TAVI Devices:
Major Complications

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Barbanti et al, Eurointervention, 2017
TAVI Complications

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

Periprocedural

- PVR
- Valve Thrombosis
- Endocarditis

Long-Term
Vascular Issues
Periprocedural Complications

1a. Vascular Issues - Access Site

- Bleeding
- Dissection
- Occlusion

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

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>M-H, Random, 95% CI</th>
<th>Odds Ratio</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>
<td></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>
<td></td>
</tr>
<tr>
<td>Ruparel et al 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>
<td></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>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>25</td>
<td>442</td>
<td>464</td>
<td>100.0%</td>
<td></td>
<td>0.32 [0.20, 0.52]</td>
<td></td>
</tr>
<tr>
<td>Total Events</td>
<td>73</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 2.44, df = 3 (P = 0.49); I² = 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>M-H, Random, 95% CI</th>
<th>Odds Ratio</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>
<td></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>
<td></td>
</tr>
<tr>
<td>Ruparel et al 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>
<td></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>
<td></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>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>12</td>
<td>482</td>
<td>544</td>
<td>100.0%</td>
<td></td>
<td>0.36 [0.11, 1.18]</td>
<td></td>
</tr>
<tr>
<td>Total Events</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.95; Chi² = 8.72, df = 4 (P = 0.07); I² = 54%
Test for overall effect: Z = 1.69 (P = 0.09)

Ando et al, Cardiovasc Revasc Medicine, 2017
Periprocedural Complications

Vascular Issues - NG Closure Devices

MANTA

InClosure VCD

PerQseal
Paravalvular Regurgitation
Periprocedural Complications

2a. Paravalvular AR- Incidence

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
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
### 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/SAPIEN XT valves)</td>
<td>2.6–25.7</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
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

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
Wires, Catheters, Valve Deployment
Hypotension, Hypertension

Late phase
30d
AF

>30d
AF
Comorbidities
Valve Thrombosis

Prakash A et al, J Cardiothoracic and Vasc Anesth, 2017
Periprocedural 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 30 days
- No significant reduction in new cerebral lesion volume, although the trend was favorable
- No difference in clinical stroke rate at 30 days

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

Preoperative Factors
- STS
- Euroscore

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

Postoperative Factors
- Shock
- Anemia
- EF

AKI
- Hypotension
- Embolization
- Nephrotoxicity
- Inflammation

Mortality

LOS

ESRD

Cost

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
Long-Term Complications

6a. 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

Transitent 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