COMPARE-Pilot RCT:

1-year results of a randomised comparison of RANGER DCB vs. IN.PACT DCB in complex SFA lesions

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Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:

Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

Study objective

First Head-to-Head RCT to compare two different Paclitaxel coated balloons (with different coatings and different paclitaxel dose density) in the treatment of patients with symptomatic femoropopliteal peripheral arterial disease

Investigational device:

Ranger Paclitaxel Coated PTA Balloon Catheter

(Acetyl tri-*n*-butyl citrate coating, Paclitaxel dose 2µg/mm^2)

Control device:

IN.PACT Admiral or IN.PACT Pacific Drug Eluting Balloon

(Urea coating, Paclitaxel dose 3.5µg/mm^2)

Study Set-up

- Investigator Initiated Trial (IIT)
- Principal Investigator: Prof. Dierk Scheinert
- Study sponsor: University of Leipzig
- Funded through a research grant of Boston Scientific

- Independent monitoring with 100% source data verification
- Independent corelab for angio and duplex
- Clinical events committee

Study Design

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (up to 414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months

- Protocol pre-specified interim analysis of the first 150 patients (COMPARE Pilot) after 12 months of follow-up
  -> Presented today

Study Sites COMPARE Pilot (n=15)

Key In- and Exclusion criteria

- Symptomatic PAD Rutherford 2-4
- Stenosis (>70%) or occlusion of the SFA or proximal popliteal artery
- De-novo or restenotic lesions (no ISR)
- No severe calcification
- Lesion length up to 30 cm
- Stratification in 3 groups
  - </=10 cm
  - >10cm and </=20cm
  - >20cm and </=30cm
- At least one patent BTK outflow vessel to the foot

Study Endpoints

Primary efficacy endpoint:

- Patency rate after 12 months
- defined as absence of clinically driven TLR (due to symptoms and drop of ABI of ≥ 20% or > 0.15 when compared to post-procedure) or restenosis with PVR > 2.4 evaluated by Duplex Ultrasound

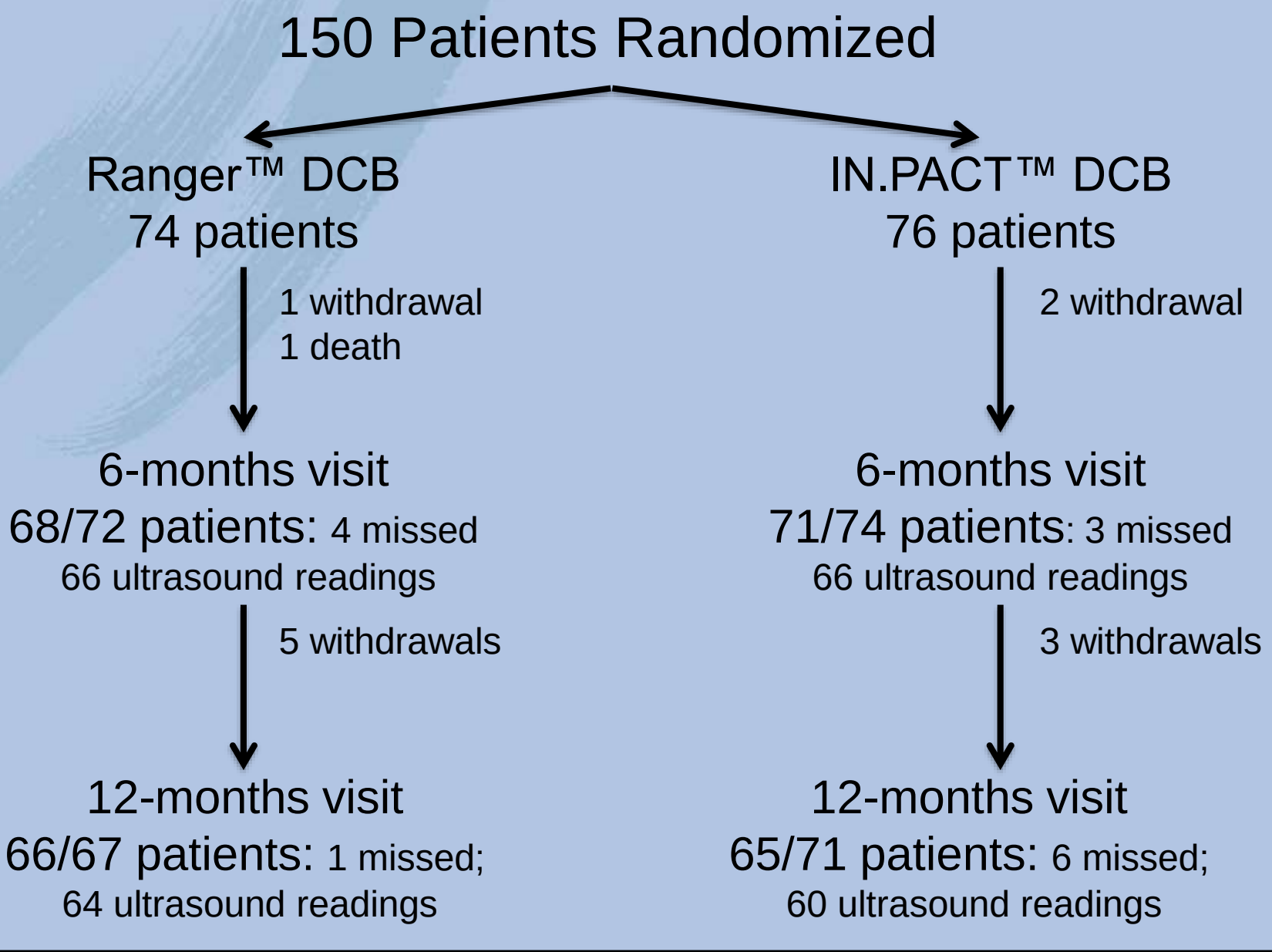
- **Primary safety endpoint:**
- Composite of freedom from device and procedure-related death through 12 months post procedure as well as freedom from both target limb major amputation and clinically-driven target vessel revascularization

Study Endpoints

Selected Secondary endpoints (assessed at 6,12, 24 mo):

- TLR rate
- Duplex-defined restenosis
- Sustained clinical improvement : improvement in the Rutherford classification of one class in amputation and TVR free surviving patients
- Walking capacity assessment by Walking Impairment Questionnaire (WIQ)

Patient flow diagram



Baseline Demographics n=150

	RANGER DCB (n=74)	**IN.PACT DCB (n=76)**	p-value
Age, y	68.6±9.2	68.9±9.5	0.5
Male gender	44 (60%)	53 (70%)	0.2
Weight, kg	77.9±15.8	79.1±14.7	0.6
Prior myocardial infarction	11 (15%)	5 (7%)	0.2
Coronary artery disease	21 (29%)	21 (28%)	0.9
Cerebrovascular disease	12 (16%)	8 (11%)	0.3
Hyperlipidemia	50 (68%)	57 (75%)	0.3
Hypertension	65 (88%)	68 (90%)	0.8
Renal Insufficiency	12 (16%)	14 (18%)	0.6
Smoking			0.4
Current	32 (43%)	38 (50%)	
Previous	27 (37%)	20 (26%)	
Diabetes mellitus	25 (34%)	28 (37%)	0.7
Claudication (RC 2-3)	69 (93%)	71 (94%)	0.6
Critical limb ischemia (RC 4)	5 (7%)	5 (6%)	

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

Lesion Characteristics* n=150

	RANGER DCB (n=74)	IN.PACT DCB (n=76)	p-value
Target lesion length, mm	117.4±100.4	122.3±91.2	0.8
Diameter stenosis, %	82.7±17.5	84.2±18.2	0.6
Reference vessel diameter, mm	4.9±0.6	5.0±0.8	0.3
Minimal vessel diameter, mm	0.8±0.9	0.8±1.0	0.9
Total occlusion	29 (39.2%)	34 (44.7%)	0.5
Total occlusion length, mm	110.9±95.1	94.8±87.9	0.5
Prox. popliteal involvement	14 (18.9%)	11 (14.5%)	0.2
Lesion calcification			0.7
None	8 (11.1%)	8 (10.7%)	0.7
Mild	21 (29.2%)	18 (24%)	
Moderate	1 (1.4%)	0 (0%)	
Moderately severe	25 (34.7%)	33 (44%)	
Severe	17 (23.6%)	16 (21.3%)	
0-1 patent run off vessels	20 (26.9%)	25 (32.9%)	0.6

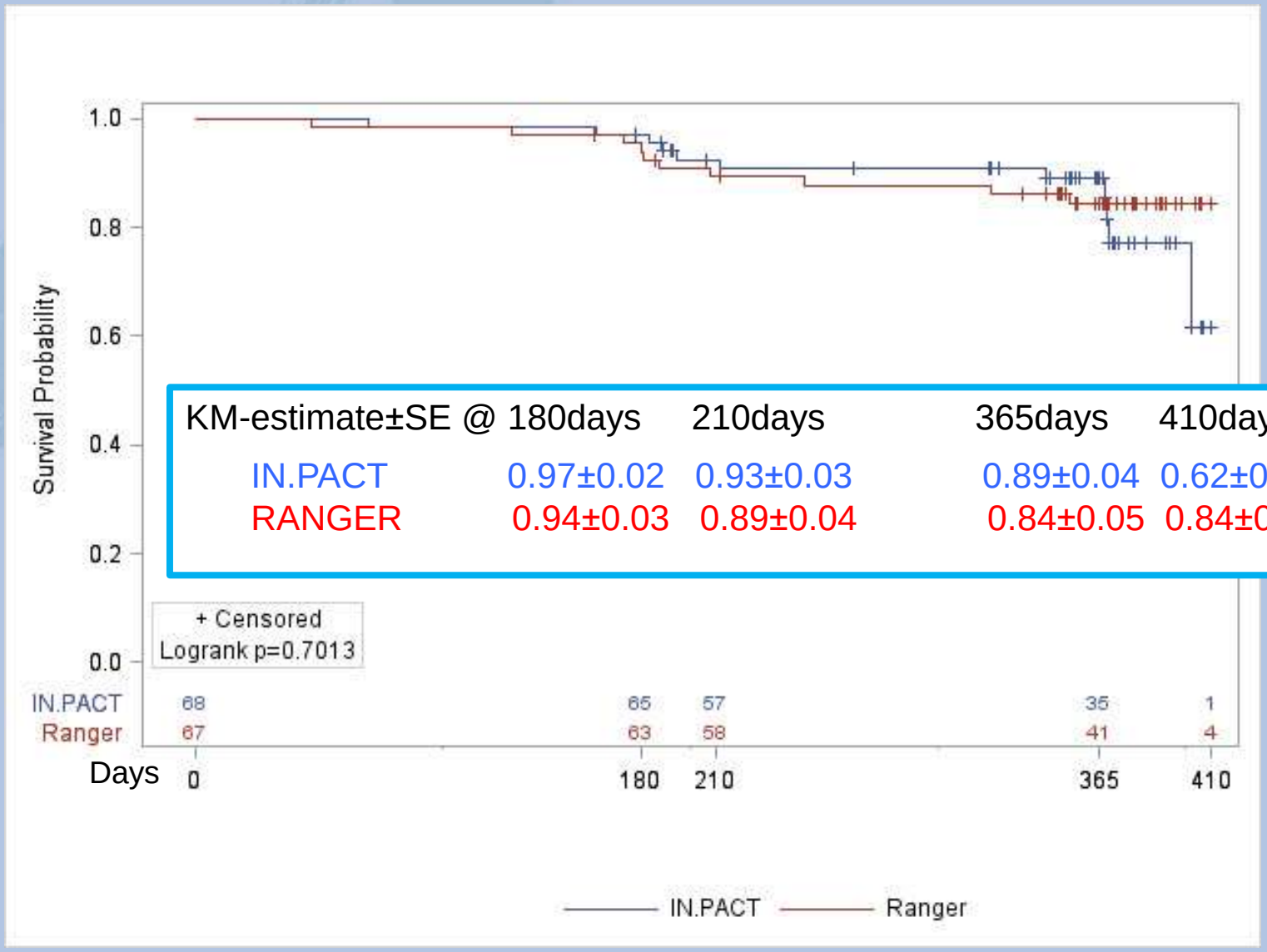
* Per angiographic core lab assessment.
Data are given as mean±SD or number (%).

Procedural Outcomes* n=150

	RANGER DCB (n=74)	IN.PACT DCB (n=76)	p-value
Bailout stent placement	19 (25.7%)	17 (22.4%)	0.6
MVD postprocedure, mm	3.6±0.6	3.7±0.8	0.6
Diameter stenosis postprocedure, %	25.8±11.6	26.0±14.6	0.9
Residual stenosis > 30%	26 (35.1)	29 (38.2)	0.7
Dissection	70 (92.1%)	70 (94.6%)	0.7
Type A/B, n (%)	54 (77.1%)	44 (62.8)	0.1
Type C-F, n (%)	16 (22.9%)	26 (37.2%)	
Complications			
Embolic event	2 (2.7%)	1 (1.3%)	
AV-Fistel (local)	5 (6.8%)	5 (6.6%)	
Target Vessel Perforation	1 (1.4%)	1 (1.3%)	

* Per angiographic core lab assessment.
Data are given as mean±SD or number (%).

Primary efficacy endpoint: Patency rate*



KM-estimate±SE @	180days	210days	365days	410days
IN.PACT	0.97±0.02	0.93±0.03	0.89±0.04	0.62±0.15
RANGER	0.94±0.03	0.89±0.04	0.84±0.05	0.84±0.05

*Patency: defined as absence of clinically driven TLR or restenosis with PVR>2.4 evaluated by duplex ultrasound scan; both per core lab assessment.

Summary

- Head-to-head comparison of Ranger DCB vs. IN.PACT DCB in femoropopliteal interventions
- Complex real world lesion subset with lesion length ~12cm and proportion of CTO`s ~40%
- Excellent efficacy at 1 year of both tested DCB in the interim analysis of first 150 randomized patients
- Similar primary patency of the low-dose Ranger DCB (2µg/mm^2) compared to the Inpact DCB (3.5µg/mm^2) during the 1year surveillance period
- Recruitment of full study cohort (414 patients) will be finished Q2/2018

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