TAVR Complications

Reported Complications Rates range from 8% to 15%

Predictors of Complications
– Gender
– Calcification
– Diameter
– Sheath Size
How Do We Keep Track?

Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document


* The Valve Academic Research Consortium (VARC) consists of representatives from several independent Academic Research Organizations, several Surgery and Cardiology Societies, members of the US Food and Drug Administration (FDA), and several independent experts. However, it is not a society document. Neither the societies nor the FDA has been asked to endorse the document.

• This document provides an overview of risk assessment and patient stratification that need to be considered for accurate patient inclusion in studies.

• Working groups were assigned to define the following clinical endpoints:
  – mortality, stroke, myocardial infarction, bleeding complications, acute kidney injury, vascular complications, conduction disturbances and arrhythmias, and a miscellaneous category including relevant complications not previously categorized.
VARC-2 Complications

Major vascular complications

- Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation or new apical aneurysm/pseudoaneurysm.
- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, haematoma, irreversible nerve injury, compartment syndrome and/or percutaneous closure device failure) leading to death, life-threatening or major bleeding,* visceral ischaemia or neurological impairment.
- Distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.
- Use of unplanned endovascular or surgical intervention associated with death, major bleeding, visceral ischaemia or neurological impairment.
- Any new ipsilateral lower extremity ischaemia documented by patient symptoms, physical exam and/or decreased or absent blood flow on lower extremity angiogram.
- Surgery for access site-related nerve injury.
- Permanent access site-related nerve injury.

Minor vascular complications

- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysms, haematoma and/or percutaneous closure device failure) not leading to death, life-threatening or major bleeding, visceral ischaemia or neurological impairment.
- Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage.
- Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication.
- Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization or stent-graft).

Percutaneous closure device failure

- Failure of a closure device to achieve haemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular balloononing).
Valve Academic Research Consortium (VARC-2)

**Major Complications:**
- Aortic Dissection, Rupture, or Apical Aneurysm
- Access Related Vascular injury leading to death, major bleeding, ischemia, or neurologic impairment.

**Minor Complications:**
- Access Related Vascular injury leading to minor bleeding.
- Closure device failure
• Partner Trial – 15.3% major and 11.9% minor complication rates

• As devices become smaller in size injuries should become less frequent
Factors Influencing Vascular Complications

Gender
Calcification
PAD
Sheath Size

a Genereux et al. J American College of Cardiology; 2014
b Toggweiler et al. J American College of Cardiology; 2012
c Barbanti et al. Eurointervention; 2013
Local Standard Of Care

• Sentara Heart Hospital
  – High Volume TAVR volume with technical success and complications that are superior to the national average.

• If we can identify patients at risk for peripheral complications we will have a better chance of prevention.
Objective

• This study was designed to create an iliac artery morphology score (IMS) to predict major vascular complications and procedural mortality for TAVR.
Methods

- July 2011 to July 2015
- Excluded:
  - Transapical access
  - Direct aortic access
  - Subclavian access
  - Inadequate CTA imaging

Total Valve Replacements
N = 341

Study criteria met
N = 198
Outcomes and Analysis

Factors found to be predictive of major complications in univariate analysis were analyzed in a multivariate model.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariate p value</th>
<th>Multivariate p value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>0.053</td>
<td>0.18</td>
<td>0.269</td>
<td>0.024 - 2.9</td>
</tr>
<tr>
<td>Sheath Size (mm)</td>
<td>0.053</td>
<td>0.487</td>
<td>1.67</td>
<td>0.392 - 7.1</td>
</tr>
<tr>
<td>SFAR</td>
<td>0.001</td>
<td>0.515</td>
<td>0.515</td>
<td>0.001 - 31.7</td>
</tr>
<tr>
<td>SEIAR</td>
<td>0.001</td>
<td>0.76</td>
<td>0.76</td>
<td>0.001 - 16.5</td>
</tr>
<tr>
<td>Iliac Morphology Score</td>
<td>0.005</td>
<td>0.038</td>
<td>2.8</td>
<td>1.1 - 7.7</td>
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<tr>
<td>Iliac Calcification</td>
<td>0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliac Diameter</td>
<td>0.02</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SFAR = sheath to femoral artery ratio; SEIAR = sheath to external iliac artery ratio
Iliac Morphology Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calcification</strong></td>
<td>none</td>
<td>&lt;25% vessel length</td>
<td>25-50% Vessel Length</td>
<td>&gt;50% of vessel length or any circumferential point</td>
</tr>
<tr>
<td><strong>Minimum Diameter (mm)</strong></td>
<td>&gt;7.1</td>
<td>6.4 &lt; x ≤ 7.1</td>
<td>5.5 &lt; x ≤ 6.4</td>
<td>≤ 5.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>All (3%)</th>
<th>Low IMS (N=143) (9%)</th>
<th>High IMS (N=55) (9%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Complications</td>
<td>6 (3%)</td>
<td>1 (0.7%)</td>
<td>5 (9%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Minor Complications</td>
<td>18 (9%)</td>
<td>13 (9%)</td>
<td>5 (9%)</td>
<td>0.559</td>
</tr>
<tr>
<td>Mortality</td>
<td>7 (3.5%)</td>
<td>2 (1.4%)</td>
<td>5 (9%)</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Conclusions

• An IMS composed of ipsilateral minimum iliac diameter plus iliac calcification is an excellent predictor of major vascular complications and mortality.

• Alternative access in patients with high IMS may reduce major vascular complications and procedural mortality.
Repair Options
Repair Options

Images A, B, and C show different repair options for a medical condition, likely related to blood vessels, based on the visual content. Each image represents a different step or method in the repair process.
Case study

84 year-old Caucasian male presented with SOB, chest pressure, and lightheadedness.

- Severe symptomatic AS with an AVA of 0.8, EF 20% in an inoperable patient due to multiple co-morbidities and frailty, prior CABG
- Transcatheter aortic valve replacement (TAVI) with 26 mm Sapien XT.
Case study

Embolized Sapiens valve

Deployment of a 2nd Sapiens valve
Case study

TEVAR rescue with ascending aortic deployment to stabilize the valve

CTA at 1 year
Conclusions

• Operating in a hybrid OR with cardiology, cardiac surgery, vascular surgery and high quality imaging has provided excellent technical success and infrequent complications with Sentara’s high volume TAVR program