TAVI Devices: Major Complications

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Barbanti et al, Eurointervention, 2017
TAVI Complications

- Vascular Issues
- Valve Deployment
- Valve Function
- Organ Injury
- Arrhythmia

- PVR
- Valve Thrombosis
- Endocarditis

Periprocedural

Long-Term
Vascular Issues
Periprocedural Complications

1a. Vascular Issues - Access Site

- Bleeding
- Dissection
- Occlusion

Risk Factors
- Sheath-to-artery ratio
- Calcification
- Tortuosity
- Closure Device

Type I: 18.8% (18/96)
Type II: 46.9% (45/96)
Type III: 26.0% (25/96)
Type IV: 8.3% (8/96)

Periprocedural Complications

1b. Access Site Bleeding - Mortality

Piccolo et al, JACC Cardiol Intv, 2017
Periprocedural Complications
1c. Vascular Issues - Prevention and Management

Prevention
- Suitable Anatomy
- Closure Device
- Continuous Access to Punctured Artery (Cross-over)

Management
- Occlusion Balloon
- Covered Stent
- Surgery
Periprocedural Complications
1d. Vascular Issues- NG Devices

Major and life threatening bleeding

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>New-generation Events</th>
<th>Total</th>
<th>Early-generation Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levi 2017</td>
<td>7</td>
<td>175</td>
<td>11</td>
<td>175</td>
<td>24.8%</td>
<td>0.62 [0.24, 1.64]</td>
</tr>
<tr>
<td>Nijhoff 2015</td>
<td>2</td>
<td>44</td>
<td>12</td>
<td>66</td>
<td>9.8%</td>
<td>0.21 [0.05, 1.01]</td>
</tr>
<tr>
<td>Ruparel 2016</td>
<td>12</td>
<td>154</td>
<td>36</td>
<td>154</td>
<td>48.2%</td>
<td>0.28 [0.14, 0.56]</td>
</tr>
<tr>
<td>Schaefer 2016</td>
<td>4</td>
<td>69</td>
<td>14</td>
<td>69</td>
<td>17.2%</td>
<td>0.24 [0.08, 0.78]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>442</strong></td>
<td><strong>73</strong></td>
<td><strong>464</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td><strong>0.32 [0.20, 0.52]</strong></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>25</td>
<td></td>
<td>73</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.00; \chi^2 = 2.44, df = 3 (P = 0.49); I^2 = 0$
Test for overall effect: $Z = 4.58 (P < 0.00001)$

Major vascular complication

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>New-generation Events</th>
<th>Total</th>
<th>Early-generation Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levi 2017</td>
<td>6</td>
<td>175</td>
<td>2</td>
<td>175</td>
<td>22.4%</td>
<td>3.07 [0.61, 15.43]</td>
</tr>
<tr>
<td>Nijhoff 2015</td>
<td>2</td>
<td>44</td>
<td>11</td>
<td>66</td>
<td>23.0%</td>
<td>0.24 [0.05, 1.13]</td>
</tr>
<tr>
<td>Ruparel 2016</td>
<td>1</td>
<td>154</td>
<td>5</td>
<td>154</td>
<td>16.9%</td>
<td>0.19 [0.02, 1.69]</td>
</tr>
<tr>
<td>Schaefer 2016</td>
<td>3</td>
<td>69</td>
<td>11</td>
<td>69</td>
<td>25.9%</td>
<td>0.24 [0.06, 0.90]</td>
</tr>
<tr>
<td>Zhang 2015</td>
<td>0</td>
<td>40</td>
<td>10</td>
<td>80</td>
<td>11.8%</td>
<td>0.08 [0.00, 1.45]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>482</strong></td>
<td></td>
<td><strong>544</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td><strong>0.36 [0.11, 1.18]</strong></td>
</tr>
<tr>
<td><strong>Total events</strong></td>
<td>12</td>
<td></td>
<td>39</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.95; \chi^2 = 8.72, df = 4 (P = 0.07); I^2 = 54$
Test for overall effect: $Z = 1.69 (P = 0.09)$

Ando et al, Cardiovasc Revasc Medicine, 2017
Periprocedural Complications

1e. Vascular Issues - NG Closure Devices

MANTA

InClosure VCD

PerQseal
Paravalvular Regurgitation
Periprocedural Complications

2a. Paravalvular AR - Incidence

Incidence of relevant (> mild) paravalvular AR post TAVR in different trials over time

- Balloon-expandable valve
- Self-expandable valve
- Mechanically expanded valve

Schmidt-Salzmann et al, Future Caridiol, 2017
Periprocedural Complications

3b. PVR - Design Evolution
Periprocedural Complications

3c. PVR-Mortality

Van Belle et al, Circulation, 2014
Periprocedural Complications
3d. PVR-Risk Factors and Management

Landing Zone Calcification
- Annular
- LVOT
- Asymmetric

Undersizing
- Prosthesis/Annulus mismatch

Malpositioning
- Deep Implantation
- High Implantation

Deformation of the valve
- Less Annular compliance

Bicuspid Valve

Right choice among different valve design

Repositioning of the valve

Snaring of the valve

Valve in Valve

Post-dilation

Percutaneous Sealing
Conduction Disturbances
Periprocedural Complications

3a. High Degree AV Block - Incidence

- The most common TAVR complication (13%)  
  5-7% for SAPIEN/SAPIEN XT  
  25-28% for CoreValve

- 2nd generation Devices have little influence on the occurrence of conduction disturbances  
  11-14% for S3 (<10% in high implantation)  
  29% with the Lotus valve system  
  12% with the Portico Valve
### Periprocedural Complications

#### 3b. HAVB - Main Predictors

<table>
<thead>
<tr>
<th>Variable</th>
<th>Multivariable Odds Ratio*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline right bundle-branch block</td>
<td>2.8–46.7</td>
</tr>
<tr>
<td>Implantation of a Medtronic CoreValve (vs Edwards SAPIEN/</td>
<td>2.6–25.7</td>
</tr>
<tr>
<td>SAPIEN XT valves)</td>
<td></td>
</tr>
<tr>
<td>Depth of implantation</td>
<td>1.1–1.5/1 mm</td>
</tr>
<tr>
<td>Oversizing/stretching of the aortic annulus/ left ventricular outflow tract</td>
<td>1.02–1.5/1%</td>
</tr>
<tr>
<td>First-degree atrioventricular block</td>
<td>4.0–11.4</td>
</tr>
</tbody>
</table>

Auffret et al, Circulation, 2017
3c. HAVB-Timing and Evolution

- 85-90% of TAVR-induced HAVB occur within 7 days postoperatively, with the majority of these events recorded within 24 hours. 
  
  Nazif et al, JACC Cardiovasc Interv, 2014

- Patients with no 1st-degree AVB and no LBBB after TAVI are of exceedingly low risk of very late conduction disturbances.
  
  Toggweiler et al, JACC Cardiovasc Interv, 2016

- HAVB may resolve in up to 48% of cases in the first 7 days after TAVR
  
  Kagase et al, Unpublished data, 2016

- New-onset LBBB is associated with a higher 30-day risk of PPM
  
  Lopez-Aguiela et al, Am J Cardiol, 2016
Periprocedural Complications

3c. LBBB Management

- Persistent LBBB (>48h post-TAVR)
  - QRS duration < 160ms
    - Without First-degree AVB
    - Consider ILR before discharge or 24-48h ECG monitoring at 30-day
  - 130 ms < QRS duration < 160 ms
    - with First-degree AVB
    - Consider PPM or ILR or EPS or 24-48h ECG monitoring at 30-day
  - QRS duration ≥ 160ms
    - Consider PPM

Discharge when clinically indicated

Auffret et al, Circulation, 2017
Periprocedural Complications

3d.HAVB Management

Auffret et al, Circulation, 2017
Periprocedural Complications
3e. PPM and Mortality

Fadahunsi et al, JACC Cardiovasc Interv, 2016
Stroke
Periprocedural Complications

4a. Stroke-Incidence

- Incidence of stroke: <5%
- Impressive improvement comparing to older studies (5-10%)
- Stroke-related 30-day mortality rate: x3.5

Patient risk
Heart team experience
Hardware design
Definition

Prakash A et al, j Cardiothoracic and Vasc Anesth, 2017
Periprocedural Complications
4b. Stroke-Timing and Etiology

Stroke after TAVI

Early phase
- First 48h
  - Mechanical manipulation
    - Thromboembolism
      - Non-embolic
        - Hypotension
        - Hypertension
  - Wires
  - Catheters
  - Valve Deployment

Late phase
- 30d
  - AF
- >30d
  - AF
  - Comorbidities
  - Valve Thrombosis

Prakash A et al, j Cardiothoracic and Vasc Anesth, 2017
Periprosthetic Complications
4c. Stroke-Prevention

• Perioperative Anticoagulation
  ➢ Unfractionated Heparin (ACT>300)
  ➢ Bivalirudin (?)

• Embolic Protection Devices
  ➢ Embrella
  ➢ Sentinel
  ➢ TriGuard

• Postoperative Pharmacology
  ➢ Dual Antiplatelet Therapy
  ➢ Peros Anticoagulation (?)
Periprocedural Complications

4d. Stroke—Embolic Protection Devices
Periprocedural Complications
4e. Stroke-Embolic Protection Devices

- No significant difference in adverse cardiac and cerebrovascular events at 30days
- No significant reduction in new cerebral lesion volume, although the trend was favorable
- No difference in clinical stroke rate at 30days

Kapadia SR et al, JACC, 2017
Acute Kidney Injury
Periprocedural Complications
5a. AKI-Incidence and Definition

- Incidence of AKI: 4.0-57% (3-10% after VARC II)

- AKI-related 30-day mortality rate: x2
- AKI-related 1-year mortality rate: x1.4

Liao et al, Eurointervention, 2017
Periprocedural Complications
5b.AKI-Risk Factors/Pathogenesis

Preoperative Factors
• CKD
• BP/DM
• EF
• PAD
• COPD

STS Euroscore

Perioperative Factors
• Bleeding/Transfusion
• Rapid Pacing
• Contrast media
• Non TF approach

Hypotension
Embolization
Nephrotoxicity
Inflammation

AKI

Mortality

LOS

ESRD

Cost

Postoperative Factors
• Shock
• Anemia
• EF

Ram et al, Clinical Cardiology, 2017
Periprocedural Complications

5c.AKI-Prevention

- Discontinuation of Nephrotoxic agents (Metformin, NSID...)
- Optimization of pre-TAVI volume status
  - RenalGuard system


- No benefit of IV sodium bicarbonate or oral acetylcysteine over placebo for the prevention of contrast-associated acute kidney injury

Weisboard et al, NEJM, 2017
Subclinical Leaflet Thrombosis
Incidence: 15% for TAVI
4% for SAVR

Chakravarty et al, Lancet, 2017
Long-Term Complications

6b. SLT-Etiology

- Leaflet trauma during crimping
- Metallic THV frame
- Incomplete THV expansion
- Incomplete THV apposition
- Balloon expansion of the valve
- Large valves
- Valve in-valve
- Low EF
Long-Term Complications
6c. SLT-Cerebrovascular Events

**Transient Ischaemic Attack**

<table>
<thead>
<tr>
<th>Study</th>
<th>OR (95% CI)</th>
<th>Events, LT present</th>
<th>Events, LT absent</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Makkar et al. (2015)</td>
<td>(Excluded)</td>
<td>0/22</td>
<td>0/33</td>
<td>0.00</td>
</tr>
<tr>
<td>Chakravarty et al. (2017)</td>
<td>6.66 (2.19, 20.21)</td>
<td>6/106</td>
<td>7/784</td>
<td>89.65</td>
</tr>
<tr>
<td>Yanagisawa et al. (2017)</td>
<td>1.92 (0.07, 50.38)</td>
<td>0/10</td>
<td>1/61</td>
<td>10.35</td>
</tr>
<tr>
<td>Overall (I-squared = 0.0%, p = 0.480)</td>
<td>5.86 (2.05, 16.75)</td>
<td>6/138</td>
<td>8/878</td>
<td>100.00</td>
</tr>
</tbody>
</table>

*Rashid et al, Eurointervention, 2018*
### Long-Term Complications

#### 6d. SLT-Prevention and Management

<table>
<thead>
<tr>
<th></th>
<th>AHA/ACC guidelines</th>
<th>ESC/EACTS guidelines</th>
<th>ACC expert consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Early after TAVI</strong></td>
<td>Aspirin 75–100 mg/day + clopidogrel 75 mg/day for 6 months (IIb)</td>
<td>Low-dose aspirin + thienopyridine</td>
<td>Aspirin 75–100 mg/day + clopidogrel 75 mg/day for 3–6 months</td>
</tr>
<tr>
<td></td>
<td><strong>VKA to achieve an INR of 2.5 for at least 3 months in patients at low risk of bleeding (IIb) (newly added from 2017)</strong></td>
<td>For patients with AF, VKA + aspirin or thienopyridine (it should be weighed against increased risk of bleeding)</td>
<td>Consider VKA (INR 2.0–2.5) if at risk of AF or VTE for 3 months</td>
</tr>
<tr>
<td><strong>Late after TAVI</strong></td>
<td>Lifelong aspirin 75–100 mg/day (IIb)</td>
<td>Aspirin or thienopyridine alone</td>
<td>Lifelong aspirin 75–100 mg/day</td>
</tr>
</tbody>
</table>

*Nakatani et al, Heart, 2017*
Take home messages

• Complications of TAVI are divided in Periprocedural and Long-term complications

• Most common periprocedural complications are access site bleeding, PVR, HAVB and distal organ injury.

• Evolution in valve design targets in reducing complication rate.

• New generation valve systems managed to significantly reduce access site bleeding and PVR

• Further evolution of existing technology and the emerge of newer devices will improve clinical outcome in the near future
Thank you for your attention