Transcatheter Valve Replacement: Current State in 2017

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Overview

• A Standard TAVR Case
• Evidence review and update for TAVR
• Evaluating Patients for TAVR
• Future of TAVR and unique TAVR populations
• Mitral valve therapies
• Complex TAVR Case
Case XX
The Evidence for TAVR

- The original data (PARTNERS)
- Intermediate Risk Patients
- Durability and Safety updates

CoreValve Evolute R

Sapien S3
Brief history of TAVR

Alain Cribier: First human transcatheter valve replacement (2002)
Brief history of TAVR

- **2010**: Landmark PARTNER clinical trials begin
- **2011**: Edwards SAPIEN valve
- **2012**: SAPIEN valve approved for high-risk patients
- **2014**: Edwards SAPIEN XT valve
- **2015**: SAPIEN 3 valve approved for high or greater-risk patients
- **2016**: Edwards SAPIEN 3 valve
- **2016**: SAPIEN 3 and SAPIEN XT valves approved for intermediate or greater risk patients

Slide Courtesy Edwards Life Sciences
Brief history of TAVR

PARTNERS Cohort B
(Inoperable)

Hazard ratio, 0.55 (95% CI, 0.40–0.74)
P < 0.001

Standard therapy

Death from Any Cause (%)
Months

No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12

PARTNERS Cohort A
(High Risk)

Hazard ratio, 0.93 (95% CI, 0.71–1.22)
P = 0.62

Surgical 26.8
Transcatheter 24.2

Death from Any Cause (%)
Months

No. at Risk
Transcatheter 348 298 260 147 67
Surgical 351 252 236 139 65

Brief history of TAVR

CoreValve Pivotal Trial
(High Surgical Risk)

CoreValve Extreme Risk Trial
(Inoperable)

<table>
<thead>
<tr>
<th><strong>Brief history of TAVR</strong></th>
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<tbody>
<tr>
<td><strong>Low mortality and stroke rates</strong></td>
<td>Patient selection, procedural techniques, device evolution</td>
</tr>
<tr>
<td></td>
<td>RetroFlex 3 delivery system</td>
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<tr>
<td></td>
<td>NovaFlex+ delivery system</td>
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<tr>
<td></td>
<td>Edwards Commander delivery system</td>
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<tr>
<td><strong>Improved vascular access</strong></td>
<td>Lower profile devices expands treatment possibilities</td>
</tr>
<tr>
<td></td>
<td>RetroFlex 3 introducer sheath</td>
</tr>
<tr>
<td></td>
<td>22F</td>
</tr>
<tr>
<td></td>
<td>Edwards eSheath introducer set</td>
</tr>
<tr>
<td></td>
<td>16F</td>
</tr>
<tr>
<td></td>
<td>Edwards eSheath introducer set*</td>
</tr>
<tr>
<td></td>
<td>14F</td>
</tr>
<tr>
<td><strong>Increased treatment range</strong></td>
<td>Larger and smaller valves</td>
</tr>
<tr>
<td></td>
<td>SAPIEN valve</td>
</tr>
<tr>
<td></td>
<td>23 mm and 26 mm</td>
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<tr>
<td></td>
<td>SAPIEN XT valve</td>
</tr>
<tr>
<td></td>
<td>23 mm, 26 mm, 29 mm</td>
</tr>
<tr>
<td></td>
<td>SAPIEN 3 valve</td>
</tr>
<tr>
<td></td>
<td>20 mm, 23 mm, 26 mm, 29 mm</td>
</tr>
</tbody>
</table>

*Only used with 20 mm, 23 mm, 26 mm valve sizes*

Slide Courtesy Edwards Life Sciences
Brief history of TAVR

- **2010**: Edwards SAPIEN valve
- **2011**: SAPIEN valve approved for inoperable patients
- **2012**: Edwards SAPIEN XT valve
- **2014**: SAPIEN valve approved for high-risk patients
- **2015**: Edwards SAPIEN 3 valve
- **2016**: SAPIEN 3 and SAPIEN XT valves approved for intermediate or greater risk patients
• 2032 patients with STS score between 4-8%.
• PCI/CABG allowed
• Sapein XT valve
236 patients (11%) were transthoracic TAVR.
PARTNER II

LEAK is BAD

The PARTNER IIA and S3i Trial
Study Design

Intermediate-Risk Symptomatic Severe Aortic Stenosis

Intermediate-Risk Assessment by Heart Team

PII S3i
n = 1078

ASSESSMENT: Optimal Valve Delivery Access

Transfemoral (TF)

TF TAVR SAPIEN 3

Transapical / Transaortic (TA / TAo)

TA / TAo TAVR SAPIEN 3

PIIA
n = 2032

ASSESSMENT: Transfemoral Access

Yes

Transfemoral (TF)

1:1 Randomization

TF TAVR SAPIEN XT

TA / TAo TAVR SAPIEN XT

No

Transapical / Transaortic (TA / TAo)

1:1 Randomization

Surgical AVR

Surgical AVR
Number at Risk:
- SAPIEN 3 TAVR
- Surgery

Months from Procedure:
- All-Cause Mortality (%)
  - TAVR with SAPIEN 3 Valve
  - Surgery (PIIA)

*The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates.

PARTNER II S3i

Number at Risk:
- Surgery: 944, 859, 836, 808, 795
- SAPIEN 3 TAVR: 1077, 1043, 1017, 991, 963

Slide Courtesy Edwards Life Sciences
PARTNER II S3i Leak

Number of Echos:
- Surgery: 755
- SAPIEN 3 TAVR: 992
- 30 Days:
  - PARTNER II S3i Trial SAPIEN 3 Valve: 3.8%
  - PARTNER IIA Trial Surgery: 0.5%
  - PARTNER II S3i Trial SAPIEN 3 Valve: 0.3%
- 1 Year:
  - PARTNER IIA Trial Surgery: 1.5%

Severe
Moderate
Mild
None / Trace

Slide Courtesy Edwards Life Sciences
• 1746 patients
• STS score 3-15% but heart team agreed intermediate risk (mean STS score was 4%).
• Corevavle 84% (Evolute R 16%).

SURTAVI

SURTAVI 30 day Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TAVR</th>
<th>SAVR</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cause death</td>
<td>2.2%</td>
<td>1.7%</td>
<td>No</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>3.4%</td>
<td>5.6%</td>
<td>No</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>25.9%</td>
<td>6.6%</td>
<td>Yes</td>
</tr>
<tr>
<td>Vascular Complication</td>
<td>6.0%</td>
<td>1.1%</td>
<td>Yes</td>
</tr>
</tbody>
</table>
PARTNER I- 5 year

[Diagram showing data with categories and comparisons over time.]
TVT Registry

42,998 implants from 2011-2015
62% had STS <8% (intermediate)

JACC 2017. 70: 29-41.
TVT Registry
The TAVR Evaluation

- Understanding risk and STS score
- TAVR diagnostic testing
- “Cohort C”
- The heart team
The TAVR Evaluation

1. Does the patient have Severe AS?
2. Is the patient having symptoms of severe aortic stenosis?
3. What is the best treatment?
The TAVR Evaluation

<table>
<thead>
<tr>
<th>Procedure Type</th>
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<tbody>
<tr>
<td>CAB Only</td>
</tr>
<tr>
<td>AV Replacement</td>
</tr>
<tr>
<td>MV Replacement Only</td>
</tr>
<tr>
<td>MV Repair</td>
</tr>
<tr>
<td>AV Replacement + CAB</td>
</tr>
<tr>
<td>MV Replacement + CAB</td>
</tr>
<tr>
<td>MV Repair + CAB</td>
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</tbody>
</table>

**RISK SCORES**

**Prior MI**
- Yes
- No
- Unknown

**Cardiac Arrhythmia**
- Yes
- No
- Unknown

**RF-Chronic Lung Disease**
- Mild
- Moderate
- Severe
- Lung disease documented, severity unknown
- No

**RF-Cerebrovascular Dis**
- Yes
- No
- Unknown

**RF-Peripheral Arterial Disease**
- Yes
- No
- Unknown

**RF-Diabetes**
- Yes
- No
- Unknown

http://riskcalc.sts.org
# The TAVR Evaluation

## RISK LEVEL

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>STS Risk of Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt;3%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>4-8%*</td>
</tr>
<tr>
<td>High</td>
<td>&gt;8%</td>
</tr>
<tr>
<td>Extreme</td>
<td>&gt;15%</td>
</tr>
</tbody>
</table>
The TAVR Evaluation

• Consultation with 1 cardiologist and 2 cardiac surgeons
• Echocardiogram
• Coronary angiogram
• Pulmonary function testing
• Carotid Dopplers
• TAVR protocol CT (gated CT with 1mm slices of the heart, chest, abdomen and pelvis)
• Fraility Evaluation
The CT is King
“Cohort C”
“Cohort C”
The Heart Team Concept

**TAVR HEART TEAM**
1. Cardiologist
2. Cardiac Surgeon
3. Interventional Cardiologist
4. Non-invasive imaging specialist
5. Cardiac Anesthesia
6. Cardiac Rehab Specialist
7. Nursing Specialist/Coordinator

**PATIENT**
The Unique “TAVR”

- Valve in Valve
- Pulmonic valve
Valve in Valve

Common Surgical Valves

Valve Failure

A: Wear and tear
B: Calcification
C: Pannus
D: Endocarditis
E: Thrombus

Perimount (Edwards)  Magna (Edwards)  Mosaic (Medtronic)  Hancock II (Medtronic)

Mitroflow (Sorin)  Trifecta (St. Jude Medical)  Epic (St. Jude Medical)
Valve in Valve

Global ViV registry
202 patients
93% Success rate

Circulation. 2012; Online.
Valve in Valve

A. Changes in hemodynamics

B. Changes in function and quality of life

Valve in Mitral

CASE
Future of TAVR

- Low Risk Trial PARTNER 3 (Corevalve low Risk) currently enrolling.
- Bicuspid Valve disease.
- PCI/TAVR versus AVR/CABG.
- Moderate AS in setting of LV dysfunction (TAVR-UNLOAD).
Transcatheter Mitral Valve Therapies

- Mitral Clip
- New valve replacement technologies
- New valve “repair” technologies

Carpentier Classification of mitral regurgitation
Mitraclip

- FDA approved for treatment of “degenerative” mitral valve disease in those at high surgical risk
- High risk: >6% mitral valve repair or >8% for replacement
- COAPT trial: treatment of functional MR in patients with LV dysfunction
- Continued Access COAPT registry
• Mitral valve position
• Valve sealing
• Obstruction of the LV outflow tract
• Delivery system
• Anchoring and retention
• Complex mitral valve anatomy
TMVR

Tendyne

Intrepid
TMVR

(A) Valve prosthesis. (B) Fluoroscopy. (C) Three-dimensional transesophageal echocardiography from the surgeon's point of view. Reprinted with permission from Cheung et al. (38).

(A) Valve prosthesis. (B) Fluoroscopy. (C) Two-dimensional transesophageal echocardiography. A was provided by Colson Interventional. B and C are courtesy of Dr. Matthew Williams, NYU Langone Medical Center, New York, New York.

(A) Valve prosthesis. (B) Fluoroscopy. (C) Transesophageal echocardiography from the surgeon's point of view. Courtesy of Dr. Rodger Lange, German Heart Center Munich, Munich, Germany.
Case XX
Conclusion

- Transcatheter aortic valve replacement has been transformative for the care of patients with Severe AS.
- Refinements in technology has improved care.
- Mitral Valve disease is the new frontier in structural heart disease.
Questions

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