Vascular complications of embolized core valve

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Disclosure’s

Speaker name: Suhail Dohad, MD

Consultant/Advisory Board/Research Grants:
- Medtronic
- Abbott Vascular
- AVINGER
- Boston Scientific
- ST Jude Medical

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- Medtronic Endovascular
- Abbott Vascular
- Boston Scientific
- AVINGER
- St Jude Medical
- Astra Zeneca
- Jansenn Pharmaceuticals
- Sanofi
- Eli Lily
- CR Bard
CoreValve Bioprosthesis

Outflow Orientation

Maximizes Flow

Constrained Portion

Supra-annular leaflet function

Valve Function

Designed to avoid coronaries

Inflow Portion

Intra-annular anchoring

Sealing

Mitigates paravalvular aortic regurgitation

TCT 2013 LBCT

Extreme Risk Study | Iliofemoral Pivotal
Study Device and Access Routes

4 valve sizes
(18-29 mm annular range)

18Fr delivery system

Transfemoral
Subclavian
Direct Aortic
Step-by-step assembly of the Medtronic CoreValve

1. Advance outflow tube towards the handle
2. Insert outflow of the THV into outflow cone
3. Secure outflow cap onto the outflow cone
4. Insert the inflow tube into the outflow cap
5. Insert distal catheter tip into inflow tube
6. Withdraw the inflow tube
7. Advance the capsule to cover the bioprosthesis
8. Advance outflow tube over radiopaque marker
9. Remove outflow cap/inflow tube from outflow cone
10. Advance the inflow cone over the THV
11. Advance bioprosthesis into the inflow cone
12. Final valve assembly
National trends in vascular access for TAVR

Registry data involving 7570 patients

Transfemoral approach is the predominant approach

<table>
<thead>
<tr>
<th>Study</th>
<th>Transfemoral (%)</th>
<th>Alternate Access (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Himbert et al.</td>
<td>68,0%</td>
<td>32,0%</td>
</tr>
<tr>
<td>Rodes-Cabau et al.</td>
<td>51,3%</td>
<td>48,7%</td>
</tr>
<tr>
<td>Thomas et al.</td>
<td>55,4%</td>
<td>44,6%</td>
</tr>
<tr>
<td>Lefevre et al.</td>
<td>53,1%</td>
<td>46,9%</td>
</tr>
<tr>
<td>Moat et al.</td>
<td>68,9%</td>
<td>31,1%</td>
</tr>
<tr>
<td>Gilard et al.</td>
<td>85,3%</td>
<td>14,7%</td>
</tr>
</tbody>
</table>

TF 51 AA 24
TF 168 AA 177
TF 463 AA 575
TF 61 AA 69
TF 599 AA 271
TF 4361 AA 751

JACC 2010
JACC 2010
Circulation 2010
EHJ 2011
JACC 2011
NEJM 2012
### Secondary Endpoints

<table>
<thead>
<tr>
<th>Events*</th>
<th>1 Month</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Stroke, %</td>
<td>3.9</td>
<td>6.7</td>
</tr>
<tr>
<td>Major, %</td>
<td>2.4</td>
<td>4.1</td>
</tr>
<tr>
<td>Minor, %</td>
<td>1.7</td>
<td>3.1</td>
</tr>
<tr>
<td>Myocardial Infarction, %</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Reintervention, %</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>VARC Bleeding, %</td>
<td>35.1</td>
<td>41.4</td>
</tr>
<tr>
<td>Life Threatening or Disabling, %</td>
<td>11.7</td>
<td>16.6</td>
</tr>
<tr>
<td>Major, %</td>
<td>24.1</td>
<td>27.6</td>
</tr>
<tr>
<td>Major Vascular Complications, %</td>
<td>8.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Permanent Pacemaker Implant, %</td>
<td>22.2</td>
<td>27.1</td>
</tr>
<tr>
<td>Per ACC Guidelines, %</td>
<td>17.4</td>
<td>19.9</td>
</tr>
</tbody>
</table>

* Percentages obtained from Kaplan Meier estimates
# Other Endpoints - US PIVOTAL

<table>
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<tr>
<th>Events*</th>
<th>1 Month</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR  SAVR  P Value</td>
<td>TAVR  SAVR  P Value</td>
</tr>
<tr>
<td>Vascular complications (major), %</td>
<td>5.9  1.7  0.003</td>
<td>6.2  2.0  0.004</td>
</tr>
<tr>
<td>Pacemaker implant, %</td>
<td>19.8 7.1 &lt;0.001</td>
<td>22.3 11.3 &lt;0.001</td>
</tr>
<tr>
<td>Bleeding (life threatening or disabling), %</td>
<td>13.6 35.0 &lt;0.001</td>
<td>16.6 38.4 &lt;0.001</td>
</tr>
<tr>
<td>New onset or worsening atrial fibrillation, %</td>
<td>11.7 30.5 &lt;0.001</td>
<td>15.9 32.7 &lt;0.001</td>
</tr>
<tr>
<td>Acute kidney injury, %</td>
<td>6.0 15.1 &lt;0.001</td>
<td>6.0 15.1 &lt;0.001</td>
</tr>
</tbody>
</table>

* Percentages reported are Kaplan-Meier estimates and log-rank P values
Case # 1

1. 91 y/o gentleman randomized in SURTAVI to TF approach with 31mm valve with large annular size
2. Low rate pacing with deployment of valve that migrated too high
3. Resheath attempt unsuccessful
4. Entire valve system pulled back into descending aorta – re attempt of re sheathing resulted in detachment of distal nose cone
5. Entire valve now brought back to distal abdominal aorta to deploy there and recapture nose cone
CoreValve ejected from the sheath during deployment

Unsuccessful resheathing of the valve
Valve deployed at the junction of the abdominal aorta and right CIA
Under-expanded proximal flare of the CoreValve probably damaged and mangled.

post-dilated with 8.0x4mm balloon
8.0x27mm VisiPro Stent deployed across the distorted proximal flare of the CoreValve
Nosecone dislodged while removing the valve delivery system

Nosecone removed using an IVC removal device into the sheath and the sheath removed
31mm CoreValve deployed successfully after placement of another sheath
Case # 2

• 88 y/o male with high surgical risk underwent commercial TF Corevalve implant with #29 valve
• Initially valve was seated and then after a few minutes valve was ejected
• During Re sheathing which was unsuccessful the nose cone was dislodged
CoreValve ejected from the sheath during removal
Nosecone dislodged while removing the valve delivery system
Nosecone free floating as wire position was lost
Nosecone successfully snared
2\textsuperscript{nd} CoreValve deployed successfully
Free flow across the CoreValve deployed in the abdominal aorta
Left renal with unimpeded flow
Failure of Perclose suture
Peripheral angiogram after manual compression for 20 minutes
Final result s/p 6.0x40mm balloon inflation across the lesion for 5 minutes
Summary

• A unique issue of dislodged nose cone with mal-deployed valve exposes a weakness in the current delivery system of core valve
• Vascular complications lower in incidence but still high especially in extreme risk cohort
• Complications can be managed using endovascular techniques predominantly
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