

**Propensity Matched Comparison of Uncoated and Paclitaxel-Coated Balloon Angioplasty for Isolated Popliteal Lesions Excluding Bail-Out Stenting: The DCB are Better**

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### Disclosures


- Consultant / Speaker / Proctor / Advisory Board
  - Abbott
  - BD Bard
  - Boston Scientific
  - Cook
  - iVascular
  - Medtronic
  - Merit
  - Penumbra
  - Philips
  - Volcano
  - W.L. Gore & Associates
  - Zyxlo Tonbridge

### Background

- DCB have demonstrated excellent results in the treatment of femoropopliteal lesions
- International guidelines include recommendations for the use of DCB in the treatment of fem-pop lesions
- No studies investigated DCB in medial and distal pop segment

**Outcomes of EVT in Popliteal Artery Disease**


Investigator	Study design	Modality	Lesion length	Primary patency @1yr	TLR @1yr
Rastan A. et al. (2015)	RCT	81/6 (n=118) POBA (n=57) / Prov stent 25.2%	42 mm	68% vs. 62% (p<0.002)	14.7% vs. 14.3%
Sago Y. et al. (2015)	Retrospective	POBA (n=103) / Prov stent 14.6%	45 mm	75.5%	NR
Scheiner D et al. (2013)	Retrospective	Supera (n=101)	58 mm	87.7%	6.9%
Rastan A. et al. (2018)	Prospective (IC and CL)	Directional Atherectomy (n=158)	58mm	75.0%	21.2%
Stavroulakis K. et al. (2017)	Retrospective	DCB (n=31) DRAET (n=41)	47/42mm	60% vs. 62% (p=0.021)	6% vs. 8% (p=0.072)
KPOP (LINC 2022)	Prospective	DCB (n=100) / Atherectomy 16.3% Prov stent 12.8%	46 mm	76%	12.8%
San Norberto E et al. (2023)	Retrospective	DAORF (n=62) Supera (n=81)	33 mm 50 mm	74% vs. 77% (p=0.233)	NR



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**Retrospective study to evaluate safety and effectiveness of DCB in isolated popliteal lesions comparing outcome to a matched cohort undergoing POBA at one-year FU**

- Primary endpoint: 1-year TLR-free survival rate by KM analysis
- Secondary endpoints: procedural success (residual TL stenosis ≤30 % by visual estimation during angiography, overall procedural complication rate, 6 and 12-mos PP, changes in RBC and ABI, amputation rate and mortality rate after 12-mos



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- 107 pts. with arteriosclerotic lesions of the popliteal artery were included
- 60 POBA and 47 DCB
- Pts. RBC 2 to 5 with a single ≥70 %\* Pop stenosis
- Calcification was classified, according to extent
- Patients who underwent debulking or bail-out stenting were not included

Over 10 years  
3483 interventions involving the popliteal segment

354 patients with an isolated popliteal artery lesion

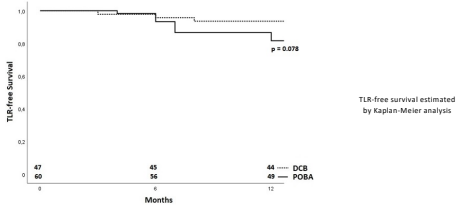
Exclusion because of:  
Bail-out Stenting  
Use of debulking devices

107 patients without adjacent treatment

60 patients in the POBA cohort      47 patients in the DCB cohort

\*Estimated by duplex US with a PSV ratio of >3.5 and/or visually on angiography

### Results



TLR-free survival estimated by Kaplan-Meier analysis

14 patients (13.1 %) had to undergo a TLR including only one lesion with complete reocclusion in the POBA cohort.

TLR-free survival: POBA 81.7 % - DCB 93.6 % (p = 0.060)

### Results

➤ Technical success: 85.1 % (n=40) DCB group - 83.3 % (n = 50) POBA group p=0.510

➤ Time to reintervention: POBA group 7.8 ± 2.8 months, DCB group 5.7±2.5 months p=0.257

Ultrasound data were available for 75 patients at 6 months, and patency could be determined for all patients at 12 months

➤ Primary Patency 6-mos 65.1% POBA - 87.5% DCB p = 0.024  
12-mos 71.7 % POBA - 85.1 % DCB p = 0.076

### Results

Clinical course - DCB Cohort			Clinical course - POBA Cohort		
	DCB	p-Value	POBA	p-Value	
ABI baseline (n = 28)	0.59 ± 0.18		0.54 ± 0.20		
ABI discharge (n = 28)	0.95 ± 0.13	<0.001	0.92 ± 0.19	<0.001	
ABI 6 months (n = 21)	0.80 ± 0.17	<0.001	0.78 ± 0.15	<0.001	
ABI 12 months (n = 29)	0.84 ± 0.24	<0.001	0.77 ± 0.19	<0.001	
RBC baseline (n = 47)	3.62 ± 0.97		3.83 ± 0.97		
RBC 6 months (n = 36)	1.57 ± 2.0	<0.001	1.1 ± 1.3	<0.001	
RBC 12 months (n = 47)	1.9 ± 2.1	<0.001	1.4 ± 1.7	<0.001	

Values are mean ± SD. ABI - ankle-brachial index, DCB - drug-coated balloon, POBA - Plain old balloon angioplasty, RBC - Rutherford-Becker class.

ABI was significantly lower in the POBA group than in the DCB group at 6 months (p = 0.017)

### Conclusions

- As reported in several studies, DCB alone or in combination (atherectomy or stent) are associated with better outcomes when compared to standard POBA
- There are few studies that have included only popliteal lesions
- The use of a DCB tends to be more effective in the treatment of isolated popliteal stenoses than treatment with POBA
- No significant results due to the small group size
- Larger scale prospective study is mandatory

