

Long term effects of paclitaxel releasing balloon dilatation catheters for AVF stenosis: the evidence to date

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Declarations

- Supported by Cardionovum to attend LINC 2019
- Paid speaker at Industry Symposium at BSIR 2018

DCBs

	 	 	 	 	 	 
Dose (µg/mm ²)	2.0	3.5	3.0	3.0	2.0	2.0
Coating	Sorbitol and polysorbate	Urea	Safepax amorphous	Butyryl tri-hexylcitrate	TransPax	Polyethylene glycol
RBP (atm)	10-12	14	18-20	12-15	12-14	12-20
Max diameter (mm)	12	7	10	7	8	6
Min shaft (cm)	40	40	40	90	80	80
	CE	CE	CE	CE	CE	CE

Some non randomized data



InPact Admiral
In stent recurrent stenoses
Controls: same patient before DCB

f-TLR @ 1y
DCB: 69%, POBA: 19%. OR: 3.6



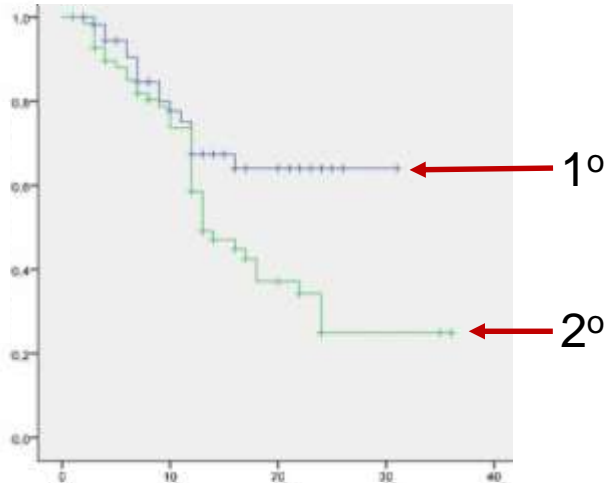
InPact Admiral
Historical controls.

f-TLR @6months
DCB: 90%, POBA: 61%. OR: 1.5
f-TLR @1y
DCB: 77%, POBA 29%. OR: 2.7



Long term results of >200 patients
with the Aperto® DCB from the
Italian Aperto registry

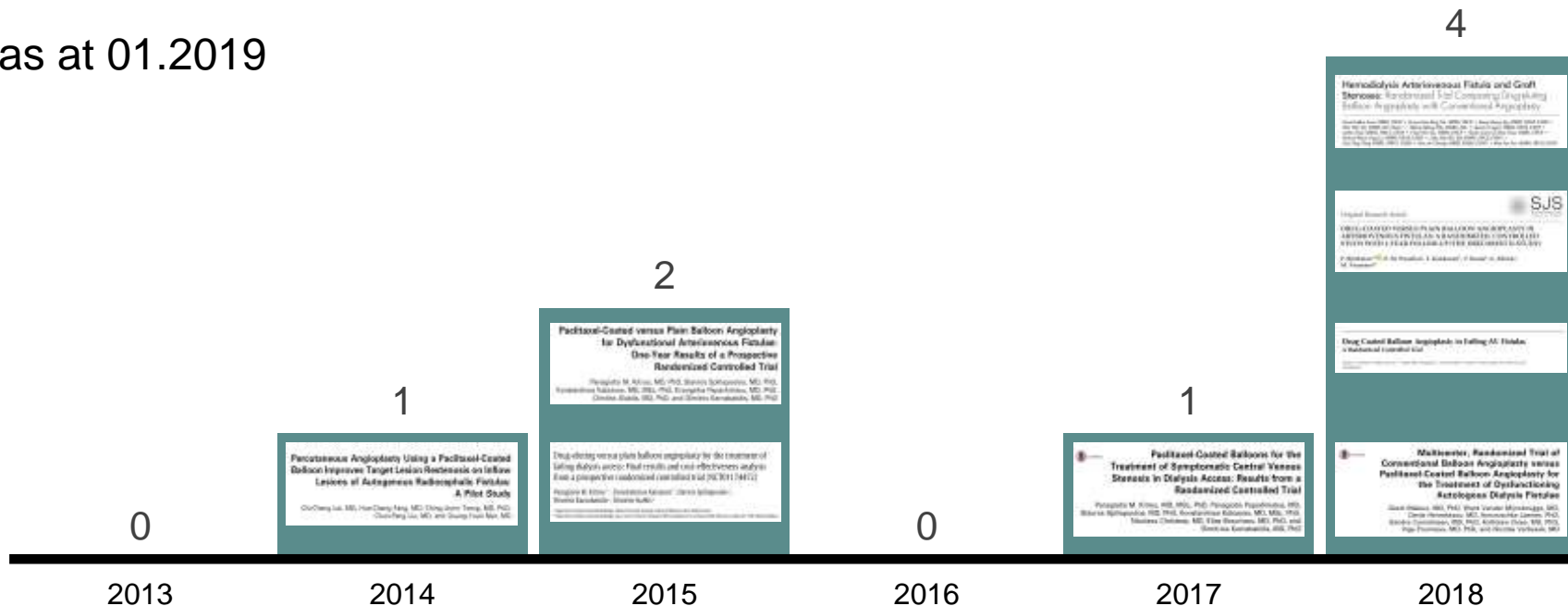
Descriptive cohort study, Italy, 4 centres, 2014-17



n	217
recruitment time	39 months
device	Aperto OTW
mean fistula age	50% <1y
type	50:50 fistulae and grafts
prior intervention	75%
endpoint time	f-TLR 6, 12 & 24 months 21 month mean FU
f-TLR DCB	6/12: 88% 1y: 64% 2y: 40%
Better patency with first interventions	

Published RCTs for DCBs in fistulae

as at 01.2019



Percutaneous Angioplasty Using a Paclitaxel-Coated Balloon Improves Target Lesion Revascularization in Bare Lesions of Arteriovenous Hemodialysis Fistulae: A Pilot Study
Choi-Chang Lee, MD, Hoon-Chang Kang, MD, Chung-Gwon Yoo, MD, PhD, Chul-Pang Lee, MD, and Chung-Feng Han, MD

Paclitaxel-Coated versus Plain Balloon Angioplasty for Dysfunctional Arteriovenous Fistulae: One-Year Results of a Prospective Randomized Controlled Trial
Prajayita M. Arora, MD, PhD, Stavros Spyridopoulos, MD, PhD, Evangelina Nakoulidou, MD, PhD, Christoforos Papadimitrakis, MD, PhD, Dimitrios Stalikis, MD, PhD, and Dimitrios Karantziolas, MD, PhD

Paclitaxel-Coated Balloons for the Treatment of Symptomatic Central Venous Stenosis in Dialysis Access: Results from a Randomized Controlled Trial
Prajayita M. Arora, MD, PhD, PhD, Prasadipati Papadimitrakis, MD, Stavros Spyridopoulos, MD, PhD, Evangelina Nakoulidou, MD, PhD, Christoforos Papadimitrakis, MD, PhD, Dimitrios Stalikis, MD, PhD, and Dimitrios Karantziolas, MD, PhD

Hemodialysis Arteriovenous Fistula and Graft Stenosis: Randomized Trial Comparing Drug-Eluting Balloon Angioplasty with Conventional Angioplasty
Prajayita M. Arora, MD, PhD, Stavros Spyridopoulos, MD, PhD, Evangelina Nakoulidou, MD, PhD, Christoforos Papadimitrakis, MD, PhD, Dimitrios Stalikis, MD, PhD, and Dimitrios Karantziolas, MD, PhD

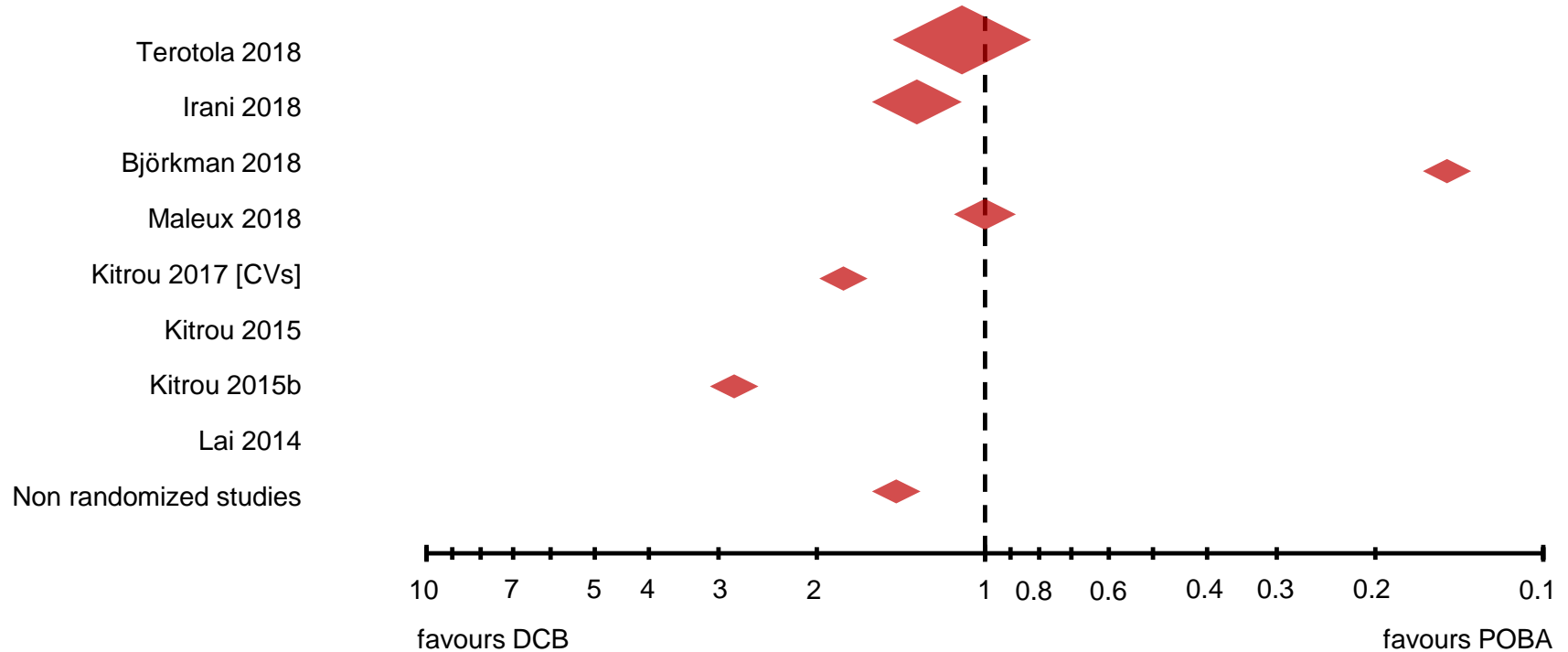
Drug-Coated Balloon Angioplasty in Failing AV Fistulae: A Randomized Controlled Trial
Prajayita M. Arora, MD, PhD, Stavros Spyridopoulos, MD, PhD, Evangelina Nakoulidou, MD, PhD, Christoforos Papadimitrakis, MD, PhD, Dimitrios Stalikis, MD, PhD, and Dimitrios Karantziolas, MD, PhD

Multicenter, Randomized Trial of Conventional Balloon Angioplasty versus Paclitaxel-Coated Balloon Angioplasty for the Treatment of Dysfunctioning Arteriovenous Dialysis Fistulae
Prajayita M. Arora, MD, PhD, Stavros Spyridopoulos, MD, PhD, Evangelina Nakoulidou, MD, PhD, Christoforos Papadimitrakis, MD, PhD, Dimitrios Stalikis, MD, PhD, and Dimitrios Karantziolas, MD, PhD

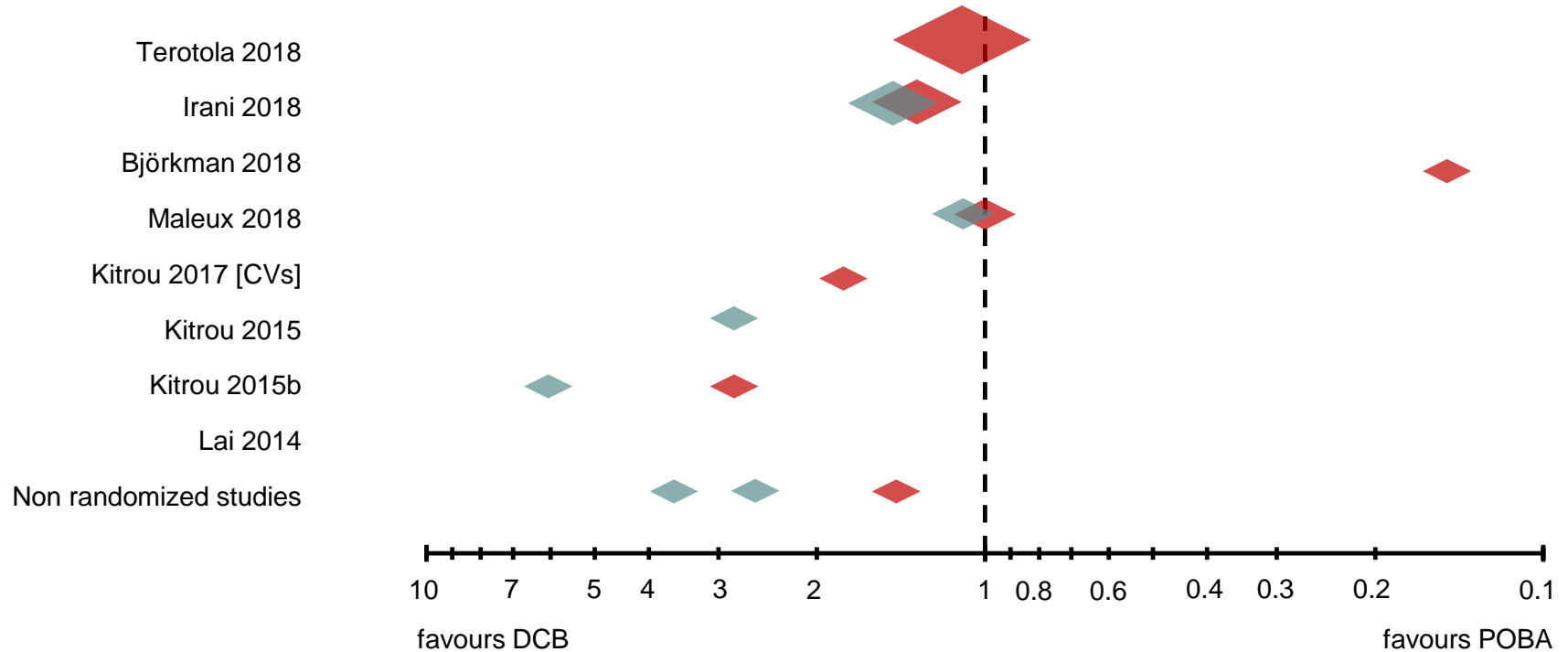
RCTs

	n	time	device	site	predilated	sham	age	matching
Terotola 2018	285	10	Lutonix	Fist	✓	✓	38	👍
Irani 2018	119	16	In.Pact	Fist, Graft	✓	✓	45	☐
Björkman 2018	39	30	In.Pact	Fist	✓	✓	6	👍
Maleux 2018	64	33	In.Pact	Fist	✓	✗	36	👍
Kitrou 2017 [CVs]	40	20	Lutonix	Central	✓	✗	34	👍
Kitrou 2015	40	17	In.Pact	Fist	✗	✗	30	☐
Kitrou 2015b	40	10	In.Pact	Fist, Graft		✗	30	☐
Lai 2014	20	12	Coronary DCB	Fist	✓	✗	26	👎

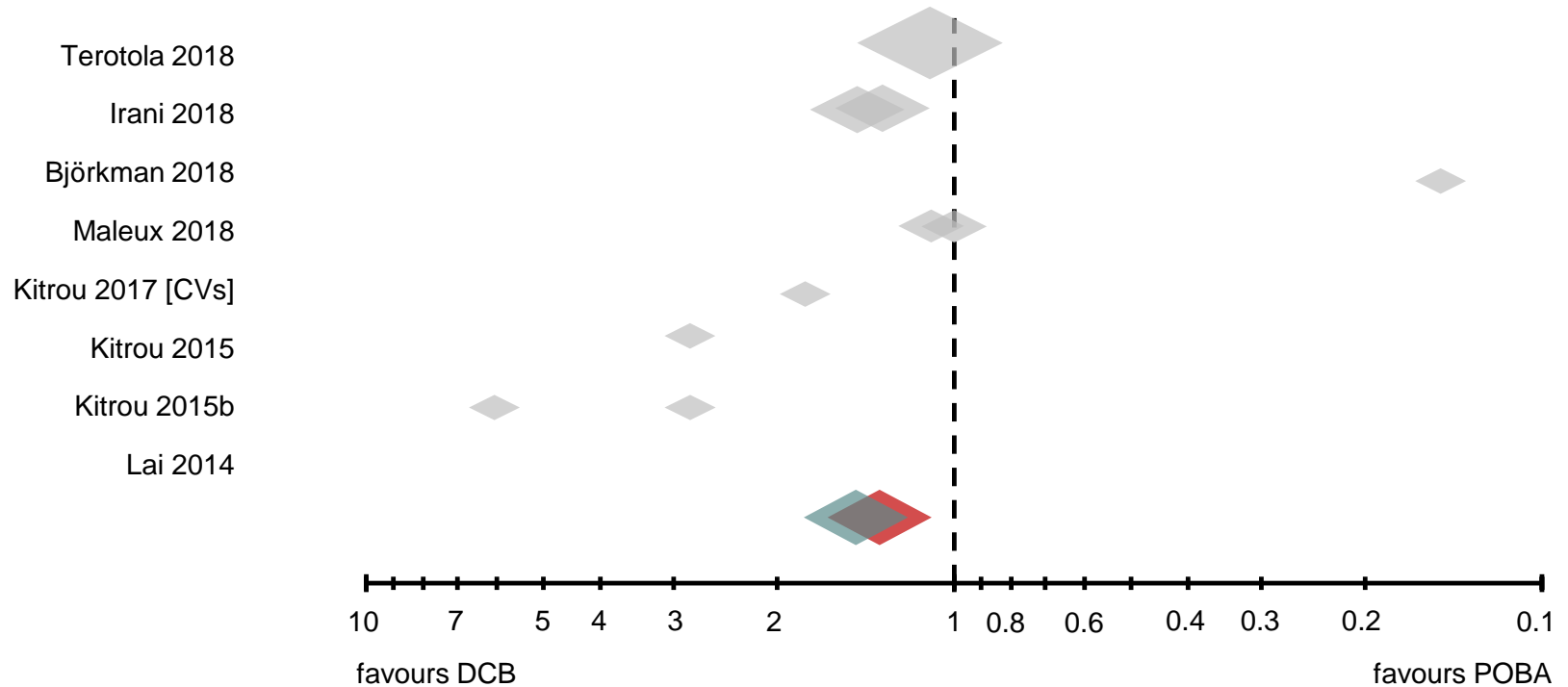
Trials – 6 month outcomes



Trials – 6 month & 1y outcomes



Aperto registry



The future



In.PACT AV access IDE study
330 patients



PAVE
211 patients, recruitment complete 2018



Aperto trial
161 patients, recruitment complete 2018, 6m FU data expected Feb 2019



UK DeVA
186 patients, recruiting

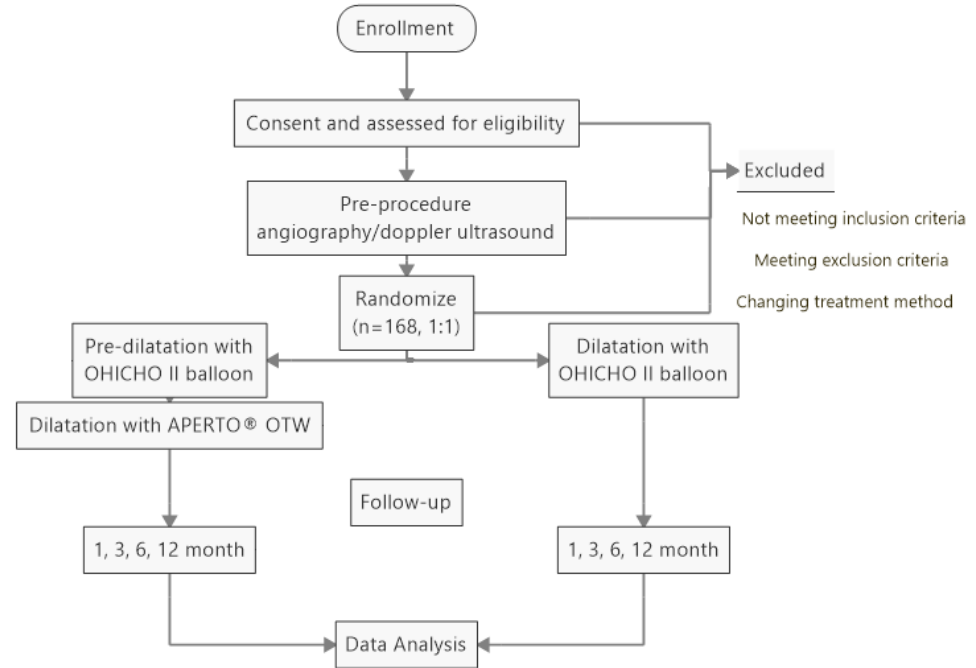


Aperto AVF trial China

Prospective multicentre RCT
OHICHO II balloon ± APERTO

F-TLR @6/12

Superiority design



A note of caution

SYSTEMATIC REVIEW AND META-ANALYSIS



Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBPI; Stavros Salikoko-Ayio, MD, PhD; Pavloskris Ekrov, MD, PhD; Wlodek Krakowski, MD, PhD; Dimitrios Karabatidas, MD, PhD

Cardiovasc Intervent Radiol
<https://doi.org/10.1007/s00270-018-2137-3>



CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Impact of Patient and Lesion Characteristics on Drug-Coated Balloon Angioplasty in the Femoropopliteal Artery: A Pooled Analysis of Four Randomized Controlled Multicenter Trials

Thomas Albrecht^{1,2} · Antonia Ekrov¹ · Michael Werk³ · Gunnar Tepe⁴ · Thomas Zeller⁴ · Dirk-Roelofs Meyer² · Marcia Kutschera⁵ · Ulrich Speck⁶ · Matthias Waliszewski^{7,8}

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Summary

- Long term outcomes after fistula intervention are poor
- Stenoses recur in perhaps half to two-thirds by 1y
- No good evidence of DCB efficacy at the moment but perhaps a signal of a small effect
- More trials on the way
- Consensus that vessel preparation is important: advantage of a high pressure DCB.

Thank you for your attention

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 @doctorhammond

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