Vascular Access in TAVI

Antonio Colombo
EMO-GVM, Centro Cuore Columbus, Milan, Maria Cecilia Hospital, Cotignola (RA) and GVM Laboratories, Italy
Nothing to disclose
TAVR Access options

- Transcarotid
- Transaortic
- Transseptal
- Transcaval
- Iliac artery
- Transapical
- Transsubclavian
- Transfemoral

Overtchouk et al, Interv Cardiol, 2018
Nonfemoral TAVR Access Consistently Results in Worse Outcomes

Traditional nonfemoral TAVR has worse mortality vs. Transfemoral TAVR
  • Significantly worse in-hospital$^1$,30-day$^2$ and 1 year mortality risk$^{2,3}$
  • Poor outcomes are exacerbated in frail patients$^4$

More recent nonfemoral access options (transcarotid, transcaval and axillary/subclavian)
  • Additional complexity and/or significant complications (vascular complications, bleeding risk and/or stroke)$^{5,6,7}$
  • Significant learning curve: Technical proficiency begins to develop at 25 cases and isn’t complete until 50 cases$^8$
  • Potential requirement of patient transfer to hospitals experienced in specific alternative access techniques

4) Drudi J et al, Interaction Between Frailty and Access Site in Older Adults Undergoing Transcatheter Aortic Valve Replacement, JACC: Interventions 2018
<table>
<thead>
<tr>
<th>Access</th>
<th>Procedural success(%)</th>
<th>30 D mortality</th>
<th>Major and life-threatening bleeding</th>
<th>Neurological events (TIA/Stroke)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trans-femoral (3–14)</td>
<td>95–100</td>
<td>2.1–5%†</td>
<td>9.3–28.1%†</td>
<td>1.4–6.7% (30 days stroke)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2–9.7%†</td>
<td>3.5–11.4%†</td>
<td>2.3–4.1% (1 year stroke)</td>
</tr>
<tr>
<td>Trans-axillarian (16)</td>
<td>97.9</td>
<td>5.7%</td>
<td>7.8% life threatening</td>
<td>2.1%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>36.2% major bleeding</td>
<td></td>
</tr>
<tr>
<td>Trans-Aortic (17–24)</td>
<td>87–100</td>
<td>6.1–13%</td>
<td>0.3–12%</td>
<td>0–3.2%</td>
</tr>
<tr>
<td>Trans-Apical (13, 25–28)</td>
<td>90–96</td>
<td>4.6–14%</td>
<td>3.6–6.1%</td>
<td>1.3–4.1%</td>
</tr>
<tr>
<td>Trans-Carotid (29)</td>
<td>100</td>
<td>6.3%</td>
<td>4.2%</td>
<td>3.1% (all TIAs, stroke not reported)</td>
</tr>
<tr>
<td>Trans-Caval (30, 31)</td>
<td>100</td>
<td>8%</td>
<td>12% (6% transcaval related)</td>
<td>5%</td>
</tr>
</tbody>
</table>

†Data derived from Partner A, Partner B, Partner II, Notion and SURTAVI trials.
††Data derived from TVT, Gary, UK TAVI, Observant and France2 registries.
Comparison Trans-Axillary vs Trans-Femoral

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<tbody>
<tr>
<td>Mortality</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>Stroke</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>-</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>Life-threatening Bleeding</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>-</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>-</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>Access site Bleeding</td>
<td>Axillary better</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>-</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>New Pacemaker</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>Femoral better</td>
<td>NO DIFF</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>No DIFF</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
<td>NO DIFF</td>
</tr>
</tbody>
</table>

- Log-rank p = 0.703
- Subclavian vs Femoral
  - P=0.04
  - P=0.02
Transcaval access

- N = 100
- Euroscore II = 10.9 +/-7.2%
- General anaesthetic: 84%
- Contrast: 166 +/-87mls

- Devices:
  - Sapien 3 57%
  - Sapien XT 23%
  - Corevalve 23%
  - Evolut R 9%

- Aortic Closure:
  - ADO/VSD 98%
  - Covered stent 1%

**OUTCOMES (n=100)**

- 30 day Mortality (In-patient) 8% (4%)
- Procedural success 99%
- VARC-2 Bleeding (life-threatening) 12%
- *Related to Transcaval 7%
- Vascular complications (major) 19%
- *Related to Transcaval (major) 13%
- Stroke 5%
- CT Retroperitoneal haematoma (moderate-large) Pre-discharge: 10%
  30 days: 1%

*Greenbaum AB et al, J Am Coll Cardiol. 2017*
Temporal Changes in TAVR Access: Decreasing TA/Tao and Increasing TAx
Hospital Volume – Mortality Relationship Strongest with Non-Femoral Access

Right Femoral Approach

Preprocedural CT report tortuosity of iliac arteries, with severe calcifications

Kinking of left common iliac artery

Rupture of common iliac artery during attempts to cross
Patient went immediately in shock requiring cardiac massage, liquids, adrenaline, intubation..

Immediate positioning of aortic occlusion balloon
Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system

**Lithotripsy**

30 years of safety data in kidney stone treatment

*Sonic Pressure Waves* preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

**Cardiovascular Lithotripsy**

Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium

*Optimized for the Treatment of Cardiovascular Calcium*

Peripheral IVL Catheters
The Shockwave IVL System consists of an IV pole-mountable generator, a connector cable, and a catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon.
## Peripheral IVL Catheter Specs

<table>
<thead>
<tr>
<th>DIAMETER (mm)</th>
<th>LENGTH (mm)</th>
<th>Max Pulse Count</th>
<th>GUIDEWIRE COMPATIBILITY (in)</th>
<th>SHEATH COMPATIBILITY</th>
<th>WORKING LENGTH (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5-6.0</td>
<td>60</td>
<td>300</td>
<td>0.014</td>
<td>6F</td>
<td>110</td>
</tr>
<tr>
<td>6.5-7.0</td>
<td>60</td>
<td>300</td>
<td>0.014</td>
<td>7F</td>
<td>110</td>
</tr>
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</table>
How Shockwave Creates Localized Lithotripsy

High Speed Sonic Pressure Wave Created Safely Inside Integrated Balloon

1. **Unfocused lithotripsy energy** is created at the emitters which are contained in a fluid filled coupler.

2. Electrical energy is delivered to the emitter, initiating the steam bubble, which expand & collapses – creating **sonic pressure waves**.

- Bubble expands - collapses
- Sonic Pressure Waves

The force generated is “similar” to 50 atm. but do not assume that this force is transmitted to the balloon, the force is in the microbubbles.
OCT demonstrated calcium disruption leading to acute luminal gain and alteration in vessel compliance in both peripheral and coronary arteries.

Micro CT demonstrated calcium fractures leading to an acute reduction in mean gradient and improved coaptation of Aortic Valve leaflet.

*The Coronary and Aortic Valve Lithotripsy Systems are not approved or available for sale in the United States.*
Summary

- Transcatheter Aortic Valve Implantation (TAVI) is most commonly performed using a transfemoral (TF) access route

- TF access is precluded or complicated by severe iliac calcification, stenosis and tortuosity

- Introduction of large devices through calcified iliacs may produce serious complications, such as rupture, and/or necessitate costly secondary interventions

- Nonfemoral access routes are required in 12-21% of patients undergoing TAVR, resulting in increased cost, complexity and complication risk

- IVL safely modifies iliac artery calcium, preserving TF access and mitigating the challenges of nonfemoral access