Final 5 year results from the COMPARE trial on low-dose versus high-dose PCB

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Disclosures

Speaker name:
Dierk Scheinert.....
I have the following potential conflicts of interest to report:
☑ Consulting: Abbott, Acotec, Boston Scientific, Concept Medical,
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s):

☐ I do not have any potential conflict of interest

COMPARE RCT: Study design

Prospective, multicenter, German, investigator-initiated (PI: Dierk Scheinert), non-inferiority trial comprising 414 patients with femoropopliteal lesions; stratification for lesion length; 1:1 randomization to high-dose versus low-dose DCB
Core lab adjudication of angios and duplex ultrasound.; 100% source data verification

Investigational Device
Low dose DCB: Ranger™
Paclitaxel Dose: 2.0µg/mm²
TransPax coating; Excipient: Citrate ester

Control Device
High dose DCB: IN.PACT Admiral™/ IN.PACT Pacific™
Paclitaxel Dose: 3.5µg/mm²
FreePac™ hydrophilic coating; Excipient: Urea

Follow-up
- In-house visits: 6, 12, 24 months
- Telephone FU for safety: 36, 48, 60 months

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	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 (%).

Primary endpoint analysis at 12 months

Efficacy: Primary patency

DCB Low dose	DCB High dose	Δ (two-sided 90% lower bound)	P non-inferiority
83% (156/188)	81.5% (141/173)	1.5% (-5.2%)	<0.01

Non-inferiority met

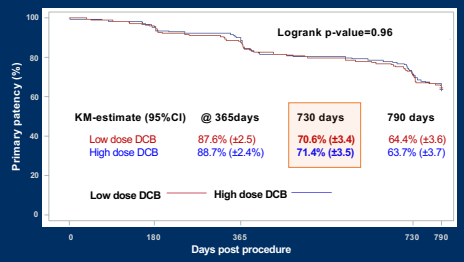
Safety: Freedom from MAE

DCB Low dose	DCB High dose	Δ (two-sided 90% lower bound)	P non-inferiority
91% (182/200)	92.6% (175/189)	-1.6% (-6.5%)	<0.01

Non-inferiority met

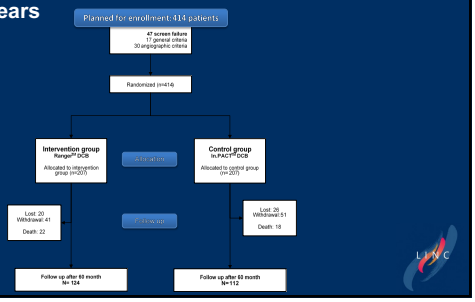
Steiner S et al. Eur Heart J 2020;41(27):2541-2552

Primary patency through 790 days

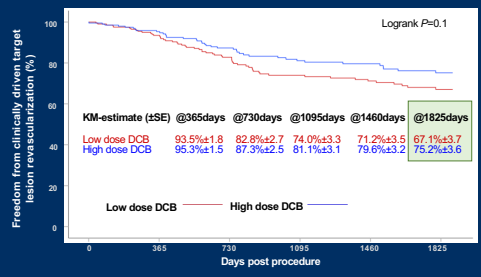


Steiner S et al. JACC CI 2022;15:2092-2102

Safety follow-up: Patient flow diagram through 5 years

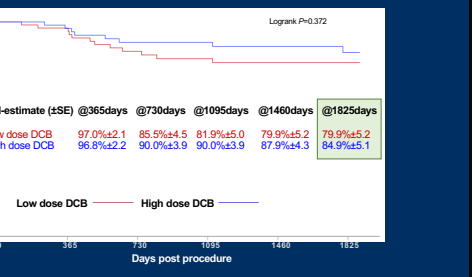


CD-TLR @ 5 years



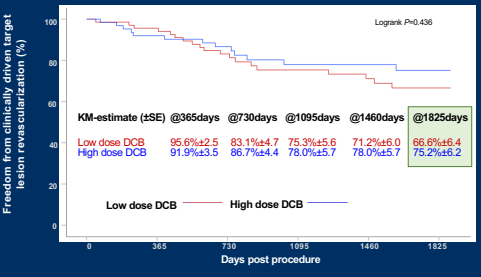
KM-estimate (±SE)	@365days	@730days	@1095days	@1460days	@1825days
Low dose DCB	93.5%±1.8	82.8%±2.7	74.0%±3.3	71.2%±3.5	67.1%±3.7
High dose DCB	95.3%±1.5	87.3%±2.5	81.1%±3.1	79.6%±3.2	75.2%±3.6

CD-TLR @ 5 years – short lesions



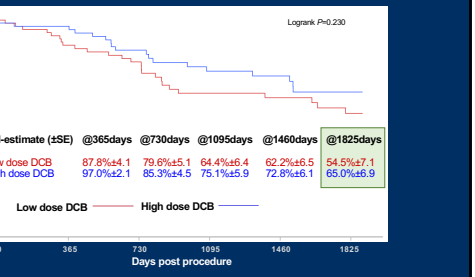
KM-estimate (±SE)	@365days	@730days	@1095days	@1460days	@1825days
Low dose DCB	97.0%±2.1	85.5%±4.5	81.9%±5.0	79.9%±5.2	79.9%±5.2
High dose DCB	96.8%±2.2	90.0%±3.9	90.0%±3.9	87.9%±4.3	84.9%±5.1

CD-TLR @ 5 years – middle lesions



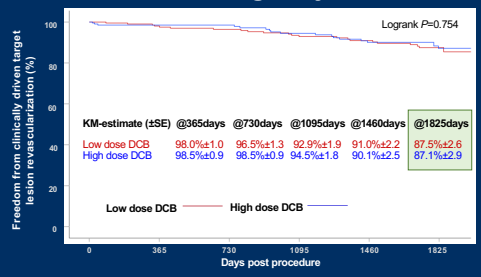
KM-estimate (±SE)	@365days	@730days	@1095days	@1460days	@1825days
Low dose DCB	95.6%±2.5	83.1%±4.7	75.3%±5.6	71.2%±6.0	66.6%±6.4
High dose DCB	91.9%±3.5	86.7%±4.4	78.0%±5.7	78.0%±5.7	75.2%±6.2

CD-TLR @ 5 years – long lesions



KM-estimate (±SE)	@365days	@730days	@1095days	@1460days	@1825days
Low dose DCB	87.8%±4.1	79.6%±5.1	64.4%±6.4	62.2%±6.5	54.5%±7.1
High dose DCB	97.0%±2.1	85.3%±4.5	75.1%±5.9	72.8%±6.1	65.0%±6.9

All cause death through 5 years



KM-estimate (±SE)	@365days	@730days	@1095days	@1460days	@1825days
Low dose DCB	98.0%±1.0	96.5%±1.3	92.9%±1.9	91.0%±2.2	87.5%±2.6
High dose DCB	98.5%±0.9	98.5%±0.9	94.5%±1.8	90.1%±2.5	87.1%±2.9

Key safety outcomes through 5 years

	Low dose DCB (n=207)	High dose DCB (n=207)	P values
60-Months MAE-Free*	63.6% (98/154)	71.7% (99/138)	0.135
All-cause mortality	15.1 (22/146)	14.0% (18/129)	0.865
Device or procedure-related death	0	0	1.0
Major amputation	0% (0/121)	0.9% (1/108)	1.0
Clinically driven TLR	35.9% (55/153)	27.5% (38/138)	0.133
All TLR*	36.4% (56/154)	28.3% (39/138)	0.169

Values are percentage (n/N). The numerator is the number of subjects with events prior to the close of the visit window. The denominator includes subjects with events or those without events having follow-up on or past the opening of the visit window.
*Includes clinically-driven TLR and duplex-driven/incidental TLR.
§ P-values based on Fisher's-exact test.

Summary

- First head-to-head comparison of two DCBs with different paclitaxel dosages and coating technologies for femoropopliteal interventions
- Complex real world lesion subset with high proportion of CTOs >40%
- Non-inferiority was met for primary efficacy and safety @1 y
- Patency rates overlapping through 2 years, no significant differences for CD-TLR through 5 years with overall low reinterventions rates dependent on lesion length stratum
- No signal for increased mortality or amputations