ESC 2023 SUM
Scientific Update Meeting

Interventional Cardiology Updates

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ESC 2023 SUM

Scientific Update Meeting

1. OCT/Imaging trials.
2. Physiology trials.
3. STOP-DAPT3.

1. OCT trials

- OCTOBER- OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions.
- OCTIVUS- Optical Coherence Tomography–guided versus IntraVascular UltraSound–guided percutaneous coronary intervention.
- ILUMIEN IV- Optical Coherence Tomography–Guided versus Angiography-Guided PCI

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions

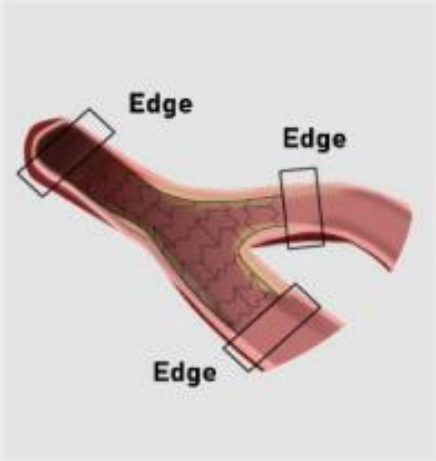
N.R. Holm, L.N. Andreasen, O. Neghabat, P. Laanmets, I. Kumsars, J. Bennett, N.T. Olsen, J. Odenstedt, P. Hoffmann, J. Dens, S. Chowdhary, P. O'Kane, S.-H. Bülow Rasmussen, M. Heigert, O. Havndrup, J.P. Van Kuijk, S. Biscaglia, L.J.H. Mogensen, L. Henareh, F. Burzotta, C. H. Eek, D. Mylotte, M.S. Llinas, L. Koltowski, P. Knaapen, S. Calic, N. Witt, I. Santos-Pardo, S. Watkins, J. Lønborg, A.T. Kristensen, L.O. Jensen, F. Calais, J. Cockburn, A. McNeice, O.A. Kajander, T. Heestermans, S. Kische, A. Eftekhari, J.C. Spratt, and E.H. Christiansen, for the OCTOBER Trial Group*

OCTOBER

- Aimed to compare OCT-guided vs. angiography-guided PCI of bifurcation coronary lesions.
- Open-labeled randomized trial.
  - 600 OCT vs 601 Angio only.
  - IVUS in Angio arm – LMCA lesions.
  - Strict OCT protocol.
  - Xience DES.
- Inclusion criteria:
  - Stable angina, unstable angina, or non–ST-segment elevation myocardial infarction (NSTEMI)
  - True bifurcation lesion - Main branch reference ≥2.75 mm, stenosis ≥50%; Side branch reference ≥2.5 mm, stenosis ≥50% within 5 mm from the ostium of the side branch
  - Main branch with functional significance (physiologically) or angiographic severity ≥80%.
- 2 years F.U

Criteria for optimization by OCT-guided PCI

Edge segments (5 mm)



Residual stenosis
Less than 30% diameter stenosis

Edge dissections
No edge dissections
1) visible by angiography, or
2) located in residual edge stenosis of more than 30% DS or a lumen smaller than 4.5 mm^2

Lipid plaque
No presence of a major lipid plaque spanning more than 180° of the edge segment circumference

Ruptured plaque
No presence of one of more plaque ruptures in the edge segment

Stented segments

Rewiring
Wire passing through a strut cell in front of the mid or distal part of the ostium.
No unintended abluminal rewiring

Stent malapposion
No malapposition

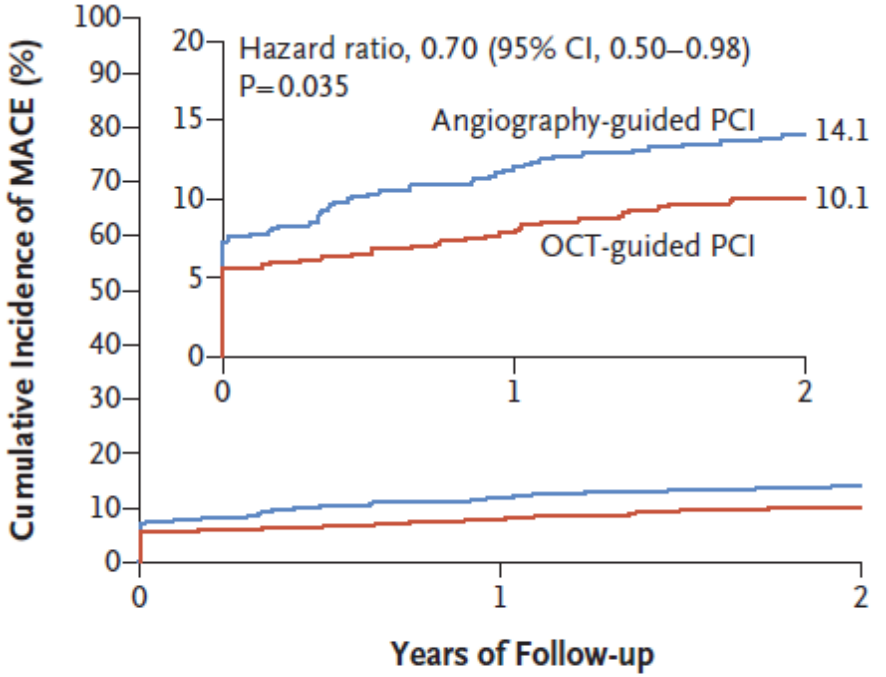
Accidental crushed stent segments
No unintend major distortion or crush of implanted stents

Stent expansion
Stent diameter ≥ 90% of the corresponding segment´s reference diameter

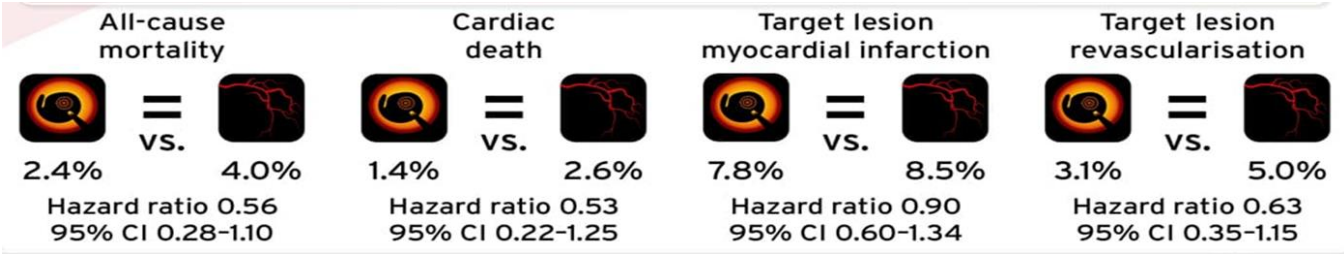
Side branch ostium in one-stent technique
Minimal lumen diameter ≥ 50% of the reference diameter

OCTOBER - RESULTS

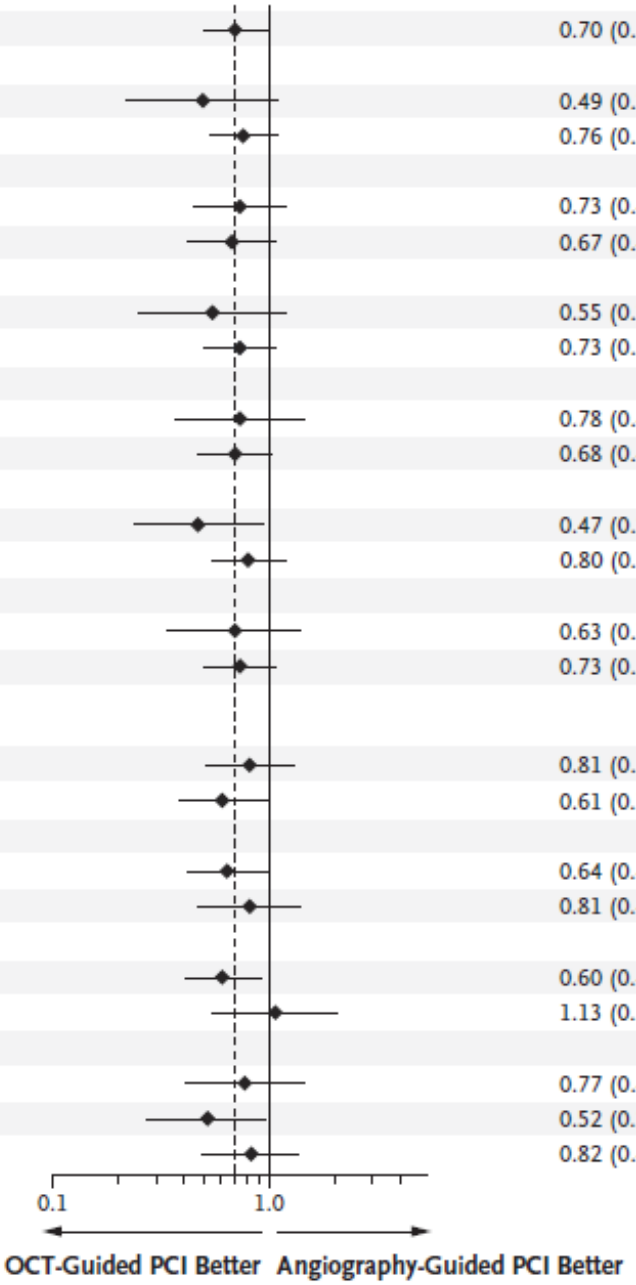
- Characteristics :
  - 21% females, mean age 66 y/o
  - Indication: Stable angina: 54%, NSTEMI: 13%
  - Median EF: 58%
  - Prior PCI: 41.7%
  - Renal failure: 2.2%
  - Left main bifurcation treated: 18.9%
  - One-stent strategy: 35%.



No. at Risk			
Angiography-guided PCI	601	509	408
OCT-guided PCI	600	537	439



Subgroup	OCT-Guided PCI (N=600)	Angiography-Guided PCI (N=601)	Hazard Ratio (95% CI)
	no. of events/total no. of patients (%)		
All patients	59/600 (10)	83/601 (14)	0.70 (0.50–0.98)
Sex			
Female	9/127 (8)	18/126 (15)	0.49 (0.22–1.08)
Male	50/473 (11)	65/475 (14)	0.76 (0.53–1.10)
Age			
<65 yr	29/249 (12)	39/248 (16)	0.73 (0.45–1.18)
≥65 yr	30/351 (9)	44/353 (13)	0.67 (0.42–1.07)
Diabetes mellitus			
Yes	10/103 (10)	16/97 (17)	0.55 (0.25–1.20)
No	48/490 (10)	66/497 (14)	0.73 (0.5–1.06)
Left main coronary artery as trial bifurcation			
Yes	15/111 (14)	20/116 (19)	0.78 (0.40–1.51)
No	44/489 (9)	63/485 (13)	0.68 (0.46–1.00)
Stent technique			
One-stent	12/209 (6)	26/219 (12)	0.47 (0.24–0.93)
Two-stent	47/388 (13)	57/382 (15)	0.80 (0.55–1.18)
Multivessel			
Yes	12/106 (12)	22/125 (18)	0.63 (0.31–1.28)
No	47/494 (10)	61/476 (13)	0.73 (0.50–1.07)
Acute coronary syndrome or staged PCI from recent AMI			
Yes	31/270 (12)	39/280 (14)	0.81 (0.51–1.30)
No	28/330 (9)	44/321 (14)	0.61 (0.38–0.98)
Calcified lesion			
None-to-minor	35/402 (9)	54/405 (14)	0.64 (0.42–0.98)
Moderate-to-severe	24/198 (13)	29/194 (15)	0.81 (0.47–1.39)
SB lesion length >5 mm by QCA			
Yes	40/425 (10)	63/413 (16)	0.60 (0.40–0.89)
No	19/159 (12)	18/169 (11)	1.13 (0.59–2.16)
SYNTAX score			
<17	17/219 (8)	22/221 (10)	0.77 (0.41–1.45)
17–21	15/189 (8)	27/181 (15)	0.52 (0.27–0.97)
>21	27/191 (14)	34/197 (18)	0.82 (0.49–1.35)



- Contrast volume use: 300 vs. 200 cc
- Procedure duration: 113 vs. 80 mins

CONCLUSIONS

- OCT-guided PCI of complex bifurcation lesions is superior to angiography-guided PCI for cardiovascular outcomes at 2 years.
  - The approach was beneficial for both LM and non-LM bifurcation PCI.
- The biggest reduction was noted in ischemia-driven target lesion revascularization.
- This came at the expense of greater contrast use and longer procedural duration of PCI.
- NNT? ARR of 4%

10.1161/CIRCULATIONAHA.123.066429

Optical Coherence Tomography-Guided or Intravascular Ultrasound Guided Percutaneous Coronary Intervention: The OCTIVUS Randomized Clinical Trial

Running title: *OCT- vs. IVUS-guided PCI*

Do-Yoon Kang, MD[1]; Jung-Min Ahn, MD[1]; Sung-Cheol Yun, PhD[2]; Seung-Ho Hur, MD[3]; Yun-Kyeong Cho, MD[3]; Cheol Hyun Lee, MD[3]; Soon Jun Hong, MD[4]; Subin Lim, MD[4]; Sang-Wook Kim, MD[5]; Hoyoun Won, MD[6]; Jun-Hyok Oh, MD[7]; Jeong Cheon Choe, MD[7]; Young Joon Hong, MD[8]; Yong-Hoon Yoon, MD[9], Hoyun Kim, MD[1]; Yeonwoo Choi, MD [1]; Jinho Lee, MD[1]; Young Won Yoon, MD[10]; Soo-Joong Kim, MD[11]; Jang-Ho Bae, MD[12]; Duk-Woo Park, MD[1]; and Seung-Jung Park, MD[1] for the OCTIVUS Investigators*

OCTIVUS

- Head to head comparison of OCT vs IVUS.
- 9 sites, South Korea.
- 2,008 patients undergoing PCI with DES or DEB (ISR).
- Non-inferiority.
- 1 year follow up
- 21% females, mean age 64 y/o.
- 66% CCS, 10% NSTEMI.
- 10% ostial lesions, 13% LMCA, 52% bifurcation, 5% CTO

OCTIVUS

Primary endpoint

Composite of death from cardiac causes, target vessel myocardial infarction or ischaemia-driven target vessel revascularisation at 1 year, which was powered for noninferiority of the OCT group as compared with the IVUS group (noninferiority margin, 3.1 percentage points)

Rate%

2.5%

3.1%

risk difference, −0.6 percentage points
upper boundary of the one-sided
97.5% CI 0.97; p<0.001 for noninferiority

Safety endpoints

Incidence of contrast-induced nephropathy was similar

=

1.4% 1.5%

Incidence of major procedural complications was lower with

vs.

p=0.048

2.2% 3.7%

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ORIGINAL ARTICLE

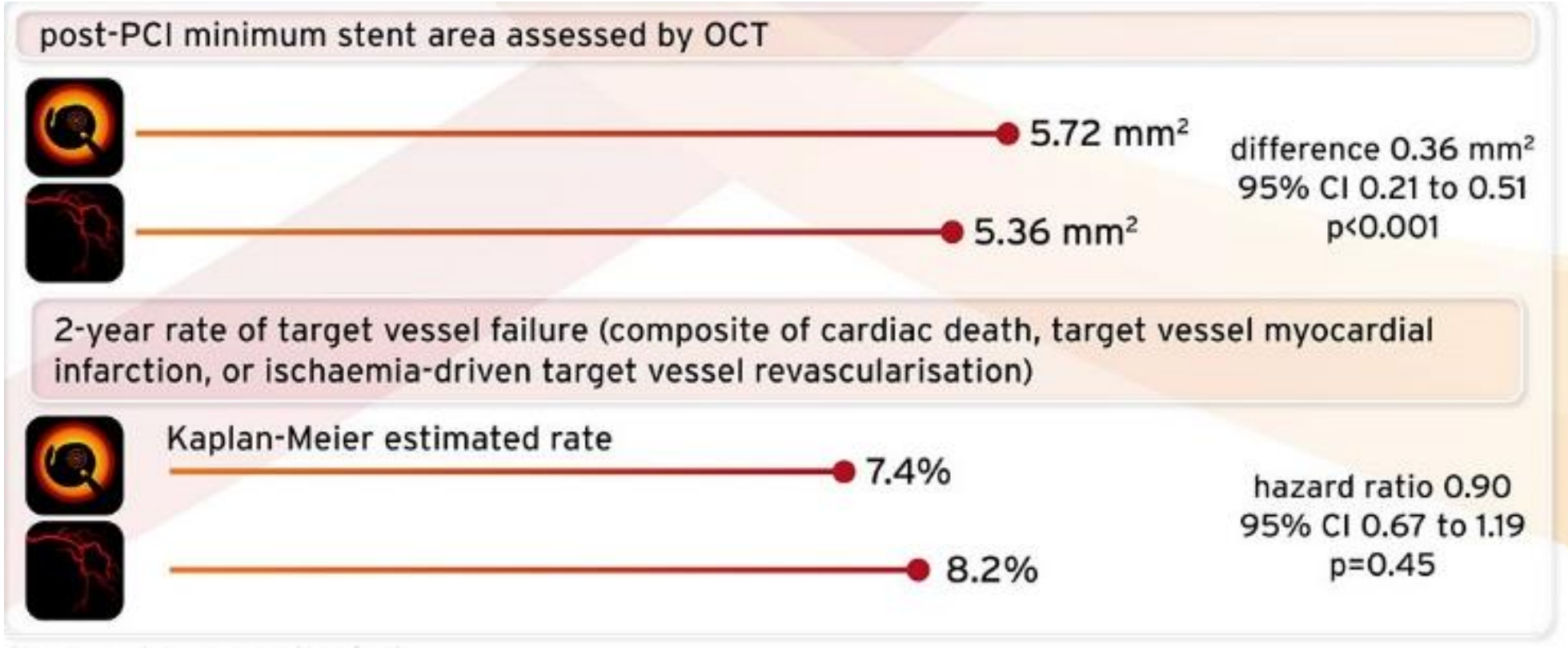
Optical Coherence Tomography–Guided versus Angiography-Guided PCI

Ziad A. Ali, M.D., D.Phil., Ulf Landmesser, M.D., Akiko Maehara, M.D., Mitsuaki Matsumura, B.S., Richard A. Shlofmitz, M.D., Giulio Guagliumi, M.D., Matthew J. Price, M.D., Jonathan M. Hill, M.D., Takashi Akasaka, M.D., Francesco Prati, M.D., Hiram G. Bezerra, M.D., William Wijns, M.D., Ph.D., David Leistner, M.D., Paolo Canova, M.D., Fernando Alfonso, M.D., Franco Fabbiocchi, M.D., Ozgen Dogan, M.D., Robert J. McGreevy, Ph.D., Robert W. McNutt, Ph.D., Hong Nie, Ph.D., Jana Buccola, M.S., Nick E.J. West, M.D., and Gregg W. Stone, M.D., for the ILUMIEN IV Investigators*

ILUMIEN IV

- OCT vs Angio PCI-
  - Outcomes: Minimal stent area, TVF.
  - Complex patients/ lesions.
    - Must had an evidence of myocardial ischemia
    - Diabetes on medication, and/or non–ST-segment elevation myocardial infarction (NSTEMI) or STEMI, long or multiple lesions (planned total stent length ≥28 mm), bifurcation lesion, severe calcification, chronic total occlusion, in-stent restenosis.
- 2,487 patients, 80 sites, 18 countries.
- Median f/u – 2 years.
- 23% females, mean age 66 y/o, 41% DM.
- ~50% ACS

Outcomes



- Lower rates of stent thrombosis 0.5% vs 1.4%

2. Physiology Trials

- FIRE trial - Complete or Culprit-Only PCI in Older Patients with Myocardial Infarction.
- Coronary revascularization guided by instantaneous wave-free ratio compared with fractional flow reserve:
  pooled 5-year mortality in the DEFINE-FLAIR and iFR-SWEDEHEART trials .
- FLOWER MI – 3 years outcomes

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

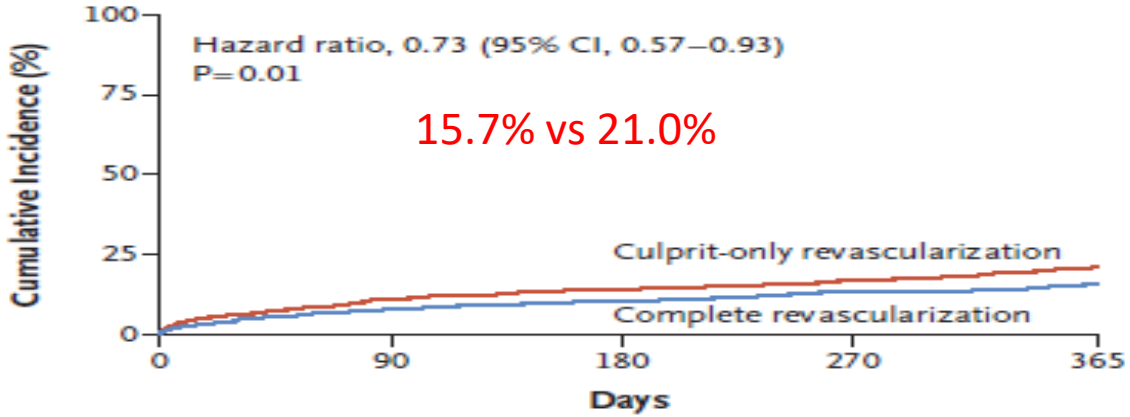
Complete or Culprit-Only PCI in Older Patients with Myocardial Infarction

S. Biscaglia, V. Guiducci, J. Escaned, R. Moreno, V. Lanzilotti, A. Santarelli, E. Cerrato, G. Sacchetta, A. Jurado-Roman, A. Menozzi, I. Amat Santos, J.L. Díez Gil, M. Ruozzi, M. Barbierato, L. Fileti, A. Picchi, V. Lodolini, G. Biondi-Zoccai, E. Maietti,* R. Pavasini, P. Cimaglia, C. Tumscitz, A. Erriquez, C. Penzo, I. Colaiori, G. Pignatelli, G. Casella, G. Iannopollo, M. Menozzi, F. Varbella, G. Caretta, D. Dudek, E. Barbato, M. Tebaldi, and G. Campo, for the FIRE Trial Investigators†

FIRE

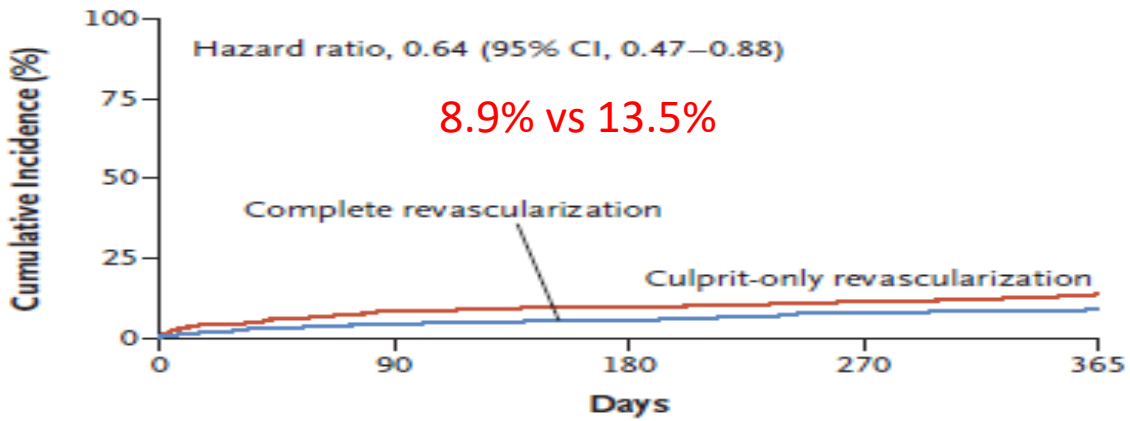
- To determine whether physiology guided complete revascularization is superior to culprit-only revascularization in elderly patients (>75 y/o) with multivessel disease suffering acute MI.
- Patients with acute MI and multivessel CAD were randomized to multivessel revascularization guided by coronary physiology (n = 720) vs. culprit-only revascularization (n = 725)- Following successful Culprit PCI.
  - In the complete revasc group – 50% underwent PCI (mean 5 days post PPCI)
- 37% females, mean age 80 y/o, DM 32%, EF-49%
  - 8% s/p stroke, 18% s/p PCI, 14% AF,
- 35% STEMI, 28% Killip ≥2

A **Death, Myocardial Infarction, Stroke, or Coronary Revascularization (Primary Outcome)**



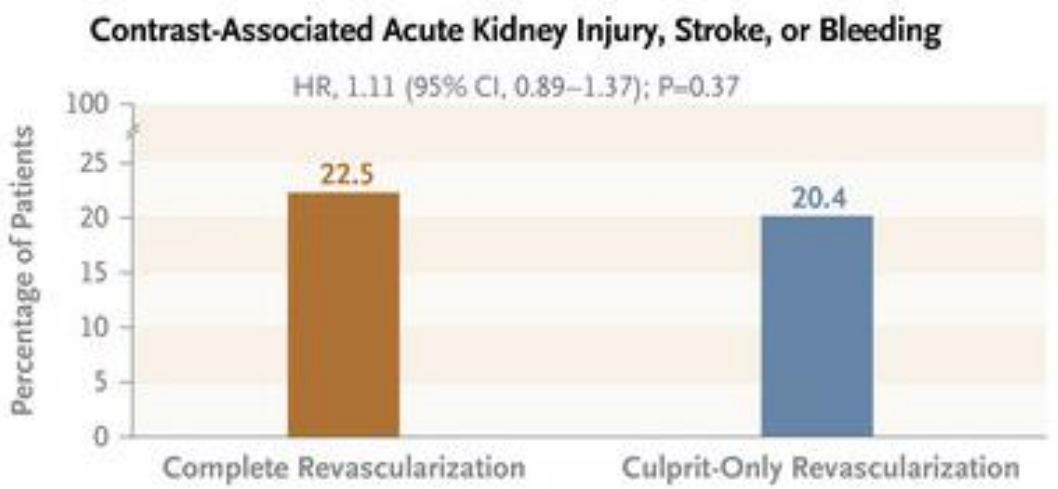
No. at Risk					
Culprit-only revascularization	725	644	621	602	573
Complete revascularization	720	664	644	625	607

B **Cardiovascular Death or Myocardial Infarction (Key Secondary Outcome)**

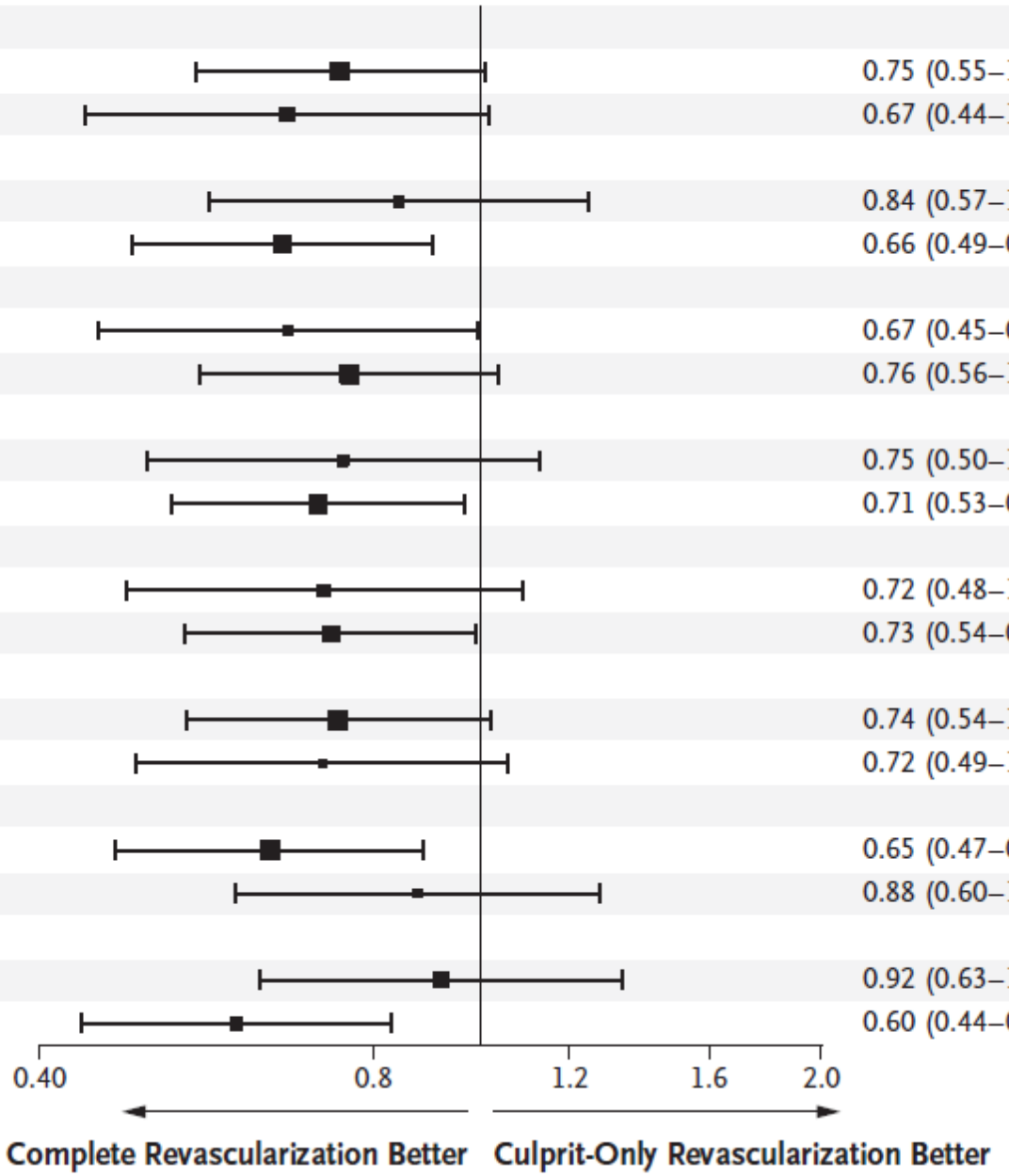


No. at Risk					
Culprit-only revascularization	725	654	634	618	592
Complete revascularization	720	675	659	641	627

Other secondary outcomes			
Death			
From any cause	93 (12.8)	66 (9.2)	0.70 (0.51–0.96)
From cardiovascular cause	56 (7.7)	36 (5.0)	0.64 (0.42–0.97)
Myocardial infarction	51 (7.0)	32 (4.4)	0.62 (0.40–0.97)
Death or myocardial infarction	133 (18.3)	93 (12.9)	0.68 (0.52–0.88)
Stroke	7 (1.0)	12 (1.7)	1.73 (0.68–4.40)
Ischemia-driven coronary revascularization	49 (6.8)	31 (4.3)	0.63 (0.40–0.98)
Other outcomes			
Noncardiovascular death	37 (5.1)	30 (4.2)	0.82 (0.50–1.32)
Cerebrovascular accident‡	9 (1.2)	18 (2.5)	2.03 (0.91–4.52)
Transient ischemic attack	2 (0.3)	6 (0.8)	3.06 (0.62–15.1)
Stent thrombosis			
Definite	5 (0.7)	6 (0.8)	1.21 (0.37–3.96)
Probable	3 (0.4)	1 (0.1)	0.34 (0.04–3.22)



Subgroup	Complete Revascularization	Culprit-Only Revascularization	Hazard Ratio for Primary Outcome (95% CI)
	no. of events (%)		
Age			
≥80 yr	77 (18.0)	95 (23.3)	0.75 (0.55–1.01)
<80 yr	36 (12.4)	57 (17.9)	0.67 (0.44–1.01)
Sex			
Female	46 (17.5)	54 (20.4)	0.84 (0.57–1.25)
Male	67 (14.7)	98 (21.3)	0.66 (0.49–0.90)
Diabetes mellitus			
Yes	42 (18.3)	60 (25.8)	0.67 (0.45–0.99)
No	71 (14.5)	92 (18.7)	0.76 (0.56–1.04)
STEMI			
Yes	41 (16.2)	54 (21.1)	0.75 (0.50–1.13)
No	72 (15.4)	98 (20.9)	0.71 (0.53–0.97)
Left anterior descending artery			
Yes	40 (13.8)	53 (18.6)	0.72 (0.48–1.09)
No	73 (17.0)	99 (22.5)	0.73 (0.54–0.99)
LVEF			
≥45%	69 (13.3)	89 (17.4)	0.74 (0.54–1.02)
<45%	44 (22.0)	63 (29.7)	0.72 (0.49–1.06)
Killip class			
I	63 (12.2)	94 (18.2)	0.65 (0.47–0.89)
≥II	50 (24.5)	58 (27.9)	0.88 (0.60–1.28)
eGFR EPI–CDK			
≥60	52 (13.3)	57 (14.5)	0.92 (0.63–1.34)
<60	61 (18.5)	95 (28.6)	0.60 (0.44–0.83)



Conclusions

- Among elderly patients with acute MI, physiology-guided complete revascularization improves outcomes compared with culprit-lesion only revascularization.
- The incidence of acute kidney injury, stroke, or major bleeding was similar between the treatment groups.

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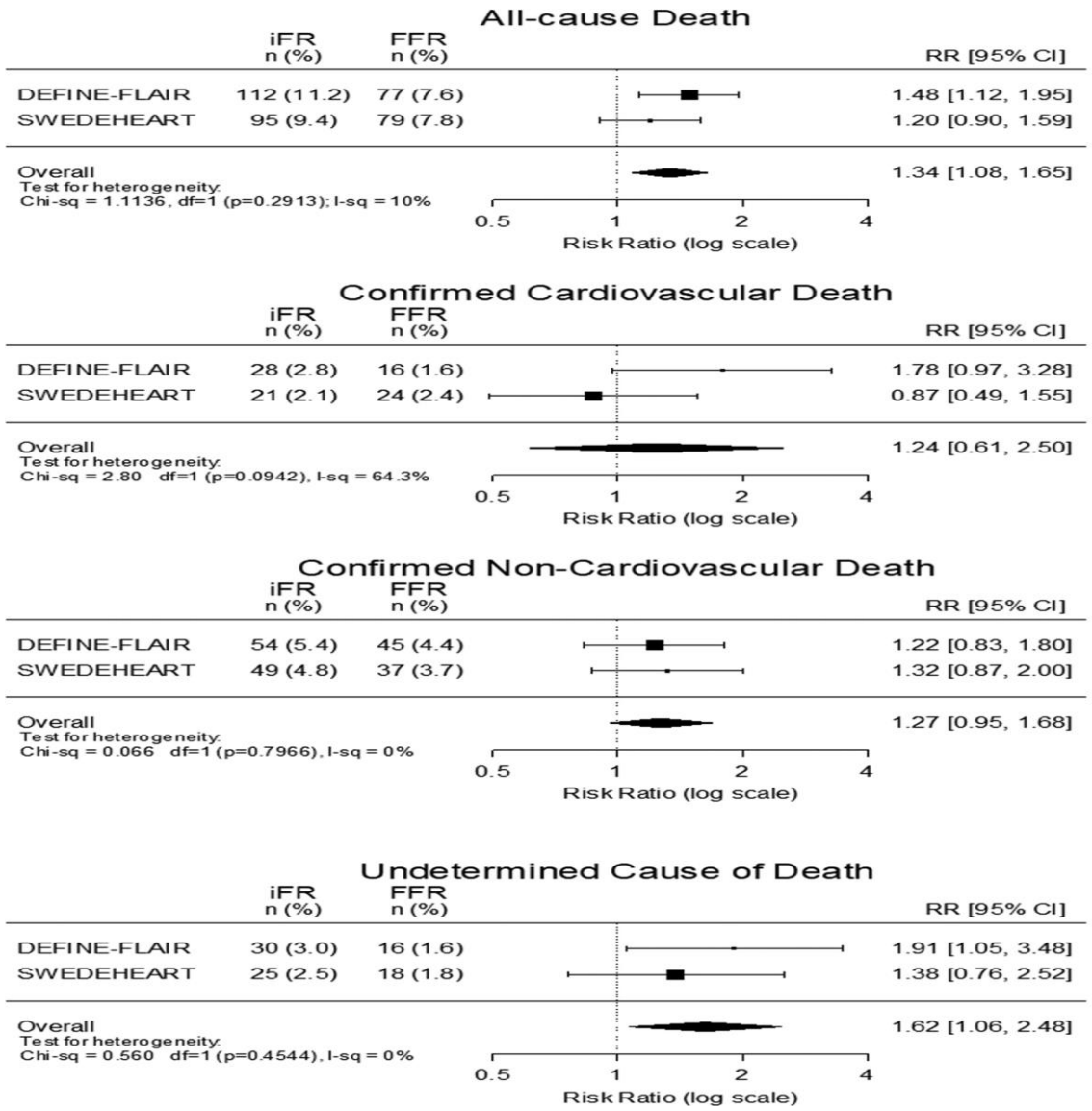
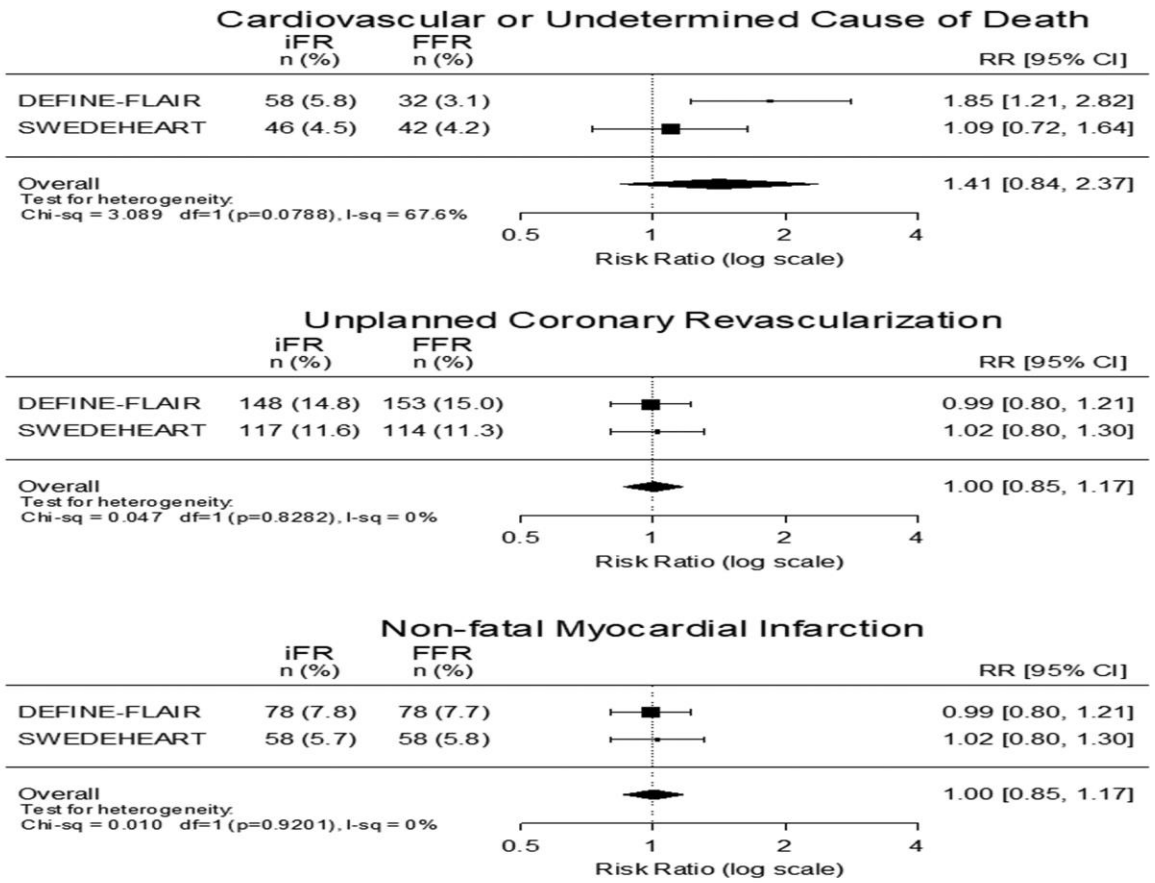
Coronary revascularization guided by instantaneous wave-free ratio compared with fractional flow reserve: pooled 5-year mortality in the DEFINE-FLAIR and iFR-SWEDEHEART trials

Coronary revascularization guided by instantaneous wave-free ratio compared with fractional flow reserve: pooled 5-year mortality in the DEFINE-FLAIR and iFR-SWEDEHEART trials

- What are the long-term outcomes between instantaneous wave-free ratio (iFR) and fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI)?
- Study-level meta-analysis of the 5-year outcome data in iFR-SWEDEHEART and DEFINE-FLAIR trials.
- iFR and FFR-guided revascularization was performed in 2,254 and 2,257 patients.
- Revascularization was more often deferred in the iFR-group (n = 1,128 [50.0%]) versus the FFR-group (n = 1,021 [45.2 %]; p = 0.001

DEFINE-FLAIR and iFR-SWEDEHEART trials





HR for Mace was 1.18 95%CI (1.035- 1.34)

21.5% vs 18.6%

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Multivessel PCI Guided by FFR or Angiography for Myocardial Infarction

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FLOWER MI – 3 years outcomes

- Patients who underwent pPCI for STEMI and had nonculprit coronary disease were randomized to FFR- (n = 590) versus angio-guided PCI (n = 581).
- Females 15%, DM 18%, mean age 63 y/o
- Nonculprit PCI: 66% in the FFR-guided group versus 97% in the angiography-guided group.
- The primary outcome of death, MI, or urgent revascularization at **12 months** 5.5% of the FFR group Vs 4.2% of the angio group (p = 0.31).
- **At 3 years:** 8.9% of the FFR-guided group compared with 7.6% of the angiography-guided group (p = 0.41)

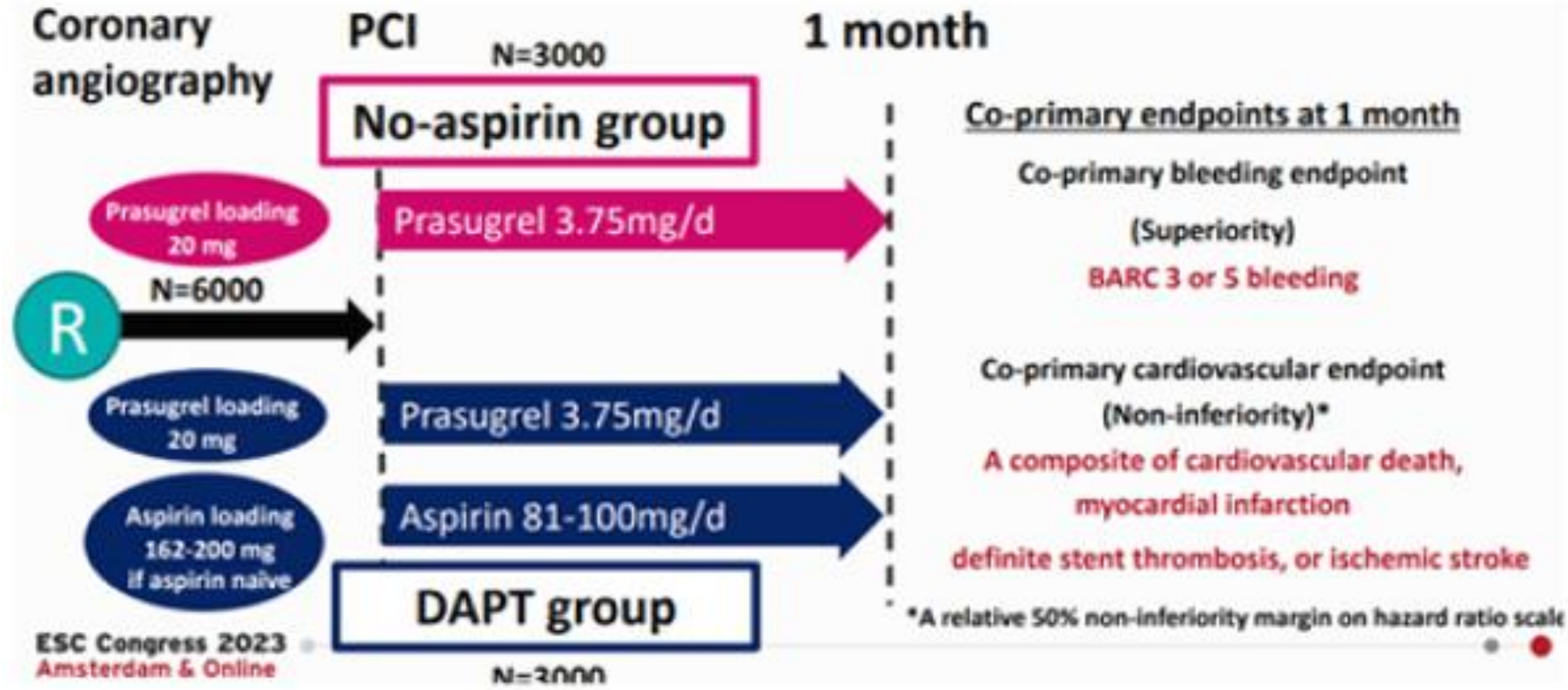
STOP DAPT-3

An Aspirin-Free antithrombotic strategy for percutaneous coronary intervention

STOPDAPT-3

Short and Optimal Duration of Dual Antiplatelet Therapy After Everolimus-Eluting Cobalt-Chromium Stent-3

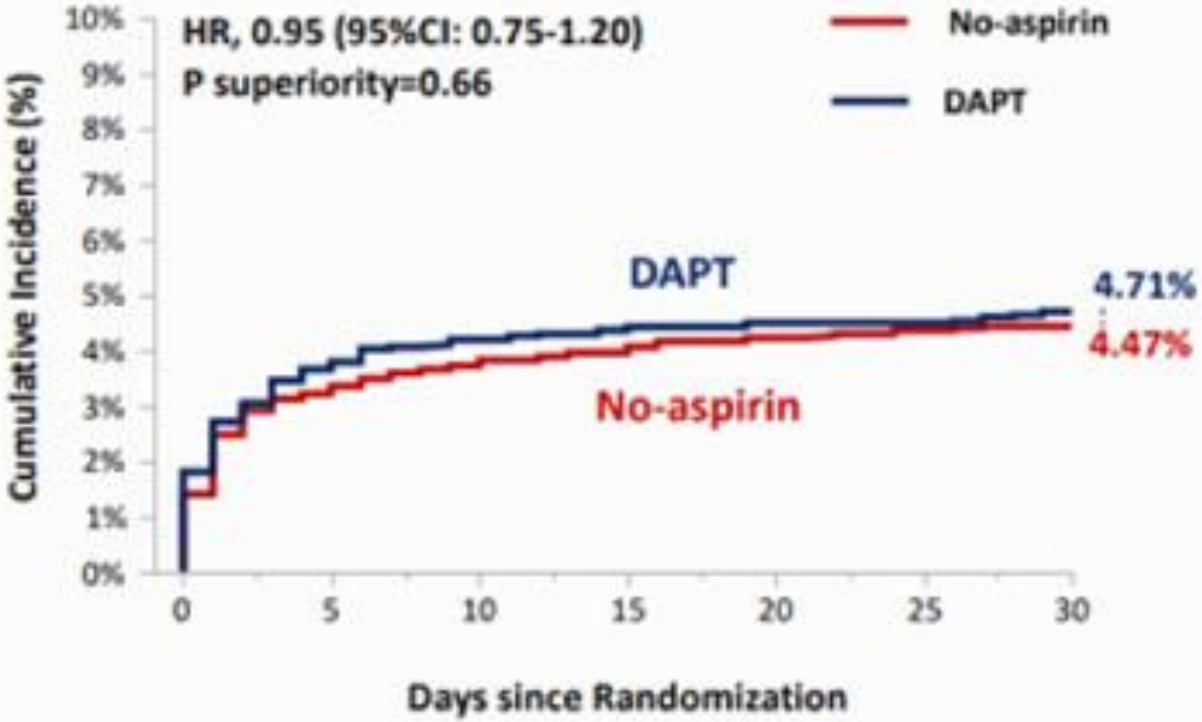
- Aimed to compare the safety and efficacy of an aspirin-free strategy among patients PCI with ACS\at high bleeding risk.
- Patients were randomized to either DAPT with aspirin and prasugrel (n = 2,982) or prasugrel monotherapy (n = 2,984).
  - Aspirin dose was 81-100 mg/day and prasugrel 3.75 mg daily.
- 72 centers in Japan.
- Inclusion – ACS/ High bleeding risk.
- Follow-up: 1 month, Mean age: 71.6 years, females 23%, 75% ACS (42% STEMI)


Coronary angiography
PCI
N=3000
1 month
No-aspirin group
Prasugrel loading 20 mg
Prasugrel 3.75mg/d
N=6000
R
Prasugrel loading 20 mg
Prasugrel 3.75mg/d
Aspirin loading 162-200 mg If aspirin naive
Aspirin 81-100mg/d
DAPT group
N=3000
Co-primary endpoints at 1 month
Co-primary bleeding endpoint
(Superiority)
BARC 3 or 5 bleeding
Co-primary cardiovascular endpoint
(Non-inferiority)*
A composite of cardiovascular death, myocardial infarction
definite stent thrombosis, or ischemic stroke
*A relative 50% non-inferiority margin on hazard ratio scale
ESC Congress 2023
Amsterdam & Online

STOPDAPT-3

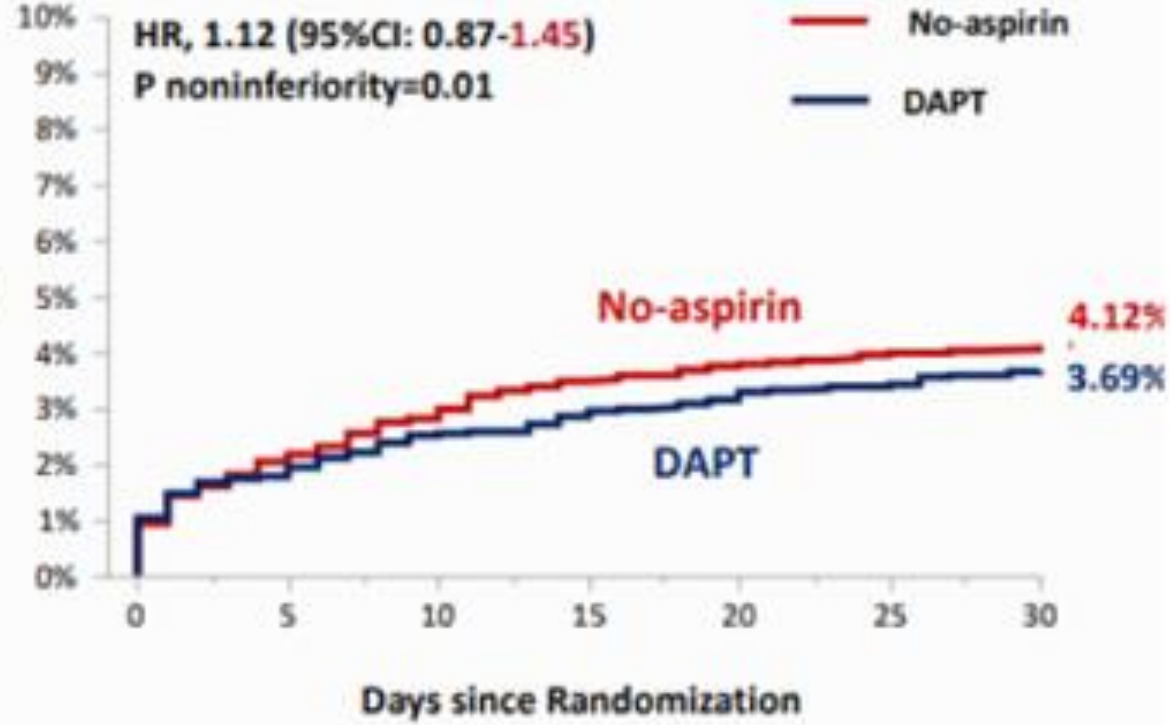
Results

Co-primary Bleeding Endpoint



No. at risk							
No-aspirin	2984	2874	2853	2836	2822	2816	2813
DAPT	2982	2863	2840	2828	2820	2816	2806

Co-primary Cardiovascular Endpoint



No. at risk							
No-aspirin	2984	2823	2900	2878	2868	2862	2859
DAPT	2982	2929	2906	2895	2886	2879	2870

STOPDAPT-3

- Major bleeding - for monotherapy vs. DAPT was: 4.47% and 4.71% (HR 0.95, 95%CI 0.75-1.20; p for superiority = 0.66).
- Cardiovascular endpoint (cardiovascular death, MI, definite stent thrombosis, or stroke) : 4.12% and 3.69% (HR 1.12, 95% CI 0.87-1.45; p for noninferiority = 0.01).
- Secondary endpoints:
  - unplanned revascularization: 1.05% vs. 0.57% (HR 1.83, 95% CI 1.01-3.30; $p < 0.05$)
  - Subacute definite or probable stent thrombosis: 0.58% vs. 0.17% (HR 3.40, 95% CI 1.26-9.23; $p < 0.05$).

Conclusion

- Prasugrel monotherapy was not superior to DAPT with aspirin and prasugrel for bleeding events among patients undergoing PCI with Xience DES either for ACS or among those considered to be at high bleeding risk.
- While recent data support de-escalation to P2Y12 inhibitor monotherapy at 1 month following PCI among select patients, a strategy of de-escalation immediately post-PCI is not beneficial and could in fact be harmful, particularly among ACS patients. DAPT should remain the standard strategy 1 month after coronary stent implantation.

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