Transcatheter procedures of the future; expanding the treatment options for patients with severe aortic stenosis

John Webb MD

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McLeod Professor of heart valve intervention, University of British Columbia
Medical director transcatheter heart valve program, Province of BC
Vancouver, Canada
Speaker's name: John, Webb, Vancouver, BC

☑ I have the following potential conflicts of interest to report:

Receipt of grants / research supports: Edwards Lifesciences
Receipt of honoraria or consultation fees: Edwards Lifesciences
30-day Mortality by Valve Platform in the PARTNER Trials

**PARTNER IB Trial (Transfemoral)**
- All-cause Mortality: 6.3%
- n = 175

**PARTNER IA Trial (Overall)**
- All-cause Mortality: 5.2%
- n = 344

**PARTNER IIB Trial (Transfemoral)**
- All-cause Mortality: 4.5%
- n = 271

**PARTNER IIA Trial (Overall)**
- All-cause Mortality: 3.6%
- n = 282

**PARTNER II HR Trial (Overall)**
- All-cause Mortality: 3.9%
- n = 1,011

**PARTNER II S3i Trial (Overall)**
- All-cause Mortality: 2.2%
- n = 583

**All-cause Mortality in Patients**
- Inoperable
- High-risk or greater
- Intermediate-risk

**SAPIEN Valve**
- Inoperable: 6.3%
- High-risk or greater: 5.2%
- Intermediate-risk: 4.5%

**SAPIEN XT Valve**
- Inoperable: 3.6%
- High-risk or greater: 3.9%
- Intermediate-risk: 2.2%

**SAPIEN 3 Valve**
- Inoperable: 1.1%
- High-risk or greater: 2.2%
- Intermediate-risk: 1.1%

**Centre for Heart Valve Innovation**
- St. Paul's Hospital, Vancouver

**UBC**
Stroke Rates Continue to Decline

<table>
<thead>
<tr>
<th>All-stroke (%)</th>
<th>PARTNER I B (TF)</th>
<th>PARTNER II B (TF)</th>
<th>PARTNER II B (TF)</th>
<th>PARTNER II HR (TF)</th>
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<tbody>
<tr>
<td>SAPIEN valve</td>
<td>179</td>
<td>271</td>
<td>282</td>
<td>491</td>
</tr>
<tr>
<td>SAPIEN XT valve</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAPIEN 3 valve</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.3%</td>
<td>4.4%</td>
<td>4.3%</td>
<td>1.4%</td>
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</table>
Do Trial Outcomes Reflect Real World Outcomes in the US TVT Registry?

Propensity Matched - TF Patients - AT

**All-cause Mortality**

<table>
<thead>
<tr>
<th></th>
<th>S3i</th>
<th>S3iCAP</th>
<th>TVT-R (IR)</th>
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<tbody>
<tr>
<td>STS</td>
<td>5.19</td>
<td>4.47</td>
<td>4.44</td>
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<tr>
<td># Patients</td>
<td>652</td>
<td>652</td>
<td>1956</td>
</tr>
<tr>
<td># Sites</td>
<td>51</td>
<td>60</td>
<td>453</td>
</tr>
<tr>
<td>O:E</td>
<td>0.17</td>
<td>0.20</td>
<td>0.18</td>
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<tr>
<td>p-value</td>
<td>0.977</td>
<td>0.927</td>
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</table>

**All Stroke**

<table>
<thead>
<tr>
<th></th>
<th>S3i</th>
<th>S3iCAP</th>
<th>TVT-R (IR)</th>
</tr>
</thead>
<tbody>
<tr>
<td># Patients</td>
<td>652</td>
<td>652</td>
<td>1956</td>
</tr>
<tr>
<td># Sites</td>
<td>51</td>
<td>60</td>
<td>453</td>
</tr>
<tr>
<td>O:E</td>
<td>2.0</td>
<td>2.3</td>
<td>2.2</td>
</tr>
<tr>
<td>p-value</td>
<td>0.927</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lower Profile Systems Mean Fewer Vascular Problems

With Newer Valves and CT Sizing Severe Leaks Are Infrequent

PARTNER II SAPIEN 3: High and Intermediate risk, 30 day TTE

- Severe: 0.1%
- Moderate: 40.7%
- Mild: 55.9%
- None/Trace: 3.4%

1 in 1,000
Durability: 10 years after TAVI

Mean gradient 11 mmHg

Mild AR
The Journey to the Vancouver Clinical Pathway

85 y.o. man admitted for elective TF TAVR with GA and TEE

- Traumatic insertion of urinary catheter prolonged anesthesia
- Successful TAVR
- Gross hematuria, continuous bladder irrigation
- Blood transfusions and urosepsis-related complications
- Respiratory failure and pneumonia
- ICU death POD 14

Avoid: Unnecessary interventions

Standardized Clinical Pathways
Lesson Learned: The Goal is to Succeed Every Time!
Standardized Patient and Family Education

Deciding to Have a Transcatheter Aortic Valve Implantation

You are Having a Transcatheter Aortic Valve Implantation
Getting Ready for the Procedure

Going Home After a Transcatheter Heart Valve Procedure
Standardized multidisciplinary practice

Nursing practice standard

TF TAVR physician orders
Standardized criteria driven discharge

- Physician’s order for discharge.
  
  *Consider multidisciplinary consensus for patient’s readiness for discharge.*

- Absence of persistent (> 3 hrs) intraventricular conduction delays.

- Absence of laboratory contraindications (i.e., clinically important change in hgb. and eGFR).

- Transthoracic echocardiogram completed and reviewed *(if required).*

- Return to baseline mobilization.

- Confirmed availability of family member or home health care staff *(To stay with patient and assist during the initial 48 hrs after discharge).*

**Discharge teaching completed.**

*Content to cover:*

- Vascular access site care
- Follow-up bloodwork and medical appointments
- Indications for emergent care
- Activity and exercise prescription
- Telephone follow-up *(confirmed contact information)*

- Confirmed telephone follow-up plan *(Site contact)*
What Does TAVI Mean?

96 year old former physician

3 hours post TAVI

Asks:

“What does TAVI mean?”

“Totally Awesome Valve Implantation”
Lesson Learned: Length of Stay is a Quality Indicator

Vancouver Program TF TAVR
Change in Median Length of Stay
(2005-2016)
Length of Stay Distribution

N=17,870
Patients with no in-hospital complications

Number of Discharges

1 Day  | 2 Days  | 3 Days  | 4 Days  | 5+ Days
---|---|---|---|---
2,258 | 5,569 | 3,954 | 2,082 | 4,007

34%
>$2,000 Savings per Day of Length of Stay Reduction

Cross Sectional Regression Estimates

Lauck S, Cohen D. TCVT 2018
Streamlining the Way We Care for TAVR Patients

- Avoid GA and intubation
- Avoid TEE
- Avoid neck lines
- Early temporary pacer removal
- Avoid opiates and sedatives
- Bedrest: 4 Hours
- Mobilize on day 0
- Discharge on day 1
The Likelihood of AV Conduction Varies by Valve Type
Time to Onset of Conduction Disturbances in PARTNER 2 S3HR and S3i

- 76% in <24 Hours
- 8% in 24-48 Hours
- 2% in 48-72 Hours
- 13% in 3 - 7 Days

Data on File, Edwards Lifesciences

- BEV: 3.0%
- SEV: 67.3%
- MEV: 95.8%
New Pacemakers by Valve Type at 30 Days

BEV: 6.60%
SEV: 24%
MEV: 32.80%

p < .0001
Late (>30-day to 1 year) Pacemaker Rate by Valve Type

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>Pacemaker Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEV</td>
<td>2.30%</td>
</tr>
<tr>
<td>SEV</td>
<td>2.90%</td>
</tr>
<tr>
<td>MEV</td>
<td>3.10%</td>
</tr>
</tbody>
</table>

$p=0.82$
Late mortality and rehospitalization in patients with new pacemakers following TAVR
New Pacemakers Add Significant Incremental Costs

Adjusted incremental hospital resource utilization associated with new pacemakers following TAVR

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost</th>
</tr>
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<tbody>
<tr>
<td>ICU/CCU</td>
<td>$1,426</td>
</tr>
<tr>
<td>OR/ Cardiology/ Cath Lab</td>
<td>$4,481</td>
</tr>
<tr>
<td>Supplies</td>
<td>$5,055</td>
</tr>
<tr>
<td>Pharmacy/ Lab/ Radiology</td>
<td>$695</td>
</tr>
<tr>
<td>Other</td>
<td>$1,132</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$12,789</strong></td>
</tr>
</tbody>
</table>

*FY 2015 MedPAR claims. Note: “Other” includes routine care, therapy services, MRI/CT, ER, Blood, inhalation, anesthesia and other.*
New AV Block Has Implications for:

Early
• Temporary pacing
• Mobilization
• EP investigations
• New pacemakers
• Morbidity
• ICU and hospital stay

Late
• Re-hospitalization
• Pacer follow-up, replacements
• LV function
• Late mortality?

Patient Experience
Cost
How we “do TAVR”

How we “care for TAVR patients”

13 North American Centres
N = 411

Vancouver: Dr. D. Wood, Dr. J. Webb, Dr. R. Cook, S. Lauck PhD
Edmonton: Dr. R. Welsh, Dr. B. Tyrell
Calgary: Dr. F. Al-Qoofi
Hamilton: Dr. J. Velianou, Dr. M. Natarajan
Sunnybrook: Dr. H. Wijeyunundera, Dr. S. Radhakrishnan
St. Michael’s: Dr. C. Buller, Dr. M. Peterson
Hôpital du Sacré-Coeur de Montréal: Dr. P. Genereux, Dr. D. Paliwaltis
Centre Hospitalier de L’Université de Montréal: Dr. J.B. Masson
Toronto General: Dr. Eric Horlick, Dr. M. Osten
Institut de Cardiologie de Montréal: Dr. A. Asgar
Columbia University Medical Center: Dr. T. Nazif, Dr. S. Kodali, Dr. M. Leon
Emory University Medical Center: Dr. V. Thourani, Dr. V. Babliratos
## Baseline and Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=411)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>84 years</td>
</tr>
<tr>
<td>STS score (mean)</td>
<td>4.9</td>
</tr>
<tr>
<td>STS score ≥8%</td>
<td>14.6%</td>
</tr>
<tr>
<td>SAPIEN 3 valve</td>
<td>41.8%</td>
</tr>
<tr>
<td>SAPIEN XT valve</td>
<td>58.2%</td>
</tr>
<tr>
<td><strong>Procedural characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Procedure Time</td>
<td>45 min</td>
</tr>
<tr>
<td>Local/Conscious Sedation</td>
<td>98.3%</td>
</tr>
<tr>
<td>Local anesthetic only</td>
<td>32.2%</td>
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<tr>
<td>Conversion to GA</td>
<td>1.5%</td>
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</table>
Endpoints at 30 Days

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Overall (N=411) KM %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>1.5</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.5</td>
</tr>
<tr>
<td>Readmission</td>
<td></td>
</tr>
<tr>
<td>Cardiac Readmission</td>
<td>9.2</td>
</tr>
<tr>
<td>PAR &gt;mild</td>
<td>3.8</td>
</tr>
<tr>
<td>Permanent Pacemaker Implantation</td>
<td>5.7</td>
</tr>
</tbody>
</table>
Place SAPIEN 3 central marker just above the annular plane to reduced pacemaker rates
Overall (N=411)  
High (N=183)  
Medium (N=80)  
Low (N=148)  

### Timing of Discharge

- **Next Day**
  - 89.5% (Overall)
  - 92.8% (High)
  - 80.0% (Medium)
  - 90.5% (Low)

### 30-Day Events

- **Mortality**
  - 1.5%

- **Stroke**
  - 1.5%

**Hospital Volume**

*P = 0.01*
SAPIEN 3 Ultra Trial
Up to 4 Sites and a minimum of 20 Patients

Severe, Calcific Aortic Stenosis

Intermediate Risk Assessment by Heart Team and STS ≥ 3 to < 8

Enrollment

TAVR
(SAPIEN 3 Ultra THV and Delivery System)

Follow-up: Discharge, 30 days, 6 months, and annually through 5 years

Primary Endpoint: freedom from all of the following at exit from the procedure room:
• Mortality
• Conversion to surgery
• Moderate or severe paravalvular regurgitation
Edwards SAPIEN 3 Ultra System

Edwards SAPIEN 3 Ultra Valve

Frame and Leaflet Design

• Proven SAPIEN 3 leaflet and frame design

Outer Skirt

• Textured 3-dimensional PET skirt design
• 40% taller skirt
• 14F sheath compatible
The Edwards SAPIEN 3 Ultra System

**Edwards SAPIEN 3 Ultra Delivery System**
- Redesigned distal end for improved crossability
- On-balloon delivery system removes the need for valve alignment
- Responsive articulation avoids contact with aortic wall

**Edwards Axela Sheath**
- Next-generation seamless expandable sheath design
- 14F sheath for all valve sizes

---

Valve Size | Sheath Size
---|---
14F 20 mm | 14F
14F 23 mm | 14F
14F 26 mm | 14F
14F 29 mm | 14F
The Edwards SAPIEN 3 Ultra System

• 74 year old male
• Bicuspid aortic valve
  – Area: 640 mm$^2$
  – Mean gradient: 43 mmHg
• Thoracic aortic replacement and LITA graft in 2010
• Plan: 29 mm SAPIEN 3 Valve
SAPIEN 3 Ultra System: Sheath Insertion

Edwards Axela Sheath

Seamless expandable sheath design

14F sheath for all valve sizes, including the largest 29mm valve
SAPIEN 3 Ultra System: Valve Delivery

Edwards SAPIEN 3 Ultra Delivery System

- Redesigned distal end for improved crossability
- On-balloon delivery system removes the need for valve alignment
- Responsive articulation avoids contact with aortic wall
- No lock
SAPIEN 3 Ultra System: Final Result

Final Result

• No paravalvular leak
• Temporary pacemaker removed
• Mobilized that evening
• Next-day discharge
Evolving How We Care for TAVR Patients

- Less invasive
- Reduced hospital stay
- Reduced AV block and pacemakers
- Improved patient experience
- Less cost