1-year Clinical Results of The DEBATE-BTK SHOCK TRIAL

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Disclosure

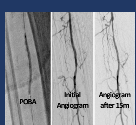
Speaker name: Francesco Liistro

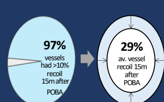
- ☐ I have the following potential conflicts of interest to report:
- ☒ Consulting: Medtronic, ACOTEC Ltd, Philips , Boston Scientific, Biotronik
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company

Other(s)I do not have any potential conflict of interest

Significant Calcium Burden

- **Calcium increases recoil and severe dissection for the need of high pressure/size balloon inflation**





Most BTK vessels undergo significant elastic recoil following angioplasty[1]

Medial calcification produces vessel recoil, dissection, reduces drug uptake increasing restenosis[2,3,4,5]

Medial calcification → **Arterial Stiffness** → **Suboptimal PTA result** → **Less drug up-take** → **Early reocclusion**

1) Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
2) Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008
3) Zettervall et al, Association of arterial calcification with CLI in patients with PAD, J Vasc Surg 2017
4) Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, AMP 2017
5F. Fanelli – Cardiovasc Interv Radiol 2014

Why IVL for peripheral interventions?

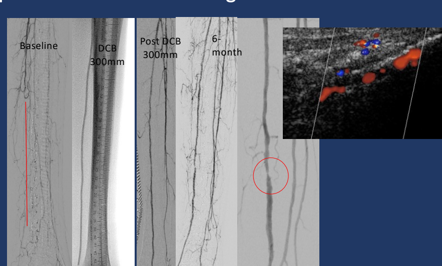
Optimal Balloon Angioplasty

- ✓ Reduce immediate recoil
- ✓ Allows complete vessel dilatation
- ✓ No tissue demage
- ✓ No distal particles embolization
- ✓ Applicable in subintimal recanalization
- ✓ Applicable in BTA arteries

Drug elution strategy

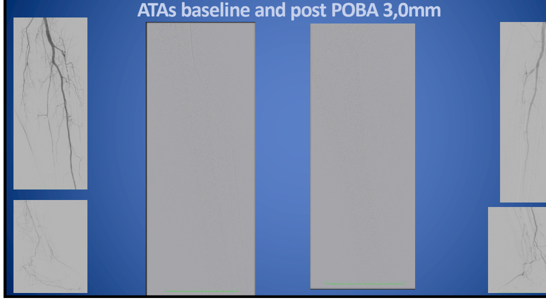
- ✓ Increase drug penetration into the vessel wall
- ✓ Increased drug storage and effect

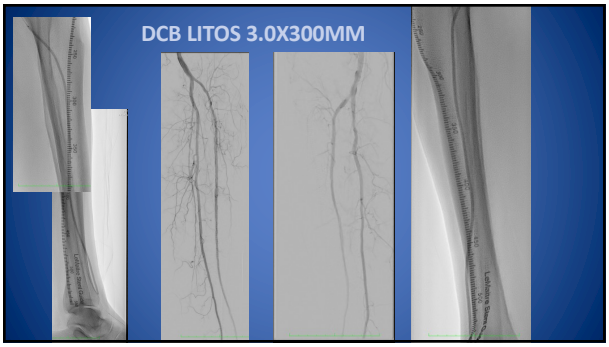
Spot restenosis due to reduced drug penetration. Is IVL the right tool?

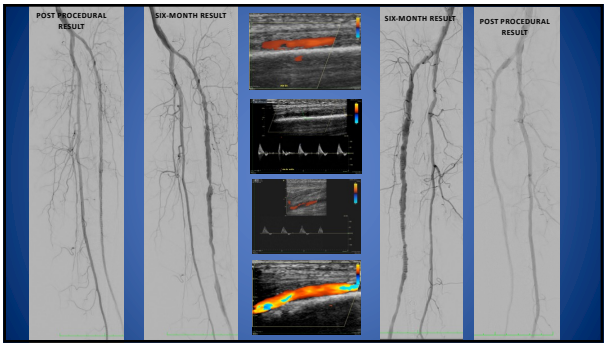


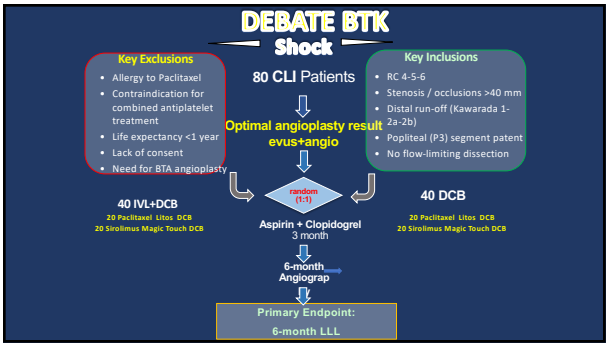
Vessel preparation and DCB

ATAs baseline and post POBA 3,0mm









Baseline Clinical Characteristics

	DCB	DCB+IVL	P value
Patient	44	41	
Male	33 (75)	38 (92)	0.03
Age	76.3±8.6	75.9±6.6	.5
Previous MI	18 (41)	12 (30)	.2
Previous stroke	5 (11)	3 (7)	.4
Diabetes	40 (91)	39 (95)	.4
Ever smoked	18 (41)	14 (35)	.1
Hypercholesterolemia	33 (75)	29 (71)	.4
Hypertension	39 (88)	36 (88)	.6
GFR<50ml/min	27 (61)	21 (52)	.3
Rutherford Classification			
4	5(11)	5(12)	.9
5	29(66)	28(68)	.9
6	10(22)	8(20)	.9

Baseline Clinical Characteristics

	DCB	IVL+DCB	P value
Patients	44	41	
Baseline Inflow lesion			
SFA	12(27)	9(22)	.8
Popliteal	8(18)	6(15)	.6
BTK baseline occlusion			
TPT-peroneal	23(52)	12(30)	0.03
PTA	32(72)	30(75)	.5
ATA	36(81)	32(80)	.5
Culprit vessel			
ATA	25(57)	29(71)	.04
PTA	11(25)	7(18)	.1
TPT-Peroneal	8(18)	5(12)	.2

Procedural data

	DCB	IVL+DCB	
Lesion	44	41	
De Novo Lesions	28(64)	31(77)	.2
Mean Length	258±56	249±62	.2
Baseline occlusion	32(73)	31(77)	.4
RVD	3.0±0.29	3.1±0.22	.3
MLD	0.10±0.23	0.15±0.29	.6
DCB diameter	3.1±0.29	3.1±0.49	.5
DCB length	282±95	274±96	.5
Sirolimus DCB	21	22	

1-Year Clinical Outcome

	DCB (44)	DCB + IVL (41)	
Death	4(9)	8(19)	.3
TLR	6 (14)	7 (17)	.5
Major amputation	0 (-)	0 (-)	-
Re-angiography	42/44 (95%)	35/41 (85%)	
Occlusive Restenosis	5/40(12)	9/35 (25)	.1

Conclusion

- ✓The DEBATE BTK SHOCK tests the hypothesis if IVL increases drug efficacy in combination therapy with DCB
- ✓The popultion enrolled is complex with long lesion and high rate of basal occlusion as in « real world» scenario
- ✓No signficant difference in TLR but reocclusion was numerically higher in IVL group
- ✓The endpoint of LLL is the most sensible to catch a signal and decide to go further with a dedicated RCT