

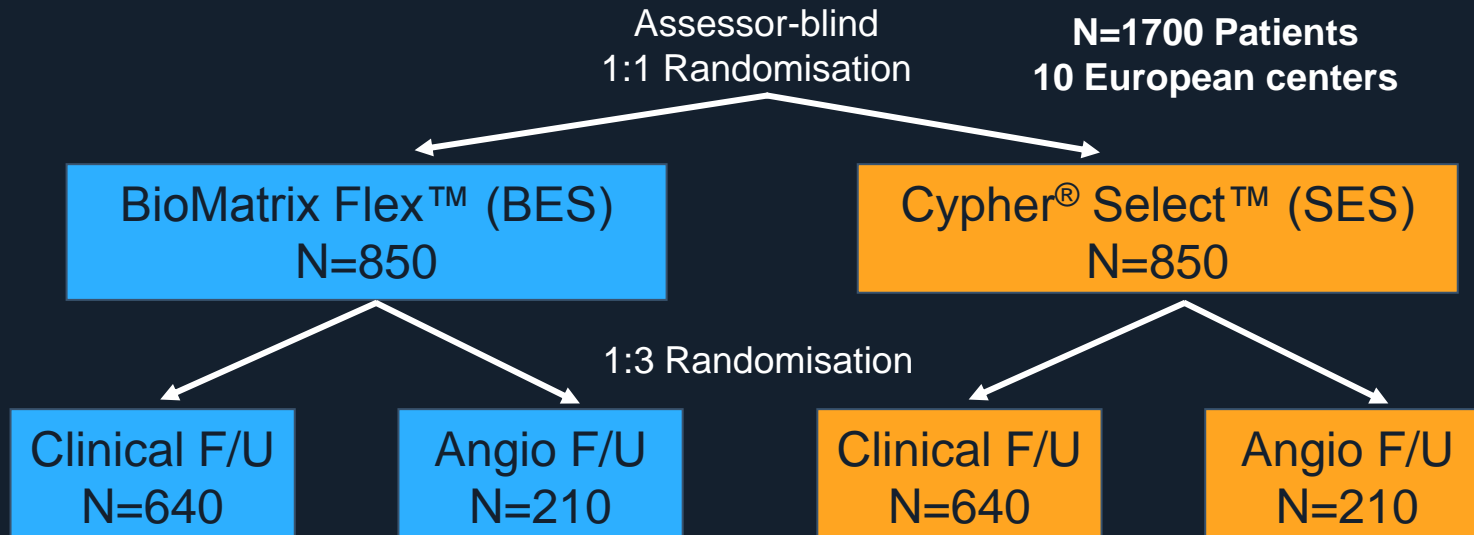
# The GOLD STANDARD in Biodegradable Polymer Technology - Long Term Evidence of Biolimus A9™ Drug Eluting Stent

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# LEADERS 'all-comers' Trial Design

Stable and ACS Patients Undergoing PCI



1° endpoint:

2° endpoints:

Angiographic study:

DAPT recommended for 12 months

**MACE: Cardiac death, MI, clinically-indicated TVR (9 mo)**

Death, CV death, MI, TLR, TVR

Stent thrombosis according to ARC

**In-stent % diameter stenosis (9 mo)**

Late loss, binary restenosis

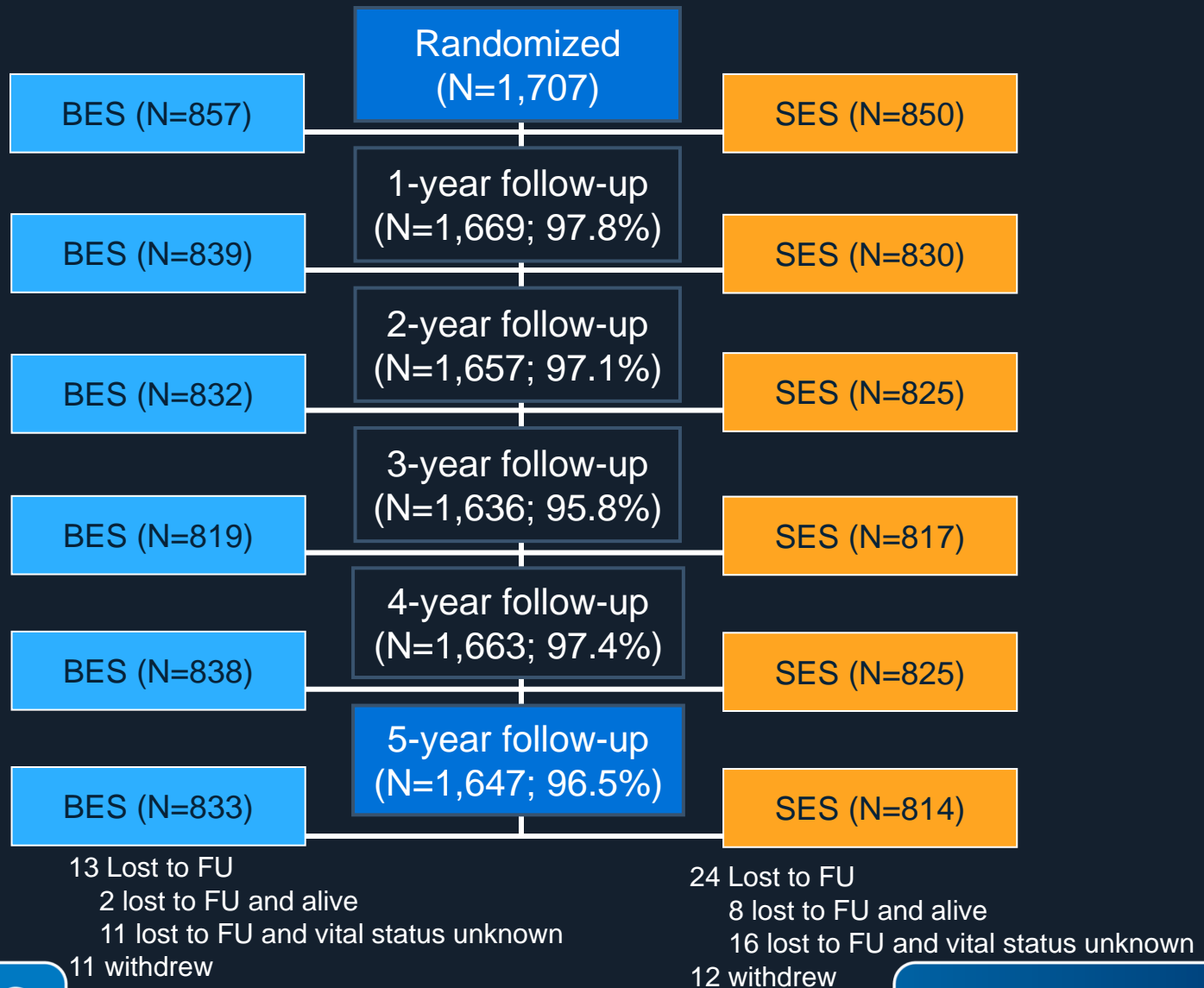
# Patient Demographics

	BES 857 Patients	SES 850 Patients
Age in years	65 ± 11	65 ± 11
Male gender	75%	75%
Arterial hypertension	74%	73%
Diabetes mellitus	26%	23%
- insulin-dependent	10%	9%
Hypercholesterolemia	65%	68%
Family history of CAD	40%	44%
Smoking	24%	25%
Previous MI	32%	33%
Previous PCI	36%	37%
- with drug-eluting stent	12%	14%
Previous CABG	11%	13%

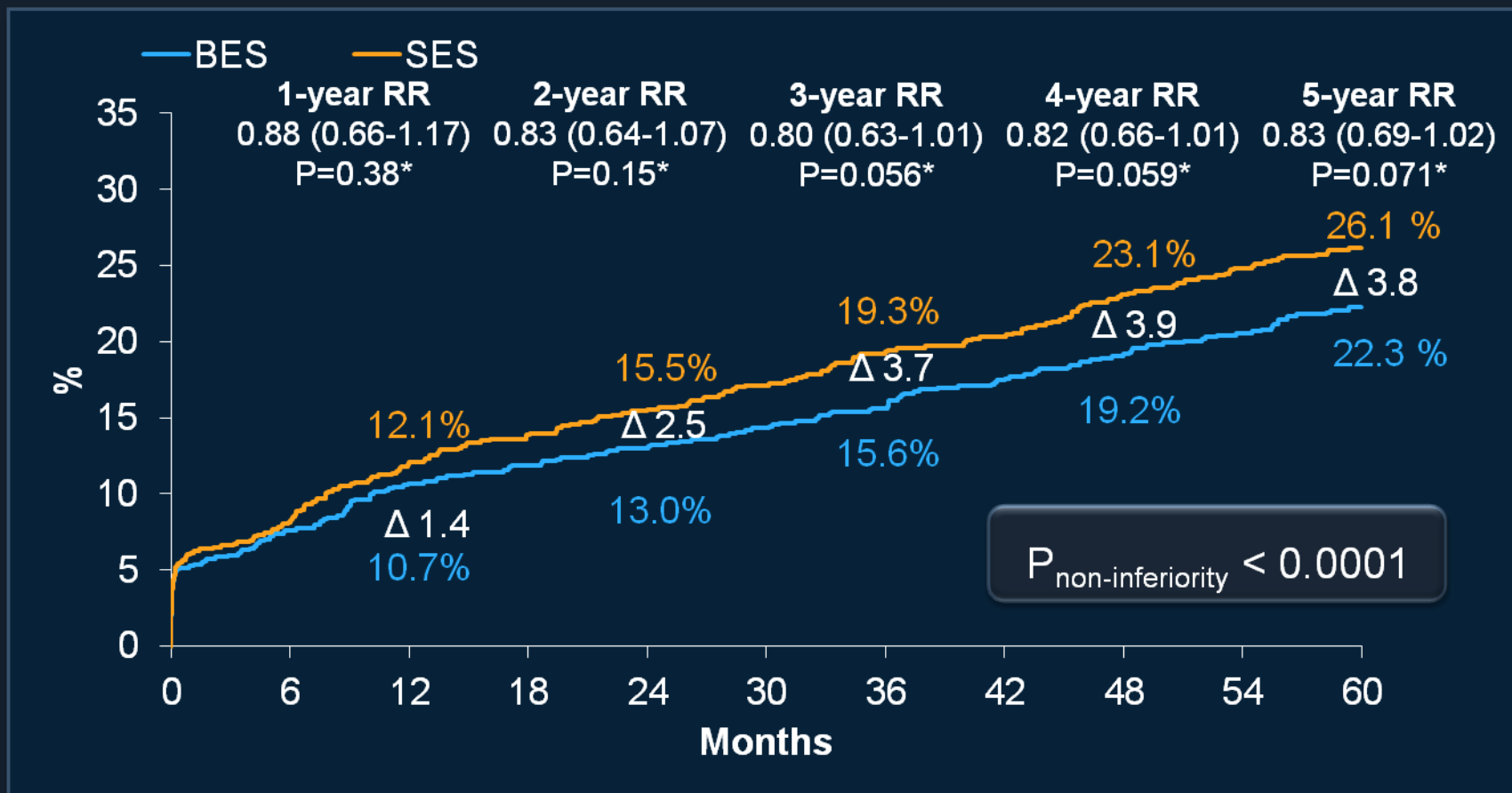
# Patient Characteristics

	BES 857 Patients	SES 850 Patients
Chronic stable angina	45%	44%
<b>Acute coronary syndrome</b>	55%	56%
• Unstable angina	22%	21%
• Non-ST-elevation MI	17%	18%
• ST-elevation MI	16%	17%
Left ventricular ejection fraction	56 ± 11%	55 ± 12%
Number of lesions per patient	1.5 ± 0.7	1.4 ± 0.7
<b>Lesions per patient</b>		
• 1 lesion	63%	69%
• 2 lesions	29%	22%
• 3 lesions	7%	8%
• > 4 lesions	1%	2%
De novo lesions	92%	91%
Long lesions (>20 mm)	31%	27%
Small vessels (RVD ≤2.75 mm)	68%	67%
<b>Off label use</b>	81%	78%

# Patient Flow - Clinical



# MACE (Cardiac Death, MI and ci-TVR)



Number at risk

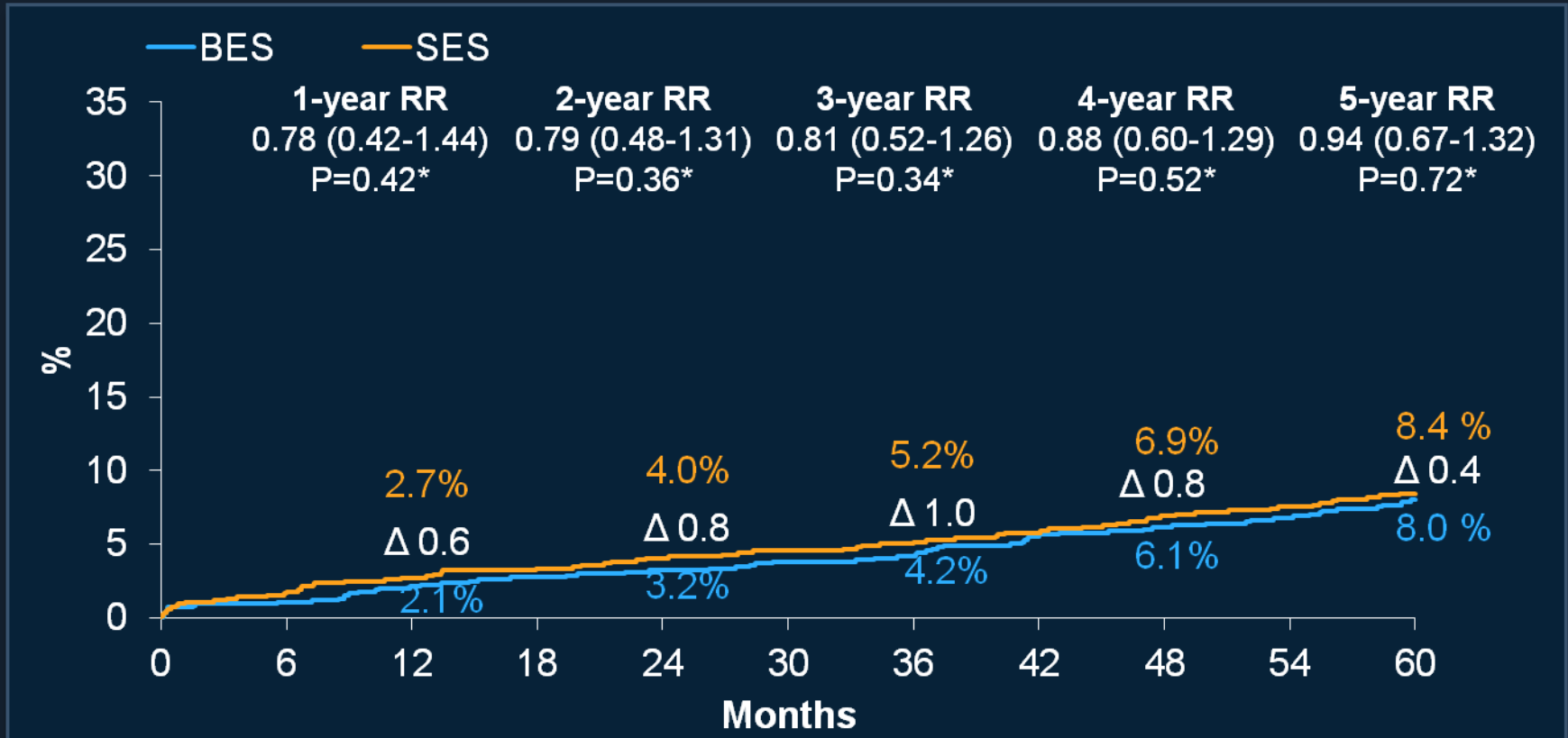
	0	6	12	18	24	30	36	42	48	54	60
SES	850	774	738	718	701	676	655	640	616	589	572
BES	857	780	749	733	723	710	697	675	657	635	618

MACE = cardiac death, MI, or clinically-indicated TVR

\* p-value for superiority

Serruys et al., oral abstract presentation, TCT 2012

# Cardiac Death

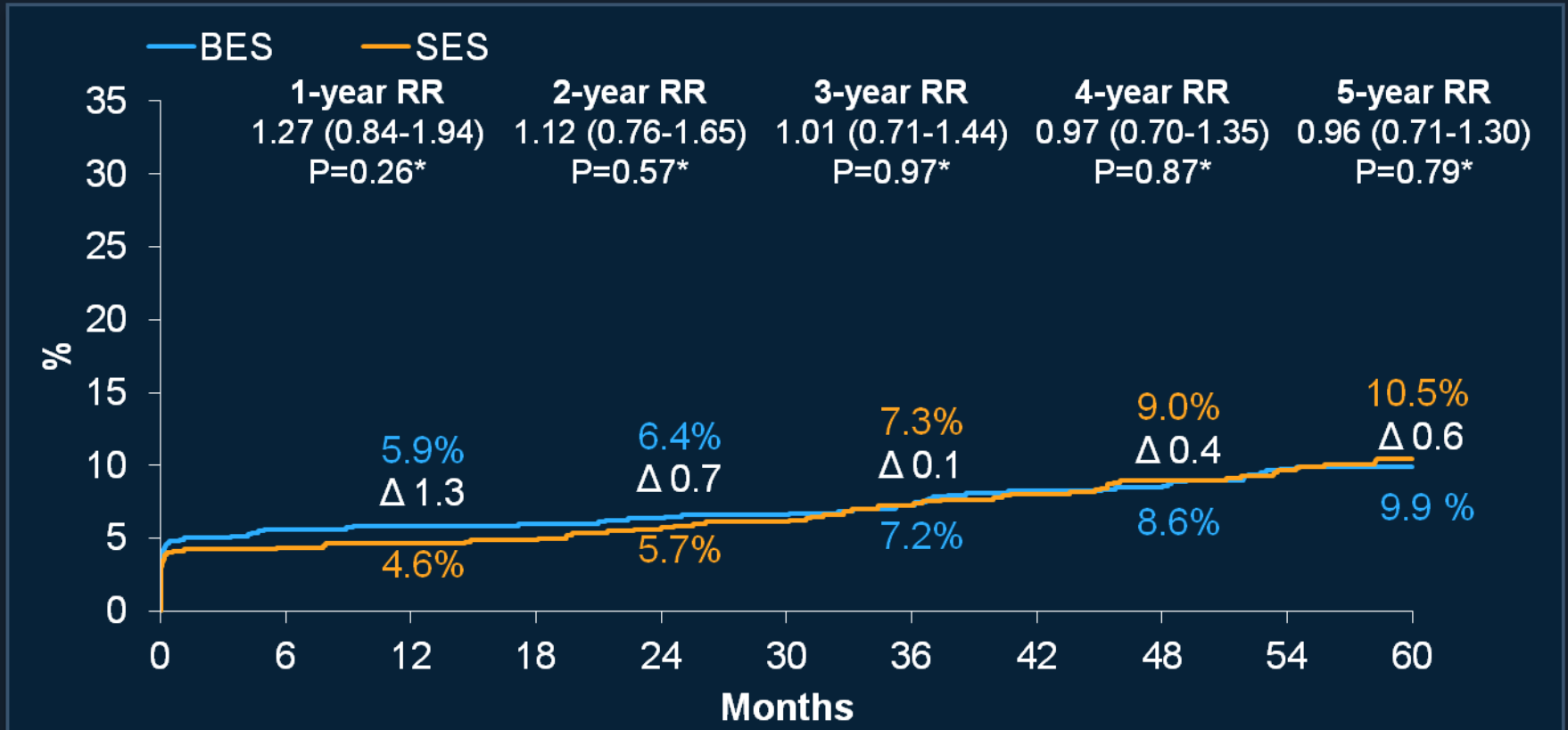


Number at risk

SES	850	829	814	802	793	776	767	753	742	721	704
BES	857	832	817	806	801	794	788	770	760	744	731



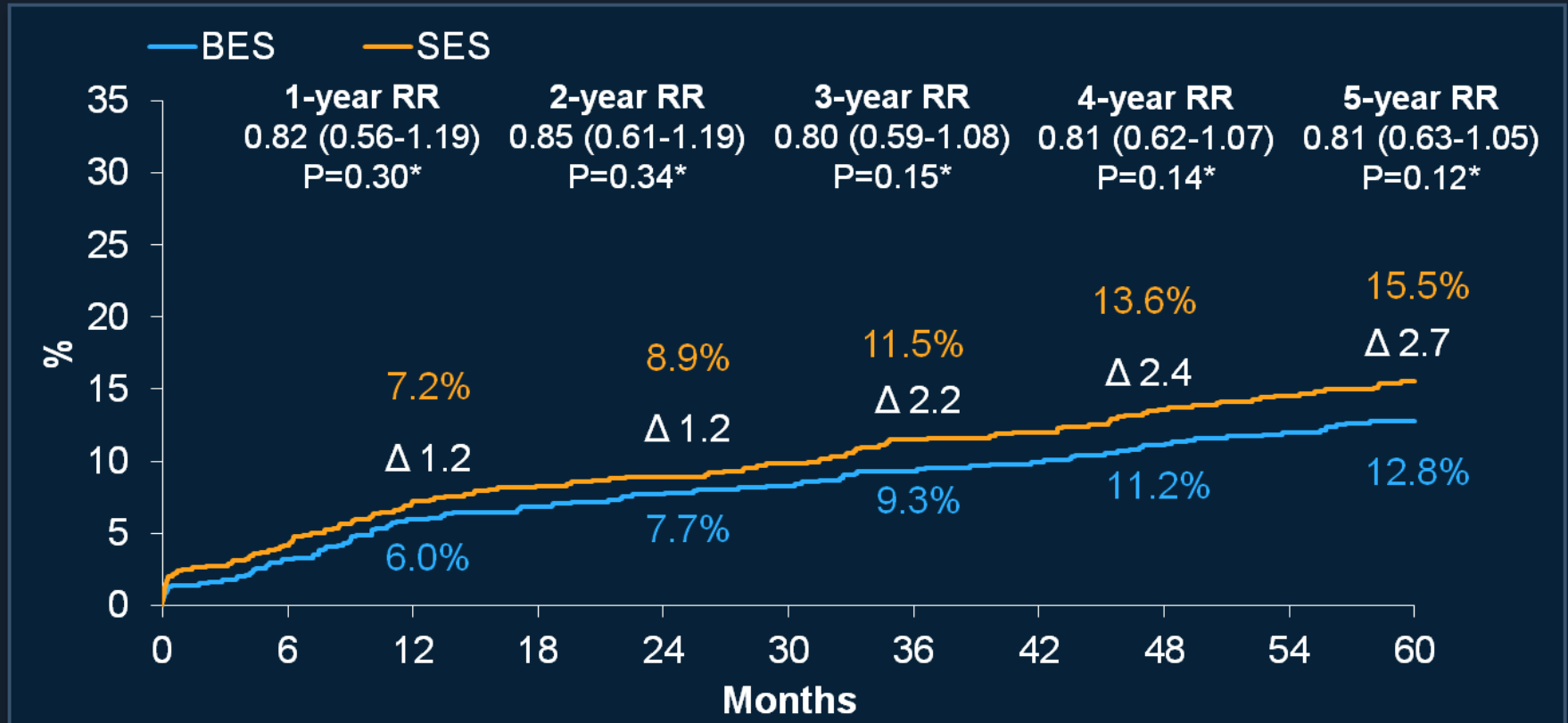
# MI



Number at risk

SES	850	796	781	767	752	733	717	700	684	661	644
BES	857	791	779	768	761	752	744	721	710	687	675

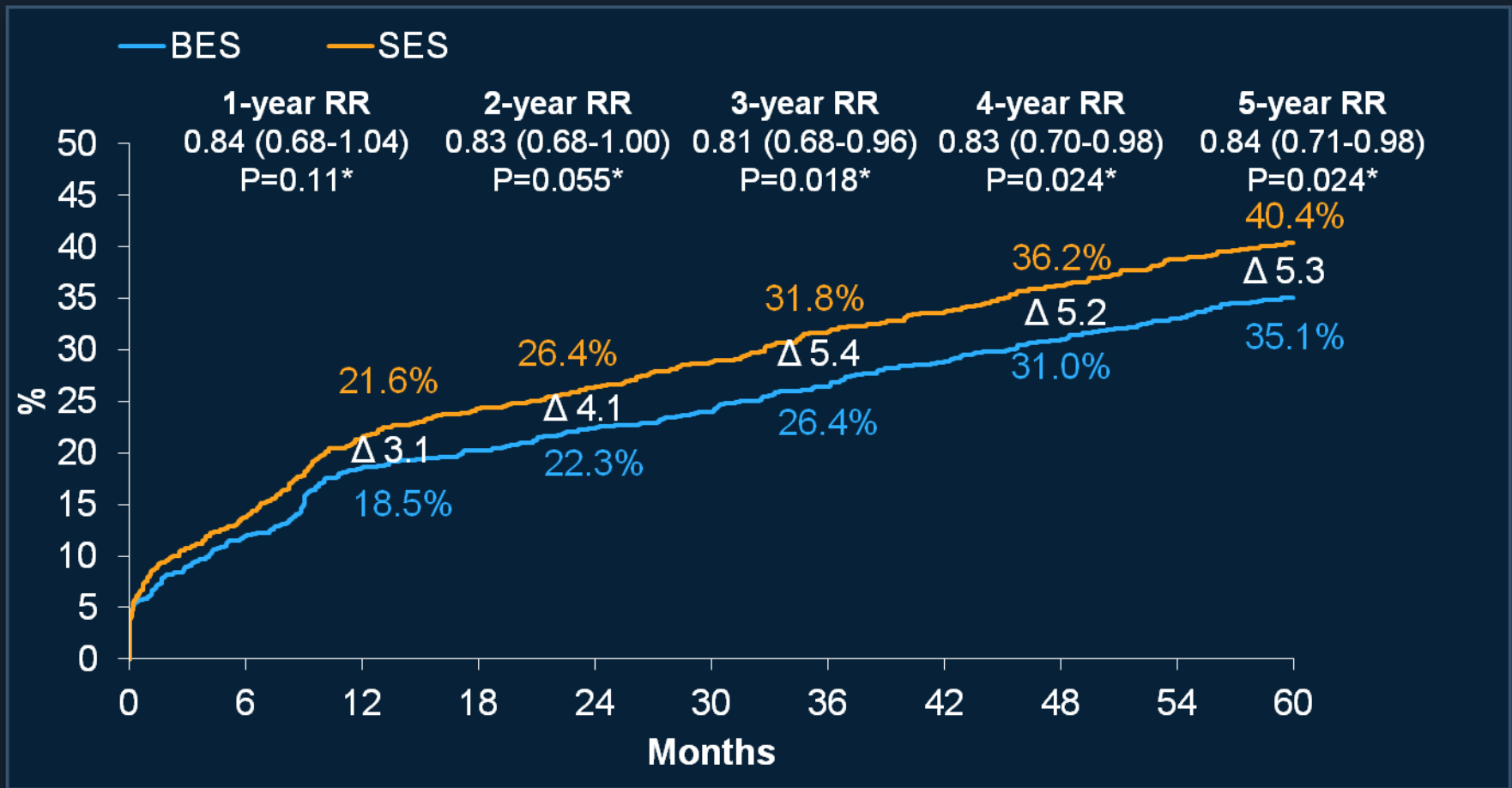
# Clinically-Indicated TVR



Number at risk

SES	850	797	760	741	727	704	685	668	646	620	600
BES	857	809	776	758	748	736	725	706	687	668	650

# Patient Oriented Composite Endpoint (All-cause Death, Any MI, All Revascularization)



Number at risk

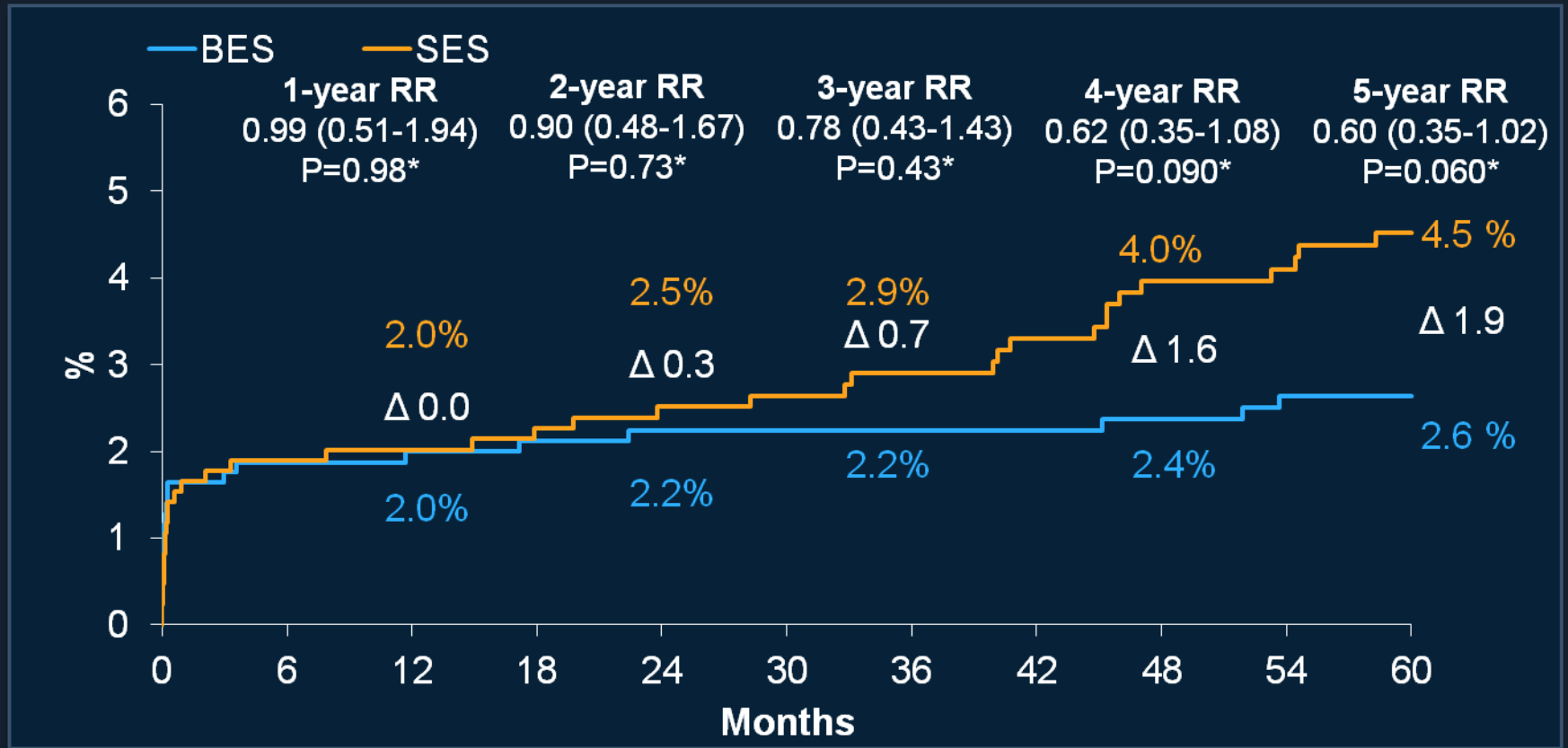
SES	850	729	661	637	618	594	569	551	530	504	491
BES	857	749	689	672	654	639	619	597	579	557	540

POCE = all death, MI, any revascularization (includes adjudicated and non-adjudicated events)

\* p-value for superiority

Serruys et al., oral abstract presentation, TCT 2012

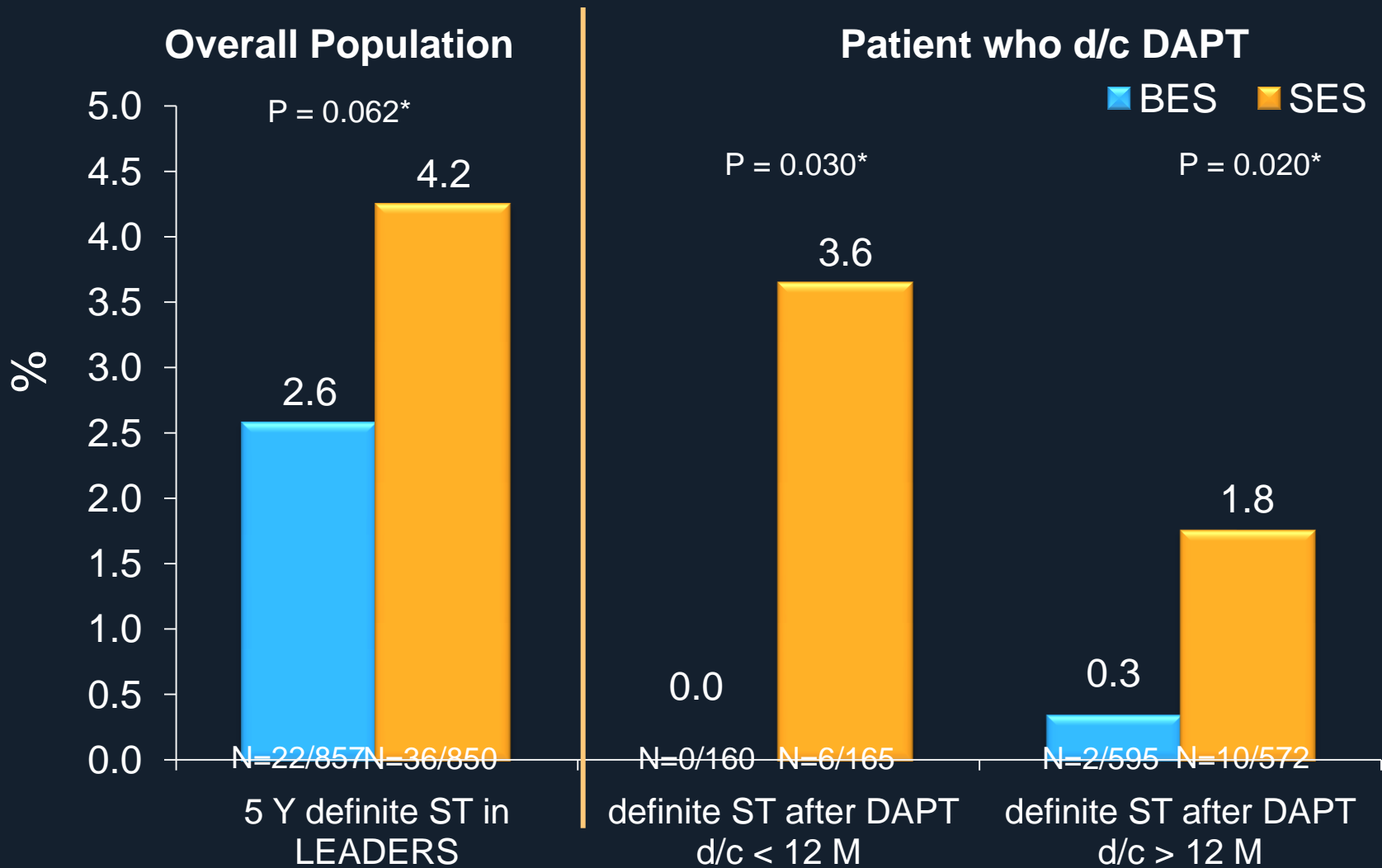
# Definite Stent Thrombosis (ARC)



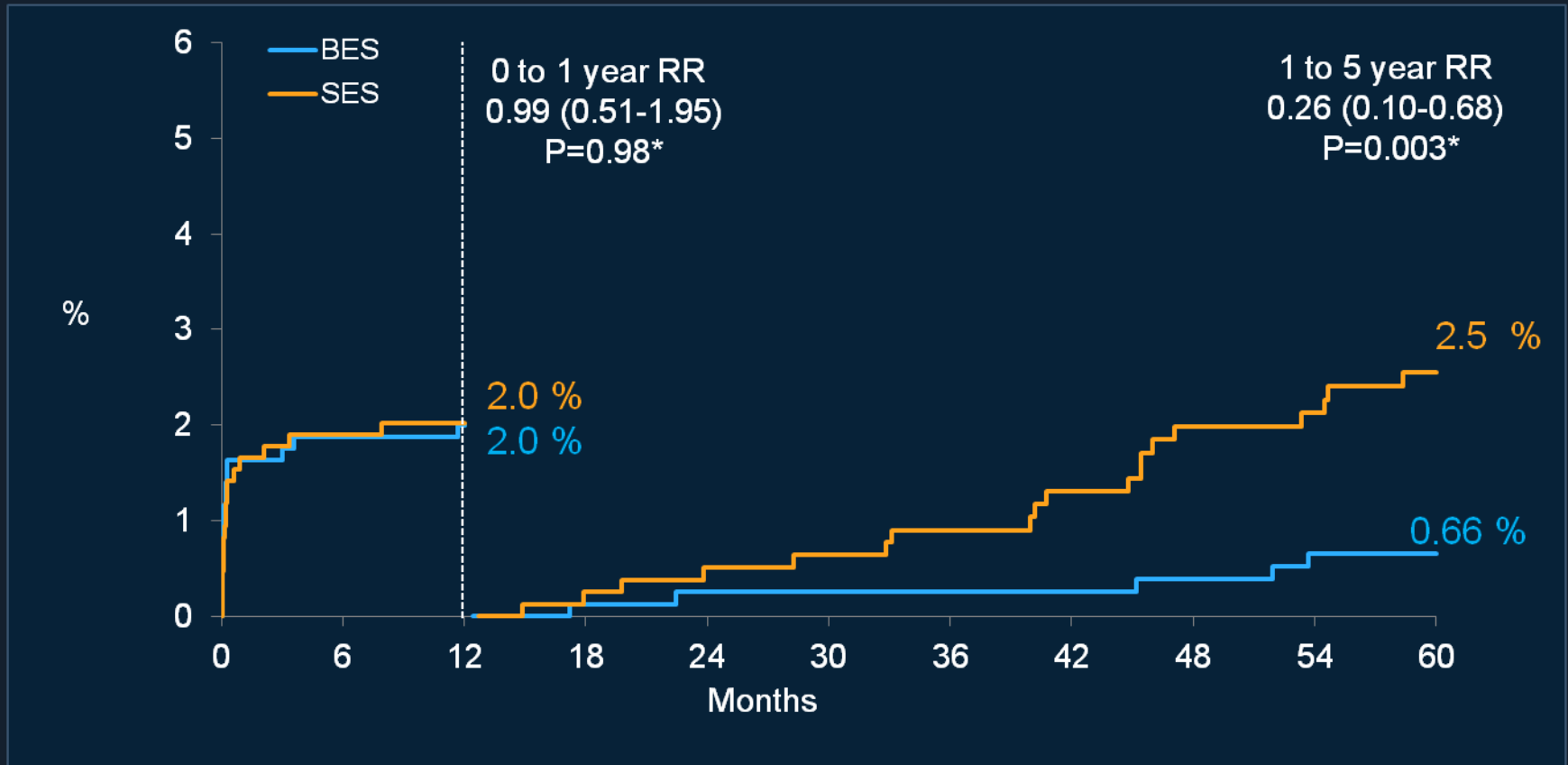
Number at risk

SES	850	816	801	787	776	759	749	732	717	696	678
BES	857	819	804	792	787	780	775	757	747	730	717

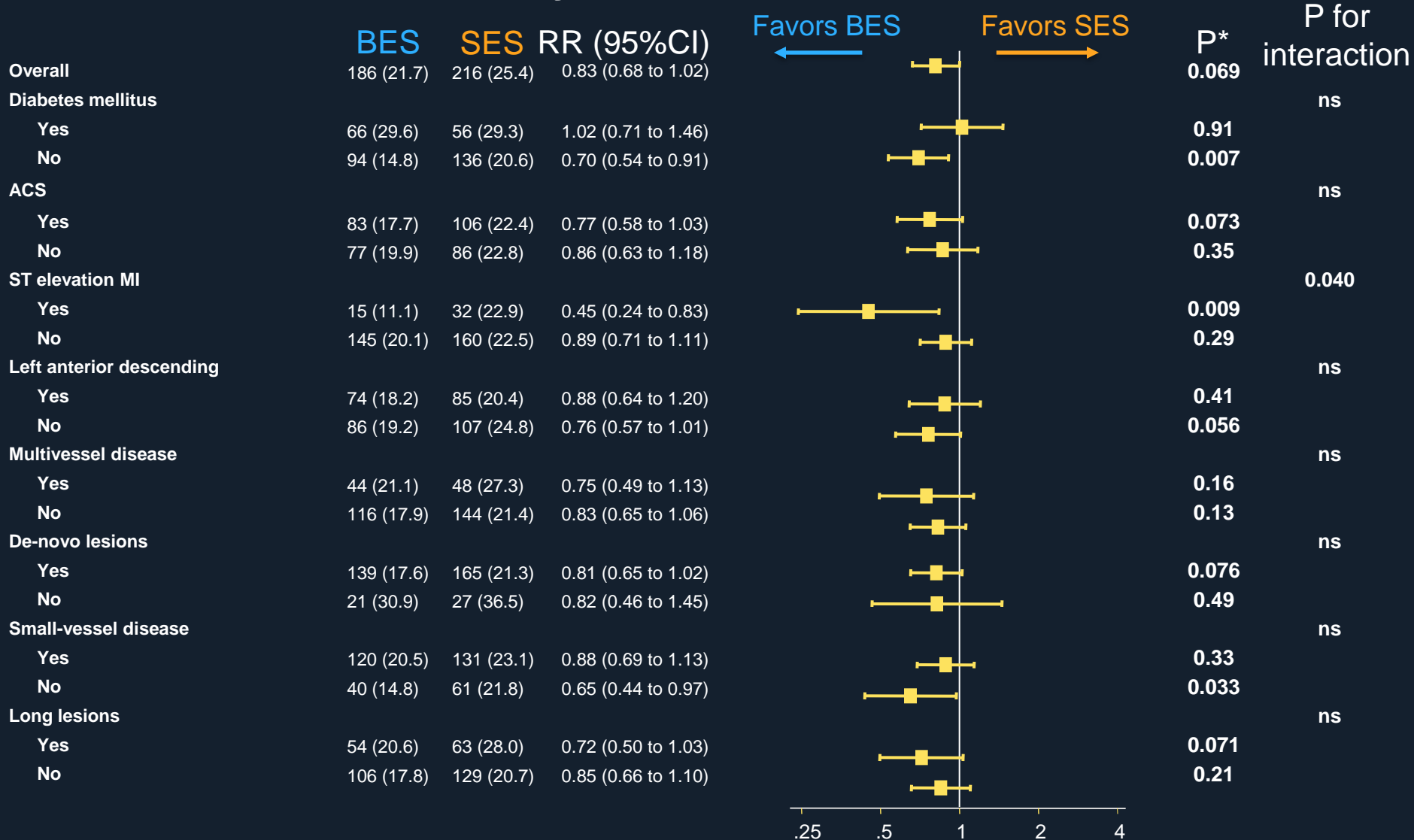
# Effect of DAPT Discontinuation



# Definite ST (ARC) Landmark Analysis @ 1 Year



# Stratified Analysis of MACE @ 5 Years



# Conclusions

- Biodegradable polymer BES maintained non-inferiority and improved long-term clinical outcomes compared to SES through 5 years ( $P_{\text{sup}} = 0.071$ )
- Biodegradable polymer BES demonstrated a 74% relative risk reduction in very late definite stent thrombosis (VLST)
- The benefit of biodegradable polymer BES emerged in the very late phase and was mainly driven by a lower risk of MACE associated with definite VLST



# The BEACON II registry: 4 year outcomes in an Asian Pacific patient population

- The purpose of the BEACON II registry was to assess clinical outcomes in Asia Pacific patients treated with BioMatrix™ stent in a *real world, all-comers* population.
- The goal of this presentation is to present, for the first time, the four year clinical follow-up data of BEACON II registry.

# BEACON II Registry Design

Prospective, Asia-Pacific, observational registry assessing clinical outcomes in Real World, All-Comers patients receiving BioMatrix™ DES

## Key Enrollment Criteria:

- Native coronary arteries and SVG
- Target vessel diameters:  $\geq 2.5 - \leq 4.0$  mm
- No limit to lesion length
- No limit to number of treated lesions or vessels
- No limit to disease / lesion pathology  
(except lesion at protected / unprotected left main)

BioMatrix™  
N = 497

## Patients enrolled from 12 Asia Pacific sites

### Clinical Follow-Up Time Points

30 d    3 mo    6 mo    12 mo    2 - 5 yr

### Primary Endpoint:

- MACE at 12 months  
(Cardiac Death, Q-Wave & Non Q-Wave MI, Ischemia Driven TLR)

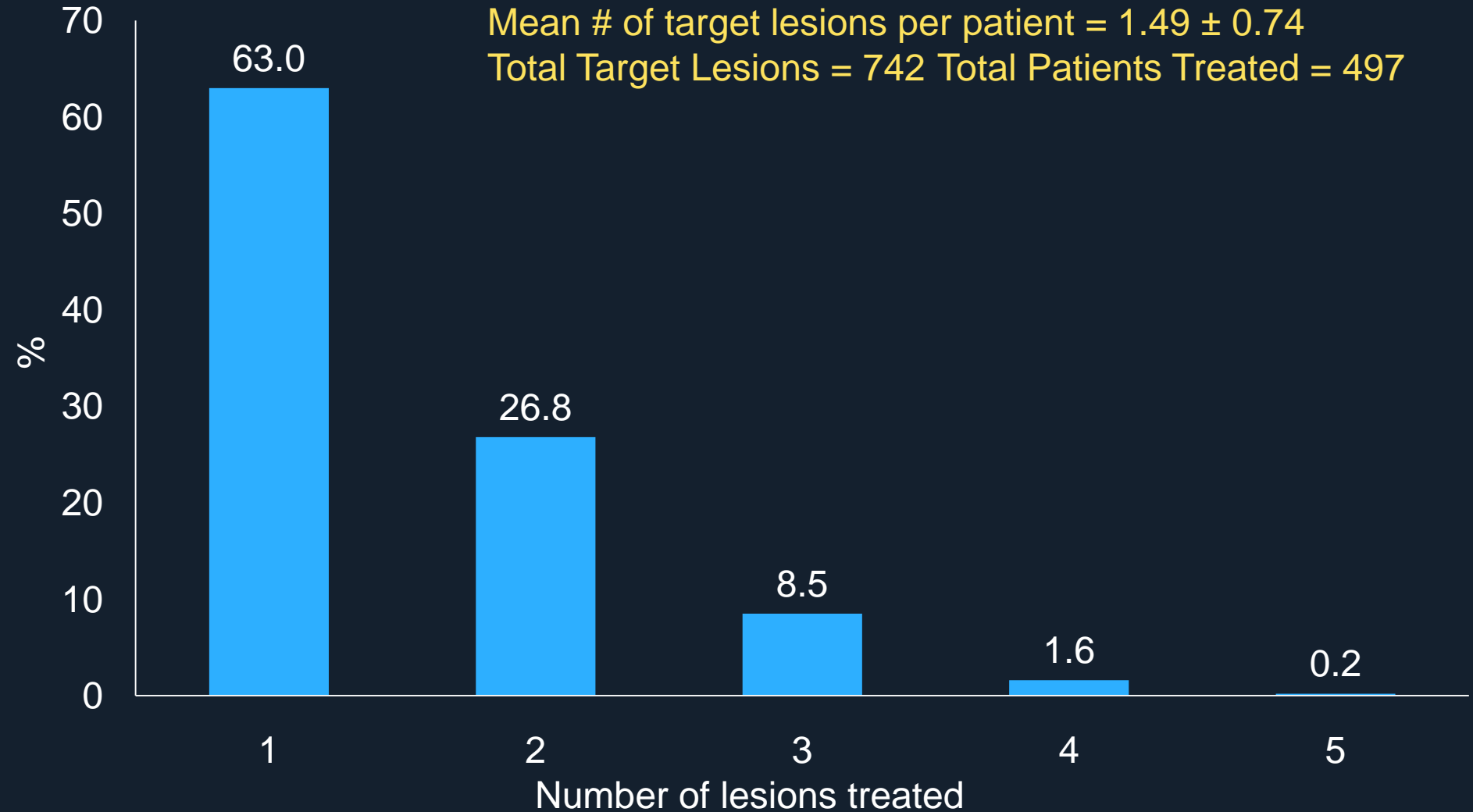
### Key Secondary Endpoints:

- Ischemia Driven TLF and TLR at 12 months
- Rates of definite stent thrombosis up to 5 years
- MACE at 30d, 90d, 6m and 2-5y

*Anti-platelet therapy recommended for 6 months (highly recommended for 12 months)*

# Lesions Treated per Patient (ITT)

Mean # of target lesions per patient =  $1.49 \pm 0.74$   
Total Target Lesions = 742 Total Patients Treated = 497



# Lesion Morphology and Characteristics

N = 742 Target Lesions	
	%
Bifurcation Lesion (Side Branch > 2mm)	14
with Moderate/Severe Calcification	4.3
Moderate/Severe Calcification	24
Long Lesions > 20 mm	31
Small Vessels < 2.75 mm	34
Total Occlusion	9.3
De Novo Lesions	95

# Procedural Characteristics

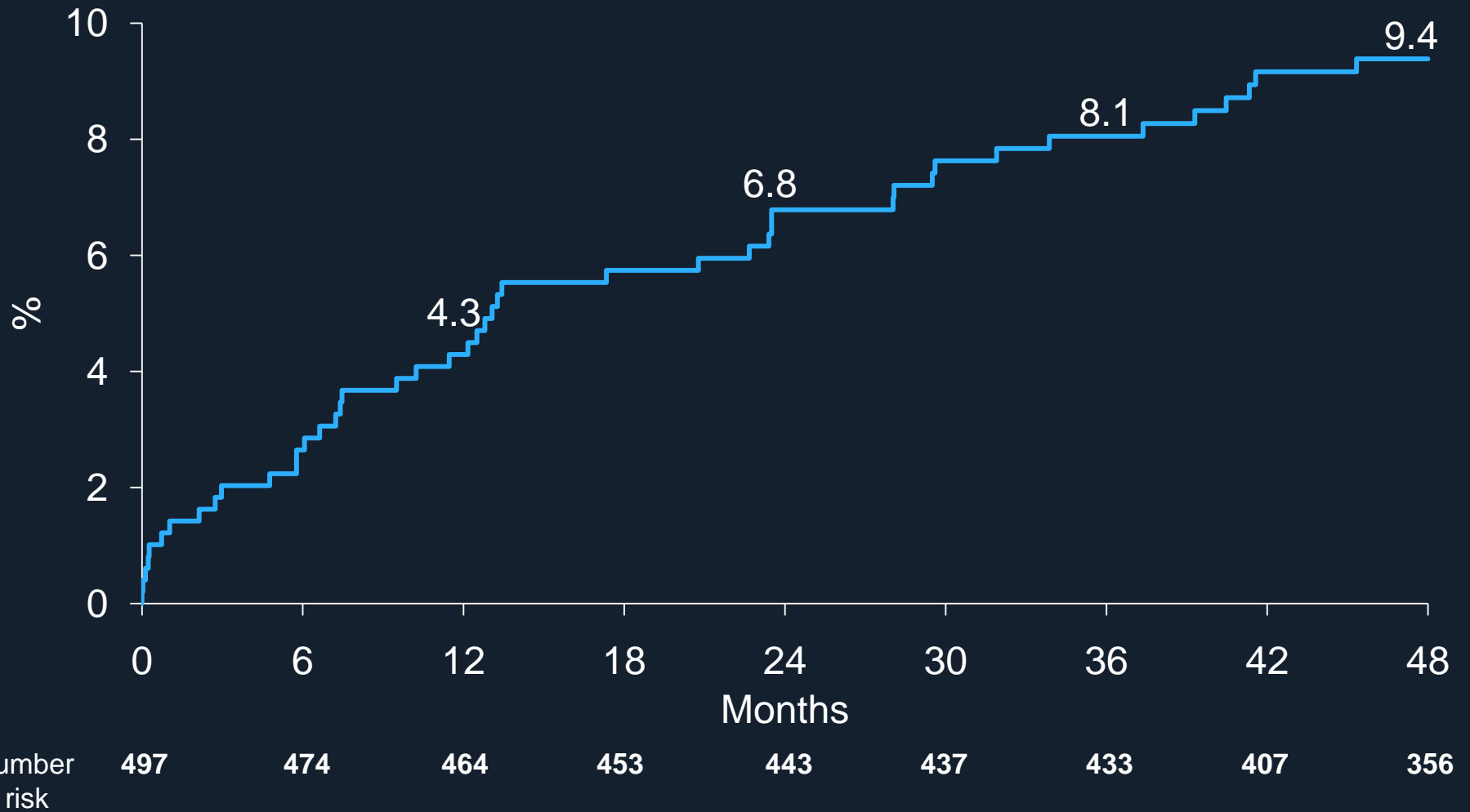
Mean Lesion Length	18.7mm ( $\pm$ 9.7)
Mean Stent Length	19.2mm ( $\pm$ 6.0)
Stents per Target Lesion	1.16 $\pm$ 0.47
Device Success <sup>1</sup>	98.5%
Lesion Success <sup>2</sup>	98.7%
Procedural Success <sup>3</sup>	97.8%

<sup>1</sup> *Device Success* defined as achievement of a final residual in-stent diameter stenosis of < 30% (visual estimate), using the BioMatrix DES.

<sup>2</sup> *Lesion Success* defined as attainment of < 30% in-stent residual stenosis of the target lesion using any percutaneous method.

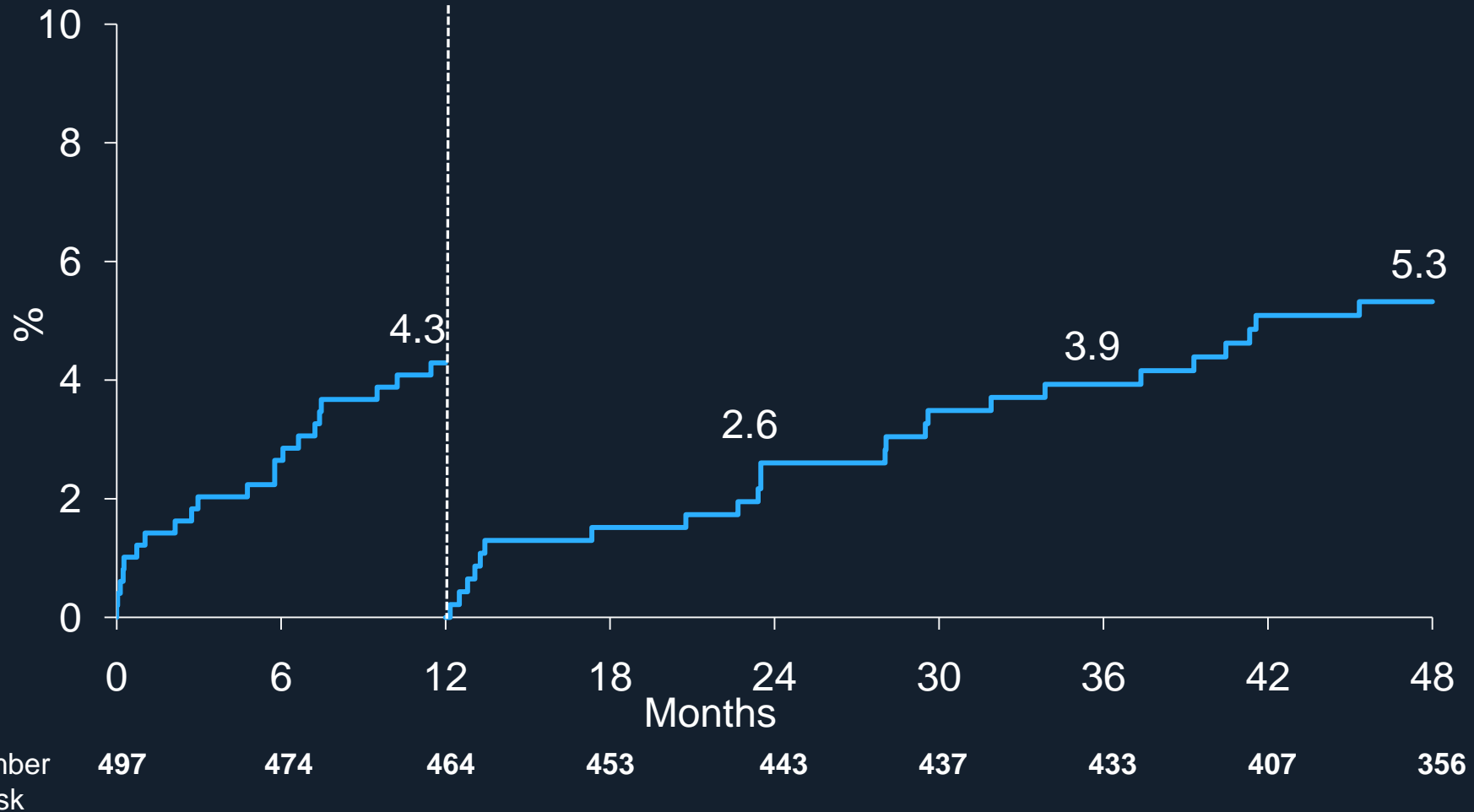
<sup>3</sup> *Procedural Success* defined as achievement of Device Success without the occurrence of in-hospital MACE.

# Hierarchical MACE



MACE defined as a composite of Cardiac death, MI (Q and Non-Q wave) and id-TLR

# Hierarchical MACE (Landmark Analysis)



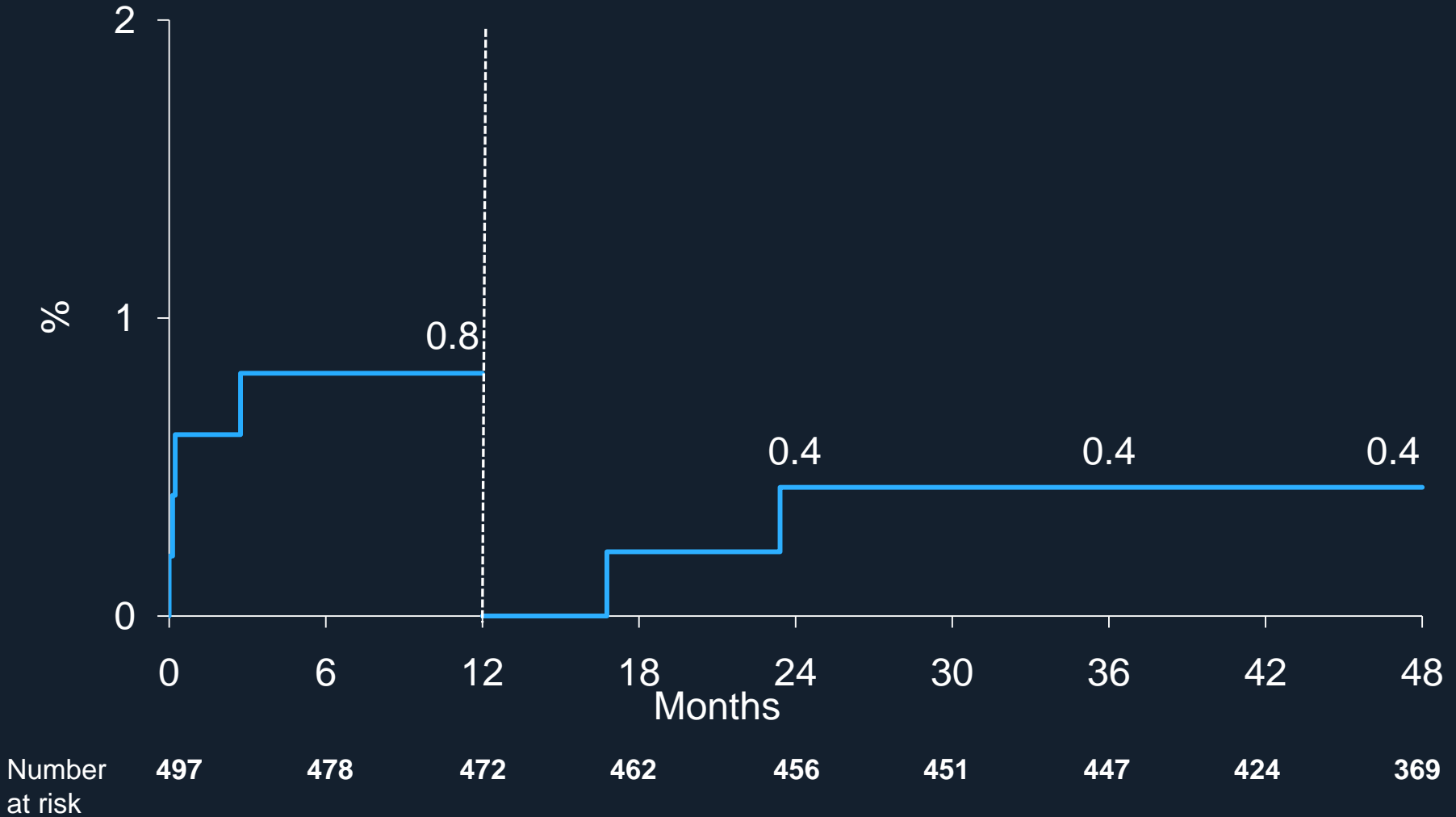
MACE defined as a composite of Cardiac death, MI (Q and Non-Q wave) and id-TLR

# Antiplatelet Agent Utilization

	%
<b>Aspirin</b>	
- At 6 Months	95.8
- At 12 Months	93.2
- At 2 Years	89.6
- At 3 Years	90.2
- At 4 Years	90.7
<b>Clopidrogel/Thienopyridine</b>	
- At 6 Months	96.2
- At 12 Months	70.7
- At 2 Years	37.0
- At 3 Years	31.5
- At 4 Years	23.8



# Definite Stent Thrombosis – ARC Defined (Landmark Analysis)



# Conclusion

- BEACON II registry confirms an excellent safety profile up to 4 years for BioMatrix™, when used in routine clinical practice in an Asian population with a low MACE rate of 9.4%
- Definite VLST
  - Although this was an all-comers registry
    - Definite VLST events were rare (0.4%)
  - No additional ST event after 2 years
  - No VLST events occurred in patients where a BioMatrix stent was implanted in native coronary arteries
- A very positive safety profile is particularly of note in an all-comers registry population.