# DAPT for less than 12 months:

Why not?

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CARDIC

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CONTRACTOR OF A DESCRIPTION OF

TORINESI TURIN, October 25<sup>th</sup>-27<sup>th</sup> 2018 Starhotels Majestic

# DAPT for less than 12 months:

Why not!

To prevent stent thrombosis To reduce the risk or recurrent ACS



#### Let's keep it long

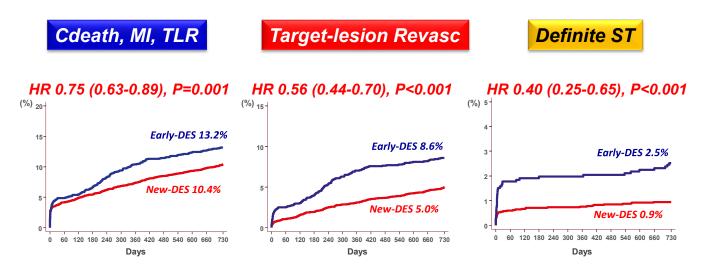
Why not?

To reduce the risk of bleeding To reduce side-effects of the drugs To reduce cost of the treatment



Let's shorten it

# Early generation vs new generation DES



#### Pooled Analysis (n =6,081): SIRTAX, LEADERS, RESOLUTE, BIOSCIENCE

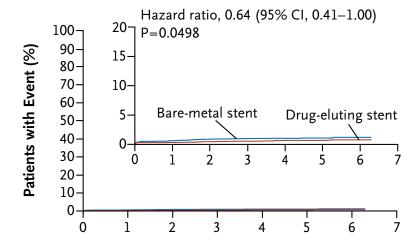
#### *New-DES (n =4,554), Early-DES (n =1,527)*

Follow-up available in 97.2% of patients at 2-year

Piccolo et al. J Am Coll Cardiol Intv 2015; 8: 1657-66

# Second generation DES

**D** Definite Stent Thrombosis



Years since Randomization

#### NORSTENT trial (2016): definite ST rate lower in DES group (0.8% vs 1.2%; P=0.0498) over 6 years FU

Bønaa KH, Mannsverk J, Wiseth R, et al: Drug-eluting or bare metal stents for coronary artery disease. NEJM 2016.



Α

# 2018 ESC/EACTS Guidelines on myocardial revascularization

| Procedural as | spects of PCI |
|---------------|---------------|
|---------------|---------------|

DES<sup>f</sup> are recommended over BMS for any PCI irrespective of:

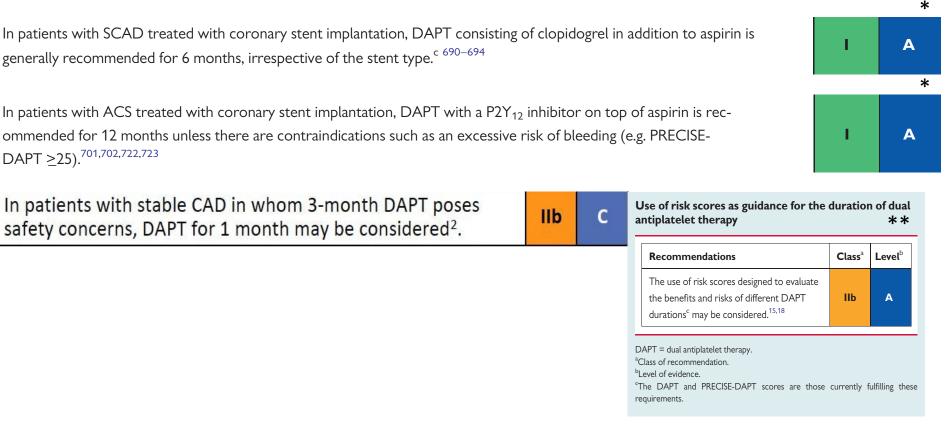
- clinical presentation
- lesion type
- planned non-cardiac surgery
- anticipated duration of DAPT
- concomitant anticoagulant therapy.

Dual antiplatelet therapy duration in high bleeding risk patients with stable coronary artery disease treated with percutaneous coronary intervention

DAPT ≥25).<sup>701,702,722,723</sup>



#### DAPT: the longer the better...?



\*Myocardial revascularization guidelines (ESC 2018) \*\* DAPT guidelines (ESC 2017)

# **OPRECISEDAPT**

|                                | PRECISE-DAPT score <sup>18</sup>                           |  |  |  |  |
|--------------------------------|--|--|--|--|--|
| Time of use                    | At the time of coronary stenting                           |  |  |  |  |
| DAPT duration                  | Short DAPT (3–6 months)                                    |  |  |  |  |
| strategies assessed            | vs.<br>Standard/long DAPT (12–24 months)                   |  |  |  |  |
| Score calculation <sup>a</sup> | HB ≥12 11-5 11 10-5 ≤10                                    |  |  |  |  |
|                                | WBC ≤5 8 10 12 14 16 18 ≥20                                |  |  |  |  |
|                                | <b>Age</b> ≤50 60 70 80 ≥90                                |  |  |  |  |
|                                | CrCl ≥100 80 60 40 20 0                                    |  |  |  |  |
|                                | Prior No Yes<br>Bleeding                                   |  |  |  |  |
|                                | Score 0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30<br>Points |  |  |  |  |
| Score range                    | 0 to 100 points  |  |  |  |  |
| Decision making cut-off        | Score $\geq 25 \rightarrow$ Short DAPT                     |  |  |  |  |
| suggested                      | Score <25 → Standard/Iong DAPT                             |  |  |  |  |
| Calculator                     | www.precisedaptscore.com                                   |  |  |  |  |

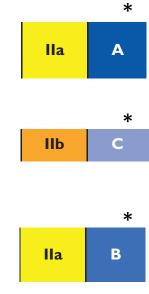


# 2018 ESC/EACTS Guidelines on myocardial revascularization

In patients with SCAD considered at high bleeding risk (e.g. PRECISE-DAPT ≥25), DAPT should be considered for 3 months.<sup>d 695,696</sup>

In patients with SCAD in whom 3 month DAPT poses safety concerns, DAPT may be considered for 1 month.

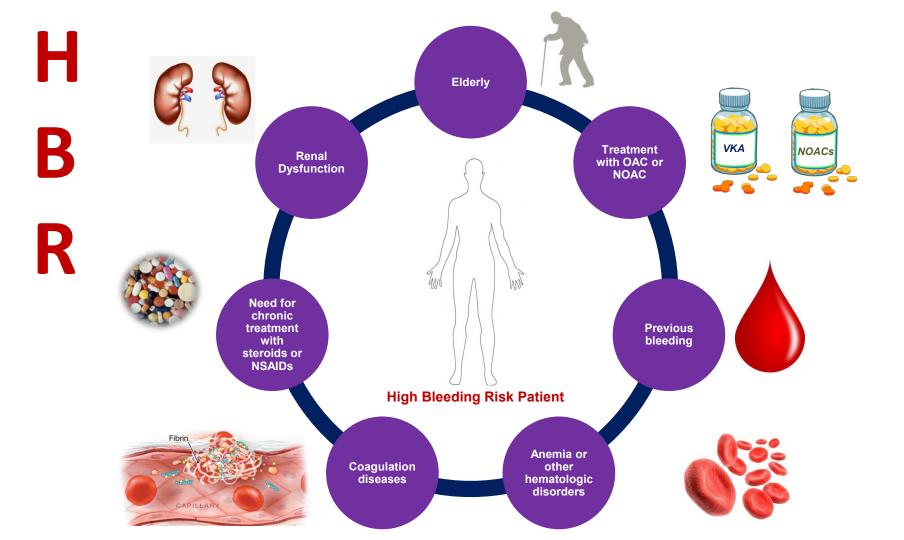
In patients with ACS and stent implantation who are at high risk of bleeding (e.g. PRECISE-DAPT  $\geq$ 25), discontinuation of P2Y<sub>12</sub> inhibitor therapy after 6 months should be considered.<sup>729,730</sup>



# Reducing DAPT duration in clinical practice



In which patients?



# Short DAPT with DES *in HBR* is it now possible?

# <6m in ACS and <3m in SCAD or 1 m for all...?</pre>

## Short DAPT trials in HBR patients

| trial                  | stent                 | type  | limus<br>kinetics | patients                   | experimental arm<br>DAPT            | control arm                | primary endpoint                                   |
|------------------------|-----------------------|---|-------------------|----------------------------|-------------------------------------|----------------------------|--|
| LEADERS FREE<br>(5)    | BioFreedom<br>BA9 DCS | polymer-free                                  | fast              | 2400 HBR                   | 1 month                             | BMS &<br>1 month DAPT      | Superiority for safety<br>Superiority for efficacy |
| ZEUS HBR (6)           | Endeavor<br>ZES       | 1 <sup>st</sup> G permanent<br>polymer        | fast              | 828 HBR                    | 30 days                             | BMS & same<br>DAPT         | Superiority for MACE                               |
| SENIOR (7)             | Synergy EES           | 2 <sup>nd</sup> G<br>biodegradable<br>polymer | slow              | 1200<br>age <u>&gt;</u> 75 | 1 month (SCAD) or<br>6 months (ACS) | BMS & same<br>DAPT         | Superiority for MACE                               |
| LEADERS FREE II<br>(8) | BioFreedom<br>BA9 DCS | polymer-free                                  | fast              | 1200 HBR                   | 1 month                             | BMS arm of<br>LEADERS FREE | Superiority for safety<br>Superiority for efficacy |

Selectively Micro-Structured Surface Holds Drug in Abluminal Surface Structures



# **LEADERS FREE Trial Design**

Prospective, double-blind randomized (1:1) trial 2466 High Bleeding Risk (HBR) PCI patients

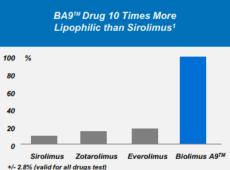


#### DAPT mandated for 1 month only, followed by long-term SAPT

• Primary safety endopoint:

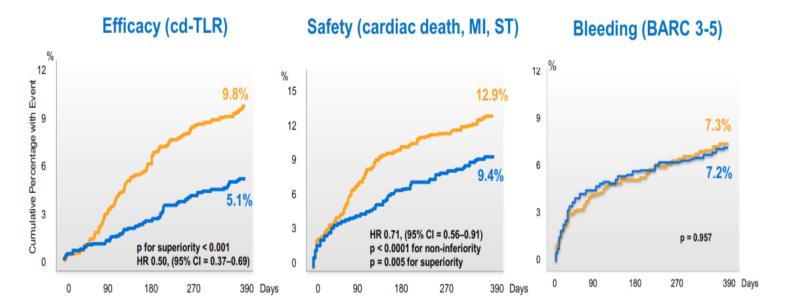
Composite of cardiac death, MI, definite/probable stent thrombosis at 1year (non-inferiority then superiority)

• Primary efficacy endpoint: Clinically driven TLR at 1 year (superiority)



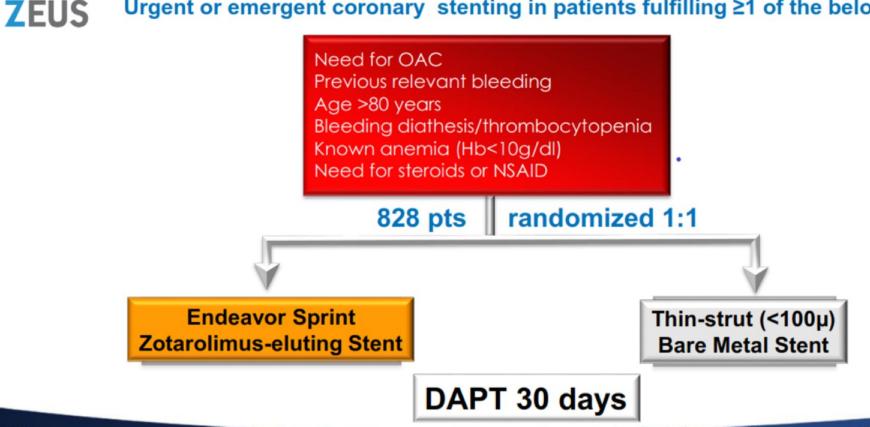
### Primary Endpoints and Major Bleeding at 1 Year





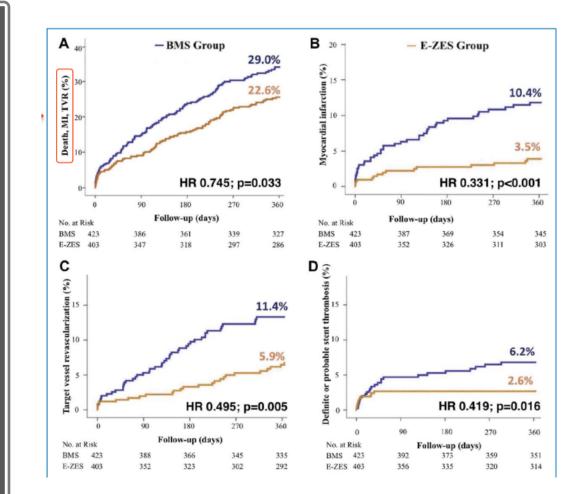
# **ZEUS-HBR study design**

Urgent or emergent coronary stenting in patients fulfilling ≥1 of the below:

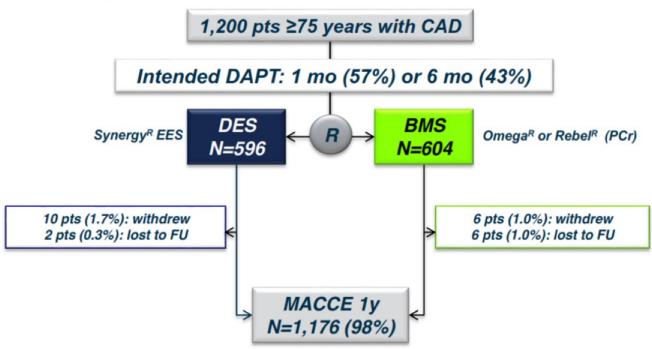


# **ZEUS HBR**

Ariotti et al. J Am Coll Cardiol Intv 2016;9:426-36

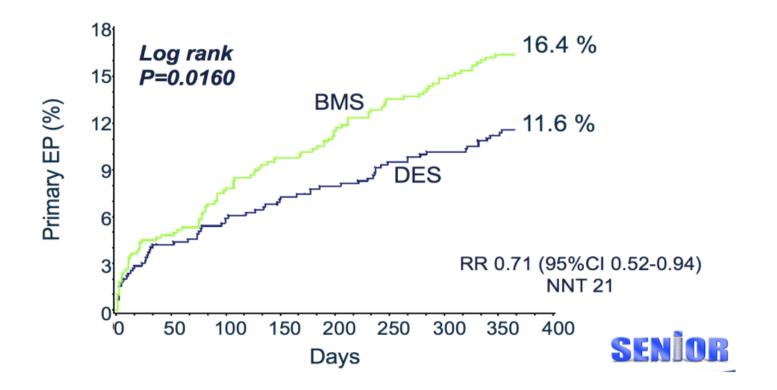






## Primary Endpoint (MACCE)

All-cause mortality, MI, stroke, ischemia-driven TLR



# HBR patients

- Efficacy: a BA9-DCS (LEADERS FREE I & II), the E-ZES (ZEUS-HBR) and a EES (SENIOR) have lower rates of TLR/TVR than a BMS with a short DAPT course
- Safety: a BA9-DCS (LEADERS FREE) I & II) and the E-ZES (ZEUS-HBR) are superior to BMS with short one month DAPT

# Short DAPT with DES in *non HBR*

Many trials aimed to analyze the *safety* and the *efficacy* of short DAPT among all-comers patients Results from a Meta-Analysis

#### Duration of Dual Antiplatelet Therapy After Drug-Eluting Stent Implantation

A Systematic Review and Meta-Analysis of Randomized Controlled Trials

| Study (Ref. #)                            | Year | Study<br>Population (n) | S-DAPT<br>(Months) | L-DAPT<br>(Months) | Time of<br>Follow-Up* | Placebo-<br>Controlled | Primary Endpoint  | Age<br>(yrs) |    | ACS<br>(%)        | 1G-DES<br>(%) | 2G-DES<br>(%) |
|---|------|-------------------------|--------------------|--------------------|-----------------------|------------------------|---|--------------|----|-------------------|---------------|---------------|
| 3- or 6-month DAPT discontinuation trials |      |                         |                    |                    |                       |                        |   |              |    |                   |               |               |
| ISAR-SAFE (16)                            | 2014 | 4,000                   | 6                  | 12                 | 6                     | Yes                    | Composite of death, MI, stroke,<br>stent thrombosis, or TIMI major<br>bleeding at 15 months after PCI           | 67           | 25 | 40                | 10            | 89            |
| ITALIC (17)                               | 2014 | 1,822                   | 6                  | 12                 | 6                     | No                     | Composite of death, MI, repeat TVR,<br>stroke, or TIMI major bleeding<br>at 12 months after PCI                 | 62           | 37 | 24                | -             | 100†          |
| SECURITY (18)                             | 2014 | 1,399                   | 6                  | 12                 | 12‡                   | No                     | Composite of cardiac death, MI,<br>stroke, stent thrombosis, or BARC 3<br>or 5 bleeding at 12 months after PCI  | 65           | 31 | 38 <mark>5</mark> | -             | 100           |
| OPTIMIZE (15)                             | 2014 | 3,119                   | 3                  | 12                 | 12                    | No                     | Composite of death, MI, stroke, or major<br>bleeding at 12 months after PCI                                     | 62           | 35 | 32 <mark>5</mark> | -             | 100           |
| PRODIGY (20)                              | 2012 | 1,970                   | 6                  | 24                 | 23                    | No                     | Composite of death, MI, or<br>cerebrovascular accidents<br>at 24 months after PCI                               | 68           | 24 | 75                | 25            | 50            |
| EXCELLENT (19)                            | 2011 | 1,443                   | 6                  | 12                 | 12                    | No                     | Composite of cardiac death, MI, or<br>TVR at 12 months after PCI  | 63           | 38 | 52                | 25            | 75            |
| RESET (14)                                | 2012 | 2,117                   | 3                  | 12                 | 12                    | No                     | Composite of cardiac death, MI,<br>stent thrombosis, ischemia-driven TVR,<br>or bleeding at 12 months after PCI | 62           | 29 | 54                | 21            | 85            |

Giustino et al., J Am Coll Cardiol. 2015 Apr 7;65(13):1298-310

#### Many trials aimed to analyze the *safety* and the *efficacy* of short DAPT among all-comers patients

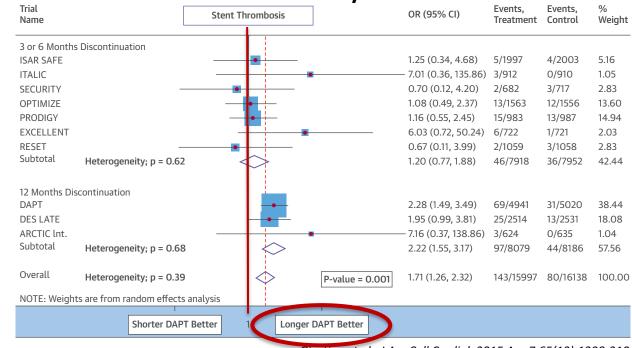
Results from a Meta-Analysis

#### Safety

| Trial<br>Name |                            | Clinically Significant Blee | ding               | OR (95% CI)       |
|---------------|----------------------------|-----------------------------|--------------------|-------------------|
| 3 or 6 Month  | s Discontinuation          |                             |                    |                   |
| ISAR SAFE     |                            |                             |                    | 0.46 (0.17, 1.22) |
| ITALIC        |                            |                             |                    | 0.71 (0.22, 2.25) |
| SECURITY      | -                          | •                           |                    | 0.52 (0.16, 1.74) |
| OPTIMIZE      |                            |                             |                    | 0.71 (0.31, 1.60) |
| PRODIGY       |                            |                             |                    | 0.55 (0.29, 1.04) |
| EXCELLENT     |                            |                             |                    | 0.50 (0.09, 2.73) |
| RESET         |                            |                             |                    | 0.50 (0.17, 1.46) |
| Subtotal      | Heterogeneity; p = 0.99    | $\langle \rangle$           |                    | 0.57 (0.40, 0.81) |
| 12 Months Di  | scontinuation              |                             |                    |                   |
| DAPT          |                            | _ <b>_</b>                  |                    | 0.68 (0.52, 0.90  |
| DES LATE      |                            |                             |                    | 0.63 (0.46, 0.87) |
| ARCTIC lnt.   | •                          |                             |                    | 0.14 (0.02, 1.17) |
| Subtotal      | Heterogeneity; p = 0.34    | $\diamond$                  |                    | 0.65 (0.52, 0.81) |
| Overall       | Heterogeneity; p = 0.95    | $\diamond$                  | P-value < 0.0001   | 0.63 (0.52, 0.75) |
| NOTE: Weigh   | ts are from random effects | analysis                    |                    |                   |
|               | Shorter DAPT B             | etter 1                     | Longer DAPT Better |                   |

Giustino et al., J Am Coll Cardiol. 2015 Apr 7;65(13):1298-310

Many trials aimed to analyze the *safety* and the *efficacy* of short DAPT among all-comers patients Results from a Meta-Analysis



All-type DES

Efficacy

Giustino et al., J Am Coll Cardiol. 2015 Apr 7;65(13):1298-310

Many trials aimed to analyze the *safety* and the *efficacy* of short DAPT among all-comers patients Results from a Meta-Analysis

> STENT THROMBOSIS Odds Ratio (95% CI) rial Name Second Generation DES DΔPT 2.64 (1.17, 5.98) ITALIC 7.01 (0.36, 135.86) SECURITY 0.70 (0.12, 4.20) PRODIGY 0.25 (0.03, 2.25) EXCELLENT 3.01 (0.31, 28.99) OPTIMIZE 1.08 (0.49, 2.37) **Subtotal** Heterogeneity; p = 0.21 1.54 (0.96, 2.47) P for Interaction = 0.008 First Generation DES DAPT 4.44 (2.22, 8.87) PRODIGY 2.30 (0.70, 7.56) **FXCELLENT** 7.12 (0.37, 138.77) Subtotal Heterogeneity; p = 0.59 3.94 (2.20, 7.05) Overall 2.33 (1.63, 3.34) Longer DAPT Better Shorter DAPT Better

Giustino et al., J Am Coll Cardiol. 2015 Apr 7;65(13):1298-310

but.. rate of ST significantly attenuated with the use of 2° gen-DES

# **Insights from the RESET Trial**

#### E-ZES 3m DAPT vs DES 12m DAPT

Journal of the American College of Cardiology © 2012 by the American College of Cardiology Foundation Published by Elsevier Inc. Vol. 60, No. 15, 2012 ISSN 0735-1097/\$36.00 http://dx.doi.org/10.1016/j.jacc.2012.06.043

# A New Strategy for Discontinuation of Dual Antiplatelet Therapy

The RESET Trial (REal Safety and Efficacy of 3-month dual antiplatelet Therapy following Endeavor zotarolimus-eluting stent implantation)

• Endeavor zotarolimus-eluting stent (ZES):

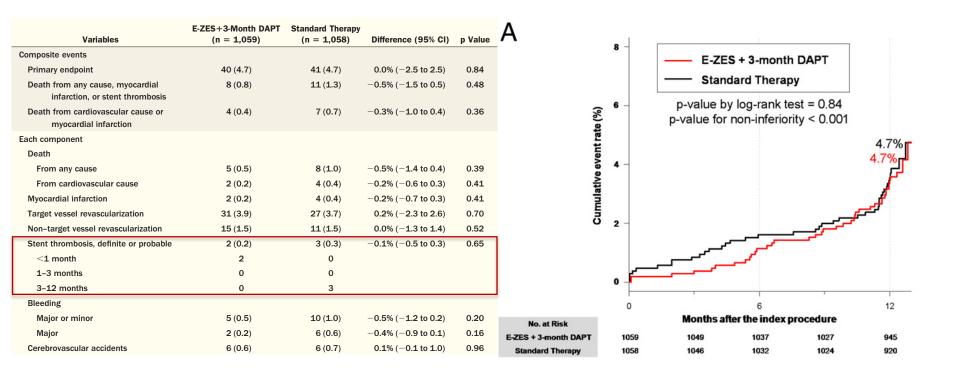
2° gen. DES with *phosphorylcholine coating*: ability to reduce thrombus formation on the coated stent struts

- 2,117 patients: E-ZES 3-month DAPT (n 1,059) versus any DES 12-month DAPT (n 1,058)
- Hypothesis: E-ZES 3-month DAPT non-inferior to the standard therapy for primary composite endpoint (cardiovascular death, myocardial infarction, stent thrombosis, target\vessel revascularization, or bleeding) at 1 year.

3m DAPT in

Stable CAD

# **Insights from the RESET Trial**



The RESET Trial - Kim et al. JACC Vol. 60, No. 15, 2012

#### E-ZES 3m DAPT vs E-ZES 12m DAPT



- To assess the clinical non-inferiority of 3 months vs 12 months of DAPT in patients undergoing PCI with E-ZES.
- 3119 patients in 33 sites in Brazil between April 2010 and March 2012
- The primary endpoint was net adverse clinical and cerebral events (NACCE; a composite of all-cause death, myocardial infarction, stroke, or major bleeding).

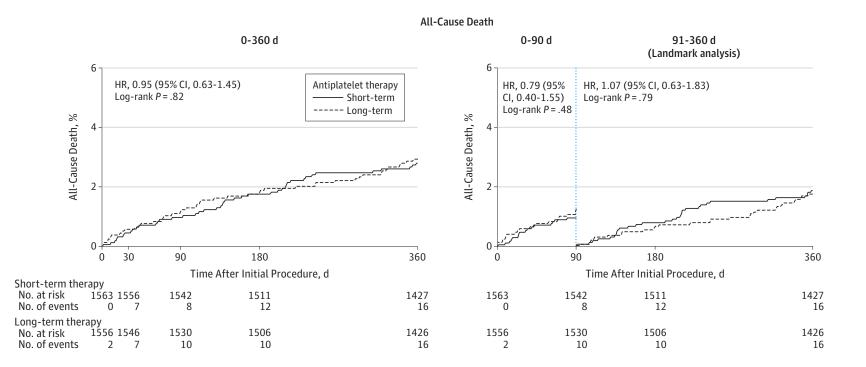
|   | Patients              | Log-Rank              |                |
|---|-----------------------|-----------------------|----------------|
| Clinical Outcomes                         | Short-term (n = 1563) | Long-term (n = 1556)  | <i>P</i> Value |
| Events up to 1 y                          |                       |                       |                |
| NACCE <sup>b</sup>                        | 93 (6.0) <sup>c</sup> | 90 (5.8) <sup>c</sup> | .84            |
| All-cause death                           | 43 (2.8)              | 45 (2.9)              | .82            |
| MI  | 49 (3.2)              | 42 (2.7)              | .47            |
| Stroke                                    | 5 (0.3)               | 5 (0.3)               | .99            |
| Major bleeding <sup>d</sup>               | 10 (0.6)              | 14 (0.9)              | .41            |
| Stent thrombosis, definite or probable    | 13 (0.8)              | 12 (0.8)              | .86            |
| Cardiac death                             | 29 (1.9)              | 32 (2.1)              | .69            |
| Cardiac death or MI                       | 70 (4.5)              | 62 (4.0)              | .49            |
| Cardiac death, MI, or stent thrombosis    | 72 (4.7)              | 65 (4.2)              | .56            |
| Death, MI, or stroke                      | 87 (5.6)              | 78 (5.1)              | .49            |
| Major adverse cardiac events <sup>e</sup> | 128 (8.3)             | 114 (7.4)             | .36            |
| Target-lesion revascularization           | 53 (3.5)              | 49 (3.2)              | .70            |
| Target-vessel revascularization           | 70 (4.6)              | 57 (3.8)              | .25            |
| Any bleeding <sup>f</sup>                 | 35 (2.3)              | 45 (2.9)              | .25            |

Up to 1 year

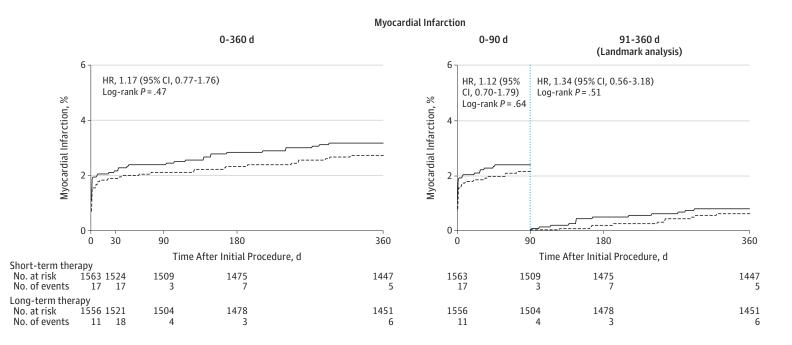
| 91 d to 1 y                               |          |          |     |
|---|----------|----------|-----|
| NACCE <sup>b</sup>                        | 39 (2.6) | 38 (2.6) | .91 |
| All-cause death                           | 28 (1.9) | 26 (1.7) | .79 |
| MI  | 12 (0.8) | 9 (0.6)  | .51 |
| Stroke                                    | 4 (0.3)  | 2 (0.1)  | .42 |
| Major bleeding <sup>d</sup>               | 3 (0.2)  | 6 (0.4)  | .31 |
| Stent thrombosis, definite or probable    | 4 (0.3)  | 1 (0.1)  | .18 |
| Cardiac death                             | 20 (1.3) | 20 (1.3) | .99 |
| Cardiac death or MI                       | 27 (1.8) | 24 (1.7) | .67 |
| Cardiac death, MI, or stent thrombosis    | 28 (1.9) | 24 (1.6) | .58 |
| Death, MI, or stroke                      | 38 (2.6) | 32 (2.2) | .47 |
| Major adverse cardiac events <sup>e</sup> | 78 (5.3) | 64 (4.3) | .23 |
| Target-lesion revascularization           | 50 (3.3) | 40 (2.7) | .30 |
| Target-vessel revascularization           | 63 (4.2) | 47 (3.2) | .12 |
| Any bleeding <sup>f</sup>                 | 6 (0.4)  | 14 (1.0) | .07 |

91 days to 1 year

Feres F. et al; JAMA. 2013 Dec 18;310(23):2510-22



Feres F. et al; JAMA. 2013 Dec 18;310(23):2510-22



In patients with stable coronary artery disease or low-risk ACS treated with zotarolimus-eluting stents, 3 months of dual antiplatelet therapy was noninferior to 12 months for NACCE, without significantly increasing the risk of stent thrombosis.

# Insights from the REDUCE Trial

COMBO DES 3m DAPT vs 12m DAPT

Randomized evaluation of short-term dual antiplatelet therapy in patients with acute coronary syndrome treated with the COMBO dual therapy stent: rationale and design of the REDUCE trial

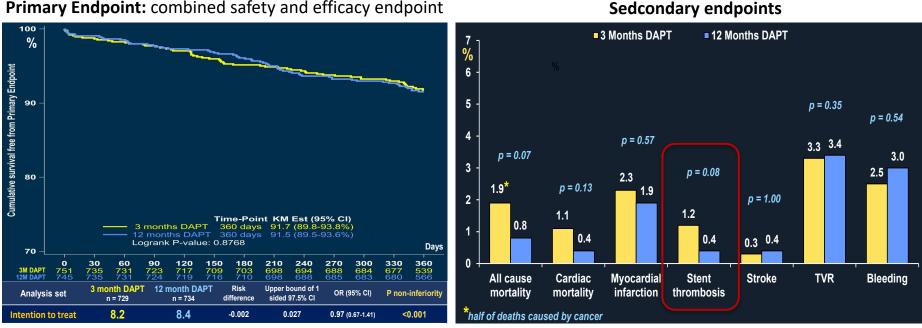
Cyril Camaro, <sup>a</sup> Sander A. J. Damen, <sup>a</sup> Marc A. Brouwer, <sup>a</sup> Elvin Kedhi, <sup>b</sup> Stephan W. Lee, <sup>c</sup> Monica Verdoia, <sup>d</sup> Lucia Barbieri, <sup>d</sup> Andrea Rognoni, <sup>d</sup> Arnoud W. J. van t Hof, <sup>b</sup> Erik Ligtenberg, <sup>c</sup> Menko-Jan de Boer, <sup>a</sup> Harry Suryapranata, <sup>a</sup> and Giuseppe De Luca, <sup>d</sup> Nijmegen, Zwolle, The Netherlands; Hong Kong; Novara, Italy; and Fort Lauderdale, USA

ACS

CrossMark

- Only **ACS** patients included
- **COMBO** Dual Therapy Stent: combines abluminal release of sirolimus (to prevent neointima formation) and **capture of Endothelial Progenitor Cells CD34 AB** (to enhance stent re-endothelialization and therefore to prevent ST)
- Short DAPT (3m, 751 pts) vs long DAPT (12m, 745 pts) in ACS pts.
- Primary endpoint: composite of all cause death, MI, ST, stroke, TVR or bleeding.

# **Insights from the REDUCE Trial**



Primary Endpoint: combined safety and efficacy endpoint

Harry Survapranata, MD: TCT 2018

Therefore, a shorter DAPT strategy could be considered, if necessary, even in ACS population

# SMART-DATE trial (2018)

6-month versus 12-month or longer dual antiplatelet therapy after percutaneous coronary intervention in patients with acute coronary syndrome (SMART-DATE): a randomised, open-label, non-inferiority trial

| <b>Clinical presentation</b>              |             |             |
|---|-------------|-------------|
| ST-elevation myocardial infarction        | 509 (37·5%) | 514 (37·9%) |
| Non-ST-elevation<br>myocardial infarction | 428 (31·5%) | 425 (31·4%) |
| Unstable angina                           | 420 (31·0%) | 416 (30.7%) |
|   |             |             |
| Type of drug-eluting stents               |             |             |
| No stent                                  | 9 (0.7%)    | 5 (0.4%)    |
| Everolimus-eluting stents                 | 476 (35·1%) | 462 (34·1%) |
| Zotarolimus-eluting stents                | 459 (33·8%) | 459 (33·9%) |
| Biolimus-eluting stents                   | 406 (29·9%) | 419 (30.9%) |
| Other stents                              | 7 (0.5%)    | 10 (0.7%)   |

2712 ACS patients randomized 1:1 (short vs standard DAPT)

PRIMARY ENDPOINT: composite of all-cause death, MI, stroke at 18 months

Joo-Yong Hahn, Young Bin Song, et al, The lancet 2018

# SMART-DATE trial (2018)

|  | 6-month<br>DAPT group<br>(n=1357) | 12-month or<br>longer DAPT<br>group (n=1355) | HR (95% CI)       | p value |
|--|-----------------------------------|--|-------------------|---------|
| Major adverse cardiac and cerebrovascular events | 63 (4.7%)                         | 56 (4·2%)                                    | 1.13 (0.79–1.62)  | 0.51    |
| Death  | 35 (2.6%)                         | 39 (2·9%)                                    | 0.90 (0.57–1.42)  | 0.90    |
| Myocardial infarction                            | 24 (1.8%)                         | 10 (0.8%)                                    | 2.41 (1.15–5.05)  | 0.02    |
| Target vessel myocardial infarction              | 14 (1.1%)                         | 7 (0.5%)                                     | 2.01 (0.81–4.97)  | 0.13    |
| Non-target vessel myocardial infarction          | 10 (0.8%)                         | 3 (0·2%)                                     | 3·35 (0·92–12·18) | 0.07    |
| Cerebrovascular accident (stroke)                | 11 (0.8%)                         | 12 (0.9%)                                    | 0.92 (0.41–2.08)  | 0.84    |
| Cardiac death                                    | 18 (1.4%)                         | 24 (1.8%)                                    | 0.75 (0.41–1.38)  | 0.36    |
| Cardiac death or myocardial infarction           | 39 (2·9%)                         | 32 (2·4%)                                    | 1.22 (0.77–1.95)  | 0.40    |
| Stent thrombosis                                 | 15 (1.1%)                         | 10 (0.7%)                                    | 1.50 (0.68–3.35)  | 0.32    |
| BARC type 2–5 bleeding                           | 35 (2.7%)                         | 51 (3.9%)                                    | 0.69 (0.45–1.05)  | 0.09    |
| Major bleeding                                   | 6 (0.5%)                          | 10 (0.8%)                                    | 0.60 (0.22–1.65)  | 0.33    |
| Net adverse clinical and cerebral events*        | 96 (7·2%)                         | 99 (7·4%)                                    | 0.97 (0.73–1.29)  | 0.84    |

Data are n (%), unless otherwise stated. Percentages are Kaplan-Meier estimates. We defined major adverse cardiac and cerebrovascular events as a composite of all-cause mortality, myocardial infarction, and stroke. DAPT=dual antiplatelet therapy. HR=hazard ratio. BARC=Bleeding Academic Research Consortium. \*Net adverse clinical and cerebral events were defined as major adverse cardiac and cerebrovascular events plus BARC type 2–5 bleeding.

#### Table 3: Clinical primary and secondary outcomes at 18 months

# **Ongoing trials**

| Study             | NCT         | Device                       | DAPT Duration               | Study Design     | Patients |
|-------------------|-------------|------------------------------|-----------------------------|------------------|----------|
| COBRA REDUCE      | NCT02594501 | Cobra PzF vs.<br>new-DES     | 2 weeks vs. 3-to-6<br>month | RCT              | 996      |
| EVOLVE Short DAPT | NCT02605447 | Synergy                      | 3 months                    | Single-arm study | 2,009    |
| MASTER-DAPT       | NCT03023020 | Ultimaster                   | 1 month                     | RCT              | 4,300    |
| Onyx ONE          | NCT03344653 | Resolute vs.<br>BioFreedom   | 1 month                     | RCT              | 2,000    |
| Onyx ONE Clear    | NCT03647475 | Resolute                     | 1 month                     | Single-arm study | 800      |
| POEM              | NCT03112707 | Synergy                      | 1 month                     | Single-arm study | 1,023    |
| STOP-DAPT2 ACS    | NCT03462498 | Xience                       | 1 vs. 12 month              | RCT              | 3,000    |
| XIENCE 90         | NCT03218787 | Xience                       | 3 months                    | Single-arm study | 2,000    |
| XIENCE 28 Global  | NCT03355742 | Xience                       | 28 days                     | Single-arm study | 800      |
| ISAR-DAPT         | NCT02609698 | Coroflex ISAR                | 3 vs. 6 months              | RCT              | 900      |
| LEADERS FREE II   | NCT02843633 | BioFreedom                   | 1 month                     | Single-arm study | 1,200    |
| HOST-IDEA         | NCT02601157 | Corofles ISAR and Orsiro SES | 3 vs. 12 months             | RCT              | 2,152    |

# **Insights from the I-LOVE-IT 2 Trial**

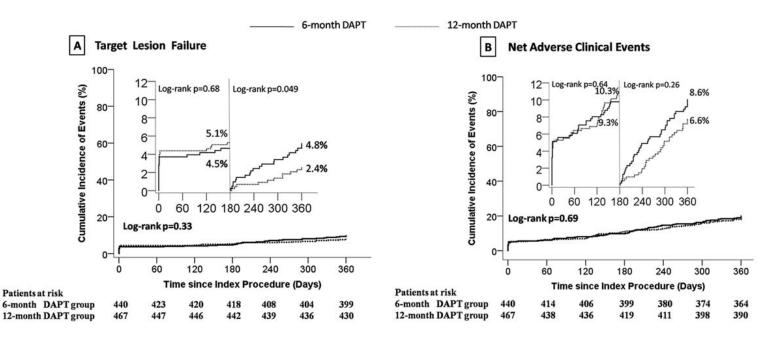
Multiple DES 6m DAPT vs 12m DAPT

Safety and Efficacy of 6-Month Versus 12-Month Dual Antiplatelet Therapy in Patients After Implantation of Multiple Biodegradable Polymer-Coated Sirolimus-Eluting Coronary Stents: Insight From the I-LOVE-IT 2 Trial

Jing Qi,<sup>1,2</sup> мd, Yi Li,<sup>1</sup> мd, Jing Li,<sup>1</sup> мd, Quanmin Jing,<sup>1</sup> мd, Kai Xu,<sup>1</sup> мd, Chuanyu Gao,<sup>3</sup> мd, Likun Ma,<sup>4</sup> мd, Zhi Zhang,<sup>5</sup> мd, Bo Xu,<sup>6</sup> мd, and Yaling Han,<sup>1\*</sup> мd, Phd

- 907 patients treated with multiple BP-SES (total stent number ≥ 2) were assigned to receive 6-month (n 5440) or 12-month (n 5467) DAPT.
- **Primary Endpoint:** 12-month target lesion failure (TLF), which is a composite of cardiac death, target vessel myocardial infarction (MI) or clinically indicated target lesion revascularization

# Insights from the I-LOVE-IT 2 Trial



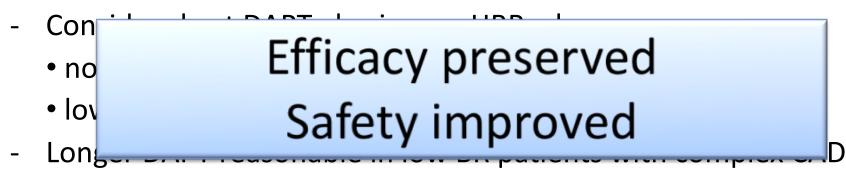
The incidence of 12-month TLF was comparable in the 6-month and 12-month DAPT groups (9.3% vs.7.5%, Log-rank P 5 0.33). How- ever, landmark analysis showed that 12-month DAPT, compared to 6-month DAPT, was associated with a significantly lower risk of TLF (4.8% vs. 2.4%, Log-rank P 0.049)

Jing Qi et al., Catheterization and Cardiovascular Interventions 89:555–564 (2017)

# Conclusions



- DES always over BMS
- Identify HBR patients: short DAPT mandatory



Word of caution in ACS patients while waiting for new evidences