DCB Data @ Leipzig

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Disclosure

I have the following potential conflicts of interest to report:

- Consulting:
  - Abbott, Bard / BD, Cook, Cordis, Reflow Medical, Upstream Peripheral

Paclitaxel-Coated Balloons for the Treatment of Femoropopliteal Lesions

- What about the mortality-risk
- Which DCB to chose for the daily case
- DCBs for the typical long SFA-lesions
- How to follow the patient

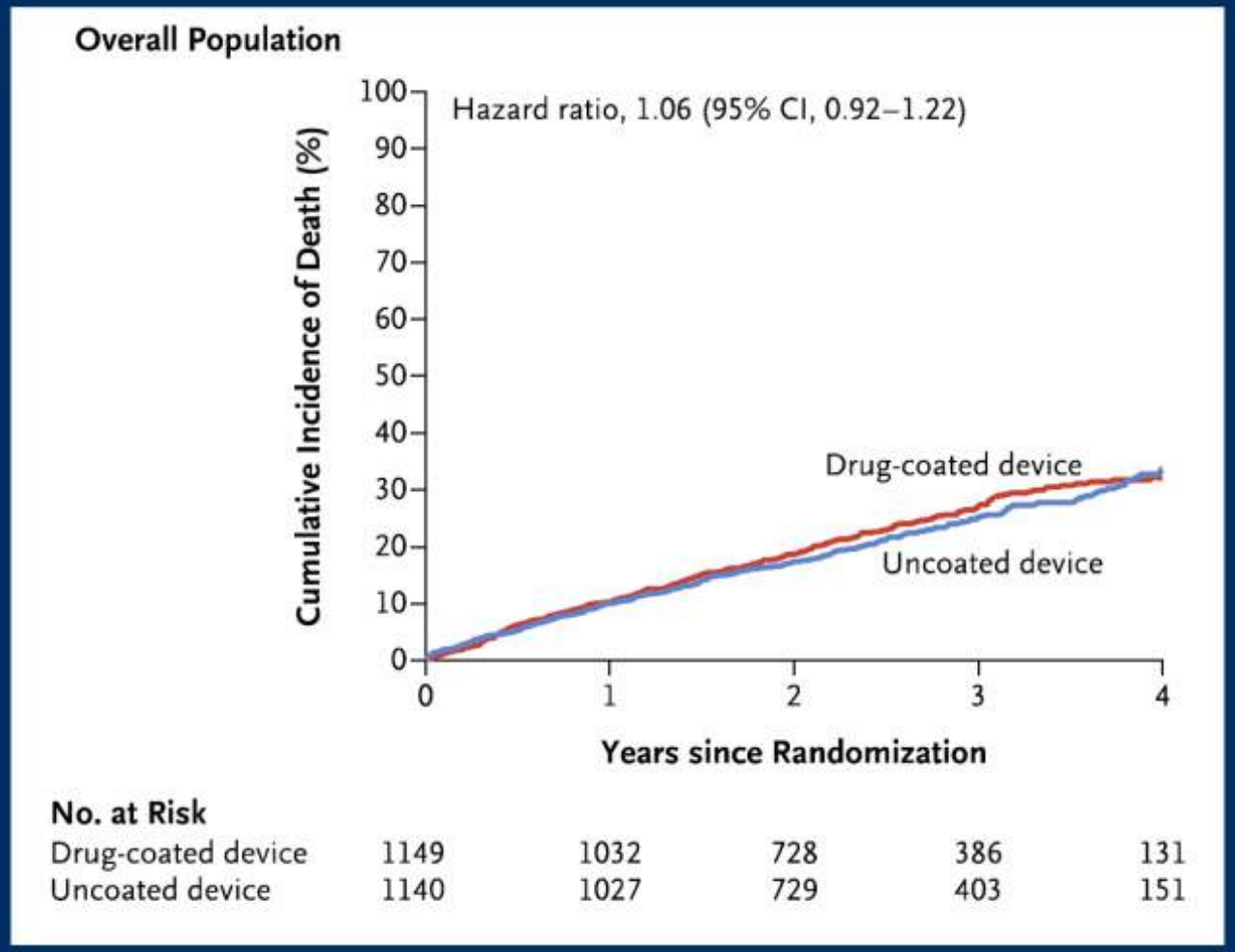
Insights on paclitaxel safety from the femoral-popliteal RCTs

SWEDEPAD RCT

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Mortality with Paclitaxel-Coated Devices in Peripheral Artery Disease



2289 patients up to 4 years F/U
Paclitaxel vs plain device
CLTI 1480, claudication 809
Femoral-popliteal target lesion >80%
Lost to follow up 0
Overall mortality:
drug-10.2% vs non-drug-9.9% (HR 1.06)

Most frequently used DCB: Lutonix (41.1%)

Nordanstig et al N Engl J Med 2020, Dec 9, DOI: 10.1056

COMPARE RCT: Study objectives

Study aim	To compare high dose vs. low dose paclitaxel coated balloons for the treatment of high grade stenotic or occluded femoropopliteal lesions
Patient population	Patients with Rutherford class 2-4
Principal investigator	Dierk Scheinert, MD; University of Leipzig
Study sites	15 sites in Germany

Investigational Device

Low dose DCB: Ranger™
Paclitaxel Dose: 2.0µg/mm^2
TransPax coating; Excipient: Citrate ester

Control Device

High dose DCB: IN.PACT Admiral™/ IN.PACT Pacific™
Paclitaxel Dose: 3.5µg/mm^2
FreePac™ hydrophilic coating; Excipient: Urea

COMPARE RCT Study Design and Methods

Study Design	➢ Investigator-initiated, prospective, multicenter, **non-inferiority** trial ➢ 414 patients undergoing 1:1 randomization ➢ Stratification according to lesion length ➢ Independent monitoring; 100% source data verification ➢ Independent corelab for angio and duplex ➢ Clinical events committee
Funding	➢ Study sponsor: University of Leipzig ➢ Funding through a research grant from Boston Scientific ➢ Funding source not involved in collecting, monitoring and analysing study data
Follow-up	➢ In-house visits: 6, 12, **24 months (efficacy and safety)** ➢ Telephone calls: 1 month, 36, 48, 60 months (safety)

This investigator-sponsored study is supported by grant funding from Boston Scientific. Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators.

Key baseline characteristics

		Low dose DCB (n=207)	High dose DCB (n=207)	P value
Demographics	Age (years)	68.2 ± 10.0	68.4 ± 9.3	0.79
	Female gender	79 (38.2)	75 (36.2)	0.68
	Rutherford class (RC) ≥ 3	184 (88.9)	176 (85)	0.56
	Diabetes mellitus	63 (30.6)	76 (36.9)	0.18
	Previous/current smoking	160 (77.3)	155 (74.9)	0.63
Lesion	Lesion length (mm)	123.9±97.8	128.3±97.3	0.65
	Total occlusions (n (%))	84 (40.6)	89 (43)	0.62
	Calcification* PACSS 3-4	105 (50.5)	117 (57.1)	0.80
	0-1 run off vessels	75 (38.5)	71 (36.6)	0.89
Procedural	Total paclitaxel dose (µg)	6971±4026	13035±7483	<0.0001
	Bail-out stenting	62 (30.0)	53 (25.6)	0.32
	Type E-F Dissection	4 (2.0)	2 (1)	0.61
	Diameter stenosis pp (%)	26.4±12.5	26.1±12.5	0.8
	Residual stenosis ≥ 30%	74 (35.8)	81 (39.1)	0.48

Data are given as mean±std or number (%).

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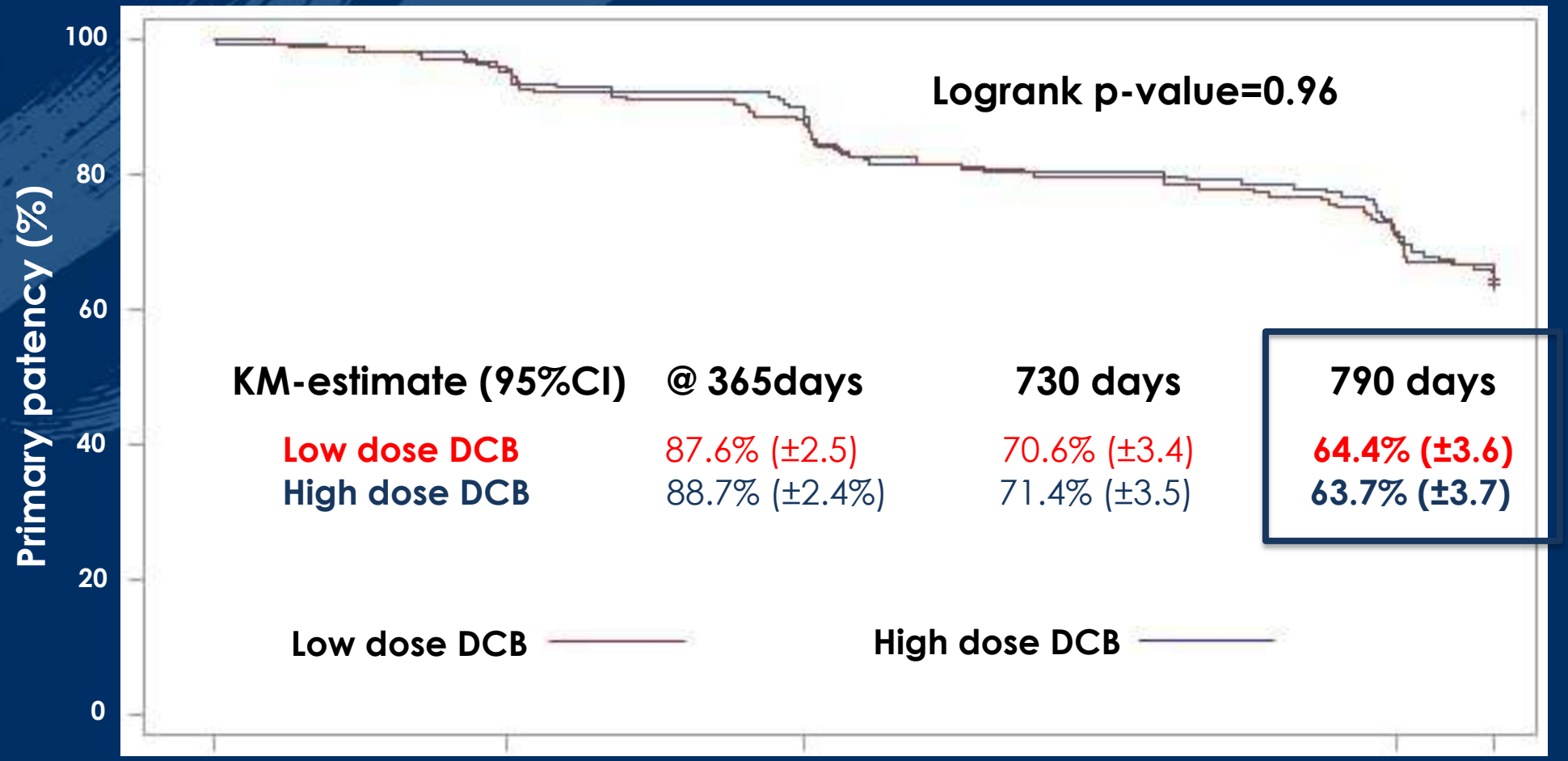
COMPARE: Primary patency through 790 days

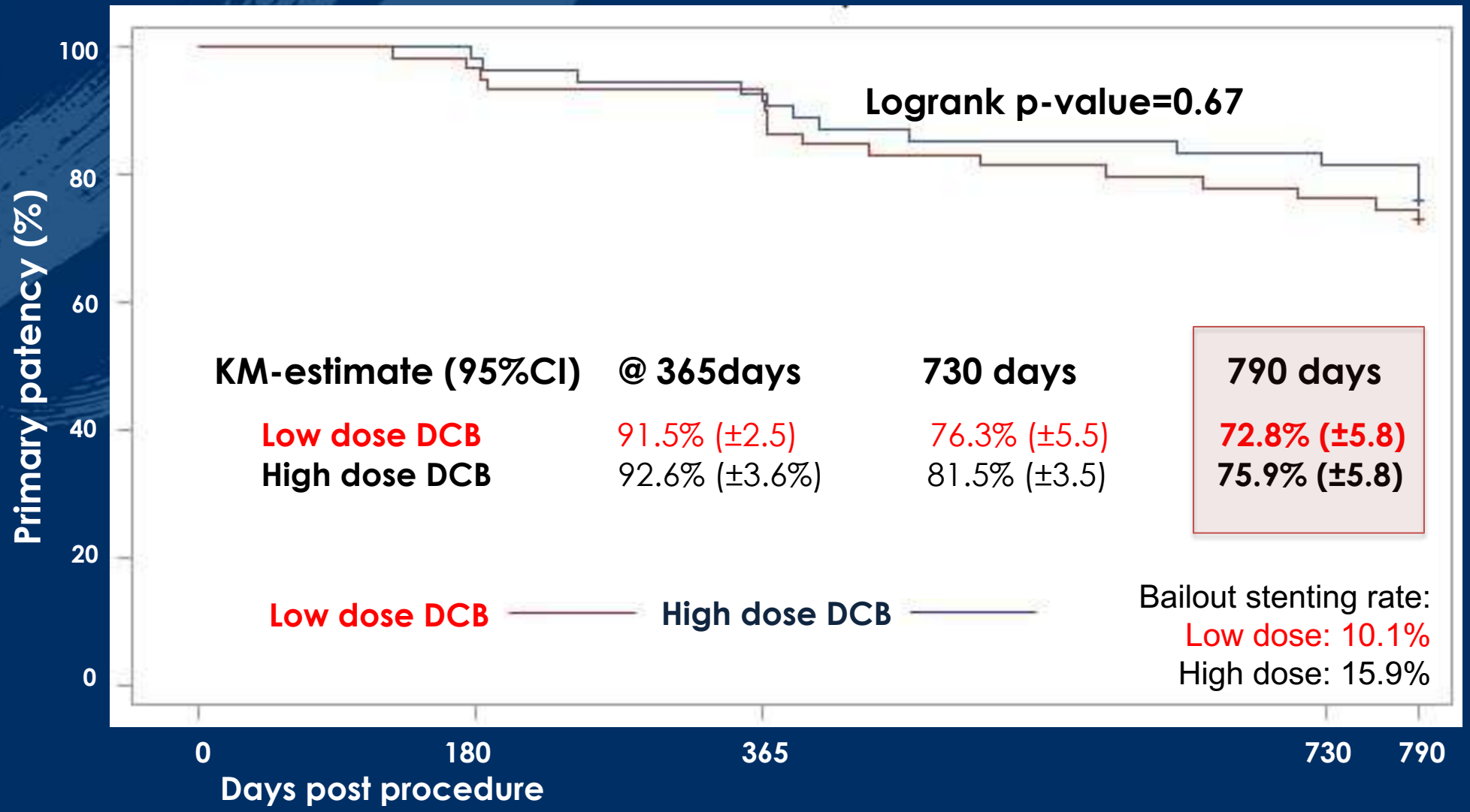
High dose DCB (In.Pact) vs. Low dose DCB (Ranger), n=414



Patients without an event at 790 days of follow-up or later were censored at 790 days.

Sabine Steiner, LINC 2021

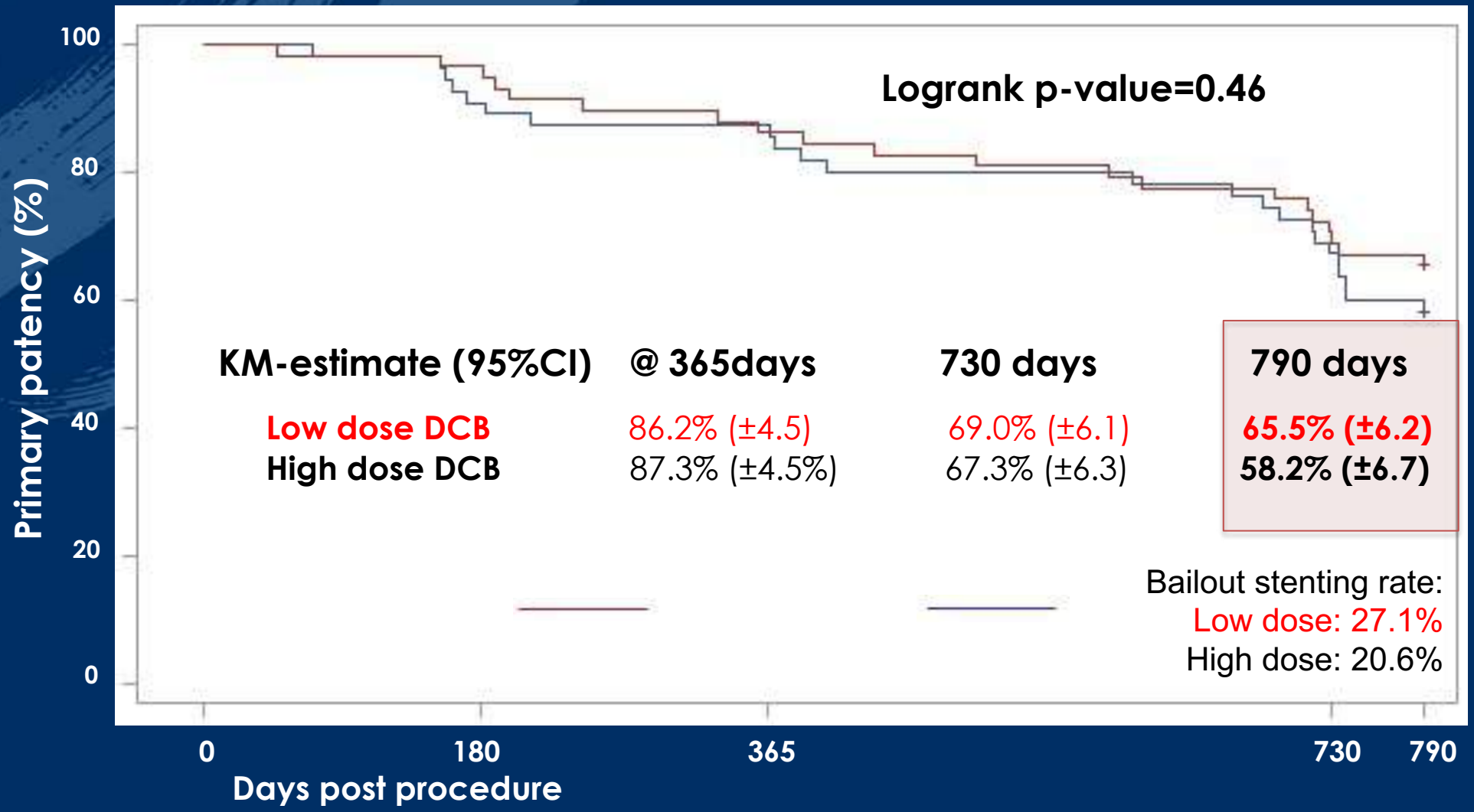
Primary patency – short lesions ≤10cm



Patients without an event at 790 days of follow-up or later were censored at 790 days.

Sabine Steiner, LINC 2021

Primary patency – middle lesions >10cm - ≤20cm



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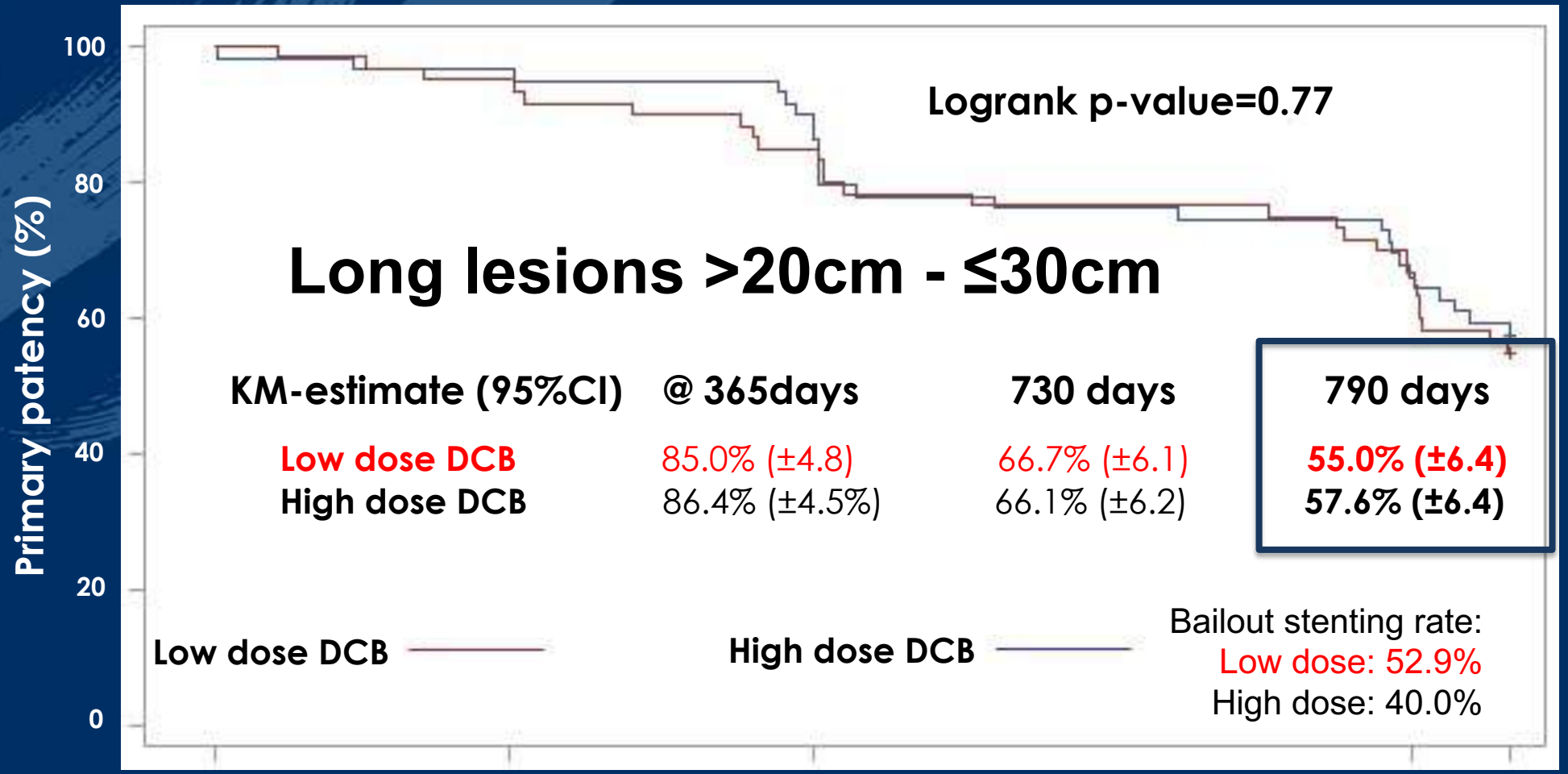

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Sabine Steiner, LINC 2021

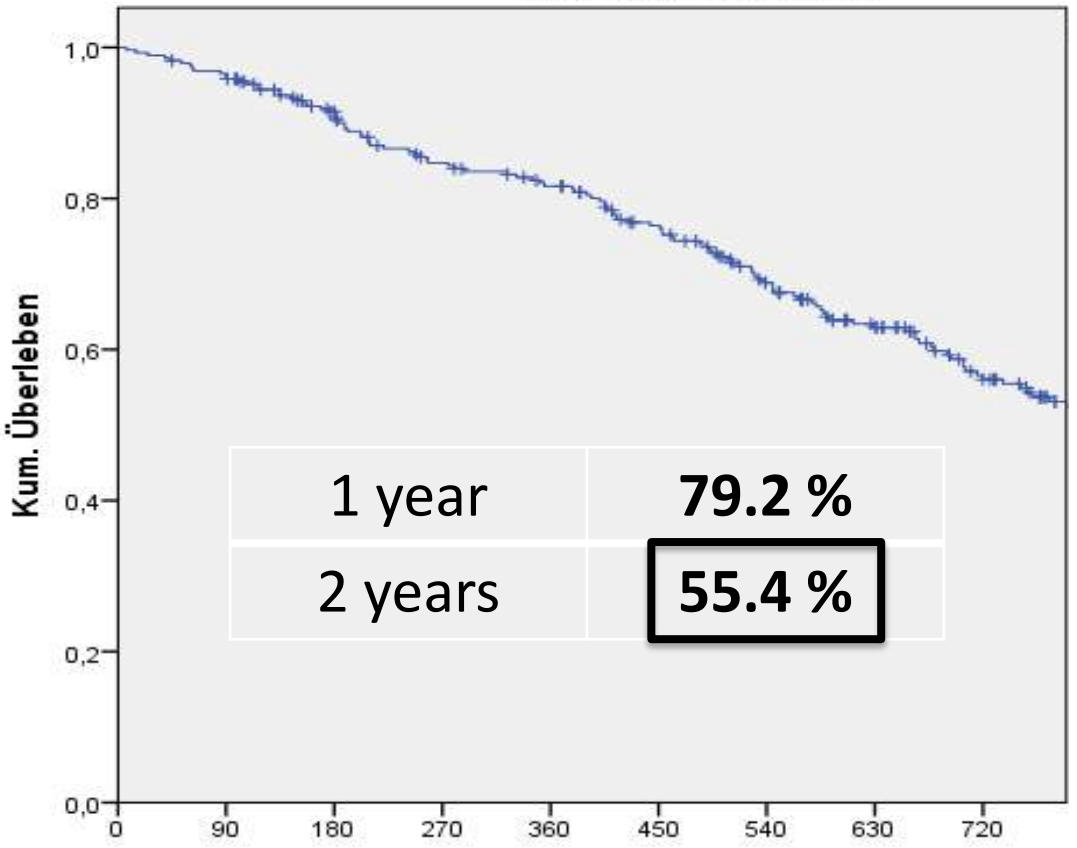
DCBs for long complex femoropopliteal lesions

2-year results DCBs
for complex SFA-lesions

- 288 fempop-lesions
- In.Pact DCB
- Lesion-length 24.0 ± 10.2 cm
- CTOs in 65.3 %

- Bail-out stenting in 23.3 %

Kaplan-Meier primary patency



Days FU	0	180	360	540	720
N at risk	288	246	209	157	103

Schmidt A et al. *JACC* Cardiovasc Intervent 2016

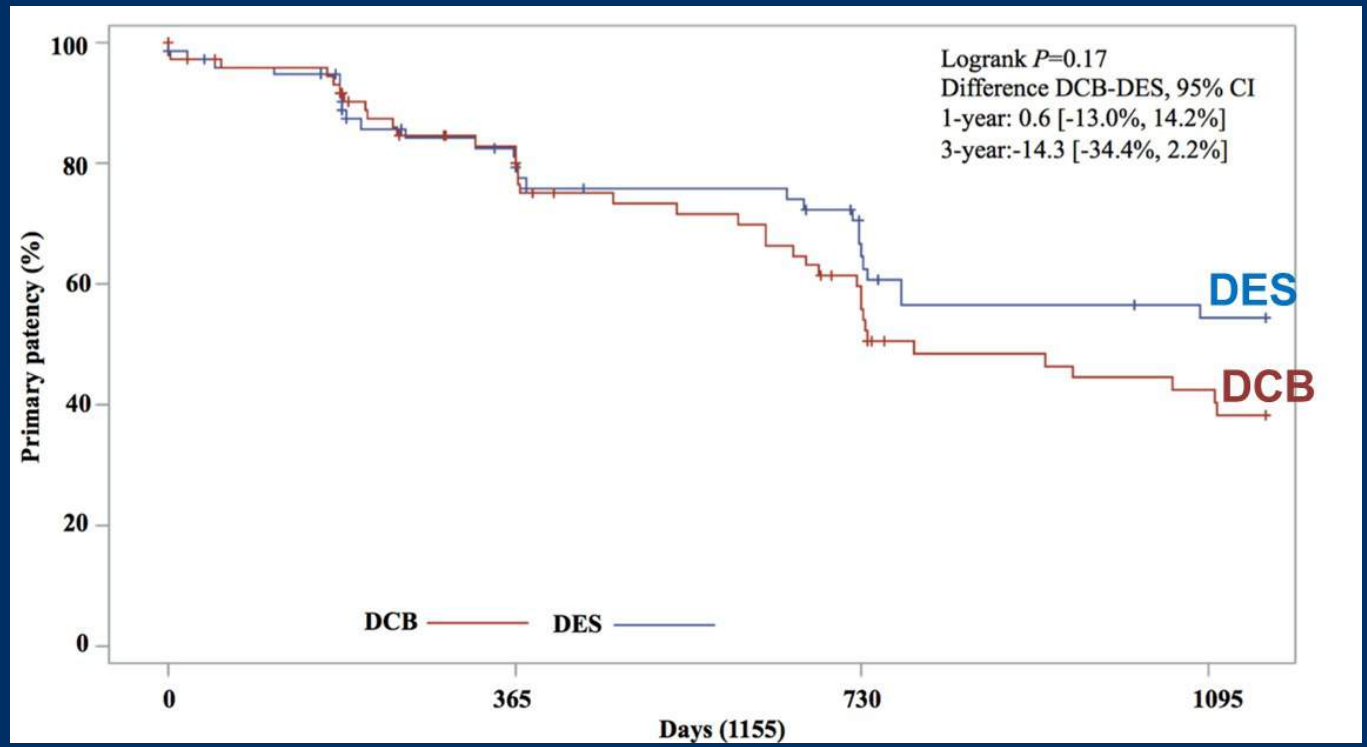
Drug-Eluting Stent Versus Drug-Coated Balloon Revascularization in Patients With Femoropopliteal Arterial Disease

Yvonne Bausback, MD,[a] Tim Wittig, MD,[a] Andrej Schmidt, MD,[a] Thomas Zeller, MD,[b] Marc Bosiers, MD,[c] Patrick Peeters, MD,[d] Steffen Brucks, MD,[e] Aaron E. Lottes, PHD,[f] Dierk Scheinert, MD,[a] Sabine Steiner, MD[a]

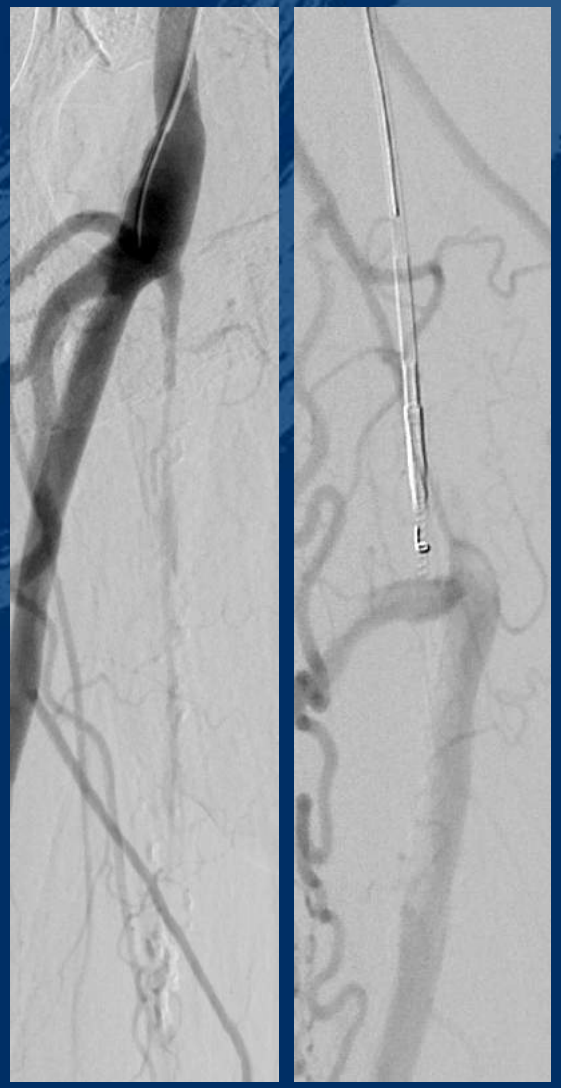
J Am Coll Cardiol 2019

- Multicenter RCT (REAL-PTX)
- 150 patients 1:1 DCB vs. Zilver-PTX
- Femoropoplitea lesions ≤ 30cm

Lesion Characteristics		
	DCB (n=75)	DES (n=75)
Lesion length, mm	149.7 ± 87.4	155.5 ± 89.4
CTOs	40 (53.3)	39 (52.0)



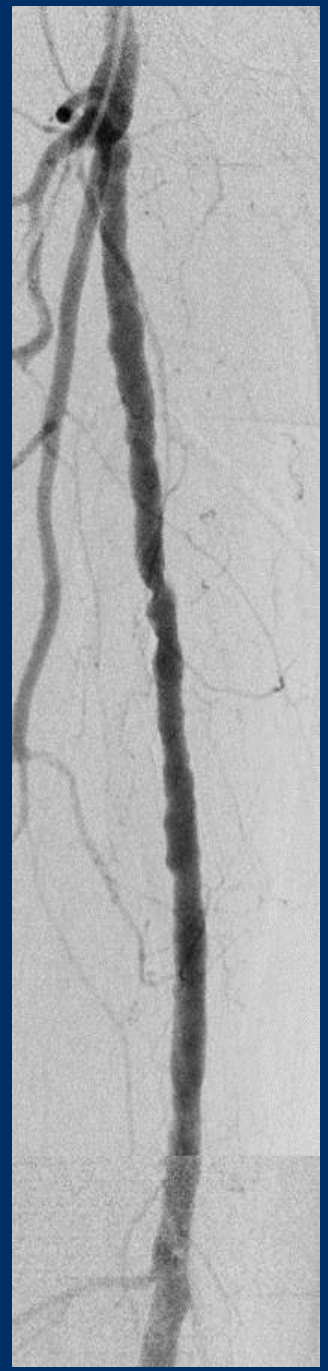
DCB for Long SFA-Lesions



Subintimal reca with Outback

After
DCB-treatment

15 mo
result

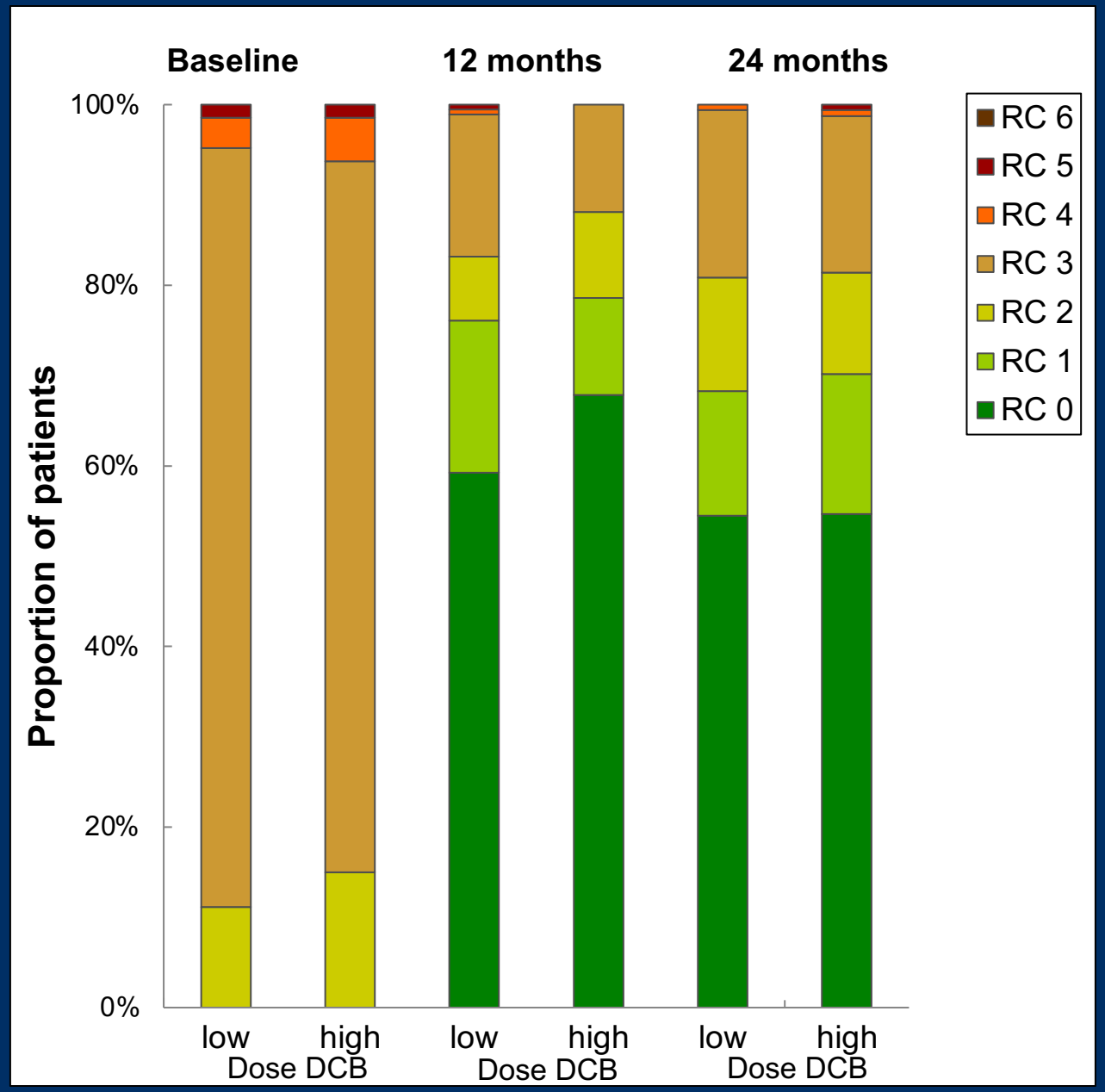


Follow-Up after DCB-Treatment of Femoropopliteal Lesions

- Patency
- Freedom from TLR
- Subjective QoL-outcomes

Compare RCT: Distribution of Rutherford categories

≈70% of patients with no or minimal symptoms @ 2y



Real World Comparison of In.Pact vs. LUTONIX DCB in Complex Femoropopliteal Lesions

Sabine Steiner, University Hospital Leipzig, Angiology

- Retrospective, non-randomized monocenter cohort study
- Symptomatic PAD patients undergoing femoropopliteal intervention with:
  - In.Pact™ DCB (Admiral/Pacific) or
  - LUTONIX® 035 DCB
- Clinical follow up:
  - Deaths
  - Target lesion revascularization
  - Rutherford stage

Real World Comparison of In.Pact vs. LUTONIX DCB in Complex Femoropopliteal Lesions

Sabine Steiner, University Hospital Leipzig, Angiology

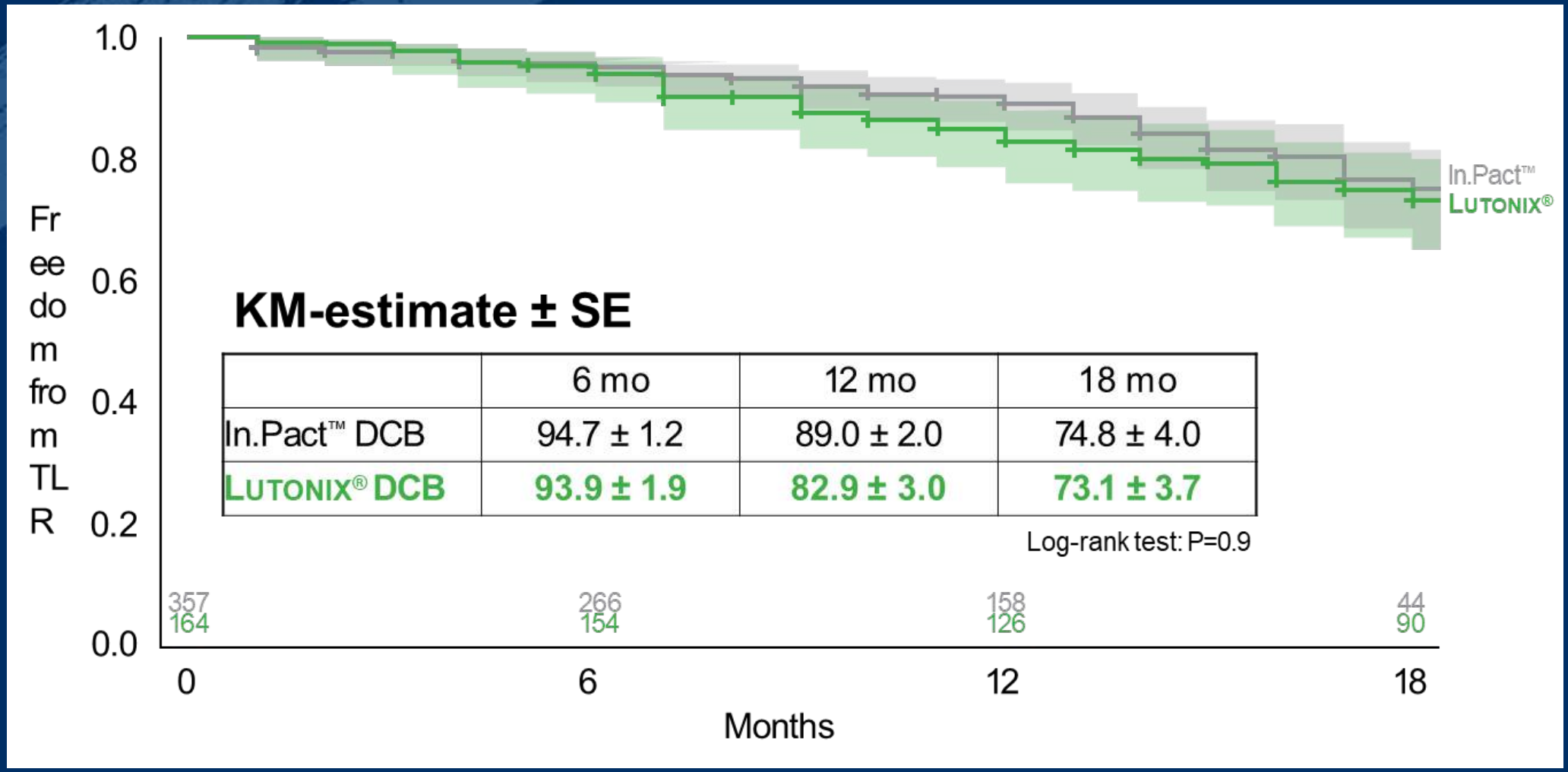
	In.Pact™ DCB (n=281)	LUTONIX® DCB (n=137)	P-Value
Age, years	68.9 ± 10.3	68.6 ± 10.0	0.91
Female, %	29.8	33.7	0.5
Rutherford stage, %	3.0 ± 0.8	3.0 ± 0.8	0.71
Hypertension, %	98	98	0.8
Hyperlipidemia, %	74	61	0.02
Obesity (BMI>30 kg/m^2),%	15	9	0.1
Diabetes: NIDDM, %	23	18	0.4
IDDM, %	20	23	
Current/former smoking, %	52	48	0.6
Coronary heart disease, %	23	34	0.01
Cerebrovascular disease, %	12	12	0.9

Real World Comparison of In.Pact vs. LUTONIX DCB in Complex Femoropopliteal Lesions

	In.Pact™ DCB (n=366)	LUTONIX® DCB (n=168)	P-Value
Cumulative device length (mm)	291 ± 124	280 ± 116	0.31
Run-off vessel	2.2 ± 0.9	2.0 ± 0.9	0.05
In-stent restenosis	17	18	0.8
Treatment of vessel occlusion, %	46	40	0.18
Dissection post PTA, &	45	39	0.19
Stent implantation, %	52	47	0.32
Inflow intervention, %	6	7	0.84
Atherectomy/thrombectomy, %	37	26	0.02
Popliteal artery treated, %	0.5	1	9

Real World Comparison of In.Pact vs. LUTONIX DCB in Complex Femoropopliteal Lesions

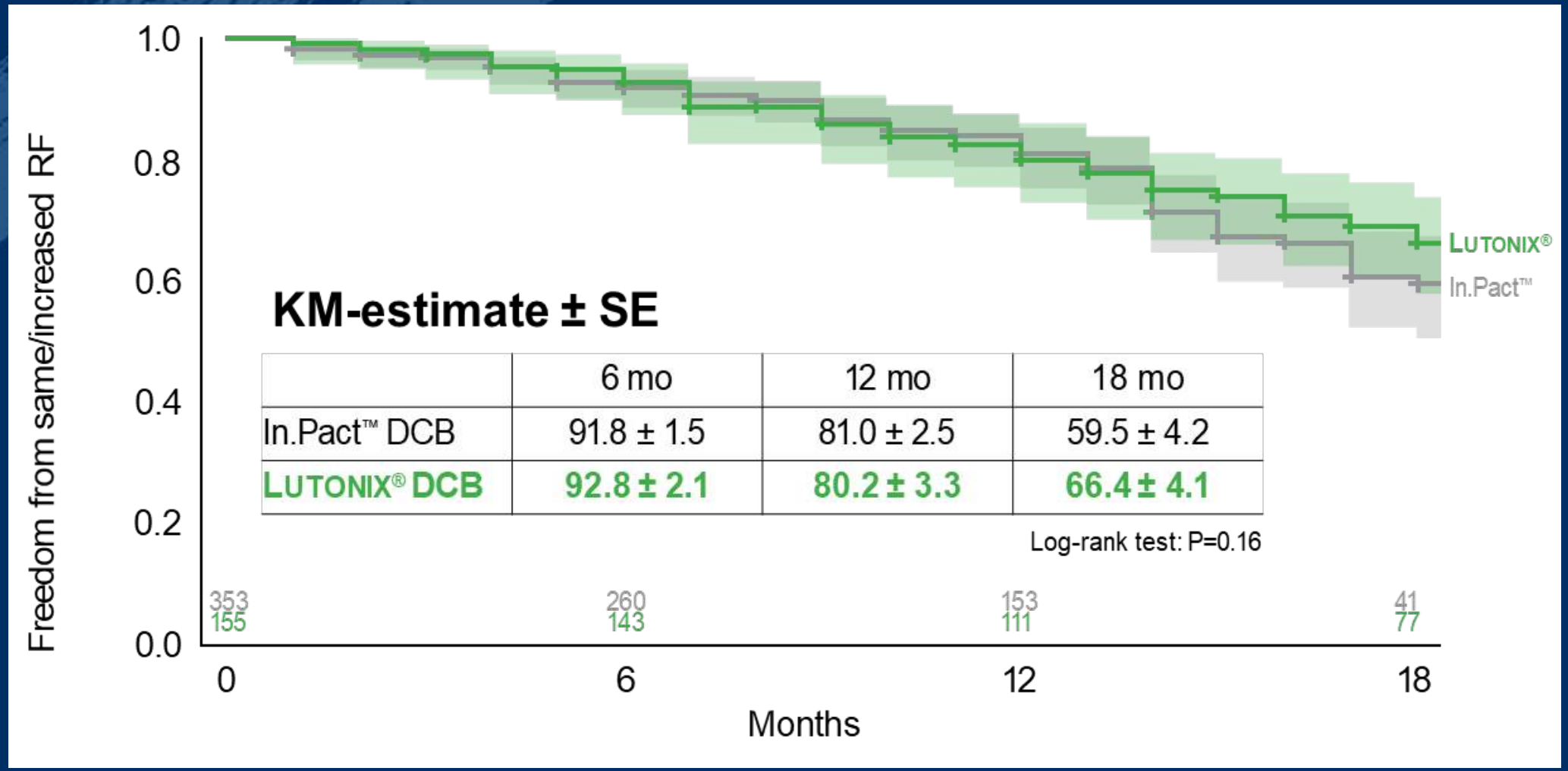
Freedom from Target Lesion Revascularization



	6 mo	12 mo	18 mo
In.Pact™ DCB	94.7 ± 1.2	89.0 ± 2.0	74.8 ± 4.0
LUTONIX® DCB	93.9 ± 1.9	82.9 ± 3.0	73.1 ± 3.7

Real World Comparison of In.Pact vs. LUTONIX DCB in Complex Femoropopliteal Lesions

Sustained Clinical Improvement



	6 mo	12 mo	18 mo
In.Pact™ DCB	91.8 ± 1.5	81.0 ± 2.5	59.5 ± 4.2
LUTONIX® DCB	92.8 ± 2.1	80.2 ± 3.3	66.4 ± 4.1

Which PTX-Balloon to prefer in daily practice ?

- Not possible to judge based on existing data

- Low-dose PTX-DCBs can be as good as high-dose DCBs

- Need for more independent head-to-head comparisons