EFFPAC trial

Multicenter Randomized Controlled Trial to Assess the Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter versus Uncoated Balloon Catheter in the Superficial Femoral and Popliteal Arteries to PreventVessel Restenosis or Reocclusion

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Luminor data_EffPac trial 5-year

Study design

Investigator initiated, prospective, multicenter, randomized controlled trial

Study objective

To assess efficacy and safety of Luminor-35 paclitaxel-coated balloon angioplasty in SFA/PA lesions up to 60-month (5-year)

PI

Prof Ulf Teichgräber

Sponsor

University of Jena, Germany

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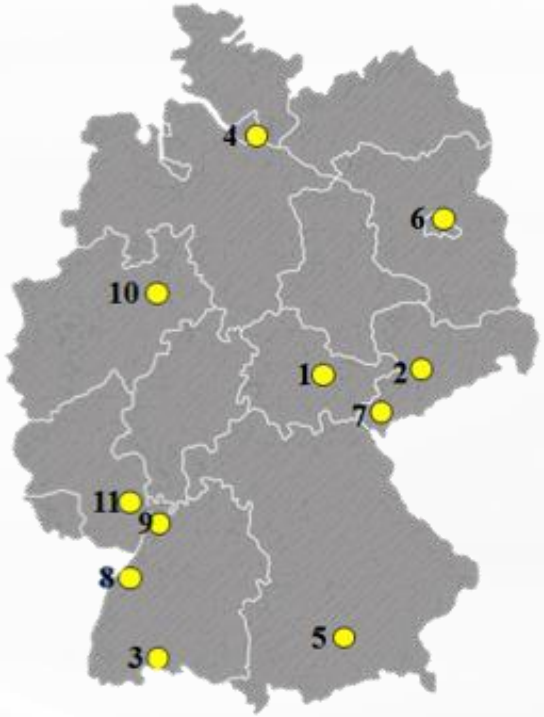
Participating Centers

1. Jena	Universitätsklinikum	R. Aschenbach
2. Arnsberg	Klinikum Arnsberg	M. Lichtenberg
3. Bad Krozingen	Herzzentrum	T. Zeller
4. Berlin	Ihre Radiologen	K. Brechtel
5. Hamburg	Angiologikum	S. Sixt
6. Kusel	Westpfalz Klinikum	P. von Flotow
7. Karlsbad	SRH Klinikum	E. Blessing
8. Leipzig	Universitätsklinikum	D. Scheinert
9. München	LMU München	M. Treitl
10. Sonneberg	Medios Kliniken	M. Thieme
11. Heidelberg	Universitätsklinik	B. Vogel



ClinicalTrial.gov Identifier: NCT02540018

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Study Endpoints and Key Eligibility Criteria

Primary Endpoint

- LLL at 6 months

Secondary Endpoints

- Binary restenosis
- Primary patency
- Freedom from TLR
- Freedom from TVR
- Rutherford category
- WIQ-score
- ABI
- EQ-5D score

- All-cause mortality
- Target limb amputation

Inclusion

- Rutherford category 2-4
- De-novo stenotic/restenotic or occluded (≥ 70%) SFA/prox. PA lesions
- Lesion length ≤ 150 mm
- 1 lesion/patient
- Successful pre-dilation

Exclusion

- Previous TV surgery
- Major amputation TL
- Severly calcified lesions (PTA resistant)
- In-stent restenosis

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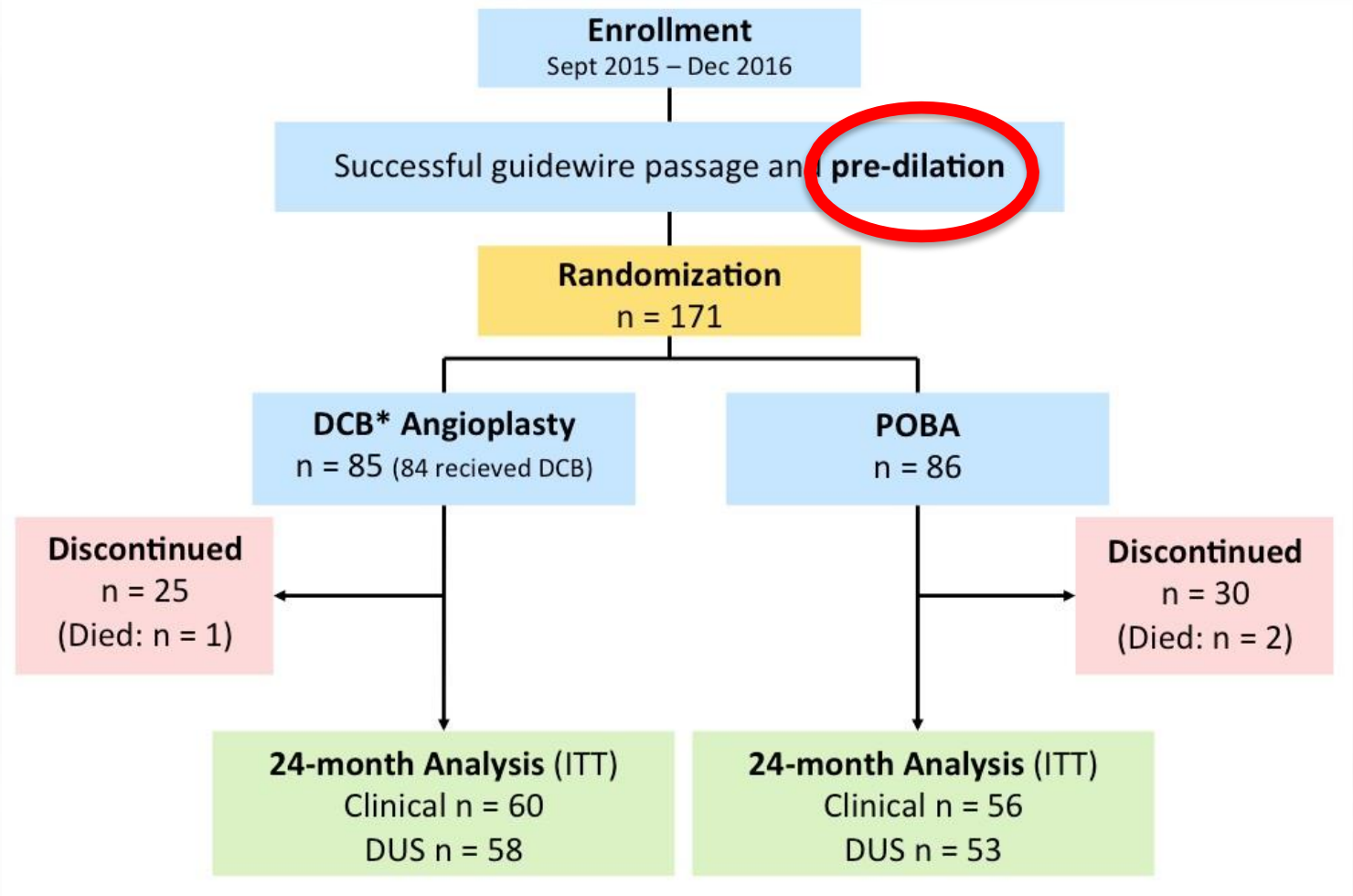
Patient Flow at 5-year



*Luminor 35:paclitaxel 3µg/mm^2

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Baseline Patient Characteristics

	Luminor n = 85	POBA n = 86	p value
Age, years	68.0 ± 7.5	68.1 ± 8.8	p = 0.979
Male, %	60.0	69.8	p = 0.239
Diabetes, %	36.5	40.4	p = 0.681
Hypertension, %	87.1	84.9	p = 0.850
Hyperlipidemia, %	70.7	68.6	p = 0.144
Current smoker, %	40.5	43.0	p = 0.856
Critical limb ischemia, %	3.6	1.2	p = 0.613
ABI	0.73 ± 0.23	0.74 ± 0.23	p = 0.929

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Lesion and Procedure Characteristics

	Luminor (n= 85)	POBA (n= 86)	p value
Lesion length, mm	59.1 ± 43.4	55.8 ± 39.1	p = 0.732
CTO, %	20.2	25.6	p = 0.492
Calcification, % Severe Moderate	 3.6 42.2	 11.6 44.2	p = 0.232
Mid / dist. popliteal artery, %	18.8	14.0	p = 0.248
Pre-dilation, %	98.8	98.8	p = 0.993
Dissection, %	37.6	40.7	p = 0.801
Bailout stenting, %	15.3	18.8	p = 0.709
Residual DS, % post-angioplasty post-treatment	 15.5 ± 16.7 7.5 ± 9.3	 14.9 ± 16.2 8.3 ± 10.1	 p = 0.807 p = 0.699

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Primary Endpoint – 6-Month Late lumen loss (LLL)

Study	DCB 6-month LLL	Control 6-month LLL	Difference DCB vs POBA (mm)
THUNDER Tepe et al. 2008 Paccocath coating	0.4±1.2	1.7±1.8	-1.3
AcoArt I Trial Jia et al. 2016 Orchid (Acotec)	0.05±0.73	1.15±0.89	-1.1
EFFPAC 2018 Luminor (iVascular)	**0.14** [CI: -0.38; 0.67]	**1.06** [CI:0.54; 1.59]	**-0.92** [CI:-1.364; -0.49] p < 0.001
RANGER Bausback et al. 2017 Ranger DCB	-0.16±0.99	0.76±1.4	-0.92
LEVANT I Scheinert et al. 2014 Lutonix (Bard)	0.46±1.13	1.09±1.07	-0.63
BIOLUX P-I Trial Scheinert et al. 2015 Passeo-18 Lux (Biotronik)	0.51±0.72	1.04±1.0	-0.53
FEMPAC Werk et al. 2008 Paccocath DCB	0.5±1.1	1.0±1.1	-0.5
CONSEQUENT 2017 SeQuent Please (B. Braun)	0.35 [CI: 0.19; 0.79]	0.72 [CI: 0.68; 1.22]	-0.37

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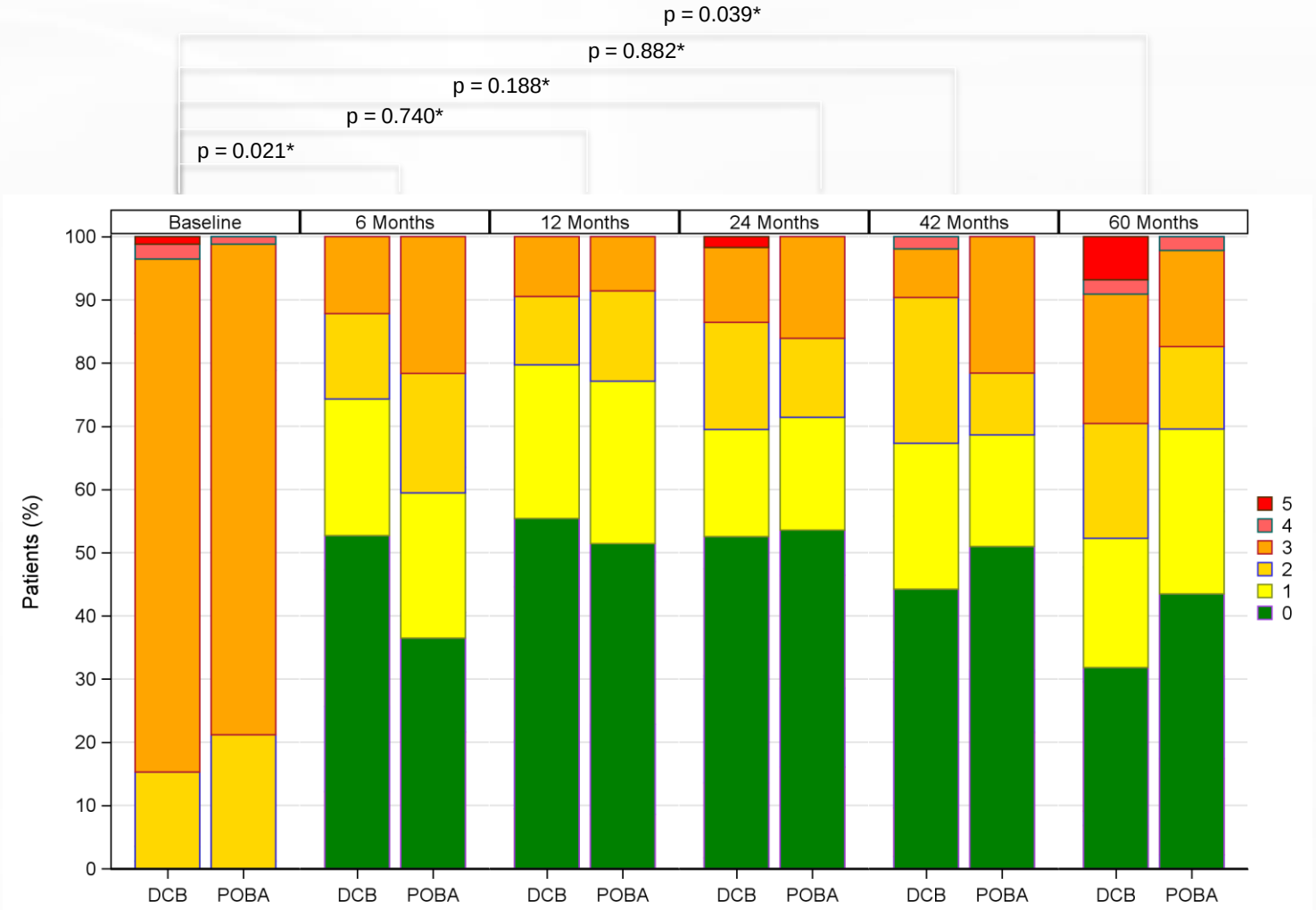
Clinical Improvement: Change of Rutherford Class – 5-year

With Luminor patients clinical improvement is better tan with POBA



*P-value for difference in change from baseline to 60 months between DCB and POBA

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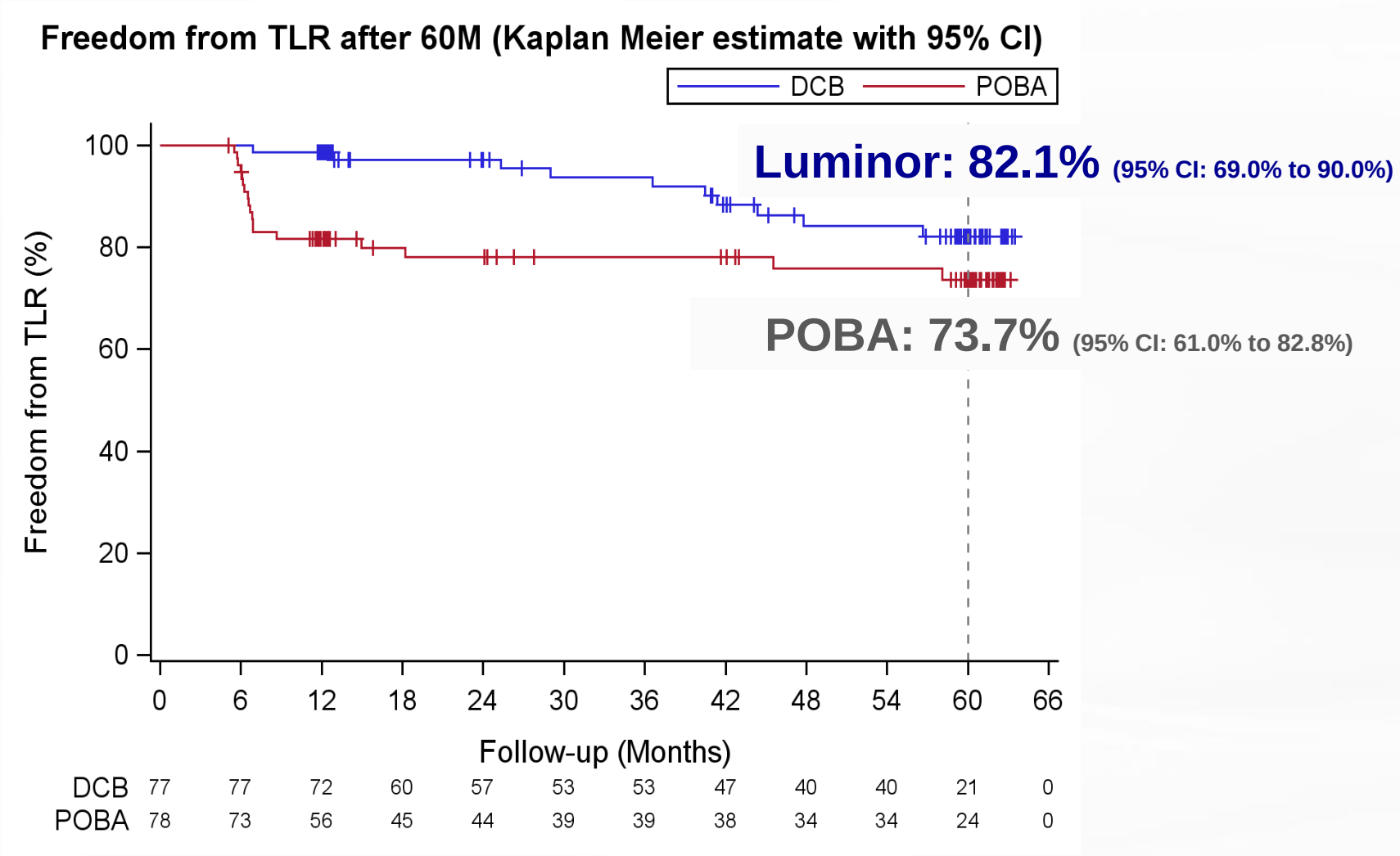
Freedom From TLR _5-year



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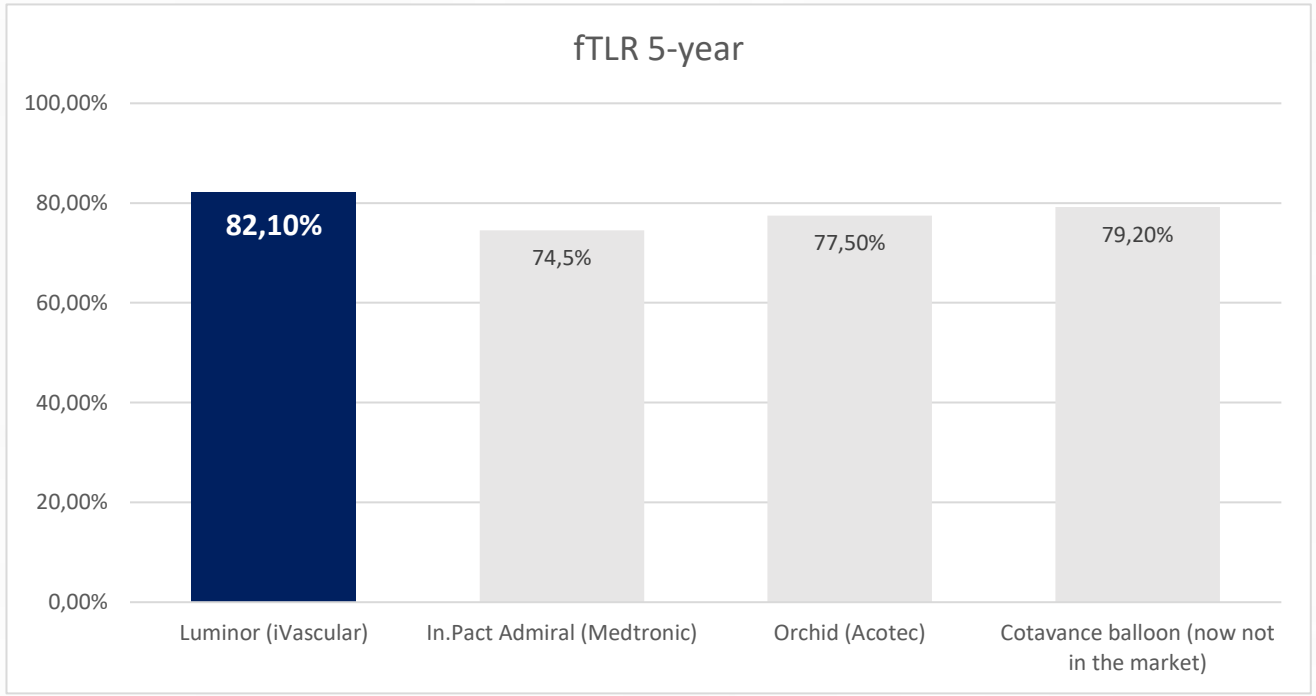
Freedom From TLR _5-year

Lesion improvement at long-term follow-up

Analysing all the existing similar DCB RCT at 5-year follow-up:



Sources:
INPACT SFA: https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007702 ; AcoArt I:https://pubmed.ncbi.nlm.nih.gov/33600928/; THUNDER: https://pubmed.ncbi.nlm.nih.gov/25616822/

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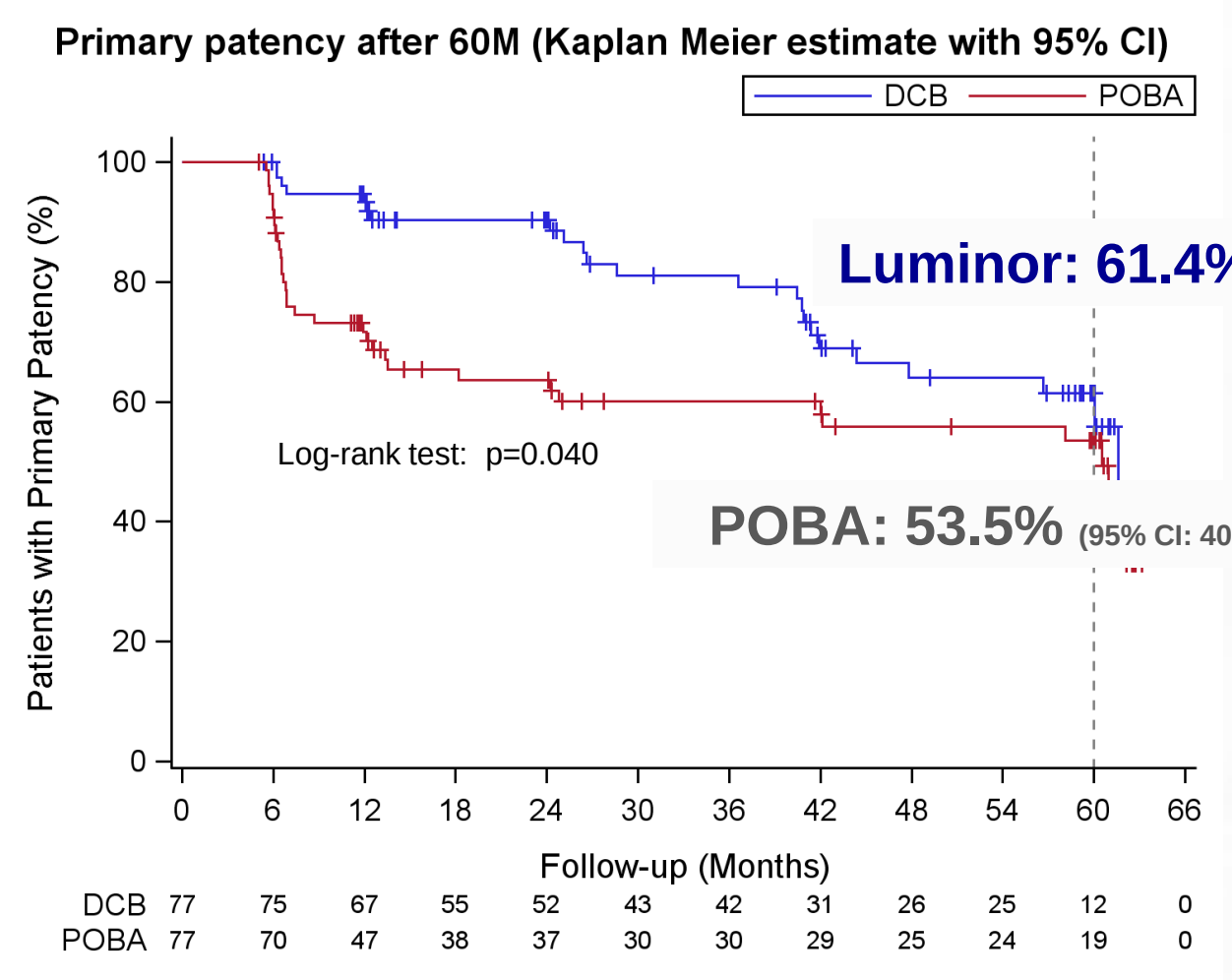
Primary Patency_5-year



Primary patency:
Freedom from restenosis (determined by duplex ultrasound PSVR < 2.5) and freedom from TLR

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Safety_ 5-year

Safety at long-term follow-up

Same safety outcomes as POBA:

	DCB	POBA	P value
All-cause mortality, %	9* (11.3)	14** (16.3)	p = 0.378
Binary restenosis, %	42 (72.4)	36 (62.1)	p = 0.323
TLR, %	10 (20.4)	18 (35.3)	p = 0.121
Periprocedural complication, % Dissection False aneurysm Thromb. embolization	 32 (37.6) 0 1 (1.2)	 35 (40.7) 1 (1.2) 0	 p = 0.801 p = 1.000 p = 1.000

* Reasons: Hyperglycemic coma, stroke, multimorbidity, lung cancer, hear failure, sepsis, cancer, unknown (2x); 5 patients could not be reached

** Reasons: suicide, cardiac arrest (2x), cholangiocellular carcinoma, multiple organ failure, respiratory failure, stroke, pneumonia, heart failure, Covid-19, cardiac insufficiency, unknown (3x)

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EffPac_ Conclusions

- Clinical improvement remains stable over 5 years
- Primary patency with Luminor is superior over POBA throughout 5 years
- No difference in long-term safety between Luminor and POBA was detected
- Luminor angioplasty should be preferred over POBA in femoropopliteal artery disease

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EffPac_ Key messages

- One of the few trials with 5-year follow-up
- Same safety outcomes than POBA
- Significant lesion improvement

luminor

The DCB you need

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Luminor clinical trials

iVasTriam
The iVascular Clinical Trial Program

LUMINOR registry
Real world registry, 1-year follow-up BTK subgroup. N= 215
PP: 85.9%; fTLR:89.6%

EffPac
Randomized controlled trial (Luminor vs PTA). N=171
5-year follow-up. fTLR=82.1%, PP=61.4%

TINTIN
Prospective trial in complex SFA lesions. N=100
3-year follow-up. fTLR= 82.2%

MERLION
Prospective BTK trial. N= 50
1-year follow-up. fTLR= 81.6%

BIBLIOS
Prospective BTK trial, N=150
Preliminary 1-year follow-up. fTLR= 88%

LUMIFOLLOW
France Registry. N=500

SOL-JAPAN
Prospective, single arm trial in Japan. N=120

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Thank you

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