What's New In the Cath-lab 2015

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The Plan

• **Diagnostics**
  - FFR – Fractional Flow Reserve
  - OCT – Optical Coherence Tomography

• **Treatment**
  - New Stents – BRS/DES
  - MI – 2015
  - Drugs – Ticagrelor/Clopidogrel
    - Statins
  - TAVR (TAVI)
Risk Assessment of patient with chest pain

High risk of CAD
- >90%
  - For example, typical angina in men aged >70 years or women >70 years
  - Optimal medical therapy ± revascularisation

Intermediate risk of CAD
- 61%-90%
  - Invasive coronary angiography
    - If angiography is not appropriate, offer functional testing

Low risk of CAD
- 10%-29%
  - Functional testing:
    - MPS with SPECT or stress echocardiography
    - or first-pass contrast-enhanced MR perfusion or MR imaging for stress-induced wall motion abnormalities
  - CT calcium scoring ± angiography (depending on score)

Low risk of CAD
- <10%
  - For example, atypical angina in men aged <30 years or women <40 years
  - Rule out non-cardiac causes of chest pain
### Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Non-anginal chest pain</th>
<th>Atypical angina</th>
<th>Typical angina</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>35</td>
<td>Lo</td>
<td>Hi</td>
<td>Hi</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td>45</td>
<td>9</td>
<td>47</td>
<td>2</td>
</tr>
<tr>
<td>55</td>
<td>23</td>
<td>59</td>
<td>4</td>
</tr>
<tr>
<td>65</td>
<td>49</td>
<td>69</td>
<td>9</td>
</tr>
</tbody>
</table>

Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol > 6.47 mmol/litre).
Lo = Low risk = none of these three.
Angiography

- Simply the best anatomical test for defining a stenosis in a patient with symptoms of ischemia. Option to proceed to PCI at time.
- 90% nationally is done radially – safer, better mobility. Risk for elective cases:
  - Death – 1/10000
  - CVA – 1/5000
  - TIA – 1/1000
  - Radial access route repair/symptomatic occlusion of RA - < 1/10000
- Radiation dose reducing
- Most cases are performed post ACS
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Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease

FAME 2

Clinicaltrials.gov NCT01132495

Bernard De Bruyne, Nico H.J. Pijls, William F Fearon, Peter Juni, Emanuele Barbato, Pim Tonino, for the FAME 2 study group
Studies have shown that a cut-off of 0.80 is predictive of a significant stenosis
Distribution of angiographic severity vs functional severity of coronary artery stenosis

**Primary Outcomes**

**PCI+MT vs. MT:** HR 0.32 (0.19-0.53); p<0.001

**PCI+MT vs. Registry:** HR 1.29 (0.49-3.39); p=0.61

**MT vs. Registry:** HR 4.32 (1.75-10.7); p<0.001
**Urgent Revascularization**

- **PCI+MT vs. MT:** HR 0.13 (0.06-0.30); p<0.001
- **PCI+MT vs. Registry:** HR 0.63 (0.19-2.03); p=0.43
- **MT vs. Registry:** HR 4.65 (1.72-12.62); p=0.009

<table>
<thead>
<tr>
<th>Months after randomization</th>
<th>MT</th>
<th>PCI+MT</th>
<th>Registry</th>
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<tbody>
<tr>
<td>0</td>
<td>447</td>
<td>441</td>
<td>166</td>
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<tr>
<td>1</td>
<td>421</td>
<td>414</td>
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<td>2</td>
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<td>12</td>
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<td>38</td>
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</tr>
</tbody>
</table>
FFR

• Patient has moderate narrowing angiographically
• Operator needs more information on whether to treat with a stent or leave to medical management.
• Medical management in a patient with a non-functionally significant stenosis has an excellent outcome
“Pull out, Betty! Pull out! ... You’ve hit an artery!”
What's New in Stent Technology?
What's New in Stent Technology?

- >90% stents implanted are drug eluting (DES)
- Most elute a drug called Everolimus over approx. 90 days
- The newest technology is called a bio-erodable scaffold (BRS). These currently account for < 5% of stent implantations. Unique in that they literally disappear over 2 years.
- These “scaffolds” are difficult to see but thanks to a new imaging modality called OCT (optical coherence tomography) we are beginning to understand them better
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  OCT
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OCT and BRS
Case Study 1: A Cautionary Tale

Bioresorbable Polymeric Vascular Scaffolds (BRS)

- 78 year old man with angina and ST depression in stage 2 of the Bruce Protocol stress test
- BRS scaffold deployed at 16 atms
- Post dilated with 3.25 mm balloon at 22 atms
Post BVS and post dilated with 3.25NC at 22 atms

Proximally: Struts not apposed to vessel wall

Distally: Struts are well apposed to vessel wall
Post-dilatation with 3.5mm compliant balloon at 16 atms gives an expected diameter of 4mm

1 Month follow-up
Angiogram shows good result
But worse on OCT
Scanning Electron Microscope (SEM) image of a deliberately damaged BVS on the bench shows overlap and change strut orientation.
Disappearing Stents
## Advantages of a stent

<table>
<thead>
<tr>
<th>Condition</th>
<th>Balloon Angioplasty</th>
<th>BMS</th>
<th>Metallic DES</th>
<th>Bioresorbable Scaffold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute occlusion</td>
<td>−</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Acute ST/scaffold thrombosis</td>
<td>NA</td>
<td>−</td>
<td>+/−</td>
<td>+</td>
</tr>
<tr>
<td>Subacute ST/scaffold thrombosis</td>
<td>NA</td>
<td>−</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Acute recoil</td>
<td>−</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Constrictive remodeling</td>
<td>−</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Neointimal hyperplasia</td>
<td>−</td>
<td>−</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Expansive remodeling</td>
<td>+</td>
<td>−</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Late luminal enlargement</td>
<td>+</td>
<td>−</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Late ST/scaffold thrombosis</td>
<td>NA</td>
<td>−</td>
<td>−</td>
<td>+</td>
</tr>
</tbody>
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"You say it's a sharp, stabbing pain. Hmmm... sharp... stabbing pain."
Time delay to treatment in MI
Relationship between time to treatment and 1-year mortality

30% increase in 1yr mortality

Y = 2.86 (± 1.46) + 0.0045X + 0.000043X^2

p < 0.001

MI 2015

• Primary PCI
• Facilitated PCI
• Lyse and ship
evidence

- System delay in PPCI Sept-Dec 2014

<table>
<thead>
<tr>
<th></th>
<th>NZ</th>
<th>Northern</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient delay</td>
<td>81</td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>Prehospital system delay</td>
<td>50</td>
<td>47</td>
<td></td>
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<tr>
<td>D2B</td>
<td>76</td>
<td>70</td>
<td></td>
</tr>
</tbody>
</table>

Symptom onset to ambulance dispatch (Patient delay)
Ambulance dispatch to door (Prehospital system delay)
CASE

• Onset pain 1145AM
• Arrived Medical Centre 1300 – ECG taken and transmitted ED. Retrieval arranged – helicopter arrived 1345.
• Helipad arrival at 1415. Cathlab arrival 1425.
• First Device crossed 1440.
Post procedure

Returned to CCU with minor CP; ECG improved but not isoelectric
Discharged 72 hours later
Compliant and symptom-free at 6–week follow-up
“To prevent a heart attack, take one aspirin every day. Take it out for a run, then take it to the gym, then take it for a bike ride...”
MI - Therapeutics

Pre Cathlab:
Aspirin 300mg sol.
Clopidogrel 300-600mg or Ticagrelor 180mg

After PCI:
Aspirin lifelong
Ticagrelor 90mg BD for 1 year
Statin aiming for LDL <1.6mmol/l
Stable Angina and a Stent

Aspirin lifelong
Clopidogrel 6 months
Statin aiming for LDL <1.6mmol/l
PLATO: Primary endpoint: CV death, MI or stroke

HR: 0.85 (95% CI = 0.74–0.97), p=0.02
Therapeutic considerations

• Based on 1,000 patients admitted to hospital for ACS, using ticagrelor instead of clopidogrel for 12 months resulted in
  – 14 fewer deaths
  – 11 fewer myocardial infarctions
  – 6–8 fewer cases with stent thrombosis
  – No increase in bleedings requiring transfusion
  – 9 patients may switch to thienopyridine treatment because of reversible symptoms of dyspnoea

• Treating 54 patients with ticagrelor instead of with clopidogrel for one year will prevent one event of CV death, MI or stroke
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TAVR (TAVI)
Aortic Stenosis – TAVR
Transcatheter Aortic Valve Replacement
5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuzcu, MD, Cleveland Clinic
• An aortic valve replacement as an alternative to traditional thoracotomy.
• Access via Femoral, direct Aortic and Apical routes
• Less invasive than traditional thoracotomy for patients considered too high risk for traditional surgery.
Two (of many) TAVR Options

Edwards Sapien Valve
- Stainless Steel Frame
- More Aortic Regurg, less AV block/PPM
- Better for severe bulky calcification.

Medtronic CoreValve
- Nitinol Frame-self expanding
- Less Aortic Regurg, More heart block/PPM
Five-Year Outcomes of Transcatheter Aortic Valve Replacement (TAVR) in “Inoperable” Patients With Severe Aortic Stenosis: The PARTNER Trial

Samir R. Kapadia, MD
On behalf of The PARTNER Trial Investigators

- TCT 2014 | September 13, 2014
PARTNER Study Design

**Symptomatic Severe Aortic Stenosis**

**Cohort A**
- **N = 699**
- **High Risk**
  - ASSESSMENT: High-Risk AVR Candidate
  - **Transfemoral Access**
    - Yes
      - Transfemoral (TF)
    - No
      - Transapical (TA)

  - 1:1 Randomization
    - N = 244
      - TF TAVR
    - N = 248
      - AVR

  - Primary Endpoint: All-Cause Mortality at 1 yr (Non-inferiority)

**Cohort B**
- **N = 358**
- **Inoperable**
  - ASSESSMENT: Transfemoral Access
  - Yes
  - No

**Total = 1,057 patients**

2 Parallel Trials: Individually Powered

**PARTNER Study Design**

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**Total = 1,057 patients**

2 Parallel Trials: Individually Powered

**COHORT B KEY INCLUSION CRITERIA**

- Predicted operative mortality or irreversible morbidity: > 50%
- NYHA functional class: ≥ II
- AVA < 0.8 cm²
- Mean gradient > 40 mmHg
- Peak jet velocity > 4.0 m/s
### Cohort A: All-Cause Mortality

<table>
<thead>
<tr>
<th>Months post Randomization</th>
<th>TAVR No. at Risk</th>
<th>AVR No. at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>6</td>
<td>298</td>
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<tr>
<td>36</td>
<td>149</td>
<td>142</td>
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</table>

HR [95% CI] = 0.93 [0.74, 1.15]

p (log rank) = 0.483
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

Cohort A

N = 699

High Risk

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

Total = 1,057 patients
2 Parallel Trials: Individually Powered

High Risk

ASSESSMENT: Transfemoral Access

No

Transfemoral (TF)

1:1 Randomization

N = 244

TF TAVR

Yes

N = 248

AVR

Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)

Cohort B

N = 358

Inoperable

ASSESSMENT: Transfemoral Access

No

N = 103

AVR

Cohort B KEY INCLUSION CRITERIA

Predicted operative mortality or irreversible morbidity > 50%

NYHA functional class ≥ II

AVA and
Mean gradient > 40 mmHg
Peak jet velocity > 4.0 m/s
Primary Endpoint: 1 Year All-cause Mortality

- Surgical: 4.5% vs. Transcatheter: 3.3%
- P = 0.04 for superiority

No. at Risk

Surgical: 357, 341, 297, 274
Transcatheter: 390, 377, 353, 329

ACC 2014
The NZ experience

Limited access due to MOH restrictions:
• Indication – must be accepted as a surgical candidate at a Heart team meeting
• Compassionate use – ‘inoperable but highly symptomatic’ not perceived as the optimal candidate in an environment of limited resources

BUT...the technology is likely to succeed and become the preferred option for most of us sitting in this room
Short-Term Memory Loss Support Group

Good evening. You’re probably all wondering why you just walked into this room.

What's New in the Cath-lab 2015

I Patrick Kay PhD FESC EAPCI BA
General and Interventional Cardiologist
Auckland

ipatkay@hotmail.com or see healthpoint
BYE
“Heads, you get a quadruple bypass. Tails, you take a baby aspirin.”