Redefining DCB in BTK Treatment: 12-month outcomes of AcoArt II Study

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Disclosure

Speaker name: **Zhidong Ye**

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

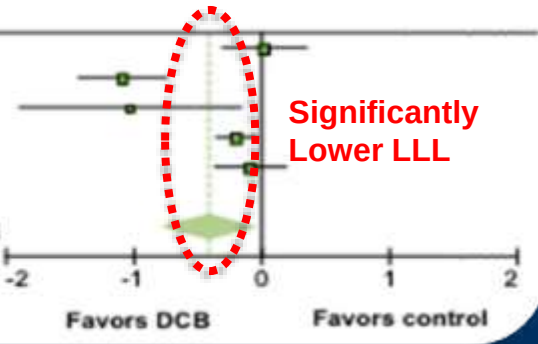
- ☑ I do not have any potential conflict of interest

Evidences of DCB in BTK treatment
Meta-analysis about DCB in BTK

Late lumen loss

Trial	DCB Mean	DCB SD	DCB Total	Control Mean	Control SD	Control Total	Weight (%)	Mean difference [95% CI]
BIOLUX P-II	0.56	0.65	32	0.54	0.66	30	21.4%	0.02 [-0.31, 0.35]
DEBATE BTK	0.91	1.1	80	2	1.1	78	21.0%	-1.09 [-1.43, -0.75]
DEBELLUM	0.66	0.9	13	1.69	1.5	17	11.0%	-1.03 [-1.89, -0.17]
IDEAS	1.15	0.3	19	1.35	0.2	25	24.3%	-0.20 [-0.36, -0.04]
IN.PACT DEEP	0.51	0.7	125	0.6	1	63	22.4%	-0.09 [-0.37, 0.19]
Overall			**269**			**213**	**100.0%**	**-0.41 [-0.79, -0.03]**

Heterogeneity: Tau² = 0.15; Chi² = 30.36, df = 4 (P < 0.00001); I² = 87%
Test for overall effect: Z = 2.09 (P = 0.04)



Cassese et al. JACC 2016

Target lesion revascularization

Amputation

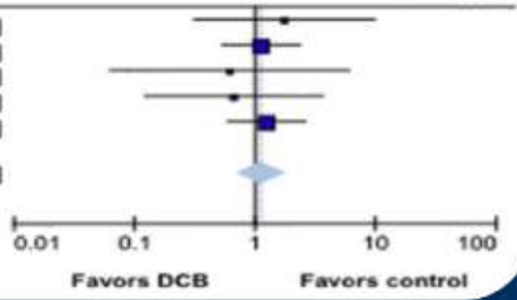
Rutherford Class 5-6

Major adverse events

Death

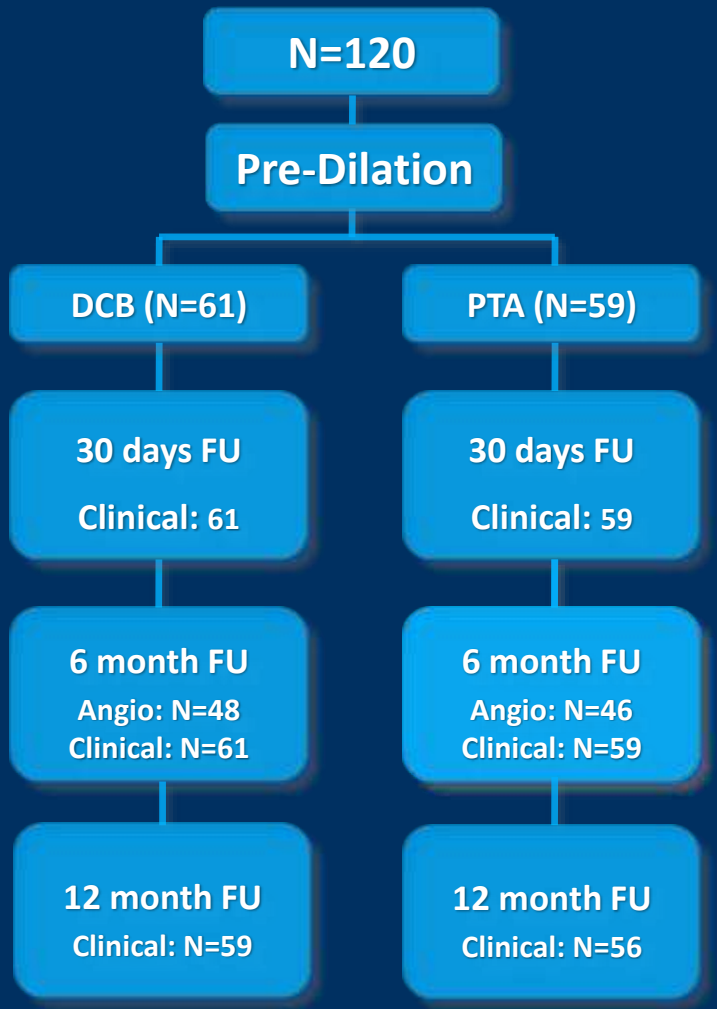
Trial	DCB Events	DCB Total	Control Events	Control Total	Weight (%)	Random-effects risk ratio [95% CI]
BIOLUX P-II	3	29	2	34	7.5%	1.76 [0.32, 9.81]
DEBATE BTK	12	65	11	67	39.9%	1.12 [0.53, 2.37]
DEBELLUM	1	13	2	16	4.2%	0.62 [0.06, 6.05]
IDEAS	2	25	3	25	7.6%	0.67 [0.12, 3.65]
IN.PACT DEEP	23	227	9	111	40.7%	1.25 [0.60, 2.61]
Overall	**41**	**359**	**27**	**253**	**100.0%**	**1.14 [0.71, 1.82]**

Heterogeneity: Tau² = 0.00; Chi² = 0.97, df = 4 (P = 0.91); I² = 0%
Test for overall effect: Z = 0.54 (P = 0.59)



AcoArt II Study Overview

- Primary Endpoint
  - 6-mon Angiographic Primary patency (PP) – freedom from target lesion occlusion, clinically-driven target revascularization (CD-TLR) and major limb amputation.
- Key Secondary Endpoint
  - Late lumen loss (LLL) at 6mon
  - CD-TLR at 6mon, 12mon
  - Ulcer healing Rate at 12mon
  - Major amputation at 12mon
- Safety Endpoint
  - MAE (death, major amputation, CD-TLR) at 30days, 6-mon, 12mon



Study Device - AcoArt Litos and Tulip DCB

- ***Litos (0.014“) & Tulip (0.018“)***® produced by Acotec Scientific Co., Ltd, Beijing, China
- Paclitaxel dose:
  - 3.3µg/mm^2
- Excipient: Mg-stearate
  - Durable paclitaxel carrier for optimized drug delivery
  - Uniform coating of balloon treatment area
- Balloon sizes
  - Diameter(mm):
    - *Litos*: 2.0-4.0, with half size design
    - *Tulip*: 2.0 -4.0, with half size design
  - Length(mm):
    - 20, 30, 40, 60, 80, 100, 120, 150, 200, 250, 300, treat long lesion easily

AcoArt Tulip
Drug Eluting Balloon 0.018"

AcoArt Litos
Drug Eluting Balloon 0.014"

AcoArt II Baseline

	DCB (N=61)	PTA (N=59)	P Value
Age, yrs	70.7±7.4	70.8±9.0	0.95
Male (%)	59%(36)	61%(36)	0.82
History of Risk Factors			
CHD	36%(22)	34%(20)	0.81
Hypertension	82%(50)	75%(44)	0.33
Hyperlipidemia	41%(25)	27%(16)	0.11
Diabetes	74%(45)	71%(42)	0.75
Current smoker	26%(16)	27%(16)	0.60
Current alcoholic	16%(10)	10%(6)	0.32
Rutherford			
3	2%(1)	0	
4	44%(27)	41%(24)	0.76
5	39%(24)	47%(28)	
6	15%(9)	12%(7)	
ABI*	0.56±0.27	0.51±0.31	0.41

Values are % (n/N), or mean ±SD. *Calculated by excluding ABI≥1.3.

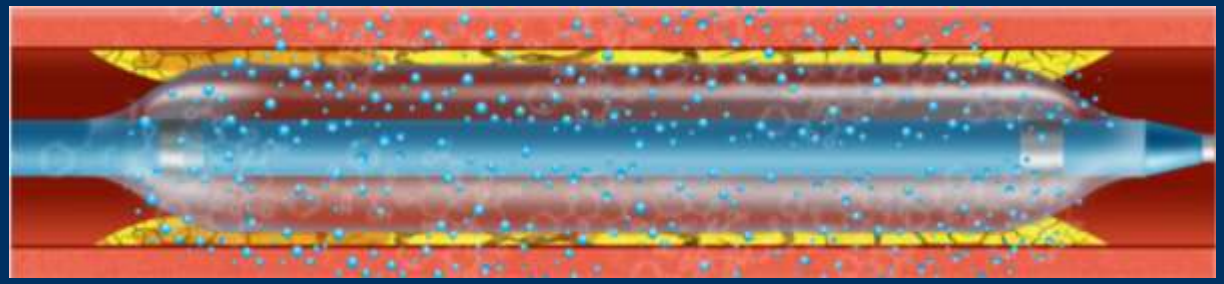
Target Lesion Characteristics

	DCB	PTA	P
Patients（No）	61	59	
Lesions （No）	65	66	
Target vessels			
TA	1.5%(1)	1.5%(1)	
TA+PTA	9.2%(6)	6.1%(4)	
TA+PA	4.6%(3)	7.6%(5)	0.59
ATA	49%(32)	50%(33)	
PTA	26%(17)	18%(12)	
PA	9.2%(6)	17%(11)	
Target lesion length (mm)	177±86	186±82	0.56
Minimal lumen diameter (mm)	0.20±0.41	0.15±0.33	0.43
Reference vessel diameter (mm)	2.55±0.34	2.53±0.35	0.71
Diameter stenosis(%)	92%	94%	0.43
CTO (%)	75.4%（49/65）	78.8%（52/66）	0.54

Values are % (n/N), or mean ±SD.
TA= tibiofibular artery; ATA= anterior tibial artery; PTA= posterior tibial artery; PA= peroneal artery

Procedural Data

	DCB	PTA	P
Treatment balloon diameter (mm)	2.72±0.25	2.64±0.25	0.07
Provisional stenting %	0	1.5% (1/66)	0.32
Device success	100%	100%	/



Appropriate diameter of DCB

- 3.0-3.5mm for upper calf
- 3.0-2.5mm for middle calf
- 2.5mm for ankle area

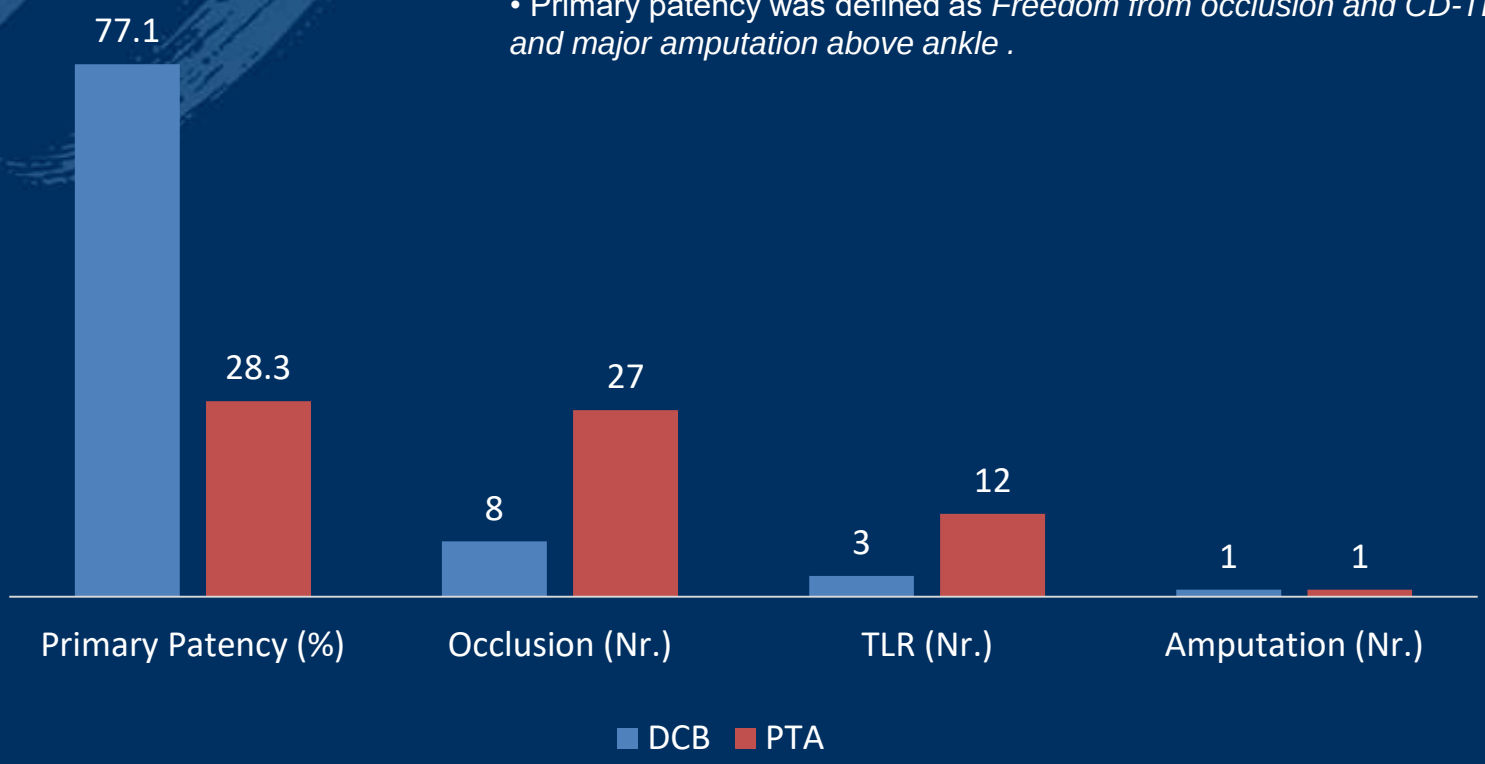
Optimal dilation

- Better drug penetration
- Better lumen gain and less residual stenosis

6-month results - Primary Endpoint

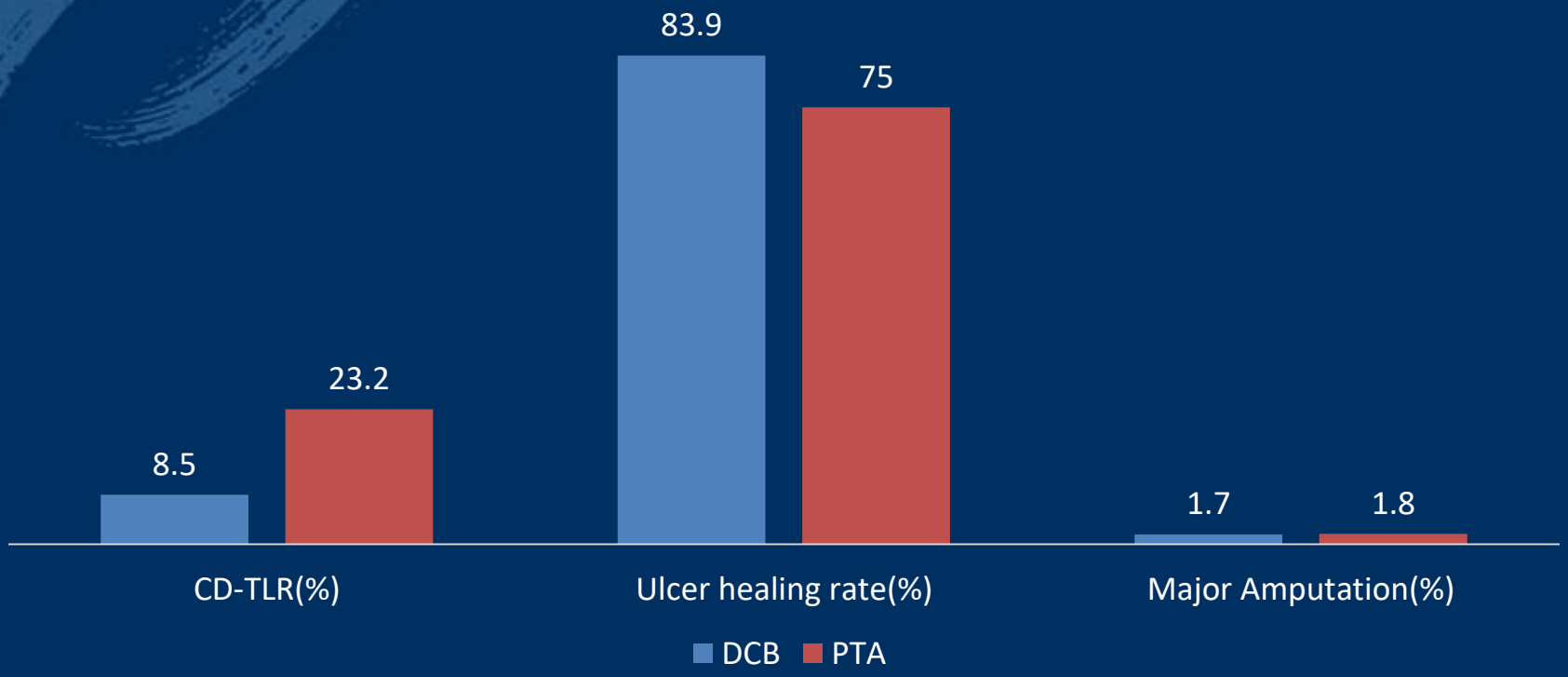
	DCB (N=48)	PTA (N=46)	P
Primary Patency	77.1% (37/48)	28.3% (13/46)	<0.001
Occlusion	8(16.7%)	27(58.7%)	
TLR	3(6.3%)	12(26.1%)	
Amputation	1(2.1%)	1(2.2%)	

- Primary patency was defined as *Freedom from occlusion and CD-TLR and major amputation above ankle .*

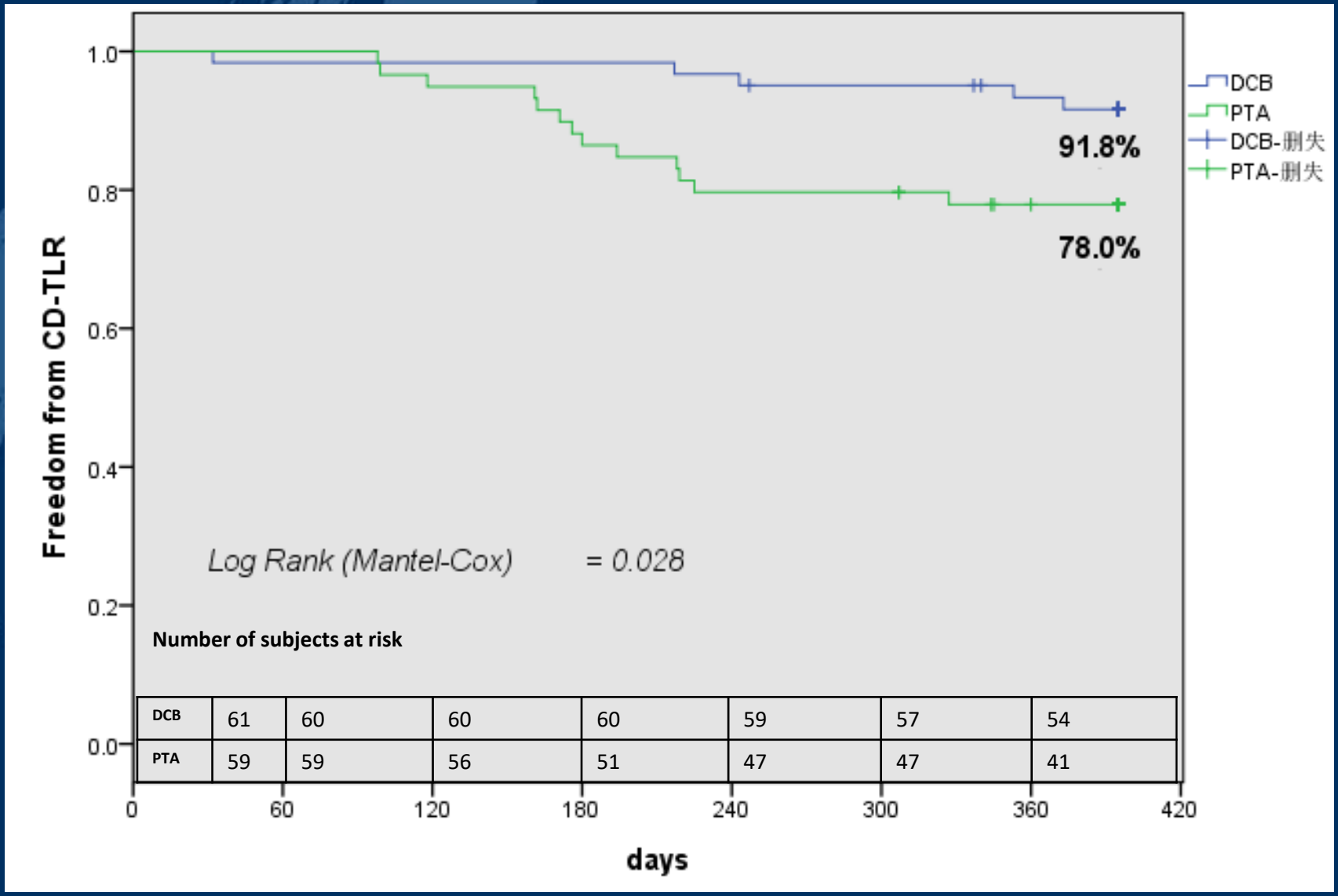


12-month Results

	DCB	PTA	*P-value*
CD-TLR	8.5%(5/59)	23.2%(13/56)	0.030
Ulcer healing rate	83.9%(26/31)	75.0%(24/32)	0.393
Major Amputation	1.7%(1/59)	1.8%(1/56)	0.971

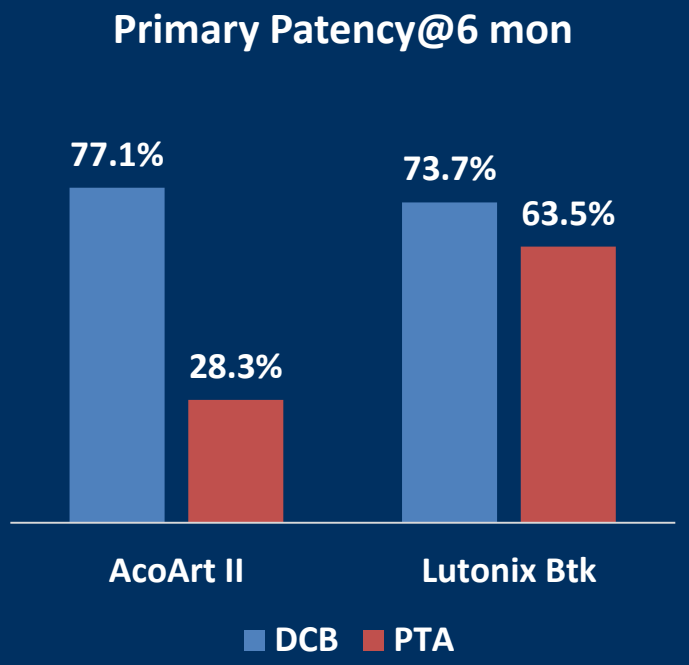


KM 12-month Freedom from CD-TLR



Primary Endpoint Comparison

	AcoArt II	Lutonix BTK
Age, yrs	70.7	72.9
RVD(mm)	2.53	2.54
Lesion Length(cm)	18.2	10.5
DS(%)	93%	86.0%
CTO(%)	77%	35%
Paclitaxel dose	3.3ug/mm^2	2.0ug/mm^2



Compared with Lutonix BTK, AcoArt II

- Enrolled the more complex lesions with longer length and higher occlusion rate
- Shows more significant difference between DCB arm and PTA arm in primary patency
- Use the DCB with higher paclitaxel dose

Major adverse event (MAE) - 12mon

	DCB	PTA	P value
Death	1.7%（1/59）	3.6%（2/56）	0.532
Major amputation	1.7%（1/59）	1.8%（1/56）	0.971
CD-TLR	8.5%（5/59）	23.2%（13/56）	0.030

Accumulative Death	DCB	PTA	P-value
24 mon going on	4(N=38)	6(N=42)	0.62

Conclusion

- AcoArt II demonstrated the safety and efficacy of Tulip and Litos DCB in treating BTK lesions.
- The positive results further improved the evidence of DCB for BTK, which inspired utilization of DCB for BTK definitely in the further clinical practice.
- Furthermore, the differences between DCB device-specifics critically determine the final clinical outcomes.
- No significant different in all-cause death and amputation between DCB and PTA groups, which is different from the result in Prof. Katsanos's meta-analysis in CLI patients.
- More well designed study and BTK-dedicated DCB may provide further data.

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THANK YOU

PRESENTER

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