

Why BTK DCB Trials Do Not Show Uniformity Better Results: Technical and Balloon Factors Matter?

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Disclosure

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- I have the following potential conflicts of interest to report:
 - Consultant for Medtronic, Biotronic, Boston Scientific, Shockwave, Acotec, Philips.

Lingering Issues in BTK DCB studies

- OBA before DCB
 - RVD and DCB sizing
 - Balloon Technology
- (Transfer and Action)
- ↑ Patency & Healing
- Target vessel flow in the 24h post
 - Diabetic foot management until healing
 - Fast track strategy for re-intervention
- FLOW AND FOOT SURVEILLANCE
- ↓ Major amputation

Negative studies with paclitaxel eluting balloon

Angio Cohort	INPACT DEEP			SINGA-PACLI		
	DEB	PTA	p	DCB	PTA	p
Baseline occlusion	38.6% (135/350)	45.9% (83/181)	0.1	35%	30%	0.6
Dialysis	-	-	-	50%	50%	-
Lesion Length	5.91±4.17	7.97 ±7.46	.06	9.0±7.3	8.1±7.1	0.5
LLL	0.51±0.66	0.60±0.97	0.5	na	na	-
Restenosis	41(25/61)	35.5 (11/31)	0.9	57%	72%	0.5
Angio f-up	61/113(54%)	31/53(57%)	0.5	-	-	-
TLR	9.2%(18/196)no n	13.1%(14/107) non amputees	0.29	20%	19%	0.9
12-month M. Amputation	8.8% (20/227)	3.6% (4/111)	0.08	25%	15%	0.1

Lack of foot-healing surveillance, unusual CLI population, SAD in dialysis, device efficacy, Interventional strategy

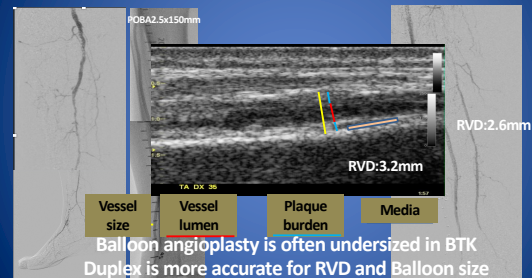
Optimal Balloon Angioplasty (OBA) (Vessel preparation)

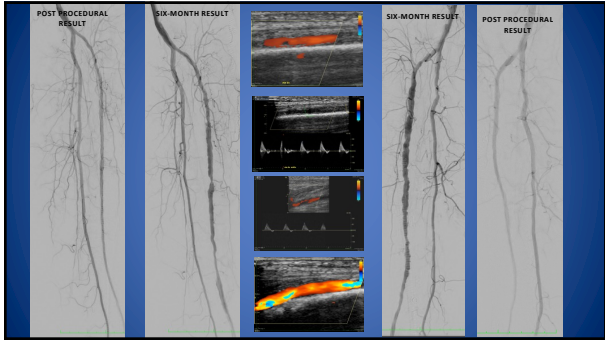
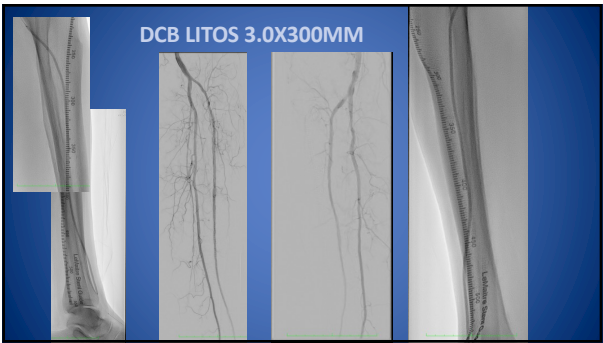
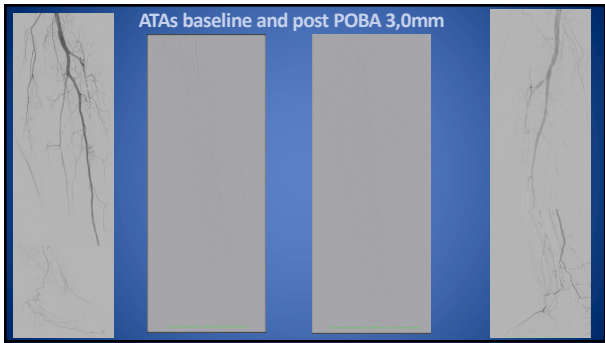
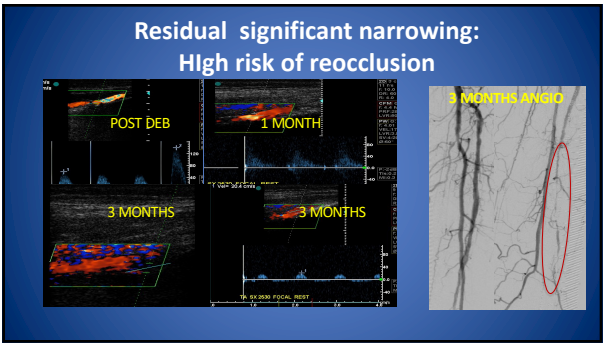
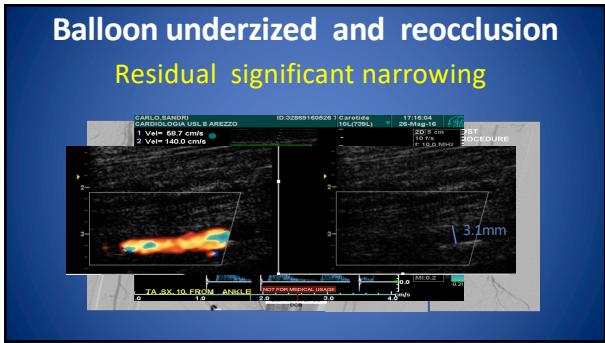
- ✓ Residual stenosis <30%
- ✓ Pulsatile flow on Duplex scan distal to target lesion
- ✓ PSVR<1.5 in the entire treated segment
- ✓ Absence of flow limiting (angio+duplex) dissection

- Plain balloon angioplasty
- Non compliant balloon
- Scoring balloon
- Atherectomy
- Litoplasty

→ **DCB (final treatment)**

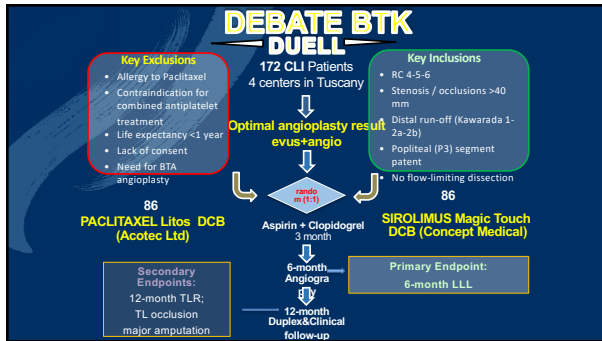
Reference Vessel Diameter and Balloon/Artery ratio: Is Angio enough?





Recent data show DCB efficacy OBA mandatory before randomization

	AcoartBTK	Acoart II	InPact BTK
Patients/lesion	105/128	120/131	53
Diabetes	100%	72%	86%
Lesion length	180 ± 110	180 ± 80	215 ± 60
CTO	68%	77%	100
Balloon Diameter	2.9(mm)	2.9(mm)	3.0(mm)
MLD post	1.9(mm)	1.6	1.8(mm)
LLL	0.51 vs 1.31	0.35 vs 1.08	0.89 vs 1.31
Reocclusion	5(8.6) vs 30(48.4)	8(16) vs 26(58)	16% vs 40%
Major Amputation	0/0	1/1	0/0



Improve vessel preparation Combination Therapy IVL Prior to DCB DEBATE BTK SHOCK 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

Combination Therapy Orbital Atherectomy Prior to DCB in Calcified Infrapopliteal Lesions

	OA+DCB	DCB	p
Numer of patients	32	34	
How do we measure how much did we cut?			
CTO	No AMIGO study deja-vu		
6-month patency	88.2%	50%	0.06
12-month patency	88.2%	54.5%	0.076

Zeller T, J Endovasc Ther. 2022 Dec;29(6):874-884.

Conclusion

- ❖ Interventional strategy to improve vessel preparation is crucial to make DCB successful in BTK disease.
- ❖ DCBs are not all the same and each device has to prove its efficacy and safety
- ❖ Standardize treatment and population is mandatory if we want to compare trial results