Prospective, Randomized Trial of Paclitaxel-Eluting Balloon versus Paclitaxel-Eluting Stent versus Balloon Angioplasty for Treatment of Coronary Restenosis in Limus-Eluting Stents

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Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis: 3 Treatment Approaches

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Disclosure Statement of Financial Interest

I, Robert A. Byrne, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Background

- The optimal treatment of drug-eluting stent (DES) restenosis remains unknown
- Drug-eluting balloon therapy has the advantage of avoiding additional stent layers but its role in the treatment of DES restenosis is poorly defined

Study Objective

To compare the anti-restenotic efficacy of:

paclitaxel-eluting balloon (SeQuent Please)

versus

paclitaxel-eluting stent (Taxus Liberte)

versus

balloon angioplasty alone

in patients with *limus*-DES restenosis

Study Organization

Design

DESIGN:
Prospective, randomized, active controlled, multicenter clinical trial

INCLUSION CRITERIA:
1. Stenosis > 50% in "limus"-eluting DES
2. Symptoms/signs of ischemia

EXCLUSION CRITERIA:
1. Lesion in left main stem
2. Acute STEMI
3. Cardiogenic shock

SPONSOR: Deutsches Herzzentrum

402 patients with DES-restenosis enrolled between August 2009 and October 2011 in 3 centers in Germany

Angiographic follow-up at 6-8 months in 84.1% (N=338)

Clinical follow-up at 12 months in 97.5% (N=392)

No significant differences across groups

Study Organization

Design

PRIMARY ENDPOINT:
Percent diameter stenosis at follow-up angiography

TEST HYPOTHESES:
PEB non-inferior to PES
%DS 35%; Delta = 7%
alpha = 0.05; Power = 80%
102 Patients/group

PEB and PES superior to balloon angioplasty
%DS 35% vs. 45%
alpha = 0.025; Power 90%
101 Patients/group

402 patients with DES-restenosis enrolled between August 2009 and October 2011 in 3 centers in Germany

- Paclitaxel-eluting balloon (SeQuent) (N=137)
- Paclitaxel-eluting stent (Taxus) (N=131)
- Balloon angioplasty alone (N=134)

Angiographic follow-up at 6-8 months in 84.1% (N=338)

Clinical follow-up at 12 months in 97.5% (N=392)

No significant differences across groups

Baseline Characteristics

Patients

	PEB N = 137	PES N = 131	BA N = 134
Age (years)	67.7	68.8	67.1
Male	76.6	67.2	70.9
Diabetes mellitus	40.9	46.6	37.3
Multivessel disease	94.2	93.1	94.8
ACS (Troponin +)	19.0	16.8	23.1

No significant differences across groups

Baseline Characteristics

Lesions

	PEB N = 172	PES N = 168	BA N = 160
ISR Morphology, %			
Focal	69.2	65.5	65.7
Diffuse	25.6	29.2	28.1
Proliferative	1.7	1.8	0.6
Occlusive	3.5	3.6	5.6

No significant differences across groups

Baseline Characteristics

Procedures

	PEB N = 172	PES N = 168	BA N = 160
Vessel size (mm)	2.75	2.80	2.72
Lesion length (mm)	12.5	12.5	12.7
MLD, pre (mm)*	0.97	0.93	0.88
Stenosis, pre (%)*	64.4	66.7	67.7

*No significant differences across groups; *in-stent analysis*

Baseline Characteristics

Procedures

	PEB N = 172	PES N = 168	BA N = 160
Treated per protocol (%)*	93.6	92.9	93.8
Balloon pressure (atm)†	13.7	15.9	15.4
MLD, post (mm)†	2.29	2.53	2.10
Stenosis, post (%)†	18.5	12.8	23.3

**No significant differences across groups*

† p<0.001

Results

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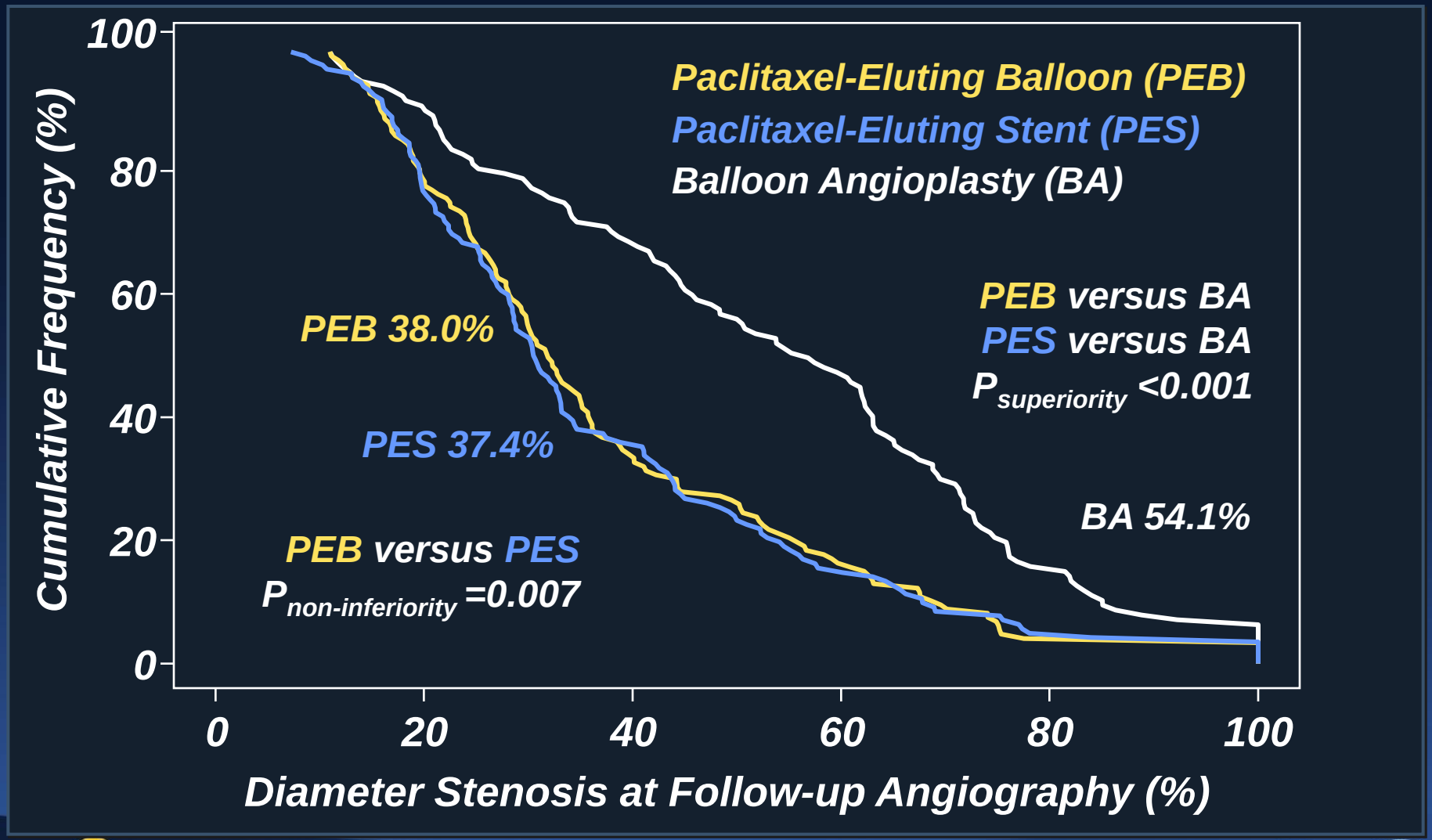
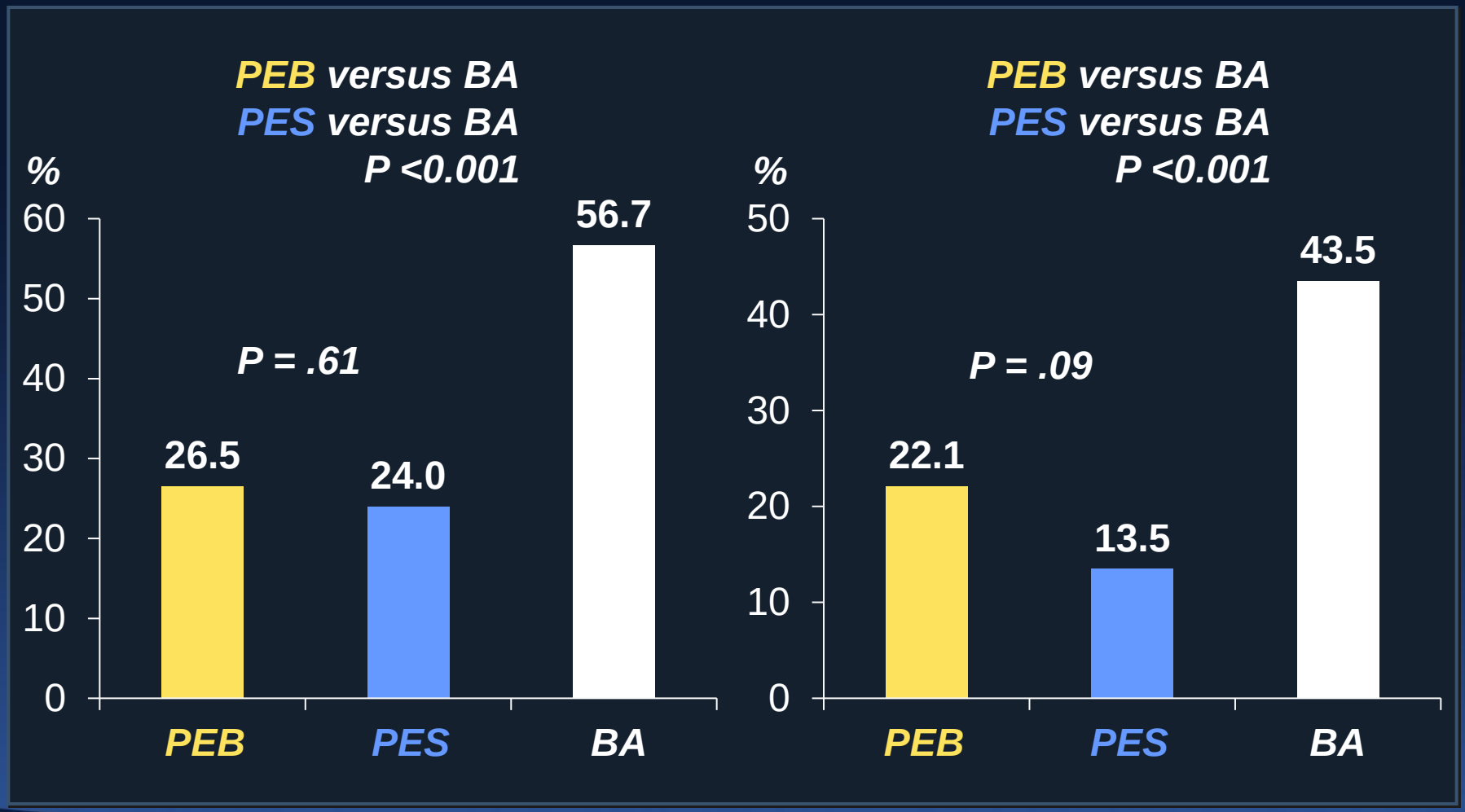
Primary Endpoint

Diameter Stenosis at Follow-up Angiography

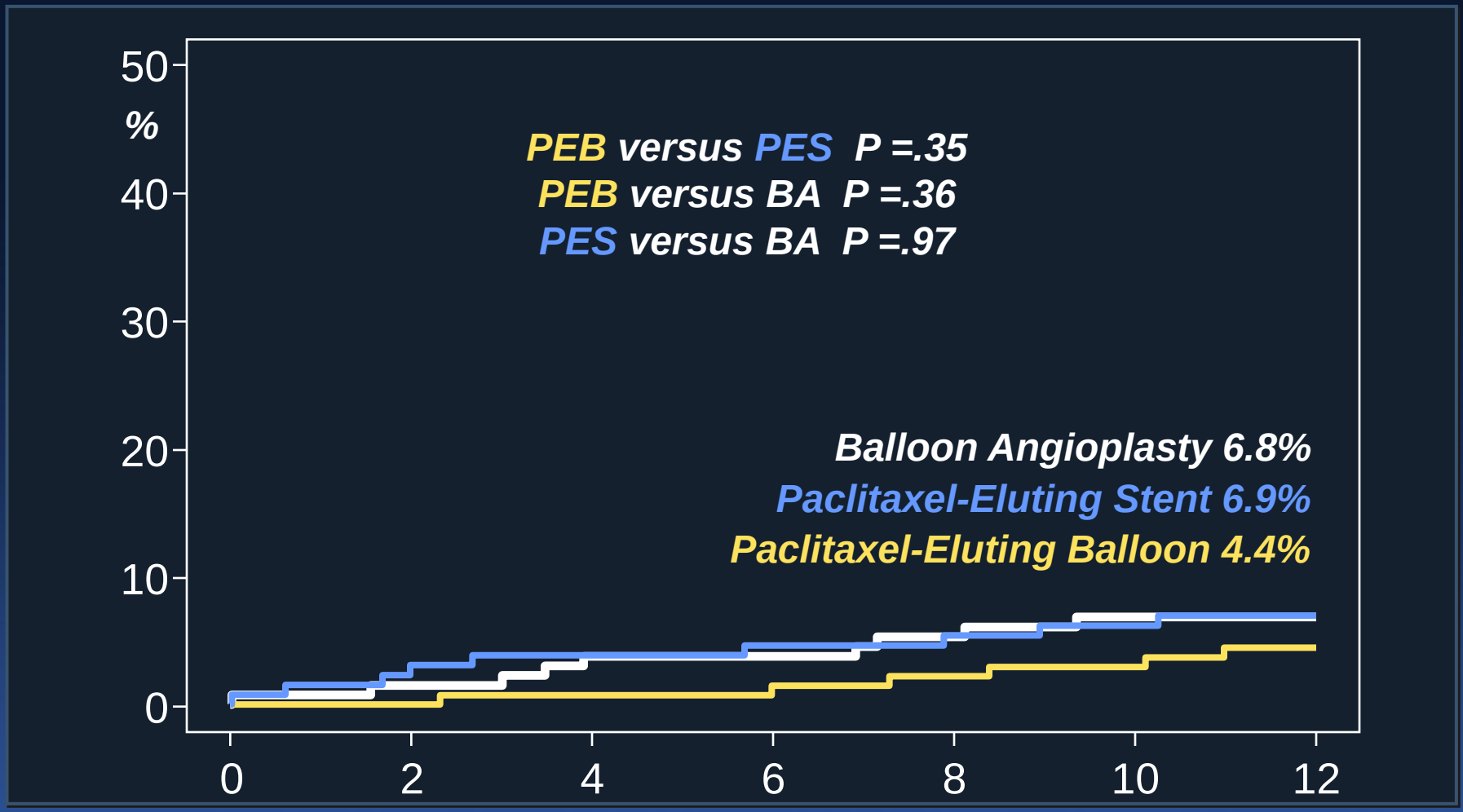


Secondary Endpoint



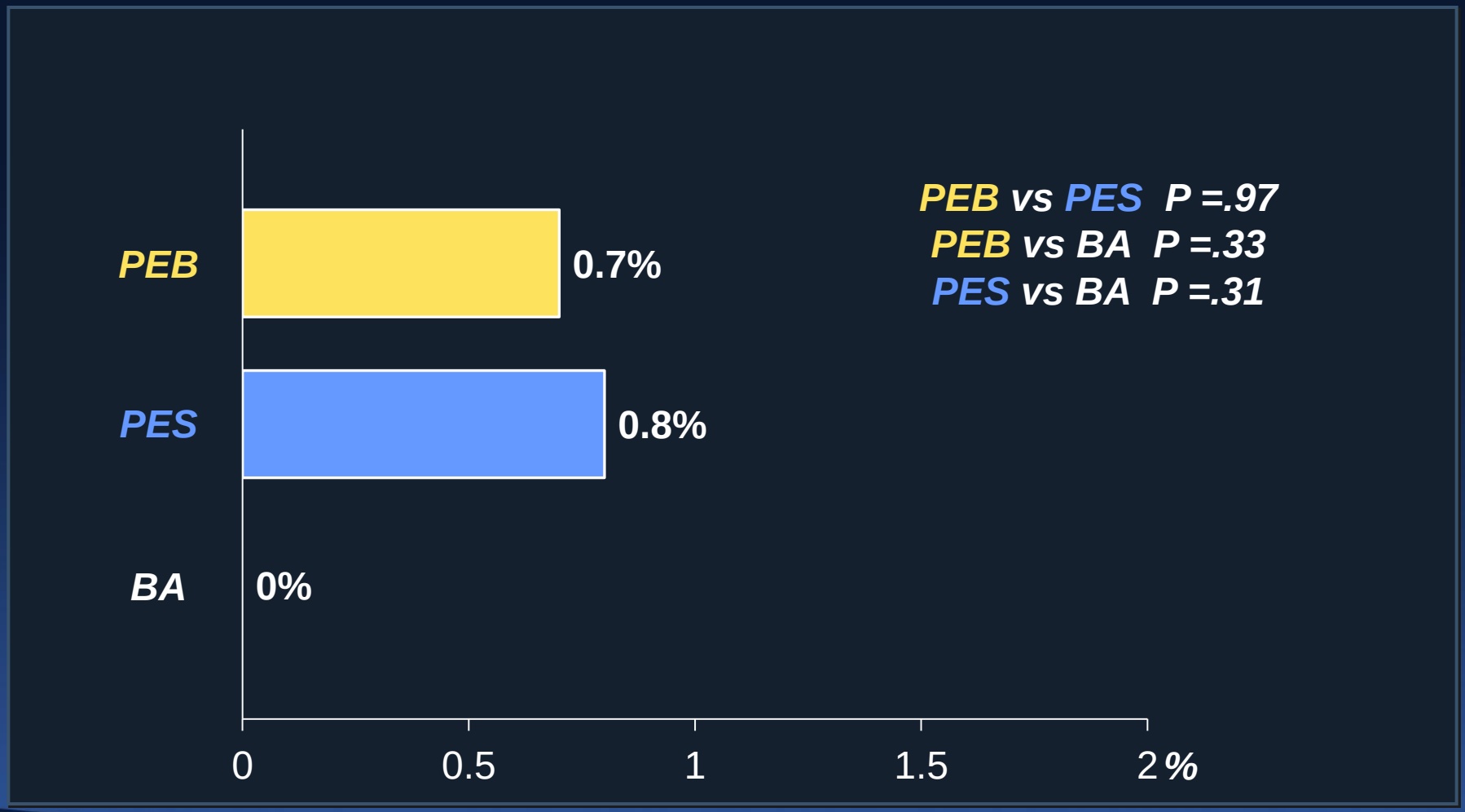
Secondary Endpoint

Death/Myocardial Infarction



Secondary Endpoint

Target Lesion Thrombosis



Conclusions

- In patients presenting with “limus”-DES restenosis, PEB therapy is non-inferior to repeat stenting with PES
- Both PEB and PES therapy are superior to balloon angioplasty alone

Conclusions

- By obviating the need for additional stent implantation treatment with a drug-eluting balloon should be the treatment of choice in patients presenting with “limus”-DES restenosis

Thank You

***I**ntracoronary **S**tenting and **A**ngiographic **R**esults: **D**rug **E**luting **S**tents for **I**n-Stent **Re**stenosis: 3 Treatment Approaches*