# Are DCB the Solution for All Patients? Lesions?

**Bruno Scheller, MD**

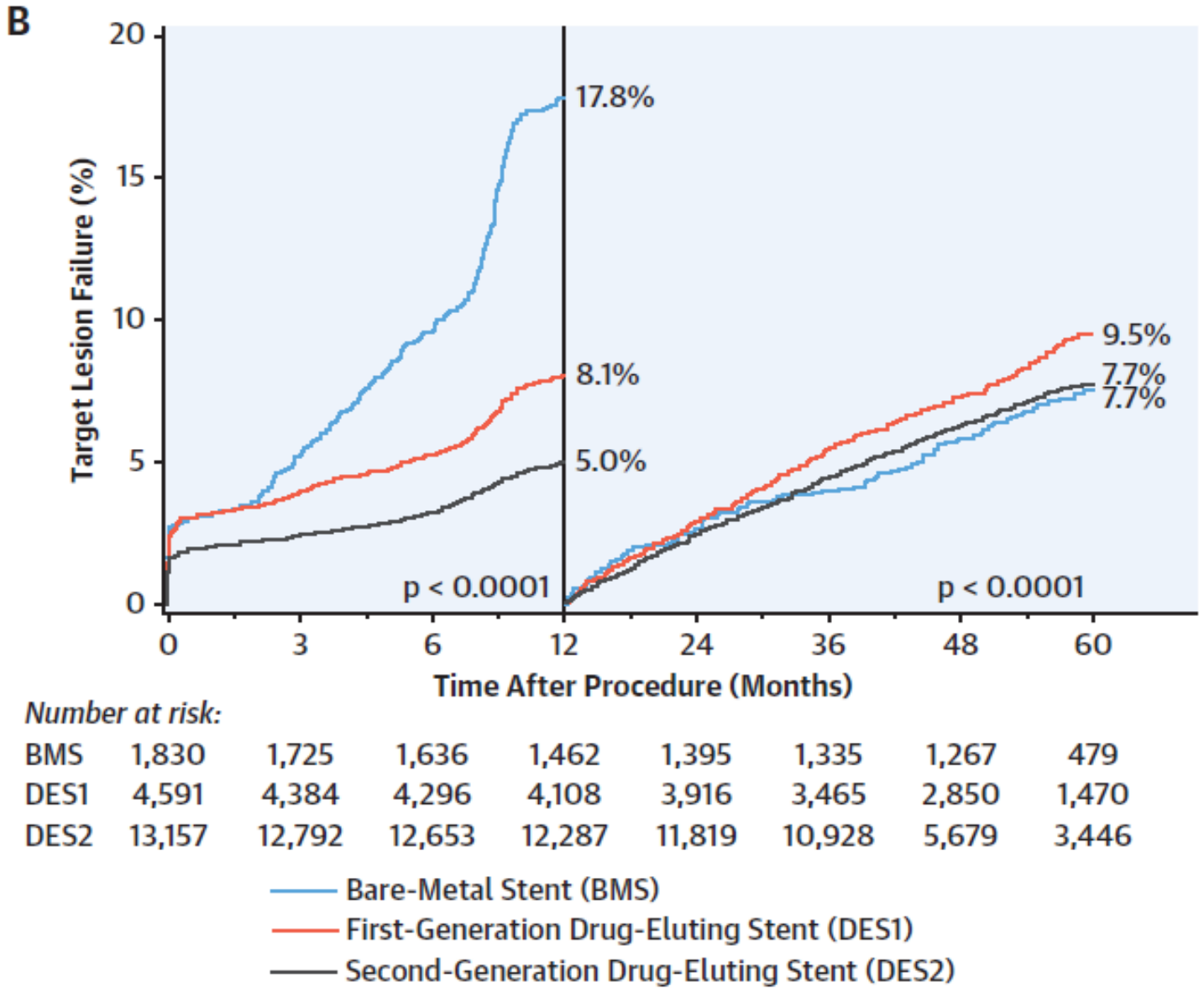
Clinical and Experimental Interventional Cardiology, Saarland University, PharmaScienceHub (PSH), Saarbrücken and Homburg/Saar, Germany

# Disclosure

- Lecture fees and travel support: B.Braun Melsungen AG, Medtronic

- Stock shareholder: InnoRa GmbH

**Stent-related event rate: 2-3% per year after first year**



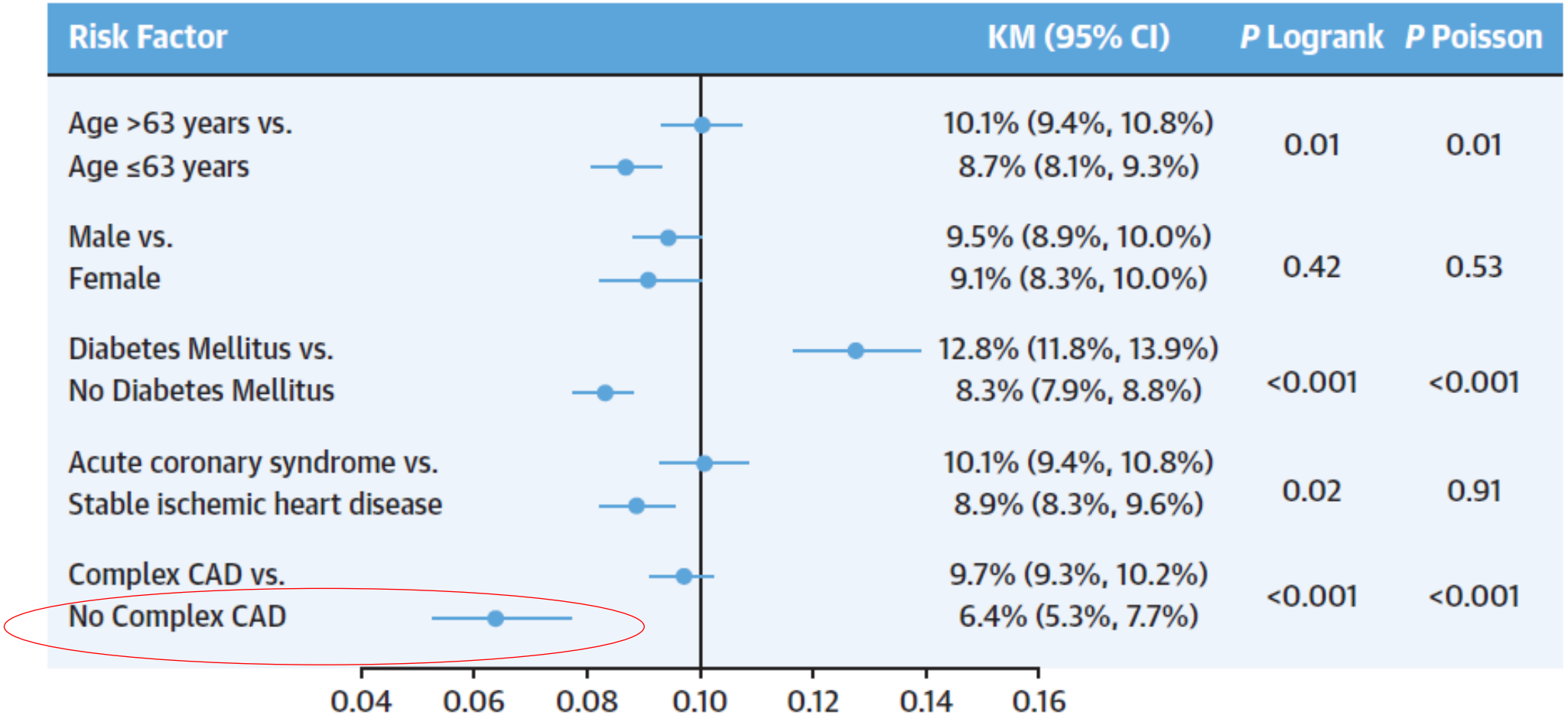





Madhavan et al. J Am Coll Cardiol 2020;75:590–604

# Non-complex CAD – best indication for DES
# DES meta-analysis, n=19,578

**FIGURE 3** Major Adverse Cardiovascular Events by Subgroups Between 1 and 5 Years



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# 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]

**TABLE 6** Multivariable Predictors of Adverse Outcomes by Poisson Regression Analysis

| | Major Adverse Cardiovascular Events | | Target Lesion Failure | | Stent Thrombosis | |
|---|---|---|---|---|---|---|
| | RR (95% CI) | p Value | RR (95% CI) | p Value | RR (95% CI) | p Value |
| Between 1 and 5 yrs | | | | | | |
| DES1 (vs. BMS) | 1.00 (0.83-1.19) | 0.95 | 1.16 (0.91-1.54) | 0.30 | 2.38 (1.30-4.35) | 0.005 |
| DES1 (vs. DES2) | 1.30 (1.09-1.56) | 0.004 | 1.25 (1.04-1.51) | 0.02 | 1.96 (1.20-3.22) | 0.007 |
| Age (per 5 yrs) | 1.00 (1.00-1.10) | 0.01 | 1.10 (1.00-1.10) | 0.005 | 0.92 (0.85-1.00) | 0.04 |
| Male | 1.10 (0.97-1.20) | 0.14 | 1.10 (0.92-1.20) | 0.42 | 1.40 (0.94-2.10) | 0.10 |
| Diabetes mellitus | 1.50 (1.30-1.60) | <0.0001 | 1.50 (1.30-1.70) | <0.0001 | 1.20 (0.85-1.80) | 0.29 |
| Recent smoker | 1.40 (1.30-1.60) | <0.0001 | 1.40 (1.20-1.70) | <0.0001 | 1.50 (1.10-2.10) | 0.02 |
| ACS (vs. stable presentation) | 0.99 (0.88-1.10) | 0.84 | 1.10 (0.92-1.20) | 0.42 | 1.10 (0.77-1.60) | 0.59 |
| Hypertension | 1.10 (0.97-1.20) | 0.17 | 1.00 (0.89-1.20) | 0.69 | 1.10 (0.75-1.50) | 0.78 |
| Hyperlipidemia | 0.92 (0.82-1.00) | 0.18 | 0.92 (0.80-1.10) | 0.27 | 1.00 (0.72-1.40) | 0.98 |
| Previous CABG | 1.90 (1.60-2.30) | <0.0001 | 2.00 (1.70-2.40) | <0.001 | 1.30 (0.75-2.40) | 0.33 |
| Previous myocardial infarction | 1.20 (1.00-1.30) | 0.04 | 1.00 (0.89-1.20) | 0.62 | 1.30 (0.92-2.00) | 0.13 |
| Previous PCI | 1.30 (1.10-1.50) | <0.0001 | 1.30 (1.10-1.50) | 0.004 | 1.50 (1.00-2.20) | 0.04 |
| Moderate-severe calcium | 1.10 (0.99-1.30) | 0.06 | 1.20 (1.00-1.30) | 0.03 | 1.10 (0.79-1.60) | 0.55 |
| LM or LAD disease | 1.10 (0.95-1.20) | 0.32 | 1.10 (0.92-1.20) | 0.48 | 1.00 (0.73-1.40) | 0.98 |
| >1 treated lesion | 1.30 (1.10-1.50) | 0.0008 | 1.30 (1.10-1.60) | 0.001 | 1.20 (0.80-1.80) | 0.38 |
| Baseline RVD (per 1 mm) | 0.79 (0.71-0.88) | <0.0001 | 0.70 (0.62-0.80) | <0.0001 | 0.81 (0.60-1.10) | 0.16 |
| Pre-procedure DS (per 5%) | 0.98 (0.96-1.00) | 0.07 | 0.98 (0.96-1.00) | 0.21 | 1.00 (0.95-1.0) | 0.88 |
| Lesion length (per 10 mm) | 1.10 (1.00-1.10) | 0.005 | 1.10 (0.99-1.10) | 0.11 | 1.20 (1.10-1.30) | 0.006 |



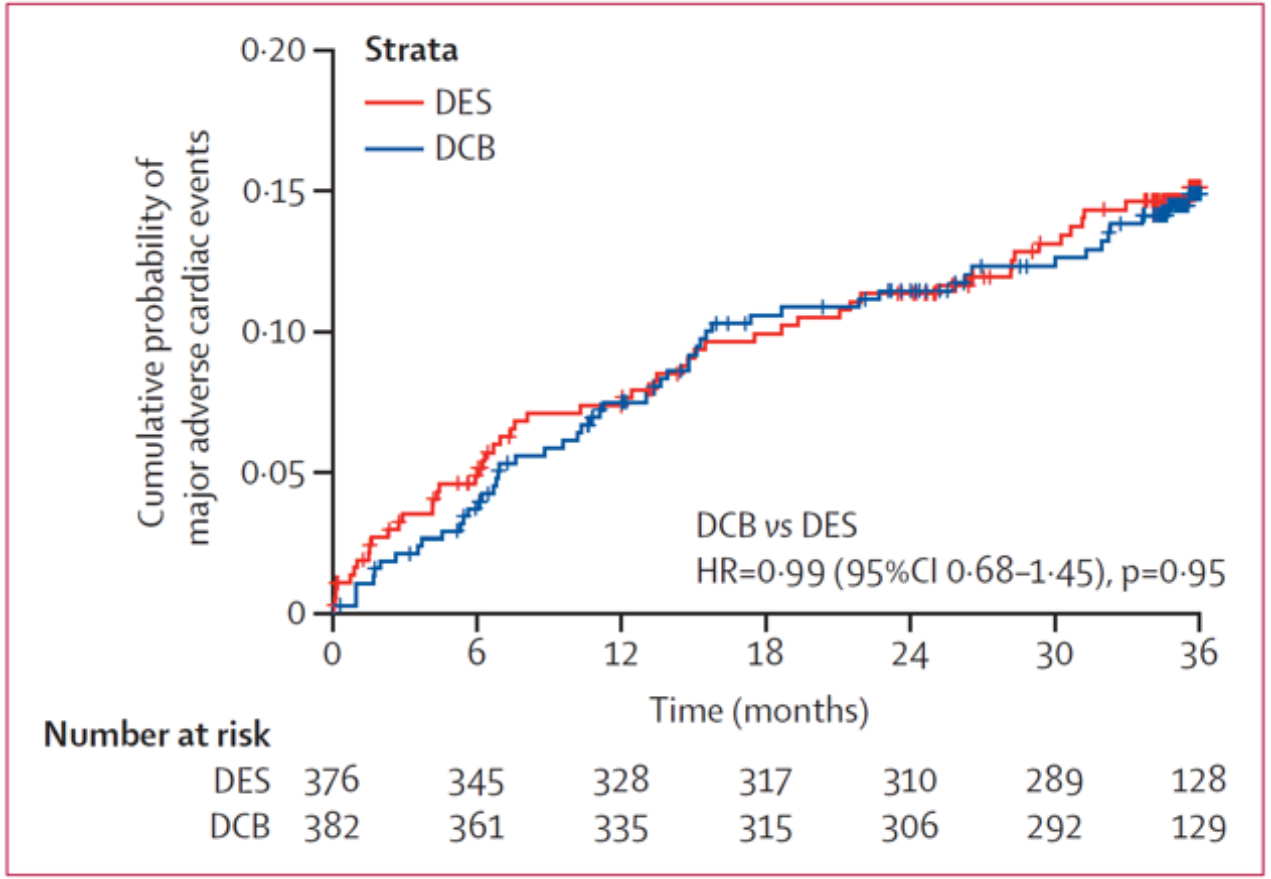
Madhavan et al. J Am Coll Cardiol 2020;75:590–604

# Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial

Raban V Jeger, Ahmed Farah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Gregor Leibu
Jochen Wöhrle, Stefan Richter, Matthias Schreiber, Felix Mahfoud, Axel Linke, Frank-Peter Stephan, Christia
Michael Coslovsky, Nicole Gilgen, Stefan Osswald, Christoph Kaiser, Bruno Scheller, for the BASKET-SMALL

# Long-term efficacy and safety of drug-coated balloons versus drug-eluting stents for small coronary artery disease (BASKET-SMALL 2): 3-year follow-up of a randomised, non-inferiority trial

Raban V Jeger, Ahmed Farah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Daniel Weilenmann, Jochen Wöhrle, Georg Stachel, Sinisa Markovic, Gregor Leibundgut, Peter Rickenbacher, Stefan Osswald, Marco Cattaneo, Nicole Gilgen, Christoph Kaiser, Bruno Scheller, for the BASKET-SMALL 2 Investigators

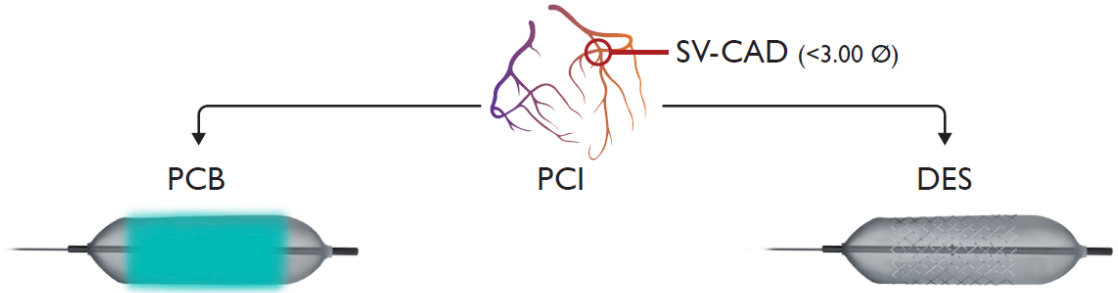





Lancet 2018; 392: 849-56
Lancet 2020; 396: 1504–10

# Individual patient data meta-analysis of paclitaxel-coated balloons vs. drug-eluting stents for small-vessel coronary artery disease: the ANDROMEDA study

Simone Fezzi [1,†], Daniele Giacoppo [2,3,4,†], Gregor Fahrni[5], Azeem Latib [6], Fernando Alfonso [7], Antonio Colombo [8], Felix Mahfoud [9], Bruno Scheller [10], Raban Jeger [5,11], and Bernardo Cortese [10,12,13,*]

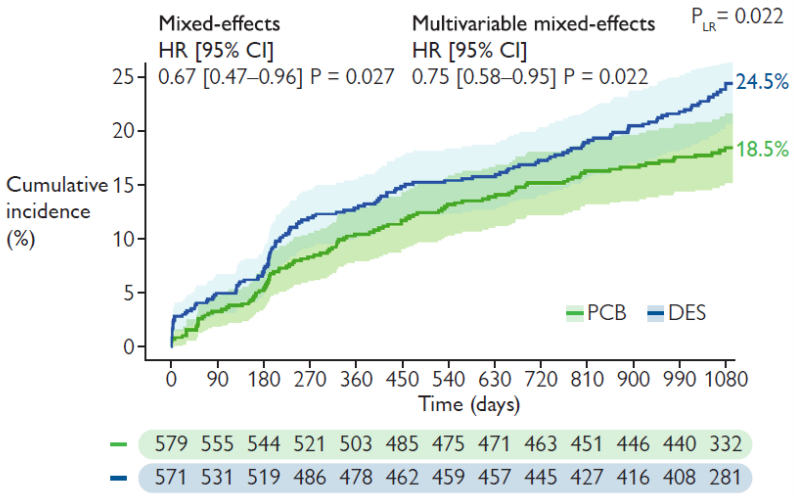



## MACE

IPD

| | |
|---|---|
| BELLO | N = 90 vs 92 |
| BASKET SMALL 2 | N = 382 vs 376 |
| PICCOLETO II | N = 118 vs 114 |

N = 1154
36-month clinical follow-up




## TLF

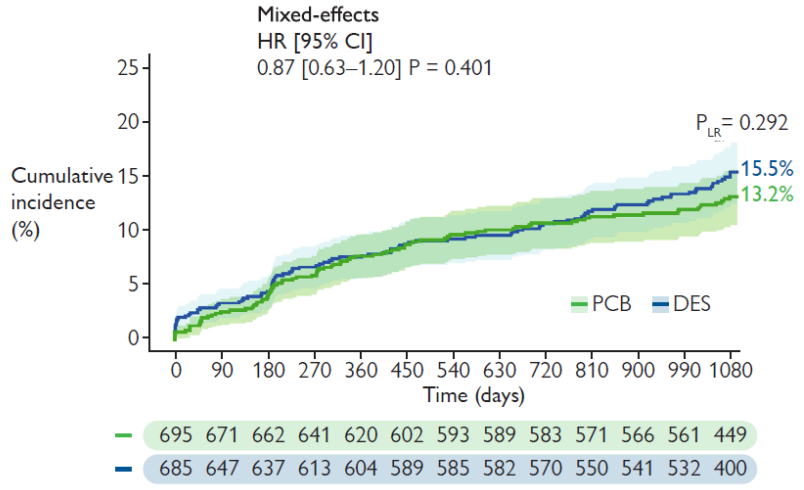
IPD

| | |
|---|---|
| BELLO | N = 90 vs 92 |
| BASKET SMALL 2 | N = 382 vs 376 |
| PICCOLETO II | N = 118 vs 114 |

rIPD

| | |
|---|---|
| RESTORE SVD China | N = 116 vs 114 |

N = 1475
36-month clinical follow-up

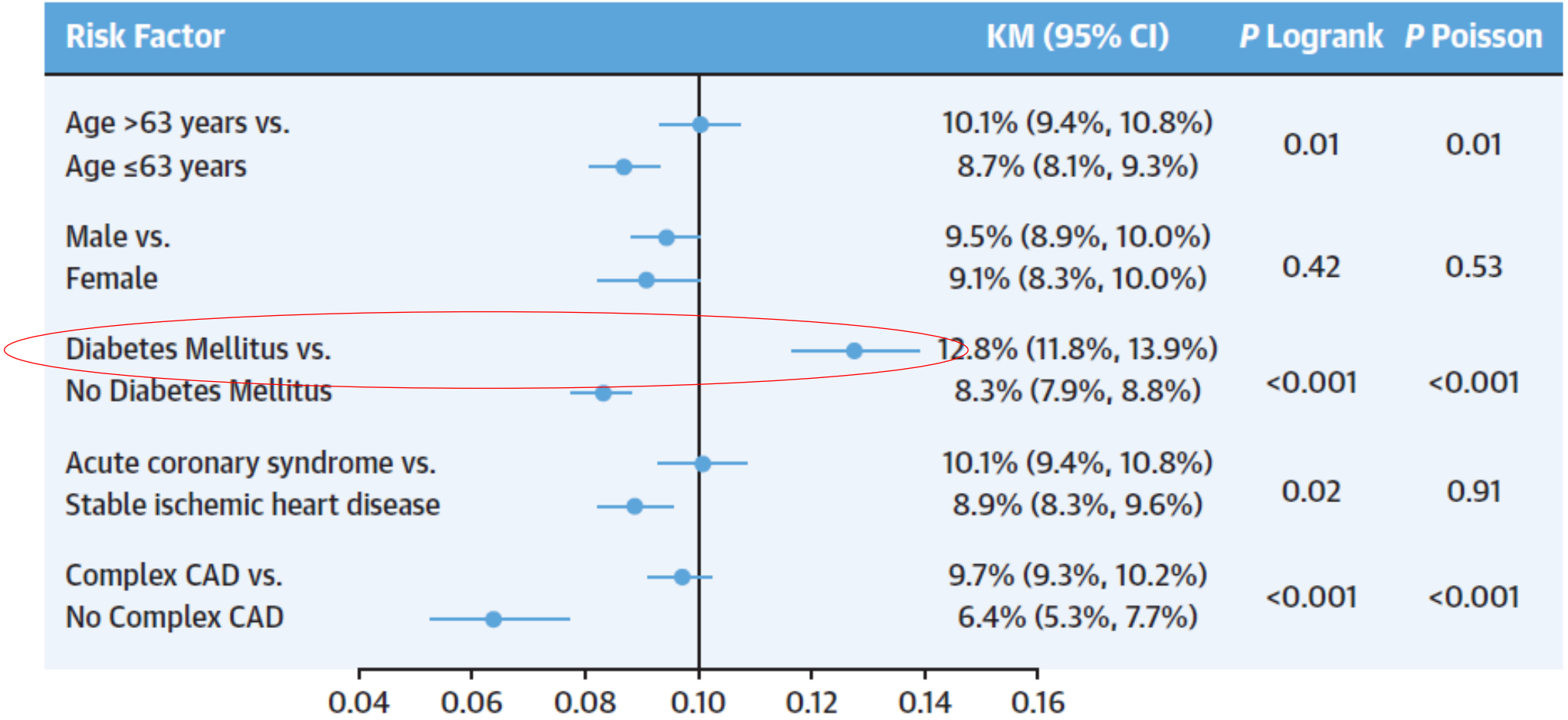





Eur Heart J. 2025 Feb 21:ehaf002. doi: 10.1093/eurheartj/ehaf002. Online ahead of print

# DES meta-analysis, n=19,578

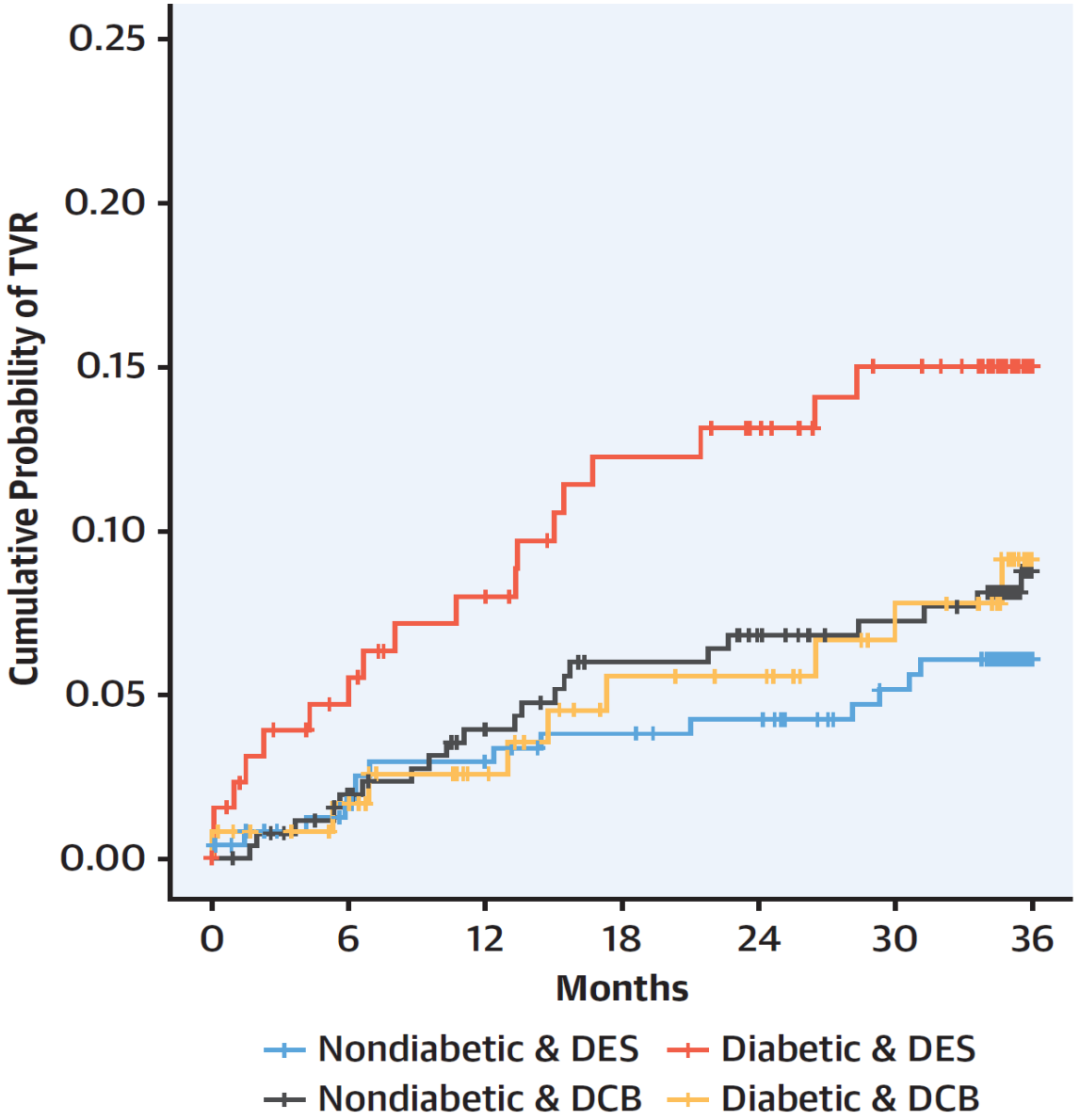
**FIGURE 3** Major Adverse Cardiovascular Events by Subgroups Between 1 and 5 Years






Madhavan et al. J Am Coll Cardiol 2020;75:590–604

# Impact of Diabetes in BASKET-SMALL 2

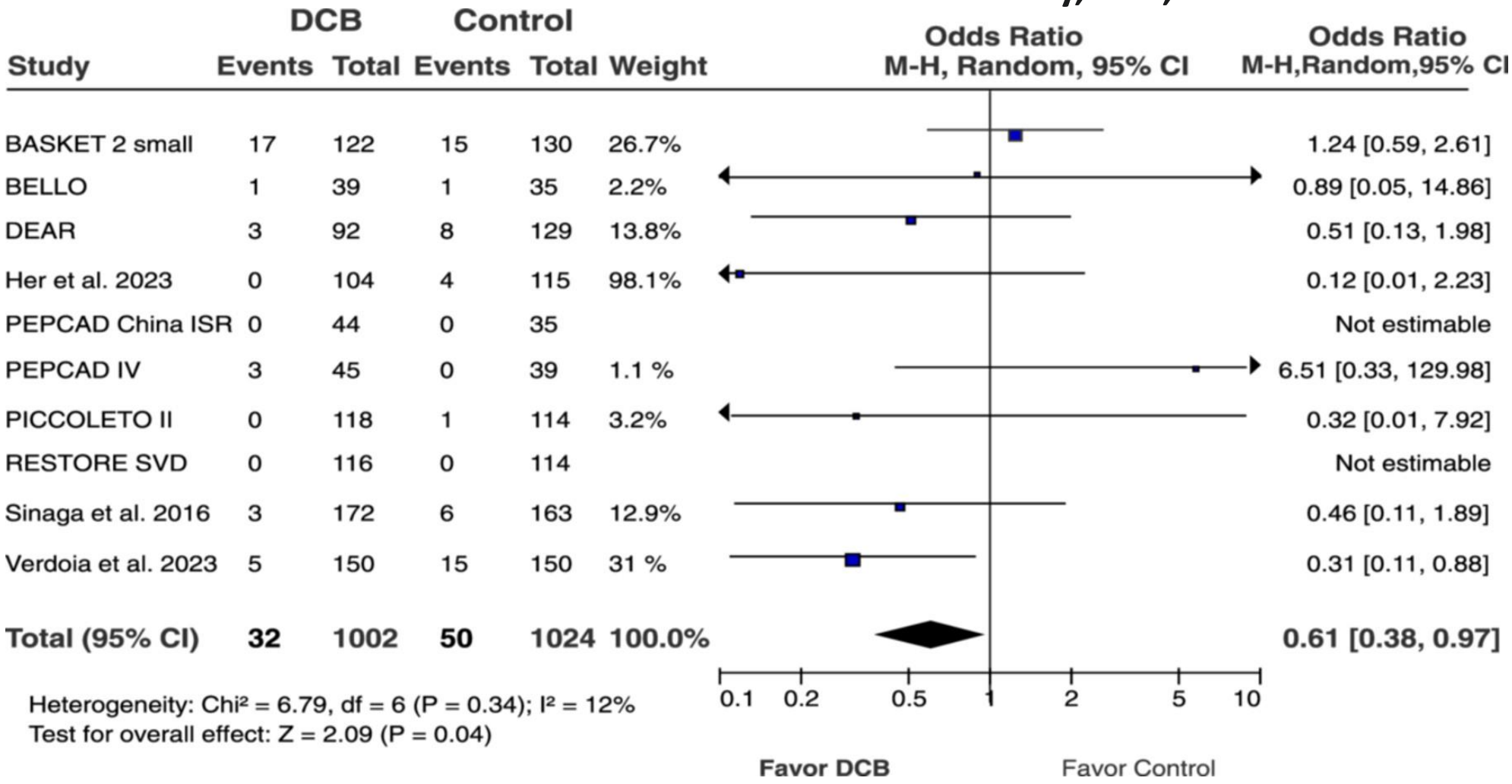





J Am Coll Cardiol Intv 2021; 14: 1789–1798

# DCB in high-risk patients and diabetes mellitus: meta-analysis of 10 studies

## All-cause mortality, n=2,026

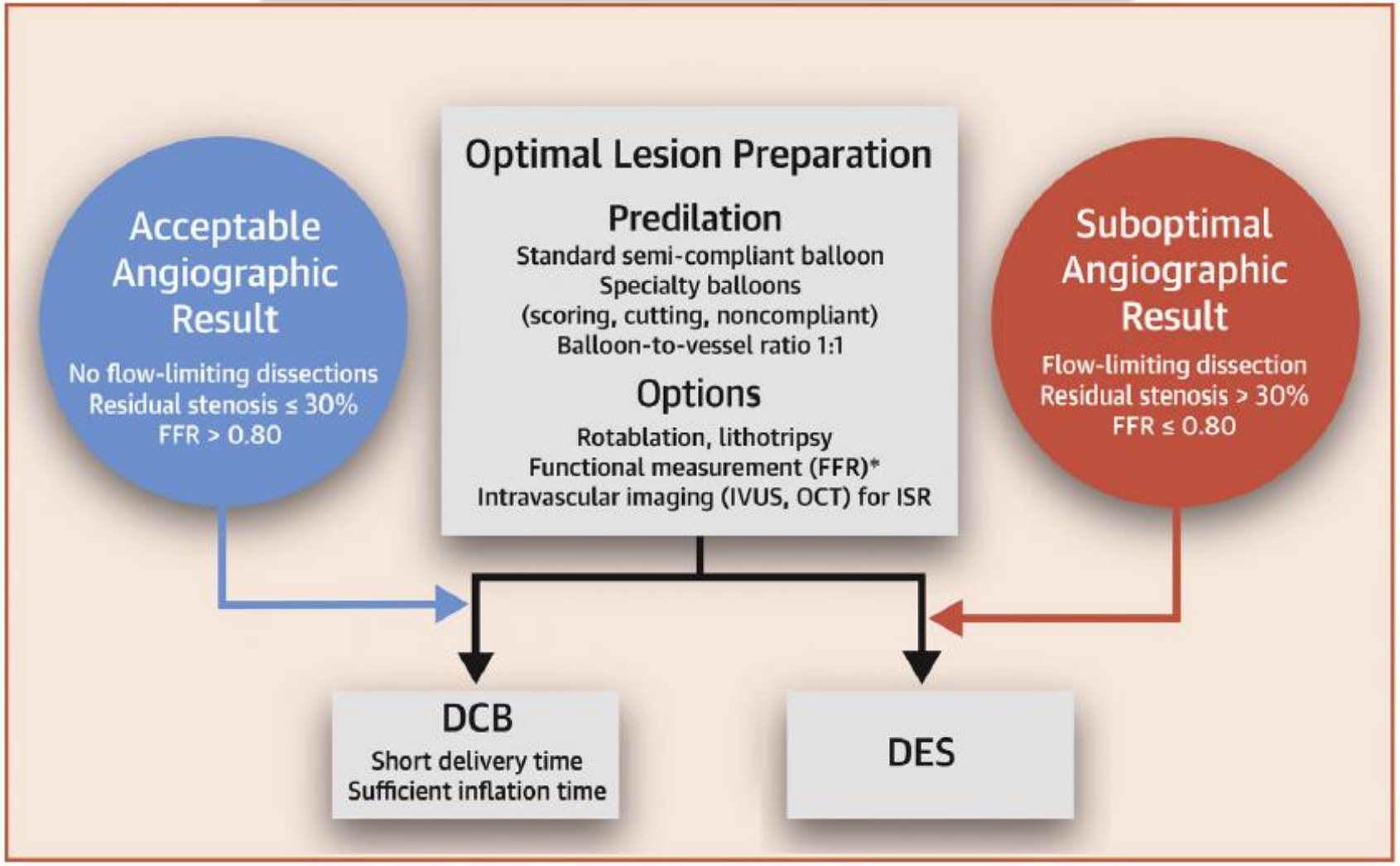



Verdoia et al. Cathet Cardio Intervent. 2024

# 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 Azman Wan Ahmad, MD,[c] Junbo Ge, MD,[d] Tudor C. Poerner, MD,[e] Eun-Seok Shin, MD,[f] Fernando Alfonso, MD,[g] Azeem Latib, MD,[h] Paul J. Ong, MD,[i] Tuomas T. Rissanen, MD,[j] Jorge Saucedo, MD,[k] Bruno Scheller, MD,[l] Franz X. Kleber, MD,[m] for the International DCB Consensus Group



# The Role of Drug-Eluting Balloons Alone or in Combination With Drug-Eluting Stents in the Treatment of De Novo Diffuse Coronary Disease

Charis Costopoulos, MD,*†‡ Azeem Latib, MD,*† Toru Naganuma, MD,*†
Alessandro Sticchi, MD,* Filippo Figini, MD,* Sandeep Basavarajaiah, MD,*†‡
Mauro Carlino, MD,* Alaide Chieffo, MD,* Matteo Montorfano, MD,* Charbel Naim, MD,*
Masanori Kawaguchi, MD,*† Francesco Giannini, MD,* Antonio Colombo, MD*†

**Table 5. Cumulative Clinical Events**

| Clinical Outcomes | DEB ± DES Strategy (n = 69) | DES-Alone Strategy (n = 93) |
|---|---|---|
| In-hospital events | | |
| MI | 3 (4.3) | 5 (5.4) |
| ST (definite/probable) | 0 | 1 (1.1) |
| Death | 0 | 0 |
| Follow-up events | | |
| Death | 4 (5.8) | 6 (6.5) |
| Cardiac cause | 2 (2.9) | 2 (2.2) |
| Noncardiac cause | 2 (2.9) | 4 (4.3) |
| TVR | 8 (11.6) | 13 (14.0) |
| TLR | 5 (7.2) | 10 (10.8) |
| MI | 0 | 1 (1.1) |
| ST (definite/probable) | 0 | 0 |
| MACE* | 13 (18.8) | 23 (24.7) |
| TLR (per lesion) | 5/93 (5.4) | 10/93 (10.8) |

Values are n (%) or n/N (%). *MACE is defined as all-cause death, TVR, and MI (including peri-procedural).

MACE = major adverse cardiac events; MI = myocardial infarction; ST = stent thrombosis; TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Table 1.

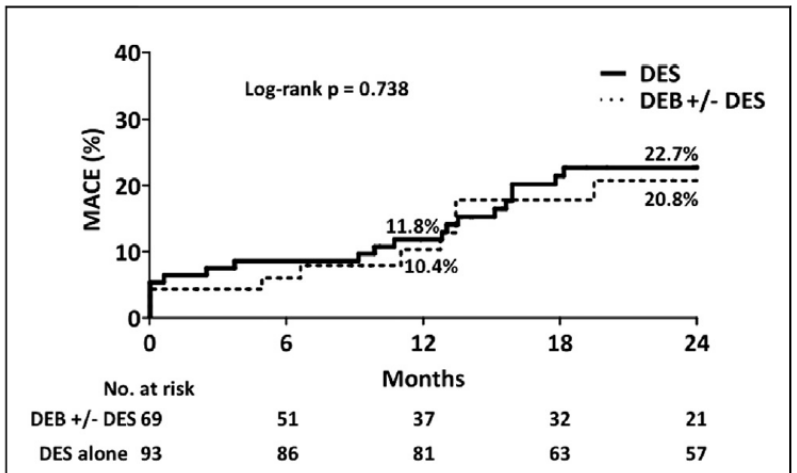



**Figure 1. Kaplan-Meier Time-to-Event Curve for MACE**

Kaplan-Meier curves for MACE according to strategy used. DEB = drug-eluting balloon(s); DES = drug-eluting stent(s); MACE = major adverse cardiac events.

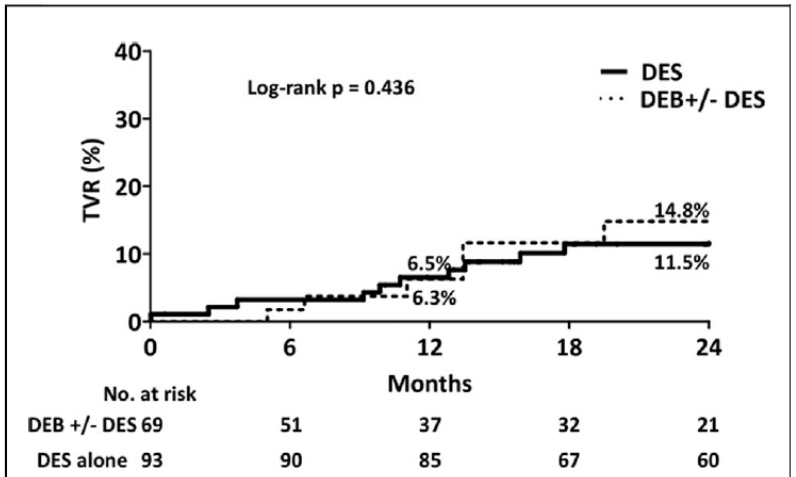


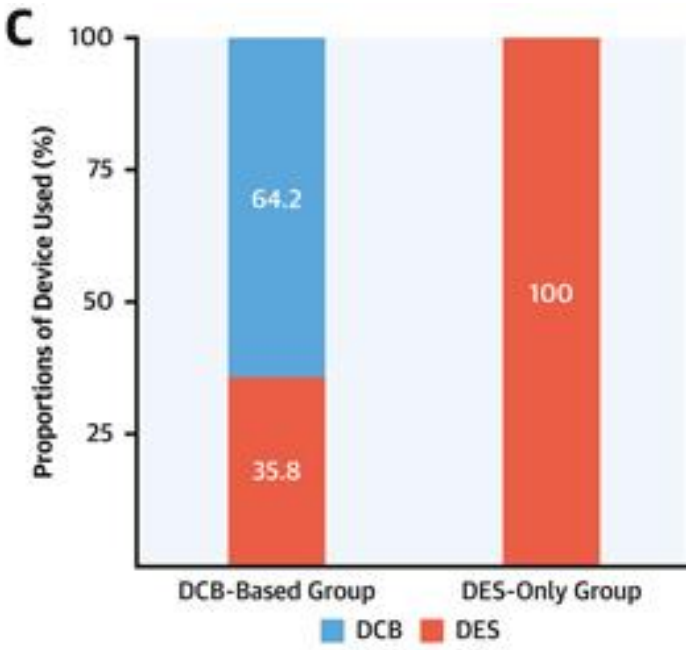

**Figure 2. Kaplan-Meier Time-to-Event Curve for TVR**

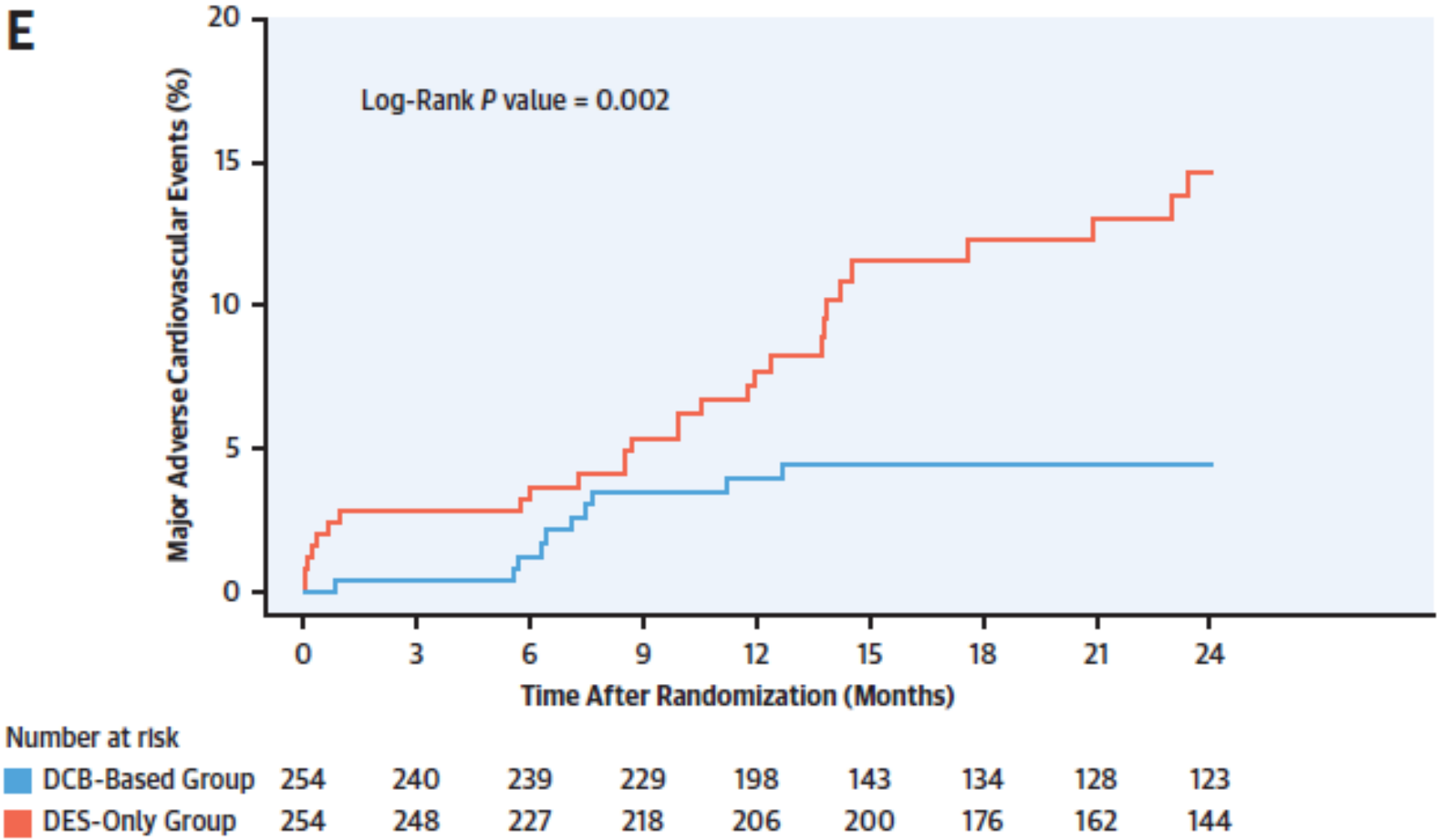
Kaplan-Meier curves for TVR according to strategy used. TVR = target vessel revascularization; other abbreviations as in Figure 1.



J Am Coll Cardiol Intv 2013; 6: 1153–9

# Clinical Impact of Drug-Coated Balloon–Based Percutaneous Coronary Intervention in Patients With Multivessel Coronary Artery Disease

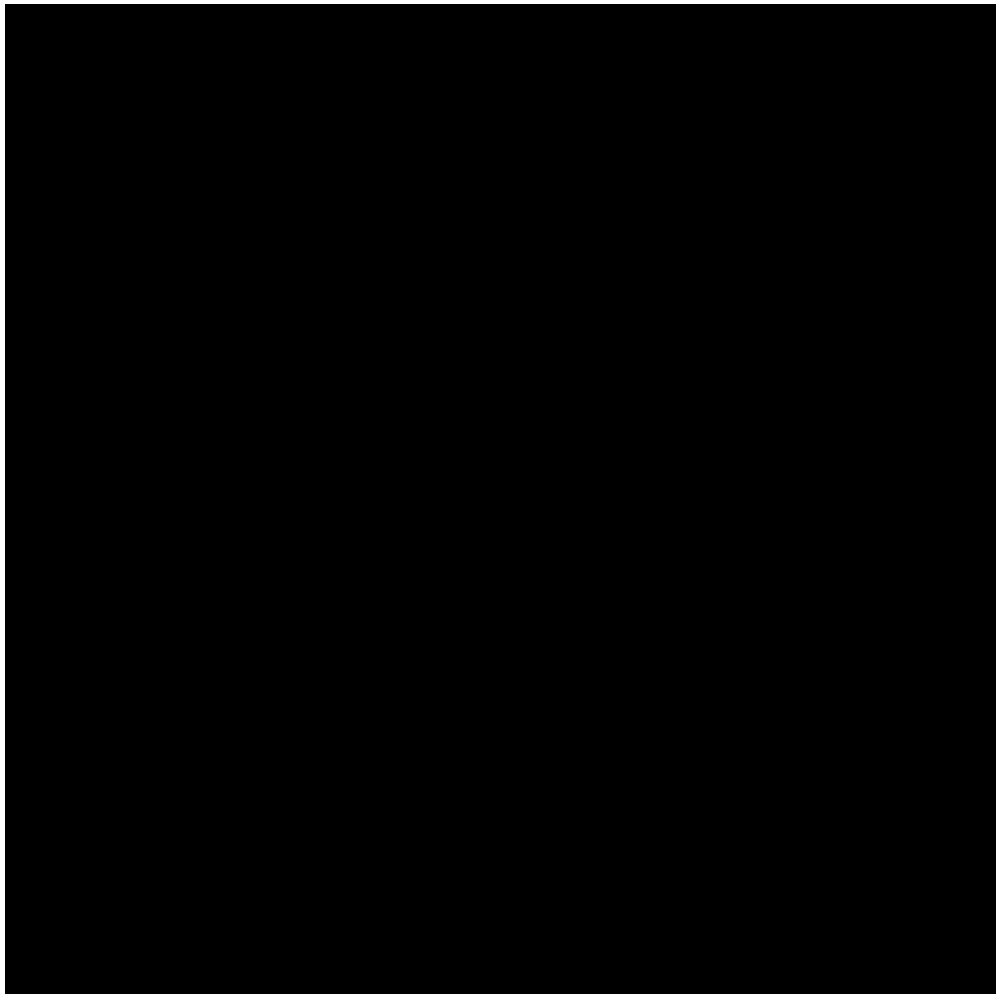


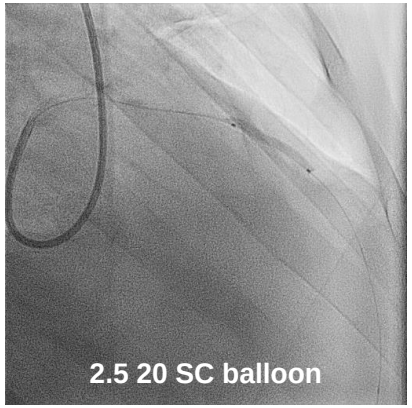



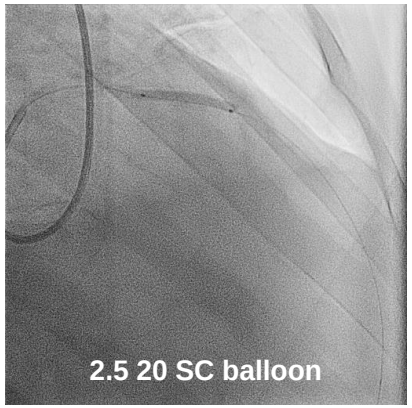


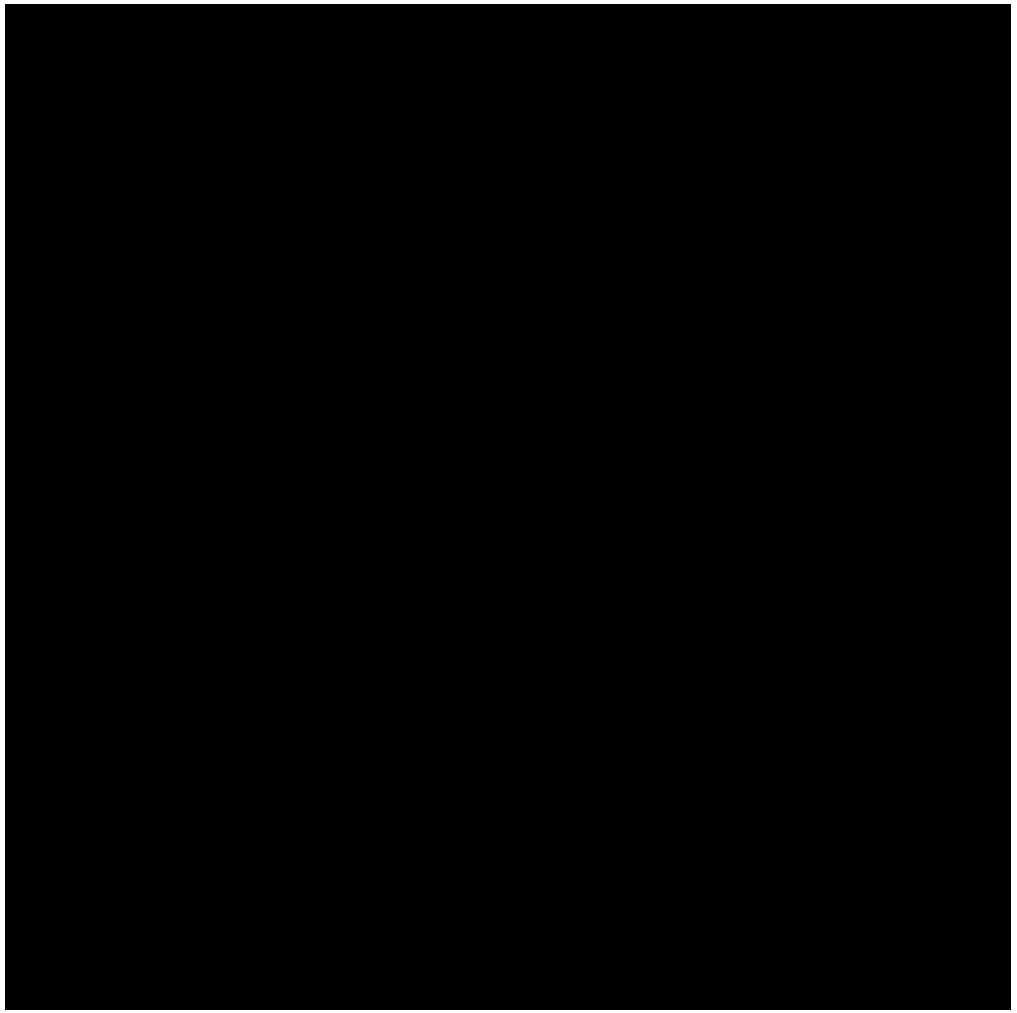

Shin et al. J Am Coll Cardiol Intv. 2023; 16: 292-9

# 68 year old male, diabetes, hypertension, ex-smoker, angina CCS III

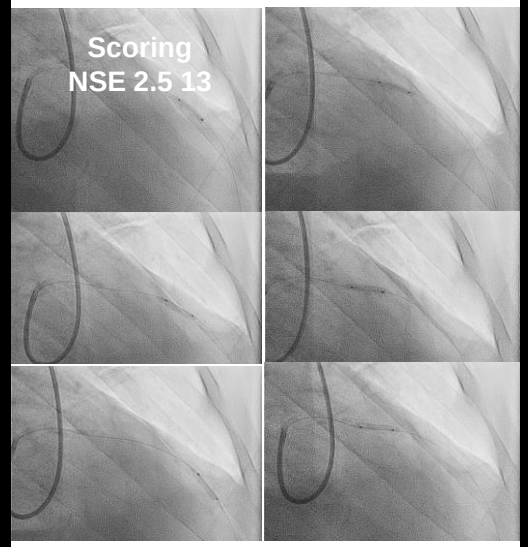




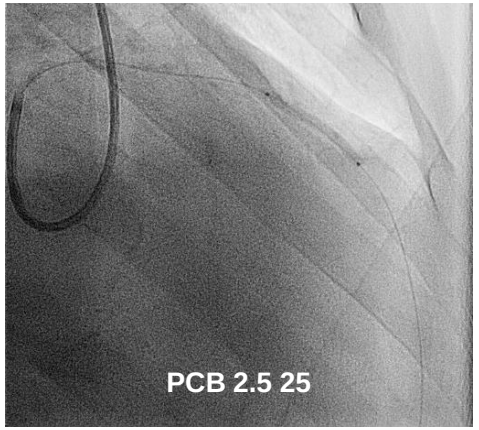



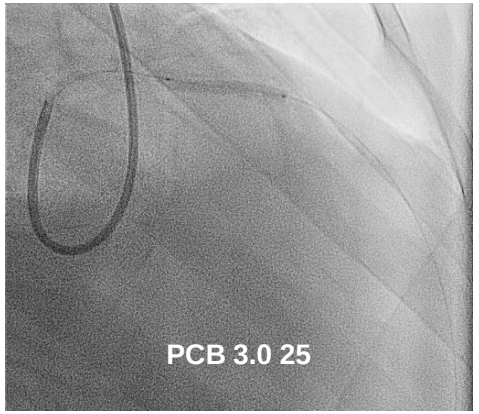



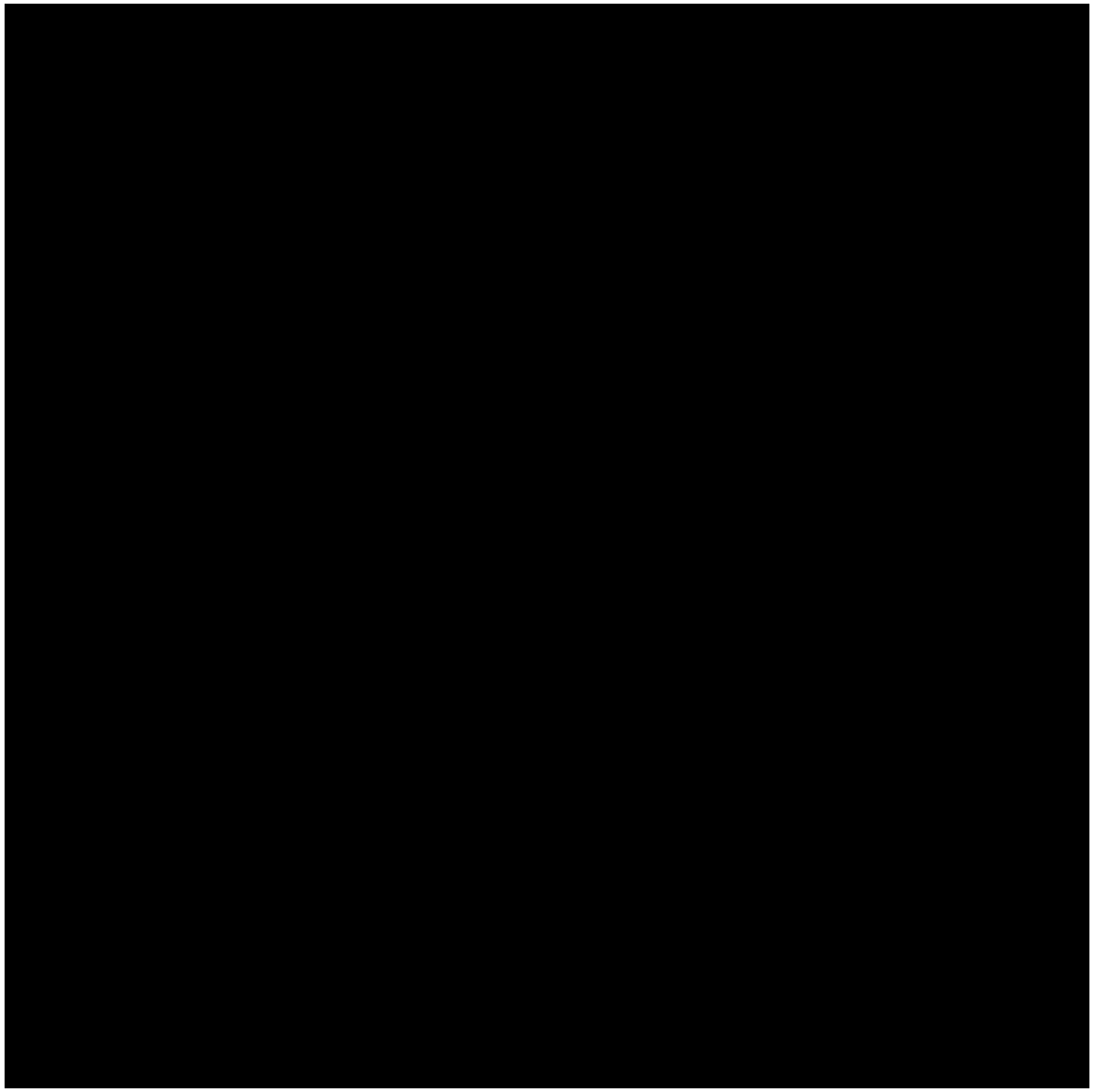
# 68 year old male, diabetes, hypertension, ex-smoker, angina CCS III



# 68 year old male, diabetes, hypertension, ex-smoker, angina CCS III



# Coronary vasomotion after treatment with drug-coated balloons or drug-eluting stents: a prospective, open-label, single-centre randomised trial

**Tsutomu Kawai**[1]*, MD; Tetsuya Watanabe[1], MD, PhD; Takahisa Yamada[1], MD, PhD; Takashi Morita[1], MD, PhD; Yoshio Furukawa[1], MD, PhD; Shunsuke Tamaki[1], MD, PhD; Masato Kawasaki[1], MD; Atsushi Kikuchi[1], MD; Masahiro Seo[1], MD; Jun Nakamura[1], MD; Kentaro Tachibana[2], MAS; Hirota Kida[2], MAS; Yohei Sotomi[3], MD, PhD; Yasushi Sakata[3], MD, PhD; Masatake Fukunami[1], MD, PhD

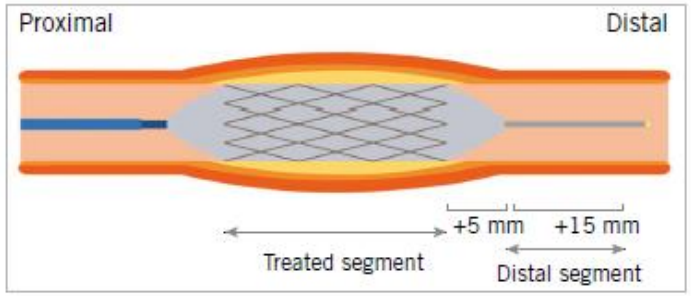
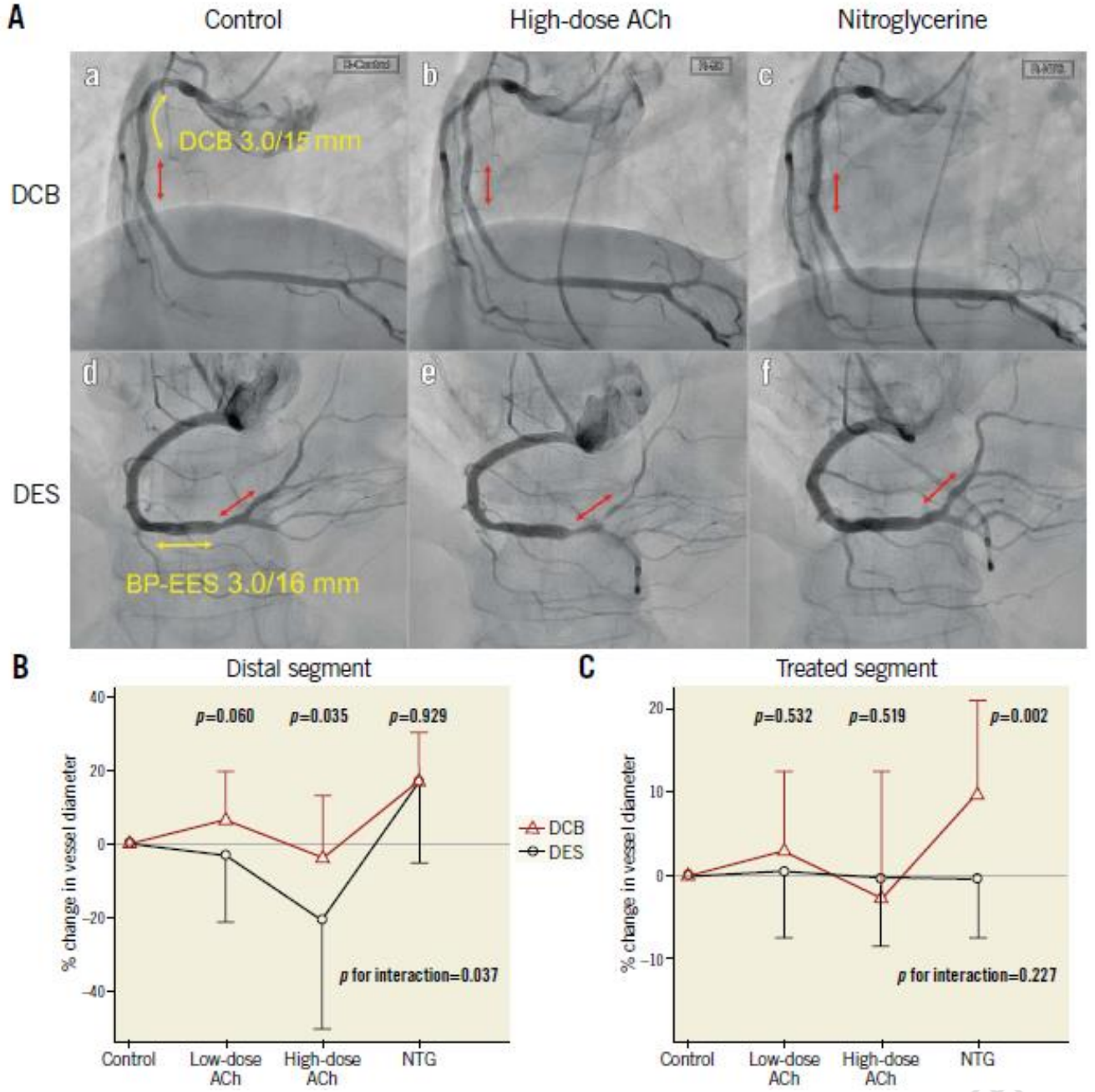



**Figure 1.** *Definition of each segment. A representation of the segment treated with the drug-coated balloon or drug-eluting stent. The distal segment begins 5 mm and ends 15 mm distal to the end of the treated segment.*



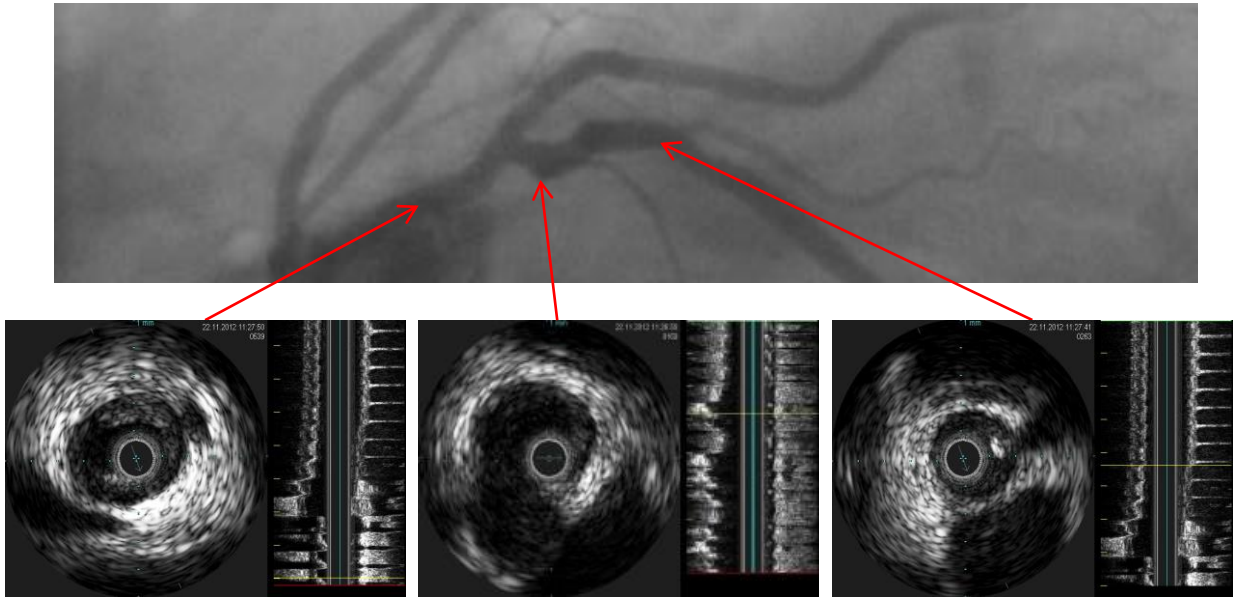



EuroIntervention 2022;18:e140-e148

# Plaque stabilization

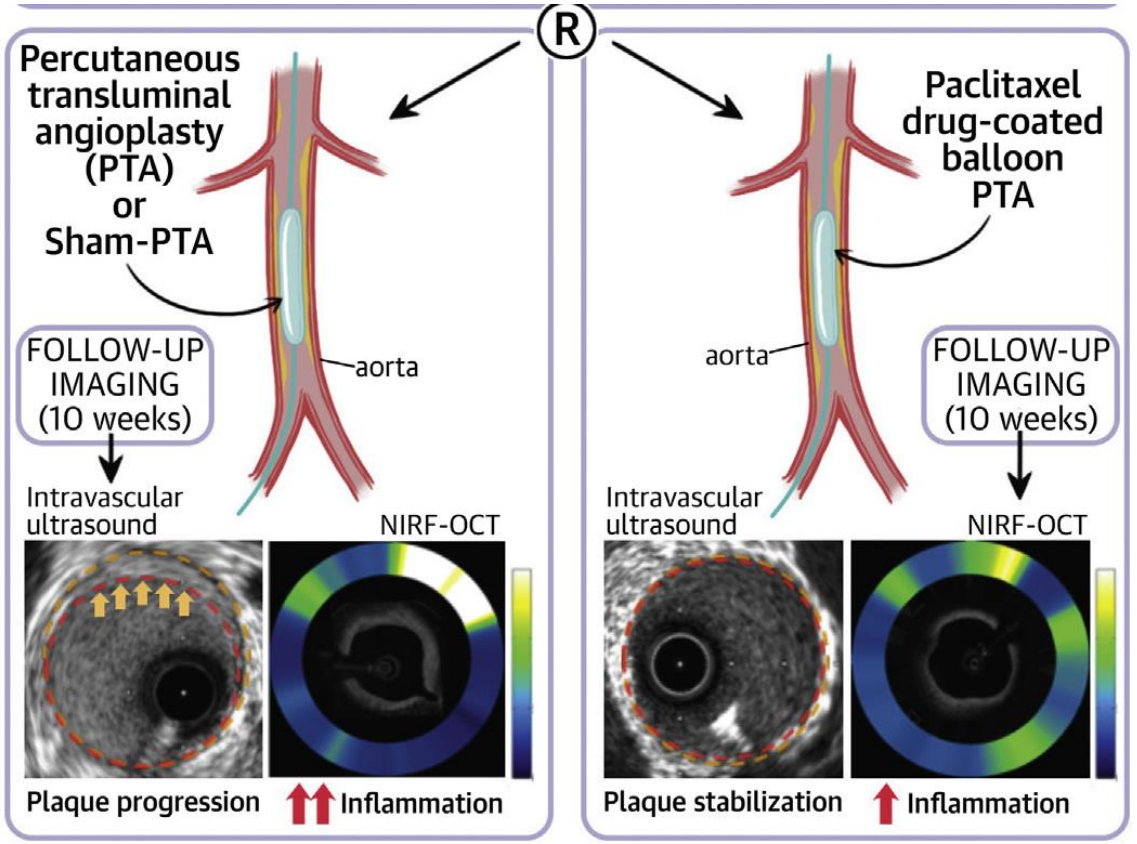
**Treatment of a coronary bifurcation lesion with drug-coated balloons: lumen enlargement and plaque modification after 6 months**

Bruno Scheller · Dieter Fischer · Yvonne P. Clever · Franz X. Kleber · Ulrich Speck · Michael Böhm · Bodo Cremers



Clin Res Cardiol. 2013; 102: 469-72

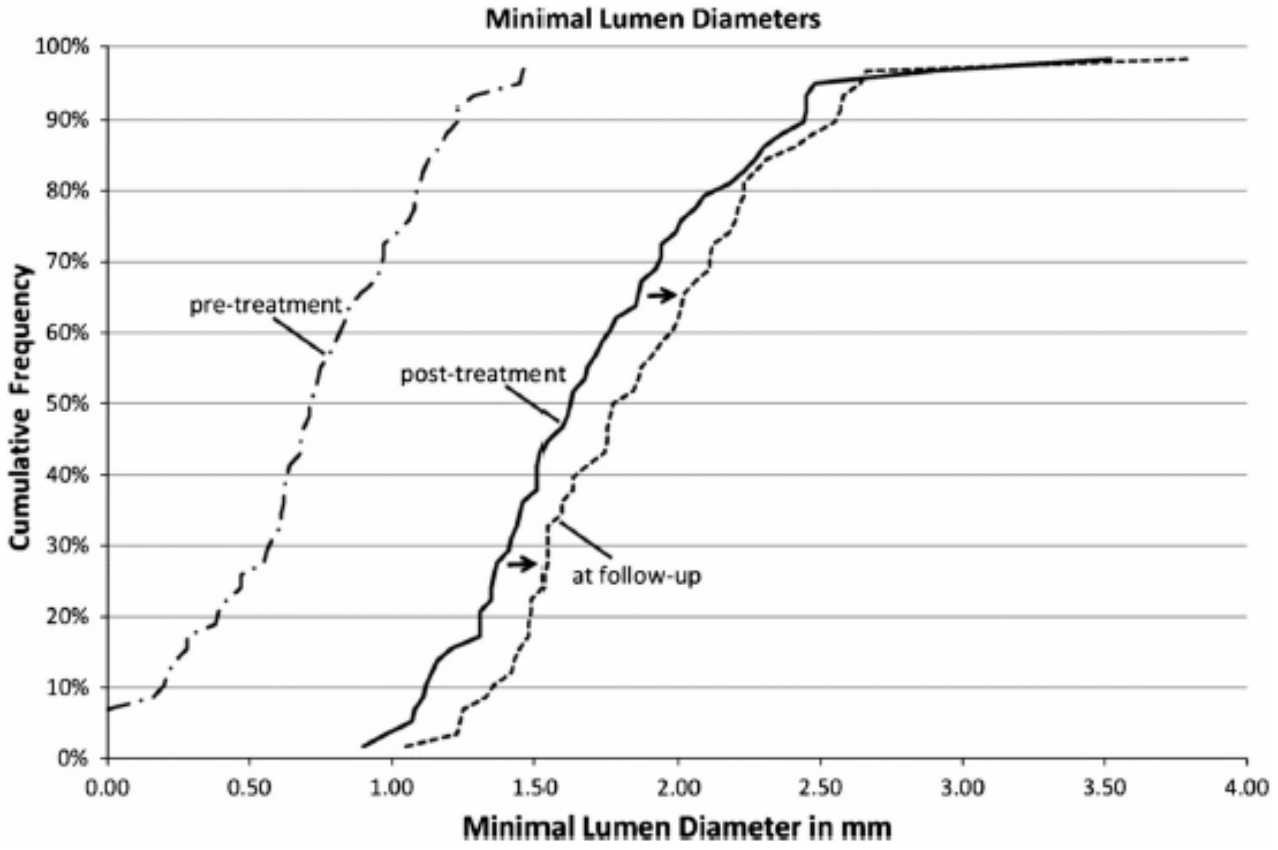
**Paclitaxel Drug-Coated Balloon Angioplasty Suppresses Progression and Inflammation of Experimental Atherosclerosis in Rabbits**

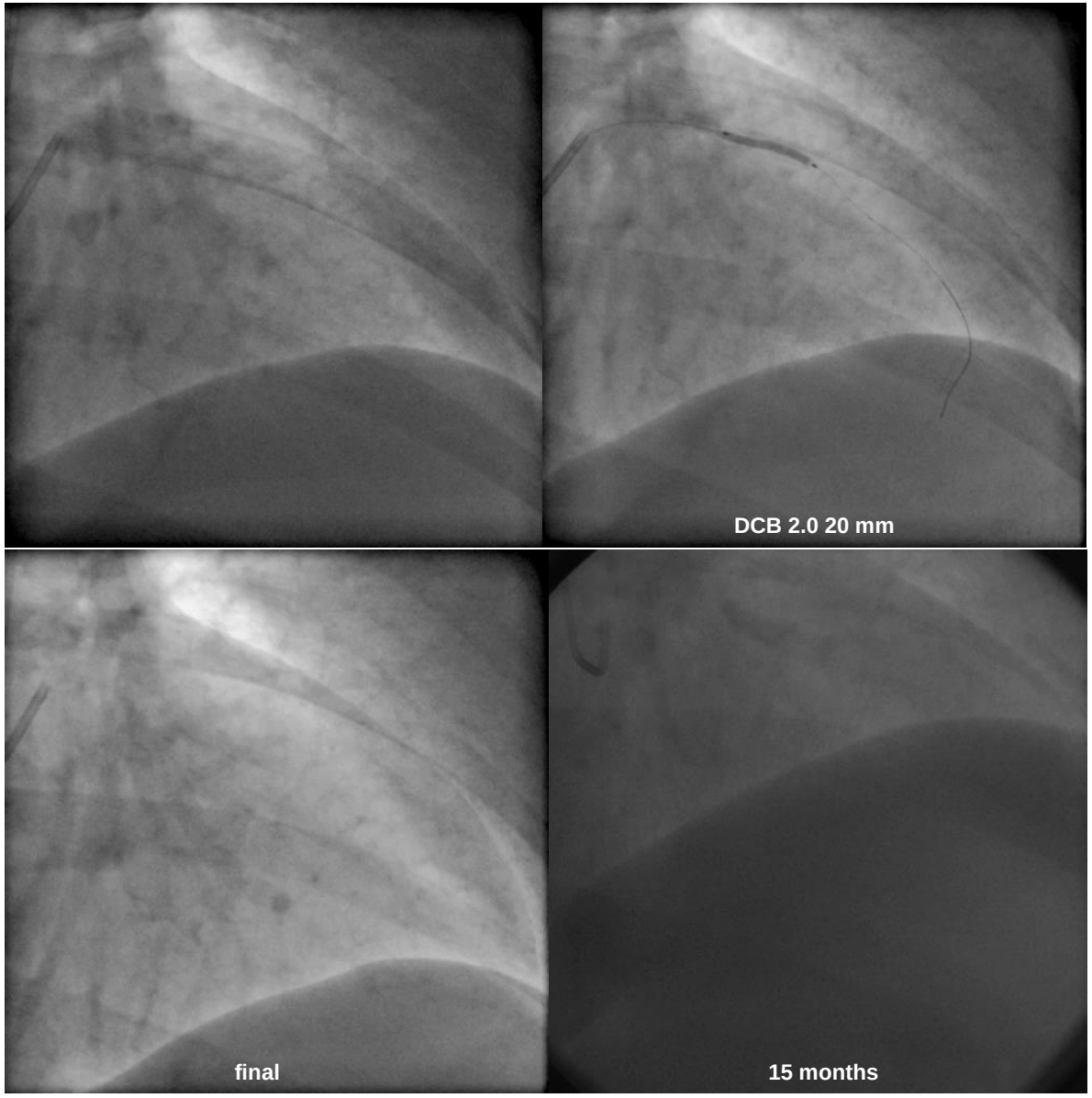



Chowdhury et al. J Am Coll Cardiol Basic Trans Science 2020; 5: 685–95

# Local paclitaxel induces late lumen enlargement in coronary arteries after balloon angioplasty

Franz X. Kleber · Antonia Schulz · Matthias Waliszewski · Telse Hauschild · Michael Böhm · Ulrich Dietz · Bodo Cremers · Bruno Scheller · Yvonne P. Clever



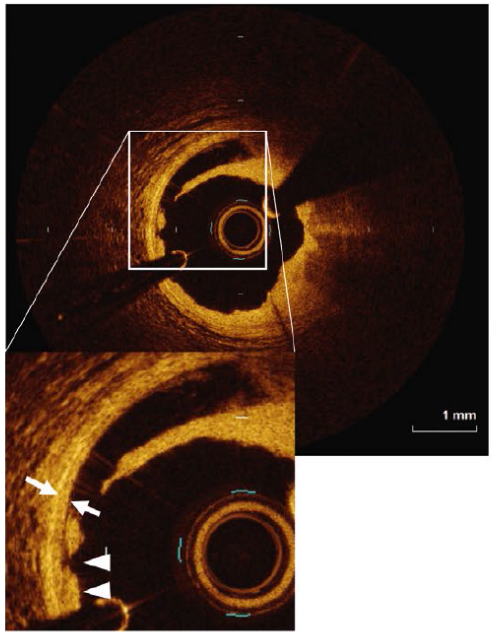




Clin Res Cardiol. 2015; 104: 217-25

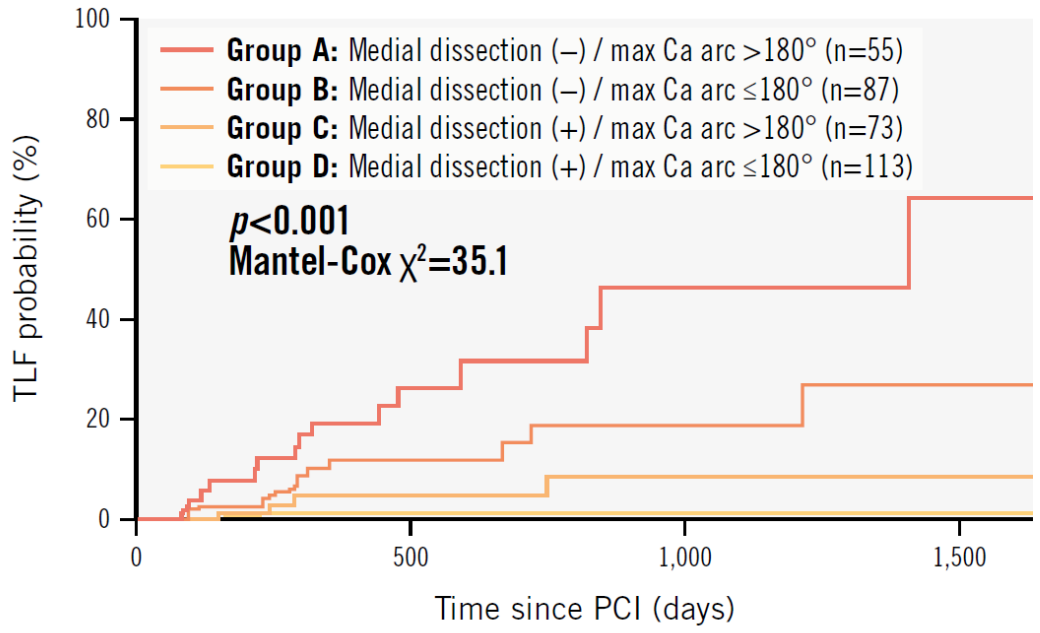
# Predictors of target lesion failure after percutaneous coronary intervention with a drug-coated balloon for *de novo* lesions

**Tetsumin Lee**[1]*, MD, PhD; Takashi Ashikaga[1], MD, PhD; Toshihiro Nozato[1], MD, PhD; Yasutoshi Nagata[1], MD; Masakazu Kaneko[1], MD, PhD; Ryoichi Miyazaki[1], MD; Toru Misawa[1], MD; Yuta Taomoto[1], MD; Shinichiro Okata[1], MD, PhD; Masashi Nagase[1], MD; Tomoki Horie[1], MD; Mao Terui[1], MD; Daigo Kachi[1], MD; Yuki Odanaka[1], MD; Kazuki Matsuda[1], MD; Michihito Naito[1], MD; Ayaka Koido[1], MD; Taishi Yonetsu[2], MD, PhD; Tetsuo Sasano[2], MD, PhD

## Predictors of target lesion failure in *de novo* coronary lesions treated with a drug-coated balloon.




A Medial dissection as assessed by OCT

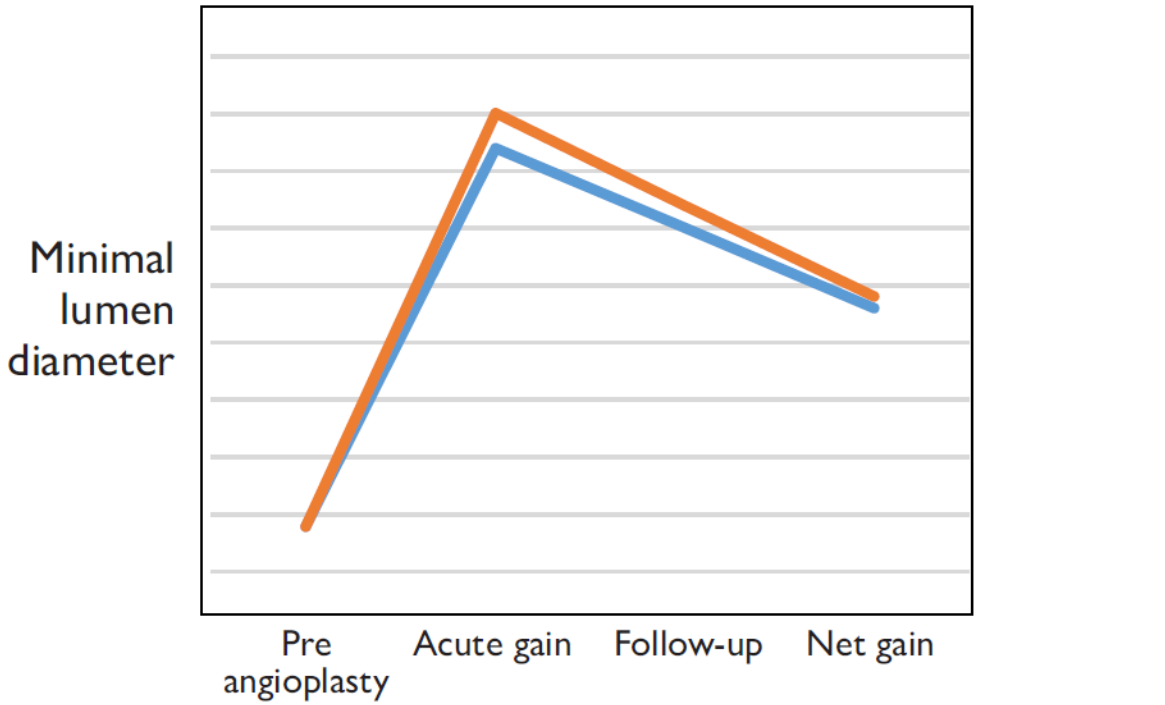



B

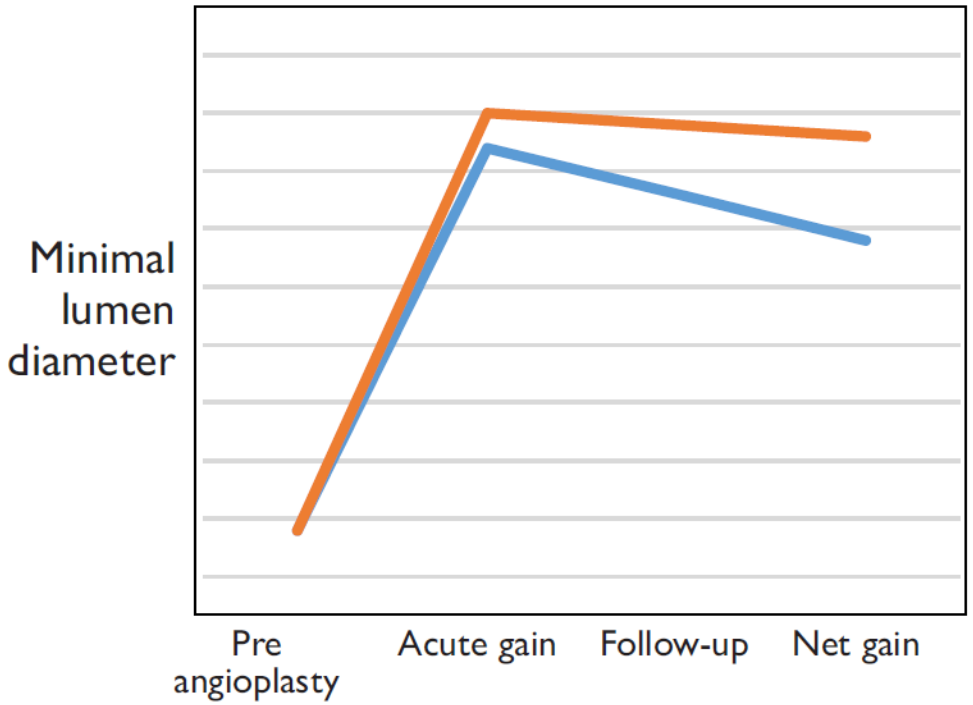
EuroIntervention 2024;20:e818-e825

# Paclitaxel-coated balloons: the more you gain the more you get

Plain angioplasty: higher lumen loss with greater acute gain




DCB: lower lumen loss with greater acute gain



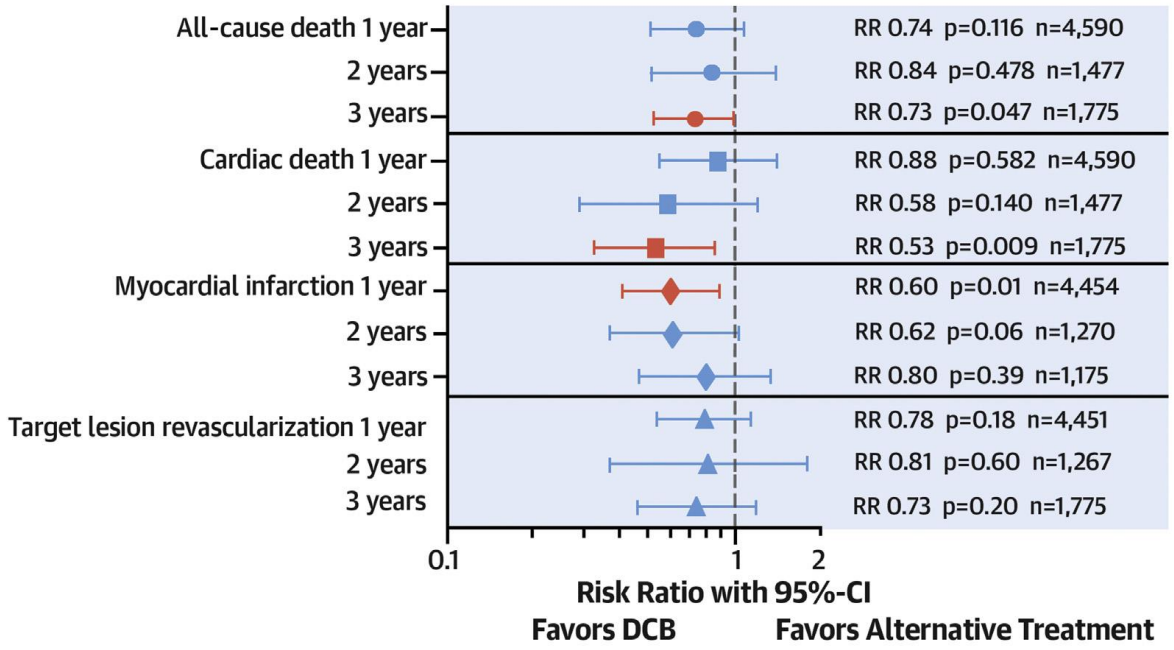


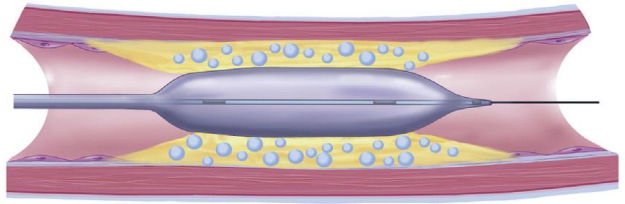

Scheller B, Zeller T. Eur Heart J. 2024; 45: 2848-50

# Survival After Coronary Revascularization With Paclitaxel-Coated Balloons

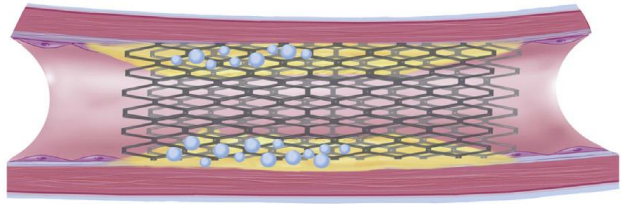
Bruno Scheller, MD,[a,b] Davor Vukadinovic, MD,[a] Raban Jeger, MD,[c] Tuomas T. Rissanen, MD,[d] Sean S. Scholz, MD,[a] Robert Byrne, MD,[e] Franz X. Kleber, MD,[f] Azeem Latib, MD,[g] Yvonne P. Clever, MD,[a] Sebastian Ewen, MD,[a] Michael Böhm, MD,[a] Yiping Yang, PhD,[h] Alexandra Lansky, MD,[h] Felix Mahfoud, MD[a]

## 4,590 Patients Enrolled in 26 RCTs Published Between 2006 and 2019



Drug-Coated Balloon



Balloon Angioplasty, Bare-Metal Stent, or Drug-Eluting Stent



J Am Coll Cardiol. 2020; 75: 1017-1028

# Conclusion

- DCBonly strategy to reduce number and length of stents
- Focus on Lesion preparation
  - Careful lesion preparation improves outcomes of DCB and DES
  - Device selection depending on lesion complexity
- Decision between DCB and DES per lesion after preparation
  - DCBonly if diameter stenosis < 30% and absence of flow-limiting dissection, otherwise DES
- Role of intravascular imaging and physiology tbd
- Future trials focusing on strategy