

# Treatment strategy for Femoropopliteal CLTI

*Tatsuya Nakama, MD*

*Tokyo Bay Medical Center, Urayasu, Japan*

# Disclosure

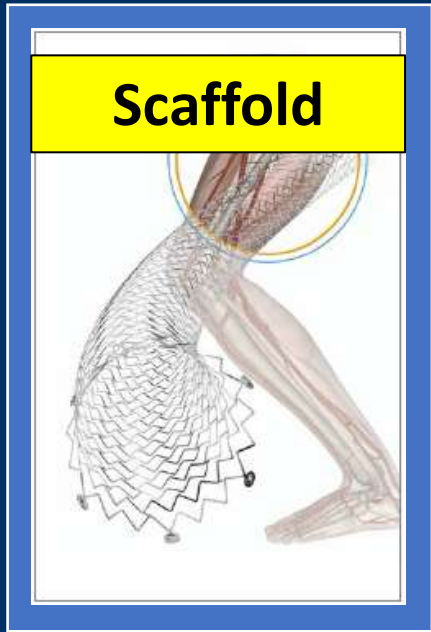


Speaker name: Tatsuya Nakama MD.

*I have the following potential conflicts of interest to report:*

- Consulting:** Boston Scientific, BD, Century Medical Inc., Medtronic
- Employment in industry: None
- Stockholder of a healthcare company: None
- Owner of a healthcare company: None
- Honoraria received from:** Abbot Vascular, Asahi Intecc., Boston Scientific, BD, COOK, Cordis, NIPRO, KANEKA, Medikit, Medtronic, Orbus Neichi, Terumo

# Many kinds of “Barrier” for restenosis



## Barrier for

- Recoil
- Dissection

## Barrier for

- Neointima

## Barrier for

- Recoil
- Dissection
- Neointima

## Barrier for

- Recoil
- Dissection
- Neointima

## Barrier for

- Recoil
- Dissection
- Calcium

# From SCAI expert consensus 2018

## Use of Drug Eluting Stent

Recommendations for drug-eluting stents as the Intended Definitive Therapy in the femoral-popliteal arterial interventions.

Drug-eluting stents	COR	LOE
1. CFA bifurcation lesion	IIA	C-EO
2. Above knee popliteal lesion	I	B-R
3. Ostial SFA lesion	I	B-R
4. Focal SFA lesion	I	B-R
5. Intermediate SFA lesion	I	B-R
6. Diffuse SFA lesion	I	B-NR
7. Moderate to severe calcified, focal lesion	I	C-LD
8. Moderate to severe calcified, intermediate lesion	I	C-LD
9. Moderate to severe calcified, diffuse lesion	I	C-EO
10. Chronic total occlusion, focal lesion	I	B-R
11. Chronic total occlusion, intermediate lesion	I	B-R
12. Chronic total occlusion, diffuse lesion	I	B-NR
13. ISR, focal lesion	IIB	C-LD
14. ISR, intermediate lesion	IIA	C-LD
15. ISR, diffuse lesion	IIA	C-LD

## Use of DCB

Recommendations for drug coated balloons as the Intended Definitive Therapy in the femoral-popliteal arterial interventions.

Drug coated balloons	COR	LOE
1. CFA bifurcation lesion	IIA	C-EO
2. Above knee popliteal lesion	I	A
3. Ostial SFA lesion	I	A
4. Focal SFA lesion	I	A
5. Intermediate SFA lesion	I	A
6. Diffuse SFA lesion	I	B-R
7. Moderate to severe calcified, focal lesion	I	C-LD
8. Moderate to severe calcified, intermediate lesion	I	C-LD
9. Moderate to severe calcified, diffuse lesion	I	C-LD
10. Chronic total occlusion, focal lesion	I	B-R
11. Chronic total occlusion, intermediate lesion	I	B-R
12. Chronic total occlusion, diffuse lesion	I	B-NR
13. ISR, focal lesion	I	B-R
14. ISR, intermediate lesion	I	B-R
15. ISR, diffuse lesion	I	B-R

**DES/ DCB**  
use is strongly recommended  
With high level evidences



# Pros and Cons of stent-based (DES-based) strategy



- **Pros** for Stent-based strategy

- Quick and Simple

- Reduce procedural time

- Avoid the acute failure due to recoil or dissection

- Avoid the down stream effect

- **Cons** for stent-based strategy

- Risk of stent thrombosis

- Long-term DAPT (bleeding risk)

- Possibly extent the lesion length

- Difficult to find “healthy zone” as a stent landing zone

# common consensus for FP disease

## For Claudicant

### DCB favor strategy

preserve the future option  
Avoid stent disease



## For CLTI

### DES favor strategy

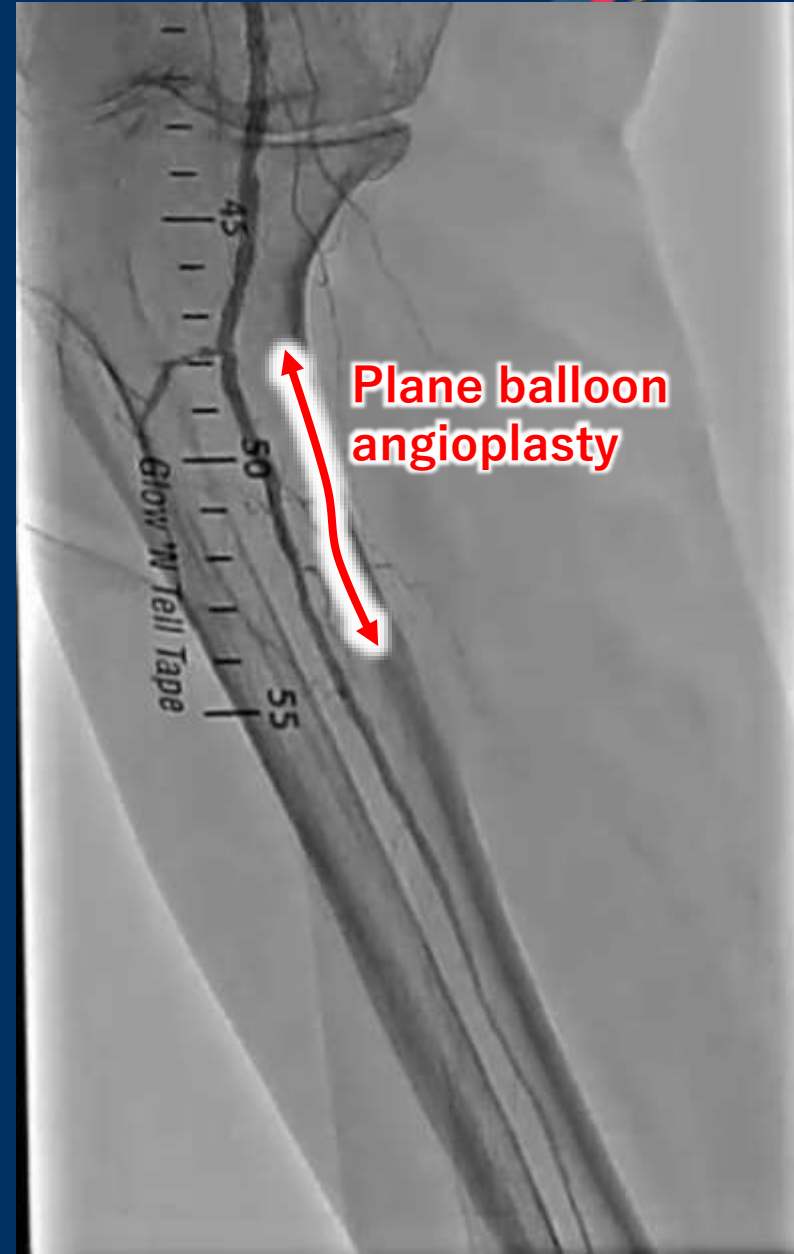
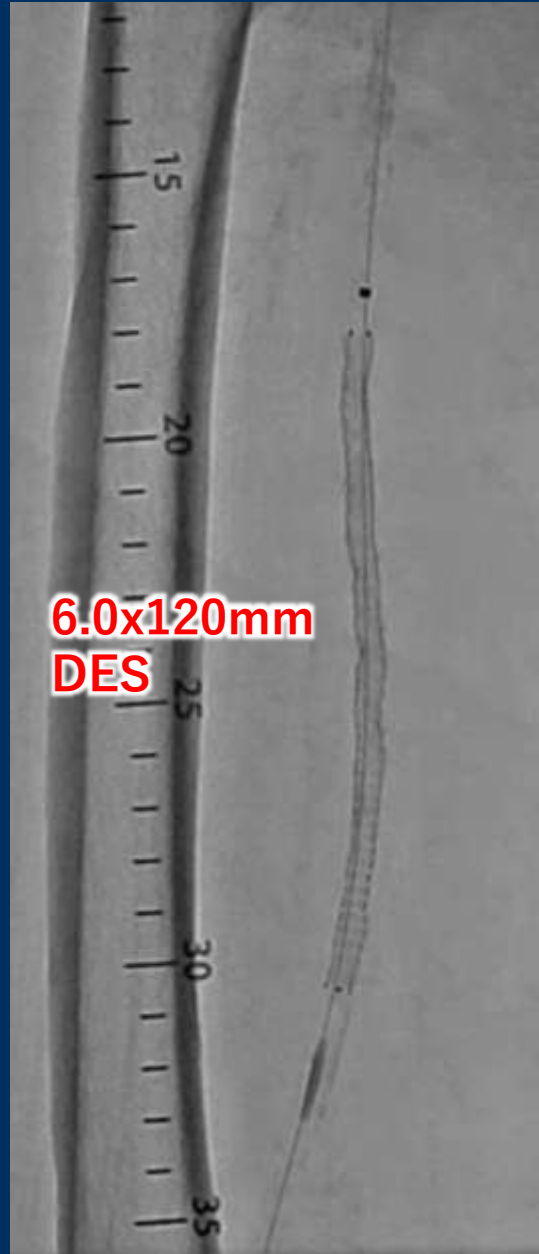
Simple and quick procedure  
Avoid downstream effect



# CLTI with multifocal FP + BTK lesion



# 3 DES were deployed for FP stenosis





# Final angiogram showed good result

LINC



**STENT** based strategy is simple, quick and promising



# However... dark side of stent strategy



**Stent thrombosis;**  
**47** days after  
**DES deployment**  
**(DAPT was continued)**



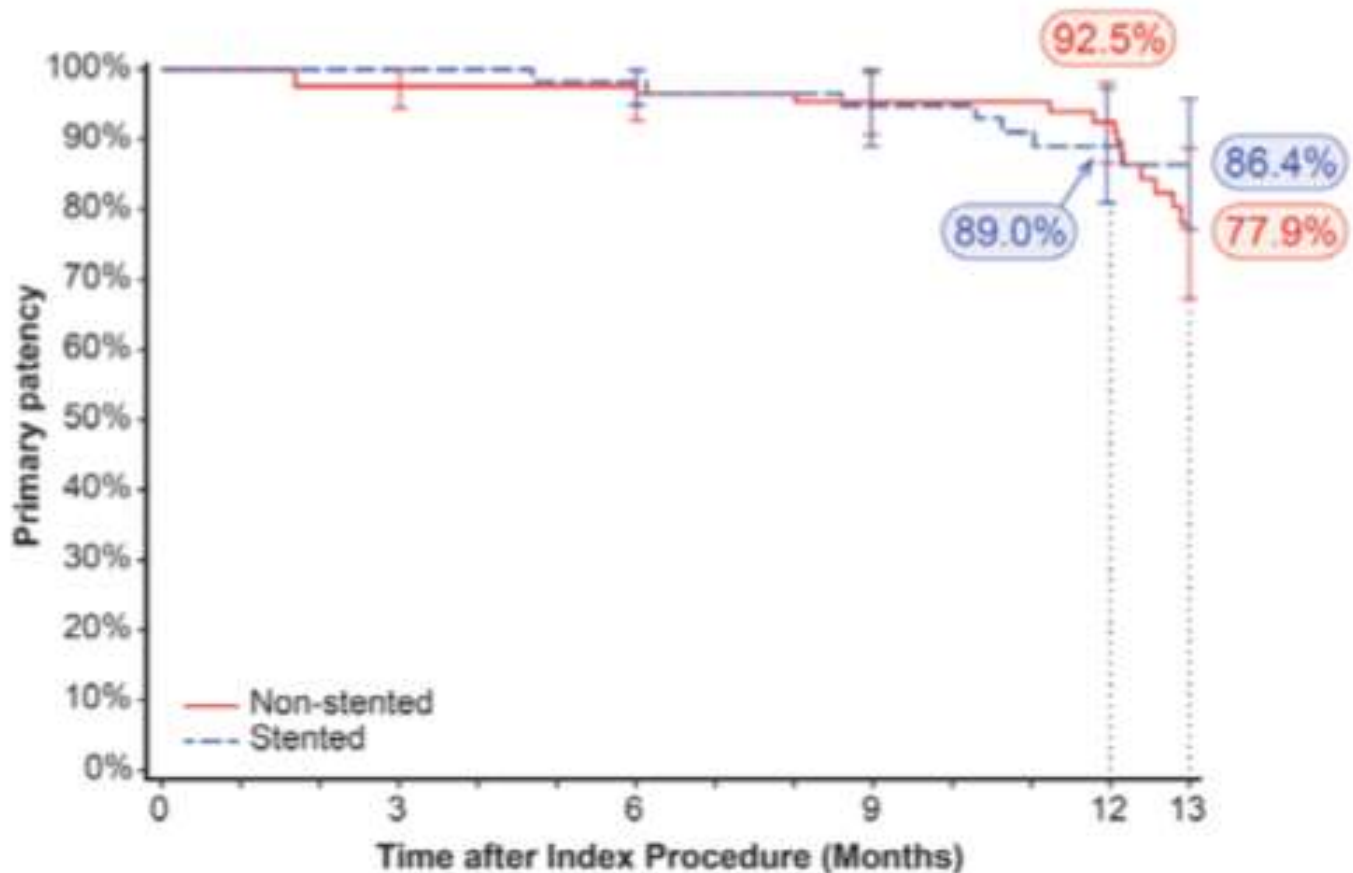
# Flow was recovered... but...



**Limb status  
became worse....  
Clinical status was  
not recovered.**



# Stent itself does not improve the patency



## Number of subjects at risk

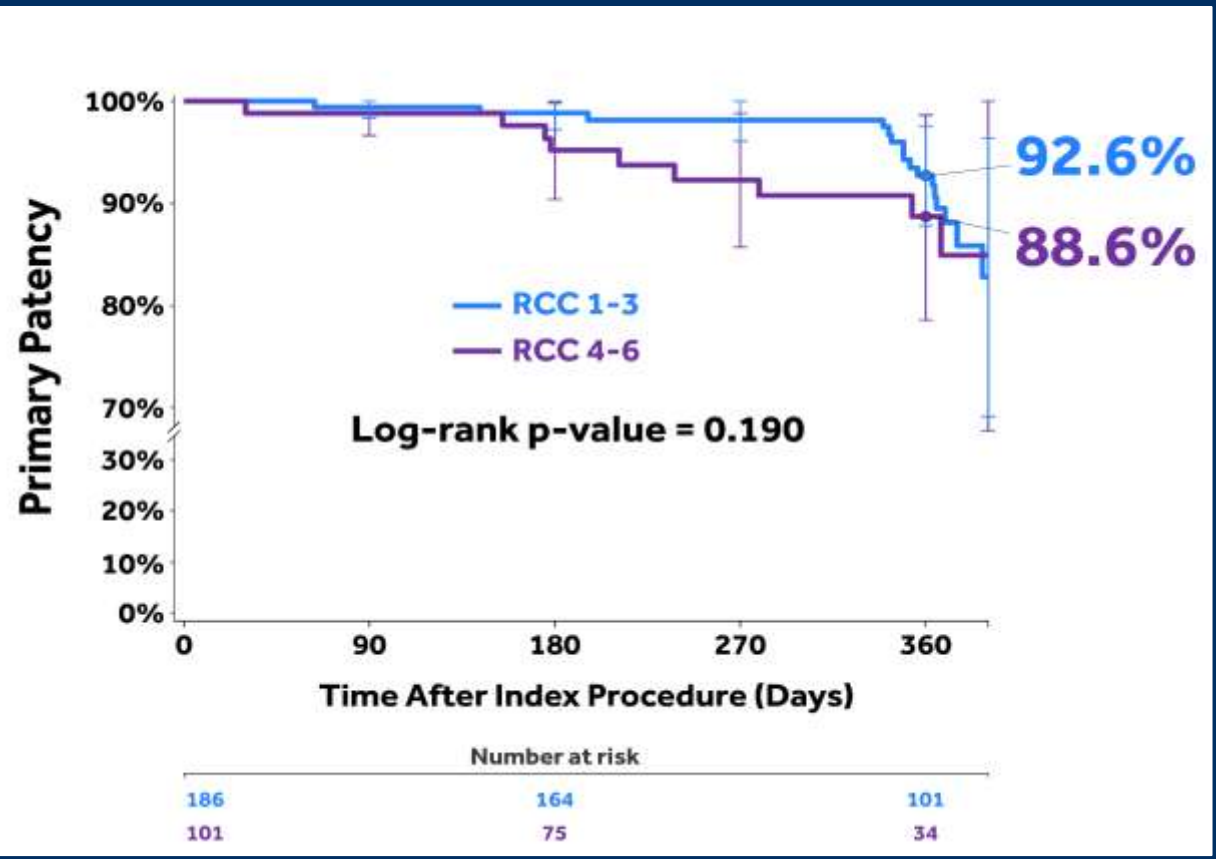
Non-stented:	93	85	84	77	71
Stented:	63	58	57	54	47

There is no significant difference  
**DCB alone**  
&  
**DCB + STENT**





# Result of High-dose DCB for CLTI in Japan



Complications within 12M	RCC 1-3 (Claudicant)	RCC 4-6 (CLTI cohort)
Major Adverse Event (MAE)		
All cause of death, n (%)	9 (6.0)	13 (17.3)
Target limb amputation, n (%)	0 (0.0)	1 (1.3)
Clinical driven TLR, n (%)	6 (4.0)	10 (13.3)
Treatment site thrombosis, n (%)	2 (1.3)	0 (0.0)
Any TLR, n (%)	7 (4.6)	8 (10.7)



# Does the downstream effect negatively affect?



Role of **A**ngioplasty with **D**rug-coated balloon for chronic **I**Schemia in wound **H**ealing



## Participant Flow

Between April 2014 and March 2019,  
Ischemic wound underwent FP-EVT

**1131 limbs** (980 pts)

Unavailable data  
72 limbs (58 pts)

**1059 limbs** (922 pts) were enrolled

DCB

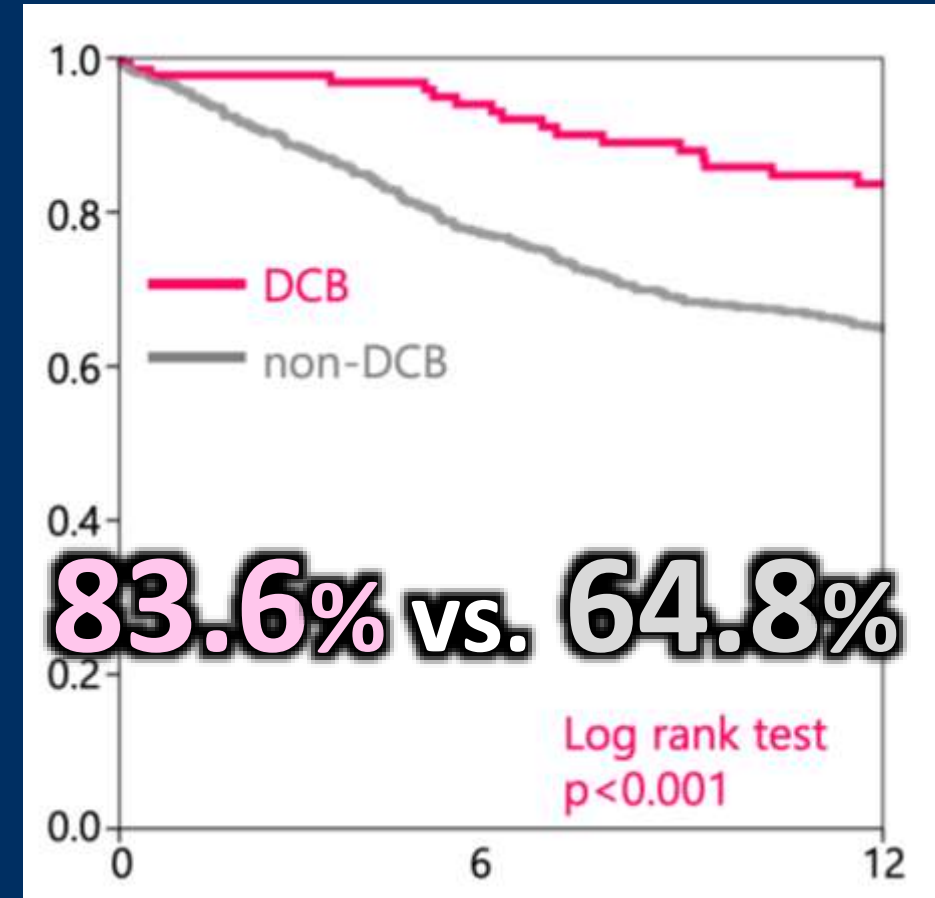
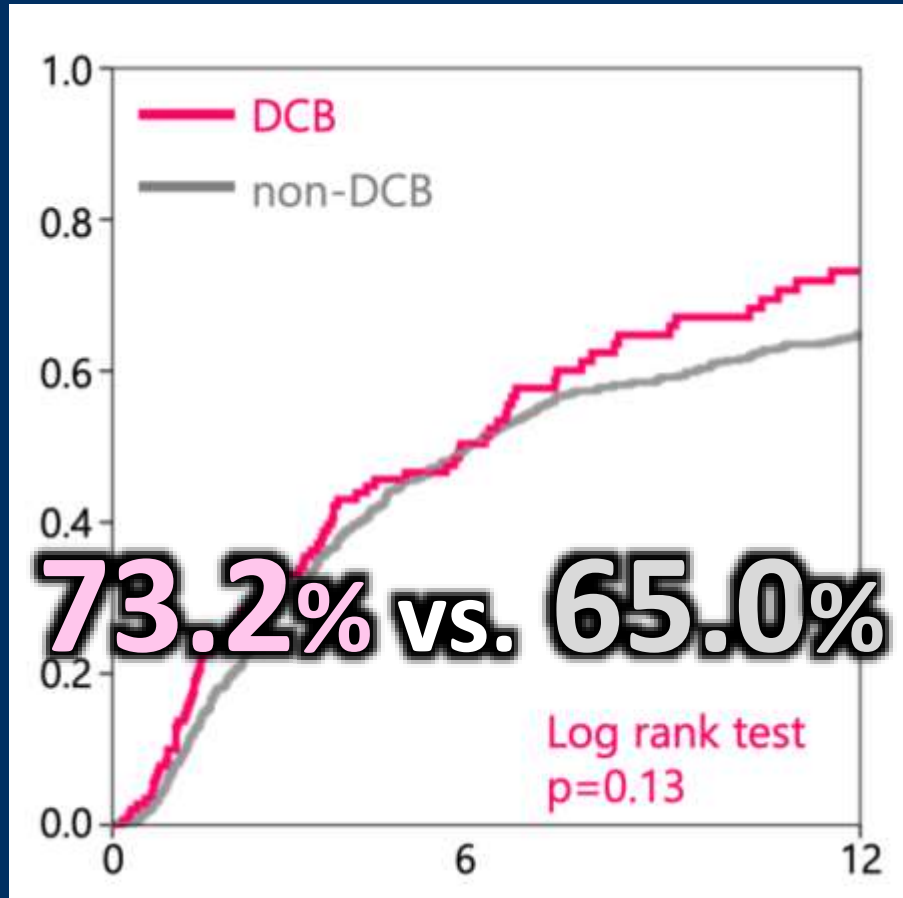
**144 limbs** (136 pts)

Non-DCB

**915 limbs** (786 pts)



# DCB for CLTI patient is safe and effective strategy



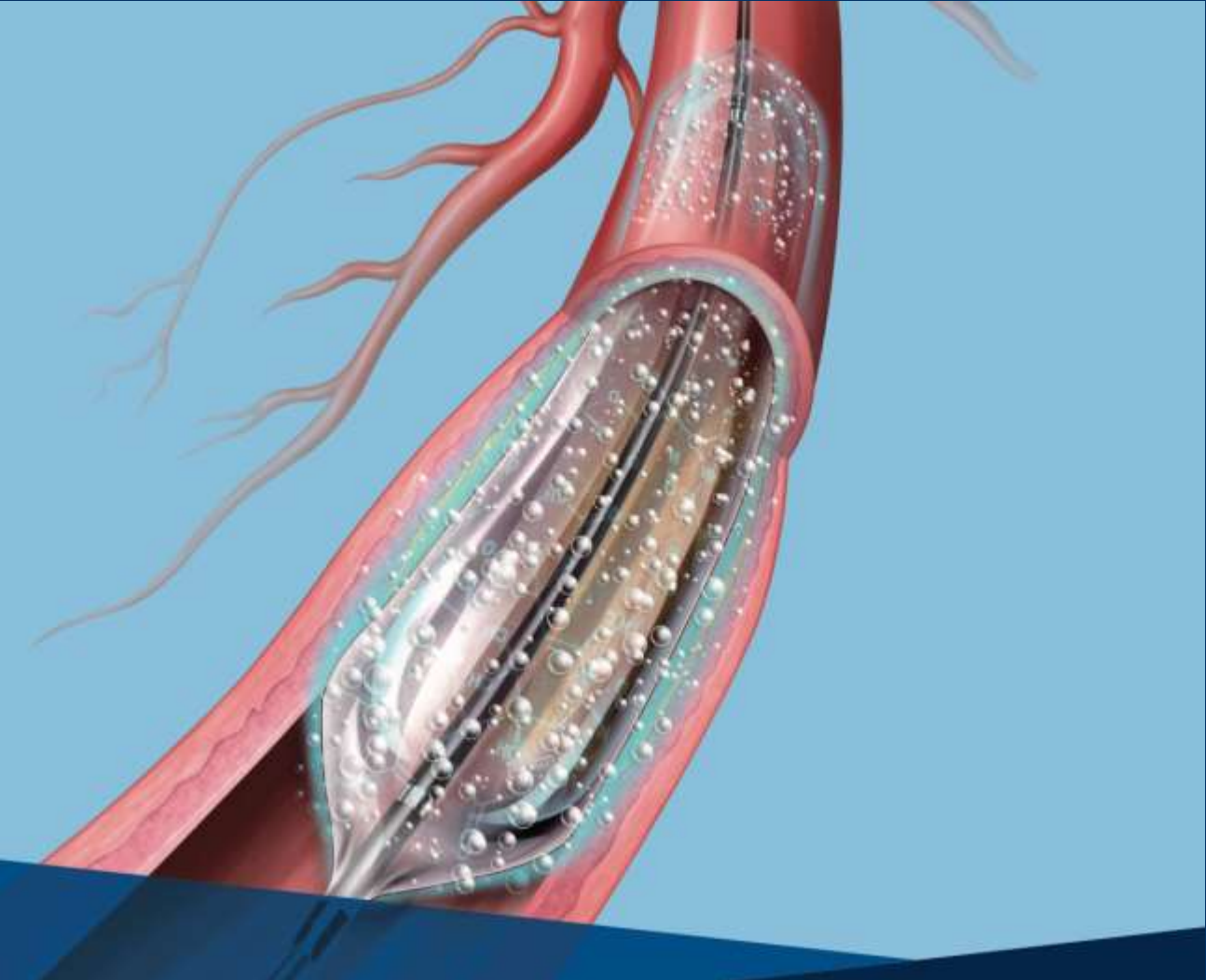
Wound healing rate@12M

Primary patency@12M

# Learn from experience and evidences

- Stent based strategy is simple, quick and promising: No recoil, dissection and downstream effect
  - considered as **basic strategy** for CLTI patients
- Stent itself **does not improve the patency**
- **NO difference** safety and efficacy between claudicant and CLTI in Japanese PMS study
- **Comparable wound healing rate and better patency** were observed in real world clinical setting CLTI patients

# Lutonix Rx: user friendly, low dose DCB



1. *Low dose ( $2.0\mu\text{g}/\text{mm}^2$ ) PTX*
2. *4.5Fr compatible*
3. *0.014-inch GW compatible*
4. *Rapid exchange system*

Fit for CLTI procedure  
Slender sheath and 0.014 GW  
Potentially reduce the  
downstream effect?

# Summary of Presentation



- Stent-based strategy is basic strategy for CLTI
- However, stent-based strategy sometimes includes several problems, like risk of Stent thrombosis.
- Japanese PMS data showed acceptable result of DCB for CLTI Downstream effect may not worsen the outcomes of CLTI patients
- **DCB-based strategy** is reasonable and important option for CLTI patients.



# Treatment strategy for Femoropopliteal CLTI

*Tatsuya Nakama, MD*

*Tokyo Bay Medical Center, Urayasu, Japan*