TAVR Procedure with Balloon-Expandable (SAPIEN) Valve
Step-By-Step Approach and Complex and Complication Cases Management

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Conflict of Interest Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>Edwards LifeSciences</td>
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<tr>
<td>Consulting Fees/Honoraria</td>
<td>Medtronic Inc</td>
</tr>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>Boston Scientific</td>
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Contemporary TAVR Devices in Korea

Sapien 3

Evolut R & Pro
TAVR in Asan Medical Center

2019/06/30, N=700
Annual >200 cases
SAPIEN
Step-By-Step Approach
Pre-Procedural Planning

**Echo findings**
- Tricuspid valve
- AVA = 0.55 cm²
- Peak / Mean PG = 119 / 63 mm Hg
- V max = 5.5 m/s
- EF = 71%
- LVOT diameter, TTE: 19.4 mm
- Severe degenerative AS
- Mild AR
- Pericardial effusion

**CT findings – Aortic annulus view**
- Aortic Annulus parameters
  - Annulus short diameter: 17.7 mm
  - Annulus long diameter: 25.4 mm
  - Annulus mean diameter: 21.5 mm
  - Annulus area: 353.6 mm²
  - Annulus area-driven diameter: 21.2 mm
  - Annulus perimeter: 68.8 mm
  - Annulus perimeter-driven diameter: 21.9 mm

**CT findings – Coronary Height**
- Coronary Height
  - LCA: 16.5 mm
  - RCA: 13.5 mm

**CT findings – Ileofemoral Angio**

**Sizing for Sapien 3**

<table>
<thead>
<tr>
<th>Size</th>
<th>Area_oversize (%)</th>
<th>Perimeter_oversize (%)</th>
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<tbody>
<tr>
<td>23</td>
<td>115.7</td>
<td>104.1</td>
</tr>
<tr>
<td>24</td>
<td>126.0</td>
<td>108.6</td>
</tr>
<tr>
<td>25</td>
<td>136.7</td>
<td>113.2</td>
</tr>
<tr>
<td>26</td>
<td>146.7</td>
<td>117.7</td>
</tr>
<tr>
<td>27</td>
<td>158.2</td>
<td>122.2</td>
</tr>
<tr>
<td>28</td>
<td>170.1</td>
<td>126.8</td>
</tr>
<tr>
<td>29</td>
<td>183.5</td>
<td>131.6</td>
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Femoral Access Screening
CTA: 3D reconstruction

R CIA prohibitive
Femoral Access: Sapien

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<table>
<thead>
<tr>
<th>THV Size</th>
<th>Minimum Vessel Diameter*</th>
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<tbody>
<tr>
<td>23 mm</td>
<td>≥ 5.5 mm (14 Fr)</td>
</tr>
<tr>
<td>26 mm</td>
<td>≥ 5.5 mm (14 Fr)</td>
</tr>
<tr>
<td>29 mm</td>
<td>≥ 6.0 mm (16 Fr)</td>
</tr>
</tbody>
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“Minimum 5.0 is possible”
Procedural Steps

• Femoral artery puncture
• Sheath insertion
• Wire crossing of native AV
• Device crossing of native AV
• Valve positioning
• Valve deployment
• Device retrieval
• Femoral artery closure
Puncture

6 Fr – Pacemaker, 7 Fr – Pigtail Catheter
Proglide

14 Fr – 1 Proglide (S3 23 mm, 26 mm)
16 Fr – 2 Proglides (S3 29 mm)
Baseline Aortogram: Coplanar View
Dilator before Sheath Insertion
Edwards E-Sheath
Wire Crossing

Catheter
- AL 1
- AL 2
- JR

Wire
- Teflon straight
- Ring toque
LV Support Wire Exchange

Widest guidewire choice with three curve sizes

- Safari
- Confida

Less Stiff: Amplatz Extra Stiff
More Stiff: Lunderquist

Amplatz Super Stiff
LV Wire Caution
79/F with severe AS

<table>
<thead>
<tr>
<th>Calcium volume</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>NCC</td>
<td>18 mm³</td>
</tr>
<tr>
<td>R-LCC</td>
<td>5 mm³</td>
</tr>
<tr>
<td>Total</td>
<td>23 mm³</td>
</tr>
</tbody>
</table>

Mean Amount of total Calcium 355.4 ± 289.9
Sapien 23mm with 1.5cc underfill
BP drop due to big and deep SAFARI wire position
Sapien 23mm with 1.5cc underfill

Mild PVL

LV Wire Caution:
One Size Does Not Fit All
Use extra-small safari for small LV
Pre-Balloon

- **Risk**
  - Embolization
  - Aortic root injury
  - Acute AR

- **Benefit**
  - Procedural stability
  - Exact positioning
  - Valve sizing estimation

Our routine is...

Pre-dilation: calcium volume $>400$ mm$^3$
Pre-Balloon Caution
88/M with severe AS

<table>
<thead>
<tr>
<th>Calcium volume</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCC</td>
<td>135 mm³</td>
</tr>
<tr>
<td>R-LCC</td>
<td>638 mm³</td>
</tr>
<tr>
<td>Total</td>
<td>773 mm³</td>
</tr>
</tbody>
</table>

Mean Amount of total Calcium 355.4 ± 289.9
Sapien 29mm with 2cc underfill
Pre-dilation with 23mm
Sapien 29mm with 2cc underfill
Hemodynamics collapse due to acute severe AR
No Mercy!! Urgent Valve Implantation

Trivial PVL

Pre-Balloon Caution:
Valve mounting should be prepared
Valve Mounting:
In-House Staff (skilled nurse) or Not

Valve Mounting Caution:
Valve mounting should be completed before predilation
E-Commander: valve delivery

DEM: Dynamic Expansion mechanism
- Allows for transient sheath expansion during valve delivery
- Reduces the time the access vessel is expanded
Balloon Retraction: Valve-on-Balloon
Ascending Aorta and Valve Pass

Gentle Valve Passage Is Important
Make Sufficient Curve
Why Gentle Valve Passage Is Important?

Mechanism of Stroke after TAVR

- Primarily ischemic in nature due to either embolic events or cerebral hypoperfusion
- Embolic events
  - Aortic atheroma
  - Gaseous emboli
- Cerebral hypoperfusion
  - Watershed infarcts on CPB
- Multiple other etiologies postulated including atrial fibrillation, hyperglycemia, cerebral hyperthermia, etc.
Why are stroke rates low?

- Delivery catheter allows atraumatic passage around arch
- Distal tip allows easier crossing of the native valve
- Use of less aggressive or no BAV during procedure
Pull Back Flex Catheter
Making Coaxial Alignment

Distal hyperflexion, push/pull of delivery system, and fine control knob

Partial flex

Distal flex

Fine control of valve positioning

Nice Coaxial Guarantee Nice Valve Positioning
Spend time for coaxial alignment
Valve Positioning and Implantation

Bottom of Center Marker at Base of Cusps

Valve Upward Slippage

Base of Cusps
<table>
<thead>
<tr>
<th>Condition</th>
<th>Oversizing Recommendation</th>
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<tbody>
<tr>
<td>Severe AS with Tricuspid</td>
<td>10~15% Area Oversizing</td>
</tr>
<tr>
<td>Severe AS with Bicuspid</td>
<td>0-5% Lesser Oversizing</td>
</tr>
<tr>
<td>Heavy Calcification (Ca volume &gt; 400 mm$^3$)</td>
<td>0-5% Lesser Oversizing</td>
</tr>
<tr>
<td>Small Sinus of Valsalva to Annulus Area ratio</td>
<td>0-5% Lesser Oversizing</td>
</tr>
<tr>
<td>Small LVOT</td>
<td>Consider Lesser Oversizing</td>
</tr>
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</table>
LVOT Calcification
Annulus Rupture

Edwards-Sapien 29mm
18% Oversize
After Successful Implantation
Final hemodynamics

Aortic Regurgitation Index

\[
\frac{RR_{\text{dia}} - LVEDP}{RR_{\text{sys}}} \times 100
\]

\[
= \frac{40 - 20}{120} \times 100 = 16.7
\]

\[
= \frac{50 - 10}{130} \times 100 = 30.8
\]

<table>
<thead>
<tr>
<th>PVL AR Grade</th>
<th>AR Index ( (DBP - LVEDP)/SBP )</th>
<th>Rough Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>( 31.7 \pm 10.4 )</td>
<td>40s</td>
</tr>
<tr>
<td>Mild</td>
<td>( 28.0 \pm 8.5 )</td>
<td>30s</td>
</tr>
<tr>
<td>Moderate</td>
<td>( 19.6 \pm 7.6 )</td>
<td>20s</td>
</tr>
<tr>
<td>Severe</td>
<td>( 7.6 \pm 2.6 )</td>
<td>10s</td>
</tr>
</tbody>
</table>
IF Significant PVL, How Do We Do?
Complex and Complication PVL Cases Management
78/F, Severe AS, Severe PVL

TF TAVR with Sapien XT 26mm

Valve Implantation

Immediate after Implantation

Severe AR
TF TAVR with Sapien XT 26mm

Post-dilation (2cc overfill)  Aortography after post-dil

Mild AR
Aortography - aortic dissection
TEE finding – Aortic dissection
Follow-up CT

1 POD

7 POD
2018 AP-Valve Live Case

80 F, ViV case: AVR(C-E 19mm) (2009)

Base of the surgical valve

<table>
<thead>
<tr>
<th>Bioprosthetic valve parameters</th>
<th></th>
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<tbody>
<tr>
<td>Valve internal short diameter</td>
<td>16.6 mm</td>
</tr>
<tr>
<td>Valve internal long diameter</td>
<td>18.1 mm</td>
</tr>
<tr>
<td>Valve internal mean diameter</td>
<td>17.3 mm</td>
</tr>
<tr>
<td>Valve internal area</td>
<td>238 mm²</td>
</tr>
<tr>
<td>Valve internal area-derived diameter</td>
<td>17.4 mm</td>
</tr>
<tr>
<td>Valve internal perimeter</td>
<td>54.9 mm</td>
</tr>
<tr>
<td>Valve internal perimeter-derived diameter</td>
<td>17.5 mm</td>
</tr>
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</table>
Fracturing, Cracking, Fracking

Perimount

Mitroflow

The Dacron sewing cuff has been partially removed to display the single separation of the polymer ring. X indicates the surgical ring which has been fractured.
Bioprosthetic Valve Fracture (BVF)

- Balloon 1mm larger than surgical valve
- Pressures 8 to 24mmHg
- Some valve with metal rings won’t fracture (Trifecta, Hancock)
CT – Coronary heights

<table>
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<tr>
<th>Coronary Height</th>
<th>Height</th>
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<tbody>
<tr>
<td>LCA</td>
<td>6.8 mm</td>
</tr>
<tr>
<td>RCA</td>
<td>8.8 mm</td>
</tr>
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</table>

BVF Caution:
Initially, Valve fracturing Is Not Planned
2018 AP-Valve Live Case

SAPIEN 3: 20mm with coronary protection

> Moderate PVR

BVF Caution:
Initially, Valve fracturing Is Never Planned
Initially, Valve fracturing Is Never Planned. However....
A non-compliant balloon is necessary
Valve Fracture with 20mm ATLAS GOLD

Tight stenosis between S3 and STJ by surgical leaflet

Initially, Valve fracturing Is Not Planned. However....Unavoidable BVF
Initially, Valve fracturing Is Not Planned. However....Unavoidable BVF
Dilation with several size of balloon under Guidzilla support

Xience: 3.5 x 15 mm
Acute recoil after 1\textsuperscript{st} stent

Stent-in-Stent to increase radial force
Final angiography after BVF
After Successful Implantation
Sapien 29 mm with 3cc underfill
Post-procedural ICE

Long Axis View
Sapien 29 mm with 3cc underfill
Post-procedural ICE

Short Axis View
Final Aortogram
Completion Angiogram and Sheath Removal
TAVR with SAPIEN

- TAVR with SAPIEN is one of standard procedure for high-, intermediate- or even low-risk patients with severe AS.
- Optimal patient selection (heart-team discussion) and procedural planning (CT and echo) is key steps for successful TAVR.
- More developed devices and more experienced expertise are associated with a lower procedural complications.
- We should also concern different complications per different patient.