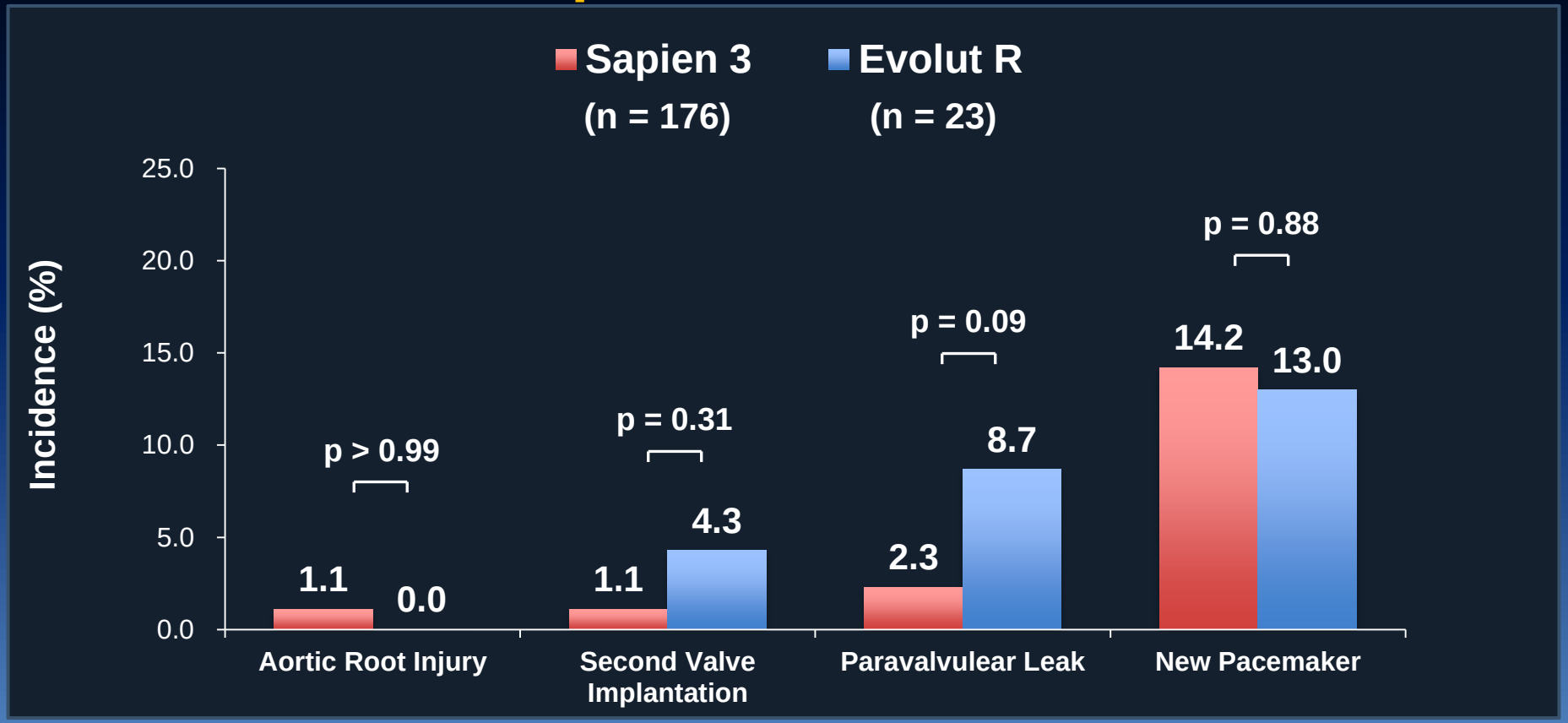
Summary

- Among patients receiving early generation devices, bicuspid AS had more frequent aortic root injury and moderate-severe paravalvular leak
- Among patients receiving new generation devices, procedural outcomes were similar between bicuspid and tricuspid AS
- All-cause mortality rates at 1-year were similar between bicuspid and tricuspid AS

Sapien 3 vs. Evolut R in Bicuspid AS

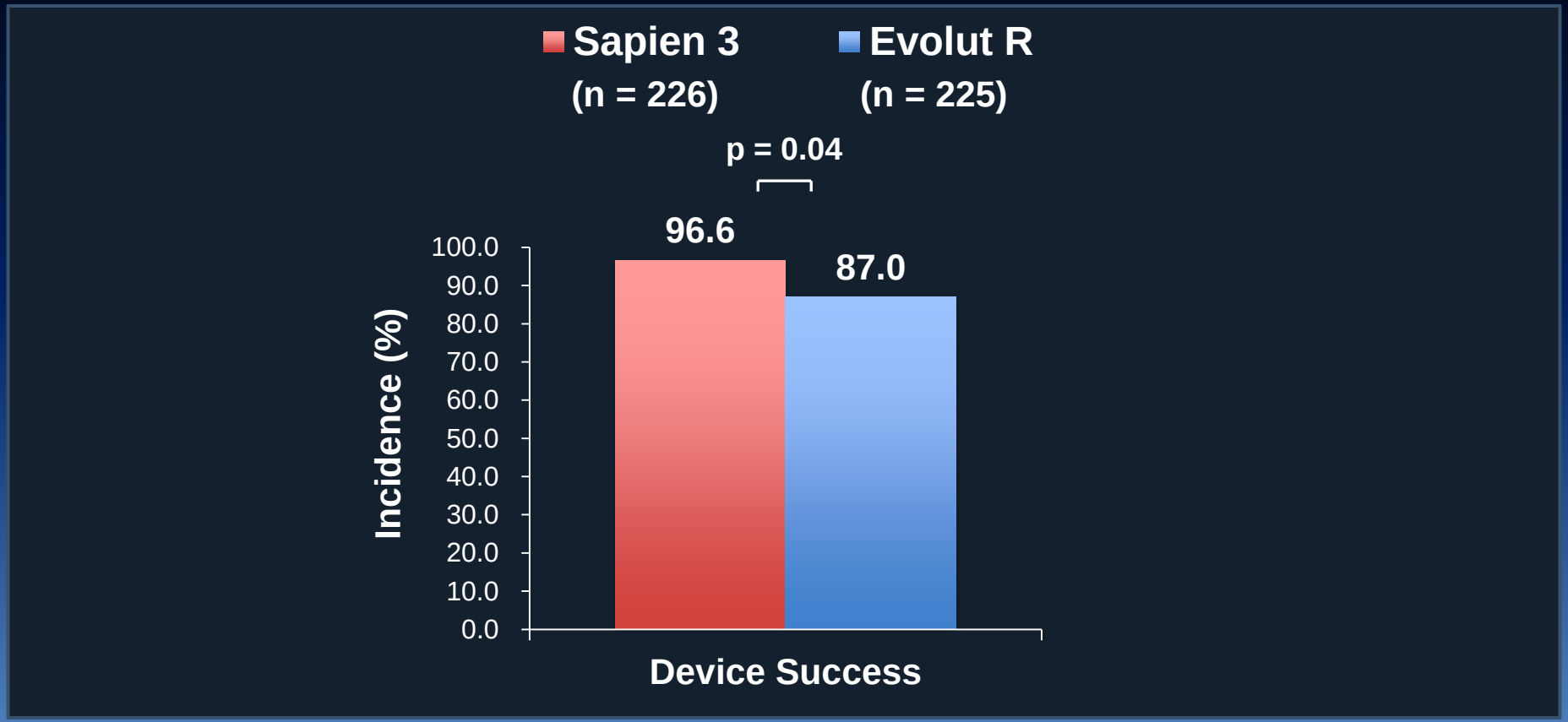
Procedural Outcomes

Sapien 3 vs Evolut R



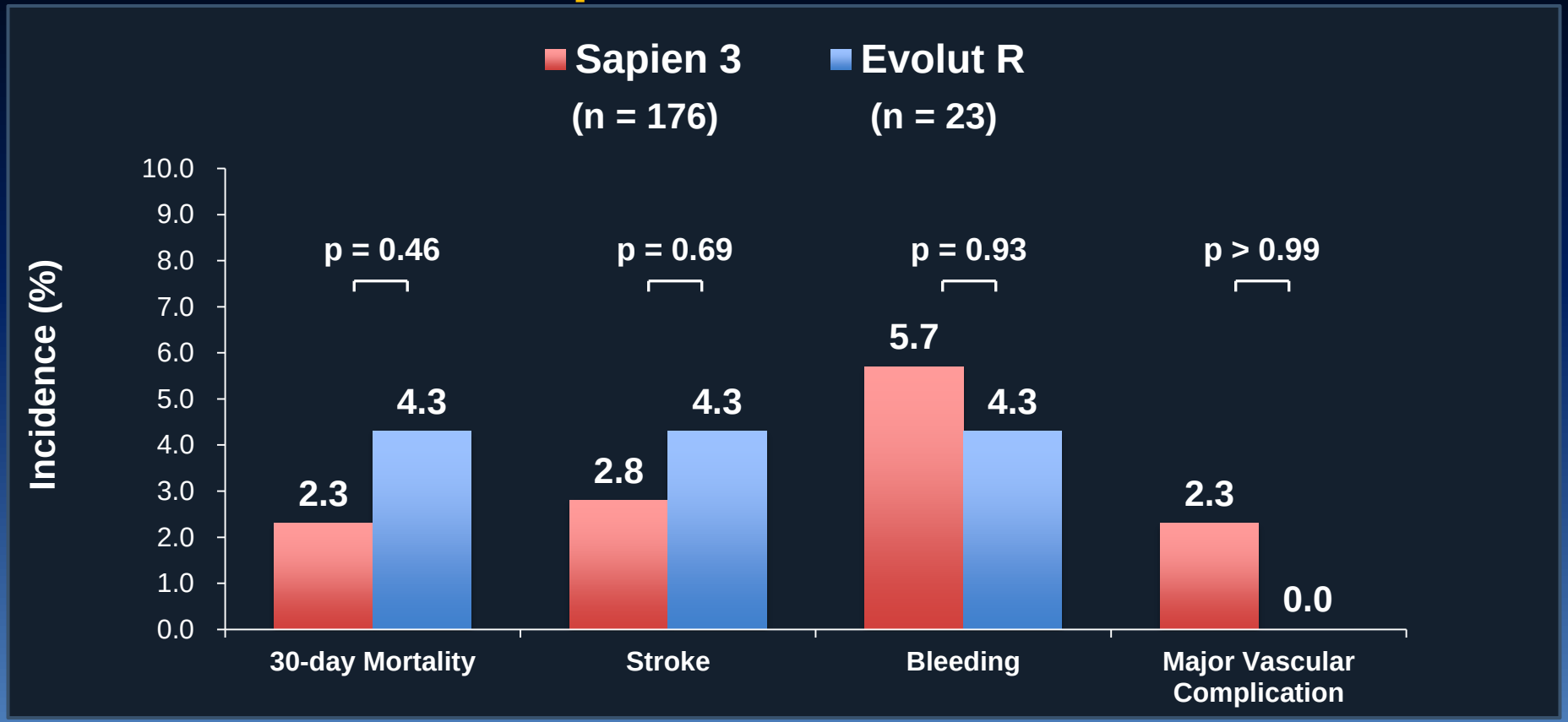
Procedural Outcomes

New Generation Devices

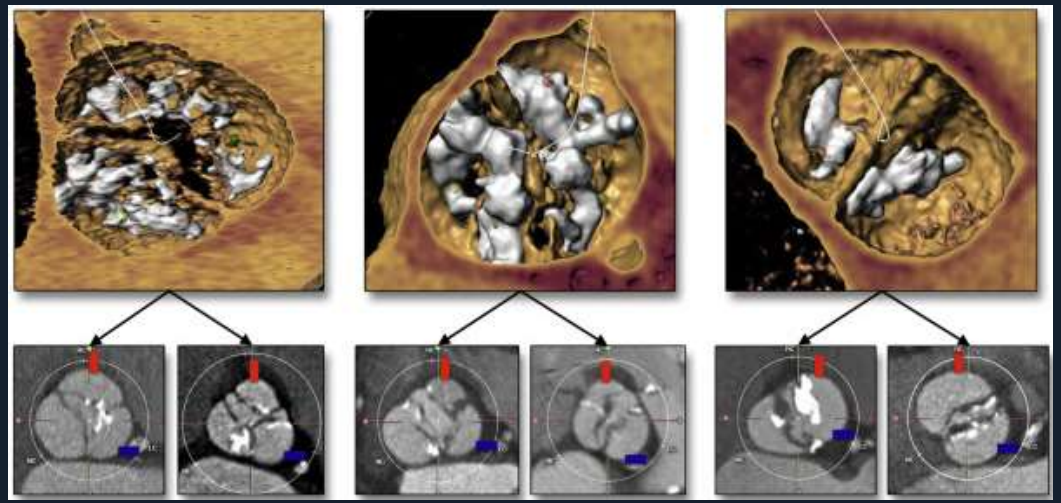


Clinical Outcomes

Sapien 3 vs Evolut R



Bicuspid AV Morphology



Hasan Jilaihawi et al; JACC: Cardiovascular Imaging, Volume 9, Issue 10, 2016, 1145–1158

Limited data exists about the impact of bicuspid morphology on outcomes of TAVR

Methods

- The Bicuspid AS TAVR multicenter registry was used to evaluate procedural and clinical outcomes
- Bicuspid aortic valve morphology was defined by independent analysis of computed tomography images
- Procedural and clinical outcomes were assessed according to VARC-2 criteria

Study Design

Bicuspid AS with MDCT available
(n = 418)

Raphe ?

No

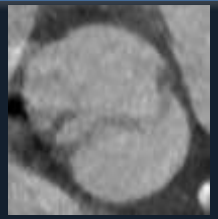
Yes

Calcified raphe?

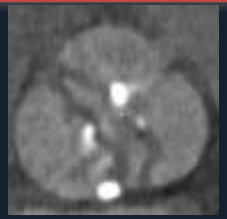
No

Yes

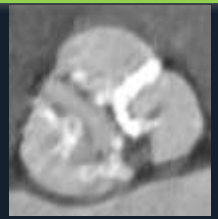
Type 0 (No Raphe)
n = 62



Type 1 (Raphe)
n = 130



Type 1 (Calcified Raphe)
n = 226



Baseline Characteristics

Demographics

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Age, years	75 ± 8	77 ± 9	76 ± 9	0.18
Male	65%	56%	66%	0.15
NYHA class III / IV	69%	80%	79%	0.24
LVEF, %	50.9 ± 16.1	54.1 ± 15.4	50.8 ± 15.9	0.15
Mean gradient, mm Hg	26.9 ± 15.8	26.2 ±15.6	28.2 ±16.2	0.44
STS score, %	4.5 ± 5.6	4.1 ± 3.2	5.2 ± 5.3	0.09
Logistic EuroSCORE, %	12.7 ± 11.8	15.4 ±11.1	14.3 ±12.3	0.50

Baseline Characteristics

Demographics

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Diabetes mellitus	24%	22%	24%	0.95
Hypertension	65%	56%	66%	0.63
COPD	21%	24%	20%	0.68
PVD	21%	19%	13%	0.23
Prior PCI	16%	19%	21%	0.67
Prior CABG	15%	12%	11%	0.70
Prior CVA	19%	14%	17%	0.59

Baseline Characteristics

Procedure

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Transfemoral access	81%	88%	89%	0.18
Device				
Early generation devices	69%	50%	53%	0.03
CoreValve	47%	19%	24%	< 0.001
Sapien XT	23%	32%	29%	0.44
New generation devices	31%	50%	47%	0.03
Sapien 3	23%	40%	38%	0.05
Lotus	8%	7%	5%	0.55
Evolut R	0%	3%	4%	0.23

Procedural Outcomes

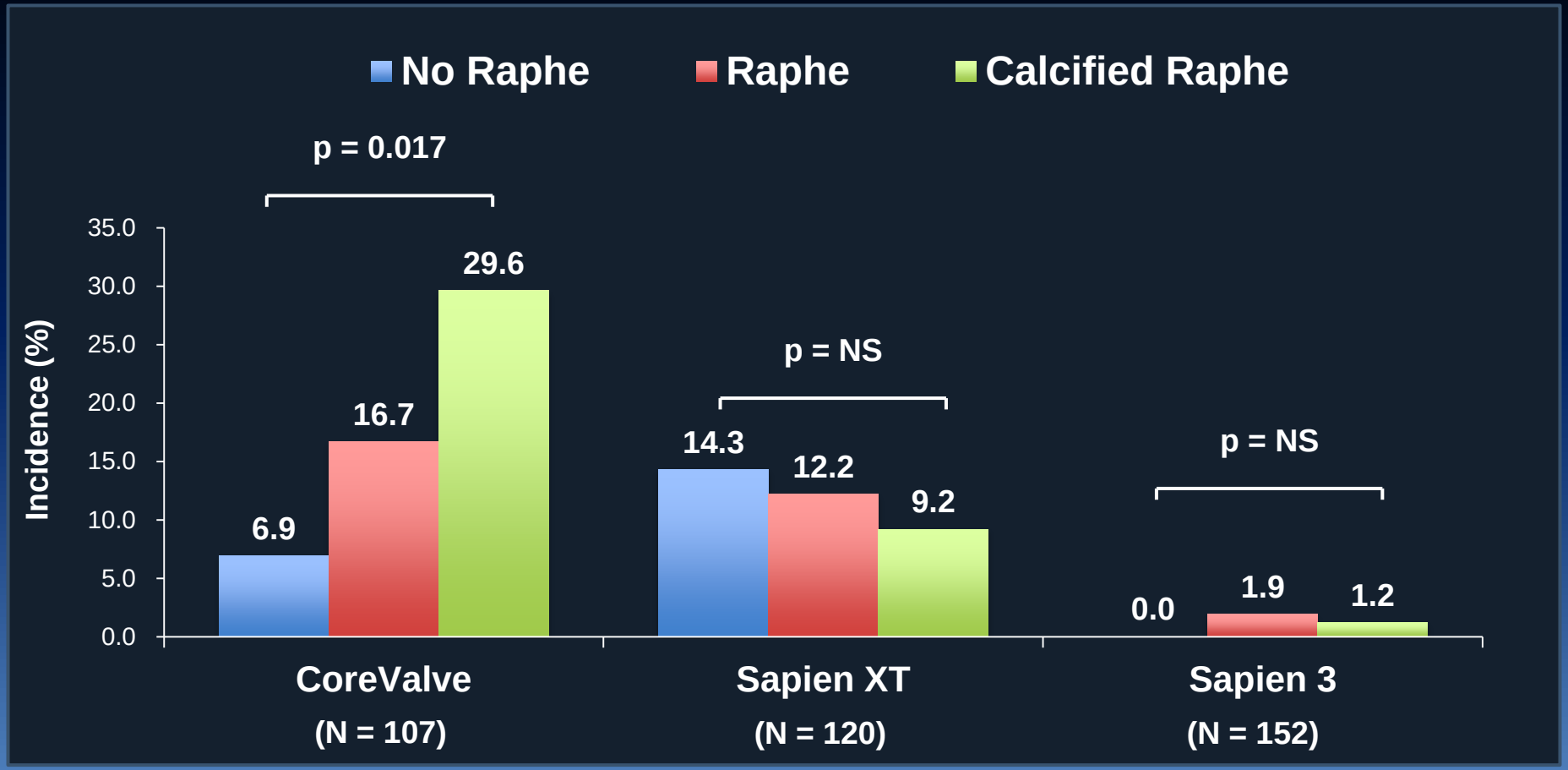
	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Device success	87.1%	90.8%	83.6%	0.17
Second valve implantation	6.5%	1.5%	5.8%	0.14
Conversion to surgery	1.6%	1.5%	2.7%	0.89
Coronary obstruction	3.2%	0.8%	0.9%	0.29
New permanent pacemaker	11.3%	16.2%	19.0%	0.34
PVL ≥ moderate	6.5%	7.7%	11.1%	0.40
Annulus rupture	0.0%	0.8%	2.7%	0.36
Procedural mortality	1.6%	0.0%	2.7%	0.17

30-day Clinical Outcomes

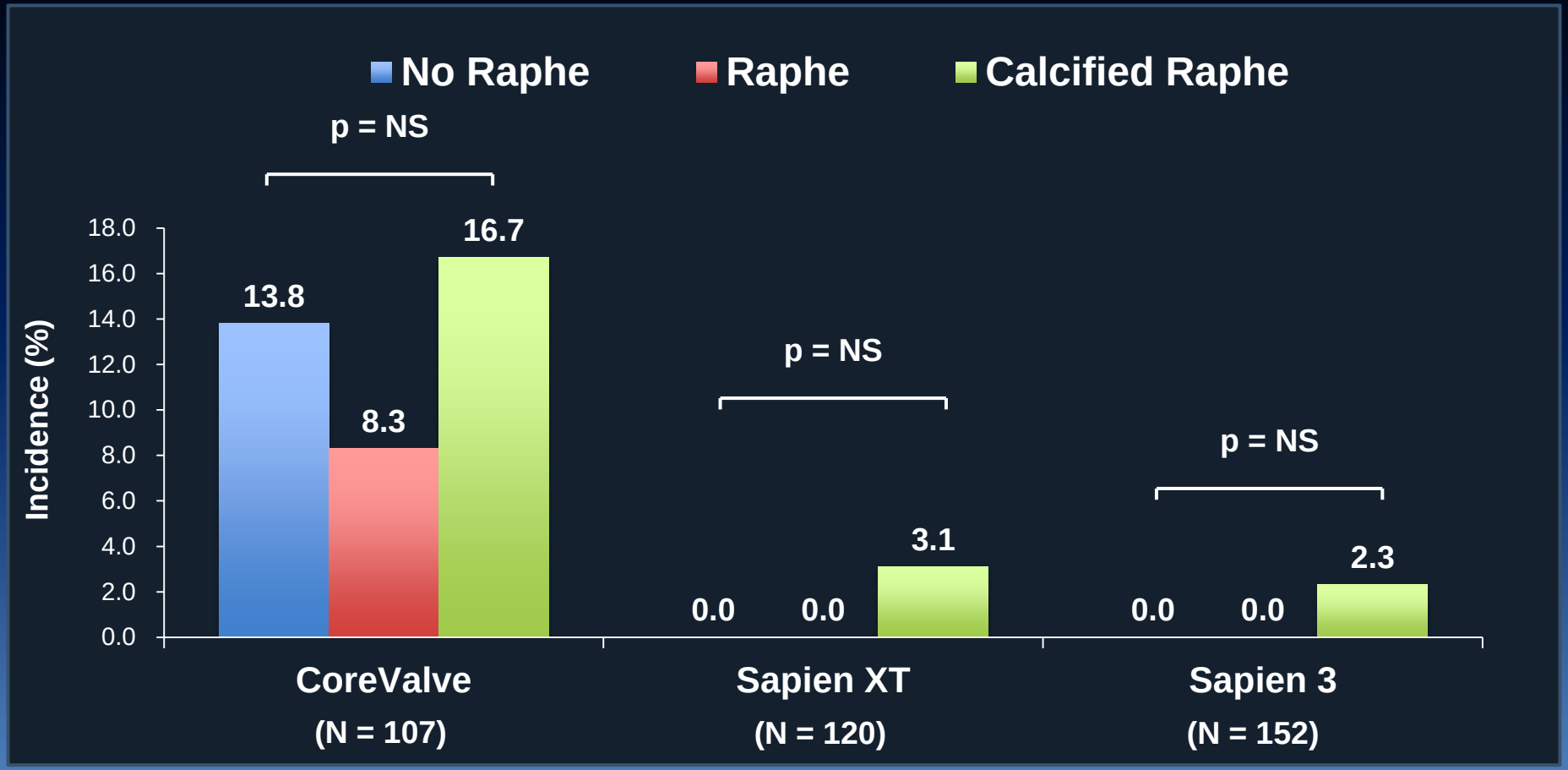
	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
30-day mortality	1.6%	0.0%	6.2%	0.003
Stroke	0.0%	3.1%	2.2%	0.52
Life-threatening bleeding	0.0%	0.0%	2.7%	0.13
Major vascular complication	0.0%	2.3%	4.9%	0.15
AKI (stage 2 or 3)	1.6%	2.3%	1.8%	0.89

Outcomes According to Device Type

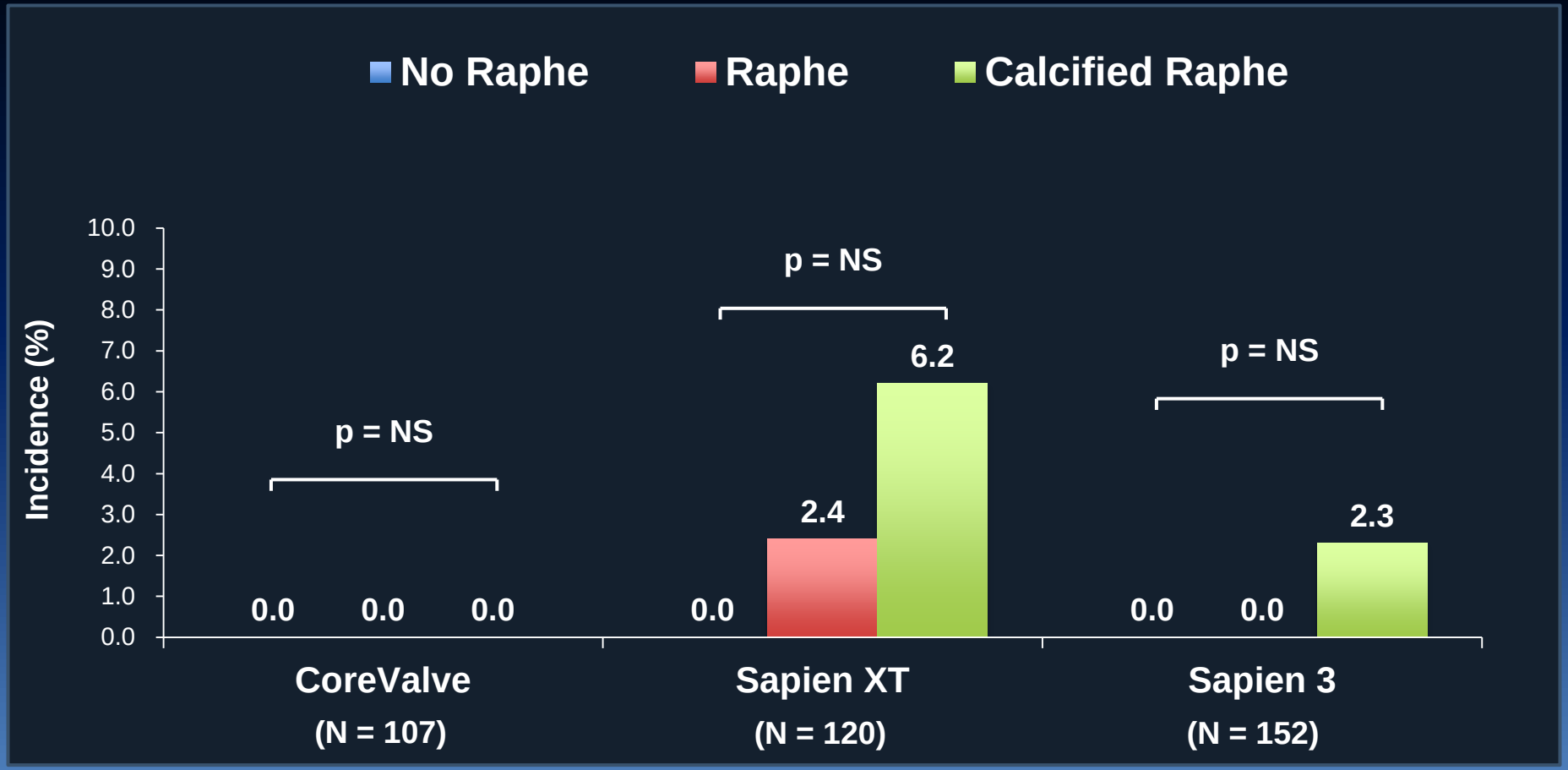
Paravalvular Leak



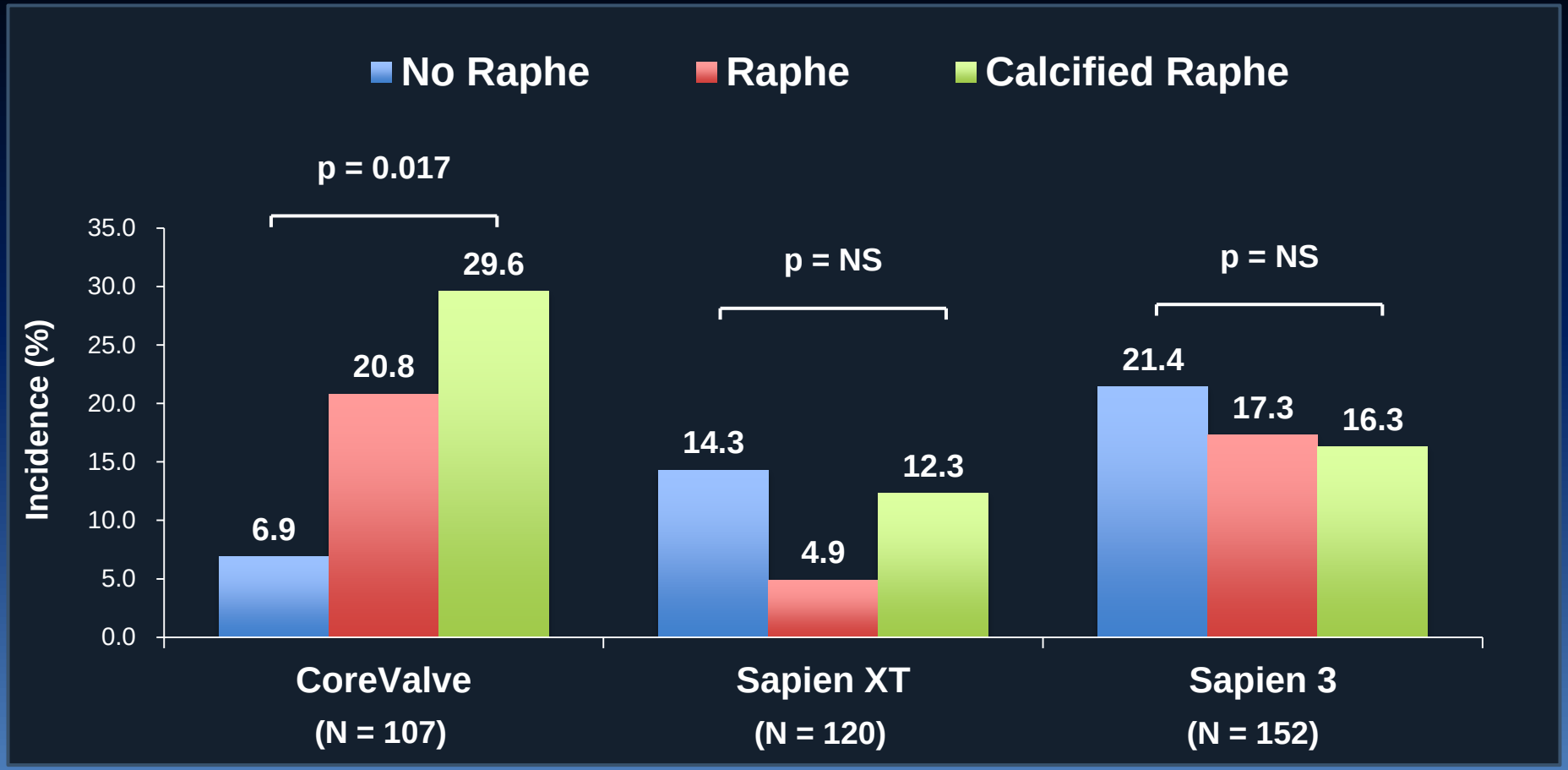
Second Valve Implantation



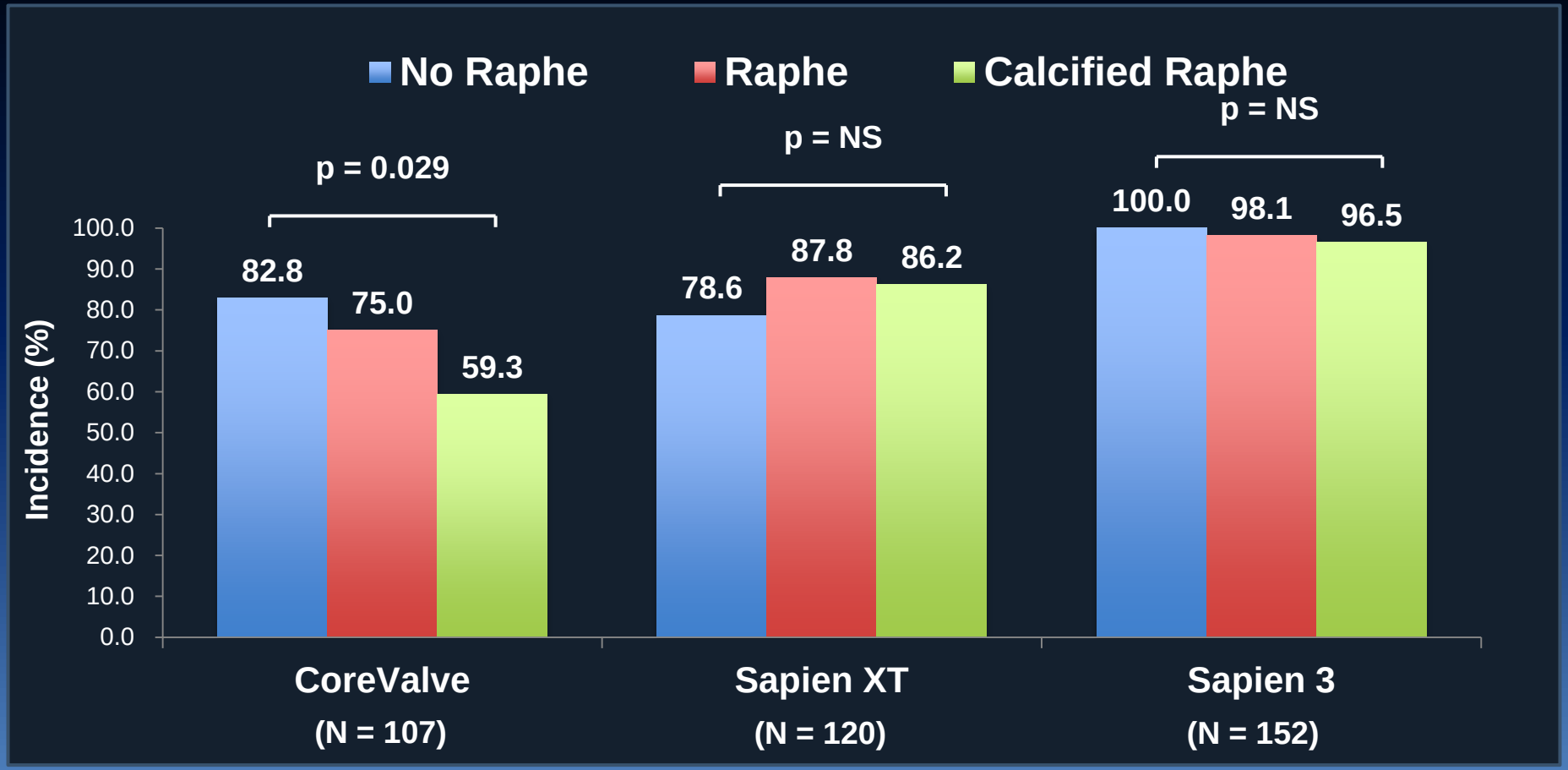
Annulus Rupture



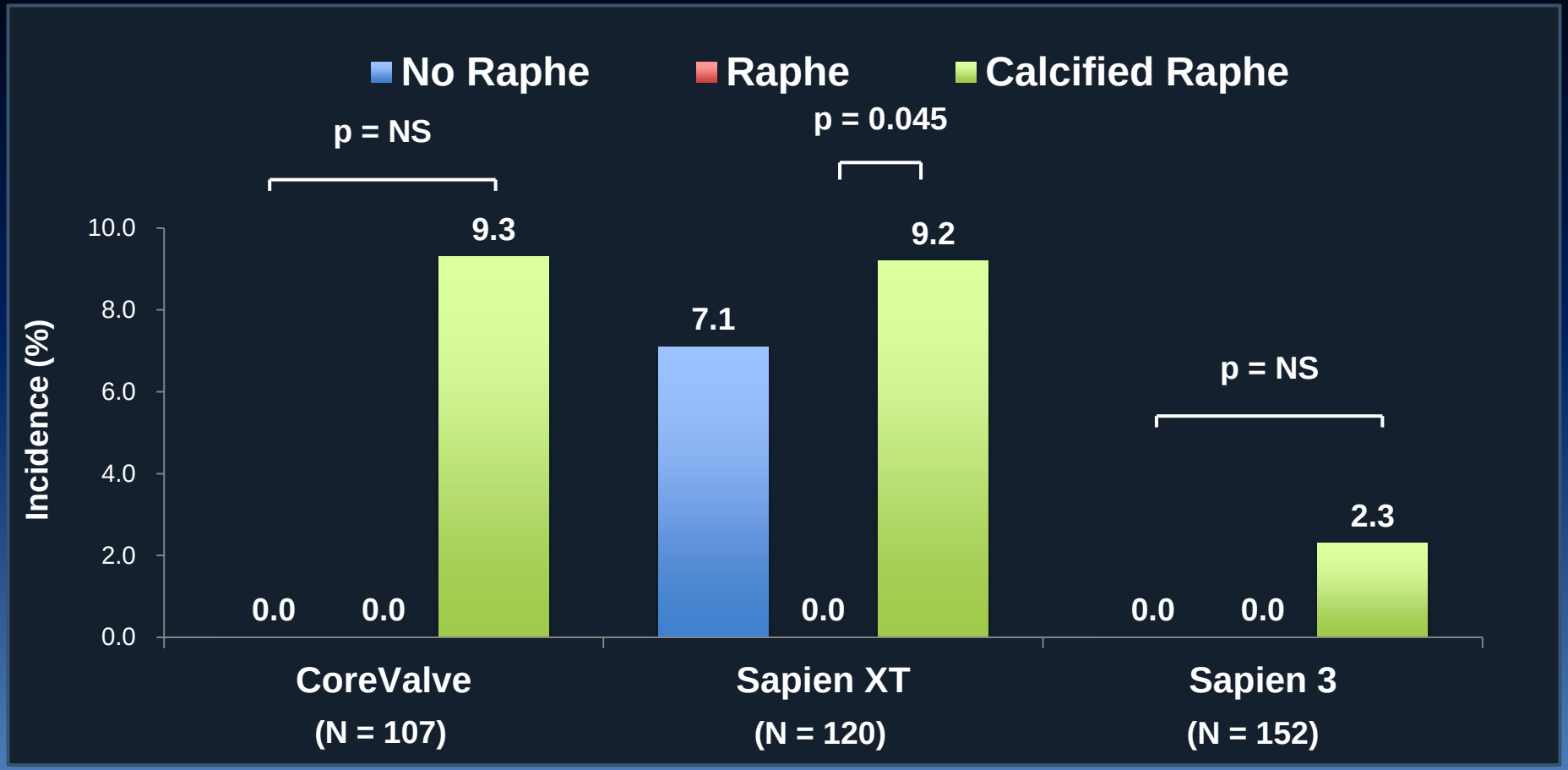
New Permanent Pacemaker



Device Success

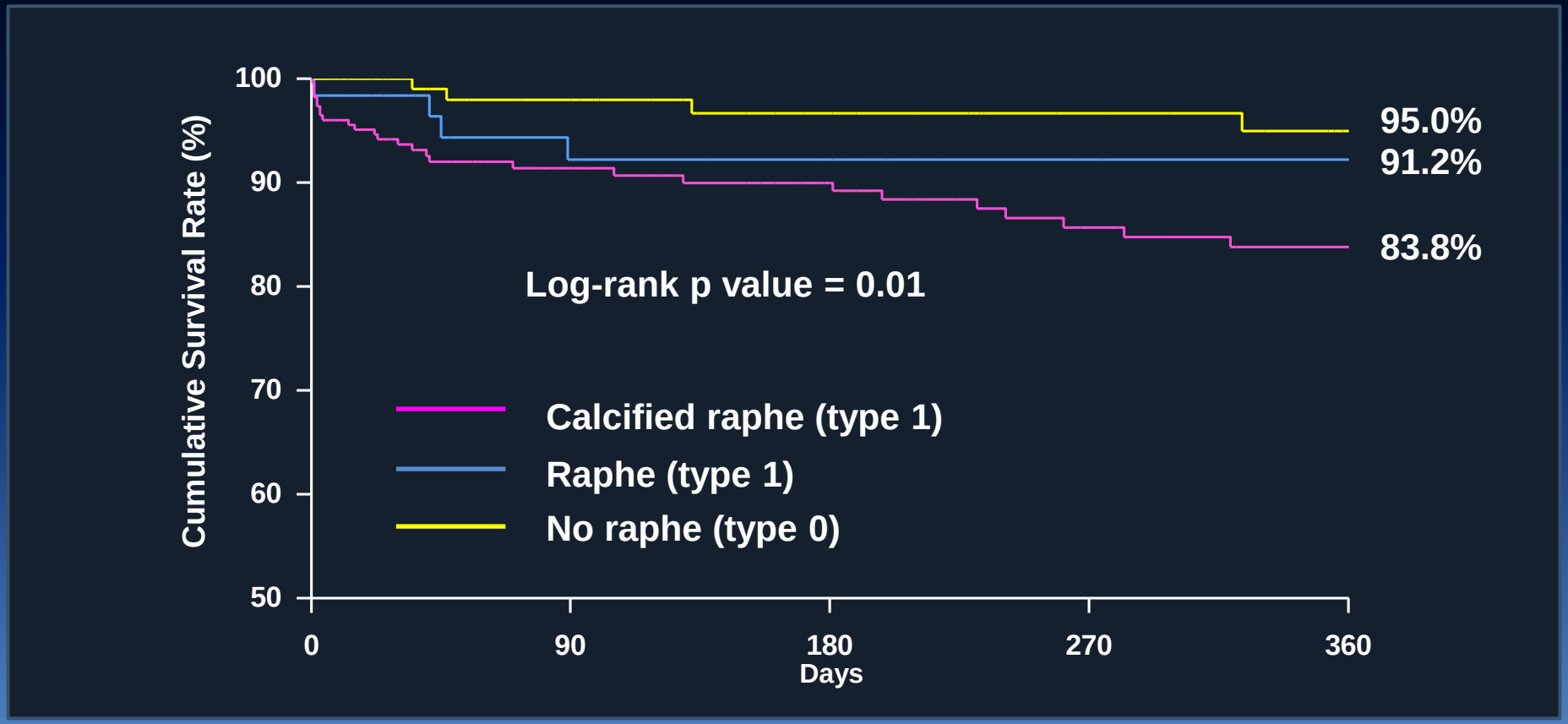


30-day Mortality



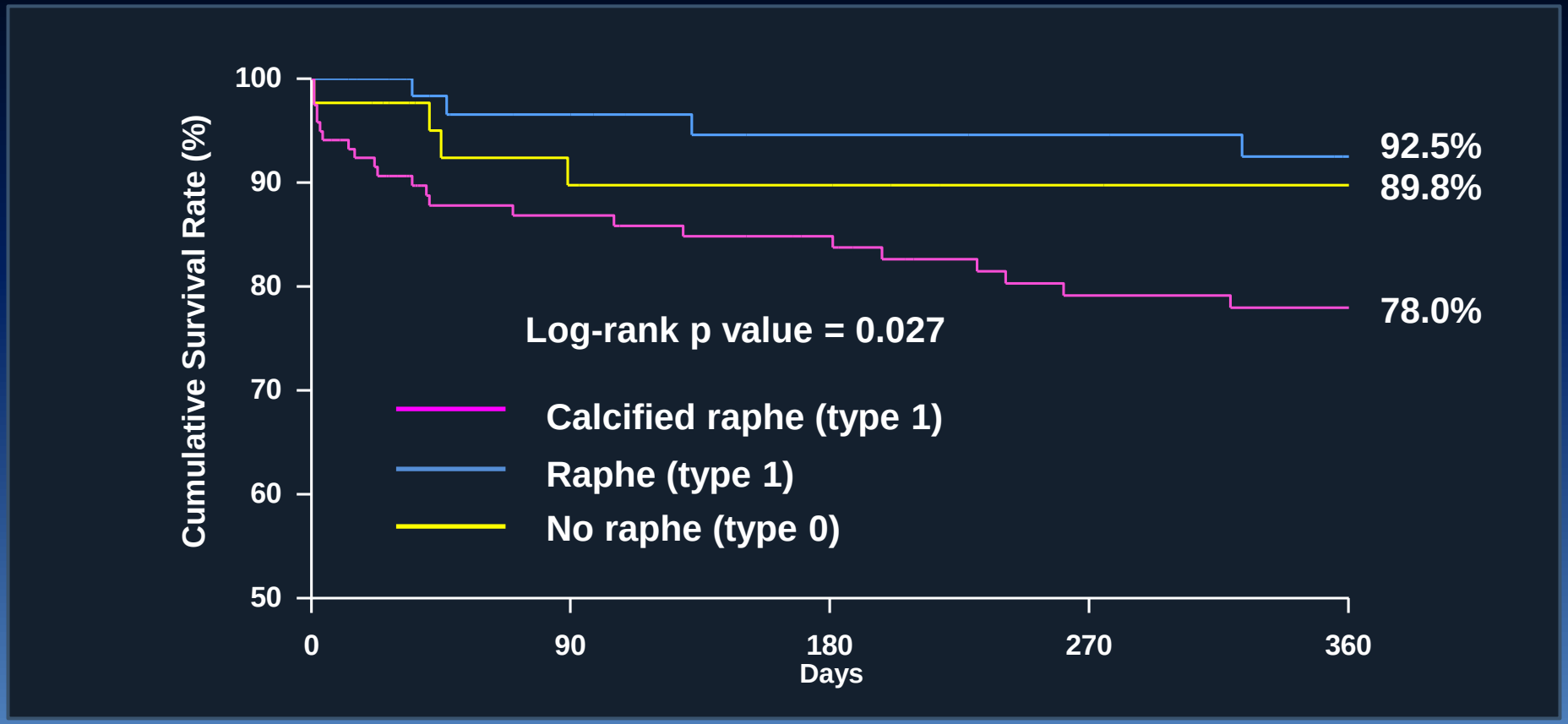
Cumulative Survival at 1 Year

Overall Cohort



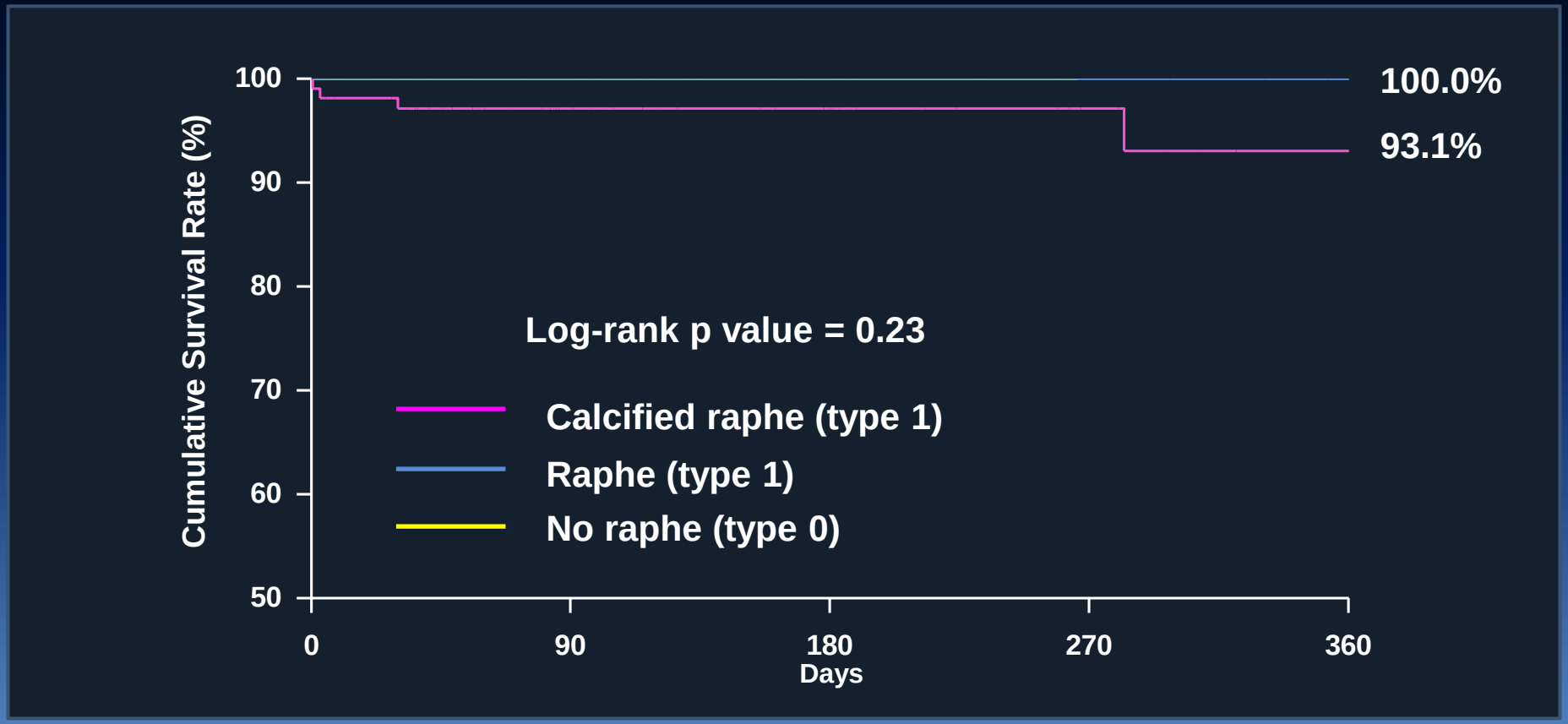
Cumulative Survival at 1 Year

Early Generation Devices



Cumulative Survival at 1 Year

New Generation Devices



Conclusions

- TAVR for bicuspid AS was feasible and safe
- When using early-generation devices, TAVR for bicuspid AS was associated with more frequent procedural complications
- However, when using new-generation devices, outcomes of TAVR for bicuspid were similar to those of tricuspid AS

Conclusions

- Outcomes of Type 0 bicuspid AS was favorable but TAVR for Type 1 bicuspid AS with calcified raphe was challenging
  - Higher rates of PVL and pacemaker and lower device success rate when using the CoreValve; High rate of annulus rupture when using the Sapien XT and Sapien 3
- 1-year all-cause mortality was higher in calcified raphe type, particularly when using early-generation devices
- 1-year all-cause mortality rates were similar between subgroups when using new-generation devices