PROMUS PLATINUM

The PLATINUM Trial

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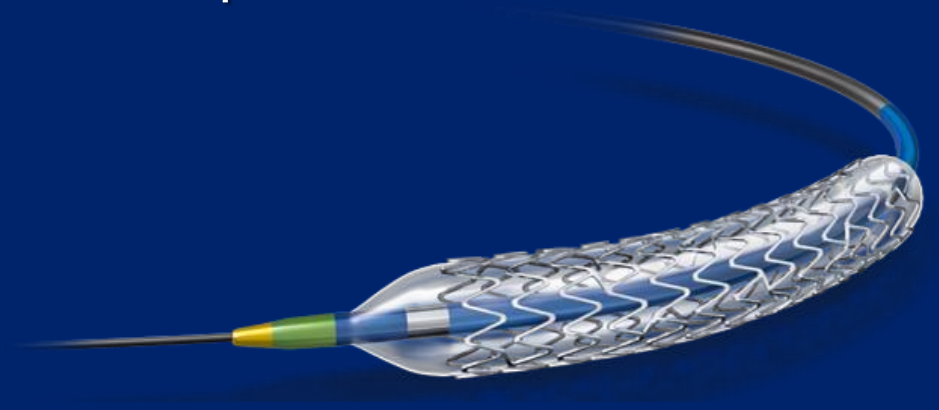

CARDIOVASCULAR SUMMIT
TCTAP2013

Conflicts of Interest

PROMUS PLATINUM

Boston Scientific Corporation

- Employee
- Stockholder

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ELEMENT Stent Platform
Clinical Trials

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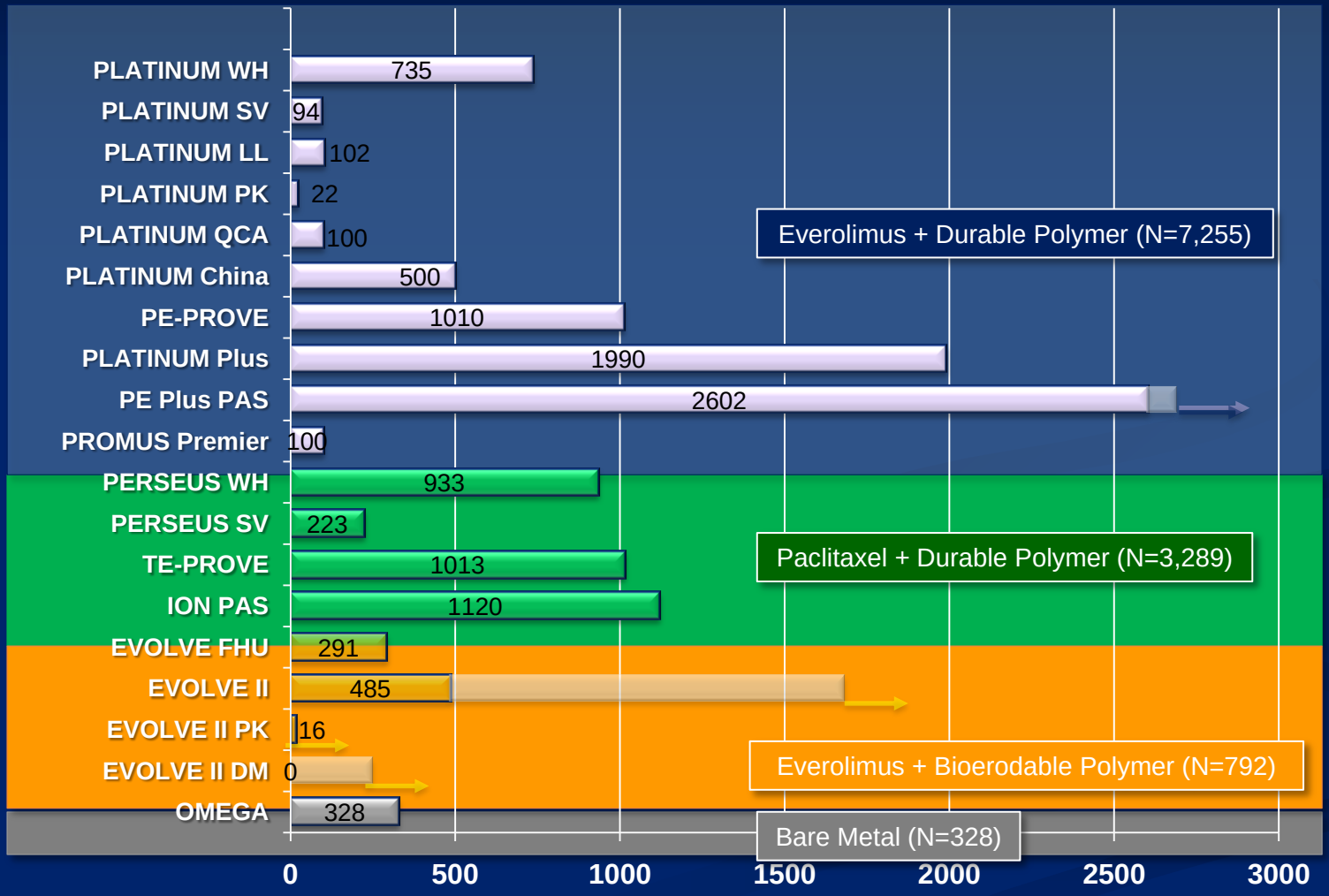

Total Patients: 11,664 (04.23.2013)

Objective

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- In the prospective, multicenter, randomized PLATINUM trial, the platinum chromium PROMUS Element Everolimus Eluting Stent (PtCr-EES) was non-inferior to the predicate cobalt chromium PROMUS/XIENCE V EES (CoCr-EES) for the 12-month primary endpoint of target lesion failure (TLF).
- Objective: To report 3-year outcomes of the PLATINUM randomized controlled trial.

PLATINUM Study Algorithm

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Patients with 1 or 2 *de novo* native coronary artery target lesions

RVD ≥2.5 to ≤4.25; Lesion length ≤24 mm

Peri-proc: ASA ≥300 mg, clopidogrel ≥300 mg load unless on chronic Rx

Randomized 1:1

Stratified by diabetes, intention to treat 1 vs. 2 target lesions, & study site

Cobalt chromium everolimus-eluting stent

Platinum chromium everolimus-eluting stent

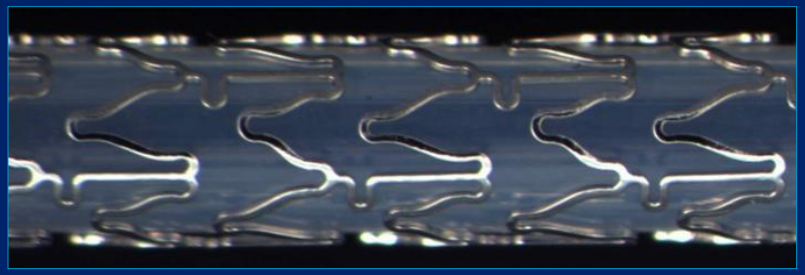
ASA indefinitely, thienopyridine ≥6 mos (≥12 mos if not high risk for bleeding)

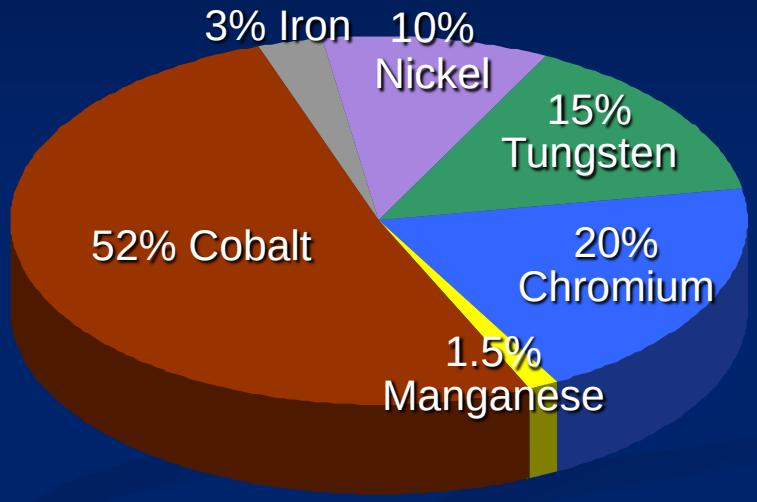
Clinical f/u only: 1, 6, 12, 18 months then yearly for 2-5 years

Everolimus-Eluting Stents

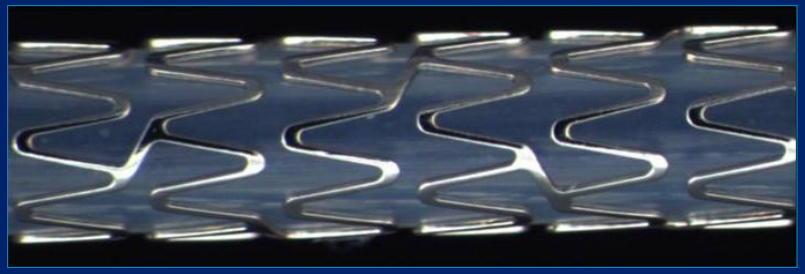
Everolimus concentration: 100 µg/cm^2
Polymer: PBMA & PVDF-HFP (7µm thickness)

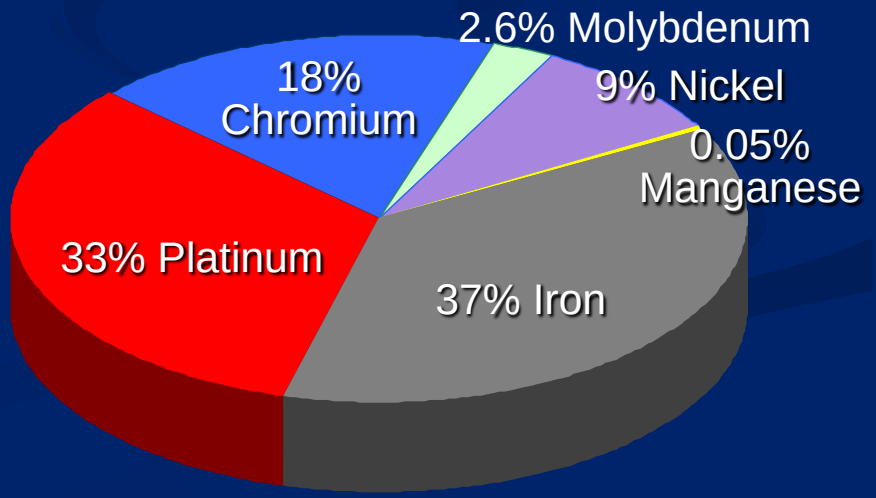
XIENCE V / PROMUS (CoCr-EES)





PROMUS Element (PtCr-EES)





PBMA=poly (n-butyl methacrylate) (primer layer);
PVDF-HFP=poly (vinylidene fluoride-co-hexafluoropropylene) (drug matrix layer)

Features of the ELEMENT Stent

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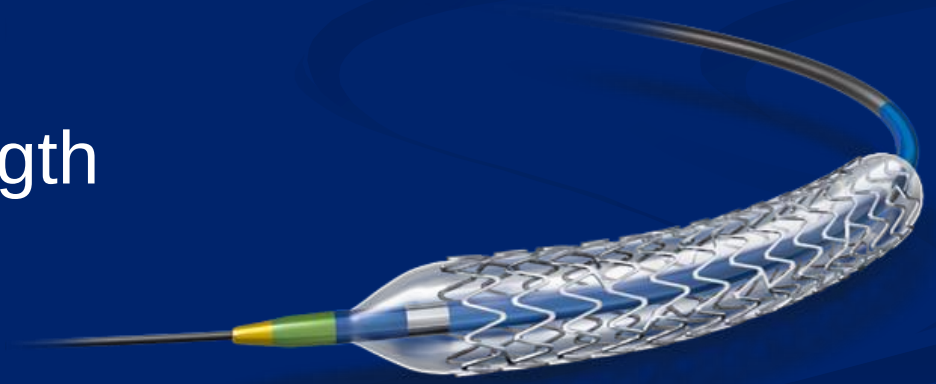
- Platinum-Chrome alloy
- Thin strut (81µm)
- Enhanced deliverability
- High radiopacity
- Conformable
- High radial strength
- Lack of recoil
- Fracture resistance



PLATINUM 3-Year Analysis

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1530 patients randomized at 132 clinical sites in Asia/Pacific (N=56), European Union (N=562), Japan (N=124), & United States (N=788)

CoCr-EES (N=762)	PtCr-EES (N=768)
No 3-yr f/u (N=46) Withdrew consent: 14 Missed 3-yr visit: 26 Lost to follow-up: 6	No 3-yr f/u (N=25) Withdrew consent: 7 Missed 3-yr visit: 10 Lost to follow-up: 6 Other: 2
No Study Stent Implanted* (N=13)	No Study Stent Implanted* (N=10)
3-Year Follow-up 93.9% (703/749)	3-Year Follow-up 96.7% (733/758)

* Patients who did not receive a study stent were only followed through 1 year

Baseline Demographics

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	CoCr-EES (N=762)	PtCr-EES (N=768)	*P* value
Age, years	63.1 ± 10.3	64.0 ± 10.3	0.09
Male	71.1%	71.6%	0.83
Hypertension	73.2%	70.9%	0.32
Hyperlipidemia	76.2%	78.2%	0.36
Diabetes	25.1%	22.0%	0.16
- Insulin treated	6.3%	7.7%	0.29
Current smoker	17.7%	21.0%	0.10
Prior MI	21.1%	21.0%	0.99
Unstable angina	24.7%	24.1%	0.80

Baseline Lesion Characteristics (QCA)

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	CoCr-EES (N=762 Patients) (N=841 Lesions)	PtCr-EES (N=768 Patients) (N=853 Lesions)	*P* value
Target lesions	1.10 ± 0.31	1.11 ± 0.31	0.66
- 2 lesions treated	10.1%	11.1%	0.54
RVD, mm	2.63 ± 0.49	2.67 ± 0.49	0.09
MLD, mm	0.74 ± 0.34	0.75 ± 0.35	0.40
DS, %	71.9 ± 11.5	71.8 ± 11.5	0.87
Lesion length, mm	12.5 ± 5.5	13.0 ± 5.7	0.10

Procedural Characteristics

	CoCr-EES (N=762 Patients) (N=841 Lesions)	PtCr-EES (N=768 Patients) (N=853 Lesions)	*P* value
Stents per patient	1.20 ± 0.48	1.16 ± 0.44	0.16
Stents per target lesion	1.08 ± 0.35	1.05 ± 0.26	0.01
Max stent diam. per lesion (mm)	3.05 ± 0.44	3.09 ± 0.45	0.07
Stent length per lesion (mm)	19.7 ± 8.9	20.5 ± 7.0	0.06
Post-dilatation	49.3%	49.8%	0.84
Max pressure overall (atm)	15.9 ± 3.2	16.3 ± 3.1	0.002
Fluoroscopy time (min)	11.3 ± 10.1	12.2 ± 11.8	0.10

Primary Endpoint

Target Lesion Failure at 12 Months

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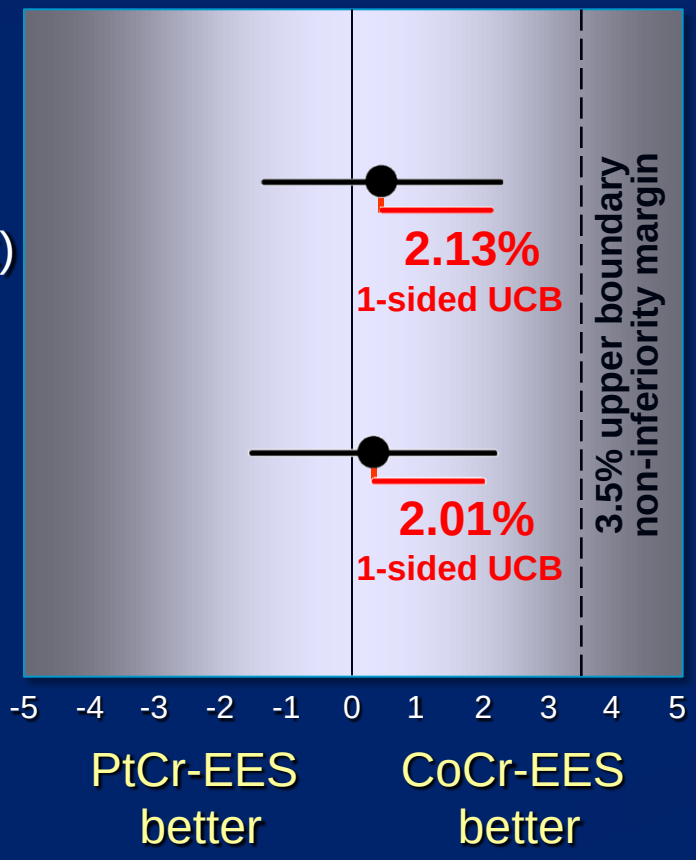
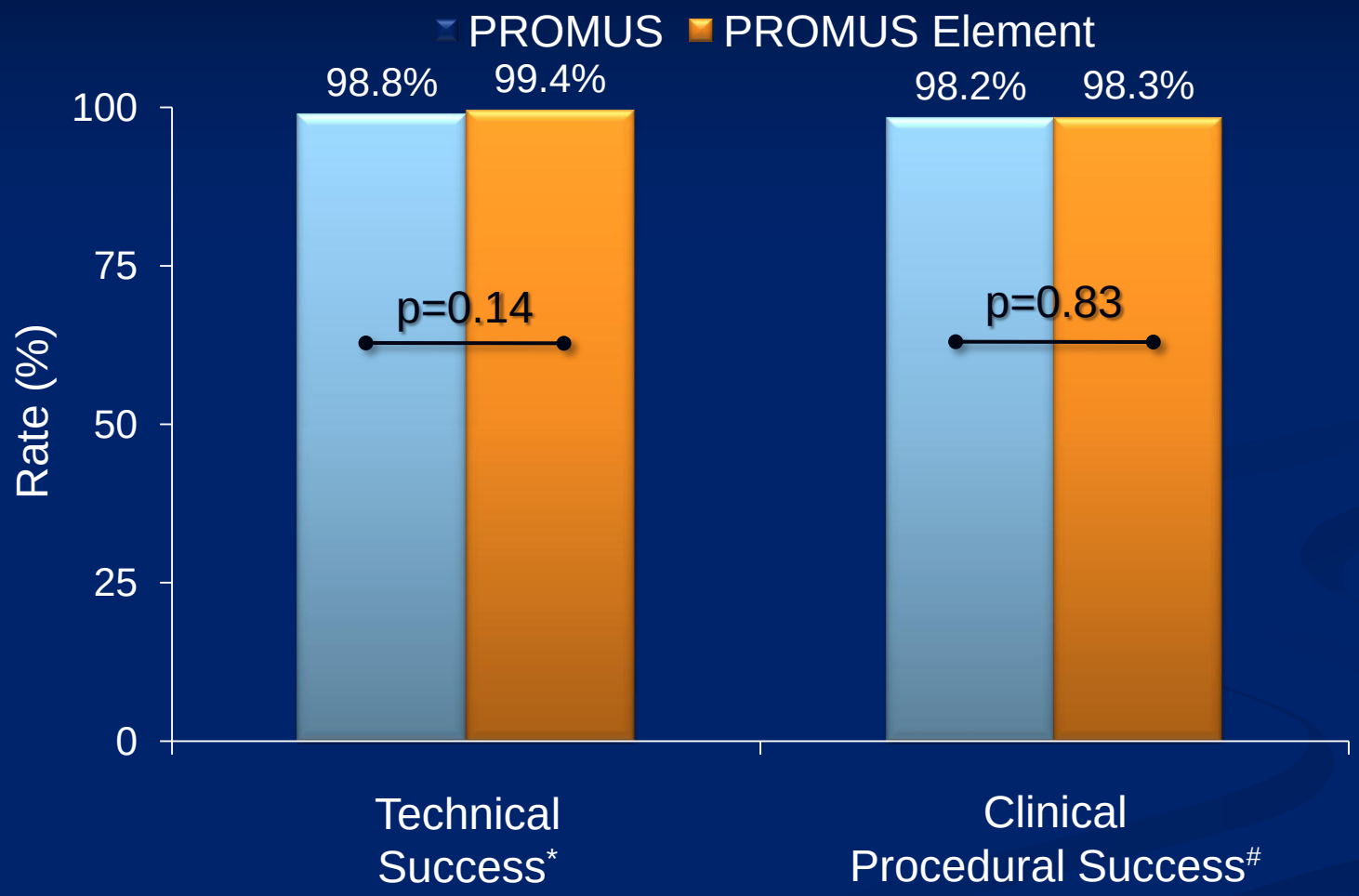
Population	Difference [2-sided 95% CI] (1-sided UCB)	CoCr-EES (N=762)	PtCr-EES (N=768)	Difference [2-sided 95% CI]	*P* Value (noninferiority) (superiority)
Per protocol (1º endpt)	2.13% 1-sided UCB	2.9% (21/714)	3.4% (25/731)	0.5% [-1.3%, 2.3%]	0.001 0.60
Intent-to-treat	2.01% 1-sided UCB	3.2% (23/727)	3.5% (26/742)	0.3% [-1.5%, 2.2%]	0.0009 0.72



UCB=upper confidence bound

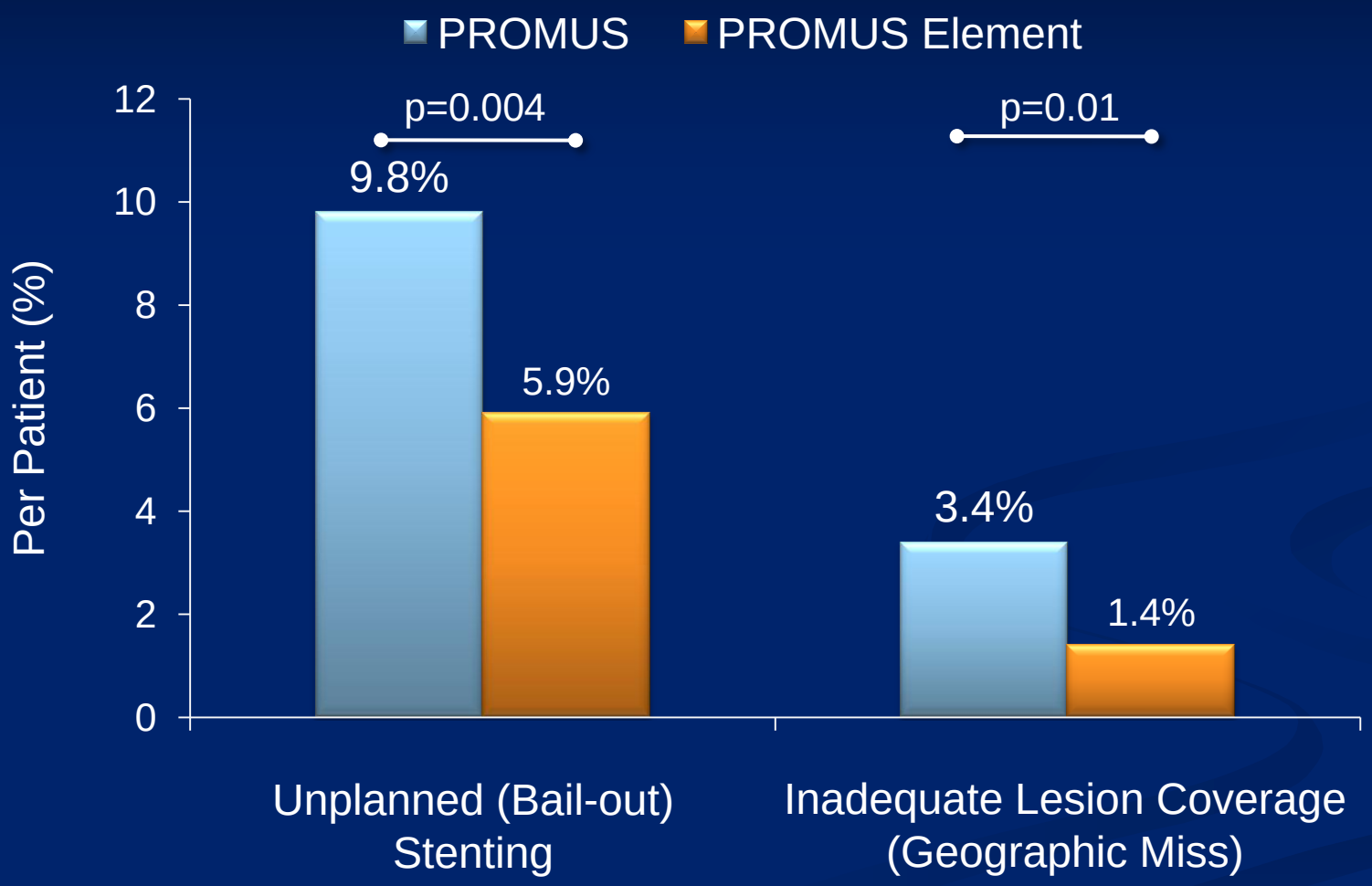
Technical & Procedural Success: I



*Successful delivery & deployment of study stent to the target vessel, without balloon rupture or stent embolization (per stent)
#Mean lesion diameter stenosis <30% with visually assessed TIMI 3 flow and without the occurrence of in-hospital cardiac death, MI, or TVR

Stone GW: J Am Coll Cardiol 2011;57:1700-1708

Technical & Procedural Success: II



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Antiplatelet Medication Usage

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Medication	CoCr-EES (N=749)	PtCr-EES (N=758)	*P* value
	Discharge		
Aspirin	99.6%	98.9%	0.14
Thienopyridine	99.2%	98.9%	0.61
Aspirin + Thienopyridine	98.9%	98.0%	0.15
	1 Year		
Aspirin	93.7%	94.7%	0.41
Thienopyridine	82.7%	84.8%	0.29
Aspirin + Thienopyridine	80.5%	83.4%	0.13
	2 Years		
Aspirin	92.7%	94.8%	0.09
Thienopyridine	50.8%	53.7%	0.25
Aspirin + Thienopyridine	48.0%	51.4%	0.19
	3 Years		
Aspirin	95.2%	95.3%	0.94
Thienopyridine	46.5%	46.0%	0.84
Aspirin + Thienopyridine	42.9%	42.7%	0.93

Target Lesion Failure

3-Year Follow-up (Primary Endpoint 1 Year)

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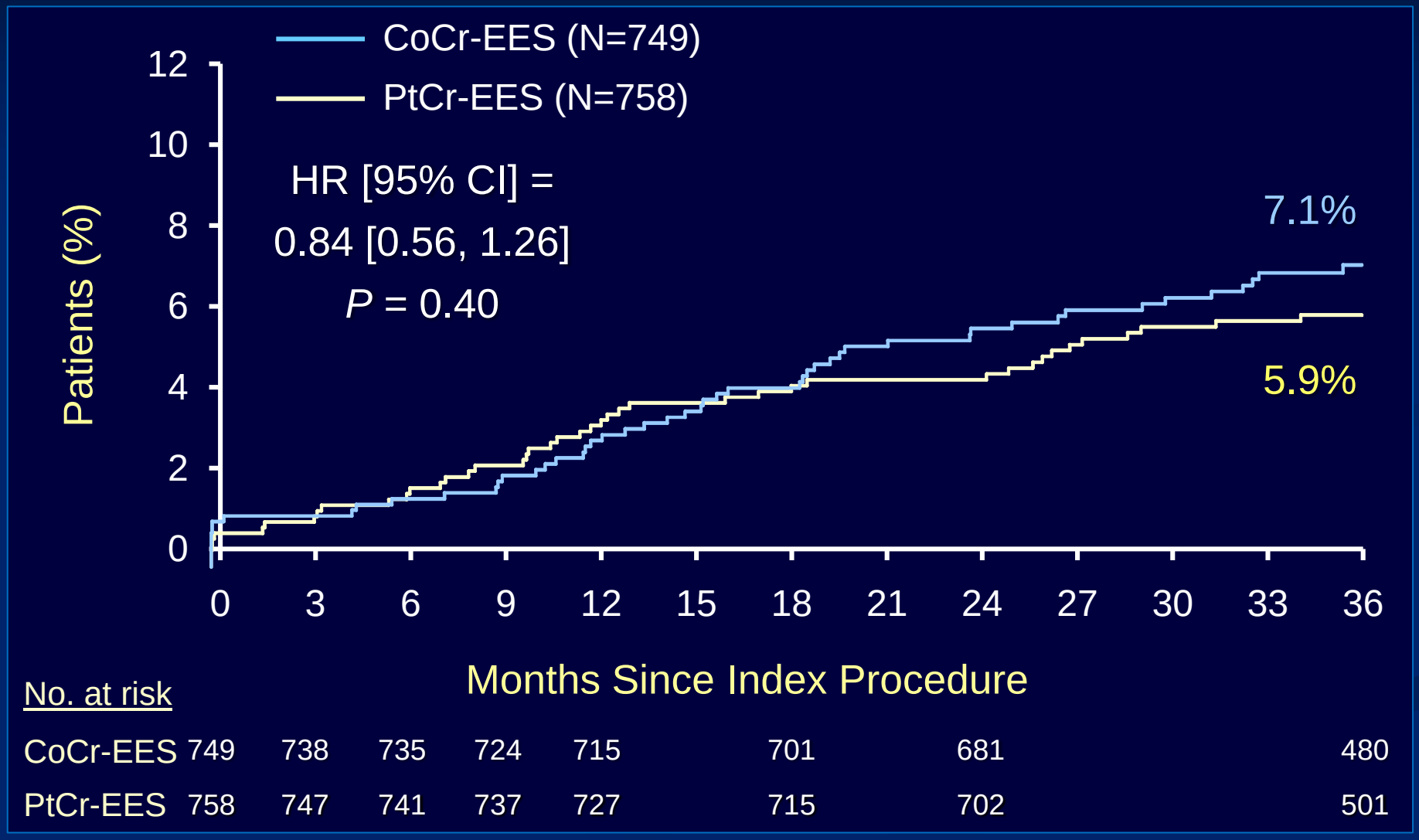

TLF = cardiac death or MI related to the target vessel or ischemia-driven TLR

Target Lesion Failure

3-Year Landmark Analysis

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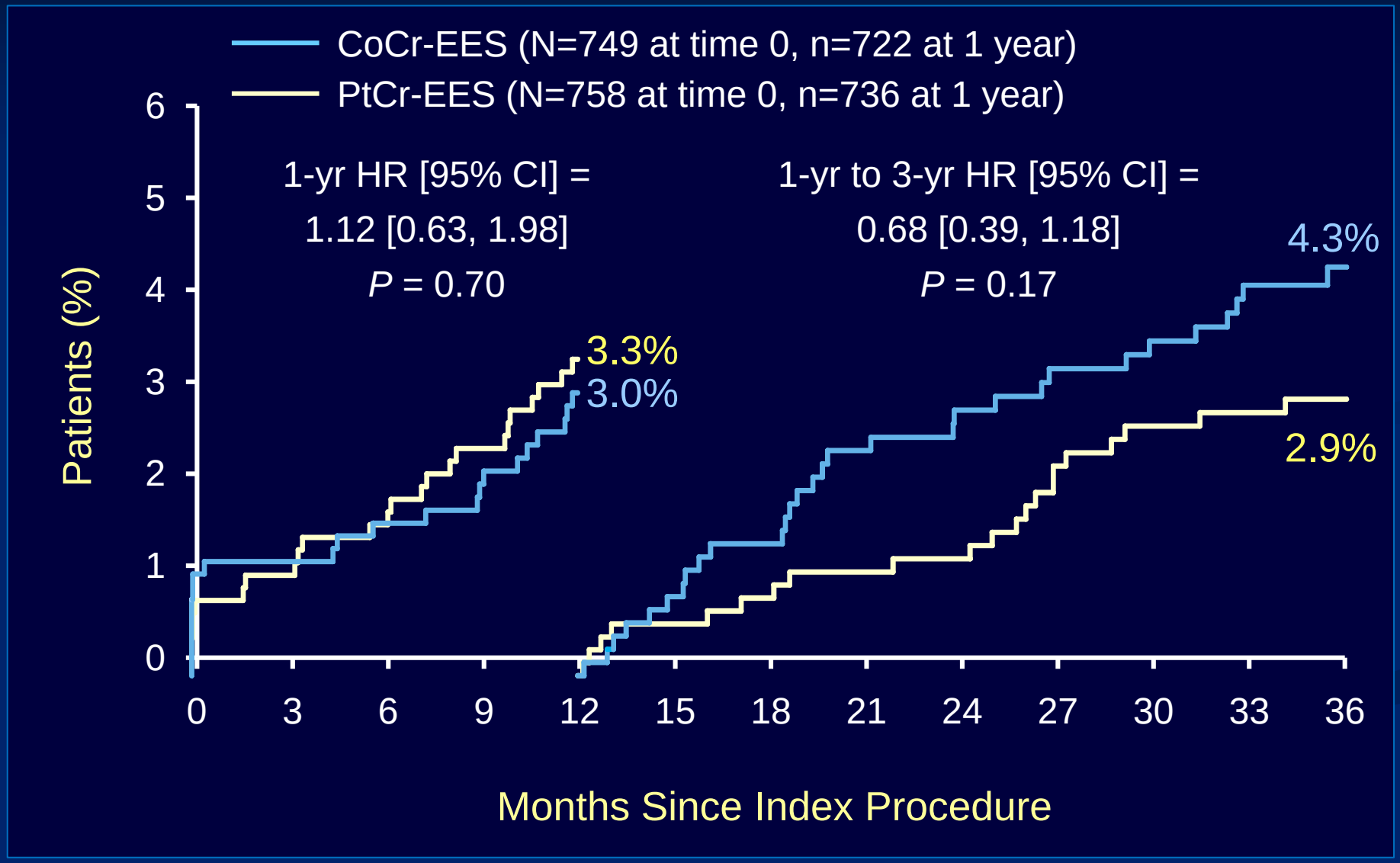

TLF = cardiac death or MI related to the target vessel or ischemia-driven TLR; Patients with Study Stents.

All-Cause Death or MI

3-Year Follow-up

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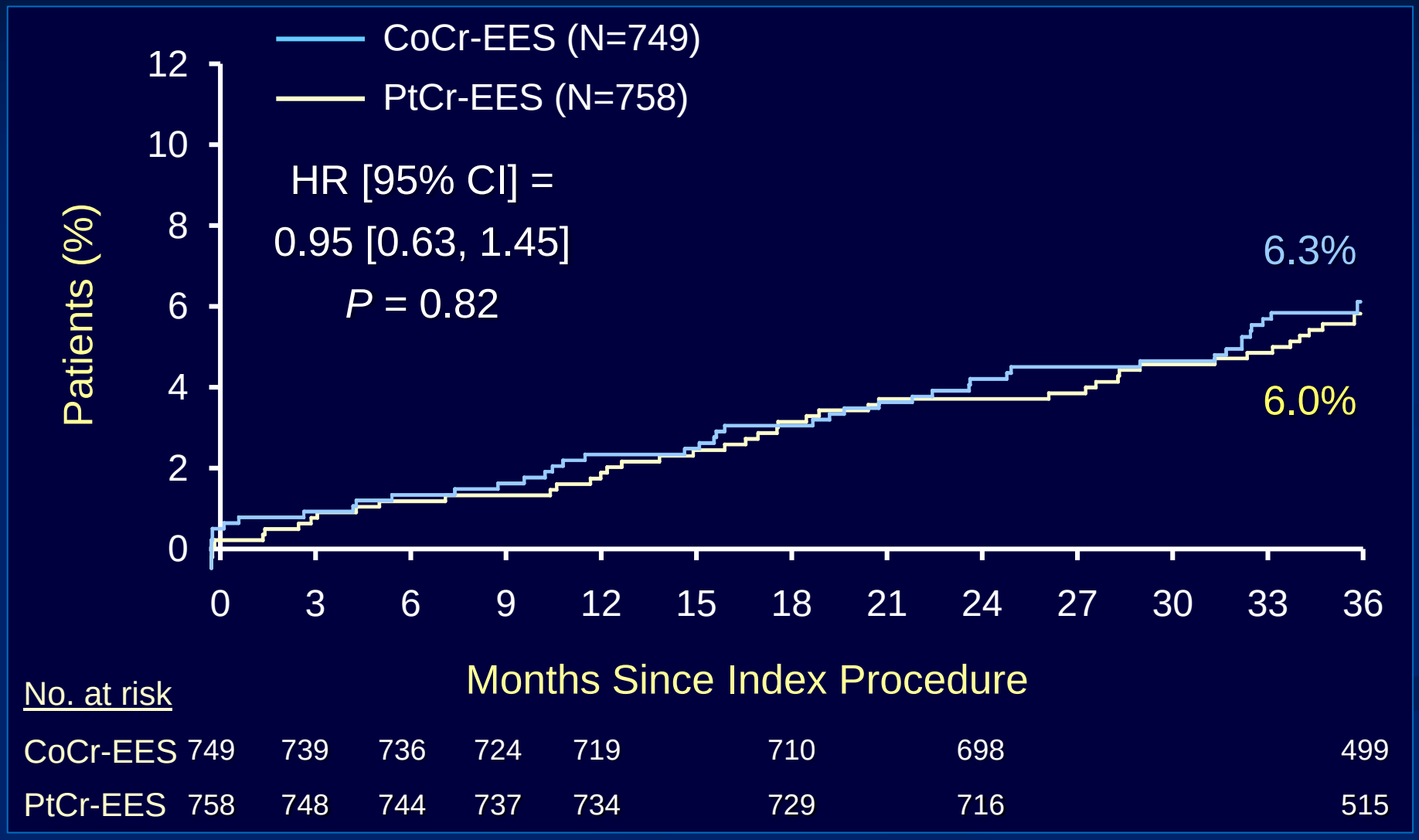

Ischemia-Driven TLR

3-Year Follow-up

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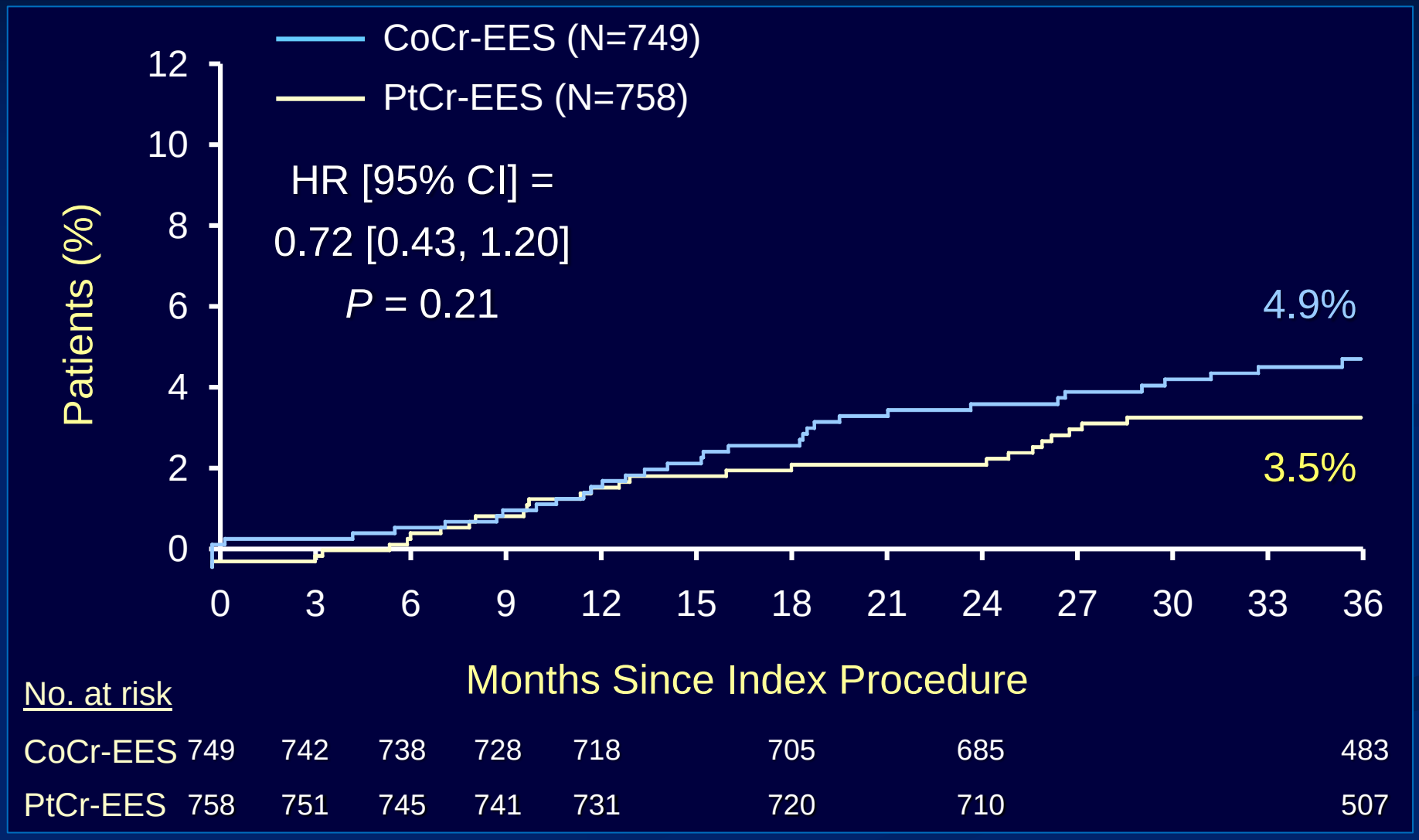

Ischemia-Driven TLR

3-Year Landmark Analysis

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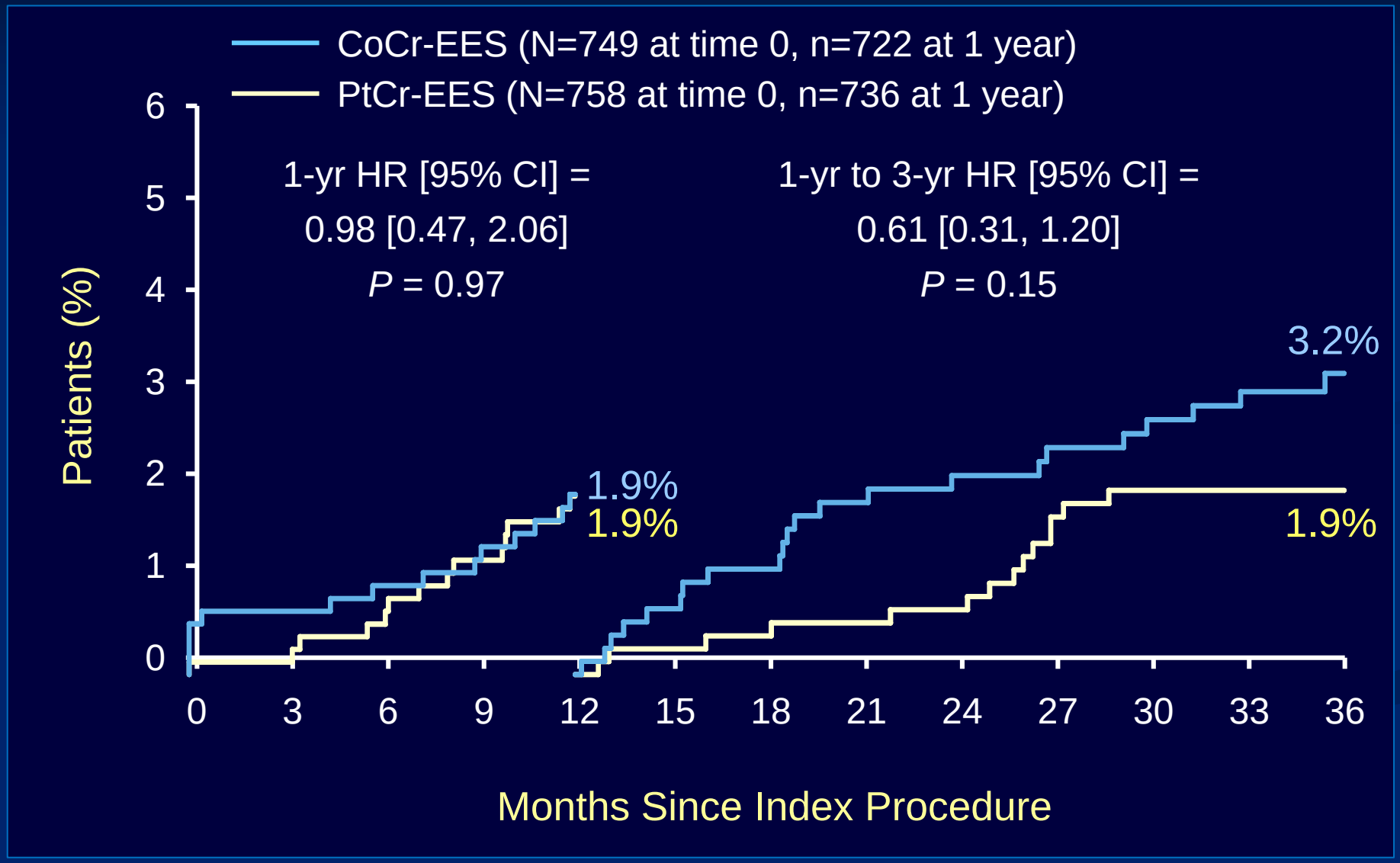

Patients with Study Stents.

Death and MI at 3 Years

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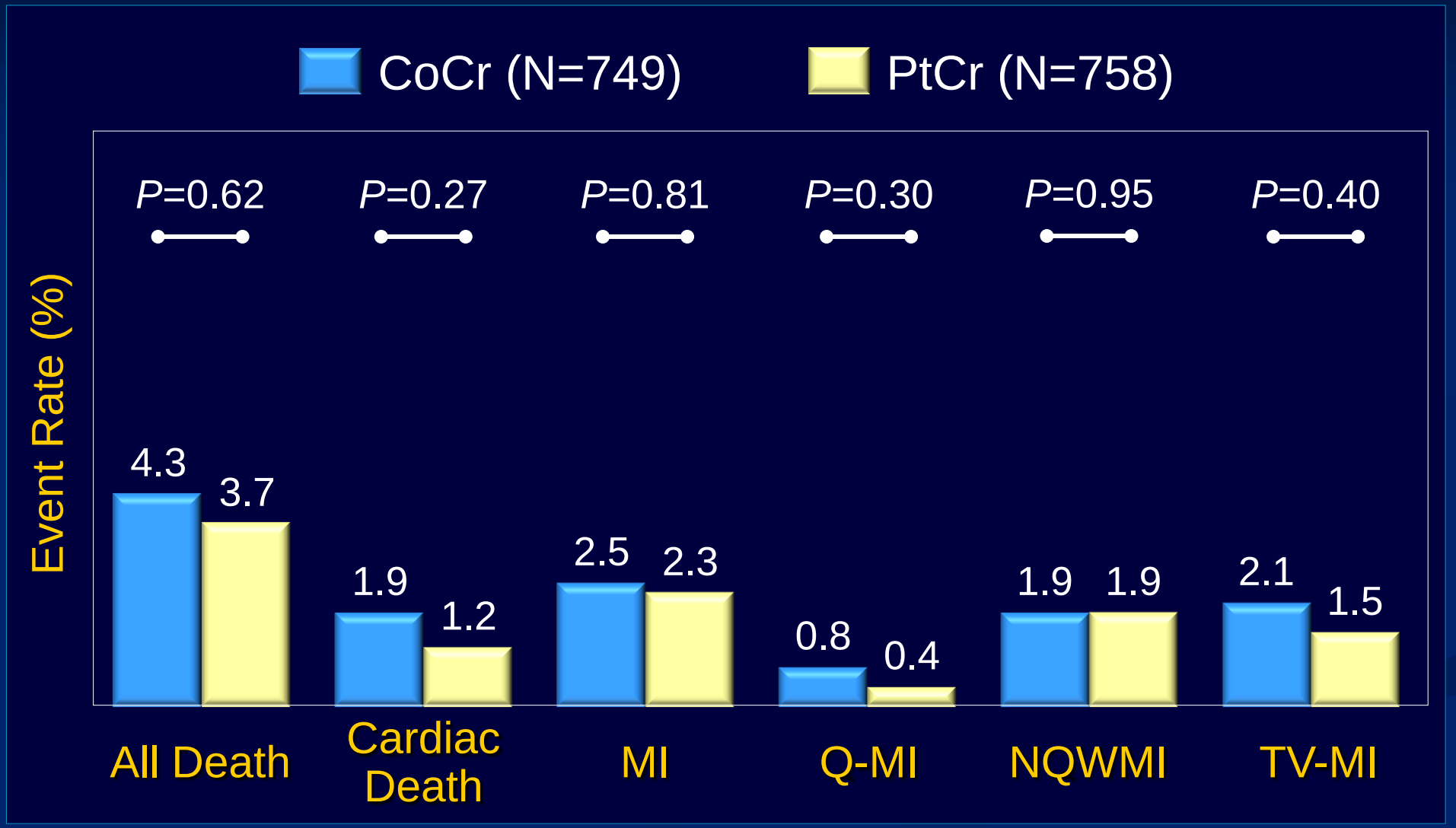

Time to Event Rates. Q-MI=Q-wave MI; NQWMI=non-Q-wave MI; TV-MI=target vessel MI

TV & TL Revascularization 3 Years

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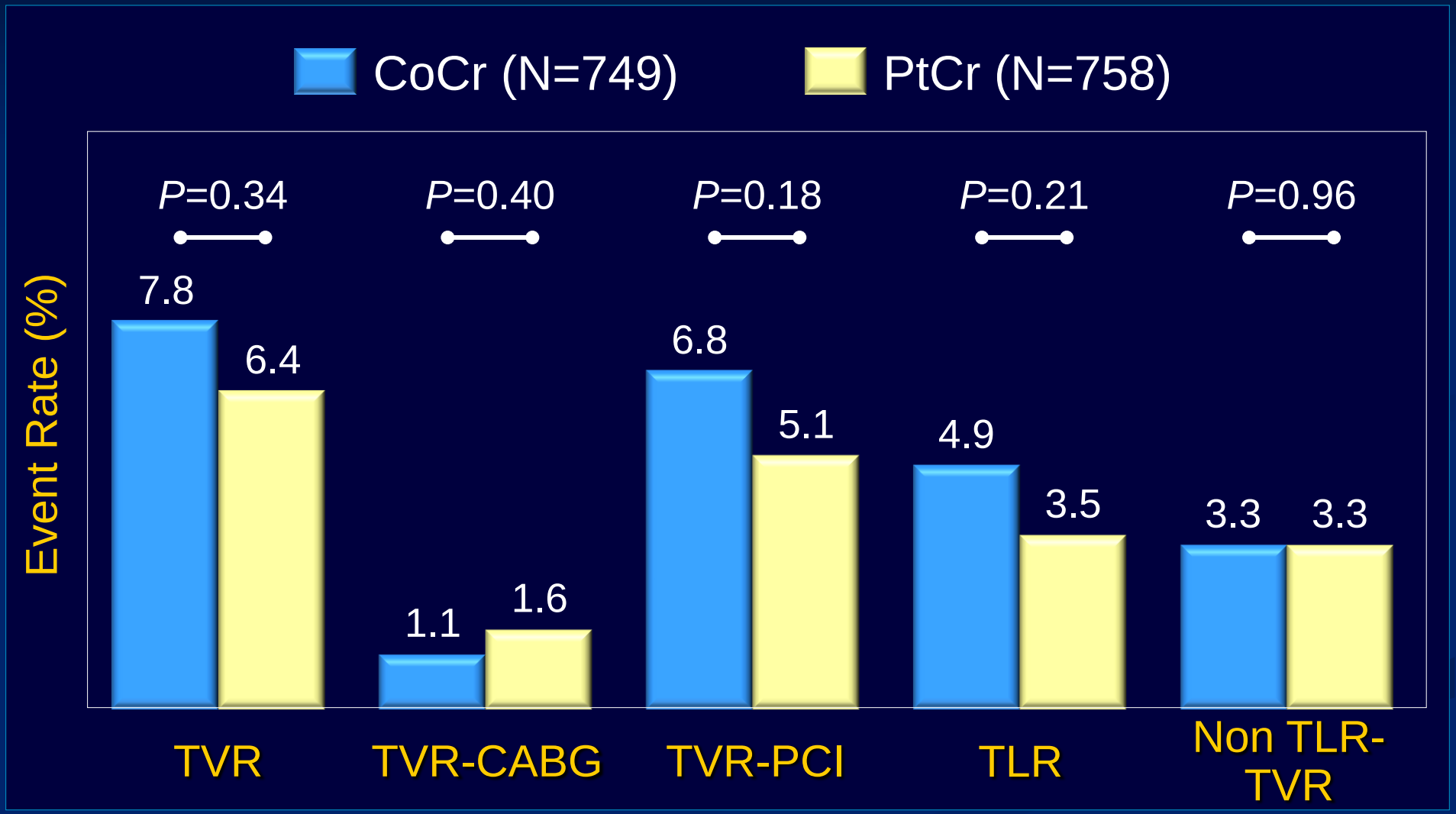

Time to Event Rates. CABG=coronary artery bypass graft; ITT=intent-to-treat; PCI=percutaneous coronary intervention; TLF=target lesion failure (cardiac death/MI related to the target vessel or ischemia driven TLR); TLR=target lesion revascularization; TVR=target vessel revascularization

Stent Thrombosis - ARC Def/Prob

3-Year Follow-up

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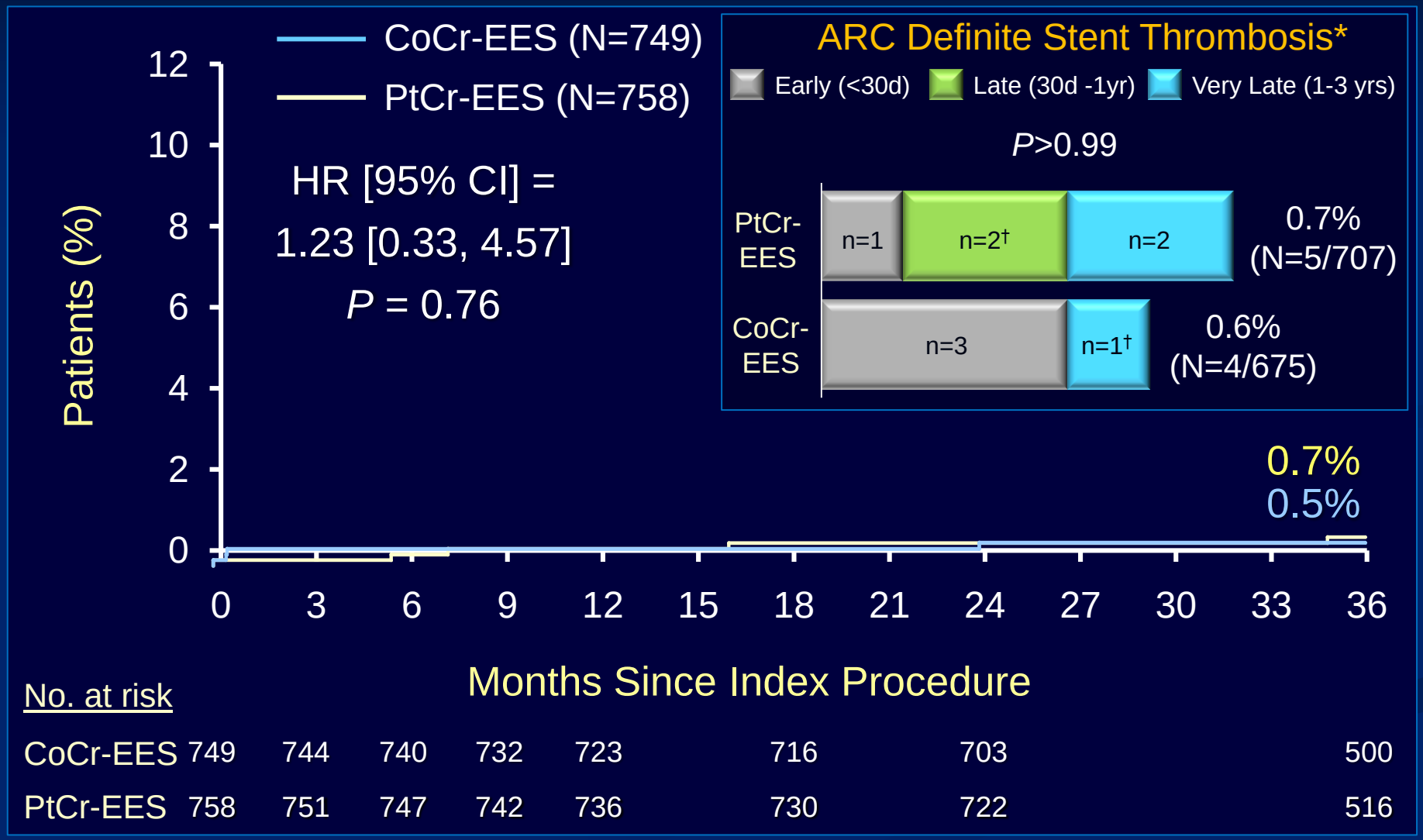

No. at risk

CoCr-EES	749	744	740	732	723	716	703	500
PtCr-EES	758	751	747	742	736	730	722	516

*There were no adjudicated ARC probable ST events through 3 years of follow-up; binary rates

†CoCr-EES: 1 ST occurred during 1-2 years; PtCR-EES: 1 ST occurred during 1-2 years and 1 during 2-3 years

ARC=Academic Research Consortium; Def/Prob=definite/probable; ST=stent thrombosis

Conclusions

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- In the prospective, multicenter, randomized PLATINUM trial, the PtCr-EES was non-inferior to the predicate CoCr-EES for the primary endpoint of TLF at 12 months
- Through 3-year follow-up, event rates were low in the studied patient population in both the PtCr-EES and the CoCr-EES arms
  - No significant differences between groups in the rates of death, MI, stent thrombosis, or ischemia-driven repeat revascularization
- Three-year results confirm the excellent safety and efficacy profile of the Promus-Element everolimus-eluting stent