

The logo for LINC (Lifestyle in Network) features the letters 'LINC' in a white, sans-serif font. The letters are positioned over a stylized graphic of a human heart and a hand, rendered in shades of blue, red, and yellow. The background of the slide is a light blue gradient with abstract, brush-stroke-like patterns in darker blue and white.

LINC

Subgroup analyses of the CONSEQUENT RCT investigating the clinical benefits of paclitaxel-resveratrol coated balloon angioplasty

Th. Albrecht*, D. Meyer, S. Müller-Hülsbeck,
I. Ott, U. Redlich, J. Ricke, Th. Zeller, G. Tepe

*Institut für Radiologie und Interventionelle Therapie
Gefäßzentrum Neukölln

Vivantes Klinikum Neukölln
thomas.albrecht@vivantes.de

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Disclosures

Speaker name: Thomas Albrecht

I have the following potential conflicts of interest to report:

- Consulting (B. Braun, Boston Scientific, Med Alliance, Olympus)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

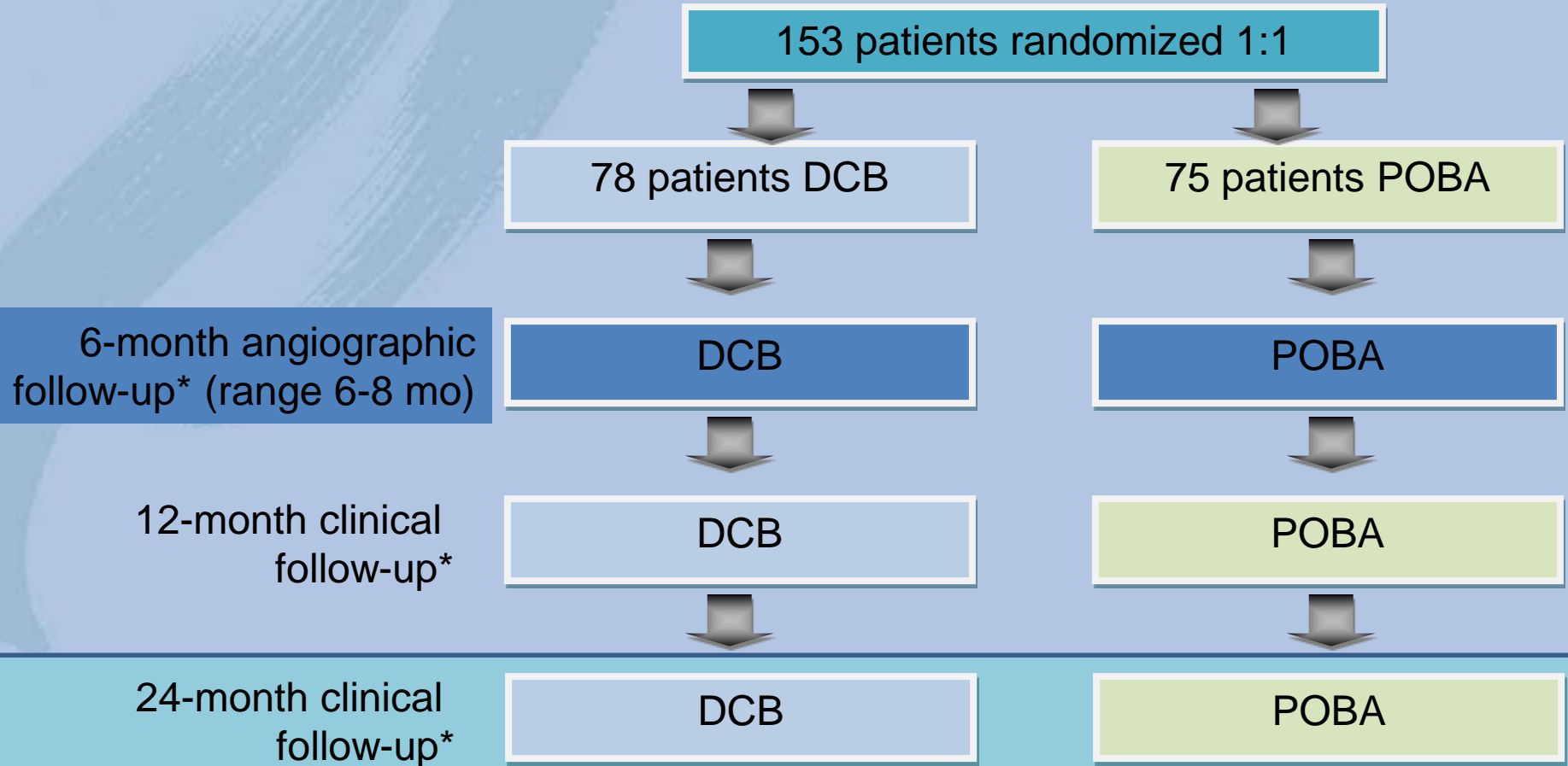
- I do not have any potential conflict of interest

Aim

To assess the affect of lesion characteristics on patency and TLR at 2 year results in the CONSEQUENT study

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NCT01970579

Study design



- including walking test, ABI and Duplex

Inclusion criteria

- De novo or restenosis post POBA in SFA or PI/ PII
- Rutherford II-IV
- Reference vessel diameters 4.0 - 7.0 mm
- Lesion lengths 4 - 27 cm
- Diameter stenosis pre-procedure $\geq 70\%$
- Adequate runoff with ≥ 1 vessel to the foot.

Exclusion criteria

- Restenosis post stent or DCB
- >2 lesions in target vessel
- Chronic total occlusions > 10 cm

Lesion details – target lesions

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Target lesions	153	78	75	-
Location				
SFA	122 (79.7%)	63 (80.8%)	59 (78.7%)	0.912
P1/P2	9 (5.9%)	4 (5.1%)	5 (6.7%)	
SFA + P1/P2	22 (14.4%)	11 (14.1%)	11 (14.7%)	
TASC A	54 (35.3%)	28 (35.9%)	26 (34.7%)	0.934
TASC B	63 (41.2%)	31 (39.7%)	32 (42.7%)	
TASC C	26 (17.0%)	13 (16.7%)	13 (17.3%)	
TASC D	10 (6.5%)	6 (7.7%)	4 (5.3%)	
Diameter stenosis, %	76.6 ± 18.1	76.0 ± 17.7	77.1 ± 18.5	0.703
Total occlusions	40 (26.1%)	18 (23.1%)	22 (29.3%)	0.462
Lesion length, cm	13.2 ± 10.4	13.7 ± 12.2	12.6 ± 8.2	0.540
Reference diameter, mm	5.22 ± 0.87	5.06 ± 0.77	5.38 ± 0.94	0.050
2 nd non-target lesion	18 (11.8%)	9 (11.5%)	9 (12.0%)	0.929

Procedural details - target lesions

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Target lesions	153	78	75	-
Intraluminal passage	132 (86.3%)	68 (87.2%)	64 (85.3%)	0.740
Subintimal passage	21 (13.7%)	10 (12.8%)	11 (14.7%)	
Predilatation	85 (55.6%)	41 (52.6%)	44 (58.7%)	0.448
Balloon diameter, mm	5.2 ± 0.8	5.1 ± 0.7	5.3 ± 0.8	0.05
Balloon length, mm	106.5 ± 37.5	105.6 ± 38.0	107.5 ± 37.0	0.701
Inflation time, sec	146.8 ± 43.2	149.8 ± 41.8	143.7 ± 44.8	0.294
Bailout stenting	25 (16.3%)	11 (14.1%)	14 (18.7%)	0.445
Residual stenosis, %	33.2 ± 11.1	33.1 ± 10.0	33.2 ± 12.2	0.986
Procedural success	153 (100%)	78 (100%)	75 (100%)	-

Clinical 24-month results

	Drug Coated Balloon	Uncoated Balloon	p-value
Number of follow-ups angiographic, sonographic, clinical & phone for TLR	68 (87.2%)	64 (85.3%)	0.740
Target lesion revascularization	13 (19.1%)	26 (40.6%)	0.007
Patency ¹	47 (72.3%) (n=65)	31 (48.4%) (n=64)	0.006
Death all causes	2 (2.9%) (n=70)	1 (1.5%) (n=65)	0.604
Increase in censored ² walking distance, m	172±103 (n=28)	52±136 (n=20)	0.001
Uncensored ³ target leg ABI	0.92±0.19 (n=56)	0.90±0.20 (n=56)	0.499
Rutherford category shift 24 months vs. pre-interventional	2.1±1.3 (n=53)	1.7±1.3 (n=53)	0.113

¹ Patency defined as binary restenosis with diameter stenosis >50% (angiographic) or PSVR>2.4 (sonographic), definition by Diehm et al. 2007 Eur Heart

² all patients with non-vascular walking limitations and/or TLR prior to the measurement of walking distance were excluded

³ all available ABI measurements were used

Logistic regression 24-month patency and its predictors in the DCB group

Variable	p-value
Lesion length	0.699
Predilatation	0.119
Calcification	0.425
Total occlusions	0.743
Inflation times	0.308
Number of balloons	0.614
Lesion passage (intraluminal vs. subintimal)	0.228

Goodness of fit Nagelkerke R Square = 0.236, N=65

Logistic regression 24-month TLR and its predictors in the DCB group

Variable	p-value
Lesion length	0.922
Predilatation	0.102
Calcification	0.227
Total occlusions	0.589
Inflation times	0.701
Number of balloons	0.271
Lesion passage (intraluminal vs. subintimal)	0.298
Constant	0.805

Goodness of fit Nagelkerke R Square = 0.175, N=68

Pre-dilatation and 24-month patency/TLR in the DCB group

	No predilatation	Predilatation
24-month patency	58.6% (17/29)	83.3% (30/36)
Overall 72.3%, 47/65, p=0.027		

	No predilatation	Predilatation
24-month TLR	29.0% (9/31)	10.8% (4/37)
Overall 19.1%, 13/68, p=0.057		

94.4% (34/36) of all total occlusions were predilated in the DCB group

Conclusions

- The studied lesion morphologic and procedural factors did not impact patency at 24 months.
- There was a signal from the logistic regression analysis that predilatation had some predictive value. Chi2 revealed that predilatation improved 24-month patency (58.6% vs. 83.3%, $p=0.027$)
- The current analyses suggest that pre-dilatation independent of the lesion type is effective to improve patency.
- Larger data sets should be analyzed to further study these findings.

Limitations

- Post-hoc analysis
- Small sample size
- Study was powered for angiographic endpoint