

**ISAR-CABG:  
Randomized, Superiority Trial of  
Drug-Eluting-Stent and Bare Metal Stent in  
Safenous Vein Graft Lesions**

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# Disclosure Statement of Financial Interest



Lecture fees from Abbott Vascular

# Background



THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

**Analysis of 14 Trials Comparing Sirolimus-Eluting Stents with Bare-Metal Stents**

Adnan Kastrati, M.D., Julinda Mehilli, M.D., Jürgen Pache, M.D., Christoph Kaiser, M.D., Marco Valgimigli, M.D., Ph.D., Henning Kelbak, M.D., Maurizio Menicelli, M.D., Manel Sabaté, M.D., Maarten J. Suttorp, M.D., Ph.D., Dietrich Baumgart, M.D., Melchior Seyfarth, M.D., Matthias E. Pfisterer, M.D., and Albert Schömig, M.D.

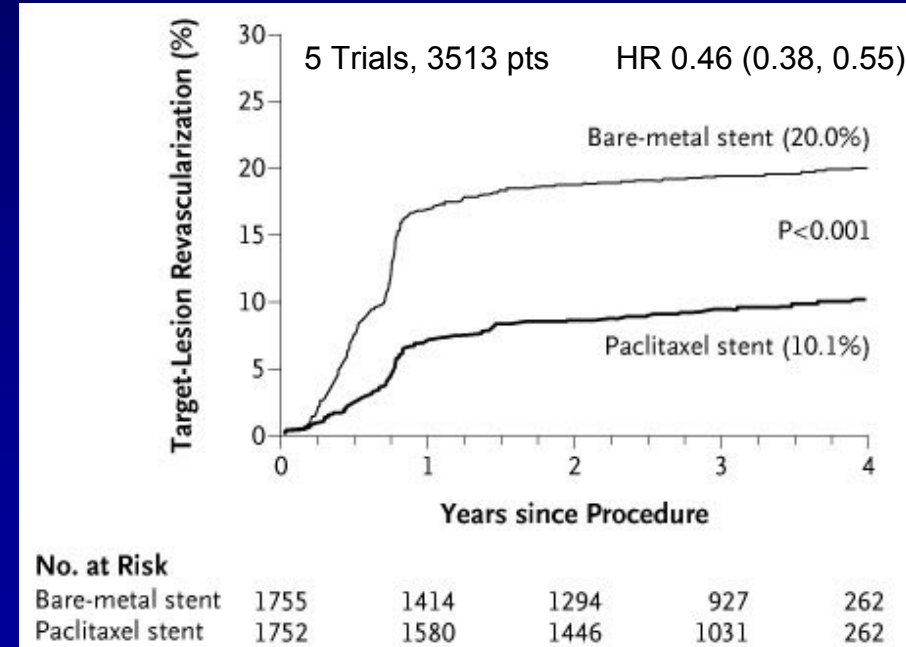
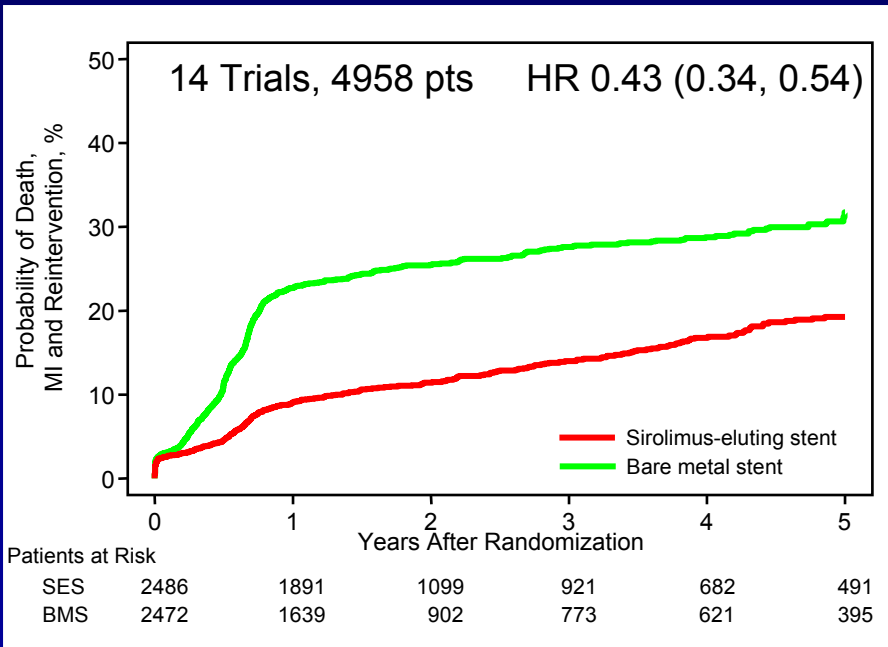
DES are more effective and as safe as their BMS predecessors in native coronary artery lesions

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

**Safety and Efficacy of Sirolimus- and Paclitaxel-Eluting Coronary Stents**

Gregg W. Stone, M.D., Jeffrey W. Moses, M.D., Stephen G. Ellis, M.D., Joachim Schofer, M.D., Keith D. Dawkins, M.D., Marie-Claude Morice, M.D., Antonio Colombo, M.D., Erick Schampajart, M.D., Eberhard Grube, M.D., Ajay J. Kirtane, M.D., Donald E. Cutlip, M.D., Martin Fahy, M.Sc., Stuart J. Pocock, Ph.D., Roxana Mehran, M.D., and Martin B. Leon, M.D.



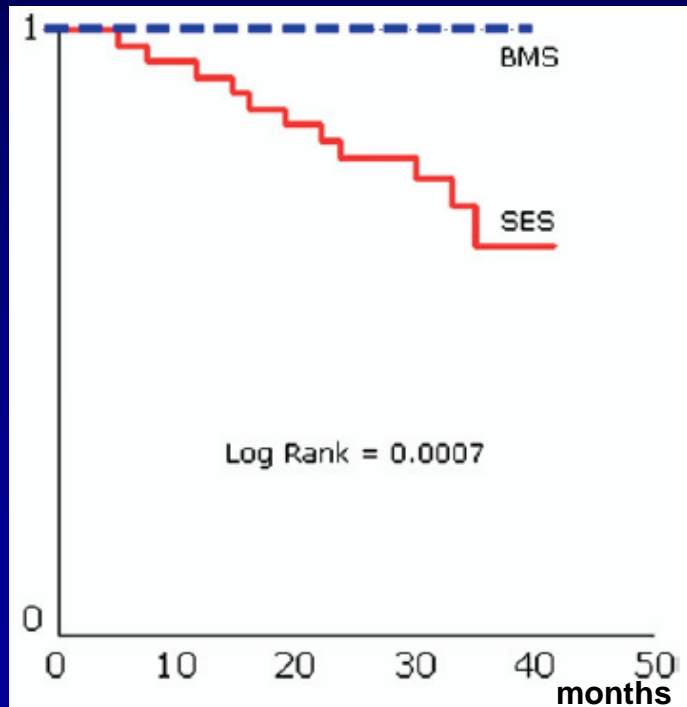
# DES vs. BMS

## in Saphenous Vein Graft Lesions

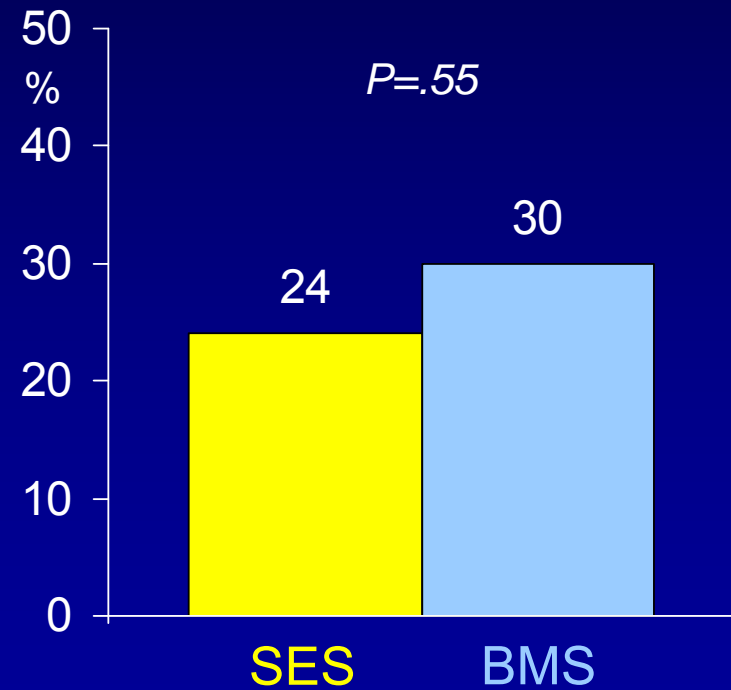


DELAYED RRISC Trial  
N=75

Survival



TLR



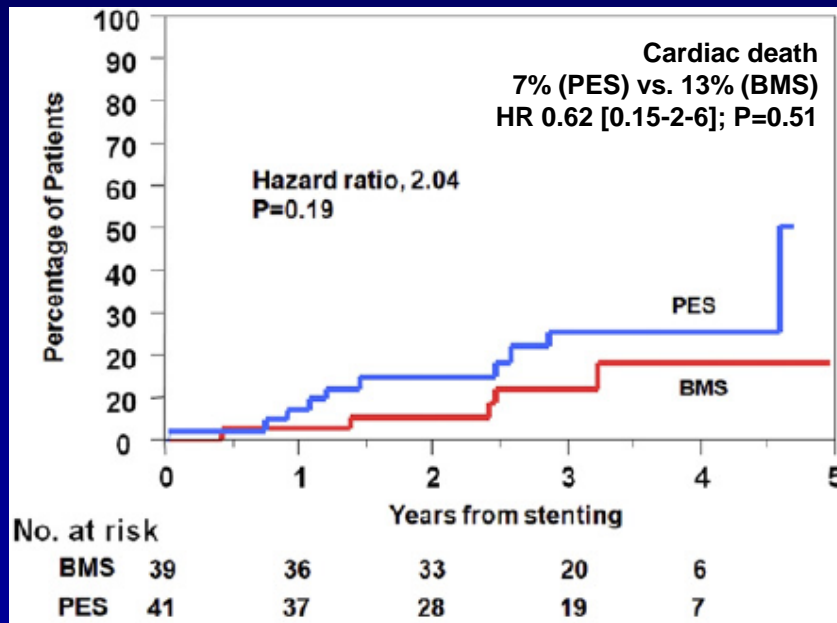
# DES vs. BMS

## in Saphenous Vein Graft Lesions

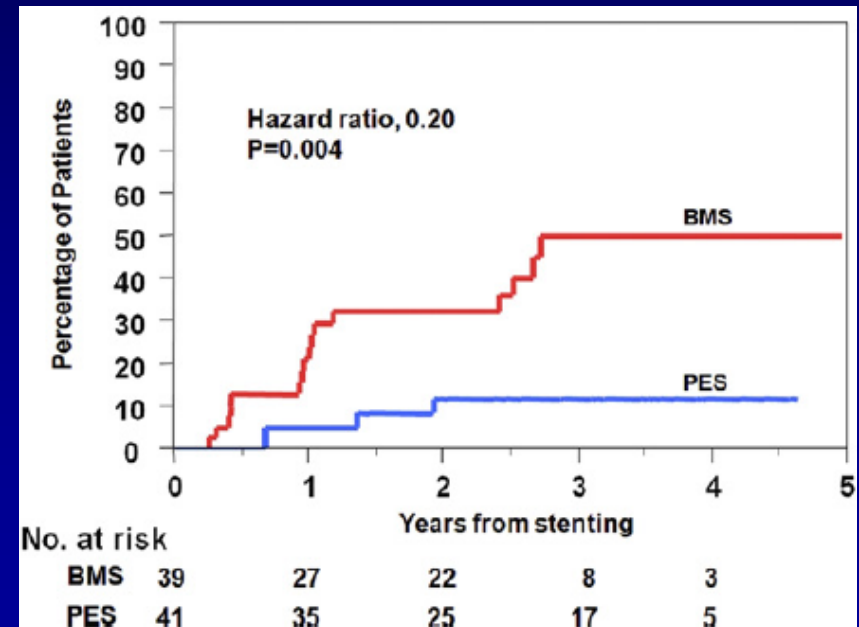


SOS Trial  
N=80

All-cause Death



Target Lesion Revascularization





## ISAR-CABG Trial:

...to compare the efficacy of drug-eluting stents against bare metal stents – in a trial powered for clinical events

## Participating Centers

Deutsches Herzzentrum Munich

1. Med. Klinik, Klinikum rechts der Isar, Munich

Herzzentrum Bad Krozingen, Bad Krozingen

Bad Segeberger Kliniken, Bad Segeberg

Germany



## Inclusion criteria

Patients with ischemic symptoms or evidence of myocardial ischemia in the presence of  $\geq 50\%$  *de novo* stenosis located in **saphenous vein grafts**

Informed, written consent

## Exclusion criteria

Cardiogenic shock

Target lesion located in arterial grafts

Malignancies with life expectancy  $< 1$  year

Allergies to study medication

# Primary Endpoint



Composite of  
death,  
myocardial infarction  
ischemia-related target lesion revascularization  
at 1-year post index PCI





All cause mortality

Myocardial infarction

Ischemia-related target lesion revascularization

Incidence of definite/probable stent thrombosis  
at 1-year post index PCI



## Hypothesis:

Drug-eluting stent (DES) is superior to bare metal stent (BMS) in terms of major adverse cardiac events

## Assumptions:

Incidence of primary endpoint in BMS group of 30%

Reduction of MACE with DES of 33%

Power of 80%

$\alpha$ -level of 0.05

Total number of patients needed: **600**

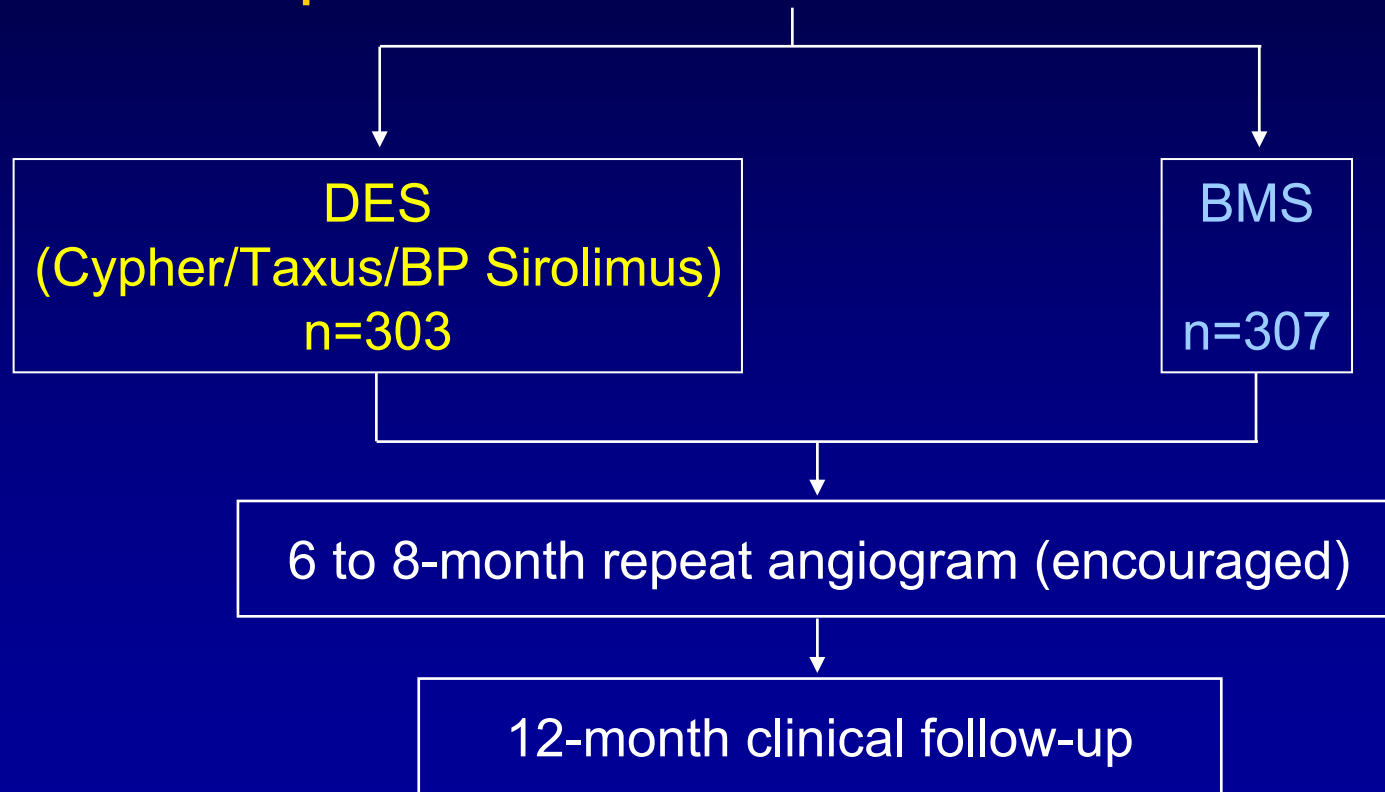
*(accounting for possible losses at follow-up)*

# ISAR-CABG



Is Drug-Eluting Stenting Associated With Improved Results in Coronary Artery Bypass Grafts?

610 patients with *de novo* SVG lesions



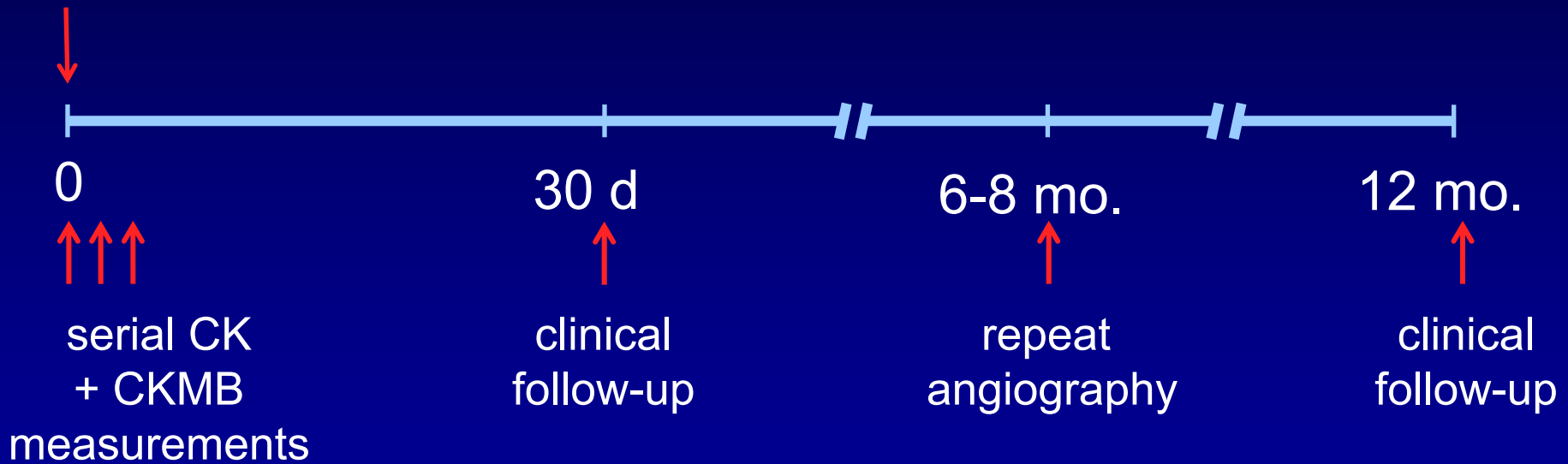
# Follow-Up Protocol



600 mg Clopidogrel

PCI

ASS 500 mg

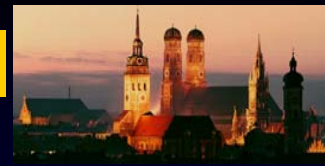


|             |  |
|-------------|--|
| Clopidogrel | 2x75 mg/day until discharge<br>75 mg at least 6 months after index PCI |
| Aspirin     | 200 mg/d indefinitely  |

# Baseline clinical characteristics



|                      | DES<br>n=303 | BMS<br>n=307 |
|----------------------|--------------|--------------|
| Age, years           | 71.4±9.0     | 71.5±9.3     |
| Female, %            | 13           | 16           |
| Art. hypertension, % | 71           | 73           |
| Diabetes, %          | 37           | 35           |
| Current smoker, %    | 8            | 6            |
| Hyperlipidemia, %    | 88           | 86           |
| SVG age, years       | 13.8±5.5     | 13.5±5.1     |
| History of MI, %     | 56           | 55           |



|                            | DES<br>n=303 | BMS<br>n=307 |
|----------------------------|--------------|--------------|
| Clinical presentation, %   |              |              |
| acute MI                   | 17           | 13           |
| unstable angina            | 21           | 27           |
| stable angina              | 62           | 60           |
| Multivessel disease, %     | 98           | 99           |
| Multilesion PCI, %         | 24           | 22           |
| >1 SVGs treated/patient, % | 4.0          | 3.6          |
| LV ejection fraction, %    | 49.2±12.2    | 49.5±13.8    |

# Angiographic characteristics



|                          | DES<br>n=386 | BMS<br>n=385 |
|--------------------------|--------------|--------------|
| Recipient vessel, %      |              |              |
| LAD/diagonal             | 32.0         | 31.0         |
| LCx/marginal             | 35.0         | 36.0         |
| RCA/PDA                  | 33.0         | 33.0         |
| Vessel size, mm          | 3.36±0.67    | 3.38±0.73    |
| Total stented length, mm | 26.8±15.4    | 27.5±17.7    |

# Distribution of SVG Degeneration Score



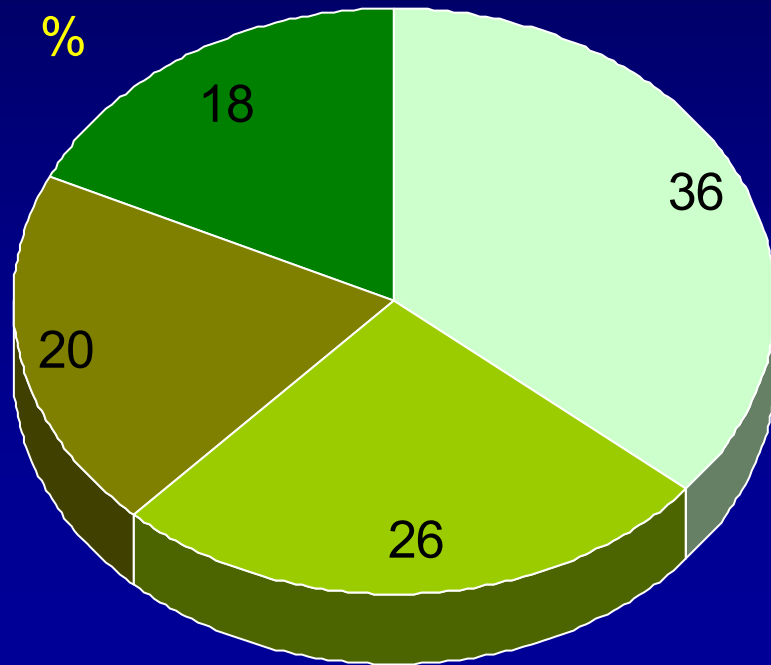
0

1

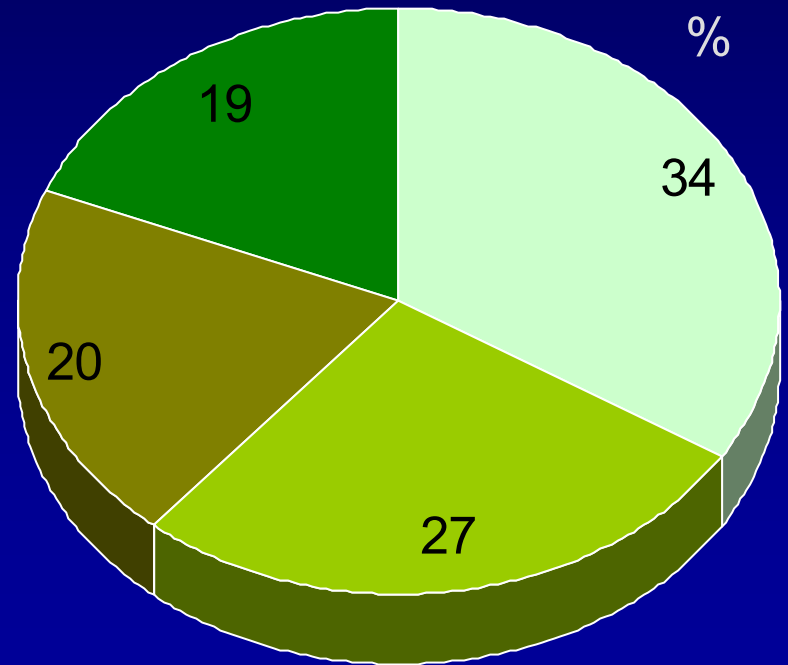
2

3

DES  
%



BMS  
%



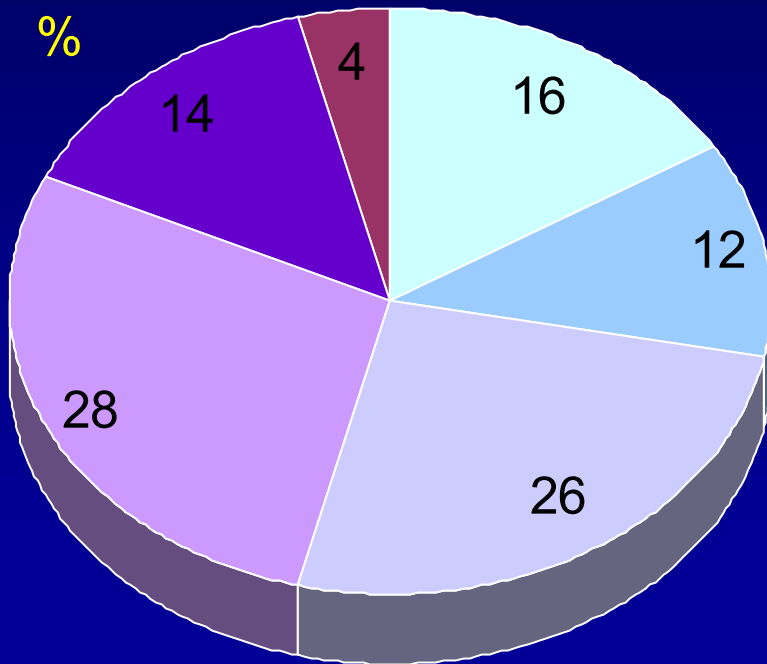


# Distribution of Lesion Location within the SVGs

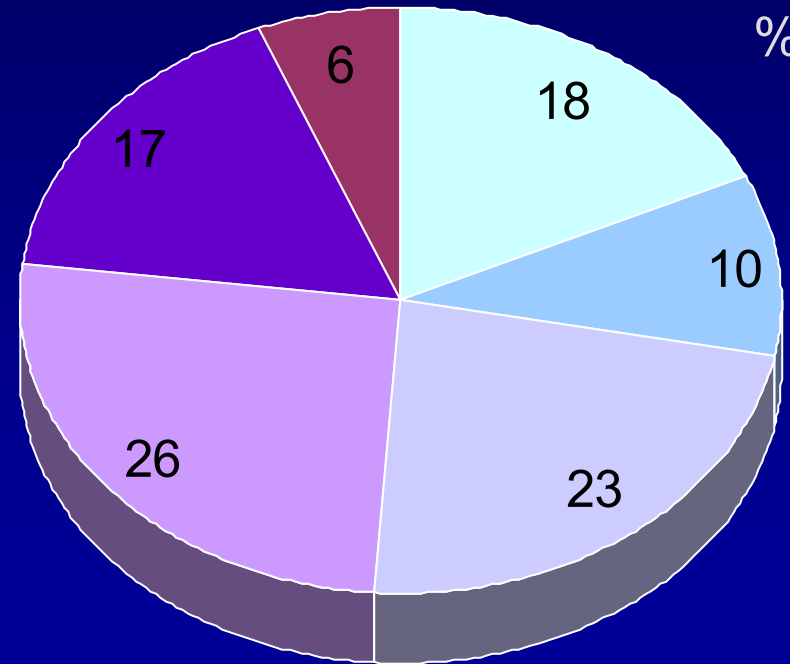


■ aortal   
 ■ coronary   
 ■ proximal   
 ■ medial   
 ■ distal   
 ■ diffuse

DES %



BMS %

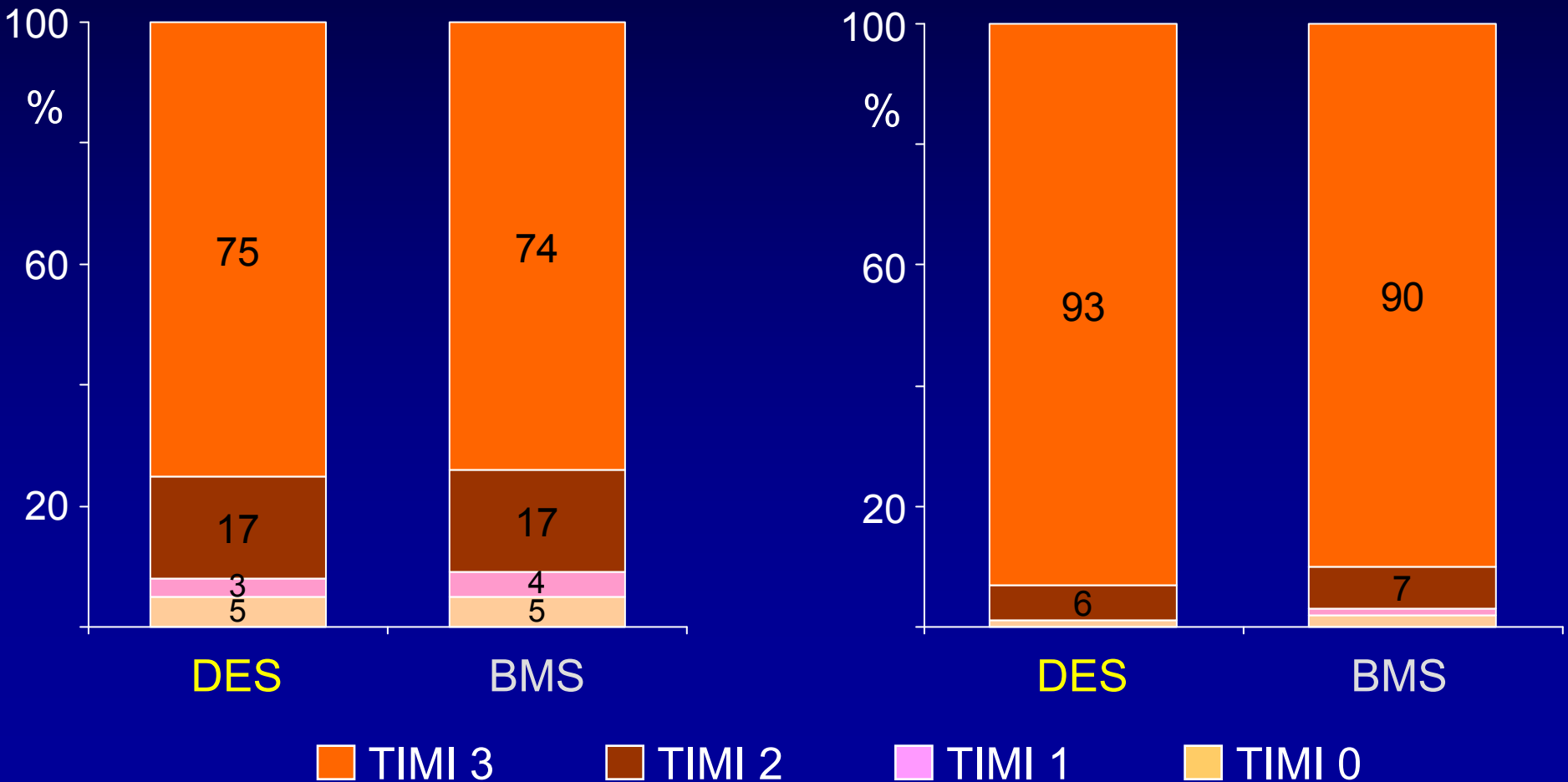


# Distribution of TIMI Flow Rates

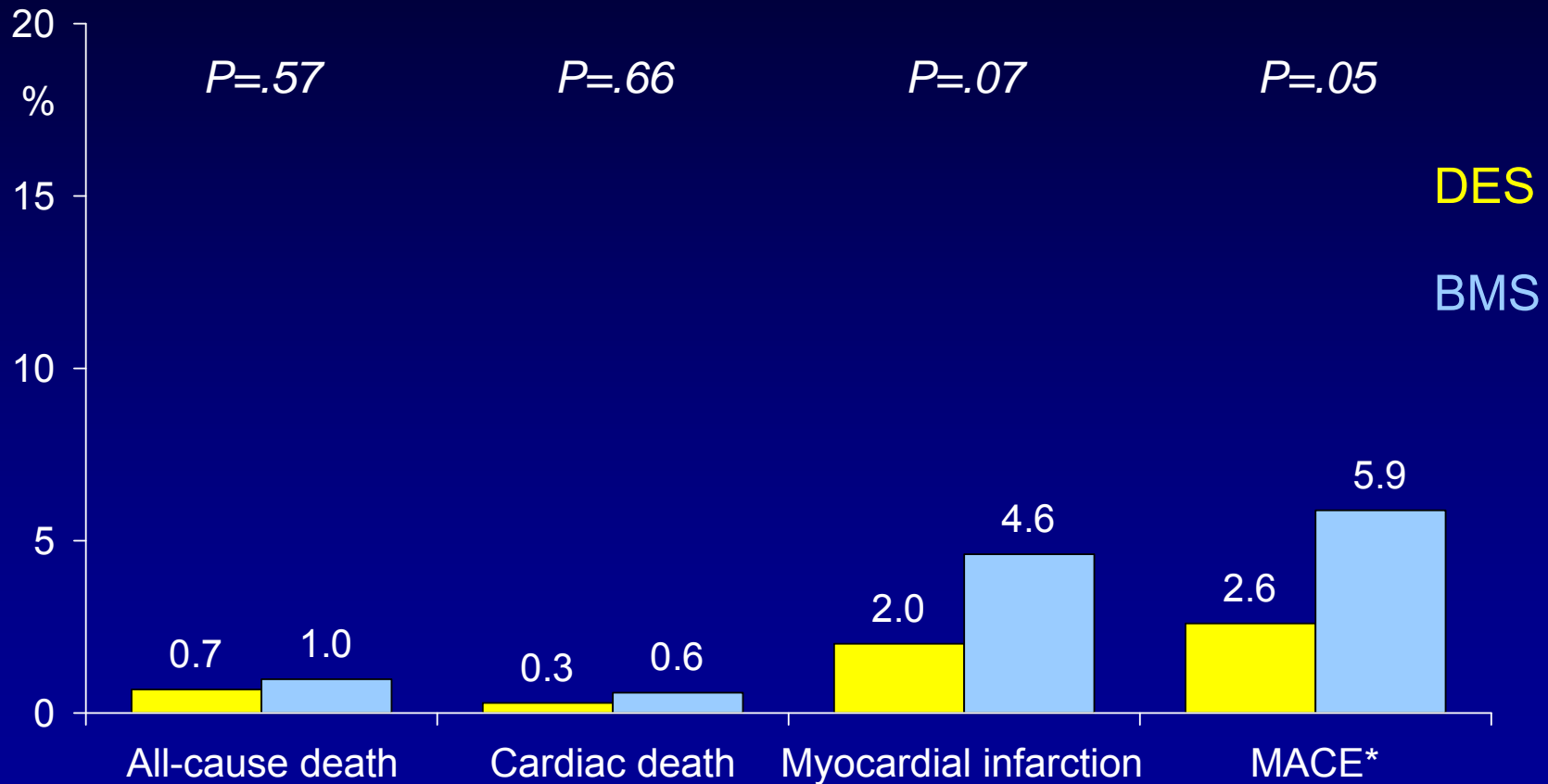


Prior to PCI

After PCI

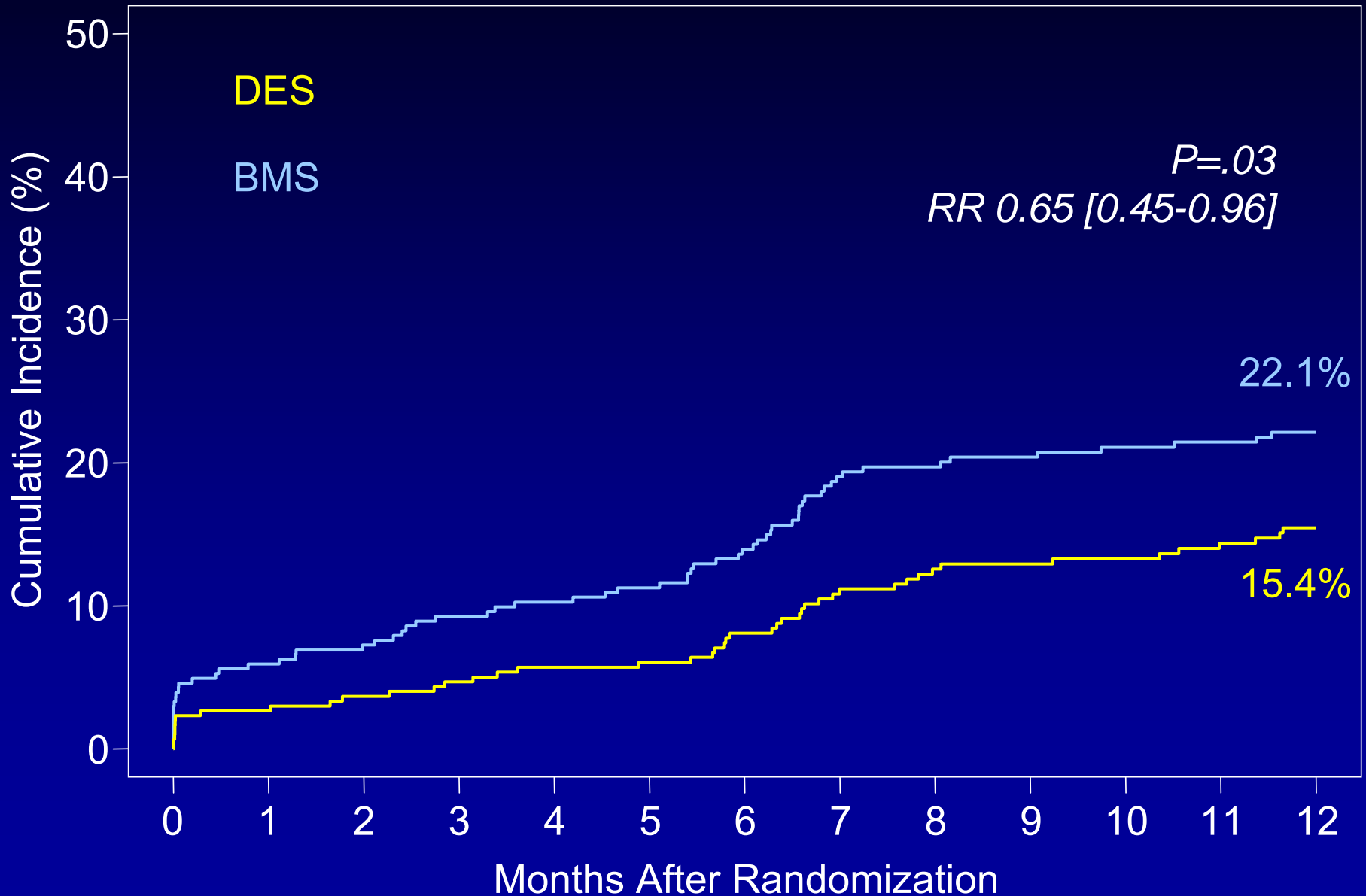


# 30-Day Clinical Outcomes

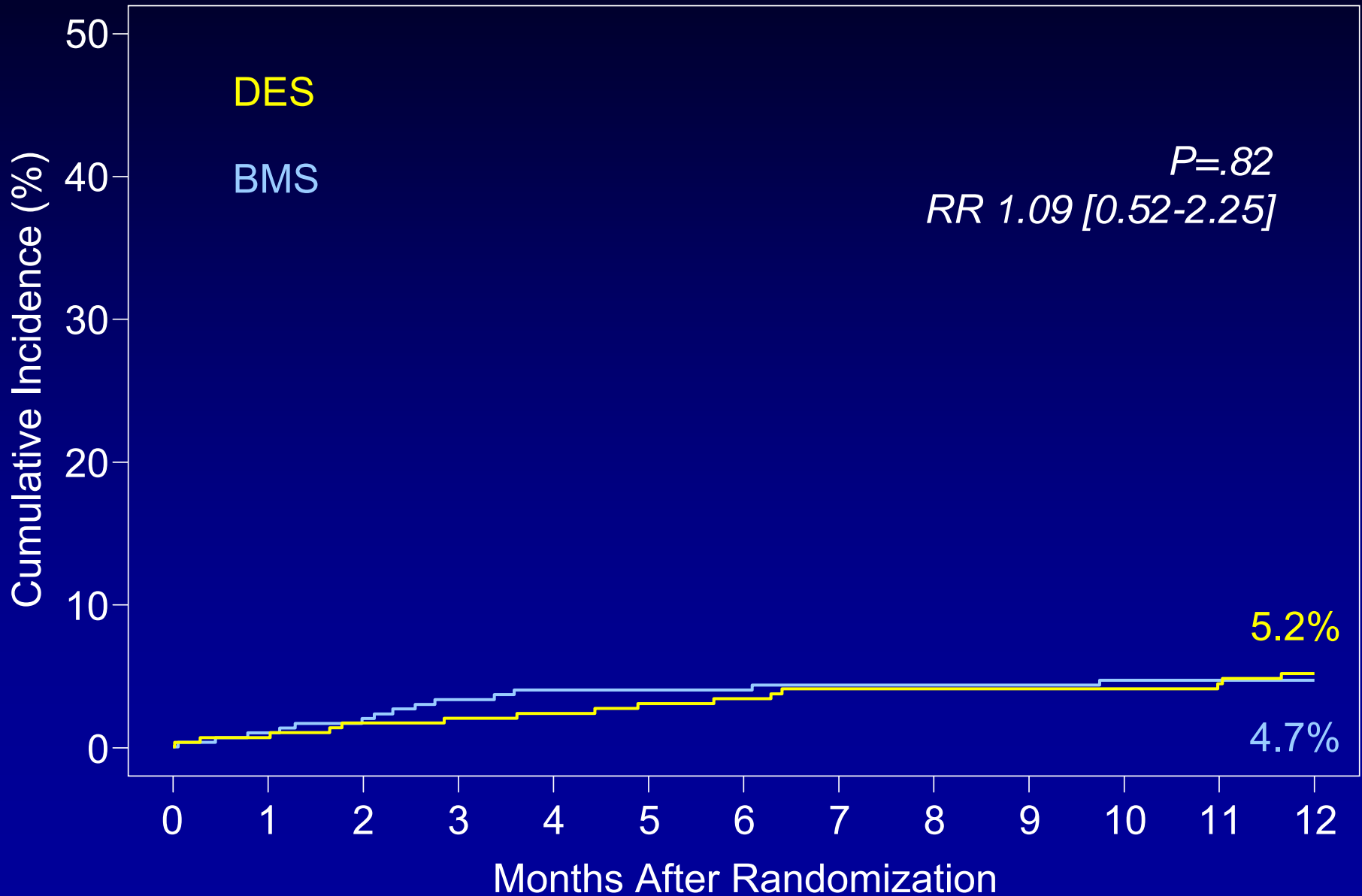


\* No TLR occurred and only 1 pt (DES) died suddenly (probable stent thrombosis) during 30-day follow-up

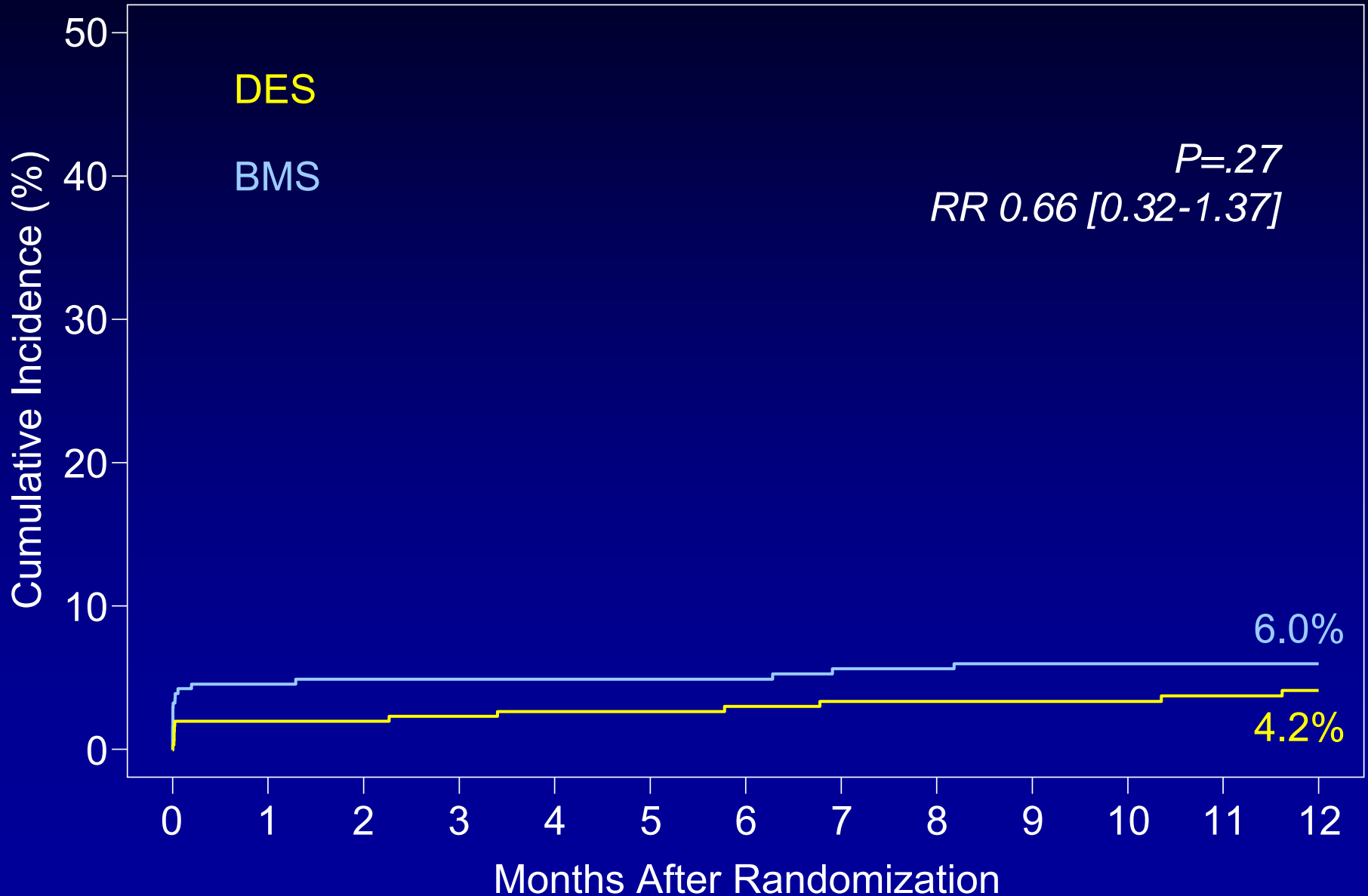
# Primary Endpoint: Death/MI/TLR



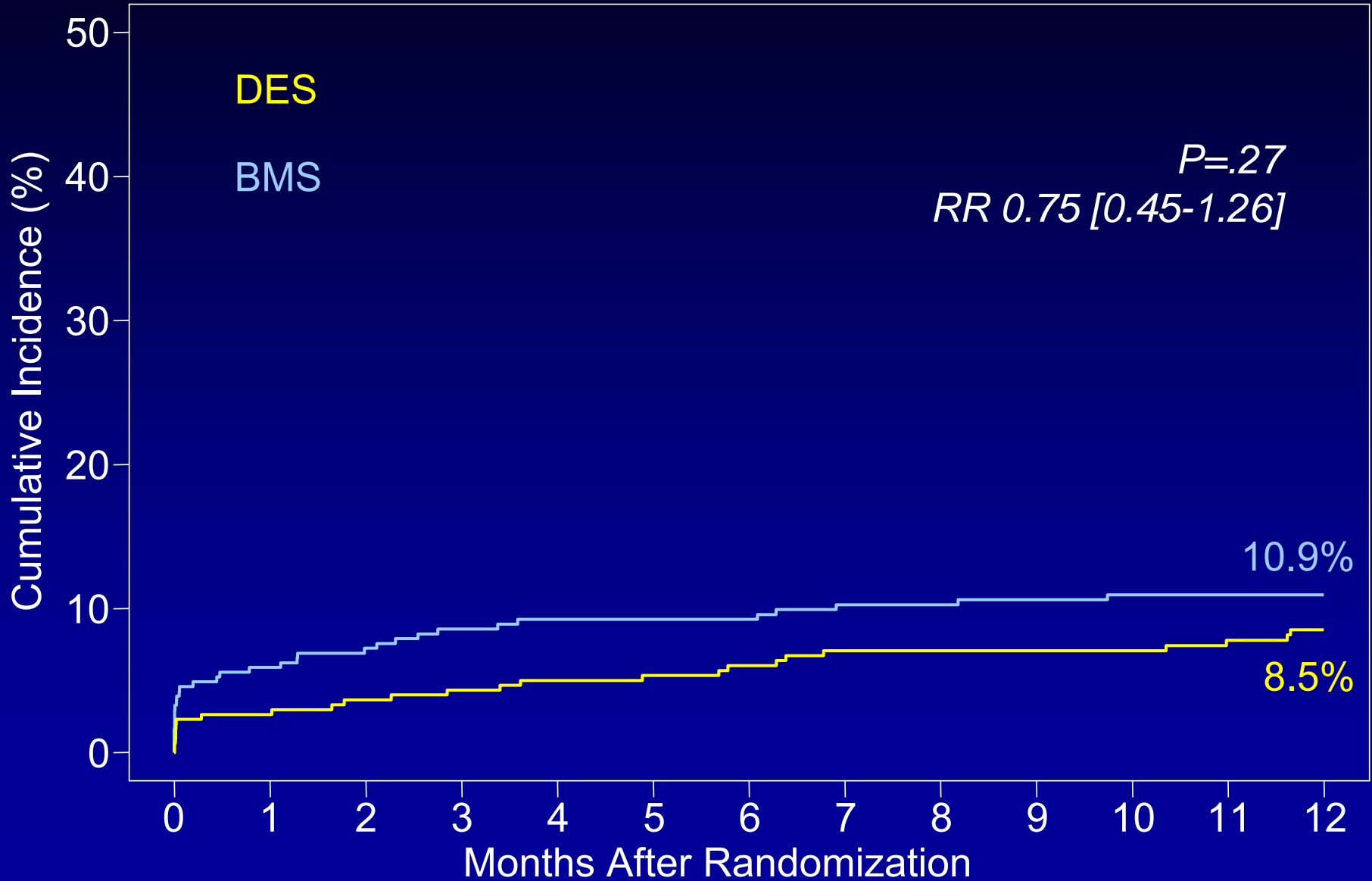
# All-cause Death



# Myocardial Infarction

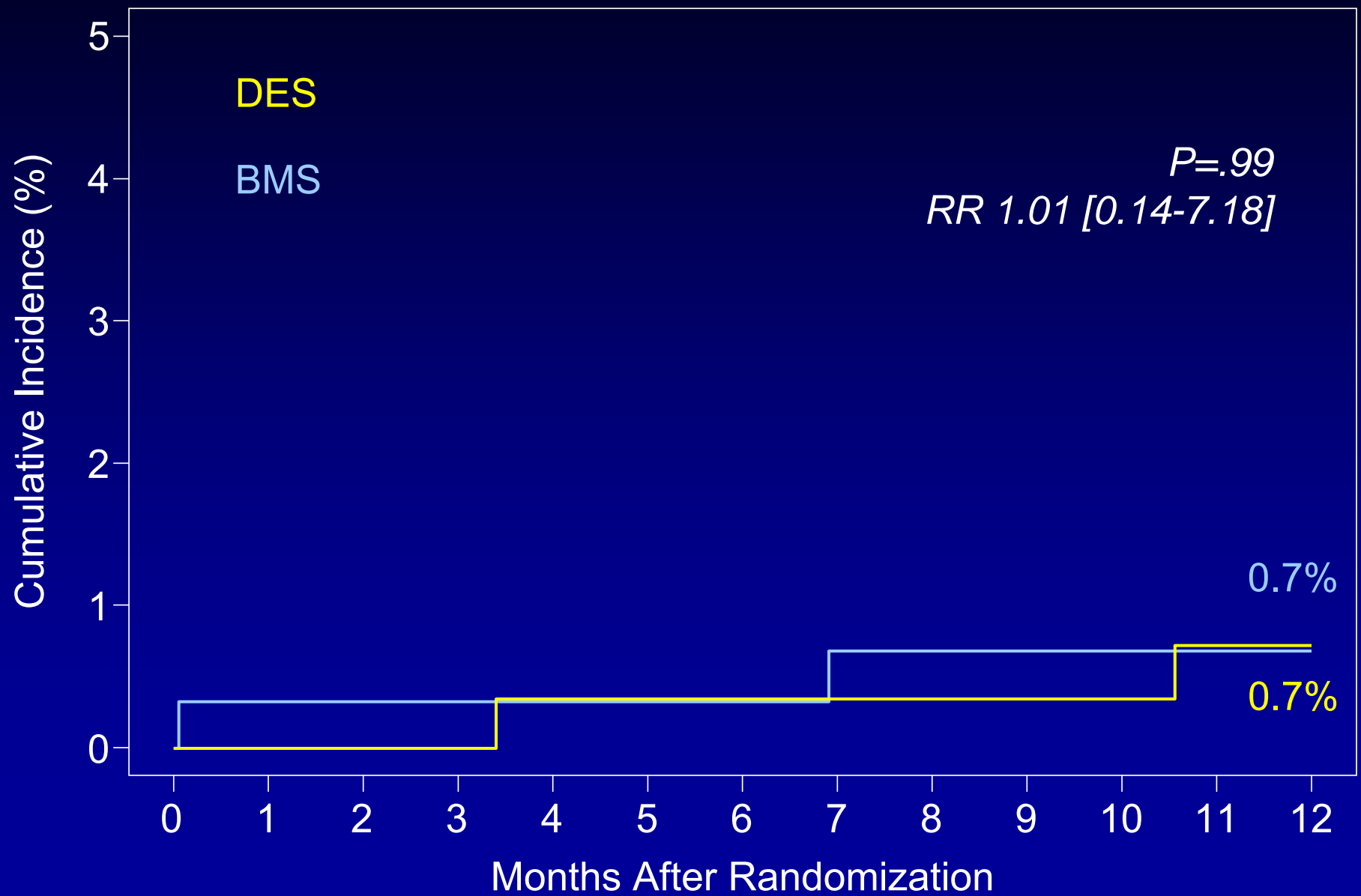


# Death or Myocardial Infarction



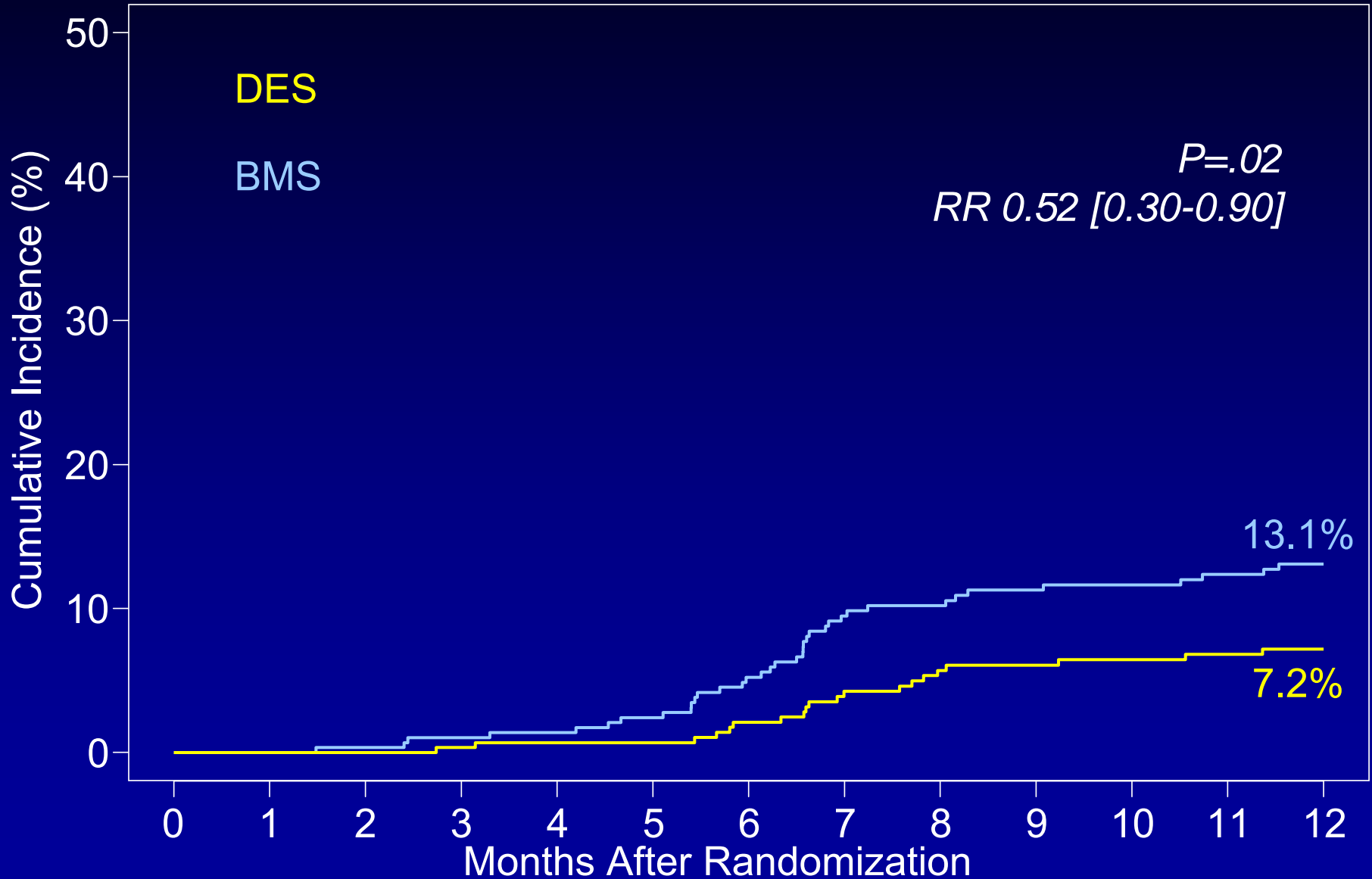


# Definite/Probable Stent Thrombosis



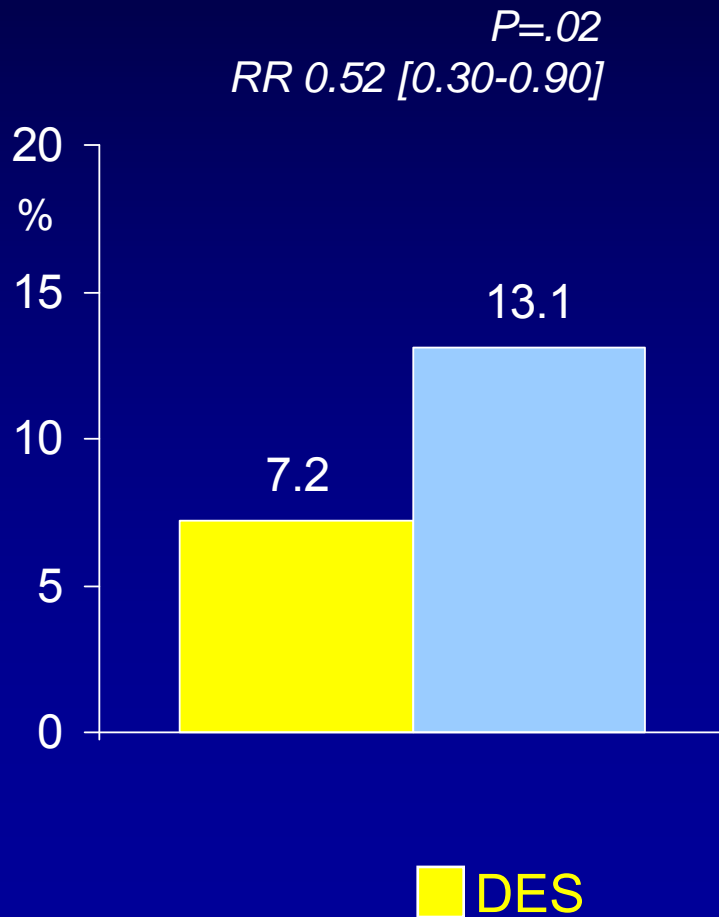


# Target Lesion Revascularization

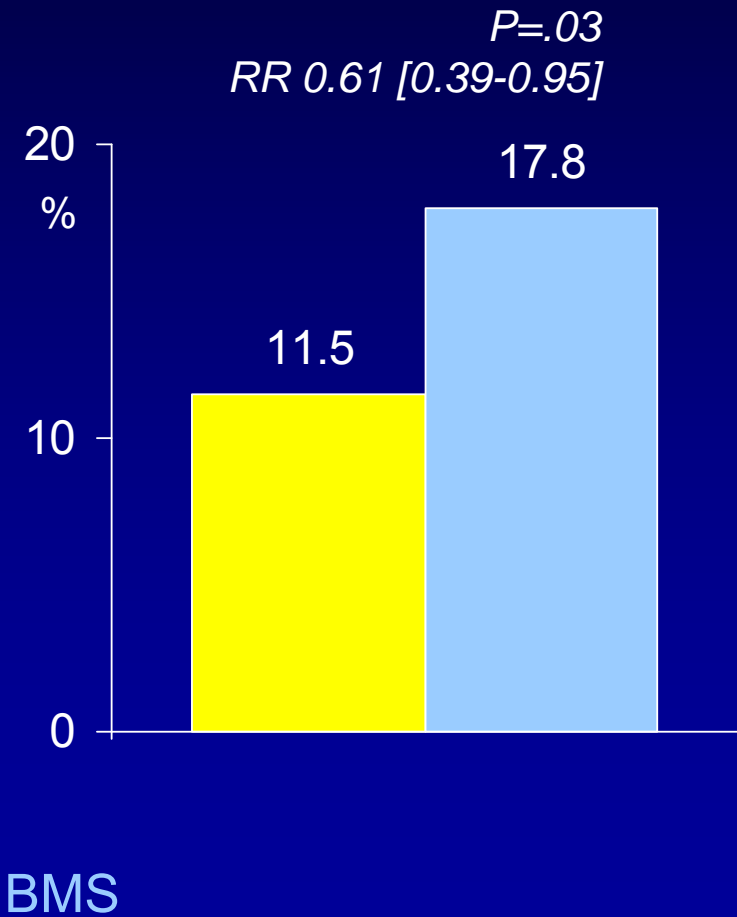




## TLR



## TVR



# Summary



Out to 12 months drug-eluting stents are superior to bare metal stents in a large-scale study powered for clinical endpoints.

The need for repeat revascularizations was reduced by ~50% with DES as compared to BMS.

DES were comparable to BMS regarding safety parameters – stent thrombosis, death or MI.