Advances in Cardiovascular Diagnosis and Therapy

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No disclosure or conflicts

Outline

• What is new with revascularization?
  • Bypass surgery (CABG) versus coronary stents (PCI)
  • Meds Vs. PCI
• Examples of complex PCI
Coronary Artery Disease

• Heart disease is the #1 killer in the US
• We are diagnosing heart disease more frequently due to better testing, improved sensitivity and increased awareness
• As a nation, we have too much obesity and lack of physical activity, risk factors for the development of coronary artery disease
How do we best treat heart disease?

- Medical therapy?
- Coronary stents (PCI)?
- Bypass surgery (CABG)?

CABG & PCI: Historical Pro & Cons

<table>
<thead>
<tr>
<th>CABG Pros</th>
<th>PCI Pros</th>
<th>CABG Cons</th>
<th>PCI Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angina relief</td>
<td>Cost effective</td>
<td>High costs</td>
<td>Fast recovery</td>
</tr>
<tr>
<td>Reduced re-intervention</td>
<td>Reduced acute complications</td>
<td>Invasive</td>
<td>Increased restenosis</td>
</tr>
<tr>
<td>Complete revascularization</td>
<td>Repeat revascularization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The pros and cons of CABG historically outweighed those of PCI.
Evolution of Revascularization

- Improved technique
- Improved stent design
- DES
- Increased restenosis
- Repeat revascularization

Off pump technique
Less invasive approach
Increased arterial revascularization
Optimal perioperative monitoring
- High costs
- Invasive
- Recovery time

Over the last decade, the standard of care for both CABG and PCI has continuously improved, leveling the playing field.

CABG vs PCI Trials
Results Summary

Superior Treatment Modality

<table>
<thead>
<tr>
<th>Trial</th>
<th>Clinical Parameters</th>
<th>Repeat Revascularization</th>
<th>Cost Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAST</td>
<td>No difference</td>
<td>CABG</td>
<td>n/a</td>
</tr>
<tr>
<td>RITA</td>
<td>No difference</td>
<td>CABG</td>
<td>n/a</td>
</tr>
<tr>
<td>ERACI</td>
<td>No difference</td>
<td>CABG</td>
<td>n/a</td>
</tr>
<tr>
<td>CABRI</td>
<td>No difference</td>
<td>CABG</td>
<td>n/a</td>
</tr>
<tr>
<td>RARI</td>
<td>No difference</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>MASS-2</td>
<td>CARG</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>AWESOME</td>
<td>No difference</td>
<td>CARG</td>
<td>n/a</td>
</tr>
<tr>
<td>ERACI-2</td>
<td>PCI</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Significant decrease of revascularization expected with DES

Mean stent length [mm]

… expanding lesion & procedural complexity with randomized trials
Syntax Overall Study Goal

- To provide real-world answers to these questions in order to develop new guidelines for the beginning of the 21st century. This goal requires a novel study approach:
  - allcomer study instead of highly selected patient population
  - consensus physician decision (surgeon & cardiologist) instead of inclusion & exclusion criteria
  - nested registry for CABG only and PCI only patients to capture patient characteristics and outcomes

Eligible Study Population

Question of optimal treatment approach?

new disease

- Isolated left main
- left main + 1-vessel disease
- left main + 2-vessel disease
- left main + 3-vessel disease

- Previous interventions (PCI or CABG) excluded
- Acute MI with CK>2x
- Concomitant valve surgery

Patient Flow

Screening: Patients with de novo 3-vessel disease and/or left main disease

Registration: Local Heart Team (surgeon and interventionalist)

Multi-center randomized controlled trial

Randomize 1500 patients

- TAXUS DES non inferior to CABG for 12 months binary MACCE rate

Registries

- define CABG only population (2750 pts)
- define PCI only population (50 pts)
- Establish profiles of non randomizable patients and their outcomes
**Follow Up and Data Collection**

- Multi-center randomized controlled trial
  - PCI: 750 pts
  - CABG: 750 pts
- Registries
  - CABG only: 750 pts
  - PCI only: <50 pts
- Post-allocation/procedure to 5 years
- MACCE
- Baseline data
- Follow Up and Data Collection
- QOL & Costs
  - Baseline to 5 years

**SYNTAX Results- 1 Year**

<table>
<thead>
<tr>
<th>End Point</th>
<th>CABG</th>
<th>Stent</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revascularization</td>
<td>5.9%</td>
<td>13.7%</td>
<td>0.001</td>
</tr>
<tr>
<td>Death/MI/Stroke</td>
<td>7.6%</td>
<td>7.7%</td>
<td>NS</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.2%</td>
<td>0.6%</td>
<td>0.001</td>
</tr>
<tr>
<td>MI</td>
<td>3.2%</td>
<td>4.8%</td>
<td>NS</td>
</tr>
</tbody>
</table>

**The Bottom Line**

- Choice between CABG and PCI is complex, and depends on patient factors as well as technical considerations
- CABG tends to have less revascularization
- There is no "one size fits all" approach
- Discussion regarding the pro's and cons of each approach is important
**COURAGE Trial**

*The Revenge of the Clinical Cardiologist*

**Interventionalists**

**Vs.**

**Clinical Cardiologists**

**Courage trial**

- **Population:** 2287 pts with objective evidence of myocardial ischemia and significant CAD
- **Primary end point:** death and non-fatal MI
- **Results:**
  - PCI showed no benefit in the primary end point vs. medical therapy (19% vs. 18.5%, \( p=0.62 \))
  - PCI showed a significant benefit in angina relief at 1 and 3 years, that was not sustained at 5 years
32,468 (91.4%) patients were excluded:
- 8,677 did not meet inclusion criteria
- 5,155 had undocumented ischemia
- 3,961 due to vessel anatomy
- 6,554 were excluded for logistic reasons
- 18,360 had one or more exclusions
  - 4,513 had undergone recent (<6 mo) revascularization
  - 4,939 had inadequate EF
  - 2,987 had contraindication to PCI
  - 2,542 had a serious coexisting illness
  - 1,285 had concomitant valvular disease
  - 1,203 had class IV angina
  - 1,071 had a failure of medical therapy
  - 947 had LM stenosis >50%
  - 722 had only PCI restenosis (no new lesion)
  - 528 had complications after MI

Highly selected study population!

Limitations: Enrollment

- 15.7% of patients randomized to PCI were not treated or did not complete follow-up vs. 8.5% of the patients assigned to OMT who were lost to follow-up.
- Trial design projection: no more than 10% of OMT patients would cross over to PCI.
- Reality: 25.5% of OMT crossed over to PCI but their outcome was evaluated as they were on drug therapy only (intention-to-treat principle).
- For various reasons, 4% of the PCI patients were not treated with an intervention but their outcome was evaluated as they were (intention-to-treat principle).

Limitations: End point choice

All cause death was a wrong endpoint (it should have been cardiac death!)

Critical point: crossover to PCI
### Limitations: Compliance to Medical Tx

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Aspirin</th>
<th>Statins</th>
<th>Beta Blockers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>95%</td>
<td>95%</td>
<td>89%</td>
</tr>
<tr>
<td>2 years</td>
<td>95%</td>
<td>92%</td>
<td>86%</td>
</tr>
<tr>
<td>3 years</td>
<td>94%</td>
<td>93%</td>
<td>86%</td>
</tr>
</tbody>
</table>

- LDL <85 mg/dl in ~70% of pts
- SBP <130 mmHg in ~65% of pts
- DPB <85 mmHg in ~94% of pts
- HgBA1C <7.0% in ~45% of pts

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### Limitations: Compliance to Medical Therapy

**Duke Clinical Research Institute, AHA 2005.


<table>
<thead>
<tr>
<th>Patient Compliance (%)</th>
<th>ASA</th>
<th>BB</th>
<th>Lipid</th>
<th>ASA + BB</th>
<th>ASA + BB + Lipid</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>71</td>
<td>46</td>
<td>43</td>
<td>36</td>
<td>21</td>
</tr>
<tr>
<td>100</td>
<td></td>
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**PCI in Chronic Stable Coronary Syndromes...**

- Improves symptoms from coronary lesions
  - usually better than drugs
  - similar to bypass surgery (in most patients)
- May reduce death and MIs in some patients
The Take Home Message

• Interventional Cardiologists are better than the following specialties:
  • Clinical Cardiologists
  • Cardiac surgeons
  • Electrophysiologists
  • Gastroenterologists
  • Endocrinologists
  • Vascular surgeons
  • Hematologists, allergists, ID, etc.
  • Other Interventional cardiologists

But see what happens if we work together!