Complications after TAVI: VARC Definitions, Frequency and Management Considerations

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Main Arena Level B

With the collaboration of the Working Group on Valvular Heart Disease of the European Society of Cardiology
Minimum Data Collection and Endpoint Requirements after TAVI

- Myocardial infarction
- Stroke
- Bleeding
- Mortality
- Acute Kidney Injury
- Vascular complications
- Composite endpoints
- Therapy specific endpoints
- Prosthetic valve associated complications
- Prosthetic valve performance
Stroke - VARC

1. Rapid onset of a focal or global neurological deficit with signs or symptoms consistent with stroke

2. Typically
   • Duration of a focal or global neurological deficit $\geq 24$ hours;
   • OR $< 24$ hours, if therapeutic intervention(s) were performed (e.g. thrombolytic therapy or intracranial angioplasty);
   • OR available neuroimaging
   OR the neurologic deficit results in death

3. Exclusion of other cause for the clinical presentation (e.g. infection, hypoglycemia, pharmacological influences…)

4. Confirmation by at least one of the following:
   • Neurology or neurosurgical specialist
   • Neuroimaging procedure (MR or CT scan or cerebral angiography)
   • Lumbar puncture (i.e. spinal fluid analysis diagnostic of intracranial hemorrhage)
#1 Stroke

More Stroke Definitions

- **Stroke:**
  - **Minor** – modified Rankin score < 2 at discharge
  - **Major** – modified Rankin score ≥ 2 at discharge

- **Transient ischemic attack:**
  - New focal neurologic deficit with rapid symptom resolution (usually 1-2 hours), always within 24 hours
  - Neuroimaging without tissue injury
#1 Stroke

**Stroke at 30 days**

- **Edwards SAPIEN**
- **Medtronic CoreValve**

Weighted average – 2.4%
<table>
<thead>
<tr>
<th>Cohort A</th>
<th>Cohort B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TAVI</strong></td>
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</tr>
<tr>
<td>3.8%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Surgery</td>
<td>Medical Rx</td>
</tr>
<tr>
<td>2.1%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

#1 Stroke

Stroke at 30 days
Partner US Trial
#1 Stroke

**Time to stroke event within 30 days**

**Partner US Cohort B**

In the CoreValve Expanded Evaluation Registry (n=646), 30% of strokes were diagnosed after 48 hours and 50% of strokes were diagnosed between 2-10 days.

Major or minor stroke event (n=11) Piazza et al. EuroIntervention 2008
#1 Stroke

Diffusion weighted MRI
Silent Cerebral Insults after TAVI

Percent of patients (%): 68%, 69%, 73%, 68%, 84%

Rodes-Cabau JACC 2011 (n=60)
Astarci EJCTS 2011 (n=80)
Ghanem JACC 2010 (n=30)
Arnold JACC Interv 2010 (n=25)
Khaler Circulation 2010 (n=32)
#1 Stroke

**Diffusion-Weighted MRI Study**

Philipp Kahlert, MD  
West German Heart Center Essen

Example of an 82-year-old patient two days after successful TAVI

**Embolic phenomenon**

Courtesy of E. Grube, MD
Diffusion weighted MRI
Silent Cerebral Insults after TAVI

No difference in the number of silent cerebral insults between:

- Transfemoral vs. Transapical TAVI
- Edwards SAPIEN vs. Medtronic CoreValve

Rodes-Cabau JACC 2011
Astarci EJCTS 2011
Khalert Circulation 2010
What is the clinical significance of silent cerebral insults after TAVI?

Silent cerebral insults had no influence on neurocognitive performance

Khalert Circulation 2010
Ghanem JACC 2010
Rodes-Cabau JACC 2011
Will Cerebral Embolic Protection Devices be the solution?

Embrella Cardiovascular (deflector)

Claret Medical (capture)

SMT (deflector)
#1 Stroke

Antiplatelet-Anticoagulant Rx
Post TAVI

Non-standardized

ASA and Plavix for 3 months

Coumadin and ASA (or Plavix) for 3 months
#2 Conduction Abnormalities

**TAVI & Conduction Abnormalities**

- **Piazza et al. JACC Interv 2008** (n=40)
- **Baan et al. Am Heart J 2010** (n=34)
- **Calvi et al. PACE 2009** (n=30)
- **Latsios et al. Cath Cardiovasc Interv 2010** (n=81)
- **Jilaihawi et al. Am Heart J 2009** (n=34)
- **Bleiziffer et al. JACC Interv 2010** (n=123)
- **Erkapic et al. Europace 2010** (n=50)
- **Piazza et al. EuroIntervention 2010** (n=91)
- **Haworth et al. CCI 2010** (n=50)
- **Roter et al. Am J Cardiol 2010** (n=67)
- **Ferreira et al. Pacing Clin Electrophysiol 2010** (n=32)
- **Fraccaro et al. Am J Cardiol 2011** (n=70)
How frequent is new-onset left bundle branch block (LBBB) after TAVI?

Medtronic CoreValve 30 to 65%
Edwards SAPIEN

Permanent pacing requirements

\approx 4 \text{ tot} 21\%
#2 Conduction Abnormalities

**Medtronic CoreValve**

**Permanent pacing requirements**

\[ \approx 18 \text{ to } 40\% \]
Indications for permanent pacemaking following TAVI

**Absolute 31%**
- 3rd degree AV block,
- 2nd degree AV block,
- LBBB and grade 1 AV block
- atrial fibrillation: pause >4 sec in the absence of rate lowering medications

**Relative 16%**
- new onset bundle branch block, even without AV delay
- RBBB and long PQ (>240 msec), alternating PQ times during monitoring.

Latsios et al. Cath Cardiovasc Interv 2010
#2 Conduction Abnormalities

**Predictors PPM**
**Medtronic CoreValve**

- Pre-existing RBBB ✔ ✔ ✔ ✔ ✔ ✔ ✔ ✔
- Depth of implantation ✔ ✔ ✔ ✔ ✔ ✔ ✔ ✔
- Small LVOT/annulus ✔ ✔ ✔
- Septal wall thickness ✔ ✔
- Calcification ✔
“Prophylactic” Pacemaker

Where do its origins lie?

Left bundle branch block following surgical AVR is associated with complete AV block and sudden cardiac death at 1 year follow-up

Am J Cardiol 2004
J Thorac Cardiovasc Surg 1982
#2 Conduction Abnormalities

CoreValve Implantation Case

Pre-procedure RBBB

Day 1 post-procedure LBBB

Day 3 Post-procedure LBBB
#2 Conduction Abnormalities

Day 6 Post-implant
Recommendations

Temporary pacemaker for 48-72 hours

Continuous in-hospital rhythm monitoring

Indications for permanent pacemaker implantation should follow published guidelines
Immediately after CoreValve implantation . . .

Severe aortic regurgitation

- Aortic diastolic pressure
  \(\sim 30-35\) mmHg
- LVEDP = 25 mmHg
- Loss of dicrotic notch
### Prosthetic Aortic Valve Regurgitation (JASE)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV size</td>
<td>Normal</td>
<td>Normal/mildly dilated</td>
<td>dilated</td>
</tr>
<tr>
<td>Jet width in central jets (% LVO diameter)</td>
<td>Narrow (&lt;25%)</td>
<td>Intermediate (26-64%)</td>
<td>Large (≥65)</td>
</tr>
<tr>
<td>Jet density /CW Doppler</td>
<td></td>
<td></td>
<td>dense</td>
</tr>
<tr>
<td>Jet deceleration time (PHT, ms) CW Doppler</td>
<td>Slow (&gt;500)</td>
<td>Variable (200-500)</td>
<td>Steep (&lt;200)</td>
</tr>
<tr>
<td>LV outflow vs. pulmonary flow: PW Doppler</td>
<td>Slightly increased</td>
<td>Intermediate Greatly increased</td>
<td></td>
</tr>
<tr>
<td>Diastolic flow reversal in desc. aorta: PW Doppler</td>
<td></td>
<td></td>
<td>Prominent, holodiastolic</td>
</tr>
<tr>
<td>Circumferential extent of paravalvular AR (%)</td>
<td>&lt;10</td>
<td>10-20</td>
<td>&gt;20</td>
</tr>
<tr>
<td>Regurgitant volume (mL/beat)</td>
<td>&lt;30</td>
<td>30-59</td>
<td>&gt;60</td>
</tr>
<tr>
<td>Regurgitant fraction (%)</td>
<td>&lt;30</td>
<td>30-50</td>
<td>&gt;50</td>
</tr>
</tbody>
</table>
#3 Aortic regurgitation

Frequency of Aortic Regurgitation
(Peer-reviewed)

- No AR
- Any AR
- Grade 2-4

10-30% for MEDTRONIC COREVALVE
70-90% for EDWARDS SAPIEN

References:
- Jilaihawi et al. Eur Heart J 2009
- Moss et al. JACC Cardiovasc Imag 2008
- Clavel et al. J Am Coll Cardiol 2009
- Himbert et al. J Am Coll Cardiol 2008
- Detaint et al. JACC Cardiovasc Interv 2009
#3 Aortic regurgitation

Paravalvular Aortic Regurgitation

PARTNER US Cohort B

At 1 year follow-up

45% - No aortic regurgitation
55% - Some degree of regurgitation

30 Day 6 Month 1 Year

None/Trace

Mild

Moderate

Severe
#3 Aortic regurgitation

Courtesy of the German Heart Center Munich (R. Lange)
#3 Aortic regurgitation

Post-procedure

Intermittent hemodynamic instability

Echocardiography - no relevant findings during times hemodynamic stability
#3 Aortic regurgitation

Post-procedural evolution

Post-operative day 3  Severe central aortic regurgitation during HD instability

Surgical exploration
Native aortic valve leaflet impinging on prosthetic valve leaflet impeding normal leaflet motion
Mechanisms of Aortic Regurgitation

- Malposition of prosthesis
- Undersizing prosthesis
- Underexpansion of prosthesis
- Malapposition of prosthesis
- Aggressive pre-dilatation during BAV
- Guidewire or pigtail catheter interfering with leaflet coaptation
#3 Aortic regurgitation

## Predictors of AR
(Edwards SAPIEN)

- **Detaint et al.**
  *JACC Interv 2009;2:82107*
  - “Cover Index” (TEE)
    - 1.22 (95% CI 1.03 to 1.52)
  - Operator experience
    - 2.24 (95% CI 1.07 to 5.22)

- **Coli et al.**
  *Circulation 2009;120:S982*
  - Degree of valve calcification (TEE)
    - 8.47 (95% CI 1.22 to 58.92)
  - Asymmetry of valve calcification (TEE)
    - 13.70 (95% CI 1.52 to 122.40)

- **Delgado et al.**
  *Circulation 2009;120:S957*
  - ↑ Annulus size (MSCT)
    - (28.2±1.8 mm vs. 24.8±2.3 mm, p=0.003)
  - Degree of valve calcification (MSCT)
    - (4127±2071 HU vs. 2470±1264 HU, p=0.037)

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## Sizing and calcium

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#3 Aortic regurgitation

Treatment of paravalvular aortic regurgitation

Moderate-severe aortic regurgitation should be treated if possible

Post-implant balloon dilatation

Valve-in-valve
Hypotension during or after TAVI

1. Cardiac tamponade (Echo)
2. Myocardial ischemia (ECG)
3. Major bleeding (MSCT)
Stepwise Care

- 24-36 hours in intensive care
- Transfer to medium care or general ward for 5 days
- Average length of stay 5-7 days.
Overall Things to Watch For

- Signs of stroke
- ECG rhythm disturbances
- Myocardial ischemia
- Cardiac tamponade

- Bleeding
- Renal problems
- Vascular access issues

Post-care TAVI needs that we acquire a new knowledge base of pathophysiological mechanisms that may lead to otherwise common signs and symptoms