Comparative Outcomes of Contemporary DES in Real-World: Is There Difference?

Data from Real-World Registry (IRIS-DES Registry)

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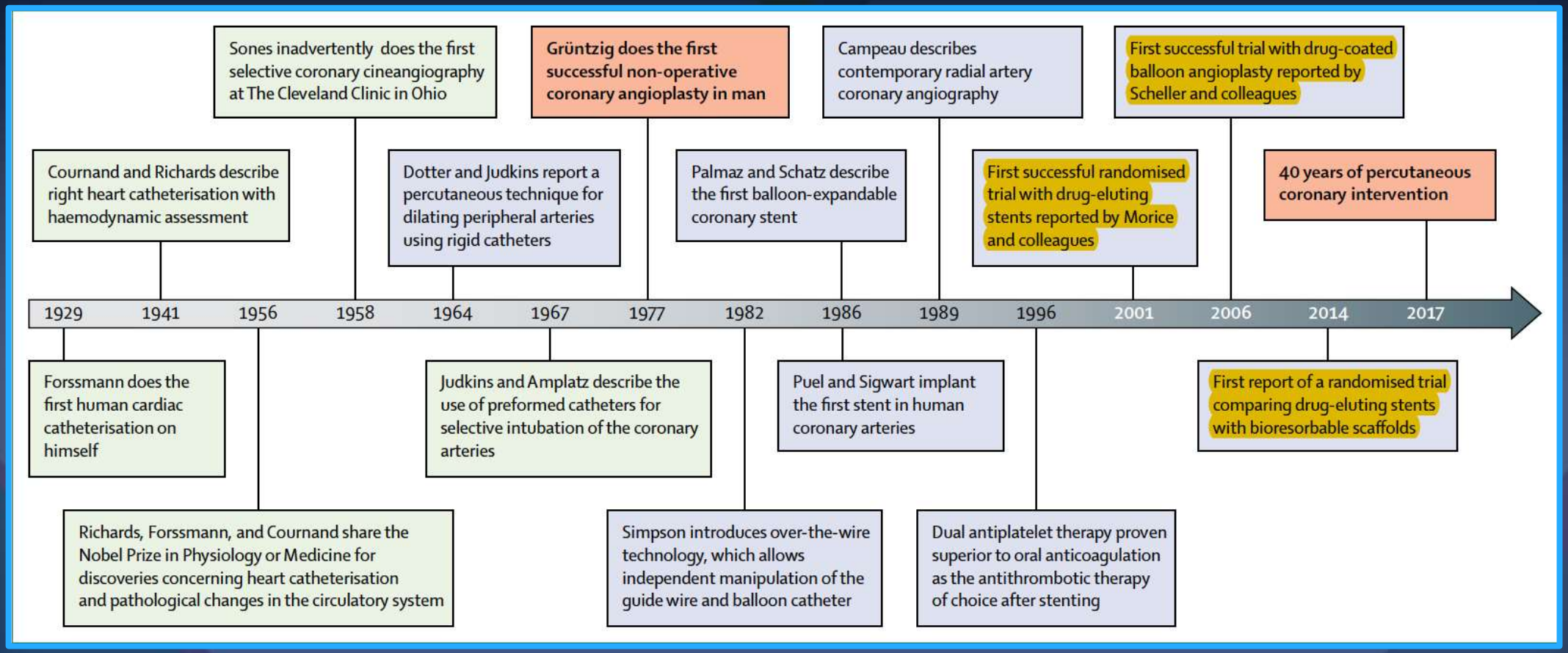
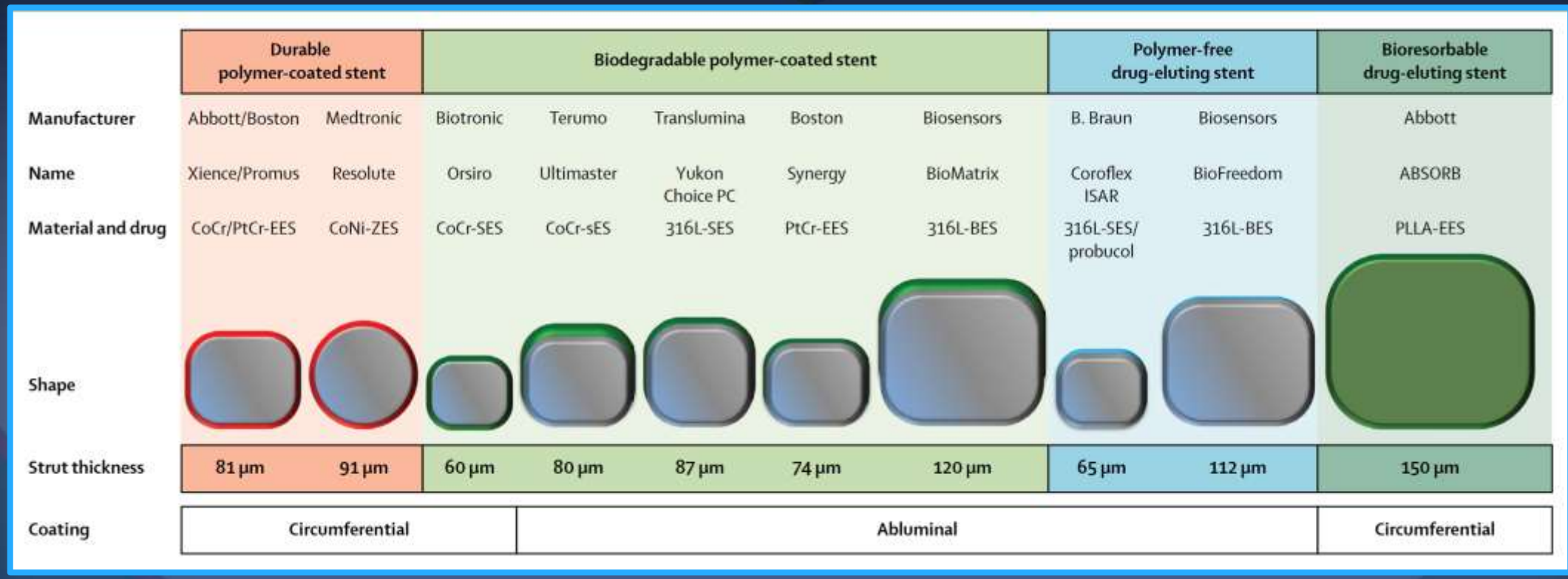
40-Years of PCI



Robert A Byrne et al. Lancet 2017; 390: 781–92

Second-Generation DES



Robert A Byrne et al. Lancet 2017; 390: 781–92

?? Difference in Outcomes Among Contemporary DES: Individual, Stent-Specific RCT

	Devices*	Total number of patients	Latest follow-up	Primary endpoint	Primary result (hazard ratio or risk difference, 95% CI)	p value
RESOLUTE AC[37]	ZES vs EES	2292	5 years	TLF	No difference (0·9%, -2·2 to 3·9)	0·61
ISAR-TEST 5[38]	SES (PF) vs ZES	3002	5 years	TLF	No difference (0·98, 0·84–1·15)	0·80
PLATINUM[39]	EES vs EES	1530	3 years	TLF	No difference (0·84, 0·56–1·26)	0·40
NEXT[40]	BES (BP) vs EES	3235	3 years	Composite of death and MI (safety), or TLR (efficacy)	No difference in death and MI (0·96, 0·77–1·19) or TLR (1·03, 0·8–1·34)	0·70 (death and MI), 0·80 (TLR)
COMPARE II[41]	BES (BP) vs EES	2707	5 years	Composite of cardiac death, MI, or TVR	No difference (1·11, 0·92–1·33)	0·26
BIOSCIENCE[42]	SES (BP) vs EES	2119	2 years	TLF	No difference (1·00, 0·77–1·31)	0·98
DUTCH PEERS[43]	ZES vs EES	1811	2 years	Composite of cardiac death, MI, or TVR	No difference (1·10, 0·81–1·50)	0·55
BASKET-PROVE II[34]†	BES (BP) vs EES	1530	2 years	Composite of death, MI, or any revascularisation	No difference (1·11, 0·77–1·62)	0·58
SORT OUT VI[44]	BES (BP) vs ZES	2999	3 years	TLF	No difference (0·90, 0·71–1·14)	0·36

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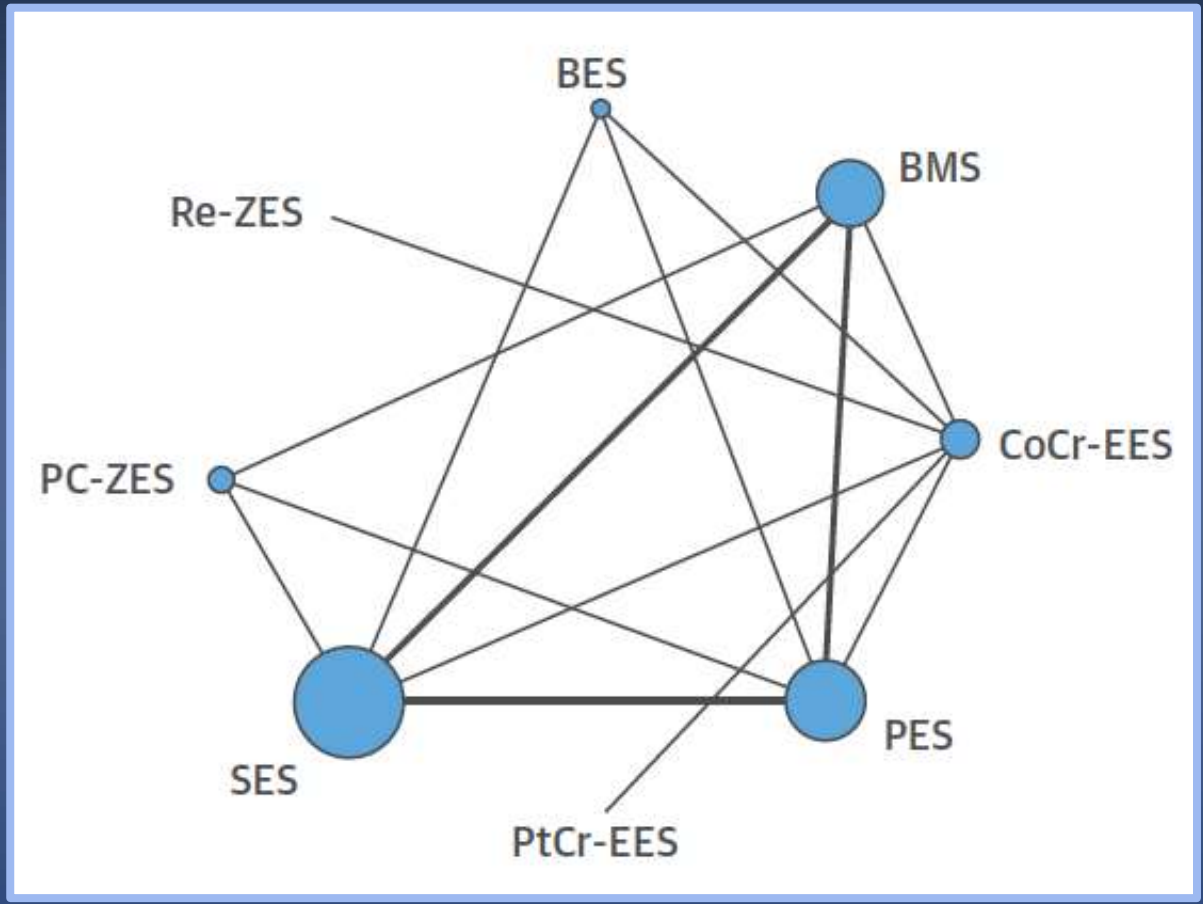
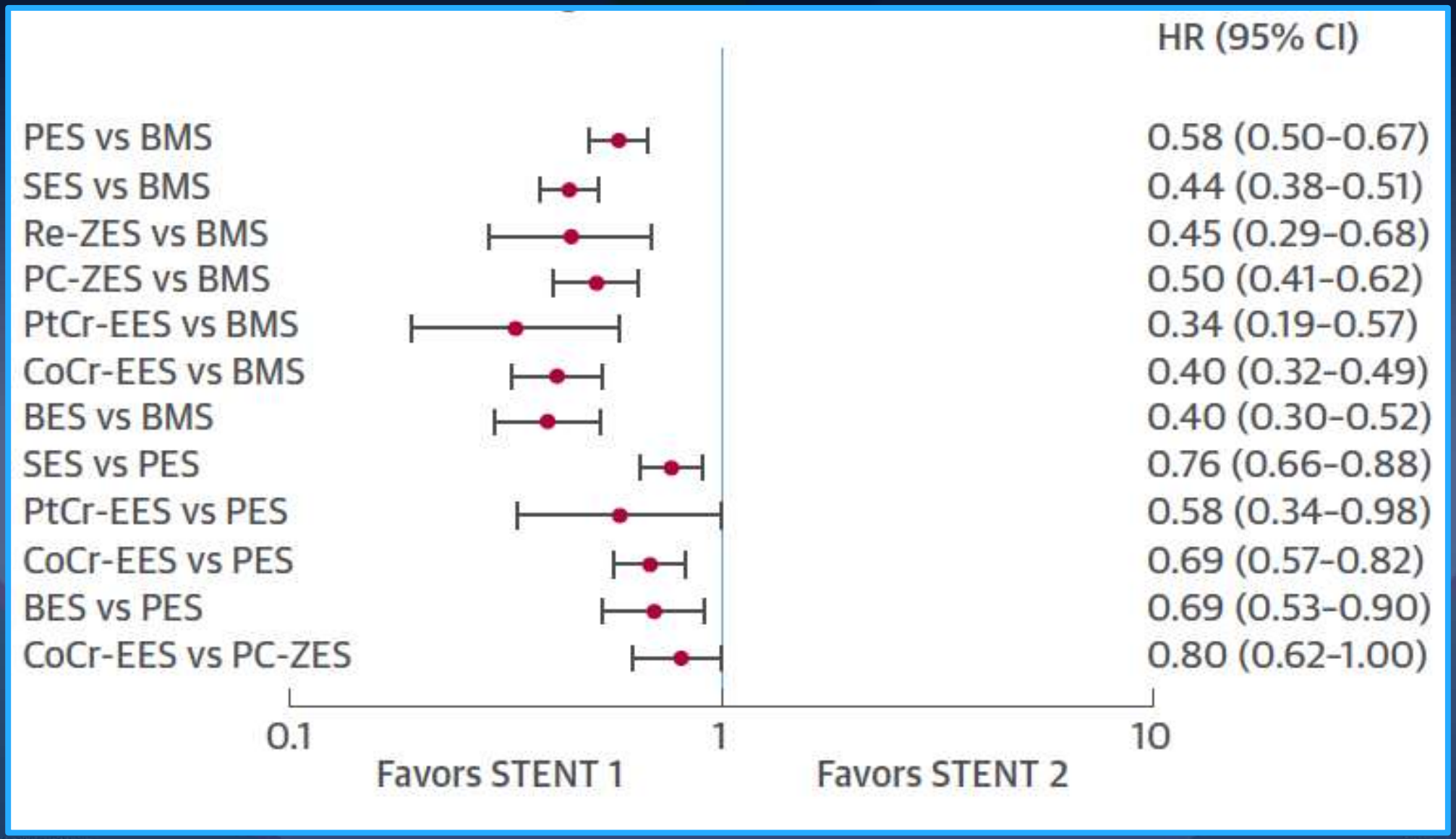
Updated Network Meta-Analysis including RCT with at least 3 year FU

51 RCTs; 52,158 patients (median 3.8 yr FU)



Palmerini et al. J AmColl Cardiol 2015;65:2496–507

Efficacy; TVR



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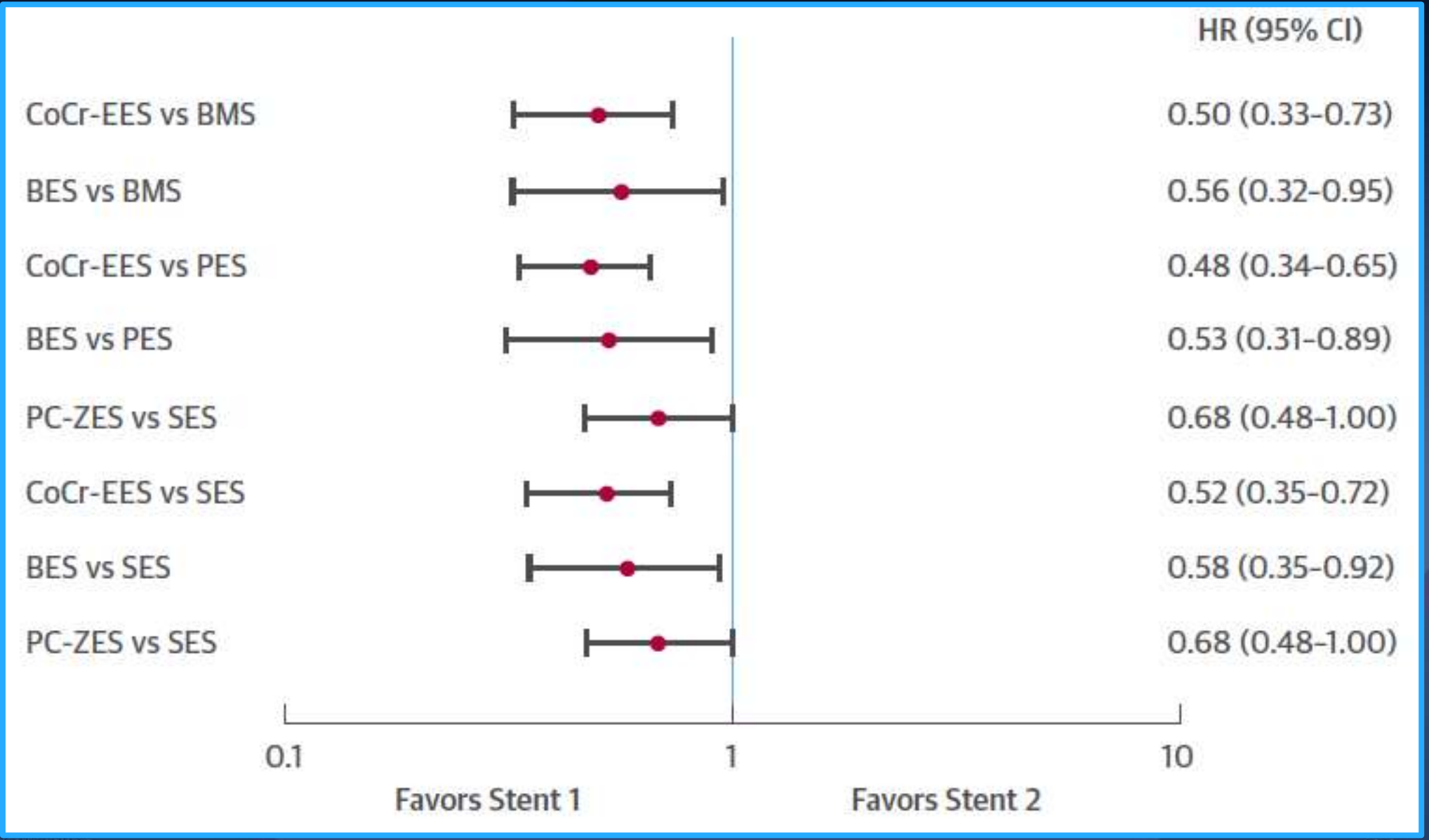
Safety; Definite or Probable ST



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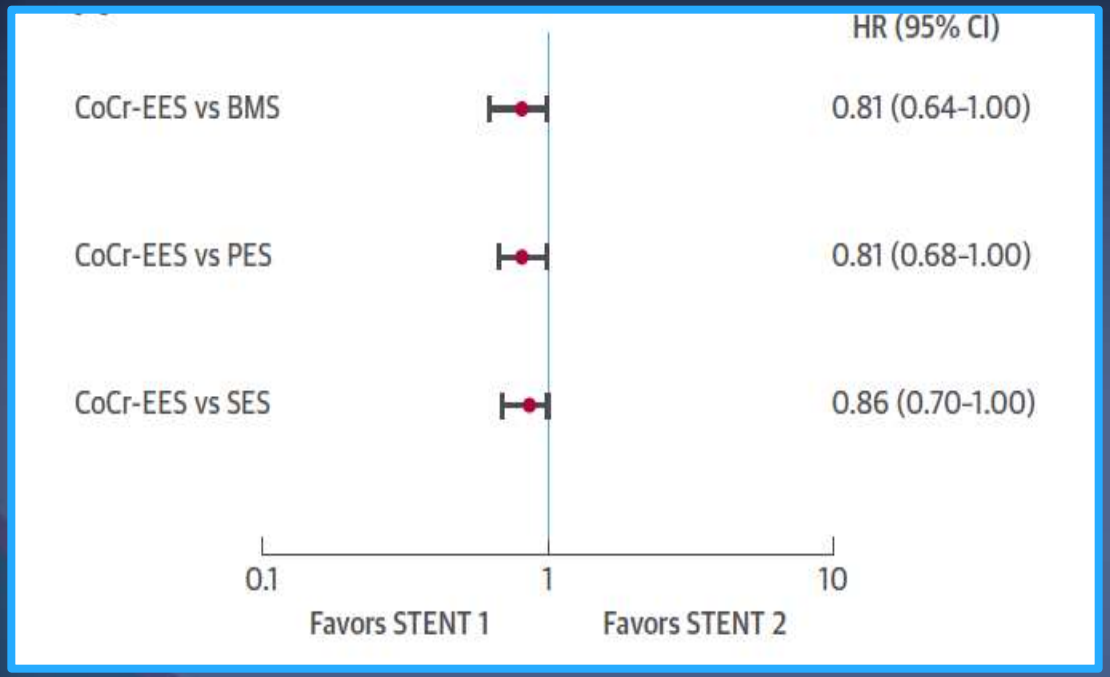
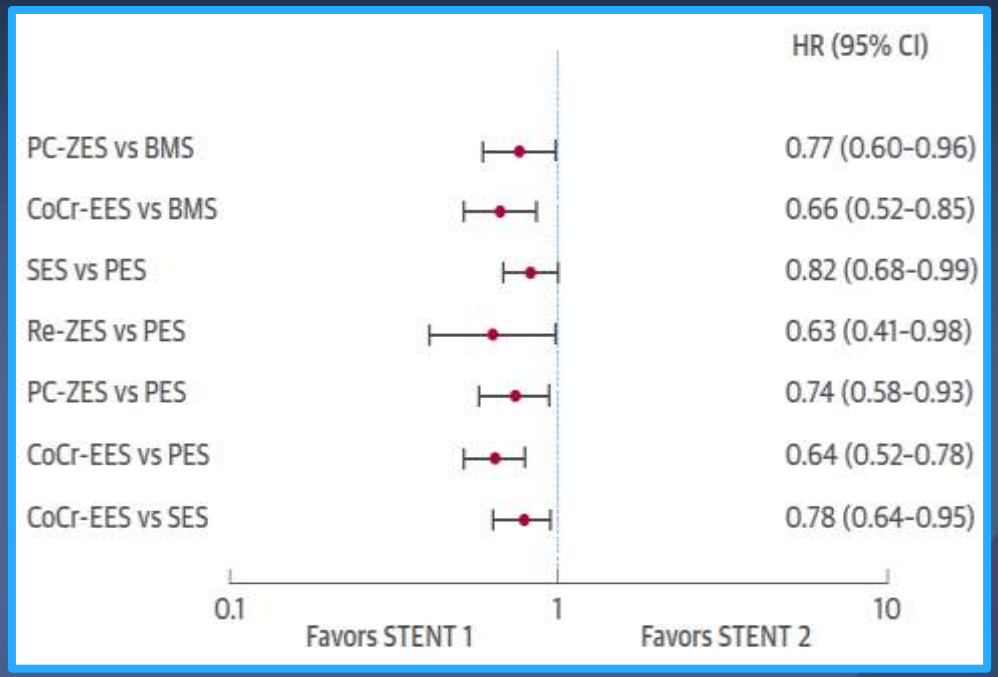
Hard Clinical Endpoints

Death



MI



Palmerini et al. J AmColl Cardiol 2015;65:2496–507

Contemporary DES in RCT; Enhanced Safety and Efficacy Outcomes

- Second-generation DES showed better safety outcomes (ST, death, or MI) than first-generation DES or BMS during long-term FU.
- By a meta-analysis of 51 comparative trials, second-generation DES showed better efficacy outcomes than either first-generation DES or BMS after a median 4-year FU.

Palmerini et al. J AmColl Cardiol 2015;65:2496–507

Are There Any MAJOR Differences in Clinical Outcomes Between the Most Widely Used Contemporary Metallic DES?

Difference in RCT and Registry?

IRIS DES registry

- Multicenter, Prospective,
  Real world observational study
- To compare the safety and efficacy of the second- or newer-generation DES and the first-generation DES in everyday clinical practice
- ClinicalTrial.gov; NCT01186133

IRIS DES registry

Inclusion Criteria

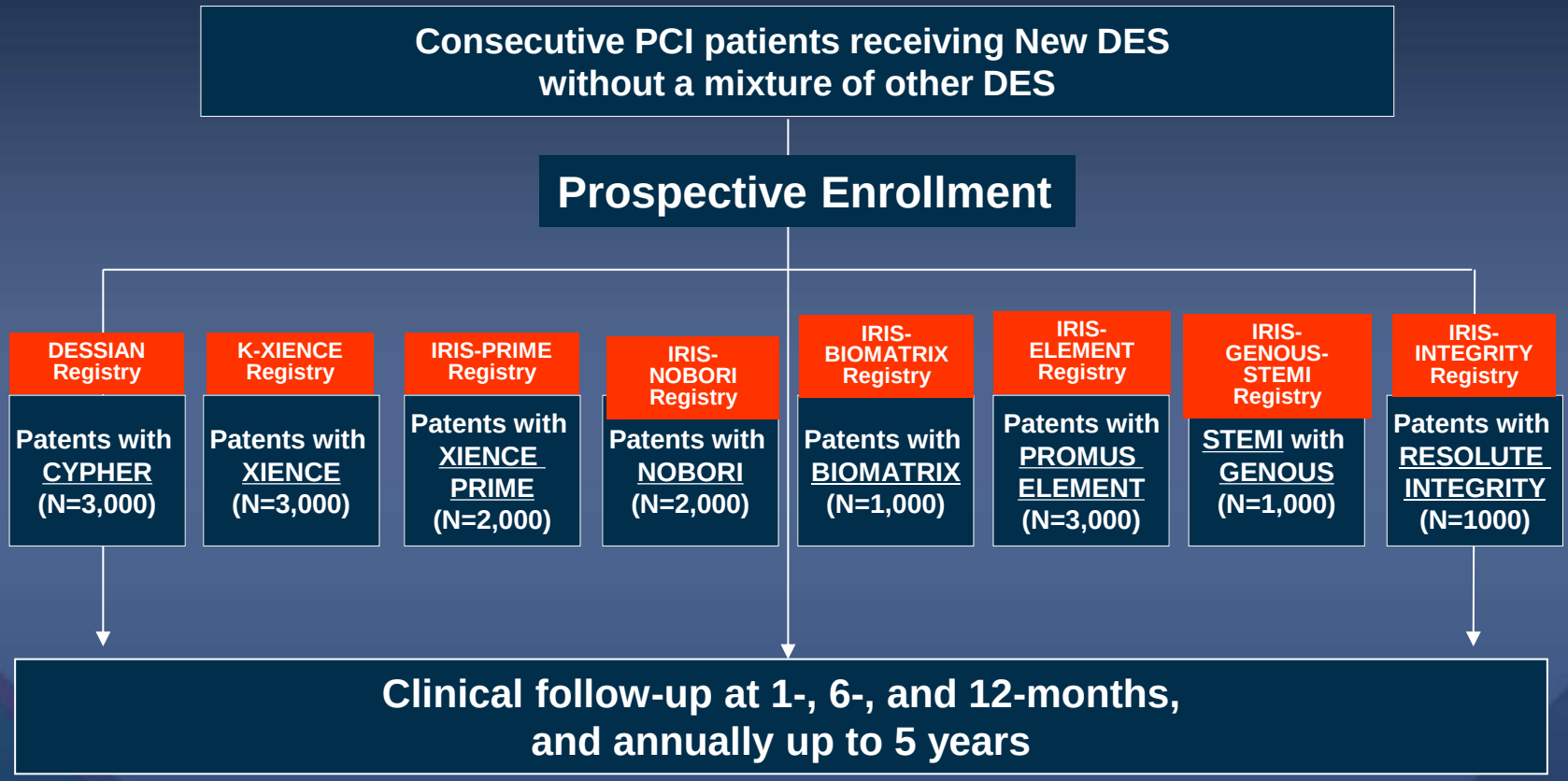
- Coronary disease amenable to percutaneous coronary intervention (PCI)

Exclusion Criteria

- **Patients with a mixture of several DES**
- **Life expectancy less than 1 year**

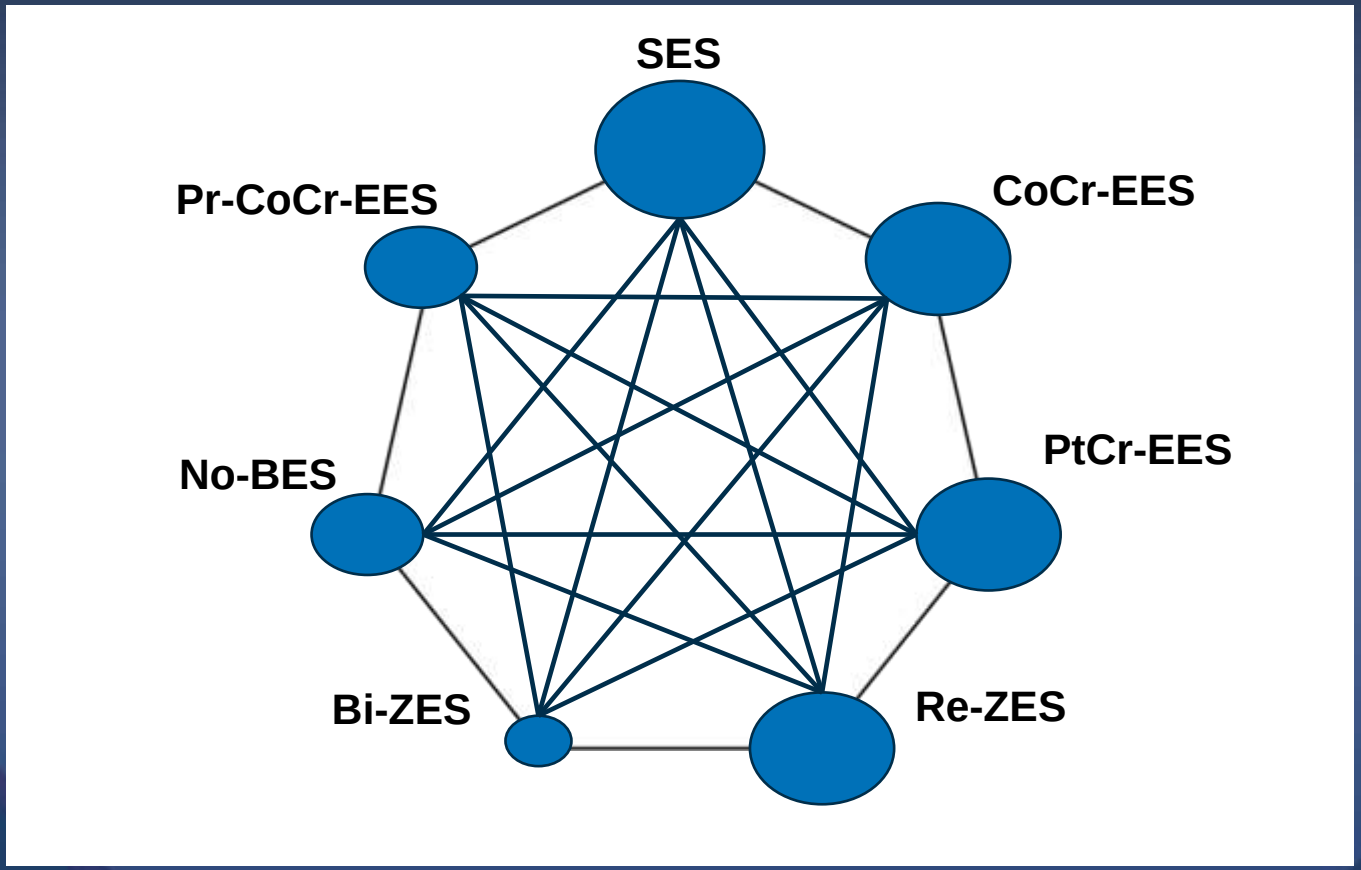
Evaluation of Effectiveness and Safety of the First, Second, and Newer Drug-Eluting Stents in Routine Clinical Practice;

IRIS-DES Registry

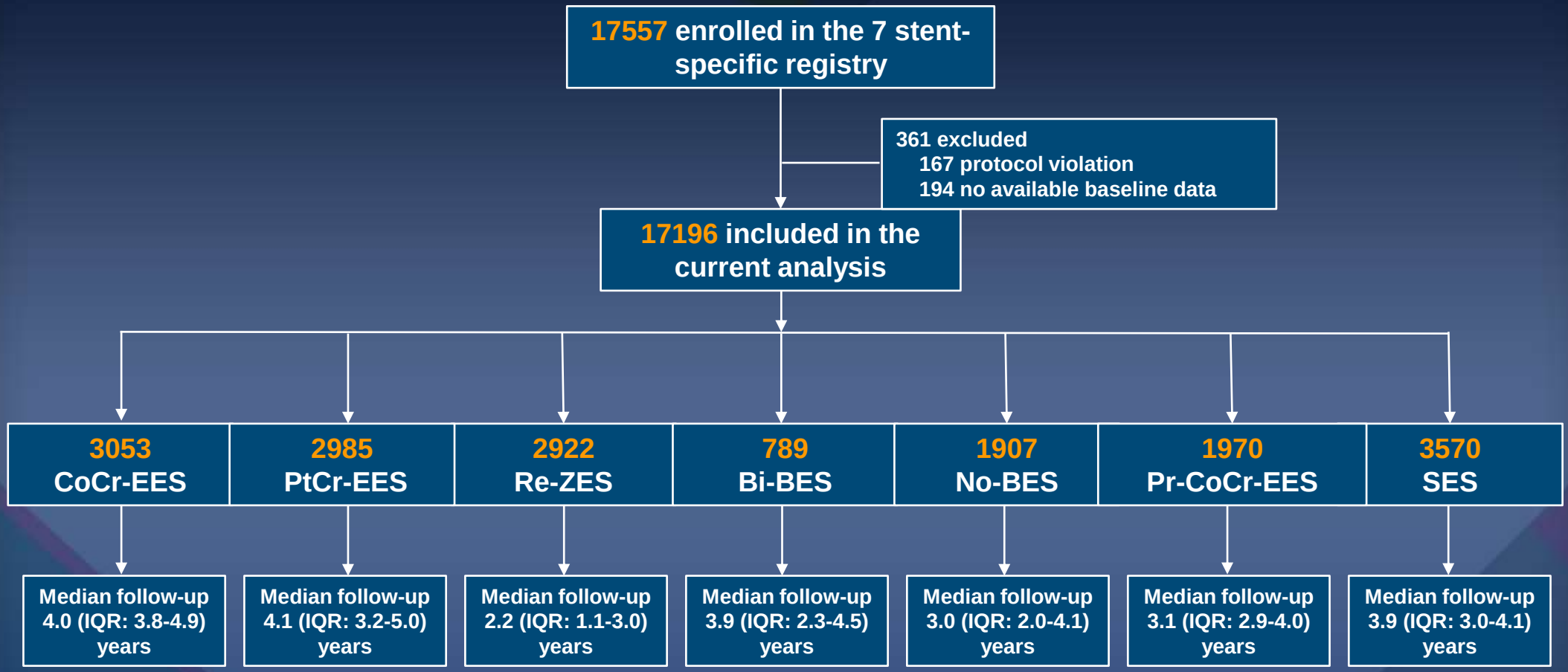


Updated Analysis of IRIS-DES Registry

7 registry; 17,196 patients, median 3.3 years



Study Flow of the IRIS-DES Registry



Clinical Characteristics

Characteristics	SES (n=3570)	CoCr-EES (n=3053)	PtCr-EES (n=2985)	Re-ZES (n=2922)	Bi-BES (n=789)	No-BES (n=1907)	Pr-CoCr-EES (n=1970)
Age (years)	63.6 ± 10.8	63.5 ± 10.8	63.8 ± 11.0	64.0 ± 10.9	64.0 ± 10.5	64.0 ± 10.8	63.9 ± 10.7
Men	66.3%	67.5%	70.6%	72.3%	68.8%	68.8%	72.0%
BMI (kg/m^2)	24.7 ± 3.1	24.7 ± 3.2	24.7 ± 3.3	24.8 ± 3.2	24.7 ± 3.1	24.6 ± 3.2	24.6 ± 3.1
Diabetes mellitus	36.4%	33.4%	33.8%	32.6%	29.2%	29.1%	35.1%
Hypertension	62.6%	62.5%	61.2%	61.1%	58.6%	59.3%	62.8%
Hyperlipidemia	40.2%	37.6%	36.4%	47.5%	37.6%	32.6%	36.3%
Current smoker	27.1%	28.9%	29.2%	28.8%	28.1%	30.2%	31.3%

Clinical Characteristics

Characteristics	SES (n=3570)	CoCr-EES (n=3053)	PtCr-EES (n=2985)	Re-ZES (n=2922)	Bi-BES (n=789)	No-BES (n=1907)	Pr-CoCr-EES (n=1970)
Family history of CAD	4.8%	3.6%	6.7%	8.0%	6.7%	4.7%	6.4%
Previous MI	7.7%	5.2%	5.0%	5.2%	4.9%	4.2%	4.6%
Previous CHF	2.4%	2.1%	2.7%	2.1%	3.0%	1.2%	2.6%
Previous PCI	19.1%	14.9%	10.8%	11.9%	7.0%	8.5%	9.4%
Previous CABG	2.4%	2.0%	1.2%	1.8%	1.3%	2.1%	1.9%
Renal failure	4.2%	3.3%	3.1%	3.4%	3.0%	2.3%	3.8%
History of stroke	7.6%	8.2%	7.3%	7.2%	7.0%	6.3%	6.7%

Clinical Characteristics

Characteristics	SES (n=3570)	CoCr-EES (n=3053)	PtCr-EES (n=2985)	Re-ZES (n=2922)	Bi-BES (n=789)	No-BES (n=1907)	Pr-CoCr-EES (n=1970)
PVD	1.1%	1.2%	2.0%	3.7%	1.9%	1.0%	2.5%
Chronic lung disease	2.5%	2.9%	2.0%	2.7%	2.5%	2.4%	1.8%
Ejection fraction (%)	59.1 ± 10.7	59.5 ± 10.9	58.8 ± 10.2	58.8 ± 10.2	59.2 ± 10.2	58.4 ± 9.8	57.9 ± 11.1
Clinical indication for PCI							
Stable angina	45.3%	41.6%	38.2%	41.0%	37.3%	42.5%	40.3%
Unstable angina	32.0%	34.3%	33.8%	32.4%	34.9%	27.8%	31.1%
NSTEMI	12.2%	10.9%	16.1%	14.5%	15.3%	14.9%	15.1%
STEMI	10.4%	13.1%	11.9%	12.1%	12.5%	14.8%	13.6%

Lesion characteristics

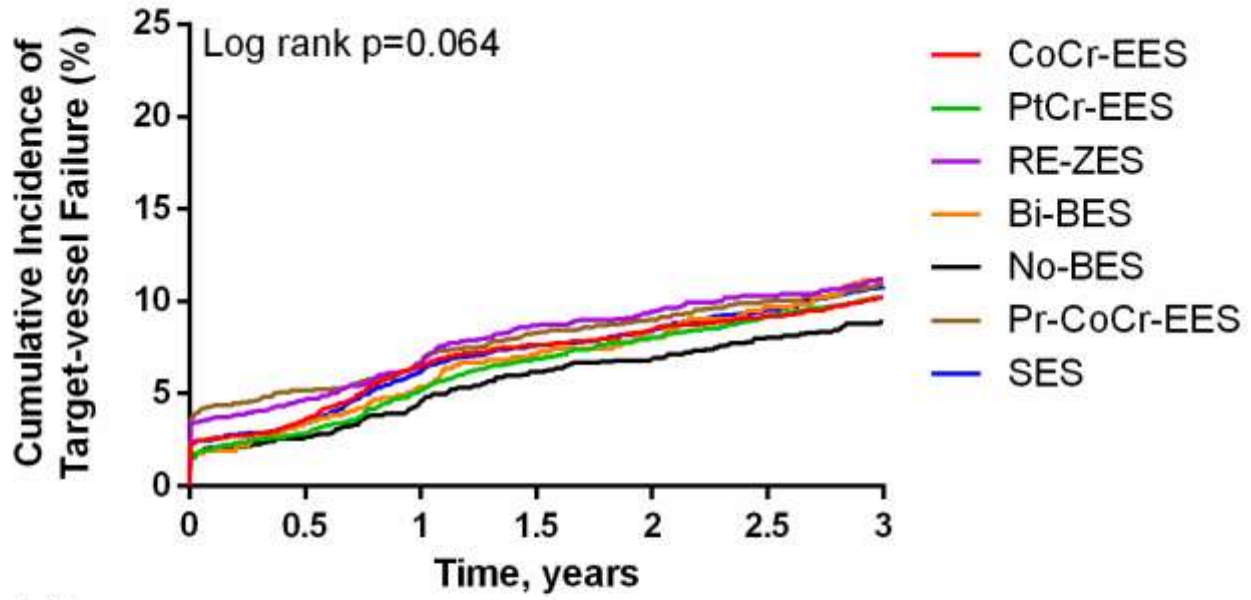
Characteristics	SES (n=3570)	CoCr-EES (n=3053)	PtCr-EES (n=2985)	Re-ZES (n=2922)	Bi-BES (n=789)	No-BES (n=1907)	Pr-CoCr-EES (n=1970)
Treated lesions							
1	64.9%	67.2%	69.9%	72.7%	79.2%	78.0%	69.4%
2	26.4%	25.1%	23.4%	21.3%	16.9%	18.6%	23.9%
3	7.2%	6.3%	5.4%	4.7%	3.5%	2.6%	5.7%
>3	1.5%	1.3%	1.2%	1.2%	0.4%	0.8%	0.9%
Location of treated lesion							
LM	3.3%	6.7%	3.8%	5.2%	1.6%	1.1%	2.3%
LAD	49.7%	47.2%	42.4%	40.9%	46.6%	45.6%	41.6%
LCX	20.2%	19.2%	24.6%	23.1%	23.0%	24.1%	24.4%
RCA	26.6%	26.7%	29.1%	30.5%	28.8%	29.2%	31.5%
Graft	0.2%	0.2%	0.1%	0.3%	0.0%	0.0%	0.2%

Procedural Characteristics

Characteristics	SES (n=5136)	CoCr-EES (n=4158)	PtCr-EES (n=5375)	Re-ZES (n=5476)	Bi-BES (n=1356)	No-BES (n=3206)	Pr-CoCr-EES (n=3647)
Lesion type							
De novo	94.6%	95.6%	97.5%	97.5%	98.7%	99.0%	97.8%
Restenotic	5.4%	4.4%	2.5%	2.5%	1.3%	1.0%	2.2%
Number of Stents	1.2 ± 0.6	1.3 ± 0.6	1.2 ± 0.5	1.2 ± 0.5	1.1 ± 0.4	1.1 ± 0.4	1.2 ± 0.5
Stent length (mm)	32.1 ± 16.6	30.1 ± 17.8	28.0 ± 14.3	30.2 ± 15.5	24.4 ± 11.1	25.0 ± 11.3	31.4 ± 15.9
Stent diameter (mm)	3.1 ± 0.4	3.2 ± 0.4	3.2 ± 0.5	3.2 ± 0.5	3.2 ± 0.4	3.1 ± 0.4	3.1 ± 0.5
Use of IVUS	48.5%	51.3%	28.4%	36.9%	32.2%	21.0%	31.0%

K-M Curves of Primary End Point

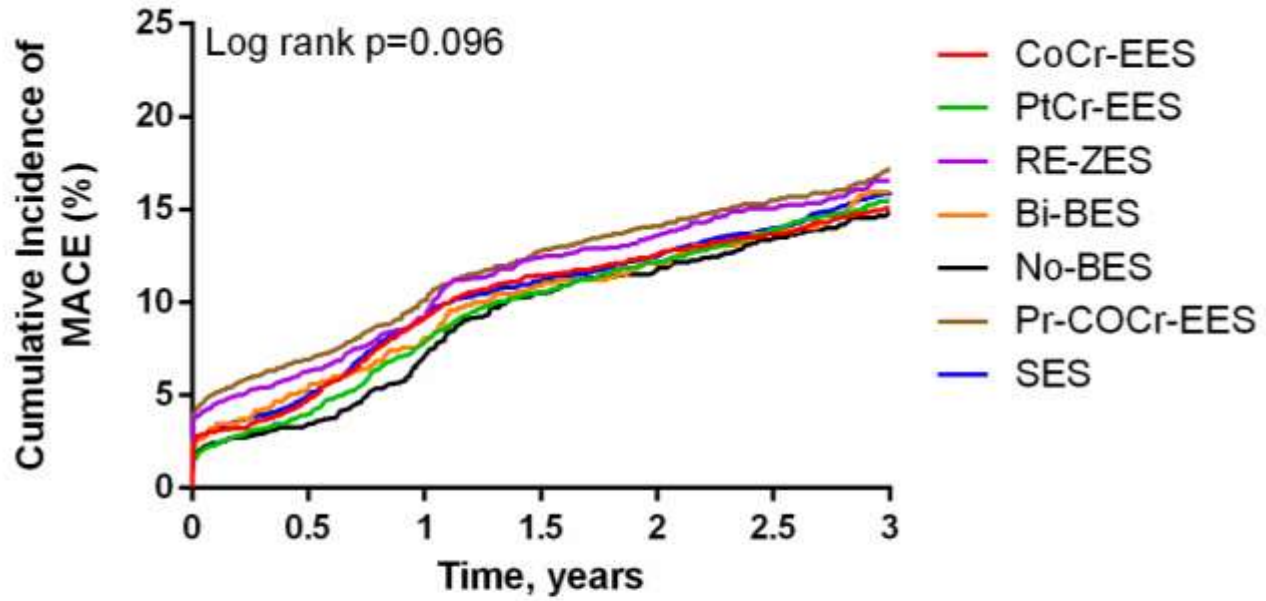
Target-Vessel Failure (CV death, target-vessel MI, or TVR)



No. at risk				
SES	3570	3210	2989	2474
CoCr-EES	3053	2743	2563	2396
PtCr-EES	2985	2667	2454	2185
RE-ZES	2922	2245	1626	831
Bi-BES	789	659	586	500
No-BES	1907	1615	1340	971
Pr-CoCr-EES	1970	1712	1585	1197

K-M Curves of Secondary End Point

Major Adverse Cardiac Event (all-cause death, any MI, any revascularization)



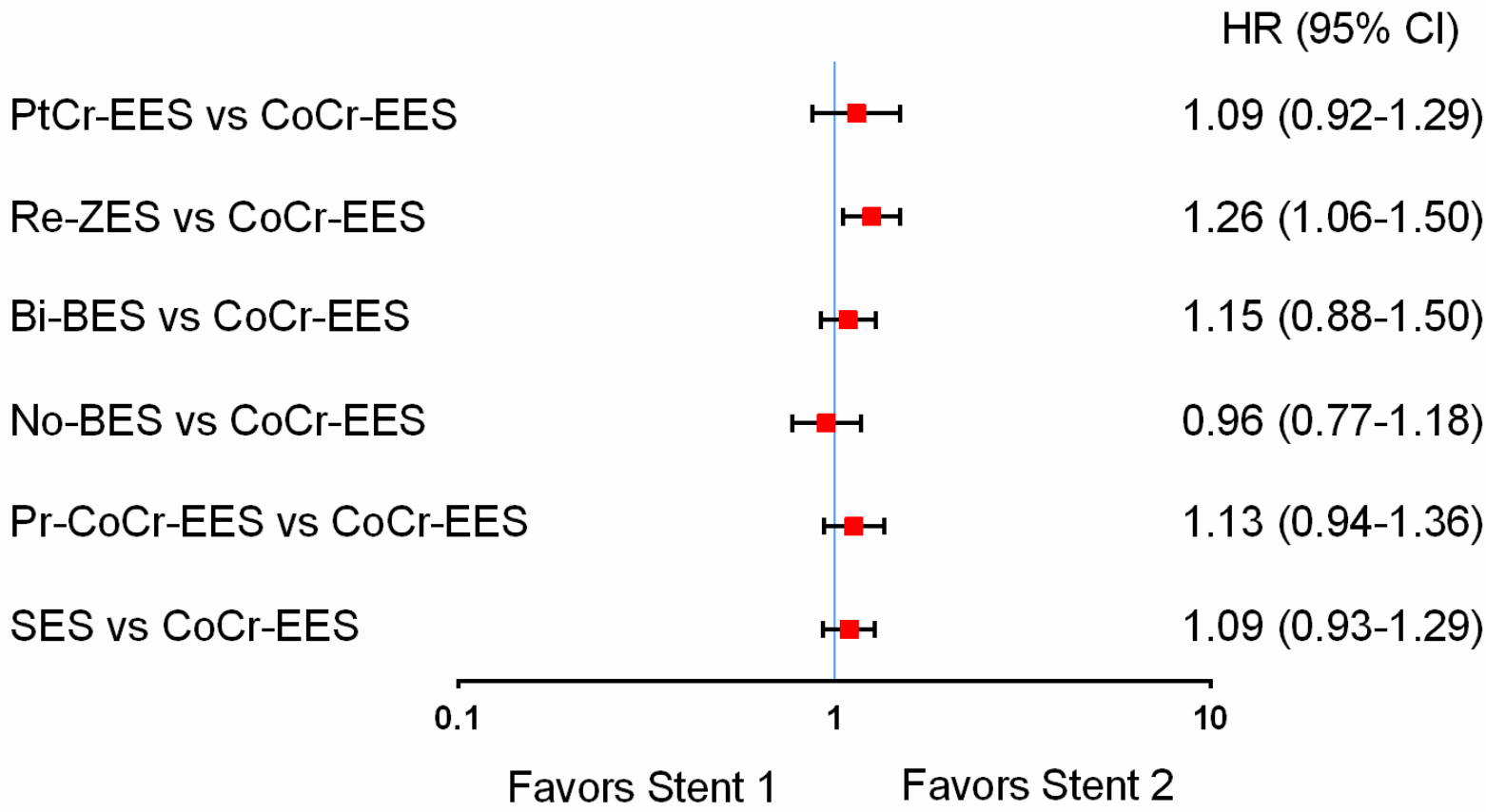
No. at risk				
SES	3570	3135	2892	2378
CoCr-EES	3053	2678	2482	2310
PtCr-EES	2985	2616	2376	2100
RE-ZES	2922	2199	1568	799
Bi-BES	789	648	570	485
No-BES	1907	1582	1283	916
Pr-CoCr-EES	1970	1661	1518	1138

Statistical Analysis

- All analyses were truncated at 3 years of follow-up owing to different follow-up duration according to DES types and the small number of patients with data thereafter.
- Kaplan-Meier estimates and compared with the log-rank test.
- **Multiple treatment-group propensity scores** using the **TWANG method** and corresponding inverse probabilities of treatment weight with generalized boosted models through an iterative estimation procedure (n=3000), by using all the related baseline characteristic.
- PROC SURVEYPHREG procedure of SAS was used to correctly interpret weights as probability weights.

Adjusted HR of Primary End Point

Target-Vessel Failure (CV death, target-vessel MI, or TVR)



Adjusted HR of Secondary End Point

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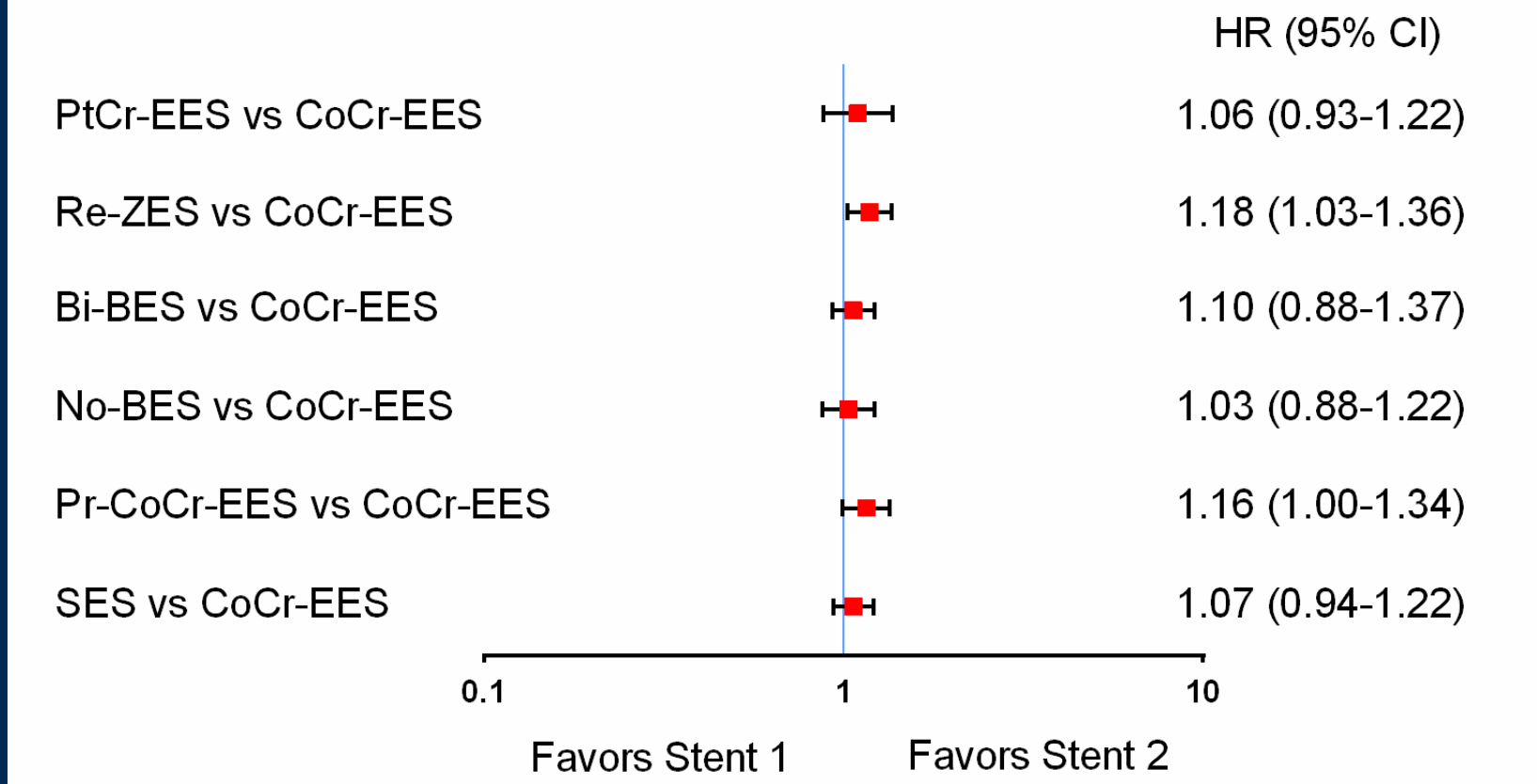
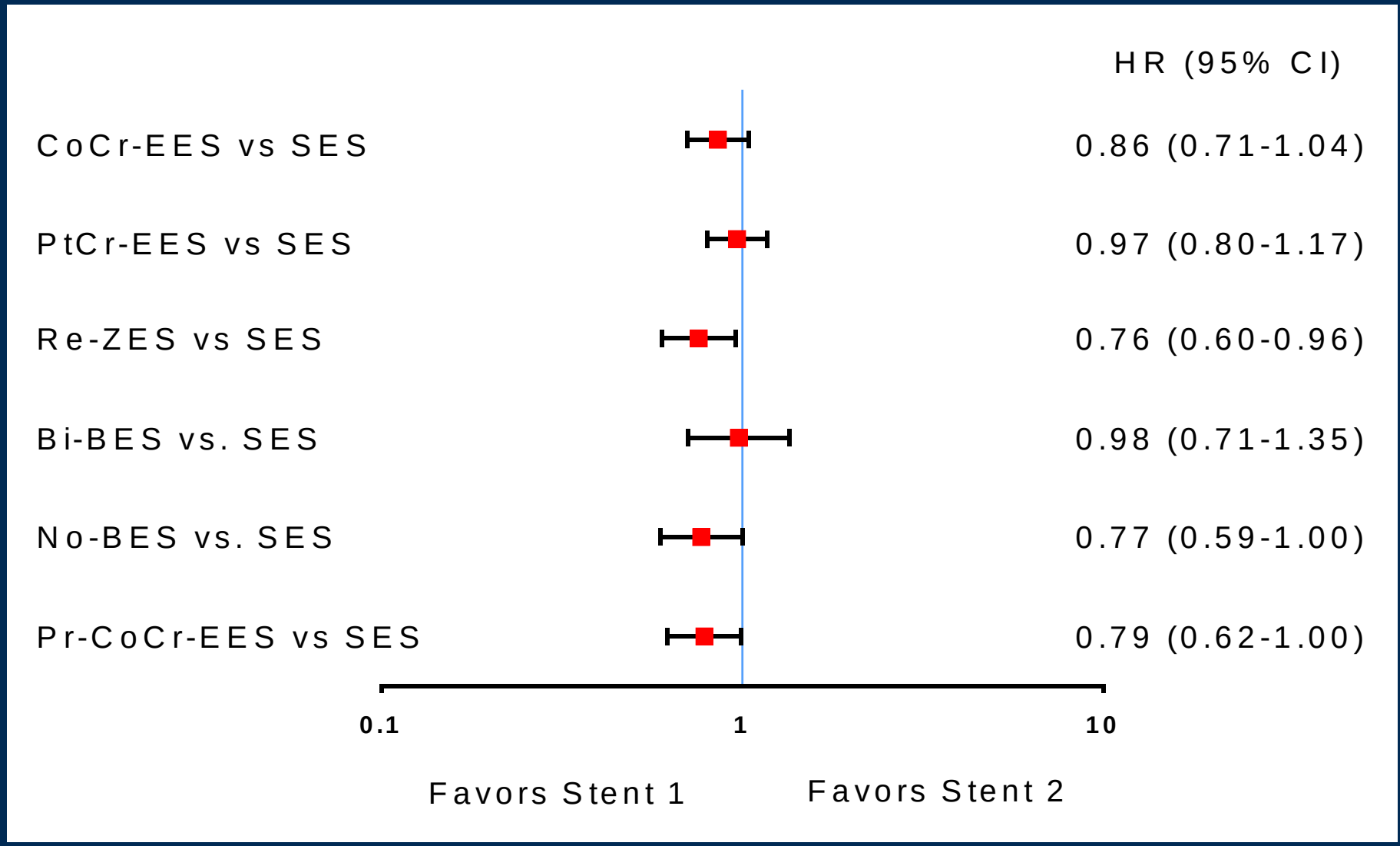
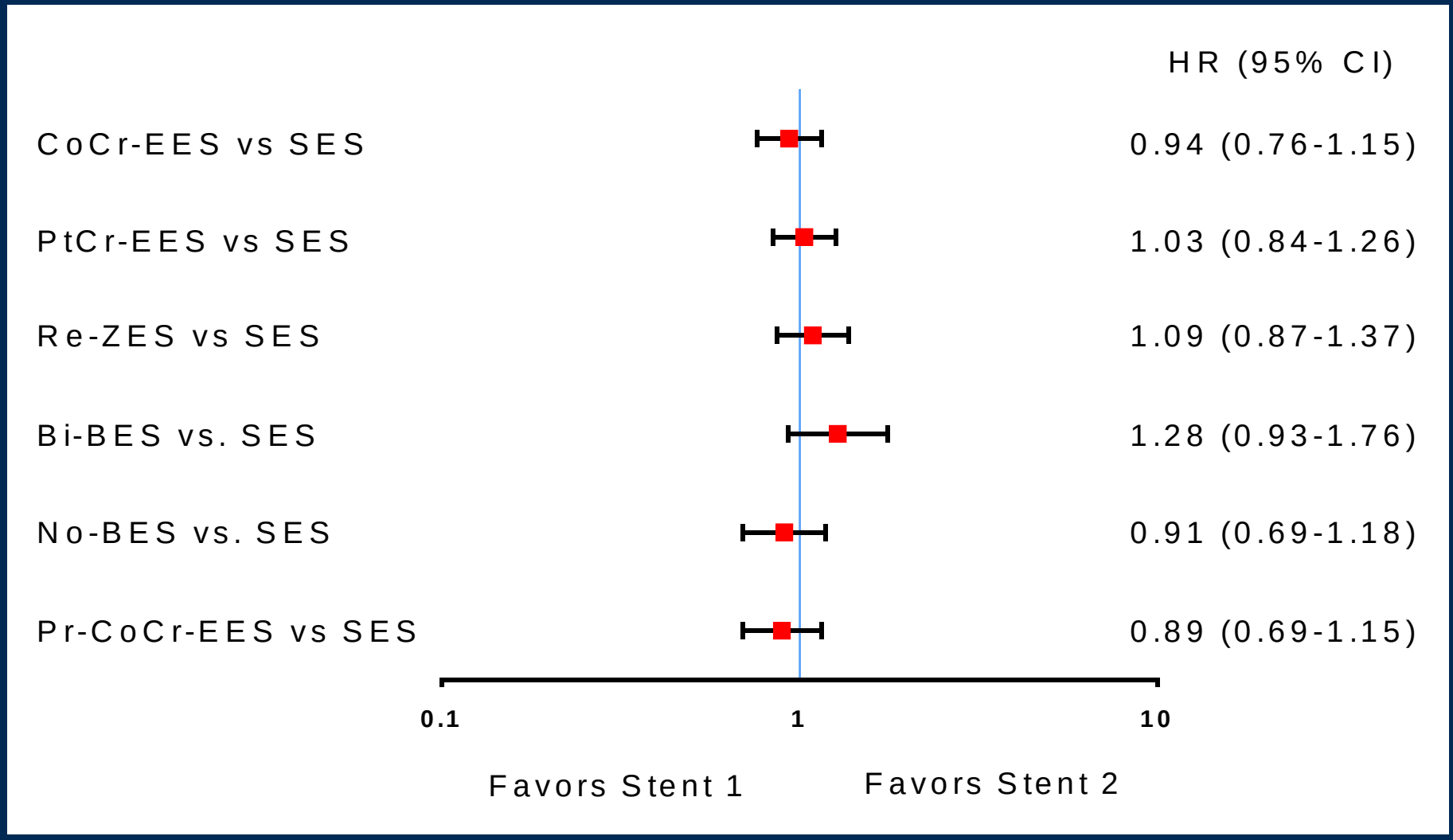


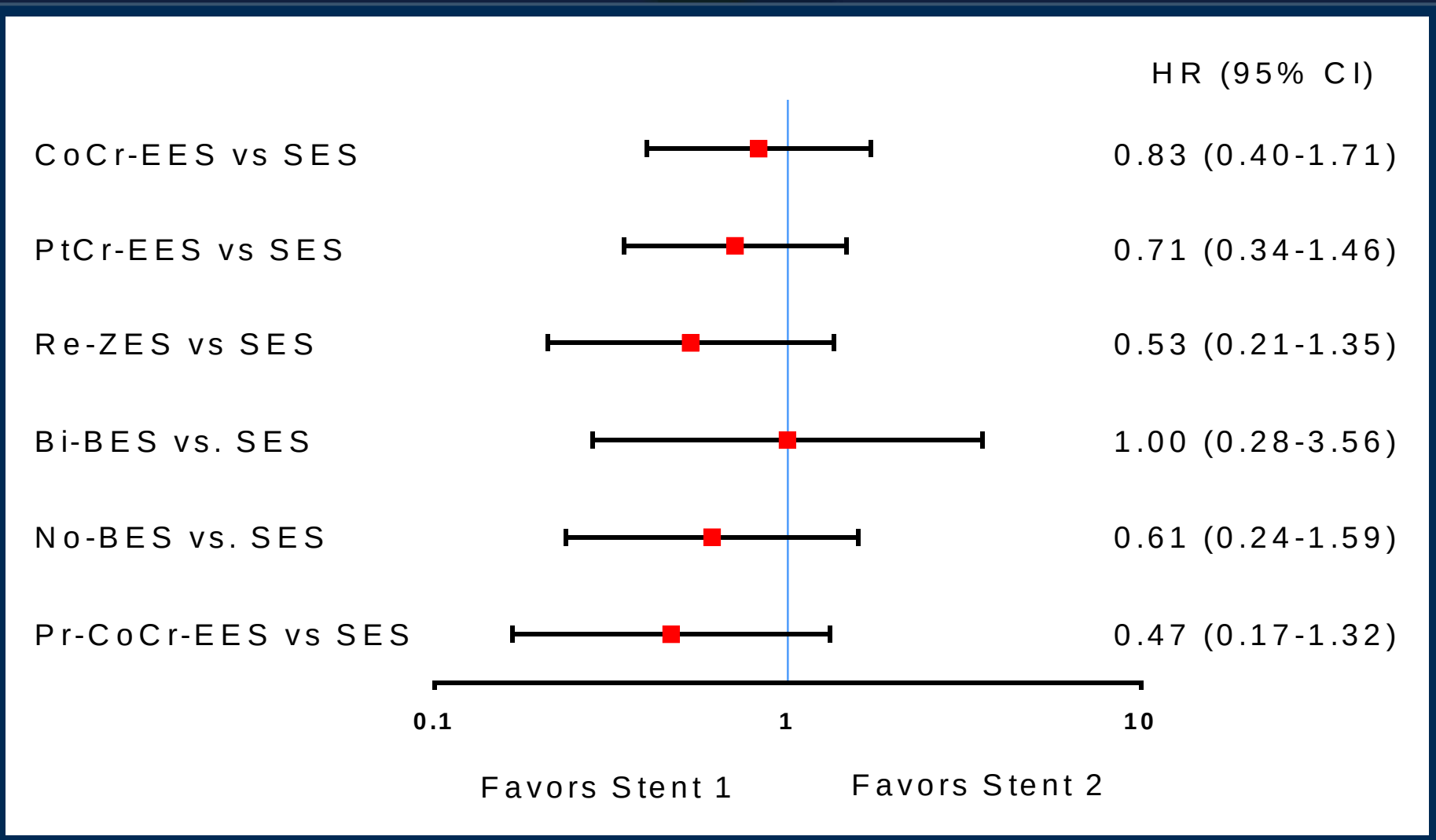
Adjusted HR: All-cause death



Adjusted HR: TVR



Adjusted HR: Definite or Probable ST



Contemporary PCI with Second-Generation DES

- In contemporary DES era, there was no remarkable between-stent difference with respect to clinically relevant efficacy and safety outcomes
- We can choose any contemporary DES on the basis of clinical and lesion subsets and combined with the physician's preference.

Contemporary DES for Complex Lesions: Is There Difference?

Left Main Disease

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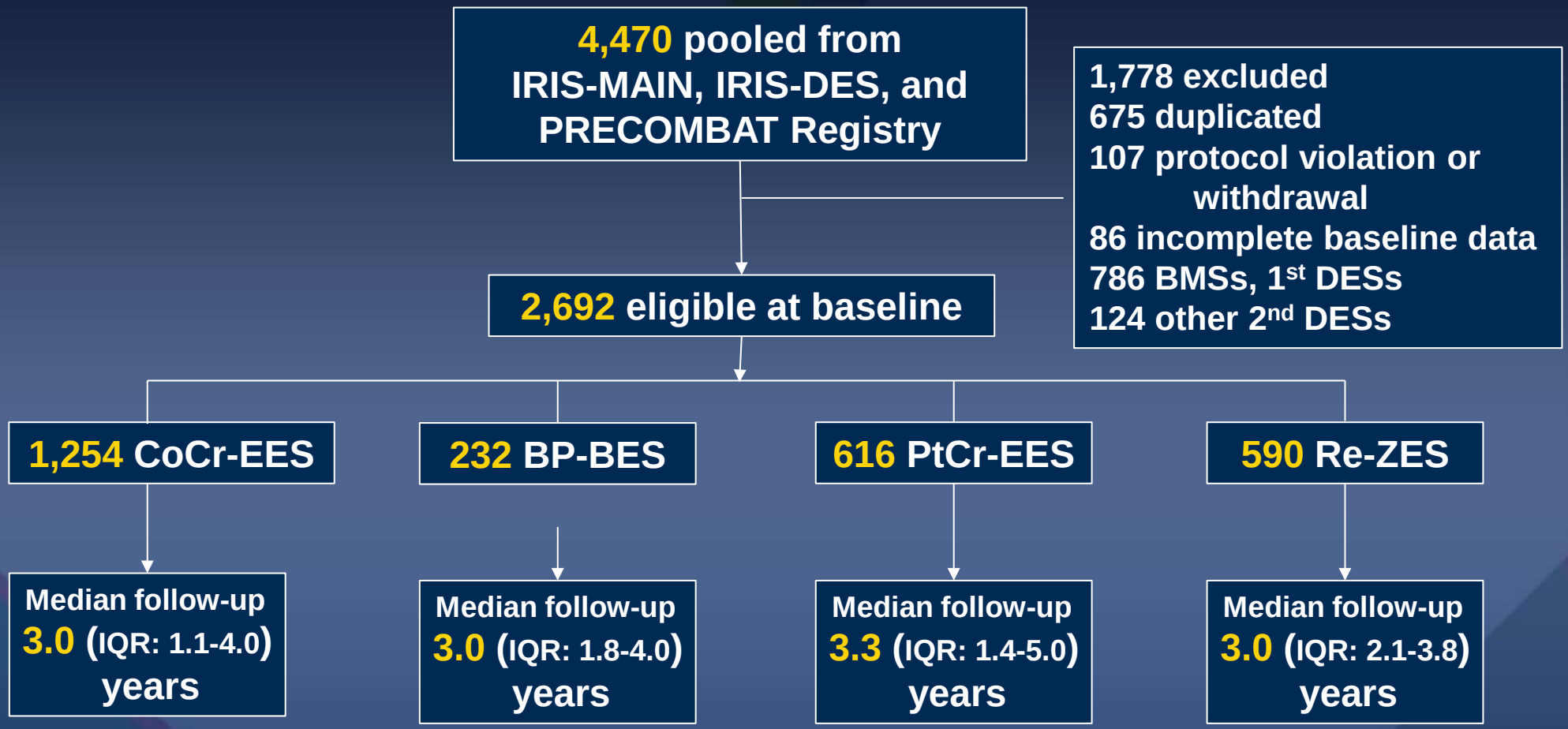
Safety and Effectiveness of Second-Generation Drug-Eluting Stents in Patients With Left Main Coronary Artery Disease

Pil Hyung Lee, MD,[a] Osung Kwon, MD,[a] Jung-Min Ahn, MD,[a] Cheol Hyun Lee, MD,[a] Do-Yoon Kang, MD,[a] Jung-Bok Lee, PhD,[b] Soo-Jin Kang, MD, PhD,[a] Seung-Whan Lee, MD, PhD,[a] Young-Hak Kim, MD, PhD,[a] Cheol Whan Lee, MD, PhD,[a] Seong-Wook Park, MD, PhD,[a] Duk-Woo Park, MD, PhD,[a] Seung-Jung Park, MD, PhD[a]

A total of 4,470 patients with unprotected LMCA disease from a pooled analysis of 3 prospective, multi-center, clinical-practice registries.

Lee PH, Park DW, Park SJ et al. J Am Coll Cardiol 2018;71:832–41

Study Flow



Lee PH, Park DW, Park SJ et al. J Am Coll Cardiol 2018;71:832–41

Statistical Analysis

- Chi-Square or Fisher exact test
- Kaplan-Meier estimates and compared with the log-rank test.
- **Multiple treatment propensity scores using the TWANG method** and corresponding inverse probabilities of treatment weight with generalized boosted models through an iterative estimation procedure.
- PROC SURVEYPHREG procedure of SAS was used to correctly interpret weights as probability weights.

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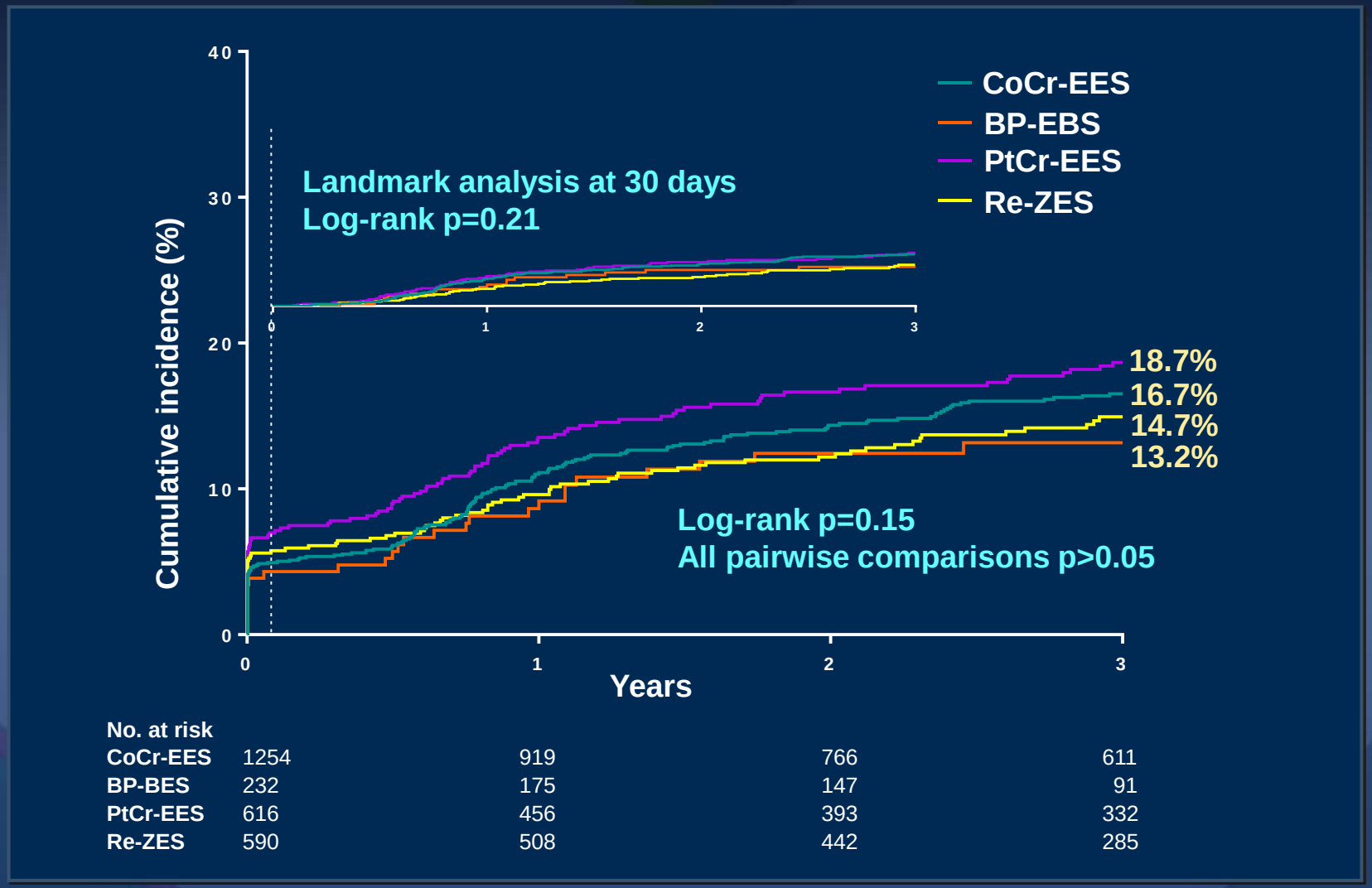
K-M Curves of Primary End Point

Target-Vessel Failure (CV death, target-vessel MI, or TVR)

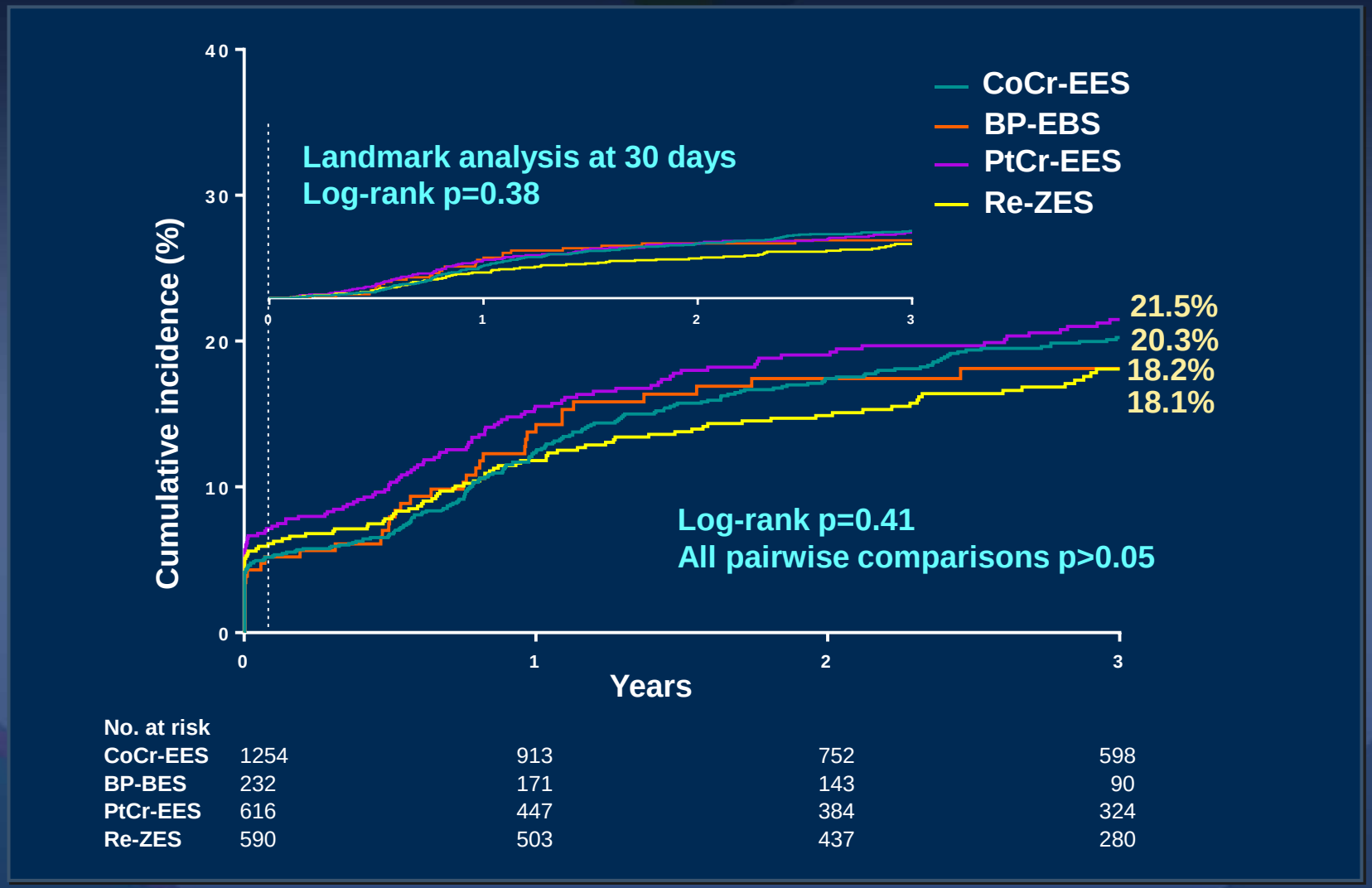


No. at risk				
CoCr-EES	1254	919	766	611
BP-BES	232	175	147	91
PtCr-EES	616	456	393	332
Re-ZES	590	508	442	285

Lee PH, Park DW, Park SJ et al. J Am Coll Cardiol 2018;71:832–41

K-M Curves of Secondary End Point

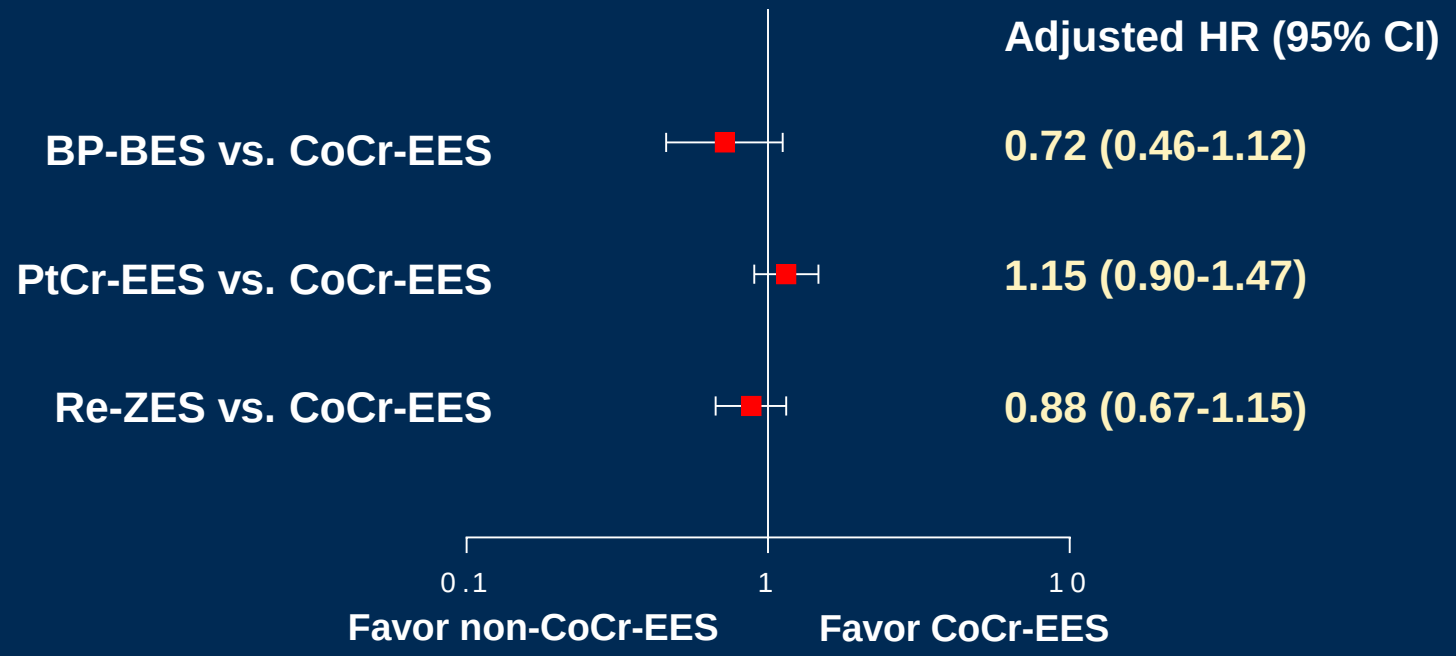
Major Adverse Cardiac Event (all-cause death, any MI, any revascularization)



Lee PH, Park DW, Park SJ et al. J Am Coll Cardiol 2018;71:832–41

Adjusted HR in the Multigroup Propensity-Score Analyses (TWANG Method)

Target-vessel Failure



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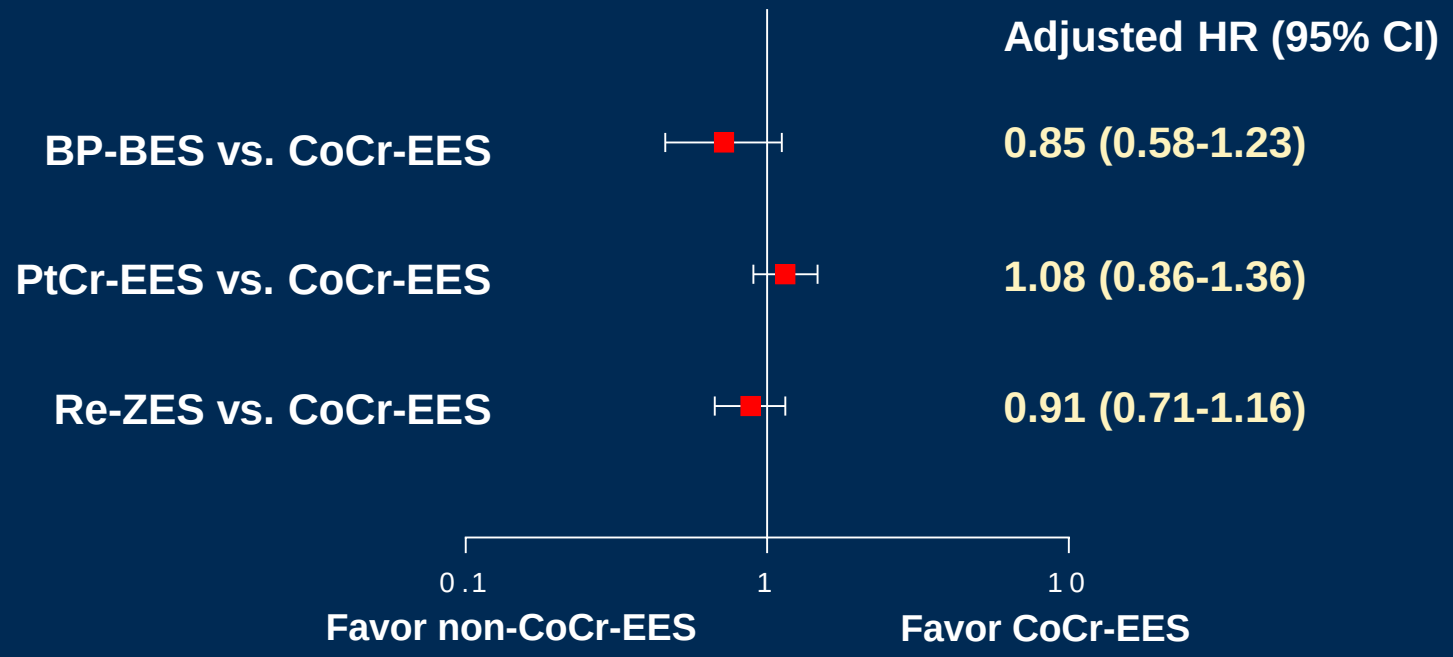
Adjusted HR in the Multigroup Propensity-Score Analyses (TWANG Method)

Major Adverse Cardiac Event



Lee PH, Park DW, Park SJ et al. J Am Coll Cardiol 2018;71:832–41

Contemporary DES for LM Disease

- In comparisons of different types of contemporary 2nd-generation DES for PCI of LMCA disease, there was no significant differences in stent-related and patient-related outcomes at 3-year follow-up.
- The small absolute difference in outcomes in our study warrants further investigation and should be confirmed or refuted through large, randomized clinical trials with long-term follow-up.

Contemporary PCI with Second-Generation DES

- In contemporary DES era, there was no remarkable between-stent difference with respect to clinically relevant efficacy and safety outcomes
- We can choose any contemporary DES on the basis of clinical and lesion subsets and combined with the physician's preference.

DES 2018:
Why Do We Need Better DES?

- We now have reached a matured milestone in PCI with contemporary DES.

- To further reduce restenosis and early and late stent thrombosis.
- To improve lifelong integrity and patency of DES.
- To reduce long-term dependency on DAPT.

“When technology stops continued innovation”, “The Knowledge will also stops”