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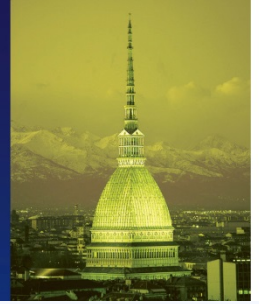
TURIN, October 25th-27th 2018 Starhotels Majestic

GIORNATE CARDIOLOGICHE TORINESI 30



UNIVERSITÁ DEGLI STUDI DI TORINO

AZIENDA OSPEDALIERO - UNIVERSITARIA Città della Salute e della Scienza di Torino

The top 5 trials in the last year: Ischemic Heart Disease

Malcolm R. Bell, MBBS, FRACP, FACC
Vice Chair, Department of Cardiovascular Medicine
Mayo Clinic, Rochester MN, USA

Conflicts and disclosures – none

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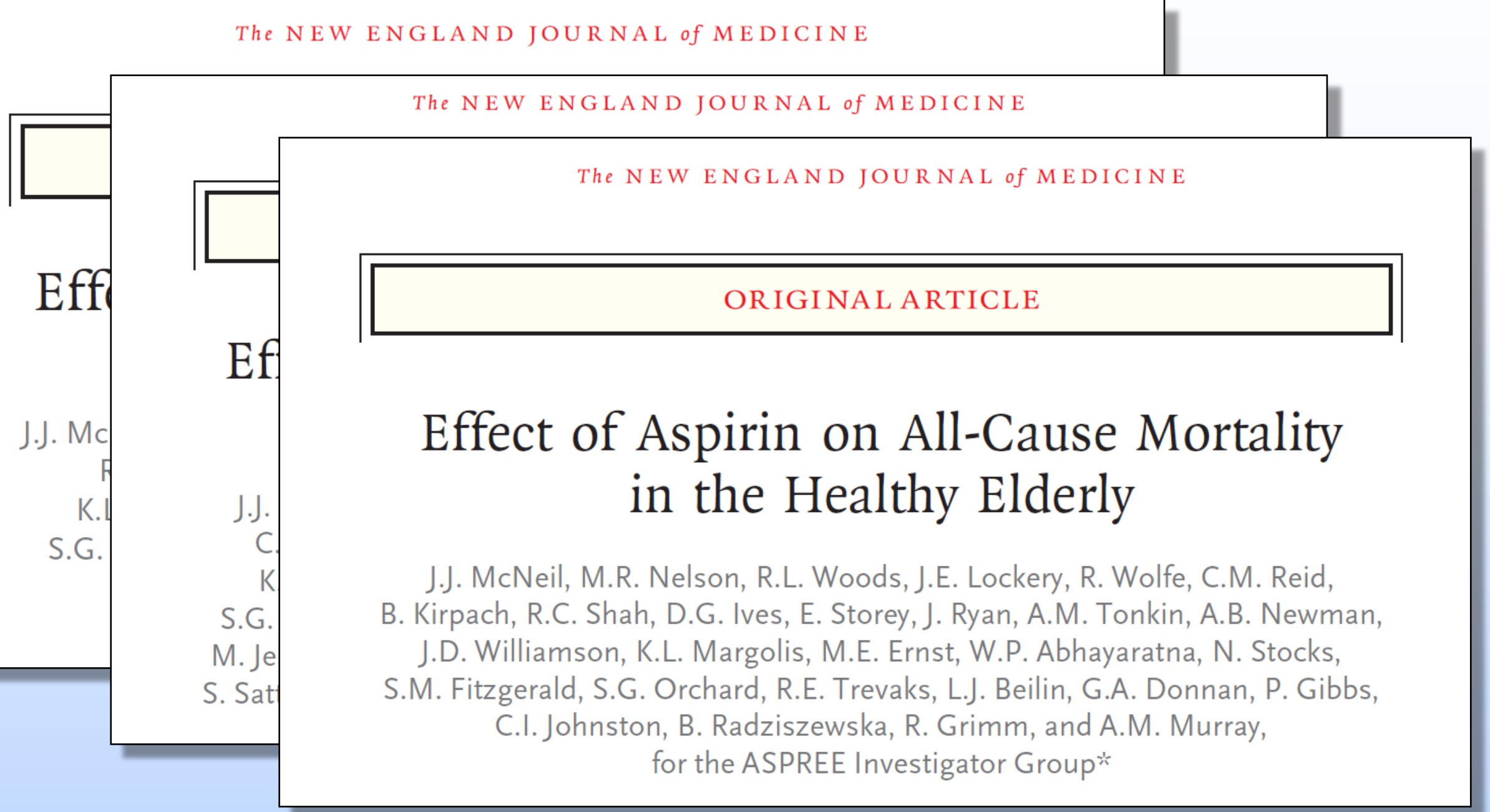

NEJM September 16, 2018

The role for ASA in primary prevention is unclear and it use diminishing

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ASPREE – Aspirin and primary prevention

Recruitment 19,114 patients between 2010-2014

≥70 yrs from Australia and USA (≥65 yrs if Black or Hispanic)

Randomized to 100-mg EC-ASA or placebo

4.7 yrs median follow-up

(trial terminated - no benefit to continued ASA)

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ASPREE results – Main Trial

	Aspirin Rate per 1000 person-yr	**Placebo** Rate per 1000 person-yr	**HR (95% CI)**	**P value**
Primary endpoint	21.5	21.2	1.01 (0.92-1.11)	0.79
Any cause death, dementia, persistent physical disability				

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McNeil JJ: NEJM 2018

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Primary endpoint	21.5	21.2	1.01 (0.92-1.11)	0.79
Any cause death, dementia, persistent physical disability				
Secondary endpoints				
Any cause death	12.7	11.1	1.14	--
Dementia	6.7	6.9	0.98	--
Persistent physical disability	4.9	5.8	0.85	--

McNeil JJ: NEJM 2018

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38% more major bleeds with ASA

Mortality higher in the ASA group
(primarily attributed to cancer-related death)

No significant difference in CV events

No overall benefit !

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 21, 2017 VOL. 377 NO. 25

PCI Strategies in Patients with Acute Myocardial Infarction

In acute MI with shock, primary end point was lower among those who had culprit-only PCI rather than multivessel PCI

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In acute MI with multivessel disease
and cardiogenic shock,
debate continues over culprit-only *vs*. multivessel PCI

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30-day CULPRIT-SHOCK results (n=706)

Endpoint	Culprit PCI	Multivessel PCI	Superior
Primary: Death or renal-replacement therapy	45.9%	55.4%	Yes
Death	43.3%	51.6%	
Renal-replacement therapy	11.6%	16.4%	

Thiele H: NEJM 2017

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Endpoint	Culprit PCI	Multivessel PCI	Superior
Primary:			
Death or renal-replacement therapy	45.9%	55.4%	Yes
Death	43.3%	51.6%	
Renal-replacement therapy	11.6%	16.4%	
Secondary:			
Bleeding (BARC 2,3 or 5)	16.6%	22.0%	No
Stroke	3.5%	2.9%	No

Thiele H: NEJM 2017

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WARNING!

Any potential advantage of multivessel PCI is outweighed by mortality hazard of the initial longer procedure

REMEMBER!

Main proven goal in shock is rapid and complete reperfusion of culprit vessel

Hochman J (NEJM editorial 2017):
Other apparently intuitive strategies – CABG, ECMO, ventricular assist devices etc – should also be subjected to RCTs

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MAYO CLINIC

Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

Olivier Varenne, Stéphane Cook, Georgios Sideris, Sasko Kedev, Thomas Cuisset, Didier Carrié, Thomas Hovasse, Philippe Garot, Rami El Mahmoud, Christian Spaulding, Gérard Helft, José F Diaz Fernandez, Salvatore Brugaletta, Eduardo Pinar-Bermudez, Josepa Mauri Ferre, Philippe Commeau, Emmanuel Teiger, Kris Bogaerts, Manel Sabate, Marie-Claude Morice, Peter R Sinnaeve, for the SENIOR investigators

Lancet 2018; 391: 41–50

Published Online
November 1, 2017
http://dx.doi.org/10.1016/S0140-6736(17)32713-7

See Comment page 4

Hôpital Cochin, Assistance Publique—Hôpitaux de Paris, Paris, France, and Cardiology Department, Université Paris Descartes, Sorbonne Paris-Cité, Paris, France

Summary

Background Elderly patients regularly receive bare-metal stents (BMS) instead of drug-eluting stents (DES) to shorten the duration of double antiplatelet therapy (DAPT). The aim of this study was to compare outcomes between these two types of stents with a short duration of DAPT in such patients.

Methods In this randomised single-blind trial, we recruited patients from 44 centres in nine countries. Patients were eligible if they were aged 75 years or older; had stable angina, silent ischaemia, or an acute coronary syndrome; and had at least one coronary artery with a stenosis of at least 70% (≥50% for the left main stem) deemed eligible for percutaneous coronary intervention (PCI). Exclusion criteria were indication for myocardial revascularisation by coronary artery bypass grafting; inability to tolerate, obtain, or comply with DAPT; requirement for additional surgery; non-cardiac comorbidities with a life expectancy of less than 1 year; previous haemorrhagic stroke; allergy to aspirin or $P2Y_{12}$ inhibitors; contraindication to P2Y$_{12}$ inhibitors; and silent ischaemia of less than 10% of the left myocardium with a

Use of DES with short DAPT duration better than BMS with short DAPT

group and 98 [9%] to the BMS group). The primary endpoint occurred in 98 (12%) patients in the DES group and 98 (16%) in the BMS group (relative risk [RR] 0·71 [95% CI 0·52–0·94]; p=0·02). Bleeding complications (26 [5%] in the DES group *vs* 29 [5%] in the BMS group; RR 0·90 [0·51–1·54]; p=0·68) and stent thrombosis (three [1%] *vs* eight [1%]; RR 0·38 [0·00–1·48]; p=0·13) at 1 year were infrequent in both groups.

Interpretation Among elderly patients who have PCI, a DES and a short duration of DAPT are better than BMS and a similar duration of DAPT with respect to the occurrence of all-cause mortality, myocardial infarction, stroke, and ischaemia-driven target lesion revascularisation. A strategy of combination of a DES to reduce the risk of subsequent repeat revascularisations with a short BMS-like DAPT regimen to reduce the risk of bleeding event is an attractive option for elderly patients who have PCI.

(Prof S Kedev MD); Département de Cardiologie, Centre hospitalier universitaire Timone, Marseille, France (Prof T Cuisset MD); Service de Cardiologie, Centre hospitalier universitaire Toulouse Rangueil, Université Paul Sabatier, Toulouse, France (Prof D Carrié MD); Institut Cardiovasculaire Paris-Sud, Ramsay Générale de Santé,

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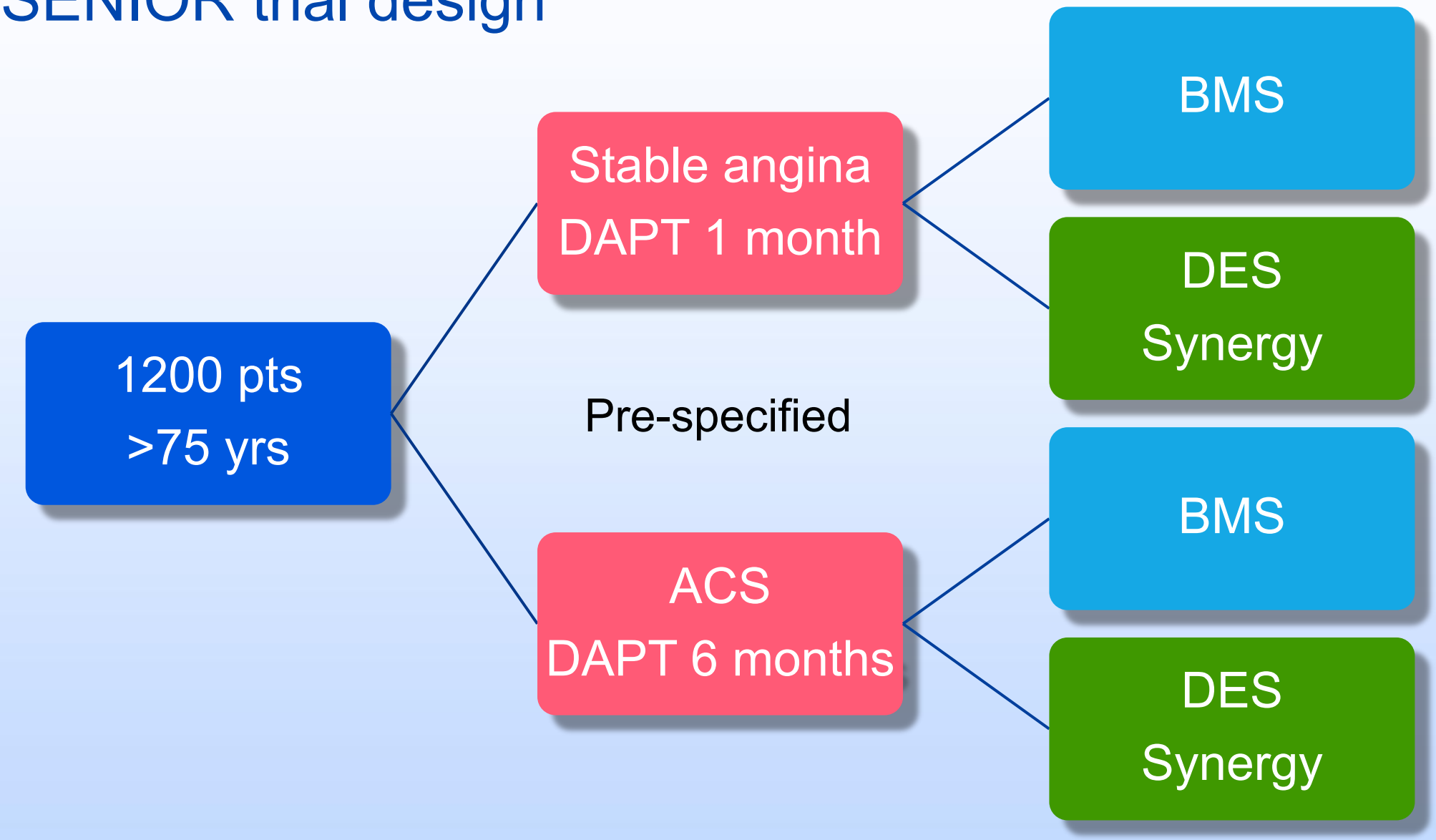
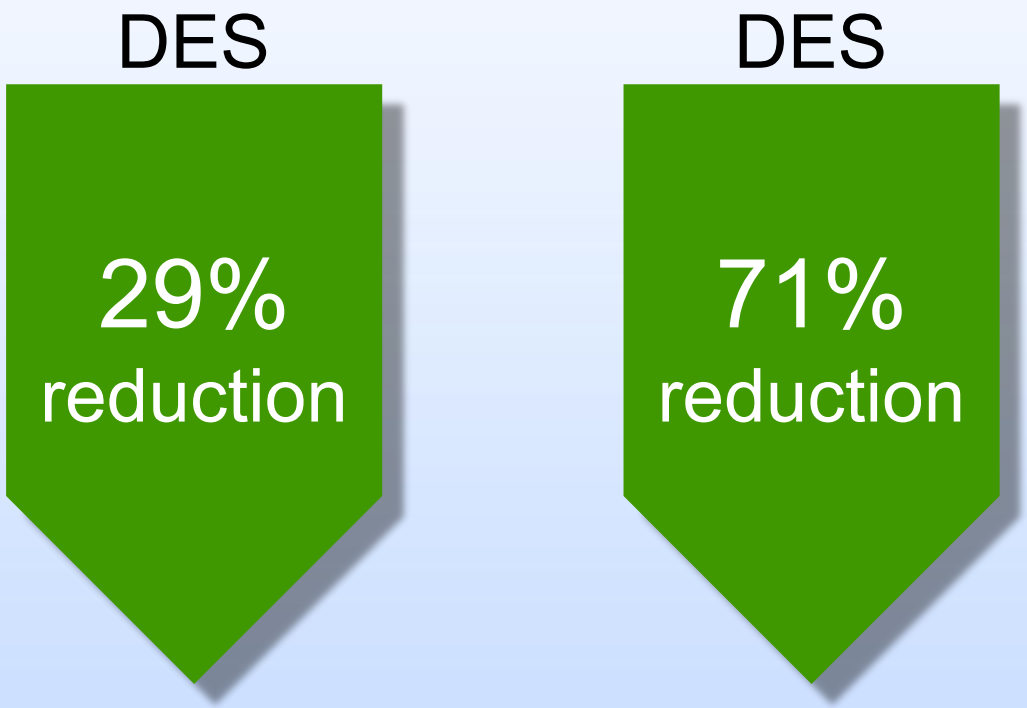
SENIOR trial design



Varenne O: Lancet 2018

SENIOR results at 1 year



Primary endpoint NNT = 25

Ischemia-driven TLR

Bleeding
no different

Stent thrombosis
numerically lower with DES

Varenne O: Lancet 2018

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Coronary CT Angiography and 5-Year Risk of Myocardial Infarction

The SCOT-HEART Investigators*

Use of CTA in stable chest pain resulted in lower rate of death or nonfatal MI at 5 years

NEJM 2018

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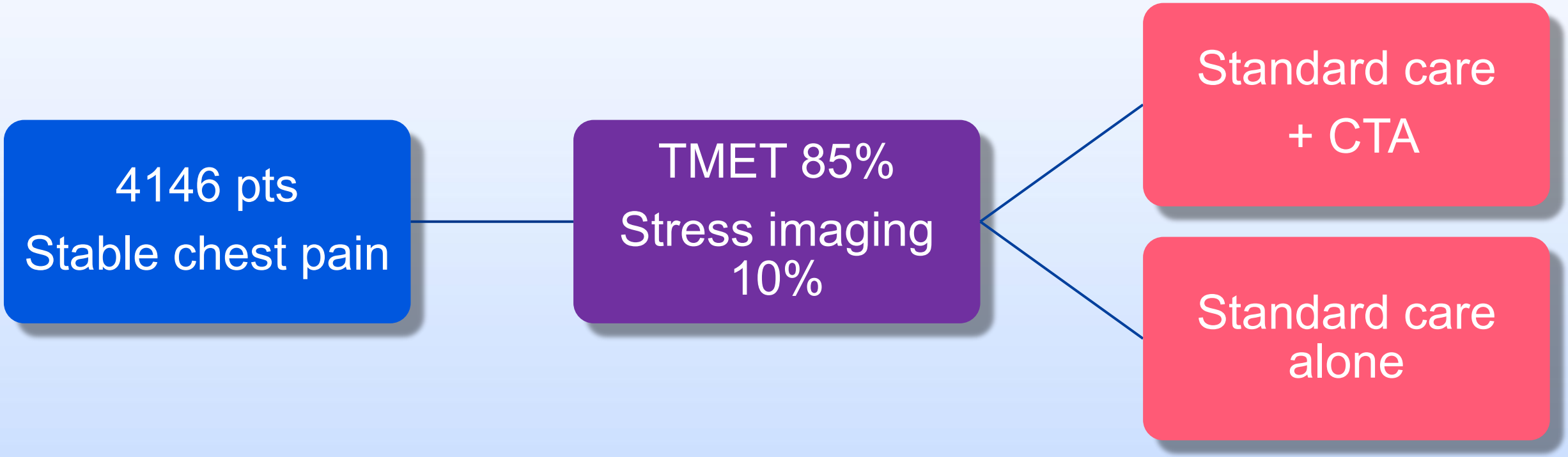
SCOT-HEART trial design



NEJM 2018

SCOT-HEART results at 5 years

Endpoint	CTA group	Standard care group	HR (95% CI)	P value
Primary: CHD death or nonfatal MI	2.3%	3.9%	0.59 (0.41-0.84)	0.004
Secondary: Nonfatal MI	2.1%	3.5%	0.60 (0.41-0.87)	--
Death from CHD	0.2%	0.4%	0.46 (0.14-1.48)	--

No significant difference in use of coronary angiography or revascularization

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Controversial

Implausible!

“Game-changer”!

Provocative!

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….the week after NEJM publication

49 yr old man with exertional chest pain

Positive family history and abnormal lipids

Negative TMET

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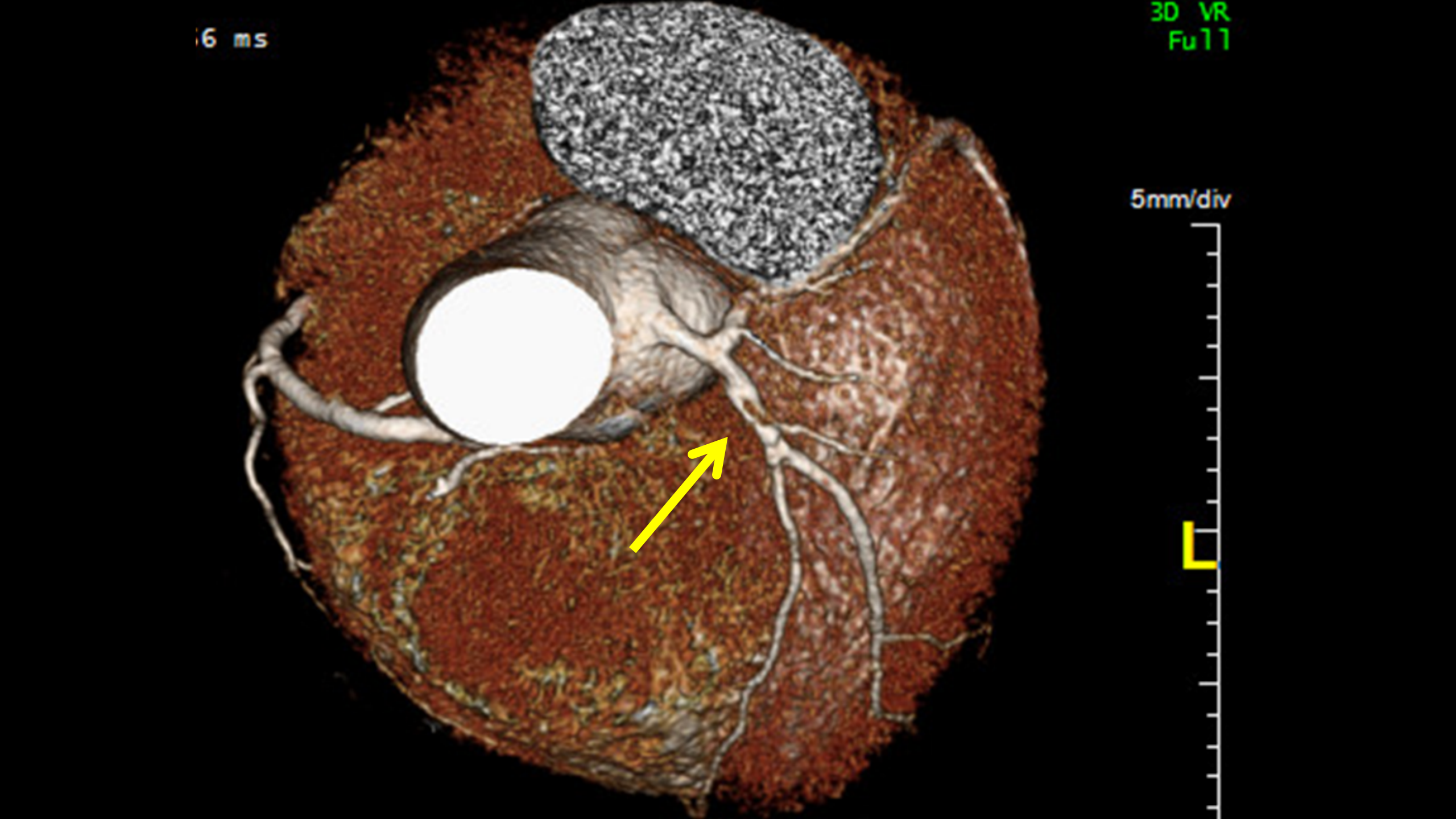
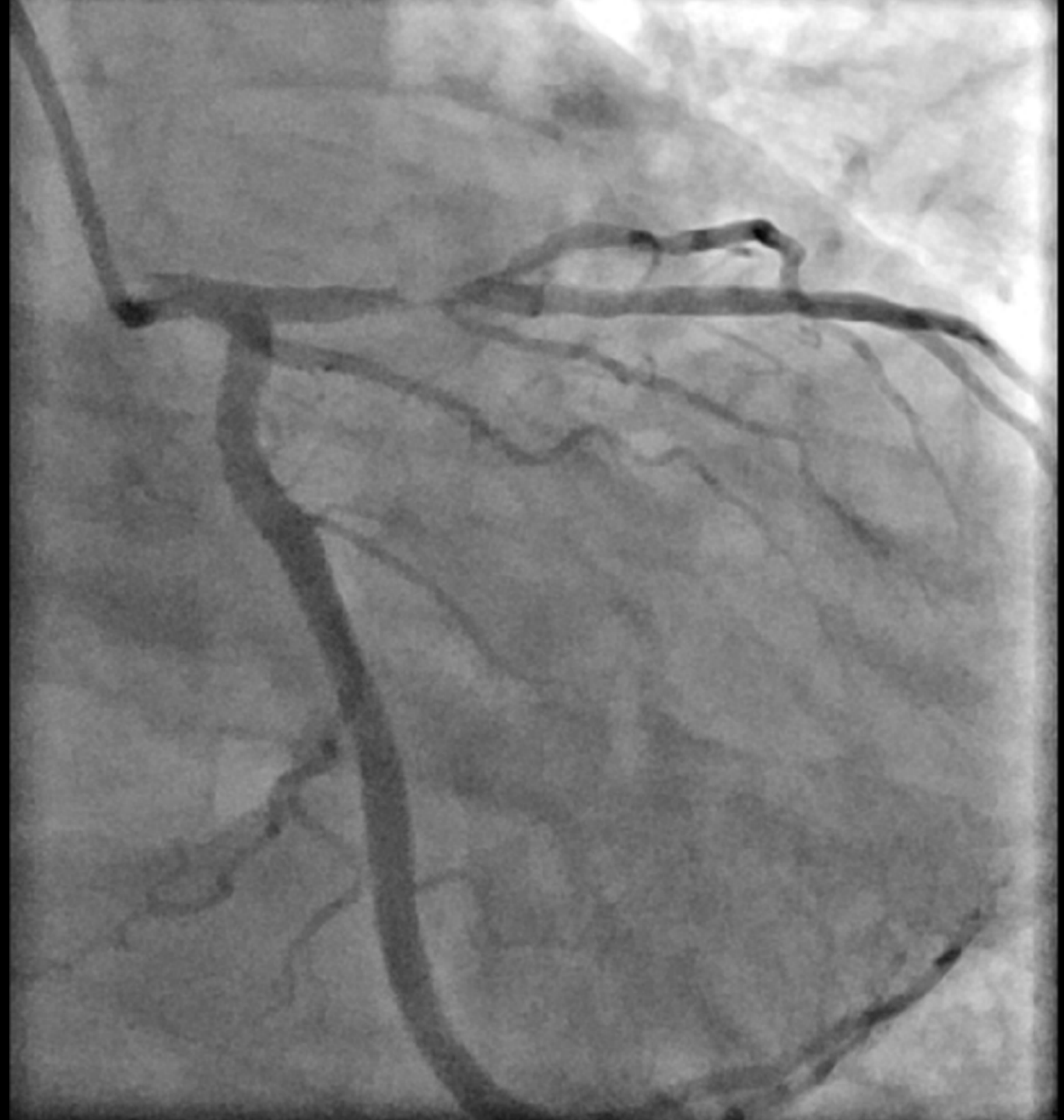

6 ms
3D VR
Full
5mm/div



MAYO CLINIC

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

*Rasha Al-Lamee, David Thompson, Hakim-Moulay Dehbi, Sayan Sen, Kare Tang, John Davies, Thomas Keeble, Michael Mielewczik, Raffi Kaprielian, Iqbal S Malik, Sukhjinder S Nijjer, Ricardo Petraco, Christopher Cook, Yousif Ahmad, James Howard, Christopher Baker, Andrew Sharp, Robert Gerber, Suneel Talwar, Ravi Assomull, Jamil Mayet, Roland Wensel, David Collier, Matthew Shun-Shin, Simon A Thom, Justin E Davies, Darrel P Francis, on behalf of the ORBITA investigators**

Lancet 2018; 391: 31–40
Published Online
November 2, 2017
http://dx.doi.org/10.1016/S0140-6736(17)32714-9

Summary

Background Symptomatic relief is the primary goal of percutaneous coronary intervention (PCI) in stable angina and is commonly observed clinically. However, there is no evidence from blinded, placebo-controlled randomised trials to show its efficacy.

Methods ORBITA is a blinded, multicentre randomised trial of PCI versus a placebo procedure for angina relief that

between Jan 6, 2014, and Aug 11, 2017, 200 patients underwent randomisation, with 105 patients assigned PCI and

Y Ahmad MRCP, J Howard MRCP,

In patients with medically treated angina and severe coronary stenosis, PCI did not increase exercise time more than a placebo procedure.

Suggests that efficacy of invasive procedures can be assessed with a placebo control, as is standard for pharmacotherapy

Funding NIHR Imperial Biomedical Research Centre, Foundation for Circulatory Health, Imperial College Healthcare Charity, Philips Volcano, NIHR Barts Biomedical Research Centre.

Prof J Mayet, M Shun-Shin, Prof S Thom, J E Davies, Prof D P Francis FRCP); **Cancer**

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Al-Lamee R: Lancet 2018

"…show unequivocally that there are no benefits for PCI compared with medical therapy for stable angina, even when angina is refractory to medical therapy…"

"Health-care providers should focus their attention on treating patients with stable coronary artery disease with optimal medical therapy, which is very effective,…."

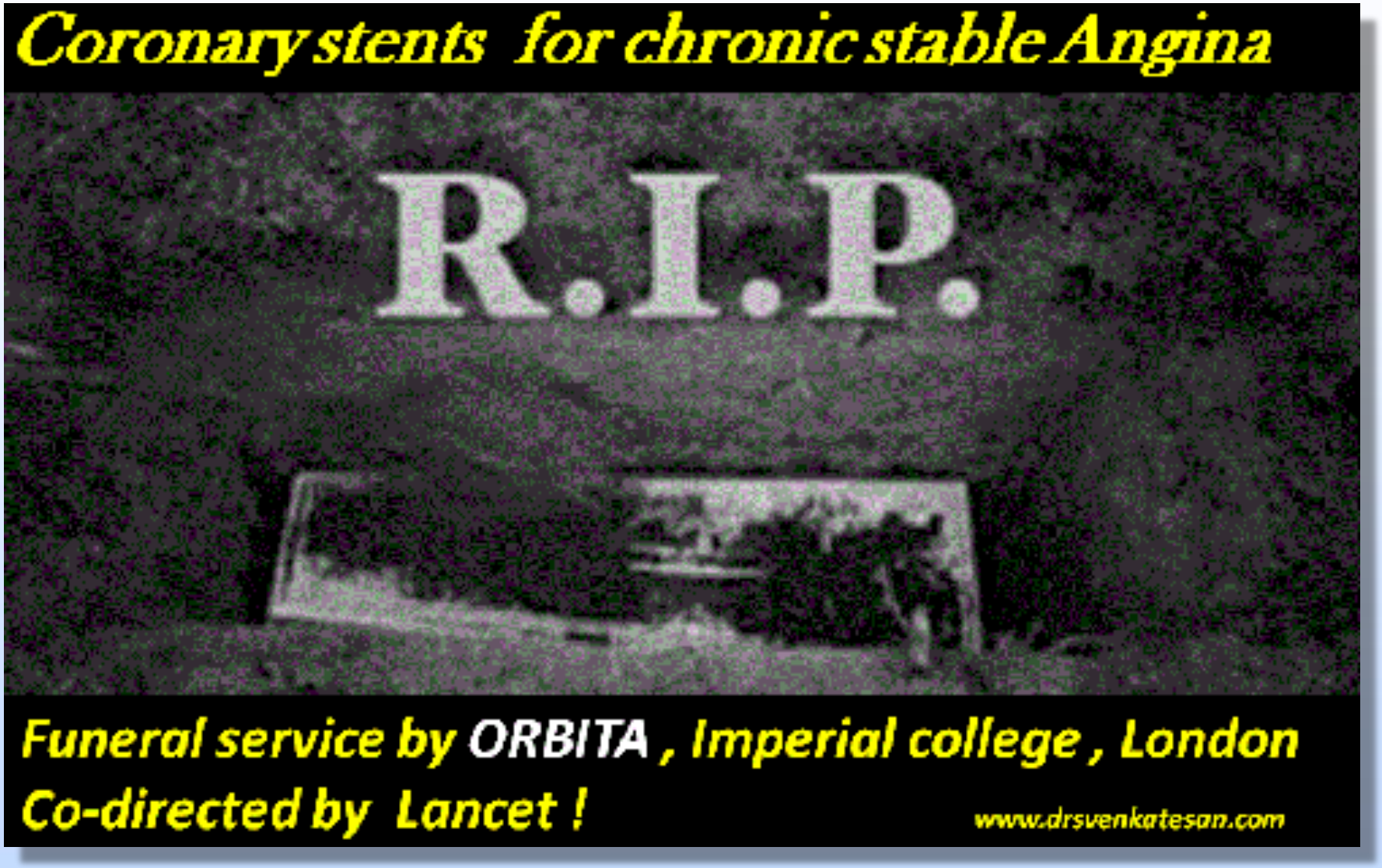
"….all cardiology guidelines should be revised to downgrade the recommendation for PCI in patients with angina despite use of medical therapy…"

Last nail in the coffin for PCI

Interventional cardiology began in 1977, when Andreas Gruentzig first successful percutaneous trans angioplasty (PTCA) on a 38-year-old and a focal proximal stenosis of descending coronary artery. De subsequent randomised trials and these trials, which have shown no re or myocardial infarction,[1] the use of percutaneous coronary intervention (PCI) has grown exponentially. Some of this growth was driven by data from cl trials suggesting that PCI was more effec relieving angina than medical therapy alon example, in 1992, the results of the Angi Compared to Medicine (ACME) study,[2] showed 6 months, 61 (64%) of 96 patients in the PTCA were free of angina compared with 47 (46%) 102 medically treated patients (p=0·01). The pa

Investigators of the Objective Randomised Blinded Investigation with optimal medical Therapy of

Brown DL and Redberg RF: Lancet 2017



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By GINA KO

CTV NEWS

Video Shows Canada World Politics Entertainment Sci-Tech

Heal

HOME HEA

Heart Stents Don't Wor
Bucks for Surgeons

In All Health Watch, Big Pharma, Featured Article, Health Wa

Study finds stents don't always relieve angina chest pain

Study questions the effectiveness of heart stents

A new study is calling into question how effective the use of a stent is during invasive heart surgeries. Pauline Chan reports.

CTV News Channel: Overreaction to study?

Interventionist Cardiologist Dr. Rasha Al-Lamee says her study on stents shows the procedure is ineffective with some patients.

Daily Mail .com

health

Stent operations 'are a waste of time' for people with angina: Study warns the procedure carries huge risks and few benefits

- Millions of people with angina get a stent put in to widen their arteries
- A study by Imperial College London found the operation has a huge risk of damaging the arteries but does not improve quality of life
- The results add to growing evidence that procedures including keyhole knee surgery and arthritis operations only work because of a 'placebo effect'

By VICTORIA ALLEN SCIENCE CORRESPONDENT FOR THE DAILY MAIL

MAYO CLINIC

Commentary on ORBITA trial

GOOD trial which was well designed and executed

Important implications trials using sham procedures

Small trial – only 200 patients

Follow up only 6 weeks

Operators blinded to FFR and iFR:

- 29% patients had FFR >0·80 and 32% had iFR >0.89

Microvascular dysfunction as cause of chest pain?

MAYO CLINIC

bell.malcolm@mayo.edu