PCI u stabilní anginy pectoris
PRO

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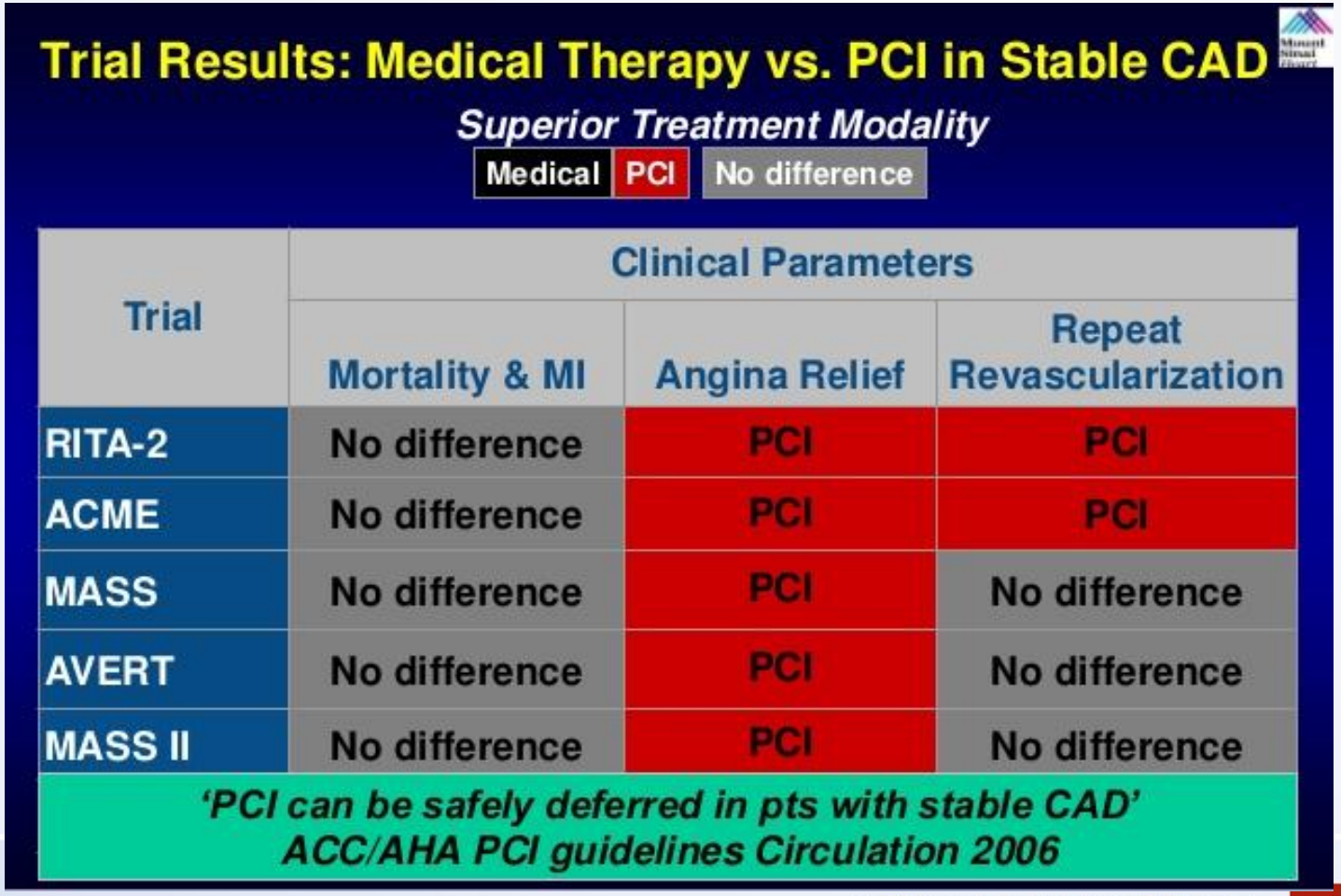
PCI vs OMT: historické studie



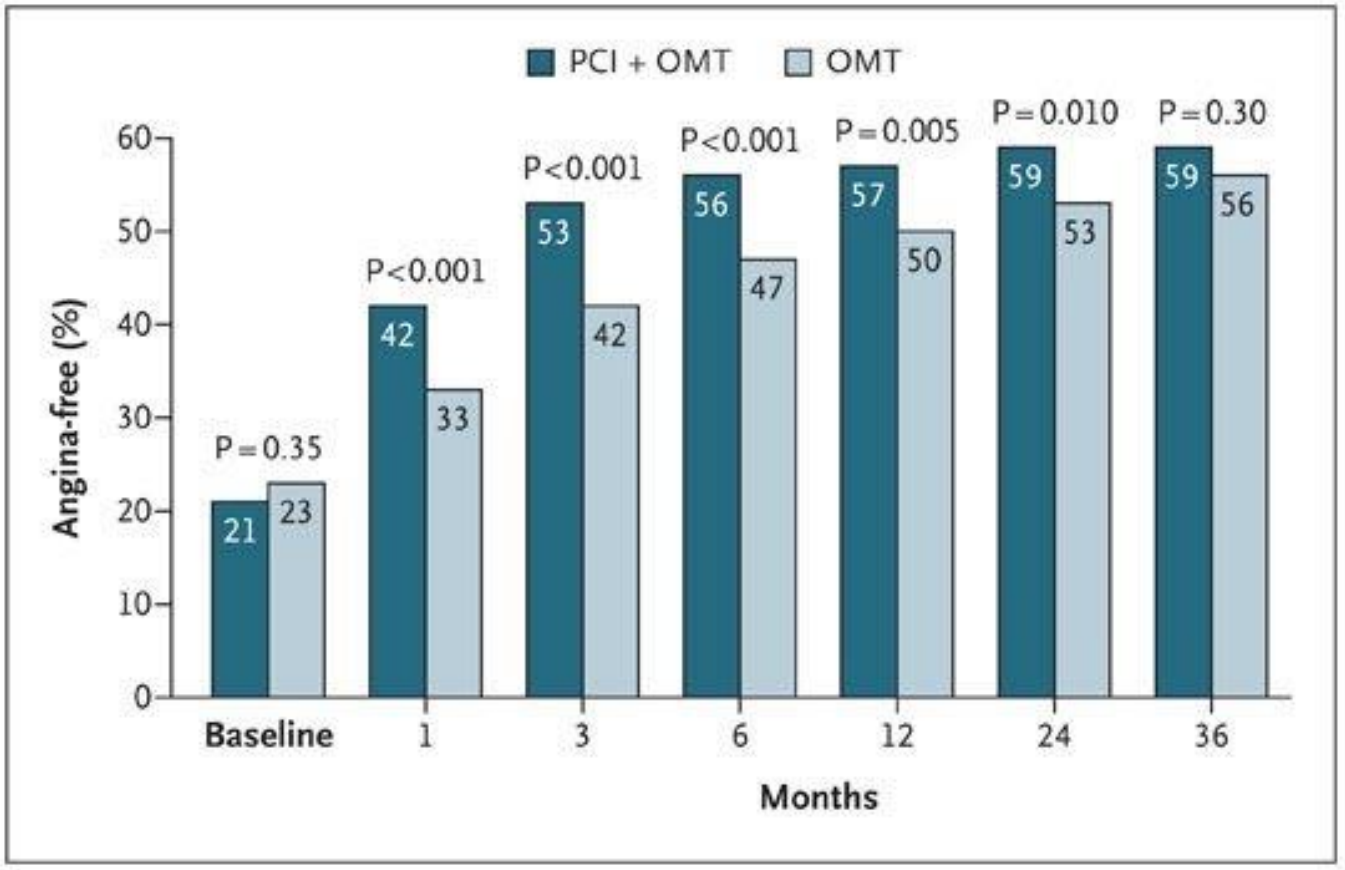
PCI vs medikamentosní léčba

Studie	Počet	Ukazatel	PCI vs konz.	p
COURAGE	2287	Úmrtí/IM	19% vs 18,5%	0,62
Metaanalýza	25338	Úmrtí/IM	RR 0,96	ns
COURAGE-Nuclear	314	Redukce rozsahu ischemie >5%	**33% vs 19%**	**0,0004**
FAME Angio vs FFR	1005	Úmrtí, IM, re-PCI, CABG	18,3% vs 13,2%	0,002

Historické studie – ACME, ACIP, AVERT, RITA-2 – zlepšení symptomů ve prospěch PCI
COURAGE: PCI – rychlejší a větší ústup AP, KONZ – 31% následných revaskularizací
FAME: angiograficky hraniční stenózy (50-70%) jsou v 65% funkčně nevýznamné (FFR>0,80)

CAVE: vysoká preselekce (vyloučeni nemocní s EF LK<30%, prognosticky význ. nálezy, AP III-IV, indikovaní k CABG …) – ve studii COURAGE 6,4%

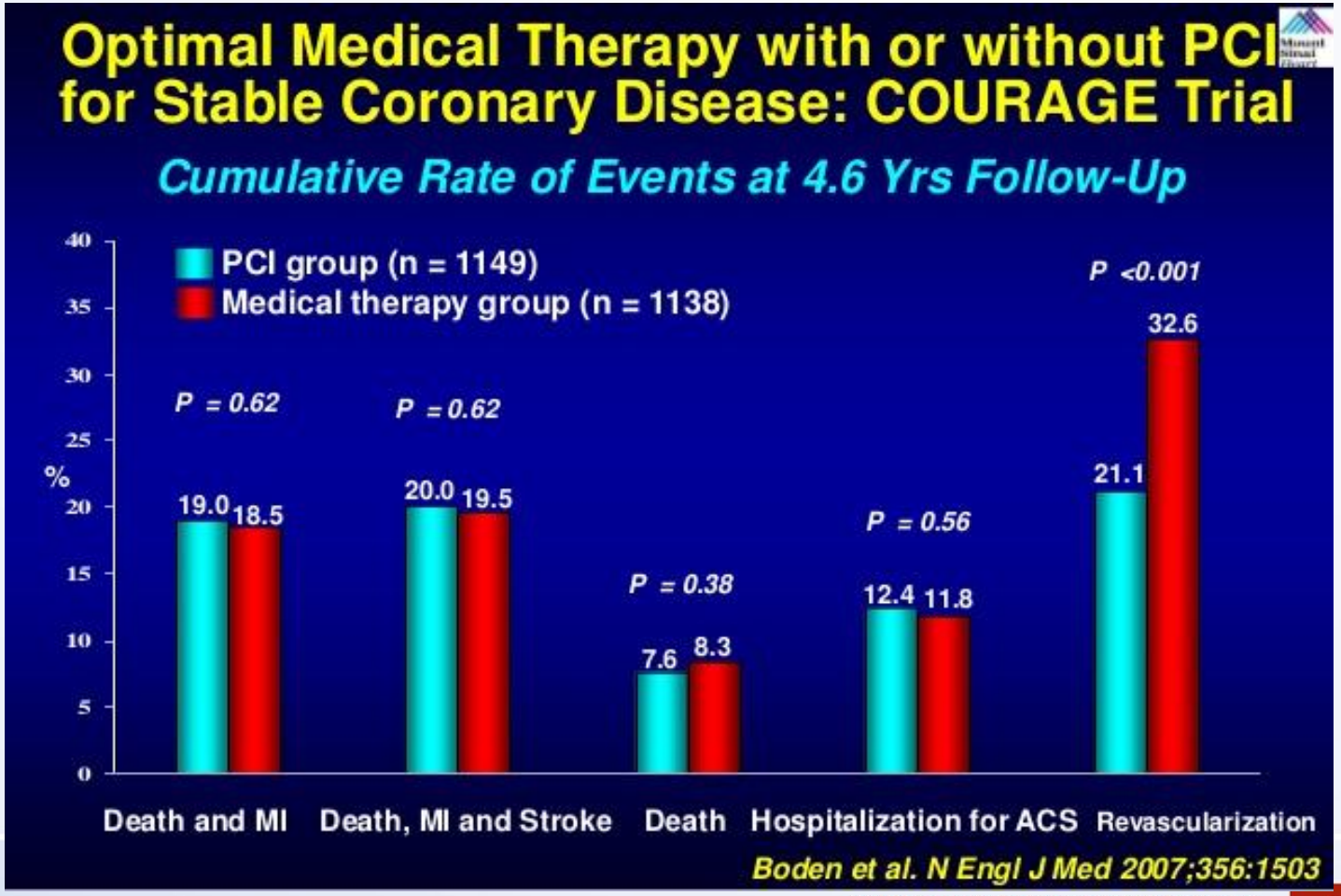
Courage:
PCI snižuje výskyt AP



N Engl J Med 2008; 359:677-687

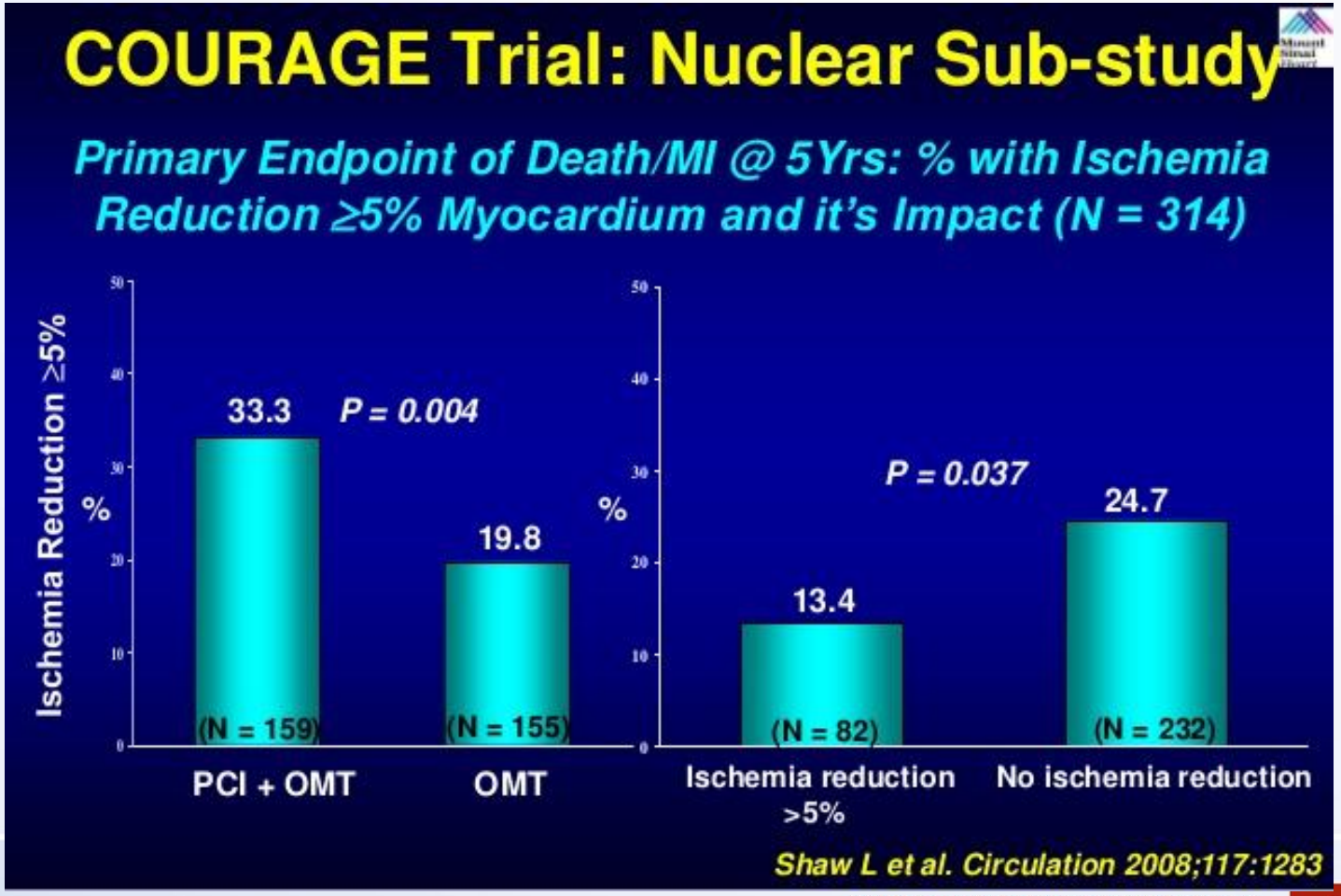
Courage:

PCI je spojena s nižší následnou revaskularizací



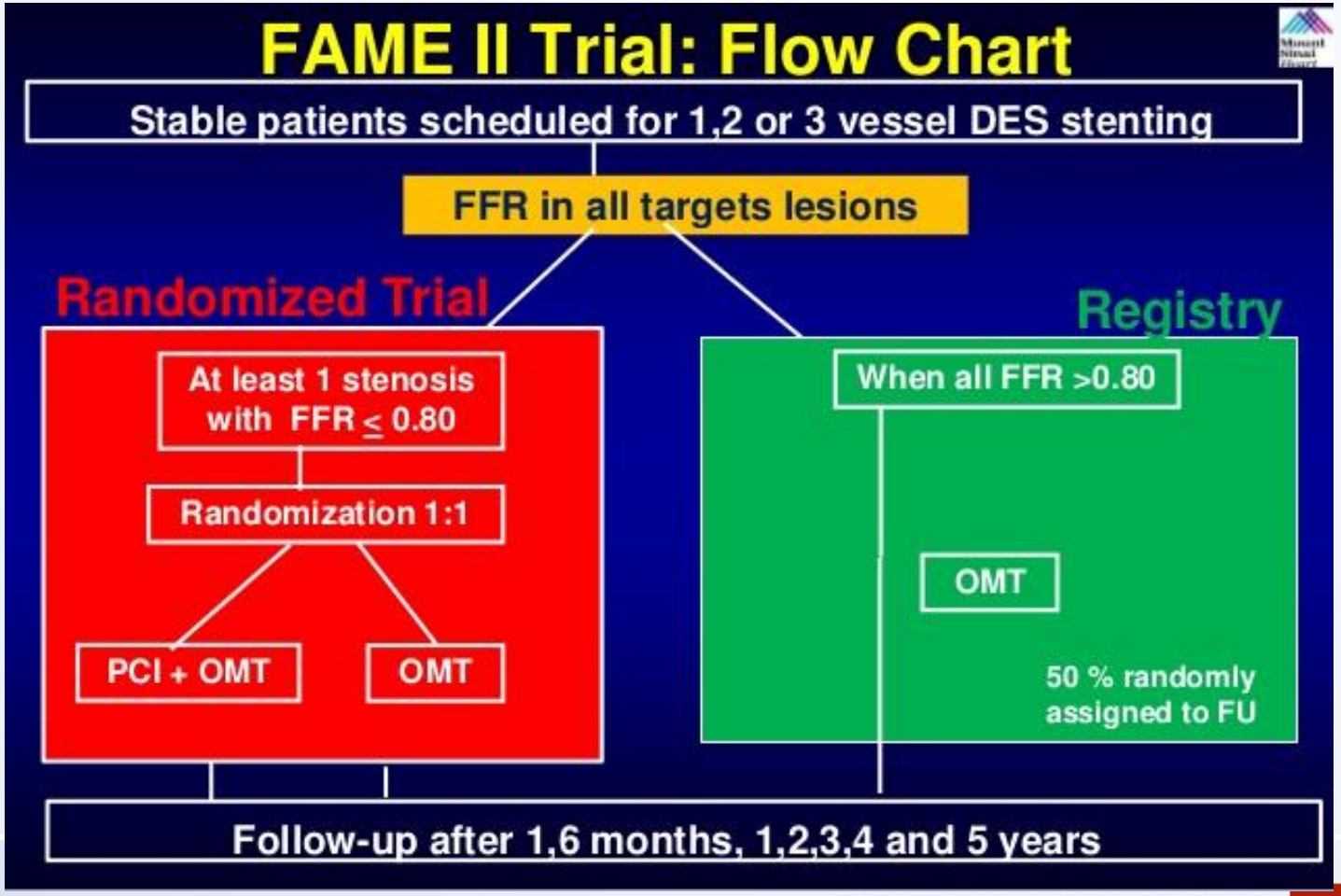
Courage:

PCI redukuje ischemii myokardu



FAME-2

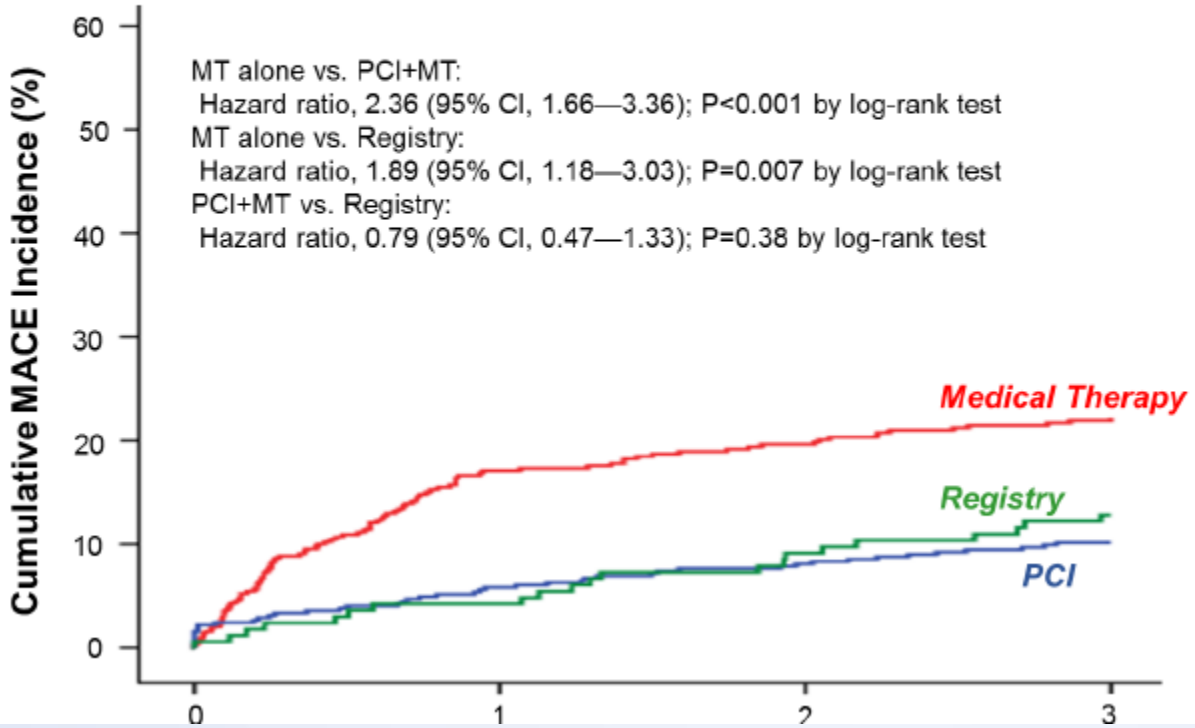
n=1220


FAME II Trial: Flow Chart
Stable patients scheduled for 1,2 or 3 vessel DES stenting
FFR in all targets lesions
Randomized Trial
At least 1 stenosis with FFR ≤ 0.80
Randomization 1:1
PCI + OMT
OMT
Registry
When all FFR >0.80
OMT
50 % randomly assigned to FU
Follow-up after 1,6 months, 1,2,3,4 and 5 years

FAME-2: 3 letý follow-up

Results: Clinical Outcome

Three Year Rate of Death, MI, or Urgent Revascularization



FAME-2

Results: Clinical Outcome

Three Year Rate of Death, MI, or Urgent Revascularization

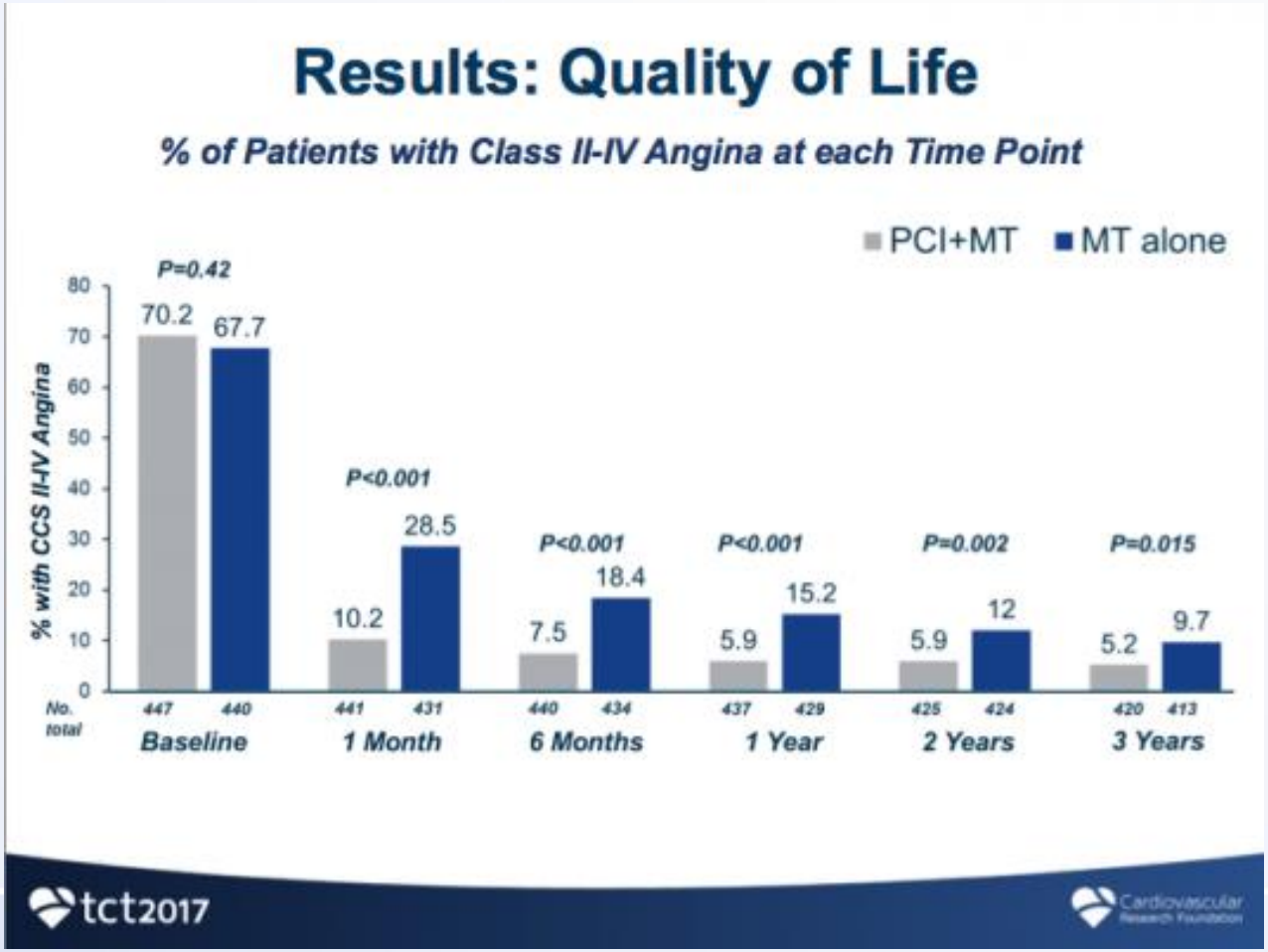
	Randomized trial N=888		P value	Registry N=322
Event	PCI+MT=447	MT=441		with FU=166
MACE	10.1%	22%	<0.001	12.7%
Death	2.7%	3.6%	0.43	3.0%
Myocardial Infarction (MI)	6.3%	7.7%	0.41	6.6%
Death or MI	8.3%	10.4%	0.28	9.0%
Urgent Revascularization	4.3%	17.2%	<0.001	6.6%

**P value compares PCI + MT patients with MT patients*

tct2017

Cardiovascular Research Foundation

FAME-2


Results: Quality of Life
% of Patients with Class II-IV Angina at each Time Point
PCI+MT
MT alone
% with CCS II-IV Angina
80
70
60
50
40
30
20
10
0
P=0.42
70.2
67.7
P<0.001
10.2
28.5
P<0.001
7.5
18.4
P<0.001
5.9
15.2
P=0.002
5.9
12
P=0.015
5.2
9.7
No. total
447 440
Baseline
441 431
1 Month
440 434
6 Months
437 429
1 Year
425 424
2 Years
420 413
3 Years
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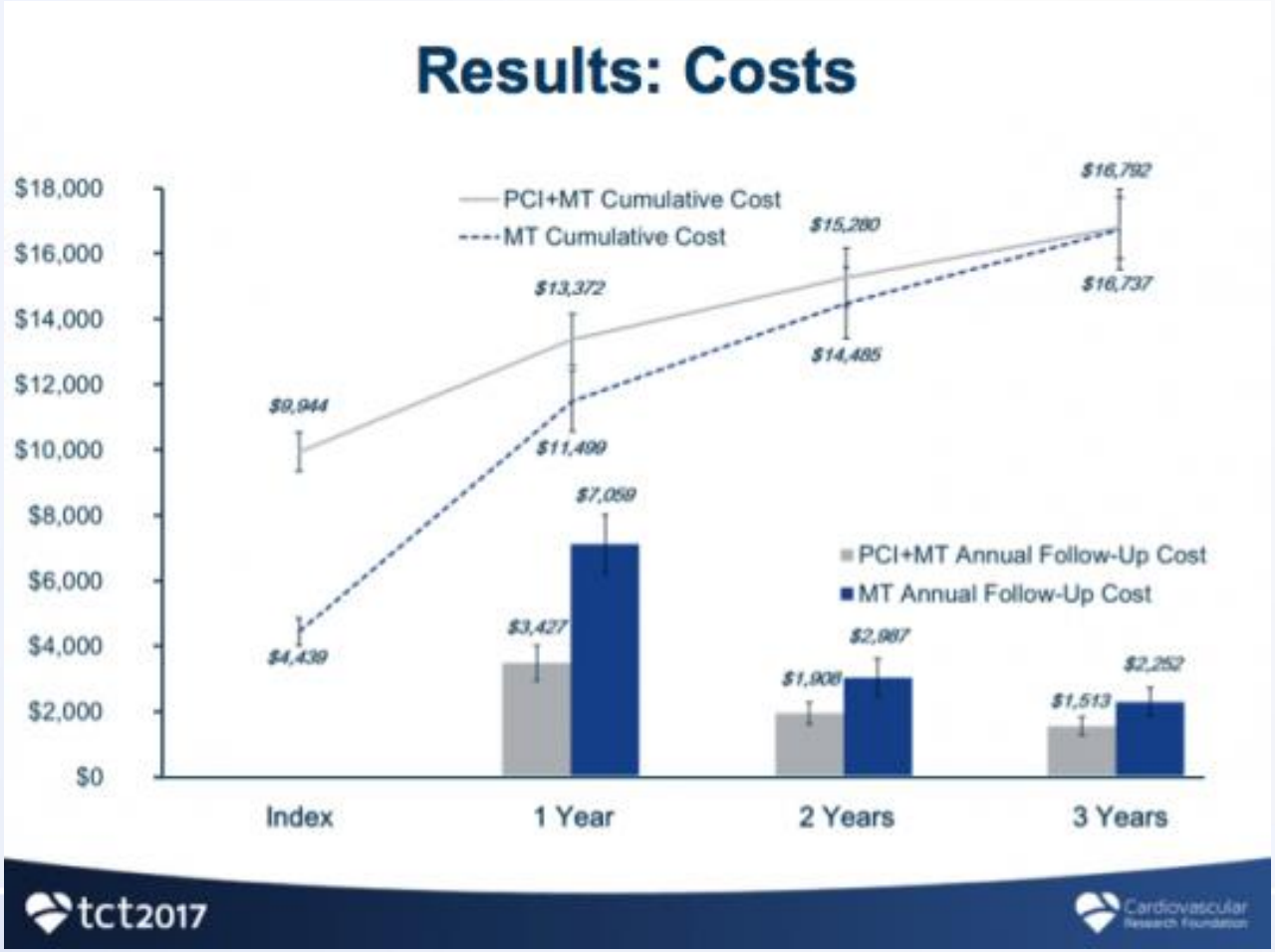
Cardiovascular Research Foundation

FAME-2


Results: Costs
$18,000
$16,000
$14,000
$12,000
$10,000
$8,000
$6,000
$4,000
$2,000
$0
PCI+MT Cumulative Cost
MT Cumulative Cost
$9,944
$13,372
$15,280
$16,792
$16,737
$14,485
$11,499
$4,439
PCI+MT Annual Follow-Up Cost
MT Annual Follow-Up Cost
$7,059
$3,427
$2,987
$1,908
$2,252
$1,513
Index
1 Year
2 Years
3 Years
tct2017
Cardiovascular Research Foundation

Objective Randomised Blinded Investigation with optimal medical Therapy of Angioplasty in stable angina (ORBITA)

Principal hypothesis:
Symptom relief in stable angina

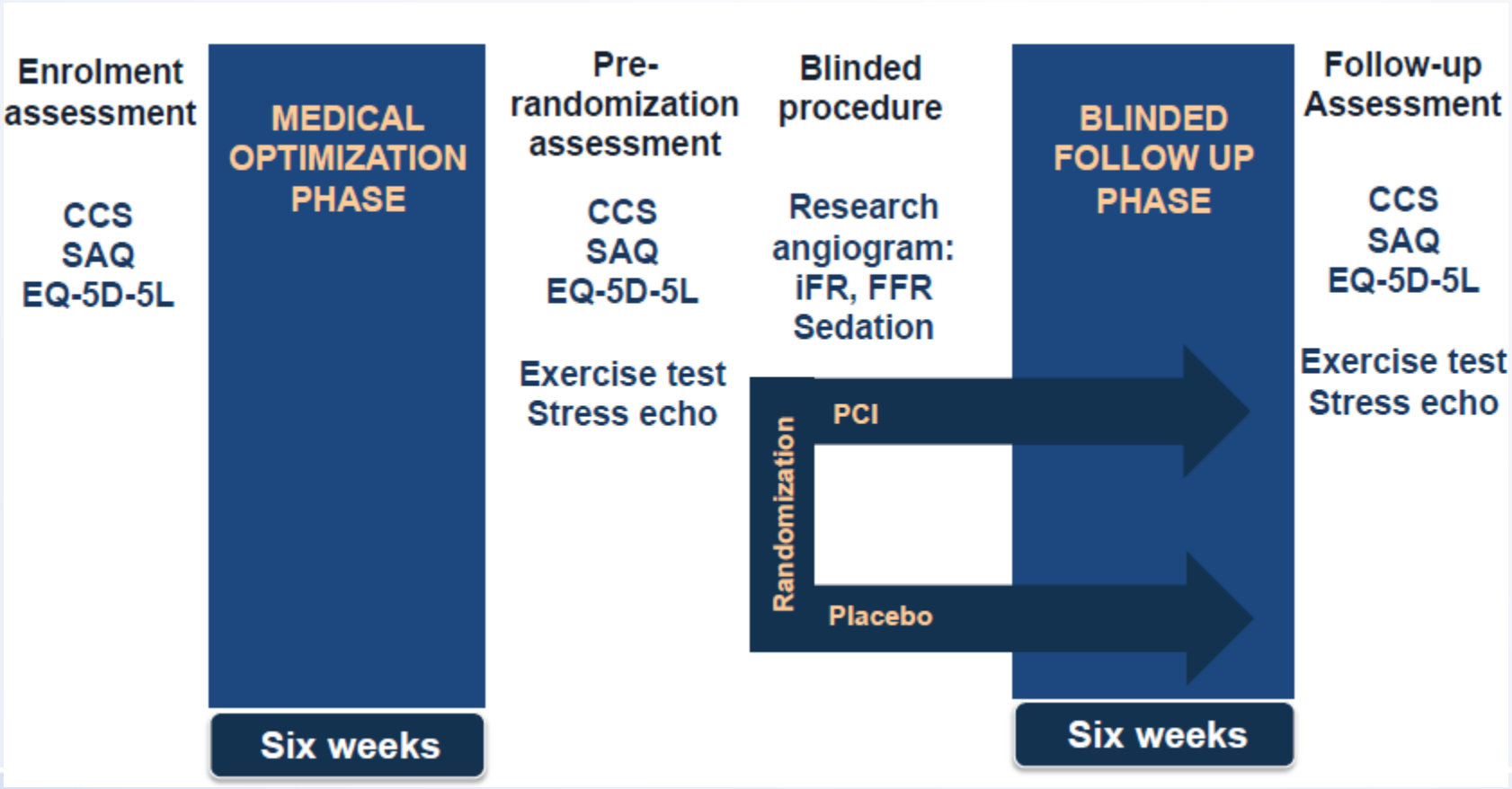
PCI increases exercise time more than placebo procedure

Primary endpoint

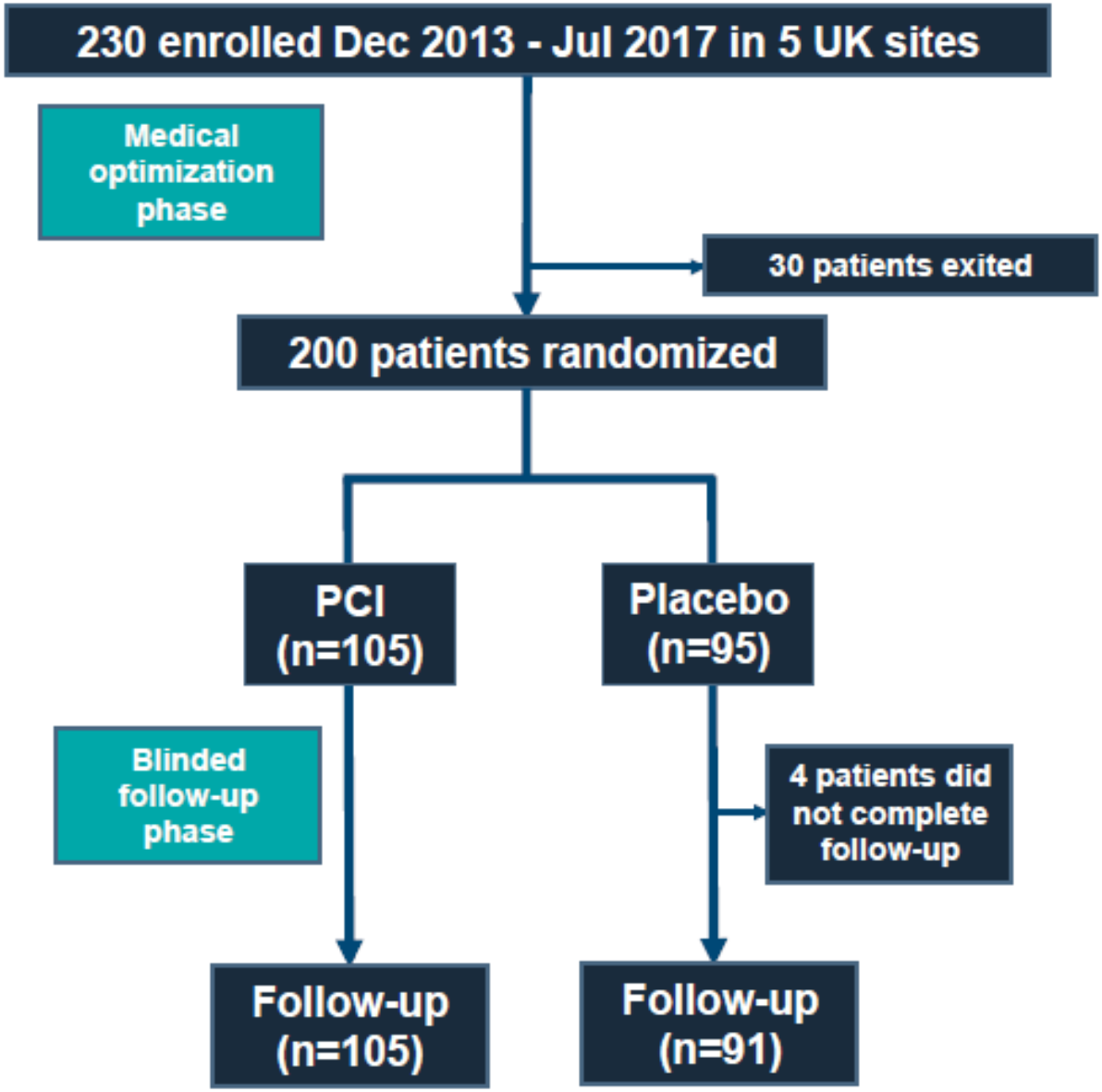
Difference in exercise time increment between the arms

Vstupní kriteria: stabilní AP, stenóza na jedné tepně > 70%, 1VD

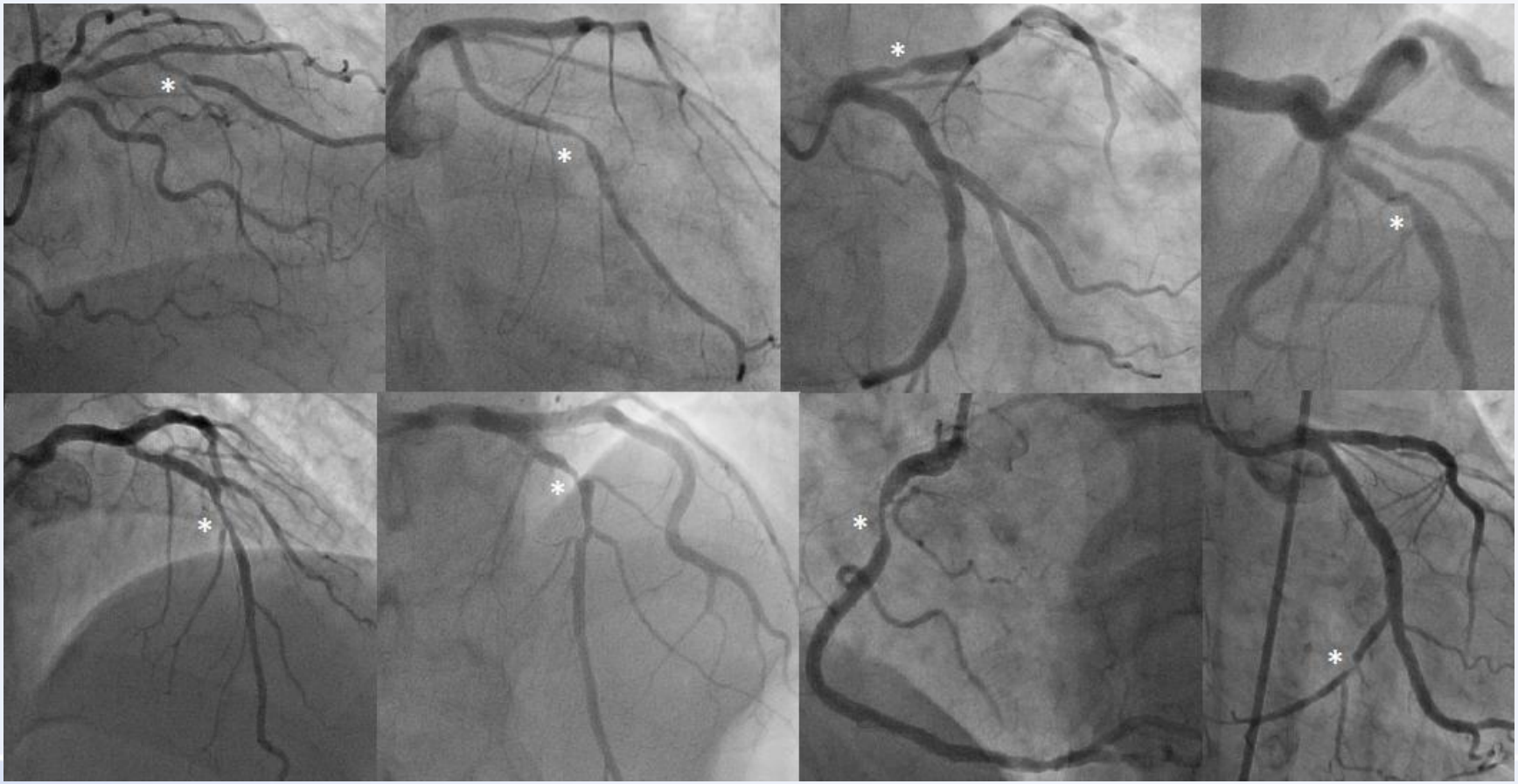
ORBITA: trial design



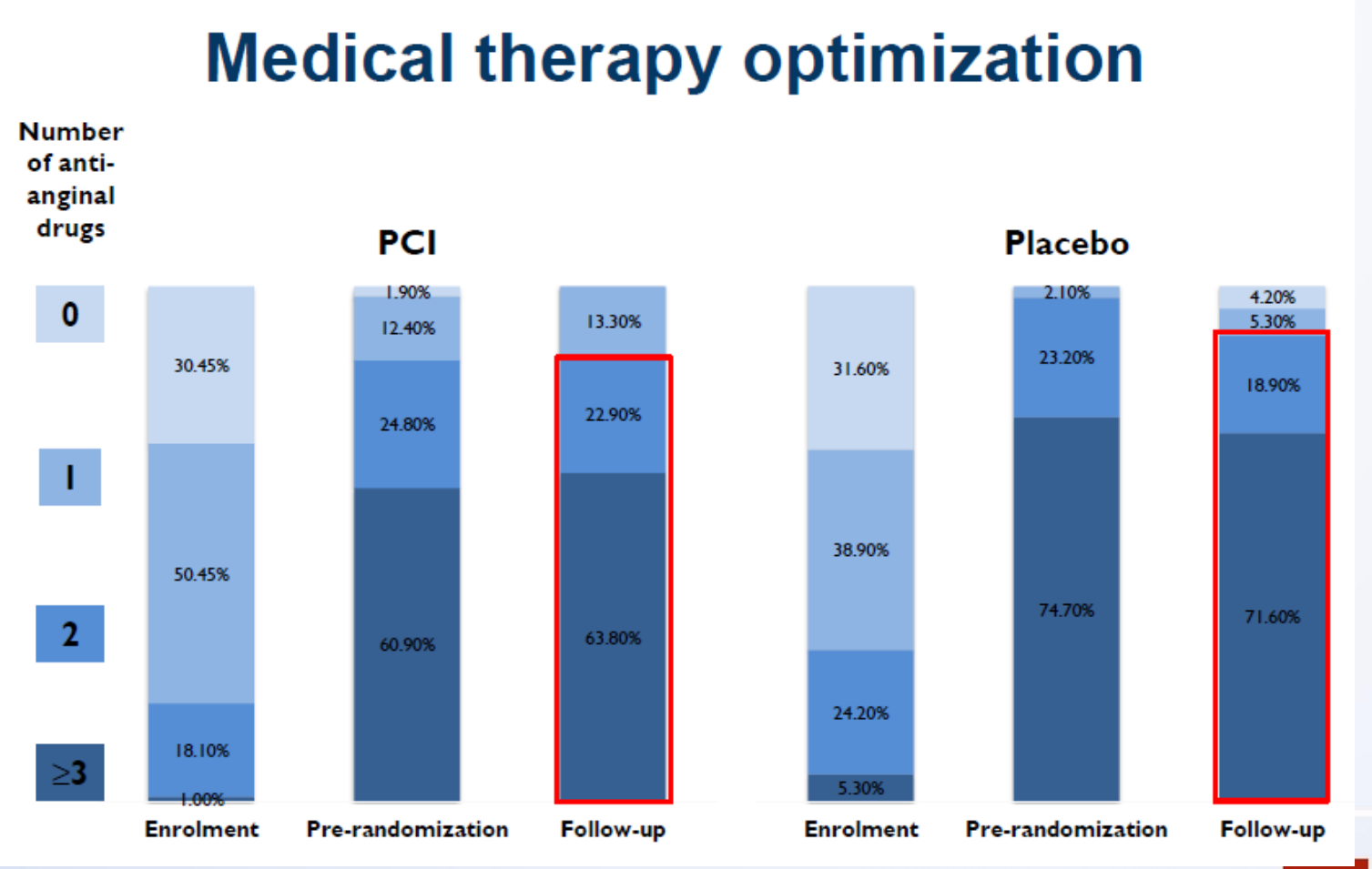
ORBITA trial



Angiografické nálezy



Agresivní farmakoterapie

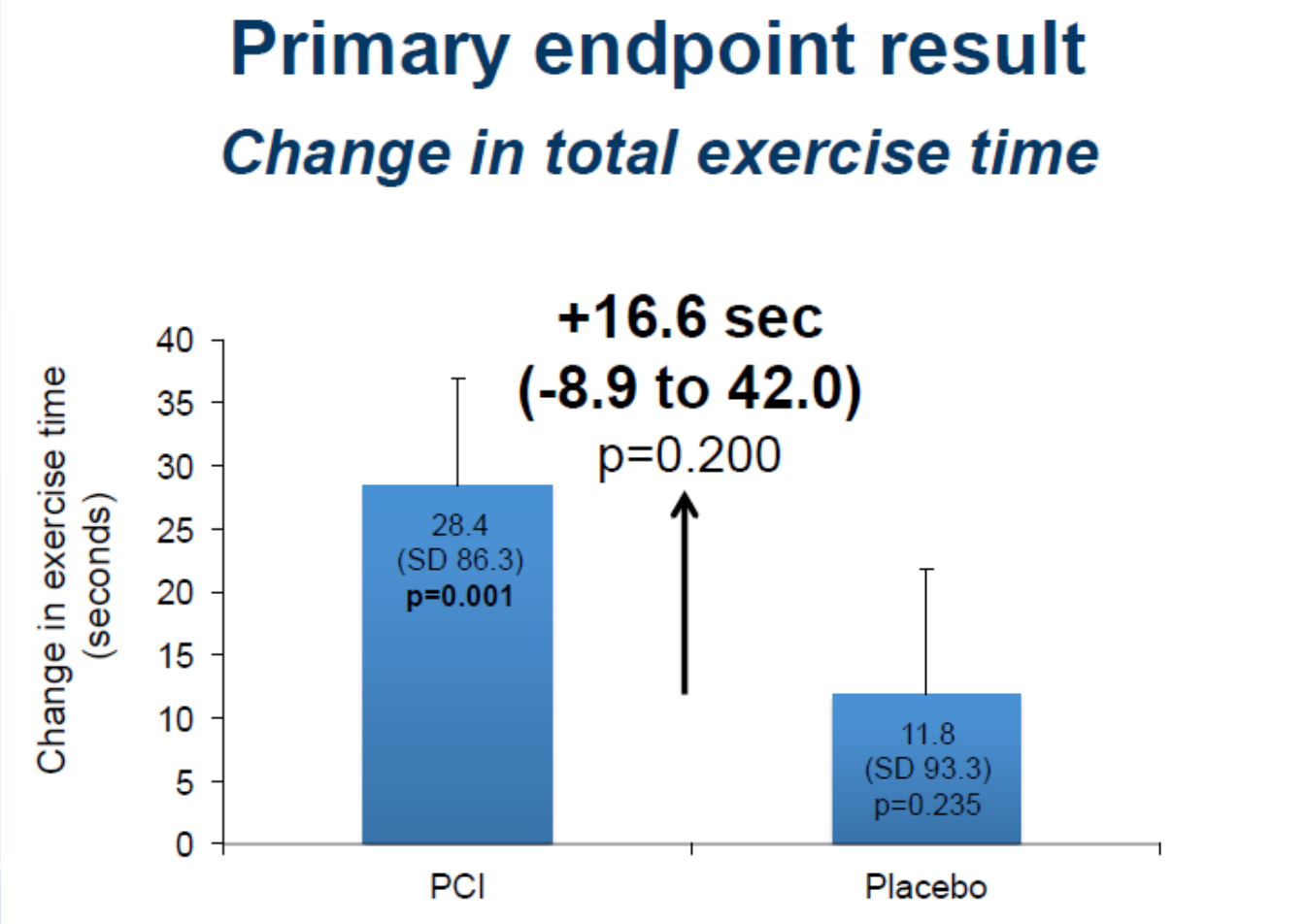


Medication	Time-interval	PCI	Placebo	p-value
Aspirin	Enrolment to pre-randomisation	103/105 (98%)	93/95 (98%)	0·919
	Pre-randomisation to follow-up	104/105 (99%)	88/91 (97%)	0·247
Clopidogrel or other antiplatelet	Enrolment to pre-randomisation	103/105 (98%)	94/95 (99%)	0·621
	Pre-randomisation to follow-up	105/105 (100%)	89/91 (98%)	0·127
Atorvastatin or other statin	Enrolment to pre-randomisation	99/105 (94%)	91/95 (96%)	0·626
	Pre-randomisation to follow-up	102/105 (97%)	87/91 (96%)	0·563
Perindopril or other ACEI or ARB	Enrolment to pre-randomisation	84/105 (80%)	74/95 (78%)	0·715
	Pre-randomisation to follow-up	85/105 (81%)	72/91 (79%)	0·749
Bisoprolol or other β blocker	Enrolment to pre-randomisation	82/105 (78%)	74/95 (78%)	0·973
	Pre-randomisation to follow-up	85/105 (81%)	69/91 (76%)	0·383
Amlodipine or other Ca channel blocker	Enrolment to pre-randomisation	95/105 (90%)	87/95 (92%)	0·786
	Pre-randomisation to follow-up	96/105 (91%)	81/91 (89%)	0·568
Long acting nitrate	Enrolment to pre-randomisation	67/105 (64%)	64/95 (67%)	0·597
	Pre-randomisation to follow-up	69/105 (66%)	60/91 (66%)	0·974
Nicorandil	Enrolment to pre-randomisation	47/105 (45%)	58/95 (61%)	**0·021**
	Pre-randomisation to follow-up	50/105 (48%)	54/91 (59%)	0·101
Ranolazine	Enrolment to pre-randomisation	7/105 (7%)	13/95 (14%)	0·099
	Pre-randomisation to follow-up	7/105 (7%)	13/91 (14%)	0·079

Průměr 7,5 léku/pacienta

IKEM

ORBITA: PCI zvyšuje toleranci zátěže



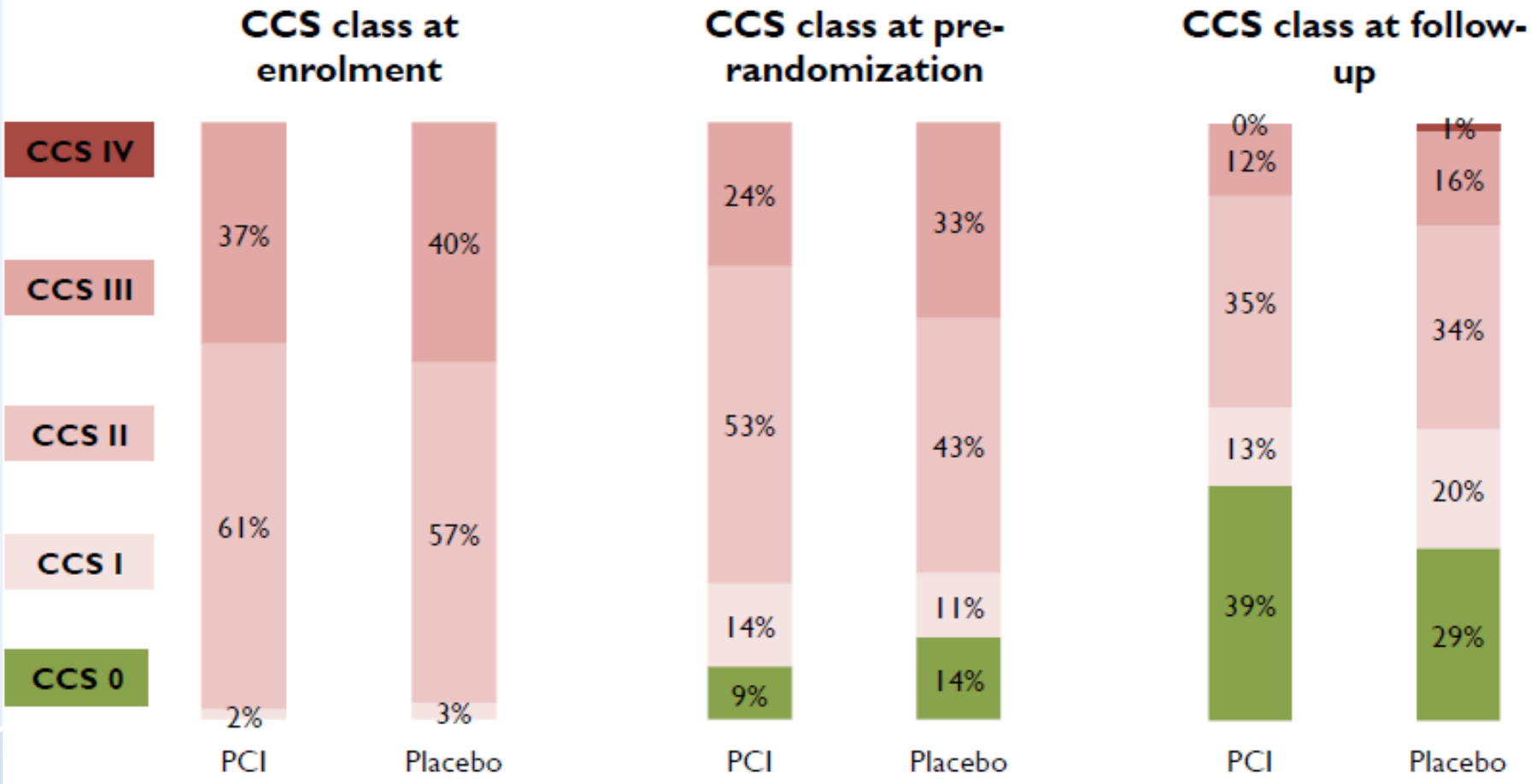
Kompletní data set (Appendix) – ergometricky tolerovaná vysoká zátěž = low risk populace z hlediska ischemie

Total exercise time		
Exercise time (seconds)	**PCI**	**Placebo**
Pre-randomisation	526·9 (178·2) n=105	482·3 (194·3) n=95
Follow-up	556·3 (178·7) n=104	501·8 (190·9) n=90

V obou skupinách velmi dobrá tolerance zátěže ještě před randomizací – 9 minut !!

Secondary endpoint results

CCS class improved in both groups



ORBITA: PCI vede k redukci rozsahu ischemie

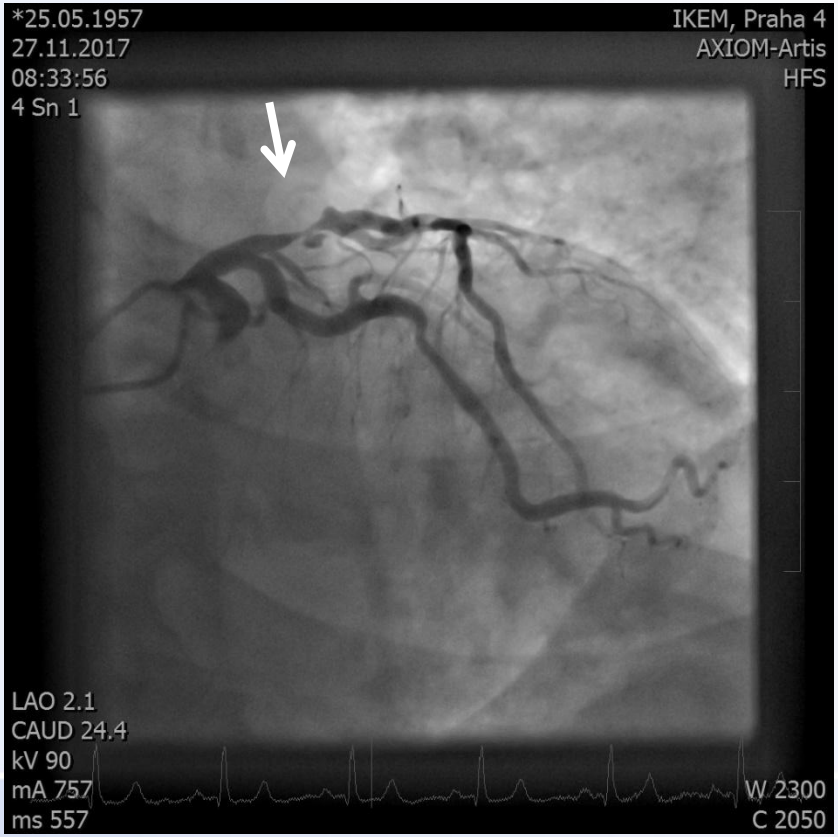
Secondary endpoint results

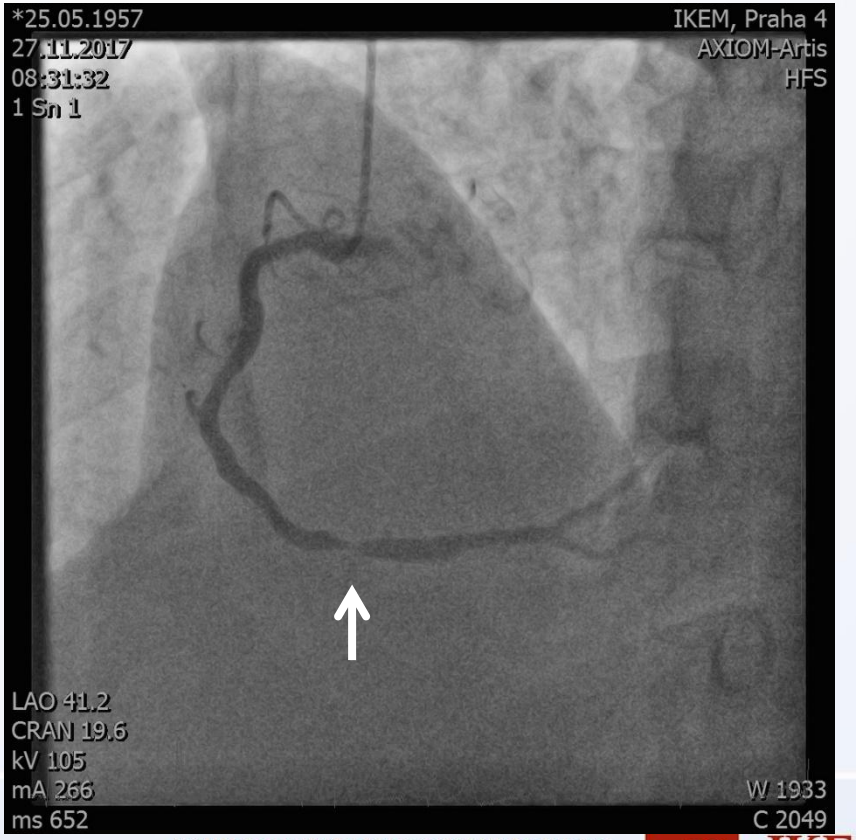
Blinded evaluation of ischaemia reduction

Peak stress wall motion index score	PCI n = 80	Placebo n = 57
Pre-randomization	1.11 (0.18)	1.11 (0.18)
Follow-up	1.03 (0.06)	1.13 (0.19)
Δ (Pre-randomization to follow-up)	-0.08 (0.17)	0.02 (0.16)
	p<0.0001	p=0.433
Difference in Δ between arms	-0.09 (-0.15 to -0.04) **p=0.0011**	

Stabilní AP CCS 2,
positivní ergo 200 W 1 mm STd V4-6

ORBITA: konzervativně + 7 léků trvale + riziko úmrtí, IM, urg. revaskularizace

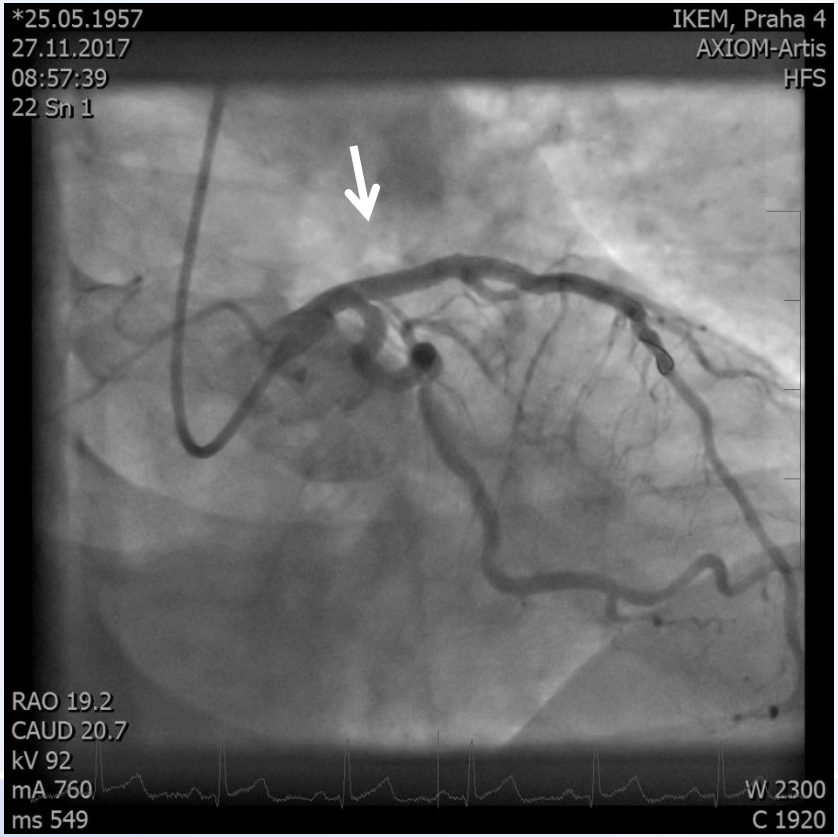


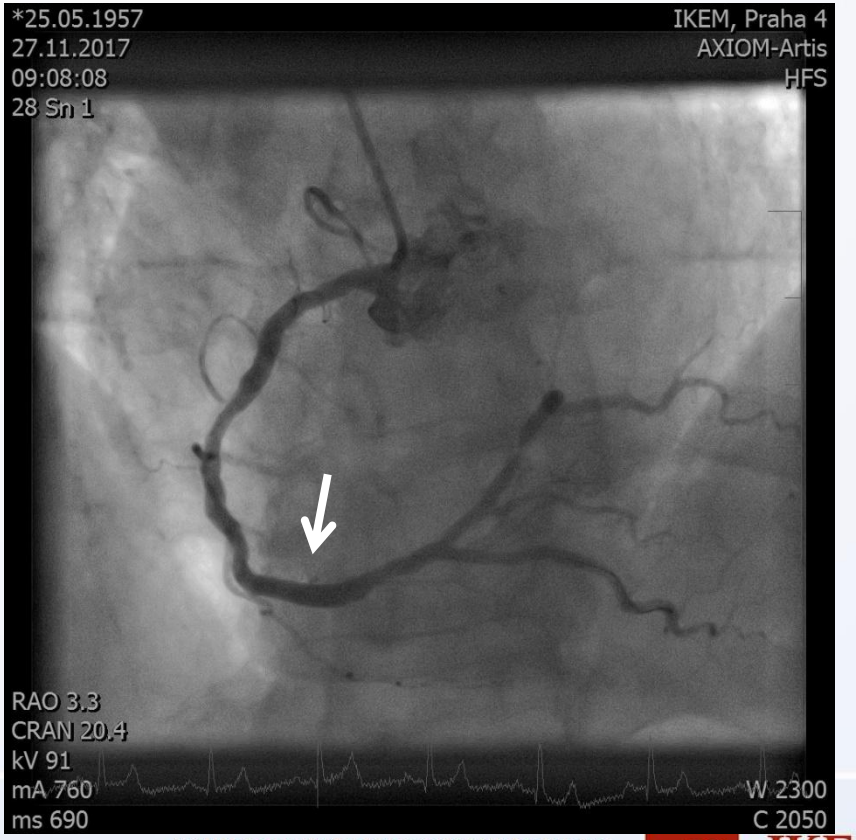


Stabilní AP CCS 2,
positivní ergo 200 W 1 mm STd V4-6

NEBO: ambulantní SKG + PCI RIA/DES, ACD/DES + DAPT na 6 měsíců

08:30 zahájena koronarografie, 09:15 ukončena PCI





Kritika studie ORBITA

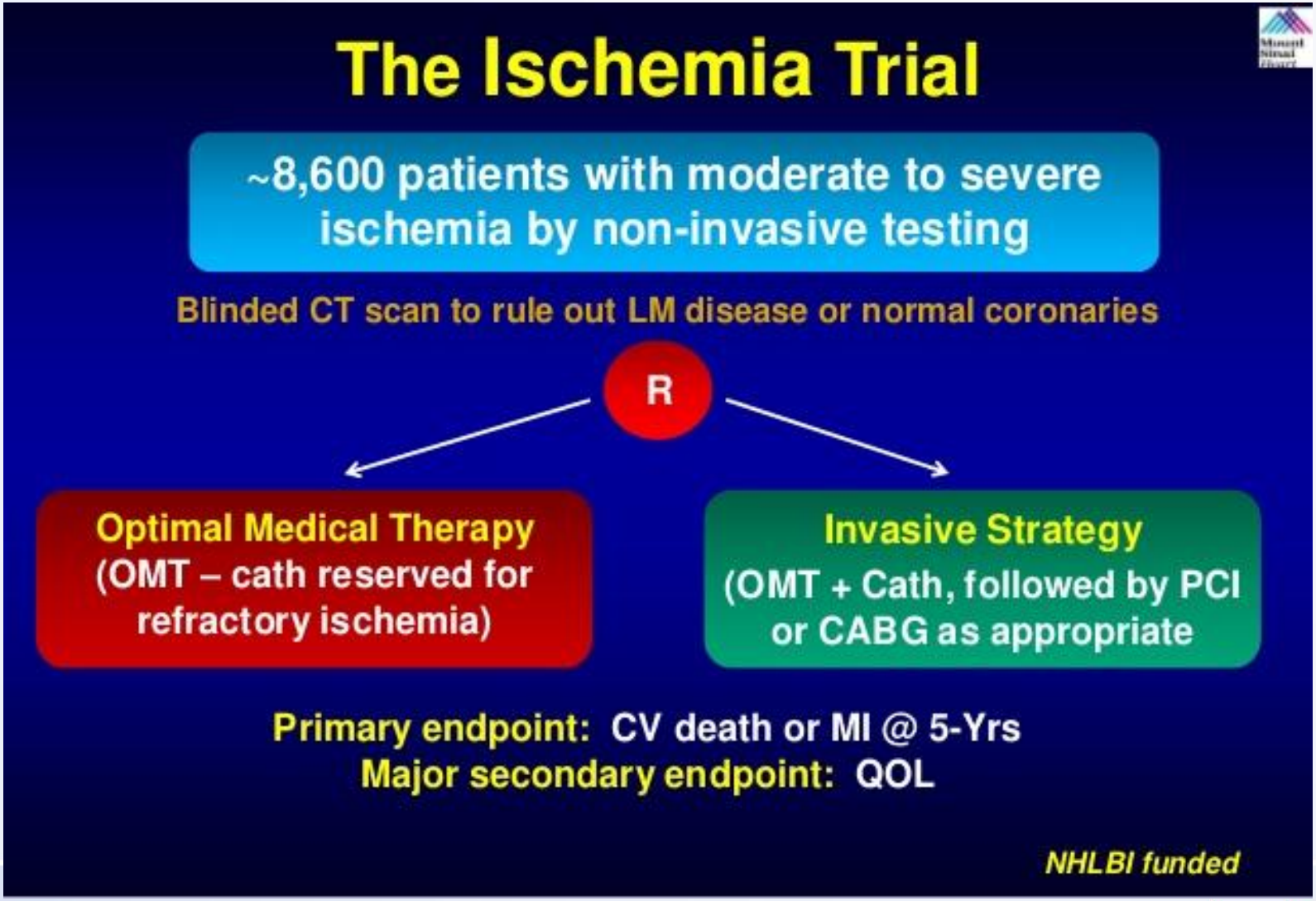
- Superselektovaný, i když dobře kontrolovaný soubor, 1VD, malý počet (n=200)
- Ergometricky tolerovaná vysoká zátěž – low risk nemocní z hlediska rozsahu ischemie
- Extrémní farmakologická léčba vč. selfmonitoringu v průběhu optimalizace před randomizací
- Velmi krátký follow-up – 6 týdnů
- Nejasný mechanismus přetrvávání AP u nemocných po PCI, naopak neznámý crossover z OMT na PCI v průběhu delšího follow-upu
- PCI bezpečná (více komplikací v OMT rameni)

PCI+ OMT vs OMT

- PCI snižuje rozsah ischemie a zlepšuje toleranci zátěže
- Benefit PCI je úměrný rozsahu koronárního postižení
- Riziko PCI je v současnosti minimální
- Studie Courage a ORBITA jsou superselektované soubory, jejich výsledky nelze aplikovat na většinu nemocných s chronickou ICHS
- OMT je možnou iniciální strategií u selektovaných nemocných se SAP za předpokladu dobré tolerance zátěže, při vyloučení prognosticky závažného postižení věnčitých tepen za cenu agresivní farmakoterapie. Cca 30% nemocných i přesto podstoupí revaskularizaci.

Indikace k revaskularizaci myokardu (PCI nebo CABG) se nemění

Extent of CAD (anatomical and/or functional)		Class[b]	Level[c]
For prognosis	Left main disease with stenosis >50%[a]	I	A
	Any proximal LAD stenosis >50%[a]	I	A
	Two-vessel or three-vessel disease with stenosis > 50%[a] with impaired LV function (LVEF<40%)[a]	I	A
	Large area of ischaemia (>10% LV)	I	B
	Single remaining patent coronary artery with stenosis >50%[a]	I	C
For symptoms	Any coronary stenosis >50%[a] in the presence of limiting angina or angina equivalent, unresponsive to medical therapy	I	A


The Ischemia Trial
~8,600 patients with moderate to severe ischemia by non-invasive testing
Blinded CT scan to rule out LM disease or normal coronaries
R
Optimal Medical Therapy (OMT – cath reserved for refractory ischemia)
Invasive Strategy (OMT + Cath, followed by PCI or CABG as appropriate
Primary endpoint: CV death or MI @ 5-Yrs
Major secondary endpoint: QOL
NHLBI funded