

## THE DEBATE BTK DUELL RCT

**Francesco Liistro**  
 Chief of Cardiovascular Intervention  
 San Donato Hospital, Arezzo, Italy

## Disclosure

Speaker name: Francesco Liistro

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, ACOTEC Ltd, Boston Scientific, Biotronic, Concept Medical
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s) do not have any potential conflict of interest

### Recent data show DCB efficacy OBA mandatory before randomization

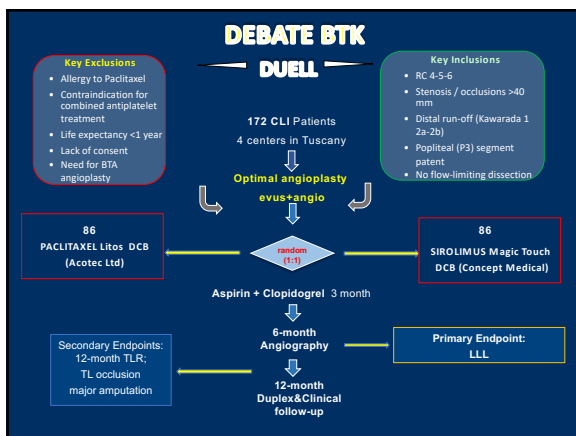
	AcoartBTK*	Acoart II**	InPact BTK***
Patients/lesion	105/128	120/131	53
Diabetes	100%	72%	86%
Lesion length	180±110	180±80	215±60
CTO	68%	77%	100
Balloon Diameter	2.9(mm)	2.9(mm)	3.0(mm)
MLD post	1.9(mm)	1.6	1.8(mm)
LLL	0.51 vs 1.31	0.35 vs 1.08	0.89 vs 1.31
Reocclusion	5(8.6) vs 30(48.4)	8(16) vs 26(58)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

\*JACC Cardiovasc Interv. 2020 Oct 12;13(19):2277-2286.  
 \*\*J Endovasc Ther. 2021 Apr;28(2):215-221  
 \*\*\*EuroIntervention. 2022 Apr 1;17(17):e1445-e1454

### Longitudinal Late Luminal Loss and DCB

9-Month Angiographic Outcome <sup>1</sup>	IN.PACT 014 DCB (N=23 Subjects N=24 Lesions)	PTA (N=22 Subjects N=23 Lesions)	P-value
Sub-Segmental Late Luminal Loss <sup>2</sup> (Mean mm ± SD)	0.59 ± 0.94	1.25 ± 0.91	0.017

ACOARTBTK	LITOS DCB	POBA	
TVAL(%)	5.87±23.16	51.37±36.27	<0.001



### Defining optimal balloon angioplasty

- ▶ Residual stenosis <30%
- ▶ Direct flow TIMI 3
- ▶ No flow limiting dissection

- ▶ Pulsatile flow with similar pattern throughout the treated segment
- ▶ PSVR < 1.5

### Sample Size

- Lesions expected to be enrolled
  - Length 16-18cm
  - CTO 70-80%
  - Diabetes >80%

} LLL of PCB 0.5±0.3 mm

Expected control angiography compliance >90%  
Expected mortality at 1 year 5%.

} Non inferiority or superiority margin (10%)  
power of 80% (1 - β ≥ 0.80;  
α = 0.05)

172 Lesions needed

**Enrolled: 147patients, 160lesions (93%)**

### Baseline Clinical Characteristics 128pts

	PEB N (%)	SEB N (%)	P value
Patient	75	72	
Male	62(83)	56(78)	.3
Age	74.8 ± 8.6	75.0±8.3	.9
BMI	26.8 ± 3.7	26.7±4.4	.4
Previous MI	25(33)	18(25)	.2
Previous stroke	8(11)	4(6)	.2
Diabetes	73(97)	68(94)	.9
Ever smoked	25(33)	23(32)	.4
Hypercholesterolemia	51(68)	49(68)	.6
Hypertension	65(87)	66(92)	.2
GFR<50ml/min	43(58)	39(54)	.4
Prev. Limb rivascularization	40(53)	32(44)	.2
Rutherford	4	8(11)	5(7)
	5	56(75)	57(79)
	6	11(15)	10(14)

### Baseline Clinical Characteristics

	PEB N (%)	SEB N (%)	P value
Patients / Lesion	75 / 80	72 / 80	
Leg side (right)	35(50)	33(48)	
<b>Baseline inflow lesion</b>			
SFA	19 (25)	14(19)	0.6
Poplitea	14 (19)	14(20)	.7
<b>BTK baseline DISEASE</b>			
TPT-per	49 (46)	47(64)	.6
PTA	63(83)	57(77)	.3
ATA	60(79)	62(85)	.1
<b>Culprit vessel</b>			
ATA	47 (59)	41(51)	
PTA	15(19)	21(26)	.5
TPT-Peroneal	18(22)	18(22)	

### Procedural data

	PEB N (%)	SEB N (%)	P value
Lesion	80	80	
De Novo Lesions	60(75)	59 (74)	.9
Mean Length	222±98	211±100	.5
Baseline occlusion	57(71)	58 (72)	.5
RVD	3.09±0.27	3.1±0.22	.7
MLD	0.10±0.23	0.14±0.29	.6
DCB diameter	3.1±0.29	3.2±0.29	.5
DCB length	259±109	230±103	.5
Procedural success	79	79	-

### Provisional Six-Month Outcome

	PEB	SEB	
Patients/Lesion lost for 6M death	9/10	5/6	
Patients with 6-m FU completed	54/57	56/61	
Death	9 (12)	5 (7)	.2
Age	81±7.6	82±4.3	
Renal failure	9(100)	5(100)	
dialysis	2 (22)	1 (17)	.4
Death Cause			
Cardiovascular (sudden included)	6	2	
Sepsis	3	2	
IDTLR	7(9)	15(19)	0.053
Major Amputation	0	0	-
Occlusive Restenosis	8 (14)	14 (23)	.2

### XTOSI MagicTouch FIH Trial

Device	• MagicTouch PTA (Concept Medical)
Study design	• Single arm
N	• 50 (20 SFA, 30 BTK)
Countries	• Singapore
Inclusion criteria	• Rutherford 4-6 • CLTI patients
Primary Endpoint	• Primary patency at 6 month (PSVR ≤ 2.4 in absence of TLR)

**Good clinical outcomes sustained to 3 years**  
**78% Freedom from TLR**  
**81% Freedom from Amputation**

**XTOSI  
2024**

	All N=50	Femoropopliteal N=20	Below the knee N=30
3 year			
Freedom from CD-TLR	84.4 (27/32)	92.9 (13/14)	77.8 (14/18)
Freedom from Major Amputation	86.1 (31/36)	93.3 (14/15)	81.0 (17/21)
Amputation Free Survival	63.3 (31/49)	70.0 (14/20)	58.6 (17/29)
Overall Survival	63.3 (31/49)	70 (14/20)	58.6 (17/29)
Ulcer free status	100 (31/31)	100 (14/14)	100 (17/17)

Choke ETC, et al. MagicTouch PTA Sirolimus Coated Balloon for Femoropopliteal and Below the Knee Disease: 3 year outcomes of XTOSI trial. Ann Vasc Surg. 2024 Apr 3.

- ## Conclusions
- The Debate-BTK Duell will provide a head-to-head comparison of paclitaxel and sirolimus DCB
  - A dedicated interventional strategy included in the protocol will limit procedural bias and will make the result more reliable
  - Up to now (93% of sample size) no significant difference between the two DCBs in terms of vessel reocclusion and a trend on a lower TLR raate for paclitaxel
  - Mortality at 6 months is higher than expected

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