DES for venous bypass grafts: ISAR-CABG trial

Julinda Mehilli, MD

Deutsches Herzzentrum,
Technische Universität, Munich, GERMANY

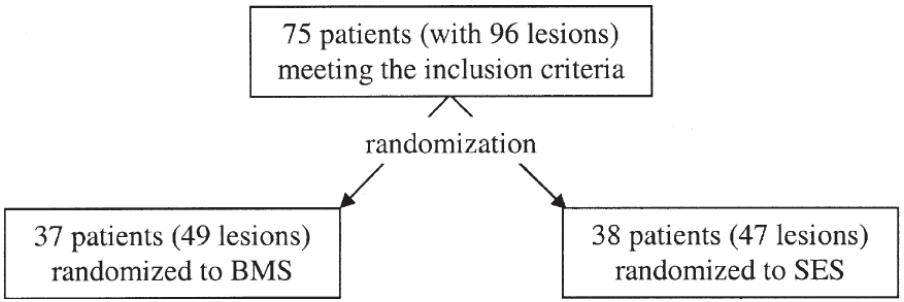
DES for Saphenous Vein Graft Failure

RRISC

Randomized Double-Blind Comparison of Sirolimus-Eluting Stent Versus Bare-Metal Stent Implantation in Diseased Saphenous Vein Grafts

Six-Month Angiographic, Intravascular Ultrasound, and Clinical Follow-Up of the RRISC Trial

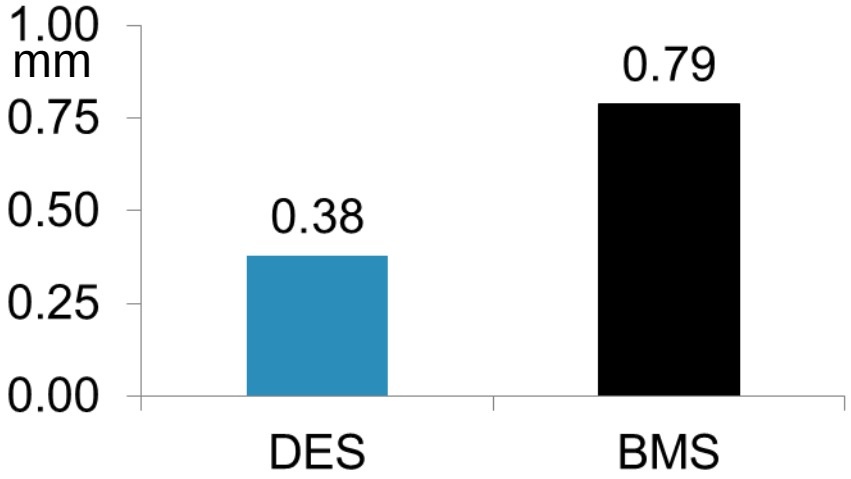
JACC 2006;48:2423-31



Primary endpoint

In-stent late lumen loss

P=0.001



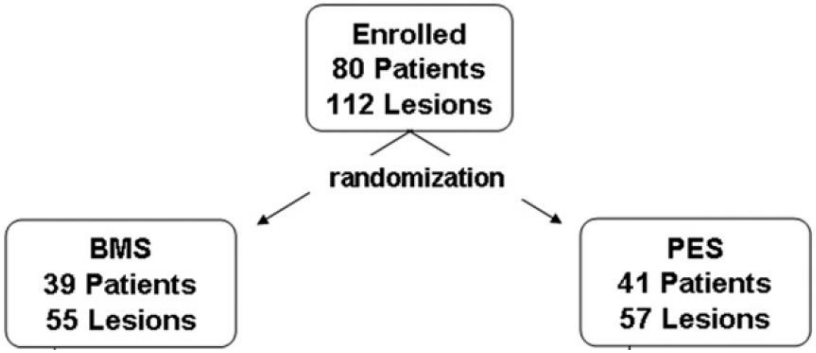
DES for Saphenous Vein Graft Failure

Stenting Of Saphenous Vein Grafts Trial

A Randomized Controlled Trial of a Paclitaxel-Eluting Stent Versus a Similar Bare-Metal Stent in Saphenous Vein Graft Lesions

The SOS (Stenting Of Saphenous Vein Grafts) Trial

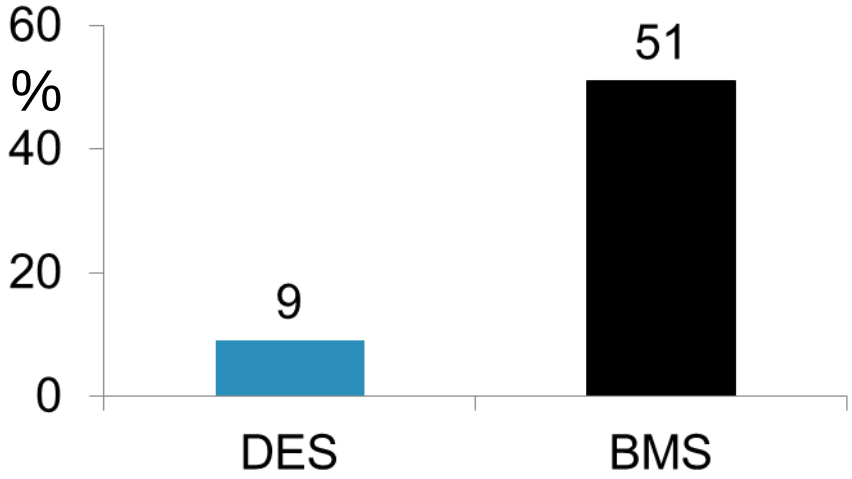
JACC 2009;53:919-28



Primary endpoint

Binary restenosis rate

P<0.001



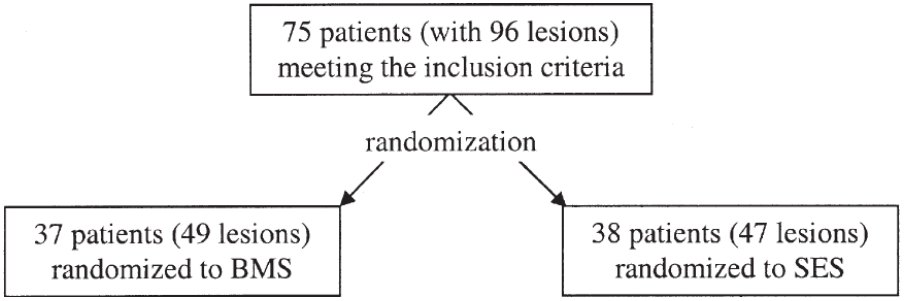
DES for Saphenous Vein Graft Failure

RRISC

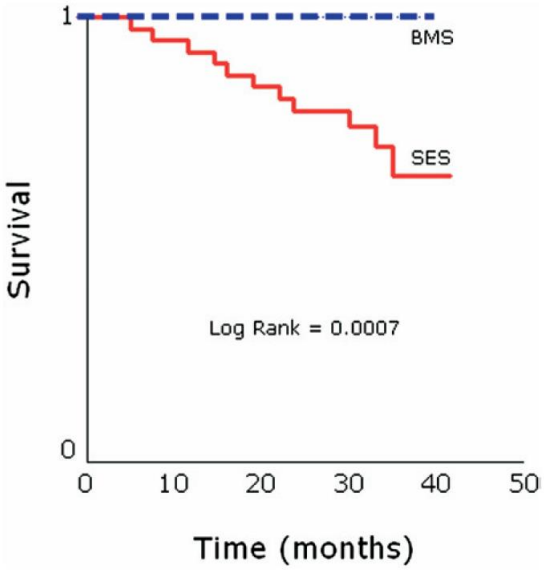
Increased Late Mortality After Sirolimus-Eluting Stents Versus Bare-Metal Stents in Diseased Saphenous Vein Grafts

Results From the Randomized DELAYED RRISC Trial

JACC 2007;50:261–7



Long term outcome

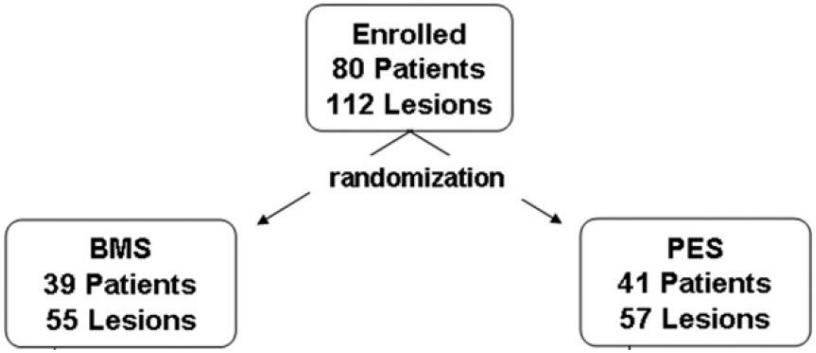


DES for Saphenous Vein Graft Failure

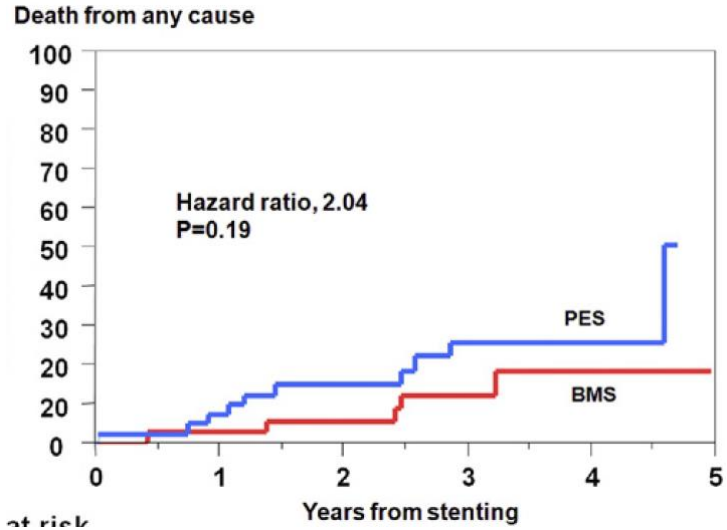
Stenting Of Saphenous Vein Grafts Trial

Continued Benefit From Paclitaxel-Eluting Compared With Bare-Metal Stent Implantation in Saphenous Vein Graft Lesions During Long-Term Follow-Up of the SOS (Stenting of Saphenous Vein Grafts) Trial

JACC Interv 2011;4:176–82



Long term outcomes



DES for Saphenous Vein Graft Failure

ISAR-CABG – Rationale

No randomized trial exists with adequate sample size for evaluating clinical outcomes of patients with bypass vein graft lesions treated with either DES or BMS.

ISAR-CABG – Trial objective

To compare clinical outcomes achieved with DES vs. BMS for treatment of bypass vein graft lesions.

ISAR-CABG
Patient selection

Main inclusion criteria

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

Main exclusion criteria

Cardiogenic shock

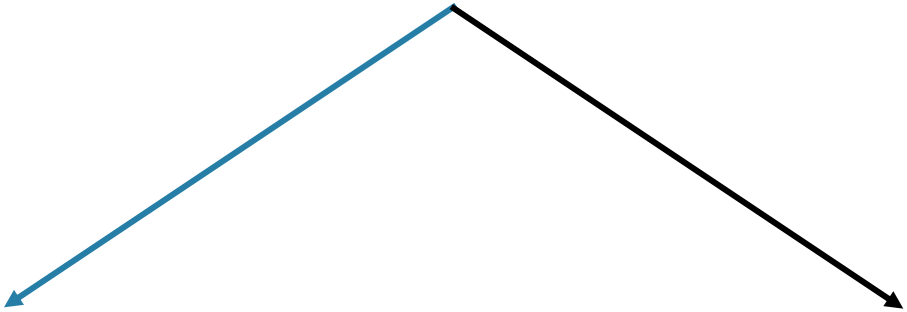
Target lesion located in arterial grafts

Malignancies with life expectancy <1 year

ISAR-CABG
Trial flow-chart

610 Pts

with PCI for bypass vein graft lesions



303 pts (386 lesions)
DES

307 pts (385 lesions)
BMS

Participating Centers

- 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)*

All in Germany

ISAR-CABG, Lancet 2011

ISAR-CABG
Baseline characteristics

	DES n=303	BMS n=307
Mean age, years	71.4	71.5
Female, %	13	16
Art. hypertension, %	71	73
Diabetes, %	37	35
Current smoker, %	8	6
Hyperlipidemia, %	88	86
Mean SVG age, years	13.7	13.5
History of MI, %	56	55

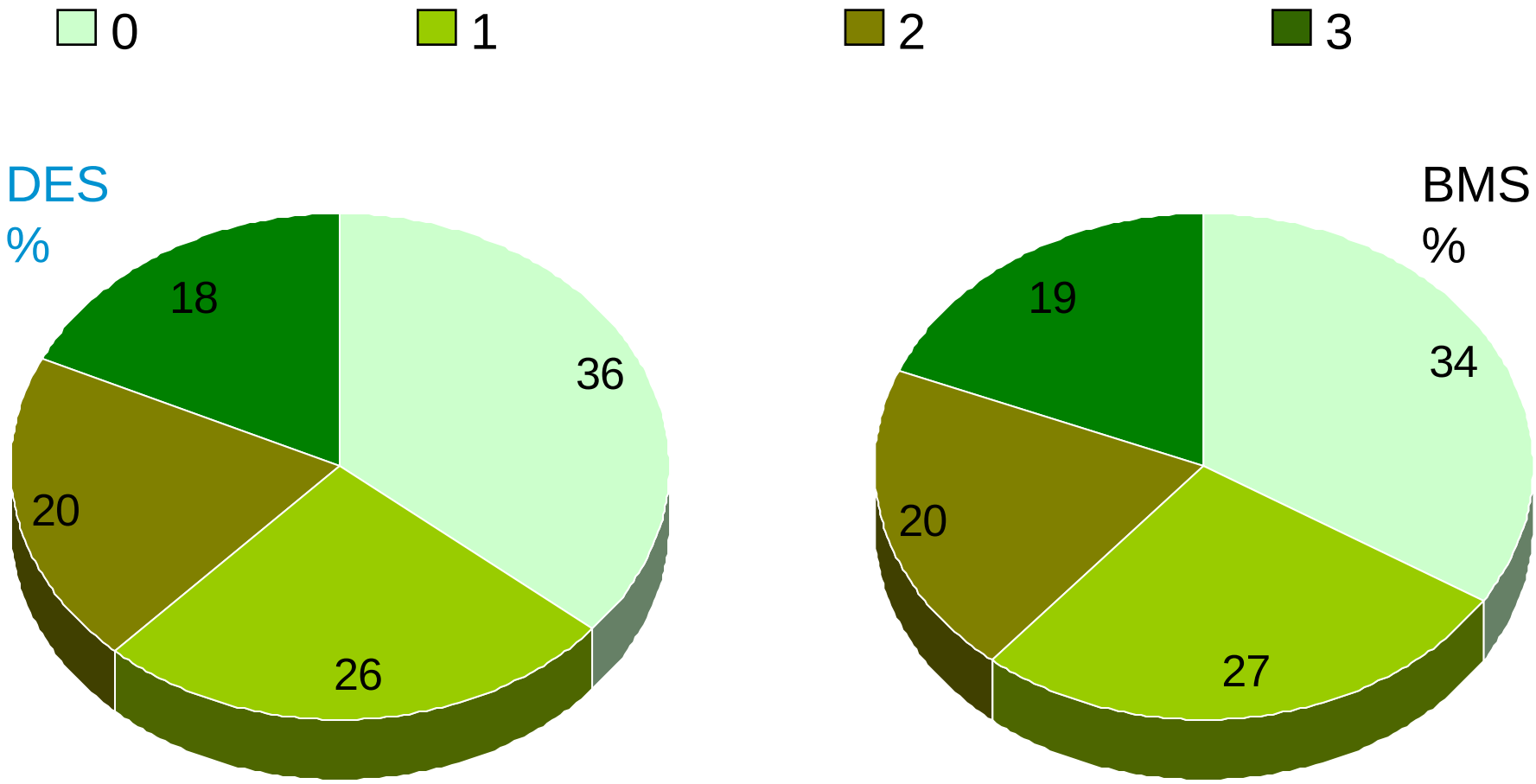
ISAR-CABG
Baseline characteristics

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

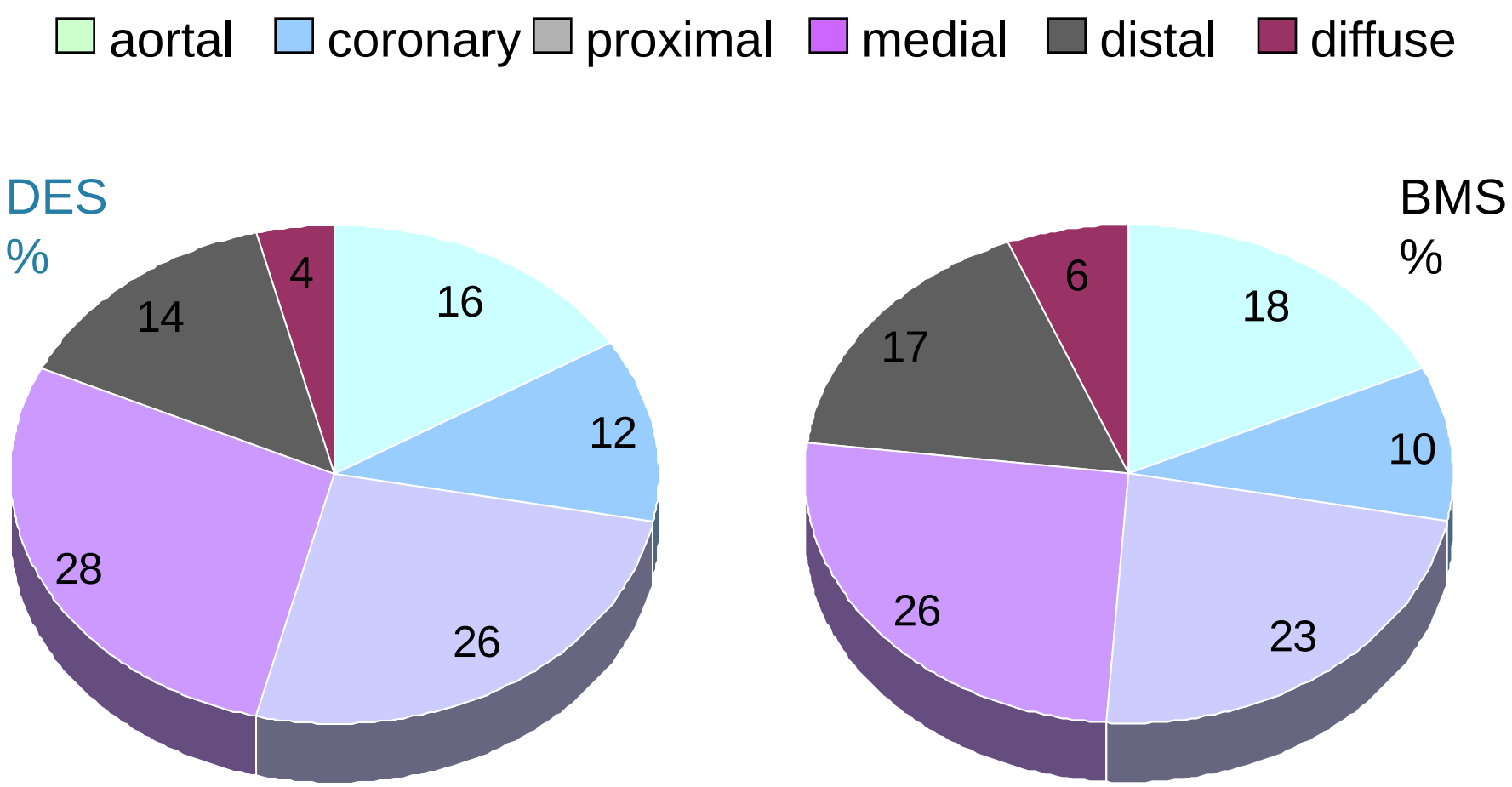
ISAR-CABG
Baseline characteristics

	DES n=386	BMS n=385
Recipient vessel, %		
LAD/diagonal	32	31
LCx/marginal	35	36
RCA/PDA	33	33
Mean vessel size, mm	3.36	3.38
Mean stented length, mm	26.8	27.5

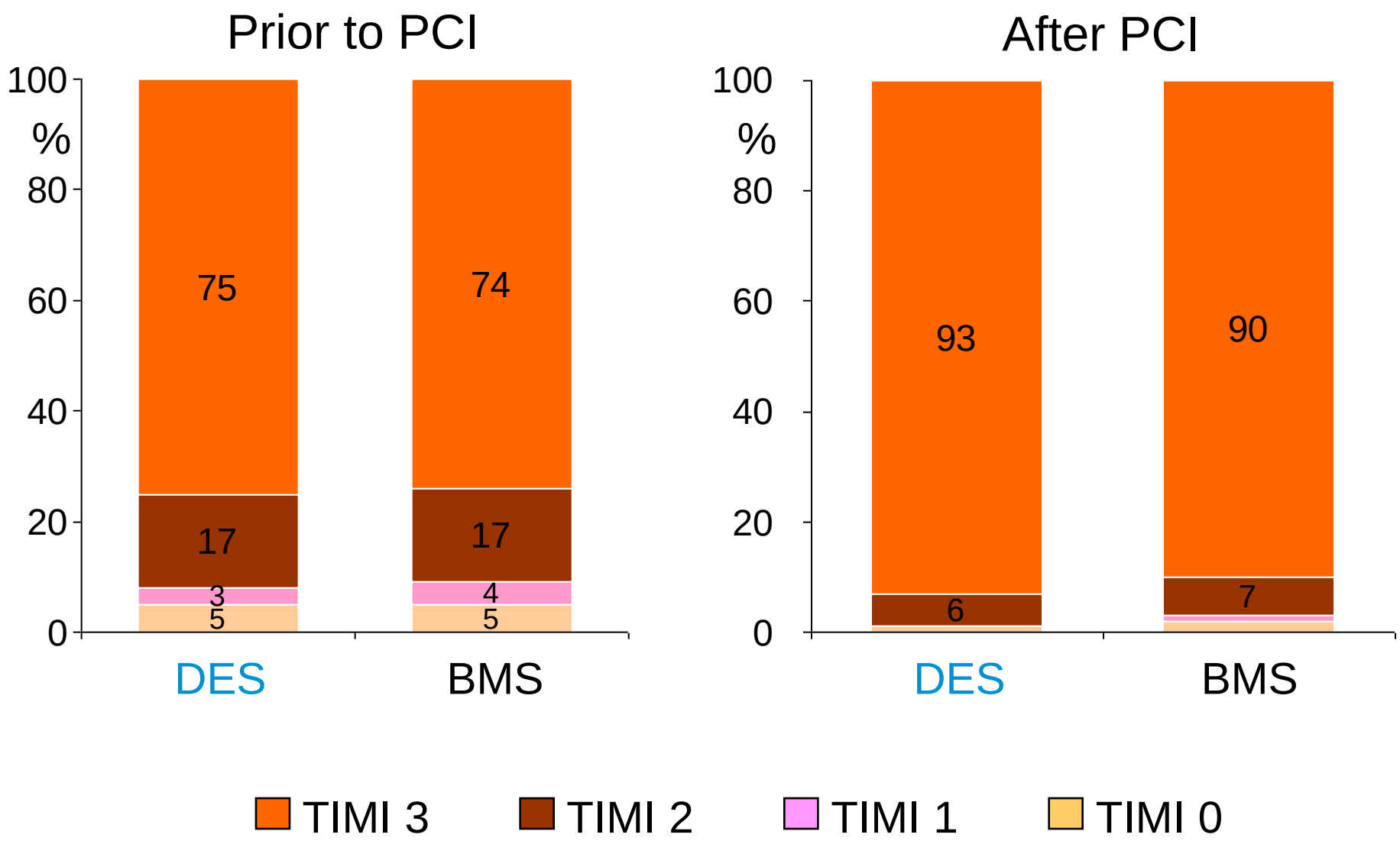
ISAR-CABG
Degeneration score



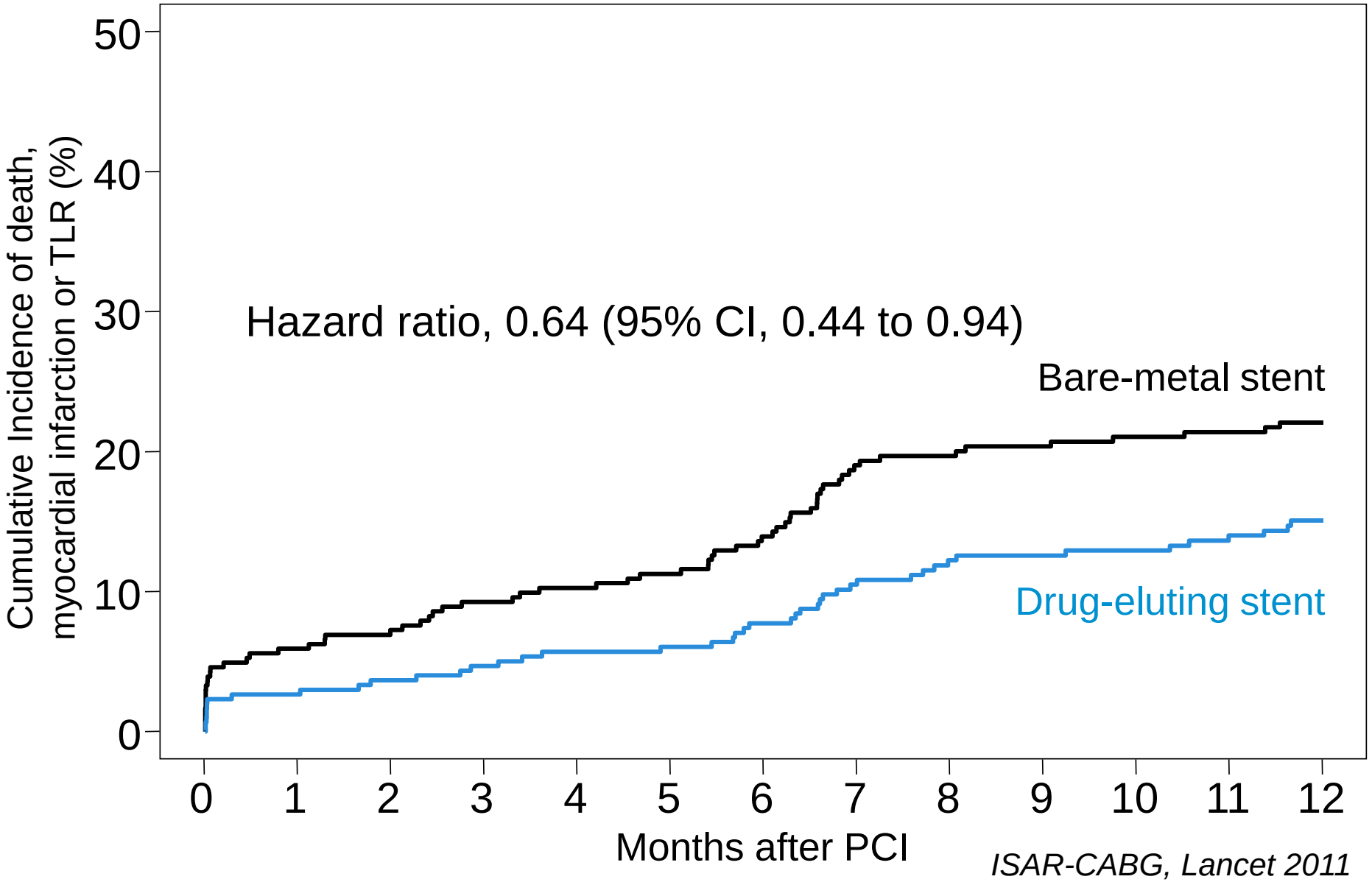
ISAR-CABG
Lesion location



ISAR-CABG
TIMI Flow

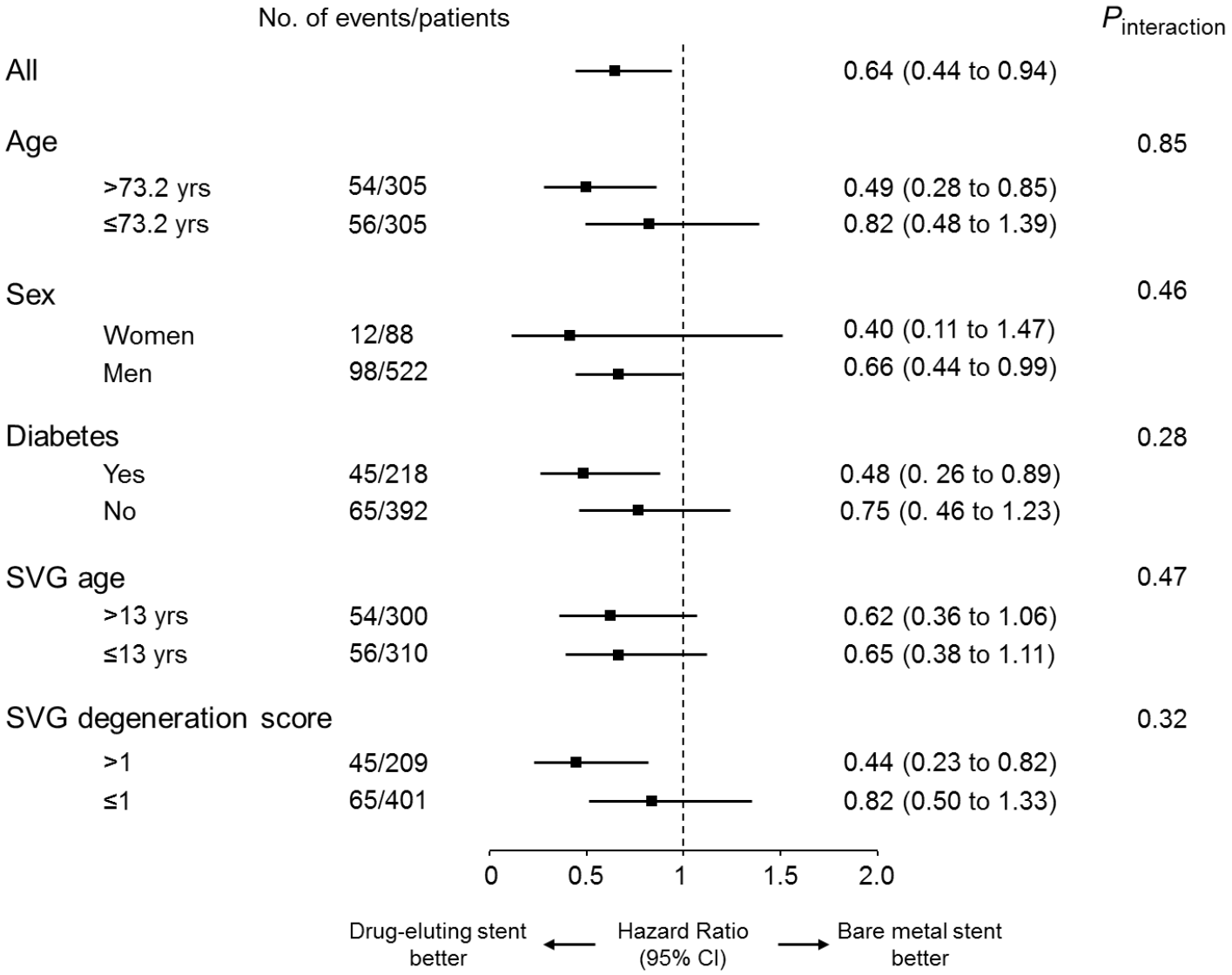


ISAR-CABG
Primary endpoint



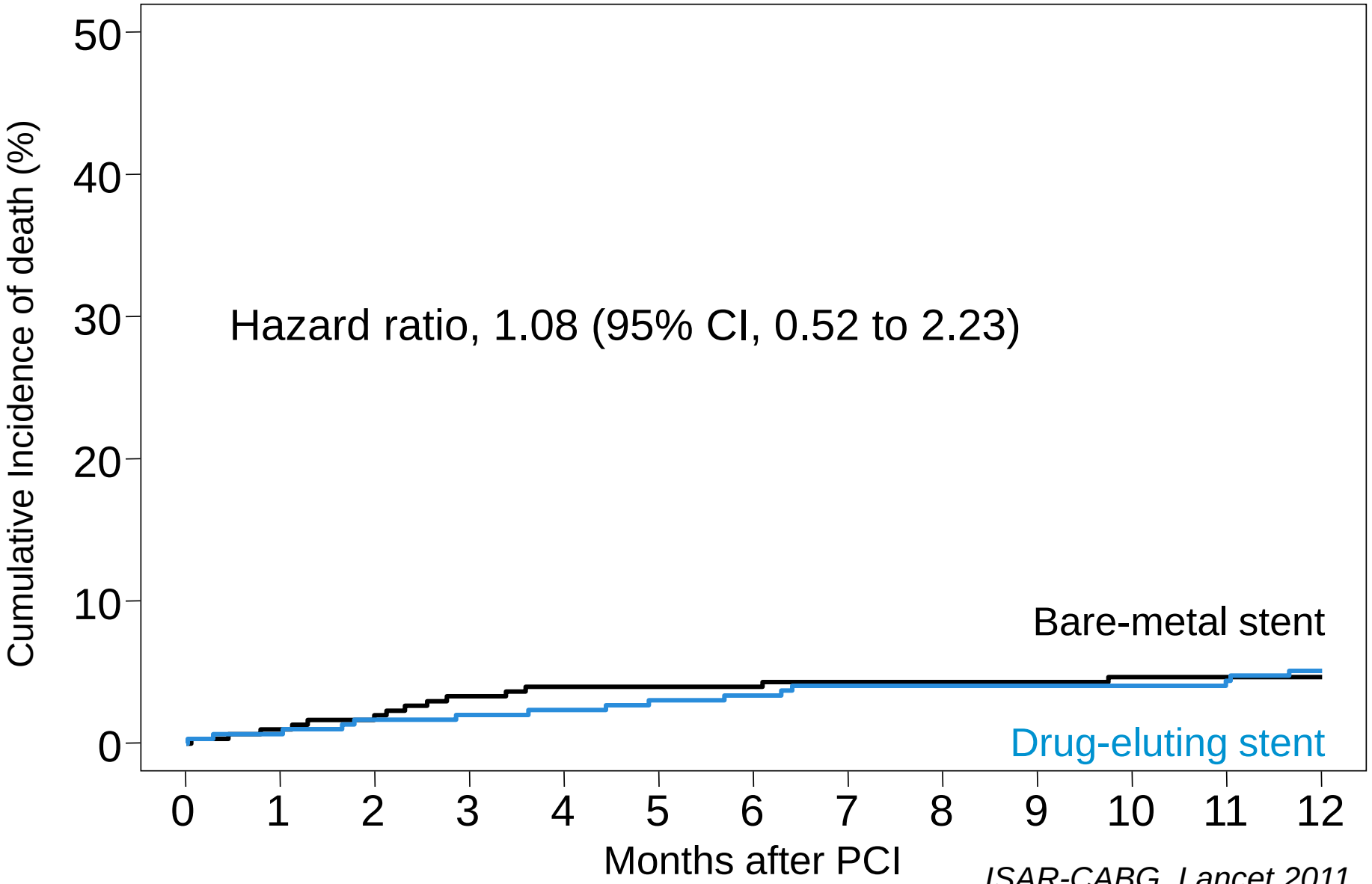
ISAR-CABG, Lancet 2011

ISAR-CABG
Primary endpoint in subgroups



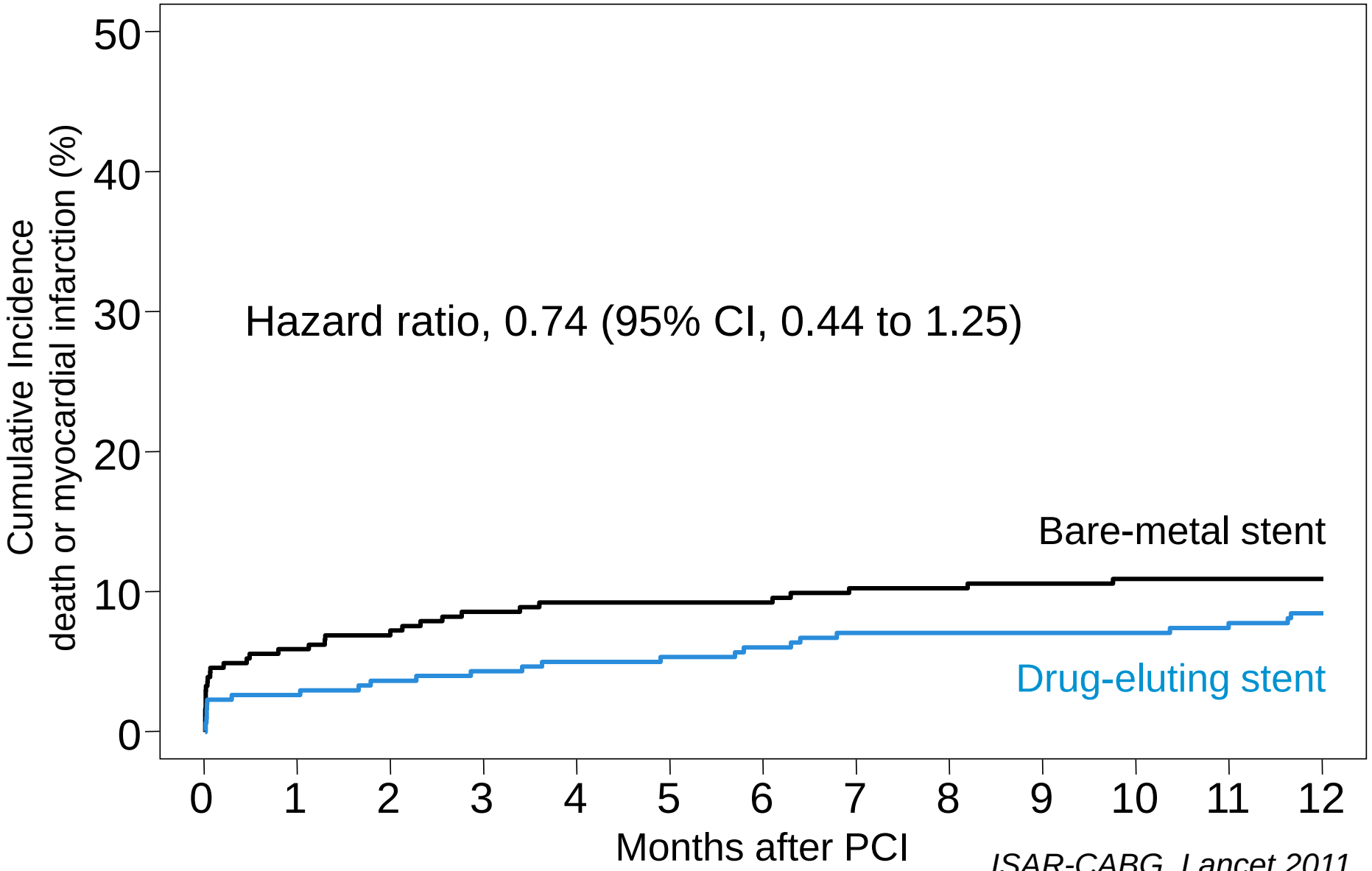
ISAR-CABG, Lancet 2011

ISAR-CABG
Mortality



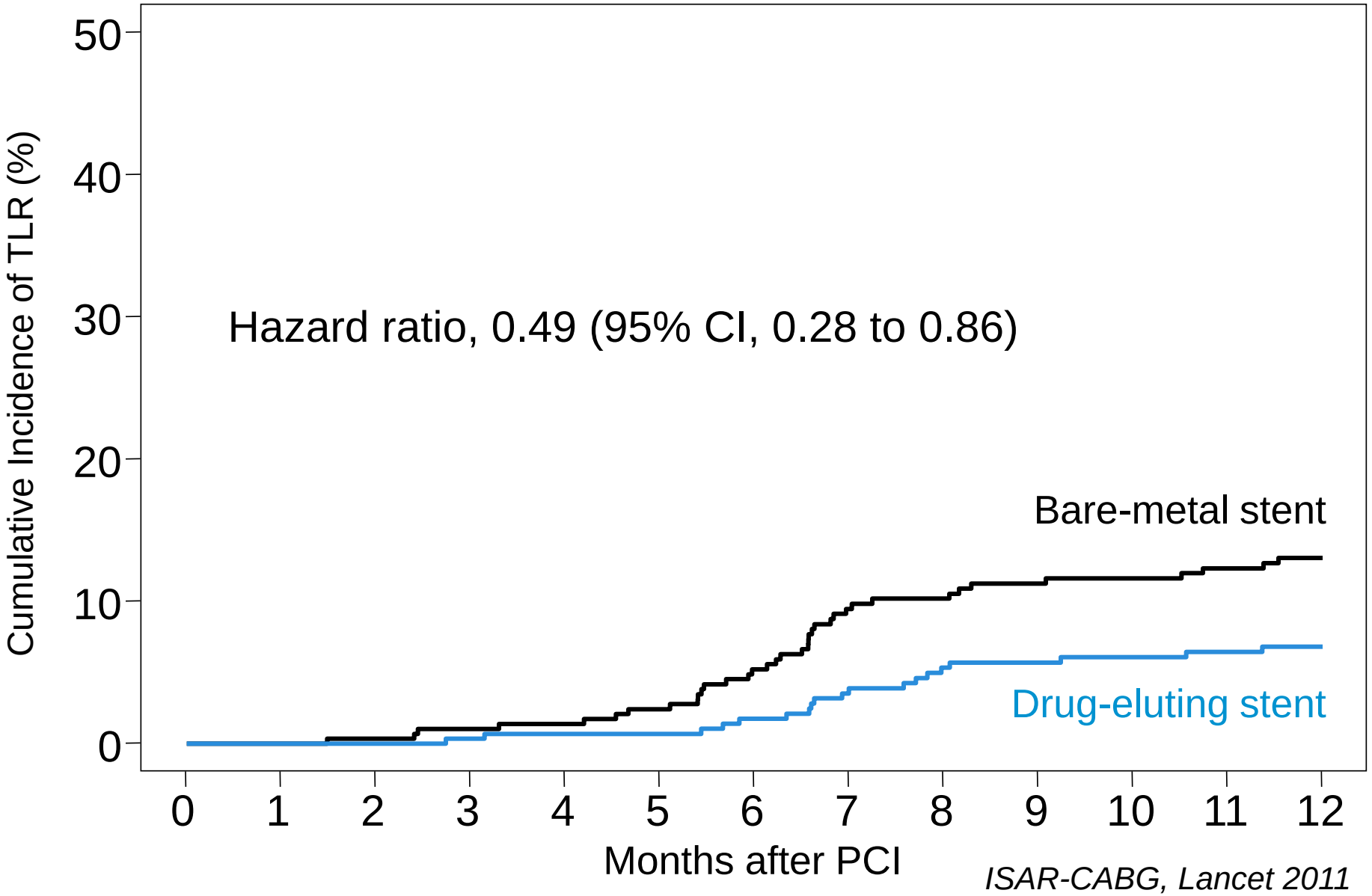
ISAR-CABG, Lancet 2011

ISAR-CABG
Death or myocardial infarction



ISAR-CABG, Lancet 2011

ISAR-CABG
Target-Lesion Revascularization



ISAR-CABG, Lancet 2011

ISAR-CABG Conclusions

Use of DES for treatment of de-novo venous graft lesions is associated with better clinical and angiographic outcomes up to 1 year after the procedure compared with BMS

The results of the ISAR-CABG trial suggest that DES might be as useful for treatment of saphenous vein graft failures as they are for lesions of native coronary vessels