# Japan update
# Optimal Strategies for Vessel Preparation and DCB usage

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# Disclosure

## Speaker name: Daizo Kawasaki

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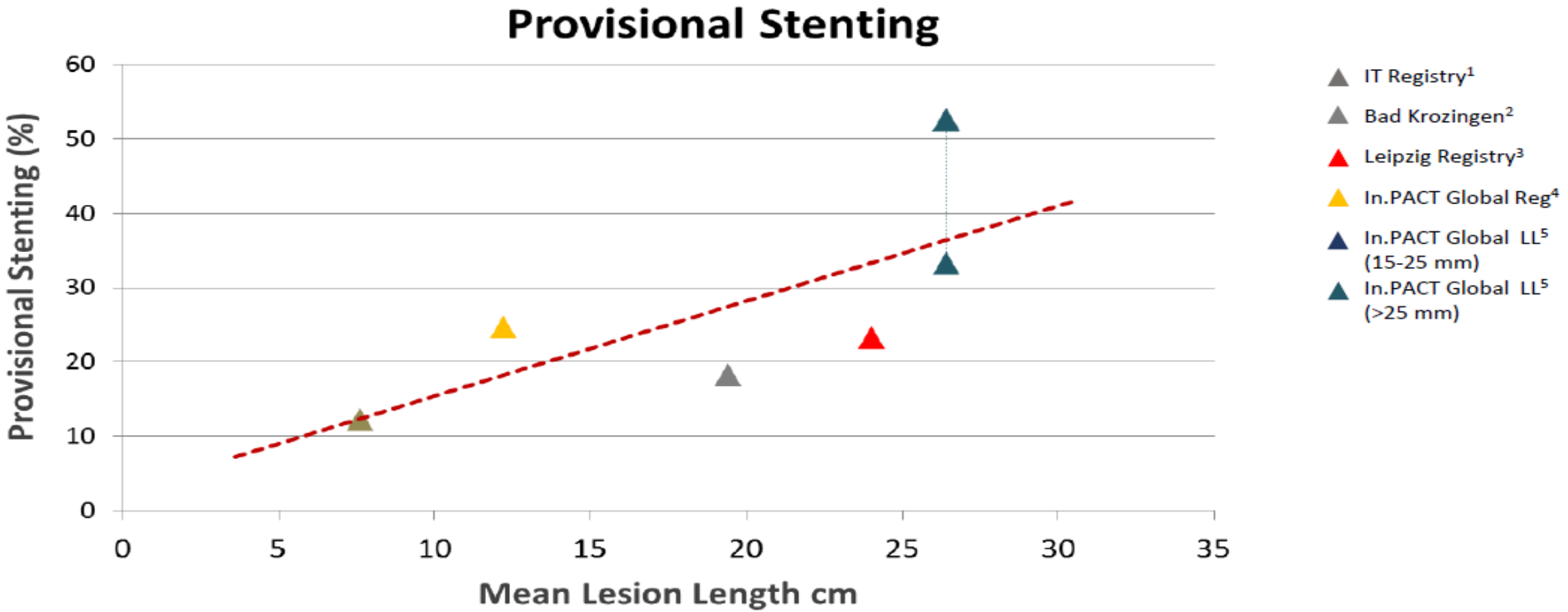
I have the following potential conflicts of interest to report:

- ☐ 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

# Provisional Stents rate in Real World DCB trials




*Results from different trials are not directly comparable.*
*Information provided for educational purposes.*

# Provisional stenting after failed DCB is not reimbursed in Japan

## Instruction For Use of DCB in Japan

### DCB

- <50% stenosis
- Non severe dissection (0-C) After Prep
- Non severe calcification

High expectation of DCB Performance

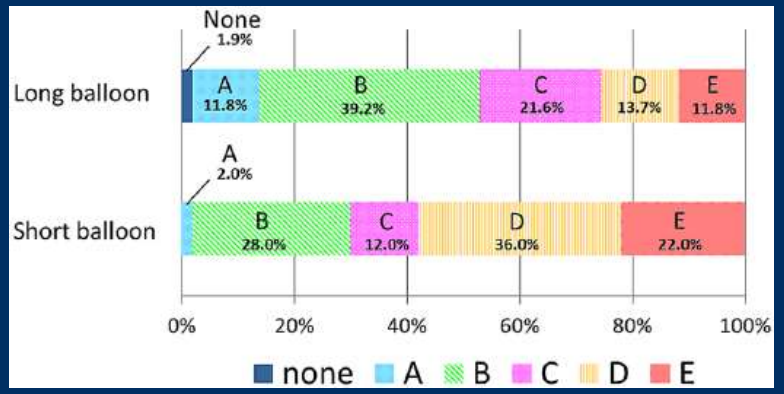
### No recommend DCB

- ≥50% residual stenosis
- Severe dissection(≥D) After Prep
- Severe calcification

No expectation of DCB Performance

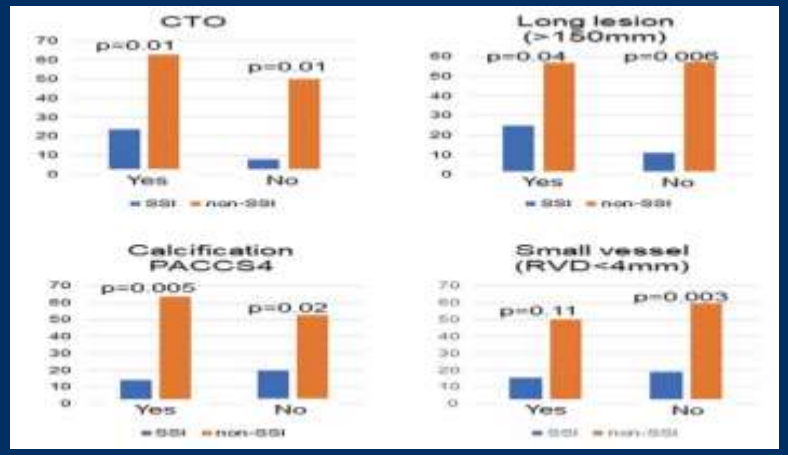
# Effort of Japanese Doctors to Minimize Dissection after Preparation

## Long Balloon




Tan M, et al. J Endovasc Ther. 2018

## Slow & Long inflation

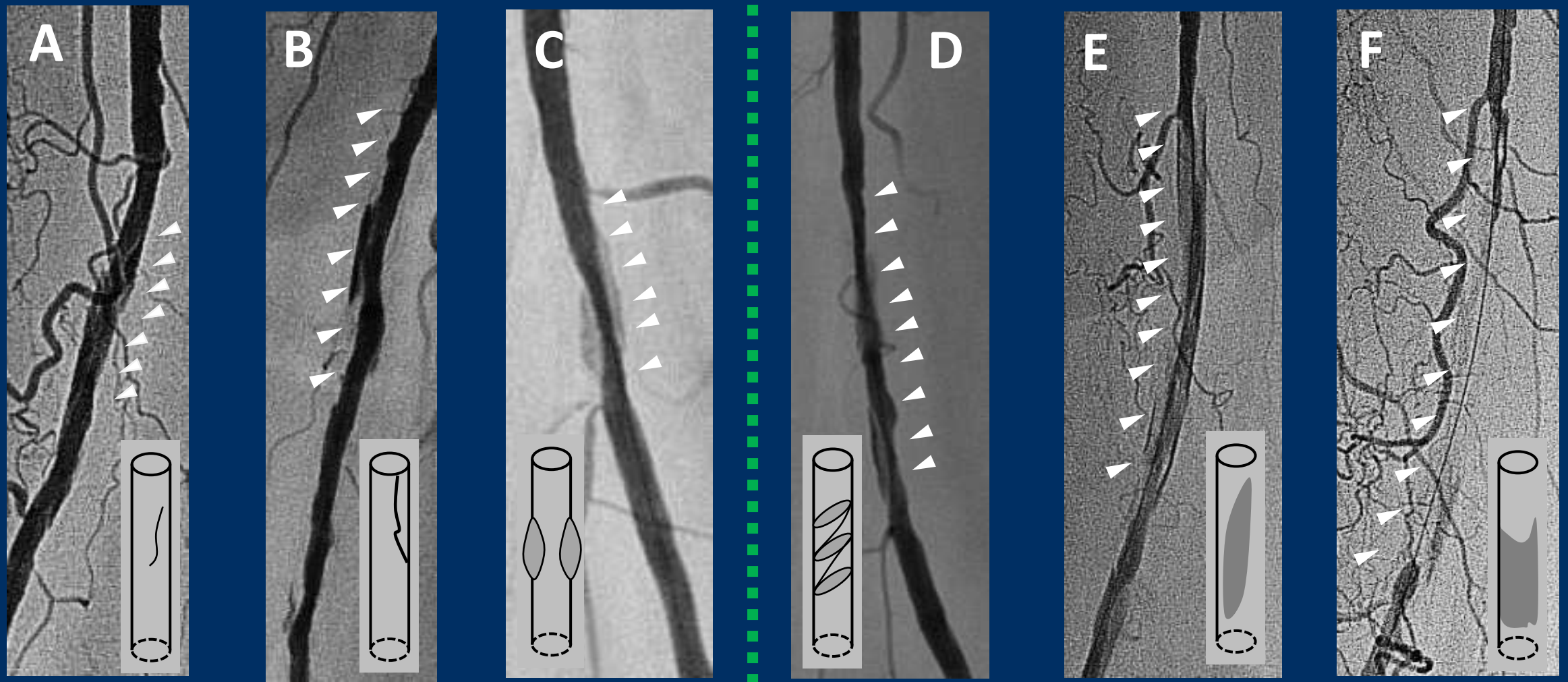



Sugihara M, et al. Circulation reports

## Scoring Balloon


Horie K, et al. J Endovasc Ther. 2020

# Fate or Result



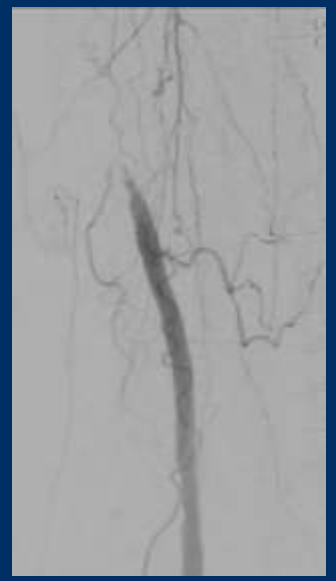

## Benign dissection

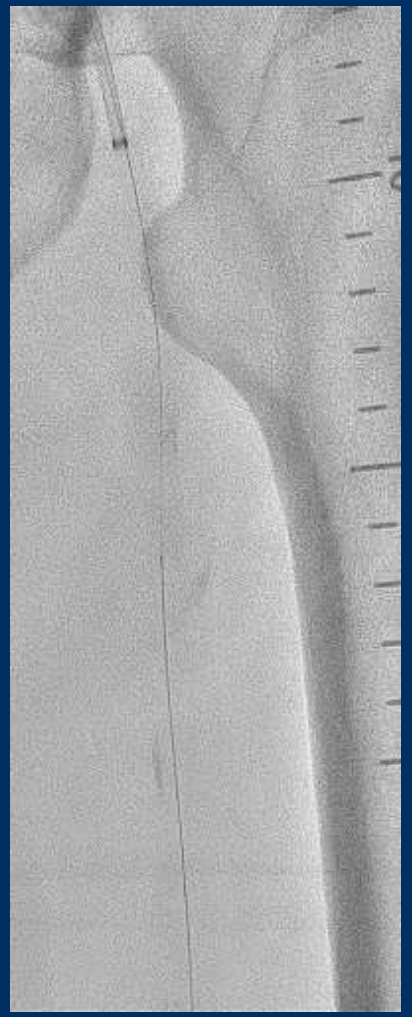
## Malignant dissection

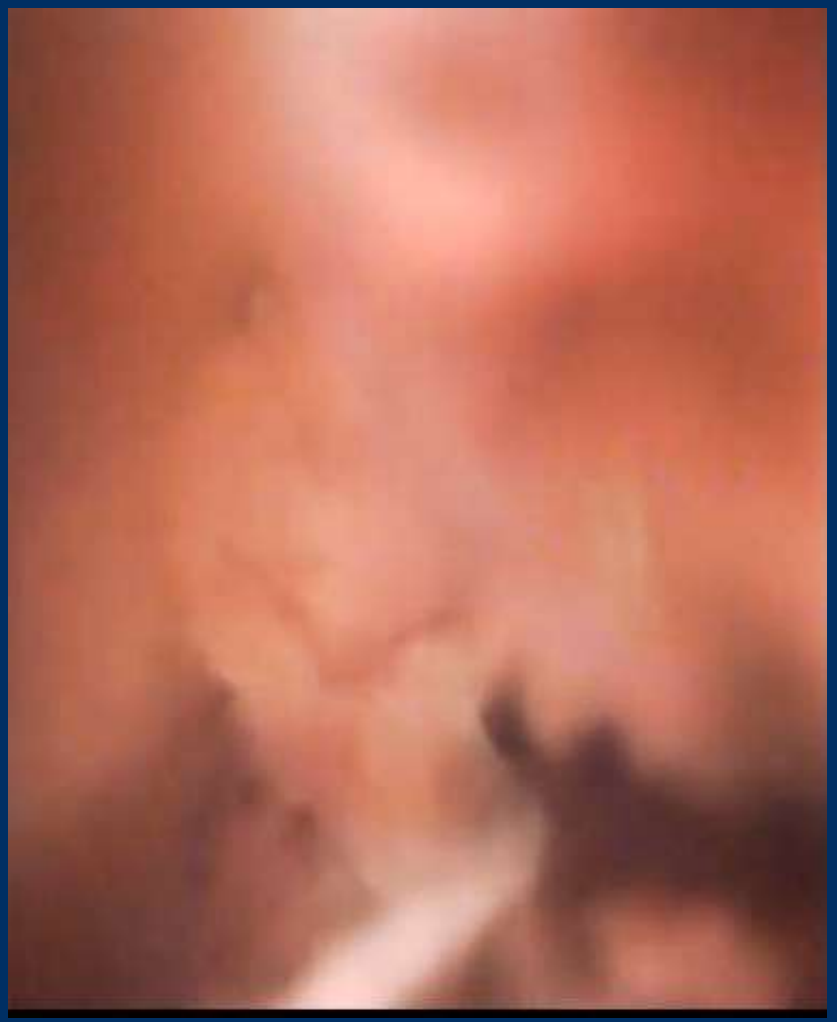
Fujihara et al. J Endovasc Ther. 2017

# Dissection D (Spiral type)

# Dissection E & F
# (Filling Defects, Total Obstruction)

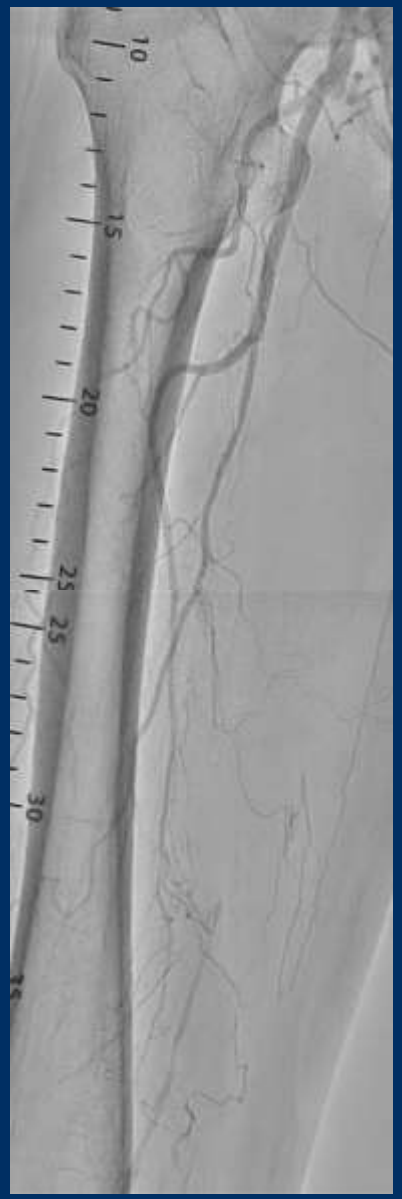



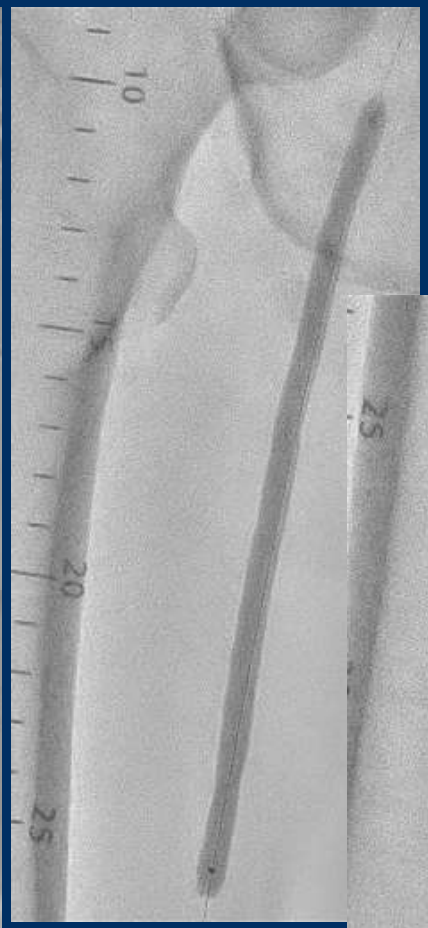


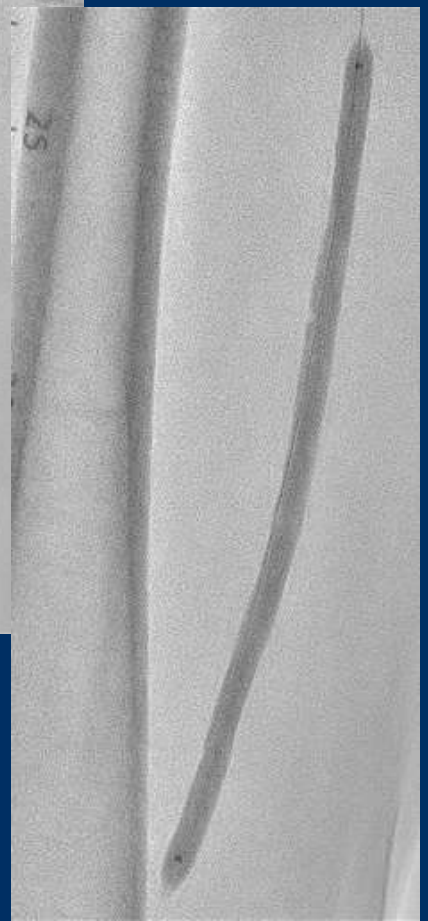


**Severe recoil of Organized Thrombus**

# Dissection 0,A,B,C (Intimal Thickness)







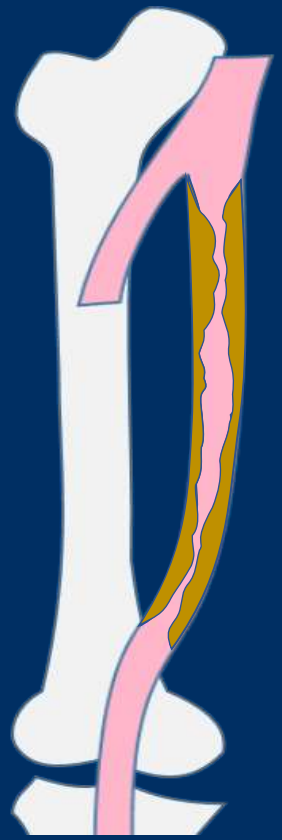
# *Highly expectation of DCB Performance*

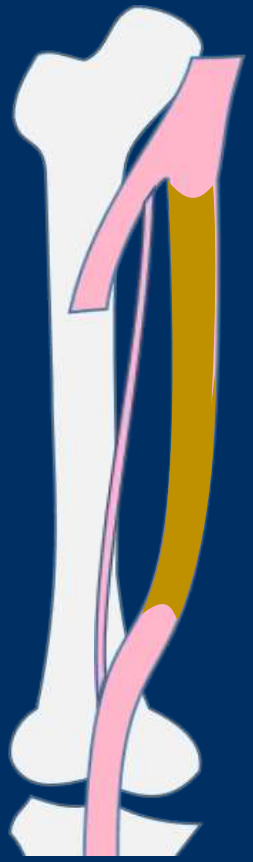
Stenosis

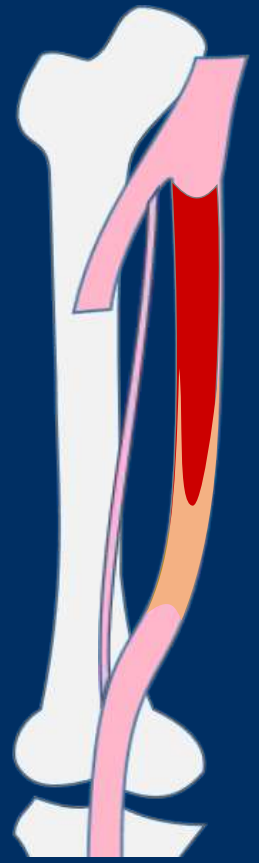
CTO
(Intimal Thickness)

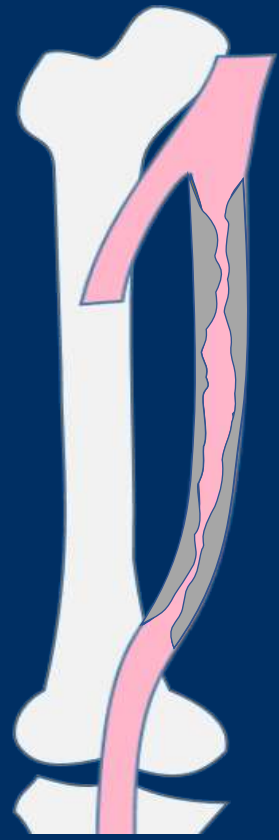
CTO
(Thrombus relate)

Calc









Total 725 EVT for FP lesion; 2018.2-2020.9 (32 months)

DCB treatment for 357 FP lesion

**Exclusion**
Death; 47 cases
Major amputation within 12 M; 10 cases
CFA lesion; 15 cases
ISR; 57 cases
Lost follow up; 34 cases
Within 12M after EVT; 94 cases

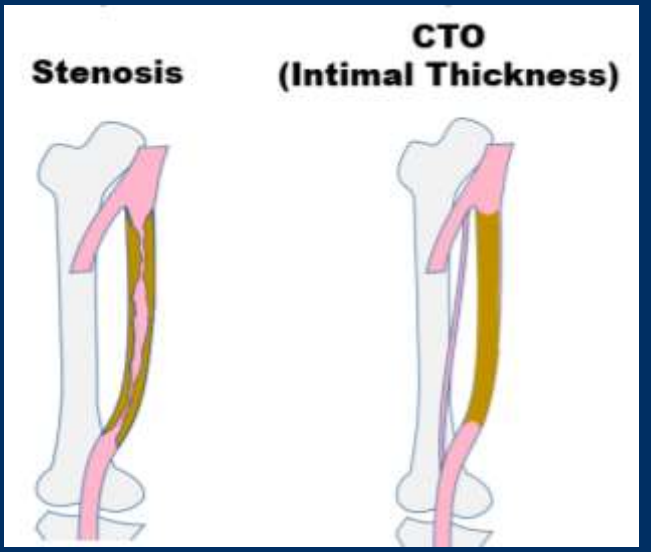
**100 Cases (LUTONIX DCB 56, IN.PACT DCB 44);**

**Complete follow up by Duplex echo examination at 12 month after EVT**

# Our Preparation Methods

## No Special Preparation

- **Conventional balloon** enough to cover the lesion
- Inflation time **30 seconds**
- **Direct DCB (17%)** for non severe calcified stenotic lesion without PreP.



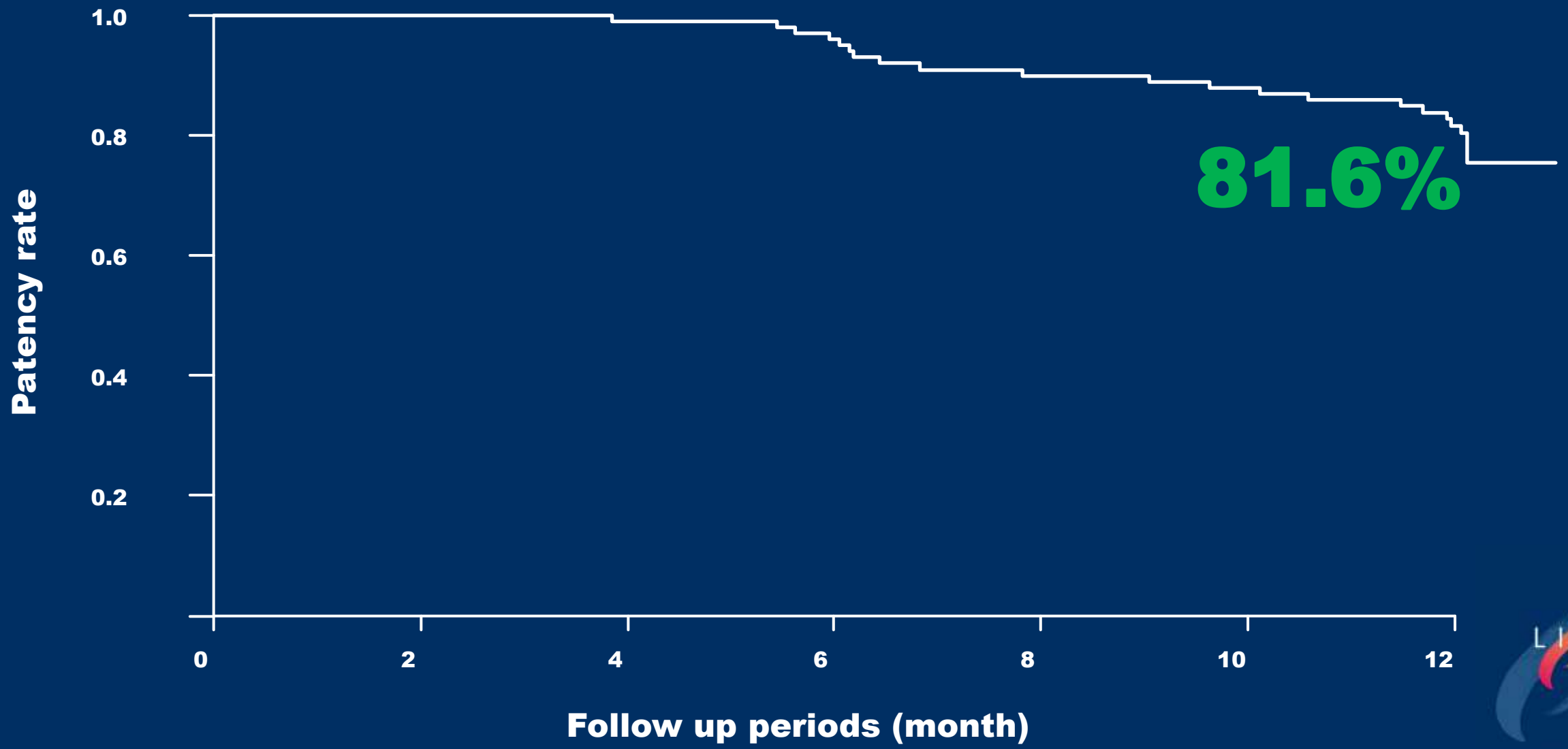
# Patients & Clinical characteristics

| | DCB (n=100) |
|---|---|
| Age, yrs | 71.6 ± 9.2 |
| Male, % | 67 |
| Diabetes Mellitus, % | 61 |
| Hemodialysis, % | 33 |
| Rutherford 4-6, % | 31 |
| Baseline ABI | 0.64 ± 0.15 |
| Lesion length, mm | 159 ± 82 |
| TASC II C/D | 52 |
| Diameter Stenosis, % | 93.0 ± 7.2 |
| CTO, % | 35 |
| PACCS 4 calcification, % | 20 |
| Vessel Diameter, mm | 4.9 ± 0.8 |
| Numbers of BTK runoff vessel | 1.53 ± 0.87 |

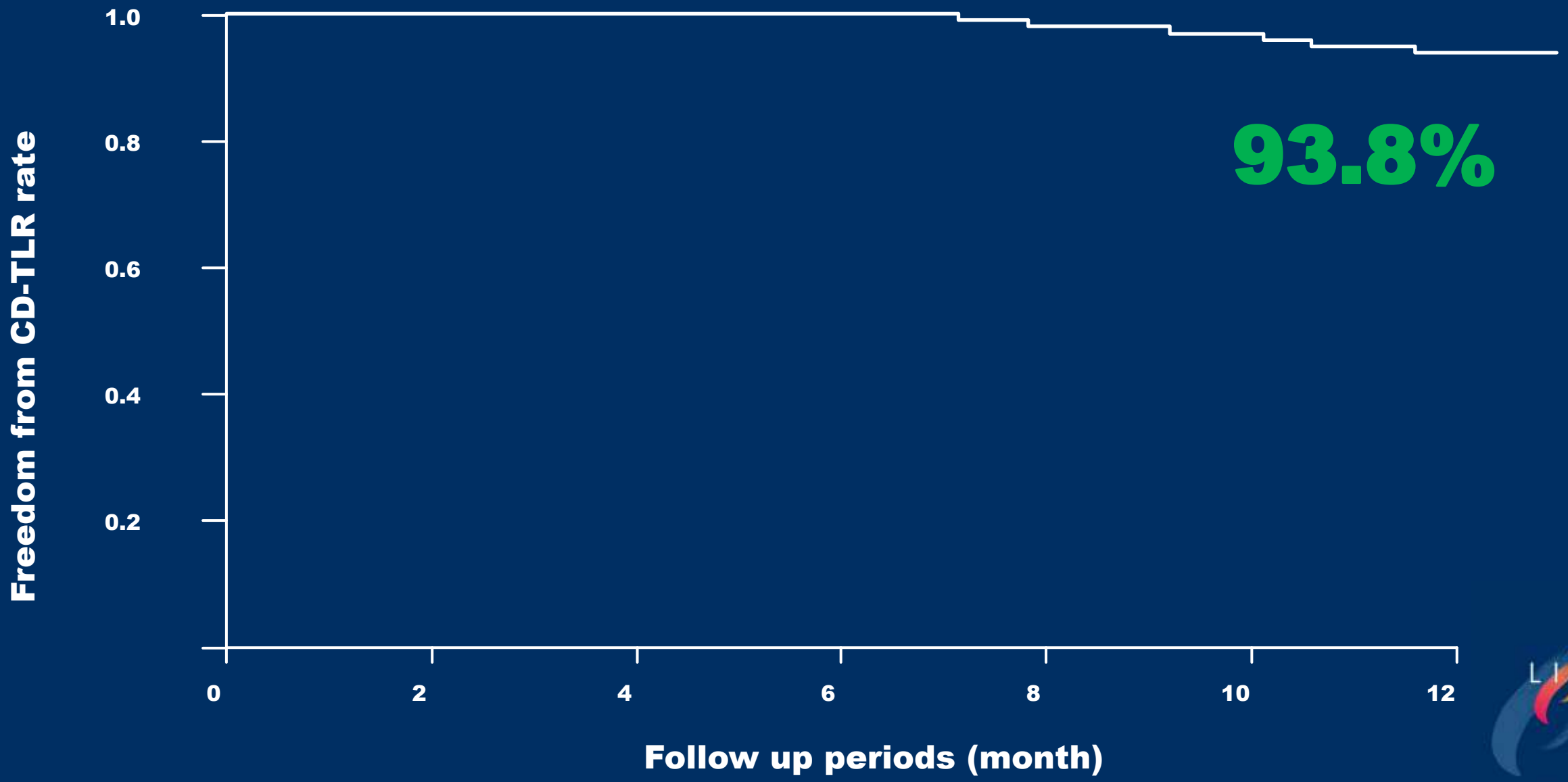
# Procedural characteristics

| | DCB (n=100) |
|---|---|
| DCB Length, mm | 152 ± 53 |
| DCB Number | 1.0 ± 0.4 |
| DCB Diameter, mm | 5.4 ± 0.6 |
| Residual Stenosis, % | 23.9 ± 4.0 |
| Dissections, % | |
| 0-C (Benign) | 100 |
| D-F (Malignant) | 0 |
| Provisional Stent, % | 0 |

# 1year Primary patency (PSVR<2.5)



# 1year Freedom from CD-TLR



# Summary

- We need to identify the lesions for which DCB is effective
- Malignant dissection is caused by organized thrombus related lesion
- Preparations for vessels with thicker intima do not need to be nervous
- Our results of DCB treatment were acceptable compare to other DCB data