12-month Results from the AcoArtII BTK Study

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on behalf of the AcoArt II Investigators

Disclosure

Speaker name: Xin Jia

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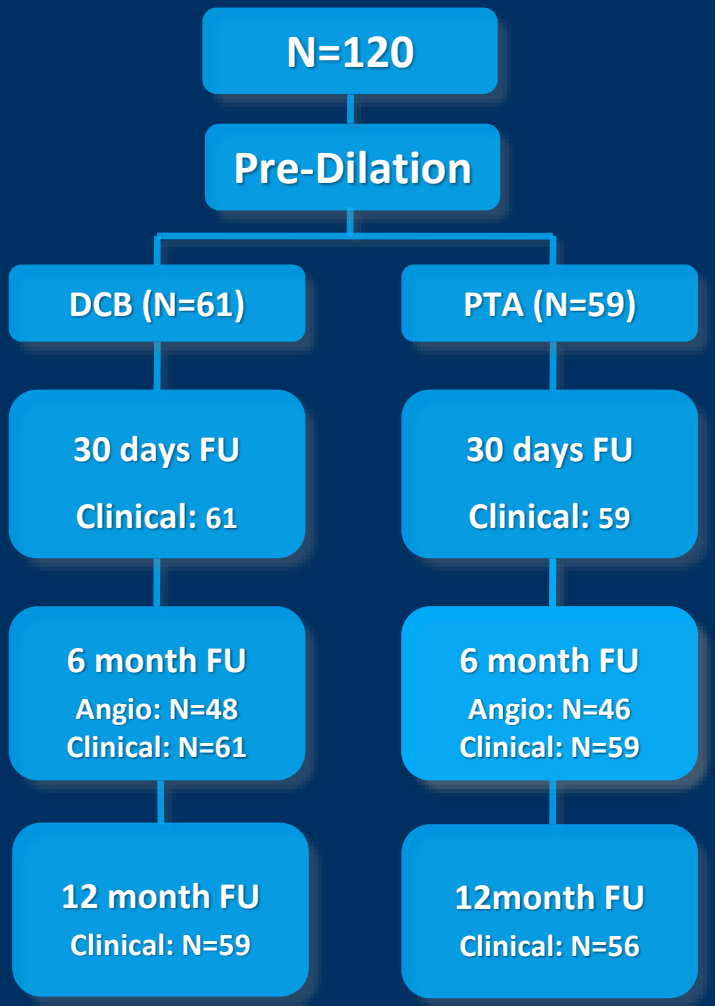
I have the following potential conflicts of interest to report:

- ☐ 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

AcoArt II Study Overview

- Primary Endpoint
  - 6-mon Angiographic Primary patency (PP) – freedom from target lesion occlusion, CD-TLR and major 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 30 days, 6mon, 12mon



Study Device - 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 0.5mm increment
    - *Tulip*: 2.0 -4.0, with 0.5mm increment
  - 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

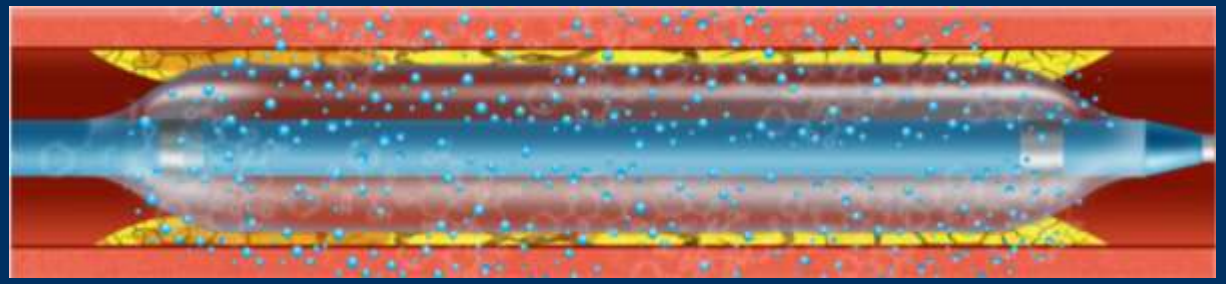
	DCB	PTA	P
Patients（No）	61	59	
Lesions （No）	65	66	
Target vessels			
TA	1.5%(1)	1.5%(1)	
TA+PTA	9.2%(6)	6.1%(4)	
TA+PA	4.6%(3)	7.6%(5)	0.59
ATA	49%(32)	50%(33)	
PTA	26%(17)	18%(12)	
PA	9.2%(6)	17%(11)	
Target lesion length (mm)	177±86	186±82	0.56
Minimal lumen diameter (mm)	0.20±0.41	0.15±0.33	0.43
Reference 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%	/

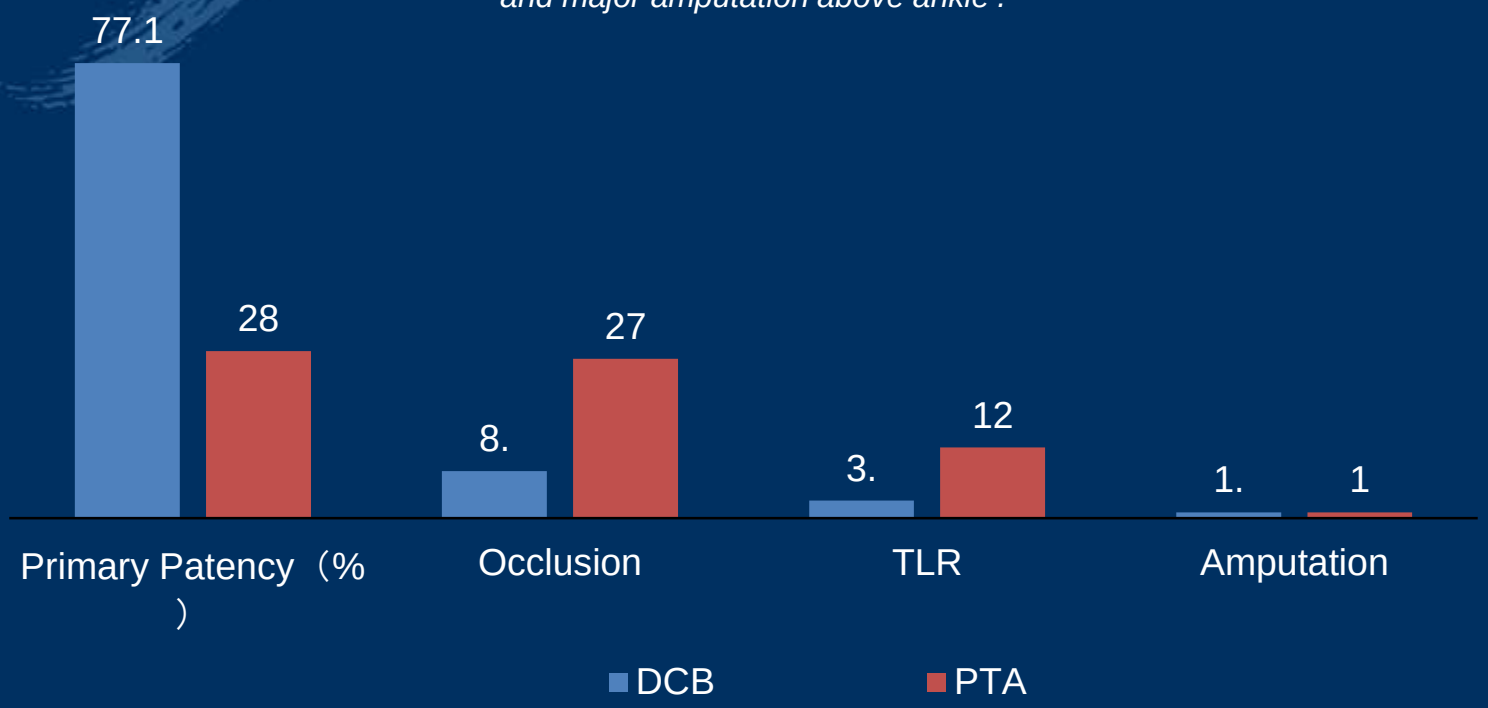


Appropriate diameter of DCB
- 3.0-3.5mm for upper calf
- 3.0-2.5mm for middle calf
- 2.5mm for ankle area

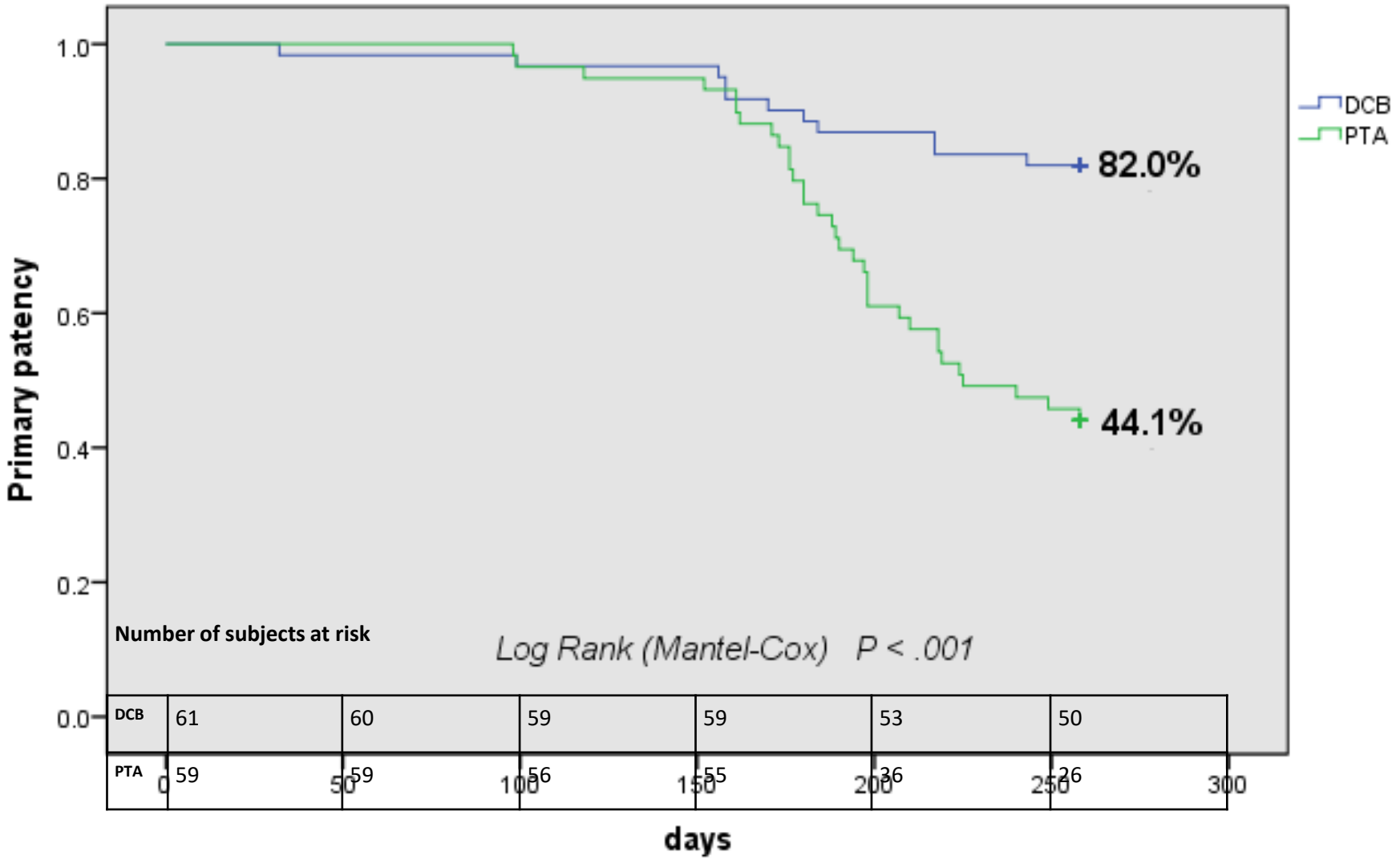
6-month results - Primary Endpoint

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

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

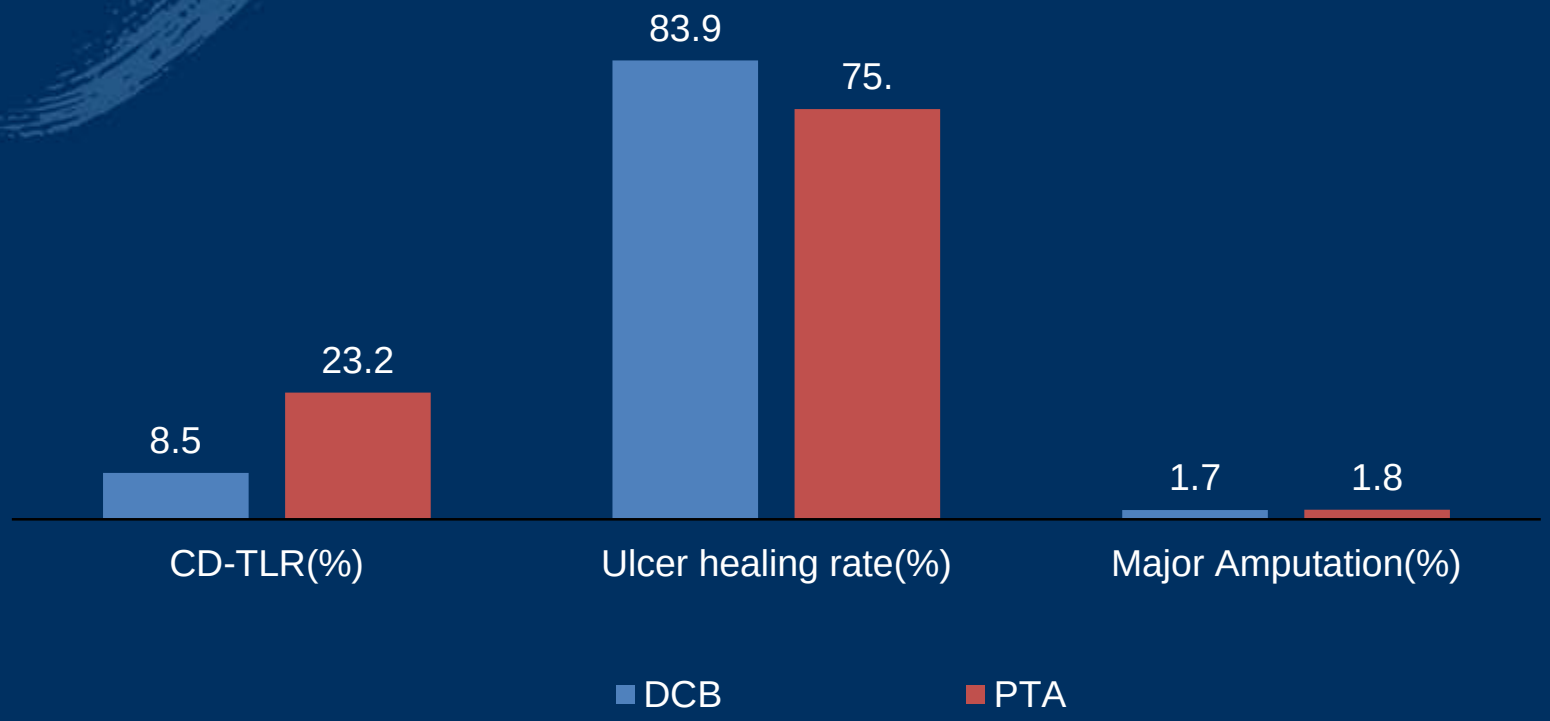


Primary Endpoint (KM 6 month)

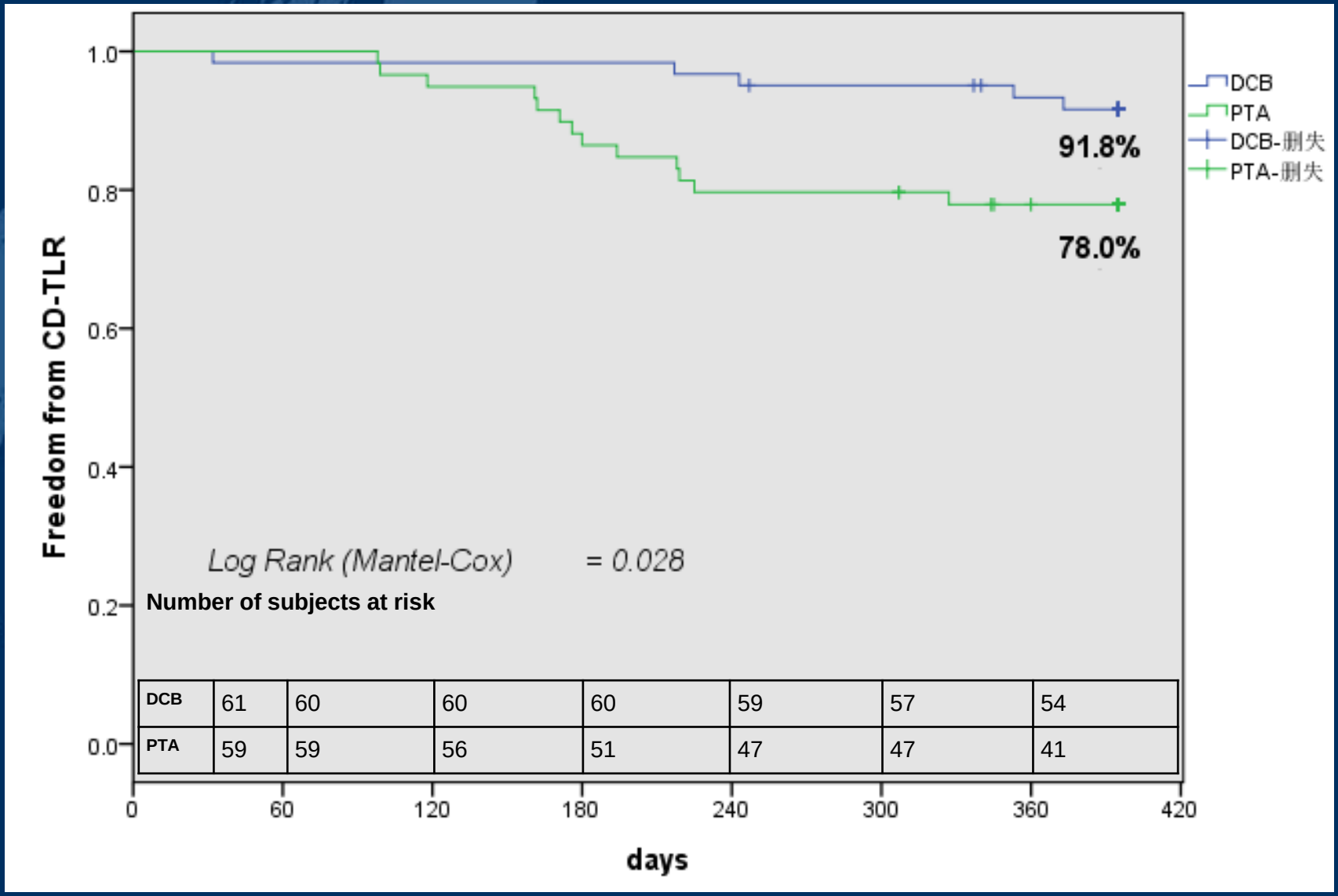


12-month Results

	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

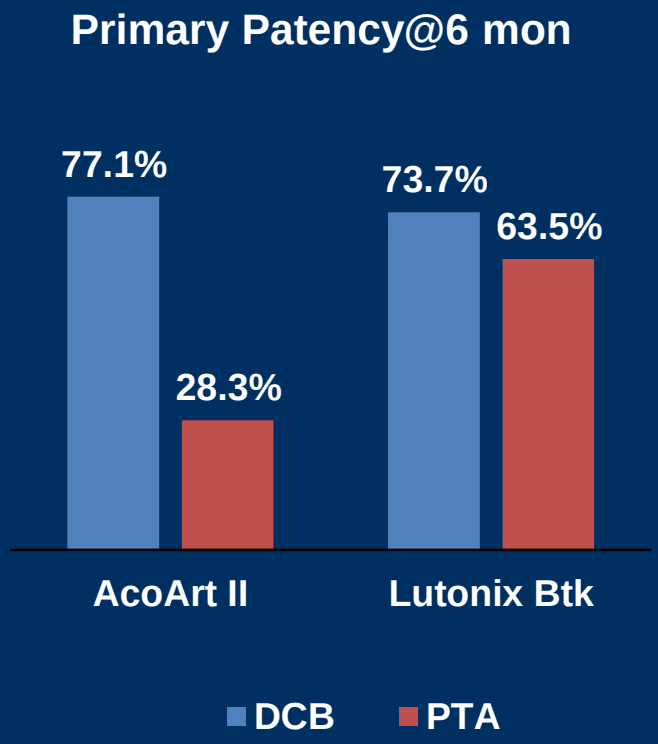


Major adverse event (MAE) - 12mon

	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

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

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

Conclusion

- AcoArt II demonstrated the safety and efficacy of Tulip/Litos DCB in treating BTK lesions.
- Further add to the evidence of DCB for BTK, which encourages utilization of DCB for future.
- More well designed study based on BTK-dedicated DCB may provide further data.

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