

# **Optimal Vessel Preparation and bail-out stent implantation evaluated by multimodality for SFA disease- Result from IGNITE study-**

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# COI Disclosure

Speaker name :

***Masahiko Fujihara, MD***

I have the following potential conflicts of interest to report:

- Consulting; Century Medical, Nipro, Terumo
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s) Boston Scientific, Medtronic

# Device selection in SFA intervention 2019-

**DCB**



**DES**



**CS**



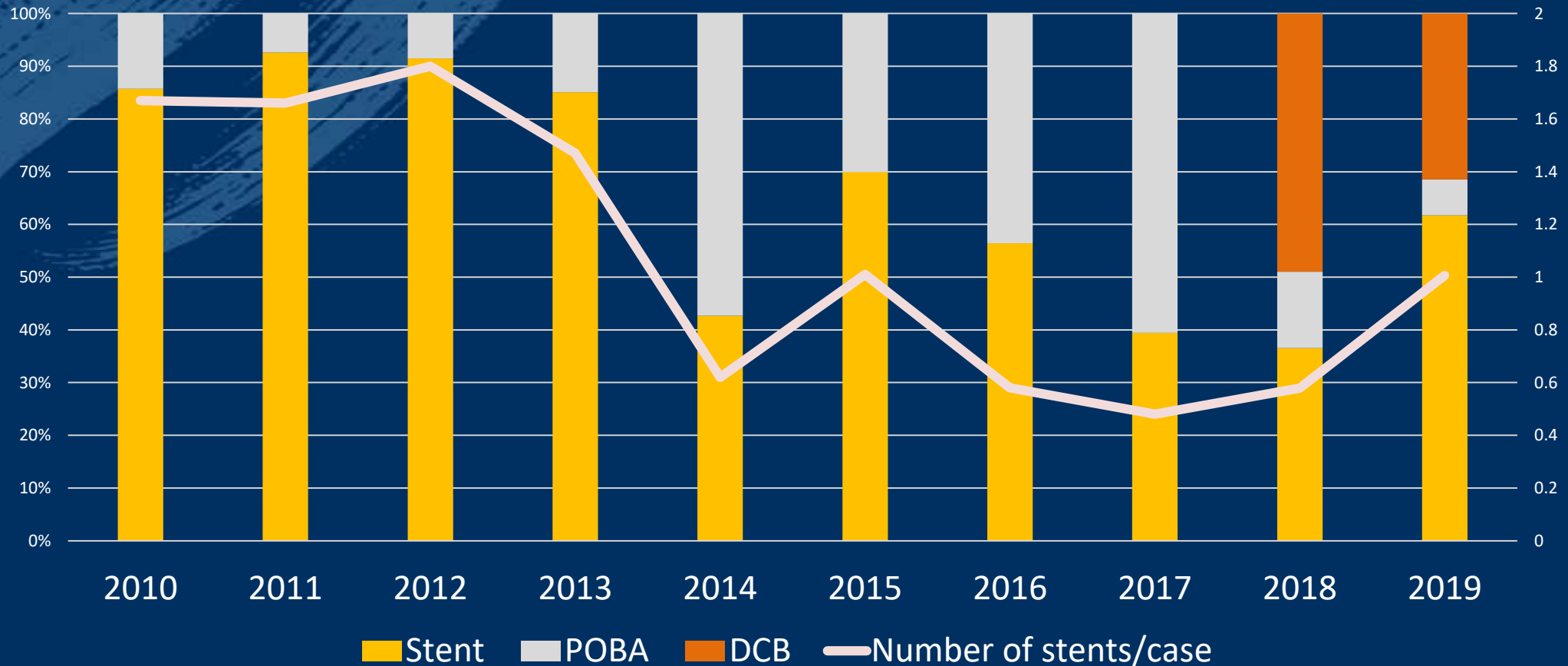
**IW**



In the end of 2017, at last drug coated balloon was reimbursement  
2019, SUPERA and ELUVIA will approve in SFA field

# First line strategy for SFA lesion in Kishiwada Tokushukai Hospital

*In 2010-2019, we treated 1114 SFA de novo lesions successfully by endovascular therapy*



# Instruction For Use of DCB

## DCB or Stent ?

- <50% stenosis
- Non severe dissection  
After pre dilatation
- Non severe calcification
- Non in stent restenosis
- $\leq 15\text{cm}$ (LUTONIX)
- $\leq 20\text{cm}$ (IN.PACT)

DCB

Highly expectation of DCB Performance

- $\geq 50\%$  residual stenosis
- Severe dissection( $\geq$ Type D)  
After pre dilatation
- Severe calcification
- In stent restenosis
- Long lesion

Stent

No expectation of DCB Performance

# What is optimal vessel preparation?

- Optimal vessel preparation before stent or balloon strategy is critical for a successful procedure.
- Achieving significant luminal gain, freedom from significant dissection and reducing pressure gradient is good vessel preparation.
- Otherwise, the definition of optimal preparation or provisional stent implantation is unclear.
- What type of balloon procedure could get the initial success is still unclear.
- This study aimed to clarify the optimal vessel preparation and optimal provisional stent strategy out stent evaluated by multi-modalities (Angio, IVUS, and Pressure gradient)

# Study Design

## Study Design

A multicenter, Prospective Clinical investigation

## Inclusion Criteria

- Age >20 years old
- Rutherford category 2-5
- **TASC II AB lesion**
- Denovo Lesion

## Exclusion Criteria

- Rutherford 6
- In stent restenosis
- **DCB/atherectomy**

## Endpoint

- 1Y Primary Patency Rate (PSVR<2.5 by Duplex)
- Successful Balloon angioplasty evaluate by angiography, IVUS and pressure gradient

## Patients enrolle period

APRIL 2016 to DECEMBER 2017, 296 patients from 13 centers

## Analysis

Angiography were evaluated by core-labo analysis (ENDOCORE)  
IVUS image were analyzed by 2 independent physicians

# Study Scheme

Patient (N=296, 13 centers)

Bare Balloon Angioplasty

- Residual Stenosis  $\leq 30\%$
- Dissection  $\leq$  Type B
- Pressure Gradient  $\leq 20$ mmHg

**Bare Balloon Alone  
Strategy**

- Residual Stenosis  $> 30\%$
- Severe Dissection  $>$  Type C
- Pressure Gradient  $> 20$ mmHg

**Standard Bare Nitinol Stent  
Strategy**



# Baseline Patients and lesion data

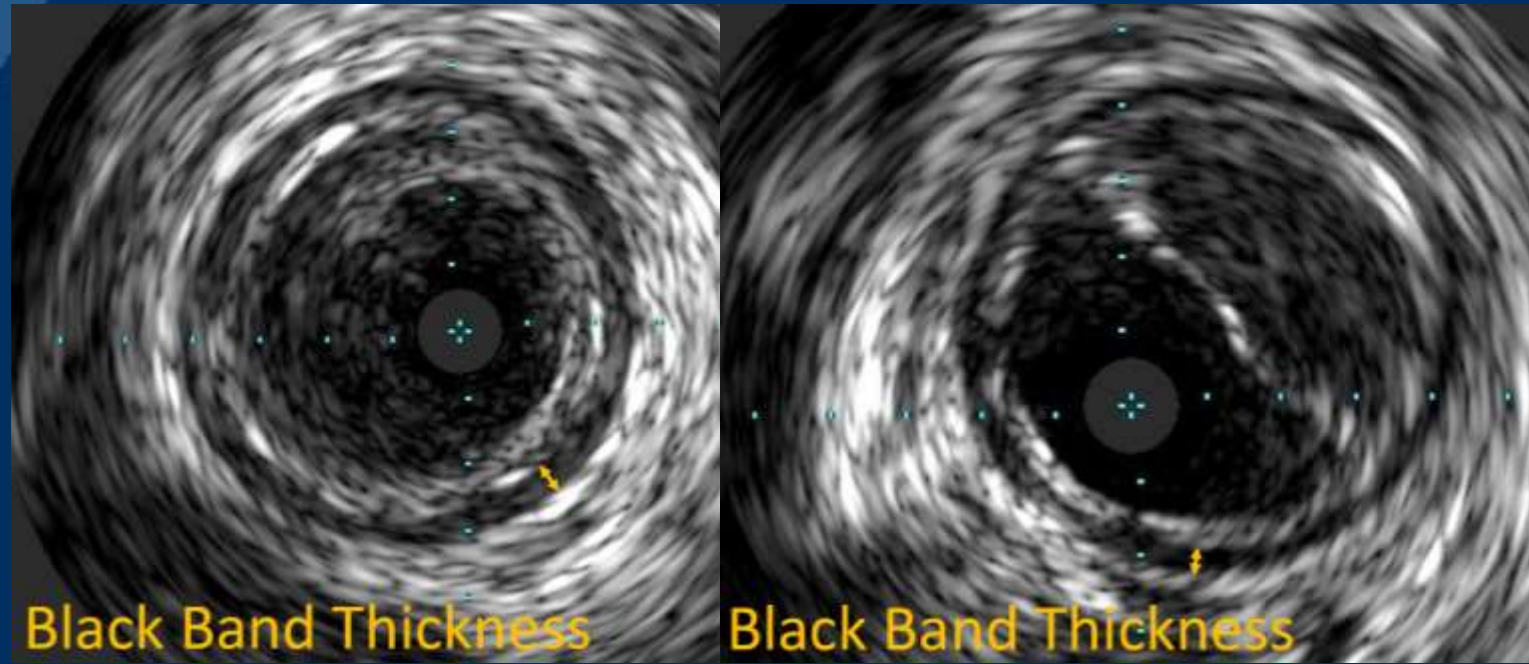
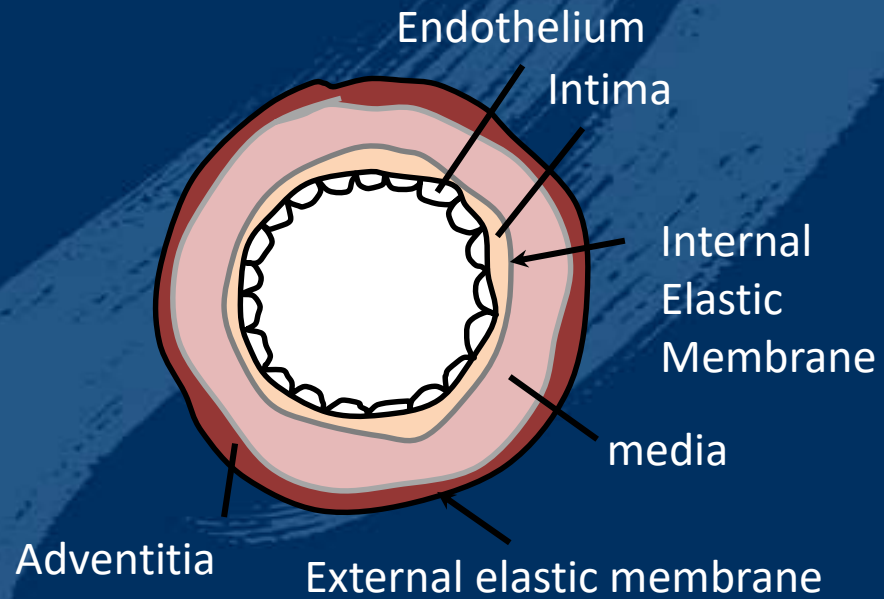
		N=296	*Data from on site data sheet
Age (years old)	<b>73.4±8.6</b>	Non ambulatory (%)	<b>8.3</b>
Male Sex (%)	<b>70.2</b>	BTK runoff	<b>1.8±8.9</b>
Hypertension(%)	<b>93.2</b>	Treated AIOD (%)	<b>19.9</b>
Diabetes (%)	<b>64.1</b>	Lesion length (mm)	<b>78.4±43</b>
Dyslipidemia (%)	<b>58.8</b>	Chronic Total Occlusion (%)	<b>12.3</b>
Current Smoking (%)	<b>31.4</b>	Max PSV ratio by DUS	<b>298±115</b>
Obesity (%) BMI>25	<b>25</b>	Max PSV ratio by DUS	<b>5.5±3.8</b>
ESRD on Dialysis (%)	<b>29.1</b>	Aspirin (%)	<b>83.8</b>
Ankle Brachial Index	<b>0.68±0.2</b>	Clopidogrel (%)	<b>72.0</b>
Rutherford 2-3 (%)	<b>82.4</b>	Cilostazol (%)	<b>28.4</b>
Rutherford 4 (%)	<b>13 (4.4)</b>	Warfarin (%)	<b>9.7</b>
Rutherford 5 (%)	<b>39(13.1)</b>	DOAC (%)	<b>5.7</b>

# Baseline Angiography and IVUS data

Angiography Analysis N=291**		IVUS Analysis N=291***			
CTO (%)	<b>12.3</b>	Prox Ref Vessel Size (mm)	<b>35.1±11</b>	MLA Plaque Eccentricity	<b>0.64±0.2</b>
<b>Lesion Length (mm)</b>	<b>93.5±51</b>	Prox Ref Lumen Size (mm)	<b>5.1±0.9</b>	% of MLA plaque (%)	<b>86.3±7.4</b>
Proximal Ref (mm)	<b>4.7±1.0</b>	Distal Ref Vessel Area (mm <sup>2</sup> )	<b>32.7±11</b>	Max Calcified Angle °	<b>107.1±128</b>
Distal Ref (mm)	<b>4.7±1.1</b>	Distal Ref Lumen Size (mm)	<b>4.8±0.9</b>	Calcified Nodule (%)	<b>27.4</b>
Lesion Ref (mm)	<b>4.7±1.0</b>	MLA Lumen Area (mm <sup>2</sup> )	<b>4.1±2.7</b>	<b>BLACKBAND Analysis</b>	
MLD (mm)	<b>1.6±0.9</b>	MLA EEM Area (mm <sup>2</sup> )	<b>31.1±9.8</b>		
<b>%Diameter Stenosis (%)</b>	<b>66.6±19</b>	<b>MLA plaque type</b>	<b>32.7±11</b>	MLA Max BlackBand (mm)	<b>0.44±0.1</b>
Non calcification (%)	<b>27.5</b>	-Soft (%)	<b>35.2</b>	MLA Min BlackBand (mm)	<b>0.17±0.1</b>
PACSS-1 (%)	<b>28.1</b>	-Fibrous (%)	<b>41.2</b>	Prox Max BlackBand (mm)	<b>0.42±0.1</b>
PACSS-2 (%)	<b>0.3</b>	-Calcified (%)	<b>23.4</b>	Prox Min BlackBand (mm)	<b>0.16±0.1</b>
<b>PACSS-3 (%)</b>	<b>26.4</b>	MLA Min Plaque thickness (mm)	<b>1.0±0.6</b>	Distal Max BlackBand (mm)	<b>0.42±0.1</b>
<b>PACSS-4 (%)</b>	<b>17.6</b>	MLA Max Plaque thickness (mm)	<b>3.1±0.8</b>	Distal Min BlackBand (mm)	<b>0.17±0.1</b>

\*\* ENDOCORE Angiographic Core Laboratory, Fukuoka, JP \*\*\*IVUS image were analyzed by 2 independent physicians

# BlackBand



*By Special courtesy of Dr. Yoshimitsu Soga*

**Black Band Thickness** is the latest evaluation parameter of vessel compliance by IVUS?

# Baseline Balloon Angioplasty Procedure data

1 <sup>st</sup> Balloon N=296		→	2 <sup>nd</sup> Balloon N=82		→	3 <sup>rd</sup> Balloon N=6	
Bare Balloon (%)	<b>199(67.2)</b>		Bare Balloon (%)	<b>63(77.0)</b>		Bare Balloon (%)	<b>6(100)</b>
Scoring Balloon (%)	<b>69(23.3)</b>		Scoring Balloon (%)	<b>17(20.7)</b>		Scoring Balloon (%)	<b>0</b>
Cutting Balloon (%)	<b>28(9.4)</b>		Cutting Balloon (%)	<b>2(2.4)</b>		Cutting Balloon (%)	<b>0</b>
Balloon Size (mm)	<b>4.6±0.9</b>		Balloon Size (mm)	<b>5.1±0.7</b>		Balloon Size (mm)	<b>5.2±0.8</b>
Max Pressure (atm)	<b>11±4</b>		Max Pressure (atm)	<b>12±4</b>		Max Pressure (atm)	<b>13±5</b>
Inflation Time (sec)	<b>131±70</b>		Inflation Time (sec)	<b>161±68</b>		Inflation Time (sec)	<b>145±61</b>
PG(Systolic) mmHg	<b>10.4±11</b>		PG(Systolic) mmHg	<b>8.2±9</b>		PG(Systolic) mmHg	<b>12.5±8</b>
% Stenosis≤30%**	<b>144(53.9)</b>		% Stenosis≤30%**	<b>31(53.4)</b>		% Stenosis≤30%**	<b>2(50)</b>
Dissection≤B**	<b>215(57.9)</b>		Dissection≤B**	<b>50(86.2)</b>		Dissection≤B**	<b>3(75.0)</b>
TIMI Flow**	<b>2.9±0.3</b>		TIMI Flow**	<b>3.0</b>		TIMI Flow**	<b>3.0</b>

\*\* Core labo analysis

# Successful of Optimal Balloon Angioplasty

Evaluation by core-labo analysis

## Success

- Residual Stenosis  $\leq 30\%$
- Dissection  $\leq$  Type B
- Pressure Gradient  $\leq 20\text{mmHg}$

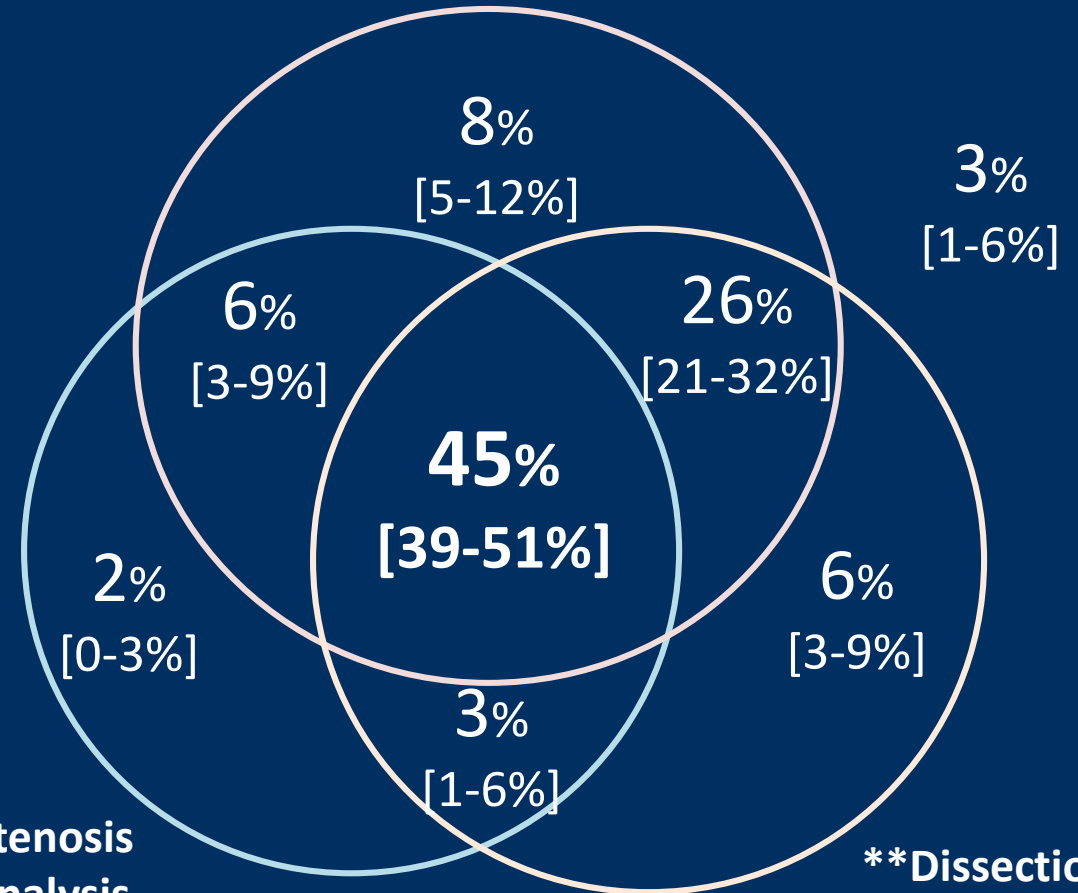
45%

## Unsuccess

- Residual Stenosis  $> 30\%$
- Dissection  $>$  Type C
- Pressure Gradient  $> 20\text{mmHg}$

55%

\*Sys Pressure gradient  
 $\leq 20\text{mmHg}$  (85% [81-90%])



\*\*Residual Stenosis  
 $\leq 30\%$  QVA analysis  
(56% [50-62%])

\*\*Dissection  $\leq$  B  
(81% [76-85%])

# The Factors of Balloon Success on Lesion Characteristics

	Systolic PG ≤20mmHg	Residual Stenosis ≤30%	Dissection ≤Type B	Success of Balloon Angioplasty
Chronic Total Occlusion	<b>0.4 [0.2-1.0] (P=0.043)</b>	0.5 [0.2-1.0] (P=0.057)	<b>0.4 [0.2-0.8] (P=0.007)</b>	0.5 [0.2-1.0] (P=0.059)
Lesion length (per 5cm longer)	0.9 [0.6-1.2] (P=0.45)	0.8 [0.6-1.0] (P=0.053)	<b>0.6 [0.5-0.8] (P=0.001)</b>	<b>0.7 [0.6-0.9] (P=0.004)</b>
Calcification PACSS 4	1.7 [0.5-5.9] (P=0.37)	0.6 [0.3-1.2] (P=0.18)	<b>5.7 [1.3-24.4] (P=0.02)</b>	1.0 [0.5-1.8] (P=0.91)
*Distal Diameter (/1mm larger)	1.1 [0.8-1.5] (P=0.65)	1.0 [0.8-1.3] (P=0.96)	1.3 [1.0-1.8] (P=0.070)	1.1 [0.8-1.3] (P=0.64)
*Distal Lumen Area (/10mm <sup>2</sup> larger)	1.1 [0.7-1.8] (P=0.70)	1.0 [0.7-1.4] (P=0.85)	<b>1.7 [1.0-2.7] (P=0.042)</b>	1.1 [0.8-1.5] (P=0.77)
*Distal EEM Area(/10mm <sup>2</sup> larger)	1.1 [0.8-1.5] (P=0.74)	1.0 [0.8-1.3] (P=0.85)	1.3 [1.0-1.8] (P=0.086)	1.1 [0.8-1.3] (P=0.62)
*Remodeling(Lesion Area-Ref Area)	0.7 [0.3-1.4] (P=0.33)	0.9 [0.6-1.5] (P=0.76)	<b>0.5 [0.3-1.0] (P=0.040)</b>	0.8 [0.5-1.4] (P=0.49)
*Plaque morphology (vs Fibrous)	1.0 (Ref)	1.0 (Ref)	1.0 (Ref)	1.0 (Ref)
-Calcification	1.0 [0.4-2.4] (P=0.98)	0.9 [0.5-1.6] (P=0.62)	<b>3.1 [1.1-9.2] (P=0.040)</b>	1.2 [0.6-2.1] (P=0.66)
-Soft	1.4 [0.6-3.1] (P=0.42)	1.2 [0.7-2.1] (P=0.52)	1.0 [0.5-1.9] (P=0.95)	1.2 [0.7-2.1] (P=0.43)
*MLA Calcified Angle(vs non calc)	1.0 (Ref)	1.0 (Ref)	1.0 (Ref)	1.0 (Ref)
-≥180°				1.2 [0.7-2.4] (P=0.49)
*Max Calcified Angle				1.0 (Ref)
-≥180°				1.2 [0.7-2.1] (P=0.47)
*Calcified Nodule				1.0 [0.6-1.7] (P=0.97)
*IVUS analysis				*OR [95 CI ] (P value)

**Longer lesion is significant factors of PTA unsuccessful**

# The Factors of Balloon Success on BlackBand Analysis

	Systolic PG ≤20mmHg	Residual Stenosis ≤30%	Dissection ≤Type B	Success of Balloon Angioplasty
*Distal Ref min BB (per 1mm larger)	0.3 [0.0-6.2] (P=0.44)	1.5 [0.2-12.8] (P=0.71)	0.3 [0.0-5.0] (P=0.43)	0.6 [0.1-5.3] (P=0.66)
*Lesion min BB (per 1mm larger)	0.1 [0.0-3.3] (P=0.19)	0.8 [0.1-7.9] (P=0.81)	0.1 [0.0-2.9] (P=0.20)	0.3 [0.0-2.9] (P=0.29)
*Distal Ref max BB (per 1mm larger)	0.6 [0.0-8.0] (P=0.66)	2.0 [0.3-13.2] (P=0.47)	0.3 [0.0-2.7] (P=0.26)	1.0 [0.1-6.6] (P=0.99)
*Lesion max BB (per 1mm larger)	4.2 [0.4-42.6] (P=0.22)	5.8 [0.9-37.3] (P=0.066)	2.1 [0.2-20.7] (P=0.53)	5.4 [0.9-30.6] (P=0.058)
*Distal Ref max-min BB (per 1mm larger)	1.6 [0.1-30.1] (P=0.76)	1.5 [0.2-11.8] (P=0.72)	0.6 [0.0-7.9] (P=0.70)	1.5 [0.2-11.7] (P=0.68)
*Lesion max-min BB (per 1mm larger)	<b>1.3 [1.0-1.7] (P=0.046)</b>	<b>1.2 [1.0-1.4] (P=0.040)</b>	1.2 [0.9-1.5] (P=0.17)	<b>1.2 [1.1-1.5] (P=0.010)</b>

\*OR [95 CI] (P value)

**The Larger Max-Min Blackband in lesion is the predictive factors of balloon angioplasty**

# The factors of balloon success on Procedure characteristics

	Systolic PG ≤20mmHg	Residual Stenosis ≤30%	Dissection ≤Type B	Success of Balloon Angioplasty
Long inflation ≥180sec	1.2 [0.5-2.7] (P=0.67)	<b>2.0 [1.1-3.5] (P=0.017)</b>	0.9 [0.5-1.8] (P=0.80)	<b>1.8 [1.0-3.1] (P=0.041)</b>
Inflation pressure ≥10atm	1.8 [0.8-3.9] (P=0.16)	1.0 [0.6-1.8] (P=0.87)	0.8 [0.4-1.5] (P=0.45)	1.1 [0.6-1.9] (P=0.82)
Cutting balloon	1.1 [0.4-3.4] (P=0.87)	1.5 [0.7-3.4] (P=0.31)	0.8 [0.3-2.2] (P=0.72)	1.3 [0.6-2.7] (P=0.56)
Scoring balloon	1.9 [0.8-4.5] (P=0.17)	0.9 [0.5-1.5] (P=0.64)	1.9 [0.9-4.0] (P=0.080)	1.1 [0.7-1.8] (P=0.73)
Balloon Size-Distal Ref(/1mm larger)	1.2 [0.8-1.8] (P=0.42)	<b>1.4 [1.0-1.8] (P=0.044)</b>	1.0 [0.6-1.7] (P=0.93)	1.2 [0.9-1.6] (P=0.16)
Balloon Size-MLA(/1mm larger)	1.2 [0.8-1.9] (P=0.39)	<b>1.4 [1.1-2.0] (P=0.022)</b>	0.9 [0.6-1.6] (P=0.78)	1.3 [1.0-1.7] (P=0.070)
*Balloon Size-Distal Ref EEM (/1mm larger)	0.9 [0.6-1.5] (P=0.76)	<b>1.5 [1.0-2.1] (P=0.034)</b>	0.9 [0.6-1.4] (P=0.60)	1.2 [0.9-1.7] (P=0.29)
*Balloon Size- Lesion EEM (/1mm larger)	1.2 [0.8-1.8] (P=0.47)	1.3 [1.0-1.8] (P=0.086)	1.0 [0.7-1.4] (P=0.89)	1.2 [0.8-1.6] (P=0.37)
*Balloon Size- Dis Ref Lumen (/1mm larger)	1.0 [0.6-1.8] (P=0.97)	<b>1.9 [1.2-2.9] (P=0.004)</b>	0.8 [0.5-1.3] (P=0.37)	1.4 [1.0-2.1] (P=0.083)
*Balloon Size- Lesion Lumen (/1mm larger)	1.0 [0.7-1.6] (P=0.91)	<b>1.6 [1.1-2.2] (P=0.006)</b>	0.9 [0.6-1.3] (P=0.58)	1.3 [0.9-1.7] (P=0.13)

\*IVUS analysis

\*OR [95 CI ] (P value)

**Long inflation over 180 sec is mandatory for successful balloon angioplasty**



# Procedure Strategy

Patient (N=296, 13 centers)

Bare Balloon Angioplasty

- Residual Stenosis  $\leq 30\%$
- Dissection  $\leq$  Type B
- Pressure Gradient  $\leq 20$ mmHg

Success BA 45%

BNS Stent 6%

BA alone 39%

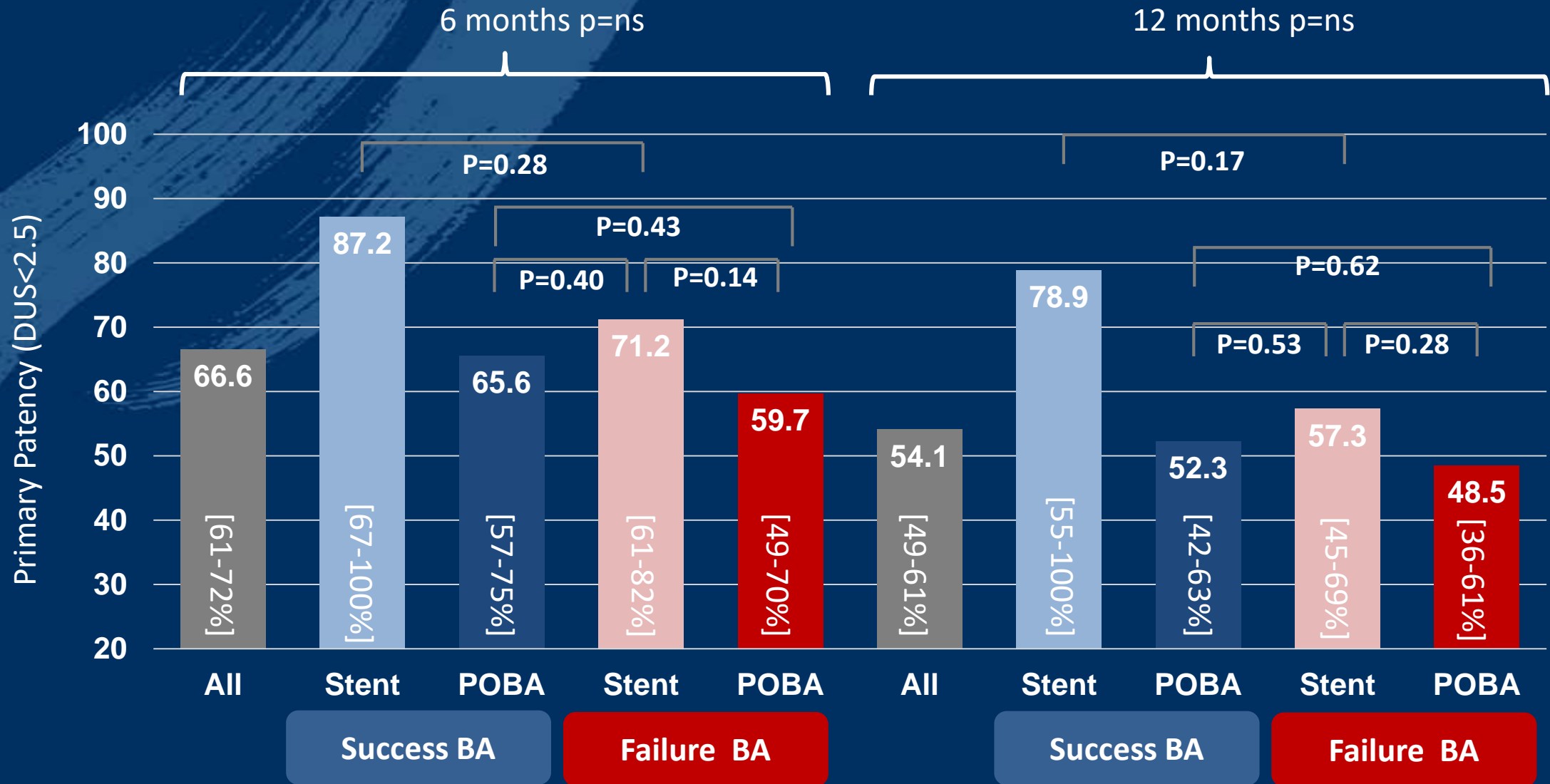
- Residual Stenosis  $> 30\%$
- Dissection  $>$  Type C
- Pressure Gradient  $> 20$ mmHg

Failure BA 55%

BNS Stent 25%

BA alone 30%

# Procedure Strategy and Patency Outcome



# The factors of Clinical Success (1-y Patency)

	OR [CI] (P value)
<b>All cohort (PTA plus Stent)</b>	
Pressure Gradient	0.63 [0.28 - 1.42] (P=0.26)
Residual Stenosis	1.09 [0.66 - 1.81] (P=0.73)
Severe Dissection	1.67 [0.90 - 3.07] (P=0.10)
<b>PTA alone cohort</b>	
Pressure Gradient	-
Residual Stenosis	1.00 [0.54 - 1.83] (P=0.98)
Severe Dissection	2.53 [0.76 - 8.45] (P=0.13)

**Successful Balloon Angioplasty did not relate  
Clinical Outcomes in bare device strategy...?**

# Result From IGNITE study

- IGNITE study evaluated optimal balloon dilatation and the definition of the provisional stent implantation.
- When we assumed the balloon success as less residual stenosis, vessel dissection, and no pressure gradient, 45% of procedures were successful in the core laboratory analysis.
- The predictive factor of the balloon success was the lesion length, BlackBand by IVS and balloon inflation time
- However, the strategies for treatment based on balloon success or not didn't correlate with 1-year patency outcomes in bare devices.
- Reconsideration is necessary for the definition of vessel preparation success.
- Long term patency may be depends on the ability to finalizing device and lesion, not vessel preparation process



# JET

Japan Endovascular Treatment Conference 2020

# 2020

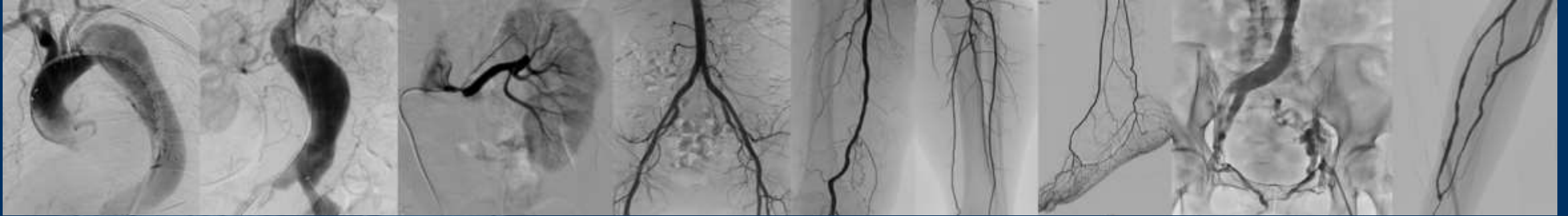
**Date** February **21**(Fri)-**23**(Sun), 2020

**Venue** Knowledge Capital Congrès Convention Center

Grand Front Osaka, 3-1 Ofukacho, Kita-ku, Osaka 530-0011, Japan

**Chairman of the executive committee**

**Osamu Iida** (Cardiovascular Center, Kansai Rosai Hospital)



**Thank you for your attention**

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**JET2020**  
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**February 21(Fri)-23(Sun) 2020**

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