CABG & OMT Evolving Again?

Microcirculation & OMT+Adherence

ACC - New York, Dec. 11, 2015
No Disclosures
## Revascularization for Coronary Artery Disease

### OMT vs PCI vs CABG

<table>
<thead>
<tr>
<th>Era</th>
<th>Rule of 2 / 3</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980’s</td>
<td>LMD, The Rule of 2 / 3 – CABG</td>
<td></td>
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<tr>
<td></td>
<td>Moderate &lt; LVEF</td>
<td>Severe - Yes, STICH</td>
</tr>
<tr>
<td></td>
<td>Severe Ischemia</td>
<td>Moderate – COURAGE OMT ISCHEMIA</td>
</tr>
<tr>
<td></td>
<td>3 Vessel Disease</td>
<td>2 Vessel in DM</td>
</tr>
<tr>
<td></td>
<td>2vd + pLAD</td>
<td>2vd in DM</td>
</tr>
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## Revascularization for Coronary Artery Disease

### OMT vs PCI vs CABG

<table>
<thead>
<tr>
<th>Period</th>
<th>Criteria</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>- Severe Ischemia</td>
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<tr>
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<td>- 3 Vessel Disease</td>
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<td>Anatomical, Isch.Score, Microc.: Ninv. - OMT+</td>
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<tr>
<td>Year</td>
<td>Revascularization Strategies</td>
<td></td>
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<tr>
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<td></td>
</tr>
</tbody>
</table>
In both STICH trials (hypotheses), 2136 patients with a left ventricular ejection fraction of \( \leq 35\% \) and coronary artery disease were allocated to medical therapy, CABG plus medical therapy, or CABG with surgical ventricular reconstruction. CABG can be performed with relatively low 30-day mortality in patients with left ventricular dysfunction. Serious postoperative complications occurred in nearly 1 in 4 patients and were associated with mortality.

*STICH (K Wrobel et al.) Circulation 2015; 132:720*
## Complex, Stable Coronary Disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>MVD</th>
<th>DM</th>
<th>Interv.</th>
<th>MT</th>
<th>EP-R</th>
<th>Data</th>
</tr>
</thead>
</table>
| Syntax| +   | -  | ++      | -  | ++   | CABG > PCI  
SYNTAX Score |
| Fame  | -   | -  | +       | -  | +    | PCI  
“ISCHEMIA” Score |
| Bari  | -   | +  | +       | +  | +    | CABG / PCI = MT  
X.OV.ER 42% |
| Courage| -  | -  | +       | +  | +    | PCI = MT  
“ISCHEMIA”>10%-Events |
| Freedom| +  | +  | ++      | (++) | + | CABG > PCI  
No Freedom of Choice? |

### Conditions

### Methods-Interests

### Conclusions
Baseline SYNTAX Score Tercile - CABG
Cumulative Event Curves For MACCE

SYNTAX (FW Mohr, PW Serruys et. al.) Lancet 2013; 381: 629
FFR As A Surrogate For Inducible Myocardial Ischaemia

**FAME I (FFR>0.8)** - OMT of Non-Isch. Les. – Prevent MI/Death

**FAME II (FFR<0.8)** - PCI Isch. Les. – Prevent MI/Death – FAME III - CABG?

FAME STUDY: CUMULATIVE EVENTS DURING 5-YEAR FOLLOW-UP

FAME (LX van Nunen et al., The Lancet 2015; 386:1853)
1. Coronary Flow Reserve (CFR)

- Measures *integrated* hemodynamic effects of epicardial CAD, diffuse atherosclerosis, vessel remodeling and microvascular dysfunction on myocardial tissue perfusion

\[
CFR = \frac{MBF_{\text{peak hyperemia}}}{MBF_{\text{rest}}}
\]

Epicardial arteries > 400 μm

Prearterioles, arterioles < 400 μm

VR Taqueti and MF Di Carli 2014
Time-activity Curves And A Polar Map Of 17-segment Coronary Flow Reserve

Coronary calcification was assessed by using the Agatston score (AS) in 214 patients suspected of having CAD who underwent coronary CTA, FFR\(_{CT}\), and FFR. The diagnostic performance of FFR\(_{CT}\) (\(\leq 0.80\)) in identifying vessel-specific ischemia (FFR \(\leq 0.80\)) was investigated across AS quartiles. FFR\(_{CT}\) provided high and superior diagnostic performance compared with coronary CTA interpretation alone in patients and vessels with a high AS.

*NXT Trial* (BL Nørgaard et al.), *J Am Coll Cardiol Img* 2015; 8:1045
Multiparametric Cardiovascular Magnetic Resonance Assessment of Cardiac Allograft Vasculopathy

Christopher A. Miller, BSc, MBChB,*†‡ Jaydeep Sarma, MA, MB BChIR, PhD,*‡
Josephine H. Naish, PhD,† Nizar Yonan, MD,*‡ Simon G. Williams, MD,*‡ Steven M. Shaw, PhD,*‡
David Clark, BSc,§ Keith Pearce, BSc,* Martin Stout, PhD,* Rahul Potluri, MBChB,*†
Alex Borg, MD,* Glyn Coutts, PhD,|| Saqib Chowdhary, PhD,*‡ Gerry P. McCann, MD,¶
Geoffrey J. M. Parker, PhD,† Simon G. Ray, MD,*‡ Matthias Schmitt, MD, PhD*‡

Manchester and Leicester, United Kingdom

Diagnostic Accuracy of Myocardial Magnetic Resonance Perfusion to Diagnose Ischemic Stenosis With Fractional Flow Reserve as Reference Systematic Review and Meta-Analysis

Min Li, MD, Tao Zhou, MD, Lin-feng Yang, MD, Zhao-hui Peng, MD, Juan Ding, MD, Gang Sun, MD, PhD
1a. Impaired CFR & Zero CAC - MACE

Non-obstructive CAD

MACE 57/901, follow up 1.5 years

P=0.24, CAC
P=0.002, CFR

Adjusted MACE (%/yr)

<table>
<thead>
<tr>
<th>CAC 0</th>
<th>CAC 1-399</th>
<th>CAC ≥400</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4%</td>
<td>1.8%</td>
<td>3.6%</td>
</tr>
<tr>
<td>5.2%</td>
<td>4.8%</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

N=214 188 163 197 53 86
1b. Diabetes - CFR w/wo Epicardial CAD, Relation To Cardiac Death

1c. Angina During Follow-up

SJ Head et. al. EHJ. 2014;35:2821 – No Stad. Signif in FREEEDOM
1d. Proportion of Outcome Events by Achieved SBP - ONTARGET Trial

ONTARGET (J Redon et al.) JACC 2012;59:74 – Microvasculature, Underperfusion?
FREEDOM (M Farkoug, V Fuster) 2015 (In Press)
Mortality in the ACCORD Population Over a Range of On-treatment HbA1c Values

**ACCORD (MC Riddle et al) Circ 2010;122:844 - Microvascular / Catecholamines ?**
1f. PCI versus CABG in Insulin and Non-Insulin Treated Diabetic Patients: Results from the FREEDOM Trial

**FREEDOM (GD Dangas, V Fuster et. al.) JACC 2014; 64: 1189**
1g. Diastolic Dysfunction & Microcirculation

Diastolic Dysfunction

HTN

Diabetes

Metabolic stress

Mitochondrial ROS

BH₄ depletion

NOS uncoupling

Oxidative stress
(S-Glutathionylation of cMyBP-C and/or other protein oxidation including nitrosylation, carbonylation, or acetylation)

Alterations of intracellular Ca²⁺ transients or myofilament Ca²⁺ sensitivity

Impaired relaxation
Increased stiffness

Ranolazine
cMyBP-C S-G

MMP, TIMP, CTGF, TGF-beta

Collagen deposition

Fibrosis
Etiologies of Chest Pain Without Obstructive CAD

MA Marinescu et. al. J Am Coll Cardiol Img 2015;8:210
# Complex, Stable Coronary Disease

## Table: Comparison of CABG vs. PCI

<table>
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<tr>
<th>Trial</th>
<th>MVD</th>
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<tr>
<td><strong>SYNTAX</strong></td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>++</td>
<td>CABG &gt; PCI</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SYNTAX Score</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>PCI “ISCHEMIA” Score</strong></td>
</tr>
<tr>
<td><strong>FAME</strong></td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CABG / PCI = MT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X.OV.ER 42%</td>
</tr>
<tr>
<td><strong>COURAGE</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>PCI = MT</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>“ISCHEMIA” &gt; 10%-%-Events</td>
</tr>
<tr>
<td><strong>FREEDOM</strong></td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>(+)</td>
<td>+</td>
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<td></td>
<td></td>
<td>No Freedom of Choice?</td>
</tr>
</tbody>
</table>

**Conditions**

**Methods-Interests**

**Conclusions**
PCI and Long-Term Survival in Patients with Stable Ischemic Heart Disease

Unadjusted hazard ratio for death, PCI plus medical therapy vs. medical therapy alone, 0.98 (95% CI, 0.83–1.15), P=0.79 by log-rank test

<table>
<thead>
<tr>
<th>Years in Study</th>
<th>Probability of Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PCI plus optimal medical therapy</td>
</tr>
<tr>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>2</td>
<td>0.94</td>
</tr>
<tr>
<td>4</td>
<td>0.88</td>
</tr>
<tr>
<td>6</td>
<td>0.81</td>
</tr>
<tr>
<td>8</td>
<td>0.78</td>
</tr>
<tr>
<td>10</td>
<td>0.76</td>
</tr>
<tr>
<td>12</td>
<td>0.74</td>
</tr>
</tbody>
</table>

No. at Risk

| PCI plus optimal medical therapy | 1149 | 1088 | 894 | 620 | 486 | 416 | 302 |
| Optimal medical therapy         | 1138 | 1072 | 869 | 590 | 455 | 403 | 280 |

COURAGE (SP Sedlis et. al.) NEJM 2015;373:1937
Effect of PCI on Long-Term Survival in Patients with Stable Ischemic Heart Disease

Extended survival information was available for 1211 patients -53% of the original population-. During an extended-follow-up of up to 15 years, we did not find a difference in survival between and initial strategy of PCI plus medical therapy and medical therapy alone in patients with stable ischemic heart disease.

# COMPLEX, STABLE CORONARY DISEASE

<table>
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<th>MVD</th>
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<td>+</td>
<td>-</td>
<td>+</td>
<td>PCI</td>
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<td></td>
<td></td>
<td></td>
<td>“ISCHEMIA” Score</td>
</tr>
<tr>
<td>BARI</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>CABG / PCI = MT</td>
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<td>PCI = MT</td>
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<td></td>
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<tr>
<td>FREEDOM</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>(+)</td>
<td>+</td>
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</table>

**Conditions**

**Methods-Interests**

**Conclusions**
FREEDOM TRIAL – MI / DEATH / STROKE

Death/Stroke/MI, %

PCI/DES
CABG
Logrank P=0.005

5-Year Event Rates: 26.6% vs. 18.7%

Years Post-randomization

New Engl. J. Med. 2012; 367: 2375 – All Subgroups (Syntax etc)
Paclitaxel-Eluting vs Everolimus-Eluting Coronary Stents in Diabetes

C Cardiac Death or Target-Vessel Myocardial Infarction

- Hazard ratio, 1.69 (95% CI, 1.04–2.75)
- P=0.03 by log-rank test
- P=0.38 for noninferiority by F–M test

No. at Risk
- Paclitaxel-eluting stent: 914
- Everolimus-eluting stent: 916

Months since Randomization

0 3 6 9 12
0 10 20 30 40 50 60 70 80 90 100
Cumulative Incidence (%)
<table>
<thead>
<tr>
<th>2012 Recommendation</th>
<th>2014 Focused Update Recommendations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class Ila</strong></td>
<td><strong>Class I</strong></td>
<td></td>
</tr>
<tr>
<td>1. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery. (Level of Evidence: B)</td>
<td>1. A Heart Team approach to revascularization is recommended in patients with diabetes mellitus and complex multivessel CAD (Level of Evidence: C)</td>
<td>New recommendation</td>
</tr>
<tr>
<td></td>
<td>2. CABG is generally recommended in preference to PCI to improve survival in patients with diabetes mellitus and multivessel CAD for which revascularization is likely to improve survival (3-vessel CAD or complex 2-vessel CAD involving the proximal LAD), particularly if a LIMA graft can be anastomosed to the LAD artery, provided the patient is a good candidate for surgery (Level of Evidence: B)</td>
<td>Modified recommendation (Class of Recommendation changed from Ila to I, wording modified, additional RCT added).</td>
</tr>
<tr>
<td>Recommendations</td>
<td>Class&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Level&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>In patients presenting with STEMI, primary PCI is recommended over fibrinolysis if it can be performed within recommended time limits.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>In patients with NSTE-ACS, an early invasive strategy is recommended over non-invasive management.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>In stable patients with multivessel CAD and/or evidence of ischaemia, revascularization is indicated in order to reduce cardiac adverse events.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>In patients with stable multivessel CAD and an acceptable surgical risk, CABG is recommended over PCI.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>In patients with stable multivessel CAD and SYNTAX score ≤22, PCI should be considered as alternative to CABG.</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>New-generation DES are recommended over BMS.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Bilateral mammary artery grafting should be considered.</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>In patients on metformin, renal function should be carefully monitored for 2 to 3 days after coronary angiography/PCI.</td>
<td>I</td>
<td>C</td>
</tr>
</tbody>
</table>
Patient-level Pooled-Analysis of the BARI 2D, COURAGE and FREEDOM Trials
Comparative Assessment of Medical Therapy, PCI, or CABG on Clinical Outcomes in Diabetic Patients with Stable CAD According Angiography and LV Function

GBJ Mancini, ME Farkouh, BR Chaitman, WE Boden, RL Frye, PM Hartigan, H Vlachos, FS Siami, MS Sidhu, VA Bittner, V Fuster, MM Brooks

AHA Annual Scientific Sessions, Orlando 2015
Patients with T2DM and SIHD:

- All comparisons between OMT and PCI + OMT were neutral.

- CABG + OMT compared with PCI + OMT reduced the risk of the primary composite of death, MI or stroke by 35%.

- These results were noted especially in patients with 2- and 3-vessel disease, whether the pLAD was involved or not and with preserved EF.

- There was a strong indication of similar benefit with 1-vessel/LAD disease or with EF < 50%.
Future For PCI / CABG – OMT ADHERENCE

2. CV Drugs Underuse - Polypill, 2ary Prevention.

FOCUS 1 & 2
Argentina
Brazil
Paraguay
Italy
Spain

FREEDOM
AETNA-DIABETES
SECURE-EC 2015

**Approved in 22 Countries**

Am. H J 2011;162:811
JACC, 2014; 64:2071

* Valentín Fuster (inventor)
### 2a. Adherence for Risk Factor Control?

**Risk Factors - Proportion of Participants at Goal % – 1 year**

<table>
<thead>
<tr>
<th>Trials</th>
<th>LDL</th>
<th>SBP</th>
<th>DBP</th>
<th>Hb A1C</th>
<th>Meet Goals Base</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>BARI-2D</td>
<td>75</td>
<td>56</td>
<td>70</td>
<td>52</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>COURAGE</td>
<td>51</td>
<td>55</td>
<td>55</td>
<td>59</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>FREEDOM</td>
<td>55</td>
<td>63</td>
<td>53</td>
<td>55</td>
<td>12</td>
<td>20</td>
</tr>
</tbody>
</table>

Freedom, Bari-2D, Courage Investigators, JACC 2013; 61:1607
PURE (S Yusuf et al.) Lancet 2011; Aug 28 - Poor Countries, 7% !!!
NHANES, AHA, NHLBI-JNC-7, NHLBI-NCEP – Significant < Adherence
P Muntner, V Fuster et al., AHJ 2011; 161: 719 – 49 seconds !!!!
2b. Time to Major CV Event by Adherence Levels (Post-MI Study)

AETNA Commercial & Medicare Advantage Population Databases

Post- MI 1/10/10-2/28/13
N=14,119

Cumulative Incidence

Time in Months

Number at Risk:
4015 3541 2421 1510 871 438 99 0

Log-Rank p-value=.0002

PDC < 40%
PDC 40-79%
PDC >= 80%
2c. SECURE / Visiting Schema

INDEX EVENT

0
Informed Consent
Labs
Blood Pressure
Adherence
QoL
Medication Supply

6m
Telephone Follow Up
Outcomes

12m
1st visit
Labs
Blood Pressure
Adherence
Outcomes
Medication Supply

18m
Telephone Follow Up
Outcomes

24m
2nd visit
Labs
Blood Pressure
Adherence
Outcomes
QoL

END OF FOLLOW UP
Revascularization for Coronary Artery Disease

OMT vs PCI vs CABG

1980’s. LMD, The Rule of 2 / 3 – CABG
- Moderate < LVEF
- Severe Ischemia
- 3 Vessel Disease
  2vd + pLAD

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CABG & OMT Evolving Again?

Microcirculation & OMT+Adherence

ACC - New York, Dec. 11, 2015  No Disclosures
CABG Versus PCI
Greater Benefit in Long-Term Outcomes With Multiple Arterial Bypass Grafting

Robert H. Habib, PhD,*‡ Kamellia R. Dimitrova, MD,§ Sanaa A. Badour, MD,† Maroun B. Yammine, MD,† Abdul-Karim M. El-Hage-Sleiman, MD,† Darryl M. Hoffman, MD,§ Charles M. Geller, MD,§ Thomas A. Schwann, MD,‖ Robert F. Tranbaugh, MD§

The Choice of Conduits in Coronary Artery Bypass Surgery

Mario Gaudino, MD,*† David Taggart, PhD,‡ Hisayoshi Suma, MD,§ John D. Puskas, MD,‖ Filippo Crea, MD,† Massimo Massetti, MD†
In the FAME study, FFR-guided PCI improved outcome compared with angiography-guided PCI for up to 2 years of follow-up. The aim in this study was to investigate whether the favourable clinical outcome with the FFR-guided PCI in the FAME study persisted over a 5-year follow-up. The results confirm the long-term safety of FFR-guided PCI in patients with multivessel disease. A strategy of FFR-guided PCI resulted in a significant decrease of major adverse cardiac events for up to 2 years after the index procedure. From 2 years to 5 years, the risks for both groups developed similarly. This clinical outcome in the FFR-guided group was achieved with a lower number of stented arteries and less resource use. These results indicate that FFR guidance of multivessel PCI should be the standard of care in most patients.

FAME (LX van Nunen et al.), The Lancet 2015; 386:1853
1. Blood flow across a coronary stenosis during maximum vasodilation, divided by expected blood flow in its absence.

2. Measured with pressure sensors as the ratio of distal coronary to aortic pressure during maximum vasodilation, and expressed as %.

3. FFR of less than 75% is highly correlated with ischaemia.

4. FFR of 75-80% is the grey zone and might be associated with ischaemia and predictive of need for revascularization.

5. FFR of less than 80% was regarded as significant in FAME and treated with coronary stenting.

*FAME (LX van Nunen et al., The Lancet 2015; 386:1853)*