

The logo for LING consists of a stylized, abstract shape resembling a flame or a brushstroke. It features a dark blue outer curve, a red inner curve, and a yellow-orange center. The letters 'LING' are written in white, uppercase, sans-serif font across the top of the shape.

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Impact of patient and lesion characteristics on drug coated balloon angioplasty of the femoro-popliteal artery – pooled analysis of four randomized controlled multicentre trials

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Disclosures

Speaker name: Thomas Albrecht

I have the following potential conflicts of interest to report:

- Consulting (Braun Melsungen, Boston Scientific, Pharmaceut, Olympus)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Background and Purpose

- Proven efficacy of DCB in the treatment of lesions of the SFA and popliteal artery
- Are there any patient or lesion subgroups, which benefit more / less from DCB use?
- If so, can this lead to more specific indications for DEB?

Methods – DEB-PTA vs. POBA

- Pooled subgroup analysis of original data of 4 RCT (THUNDER, FEMPAC, PACIFIER, CONSEQUENT)
- 433 patients / lesions
- Similar design and common primary endpoint: Late lumen loss (LLL) on angio at 6 mths. (Core Lab)
- 335 patients with Core Lab angio (161 x DEB, 174 x POBA)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Local Delivery of Paclitaxel to Inhibit Restenosis during Angioplasty of the Leg

Gunnar Tepe, M.D., Thomas Zeller, M.D., Thomas Albrecht, M.D., Stephan Heller, M.D., Uwe Schwarzwälder, M.D., Jean-Paul Beregi, M.D., Claus D. Claussen, M.D., Anja Oldenburg, M.D., Bruno Scheller, M.D., and Ulrich Speck, Ph.D.

Original Article

Paclitaxel-Coated Balloons Reduce Restenosis After Femoro-Popliteal Angioplasty Evidence From the Randomized PACIFIER Trial

Michael Werk, MD; Thomas Albrecht, MD; Dirk-Roelfs Meyer, MD; Mohammed Nabil Ahmed, MD; Andrea Behne, MD; Ulrich Dietz, MD; Götz Eschenbach, MD; Holger Hartmann, MD; Christian Lange, MD; Beatrix Schnorr, DVM; Heiner Stiepani, MD; Giuseppe Biondi-Zoccai, MD; Enrique Lopez Hänninen, MD

Inhibition of Restenosis in Femoropopliteal Arteries Paclitaxel-Coated Versus Uncoated Balloon: Femoral Paclitaxel Randomized Pilot Trial

Michael Werk, MD; Soenke Langner, MD; Bianka Reinkensmeier, MS; Hans-Frank Boettcher, MD; Gunnar Tepe, MD; Ulrich Dietz, MD; Norbert Hosten, MD; Bernd Hamm, MD; Ulrich Speck, PhD; Jens Ricke, MD

Angiographic and Clinical Outcomes After Treatment of Femoro-Popliteal Lesions with a Novel Paclitaxel-Matrix-Coated Balloon Catheter

Gunnar Tepe¹ · Özlem Gögebakan² · Ulf Redlich³ · Jörg Tautenhahn³ · Jens Ricke⁴ · Zuhir Halloul⁴ · Dirk-Roelfs Meyer⁵ · Matthias Walliszewski⁶ · Beatrix Schnorr⁷ · Thomas Zeller⁸ · Stefan Müller-Hilsbeck⁹ · Ilka Ott¹⁰ · Thomas Albrecht²

Patient characteristics

Study name	THUNDER		FEMPAC		PACIFIER		CONSEQUENT	
Study group	POBA	DCB	POBA	DCB	POBA	DCB	POBA	DCB
Patients (N)	54	48	42	45	47	44	78	75
Age (years)	68 ± 9	69 ± 8	70	67	71 ± 7	71 ± 9	68 ± 9	68 ± 9
Female gender	37%	35%	40%	40%	36%	41%	24%	40%
Diabetes	46%	50%	55%	40%	28%	43%	39%	35%
Hypertension	83%	79%	81%	78%	66%	66%	80%	77%
Hyper-cholesteremia	63%	69%	59%	58%	47%	50%	52%	56%
History of smoking	22%	23%	36%	40%	60%	49%	49%	46%
Coronary artery disease	35%	31%	41%	38%	32%	32%	40%	42%
Cerebro-vascular disease	35%	31%	41%	38%	11%	32%	5%	4%
Claudicants	98%	90%	98%	96%	96%	100%	100%	100%
Critical limb ischemia	2%	10%	7%	4%	4%	0%	0%	0%

Results – patient characteristics

Impact on LLL at 6 months?

- Age NS
- Gender NS
- Diabetes NS
- Hypertension NS
- CAD NS
- Claudication vs. CLI NS
- Smoking NS
- Hypercholesterol. NS
- Cerebro-vasc. dis. $p < 0.05$

Cerebro-vascular disease and LLL

	DCB	POBA	
No cerebro- vasc. dis.	0.35±1.08 (n=143)	1.11±1.31 (n=155)	$P_{\text{no cer.vasc.dis.}} < 0.001$
Cerebro- vasc. Dis.	0.38±1.08 (n=18)	1.13±1.41 (n=19)	$P_{\text{cer.vasc. Dis.}} = 0.079$
	$p_{\text{DCB}} = 0.911$	$p_{\text{POBA}} = 0.942$	

Lesion morphological and procedural characteristics

Study name	THUNDER		FEMPAC		PACIFIER		CONSEQUENT	
Study group	POBA	DCB	POBA	DCB	POBA	DCB	POBA	DCB
Mean lesion length (cm)	7.4	7.5	4.7	4.0	6.6	7.0	12.6	13.7
Occlusions	26%	27%	19%	13%	23%	38%	29%	23%
Mean diameter stenosis	91%	98%	84%	84%	80%	73%	77%	76%
Restenotic lesions treated	30%	38%	33%	36%	17%	32%	5%	8%
Lesion Calcification	52%	50%	52%	53%	66%	64%	68%	53%
Subintimal crossing	9%	4%	NA	NA	6%	2%	15%	13%
Post-dilatation	29%	43%	10%	16%	36%	51%	44%	40%
Dissections	47%	74%	52%	53%	53%	41%	46%	44%
Bail-out stenting	22%	4%	14%	9%	34%	21%	19%	14%

Results – lesion characteristics

Impact on LLL at 6 months?

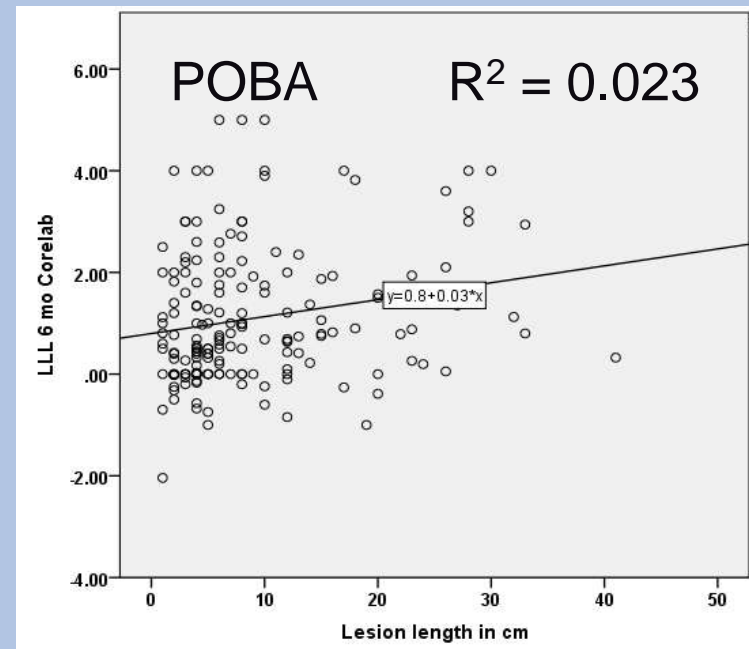
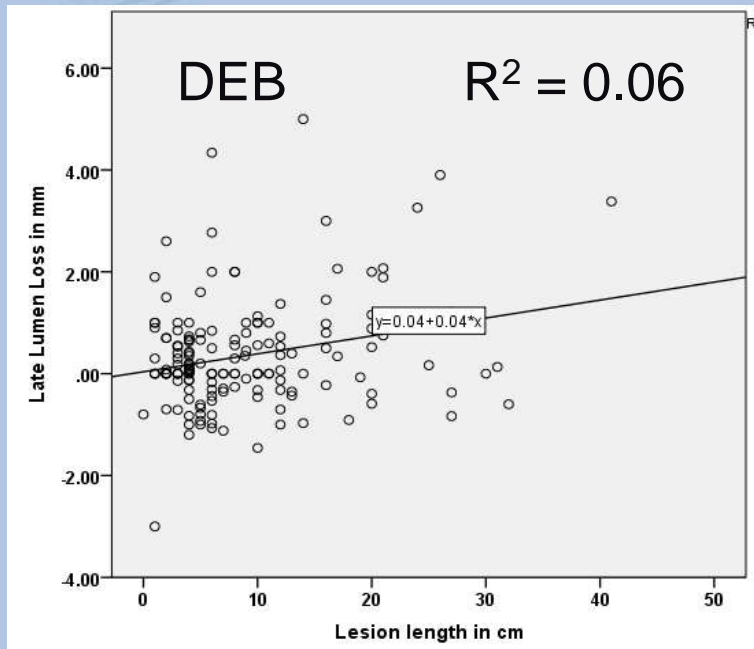
- Stenosis vs. occlusion NS (for DCB and POBA)
- Ca⁺⁺ : yes vs. no NS (for DCB and POBA)
- Post-dilatation NS (for DCB and POBA)
- Lesion location $p < 0.05$
- Lesion length $p < 0.05$
- Subintimal crossing $p < 0.05$
- Dissection $p < 0.05$
- Bail-out stent $p < 0.05$

Lesion location and LLL

	DCB	POBA	
SFA only	0.25±0.95 (n=137)	1.02±1.25 (n=132)	$p_{\text{SFA}} < 0.001$
PA only	0.75±1.53 (n=20)	1.58±1.63 (n=29)	$p_{\text{PA}} = 0.077$
	$p_{\text{DCB}} = 0.172$	$p_{\text{POBA}} = 0.041$	

Lesion length and LLL

	DcB	POBA	
≤ 5 cm	0.19±0.81 (n=70)	0.78±1.16 (n=79)	$p_{\leq 5\text{cm}}=0.001$
> 5 - 10 cm	0.31±1.15 (n=33)	1.40±1.26 (n=39)	$p_{>5-10\text{cm}}<0.001$
> 10 cm	0.52±1.1 (n=35)	1.19±1.37 (n=39)	$p_{>10\text{cm}}=0.02$
	$p_{\text{DCB}}=0.032$	$p_{\text{POBA}}=0.016$	



Subintimal crossing and LLL

	DCB	POBA	
intraluminal	0.33±1.05 (n=152)	1.09±1.30 (n=160)	$p_{\text{intra}} < 0.001$
subintimal	0.80±1.36 (n=9)	1.37±1.43 (n=17)	$p_{\text{subintimal}} = 0.358$
	$p_{\text{DCB}} = 0.197$	$p_{\text{POBA}} = 0.446$	

Dissections and LLL

	DCB	POBA	
no dissection	0.23±1.00 (n=97)	1.01±1.20 (n=95)	$p_{\text{no dissection}} < 0.001$
dissection not flow limiting	0.59±1.22 (n=54)	1.37±1.42 (n=55)	$p_{\text{not flow lim.}} = 0.002$
dissection flow limiting	0.36±0.83 (n=9)	0.40±1.02 (n=18)	$p_{\text{flow limiting}} = 0.914$
	$p_{\text{DCB}} = 0.145$	$p_{\text{POBA}} = 0.016$	

Bail-out stenting and LLL

	DCB	POBA	
bailout stenting	0.43±1.25 (n=18)	0.74±1.07 (n=39)	$p_{\text{stent}} = 0.348$
no bailout stenting	0.34±1.05 (n=143)	1.22±1.36 (n=135)	$p_{\text{no stent}} < 0.001$
	$p_{\text{DCB}} = 0.749$	$p_{\text{POBA}} = 0.043$	

Interdependence of subintimal crossing, flow limiting dissections and bail-out stenting

POBA

N=46

Bailout stenting
n=28

N=22

Flow-limiting
dissection

n=13

n=3

n=5

n=2

n=1

Subintimal
crossing

N=20

DCB

N=26

Bailout stenting
n=17

N=14

Flow-limiting
dissection

n=9

n=1

n=11

Subintimal
crossing

N=12



Summary

- Patient characteristics
 - DCB superior to POBA in all patient subgroups
 - Exception: cerebrovascular disease (small sample size)
- Lesion characteristics
 - DCB superior independent of Ca^{++} and lesion length
 - DCB not superior in PA (small sample size)
 - DCB not superior in subintimal crossing, flow limiting dissections and bail-out stenting (small sample size)

The logo for LING, featuring the letters 'LING' in a white, sans-serif font. The letters are positioned over a stylized graphic of a hand or a flame, rendered in shades of blue, red, and yellow. The background of the slide is a light blue gradient with a large, faint, stylized graphic of a hand or flame in the background.

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