Transcatheter aortic valve replacement (TAVR)
State-of-the-art

Ole De Backer, MD, PhD – Rigshospitalet, Copenhagen, Denmark
“This is the stupidest idea I have ever heard!”
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

Alain Cribier, Helene Eltchaninoff, Assaf Bash, Nicolas Borenstein, Christophe Tron, Fabrice Bauer, Genevieve Derumeaux, Frederic Anselme, François Laborde, and Martin B. Leon

First TAVR: Trans-septal
Since 2002, a lot has changed...

- Patient selection
- Pre-procedural TAVR work-up
- New-generation THV devices
- Minimalist TAVR approach
- Post-procedural set-up / early discharge
TAVR – State-of-the-art

Since 2002, a lot has changed...

• **Patient selection**
  • Pre-procedural TAVR work-up
  • New-generation THV devices
  • Minimalist TAVR approach
  • Post-procedural set-up / early discharge
TAVR in Copenhagen

- In the first few years, only treatment of inoperable & high surgical risk patients with symptomatic, severe aortic valve stenosis.
- However, this has changed since 2012...
TAVR in Copenhagen

<table>
<thead>
<tr>
<th>Year</th>
<th>All SAVR</th>
<th>All TAVR</th>
<th>% TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>319</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2006</td>
<td>330</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2007</td>
<td>337</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>2008</td>
<td>343</td>
<td>28</td>
<td>7.6</td>
</tr>
<tr>
<td>2009</td>
<td>348</td>
<td>42</td>
<td>10.8</td>
</tr>
<tr>
<td>2010</td>
<td>357</td>
<td>80</td>
<td>18.3</td>
</tr>
<tr>
<td>2011</td>
<td>362</td>
<td>91</td>
<td>20.1</td>
</tr>
<tr>
<td>2012</td>
<td>366</td>
<td>134</td>
<td>26.8</td>
</tr>
<tr>
<td>2013</td>
<td>357</td>
<td>122</td>
<td>25.5</td>
</tr>
<tr>
<td>2014</td>
<td>348</td>
<td>126</td>
<td>26.6</td>
</tr>
<tr>
<td>2015</td>
<td>340</td>
<td>192</td>
<td>36.1</td>
</tr>
</tbody>
</table>
TAVR in Copenhagen
TAVR in Copenhagen
# TAVR in Copenhagen

<table>
<thead>
<tr>
<th>STS Score</th>
<th>&lt;65y</th>
<th>≥65y</th>
<th>≥70y</th>
<th>≥75y</th>
<th>≥80y</th>
<th>≥85y</th>
<th>≥90y</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥8</td>
<td>3 (100%)</td>
<td>1 (100%)</td>
<td>1 (100%)</td>
<td>6 (100%)</td>
<td>13 (100%)</td>
<td>10 (100%)</td>
<td>3 (100%)</td>
</tr>
<tr>
<td>6-8</td>
<td>1 (100%)</td>
<td>2 (100%)</td>
<td>5 (100%)</td>
<td>11 (91%)</td>
<td>17 (100%)</td>
<td>24 (96%)</td>
<td>4 (100%)</td>
</tr>
<tr>
<td>4-6</td>
<td>7 (0%)</td>
<td>11 (18%)</td>
<td>24 (38%)</td>
<td>32 (47%)</td>
<td>67 (64%)</td>
<td>24 (83%)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>2-4</td>
<td>12 (0%)</td>
<td>18 (5%)</td>
<td>45 (18%)</td>
<td>57 (21%)</td>
<td>79 (24%)</td>
<td>18 (78%)</td>
<td>-</td>
</tr>
<tr>
<td>0-2</td>
<td>87 (0%)</td>
<td>111 (0%)</td>
<td>142 (1%)</td>
<td>90 (2%)</td>
<td>26 (4%)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**TAVR-penetration**

0% 25% 50% 75% 100%
The expectation is that TAVR will be used to treat younger patients with lower surgical risk.
Evidence for TAVR in lower risk patients

- **NOTION Trial**
  Intermediate-to-Low Risk Cohort (280 patients)
- **PARTNER II Trial**
  Intermediate Risk Cohort – Sapien THV (1076 patients)
- **SURTAVI Trial**
  Intermediate Risk Cohort – CoreValve THV (1746 patients)

Evidence for TAVR in younger patients < 75 years

- **NOTION II Trial**
  Intermediate-to-Low Risk Cohort with Age < 75 years (980 patients)
TAVR – State-of-the-art

Since 2002, a lot has changed...

• Patient selection
• Pre-procedural TAVR work-up
• New-generation THV devices
• Minimalist TAVR approach
• Post-procedural set-up / early discharge
Pre-procedural TAVR work-up

- Central role for TVT nurses
  - Intake conversation with all patients
  - Frailty index
  - Coordination of pre-procedural investigations
  - ...

- Switch from TEE- to MSCT-based sizing
- Standardized approach
- Important for research nurses
CT-based sizing - annulus
How does Standardization Help?

- Standard
- Wheel of improvement
- High-quality consciousness
- Quality
- Time
TAVR – State-of-the-art

Since 2002, a lot has changed...

- Patient selection
- Pre-procedural TAVR work-up
- **New-generation THV devices**
- Minimalist TAVR approach
- Post-procedural set-up / early discharge
Evolution of the Edwards Balloon-Expandable Transcatheter Valves

- **Cribier-Edwards** (2002)
- **SAPIEN** (2006)
- **SAPIEN XT** (2009)
- **SAPIEN 3** (2013)

* Sheath compatibility for a 23 mm valve
SAPIEN 3 Transcatheter Heart Valve
Distinguishing Features

- Bovine pericardial tissue
- Outer skirt to reduce PVL
- Low frame height
- Enhanced frame geometry for ultra-low delivery profile
A ‘tailored’ approach – One does not fit all...
Challenging conditions

- Small, tortuous, diseased peripheral arteries
- Tortuous, porcelain aorta
- Horizontal aorta
- Bicuspid/extremely eccentric aortic valve annulus
- Heavy calcifications: aortic valve, LVOT
- Pure aortic regurgitation
- Valve-in-valve for degenerated surgical bioprostheses
- Low ejection fraction
TAVR – State-of-the-art

Since 2002, a lot has changed...

• Patient selection
• Pre-procedural TAVR work-up
• New-generation THV devices
• **Minimalist TAVR approach**
• Post-procedural set-up / early discharge
Simplistic Approach

- Early Discharge
- Conscious Sedation
- Cathlab Procedure
- Minimalistic Approach
# Outcomes with Minimalist approach

## Standard Approach
- Hybrid operating room
- General anesthesia
- Intubation

<table>
<thead>
<tr>
<th>Procedure Room Time</th>
<th>218 minutes</th>
<th>150 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive Care Unit Time</td>
<td>28 hours</td>
<td>22 hours</td>
</tr>
<tr>
<td>Length of Stay</td>
<td>5 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Hospital Costs</td>
<td>$55.3k</td>
<td>$45.5k</td>
</tr>
<tr>
<td>In-Hospital Mortality</td>
<td>4.2%</td>
<td>0%</td>
</tr>
<tr>
<td>Discharge to Home</td>
<td>84%</td>
<td>83%</td>
</tr>
</tbody>
</table>

## Minimalist Approach
- Cardiac catheterization lab
- Local anesthesia
- Minimal conscious sedation

Benefits of Minimalist approach:

**Patient Selection:**
- Appropriate for minimalist approach

**Procedure Location:**
- Cardiac catheterization lab

**Mode of Anesthesia:**
- Local anesthesia
- Minimal conscious sedation

In appropriately selected patients, the morbidity & mortality is the same as standard approach patients.

The shorter LOS and lower resource utilization with MA-TF significantly lowers hospital costs.

These results have important implications for the financial viability of U.S. TAVR programs in the future.

SEMINAR ON MINIMALIST TF-TAVI LIVE CLINICAL CASES

by Prof. Alain Cribier
CARDIOLOGY

PROCEDURES

- Seminar on Minimalist TF-TAVI Live Clinical Cases

MEDICAL DEVICES

STARTS
24 NOVEMBER 08:00 AM

ENDS
25 NOVEMBER 02:00 PM

ROUEN NORMANDY MEDICAL TRAINING CENTER
Rouen, France

TOTAL
€880
Less invasive non-TF approaches

Transsubclavian

Transcaval
+ Cerebral protection devices

Sentinel™ CPS  
TriGuard™ CPS
TAVR – State-of-the-art

Since 2002, a lot has changed...

• Patient selection
• Pre-procedural TAVR work-up
• New-generation THV devices
• Minimalist TAVR approach
• Post-procedural set-up / early discharge
Post-procedural set-up / early discharge

• Transfer to regular ward...however, with:
  • Continuous presence of a nurse in the room for the first 6 hours
  • Dedicated nurses with expertise in TAVR
  • Telemetry/monitoring
  • Telephonic ‘hotline’ to MD fellow
Post-procedural set-up / early discharge

- Double # of TAVR procedures from 2014 → 2016
- Marked reduction in hospitalization length

![Hospitalization days graph](image)
"Outpatient" Same-Day TAVR

Sacre-Coeur Hospital; Montreal, CN
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

Enrico Cerrato, Luis Nombela-Franco, Tamim M. Nazif, Helene Eltchaninoff, Lars Søndergaard, Henrique B Ribeiro, Marco Barbanti, Fabian Nietlispach, Peter De Jaegere, Pierfrancesco Agostoni, Ramiro Trillo, Pilar Jimenez-Quevedo, Fabrizio D’Ascenzo, Olaf Wendler, Gabriel Maluenda, Mao Chen, Corrado Tamburino, Carlos Macaya, Martin B. Leon, Josep Rodes-Cabau

To appear in: International Journal of Cardiology

Received date: 7 August 2016
Accepted date: 6 November 2016
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

Globally, still large differences in TAVR approach...
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

<table>
<thead>
<tr>
<th>Anesthetic regimen</th>
<th># of centres</th>
<th>% of centres</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% G.A.</td>
<td>98</td>
<td>39.5%</td>
</tr>
<tr>
<td>50-99% G.A</td>
<td>51</td>
<td>20.6%</td>
</tr>
<tr>
<td>&lt; 50% G.A</td>
<td>99</td>
<td>39.9%</td>
</tr>
</tbody>
</table>
What percentage of your TAVI candidates are:

- Patients with a contraindication or prohibitive risk for cardiac surgery: 30 (15-50)
- Patients at high surgical risk (STS score >8): 50 (30-60)
- Patients at moderate surgical risk (STS score 4-8): 15 (5.75-25)
- Patients at low surgical risk (STS score < 4): 0 (0-5)
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

**Do you regularly perform these tests?**

- Frailty: 43.6%
- Quality of life: 28.2%
- 6-minute walking test: 21.3%
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

How do you assess aortic regurgitation immediately after valve implantation?

- Aortography: 84.1%
- Hemodynamic assessment: 62.6%
- TEE: 62.2%
- TTE: 30.9%
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

In case of discrepancy, which method is your gold standard for aortic regurgitation assessment?

- TEE: 46.7%
- Aortography: 25.8%
- Hemodynamic assessment: 18.4%
- TTE: 9.0%
Evaluation of current practices in transcatheter aortic valve implantation: The WRITTEN (WoRldwIde TAVI ExperieNce) survey

How long is the temporary pacemaker maintained after balloon and self-expandable valve implantation (if no AV-block or new conduction disturbance occurs)?

- Always removed at the end: 48.1%
- At least 12 hr: 6.9% (BEV), 8.9% (SEV)
- At least 24 hr: 16.2% (BEV), 30.2% (SEV)
- At least 48 hr: 6.0% (BEV), 30.7% (SEV)
- Not a standard protocol: 22.7% (BEV), 20.4% (SEV)

p=0.001
Antithrombotic therapy regimen and duration at hospital discharge with no other indication for anticoagulant therapy

- Aspirin alone, lifelong: 6.7%
- 1 month: 14.2%
- 3 months: 41.0%
- 6 months: 32.6%
- 12 months: 5.0%
- DAPT, lifelong: 1.3%
Estimated Global TAVR Growth

In the next 10 years, TAVR growth will be 4X!

SOURCE: Credit Suisse TAVI Comment – January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW
Change ...before you have to!

Jack Welch
Comprehensive Heart Team Approach

Heart Team

- Cardiothoracic Surgeon
- Cardiac Anaesthetist
- Treating Cardiologist/Physician
- CCU Nursing Staff
- Cath Lab Nursing Staff
- Research Co-ordinator
- Program Co-ordinator
- Interventional Cardiologist
- Imaging Cardiologist
- Psychologist and/or Psychiatrist