Interventional Cardiology « Update 2016 »

P. Motreff, 12 Janvier 2017
Disclosure Statement of Financial Interest

I currently have, or have had over the last two years, an affiliation or financial interests or interests of any order with a company or I receive compensation or fees or research grants with a commercial company:

Consultant: Abbott Vascular, St Jude Medical, Terumo, Biotronik
Guidelines

Guidelines published in 2016

- Cardio-Oncology (Position Paper)
  Chairpersons: Jose Luis Zamorano & Patrizio Lancellotti
- Dyslipidaemias
  Chairpersons: Ian Graham & Alberico Catapano
- CVD Prevention
  Chairpersons: Massimo Piepoli & Arno W. Hoes
- Atrial Fibrillation
  Chairpersons: Paulus Kirchhof & Stefano Benussi
- Heart Failure
  Chairpersons: Piotr Ponikowski & Adriaan Voors

Publications planned in 2017

- AMI-STEMI
  Chairpersons: Stefan James & Borja Ibanez
- Focused Update on Dual Anti-platelet Therapy
  Chairperson: Marco Valgimigli
- Peripheral Artery Disease
  Chairpersons: Victor Aboyans & Jean-Baptiste Ricco
- Valvular Heart Disease
  Chairpersons: Jose Luis Zamorano, Helmut Baumgartner & Volkmar Falk
### Guidelines

### Structural

### Stents

### Diagnostic tools

### Pharmacology

### Coronary disease

### News from GACI
Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

CONCLUSIONS
In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke.
TAVI in low and intermediate risk

Low and intermediate risk: systematic review and meta-analysis
Siemieniuk RA, BMJ 2016

TAVI vs SAVR for treatment of severe aortic stenosis: a meta-analysis of randomized trials
Siontis GCM, Eur Heart J 2016
Long term performance of TAVI

Partner 1 Trial, 5 years follow-up

Edwards Sapien Valves Demonstrate Excellent Durability In 5-Year Echo Study

Quality of life after TAVI

Partner 2, Quality of life

Compared with SAVR, TAVR improved QOL at 1 month
(significant improvement only in the TransFemoral subgroup \(P < .001\))
QOL scores were similar among TAVR and SAVR patients at 12 and 24 months
Cerebral Embolic Protection During TAVR

*Latib A, J Am Coll Cardiol 2016*

**363 TAVR**

- Safety confirmed
- Sentinel-Trial fails to meet overall primary efficacy endpoint

Despite the finding of **histopathologic debris within filters in 99% of pts**, which included thrombus, calcification, valve tissue, artery wall and foreign material, all strokes at 30 days were not significantly different in the device and safety arms versus the control arm (5.6% vs. 9.1%, P=0.25).
Interventional Cardiology 2016

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News from GACI
Comparison of 3 types of Drug Eluting Stent:

3514 allcomers pts randomized (70% ACS)

Non-inferiority of the everolimus-eluting stents and sirolimus-eluting stents compared with zotarolimus-eluting stents was confirmed

12 months follow-up:

5% MACE (cardiac death, MI, TVR)
0.3% Stent thrombosis
The LEADERS FREE trial showed that clinical outcomes following biolimus A9 DCS implantation are superior to BMS in patients with high bleeding risk and who are able to take only 1 month of dual antiplatelet therapy (n=2466 pts).
The trial did not meet its mechanistic co-primary endpoints of:

- **superior vasomotor reactivity** because Xience showed unexpected vasomotion.
- non-inferior **late luminal loss** with respect to Xience that was found to have lower late luminal loss than Absorb.

*Serruys PW, Lancet 2016*
**ABSORB 2 at 3 years, Clinical Outcomes**

**Absorb (N=325)**
- Event Free = 79.1%
- PoCE = 20.9%
- DoCE = 10.5%
- Def/Prob ST = 2.8%

**XIENCE (N=161)**
- Event Free = 75.8%
- PoCE = 24.2%
- DoCE = 5.0%
- Def/Prob ST = 0.0%

**Scaffold or stent thrombosis**

<table>
<thead>
<tr>
<th></th>
<th>Absorb 335 patients</th>
<th>Xience 166 patients</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definite</td>
<td>2.5% (8)</td>
<td>0.0% (0)</td>
<td>0.06</td>
</tr>
<tr>
<td>Acute (0–1 day)</td>
<td>0.3% (1)</td>
<td>0.0% (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Sub-acute (2–30 days)</td>
<td>0.3% (1)</td>
<td>0.0% (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Late (31–365 days)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Very late (&gt;365 days)</td>
<td>1.8% (6)</td>
<td>0.0% (0)</td>
<td>0.19</td>
</tr>
</tbody>
</table>
### ESC Guidelines 2014, Eur Heart J

<table>
<thead>
<tr>
<th>Recommendations according to extent of CAD</th>
<th>CABG</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class</td>
<td>Level</td>
</tr>
<tr>
<td>Left main disease with a SYNTAX score ≤ 22.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Left main disease with a SYNTAX score 23–32.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Left main disease with a SYNTAX score &gt;32.</td>
<td>I</td>
<td>B</td>
</tr>
</tbody>
</table>

### NOBLE EXCEL

- Mäkikallio T, Lancet 2016
**Patients allocated to PCI in analysis (n=592)**
- Received PCI (n=585)
- Did not receive PCI (n=13)
  - Died before PCI (n=1)
  - Patient declined PCI (n=4)
  - PCI operator declined (n=4)
  - LMCA lesion not significant (n=4)

**Lost to follow-up (n=6)**
- Emigration (n=1)
- Contact lost (n=2)
- Withdrawal (n=3)

**Patients allocated to PCI in analysis (n=592)**
- 580 received PCI
- 7 received CABG

**Patients allocated to CABG in analysis (n=592)**
- Received CABG (n=567)
- Did not receive CABG (n=25)
  - Died before CABG (n=1)
  - Patient declined CABG (n=15)
  - Not eligible for CABG (n=15)
  - Cross over by mistake (n=2)

**Lost to follow-up (n=11)**
- Emigration (n=0)
- Contact lost (n=0)
- Withdrawal (n=11)
Results

MACCE: Death, MI, stroke

HR 1.47 95% CI (1.06-2.05) p=0.02

Mäkikallio T, Lancet 2016
All Cause Mortality

Repeat Revascularization

Non procedural MI

Stroke

HR 1.07 (0.67–1.72); p=0.77

HR 2.88 (1.40–5.90); p=0.004

HR 1.50 (1.04–2.17); p=0.03

HR 2.25 (0.92–5.48); p=0.07

11.6%

9.5%

6.9%

1.9%

16.2%

10.4%

4.9%

1.7%
Conclusions

• PCI did not meet non-inferiority for the primary endpoint of 5-year MACCE compared to CABG

• **CABG was superior to PCI**

• PCI resulted in higher rates of non-procedural myocardial infarctions

• Repeat revascularization was higher after PCI, primarily due to de novo lesions and non LMCA target lesion revascularization

• All-cause mortality was similar for PCI and CABG
Follow-up: 1 month, 6 months, 1 year, annually through 5 years

Primary endpoint: Measured at a median 3-yr FU, minimum 2-yr FU
Primary Endpoint
Death, Stroke or MI at 3 Years

Death, stroke or MI (%)

No. at Risk:
PCI    948    896    875    850    784    763    445
CABG  957    868    836    817    763    458

HR [95%CI] = 1.00 [95% CI: 0.79, 1.26]
P = 0.98
Conclusions

• Treatment of patients with LMCAD and low or intermediate SYNTAX scores with CoCr-EES resulted in similar rates of the primary endpoint of death, stroke or MI at 3 years, with fewer adverse events within 30 days compared to CABG.

• PCI may thus be considered an acceptable or even preferred revascularization modality for selected patients with LMCAD, a decision which should be made after heart team discussion, taking into account each patient’s individual circumstances and preferences.
take-home message “is that the majority of patients with unprotected left main coronary artery disease, which was a very serious, life-shortening, and disabling condition early in my professional lifetime, can now be managed equally by means of two strategies of revascularization if carried out by expert, experienced teams such as those participating in the EXCEL trial
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- Guidelines
- Structural Stents
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- Pharmacology
- Coronary disease
- News from GACI
The FUTURE trial was prematurely halted due to an excess of the all-cause mortality (HR 2.39, p=0.02) in the group of patients with FFR assessment (DSMB evaluation on n=836 pts).

As of today, the follow-up indicates a persistent but non significant (p=0.11) difference in the 12-month all-cause mortality (797 pts).
OCT guidance during PCI in patients with NSTEMI

Change in **procedural strategy in half the cases** in the OCT-guided group. OCT **improved functional outcome** compared with PCI guided by fluoroscopy alone, as assessed by FFR. This improvement seemed to be explained by optimization of **stent expansion**.

![Graph showing final diameter stenosis and stent expansion](image)
Mechanisms of Stent Thrombosis (n=120)

- Malapposition 34%
- Neoatherosclerosis 22%

OCT influences management in 55% of ST cases

- POBA 37%
- Medical therapy in 32%
- Stenting 31%
Platelet function monitoring to adjust antiplatelet therapy in elderly patients stented for an acute coronary syndrome (ANTARCTIC): an open-label, blinded-endpoint, randomised controlled superiority trial

**875 Elderly ACS Patients**

**Group 1**
- Conventional Arm: Prasugrel 5 mg
- No monitoring

**Group 2**
- Monitoring Arm: Prasugrel 5 mg
- 1st assessment: Verifynow P2Y₁₂: 2 weeks ± 2 d
  - PRU ≥ 208: Prasugrel 10 mg
  - 85 < PRU < 208: Prasugrel 5 mg
  - PRU ≤ 85: Clopidogrel 75 mg
- 2nd assessment and adjustment: Verifynow P2Y₁₂: 2 weeks ± 2 d

Primary end point (net clinical benefit) over 12 months: Bleeding type 2,3,5 of the BARC definition and MACE (CV death, MI, urgent revascularisation, stent thrombosis, stroke)
• Largest randomized PCI study in the elderly
• Platelet function monitoring to adjust antiplatelet therapy in elderly patients stented for an ACS does not improve their clinical outcomes
PIONEER AF-PCI


- 2100 patients with NVAF
- Coronary stenting
- No prior stroke/TIA, GI bleeding, Hb<10, CrCl<30

Randomize

1, 6, or 12 months
Pre randomization MD Choice

Rivaroxaban 15 mg
Clopidogrel 75 mg

Rivaroxaban 2.5 mg bid
Clopidogrel 75 mg
Aspirin 75-100 mg

Rivaroxaban 15 mg
Aspirin 75-100 mg

VKA (target INR 2.0-3.0)
Clopidogrel 75 mg
Aspirin 75-100 mg

VKA (target INR 2.0-3.0)
Aspirin 75-100 mg

End of treatment 12 months

- Primary endpoint: TIMI major + minor + bleeding requiring medical attention
- Secondary endpoint: CV death, MI, and stroke (Ischemic, Hemorrhagic, or Uncertain Origin)
First Occurrence of Clinically Significant Bleeding Events

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Days 0-30</th>
<th>Days 31-90</th>
<th>Days 91-180</th>
<th>Days 181+</th>
</tr>
</thead>
<tbody>
<tr>
<td>VKA + DAPT</td>
<td>26.7%</td>
<td>18.0%</td>
<td>16.8%</td>
<td></td>
</tr>
<tr>
<td>Riva + DAPT</td>
<td>18.0%</td>
<td>16.8%</td>
<td>15.5%</td>
<td></td>
</tr>
<tr>
<td>Riva + P2Y12</td>
<td>16.8%</td>
<td>15.5%</td>
<td>14.3%</td>
<td>13.2%</td>
</tr>
</tbody>
</table>

**Comparison:**
- Riva + P2Y12 v. VKA + DAPT
  - HR = 0.59 (95% CI: 0.47-0.76)
  - p < 0.000013
  - ARR = 9.9
  - NNT = 11
- Riva + DAPT v. VKA + DAPT
  - HR = 0.63 (95% CI: 0.50-0.80)
  - p < 0.00018
  - ARR = 8.7
  - NNT = 12

*Gibson CM, New Engl J Med 2016*
First Occurrence of CV Death, MI or Stroke

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Days</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VKA + DAPT</td>
<td>180</td>
<td>6.0%</td>
</tr>
<tr>
<td>Riva + DAPT</td>
<td>180</td>
<td>5.6%</td>
</tr>
<tr>
<td>Riva + P2Y&lt;sub&gt;12&lt;/sub&gt;</td>
<td>180</td>
<td>6.5%</td>
</tr>
</tbody>
</table>

Riva + P2Y<sub>12</sub> v. VKA + DAPT
HR = 1.08 (95% CI: 0.69-1.68)
p = 0.750

Riva + DAPT v. VKA + DAPT
HR = 0.93 (95% CI: 0.59-1.48)
p = 0.765

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News from GACI
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• Website, Newsletter
• Studies Support (PAPYRUS, DISCO, WAMIF, MITRA...)
• Registries: France TAVI
  France Absorb
  France-PCI = « French SCAAR »
• Journées GACI

Paris, 23-24 Mars 2017