

# PCB vs POBA:

Drecorest II RCT results

Eeva-Maija Weselius, M.D., PhD  
Helsinki University Hospital

CACVS, Paris 2020

**Drug-Coated Versus Plain Balloon  
Angioplasty In Arteriovenous Fistulas: A  
Randomized, Controlled Study With 1-  
Year Follow-Up (The Drecorest II-Study)**  
**P. Björkman, E. -M. Weselius, T.  
Kokkonen, V. Rauta, A. Alback, M. Venermo**

**Scand J Surg 2018**

# Disclosures

I do not have any potential conflict of interest

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# Introduction

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Access failure is common due to neointimal hyperplasia (NIH) and subsequent stenosis

The biomechanical and flow conditions differ from the arterial environment (Dunque et al. 2017)

Arterial pressure and surgical trauma - > NIH and stenosis?

(Wasse et al. 2012)

Repetitive punctures -> traumas

# Introduction

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Kitrou et al 2015

- “PCBs resulted in superior TLR-free survival” at 1 y follow-up
- Included prosthetic grafts
- Mean time from fistula creation 2.5 years

Khawaja et al, 2016

- Meta-analysis of 4 cohorts and 2 RCTs (N=254)
- Better patency at 6 mo, no difference at 12 mo
- “Clinically heterogeneous population”

Kennedy et al, 2019

Meta-analysis: DCB better than POBA at 3, 6, 12 and 24 months

Trerotola et al 2020

Lutonix trial, 2 y follow-up. PCB better at 9 months with lower TLR rate

# Paclitaxel

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Antiproliferative drug

Uptake unpredictable in arterial tissue

Rare/ none published data on venous uptake

- - clinically studied in venous bypass grafts in vascular surgery (Björkman et al 2018, DRECOREST I study)





# Study Design

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Conventional balloon angioplasty (BA) vs. drug-coated balloon angioplasty (DCB)

- Randomized 1:1

Primary outcome measure: target lesion revascularization (TLR) during 1 yr follow-up



# Study Design

<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
<p>US documented stenosis</p> <p>Eligible for angioplasty</p> <p>Adequate flow above lesion</p> <p>Age &gt;18</p> <p>Signed and dated consent</p> <p>Negative pregnancy test when applicable</p>	<p>Previous DCB-treatment</p> <p>Known allergy to paclitaxel</p> <p>Coagulopathy</p> <p>Occluded AVF</p> <p>Perianastomotic stenosis (&lt; 1,5 cm)</p> <p>Life expectancy &lt;1 year</p>

# Methods & Materials

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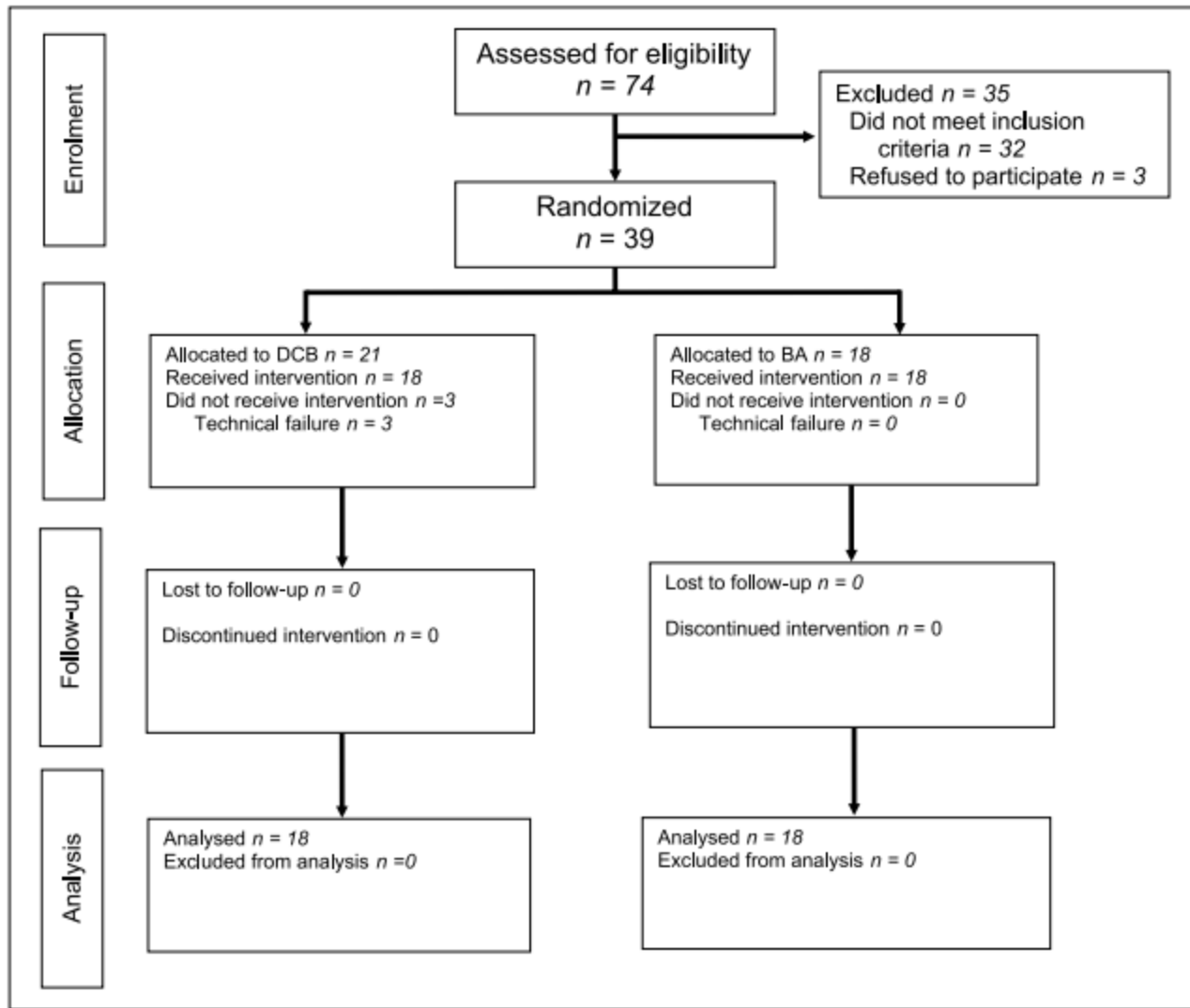
Randomization: 8/2013- 2/2016

No difference in baseline characteristics

Autologous AVFs (incl. cimino and proximal AVFs)

Stenosis detected after difficult or failed dialysis

All AVFs were in use



		BA		DCB		p-value
		Mean	Range	Mean	Range	
Age		67.0	28-82	67.4	46-87	0.669
		<i>N</i>	%	<i>N</i>	%	
Sex	Female	5		8		0.305
	Male	13		10		
Diabetes	None	7	38.9	7	38.9	0.910
	T2, diet controlled	2	11.1	1	5.6	
	T2, insulin controlled	6	33.3	8	44.4	
	T1	3	16.7	2	11.1	
Hyperlipidemia	None	7	38.9	4	22.2	0.337
	Statin controlled	11	61.1	14	77.8	
Cerebrovascular	None	17	94.4	13	72.2	0.088
	Asymptomatic, evidence of disease	0	0	2	11.1	
	TIA, resolved stroke	0	0	3	16.7	
	Stroke with permanent deficit	1	5.6	0	0	
Hypertension	None	4	22.2	2	11.1	0.457
	1 drug	8	44.4	8	44.4	
	2 drugs	3	16.7	6	33.3	
	>2 drugs	3	16.7	2	11.1	
Cardiac	None	10	55.6	6	33.3	0.083
	AMI >6 mo, asymptomatic CHF	3	16.7	3	16.7	
	Stable AP, asymp. arrhythmia	5	27.8	7	38.9	
	Unstable AP, symp. arrhythmia, severe CHF	0	0	2	11.1	
Pulmonary	None	13	72.2	16	88.9	0.285
	Mild	4	22.2	1	5.6	
	Moderate	1	5.6	0	0	
	Severe	0	0	1	5.6	
Smoking	None	15	83.3	15	83.3	0.964
	No, quit within 10 years	2	11.1	2	11.1	
	Yes, <20/day	1	5.6	1	5.6	
	Yes, >20/day	0	0	0	0	
ASA	Yes	14	77.8	14	77.8	0.932
	No	4	22.2	4	22.2	
Clopidogrel	Yes	1	5.6	3	16.7	0.271
	No	17	94.4	15	83.3	
Warfarin	Yes	2	11.1	5	27.8	0.187
	No	16	88.9	13	72.2	
Brachial flow (ml/min)		584.2	100-2000	501.2	300-1000	0.811

# Methods

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Puncture 4-6F, usually brachial artery (angioradiologist)

Predilatation with conventional PTA (1 mm smaller) before randomization (90 s)

Dilatation with DCB/BA (mean 274/ 278 s,  $p=0.84$ )

- DCB with paclitaxel dose  $3.5 \mu\text{g}/\text{mm}^2$
- (DCB: IN.PACT, Medtronic, Minneapolis, MN, USA)

Technical success: residual stenosis  $< 30 \%$

Duplex US before procedure, after and at 1, 6 and 12 months after

Dual antiplatelet therapy 1 mo

# Results

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36 patients analyzed (18 DCB and 18 BA)

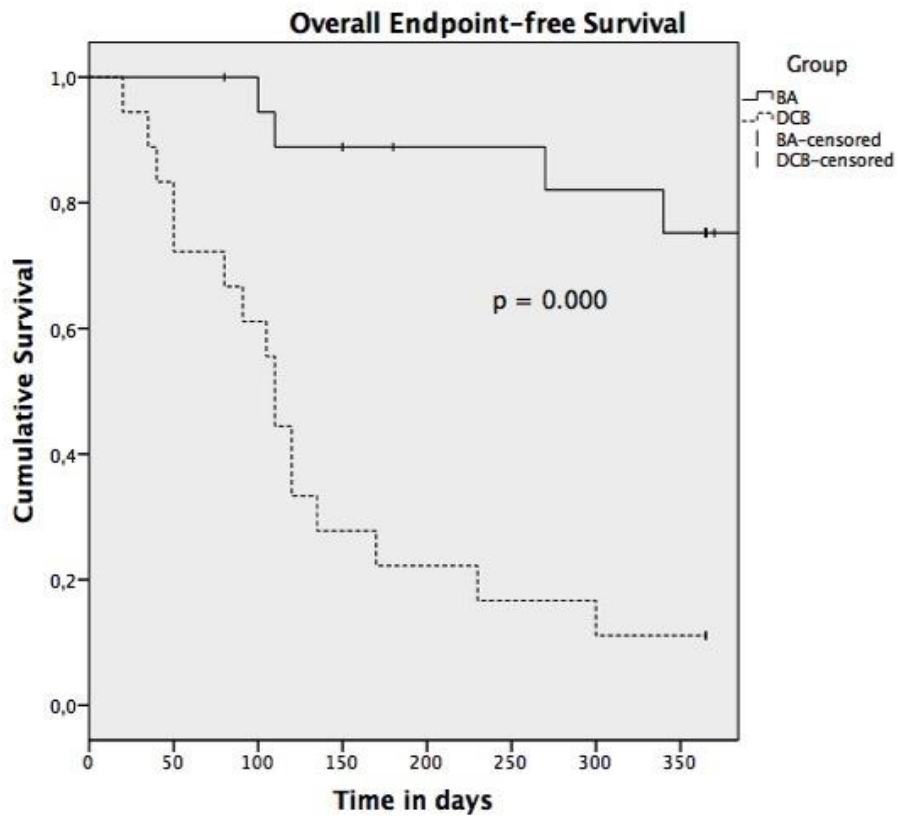
A-V age: DCB mean 165 d vs BA 292 (P=0.169)

Overall TLR-rate 88.9% (DCB) and 22.2% (BA), P<0.001

Mean time to TLR: 110 d (DCB) vs. 193 d (BA), P=0.06



# Results



Overall TLR-rate  
88.9% (DCB) and  
22.2% (BA)

Log-rank  
 $P < 0.001$

# Results

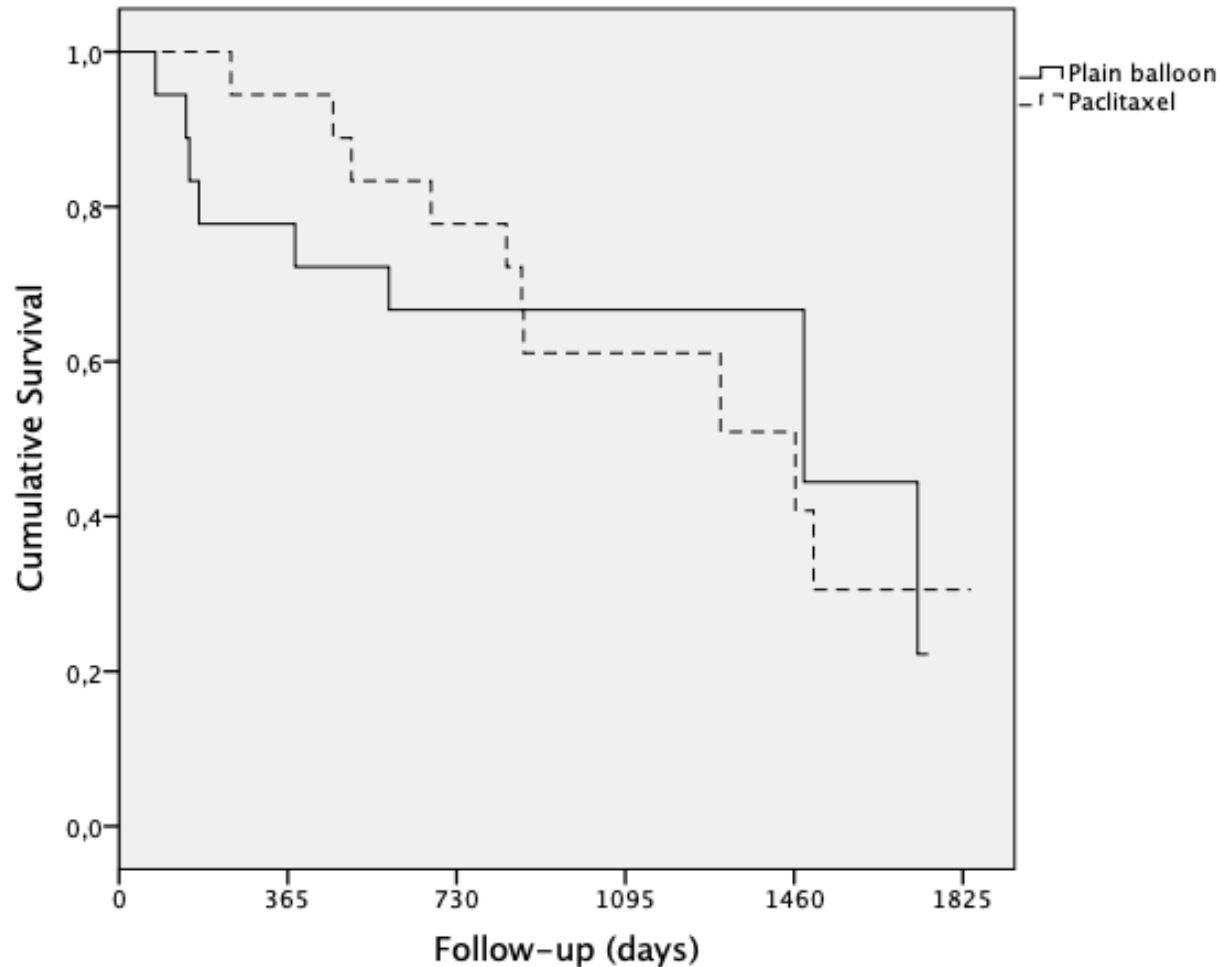
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No difference in endpoints

- Re-PTA
- Proximalisation of AVF
- Occlusion of AVF

# No difference in mortality (post hoc analysis)

DRECOREST2 (AVF)



# Limitations

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Small sample size, did not reach power calculation targets

-> Risk of type I error

Strict criteria - slow recruitment

Study design

- - No perianastomotic lesions included (< 1,5 cm)
- - No high pressure balloons used in this series
- - the role of dual antiplatelet medication?
- - much younger fistulas than in other series

# Discussion

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Is especially paclitaxel "the agent to go" in the treatment of (neo)intimal hyperplasia of a-v fistulas?

Different study designs and protocols may effect on results and on conclusions (design/protocol vs Paclitaxel's effect)

- - Kennedy et al 2019

# Conclusions

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DCB may be harmful for recently constructed AVFs, therefore  
DCB-assisted *maturation* may be discouraged

More studies are needed on AVF biology and paclitaxel uptake



