Revascularization in Multivessel CAD
PCI vs. CABG

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7-year Survival in BARI Trial

BARI Investigators. NEJM 1996 and JACC 2000
Clinical alert to physicians by the NHLBI (National Heart, Lung and Blood Institute)

- CABG is the better revascularization alternative in diabetic patients with multivessel disease suitable for both PTCA and CABG

However
Revascularization trends before and after BARI

Clinical Alert 9/21/1995
Manuscript Published 7/25/1996

BARI-eligible Diabetic Patients Undergoing PTCA (%)

- Overall
- 2-Vessel
- 3-Vessel

* trends = NS

Surgical Technique
- Arterial grafts, Off pump etc.

PCI Technique
- BMS, DES, Adjunct pharmacology

Medical Treatment
- Statins, Antihypertensives, Antidiabetics, Antiplatelets etc.
ארועים חודשים לآثار רוסקולהידיזציה魔王חת
PCI or CABG

בטוח הקצר - כשנה
PCI

רסטנוזיס / טרומבוזיס ארוהי

 narzędzi

טסימת שלט לארחר ניתוח

בטוח הארוך
CABG

כשלון מעקפה לארחר

פרוגרסיה של הטרשת
Disease progression in non-stented lesions causes most late CV events

N = 1228 in 2nd-generation coronary stent trials*

*Non-drug eluting stents

اورוים ח避けים לאחר רוסקולהידיציה מצלחת PCI or CABG

בשעות הקצר - כשב PCI

רגוטנואים / טרומבוזים אחריה

הסימת שלול לאחר הניתו

בשעות הארוכ

CABG כשלים מעקפים לאחר

פרוגרסיה של התרסות

המשמעויות毕竟是 לאזור האזור – סיפול תרופתי
CABG vs. PCI: Randomized Trial Results Summary

- CABG has NO clear death/MI benefit over PCI in patients suitable for either
- CABG historically showed benefit over PCI in repeat revascularization

### Superior Treatment Modality

<table>
<thead>
<tr>
<th>Trial</th>
<th>Mortality &amp; MI</th>
<th>Angina Relief</th>
<th>Repeat Revascularization</th>
</tr>
</thead>
<tbody>
<tr>
<td>GABI</td>
<td>PCI</td>
<td>PCI</td>
<td>CABG</td>
</tr>
<tr>
<td>EAST</td>
<td>No difference</td>
<td>CABG</td>
<td>CABG</td>
</tr>
<tr>
<td>RITA</td>
<td>No difference</td>
<td>CABG</td>
<td>CABG</td>
</tr>
<tr>
<td>ERACI</td>
<td>No difference</td>
<td>CABG</td>
<td>CABG</td>
</tr>
<tr>
<td>CABRI</td>
<td>No difference</td>
<td>CABG</td>
<td>CABG</td>
</tr>
<tr>
<td>BARI</td>
<td>No difference</td>
<td>n/a</td>
<td>CABG</td>
</tr>
<tr>
<td>MASS-2</td>
<td>CABG (MI)</td>
<td>n/a</td>
<td>CABG</td>
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<tr>
<td>AWESOME</td>
<td>No difference</td>
<td>No difference</td>
<td>CABG</td>
</tr>
<tr>
<td>ERACI-2</td>
<td>PCI</td>
<td>n/a</td>
<td>CABG</td>
</tr>
<tr>
<td>SoS</td>
<td>CABG (Mortality)</td>
<td>CABG</td>
<td>CABG</td>
</tr>
<tr>
<td>ARTS</td>
<td>No difference</td>
<td>n/a</td>
<td>CABG</td>
</tr>
</tbody>
</table>

### Source references listed in appendix
5 year Mortality of CABG vs. PCI: a collaborative analysis of individual patient data from ten randomised trials

Relative risk CABG vs. CABG

- Non diabetics: $0.98 (0.86 - 1.12)$
- Diabetics: $0.70 (0.56 – 0.87)$
- Interaction p value: $0.014$

Mortality of CABG vs. PCI: a collaborative analysis of individual patient data from ten randomised trials

Excluding BARI patients

Proximal Triple Vessel Disease in a Diabetic Patient
Standard therapy – CABG with 3 grafts

Advantage: Protection from MI and death from new lesions
Coronary Revascularization in Patients with Multivessel Disease – Registry Data

3,220 Patients Duke UMC

Unadjusted Survival (%)

Years after revascularization

- Nondiabetics CABG
- Diabetics CABG
- Nondiabetics PTCA
- Diabetics PTCA

No DM
88 86

DM
76 74

Barsness: Circulation, 1998
Randomized Trials and Registries

Cardiac Catheterization Result

Willing to Randomize?

Yes
Unclear what is best for my patient

No
I know what is best for my patient!

Selection bias

Registry

CABG

PCI

Physician’s decision is a major un-adjustable confounding factor
New-York Revascularization Registry

- **Included:**
  - New York residents with multivessel coronary artery disease

- **Excluded:**
  - previous revascularization, left main disease, acute myocardial infarction

- The study group comprised:
  - 37,212 - CABG
  - 22,102 - PCI

Hannan et al. NEJM 2005, 352:2174-2183
### Baseline Criteria

#### Double Vessel Disease:
- **PCI** - 17770
- **CABG** - 11424

####Triple Vessel Disease:
- **PCI** - 4331
- **CABG** - 25788

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stenting (N=271,002)</th>
<th>CABG (N=177,313)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic characteristics</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age (% of patients)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20 yr</td>
<td>11.7</td>
<td>7.3</td>
<td></td>
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<tr>
<td>20–34 yr</td>
<td>22.3</td>
<td>19.7</td>
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<tr>
<td>35–49 yr</td>
<td>20.0</td>
<td>16.7</td>
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<tr>
<td>50–64 yr</td>
<td>27.3</td>
<td>33.9</td>
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<tr>
<td>65–74 yr</td>
<td>19.8</td>
<td>13.8</td>
<td></td>
</tr>
<tr>
<td>Median age (yr)</td>
<td>65</td>
<td>67</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex (% of patients)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male</td>
<td>68.5</td>
<td>76.0</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>31.5</td>
<td>24.0</td>
<td></td>
</tr>
<tr>
<td>Hispanic ethnicity (% of patients)</td>
<td>6.3</td>
<td>5.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Race (% of patients)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
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<tr>
<td>White</td>
<td>87.0</td>
<td>85.2</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>6.4</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3.7</td>
<td>5.3</td>
<td></td>
</tr>
<tr>
<td>Coexisting conditions or other risk factors</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ejection fraction (% of patients)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&lt;20%</td>
<td>0.7</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>20–29%</td>
<td>3.1</td>
<td>7.3</td>
<td></td>
</tr>
<tr>
<td>30–39%</td>
<td>3.0</td>
<td>14.9</td>
<td></td>
</tr>
<tr>
<td>≥40%</td>
<td>81.3</td>
<td>74.1</td>
<td></td>
</tr>
<tr>
<td>Data missing</td>
<td>6.3</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Median ejection fraction (%)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>16.8</td>
<td>16.8</td>
<td></td>
</tr>
<tr>
<td>1–7 days</td>
<td>22.8</td>
<td>16.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥8 days</td>
<td>4.6</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>4.4</td>
<td>4.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>1.4</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>No. of diseased vessels (% of patients)</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2</td>
<td>80.4</td>
<td>30.7</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>19.6</td>
<td>93.3</td>
<td></td>
</tr>
</tbody>
</table>

*Because of rounding, percentages may not total 100. To convert values for creatinine to micromoles per liter, multiply by 83.4.

† Diseased vessels were defined by the presence of stenosis of at least 70 percent.
NY Registry: Patients with Double Vessel Disease - Survival

Unadjusted data: 2 vessel CAD:
- Advantage of PCI over CABG without LAD involvement
- Similar PCI and CABG outcome with proximal LAD

However
- Groups are different and statistical adjustment is required
NY Registry: Survival of Patients with Double Vessel Disease

- What is more relevant for the clinician?
  - Unadjusted data?
    - Reflects real life outcome with intelligent decision making by treating physicians
  - Adjusted data?
    - Limited by the residual effect of hidden confounders
During the present decade, major developments in CABG (e.g. off-pump technique, less invasive approach, increased arterial revascularization and optimal perioperative care).

In PCI (e.g. improved technique, stent design, guide wires, anti-platelet therapy, and drug-eluting stents) have made it important to reassess the respective values of the two revascularization techniques in an all-comers population as seen by the surgeon and the interventional cardiologist in their daily practice.
SYNTAX Eligible Patients

De novo disease

Limited Exclusion Criteria
- Previous interventions
- Acute MI with CPK > 2x
- Concomitant cardiac surgery

Left Main Disease
(isolated, +1, +2 or +3 vessels)

3 Vessel Disease
(revasc all 3 vascular territories)
Patient Profiling – SYNTAX Score

The SYNTAX score is used to quantify the complexity of coronary artery disease. It is based on the SYNTAX score, which evaluates the anatomy of the coronary arteries. The SYNTAX score ranges from 1 to 40, with higher scores indicating more complex anatomy. The SYNTAX score is used to guide the decision between medical therapy and percutaneous coronary intervention (PCI) for patients with coronary artery disease.

- **BARI classification of coronary segments**
  - Leaman score, Circ 1981;63:285-299

- **Lesions classification ACC/AHA**, Circ 2001;103:3019-3041

- **Bifurcation classification**, CCI 2000;49:274-283

- **CTO classification**, J Am Coll Cardiol 1997;30:649-656

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The SYNTAX score is calculated based on the following parameters:

- **Calcification**
- **Thrombus**
- **Bifurcation**
- **Tortuosity**
- **Dominance**
- **Location of lesion**
- **No. of vessels**
- **Left Main**
- **3 Vessel**
- **CTO**

The SYNTAX score is higher for lesions with more complex anatomy, which may indicate the need for more invasive procedures to achieve revascularization.
There is ‘3-vessel disease’ and ‘3-vessel disease’

**Patient 1**

- LCx: 70–90%
- LAD: 70–90%
- RCA2: 70–90%
- RCA3: 70–90%
- SYNTAX SCORE: 21

**Patient 2**

- LM: 99%
- LAD: 99%
- LCx: 100%
- RCA: 100%
- SYNTAX SCORE: 52
SYNTAX Trial Design

Heart Team (surgeon & interventionalist)

Amenable for both treatment options
Amenable for only one treatment approach

Stratification: LM and Diabetes

Randomized Arms
N=1800
- CABG N=897 vs. TAXUS N=903
  - DM 28.5%, Non DM 71.5%
  - DM 28.2%, NonDM 71.8%

Two Registry Arms
N=1275
- CABG N=1077
- PCI N=198

62 EU Sites + 23 US Sites

112 US Sites
62 EU Sites

SYNTAX Trial Design

TAXUS Express
MACCE is defined as:

- All cause Death
- Cerebrovascular Accident (CVA/Stroke)
- Documented Myocardial Infarction (ARC definition)
- Any Repeat Revascularization (PCI and/or CABG)
- All events CEC Adjudicated

*ARC MACCE definition Circ 2007; 115:2344–2351
## Patient Characteristics (I)

### Randomized Cohort

<table>
<thead>
<tr>
<th></th>
<th>CABG N=897</th>
<th>TAXUS N=903</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean ± SD (y)</strong></td>
<td>65.0 ± 9.8</td>
<td>65.2 ± 9.7</td>
<td>0.55</td>
</tr>
<tr>
<td><strong>Male, %</strong></td>
<td>78.9</td>
<td>76.4</td>
<td>0.20</td>
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<tr>
<td><strong>BMI, mean ± SD</strong></td>
<td>27.9 ± 4.5</td>
<td>28.1 ± 4.8</td>
<td>0.37</td>
</tr>
<tr>
<td><strong>Diabetes, %</strong></td>
<td>28.5</td>
<td>28.2</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>Hypertension, %</strong></td>
<td>77.0</td>
<td>74.0</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Hyperlipidemia, %</strong></td>
<td>77.2</td>
<td>78.7</td>
<td>0.44</td>
</tr>
<tr>
<td><strong>Current smoker, %</strong></td>
<td>22.0</td>
<td>18.5</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Prior MI, %</strong></td>
<td>33.8</td>
<td>31.9</td>
<td>0.39</td>
</tr>
<tr>
<td><strong>Unstable angina, %</strong></td>
<td>28.0</td>
<td>28.9</td>
<td>0.67</td>
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<tr>
<td><strong>Additive EuroSCORE, mean ± SD</strong></td>
<td>3.8 ± 2.7</td>
<td>3.8 ± 2.6</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Total Parsonnet score, mean ± SD</strong></td>
<td>8.4 ± 6.8</td>
<td>8.5 ± 7.0</td>
<td>0.76</td>
</tr>
</tbody>
</table>
# Patient Characteristics (II)

## Randomized Cohort

<table>
<thead>
<tr>
<th></th>
<th>CABG N=897</th>
<th>TAXUS N=903</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient-based</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total SYNTAX Score</td>
<td>29.1 ±11.4</td>
<td>28.4 ±11.5</td>
<td>0.19</td>
</tr>
<tr>
<td>Diffuse disease or small vessels, %</td>
<td>10.7</td>
<td>11.3</td>
<td>0.69</td>
</tr>
<tr>
<td>No. lesions, mean + SD</td>
<td>4.4 ±1.8</td>
<td>4.3 ±1.8</td>
<td>0.44</td>
</tr>
<tr>
<td>3VD only, %</td>
<td>66.3</td>
<td>65.4</td>
<td>0.70</td>
</tr>
<tr>
<td>Left main, any, %</td>
<td>33.7</td>
<td>34.6</td>
<td>0.70</td>
</tr>
<tr>
<td>Left Main only</td>
<td>3.1</td>
<td>3.8</td>
<td>0.46</td>
</tr>
<tr>
<td>Left Main + 1 vessel</td>
<td>5.1</td>
<td>5.4</td>
<td>0.78</td>
</tr>
<tr>
<td>Left Main + 2 vessel</td>
<td>12.0</td>
<td>11.5</td>
<td>0.72</td>
</tr>
<tr>
<td>Left Main + 3 vessel</td>
<td>13.5</td>
<td>13.9</td>
<td>0.78</td>
</tr>
<tr>
<td>Total occlusion, %</td>
<td>22.2</td>
<td>24.2</td>
<td>0.33</td>
</tr>
<tr>
<td>Bifurcation, %</td>
<td>73.3</td>
<td>72.4</td>
<td>0.67</td>
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<tr>
<td>Trifurcation, %</td>
<td>10.6</td>
<td>10.7</td>
<td>0.92</td>
</tr>
</tbody>
</table>
### Procedural Characteristics

**PCI Randomized Cohort**

<table>
<thead>
<tr>
<th>Patient-based</th>
<th>TAXUS N=903</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staged procedure, %</td>
<td>14.1</td>
</tr>
<tr>
<td>Lesions treated/pt, mean + SD</td>
<td>3.6 ± 1.6</td>
</tr>
<tr>
<td>No. stents implanted, mean + SD</td>
<td>4.6 ± 2.3</td>
</tr>
<tr>
<td>Total length implanted, mm + SD</td>
<td>86.1 ± 47.9</td>
</tr>
<tr>
<td>Range, mm</td>
<td>8 – 324</td>
</tr>
<tr>
<td>Long stenting (&gt;100 mm), %</td>
<td>33.2</td>
</tr>
</tbody>
</table>
## Procedural Characteristics

### CABG Randomized Cohort

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off-pump surgery, %</td>
<td>15.0</td>
</tr>
<tr>
<td>Graft revascularization, %</td>
<td></td>
</tr>
<tr>
<td>At least one arterial graft</td>
<td>97.3</td>
</tr>
<tr>
<td>Arterial graft to LAD</td>
<td>95.6</td>
</tr>
<tr>
<td>LIMA+venous</td>
<td>78.1</td>
</tr>
<tr>
<td>Double LIMA/RIMA</td>
<td>27.6</td>
</tr>
<tr>
<td>Complete arterial revascularization</td>
<td>18.9</td>
</tr>
<tr>
<td>Radial artery</td>
<td>14.1</td>
</tr>
<tr>
<td>Venous graft only</td>
<td>2.6</td>
</tr>
<tr>
<td>Grafts per patient, mean ± SD</td>
<td>2.8 ± 0.7</td>
</tr>
<tr>
<td>Distal anastomosis/pt, mean ± SD</td>
<td>3.2 ± 0.9</td>
</tr>
</tbody>
</table>

CABG N=897
All-Cause Death to 12 Months

Event Rate + 1.5 SE. *Fisher’s Exact Test

ITT population
CVA to 12 Months

ITT population

P = 0.003*

Event Rate + 1.5 SE. *Fisher’s Exact Test

CABG (N=897)  
TAXUS (N=903)
Myocardial Infarction to 12 Months

Event Rate + 1.5 SE. *Fisher’s Exact Test

ITT population

CABG (N=897) TAXUS (N=903)

$P=0.11^*$
All-Cause Death/CVA/MI to 12 Months

\[ P = 0.98^* \]

Event Rate + 1.5 SE. *Fisher’s Exact Test

ITT population

CABG (N=897)  
TAXUS (N=903)
Symptomatic Graft Occlusion & Stent Thrombosis to 12 Months

- **CABG (N=897)**
- **TAXUS (N=903)**

\[ P = 0.89 \]

<table>
<thead>
<tr>
<th>Patients (%)</th>
<th>CABG</th>
<th>TAXUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>27</td>
<td>28</td>
</tr>
<tr>
<td>Rate (%)</td>
<td>3.4</td>
<td>3.3</td>
</tr>
</tbody>
</table>

ITT population
Repeat Revascularization to 12 Months

**CABG (N=897)**

- PCI Group: 4.7%
- CABG Group: 1.3%

**TAXUS (N=903)**

- PCI Group: 11.4%
- CABG Group: 2.8%

*P<0.0001*

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Event Rate + 1.5 SE. *Fisher’s Exact Test

ITT population
MACCE to 12 Months – Study Endpoint

\[ P = 0.0015^* \]

\begin{align*}
\text{CABG (N=897)} & \quad \text{TAXUS (N=903)} \\
12.1\% & \quad 17.8\% \\
12.1\% & \quad 17.8\%
\end{align*}

Event Rate + 1.5 SE. *Fisher’s Exact Test

ITT population
SYNTAX Trial Design

62 EU Sites + 23 US Sites

Total enrollment
N=3075

Stratification: LM and Diabetes

Randomized Arms
N=1800

CABG
N=897 vs. TAXUS*
N=903

Two Registry Arms

CABG
N=1077

PCI
N=198

*TAXUS Express
Reasons for Registry Allocation

PCI Registry– CABG ineligible due to:
- Co-morbidities (70.7%)
- No graft material (9.1%)
- Small or poor quality of distal vessel (1.5%)
- Patient refused CABG (5.6%)
- Other (13.1%)

CABG Registry– PCI ineligible due to:
- Complex anatomy (70.9%)
- Untreatable CTO (22.0%)
- Unable to take anti-platelet medications (0.9%)
- Patient refused PCI (0.5%)
- Other (5.7%)
## Procedural Characteristics

### Notable Differences: PCI RCT + Registry

<table>
<thead>
<tr>
<th></th>
<th>TAXUS RCT*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=903</td>
</tr>
<tr>
<td>Staged Procedure, %</td>
<td>14.1</td>
</tr>
<tr>
<td>Bi/trifurcation lesions treated, %</td>
<td>24.8</td>
</tr>
<tr>
<td>Lesions treated, mean±SD</td>
<td>3.6±1.6</td>
</tr>
<tr>
<td>Stents implanted, mean±SD</td>
<td>4.6±2.3</td>
</tr>
<tr>
<td>Total length implanted, mm</td>
<td>86.1±47.9</td>
</tr>
<tr>
<td>Range, mm</td>
<td>8.0–324.0</td>
</tr>
<tr>
<td>Long stenting (&gt;100 mm), %</td>
<td>33.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>PCI Reg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=192</td>
</tr>
<tr>
<td>Staged Procedure, %</td>
<td>13.0</td>
</tr>
<tr>
<td>Bi/trifurcation lesions treated, %</td>
<td>64.4</td>
</tr>
<tr>
<td>Lesions treated, mean±SD</td>
<td>2.5±1.3</td>
</tr>
<tr>
<td>Stents implanted, mean±SD</td>
<td>3.1±1.8</td>
</tr>
<tr>
<td>Total length implanted, mm</td>
<td>58.5±41.2</td>
</tr>
<tr>
<td>Range, mm</td>
<td>8.0–252.0</td>
</tr>
<tr>
<td>Long stenting (&gt;100 mm), %</td>
<td>12.2</td>
</tr>
</tbody>
</table>

*For descriptive purposes only; no statistical comparisons done*
## Procedural Characteristics

### Notable Differences CABG RCT + Registry

<table>
<thead>
<tr>
<th>Procedure-related</th>
<th>CABG RCT* n=897</th>
<th>CABG Reg n=644</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off-pump surgery, %</td>
<td>15.0</td>
<td>18.6</td>
</tr>
<tr>
<td>Graft revascularization, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least one arterial graft</td>
<td>97.3</td>
<td>96.7</td>
</tr>
<tr>
<td>Arterial graft to LAD</td>
<td>95.6</td>
<td>94.7</td>
</tr>
<tr>
<td>LIMA + venous</td>
<td>78.1</td>
<td>85.1</td>
</tr>
<tr>
<td>Double LIMA/RIMA</td>
<td>27.6</td>
<td>16.1</td>
</tr>
<tr>
<td>Complete arterial revascularization</td>
<td>18.9</td>
<td>11.2</td>
</tr>
<tr>
<td>Venous graft only</td>
<td>2.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Grafts per patient, mean +SD</td>
<td>2.8 + 0.7</td>
<td>3.0 + 0.9</td>
</tr>
<tr>
<td>Distal anastomoses, mean +SD</td>
<td>3.2 + 0.9</td>
<td>3.5 + 1.0</td>
</tr>
</tbody>
</table>

*For descriptive purposes only; no statistical comparisons done*
# 12 Month MACCE Rates

**PCI Registry (N=192)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Patients (%)</th>
<th>In-Hospital MACCE</th>
<th>Randomized PCI MACCE = 17.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Death</td>
<td>7.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>4.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death/CVA/MI</td>
<td>10.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revascularization</td>
<td>12.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total MACCE</td>
<td>20.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Per-protocol population
12 Month MACCE Rates

**CABG Registry (N=644)**

### In-Hospital MACCE

- **All Death**: 2.5%
- **CVA**: 2.2%
- **MI**: 2.5%
- **Death/CVA/MI**: 6.6%
- **Revascularization**: 3.0%
- **Total MACCE**: 8.8%

Randomized CABG MACCE = 12.1

Per-protocol population
Randomized Cohort

SYNTAX Score

Nomor, வினோம், பொருந்த

 sokrat

செம்பொருள் முறற்பிடி, Sokrat (லல் ஓமெ ஆகுலோன்)
MACCE at 2 years: Low SYNTAX score (0-22)
MACCE at 2 years:
Intermediate SYNTAX score (23-32)

<table>
<thead>
<tr>
<th></th>
<th>CABG (N=300)</th>
<th>TAXUS (N=310)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean baseline SYNTAX Score</td>
<td>27.4 ± 2.8</td>
<td>27.3 ± 2.8</td>
</tr>
</tbody>
</table>

$P=0.06$
MACCE at 2 years: High SYNTAX score (> 33)

![Graph showing cumulative event rate over time for CABG and TAXUS groups. The graph includes a table showing mean baseline SYNTAX scores: CABG 41.5 ± 7.1 and TAXUS 41.7 ± 7.8. There is a p-value of <0.001 indicating statistical significance. The cumulative event rates at 24 months are 15.4% for CABG and 28.2% for TAXUS.](image)
SYNTAX: 12 months MACE Rate
Superiority of CABG increases with increase in metabolic abnormality

![Graph showing MACE rate by metabolic abnormality](image_url)
מסקנה

הבדל בנתונים לטוב שCABG ייחר מודגש כל ש

SYNTAX החומרה האנטומיות של המחללה הכלילית קשה ייחר

Score

הפרעה המטבולית של החולה (טסמון מטבולית, סוכרת

וכו) קשה ייחר

הסבר קשור בכך שליניות מעקפים (לא לא PCI) שיש אפקט

мен מפלת התוזאת הקשהה בתוקף המחללה והטרשטי

היצורים פורוקסמיים לאנסטומוזה

מדגיש את הצור 돌아ף תרופתי אינטנסיבי למחלל החולים

הנckiים לורוסקולרייזת
MACCE to 12 Months – Study Endpoint

CABG (N=897)    TAXUS (N=903)

ITT population

Event Rate + 1.5 SE. *Fisher’s Exact Test

FFR-guided
MACE = 13.2%

Angio-guided (Standard)
MACE = 18.4%
הארכיון לדיה כלילית
אנטומיה או פונקציה?
היפורדה

ה настоящה / נזק בקושר ל PCI הוא תוצאת של
שוי משקל בין

מגיעה נזק הקושר לאיסכמייה הגנרטית כתוצרה
מנוכחות הגנרטות

نزק הגנרט כתוצרת מסיבוכי פעולות

מידיות ומאוזרות יוצר

הⵔחבת יצירותי שעינן גורמת לחרפת

ברירהaina מומלצת

DEFER מתקר
Fractional Flow Reserve in Clinical Practice

REST

HYPERMIA

Crossing the lesion

Distal to the lesion

FFR = 58/112 = 0.52
FFR threshold for ischemia

FFR < 0.75 → inducible ischemia (spec. 100 % )
FFR > 0.75 → no inducible ischemia (sens. 90 % )

Pijls, De Bruyne et al, NEJM 1996
Diameter Stenosis versus FFR

- Diameter stenosis is the main determinant of coronary stenosis

However

- Resistance is also influenced by lesion length and the 3D morphology of the stenosis

- Anatomical assessment is not accurate enough to determine physiological significance
- Coronary angiography provides only the anatomical data
FAME study: **HYPOTHESIS**

**FFR** guided Percutaneous Coronary Intervention (PCI) in multivessel disease, is superior to current angiography guided PCI.
Angiography-guided PCI

Indicate all stenoses $\geq 50\%$ considered for stenting

Randomization

Patient with stenoses $\geq 50\%$ in at least 2 of the 3 major epicardial vessels

Stent all indicated stenoses

FLOW CHART

FFR-guided PCI

Measure FFR in all indicated stenoses

Stent only those stenoses with FFR $\leq 0.80$

1-year follow-up

Patient with stenoses $\geq 50\%$ in at least 2 of the 3 major epicardial vessels

Indicate all stenoses $\geq 50\%$ considered for stenting

Randomization

Angiography-guided PCI

Stent all indicated stenoses
## FAME study: Baseline Characteristics (2)

<table>
<thead>
<tr>
<th></th>
<th>ANGIO-group N=496</th>
<th>FFR-group N=509</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td># indicated lesions per patient</td>
<td>2.7±0.9</td>
<td>2.8±1.0</td>
<td>0.34</td>
</tr>
<tr>
<td>Reference diameter (mm)</td>
<td>2.5±0.6</td>
<td>2.5±0.7</td>
<td>0.81</td>
</tr>
<tr>
<td>% stenosis severity</td>
<td>61±17</td>
<td>60±18</td>
<td>0.24</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>1.0±0.4</td>
<td>1.0±0.5</td>
<td>0.35</td>
</tr>
<tr>
<td>50-70% narrowing, No (%)</td>
<td>550 (41)</td>
<td>624 (44)</td>
<td>-</td>
</tr>
<tr>
<td>70-90% narrowing, No (%)</td>
<td>553 (41)</td>
<td>530 (37)</td>
<td>-</td>
</tr>
<tr>
<td>90-99% narrowing, No (%)</td>
<td>207 (15)</td>
<td>202 (14)</td>
<td>-</td>
</tr>
<tr>
<td>Total occlusion, No (%)</td>
<td>40 (3)</td>
<td>58 (4)</td>
<td>-</td>
</tr>
<tr>
<td>Patients with ≥1 total occlusion (%)</td>
<td>7.5</td>
<td>10.6</td>
<td>0.08</td>
</tr>
</tbody>
</table>
## FAME study: Procedural Results (1)

<table>
<thead>
<tr>
<th># indicated lesions per patient</th>
<th>ANGIO-group N=496</th>
<th>FFR-group N=509</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions succesfully measured, No (%)</td>
<td>-</td>
<td>1329 (98%)</td>
<td>-</td>
</tr>
<tr>
<td>Lesions with FFR ≤ 0.80 ,No (%)</td>
<td>-</td>
<td>874 (63%)</td>
<td>-</td>
</tr>
<tr>
<td>Lesions with FFR &gt; 0.80 ,No (%)</td>
<td>-</td>
<td>513 (37%)</td>
<td>-</td>
</tr>
</tbody>
</table>

### FFR results

- ANGIO: 2.7 ± 0.9
- FFR: 2.8 ± 1.0

- P-value: 0.34
# FAME study: Procedural Results (1)

<table>
<thead>
<tr>
<th></th>
<th>ANGIO-group</th>
<th>FFR-group</th>
<th>P-value</th>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td>2.8 ± 1.0</td>
<td>0.34</td>
</tr>
<tr>
<td>FFR results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesions succesfully measured, No (%)</td>
<td>-</td>
<td>1329 (98%)</td>
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<tr>
<td>Lesions with FFR &gt; 0.80 ,No (%)</td>
<td>-</td>
<td>513 (37%)</td>
<td></td>
</tr>
<tr>
<td>stents per patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesions succesfully stented (%)</td>
<td>92%</td>
<td>94%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DES, total, No</td>
<td>1359</td>
<td>980</td>
<td></td>
</tr>
</tbody>
</table>
**FAME study: Event-free Survival**

Absolute difference in MACE-free survival

- **30 days:** 2.9%
- **90 days:** 3.8%
- **180 days:** 4.9%
- **360 days:** 5.3%

Days since Randomization

Survival Free of MACE
SYNTAX: MACCE to 12 Months – Study Endpoint

- ITT population

**CABG** (N=897)

**TAXUS** (N=903)

Event Rate + 1.5 SE. *Fisher’s Exact Test

**P=0.0015**

- Cumulative Event Rate (%)
  - **CABG**: 12.1%
  - **TAXUS**: 17.8%

- Months Since Allocation
  - **CABG**: 5.7%
  - **TAXUS**: 12.1%
המחקר הנמצא בתוכנו: PCI vs. CABG

_PCI_

VertexAttrib
toch שימשו בסטנטים המוצפים מהדור החדש PCI, בתוכנו שימשו לирующוסקוקליריזיה כירורגית עijkeת CABG – שימשו נרחב בирующוסקוקליריזיה ist session FFR bevashר לирующוסקוקליריזיה כירורגית
Mode of revascularization in a specific patient is determined by:

- Physician’s preference (clinical judgment)
  - Age, coronary anatomy, LV function, Comorbidities
  - Clinical trials results
    - Registry and randomized trials
- Patient’s preference
- Physicians will rarely follow recommendations that are against their clinical judgment
תודה