Recurrent Revascularization After Treatment Of Drug-Eluting Stent Restenosis With Plain Balloon, Drug-Coated Balloon Or Drug-Eluting Stent

10-Year Results From the Randomized ISAR-DESIRE 3 Trial

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On behalf of the ISAR-DESIRE 3 investigators

October 26th, 2023

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Disclosure of Relevant Financial Relationships

I, Tobias Koch, DO NOT have any relevant financial relationships to disclose.

Faculty disclosure information can be found on the app

Background

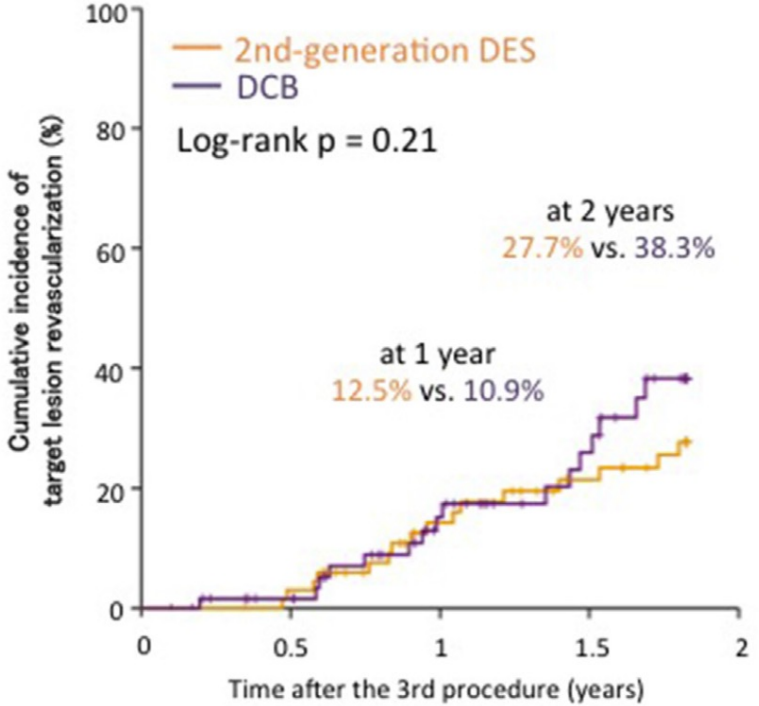
ESC Guidelines on Myocardial Revascularization 2018

Restenosis *		
DES are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379] *	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	IIa	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	IIa	C

*Neumann FJ, European Heart Journal 2019; 40: 87-165
*Byrne RA, Lancet, 2013; 381: 462-67

Background

- Rates of R-TLR are reported up to 40% after PCI of DES-ISR
- Long-term total revascularization event burden after PCI of DES-ISR are not investigated
- Recurrent events are censored in time-to-first-event analyses



Kawamoto H, JACC Cardiovasc Interv. 2015; 8(12):1586-94

R-TLR: repeat target lesion revascularization; DES-ISR: drug-eluting stent in-stent restenosis

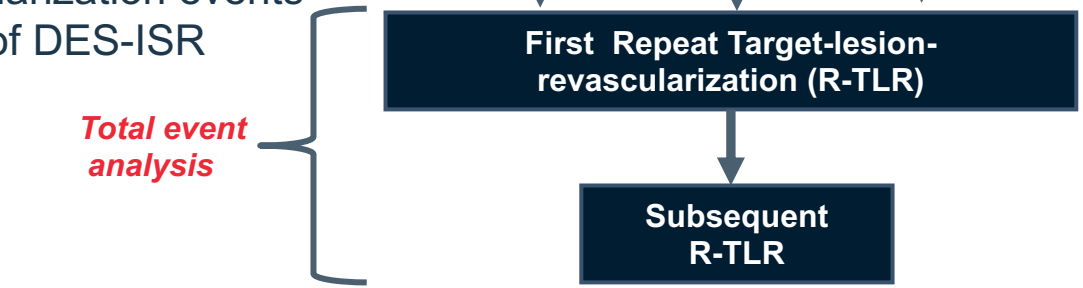
Study Flow

Total Events of ISAR-DESIRE 3 trial

- **DESIGN:** Total event analysis of the 10-years follow-up of a prospective, randomized, multi-center clinical trial evaluating the treatment of limus-eluting stent restenosis.

- **OBJECTIVE:** To investigate long-term incidence of recurrent revascularization events after percutaneous treatment of DES-ISR

Median Follow-Up
10.3 [25th-75th percentile, 9.5-10.6] years



Endpoints

Primary Endpoint

Total Revascularization Burden in terms of Repeat target lesion revascularization (R-TLR)

- Defined as any repeat revascularization procedure (PCI or CABG) of the index lesion

Secondary Endpoints

R-TLR according to

- randomized treatment arm
- no, single or multiple R-TLR

Baseline Patient Characteristics

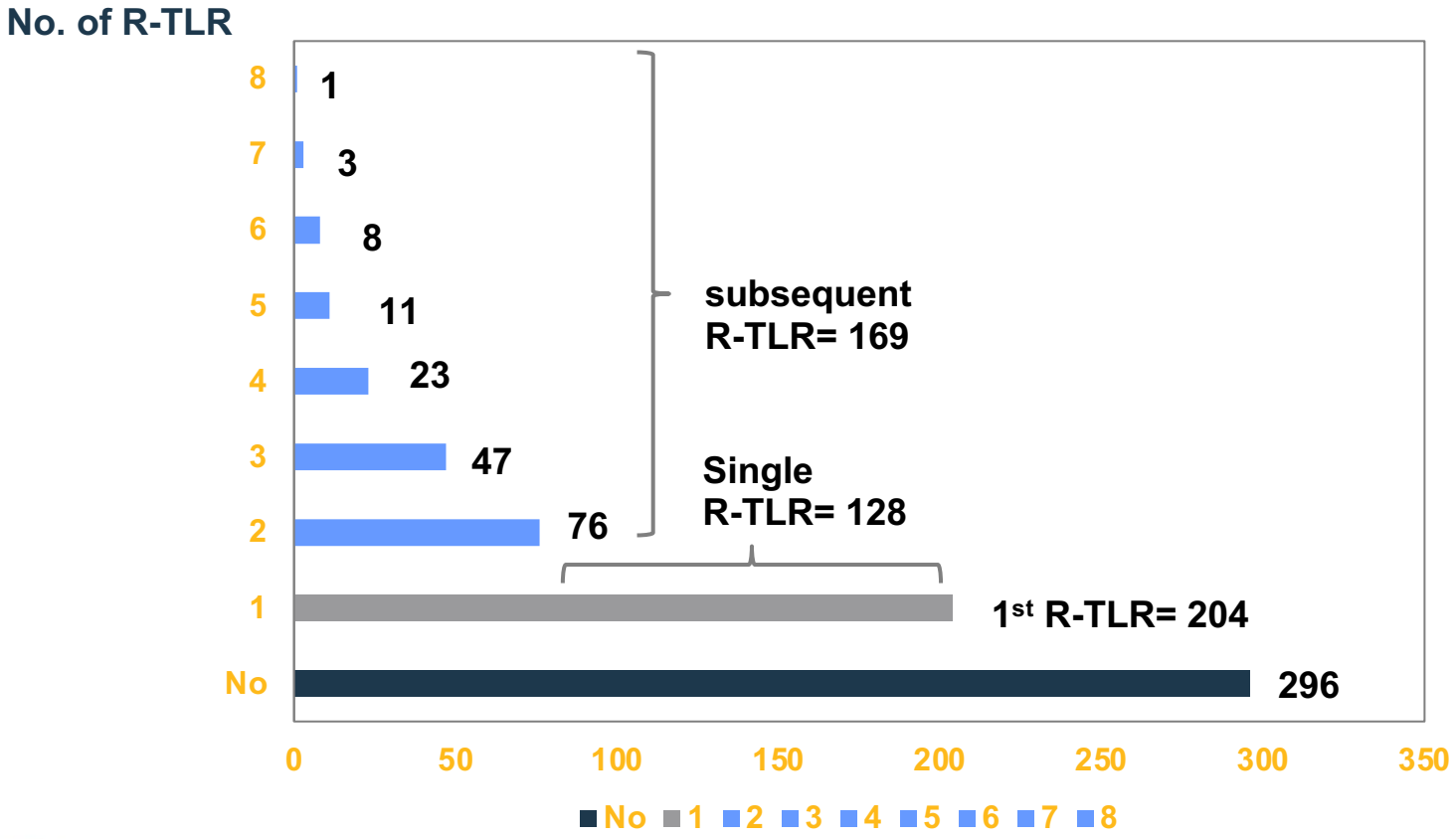
	Events, No. (%)			
Characteristic	No R-TLR (n=236)	Single R-TLR (n=106)	Multiple R-TLR (n=60)	p-Value
Treatment group				**0.005**
PB (n=134)	64 (27.1)	42 (39.6)	28 (46.7)	
DCB (n=137)	80 (33.9)	39 (36.8)	18 (30.0)	
DES (n=131)	92 (39.0)	25 (23.6)	14 (23.3)	
Age	68.7 (±9.77)	67.2 (±10.3)	66.0 (±9.86)	0.121
Male	162 (68.6)	83 (78.3)	43 (71.7)	0.187
Clinical presentation				**0.030**
Stable Angina	37 (15.7)	24 (22.6)	18 (30.0)	
Unstable Angina	199 (84.3)	82 (77.4)	42 (70.0)	
Multivessel Disease	221 (93.6)	101 (95.3)	56 (93.3)	0.848
Diabetes mellitus	96 (40.7)	45 (42.5)	26 (43.3)	0.910
Smokers	40 (16.9)	12 (11.3)	4 (6.7)	0.081
Hypertension	230 (97.5)	105 (99.1)	60 (100)	0.341
Hypercholesterinemia	186 (78.8)	75 (70.8)	52 (86.7)	0.052

Baseline Lesion Characteristics

	Lesions, No. (%)			
Characteristic	No R-TLR (n=296)	Single R-TLR (n=128)	Multiple R-TLR (n=76)	p-Value
Vessel				0.349
Left anterior descending	98 (33.1)	38 (29.7)	25 (32.9)	
Left circumflex	89 (30.1)	51 (39.8)	31 (40.8)	
Right coronary artery	108 (36.5)	39 (30.5)	20 (26.3)	
Left main	1 (0.3)	0 (0.0)	0 (0.0)	
Restenosis pattern				0.104
Focal	212 (71.6)	74 (57.8)	48 (63.2)	
Diffuse	70 (23.6)	43 (33.6)	25 (32.9)	
Proliferative	4 (1.4)	3 (2.3)	0 (0.0)	
Occlusive	10 (3.4)	8 (6.3)	3 (4.0)	
Bifurcational	64 (21.6)	43 (33.6)	17 (22.4)	**0.028**
Ostial	69 (23.3)	36 (28.1)	21 (27.6)	0.502
Multiple stent layers	47 (15.9)	27 (21.1)	23 (30.3)	**0.016**
Vessel size (mm)*	2.76 (±0.52)	2.78 (±0.45)	2.71 (±0.41)	0.551

*Data available for 497 lesions (99.4%)

Results for the Primary Endpoint R-TLR at 10 years



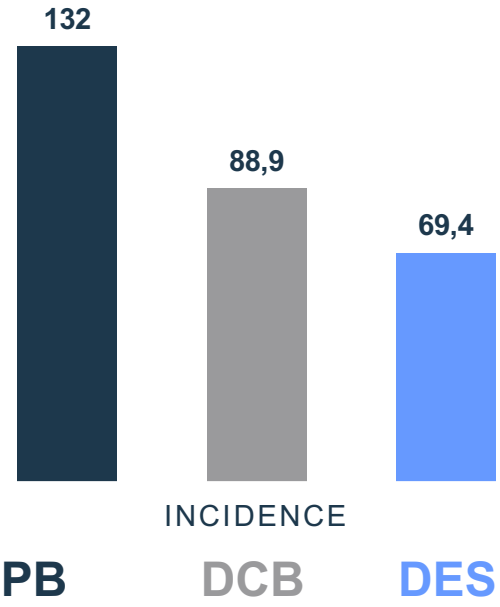
Values are absolute numbers; R-TLR: repeat target lesion revascularization

Results According to Randomized Treatment Group

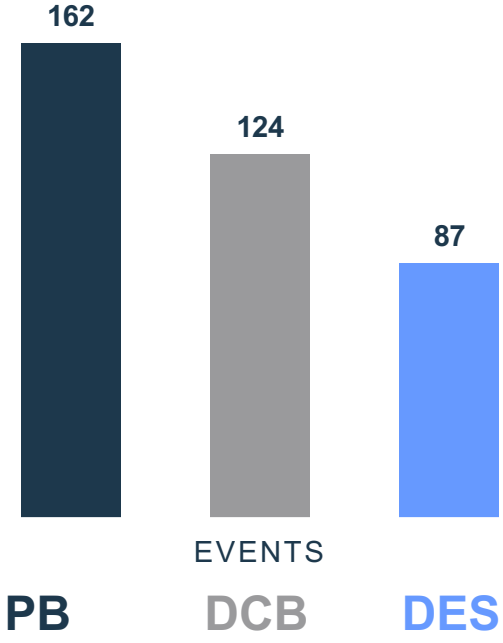
	Lesions, No. (%)			
	PB (n=160)	DCB (n=172)	DES (n=168)	p-Value
Frequency of R-TLR				0.003
No R-TLR	78 (48.8)	102 (59.3)	116 (69.0)	
Single R-TLR	47 (29.4)	47 (27.3)	34 (20.2)	
Multiple R-TLR	35 (21.9)	23 (13.4)	18 (10.7)	

Results According to Randomized Treatment Group

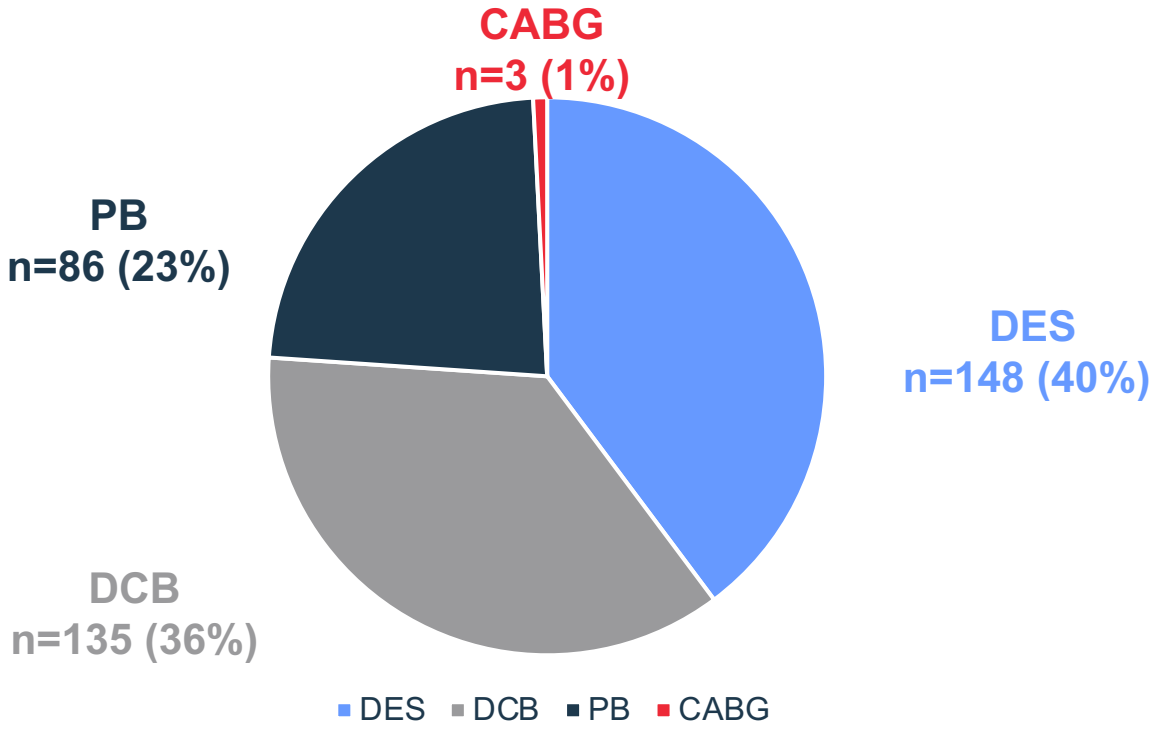
INCIDENCE PER 1000 PATIENT YEARS



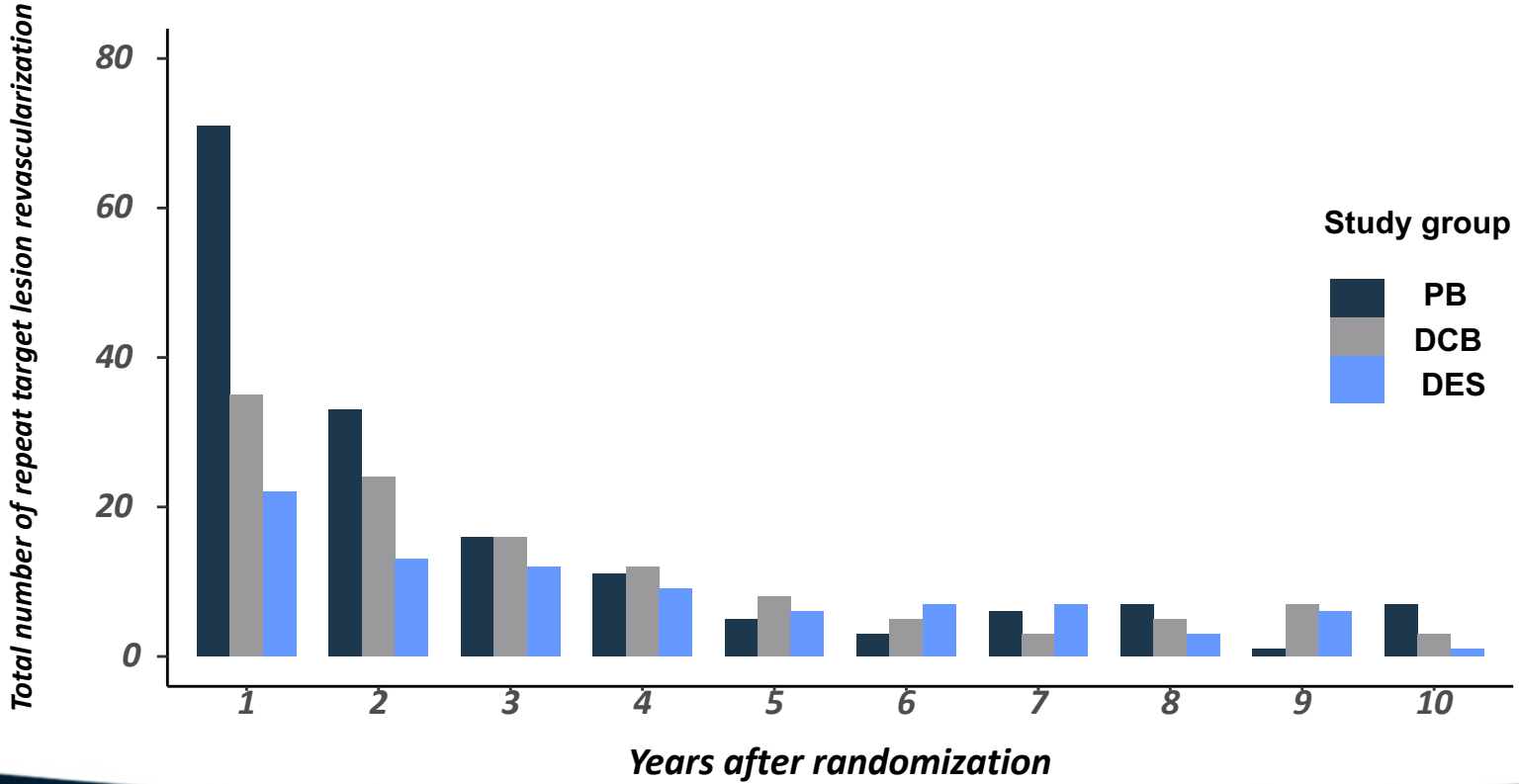
R-TLR EVENTS



Treatment strategies in Lesion with R-TLR

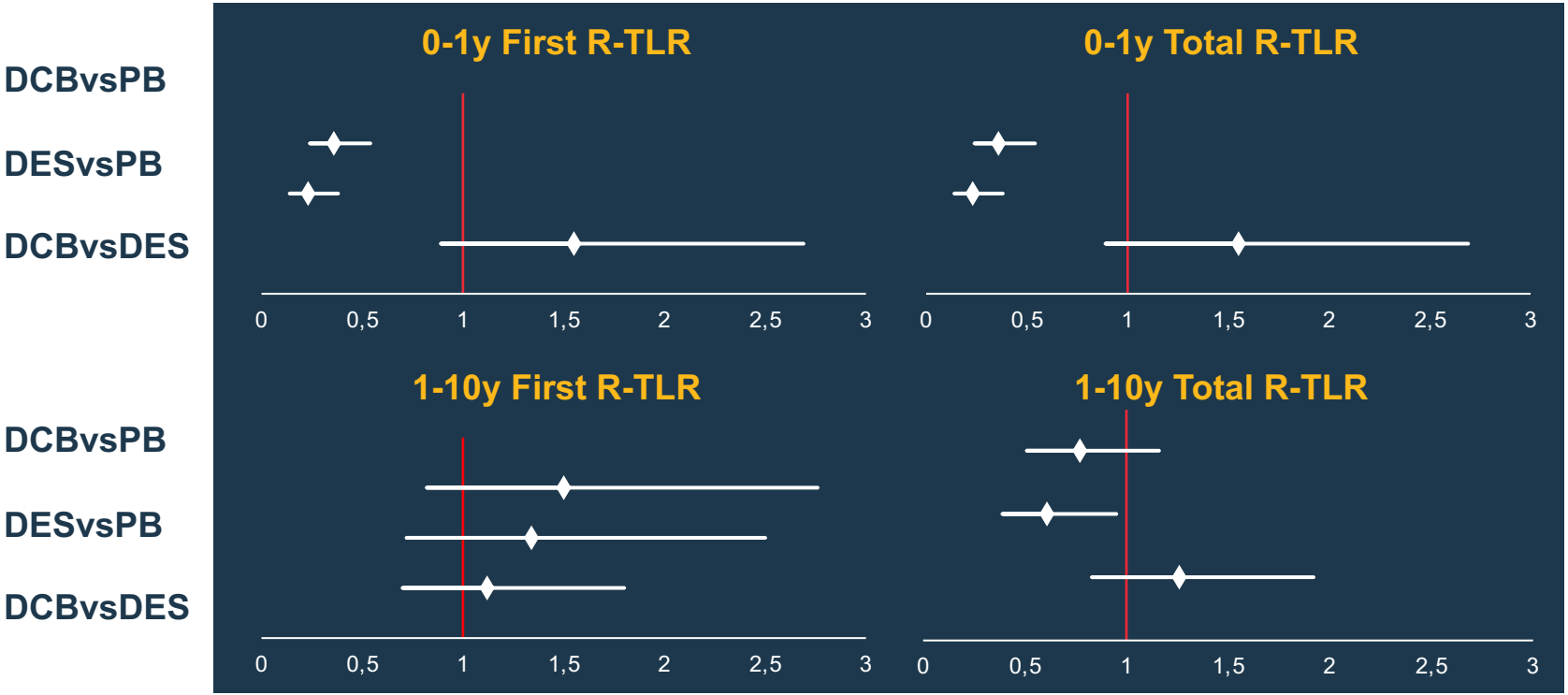


Total Number of Repeat Target Lesion Revascularizations According to Randomized Treatment Group



Values are absolute numbers; R-TLR: repeat target lesion revascularization; PB: plain balloon; DCB: drug-coated balloon; DES: drug-eluting stent

Results of the Lesion-based Analysis of the Effect of Treatment Arm on First and Total R-TLR



Conclusions I

- In patients undergoing percutaneous treatment of DES-ISR, recurrent restenosis occurred in one third of cases.
- 45% of R-TLR were subsequent recurrent events, not displayed in conventional time-to-first-event analyses

Conclusion II

- DCB and in particular DES are able reduce the need of both, first and recurrent revascularizations as compared with PB
- Addition of total R-TLR in the analysis enabled capturing of treatment effects over the entire 10-year follow-up that were not observable in the analysis confined to first R-TLR only

Acknowledgments

- Prof. Sebastian Kufner
- Prof. Adnan Kastrati
- Prof. Heribert Schunkert
- ISAResearch Center @ German Heart Center Munich

Simultaneous Publication

JACC: Cardiovascular Interventions