

# Propensity-matched analysis in claudicants treated with a drug-coated balloon vs. PTA: 5 year mortality outcomes from a real-world study

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# Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting: Boston, Cook, Cordis, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- CEO Vascupedia
  
- I do not have any potential conflict of interest

# Background

- Strong evidence regarding the clinical utility of the use of paclitaxel-coated technologies
- A meta-analysis concluded that there is an **increased risk of death** at 2 and 5 ys. after DCB
- We need to assess whether the unexpected findings of the Katsanos meta-analysis may be **reproduced** in broad real-world clinical studies

# Aim of the study

5-year evaluation of long-term, all-cause mortality after treatment of femoro-popliteal lesions with paclitaxel-coated vs. plain balloon angioplasty for claudication

# Study design

- Inclusion: All claudicants who underwent endovascular treatment of a de novo femoropopliteal lesion 2013
- Exclusion: Patients with in-stent restenosis, concomitant severe (>50%) CFA stenosis, bypass stenosis, iliac or infrapopliteal lesions

# Patients included – 1. Step

- **238** consecutive patients with claudication and femoropopliteal lesion in 2013
- **GROUP A :113** Pat. with PTA/Stent
- **GROUP B: 125** Pat. with DCB/Stent
- **15** patients were lost to follow up
- **223** Pat.
- **Group A, n=102** with intention to treat with PTA
- **Group B, n= 121** with intention to treat with DCB

Variables	GROUP A PTA (n=102)	GROUP B DCB (n=121)	P - test	
<b>CLINICAL AND OPERATIVE DATA</b>				
Occlusion (%)	24 – 23.5	37 – 30.6	.239	Pearson Chi
<b>Stenting (%)</b>	<b>62 – 60.8</b>	<b>33 – 27.3</b>	<b>&lt;.001</b>	<b>Pearson Chi</b>
Reintervention (%)	24 – 23.5	30 – 24.8	.826	Pearson Chi
No of treated vessels (median, min-max)	1 (1 – 4)	1 (1 – 3)	.562	Mann-Whitney
<b>Balloon length (median)</b>	<b>200</b>	<b>120</b>	<b>.004</b>	<b>Mann-Whitney</b>
No of stents* (med min-max)	1 (1 – 3)	1 (1 – 2)	.273	Mann-Whitney
Total stent length* (median)	140	135	.832	Mann-Whitney
<b>RESULTS</b>				
Follow-up mortality (n,%)	<u>24 (23.5%)</u>	<u>17 (14.0%)</u>	.069	Pearson Chi
Follow-up (median, IQR)	61.4 – 22.4	62.6 – 11.4	.211	Mann-Whitney

Variables	GROUP A PTA (n=102)	GROUP B DCB (n=121)	P - test	
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### DEMOGRAPHICS and COMORBIDITIES

<b>Age (median, IQR)</b>	<b>73.2 – 10.5</b>	<b>68.5 – 16.1</b>	<b>&lt;.001</b>	<b>Mann-Whitney</b>
Male gender (n,%)	66 – 64.7	73 – 60.3	.502	Pearson Chi
Smoking (n,%)	25 – 24.5	42 – 34.7	.098	Pearson Chi
Hypertension (n,%)	83 – 81.8	99 – 81.8	.932	Pearson Chi
Hyperlipidaemia (n,%)	60 – 58.8	75 – 62.0	.631	Pearson Chi
Diabetes Melitus (n,%)	28 – 27.5	36 – 29.8	.705	Pearson Chi
Coronary Artery Disease (n,%)	45 – 44.1	46 – 38.0	.356	Pearson Chi
<b>Renal insufficiency (n,%)</b>	<b>18 – 17.6</b>	<b>8 – 6.6</b>	<b>.011</b>	<b>Pearson Chi</b>
Dialysis (n,%)	4 – 3.9	2 – 1.7	.297	Pearson Chi
COPD (n,%)	14 – 13.7	12 – 9.9	.377	Pearson Chi
Statin medication (n,%)	56 – 54.9	72 – 59.5	.489	Pearson Chi
Clopidogrel medication (n,%)	18 – 17.6	25 – 20.7	.570	Pearson Chi



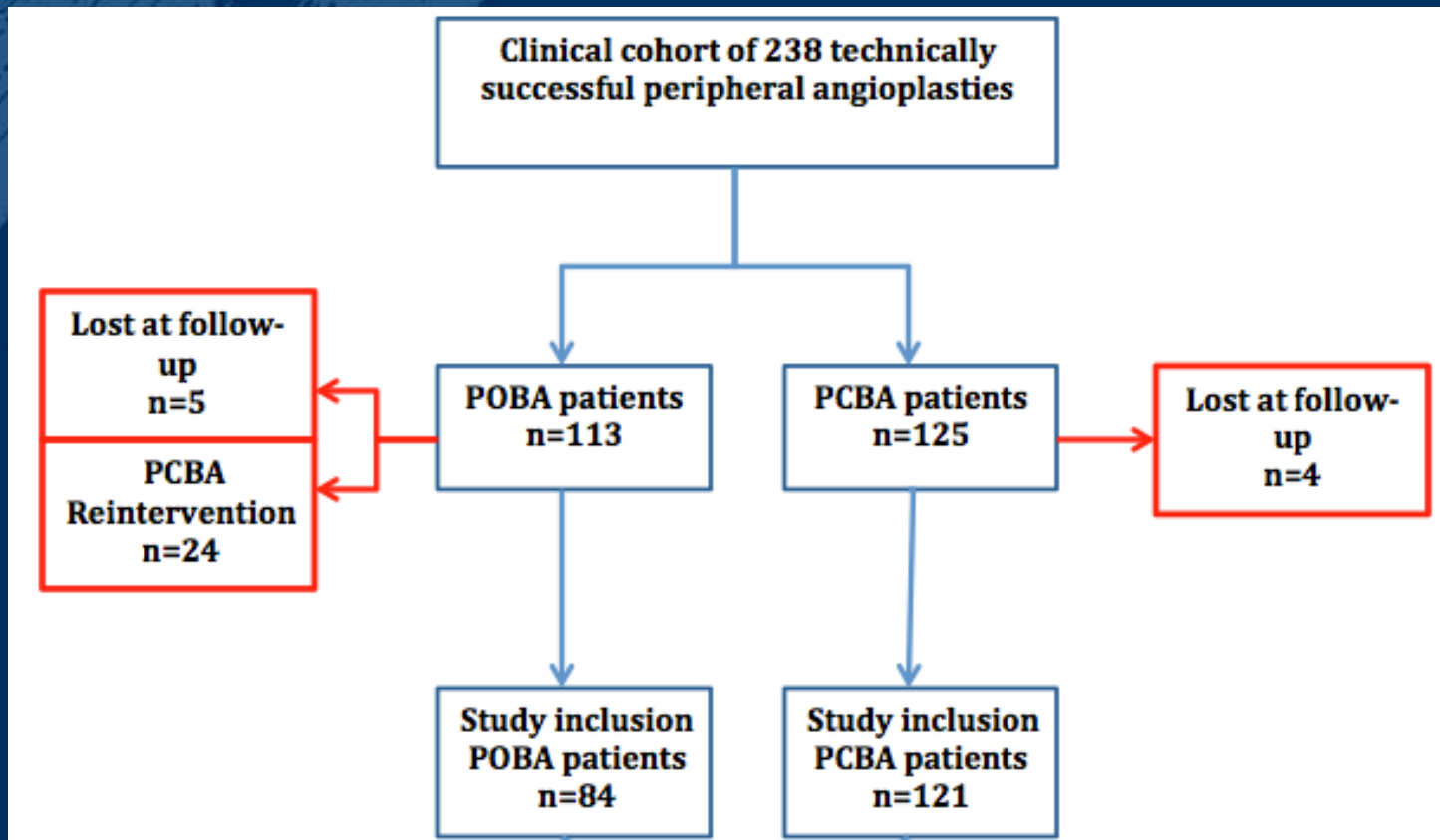
# Evaluation during FU

102 Patienten with POBA



18 Patienten (17.6%) received during the FU reinterventions with DCB-> 84 Patienten without any DCB treatment during FU.

# Flow chart – Evaluation based on crossover



Variables	Group A: PTA(n=84)	Group B: DCB(n=121)	P - test	
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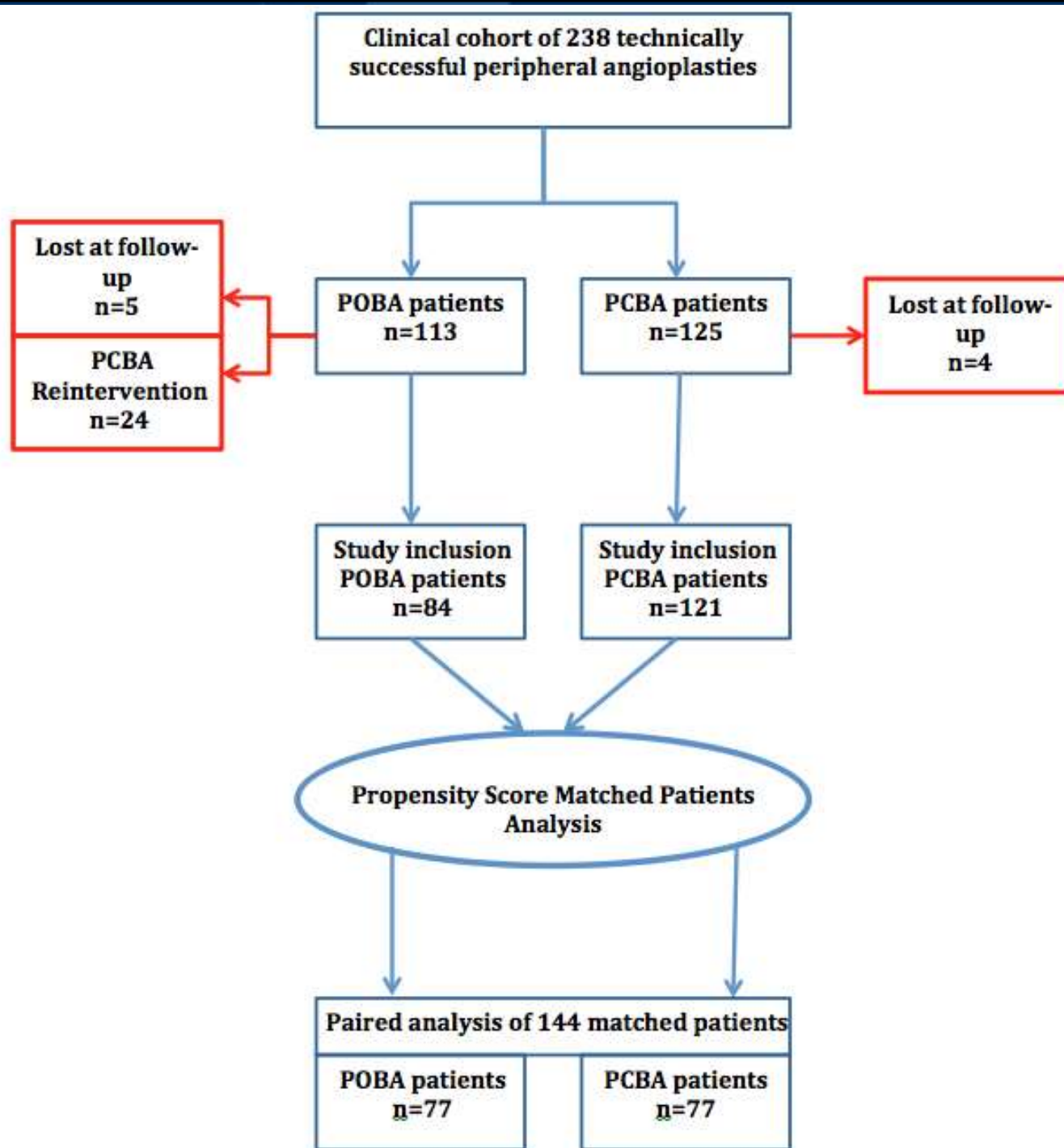
### CLINICAL AND OPERATIVE DATA

Occlusion	21 – 25	37 – 30.6	.383	Pearson Chi
Stenting	52 – 61.9	33 – 27.3	<.001	Pearson Chi
Reintervention	24 – 23.5	30 – 24.8	.826	Pearson Chi
Total balloon length (median IQR)	165	120	.039	Mann-Whitney
No of stents (median, min-max)	1 (1 – 3)	1 (1 – 2)	.594	Mann-Whitney
Total stent length (median)	150	120	.026	Mann-Whitney

### RESULTS

Follow-up mortality (n,%)	<u>22 (26.2%)</u>	<u>17 (14.0%)</u>	<u>.029</u>	<u>Pearson Chi</u>
Follow-up in months (median, IQR)	61.6 – 17.7	62.9 – 8.7	.623	Mann-Whitney

Variables	Group A:	Group B:	P - test	
	PTA(n=84)	DCB(n=121)		
<b>DEMOGRAPHICS and COMORBIDITIES</b>				
<b>Age (median, IQR)</b>	<b>73.9 – 10.2</b>	<b>66.1 – 16.8</b>	<b>&lt;.001</b>	<b>Mann-Whitney</b>
Male gender (n,%)	57 – 67.9	73 – 60.3	.271	Pearson Chi
<b>Smoking (n,%)</b>	<b>17 – 20.2</b>	<b>42 – 34.7</b>	<b>.024</b>	<b>Pearson Chi</b>
Hypertension (n,%)	70 – 83.3	99 – 81.8	.779	Pearson Chi
Hyperlipidaemia (n,%)	53 – 63.1	75 – 62.0	.872	Pearson Chi
Diabetes Melitus (n,%)	20 – 23.8	36 – 29.8	.348	Pearson Chi
Coronary Artery Disease (n,%)	39 – 46.4	46 – 38.0	.229	Pearson Chi
<b>Renal insufficiency (n,%)</b>	<b>18 – 21.4</b>	<b>8 – 6.6</b>	<b>.002</b>	<b>Pearson Chi</b>
Dialysis (n,%)	2 – 2.4	2 – 1.7	.711	Pearson Chi
COPD (n,%)	13 – 15.5	12 – 9.9	.232	Pearson Chi
Statin medication (n,%)	49 – 58.3	72 – 59.5	.867	Pearson Chi
Clopidogrel medication (n,%)	13 – 15.5	25 – 20.7	.347	Pearson Chi



## Propensity Score Matched Patients Analysis

77 comparable patients in each arm

Criteria: age/comorbidities/operative data

Donas K et al. Cardiovasc Intervent Radiol (2019). <https://doi.org/10.1007/s00270-019-02329-z>

# PROPENSITY SCORE ANALYSIS

Variables	Group A: PTA (n=77)	Group B: DCB	P - test	
<b>DEMOGRAPHICS and COMORBIDITIES</b>				
Age (median, IQR)	73.2 – 9.0	72.9 – 13.0	<b>.534</b>	Mann-Whitney
Male gender (n,%)	50 – 64.9	48 – 62.3	<b>.738</b>	Pearson Chi
Smoking (n,%)	17 – 22.1	23 – 39.9	<b>.270</b>	Pearson Chi
Hypertension (n,%)	64 – 83.1	67 – 87.0	<b>.498</b>	Pearson Chi
Hyperlipidaemia (n,%)	48 – 62.3	54 – 70.1	<b>.307</b>	Pearson Chi
Diabetes Melitus (n,%)	18 – 23.4	17 – 22.1	<b>.848</b>	Pearson Chi
Coronary Artery Disease (n,%)	34 – 44.2	30 – 39.0	<b>.513</b>	Pearson Chi
Renal insufficiency (n,%)	16 – 20.8	8 – 10.4	<b>.076</b>	Pearson Chi
Dialysis (n,%)	2 – 2.6	2 – 2.6	<b>1.00</b>	Pearson Chi
COPD (n,%)	12 – 15.6	9 – 11.7	<b>.481</b>	Pearson Chi
Statin medication (n,%)	44 – 57.1	54 – 70.1	<b>.093</b>	Pearson Chi
Clopidogrel medication (n,%)	12 – 15.6	17 – 22.1	<b>.410</b>	Pearson Chi

# PROPENSITY SCORE ANALYSIS

Variables	Group A: PTA (n=77)	Group B: DCB (n=77)	P - test	
<b>CLINICAL AND OPERATIVE DATA</b>				
Occlusion	19 – 24.7	20 – 26.0	.853	Pearson Chi
Reintervention in FU	5 – 6.5	15 – 19.5	.017	Pearson Chi
Total balloon length (median IQR)	150 – 155	120 – 120	.055	Mann-Whitney
No of stents* (median, min-max)	1 (1 – 3)	1 (1 – 2)	.610	Mann-Whitney
Total stent length* (median, IQR)	150 – 190	100– 140	.060	Mann-Whitney
<b>RESULTS</b>				
Follow-up mortality (n,%)	<b><u>20 (26%)</u></b>	<b><u>16 (20.8%)</u></b>	<b><u>.446</u></b>	<b><u>Pearson Chi</u></b>
Follow-up in months (median, IQR)	<b>61.7 – 14.7</b>	<b>61.8 – 11.4</b>	<b>.859</b>	<b>Mann-Whitney</b>



# Paclitaxel dose and mortality

Table 5 In DCB Subgroup correlation of mortality with paclitaxel dose.			
	SURVIVED	DECEASED	P
	n=104 [26.0]	n=17 [14.0]	
<b>ANGIOPLASTY DATA</b>			
Area [mm <sup>2</sup> ]	2355 [2404]	2355 [2551]	.489
Dose [µg/mm <sup>2</sup> ]	8243 [8414]	8243 [8930]	.489
Stenting	27 [26.0]	6 [35.3]	.423
Continuous data presented as median [IQR]. Categorical data presented as n [%].			

Area calculated as  $\pi R^2 \times$  balloon length (R= balloon diameter/2)

Dose calculated as Area  $\times$  3,5µg/mm<sup>2</sup> (Impact – Medtronic)

# Conclusions

5-year evaluation shows:

No increased mortality in patients treated by DCB vs POBA

Mortality does not correlate with the Paclitaxel dose

# Strengths of the evaluation

1. Only pat. with claudication included (100% vs. 92% *Katsanos*)
2. Small number of Pat. Lost to follow up at 5 y. (6% vs 80% *Katsanos*)
3. Evaluation of medication (Clopidogrel/Statins)
4. Only one type of DCB used (MDT; 3.5  $\mu\text{g}/\text{mm}^2$ ) vs 11 DCBs (*Katsanos*)
5. Patient-level data (including sizes of the balloons and PTX dosis)
6. Patients initially treated with PTA and receiving DCB during the FU considered



homepage: [www.gefaesschirurgie-muenster.de](http://www.gefaesschirurgie-muenster.de)

Thank you!



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