Stent jako prevence infarktu myokardu. Mýty a realita intervenční kardiologie.

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Stent (PCI) jako prevence IM

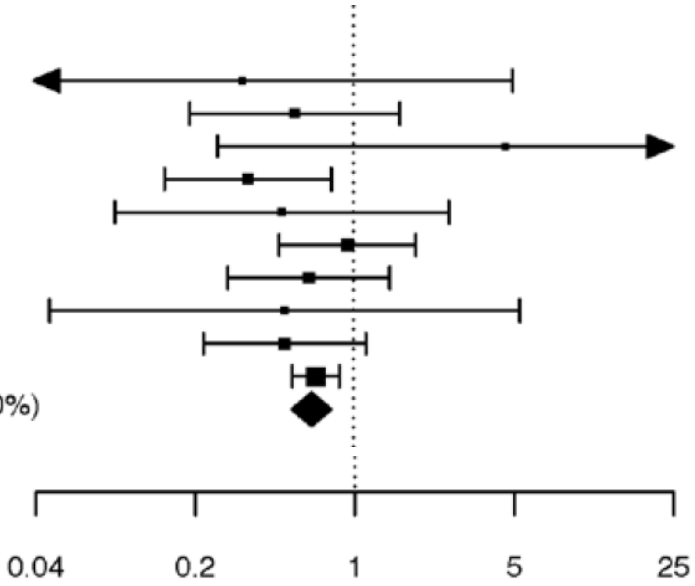
1. Akutní koronární sy
   a. STEMI a MVD - po culprit vessel PCI
   b. NSTE-AKS
   c. Nerevaskularizovaní pac. po AIM
2. Chronické koronární sy – stabilní ICHS

Chacko L et al.: Circ Cardiovasc Qual Outcomes 2020;13

1. STEMI a MVD - po culprit vessel PCI

Infarkt myokardu

Study and Year	Active Events	N	Control Events	N	Relative risk [95% CI]
Unstable CAD – Multivessel disease following STEMI					
Help–AMI, 2009	1	52	1	17	0.33 [0.02, 4.95]
Politi, 2010	6	130	7	84	0.55 [0.19, 1.59]
Dambrink, 2012	4	79	0	40	4.61 [0.25, 83.61]
PRAMI, 2013	7	234	20	231	0.35 [0.15, 0.80]
CvLPRIT, 2015	2	150	4	146	0.49 [0.09, 2.62]
DANAMI 3, 2015	15	313	16	314	0.94 [0.47, 1.87]
Zhang, 2015	9	215	14	213	0.64 [0.28, 1.44]
Hamza, 2016	1	50	2	50	0.50 [0.05, 5.34]
Compare ACUTE, 2017	7	295	28	590	0.50 [0.22, 1.13]
Complete, 2019	109	2016	160	2025	0.66 [0.54, 0.87]
Multivessel disease following STEMI studies (**p < 0.0001**, Q = 6.10, df = 9, p for heterogeneity = 0.73; I^2 = 0.0%)					0.66 [0.54, 0.80]

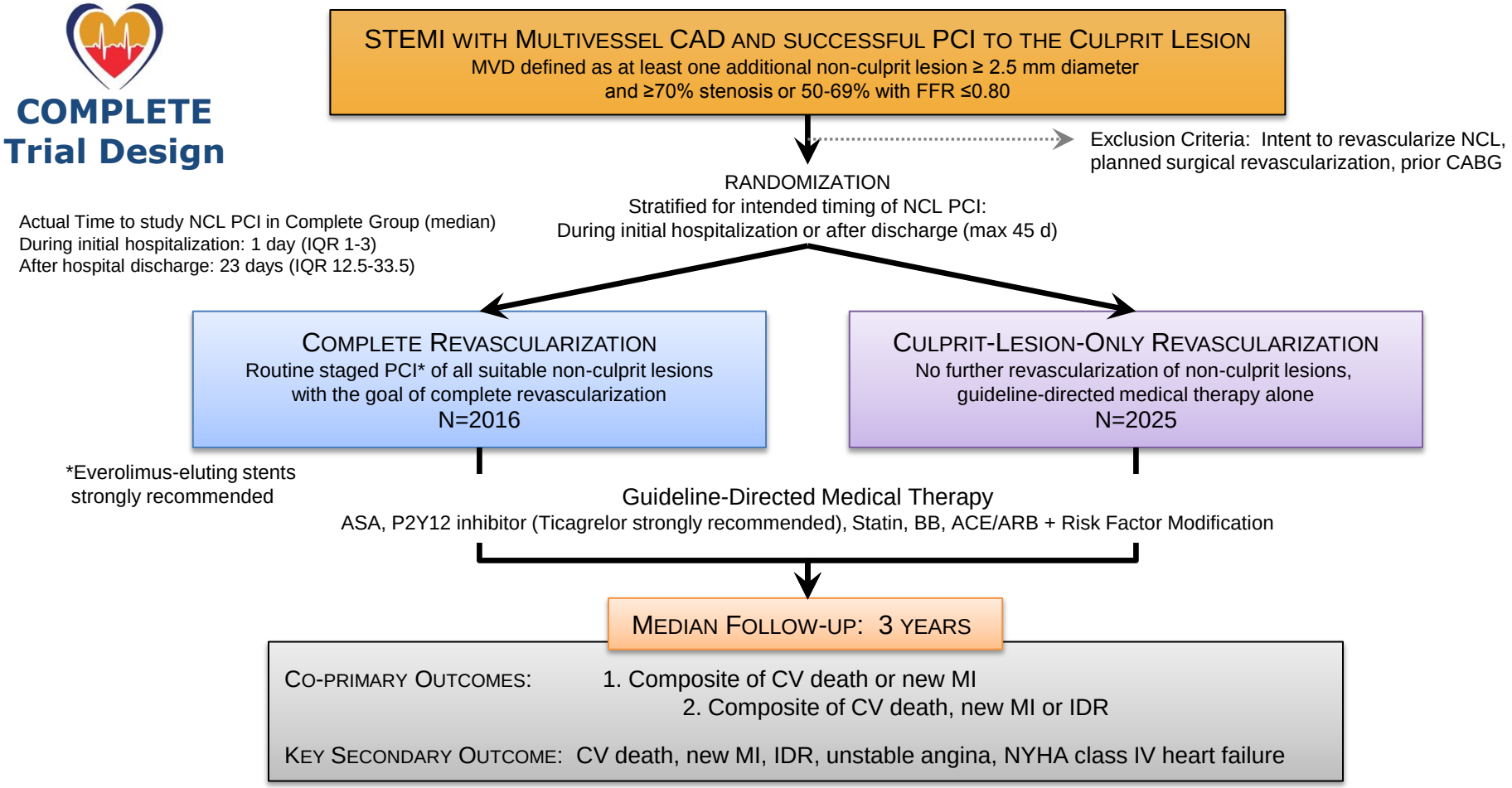


Celková mortalita 0,84 (0,69-1,04); p=0,11

KV mortalita 0,68 (0,47-0,98); p=0,04

Chacko L et al.: Circ Cardiovasc Qual Outcomes 2020;13

COMPLETE Trial Design



Mehta SR et al. *Am Heart J* 2019; 215:157-166.

Mehta et al.: NEJM 2019;381:1411-1421

COMPLETE TRIAL

Procedural Characteristics

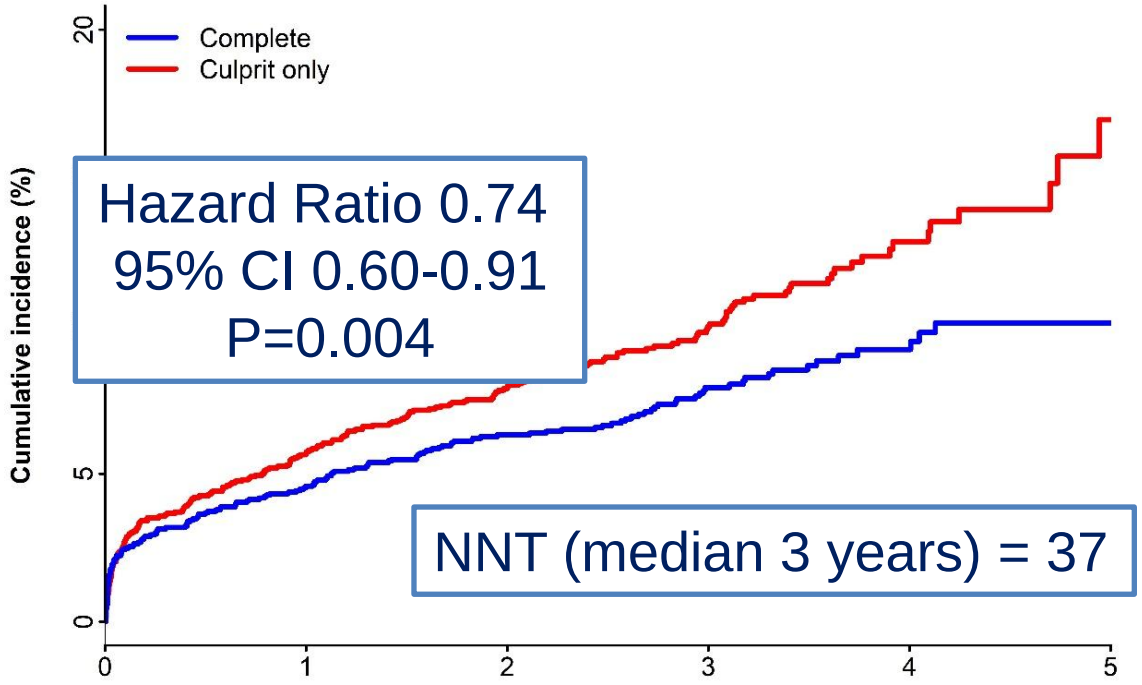
	Complete N=2016	Culprit-only N=2025
Index PCI for STEMI		
Primary	**91.9%**	**93.1%**
Pharmaco-invasive	**3.2%**	**3.0%**
Rescue	**4.9%**	**3.9%**
Radial access	**80.8%**	**80.7%**
Residual diseased vessels		
1	**76.1%**	**77.1%**
≥2	**23.9%**	**22.9%**
NCL location		
Left main	**0.4%**	**0.1%**
LAD	**38.0%**	**41.2%**
Proximal LAD	**9.8%**	**10.4%**
Mid LAD	**21.7%**	**23.7%**
Circumflex	**36.4%**	**35.6%**
RCA	**25.3%**	**23.2%**

	Complete N=2016	Culprit-only N=2025
NCL diameter	**2.8 mm**	**2.9 mm**
Mean NCL stenosis (visual)	**79.3%**	**78.7%**
NCL stenosis (visual)		
50-69% and FFR<0.80	**0.8%**	**0.6%**
70-79%	**41.3%**	**45.1%**
80-89%	**33.5%**	**32.6%**
90-99%	**22.3%**	**19.7%**
100%	**2.1%**	**2.0%**
SYNTAX score (Core Lab)		
Baseline	**16.3**	**16.0**
Culprit lesion specific	**8.8**	**8.6**
Non-culprit lesion specific	**4.5**	**4.5**
Residual (after index PCI)	**7.2**	**7.0**

Complete revascularization was achieved in 90.1% after NCL PCI

COMPLETE TRIAL

First Co-Primary Outcome:
CV Death or New MI



No. at Risk						
Complete	2016	1904	1677	938	337	70
Culprit only	2025	1897	1666	933	310	59

Mehta et al.: NEJM 2019;381:1411-1421

COMPLETE TRIAL

Efficacy Outcomes

	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)	P value
	N (%)	%/year	N (%)	%/year		
Co-Primary Outcomes						
CV death or MI	**158 (7.8)**	**2.7**	**213 (10.5)**	**3.7**	**0.74 (0.60-0.91)**	**0.004**
CV death, MI or IDR	**179 (8.9)**	**3.1**	**339 (16.7)**	**6.2**	**0.51 (0.43-0.61)**	**<0.001**
Key Secondary Outcome						
CV death, MI, IDR, unstable angina or class IV HF	272 (13.5)	4.9	426 (21.0)	8.1	0.62 (0.53-0.72)	<0.001
Other Secondary Outcomes						
MI	109 (5.4)	1.9	160 (7.9)	2.8	0.68 (0.53-0.86)	0.002
IDR	29 (1.4)	0.5	160 (7.9)	2.8	0.18 (0.12-0.26)	<0.001
Unstable Angina	70 (3.5)	1.2	130 (6.4)	2.2	0.53 (0.40-0.71)	<0.001
CV death	59 (2.9)	1.0	64 (3.2)	1.0	0.93 (0.65-1.32)	0.68
All-cause Death	96 (4.8)	1.6	106 (5.2)	1.7	0.91 (0.69-1.20)	0.51

Mehta et al.: NEJM 2019;381:1411-1421

COMPLETE TRIAL

Sub-types of MI

	Complete Revasc. N=2016		Culprit Lesion Only N=2025		HR (95% CI)
	N (%)	%/year	N (%)	%/year	
Subtype of MI					
NSTEMI	66 (3.27)	1.11	105 (5.19)	1.78	0.63 (0.46-0.85)
STEMI	43 (2.13)	0.72	53 (2.62)	0.88	0.81 (0.54-1.22)
Universal MI Definition					
Type 1	63 (3.13)	1.05	128 (6.32)	2.17	0.49 (0.36-0.66)
Type 2	16 (0.79)	0.26	13 (0.64)	0.21	1.24 (0.60-2.58)
Type 3	4 (0.20)	0.07	1 (0.05)	0.02	4.04 (0.45-36.17)
Type 4a	16 (0.79)	0.27	8 (0.40)	0.13	2.01 (0.86-4.70)
Type 4b	8 (0.40)	0.13	13 (0.64)	0.21	0.62 (0.26-1.49)
Type 5	1 (0.05)	0.02	1 (0.05)	0.02	1.00 (0.06-15.92)

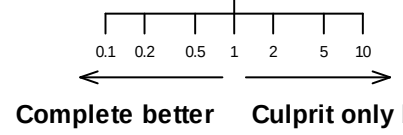
Mehta et al.: NEJM 2019;381:1411-1421

COMPLETE TRIAL

Main Pre-Defined Subgroup Analyses

CV death/MI

Subgroup	Complete	Culprit only	HR (95% CI)	P value for Interaction
	no. of events/total no. (%/yr)			
Overall	158/2016 (2.7)	213/2025 (3.7)	0.74 (0.60-0.91)	
Main pre-defined:				
Proximal/mid LAD non-culprit stenosis				0.2
Presence	64/820 (2.7)	78/849 (3.1)	0.86 (0.62-1.20)	
Absence	87/1097 (2.7)	129/1085 (4.2)	0.65 (0.49-0.85)	
Non-culprit stenosis severity ≥ 80% visual or ≥ 60% core lab				0.033
Presence	127/1668 (2.6)	183/1631 (3.9)	0.67 (0.53-0.84)	
Absence	31/346 (3.2)	29/392 (2.6)	1.23 (0.74-2.04)	
Residual SYNTAX score				0.32
<6(median)	60/885 (2.3)	90/870 (3.6)	0.65 (0.47-0.90)	
≥ 6(median)	91/1033 (3.0)	117/1070 (3.8)	0.80 (0.61-1.05)	



Mehta et al.: NEJM 2019;381:1411-1421

FLOWER MI trial
Primary outcome

Primary outcome at 1 year	FFR-Guided PCI (n=586)	Angio-Guided PCI (n=577)	HR (95% CI)	P Value
MACE*	5.5	4.2	1.32 (0.78-2.23)	0.31
Death from any cause	1.5	1.7	0.89 (0.36-2.20)	-
Myocardial infarction	3.1	1.7	1.77 (0.82-3.84)	-
Unplanned hospitalization leading to urgent revascularization	2.6	1.9	1.34 (0.62-2.92)	-
• *% of non-culprit lesions treated*	53.3	27.3		

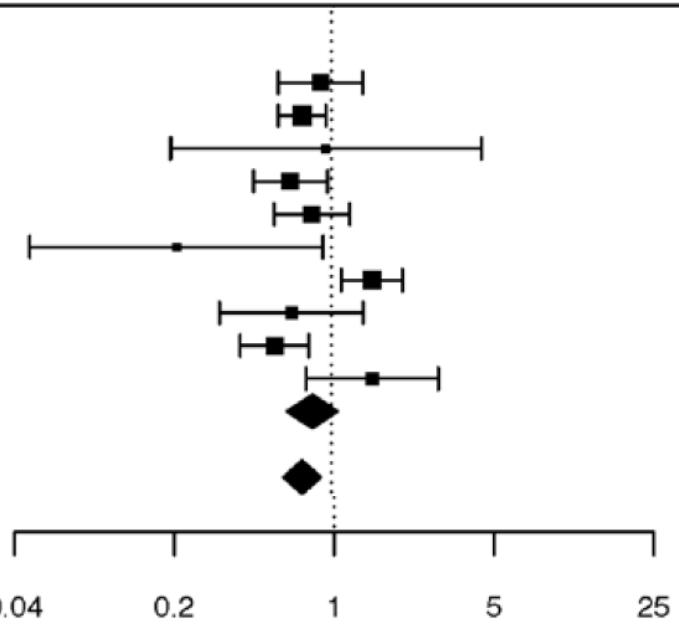
** Major Adverse Cardiac Events (MACE) denotes the composite of all-cause mortality, nonfatal MI, and unplanned hospitalization leading to urgent revascularization, at one year*

Puymirat et al.: NEJM 2021;385:297-308

2. NSTE–AKS

Infarkt myokardu

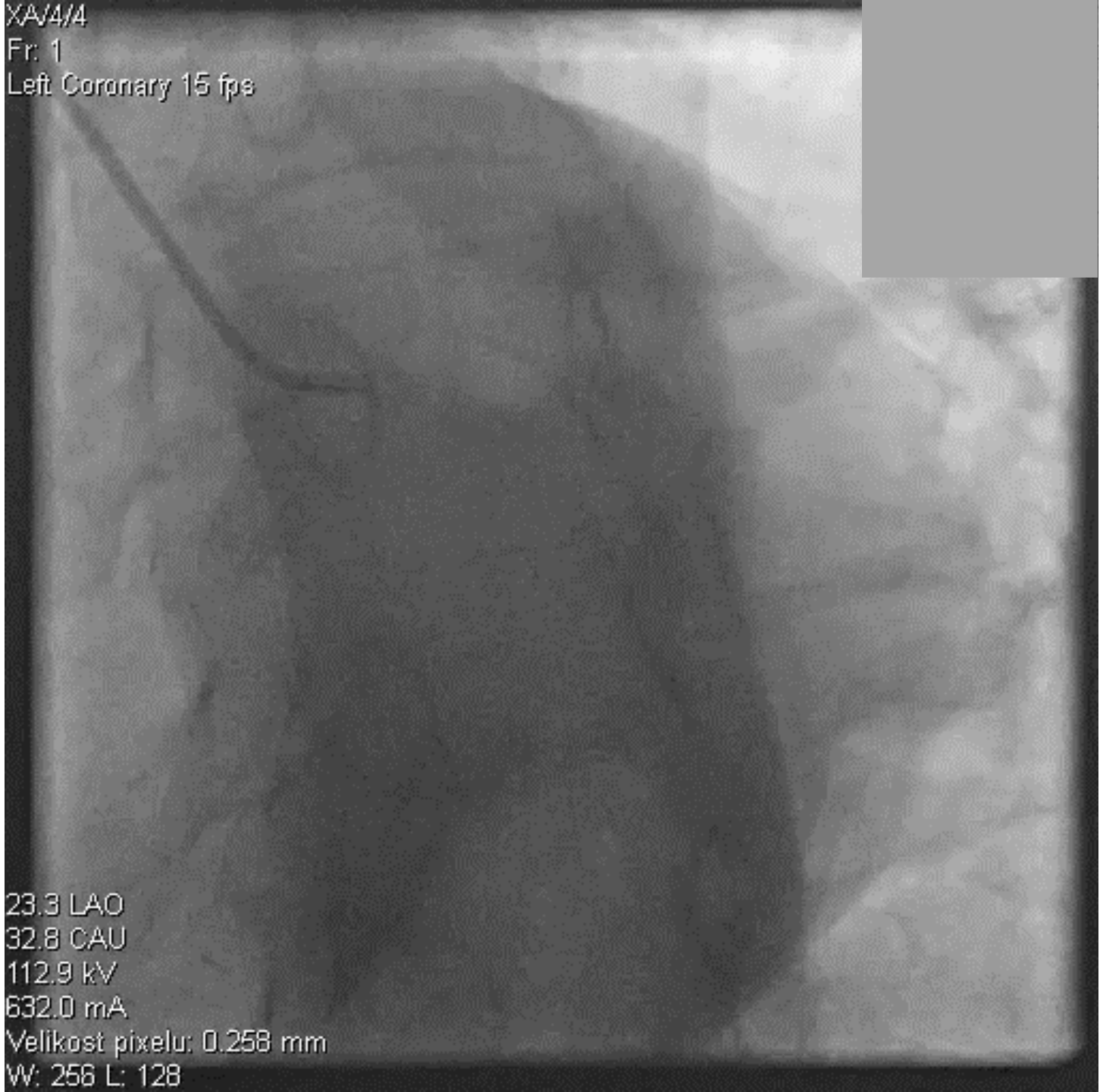
Study and Year	Active Events	N	Control Events	N	Relative risk [95% CI]
Unstable CAD – NSTEACS					
TIMI IIIB, 1994	38	740	42	733	0.90 [0.58, 1.37]
FRISC II, 2000	105	1219	143	1234	0.74 [0.59, 0.94]
TRUCS, 2000	3	76	3	72	0.95 [0.20, 4.54]
TACTICS 18, 2001	44	1114	66	1106	0.66 [0.46, 0.96]
RITA 3, 2002	45	895	56	915	0.82 [0.56, 1.20]
VINO, 2002	2	64	10	67	0.21 [0.05, 0.92]
ICTUS, 2005	90	604	59	596	1.51 [1.11, 2.05]
Savonitto, 2012	11	154	17	159	0.67 [0.32, 1.38]
After 80, 2016	39	229	69	228	0.56 [0.40, 0.80]
Sanchis, 2016	16	52	11	54	1.51 [0.78, 2.94]
NSTEMI studies (**p = 0.14**, Q = 28.31, df = 9.00, p for heterogeneity = 0.00; I^2 = 66.9%)					0.83 [0.64, 1.06]
Unstable CAD studies (p = 0.002, Q = 64.78, df = 30.00, p for heterogeneity = 0.00; I^2 = 57.6%)					0.74 [0.62, 0.90]



Celková mortalita 0,84 (0,72-0,97); p=0,02

KV mortalita 0,80 (0,59-1,08); p=0,14

Chacko L et al.: Circ Cardiovasc Qual Outcomes 2020;13



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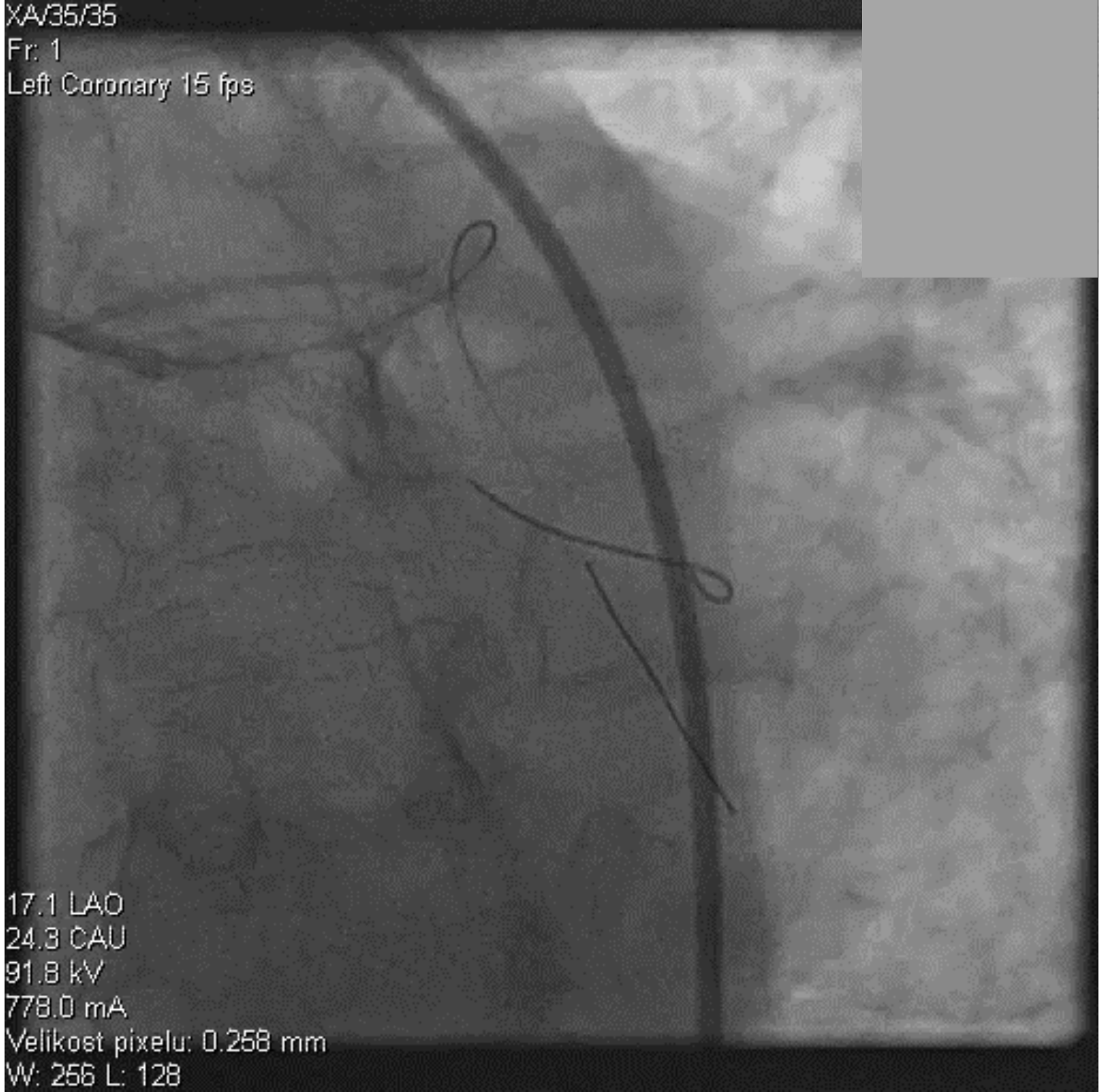
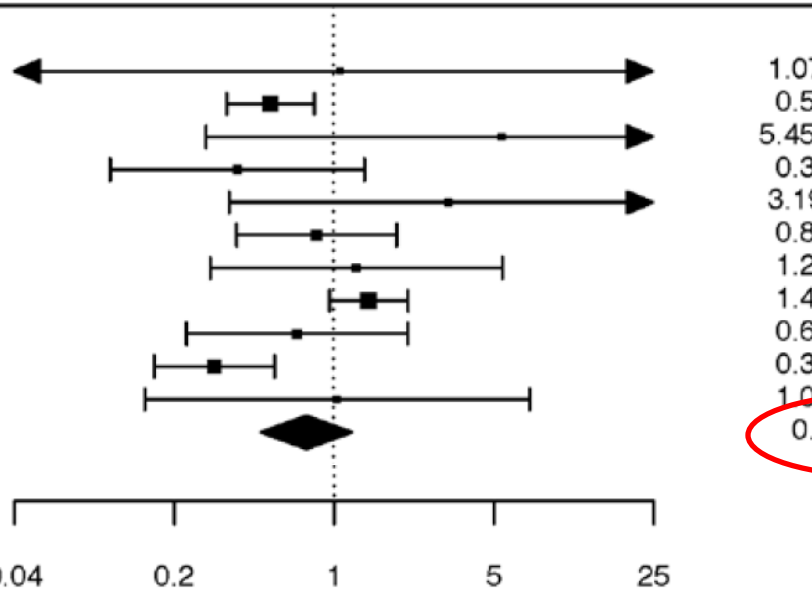
NSTEMI


XA/35/35
Fr: 1
Left Coronary 15 fps
17.1 LAO
24.3 CAU
91.8 kV
778.0 mA
Velikost pixelu: 0.258 mm
W: 256 L: 128

3. Nerevaskularizovaní pac. po AIM

Infarkt myokardu

Study and Year	Active Events	N	Control Events	N	Relative risk [95% CI]
Unstable CAD – Unrevascularized post–MI					
TOPS, 1992	0	42	0	45	1.07 [0.02, 52.73]
DANAMI, 1997	28	503	53	505	0.53 [0.34, 0.82]
DAKIK, 1998	2	21	0	23	5.45 [0.28, 107.47]
Horie, 1998	3	44	7	39	0.38 [0.11, 1.37]
TOAT, 2002	3	32	1	34	3.19 [0.35, 29.09]
ALKK, 2003	10	149	12	151	0.84 [0.38, 1.89]
DECOPI, 2004	4	109	3	103	1.26 [0.29, 5.49]
OAT, 2006	57	1082	40	1084	1.43 [0.96, 2.12]
INSPIRE, 2006	5	104	7	101	0.69 [0.23, 2.11]
SWISSI 2, 2007	11	96	40	105	0.30 [0.16, 0.55]
VIAMI, 2012	2	106	2	110	1.04 [0.15, 7.23]
Unrevascularized post–MI studies (**p = 0.24**, Q = 26.36, df = 10, p for heterogeneity = 0.00; I^2 = 57.8%)					0.76 [0.48, 1.20]



Celková mortalita 0,68 (0,45-1,03); p=0,07

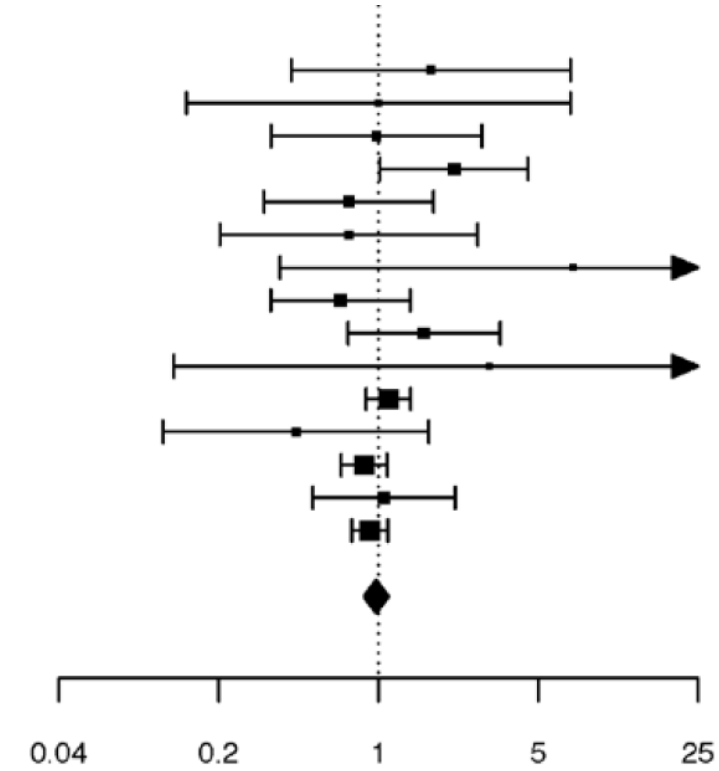
KV mortalita 0,55 (0,27-1,13); p=0,10

Chacko L et al.: Circ Cardiovasc Qual Outcomes 2020;13

4. Stabilní ICHS

Infarkt myokardu

Study and Year	Active Events	N	Control Events	N	Relative risk [95% CI]
Stable CAD					
ACME 1, 1992	5	105	3	107	1.70 [0.42, 6.93]
MASS 1 PCI ONLY, 1995	2	72	2	72	1.00 [0.14, 6.91]
ACME 2, 1997	6	51	6	50	0.98 [0.34, 2.84]
RITA 2, 1997	21	504	10	514	2.14 [1.02, 4.50]
ACIP, 1997	7	192	18	366	0.74 [0.32, 1.74]
AVERT, 1999	4	177	5	164	0.74 [0.20, 2.71]
DEFER, 2001	3	90	0	91	7.08 [0.37, 135.07]
TIME, 2001	12	153	17	148	0.68 [0.34, 1.38]
MASS 2 PCI ONLY, 2004	16	205	10	203	1.58 [0.74, 3.41]
Hambrecht, 2004	1	50	0	51	3.06 [0.13, 73.35]
COURAGE, 2007	143	1149	128	1138	1.11 [0.88, 1.38]
JSAP, 2008	3	188	7	191	0.44 [0.11, 1.66]
BARI 2D, 2009	118	1176	138	1192	0.87 [0.69, 1.09]
FAME 2, 2012	15	447	14	441	1.06 [0.52, 2.16]
ISCHEMIA, 2019	206	2588	225	2591	0.92 [0.76, 1.10]
Stable CAD studies ($p = 0.72$, $Q = 14.34$, $df = 14.00$, p for heterogeneity = 0.42; $I^2 = 4.9\%$)					0.98 [0.86, 1.11]

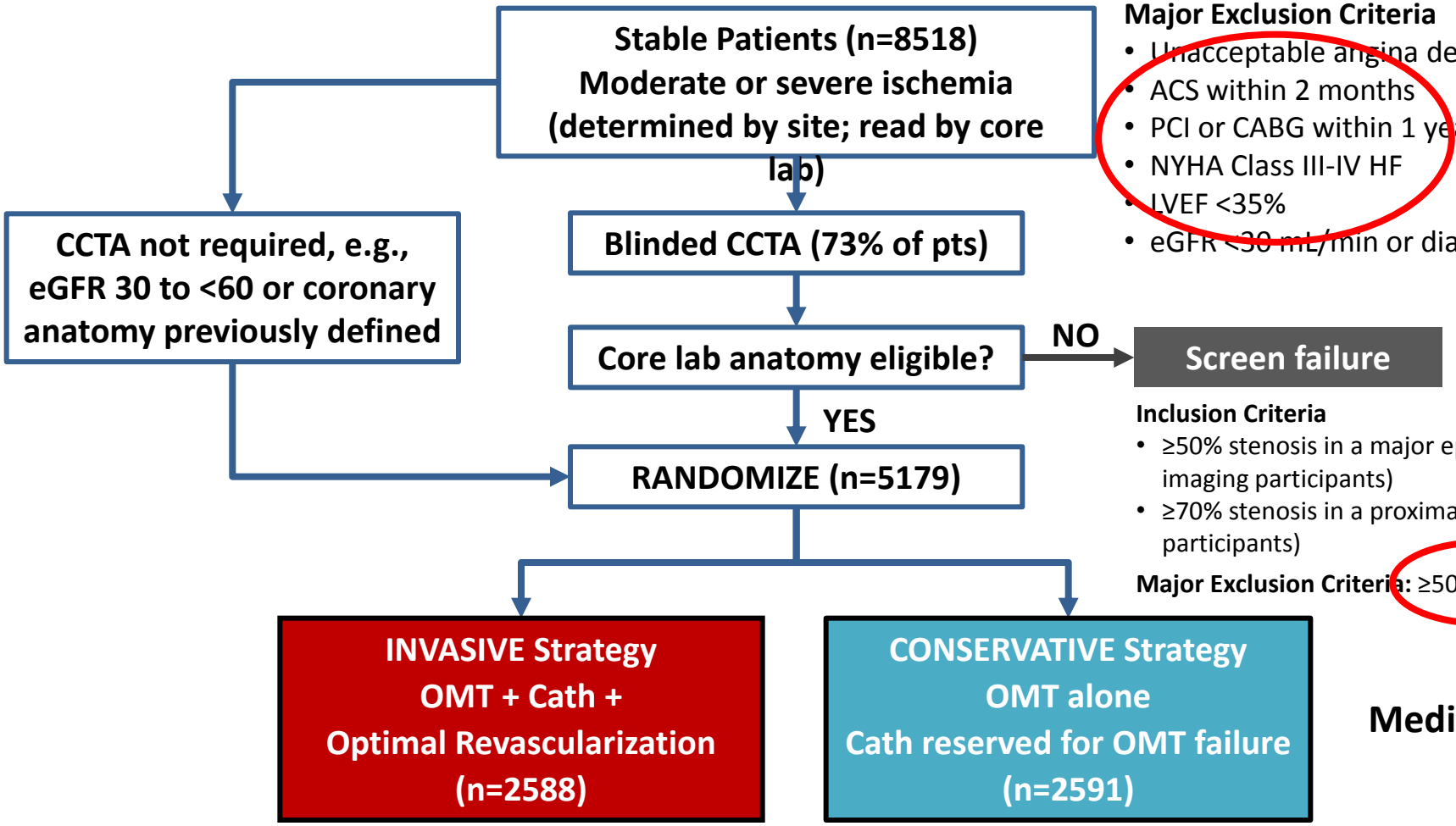


Celková mortalita 0,98 (0,87-1,12); p=0,79

KV mortalita 0,88 (0,70-1,12); p=0,30

Chacko L et al.: Circ Cardiovasc Qual Outcomes 2020;13

ISCHEMIA Trial: Patient Flow



Major Exclusion Criteria

- Unacceptable angina despite medical therapy
- ACS within 2 months
- PCI or CABG within 1 year
- NYHA Class III-IV HF
- LVEF <35%
- eGFR <30 mL/min or dialysis → ISCHEMIA CKD

Inclusion Criteria

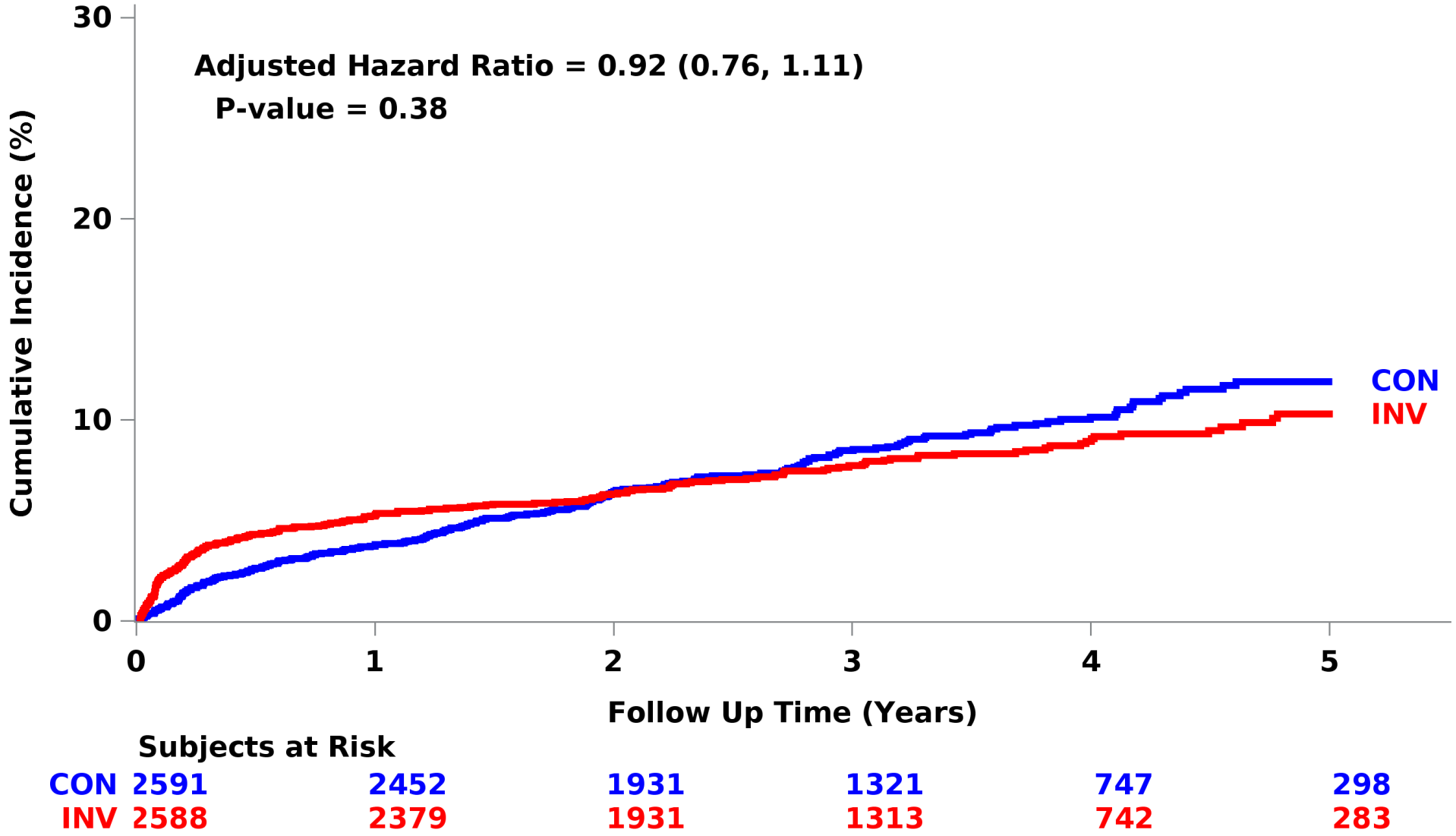
- ≥50% stenosis in a major epicardial vessel (stress imaging participants)
- ≥70% stenosis in a proximal or mid vessel (ETT participants)

Major Exclusion Criteria: ≥50% LM ds.

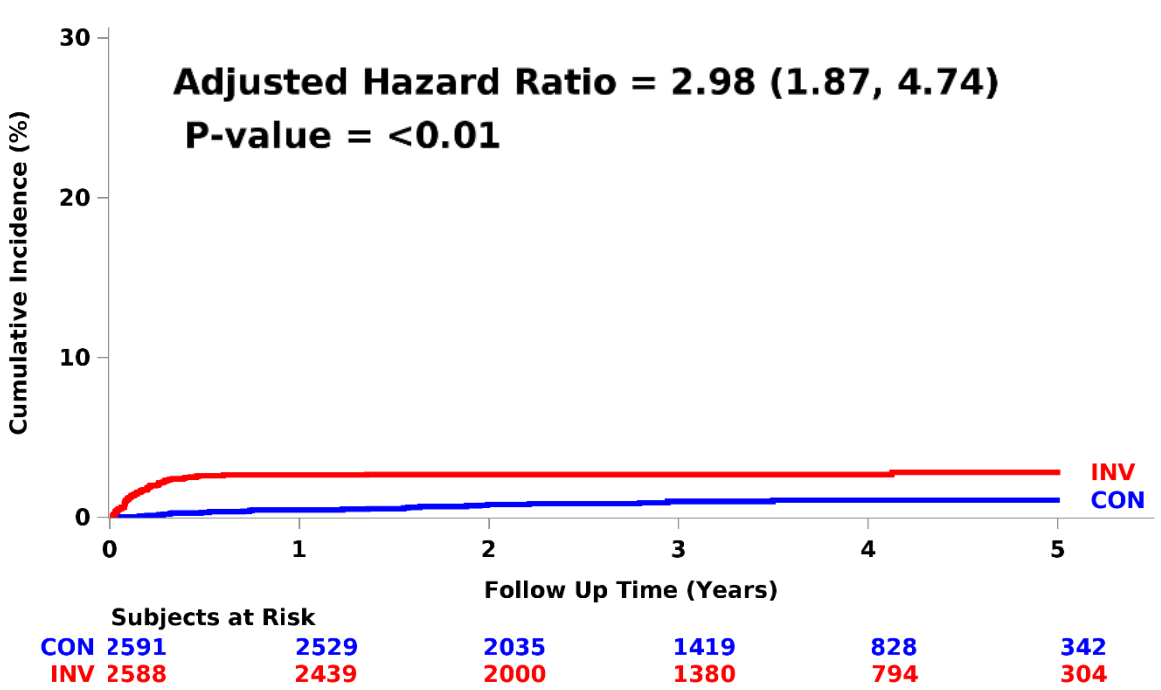
Median FU 3.2 years

Hochman JS. AHA 2019, Maron DJ et al.: NEJM 2020;385,15

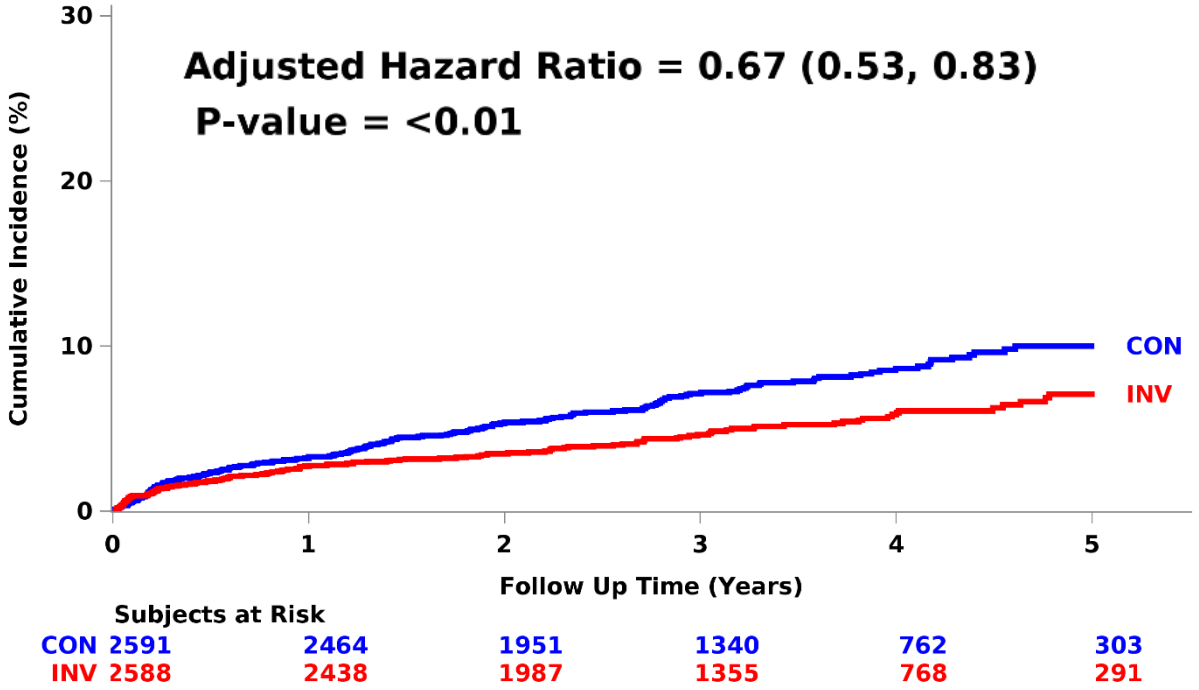
Myocardial Infarction



Procedural MI
Types 4a or 5 MI



Non-procedural MI
Types 1, 2, 4b, or 4c MI

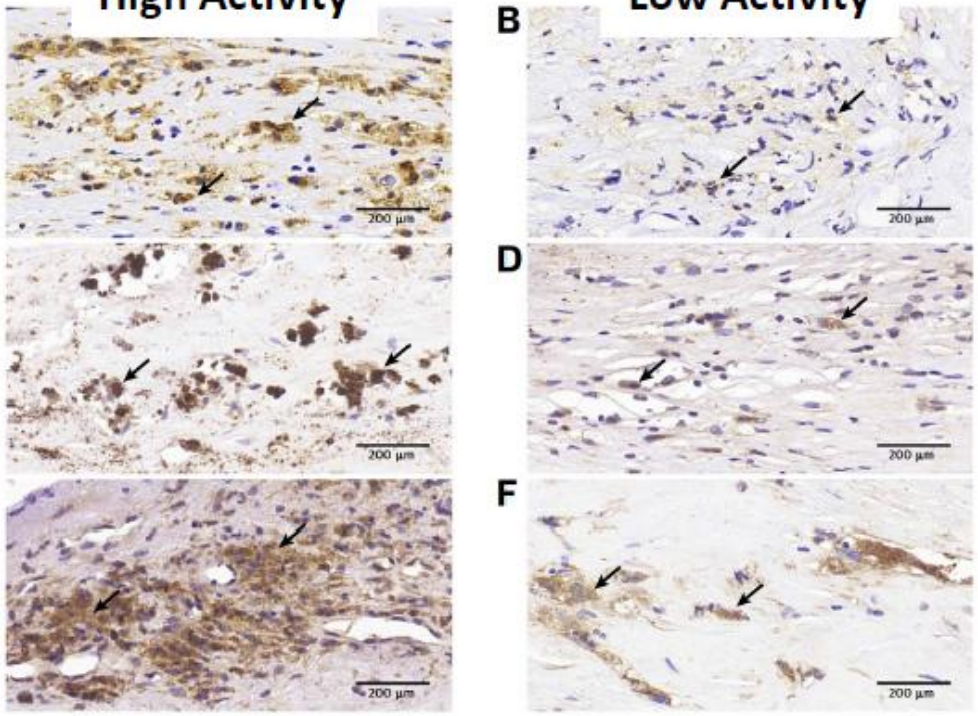


Newby D. et al.: ESC 2022

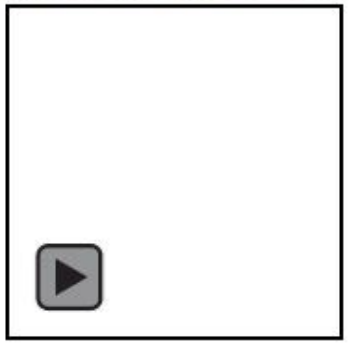
Coronary ^{18}F-Sodium Fluoride Uptake

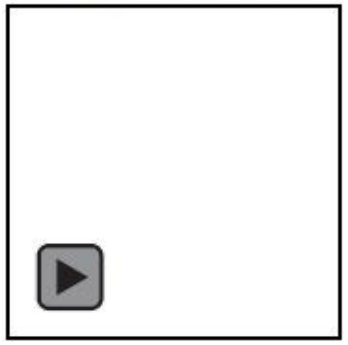
The PRE FFIR Study

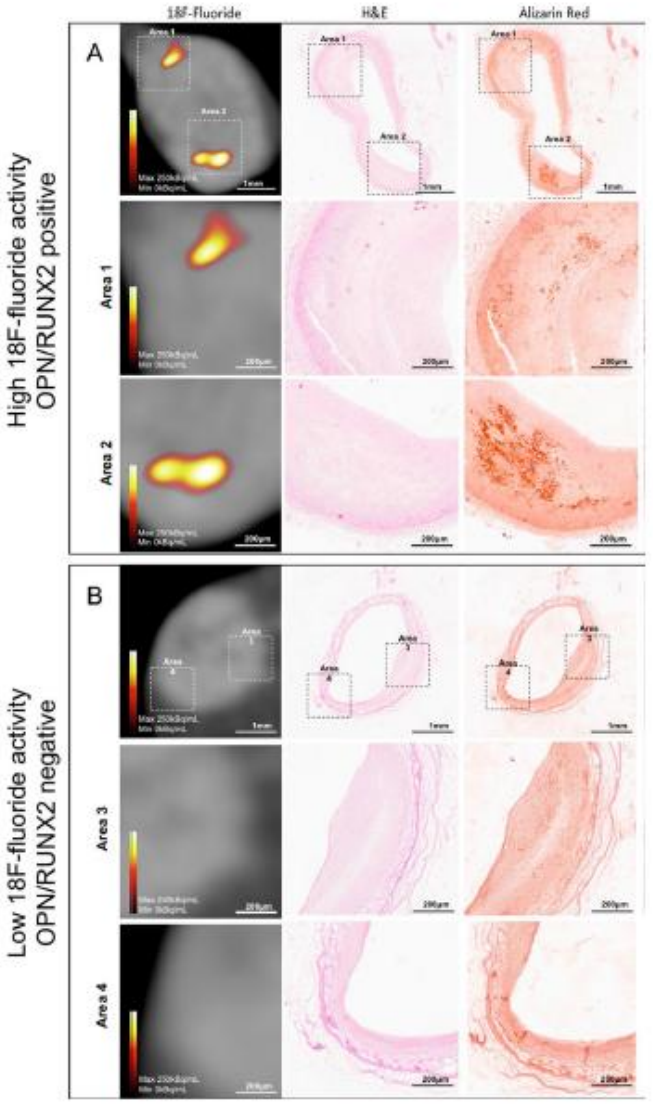
Histology of Coronary Endarterectomy

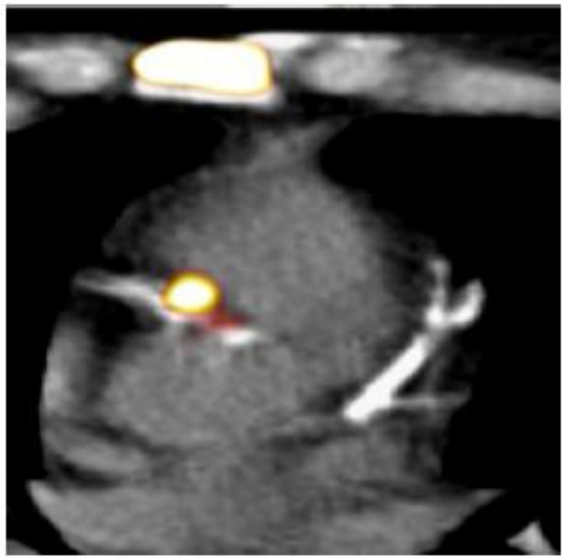


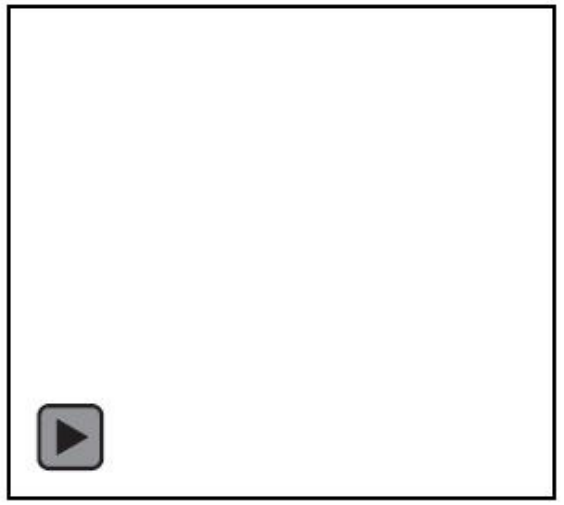
IVUS











Wen et al. JACC Cardiovasc Imaging 2022; in press

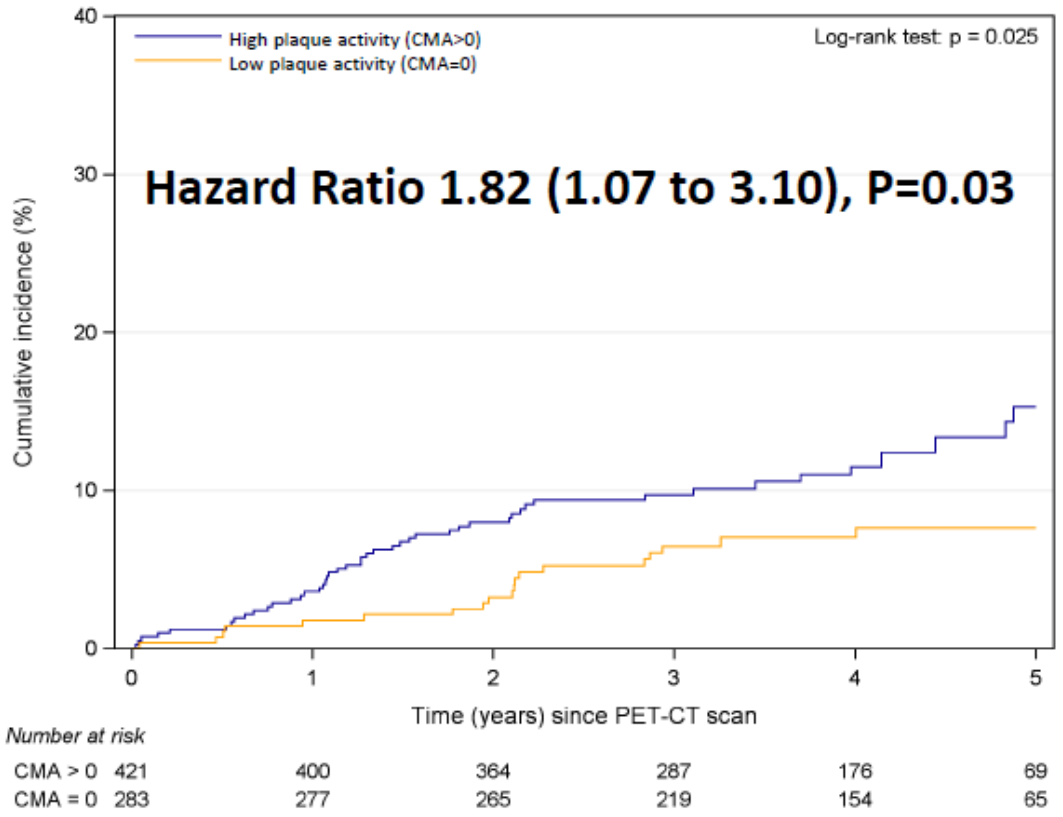
Moss et al. Sci Rep 2020;10:21072

Joshi et al. Lancet 2014;383:705-713

The PREFFIR Study

Original Primary Endpoint and All-cause Death

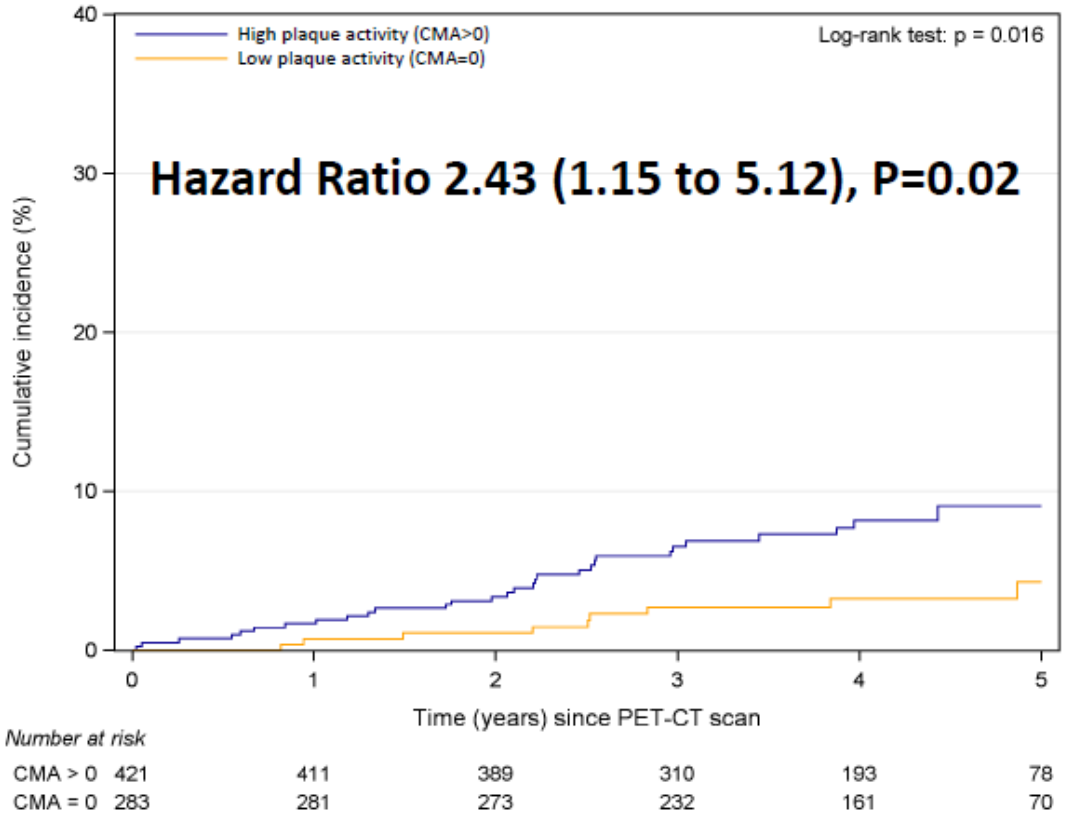
Cardiac death or non-fatal myocardial infarction



Number at risk

CMA > 0	421	400	364	287	176	69
CMA = 0	283	277	265	219	154	65

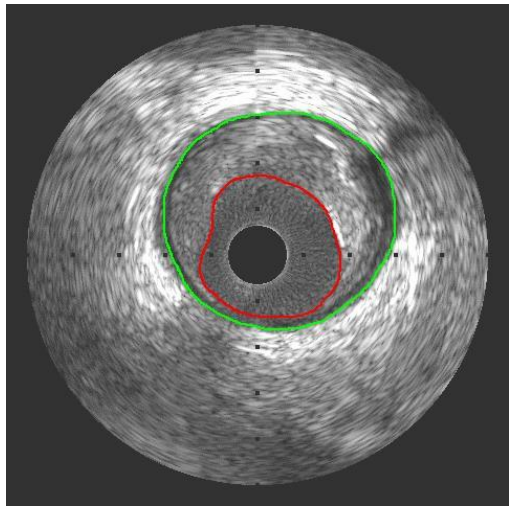
All-cause death

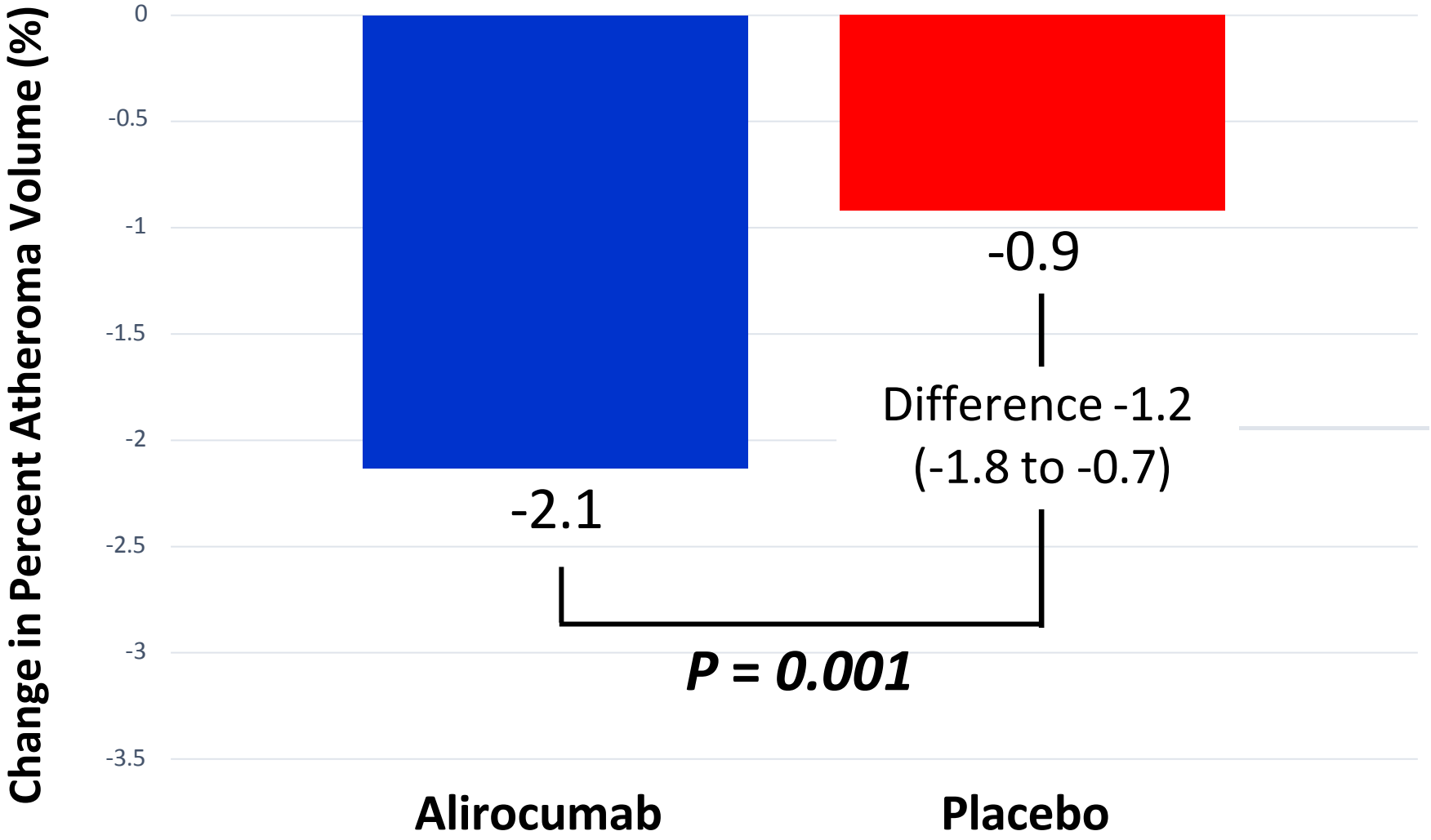


Number at risk

CMA > 0	421	411	389	310	193	78
CMA = 0	283	281	273	232	161	70

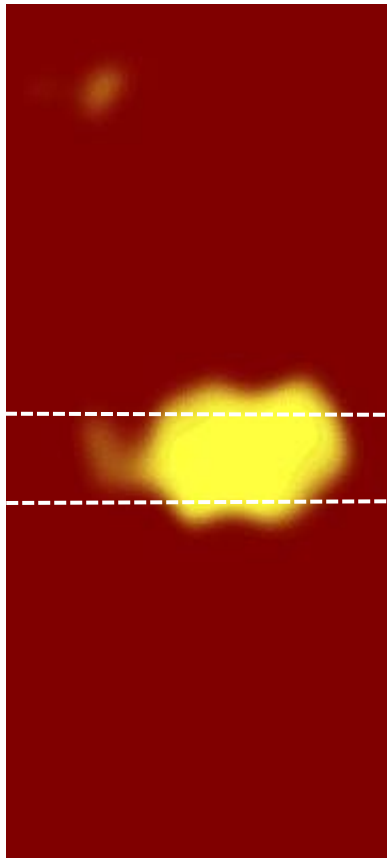
Primary EP:
Change in Percent Atheroma Volume (IVUS)

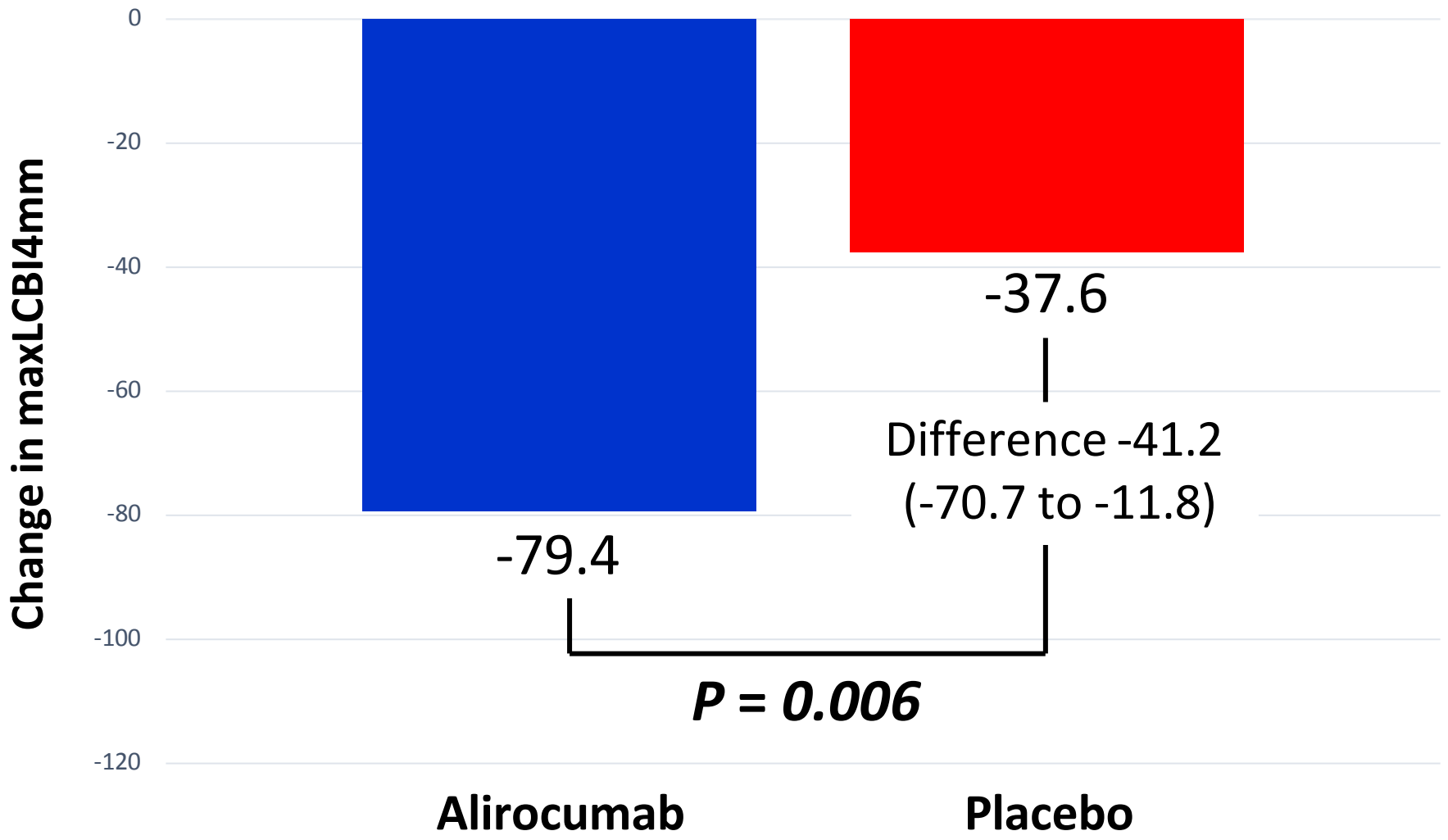




Räber L et al.: ACC 2022

Powered Secondary EP:
Change in maxLCBI$_{4mm}$ (NIRS)





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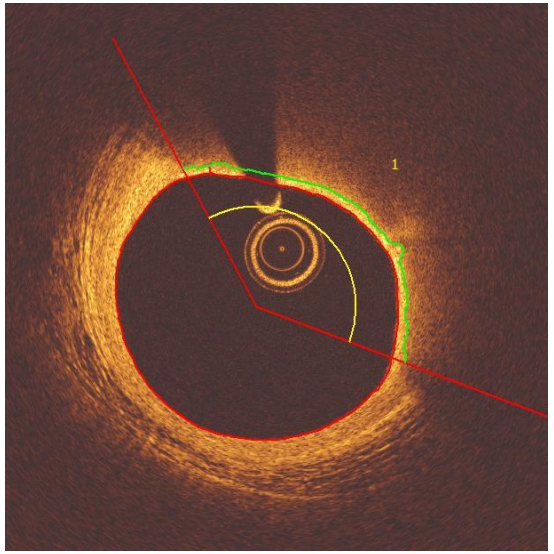
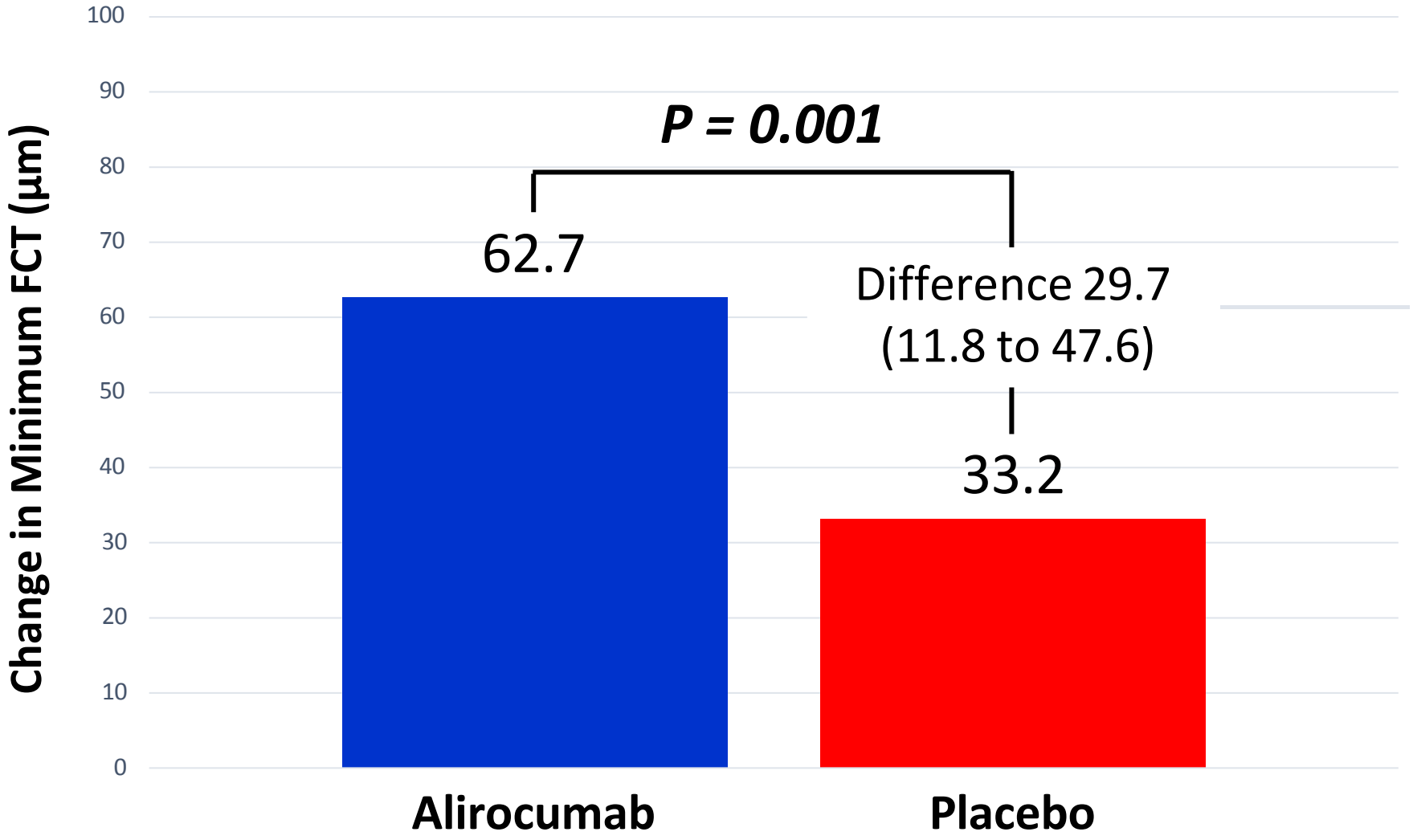
Powered Secondary EP:
Change in Minimum FCT (OCT)





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Závěry

1. PCI snižuje riziko infarktu myokardu u pac. po AKS
2. PCI způsobuje periprocedurální IM
3. PCI nesnižuje riziko IM u stabilní ICHS

4. Riziko IM roste s významností stenózy (angio, OCT, IVUS, NIRS, CT PET)
5. Farmakologická léčba (AA, statiny, PCSK9 inh.)

Mýtus

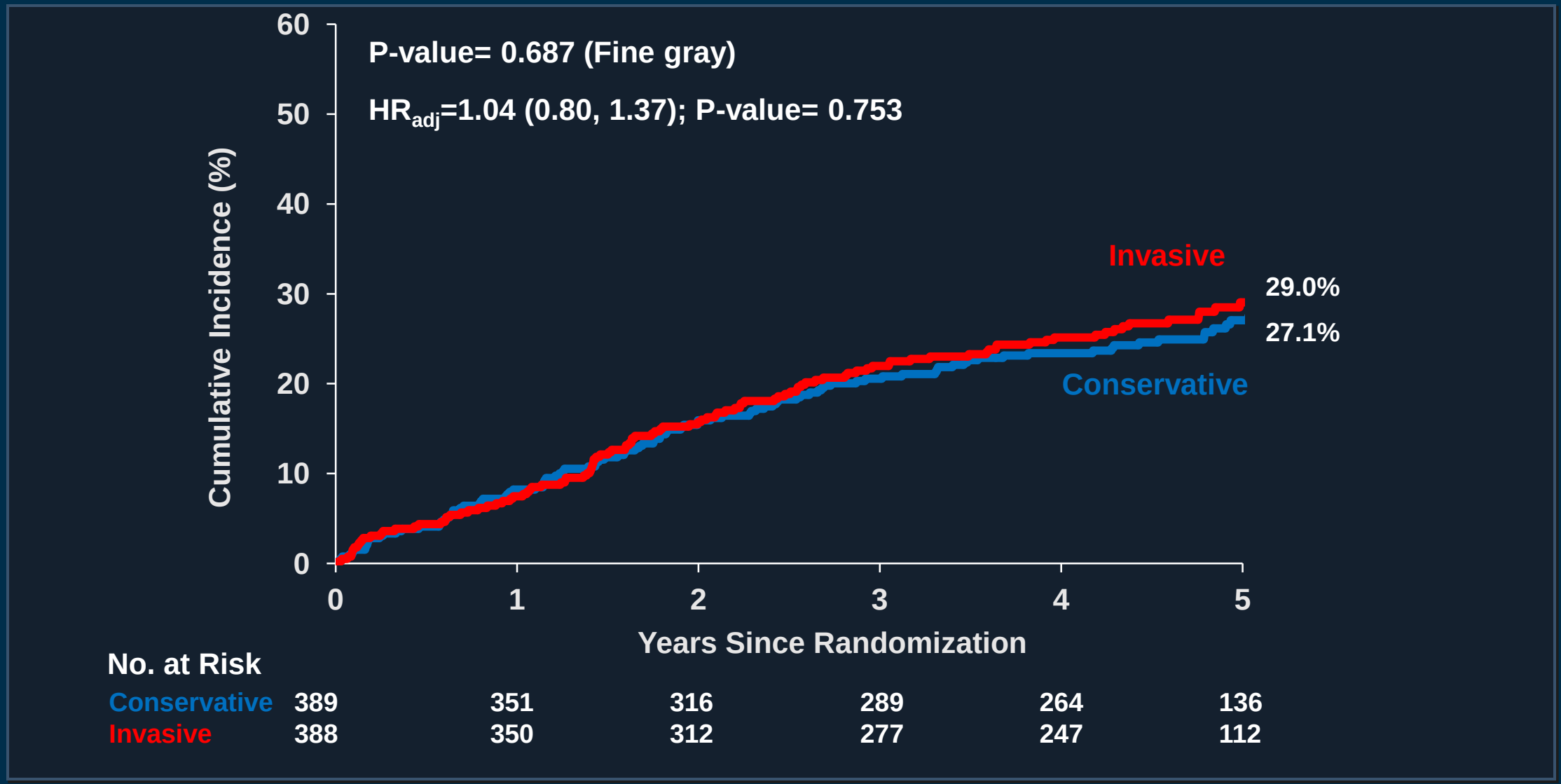
1. Mýtus (řecky μύθος, vyprávění) - symbolické vyprávění vyjadřující víru v plnost a celistvost nadčasového řádu, typicky báje, tradiční, obvykle anonymní epický útvar, který dává odpovědi, aniž klade otázky. Vznikl totiž v neproblematickém světě, kde pro individuální tázání a pochybnosti nebylo místo.

2. V soudobém hovorovém jazyce se slovo „mýtus“ povrchním způsobem používá též pro všeobecně rozšířenou nepravdu, vymyšlené tvrzení bez dostatečných důkazů, což škodlivě odvádí pozornost od jeho závažné podstaty.

https://cs.wikipedia.org/wiki/Mýtus

ISCHEMIA-CKD EXTEND- 5 Years

Cardiovascular Death



eGFR<30 a střední až závažná ischémie

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