



# **ISAR-DESIRE 3:**

## **DEB, Desirable Option for DES-ISR**

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# Background

The optimal treatment of drug-eluting stent (DES) restenosis remains unknown

Paclitaxel-eluting stents (PES) are at least as effective as sirolimus-eluting stents (SES) for treatment of „limus“-stent restenosis (ISAR-DESIRE 2)

Drug-eluting balloon therapy may avoid 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:

Prospective, randomized, active controlled, multicenter clinical trial

## INCLUSION CRITERIA:

1. Stenosis > 50% in “limus”-eluting DES
2. Symptoms/signs of ischemia

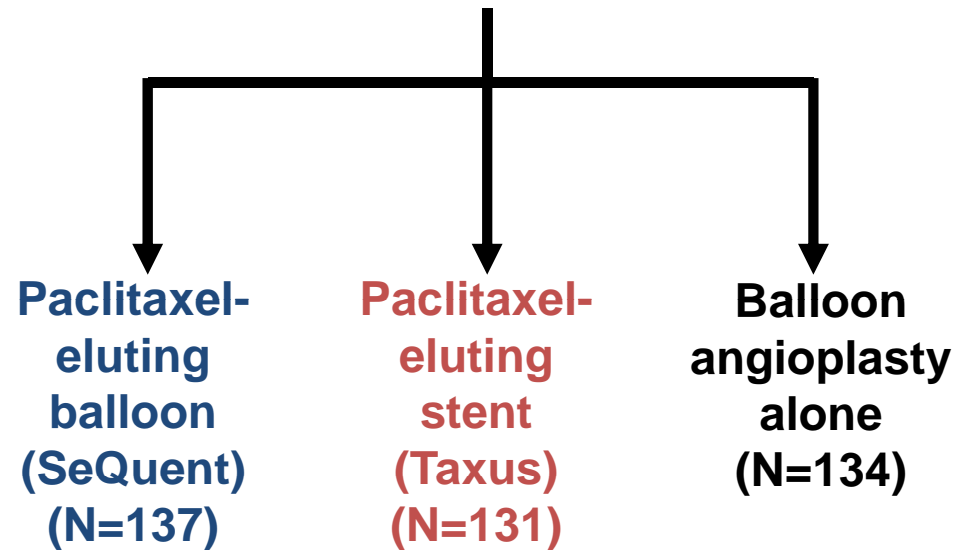
## EXCLUSION CRITERIA:

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

## CENTERS:

Deutsches Herzzentrum, Technische Universität, Munich  
Universitäts-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen  
1. Medizinische Klinik, Klinikum rechts der Isar, Munich

402 patients with DES-restenosis enrolled between August 2009 and October 2011



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

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

# Baseline Characteristics

## *Patients*

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

*No significant differences across groups*

# Baseline Characteristics

## *Lesions*

	<b>PEB</b> <b>N = 172</b>	<b>PES</b> <b>N = 168</b>	<b>BA</b> <b>N = 160</b>
<b>ISR Morphology, %</b>			
focal margin	18.0	14.9	14.4
focal body	40.7	41.7	43.8
multifocal	10.5	8.9	7.5
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

## *Lesions: QCA*

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

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

# Baseline Characteristics

## *Procedures*

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

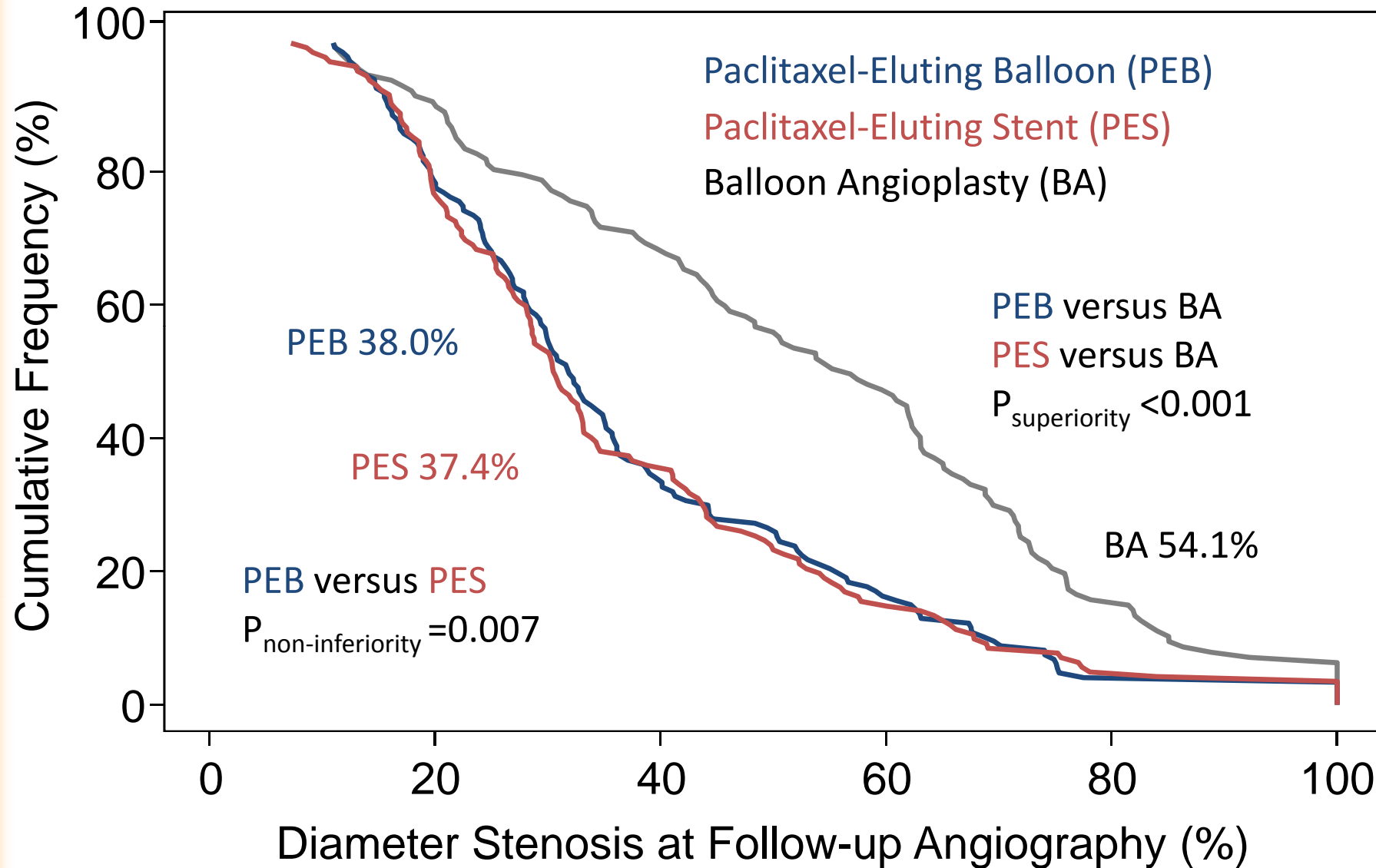
† p<0.001

*\*No significant differences across groups*



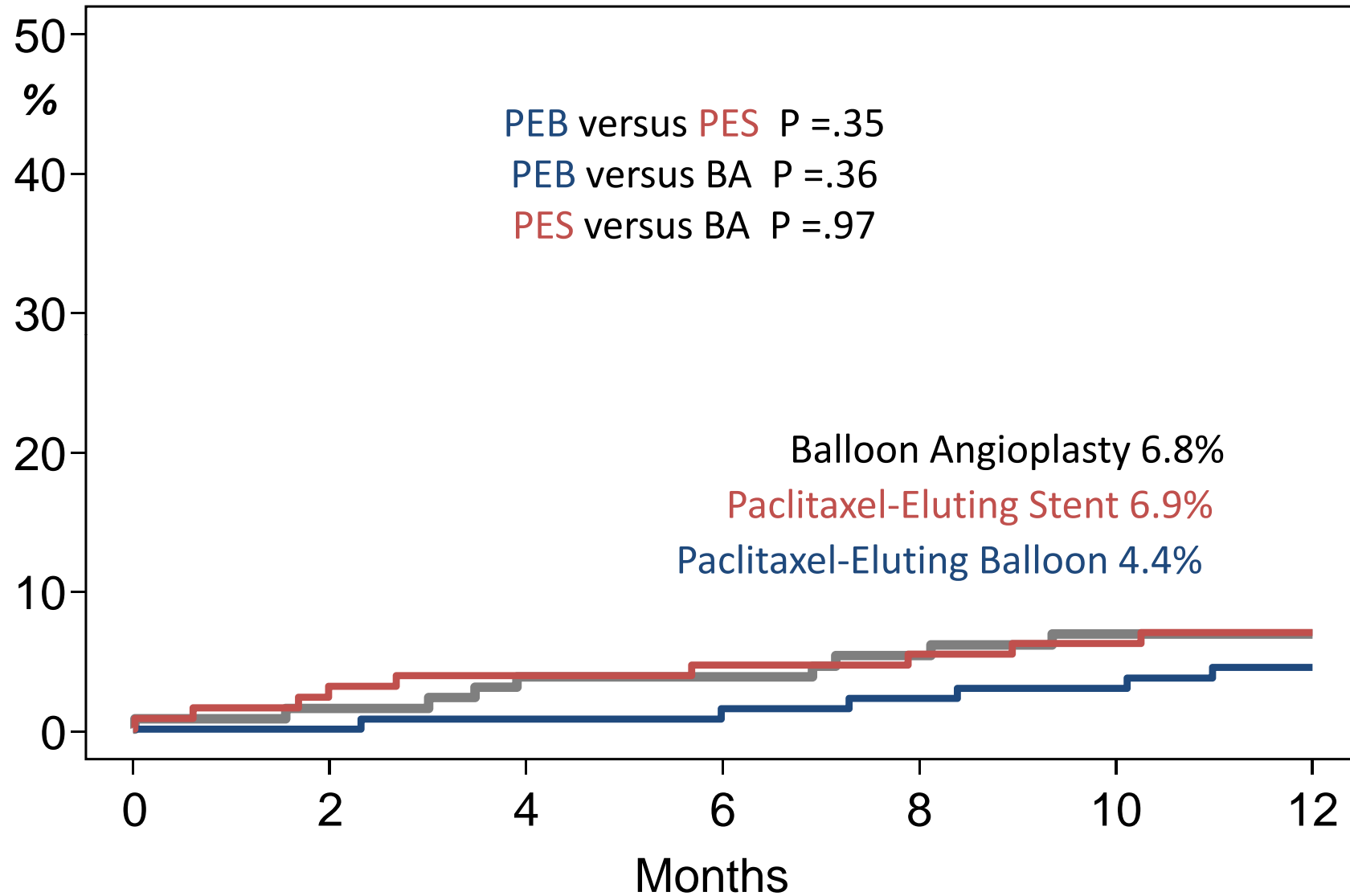
# Primary Endpoint

## Diameter Stenosis at Follow-up Angiography



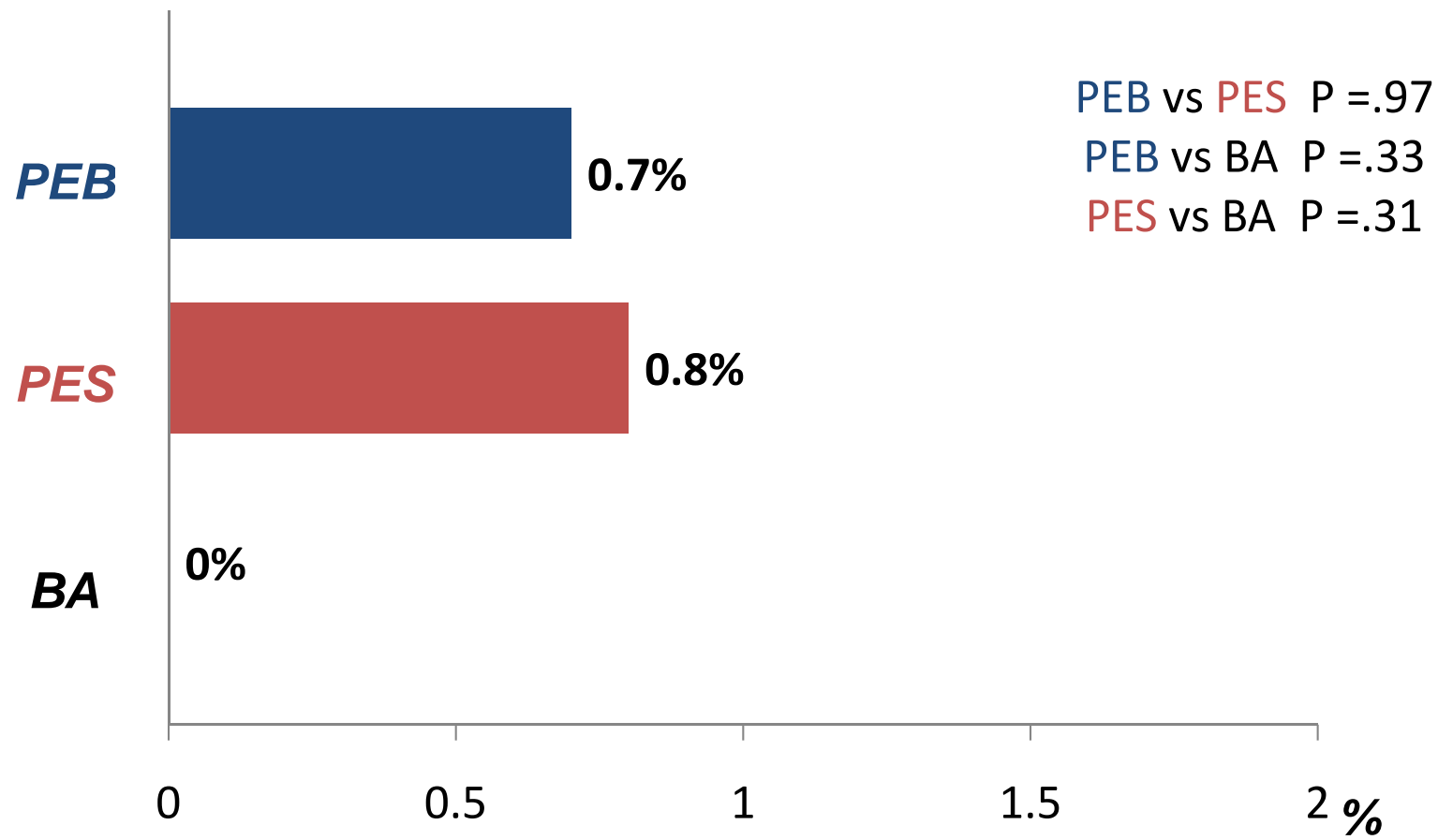
# Secondary Endpoint

## *Death/Myocardial Infarction*



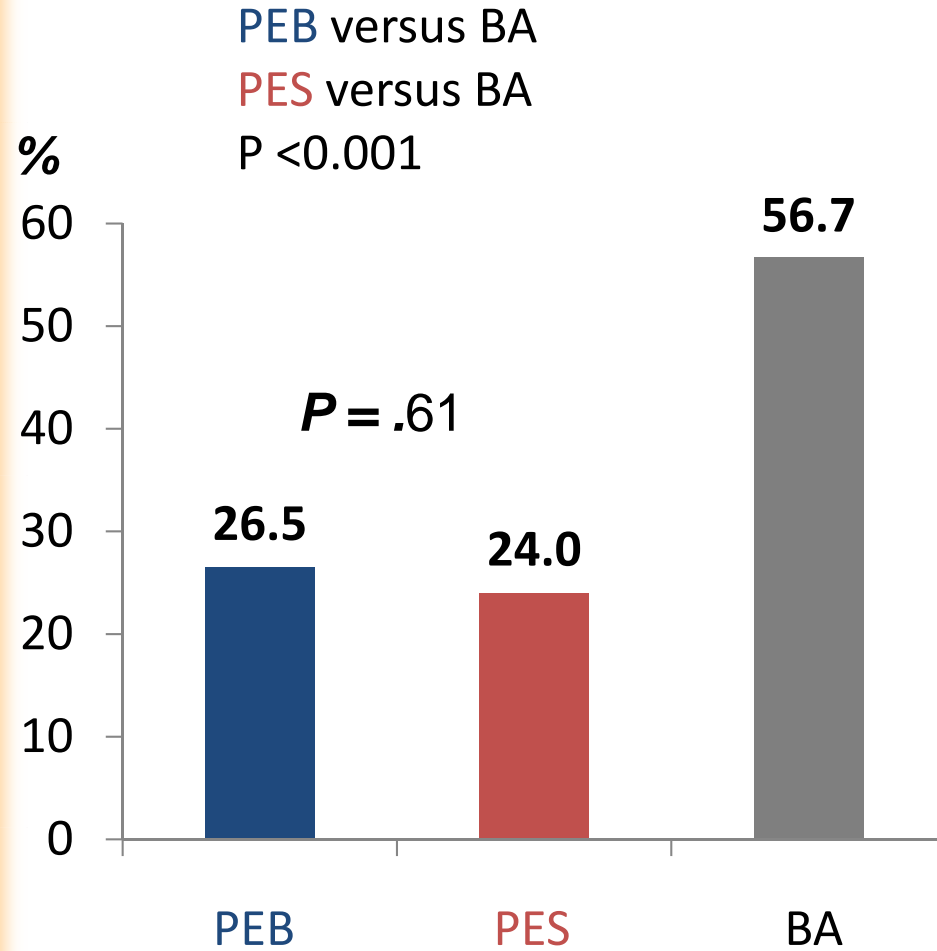
# Secondary Endpoint

## Target Lesion Thrombosis

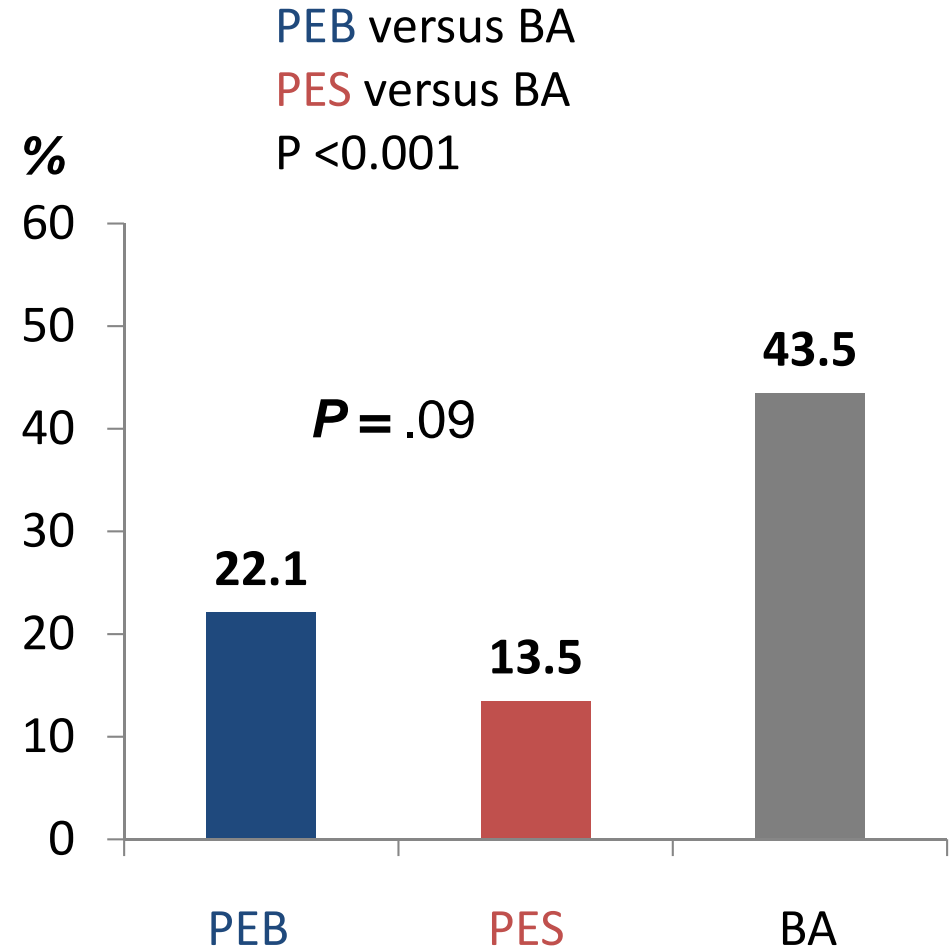


# Secondary Endpoint

## Binary Restenosis



## Target Lesion Revascularization



# Characteristics of recurrent restenosis

	<b>PEB</b> <b>N = 39</b>	<b>PES</b> <b>N = 34</b>	<b>BA</b> <b>N = 72</b>
<b>ISR Morphology, %</b>			
focal margin	7.7	14.7	9.7
focal body	46.2	41.2	30.6
multifocal	7.7	5.9	8.3
diffuse	20.5	20.6	38.9
proliferative	2.6	0.0	1.4
occlusive	15.4	17.6	11.1

*No significant differences across groups*

# 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 may be the treatment of choice in patients presenting with “limus”-DES restenosis

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Paclitaxel-eluting balloons, paclitaxel-eluting stents, and balloon angioplasty in patients with restenosis after implantation of a drug-eluting stent (ISAR-DESIRE 3): a randomised, open-label trial



*Robert A Byrne, Franz-Josef Neumann, Julinda Mehilli, Susanne Piniel, Britta Wolff, Klaus Tiroch, Stefanie Schulz, Massimiliano Fusaro, Ilka Ott, Tareq Ibrahim, Jörg Hausleiter, Christian Valina, Jürgen Pache, Karl-Ludwig Laugwitz, Steffen Massberg, Adnan Kastrati, for the ISAR-DESIRE 3 investigators*

*Lancet 2013; 381: 461-67*