Reducing vascular complications in TAVI

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Potential for Conflicts of Interest

I, Francesco Maisano, have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

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Shareholder of: Cardiovalve, Magenta, SwissVortex, Transseptalsolutions, Occlufit, 4Tech, Perifect
Trend and type of Access site complications (Cleveland Clinic)

Kubber et al JACC Interv 2019: 12: 2210-20
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>30 Days</th>
<th></th>
<th>1 Year</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR (N=496)</td>
<td>Surgery (N=454)</td>
<td>P-value</td>
<td>TAVR (N=496)</td>
</tr>
<tr>
<td>Bleeding - Life-threat/Major</td>
<td>3.6% (18)</td>
<td>24.5% (111)</td>
<td>&lt;0.001</td>
<td>7.7% (38)</td>
</tr>
<tr>
<td>Major Vascular Complics</td>
<td>2.2% (11)</td>
<td>1.5% (7)</td>
<td>0.45</td>
<td>2.8% (14)</td>
</tr>
<tr>
<td>AKI - stage 2 or 3*</td>
<td>0.4% (2)</td>
<td>1.8% (8)</td>
<td>0.05</td>
<td>0.4% (2)</td>
</tr>
<tr>
<td>New PPM (incl baseline)</td>
<td>6.5% (32)</td>
<td>4.0% (18)</td>
<td>0.09</td>
<td>7.3% (36)</td>
</tr>
<tr>
<td>New LBBB</td>
<td>22.0% (106)</td>
<td>8.0% (35)</td>
<td>&lt;0.001</td>
<td>23.7% (114)</td>
</tr>
<tr>
<td>Coronary Obstruction</td>
<td>0.2% (1)</td>
<td>0.7% (3)</td>
<td>0.28</td>
<td>0.2% (1)</td>
</tr>
<tr>
<td>AV Re-intervention</td>
<td>0% (0)</td>
<td>0% (0)</td>
<td>NA</td>
<td>0.6% (3)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0% (0)</td>
<td>0.2% (1)</td>
<td>0.29</td>
<td>0.2% (1)</td>
</tr>
<tr>
<td>Asymp Valve Thrombosis</td>
<td>0.2% (1)</td>
<td>0% (0)</td>
<td>0.34</td>
<td>1.0% (5)</td>
</tr>
</tbody>
</table>

Event rates are KM estimates (%) and p-values are based on Log-Rank test

* Event rates are incidence rates and p-value is Fisher’s Exact test
# Vascular complication rate in Portico registry

## Table of Vascular Complications

<table>
<thead>
<tr>
<th>EVENT</th>
<th>30 DAYS</th>
<th>1 YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality (%)</td>
<td>2.7</td>
<td>12.1</td>
</tr>
<tr>
<td>▪ CV mortality (%)</td>
<td>2.4</td>
<td>6.6</td>
</tr>
<tr>
<td>All stroke (%)</td>
<td>3.0</td>
<td>5.3</td>
</tr>
<tr>
<td>▪ Disabling (%)</td>
<td>1.6</td>
<td>2.2</td>
</tr>
<tr>
<td>▪ Non disabling + TIA (%)</td>
<td>1.4</td>
<td>3.1</td>
</tr>
<tr>
<td>AKI Stage 2 and 3 (%)</td>
<td>3.0</td>
<td>4.2</td>
</tr>
<tr>
<td>Major vascular complications (%)</td>
<td>5.5</td>
<td>5.7</td>
</tr>
<tr>
<td>Life threatening bleeding (%)</td>
<td>3.1</td>
<td>3.2</td>
</tr>
<tr>
<td>Major bleeding (%)</td>
<td>8.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Myocardial Infarction (%)</td>
<td>1.6</td>
<td>2.5</td>
</tr>
<tr>
<td>Overall New PM Implantation (%)</td>
<td>17.1</td>
<td>19.5</td>
</tr>
<tr>
<td>▪ Naïve PM (%)</td>
<td>18.7</td>
<td>21.3</td>
</tr>
</tbody>
</table>

1. In patients with no prior PM,
2. 30 Day rates are based on proportion,
3. 1 Year rates are KM estimates.
A Direct Comparison of Self-Expandable Portico Versus Balloon-Expandable Sapien 3 Devices for Transcatheter Aortic Valve Replacement: A Case-Matched Cohort Study

Silvia Mas-Peiro, MD, MS; Philipp Christian Seppelt, MD; Helge Weiler, MD; Gina-Lisa Mohr, MD; Nestoras Papadopoulos, MD; Thomas Walther, MD; Andreas M. Zeiher, MD; Stephan Fichtlscherer, MD; Mariuca Vasa-Nicotera, MD

ABSTRACT: Objectives. Pairwise comparisons of clinical and hemodynamic outcomes with new transcatheter aortic valve replacement (TAVR) prostheses are needed to help interventionists select the most appropriate device. The self-expandable Portico valve [Abbott Vascular] was compared with the balloon-expandable Sapien 3 valve [Edwards Lifesciences] at a high-volume center in a real-world setting. Methods. All patients undergoing TAVR with a new-generation device from March 2015 to September 2017 at a single center were included. Baseline, peri-interventional, and postoperative 30-day follow-up data were obtained. A nearest-neighbor propensity-score matching procedure [23] was used, based on age, STS score, EuroScore II, New York Heart Association (NYHA) status, and sex. Primary endpoint was 30-day all-cause mortality. Secondary endpoints included procedural results, complications according to Valve Academic Research Consortium (VARC)-2 criteria, and echocardiographic findings. Results. A total of 177 out of 273 patients were matched (64 Portico valves and 73 Sapien 3 valves). Procedural success rates were 99.0% vs 98.6%, respectively; P=NS. Contrast dye use [160 mL for Portico vs 120 mL for Sapien 3; P<.001] and fluoroscopy time [19.0 min for Portico vs 15.5 min for Sapien 3; P=.048] were significantly lower with the Sapien 3 device. Thirty-day mortality rate was 5.8% for the Portico group vs 4.1% for the Sapien 3 group (P=.74). Complication rates were similar between Portico and Sapien 3: acute stroke (2.9% vs 4.1%, respectively; P=.48), major bleeding (13.8% vs 5.6%, respectively; P=.51), major.
No difference in vascular access complications

Mas-Peiro et al, J INVASIVE CARDIOL 2019;31(7):E199-E204.
**Original Studies**

**Feasibility and Safety of Transfemoral Sheathless Portico Aortic Valve Implantation:** Preliminary Results in a Single Center Experience

Maurizio Taramasso,1, 2MD, Andrea Denegri,1 MD, Shingo Kuwata,1 MD, Hans Rickli,1,2 MD, Philipp K. Haeger,2 MD, Gabor Sutsch,1 MD, Hector Rodriguez Cetina Biefer,1 MD, Jan Kottwitz,1 MD, Fabian Nielispach,1 MD, PhD, and Francesco Maisano,1 MD

**TABLE II. Thirty-Day Outcomes**

<table>
<thead>
<tr>
<th>30-Day Outcome (n = 81)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
</tr>
<tr>
<td>Major stroke</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>0</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>Minor vascular complication</td>
<td>17 (21%)</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td>Repeat procedure for valve dysfunction</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>Permanent pacemaker implantation</td>
<td>11/77 (14%)</td>
</tr>
<tr>
<td>Readmission to hospital</td>
<td>1 (1.2%)</td>
</tr>
<tr>
<td>Early safety composite outcome</td>
<td>75 (93%)</td>
</tr>
</tbody>
</table>
Strategy to reduce vascular complications

• Patient selection / alternative access
• CT planning
• Micropuncture/ echoguided puncture
• Prevention (Crossover/same side access
• Sheathless
• Experience and extreme care
Strategy to reduce vascular complications

- Patient selection / alternative access
- CT planning
  - Micropuncture/ echoguided puncture
  - Prevention (Crossover/same side access)
- Sheathelss
- Experience and extreme care
Calcification – Tortuosity - Size
Access choice

• Invasiveness
  – Peripheral access
    » Transfemoral
    » Axillary
  – Direct access
    » Apical
    » Ascending aorta
  – Retroperitoneal

• Decision making factors
  • General vs local anesthesia
  • Risk of malpositioning
  • Risk of complications

Alternative routes are necessary in 20-30% of TAVI
Local anesthesia
Axillary artery step 1

Pectoralis major
Subclavian vein retracted

- Just below the pectoralis major fascia
- The artery lies in a plane cranial and posterior to the vein
- The pectoralis minor is on the lateral end of the skin incision
Axillary artery isolation

- Vessel loops are placed around the proximal and distal portion of the first segment of the axillary artery.
- Tension is placed on the distal loop to stabilize the artery during manipulation.
Purse strings at the puncture site
Puncture and 10F sheath insertion

- Following puncture, a 10F sheath is inserted in the artery under direct vision.
- The arterial entry site is cut rather than dilated with the dilator.
TABLE 1  Baseline Characteristics and Outcome

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>LSA</th>
<th>TF</th>
<th>p Value</th>
<th>LSA 1</th>
<th>LSA 2</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 120)</td>
<td>(n = 91)</td>
<td>(n = 29)</td>
<td></td>
<td>(n = 45)</td>
<td>(n = 46)</td>
<td></td>
</tr>
<tr>
<td>Age, yrs</td>
<td>80 (76-84)</td>
<td>80 (75-83)</td>
<td>82 (78-85)</td>
<td>0.14</td>
<td>80 (76-84)</td>
<td>79 (75-83)</td>
<td>0.57</td>
</tr>
<tr>
<td>Logistic EuroSCORE-I, %</td>
<td>15.0 ± 9.8</td>
<td>13.9 ± 9.5</td>
<td>18.5 ± 10.0</td>
<td>&lt;0.01</td>
<td>13.6 ± 7.6</td>
<td>14.2 ± 11.1</td>
<td>0.56</td>
</tr>
<tr>
<td>LIMA used in CABG</td>
<td>17 (14.2)</td>
<td>2 (2.2)</td>
<td>15 (51.7)</td>
<td>&lt;0.01</td>
<td>0 (0.0)</td>
<td>2 (4.3)</td>
<td>0.50</td>
</tr>
<tr>
<td>LVEF 30% to 49%</td>
<td>27 (22.5)</td>
<td>21 (23.1)</td>
<td>6 (20.7)</td>
<td>0.79</td>
<td>13 (28.9)</td>
<td>8 (17.4)</td>
<td>0.19</td>
</tr>
<tr>
<td>LVEF &lt;30%</td>
<td>2 (1.7)</td>
<td>1 (1.1)</td>
<td>1 (3.4)</td>
<td>0.43</td>
<td>0 (0.0)</td>
<td>1 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Device success</td>
<td>115 (95.8)</td>
<td>88 (96.7)</td>
<td>27 (93)</td>
<td>0.59</td>
<td>43 (95.6)</td>
<td>45 (97.8)</td>
<td>0.62</td>
</tr>
<tr>
<td>Paravalvular leakage ≥moderate</td>
<td>3 (2.5)*</td>
<td>2 (2.2)</td>
<td>1 (3.4)</td>
<td>0.56</td>
<td>2 (4.4)</td>
<td>0 (0.0)</td>
<td>0.24</td>
</tr>
<tr>
<td>Mortality 30 days</td>
<td>4 (3.3)</td>
<td>4 (4.4)</td>
<td>0 (0.0)</td>
<td>0.57</td>
<td>2 (4.4)</td>
<td>2 (4.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>2 (1.7)</td>
<td>2 (2.2)</td>
<td>0 (0.0)</td>
<td>1.0</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Life-threatening bleeding</td>
<td>3 (2.5)</td>
<td>2 (2.2)</td>
<td>1 (3.4)</td>
<td>0.57</td>
<td>0 (0.0)</td>
<td>2 (4.3)</td>
<td>0.50</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>3 (2.5)</td>
<td>3 (3.3)</td>
<td>0 (0.0)</td>
<td>1.0</td>
<td>3 (6.7)</td>
<td>0 (0.0)</td>
<td>0.12</td>
</tr>
<tr>
<td>TIA/stroke</td>
<td>7 (5.8)</td>
<td>5 (5.5)</td>
<td>2 (6.9)</td>
<td>0.68</td>
<td>4 (8.9)</td>
<td>1 (2.2)</td>
<td>0.20</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (1.7)</td>
<td>2 (2.2)†</td>
<td>0 (0.0)</td>
<td>1.0</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>14 (11.7)</td>
<td>13 (14.3)</td>
<td>1 (3.4)</td>
<td>0.18</td>
<td>10 (22.2)</td>
<td>3 (6.5)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Values are median (interquartile range), mean ± SD, or n (%). *No severe paravalvular leakage. †Myocardial infarction did not occur in patients with LIMA in use after CABG.

CABG = coronary artery bypass grafting; LIMA = left internal mammary artery; LSA = left subclavian artery; LSA1 = first 45 patients (early cohort); LSA2 = last 46 patients (later cohort); LVEF = left ventricular ejection fraction; TF = transfemoral; TIA = transient ischemic attack.

Procedural Success and Clinical Outcome of the Portico Transcatheter Aortic Valve Using the Left Subclavian Artery as Primary Access

Transcatheter aortic valve replacement (TAVR) is becoming the standard of care in high-risk patients with severe aortic stenosis and has proven to be a valid alternative also in patients with intermediate surgical risk (1,2). The Portico valve (St. Jude Medical, St. Paul, Minnesota) is a second-generation self-
Strategy to reduce vascular complications

- Patient selection / alternative access
- CT planning
- **Micropuncture/ echoguided puncture**
- Prevention (Crossover/same side access)
- Sheathless
- Experience and extreme care
Identification of the femoral bifurcation
Strategy to reduce vascular complications

• Patient selection / alternative access
• CT planning
• Micropuncture/ echoguided puncture
• Prevention (Crossover/same side access)
• Sheathless
• Experience and extreme care
Same side access

V18 peripheral support wire

2-3 cm

6F sheath

Therapy sheath

Unilateral Access Is Safe and Facilitates Peripheral Bailout During Transfemoral-Approach Transcatheter Aortic Valve Replacement

Shawonri Khubber, MD; Naligol Bouzoubaa, MD; Dhirysaha Mohanani, MD; Aner Kafaf, MD; Mohanned M. Ela, MD; Margaret Kieser, MD; Yuvaraj R. Venkateswaran, MD; Megan Lebel, BS; Arlene R. Shusta, MD; Beni Verma, MD; Vivek Menon, MD; Stephen L. Kim, MD; Gao W. Reed, MD; Hiroshi Fets, MHRS; P. Lenz Strowman, MD; Pete L. Neuma, MD; E. Monetary Tacc, MD; Aner Kishenwane, MD; Sumeet R. Kelapala, MD

ABSTRACT

OBJECTIVES The aim of this study was to compare the rate and trend of vascular complications when placing a second arterial sheath in the contralateral femoral artery during transcatheter aortic valve replacement (TAVR) unilaterally versus bilaterally.

BACKGROUND Vascular complications occur in approximately 3% to 8% of TAVR procedures. Many operators place a second arterial sheath in the contralateral femoral artery to perform aortic root angiography. The authors assumed that placing the second sheath ipsilaterally and distal to the delivery sheath would be an easier option with similar safety.

METHODS The Cleveland Clinic Aortic Valve Center TAVR database was accessed, and data for patients undergoing transfemoral TAVR (TF-TAVR) from January 2014 to December 2017 were analyzed retrospectively. The primary outcome was the rate of peripheral vascular complications.

RESULTS A total of 1,928 patients who underwent TF-TAVR were included in this study. The thousand seven patients (83.36%) underwent bilateral femoral access, and 201 patients (16.64%) underwent TF-TAVR using a unilateral femoral approach. Over the study duration, use of the unilateral access approach trended upward significantly, reaching 43.7% of initial cases in 2017. A gradual decline in access site-related complications was observed, from 13.7% in 2016 to 7.4% in 2017. After propensity-score matching, peripheral vascular complications were similar between bilateral access and unilateral access (0.90% vs. 0.89%) (p = 0.945).

CONCLUSIONS There was a significant decline in vascular complications from 2016 to 2017. Unilateral-access TF-TAVR provided similar safety compared with bilateral access TF-TAVR and is a more accessible approach for managing access site-related complications and possibly achieving better patient satisfaction.

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Same side access

V18 peripheral support wire

6F sheath

Therapy sheath
Easy crossover (bend-to-cross technique)
Strategy to reduce vascular complications

- Patient selection / alternative access
- CT planning
- Micropuncture/ echoguided puncture
- Prevention (Crossover/same side access)
- Sheathless
- Experience and extreme care
1mm Exposure of the Nosecone
FlexNav™ Delivery System for Portico™

- **Integrated sheath**
  - Sheathless option
  - 18/19F OD and 14/15 ID
  - Decreased vessel indication
- **Hydrophilic coating**
  - Enhanced deliverability
  - Coating is on nosecone, catheter and integrated sheath
- **Stability Layer**
  - Increased responsiveness during valve deployment
  - Improved placement accuracy
- **Smaller vessel indication**
  - Ability to treat more patients
- **Restyled handle**
  - Easy to use
  - More intuitive deployment lock
  - Quick closure post deployment
- **Improved retainer tabs**
  - Designed for easier release at deployment
- **Atraumatic capsule design**
  - Avoids stiff capsule with no rigid spine
- **Redesigned nosecone**
  - Longer taper for sheathless use
  - Smoother transitions
- **Abbott**

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