

Stable angina, medical treatment enough ?

From COURAGE, ORBITA and ISCHEMIA

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PCI classification

Cosmetic Angioplasty

Non-Viable
Asymptomatic
Small ischemic
Myocardium,
FFR > 0.80,
No Evidence of ischemia

Symptomatic Angioplasty

For Angina relieve

Survival Angioplasty

Left main and 3 vessel
disease
For Large ischemic burden

PCI classification

Cosmetic Angioplasty

Non-Viable

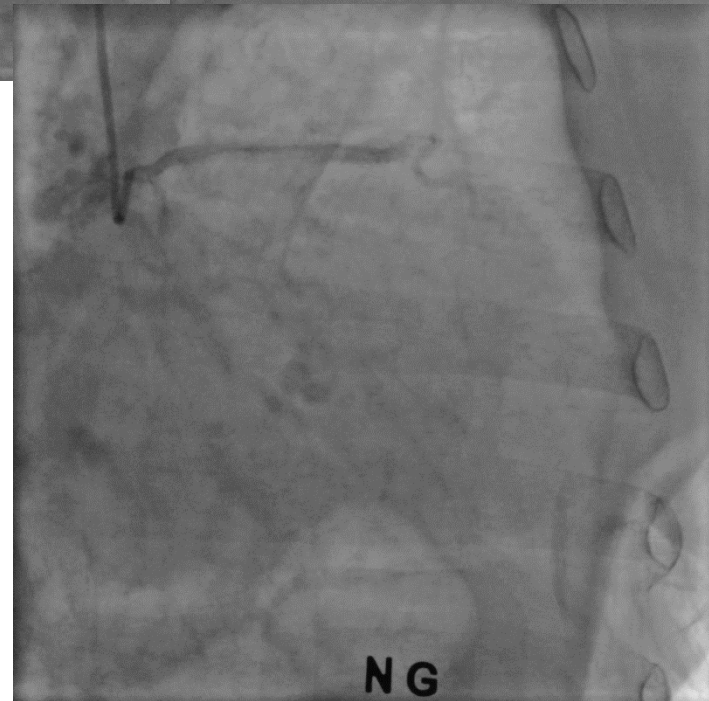
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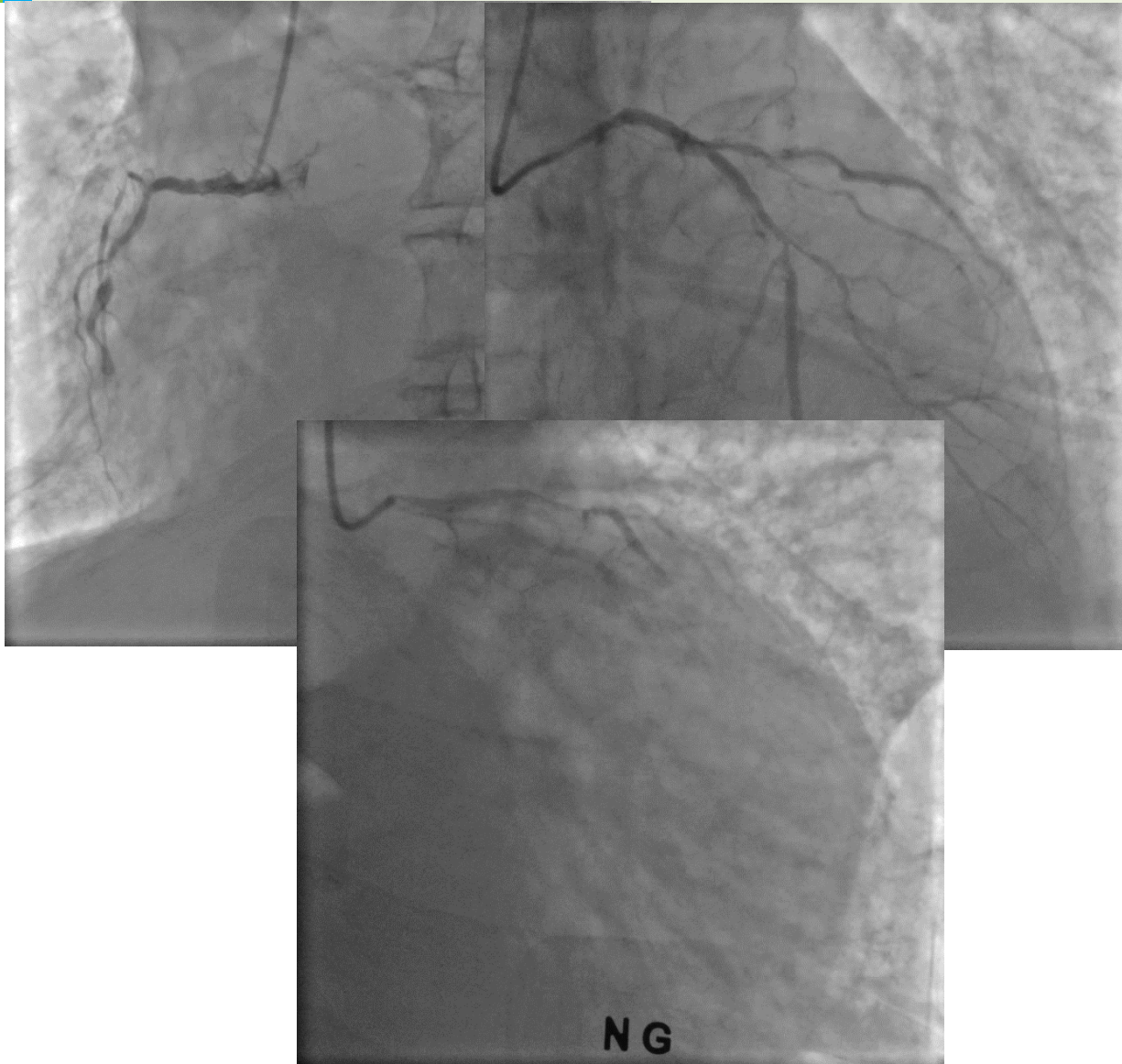
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FFR > 0.80,

No Evidence of ischemia



PCI classification



Survival

Angioplasty

Left main and 3 vessel
disease

For Large ischemic burden

Stable angina with myocardial ischemia

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For Angina relieve

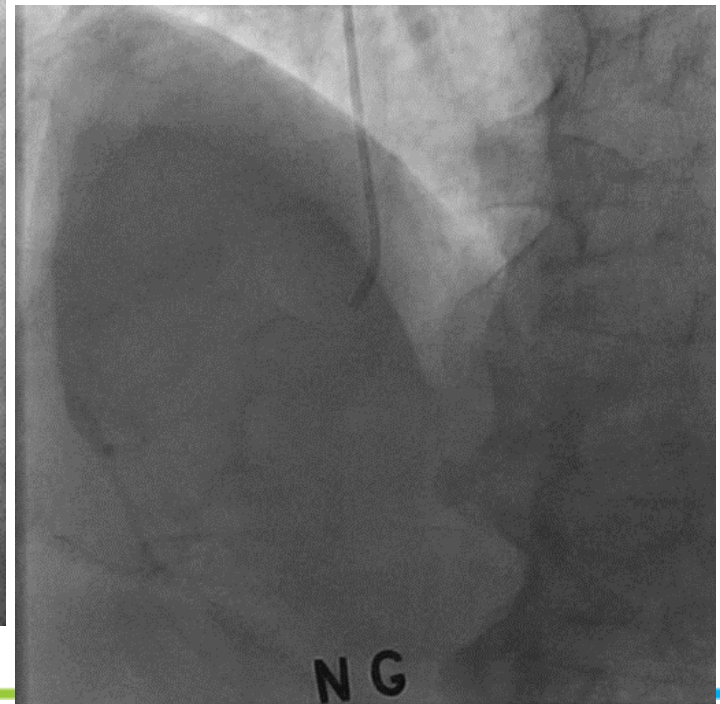
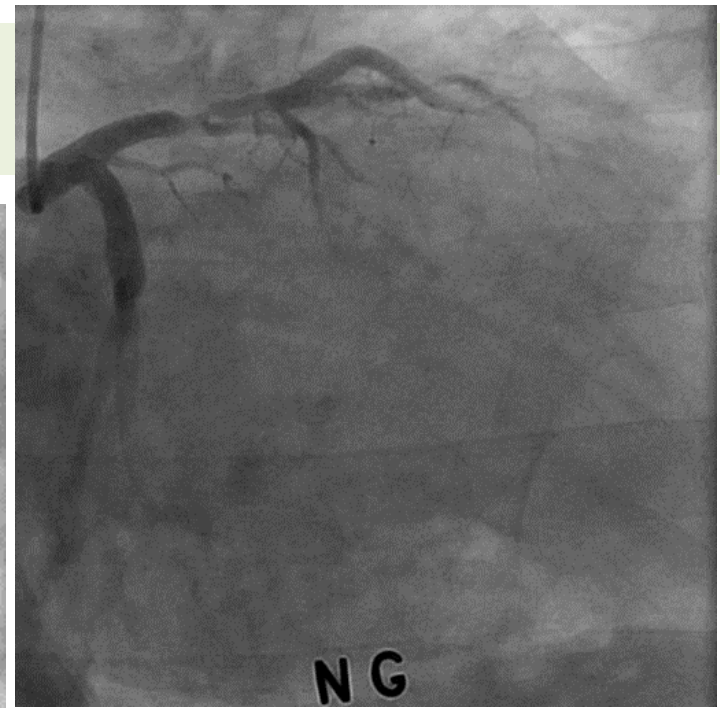
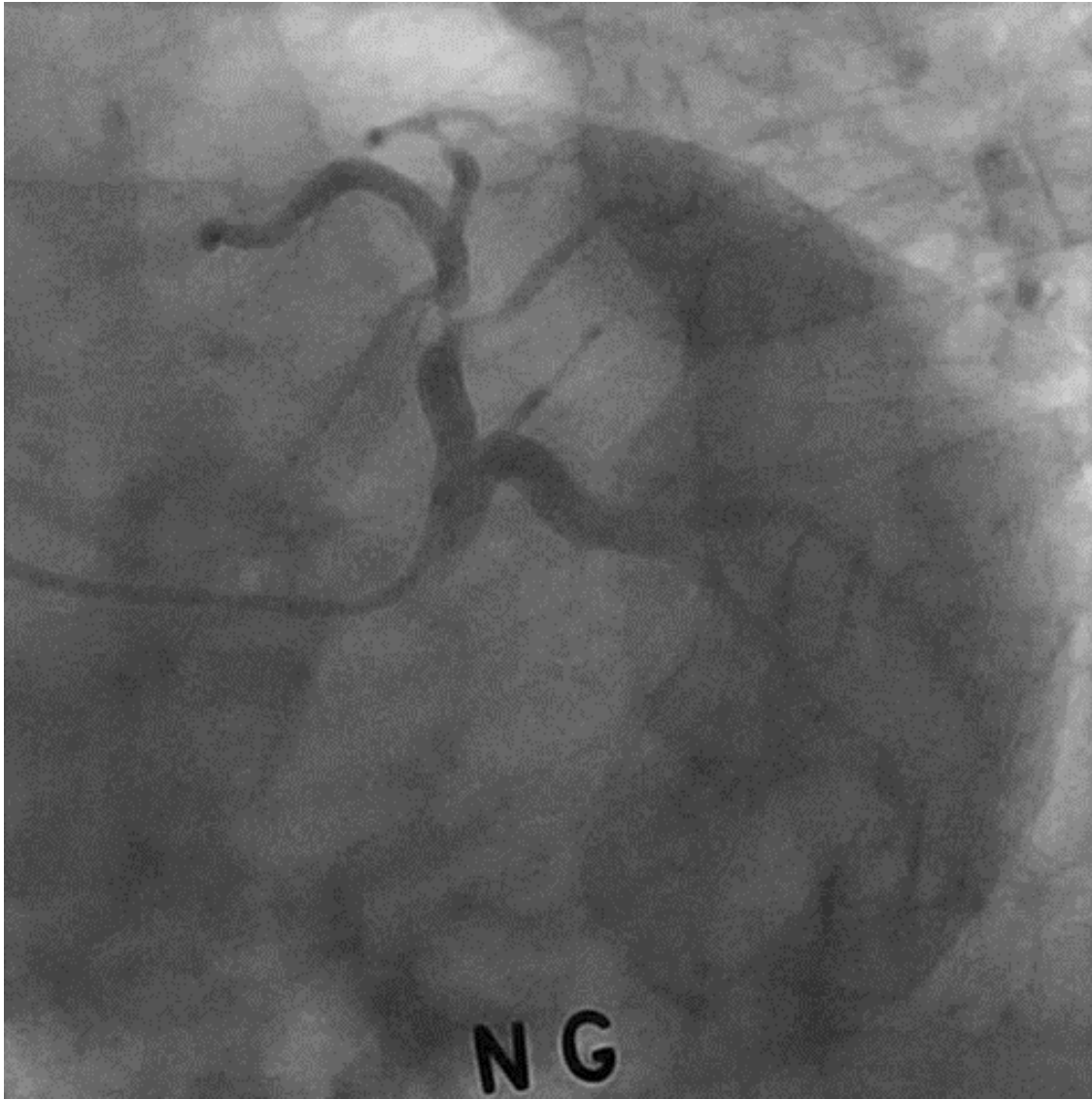
Survival Angioplasty

Left main and 3 vessel
disease
For Large ischemic burden

ORVITA type patient : M/60

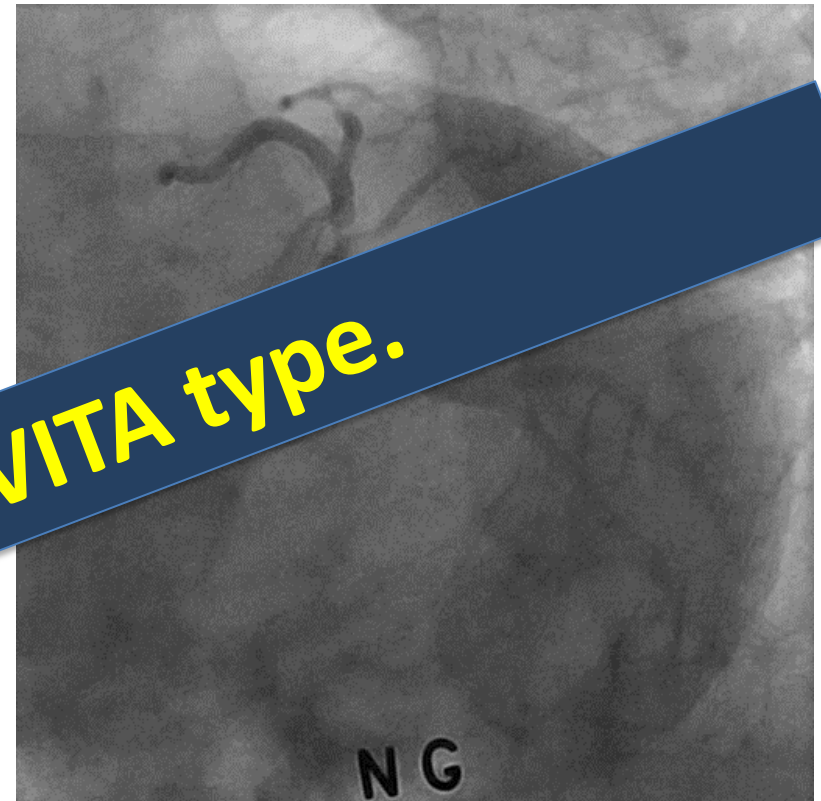
- 60-year-old male
- very active patient
- Reproducible chest pain, 5MA
- exercise ECG test : ST depression in leads V4-6
- stress echocardiography : hypokinetic apical anterior and anteroseptal myocardial segments

M/60



How to treat ?

1. CABG
2. PCI
3. OMT (optimal medical treatment)
4. None of above



- 60-year-old male
- with a history of chest pain, 5MA
- exercise ECG test : ST depression in leads V4-6
- stress echocardiography : hypokinetic apical anterior and anteroseptal myocardial segments

COURAGE (NEJM 2007) and ORBITA (Lancet 2017)

- Results and Controversy Surrounding Two Key Trials, COURAGE (NEJM 2007) and ORBITA (Lancet 2017)

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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., Merrill 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. Tittle, 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*

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02 November 2017

Percutaneous coronary intervention in stable angina (ORBITA) a double-blind, randomised controlled trial

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COURAGE trial

COURAGE: Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation

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- Sponsored by Department of VA Cooperative Study Program
- Randomized, multicenter
- Subjects entered from 1999-2004
- Follow-up period of 2.5 to 7.0 years (median 4.6)

- Population

Patients with objective evidence of myocardial ischemia and significant coronary disease

2287 subjects from 50 sites in US and Canada, randomized 1:1

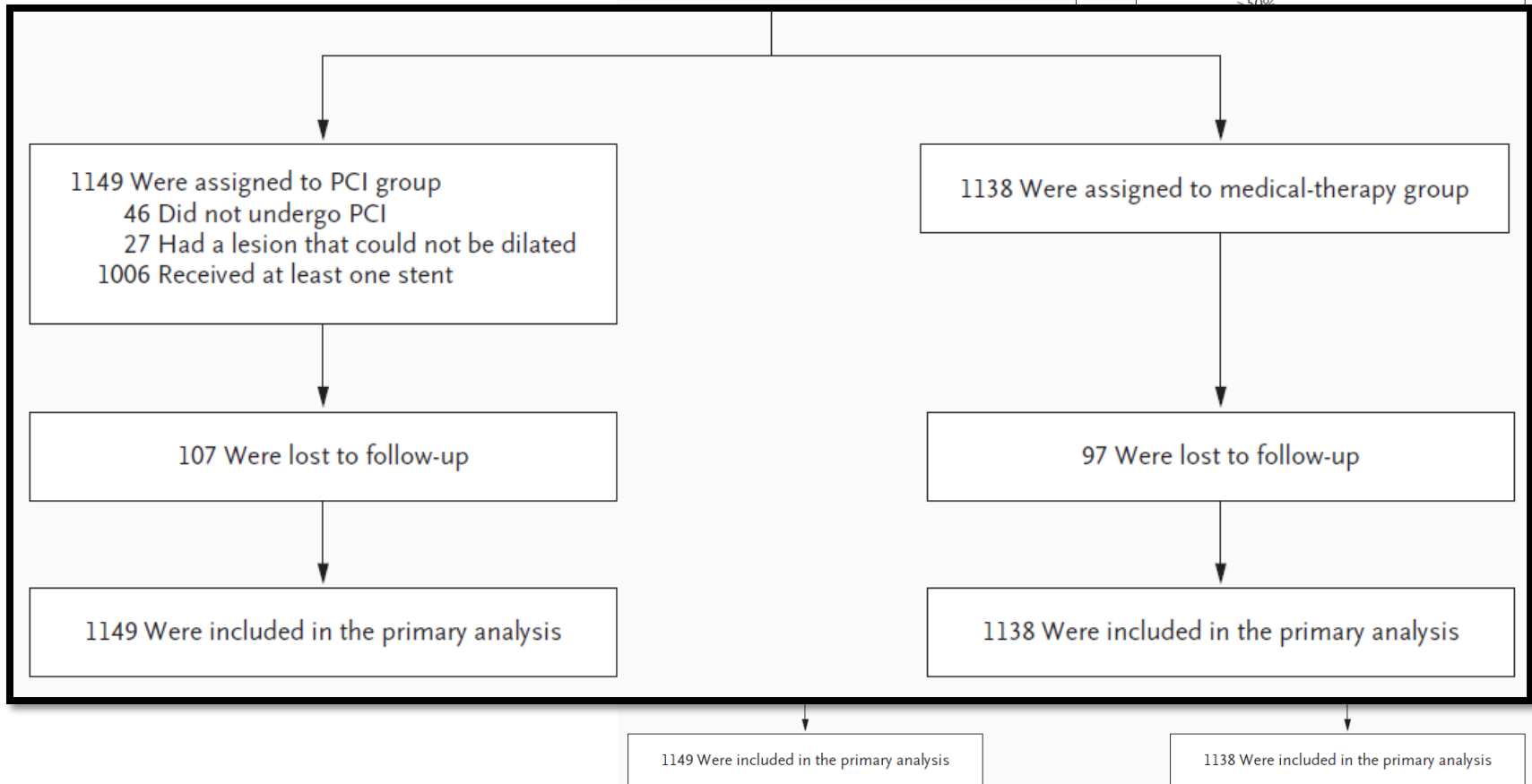
1149 to undergo PCI with optimal medical therapy

1138 to receive optimal medical therapy alone

Patient enrollment

35,539 Patients underwent assessment

32,468 Were excluded
8677 Did not meet inclusion criteria
5155 Had undocumented ischemia
3961 Did not meet protocol for vessels
6554 Were excluded for logistic reasons
18,360 Had one or more exclusions
4513 Had undergone recent (<6 mo) revascularization
4939 Had an inadequate ejection fraction
2987 Had a contraindication to PCI
2542 Had a serious coexisting illness
1285 Had concomitant valvular disease
1203 Had class IV angina
1071 Had a failure of medical therapy
947 Had left main coronary artery stenosis
= 50%



Baseline Characteristics

| Characteristic | PCI Group (N=1149) | Medical-Therapy Group (N=1138) | P Value |
|---------------------------------|--------------------|--------------------------------|---------|
| Demographic | | | |
| Age — yr | 61.5±10.1 | 61.8±9.7 | 0.54 |
| Sex — no. (%) | | | 0.95 |
| Male | 979 (85) | 968 (85) | |
| Female | 169 (15) | 169 (15) | |
| Race or ethnic group — no. (%)† | | | 0.64 |

eristics

| Angina (CCS class) — no. (%) | | | 0.24 |
|------------------------------|----------|----------|------|
| 0 | 135 (12) | 148 (13) | |
| I | 340 (30) | 341 (30) | |
| II | 409 (36) | 425 (37) | |
| III | 261 (23) | 221 (19) | |

Stress test‡

| | | | |
|----------------------------------|----------|----------|------|
| Total patients — no. (%) | 972 (85) | 977 (86) | 0.84 |
| Treadmill test — no. (%) | 555 (57) | 553 (57) | |
| Duration of treadmill test — min | 7.0±2.7 | 6.9±2.3 | 0.43 |
| Pharmacologic stress — no. (%) | 417 (43) | 424 (43) | |
| Echocardiography — no. (%) | 63 (6) | 54 (6) | |
| Nuclear imaging — no. (%) | 685 (70) | 708 (72) | 0.59 |
| Single reversible defect§ | 154 (22) | 161 (23) | 0.09 |
| Multiple reversible defects§ | 444 (65) | 483 (68) | 0.09 |

| | | | |
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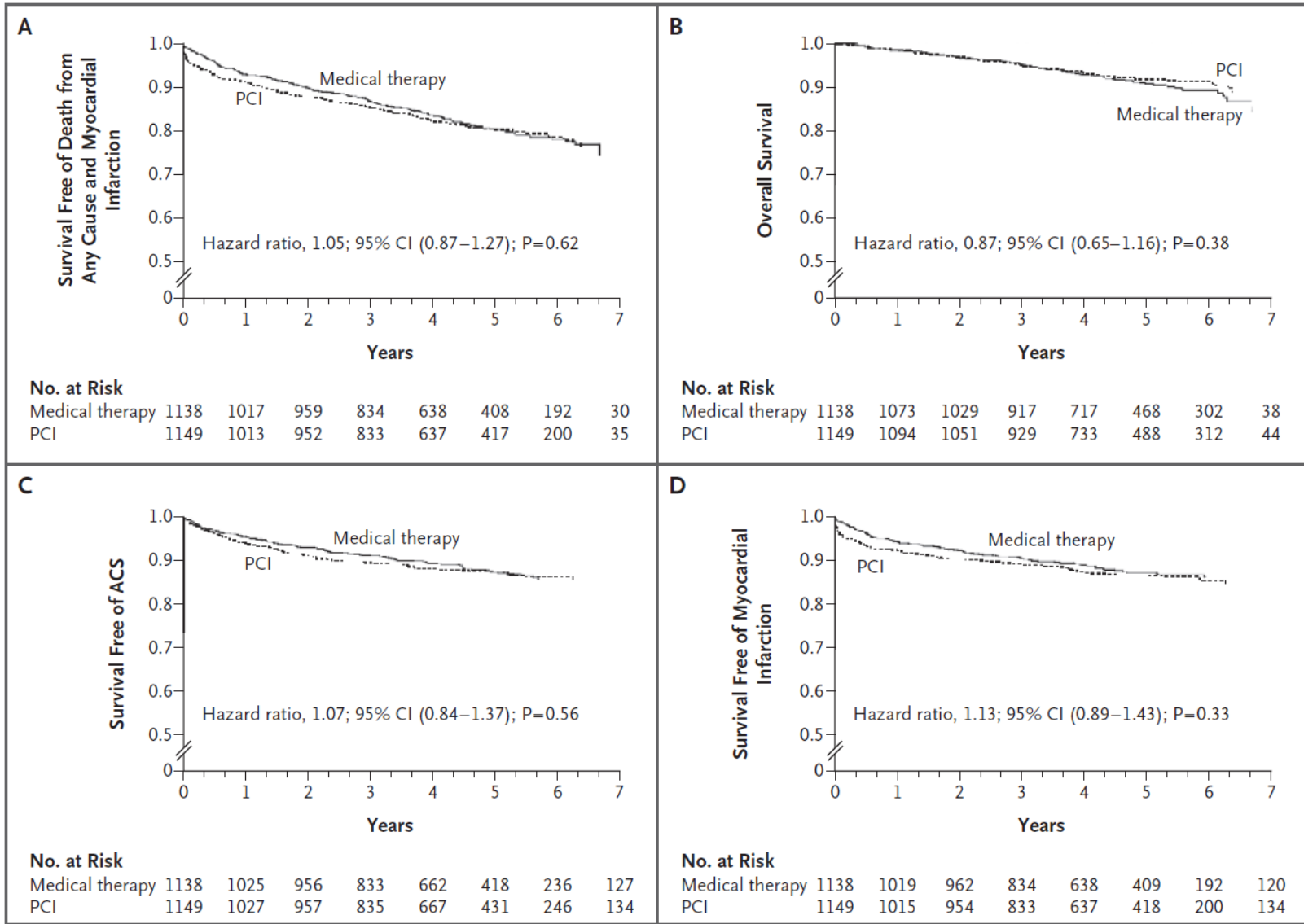
Clinical Status, Risk and Lifestyle Factors, and Use of Medication

| Variable | PCI Group (N=1149) | | | | Medical-Therapy Group (N=1138) | | | |
|--|--------------------|-----------|-----------|-----------|--------------------------------|-----------|-----------|-----------|
| | Baseline | 1 Yr | 3 Yr | 5 Yr | Baseline | 1 Yr | 3 Yr | 5 Yr |
| | <i>median ±SE</i> | | | | | | | |
| Clinical status | | | | | | | | |
| No. evaluated | 1148 | 1031 | 820 | 423 | 1137 | 1010 | 824 | 406 |
| Blood pressure — mm Hg | | | | | | | | |
| Systolic | 131±0.77 | 126±0.64 | 125±0.68 | 124±0.81 | 130±0.66 | 124±0.73 | 123±0.78 | 122±0.92 |
| Diastolic | 74±0.33 | 72±0.35 | 70±0.52 | 70±0.81 | 74±0.33 | 70±0.43 | 70±0.52 | 70±0.65 |
| Cholesterol — mg/dl | | | | | | | | |
| Total | 172±1.37 | 156±1.17 | 148±1.13 | 143±1.74 | 177±1.41 | 150±1.10 | 145±1.30 | 140±1.64 |
| HDL | 39±0.39 | 42±0.39 | 43±0.47 | 41±0.67 | 39±0.37 | 41±0.42 | 42±0.49 | 41±0.75 |
| LDL | 100±1.17 | 84±0.97 | 76±0.85 | 71±1.33 | 102±1.22 | 81±0.86 | 74±0.92 | 72±1.21 |
| Triglycerides — mg/dl | 143±2.96 | 129±2.74 | 124±2.79 | 123±4.13 | 149±3.03 | 133±2.90 | 126±2.84 | 131±4.70 |
| Body-mass index | 28.7±0.18 | 28.5±0.19 | 29.0±0.21 | 29.0±0.34 | 28.9±0.17 | 29.0±0.19 | 29.3±0.21 | 29.5±0.31 |
| Angina-free — no. (%) [†] | 135 (12) | 680 (66) | 602 (72) | 316 (74) | 148 (13) | 595 (58) | 558 (67) | 296 (72) |
| Risk or lifestyle factor | | | | | | | | |
| Current smoker — no. (%) | 260 (23) | 206 (20) | 156 (19) | 74 (17) | 259 (23) | 206 (20) | 160 (19) | 80 (20) |
| AHA Step 2 diet — no. (%) | 626 (55) | 803 (78) | 631 (77) | 326 (77) | 613 (54) | 800 (79) | 660 (80) | 312 (77) |
| Moderate activity — no. (%) [‡] | 290 (25) | 473 (46) | 351 (42) | 179 (42) | 279 (25) | 433 (43) | 330 (40) | 146 (36) |
| Glycated hemoglobin in patients with diabetes | | | | | | | | |
| No. evaluated | 319 | 239 | 197 | 97 | 336 | 286 | 233 | 123 |
| Level — % | 6.9±0.1 | 7.1±0.1 | 7.1±0.1 | 7.1±0.1 | 7.1±0.1 | 7.0±0.1 | 7.1±0.1 | 7.1±0.1 |
| Medication | | | | | | | | |
| No. evaluated | 1147 | 1044 | 837 | 428 | 1138 | 1028 | 838 | 417 |
| ACE inhibitor — no. (%) | 669 (58) | 668 (64) | 536 (64) | 284 (66) | 680 (60) | 633 (62) | 522 (62) | 260 (62) |
| ARB — no. (%) | 48 (4) | 93 (9) | 104 (12) | 49 (11) | 54 (5) | 99 (10) | 108 (13) | 67 (16) |
| Statin — no. (%) | 992 (86) | 972 (93) | 780 (93) | 398 (93) | 1014 (89) | 972 (95) | 769 (92) | 386 (93) |
| Other antilipid — no. (%) | 89 (8) | 236 (23) | 324 (39) | 211 (49) | 94 (8) | 253 (25) | 321 (38) | 224 (54) |
| Aspirin — no. (%) | 1097 (96) | 995 (95) | 792 (95) | 408 (95) | 1077 (95) | 977 (95) | 796 (95) | 391 (94) |
| Beta-blocker — no. (%) | 975 (85) | 887 (85) | 705 (84) | 363 (85) | 1008 (89) | 916 (89) | 724 (86) | 357 (86) |
| Calcium-channel blocker — no. (%) [§] | 459 (40) | 415 (40) | 360 (43) | 180 (42) | 488 (43) | 501 (49) | 418 (50) | 217 (52) |
| Nitrates — no. (%) [¶] | 714 (62) | 553 (53) | 396 (47) | 173 (40) | 825 (72) | 690 (67) | 511 (61) | 237 (57) |

Primary and Secondary Outcomes

| Outcome | Number of Events | | Hazard Ratio (95% CI) [†] | P Value [‡] | Cumulative Rate at 4.6 Years | |
|---|------------------|-----------------------|------------------------------------|----------------------|------------------------------|-----------------------|
| | PCI Group | Medical-Therapy Group | | | PCI Group | Medical-Therapy Group |
| | | | | | | % |
| Death and nonfatal myocardial infarction [‡] | 211 | 202 | 1.05 (0.87–1.27) | 0.62 | 19.0 | 18.5 |
| Death§ | 68 | 74 | | | | |
| Periprocedural myocardial infarction | 35 | 9 | | | | |
| Spontaneous myocardial infarction | 108 | 119 | | | | |
| Death, myocardial infarction, and stroke | 222 | 213 | 1.05 (0.87–1.27) | 0.62 | 20.0 | 19.5 |
| Hospitalization for ACS | 135 | 125 | 1.07 (0.84–1.37) | 0.56 | 12.4 | 11.8 |
| Death§ | 85 | 95 | 0.87 (0.65–1.16) | 0.38 | 7.6 | 8.3 |
| Cardiac | 23 | 25 | | | | |
| Other | 45 | 51 | | | | |
| Unknown | 17 | 19 | | | | |
| Total nonfatal myocardial infarction | 143 | 128 | 1.13 (0.89–1.43) | 0.33 | 13.2 | 12.3 |
| Periprocedural myocardial infarction | 35 | 9 | | | | |
| Spontaneous myocardial infarction | 108 | 119 | | | | |
| Death, myocardial infarction, and ACS | 294 | 288 | 1.05 (0.90–1.24) | 0.52 | 27.6 | 27.0 |
| Stroke | 22 | 14 | 1.56 (0.80–3.04) | 0.19 | 2.1 | 1.8 |
| Revascularization (PCI or CABG) [¶] | 228 | 348 | 0.60 (0.51–0.71) | <0.001 | 21.1 | 32.6 |

Kaplan–Meier Survival Curves



Conclusion of Authors

- “Our findings reinforce existing clinical practice guidelines, which state that **PCI can be safely deferred in patients with stable CAD** ... provided that intensive, multifaceted medical therapy is instituted and maintained.”
- “Although the **addition of PCI to optimal medical therapy reduced the prevalence of angina**, it did not reduce long-term rates of death, nonfatal MI and hospitalization for ACS.”

Concerns Raised in Letters to the NEJM Editor

- Authors overestimated number of elective procedures – results reflect findings in only small minority of patients with CAD
- **Patient-selection bias** (35,539 screened, 2287 randomized)
- **PCI methodology** (not all vessels stented, not drug-eluting stents)
- **Failed to stratify by ischemic burden**
- Analyzed ITT, **but lots of cross-over** (**33% subsequent revascularization** in MT group)
- Possible under-treatment of clopidogrel in those who received stents

Truth and Consequences of COURAGE

Expedited publication in JACC by 14 authors

- Examine the construct, execution, and observations of the COURAGE trial (the “truth”)
 - Findings are nothing new
 - Subject selection, low levels of angina
 - Underpowered (low event rate)
 - Surprisingly high rate of “crossover”
 - Non-optimal performance of PCI; underuse of DES
 - Use of all cause mortality might have obscured important differences
 - Disparity in outcomes based on where procedure was performed
 - Unrealistically high levels of compliance with MT

Summaries of trials comparing PCI vs OMT for SA

- No difference in mortality and MI
- Confusion in angina relief and QOL

All trials were unblinded.

| Trial (Ref. #) | Mortality and MI | Angina Relief | Repeat Revascularization |
|----------------|------------------|---------------|--------------------------|
| RITA-2 (7) | No difference | PCI | PCI |
| ACME (8) | No difference | PCI | PCI |
| ACME-2 (16) | No difference | PCI | NA |
| MASS (9) | No difference | PCI | NA |
| MASS-II (11) | No difference | PCI | PCI |
| AVERT (10) | No difference | PCI | PCI |
| TIME | No difference | PCI | PCI |
| COURA | No difference | No difference | PCI |

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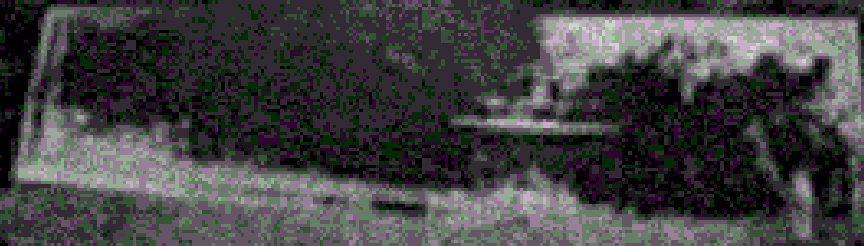
Percutaneous coronary intervention in stable angina (ORBITA) a double-blind, randomised controlled trial

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Stents... Rest in peace

Coronary stents for chronic stable Angina

R.I.P.



Funeral service by ORBITA , Imperial college , London
Co-directed by Lancet !

www.drsvenkatesan.com

Background of ORBITA trial

ORBITA: Objective Randomized Blinded Investigation with Optimal Medical Therapy of Angioplasty in Stable Angina

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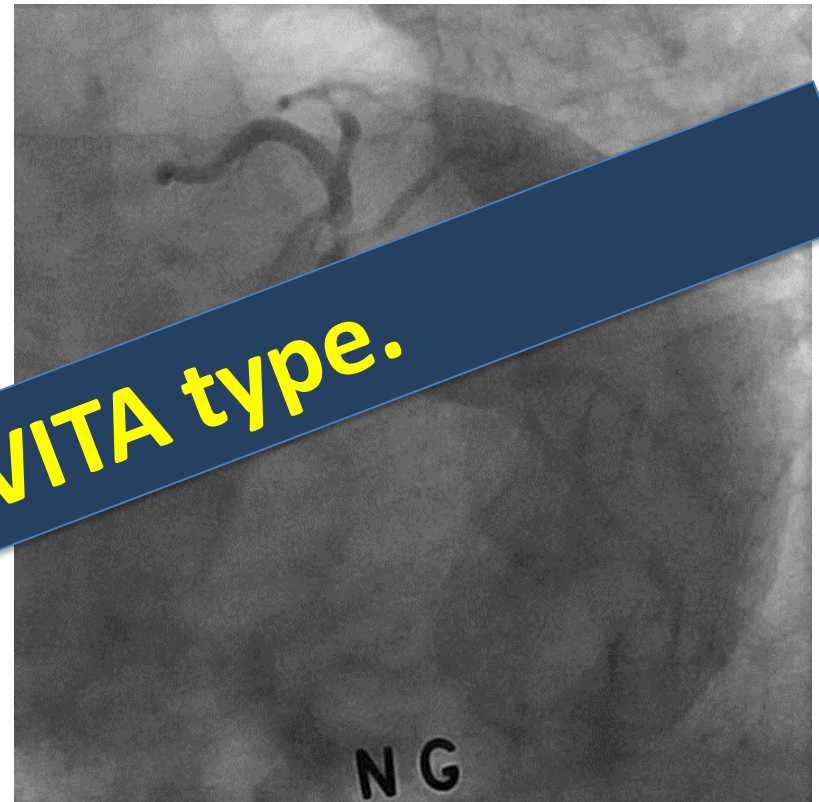
- Data from **unblinded randomized trials** show significant improvement in exercise time, angina relief, QOL improvement from PCI
- **Placebo effects** known to be larger for **invasive treatments**
- **Cardiologists resistant** to idea of **placebo-controlled trial**
- Widespread perception that **PCI unquestionably improves angina**
- Might be **unethical to expose** patients to invasive placebo procedure
- Essential to identify true efficacy of intervention

Overview of Trial

- Sponsored by NIHR Research Centre (investigator-initiated)
- Multicenter (UK), randomized, double-blind, sham placebo procedure controlled trial
- 2014 through 2017
- Goal: to assess the efficacy of PCI compared with a **sham placebo procedure** for angina relief among patients with stable angina

How to treat ?

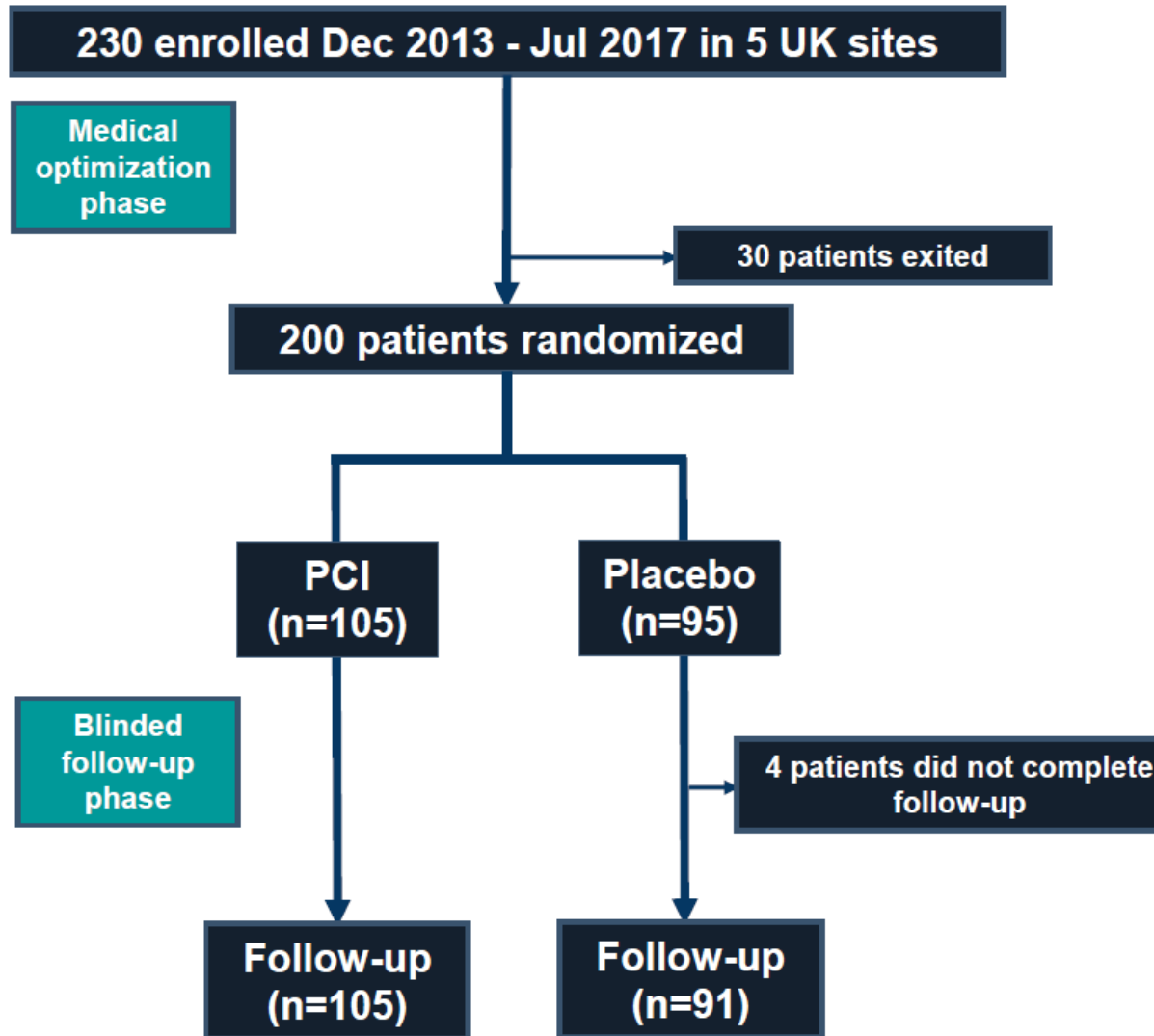
1. CABG
2. PCI
3. OMT (optimal medical treatment)
4. None of above



This is ORVITA type.

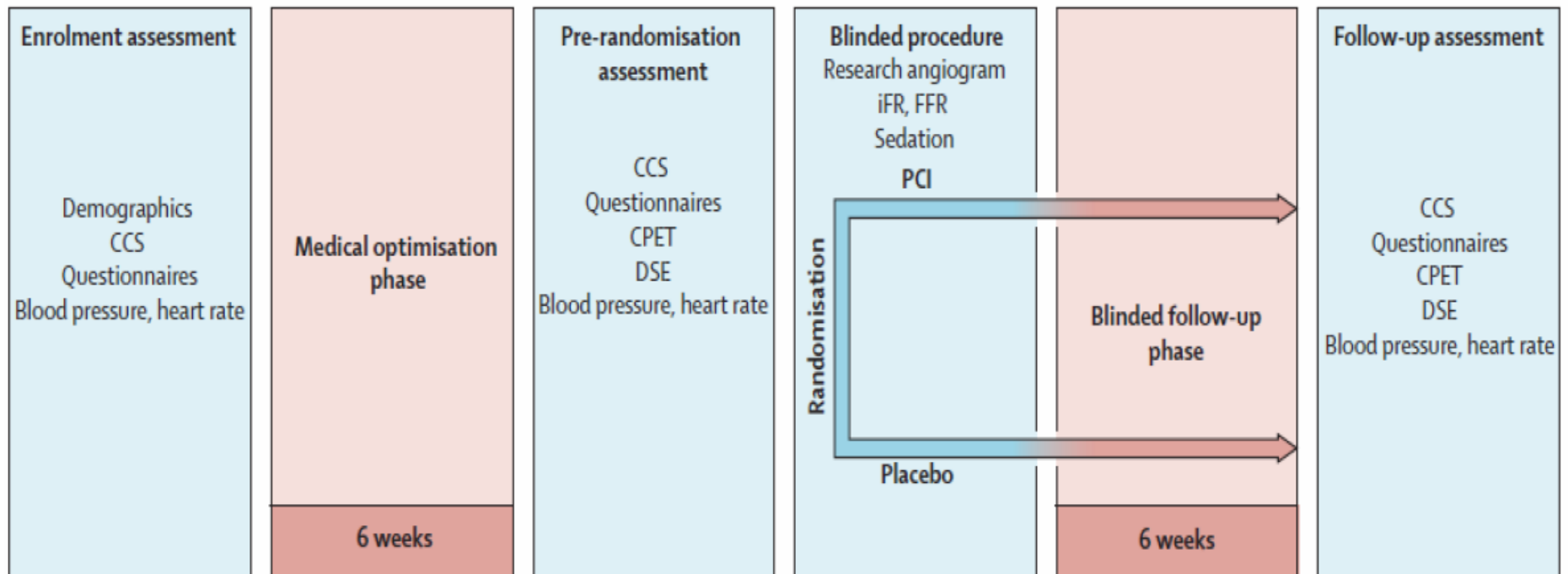
- 60-year-old male
- with a history of chest pain, 5MA
- exercise ECG test : ST depression in leads V4-6
- stress echocardiography : hypokinetic apical anterior and anteroseptal myocardial segments

ORBITA trial



Study flow

- 6weeks and 6weeks



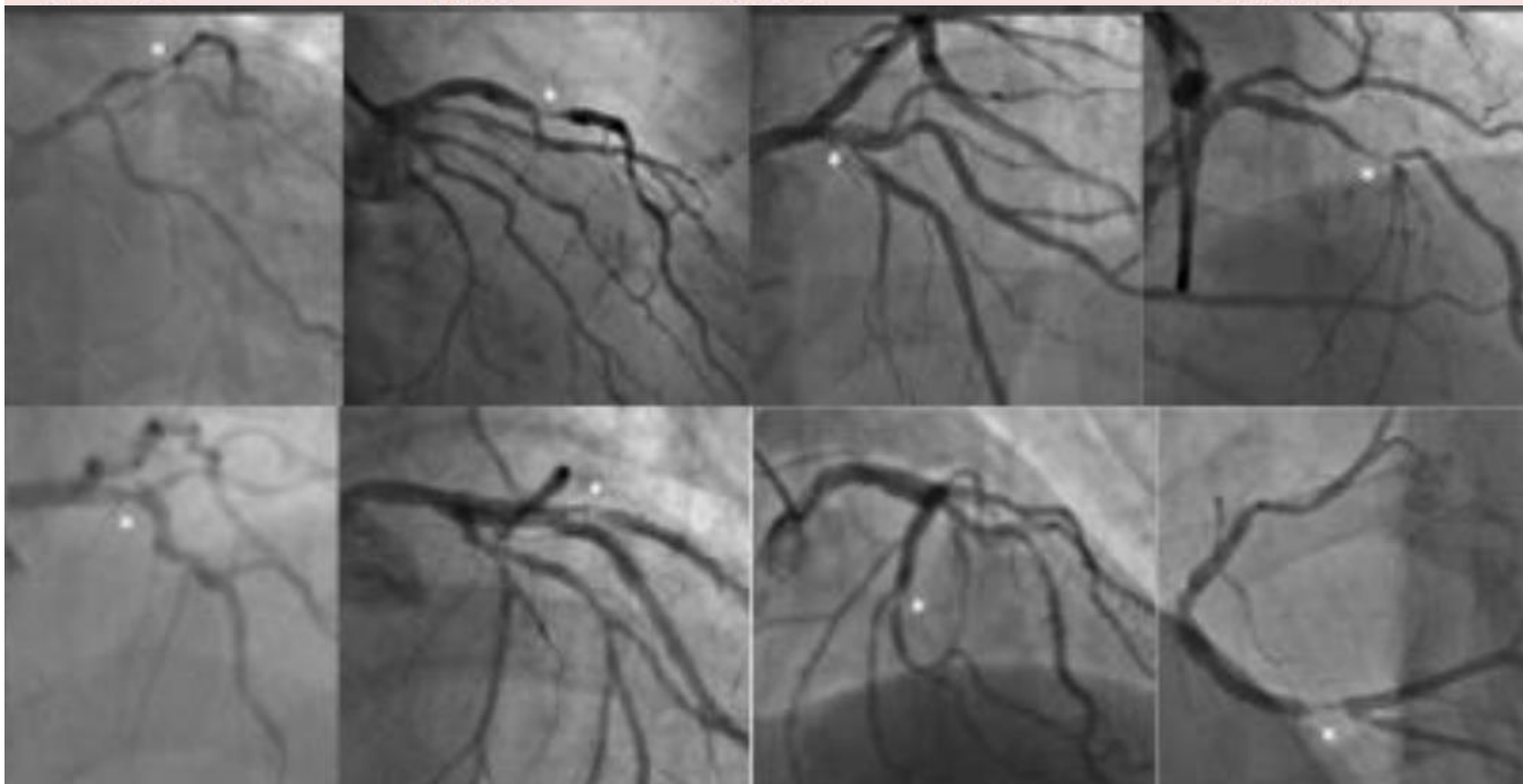
Baseline

| | PCI (n=105) | Placebo (n=95) | All (n=200) |
|----------------------------------|-------------|----------------|-------------|
| Age (years) | 65.9 (9.5) | 66.1 (8.4) | 66.0 (9.0) |
| Male | 74 (70%) | 72 (76%) | 146 (73%) |
| BMI (kg/m ²) | 28.0 (4.7) | 29.5 (5.1) | 28.7 (5.0) |
| Diabetes | 15 (14%) | 21 (22%) | 36 (18%) |
| Hypertension | 72 (69%) | 66 (69%) | 138 (69%) |
| Hyperlipidaemia | 81 (77%) | 62 (65%) | 143 (72%) |
| Current smoker | 11 (10%) | 15 (16%) | 26 (13%) |
| Previous myocardial infarction | 5 (5%) | 7 (7%) | 12 (6%) |
| Previous PCI | 10 (10%) | 15 (16%) | 25 (13%) |
| Left ventricle systolic function | | | |
| Normal | 98 (93%) | 85 (89%) | 183 (92%) |
| Mild impairment | 3 (3%) | 7 (7%) | 10 (5%) |
| Moderate impairment | 4 (4%) | 3 (3%) | 7 (4%) |
| CCS class | | | |
| I | 2 (2%) | 3 (3%) | 5 (3%) |
| II | 64 (61%) | 54 (57%) | 118 (59%) |
| III | 39 (37%) | 38 (40%) | 77 (39%) |
| Angina duration (months) | 9.5 (15.7) | 8.4 (7.5) | 9.0 (12.5) |

Data are mean (SD) and n (%). BMI=body-mass index. PCI=percutaneous coronary intervention. CCS=Canadian Cardiovascular Society.

Table 1: Baseline characteristics

| | PCI (n=105) | Placebo (n=95) | p value (PCI vs placebo) | All (n=200) |
|--------------------------|-------------|----------------|--------------------------|-------------|
| Procedural time (min) | 90 (27) | 61 (17) | <0.0001 | 76 (27) |
| Vessel name | .. | .. | 0.509 | .. |
| Left anterior descending | 72 (69%) | 66 (69%) | .. | 138 (69%) |
| Right coronary artery | 17 (16%) | 15 (16%) | .. | 32 (16%) |



| | | | | |
|-----------------|------------------|----|----|----|
| Post-dilatation | 103 (75%)* | .. | .. | .. |
| FFR post PCI | 0.90 (0.06) | .. | .. | .. |
| Median (IQR) | 0.90 (0.87-0.94) | .. | .. | .. |
| iFR post PCI | 0.95 (0.04) | .. | .. | .. |
| Median (IQR) | 0.94 (0.92-0.97) | .. | .. | .. |

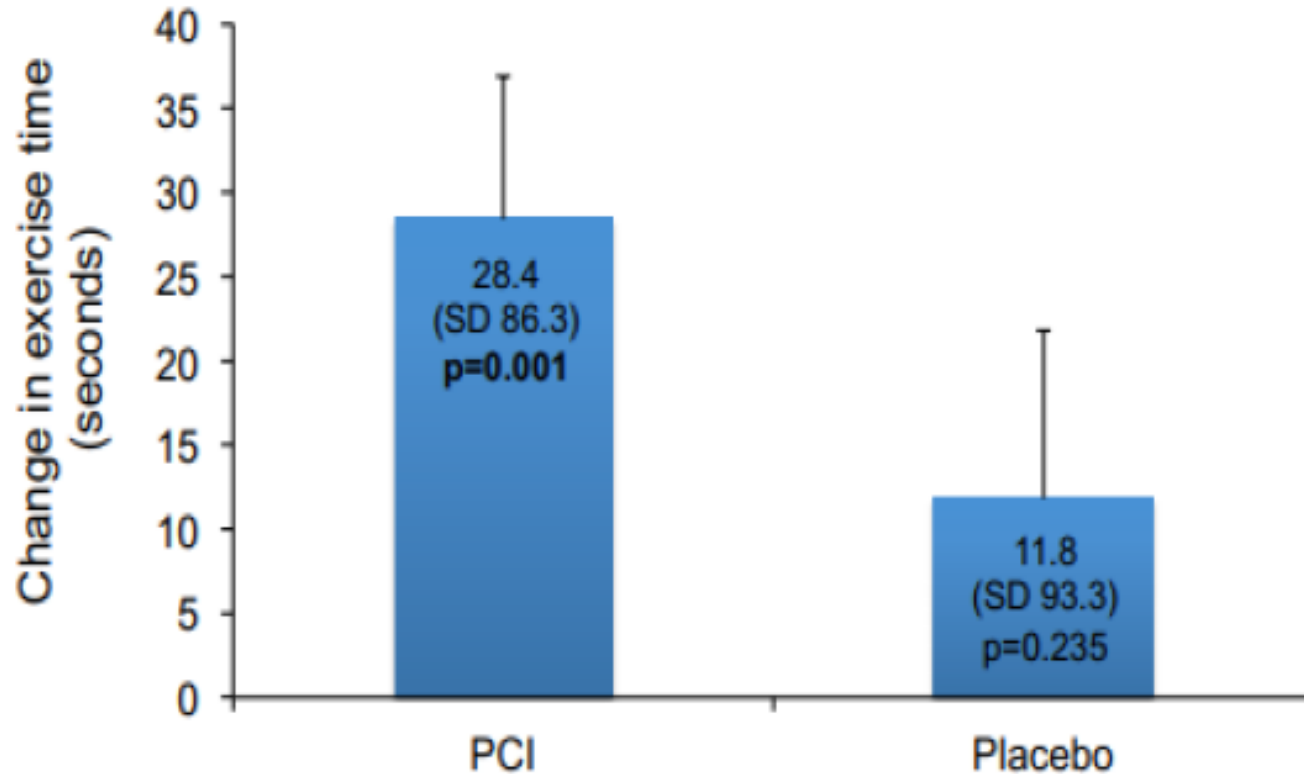
Procedural demographics : Sham procedure



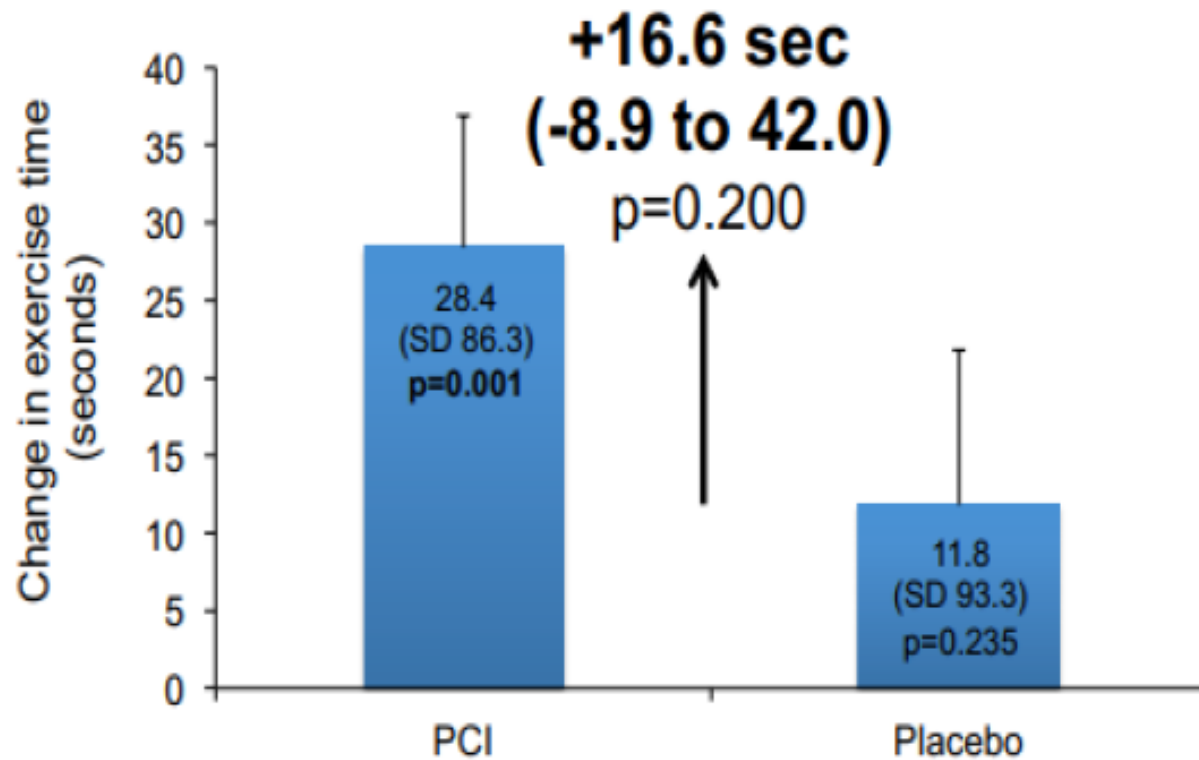
Sham procedure

| | PCI n = 105 | Placebo n = 95 | P |
|-----------------------|----------------|-------------------|---------|
| Procedural time (min) | 90 (27) | 61 (17) | <0.0001 |
| Vessel | | | |
| LAD | 72 (69%) | 66 (69%) | |
| RCA | 17 (16%) | 15 (16%) | |
| Circumflex | 9 (9%) | 10 (11%) | |

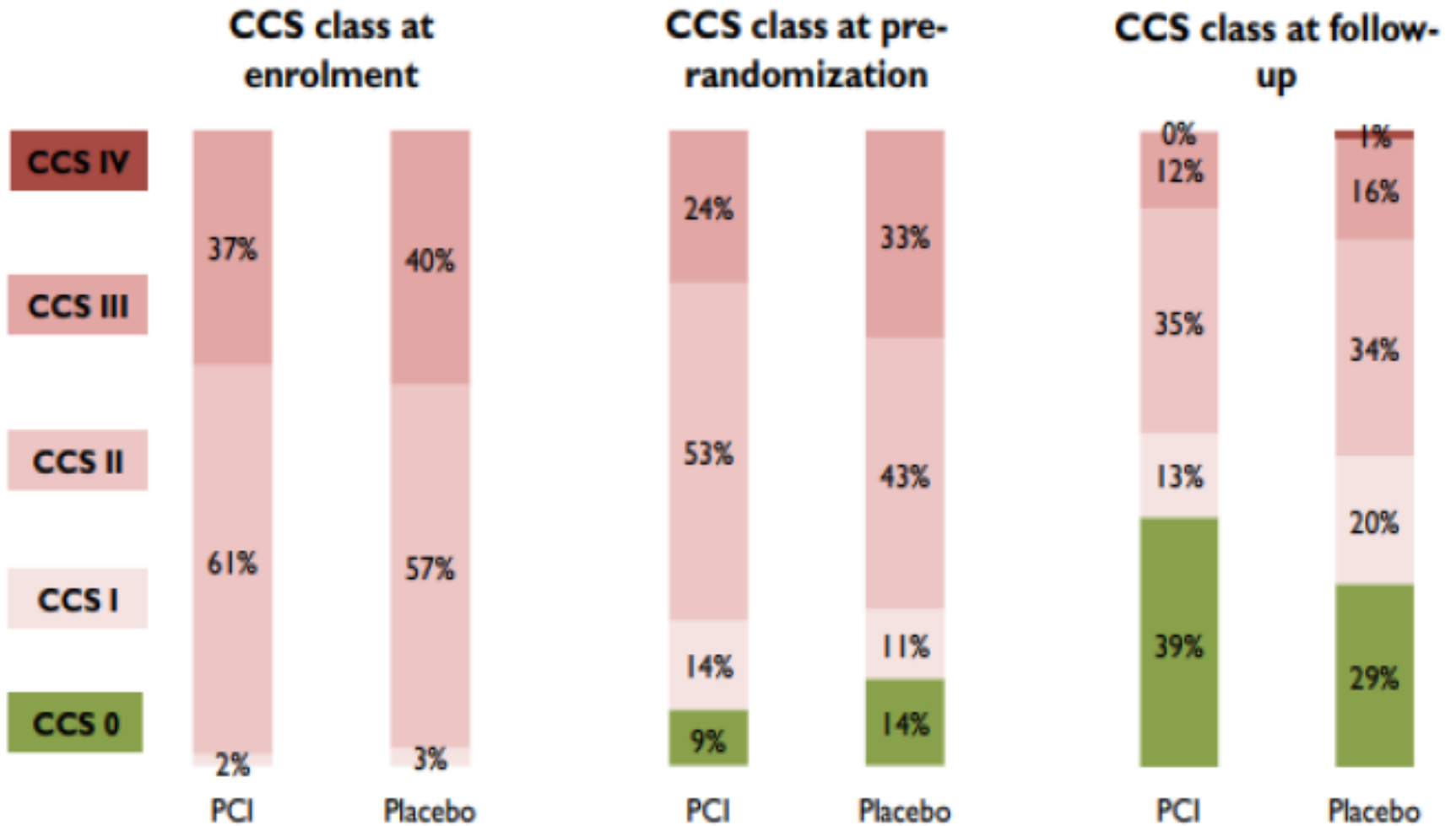
Primary endpoint : change in total exercise time



Change of total exercise time



Secondary EP : CCS class improved in both groups

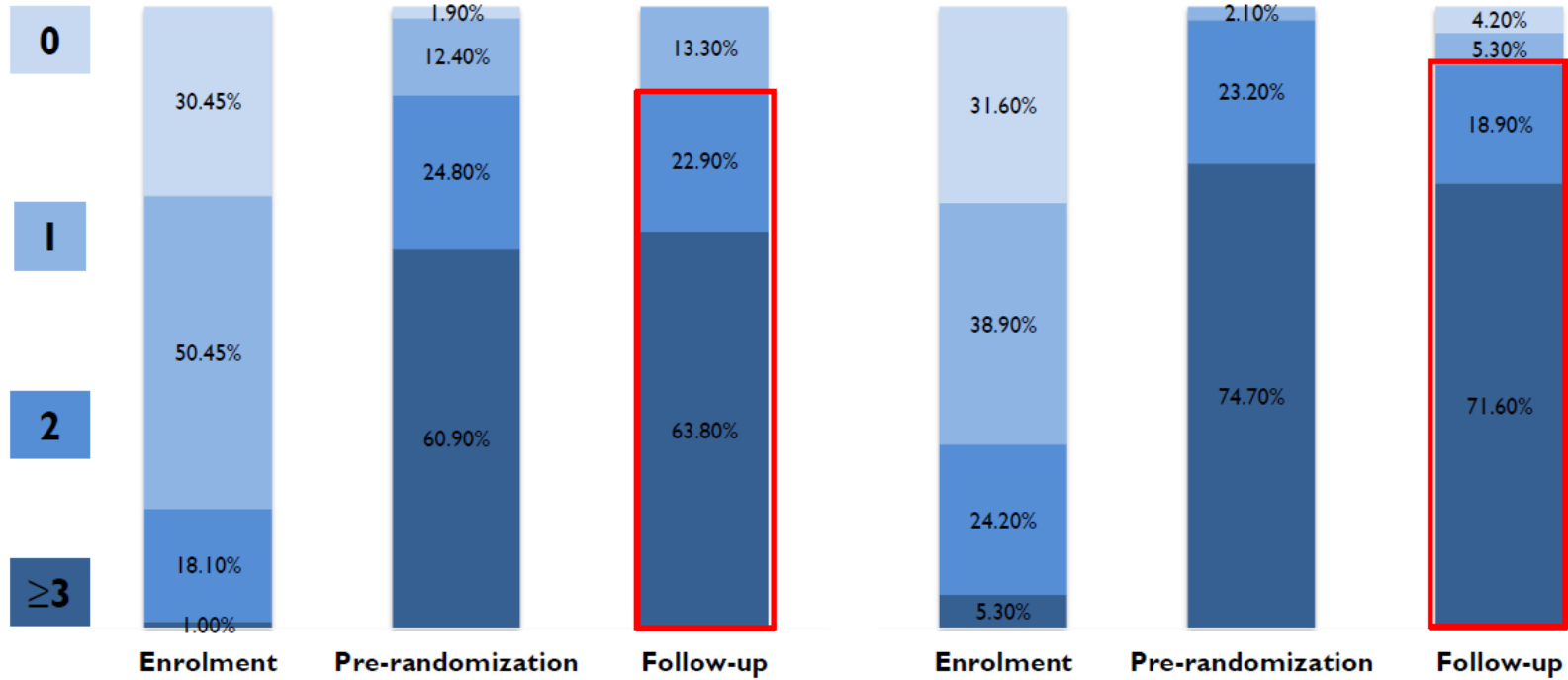


Secondary EP : blinded evaluation of ischemia reduction

| 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 | |

Medical therapy optimization

Number of anti-anginal drugs



Secondary EP No difference in Sx improvement or quality of life

Physical limitation score (SAQ)

| | |
|-------------------------------------|-------------------|
| Difference in Δ between arms | 2.4 (-3.5 to 8.3) |
| | p=0.420 |

Angina frequency score (SAQ)

| | |
|-------------------------------------|--------------------|
| Difference in Δ between arms | 4.4 (-3.3 to 12.0) |
| | p=0.260 |

Quality of life (EQ-5D-5L)

| | |
|-------------------------------------|----------------------|
| Difference in Δ between arms | 0.00 (-0.04 to 0.04) |
| | p=0.994 |

Conclusion of ORBITA trial

- ORBITA is the **first placebo-controlled randomized trial** of PCI in stable angina.
- Area stenosis QCA 84.4%, FFR 0.69, iFR 0.76
- PCI was safe and physiologically effective
- PCI significantly reduced ischemic burden as assess by stress echo
- In the single vessel, angiographically guided trial there was **no difference in exercise time increment** between PCI and placebo.

Issue and limitation of ORBITA trial

- ORBITA raises the issue of whether the symptom relief of PCI in the specific setting of stable single-vessel CAD may be related at least in part to a placebo effect.
- Limitations
 - short observation period (6 weeks)
 - inclusion of patients with mild symptoms pre-randomization (CCS class 0–I in 25% of patients)
 - group imbalance in ostial and proximal lesions (37 vs. 57%, $P = 0.005$)
 - loss to follow-up after randomization
 - insufficient power to detect a true difference.

Criticisms/Caveats in Cardiosource Articles

- Clinical consequences largely already supported by guidelines
- Trial was **too small** to answer such a big question
 - Lack of precision in estimating effect sizes
 - Changes in exercise time and Duke treadmill **numerically higher in PCI group**
- Subjects selection
 - **Low frequency of multi-vessel CAD**
 - **Low angina burden prior to randomization**
- Questionable choice of endpoint
 - **Exercise time** as primary endpoint
 - **Short duration of F/U**
- Less about lack of effect of PCI, and more about power of optimal medical therapy
 - **Medical optimization phase more intensive** than routine clinical practice
 - Patients prefer few medications

Gap in evidence

- It remains to be determined whether revascularization by PCI improves prognosis in patients with SCAD.
- The **ISCHEMIA** (International Study of Comparative Health Effectiveness With Medical and Invasive Approaches) study (NCT01471522) is currently recruiting **5000 patients with SCAD** and evidence of **moderate-to-severe ischaemia** detected by non-invasive imaging, who are randomized before coronary angiography to medical therapy or an invasive strategy to detect differences in the primary endpoint of **death or MI**.

Background of ISCHEMIA trial

Limitation of COURAGE trial

- **60%** of patients : no ischemia or very mild ischemia on provocative testing
 - new resting ST-T wave changes, ≥ 1 mm exertional ST segment changes, or ≥ 1 ischemic imaging defect
 - permitted for patients with angina and $\geq 70\%$ stenosis without any stress test requirement
- **electrocardiographic changes and small amounts of ischemia** are **suboptimal** in predicting event risk and obstructive CAD severity
- In a substudy within the COURAGE trial, **serial nuclear imaging** at baseline and 1-year post-randomization revealed that **PCI with optimal medical therapy** led to **greater ischemia reductions** compared with optimal medical therapy alone.

ISCHEMIA trial



ISCHEMIA Trial

International Study of Comparative Health Effectiveness with Medical & Invasive Approaches

- **Patients:** Stable w/ at Least Moderate Ischemia (Core Lab)

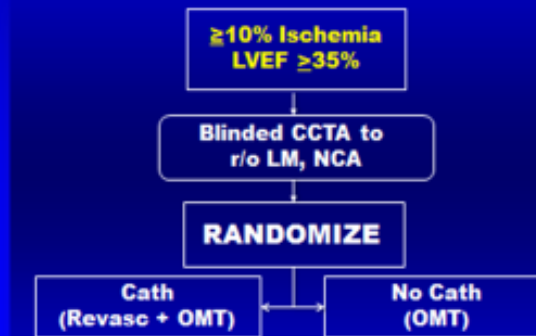
| | | |
|------------------|--|--------------------------|
| SPECT ≥10% LV | Echo / CMR RWMA ≥3/16 segments New / Worse WMA | CMR Perfusion >12% LV |
|------------------|--|--------------------------|

OR

Ex ECG
ST ↓ ≥1.5 mm in 2 leads or
≥2.0 mm in ≥1 lead OR
ST ↑ ≥1.0 mm in non-infarct territory

- **Primary Aim:** To Determine if Initial Invasive Strategy of Cath & PCI / CABG + Medical Therapy Will Reduce Events Compared to a Strategy of Medical Therapy Alone (Cath - Reserved for Failed Medical Therapy)
 - **Sample Size:** 5,000 Followed for ~4 years

Chair – Judith Hochman, MD; Co-Chair / PI: David Maron, MD
Imaging Coordinating Center: Leslee Shaw, PhD



More severe ischemia than COURAGE trial

Blinded CCTA – to rule out LM disease and no coronary artery disease

ESC guideline 2018

- Indications for revascularization in patients with stable angina or silent ischemia

| Extent of CAD (anatomical and/or functional) | | Class ^a | Level ^b |
|--|---|--------------------|--------------------|
| For prognosis | Left main disease with stenosis >50%. ^{c 68-71} | I | A |
| | Proximal LAD stenosis >50%. ^{c 61,68,70,72} | I | A |
| | Two- or three-vessel disease with stenosis >50% with impaired LV function (LVEF ≤35%). ^{c 61,62,68,70,73-83} | I | A |
| | Large area of ischaemia detected by functional testing (>10% LV) or abnormal invasive FFR. ^{d 24,59,84-90} | I | B |
| | Single remaining patent coronary artery with stenosis >50%. ^c | I | C |
| For symptoms | Haemodynamically significant coronary stenosis with insufficient response to optimal medical therapy. ^e | I | A |

For Symptoms
 Hemodynamically significant coronary stenosis in presence of limiting angina or angina equivalent, with insufficient response to optimal medical therapy
 → Class I, Evidence level of A

Conclusion

- The summary from prior SCAD trials was that an index strategy of optimal medical therapy alone was safe and equally effective as PCI with optimal medical therapy.
- The ORBITA study underlines the value of optimal medical therapy in the management of SCAD.
- But because of the limitation of prior trials and ORBITA study, it remains to be determined whether revascularization by PCI improves prognosis in patients with SCAD.
- The ISCHEMIA trial offers huge opportunities for imaging to be a core component and decision trigger for SIHD clinical management.

Will ORBITA change my practice?

- Proceedings of EuroPCR 2018

Major arguments for a change in practice

- In patients with stable angina, PCI did not result in greater improvements in exercise times or chest pain frequency compared with a sham procedure and medical treatment.
- PCI did not result in improvement of quality of life.

Major arguments against a change in practice

- ORBITA demonstrated that PCI improves freedom from angina with a number needed to treat (NNT) of 5.
- ORBITA applies to patients with stable anginal symptoms and single-vessel disease and not to patients with acute coronary syndrome, left main or multivessel disease and might not reflect clinical reality.



Thank you for your attention.