IS CORONARY STENTING PCI OVERUSED AS THE ORBITA RCT SUGGESTS?

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WHAT WAS THE ORBITA TRIAL?

THE LANCET

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

Al-Lamee et al Lancet 2018;391:31-40

ORBITA

230 ENROLLED
PRE-RANDOMIZATION ASSESSMENT

250 RANDOMIZED
MEDICAL OPTIMIZATION PHASE 6 WKS

PCI (105)
PLACED (5)

6 WKS BLIND FOLLOW-UP
FOLLOW-UP ASSESSMENT

THE LANCET

“...in patients with medically treated angina and severe coronary stenosis, percutaneous coronary intervention did not increase exercise time by more than the effect of a placebo procedure...”

Al-Lamee et al Lancet 2018;391:31-40

DISCLOSURES

Affiliations/Financial Relationships

Consultant
Abbott Laboratories (paid to the institution), Abiomed (spouse), Boston Scientific, Cardiovascular Systems Inc, Medtronic, St Jude Medical, Spectranetics, The Medicines Company, Vascular Solutions Inc, Volcano Corporation

Research Funding to Institution
AstraZeneca, Bayer, Biotronik, Boston Scientific, Chemuris, Eli Lilly/DSI Merck, Novartis Pharmaceuticals, OnoPharmaceuticals, OrklaPharma

Equity, <1%
Clare Medical, Clive Medical

Advisory Board Funding to Institution
Bristol-Myers Squibb

Executive Committee
Janssen Pharmaceuticals, Otsuka Medical

DSMB membership paid to the Institution
Watermark Research Partners
**SCOPE OF CORONARY ARTERY DISEASE**

- **POPULATION:** 326 million
- **PREVALENCE OF CAD:** 16.5 million
- **CATH-PCI:** 667,424 performed

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**SUPPORTIVE EVIDENCE FOR INITIAL ROUTINE REVASCULARIZATION + GDMT vs. GDMT ALONE**

- Observational and RCT data suggests a relationship between ischemia and death/MI
- Revascularization relieves ischemia to a greater extent than best medical therapy
- Large scale studies have shown a reduction in spontaneous MI following revascularization vs. GDMT alone
- Continual improvement in PCI & CABG techniques with more effective relief of symptoms
- Adherence to GDMT is difficult and not routinely achieved.
- More immediate reduction in symptoms is preferred by patients vs. continued GDMT
- By reducing the requirement for antianginal medications, revascularization may facilitate compliance with GDMT proven to reduce MI and death.

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**Variation in rates of PCI**

Source: Dartmouth Atlas

- 1.3 to 2.9
- 1.1 to < 1.3
- 0.9 to < 1.1
- 0.75 to < 0.9
- 0.35 to < 0.75
- Not Populated

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**Appropriate Use Criteria for Coronary Revascularization Focused Update 2012**

Endorsed by:
- American Society of Nuclear Cardiology
- American College of Cardiology
- American Heart Association
- American Association for Thoracic Surgery
- Society for Cardiovascular Angiography and Interventions

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**Media Hysteria! Stent Overuse...**

- **Heart Stents Still Overused, Experts Say**
  - NY Times, August 15, 2013
- **Deaths Linked to Cardiac Stents Rise as Overuse Seen**
  - Bloomberg, Sept. 26, 2013
- **Stents Overused in Stable Heart Patients**
  - WebMD, Feb. 27, 2012
- **Heart Treatments Overused, Study Says**
  - WSJ, July 6, 2011
REVASCULARIZATION vs. OMT IN RELIEF OF ANGINA AND IMPROVEMENT OF EXERCISE CAPACITY

2018 ESC/EACTS Guidelines on Myocardial Revascularization

**COURAGE TRIAL – NUCLEAR SUBSTUDY**

- Compared the effectiveness of PCI for ischemia reduction added to OMT with the use of myocardial perfusion single photon emission computed tomography (MPS)
- 314 subjects included for serial rest/stress MPS performed
- The reduction in ischemic myocardium was greater with PCI+OMT (−2.7%; 95% CI, −1.7%, −3.8%) than with OMT (−0.5%; 95% CI, −1.6%, 0.6%; \( p < 0.0001 \))

**FAME II TRIAL**

- The Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 Trial
- Randomized, "all-comer" population
- Recruitment was halted prematurely after enrollment of 1220 patients because of a significant between-group difference in the percentage of patients who had a primary end-point event: 4.3% in the PCI group and 12.7% in the medical-therapy group

**COMPARATIVE-EFFECTIVENESS OF REVASCULARIZATION vs. ROUTINE MEDICAL THERAPY FOR SIHD**

- 39,131 SIHD patients: 15,139 GDMT; 23,992 REVASCULARIZED (15,604 PCI; 8,388 CABG)

**PCI vs. OMT IN STABLE CORONARY ARTERY DISEASE**

- Meta-analysis of 12 RCTs with 7182 individuals

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Favor PCI</th>
<th>Favor MT</th>
<th>RR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality*</td>
<td>0.85 (0.71-1.01)</td>
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<td>0.07</td>
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<tr>
<td>Cardiac death</td>
<td>0.71 (0.47-1.06)</td>
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<td>0.09</td>
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<tr>
<td>Nonfatal MI</td>
<td>0.83 (0.50-1.34)</td>
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<td>0.61</td>
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<tr>
<td>Repeat Revascularization</td>
<td>0.93 (0.76-1.14)</td>
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<td>0.47</td>
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<tr>
<td>Angina</td>
<td>0.83 (0.73-0.94)</td>
<td></td>
<td><strong>0.005</strong></td>
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</tr>
</tbody>
</table>

*All-cause mortality in trials with >50% stent use: 0.89 (0.79-1.01)
FREEDOM FROM ANGINAL SYMPTOMS: PCI vs. OMT

2018 ESC/EACTS GUIDELINES ON REVASCULARIZATION

Upcoming ISCHEMIA TRIAL

- International Study of Comparative Health Effectiveness with Medical and Invasive Approaches, with ~8,000 participants randomized
- Primary objective: determine whether an invasive strategy of routine early cardiac catheterization with intent for optimal revascularization in addition to OMT in patients with SIHD and at least moderate ischemia on stress imaging reduces the incidence of the composite of cardiovascular death or nonfatal MI compared with a conservative strategy of OMT alone.

CONCLUSIONS

- Current guidelines recommend use of revascularization procedures for relief of symptoms in patients with CAD
- While placebo remains an important aspect of the medical care, an upfront revascularization procedure for many patients will always be the first choice.
- Optimal treatment modality for the patient should ALWAYS be made by the Heart team.

“Strive not to be a success but of value”
Albert Einstein

“Do the best you can until you know better, when you know better, do better”
Maya Angelou