

LINC

# IN.PACT Admiral DCB In Upper Limb Arteriovenous Fistulae/Grafts A South African Single Unit Audit

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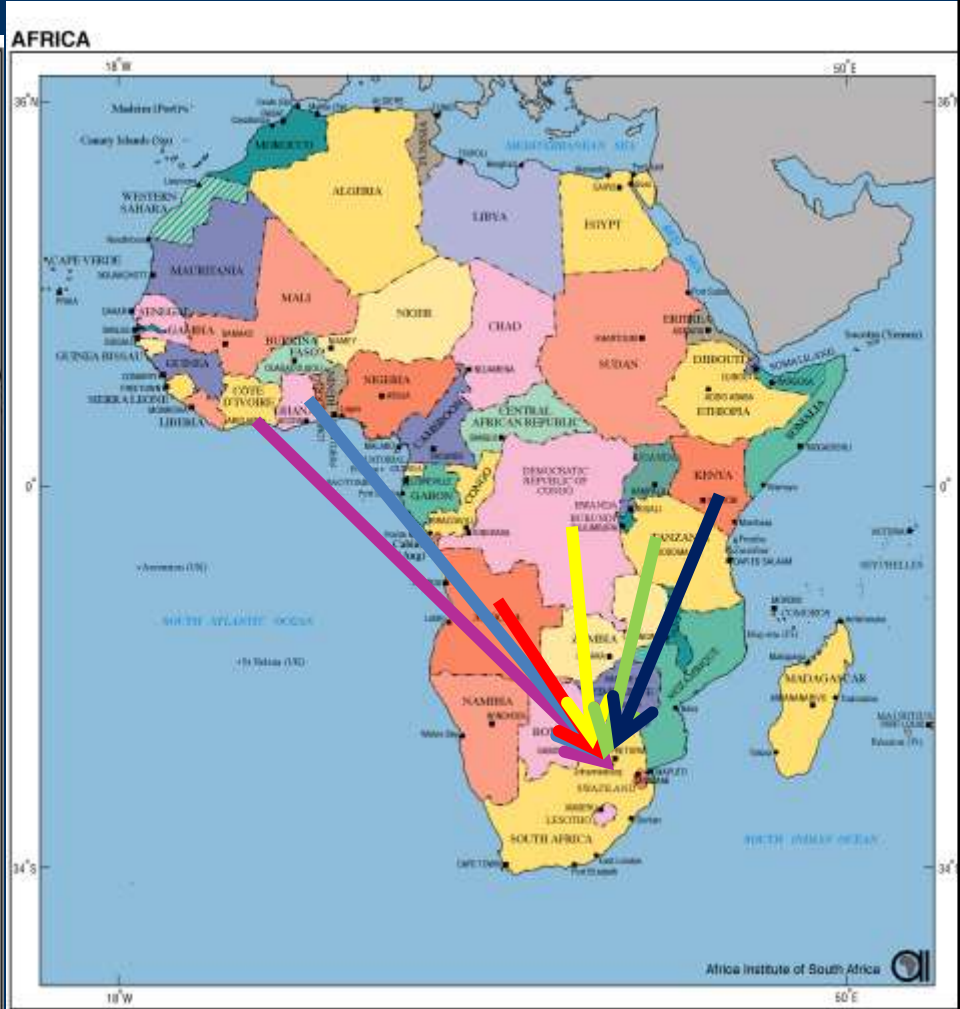
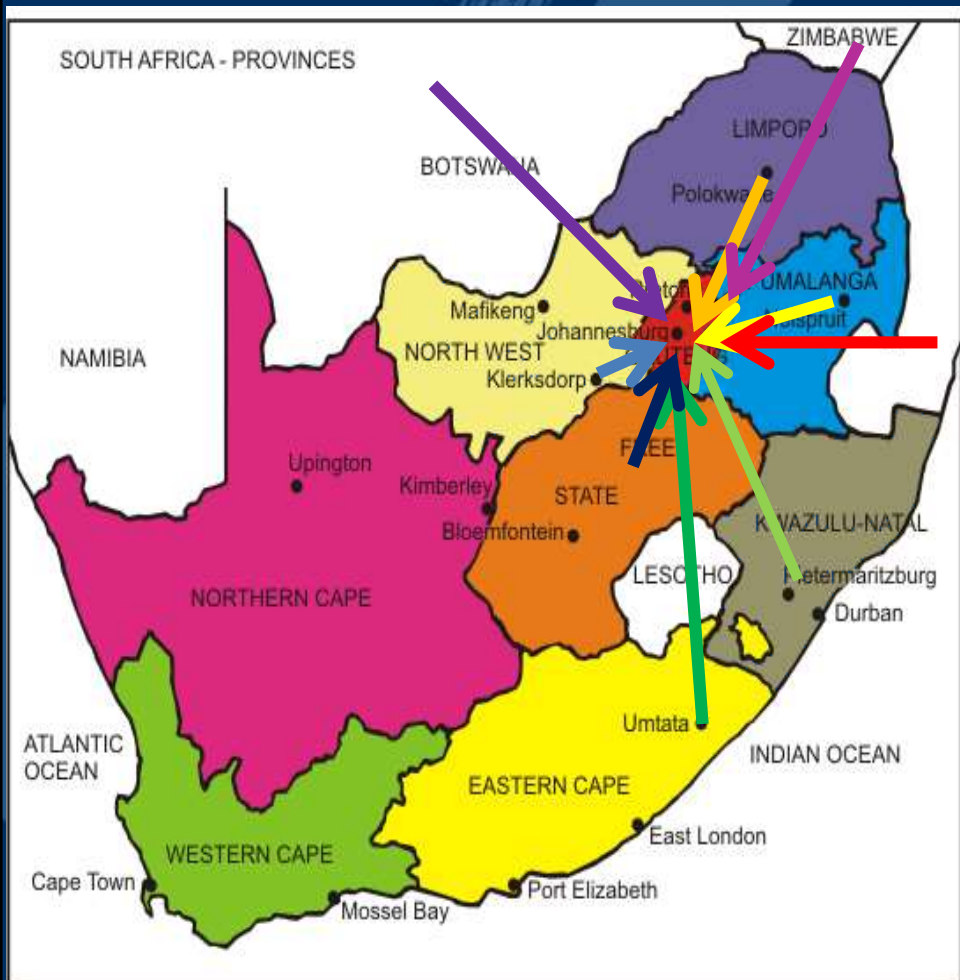


# Disclosure

Speaker name: Dirk le Roux

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I have the following potential conflicts of interest to report:



# Unit Audit

D le Roux P Mistry

- Compare patency intervals between POBA and DCB.
- Cost Saving?
- Time (workdays) Saving?
- Comparison to RCT's
- Overall, 40% of fistulas (AVF) fail within a year of creation & grafts (AVG) fare worse.<sup>1</sup>

<sup>1</sup>Al-Jaishi et al. Patency rates of the AVF for HD: A systematic review & meta-analysis. Am J Kid Dis. 2014; 4(63):464-78

# Our Practice

- From 01 Jan 2016: All AVF PTA's
  - Sample 28 random Patient Files were drawn.
  - 90 interventions - 45 in each treatment modality
  - Retrospective from 2013 onwards

# Inclusion Criteria

- Intervention in:
  - Upper arm AVF / AVG

# Indication for interventions

- Decreased dialysis and Physical Examination
  - PE at each HD session provides a simple, cost effective, bedside tool - the “backbone” of screening programme
  - Prolonged bleeding from needle site
  - Difficulty with needling & aspiration of clots
  - Provide equivalent benefit to surveillance but should be complementary
  - Flow >25% drop threshold 400ml/min
- Oedema of arm

# Indication for interventions

- Occluded / thrombosed AVF or AVG
- DDoppler –
  - A significant stenosis of  $>70\%$  defined on the basis of reduction in diameter as compared to an adjacent normal segment ,
  - doubling of peak systolic velocity or
  - absolute minimum diameter of 2.7mm.
  - 3 to 4 monthly follow up if possible.



# Patency Definition

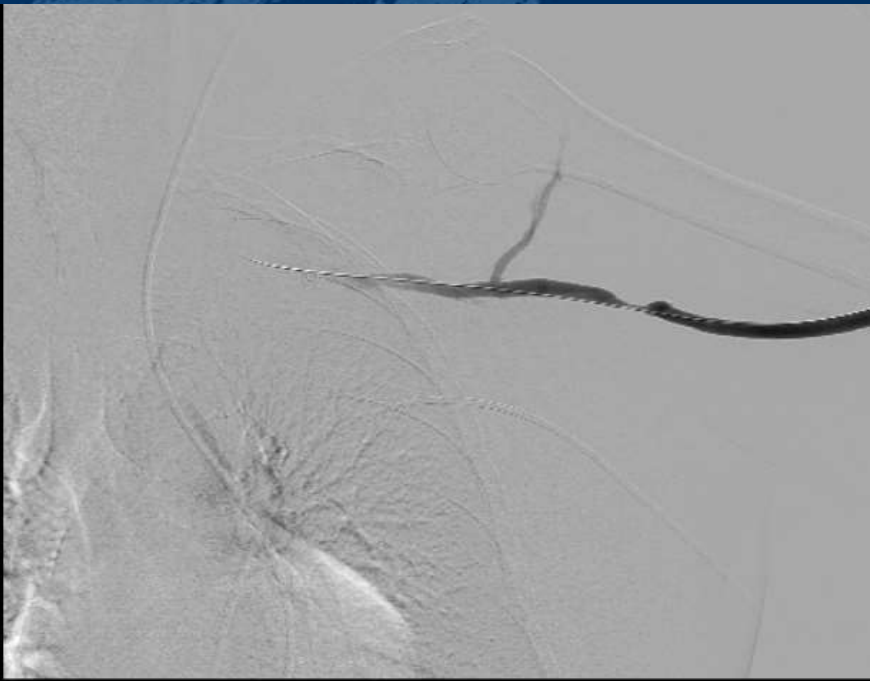
- Primary Patency – Index procedure until occlusion.
- POBA and DCB - Between intervention days.
- Patent or non – patent at demise.
- Until abandonment of access with new access.
- Until 31 August 2018.

# Procedure

- **DCB** 2 min inflation –primary dilation catheter unless not able to pass then pre-dilatation with 3-4 mm balloon catheter.
- **POBA** 2 min inflation.
- All patients received Clopidogrel 75mg daily and immediately post op for 6 weeks.
- Aspirin 81mg.
- Continue with chronic meds.

# Case Example 12/7/2016

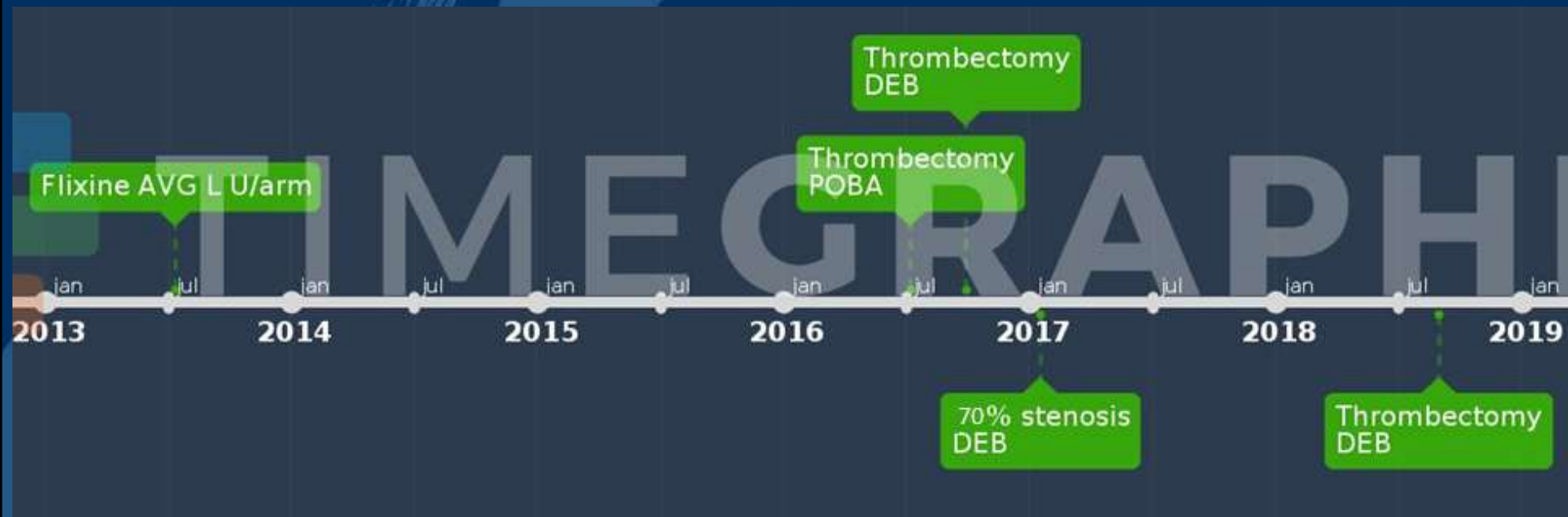
## POBA + Thrombectomy



# Case Example 30/08/2018

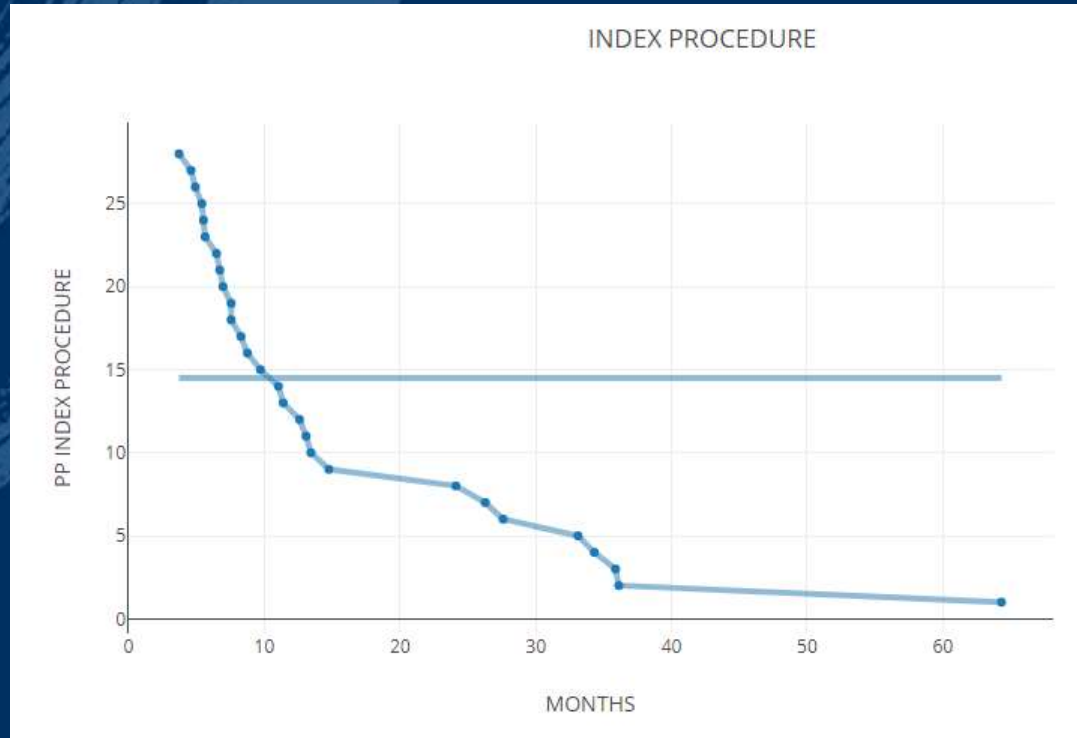
**DCB + Thrombectomy**





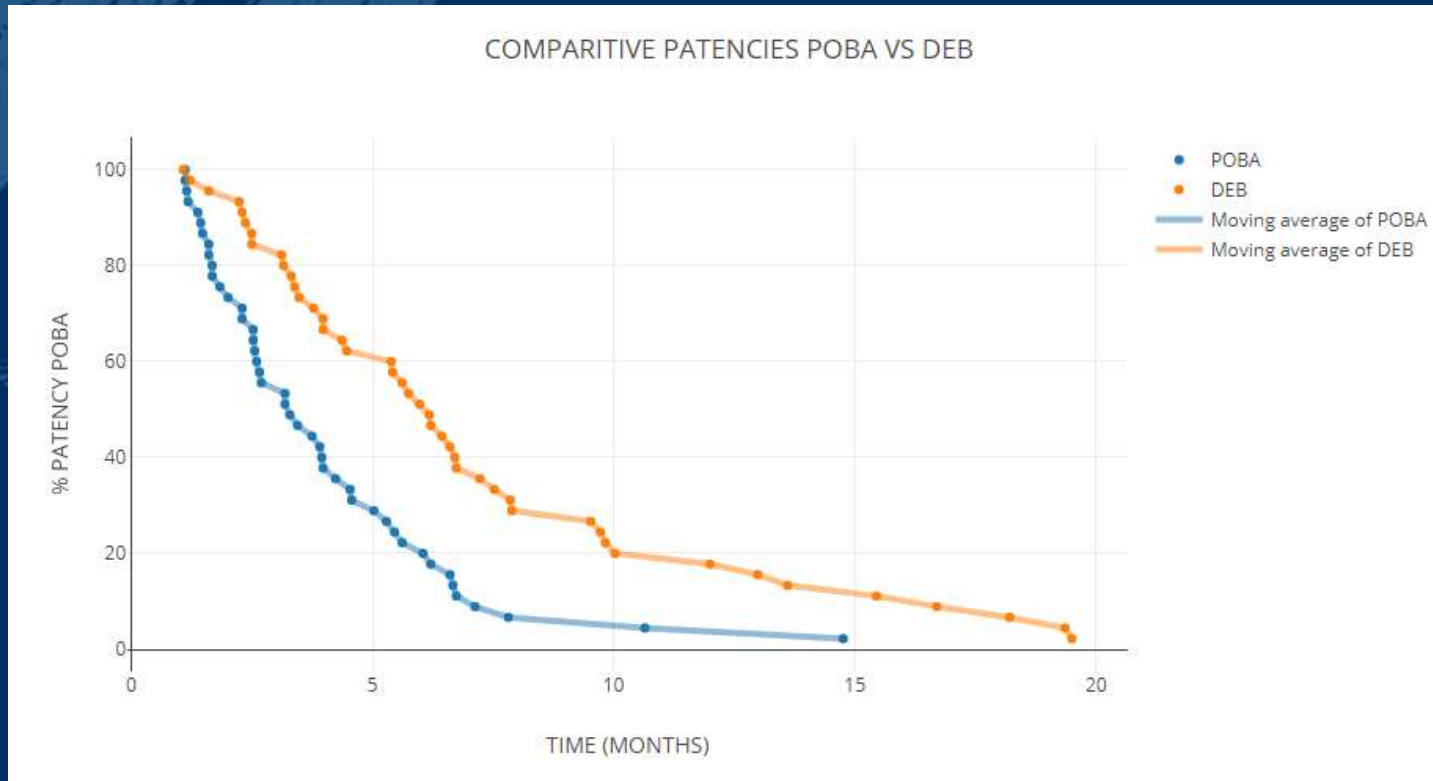
- PP Index 36 months
- POBA patency 2 months
- 1<sup>st</sup> DCB Patency 4 months
- 2<sup>nd</sup> DCB Patency 19 months

# Index Procedure

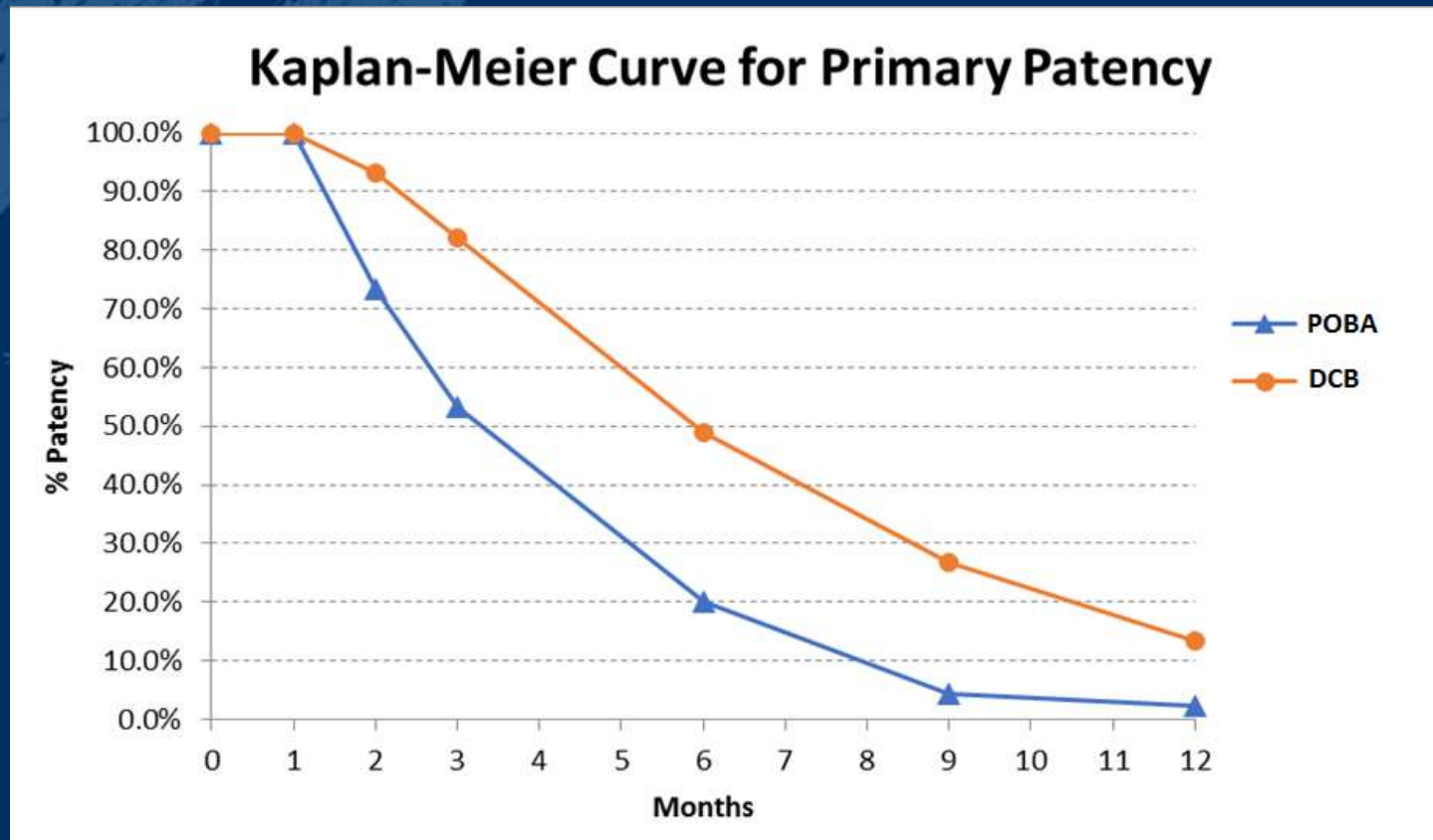


- **50% median PP at 1 year**
- **16 month mean patency**

# Comparative Patency POBA vs DCB



# Primary Patency Through 12 Months





# Results and Analysis

Variable	T-tests; Grouping: POBA or DCB (DEB VS POBA)							
	Mean DCB	Mean POBA	t-value	df	p	Valid N DCB	Valid N POBA	Std Dev DCB
Patency Days	214.5333	118.6000	3.763555	88	0.000302	45	45	149.5772
Patency Months	7.0532	3.8992	3.763555	88	0.000302	45	45	4.9176

Variable	T-tests; Grouping: POBA or DCB (DEB VS POBA)			
	Std Dev POBA	Mean 1 - Mean 2	Confidence -95.000%	Confidence +95.000%
Patency Days	82.85623	95.93333	45.27715	146.5895
Patency Months	2.72404	3.15397	1.48856	4.8194

## Patency Rates

- Index procedure 489 days or 16 months mean PP.
- **POBA** 118 days or 3.9 months mean Patency
- **DCB** 215 days or 7.1 months mean Patency
- {We assessed each intervention as a new index event until the next event (thrombosis or dialysis problem)}

## Compared to RCT's?

- At 6 months, cumulative target lesion primary patency was significantly higher after PCB application (70% in PCB group vs. 25% in BA group,  $p,0.001$ ; HR 0.30, 95% CI 0.12 to 0.71,  $p,0.006$ ).<sup>2</sup>
- (52% DCB(PCB) vs 22% POBA (BA) in our audit)

<sup>2</sup> Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation for the Treatment of Failing Dialysis Access: 6-Month Interim Results From a Prospective Randomized Controlled Trial Konstantinos Katsanos J et al ENDOVASC THER 2012;19:263–272

- At 1 year, cumulative target lesion primary patency was significantly higher after DEB application (35% vs. 5% after BA,  $p < 0.001$ ). Overall, median primary patency was 0.64 years in case of DEB vs. 0.36 years in case of BA ( $p = 0.0007$ )<sup>3</sup>
- Audit – Median patency at .56 years for DCB vs .32 years in case of POBA

<sup>3</sup> Drug-eluting versus plain balloon angioplasty for the treatment of failing dialysis access: Final results and cost-effectiveness analysis from a prospective randomized controlled trial P. Kitroua et al European Journal of Radiology 84 (2015) 418–423

# Costs ?

	DCB	POBA
Cost of Balloon	R10100 (US\$ 666)	R3400 (US\$ 224)
Hospital Cost /Event*	R38100 (US\$ 2514)	R31400 (US\$ 2072)
Cost per year	R64394 (US\$ 4250)	R99157(US\$ 6545)

- US\$:R 1:15,15
- Cost saving per year R 34763 (US\$ 2295)
- \* Including Theatre Cost, High Care 2 days and 1 acute dialysis session and balloon dilation catheter.
- Days off work: DCB 5 / year vs POBA 9 / year

## Conclusion

- Intervals for lesions treated with DCB patent for longer on average.
- Mean patencies 7.1 months for DCB vs 3.9 months for POBA (+-22% 6 month) P=.0003
- Patencies are poor with POBA and DCB almost doubles patency rates.
- Compares well to RCT's data.

## Future Questions?

- Role of Vessel Prep with scoring, HPB?
- Is there a trend for longer intervals between DCB treatments- Thus longer Assisted PP or Secondary Patency? We think so – working on study protocol.
- Protocol to do routine intervention before occlusion of access.
  - Day procedure. Monetary and Social cost savings?

A serene landscape photograph capturing a sunset over a calm body of water. The sky is a mix of soft pinks, oranges, and blues, with wispy clouds. The water in the foreground is still, reflecting the colors of the sky. A dense line of dark, silhouetted trees runs across the middle ground, their forms mirrored in the water. The overall mood is peaceful and tranquil. The image is framed by a dark blue border at the top and bottom.

[www.vascare.co.za](http://www.vascare.co.za)



The LINC logo features a stylized, abstract shape in red and orange, resembling a flame or a dynamic motion, set against a dark blue background. The letters 'LINC' are positioned to the right of this graphic.

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