Very Long-term Outcomes of DES

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Disclosure Statement of Financial Interest

I, Adnan Kastrati 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.

Long-Term Outcomes after DES in Native Vessels and Venous Grafts

- **Five-year results of the ISAR-CABG trial**
- **Ten-year results of the ISAR-TEST 4 trial**

ISAR-CABG:Trial flow-chart

November 2007 to February 2010

610 Pts
with PCI for bypass vein graft lesions

303 pts (386 lesions) DES
Yukon PC, Cypher, Taxus

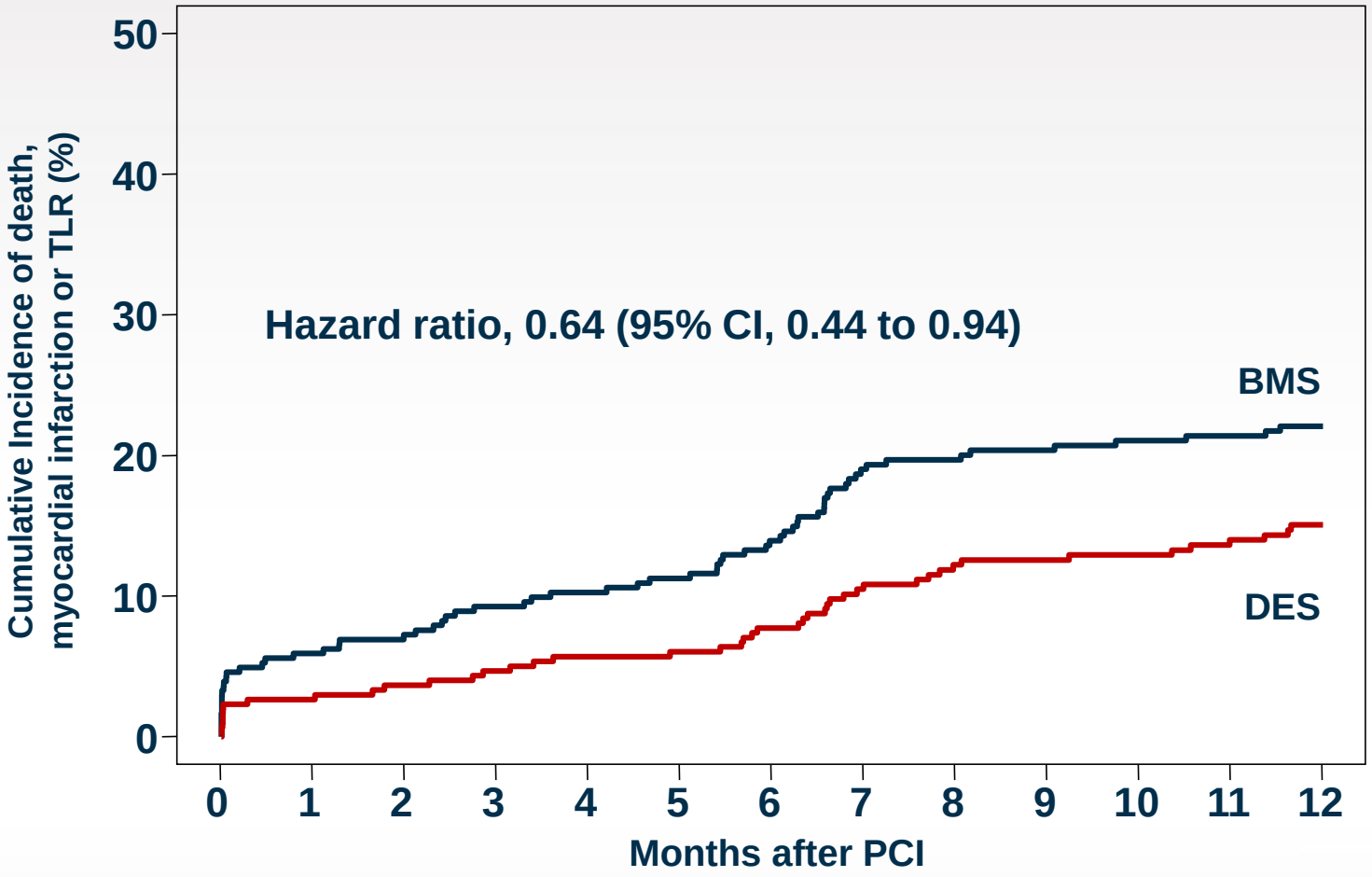
307 pts (385 lesions) BMS

Participating Centers (all in Germany)

- Deutsches Herzzentrum Munich (PI: J. Pache, MD)
- 1. Med. Klinik, Klinikum rechts der Isar, Munich (PI: K.L. Laugwitz, MD)
- Herzzentrum Bad Krozingen, Bad Krozingen (PI: F.J. Neumann, MD)
- Bad Segeberger Kliniken, Bad Segeberg (PI: G. Richardt, MD)

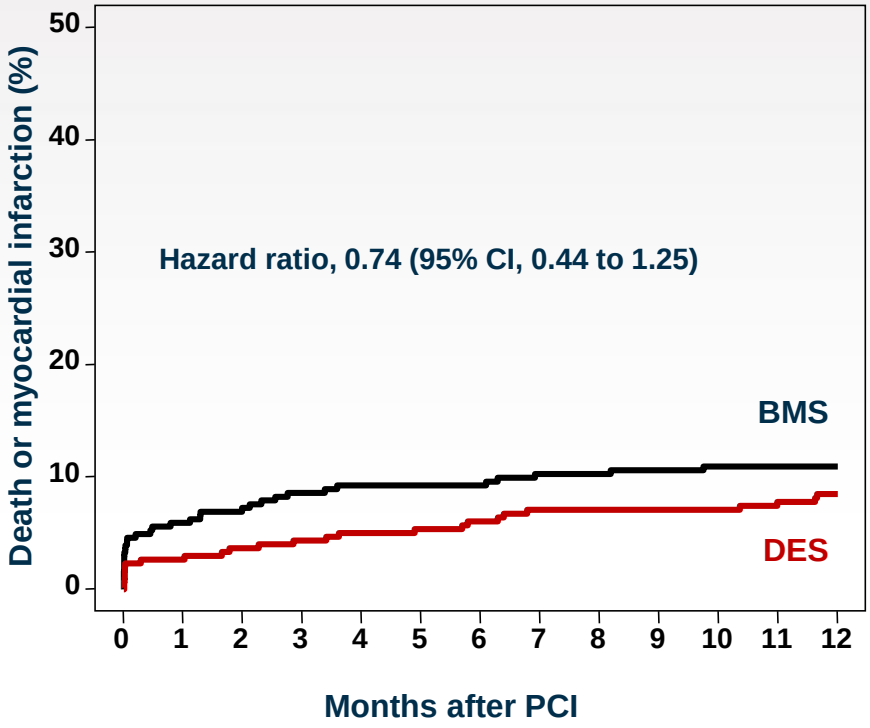
ISAR-CABG, Lancet 2011

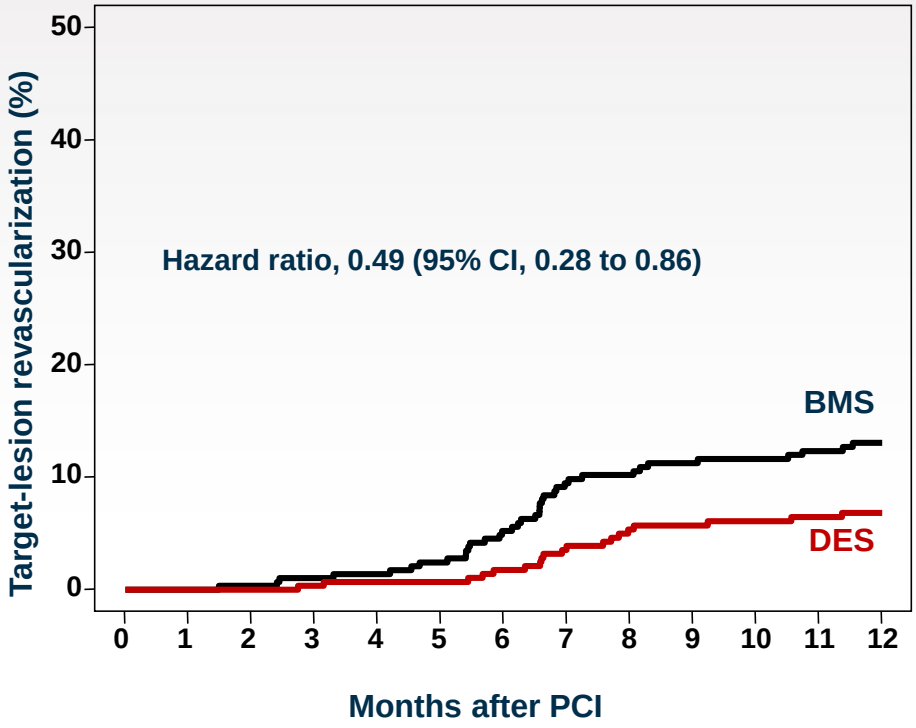
ISAR-CABG: Primary endpoint



ISAR-CABG, Lancet 2011

ISAR-CABG: Secondary endpoints





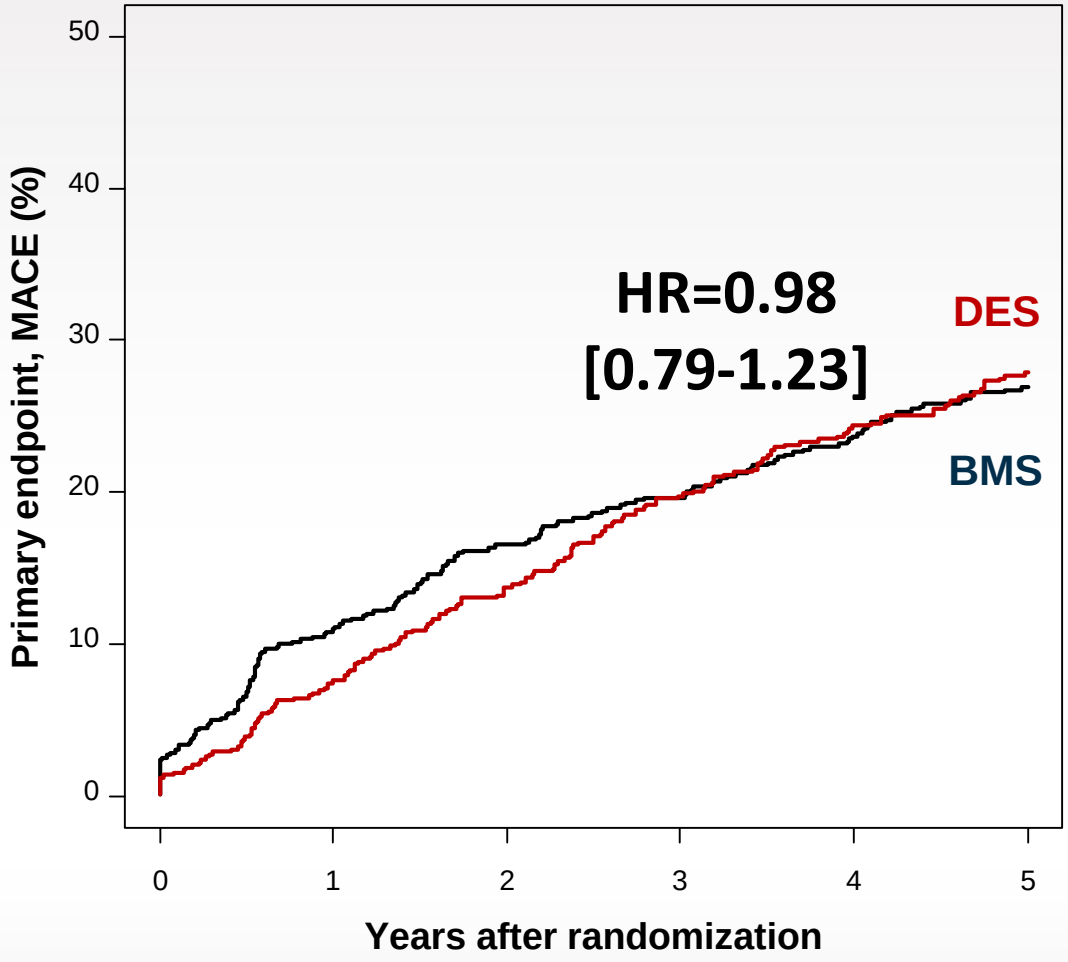
ISAR-CABG, Lancet 2011

ESC Guidelines 2014
– treatment of venous graft failure–

Repeat revascularization

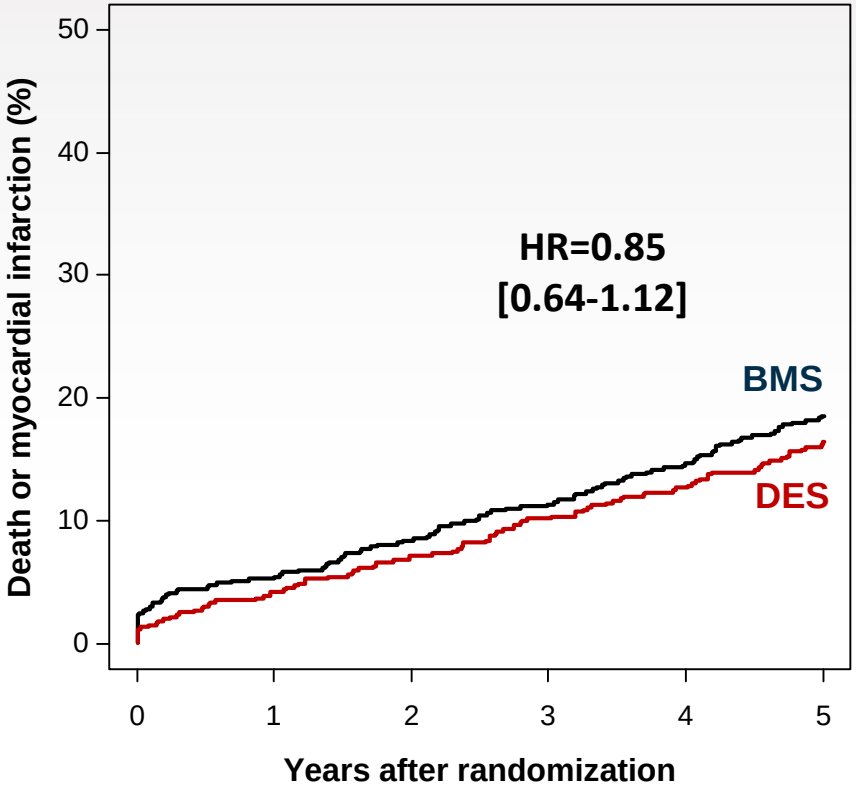
Recommendations	Class[a]	LoE[b]	Ref[c]
Disease progression and late graft failure			
Repeat revascularization is indicated in patients with severe symptoms or extensive ischaemia despite medical therapy if technically feasible.	I	B	54,143
PCI should be considered as a first choice if technically feasible, rather than re-do CABG.	IIa	C	
PCI of the bypassed native artery should be the preferred approach, if technically feasible.	IIa	C	
IMA, if available, is the conduit of choice for re-do CABG.	I	B	481
Re-do CABG should be considered for patients without a patent IMA graft to the LAD.	IIa	B	481
Re-do CABG may be considered in patients with lesions and anatomy not suitable for revascularization by PCI.	IIb	C	
PCI may be considered in patients with patent IMA graft if technically feasible.	IIb	C	
DES are recommended for PCI of SVGs.	I	A	489–495
Distal protection devices are recommended for PCI of SVG lesions if technically feasible.	I	B	484,485

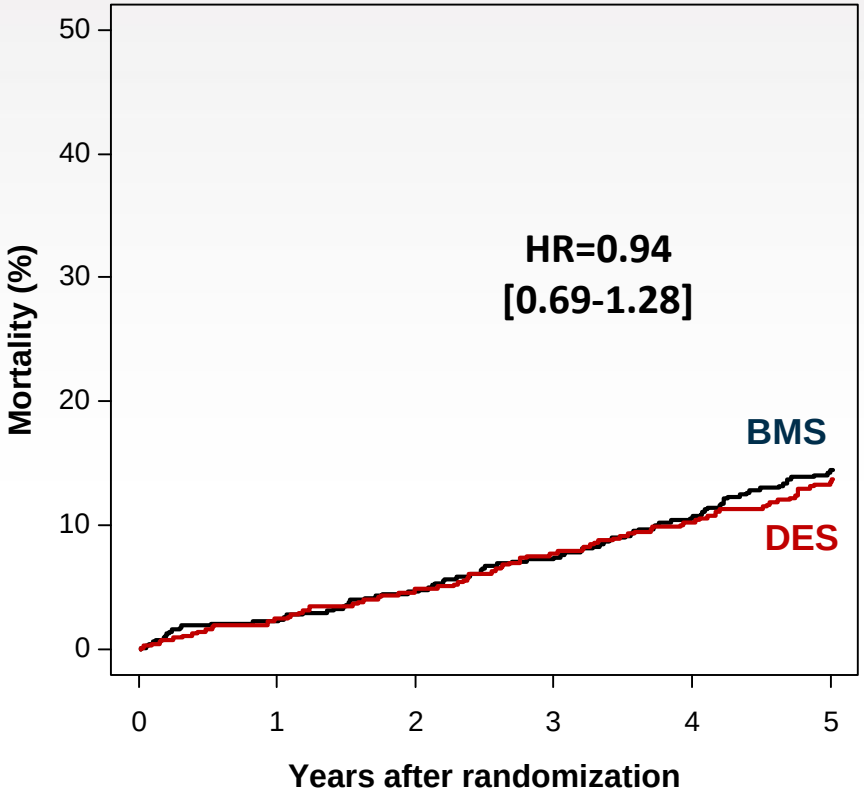
ISAR-CABG
5-year outcomes



ISAR-CABG 5-year results, JACC 2018

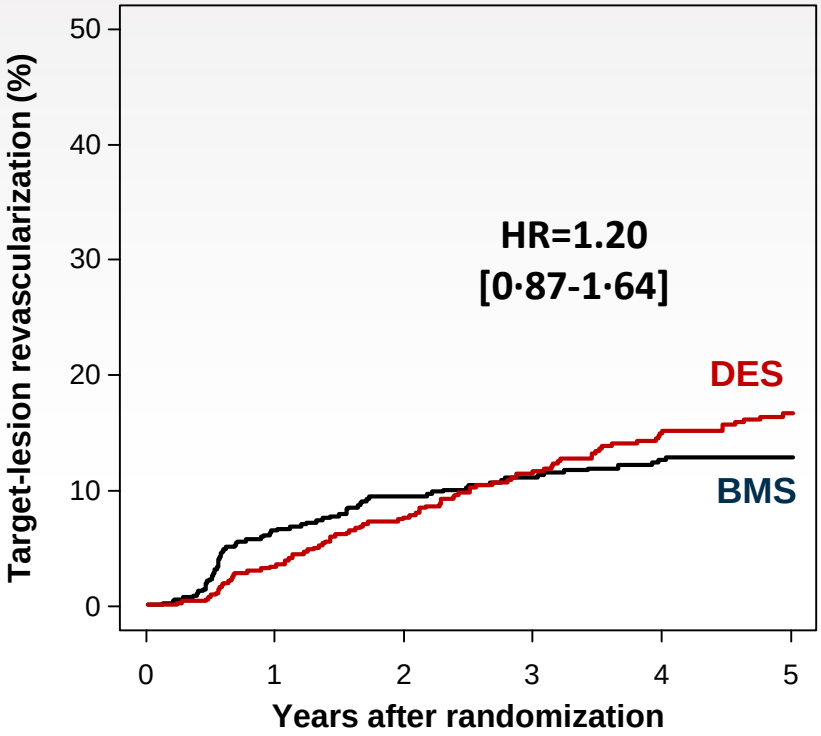
ISAR-CABG
5-year outcomes

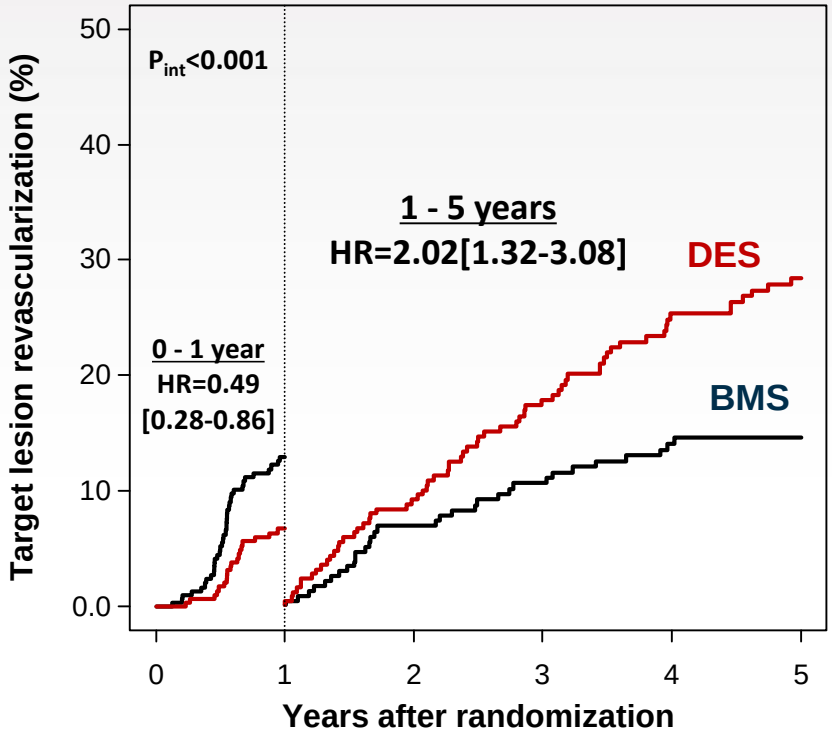




ISAR-CABG 5-year results, JACC 2018

ISAR-CABG
5-year outcomes





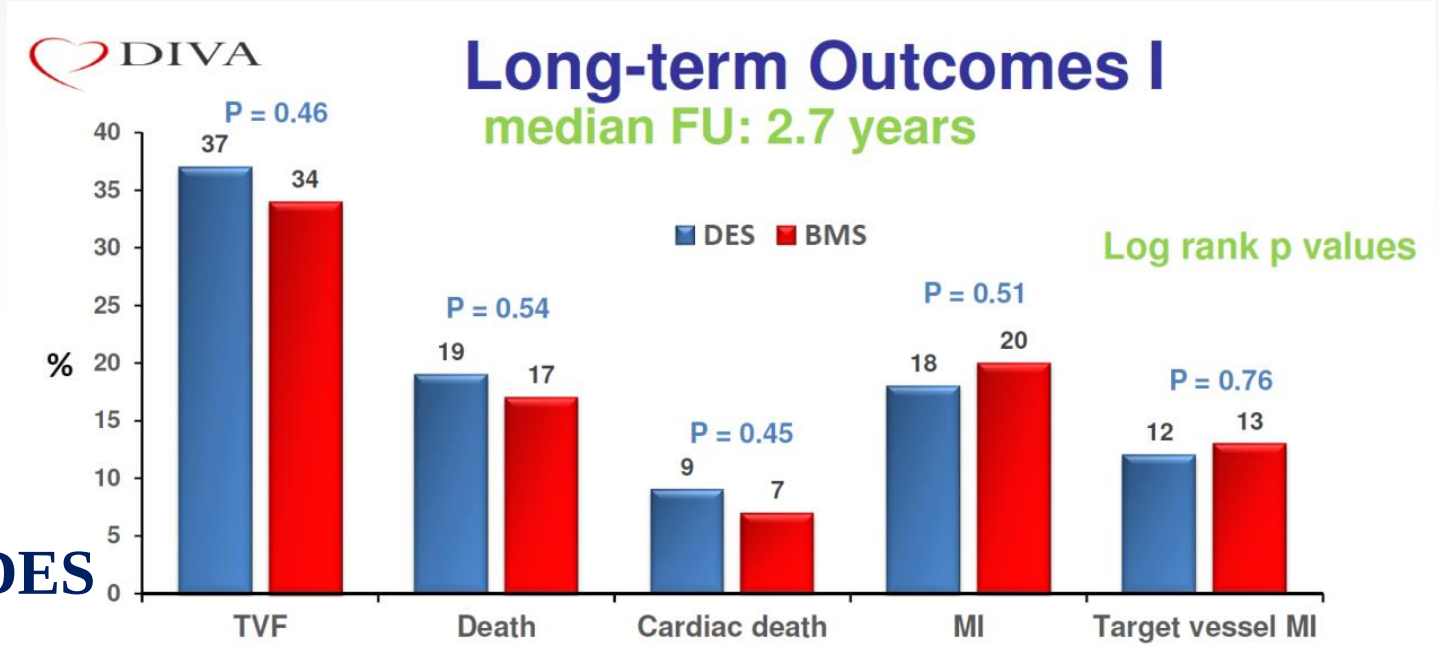
ISAR-CABG 5-year results, JACC 2018

ISAR-CABG 5-year outcomes Limitations

Most of the DES used were 1° generation DES

However:

597 pts
89% 2° gen DES



DIVA, Lancet 2018

ISAR-CABG 5-year outcomes Conclusions

<u>In patients undergoing PCI of SVG lesions:</u>

Safety outcomes for DES and BMS remained comparable at long-term follow-up

The advantage of DES over BMS demonstrated at 1 year was lost at 5-year follow-up due to higher attrition of efficacy in the DES group

Long-Term Outcomes after DES in Native Vessels and Venous Grafts

- **Five-year results of the ISAR-CABG trial**
- **Ten-year results of the ISAR-TEST 4 trial**

Methods *ISAR-TEST 4 study design*

Patients enrolled between 09/2007 and 08/2008 at two centers in Munich, Germany

Inclusion Criteria:

- ischemic symptoms or evidence of myocardial ischemia +
- presence of ≥50% stenosis in native coronary arteries

Exclusion Criteria:

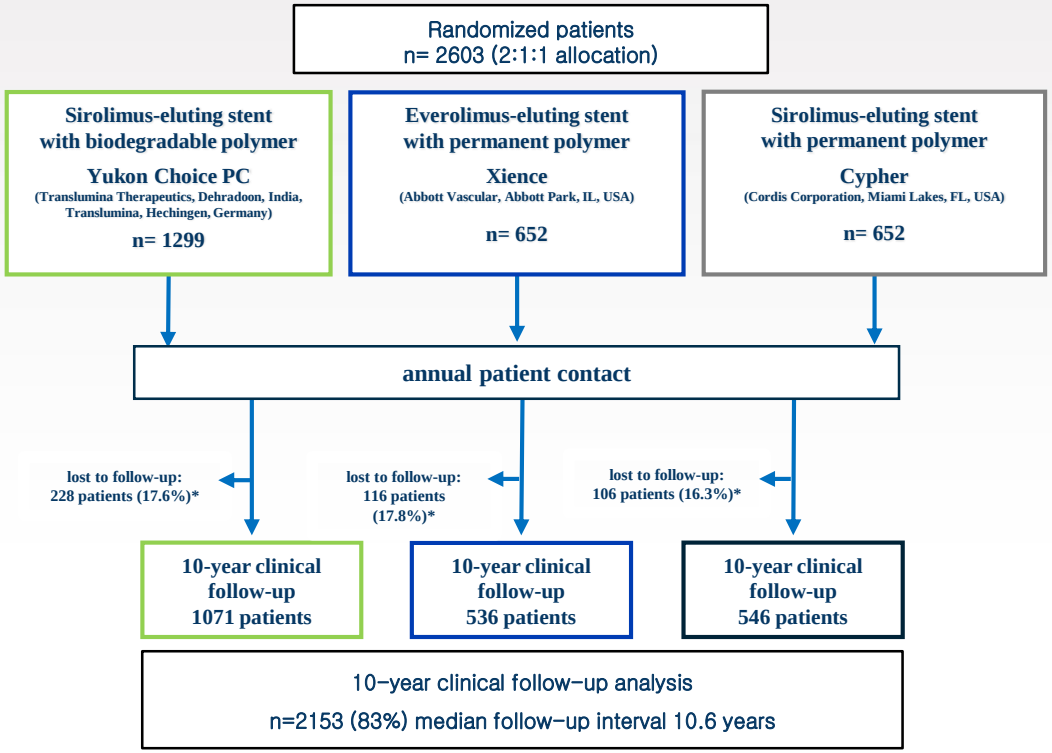
Target lesion in left main stem
In-stent restenosis lesion

Primary Endpoint:

MACE = combined incidence of all-cause death, myocardial infraction and target lesion revascularisation at 10 years

Secondary Endpoints:

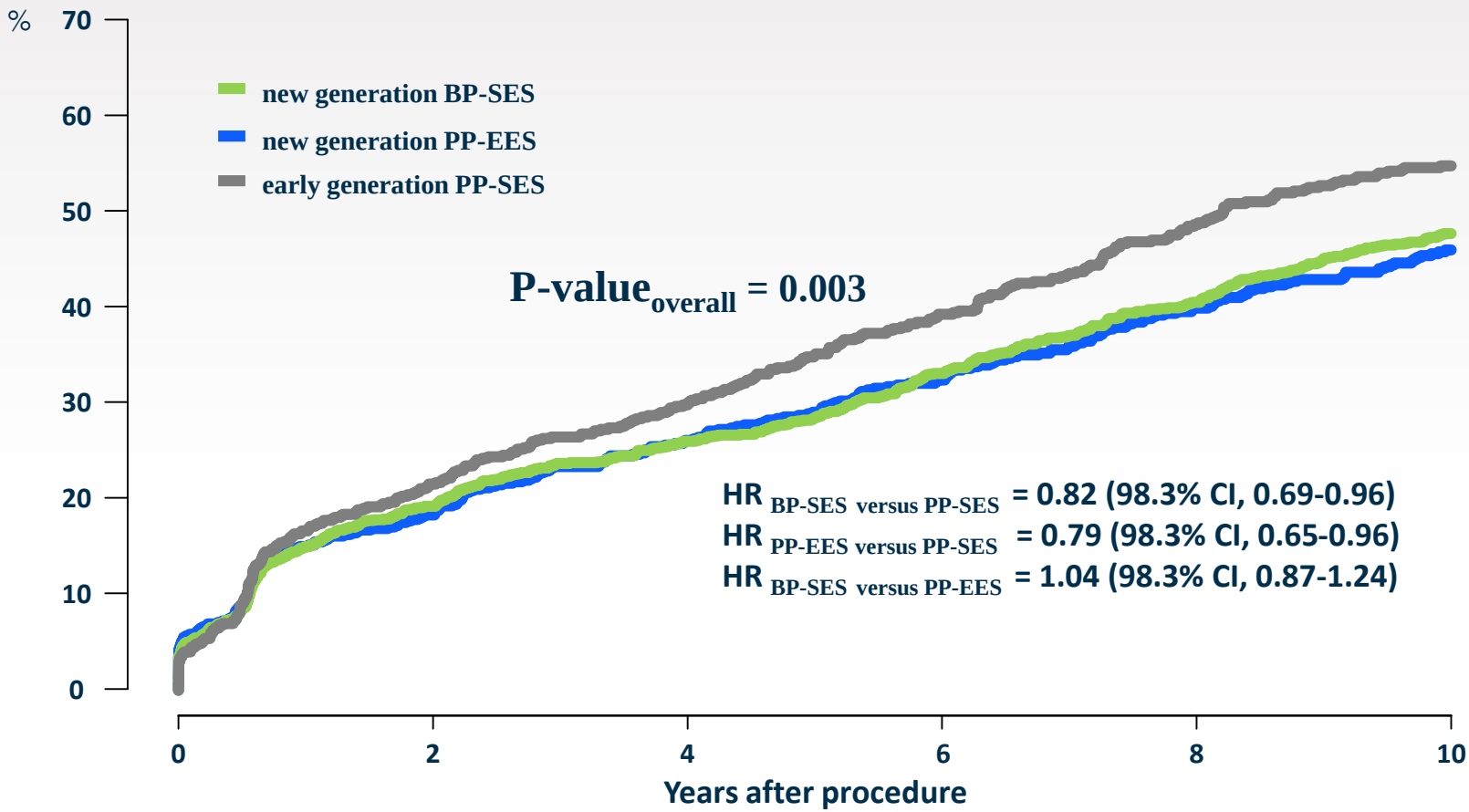
1. individual components of the primary endpoint at 10 years
2. Definite or probable stent thrombosis at 10 years



* = in patients without complete follow-up out to 10 years, median follow-up interval was 5.9 years

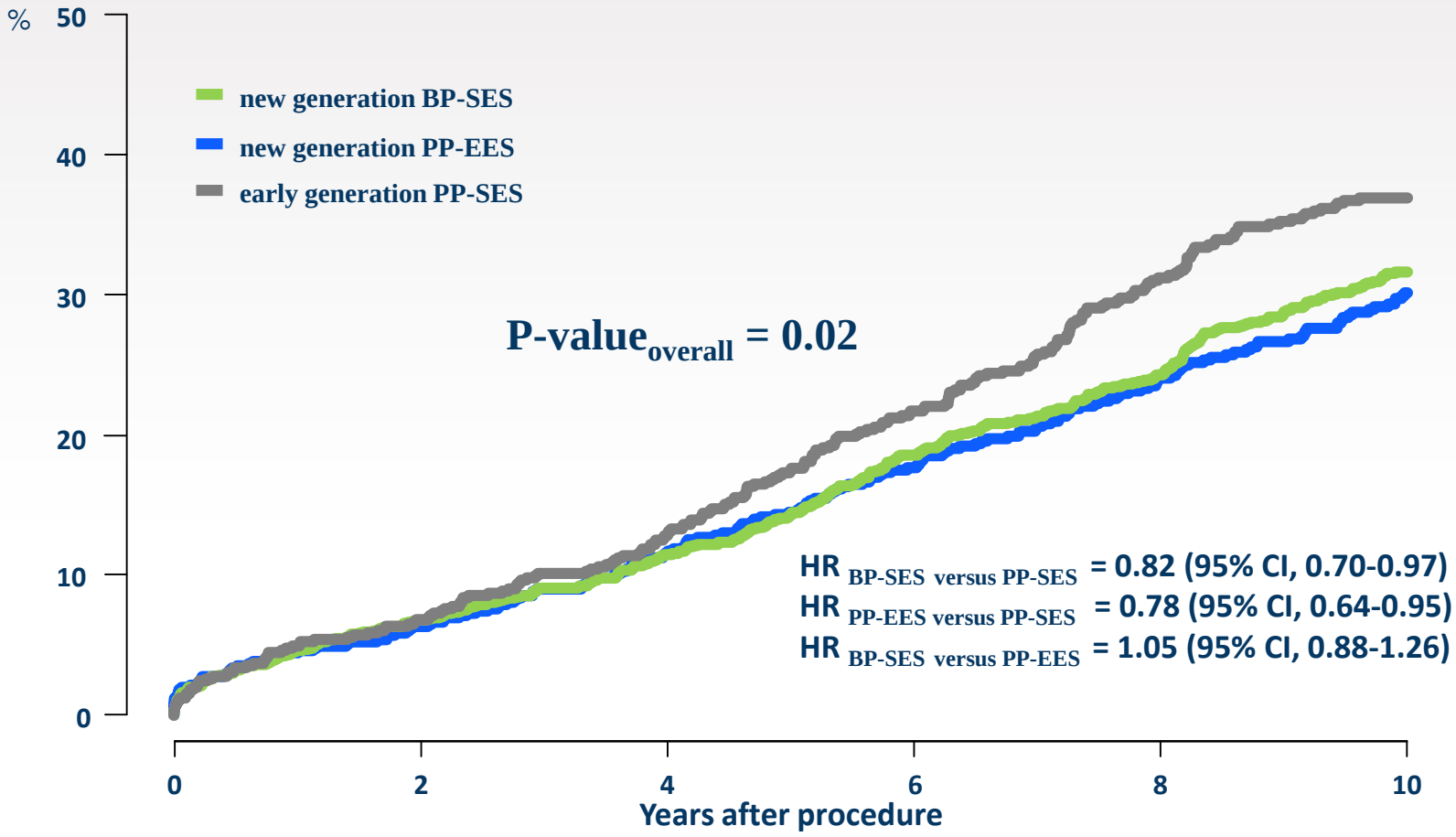
Kufner et al., Circulation 2019

Results *primary endpoint: MACE at 10 years*



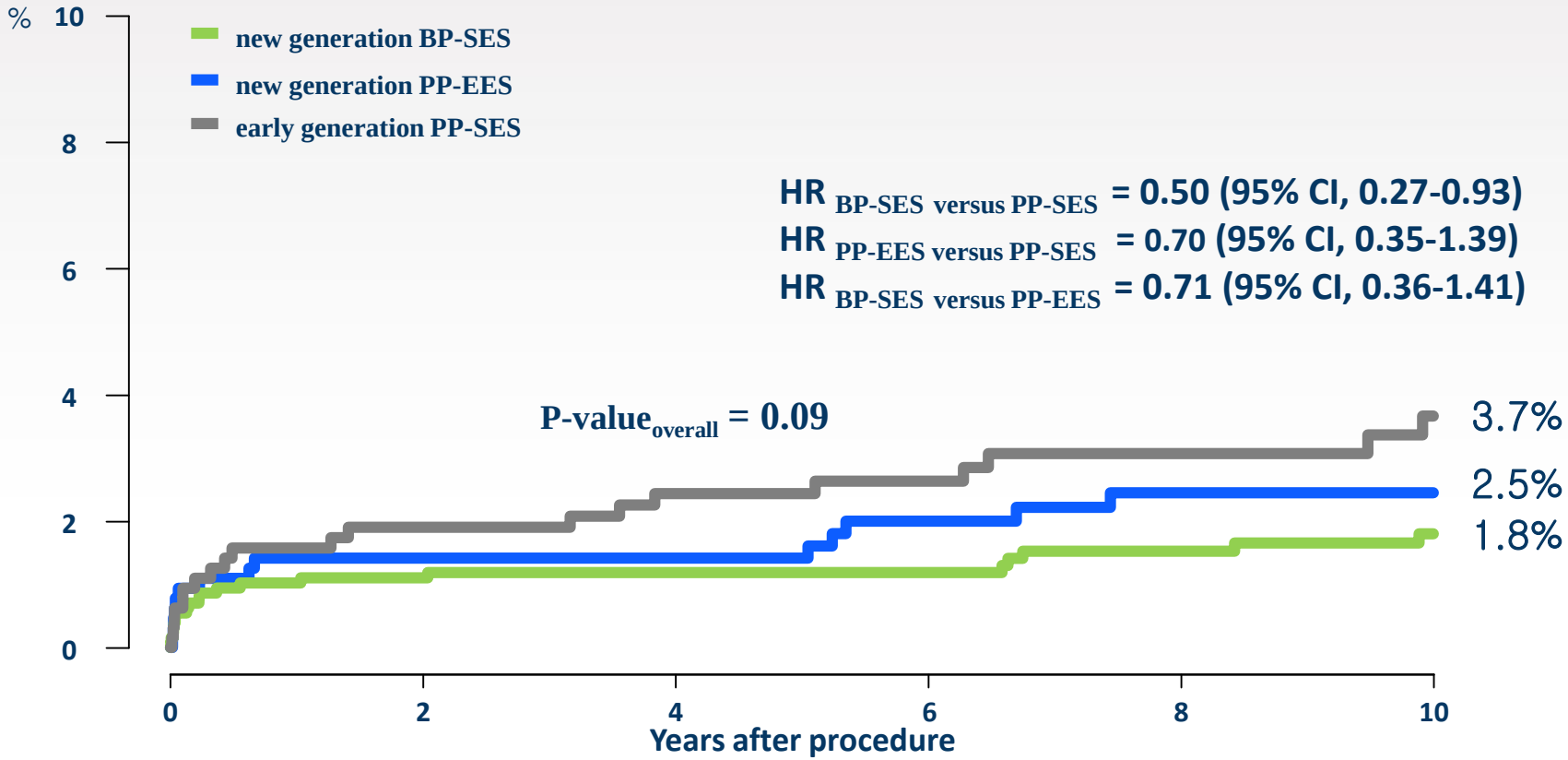
Kufner et al., Circulation 2019

Results *all-cause mortality at 10 years*



Kufner et al., Circulation 2019

Results *def/prob stent thrombosis at 10 years*



Kufner et al., Circulation 2019

Conclusions of ISAR-TEST 4 @ 10 years

In this unique long-term analysis…

- New-generation DES are superior to early-generation DES in terms of clinical outcomes
- The favorable outcome after new-generation DES is driven by increasing event rates over time in patients treated with early-generation DES
- Both, biodegradable polymer-based sirolimus-eluting stents and permanent polymer-based everolimus-eluting stents showed comparable clinical outcomes out to 10 years

Kufner et al., Circulation 2019

Thank you for your attention!