A monocenter randomized clinical trial of PAClitaxel drUg-eluting balloon versus standard percutaneous transluminal angioplasty to reduce restenosis in patients with in-stent stenoses in the superficial femoral and proximal popliteal artery (PACUBA I Trial)

C Kinstner, J Lammer, A Willfort-Ehringer, W Matzek, M Gschwandtner, D Javor, M Funovics, M Schoder, R Koppensteiner, C Loewe, R Ristl, F Wolf.

Medizinische Universität Wien

Disclosure

Speaker name:

Johannes Lammer

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Lecture honorarium from EUROCOR GmbH

- ☐ I do not have any potential conflict of interest

PACUBA Trial

(clinicaltrials.gov NCT01247402)

Study design

RCT of Paclitaxel DEB versus POBA in in-stent restenosis (ISR) of femoropopliteal arteries.

Primary endpoint

Primary patency at 12-month follow-up, defined as <50% stenosis as demonstrated by CDUS and CTA, absence of TLR

Inclusion criteria

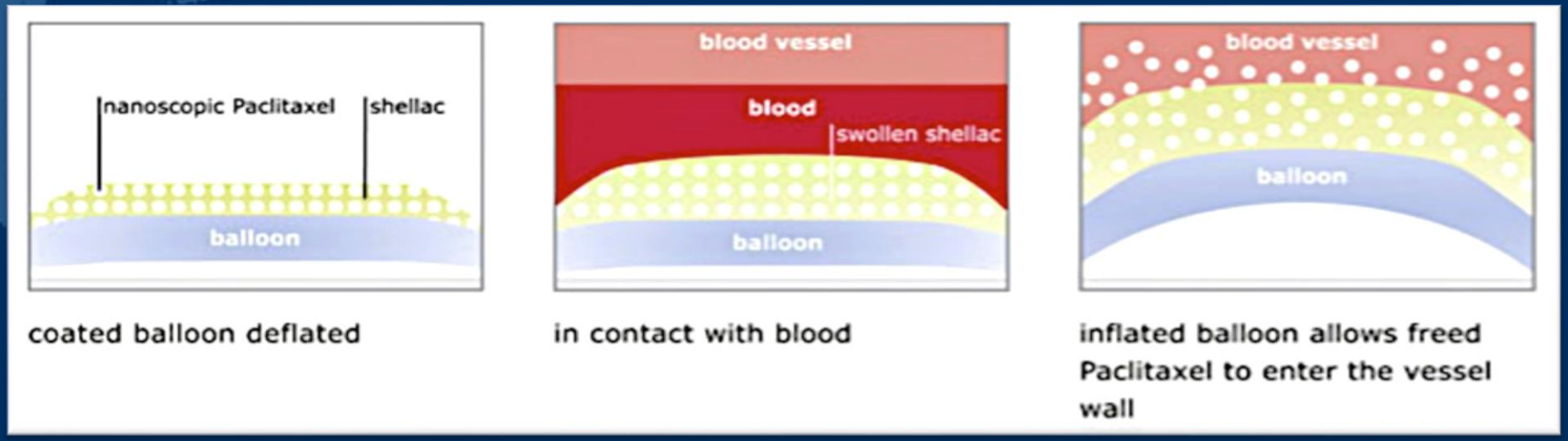
- symptomatic PAD Rutherford-Becker 2-3 (IC)
- in-stent restenosis in the SFA and P1 segment
- tibial run-off of at least 1 artery

Study device:

FREEWAY® 035” Paclitaxel eluting balloon (Eurocor GmbH).

Balloon coating: shellac matrix composed of shellolic and alleuritic acid. In contact with body liquid the hydrophilic shellac-network swells and opens for the pressure-induced release of Paclitaxel.

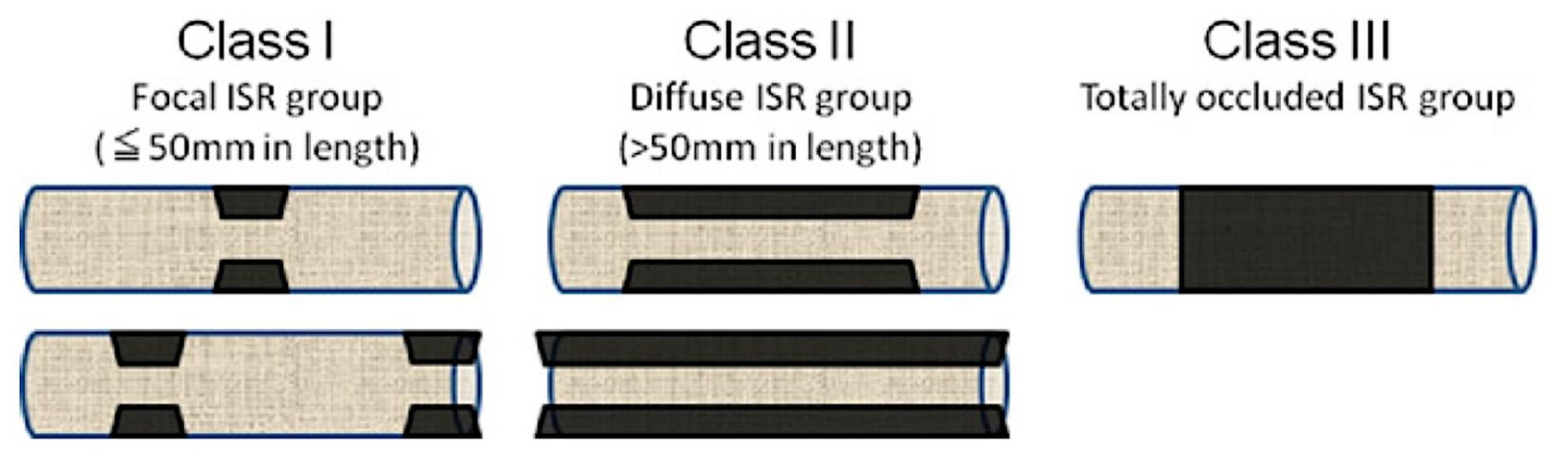
Drug: Paclitaxel 3 µg/mm2.



Patient and lesion characteristics

	DEB	POBA	p
N	35	39	
Age (mean)	68	68	0.95
Male/female	20/15	23/16	1
Diabetics	17	13	0.39
Lesion length cm (mean)	17.3	18.4	0.65
Vessel diameter mm (mean)	5.7	5.4	0.18
TASC A+B	16	16	
TASC C+D	19	23	0.08
ABI before (mean)	0.65	0.65	0.98

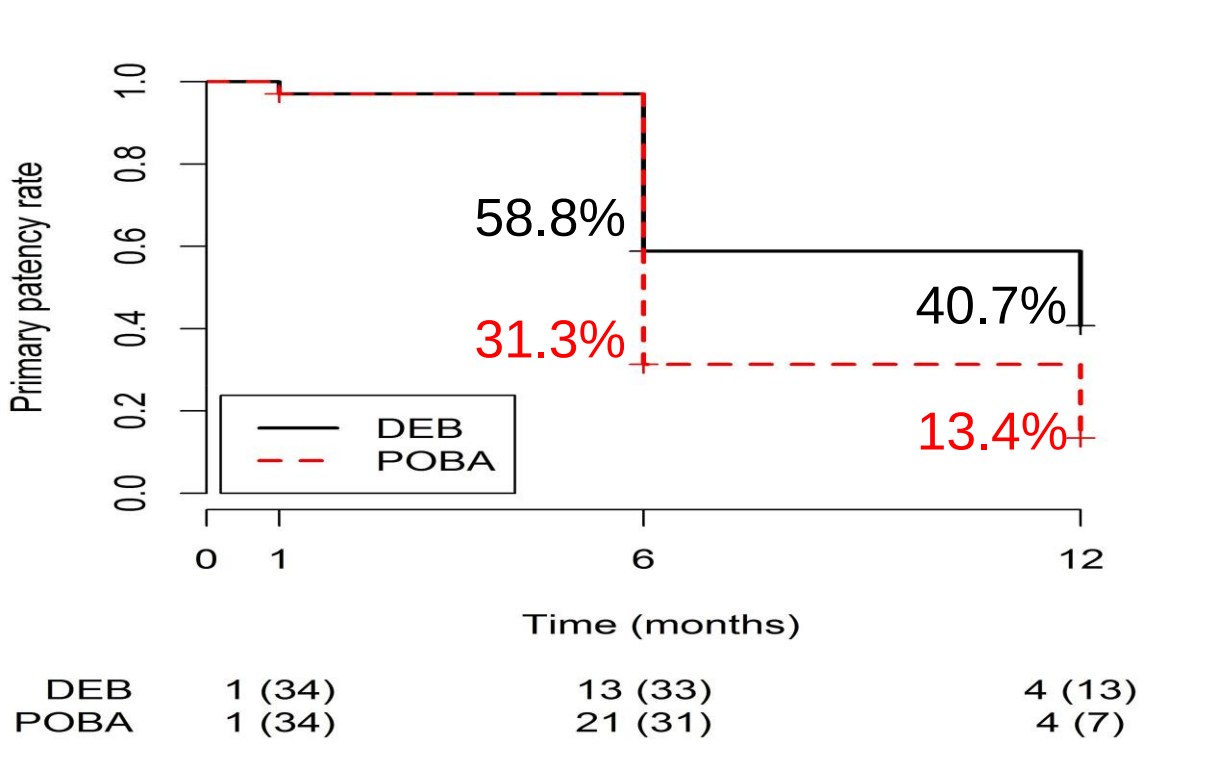
TOSAKA Classification



Tosaka class	DEB	PTA	p
Class I	8/23%	2/5%	
Class II	16/46%	26/67%	
Class III	11/31%	11/28%	0.52

Tosaka A, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. JACC. 2012;59:16-23.

PACUBA Trial - Primary Patency Rate



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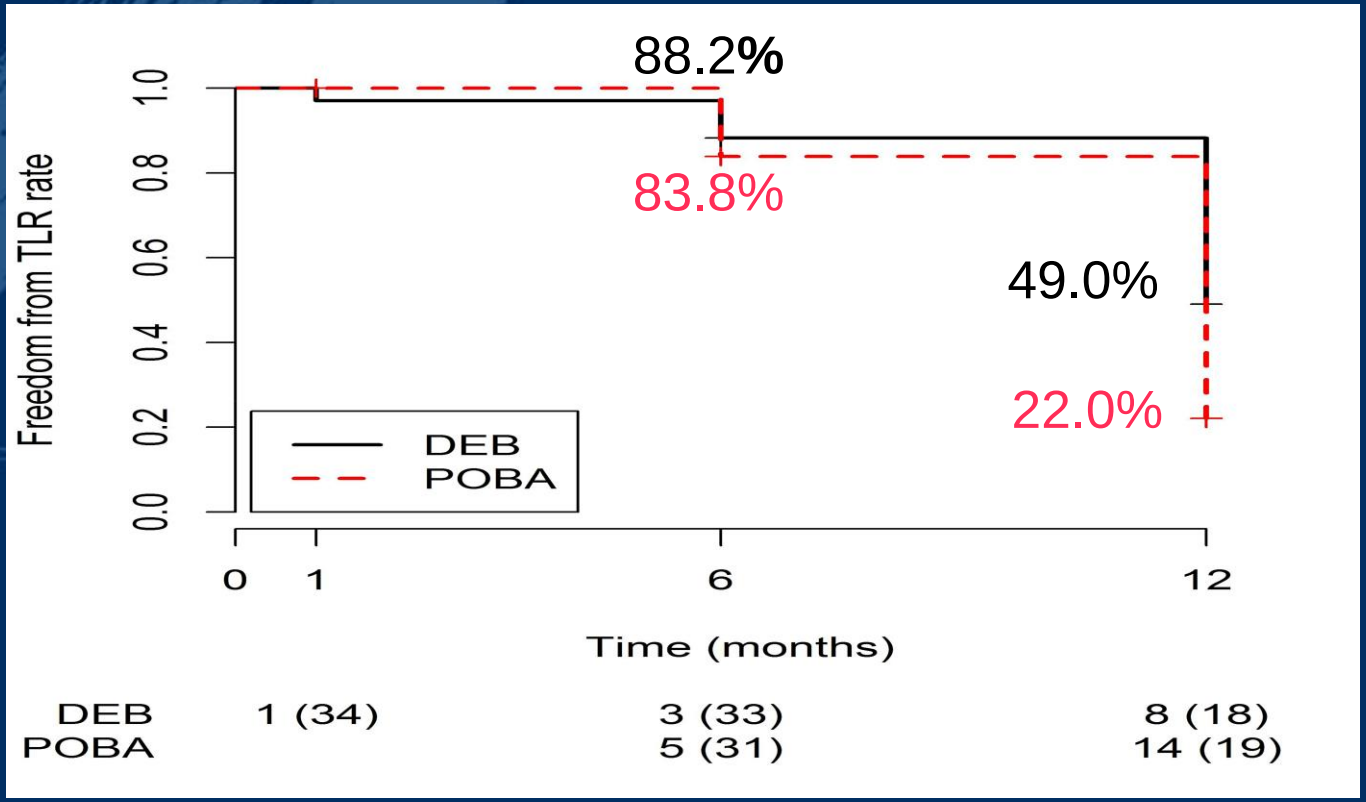
Restenosis	DEB (events)	Patency rate %	POBA (events)	Patency rate %
1-month	1	97.0	1	97.0
6-month	13	58.8	21	31.3
12-month	4	40.7	4	13.4

Kinstner C, Lammer J, et al. JACC Cardiovasc Intervent 2015 (in revision)

PACUBA Trial - Freedom from TLR



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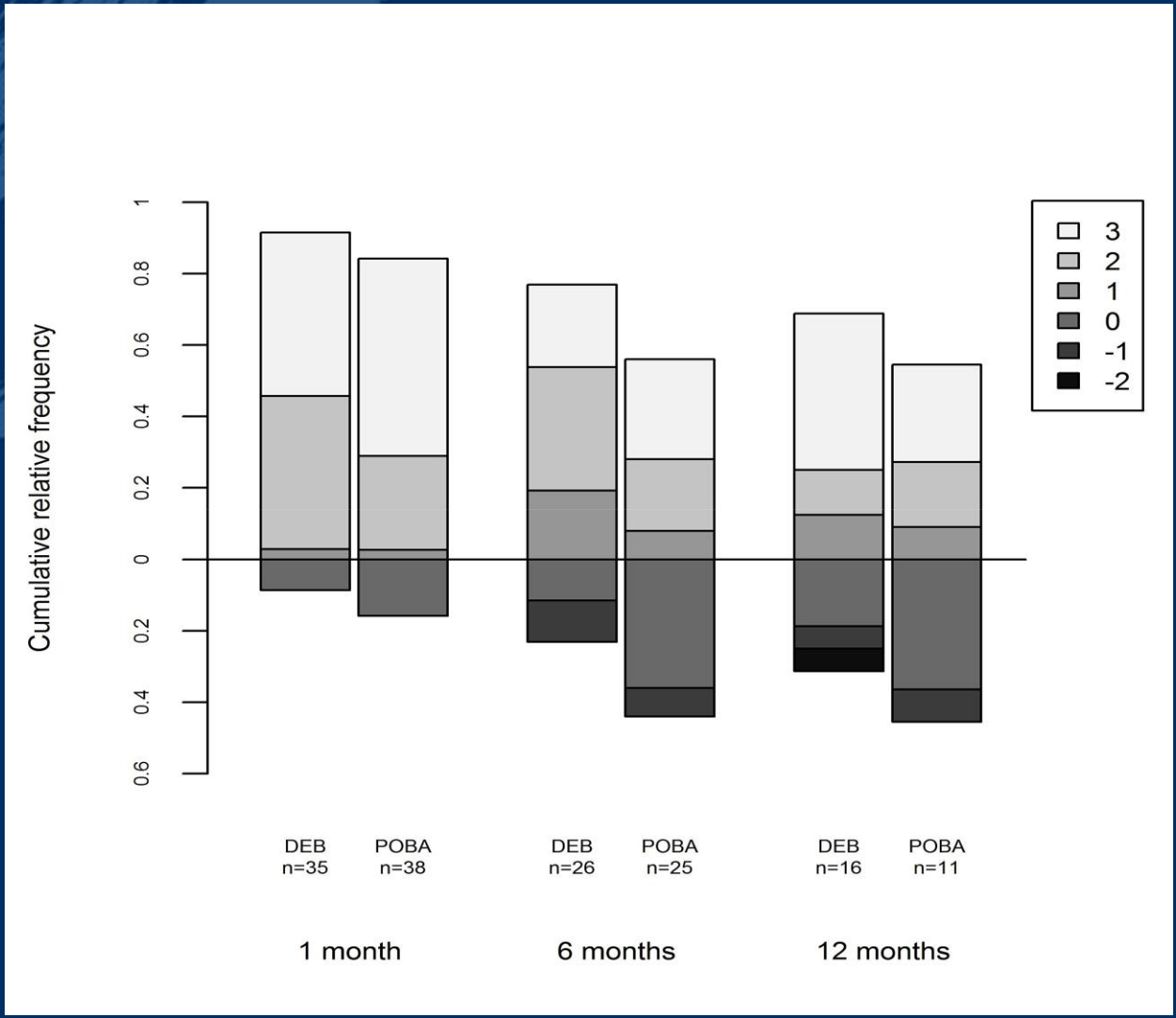
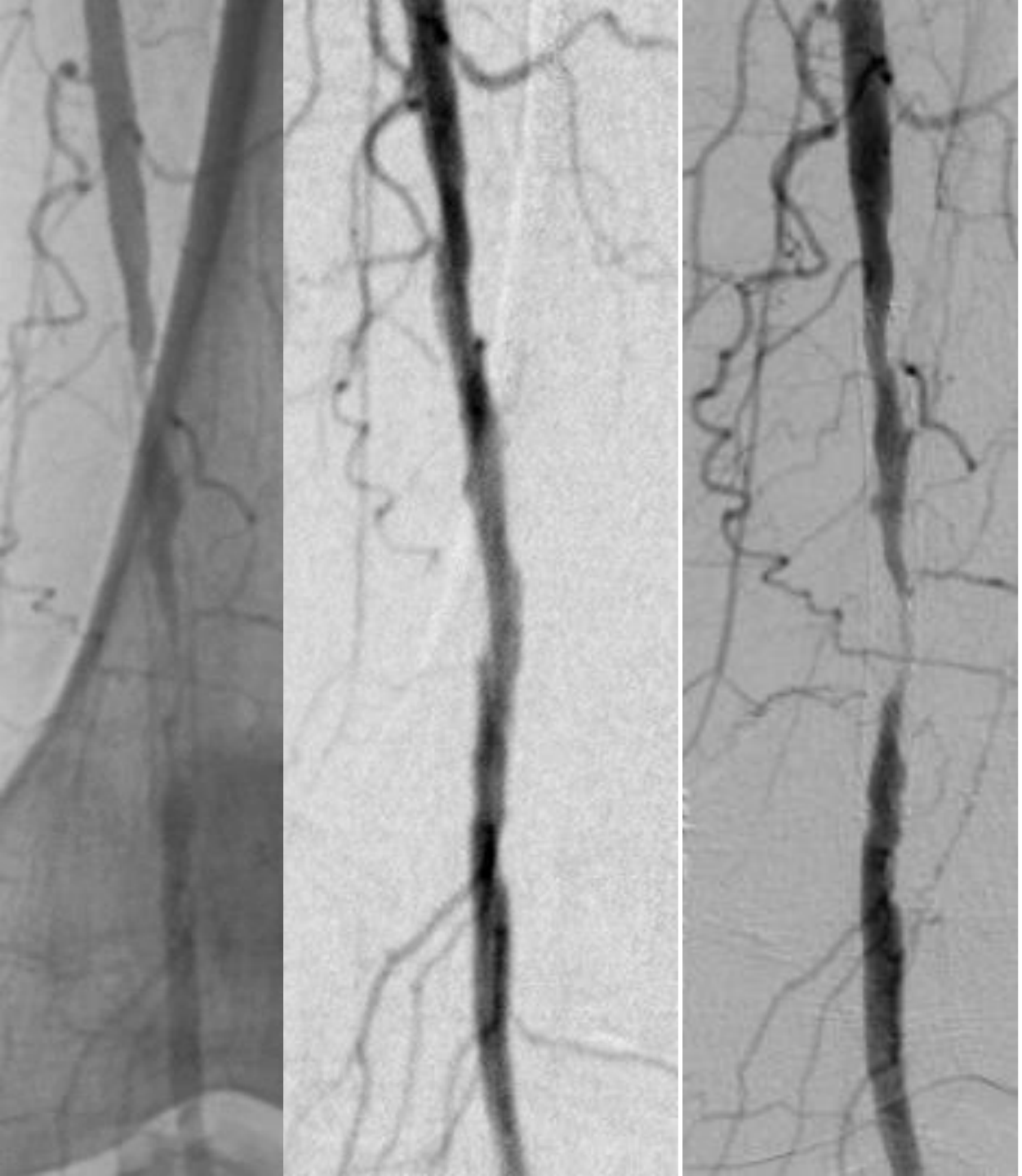
TLR	Freeway DEB (events)	Freedom TLR %	POBA (events)	Freedom TLR %
1-month	1	97.0	0	100.0
6-month	3	88.2	5	83.8
12-month	8	49.0	14	22.0

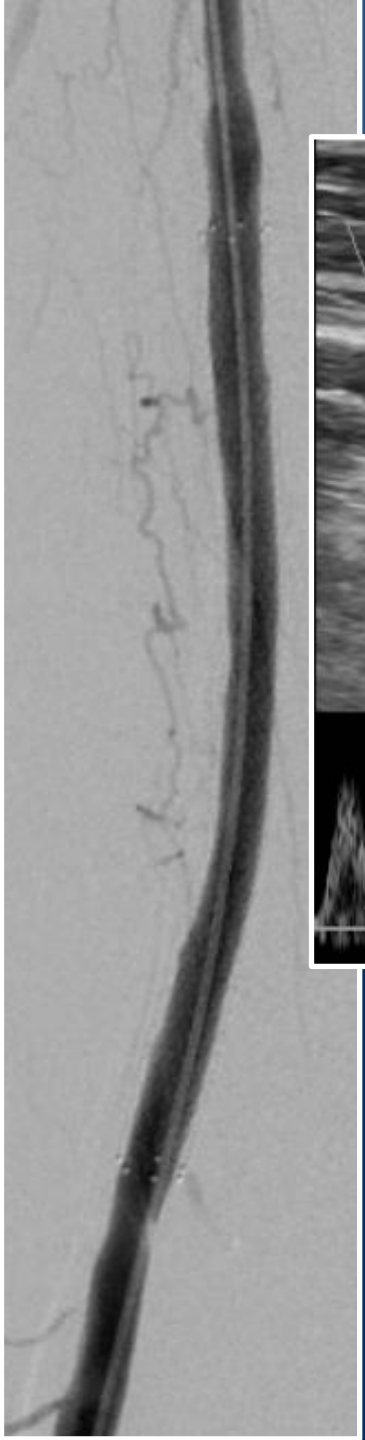
Kinstner C, Lammer J, et al. JACC Cardiovasc Intervent 2015 (in revision)

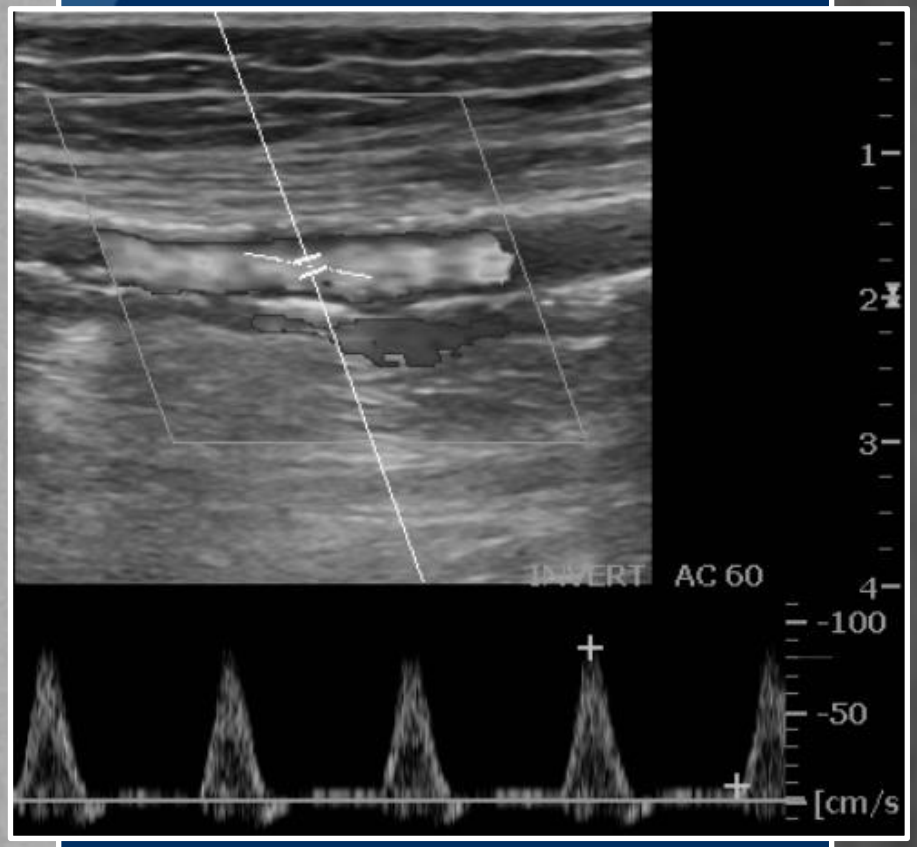
Clinical improvement – Rutherford class

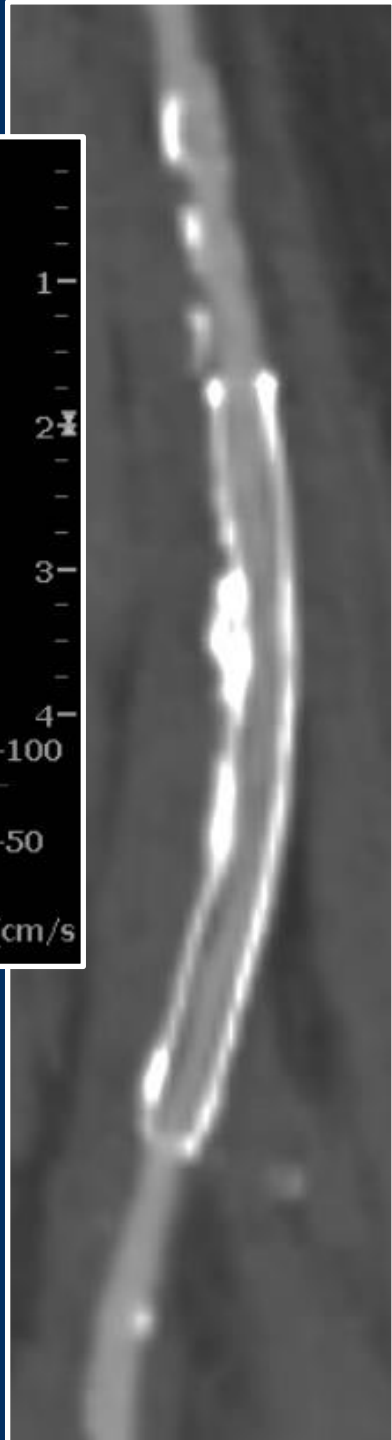




78a, female., CI, RB 3, TASC A, Tosaka Class I, PTA und 6 Mo f/u







67y, male, CI, RB 3,
TASC B, Tosaka Class II,
DEB and 6 Mo f/u

Conclusion

In ISR of femoropopliteal arteries

- DEBs achieve a significantly higher 1-year PP rate.
- Treatment of ISR with POBA is not a recommendable therapy.

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