How to Prevent Thromboembolic Complications in TAVI

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Potential Conflicts of Interest

• Proctoring and lecture fees from Medtronic, Edwards Lifesciences and Boston Scientific
Objectives/Learning Issues

• To understand neurological complications
• To learn the actual rate of these complications in contemporary series
• To develop clinical strategies to decrease these complications
Prevalence of Stroke in the US
Roger VL et al. Circulation 2011; 123: e18-e209

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Both sexes</td>
<td>7 000 000 (3.0%)</td>
<td>795 000</td>
<td>135 952</td>
<td>829 000</td>
<td>$40.9 billion</td>
</tr>
<tr>
<td>Males</td>
<td>2 800 000 (2.7%)</td>
<td>370 000 (46.5%)†</td>
<td>54 111 (39.8%)†</td>
<td>371 000</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>4 200 000 (3.3%)</td>
<td>425 000 (53.5%)†</td>
<td>81 841 (60.2%)†</td>
<td>458 000</td>
<td></td>
</tr>
</tbody>
</table>
Stroke Risk Profile


- Female Gender
- Active Smoking
- Atrial Fibrillation
- LV Hypertrophy
- Systemic Hypertension
- Diabetes Mellitus
Aortic Stenosis Patients

S. E., 83 YO Female

10-Year Stroke Probability

Calculated Risk: 84%
Expected Risk: 23.9%

Assessment of Aortic Arch Atheroma by TEE and Correlation With Aortic Stenosis
Osranek et al, Am J Cardiol 2009;103:713-17

• Prevalence of severe aortic atheroma increased with severity of aortic stenosis

• 54% of patients with severe aortic stenosis had severe aortic arch atheroma

• 61% of patients >65 years with severe aortic stenosis had severe aortic arch atheroma
Stroke due to CV Interventions

- Isolated Valve: 4.8 – 8.8%
- Isolated CABG: 1.4 – 3.8%
- Double Valve: 9.7%
- CABG and Valve: 7.4%
- PCI: 0.4%
- TAVI: 0 – 9.6%

Fuchs et al., Circulation 2002; 106
Selim et al. NEJM 2007;356:706-13
Incidence of Major/Disabling Stroke in TAVI/SAVR
Cerebrovascular Events After 30 Days and 1 Year – Partner A Cohort

Smith et al. NEJM 2011;364:2187-98

Major Stroke

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>1 Year</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI</td>
<td>3.8</td>
<td>2.1</td>
<td>0.20</td>
</tr>
<tr>
<td>SAVR</td>
<td>2.4</td>
<td>2.4</td>
<td></td>
</tr>
</tbody>
</table>

All Stroke or TIA

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>1 Year</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI</td>
<td>5.5</td>
<td>4.3</td>
<td>0.04</td>
</tr>
<tr>
<td>SAVR</td>
<td>5.5</td>
<td>2.4</td>
<td>0.04</td>
</tr>
</tbody>
</table>

p = 0.04
**All-Cause Mortality or Stroke**

*All Patients (n=699)*

HR [95% CI] = 0.95 [0.73, 1.23]

P (log rank) = 0.70
All Stroke

Transcatheter vs Surgical

Δ = 3.8

Δ = 5.7

12.5%

8.7%

10.9%

16.6%

Log-rank P=0.05

No. at Risk

Transcatheter 391 364 335 318 205

Surgical 359 324 281 256 169

Months Post-Procedure
Impact of Stroke on Mortality

- Major Stroke (n=15)
- No Major Stroke (n=164)

P (log rank) < 0.0001

66.7% mortality for Major Stroke group.

Figure 3:
-Freedom from All-cause Mortality (%)

- Stroke Within 30 Days
- No Stroke Within 30 Days

Log-rank P = 0.002
Results – Outcome

Cerebrovascular Events

- Without CABG: 2.2%
- With CABG: 3.6%
- Transvascular: 3.7%
- Transapical: 3.5%

n=6517, n=3458, n=2689, n=1177

Surgical AVR
TAVI
## Clinical Outcomes at 30 Days (1)

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>TF (N = 96)</th>
<th>TAA (N = 54)</th>
<th>Overall (N = 150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>2 (2.1%)</td>
<td>6 (11.1%)</td>
<td>8 (5.3%)</td>
</tr>
<tr>
<td>Cardiac Mortality</td>
<td>2 (2.1%)</td>
<td>5 (9.3%)</td>
<td>7 (4.7%)</td>
</tr>
<tr>
<td>All-Stroke*</td>
<td>1 (1.0%)</td>
<td>3 (5.6%)</td>
<td>4 (2.7%)</td>
</tr>
<tr>
<td>Disabling Stroke</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Major Vascular Complication</td>
<td>5 (5.2%)</td>
<td>4 (7.4%)</td>
<td>9 (6.0%)</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>19 (19.8%)</td>
<td>11 (20.4%)</td>
<td>30 (20.0%)</td>
</tr>
<tr>
<td>Life-Threatening Bleeding</td>
<td>2 (2.1%)</td>
<td>3 (5.6%)</td>
<td>5 (3.3%)</td>
</tr>
<tr>
<td>Rehospitalization†</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

## Event Rate in the VI Population

<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>TF (N = 95)</th>
<th>TAA (N = 54)</th>
<th>Overall (N = 149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>1 (1.1%)</td>
<td>6 (11.1%)</td>
<td>7 (4.7%)</td>
</tr>
</tbody>
</table>

* Severity of the one TF stroke unknown.
† Rehospitalization for valve-related symptom or worsening of congestive heart failure.
Incidence of Major/Disabling Stroke in TAVI Patients

- In high-risk patients: 3-5 %
- In intermediate risk patients: 1-3%
Incidence of Silent Brain Ischemia?
Cerebral Ischemia After TAVI
Kahlert PK et al. Circulation 2010;121:870-878

![Graph showing new lesions and lesion volume](image)

**New Lesions**
- Edwards: 86%
- CoreValve: 80%
- SAVR: 48%

**Lesion Volume**
- Edwards: 81 mm³
- CoreValve: 61 mm³
- SAVR: 224 mm³
Transcranial Doppler Sound Detection of Cerebrovascular Microembolism

Erdös G et al. EJCTS 2011

Transfemoral vs. Transapical TAVI

Self- vs. Ballonexpandable TAVI

<table>
<thead>
<tr>
<th>Period in min</th>
<th>IN</th>
<th>BV</th>
<th>DP</th>
<th>PI</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TF-AVI</td>
<td>36 (17-58)</td>
<td>3 (2-6)</td>
<td>2 (1-5)</td>
<td>26 (15-60)</td>
<td>70 (49-117)</td>
</tr>
<tr>
<td>TA-AVI</td>
<td>36 (17-58)</td>
<td>3 (2-6)</td>
<td>2 (1-5)</td>
<td>26 (15-60)</td>
<td>70 (49-117)</td>
</tr>
</tbody>
</table>

p = .004

<table>
<thead>
<tr>
<th>Period in min</th>
<th>IN</th>
<th>BV</th>
<th>DP</th>
<th>PI</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
</tr>
<tr>
<td>BE</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
<td>1454</td>
</tr>
</tbody>
</table>

p = .027

p = .024
Mechanism of Thromboembolic Events

- Transcatheter Aortic Valve Implantation

- Acute
- Subacute
- Late Predictors for Cerebrovascular Event

- NOAFib

- Chronic Afib
- Atherosclerotic Disease Burden

- TAVI
- Spontaneous Risk

- Age, Gender and Risk Factor
  Matched Patient Population

- Stroke
  - Minimal Touch Technique
  - Embolic Protection Device
  - New Generation Valve Prosthesis

- Protection
  - Intra- and peri-procedural Antithrombotic Therapy

- Strategy
  - (N)OACs

- Patients with Sinus Rhythm
- Patients with Afib

Stortecky et al 2014
Therapeutic Options for Stroke Prevention

Drugs

Risk assessment

Protection Devices
Summary

• Stroke remains an important issue for patients undergoing TAVI
• Further improvements in the field of antiplatelet and anticoagulation treatment are warranted
• The role of protection devices need be determined
Thank you

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Bern, Switzerland
AK St Georg Study

**Embolic debris captured during TAVI procedures at AK St Georg (Hamburg RECAPTURE)**

52 cases of TAVI using Claret Medical Cerebral Protection System performed at AK St Georg (Hamburg)
- Using Sapien S3/XT, CoreValve, etc. valves

Filter contents subsequently analyzed by CVPath Institute
- Debris captured in 96% of patients

**Cerebral embolic debris captured in TAVI patients (n=52)**

<table>
<thead>
<tr>
<th>Debris Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any debris</td>
<td>100%</td>
</tr>
<tr>
<td>Acute thrombus</td>
<td>99%</td>
</tr>
<tr>
<td>Organizing thrombus</td>
<td>79%</td>
</tr>
<tr>
<td>Valve Tissue</td>
<td>65%</td>
</tr>
<tr>
<td>Arterial Wall</td>
<td>47%</td>
</tr>
<tr>
<td>Calcification</td>
<td>38%</td>
</tr>
<tr>
<td>Foreign material</td>
<td>15%</td>
</tr>
</tbody>
</table>

Note: percentages reflect percent of filters in the series in which each particular tissue type was captured. Some filters captured several types of debris, so percentages will not add to 100%