MEXICO CITY

JUNE 22 – 24, 2017

GLOBAL EXPERTS, LOCAL LEARNING

ACC Latin America Conference 2017

June 23rd, 1:15 p.m. - 2:00 p.m.

Unanswered Questions in Coronary Artery Disease

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The Andreas Gruentzig Cardiovascular Center
Editor-in-Chief: JACC Cardiovascular Interventions

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Unanswered Questions in Coronary Artery Disease

-1-

Does PCI Improve Survival in SIHD?

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The NEW ENGLAND JOURNAL of MEDICINE

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

N Engl J Med 2007;356:150316

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

N Engl J Med 2007;356:150316

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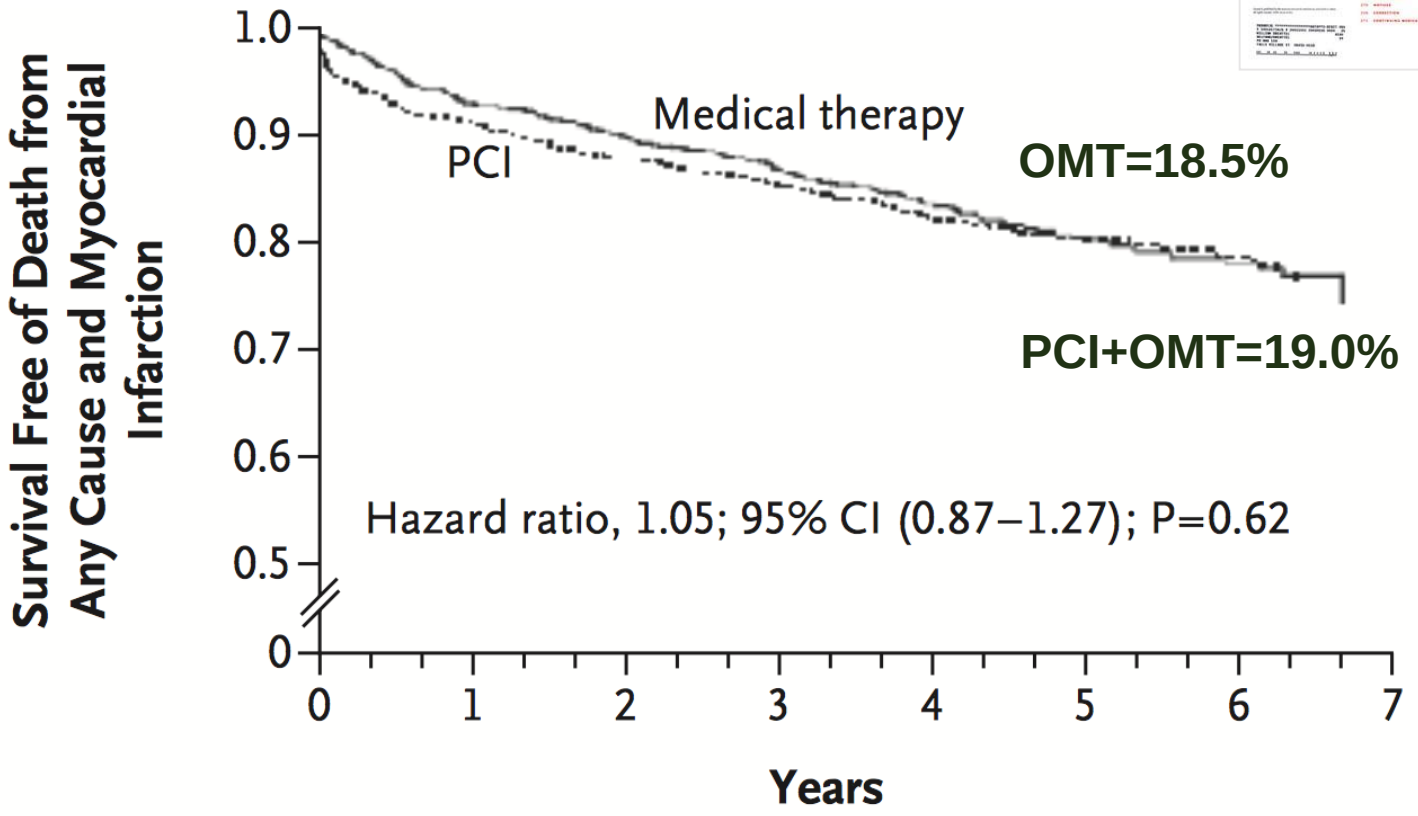

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

N Engl J Med 2007;356:150316

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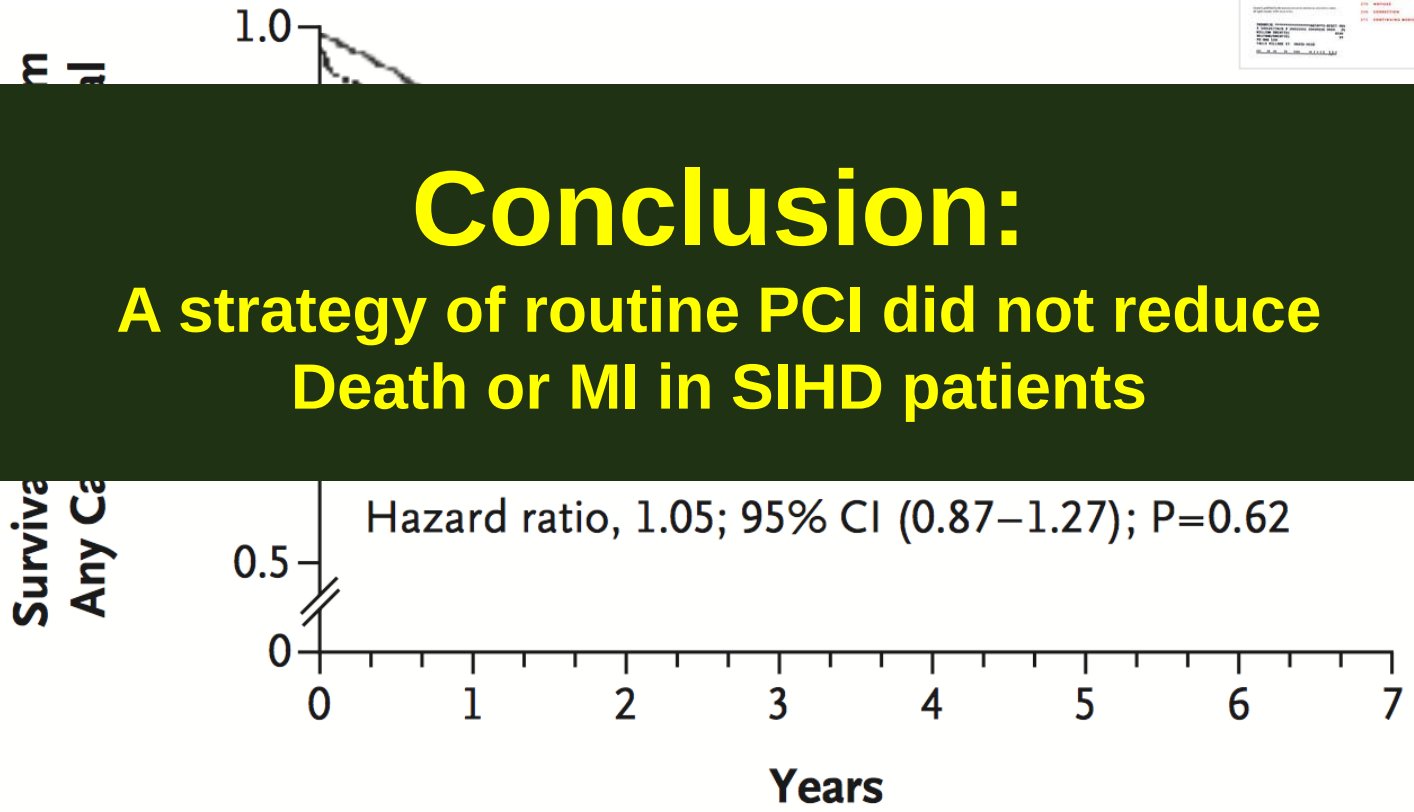
Conclusion:

A strategy of routine PCI did not reduce Death or MI in SIHD patients



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The NEW ENGLAND JOURNAL of MEDICINE

Fractional Flow Reserve–Guided PCI for Stable Coronary Artery Disease

Bernard De Bruyne, M.D., Ph.D., William F. Fearon, M.D., Nico H.J. Pijls, M.D., Ph.D., Emanuele Barbato, M.D., Ph.D., Pim Tonino, M.D., Ph.D., Zsolt Piroth, M.D., Nikola Jagic, M.D., Sven Mobius-Winckler, M.D., Gilles Rioufol, M.D., Ph.D., Nils Witt, M.D., Ph.D., Petr Kala, M.D., Philip MacCarthy, M.D., Thomas Engström, M.D., Keith Oldroyd, M.D., Kreton Mavromatis, M.D., Ganesh Manoharan, M.D., Peter Verlee, M.D., Ole Frobert, M.D., Nick Curzen, B.M., Ph.D., Jane B. Johnson, R.N., B.S.N., Andreas Limacher, Ph.D., Eveline Nüesch, Ph.D., and Peter Jüni, M.D., for the FAME 2 Trial Investigators*

N Engl J Med 2014;371:1208-17

Fractional Flow Reserve–Guided PCI for Stable Coronary Artery Disease

N Engl J Med 2014;371:1208-17

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Stable CAD patients scheduled for 1-, 2- or 3-vessel DES-PCI (N = 1220)

FFR in all target lesions

At least 1 stenosis with FFR ≤ 0.80 (n=888)

Randomization 1:1

PCI + MT

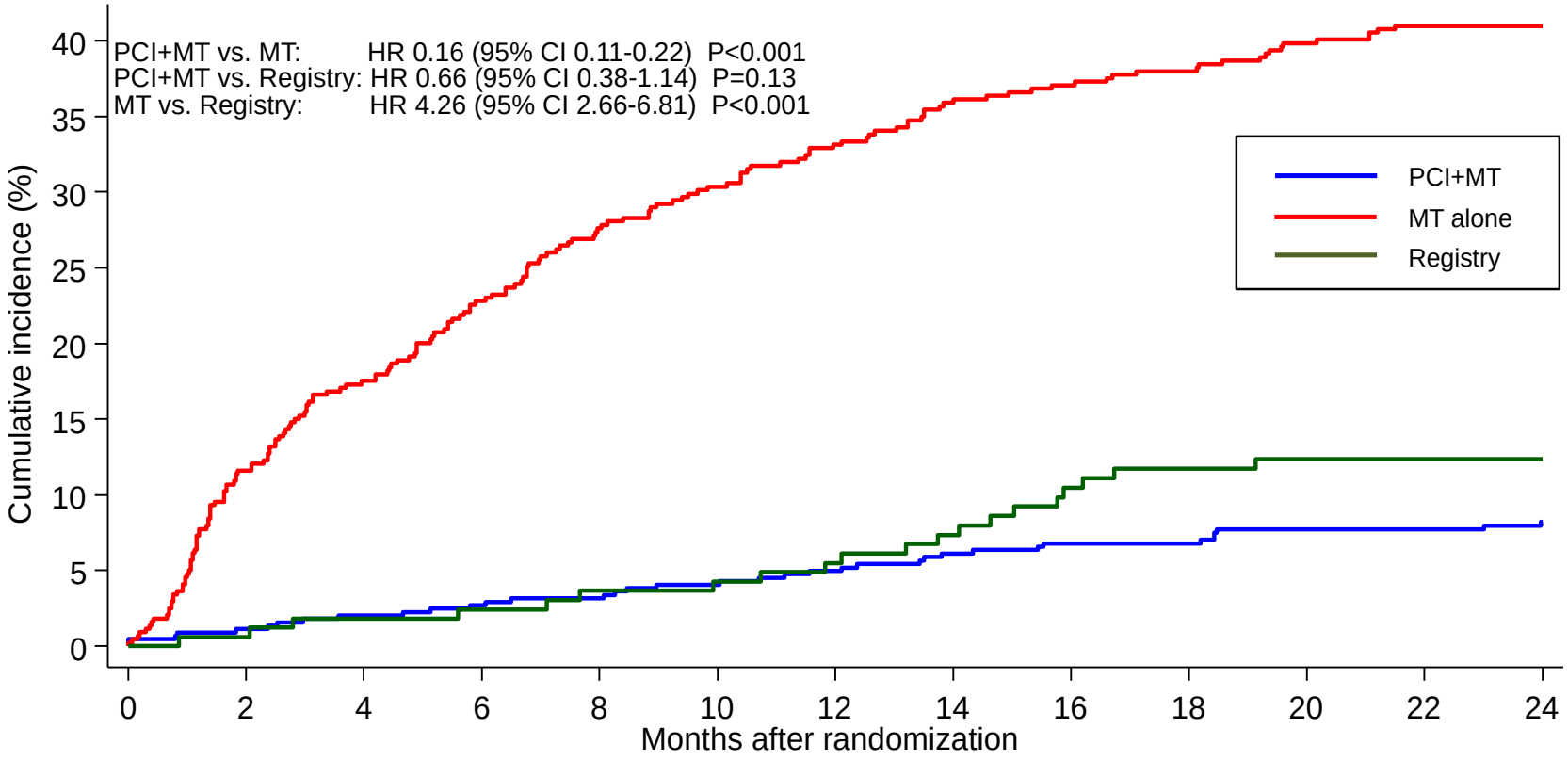
MT

When all FFR > 0.80 (n=332)

MT

Follow-up after 1 mo, 6 mo, 1, 2, 3, 4, and 5 years

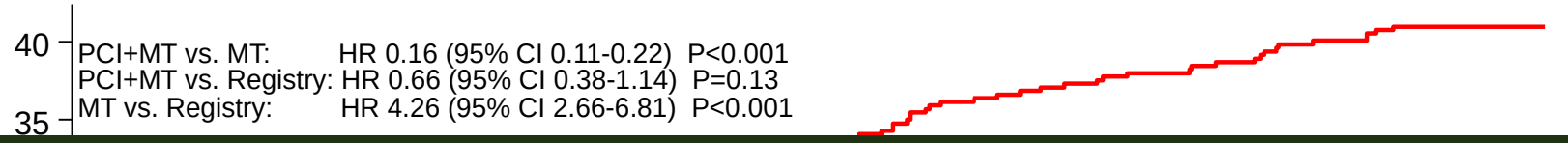
Fractional Flow Reserve–Guided PCI for Stable Coronary Artery Disease



No. at risk

MT	441	389	360	337	315	302	290	277	272	268	260	254	218
PCI+MT	447	440	434	429	427	422	417	410	407	406	402	399	343
Registry	166	165	162	160	157	156	153	149	144	142	141	141	116

Fractional Flow Reserve–Guided PCI for Stable Coronary Artery Disease



Conclusion:

In patients with stable CAD and functionally significant stenoses, FFR-guided PCI plus the best OMT as compared to OMT alone, decreased the need for urgent revascularization.

The trial was underpowered for mortality which was <1%

No. at risk													
MT	441	389	360	337	315	302	290	277	272	268	260	254	218
PCI+MT	447	440	434	429	427	422	417	410	407	406	402	399	343
Registry	166	165	162	160	157	156	153	149	144	142	141	141	116

The NEW ENGLAND JOURNAL of MEDICINE

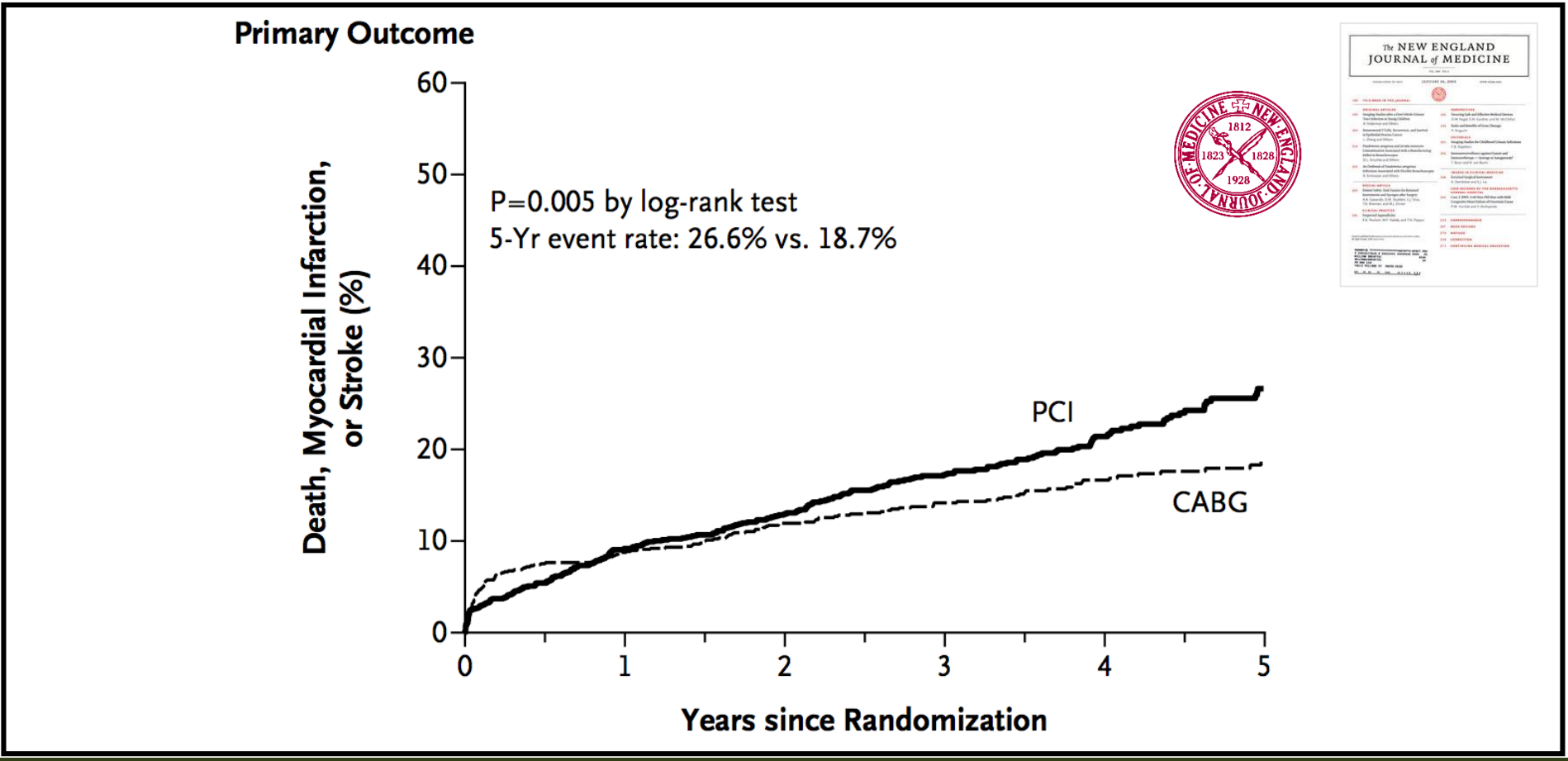
Strategies for Multivessel Revascularization in Patients with Diabetes

Michael E. Farkouh, M.D., Michael Domanski, M.D., Lynn A. Sleeper, Sc.D., Flora S. Siami, M.P.H., George Dangas, M.D., Ph.D., Michael Mack, M.D., May Yang, M.P.H., David J. Cohen, M.D., Yves Rosenberg, M.D., M.P.H., Scott D. Solomon, M.D., Akshay S. Desai, M.D., M.P.H., Bernard J. Gersh, M.B., Ch.B., D.Phil., Elizabeth A. Magnuson, Sc.D., Alexandra Lansky, M.D., Robin Boineau, M.D., Jesse Weinberger, M.D., Krishnan Ramanathan, M.B., Ch.B., J. Eduardo Sousa, M.D., Ph.D., Jamie Rankin, M.D., Balram Bhargava, M.D., John Buse, M.D., Whady Hueb, M.D., Ph.D., Craig R. Smith, M.D., Victoria Muratov, M.D., M.P.H., Sameer Bansilal, M.D., Spencer King III, M.D., Michel Bertrand, M.D., and Valentin Fuster, M.D., Ph.D., for the FREEDOM Trial Investigators*

N Engl J Med 2007;356:150316

Strategies for Multivessel Revascularization in Patients with Diabetes

1900 patients with DM and MVD underwent either PCI with DES or CABG. The patients were followed for a minimum of 2 years (median among survivors, 3.8 years).



Strategies for Multivessel Revascularization in Patients with Diabetes

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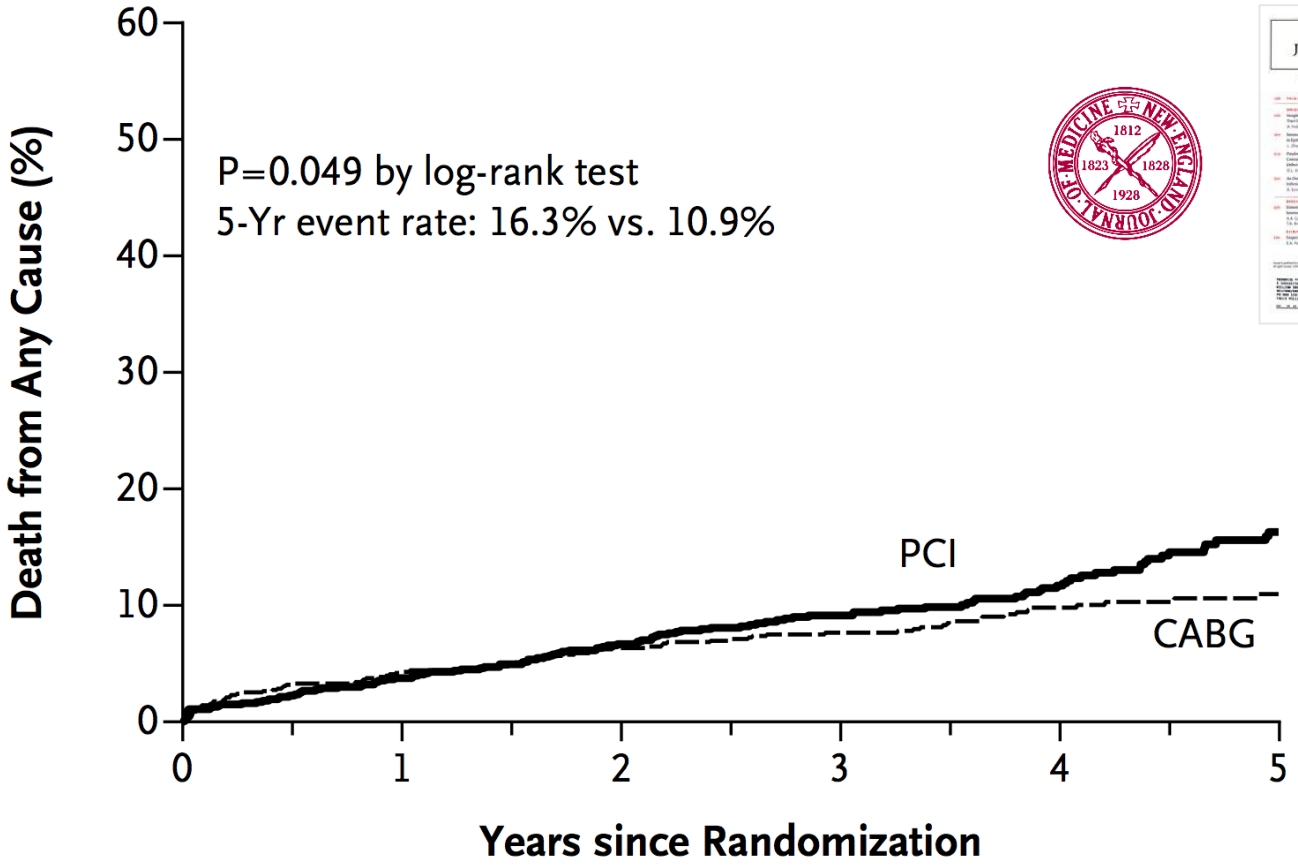

Strategies for Multivessel Revascularization in Patients with Diabetes

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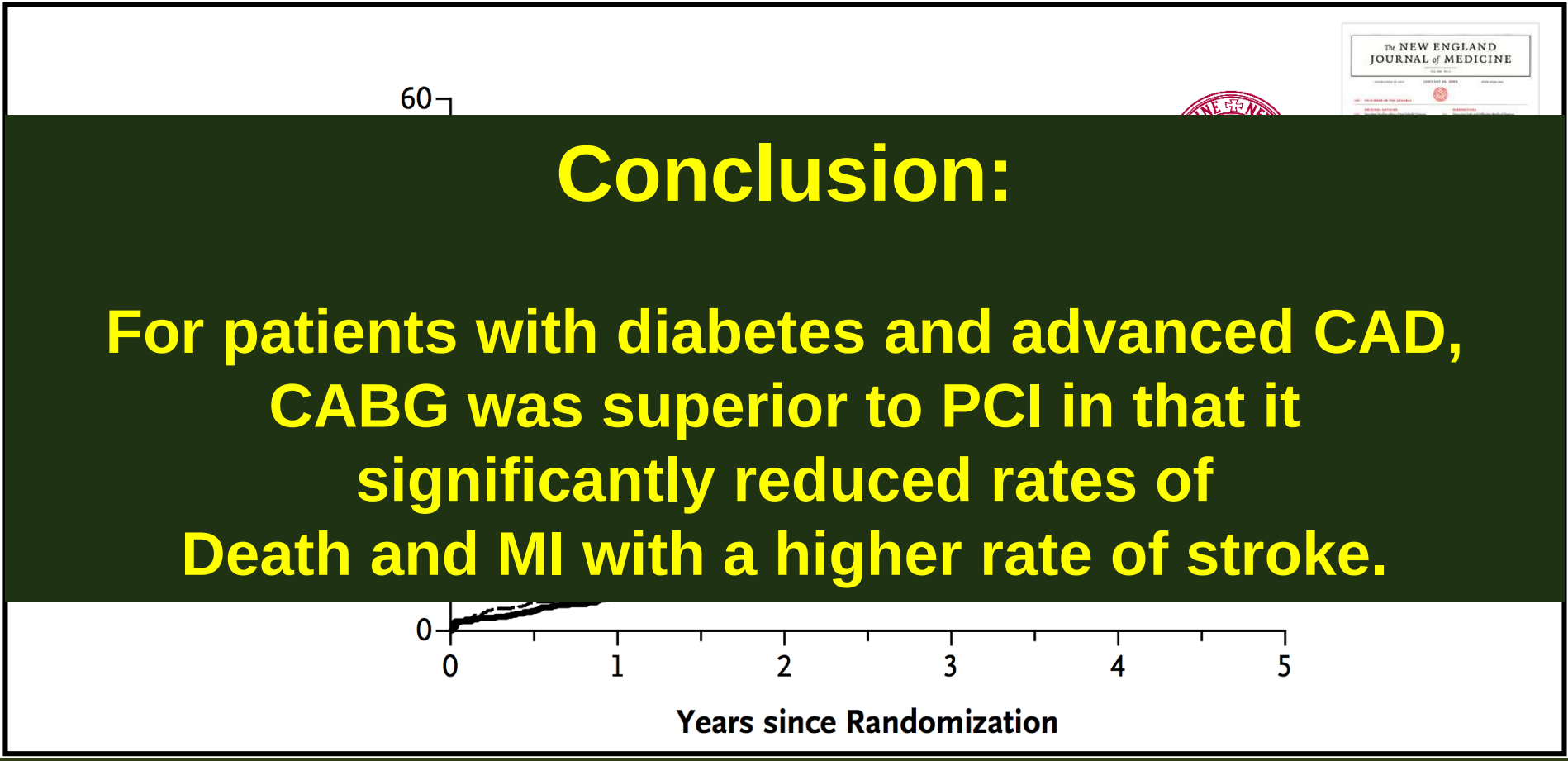

Conclusion:

For patients with diabetes and advanced CAD, CABG was superior to PCI in that it significantly reduced rates of Death and MI with a higher rate of stroke.

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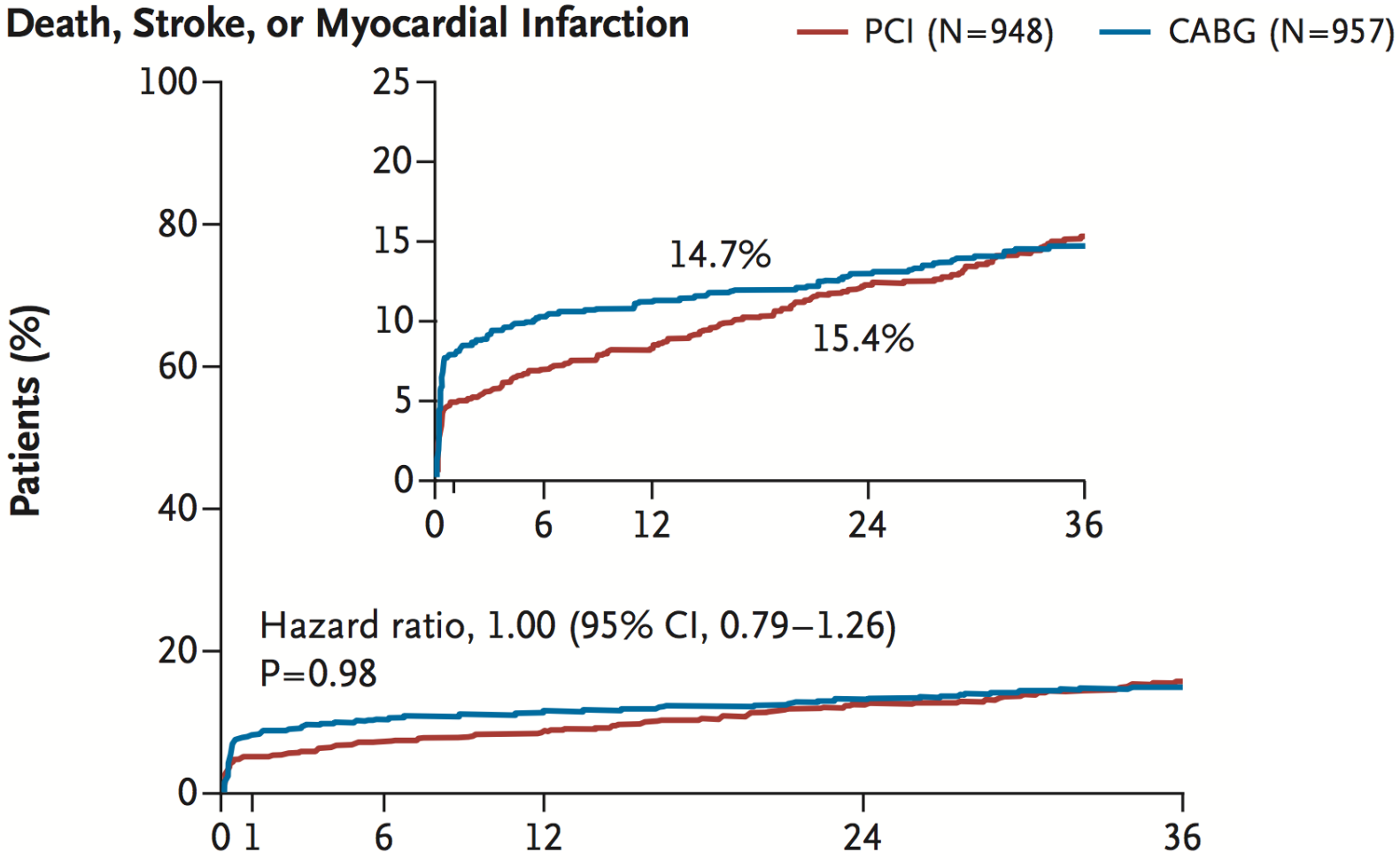
Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

G.W. Stone, J.F. Sabik, P.W. Serruys, C.A. Simonton, P. Généreux, J. Puskas, D.E. Kandzari, M.-C. Morice, N. Lembo, W.M. Brown III, D.P. Taggart, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.J. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P. Buszman, A. Bochenek, E. Schampaert, P. Pagé, O. Dressler, I. Kosmidou, R. Mehran, S.J. Pocock, and A.P. Kappetein, for the EXCEL Trial Investigators*

N Engl J Med 2016; 375:2223-2235

Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

1905 patients with LM disease and SX Score < 32 underwent PCI or CABG



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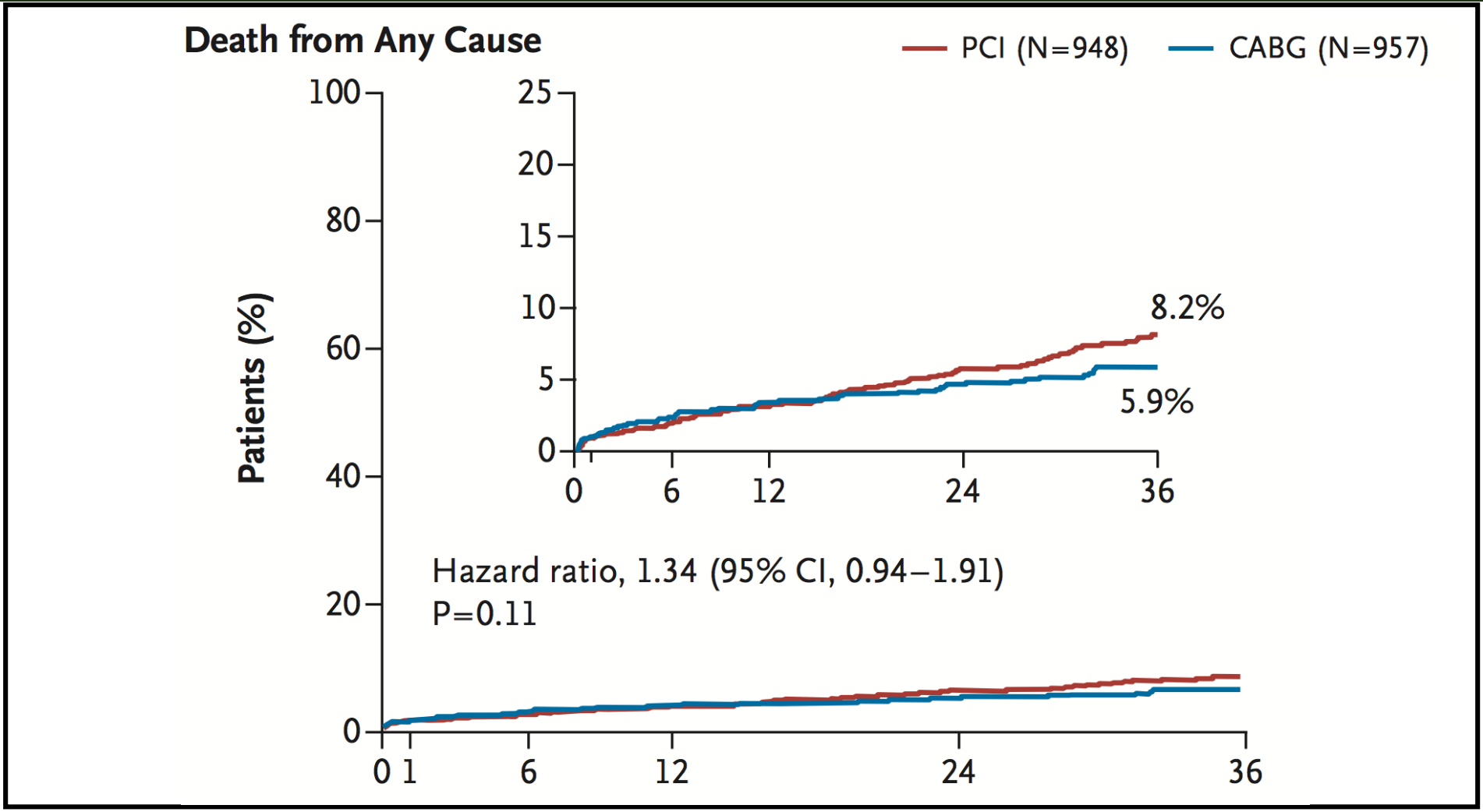

Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

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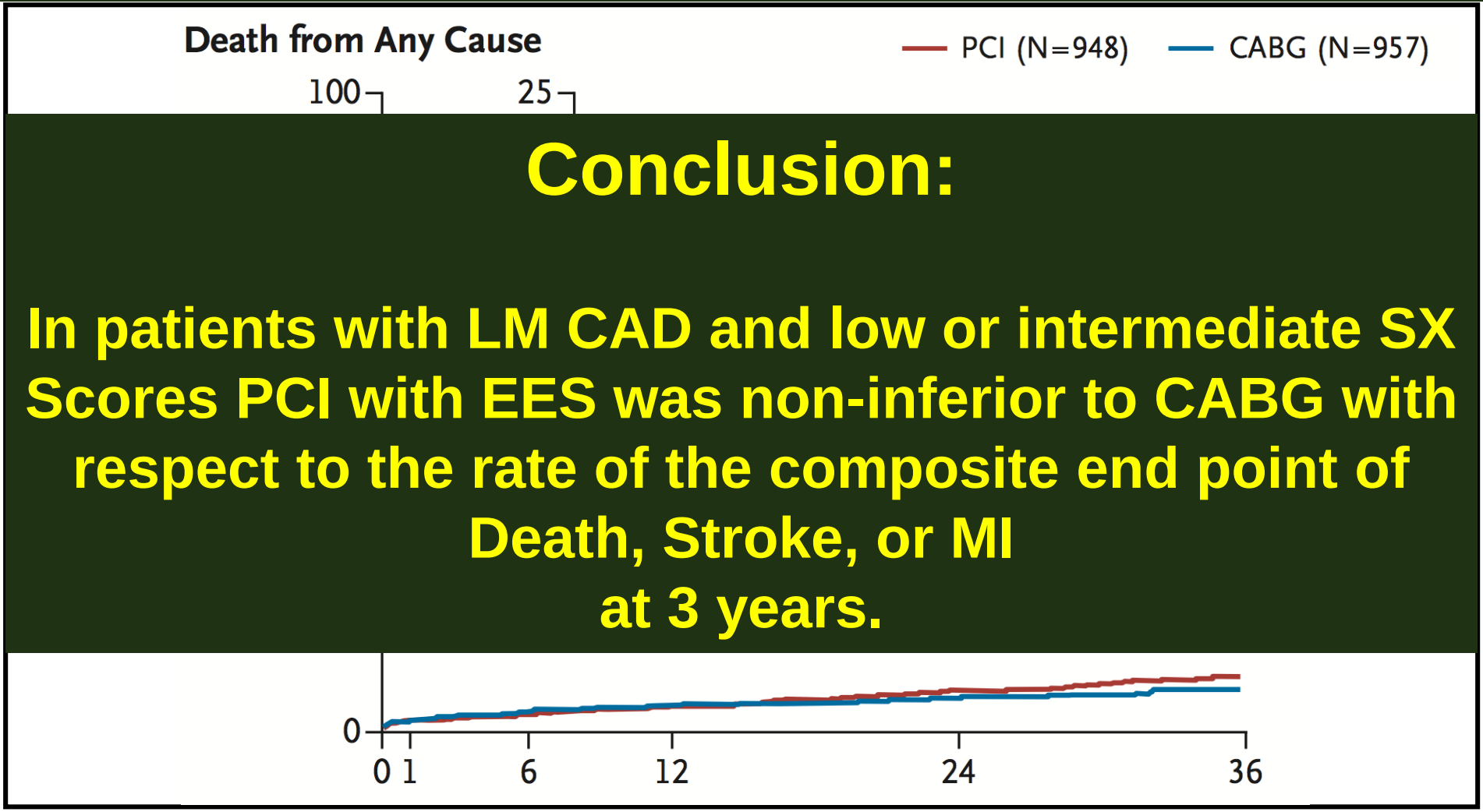

Conclusion:

In patients with LM CAD and low or intermediate SX Scores PCI with EES was non-inferior to CABG with respect to the rate of the composite end point of Death, Stroke, or MI at 3 years.

Does PCI improve survival over medical therapy in SIHD?

- Average RCT outcomes will not help very much.
- Trials, large enough to drill down to many subsets are needed.
- New trials of low ischemic risk should compare PCI with OMT.
- The ongoing ISCHEMIA Trial is looking at higher risk patients with selection based on physiology (large ischemic burden on nuclear scan).
- Trials with selection based on anatomy (invasive angiography or CTA) are also needed.

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Unanswered Questions in Coronary Artery Disease

-2-

Is Completeness of Revascularization Needed in SIHD?

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Unanswered Questions in Coronary Artery Disease

-3-

Is Completeness of Revascularization Needed in the Clinical Setting of STEMI & MVD?

Survival After Varying Revascularization Strategies in Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Coronary Artery Disease

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Giuseppe Tarantini, MD, PhD,[a] Gianpiero D'Amico, MD,[a] Sorin J. Brener, MD,[b] Paola Tellaroli, MSc, PhD,[c] Marco Basile, MD,[d] Alessandro Schiavo, MD,[a] Marco Mojoli, MD,[a] Chiara Fraccaro, MD, PhD,[a] Alfredo Marchese, MD,[d] Giuseppe Musumeci, MD,[e] Gregg W. Stone, MD[f]

J Am Coll Cardiol Intv 2016;9:1765–76

Objectives: We conducted a systematic pairwise and network meta-analysis to assess optimal treatment strategies in patients with **ST-segment elevation myocardial infarction (STEMI) and multivessel coronary artery disease (MV-CAD)** undergoing primary PCI.

Background: Patients with STEMI and MV-CAD have a worse prognosis than those with single-vessel CAD. The optimal revascularization strategy for these patients is uncertain.

32 Studies

Total N= 54,148 patients

N= 42,112 Infract Related Artery-only PCI

N= 8,138 single procedure MV-PCI

N= 3,898 staged MV-PCI

Survival After Varying Revascularization Strategies in Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Coronary Artery Disease

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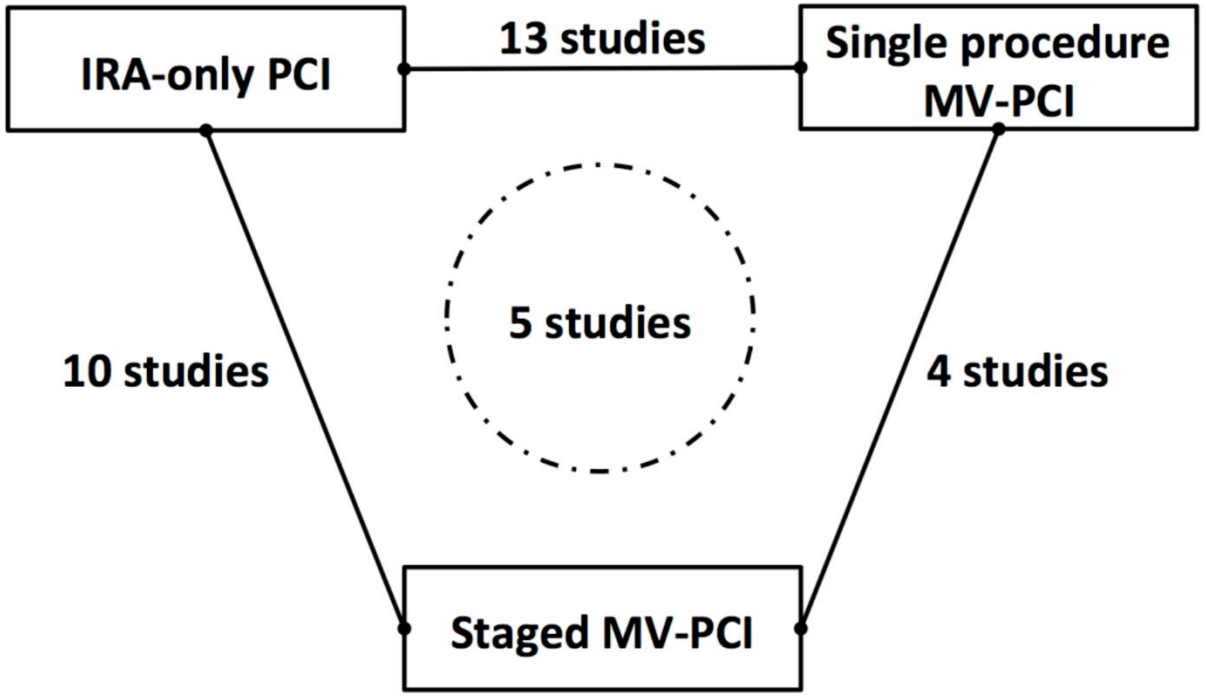

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Infract Related Artery only PCI vs. Multivessel Single Procedure PCI

Long-term mortality

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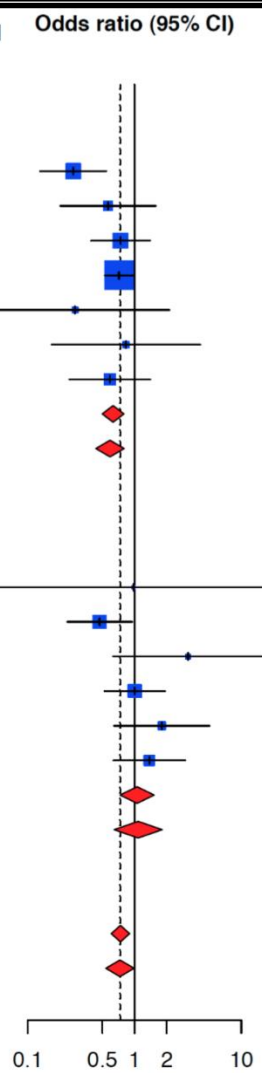
Study	IRA–only PCI Events	IRA–only PCI Total	Single procedure MV–PCI Events	Single procedure MV–PCI Total	OR 95% CI
Retrospective					
Abe (2013)	24	220	17	54	0.27 [0.13; 0.54]
Corpus (2004)	42	354	5	26	0.57 [0.20; 1.58]
Hannan (2010)	14	259	36	503	0.74 [0.39; 1.40]
Iqbal (2014)	255	3429	56	555	0.72 [0.53; 0.97]
Mohamad (2011)	3	30	2	7	0.28 [0.04; 2.11]
Qarawani (2008)	2	25	9	95	0.83 [0.17; 4.11]
Roe (2001)	10	61	17	68	0.59 [0.25; 1.41]
Fixed effect model		**4378**		**1308**	**0.63 [0.50; 0.80]**
Random effects model					**0.59 [0.43; 0.80]**
Heterogeneity: I–squared=18%, tau–squared=0.03, p=0.29					
Prospective					
Di Mario (2004)	0	17	1	52	0.98 [0.04; 25.20]
Dziewierz (2010)	57	707	11	70	0.47 [0.23; 0.95]
Gershlick (2015)	6	146	2	150	3.17 [0.63; 15.98]
Jeger (2014)	40	1467	12	442	1.00 [0.52; 1.93]
Politi (2010)	13	84	6	65	1.80 [0.64; 5.03]
Wald (2013)	16	231	12	234	1.38 [0.64; 2.98]
Fixed effect model		**2652**		**1013**	**1.06 [0.73; 1.53]**
Random effects model					**1.08 [0.64; 1.82]**
Heterogeneity: I–squared=40.8%, tau–squared=0.16, p=0.13					
Fixed effect model		**7030**		**2321**	**0.74 [0.61; 0.90]**
Random effects model					**0.73 [0.54; 0.99]**
Heterogeneity: I–squared=40.9%, tau–squared=0.11, p=0.06					



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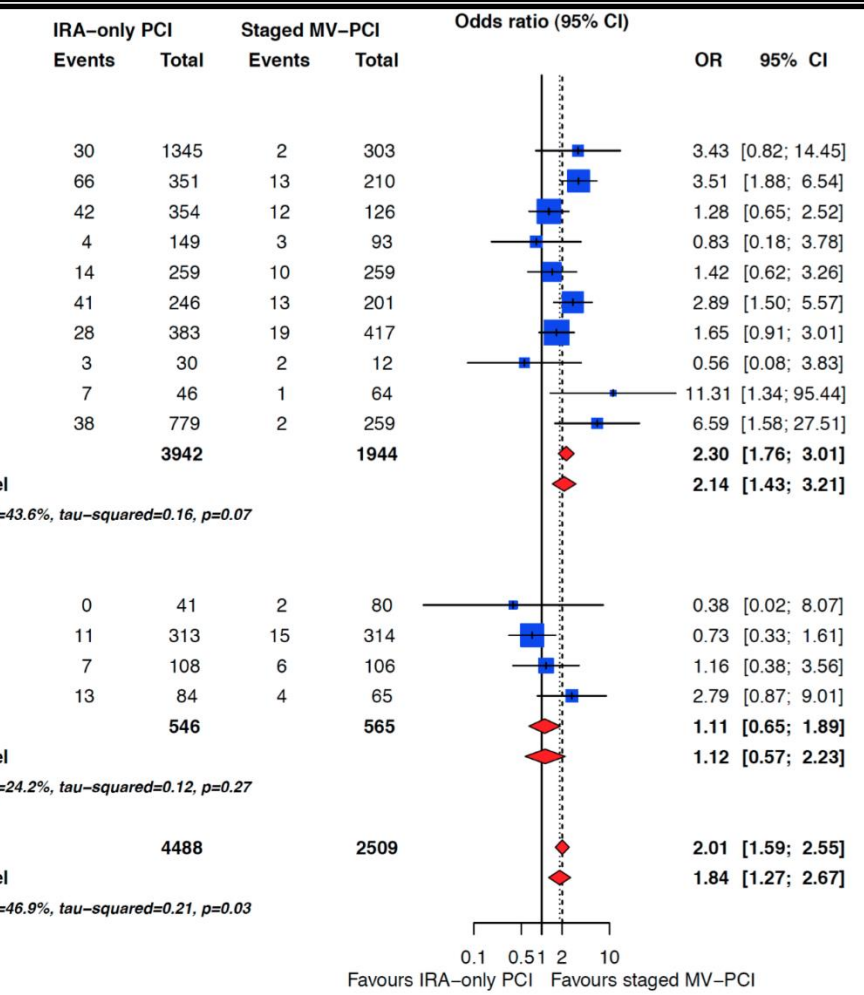
J Am Coll Cardiol Intv 2016;9:1765–76

Favors IRA-only PCI ← → **Favors MV-PCI**

Infract Related Artery only PCI vs. Staged Multivessel PCI

Long-term Mortality



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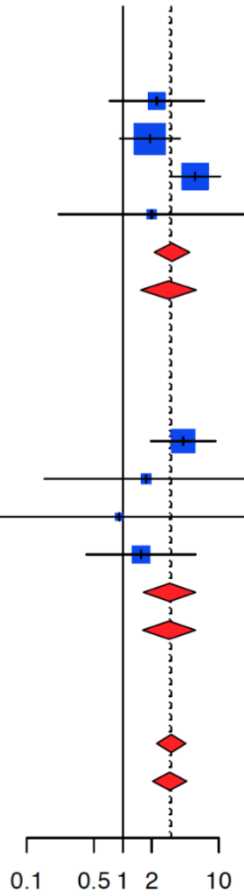
Favors IRA-only PCI **Favors Staged MV-PCI**

MV-PCI Single procedure vs. Staged MV-PCI

Long-term Mortality

Study	Single procedure MV–PCI Events	Total	Staged MV–PCI Events	Total	OR	95% CI
Retrospective						
Corpus (2004)	5	26	12	126	2.26	[0.72; 7.09]
Hannan (2010)	36	503	10	259	1.92	[0.94; 3.93]
Jensen (2012)	36	354	16	820	5.69	[3.11; 10.40]
Mohamad (2011)	2	7	2	12	2.00	[0.21; 18.69]
Fixed effect model		**890**		**1217**	**3.26**	**[2.13; 4.98]**
Random effects model					**3.00**	**[1.53; 5.87]**
Heterogeneity: I–squared=49.5%, tau–squared=0.22, p=0.11						
Prospective						
Kornowski (2011)	25	275	9	393	4.27	[1.96; 9.29]
Maamoun (2011)	2	42	1	36	1.75	[0.15; 20.14]
Ochala (2004)	0	48	0	44	0.92	[0.02; 47.22]
Politi (2010)	6	65	4	65	1.55	[0.42; 5.78]
Fixed effect model		**430**		**538**	**3.08**	**[1.64; 5.76]**
Random effects model					**3.04**	**[1.61; 5.75]**
Heterogeneity: I–squared=0%, tau–squared=0, p=0.51						
Fixed effect model		**1320**		**1755**	**3.20**	**[2.25; 4.55]**
Random effects model					**3.09**	**[2.05; 4.65]**
Heterogeneity: I–squared=15.5%, tau–squared=0.05, p=0.31						



Favors MV-PCI Single procedure

Favors Staged MV-PCI

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Survival After Varying Revascularization Strategies in Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Coronary Artery Disease

Giuseppe Tarantini, MD, PhD,[a] Gianpiero D'Amico, MD,[a] Sorin J. Brener, MD,[b] Paola Tellaroli, MSc, PhD,[c] Marco Basile, MD,[d] Alessandro Schiavo, MD,[a] Marco Mojoli, MD,[a] Chiara Fraccaro, MD, PhD,[a] Alfredo Marchese, MD,[d] Giuseppe Musumeci, MD,[e] Gregg W. Stone, MD[f]

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J Am Coll Cardiol Intv 2016;9:1765–76

Conclusion:

In patients with MV-CAD presenting with STEMI undergoing primary PCI, a staged multivessel revascularization strategy may improve survival.

JACC Cardiovascular Interventions A Journal of the American College of Cardiology

Culprit Vessel Versus Multivessel Versus In-Hospital Staged Intervention for Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Disease

Stratified Analyses in High-Risk Patient Groups and Anatomic Subsets of Nonculprit Disease

M. Bilal Iqbal, MD, PhD,[a,b] Imad J. Nadra, MD, PhD,[a,b] Lillian Ding, MSc,[c] Anthony Fung, MD,[d] Eve Aymong, MD,[e] Albert W. Chan, MD,[f] Steven Hodge, MD,[g] Anthony Della Siega, MD,[a,b] Simon D. Robinson, MD,[a,b] on behalf of the British Columbia Cardiac Registry Investigators

METHODS We compared revascularization strategies (MVI, CVI-O, and CVI-S) in 6,503 patients with STEMI and multivessel disease enrolled in the British Columbia Cardiac Registry (2008 to 2014). We evaluated all-cause mortality and repeat revascularization at 2 years.

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JACC Cardiovasc Interv. 2017 Jan 9;10(1):11-2

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Culprit Vessel Versus Multivessel Versus In-Hospital Staged Intervention for Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Disease

Stratified Analyses in High-Risk Patient Groups and Anatomic Subsets of Nonculprit Disease

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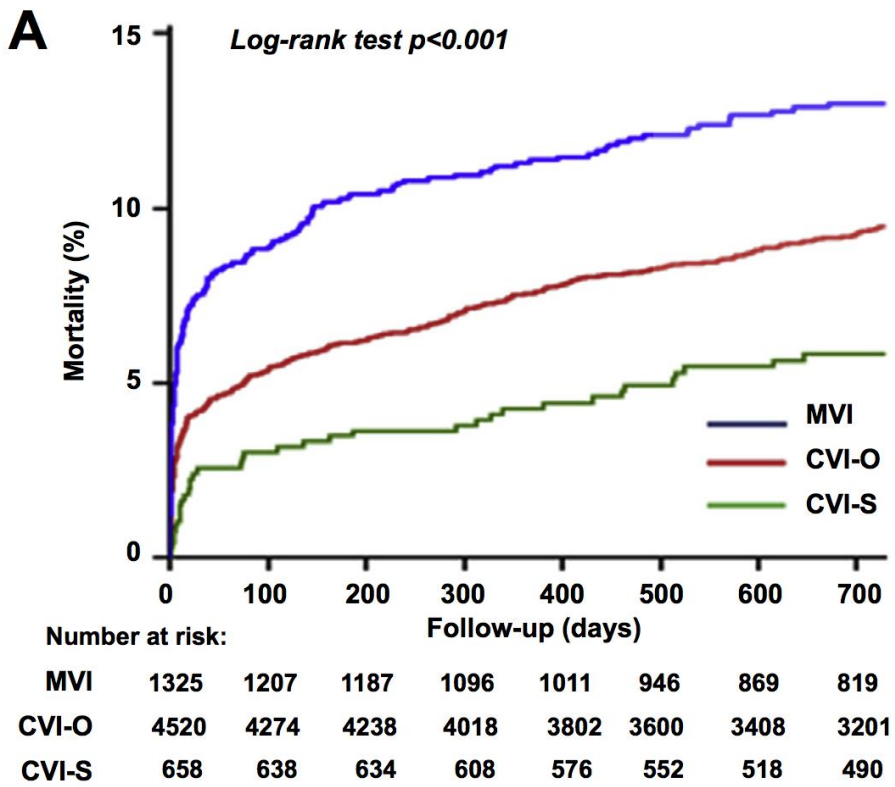

MVI

CVI Only

CVI-Staged

Culprit Vessel Versus Multivessel Versus In-Hospital Staged Intervention for Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Disease

Stratified Analyses in High-Risk Patient Groups and Anatomic Subsets of Nonculprit Disease

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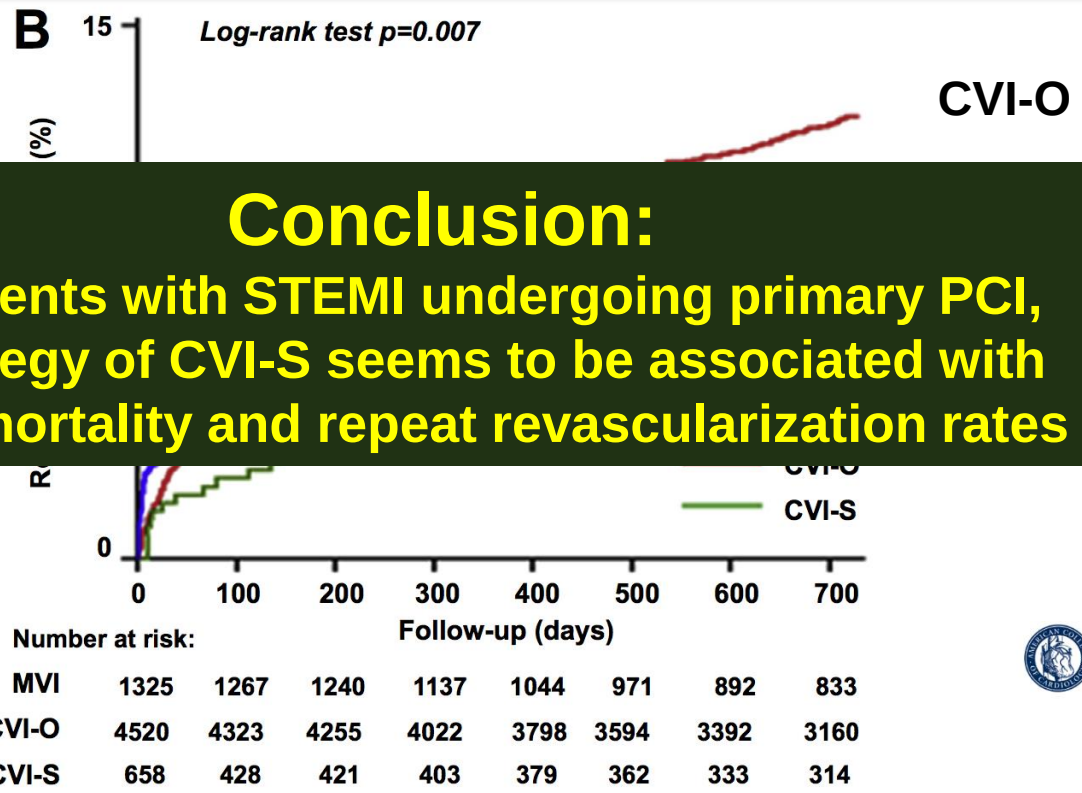

Conclusion:

In patients with STEMI undergoing primary PCI, a strategy of CVI-S seems to be associated with lower mortality and repeat revascularization rates

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The NEW ENGLAND JOURNAL of MEDICINE

Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

Pieter C. Smits, M.D., Ph.D., Mohamed Abdel-Wahab, M.D., Franz-Josef Neumann, M.D., Bianca M. Boxma-de Klerk, Ph.D., Ketil Lunde, M.D., Carl E. Schotborgh, M.D., Zsolt Piroth, M.D., David Horak, M.D., Adrian Wlodarczak, M.D., Paul J. Ong, M.D., Rainer Hambrecht, M.D., Oskar Angerås, M.D., Gert Richardt, M.D., Ph.D., and Elmir Omerovic, M.D., for the Compare-Acute Investigators*

N Engl J Med 2017;376:1234-44

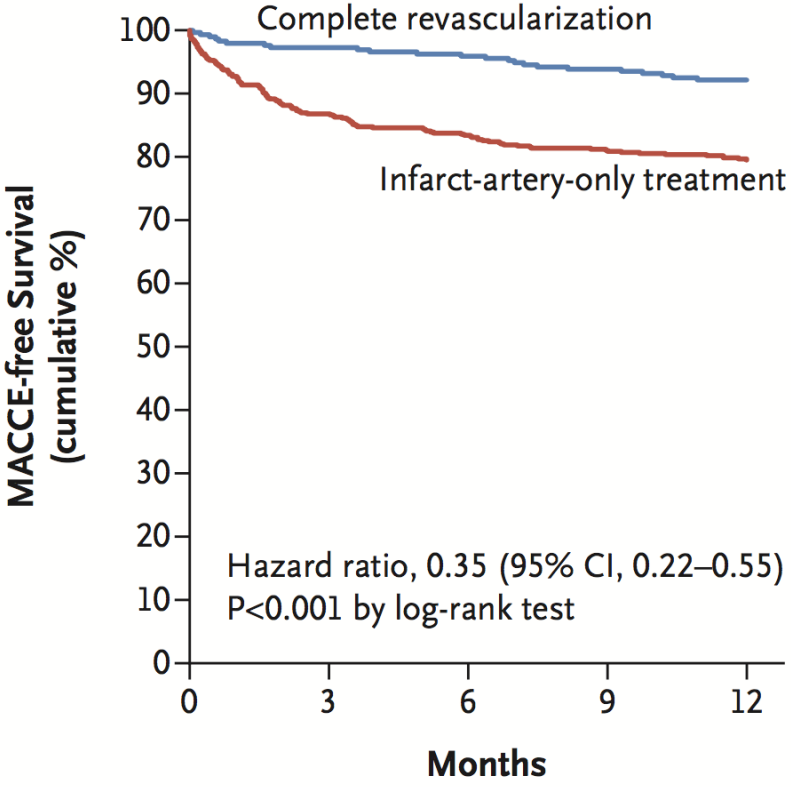
The NEW ENGLAND JOURNAL of MEDICINE

Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

885 patients with STEMI and MVD who had undergone primary PCI of an infarct-related coronary artery were randomized to 1:2 ratio to undergo complete revascularization of a non–infarct-related coronary artery guided by FFR *(295 patients)* or to undergo no revascularization of non– infarct-related coronary artery *(590 patients)*

Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

MACCE denotes the composite of all-cause mortality, nonfatal myocardial infarction, any revascularization, and cerebrovascular events.



N Engl J Med 2017;376:1234-44.

Complete or Culprit-Only Revascularization for Patients With Multivessel Coronary Artery Disease Undergoing Percutaneous Coronary Intervention

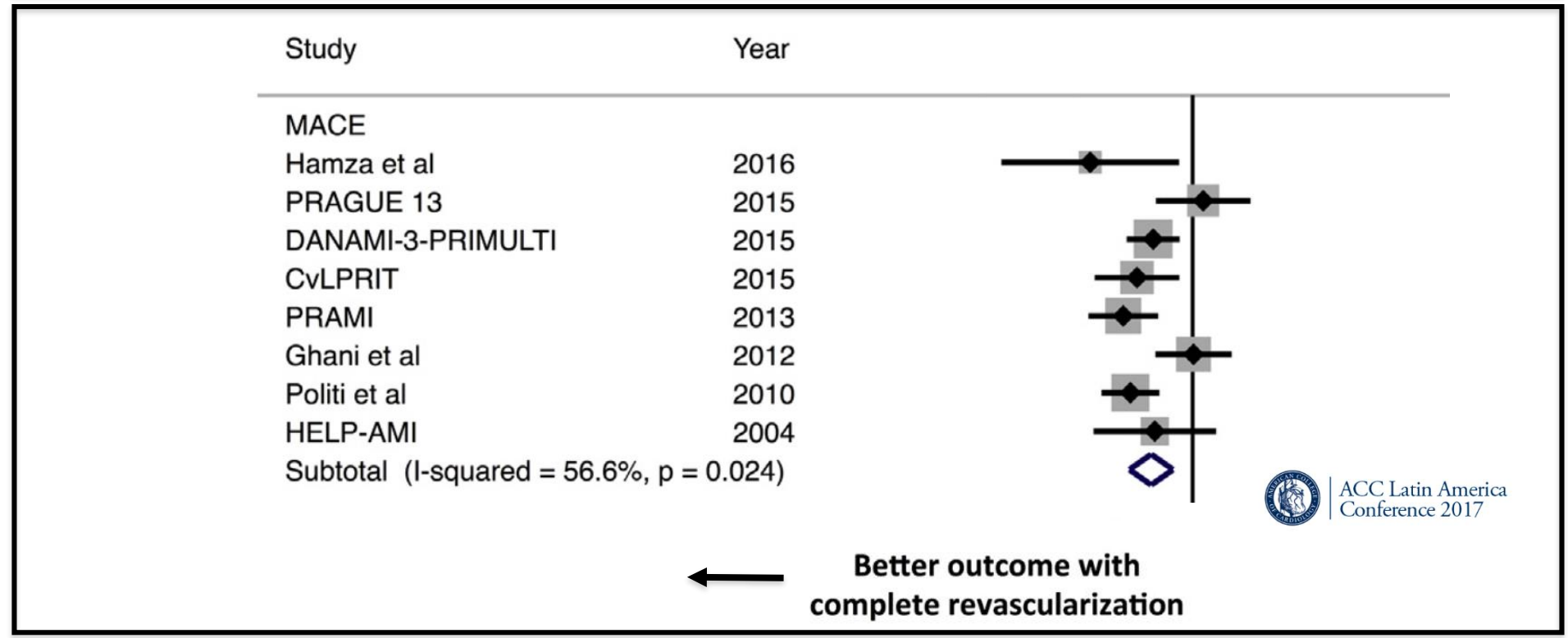
Islam Y. Elgendy, MD,[a] Ahmed N. Mahmoud, MD,[a] Dharam J. Kumbhani, MD, SM,[b] Deepak L. Bhatt, MD, MPH,[c] Anthony A. Bavry, MD, MPH[a,d]

Trials that randomized 2285 STEMI patients with MVD to any combination of the 4 different revascularization strategies (i.e., complete revascularization at the index procedure, staged procedure during the hospitalization, staged procedure after discharge or culprit-only revascularization) were included.

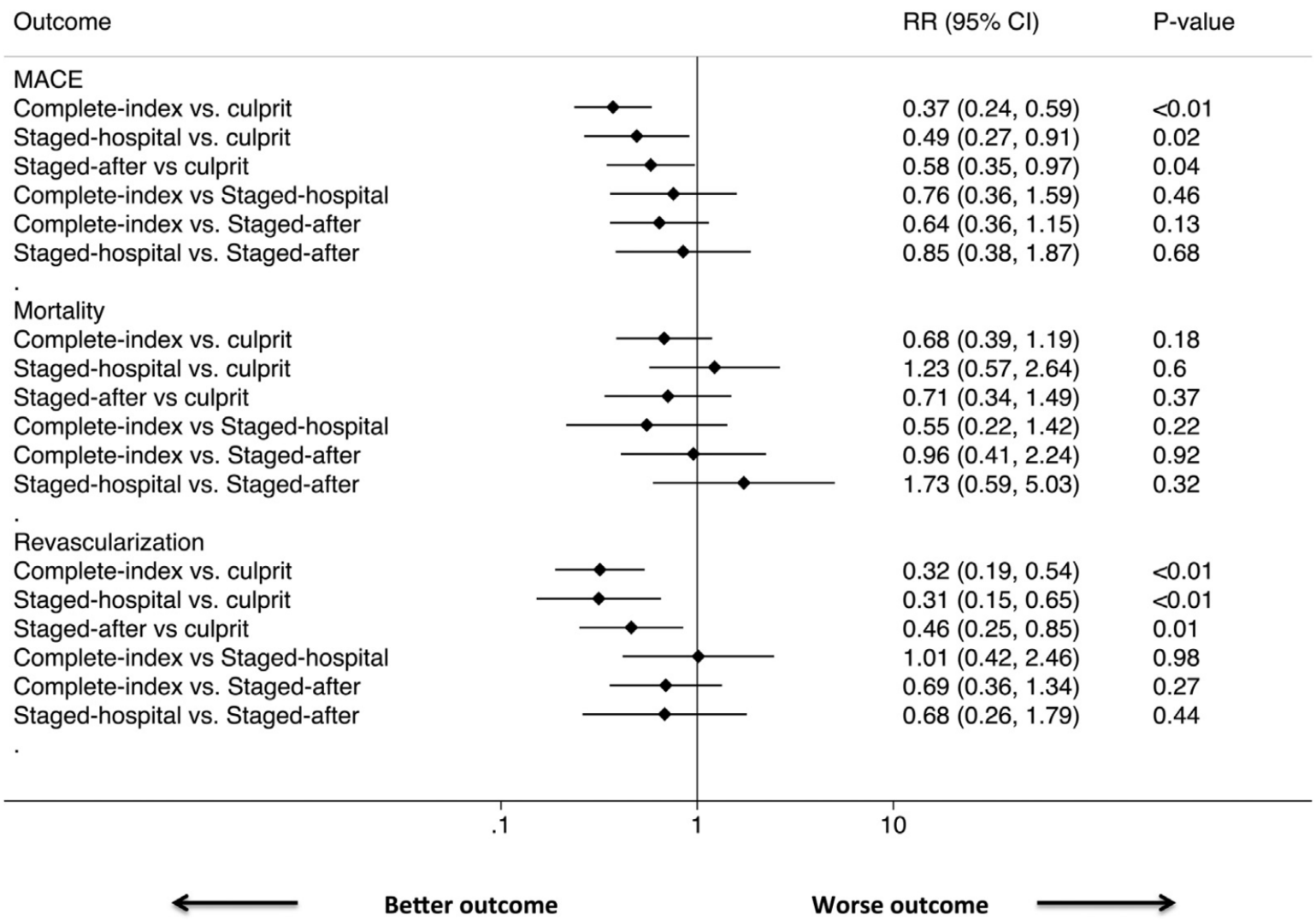
JACC Cardiovasc Interv. 2017 Feb 27;10(4):315-324

JACC Cardiovascular Interventions

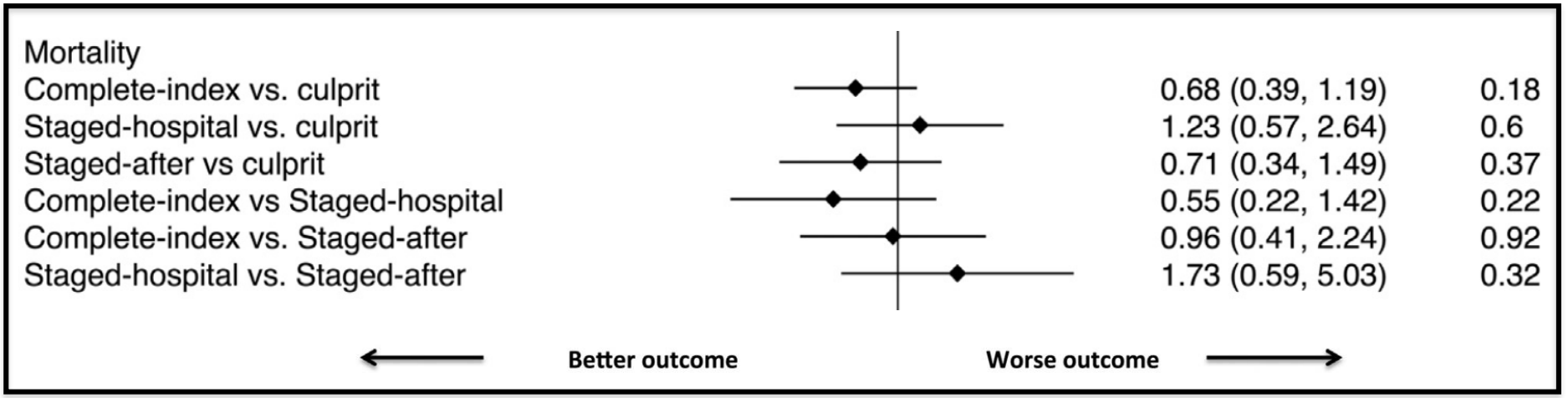
Complete or Culprit-Only Revascularization for Patients With Multivessel Coronary Artery Disease Undergoing Percutaneous Coronary Intervention



Comparison of timing of revascularization strategies



Comparison of timing of revascularization strategies



Conclusion:

None of the strategies have been shown to reduce the overall mortality.

In the absence of other evidence decisions must be highly individualized.

Comparison of timing of revascularization strategies

Factors influencing decisions in approaching STEMI patients:

1. Severity and importance of the non-culprit lesion
2. Time of presentation, regular vs. off hours
3. Expertise of operator and team

Is culprit vessel primary PCI inferior to MVD primary PCI?

- Future trials should have the vessels stratified by the non culprit vessel. (Is the vessel left unrevascularized the LAD?)
- Current studies are inconclusive.
- Future studies should aim at establishing which scenarios are unsafe for leaving non culprit vessels unrevascularized.

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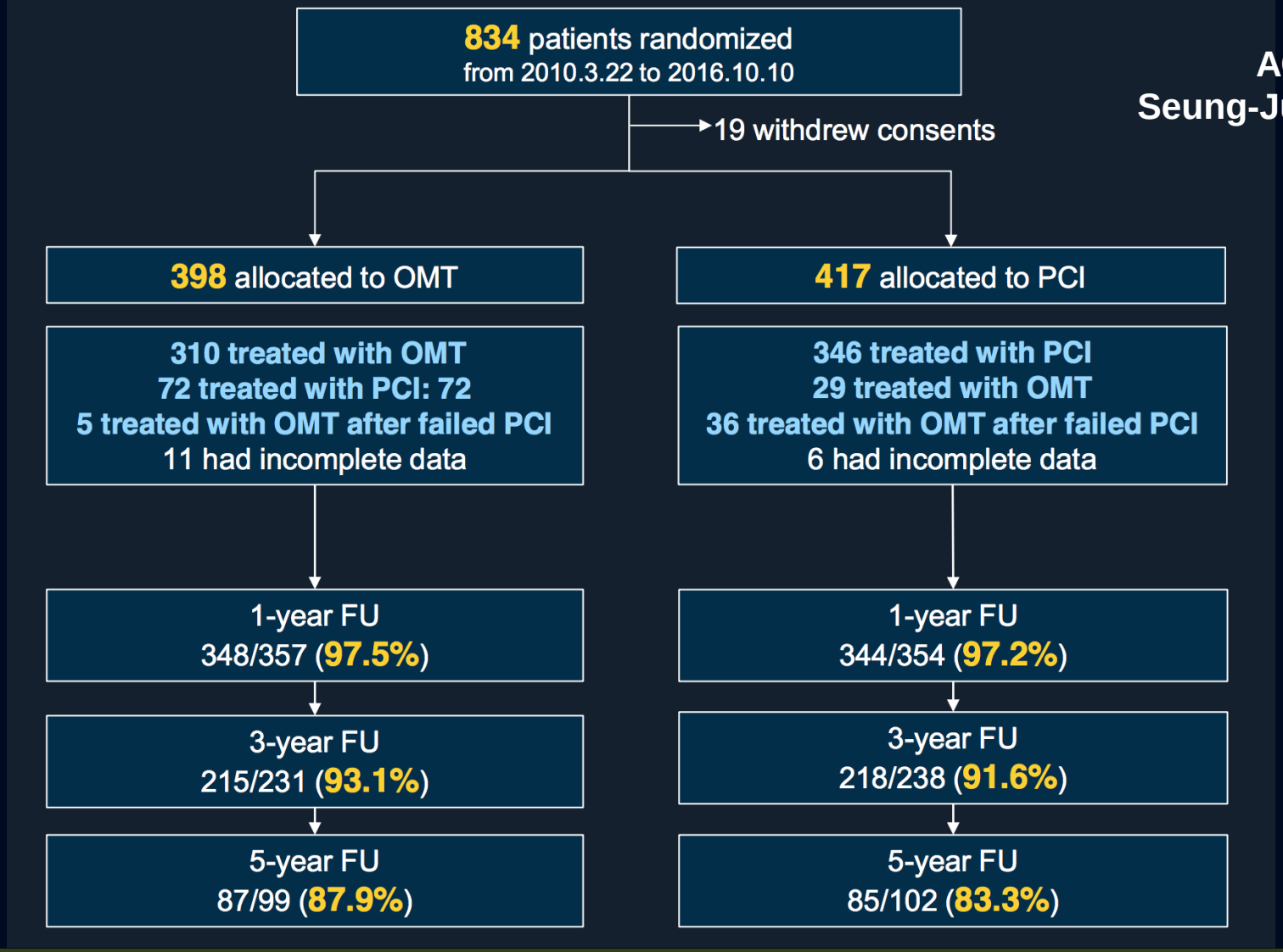
Unanswered Questions in Coronary Artery Disease

-4-

CTO: Who needs Revascularization?

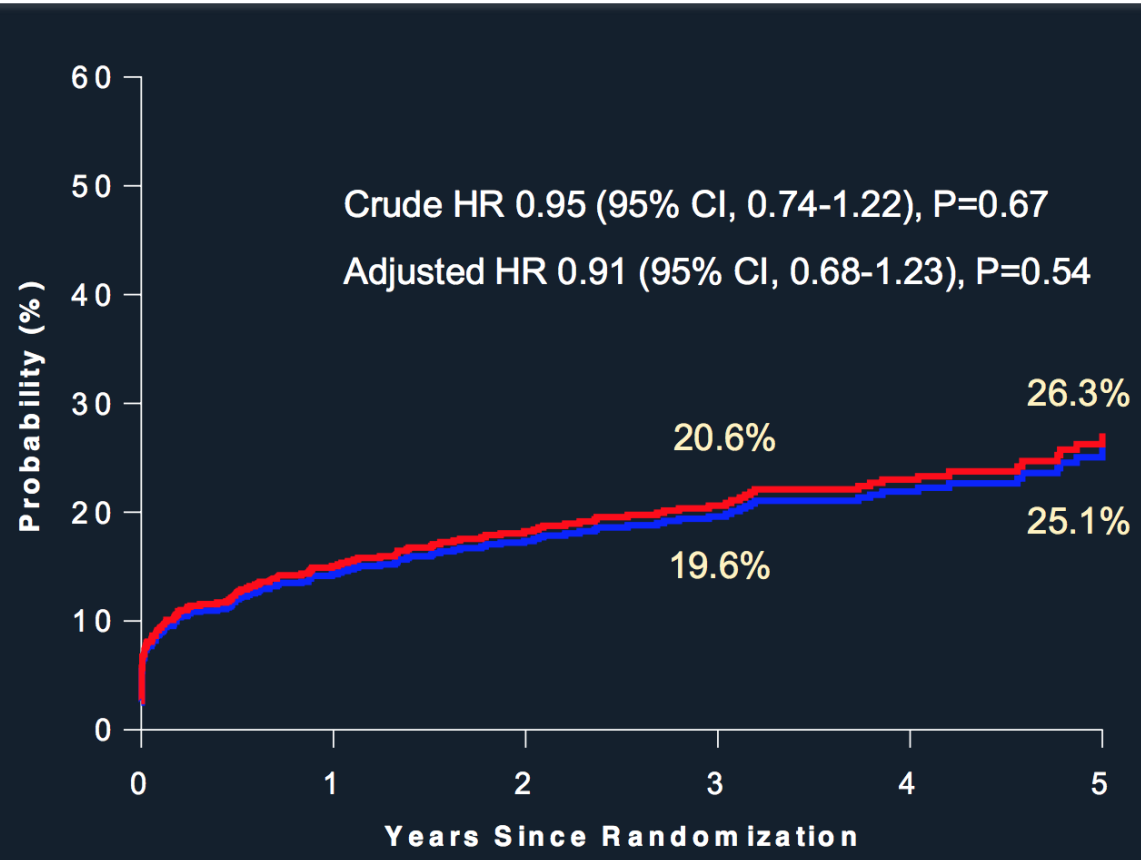
DECISION-CTO



ACC 2017,
Seung-Jung Park

DECISION-CTO

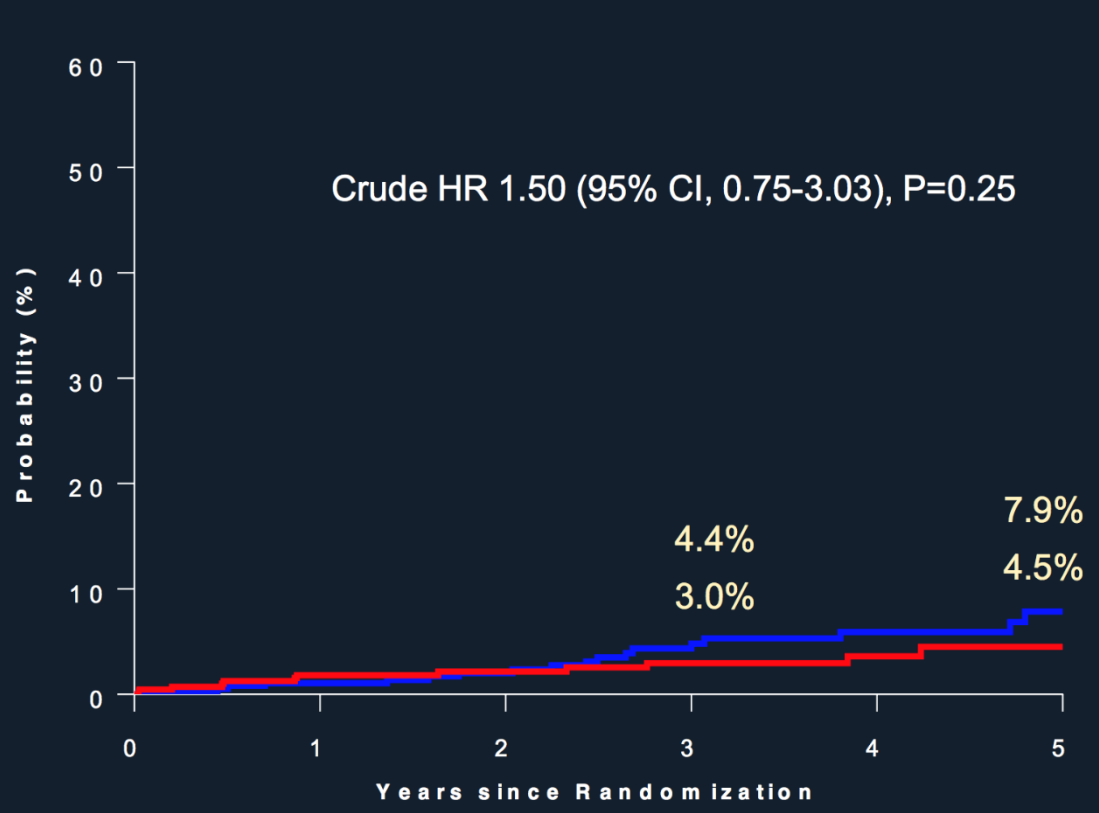
Primary Endpoint: Death, MI, Stroke, Any Revasc



No. at Risk						
OMT	398	305	246	178	129	72
PCI	417	293	241	175	117	65

ACC 2017, Seung-Jung Park

DECISION-CTO: Death



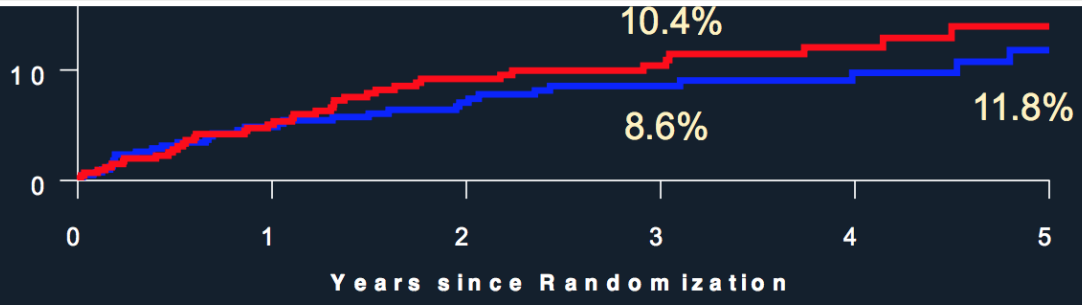
No. at Risk						
OMT	398	344	285	207	140	81
PCI	417	337	285	202	142	74

ACC 2017, Seung-Jung Park

DECISION-CTO

Primary Endpoint: Any Revasc

OMT as an initial strategy was non-inferior to PCI with respect to the primary endpoint of the composite of Death, MI, Stroke, or any Revascularization at 3 years.



No. at Risk						
OMT	398	330	270	292	129	74
PCI	417	321	259	181	129	65

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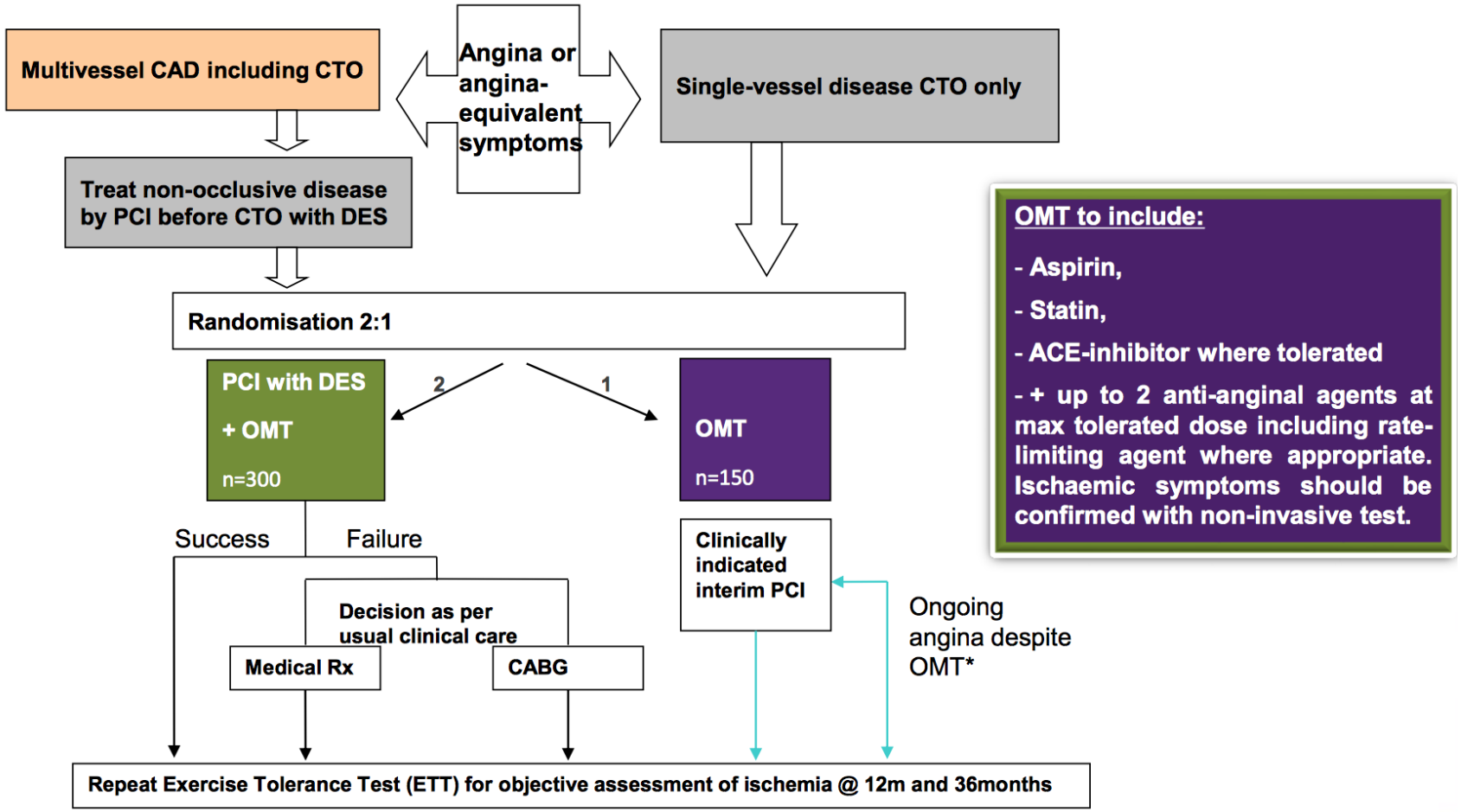
Seung-Jung Park

A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions

EURO-CTO

A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions



A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions

407 patients with a CTO from 26 participating centers and randomized them 2:1 to PCI or OMT

MACCE at 12 months was similar between the PCI and OMT arms (5.2% vs 6.7%; *P* = 0.52) and included two non-CTO-related deaths, five MIs, and one stent thrombosis event in the PCI cohort.

The study showed significant improvement in angina frequency with CTO PCI over OMT (*P* = 0.009) as well as greater improvements in Canadian Cardiovascular Society angina scores with PCI over OMT (*P* < 0.001).

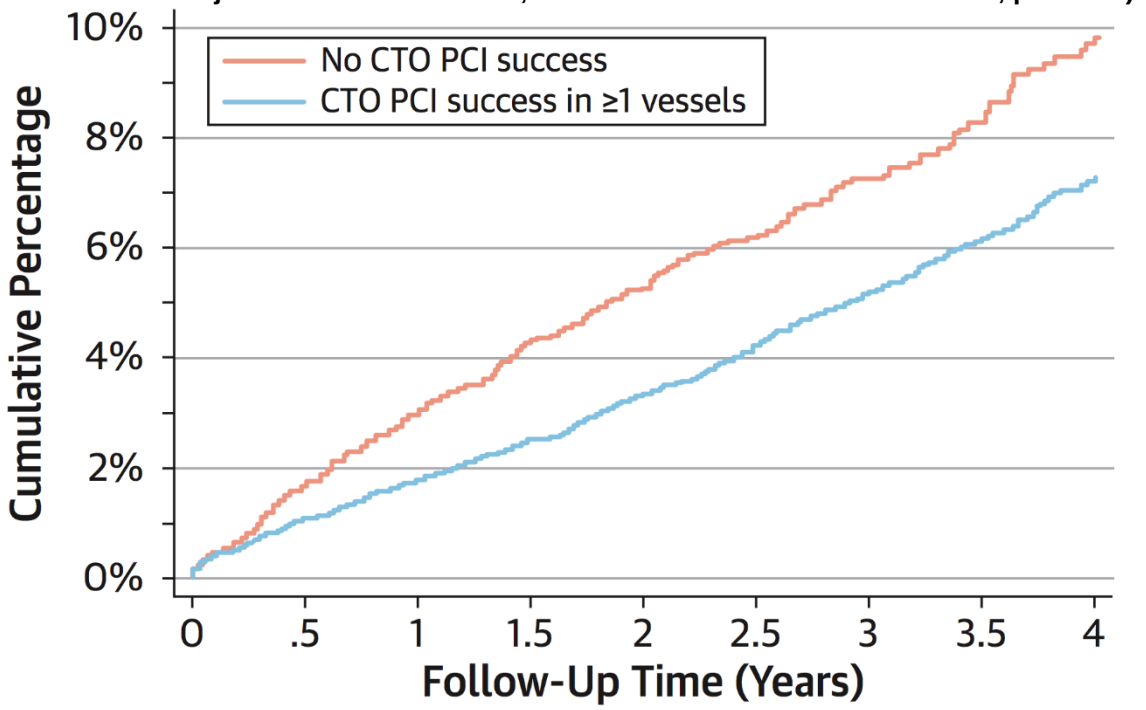
Long-Term Follow-Up of Elective Chronic Total Coronary Occlusion Angioplasty

Analysis From the U.K. Central Cardiac Audit Database

ACC Latin America Conference 2017

Sudhakar George, MD,* James Cockburn, MD,* Tim C. Clayton, MSc,† Peter Ludman, MD,‡ James Cotton, MD,§ James Spratt, MA,|| Simon Redwood, MD,# Mark de Belder, MD,¶ Adam de Belder, MD,* Jonathan Hill, MA,** Angela Hoye, MBChB, PhD,†† Nick Palmer, MD,‡‡ Sudhir Rathore, MD,§§ Anthony Gershlick, MB BS,|||| Carlo Di Mario, MD, PhD,## David Hildick-Smith, MD,* on behalf of the British Cardiovascular Intervention Society and the National Institute for Cardiovascular Outcomes Research

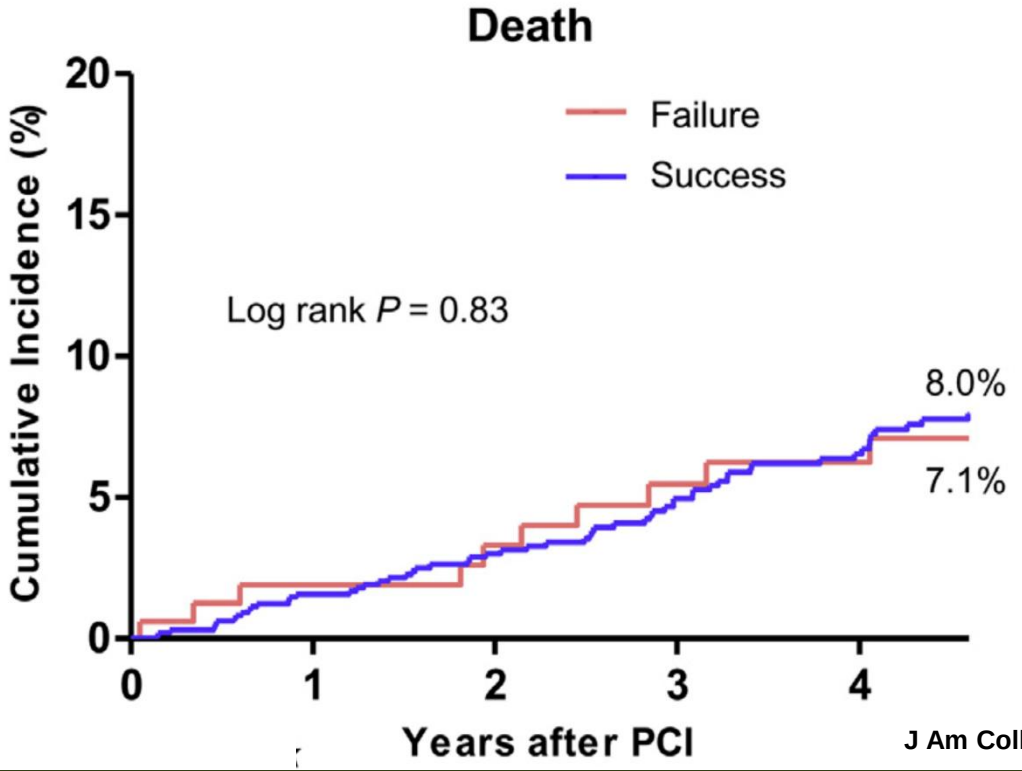
Adjusted hazard ratio: 0.72; 95% confidence interval: 0.62 to 0.83; p < 0.001).



Successful Recanalization of Native Coronary Chronic Total Occlusion Is Not Associated With Improved Long-Term Survival

ACC Latin America Conference 2017

Pil Hyung Lee, MD, Seung-Whan Lee, MD, PhD, Hee-Soon Park, MD, Se Hun Kang, MD, Byeong Joo Bae, MD, Mineok Chang, MD, Jae-Hyung Roh, MD, Sung-Han Yoon, MD, Jung-Min Ahn, MD, Duk-Woo Park, MD, PhD, Soo-Jin Kang, MD, PhD, Young-Hak Kim, MD, PhD, Cheol Whan Lee, MD, PhD, Seong-Wook Park, MD, PhD, Seung-Jung Park, MD, PhD



JACC Cardiovascular Interventions

J Am Coll Cardiol Intv 2016;9:530–8

Do CTO interventions save lives?

- Requires randomized controlled trials
- Observational studies can not avoid bias
- Trials should be large enough to allow subset analysis of:
    1. Isolated CTO
    2. CTO as part of multivessel revascularization
    3. CTO of LAD or other vessels

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Unanswered Questions in Coronary Artery Disease

-5-

BRS: Where are we?

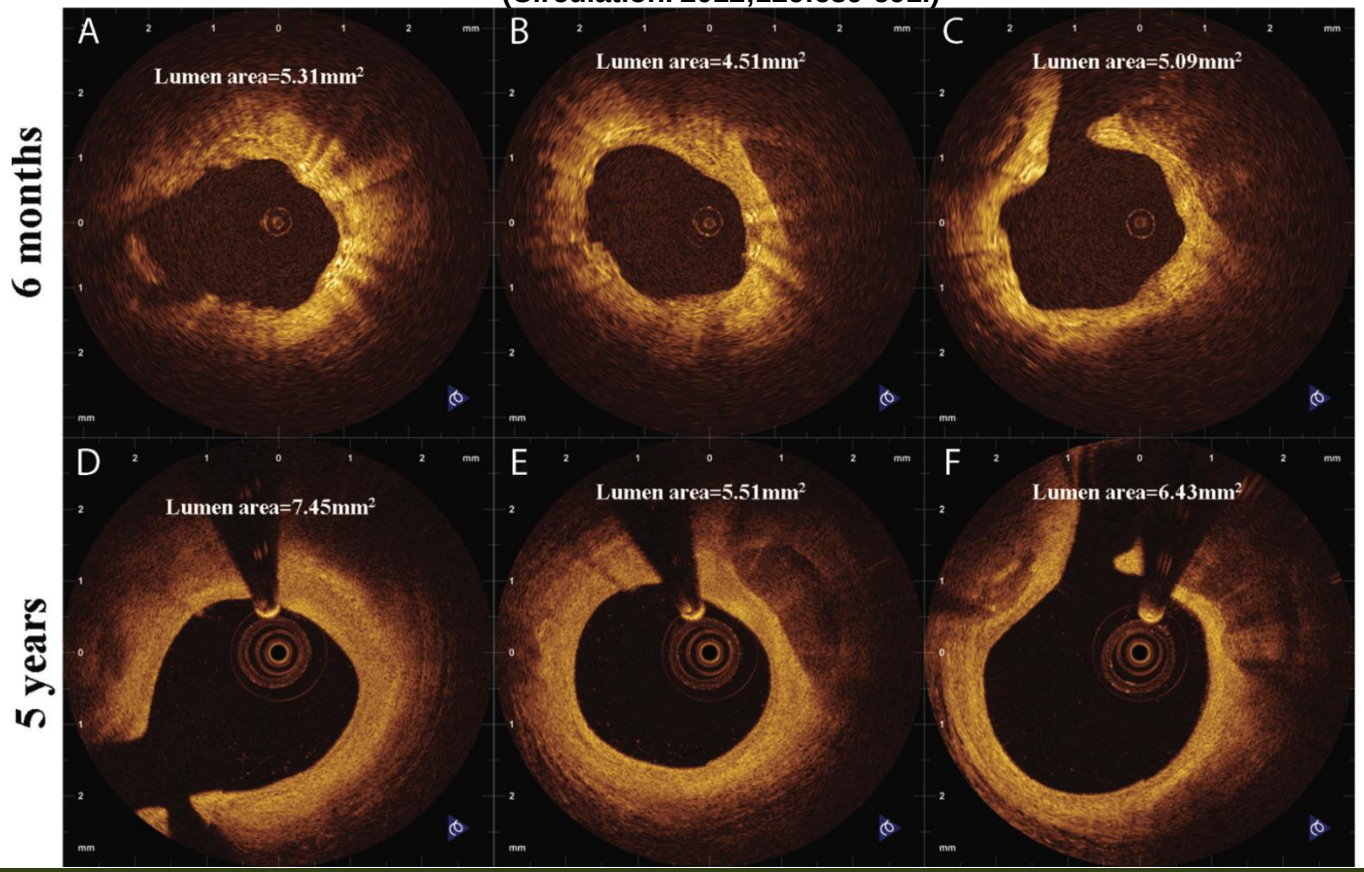
Five-Year Optical Coherence Tomography Follow-Up of an Everolimus-Eluting Bioresorbable Vascular Scaffold

Changing the Paradigm of Coronary Stenting?

American Heart Association. Learn and Live

Antonios Karanasos, MD; Cihan Simsek, MD; Patrick Serruys, MD, PhD; Jurgen Ligthart, BSc; Karen Witberg, CCRN; Robert-Jan van Geuns, MD, PhD; George Sianos, MD, PhD; Felix Zijlstra, MD, PhD; Evelyn Regar, MD, PhD

(Circulation. 2012;126:e89-e91.)



The NEW ENGLAND JOURNAL of MEDICINE

Bioresorbable Scaffolds versus Metallic Stents in Routine PCI

Joanna J. Wykrzykowska, M.D., Ph.D., Robin P. Kraak, M.D., Sjoerd H. Hofma, M.D., Ph.D., Rene J. van der Schaaf, M.D., Ph.D., E. Karin Arkenbout, M.D., Ph.D., Alexander J. IJsselmuiden, M.D., Ph.D., Joëlle Elias, M.D., Ivo M. van Dongen, M.D., Ruben Y.G. Tijssen, M.D., Karel T. Koch, M.D., Ph.D., Jan Baan, Jr., M.D., Ph.D., M. Marije Vis, M.D., Ph.D., Robbert J. de Winter, M.D., Ph.D., Jan J. Piek, M.D., Ph.D., Jan G.P. Tijssen, Ph.D., and Jose P.S. Henriques, M.D., Ph.D., for the AIDA Investigators*

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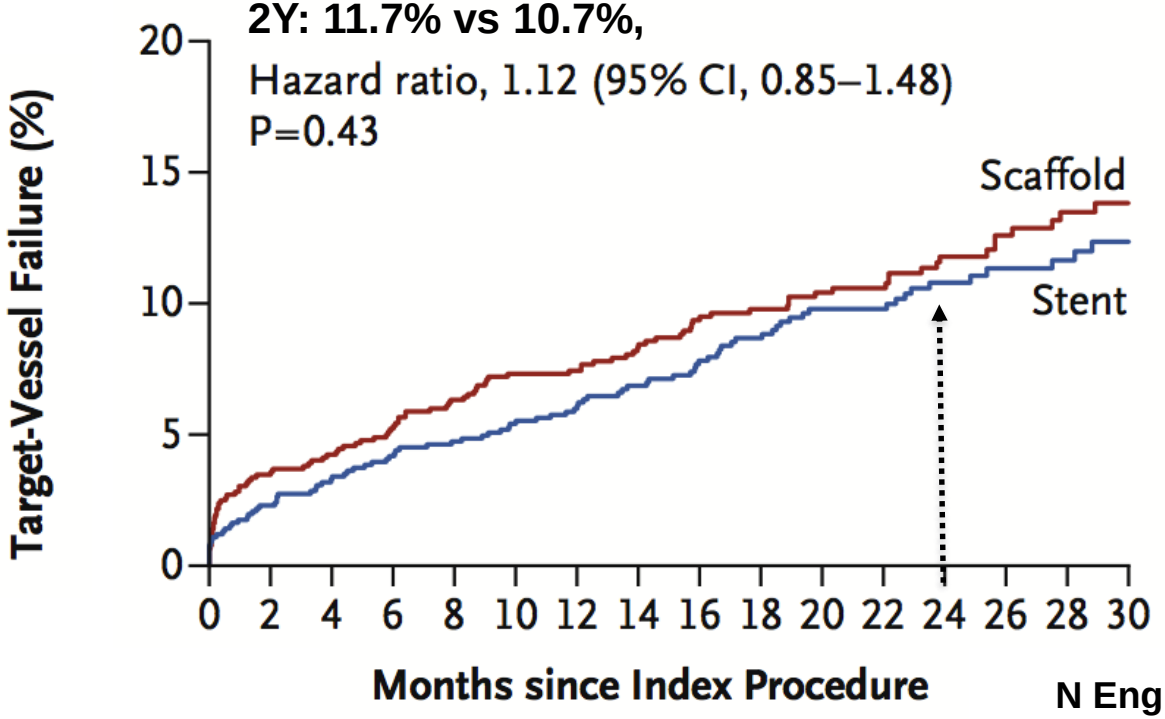
N Engl J Med. 2017 Mar 29

Bioresorbable Scaffolds versus Metallic Stents in Routine PCI

1845 patients undergoing PCI: BVS (n=924) or a metallic Xience stent (n=921)
The primary end point was TVF (a composite of cardiac death, MI, or TVL).
All comers: ACS (STEMI-NSTEMI), SAP



N Engl J Med. 2017 Mar 29

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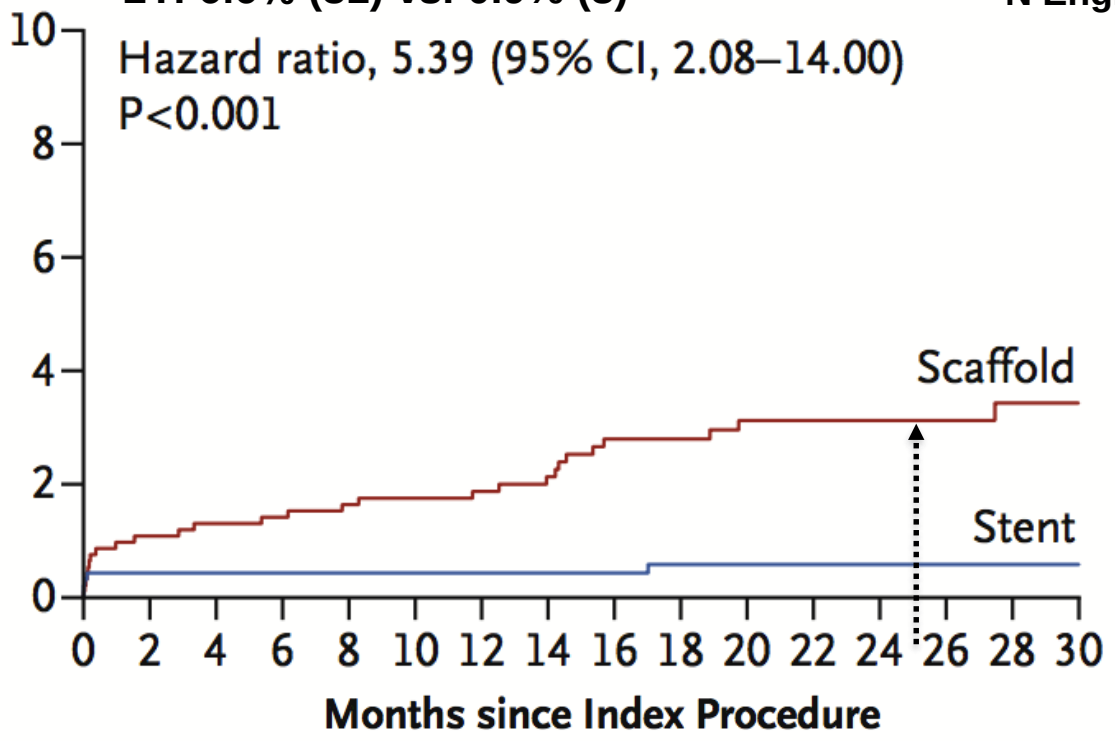
The primary end point was TVF (a composite of cardiac death, MI, or TVL).
All comers: ACS (STEMI-NSTEMI), SAP

2Y: 3.5% (31) vs. 0.9% (8)

N Engl J Med. 2017 Mar 29



The NEW ENGLAND JOURNAL of MEDICINE

Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease

Stephen G. Ellis, M.D., Dean J. Kereiakes, M.D., D. Christopher Metzger, M.D., Ronald P. Caputo, M.D., David G. Rizik, M.D., Paul S. Teirstein, M.D., Marc R. Litt, M.D., Annapoorna Kini, M.D., Ameer Kabour, M.D., Steven O. Marx, M.D., Jeffrey J. Popma, M.D., Robert McGreevy, Ph.D., Zhen Zhang, Ph.D., Charles Simonton, M.D., and Gregg W. Stone, M.D., for the ABSORB III Investigators*

2008 patients with stable or unstable angina were randomly assigned in a 2:1 ratio to receive an Absorb BVS (1322 patients) or an XV stent (686 patients).

The primary end point, which was tested for both non-inferiority and superiority, was *TLF at 1year.*

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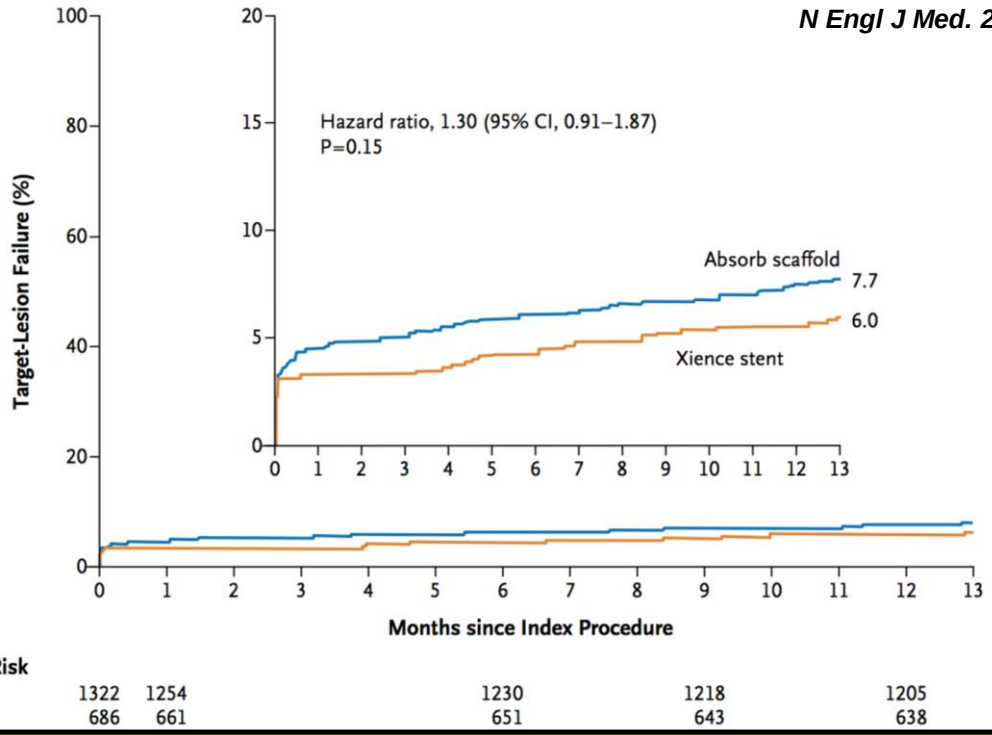
Target Lesion Failure @ 1Y:

7.8% of patients in the Absorb group and in 6.1% of patients in the Xience group

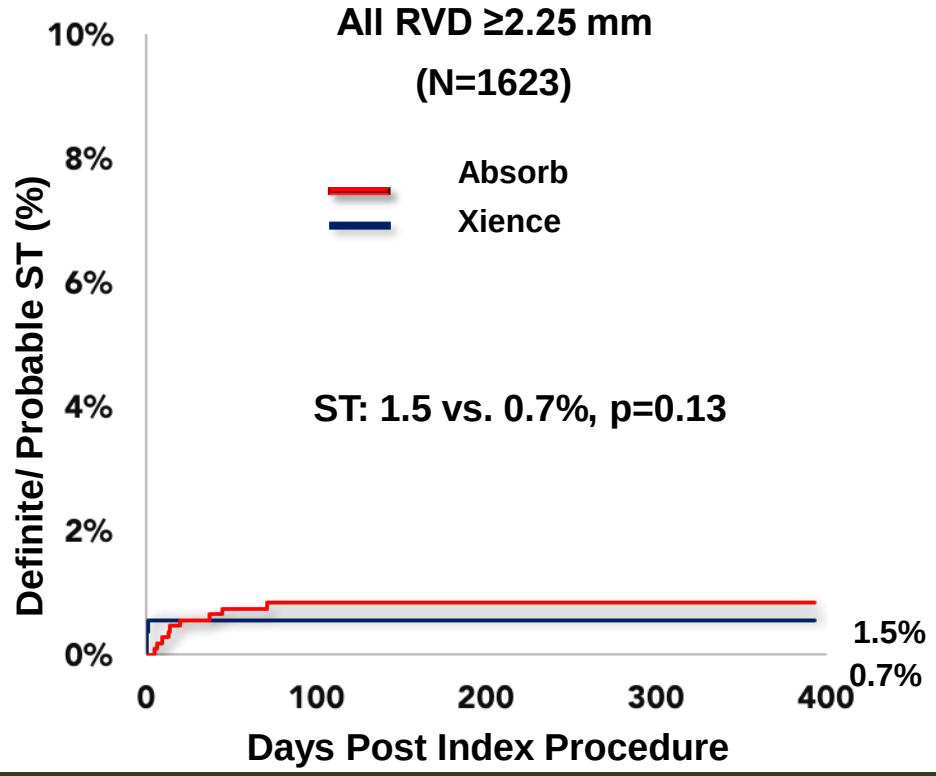
N Engl J Med. 2015 Nov 12;373(20):1905-15



The NEW ENGLAND JOURNAL of MEDICINE

Device thrombosis within 1y occurred in 1.5% of patients in the Absorb group and in 0.7% of patients in the Xience group (p=0.13)

N Engl J Med. 2015 Nov 12;373(20):1905-15



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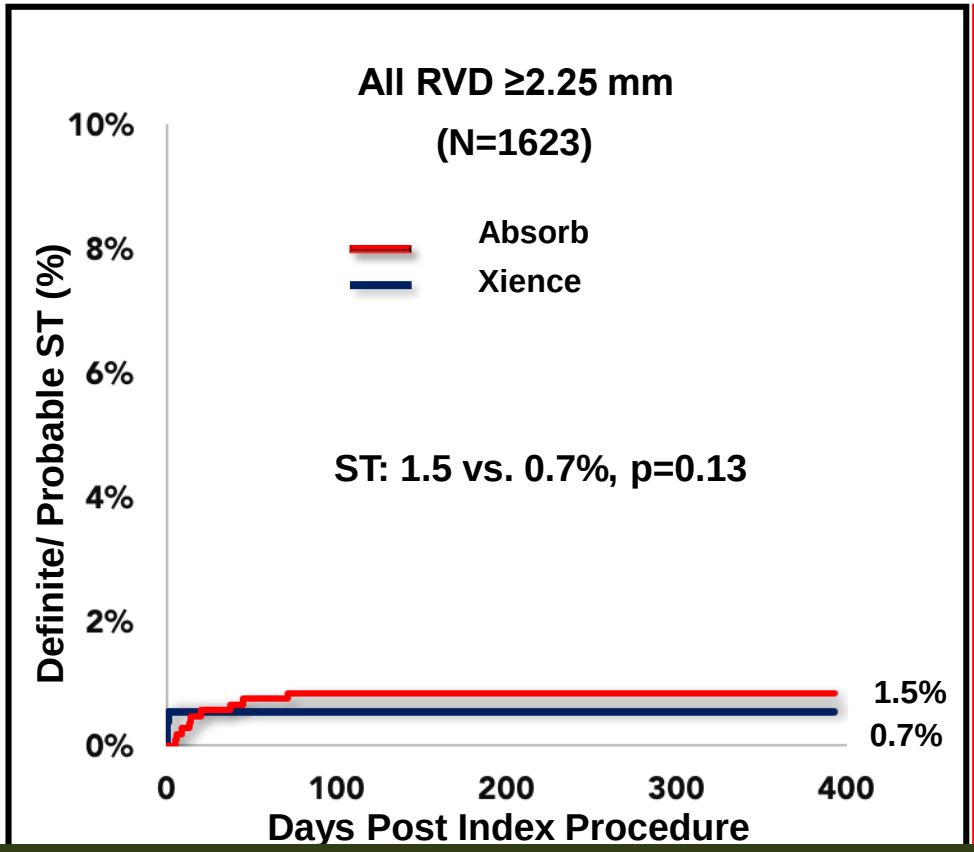

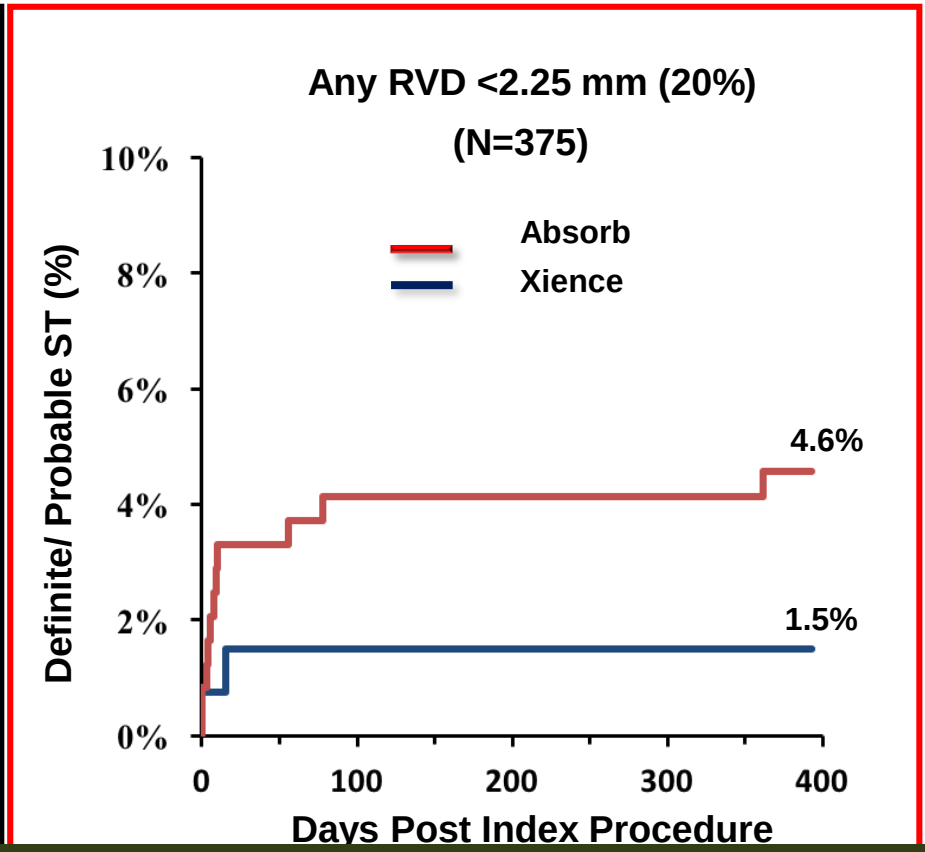

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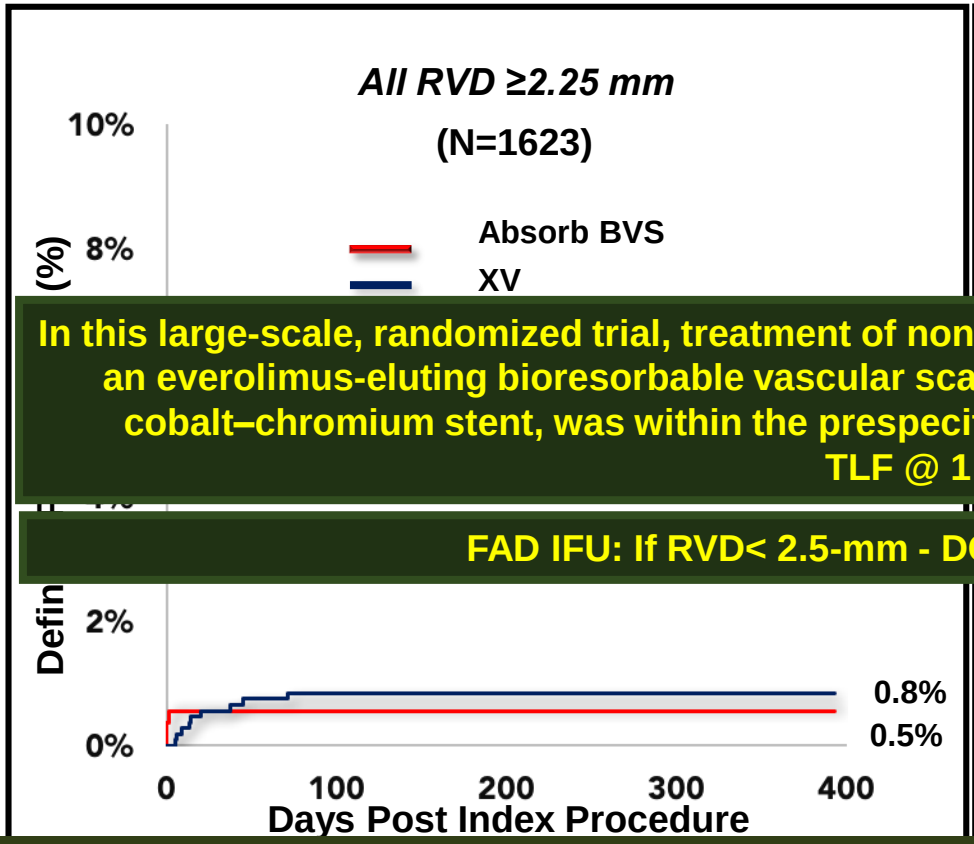
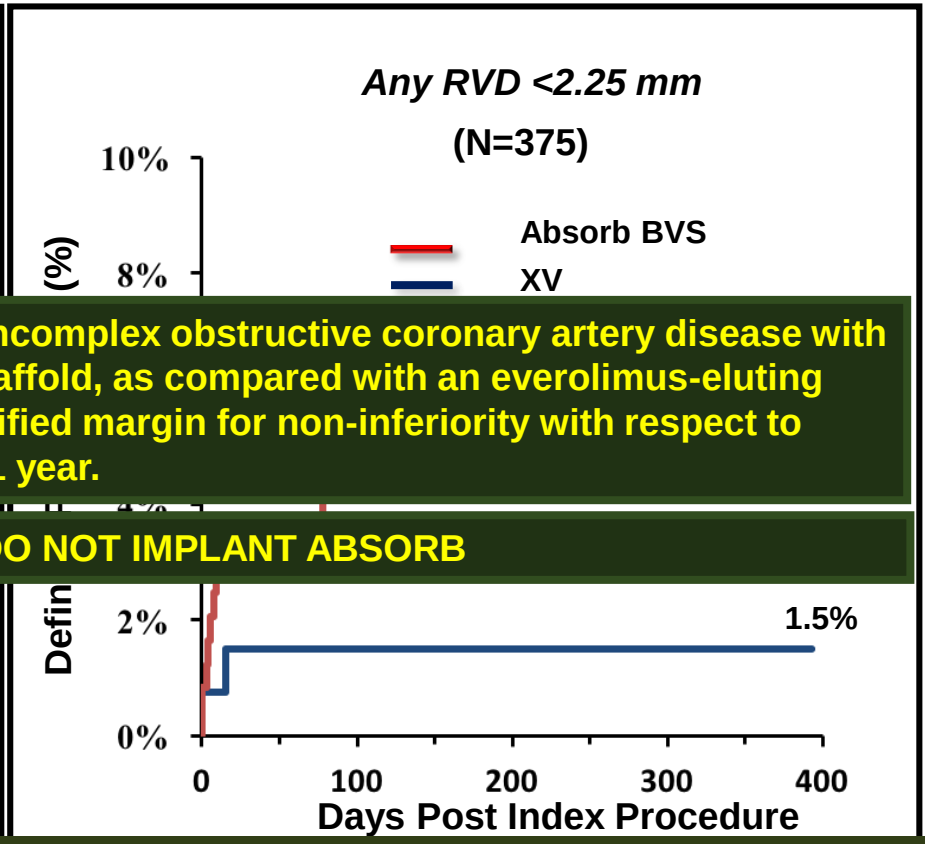


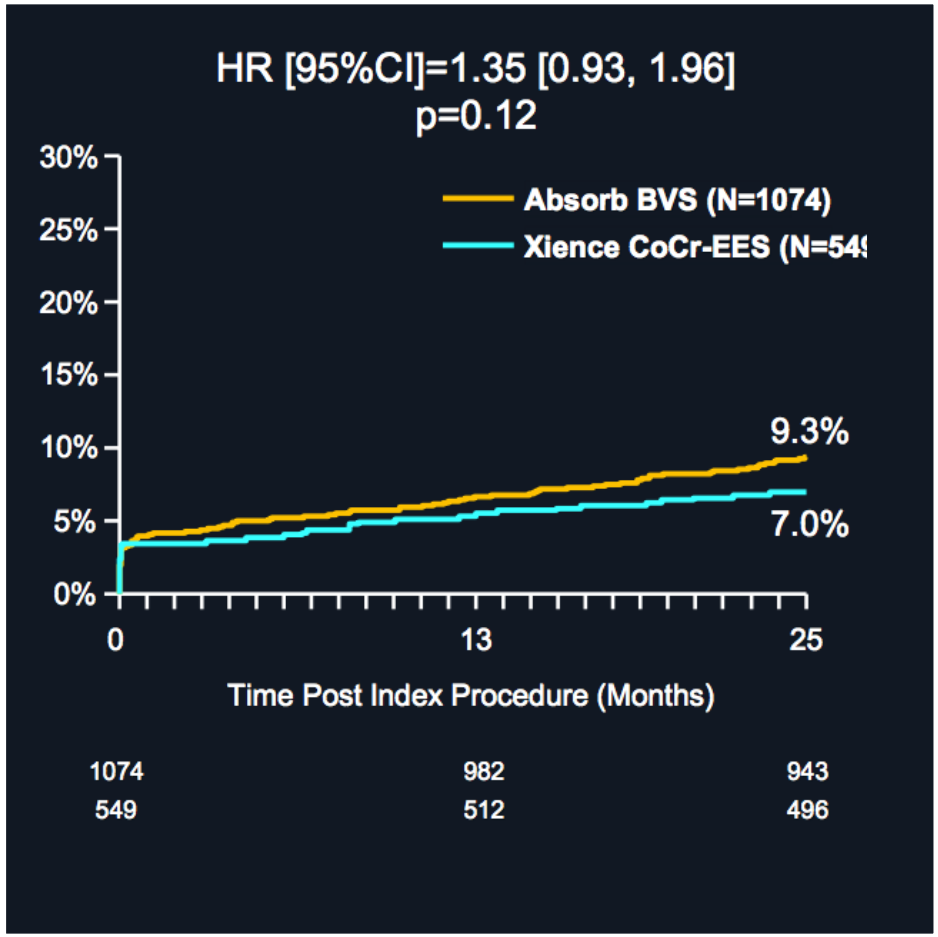


In this large-scale, randomized trial, treatment of noncomplex obstructive coronary artery disease with an everolimus-eluting bioresorbable vascular scaffold, as compared with an everolimus-eluting cobalt–chromium stent, was within the prespecified margin for non-inferiority with respect to TLF @ 1 year.

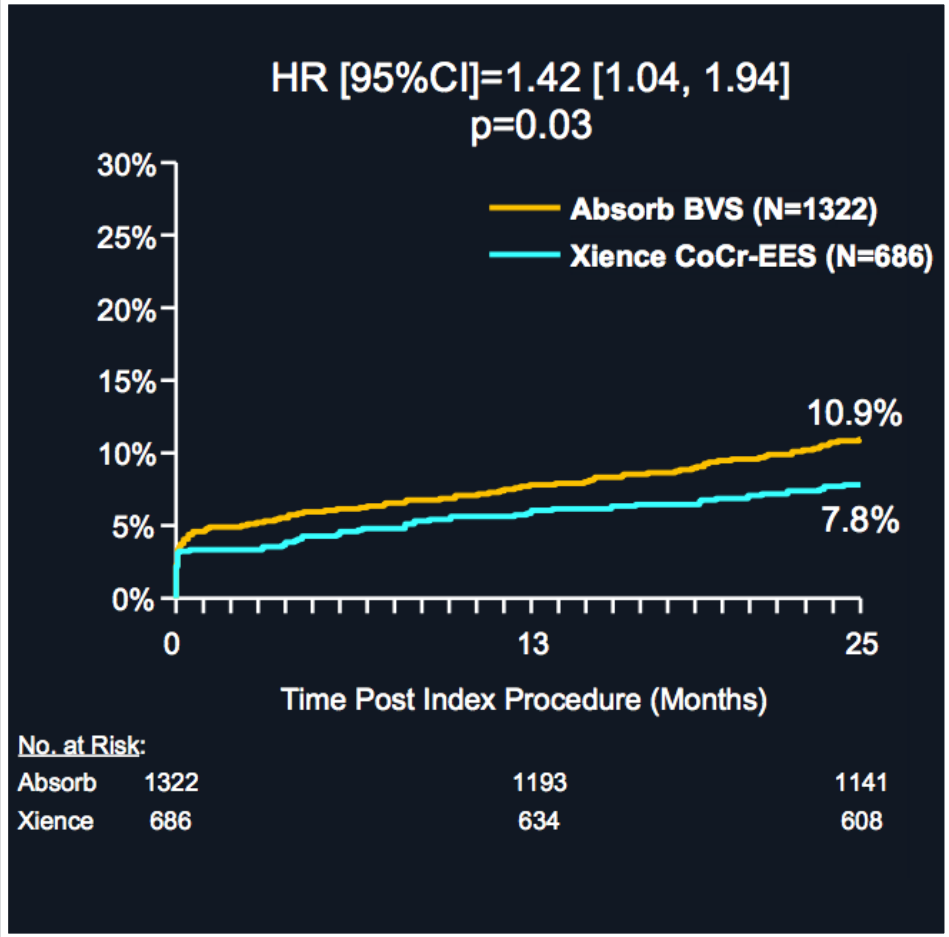
FAD IFU: If RVD< 2.5-mm - DO NOT IMPLANT ABSORB

ABSORB III: TLF by 2 Years

QCA RVD > 2.25 mm



Overall



TCT 2016: Stephen G. Ellis, MD, Dean J. Kereiakes, MD, & Gregg W. Stone, MD for the ABSORB III Investigators

ABSORB III: Clinical Endpoints by 2 Years

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
TLF	11.0% (143)*	7.9% (53)*	9.4% (99)	7.0% (38)
Cardiac Death	1.1% (14)	0.6% (4)	0.9% (10)	0.4% (2)
TV-MI	7.3% (95)**	4.9% (33)**	6.5% (68)	4.8% (26)
ID-TLR	5.3% (69)	4.3% (29)	4.1% (43)	3.0% (16)
ST (Def/Prob)	1.9% (24)	0.8% (5)	1.3% (13)	0.6% (3)

ABSORB III: Clinical Endpoints by 2 Years

	Overall		QCA RVD ≥ 2.25mm	
	Absorb (N=1322)	XIENCE (N=686)	Absorb (N=1074)	XIENCE (N=549)
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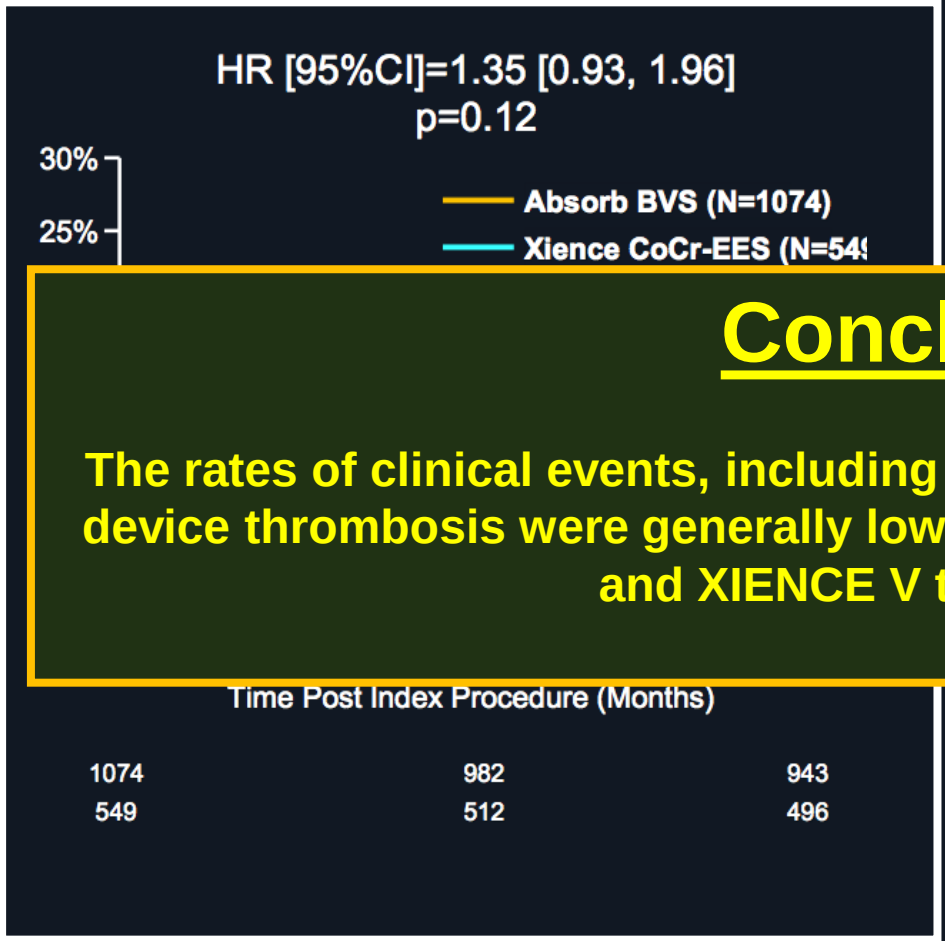
ST (Def/Prob)	1.9% (24)	0.8% (5)	1.3% (13)	0.6% (3)

Letter to Healthcare providers:

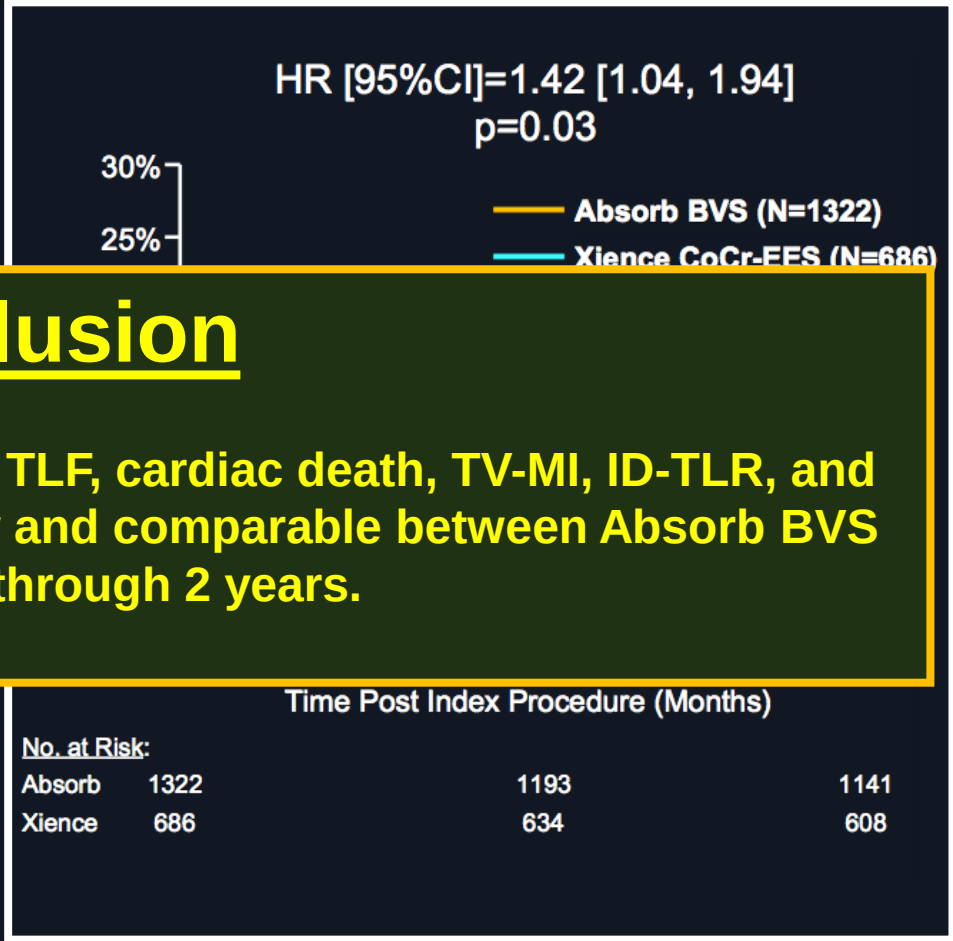
FDA Investigating Increased Rate of Major Adverse Cardiac Events Observed in Patients Receiving Abbott Vascular's Absorb GT1 Bioresorbable Vascular Scaffold (BVS)

ABSORB III: TLF by 2 Years

QCA RVD > 2.25 mm



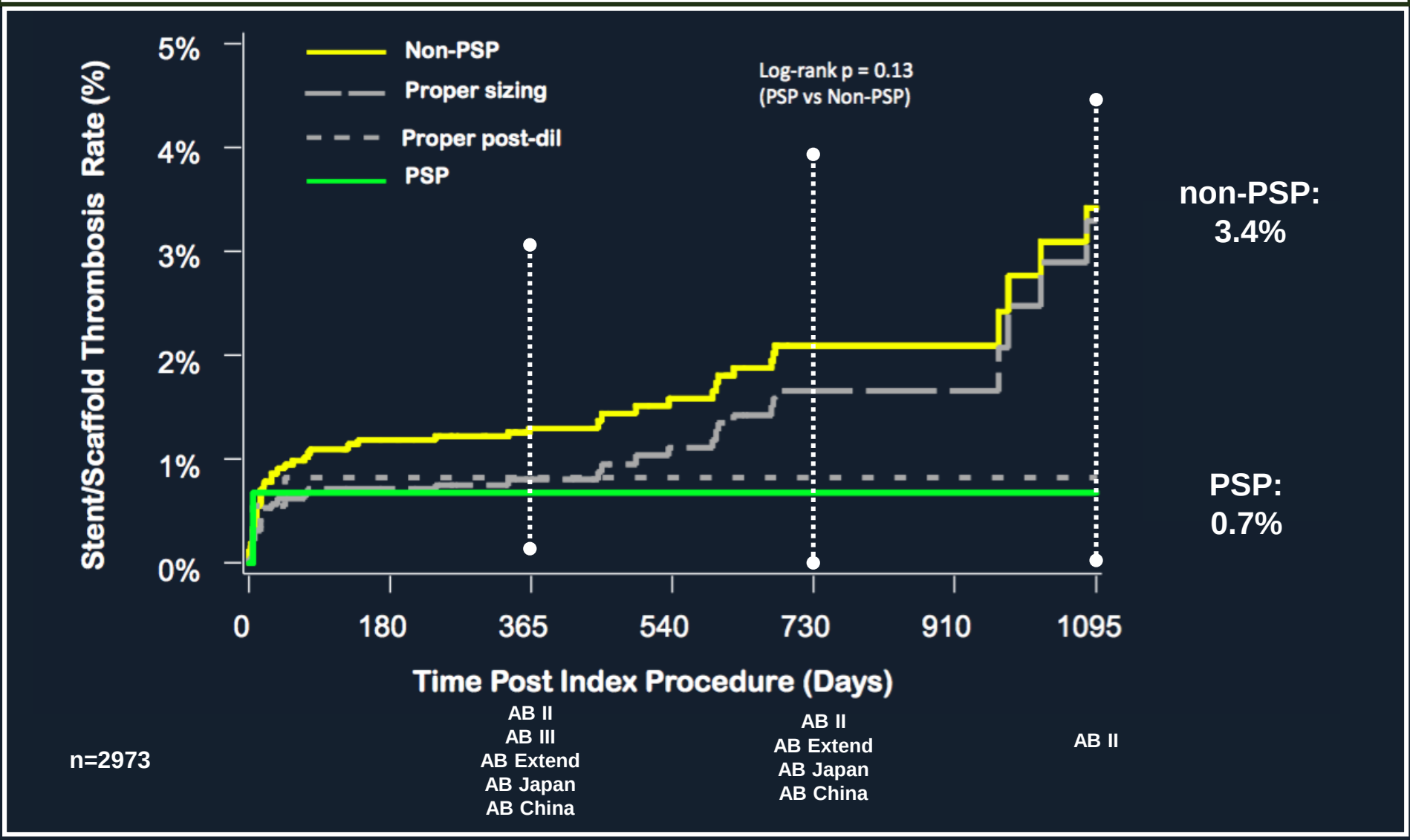
Overall



Conclusion

The rates of clinical events, including TLF, cardiac death, TV-MI, ID-TLR, and device thrombosis were generally low and comparable between Absorb BVS and XIENCE V through 2 years.

Scaffold Thrombosis @ 1, 2 & 3 Years based on PSP Implementation in the ABSORB Trials



ARTICLE IN PRESS

Long-term Clinical Outcomes of Patients Treated with Everolimus-eluting Bioresorbable Stents in Routine Practice

2-Year Results of the ISAR-ABSORB Registry

Wiebe J et al. 2017 in press

The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months

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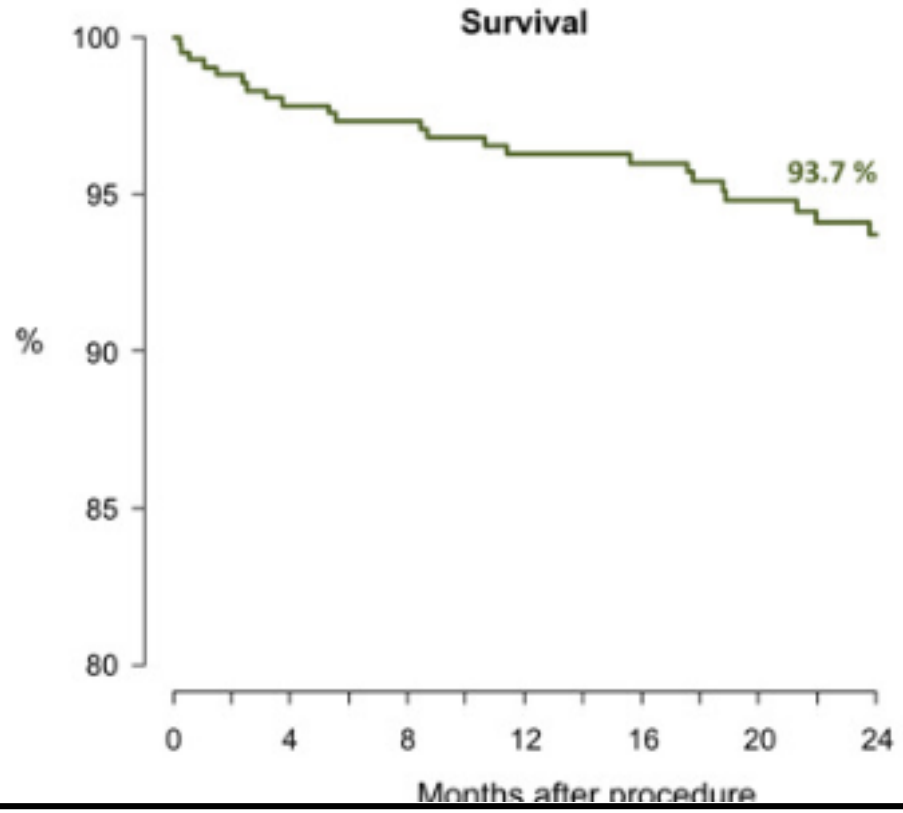

JACC Cardiovascular Interventions

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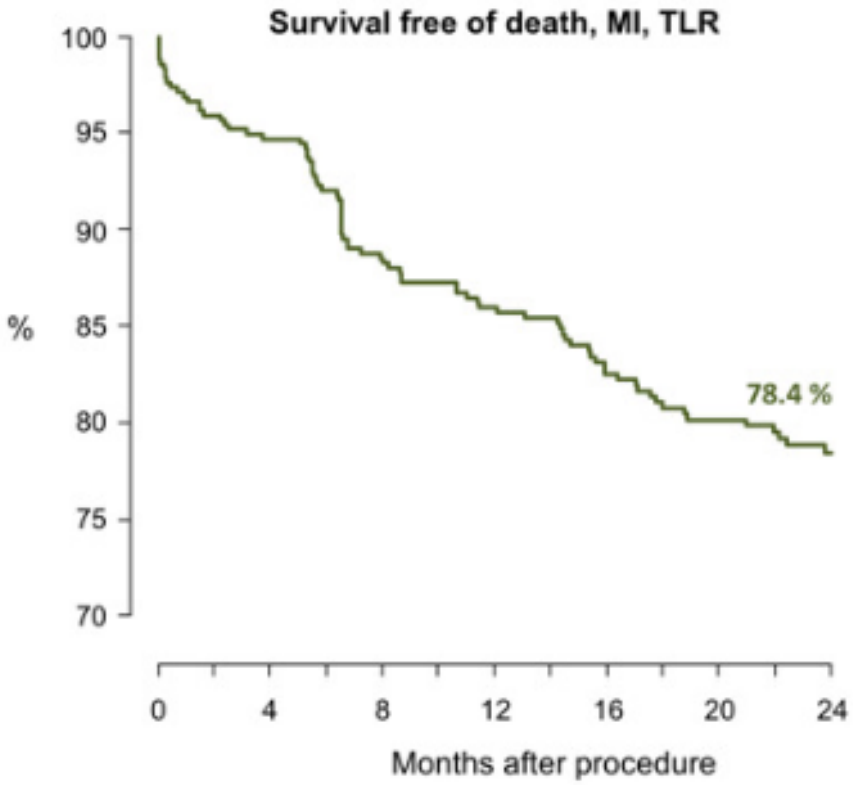

JACC Cardiovascular Interventions

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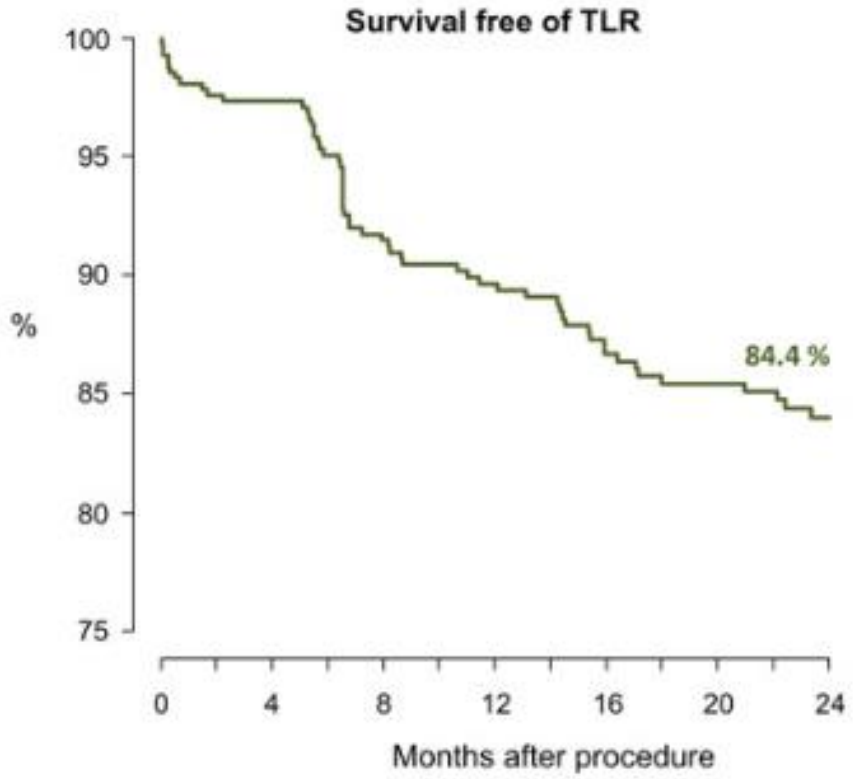

JACC Cardiovascular Interventions

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The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months

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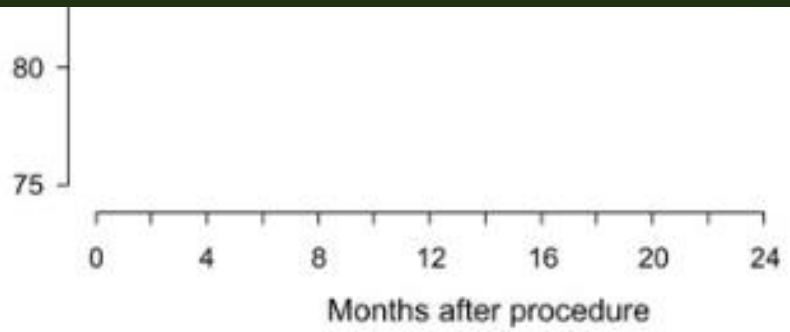
Conclusion:

Long-term follow-up of patients treated with BRS in routine practice showed higher event rates than expected.



JACC Cardiovascular Interventions

What needs to be done to establish the value of Bioresorbable scaffolds?

Preclinical technological improvements to achieve

- improved strut profile
- low thrombogenicity
- good biocompatibility

need to precede any further large clinical trials

Unanswered Questions in Coronary Artery Disease

-6-

What is the role of Percutaneous Assist Devices in Cardiogenic Shock?

The NEW ENGLAND JOURNAL of MEDICINE

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

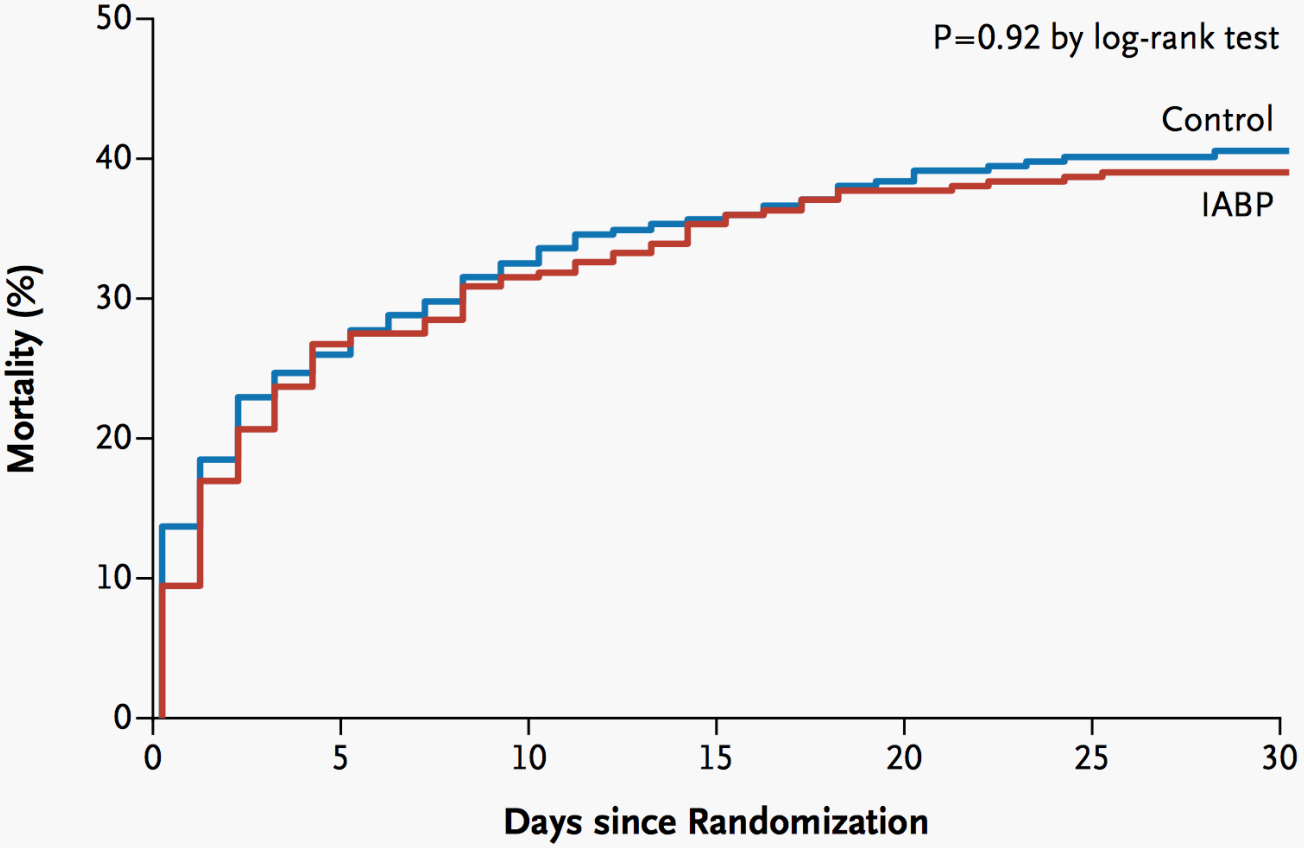
Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*

600 patients with cardiogenic shock complicating acute myocardial infarction to IABP (n=301 patients) or no intraaortic balloon counterpulsation (control group, n=299 patients).

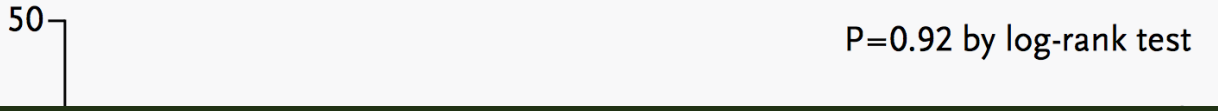
ACC Latin America Conference 2017

N Engl J Med 2012;367:1287-96

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

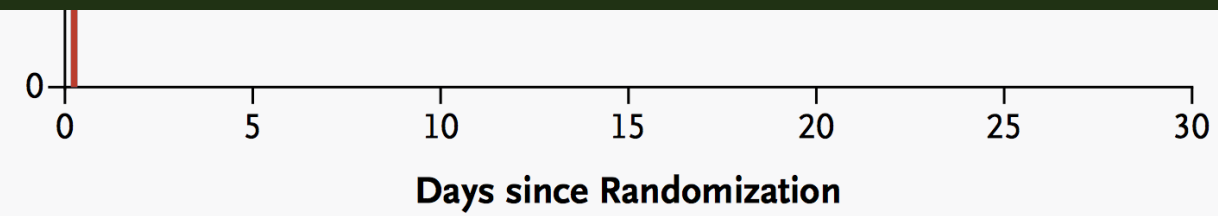


Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock



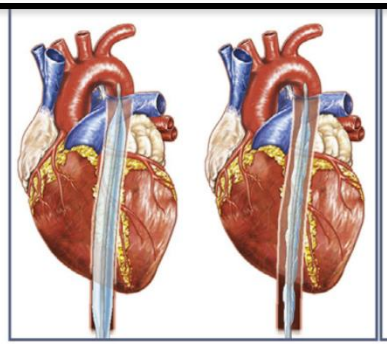
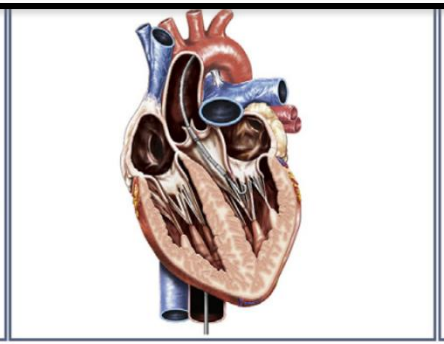
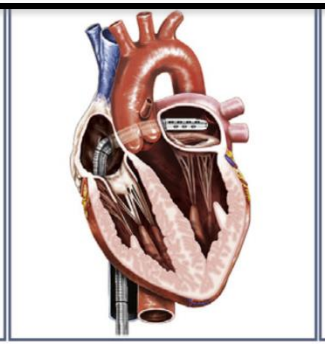
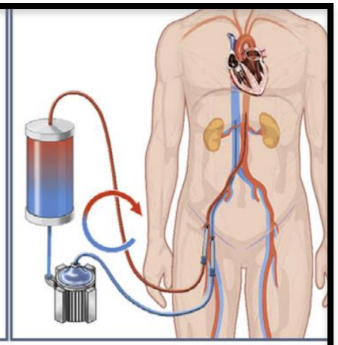
Conclusion:

The use of IABP did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned.



A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

Tamara M. Atkinson, MD,[a] E. Magnus Ohman, MD,[b] William W. O'Neill, MD,[c] Tanveer Rab, MD,[d]
Joaquin E. Cigarroa, MD,[a] on behalf of the Interventional Scientific Council of the American College of Cardiology

	IABP	IMPELLA	TANDEMHEART	VA-ECMO
Cardiac Flow	0.3-0.5 L/ min	1-5L/ min (Impella 2.5, Impella CP, Impella 5)	2.5-5 L/ min	3-7 L-min
Mechanism	Aorta	LV → AO	LA → AO	RA → AO
Maximum implant days	Weeks	7 days	14 days	Weeks
Sheath size	7-8 Fr	13-14 Fr Impella 5.0 - 21 Fr	15-17 Fr Arterial 21 Fr Venous	14-16 Fr Arterial 18-21 Fr Venous
Femoral Artery Size	>4 mm	Impella 2.5 & CP - 5-5.5 mm Impella 5 - 8 mm	8 mm	8 mm

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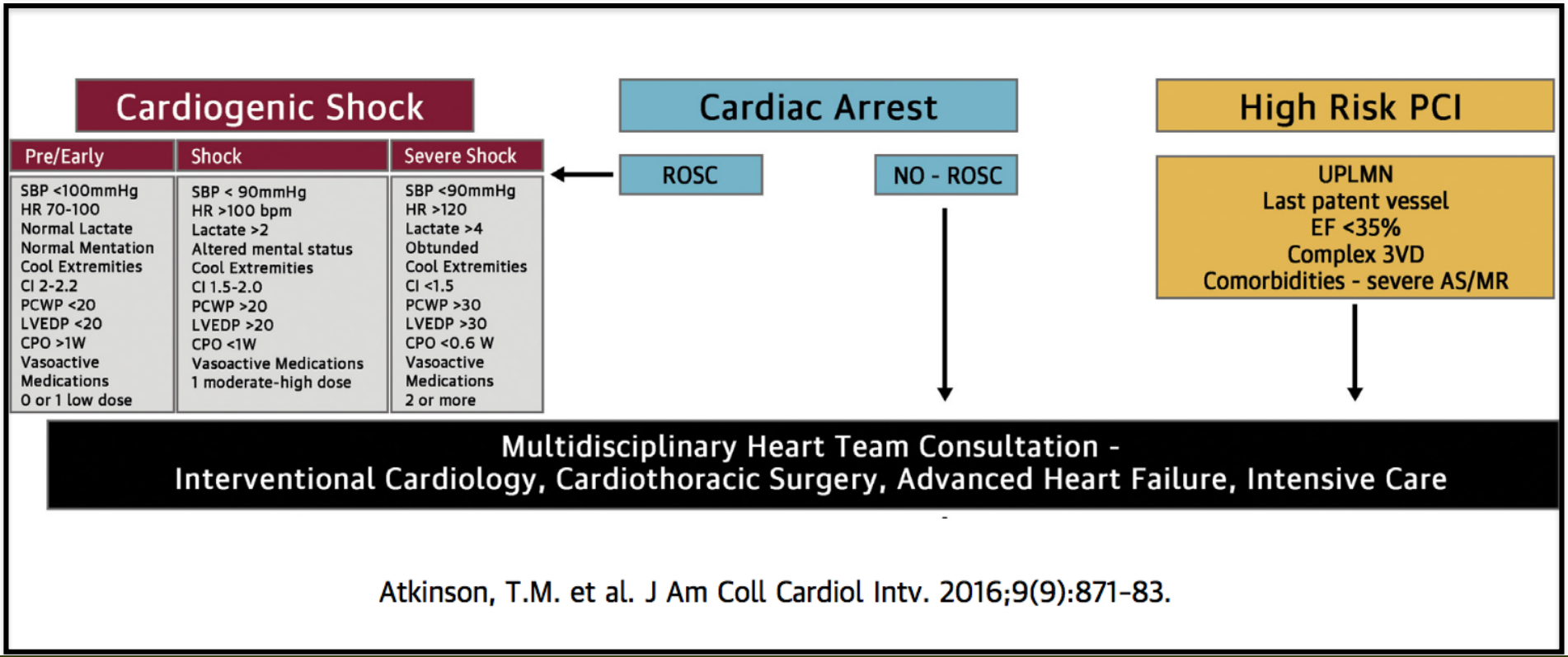
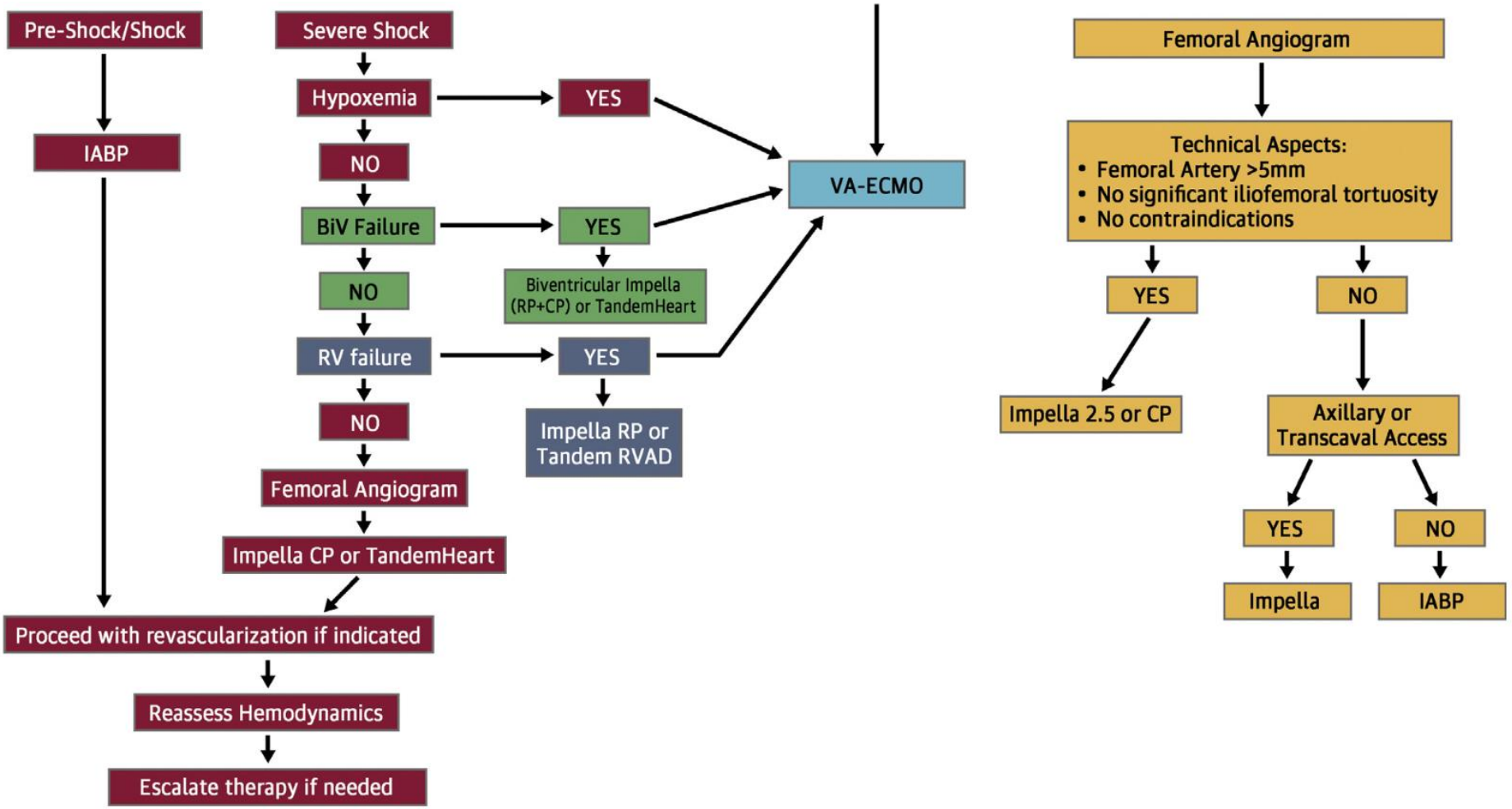


Atkinson, T.M. et al. J Am Coll Cardiol Intv. 2016;9(9):871-83.



Atkinson, T.M. et al. J Am Coll Cardiol Intv. 2016;9(9):871-83.

What hemodynamic support should be used in cardiogenic shock?

- Balloon pumping was not effective in the SHOCK Trial however it is the most commonly used device.
- Trials of hemodynamically effective devices such as the 3.5 L Impella or Tandem Heart device are needed to document survival advantage.
- However these are unlikely to be done therefore single arm registries should be compared to historic controls.

Unanswered Questions in Coronary Artery Disease

-7-

How long should antiplatelet therapy be used following PCI?

The NEW ENGLAND JOURNAL of MEDICINE

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Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

Laura Mauri, M.D., Dean J. Kereiakes, M.D., Robert W. Yeh, M.D., Priscilla Driscoll-Shempp, M.B.A., Donald E. Cutlip, M.D., P. Gabriel Steg, M.D., Sharon-Lise T. Normand, Ph.D., Eugene Braunwald, M.D., Stephen D. Wiviott, M.D., David J. Cohen, M.D., David R. Holmes, Jr., M.D., Mitchell W. Krucoff, M.D., James Hermiller, M.D., Harold L. Dauerman, M.D., Daniel I. Simon, M.D., David E. Kandzari, M.D., Kirk N. Garratt, M.D., David P. Lee, M.D., Thomas K. Pow, M.D., Peter Ver Lee, M.D., Michael J. Rinaldi, M.D., and Joseph M. Massaro, Ph.D., for the DAPT Study Investigators*

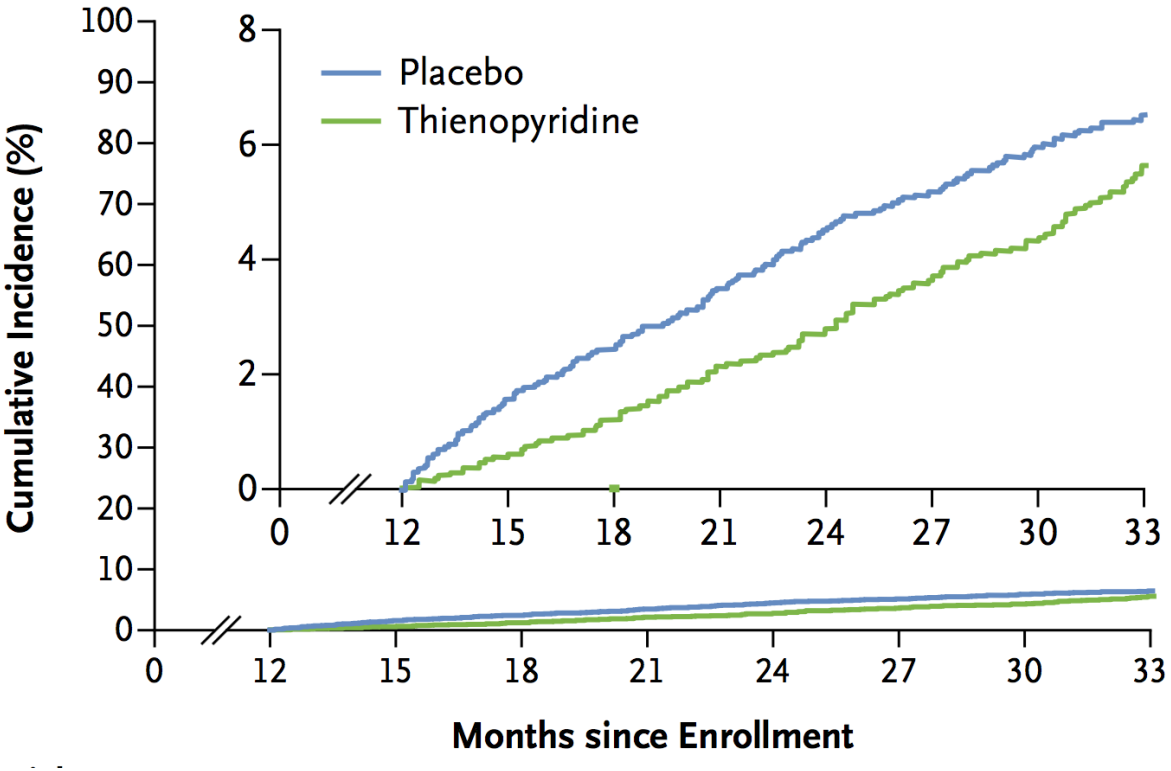
ACC Latin America Conference 2017

Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

Major Adverse Cardiovascular and Cerebrovascular Events

12–30 mo Thienopyridine vs. placebo, 4.3% vs. 5.9%; hazard ratio, 0.71; P<0.001

12–33 mo Thienopyridine vs. placebo, 5.6% vs. 6.5%; hazard ratio, 0.82; P=0.02



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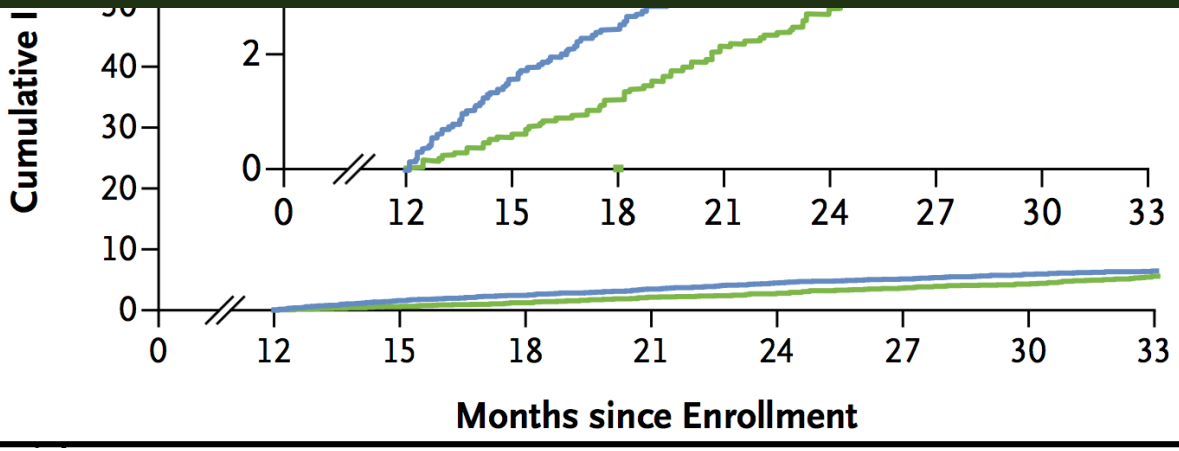
12–33 mo Thienopyridine vs. placebo, 5.6% vs. 6.5%; hazard ratio, 0.82; P=0.02

Conclusion:

DAPT beyond 1 year after placement of a DES, as compared with aspirin therapy alone, significantly reduced the risks of stent thrombosis and major adverse cardiovascular and cerebrovascular events but was associated with an increased risk of bleeding.



The NEW ENGLAND JOURNAL of MEDICINE

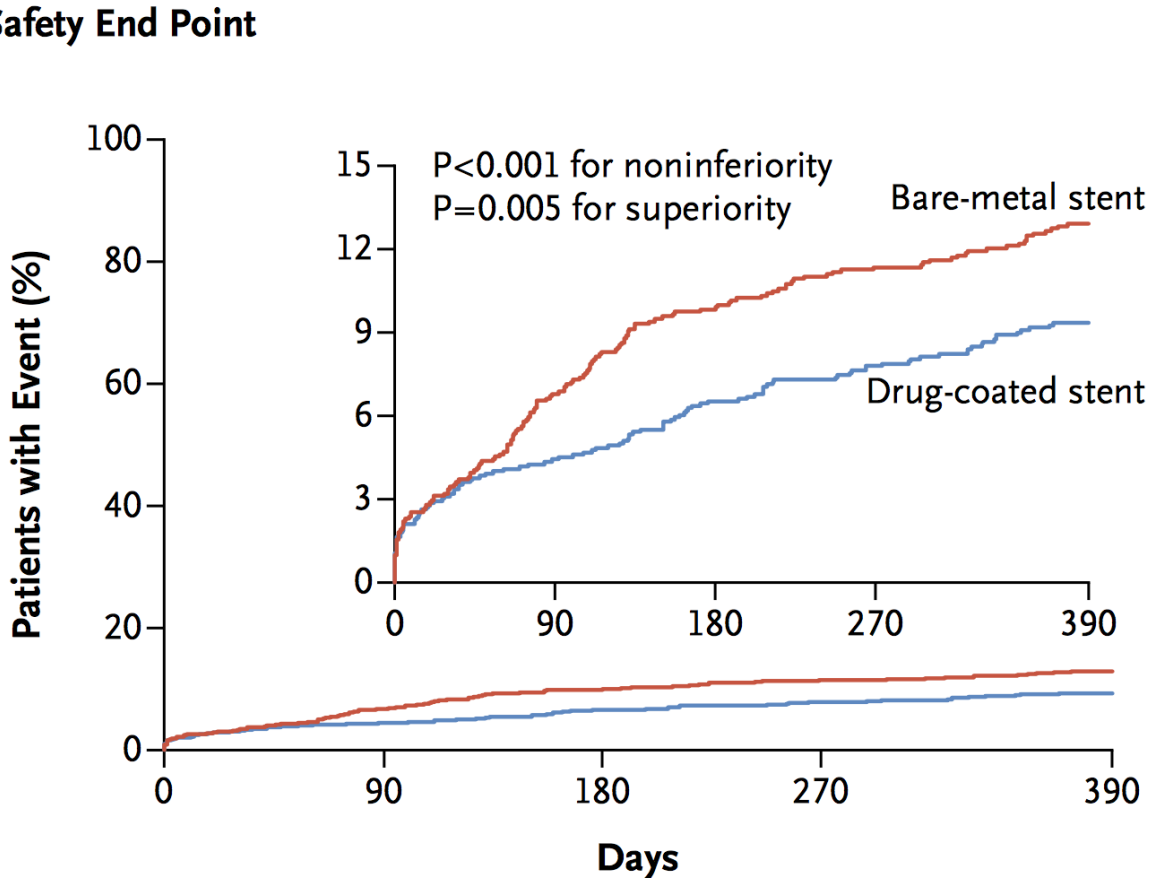
Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

Philip Urban, M.D., Ian T. Meredith, M.B., B.S., Ph.D., Alexandre Abizaid, M.D., Ph.D., Stuart J. Pocock, Ph.D., Didier Carrié, M.D., Ph.D., Christoph Naber, M.D., Ph.D., Janusz Lipiecki, M.D., Ph.D., Gert Richardt, M.D., Andres Iñiguez, M.D., Ph.D., Philippe Brunel, M.D., Mariano Valdes-Chavarri, M.D., Ph.D., Philippe Garot, M.D., Suneel Talwar, M.B., B.S., M.D., Jacques Berland, M.D., Mohamed Abdellaoui, M.D., Franz Eberli, M.D., Keith Oldroyd, M.B., Ch.B., M.D., Robaayah Zambahari, M.B., B.S., M.D., John Gregson, Ph.D., Samantha Greene, B.A., Hans-Peter Stoll, M.D., and Marie-Claude Morice, M.D., for the LEADERS FREE Investigators*

ACC Latin America Conference 2017

Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

Primary Safety Endpoint: Death, MI, Stent Thrombosis



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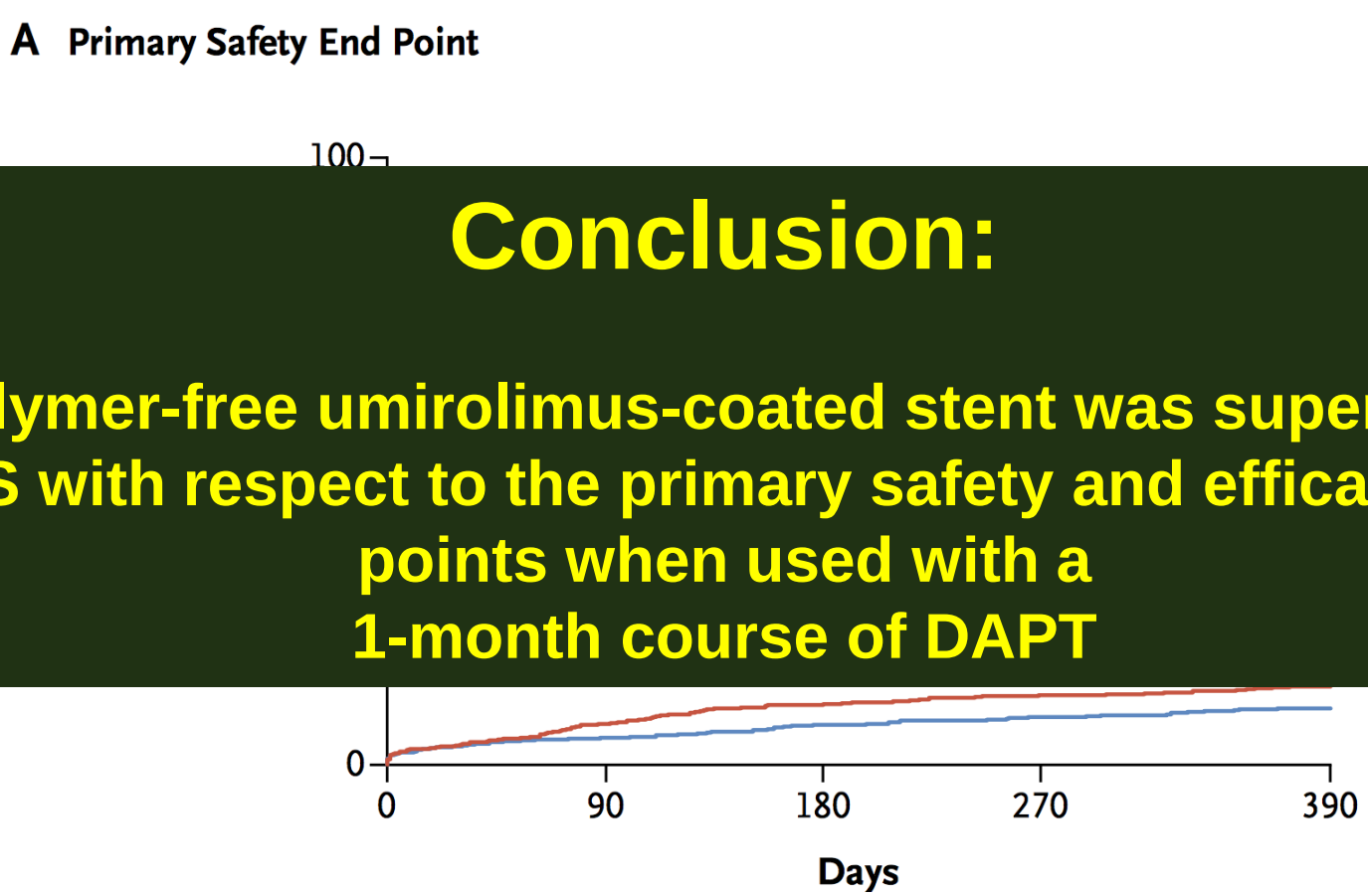

Conclusion:

A polymer-free umirolimus-coated stent was superior to a BMS with respect to the primary safety and efficacy end points when used with a 1-month course of DAPT

ARTICLE IN PRESS

Dual Antiplatelet Therapy for 6 versus 18 Months after Biodegradable Polymer Drug Eluting Stent Implantation

Didier et al. in press 2017

Out of 2,031 patients 926 were randomized to 6 months and 924 to 24 months DAPT

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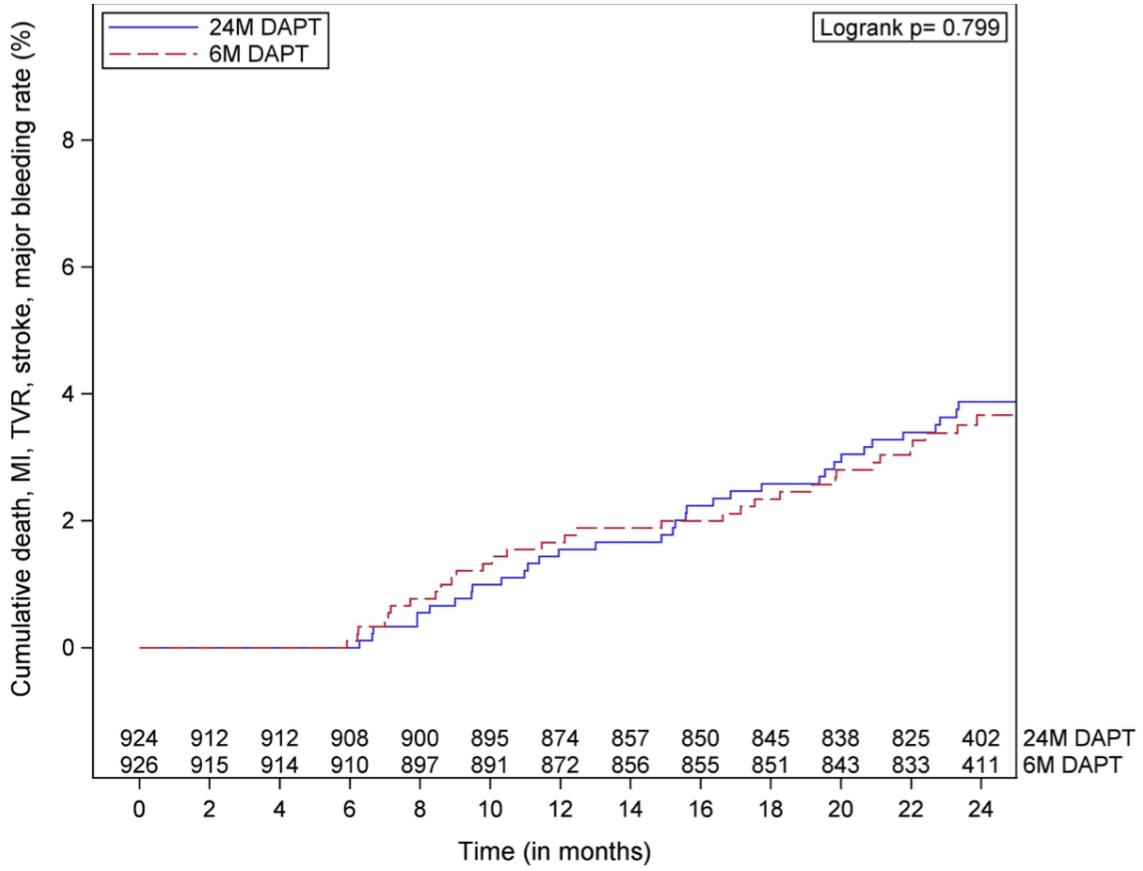

JACC Cardiovascular Interventions

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Dual Antiplatelet Therapy for 6 versus 18 Months after Biodegradable Polymer Drug Eluting Stent Implantation

Composite endpoint at 2 years in patients with previous myocardial infarction

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Two-year outcomes in the ITALIC trial confirmed the 1-year results and showed that patients receiving 6 months DAPT after PCI with second-generation DES have similar outcomes with those receiving 24 months.

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Dual Antiplatelet Therapy for 6 versus 18 Months after Biodegradable Polymer Drug Eluting Stent Implantation

Nakamura et al. 2017 in press

3773 patients with SIHD or ACS undergoing Nobori stent implantation were randomized 1:1 to receive DAPT for 6 or 18 months.

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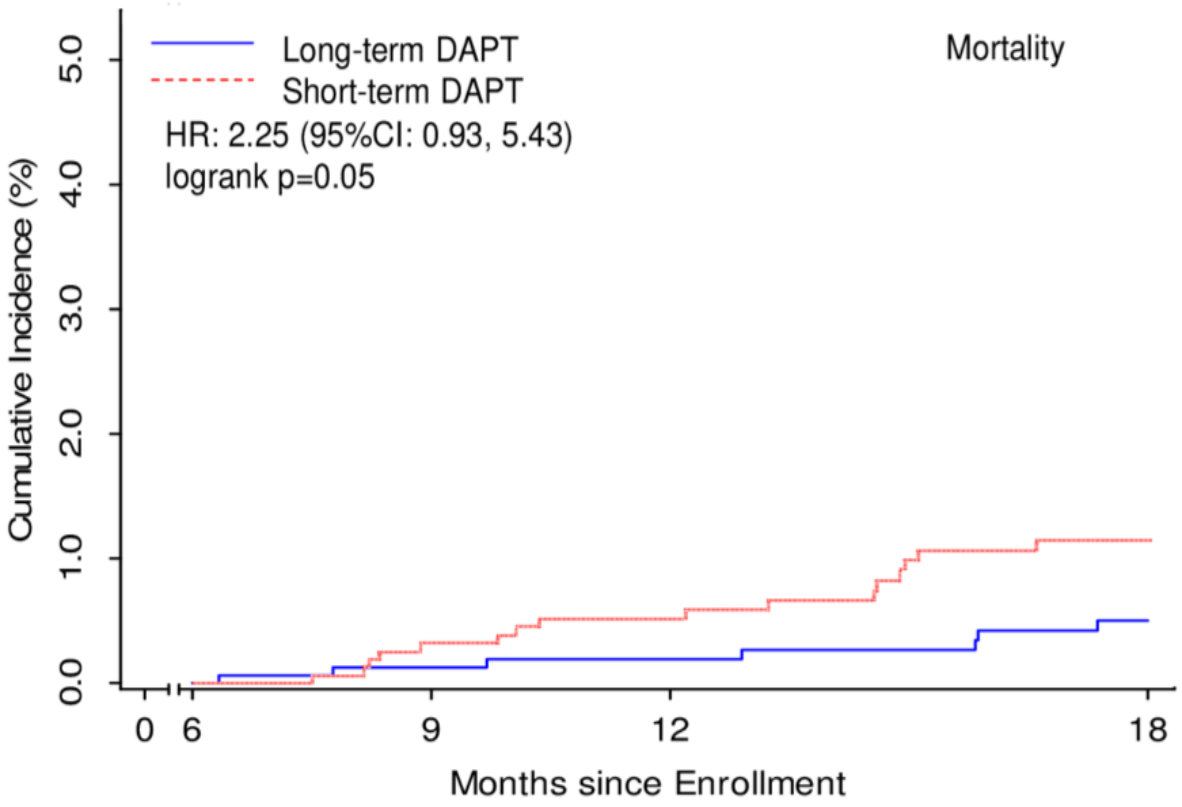

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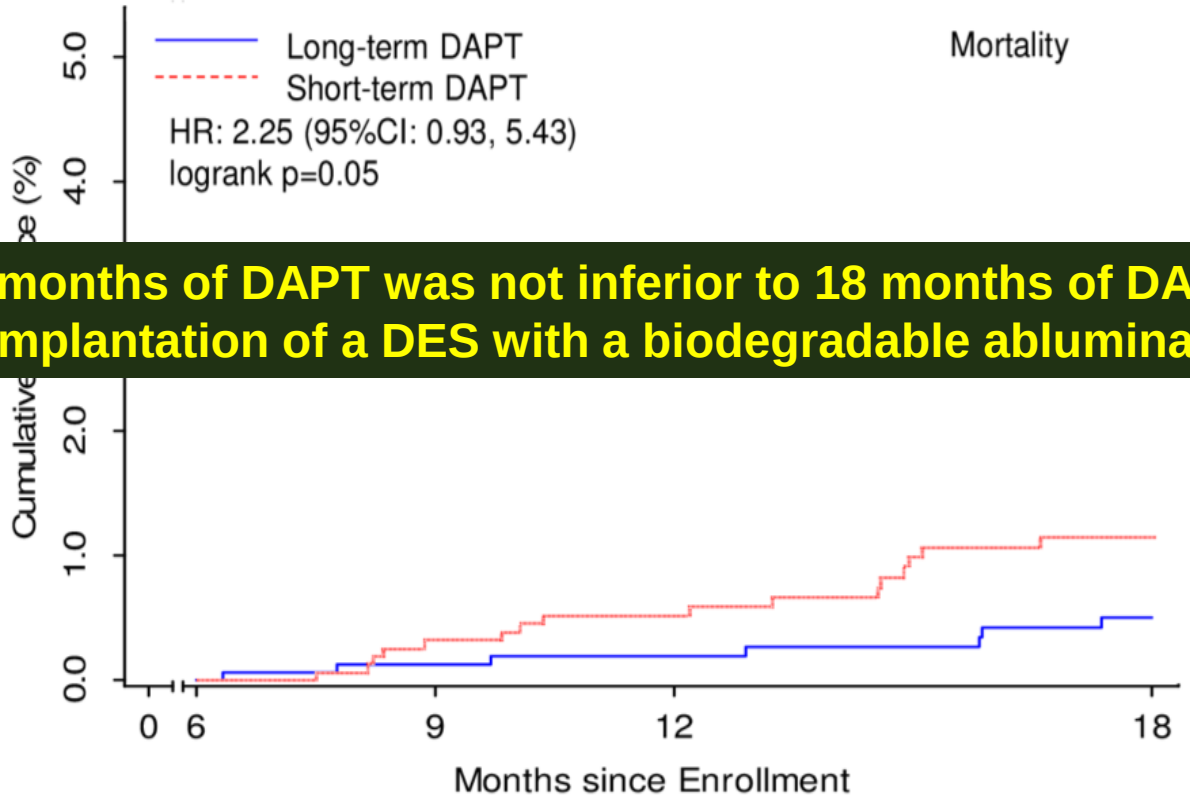

Six months of DAPT was not inferior to 18 months of DAPT following implantation of a DES with a biodegradable abluminal coating.

JACC Cardiovascular Interventions

How long is DAPT (dual antiplatelet therapy) needed?

- Longer and shorter duration is now advocated.
- Studies are needed for specific indications such as high bleeding risk as well as high thrombotic risk patients.
- New agents with and without ASA need further evaluation
- Study new combinations when oral anticoagulant therapy is required (atrial fibrillation).

Thank you