Innovation to Practice with DCB and DAART: A Real-World Experience for SFA Treatment



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Severance Hospital Experience

- Between 2013 and 2015
- 110 patients (118 limbs) treated with In.PACT DCB
- De novo lesions (n=51)
- ISR lesions (n=67)
- Mean FU durations: 436.2 ±338.0 days



Baseline Clinical Data



	Total (n=118)	De novo (n=42)	ISR (n=67)	Р
Age, yrs	66.5 ± 11.4	66.5 ± 11.9	66.5 ± 11.1	0.981
Male	102 (86.4%)	42 (82.4%)	60 (89.6%)	0.288
HTN	68 (57.6%)	30 (44.1%)	38 (55.9%)	0.853
DM	67 (56.8%)	32 (62.7%)	35 (52.2%)	0.268
CKD	14 (11.9%)	8 (15.7%)	6 (9.0%)	0.389
ESRD	6 (5.1%)	3 (5.9%)	3 (4.5%)	1.000
Dyslipidemia	71 (60.2%)	28 (54.9%)	43 (64.2%)	0.346
CAD	61 (51.7%)	25 (49.0%)	36 (53.7%)	0.711
Stroke	15 (12.7%)	6 (11.8%)	9 (13.4%)	1.000
CLI	37 (31.4%)	18 (35.3%)	19 (28.4%)	0.431

Lesion & Procedure Data

	Total (n=118)	De novo (n=42)	ISR (n=67)	Ρ
TASC C/D	88 (74.6%)	33 (64.7%)	55 (82.1%)	0.036
СТО	64 (54.2%)	22 (43.1%)	42 (62.7%)	0.041
Lesion length, cm	22.9 ± 12.7	18.4 ± 12.6	26.3 ± 11.8	0.001
TOSAKA ISR class 3		-	67 (100%)	
Technical success	118 (100%)	42 (100%)	67 (100%)	1.000
Subintimal approach		7 (13.7%)	-	
Bail-out stenting	18 (15.3%)	9 (17.6%)	9 (13.4%)	0.609
Atherectomy	7 (5.9%)	5 (9.8%)	2 (3.0%)	0.237



TLR-free Survival



Overall

De novo vs. ISR lesions







- CC: Lt. foot, toe necrosis
 & ulcer (Rutherford 5)
- Risk factors:
 - HTN, Dyslipidemia





Subintimal Angioplasty



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DCB after Predilation



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Stenting





Absolut Pro 7 x 80



Absolut Pro 8 x 150





Follow-up at 9 months





Contract of the local division of the local

ABI 0.56/0.92





- Left leg cludication at 100M (Rutherford 3)
- Risk factors: DM, HTN, smoker
- PHx:
 - 1992 AMI
 - 2004 Stroke







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1st Treatment: Subintimal Angioplasty

2009/2/9







Subintimal Angioplasty



2nd Treatment

(2010/5/27)







2nd Treatment: SIA & Stent





3rd Treatment: Balloon & Stent

2012/8/26



2012/8/28 Balloon angioplasty & stenting

2012/8/29





Sx:

Claudication at 50 M, left leg







2013/6

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Recurrence of Sx



4th Treatment:



(2013/6/4)



DEB



Admiral InPACT 6 x 120 * 2





InPACT 6 x 60







US Follow-up at 1 year



ABI Follow-up

nths



At 18 months



InPACT SFA: 2-year Outcomes

Lesion length 8~9 cm, CTO 20~25%

Primary patency

TLR-free survival



Laird JR, J Am Coll Cardiol 2015;66:2329



DCB for ISR: FAIR Trial

RCT, Lesion length ~8 cm, In.PACT DCB)



TLR-free Survival at 12 months: 90.8%



Severance Cardiovascular Hospital, Yonsei University Health System Circulation. 2015;132:2230

In.PACT Global: Long lesion Imaging Cohort

PCR IN.PACT Global Long Lesion Imaging Cohort: Lesion/Procedural Characteristics

Lesions (N)	164
<u>Lesion Type:</u> de novo restenotic (no ISR) ISR	83.2% (134/161) 16.8% (27/161) 0.0% (0/161)
Lesion Length	$\rm 26.40 \pm 8.61cm$
Total Occlusions	60.4% (99/164)
Calcification Severe	71.8% (117/163) 19.6% (32/163)
RVD (mm)	$\textbf{4.594} \pm \textbf{0.819}$
Diameter Stenosis (pre- treatment)	90.9% ± 14.2
Dissections: 0	37.9% (61/161)
A-C	47.2% (76/161)
D-F	14.9% (24/161)

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Device Success [1]	99.5% (442/444)
Procedure Success [2]	99.4% (155/156)
Clinical Success [3]	99.4% (155/156)
Pre-dilatation	89.8% (141/157)
Post-dilatation	39.1% (61/156)
Provisional Stent - LL 15-25 cm: - LL > 25 cm:	40.4% (63/156) 33.3% (33/99) 52.6% (30/57)

- Device success: successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
- Procedure success: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
- Clinical success: procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge



In.PACT Global: Long lesion Imaging Cohort





DCB: Leipzig Data

288 limbs (260 patients), Lesion length 24 cm, CTO 65%, ISR 37%, InPACT DCB



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Remaining Challenges

- Long lesions:
 - more plaque burden, higher risk of dissection
- Calcification:
 - higher residual stenosis, insufficient drug delivery, higher risk of dissection
- ISR lesions:
 - remaining neointimal burden (residual stenosis)



Optimization of DCB

- Pretreatment with atherectomy (DAART)?
- Better stent for bail-out stenting?
- IVUS image guidance?



Summary & Conclusions

- DCB has shown excellent efficacy for both de novo and ISR lesions for real world practice.
- DCB should be considered a s primary treatment option in various lesions of femorpopliteal artery.
- Heavily calcified lesions or complex de novo or ISR
 lesions still remain challenging.
- Optimization of DCB treatment strategies are needed to improve outcomes in such complex lesions.





Thank you for your attention!

And Andreas Andre

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