# Opticross HD™ Imaging and Physiology-guided DCB Application

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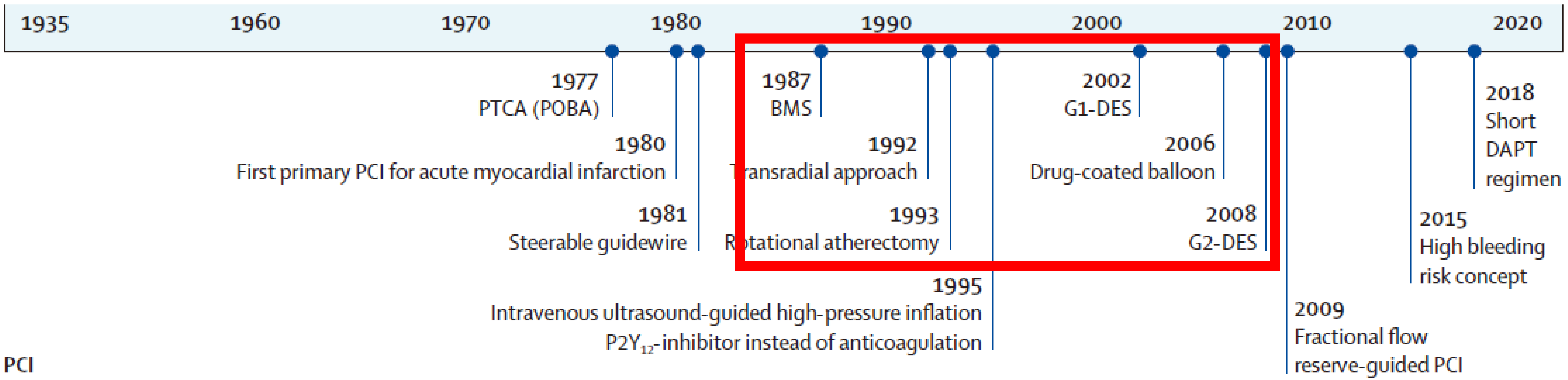
# Key Advancements in PCI




Gaudino M, et al. Lancet. 2023;401(10388):1611-1628

# Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention

Mahesh V. Madhavan, MD,[a,b] Ajay J. Kirtane, MD, SM,[a,b] Björn Redfors, MD, PhD,[b,c] Philippe Généreux, MD,[b,d,e] Ori Ben-Yehuda, MD,[a,b] Tullio Palmerini, MD,[f] Umberto Benedetto, MD, PhD,[g] Giuseppe Biondi-Zoccai, MD, MStat,[h,i] Pieter C. Smits, MD,[j] Clemens von Birgelen, MD, PhD,[k] Roxana Mehran, MD,[b,l] Thomas McAndrew, PhD,[b] Patrick W. Serruys, MD,[m] Martin B. Leon, MD,[a,b] Stuart J. Pocock, PhD,[n] Gregg W. Stone, MD[b,l]

**ABSTRACT**

**BACKGROUND** The majority of stent-related major adverse cardiovascular events (MACE) after percutaneous coronary intervention (PCI) are believed to occur within the first year. Very-late (>1-year) stent-related MACE have not been well described.

**OBJECTIVES** The purpose of this study was to assess the frequency and predictors of very-late stent-related events or MACE by stent type.

**METHODS** Individual patient data from 19 prospective, randomized metallic stent trials maintained at a leading academic research organization were pooled. Very-late MACE (a composite of cardiac death, myocardial infarction [MI], or ischemia-driven target lesion revascularization [ID-TLR]), and target lesion failure (cardiac death, target-vessel MI, or ID-TLR) were assessed within year 1 and between 1 and 5 years after PCI with bare-metal stents (BMS), first-generation drug-eluting stents (DES1) and second-generation drug-eluting stents (DES2). A network meta-analysis was performed to evaluate direct and indirect comparisons.

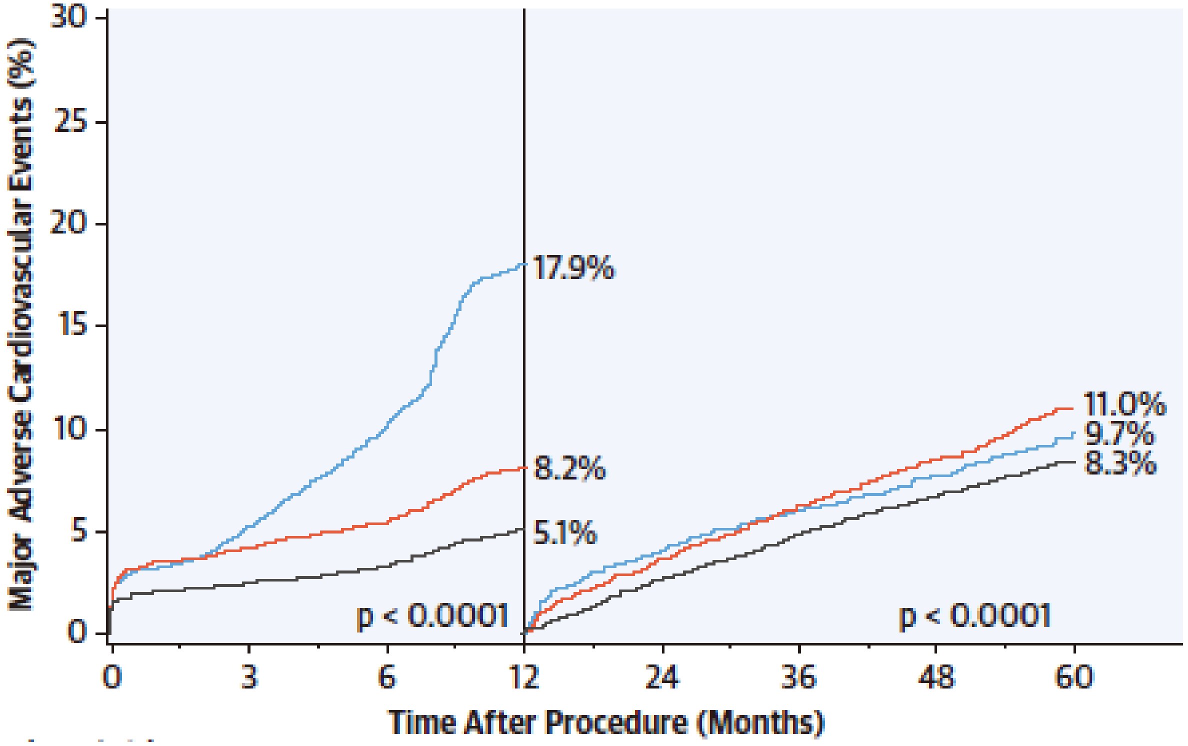
**RESULTS** Among 25,032 total patients, 3,718, 7,934, and 13,380 were treated with BMS, DES1, and DES2, respectively. MACE rates within 1 year after PCI were progressively lower after treatment with BMS versus DES1 versus DES2 (17.9% vs. 8.2% vs. 5.1%, respectively, $p < 0.0001$). Between years 1 and 5, very-late MACE occurred in 9.4% of patients (including 2.9% cardiac death, 3.1% MI, and 5.1% ID-TLR). Very-late MACE occurred in 9.7%, 11.0%, and 8.3% of patients treated with BMS, DES1, and DES2, respectively ($p < 0.0001$), linearly increasing between 1 and 5 years. Similar findings were observed for target lesion failure in 19,578 patients from 12 trials. Findings were confirmed in the network meta-analysis.

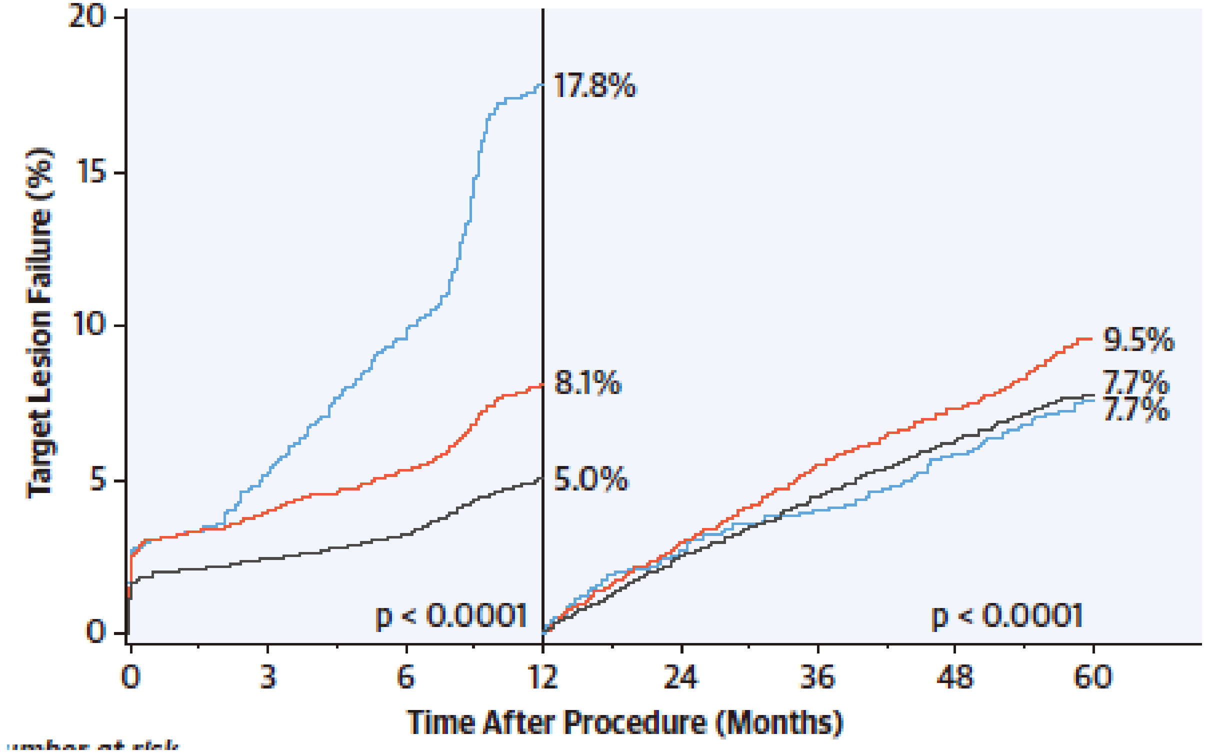
**CONCLUSIONS** In this large-scale, individual patient data pooled study, very-late stent-related events occurred between 1 and 5 years after PCI at a rate of ~2%/year with all stent types, with no plateau evident. New approaches are required to improve long-term outcomes after PCI. (J Am Coll Cardiol 2020;75:590-604) © 2020 by the American College of Cardiology Foundation.

Individual patient data from 19 randomized metallic stent trials maintained at a leading academic research organization were pooled.

Among 25032 total patients, 3718, 7934, and 13380 were treated with BMS, DES1, and DES2.

Very-late MACE (a composite of cardiac death, myocardial infarction [MI],
or ischemia-driven target lesion revascularization [ID-TLR]), and target lesion failure (cardiac death, target-vessel MI, or ID-TLR)

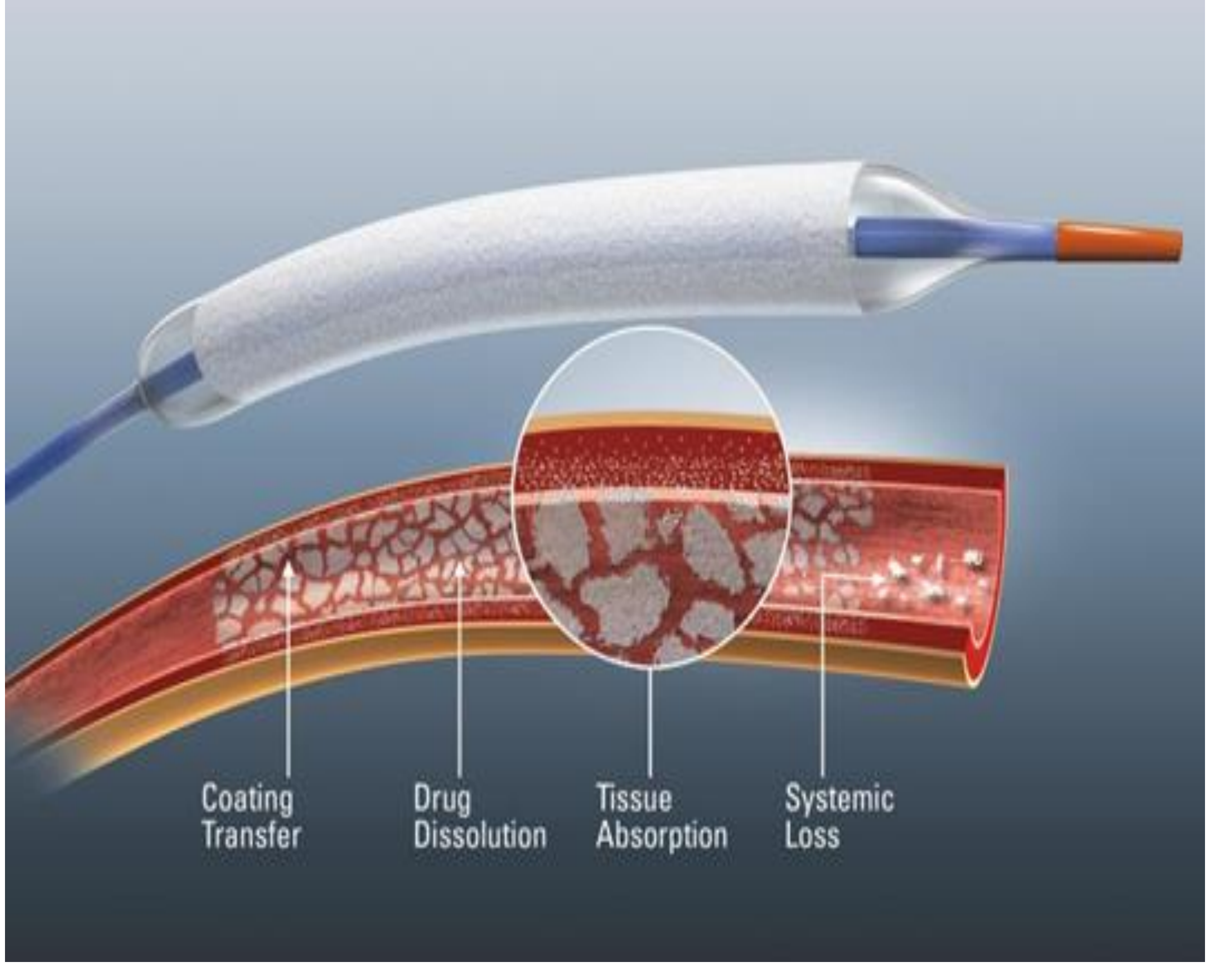



Very-late (>1 Year) stent-related events occurred between 1 and 5 years after PCI at a rate of **~2%/year** with all stent types, with no plateau evident

# Potential Advantages of Drug-coated Balloon

- Drug delivery to the arterial wall without foreign objects left behind
- Positive remodeling
- Simple procedure
- Use of short dual-antiplatelet therapy

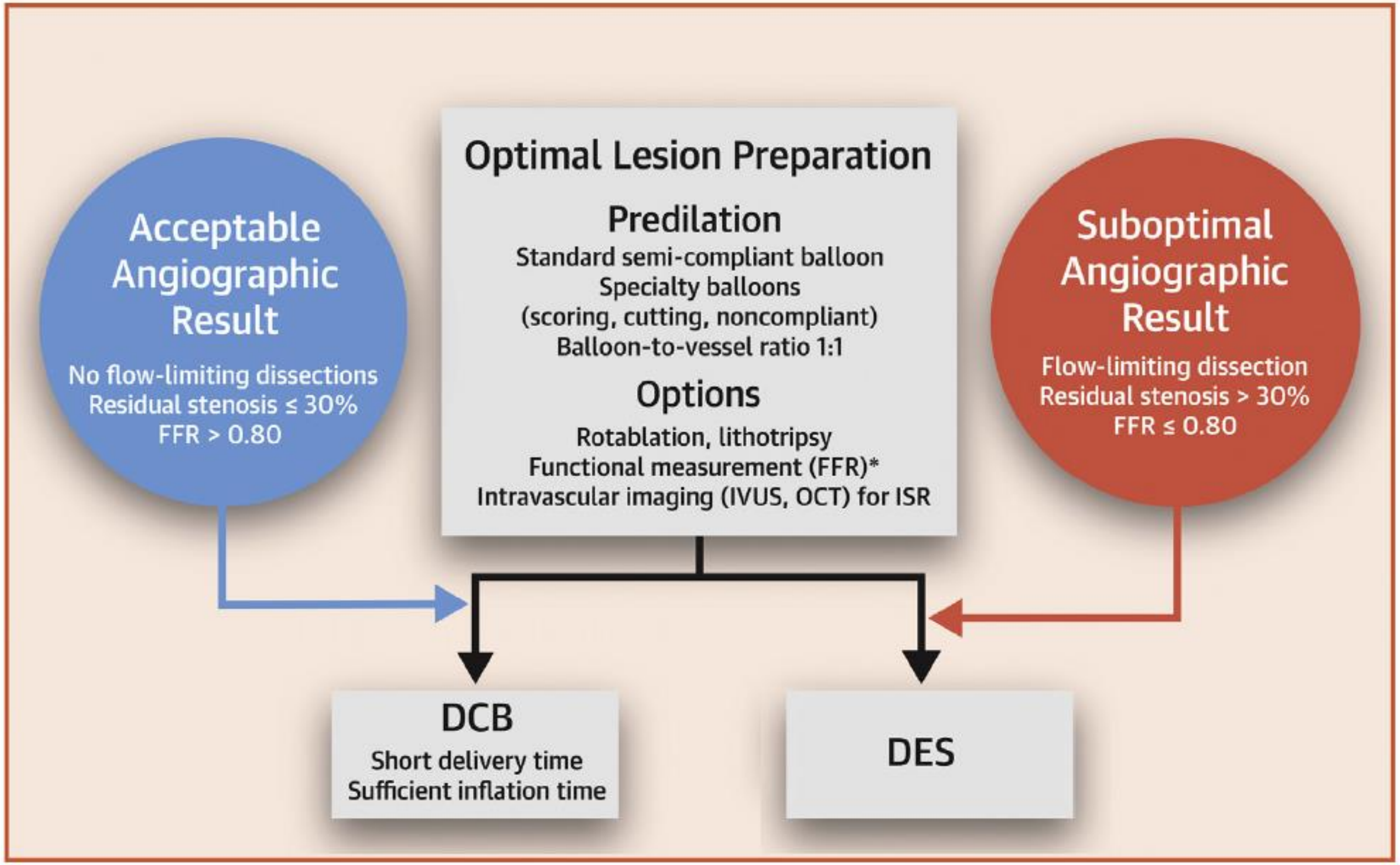


# How can Imaging help us during DCB application?

# Drug-Coated Balloons for Coronary Artery Disease

## Third Report of the International DCB Consensus Group

Raban V. Jeger, MD,[a] Simon Eccleshall, MD,[b] Wan A
Eun-Seok Shin, MD,[f] Fernando Alfonso, MD,[g] Azee
Jorge Saucedo, MD,[k] Bruno Scheller, MD,[l] Franz X.




With the intravascular imaging guidance, we can accurately measure the vessel size.

Jeger, R.V. et al. J Am Coll Cardiol Intv. 2020;13(12):1391-402.

# Lesion Preparation: Device Size Selection

## Mean Stent Diameter

| | IVUS-guidance N | Angio-guidance N | IVUS-guidance (mm) | Angio-guidance (mm) | P-value |
|---|---|---|---|---|---|
| Chieffo et al.[1] | 142 | 142 | 2.95±0.38 | 2.86±0.36 | 0.19 |
| CTO-IVUS[2] | 201 | 201 | 2.91±0.52 | 2.85±0.41 | 0.23 |
| ADAPT-DES[3] | 3349 | 5234 | 3.4±0.6 | 3.0±0.7 | <0.001 |
| AIR-CTO[4] | 115 | 115 | 3.05±0.46 | 2.86±0.37 | 0.001 |
| Hong et al.[5] | 201 | 201 | 2.96±0.38 | 2.83±0.37 | 0.001 |
| EXCELLENT[6] | 463 | 463 | 3.21±0.43 | 3.04±0.42 | <0.001 |

(1) Chieffo A et al, Am Heart J. 2013;165:65-72
(2) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(3) Witzenbichler B et al. Circulation. 2014;129:463-470
(4) Tian NL et al. EuroIntervention 2015:10:1409-17
(5) Hong SJ, et al. Am J Cardiol. 2014;114:534-540
(6) Park KW. Int J Cardiol. 2013;167:721-726

# Lesion Preparation: Device Size Selection

## Final Balloon Size or Balloon Pressure*

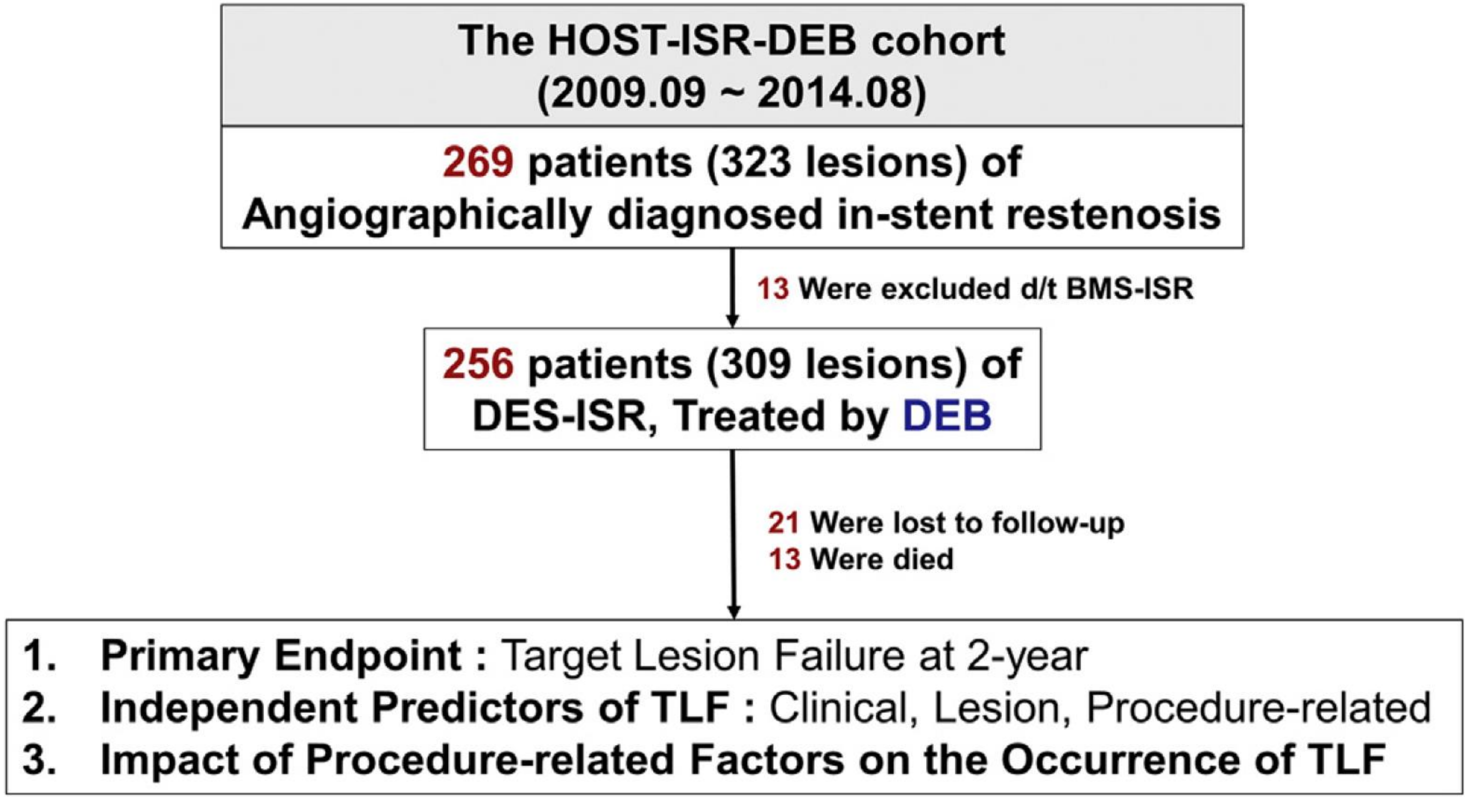
| | IVUS-guidance N | Angio-guidance N | IVUS-guidance (mm or atm*) | Angio-guidance (mm or Atm*) | P-value |
|---|---|---|---|---|---|
| Chieffo et al.[1] | 142 | 142 | 3.39±0.47 | 3.15±0.40 | 0.002 |
| CTO-IVUS[2] | 201 | 201 | 14.6±3.7* | 13.8±3.8* | 0.040 |
| ADAPT-DES[3] | 3349 | 5234 | 16.9±3.7* | 16.7±3.5* | 0.13 |
| RESET-IVUS[4] | 297 | 246 | 3.2±0.4 | 3.1±0.3 | 0.03 |
| IVUS-XPL[5] | 700 | 700 | 3.14±0.43 | 3.04±0.42 | <0.001 |


(1) Chieffo A et al, Am Heart J. 2013;165:65-72
(2) Kim BK, et al. Circ Cardiovasc Interv 2015:8:e002592
(3) Witzenbichler B et al. Circulation. 2014;129:463-470
(4) Kim JS et al. JACC Cardiovasc Interv. 2013;6:369-376
(5) Hong SJ, et al. JAMA. 2015;314:2155-2163

# Impact of Optimized Procedure-Related Factors in Drug-Eluting Balloon Angioplasty for Treatment of In-Stent Restenosis

Tae-Min Rhee, MD,[a,*] Joo Myung Lee, MD, MPH, PhD,[b,*] Eun-Seok Shin, MD, PhD,[c] Doyeon Hwang, MD,[a] Jonghanne Park, MD, PhD,[a] Ki-Hyun Jeon, MD,[d] Hack-Lyoung Kim, MD, PhD,[e] Han-Mo Yang, MD, PhD,[a] Jung-Kyu Han, MD, PhD,[a] Kyung Woo Park, MD, PhD,[a] Joo-Yong Hahn, MD, PhD,[b] Bon-Kwon Koo, MD, PhD,[a] Sang-Hyun Kim, MD, PhD,[e] Hyo-Soo Kim, MD, PhD[a]

To investigate the impact of optimizing procedure-related factors during drug eluting balloon (DEB) angioplasty on clinical outcomes of drug-eluting stent in-stent restenosis (ISR).



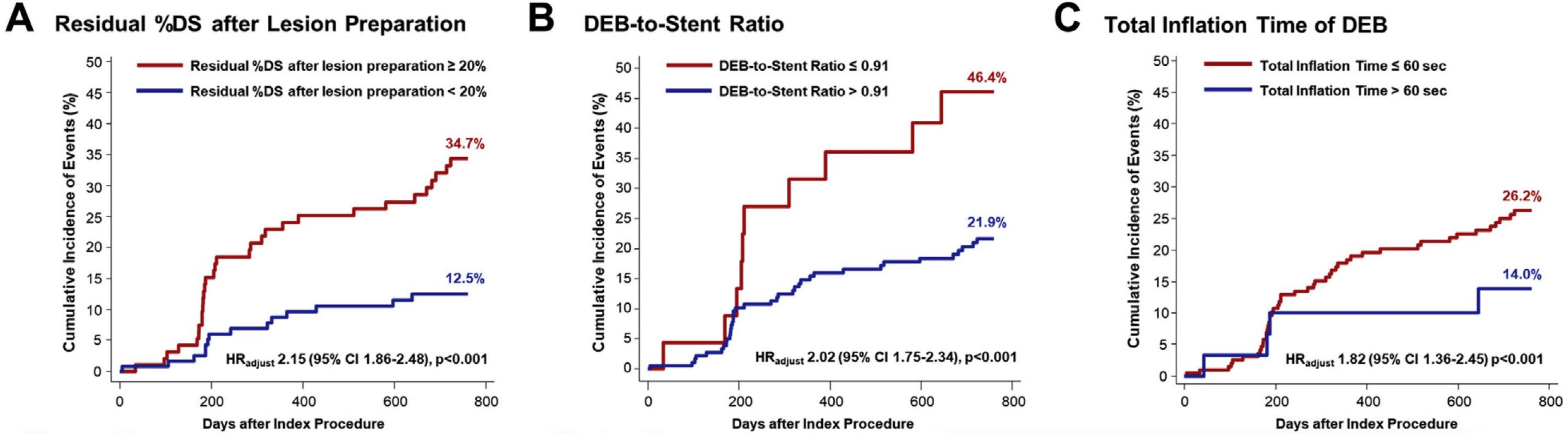
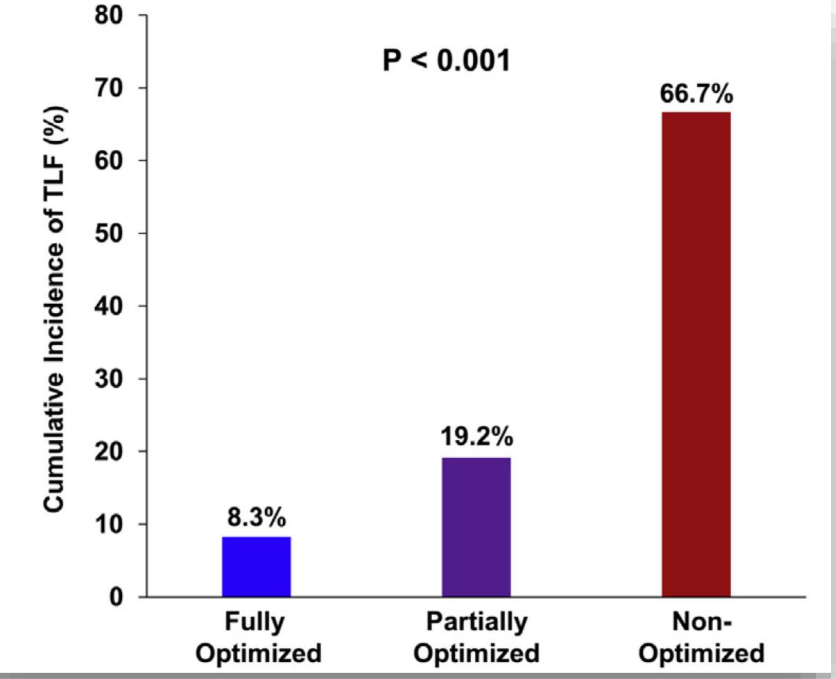



**FIGURE 4** Incidence of Target Lesion Failure According to Combined Procedure-Related Factors



# OPTICROSS™ HD 60 MHz Image Examples

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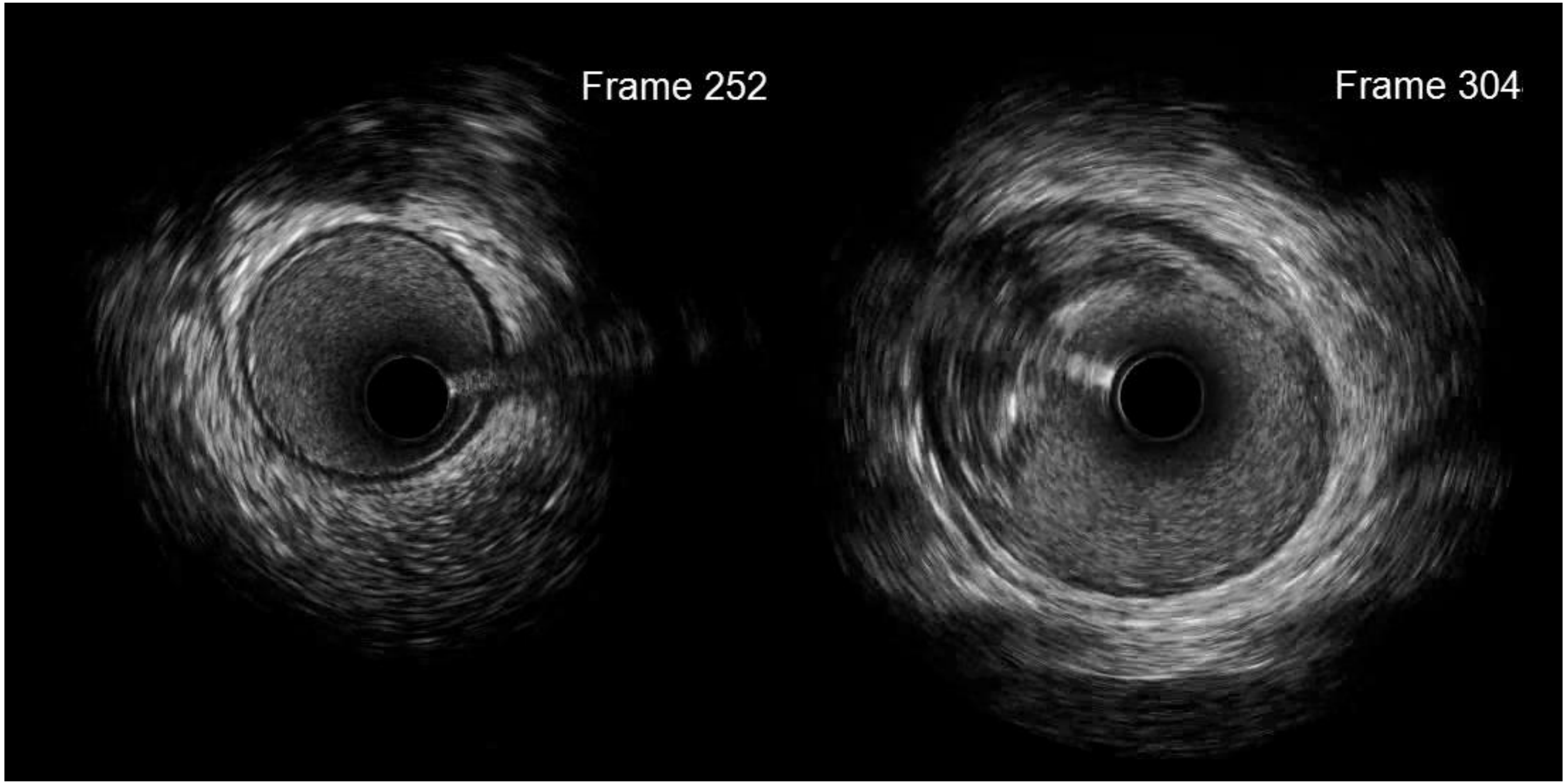
With the intravascular imaging guidance before DCB application, plaque characteristics are clearly identified, which can be helpful to decide the requirement of plaque modification.




**Healthy Vessel** **Fibrotic Plaque**

Images courtesy of David P. Lee, MD Stanford University Medical Center

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

# OPTICROSS™ HD 60 MHz Image Examples

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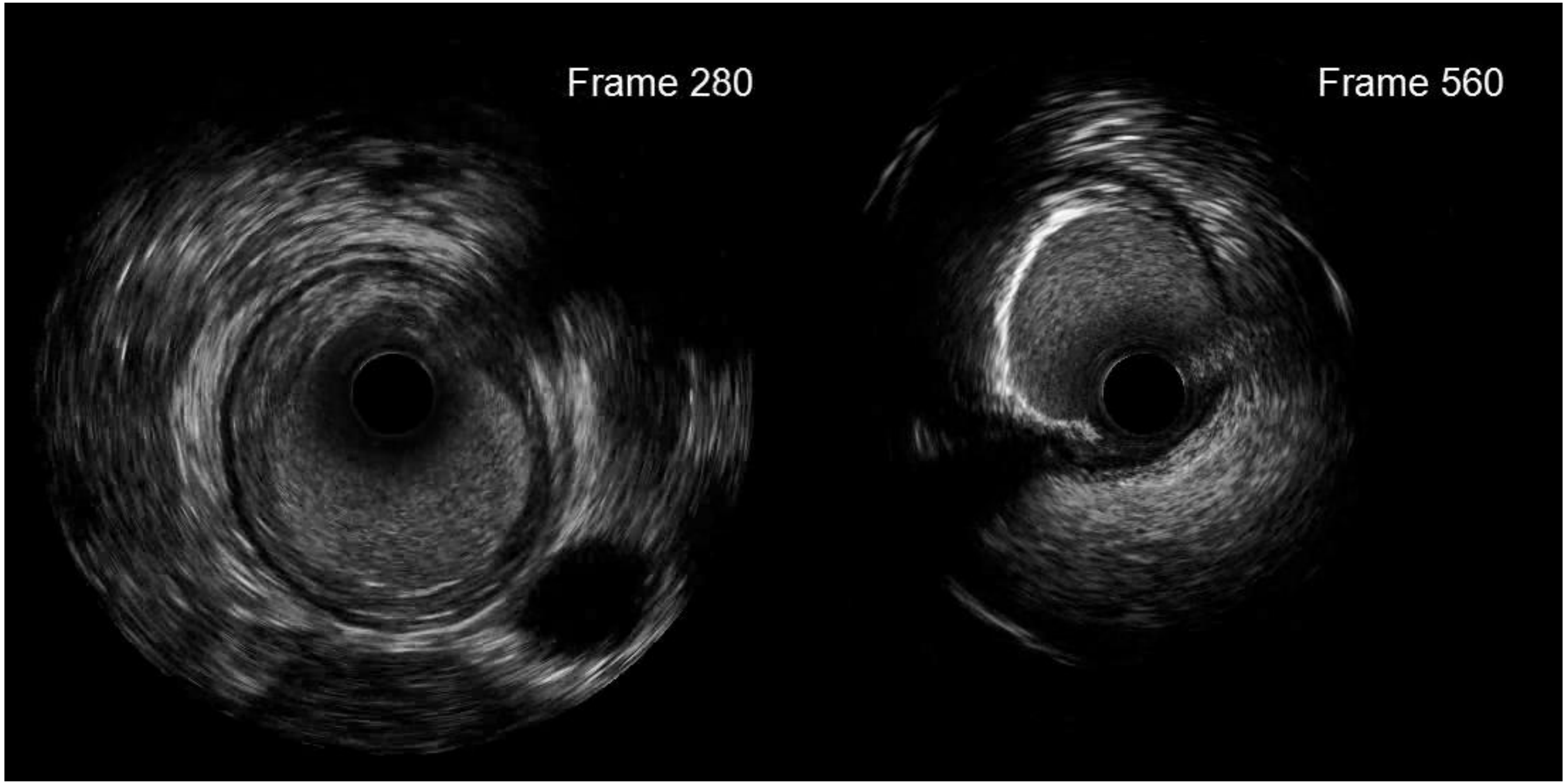
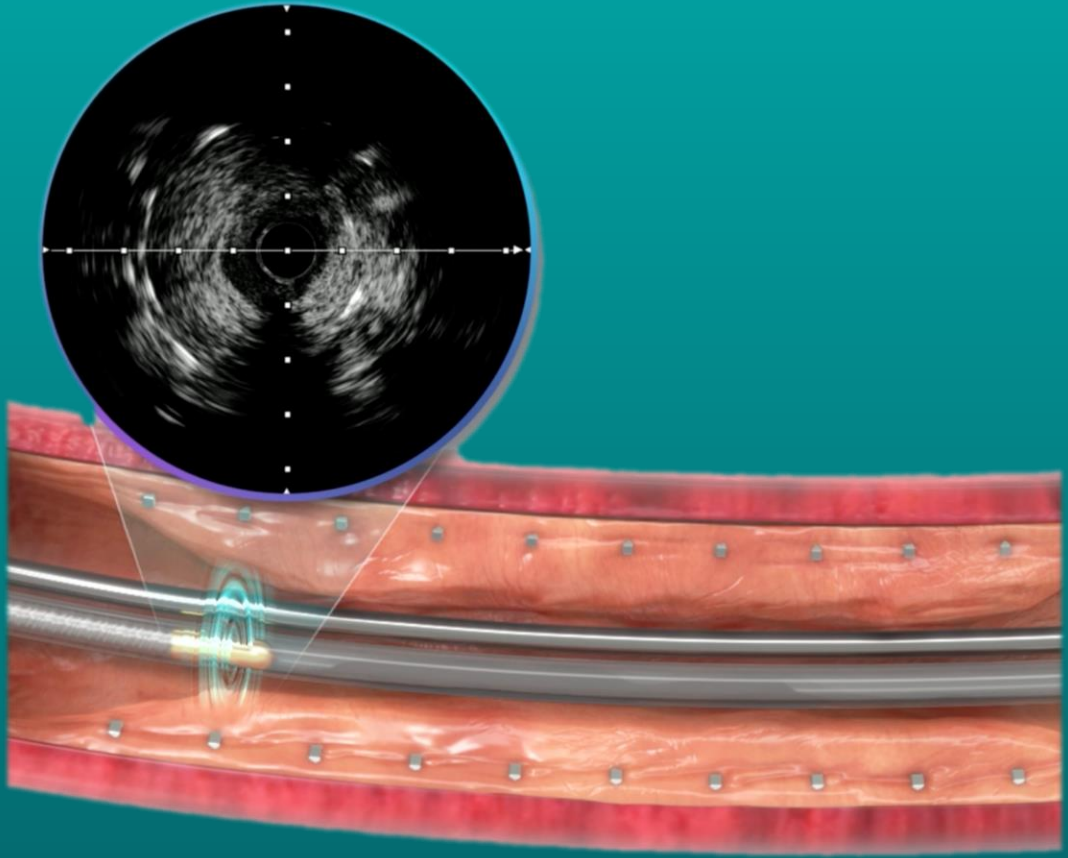



**Mixed Plaque** **Calcific Plaque**

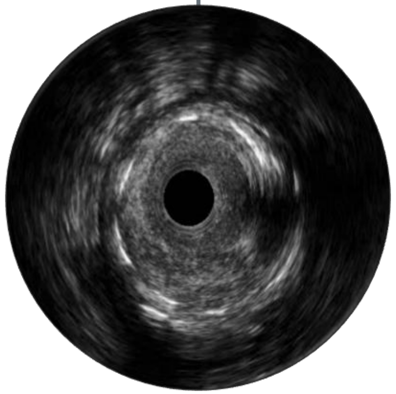
Images courtesy of David P. Lee, MD Stanford University Medical Center
Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

# HD-IVUS for Stent Failure



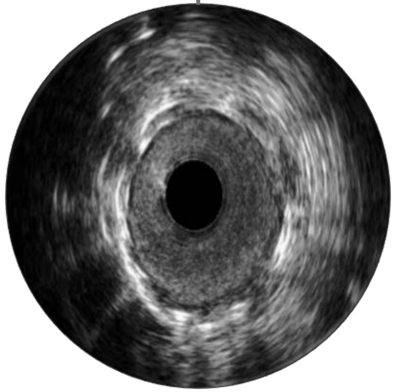
# Why Use IVUS in Stent Failure?

## What is the ISR cause and optimal treatment by angiography?

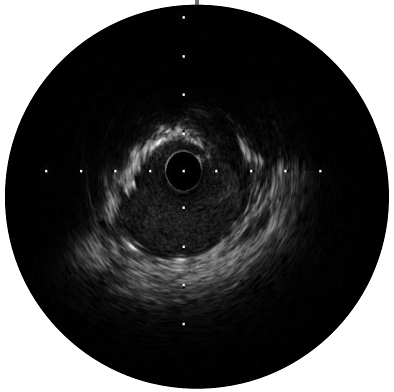


Neointimal Hyperplasia

Calcific Neoatherosclerosis



Stent undersizing
Stent underexpansion

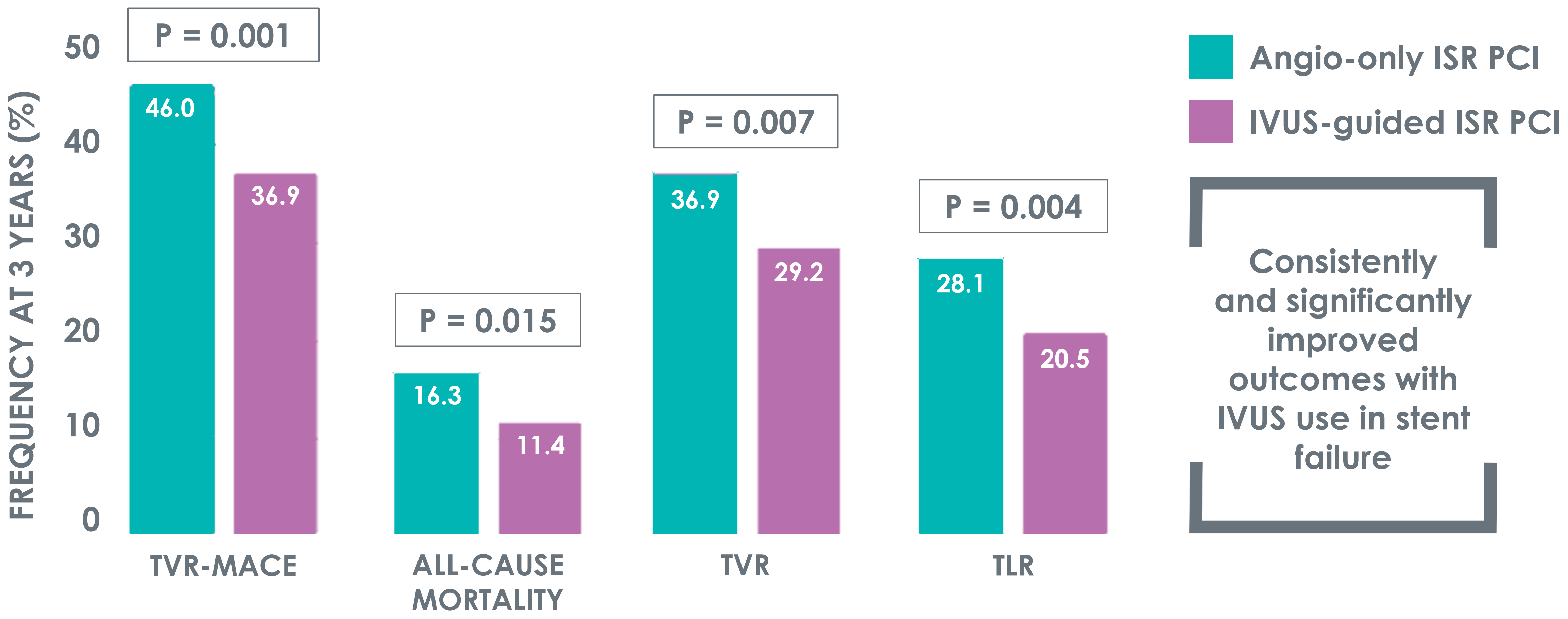


Stent fracture
(10 o'clock – 1 o'clock)

# HD-IVUS in Stent Failure

## Clinical Evidence

### Superior outcomes for N=1522 ISR patients treated with IVUS-guidance




Consistently and significantly improved outcomes with IVUS use in stent failure



Shlofmitz E, et al. Int J Cardiol . 2021 Oct 1;340:17-21

# HD-IVUS in Stent Failure

## Clinical Guidelines

| Restenosis (US) | | |
|---|---|---|
| In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism | 2a | C-LD |

Lawton et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization. JACC 2022

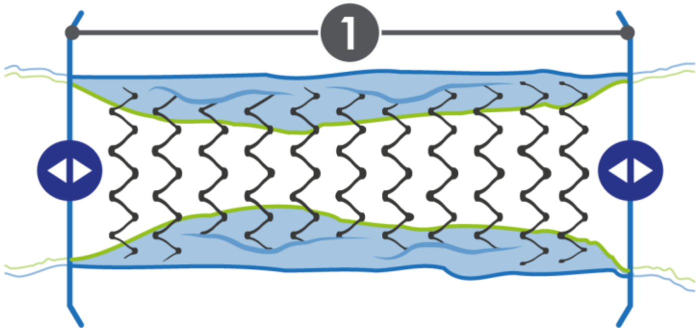
| Restenosis (EU) | | |
|---|---|---|
| IVUS and/or OCT should be considered to detect stent related mechanical problems relating to restenosis | IIA | C |

Neumann et al 2018 ESC/EACTS Guidelines on myocardial revascularization. EHJ 2019

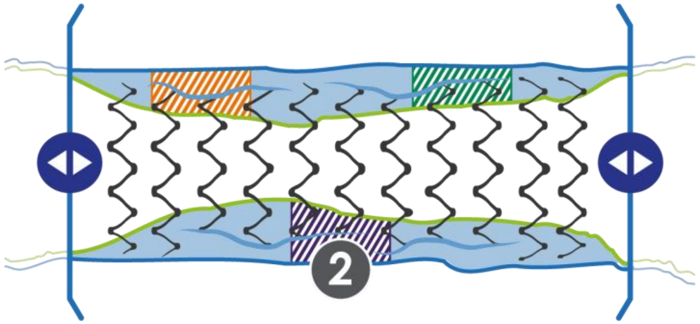
# Pre-Procedure IVUS

## What's the Root Cause?

1 | How long is the lesion?




2 | What is the neointimal morphology?

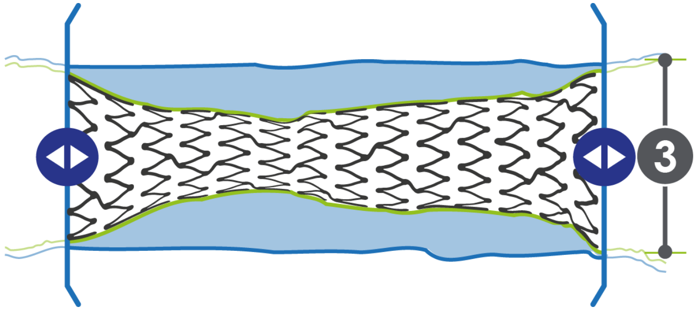



Lipid?

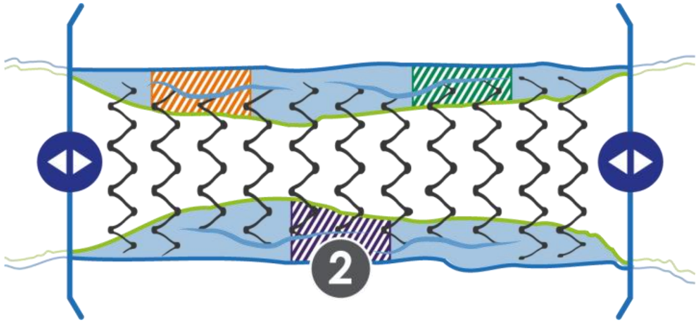
Fibrotic?

$Ca^{2+}$?

3 | Stent integrity: Expansion? Fracture?

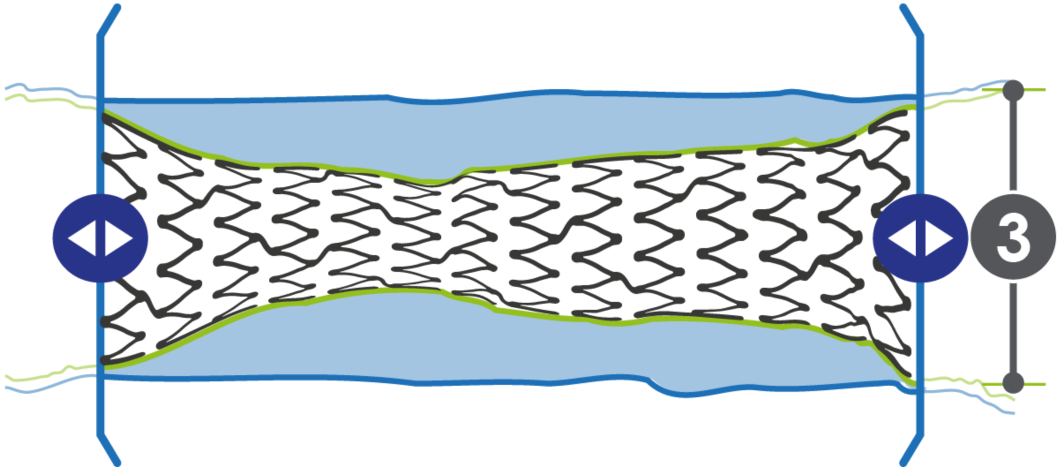


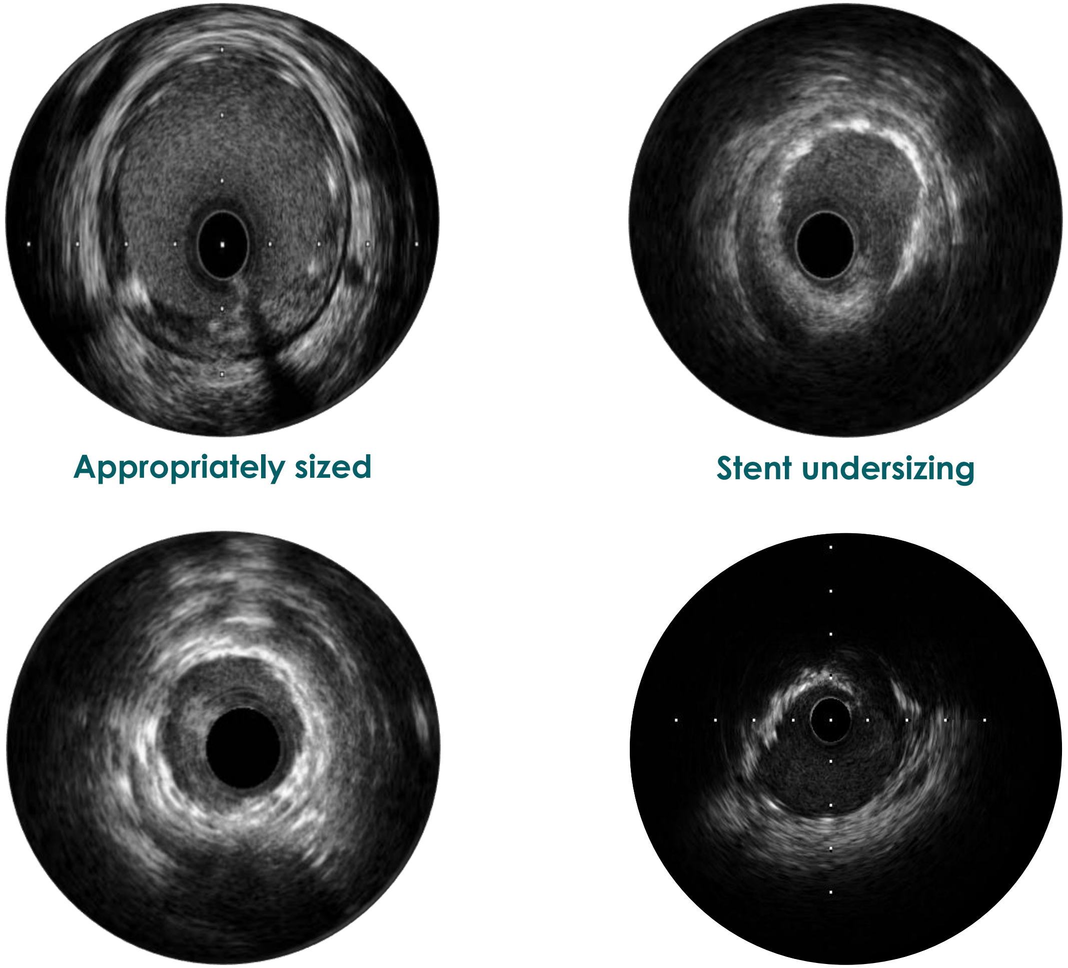
# 2. What Is the Neointimal Morphology?




- Lipid?
- Fibrotic?
- $Ca^{2+}$?

# 3. Stent Integrity: Expansion? Fracture?



Appropriately sized

Stent undersizing

Stent underexpansion

Stent fracture

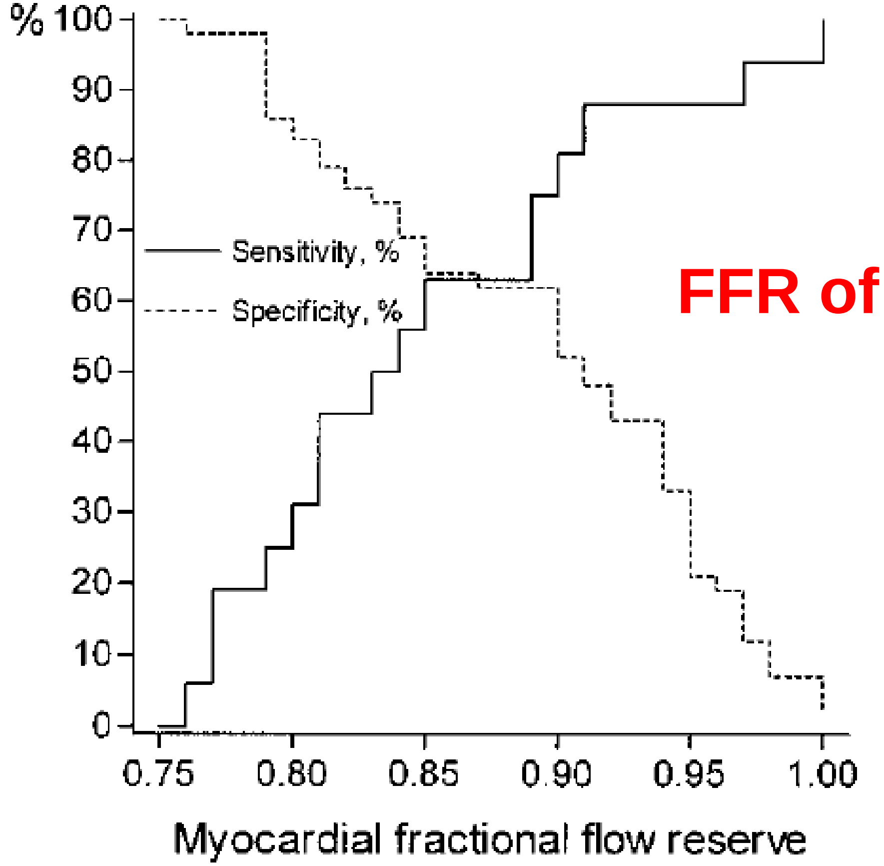
# Summary-1

## How can Intravascular Imaging help us during DCB application?

- With the intravascular imaging, we can accurately measure the vessel size.
- Before DCB application, plaque characteristics are clearly identified, which can be helpful to decide the requirement of plaque modification.
- Particularly in patients with in-stent restenosis, intravascular imaging is helpful to understand the mechanism and treat stent failure.

# How can Physiology help us during DCB application?

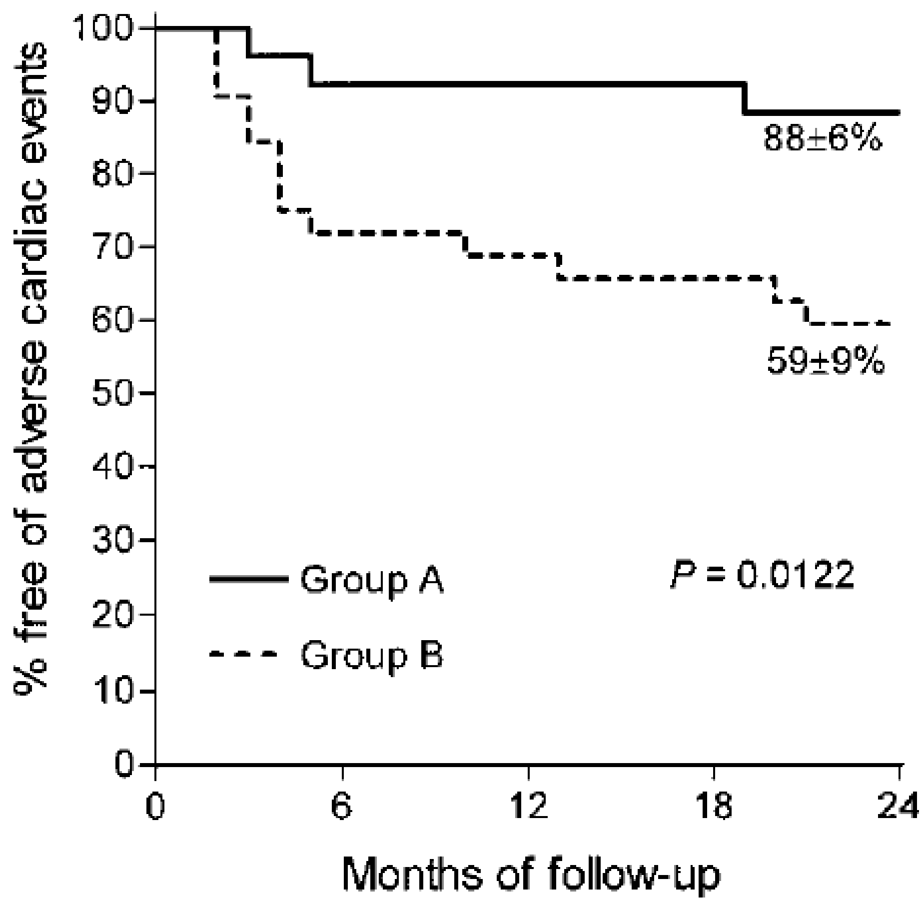
# A cutoff predicting better clinical outcomes following PLAIN balloon angioplasty




FFR of >0.90

60 consecutive patients with single-vessel disease

Death, MI, UA, repeat revascularization, and recurrence of angina




FFR of > 0.90 has been identified as a cutoff predicting better clinical outcomes following conventional balloon angioplasty.

Bech GJ, et al. Circulation 1999;99:883–888

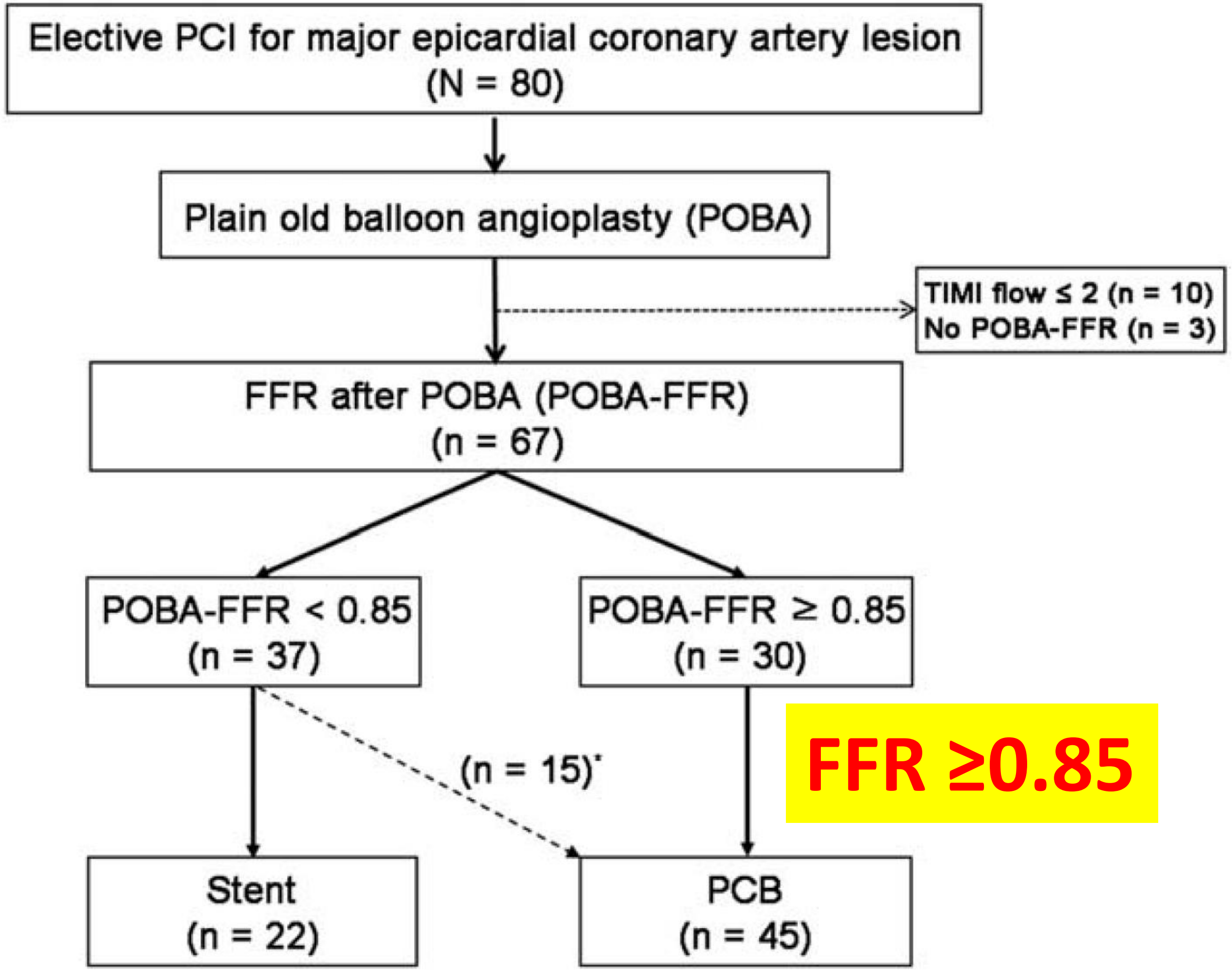
# FFR-Guided PCB Treatment

## Fractional Flow Reserve-guided Paclitaxel-coated Balloon Treatment for De Novo Coronary Lesions

Eun-Seok Shin,[1*] MD, PhD, Soe Hee Ann,[1] MD, Gillian Balbir Singh,[1] MBCHB, FRA
Kyung Hun Lim,[1] MD, Franz X. Kleber,[2] MD, and Bon-Kwon Koo,[3] MD, PhD

Objectives: To assess the safety and efficacy of fractional flow reserve (FFR) guided paclitaxel-coated balloon (PCB) treatment for de novo coronary artery lesions. Background: There is limited data on PCB treatment for de novo lesions especially of major epicardial coronary arteries. Methods: Sixty-six patients with 67 de novo lesions who underwent successful plain old balloon angioplasty (POBA) were included. If POBA-FFR was favorable (≥ 0.85), PCB was applied and if POBA-FFR was <0.85, stent implantation was preferred over PCB. Results: Forty-five lesions were treated with PCB (67.2%) and 22 lesions with stents (32.8%). Dual antiplatelet therapy duration was 6 weeks. Late luminal loss with PCB was significantly less than stent (0.05 ± 0.27 mm vs. 0.40 ± 0.54 mm, $P = 0.022$). The baseline FFR of target lesions was 0.69 ± 0.16 in PCB and 0.60 ± 0.11 in stent group ($P = 0.015$), however, the FFR at 9 months was not different between groups (0.85 ± 0.08 in PCB vs. 0.85 ± 0.05 in stent group, $P = 0.973$). At 1 year, one myocardial infarction and one target lesion revascularization related to in-stent restenosis were detected, both in the stent group. Conclusion: POBA-FFR-guided PCB treatment is safe and effective for de novo coronary lesions with good anatomical and physiological patency at mid-term follow-up. 

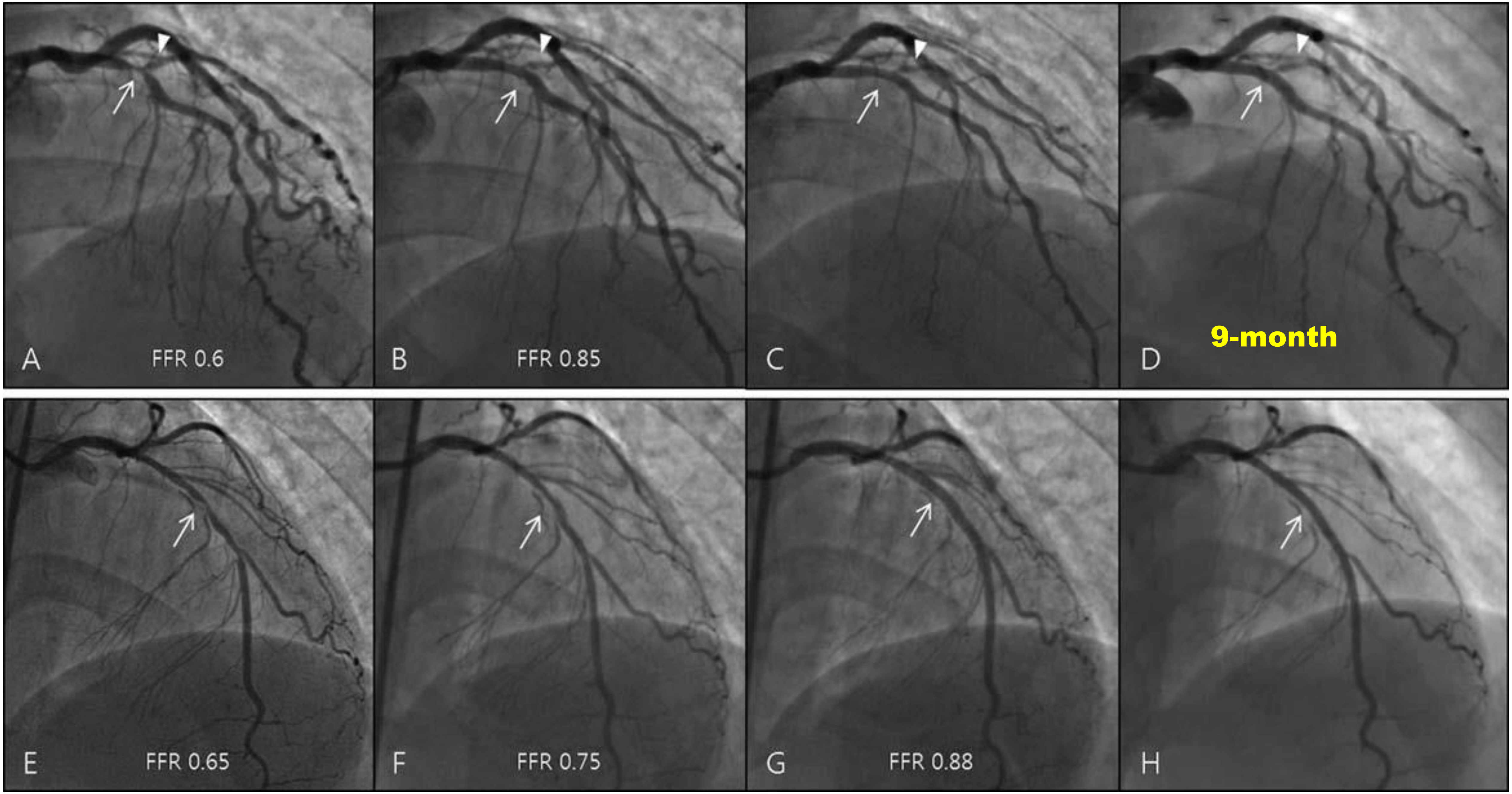
Key words: paclitaxel-coated balloon; fractional flow reserve; plain old balloon angioplasty; de novo lesion; late luminal loss




FFR ≥0.85

*FFR of 11 lesions > 0.8

Shin ES, et al. Catheter Cardiovasc Interv. 2016;88:193-200




Shin ES, et al. Catheter Cardiovasc Interv. 2016;88:193-200

| | PCB ($n = 45$) | Stent ($n = 22$) | *P* value |
|---|---|---|---|
| **Before procedure** | | | |
| Lesion length (mm) | 21.5 ± 5.6 | 24.9 ± 7.2 | 0.064 |
| Reference diameter (mm) | 2.55 ± 0.41 | 2.70 ± 0.42 | 0.188 |
| Minimal lumen diameter (mm) | 1.02 ± 0.42 | 0.94 ± 0.36 | 0.430 |
| Diameter stenosis (%) | 60.0 ± 14.4 | 65.1 ± 11.8 | 0.123 |
| Pre-procedural FFR* | 0.69 ± 0.16 | 0.60 ± 0.11 | **0.015** |
| **After procedure** | | | |
| Minimal lumen diameter (mm) | 1.92 ± 0.42 | 2.65 ± 0.35 | **<0.001** |
| Diameter stenosis (%) | 28.3 ± 11.2 | 9.6 ± 5.2 | **<0.001** |
| Acute gain (mm) | 0.90 ± 0.51 | 1.71 ± 0.46 | **<0.001** |
| Post-procedural FFR | 0.86 ± 0.06 | 0.83 ± 0.08 | 0.105 |
| **9-months follow up** | PCB ($n = 36$) | Stent ($n = 17$) | *P* value |
| Minimal lumen diameter (mm) | 1.91 ± 0.57 | 2.23 ± 0.66 | 0.068 |
| Diameter stenosis (%) | 25.9 ± 13.1 | 21.2 ± 19.3 | 0.295 |
| Late luminal loss (mm) | 0.05 ± 0.27 | 0.40 ± 0.54 | **0.022** |
| Net gain (mm) | 0.88 ± 0.61 | 1.28 ± 0.72 | **0.038** |
| 9 months-FFR | 0.85 ± 0.08 | 0.85 ± 0.05 | 0.973 |

Clin Res Cardiol (2017) 106:18–27
DOI 10.1007/s00392-016-1019-4

ORIGINAL PAPER

# Fractional flow reserve-guided coronary angioplasty using paclitaxel-coated balloons without stent implantatio safety and 6-month results by angiography and opti tomography

Tudor C. Poerner[1] · Corinna Duderstadt[1] · Björn Goebel[1] · Daniel Kretzschmar[1] ·
Hans R. Figulla[1] · Sylvia Otto[1]

In 46 patients (54 lesions) with stable symptomatic coronary artery disease (CAD), DCB-only treatment was applied to 43 patients (51 lesions), while 3 patients (3 lesions) needed provisional stenting.

**FFR ≥0.80**

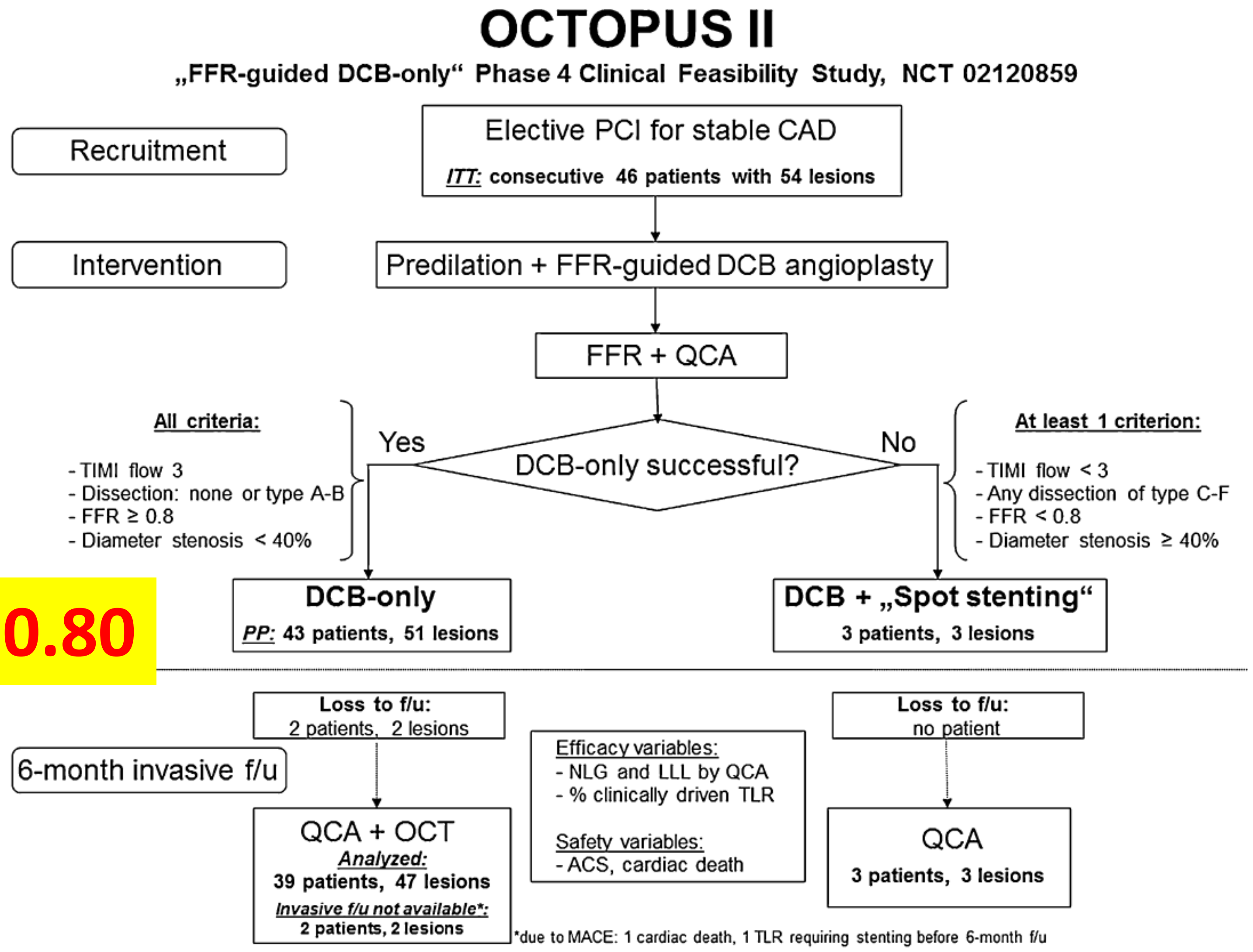


**Table 3** Primary, secondary, and clinical outcome measures at follow-up

| | Outcome measures | $N$ = 39 patients (47 lesions) |
|---|---|---|
| Primary | LLL (mm) | −0.13 ± 0.44 |
| Secondary | NLG (mm) | 1.1 ± 0.53 |
| Clinical | TLR at 6-month f/u | 1/2[a] |
| | MACE at 6-month f/u | 2/3[a] |
| | MACE at 1-year f/u | 2/3[a] |

The International Journal of Cardiovascular Imaging (2018) 34:1339–1347
https://doi.org/10.1007/s10554-018-1351-z

ORIGINAL PAPER

CrossMark

# Paclitaxel-coated balloon treatment for functionally nonsignificant residual coronary lesions after balloon angioplasty

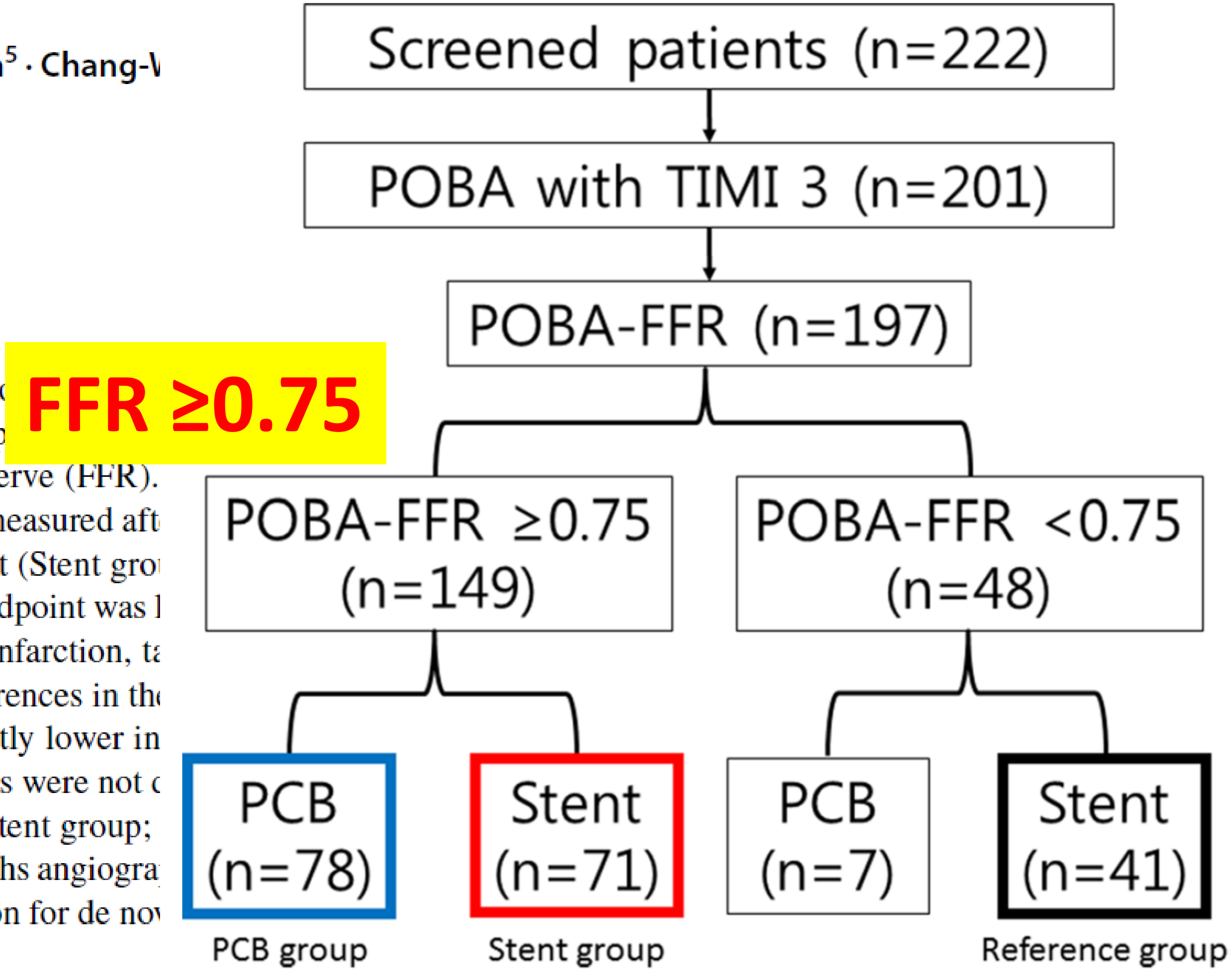
Ae-Young Her[1] · Eun-Seok Shin[2] · Joo Myung Lee[3] · Scot Garg[4] · Joon-Hyung Doh[5] · Chang-W
Bon-Kwon Koo[7]

Received: 21 November 2017 / Accepted: 11 April 2018 / Published online: 26 April 2018



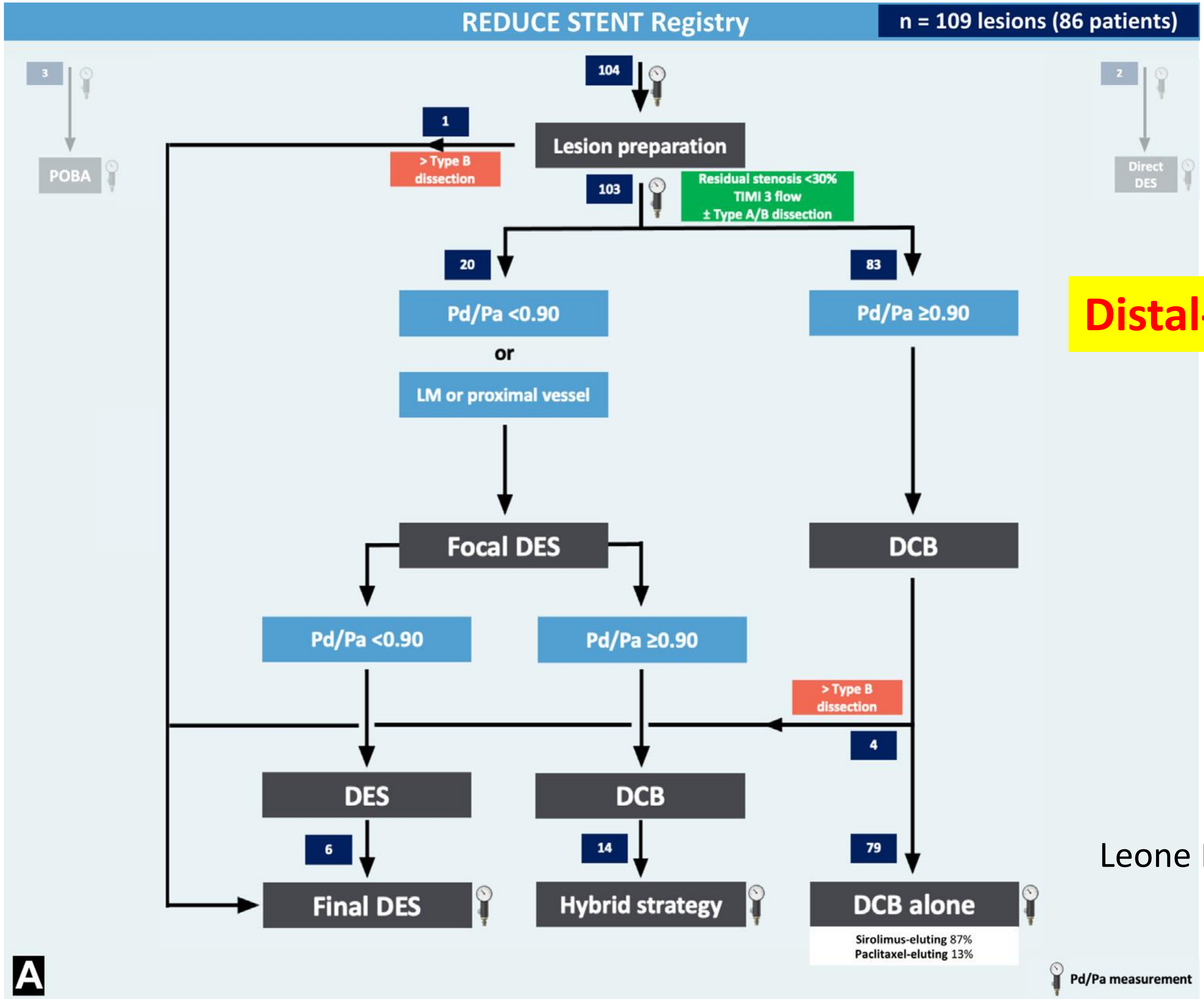
## Abstract

There is limited data on the efficacy of paclitaxel-coated balloon (PCB) compared to
The purpose of this study was to compare the efficacy of PCB treatment with stent imp
after successful plain old balloon angioplasty (POBA) guided by fractional flow reserve (FFR).
for elective percutaneous coronary intervention (PCI) for de novo lesions, FFR was measured aft
POBA–FFR was ≥0.75, patients were treated with PCB (PCB group, n=78) or stent (Stent gro
was <0.75, stent was implanted as planned (Reference group, n=42). The primary endpoint was l
and the secondary endpoint was adverse cardiac events (cardiac death, myocardial infarction, ta
repeat revascularization) at 12 months follow-up. There was no between-group differences in th
in PCB, 0.89±0.06 in stent, p=0.101). At 9 months, late lumen loss was significantly lower in
to the Stent group (0.05±0.33 vs. 0.59±0.76 mm, p<0.001). Adverse cardiac events were not c
Stent and Reference groups (2.6, 5.5, and 9.5% respectively; p=0.430 for PCB vs. Stent group;
vs. both other groups). PCB treatment guided by POBA–FFR showed excellent 9 months angiogra
as well as comparable 12 months clinical outcomes, compared with stent implantation for de nov


**Keywords** Paclitaxel-coated balloon · Stent · Fractional flow reserve · Balloon angioplasty · De novo lesion · Coronary

# REDUCE-STENT Registry




**Distal-to-aortic pressure ratio ≥0.9**

Leone PP, et al. J Am Coll Cardiol Intv. 2023;16:363–365

## Third Report of the International DCB Consensus Group

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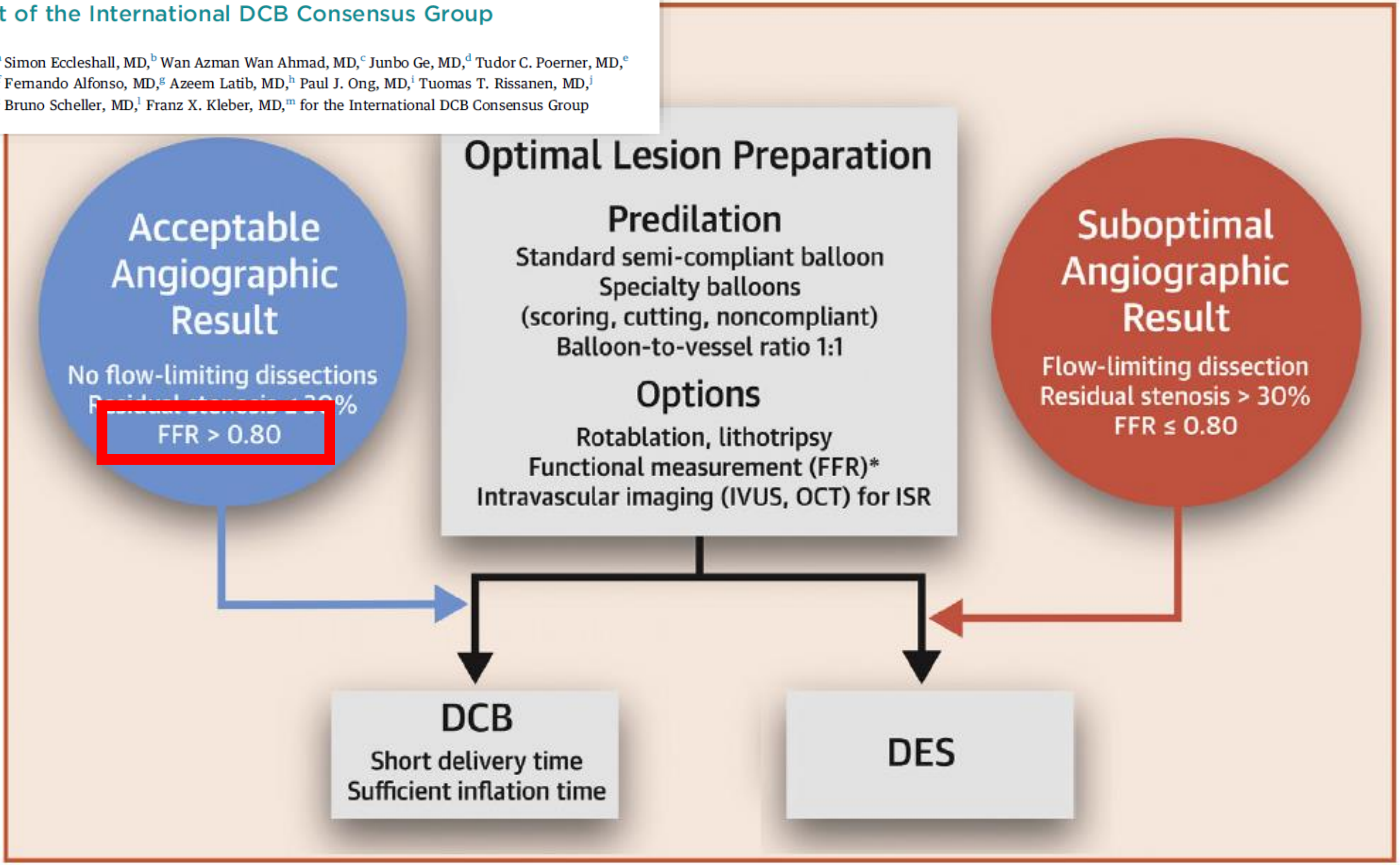


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EXPERT CONSENSUS DOCUMENT

Clinical expert consensus document on drug-coated balloo
for coronary artery disease from the Japanese Association
of Cardiovascular Intervention and Therapeutics

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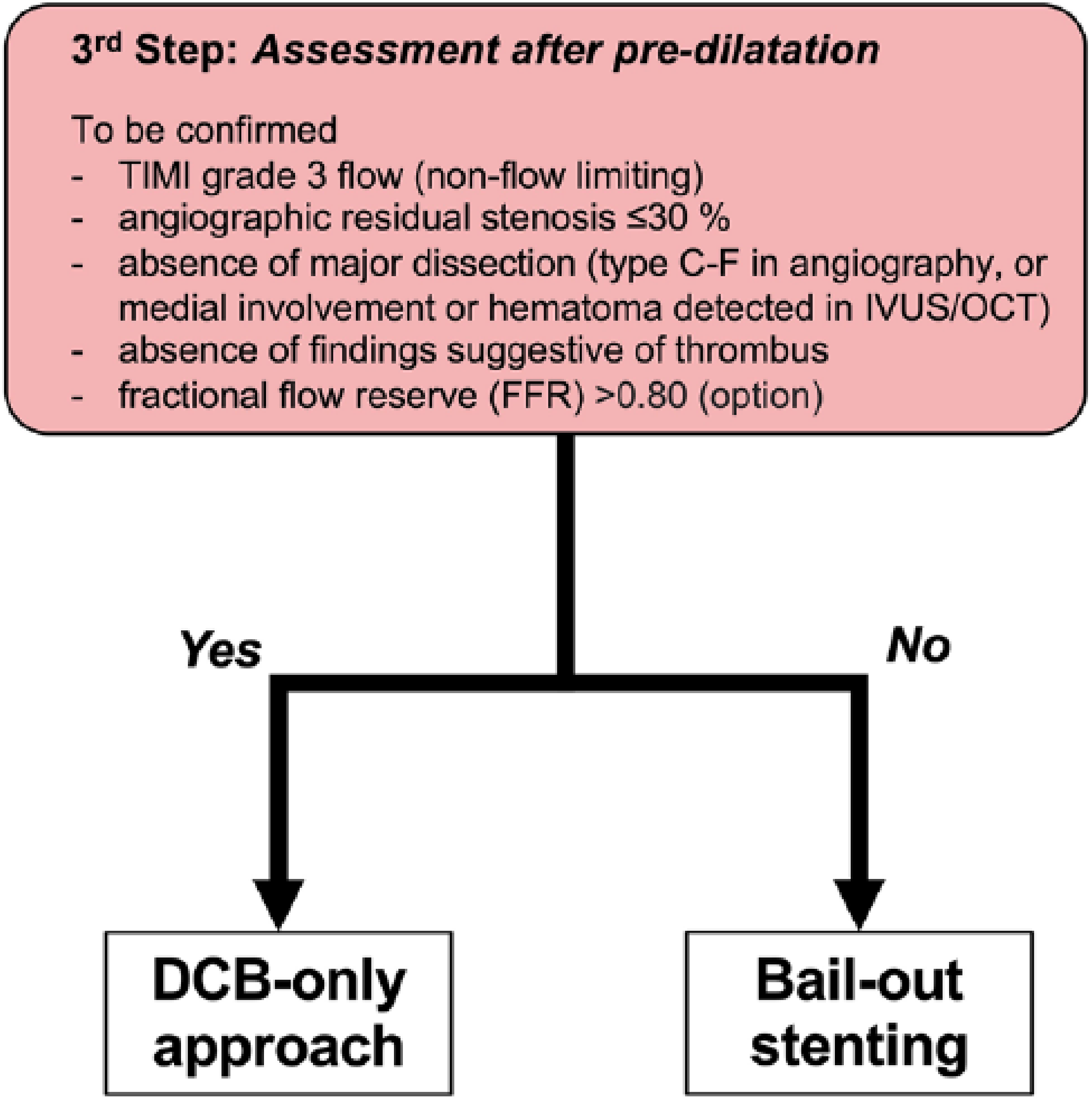
Masato Nakamura[13] · The Task Force of the Japanese Association of Cardiovascular Interv
(CVIT)

# Functional assessment after the lesion preparation

Expert consensus would propose FFR of >0.80 after lesion preparation as a reasonable cutoff to proceed to the DCB-only strategy.



# Summary-2

## How can Physiology help us during DCB application?

- Though optimal cut-off values for functional assessment are needed to be further evaluated, functional assessment after the lesion preparation can help our decision-making for the DCB-only strategy.

# Conclusions

- Coronary physiology and intravascular imaging guidance for percutaneous coronary interventions have been associated with improved outcomes compared with angiography alone.

- Although the amount of evidence on coronary physiology and intravascular imaging techniques in PCI with DCBs is limited, intracoronary imaging is helpful during lesion preparation and device sizing and functional assessment after the lesion preparation can help our decision-making for the DCB-only strategy.