Importance of the Prosthesis Choice in the Valve-in-Valve Era

Dr. T. Modine MD, PhD, MBA
Heart team
CHRU de Lille
Speaker's name: Thomas Modine

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

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>Edwards</td>
</tr>
<tr>
<td>Consulting Fees / Honoraria</td>
<td>Abbott, Boston Scientific, Medtronic, Edwards, Cephea, Microport, GE</td>
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<tr>
<td>Major Stock Shareholder/Equity</td>
<td>Nanosurg</td>
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<tr>
<td>Royalty Income</td>
<td>Microport</td>
</tr>
<tr>
<td>Ownership/Founder</td>
<td>Valmy Ltd</td>
</tr>
<tr>
<td>Intellectual Property Rights</td>
<td>Yes</td>
</tr>
<tr>
<td>Other Financial Benefit</td>
<td>Nil</td>
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Background

- STS Database from 1997-2006
- Over the last 10 years, the majority of surgically implanted aortic valves have been bioprosthetic (80% increase).

J Thorac Cardiovasc Surg 2009; 137:82-90
International market

valve type distribution

- 1998:
  - Valve tissu: 73%
  - Valve mécanique: 27%

- 2012:
  - Valve tissu: 72%
  - Valve mécanique: 28%
Risk of re-do surgery after surgical aortic valve replacement
Evidence based data

Elderly patients with comorbidities, redo surgery may be a risky situation.

– Operative mortality for an elective redo surgery ranges from 2% to 8%
– It can increase to 30% in high-risk
Repeat Heart Valve Surgery

671 pts (mean age 54.7 yrs) – 1st repeat heart valve surgery between 1969-1998 @ Royal Victoria Hospital, Belfast, Northern Ireland

Overall mortality – 8.6%

TAVI inValve
How to proceed?

- Type of valve
TAVlinValve
How to proceed?

- Mechanism of failure
<table>
<thead>
<tr>
<th>Type</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcification</td>
<td>Residual glutaraldehyde may serve as potential binding sites by:</td>
</tr>
<tr>
<td></td>
<td>1. Residual glutaraldehyde</td>
</tr>
<tr>
<td></td>
<td>2. Phospholipid extraction</td>
</tr>
<tr>
<td></td>
<td>3. Residual glutaraldehyde</td>
</tr>
<tr>
<td>Pannus</td>
<td>Host tissue response:</td>
</tr>
<tr>
<td></td>
<td>- Post-prosthesis interface</td>
</tr>
<tr>
<td></td>
<td>- Pannus is composed of myofibroblasts, fibroblasts, and capillary</td>
</tr>
<tr>
<td></td>
<td>- Pannus is normally expected and functions to form a nonthrombogenic</td>
</tr>
<tr>
<td>Wear &amp; Tear</td>
<td>Calcific debris tendency to develop in areas where leaflet flexion</td>
</tr>
<tr>
<td></td>
<td>- At the basal and commissural attachment</td>
</tr>
<tr>
<td></td>
<td>- In three-quarters of patients with leaflet calcification</td>
</tr>
<tr>
<td>Thrombosis / Endocarditis</td>
<td>Thrombosis tends to occur less frequently than other mentioned</td>
</tr>
<tr>
<td></td>
<td>modes of prosthetic failure, occurring at a rate of 0.77% and 1.2% per</td>
</tr>
<tr>
<td></td>
<td>year, respectively. Patients presenting with prosthetic endocarditis</td>
</tr>
<tr>
<td></td>
<td>are contraindicated for implantation of a CoreValve</td>
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</table>
Bioprosthetic Valves world

**Carpentier-Edwards**
- Magna
- Theon
- CE SAV
- Perimount

**Sorin**
- Pericarbon
- Mitroflow
- Solo
- Soprano

**St Jude Medical**
- Toronto SPV Stentless
- Biocor
- Epic
- Trifecta

**Medtronic**
- Hancock II
- Mosaic
- Freestyle Stentless

**Shelhigh**
- NR 2000 Semistented
- NR 900 A Tricuspid valve

**Vascutek**
- Aspire stented
- Elan stentless

**Ionescu Shiley**
- TLPB-A-Supra
- Kiros

**Labcor laboratories**
- Dokimos
- Maxime
- Imperiii stentless
- Cryolife O’Brien stentless
Surgical bioprosthesis valves

Stented

Bovine pericardial
- Medtronic Perimount Magna Ease
- Sorin Mitroflow

Porcine aortic valve
- Medtronic Hancock II
- Medtronic Mosaic
- CE Perimount Magna Ease
- St. Jude Biocor
Components of stented bioprosthesis

Stent posts + Base ring = Prosthesis

Elgiloy wireform stent
Elgiloy and Polyester ring and stent posts
Edwards PERIMOUNT Magna

Acetyl homopolymer stent
Stellite ring
Haynes Alloy eyelets

Medtronic Hancock II
Components of stented bioprosthesis

Stent posts + Base ring = Prosthesis

Acetyl stent

Silicone base ring

Polyester covered stent and base ring with outer single layer of pericardium

Sorin Mitroflow
Surgical Valves are different

**Medtronic Hancock II**
- Markers located in crown

**CE Porcine**
- Markers located in sewing ring

**Sorin Mitroflow**

**St. Jude Biocor Supra**
- Markers located below sewing ring
Fluroscopic images of bioprosthetic valves

Sorin Soprano

Mitroflow
Can you identify these valves?
Can you identify these valves?
Surgical bioprosthetic valves

Stentless

Bovine pericardial

Porcine aortic valve

Homograft

Edward Prima Plus

Medtronic Freestyle

St. Jude SPV

Sorin Freedom
Flouroscopy quizz!

Medtronic Freestyle
TAVI inValve
How to proceed?

➢ Surgical technique
Intra/ Supra-Annular = Valves are different

Intra-Annular placement

Supra-Annular placement
Aortic Protrusion= valves are different

References:
2. St. Jude Medical SJM Biocor® and SJM Biocor® Supra marketing collateral (ITEM 1860/0705/7.5M/EN/BD).
3. Medtronic Mosaic® and Hancock® II Porcine Bioprostheses Inservice Guide (UC200102908b EN).
Dimensions of surgical stented bioprosthesis

- A – Stent outer diameter
- B – Stent inner diameter
- C – Sewing ring outer diameter
- D – Stent height
# Size 21 mm

Dimensions in (mm)

<table>
<thead>
<tr>
<th>Labeled Valve Size</th>
<th>Stent Outer Diameter (1)</th>
<th>Stent Inner Diameter (2)</th>
<th>Suture Ring Outer Diameter (3)</th>
<th>Valve Height (4)</th>
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<tbody>
<tr>
<td><strong>Porcine Aortic Valves</strong></td>
<td></td>
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<tr>
<td>Medtronic Mosaic</td>
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<td>21</td>
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<tr>
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<td>28</td>
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<td>St. Jude Biocor/Epic</td>
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<td>19</td>
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<td>Edward Perimount</td>
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<td>20</td>
<td>28</td>
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<tr>
<td>Edward Perimount Magna</td>
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<td>21</td>
<td>20</td>
<td>28</td>
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<tr>
<td>Sorin Mitroflow</td>
<td>21</td>
<td>20.6</td>
<td>N/A</td>
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# Size 23 mm

Dimensions in (mm)

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<th>Stent Outer Diameter (1)</th>
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<td>Medtronic Mosaic</td>
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<td>Medtronic Hancock II</td>
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<td><strong>Pericardial Aortic Valves</strong></td>
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<td>Edward Perimount Magna</td>
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<td>Sorin Mitroflow</td>
<td>23</td>
<td>23</td>
<td>19</td>
<td>26</td>
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</table>
“Hindsight” analysis

1. Space occupying calcific mass
2. Left main coronary
3. Stent post of prosthesis
MSCT

Stent Internal Diameter

23-mm Edwards Perimount
(21 x 21 mm)
Now part of routine screening

Coronaries free from stent posts

Stent posts
Because this what we should end up with

Soprano  
CE  
Mitroflow
VIV Procedure: **Pre-case Planning**
Careful pre-case planning is essential to Valve-in-Valve procedural success

### Patient Selection

**Avoid patients:**
- Concomitant PVL
- Is not securely fixed in the native annulus
- Has a partially detached leaflet (embolization risky)

### Valve Identification

through patients charts & flouroscopic imaging

- CT is highly recommended bioprosthesis
- Determine valve size and different diameters

### Valve Sizing

Select appropriate appropriate TAVI to implant
Global Valve-in-Valve Registry

**Overview:** Retrospective collection of data; 38 centers from Europe, North America, Australia, New Zealand and the Middle East.

- The CoreValve 26mm & 29mm and Sapien 23mm & 26mm devices were used in this study.

**Purpose:** To evaluate the efficacy and safety of ViV procedures

**Objectives:**

- Examine clinical outcomes
- Evaluate results of ViV procedures performed inside bioprostheses types
- Give correlates for high post-procedural gradients
- Supply data on possible rare complications
- Compare procedural characteristics and clinical results of performing Valve in Valve between SAPIEN and CoreValve

*Dvir et al., Circulation AHA. Oct 2012*
Global Valve-in-Valve Registry Results

Improvements in AV area, mean gradients, and regurgitation in Valve in Valve procedures

<table>
<thead>
<tr>
<th></th>
<th>AV Area (cm²)</th>
<th>AV Mean Gradients (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post-Procedure</td>
</tr>
<tr>
<td>Stenosis (n=182)</td>
<td>0.70 ± 0.20</td>
<td>1.37 ± 0.33</td>
</tr>
<tr>
<td>Regurgitation (n=139)</td>
<td>1.48 ± 0.60</td>
<td>1.56 ± 0.49</td>
</tr>
<tr>
<td>Combination (n=139)</td>
<td>0.91 ± 0.30</td>
<td>1.56 ± 0.65</td>
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<tr>
<td>p value</td>
<td>&lt;0.001</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Dvir et al., TCT. Miami, Fl. Oct 2012
Global Valve-in-Valve Registry

Hemodynamic Results

Rate of Post-Procedural Gradients >20 mmHg (%)\textsuperscript{5}

- \(43\%\)
- \(37\%\)
- \(24\%\)
- \(21\%\)
- \(21\%\)

CoreValve
SAPIEN

Small <20
Intermediate ≥20 and <23
Large ≥23

Surgical Valve Internal Diameter (mm)

N=460

Dvir et al., TCT. Miami, Fl. Oct 2012
AVR in the era of TAVI

- Valve type and dimensions
  - The bigger the better (gradient, coronary obstruction)
  - Lower profile

- Mode of implantation
  - Intra- or supra-annular

- Distance from the LMCA and RCA

- Decalcification, root enlargement... TAVI in elderly female
Conclusion

TAV-in-SAV may “disrupt” conventional surgical practice patterns