

Percutaneous Coronary Intervention in Stable Angina (ORBITA): a Double- blind, randomized controlled trial

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The role of PCI in Coronary artery disease

- Symptom relieve
 - The main role in stable angina
- Improve prognosis
 - The main role in ACS

After ORBITA trial.....

There are many stories about PCI

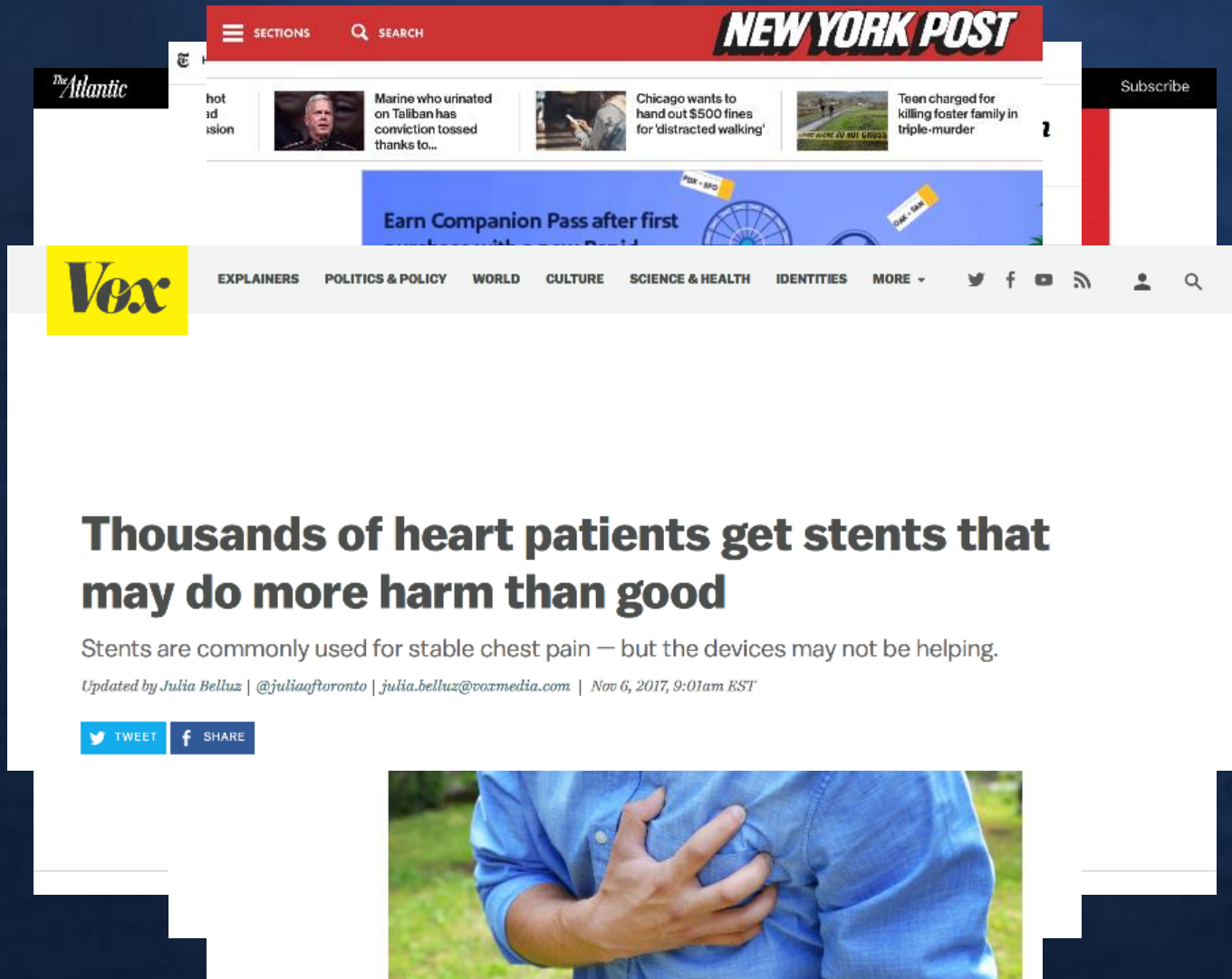


“It’s like asking a barber if you need a haircut... to an interventional cardiologist, stents are good for almost everyone.”

Quote from R. Redberg, www.bloomberg.com 10/29/13

After ORBITA trial.....

There are many stories about PCI



The image is a screenshot of a web browser displaying a Vox article. At the top, there are several navigation bars. The first is a red bar for the 'NEW YORK POST' with a search icon and the word 'SECTIONS'. Below this is a black bar with 'The Atlantic' logo on the left and a 'Subscribe' button on the right. A row of four news snippets follows: 'hot id ision', 'Marine who urinated on Taliban has conviction tossed thanks to...', 'Chicago wants to hand out \$500 fines for 'distracted walking'', and 'Teen charged for killing foster family in triple-murder'. Below these is a blue banner for a 'Companion Pass' promotion. The main navigation bar is white with the 'Vox' logo on the left and a list of categories: EXPLAINERS, POLITICS & POLICY, WORLD, CULTURE, SCIENCE & HEALTH, IDENTITIES, and MORE. Social media icons for Twitter, Facebook, YouTube, RSS, and a user profile icon are on the right. The article title 'Thousands of heart patients get stents that may do more harm than good' is in large, bold, black font. Below it is a subtitle: 'Stents are commonly used for stable chest pain — but the devices may not be helping.' The byline reads: 'Updated by Julia Belluz | @juliabelluz | julia.belluz@voxmedia.com | Nov 6, 2017, 9:01am EST'. There are two buttons: 'TWEET' and 'SHARE'. At the bottom, there is a photograph of a person's hand clutching their chest, suggesting chest pain.

NEW YORK POST

SECTIONS SEARCH

The Atlantic

hot id ision

Marine who urinated on Taliban has conviction tossed thanks to...

Chicago wants to hand out \$500 fines for 'distracted walking'

Teen charged for killing foster family in triple-murder

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Thousands of heart patients get stents that may do more harm than good

Stents are commonly used for stable chest pain — but the devices may not be helping.

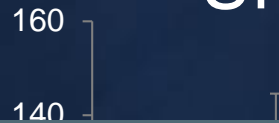
Updated by Julia Belluz | @juliabelluz | julia.belluz@voxmedia.com | Nov 6, 2017, 9:01am EST

TWEET SHARE

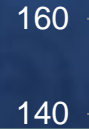


Previous data showed PCI can increase exercise duration

Unblinded PCI



Single drug vs. placebo

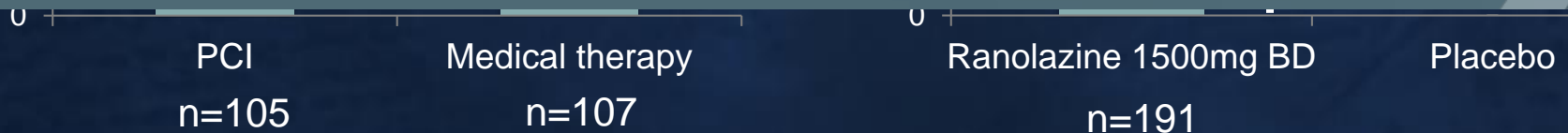


ARTICLES | [VOLUME 391, ISSUE 10115, P31-40, JANUARY 06, 2018](#)

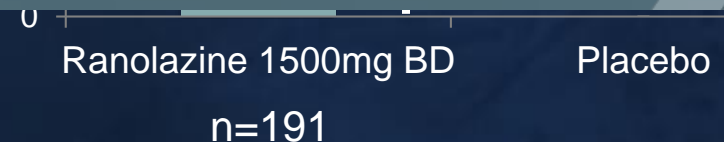
Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial

[Rasha Al-Lamee, MRCP](#) • [David Thompson, MRCPI](#) • [Hakim-Moulay Dehbi, PhD](#) • [Sayan Sen, MRCP](#) • [Kare Tang, FRCP](#) • [John Davies, MRCP](#) • et al. [Show all authors](#) • [Show footnotes](#)

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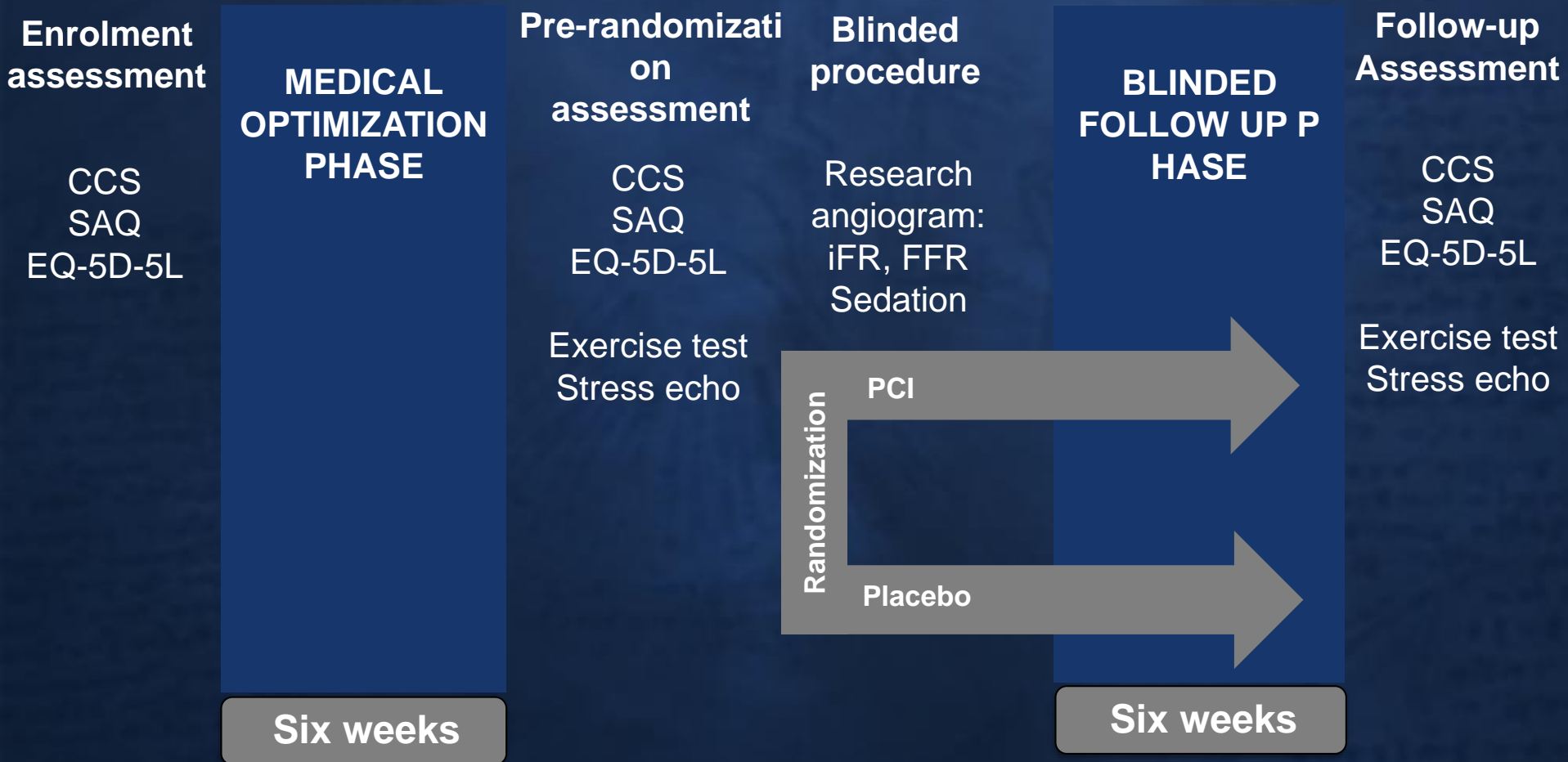
Parisi et al; 326:10-6 NEJM 1992



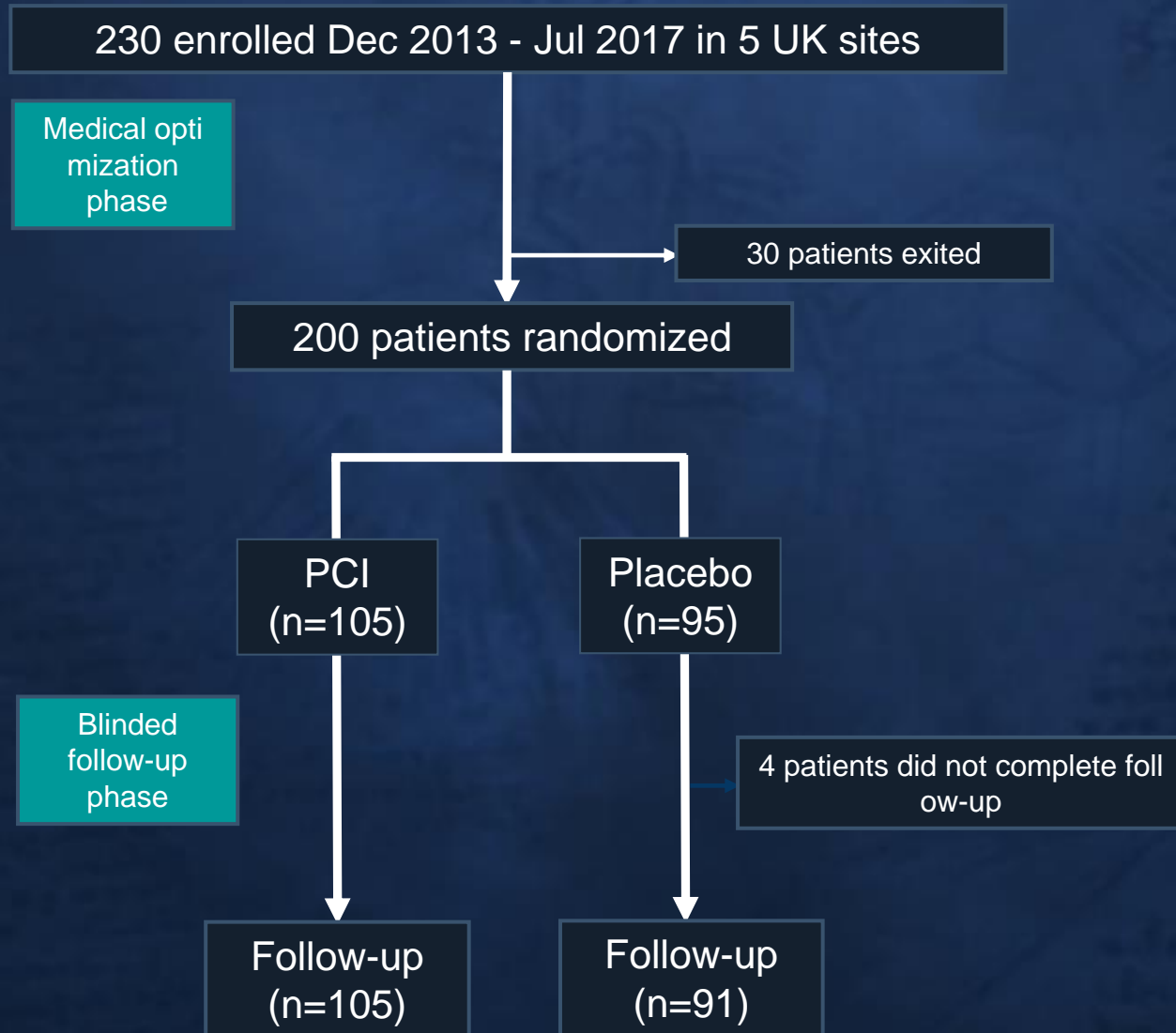
Chaitman et al; 43,8:1375-82 JACC 2004

Error bars are standard errors of the mean

Trial design



ORBITA trial



Baseline demographics

	PCI n = 105	Placebo n = 95
Age (yrs)	65.9 (SD 9.5)	66.1 (SD 8.4)
Male	74 (70%)	72 (76%)
Type II diabetes	15 (14%)	21 (22%)
Hypertension	72 (69%)	66 (69%)
Hyperlipidaemia	81 (77%)	62 (65%)
Current smoker	11 (10%)	15 (16%)
Previous MI	5 (5%)	7 (7%)
Previous PCI	10 (10%)	15 (16%)

Baseline demographics

	PCI n = 105	Placebo n = 95
LV systolic function		
Normal	98 (93%)	85 (89%)
Mild	3 (3%)	7 (7%)
Moderate	4 (4%)	3 (3%)
CCS Class		
I	2 (2%)	3 (3%)
II	64 (61%)	54 (57%)
III	39 (37%)	38 (40%)
Angina duration (mo)	9.5 (SD 15.7)	8.4 (SD 7.5)

Stenosis severity

	PCI n = 105	Placebo n = 95
Area stenosis by QCA (%)	84.6 (SD 10.2)	84.2 (SD 10.3)
FFR	0.69 (SD 0.16)	0.69 (SD 0.16)
iFR	0.76 (SD 0.22)	0.76 (SD 0.21)

Procedural demographics

	PCI n = 105
Drug eluting stents	138 (100%)*
Stent length (mm)	24 (IQR 18-33)
Stent diameter (mm)	3.1 (SD 0.5)
Post-dilatation	103 (75%)*
FFR post-PCI	0.90 (SD 0.06) p<0.0001
iFR post-PCI	0.95 (SD 0.04) p<0.0001

* Calculated out of 138 stents
p values are for change in pre to post FFR and iFR

Primary endpoint result

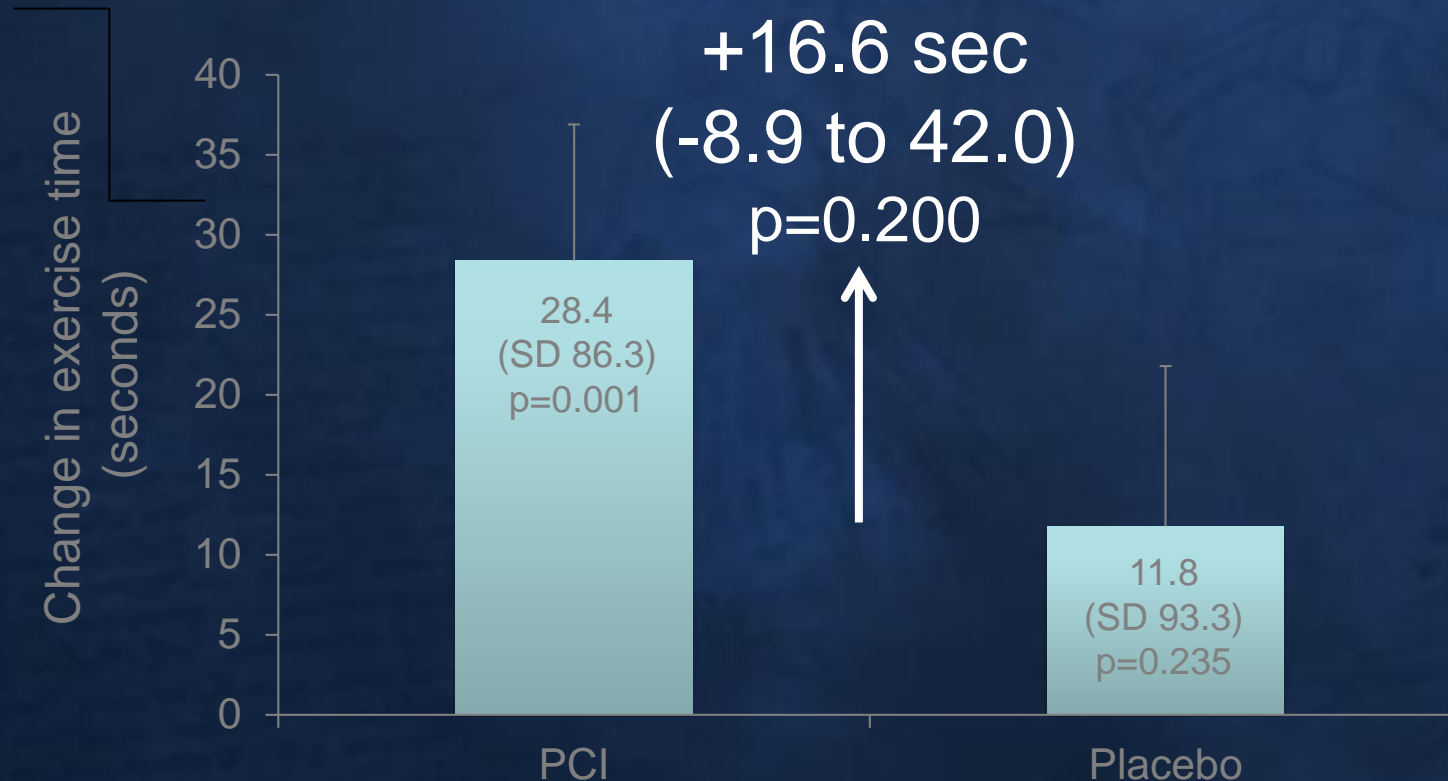
Change in total exercise time



Error bars are standard errors of the mean

Primary endpoint result

Change in total exercise time



Error bars are standard errors of the mean

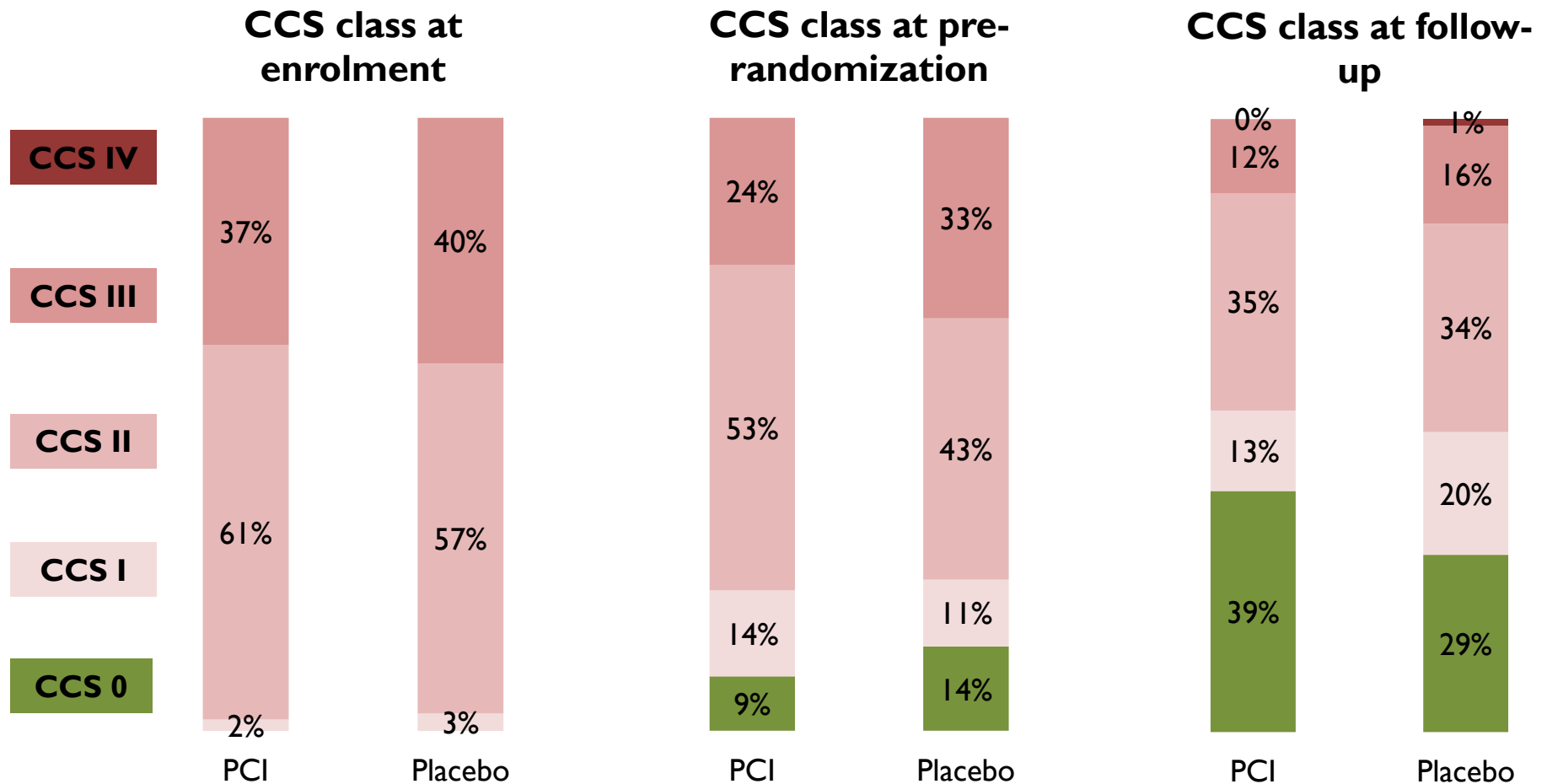
Secondary endpoint results

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) p<0.0001	0.02 (0.16) p=0.433
Difference in Δ between arms	-0.09 (-0.15 to -0.04) p=0.0011	

Secondary endpoint results

CCS class improved in both groups



Secondary endpoint results

No difference in symptom improvement or

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

Differences are Δ PCI minus Δ placebo

Adverse clinical events

Adverse clinical event	PCI n = 105	Placebo n = 95
All cause death	0	0
Myocardial infarction	0	0
Cerebrovascular event	0	0
Unplanned revascularization	0	5

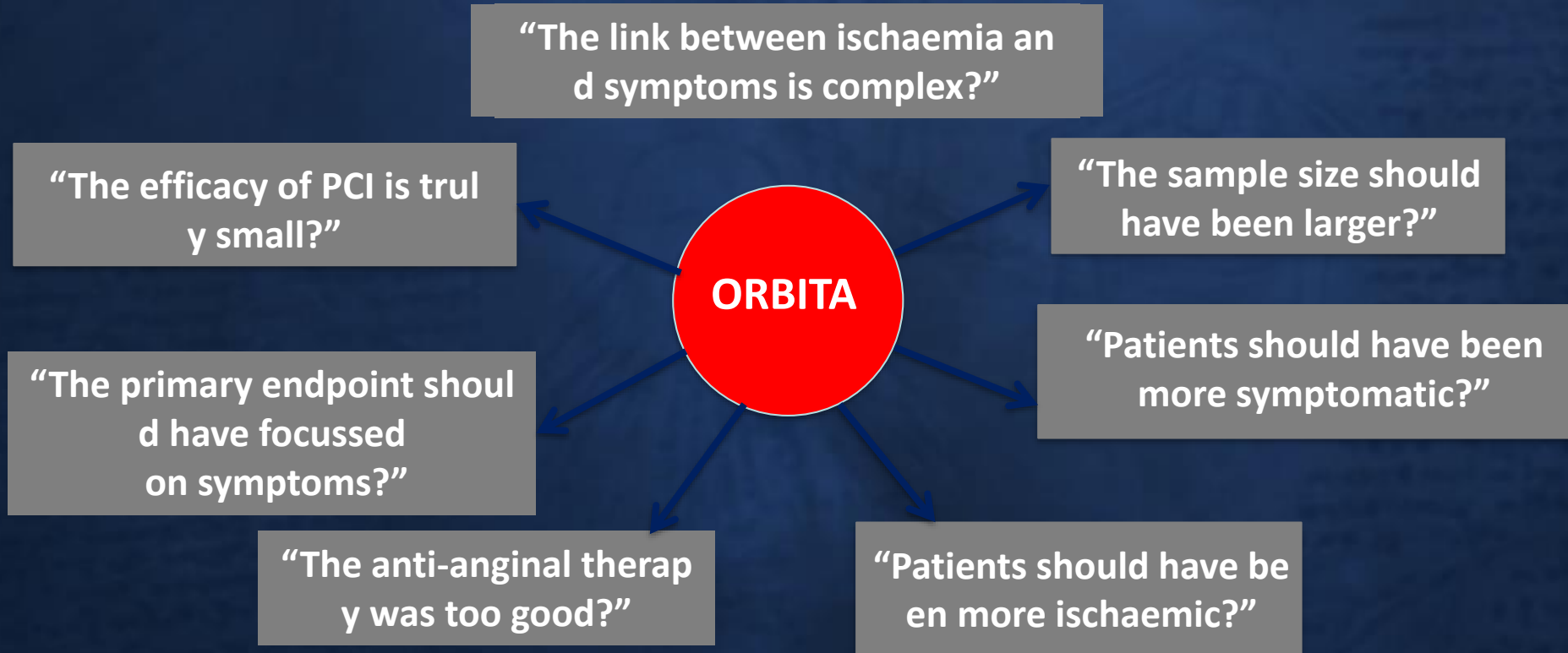
ORBITA trial conclusions

- **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 assessed by stress echo**
- **In this single vessel, angiographically guided trial there was no difference in exercise time increment between PCI and placebo**

limitation

- Small study
- Single vessel disease
- Patients had a good exercise capacity to begin with
- Interaction with investigational team x3 /week
- 25% Class 0-1 angina : need for PCI?
- 33% normal FFR or iFR
- Patients aware 50% chance no treatment *yet*
- Limit their confidence – “reverse placebo effect”

Why were the ORBITA results not as we expected?

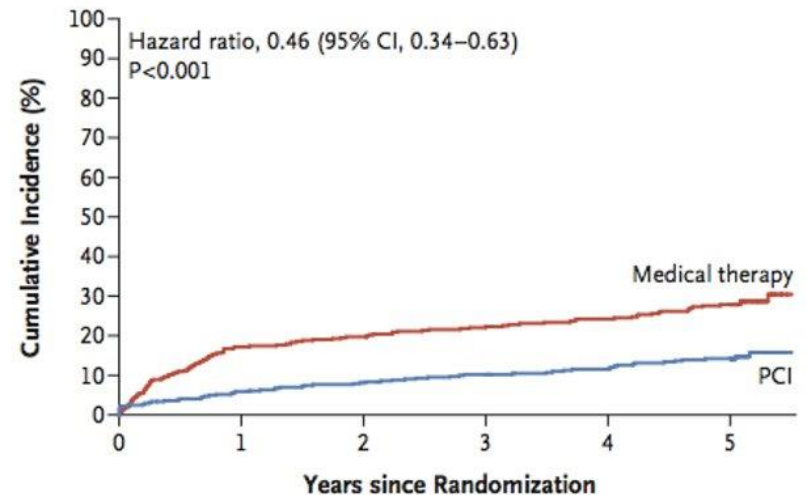


FAME II trial

- More large number
- FFR guided PCI

Five-Year Outcomes with PCI Guided by Fractional Flow Reserve

P. Xaplanteris, S. Fournier, N.H.J. Pijls, W.F. Fearon, E. Barbato, P.A.L. Tonino, T. Engstrøm, S. Kääb, J.-H. Dambrink, G. Rioufol, G.G. Toth, 7 Dierckx, N. Witt, O. Fröbert, P. Kala, A. Linke, N. Jagic, M. Mates, K. Mavroukakis, A. Irimpen, K. Oldroyd, G. Campo, M. Rothenbühler, P. Juni, for the FAME 2 Investigators*



No. at Risk

Medical therapy	441	360	349	337	271	258
PCI	447	416	403	391	334	321

MEDICAL NEWS | PHYSICIAN'S FIRST WATCH, CARDIOLOGY, EMERGENCY MEDICINE

November 18, 2019

ISCHEMIA: Invasive Treatment Not Better Than Meds in Patients with Stable Ischemic Heart Disease

*By Amy Orciari Herman**Edited by Susan Sadoughi, MD, and André Sofair, MD, MPH*

In patients with stable ischemic heart disease, invasive treatment appears no better than optimal medical therapy for preventing cardiovascular (CV) events, according to the international ISCHEMIA trial. The findings were presented on Saturday at the American Heart Association's annual meeting in Philadelphia.

Nearly 5200 adults with stable ischemic heart disease and moderate-to-severe ischemia (usually diagnosed by stress imaging) were randomized to invasive or conservative management. In the invasive group, patients underwent cardiac catheterization followed by percutaneous coronary intervention or coronary artery bypass grafting, when feasible; they also received optimal medical therapy. The conservative group received optimal medical therapy alone. Of note, patients with left main disease were excluded.

At 4 years, incidence of the primary endpoint — a composite of CV death, myocardial infarction (MI), resuscitated cardiac arrest, hospitalization for unstable angina, or heart failure — did not differ significantly between the invasive and conservative groups (13.3% and 15.5%, respectively). A major secondary endpoint comprising CV death or MI also did not differ significantly (11.7% and 13.9%).

Dr. Harlan Krumholz, editor-in-chief of *NEJM Journal Watch Cardiology*, offered his take: "The ISCHEMIA study is a lot to digest — and the results haven't yet been published in a peer-reviewed journal. Yet, what seems clear is that patients with stable ischemic disease are safe with medical therapy, which is consistent with many other studies. A side question is whether stress myocardial perfusion studies are providing much value for these patients."

In current status, conclusion

No trial is without limitations

Placebo is an important part of medical care

The true physical effect of PCI may be increased if we select certain patient subgroups

The medical treatment will be first line treatment option for many patients in stable angina

**Thank You
for your Attention**

